Genrui

Auto Chemistry Analyzer

Model: GS480A/GS450/GS450A

Operation Manual

For In Vitro Diagnostic Use

Intellectual Property

IVD

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Statement

The current version number of this manual is A/1, released on 2018-11. This manual may be modified as needed without prior notice.

Genrui shall be liable for product safety, reliability and performance provided that the following requirements are met:

1) All installation operations, expansions, changes, modifications and repairs of this product are conducted by Genrui authorized personnel.
2) All replaceable parts involved in maintenance as well as the related accessories and consumables are original or approved by Genrui.
3) Any associated electrical equipment complies with national standards and the requirements of this manual.
4) Use and operation of this product are performed in strict accordance with this manual.

Warranty Service

The entire machine is covered by a comprehensive warranty for a full year from the date of production. However, damage occurring under the following conditions shall not be covered by this warranty:

1) Man-made damage or damage caused by improper use.
2) Damage caused by mishandling during shipment.
3) Damage caused by uncontrollable natural factors such as earthquake, fire or war.
4) Environment in which the machine is used does not meet the requirements indicated in this manual.
5) Damage caused by use of an unspecified power supply or any other abnormality in the power supply.
6) Damage caused as a result of maintenance performed by personnel not authorized by Genrui.
7) Malfunction of the instrument whose serial number is not legible enough.
8) Malfunction not caused by the instrument itself.

In the event you have any inquiries or questions while using the instrument, you can always contact Genrui.

Customer Service Department

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www.CE-Marking.EU

Warning:

1) This analyzer can only be operated by test professionals, doctors or laboratory technicians who have been trained by Genrui or its distributors.



2) It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.

3) Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.

Note:

1) This operation manual is written for the following laboratory professionals:



- Daily system operators
- Personnel for system maintenance and troubleshooting
- Learners for system operation

2) When the instrument reaches the retirement period, it is recommended to stop using it or conduct a comprehensive inspection and maintenance before re-using it again.

Introduction

We would like to sincerely thank you for choosing to purchase Genrui product.

Please read this manual carefully in order to ensure correct use of the product. After carefully reading this manual, please keep it safely stored so that you can refer to it when necessary.

Product Name: Auto Chemistry Analyzer

Model: GS480A/GS450/GS450A

Safety Classifications: Electric shock safeguard class I, overvoltage category II, pollution degree 2

Management Classification: A kind of biochemical analysis system in the category of analyzing instruments for clinical tests (6840); management category: Class II

Product Composition: This product primarily comprises an analysis unit and operating unit

Scope of Product Application: This product is suitable for use in the in vitro quantitative analysis of compositions of clinical chemistries in serum, plasma, urine and cerebrospinal fluid (CSF) samples.

Manufacturer: Genrui Biotech Inc.

Registered Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

Date of Manufacture: See the nameplate of the instrument

Instrument Service Life: 8 years

Manual Preparation Date: December 21, 2017

Item No.: P01.91.300324-01

REF 11000019 (GS480A) / 11000020 (GS450) / 11000021 (GS450A)

Manual Overview

This manual is focused on helping users to understand several aspects of the auto chemistry analyzer, including safety, installation, structure and function, analysis principles, operating procedures, maintenance and repair, alarms and treatment. Please operate the analyzer in strict accordance with this manual in order to ensure proper use.

Who Should Read This Manual

This manual contains information written for medical laboratory professionals or trained doctors, nurses or laboratory technicians to:

- Learn about hardware and software of the analyzer.
- Set system parameters.
- Perform daily operations.
- Perform system maintenance and troubleshooting.

How to Find Information

This manual contains 10 chapters and 1 appendix. Refer to the table below to find the information you need.

If you want to…	**Please refer to…**
learn about safety and precautions of the analyzer	Chapter 1 Safety and Precautions
learn about installation requirements of the analyzer	Chapter 2 Installation
learn about the intended use, parameters, structure, operation interface, etc. of the analyzer	Chapter 3 System Description
learn about basic operations and software parameter settings	Chapter 4 Basic Operations
learn about common operations and software parameter settings	Chapter 5 Common Operations

If you want to…	Please refer to…
learn about how the analyzer works	Chapter 6 Analysis Principle and Computational Methods
learn about methods of maintenance and care of the analyzer	Chapter 7 Maintenance
learn about the causes and treatments of the analyzer	Chapter 8 Alarm Information and Processing
learn about the transportation and storage methods of the analyzer	Chapter 9 Transportation and Storage
learn about the common consumables and ordering methods of the analyzer	Chapter 10 Commonly-used Consumables and Ordering Method
learn about the common terms, supporting reagents, piping diagram, etc.	Appendix A

Symbols

You will find the following symbols in this manual:

Symbols	Meaning
	Warning! May cause damage to the analyzer or affect test results.
	May result in biological contamination. (The background color of this symbol is yellow, the symbol itself and the outline is black.)
	May result in electric shock.
	May cause corrosive damage.
	High temperature which may cause injury.
	Glare which may cause eye injury.
	May result in bodily injury.
	Flammable substance which may result in a fire.

Screen Printings and Labels

The screen printings and labels listed below are used in this manual.

Labels	Meaning
SN	Product serial number
IVD	The product is an *in vitro* diagnostic device
	Date of manufacture
	Manufacturer
CE	CE marking. The device is fully in conformance with the Directive 98/79/EC on in vitro diagnostic medical devices
EC REP	Authorized representative in the European Community
	The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.
	Alternating current
	Equipotential terminal
	Power On

Labels	Meaning
	Power Off
CHEMISTRY ANALYZER	Biochemical Analyzer
MAIN POWER	Main Power
ANALYZING UNIT POWER	Analyzing Unit Power
ON	Power On
OFF	Power Off
	Network Port
High Concentration Waste Liquid Outlet	High Concentration Waste Liquid Outlet
Low Concentration Waste Liquid Outlet	Low Concentration Waste Liquid Outlet
Deionized Water Inlet	Deionized Water Inlet

Figures

All figures included in this manual are used for descriptive purposes or as examples only, and are not intended to be used for any other purposes.

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1. Safety and Precautions

The following are warning symbols used for the analyzers. Ignoring these symbols may result in death or serious injury. The order in which the symbols are given is in no way indicative of importance and all symbols are of equal importance.

1.1. Safety

	**High Temperature** 1) Before replacing the lamp, turn off the power switch and wait at least 30 minutes until the lamp has cooled down. 2) Contact with the print head or metal objects around the print head may cause burns.
	**Bodily Injury** 1) Keep away from the sharp parts of the analyzer, such as sample probe tip, reagent probe tip and stirrer in case of body injury. 2) Do not touch the moving parts, such as sample probe, reagent probe, stirrer and fan when the analyzer is running.
	**Glare** Do not look directly into any beams to prevent possible damage to your eyes.
	**Electric Shock** 1) Front, side and back covers mustn't be opened when the power is on, except by authorized service personnel. 2) Do not splash liquid on the analyzer's countertop. In case liquid gets into the analyzer, turn of the power and contact Genrui or its local distributors immediately. 3) Keep away from the inside of computer and printer in case of high voltage.

	**Biohazard** 1) All test samples, calibrators, controls, etc., should be considered contagious and protective gloves should be worn when coming into contact with these objects. 2) All waste liquid should be considered contagious and protective gloves should be worn when coming into contact with it. 3) Parts that have contacts with samples, such as sample probe, reagent probe, stirrer, cuvette, waste liquid tubing and waste liquid container should be regarded as contagious and protective gloves should be worn when coming into contact with these objects. 4) When the instrument reaches its service life, it should be disposed according to the requirements of the local environmental protection department, cannot be disposed and discarded as common wastes.
	**Corrosion** 1) Some reagents are corrosive. Keep your hands and clothes away from them. Once contacted, wash with plenty of water and soap until they are clean. 2) If the reagents get in eyes, wash with plenty of water and consult an ophthalmologist.
	**Combustion** Do not use flammable dangerous goods, such as alcohol, ether, etc. near the analyzer.

1.2. Precautions

	**Intended Use** 1) The analyzer is designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine and cerebrospinal fluid (CSF) samples. Please consult Genrui first if you want to use the system for other purposes. 2) To draw a clinical conclusion, please also refer to the patient's clinical symptoms and other test results.
	**Operator** The analyzer can only be operated by personnel who have been trained and authorized by Genrui or its local distributors for safety purposes.
	**Installer and Service Personnel** The analyzer can only be installed, repaired and maintained by personnel who have been authorized by Genrui or its local distributors according to the safety requirements in order to reduce the risks during the whole process.
	**Intermittent Operation Limits** 1) Computer settings: do not allow the computer to sleep. 2) Network port settings: do not turn off the host power, and configure the network adapter with the "Allow this device to wake the computer" and "Allow the computer to turn off this device to save power" options turned off.
	**Consumables** The operators should only use consumables within their expiration date.
	**Hazardous Substances** The handling, containment and exhaust of hazardous substances should comply with local regulations.
	**Operating Precautions** Do not open the covers of the reagent/sample/reaction disk and touch the moving parts, such as sample probe, reagent probe, stirrer and fan when the analyzer is running.

	**Actions Taken in case of Failure** If the instrument has dangerous failure, such as fire, odor, smoke, etc., anyone can directly disconnect the power of the instrument or the main power and contact Genrui immediately.
	**Operating Environment** 1) Please install and operate the analyzer in an environment specified by this manual. Installing and operating the analyzer in other environment may lead to unreliable results and even analyzer damage. 2) If the operating environment of the analyzer needs to be modified, please contact Genrui or the authorized Genrui distributor for your region.
	**Electromagnetic Interference** 1) The analyzer is susceptible to electromagnetic interference during operation which may affect test results and lead to operational errors. Please do not use devices that emit electromagnetic radiation, such as electric drills, mobile phones or interphones while the analyzer is running 2) The analyzer will emit electromagnetic radiation during operation. Do not install or use electromagnetically-sensitive devices near the analyzer. 3) In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
	**Improper Grounding** 1) The power supply must be properly grounded, or there is a risk of electric shock. 2) Ground impedance must be less than 0.1Ω. Poor grounding can cause instability in test results and electrical leakage from the enclosure, producing an electric shock hazard.
	**Improper Operation** Be careful when loading and unloading of samples and regents, otherwise it may affect the test results or cause injury to the operator.
	**Liquid Leakage** 1) Check the pipe joints for possible leakage before conducting tests. Liquid leakage can cause inaccurate aspiration and discharge volume. 2) Do not place reagents and samples on the analyzer bench to avoid liquid spillage or leakage.

	**Probe Obstruction** Carefully check reagents and samples and make sure they do not contain insoluble floating substance such as cellulose and protein fibrin in case the probes may be blocked.
	**Water Quality** Water quality should meet Class 2 national standards for laboratory water, otherwise damage to valve and pump as well as difficulty in cleaning can be resulted.
	**Device Connection** 1) For a device not permanently connected, please do not place it at a location that is hard to disconnect. 2) For all the external switches or breakers and external over-current protection device, it is recommended to place them near the analyzer. 3) Devices connected with the network port of the analyzer should conform to the requirements of National Standards GB4793.1-2007 and GB4793.9-2013 of China as well as IEC60950. 4) It is forbiden to use detachable MAINS supply cord with inadequate rating.
	**Analysis Parameters** Perform calibration for different batches of reagents. Incorrect analysis parameters can lead to wrong test results. Please consult Genrui or your reagent supplier for more information.
	**Treating Waste Analyzer** Materials of the analyzer are subject to contamination regulations. Dispose of the waste analyzer in accordance with your local or national guidelines for waste disposal.
	**Safety Summary** All safety related regulations and instructions that appear on the instrument must be observed to ensure personal safety and to prevent damage to the instrument. If used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

2. Installation

2.1. Overview

The analyzer is checked and packed with care before it is shipped from the factory. Inspect the carton carefully after arrival. If any sign of damage is found, contact Genrui or your local distributor immediately.

2.2. Installer

The analyzer should only be installed by Genrui personnel or Genrui-authorized distributor. Users should provide appropriate environment and space for the installation. When the analyzer needs to be relocated, please contact Genrui or Genrui-authorized distributor. When you received your analyzer, please immediately notify Genrui or its authorized local distributor.

2.3. Checking before Installation

Inspection for Damage

All the analyzers have been inspected strictly by Genrui before packing and shipping. When you received your analyzer, before opening the packaging, perform a thorough inspection and note whether there is any of the following damage:

1) Up-side-down or distortion of the packaging.
2) Obvious water marks on the packaging.
3) Obvious signs of being striked on the packaging.
4) Packaging shows signs of having been opened previously.

If you notice any of the above instances of damage, please immediately notify Genrui or Genrui-authorized local distributor.

If the outer packaging is intact, unpack it in the presence of Genrui staff and/or authorized distributor personnel, and conduct the following inspection:

1) Check all the parts against the packing list contained inside the packaging.
2) Check the surface of all the parts for any crack, strike or distortion.

If you notice any shipment damage or missing part, please immediately notify Genrui or Genrui-authorized local distributor.

Packing List

Check all the parts according to the packing list contained inside the packaging. If you notice any missing part, please immediately notify Genrui or its authorized local distributor.

2.4. Installation Requirements

2.4.1. Environmental Requirements

2.4.1.1. Power Supply

1) Power supply: 100-240V~, 50/60Hz, voltage fluctuation ± 10%.

2) Well-grounded, grounding resistance less than 0.1Ω.

Warning:

1) Make sure the power socket is grounded correctly. Improper grounding may lead to electric shock and/or instrument damage.

2) Be sure to connect the instrument to a power socket that meets the above mentioned requirements and has a proper fuse installed.

2.4.1.2. Site and Space

1) The ground on which the instrument is placed should be level with an incline gradient of less than 1/200 and sufficient strength to withstand a weight of 1000kg.

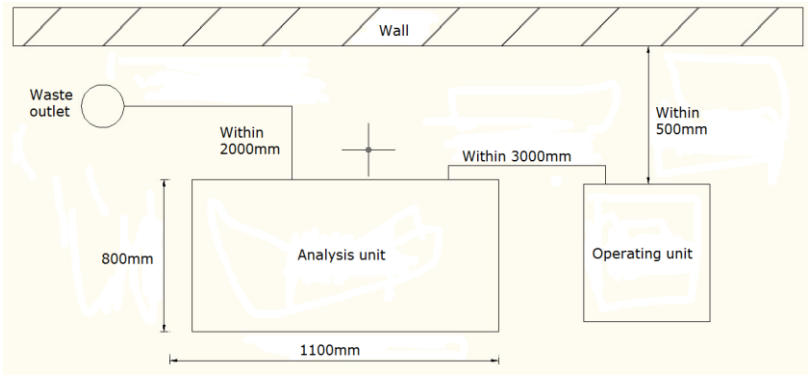
2) The environment should be free of dust as well as corrosive and flammable gases, heat and air sources, and mechanical vibration.

3) Avoid exposure to direct sunlight.

4) Air exchange with the outside through smooth airflow. The wind source does not flow directly to the analysis unit.

5) The instrument should not be placed near brush-type motors and electric contact devices that are frequently powered on and off.

6) Space requirements:



Caution:

The environment should be well ventilated. Use ventilation equipment if necessary. The wind source should not blow over the instrument directly, as this might affect reliability of the data.

2.4.1.3. Temperature, Humidity and Atmospheric Pressure

1) Ambient temperature: 10℃-30℃
2) Ambient humidity: ≤ 85%
3) Atmospheric pressure: 70.0kPa-106.0kPa

Caution:



1) Strictly follow the specified environmental requirements to store and use the instrument. Otherwise, you may not obtain reliable results.
2) If the ambient temperature and humidity does not meet the specified requirements, be sure to use air-conditioning equipment.

2.4.2. Computer Requirements

The computer must meet the relevant safety requirements.

The recommended configuration of the computer is Windows 7/ Windows 8, compatible with 32 and 64 bits, with a hard disk of 500G, a CPU clock speed of 3.30GHz, and memory of 4.0G. The computer should be equipped with a 17-inch display screen with resolution of 1440*900 pixels.

Any problem related to integration into systems or effects resulting from special conditions, please refer to the above computer requirements.

2.4.3. Connection Requirements

Pipe connection should be smooth without bending.

The power cable and the network cable can not be crossed together during connection. Do not place the cables together with the liquid pipes.

All input connections are in line with safety requirements.

2.5. Water Supply and Drainage Requirements

2.5.1. Water Supply Requirements

The quality of water supplied to the instrument should comply with CAP Class 2 water standards:

1) Particle diameter < 200μm;
2) Electrical resistivity > 0.5MΩcm;
3) Count of bacterial colonies < 10cfu/ml;
4) Soluble silicon < 0.1mg/L.

If the analyzer is directly connected to the water supply device, check whether the output water pressure is within 0.2MPa ~ 0.5MPa. Otherwise the water supply may be insufficient or the automatic water supply control can not be achieved.

Water consumption of the analyzer for 1 hour of continuous test is about 18L.

2.5.2. Drainage Requirements

1) Follow local environmental regulations to discharge waste.

2) The waste liquid discharge port must be within 15cm higher than the ground.

3) Waste liquid tube length should not exceed 2 meters.



Note: Biohazard

Treat waste liquid discharged by the analyzer according to your local waste emission standards.

2.6. Instrument Installation

1) Open the carton and check the instrument carefully, verify if the parts in the box match with the packing list. If there is any shortage or damage, contact with the suppliers in time.

2) Take out the instrument carefully after checking and then place it according to the requirements in “2.4. Installation Requirements”.

3) Take out the power cable and connect one side to the instrument’s power socket, then connect the other side to the three-line plug which has connected earth-line, the grounding impedance should be less than 0.1Ω.

4) Take out the network cable, and then connect one end to the network port of the instrument, the other end to the network port of the computer.

5) Take out the deionized water bucket, filled with water meeting the water quality requirements of “Installation Requirements”, and then put the deionized water tube and deionized water level sensor terminals into the deionized water bucket.

6) Find a waste container, connect one end of the waste liquid tube to the waste liquid outlet of the instrument and put the other end into the waste container. The waste liquid discharge port must be within 15cm higher than the ground. If you need to lengthen the waste liquid tube, the length of the tube should not be more than 2 meters.

7) To connect with the hospital laboratory system or hospital-wide system, please contact Genrui or your local distributor.

8) In order to implement certain functions, a potential reference is required for different devices to work together. In this case, equipotential bonding terminals are required to be connected. Through the equipotential bonding to suppress the potential difference, thus to eliminate the electromagnetic interference. For equipotential bonding, take out the supporting equipotential ground wire and connect it to the equipotential seat of the instrument.

9) Specification of fuse for this instrument is “250V/10A”, it is a double cap fast break glass tube lead type, the rated current is 10A and rated voltage is 250V.

10) Do not place the instrument at the site where it is difficult to operate the disconnection device.

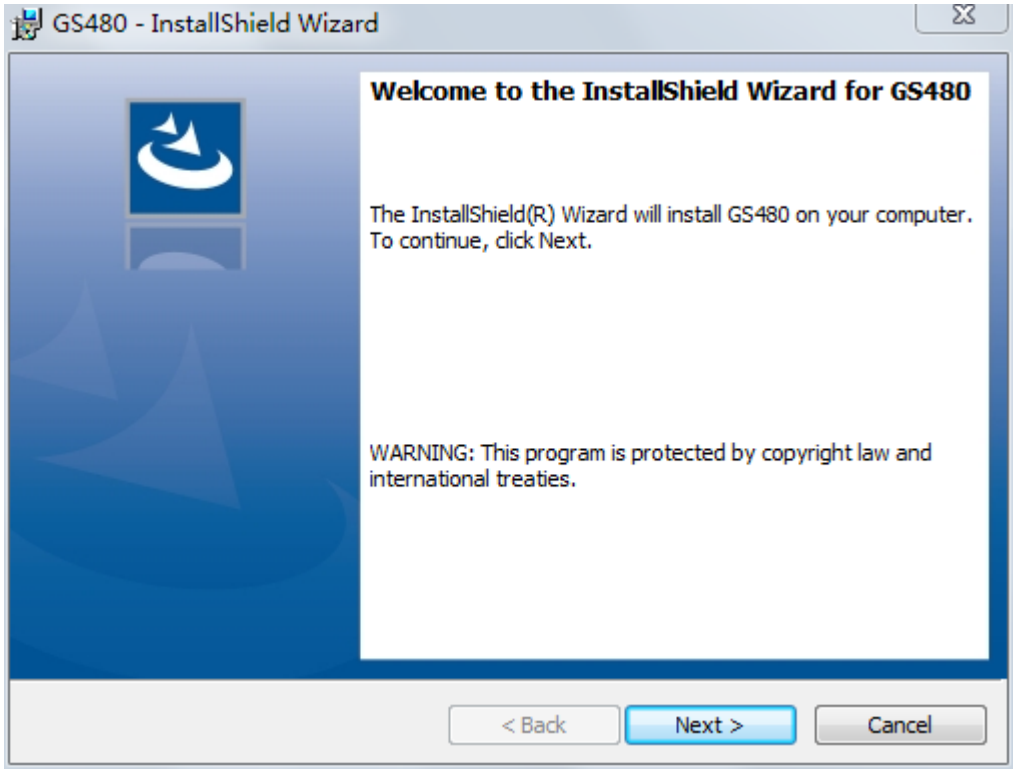
2.7. Software Installation

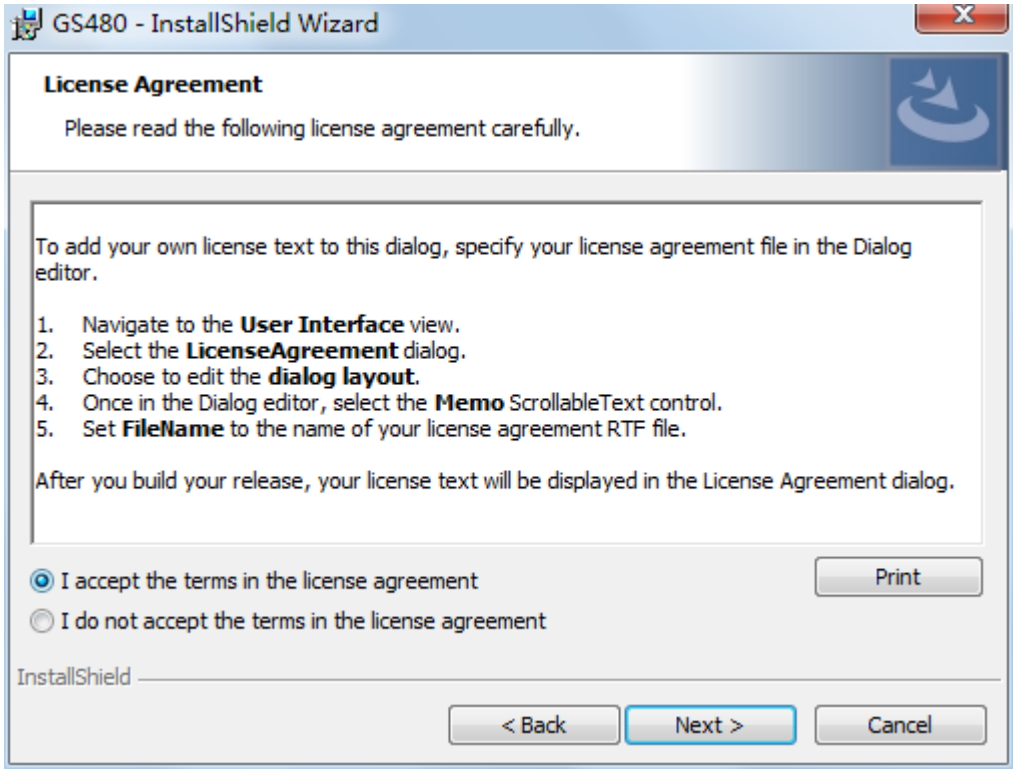
Be sure to back up your data before reinstalling the system. Otherwise, all existing data will be lost. When you install the system for the first time, you do not need to back up data.

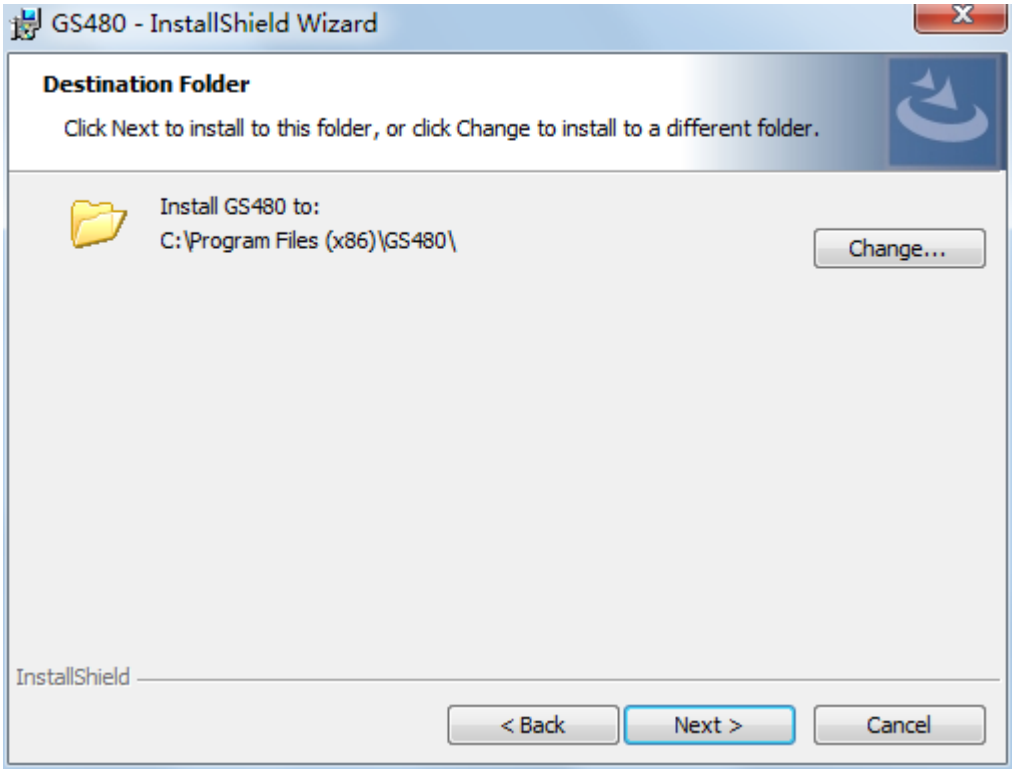
1) Operating software installation

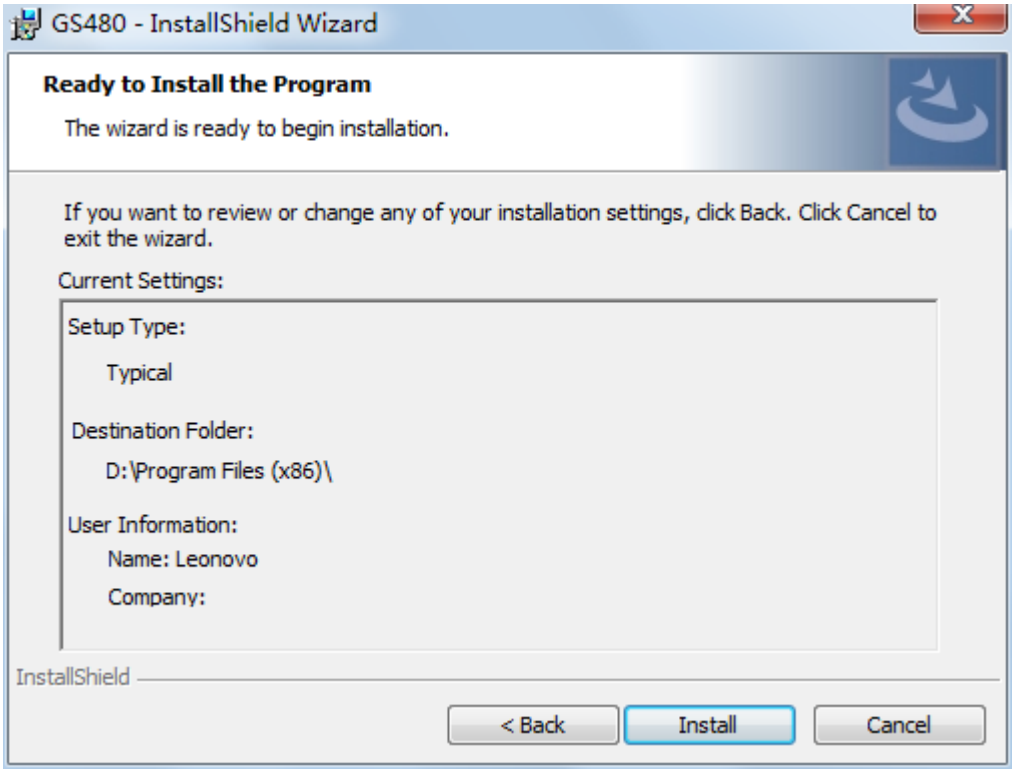
Take out the installation CD-ROM and place it into the computer CD-ROM drive (if the computer does not contain CD-ROM, you need to read the file in other CD-ROM drive and copy the file to U disk). Depending on the model, double-click the appropriate installation file (***.exe) and install the software according to the following figures:

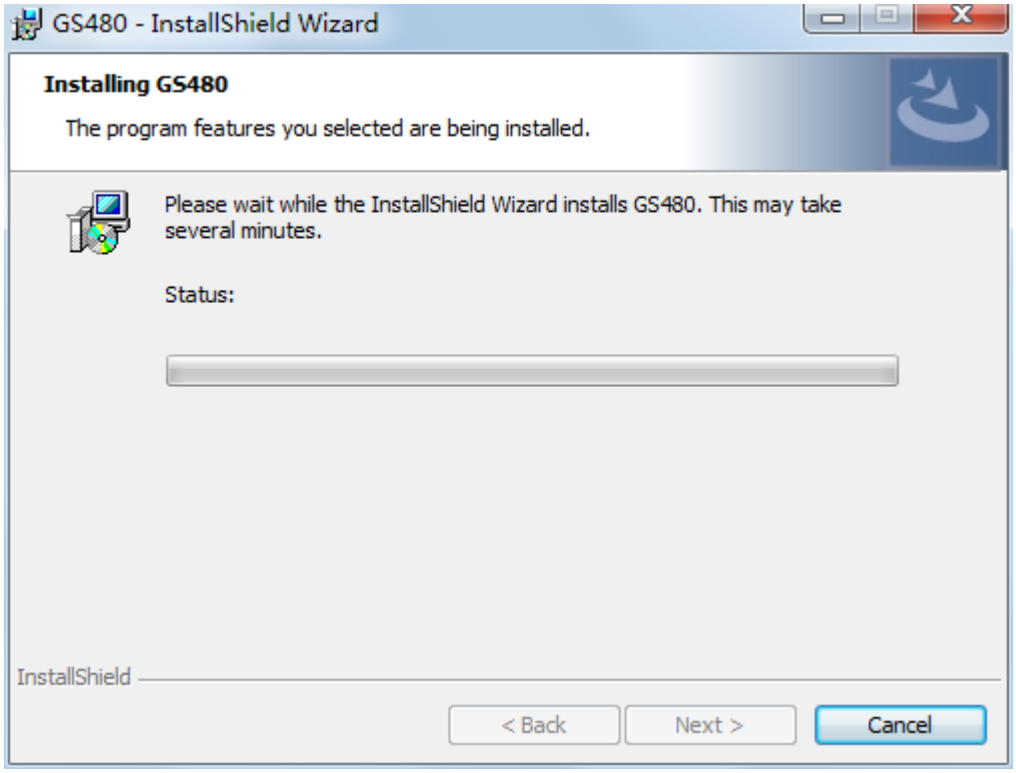


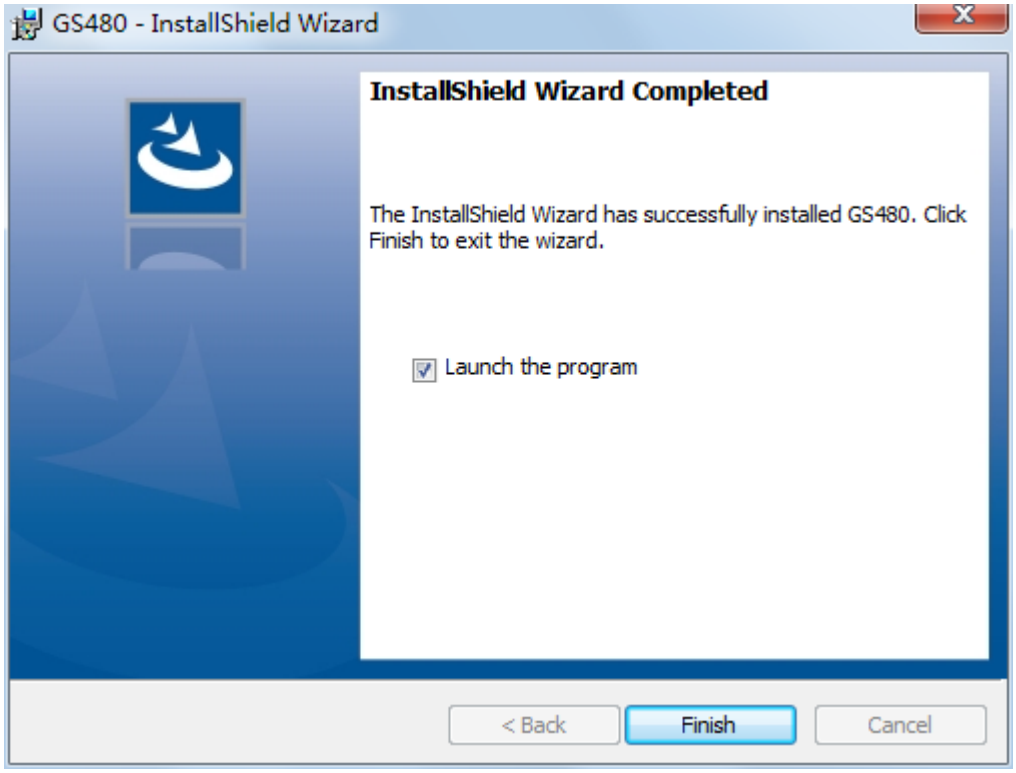

GS480 - InstallShield Wizard
Welcome to the InstallShield Wizard for GS480
The InstallShield(R) Wizard will install GS480 on your computer. To continue, click Next.
WARNING: This program is protected by copyright law and international treaties.
< Back
Next >
Cancel


GS480 - InstallShield Wizard
License Agreement
Please read the following license agreement carefully.
To add your own license text to this dialog, specify your license agreement file in the Dialog editor.
1. Navigate to the User Interface view.
2. Select the LicenseAgreement dialog.
3. Choose to edit the dialog layout.
4. Once in the Dialog editor, select the Memo ScrollableText control.
5. Set FileName to the name of your license agreement RTF file.
After you build your release, your license text will be displayed in the License Agreement dialog.
I accept the terms in the license agreement
I do not accept the terms in the license agreement
Print
InstallShield
< Back
Next >
Cancel


GS480 - InstallShield Wizard
Destination Folder
Click Next to install to this folder, or click Change to install to a different folder.
Install GS480 to:
C:\Program Files (x86)\GS480\
Change...
InstallShield
< Back
Next >
Cancel


GS480 - InstallShield Wizard
Ready to Install the Program
The wizard is ready to begin installation.
If you want to review or change any of your installation settings, click Back. Click Cancel to exit the wizard.
Current Settings:
Setup Type:
Typical
Destination Folder:
D:\Program Files (x86)\
User Information:
Name: Leonovo
Company:
InstallShield
< Back
Install
Cancel



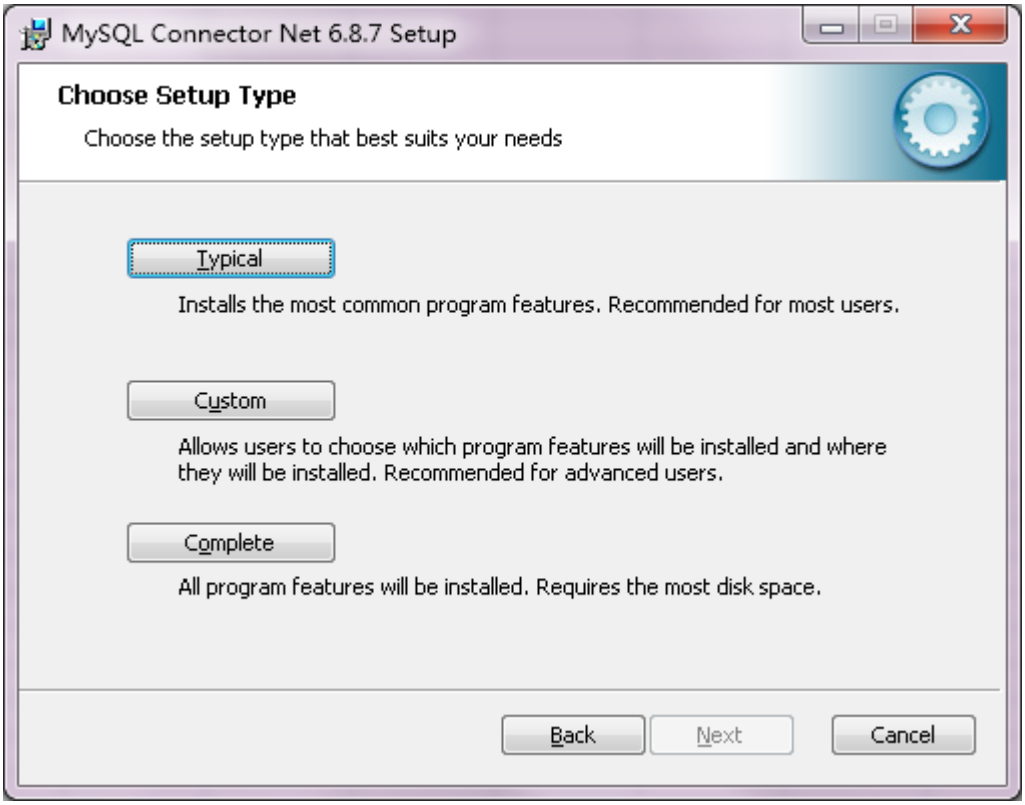


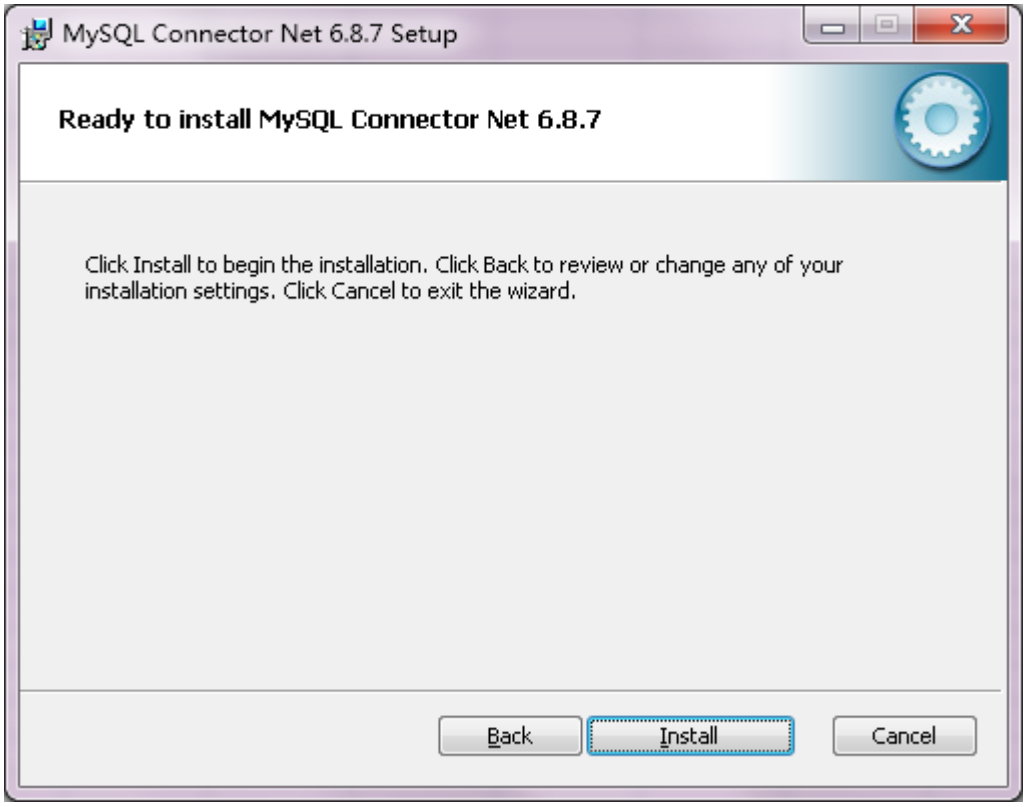
Note: Be sure to check the “Launch the program” option. Otherwise, the database may not be configured correctly.

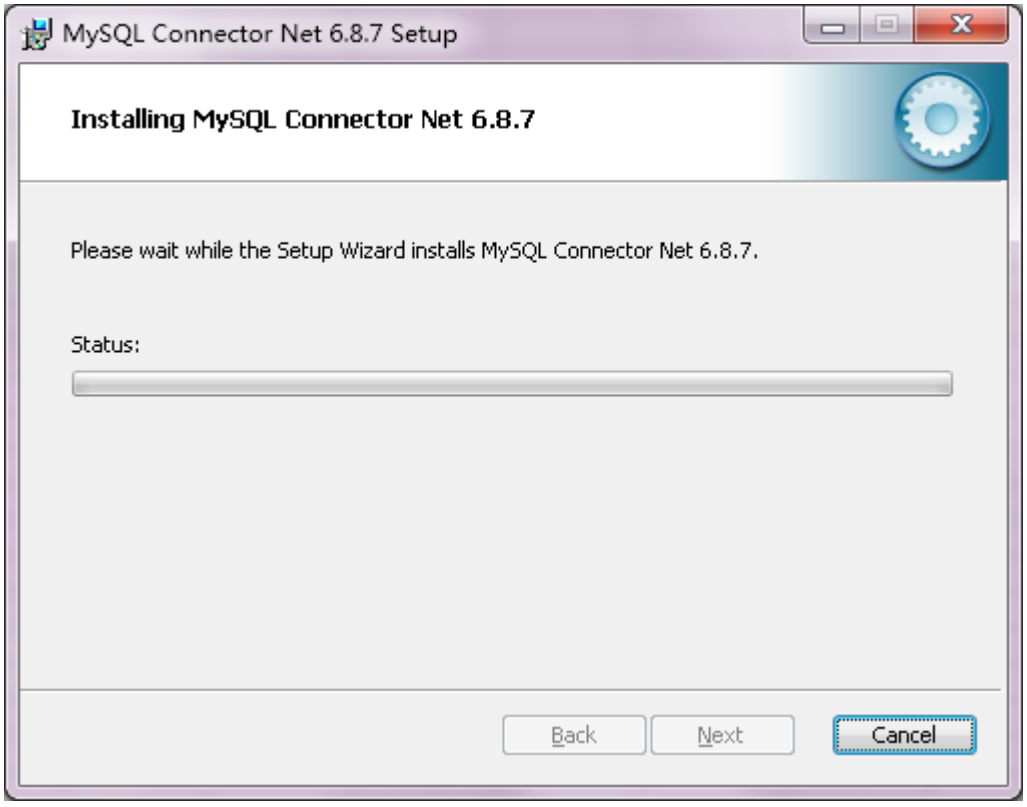
2) Database installation has the following two cases: A and B.

