BIOBASE®

Automatic Chemistry Analyzer
BK-280
User Manual

BIOBASE GROUP

Version 2020.07

Content

Foreword

Thank you for purchasing Automatic chemistry analyzer BK-280.

Product name: Automatic chemistry analyzer

Model: BK-280

Product performance structure and composition:

It consists of analysis department, operation department (computer system), result output department (printer), accessories and consumables.

Intended use:

It is used to quantitatively analyze the clinical chemistry of human serum, plasma, urine, cerebrospinal fluid and other samples. Do not use for other purposes.

Objects：

This manual is intended for the clinical laboratory technician who operates the instrument.

Before using the product, please read the contents of this manual carefully and use the product correctly.Please keep this manual properly for easy viewing at any time. If you do not comply with the precautions described in this manual, you will not be subject to warranty.

Period of use:

The expected life of the instrument is 5 years. The expected service life of this product is determined by the durability test method. The operator maintains and repairs the product according to the requirements of the user manual.

User's manual instructions

File Name: Automatic chemistry analyzer BK-280 User Manual
Version: V1.0
Contents: This manual describes in detail the use of the product, function and use of methods to ensure that the clinical laboratory technician to carry out the smooth detection of the daily work, recorded the relevant daily maintenance content. The pictures in this manual are only for illustrative and illustration and not intended for any other purpose. The actual picture is subject to the product. In this manual, the mouse operation as an example, explain the various methods of operation.
If the contents of this user manual are changed, the user will not be notified.

Statement and disclaimer

Statement

Biobase Biodustry (Shandong) Co., Ltd (hereinafter referred to as “our company” or “us”) has the final interpretation of this manual.

In the event that all of the following requirements are met, our company considers that it is responsible for the safety, reliability and performance of the product.

Namely:

Assembly operations, expansion, re-adjustment, improvement and repair are carried out by qualified personnel of our company.

All repairs involving replacement parts and supporting accessories and consumables are original (original) or approved by our company.

The relevant electrical equipment complies with national standards and the requirements of this user manual.

The product is operated in accordance with this instruction manual

Disclaimer

Our company shall not be liable for any damage or damage to the equipment, or the direct or indirect damage that occurred during the use of the equipment in the following cases.

1.Failure and damage caused by violation of the methods of use, precautions and use described in this manual.

2.Due to the external company repair or modification caused by the failure and damage.

3.Failure and damage caused by the use of external instruments at the same time.

4.Fault and damage caused by inconsistency operating environment (power supply conditions, installation environment, etc.) specified by company.

5.Due to earthquakes, floods and other natural disasters caused by failure and damage.

6.After the installation of the equipment, due to unauthorized movement or transfer (transport) caused by the failure and damage.

Product description

Dimensions and weight of the instrument
Dimensions: 950mm (length) × 603mm (width) × 505mm (height)
Weight: 80kg
Product category
The classification criteria are described below:
Overvoltage categories: Overvoltage Category (Class Ⅱ)
Pollution: Pollution degree (Class Ⅱ)
Installation environment conditions:
A) Indoor use.
B) Altitude of not more than 2000m.
C) Temperature range 15℃ ~ 30℃.
D) The maximum relative humidity of 85% when the temperature is below 30℃.
E) The power supply voltage fluctuation is not more than ± 10% of the nominal voltage.
F) Typical transient overvoltage appears on the grid power supply.
Note: The nominal level of the transient overvoltage is the pulse withstand voltage (overvoltage) category II specified in IEC 60364-4-443.
G) Applicable rated pollution degree.
Equipment category: Laboratory equipment
Connection to the network power supply: Removable power cord
Operating conditions: Continuous

Transportation and storage

Transport

In the packaging states, the instruments conduct transportation according to the requirements of the transport contract, in the transport process to prevent rain and sun exposure, to prevent severe impact, weight and dumping.

Note: If the instrument has been unpacked, before moving the instrument, please re- packaging equipment before transport.

Store

The equipment after packaging should be stored at -10℃~ 40℃, relative humidity of not more than 85%, non-corrosive gases and well-ventilated environment.

After-sales service and contact information

After sales service

Please contact our company's customer service center.

Service

a) Confirm the fault and repair method: First contact the customer service center to confirm the fault condition, and confirm that the repair method is home repair or return to the factory for repair.

b) Maintenance costs are negotiated with our company according to the specific situation.

c) Freight: If the instrument is shipped to our company for maintenance, the user must bear the freight (including customs fees).

Return

a) Obtain a return permission. Get in touch with our company's customer service center and inform the product serial number (see the instrument nameplate) to explain the reason for the return. If the product serial number cannot be clearly identified, our company will not return the product.

b) Under the premise of obtaining the right to return the goods, please follow our company's requirements to handle the relevant procedures.

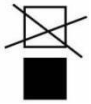
Safety information

This chapter describes the safety symbols used in the manual and its meaning, summarizes the safety hazards and precautions used in the instrument and the labels and specific meanings on the instrument, and lists the toxicities contained in the various parts of the instrument whether the content of harmful substances or elements meet the relevant standards.

Safety symbols

Various safety symbols are used in this instruction manual to remind you of what you need to be aware of during operation. As shown in the following table:

Symbol	Sign language	Description
	Biological infection risk	Used for R&S needles and waste drains. Indicates a risk of biological infection, and if not followed, there may be a risk of biological infection.
	Prevent burns	Used for halogen lamp position. Indicates a burn hazard and may be burnt if contacted or not followed.
	Electrostatic sensitive device	Used to indicate a static-sensitive device or to indicate a device or connector that has not been tested for antistatic.
	Prevent moving parts	Used for the position of moving parts such as R&S arm, stirring arm, cleaning mechanism, etc.. Indicating potential danger, the operator must be trained, if not in accordance with the instructions, may cause personal injury.
	Protective grounding	For internal and external grounding. Please ensure that the instrument is well grounded.
	This way up	Indicates correct upright position of the transport package.
	Fragile	Contents of the transport package are fragile therefore it shall be handled with care.
	Keep away from rain	Transport package shall be kept away from rain.

	Do not roll	Transport package shall not be rolled.
	Do not stack	Stacking of the transport package is not allowed and no load should be placed on the transport package.

Safety precautions

Use this instrument for safety, please read the following safety precautions carefully.

Any operation that violates the following safety precautions can result in personal injury or damage to the instrument.

 **Warning:**

If you do not follow the instruction manual to guide the use of this instrument, the protective measures provided by this equipment will likely fail.

Biological dangerous protection

For the effective protection of biological danger, please observe the following precautions.

 **Risk of biological infection:**

- Improper use of the sample may result in infection. Do not touch samples, controls, calibrators, mixtures, and waste water by your hands. Be sure to wear gloves when handling, wear work clothes to prevent infection, wear protective glasses if necessary.
- If the specimen is inadvertently exposed to the skin, please immediately follow the user's work standard and consult a doctor

To prevent personal injury caused by moving parts

To prevent personal injury when the instrument is running, observe the following precautions.

 **Warning:**

- Do not touch the moving parts of the instrument when the instrument is working. The moving part comprise reagent needle, sample needle, stirrer and cuvette automatic cleaning mechanism.
- Do not put your fingers or hands into open parts while the instrument is working.

Prevent burns

To prevent burns from halogen lamps, observe the following precautions.

 **To prevent burns:**

- Do not touch the light source after the system is switched on

- When changing halogen lamps, must be turned off thepower supply, wait for halogen lamp to be cooled to change the lamp operation, otherwise the halogen lamp of high temperature and light source box can cause scalding.

To prevent personal injury caused by light source

To prevent personal injury from light or bar code scanners, observe the following precautions.

 **Warning:**

- When using the instrument, do not look directly at the light beam emitted by the light source or the bar code scanner. These beams can cause eye damage.
- Before checking the light source, disconnect the main power supply of the analyzer and wait for at least 15 minutes until the light source cools. Do not touch the light before cooling to avoid burns.

Chemistry hazard protection

 **Warning:**

Certain agents, concentrates detergent may damage the skin. Carefully use reagents, concentrate detergent to prevent direct contact with hands and clothing. If you accidentally touch your hands or clothing, rinse immediately with soap and water. If enter the eyes, rinse with plenty of water immediately and consult an ophthalmologist

Waste treatment

In order to prevent environmental pollution and personal injury caused by waste liquid, please pay attention to the following precautions when handling waste liquid.

 **Risk of biological infection:**

Reagents, QC solutions, calibration fluid, Cleaning fluid, waste some of the substances in the pollution regulations and emission standards control. Please comply with local discharge standards and consult the relevant reagent manufacturer or distributor.

When handling waste, be sure to wear gloves, wear work clothes to prevent infection, and wear protective glasses if necessary.

Dispose of instrument

Please waste processing apparatus in accordance with the following requirements.

 **Warning:**

Some of the substances in the waste instrument are subject to pollution regulations. Please observe the local waste disposal standards for disposal of waste instruments.

Prevent fire and explosion

To prevent the occurrence of fire and explosion, observe the following precautions.

 **Warning:**

Alcohol is flammable, must be very careful when using.

Operation precautions

To use the instrument correctly and effectively, please read the following precautions carefully.

Instrument use

 **Warning::**

The instrument is used for quantitative analysis of serum, plasma, urine, cerebrospinal fluid and other clinical Chemistry composition of the sample.

Analysis results based on clinical judgment, consider the clinical symptoms or other test results.

Operator

 **Warning::**

This instrument is limited to our company or our trained professional testing, medical or laboratory technician to operate..

Use the environment

 **Be careful:**

Install the instrument correctly according to the installation environment specified in the instruction manual. Installation outside of the specified conditions, the use of this instrument may result in unreliable results and may result in damage to the instrument.

Prevent noise and electromagnetic wave

 **Be careful:**

Do not place unusual noise near the instrument. Please turn off the equipment that emits electromagnetic waves in the room where the instrument is located (such as a cell phone, radio, etc.) and do not use other CRT monitors near the instrument. Noise, electromagnetic interference may cause the instrument to malfunction.

Do not use other medical equipment near the instrument. The electromagnetic waves emitted by this instrument may cause other medical equipment nearby to malfunction.

Instrument maintenance

 **Be careful:**

(1) Follow the instructions in the operating instructions to maintain the instrument. Improper maintenance may result in incorrect analysis of the results and may even result in damage to the instrument or personal injury.

(2) The instrument is placed for a long time, and the surface may accumulate dust. When cleaning, please use a clean soft cloth soaked in water, gently wipe its surface, if necessary, soak a small amount of soap. Do not use organic solvents such as alcohol. After cleaning, wipe the surface with a dry cloth.

Before cleaning, turn off all power to the instrument and unplug the power cord. In the cleaning process, take the necessary precautions to prevent water from entering the instrument, as this may result in damage to the instrument or personal injury.

(3) Check the main components, such as replacement of halogen lamps, reagent needles, sample needle, stirrer, injection parts, must be calibrated analysis.

Instrument use

 **Be careful:**

(1) Please follow the instructions in the instruction manual to use the instrument. Incorrect use may result in incorrect measurement results and may even result in damage to the instrument or personal injury.

(2) Before using the instrument for the first time, please calibrate and then control to confirm that the instrument is working properly.

(3) When using the instrument, must carry out the quality control program, otherwise it cannot guarantee the reliability of the results.

(4) Do not open the reagent / sample tray cover during the analysis.

(5) The Network interface of the analysis unit is set to be connected to the operation unit. It must not be used for cables connected to any other equipment. Please use the dedicated cable connection analysis unit and the operation unit provided by our company.

(6) The operating department is a computer that operates the instrument-specific operating software. The installation of any software or hardware other than the contents specified by our company on this computer may prevent the instrument from functioning properly. Do not run other software while the instrument is working. A computer virus may destroy software and data. Please do not use the computer for other purposes or connect to the Internet.

(7) Do not touch the monitor, mouse, or keyboard of the operation section with wet or sticky Chemistry hands.

(8) Do not turn on the power switch again within 10 seconds after turning off the main power of the analyzer. Otherwise, the instrument may enter the protection state. If the instrument enters the protection state, please turn off the main power and then open it again.

Parameter setting

 **Be careful:**

The instrument needs to set parameters such as sample volume, reagent volume and measurement wavelength. When setting these parameters, follow the instructions in the manual and refer to the instructions that come with the reagents.

Sample

 **Be careful:**

(1) Use separate serum samples and urine samples without suspended. If the serum sample contains fibrin, or urine samples containing suspended solids and other insoluble impurities, are likely to block the reagent needle, sample needle, affect the analysis results.

The presence of drugs, anticoagulants, preservatives, etc. in the sample may interfere with certain analytical results. Samples of hemolysis, jaundice, chylomicrons and other substances may affect the analysis results, it is recommended to do the sample blank test.
(2) Please use the correct sample storage measures. Incorrect sample storage measures may alter the composition of the sample and result in incorrect analysis of the results.
(3) To prevent sample volatilization, do not place the sample open for a long time. If the sample is volatile, it may result in incorrect analysis of the results.
(4) Some samples may not be analyzed according to the test parameters and the reagents used. For these samples, please consult with the manufacturer or distributor of reagents and distributors of our company.
(5) If some samples are to be pretreated for analytical purposes, consult the relevant reagent manufacturer or distributor.
(6) The instrument analysis of the sampling requirements. When sampling, please use the instructions in this manual to determine the appropriate sample size.
(7) Before analysis, make sure that the sample is placed at the correct sample level, otherwise the correct result may not be obtained

Reagents, calibrators, control solution

 **Be careful:**

(1) The use of equipment for analysis, the need for appropriate reagents, calibration fluid and QC solutions.
(2) Please use the appropriate reagents according to the instrument. If you are unsure whether the reagent is available, consult a distributor of our company.
(3) The use and storage of reagents, calibrating liquid, quality control liquid, etc. Please follow the instructions of the manufacturer or distributor of the reagent. If the reagents, calibrators, and QC solutions are not properly stored, the correct test results and the best instrument performance are not available even on the due date.
(4) After checking the reagent, perform the calibration analysis.No calibration analysis may lead to a correct analysis of the results.
(5) Reagent cross-contamination may affect the results of the analysis. For reagents cross-contamination information, please consult the manufacturer or our company.

Data backup

 **Attention:**

The instrument has the function of automatically storing data on the computer's hard disk, but the computer's hard disk data is deleted or the hard disk is damaged due to other causes, which cannot recover the data. Periodically back up the analysis data and measurement parameters to other removable storage devices.

Computers and printers

 **Attention:**

The computer and printer use precautions, refer to the instructions for its use.

1. Main Introduction

1.1 System composition

Automatic chemistry analyzer is mainly used for the quantitative determination of serum, plasma, urine, cerebrospinal fluid of clinical biochemistry project, immunization programs, therapeutic drug monitoring and drug abuse monitoring. The system consists of analyzer, computer, LCD monitor, keyboard, mouse and printer.

The appearance of the analyzer as figure1-1.

1.2 Instrument parameter

Sheet 1-1 Instrument parameter

Performance index		Standard
The basic	Test speed	280 tests per hour
	Wavelength range	340～800nm,the spectral system, acquisition and processing simultaneously wavelength
	Wavelength accuracy	±1nm

characters	Reaction temperature	37℃±0.2℃
	Test item	Up to 56 test items
	Test method	One-endpoint, Two-endpoint, Rate method, Fixed- time method
Sample system	Sample position	Total of 49 positions, edit calibration QC and sample arbitrarily, original test tube, centrifuge tube, standard cup are available.
	Sample types	Serum, urine, cerebrospinal fluid and other body fluids
	Sample volume	2 ~ 70μl(0.1μl stepping). Equipped with high precision million times life syringes
	Sample margin	50μl sample fluid volume requirements
	R&S needle	Liquid level detection, remaining detection, vertical collision detection
	R&S needle cleaning	Inner and outer walls cleaning
Reagent system	Reagent tray and reagent position	Reagent dish with frozen. Liquid medium conduction cooling refrigeration. total of 56 reagent positions
	Reagent volume	20 ~ 350μl(0.5μl stepping)
	Reagent bottle specifications	20mL, 50mL
	Reagent margin	Reagent solution requires greater than 1mL
	R&S needle	Liquid level detection, remaining detection, vertical collision detection
	R&S needle cleaning	Inner and outer walls cleaning
	Reagent storage temperature	2℃ ~ 8℃ storage 24 hours working
	Reaction system	Discrete
	The number of cuvettes	6 groups, each group of 20, a total of 120

Reaction system	Reaction time	About 10 minutes
	The reaction liquid volume	120 ~ 500μl
	Absorbance range	0 ~ 3.3Abs
	Light source	20W/12V Long life quartz halogen lamp
	Resolution Ratio	0.0001
	Calibration	One-point linear, Two-point linear, Multi-point linear, Logit-log4p, Logit-log5p, Polyline, Spline and so on
	QC	QC interval: Month QC, Daily QC, Real Time QC, add QC at any time, up to 6 QC for one items. QC rules: Westgard rules QC, Cumulative Sum Check QC and Twin-Plot QC, supports three levels of QC
	Automatic cleaning	Automatic cleaning cuvettes, R&S needle, stirrer.
	Mixer system	Speed adjust, Teflon coating, Mixing alone after filling sample and reagent
Data system	Interface	Network interface
	Data processing	Showing reaction curves and data simultaneously
	Printer	Ordinary inkjet or laser printer, Chinese and English reporter, the report supports user-defined mode.
	LIS system connection	LIS system can be connected
The whole system	Weight	80kg
	Dimensions	950mm(L)×603mm(W)×505mm(H)
	Power(VA)	300VA
	Water consumption	5L/h
	Power supply	AC220/110V±10%, 50/60Hz±1Hz

Installation conditions	Environment	Storage temperature of the system is -10℃ ~ 40℃, fluctuation <± 2℃/H, system storage humidity is lower than 80%RH, non-condensing. When the system is working, the ambient temperature is 15℃ ~ 30℃, fluctuation <± 2℃/H, humidity 35%RH ~ 80%RH, non-condensing. The altitude is no more than 2000 meters.

1.3 Introduction of analysis parts

The structure is based on the "two trays + one needle + one stirring"(reaction tray and R&S tray, one R&S needle, one stirring arm). The R&S needle is used for adding sample, reagent 1 and reagent 2. Stirring arm is used for mixing reagent and sample. Optical measurement part adopts after spectrophotometry to the cuvettes for photoelectric collection. During the test, the cuvettes will be washed automatically by the cleaning needle.

1.3.1 Instrument appearance

Figure 1-2 Front view

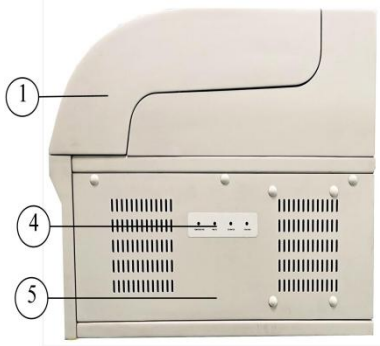


Figure 1-3 Right side view

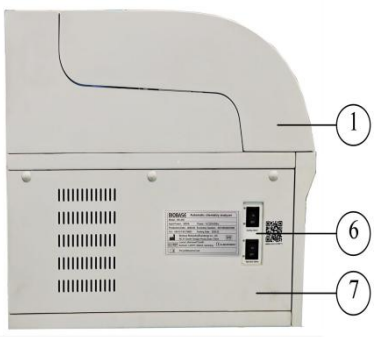


Figure 1-4 Left side view

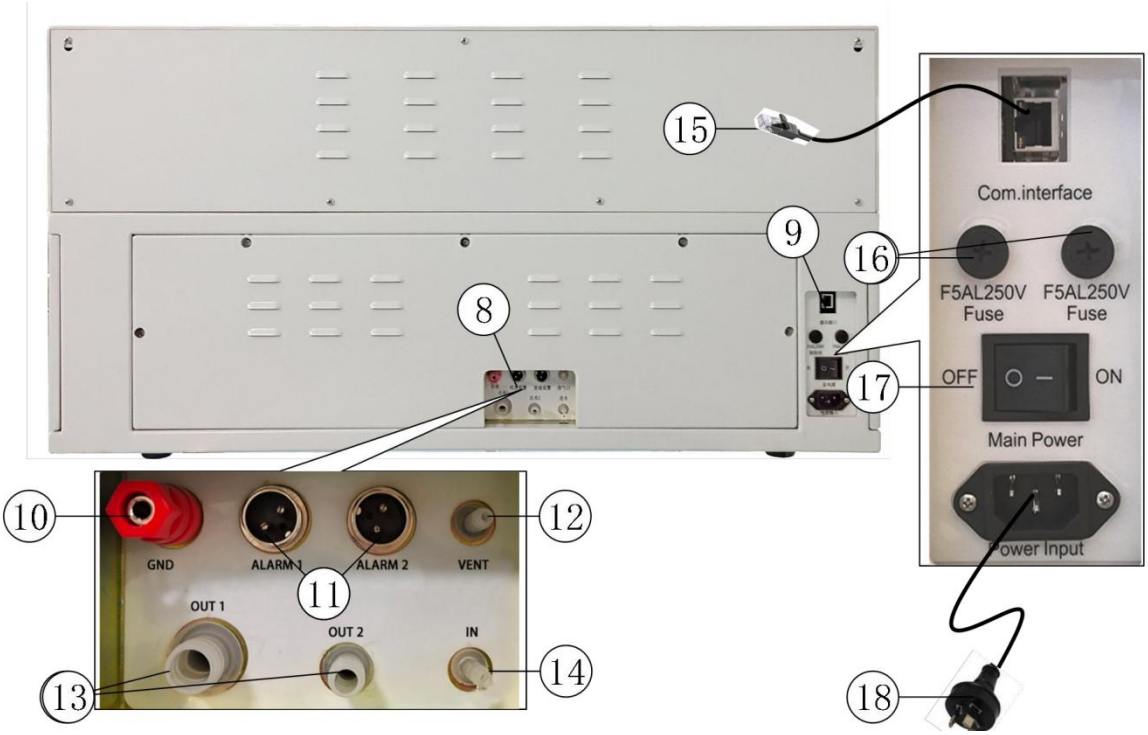


Figure 1-5 Rear view

No	Name	Remark
1	Header	Protect adding system, detection unit, sample and reagent tray.
2	Window	Watch adding system and detection units from here.
3	Front panel	Strike when maintenance the machine.
4	Alarm indicator lamp	Liquid level alarm and temperature alarm.
5	Right side panel	Strike when adding cooling oil and maintenance water system.
6	Power switch	Operation switch and cooling switch.
7	Left side panel	Power switch is located on the left side panel.
8	L-type support	Connect grounding line, water alarm float switch and water tube connection.
9	Power panel	Open or close power supply and power line connection.
10	Earth stud	Used to connect earth line.
11	Aviation joint	Connect water alarm float switch to alarm purifier and waste water.
12	Vent	Used for the gas out of the pure water tank.
13	Outfall	Connect armored tube, empty waste water.
14	Inlet	Connect silicone tube, provide purifier water.
15	Communication interface	Used to connect analyzer and PC.
16	Fuse	Protect the safe operation of the circuit.
17	Main switch	Used to control the main power of the analyzer.

18	Power line	Connect power supply.

1.3.2 Instrument roof structure

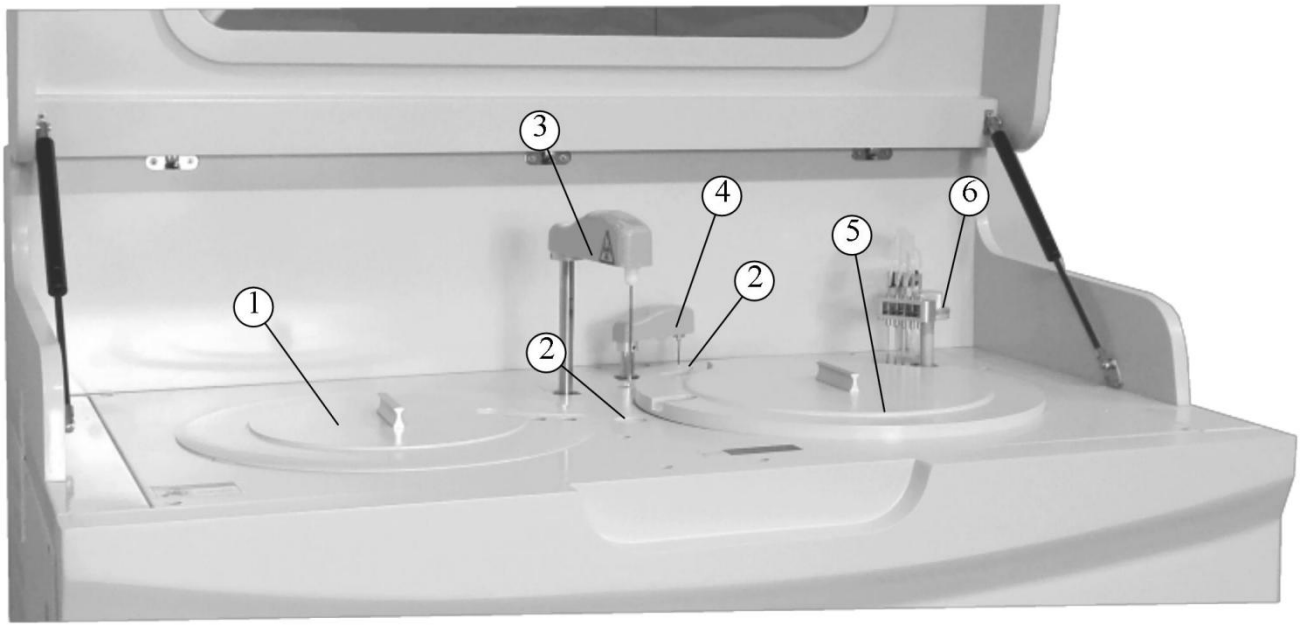
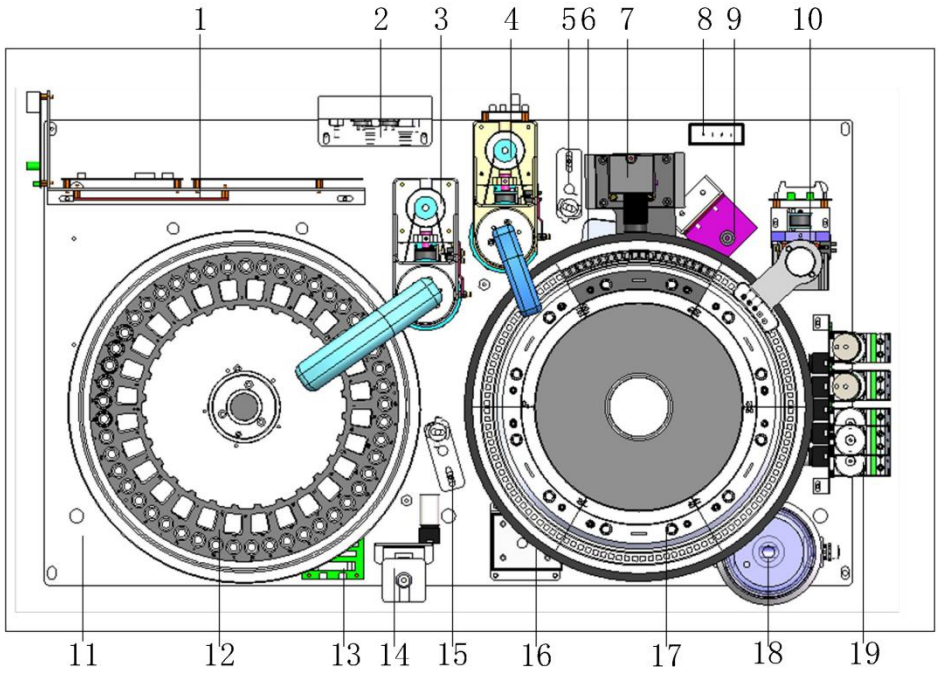


Figure 1-6 Internal structure

No	Name	Remark
1	R&S tray	Put reagent bottle, sample cup and test tube.
2	Cleaning cup	Clean R&S needle.
3	Sample system	Extraction reagent and sample from R&S tray, and distribute to the cuvettes.
4	Mixing system	Mix reagent and sample in the cuvettes.
5	Reaction system	Fixed cuvettes, keep suitable temperature and provide reaction conditions.
6	Cleaning system	Used to clean cuvettes.

1.3.3 Instrument structure



1-Circuit board, 2-Water L frame, 3-R&S arm, 4-Stirring arm, 5-Cleaning cup, 6-Pinboard of AD, 7-Halogen lamp, 8-Terminal block, 9-Optical component, 10- Cleaning arm, 11-Baseplate, 12-R&S tray, 13-Pinboard, 14-Sample pump, 15- Cleaning cup, 16-Circulating pump, 17-Reaction tray, 18-Container, 19-Pump and valve component

Figure 1-7 Instrument structure

1.4 Structure and function

The analyzer consists of operation part and analysis part, which are connected by Internet interface. As shown in figure 1-8.

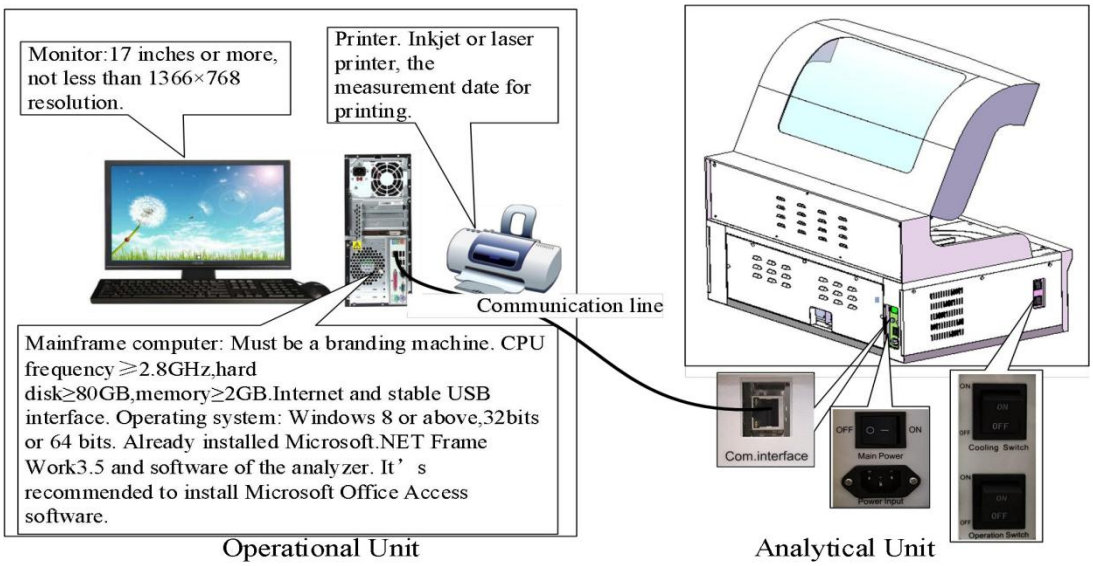


Figure 1-8 System connection

1.4.1 Operation part

Operation part consists of computer, monitor, keyboard, mouse and printer etc.

Operation system: Windows 8 or above, 32 bits or 64 bits. Already installed the special software.
Computer configuration: Must be a branding machine CPU frequency ≥ 2.8GHz, hard disk ≥ 80G, memory ≥ 2G. Internet port and USB interface.
Monitor: 17 inches or more, not less than 1366 x 768 resolution.
Printer: Inkjet or laser printer, print the test report.
Mouse: Able to complete the operation of the software.
Keyboard: Able to edit each function of analyzer.

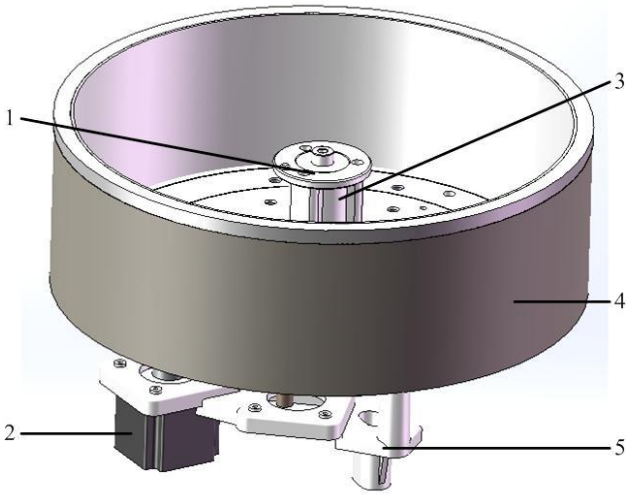
1.4.2 Analysis part

Analysis section is mainly composed of R&S tray, R&S arm, reaction system, stirring arm, cleaning arm, cooling system, optical system, water system and alarm system.

1.4.2.1 R&S tray

1-Sample positions, 2-Outer ring, 3-Inner ring
Figure 1-9 R&S tray structure

As shown in figure 1-9, sample tray is divided into inner ring and outer ring and sample positions, a total of 49 samples. We can put the standard cup that contain sample, calibration liquid, quality control liquid in the designated position, through the sample disc rotating to send samples to dispensing position of the R&S arm.



1-Gear positioning tray, 2-Step motor, 3-Shaft, 4-Outline frame, 5-Support base

Figure 1-10 R&S tray structure

1-Above tray, 2-Middle tray, 3-Tray support, 4-Hand grip

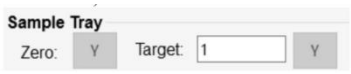
Figure 1-11 Structure

As figure 1-10&1-11 shows, R&S tray consist of support pillars, frame, tray shaft, positioning tray, driving motor, sample tray and the handle etc.

After turning on the power, the drive motor drives the gear to rotate, so that the position of the first position is rotated to the sample position. When the sample is tested, the driving motor drives the R&S tray to rotate, and the sample bit number or the reagent position of the sample is rotated to the sample adding position. When initializing, the same action with the power on.

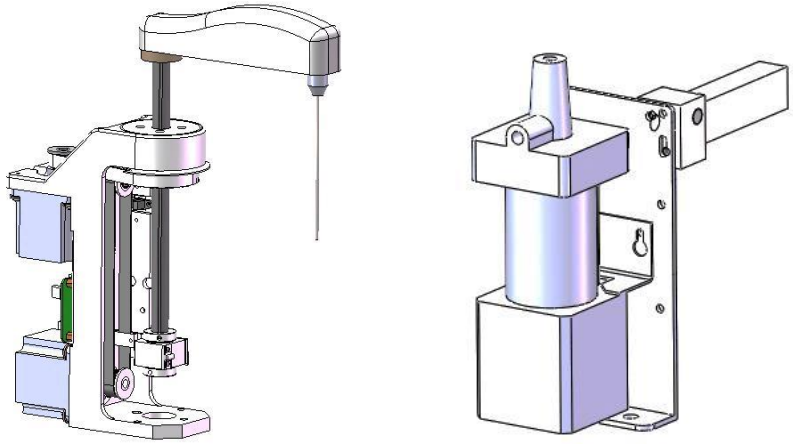
When installation, must aim at the sample tray guide pin, make sample tray flat and level, with the hand gently turns non-slip, then tighten the reagent tray handle. When remove, screw the handle counterclockwise then take out whole sample tray.

When check movement, find the "Instrument Check", input target value in "Target Position", and click “Y” to check. "Zero Position" is back to original position.



1.4.2.2 Dispensing system

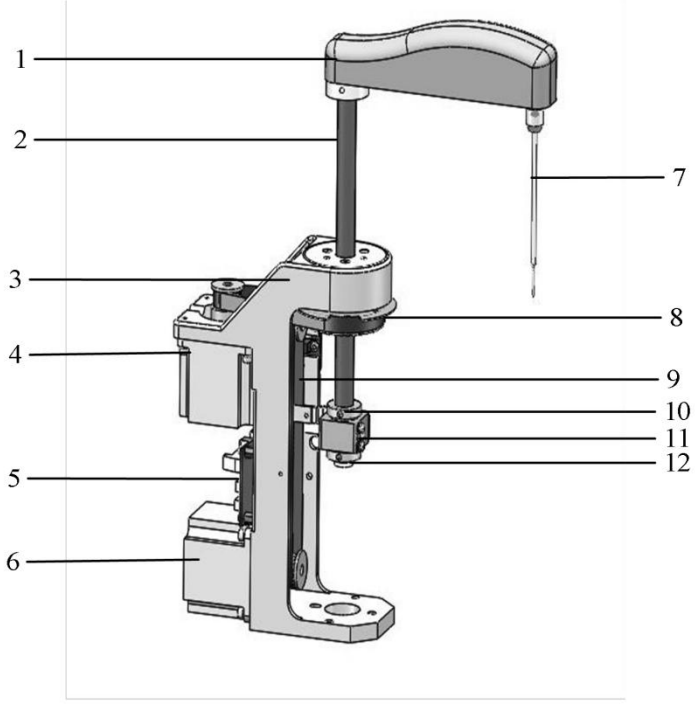
As figure 1-12 is shown, the R&S arm is composed of R&S arm, dispensing pump and solenoid valve, which is controlled by solenoid valve and plunger pump.



R&S arm Dispensing pump

Figure 1-12 Dispensing system

As Figure 1-13 is shown, R&S arm consist of R&S needle, cross arm, linear optical axis, drive motor and photoelectric switch etc.



1-Cap, 2-Spline shaft, 3-Main frame, 4-Step motor left&right, 5-Pin board, 6-Step motor up&down, 7-R&S needle, 8-Left and right synchronous belt, 9-Up and down synchronous belt, 10-Shaft bearing sleeve, 11-Pipe clamp, 12-Up and down drive seat.

Figure 1-13 R&S arm

R&S arm also used for adding sample and reagents.

R&S arm is used to take quantitative sample from sample cup and fill into the cuvettes. The liquid level detection function of the R&S needle can detect the remaining amount of the sample or reagent. The R&S needle have an anti-collision function. After the needle strikes, the anti-collision protection function is activated. And after the test of the sampled project is completed, the software prompts the alarm, and according to the processing suggestions and prompts, the initialization is performed to eliminate the striker operation, and then the normal test can be resumed. R&S needle volume range is 2μl-70μl, 0.1μl stepping. The minimum liquid level detection sample volume is 50μl, the minimum requirement of sample volume is above 50μl.

R&S needle withdraws fix quantify reagent from the reagent bottle and then add to cuvettes. The needle also have level senor which can detect the remaining volume of the reagent. As figure 1-14 shown:

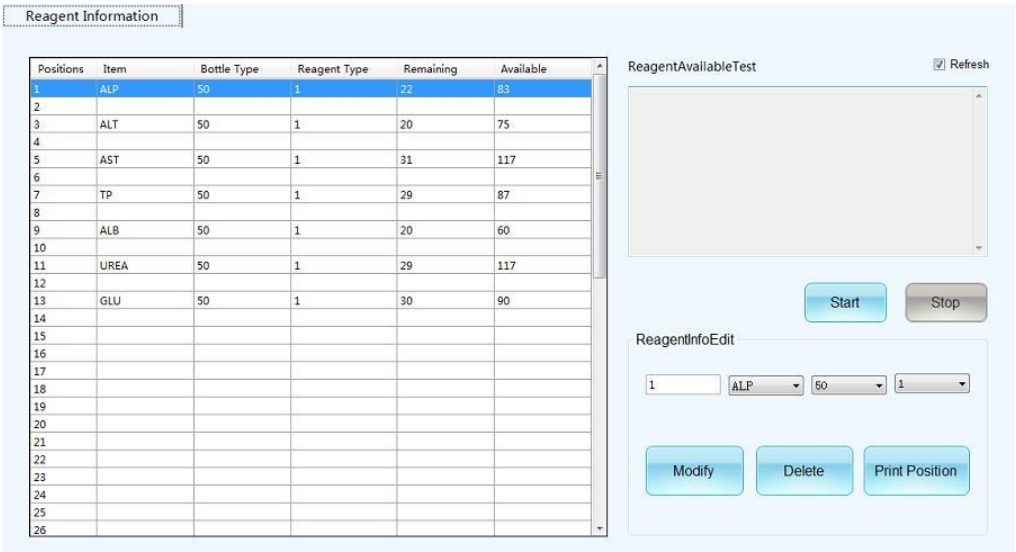


Figure 1-14 Remaining volume of reagent

In the process of taking reagent, in case of reagent dilution, the needle takes reagent in accordance with the "set quantitative+ allowance" rule and add in the cuvettes. Reagent volume is 20μl-350μl generally. The setting unit can be 1μl. After turn on the power, the needle will first rise and move to the top of the cleaning cup and drop down for washing, then rise up.

During testing, the needle follow the order sample position, reaction position, and cleaning cup. After testing, if we need to add clean fluid to wash reaction tray cuvettes, select "Clean fluid" in the "Washing&&Background" window. It can set the clean fluid position in reagent tray and the amount and the cuvettes that needed. Generally, setting number is 28 and the volume is 300μl.

Click "  ", initialization process is the same as the power on process. In the process of drawing sample, the needle will detect the liquid level first, and then go on falling more 3mm to draw the sample.

During testing, click "instrument check" button, as figure 1-15 shown, R&S tray and rotating to a certain number. Click instrument check to test the position of arms and trays, including the washing position, needle horizontal position, needle vertical position and cuvette position.

Figure 1-15 R&S arm adjustment

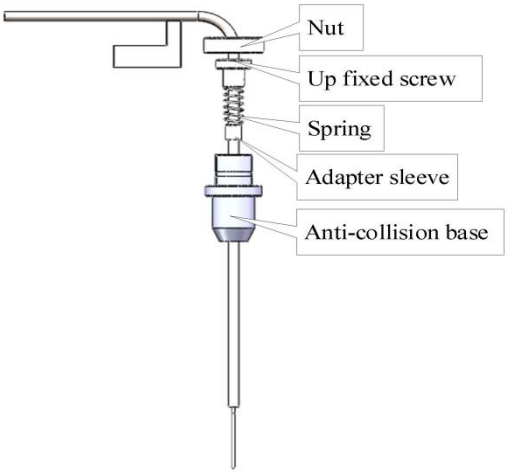


Figure 1-16 R&S needle

As figure 1-16 shown, the R&S needle is consist of anti-collision needle, up fixed screw, spring, adapter sleeve and nut.

1.4.2.3 Reaction tray system

As figure1-17 shown, reaction tray system consists of tray, cover, cuvettes and thermostat.

Cuvettes positioning tray: Rotated by stepper motor.

Cuvettes: Total 120 units, can be replaced independently by micro organic material, its standard optical path is 6 mm. Reflection cup group: Total of 6, each part is installed 20 cuvettes, fixed on the reaction tray cover by two pins, as shown in figure 1-18.

Thermostat bath: Allow the sample to react with the reagent in the thermostat while temperature monitoring is performed by a temperature control system.

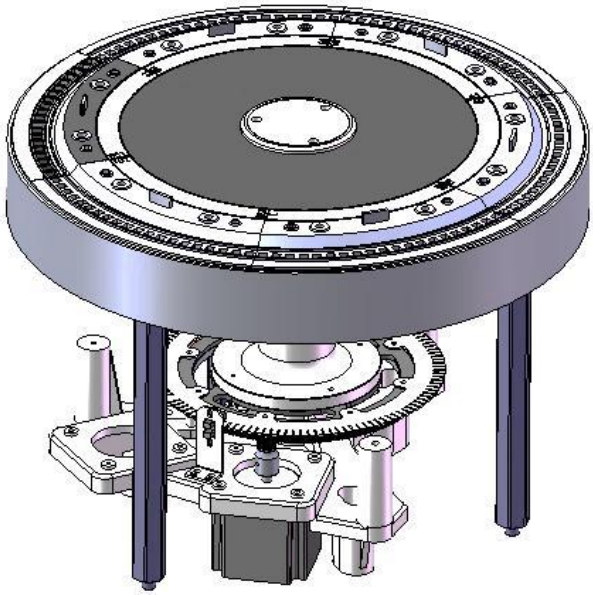
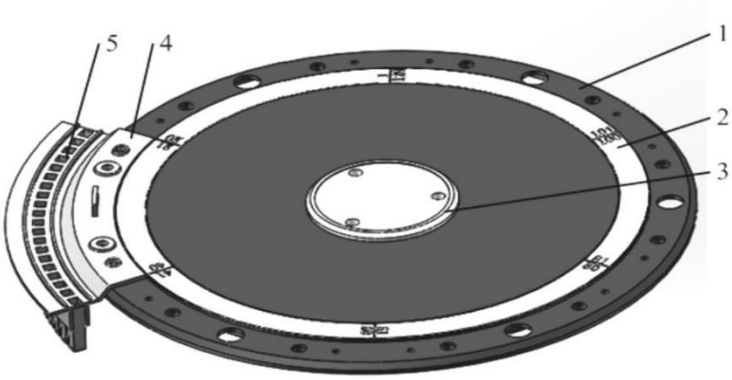
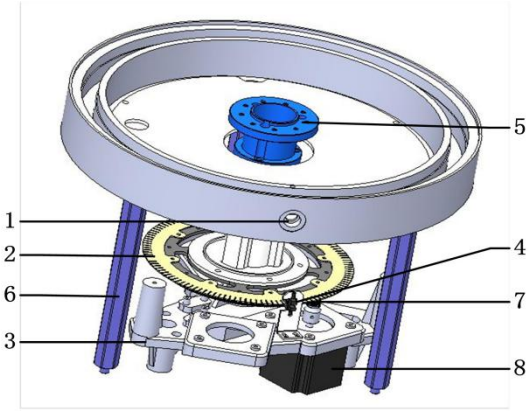


Figure 1-17 Reaction tray



1-Cuvettes positioning tray, 2-Reaction tray lamination, 3-Reaction tray cap, 4-Cuvettes group, 5-Cuvettes.

