Full-Automated Biochemistry Analyzer

User Manual

Version: V1.0

Qingdao Hightop Biotech Co.,Ltd.

Content

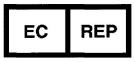
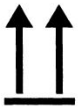
Preface

First of all,thank you very much for your purchasing HTSH series Full-Automated Biochemistry Analyzer (hereinafter referred to as Analyzer) manufactured by Qingdao Hightop Biotech Co.,Ltd. (hereinafter referred to as Hightop Biotech).

Please read the instructions carefully to use the analyzer correctly.
Save the instructions carefully after reading and place the instructions in a convenient location.
To ensure the safe operation of the instrument, please observe the following precautions:

- The contents of this manual include all the optional devices and optional functions (sold separately). If you have not purchased these optional devices or optional functions, please skip these contents when reading the manual.
- The analyzer is intended for quantitative analysis of clinical biochemical analysis of bodily fluids such as serum,plasma, urine, cerebrospinal fluid, pleural effusion, etc. for clinical and laboratory tests. Other than that, the analyzer may not work properly.
- For clinical testing,use under the supervision of a clinical laboratory technician, hygienic laboratory technician, or physician.
- Please have received or trained by the designated technical personnel to operate.
- Before using the analyzer,must be familiar with the instructions,analyzer should be used when instructions are well known.
- Do not use methods not specified in the instructions as it may cause danger and damage to the analyzer.
- When using the analyzer, monitor the instrument for proper operation by measuring the quality control. Incorrect measurement results may cause incorrect diagnosis.
- Please refer to the instructions provided by the manufacturer for the methods of storage (including before and after unsealing),methods of use and precautions of reagents,quality controls, and standard liquid.
- Units of analyzer couldn't be disassembled or modified without Hightop Biotech's permission,because it may cause danger to personnel and damage to the instrument.
- Transfer machines,expansion,reorganization,improvement and repair should be conducted by staff approved by Hightop Biotech.
- The power switch must be easily accessible to safely disconnect the power from the device and do not place the device in a location where it is difficult to operate the disconnect device.
- This analyzer is not suitable for home use.
- This analyzer is not suitable for outdoor use.

Product Information

Icon	Meaning	Description
	**In vitro diagnosis**	
	**CE mark**	It is a symbol of EU's unanimous protection,products therefore complies with the requirements of Directive 98/79/EC.
	**EU representative**	
	**People's Republic of China manufacturing license for measuring instruments**	
	**Product Serial Number**	The serial number of the product shipped
	**Manufacturing date**	**Manufacturing date of product**
	**Maufacturer**	Qingdao Hightop Biotech Co.,Ltd.
	**Warning**	Advise users to pay attention to potential dangers and e-waste, they are easy to pollute the environment. Contact the manufacturer to recycle or dispose of these potential sources of contamination as required by the local government.
	**Fragile**	
	**Afraid of rain**	
	**Up**	
	**Stacking layer limit**	
	**Temperature range**	

Copyright and Declaration

Product warranty

Warranty period

One year from the date of completion of the installation or in accordance with the contractual agreement.

Guarantee content

Hightop Biotech will be responsible for the safety, reliability and performance of our products if all of the following requirements are met, namely:

1. Assembly operations, extensions, recalls, improvements and repairs are carried out by accredited personnel by Hightop Biotech.
2. The relevant electrical equipment complies with national standards.
3. Product operation should be in accordance with the "User Manual".

During the warranty period if fault are caused by Hightop Biotech's design, manufacturing defects the, will be repaired free of charge,but the repair method will be determined by Hightop Biotech, according to the content of the fault to take relevant measures.

Non-guarantee items (not responsible items)

The following conditions will not be guaranteed even during the warranty period:

1. Failure to use the product outside the operating environment required by this User Manual.

2. Failure caused by user brutal operation, misuse, misuse.

3. Improper maintenance, or failure due to maintenance by a non-Hightop Biotech maintenance company.

4. Failure caused when consumables and parts with specified period of use are not changed when expiry.

5. Failure caused by the use of hardware, software or accessories other than those supplied by Hightop Biotech.

6. Failure caused from circuit corrosion caused by strong corrosive gas in the air and obvious aging of optical element.

7. Failure from scrapped analyzer or analyzer purchased from others without contact with Hightop Biotech.

8. Storage data is lost due to analyzer failure(Suggest users to make timely data backup or output.)

After installation, using the method not approved by Hightop Biotech to move, transport, install, lead to breakdown.

Failure to disassemble or modify without permission of Hightop Biotech.

Failures caused by fire, earthquakes, wind damage, floods, lightning strikes and other irresistible natural disasters.

Storage conditions during use and transport of the instruments

Installation at the time of purchase is carried out by Hightop Biotech designated installation service department.

The analyzer must be used if the following conditions are met and the environment is maintained:

1. Instrument transport conditions:
   Ambient temperature: -4℃~40℃ Relative humidity: 30%~80%
   Atmospheric pressure: 860hPa~1060hPa

2. Safety conditions use of instrument:
   1）Indoor use.
   2）Altitude does not exceed 3000m.
   3）Temperature 5℃～40℃.

4）When the temperature is below 31 ℃, the maximum relative humidity is 80%; When the temperature is 40 ℃, the relative humidity decreases linearly to 50%.

5）Supply voltage fluctuations do not exceed ± 10% of nominal voltag.

6）Typical transient overvoltage appeared on the grid power supply.

7）Appropriate rated pollution level.

3. Instrument normal working conditions:

1）Indoor use.

2）Rated power supply voltage: ～220V 50Hz.

3）Range of rated power supply voltage：～220V±10% 50Hz±1Hz;

4）Operating temperature：10℃～35℃;

5）Operating relative humidity (extended conditions): ≤90%,No condensation.

6）Storage relative humidity (extended conditions): ≤95%.

7）Altitude is below 3000m;

8）Pollution level: Class Ⅱ

4. Other environmental conditions:

1）Low dust, good ventilation

2）Avoid direct sunlight

3）The instrument can be used at room temperature, however, in order to ensure accurate test results, it is recommended that the room temperature be kept at 10 ° C to 35 ° C, indoor temperature changes within ± 2 ℃ in the measurement process.

4） The instrument is prohibited to use when humidity greater than 90%, when use the instrument in an environment of less than 10 °C or above 35 °C.Air-conditioning is recommended.

5）No detectable vibration.

6）Power supply has no drastic changes.

7）There is no abnormal high frequency machine nearby.

8）There is a separate ground terminal(Ground resistance of 10Ω or less)

9）Data may be effected if the instrument was effected by strong electromagnetic signal,so keep away from strong electromagnetic fields.

10）The instrument should be stored in: -10 ℃~55 ℃, relative humidity less than 95%, 3000 meters above sea level, non-corrosive gases, well-ventilated, clean indoor.

Reader

Before using the analyzer, please read and understand the contents of this User Manual carefully so that the system can be used properly.

Readership of the "Manual" for the following laboratory professionals:

1. Daily operator of the analyzer;
2.System maintenance and troubleshooting staff of the analyzer;
3. Personnel who study analyzer operations.

Warnings

- Biochemical analyzers and operating software are limited to be operated by trained person by and Hightop Biotech or distributors authorized by Hightop Biotech.

After Sale Service

Service unit: Qingdao Hightop Biotech Co.,Ltd.

Use of User Manual

As use guidance of analyzer,the User Manual mainly help users understand the working principle of automatic biochemical analyzer, structure, methods of operation, routine maintenance and simple troubleshooting and so on.

Safety instructions

Before use,please carefully read this Safety Instructions and Use Manual to operate correctly.
In order to allow you to use the analyzer safely and correctly, a variety of symbols are used in the User Manual.
Please fully understand the contents of its statement, then read the text of the manual.

Symbol and meaning:

Symbol	Meaning	Description
Turn on	**Turn on the power**	
Turn off	**Turn off the power**	
~	**AC power**	
	**Warning: Be carefuly,electric shock hazard**	Remind users to avoid electric shock.
	**Ground terminal**	
	Notice	It is used to describe the important information in the procedure. If you do not follow the instructions, the output may be affected or the performance may be damaged.
	**Warning:** **Be careful,dangerous**	Advise users to pay attention to the potential dangers, if not follow the instructions may cause human injury, or the occurrence of damage to the goods.
	**Biohazard**	Indicates the presence of a substance or condition that is biohazardous.
	**Ramark**	Indicates useful information during operation of the instrument.
	**Important**	Indicates information we hope you need to know to ensure instrument performance and to avoid injury.

Safety Precautions

For safe use of the analyzer, please read the following safety precautions carefully. Any operation that violates the following safety precautions could result in system damage and personal injury.

Warning

- If the user does not follow the instructions of Hightop Biotech for use of the analyzer, the protection provided by the analyzer system may be compromised.

Be careful, dangerous electric shock

To prevent electric shock, observe the following precautions.

Warning

- When the main analyzer power is on, do not open the back cover or side cover with unauthorized service personnel.
- If liquid enters the analyzer or the instrument leaks, immediately turn off the power, and contact the after-sales service department of Hightop Biotech or the distributor in your area. To prevent improper operation of the instrument, it may cause the risk of electric shock and cause system damage.
- Connect the appropriate output power to prevent other devices (recommended independent power supply) or cause the analyzer to malfunction.

Prevent personal injury from light source

To prevent personal injury from light sources, please observe the following precautions.

Warning

- When working with the analyzer, do not use your eyes to direct the light emitted by the light source. These light beams may cause eye damage.
- Before replacing the light source, disconnect the main power of the analyzer and wait for at least 30 minutes until the light source cools. Do not touch before the light source cools to avoid burns.

Prevent bodily injury from moving parts

To prevent bodily injury from moving parts while the analyzer is working, observe the following precautions.

Warning

- When the analyzer is working, do not touch the moving parts of the analyzer mainframe to avoid bodily injury.
- When working with the Analyzer, do not put your fingers or hands into the open parts.

Biochemical hazard protection

For effective protection against biochemical hazards, observe the following precautions.

Biohazard

● Do not touch the sample, mixture and waste directly with your hands. Wear gloves and workwear when working to prevent contamination, wear safety goggles when necessary, inadvertently contact with samples cause infection.

● If the sample comes in contact with the skin,please immediately dispose follow the working standard of the working unit and consult your doctor.

● Some reagents are strongly acidic or strongly basic. Carefully use reagents to prevent direct contact with hands and clothing. If hands or clothes inadvertently contact with reagents, immediately wash with soap and water or according to the reagent manual requirements. If the reagent accidentally enters the eyes, rinse immediately with plenty of water and consult an ophthalmologist.

Dispose of waste liquid

To prevent environmental pollution and bodily injury caused by the waste, please observe the following precautions when handling the waste liquid.

Biohazard

● Reagents, quality control solution, calibration fluid, intensive cleaning fluid, some substance of the waste liquid are controlled by pollution regulations and emission standards. Please comply with the statutory emission standards, and consult the reagent manufacturer or distributor.

Prevent fire and explosion

To prevent fire and explosion, observe the following precautions.

Warning

● Do not use flammable hazardous materials near the system.

Using Precaution:

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

Analyzer Usage

Warning

● Analyzer is mainly used for quantitative analysis of serum,plasma,urine,cerebrospinal fluid,pleural effusion and other fluid samples of clinical biochemical analysis project. If you need to go beyond this range,please consult with Hightop Biotech.

● When make clinical judgement as per analysis results,please consider the clinical symptoms or other test results.

Operator

Warning

● The analyzer is limited to operators who have been trained and authorized by Hightop Biotech or distributors of Hightop Biotech.

Operational Environment

Notice

● Please install the instrument according to the specified installed instruction in the manual. Otherwise, the results may not reliable even may cause system damage.

● Please contact Hightop Biotech if system state is changed.

Prevent electromagnetic waves and noise

Notice

● Keep the instrument away from strong noise source and electromagnetic wave. Turn off mobile phones and transmitter-receiver when operating the instrument since the electromagnetic wave may cause an adverse effect on instrument.

● Do not use other medical instrument around the system that may generate electromagnetic wave interfere with their operations.

Systematic Usage

Notice

● Please operate system follow the "User Manual". Improper use may result in incorrect measurements and may even result in system damage or personal injury.

● Before using the system for the first time, calibrate it first and then conduct quality control to confirm that the system is working properly.

● Do not open the sample/reagent disk cover during the analysis.

● The RS-232 interface of the analyzer is set for connection to the RS-232 interface of the operating unit. Do not connect to any other device's cables. Please use the special cables provided by Hightop Biotech or distributors to connect the analyzer and operation department.

● The operating part is a computer running operating system-specific operating software. Installation of any hardware or software other than those designated by Hightop Biotech in this computer may hinder the normal operation of the system. Do not run other software while the system is working.

● Do not use this computer for other purposes. Improper use may result in system software infection with computer viruses.

System Maintenance

Notice

1) ● Maintaining according to the User Manual. Incorrect maintenance may lead to wrong result even caused system damage and bodily injury.

2) ● Analyzer placed for a long time, the surface may accumulate dust. When cleaning, please use a clean, soft cloth soaked in water, gently wipe the surface, if necessary, dip a small amount of soap solution. Do not use alcoholic organic solvents. After cleaning, dry it with a dry cloth.

3) ● Before cleaning, please turn off all the power and unplug the power cord; during the cleaning process, take the necessary measures to prevent water droplets from entering the system, otherwise it may cause system damage or bodily injury.

4) ●If replace the main analyzer components, such as light source, sample needle, stirring rod, calibration analysis must be carried out.

Sample

- Use a completely separated serum or plasma sample and urine samples without suspended matter. If the serum sample contains fibrin, or if the urine sample contains suspended material, it may clog the sample needle and affect the analysis.
- The presence of drugs, anticoagulants, preservatives, etc. in the sample may interfere with some of the analytical results.
- Hemolysis, jaundice, chylomicron, etc. in sample may affect the analysis results,recommended to do a blank sample test.
- Please use the correct sample storage measures. Incorrect sample storage may alter the sample's component structure and lead to incorrect analysis results.
- Some samples need to be pre-processed for analytical purposes, consult the reagent manufacturer or distributor.
- The sample size is required when analyzing. When sampling, according to the instructions of this User Manual to determine the appropriate sample size.
- Before analysis, make sure that the sample is placed in the correct sample position, otherwise you may not get the correct result.

Reagents, Calibration and Control

Notice

- When using an analyzer for analysis, you need appropriate reagents, calibration and controls.
- Please select the well-matched reagent according to the analyzer. If you are not sure whether the reagent is available,please consult reagent manufacturers or distributors and Hightop Biotech or distributors of Hightop Biotech.
- Usage and storage of reagents, calibration, controls observe the instructions for the manufacturer or distributor of the reagents.
- Improper storage of reagents, calibration and controls can result in failure to obtain the correct test results and the best system performance, even during the expiration date.
- After replace reagent, please carry out calibration analysis. Without a calibration analysis, the correct analysis may not be obtained.
- The cross-contamination of reagents may affect the analysis results. For information,please consult your reagent manufacturer or distributor for relative information.

Setup of Parameters

Important

- Analyzer needs to set the sample size, reagent volume, measurement wavelength and other parameters, set these parameters, please follow the " User Manual",and refer to the instructions provided with reagents.

Data Back Up

Important

- Please backup the analysis data and measurement parameters regularly.

Computer and printer

Notice

- Please refer to the operating instructions for computer and printer usage notes.