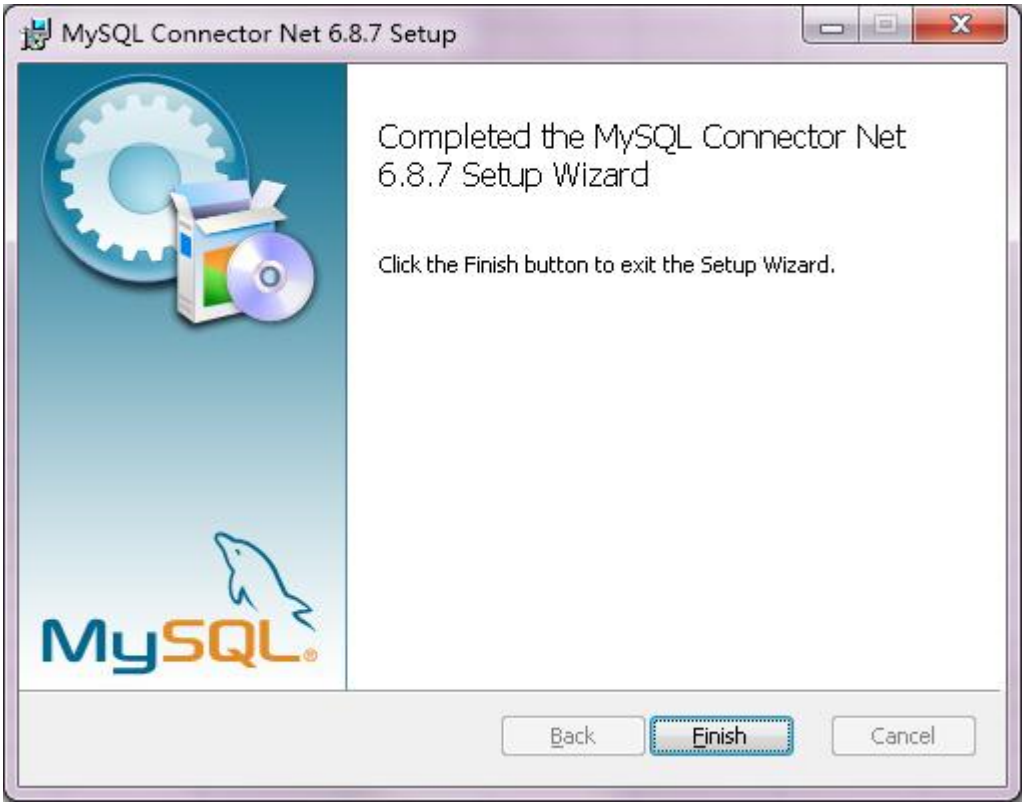


A. When the following prompt boxes appear, operate according to the instructions until it is finished.

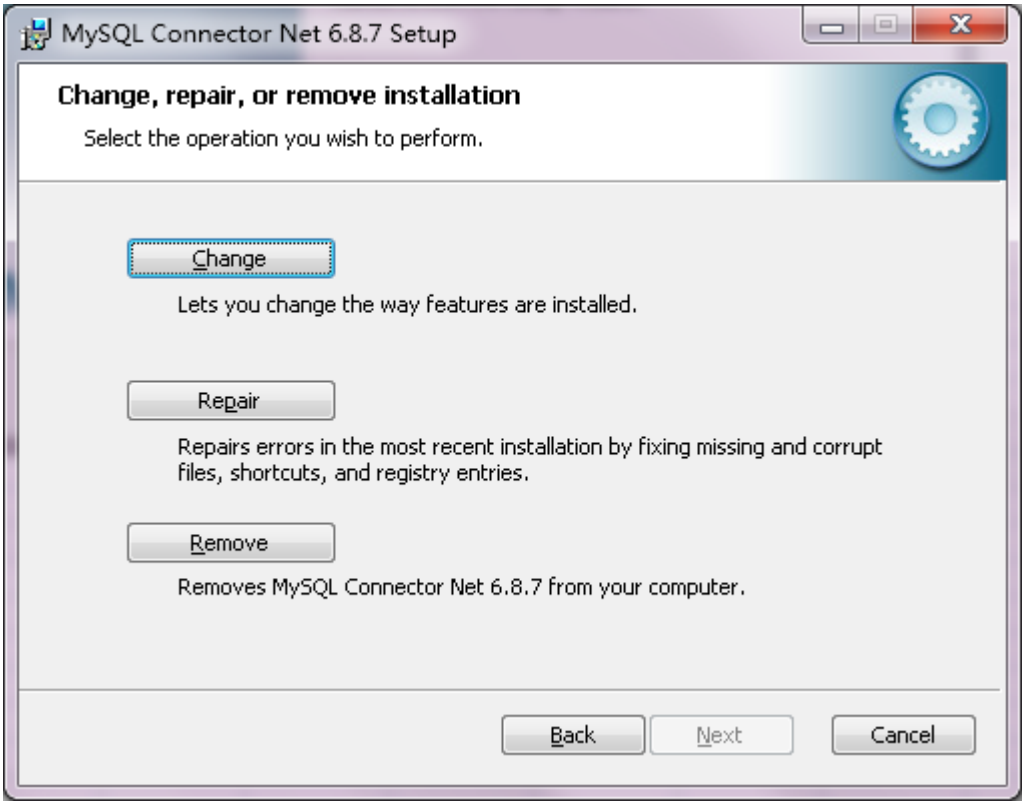


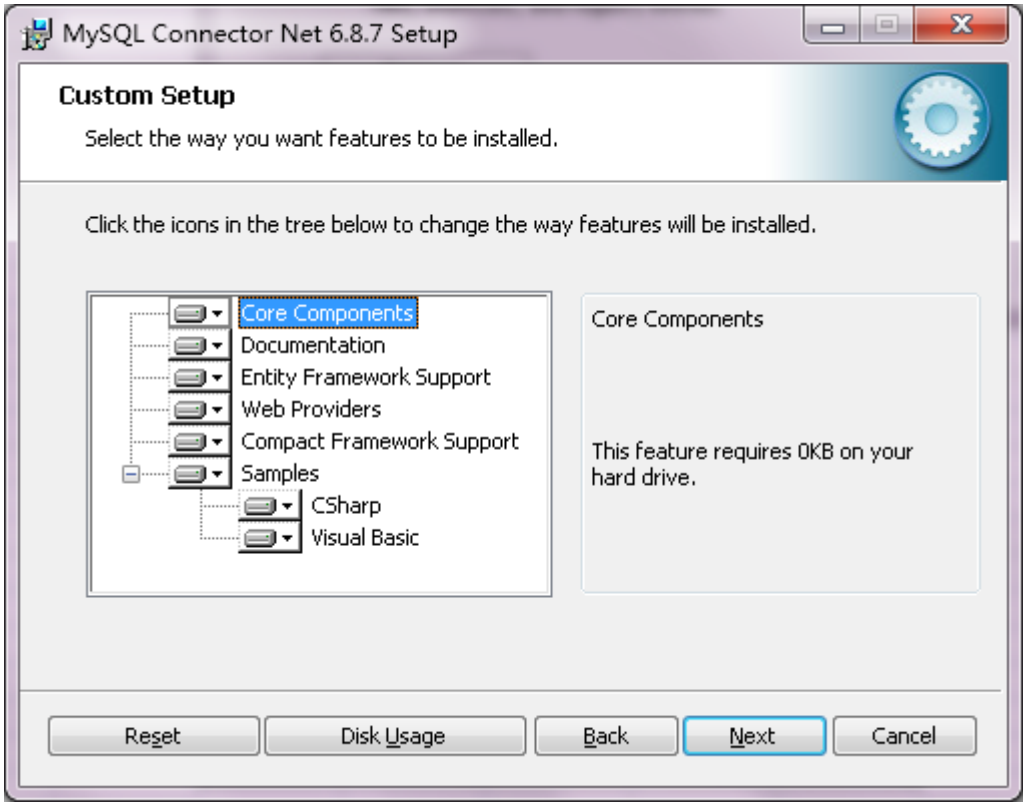

MySQL Connector Net 6.8.7 Setup
Ready to install MySQL Connector Net 6.8.7
Click Install to begin the installation. Click Back to review or change any of your installation settings. Click Cancel to exit the wizard.
Back
Install
Cancel

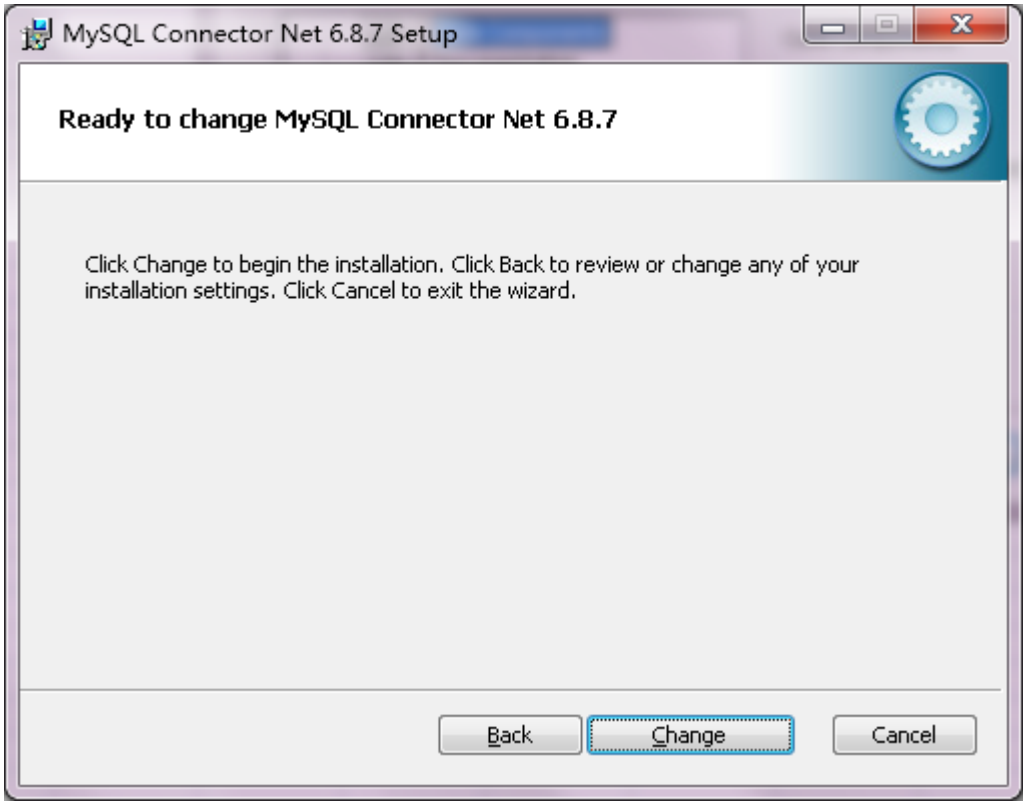

MySQL Connector Net 6.8.7 Setup
Installing MySQL Connector Net 6.8.7
Please wait while the Setup Wizard installs MySQL Connector Net 6.8.7.
Status:
Back
Next
Cancel

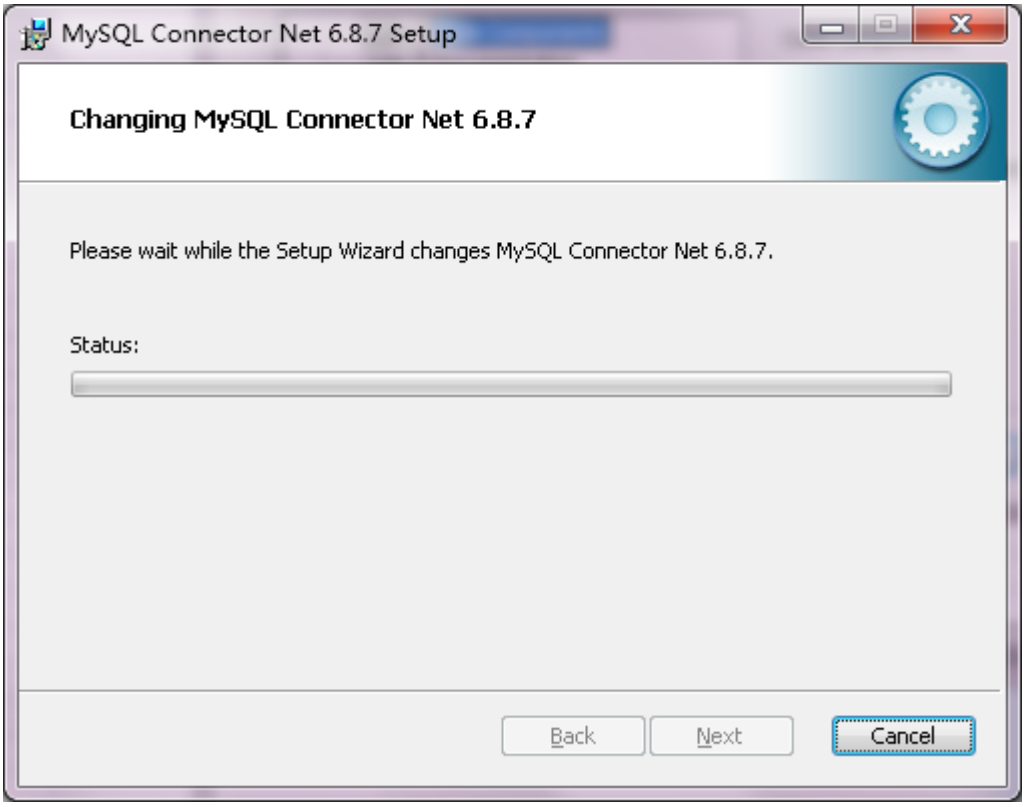


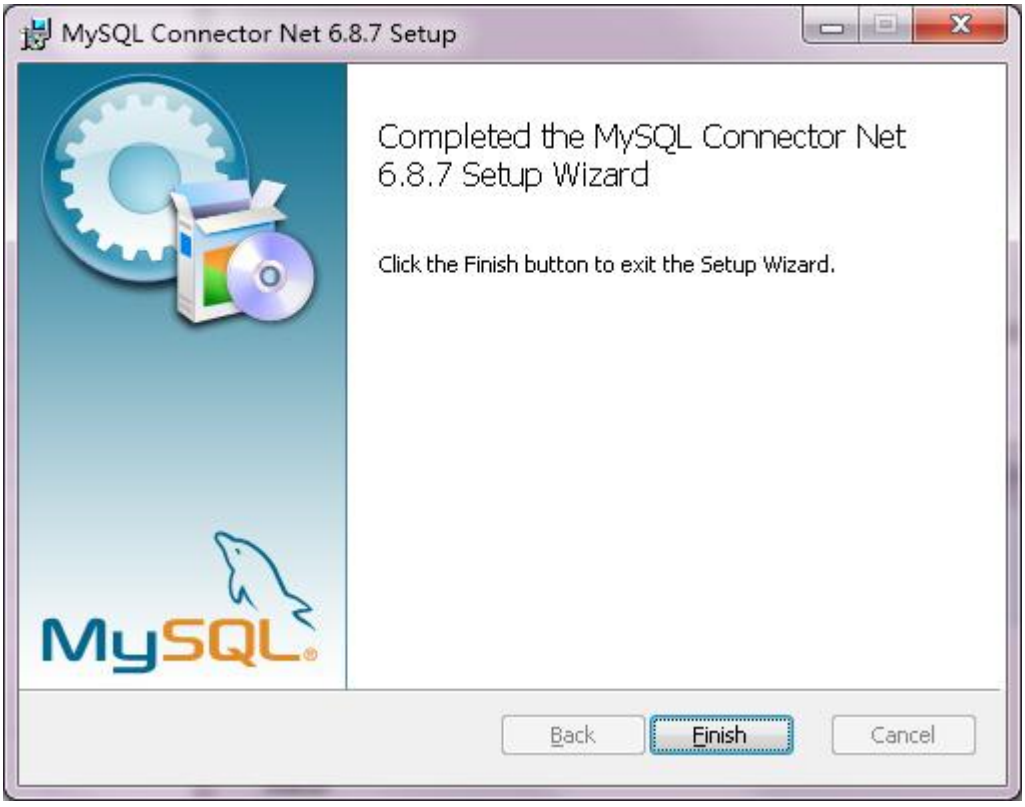
B. When the installation data appears the following prompt boxes, operate according to the instructions until it is finished.



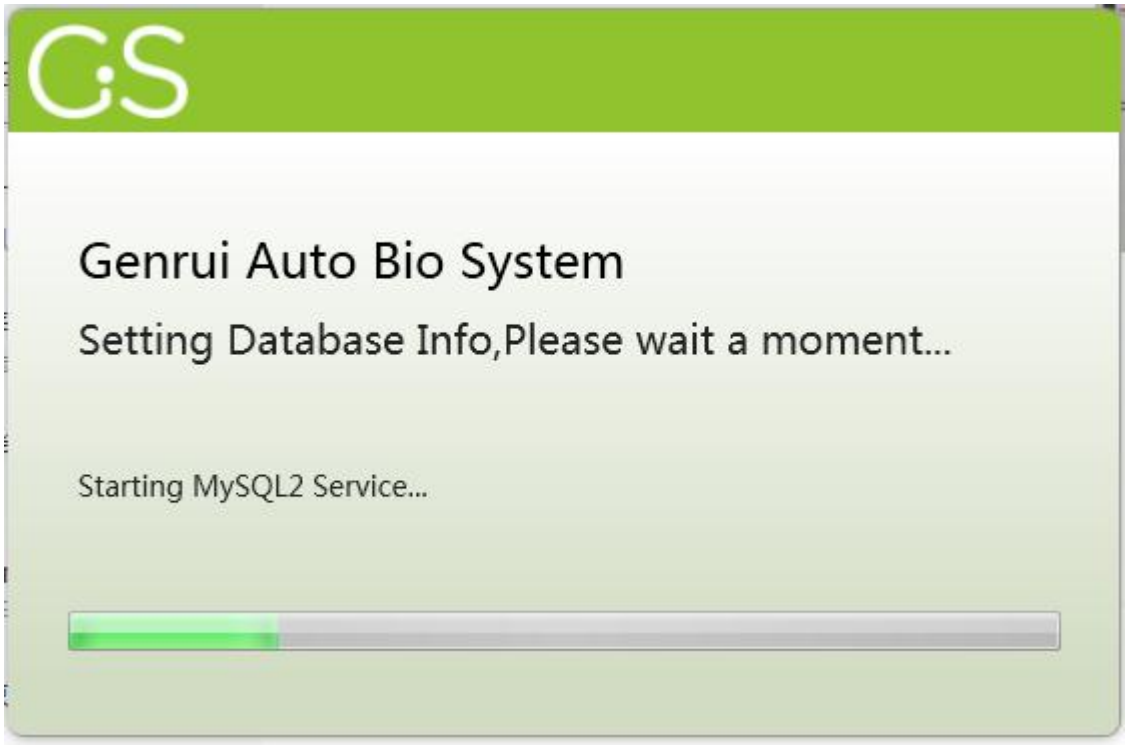

MySQL Connector Net 6.8.7 Setup
Custom Setup
Select the way you want features to be installed.
Click the icons in the tree below to change the way features will be installed.
Core Components
Documentation
Entity Framework Support
Web Providers
Compact Framework Support
Samples
CSharp
Visual Basic
Core Components
This feature requires 0KB on your hard drive.
Reset
Disk Usage
Back
Next
Cancel


MySQL Connector Net 6.8.7 Setup
Ready to change MySQL Connector Net 6.8.7
Click Change to begin the installation. Click Back to review or change any of your installation settings. Click Cancel to exit the wizard.
Back
Change
Cancel

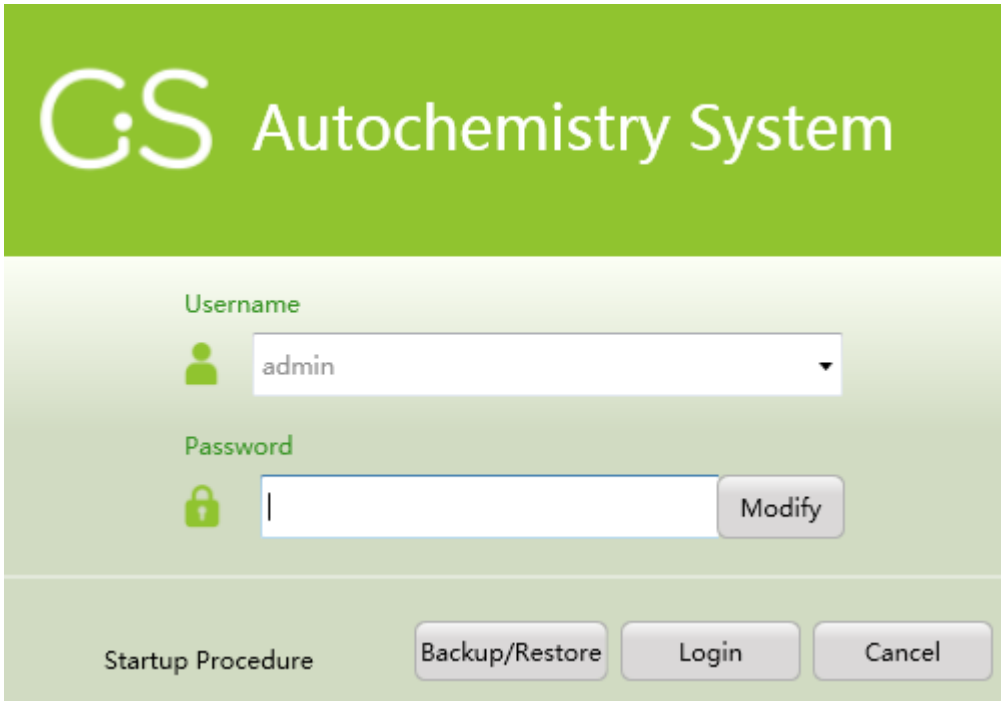




3) Click “Finish”, the following interface pops up:



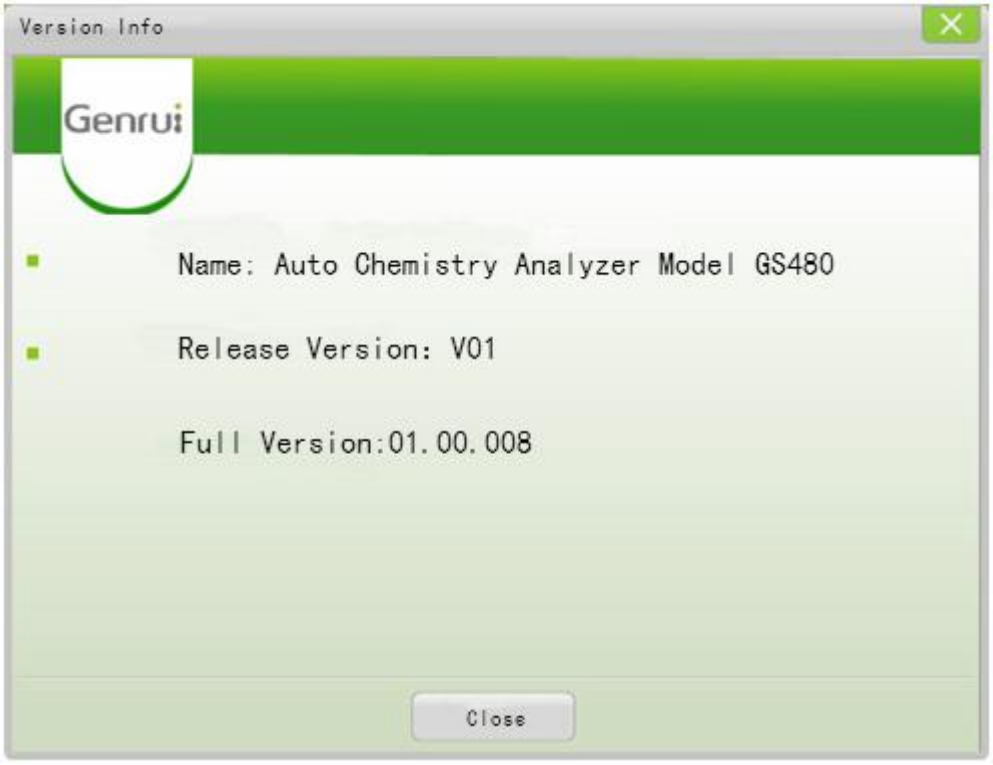
4) After the system auto-configuration completes, the following prompt box will pop up:



You can login to the system with the default password of 123456.

2.8. Software Version Information

The information of the software version applies to manual of this version is as shown below:



2.9. Checking after Installation

Before doing tests, check whether the pipe and cable connections are reliable. Check if the function of the analyzer is correct, if incorrect, it may cause a hazard.

3. System Description

This chapter mainly introduces the basic performance and parameters, structure and function of the analyzer.

3.1. Basic Performance and Parameters

3.1.1. Basic Performance

Stray light	Absorbance ≥ 2.5
Absorbance linearity	Maximum absorbance ≥ 3.5 when the relative bias within the range of ± 5%
Absorbance accuracy	Deviation ≤ ±0.015 when the absorbance is 0.5 Deviation ≤ ±0.025 when the absorbance is 1.0
Absorbance stability	Change in absorbance should not be greater than 0.005
Absorbance repeatability	Indicate by the coefficient of variation, ≤ 1.0%
Temperature accuracy and fluctuation	Deviation ≤ ±0.2℃, fluctuation ≤ ±0.1℃
Sample carryover	≤ 0.5%
Sampling deviation and CV	Test the nominal minimum and maximum sample volume and sample volume close to 5μl, the sampling accuracy error does not exceed ± 5%, the coefficient of variation does not exceed 2%
Clinical intra-assay precision (CV%)	ALT ≤ 5%, TP ≤ 2.5%, BUN ≤ 2.5%
Throughput	Constant speed, 400 tests/hour

3.1.2. Basic Parameters

Wavelength selector	Grating type
Absorption cell type	Array type
Analysis method	End-point method, two-point method, kinetic method, support for dual-reagent and dual-wavelength
Reaction disk	120 cuvettes, optical path: 6mm
Usage mode of cuvettes	Semi-permanent plastic cuvettes, automatic cleaning, recycling
Sample volume	2μL-60μL, with increment of 0.1μL
Reagent volume	20μL-500μL, with increment of 1μL
Sample probe, reagent probe	Have liquid level detection and full range anti-collision function
Wavelength	340nm-850nm
Power	Maximum of 1100VA
Dimension	1110mm × 800mm × 1200mm (Width × Depth × Height)
Net weight	210Kg

3.2. Structure and Function

The analyzer consists of two major components: an analysis unit and an operating unit. The analysis unit automatically completes the operational process for each test, including loading of the first reagent, sample loading, sample stirring, loading of the second reagent, stirring of the second reagent and absorbance measurements performed during the reaction process. The operating unit drives and controls the analysis unit during the completion of all analysis procedures.

3.2.1. Composition of the Analysis Unit

3.2.1.1. Overall Structure



Figure 3-1: Diagram of the Overall Structure of the Analysis Unit

1. Main enclosure
2. Air spring
3. Tension spring
4. Reagent loading mechanism
5. Sample stirring mechanism
6. Reagent disk
7. Sample loading mechanism
8. Reagent stirring mechanism
9. Sample disk
10. Cleaning mechanism
11. Reaction disk
12. Left front cover
13. Right front cover

3.2.1.2. Front Structure



Figure 3-2: Diagram of the Front Structure of the Analysis Unit (Door closed)



Figure 3-3: Diagram of the Front Structure of the Analysis Unit (Door open)

1. Reagent syringe pump
2. Sample syringe pump
3. Deionized water, deionized water level sensor terminal
4. Deionized water bucket
5. Wash solution syringe pump
6. Hot water washing syringe pump

3.2.1.3. Rear Structure

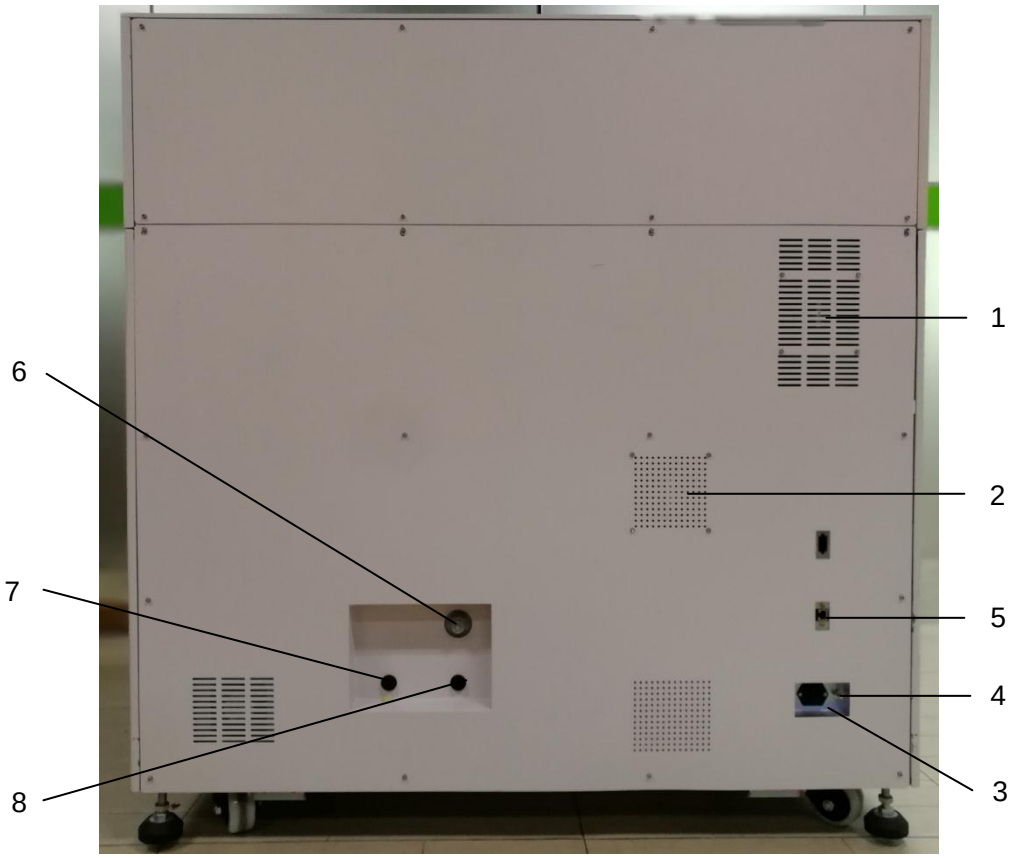


Figure 3-4: Diagram of the Rear Structure of the Analysis Unit

1. Cooling module air vent
2. Power module air vent
3. Power socket
4. Protective ground terminal
5. Network communication port
6. Low concentration waste liquid outlet
7. High concentration waste liquid outlet
8. Deionized water inlet

3.2.1.4. Structure of the Left Side of the Analysis Unit

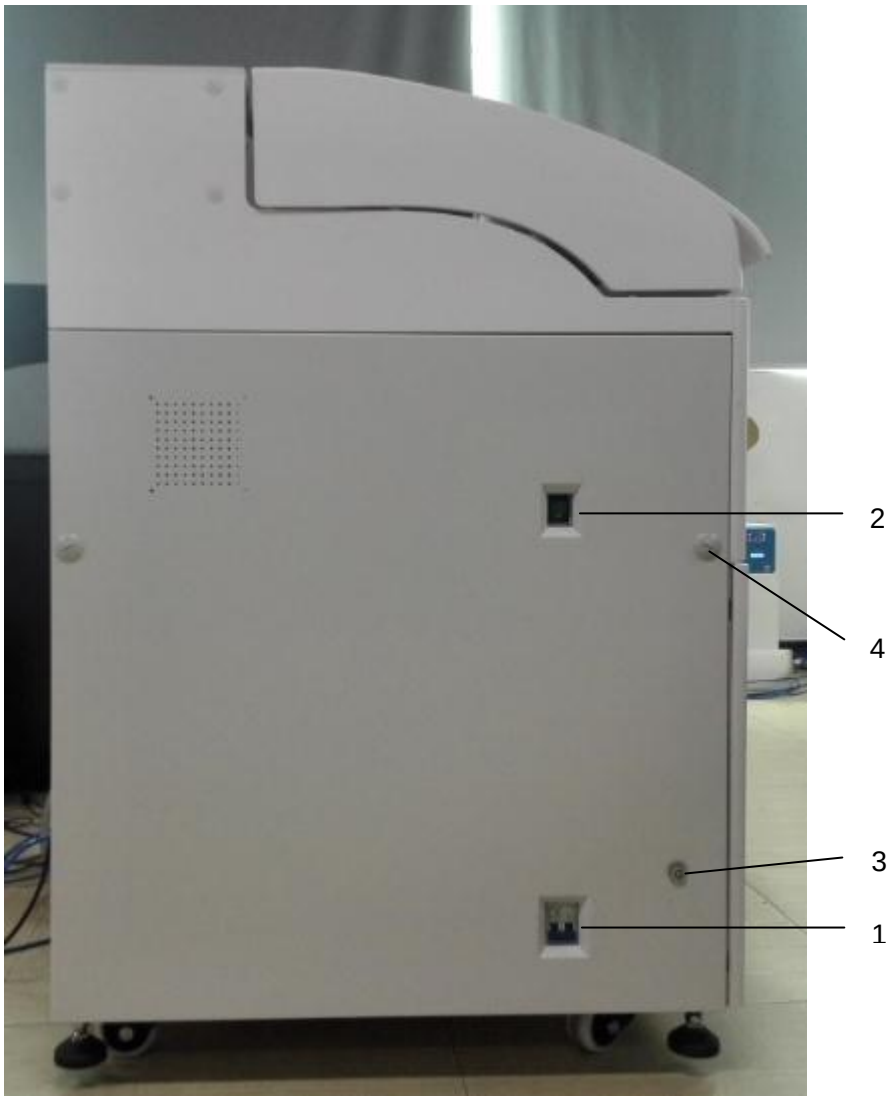


Figure 3-5: Diagram of the Left Side Structure of the Analysis Unit

1. Main power switch
2. Analysis unit power switch
3. Cam lock
4. Side cover hole cap

3.2.1.5. Structure of the Right Side of the Analysis Unit

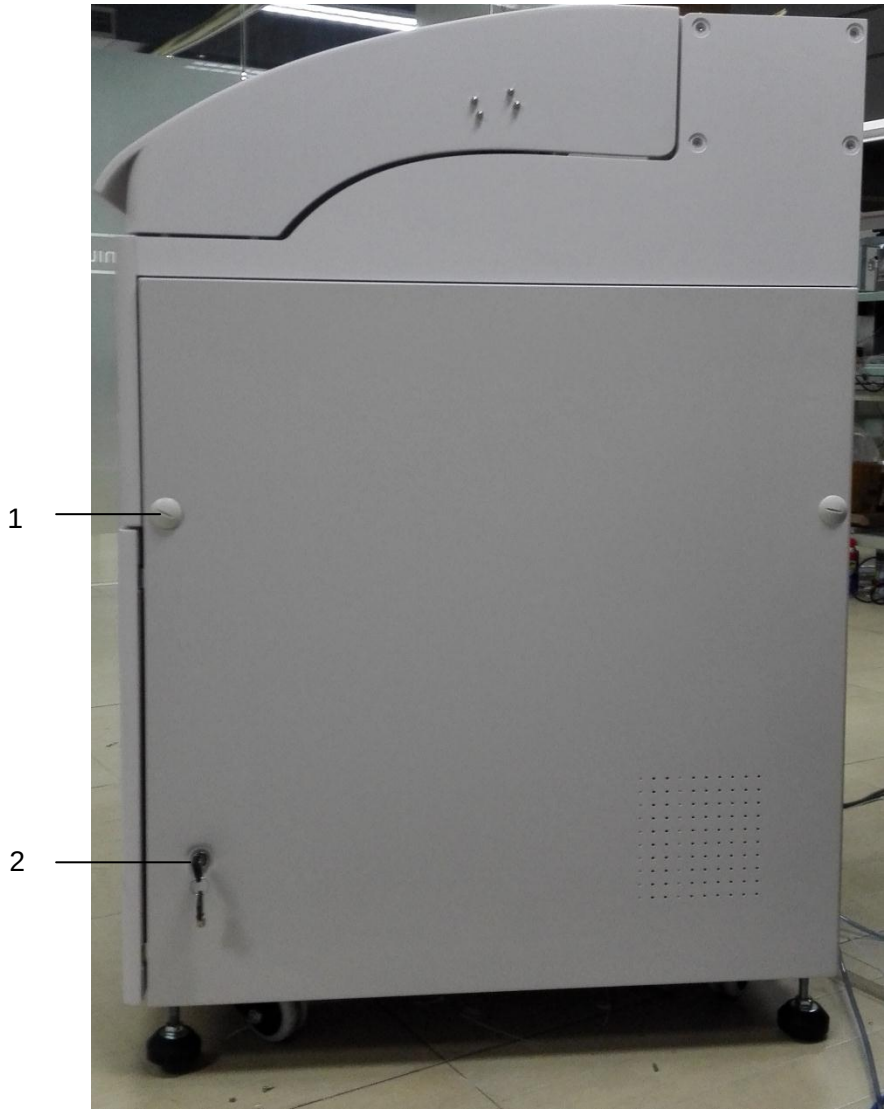


Figure 3-6: Diagram of the Right Side Structure of the Analysis Unit

1. Side cover hole cap 2. Cam lock

3.2.2. Function Module

3.2.2.1. Sample Disk

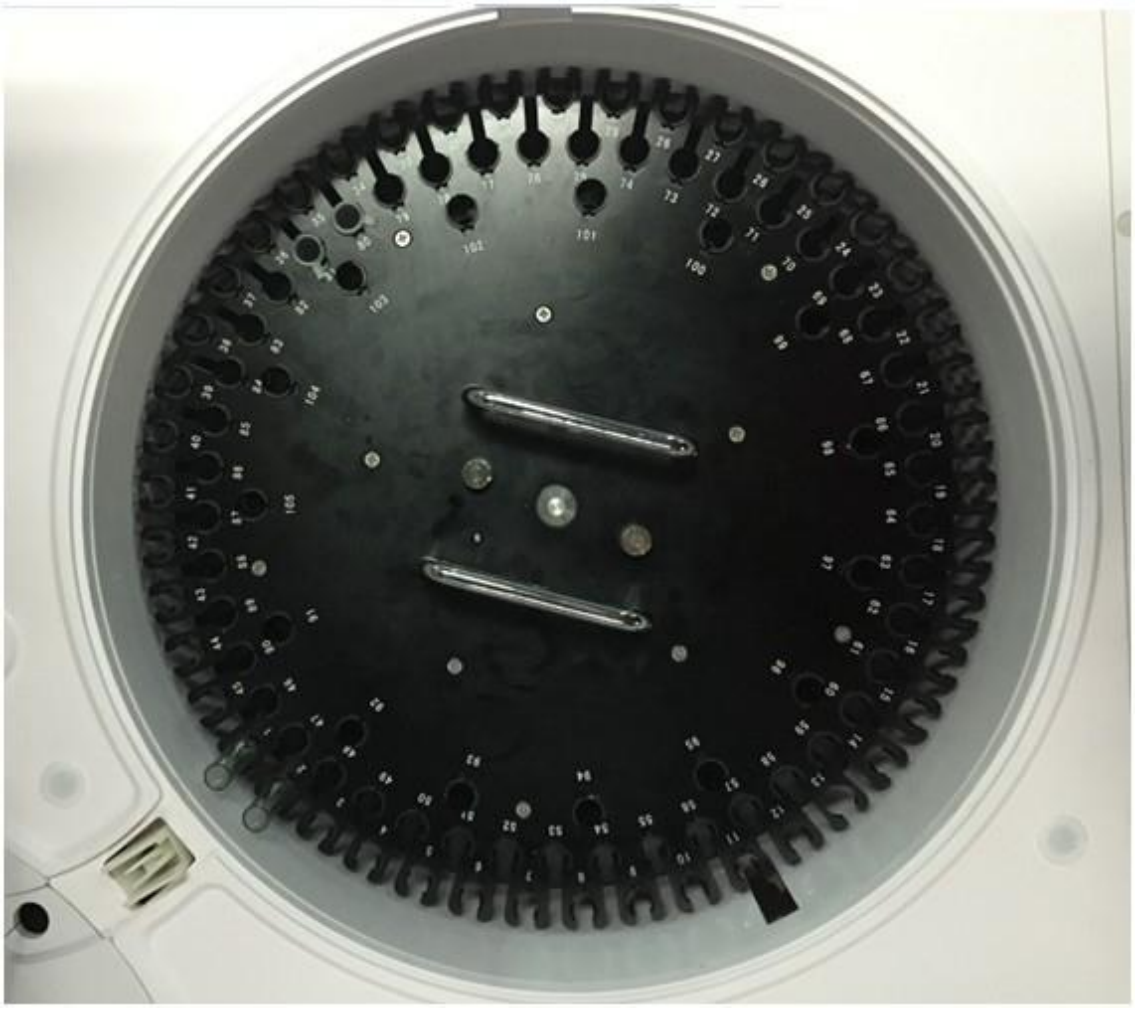


Figure 3-7: Structure of Sample Disk

a. Function

Hold sample tubes

b. Specification

Disk shape, with 105 positions

c. Action

Rotate the specified sample cuvette to the bottom of sample probe.

3.2.2.2. Reagent/Sample Aspiration Mechanism

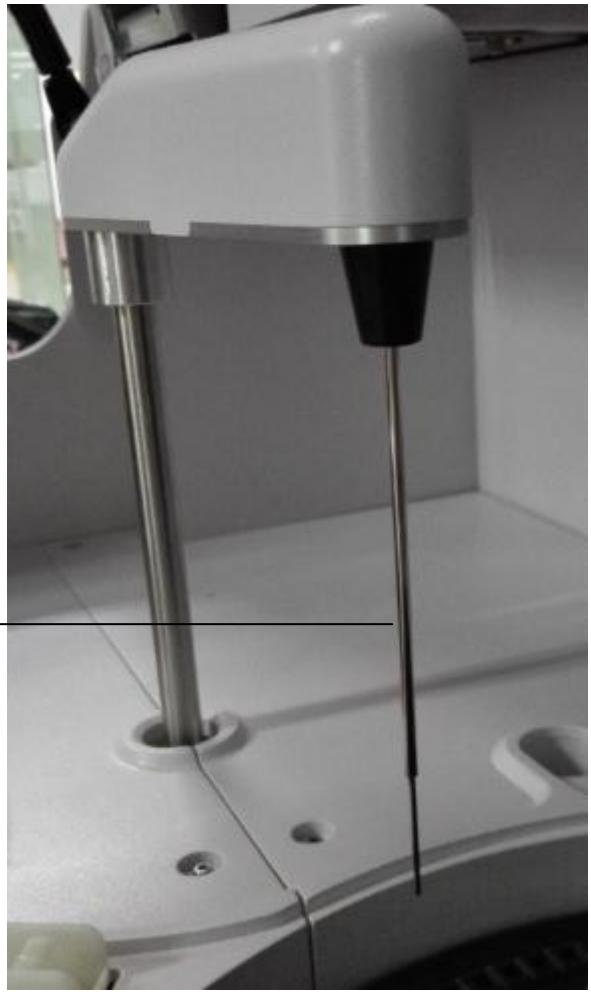


Figure 3-8: Aspiration Mechanism

a. Function

Aspirate a predetermined volume of reagent/sample from a reagent bottle/sample tube and discharge the reagent/sample into a cuvette.