Figure 1-18 Cover of reaction tray

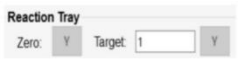


1-Optical fiber fixed orifice, 2-Big gear, 3-Fixed base, 4-Photoelectric switch, 5-Pillar support, 6-Reaction tray column, 7-Small gear, 8-Stepper motor

Figure 1-19 Reaction tray

As figure 1-17, 1-18, 1-19 shown, reaction tray consists of cover, tray, drive motor, support pillar and optical fiber fixed tray etc.

After turning on the power, reaction tray rotates clockwise, move to the number 1 position.

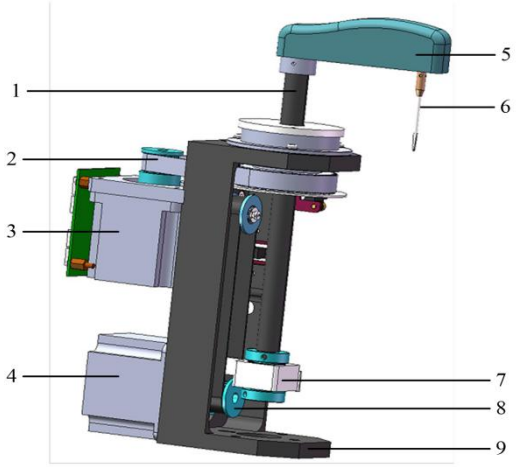
When check movement, click "Instrument Check", choose " 

" button, then input any cup number (1-120), click "Y" to check. When finished, click "Zero Position".

1.4.2.4 Stirring arm

The stirring arm consists of stirring arm and stirrer. The structure of stirring arm is similar with R&S arm. The difference is component: dispensing component and stirrer component.

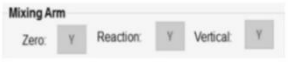
As figure 1-20 shown, stirring arm consists of drive motor, photoelectric switch, big and small belt wheel, guide shaft etc.



1-Spline shaft, 2-Left and right belt wheel, 3-Left and right driving motor, 4-Up and down driving motor, 5-Stirrer cap, 6-Stirrer, 7-Stirring arm drive seat, 8-Up and down belt wheel, 9-Stirring arm frame

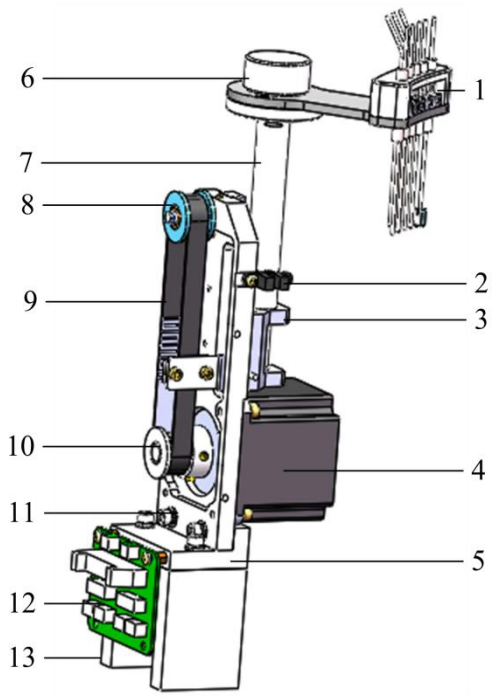
Figure 1-20 Stirring arm

When power on, the stirrer rises up ,swing left and right, stops at the top of cleaning position , then fall down to the cleaning cup, when finish, back to upward side. Initialization process is the same motion state after turning on the power supply. When run test, the stirring arm fall vertical to washing position first, then swing to 105 position in reaction tray to stir reaction fluid. When check

movement, click "Instrument Check", click " 

", click "Zero", "Reaction", and "Vertical" to adjust the stirring arm respectively.

1.4.2.5 Cleaning arm



1-Cleaning needle, 2-Photoelectric switch, 3- Slider block, 4-Stepper motor, 5-Large motor cleaning arm base, 6-Cleaning and pressing screw, 7-fixed shaft, 8-Synchronous belt from the pulley, 9-Synchronous belt, 10-Synchronous belt wheel up and down, 11-Large motor cleaning cup main board, 12-Pinboard, 13-Block

Figure 1-21 Cleaning arm

As figure 1-21 shown, cleaning arm consists of cleaning needle, drive motor, photoelectric switch etc. When turning on the power supply, cleaning arm rises up and then drop into the cuvettes, cleaning cuvettes, after cleaning up and stopped above the cuvettes.

When check movement, click "Instrument check", choose " 

", then cooperate with reaction tray rotation to test set-up cleaning needle position.

1.4.2.6 Cooling system

Cooling system consists of R&S pot assembly, Peltier, circulating pump, heat exchanger, fan, tubes and so on. The pipeline diagram as shown in figure 1-22.

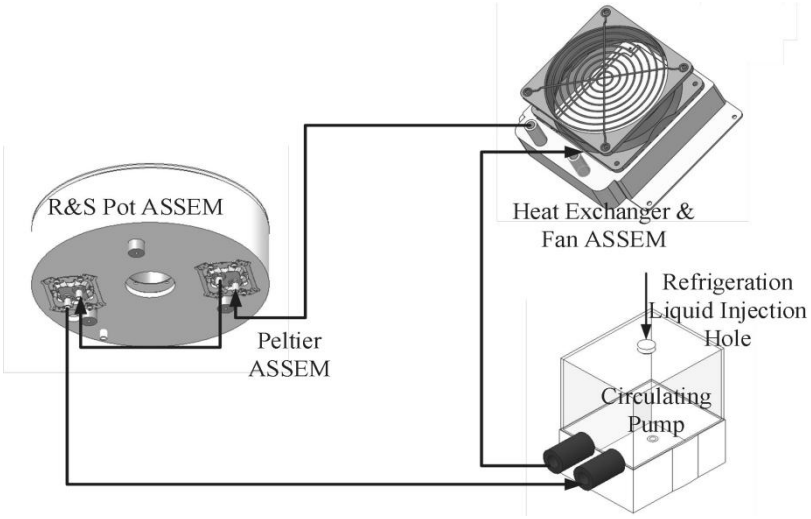


Figure 1-22 Cooling system pipeline diagram

1. Cooling components of R&S tray

Cooling components of R&S tray are composed by Peltier, water cooled joint, the pagoda joint, fixed film, as shown in figure 1-23.

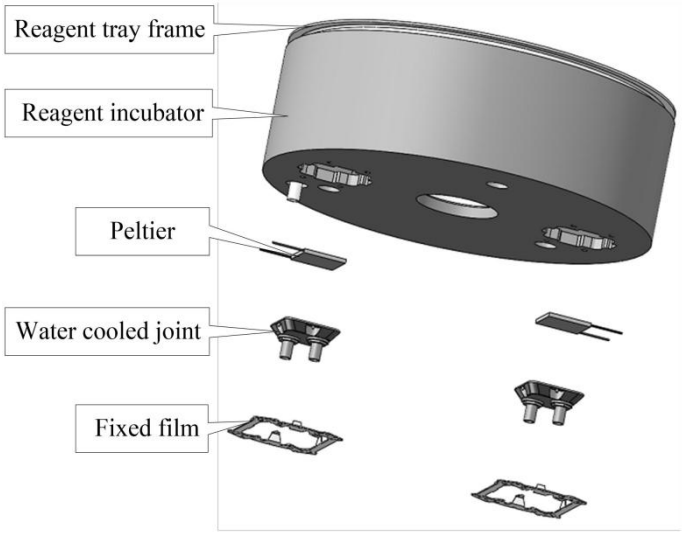


Figure 1-23 Cooling components of R&S tray

Peliter is divided into cold and hot surface, please notice the difference when installation.

2. Cooling control system

Cooling control system is mainly composed of cooling control board and circulating pump, through cooling panel to achieve control of the circulating pump and cooling piece, keep reagent tray temperature within 2℃～8℃.

The refrigeration temperature can be obtained through software operation, the operation is as follows:

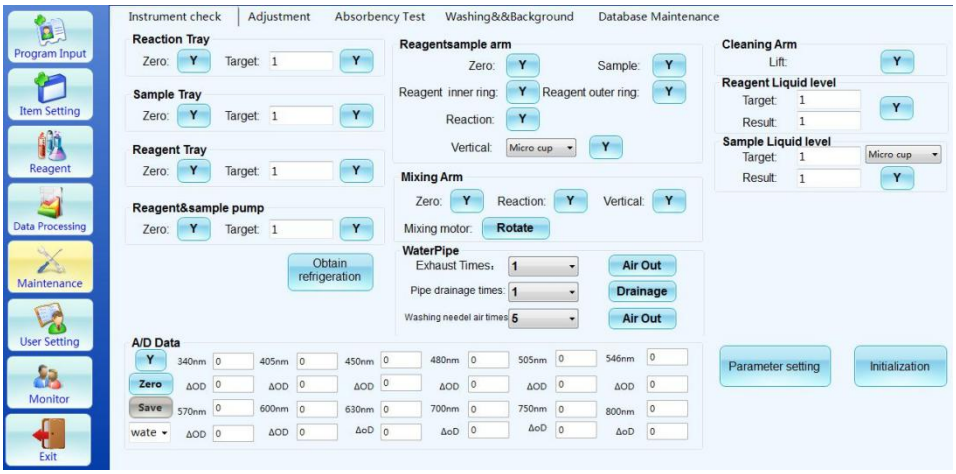
1) Click the [Maintenance] – [Instrument check].

2)Click [Obtain refrigeration], and pop up the box of temperature obtain.

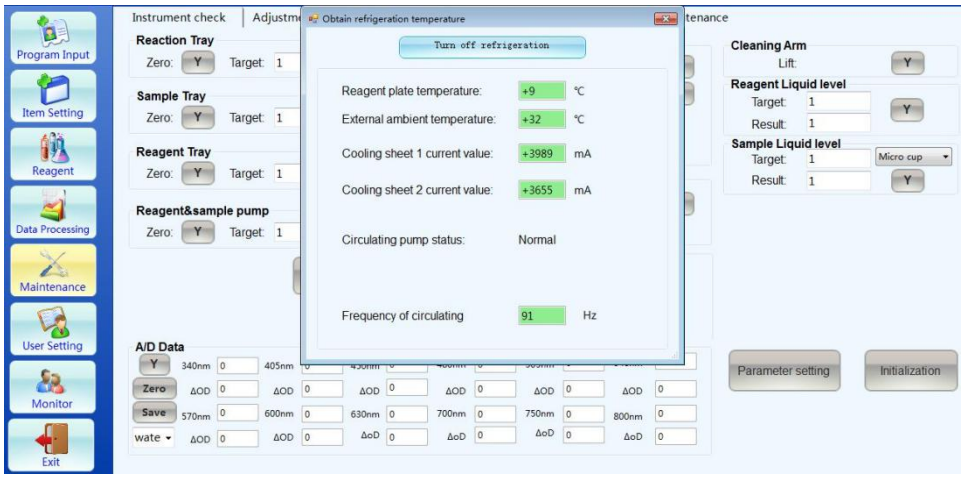
Note: If the cooling switch is off, please turn on the cooling switch.

3)Click [Obtain refrigeration temperature], and obtain the real-time temperature of reagent tray.

4)Click [Turn off refrigeration], and stop getting the temperature of reagent tray.



a)



b)

Figure 1-24 Obtain refrigeration temperature

1.4.2.7 Optical inspection system

Optical detection system is used to measure the absorbance of the reaction fluid in the cuvettes. The system consists of optical system and signal detection, its main function is to detect the change of light intensity through reactant, by the method of photoelectric converting optical signal to electrical signals, by measuring electrical signal variation amount to reflect the change of light intensity. Its working principle diagram is shown in figure 1-25.

Optical system is composed of light source, colorimetric system and fiber optic components, used to provide enough intensity monochromatic light, after the light source produce stable and continuous spectrum, polychromatic light divide into monochromatic light through the fiber optic components, then after filtering the specific wavelengths of monochromatic light into the signal detection system.

Signal detection system includes photoelectric conversion section and AD collection and processing. Its main function is to convert the light of the transmission to electrical signals, then amplify, analysis and processing, acquiring the light path signal.

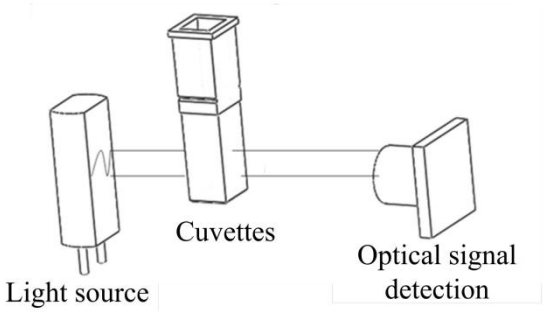


Figure 1-25 Optical detection system

Light system adopts the after spectrophotometry techniques, Wavelength range is 340 ～800nm (three wavelengths can be defined by the user).

1.4.2.8 Water system

The water system includes the pump liquid and the drain liquid way. The whole water system diagram is shown in the attachment B Water system diagram.

1.4.2.9 Alarm system

Alarm system includes R&S tray temperature alarm, waste fluid alarm, pure water alarm, cooling liquid level alarm.

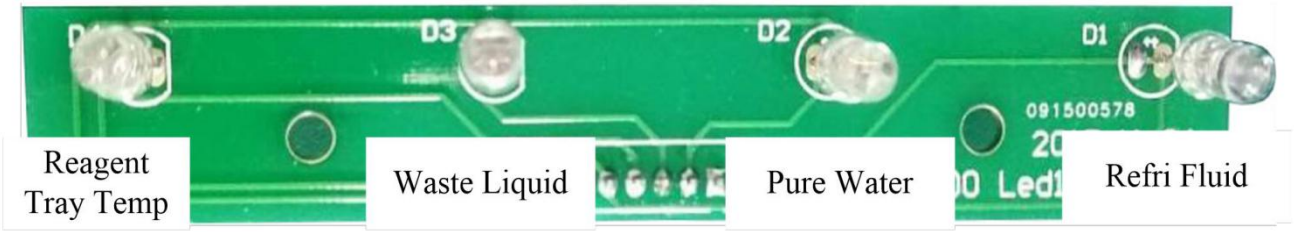


Figure 1-26 Alarm indicator diagram

The temperature of the reagent tray is abnormal: When the temperature of the tray is higher than 45°C, the buzzer will sound and the TEMPERATURE- LED will flash.

The flashing frequency is 0.5 seconds on and off for 0.5 seconds.

The temperature of the environment is abnormal: When the temperature of the environment is higher than 45°C, the buzzer will sound and the TEMPERATURE- LED will flash. The flashing frequency is 1.5 seconds on and off for 0.5 seconds. If the temperature of the reagent tray and the temperature of environment are abnormal at the same time, the buzzer sounds and the TEMPERATURE- LED is on.

Waste liquid alarm: When the waste liquid barrel is full, the buzzer will sound and the WASTE- LED will flash.

Pure water alarm: When the pure water level is low, the buzzer will sound and the DI WATER- LED will flash.

Refrigerant level alarm: When the refrigerant level is low, the buzzer will sound and the COOLING- LED will flash. The flashing frequency is 0.5 seconds on and off for0.5 seconds.

Peltier alarm: When the Peltier is abnormal, the relay module on the refrigeration circuit board is powered off, the buzzer sounds and the COOLING- LED flashes, the flashing frequency is 1.5 seconds on and off for 0.5 seconds.

If the refrigerant liquid level and Peltier are abnormal at the same time, the buzzer will sound and the COOLING- LED will be on.

2. Installation

In order to ensure the normal operation of the instrument after installation, only person authorized by the company is allowed to doing the initial installation and setting.

2.1 Unpacking

2.1.1 Unpacking steps

After the goods arrival, please carefully check the instrument packaging, to see if there is physical damage. If any damage, please contact with the company or local distributor. After confirming no external damage, unpacking follow steps below:

- Up Place package box as the up arrow.
- Open the accessory box and check whether object is complete according to the packing list or not. If there is any missing, please contact with the company or local distributor.
- Carefully check the instrument appearance, if there is any damage, please contact with the company or local distributor.

2.1.2 Instrument transporting

- Ensure all parts of instrument are in good appearance without damage before transporting.
- All moving and transportation must keep instrument upright direction, do not tilt or side up.
- Avoid vibration while transporting, please check and debug after transporting. If all is OK, please follow chapter 2.2.

2.2 Installation requirement

Install the instrument as shown in figure 2-1.

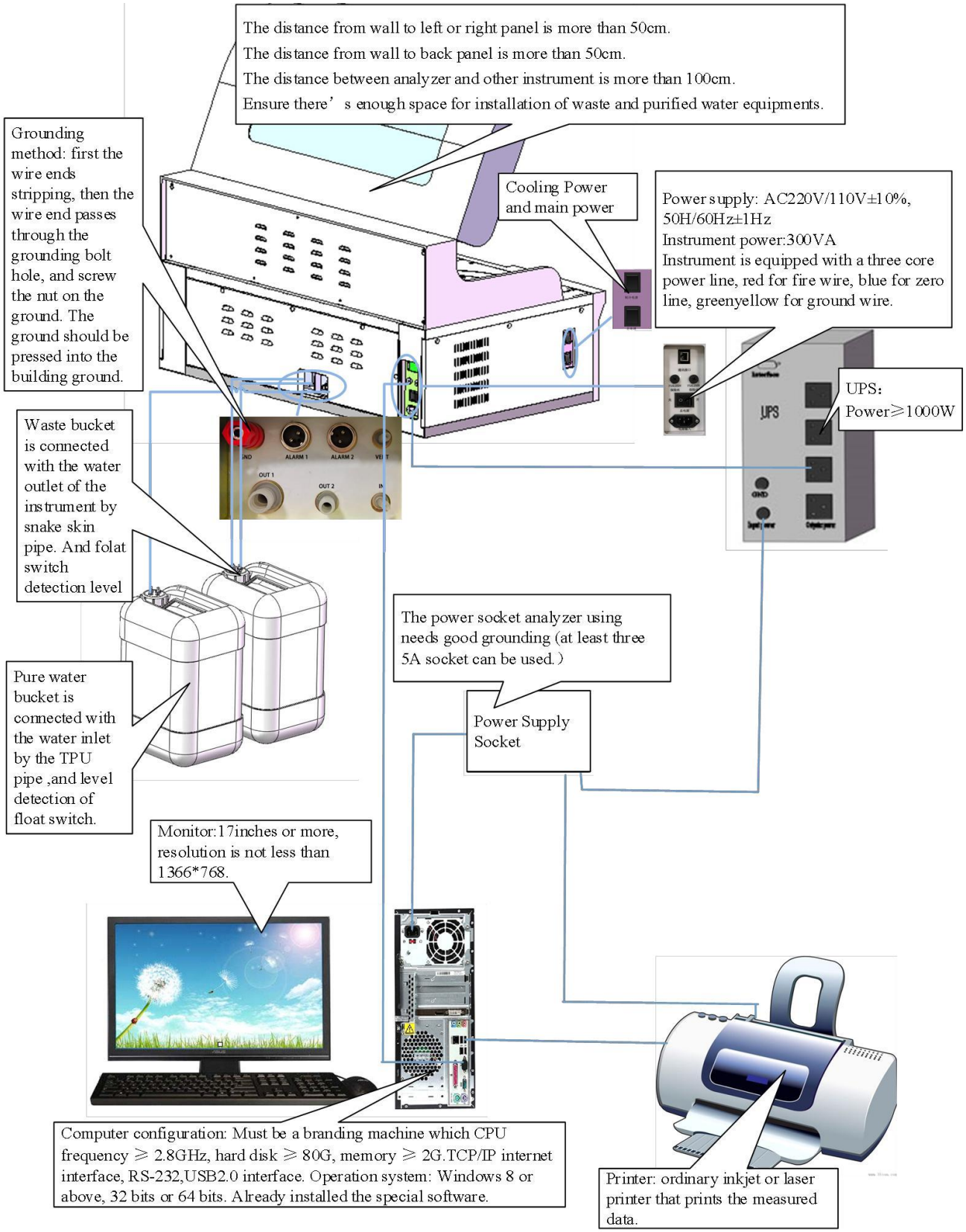


Figure 2-1 Install the instrument

In figure 2-1, the connecting lines indicate the corresponding piping or lines.

2.2.1 Space requirement

To convenient for the equipment operation maintenance and repair, auto chemistry analyzer need to satisfy the following conditions when installation.

a) The distance between the left and right sides against the wall should be greater than 500mm.

b) The distance between the rear panel against the wall should be greater than 500mm.

c) The distance between front side of the analyzer and other instruments should be greater than 1000mm.

d) The space of the waste liquid discharging device and the pure water supplying device should be ensured while installation.

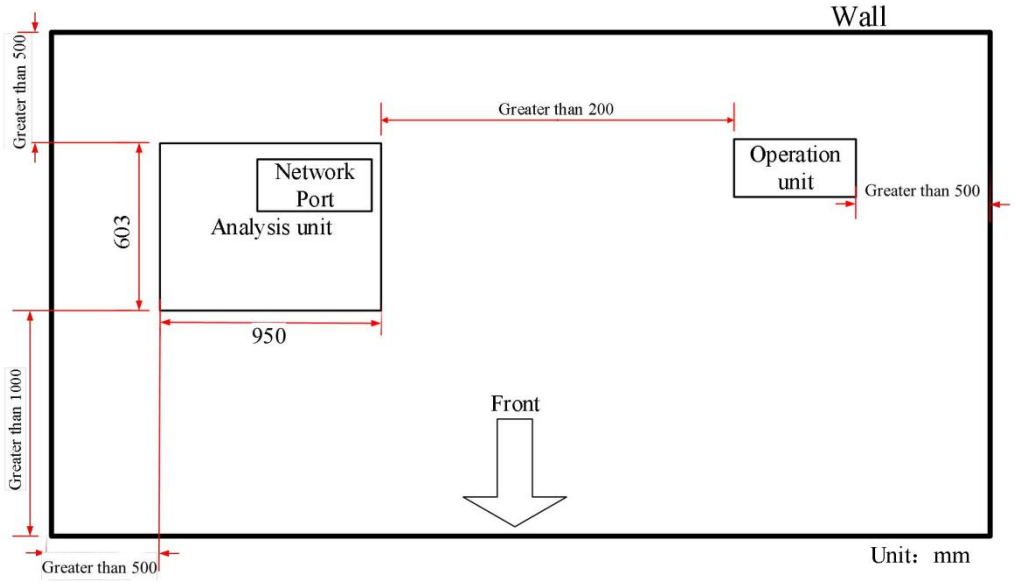


Figure 2-2 Space requirement

2.2.2 Power requirement

Power supply: AC220V/110V±10%, 50H/60Hz±1Hz.

Instrument power: 300VA.

The electrical socket used for this instrument needs to be well grounded (at least three 5A sockets can be used). Large electrical equipment, such as air conditioners refrigerators and ovens, should not be used with the same socket.

The earth stud is located on the rear panel L, and the ground wire must be connected.

The protective grounding must be good. As shown in figure 2-3.

Figure 2-3 The earth stud

Warning:

The protective grounding must be well protected to against electrical shock and instrument malfunction.

2.2.3 Environmental requirement

Environment temperature is 15 ℃ ~ 30 ℃.
Relative humidity is 40% ~ 85%.
Atmospheric pressure is 86 kpa to 106 kpa.
Series full automatic biochemical analyzers are only in indoor use. The environment should be clean, without mechanical vibration and noise source and the power interference.
The ground should be flat and of sufficient strength.
Don't get analyzer close to brush type generator, flashing fluorescent, and often switching electric contact device.
Avoid direct sunlight or in front of heat source and pouring.
Keep the instrument well ventilated.

 **Note:**

The instrument will not guarantee the accuracy of the normal operation and test data in the rugged environment mentioned above. If the temperature and humidity cannot meet the above requirements, please use the air conditioning equipment. In the working process, the instrument can produce heat and it is discharged through the instrument back. Working environment should be kept well ventilation and ventilation equipment can be used when necessary. Direct flow of air should be avoided to the instrument, or it may affect the accuracy of the instrument test.

2.3 Water supply and drainage

The following requirements of water supply and drainage must be met before the instrument is delivered:
Instrument requires deionized water, the conductivity below 1μs/cm, water consumption is 5L per hour. We recommend to use 15L water machine.
Ensure that the instrument water supply hole and pipe installation should be unimpeded. In addition, the inlet hole of L rack should be higher than the pure water barrel, and difference of feed water level should be less than 50cm.
Ensure that the instrument drain hole and pipe installation should be unimpeded, and the equipment L rack outlet hole should be higher than the waste barrel (or waste discharge), waste pipe length should not exceed 2m.

2.4 Software installation

See the instruction of software installation for detail.

3. Software Operation

3.1 Software login

Run the desktop icon 

. When you run the software for the first time, it will tip On line setup, as shown in figure 3-1. Click "OK", the dialog box shown in figure 3-2 will pop up and then click the software configuration. If the following figure 3-3 dialog box appears, the software configuration is successful.

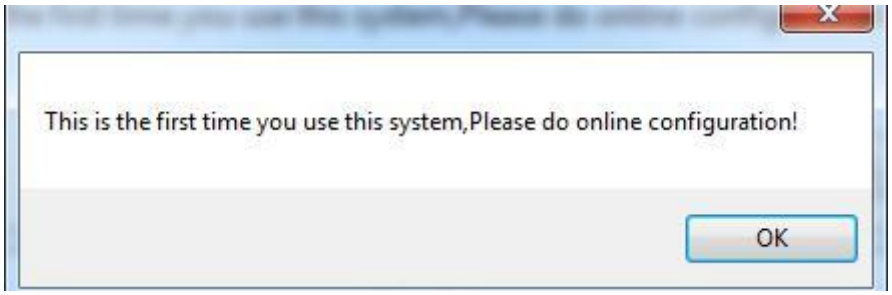


Figure 3-1 Software operation

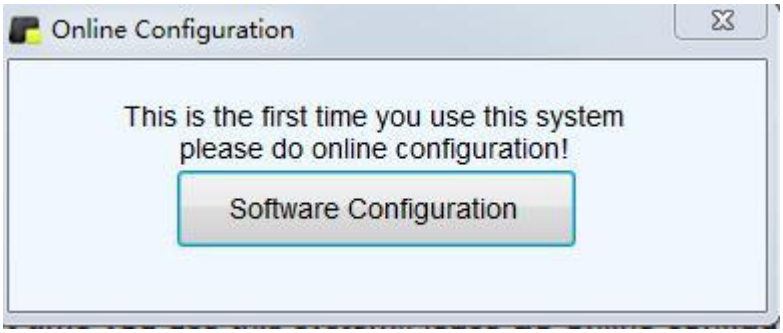


Figure 3-2 Software operation

Figure 3-3 Software operation

Run the icon again 

, and input the user name and password (The initial password is 12345), click the button 

to open the software.

Figure 3-4 Login information interface

After login the software, will prompt the maintenance operation, as shown in figure 3- 5, click the "OK" button, the instrument carries out initialization operation and exhaust operation, after the exhaust into the main interface, the instrument into the standby state, as shown in figure 3-6.

The initialization operations are as follows:

1 Lift the R&S arm, lift the stirring arm, lift cleaning arm.

2 The R&S arm and stirring arm swing from side to side and return to the cleaning position.

3 Washing the R&S needle and stirrer.

4 The R&S tray rotates, and the reaction tray rotates clockwise,both tray return to zero.

5 Dry the reaction cup.

6 The instrument enters the standby state.

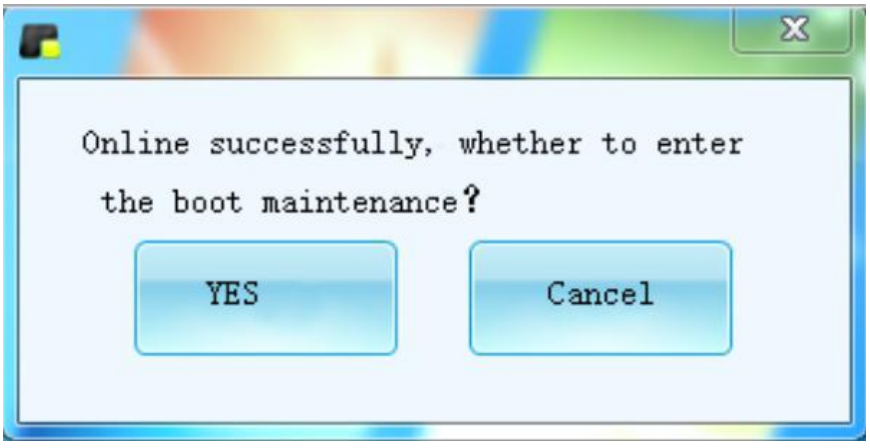


Figure 3-5 Maintenance interface

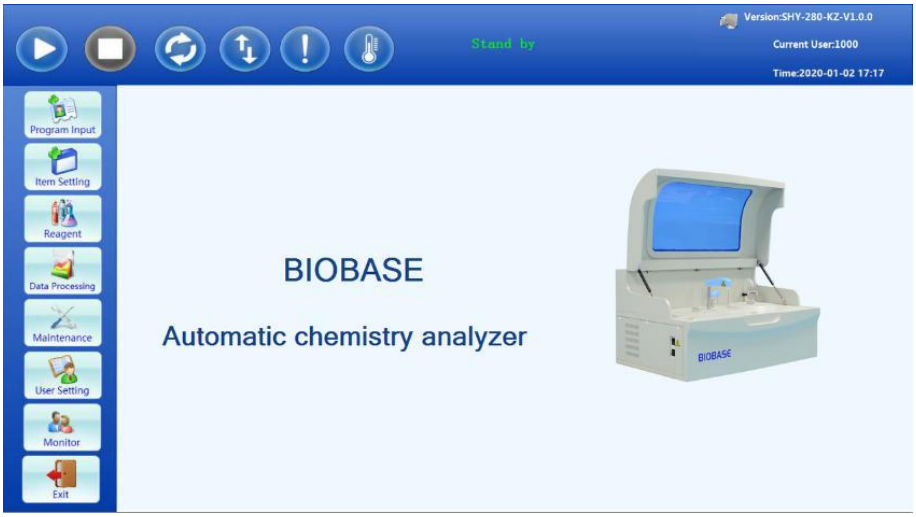


Figure 3-6 Software interface

3.2 Software interface

Software interface consists of several major parts: the menu bar, toolbar, workspace, the status bar, as shown in figure 3-7.

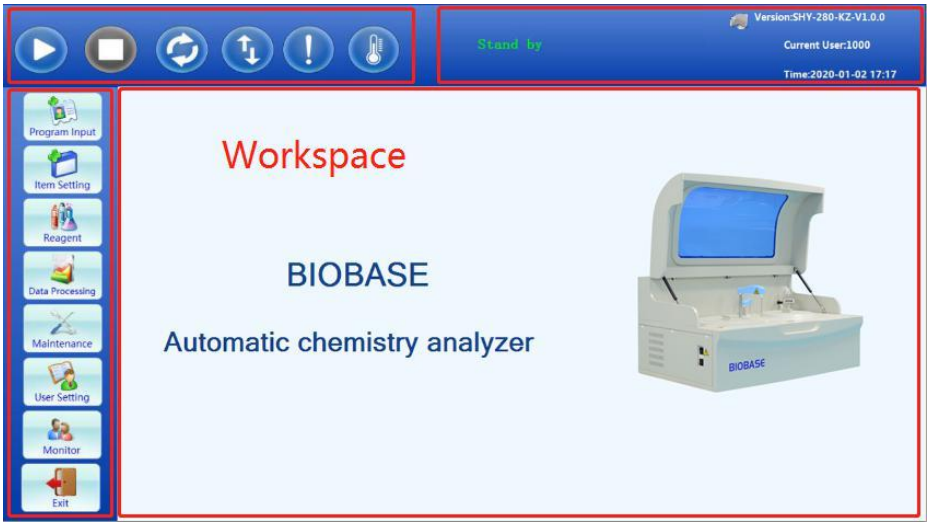


Figure 3-7 Software composition

1. Menu bar

Menu Bar: Displays the function menu of the instrument software. Click the menu bar to display the submenu, Click the submenu to display the software operation interface The menu bar is located on the left side of the main interface, display the function menu for the operation of the software, the menu bar icons and functions are shown in sheet 3-1.

Sheet 3-1 Menu bar icons and functions

NO.	Icon	Function
1		Enter the sample information that needs to be tested and carry out calibration and QC entry for new items.
2		Edit the item parameters, edit the calibration, and QC parameters, and edit special item parameters.

3		Edit the position information of the reagent so that it corresponds to the reagent location
4		Test curve, test result query, QC result query, report printing, data maintenance, export.
5		Instrument inspection, instrument calibration, absorbance test, cleaning the cup and reading the background information.
6		Data statistics, user management setting, version information query.
7		Sample tray, reagent tray, reaction tray status monitoring during the test.
8		Exit the Chemistry software operation.

2. Status bar

Located in the top right of the main interface, real-time display the current user, display computer system time, as well as current working state or testing process.

Display as shown in figure 3-8：

Figure 3-8 Status bar

: Displays the name of the current software operator. Users can add and delete in the “Add” and “Delete” users under the [User Setting] form.

: Display the time of system.


: Display whether to connect to the LIS system.

: Display working status.

3. Tool bar

Located in the main interface of the upper left, several commonly used functions of the software are placed in the toolbar. It is convenient to user for corresponding operation, as shown in figure 3-9, selected by mouse click.

Start Stop Initialization Online Alarm Temperature

Figure 3-9 Tool bar

4. Workspace

According to user's choice, it can appear the corresponding functions in the interface window. Such as in the menu bar, click on the "project input" button, the display as shown in figure 3-10 sample input software interface.

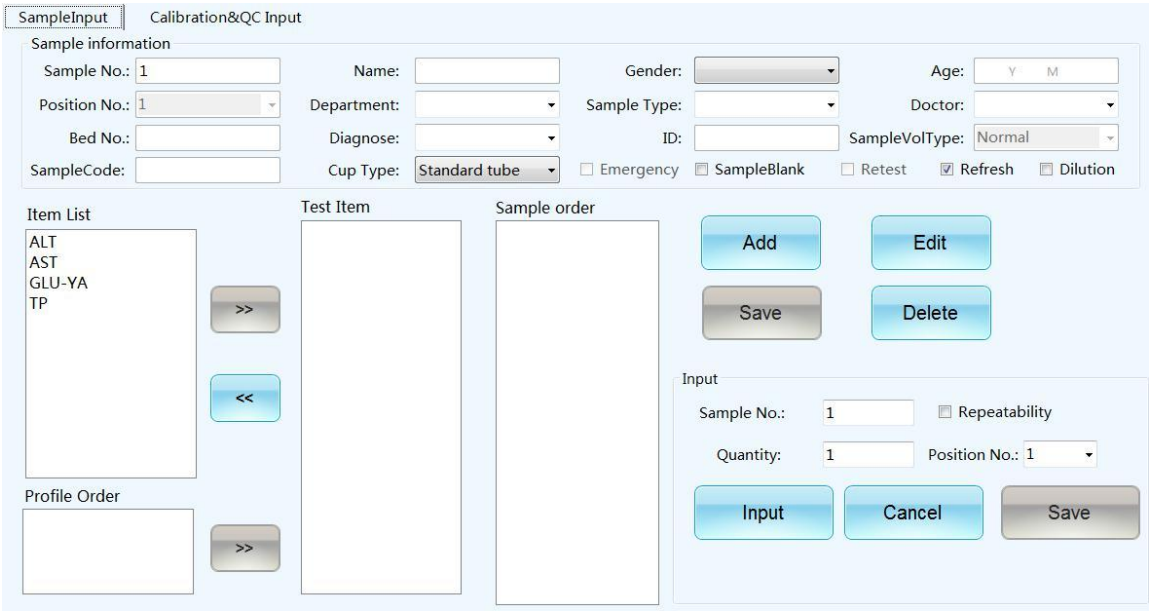


Figure 3-10 Sample input

5. Version information

Software version 

display in status bar, analyzer software version: Click 

, working area will display user manager interface, click [About], then click [Get Version], then the software version and analyzer number will be display.

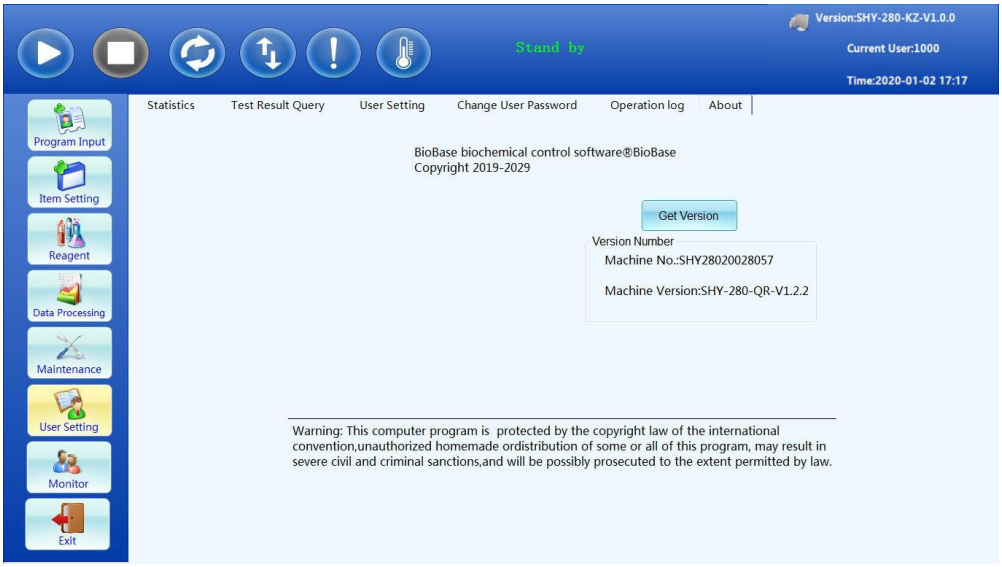


Figure 3-11 Version information

3.3 Software operation

Choose software operation by the way of mouse clicking. Input number, word by the use of keyboard (Input method according to Windows system, can transform by Shift+Ctrl button).

3.4 Software function chart

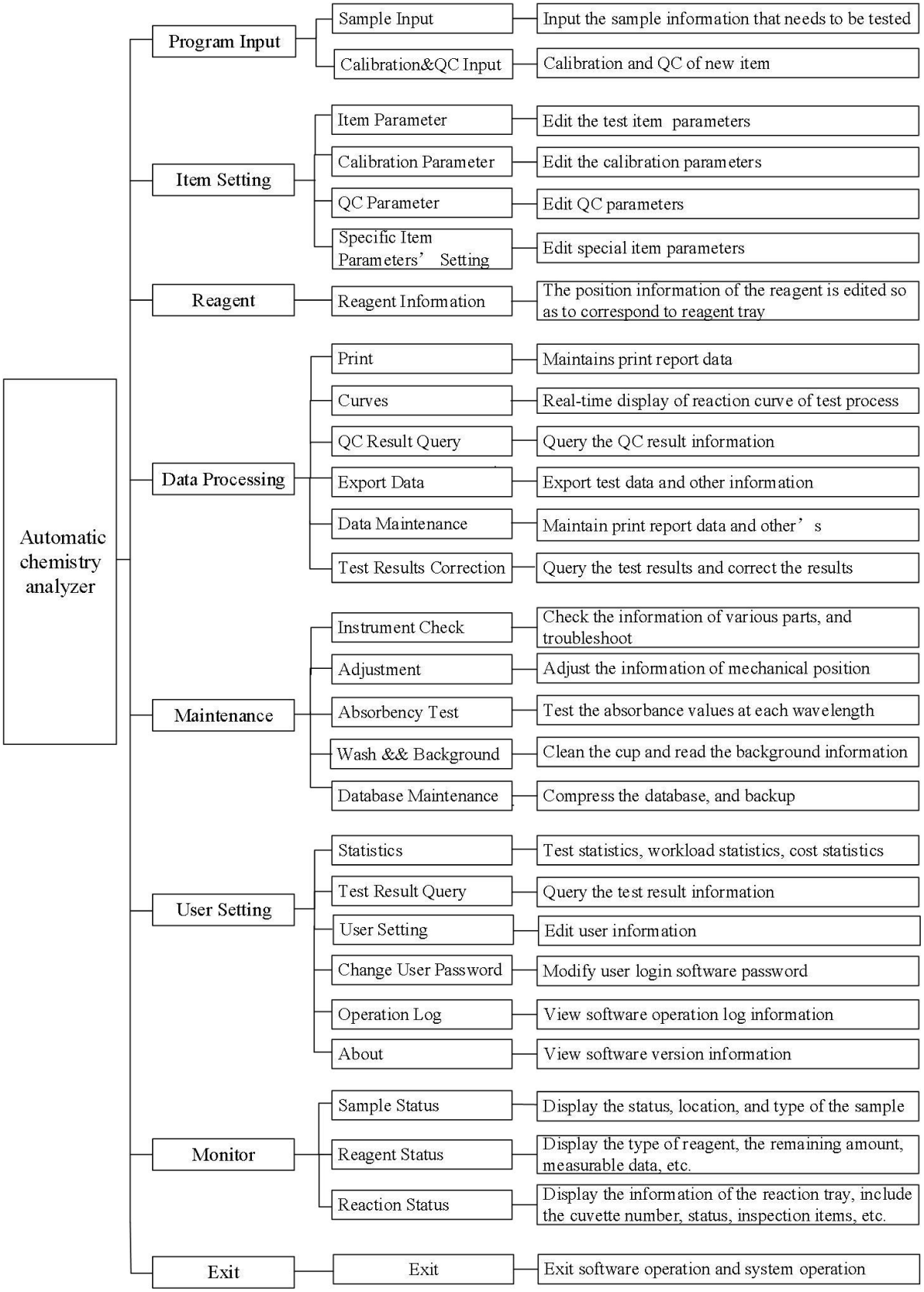


Figure 3-12 Software function chart

4. Testing Process

Refer to sheet 1-1 for the standard specifications of the instrument.