External devices

Warning

- External devices connected to the analyzer, such as computers, are required to meet the requirements of IEC 60950 or EN 60950.

Chapter 1 Installation

1.1 Preparation

The installation of the analyzer can only be performed by the technicians of the Hightop Biotech or authorized by Hightop Biotech.The user needs to provide the corresponding environment and space.

Warning

● The installation of the analyzer can only be performed by the technicians of the Hightop Biotech or authorized by Hightop Biotech.

1.1.1 Pre-installation check

Before installation, should carefully check the packaging.If handling damage should immediately declare to the User Sevice Department of Hightop Biotech Biological or local distributors.

After unpacking, carefully check the appearance of the instrument and the packing list.

1.1.2 Installation requirements

Warning

● The analyzer should be installed where the following conditions are met. Otherwise,analytical performance can not be guaranteed.

1.1.2.1 Installation environment requirements

For indoor installation only;
Table (or ground) should be flat (less than 1/200 tilt);
Table (or ground) can support at least 50Kg weight;
Ventilation is good; the space is large enough, can not be crowded after installing the analyzer to ensure operator safety and efficient maintenance space. Do not place the instrument in a location where it is difficult to disconnect device (such as a power switch).
Environment as clean as possible;
Avoid direct sunlight;
Avoid placing it near sources of heat and air;
Non-corrosive and flammable gas;
Table (or ground) without shake;
No loud noise source and power supply interference;
Do not touch the brush-type engine and often switch the electrical contact equipment;
Do not get close to devices that emit electromagnetic waves,such as cell phones, radio transceivers, etc.

1.1.2.2 Power requirements

Power supply: ~220V,50Hz, power 800W, three-core power cord, good grounding.
The analyzer needs a well-grounded electrical outlet to provide the required power.
The distance between the socket and the analyzer is less than 3 meters.

Warning

● Power should be properly grounded.Improper grounding may cause electric shock and damage to the analyzer.
● Make sure the outlet voltage of the power outlet meets the requirements of the analyzer and that a suitable fuse has been installed.

1.1.2.3 Temperature and humidity requirements

1）Storage temperature and humidity

The analyzer's storage temperature -10℃～55℃, volatility<±2℃/H;
The analyzer's storage humidity ≤95%RH, no condensation.

2）Operating temperature and humidity

When analyzer is working,environment temperature 10℃～35℃,volatility ±2℃/H;
When analyzer is working,environment humidity≤90%RH, no condensation.

Notice

● The analyzer must be operated at the specified ambient and humidity temperature,otherwise the results may not be reliable.
● If the ambient temperature and humidity outside the above range, air conditioning equipment should be used.

1.1.2.4 Water supply and drainage requirements

Water quality must meet the GB-6682 three-level water requirements;
Water temperature is 5~50℃；
If water purification equipment is used, the pressure of the water supply must be between 49kPa and 392kPa.

Biohazard

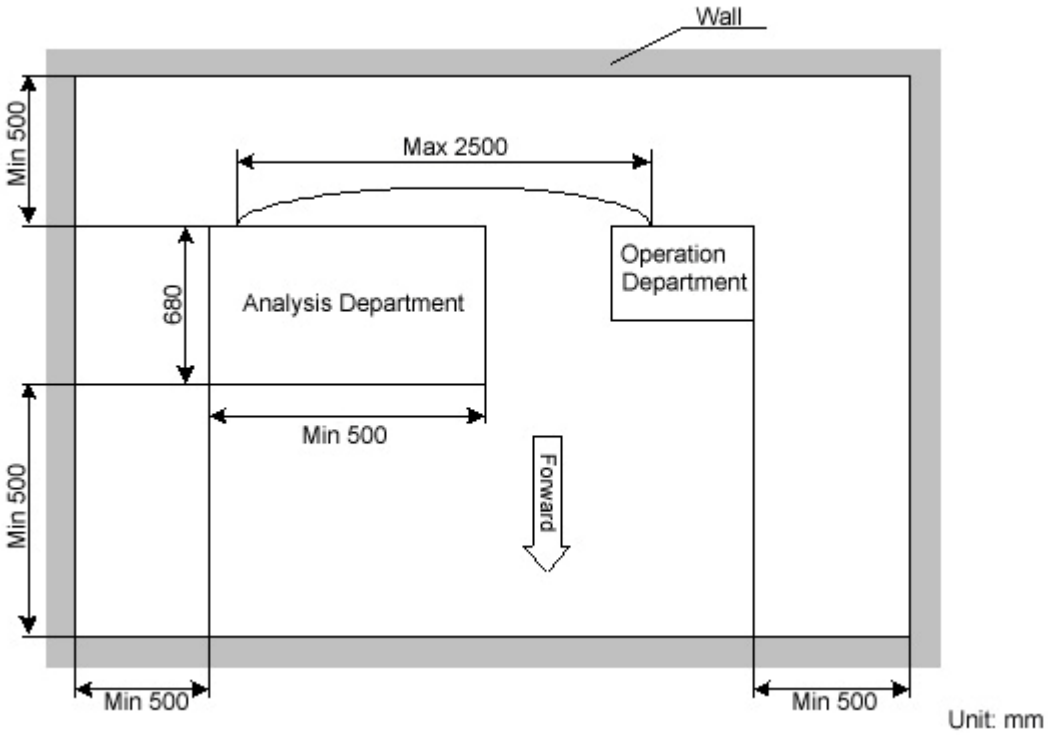
● The effluent from the analyzer should be disposed of according to local emission standards.

Notice

● Water quality must meet the GB-6682 three-level water requirements; Otherwise, insufficient water purity may interfere with the test results.

1.1.2.5 Space requirements

The installation and use of the system need to meet the following space requirements.

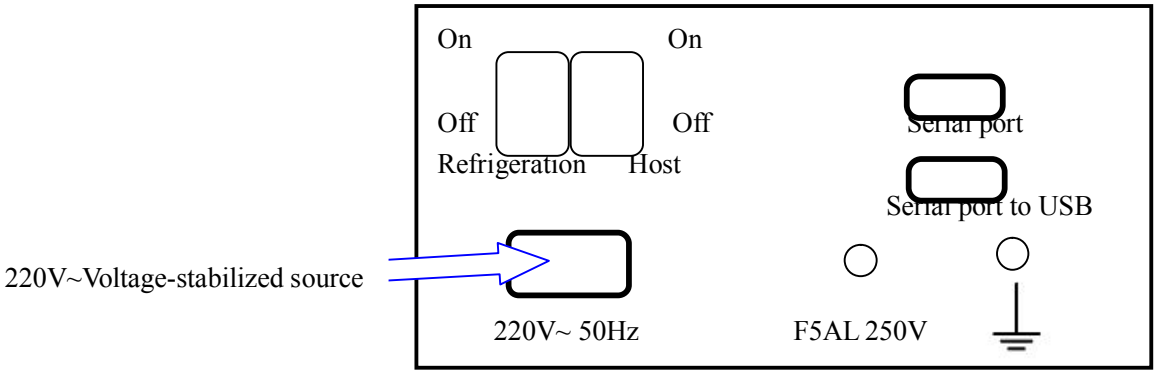


1.2 Installation

1.2.1 Instrument out of the carton

This instrument is a precious precision instrument,especially in transportation and handling should pay attention to put lightly,can not be inverted; When you receive the instrument,carefully check the packaging,if you find signs of damage, please contact the after service or local distributor. After opening the package, check the appearance of the instrument and check the goods according to the packing list. If you find missing or damaged, please contact the service or local dealer. After the inspection, by pulling the wheel positioning lock, so that the four rotating wheels of the device in a movable state, move the equipment to the preparation place, and then turn the wheel lock positioning lock, so that the four wheels of the device in the Immovable state,lock the device.

1.2.2 Connect the power cord



1.2.3 Connect serial communication line

Connect the computer correctly; Connect the instrument to the computer's RS232 port; Take out the communication line carried by the computer. One end is connected with the COM serial communication port of the computer, the other end is connected with the COM serial communication port of the instrument, and fixed with screws to prevent the communication line from falling off and causing communication errors.

1.2.4 Connect to the distilled water bucket

Biohazard

● When working,always wear gloves,work clothes in uniforms to prevent infection, and wear protection goggle when necessary.

Notice

● When placing a distilled water bucket,the top of the bucket can not be higher than the bottom of the cabinet above the analyzer.
● Make sure that the DI water tubing is clear and free from bending and distortion.

1.2.5 Connect the waste bucket

Biohazard

● When working,always wear gloves,work clothes in uniforms to prevent infection, and wear protection goggle when necessary.

Notice

● When placing a distilled waste bucket,the top of the bucket can not be higher than the bottom of the cabinet above the analyzer.
● Make sure that the waste liquid conduit is all above the waste bucket and is clear. Otherwise, liquid may leak from the analyzer panel due to poor drainage, which may result in serious damage to the analyzer.

1.2.6 Handling Sample/Reagent Tray

Warning

● Before loading or unloading the sample/reagent tray,make sure the analyzer stops working or the power is off and the sample/reagent tray is stopped.

Biohazard

● When working,always wear gloves,work clothes in uniforms to prevent infection, and wear protection goggle when necessary.

When loading the sample/reagent tray,hold the handle upright and align the hole on the sample/reagent tray handwheel with the metal rod on the drive shaft, gently lower and tighten the screw on the tray so that the sample/reagent tray locked to the drive shaft.

When removing the sample/reagent tray,loosen the screw and hold the handle straight up to remove it.

Notice

● Sample/reagent bin and sample/reagent tray may be contaminated with sample during use. When a sample splashes into the sample/reagent bin or on the sample/reagent tray,wipe it off with a cloth soaked in water or a disinfectant as soon as possible after turning off the power to the analyzer.

1.2.7 Load and unload the sample tube

Warning

● Before installing or removing the sample tube/cup,confirm the sample/ reagent tray and the sample needle is stopped.

● Do not use sample containers other than those specified.

When loading the sample tube,insert the tube containing sample into the tube holder until the bottom of the tube contacts the annular groove of the tube holder.

When removing the sample tube, hold the sample tube by hand and lift it straight up.

1.2.8 Loading and unloading reagent bottle

Warning

●When loading reagent bottles, confirm the sample/ reagent tray and the sample needle is stopped.

●Do not use reagent bottles other than those specified.

When loading a reagent bottle, insert the reagent bottle containing the reagent into the reagent bottle receptacle until the bottom of the reagent bottle contacts the bottom of the reagent bottle receptacle.

When removing the reagent bottle, hold the sample tube by hand and lift it straight up.

1.2.9 Loading and unloading reaction cup

Biohazard

●When working,always wear gloves,work clothes in uniforms to prevent infection, and wear protection goggle when necessary.

●Abandoned reaction cups should comply with the relevant provisions of the proper disposal.

Lock the fixed nut on the holder of a row of cuvette,you can load a row of cuvette.

1.2.10 Fuse installation steps

Turn off the instrument power, unscrew the back cover of fuse holder with a cross screwdriver,remove the bad fuse, insert the new fuse of the same model into the back cover of the fuse,tighten the back cover of fuse holder with a cross screwdriver,the fuse is a designated type of Φ5×20，T5A L 250V.

Be careful,dangerous

- When replace fuse,you must cut off the power firstly, replace the fuse of the same specification to prevent electric shock and malfunction.
- There is a danger of electric shock, the replacement of fuses by professionals.

1.3 Electromagnetic compatibility requirements

The analyzer meets the emission and immunity requirements of GB/T 18268.26-2010. The analyzer are in accordance with GB4824 Class A equipment design and testing. In a home environment,this analyzer may cause radio interference,require protective measures.

This fully automatic biochemical analyzer should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed that the verification is working correctly in the configuration in which it is used. It is forbidden to use this automatic biochemical analyzer beside the strong radiation source (such as unshielded RF source), otherwise it may interfere with the normal operation of the equipment.

Chapter two Introduction

2.1 Work Principals

Work principle of analyzer: The substance is qualitatively and quantitatively determined by measuring the absorbance of light at a specific wavelength or within a certain wavelength range. When a certain light source emits a bundle of monochromatic light into the liquid under test, part of the optical signal transmitted through the measured liquid is absorbed, and the other part is converted into an electrical signal by the solution, after conversion and compute,the amount absorbed by the substance is proportional to the concentration of the substance and the thickness of the liquid layer (optical path length), so that the concentration (A) of the substance to be measured is known.

2.2 General introduction

2.2.1 Accessories and consumables

To ensure personal safety and ensure system performance, please use the parts manufactured or recommended by Hightop Biotech.If necessary,please contact the user services department of Hightop Biotech or distributor in your area.

Part name	Location	Remark
Lamp for light source (20W Halogen tungsten lamp)	Light box	Replace parts regularly. Replace when use more than 3000 hours or the system prompt.
Component of samople needle	Rocker arm of sample needle	Replace parts regularly. Replace when use for one year or bend.
Mixing rod	Mixing rod rocker arm	Replace parts regularly. Replace when damaged.
Reaction cup	Reaction plate	Consumable
40mlReagent bottle	Reagent tray	Consumable

2.2.2 Technical Parameters

Instrument type	Fully automatic discrete, random optional mode of work
Specimen type	Serum, plasma, urine, cerebrospinal fluid, pleural effusion and so on
System functions	24 hours continuous boot, reagent open, emergency priority testing, automatic dilution retest
Test speed	240t/h
Items analyzed at the same time	40 items
Test method	Post-spectrometry
Analytical method	End point method, fixed time method (two-point method), kinetic method (rate method),single/dual wavelength method, single/double reagent, turbidimetric method, immune turbidimetry, multi-standard method, the detection method is fully open.
Sample tube	Micro sample cup, the original blood collection tubes, plastic tubes and other specifications
Sample tray	50 sample position; All kinds of samples are placed mixedly.
Reagent tray	40 reagent position,24 hours continuous refrigeration,the capacity of 40ml,the system automatically detects reagent bottle margin.
Sample size	2-50ul，0.1μl increments
Reagent volume	10-300ul，1μl increment
Reagents refrigerated	2-8℃,24 hours continuous refrigeration,reagent completely open.
Emergency sample processing	Emergency can be inserted at any time; emergency treatment priority
Sample needles,reagent needles	With liquid level detection function,the system can automatically detect reagent bottle margin; Three-dimensional collision detection function; With the amount of tracking function, blocking detection, automatic cleaning function.
Cleaning system	Yongquan type deionized water inner and outer wall cleaning,test cup automatic eight-stage flushing,water consumption is 5 liters/hour,the cuvette is automatically dried,sample needle has plugging detection and automatic cleaning function.
Cross contamination rate	Not more than 0.1%.
Independent mixing needle	Stir immediately after adding the sample(at a same period); For double reagent test, Stir immediately after adding the sample(at a

	same period).
Reaction tray	80 reaction cup, recyclable.
Reaction temperature	37±0.1˚C,temperature fluctuations should be ± 0.1˚C, With adjustable thermostat,temperature real-time monitoring display.
Reaction cup	5mm×6mm×25mm,light path 5.0mm,semi-permanent cuvettes made from 80 micro specialty materials
The total amount of reaction solution	150~400μl
Minimum reaction test volume	≤150μl
Optical system	Post-spectroscopy
light source	12V, 20VA Halogen Tungsten, Halogen, Iodine Tungsten
Wavelength	340nm,405nm,450nm,510nm,546nm,578nm,620nm,660nm,690nm, A total of nine wavelengths(open-ended),wavelength precision 0.1nm.
Absorbance range	-0.30000-5.0000Abs,resolution 0.0001Abs
Sample dilution/retest	The instrument automatically dilutes and re-tests the sample when the result is outside the linear range or when the sample is insufficient
Measurement cycle	7.5 seconds
Reaction time	2-15 minutes,optional
Calibration	Linear/nonlinear multi-point calibration
Calibration and quality control	Linear calibration and non-linear calibration,calibration cycles can be set automatically and manually,and has a calibration track, real-time quality control, the day of quality control, day quality control, out of control processing function
Repeatability	Signify with coefficient of variation CV,not more than 1%.
Stability	Within 1h,absorbance changes of not more than 0.01.
Items settings	Provide any combination of items and optional computing items.
Test setting	Single,multiple,combination,batch and contrast settings
Operating system	Windows7 and above operating system environment, the English and Chinese version is optional.
Data processing	Can edit more than 300 testing parameters and long-term storage,instrument can long-term store of more than 200,000 patient information.
Print	A variety of reports printing formats, you can choose.
Pure water machine (optional)	● Resistivity：18.25 MΩ ● Conductivity：0.055μs/cm ● Total Organic Carbon (Toc)：1-3ppb ● Heavy metal：<0.1 ppb ● Silicate：Soluble silica [calculated as (SiO2):<1ppb ● Pyrogen：＜0.02EU/ml ● Microbes：＜1CFU/ml ● Debris particles（>0.1μM）：(0.1μm)<1/ml ● Water production / flow rate：10L/h ● In line with "Chinese Pharmacopoeia" water for injection 2005 edition,"China Laboratory Water Specifications" GB6682-92,"Drinking Water Health Standards" GB 5749-85,"Reverse Osmosis Water Treatment Equipment" GB/T19249-2003.
Power supply	220V ~,50Hz,1KVA three-core power cord,good grounding.
Fuse	T5AL 250V