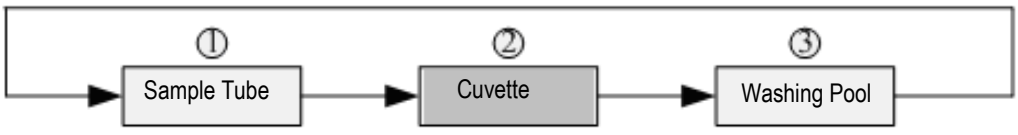
b. Specification

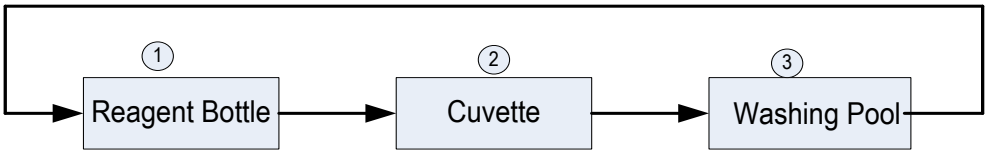
Reagent: 20-500μL, in 1μL increments

Sample: 2-60μL, in 0.1μL increments

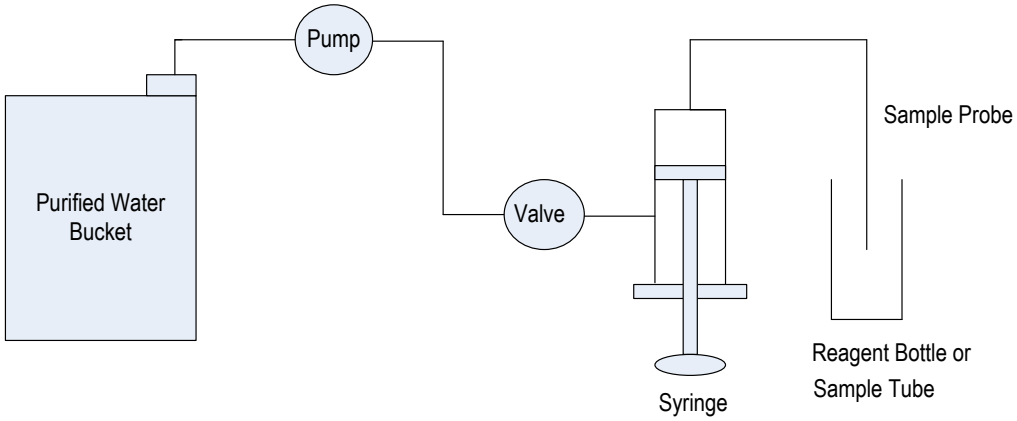
c. Action

Lower or rise in the following positions





d. Fluid Line Diagram



3.2.2.3. Reagent Disk

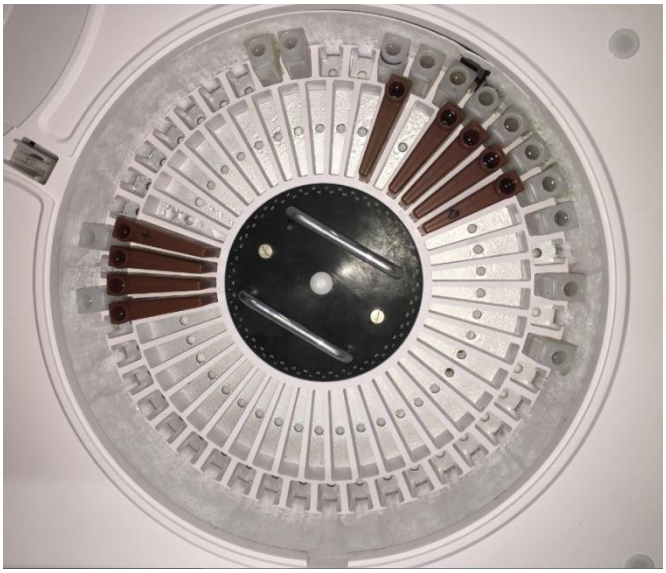


Figure 3-9: Structure of Reagent Disk

a. Function

Hold various reagent bottles

b. Specification

Disc with two concentric circles for a total of 90 positions

c. Action

Rotate the specified reagent bottle to the bottom of sample probe

3.2.2.4. Reaction Disk

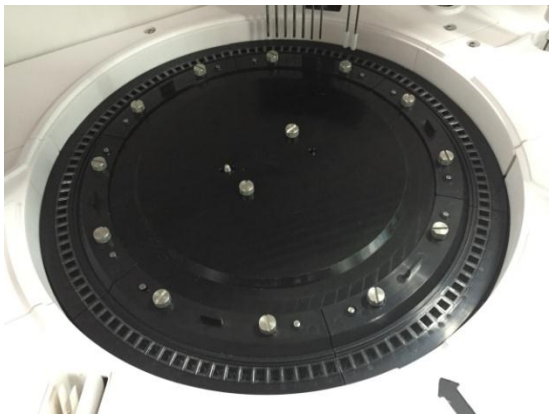


Figure 3-10: Structure of Reaction Disk

a. Function

Hold cuvettes and allow the sample and reagents to react at 37℃ in the incubator. Colorimetry measurements are carried out directly using the cuvette.

b. Specification

Number of cuvettes: 120, Optical path: 6mm

Cuvette materials: Semi-permanent specialty plastic

c. Action

Clockwise and counterclockwise rotation

3.2.2.5. Reaction Incubator

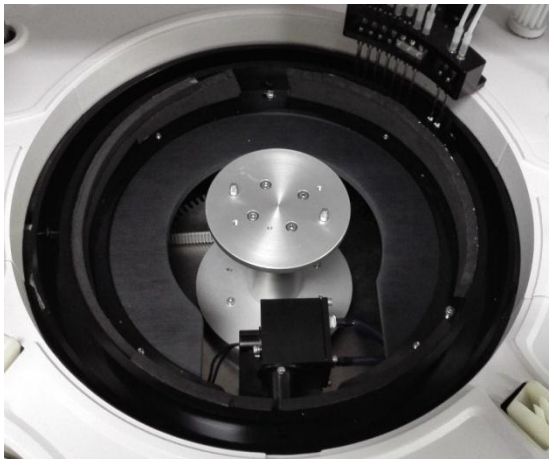


Figure 3-11: Structure of Reaction Incubator

a. Function

Keep the reaction liquid in the cuvettes at 37℃

b. Specification

Preset temperature: 37℃ Temperature fluctuation: ±0.1℃

3.2.2.6. Cuvette Cleaning Mechanism

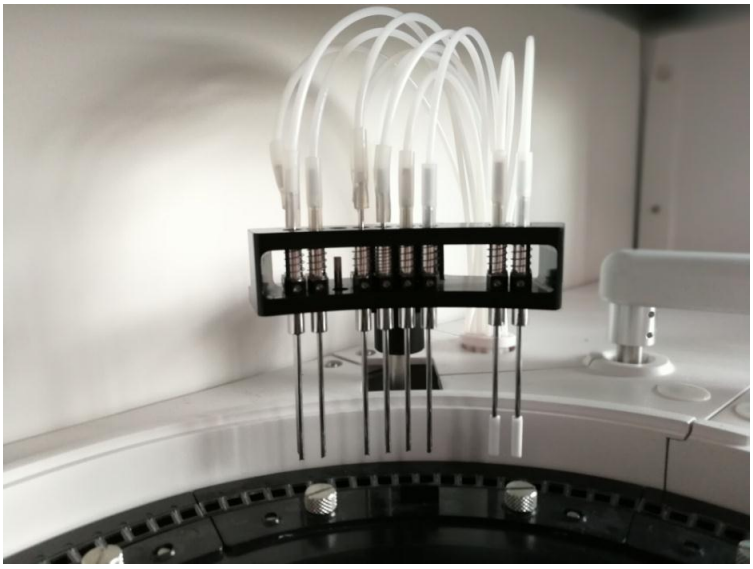


Figure 3-12: Cuvette Cleaning Mechanism

a. Function

Aspirate the reaction liquid from the cuvette and dispense deionized water to it, and then drain the water in the cuvette.

b. Specification

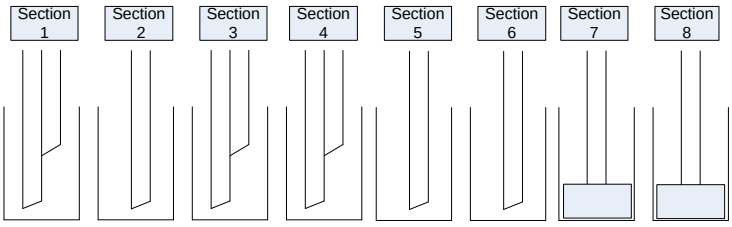
There are a total of 8 cleaning heads, of which:

- Section 1: Aspirate the reaction liquid and dispense the deionized water
- Section 2: Aspirate the former wash solution
- Section 3: Aspirate the former wash solution and dispense the deionized water
- Section 4: Aspirate the former deionized water and dispense the deionized water
- Section 5: Wipe out the residual deionized water on the wall of the cuvette
- Section 6: Dispense the heated deionized water into the cuvette
- Section 7: Aspirate the residual deionized water in the cuvette
- Section 8: Wipe out the residual deionized water on the wall of the cuvette

c. Action

Lower or rise in the fixed positions

d. Schematic diagram



3.2.2.7. Stirring Mechanism

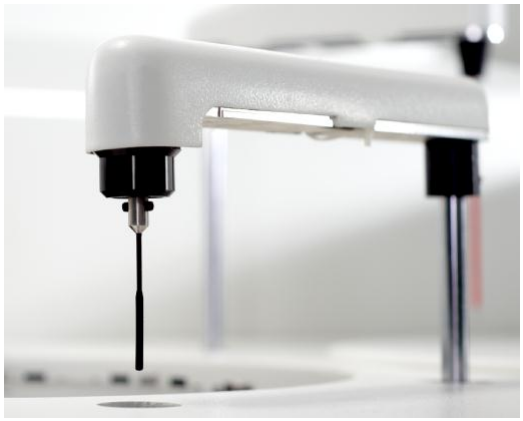


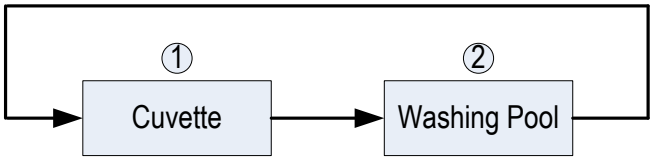
Figure 3-13: Stirring Mechanism

a. Function

Stir the reaction liquid in the cuvettes

b. Action

Lower, turn or rise in the following positions



3.2.2.8. Photometer

a. Function

Measure the absorbance of the reaction liquid in the cuvettes during rotation of the reaction disk.

b. Specification

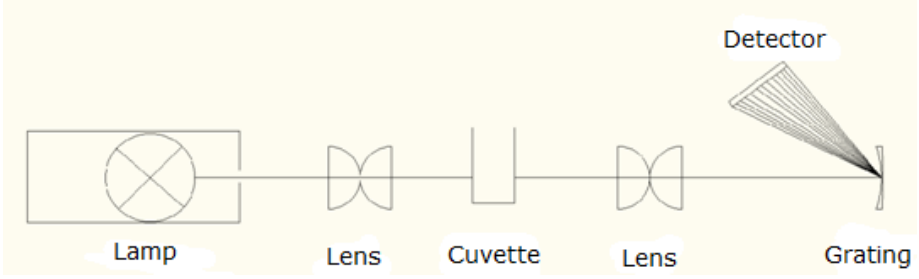
Wavelength: From 340nm to 850nm

Number of wavelengths that can be measured simultaneously: One or more

Detector: Photodiode array

Light source: halogen lamp, 12V 20W

c. Schematic diagram



4. Basic Operations

All pictures shown in this chapter are examples only; please perform operations according to the actual interface displayed.

4.1. Overview

This chapter describes the basic operation process of the system. After learning the content of this chapter, users will be able to use this system to complete the basic daily operation process.

4.2. Daily Operation Process

1) Test preparation

In order to meet test conditions of the instrument, carry out the necessary preparations before starting the test.

2) Test and analysis

Follow the correct test procedures to do the tests and perform query, edit, output and other operations of the test results.

3) Work after analysis

Other work needed to be done after analysis.

4.3. Preparation for Analysis

4.3.1. Initial Checks

1) Check to make sure the power supply is energized and capable of providing the correct voltage.
2) Check to make sure that the communication cable and power cable are connected and not loosened.
3) Check to make sure that the deionized water and wash solution pipes at the rear of the instrument are properly connected and their remaining volumes are sufficient.
4) Check to make sure the waste liquid container is not full, if full, deal with it in time.
5) Check to make sure the sensor line, ground terminal or other devices are properly connected.

4.3.2. Starting Up

When the system is charged with electricity, turn on the main power and then the working power.

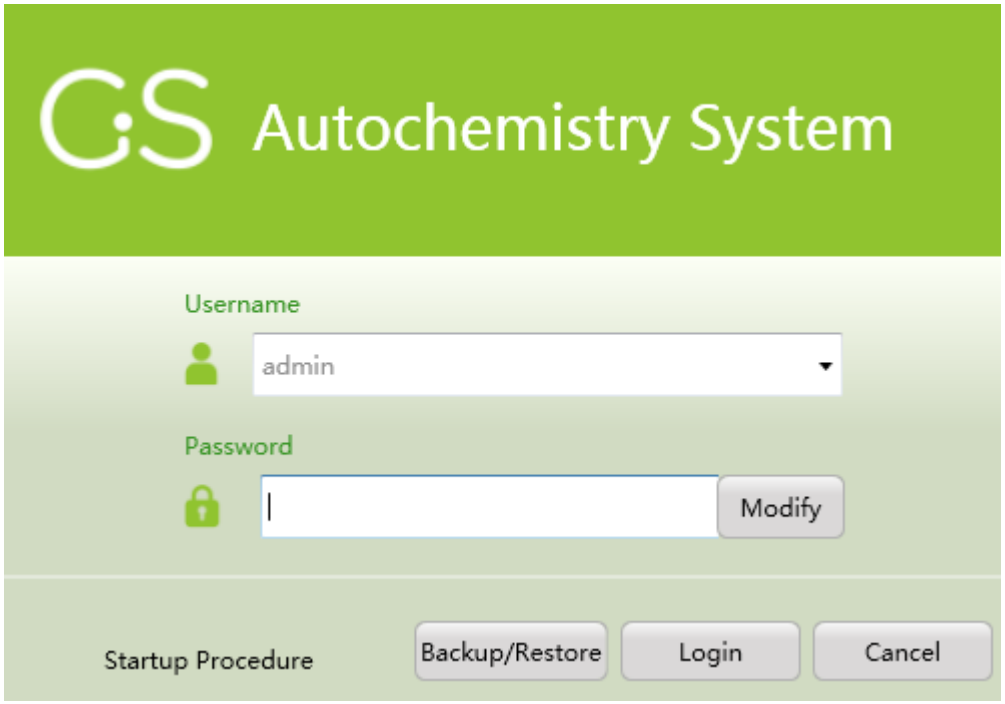
4.3.3. Opening the Front Panel

Hold the window cover and turn it 90 degrees upward to open it.

4.4. Detailed Operating Procedure

4.4.1. Starting the Operating Software

Double-click the shortcut icon of the operating software to enter the user login interface. Enter the appropriate username and password, you can log on to the software. In the login screen, you can also select the startup procedure, modify the password and backup/restore the database.



4.4.2. Interface Layout

The operating interface of the analyzer includes a function menu area, function display area, message alert area, status bar and shortcuts area. These are described in detail below.

4.4.2.1. Function Menu Area

There are 7 major menus within the operating system:

1) Test Request
2) Working Condition
3) Query Results
4) Statistics
5) Parameter Setting
6) System Setup
7) System Maintenance

4.4.2.2. Function Display Area

This area displays information such as various data for corresponding menus when you click on a function menu or submenu.

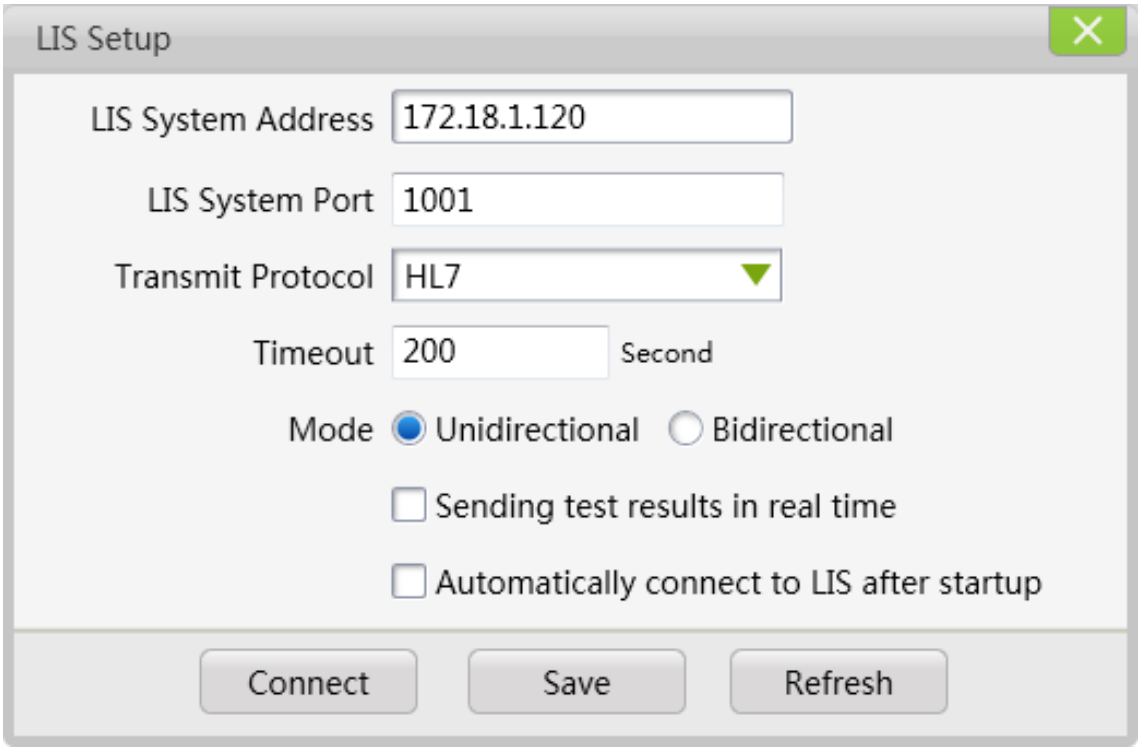
4.4.2.3. Message Alert Area

When using certain functions such as requesting tests, etc. or if the system malfunctions or experiences an error, the information bar will display corresponding information or warnings; the following function buttons are available:

1) “<”, “>”: View the “previous” or “next” message.
2) “C”: Clear the current message.
3) “A”: Error log. Click to view information recorded by the system related to various errors.
4) “V”: Check the software name and version information.
5) “?”: View help information.

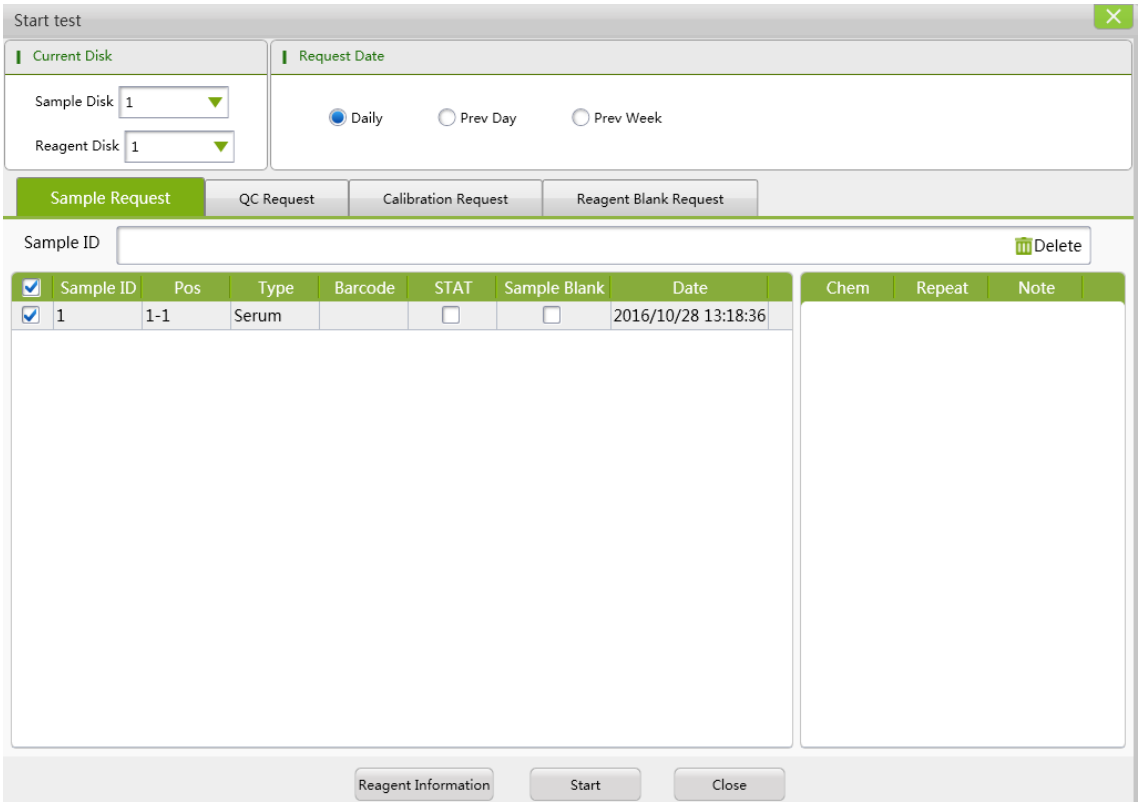
4.4.2.4. Status Bar

This area displays the lamp, temperature, wash solution, waste liquid container and LIS connection status. Lamp, temperature, wash solution and waste liquid container statuses are directly displayed as icons and cannot be interacted with. Click LIS icon to open the LIS Setup dialog box where you can setup and connect to LIS, as shown below:



4.4.2.5. Shortcut Menu Area

1) Start: Click  button to bring up the start test interface, as shown below:



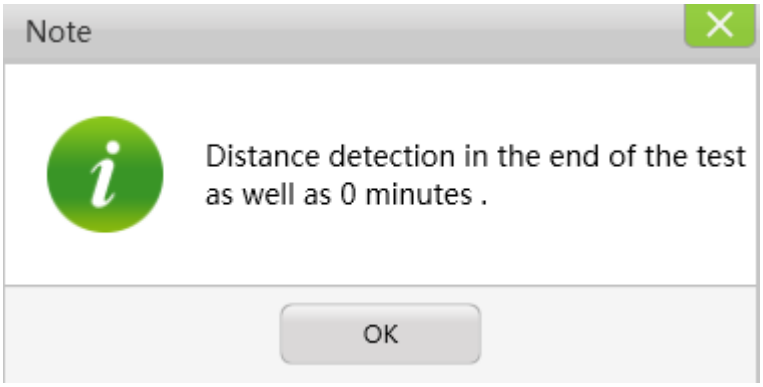
(1) Select the desired sample disk, reagent disk and request date.

(2) Select the type of test.

(3) Enter the sample ID range needed to start the test or directly select the sample ID; in the event that no input is given, the software will start all tests by default (including calibration, quality control, sample and reagent blank tests for which an application was made).

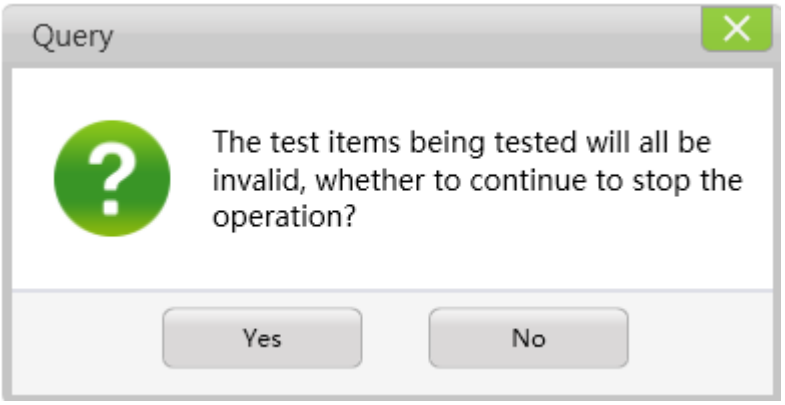
(4) Click the “Reagent Information” button to view the reagent information for the item to be tested. Click the “Start” button to confirm that you want to start the test. Click the “Close” button to cancel starting the test.

2) Pause: Click  button, the following dialog box pops up:



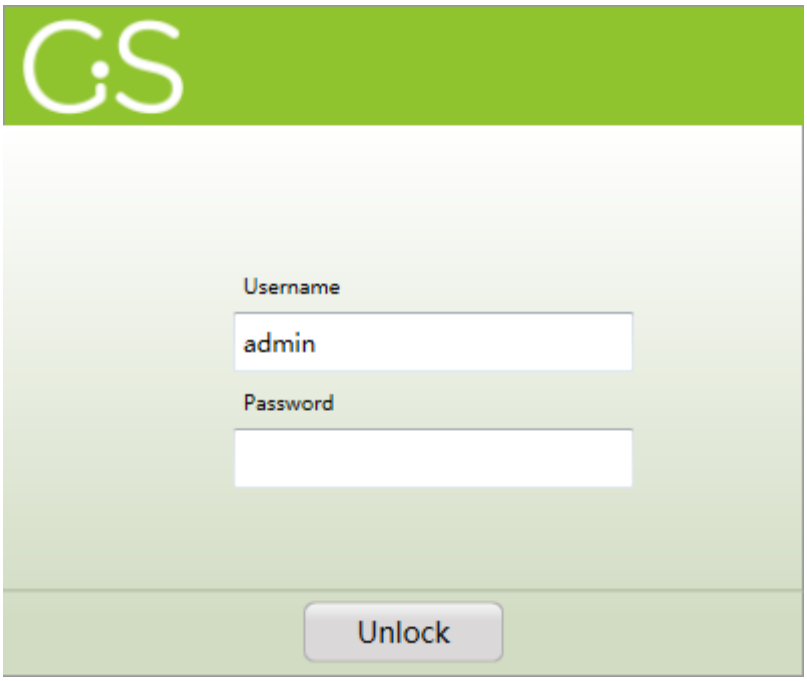
Click “OK” to suspend all ongoing tests for which R1 has not yet been added. Tests for which R1 has already been added will continue with the addition of S (sample) and R2 to complete the test. When pipetting is suspended, the reaction disk will continue to run. Operations such as loading reagents can be performed after the sample disk and sample probe stopped.

3) Stop: Click  button, the following dialog box pops up:



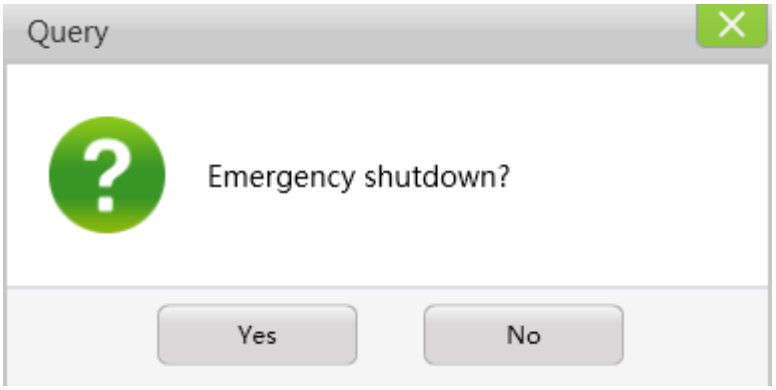
Click “Yes” to stop all the tests immediately, the ongoing test items will be voided. Click “No” to close the dialog box.

4) Lock: Click  button, the system will be locked.



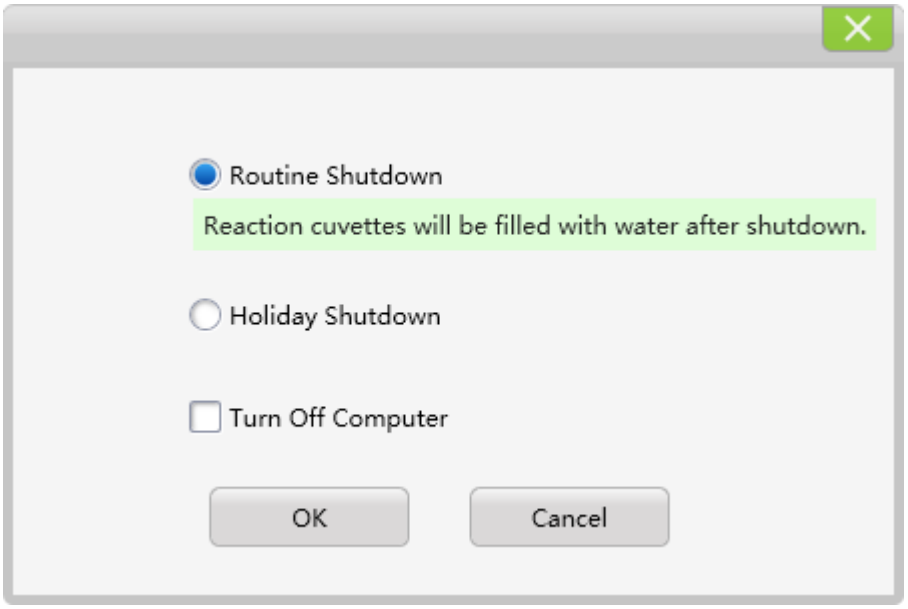
You need to enter the password again to unlock it.

5) Emergency Shutdown: Click  button, a confirmation dialog box pops up.



Click “Yes” to immediately stop all operations and exit the software system. Click “No” to close the dialog box.

6) Shutdown: Click  button, the shutdown selection interface pops up.



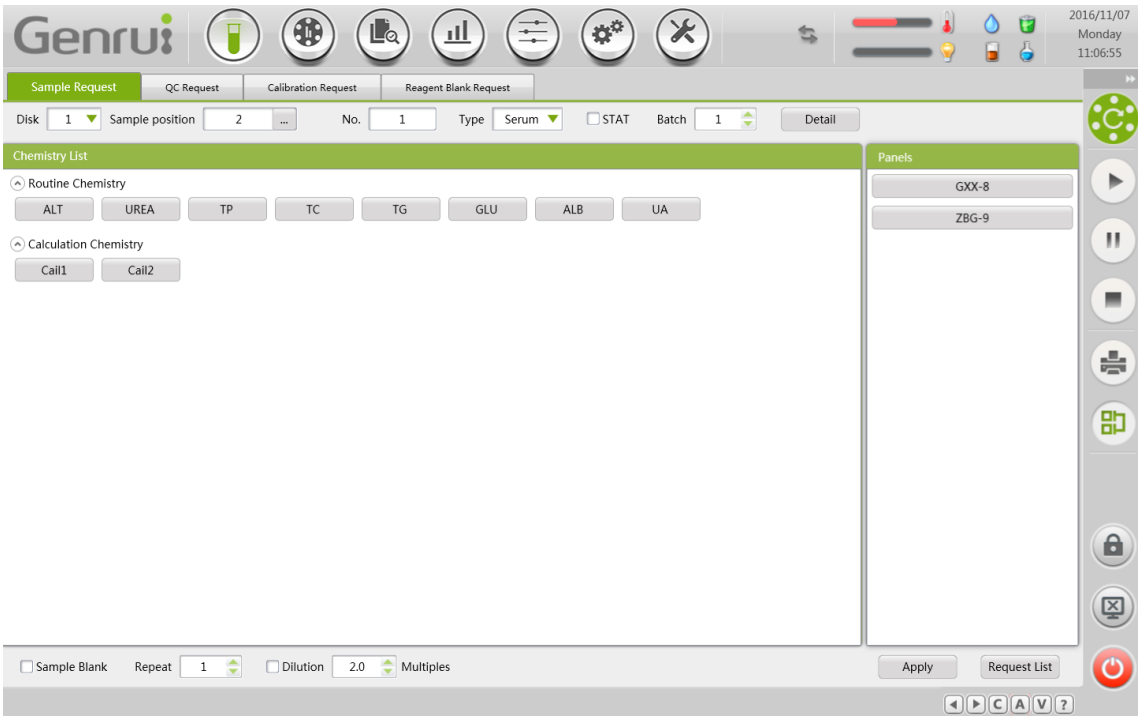
You can select “Routine Shutdown” or “Holiday Shutdown” mode, and also check the “Turn Off Computer” box. Click “OK” to send the shutdown command according to the selected shutdown mode and exit the software system. When you check the “Turn Off Computer” box, the computer will be turned off at the same time.

4.4.3. Test Request

Requests for sample, QC, calibration and reagent blank testing can be made via the Test Request menu. The menu also supports various functions such as the entry of patient information, selection of sample numbers, batch requests, retesting, dilution testing, etc.

4.4.3.1. Sample Request

The “Sample Request” interface is as shown in the figure below:



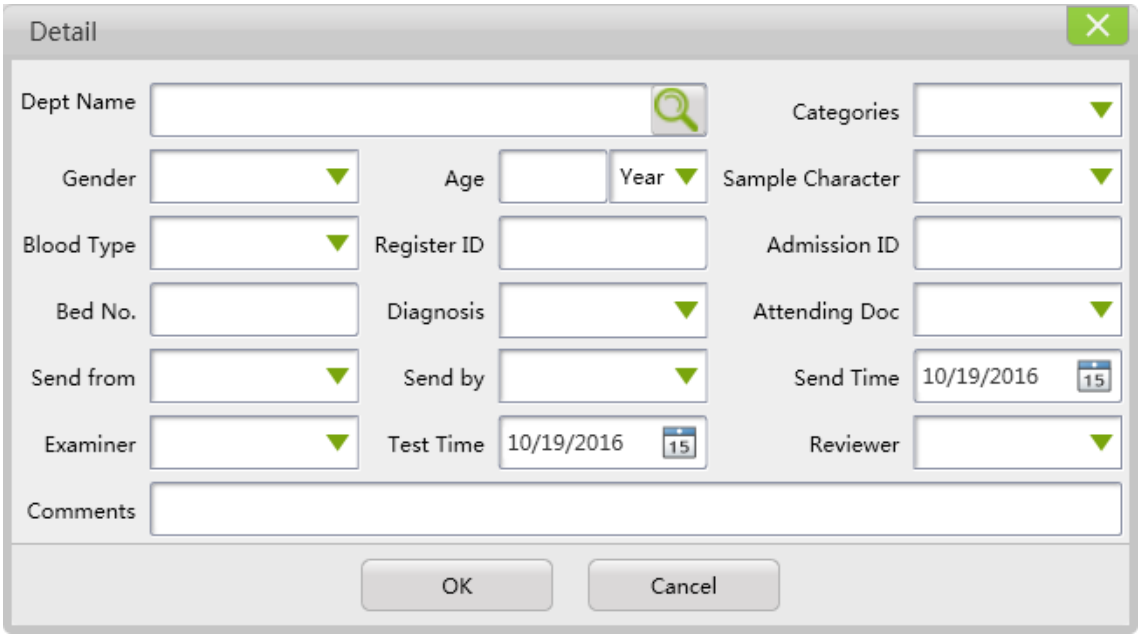
① Parameter explanation

Parameter	Meaning	Operation
Disk	Sample disk number	Select from the drop-down box.
Sample position	The cuvette position number (a total of 105) of the selected sample disk	The number can be entered directly or you can click “…” on the right side of this parameter to select a number from the sample disk empty cuvette list.
No.	The number of the test sample	Can be entered directly into the corresponding box and once the request is successful it increases in ascending order; can enter a prefix and suffix.
Type	The sample type	Select from the drop-down box.
STAT	Whether the sample is an	When checked, the currently requested

Parameter	Meaning	Operation
	emergency sample	sample is designated as an emergency sample and given priority during testing.
Batch	The number of samples requested simultaneously	Enter directly into the box, or press the up or down arrows to add or subtract.
Detail	Click to enter the detailed information input interface and enter detailed information regarding a specific sample	Click
Chemistry List	Displays all routine and calculation items	Directly select specific requests based on your testing needs.
Panels	Displays all panels	Directly select specific requests based on your testing needs.
Sample Blank	Whether to perform a sample blank test	When checked, a sample blank test will be requested.
Repeat	The number of repetitions of the test	Enter directly into the box, or press the up or down arrows to add or subtract.
Dilution	Whether to perform a dilution test	When checked, set according to demand.
Multiples	Dilution multiples of dilution test	Enter directly into the box, or press the up or down arrows to add or subtract.
Apply	Sample test request	Click after setting the sample test information.
Request List	View the already-requested samples and items; can perform deleting operation	Click

② Details

Set the patient and specimen details for the sample. The interface is as follows:



For explanations of different parameters and operations corresponding to the “Detail” interface, see the following table:

Parameter	**Meaning**	**Operation**
Name	Name of the current patient	Enter directly into the box, or click the search button on the right side to select from the search results.
Gender	Gender of the current patient	Select from the drop-down box.
Age	Age of the current patient	Enter directly into the first box, and select from the drop-down box for the second box.
Categories	Current sample source type	Select from the drop-down box.
Sample Character	The appearance of the sample	Select from the drop-down box.
Blood Type	Blood type of the current patient	Select from the drop-down box.
Register ID	Outpatient number of the current patient	Enter directly into the box.
Admission ID	Inpatient number of the current patient	Enter directly into the box.

Parameter	Meaning	Operation
Bed No.	Bed number of the current patient	Enter directly into the box.
Diagnosis	Clinical diagnosis of the current patient	Select from the drop-down box.
Attending Doc	Attending physician of the current patient	Select from the drop-down box.
Send from	Department where the current patient resides	Select from the drop-down box.
Send by	Physician who requested the current sample	Select from the drop-down box.
Send Time	Time of sample submission	Enter directly or click the date control to select.
Examiner	Physician responsible for testing the patient's sample	Select from the drop-down box.
Test Time	Time of sample testing	Enter directly or click the date control to select.
Reviewer	Person who audits the inspection report	Select from the drop-down box.
Comments	Indicates special circumstances concerning the current sample or other related information	Enter directly into the box.
OK	Save patient information	Click to save the patient's information
Cancel	Cancel the registration of patient information	Click to return to the previous interface

③ Basic operational steps

1) Click “Test Request” - “Sample Request”;

2) Select the sample disk number, sample position and sample type;

3) Enter the sample number;

4) Choose whether or not the sample corresponds to an emergency or is a batch sample and input detailed information according to actual clinical conditions;

5) Click the item that needs to be measured in the Chemistry List, click once to select and click again to cancel the selection. Or click the specified combination in the Panels selection area, click once to select and click again to cancel the selection;

6) Click the “Apply” button to bring up a pop-up box;

7) View or delete the request records in the request list.

④ Repeat test

When requesting a sample, enter the number of times you want to repeat the test into the “Repeat” function selection box as needed for the corresponding item. It will take effect once the request is successful.

⑤ Sample blank

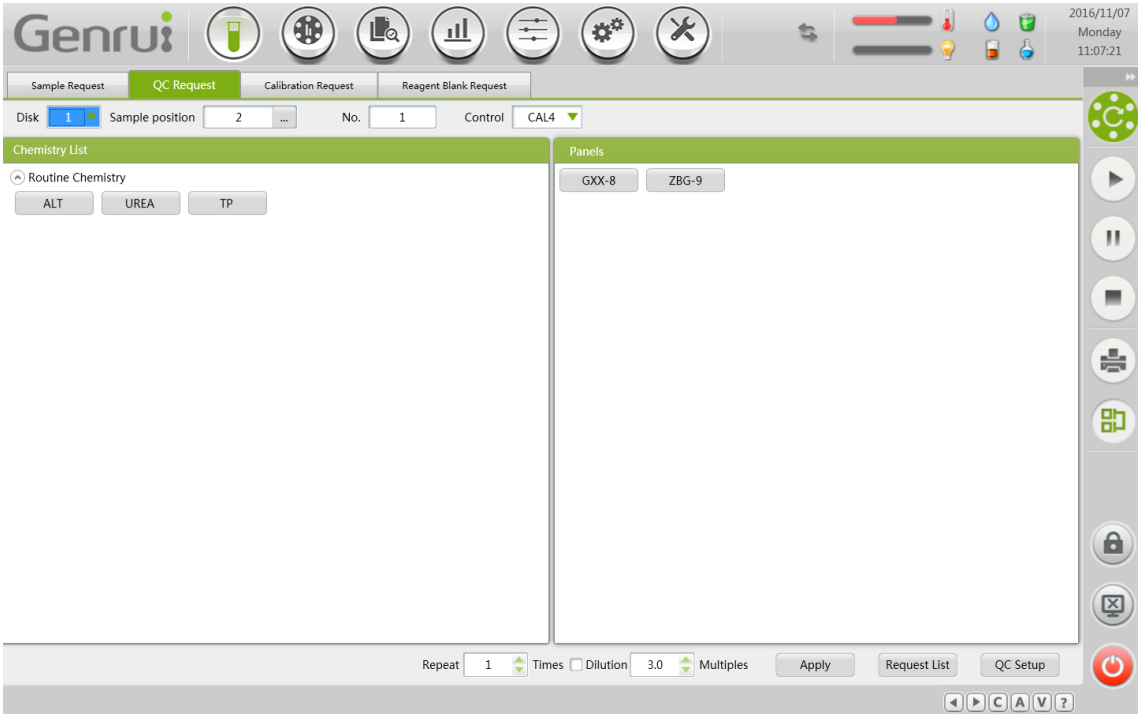
When requesting a sample, select whether or not to test a “Sample Blank” for the corresponding item. It will take effect once the request is successful.

⑥ Dilution test

Dilution functionality is divided into automatic dilution and manual dilution. “Multiples” refers to the factor by which the dilution is performed (also called the post-dilution factor), which must be set to equal to or greater than 2. When performing an automatic dilution, the original sample volume which refers to the amount of original sample drawn by the sample probe during dilution, needs to be set. It is recommended when performing an automatic dilution that the product of the dilution factor and the dilution amount falls between 200μL-400μL, in order to achieve the best dilution results. When performing a manual dilution, the user should first dilute the sample, select manual dilution and enter the dilution factor. An already-diluted sample is used to perform testing.

4.4.3.2. QC Request

In the QC Request menu, users can request quality control testing. Any of the preset quality control items can be selected to request a test based on the user's actual needs. Both repeat testing and dilution testing functions are available. Quality control request records can be viewed and deleted in the Request List menu.



① Parameter explanation

Parameter	Meaning	Operation
Disk	Sample disk number of the QC test	Select from the drop-down box.
Sample position	The cuvette position number of the selected sample disk	The number can be entered directly or you can click "…" on the right side of this parameter to select a number from the sample disk empty cuvette list.
No.	Number of the QC sample	Enter directly into the box
Control	The selected quality control solution	Select from the drop-down box.
Chemistry List	Displays all routine and calculation items	Directly select specific requests based on your testing needs.
Panels	Displays all panels	Directly select specific requests based on your testing needs.

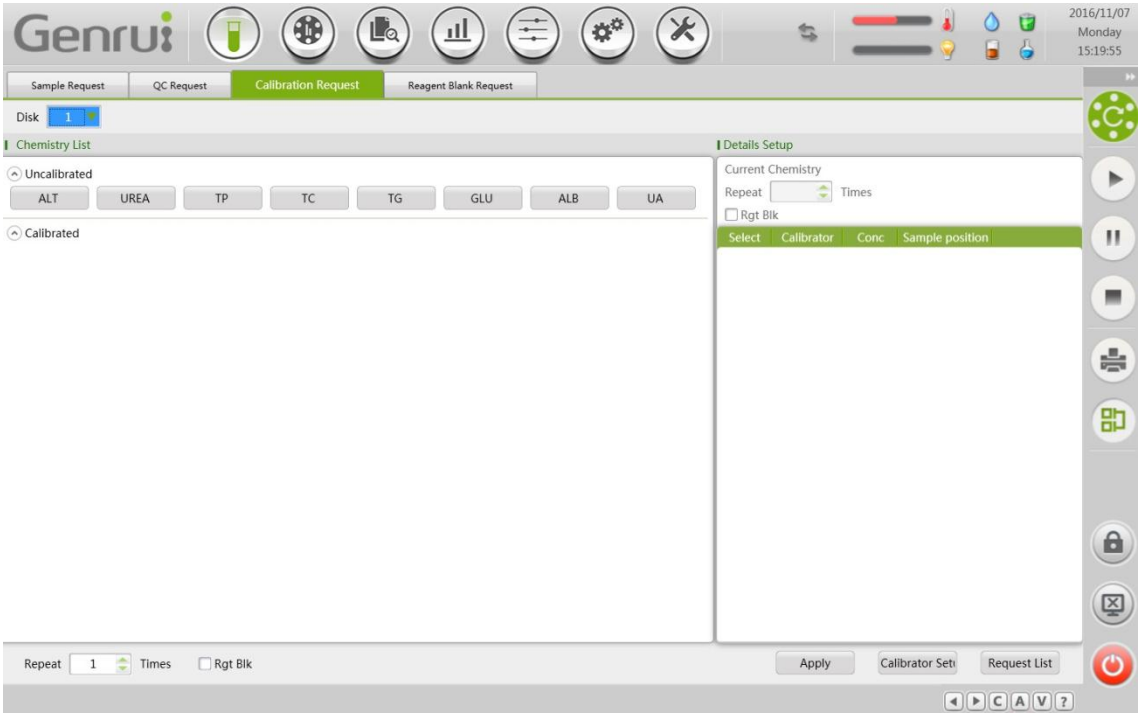
Parameter	Meaning	Operation
Repeat	The number of repetitions of the test	Enter directly into the box, or press the up or down arrows to add or subtract.
Dilution	Whether to perform a dilution test	When checked, set according to demand.
Multiples	Dilution multiples of dilution test	Enter directly into the box, or press the up or down arrows to add or subtract.
Apply	QC test request	Click after setting the QC test information.
Request List	Click to view the already requested QC test list	Click
QC Setup	Click to enter the control liquid setting screen	Click

② Basic operational steps

1) Click “Test Request” - “QC Request”;
2) Select a disk number, sample position and control solution, and enter the sample number;
3) Click the item that needs to be measured, click once to select and click again to cancel the selection. Or click the specified combination in the Panels selection area, click once to select and click again to cancel the selection;
4) Choose whether or not to perform repeat testing and dilution testing based on the actual requirements;
5) Click the “Apply” button after which the software should indicate that the request is successful. View or delete request records in the request list.

4.4.3.3. Calibration Request

A calibration test can be requested on the calibration request screen where users can also view the list of requests as well as set up the calibration.



① Parameter explanation

Parameter	Meaning	Operation
Disk	Sample disk number for the calibration test	Select from the drop-down box.
Chemistry List	List all calibrated and uncalibrated routine items	Directly select the desired item as required.
Details Setup - Repeat	Set the number of test repetitions for a single item	Enter directly into the box, or press the up or down arrows to add or subtract.
Details Setup - Rgt Blk	Set whether to perform a reagent blank test for a single item	When checked, the current item will request a reagent blank test.
Details Setup - Calibrator List	Calibrator used for the calibration test of the current item	Select the calibrator to be used as required.
Repeat	Set the number of repeations for all calibration tests	Enter directly into the box, or press the up or down arrows to add or subtract.

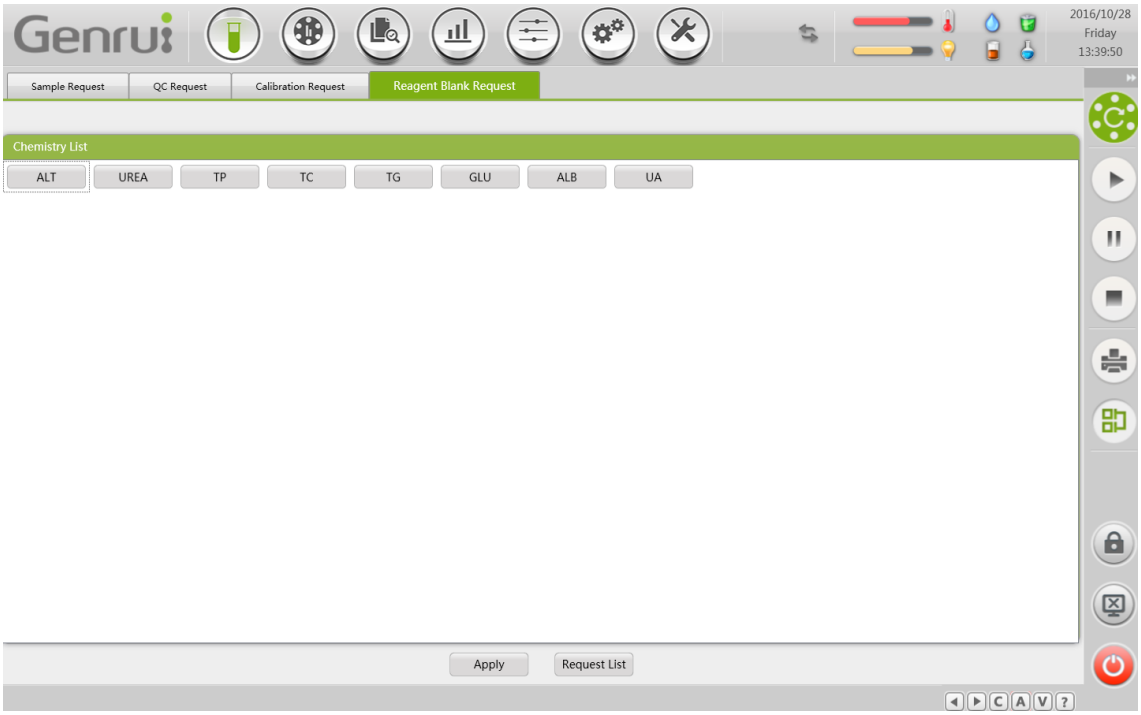
Parameter	Meaning	Operation
Rgt Blk	Set whether to perform reagent blank test for all items	When checked, all the items will request reagent blank test.
Apply	Request the calibration test	Click after setting the calibration test information.
Calibrator Setup	Click to enter the calibration liquid setting screen	Click
Request List	Click to view the already requested calibration test list	Click

② Basic operational steps

1) Click “Test Request” - “Calibration Request”;
2) Select a disk number, and click the item that needs to be calibrated, click once to select and click again to cancel the selection;
3) Select the calibrator that needs to be tested in the details setup box on the right hand side of the screen;
4) Set the number of repetitions for calibration test and reagent blank based on the actual requirements;
5) Click the “Apply” button after which the software should indicate that the request is successful. View or delete request records in the request list.