4.1 Test procedure

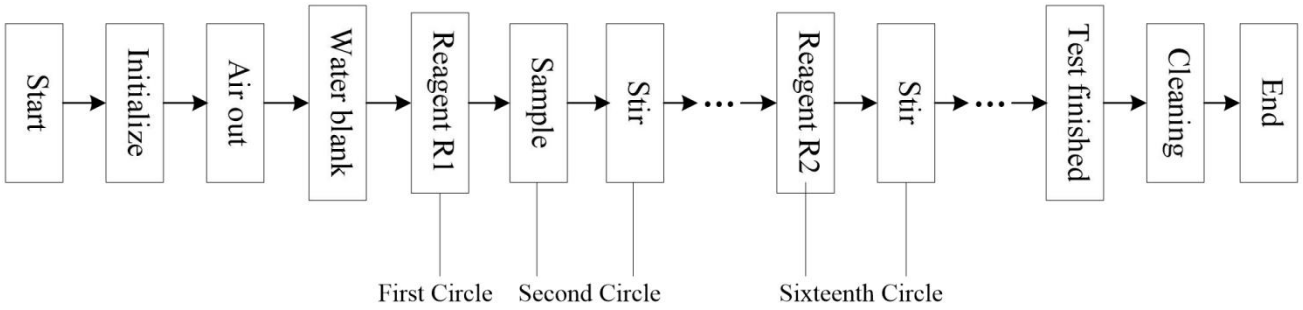


Figure 4-1 Test procedure

4.2 Cleaning needle action sequence

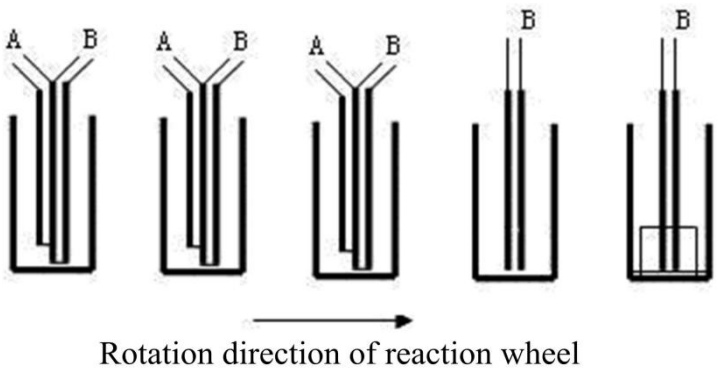


Figure 4-2 Cleaning needle

There are five cleaning needles, including the top three needles are double needle, needle A is responsible for water, needle B is responsible for pumping, the following two needles only B, responsible for pumping.

The washing step of the cuvettes is: Reaction wheel turned to the position, cleaning arm vertically downward, cleaning needle B to draw dry cuvettes, cleaning needle A add water, two needle work at the same time when cleaning arm rise, the cleaning arm stops for a short period at the top of the cuvettes and in the meantime the needle A and B stops working, the cleaning arm back to its original position.

4.3 Optical measurement operation sequence

This instrument uses the whole journey mode, when the reaction tray is rotated, the absorbance of the pure water and the reaction solution in the cuvettes is determined continuous.

The reaction tray rotates in 1 laps for about 18 seconds, and the absorbance value is measured by the 120 cuvettes when the optical axis of a spectrophotometer is passed. 36 times (36 metering points) were determined for each cuvettes.

Light emitted from the light source is focused by a lens, first pass the cuvettes, then to the photoelectric receiver transformed into electrical signals. After the two-stage amplification and Log

conversion obtained after the absorbance or absorbance rate of change. Can be used single / dual wavelength test.

4.4 Reagent cooling system

(1) Composition and function
Cooling system is the reagent preservation system
(2) Specifications
Cooling temperature: 2℃～8℃.
Note 1: When the main power supply access, the analysis of the power supply and cooling system power respectively through the independent switch control. Even though the analysis department does not work, the cooling system can also be in the working state.
Note 2: The use, storage and disposal of reagents should be carried out in strict accordance with the instruction manual.

5. Instrument Operation Principle

The principle of the instrument includes the action principle and the method of analysis.

5.1 Initialization principle

The mechanical part of the automatic biochemical analyzer is composed of sample tray, sample filling mechanism, reagent tray, reagent filling mechanism, reaction tray, stirring mechanism, cleaning mechanism and optical road system.

After the instrument analysis department is started, the instrument will be reset first, details initialization action as follows:

1 Lift the stirring arm, lift cleaning arm.

2 The stirring arm swings from side to side and returns to the cleaning position.

3 Resetting of the reaction tray.

4 Repeat steps 1 and 2.

5 The R&S arm is lifted and moved from side to side.

6 The R&S tray resets and rotates clockwise.

7 Repeat steps 5 and 6,the analyzer goes into standby state.

Attention:

After the machine electricity and into the standby mode, each position is not at the initial position, you should entry the software and click initialization, then can be corresponding to the initial position.

5.1.1 Action position

The relative position of the needle and cuvette is: R&S needle 1 position, mixing needle 105 position, cleaning needle 75 positions.

5.1.2 Analysis process

Instrument analysis process shows on the figure 4-1.

5.1.3 Optical characteristics

The instrument uses the entire metering mode. During reaction process, the machine will continuously measure the absorbance of pure water and the reaction liquid within the cuvette. It takes about 18 seconds reaction rotate 1 circle. When 120 cuvettes passing through the optical axis of the photometer, absorbance values are measured individually. Each cuvette in the reaction time is measured 36 times (36 metering points). Light emitted from the light focused by a lens, go through the cuvette first, then though the photoelectric receiver transformed into electrical signals, for secondary amplification, after log conversion rate determined absorbance or absorbance change.

5.2 Analysis method

Chemical analyzer is based on the material selective absorption of light, analysis methods that established on Lambert-Beer law.

Its detection principle is: The specific wavelength of monochromatic light through a cuvette containing sample solution, it is proportional that intensity of monochromatic light is absorbed (absorbance), concentration of the sample solution and distance light pass through the solution(optical path).

$$A = \lg\left(\frac{1}{T}\right) = \lg\left(\frac{I_0}{I_t}\right) = \varepsilon bc$$

Among them:
A - Absorbance is absorbed by solution.
T - The Ratio of transmitted light intensity and incident light intensity, transmittance.
I0 - Intensity of incident light.
It - Intensity of transmitted light.
ε - Molar extinction coefficient (ml × mmol-1 × cm-1).
c - Molar concentration of the solution (mmol/ ml).
b - Solution layer thickness (cm).
Solution layer thickness (b), that is, the optical path is fixed and known instrument.
Solution molar extinction coefficient (ε) is the wavelength, the solution and the solution temperature correlation coefficient, when the guaranteed solution temperature stability, in its single wavelength, the concentration of the solution and absorbance has linear relationship (ε is given directly in manufacturers reagent kit).
When the test sample is a homogeneous distribution of the solution, it was limited to the role of incident monochromatic light absorption process, and fluorescence, scattering and photochemical phenomenon does not occur, and in the absorption process solution without interaction of each substance, each substance's absorbance having additivity, such systems comply with Lambert-Beer law.

5.2.1 Analysis types

Please refer to the specification of the requirements set reagent chemical parameter.
Note 1: When the equipment measuring, the reaction solution volume range should be 120～500μl.
Note 2: For reading point is not used, be sure to enter "0."
1. One endpoint method
After adding samples and reagents, absorbance was measured at a metering point specified, the method to calculate the concentration of the sample that is one endpoint method. Response curve shown in figure 5-1.

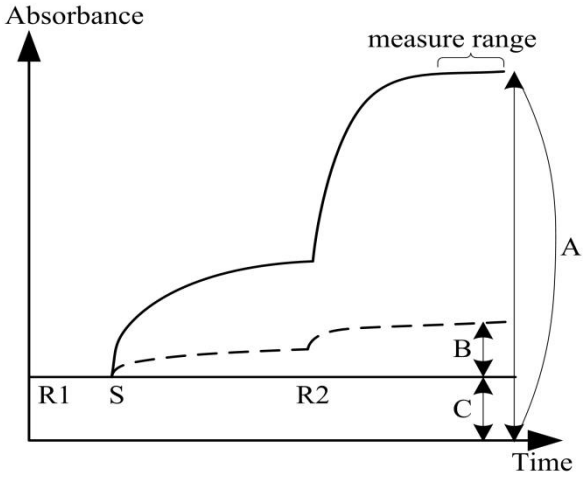


Figure 5-1 One endpoint reaction curve

(a) Metering point:[L]-[M]-[0]-[0](1＜M＜L≤36)

(b) Absorbance calculation:

Take the metering point L&M absorbance average, calculated is follow:

$$A_X = \frac{A_L + A_{L-1} + \ldots + A_{M+1} + A_M}{(L-M)}$$

(c) Concentration calculation

$C_X = \{K \times (A_X - A_1)\} \times IFA + IFB$

Cx is a sample concentration to be test, A1 is the first point absorbance value, K is K factor, B is the absorbance of reagent blank, IFA and IFB is a constant of the instrument, are represented by the slope and intercept.

(d) Analysis Item:

Like TP, ALB etc.

2. Two endpoint method

When analysis response has not yet started, select the first metering point, reached the end of the reaction or equilibrium select the second metering point, the difference in absorbance between these two metering points are used to calculate sample concentration, called two endpoint, reaction curve shows below:

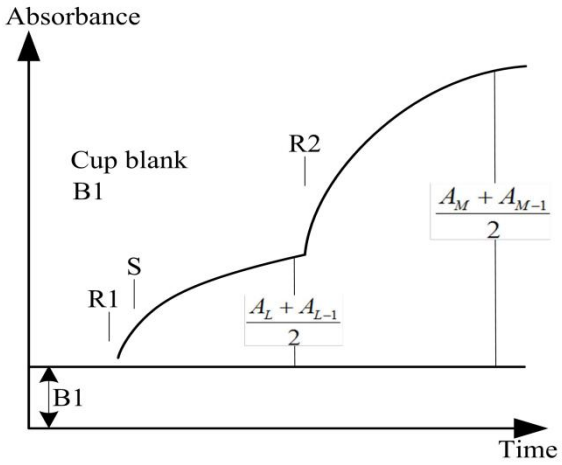


Figure 5-2 Two endpoint reaction curve

(a) Metering points: [L]-[M]-[0]-[0] (1＜L＜M≤36)

(b) Calculation of absorbance

Using M and N's absorbance average minus L and H's absorbance average, the difference value is the absorbance, computational formula is below:

$$A_X = \frac{A_M + A_{M-1} + \ldots A_{N+1} + A_N}{(M-N)} - k \times \frac{A_L + A_{L-1} + \ldots + A_{H+1} + A_H}{(L-H)}$$

Among them:

$$k = \frac{S + \sum_{j=1}^{a} Rj}{S + \sum_{i=1}^{b} Ri}$$

a: Determination of the number of AL reagent.

b: Measuring of the number of reagent AM.

(c) Concentration Calculation

$C_X=\{K\times(A_X-B)+C_1\}\times IFA+IFB$

B is water blank, R1～R2 is add location of reagent, Ax is the absorbance difference value of L and M, Cx is a sample concentration to be test, C1 is calibration 1(reagent blank) concentration, K is K factor, B is calibration 1(reagent blank)'s absorbance. IFA, IFB is a constant of the instrument, are represented by the slope and intercept.

(d) Analysis Item:

Like CRE etc.

3. Fixed time method

Measuring two metering point, neither the two points is the initial reaction absorbance nor the end point absorbance, calculates the difference between two absorbance in the unit used to calculate the concentration of the sample, it called 2 point rate/fixed time, reaction curve shows as figure 5-3:

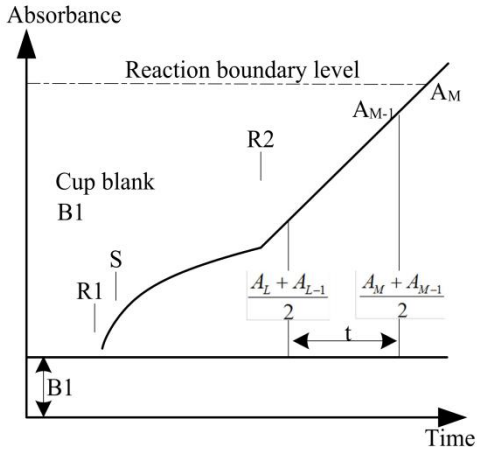


Figure 5-3 Fixed time reaction curve

(a) Metering points: [L]-[M]-[0]-[0] (1＜L＜M≤36)

(b) Calculation of absorbance

The metering points M and M-1 absorbance metering point average and the average of L and L-1 absorbance subtraction, the difference divided by the time as absorbance, is calculated as follows:

$$Ax=\frac{\frac{(A_M+A_{M-1})}{2}-\frac{(A_L+A_{L-1})}{2}}{t}$$

Among them:

t: Interval of L and M metering points (minutes).

(c) Calculation of Concentration

$C_X=\{K\times(A_X-B)+C_1\}\times IFA+IFB$

B is cup blank, R1～R2 is add position of reagent, Ax is the average metering point between L and M change in absorbance per minute, Cx is sample concentration to be test, C1 is the concentrations of calibration solution 1 (reagent blank), K is K factor, B is the calibration solution 1 (reagent blank) absorbance, IFA and IFB is a constant of the instrument, are represented by the slope and intercept.

(d) Analysis Item:

BUN, Picric acid method CRE, etc.

4. Rate method

Measuring method according to the rate of change in absorbance per minute to calculate the concentration or activity values between the two metering points, known as rate method, the reaction curve show as below:

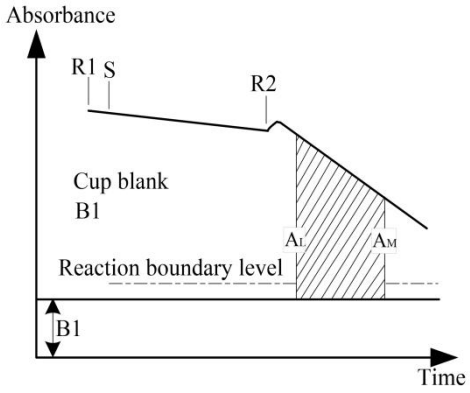


Figure 5-4 Rate method reaction curve

(a) Metering point: [L]-[M]-[0]-[0](1＜L＜M≤36, L+2＜M)

(b) Calculation of absorbance

Get metering point L, the rate of change in absorbance per minute between M by the least squares method.

$A_X = \Delta A(M - L)$

(c) Concentration calculation

$C_X = \{K \times (A_X - B) + C_1\} \times IFA + IFB$

B is water blank, R1～R2 is additional reagent position, △A(M-L) is the average metering point between L and M change in absorbance per minute, Cx is sample concentration to be test, C1 is the concentrations of calibration solution 1 (reagent blank). K is K factor, B is calibration fluid 1(reagent blank) change in absorbance per minute. IFA, IFB is a constant of the instrument, are represented by the slope and intercept.

5.2.2 Calibration method

1. One point linear method (K factor method)

Though measuring the calibration solution 1's absorbance and input K factor to get working curve, shows as below:

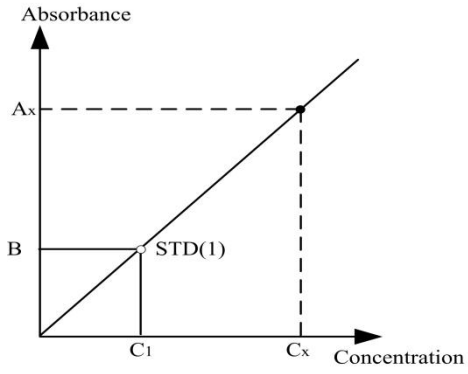


Figure 5-5 One point linear calibration curve (K factor method)

(a) Calibration parameter input

Calibration type: [1 point linear]

Calibration point: [1] (the number of calibration fluid)
Range point: [0]
(b) Confirm the K factor
Enter the K factor in the Calibration Result form.
(c) Calculation of working curve parameter
B(S1ABS): The absorbance of the calibration solution 1 or the rate of change in absorbance per minute.
K: Input value
C1: The concentration of the calibration solution 1 is the input value.
(d) Calculation of Concentration
$C_x=\{K\times(A_x-B)+C_1\}\times IFA+IFB$
C_x is a sample concentration to be test, Ax is the sample absorbance or absorbance change per minute, IFA and IFB is the instrument constant, are represented by the slope and intercept.
(e) Applicable analysis methods
One endpoint method, fixed time method, two endpoint method, rate method.
2. Two point linear method
Determination of the calibration liquid 1 and calibration liquid 2, formation of a linear working curve, as shown in figure 5-6.

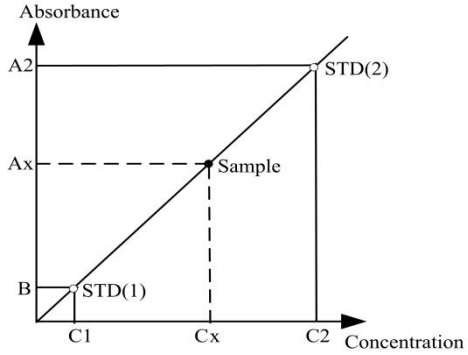


Figure 5-6 Two point linear calibration curve

(a) Calibration parameter input
Calibration type: [2 point linear]
Calibration point: [2] (the number of calibration fluid)
Range point: [2 ~ 6]
(b) Calculation of working curve parameter
B(S1ABS): Determination of the absorbance of the calibration solution 1 or the change of absorbance per minute
K: the proportional constant of the linear working curve. The determination values of the calibration solution 1 and the calibration solution 2 are calculated by the input value.
C1: Input calibration solution 1's concentration.
C2: Input calibration solution 2's concentration.
A2: The absorbance of the calibration solution 2 or the rate of change of absorbance per minute of the calibration solution 2.
(c) Calculation of concentration
$C_x=\{K\times(A_x-B)+C_1\}\times IFA+IFB$

Cx is the sample concentration to be test, Ax is the sample absorbance or absorbance change per minute, IFA and IFB is the instrument constant, are represented by the slope and intercept.

(d) Applicable analysis method

One endpoint method, fixed time method, two endpoint method, rate method.

3. Multipoint linear method

By blank (or calibration solution 1) and calibration solution (second calibration solution and sixth calibration solution) was determined by linear regression curve made linear calibration curve shown in figure 5-7:

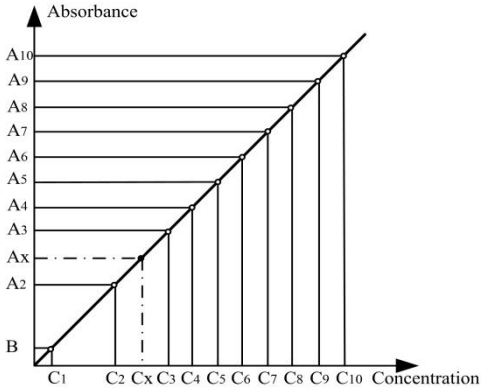


Figure 5-7 Multipoint linear calibration curve(linear)

(a) Calibration parameter input

Calibration type: [multi-linear]

Calibration points: [3-6] (Number of calibration solution)

Range point: [3-6]

(b) Calculation working curve parameter

B(S1ABS): Absorbance or rate of change in absorbance of the calibration liquid 1 per minute, the intercept of a linear regression equation.

K: Reciprocal of linear regression curve slope.

The formula of S1ABS(B) and K

$$S1ABS(B) = \overline{A} - \frac{X \times \overline{C}r}{Y}$$

$$K = \frac{Y}{X}$$

$$X = \sum_{i=1}^{n} \left(Cri - \overline{C}r\right) \times \left(Ai - \overline{A}\right)$$

$$Y = \sum_{i=1}^{n} \left(Cri - \overline{C}r\right)^2$$

$$\overline{A} = \left(\sum_{i=1}^{n} Ai\right) / n$$

$$\overline{C}r = \left(\sum_{i=1}^{n} Cri\right) / n$$

A1, A2 is the two measured values of calibration solution (1), n is the number of calibration solution N×2, Cri is the concentration calibration solution (i) .

(c) Calculation of concentration

$C_x=\{K\times(A_x-B)+C_1\}\times IFA+IFB$

Cx is the sample concentration to be test, Ax is the sample absorbance or absorbance change per minute, IFA and IFB is the instrument constant, are represented by the slope and intercept.

(d) Applicable analysis method

One endpoint method, fixed time method, two endpoint method, rate method.

4. Logit-log4P (nonlinear method)

Suitable for the working curve that absorbance showed convergence with the concentration increase, Logit-log4P (nonlinear method) calibration curve shown in figure 5-8:

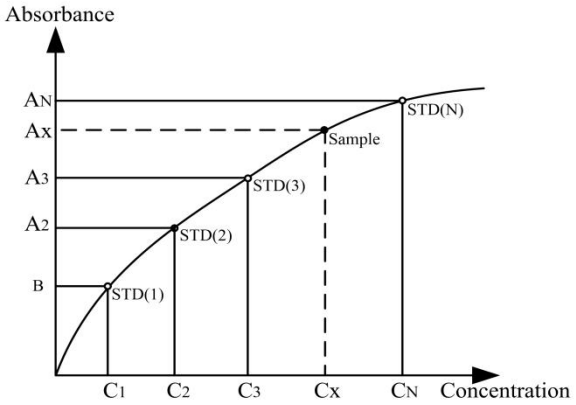


Figure 5-8 Logit-log4P calibration curve (nonlinear method)

(a) Calibration parameter input

Calibration model:[Logit-log4P]

Calibration point:[4～6](Calibration fluid quantity)

Range point:[0]Range calibration nullity.

(b) Calculation of curve parameter

B: the approximation of absorbance or the change when Cx approaching ∞ per minute.

K: value of the absorbance of calibration fluid 1 or change rate minus B

a, b: Approximation of coefficient, calculate automatically.

S1ABS, K, a, b displayed in the calibration result interface.

(c) Calculation of concentration

$$C_X = (C + C_1)\times IFA + IFB$$

$$A_X = B + \frac{K}{1 + aC^b}$$

$$C = \sqrt[b]{\frac{1}{a}\times\left\{\frac{K-(A_X-B)}{A_X-B}\right\}}$$

Cx is concentration of testing sample, C1 is blank concentration. Ax is absorbance of sample of the change value per minute. K is approximation of coefficient. When Cx is closer to ∞, Ax is closer to B. If K＜0, Ax≤B+K or K＞0, Ax≥B+K, so C1=0, IFA&IFB is coefficient of analyzer, which displays the slope and intercept.

(d) Calculation of SD

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij}-A_{i}'\right)^{2}}{2N-4}}$$

(N=4～6, j=1 or2)

(Aij-Ai') is d-value of absorbance between Ai' from fitting equation and Aij from testing or the d-value between Aij and A12. Every calibration fluid test twice, and the maximum value of Aij is 12.

(e) Applicable methods

One endpoint method, fixed time method, two endpoint method, rate method.

5. Logit-log5P (nonlinear method)

Same characteristic with Logit-log4P, and Logit-log5p has one more calculate parameter, so the result is more accuracy. Calibration is shown curve as figure 5-9.

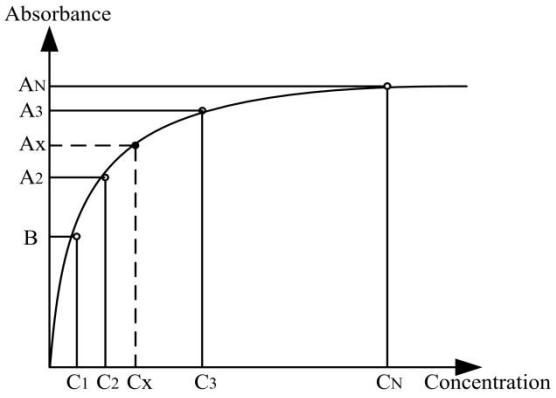


Figure 5-9 Logit-log5P calibration curve (nonlinear method)

(a) Calibration parameter input

Calibration model:[Logit-log5P]

Calibration points:[5～6](Calibration fluid quantity)

Range point:[0]Range calibration nullity.

(b) Calculation of curve parameter

B: The approximation of absorbance or the change when Cx approaching ∞ per minute.

K, a, b, c: Approximation of coefficient, calculate automatically.

S1ABS, K, a, b, c displayed in the calibration result interface.

(c) Calculation of concentration

$$a+b\times lnC+c\times C-ln\left\{\frac{A_X-B}{K-\left(A_X-B\right)}\right\}=0$$

Get C from Newton Approximation

$C_X=(C+C_1)\times IFA+IFB$

$$Ax=B+\frac{K}{1+\exp\left(-a-b\times \ln C-c\times C\right)}$$

Cx is concentration of testing sample, C1 is blank concentration. Ax is absorbance of sample of the change value per minute. K is approximation of coefficient. When Cx is closer to ∞, Ax is closer to

B. If K＜0, Ax≤B or K＞0, Ax≥B, so C=0, IFA&IFB is coefficient of analyzer, which displays the slope and intercept.

(d) Calculation of SD

$$SD=\sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij}-A_i\right)^2}{2N-5}}$$

(N=5～6, j=1 or 2)

(Aij-Ai') is d-value of absorbance between Ai' from fitting equation and Aij from testing or the d-value between Aij and A12. Every calibration fluid test twice, and the maximum value of Aij is 12.

(e) Applicable methods

One endpoint method, fixed time method, two endpoint method, rate method.

6. Polyline method (nonlinear method)

Test from fluid 1 to fluid 5 or fluid6, and get the curve line, and link those points with straight line. As figure 5-10 shown.

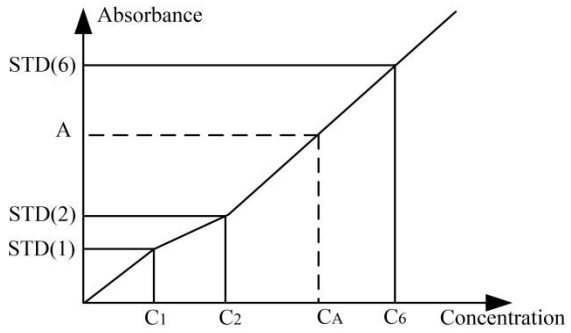


Figure 5-10 Curve of Polyline (nonlinear method)

(a) Calibration parameter input

Calibration model:[Polyline method]

Calibration point:[5～6](Calibration fluid quantity)

Range point:[0] Range calibration nullity.

(b) Calculation of curve parameter

S1ABS is average value of twice test for calibration fluid 1 for absorbance or change value of absorbance.

$$K=\frac{C_2-C_1}{A_2-B}$$

B: Absorbance or change rate of Calibration fluid 1.

A2: Absorbance or change rate of Calibration fluid 2.

C1: Concentration of Calibration fluid 1.

C2: Concentration of Calibration fluid 2.

Calculate K2, K3, K4, K5 with same method

(c) Calculation of concentration

$C_X=\{K_N\times(A_X-A_N)+C_N\}\times IFA+IFB$

(d) Applicable methods

One endpoint method, fixed time method, two endpoint method, rate method.

7. Spline method (nonlinear method)

In this line, every value of calibration linked to a complete curve, and the error is also fitting in the curve, so the curve fitting is better than poly line. The calibration curve is shown as figure 5-11.

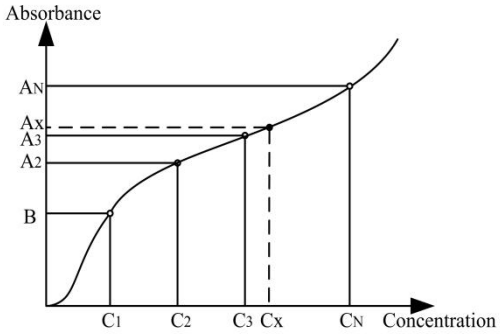


Figure 5-11 Spline method (nonlinear method)

$$Ax = a(I) + b(I) \times (C_X - C(I) + c(I)) \times (C_X - C(I)^2) + d(I) \times (C_X - C(I))^3$$

$$f \times (C_X - C(I)) = a \times (I) + b \times (I) \times (C_X - C(I)) + d \times (I) \times (C_X - C(I))^2 + d(I) \times (C_X - C(I))^3 - A_X$$

Get C from Newton Approximation

$$C_X = (C + C_1) \times IFA + IFB$$

Cx is concentration of testing sample, C1 is blank concentration. C2~CN is concentration of calibration fluid. Ax is absorbance of sample or the change value per minute. A2~AN is absorbance of calibration fluid or the change value per minute. IFA&IFB is coefficient of analyzer, which displays the slope and intercept.

(d) Calculation of SD

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{2}\left(A_{ij} - A_i'\right)^2}{2N-4}}$$

(N=5～6, j=1 or 2)

(Aij-Ai') is d-value of absorbance between Ai' from fitting equation and Aij from testing or the d-value between Aij and A12. Every calibration fluid test twice, and the maximum value of Aij is 12.

(e) Applicable methods

One endpoint method, fixed time method, two endpoint method, rate method.

5.2.3 Calibration type

1. Water blank checking

The water blank check is used to detect the absorbance after the purified water is distributed to the cuvette.

Each cuvette used for testing should be tested for water blank. The results will be used to correct differences among cuvettes. The test results will also be used to assess contamination of the cuvette.

2. Reagent blank testing

The reagent blank check is used to test the absorbance of the cuvette containing the reagent. The reagent blank test value can be used to correct the absorbance of the sample, resulting in more accurate test results.

3. Sample blank testing

The sample blank is the concentration of a sample used as a zero reference in a test procedure. The sample blank can counteract the positive error caused by the color or turbidity of the sample itself before the addition of the test reagent. Due to hemolysis, lipidemia, jaundice, etc., the sample's absorbance will affect the testing results. So, measuring the absorbance of sample can remove the impacts. Measurement method is based on the normal test reagents and sample size, changing the reagent into distilled water or saline, and then testing.

6. Instrument Operation

6.1 Brief operation

The brief sequence of operation is shown in sheet 6-1, and the details in "6.2 detailed operations."

Sheet 6-1 Schematic instruments operation sequence sheet.

Operation steps	Procedure Form / key	Operation
1. The pre-test check	——	The power should be checked before the test.
2. Connect the water installations and power of the analyzer. Login Software	Log analyzer system	Connect the external water input and output devices to water purifier and waste water pipes, and turned on the power of pure water device and analyzer. Input operator's user name and password in the login form of the system software.
3. Confirm the status of instrument (1) Alarm confirmation (2) Confirm the light of photometer (3) Confirm the cup blank (4) Confirm the temperature of the reaction vessel	Alarm information System maintenance Status Bar	Check the light to confirm whether the measured value is within the allowable range. Check the cup blank to confirm whether the measured value is within the allowable range. To confirm whether the temperature of the reaction tank is (37.0±0.2) ℃.
4. Confirm the analysis conditions (1) Projects addition (2) The logging and confirmation of chemical parameter (3) Confirmed the value of K	System setting Calibration information	Add items. Confirm project parameter. Confirm the calibration curve and K factor.
5. Prepare reagent (reagent information) (1) Confirm of the residual reagent volume (2) Colorimetric analysis items	Reagent information	Confirm the residual reagent volume and testing times of each items of reagent. Put the reagent that testing required o the proper position.
6. Set calibration and QC items	Calibration information QC	Confirm the project name required calibration analysis. Confirm the project name required QC tests.

7.Sample registration and testing	Sample registration	To carry out a single or batch of routine sample registration and a single emergency sample registration, patient information editing, information modification and deletion.
8. Start testing (1) Preparation of sample, calibration solution and QC solution. (2) Set starting conditions and send test instructions.	Start condition	Put sample, calibration liquid and QC liquid on the sample tray. Select test conditions, then perform the "start test".
9. Testing process (1) System monitoring (2) Suspension and continuation of adding sample (3) Emergency stop (4) Additional sample	System monitor Add pause / continue Emergency stop Sample registration	Test status of real time monitoring instruments. Edit the sample in the test process and click start testing.
10. Confirmation of the testing result (result data)	Testing result	Query, modify, delete, review and print the test results. Sample response curve.
11. Determination of re-examining samples	Testing result	Confirm the condition for re-examining items in the form of "adding the re-examine items".
12. The analysis finished (1) The result of the re confirmation (2) Database backup (3) System shutdown (4) Cut off the power supply (5) Preparation before the next work	Testing result system management	Confirm, check and print the result of re-examining items. Regular database backup, suggest that the normal case of a week. Cut off the power supply for instrument, computer and pure water device. Clean up the equipment to prepare for next use.

6.2 Detailed operation

6.2.1 Inspection before test

The following tests should be performed before the test:

Check whether the power supply, the voltage is correct or not.

Check the communication lines and power lines between the equipment, the computer and the printer to ensure that the connection is correct and there is no loosening.
Check the printing paper is sufficient, please install the printing paper if not.
Check the R&S needle, the stirrer and cleaning needle mechanism in front without adhesion of water droplets, no smudge or bending.
Check whether the water inlet pipe is under the level of the liquid, and the amount of water is sufficient. If the device is directly connected to the water pipeline, then the operation is not in use.
Check whether there is bubble in the syringe (the leakage and the bubble will cause the data inaccurate).
Check whether the amount of cleaning fluid is sufficient, the reagent tray number 45 position need to be placed specific cleaning fluid of series.

Warning:

The series of cleaning fluid should be regarded as liquid corrosive liquid. Once you hurt the skin or eyes, rinse with plenty of water.

6.2.2 Power on and login

(a) Power on the analyzer. The switch on the left side of the analysis apparatus is power switch, when a reagent on the reagent tray the switch should be in the open state, to ensure the normal operation of the cooling system. Switch on the right side of the equipment is power supply for analysis apparatus.
(b) Login the the analyzer application software, if you want to test, you should first execute online instruction.

6.2.3 Light checking

(a) A/D Reading

In the light conditions, click the button Instrument check in the menu button Maintenance, after entering the maintenance form, choose the "A/D reading" option in the maintenance list, click "Y" button, the instrument will perform the inspection of light, the amount of light with previous test results values are displayed in the result bar. As shown below:

Figure 6-1 A/D reading

In the light case, adjust the instrument and amplifier voltage, A/D readings is about 58000, it is required that the range of delta OD is about ± 0.0015.
(b) Absorbance testing and instrument stability

Click on the 

menu Absorbency Test button, open the "Absorbance test" window, click the " Test " button, instrument began reading. Reading is completed, which shows the cuvette number and corresponding absorbance values.

Pull the scroll bar on the right side, all absorbance value will display.

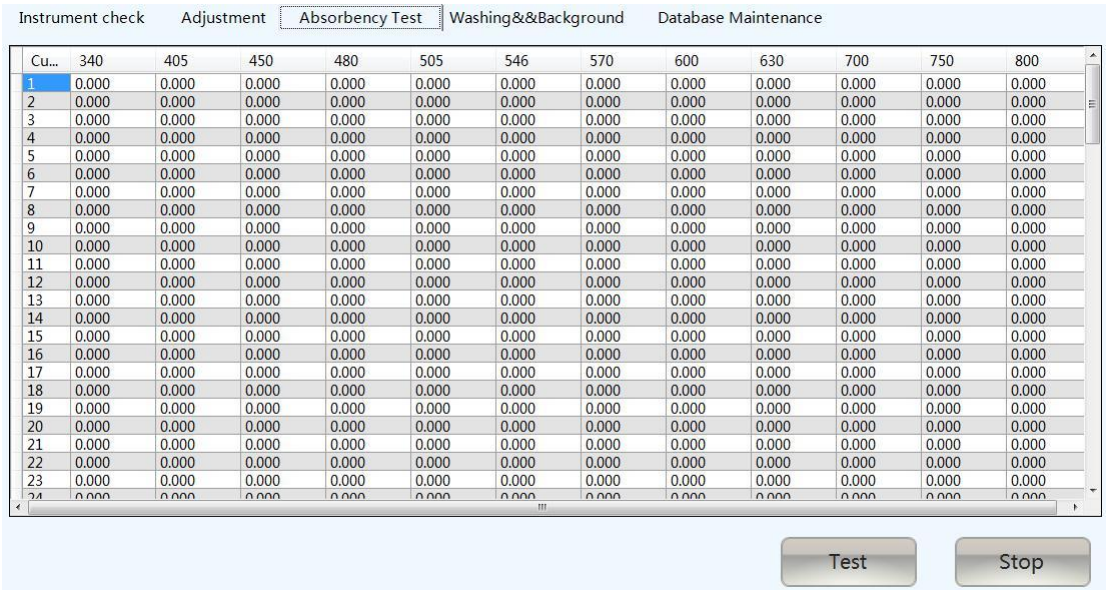


Figure 6-2 Absorbance test

6.2.4 Confirm the temperature of the reaction tray

Click the software Toolbar "  " menu, open the temperature display, observe the status bar  . Confirm whether the temperature in the reactor is (37.0±0.2)℃.

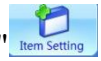
After energization, the temperature in the reaction tray is stabilized at (37.0±0.2)℃ for approximately 20 minutes. And the stability of the light source also takes a few minutes, so after the instrument is turned on, you can view the form of information, the entry of the parameter of the item, the alarm information, etc., and after temperature stability, the sample can be tested.

6.2.5 Confirm analysis condition

Before the test, first of all to carry out the analysis of the item to add, and then carry out the item parameter, calibration parameter, QC parameter setting.

Analysis the parameter setting, using methods, precautions and save of used reagents, calibration liquid, QC solution please refer to the instructions or to the relevant manufacturers, vendors consulting.

6.2.5.1 Item parameter confirmation

In the menu bar " 

", click" ItemPar ", enter the item parameter interface, determine the item parameter, as shown in figure 6-3.

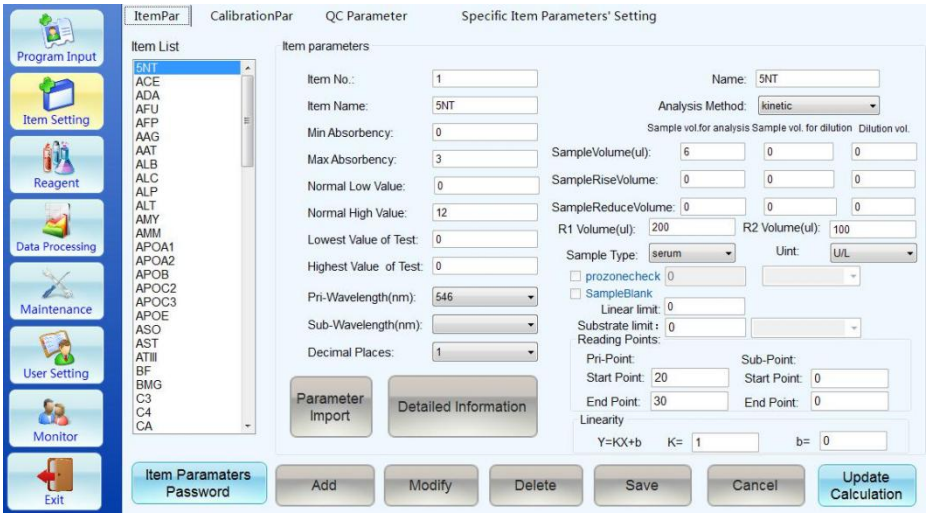


Figure 6-3 Project parameter interface

The setting or confirmation of the reagent item parameter is carried out according to the requirements of the reagent specification. Some parameter for the test must have the conditions, such as: test item name, analysis method, the main / auxiliary reading points, the main / sub-wavelength, sample size, reagent and so on. Although some of the parameter do not affect the results of the test, but for measuring the reliability of the test results are important, such as the normal range, absorbance limit, it is recommended that the operator one by one input parameter correctly and then test.

6.2.5.2 Setting of item portfolio

Item portfolio is the combination of the relevant items together, such as a full set of liver function, full set of renal function, just click on the name of the portfolio item can complete a number of item registration function to facilitate the sample registration of the fast entry.

Click the "special items" button on the toolbar, enter the "special item parameter setting" form and click the "increase" option at the right side of the portfolio item, fill in the relevant items as needed.

As shown in figure 6-4: Click the first increase, fill in the "item number" according to the serial number, fill in "item short", "full name", "full name" according to user's needs, and click ""In the selection of items click on" >> ". Added to the "Select item column" table, click on" << "execute cancel the relevant item operation, select the end click on "Save" to complete the operation.

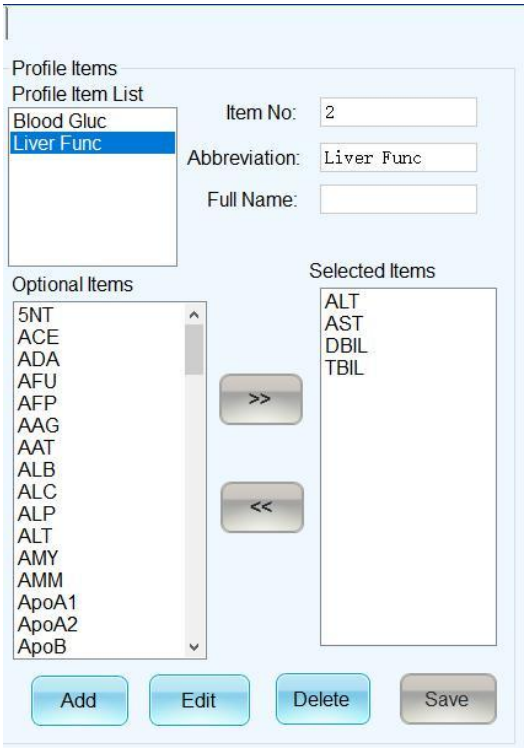


Figure 6-4 Combination project

6.2.5.3 Setting the calculating items

The calculation item is to use the measurement results of two items or items of A and B to calculate the measurement result of another new item.

Click the "special items" toolbar, enter the "special item parameter setting" form,

Click on the lower left side" Calculated Item " the "Add" button in the combo box is configured as required by the user.

As shown in figure 6-5, click "Add", fill in the "item number" according to the serial number, fill in the item name "Full name", "Abbreviation", and according to the need to add the item specifications fill in "Unit", "High Value", "Low Value", "Decimal Place", "Calculation Formula", fill in and click "Save".

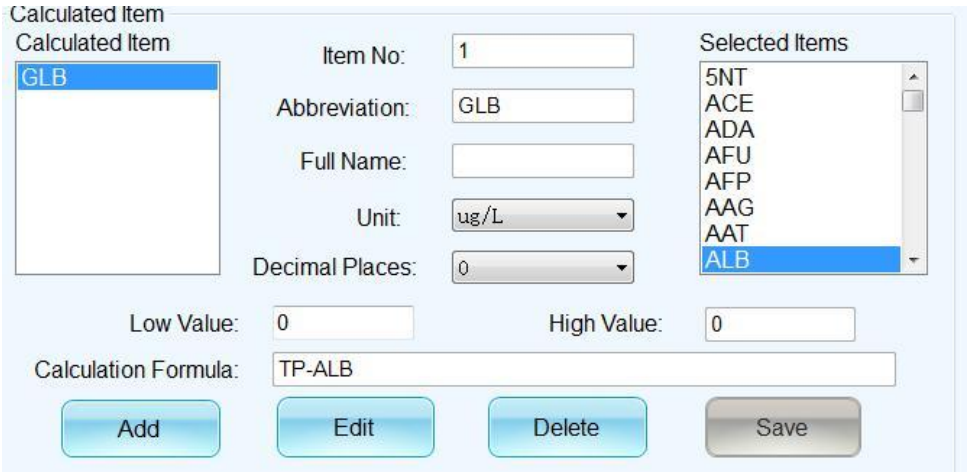


Figure 6-5 Calculated item

6.2.6 Reagent preparation (reagent information)

6.2.6.1 Use and precautions of reagent

1. Use of reagent

Reagents to prepare, use storage must be strictly in accordance with the reagent instructions, do not make the reagent foam. As the reagents contain surfactants, vigorous shaking will produce foam, the test process if the R&S needle and foam contact will be mistaken for exposure to reagents, resulting in the amount of reagent is not accurate, affecting the test results.

2. Do not mix reagents.

If the reagents continue to add different manufacturers or manufacturers of different batches of reagents, it will change the composition of the reagents, resulting in inaccurate test results.

6.2.6.2 Reagent login

Auto chemistry analyzer reagent information entry is divided into two kinds, which are closed and open. The two kinds of software login reagent information respectively are bar code scanning and manual input.

1. Closed reagent information entry

Click " 

" on the software menu bar to display the "Reagent Information" operation interface. As shown in Figure 6-6, scan the reagent barcode with the scanner in the order of the reagent tray and click "Add"

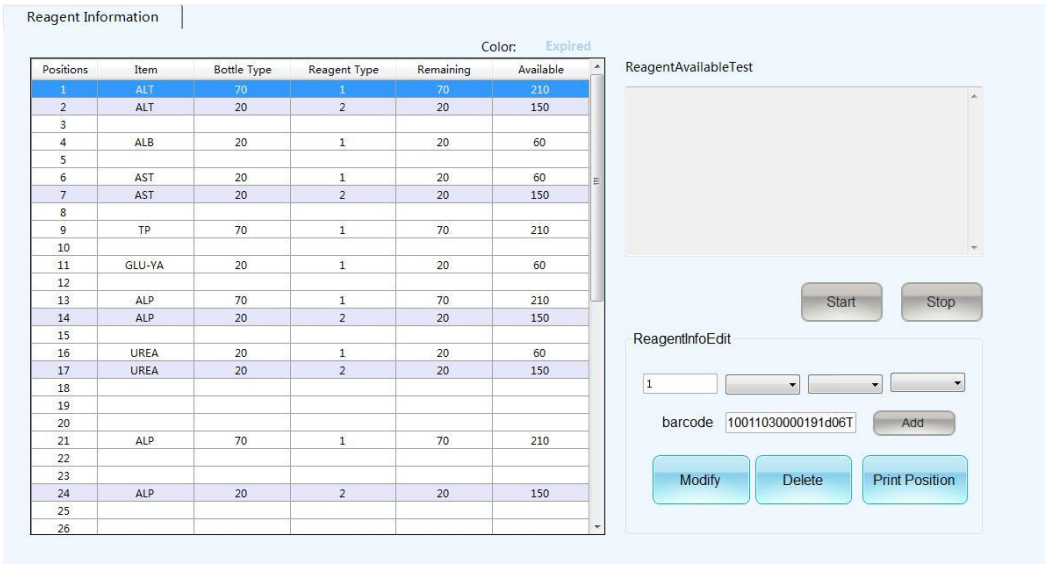


Figure 6-6 Reagent information (closed)

If the reagent input sequence is incorrect, use the "Delete" key to delete the item and re-scan.