Input power	800VA
Storage environment requirements	Temperature：-10˚C～55˚C
	Humidity:≤95%RH ,no condensation
	Atmospheric pressure：50kPa～106kPa
	Altitude：below 3000m
Work environment requirements	Temperature： 10˚C～ 35˚C
	Humidity: ≤90%RH, no condensation.
	Atmospheric pressure:70.0kPa～106.0kPa
	Altitude: below 3000m
Size	660mm X 450mm X 440mm()
Weight	34Kg
Communication Interface	Analysis department and operation department interface：RS-232
Security classification	Product Equipment Category: Laboratory
	Overvoltage category: Class II
	Pollution levels: 2 categories
	Environmental conditions:Extended conditions
	Equipment Category: Stationary
	Connection to the network power: detachable power cord
	Operating conditions: continuous operation
	Protection grade：IP10

2.3 Reagent

The use of reagents need to refer to the reagent manual,the reagent classification and principles here will be a brief introduction.

2.3.1 Reagent classification

Reagents can be divided into:

- Dry powder reagents

Dry powder reagent,in using process,need to be diluted by buffer or distilled water(Deionized water) to dissolve before using the reagent.

- Liquid single reagent

Liquid single reagent refers to those no need any disposal before put in machine, just take it out of the refrigerator and use it directly,and only need one reagent during use.

- Liquid double (multi) reagent

Liquid double (multi) reagent refers to those no need any disposal before put in machine,just take it out of the refrigerator and use it directly, but in the process of using two or more reagents are needed.

2.3.2 Reagents reaction principle

- End point method

(1) Commonly used endpoint reagent

Total bilirubin, total bilirubin, total protein, albumin, glucose, uric acid, total cholesterol, triglyceride, HDL cholesterol, LDL cholesterol, calcium, phosphorus ,magnesium and so on.

The measured substance is completely transformed into products in the reaction process,reach the end of the reaction,according to the size of the end absorbance to find the measured concentration,known as the terminal method.

(2) Determination of time of end

①According to the time - absorbance curve to determine,

②According to the measured end of the reaction, combined with the reaction of interfering substances to determine.

- Fixed-time method: Creatinine, urea, total bile acids using this method

Select two photometry points on the time-absorbance curve. These two points are neither the initial absorbance nor the end absorbance, and the absorbance difference between these two points is used in the result compute. Sometimes called this method is two-point method.

- Rate asy

For the determination of enzyme activity,should generally be used continuous monitoring method,such as alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase, alkaline phosphatase, gamma glutamyl transferase, amylase, hydroxybutyrate dehydrogenase, cholinesterase, acid phosphate Enzymes, creatine kinase isozymes and creatine kinase.

Rate asy, in determining the enzyme activity or enzymatic determination of metabolites, the absorbance value of the linear-phase (absorbance difference between two points is equal) in the time-absorbance curve is continuously selected, and the change of the unit absorbance value (ΔA/min) in the linear period is computed for results.

2.3.3 Automatic monitoring of the measurement process

2.3.3.1 Reagent blank monitoring

① Reagent blank absorbance is automatically detected before each bottle of reagent is used

② Reagent blank absorbance should be tested before the samples are tested.Taken by the analyzer of first reagent after sample.

2.3.3.2 Reagents blank changes rate monitoring

After setting this monitor,the analyzer automatically subtracts the reagent blank rate of change from the result compute.In assays to measure NAD(P)H reduction as an indicator of enzyme activity,the blank rate monitors and eliminates the decrease in absorbance caused by NADH's own oxidation; In the determination of the enzymatic activity of the chromogen as a substrate,the blank rate monitors and eliminates the increase in absorbance caused by the breakdown of the substrate itself. The effect of blank rate monitoring on the determination of creatinine negative interference with bilirubin on the basic picric acid rate assay has been described above.

2.3.3.3 Sample information monitoring

Due to the sample hemolysis, turbidity, jaundice will reduce non-chemical reaction interference in results. According to spectral absorption characteristics of hemolysis, lipid cloud, jaundice,detect its nature and extent with dual wavelength or multi-wavelength,generally test absorbance ratio of the samples at 600nm / 570nm,700nm/660nm and 505nm/480nm to judge the sample hemolysis,turbidity and jaundice.

2.3.3.4 Results Reliability Monitoring

（1）End point monitoring

（2）Linear period monitoring

2.3.3.5 Substrate consumption monitoring

In the continuous monitoring method for the determination of enzyme activity,if the absorbance rises or falls over its substrate depletion during the monitoring period, the enzyme activity of the sample is very high,the substrate will be depleted,the absorbance of the monitoring period will deviate from the linear,make the measurement result unreliable. This monitoring is important for methods of analyzing enzymatic activity using negative reactions.

2.3.3.6 Method Linear range monitoring

Each test analyte has a measurable concentration or range of activities,if the sample result exceeds this range, the analyzer will display a prompt that the measured result exceeds the linear range. Most analyzers will automatically re-measured with the beomg subtracted or incremental.

2.3.4 Single wavelength and dual wavelength

2.3.4.1 Concept

The method of using one wavelength to detect the light absorption intensity of a substance is referred to as single wavelength method. It can be used when one component is contained in the reaction solution or when the absorption peak of the component to be measured in the mixed reaction solution does not overlap with the absorption wavelength of other coexisting substances.
Using a dominant wavelength and a sub-wavelength called dual-wavelength method. When there is a large absorption of interfering substances in the reaction solution, which affects the accuracy of the determination result, it is better to adopt the dual-wavelength method.

2.3.4.2 Effect of dual wavelength

①Eliminate noise interference;
②Reduce stray light effects;
③Reduce the interference of light absorption of the sample itself: If non-chemical interferences are present in the sample such as triglycerides,hemoglobin,bilirubin, will produce non-specific light absorption,dual wavelength mode can partially eliminate this type of light absorption interference.

2.3.4.3 Determinatio method of sub-wavelength

When the main wavelength of the measured object is determined,the subwavelength is chosen according to the characteristics of the interfering absorption spectrum,to make the interference at main and sub-wavelength has as same light absorption valueas as possible.
Generally speaking,the sub-wavelength should be greater than the main wavelength of 100nm.

2.3.5 Reagent packaging and use of the period

1）Reagent packaging should pay attention to manufacturer identification,should comply with the laws and regulations.
2) Reagents should be in line with industry standards or business standards.
3) Reagents should have a suitable shelf life and should be clearly marked.

2.3.6 Precautions for reagents

1) Reagents should be used within the validity period
2) Reagents should be used with the instrument to form a unified system.
3) Reagents should be stored according to the manufacturer's requirements.
4) Reagents should be used accord with the use conditions and the cope of use of manufacturer.
5) Reagents are for in vitro diagnostic use only.

2.4 Calibrators and quality control material

2.4.1 Concept

Calibrator: Calibrate with secondary standard material,regular method to fix value. Used for calibration of conventional methods and instruments.

Control: With characteristics adapt to the detection process, its composition is the same as or similar to that of the test specimen. Control material should be fully uniform and good stability,the bottleneck variation must be less than the expected variation in the monitoring system. Its routine testing helps confirm the scope of the report.

2.4.2 Packaging and use of the period of calibrator and quality control

1) Packaging of calibrator and quality control should pay attention to manufacturer identification,should comply with the laws and regulations.

2) Calibration and quality control should have a suitable period of use. And should be clearly marked

2.4.3 Precautions for calibrators and quality control material

1) Calibration and quality control should be used within the validity period.
2) Calibration and quality control materials should be used in conjunction with the instrument to form a unified system.
3) Calibrators and controls should be stored according to the manufacturer's requirements.
4) Calibrators and controls should be used under the conditions of use and scope of use required by the manufacturer.
5) Calibrators and controls are for in vitro diagnostic use only.

Chapter 3 Instrument Description

3.1 System Structure

This chapter mainly introduces the structure of the analyzer,interface,basic operations and so on.

The full name of the product is Full-Automated Biochemistry Analyzer,mainly used for quantitative analysis of serum, urine and other clinical biochemical items.

The Full-Automated Biochemistry Analyzer is composed of analysis system,operating system,output system, accessories and consumables.

3.1.1 Analysis system

The analysis system mainly consists of sample tray,reagent tray, liquid extraction part,stirring part,reaction tray,optical and other units,used for analysis.

3.1.1.1 Reagent tray,sample tray

The reagent tray is used for placing the first reagent and the second reagent.

Sample tray is used for placing sample and quality control.

The sample positions can be placed the following sample tube: Micro sample cup,original blood collection tube.

The number of reagent position of the ananlyzer is up to 40,only can place reagent bottle of Hightop Biotech.The biggest volume of reagent bottle is 40 ml.

Reagent disc storage has refrigeration,refrigeration temperature 2℃~8℃.

Notice

●According to the number of reagent positons,to determine whether the reagent positons are placed reagent bottle of Hightop Biotech or universal reagent bottle.

3.1.1.2 Intake system

Intake system mainly includes reagent feeding system, sample feeding system,consists of sample needle,rocker arm and drive shaft,used to aspirate a specified amount of reagent or sample from a reagent bottle or sample cup and into a cuvette.

After the feeding action is completed, the reagent needle and the sample needle automatically move to the designated cleaning position, and wash the inner and outer walls of the needle.

Sample size: 2 ~ 50μl, 0.1μl increment.

The first dose:10 ~ 300μl,1μl increments, the second dose:10 ~ 300μl,1μl increments.

Intake system has liquid level detection function,with the amount of tracking function and vertical collision protection.

Warning

● Do not place any part of the body on the swing path of the rocker arm or place any obstacle on the swing path of the rocker arm during operation. Otherwise, personal injury or system damage may occur.

3.1.1.3. Mixing system

Mixing system is mainly composed of stirring rod, rocker arm and drive shaft, which is used for mixing the reaction liquid in the cuvette.

In the item test, the cuvette is stirred once after adding the sample and the second reagent to the cuvette.

After the stirring action is completed, the stirring system automatically moves to the position of the stirring rod cleaning pool, and the stirring rod is cleaned.

Warning

● Do not place any part of the body on the swing path of the rocker arm or place any obstacle on the swing path of the rocker arm during operation. Otherwise, personal injury or system damage may occur.

3.1.1.4. Reaction tray

The reaction tray was used to place cuvettes as a reaction vessel and a colorimetric cuvette.

During the analysis,the specified cuvette is stopped at the sample loading position or the stirring position for sample loading or stirring, and the colorimetric measurement is

performed when passing through the optical axis of the colorimetric optical path.

The cuvette can be recycled.Need to be replaced by hand.

The reaction tray is placed in a temperature-controlled chamber,and the temperature-controlled chamber provides a constant temperature environment of 37±0.1°C.

3.1.1.5. Optical unit

The optical unit is inside the analyzer chassis and is used to determine the absorbance of the reaction solution in the cuvette.

The optical unit provides 9 wavelengths, 340nm, 405nm, 450nm, 510nm, 546nm, 578nm, 620nm, 690nm respectively, open ended.

3.1.2 Operating system

The operating system is a computer,which has internal control software for the running, operation and data processing of the control system.

3.1.3 Output system

The output system is a printer for printing data.

3.2 Interface basic operation

3.2.1 Interface composition

The main interface of software control is as shown.

Software main interface

Group button area

Located on the left side of the screen, it is used to set parameters, QC management, maintenance and historical results review. When you click a group button with the left mouse button, a working page corresponding to this button will appear.

Work status area

Under the group button area is the working status area, display time, sample ID, sample cup number and patient information.

Biochemical testing area

Located on the left and right of the interface for biochemical and emergency testing.

Work page display area

Shows the selected button corresponds to the parameters, processes, results and other values and graphics. There is a note area below the area.

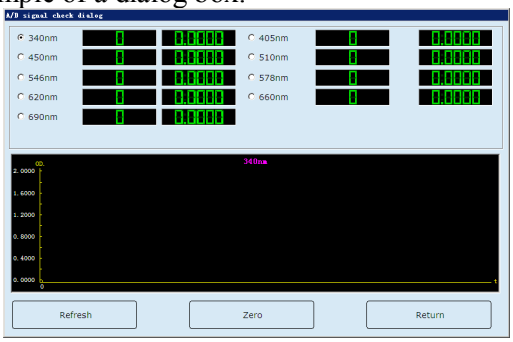
The current user display area

Display the current user.

3.2.2 Common interface elements

Dialog box

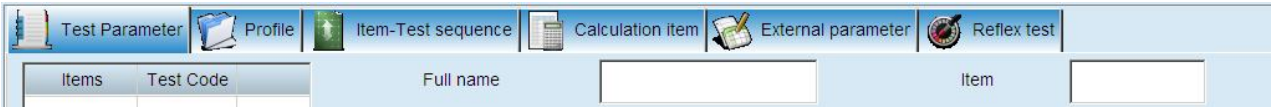
Dialog box is a common interface to complete human-computer interaction in the system. The figure below is an example of a dialog box.



Dialog box

Tab

Click the left mouse button on a tab to switch the display area of the working page.The following figure shows an example of a tab

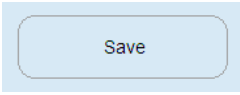


Drop down box

Click the left mouse button on drop down box ,choose an option. The picture below shows an example of a drop-down box.

Button

The purpose of the button is to open a dialog box or perform other defined functions. The figure below is an example of a button. Click the button with the left mouse button to execute the corresponding operation of this button.



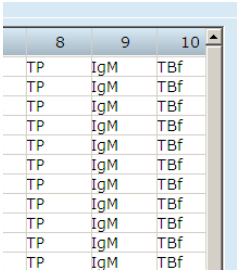
Edit box

The edit box accepts and displays the characters entered by the user through the keyboard. The picture below shows an example of an edit box.