4.4.3.4. Reagent Blank Request

A reagent blank test can be requested on the reagent blank request screen where users can also view the list of requests.



① Parameter explanation

Parameter	Meaning	Operation
Chemistry List	List all routine items	Directly select the desired item as required.
Apply	Request the reagent blank test	Click after setting the reagent blank test information.
Request List	Click to view the already requested reagent blank test list	Click

② Basic operational steps

1) Click “Test Request” - “Reagent Blank Request”;

2) Click the item that needs to be calibrated, click once to select and click again to cancel the selection;

3) Click the “Apply” button after which the software should indicate that the request is successful. View or delete request records in the request list.

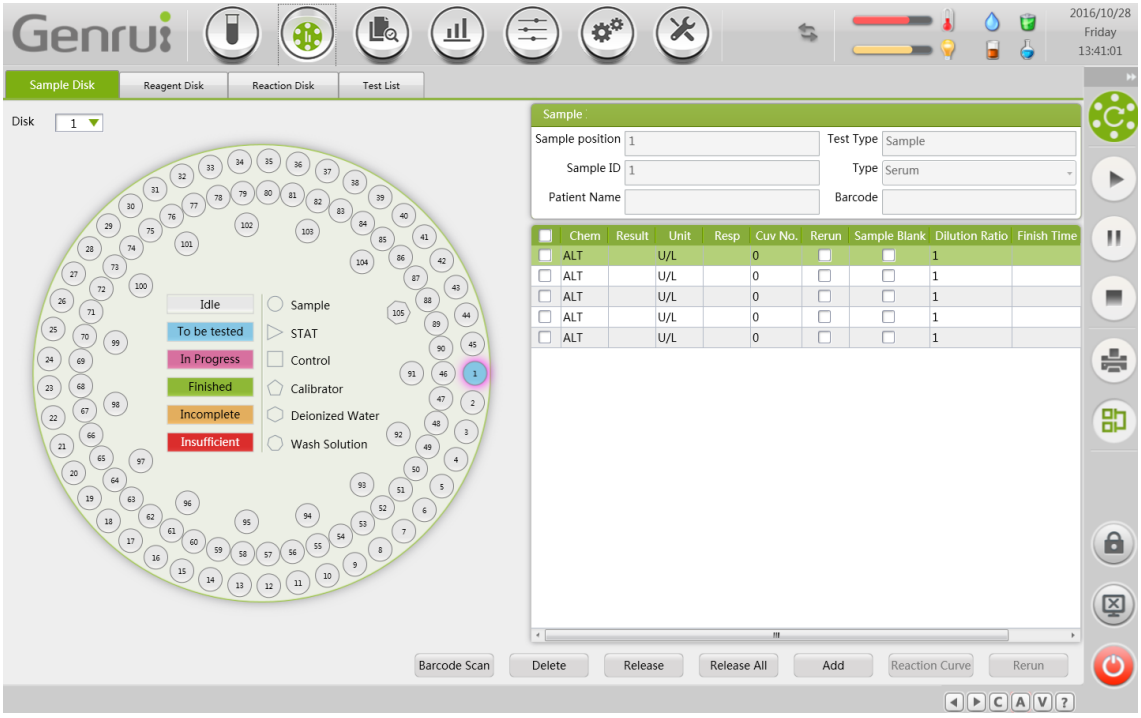
4.4.4. Working Condition

The “Working Condition” menu primarily shows information such as the current status of the sample disk, reagent disk and reaction disk as well as tests currently being performed. The menu also includes a test list submenu which shows the status of tests currently being

carried out by the instrument. These are described in detail below.

4.4.4.1. Sample Disk Status

In the “Sample Disk” menu, you can view the test status and sample information of test samples that have already been requested, as well as a list of requested items, you can also perform basic operations.



① Status explanation

1) For information concerning the meanings of various sample colors shown in the “Sample Disk” screen, see the following table:

Status	Color	Meaning
Idle	Blank	Unoccupied position, can request a sample
To be tested	Blue	A sample has been requested but the test has not been started
In Progress	Light purple	Sample currently being tested
Finished	Green	All tests for the sample have been completed
Incomplete	Yellowish brown	Test completed, but, due to various causes, a result cannot be computed
Insufficient	Red	Insufficient sample margin

2) For the meanings of different sample position shapes in the “Sample Disk” screen, see the table below:

Sample position shape	Meaning
Circle	Standard sample
Triangle	Emergency sample
Square	Quality control solution
Pentagon	Calibrator
Hexagon	Deionized water
Heptagon	Wash solution

② Parameter explanation

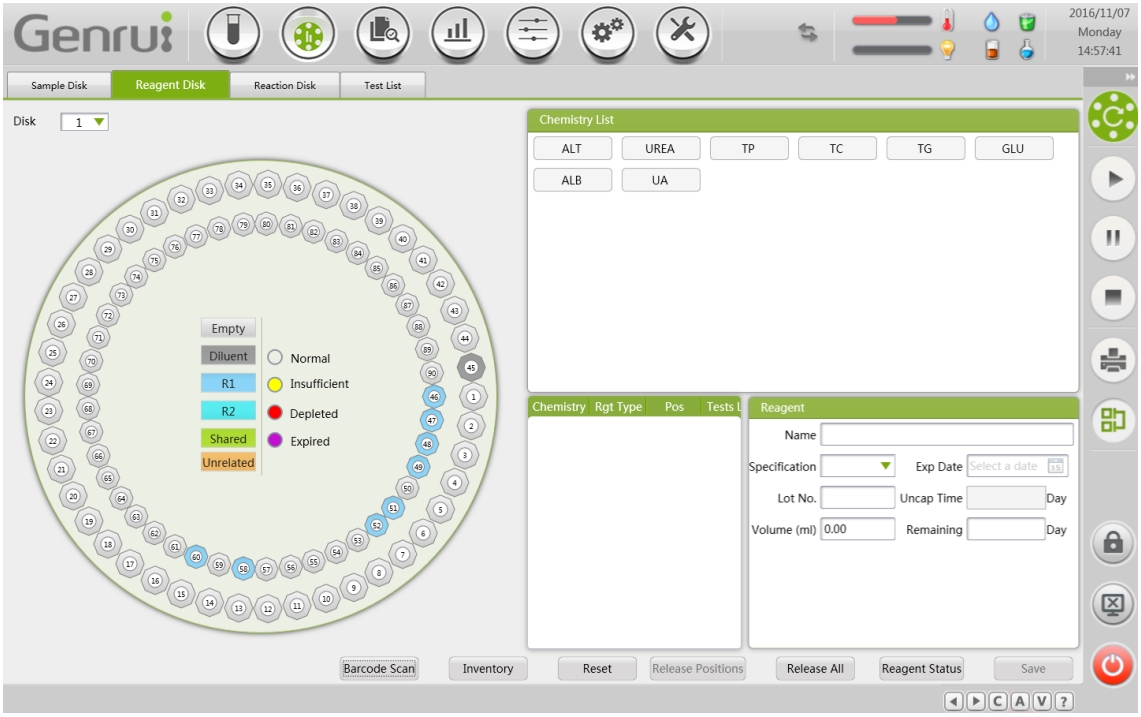
Parameter	Meaning
Disk	Current sample disk number
Sample	Information concerning the sample in the selected position, including sample position, sample ID, test type, patient name, sample type and barcode
Test List	Display a list of tests, results and additional notes for the currently selected sample

③ Function introduction

Button	Function explanation and basic operation
Barcode Scan	Click to enter the barcode scanning interface, select the position you want to scan and the desired scan mode and, after verifying the input, start scanning the sample
Delete	Delete all information corresponding to the selected sample (samples under test can not be deleted and released)
Release	Release the position of the selected sample
Release All	Release all sample positions on the current disk (available only when the instrument is in a stopped state)
Add	Click after selecting a sample to enter the Sample Request screen and add additional test items to already-requested samples
Reaction Curve	After selecting a sample and test item(s), click to view the corresponding reaction curve(s)
Rerun	Select samples and items requiring a retest, click Rerun to perform a retest (can only be used for chemistries for which testing has already been completed)

4.4.4.2. Reagent Disk Status

The status of all reagents can be viewed in the “Reagent Disk” screen, and operations such as setting the reagent position and monitoring residual volume can be performed.



Detailed information corresponding to all reagent positions is shown on the left side of the Function Display Area. Different colors indicate different reagent types and statuses as well as other information. The Item List Area on the right-hand side shows abbreviations for all items and users can page through the list using the Next and Previous buttons. The two boxes on the lower right part of the screen show the position of currently selected reagent or detailed reagent category, position and residual volume information corresponding to the item currently selected. The different colored circles in the middle of each reagent position indicate different reagent statuses: normal, insufficient, depleted and expired.

① Status explanation

The meaning of various statuses and parameters which appear on the “Reagent Disk” screen are as shown below:

Status	**Color**	**Meaning**
Empty	Blank	The current reagent position is empty
Diluent	Light gray	Diluent position
R1	Light blue	Reagent 1 is in the current position
R2	Brilliant blue	Reagent 2 is in the current position
Shared	Green	The current reagent position is shared by reagents across multiple items
Unrelated	Yellowish brown	The current reagent position is not associated with an item

The center circle colors of the reagent positions are as shown in the following table:

Status	**Color**	**Meaning**
Normal	Blank	The residual reagent volume is normal
Insufficient	Yellow	The residual reagent volume is insufficient
Depleted	Red	Reagent has run out
Expired	Blue	Reagent has expired

② Parameter explanation

Parameter	**Meaning**	**Operation**
Disk	Reagent disk number	Select from the drop-down box
Chemistry List	List of abbreviations for all items	Click to make a selection
Name	Reagent name	The default is “ItemName_ReagentType” and can be entered directly
Specification	Reagent bottle specification	Select the corresponding specifications in the drop-down box, depending on the reagent bottle size actually used
Exp Date	The expiry date of the reagent	Default is 1 year. Use the drop-down box to select a date

Parameter	Meaning	Operation
Lot No.	Lot number information for the reagent kit	Directly enter the lot number information provided with the reagent kit
Uncap Time	Refers to the number of days until the reagent expires after the reagent bottle is opened. The number of days after the reagent bottle is opened is calculated from the time the reagent position is set.	Blank by default, the user can set a value as needed. The cumulative number of days following opening of the reagent bottle will be cleared after a refresh or residual volume detection operation is performed, and the calculation of the number of days following opening of the reagent bottle is restarted.
Volume (ml)	The remaining amount of reagent	Automatic calculation, can not be modified
Remaining	The number of days remaining until the reagent expires	Automatic calculation, can not be modified

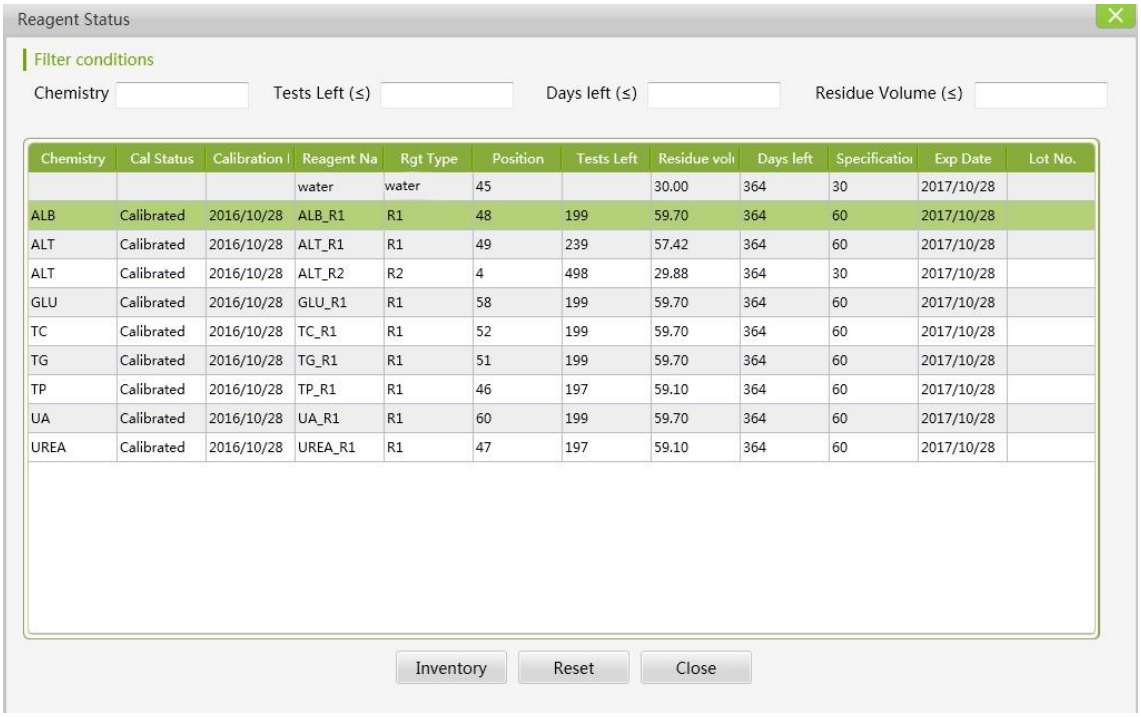
③ Reagent Position Settings

The basic procedure is as follows:

1) Left-click to select a reagent bottle position.
2) Move the mouse to the item that needs to be set in the item list area.
3) In the dialog box that pops up, select the reagent category that you wish to set: R1 or R2.
4) Reagent Information Settings: Name is displayed by default by the system based on the item and reagent type selected. Specifications, expiration date, time to expiration after opening, residual volume and number of days remaining are set to their default values when set up for the first time and any of these parameters can be adjusted manually according to the needs of the user.
5) Click the “Save” button in the reagent information box to save the corresponding reagent information.

④ Reagent Status

Click the “Reagent Status” button to open the Reagent Status screen and view detailed information regarding all reagents on the reagent disk, including their positions, lot numbers, residual volumes, number of viable tests, expiration dates, reagent specifications and calibration status for corresponding items, it is possible to perform residual volume detection and reset operations on this screen. Enter the appropriate conditions in the filter conditions box and the system will automatically filter for reagents which meet the conditions specified, allowing for easy examination and operation of reagents.



Chemistry	Cal Status	Calibration I	Reagent Na	Rgt Type	Position	Tests Left	Residue vol	Days left	Specificatio	Exp Date	Lot No.
			water	water	45		30.00	364	30	2017/10/28	
ALB	Calibrated	2016/10/28	ALB_R1	R1	48	199	59.70	364	60	2017/10/28	
ALT	Calibrated	2016/10/28	ALT_R1	R1	49	239	57.42	364	60	2017/10/28	
ALT	Calibrated	2016/10/28	ALT_R2	R2	4	498	29.88	364	30	2017/10/28	
GLU	Calibrated	2016/10/28	GLU_R1	R1	58	199	59.70	364	60	2017/10/28	
TC	Calibrated	2016/10/28	TC_R1	R1	52	199	59.70	364	60	2017/10/28	
TG	Calibrated	2016/10/28	TG_R1	R1	51	199	59.70	364	60	2017/10/28	
TP	Calibrated	2016/10/28	TP_R1	R1	46	197	59.10	364	60	2017/10/28	
UA	Calibrated	2016/10/28	UA_R1	R1	60	199	59.70	364	60	2017/10/28	
UREA	Calibrated	2016/10/28	UREA_R1	R1	47	197	59.10	364	60	2017/10/28	

⑤ Release All

The basic procedure is as follows:

1) Select the reagent disk number.

2) Click “Release All” to release all the positions on the reagent disk.

Note: Unable to release all the positions on the reagent disk when there is requested item on the sample disk. To release all the positions on the reagent disk, delete the item on the sample disk first.

⑥ Release Positions

The basic procedure is as follows:

1) Select the reagent disk number.

2) Click on a reagent in the reagent disk that requires a position change and click “Release Positions” to release the reagent position.

Note: If there is requested item on the sample disk, it is unable to release the reagent position of the corresponding item. To release reagent position of the item, delete the test request of the corresponding item first.

⑦ Reset Residual Volume

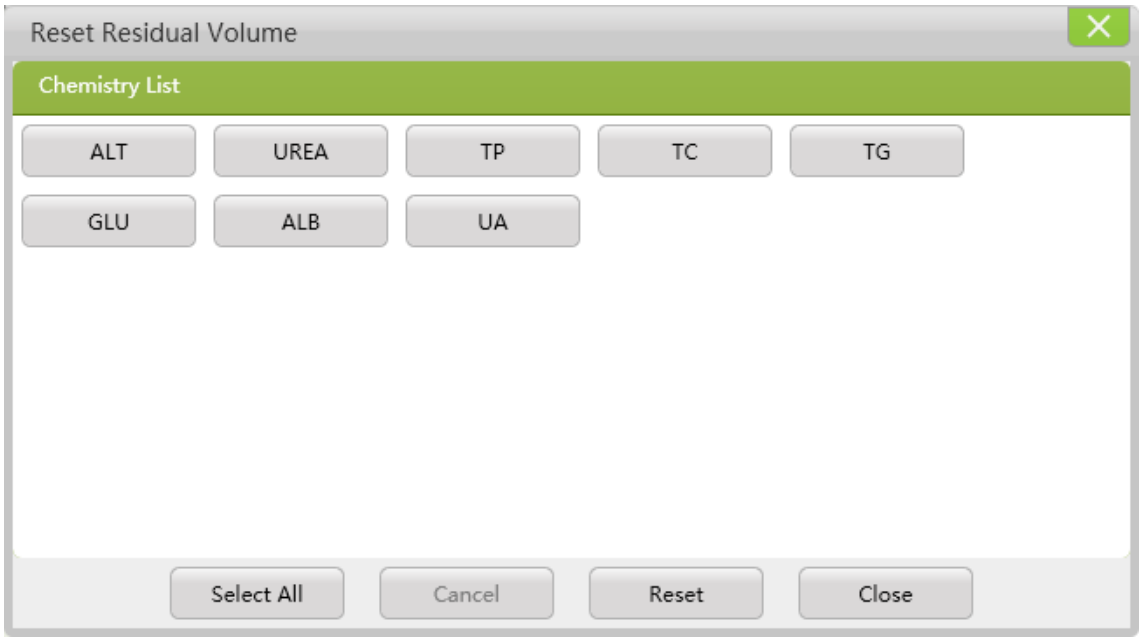
When lack of reagent for a certain item, you must perform the reset operation after adding reagent to start testing the item. The basic procedure is as follows:

1) Select the reagent position that needs to be reset in the Reagent Disk screen on the left.

2) Click the “Reset” button to reset the reagent residual volume and expiration date.

3) If you need to reset residual volumes for all reagents or multiple reagents, first, left-click on the item selection area.

4) Click the “Reset” button to bring up the following screen:



Select items that need to be reset. If all items need to be refreshed, click “Select All”.

5) Click the “Reset” button to reset the residual volume and expiration date of the reagent corresponding to the selected item. Once the reset is successful, a status message will pop up.

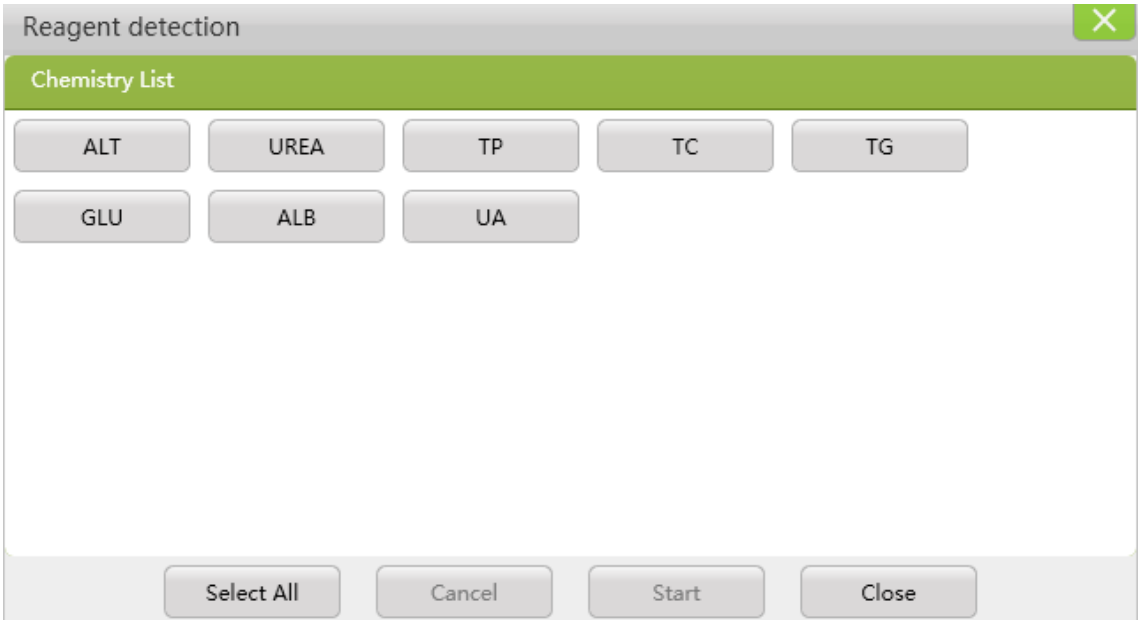
6) Otherwise, click the “Close” button to cancel resetting the residual volume.

⑧ Inventory

The basic procedure is as follows:

1) Select the reagent disk.

2) Click the “Inventory” button to bring up the residual volume detection interface.

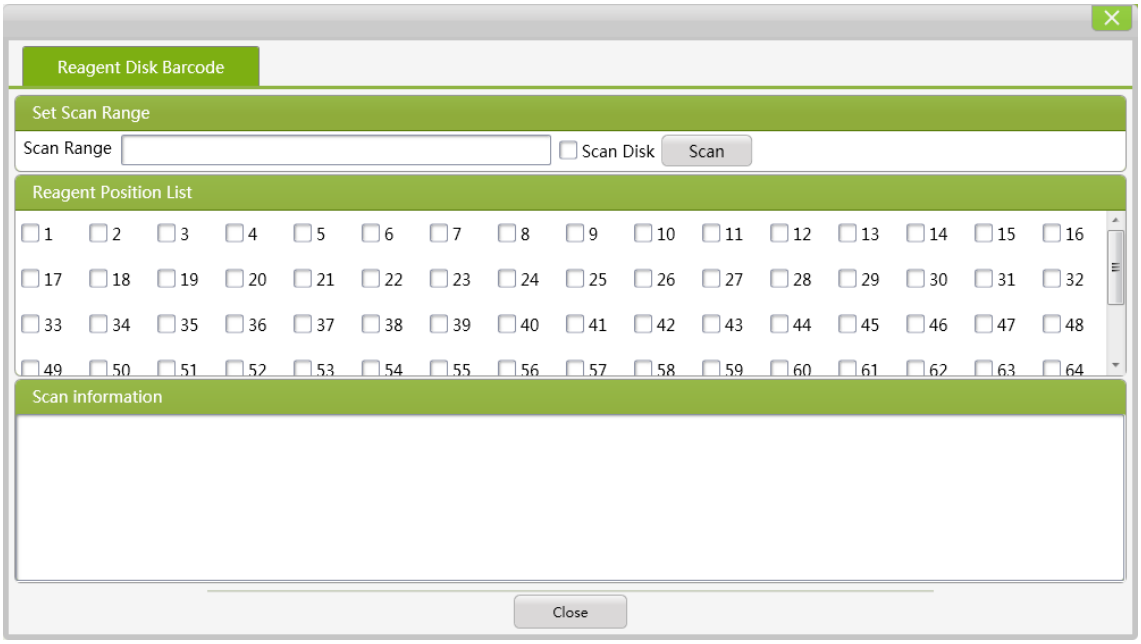

Reagent detection
Chemistry List
ALT
UREA
TP
TC
TG
GLU
ALB
UA
Select All
Cancel
Start
Close

3) Select the reagent for which residual volume detection needs to be performed.

4) Click the “Start” button to start residual volume detection or click the “Close” button to cancel residual volume detection.

⑨ Reagent Scan

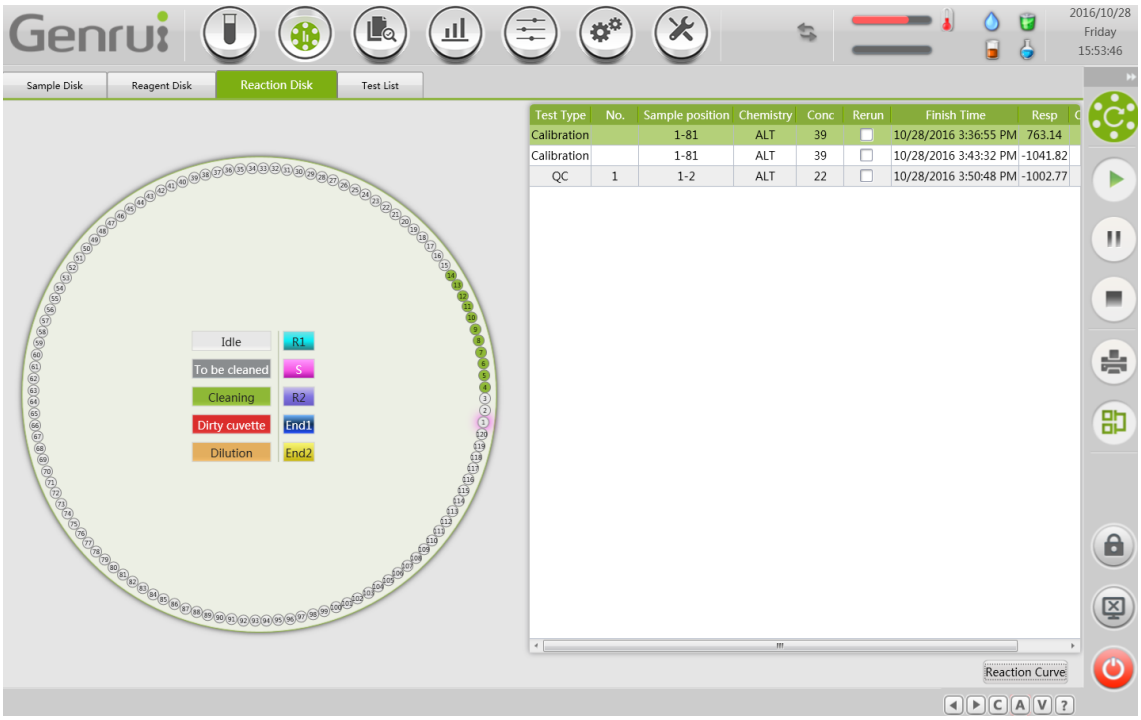
1) Click the “Barcode Scan” button to bring up the reagent scan interface.



2) In the pop-up dialog box, select the position you want to scan and click on the “Scan” button or click “Close” to exit.

4.4.4.3. Reaction Disk Status

Enter the “Reaction Disk” screen from “Working Condition” to view the overall condition of the reaction disk as well as the status of reaction cuvettes. Colors are used to display in real-time the current status of each reaction cuvette, including the cleaning status and sample loading status of each reaction cuvette, and observe the reaction curve of valid tests (samples, calibration, quality control, sample blank and reagent blank). Clicking on a reaction cuvette will display testing information for the position indicated on the right-hand side of the screen.



① Status explanation

There are a total of 10 different reaction cuvette statuses which may be displayed in the “Reaction Disk” screen, including idle, to be cleaned, cleaning, etc., different colors are used to display the current status of each reaction cuvette in real time. Status information displayed in the center of the virtual reaction disk schematic includes the following:

Status	**Color**	**Meaning**
Idle	Blank	Clean cuvette, can be added to a test
To be cleaned	Dark gray	Indicates cuvettes that have not been cleaned or reserved immediately following startup of the instrument, a cleaning operation may be performed on cuvettes of this type
Cleaning	Green	The cuvette is currently under cleaning and once cleaning is completed, a cuvette blank test can be used to determine whether the cuvette is clean or dirty

Status	Color	Meaning
Dirty cuvette	Red	The cuvette is not clean, or the cuvette is already occupied with waste product (e.g. voided test)
Dilution	Yellowish brown	Dilution is currently being performed in the current cuvette position
R1	Light blue	Addition of a first reagent for a given test
S	Pink	Addition of a sample for a given test
R2	Purple	Addition of a second reagent for a given test
End1	Dark blue	The current test ended normally but the corresponding results have yet to be computed
End2	Yellow	The current test ended normally and the corresponding results have been computed

② Parameter explanation

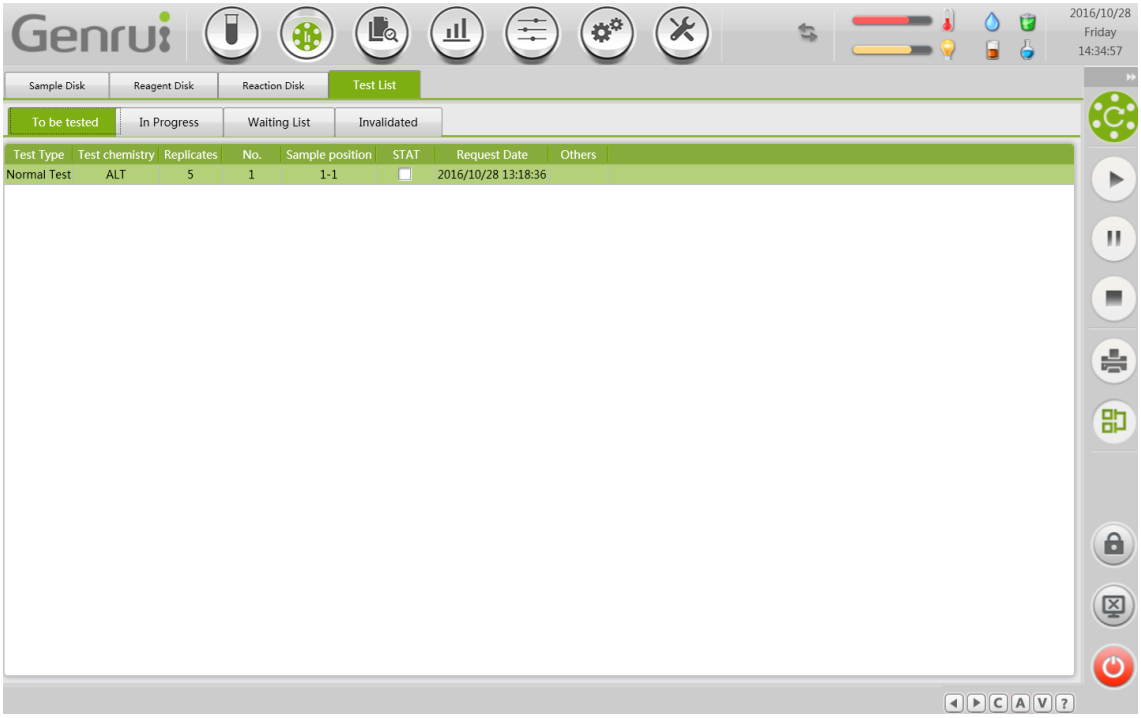
Parameter	Meaning
Test Type	Automatically displays the type of test corresponding to the selected cuvette, including calibration, quality control, sample tests, sample blank and reagent blank (a total of 5 test types)
No.	Number of the sample corresponding to the current test
Sample position	Position of the sample corresponding to the current test
Chemistry	Abbreviation of the item being tested in the reaction cuvette
Concentration	Results of the test being carried out in the reaction cuvette
Rerun	Indicate whether or not the current test needs to be retested, if so, the box should be marked with a check-off sign
Finish Time	The time to completion for tests carried out in the selected reaction cuvettes
Reactivity	The remaining amount of reagent
Comments	Show error information related to testing performed in the selected cuvette

③ Reaction Curve

Select a reaction cuvette on the Reaction Disk screen, which is currently under testing during a cyclical test and click on the “Reaction Curve” button to bring up a reaction curve screen which shows the reaction curve for tests performed in the reaction cuvette. When the selected reaction cuvette contains a diluted sample or is empty, this button is disabled.

4.4.4.4. Test List

You can view information for tests that are to be tested, in progress, waiting list or invalidated in the test list screen.



① Explanation of Status and Function

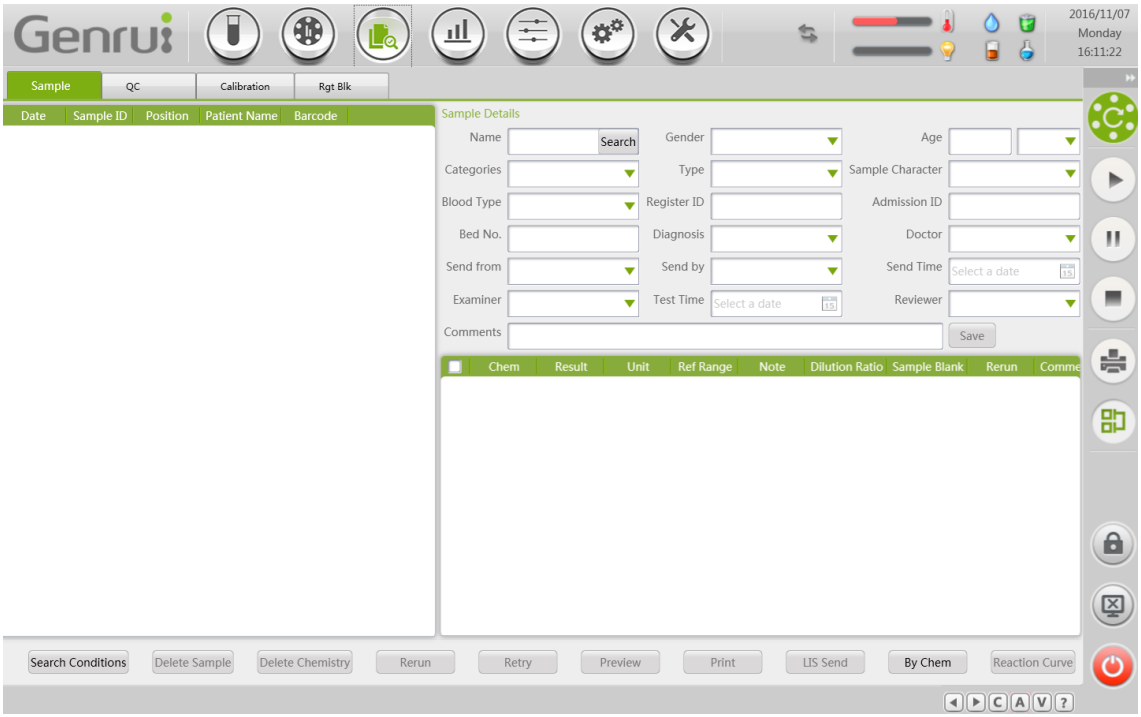
Status	Description of Status and Function
To be tested	The items in this list have already been requested but testing has yet to be initiated and they cannot be operated on
In Progress	Already under testing or the system has already allocated a list of test information
Waiting List	The test has been started and is currently waiting for the system to arrange the test and they cannot be operated on
Invalidated	An item for which the corresponding test was rendered invalid due to an error such as malfunction or lack of samples/reagents; the user can select the corresponding item and start a retest as needed

4.4.5. Query Results

The Query Results screen allows users to query sample, calibration, quality control and reagent blank results. These will be described in the following section.

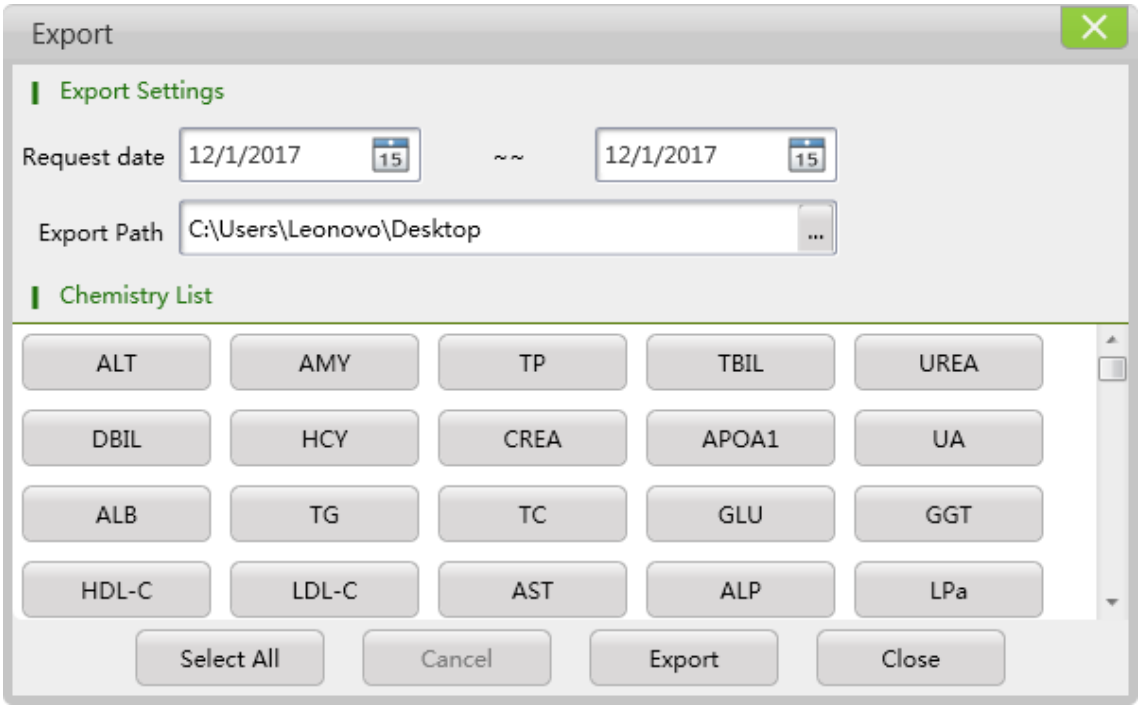
4.4.5.1. Sample Result Query

The left side of the Function Display Area on the Sample Result Query screen shows sample records which meet the current query criteria (samples for the current day are displayed by default) including request time, sample number, sample position, patient name and barcode. Detailed information corresponding to the sample is shown in the upper right section of the screen. The contents of this information are identical to the “Test Request - Sample Request” screen and can be edited and saved for later. A list of tests for the selected samples is shown in the lower right section of the screen.



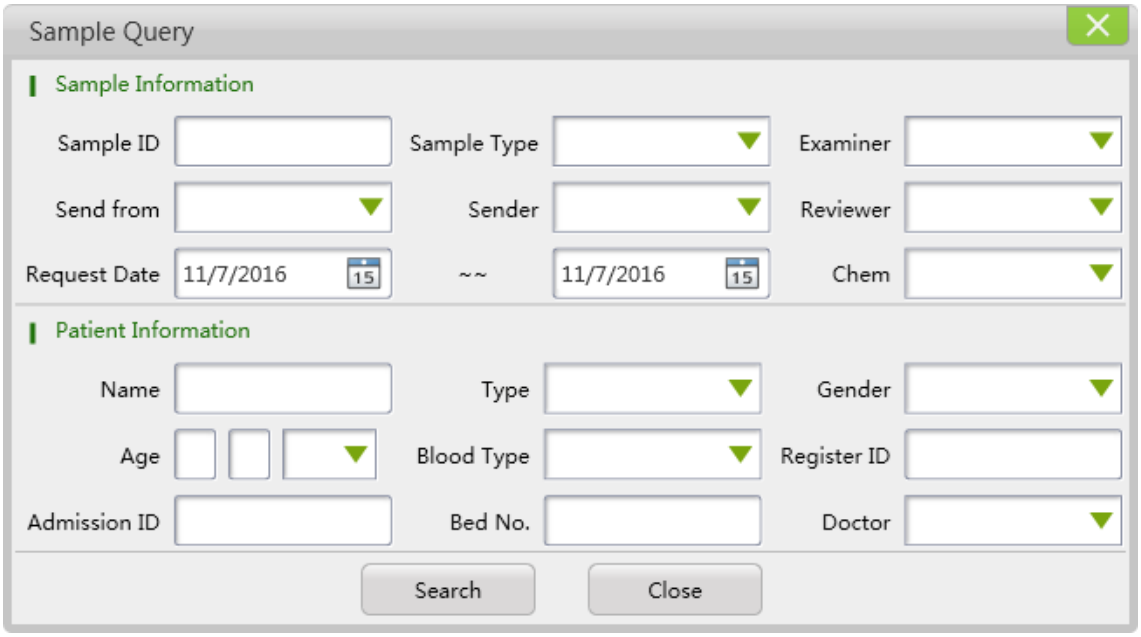
① Export

Click the “Export” button in the Sample Results Query interface to enter the Export interface. The Request Date is the date of the day by default, you can click the calendar icon to modify it. The Export Path is the desktop path by default, you can click the “...” button to modify it. Click the item to be exported in the Chemistry List area, an excel file containing item information will be created under the selected path.



② Query criteria

By default, the Sample Results Query interface displays a record of tests performed on the current day. If you need to check older results, click the “Search” button to bring up the “Sample Query” dialog box and, after entering your query criteria, a corresponding sample record should be displayed. Click “Close” to end the query.



③ Delete sample

Select the sample you want to delete, click the “Delete Sample” button, a confirmation dialog box appears, delete it after confirmation. Samples that are currently being tested cannot be subject to a “Delete Sample” operation.

④ Delete item

Select the sample that needs to be deleted and select the items you want to delete from the Item List Area. Then, click the “Delete Chemistry” button, a confirmation dialog box appears, delete it after confirmation. Samples that are currently being tested cannot be subject to a “Delete Chemistry” operation.

⑤ Rerun

Select the item requiring a retest to bring up the retest confirmation prompt and click “Yes” to start a retest or click “No” to cancel. Only unreleased items for which testing has been completed may be subject to a retest, unreleased samples include “samples requested on the same day as well as samples requested on a previous day but which were saved and not released from the sample disk as a result of not exiting the software for an extended period of time”.

⑥ Retry

“Retry” allows you to recalculate results and you can recalculate test results under various conditions depending on your needs.

⑦ Preview/Print

After selecting a sample, click “Preview” to display the results of the current sample and print a preview image. Click “Print” to print the results directly.

⑧ Send to LIS

After selecting a sample, click “LIS Send” to directly send the selected sample results to an LIS system.

⑨ View by item

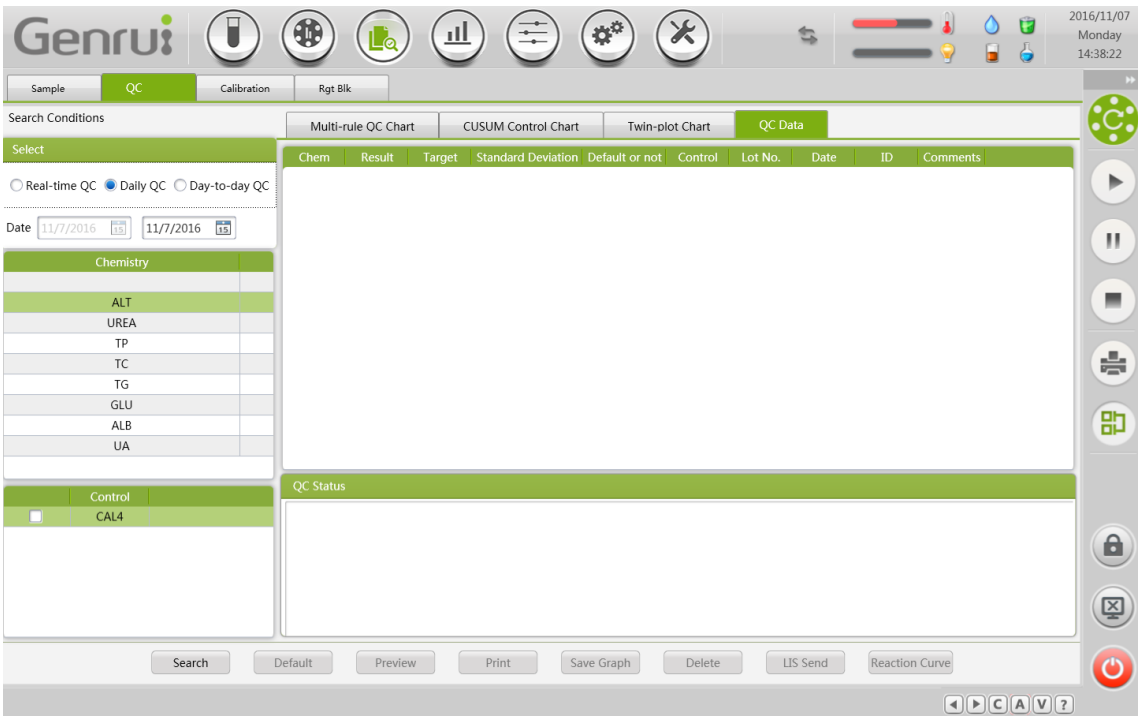
Click the “By Chem” button to enter the view results by item screen which includes the following 5 functional buttons: Search, Delete Chem, Rerun, By Sample and Reaction Curve. The Search, Delete Chem, Rerun and Reaction Curve are functionally equivalent to corresponding features of the View By Sample screen, which allows users to switch to view results by sample.

⑩ Reaction curve

After selecting a sample and test item, click the “Reaction Curve” button to bring up the reaction curve corresponding to the current results record.

4.4.5.2. Quality Control Result Query

The Quality Control Result Query function provides three quality control types: real-time QC, Daily QC and Day-to-day QC, and three different quality control chart types: Multi-rule QC chart, Cumulative sum QC chart and Twin-plot QC chart. QC data can be displayed by either quality control liquid or item. The “Quality Control Result Query” screen is as shown in the figure below.