2. Open reagent information entry

Click " 

" on the software menu bar to display the "Reagent Information" operation interface. As shown in Figure 6-7, query the reagent items in the order of the reagent tray, and select the reagent information, bottle size and reagent type and click "Modify", and then input.

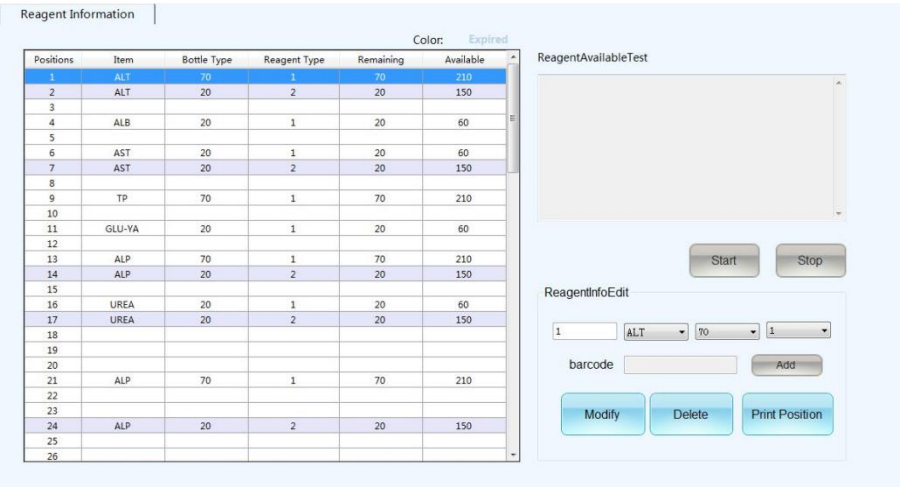


Figure 6-7 Reagent information (open)

Warning:

No. 28 of reagent tray only can put the company series machine special cleaning fluid.

6.2.6.3 Residual amount of reagent

In the "reagent information" form, click the "Start", the instrument automatic detection reagent remaining amount, the remaining test number, the results of the test information is displayed in the "reagent information" list box.

Figure 6-8 Interface of reagent detect number

During the testing process, as long as the reagent is used to absorb the reagent, the residual amount of the reagent is detected, and the remaining amount of the reagent and the remaining test number are updated.

6.2.7 Calibration item login

Click software menu bar "Item Setting", "CalibrationPar" is shown as in figure 6-9.

Set the calibration parameter according to the calibration instructions.

Click "Calibration Setting" button, following calibration instructions to modify the "standard number", "concentration" option, modify "Cup No." according to the position where the calibrators placed in, "repetitions" according to the requirement, after finished setting, click "Edit" and then click "Save".

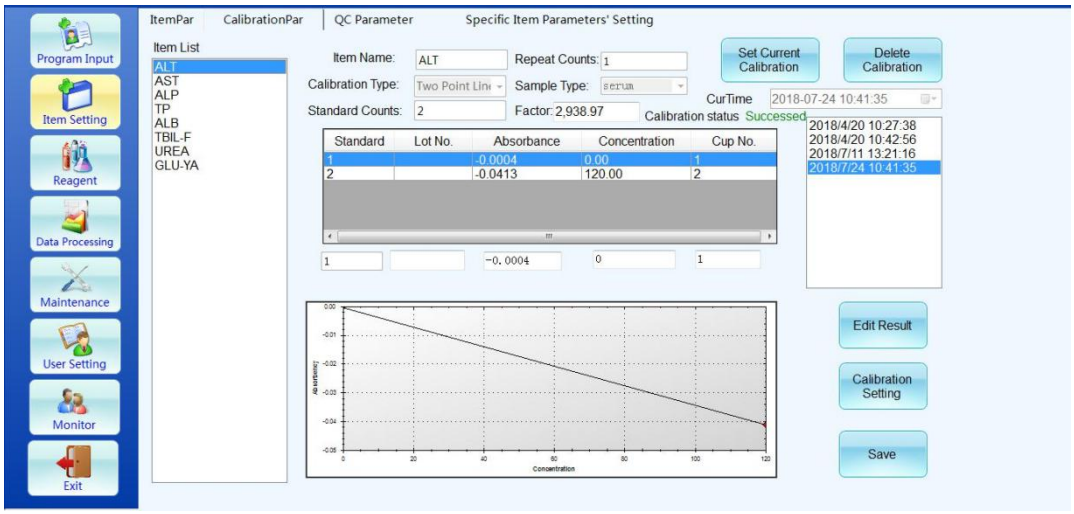


Figure 6-9 Calibration parameter

The difference of calibration type see sheet 6-2:

Sheet 6-2 Calibration methods

Calibration method	Number of calibration fluid	Application examples
Factor	—	CK-MB
One-point linear	Water blank	GLU, TP, ALB
Two-points linear	1 calibration fluid, water blank	TBIL, DBIL
Multi-point linear	3 ~ 6 calibration fluid	—
Logit-Log 4P	4～6 calibration fluid	ApoA1, ApoB
Logit-Log 5P	5～6 calibration fluid	C3, IgA, IgG, IgM
Spline	5～6 calibration fluid	C4
Polyline	5～6 calibration fluid	AFP, CRP

6.2.8 QC item login

Click the menu bar " 

", the "Calibration Par" operation interface is displayed, click on to select the lower right side of the window " 

", the "QC Parameter" interface is displayed, as shown in figure 6-10.

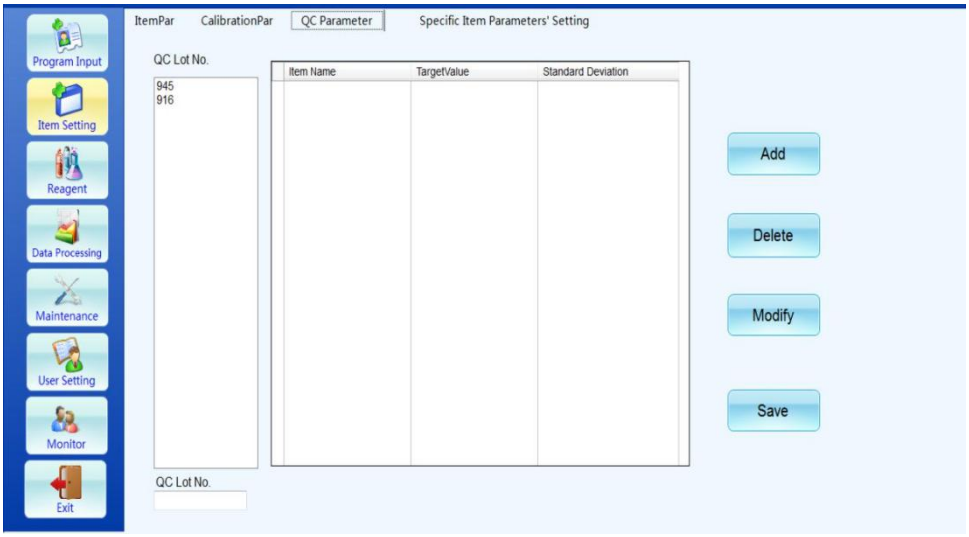


Figure 6-10 QC parameter A

Add a new QC item steps: First click on the "QC parameter" window " Add ", fill in the lot number according to the lot number of the QC manual, as shown in figure 6-11,select the QC item, click on " >> " it is selected, after the selection is complete click on " Save ".

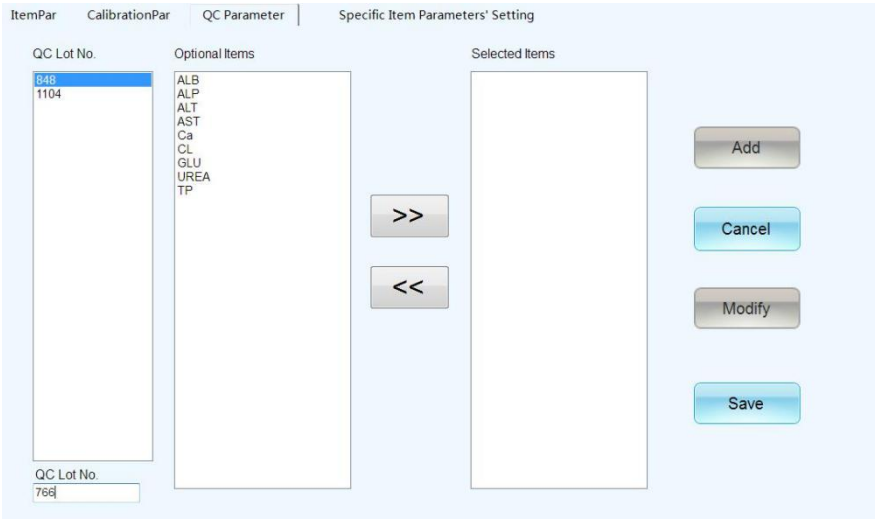


Figure 6-11 QC parameter B

QC Parameter window appears after storage, shown in figure 6-12.

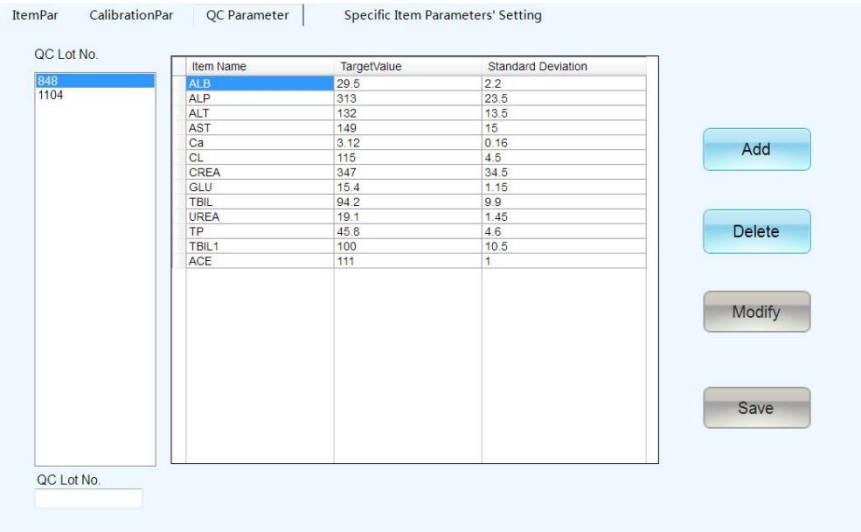


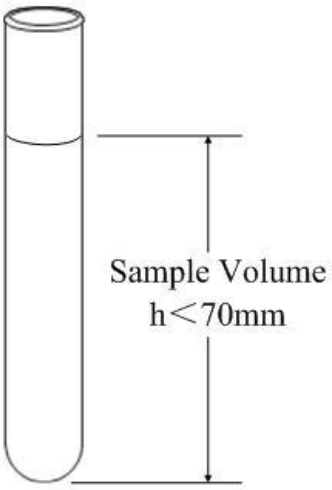
Figure 6-12 QC parameter C

For example: Select the newly QC 766, the need items for QC on the right side, according to the QC 766 to add the "Target Value" and "Standard Deviation", modify the window to complete the operation.

6.2.9 Sample input and testing

Warning:

When using blood vessels, the sample volume should be less than 70mm, otherwise, the liquid level detection will be affected, as shown below.



(a) Add test items

Click the " 

" button in the toolbar, enter the "entry" form, as shown in the figure below:

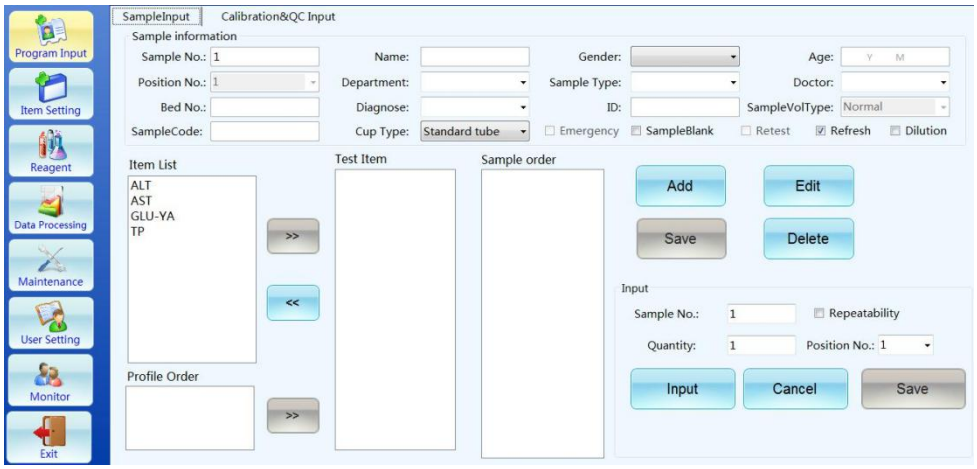


Figure 6-13 Project entry

Single sample entry: Click 

, and choose test items in the left column, click " 

" to move test item to "selected test items" column, the sample number is generally from the beginning of 1, followed by accumulation, a number can not be repeated, and then fill in the information of patients "name", "gender", "age", edit "inspection department" and "sample type", "submission of doctors' information, when completed, click 

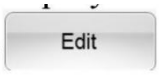
to complete the operation. Batch sample login: If there is more than one sample to test in the same project you can use the "batch input", placing the sample on the sample tray continuously, click the 

fill in the quantity and starting position number that to be tested, sample position number imputing is from 1 to 49, from 49 on, sample position number plus 1, increasing gradually start from 1, save the selected items to be tested, complete the operation.

Project portfolio login: If in the process of sample inputting, the project selected is the combination that has been set up, you can directly select in the combination bar that in the left side of interface, click 

directly add to the "selected project determination" column.

You can edit the information you have input. In the landing list column, you can choose one sample number to choose, which display the patient information and testing items information, press " 

" or " 

" button, to edit, delete the contents, after modified click " 

" to confirm.

(b) Preparation before testing

Preparation of cleaning fluid, calibration liquid, quality control solution and sample:

The calibration liquid, quality control liquid, sample and cleaning fluid used in the analysis, which are placed in the corresponding position of the sample tray.

Cleaning fluid: The cleaning fluid C is generally placed in the reagent position of 28.

Standard solution, QC liquid: standard solution and QC liquid are set according to the calibration, QC setting.

Sample: Sample tray according to the number of landing position.

(c) Testing procedure

Sample landing completed, the temperature is stable, the other testing conditions are set finished, click the start button  , will pop up the dialogue as shown in the figure 6-14, choose "cleaning fluid", automatically adding cleaning fluid to cuvette and cleaning the used cuvette. Click "Start", enter the process of sample testing.

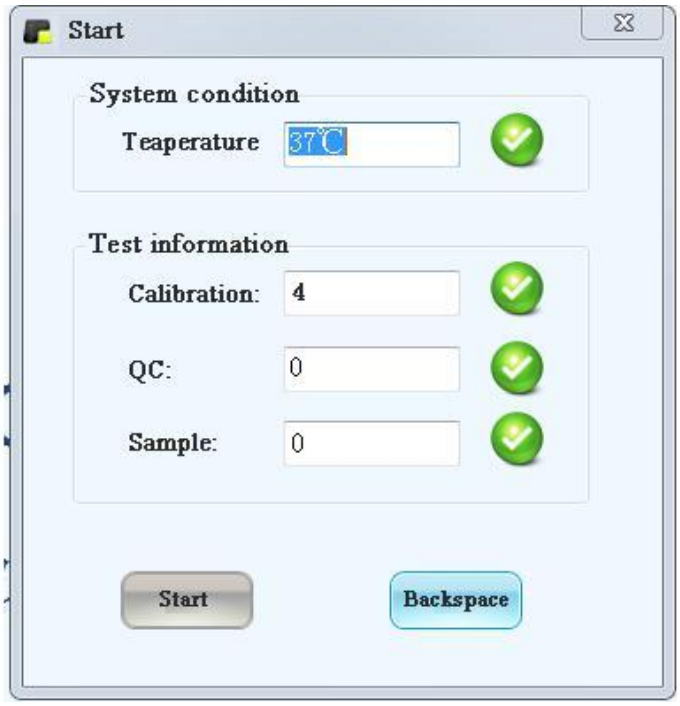


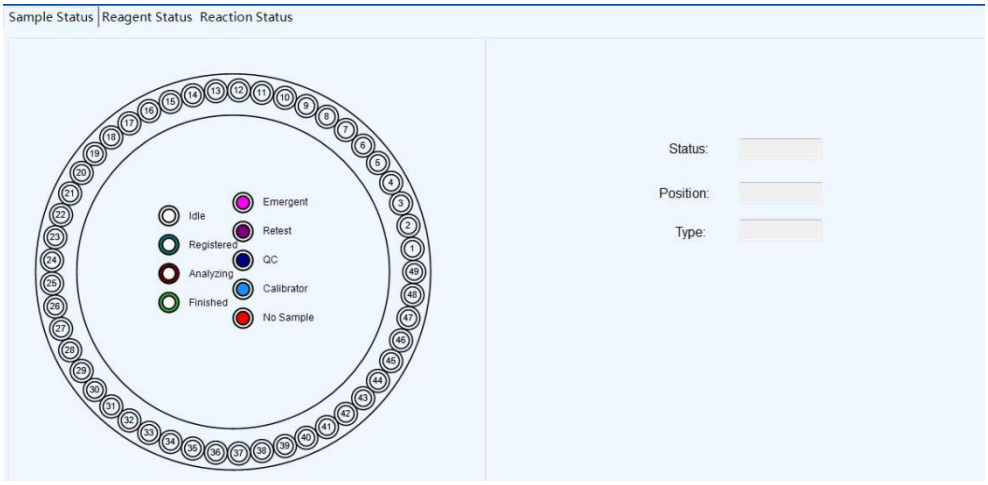
Figure 6-14 Choose cleaning fluid

During the test, the status of the sample testing is displayed in the status bar, as shown in figure 6-15a).

During the sample testing, click 

on the menu bar to perform real-time monitoring of the instrument sample tray, reagent tray, reaction tray status, as shown in figure 6-15 b).

a) Sample test status



b) Status monitor

Figure 6-15 Sample test

Sample tray monitoring: Click "sample trays status" under the "monitor" form, as shown in figure 6-16, wherein the sample tray with different colors to distinguish the status of samples.

Reagent tray monitoring: Click the "reagent tray status" in the "monitor" form, respectively, the reagent tray test status will display in the left of the form, as shown in figure 6-17:

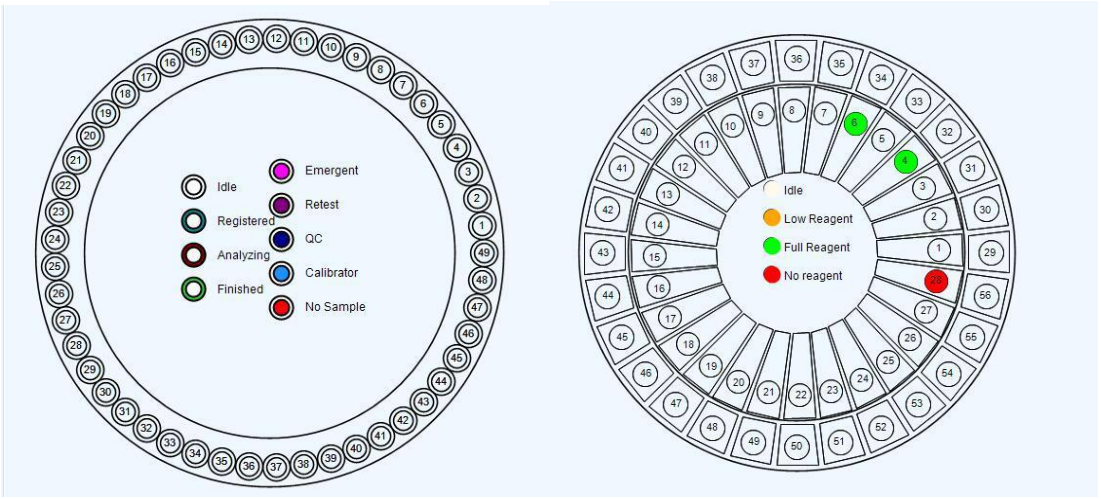


Figure 6-16 Sample tray monitor Figure 6-17 Reagent tray monitor

Reagent tray by serial number indicates that the reagent placed number, when the instrument starts testing, R&S needle after taking the reagent, the software will automatically calculate the residual of the reagent, and the reagent information displayed on the inside. In the reagent tray: white indicates empty yellow indicates less reagent, green indicates that the reagent sufficient, red means no reagent.

The reaction tray detection: The reaction tray in real time display the status of the reaction at the time of sample testing. As shown in figure 6-18, wherein the different colors represent the cuvette in different working conditions.

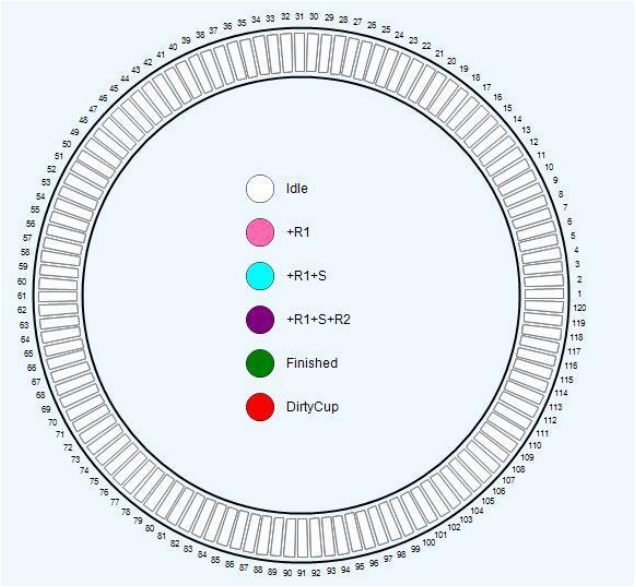


Figure 6-18 Reaction monitor

(d) Test pause, continue and terminate

Sample test in progress, click push button the editor toolbar "  ", "  " or "  ", achieve the control in the testing process.

Click "  " to temporarily stop the test process, click '  ' to continue testing, click the "  " emergently stop test state.

(e) Additional samples

During the test, if there is need for adding samples, you can click on the "sample login" according to the requirement to add the sample to be tested.

6.2.10 Test result query

The test result values are displayed in the "Print" interface of "Data processing", and in the "Test Result Query" interface of "User Setting", can query the test results. As shown in figure 6-19 and figure 6-20.

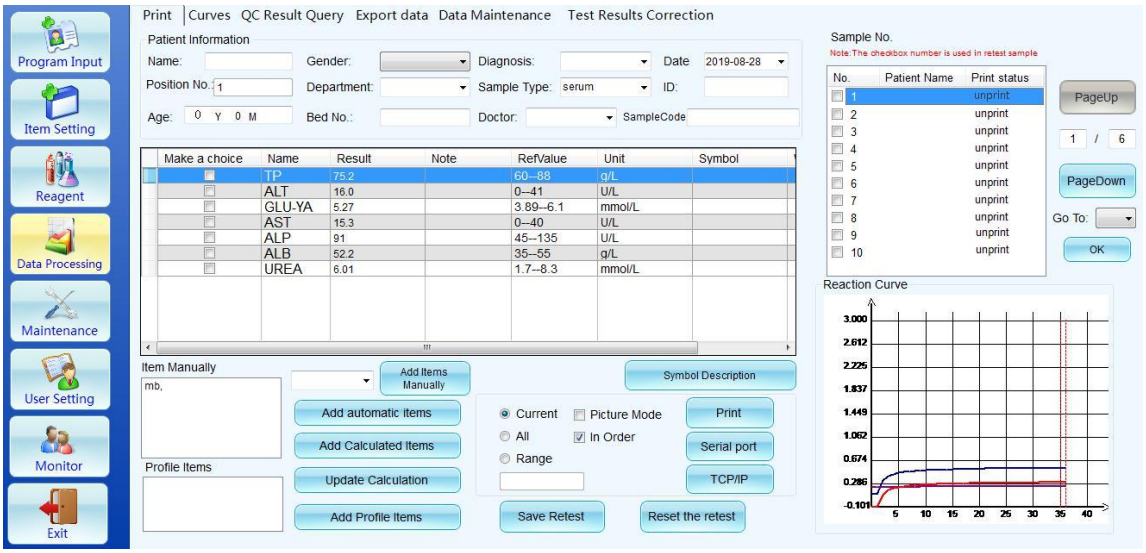


Figure 6-19 Print interface

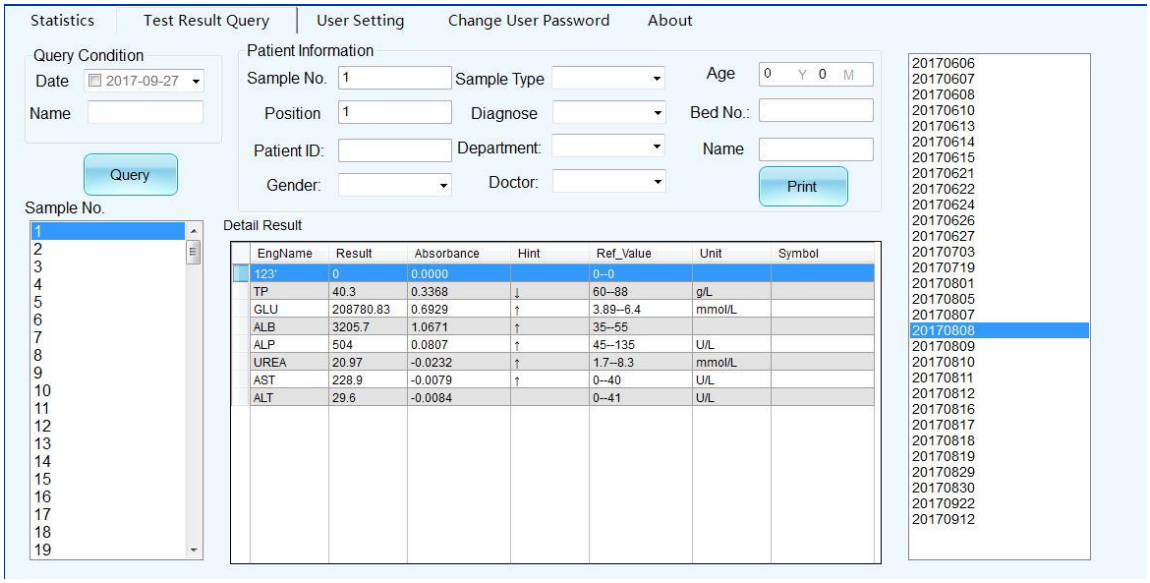


Figure 6-20 Test result query interface

As shown in the figure, in the "Print" or "Test Result Query", select "Date", "Name", "Patient Information", can query the history test results.

6.2.11 Sample retest

In the "Sample Input" interface, select "retest" as shown in figure 6-21, and select re- test the sample number, click "Edit", and select re-test items. Then, click "Save",

Complete the retesting sample or item input.

Or in the "Print" interface of "Data Processing", click the "Save retest", and select the retested sample or items, as shown in figure 6-22.

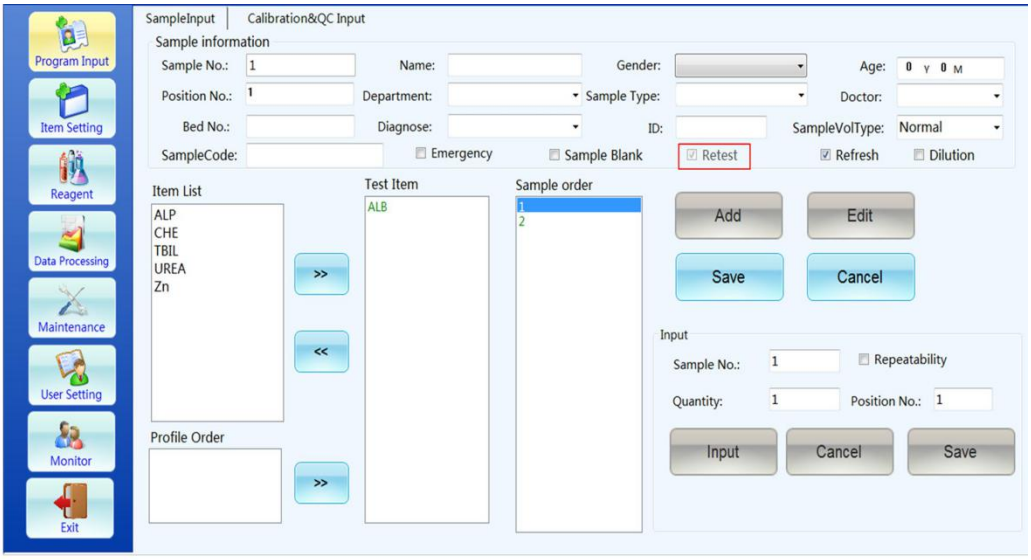


Figure 6-21 Sample retest

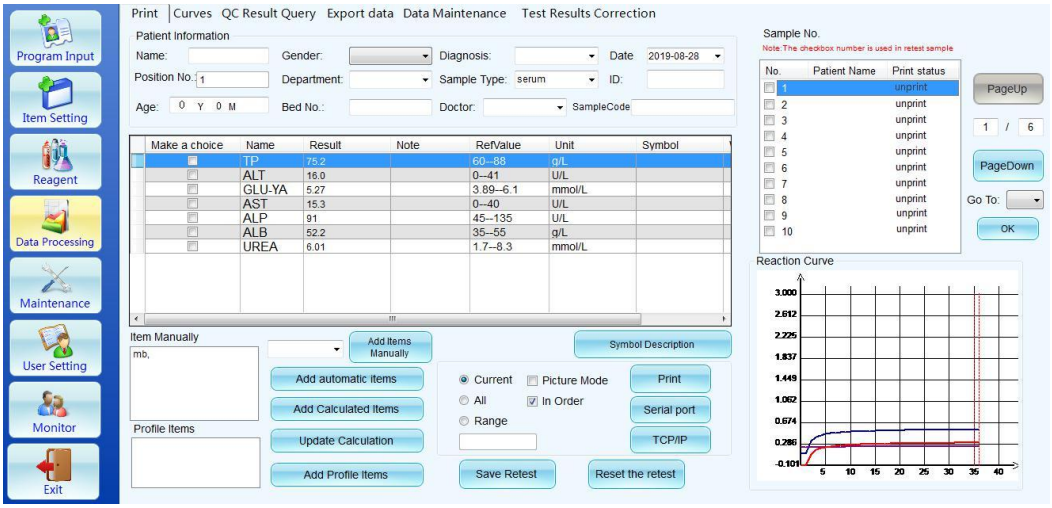


Figure 6-22 Reset sample retest

If the sample is testing, the retest items will be retested automatically. If the testing is over, need to restart the test task, and click the button "  ". If need to cancel the retest, click the "Reset the retest".

Note: Only the test data of the day, which can be re-tested.

6.2.12 Operation after test

Test finished, if there are no objection for the data, select "Washing & background" in the menu bar "Maintenance", and in the "Washing&&background" interface select "Cleaning" function, after cleaning, close biochemical analyzer power. Unused biochemical reagents needed be save, remove the extra reagent and use reagent bottle caps cover it, then put it into the medical refrigerator. Remove the already tested sample, calibration and control solution where in the sample tray. If you use waste container, dispose of the liquid in a safety way. Detecting the equipment table is dirty or not, and clean the table.

7. Calibration and QC

In software interface, click the 

, then, click the "CalibrationPar", you can check the calibration parameter, and change the calibration parameter.

7.1 Calibration

7.1.1 Calibration parameter setting

Click "Item Setting", then click the "CalibrationPar" , input the calibrator parameter.

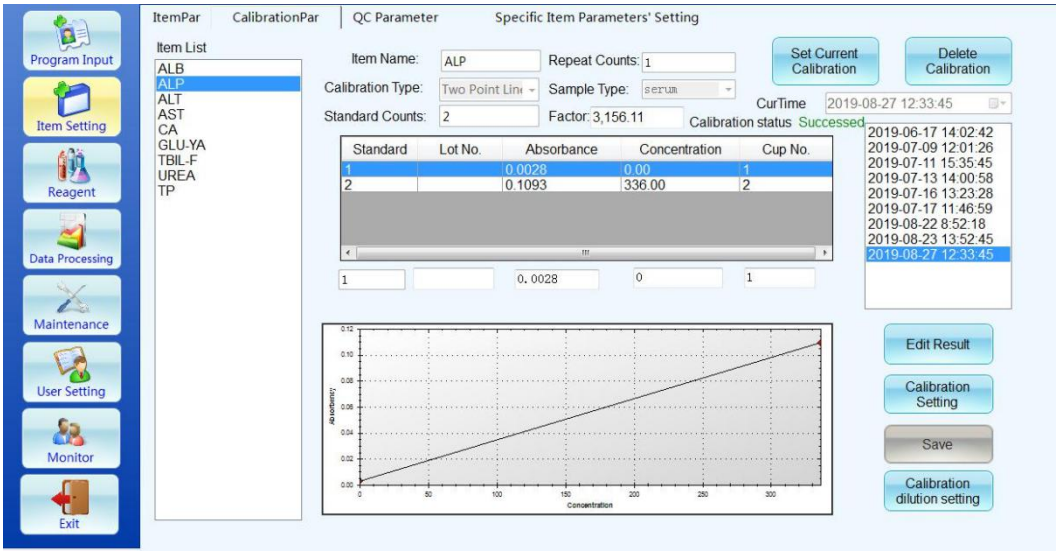
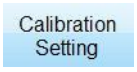


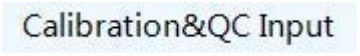
Figure7-1 Calibration parameter

After we finished the input reagents parameter, in this interface, select test items which need be calibration. Then click on the right " 

". After input the correct parameter, in "Calibration type", "Standard counts", "Repeat counts", "Sample type", "Concentration", "Cup No.", finally click "Save". "Concentration" and "Cup No", need according to the calibrator and the calibrators location number in reagents tray, then click "Edit".

7.1.2 Calibration input

In the " 

" interface, select " 

", and select the need calibrator test items, click the 

. Then, click "Save" to prompt you to save the success box. As shown in figure 7-2.

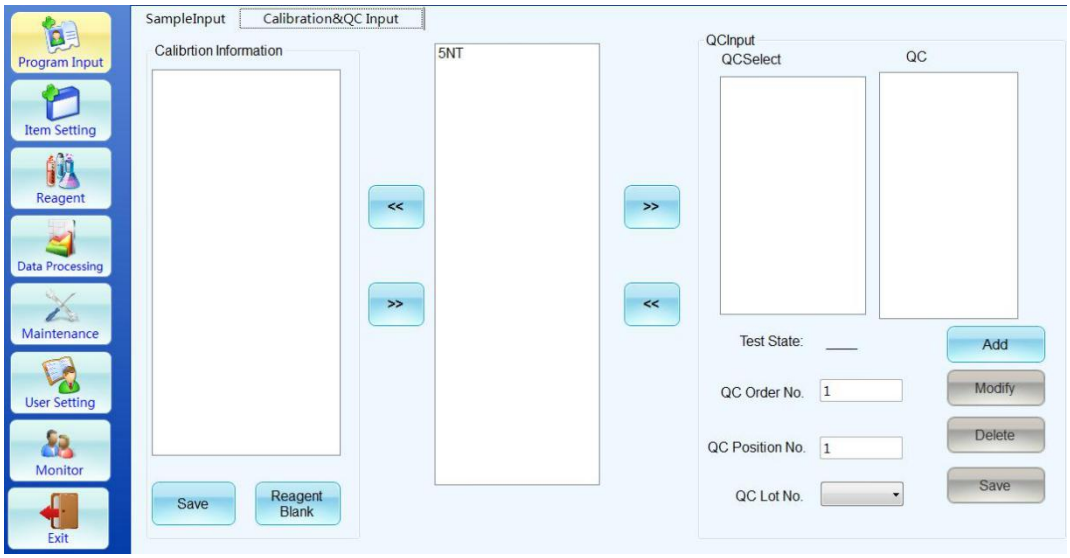


Figure 7-2 Calibration test

7.1.3 Calibration test

Click the Start button "  ", and then do calibration test, and the status bar displays the testing process, as shown in figure 7-3.

Figure 7-3 Calibration testing process

In the calibration process, if an emergency situation need to stop the test, click on the button "" to stop the test operation is completed.

7.1.4 Calibration result query

1. Calibration curve inquiry

After the completion of the calibration test, in software toolbar 

, select response curve interface, as shown in figure 7-4.

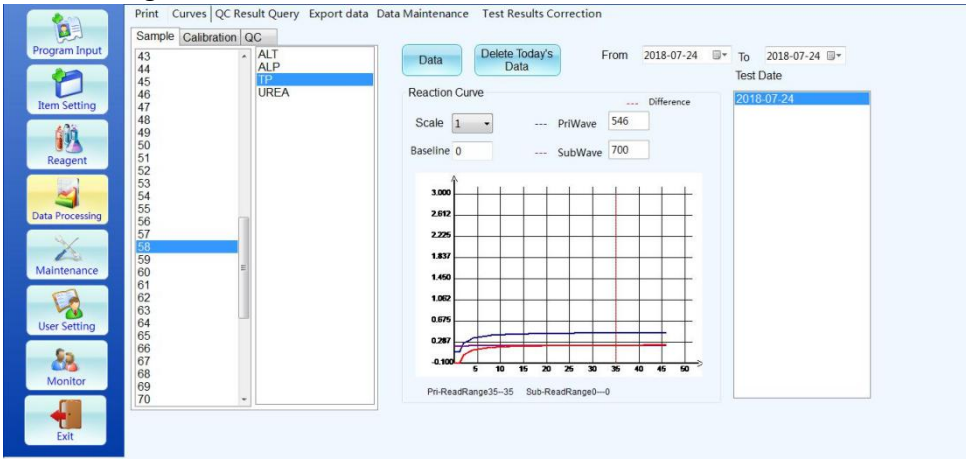


Figure 7-4 Query response curve

In Curves interface, at "Test Date", select the calibration date and the need queried items. Then, we can get the calibration curve.

As shown in figure 7-4, in response curve interface, select the "calibration" column query calibration curve, select the right side of the interface "test date" calibration time, in the right side of the interface need to inquire about items directly query the calibration curve based on calibration to a specific time.

2. Calibration result query

Under "Item setting" window, left-click to enter "CalibrationPar" screen, select the desired view of the direct results of the item, as shown in figure 7-5.

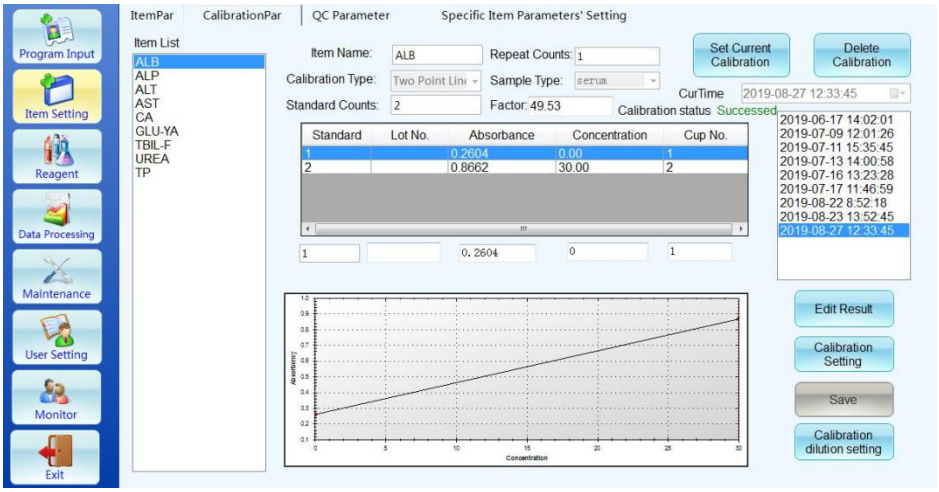


Figure 7-5 Calibration result query

As shown in figure 7-5, in "Calibration Par" screen, first in the "item list" column select the name of the item you want to view, and then the right choice at the interface between the specific calibration time, check calibration result.

7.2 QC

The purpose of laboratory QC is to ensure the reliability of each sample. The reliability of the measurement results includes two aspects of meaning, one is the precision, that is, the results of the repeatability is good, the laboratory daily changes in the results of small changes, mainly to eliminate or reduce the impact of random errors. The other is the accuracy High, that is, the measurement results are correct, close to the true value, the main elimination or reduce the impact of system error.

Random error: The difference between the measured results and the average of the results obtained by infinitely many measurements of the same measured under repetitive conditions is called random error.

System error: Under repeated conditions, the difference between the average of the results obtained by infinitely many measurements of the same measurement and the measured true value is called the system error. It is the error component of the measurement result that is not zero.

Accuracy: Accuracy is the measurement of the system error and random error of the synthesis, said the measurement results and the true value of the degree of consistency.

Precision: Indicates the degree of random error in the measurement result. Precision refers to the degree of compliance between the measured results when multiple measurements are made under certain conditions.

L-J (Levey Jennings) QC chart: The QC chart is a graph with a QC limit. The QC limits are determined by the mean value ($\bar{X}$) and standard deviation (SD) of the known specimen (usually the control solution) by the controlled analysis method. $\bar{X}$±2SD is the warning limit, and $\bar{X}$±3SD is the loss of control.

7.2.1 QC rules setting

In the "Data Processing" menu, open the "QC Result Query" window and select the corresponding QC rules in the QC Rules drop-down list, as follows:

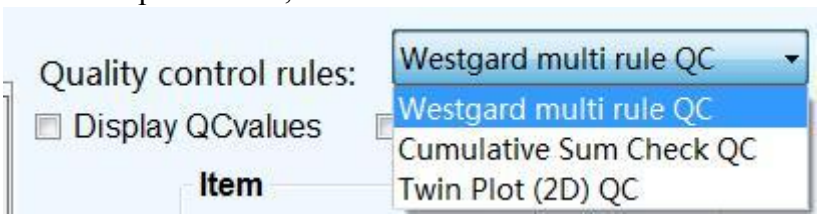


Figure 7-6 QC rules

1. Westgard multi-rule QC

The operator according to the test needs, by clicking the way to select Westgard multi -rule QC, select 

, pop-up Westgard multi-rule QC rules as shown in the figure 7-7.

Figure 7-7 Westgard multi-rule QC

The operator according to the test needs, by clicking the way to select the appropriate QC rules, click the "Save" button to return to the QC results query window, while the QC rules to save the setting. After setting, in the "day QC" and "month QC" window will be set in accordance with the rules of QC data out of control analysis.

According to Westgard multi-rule judgment benchmark for the measured QC results, perform out of control analysis. Figure 7-8 shows the Westgard multi-rule logic diagram.