Scroll bar

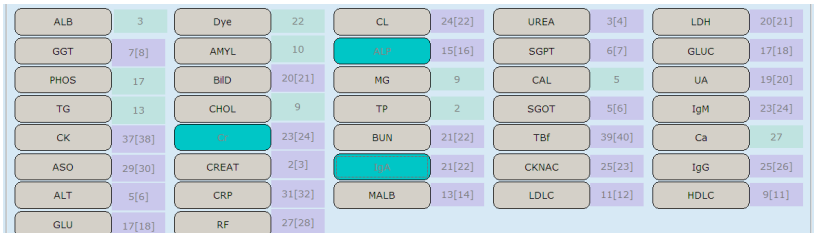
If the display exceeds the set size, a scroll bar will appear. The picture below shows an example of a scroll bar. Move the mouse arrow to the scroll bar, hold down the left mouse

button, move the mouse, you can drag the scroll bar to the desired location.



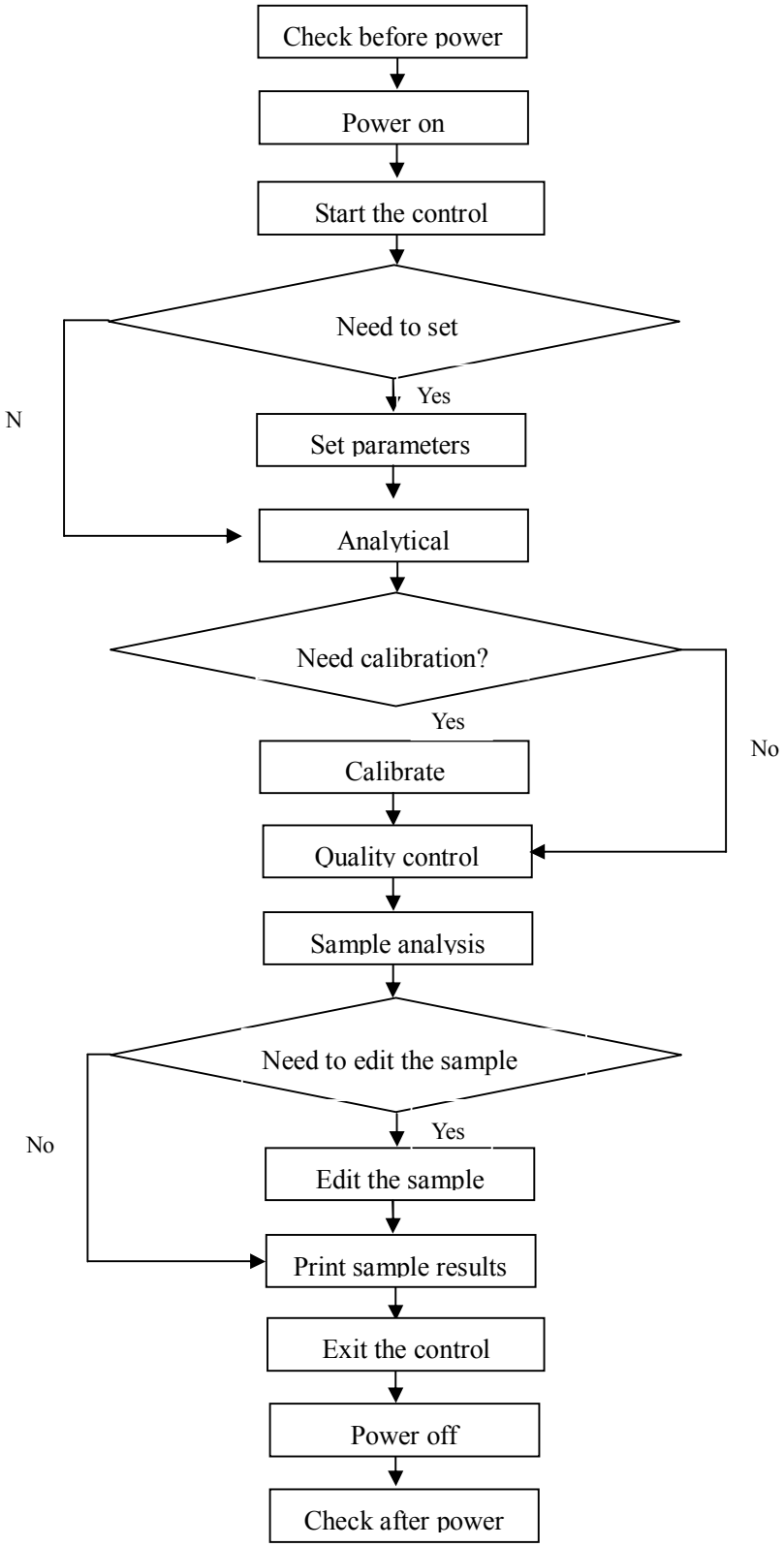
List

The list lists the names of one or more items or combinations of items. The following figure shows an example of a list of items. Left-click the item, you can select the item; click the item with the left mouse button again, you can uncheck it.



Chapter 4 Basic Operation

4.1 Daily Operation



4.2 Operation Rule

4.2.1 Analytical preparation

4.2.1.1Check before power on

Before turning on the machine, carry out the following inspection measures to ensure the normal operation of the system after power-on.

1) Check the power, make sure the power is on and provide the correct voltage.
2) Check the communication cables and power cables between the analyzer, the computer, and the printer to confirm that they are connected and not loose.
3) Check if the paper is enough. If not enough, add paper.
4) Confirm the cleaning solution has been put away.
5) Confirm that the sample needle is in the normal position (cleaning position).
6) Confirm that the stirring needle is in the normal position (cleaning position).
7) Confirm the deionized water inside the bucket,there should be enough deionized water.
8) Check if the waste bucket is empty. If not empty, empty the waste bucket.
9) Prepare a sufficient amount of reagent based on the sample size of the day.

4.2.1.2 Power on

After the system is powered on, turn on the power in the following order:

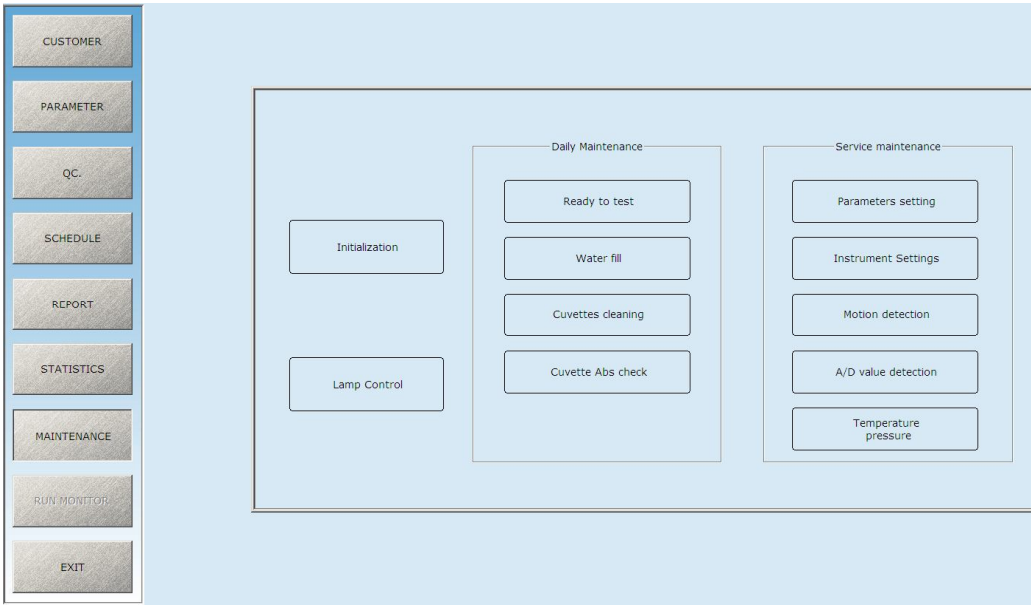
1) Analyzer power
2) Computer monitor power
3) Computer host power
4) Printer power

4.2.1.3 Start the control software

After logging in the Windows operating system, double-click the shortcut icon of the control software on the desktop or select the control software program from the software package to start the control software.

After starting,the system will automatically check the operating system, screen resolution,turn off the screen saver,check the color configuration, initialize the database, detect the printer.

After checking, the dialog box will pop up, enter the user name and password, click "OK" button.



Notice

● “Admin”。 The system administrator user name is "Admin" and the initial password of the user name is "Admin".

Notice

● To ensure accurate results, start the analysis test at least half an hour after powering on.

4.2.1.4 Set parameters

Only correct and reasonable setting of parameters, to be able to carry out biochemical tests and other operations.

The first time the system is used, you must set the parameters. In daily use, you can set the parameters as needed.

Before applying for a test, you must set at least the following parameters:

1) Hospital settings.
2) Operator Settings.
3) Calibration fluid settings.
4) Quality control settings.
5) Biochemical project parameters set.

4.2.1.5 Place reagent

Place the appropriate reagent on the reagent position set on the reagent tray and open the reagent bottle cap.

Warning

● Care should be taken to avoid being scratched by the needle tip.

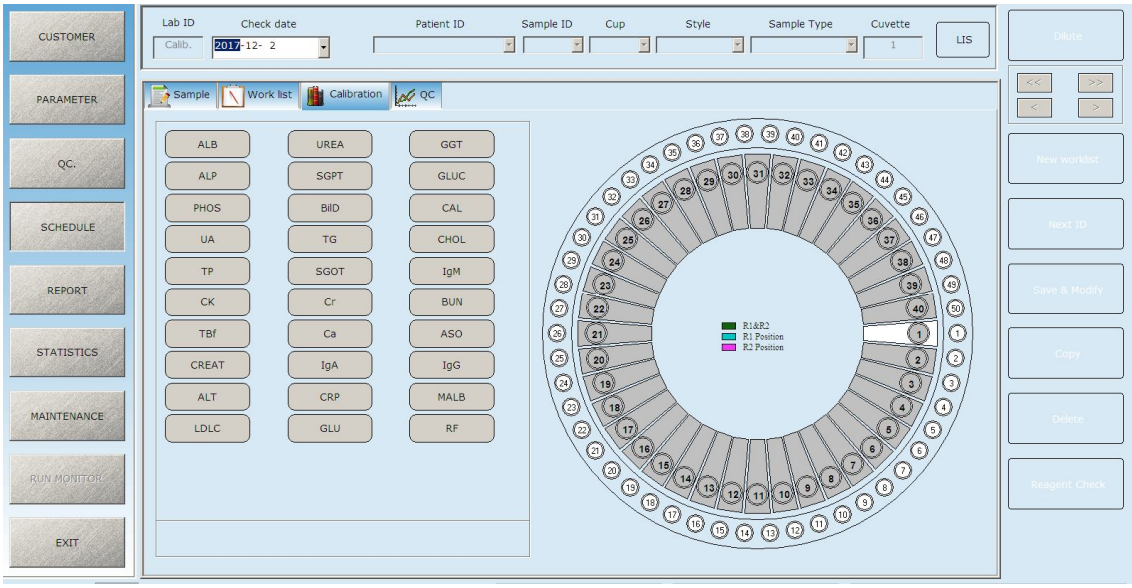
Biohazard

● Always wear gloves, wear workwear to prevent infection, and wear safety goggles when necessary.

4.2.2 Testing analysis

4.2.2.1 Calibration

Calibrate before testing,test according to the selection of fllowing figure.



Warning

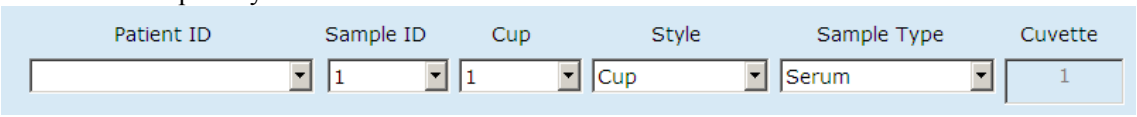
● Changing the batch number of the kit, changing the test parameters, changing the lamp, and other causes will result in change to assay conditions,need to re-calibrate.

4.2.2.2 Indoor quality control

The indoor quality control is as a sample interspersed in the sample test. And can be prepared quality control chart.

4.2.2.3 Sample analysis

Set sample as the figure below. After applying for a sample, place the sample at the position set on the sample tray.



Notice

● The operation of emergency application is basically the same as the operation of ordinary sample application.

● Make sure the sample is placed in the correct location.otherwise the correct analysis may not be obtained.

4.2.3 Results processing

4.2.3.1 Edit sample results

Notice

● Results editors should be under the guidance of a higher level doctor.

4.2.3.2 Print sample results

4.2.4 End the analysis

4.2.4.1 Exit the control software

All tests are completed, the system is in standby mode, you can exit the control software.

4.2.4.2 Power off

After exiting the Windows operating system, turn off all parts of the power in the following order:

1) Printer power
2) Computer power
3) Analyzer power

4.2.4.3 Opertation after powering off

1) Close the lid of each sample/reagent bottle in the sample/reagent tray.
2) Remove the calibration solution,control solution and samples and reagents from the sample/reagent tray.
3) Empty the waste bucket.
4) Check if there is stains on table-board of analysis part. If yes,wipe off with a clean,soft cloth.

Chapter 5 Software Operation

In this chapter, the interface and functions are introduced one by one according to the shortcut buttons and grouping buttons in the control software interface. Please read the instructions carefully before installation and use.

The software is used with the of biochemical analyzer, carry out customer data,parameter settings,indoor quality control,biochemical testing, test reports,query statistics,equipment maintenance and other tasks.

Hightop Biotech provide support and maintenance services for the software.

When the software has a new version, provide users with upgrade services.

In the event of a user interface error, the application program's own logic error,system or network resource availability error, please shut down the current running software,restart the software before use;If can not be resolved after restart,please contact after-sales service department or local dealer of Hightop Biotech.

Warning

●Biochemical analyzers and operating software are limited to those trained and authorized by Hightop Biotech or distributors of Hightop Biotech.

Data backup

Important

●The analyzer software has the function of automatically storing data on the computer's hard disk. However, if the hard disk data is deleted or the hard disk is damaged due to other reasons, the data can not be recovered. Regularly back up data and measurement parameters to other media.

5.1 Software operating environment and configuration requirements

5.1.1 Hardware environment

CPU dual-core 2.1GHz,2G memory,120GB hard drive and above.

5.1.2 Software Environment

Windows 7 English and above.

5.2 Software installation introduction

5.2.1 Installation

Read the software CD,copy,paste, double-click the software executive program.