① Parameter explanation

Parameter	Parameter Explanation and Operation
Select	Provides three quality control types: real-time QC, Daily QC and Day-to-day QC, can be selected directly
Date	Date on which quality control data needs to be examined, can be selected directly
Chemistry	List of abbreviations for quality control items, can directly select the desired item, when nothing is selected, it defaults to showing quality control data for all items
Control	List of control solutions, can be selected and viewed directly
Multi-rule QC Chart	Click to view a quality control chart created based on quality control data for the selected item and within the selected time period according to the preset Westgard quality control rules.
CUSUM Control Chart	Click to view a quality control chart created based on quality control data for the selected item and within the selected time period according to the preset cumulative sum quality control rules.
Twin-plot Chart	Click to view a twin-plot chart created based on quality control data for the selected item and within the selected time period.
QC Data	Click to display quality control data filtered based on specific quality control conditions.

② Function introduction

Button	Function Explanation and Operation
Search	Click directly to query corresponding quality control data based on the conditions selected
Default	Quality control data is selected by default, the system automatically treats the last successful result for a given day and a given item as the default result. When there are multiple successful results for a given day, the default result can be selected manually
Preview	Click to initiate a print preview of quality control data and corresponding quality control charts
Print	Click to print quality control data and corresponding quality control charts
Save Graph	Save the quality control chart
Delete	Delete quality control data. Click after selecting the data you want to delete. By default, quality control data cannot be deleted
LIS Send	Send quality control data to a LIS system

Button	Function Explanation and Operation
Reaction Curve	Click to view reaction curves corresponding to the selected quality control test results

③ Basic operational steps

1) Select the type of quality control you want to view on the left-hand side and select the start and end dates you wish to query.

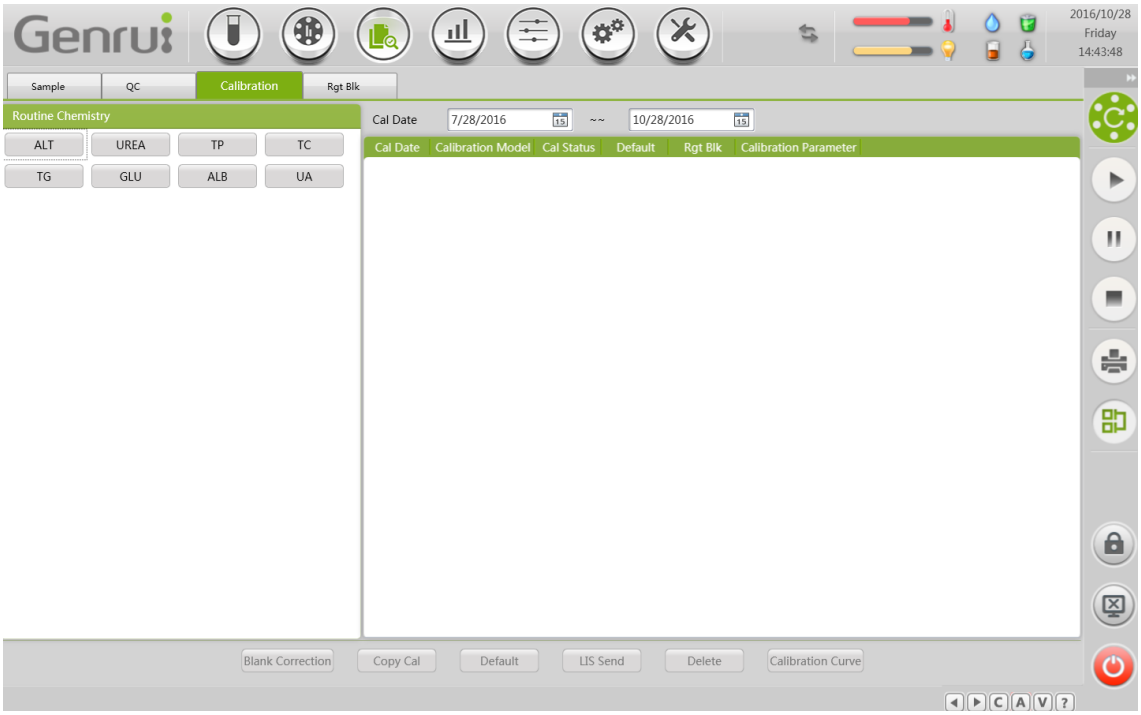
2) Select the desired item and control solution name and the system will automatically bring up the corresponding quality control data.

3) Select the “QC Data” menu to show all test results for the current item for the selected time period.

4) Select the “Multi-rule QC Chart”, “CUSUM Control Chart” or “Twin-plot Chart” menu to view the corresponding QC chart for the given item within the given time period.

4.4.5.3. Calibration Result Query

After selecting an item in the Calibration Result Query menu, enter the appropriate date and the system will automatically find calibration records for all items. Furthermore, functions such as blank correction and calibration copying can be invoked as needed. The “Calibration Result Query” screen is as shown in the figure below.



① Parameter explanation

Parameter	Meaning and Basic Operation
Routine Chemistry	Shows all standard items. Directly select the item you want to view
Cal Date	The date of the calibration data you want to view. Directly selected
Cal Date	Time at which the calibration test was requested
Calibration Method	Calibration method for the current item
Cal Status	The recorded status of each calibration, can be either “test complete” or “request pending”
Default	Shows the current default calibration results
Rgt Blk	Reagent blank data used during calibration
Calibration Parameter	Displays calibration parameters derived from linear calibration results

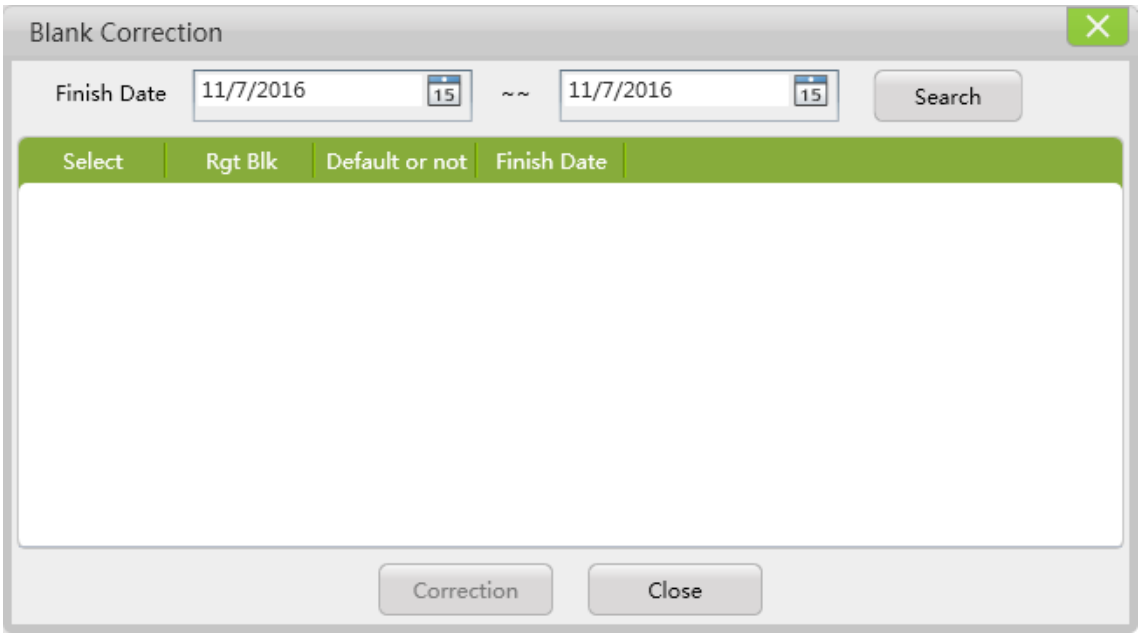
② Basic operational steps

1) Select the date to view the calibration data as needed.

2) Select the item you want to view the calibration data.

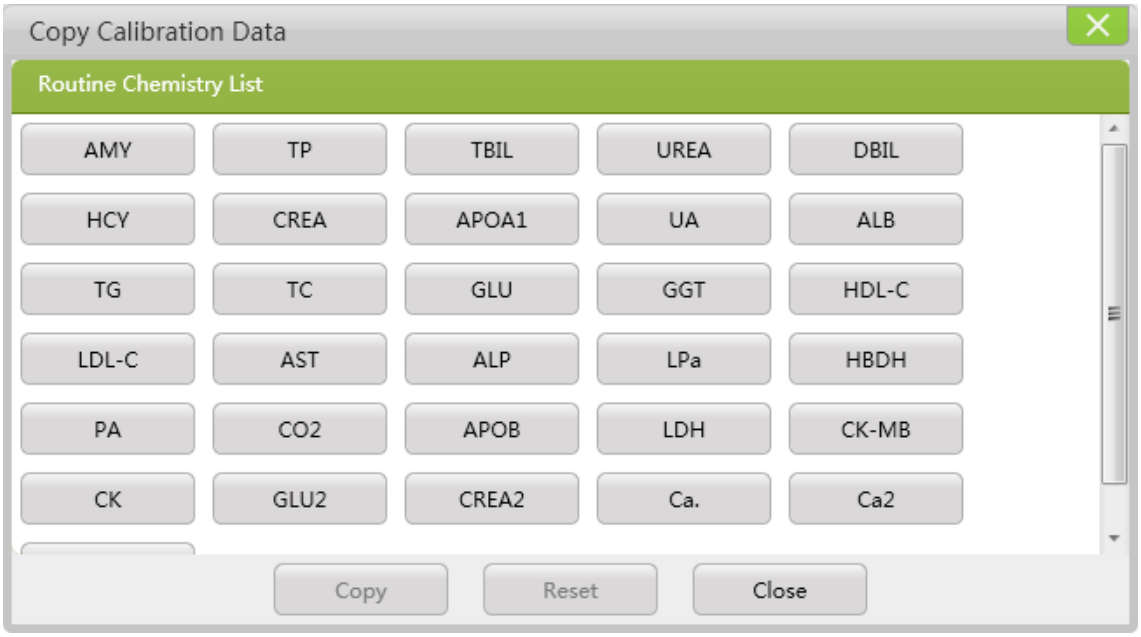
③ Blank correction

Click “Blank Correction” to bring up a dialog box, after selecting the appropriate date, check the reagent blank results. Select the reagent blank result that needs to be used for the correction and click “Correction” to start the correction process or click “Close” to exit. The “Blank Correction” screen is as shown in the figure below.



④ Calibration copying

Select the calibration results that need to be replicated, click on the “Copy Cal” button to bring up the “Copy Calibration Data” interface, select the target item to which you want to copy the calibration parameters, click “Reset” to make another selection, click “Copy” to start the copying process and click “Close” to exit.



⑤ Default

Set the selected calibration result to the default result. Only non-default and completed calibration results are valid.

⑥ Send to LIS

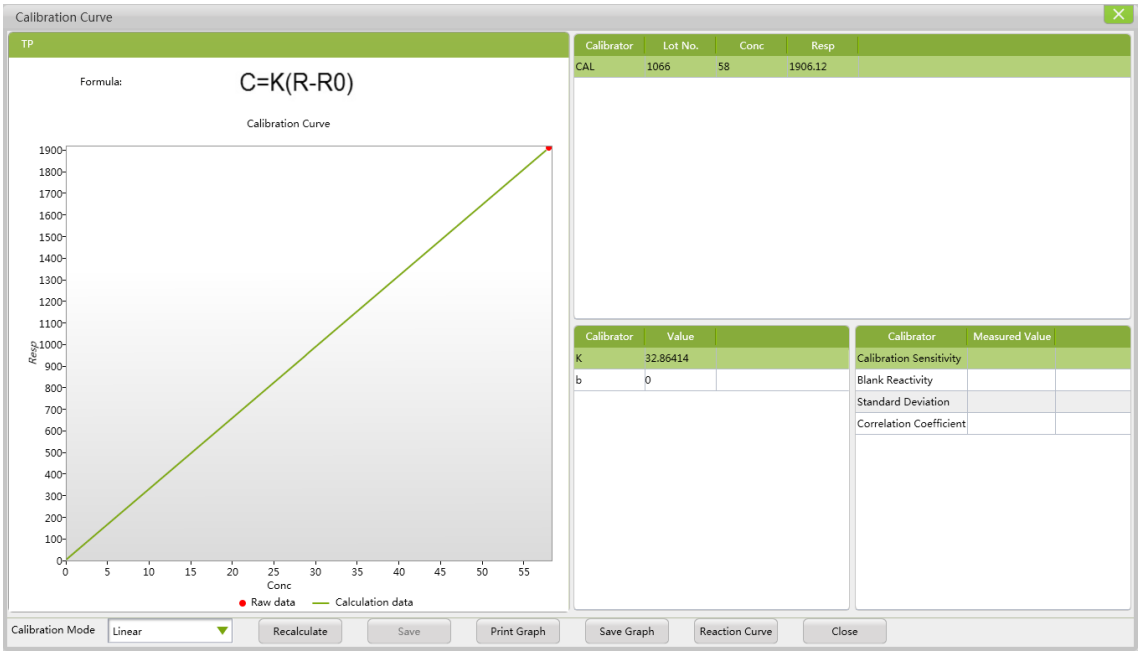
This function is available under LIS connection status, click to send the selected calibration results to the LIS system.

⑦ Delete

Directly delete the selected calibration results, default results cannot be deleted.

⑧ Calibration curve

Select a record corresponding to a single instance of successful calibration, click “Calibration Curve” to view the calibration curve corresponding to the selected result, as shown in the figure below:

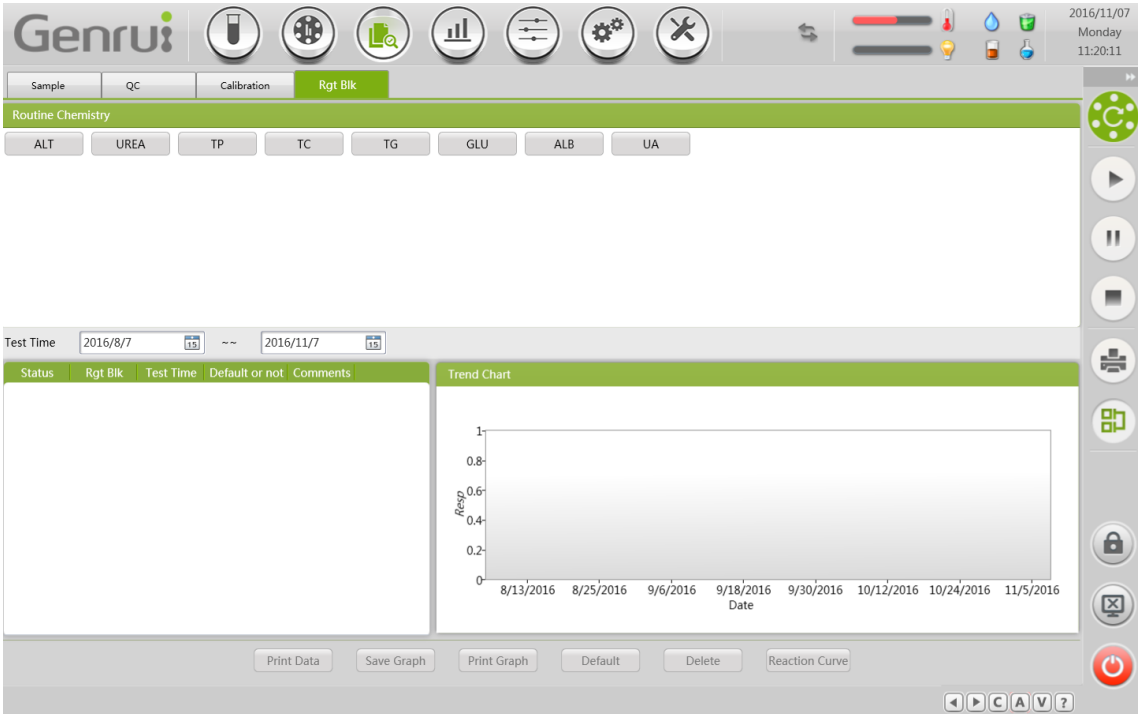


In the Calibration Curve interface, you can use functions such as modify calibration parameters, recalculate, save parameters, print graph, save graph and view reaction curve. See the following table for explanations concerning the function of the various buttons:

Button	**Function Explanation and Operation**
Recalculate	Using existing calibration data, you can select different calibration methods to recalculate calibration parameters. Click directly to use.
Save	Save new calibration parameters after calibration curve parameters have been modified or a recalculation has been performed
Print Graph	Print a calibration curve
Save Graph	Save a calibration curve
Reaction Curve	Click to view reaction curves corresponding to the selected calibration test results
Close	Directly click to close the current screen

4.4.5.4. Reagent Blank Query

While querying a reagent blank, it is possible to view reagent blank results and a reagent blank trend graph on an item-by-item basis.



① Basic operational steps

1) In the chemistry list box, select the item you want to query.

2) Select the start and end dates of the reagent blank you want to query.

3) The system will automatically find corresponding reagent blank data and produce a trend graph.

② Function introduction

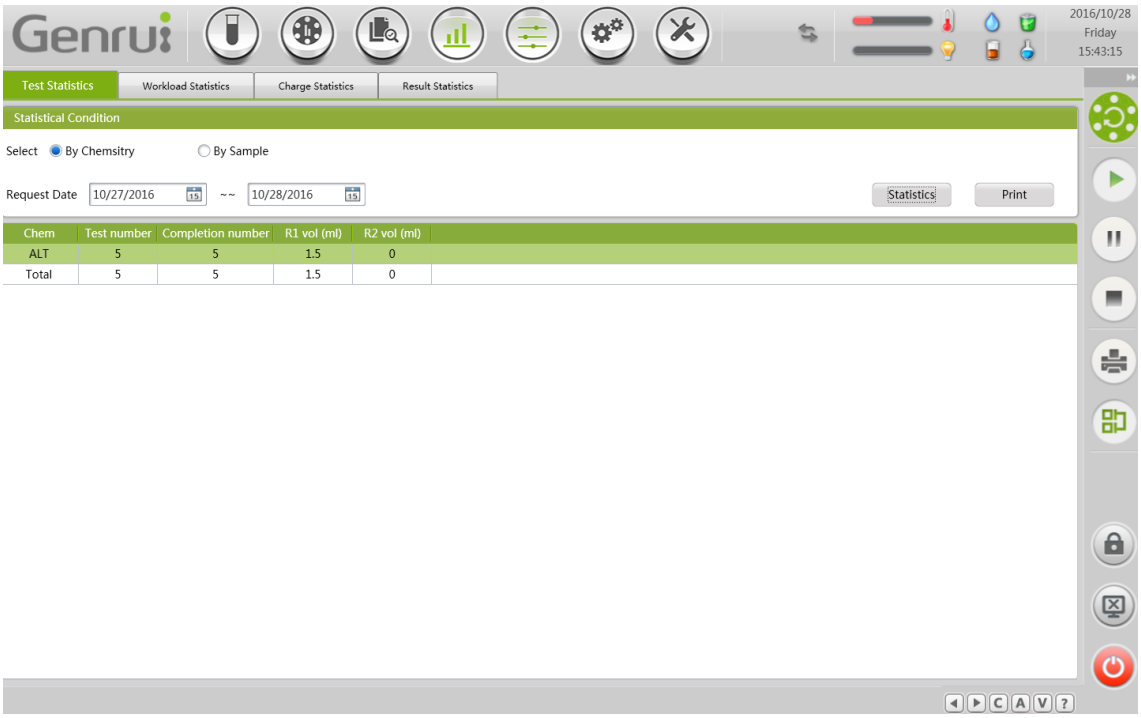
Button	Function Explanation and Operation
Print Data	Print reagent blank data found under the current query. Click to use
Save Graph	Save the reagent blank trend graph. Click to use
Print Graph	Print the reagent blank trend graph. Click to use
Delete	Delete reagent blank data. Select the data you want to delete and click to delete it. Default reagent blank data cannot be deleted
Reaction Curve	Click to view a reaction curve corresponding to the selected reagent blank results.

4.4.6. Statistical Reports

Includes four subsections: test statistics, workload statistics, cost statistics and result statistics. These functions are described in detail below.

4.4.6.1. Test Statistics

The “Test Statistics” interface is as shown below:



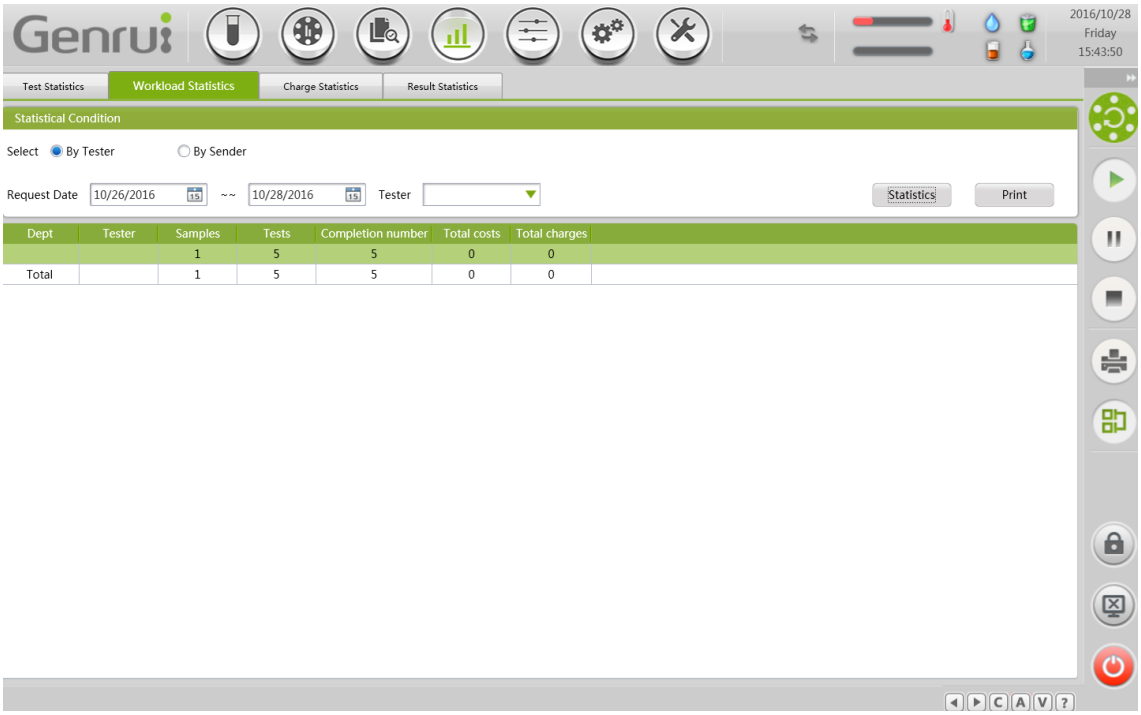
① Parameter explanation

Parameter	Meaning	Operation
Select	Include “By Chemistry” and “By Sample”	No operation
By Chemistry	Generate statistics concerning the amount of tests performed, number of tests completed, R1 consumption and R2 consumption for each item over a requested period of time as well as totals for tests performed, number of tests completed, R1 consumption and R2 consumption across all items	Click the circle next to the “By Chemistry” option until it turns blue
By Sample	Generate statistics concerning the amount of samples processed, number of items processed, number of tests completed, statistical items, manual items and ISE items for each day over a requested period of time as totals for tests performed, number of tests completed, R1 consumption and R2 consumption across all days	Click the circle next to the “By Sample” option until it turns blue

Parameter	Meaning	Operation
Request Date	Generate statistics concerning a requested date range with the range set to the current day only by default. Enter the start date in the first box and the end date in the second box. The start date cannot be later than the end date	Enter directly or select by clicking on the calendar icon to the right of the box
Statistics	Query test statistics related content according to the entered statistical condition	Click
Print	Print a test statistics information table	Click

4.4.6.2. Workload Statistics

The “Workload Statistics” interface is as shown below:

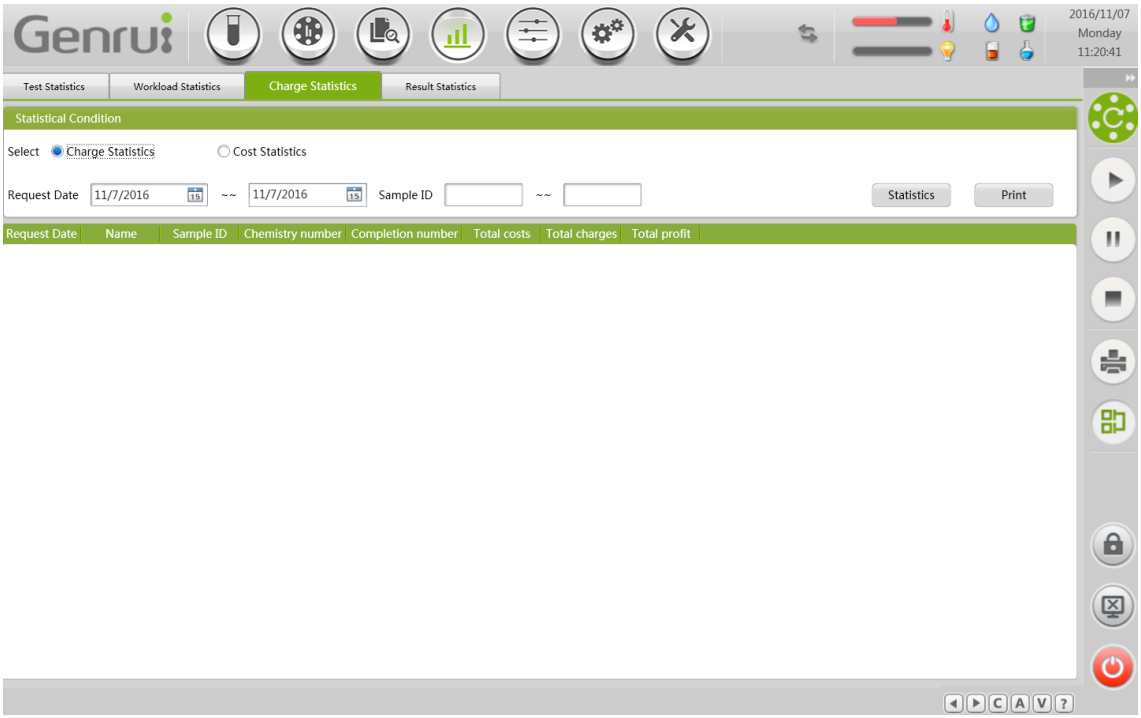


① Parameter explanation

Parameter	Meaning	Operation
Select	Include “By Tester” and “By Sender”	No operation
By Tester	Select “By Tester”, if nothing is entered into the boxes corresponding to the examining department and the examining physician, then the total workload of all examining physicians in the examining department will be computed, when an examining physician is entered into the box corresponding to the examining physician, then only the workload of the physician in question is computed	Click the circle next to the “By Tester” option until it turns blue
By Sender	Select “By Sender”, if nothing is entered into the boxes corresponding to the submitting department and the submitting physician, then the total workload of all submitting physicians not in the examining department will be computed, if a department is entered into the box corresponding to the submitting department, then the total workload of all submitting physicians in the indicated department will be computed, if both a submitting department and submitting physician are entered into the corresponding boxes, then the total workload of the indicated physician in the indicated department will be computed	Click the circle next to the “By Sender” option until it turns blue
Request Date	Generate statistics concerning a requested date range with the range set to the current day only by default. Enter the start date in the first box and the end date in the second box. The start date cannot be later than the end date	Enter directly or select by clicking on the calendar icon to the right of the box
Statistics	Check data related to workload statistics according to the statistical condition entered.	Click
Print	Print a workload statistics information table	Click

4.4.6.3. Charge Statistics

The “Charge Statistics” interface is as shown below:



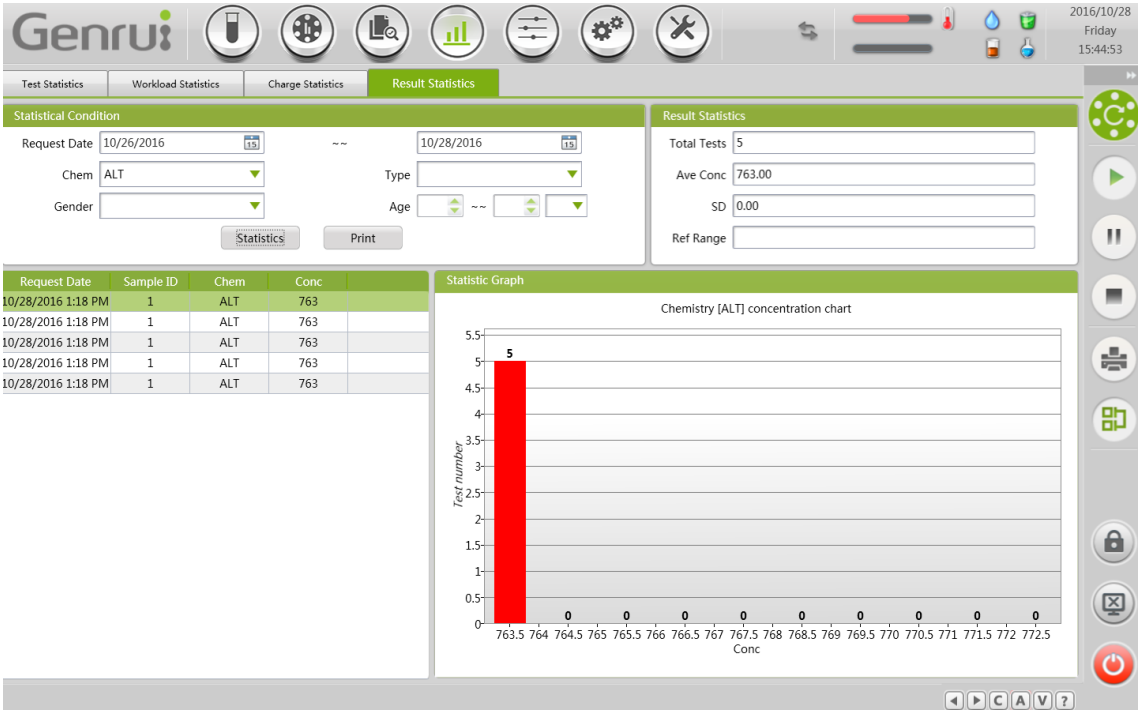
① Parameter explanation

Parameter	Meaning	Operation
Select	Include “Charge Statistics” and “Cost Statistics”, expenses statistics include the number of items, number of items completed, total costs, total charges and total revenues	No operation
Charge Statistics	Select the patient cost statistics. A range of sample serial numbers to be incorporated in patient cost statistics needs to be set.	Click the circle next to the “Charge Statistics” option until it turns blue
Cost Statistics	Select cost accounting statistics. The user must set items included in cost account statistics	Click the circle next to the “Cost Statistics” option until it turns blue
Request Date	Generate statistics concerning a requested date range with the range set to the current day only by default. Enter the start date in the first box and the end date in the second box. The start date cannot be later than the end date	Enter directly or select by clicking on the calendar icon to the right of the box
Sample ID	The numbering range of the test sample	Enter directly into the box
Statistics	Check data related to charge statistics according to the statistical condition entered.	Click

Parameter	Meaning	Operation
Print	Print a charge statistics information table	Click

4.4.6.4. Result Statistics

The “Result Statistics” interface is as shown below:



① Parameter explanation

Parameter	Meaning	Operation
Request Date	Generate statistics concerning a requested date range with the range set to the current day only by default. Enter the start date in the first box and the end date in the second box. The start date cannot be later than the end date	Enter directly or select by clicking on the calendar icon to the right of the box
Chem	Name of the test item	Select from the drop-down box.
Type	Sample type of the result statistics	Select from the drop-down box.
Gender	Patient gender of the results statistics	Select from the drop-down box.

Parameter	Meaning	Operation
Age	Patient's age range and unit of the result statistics	The patient's age range is entered directly into the corresponding box and age unit is selected from the drop-down box
Total Tests	The total number of tests that have been completed and produced results under the given statistical condition	No operation
Ave Conc	The average concentration of all test results under the given statistical condition	No operation
SD	The average standard deviation of all test results under the given statistical condition	No operation
Ref Range	Reference range of the statistical item	No operation
Statistics	Check data related to result statistics according to the statistical condition entered.	Click
Print	Print a result statistics information table	Click

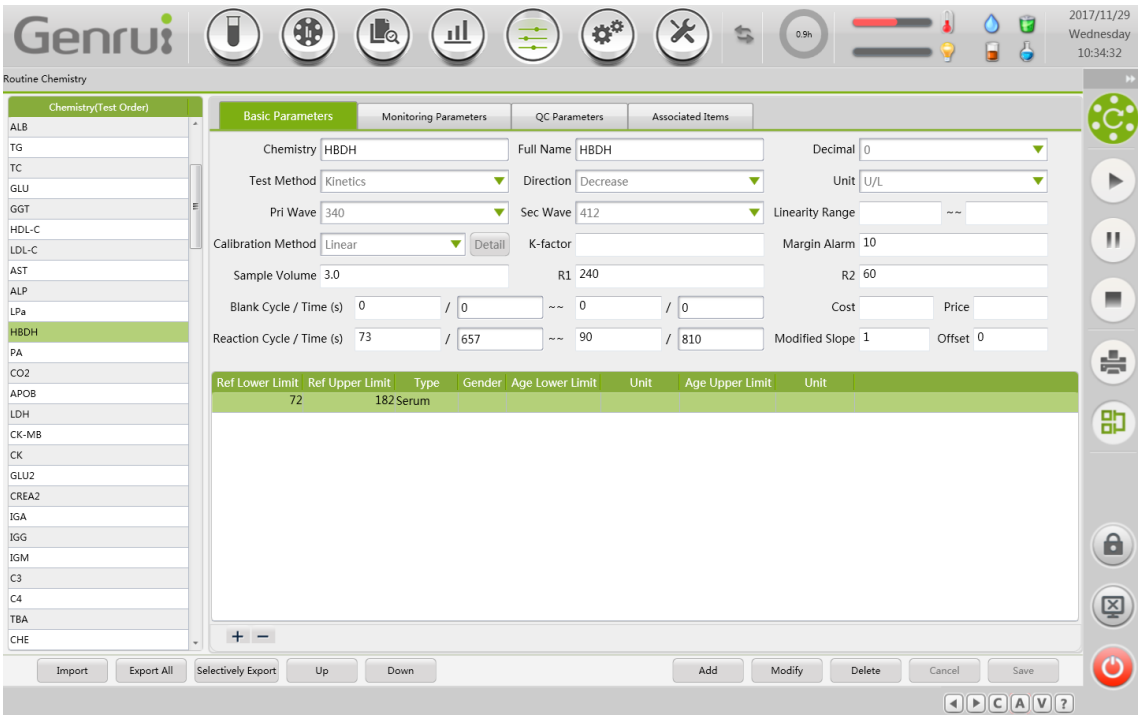
4.4.7. Parameter Setting

This menu includes the Routine Chemistry, Calculation Chemistry, Panels, Carryover, Calibrator Setup and QC Setup submenus. Each submenu can be used to invoke corresponding functions.

4.4.7.1. Routine Chemistry

Routine chemistry includes basic parameters, monitoring parameters and quality control parameters. Set parameters in the following order: “Basic Parameters” → “Monitoring Parameters” → “QC Parameters”, these are described in detail below:

① Basic Parameters



For explanations of different parameters and operations corresponding to the “Basic Parameters” screen, see the following table:

Parameter	**Meaning**	**Operation**
Chemistry	Item abbreviations	Enter directly into the box
Full Name	Full name of the item	Enter directly into the box
Decimal	Number of decimal places retained by the results	Select from the drop-down box Select the “...” button to enter the “Data Dictionary” interface and click on the “Add” button to edit and specify any number of decimal places with which results will be

Parameter	Meaning	Operation
		retained. Click the “Save” button once you have finished editing to save the change or click “Cancel” if you do not need to save the change
Test Method	Set the test method for a given item	Select from the drop-down box
Direction	The direction of change in absorbance which occurs during the reaction	Select from the drop-down box
Unit	Units of the test results	Select from the drop-down box Select the “...” button to enter the “Data Dictionary” interface and click on the “Add” button to edit any unit of results. Click the “Save” button once you have finished editing to save the change or click “Cancel” if you do not need to save the change
Pri Wave	The measured primary wavelength	Select from the drop-down box
Sec Wave	The measured secondary wavelength	Select from the drop-down box
Linearity Range	Linear range of the reagent kit	Directly enter the upper and lower concentration limits for the reagent's linear range as indicated in the reagent kit instructions
Calibration Method	Set the calibration method for a given item	Select from the drop-down box Enter the specific K-factor value in the corresponding box if you select the K-factor method Click the “Detail” button to edit the specific calibration parameters, including the repeated measurement’s differential limit, blank solution reaction range, calibration sensitivity, calibration curve standard deviation and calibration curve correlation coefficient. If you need to save your changes

Parameter	Meaning	Operation
		after editing is complete, click “OK” button or click “Cancel” if you do not want to save your changes
Margin Alarm	Number of remaining tests for the reagent kit	Enter directly into the box
Sample Volume	The amount of sample loaded for a normal test. The unit is microliter	Enter directly into the box
R1	The amount of Reagent 1 loaded for a normal test. The unit is microliter	Enter directly into the box
R2	The amount of Reagent 2 loaded for a normal test. The unit is microliter	Enter directly into the box
Blank Cycle / Time (s)	The blank cycle time. For a single reagent, this refers to the cycle time before the sample is loaded, while for two reagents, this refers to the cycle time after the sample is loaded prior to the loading of R2	Enter directly into the box
Reaction Cycle / Time (s)	The start and end optical metering points for calculation	Enter directly into the box
Cost	Cost of the item	Enter directly into the box
Price	Item price	Enter directly into the box
Modified Slope	Uses the formula y=ax+b to correct the test results, where x is the actual measured result, y is the corrected result, a is the slope in the correction formula and b is the intercept in the correction	Enter directly into the box, 1 by default

Parameter	Meaning	Operation
	formula	
Offset		Enter directly into the box, 0 by default
Ref Lower Limit	Enter the default lower limit of the reference range	Enter a number in the box based on the reference range provided by the reagent's instruction or other professional reference book
Ref Upper Limit	Enter the default upper limit of the reference range	Enter a number in the box based on the reference range provided by the reagent's instruction or other professional reference book Click "+" to set the upper and lower limits of the reference range, click "-" to delete the content related to the reference range. Click the corresponding area to add additional conditions for a reference range, including sample type, gender, age lower limit, age upper limit and age units
Import	Import item related parameters from an external source	Click the "Import" button, select item related parameters you want to import and perform the import operation
Export All	Export all current item related parameters	Click the "Export All" button to export all item-related parameters to an external storage device
Selectively Export	Select some of the item-related parameters to export	Click the "Selectively Export" button to export some of the item-related parameters to an external storage device
Up	Change the order in which tests are displayed for a given item in the Item Abbreviation field	Click the "Up" button to move the item ahead in the current test sequence
Down	Change the order in which tests are displayed for a given item in the Item Abbreviation field	Click the "Down" button to move the item back in the current test sequence

Basic Operations

Add Item Parameters

1) Click the “Add” button.

2) Enter parameter data directly into the corresponding item parameter box or make a selection from the drop-down box.

3) Click the “Save” button to save the data after completing the above operations, or click “Cancel” not to save the data.

Modify Item Parameters

1) Select the item you want to modify in the list of routine chemistry.

2) Click the “Modify” button to modify parameter data for the current item.

3) Click the “Save” button to save the change after completing the above operations, or click “Cancel” not to save the change.

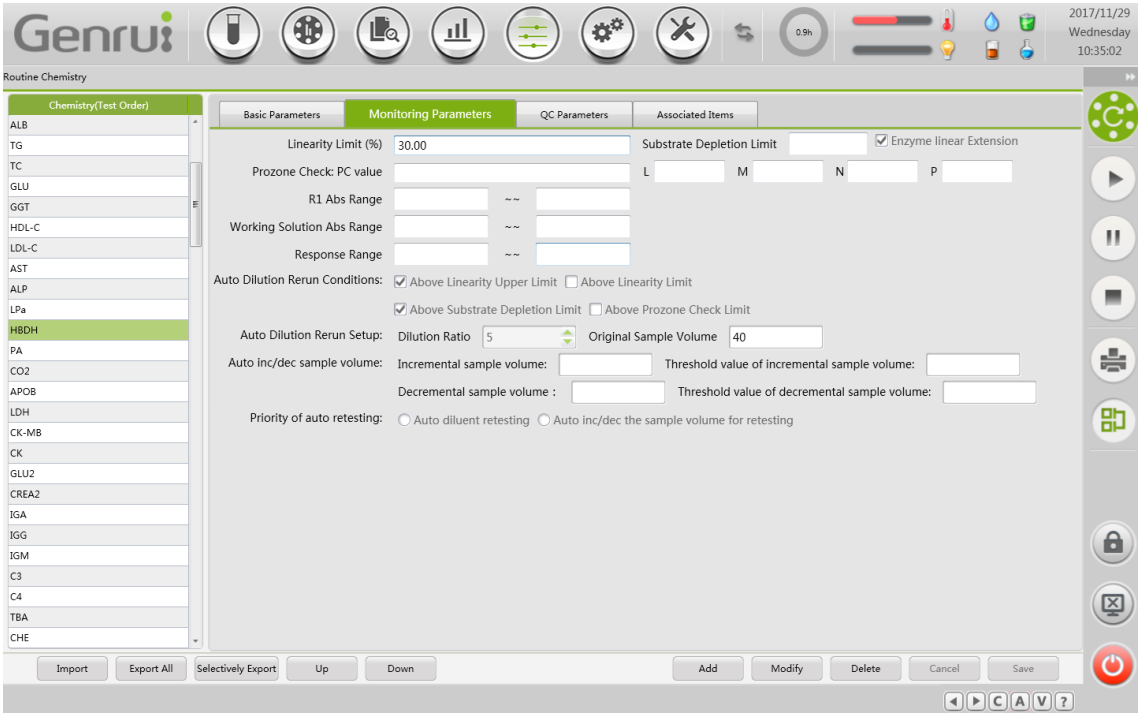
Delete Item Parameters

1) Select the item you want to delete in the list of routine chemistry.

2) Click the “Delete” button to bring up a warning dialog box (“Are you sure you want to delete the currently-selected routine item(s)?”), click the “Yes” button to delete the item or click “No” to cancel deletion of the item.

Note: Items that have generated test data are not allowed to be deleted.

② Monitoring Parameters



For explanations of different parameters and operations corresponding to the “Monitoring Parameters” screen, see the following table:

Parameter	**Meaning**	**Operation**
Linearity Limit (%)	Determine the linearity of the reaction curve. Only applicable to the kinetic method	Enter any value between 0 and 100
Substrate Depletion Limit	The limit set to determine substrate depletion during the reaction process. Must be an absorbance value multiplied by 10000. Only applicable to the kinetic method and two-point method	Enter an integer value between -40000 - 40000
Enzyme Linear Extension	When the optical metering point in a zero-order kinetics reaction interval is n ≤ 2, the enzyme linear range expansion functionality can be activated to calculate the reaction rate (ΔAmax) based on all optical metering point data for which substrate depletion has not occurred, including delay times, as an indicator of the sample’s reactivity	Place a √ in the selection box or click the √ to cancel your selection
Prozone Check PC value L M N P	Prozone check limit Reaction time optical metering point	Enter an integer value between 0 and 100 Enter a corresponding optical metering point according to the instructions contained in the section about the specific prozone check PC value algorithm
R1 Abs Range	Enter the lower / upper limits of the first reagent’s absorbance. Values must be absorbance values multiplied by 10000	Enter specific values between -40000 and 40000 directly into the box without exceeding the upper absorbance limit of the first reagent
Working Solution Abs Range	Enter the lower / upper limits of the working solution’s absorbance. Values must be absorbance values multiplied by 10000	Enter specific values between -40000 and 40000 directly into the box without exceeding the upper

Parameter	Meaning	Operation
		absorbance limit of the working solution
Response Range	Reaction amplitudes corresponding to the upper and lower limits of the linear range. Values must be reactivity values multiplied by 10000	Enter specific values between -40000 and 40000 directly into the box
Auto Dilution Rerun Conditions	Include Above Linearity Upper Limit, Above Linearity Limit, Above Substrate Depletion Limit and Above Prozone Check Limit	Place a √ in the selection box or click the √ to cancel your selection
Auto Dilution Rerun Setup	Include Dilution Ratio and Original Sample Volume	Enter specific values into the box

Basic Operations

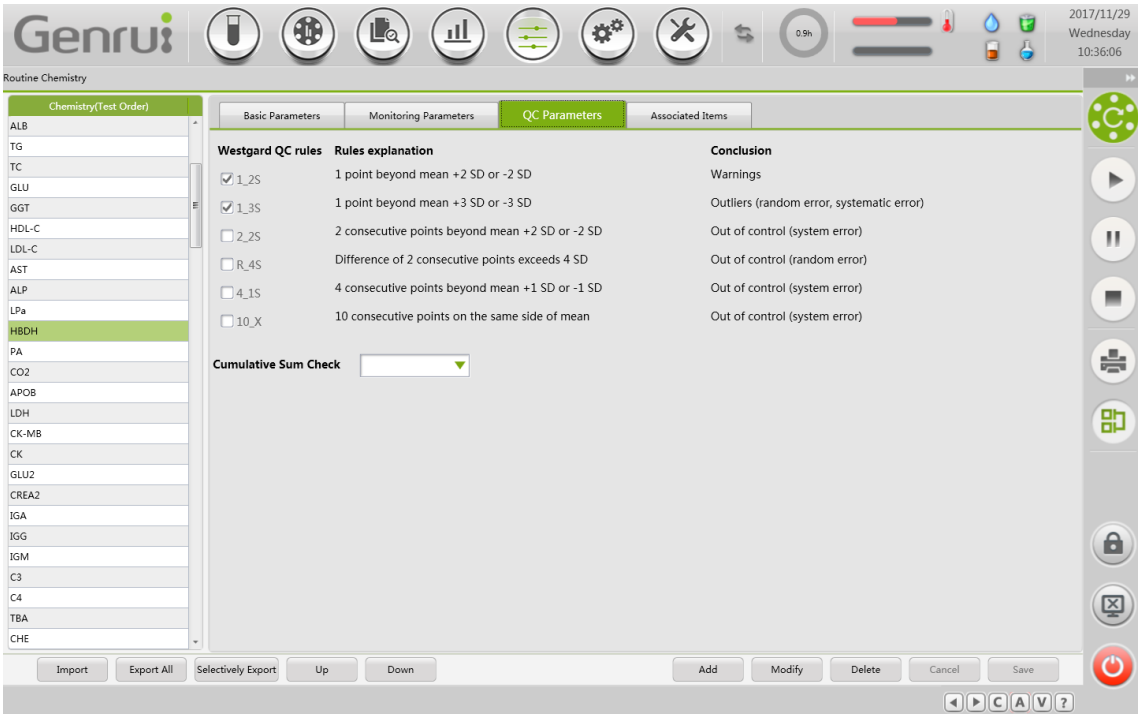
Set or Modify Monitoring Parameters

1) Select the item you want to set or modify in the list of routine chemistry.