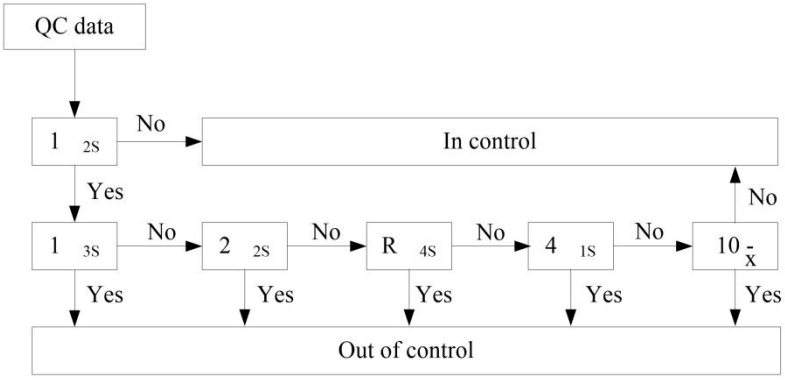


Figure 7-8 Westgard multi-rule logic diagram

Sheet 7-1 Determine the baseline description

QC rules	Description	Result marker	Out of control symbols
1_{2S}	Indicating that there is a test result in the control over 2 ± 2SD, but less than ± 3SD	no	no
1_{3S}	Indicating that there is a test result in the control over ± 3SD	1_{3S}	*(1)
2_{2S}	Indicating that there are two consecutive test results in the QC over +2 SD or -2SD, such as (Xn, Xn-1)	2_{2S}	#(2)
R_{4S}	That there is a test results in more than +2 SD test results, another test results more than -2SD	R_{4S}	#
4_{1S}	Indicating that there are four consecutive test results in the control over + 1 SD or -1 SD, such as (Xn, Xn-1, Xn-2, Xn-3)	4_{1S}	#
10-x	Indicating that there are 10 consecutive test results (10 data) on the same side of the mean, such as (Xn, Xn-1, Xn-2…Xn-9)	10-x	#

(1) "*" Means random error, you can not take any operation, but still can not be ignored.

(2) "#" Indicates system error and needs attention.

2. Cumulative Sum Check QC

Cumulative Sum Check QC rules are as follows:

(1) Calculate K value (± 1SD) and control limit H (2.7SD) according to the QC target and standard deviation.

(2) When the QC value does not exceed the K value, the cumulative sum is not calculated.

(3) When the QC value exceeds the K value (greater than the upper limit or less than the lower limit) of the data points, began to accumulate and calculate.

(4) For the subsequent points, continuous calculation of cumulative sum.

(5) Calculate, accumulate and clear when accumulating and just changing the symbol (positive or negative) and accumulate the sum for the subsequent data points.

(6) When the accumulated and over control limit H (greater than the upper limit or less than the lower limit), then judged to be out of control.

3. Twin-Plot (two-dimensional) QC

Twin-Plot (two-dimensional) chart to the QC X test results for the horizontal axis, QC Y test results for the vertical axis, will participate in the joint test results for the vertical axis, will participate in joint judgment of the two QC, and the same batch of test results are plotted to determine system errors and random errors.

7.2.2 QC test

After the QC information is registered, click "QC parameter" in the menu item "Item parameter", click "Add" in the QC area on the right side of the interface, select the lot number in the "Control Lot", "QC number" in the input control of the sample placed in the sample tray number, in the "QC test items" need to select the QC of the item, "QC List" shows the number of editing QC test, click "Save" to complete the operation. As shown in figure 7-9.

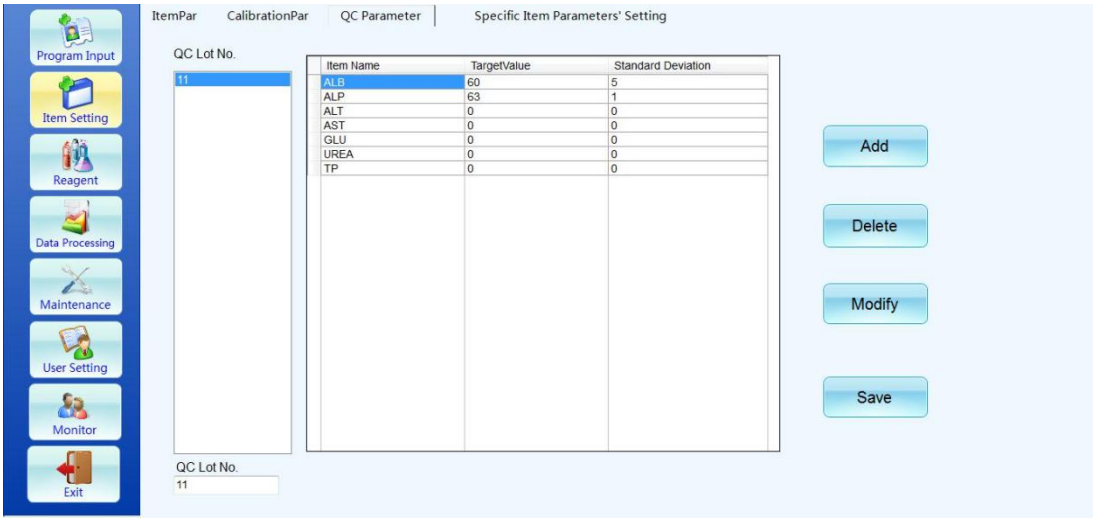


Figure 7-9 QC item input

After the QC item input is completed, click the start button to test the QC item.

QC test is completed, the instrument automatically calculate the measured QC target (average), standard deviation, coefficient of variation and other data.

Target($\bar{X}$): $\frac{\sum_{i=1}^{N} Xi}{N}$

Standard deviation(SD): $\sqrt{\frac{\sum_{i=1}^{N}(Xi-\text{average})^2}{N-1}}$

Coefficient of variation(CV%): $\frac{SD}{\text{average}} \times 100\%$

Deviation: Xi - (average)

%Error: $\frac{\text{Deviation}}{\text{average}} \times 100\%$

Among them:

N is the number of measurements, Xi is the test result.

7.2.3 QC results query

1. QC curve query

Query method with 7.1.4 calibration curve query.

2. QC results query

In the software menu bar, select "data processing" menu, and sub-menu "QC results query" menu, as shown in figure 7-10.

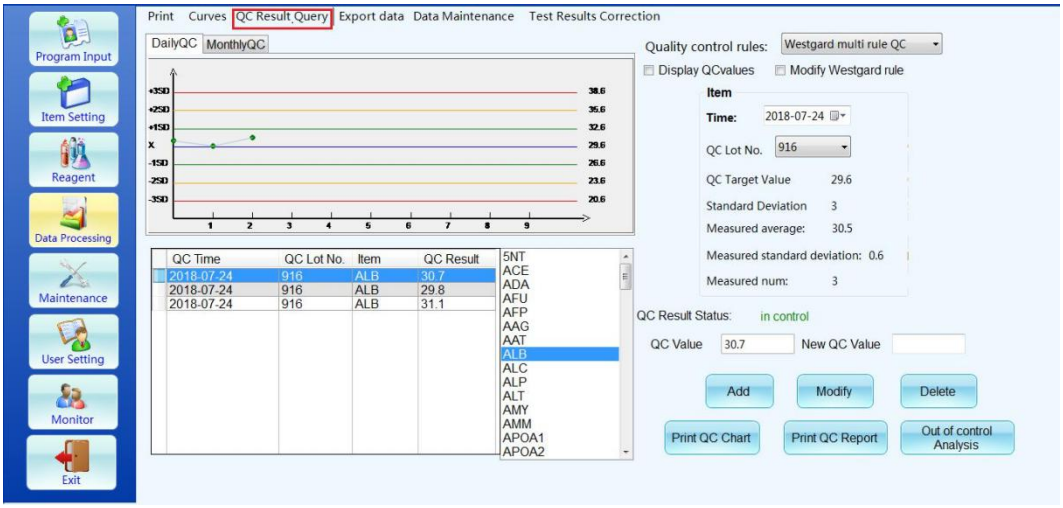
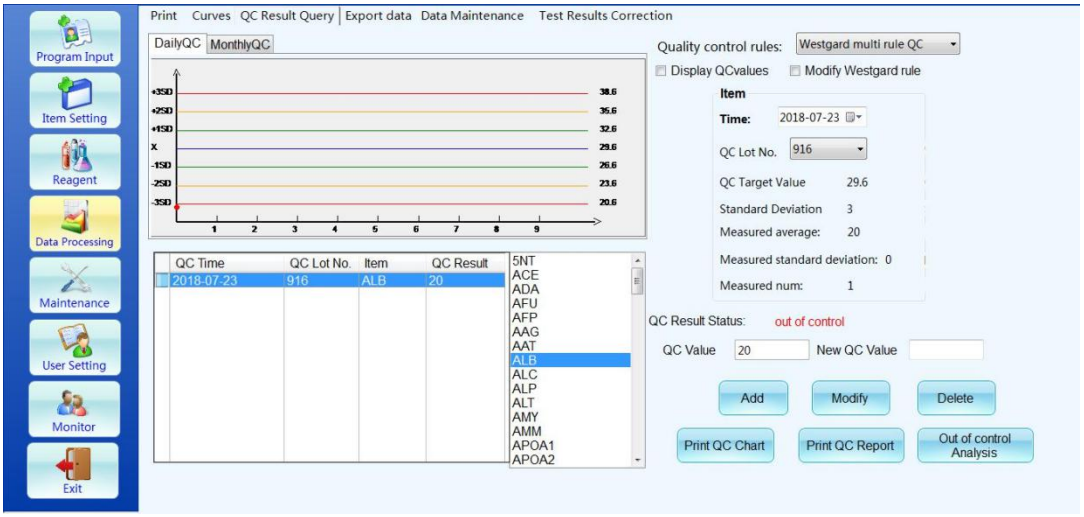
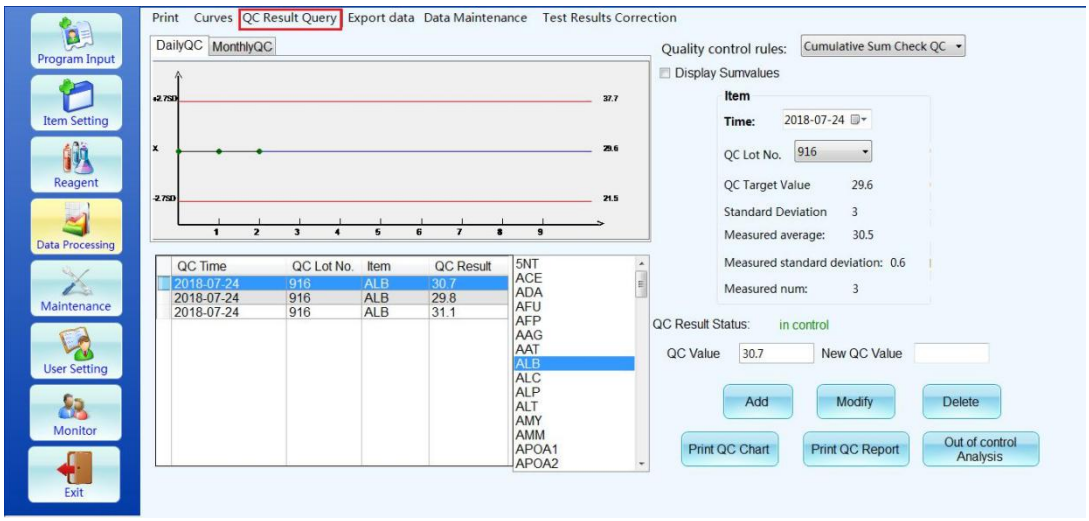


Figure 7-10 QC results query

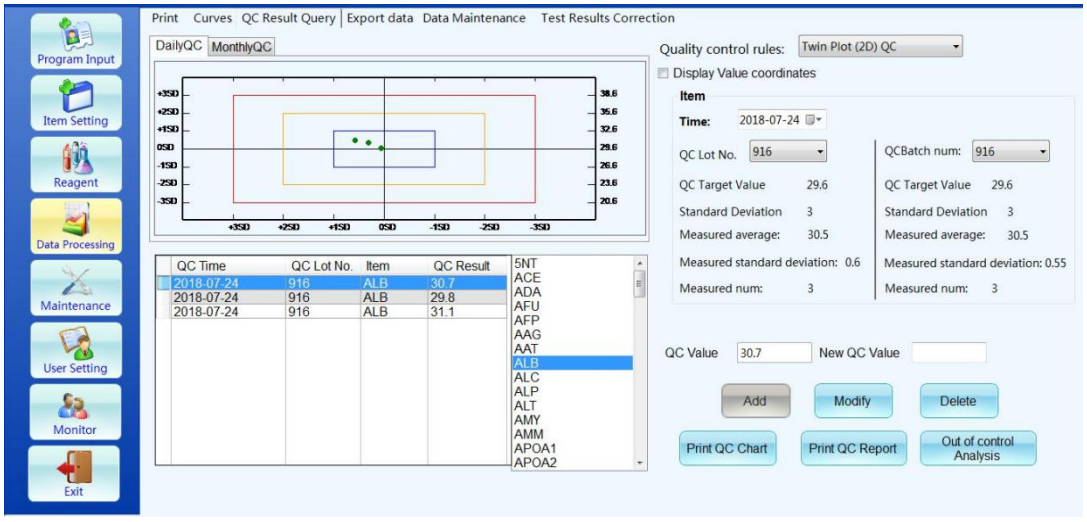
As shown in the figure, in the "QC results query" interface, first select the item to be inquired and the QC batch number, and then according to the QC test time to find the QC results. Can choose different QC rules view The corresponding QC trend, as shown in figure 7-11.



a) Westgard multi-rule QC results query



b) Cumulative sum check QC results query



c) Twin-plot (two-dimensional) QC results query

Figure 7-11 QC results query trend chart

At the same time the system supports manual entry of "new QC value", the QC results out of control analysis, click "Add", enter the new QC value, click "Save" to display the QC results status. Click "Out of control analysis" to display out of control results.

3. QC chart printing

In the QC results query, click "Print QC Chart", and then print daily QC or monthly QC chart.

4. QC report printing

In the QC results query, click "Print QC Report", and then print daily QC or monthly QC report, as shown in figure 7-12, click "Print".

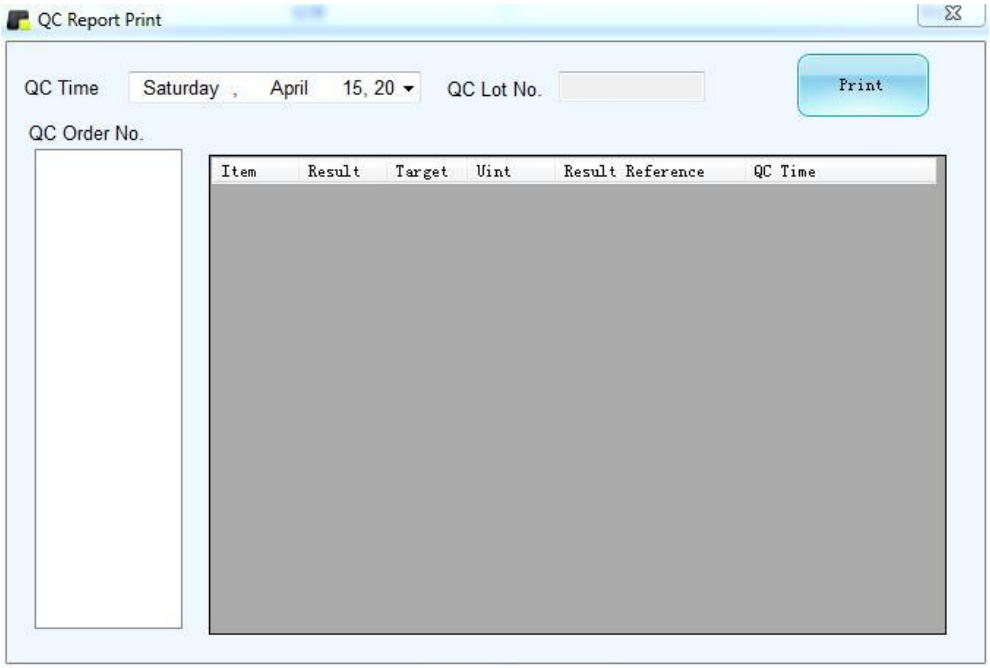


Figure 7-12 QC report printing

5. Out of control analysis

In the QC results query, click "Out of control Analysis", out of control analysis results displayed in the right window, as shown in figure 7-13.

Figure 7-13 Out of control results

7.3 Factor correction

The calibration and QC test are completed, the query results of QC in the QC target range, then the scaling factor can be directly used for sample testing. If the QC results of deviation from the target range, it is necessary to control the scaling factor of QC in the target range.

The method of correcting factor is calculated according to the QC value and target value, and the formula is as follows:

Formula:

New factor= (Old factor * Target value)/ QC value

After adjusting the factor, we must re-QC, and determine the value of QC in the range of target value, to determine the correct adjustment of the factor, in order to carry out the sample test.

7.4 Calibration and QC flow chart

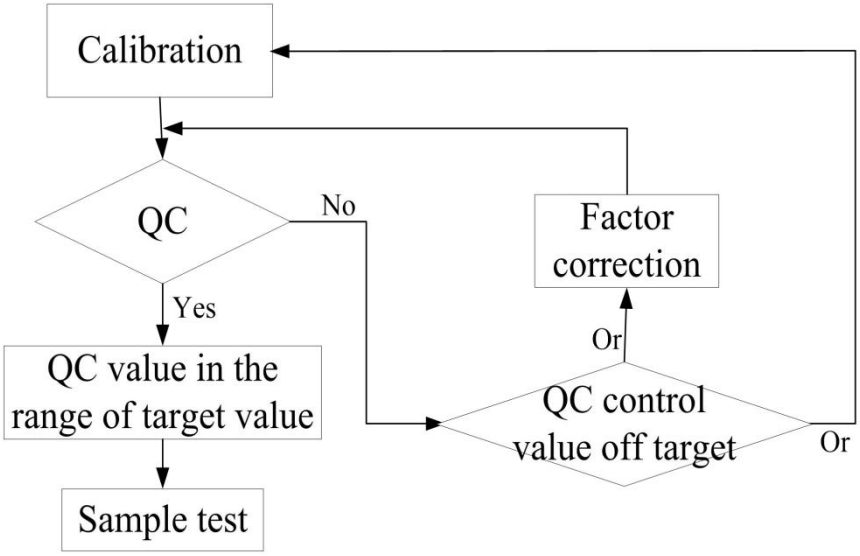


Figure 7-14 Calibration and QC flow chart

8. Data Processing

This chapter describes the backup of various test result data, print template settings, automatic printing and manual printing methods, and describes the style of printing reports.

8.1 Data export

8.1.1 Introduction

The system supports data serial port/network port LIS transmission data export function. Exporting data is allowed only when the system is in standby and fault conditions.

The export function allows you to export the following data for backup:

•Sample results, including all duplicate test results—are transmitted to the LIS host for backup via serial or network port.

Note:

Our company only provides LIS communication protocol, the system supports serial/network port LIS transmission, but does not provide LIS system.

8.1.2 Export data to LIS host

The system supports data transmission with the LIS host for auditing and backup. The system supports real-time and manual sending of sample results and QC results to the LIS host for review and backup. Real-time transmission means that after the sample test is completed, the system automatically sends all test results of the sample to the LIS. Manual transmission allows the test results of selection for this sample to be sent to the LIS.

Through the results query interface, view the results and then transmitted to the LIS.

Exporting data is allowed only when the system is in standby.

Precaution:

Do not turn off the analysis main power or exit the operating software during data export.

1.Select [Data Processing] - [Export data], and open the “Export data” interface.

2. Check the “Export Data”.

3. Select its export mode, serial port or TCP/IP in the [Export Mode] drop-down menu.

TCP/IP export:

Select the TCP/IP export mode, it is necessary to set the corresponding server IP, port number, encoding format and other data.

Confirm whether it is transmitted in real time.

Click [Connected], and then see if the connection is successful in the status bar.

Serial port export:

Select serial port export mode, it is necessary to set the corresponding port and baud rate.

After clicking [Open], a prompt box for confirming whether to transmit in real time will appear. If you need real-time transmission, click [OK], otherwise click [Cancel].

Figure 8-1 LIS transmission settings

4. After the LIS connection is completed, click [Save] to save the LIS connection information and facilitate the next LIS connection operation.

5. Select [Data Processing] - [Print], and click the [Serial Port] or [TCP/IP] button to transmit the sample results to the LIS host.

8.2 Data backup

The system provides data backup function, which allows data results to be backed up for archiving and future viewing.

8.2.1 Database maintenance

In the [Maintenance] - [Database Maintenance] interface, parameters data and test results data can be backed up or reduction.

Figure 8-2 [Database Maintenance] interface

1. Select [Maintenance] - [Database Maintenance].

2. Click the [Backup] button to back up the data of parameters, test results, calibration results and QC results to the folder “ BackUp ” under the installation directory of operation software.

3. If you click the [Reduction] button, the database contents in the operating software will be replaced by the database contents in the folder " BackUp ".

8.2.2 Data statistics

The statistics can be backed up in the [Statistics] interface under the [User Setting] menu. Such as: test statistics, workload statistics, expense statistics

Test statistics:

The statistical methods of test statistics can be divided into sample statistics and project statistics. After confirming the statistics mode, start time, and end time, click [Statistic] to list related data in the sample list. Click [Export], and the data can be backed up. The backup file is named by default with the date and time of the backup, and the format is .csv.

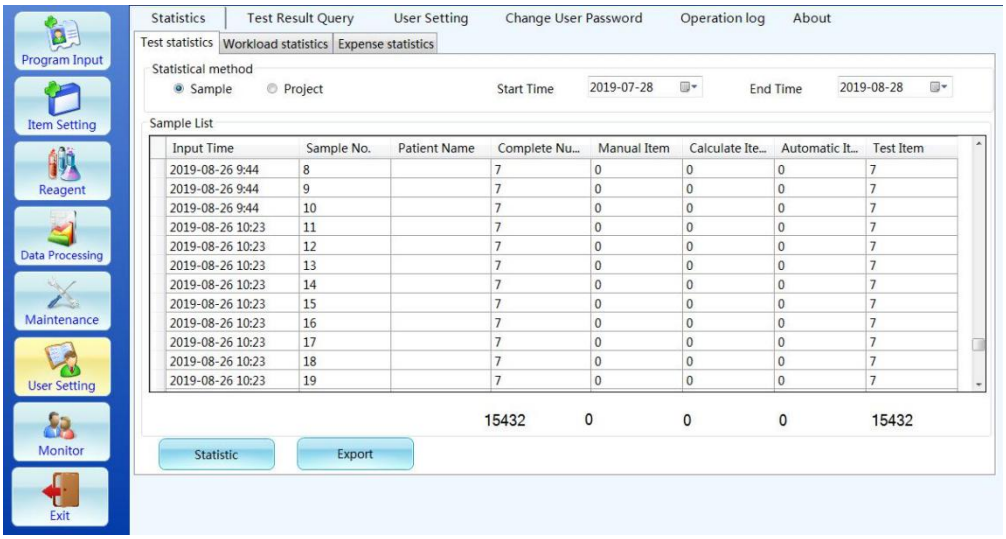


Figure 8-3 [Test statistics] interface

Workload statistics:

The statistical condition of workload statistics can be divided into the inspector or the submission and date. After confirming the statistical conditions, click [Statistic] to list the relevant data in the sample list, and click [Export], and the data can be backed up. The backup file is named by default with the date and time of the backup, and the format is .csv.

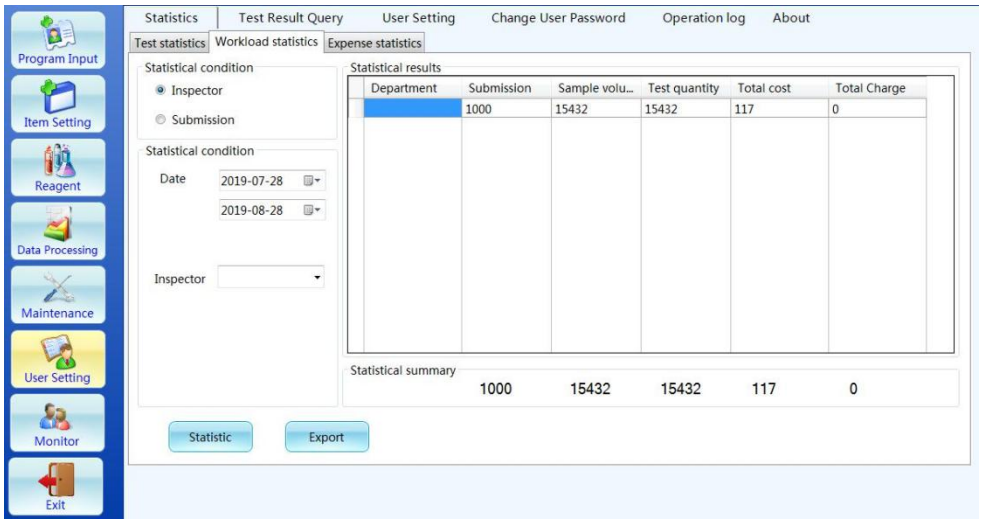


Figure 8-4 [Workload statistics] interface

Expense statistics:

The statistical method of expense statistics can be divided into patient charge statistics and cost accounting statistics. Click [Price] to set the cost price and charge price of the item. After confirming the statistical method, statistical condition and sample number, click [Statistic] to list the relevant data in the sample list. Click [Export], and the data can be backed up. The backup file is named by default with the date and time of the backup, and the format is .csv.

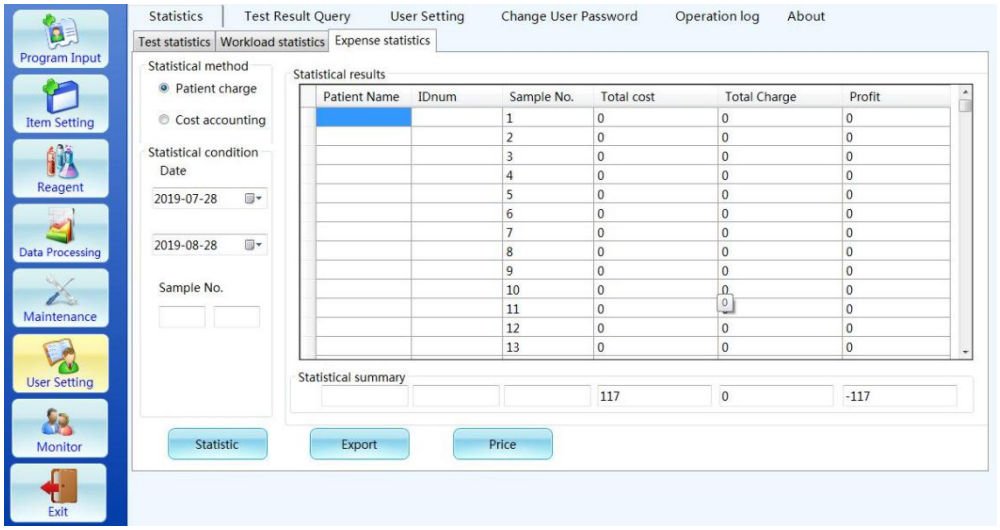


Figure 8-5 [Expense statistics] interface

8.3 Data maintenance

8.3.1 Introduction

The units, diagnosis, sample type, doctor, department, project test order, prevent cross contamination, and print order of each sample can be set by data maintenance.

Following is a detailed description of the data settings.

8.3.2 Data items setting

When printing a sample report or inputting sample information, it is necessary to set the measurement units, diagnosis and sample type of the sample, and doctor, department, etc..

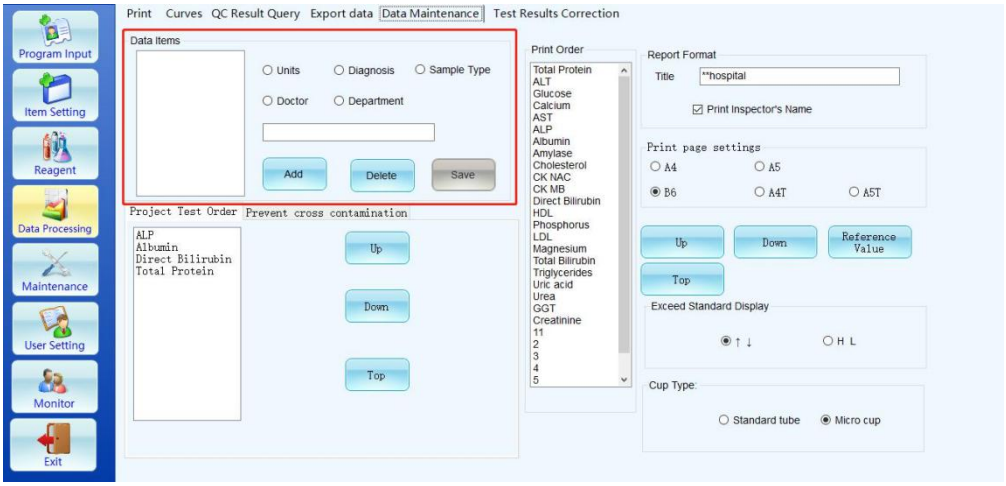


Figure 8-6 Data items setting interface

1. Select [Data Processing] - [Data Maintenance].
2. Select the instrument information to be set in the “Data Items” setting column. If you need to add information, click [Add] and input the relevant information in the input box. If you need to delete the information, select the instrument information to be deleted and then click [Delete], and click [OK] in the prompt box.
3. Click [Save] to save the relevant settings.

8.3.3 Project test order

When testing the sample, you can select the test order of the item. The specific operations refers to the following:

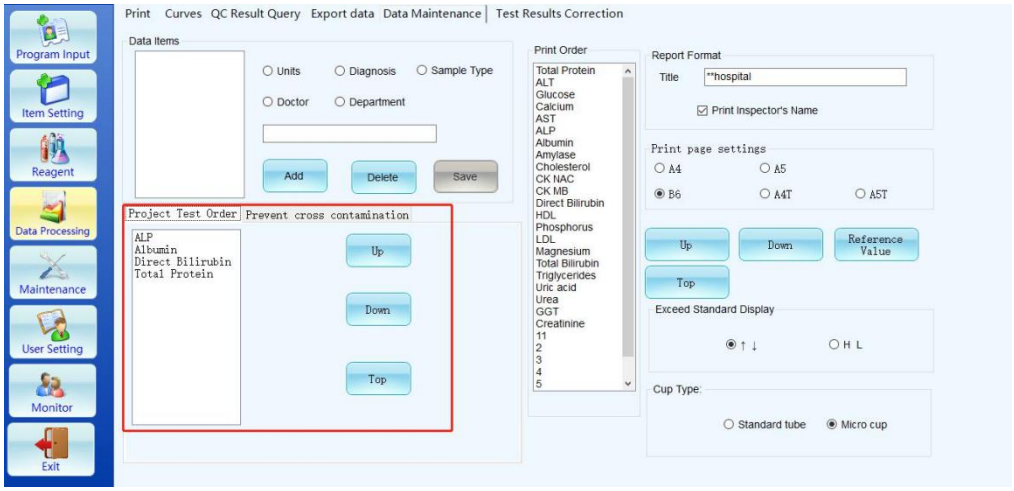
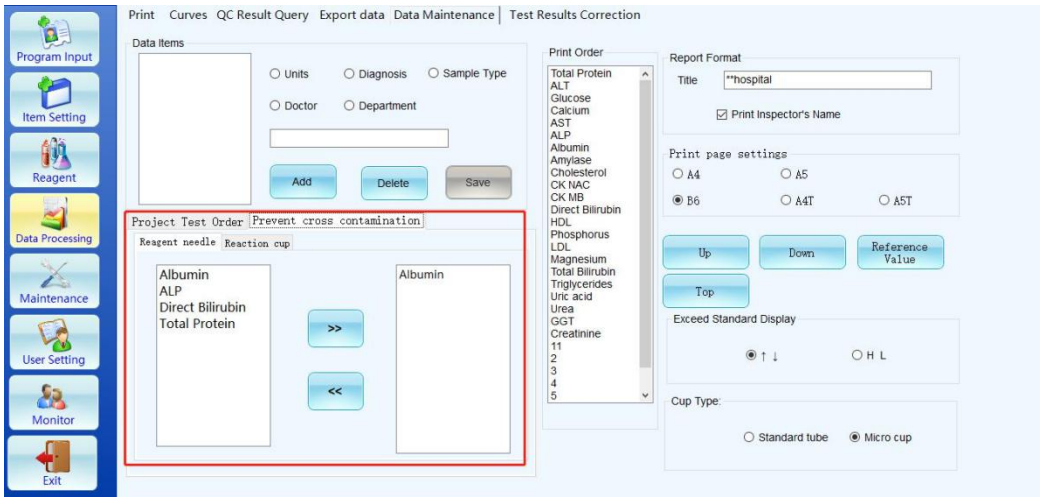


Figure 8-7 Project test order interface

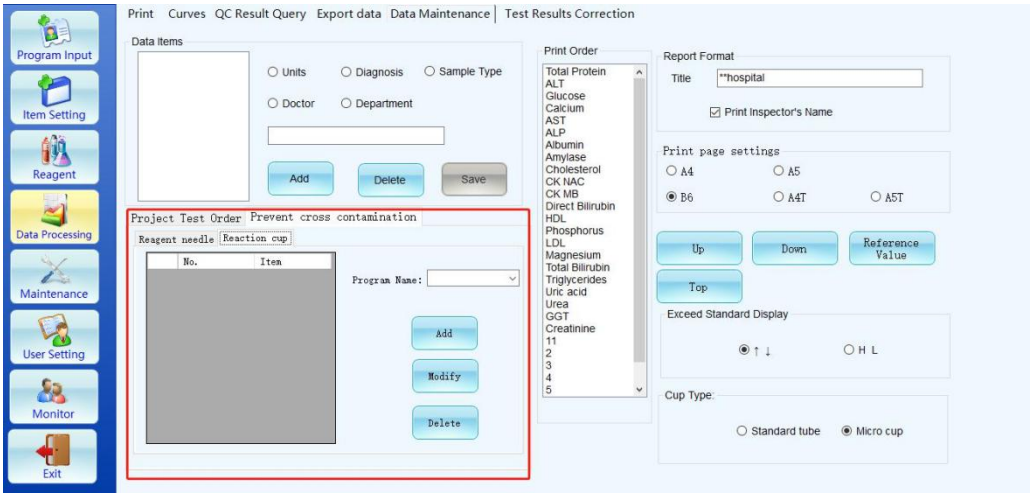
1. Select [Data Processing] - [Data Maintenance].
2. After selecting the items that need to change the test order in the “Project Test Order” column, click the [Up], [Down] or [Top] buttons on the right to set the test order of the items.

8.3.4 Prevent cross contamination

In order to prevent the deviation of test results caused by cross-infection among projects, we can choose the project which has a great impact on some results to set up anti-cross-contamination settings. The specific operations refers to the following:



a)



b)

Figure 8-8 Prevent cross contamination interface

1. Select [Data Processing] - [Data Maintenance].
2. Select the “Prevent cross contamination” column, and set up the column of “Reagent Needle” and “Reaction Cup” to prevent cross contamination.

- Prevent cross contamination of reagent needle: After selecting the item that needs to prevent cross contamination in the “Reagent Needle” column, click the “ >> ” button on the right to set the item to prevent cross-contamination. For example, when setting AST item, before the item is tested, the system automatically cleans the reagent needle with the cleaning fluid.
- Prevent cross contamination of cuvette: Select the “Reaction cup” column, and select the item that needs anti-cross-contamination in the “Program Name” list drop-down box, click [Add] to set the item to prevent cross-contamination. Such as ALT, after the test of the item is completed, the cuvette used in the item will be immersed in the cleaning fluid. The cuvette will not be used during the sample test, until the end of the sample test, the cuvette and other cuvettes are cleaned together with the background operation.

8.3.5 Print order

When printing the sample results, you can select the print order of items. The specific operation refers to the following:

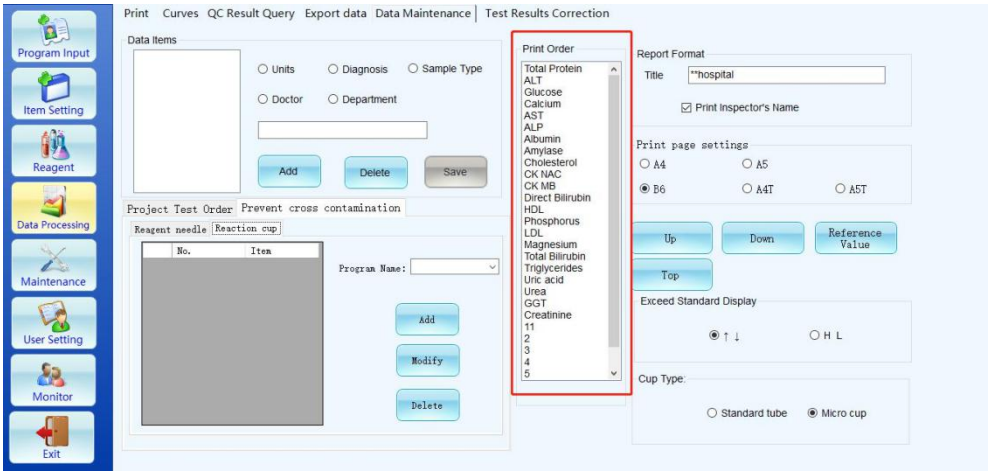


Figure 8-9 Print order interface

1. Select [Data Processing] - [Data Maintenance].

2. Selecting the item that needs to be changed in the print order in the “Print Order” column, click the [Up], [Down] or [Top] buttons on the right to set the print order of the item.

8.3.6 Item manually reference setting

When evaluating the sample results, there are some other qualitative references for data references, such as “negative”, “positive”, “+”, “++”, etc.. The specific operation refers to the following:

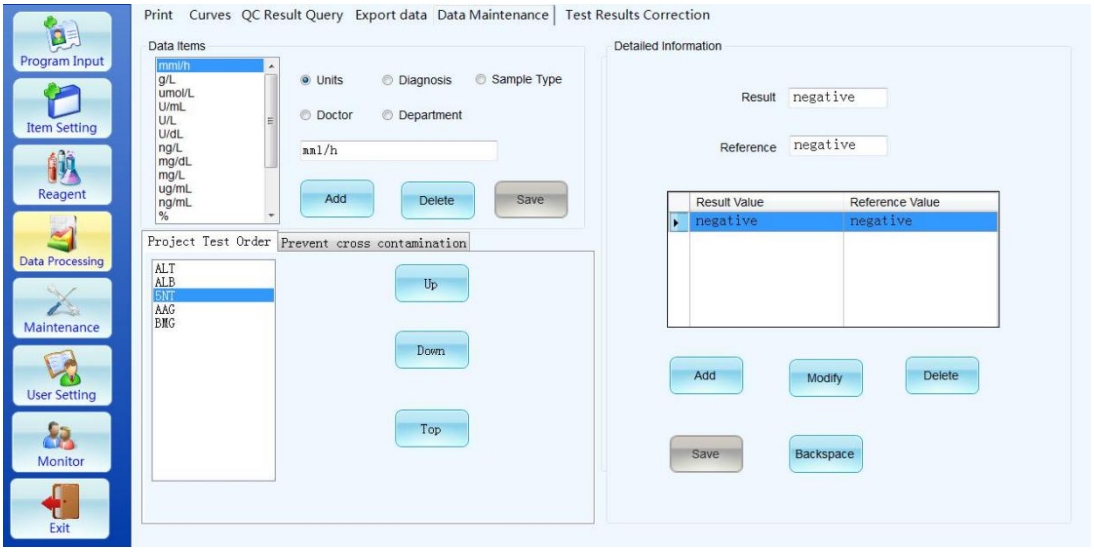


Figure 8-10 Item manually reference value interface

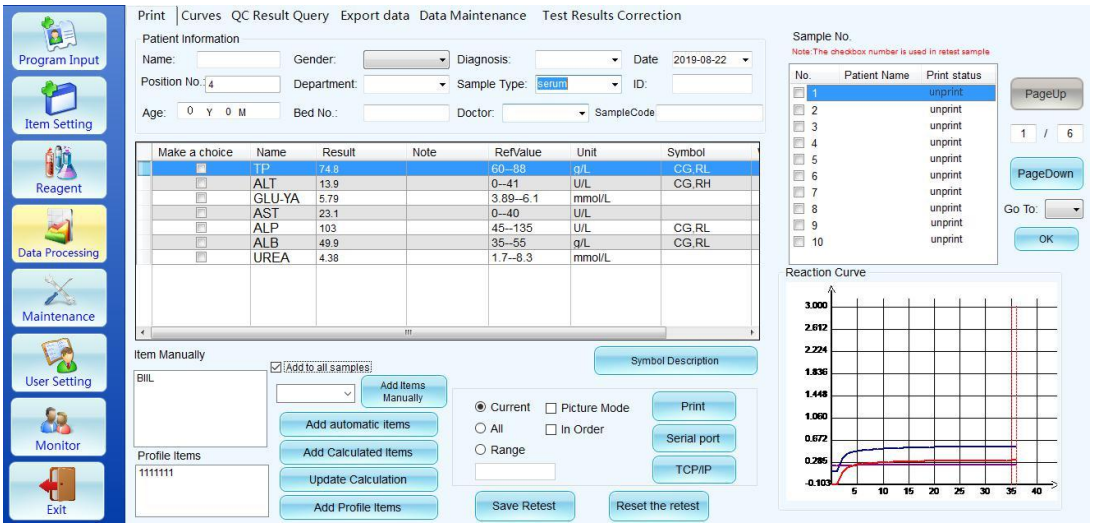


Figure 8-11 Item manually reference value selection interface

1. Select [Data Processing] - [Data Maintenance].
2. Click [Reference Value].
3. Select [Add] / [Modify] to set the result value and reference value.
4. Click [Save] after setting up.
5. Select [Data Processing] - [Print], and select the “Sample NO.”. In the “Add Items Manually” drop-down list box, you can select the reference value which set before.
6. Click [Add Items Manually], and finish the manual items adding.

- If all samples add the same manual items, check Add to all samples, and click [Add Items Manually] to finish the manual items adding for all samples.

8.4 Sample report printing

8.4.1 Introduction

The sample report are used to print test results, sample lists, reaction curves and data for patient samples, as well as sample blanks reaction curve and data.

The printing method and report form of the report are described in detail below.

8.4.2 Sample report

The sample report prints all item test results of a sample into a single report, including emergency samples, regular samples, and QC samples. And you can choose a variety of types of printing, such as: single sample report printing, batch sample report printing, etc., the report can be printed through the following interface:

Method one:

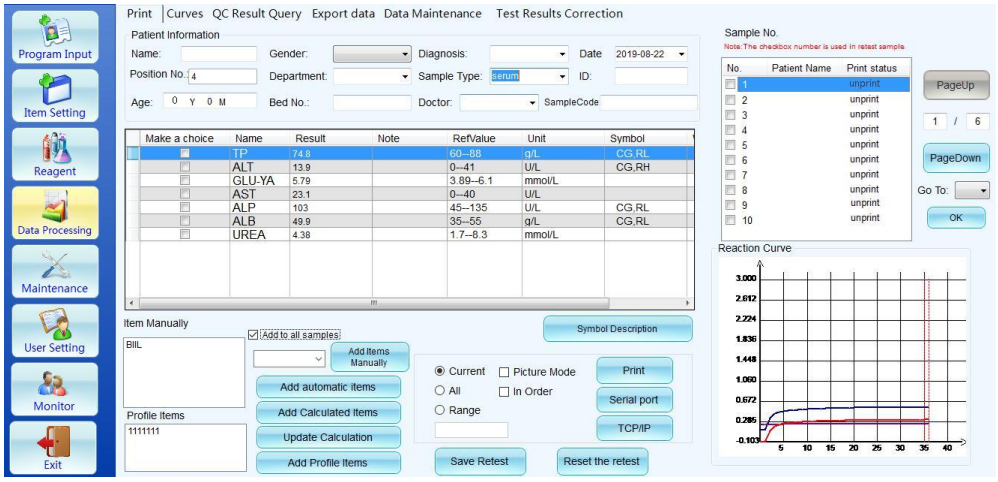
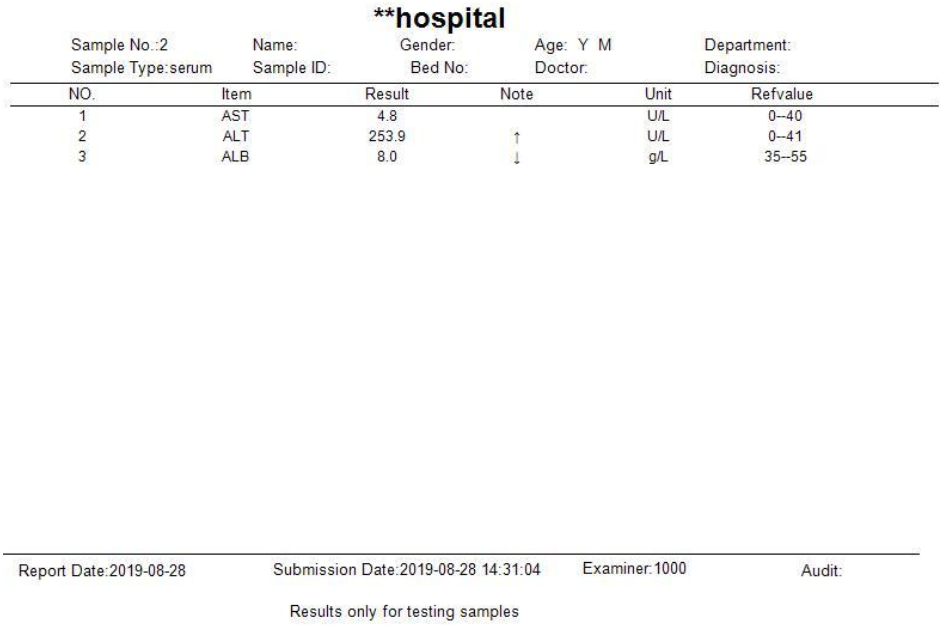


Figure 8-12 [Print] interface

Print the sample report according to the following steps:

1. Select [Data Processing] - [Print].
2. Select the sample to be printed in the “Sample No.” bar.
3. Selection of Printing Range:
   - Current: Print the report of the patient information displayed on the current page.
   - All: Print all test reports of this batch.
   - Picture mode: Print the report in image format.
   - In order: Print report according to the current list order.
   - Range: Print some sample reports needed by inputting the relevant sample number below.
4. Click [Print] to complete the report printing.