5.3 Work menu sheet

Work menu	Auxiliary menu	Function item	Purpose
1.Customer information	Hospital setting	Hospital name Hospital address Contact number Department and doctor Settings bar Save Delete	Set hospital information.
	Operator Settings	Login ID Operator name User rights Operator old password Operator new password Save Delete	Set operator information.
	Data dictionary settings	Category content Corresponding entry related information Save Delete	You can set some notes on the test items.
2.Parameter settings	Biochemical items settings	Basic parameters Reference range Scaling rules Delete Save Preview Print	Determine the parameter values for each item.
	Computed items settings	Computed items Expression Import Clear Increase Delete Save	Items for which test results can be computed by compute.
	External items settings	Content input bar Type of data Save	For a same specimen,tests results from other instruments need to be

		Delete	printed on a same test report with test reslts of the analyzer.
	Combinations items settings	Combinations items names Biochemical combination iems New Save Delete	Set the combination item.
	Project items order setting	First Up Down At last Increase Delete Save	Set the order of test items,according to the settings, the instrument automatically operate.
	Linkage detection	Items type Linkage conditions Save Delete	
3.Indoor quality control	Quality control batch number setting	Biochemical items Quality control target value, expiration date, batch number, standard deviation, concentration level Increase Save Delete the item Increase the lot number Delete the lot number	Set the desired test control solution information.
	Daily quality control	Biochemical projects Quality control target value,expiration date, test date,lot number, standard deviation, result,test time, concentration level,QC data list,QC chart Save Delete	Set the desired quality control solution information. Enter the value and information of testing biochemical fluid. Automaticly draw quality control chart.
	Month quality control	Biochemical items Control target,test date, lot number,standard deviation,result,test time,concentration level, QC data list,QC chart Refresh Print Preview	Select quality control information, automatic quality control plot and list. You can preview and print QC charts.
	Quality control value printing	Concentration level Items Batch number Result Check the date Test time Sort by Quality control rules	Quality control values can be previewed and printed.

		Save Preview Print	
4.Instrument maintenance	Bulb control	Turn on Turn off Back	
	Instrument initialization	Instrument initialization Back	Restore the mechanical parts of the instrument to the starting point.
	Cuvette cleaning	Clean all cuvettes Select cup number to clean	The cuvette is washed by selection.
	Cuvette check	Add distilled water Evacuate the cuvette Test cup signal Test cup quality Absorbance Signal value Print Back	By detecting the water blank, to determine the cuvette replacement. Make sure the cuvette is zeroed.
	Instrument parameter setting	Mechanical arm motion parameter setting Cleaning arm movement parameter settings Mixing arm set Working hours set Arm reset Arm up Detection Wavelength setting Save Back	Adjust the position of the moving parts so that they are in the best position. Installation has been set by the installation engineer,users don't need to reset. However, when the replacement of some parts or reload a part, need to re-adjust.
	Moving parts inspection	Solenoid valve detection bar Pump and syringe detection bar Sensor detection Syringe Bulb control Stop Detection Back	Detect if moving part is in normal condition. This menu can be used to check faults of moving parts.
	Temperature and pressure	Set the maximum temperature and pressure Set Back	Observe and test the control and calibration of the instrument reaction tray temperature and pressure.
	A/D signal detection	Wavelength signal display Graph Refresh Zero Back	Check the performance of the grating and the performance of the light source. When you find the absorbance is low or the measured value is low, you can check this menu.
	System settings	Device communication port	

		selection Interface color settings Verification code Automatic retest setting LIS communication port Settings Select Back	
	Shutdown procedure	Start Back	
	Boot system	Absorbance Signal value Start Back	
5.Query statistics	Results query	Items Test date Sample ID Name Case number Result Unit Reference range Test time Correction value Amend Save Delete Preview Print	The result can be corrected by the correction value.
	Historical data	Test date Query mode Serial number,sample ID, medical record number, project,test time Result, Incubation time Refresh	Displays the test items which are seted test date, re-compute and save.
	Charge statistics	Item price setting Statistical methods	After settng the project price, make charging statistics.
	Query	Patient information query display bar Test results display bar Query mode selection bar Inquery	
6.Test Report	Patient information	Test date Patient information input bar Sample ID Save Delete Print Preview Scan barcode Data upload	
	Results editing	Test date Item type Project Name,English Name,	

		Result,sample ID Confirm Delete Save	
	Reaction curve	Test date Item Result Test time Sample ID Medical record number Detection method Refresh	
7.Biochemical tests	Sample application	Test date Medical record number, sample ID,cup number,cup type, sample type Dilution New worksheet ID++ Save&Modify Copy Delete Reagent Amount Measurement	
	Work list	Test date Sample ID,medical record number,cup number,cup type,sample type Dilution New worksheet ID ++ Save&Modify Copy Delete Reagent Amount Measurement	
	Calibration application	Calibration item selection bar Dilution New worksheet ID ++ Save&Modify Copy Delete Reagent Amount Measurement	
	Quality control application	Test date Sample ID,medical record number,cup number,cup type, sample type Dilution Concentration level New worksheet ID++ Save&Modify Copy Delete Reagent Amount	

		Measurement	
8.Emergency testing	Sample application	Test date Medical record number, sample ID,cup number,cup type, sample type Dilution New worksheet ID++ Save&Modify Copy Delete Reagent Amount Measurement	
	Work list	Test date Medical record number, sample ID,cup number,cup type, sample type Dilution New worksheet ID++ Save&Modify Copy Delete Reagent Amount Measurement	
9.Detection display	Sample information	Sample ID Medical record number Cup number Cup type	
	Reagent information	Items Test method The actual number of samples Reagent position Reagent margin Detectable quantity Average value CV value	
	Reaction cup information	Sample ID The cuvette position First reagent position Incubation time Absorbance Standard Sample position Items The second reagent position Test time Result Detect wavelength information Image	
	Warning message		
10.Exit			Exit the software

5.4 Operation menu introduction

5.4.1 Log in

The initial password is "Admin".

5.4.2 Sample

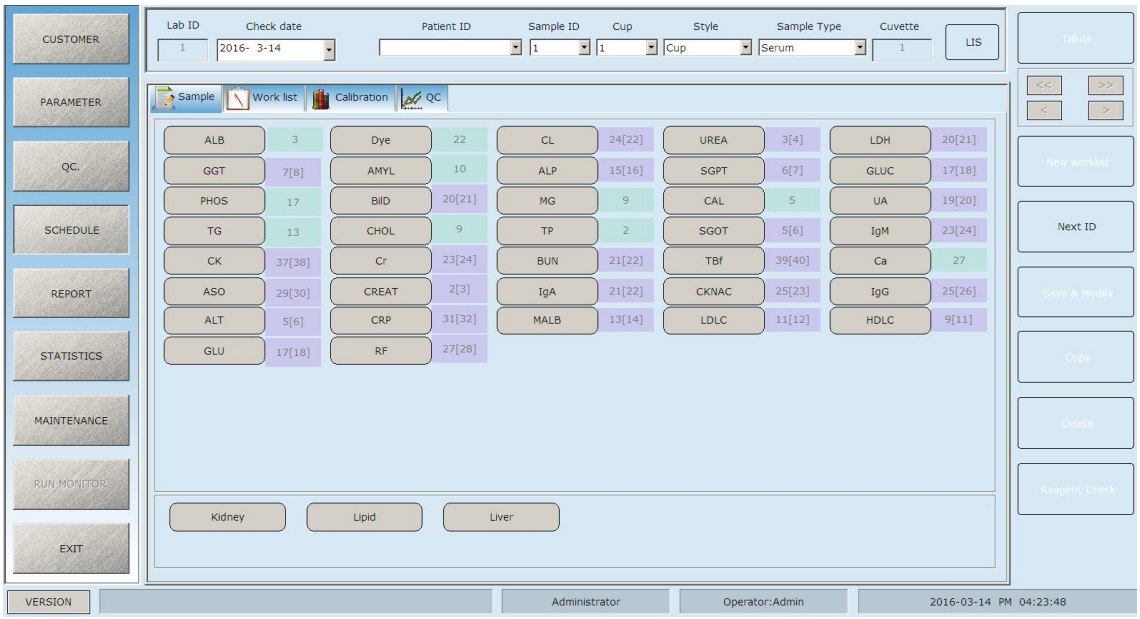
Sample input and detection are under the operation menu of biochemical test.

5.4.2.1Biochemical tests

Click the "Biochemical Test" button on the main menu to enter the biochemical test interface. There are three sub-items.

1）Biochemical items

As shown in Figure 5.1,enter the sample ID, sample cup number and brief patient information. Select the items to be tested, click the "Copy" button,if you want to continue to enter,then press "ID ++" button,the sample ID is automatically increased by 1,select test items,click "Copy". When entering a sample ID,you can not enter a same number repeatedly,otherwise, the result of the latter sample will overwrite the result of the previous sample.



Fiture 5.1

If sample value is too large, dilute it with dilution mode and set the dilution factor yourself.
These two lines are the portfolio list,the setting of the combination list is in the parameter menu.

Remark

- In the "Biochemical Items" list, the background color of the item reflects the current status of the item:
  - Blue or blue green indicates that the item is selected;
  - Beige means the item is optional;
- The colors in the "Portfolio List" and "Manual Item List" in the Parameters Menu are also displayed the same as the colors indicated in the biochemical items list.

- Biochemical tests-select items-click to copy

After selecting the test items, click "Copy" in the interface to display the screen shown in Figure 5.2. Depending on the options,different samples do the same project and the same sample to do multiple tests.

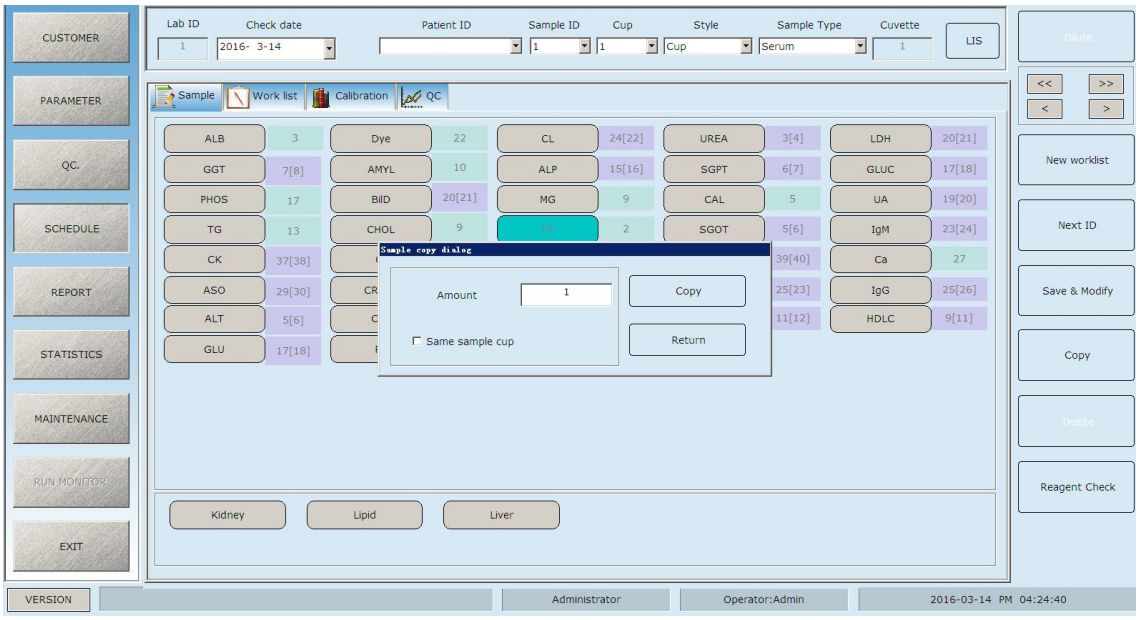


Figure 5.2

Click "Copy" to confirm,click "Back" to cancel.

- Biochemical tests- select items-click Reagent Amount Measurement-pop up reagent detection dialog box.

Click "Test" to see the screen shown in Figure 5.3.Routine testing,qualit control operations and calibration operations need to operate the interface,which is the fianl opeartion interface for testing samples.

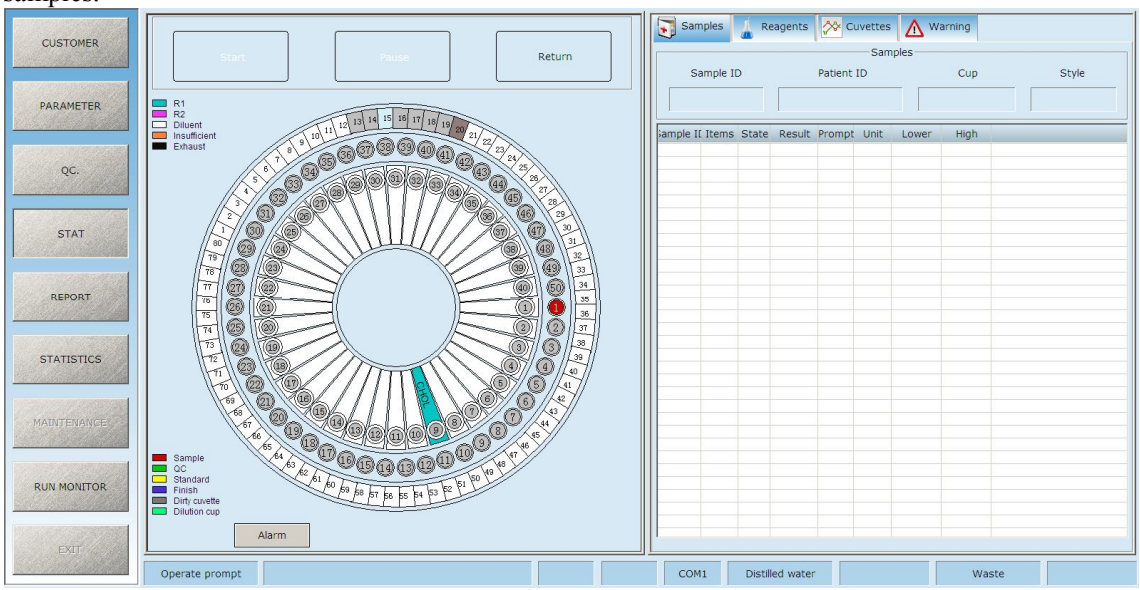


Figure 5.3

2）Test items list

As a auxiliary menu of biochemical items menu.Before setting the biochemical items, click on the inspection work list to see if the current page exists the test items.

Remark

- When the test items of a previous batch are finished and start setting and testing of a next batch of test items,need to delete the list of test items of the previous batch,otherwise the test items of a previous batch will be re-tested.

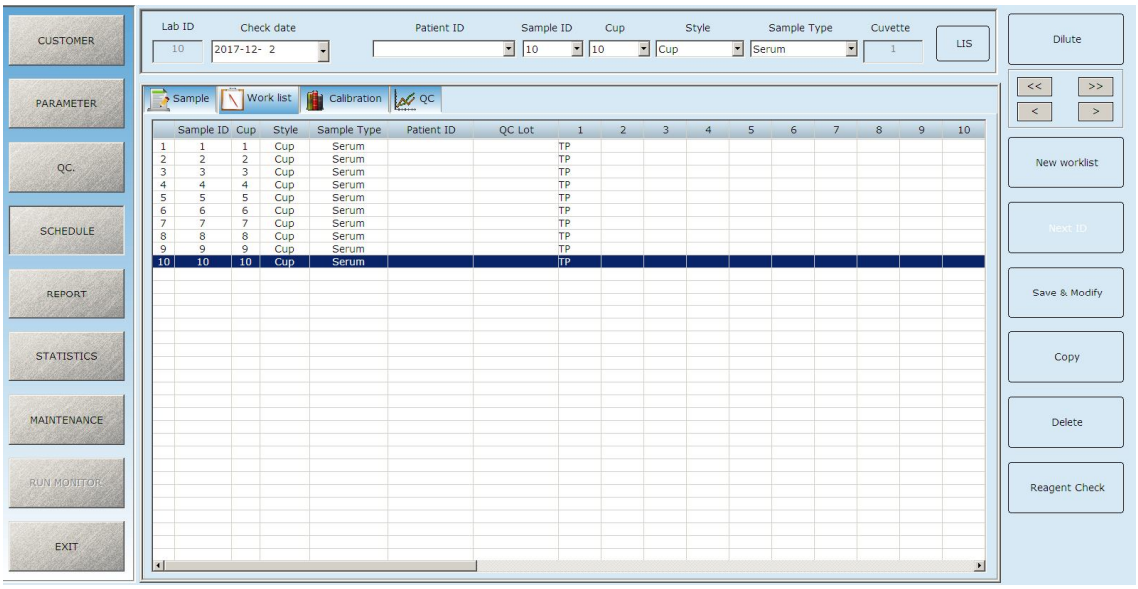


Figure 5.4

- Biochemical tests-select biochemical items- click to copy
  Interface displayed(Input 10 times,select a same number of sample cup.)