2) Enter corresponding data into each monitoring parameter input box.

3) Click the “Save” button to save the data after completing the above operations, or click “Cancel” not to save the data.

③ QC Parameters



For explanations of different parameters and operations corresponding to the “QC Parameters” screen, see the following table:

Parameter	Meaning	Operation
Westgard QC rules	Set an item’s Westgard multi-rule quality control	Tick the box in front of the corresponding rule to select it
Rules explanation	Explanation of the conditions for determining whether or not a loss of control has occurred under the Westgard rules	No operation
Conclusion	The judgment of the error sources of Westgard’s out-of-control rules. Should only be used as a guide	No operation
Cumulative Sum Check	Set an item’s cumulative sum quality control rules	Select from the drop-down box.

Basic Operations

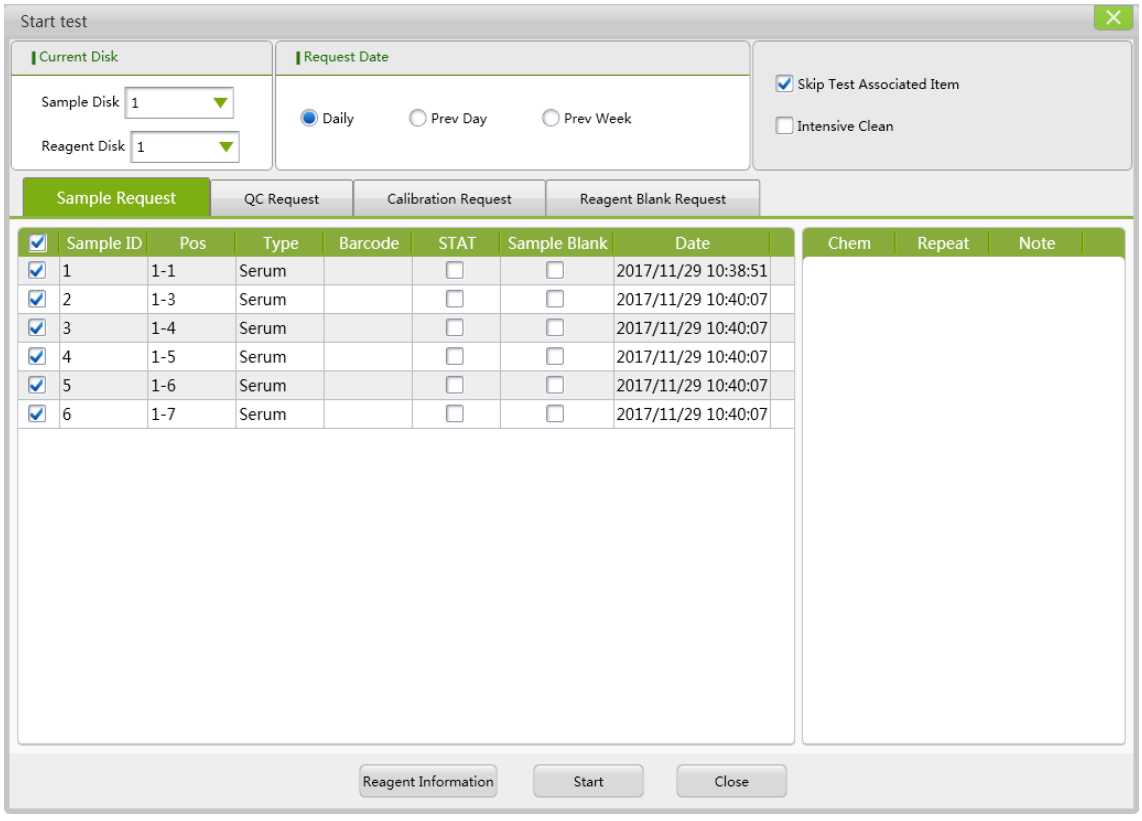
Set or Modify QC Parameters

1) Select the item you want to set or modify in the list of routine chemistry.
2) Select or modify Westgard multi-rule quality control rules.
3) Select or modify cumulative sum quality control rules.
4) Click the “Save” button to save the data after completing the above operations, or click “Cancel” not to save the data.

④ Associated Items



Two or more items that require the same sample volume and reagent volume can be associated in the Associated Items interface.

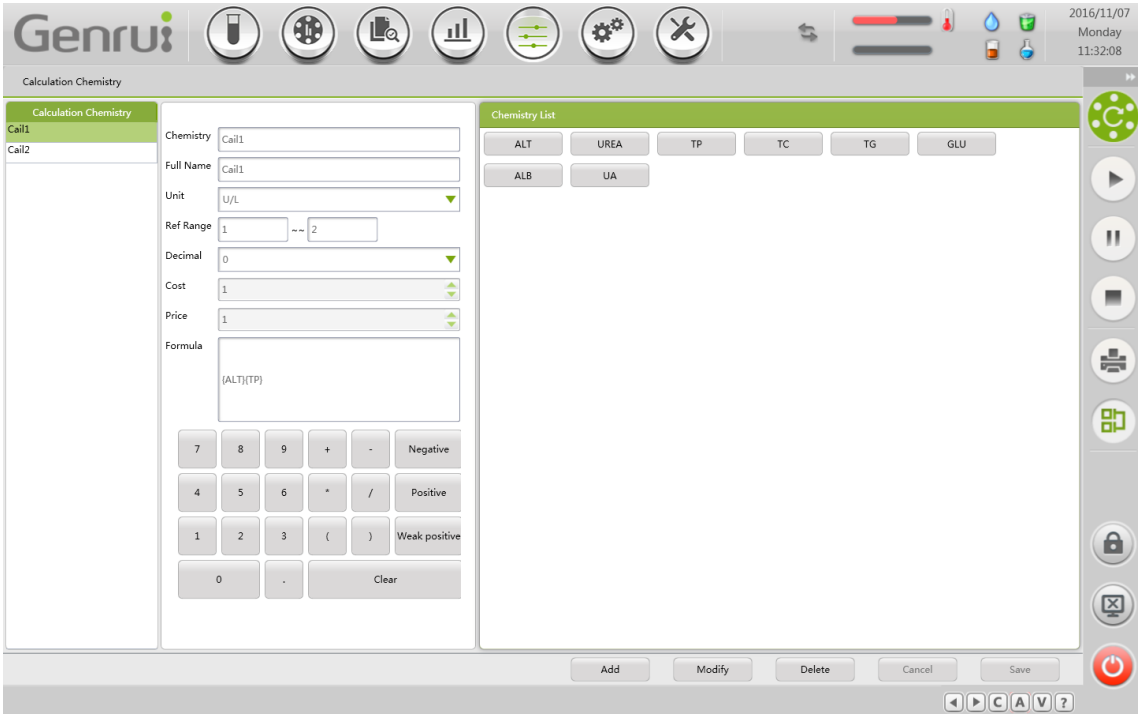


Check the Skip Test Associated Item option at the top right corner in the Start Test interface,

test one of the associated items for the same sample, the other associated items can be given results directly without being tested.

4.4.7.2. Calculation Chemistry

The “Calculation Chemistry” interface is as shown below:



① Parameter explanation

Parameter	Meaning	Operation
Chemistry	Item abbreviations	Enter directly into the box
Full Name	Full name of the item	Enter directly into the box
Unit	Units of the test results	Select from the drop-down box. Select the “...” button to enter the “Data Dictionary” interface and click on the “Add” button to edit any unit of results. Click the “Save” button once you have finished editing to save the change or click “Cancel” if you do not need to save the change
Ref Range	Enter the default reference range	Enter a specific value into the box based on the reference range provided by the reagent’s instruction or other professional reference book

Parameter	Meaning	Operation
Decimal	Number of decimal places retained by the results	Select from the drop-down box. Select the "..." button to enter the "Data Dictionary" interface and click on the "Add" button to edit and specify any number of decimal places with which results will be retained. Click the "Save" button once you have finished editing to save the change or click "Cancel" if you do not need to save the change
Cost	Cost of the item	Enter directly into the box
Price	Item price	Enter directly into the box
Formula	Use the buttons in the formula editing area and the items that participate in the calculation to complete the formula editing operation.	Enter directly into the box

② Basic operations

Add Computational Item

1) Click the "Add" button.
2) Enter or select parameter data corresponding to the current computational item and use the buttons in the formula editing area and the items that participate in the calculation to complete the formula editing operation.
3) Click the "Save" button to save the data after completing the above operations, or click "Cancel" not to save the data.

Modify Computational Item

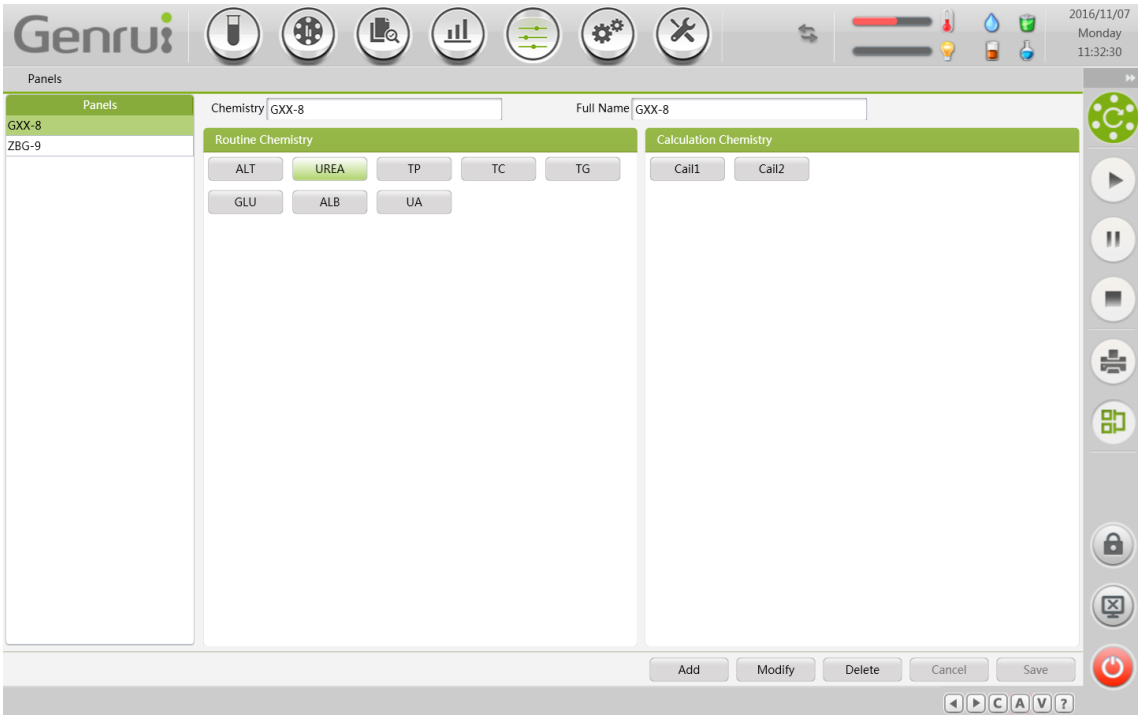
1) Select the item you want to modify in the list of computational items.
2) Click the "Modify" button to modify corresponding parameter data for the current item.
3) Click the "Save" button to save the change after completing the above operations, or click "Cancel" not to save the change.

Delete Computational Item

1) Select the item you want to delete in the list of computational items.
2) Click the "Delete" button to bring up a warning dialog box ("Are you sure you want to delete the currently-selected computational item(s)?"), click the "Yes" button to delete the item or click "No" to cancel deletion of the item.

4.4.7.3. Panels

The “Panels” interface is as shown below:



① Parameter explanation

Parameter	Meaning	Operation
Chemistry	Item abbreviations	Enter directly into the box
Full Name	Full name of the item	Enter directly into the box
Routine Chemistry	A list of all routine items	Select as needed
Calculation Chemistry	A list of all computational items	Select as needed

② Basic Operations

Add Panel

1) Click the “Add” button.
2) Select the desired panel from the routine item and computational item lists.
3) Click the “Save” button to save the data after completing the above operations, or click “Cancel” not to save the data.

Modify Panel

1) Select the panel you want to modify in the list of panels.

2) Click the “Modify” button to modify items corresponding to the current panel.

3) Click the “Save” button to save the change after completing the above operations, or click “Cancel” not to save the change.

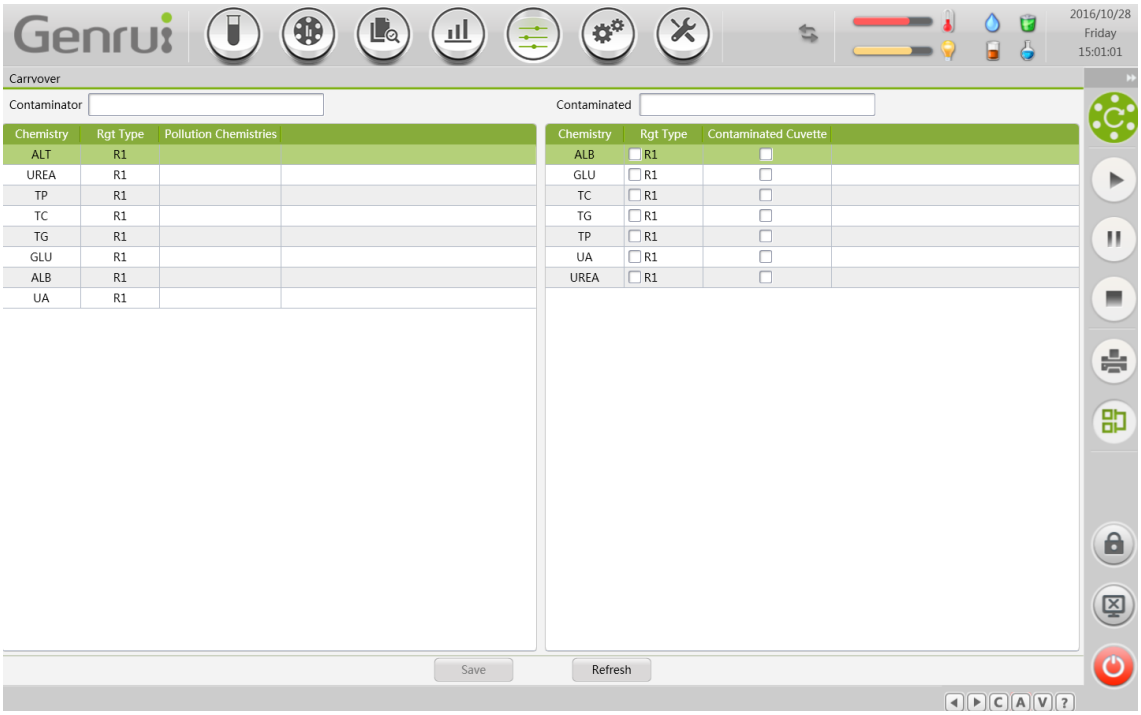
Delete Panel

1) Select the panel you want to delete in the list of panels.

2) Click the “Delete” button to bring up a warning dialog box (“Are you sure you want to delete the currently-selected panel(s)?”), click the “Yes” button to delete the item or click “No” to cancel deletion of the item.

4.4.7.4. Carryover

The “Carryover” interface is as shown below:



① Parameter explanation

Parameter	Meaning	Operation
Contaminator	Abbreviation of contamination source item	Enter directly into the box
Contaminated	Abbreviation for contaminated items	Enter directly into the box

② Basic Operations

Carryover Settings

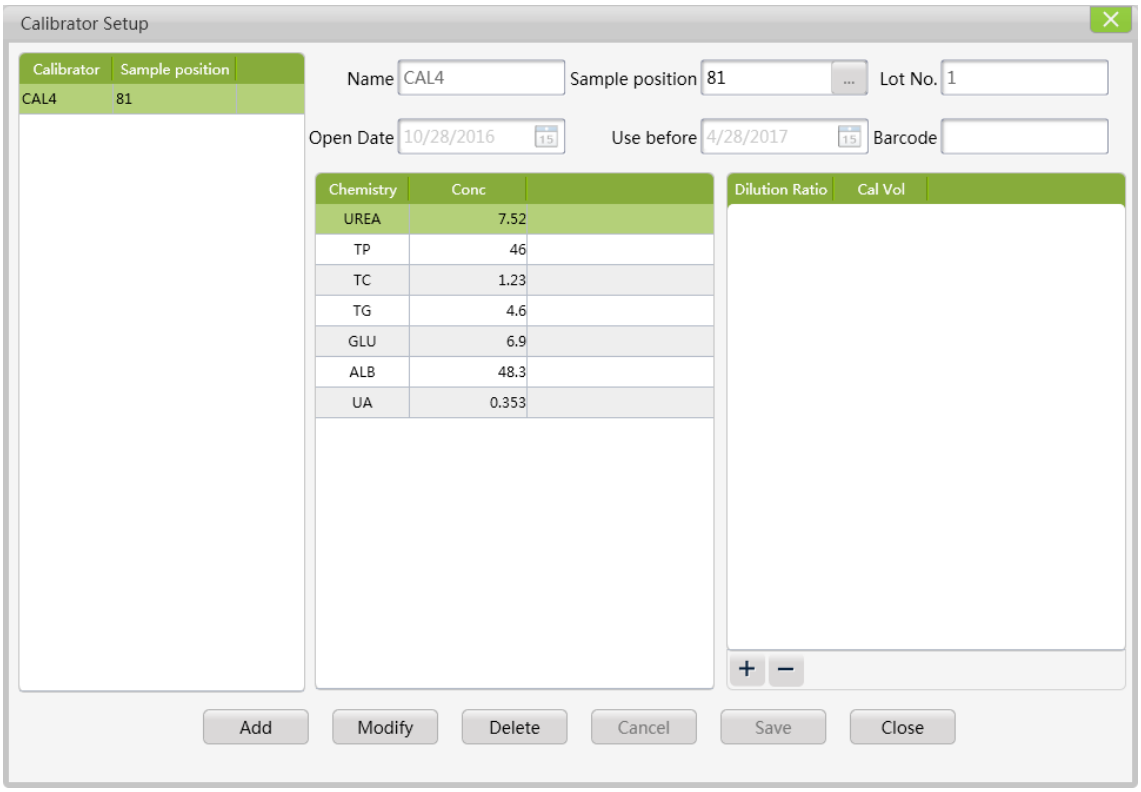
1) Select a contaminator from the contamination source item list and enter the item abbreviation in the box to quickly find the item.

2) Select a contaminated item from the contaminated item list and enter the item abbreviation in the box to quickly find the item. Once a selection has been made, place a √ in the box next to the reagent type. If there is contamination of the reaction cuvette, place a √ in the box next to “Contaminated Cuvette”. Once complete, click the “Save” button.

3) If you need to modify or delete a cross-contamination pair that has already been set, select a contaminator from the contamination source item list, remove the √ in the box next to the reagent type for the contaminated item and, once complete, click the “Save” button.

4.4.7.5. Calibrator Setup

The “Calibrator Setup” interface is as shown below:



① Parameter explanation

Parameter	Meaning	Operation
Name	Name of the calibrator	Enter directly into the box
Sample position	The position of the calibrator on the sample disk	Select the "..." button to enter the sample disk status and select a sample position where the calibrator will be placed
Lot No.	Lot number of the calibrator	Enter directly into the box
Open Date	Date on which the calibrator was opened and a solution was prepared	Enter directly into the box or select by clicking on the calendar icon to the right of the box
Use before	Calibrator expiration date	Enter directly into the box or select by clicking on the calendar icon to the right of the box
Barcode	Barcode of the calibrator	Enter directly into the box or click on the "Scan" button in the sample disk screen to display directly

② Basic Operations

Add Calibrator, Set Calibrator Concentration and Dilution Factor for Each Item

1) Click "+" to set the dilution factor and the amount for the item corresponding to the current calibrator. Click "-" to delete the dilution factor and the amount for the item corresponding to the current calibrator.
2) Click the "Save" button to save the data after completing the above operations, or click "Cancel" not to save the data.
3) When finished, click the "Close" button to exit the calibrator setup screen.

Modify Calibrator

1) Select the calibrator that you want to modify from the calibrator name list.
2) Click the "Modify" button to modify information corresponding to the current calibrator.
3) Click the "Save" button to save the change after completing the above operations, or click "Cancel" not to save the change.
4) When finished, click the "Close" button to exit the calibrator setup screen.

Delete Calibrator

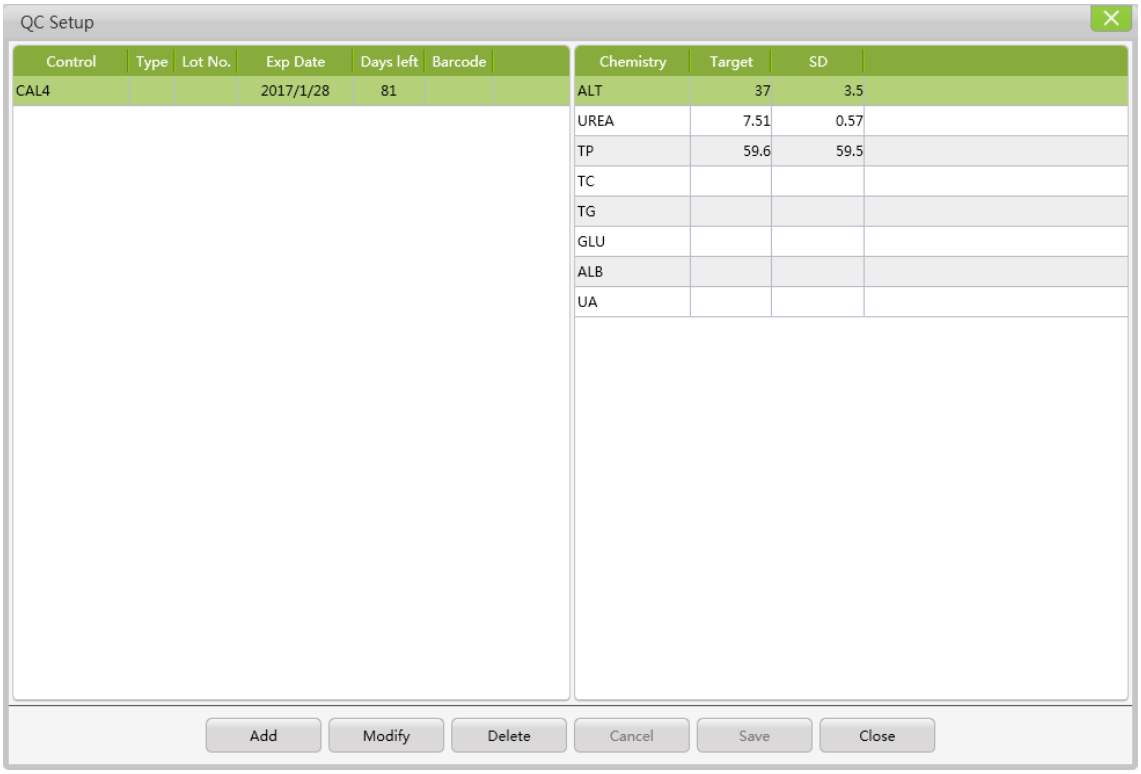
1) Select the calibrator that you want to delete from the calibrator name list.

2) Click the “Delete” button to bring up a warning dialog box (“Are you sure you want to delete the currently-selected calibrator(s)?”), click the “Yes” button to delete the calibrator or click “No” to cancel deletion of the calibrator.

3) When finished, click the “Close” button to exit the calibrator setup screen.

4.4.7.6. QC Setup

The “QC Setup” interface is as shown below:



① Parameter explanation

Parameter	Meaning	Operation
Control	Name of the QC solution	Enter directly into the box
Type	Type of QC solution, including serum, plasma, urine and cerebrospinal fluid (CSF)	Select from the drop-down box.
Lot No.	Lot number of the QC solution	Enter directly into the box

Parameter	Meaning	Operation
Exp Date	Expiration date of the QC solution	Enter directly into the box or select by clicking on the calendar icon to the right of the box
Days left	The remaining days until QC solution expires	Enter the expiration date of the QC solution and the system will automatically display its remaining days until expiration
Barcode	Barcode of the QC solution	Enter directly into the box or click on the “Scan” button in the sample disk screen to display directly
Target	Target value for item corresponding to a given QC solution	Enter directly into the box
SD	Standard deviation value for item corresponding to a given QC solution	Enter directly into the box

② Basic Operations

Add QC Solution, Set QC Solution Concentration for Each Item

1) Click the “Add” button
2) Set parameter information corresponding to the QC solution
3) Enter a target value and standard deviation value in the target value and standard deviation fields which follow the name of the item corresponding to the current QC solution.
4) If you need to save the data after completing the above operations, click the “Save” button, or click the “Cancel” button if you do not want to save your data.
5) When finished, click the “Close” button to exit the QC Setup screen.

Modify QC Solution

1) Select the QC solution that you want to modify from the QC solution list.
2) Click the “Modify” button to modify information corresponding to the current QC solution.
3) Click the “Save” button to save the change after completing the above operations, or click “Cancel” not to save the change.
4) When finished, click the “Close” button to exit the QC Setup screen.

Delete QC Solution

1) Select the QC solution that you want to delete from the QC solution list.

2) Click the “Delete” button to bring up a warning dialog box (“Are you sure you want to delete the currently-selected QC solution(s)?”), click the “Yes” button to delete the QC solution or click “No” to cancel deletion of the QC solution.

3) When finished, click the “Close” button to exit the QC Setup screen.

4.4.8. System Setup

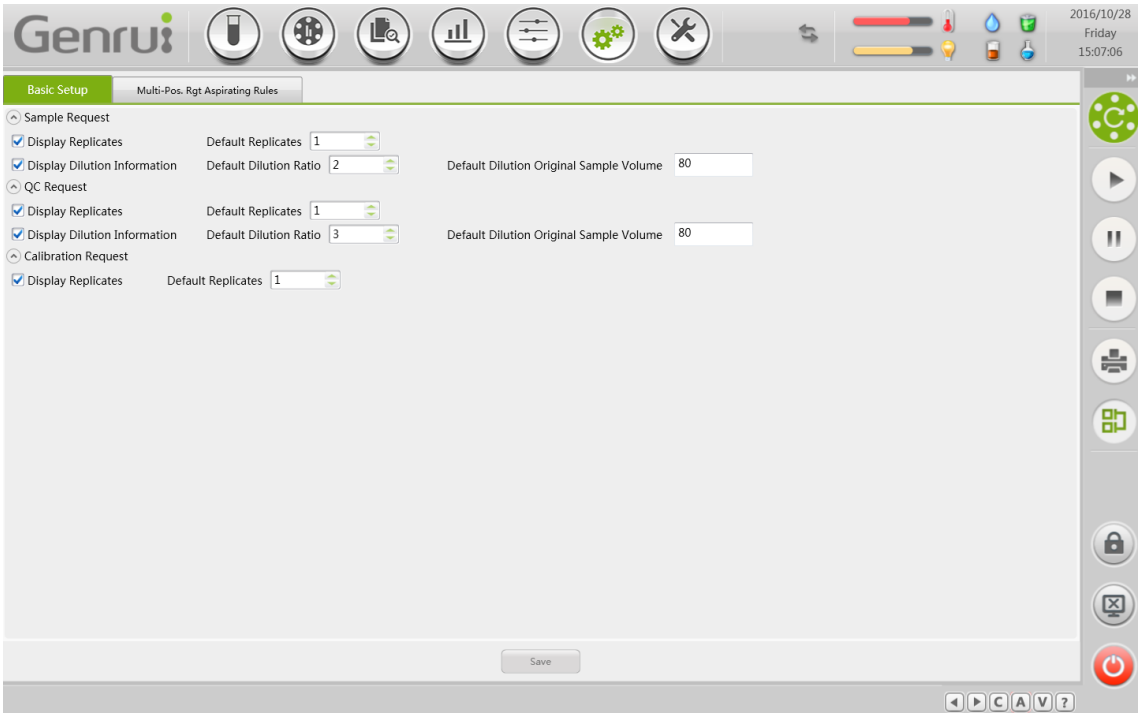
In the operating software main interface, click the “System Setup” button to bring up a drop-down menu which includes the following 6 selectable menus: System Setup, Hospital Setup, User Manage, Print Setup, Barcode Setup and Switch to Chinese. These functions are described below in detail separately:

4.4.8.1. System Setup

Click the “System Setup” button to bring up a drop-down menu, click on the “System Setup” button and enter the System Setup screen, which is used primarily for function activation settings and settings concerning the aspirating rules for multiple reagent positions.

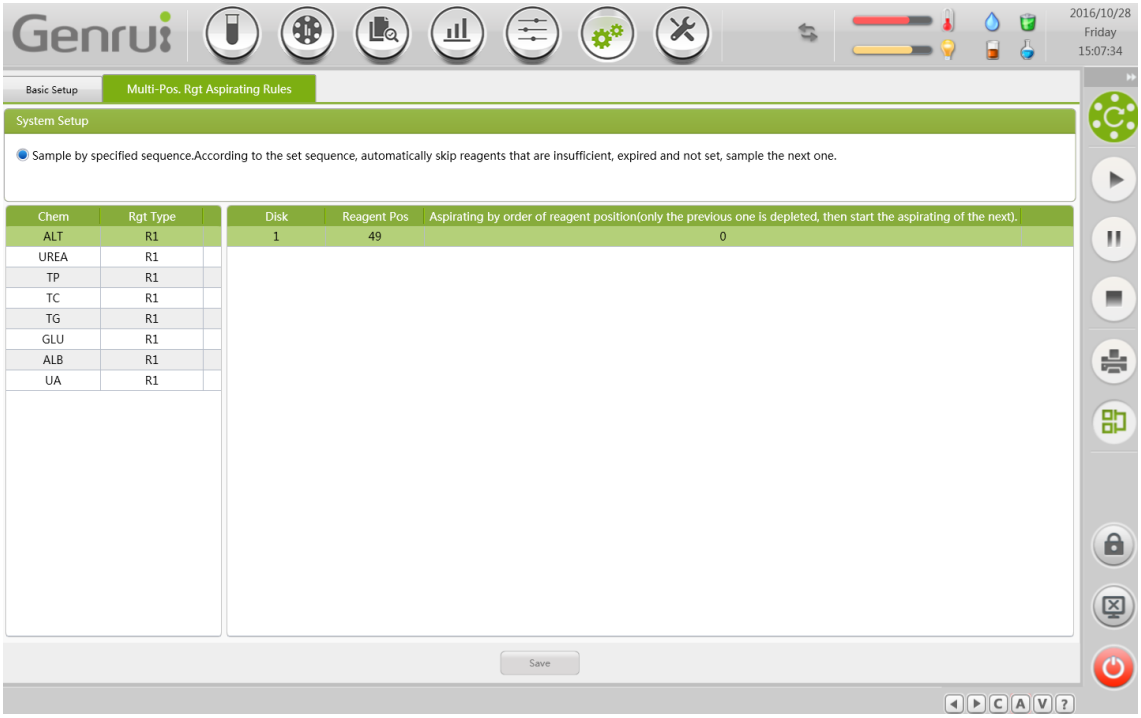
① Function Activation

In this screen, you can set whether to display the number of repetitions, dilution factor and dilution amount for sample request, QC request and calibration request.



② Multi-Pos. Rgt Aspirating Rules

When a reagent has been assigned multiple reagent positions, you can set the aspirating sequence for multiple reagent positions in this screen.

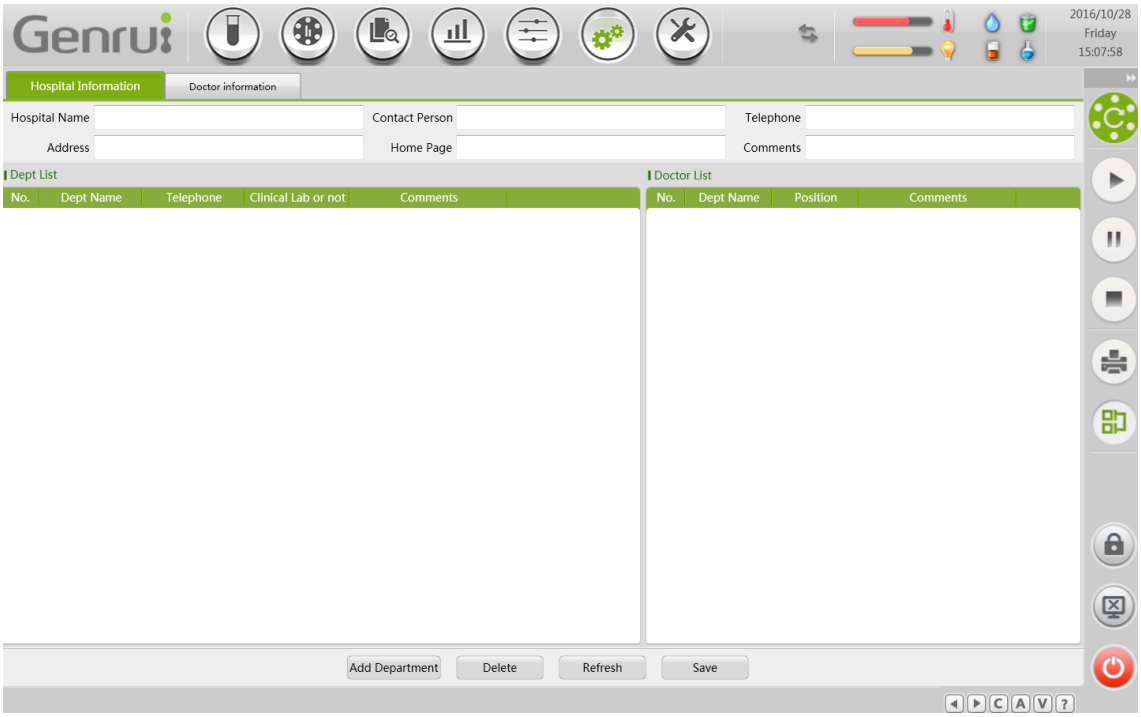


4.4.8.2. Hospital Setup

Click the “System Setup” button to bring up a drop-down menu, click on the “Hospital Setup” button and enter the Hospital Setup screen, which is used to set hospital and doctor-related information.

① Hospital Information

The “Hospital Information” interface is as shown below:



Parameter explanation:

Parameter	Meaning	Operation
Hospital Name	Name of the hospital	Enter directly into the box
Contact Person	Name of the person in charge of the hospital	Enter directly into the box
Telephone	Hospital phone number	Enter directly into the box
Address	Hospital address	Enter directly into the box
Home Page	Hospital website	Enter directly into the box

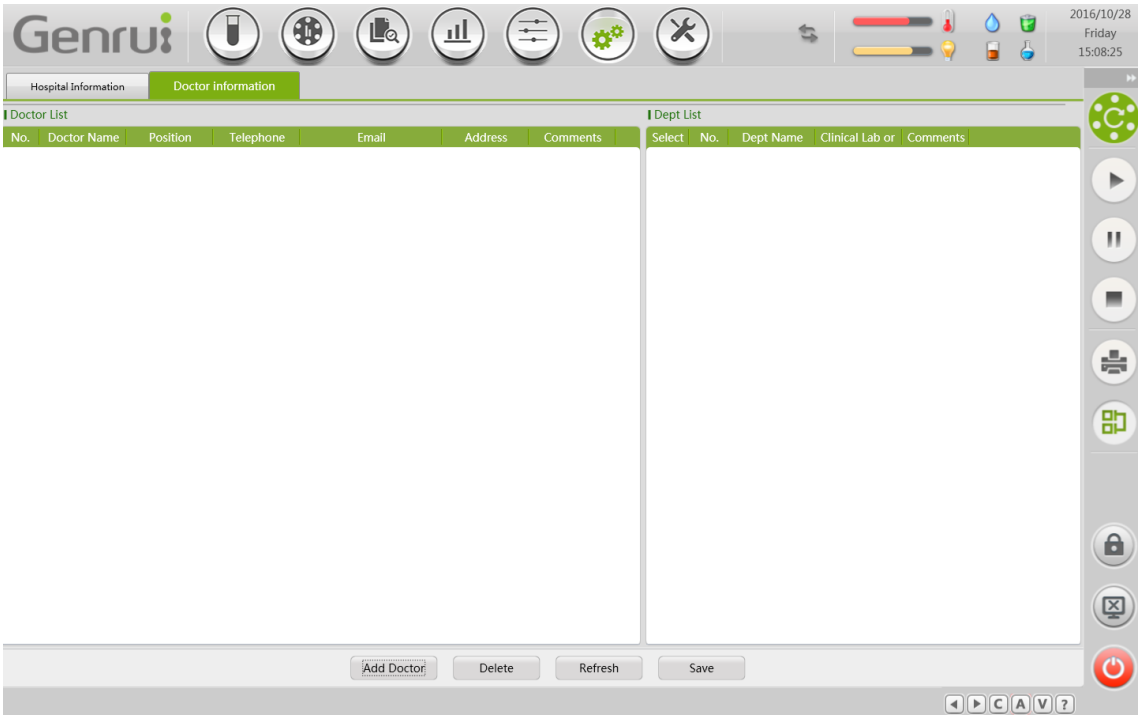
Parameter	Meaning	Operation
Comments	Explanation and description of the hospital	Enter directly into the box
Dept List	Display the department number, department name, telephone number, whether it is clinical lab and additional remarks	Click to add a new department
Doctor List	Display the doctor’s number, name, position and additional remarks	None

Function introduction:

Button	Function Explanation and Operation
Add Department	Click this button to add an additional input box to the department list. The user can then enter the corresponding departmental information.
Delete	Select a department and click on this button to delete the selected department.
Refresh	Click this button to have the screen display department and doctor information saved in the system database.
Save	After adding or modifying records in the data list, click this button to save the changes.

② Doctor Information

The “Doctor Information” interface is as shown below:



Parameter explanation:

Parameter	Meaning	Operation
Doctor List	Display the doctor’s number, name, position and additional remarks	Click to add a new department
Dept List	Display the department number, department name, telephone number, whether it is clinical lab and additional remarks	None

Function introduction:

Button	Function Explanation and Operation
Add Doctor	Click this button to add an additional input box to the doctor list. The user can then enter the corresponding doctor information.
Delete	Select a doctor and click on this button to delete the selected doctor.
Refresh	Click this button to have the screen display department and doctor information saved in the system database.
Associated	Select a doctor and select a department from the department list on the

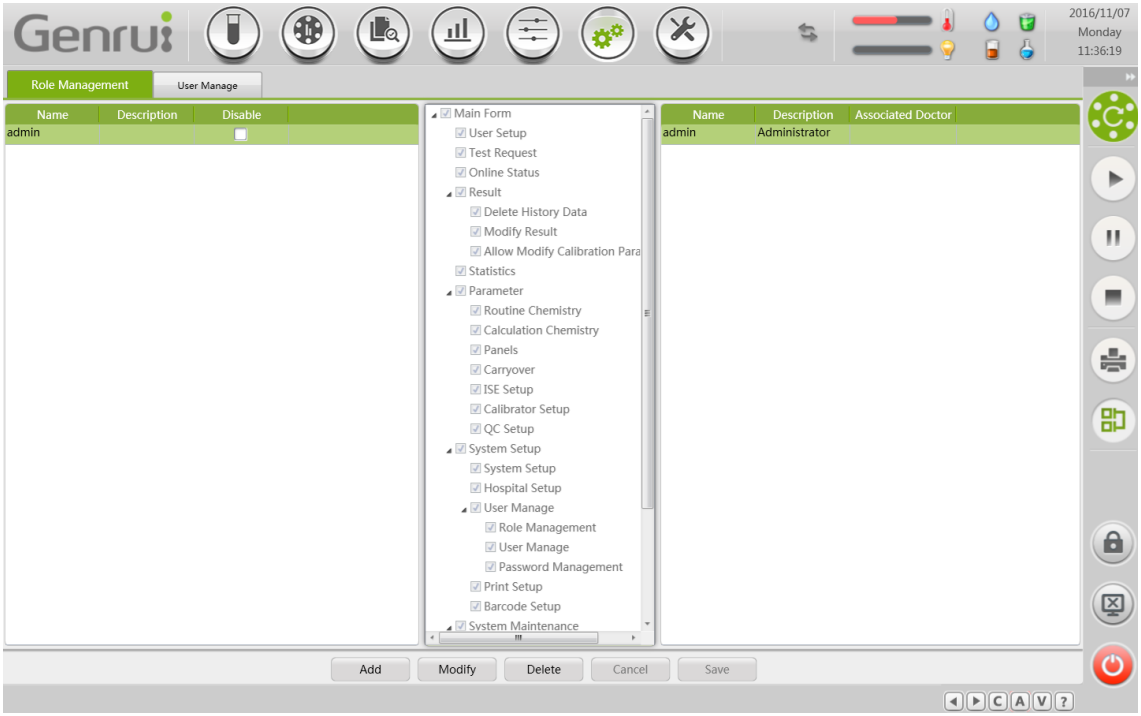
Button	Function Explanation and Operation
Department	right to associate the doctor with the selected department.
Save	After adding or modifying records in the data list, click this button to save the changes.

4.4.8.3. User Manage

Click the “System Setup” button to bring up a drop-down menu, click on the “User Manage” button to enter the User Manage screen, which includes role management and user management. These are described below in detail separately:

① Role Management

The “Role Management” screen is used to set appropriate permissions for a given role.



Parameter explanation:

Parameter	Meaning	Operation
Name	Name of the set role	Click to add and enter information into the corresponding box
Description	Detailed description of the set role	Click to add and enter information into the corresponding box
Disable	Disables the current role	Check the corresponding box

Function introduction:

Button	Function
Add	Add a new role
Modify	Modify permissions for the selected role
Delete	Delete the selected role
Cancel	Cancel the current operation
Save	After adding or modifying records in the data list, click this button to save the changes

② User Management

The “User Management” screen is used to assign appropriate roles to the user.



Parameter explanation:

Parameter	Meaning	Operation
Name	Username used to log into the software	Click to add and enter information into the corresponding box
Description	Detailed description of the set account	Click to add and enter information into the corresponding box
Password	Password of the account	Click to add and enter information into the

Parameter	Meaning	Operation
		corresponding box
Associated Doctor	Name of the doctor using the account	Click to add and enter information into the corresponding box
Disable	Stop using the account	Check the corresponding box

Function introduction:

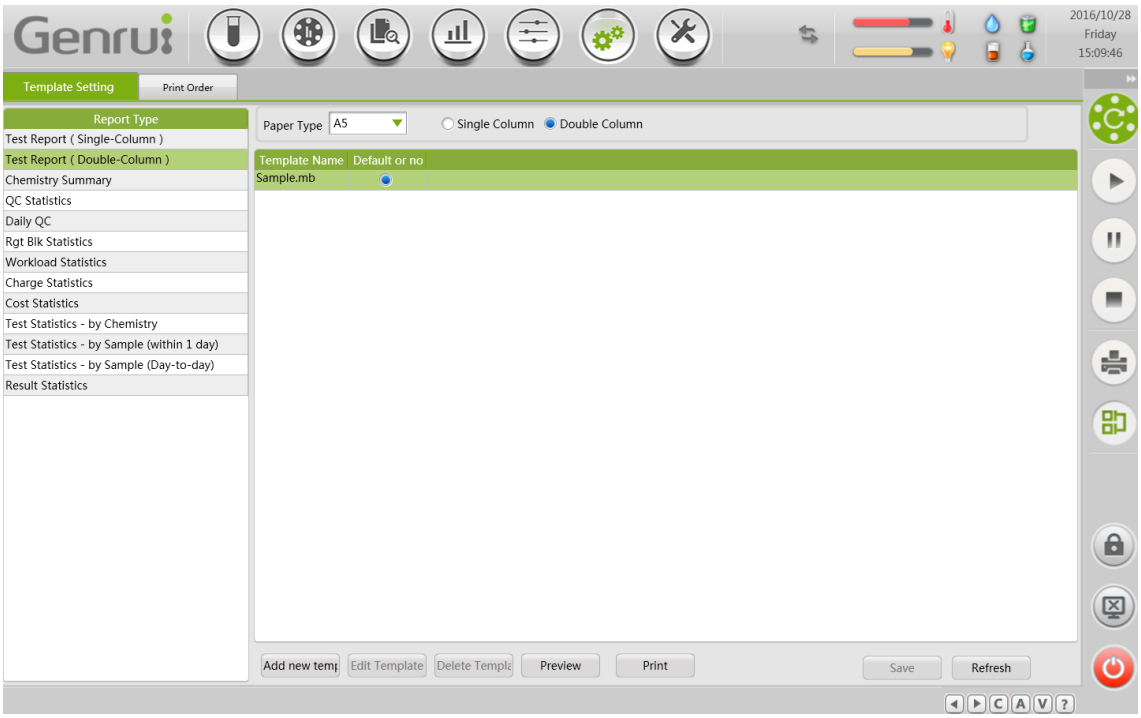
Button	Function
Add	Add a new user
Modify	Modify the role assigned to the selected user
Delete	Delete the selected user
Cancel	Cancel the current operation
Save	After adding or modifying records in the data list, click this button to save the changes

4.4.8.4. Print Setup

Click the “System Setup” button to bring up a drop-down menu, click on the “Print Setup” button to enter the Print Setup screen, which includes template setting and print order. These are described below in detail separately:

① Template Setting

In the Template Setting screen, users can set corresponding print formats and templates for different printing types based on their specific needs.