**hospital

Sample No.:2 Name: Gender: Age: Y M Department:
Sample Type:serum Sample ID: Bed No: Doctor: Diagnosis:

NO.	Item	Result	Note	Unit	Refvalue
1	AST	4.8		U/L	0--40
2	ALT	253.9	↑	U/L	0--41
3	ALB	8.0	↓	g/L	35--55

Report Date:2019-08-28 Submission Date:2019-08-28 14:31:04 Examiner:1000 Audit:

Results only for testing samples

Figure 8-13 Print sample result in the [Print] interface

Method two:

1.Select [User Setting] in the menu bar, and open the [Test Results Query] interface, as shown below:

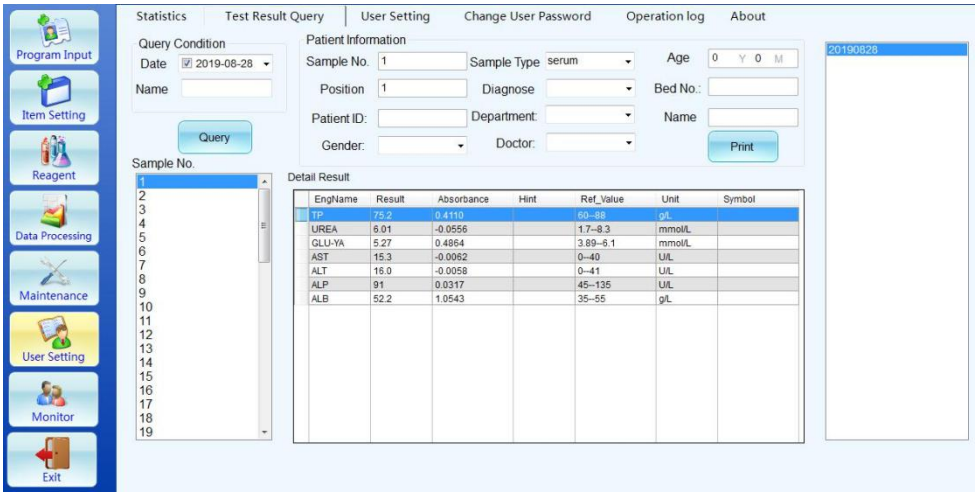


Figure 8-14 [Test Results Query] interface

2. According to the "Date" or “Name”, click [Query] to view the current test results and historical test results.

3. Click [Print] to complete the report printing.

8.5 Reagent report print

8.5.1 Introduction

The reagent reports are used to print the list of reagents, as well as the reagent position, reagent type, remaining, and calibration status.

8.5.2 List of reagent information

The reagent calibration list report can be printed through the reagent information interface.

1. Select [Reagent] - [Reagent Information]
2. Click [Print Position] to print the reagent information.

Reagent Information

Print Time:2019-11-15 16:46:46

Position	Item	Bottle Typ	Remaining	Available	Reagent Ty	Position	Item	Bottle Typ	Remaining	Available	Reagent Ty
1	5NT	50	50	150	1	29					
2	5NT	50	50	375	2	30					
3						31					
4						32					
5						33					
6						34					
7						35					
8						36					
9						37					
10						38					
11						39					
12						40					
13						41					
14						42					
15						43					
16						44					
17						45	5NT	20	20	150	2
18						46					
19						47					
20						48					
21						49					
22						50					
23						51					
24						52					
25						53					
26						54					
27						55					
28	Wash	50	50	150	5	56					

Figure 8-15 Reagent sheet

8.6 QC report print

8.6.1 Introduction

The QC reports are used to print data related to QC results, including QC test results, Levey-Jennings chart, Twin-Plot chart, QC data and QC data summary.

8.6.2 QC result

After the QC test is finished, you can print test result through the [Data Processing] interface.

1. Select [Data Processing] - [QC Result Query].
2. Query the QC result that needs to be printed.
3. Select the QC result.
4. Click [Print QC Chart] or [Print QC Report].

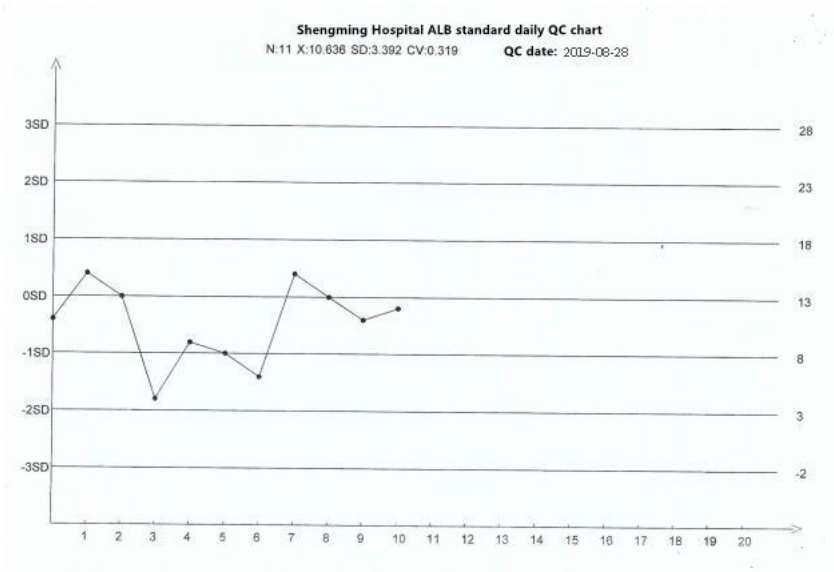


Figure 8-16 QC chart

Detailed Information 2019/8/28 14:31

QC time	QC batch	Items	QC value
2019-08-28	12	ALB	11
2019-08-28	12	ALB	15
2019-08-28	12	ALB	13
2019-08-28	12	ALB	4
2019-08-28	12	ALB	9
2019-08-28	12	ALB	8
2019-08-28	12	ALB	6
2019-08-28	12	ALB	15
2019-08-28	12	ALB	13
2019-08-28	12	ALB	11
2019-08-28	12	ALB	12

Figure 8-17 QC result report

9. User Setting

9.1 Statistics

For details on data statistics, see chapter 8.2.2.

9.2 Test result query

For details on test result query, see chapter 6.2.10.

9.3 User setting

Click the "User Setting", can add or delete the account, change user password. As shown in figure 9-1.

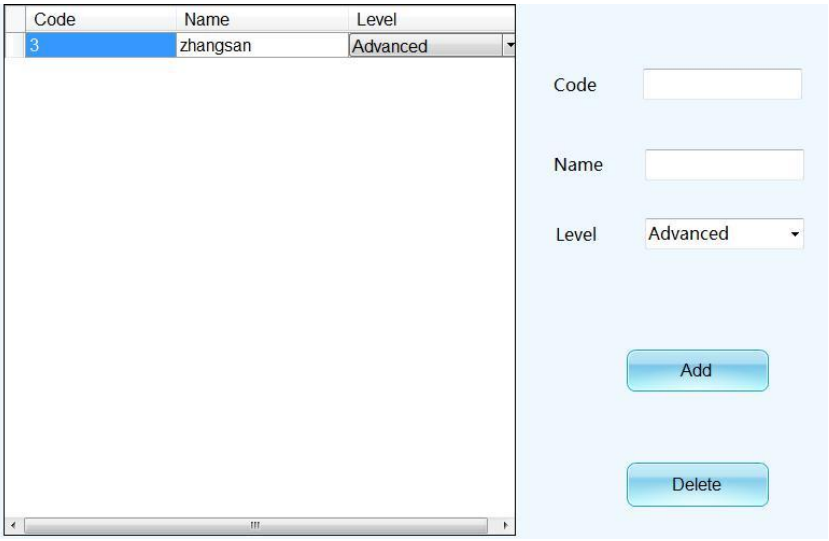


Figure 9-1 User setting

As shown in figure 9-1, in the user code, user name, respectively, enter the corresponding name, and select the user level, click "Add" to increase a system user.

If the advanced user login software, you can select a user left button, click "Delete" to delete the current user.

9.4 Change user password

9.4.1 User password

Under “User Setting” menu, click the "Change User Password", open the “user password”, and change the password of current user. As shown in figure 9-2.

Figure 9-2 Change user password

9.4.2 Item setting password

Under “User Setting” menu, click the "Change User Password", and then click “Item Setting password”, and change the password of item setting. As shown in figure 9-3.

Figure 9-3 Change item setting password

9.5 Operation log

9.5.1 Introduction

The operation log records all software operations of the analyzer, including “Login log”, “Operation log”, and “Maintenance log”. The user can query the operator, operation time and corresponding operation contents through the operation log, which is convenient for later maintenance and use of the instrument.

9.5.2 Login log

The login log shows the login and exit records of the operating software.

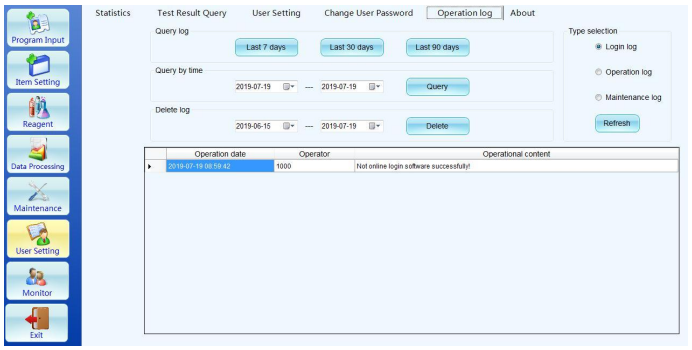


Figure 9-4 Login log

1. Select [User Setting] - [Operation Log].
2. Select the “Login log” in the “Type selection” list, and display related operation operations such as operation date, operator and operation content at the bottom of the page.
3. If you query the login log for a certain period of time, you can select the “Last 7 days”, “Last 30 days” and “Last 90 days” convenient queries in the “Query Log” list, or select a certain date in the “Query by time” list, and click [Query] to query the login log for the period of time.
4. If you need to delete the login log for a certain period of time, select a specific date in the “Delete Log” list, and click [Delete] to delete the login log for the period.

9.5.3 Operation log

The operation log shows the operation records of the analyzer and operating software.

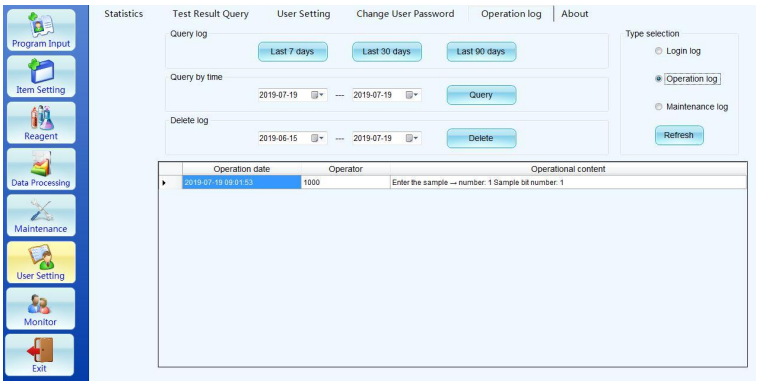


Figure 9-5 Operation log

1. Select [User Setting] - [Operation Log].
2. Select the “Operation log” in the “Type selection” list, and display the operation related to the operation date, operator and operation content at the bottom of the page.
3. For details on querying and deleting the operation log, refer to step 3-4 in "9.5.2 Login Log".

9.5.4 Maintenance log

The maintenance log shows the maintenance records of the analyzer.

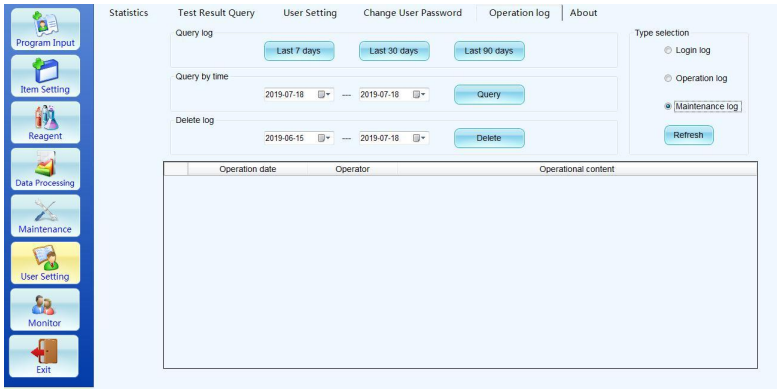


Figure 9-6 Maintenance log

1. Select [User Setting] - [Operation Log].
2. Select the “Maintenance log” in the “Type selection” list, and display the operation related to the operation date, operator and operation content at the bottom of the page.
3. For detailed operations on querying and deleting maintenance logs, refer to step 3-4 in "9.5.2 Logging log".

9.6 About

"About" is a software version of the introduction. Click [Get Version], the version number will be displayed. As shown in figure 9-7.

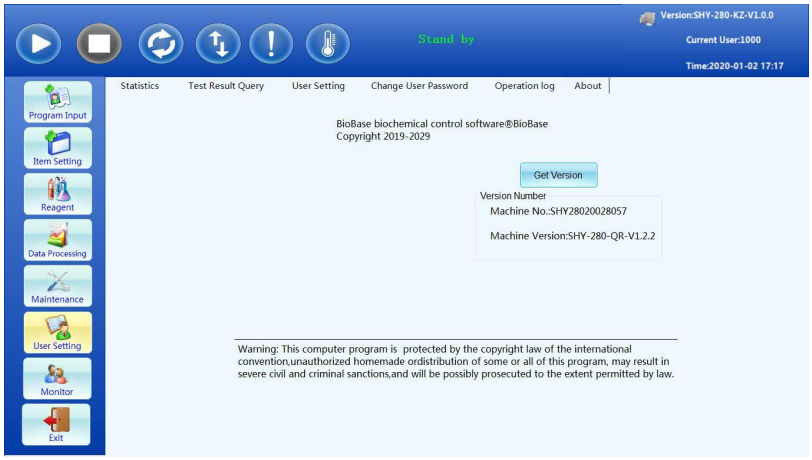


Figure 9-7 Software version

10. Maintenance

10.1 Prepare before system maintenance

To ensure the precision and accuracy of the auto chemistry analyzer, the operator must obey "Auto Chemistry Analyzer User Manual" for the operation and required maintenance. Thus the instrument will provide reliable results and ensure longer service life of the instrument.

10.1.1 Required tools

Before the system maintenance, please prepare below tools:

1. Tools in accessory box

Screw driver……...(Used to open instrument cover plate)

Needle(0.3mm/0.5mm)…..(Used for dredging R&S needle and cleaning needle)

Funnel…….....(Used for adding refrigerant fluid to the cooling system)

2. Users should prepare

Clean cotton cloth……(Clean for machine)

Cotton swab…….(Used to clean R&S needle, stirrer, cleaning needle)

Water tank (1unit)……(Used to store waste)

10.1.2 Purified water

In the daily operation and maintenance of the system, use deionized water, electrical conductivity is less than 1 μs/cm. When using pure water equipment, please do not forget the regular maintenance and inspection of water purification equipment. Please refer to the manual of the pure water device, or contact the manufacturer or distributor of the water purifier.

10.1.3 Cleaning fluid

Cleaning fluid is used for cleaning the equipment, should be provided by the company. If replaced by other cleaning fluid, may cause that cuvettes, needle, stirrer, cleaning needle and others are not clean, thus affecting the accuracy of test results and precision. The company is not responsible for inaccurate measurement of the equipment not use the company Cleaning fluid.

The designated position of the analyzer is the reagent position 28, for cleaning the cuvette.

10.2 Software maintenance

10.2.1 Initialization

Click the software Toolbar "initialization", the instrument automatically back to zero position. In the reset process, do not allow emergency stop. Other operations can be carried out after theinitialization is completed.

Attention:

When the instrument is powered into the standby state, each position is not in the zero position, and it is necessary to enter the software click initialization command to perform an initializationoperation to return to zero!

10.2.2 Instrument adjustment

Sheet10-1 Adjustment position

Component name	Cleaning position	Reaction position	Sample position	Reagent inner ring	Reagent outer ring

R&S arm	Cleaning position	1	1	1	29
Stirring arm	Cleaning position	105	#	#	#
Cleaning arm	Cleaning position	75	#	#	#

Attention:

1. Vertical cleaning position of the R&S needle: Thinner part of the needle should be completely in the cleaning cup. R&S needle vertical depth of cuvette: Point of needle is 30 steps distance to the bottom of the cuvette. Reagent position depth is 20 steps distance to the bottom of the reagent bottle. Sample position depth is 10 steps distance to the bottom of sample cup.
2. Cleaning position of the stirrer should be enough deep but not touch the bottom of the cleaning cup. Reaction position of stirrer should be 20 steps distance to the bottom of the cuvette.
3. Cleaning arm position adjustment should make sure all the needle except the one with dry unit, just reach the bottom of the cuvettes. The last needle should 2mm lower than other needles.

10.2.3 Optical system maintenance

10.2.3.1 Spot detection

To take away the cuvettes which block aperture in the reaction tray, use darker paper block the light source, the light spot formed on paper. The paper moves back and forth to see the brightest spot on the track cup campaign. Spot shape around a long 5mm, rectangular spot width of about 1.5mm, If there is a problem spot brightness, check halogen installation location is correct (This position is generally not adjusted).

10.2.3.2 One key gain calibration

One-key gain calibration enables automatic calibration of A/D readings, as follows:

In the "Maintenance" form, open the "Instrument check" interface, click the "Parameter Setting" button, enter the password in the password box: 00000000, you can jump to a key gain calibration interface, enter the target AD value of 58000, click "One Key Auto Gain" button, you can achieve automatic gain adjustment, as shown below:

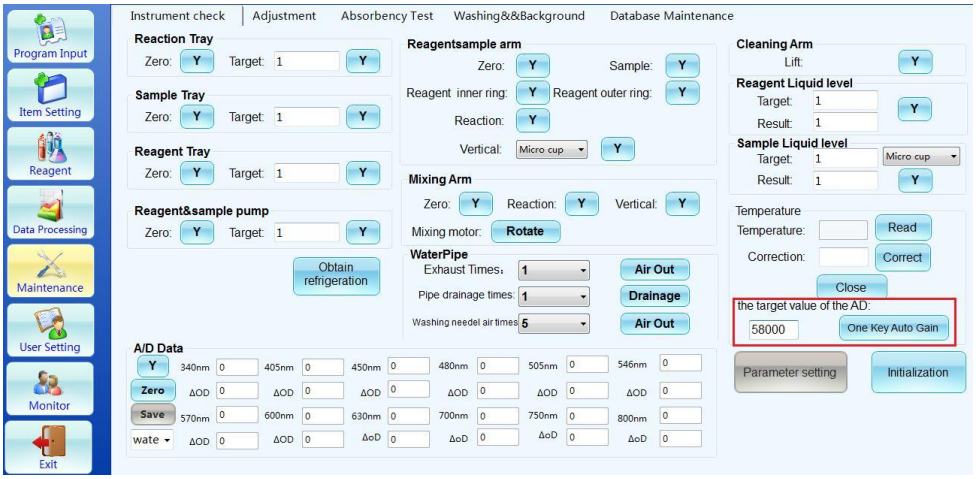


Figure 10-1 One key auto gain

Attention:

In order to the calibration results, please take out all cuvettes before one-key gain calibration.

10.2.3.3 AD stability adjustment

After adjust the AD board voltage. Click Software Toolbar "instrument check" button, enter "instrument check" interface. If the optical system △OD has larger changes,

Please adjust as follows:

(a) Check the lamp is uniform, spot size is suitable.

(b) 12V input voltage is stable, if separate power supply or not.

(c) Grounding line is good. requirements to external and internal ground only on a single-point ground power supply. External power supply on the ground must be connected.

10.2.3.4 AD absorbance test

In "Maintenance" menu bar, open the "Absorbance Test" interface. As shown in figure 10-2.

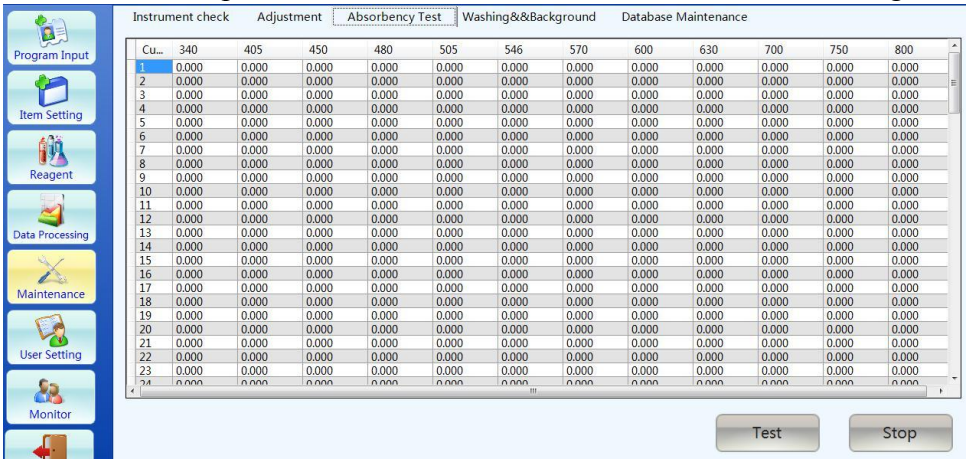


Figure 10-2 AD absorbance test

In the "Absorbance Test" interface, click "Test" button, the reaction tray rotates two circles, read the absorbance of each cuvette. Finished reading, corresponding absorbance value with cuvette number display in the interface. Pull the scroll bar to read the absorbance value with all cuvettes.

10.2.4 Thermostat system

Adopt direct air heating incubation, 37 (±0.2) ℃ maintenance free. No need extra maintenance fees for incubation system.

10.2.5 Water system maintenance

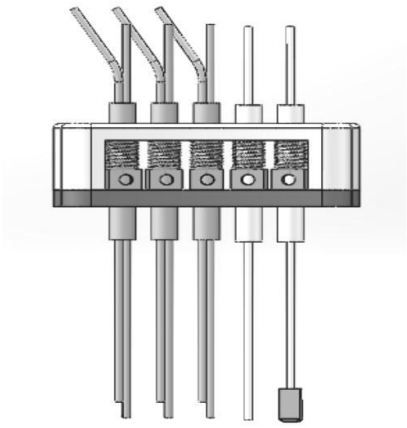


Figure 10-3 Cleaning needle

As shown in figure 10-3, cleaning arm cleaning needle includes three injection pipe and five suction pipe, 3 injection pipe corresponding solenoid valve V6, V5, V4, 5 suction pipe respectively miniature diaphragm pump P7, P6, P5, P4, P3. Miniature diaphragm pump P2 connect dispensing piston arm. Miniature diaphragm pumps P1 connect cleaning needle injection pipe, R&S needle cleaning cup and stirrer cleaning cup.

L frame has four waterways adapter, two small linker are water inlet. The installation of water pipes should be as short as possible, and install water fall head. Ensure the machine waterway is normal.

Attention:

When installation of water pipes make sure the smooth flow of waste water outlet.

Each cleaning needle connected with a corresponding waterway through a polyethylene tube.

When added head or pumping head is abnormal, sequentially check the pipe joints are connected, solenoid valves and micro diaphragm pump.

10.3 Check before test

10.3.1 Power on checking

When finished the installation of all parts and water system, please power on the machine and check the conditions:

(1) Moving conditions of reaction tray, R&S tray.

(2) Moving conditions of mechanical arms left&right, and up&down.

(3) Working conditions of syringe pump, solenoid vale and diaphragm pump.

(4) R&S tray cooling condition, and if there is any leakage of refrigerant fluid.

As below figure 10-4 shows, power supply port and Network interface.

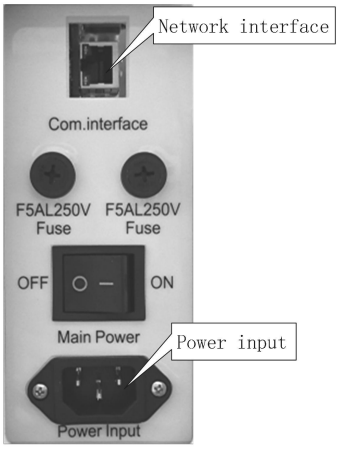


Figure 10-4 Instrument power supply port

10.3.2 Purified water, waste water and cooling alarm checking

If instrument is alarming when power on, please follow the alarm indicator and check if waste water is full, less purified water or less refrigerant fluid. Change waste container, add refrigerant fluid or adding purified water.

10.3.3 Water pipe exhaust

1.Water pipe exhaust

Enter software, click Maintenance, and then click Instrument check button, find "Water Pipe", and choose the times of "Number of exhausts", and then click Air Out. The piston of the pump is pulled up and down again, then the air in the plunger pump and the pipeline is excluded. The operation is shown in Figure 10-5 a). During the air out procedure, do not suddenly stop. Execute other movements when it finished.

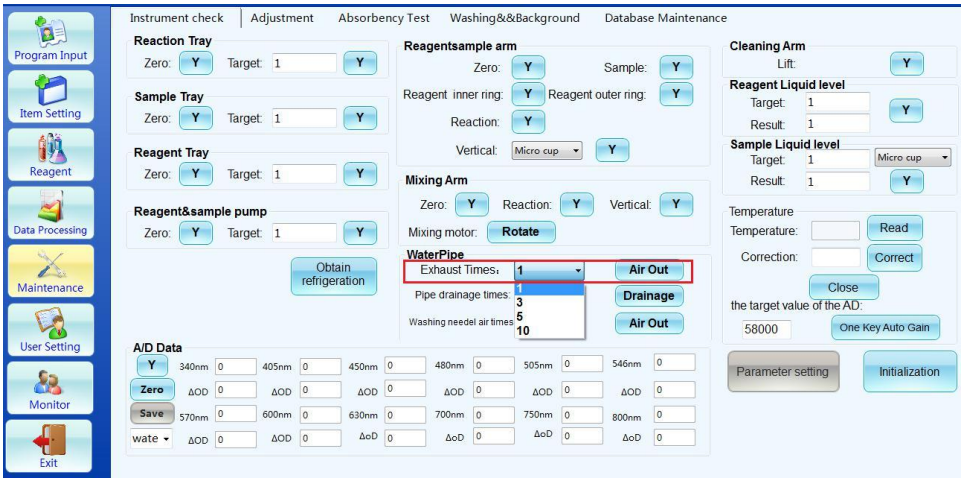
2.Pipe drainage

If the analyzer needs to be left unused for more than one week or longer, please perform the pipe drainage function. Enter software, click Maintenance, and then click Instrument check button, find "Water Pipe", and choose the times of pipe drainage, and then click drain. The water in the water tank will be drained. If it is found that it is not empty, please perform the drainage operation again. The operation is shown in Figure 10-5 b).

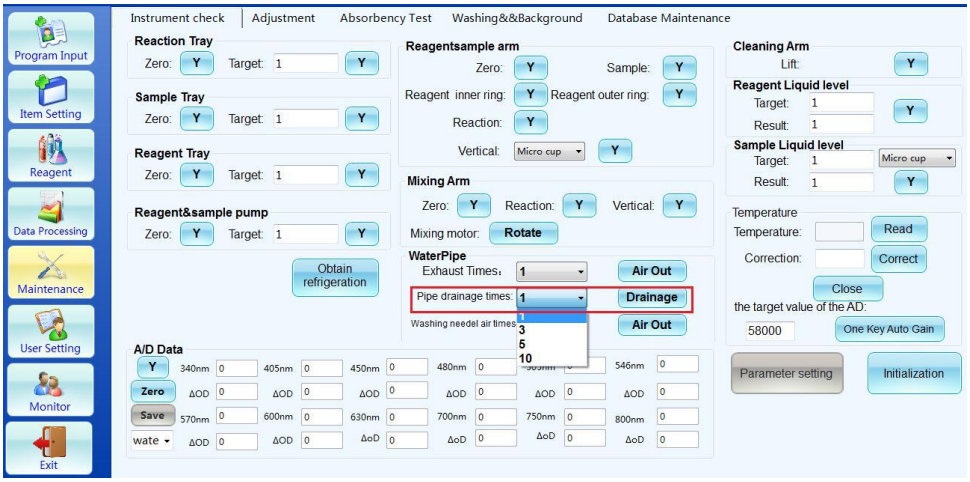
3.Washing needle exhaust

Enter software, click Maintenance, and then click Instrument check button, find "Water Pipe", select washing needle air times and click Air Out. Perform cleaning reaction cup operation, washing needle pipe exhaust. The operation is shown in Figure 10-5 c).

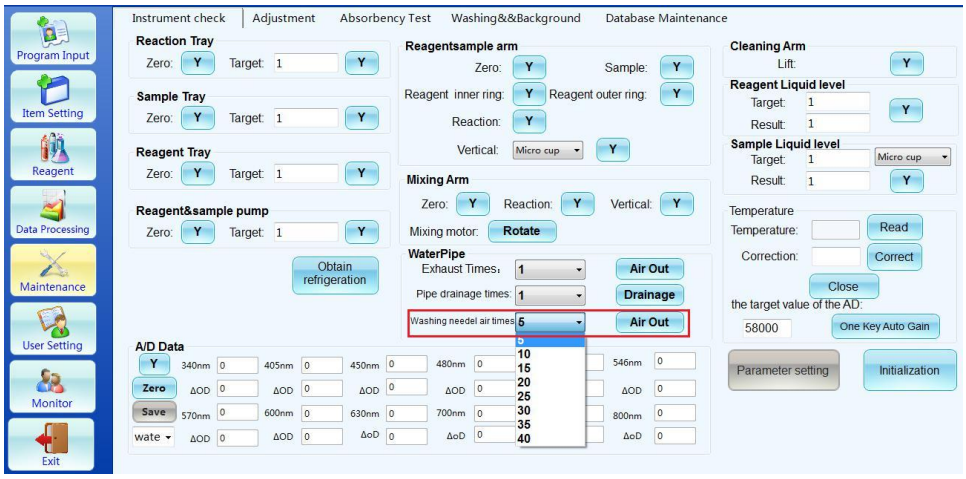
During the air out procedure, do not suddenly stop. Execute other movements when it finished.



a)



b)



c)

Figure 10-6 Water Pipe

Attention:

After replacing the plunger pump and the water line, or before the instrument is used for a long time, please refer to the first boot to start the water pipe exhaust function.

10.4 Software maintenance

10.4.1 Closed software can not be opened

If the auto chemistry analyzer appears below interface figure 10-6, please use below "Repair Tool" in the "bin" folder. The "Repair Tool" icon is shown as figure 10-7.

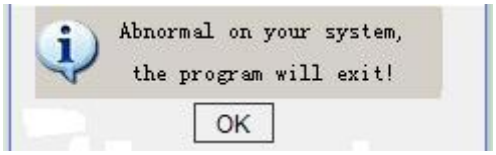


Figure10-6 Error alarm

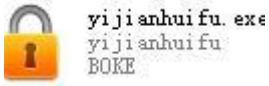


Figure10-7 Repair tool

Operation procedure as below: Double click the repair tool, appear figure 10-8 operation interface, chose "OK" button, appears figure 10-9 interface. Click confirm to complete the repair. When finish repairing, will indicate that the repair is completed, please re login the software.

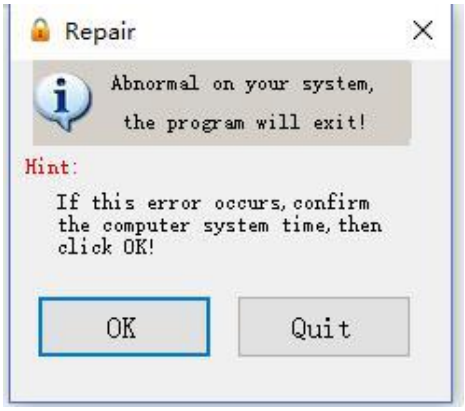


Figure 10-8 Repair

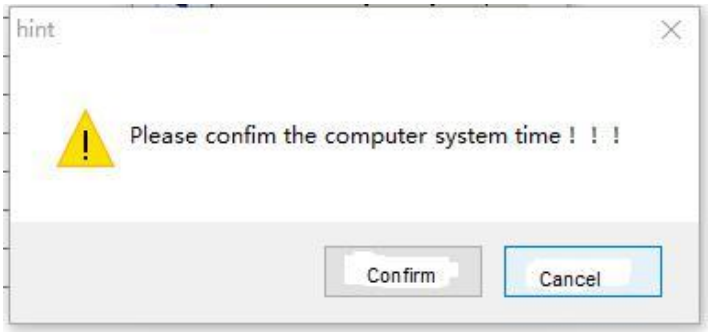


Figure 10-9 Confirm to modify

10.4.2 Mismatching of the software and the machine

Click login button, appears below interface, software and instrument not match.

Please click cancel to close the interface.

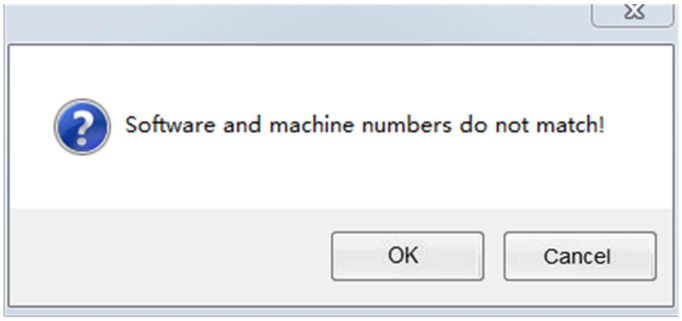


Figure 10-10 Software and instrument not match

Click "login" button and at the same time press the "Ctrl" button. Enter software operation interface. Click "Ctrl + Alt + R", then click "OK" as figure 10-11 shows and click "exit" button to exist the software.

Click login again. Appears figure 10-12 interface. Click software configuration, appears figure 10-13 interface, that means the software configuration is successful.

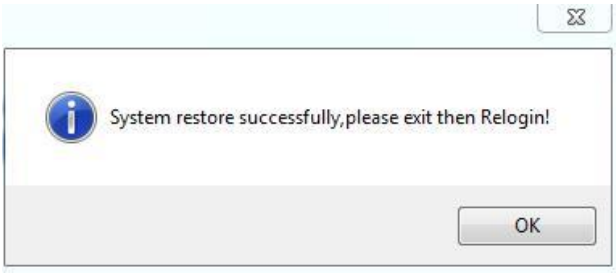


Figure 10-11 System restore

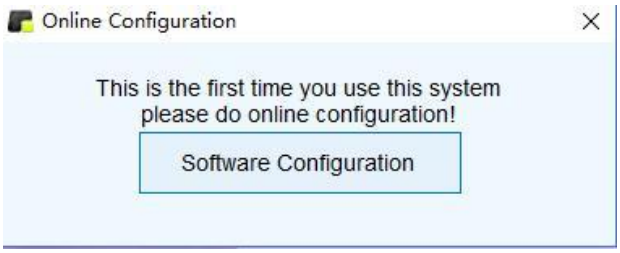


Figure 10-12 Online configuration

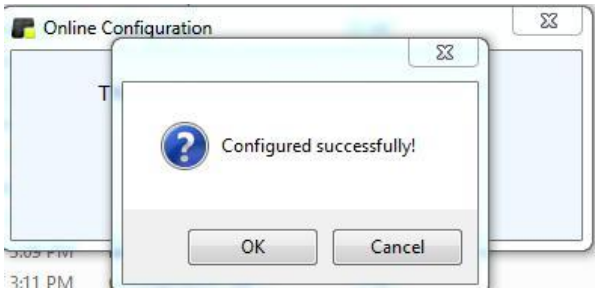


Figure 10-13 Configuration successfully

If not appear configuration successfully. Please release the compressed software in the software CD. If still appears "No connection, please check the communication line", please check the hardware connection. If it's OK, please check the communication chip.

Attention:

One computer can only control one biochemistry analyzer, if move the Software to other computers, please contact our engineer.

10.4.3 Other problems

Bar code scan problem:

Some computer may no identify the scanner. For example, when you open the txt bar code file and scan, the scanner only give alarm, but can't scan any bar code. Please change another bar code scanner that can match the computer.

10.5 Equipment maintenance

10.5.1 Regular clean, inspection and replace parts

Regular clean, check and replace part, please see sheet 10-2 (Supposed using the instrument 5 hours per day):

(○: Regular clean, inspection ●: Regular replace, adding)

Sheet 10-2 Regular replacement of accessories

No	Items	Needs for one time	Yearly consumption	Period						
				Daily	Timely	Weekly	Monthly	Every 3 months	Every 6 months	Yearly
1	Sample cup				●					
2	R&S needle			○						
3	Cleaning cups of R&S needle and stirrer						○			
4 (Note a)	Cuvettes (20 units/group)	6 groups	24 groups	○				●		
5	Reaction tray and heating						○			
6	Halogen lamp	1	2						●	
7	Cleaning needle			○						
8	Stirrer			○						
9	Dispensing pump				●					
10	Water supply filter net						○			
11	Reagent tray cooling system						○			
12	Cooling fan							○		
13	Purified water system			○	●					
14	Waste water exhaust				○					

Note:

(a) Number in the sheet is maximum.

(b) Halogen lamp life is 2000 hours. To ensure the accuracy and precision, suggest replace the lamp after using for 1500 hours.

(c) Instrument is suitable for wire printers, inkjet printers, and laser printers, the user according to the printer select printer supplies.

(d) Execute save the blank weekly. Otherwise will indicate cell blank abnormal alarm.

(e) If conductivity of purified water is more than 1μs/cm, please replace water purifier consumables.

10.5.2 Users regular replacement accessories sheet

Please prepare below accessories, in case any faults need replacement, please check sheet 10-3:

Sheet 10-3 Regular accessories sheet

No.	Accessories Name	Remarks	Suggest Stock quantity /Year
1	Halogen Lamp	12V 20W	1
2	Cuvettes	(20 units/group×6 group)	12 group
3	TPU tube	3.2mm×6.4mm	5m
4	Water supply filter net, water supply filter holder	Used for water tube	1
5	R&S needle	Dispensing reagent and sample	1
6	Stirrer	Used for mixing	1
7	Cleaning needle	Clean the cuvettes	1

10.5.3 Maintenance procedure

Attention:

●Do not drop water, reagent or cleaning fluid to any mechanical or electrical parts, avoid damage to the instrument.

●When operating, do not touch R&S needle, stirrer and cleaning needle. Avoid the risk of infection or injury.

●During operation, should take preventive measures, with protective gloves, wear work clothes. Otherwise, it is possible to contact contaminated areas, contaminated fluid and infected, or contact with corrosive liquids and damage the skin. If there is contamination or corrosive liquid accidentally touching the body, please immediately washing by water and disinfection.

10.5.3.1 R&S needle maintenance

If internal and external of the needle is polluted, it is easy to attach serum, reagent and water drops, also easy to cause the blockage of the syringe tube inside, thus affecting the instrument test results. Therefore, it is necessary to regularly check and timely cleaning.

1.Clean R&S needle outside

(a) Close the total power switch of the instrument.

(b) Scrub the outer wall with cotton swab dipped in alcohol (During the process of cleaning, do not bend the needle). As shown in figure 10-18.

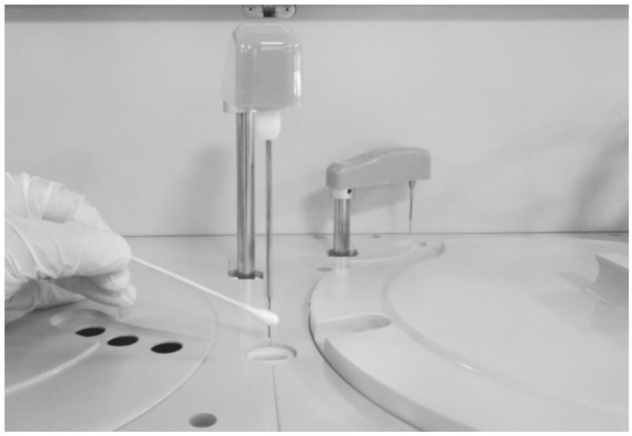


Figure 10-18 Clean R&S needle outside

(c) After start up again, R&S needle automatically return to the position of the reset.

2.R&S needle jam clean up

When the instrument needle blocking, or needles out of flow discontinuity and not vertical, dripping water, should cleaning the blocked needle.

(a) Close the total power switch of the instrument.

(b) Remove the R&S tray cover, revolve the R&S needle by hand under the arm, make it moved to the above R&S tray. As shown in figure 10-19.

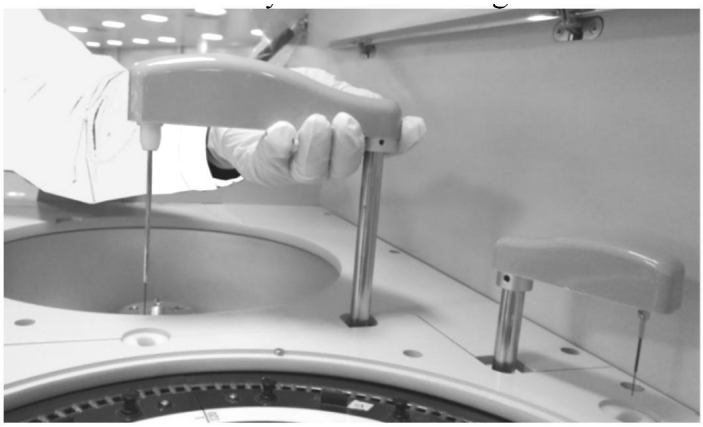


Figure 10-19 Remove cover

Warning:

Do not hold R&S needle cap top with hands to revolve the needle.

Faulty operation as shown in figure 10-20.

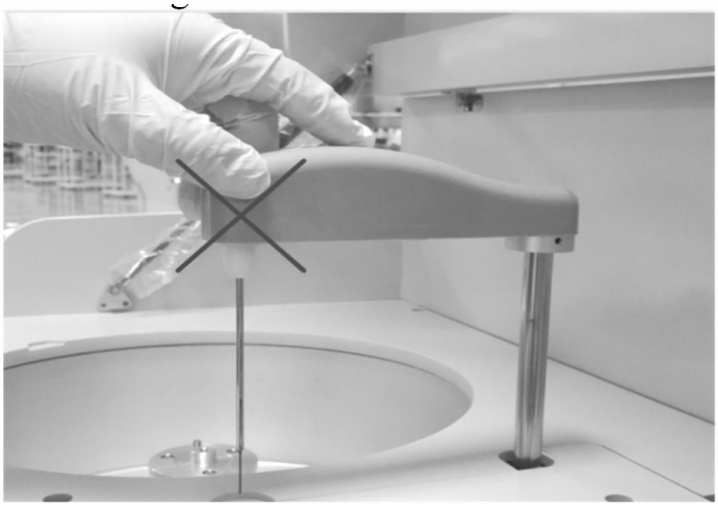


Figure 10-20 Remove cover

(c) Gently holding needle cap with one hand, move the cap to one side, then loose on the other side, can take down the needle cap after lift, as shown in figure 10-21.