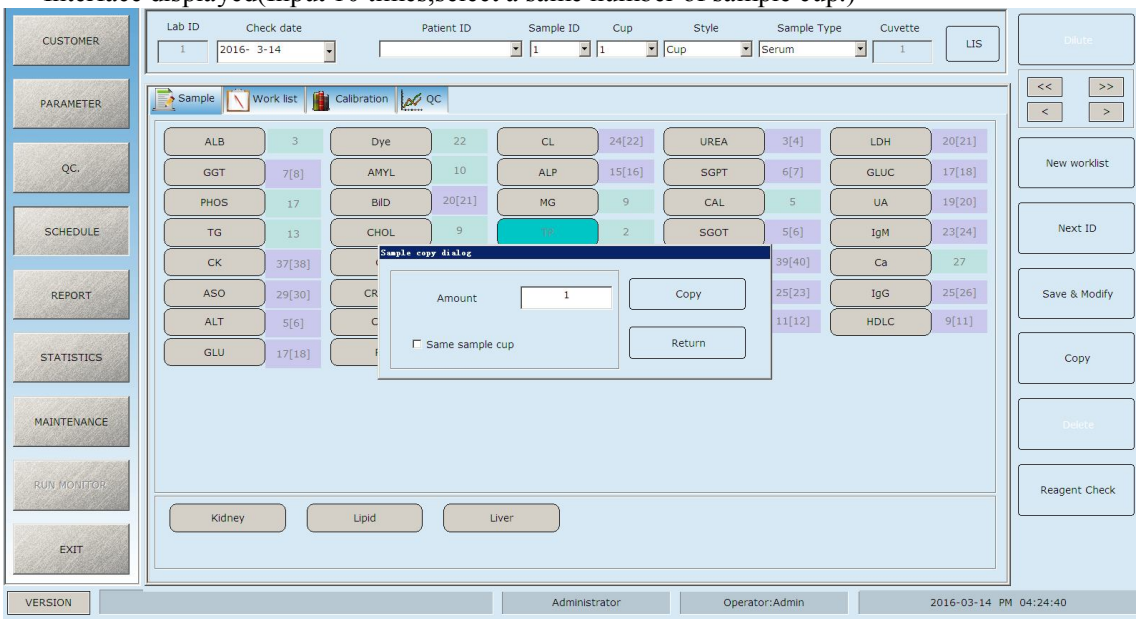


Figure 5.5

- Biochemical Test-Work List-click to delete
  Interface displayed

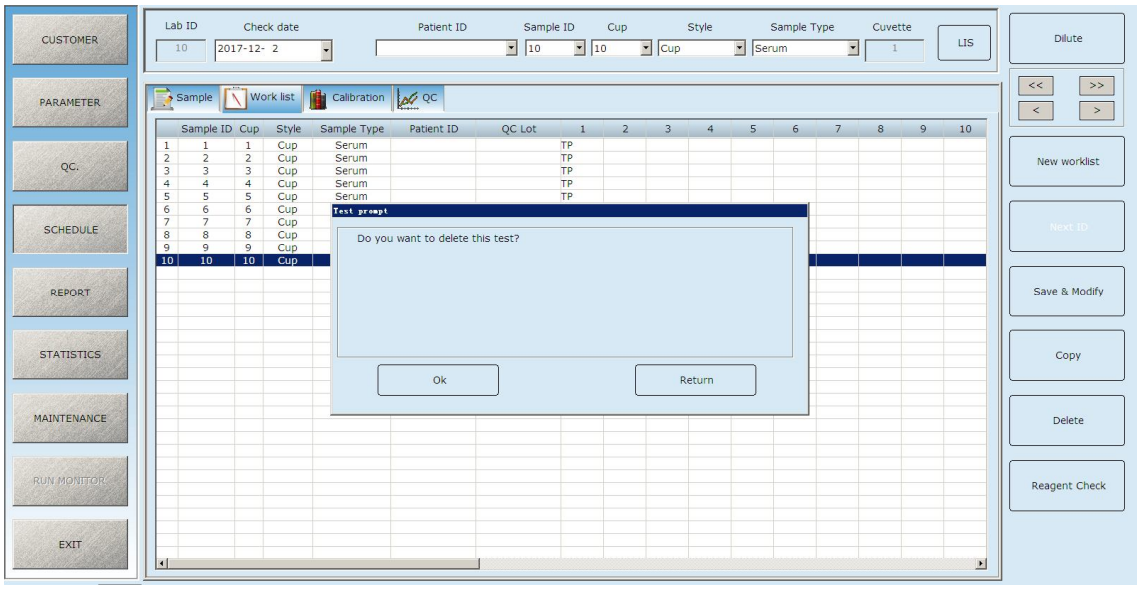


Figure 5.6

3）Calibration setting

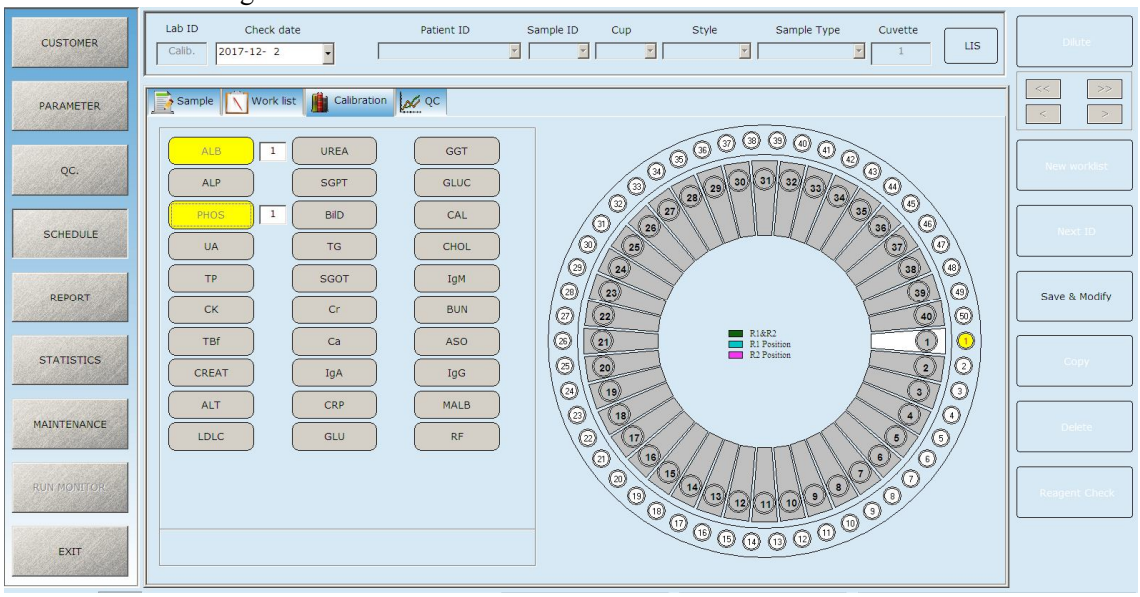


Figure 5.7

Explanation of interfaces and buttons on interface.

Parameter/ function	**Meaning**
Sample ID	The unique number of each sample,the sample number is unique in a same day.
Cup #	The user can choose where the sample will be placed.
Reaction cup	Start to test from any cup number.
Save and Modify	After selecting the test items for the sample, click to add to the list of test items.
ID++	The sample ID is automatically incremented by 1, allowing you to enter new sample information.

Parameter/ function	Meaning
Copy	If n samples do the same project, you can click "Copy" after selecting the project and select " Copy Number" to input n.If you select the "Same Cup Number" means the same sample will made n times of same item testing.
Delete	Use the mouse to select the item to be deleted, make it dark, click "Delete", you can delete the selected item.
Reagent Amount Measurement	Insert emergency test samples for priority testing.

5.4.2.2 Emergency test

Emergency testing menu is same as biochemical testing menu,it can insert sample testing in the ongoing test.Under biochemical testing menu,can not insert samples being tested.

5.4.2.3 Modify the sample test information

Input sample ID to be modified in the "Work List" interface of "Save and Modify", change the sample's testing information,then click "Save&Modify" (If you have already started testing, you can not modify).

5.4.2.4 Sample test

1）Sample test interface

After the sample and control inputs are completed in the "Biochemical Test" and "Emergency Test" menus,click the "Test" button to bring up the biochemical test interface as shown in the figure.

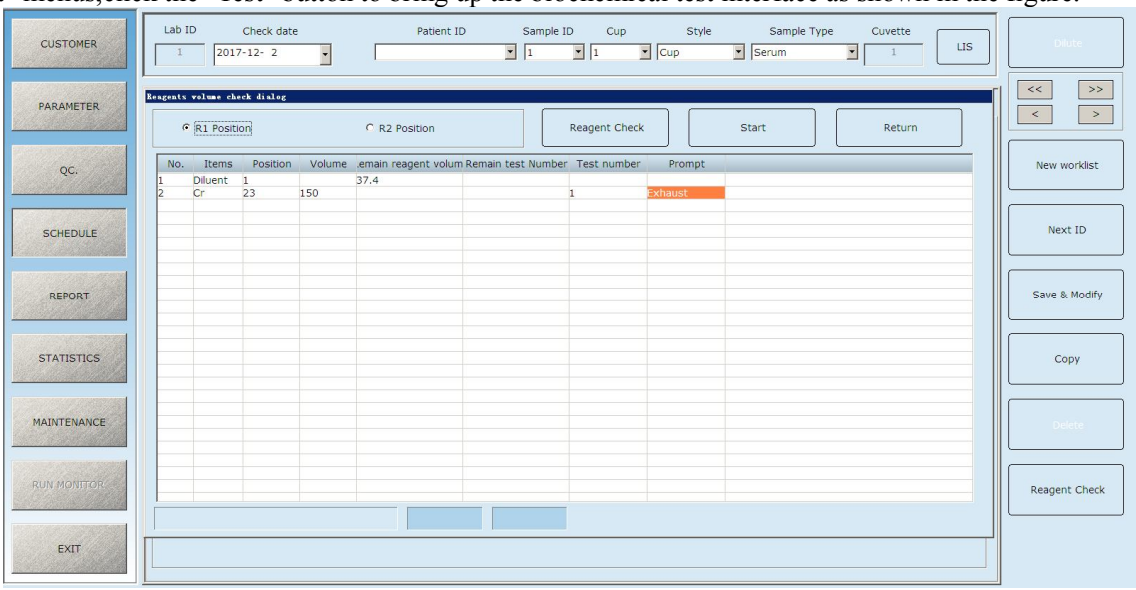


Figure 5.8

2）Sample test interface

In the above interface,click "Test",the test begins. The "Sample,Reagent,Reaction Cup" tab appears in this interface.Click on each option to see the working status of each element in this option,

These displayed parameters are set in the "Parameter" setting.

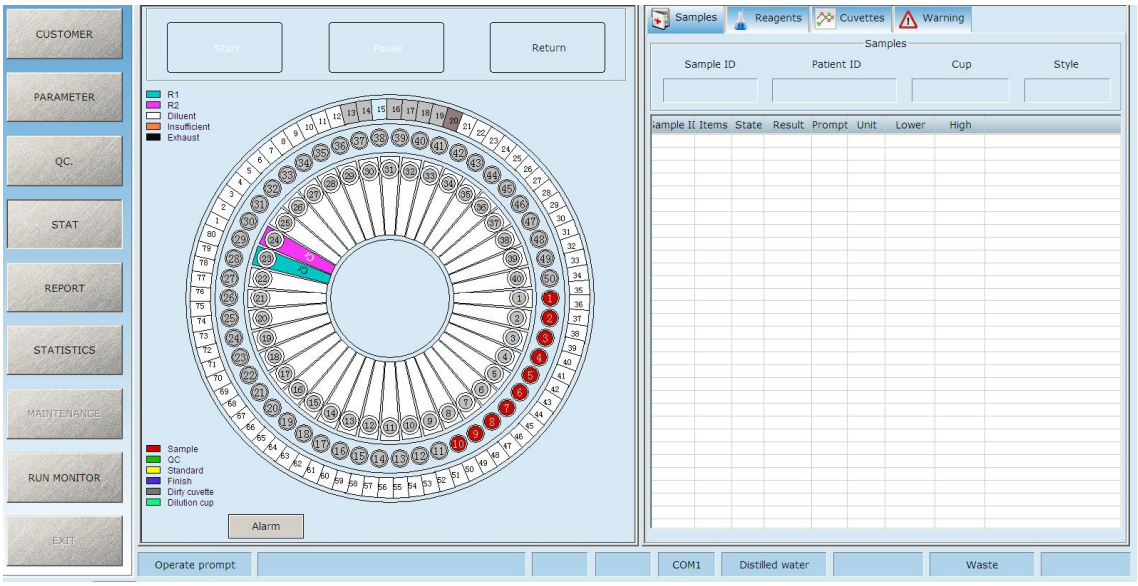


Figure 5.9

3) Query the results of the test interface

When the test is finished,the current test result is displayed in the "Sample Test Items List Box" under "Sample Information".It also display the washing status of reaction tray. In addition,the current results can also be viewed from the "Query Statistics" function.

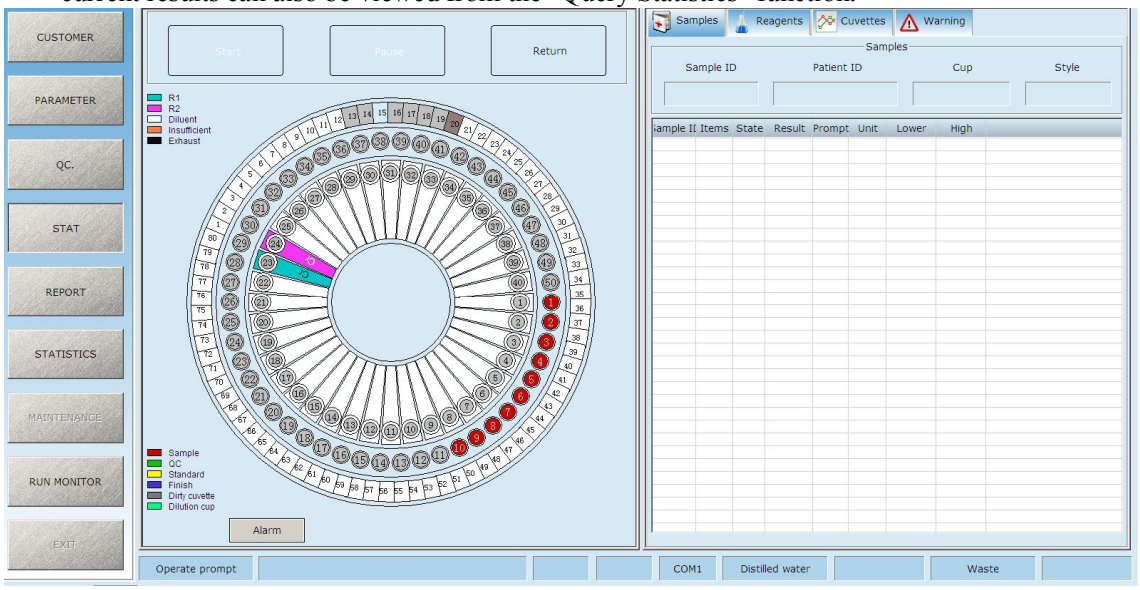


Figure 5.10

Different colors represent the various stages of the whole reaction.