Parameter explanation:

For a detailed explanation of the various “Report Type” in the “Template Setting” screen, see the table below:

Report Type	**Details**
Test Report	Individual patient’s inspection report, including brief patient information, sample information, test results and diagnostic information
Chemistry Summary	Summarize test results obtained over a given period by item, including a summary of the item’s information and test results
QC Statistics	Print interday quality control curves and quality control data for a given item
Daily QC	Print real time quality control curves and quality control data for a given item

Report Type	Details
Rgt Blk Statistics	Provide summary information for reagent blanks, including the blank's absorbance, reactivity and blank limit
Workload Statistics	Print statistics for the total testing workload of tester within a given period of time, including sample amounts and number of tests
Charge Statistics	Print information regarding test fees for some or all samples within a given period of time
Cost Statistics	Print the statistics concerning the total costs, charges and profits of all test items within a given period of time
Test Statistics - by Chemistry	Print information concerning the total number of tests and reagent consumptions for all items within a given period of time
Test Statistics - by Sample (within 1 Day)	Print the number of samples requested, the corresponding number of tests, test information and serum information for a single day
Test Statistics - by Sample (Day-to-day)	Print the number of samples requested, the corresponding number of tests, test information and serum information for a given period of time (multiple days)
Result Statistics	Print out a test results distribution trend chart and trend data for a given item for a given period of time

Function introduction:

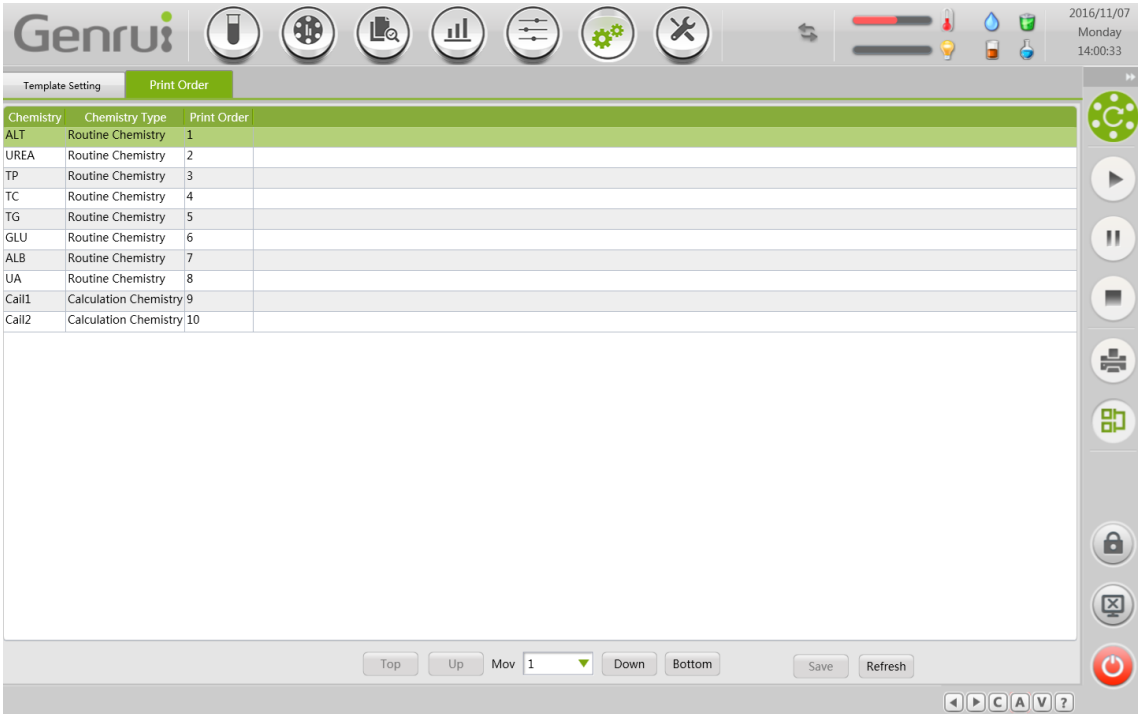
For an explanation of the function of buttons present in the "Template Setting" screen, see the table below:

Button	Function Description
Add new template	Add new printing templates
Edit Template	Edit template formats that already exist within the system
Delete Template	Delete templates that already exist within the system. Default templates cannot be deleted
Preview	View a preview for the selected template
Print	Print the selected template
Save	Save the information after adjusting the template information

Button	Function Description
Refresh	There is no need to save after editing template information. Use the refresh button to restore the template to its pre-edited state

② Print Order

In the Print Order screen, users can adjust the print order of each item based on their specific needs.



Function introduction:

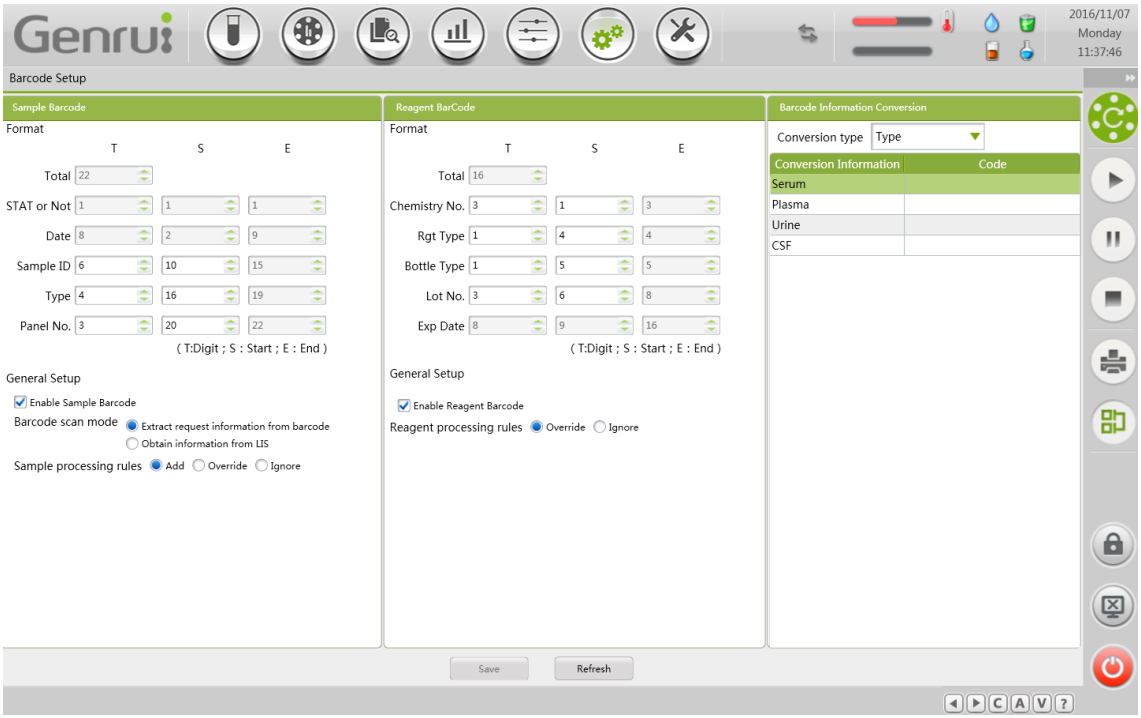
For an explanation of the function of buttons in the “Print Order” screen and the operation thereof, see the following table:

Button	Function Explanation and Operation
Top	Move the selected item directly to the top
Up	Move the position order of the selected item up by one
Move to	Use the drop-down menu to select the desired location and move the selected item directly to the specified location
Down	Move the position order of the selected item down by one
Bottom	Move the selected item directly to the bottom

Button	Function Explanation and Operation
Save	Save the modified order list
Refresh	Display the item print order saved to the current database

4.4.8.5. Barcode Setup

Click the “System Setup” button to bring up a drop-down menu, click on the “Barcode Setup” button to enter the Barcode Setup screen, which is mainly used to set the working modes for the sample and reagent barcode scanning systems, barcode symbology and encoding rules.



① Parameter explanation

Sample Barcode

For an explanation of the function and operation of the “Barcode Setup - Sample Barcode” screen, see the table below:

Parameter	**Meaning**
Total	The total number of digits in a sample barcode. Can be changed by the system automatically but may not be modified manually. The “S” and “E” read-only fields indicate the sample barcode’s start and end positions respectively.
STAT or Not	Routine and emergency. Can be set to 1 bit, can not be modified.
Date	Year - Month - Day. This option defaults to 8 bits, can not be modified.
Sample ID	Set the number of digits in a sample serial number.
Type	The sample type (serum, etc.) defined in the data dictionary.
Panel No.	Number of the panel. If the user is unable to obtain request information for an LIS host but does not want to enter request information manually, information for the requested item can be included in the barcode, thus, the group contains a definition of panels for which a request is possible.
Enable Sample Barcode	Select this option to indicate that sample barcodes can be used within the operating system. All buttons associated with sample barcode functions are active. If, on the other hand, this option is not selected, the corresponding buttons are inactive.
Barcode scan mode	There are 2 options: Extract request information from barcode and Obtain information from LIS. Selecting “Extract request information from barcode”, you can obtain the request information from the barcode based on the barcode setting rules; selecting “Obtain information from LIS”, you can obtain the request information from LIS system by barcodes.
Sample processing rules	There are 3 options: Add, Override and Ignore. Select “Add” to add a test item when a sample exists; select “Overwrite” to overwrite the existing test item; or “Ignore” to ignore the new sample.

Reagent Barcode

For an explanation of the function and operation of the “Barcode Setup - Reagent Barcode” screen, see the table below:

Parameter	Meaning
Total	The total number of digits in a reagent barcode. Can be changed by the system automatically but may not be modified manually. The “S” and “E” read-only fields indicate the reagent barcode’s start and end positions respectively.
Chemistry No.	Number of the test item.
Rgt Type	R1/R2. This option is 1 bit.
Bottle Type	Outer 20ml, inner 40ml. This option is 1 - 3 bits.
Lot No.	Reagent production batch.
Exp Date	Year - Month - Day. This option defaults to 8 bits, can not be modified.
Enable Reagent Barcode	Select this option to indicate that reagent barcodes can be used within the operating system. All buttons associated with reagent barcode functions are active. If, on the other hand, this option is not selected, the corresponding buttons are inactive.
Reagent processing rules	There are 2 options: Override and Ignore. Select “Overwrite” to overwrite the existing reagent; or “Ignore” to ignore the new reagent.

Barcode Conversion

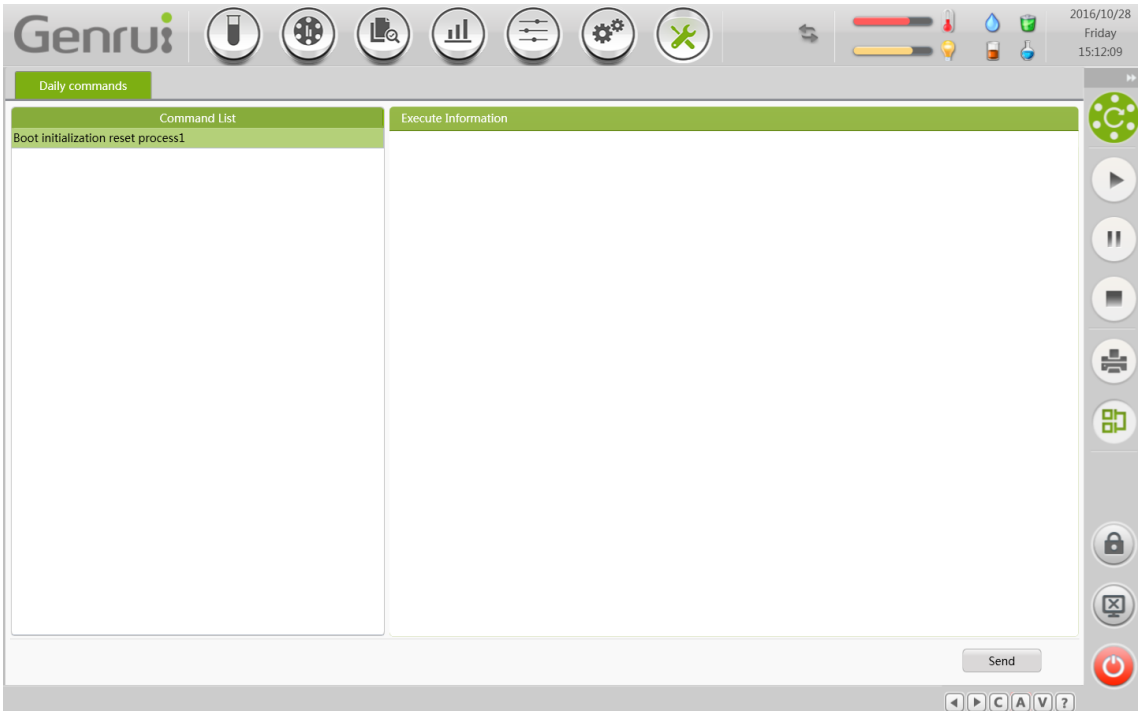
Barcode data conversion, users can convert sample types, panel numbers, item numbers, reagent types and bottle sizes to corresponding barcode values based on their specific needs.

4.4.9. System Maintenance

In the operating software main interface, click the “System Maintenance” button to bring up a drop-down menu which includes the following 5 selectable menus: Routine Maintenance, Log Management, Temperature Curve, Enter Maintenance and Instrument Parameter Settings (Only for Specified Users). These functions are described below in detail separately:

4.4.9.1. Routine Maintenance

The daily maintenance commands interface is as shown below:



① Parameter explanation

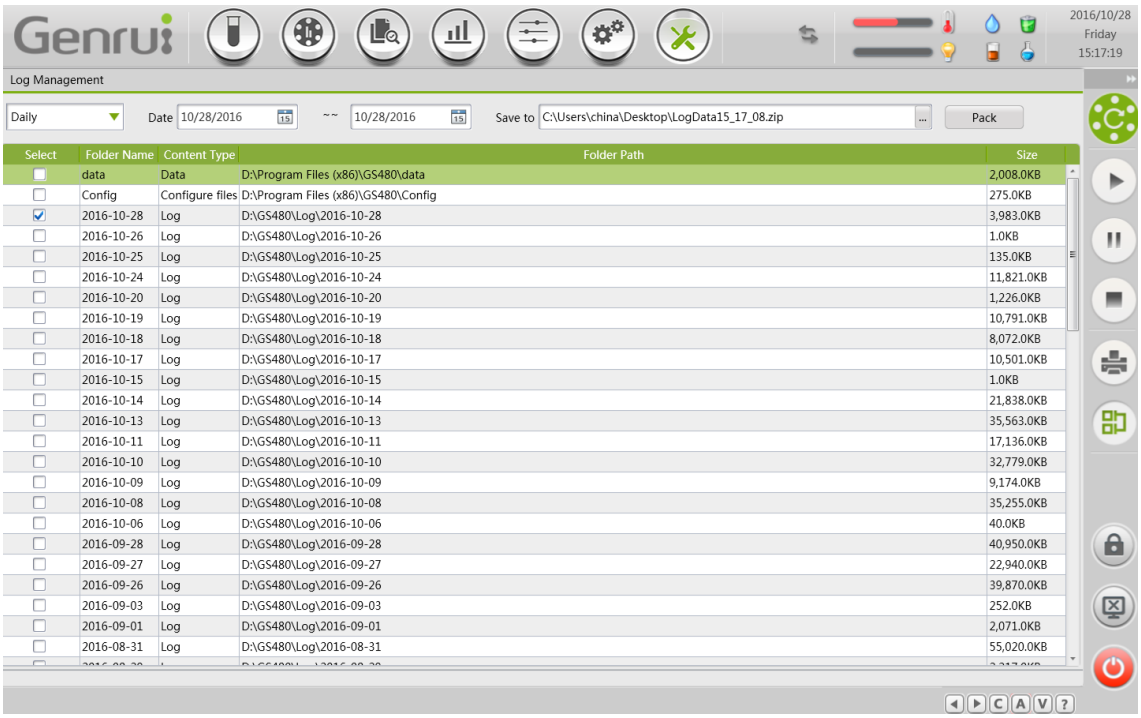
Parameter	Meaning
Command List	Read instruction from the configuration file and display it in the list
Execute Information	Display the instruction execution information

② Basic Operations

1) When connecting the computer, select the instruction to be executed.
2) Click the “Send” button to send instructions to the computer.
3) In the execution information, view the results of instruction execution.

4.4.9.2. Log Management

The log maintenance interface is as shown below:



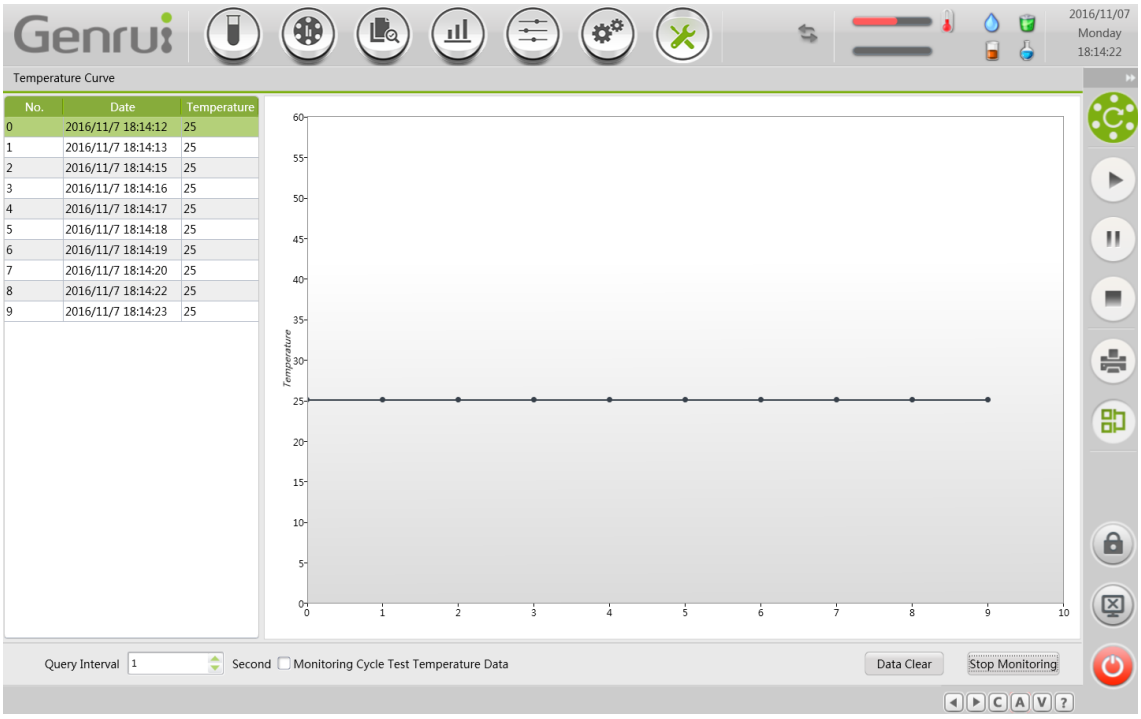
① Parameter explanation

Parameter	Meaning	Operation
Date	Select the date range of the log you want to export	The date range can be selected from the drop-down box to the left of the “Date” field: Daily, Within three days, Within five days, Within ten days and Within one month for a total of five options. Alternatively, you can click on the calendar icon in the right of the “Date” field to select a date range.
Save to	Select the directory where the packaged files are stored	Enter the file storage directory into the “Save to” field or click “…” to select a storage path.
Pack	Allow users to export a file to the export directory in the form of a zip file	Click the “Pack” button to execute the export operation.
Select	Select files to be exported by inserting a “☑” in the appropriate boxes in the	Select a given file for export by placing a “☑” in the box on the same line as the name of the folder you would like to export.

Parameter	Meaning	Operation
	lower part of the screen	
Folder Name	Name of the folder corresponding to files designated for export	/
Content Type	Type of data contained in files designated for export, including raw data, configuration files and logs	/
Folder Path	Path of directory in which exported files are stored	/
Size	Size of data contained in files designated for export	/

4.4.9.3. Temperature Curve

Click the “Temperature Curve” button to enter the temperature status screen where you can check and monitor the temperature of the reaction disk.



① Parameter explanation

Parameter	**Meaning**	**Operation**
No.	Serial number of monitoring data	/
Date	The time at which monitoring data was created	/
Temperature	Temperature of monitoring data	/
Temperature Trends Chart	A trend chart showing temperature monitoring data	/
Interval Time / Monitoring Cycle Test Temperature Data	Select the interval mode for monitoring data	The default interval is 30s between temperature monitoring. Users can perform temperature monitoring according to cyclical testing, by placing a "☑" in the box next to "Monitoring Cycle Test Temperature Data".
Data Clear	Clear the temperature monitoring data	Click "Data Clear", the software will clear the acquired monitoring data.
Start Monitoring	Start monitoring of temperature data	Click "Start Monitoring", the software will monitor the reaction disk temperature according to the selected data monitoring interval method.

4.4.9.4. Enter Maintenance

Click the “Enter Maintenance” button to open the maintenance tools screen, including 3 tabs: protocol command, macro command and custom data.

① Protocol Command

Parameter explanation:

Parameter	**Meaning**
Component Name	Name of the component that send the instruction, can be selected by .
Instruction List	Instruction list below components
Instruction (XX) Parameter	Specific instructions and parameters
Data Transmission Area	Display the instruction information sent to the computer.
Data Receipt Area	Display the instructions received from the computer.
Send Control Area	Set the send control information, such as the number of cycles, send intervals.
Custom Data Area	Not available.
Send Function Area	Click “Send command” to send command to the computer.

② Macro Command

Parameter explanation:

Parameter	**Meaning**
Instruction List	Instruction list below components
Data Transmission Area	Display the instruction information sent to the computer.
Data Receipt Area	Display the instructions received from the computer.
Send Control Area	Set the send control information, such as the number of cycles, send intervals.
Custom Data Area	Not available.
Send Function Area	Click “Send command” to send command to the computer.

③ Custom Data

Parameter explanation

Parameter	**Meaning**
Data Transmission Area	Display the instruction information sent to the computer.
Data Receipt Area	Display the instructions received from the computer.
Send Control Area	Set the send control information, such as the number of cycles, send intervals.
Custom Data Area	Directly enter the data to be sent to the computer
Send Function Area	Click “Send command” to send command to the computer.

4.4.9.5. Instrument Parameter Settings (Only for Specified Users)

① Parameter explanation

Parameter	Meaning
Component Name	Name of the component
Description	Description of the instrument parameter
Range	The value range of the instrument parameter
Set Value	The set value of the instrument parameter
Comments	Other information about the instrument parameter
Debugging Instruction	Debug instructions for the instrument parameter
Parameter Name	The parameter name of the instruction to debug the instrument parameter
Value	The parameter value of the instruction to debug the instrument parameter

② Basic operational steps

1) Select the component for which you want to set parameters
2) Select the parameter to be set.
3) Select the instruction to debug the set parameters.
4) Click “Execute command” to debug the instruction.
5) Set instrument parameters debugged.
6) Click “Configuration Effective” to set parameters of the instrument to the computer.
7) Click “Save Configuration” to save the set parameters to the configuration file.

5. Common Operations

5.1. Item Setup

5.1.1. Routine Item Setup

1) Click the “Parameter Setting” button in the main menu;
2) Select “Routine Chemistry” to enter the item parameter edit interface;
3) Click “Add” button and enter the corresponding parameters into “Basic Parameters”, “Monitoring Parameters” and “QC Parameters” according to the meaning of each parameter and reagent instruction;
4) Click “Save” button to save parameters of routine items.

5.1.2. Calibrator Setup

1) Click the “Parameter Setting” button in the main menu;
2) Select “Calibrator Setup” to enter the calibrator edit interface;
3) Click “Add” button, then click each blank field to active “Name”, “Sample position” and others to enter the corresponding information;
4) Enter corresponding concentration or activity value of calibrator for each item into “Conc” field;
5) Click “Save” button to save the calibrator information.

5.1.3. QC Setup

1) Click the “Parameter Setting” button in the main menu;
2) Select “QC Setup” to enter the QC edit interface;
3) Click “Add” button, then click each blank field to active “Control”, “Lot No.”, “Exp Date” and others to enter the corresponding information;
4) Enter the target value and standard deviation information for each item on the right side of the screen.
5) Click “Save” button to save the QC information.

5.2. Reagent Position Setup

1) Click the “Working Condition” button in the main menu;
2) Select “Reagent Disk”;
3) Choose one empty reagent position, move mouse to the upper part of the item at the pre-set position of “Chemistry List” on the right side of the interface, select R1 or R2;

4) Enter reagent information into the lower right part of the “Reagent” area, including “Name”, “Specification”, “Exp Date”, “Lot No.”, etc.;

5) Click “Save” button to save the edited information.

5.3. Reagent Blank Test

5.3.1. Reagent Blank Request

1) Click “Test Request” button in the main menu;

2) Click “Reagent Blank Request” to enter the reagent blank request interface;

3) Choose item for reagent blank test;

4) Click “Apply” button to finish the request.

5.3.2. Reagent Blank Test

1) Place the reagent blank sample (normally use deionized water or saline) in the specified sample position (it defaults to the 40th sample position);

2) Click the start button in the shortcut button area on the right side of the main menu;

3) Choose the sample disk and reagent disk corresponding to the current test;

4) Click “OK” to start testing.

5.4. Calibration Test

5.4.1. Calibration Request

1) Click “Test Request” button in the main menu;

2) Click “Calibration Request” to enter the calibration request interface;

3) Choose an item that requires a calibration test, the repeated test times and the calibrator;

4) Click “Apply” button to finish the request.

5.4.2. Calibration Test

1) Place calibrator at the corresponding sample position;

2) Click the start button in the shortcut button area on the right side of the main menu;

3) Choose the sample disk and reagent disk corresponding to the current test;

4) Click “OK” to start testing.

Note: Be sure to test reagent blank when performing calibration for a new item.

5.5. QC Test

5.5.1. QC Request

1) Click “Test Request” button in the main menu;
2) Click “QC Request” to enter the quality control request interface;
3) Choose sample disk and sample position;
4) Enter QC sample No. into the “No.” field and select QC solution in “Control” field;
5) Choose QC test item;
6) Click “Apply” button to finish the request.

5.5.2. QC Test

1) Place QC solution at the corresponding sample position;
2) Click the start button in the shortcut button area on the right side of the main menu;
3) Choose the sample disk and reagent disk corresponding to the current test;
4) Click “OK” to start testing.

5.6. Sample Test

5.6.1. Sample Request

1) Click “Test Request” button in the main menu;
2) Click “Sample Request” to enter the sample request interface;
3) Choose whether it is emergency test (“STAT”), sample disk and sample position;
4) Enter the sample “No.” and other information;
5) Choose the test item;
6) Click “Apply” button to finish the request.

5.6.2. Sample Test

1) Place sample at the corresponding sample position;
2) Click the start button in the shortcut button area on the right side of the main menu;
3) Choose the sample disk and reagent disk corresponding to the current test;
4) Select the range of samples to be tested, if you want to test some of the samples, enter the range of the sample;
5) Click “OK” to start testing.

5.7. Test Results Query

5.7.1. Sample Results Query

1) Click “Query Results” button in the main menu;
2) Click “Sample” to enter the sample results query interface;
3) Click “Search Conditions” button to search by the selected query condition;
4) Print sample test results as required.

5.7.2. QC Results Query

1) Click “Query Results” button in the main menu;
2) Click “QC” to enter the QC results query interface;
3) Choose QC query type, item, date and control solution condition to search;
4) View the QC status, results and charts on the right side of the interface.

5.7.3. Calibration Results Query

1) Click “Query Results” button in the main menu;
2) Click “Calibration” to enter the calibration results query interface;
3) Choose item and calibration date to search directly;
4) Choose certain calibration record and then click “Calibration Curve” to enter the specific calibration interface.

5.7.4. Reagent Blank Query

1) Click “Query Results” button in the main menu;
2) Click “Rgt Blk” to enter the reagent blank results query interface;
3) Choose item and test time to view directly;
4) View the reagent blank response and trend chart on the lower right side of the interface.

5.8. Shutdown

Click the shutdown button in the shortcut button area on the right side of the main menu and choose shutdown mode in the pop-up interface, and then operate shutdown procedure by the following order:

1) Choose “Routine Shutdown” to execute routine shutdown instructions. If choose “Holiday Shutdown”, then execute vacation shutdown instructions;
2) Exit the software.

If need to shut down the computer, choose “Turn Off Computer”, the computer will be automatically turned off after exiting the software.

6. Analysis Principle and Computational Methods

6.1. Analysis Principle

The analyzer uses the absorption law of solutions exposed to a light source or the transmission law of suspensions to a light source to monitor the absorbance of each optical metering point throughout the reaction process and, based on changes to absorbance bfore and after the reaction or the rate of change of absorbance throughout the reaction process, in conjunction with corresponding calibration parameters or computational factors, to compute the concentration or activity of the substance examined (the optical colorimetry, optical nephelometry).

6.2. Analysis Procedure

The procedure is described in terms of the action process, the position where each action occurs, the testing process and the system's optical metering point.

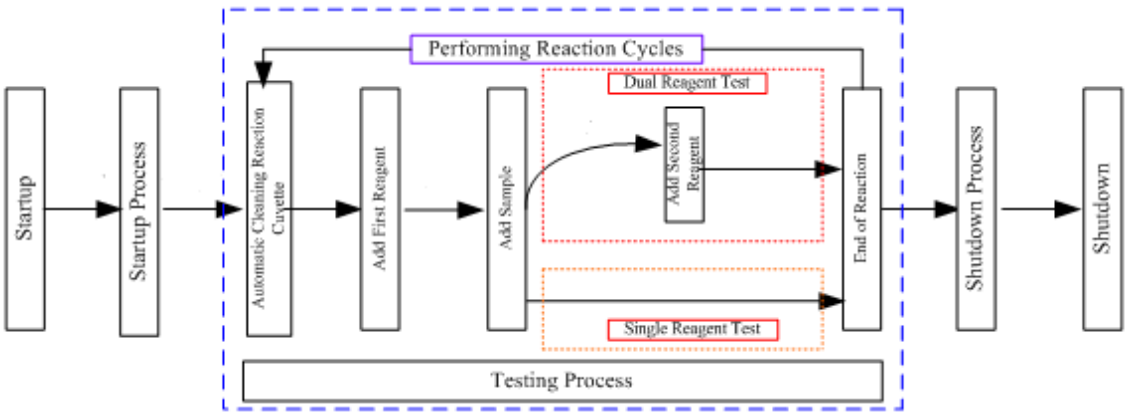
6.2.1. Actions Performed by the Device

Perform the following actions in a circular manner to complete all assigned tests:

1) Rotate the cuvette underneath the reagent probe to add the first reagent.
2) Rotate the cuvette underneath the sample probe to add the sample.
3) Rotate the cuvette underneath the reagent probe to add the second reagent.
4) Rotate the cuvette for photoelectric data acquisition.

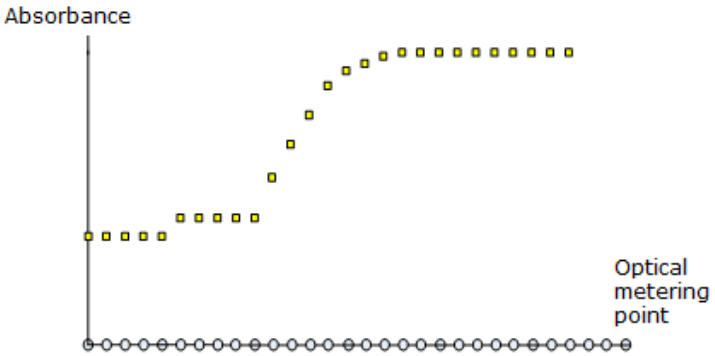
6.2.2. Testing Process

The analyzer performs fixed testing procedures with each reaction including a maximum of 103 test cycles. In constant speed mode, each cycle takes about 9 seconds, as shown in the following figure:



6.2.3. Optical Metering Point

For a given reaction, a single optical measurement is taken once every cycle for a maximum of 103 optical metering points. In constant speed mode, the time interval between two adjacent optical metering points is 9 seconds. The reference reaction curve is as shown in the figure below:



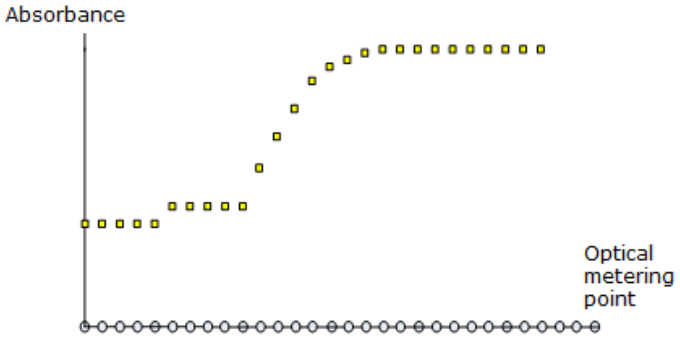
6.3. Analysis Methods

Reaction classification is performed based on the characteristics of a particular reaction's speed during the reaction process. The analyzers divide all reactions into three types: end-point method, two-point method and kinetic method. These are described below in detail separately:

6.3.1. End-point Method

Reaction is carried out thoroughly and the absorbance of the reaction liquid does not increase (or decrease). The increase (or decrease) of absorbance before and after the reaction is proportional to the initial concentration of the measured substance.

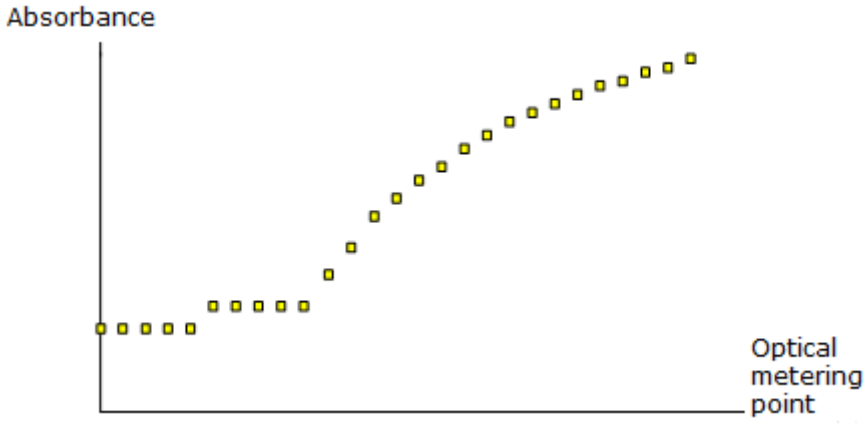
Typical reaction curve of an end-point reaction is shown in the following diagram:



6.3.2. Two-point Method

In the specific period of time, reaction speed is in proportional to first power of the concentration of measured substance. For the continuous consumption of the measured substance, the reaction speed reduced and the speed for the increase (or decrease) of the absorbance (△ A/t) shall slow down. At this period of time, the increase (or decrease) of the absorbance shall be proportional to the initial concentration of the measured substance.

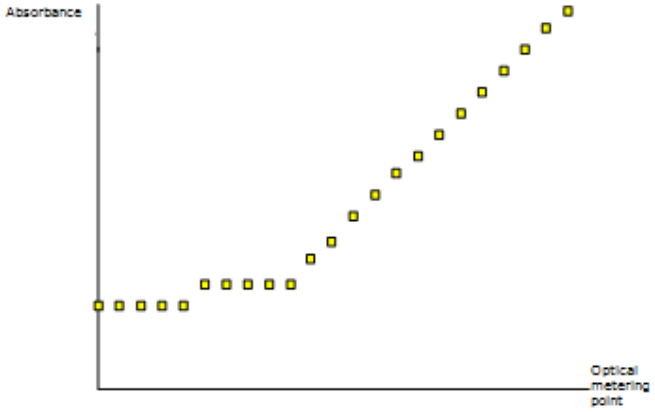
Typical reaction curve of a two-point reaction is shown in the following diagram:



6.3.3. Kinetic Method

In the specific reaction period, the reaction speed is kept at the maximum (Vmax), monitored substance is evenly generated at the top speed. The decrease or increase of the absorbance (△A/t) is proportional to the activity or concentration of the measured substance.

Typical reaction curve of a kinetic reaction is shown in the following diagram:



6.4. Absorbance and Reactivity

6.4.1. Absorbance

The formula used to calculate absorbance (A) is as follows:

$$A = Log \quad \frac{I}{T}$$

Where:

1) “Log” refers to the common logarithm on the base number of 10.
2) “I” stands for AD value when the cuvette is filled with deionized water.
3) “T” stands for AD value when the cuvette is filled with reaction solution.

6.4.2. Reactivity (R)

Reactivity (R) is defined as the change or rate of change of absorbance between the start point to the end point of the reaction. The reaction rate is a very important intermediate data in the calculation process, and is essential for the calculation of the calibration parameter and the concentration. For different types of analysis methods, the reaction amplitude calculation method is not the same, as described below:

(1) Endpoint method

$$R = A_{END} - A_{START} \times k_v$$

Where:

1) A_{END} and A_{START} stands for the absorbance of the end point and start point. The end point and the start point are set by the user in the “Item Parameter”.

2) For single wavelength, the absorbance is the absorbance of the main wavelength; for dual wavelength, the absorbance of each point is the absorbance of the main wavelength minus the absorbance of the secondary wavelength.

3) k_v stands for volume correction factor, $k_v = \frac{v_{START}}{v_{END}}$

(2) Two-point method

$$R = A_{END} - A_{START}$$

Where:

1) A_{END} and A_{START} stands for the absorbance of the end point and start point. The end point and the start point are set by the user in the “Item Parameter”.

2) For single wavelength, the absorbance is the absorbance of the main wavelength; for dual wavelength, the absorbance of each point is the absorbance of the main wavelength minus the absorbance of the secondary wavelength.

(3) Kinetic method

$$R = \frac{\Delta A}{\Delta t}$$

Where:

1) ΔA stands for the change of the absorbance between the start point to the end point. The end point and the start point are set by the user in the “Item Parameter”.

2) Δt stands for the time between the start point to the end point.

3) For single wavelength, the absorbance is the absorbance of the main wavelength; for dual wavelength, the absorbance of each point is the absorbance of the main wavelength minus the absorbance of the secondary wavelength.

6.5. Calibration

6.5.1. Calibration Type

Calibration is divided into linear and non-linear calibration. Linear calibration, including single-point, dual-point and multi-point calibration, is applicable to items of which the reaction liquid is solution. Non-linear calibration, including Logit-4P, Logit-5P, Exponential-5P, Polynomial-5P and Spline, is applicable to items of which the reaction liquid is suspension, such as immune turbidimetric items.

6.5.2. Calibration Parameters

For different calibration types, the number of calibration parameters and calculation methods are not the same, as described below separately.

(1) Single-point linear calibration

The formula $C = \frac{R}{k}$ includes one calibration parameter, k.

$$k = \frac{R_{Cal}}{C_{Cal}}$$

Where:

1) C_{cal} is the concentration of the calibrator

2) R_{cal} is the reactivity of the calibrator

(2) Dual-point linear calibration

The formula $C = \frac{R - b}{k}$ includes two calibration parameters, k and b.

$$k = \frac{R_2 - R_1}{C_2 - C_1}, \quad b = R_1 \quad \frac{C_1 \times (C_2 - C_1)}{R_2 - R_1}$$

Where:

1) C_1, C_2 are the concentrations of calibrator 1 and 2

2) R_1, R_2 are the reactivities of calibrator 1 and 2

(3) Multi-point linear calibration

The formula $C = \frac{R - b}{k}$ includes two calibration parameters, k and b.

Use a multi-point linear regression to calculate the calibration parameters.

(4) Logit-4P

The formula $R = R_0 + \frac{K}{1 + e^{(a + b\ln C)}}$ includes four calibration parameters, R_0, K, a and b.

At least four calibrators are needed, including one of which the concebtration (or activity) is zero, and its reactivity is R_0. Other parameters are obtained through iteration procedure.

(5) Logit-5P

The formula $R = R_0 + \frac{K}{1 + e^{(a + b\ln C + cC)}}$ includes five calibration parameters, R_0, K, a, b and c.

At least five calibrators are needed, including one of which the concebtration (or activity) is zero, and its reactivity is R_0. Other parameters are obtained through iteration procedure.

(6) Exponential-5P

The formula $R = R0 + Ke^{\left[a\ln C + b(\ln C)^2 + c(\ln C)^3\right]}$ includes five calibration parameters, R_0, K, a, b and c.

At least five calibrators are needed, including one of which the concebtration (or activity) is zero, and its reactivity is R_0. Other parameters are obtained through iteration procedure.

(7) Polynomial-5P

The formula $\ln C = a + b(R - R_0) + c(R - R_0)^2 + d(R - R_0)^3$ includes five calibration parameters, R_0, a, b, c and d.

At least five calibrators are needed, including one of which the concebtration (or activity) is zero, and its reactivity is R_0. Other parameters are obtained through iteration procedure.

(8) Spline

The formula $C - C_i = R_{0i} + ai(C - Ci) + bi(C - Ci)^2 + ci(C - Ci)^3 - R$ includes 4i parameters, R_{0i}, ai, bi and ci.

At least two calibrators are needed. Parameters at each segment are obtained through iteration procedure.

6.6. Concentration Calculation

(1) When the analysis method type is kinetic method, calibration can be omitted. In this case, the theoretic calculation factor F can be entered directly, concentration of the item is equal to the product of reactivity R and F. For other types of assays, calibration must be done beforehand. The concentration can be calculated only after calibration parameters are obtained.

(2) For linear calibration, Logit-4P or Polynomial-5P, concentration can be calculated with calibration parameters and reactivity R.

(3) For Logit-5P, Exponential-5P or Spline, concentration can be calculated by using dichotomy to get positive real root with reactivity R and calibration parameters.

6.7. QC

6.7.1. QC Type

There are three types of QC: real-time QC, daily QC and day to day QC. Determine QC status according to the set QC rules.

Real-time QC: Carry on the QC status judgment for 10 consecutive QC data within the day.

Daily QC: Carry on the QC status judgment for all QC data within the day.

Day to day QC: Carry on the QC status judgment for all QC data for several days.

6.7.2. QC Chart

There are three types of QC charts: L-J, cumulative sum and Twin-Plot QC charts.

1) L-J QC chart

Using the actual QC data as the vertical axis, a horizontal line is drawn from the QC target value and 6 parallel lines are drawn to the mean line at the upper +1SD (standard deviation, abbreviated as SD), +2SD, +3SD and at the lower -1SD, -2SD, -3SD. Furthermore, ±1SD、±2SD and ±3 SD are marked clearly and each test result of the quality control is marked on the QC chart. Adjacent points are connected with a thin line.

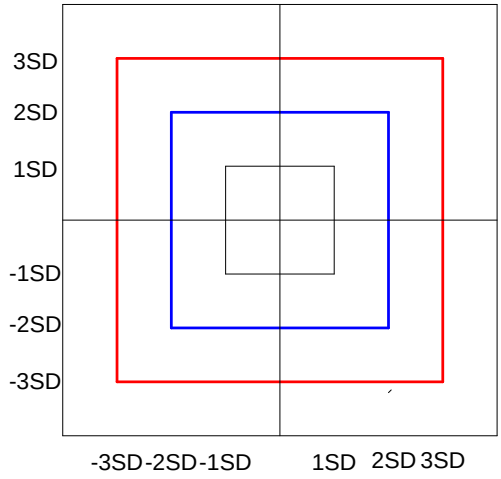
2) Cumulative sum QC chart

In calculating the cumulative sum of a control solution, the cumulative sum value is taken as the vertical axis, and the number of tests as the horizontal axis. A horizontal line is drawn from 0 and at the upper and lower cumulative sum's control limit h (this limit is automatically calculated according to the QC rules that the user has selected in the QC setup), two parallel lines are drawn to the horizontal, each cumulative sum is marked on the chart and the adjacent points are connected via a thin line to yield a cumulative sum QC chart. Any points that are outside the upper and lower parallel lines are regarded as outliers.

3) Twin-Plot QC chart

When simultaneously analyzing control solutions of two concentrations under a single item,

the Twin-Plot QC chart can be displayed. According to each control solution's target value and standard deviation SD (entered by the user in the QC setup) and taking one of the control solution's test values as the horizontal axis (usually the low concentration control solution), the other control solution's test values as the horizontal and vertical axes (usually the high concentration control solution), and the mean value as the central line, ±1SD, ±2SD and ±3SD lines are marked and one point is established using the test results of the two control solutions corresponding to the same test. The point lies on the coordinates as shown in the figure below:



This chart can sensitively reflect systematic and random errors. When data falling within the blue circle (±2SD), it is within control. When falling within the first or third quadrant between the red and blue circles, there is systematic error. When falling within the second or fourth quadrant between the red and blue circles, there is random error. When falling outside the red circle, it is also regarded as indicative of random errors.

7. Maintenance

To maximize the performance of the analyzer, ensure its reliability and extend its life, maintenance should be performed in strict accordance with the requirements outlined in this chapter.

7.1. Preparation of Tools

1) M3, M4 hex wrenches
2) Stainless steel wire (Inner diameter: 0.3mm)
3) Plastic syringe (approx. 10ml, without probe)
4) Clean gauze
5) Clean cotton swabs
6) Brush (used to clean containers)
7) Non-ionic surfactant detergent
8) 75% alcohol
9) Disinfector
10) Medical latex gloves

7.2. Daily Maintenance

7.2.1. Wipe Down the Analyzer Countertop

The analyzer countertop can easily become dirty due to spilling of reagents, reaction solution and serum, and should be cleaned promptly. The instrument should be cleaned every day after shutdown, in accordance with the following steps:

1) Wet a towel with cleaning solution and wipe the analyzer countertop until all visible dirt is wiped clean.
2) Wet a towel with disinfectant and wipe down the analyzer countertop.
3) After fifteen minutes, wring out a wet towel and wipe down the countertop to remove any residual disinfectant.