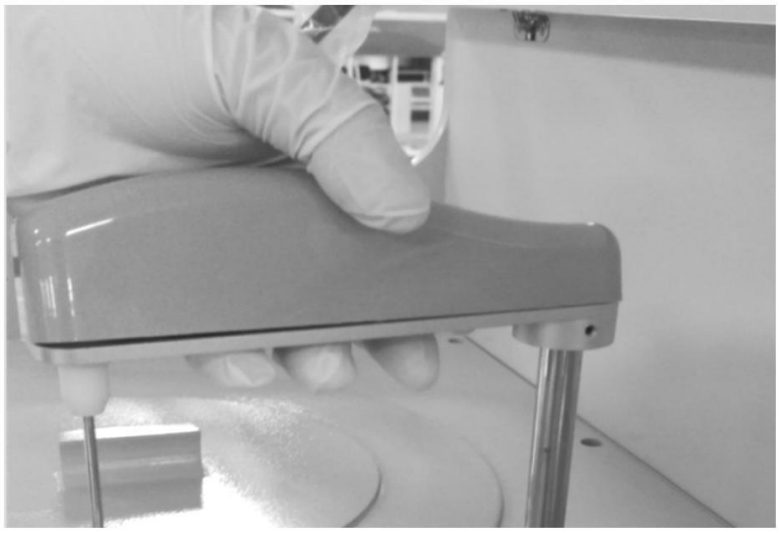


Figure 10-21 Remove cap

(d) Clipping the fixed cable tie of liquid level signal lines by diagonal pliers, as shown in figure 10-22.

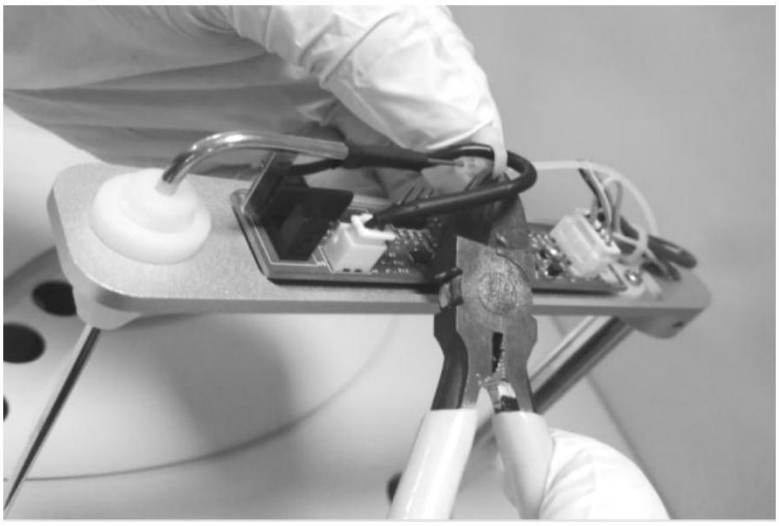


Figure 10-22 Clipping fixed cable

(e) Remove the liquid level signal lines, need to hold cross arm from below with one hand, hold 2 p terminal with other hand, remove the liquid level signal lines. Note, cannot pull liquid level signal lines, to prevent the terminal loss, as shown in figure 10 -23.

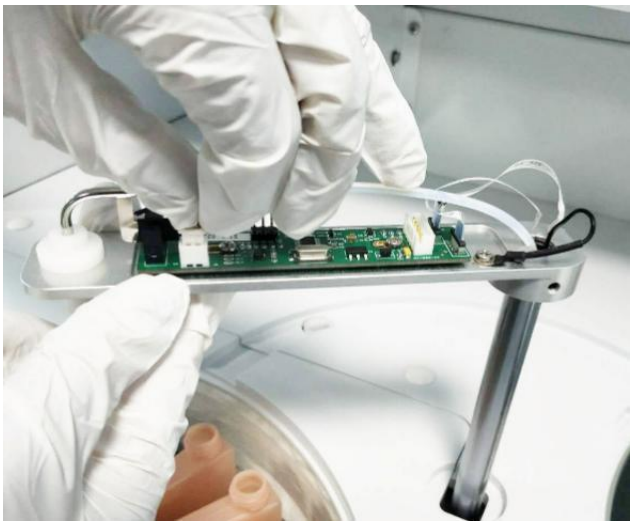


Figure 10-23 Remove liquid signal line

(f) Stack up absorbent cotton pad on the liquid level board, prevent water droplets on the liquid level board when remove hoses, as shown in figure 10-24.

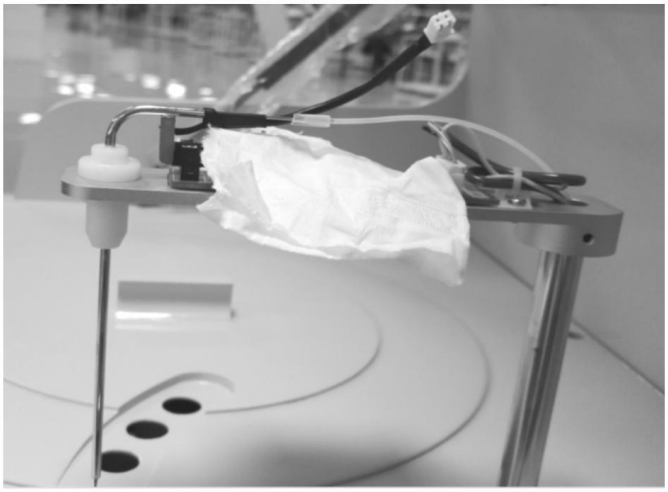


Figure 10-24 Put cotton

(g) Unplug the pipeline of one side of the R&S needle. As shown in figure 10-25.

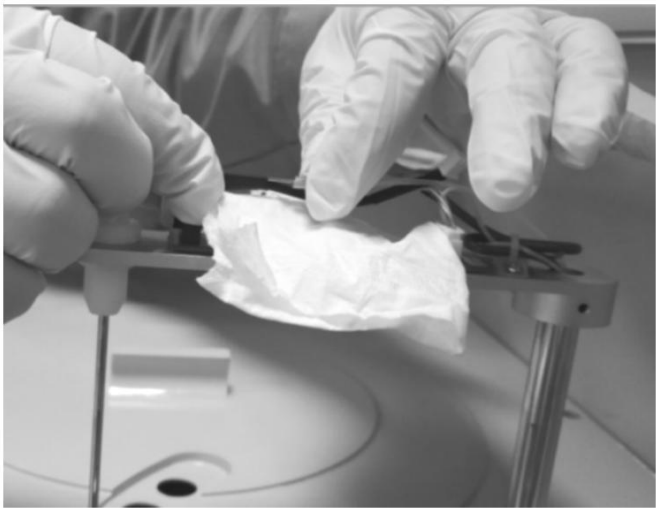


Figure 10-25 Unplug the pipeline

(h) Counterclockwise unscrewing the needle fixed on the nut, remove the needles.

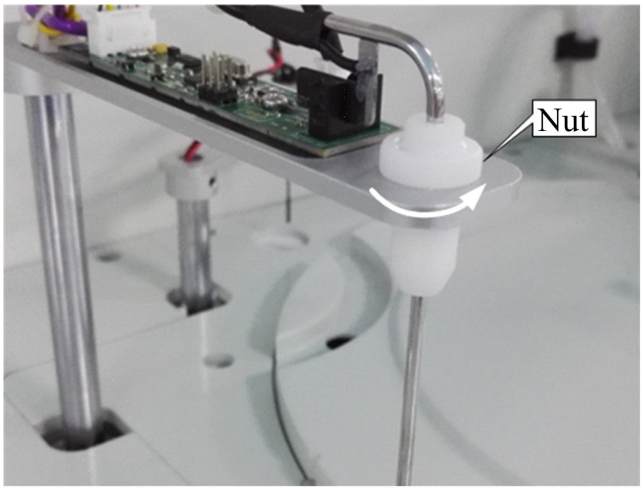


Figure 10-26 Loosen nut

(i) Put the needle into the needle to clean up from the bottom of the needle. As shown in figure 10-27.

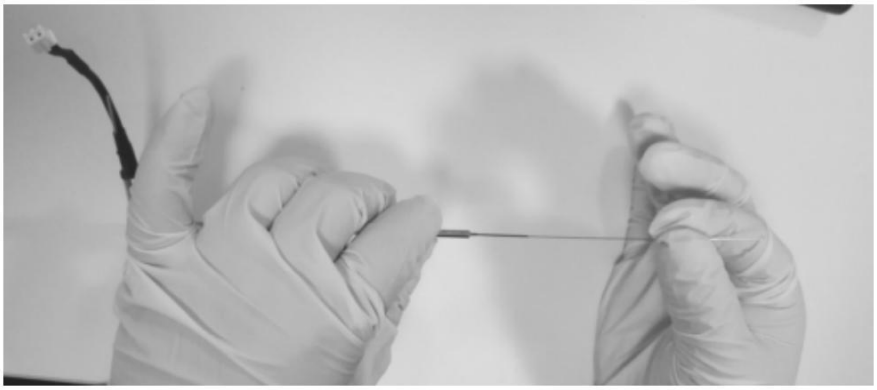


Figure 10-27 Clean R&S needle

(j) After clean up the needle with needle, extract 10ml of pure water by injection syringe. Put the pure water in the syringe injection needle from the upper, water flows from needlepoint place, all 10ml of water discharge, and the water flow unhindered, as shown in figure 10-28.

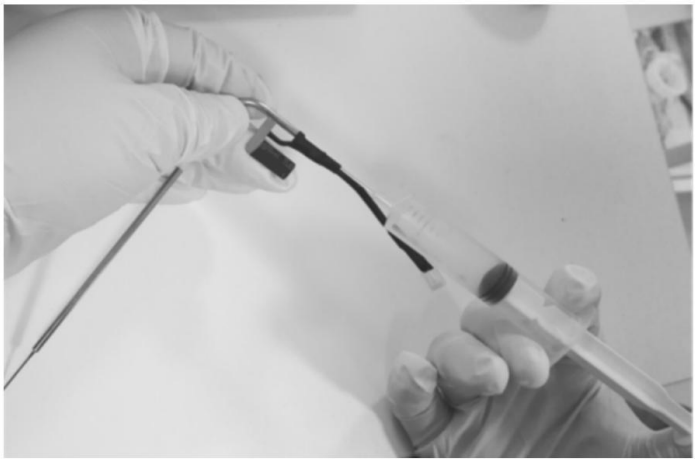


Figure 10-28 Water injection

(k) Install the needle on the cross arm in the reverse order, and installed water pipe, line, etc.

3.R&S needle position adjustment and confirmation

(a) Open the instrument of the total power switch.

(b) Click the menu bar of the "maintenance", open the instrument detection window, in the test project list to find R&S arm. As shown in figure 10-29.

Figure 10-29 R&S arm

(c) A check of R&S needle horizontal position: Click on the sample position "Y", R&S needle turn left, when the R&S needle stop at the upward side of sample position of R&S tray, check whether the pinpoint of R&S needle is in the center of the sample cup, as shown in figure 10-30, then click the zero position "Y", R&S needle is placed back to the initial position.

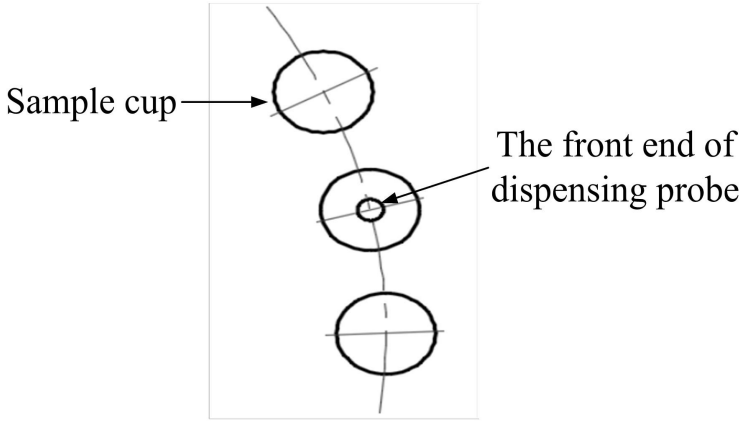


Figure 10-30 Check position

Attention:

If the sample with the tip of the needle is not in the center of the sample cup, please contact maintenance personnel.

(d) Reagent inner ring level examination: Click the reagent inner ring "Y", R&S needle turn left, when the R&S needle stop at the upward side of reagent inner ring of R&S tray, check whether the pinpoint of R&S needle is in the center of the reagentposition of reagent inner ring, then click the zero position "Y", R&S needle is placed back to the initial position.

Attention:

If the sample with the tip of the needle is not in the center of the reagent bottle of reagent inner ring, please contact maintenance personnel.

(e) Reagent outer level examination: Click the reagent outer ring "Y", R&S needle turn left, when the R&S needle stop at the upward side of reagent outer ring of R&S tray, check whether the pinpoint of

R&S needle is in the center of the reagent position of reagent outer ring, then click the zero position "Y", R&S needle is placed back to the initial position.

Attention:

If the sample with the tip of the needle is not in the center of the reagent bottle of reagent outer ring, please contact maintenance personnel.

(f) Cuvette level examination: Click the cuvette position "Y", R&S needle turn right, when the R&S needle stop at the upward side of cuvette of the reaction tray, check whether the sample with the tip of the needle is in the center of the cuvette, as shown in figure 10-31, then click the zero position "Y", R&S needle is placed back to the initial position.

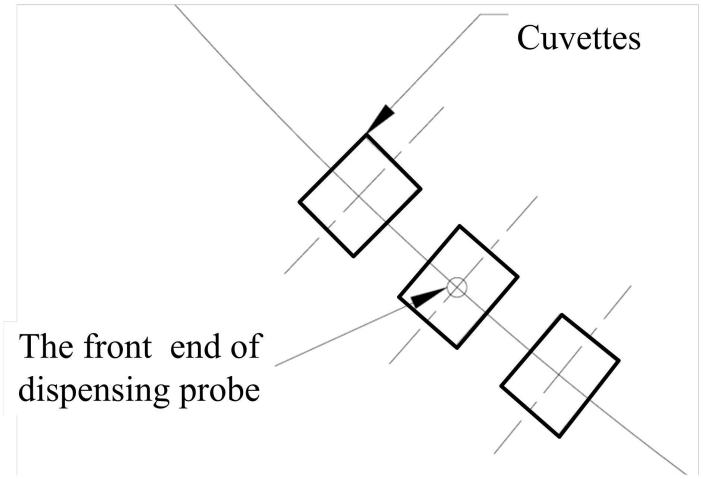


Figure 10-31 Check position

Attention:

If the sample with the tip of the needle is not in the center of the cuvette, please contact maintenance personnel.

(g) Sample vertical position examination: Click the sample position "Y", R&S needle turn left and stop at the top of the sample position, click the vertical position "Y", the R&S needle will continue to drop until the needle tip touches the bottom of the sample cup, then click the vertical position "Y", the needle is lifted above the sample position, then click the zero position "Y", R&S needle turn right and placed back to the initial position.

(h) Reagent inner ring vertical position examination: Click the reagent inner ring "Y", R&S needle turn left and stop at the top of the reagent inner ring, click the vertical position "Y", the R&S needle will continue to drop until the needle tip touches the bottom of the reagent cup, then click the vertical position "Y", the needle is lifted above the reagent inner ring, then click the zero position "Y", R&S needle turn right and placed back to the initial position.

(i) Reagent outer ring vertical position examination: Click the reagent outer ring "Y", R&S needle turn left and stop at the top of the reagent outer ring, click the vertical position "Y", the R&S needle will continue to drop until the needle tip touches the bottom of the reagent cup, then click the vertical position "Y", the needle is lifted above the reagent outer ring, then click the zero position "Y", R&S needle turn right and placed back to the initial position.

(j) Cuvette vertical position examination: Click the cuvette position "Y", R&S needle turn right and stop at the top of the cuvette, click the vertical position "Y", the R&S needle will go down, put the part of the needle which coated with Teflon into the cuvette, then click the vertical position "Y", the needle is lifted above the cuvette, then click the zero position "Y", R&S needle turn left and placed back to the initial position.

4.Clean up the cleaning cup

Long time without cleaning cup will produce the dirt on the inner wall of the cleaning cup, and there will be lots of bacteria growing and breeding, under normal circumstances can be clean once a month. If the instrument is in use process found dirt, should be cleaned up in time.

(a) If the cleaning cup is contaminated, wipe it with a swab dipped in an alkaline cleaning fluid. As shown in figure 10-32.

Figure 10-32 Clean the cleaning cup

(b) Then, about 100mL of pure water was poured into each of the cleaning cup to be washed.

10.5.3.2 Reaction tray maintenance

If the cuvette or thermostat is contaminated, may result in inaccurate test results. In addition, the cuvette will occur for a long time aging, so the cuvette should be cleaned regularly, and check the cuvette absorbance, when the absorbance value is abnormal, the cuvette should be replaced in time.

Warning:

Non-professional maintenance personnel, prohibit the demolition reaction tray gland film, reaction tray gland and cuvette positioning tray, otherwise it will affect the light path, the cuvette positioning.

1. Cleaning cuvette

It is recommended that the user perform a cleaning cuvette function every day to avoid contamination of the cuvette and affect the test results, the operation should be carried out at the end of each day after the 120 cuvettes cleaning, the specific operation is as follows.

(a) Add the cleaning fluid to the reagent position: The cleaning fluid C placed in the reagent bit 28 as figure 10-33.

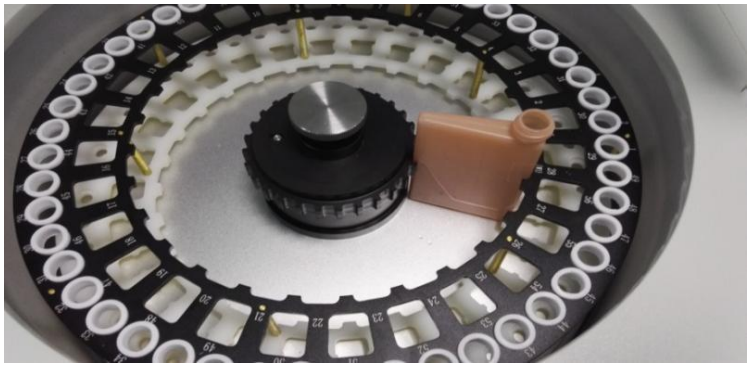


Figure 10-33 Cleaning fluid

(b) Add the cleaning fluid to the cuvette: In the "Maintenance" form, click the "clean background", then click the "cleaning fluid" on the right side to select the need to wash the cuvettes range (E.g. 1-120). Click "OK", the instrument begin to add cleaning fluid, the software interface is as follows figure 10-34.

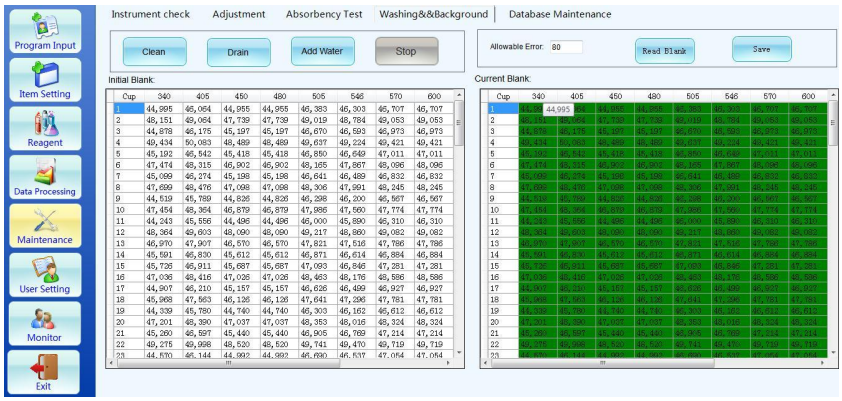


Figure 10-34 Software interface

(c) Soak for 5 minutes.

(d) Wash the cuvette, in the "Maintenance" form, click "Cleaning", select the right side of the need to wash the cupping range (E.g 1-120). Click "OK", the instrument begins to clean, the software operation interface is as follows figure 10-35.

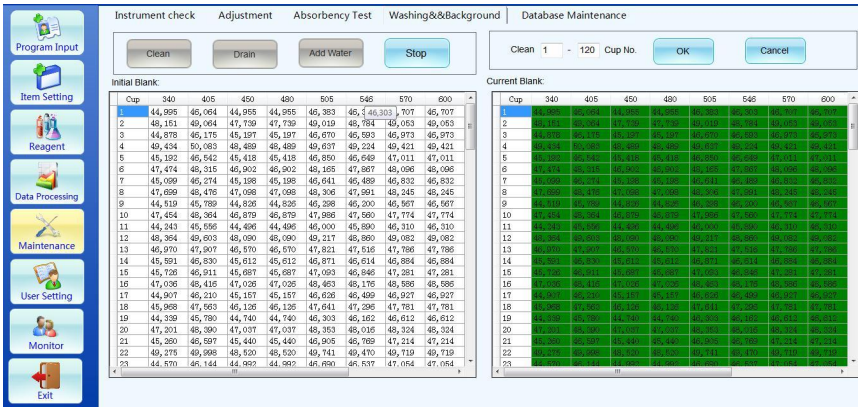


Figure 10-35 Cleaning interface

2. Confirmation of cuvette status

During the sample test, click on the menu bar 

, can realize real-time monitoring of the reaction state of the instrument, if the dirty cup is detected during the test, the instrument will

automatically skip the dirty cup and use the next cup. In the monitoring, the cup will show red, as shown in figure 10-36.

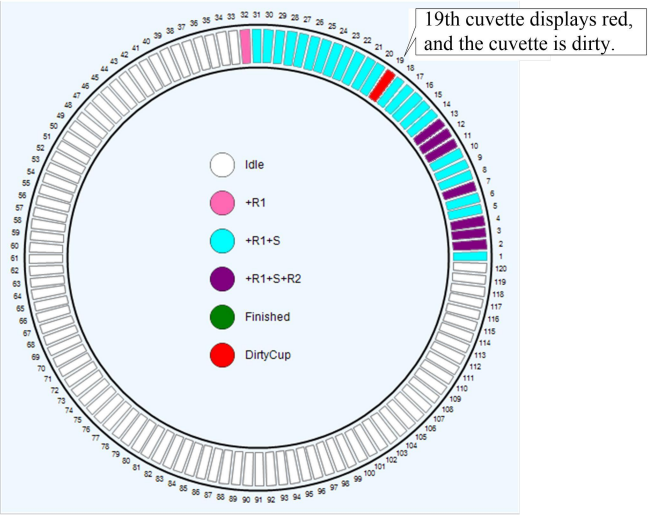


Figure 10-36 Reaction tray monitor

3. Replace the cuvette

When there are too many dirty cup, test speed will be affected. If in the software 

shows the number of dirty cups is more than 1/3 of reaction tray, please replace new cuvette. Operations are as follows:

(a) Turn off the instrument main power switch, remove the reaction tray.

(b) Wear protective gloves and unscrew the cuvette pins, as shown in figure 10-37.

Figure 10-37 Replace cuvettes

(c) Remove the six groups cuvettes, as shown in figure 10-38.

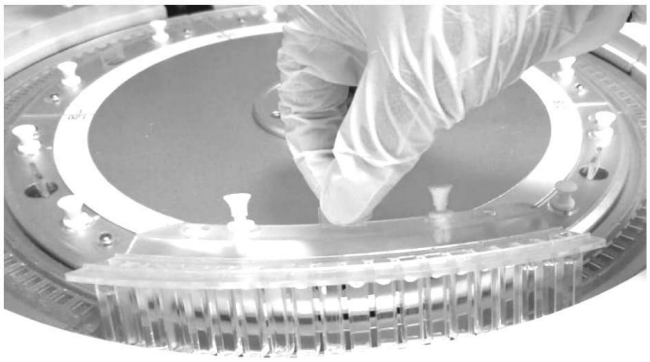


Figure 10-38 Replace cuvettes

(d) Install the six new cuvettes in the reverse order onto the reaction tray.
(e) Turn on the instrument's power switch.
(f) Perform the "Washing&&Background" in the "Maintenance" form and use the cleaning fluid to clean the cuvette before testing.

Attention 1:

If the used cuvette is exposed to air for long period of time, contaminants may build up on the cup wall. So should be promptly covered with reaction tray cover. In addition, if the emergency stop during the test, should clean cuvettes which not be cleaned or rinse them with pure water to avoid the reaction fluid remain in the cuvette for a long time.

Attention 2:

Forbid to use organic solvents (benzene, alcohol, etc.) scrub or soak the cuvette.
4.Clean the reaction tank
After long-term use of the reaction tan, it should be promptly cleaned to prevent dust and other effects of test results. In addition, please wipe timely, especially when water flows into, to prevent contamination of the cuvette and lighting path, affecting the test results.
Reaction tank cleaning method:
(a) Turn off the instrument main power switch, remove the reaction tray cover.
(b) Wear protective gloves and remove the cuvette, as shown in figure 10-37.
(c) Remove the six groups of cuvettes, placed in pure water or clean place, as shown in figure 10-38.
(d) Wipe the reaction tank with a clean and wet gauze (not to wipe the photometric window), as shown in figure 10-39.

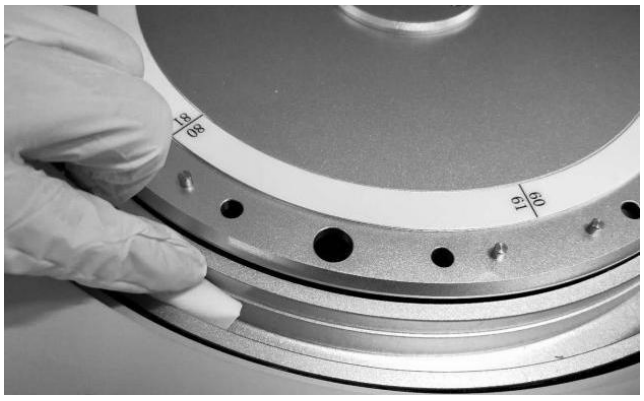
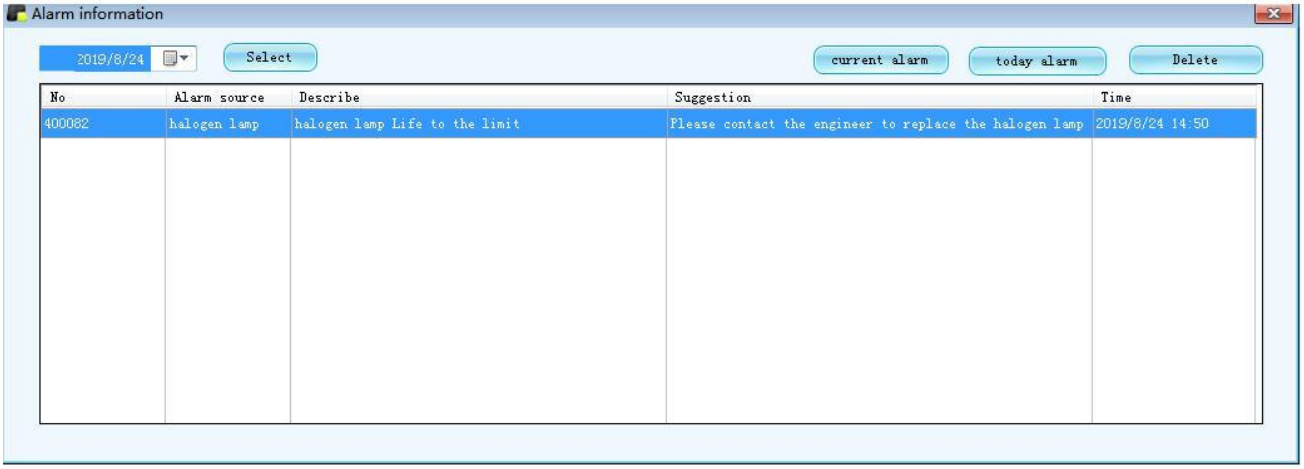


Figure 10-39 Wipe reaction tray

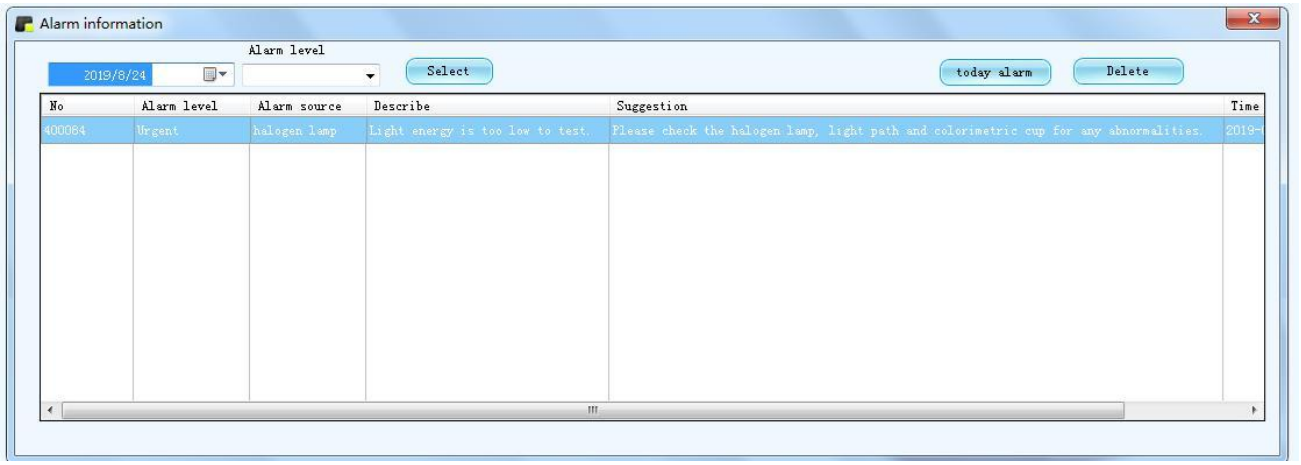
(e) After cleaning the reaction tank, install the cuvette and cover the reaction tray cover.
10.5.3.3 Lamp maintenance
If light source lamp aging, light energy will deviate from the light measurement range.
During the sample test, it won't test correctly because of interfere.
In the [Instrument Check] interface for non-blocking AD readings test, if less than 58000, should replace the halogen lamp.

When the halogen lamp reaches the end of its service life, and entering the main interface of the software, click the red alarm button, and the alarm message “Halogen lamp life to limit” will be displayed. As shown in figure 10-40 a). The halogen lamp should be replaced.

When the halogen light value is low, and entering the main interface of the software, click the red alarm button, and the alarm message “The light energy is low, can't be tested” will be displayed. As shown in figure 10-40 b). The halogen lamp should be replaced.



a)



b)

Figure 10-40 The alarm message of halogen lamp

To replace the halogen lamp, proceed as follows:

(a) Prepare one new halogen lamps, as shown in figure 10-41:

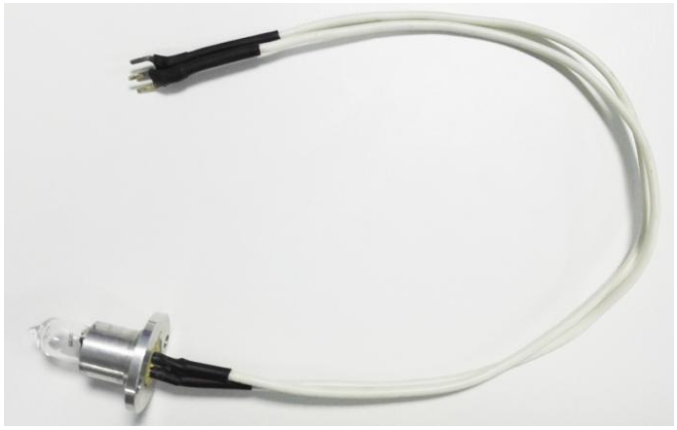


Figure 10-41 Halogen lamp

Attention:

Do not touch the surface of the halogen lamp, otherwise the amount of light will be affected. If you find fingerprints and other stains on the surface, you can wipe with alcohol gauze.

(b) Turn off the instrument's main power switch, and after about 30 minutes (wait the lamp compartment to cool completely), perform the next operation to avoid burns.

(c) Remove the 5 plugs on the rear panel and unscrew the 5 screws with a phillips screwdriver. Operation as shown in figure 10-42.

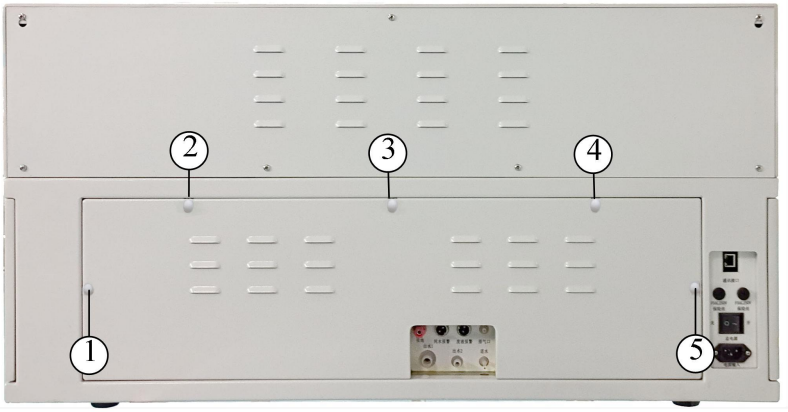


Figure 10-42 Rear panel

(d) Remove the rear plate, as shown in figure 10-43.

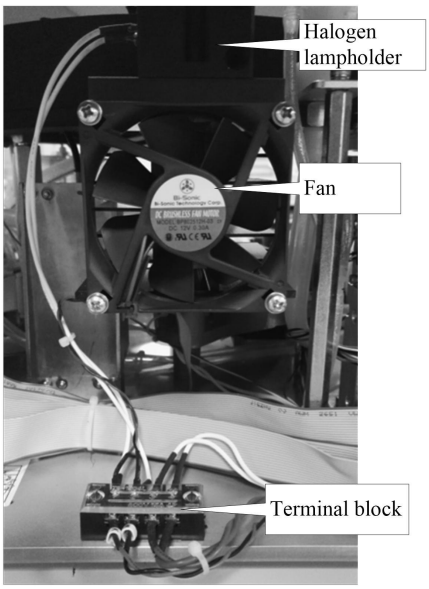


Figure 10-43 Remove the rear plate

(e) Remove the protective cover from the terminal block. Use a Phillips screwdriver to unscrew the two fixing posts of the halogen lamp lead. Remove the white silicone leads and cut the two tie strips with a slanting mouth to facilitate replacement of the halogen lamp. As shown in figure 10-44.

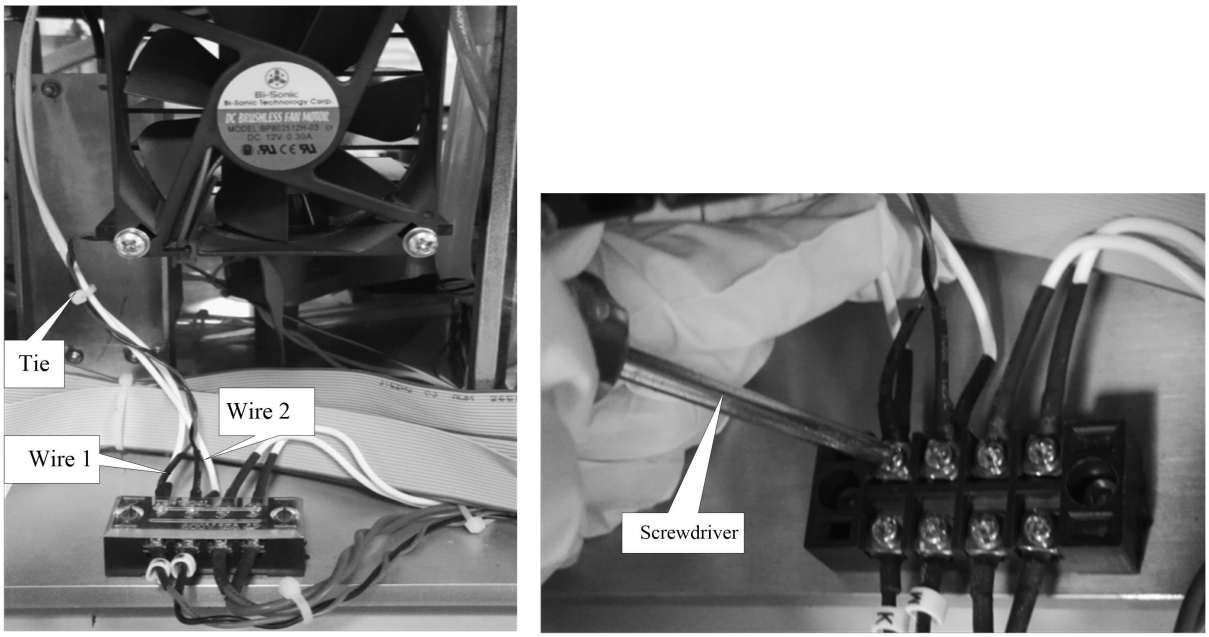


Figure 10-44 Replace halogen lamp

(f) Unscrew the two fixing screws on the light source holder (located above the rear fan), remove the halogen lamp holder screw, and remove the halogen lamp as shown in figure 10-45.

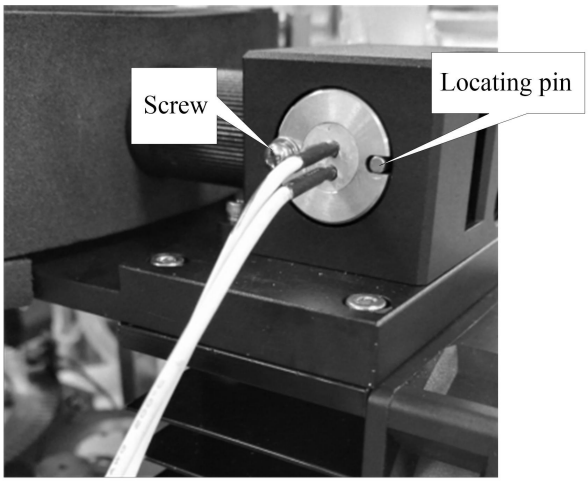


Figure 10-45 Loosen screws

(g) According to the above converse steps to replace the new halogen lamps, pay attention to tighten the screws. Lead wire should not be loose or cocked.

(h) Turn on the power. After the instrument is in standby mode, check the spot to meet the size of 6mm. Then, the gain of the non-blocking AD reading is performed on the “Instrument Detection” interface, and the test can be performed when the value is stable at around 58000.

Attention:

The protective cover on the terminal block must be installed to prevent short circuit on the terminal block.

10.5.3.4 Cleaning mechanism maintenance

If the nozzle of the cleaning mechanism is clogged, the cuvette can not be cleaned, which will affect the accuracy and precision of the test result, and may cause other faults of the instrument. In addition, if the cleaning water spills into the reaction tank, it may cause the test data not accurate.

1. Clean the cleaning needle outer wall

(a) Turn off the instrument's main power switch.

(b) Wipe the outer wall of the nozzle with a cotton swab dampened with an alkaline cleaning fluid, and wipe off the cleaning fluid on the surface of the pin with a cotton swab dampened with pure water (do not bend the needle during wiping). As shown in figure 10-46.

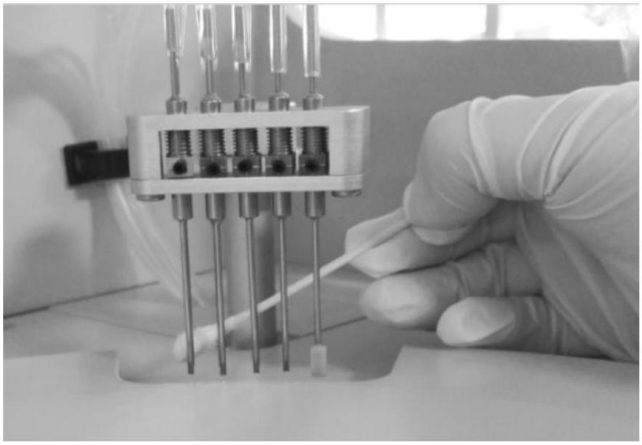


Figure 10-46 Clean cleaning needle

2. Clean the cleaning needle block

(a) Turn off the instrument's main power switch.

(b) Unscrew the corresponding cleaning needle silicone tube, as shown in figure 10- 47:

Figure 10-47 Cleaning needle silicone tube

(c) With 0.5mm needle from the bottom of the nozzle through the plug to clean up the block, as shown in figure 10-48.

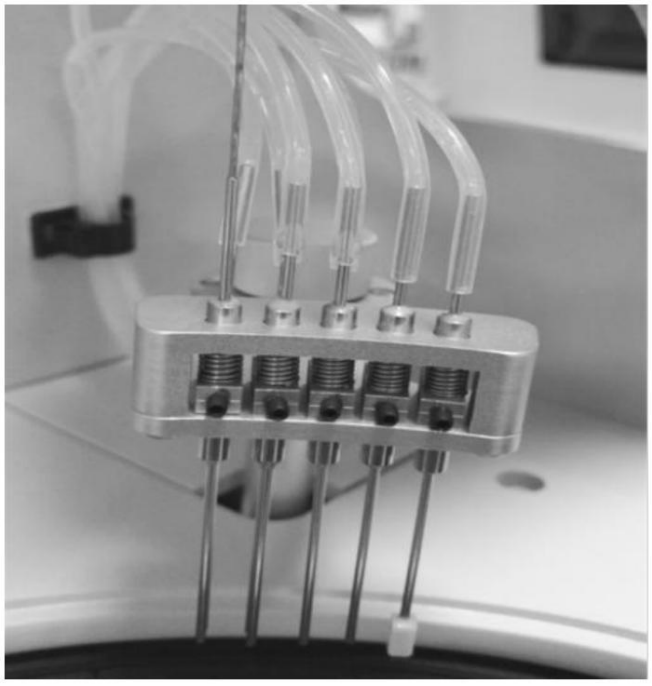


Figure 10-48 Clean the block

Attention:

Do not bend the nozzle during operation.

(d) Insert the silicone tube.

(e) Turn on the instrument's power switch.

(f) In the "Maintenance" menu bar, click the "instrument check" form, find the "Washing&&background", check whether the cleaning needle injecting water is normal, pumping is clean.

10.5.3.5 Stirrer maintenance

If the stirrer is contaminated, it will cause cross-contamination, thus affecting the accuracy and precision of the test results. So should wipe the outer wall of the needle regularly dipped in alkaline cleaning fluid with a cotton swab. In addition, replace the pin if the it is bent.

1. Stirrer cleaning

Stirrer cleaning: Wipe with a cotton swab dipped in alkaline cleaning fluid, and then wipe with a cotton swab dipped in water to clean the clean fluid on the surface of it (in the wiping process, do not bend the stirrer), as shown in figure 10-49:

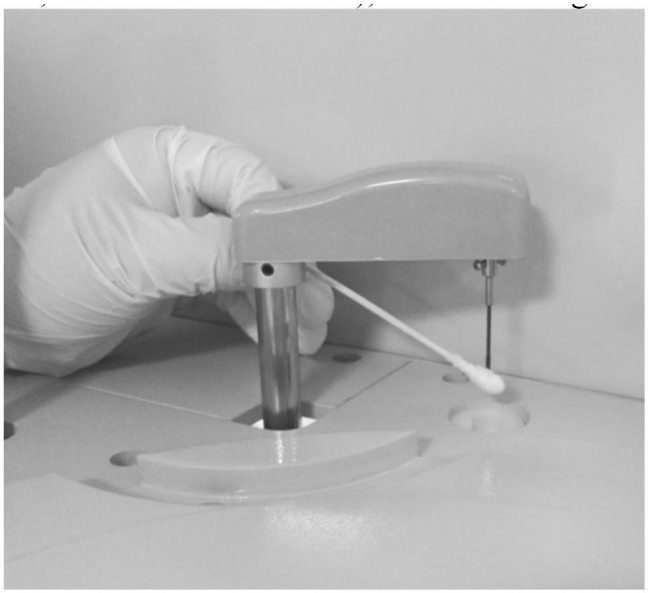


Figure 10-49 Clean stirrer

2. Stirrer replace

(a) Turn off the instrument's main power switch.