If you think the result is questionable and needs to be retested,start with Biochemical Testing.

The following describes the options on this interface..

Option	Function
Sample	Display the information for each sample
Reagent	Reagent information for each reagent position is displayed
Reaction cup	Display information for each cuvette
Back	After finish the test,click the button to return.

5.4.3 Quality Control

5.4.3.1 Quality control sample input

Sample input under biochemical test interface

Click the "Biochemical Test" button,you can enter the biochemical test interface, click "Quality Control Application",enter the quality control position,that is,"Cup Number", select "Concentration Level",and then select the biochemical test items can be controlled,click "Save & Modify" button,select the lot number for each item,then "Save & Modify",click on "Reagent Amount Measurement"and then "Test". As the picture shows.This interface is used for quality control.

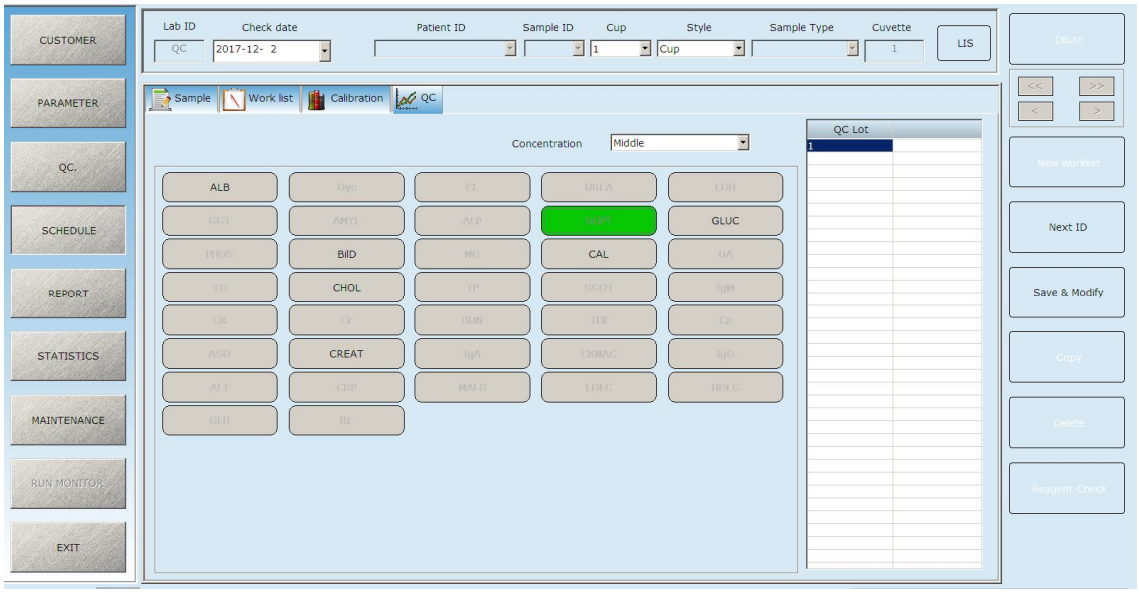


Figure 5.11

Remark

- In the "Item List", the background color of the item reflects the current status of the item:
  - Blue or blue green indicates the item is selected;
  - Beige means the item is optional;

5.4.3.2 Quality Control Interface

Click the "Indoor Quality Control" button, enter the quality control interface.

1）Quality control batch number setting

You can set the quality control lot number,target value,expiry date and concentration for each item. As the picture below.

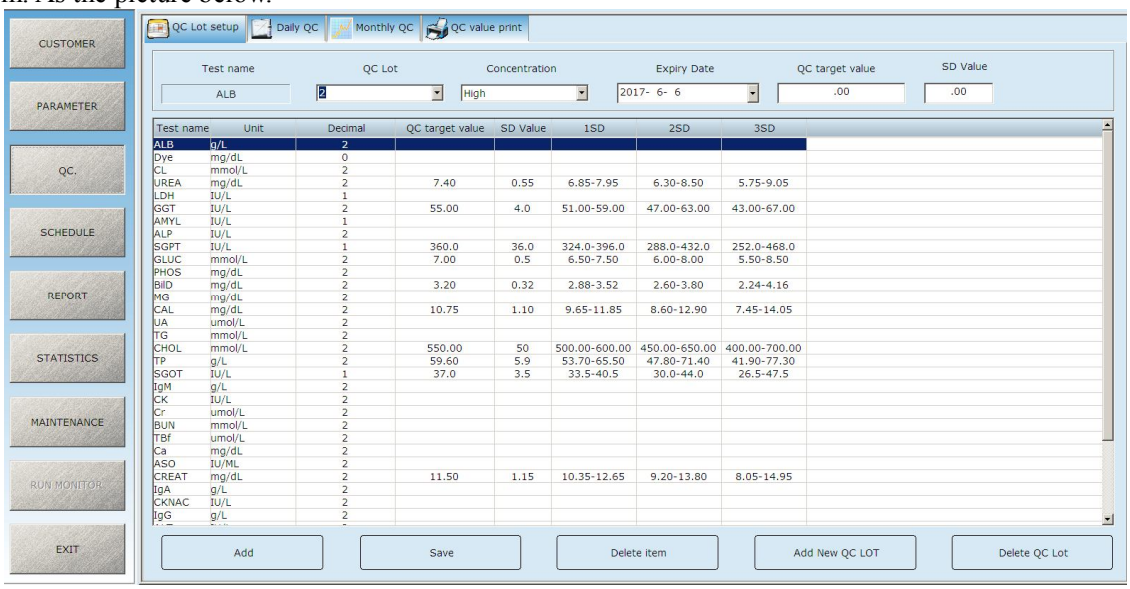


Figure 5.12

2）Quality control data display

In this option you can view the measured quality control values.As the picture shows.

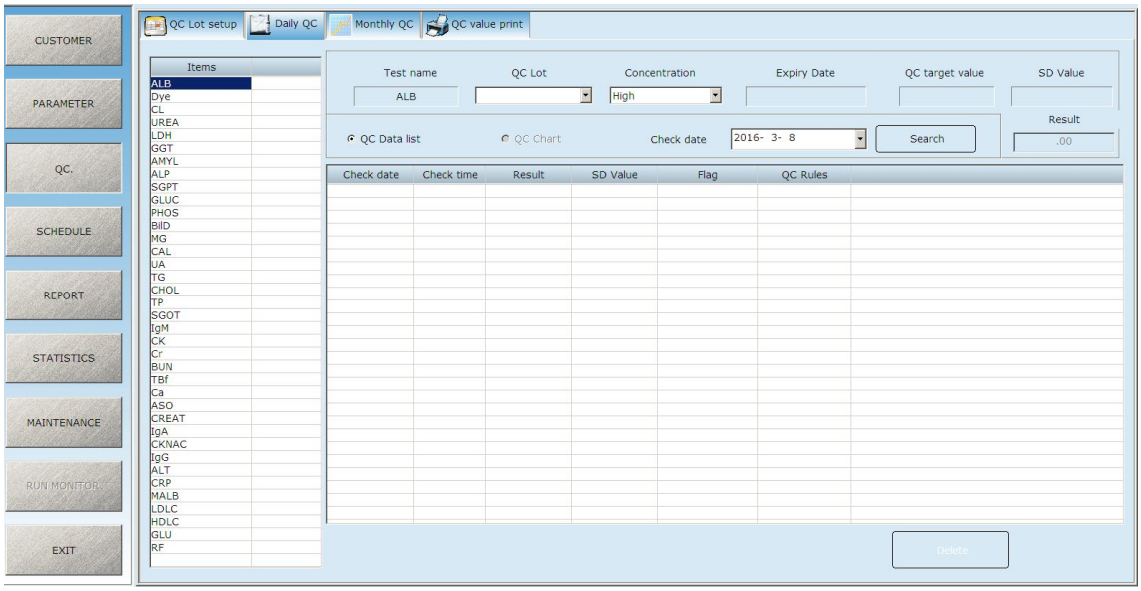
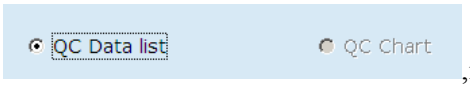


Figure 5.13

In 

,if you select "QC Data List," you get the list of QC values shown above.If you select "QC Chart", a dynamic QC chart will be displayed.

3) Quality Control Chart Analysis

Under this option, you can check the quality control chart for each lot of each item. Similarly, if you select "QC Data List", you will get a list of QC values shown in the figure below. If you choose Control Chart,a dynamic control chart is displayed.

The following describes the parameters.

Parameter	Meaning
Biochemical item	Select the items you want to set and view.
Batch number	Batch number of quality control.
QC target value	Original target value of QC.
Concentration level	Choose high, medium or low.
Expiry date	Deadline of effectiveness of QC.
Result	Test results of quality control
Standard deviation	Select items for using selecting quality control liquid for standard deviation of quality control.
QC Data List	List shows QC results.
QC Chart	Chart showing dynamic changes of quality control.

The following describes the button in this interface.

Button	Function
Add	Add new test items
Save	Save data settings,that is, changes made.

Button	Function
Delete	You can delete the items request quality control or content in QC value list.

Notice

●Correctly set the expiry date of the control solution,so that the system can correctly judge whether it is valid or not.

5.4.4 Customer information

Click the "Customer Information" button,enter the interface as shown in the figure, mainly for client unit settings, operator settings and data dictionary settings.

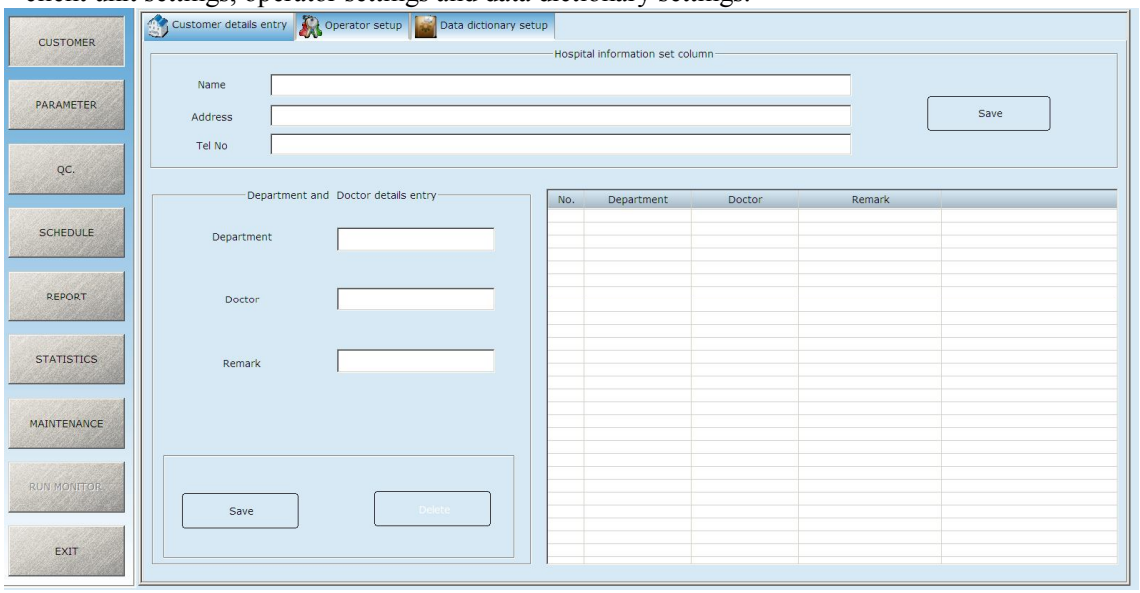


Figure 5.14

The following tabs are introduced one by one.

5.4.4.1 Hospital setting

"Hospital Settings" interface as shown above, used to set the hospital name, address, telephone number, department name, doctor's name and so on.

The following describes the parameters in this interface.

Parameter	Meaning
Hospital name	The name of the hospital where the instrument is located, after input, can be displayed in the report print.
Hospital address	The address of the hospital where the instrument is located, after input, can be displayed in the report print.
Telephone number	The telephone of the hospital where the instrument is located, after input, can be displayed in the report print
Department name	Department name where sample was sent.
Doctor's name	The name of the doctor the patient is on.
Remark	The above parameters are not clear,text need to explain again.

The following describes the button in this interface.

Button	Function
Save	Save the entered information
Delete	Delete the input information

5.4.4.2 Operator Settings

Select "Operator Settings" option,enter the following interface:

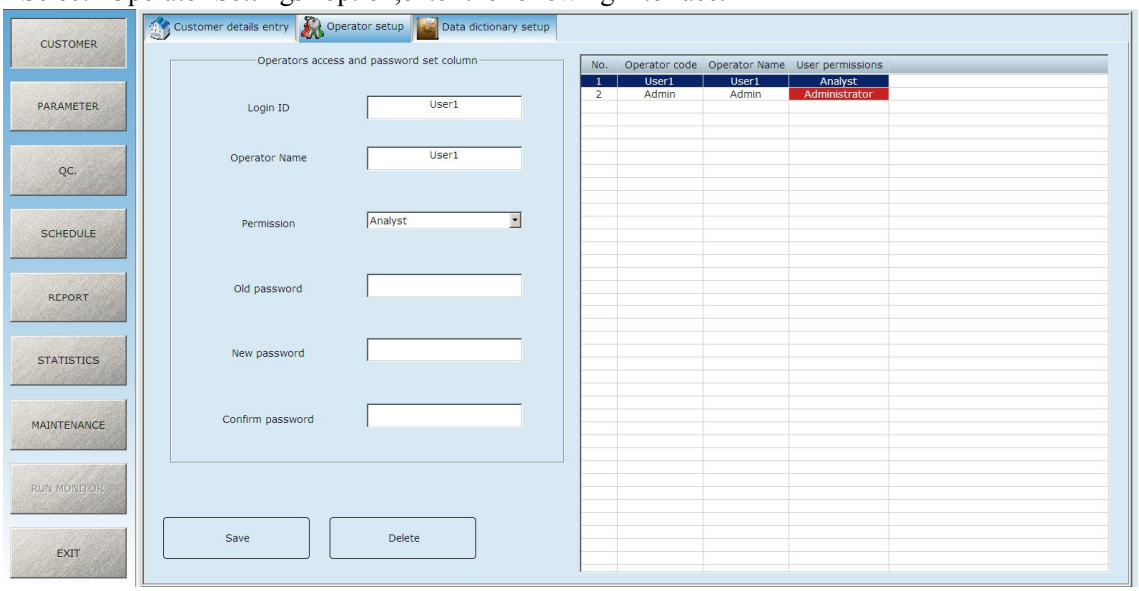


Figure 5.15

The following describes the parameters in this interface.

Parameter	Meaning
Login ID	Set the operator's short code to replace the name.
Operator name	Set the name of the operator.
User rights	Select the operator's authority.
Operator old password	The operator sets the previous password.
Operator new password	The operator replaces the previous password with the new password.
Confirm new password	Enter the new password again to confirm.