Note: Corrosion

The cleaning solution is chemically corrosive and protective gloves should be worn during use.

Note: Biohazard

The countertop should be considered contagious and gloves should be worn during handling.

7.2.2. Clean Probe and Stirrer

The outer wall and tip of sample probe, reagent probe and the stirring part of the stirrer can be attached with serum, reagent and water. Inspect carefully every day after system shutdown. If any of the above issues is observed, cleaning should be carried out promptly.

Note: Combustion

Ethanol is flammable. Make sure the analyzer is switched off when cleaning and the amount of ethanol is no more than 10ml.

Note: Biohazard

All analyzer parts should be considered to be infectious and gloves should be worn during handling.

7.2.2.1. Clean Sample Probe/Reagent Probe

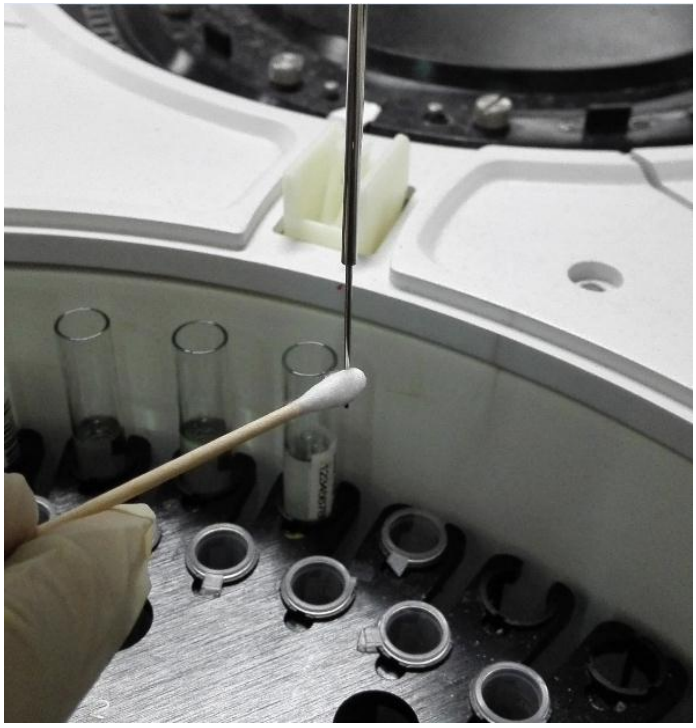


Figure 7-1: Wiping Down the Sample Probe/Reagent Probe

1) Move sample probe/reagent probe to the appropriate position.

2) Soak clean cotton swab in 75% alcohol and gently wipe the sample probe/reagent probe tip until no foreign matter remains on the probe.

7.2.2.2. Clean Stirrer

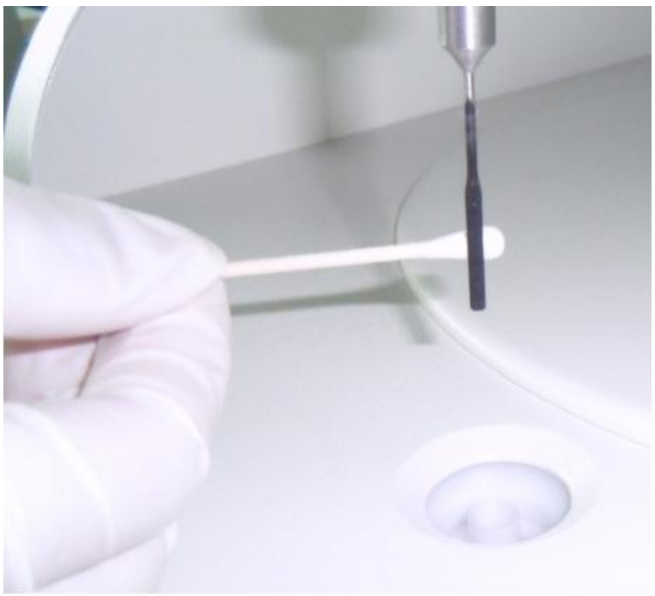


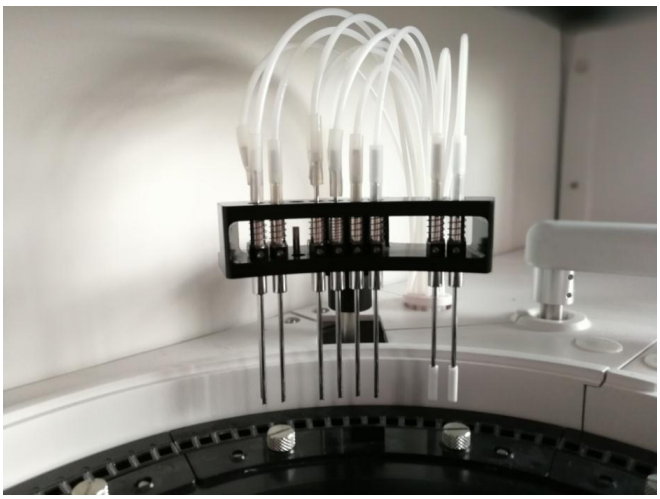
Figure 7-2: Wiping Stirrer

1) Move the stirrer to the appropriate position.

2) Soak clean cotton swab in 75% alcohol and gently wipe the flat part of the stirrer until no foreign matter remains on the rod.

7.2.3. Clean the Cuvette Cleaning Mechanism Probe/Nozzle

When the cuvette cleaning mechanism probe is dirty, it may contain reaction solution or excess water and should be checked daily after system shutdown. If any of the above issues is observed, cleaning should be carried out promptly.



1) Soak clean cotton swab in 75% alcohol and gently wipe the drainage probe and tip until no foreign matter remains on the probe.

2) Soak clean cotton swab in 75% alcohol and gently wipe the absorption probe and tip until no foreign matter remains on the probe.

7.2.4. Inspect the Deionized water Bucket

Check the deionized water bucket in accordance with the following procedure:

1) Check whether the bottom of the bucket is clean.

2) If the bottom of the bucket is dirty, clean the bucket thoroughly before using it again.

7.2.5. Inspect the Waste Bucket/Pipe

Waste pipe and its joint are at the rear of the analysis unit. Check the waste pipe/bucket in accordance with the following procedure:

1) Check if there is any bending of the waste pipe, if so, straighten it.

2) If waste bucket is used, check if there is any leakage or overflow. If there is leakage, replace the waste bucket. If there is overflow, empty the waste bucket.

3) If waste is discharged directly into the sewage, check if there is any overflow. If so, clean out the sewage.



Note: Biohazard

1) All wastes should be considered to be infectious and gloves should be worn during handling.
2) Waste discharge must be in conformity with the requirement of local environmental protection authorities.

7.3. Weekly Maintenance

7.3.1. Clean Waste Bucket

This step can be omitted if waste is discharged directly into a sewer system. Otherwise, cleaning should be performed in the following order:

1) Open the waste bucket lid and remove the waste pipe.

2) Pour the waste liquid into the waste tank.

3) Clean the waste bucket thoroughly with a brush and place it back.



Note: Biohazard

All wastes should be considered to be infectious and gloves should be worn during handling.

7.3.2. Clean Reagent Disk/Sample Disk/Sample Storehouse/Reagent Cooling Unit

1) Turn off the analysis unit's power supply.

2) Remove the covers of the reagent/sample/reaction disk, loosen the tightening screws, take out the reagent bottle and sample bottle and remove the reagent/sample disk.

3) Use a piece of clean gauze dipped in cleaning solution to clean all parts of the

reagent/sample/reaction disk until there are no visible stains, then dry them with clean gauze.

4) Use a piece of clean gauze dipped in wash solution to clean the sample storehouse and the reagent cooling unit until there are no visible stains present. Then use a clean piece of gauze to wipe the interior dry.

5) Reinstall the reagent/sample disk.

6) Place the cover back on the reagent/sample/reaction disk.



Note: Biohazard

All stains encountered should be considered to be infectious and gloves should be worn during handling.

7.4. Monthly Maintenance

7.4.1. Clean the Wash Well

Clean the wash well in the following order:

1) Turn off the power supply of the analysis unit.

2) Remove sample probe/reagent probe from the cleaning position.

3) Dip a clean cotton swab in detergent to gently wipe the outer and inner wall of the wash well of sample probe/reagent probe until no stains are visible, then dry with clean gauze.

4) Remove the stirrer from the cleaning position.

5) Dip a clean cotton swab in detergent to gently wipe the outer and inner wall of the wash well of the stirrer until no stains are visible, then dry with clean gauze.

6) Move the sample probe, reagent probe and stirrer back to the tops of the corresponding wash wells.



Note: Biohazard

All stains encountered should be considered to be infectious and gloves should be worn during handling.

7.4.2. Clean the Thermostatic Groove of the Reaction Disk

Clean the thermostatic groove of the reaction disk in the following order:

1) Turn off the power supply of the analysis unit.
2) Remove the cover of the reaction disk.
3) Loosen the screws that fix the reaction disk in place and remove a set of cuvettes that are put in symmetry.
4) Move the vacant cuvette position underneath the cleaning probe, hold both sides of the reaction disk with both hands and apply a uniform upward force to remove the reaction disk.
5) Dip clean gauze or cotton swab in detergent to clean each part of the inner wall of the reaction compartment until no stains are visible, then dry with clean gauze.
6) Reinstall the reaction disk and fix in place with the corresponding fastening screws.
7) Place cuvettes into the reaction disk and then place the cover on the reaction disk.



Note: Biohazard

All stains encountered should be considered to be infectious and gloves should be worn during handling.

7.4.3. Wiping the Driving Rod

Wipe the driving rod in the following order:

1) Turn off the power supply of the analysis unit.
2) Move the stirrer, so that the driving rod is at an angle suitable for wiping.
3) Use clean gauze to gently wipe the driving rod up and down until no stains are visible. Then apply lubricant oil to the rod and pull up and down on the driving rod so that the lubricant is evenly distributed along the driving rod.
4) Use the same method to wipe the driving rods of reagent probe, sample probe and cleaning mechanism.
5) Move the probes and stirrer to the tops of the corresponding wash well.

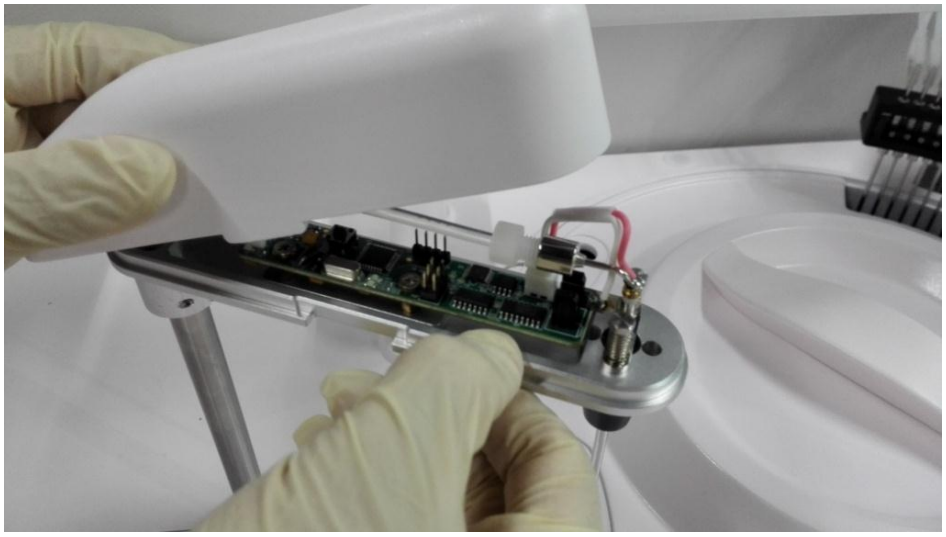
7.5. Unscheduled Maintenance

7.5.1. Unblock the Sample Probe

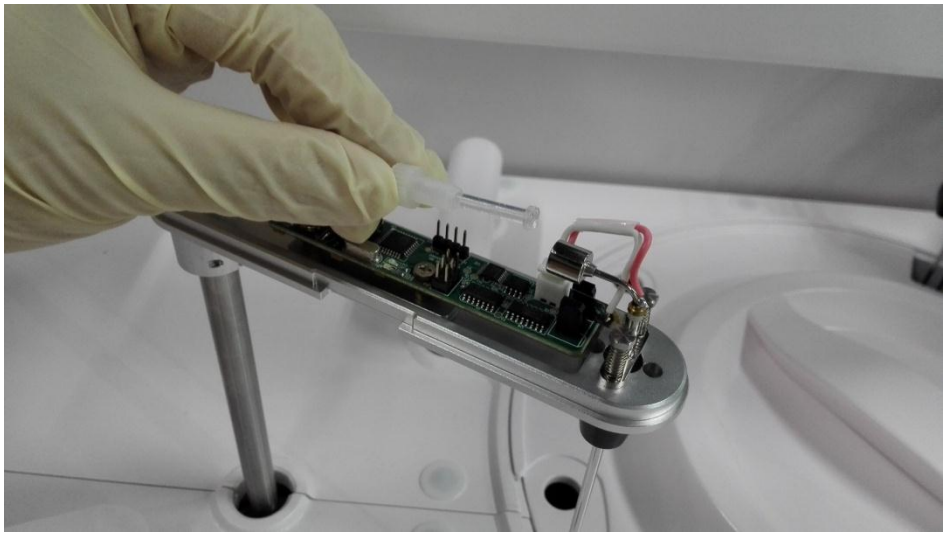
When clogging of a probe occurs, it should be cleared immediately in the following order:

1) Turn off the power supply of the analysis unit.

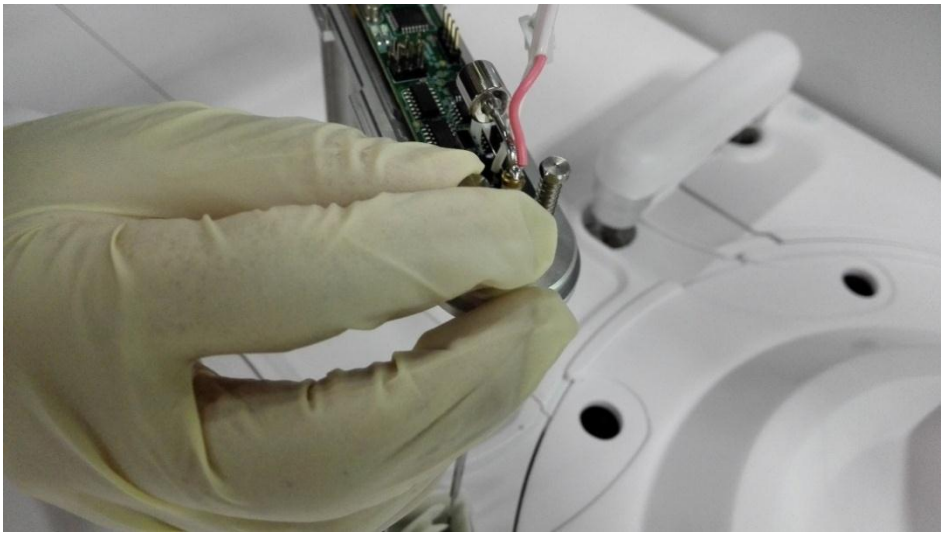
2) Turn the probe to an appropriate position and open the upper cover of the rocker arm, as shown in the following figure:



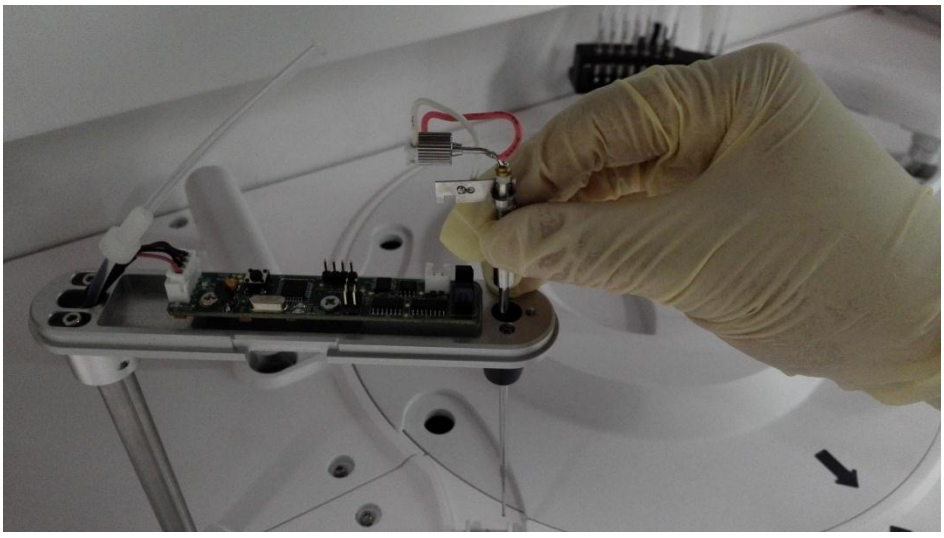
3) Remove the pipe from the end of probe, as shown in the following figure:



4) Loosen the fixing screws, as shown in the following figure:

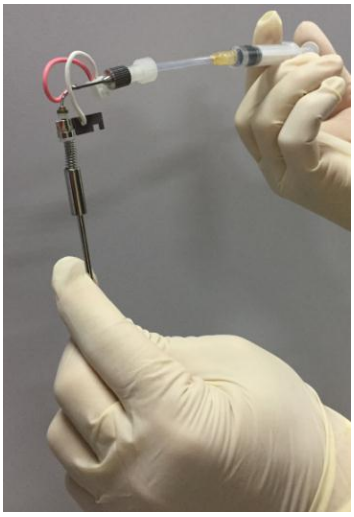


5) Unplug the connection cable from the liquid level detection plate and pull upward the probe to remove it, as shown in the following figure:



6) Pierce the probe tip with stainless steel wire with inner diameter at 0.3mm for several times.

7) Connect syringe with probe using a suitable pipe and press water into the probe, as shown in the following figure. Make sure water is ejected in a straight line, which shows that the probe is unblocked.



8) Replace the probe in the reversed order and close the cover of the rocker arm.

9) Move the probe to the top of the wash well.



Note: Biohazard

The probe should be considered a source of contagion and gloves should be worn during handling.

7.5.2. Replace the Sample Probe

When the probe is blocked, broken or bent, it needs to be replaced immediately in accordance with the following sequence:

1) Turn off the power supply of the analysis unit.

2) Move the probe to an appropriate position. Open the cover of the rocker arm, pull out the pipe from the end of probe and unplug the cable for liquid level detection plate.

3) Loosen the compression spring to remove the sample probe.

4) Install the new probe on the rocker arm, reapply the spring, connect the pipe, plug in the liquid level detection sensor leads and close the cover of the rocker arm.

5) Move the probe to the top of the wash well.



Note: Biohazard

The probe should be considered a source of contagion and gloves should be worn during handling.

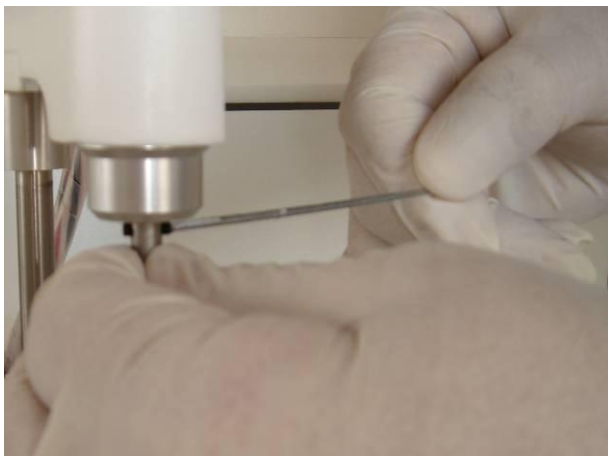
7.5.3. Replace the Stirrer

When the stirrer is broken, bent or constantly holds liquid, it needs to be replaced immediately in accordance with the following sequence:

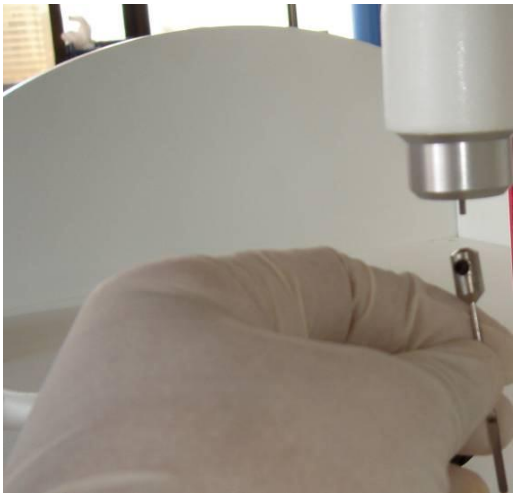
1) Turn off the power supply of the analysis unit.

2) Move the stirrer to an appropriate position.

3) Loosen the two top wire screws fixed to the rotating shaft of the stirring motor, as shown in the following figure:



4) Remove the stirrer, as shown in the following figure:



5) Install the new stirrer upward into the motor shaft until it is stopped.

6) Use two top wire screws to fix the stirrer into the stirring motor shaft.

7) Move the stirrer to the top of the wash well.



Note: Biohazard

The stirrer should be considered a source of contagion and gloves should be worn during handling.

7.6. Replaceable Device List

7.6.1. Parts that can be replaced by users

1) Sample probe
2) Stirrer



Replacing the Fuse

1) The fuse that is integrated into the main power switch is an overcurrent release fuse and does not need to be replaced by users.
2) If you need to replace the fuse, please notify Genrui's service engineer.

7.6.2. Parts that need to be replaced by service engineers

1) Main power supply switch
2) Analysis unit's power supply switch
3) PCB circuit board system
4) Syringe pump
5) Light source lamp

7.7. Instructions for Eliminating or Reducing Disuse

Provide the responsible person with instructions to eliminate or reduce disuse and risks involved in transportation or disposal. The instructions should contain the requirements to minimize the biohazard:

1) Serum, reagents or other liquids are deemed to be infectious. If a small amount of liquids spattered onto the instrument surface, use a cotton ball dipped with "75% alcohol" to wipe it away, otherwise, contact with the surface may lead to infection and other biohazard; if a large amount of liquids splashed and penetrated into the instrument, stop using it and pull out the plug, then contact Genrui or your local distributor.
2) For any carry, transfer, presentation, lending, maintenance, etc., thoroughly disinfect the instrument surface to minimize the biohazard. Once the instrument gets any collision or falls off, no matter if there's any obvious surface or internal damage, stop using it immediately and contact Genrui or your local distributor.
3) If the instrument breaks down after the warranty period, ask Genrui service engineer, hospital equipment department engineer or other authorized maintenance engineer to repair it. Otherwise it may lead to risks such as electric shock. It is suggested to get in contact with Genrui before the maintenance.

4) It is recommended to stop using the instrument when it reaches the retirement period, or continue the use based on an overall inspection and maintenance of Genrui.

5) Only personnel trained and authorized by Genrui or its distributors can use this instrument, otherwise it may damage the protection provided by the instrument or greatly affect the test results.

7.8. Preventive Maintenance and Inspection

1) Check whether the power cable is well connected and grounded or not before starting the instrument.

2) Check whether the equipotential rod is well connected or not before starting the instrument.

3) Check whether the deionized water inlet, waste liquid outlet and other liquid interface is well connected or not.

4) Strictly comply with the requirements described in this chapter to perform maintenance of the instrument.

5) Verify the safe state of the instrument after repair.

7.9. Maintenance Log

The following table lists components that need maintenance and provides a recommended maintenance schedule. Please make a copy of these tables and record in the corresponding column of the maintenance log when maintenance is performed.

Table 7-1 Daily Maintenance

_____Year__Month__Day

	Maintenance Performed (Daily)	**Maintenance Record**																													
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
1	Wipe down the analyzer contertop																															
2	Clean the sample probe																															
3	Clean the reagent probe																															
4	Clean the sample stirrer																															
5	Clean the reaction solution stirrer																															
6	Inspect the deionized water																															
7	Inspect the waste bucket/pipe																															

Table 7-2 Weekly Maintenance

_____Year__Month__Day

	Maintenance Performed (Weekly)	**Maintenance Record**																														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
1	Clean the waste bucket																															
2	Clean the reagent disk																															
3	Clean the sample disk																															
4	Clean the reaction disk																															
5	Clean the sample storehouse																															
6	Clean the cooling unit																															

Table 7-3 Monthly Maintenance

_____Year__Month__Day

	Maintenance Performed (Monthly)	**Maintenance Record**																														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
1	Clean the wash well																															
2	Clean the reaction compartment																															
3	Wipe the driving rod																															

Table 7-4 Unscheduled Maintenance

_____Year__Month__Day

	Maintenance Performed (When needed)	**Maintenance Record**																														
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
1	Unblock the sample probe																															
2	Replace the sample probe																															
3	Replace the stirrer																															

8. Alarm Information and Processing

8.1. Overview

When the analyzer gives an alarm, the system can handle it automatically according to the level of the alarm by using the following 5 methods and display in bright red. Click the red button to get the detailed information of the symptom, possible reason and solution.

1) Test Forbidden

Only diagnosis and maintenance is allowed. Any test is forbidden.

2) Pause

All the tests are stopped and the analyzer is at standby status for interference.

3) Stop New Test

Stop all the tests that are not started and continue that have been started.

4) Alarm

The analyzer gives alarm but does not take any action.

5) Notice

The analyzer gives remind but does not take any action.

This chapter lists all the alarm information and corresponding solutions. Please take corresponding measures according to the solution provided. If the alarm cannot be released after the action is taken, contact Genrui or its local distributor.

8.2. Alarm Information Query

8.2.1. Error Level Definition

The system fault alarm information is classified according to their level. Different levels represent different meanings.

Error level	Definition
1	Reminder: The malfunction will not affect the operation of the instrument, but the user is prompted to be aware of the error.
2	Stop directly.

8.2.2. Alarm Information

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
4101	2	Reaction disk does not reach the assigned position	Reaction disk does not reach the assigned position	1. Stepping motor cable is not well connected or broken; 2. Motor drive board cable is not well connected or broken; 3. Synchronous belt is loosened.	If the trouble remains, please contact with Genrui.
4102	2	Current position of reaction disk is unknown	Current position of reaction disk is unknown	Reaction disk is not at the reset position.	Operate reaction disk reset command. If the trouble remains, please contact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
4103	2	Reaction disk cannot reach the home position	Reaction disk cannot reach the home position	1. Stepping motor cable is not well connected or broken; 2. Motor drive board cable is not well connected or broken; 3. Synchronous belt is loosened.	If the trouble remains, please contact with Genrui.
4204	2	Wash station cannot reach the home position	Wash station cannot reach the home position	1. Stepping motor cable is not well connected or broken; 2. Motor drive board cable is not well connected or broken; 3. Sensor is defective or cable is not well connected; 4. Synchronous belt is loosened.	If the trouble remains, pleasecontact with Genrui.
4106	1	Wash solution syringe pump cannot reach the home	Wash solution syringe pump cannot reach the home position	1.Stepping motor cable is not well connected or	If the trouble remains, pleasecontact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
		position		broken; 2. Motor drive board cable is not well connected or broken; 3.Sensor is defective or cable is not well connected; 4. Synchronous belt is loosened.	
4001	1	Lack of deionized water	Lack of deionized water	1. Lack of deionized water; 2. Deionized water sensor is not well connected or defective.	Try to reconnect the sensor cable, if the trouble remains, please contact with Genrui.
4602	2	Sample probe position is unknown	Sample probe position is unknown	Sample probe is not at the vertical home position.	Operate sample probe vertical reset command. If the trouble remains, please contact with Genrui.
4603	2	Sample probe cannot reach the vertical home position	When sample probe is moving to the vertical home position, the corresponding sensor signal is still not detected after finishing	1. Stepping motor cable is not well connected or broken; 2. Motor drive	After turning off the analyzer, move the sample probe manually and

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
			maximum steps.	board cable is not well connected or broken; 3. Sensor is defective or cable is not well connected; 4. Signal cable is not well connected or cable is broekn; 5. Synchronous belt is loosened.	then restart the analyzer. If the trouble remains, please contact with Genrui.
4604	1	Sample probe collides	Sample probe collides when moving downward vertically	1. Sample tube cap is not open; 2. Sample disk cover is not at correct position; 3. Collision sensor is defective, or cable is not well connected or defective; 4. Collision signal cable is not well connected or defective.	Check sample tube cap, sample disk cap, and restart the analyzer. If the trouble remains, pleasecontact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
	2	Sample probe collides	Sample probe collides when moving downward vertically	1.Reaction disk cover is not at correct position; 2. Collision sensor is defective, or cable is not well connected or defective; 3. Collision signal cable is not well connected or defective.	Check reaction disk cover, and restart the analyzer. If the trouble remains, pleasecontact with Genrui.
4606	2	When the sample probe is ready to rotate horizontally, sample probe is not at vertical home position	When the sample probe is ready to rotate horizontally, sample probe is not at vertical home position	1. Sample probe is not at vertical home position; 2. Sensor is defective or cable is not well connected.	Operate sample probe vertical reset command. If the trouble remains, pleasecontact with Genrui.
4608	1	Sample probe misjudge the sample tube's liquid level	When moving down, the sample probe detect liquid level before it reach to sample tube	1.There are some water at the tip of the probe; 2.Lack of water at water bucket; 3. Inner andoutward chips is loosen; 4. Level detector cable	1. Add deionized water; 2. Gently wipe sample probetip byabsorbent cotton swabs with ethyl alcohol. If the trouble remains, pleasecontact

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
				is not well connected or defective; 5. Level detect board is not well connected to the ground; 6. Level detect board is defective.	with Genrui.
4901	2	Sample disk does not reach assigned position	Sample disk does not reach assigned position	1.Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Synchronous wheel is loosened.	If the trouble remains, pleasecontact with Genrui.
4902	2	Current position of sample disk is unknown	Current position of sample disk is unknown	Sample disk is not at the reset position.	Operate sample disk reset command. If the trouble remains, please contact with Genrui.
4903	2	Sample diskcannot find home position	Sample disk cannot find home position	1. Stepping motor cable is not well connected or defective;	If the trouble remains, pleasecontact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
				2. Motor drive board cable is not well connected or defective; 3. Synchronous wheel is loosen.	
4B02	2	Current position of reagent probe is unknown	Current position of reagent probe is unknown	Reagent probeis not at the reset position.	Operate reagent probe vertical reset command. If the trouble remains, please contact with Genrui.
4B03	2	Reagent probe cannot reach vertical home position	When reagent probe is moving to vertical home position, corresponding sensor signal is still not detected after finishing maximum steps.	1. Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Sensor is defective or cable is not well connected; 4. Signal cable is not well connected or cable is defective;	After turning off the analyzer, move the reagent probe manually and then restart the analyzer.If the trouble remains, please contact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
				5. Synchronous belt is loosened.	
4B04	1	Reagent probe collides	Reagent probe collides when moving downward vertically	1. Reagent bottle cap is not open; 2. Reagent disk coveror reaction disk cover is not at correct position; 3. Collision sensor is defective, or cable is not well connected or defective; 4. Collision signal cable is not well connected or defective.	Check reagentbottle cap, reagent disk cover and reaction disk cover, and then restart the analyzer. If the trouble remains, pleasecontact with Genrui.
	2	Reagent probe collides	Reagent probe collides when moving downward vertically	1. Reaction disk cover is not at correct position; 2. Collision sensor is defective, or cable is not well connected or defective; 3. Collision signal cable is not well	Check reaction disk cover and then restart the analyzer. If the trouble remains, please contact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
				connected or defective.	
4B05	1	Lack of reagent	The reagent probe can detect the liquid level. But the volume is too small and the probe move down by less than 5 steps before reaching the bottom	1.Lack of reagent; 2. Reagent is not at correct position; 3. Level detect board is defective.	1. Check reagent position; 2. Add reagent. If the trouble remains, please contact with Genrui.
4B06	2	When the reagent probe is ready to rotate horizontally, sample probe is not at vertical home position	When the reagent probe is ready to rotate horizontally, reagent probe is not at vertical home position	1. Reagent probe is not at vertical home position; 2. Sensor is defective or cable is not well connected.	Operate reagent probe vertical reset command. If the trouble remains, please contact with Genrui.
4B08	1	Reagent probe misjudge the sample tube's liquid level	When moving down, the reagent probe detect liquid level before reaching to sample tube	1.There are some water at the tip of the probe; 2. Lack of water at water bucket; 3. Inner andoutward chips is loosen; 4. Level detector cable is not well connected or defective;	1. Add deionized water; 2. Gently wipe sample probe tip byabsorbent cotton swabs with ethyl alcohol. If the trouble remains, please contact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
				5. Level detect board is not well connected to the ground; 6. Level detect board is defective.	
4E01	2	Reagent disk does not reach assigned position	Reagent disk does not reach assigned position	1.Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Synchronous wheel is loosened.	If the trouble remains, please contact with Genrui.
4E02	2	Current position of reagent disk is unknown	Current position of reagent disk is unknown	Reagent disk is not at the reset position.	Operate reagent disk reset command. If the trouble remains, please contact with Genrui.
4E03	2	Reagent disk cannot find home position	Reagent disk cannot find home position	1.Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well	If the trouble remains, pleasecontact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
				connected or defective; 3. Synchronous wheel is loosened.	
4303	1	Probe cleaning syringe cannot find home position	Probe cleaning syringecannot find home position	1.Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Sensor is defective or not well connected.	If the trouble remains, please contact with Genrui.
4403	1	Cleaning solution syringe cannot find home position	Cleaning solution syringe cannot find home position	1.Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Sensor is defective or not well connected.	If the trouble remains, please contact with Genrui.
4703	1	Samplesyringe cannot find	Samplesyringecannot find home position	1.Stepping motor cable is not well	If the trouble remains, please contact

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
		home position		connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Sensor is defective or not well connected.	with Genrui.
4C03	1	Reagentsyringe cannot find home position	Reagentsyringecannot find home position	1.Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Sensor is defective or not well connected.	If the trouble remains, please contact with Genrui.
5802	2	Reagent mixer position is unknown	Reagent mixer position is unknown	Reagent mixer is not at vertical home position	Operate reagent mixer vertical reset command. If the trouble remains, please contact with Genrui.
5803	2	Reagent mixer cannot reach vertical home position	When reagent mixer is moving to vertical home position, corresponding sensor	1.Stepping motor cable is not well connected or	After turning off the analyzer, move the

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
			signal is still not detected after finishing maximum steps.	defective; 2. Motor drive board cable is not well connected or defective; 3. Sensor is defective or cable is not well connected; 4. Signal cable is not well connected or cable is defective; 5. Synchronous belt is loosened.	reagent mixermanually and then restart the analyzer. If the trouble remains, please contact with Genrui.
5806	2	When the reagent mixer is ready to rotate horizontally, sample probe is not at vertical home position	When the reagent mixer is ready to rotate horizontally, sample probe is not at vertical home position	1. Reagent mixer is not at vertical home position; 2. Sensor is defective or cable is not well connected.	Operate reagent mixervertical reset command. If the trouble remains, please contact with Genrui.
5502	2	Sample mixer position is unknown	Sample mixer position is unknown	Sample mixer is not at vertical home position	Operate reagent mixer vertical reset command. If the trouble remains, please contact with Genrui.

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
5503	2	Sample mixer cannot reach vertical home position	When sample mixer is moving to vertical home position, corresponding sensor signal is still not detected after finishing maximum steps.	1.Stepping motor cable is not well connected or defective; 2. Motor drive board cable is not well connected or defective; 3. Sensor is defective or cable is not well connected; 4. Signal cable is not well connected or cable is defective; 5. Synchronous belt is loosened.	Operate sample mixerreset command. If the trouble remains, please contact with Genrui.
5506	2	When the sample mixer is ready to rotate horizontally, sample mixer is not at vertical home position	When the sample mixer is ready to rotate horizontally, sample mixer is not at vertical home position	1. Sample mixer is not at vertical home position; 2. Sensor is defective or cable is not well connected.	Operate sample mixer vertical reset command. If the trouble remains, please contact with Genrui.
5702	2	When the reagent mixer is ready to rotate	When the reagent mixer is ready to rotate horizontally, position is unknown	1. Not at horizontal position 2. Sensor is	Operate reagent mixer horizontal reset

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
		horizontally, position is unknown		defective or cable is not well connected.	command. If the trouble remains, please contact with Genrui.
5703	2	When the reagent mixer is ready to rotate horizontally, sample probe is not at horizontal home position	When the reagent mixer is ready to rotate horizontally, sample probe is not at horizontal home position	1. Not at horizontal position; 2. Sensor is defective or cable is not well connected.	Operate reagent mixer horizontal reset command.If the trouble remains, please contact with Genrui.
5402	2	When the sample mixer is ready to rotate horizontally, position is unknown	\When the sample mixer is ready to rotate horizontally, position is unknown	1. Not at horizontal position; 2. Sensor is defective or cable is not well connected.	Operate sample mixer horizontal reset command. If the trouble remains, please contact with Genrui.
5403	2	When the sample mixer is ready to rotate horizontally, reagentmixer is not at horizontal home position	When the sample mixer is ready to rotate horizontally, reagentmixer is not at horizontal home position	1. Not at horizontal position; 2. Sensor is defective or cable is not well connected.	Operate sample mixer horizontal reset command. If the trouble remains, please contact with Genrui.
4A02	2	When the reagent probe is ready to rotate horizontally, position is	When the reagent probe is ready to rotate horizontally, position is unknown	1. Not at horizontal position; 2. Sensor is defective or	Operate reagent probe horizontal reset command. If the trouble

Error Code	Error Level	Description	Explanation	Possible Reason	Solution
		unknown		cable is not well connected.	remains, please contact with Genrui.
4A03	2	When the reagent probe is ready to rotate horizontally, reagent probe is not at horizontal home position	When the reagent probe is ready to rotate horizontally, reagent probe is not at horizontal home position	1. Not at horizontal position; 2. Sensor is defective or cable is not well connected.	Operate reagent probe horizontal reset command. If the trouble remains, please contact with Genrui.
4502	2	When the sample probe is ready to rotate horizontally, position is unknown	When the sample probe is ready to rotate horizontally, position is unknown	1. Not at horizontal position; 2. Sensor is defective or cable is not well connected.	Operate sample probe horizontal reset command.If the trouble remains, please contact with Genrui.
4503	2	When the sample probe is ready to rotate horizontally, reagent probe is not at horizontal home position	When the sample probe is ready to rotate horizontally, reagent probe is not at horizontal home position	1. Not at horizontal position; 2. Sensor is defective or cable is not well connected.	Operate sample probe horizontal reset command. If the trouble remains, please contact with Genrui.

In the event that the errors cannot be removed after performing the required actions, or faults not present in the above list or caused by user operation errors occurred, please contact Genrui customer service department.

9. Transportation and Storage

9.1. Transportation Requirements

The analyzer must be lifted, carried and transported in its intact packaging according to the order contract and safety icons, and protected against severe shocks, vibration, rain, snow and sunlight.

9.2. Storage Conditions

The packaged analyzer should be stored at -10℃～+55℃ and in a well ventilated environment with relative humidity less than 93% and without corrosive gases.



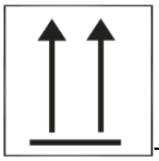
Special Requirements

Do not place heavy objects on the analyzer during transportation and storage. Otherwise it may damage the analyzer.

9.3. Product's Outer Packaging Illustration



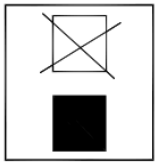
——"Fragile": Carefully carry and place.



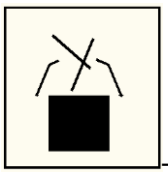
——"Up": Upward to place and transport the product.

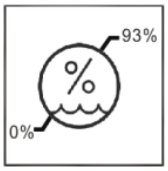


——"Rain Proof": Protect the package from the rain.

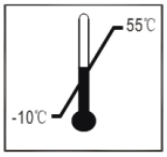


——"No Stacking": This package can only be in one layer.

——“No Turning Over”: Keep upwards, do not turn over the package.



——“Humidity Limit”: Humidity limit for transportation and storage environment.



——“Temperature Limit”: Temperature limit for transportation and storage environment.

Note: The illustrations are for reference only, subject to pictures on the outer package.

10. Commonly-used Consumables and Ordering Method

10.1. Commonly-used Consumables

During normal use and maintenance of the analyzer, the required consumables are listed as follows:

No.	Name	Specification	Replacement cycle	Replacement method
1	Reagent	General type	Replace when runs out	Replace directly
2	Cuvette	0.6cm	Six months	Replace directly
3	Reagent bottle	10ml-70ml	Replace when damaged	Replace directly
4	Lamp	OSRAM 12V	2000 hours (working time)	Replace directly
5	Probe	High quality stainless steel	Replace when bended	Replace directly
6	Wash solution	500ml	Replace when runs out	Replace directly

Note:

The accessories for safe operation of the analyzer should be specified by Genrui, otherwise it may cause safety risks.

Note:

Direct replacement of consumables shall be performed by personnel of Genrui or qualified personnel trained by Genrui.

10.2. Ordering Method

1) Order via your local consumable distributor.

2) Order from the manufacturer by phone.

Ordering hotline: +86 755 26835560

Fax: +86 755 26678789

Appendix A

A.1. Terminology

A.1.1. AD Value

The photocurrent generated by light reaching the sensor. The current passes through a fixed resistor and, after amplification, is converted into a photoelectric voltage (analog signal). This voltage is then subject to an AD conversion (digital-analog conversion) to create a value of corresponding size (the size is correlated with the bit value of the selected AD). This value is the AD value.

A.1.2. Dark Current

It is the value output by the electrical circuit when the light source is not on (i.e. when there is no signal light), expressed as an AD value.

A.1.3. Reagent Blank

Reagent blank is to test the AD value when there is reagent in the reaction cuvette.

A.1.4. Optical Metering Point

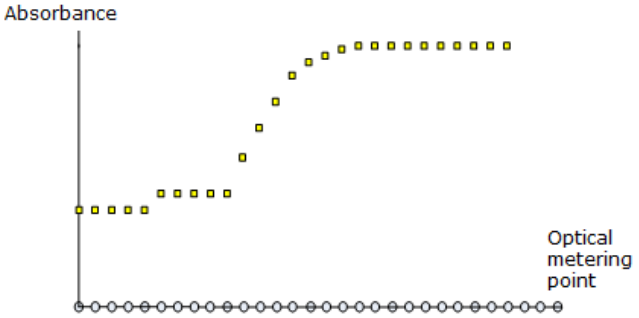
This value is typically shown as a specific value when performing a photoelectric test. There are strict and fixed time relationships between each optical metering point. There are a maximum of 103 optical metering points per reaction, and in constant speed mode, the time intervals between two adjacent optical metering points is 9 seconds.

A.1.5. Absorbance

The value obtained by taking the negative common logarithm (base 10) of the transmitted light intensity divided by the incident light intensity.The incident light intensity is the AD value of a blank reaction cuvette. The absorbance shown is the computed absorbance × 10^4.

A.1.6. Reaction Curve

A series of points plotted on a plane where optical metering points are plotted on the horizontal axis and absorbance is plotted on the vertical axis. A typical reaction curve is as follows:



A.1.7. Reactivity

It is the change or rate of change in absorbance before and after or during the reaction.

A.1.8. Calibration

It is also referred to as alignment. The reaction amplitude of one or more calibrators with known concentration (or activity) is measured and, based on the calibration method selected by the user (linear or nonlinear), the data set (concentration, reactivity) is fitted with an optimal curve, and the mathematical expression for this curve is calculated. By using this curve and determining the reactivity of a sample of unknown concentration (or activity), it is possible to calculate the concentration (or activity) of the sample.

A.1.9. Calibration Curve

Points are arranged on a coordinate plane with concentration (or activity) displayed on the horizontal axis and reactivity displayed on the vertical axis. Curve is fitted with an optimal mathematical formula.

A.1.10. Calibration Parameter

Refers to all terms present in the calibration curve expression with the exception of concentration and reactivity.

A.2. Reagent Kit

Each item has the corresponding reagent kit.

A.3. Sound Pressure

Maximal sound: 30 dBA

NOTE

Be sure to use and store the analyzer in the specified environment.

A.4. Training

To ensure that users can properly use the analyzer and that the device will perform optimally, Genrui will send an internal dedicated service engineer or a Genrui designated distributor to the user to assist with the training.

A.5. Contraindication

None.

A.6. Hazardous Substances

Parts name		Hazardous substances					
		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Host	Host shell	○	○	○	○	○	○
	Host PCBA	×(1)	○	○	○	○	○
	Host sheet metal parts	○	○	○	○	○	○
	Host machining part	○	○	○	○	○	○
	Host plastic pieces	○	○	○	○	○	○
	Host metal pieces	○	○	○	○	○	○
	Host connection cable	○	○	○	○	○	○
	Host fluid path components	○	○	○	○	○	○
Accessories	Labels	○	○	○	○	○	○
	Maintenance tools	○	○	○	○	○	○
	Tubes	○	○	○	○	○	○
	Cuvette holder assembly	○	○	○	○	○	○
	Water barrel	○	○	○	○	○	○
Package	Packaging materials	○	○	○	○	○	○

○: means the content of the hazardous substance in all homogeneous materials of the part is in the limited requirement according to the standard of SJ/T 11363-2006.

×: means the content of the hazardous substance in at least one of the homogeneous materials of the part is beyond the limited requirement according to the standard of SJ/T 11363-2006.

(1): some parts of the circuit board used lead solder during processing.

Notice: the product marked with "×" is because there has no other technologies or parts to be replaced at present stage, under normal use conditions, leak and mutation will not occur in 5 years, and it will not cause environment pollution or harm to people and property.

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