(b) Remove the reaction tray cover.

(c) Rotate the stirring arm in the direction of the cuvettes by hand (same as R&S arm operation), as shown in figure 10-50.

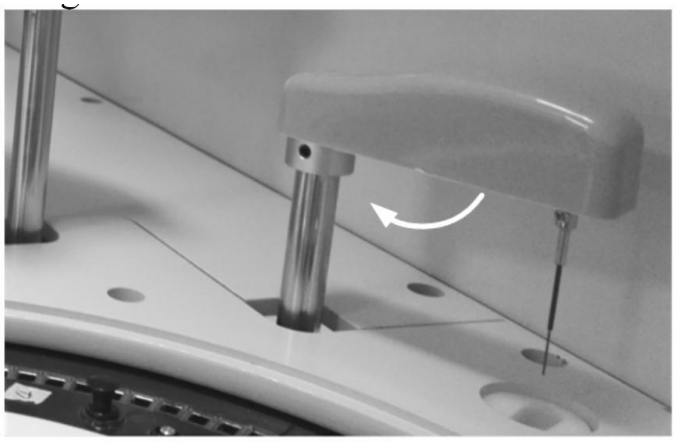


Figure 10-50 Raise stirring arm

(d) Loosen the two setscrews with a phillips screwdriver for a round, as shown in figure 10-51.

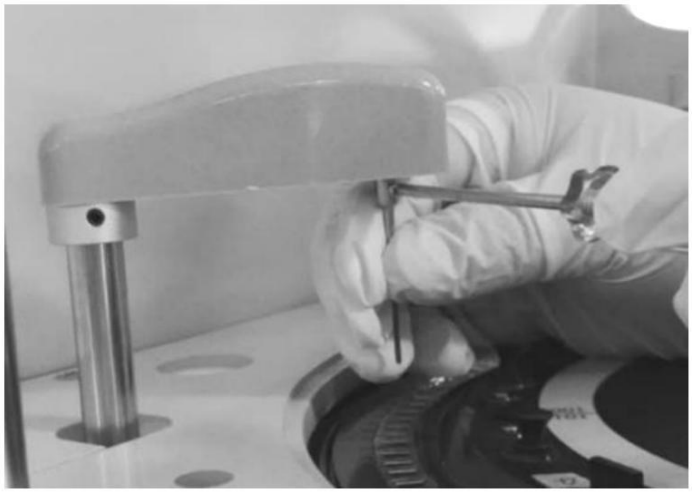


Figure 10-51 Loosen screw

(e) Wipe the tip of the new stirrer with a cotton swab dampened with an alkaline cleaning fluid, and wipe off the cleaning fluid on the surface of the needle with a cotton cloth dampened with pure water (do not bend the stirrer during wiping).

(f) When installing the new stirrer, insert the pin into the shaft of the motor shaft and secure with the M2 screw, as shown in figure 10-52. The height of the stirrer is about 1.3cm to reaction tray.

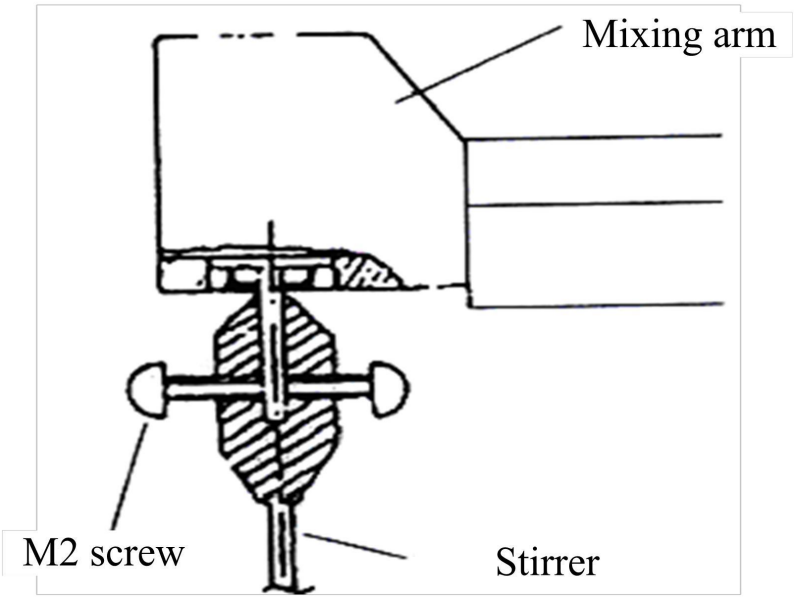


Figure 10-52 Stirrer installing

Note: The stirrer must be securely fastened to prevent instrument malfunction.

(g) Raise the stirring arm to the top, and rotate the stirring arm in the direction of the cleaning position by hand.

(h) Turn on the power.

(i) Open the "instrument check" form in the menu "Maintenance", find the stirring arm, as shown below, click the cuvettes position"Y", check the level position of the cuvette, confirm whether in the center of the cuvette. If yes, click zero position "Y" and the stirrer will return to the top of the clean cup.

Figure 10-53 Stirring arm check

See the location of the pin in relation to the cuvette in a top-down view, as shown in figure 10-54:

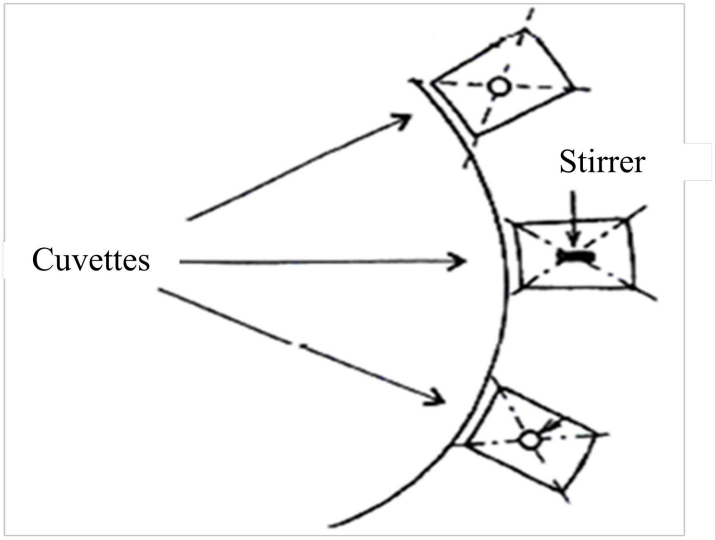


Figure 10-54 Check position

Note: If not in the center of the cuvette, please contact the service staff.

(j) Stirrer's vertical position check: In the "Instrument Check" window, click the cuvette position "Y", the needle will move to the top of the cuvette, then click the vertical position "Y", the stirrer down. Click the vertical position "Y" again, the stirrer lift. Finally click the zero position "Y", the stirrer will return to the top of the cleaning cup.

10.5.3.6 R&S tray maintenance

The instrument R&S tray has reagents refrigerated storage reagent function. R&S tray is divided into sample position, reagent inner ring and reagent outer ring. Including 49 sample positions, 56 reagent positions, as shown in figure 10-55.

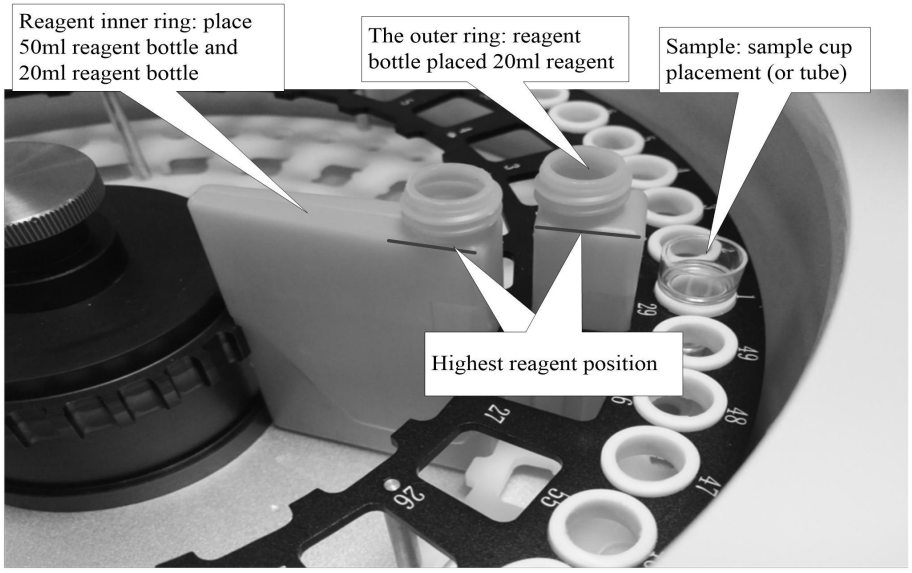


Figure 10-55 Reagent position

Attention:

Reagent can not be too full to ensure that below the top of the reagent location as above figure, otherwise it will affect the level detection.

Replace the reagent bottle.

When reagent less than the remaining time, please replace the reagent bottle. 50mL reagent bottle can only be placed in the reagent inner circle, 20mL reagent bottle can be set not only in the reagent outer ring, but also in the reagent inner ring. Place the reagent bottle as follows:

(a) 50mL reagent bottle placed: bottle near the reagent outer ring.

(b) 20mL reagent bottle placed in the reagent outer ring: the mouth of the bottle near the reagent inner ring.

(c) 20mL reagent bottle placed in the reagent inner ring: The bottle near the reagent outer ring, and need to be fixed (Fix the block in the box) as shown in figure 10-56.

After placing the reagent bottle, fix the reagent bottle with the fixing piece and then insert the fixing block vertically into the bottom.

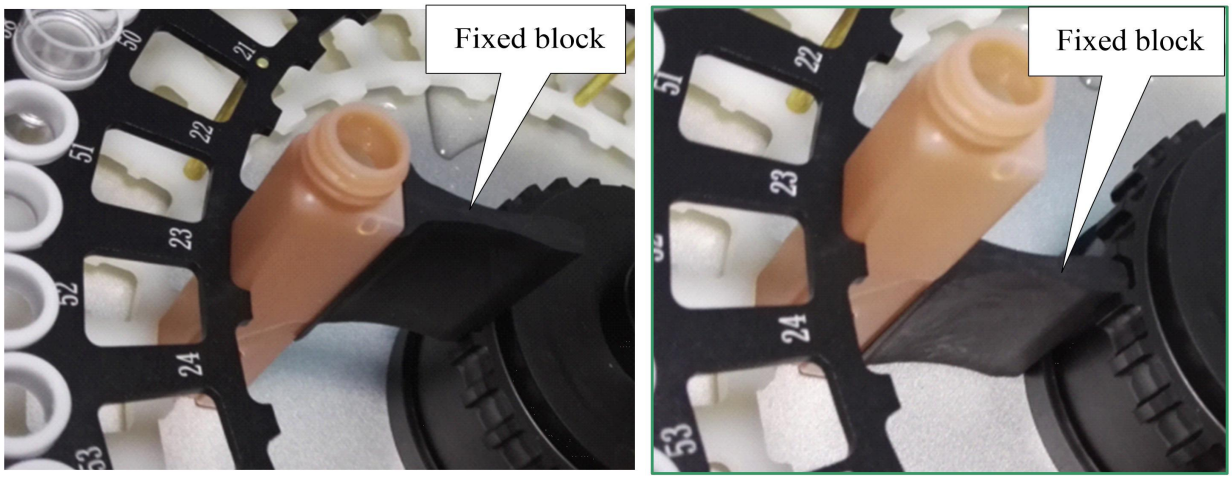


Figure 10-56 Fixed block

Attention:

Must put the reagent bottle first, and then put a fixed block, to prevent friction damage to the reagent bottle bar code.

1.R&S tray clean

The sample tray will be contaminated with reagents, samples and dust for a long time use, and condensation water will be generated during the cooling process, so it should be cleaned once a day.

(a) Remove the R&S tray cover.

(b) Unscrew the reagent tray handle counterclockwise to remove the R&S tray.

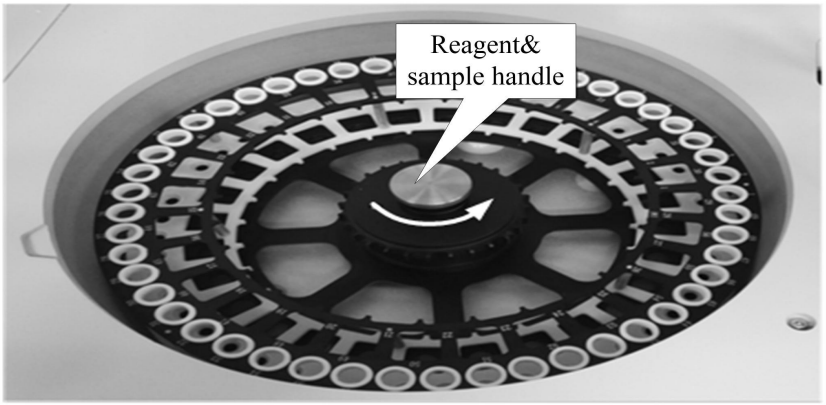


Figure 10-57 Remove reagent tray

(c) Wipe the inside of the reagent sample pan with a wet gauze and wipe the condensate from the reagent sample pan to the condensate drain.

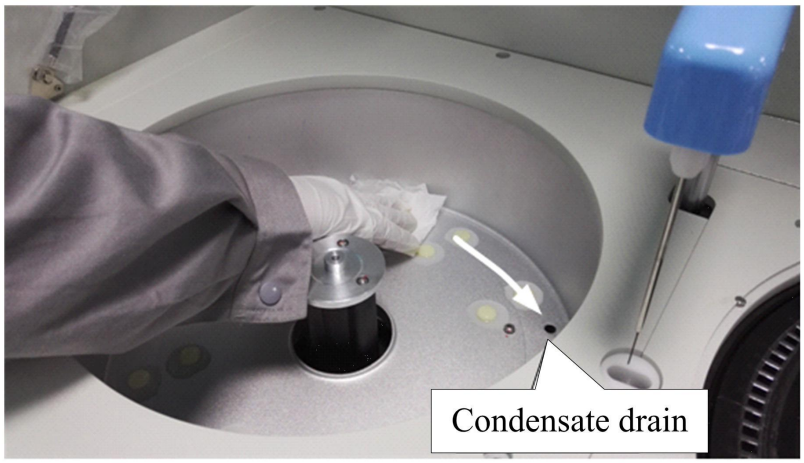


Figure 10-58 Wipe out the water

10.5.3.7 Refrigeration liquid adding

When the cooling level float switch is lowered to the lowest level, the liquid level alarm panel will sound an alarm and the right side panel alarm indicator flashes to indicate the lack of cooling liquid, as shown in figure 10-59.

Figure 10-59 Alarm Board

The procedure for adding the refrigerant is as follows:

1 Turn off the power switches of the analyzer.

2 Twist the cleaning compression screw, take off the cleaning needle assembly and place well. Remove the 15 plugs on the face panel,unscrew the fifteen M4*10 screws.

3 Remove the face panels as Figure 10-60.

Figure 10-60 Take down the tray cover and panel

4 Twist the plug on the circulating pump with slot screwdriver.

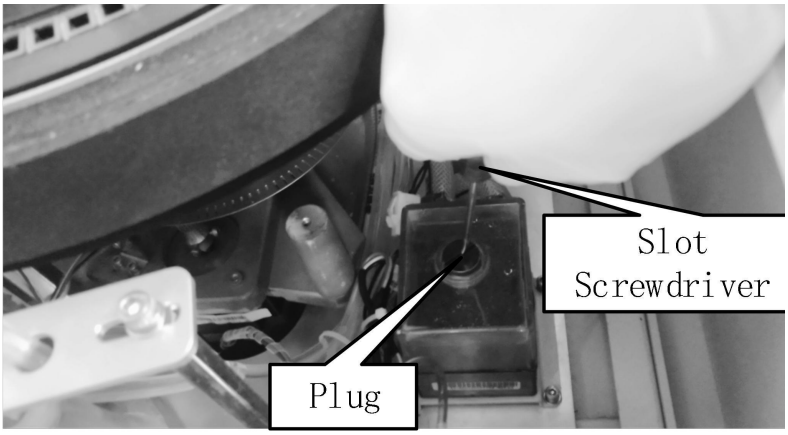


Figure 10-61 Circulating pump

5 In the accessories box, find the funnel which is connected with the 30cm pipe, put the funnel into the hole and slowly add refrigeration liquid.

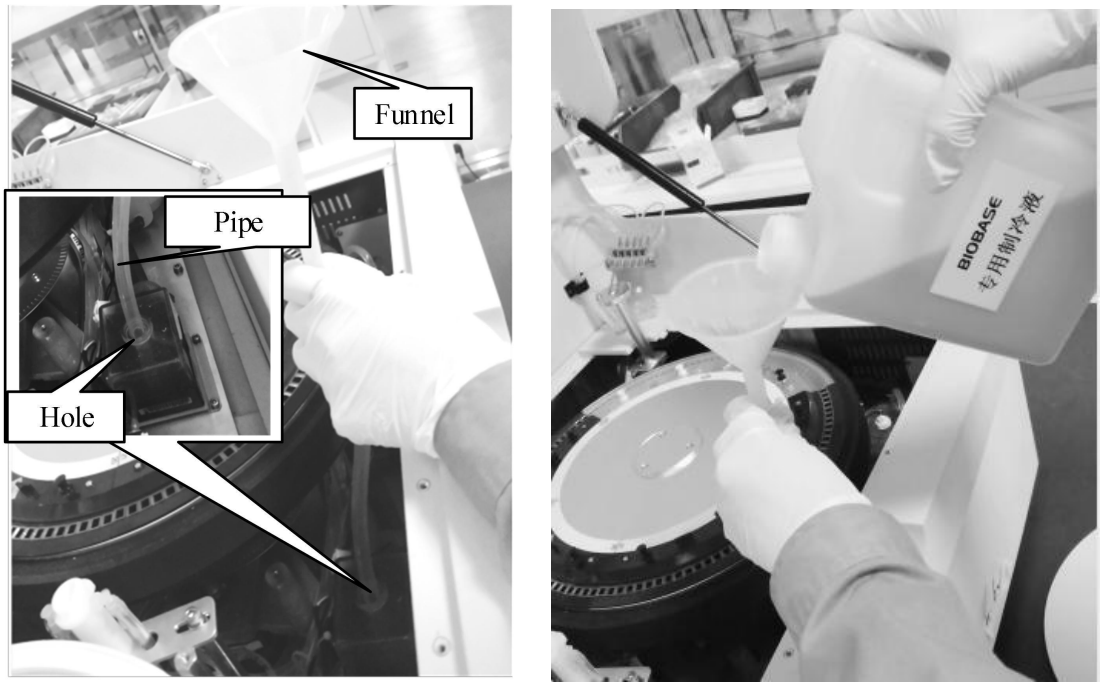


Figure 10-62 Refrigeration fluid adding

6 Fill up the circulating pump with refrigeration liquid as shown below, then take out the funnel, and then screw the upper plug.

7 Turn on the cooling power to run the cooling system. When the refrigerant liquid drops completely in the circulating pump.

8 Turn off the cooling power. Repeat steps 2-5. When the refrigerating liquid level in the circulating pump has no drawdown obviously and there is no bubbles in the refrigerating liquid, turn off the cooling power.

9 Slowly add refrigeration liquid to the 4/5 position in the circulating pump, then tighten the plug, and then install the panel, finish the addition of refrigeration liquid.

If cooling alarm occurs after starting up, check whether the environment temperature of the analyzer is too high, or whether the temperature of the R&S tray is too high. If the environment temperature is too high, use air conditioner to control the temperature between 15 ℃ and 30℃. If the temperature of the R&S tray is too high, it is necessary to check the condition of the cooling system. It may be that there is too many air bubbles in the circulating pump need to be discharged.

10.5.3.8 Cleaning fluid C adding

Cleaning fluid C level is set with liquid level alarm function. When the needle detects the Cleaning fluid level below the limit value, the software prompts the alarm. Click "alarm" interface to view the details, then need to add Cleaning fluid.

When the instrument is not running, the Cleaning fluid is added as follows:

1. Open the R&S tray cover.

2. Reagent position cleaning fluid adding method: Cleaning fluid C is placed in the 28th position of reagent position, as shown in figure 10-63.

3. Sample position cleaning fluid adding method: Cleaning fluid C is added to the sample cup, and it is placed in the 49th position of sample position, as shown in figure 10-64.

Note:

When setting prevent cross contamination, you need to perform cleaning fluid C addition in sample position.

4. Cover the R&S tray cover, and finish the addition of Cleaning fluid C.

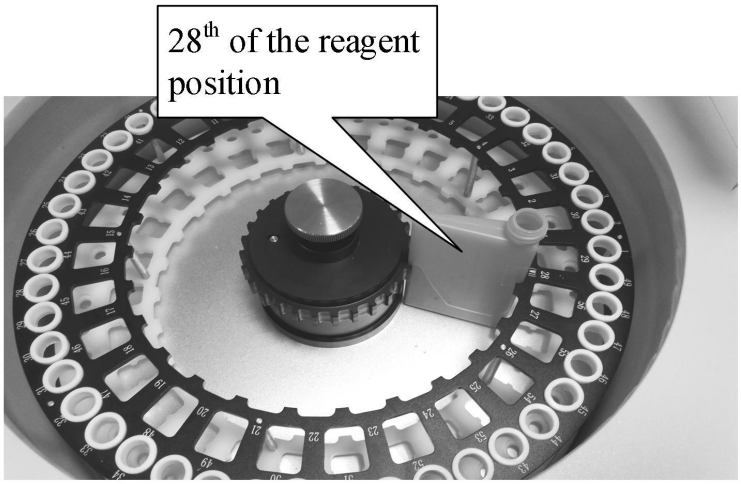


Figure 10-63 Reagent position Cleaning fluid adding

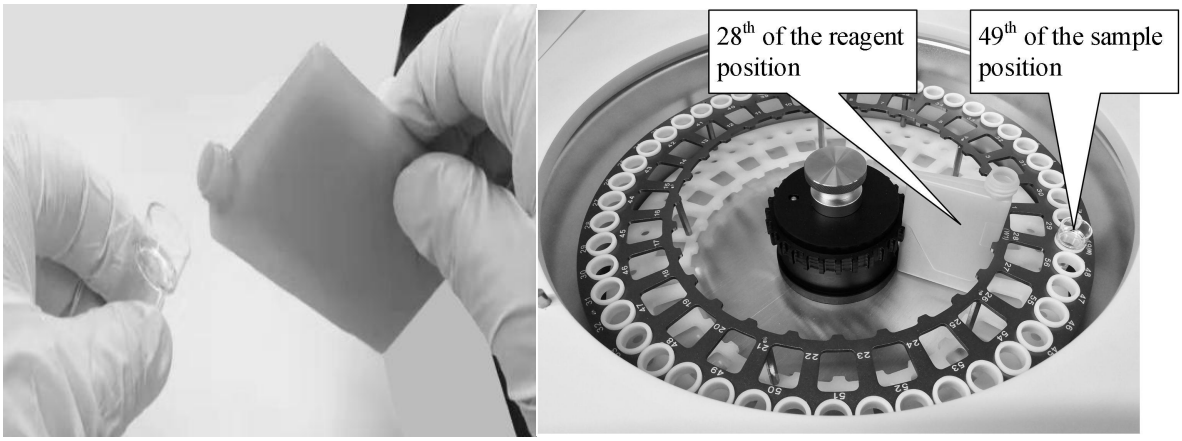


Figure 10-64 Sample position cleaning fluid adding

Attention:

1. When adding Cleaning fluid, beware of overflow, the company Cleaning fluid is a corrosive liquid. Once it hurts the skin or eyes, rinse with plenty of water.
2. When adding Cleaning fluid, ensure that the instrument has stopped running, to prevent damage to the machine, or even personal injury.

10.5.4 Daily operation

Starting up operation:

1. Check the pure and waste water bucket before the test.
2. Check the R&S needle, whether or not blocked.
3. Check the cleaning cup and waste water pipe whether or not blocked.

Turn off operation:

1. Clean the cuvette, empty the sample tray to test the sample, the reagent covered with the corresponding cap, then cold storage.
2. Treatment of waste water bucket.

3. Add pure water to the cuvette, then save the background.
4. Turn off the machine power supply, cover the machine cover.

10.6 Instrument failure and treatment

The fault of the instrument can be divided into failure and alarm failure according to different problems.

10.6.1 The way to deal with the failure of alarm

Analysis and solution of instrument failure alarm as sheet 10-4.

Sheet 10-4 Instrument failure alarm analysis sheet

Fault information	Main reason	Solution
R&S needle tip with water droplets	1. Sample tip is dirty 2. There is a leak in the pipeline or filler of the sampling filling mechanism	1. Wipe the needle with cotton swab alkaline cleaning fluid 2. Maintenance and inspection
There is a drop of water droplets on the washing needle.	1. The cleaning mechanism of pipeline leakage 2. Nozzle, pipe blockage	1. Check interface 2. Clean the maintenance of the body, if you want to replace the hose please contact the sales staff
Clean nozzle without the water	Nozzle, pipe blockage	Clean the maintenance of the body, if you want to replace the hose please contact the sales staff
Cuvette water overflow	Nozzle, pipe blockage	Clean the maintenance of the body, if you want to replace the hose please contact the sales staff
Injection pump leakage	1. Poor interface parts 2. Pump leakage	1. Confirm leaks and reinstall 2. Replace injection pump
There are bubbles in the injection pump.	1. Interface parts install not good. 2. Filling device exhaust is not enough	1. Confirm the air inlet and reinstall 2. Implementation of the system in the maintenance of the exhaust, if there is a small bubble can not be removed, you can move in the reagent or cleaning water, gently tap the injection pump, use of vibration to eliminate
Abnormal level of liquid level	1. Problem of liquid level sensitivity setting 2. Instrument grounding problems 3. There is a large electro-magnetic interference	1. Confirm whether the level tray sensitivity is set correctly 2. Check whether the ground is connected 3. Check whether there is a large elec-tromagnetic interference around

Absorbance beyond	The absorbance of the reaction liquid is beyond 3.3Abs	1. Make sure the reagent is prepared and the position is correct 2. Check whether has impurity in sample 3. Check whether there is any impurity in the reaction tank warm water 4. Check the cuvette whether or not cracks and scratches 5. Check whether the optical window is clean or has water
Reaction tray anomaly	1. Reaction tray Unable to locate stop position 2. The reaction tray is not in the specified position	1. Confirm the optocoupler under the covered on the disc tray without abnormal reaction 2. Check the optocoupler and the electrical wiring whether or not off and abnormal contact
Sample needle moves abnormal	1. Left and right motion abnormalities 2. Up and down motion abnormalities	1. Check whether the optocoupler block is abnormal 2. Check whether the corresponding optical coupler and the electrical wiring of the electric machinery is abnormal 3. Check whether the corresponding drive tray installation is abnormal
R&S tray anomaly	1. R&S tray moves anomaly 2. R&S tray is not initialized at zero position	1. Confirm the optocoupler plate under the R&S tray is normal 2. Check whether the optocoupler and the electrical wiring is off or abnormal contact 3. R&S tray Pallet is loosing 4. The R&S tray adjustment position is unreasonable, and the zero position should be on the R&S needle horizontal within the range of 90 degrees

Reproducibility not good	1. Do not maintain the equipment regularly 2. Chemical reagents go bad, There are chemical substances Precipitation or has impurity substance 3. Purifier water quality is not good 4. Cleaning is not thorough 5. Reagent crystallization 6. Analysis of projects have Cross contamination 7. Sample unqualified(Fibrin in the sample) 8. There is a large electromagnetic interference	1. Maintain the equipment regularly according to user's Manual 2. Replace the new reagent, and correct storage and use of reagents 3. The conductivity of pure water should be below 1 s/cm 4. Add the cleaning fluid to clean the cuvette thoroughly 5. Replace reagent 6. Spacing placement the reagent which has Cross contamination, or use the Cross contamination program to avoid it 7. The samples unqualified were centrifuged again 8. Remove interference source
Poor accuracy	1. Calibration solution concentration or Invalid 2. Analysis condition setting is not good	1. Add The calibration liquid to the sample cup immediately use and preserve correctly 2. Set parameter correctly
No response after the instrument boot	1. Poor contact of power plug 2. Instrument insurance tube burn	1. Check the power input part wiring 2. Replace the safety tube and check the line

10.6.2 The content and solution of alarm information

The analysis and solution of the instrument failure of alarm as sheet 10-5:

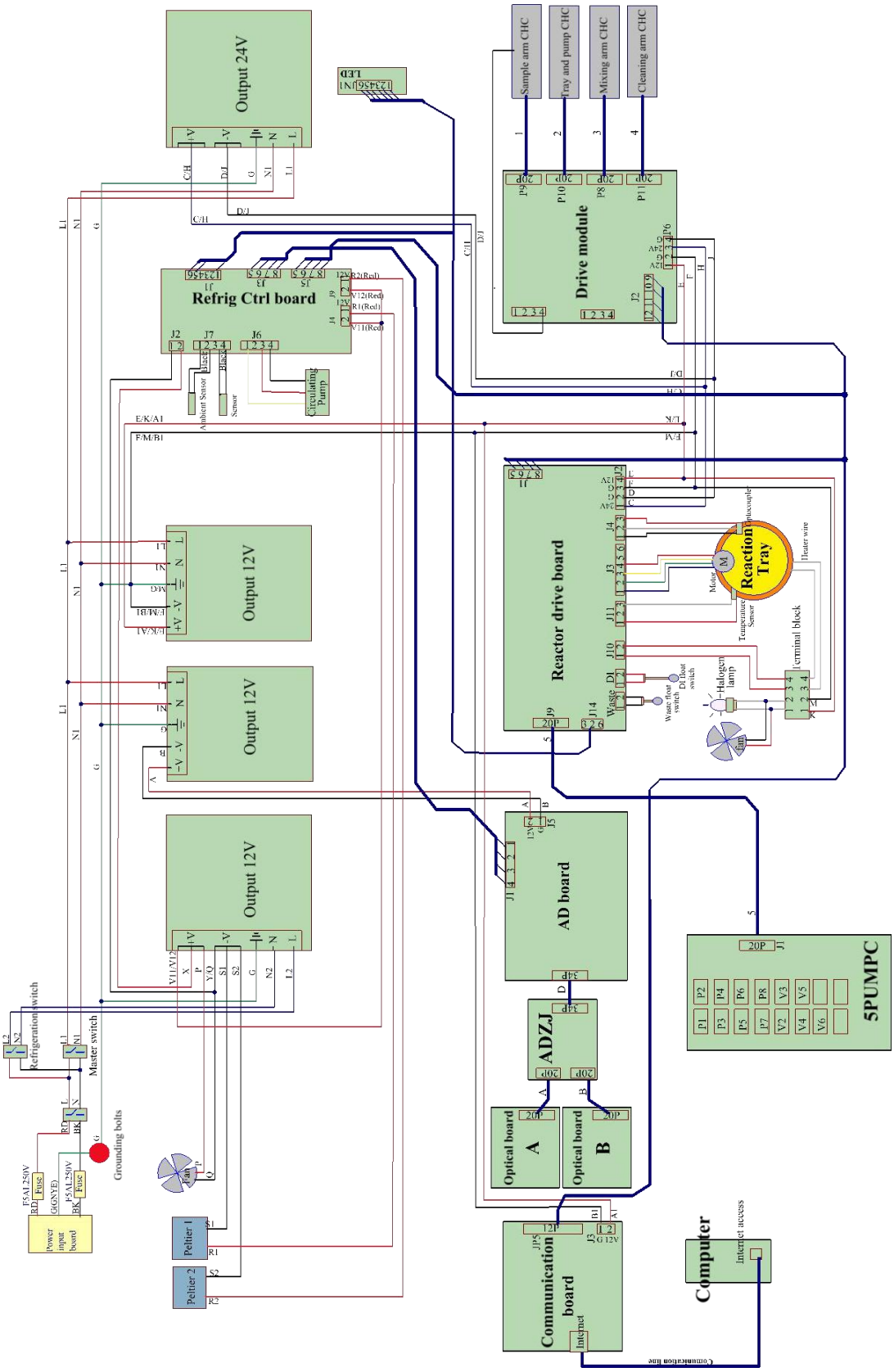
Sheet 10-5 The analysis and solution of the instrument failure of alarm sheet

Alarm No.	Alarm source	Description	Handling suggestions
2307	Pure Water Tank	Pure water tank water shortage.	Please check in time.
5530	Data processing	There is no cleaning fluid in No.49 position.	Please ADD cleaning fluid in No.49 position.
5558	Data processing	There is no cleaning fluid in No.28 position.	Please ADD cleaning fluid in No.28 position.
8602	Photoelectric switch	Abnormal vertical photoelectric switch reagent sample arm	Please check the reagent sample arm vertical photoelectric switch
8603	Photoelectric switch	Abnormal reagent sample arm around photoelectric switch	Please check the reagent sample arm around photoelectric switch
8604	Photoelectric switch	Abnormal reaction plate of photoelectric switch	Please check the reaction plate of photoelectric switch

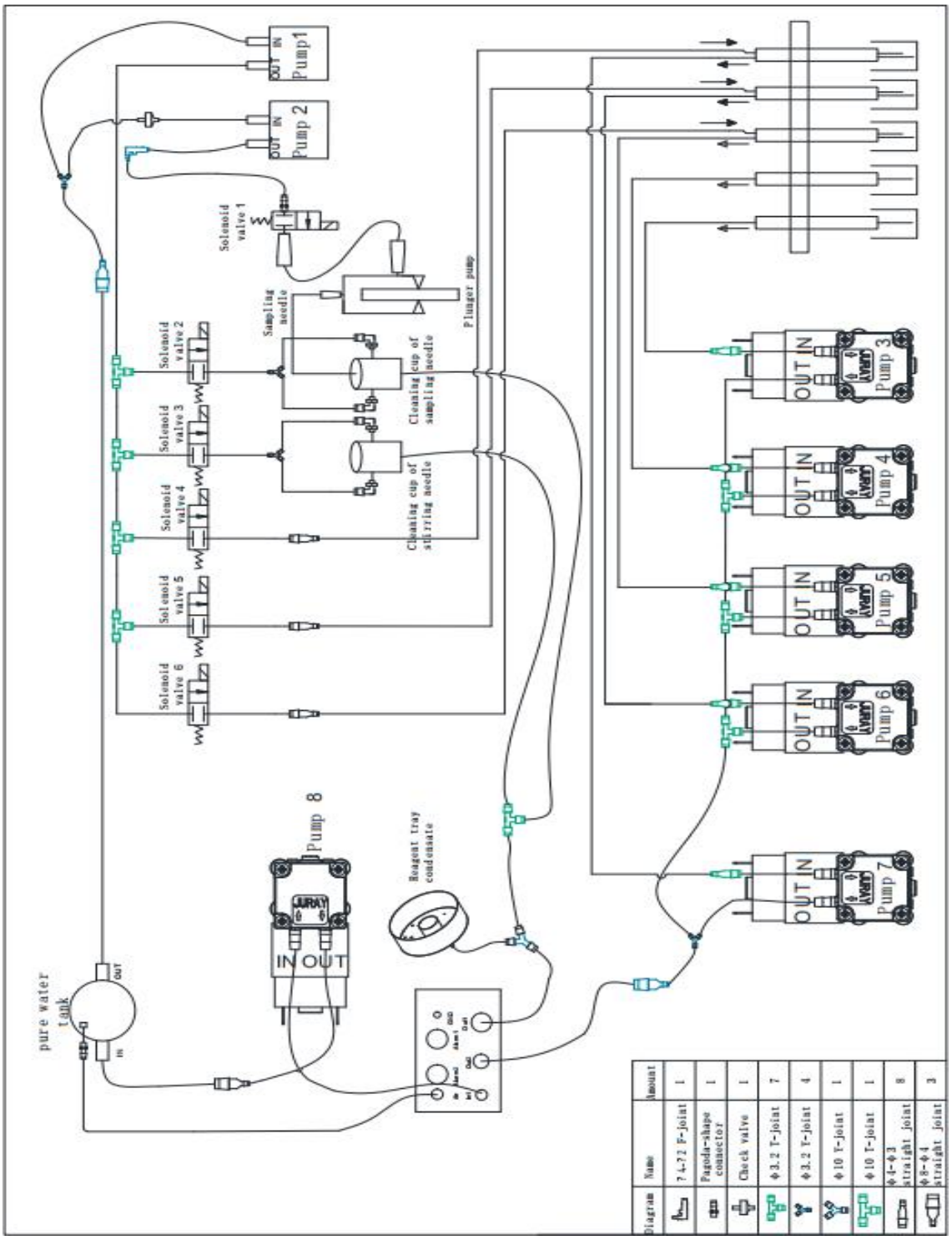
8605	Photoelectric switch	The cleaning arm photoelectric switch	Please check the cleaning arm photoelectric switch
8606	Photoelectric switch	Reagent sample plate of photoelectric switch anomalies	Please check the reagent sample plate of photoelectric switch
8607	Photoelectric switch	Abnormal reagent sample pump photoelectric switch	Please check the pump reagent sample photoelectric switch
8608	Photoelectric switch	Abnormal vertical mixing arm photoelectric switch	Abnormal vertical mixing arm photoelectric switch
8609	Photoelectric switch	The stirring arm around photoelectric switch	Please check the stirring arm around photoelectric switch
60002	Communication	Communication exception!	Please trun off the host computer software, and then restart the instrument, and then re run the PC software.
60003	Communication board	Data return length error!	Please check the communication line or communication board.
60004	Communication	Software and instrument number does not match!	Please contact the engineer to re configure the software.
60006	Adaper	Network disconnected!	Please trun off the host computer software, and then restart the instrument, and then re run the PC software.
60014	LIS	LIS connection failed	Please connect LIS manually
100000	Reagent Disk	Could not find reagent parameters. Test code is {0}.	Check the reagent parameters to make sure it is correct and on reagent disk.
400074	Drive module 1	Driver module a communication exception	Please check the drive module.
400075	Driver module 2	Driver module two communication exception	Please check the drive module two
400076	Reaction disk module	Reaction disk module communication exception	Please check the reaction disk module
400077	AD module	AD module communication exception	Please check the AD module
400078	Circuit	Exhaust not completed	Please check the circuit
400081	Circuit	Drainage not completed	Please check the circuit. If it is not resolved, please contact the engineer in time.
400082	halogen lamp	halogen lamp Life to the limit	Please contact the engineer to replace the halogen lamp

400083	Circuit	Cleaning needle exhaust is not completed	Please check the circuit
400084	halogen lamp	Light energy is too low to test.	Please check the halogen lamp, light path and colorimetric cup for any abnormalities.
400302	During the test	Dirty cup appeared in the No. {0} reaction cup	Please change the reaction cup in time
500016	Data processing	Circulating pump may be blocked	Please check circulating pump
500017	Data processing	Circulating pump water level is low	Please check circulating pump and add the refrigerant fluid.
500019	Refrigeration module	The connection is broken and no cooling information is obtained.	Please confirm if the cooling is turned on. If it is not resolved, please contact the engineer in time.

Appendix A: Electrical Schematic Diagram



Appendix B: Water System Diagram



Appendix C: Reagents Parameter Sheet

Item	Full Name	Sample Volume	R1 Volume	R2 Volume	Primary Wavele-ngth	Analysis Method	Sample Types	Deci-mal Place	Unit	Min Abs	Max Abs	Pri-Start Point	Pri-End Point	Sub-Start Point	Sub-End Point	Normal High Value	Normal Low Value
ALB	Albumin	5	300	0	570	One Point End	serum	1	g/L	0	3.3	30	30	0	0	55	35
ALP	Alkaline Phosphatase	6	240	60	405	Rate method	serum	0	U/L	0	3.3	22	30	0	0	135	45
ALT	Alanine Amino Transferase	22	240	60	340	Rate method	serum	1	U/L	0	3.3	23	33	0	0	41	0
AMY	α-Amylase	7	250	90	405	Rate method	serum	0	U/L	0	3.3	23	33	0	0	104	25
ApoA1	Apolipoprotein A1	5	225	75	340	Two Point End	serum	2	g/L	0	3.3	35	35	12	13	1.9	1.2
ApoB	Apolipoprotein B	5	225	75	340	Two Point End	serum	2	g/L	0	3.3	35	35	12	13	1.5	0.6
ASO	Antistreptococcus O	5	240	60	570	Two Point End	serum	0	IU/mL	0	3.3	28	29	19	20	166	0
AST	Aspartate Amino Transferase	22	240	60	340	Rate method	serum	1	U/L	-1	3.3	22	33	0	0	40	0
BMG	β2-Micro Globulin	5	225	75	570	Fixed time method	serum	1	mg/L	0	3.3	21	28	0	0	1.8	0.8
CHE	Cholinesterase	5	250	50	405	Rate method	serum	0	U/L	0	3.3	22	30	0	0	12600	3930
CHO	Cholesterol	4	300	0	505	One Point End	serum	2	mmol/L	0	3.3	15	15	0	0	5.2	2.34
CK	Creatine Kinase	15	240	60	340	Rate method	serum	0	U/L	0	3.3	22	30	0	0	190	0
CK-MB	Creatine Kinase Isozyme	15	240	60	340	Rate method	serum	1	U/L	0	3.3	22	30	0	0	25	0
CREA	Creatinine (Alkalinity Picric Acid Method)	15	240	60	505	Fixed time method	serum	1	umol/L	0	3.3	22	30	0	0	115	53
CRP	C-reaction protein(normal)	20	225	75	340	Two Point End	serum	2	mg/dL	0	3.3	35	35	12	13	0.8	0
DBIL	Direct Bilirubin (Vanadate oxidation method)	9	240	60	450	Two Point End	serum	2	umol/L	0	3.3	35	35	12	13	6.8	0
GLU	Glucose(Oxidase Method)	6	300	0	505	One Point End	serum	2	mmol/L	0	3.3	34	35	0	0	6.4	3.89
HbA1c	SaccharifyGemoglobin (Latex enhanced immune turbidimetry)	10	225	75	630	Two Point End	original blood	2	%	0	3.3	33	33	20	21	5.8	3.8
HCY	Homocysteine	24	240	60	340	Rate method	serum	1	umol/L	0	3.3	21	29	0	0	15	0
HDL-C	HDL-Cholesterol	5	225	75	546	Two Point End	serum	2	mmol/L	0	3.3	35	35	12	13	2.25	0.77
LDH	Lactic Dehydrogenase	6	240	60	340	Rate method	serum	0	U/L	0	3.3	22	30	0	0	225	135
LDL-C	LDL-Cholesterol	5	225	75	546	Two Point End	serum	2	mmol/L	0	3.3	35	35	12	13	3.35	0
TBA	Total Bile Acid	5	225	75	405	Fixed time method	serum	1	umol/L	0	3.3	22	28	0	0	20	0

TG	Triglyceride	5	300	0	505	One Point End	serum	2	mmol/L	0	3.3	35	35	0	0	1.7	0.7
UA	Uric Acid	5	240	60	546	Two Point End	serum	0	umol/L	0	3.3	35	35	12	13	480	140
UREA	Urea	5	225	75	340	Fixed time method	serum	1	mmol/L	0	3.3	22	30	0	0	8.3	1.7
TP	Total Protein	6	300	0	546	One Point End	serum	1	g/L	0	3.3	34	35	0	0	88	60
α-HBDH	α-Hydroxybutyric Acid Dehydrogenase	5	240	60	340	Rate method	serum	0	U/L	0	3.3	22	30	0	0	182	72
GGT/γ-GT	γ-GlutamoylTransferase	6	225	75	405	Rate method	serum	0	U/L	0	3.3	22	30	0	0	47	0

Appendix D: Cross Contamination Reference Sheet

Project name	Method principle		Method principle	Method principle
TG	Oxidase methods	→	TBA	Enzymatic cycling assay
TC	Oxidase methods	→	TBA	Enzymatic cycling assay
CHE	Substrate hydrolysis	→	TG	Oxidase method
LDL-C	Direct method of determination	→	GLU(OX)	Oxidase method
HDL-C	Direct method of determination	→	GLU(OX)	Oxidase method
CK	IFCC	→	Mg	Methylene Blue
FMN	NBT return method	→	CHE	Substrate hydrolysis

The above cross-contamination only is taken for example when the company reagent is tested on the analyzer.

The reagent formula's changing in cross-contamination, so the above test is only for reference, if not, please refer to the actual test situation.

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