Note:Super User Permissions:Features that the executable software has.

Common User Permission: Biochemical parameter setting, external item parameter setting, computed item setting and project combination setting in reagent parameter setting can not be modified; Reference value range setting in reagent parameter setting can not be modified;Can not modify the other settings of customer information in addition to your own password.

The following describes the button in this interface.

Button	Function
Save	Save the input information.
Delete	Delete the input information.

5.4.4.3 Data dictionary settings

Select "Data Dictionary Settings" option,enter the following interface:

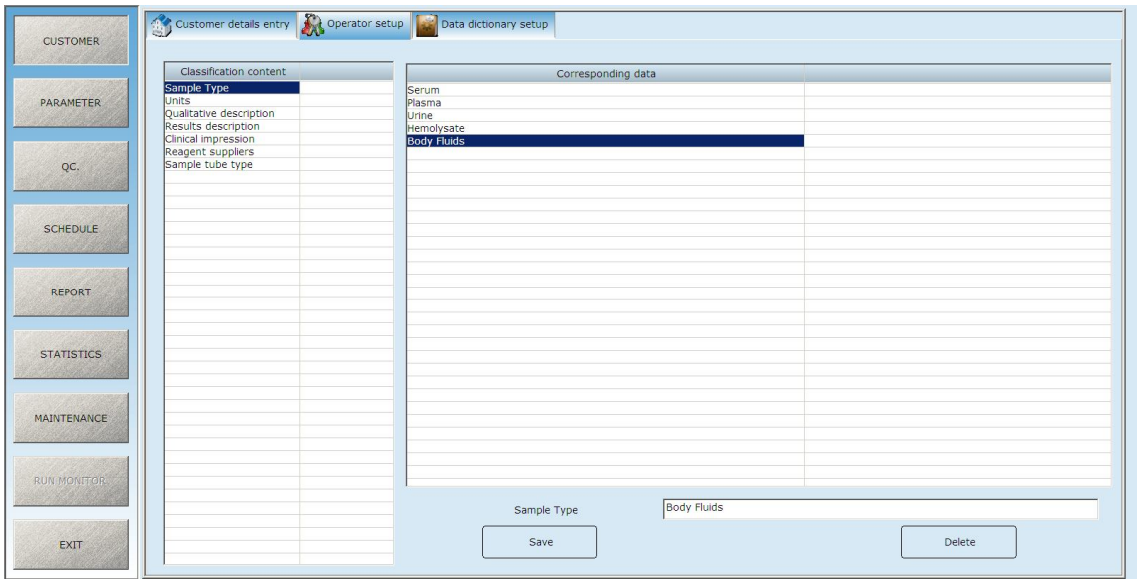


Figure 5.16

The following describes the parameters in this interface.

Parameter	Meaning
Category content	Select the desired content in the category bar.
Corresponding entry	In the corresponding entry bar, the content corresponding to the classified content is displayed.
Related information	Enter the relevant content in the text box will be displayed in the corresponding entry. Here you can increase the sample type,result unit and reagent bottle model and other classification content.

The following describes the button in this interface.

Button	Function
Save	Save your changes.
Delete	Delete the selected content.

5.5.5 Instrument maintenance

Click "Instrument Maintenance" button to enter the interface as shown in the figure, which is used to maintain the system and data.

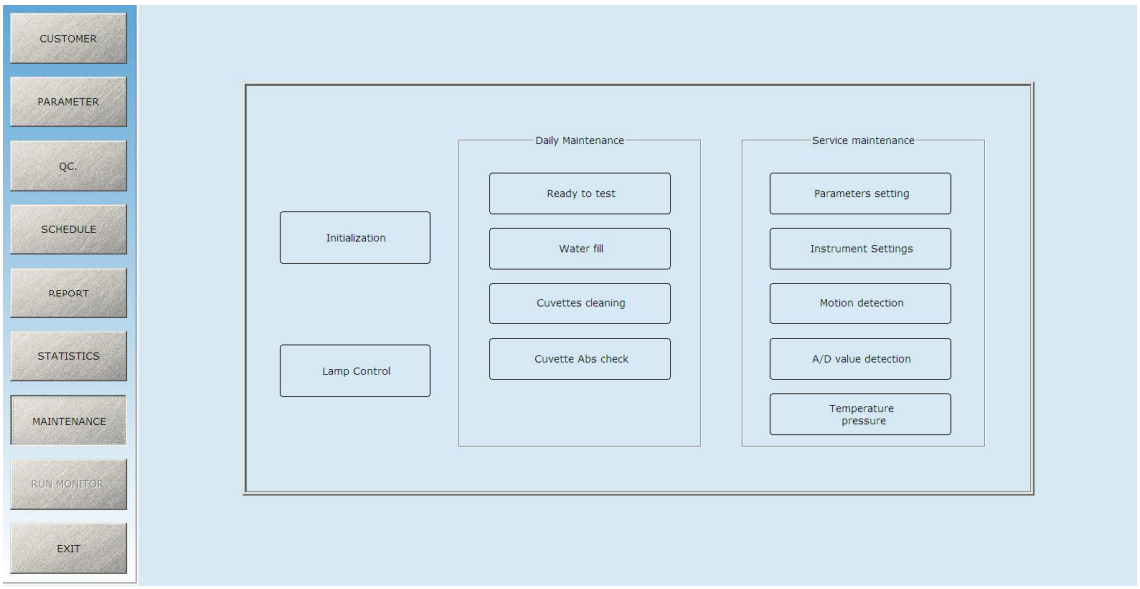


Figure 5.17

5.5.5.1 Communication serial settings

Click on the "System Settings" interface as shown, used to set the system.

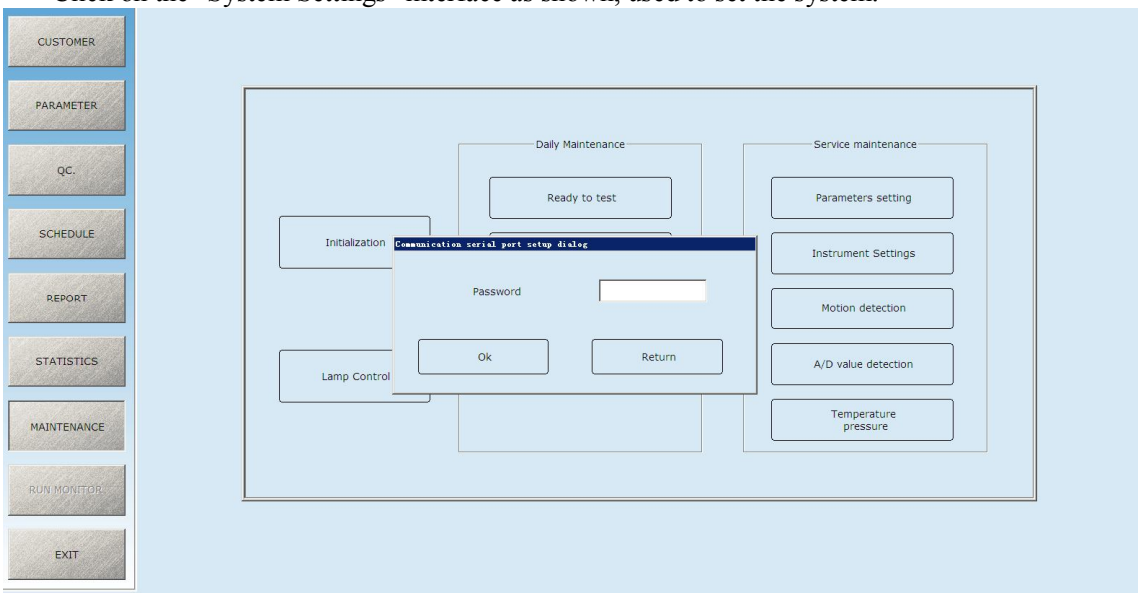


Figure 5.18

Enter the password "sages" into the interface, you can choose the instrument model, and set the communication serial port.

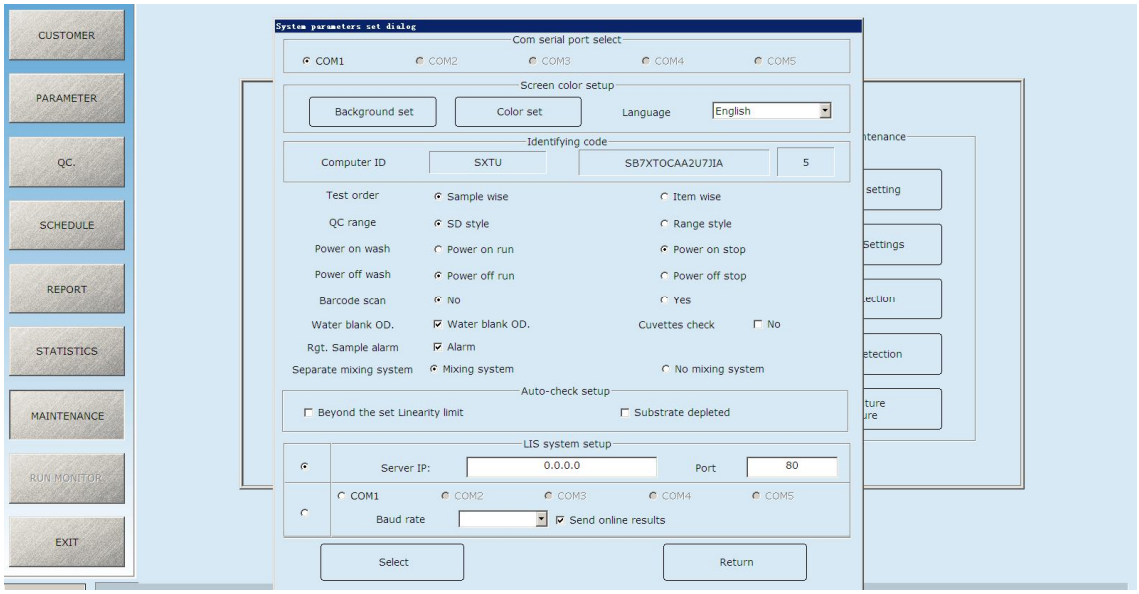


Figure 5.19

The following describes the parameters in this interface.

Parameter	Meaning
Biochemical analyzer serial port settings choice	Instrument and computer serial port, usually set by the engineer.
Electrolyte serial port settings choice	Instrument and computer serial port, usually set by the engineer.
mechanical arm selection bar	Divided into the old mechanical arm and the new mechanical arm,usually set by the engineer.

The following describes the button in this interface.

Button	Function
Confirm	Enter the password and click to enter the dialog box.
Back	Click to return to " Maintenance" main page.

5.5.5.2. Motion parameter setting

1) Click the "Instrument Parameter Setting" button,enter the following interface, enter the password "sages",enter the motor parameters setting dialog box,you can set the mechanical arm's motion parameters,and the detection of the arm.This step is operated by the engineer.

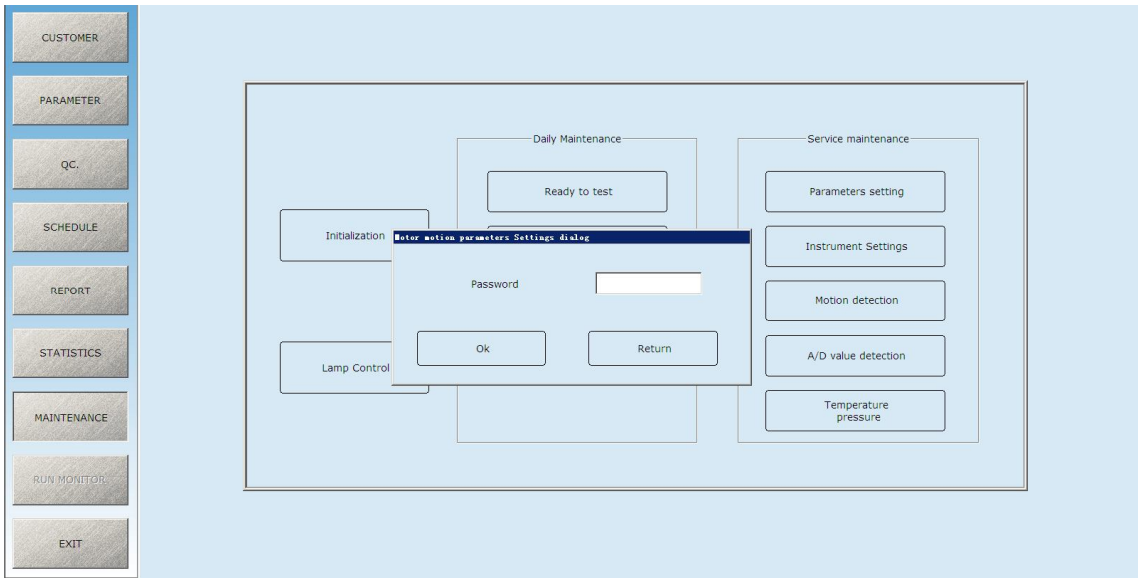


Figure 5.20

Notice

- This step must operated by the engineer,otherwise resulting in unforeseen failures,at customers' own risk.

2) Input the password,enter the following interface.This interface need change settings only when initial installation,replacing the mechanical arm and move location.

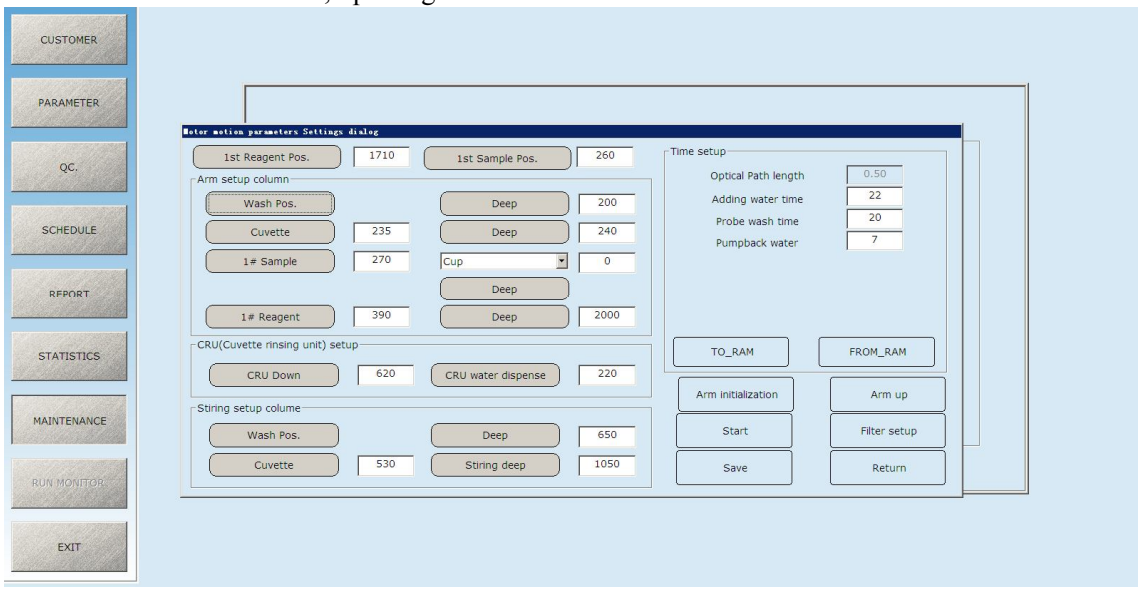


Figure 5.21

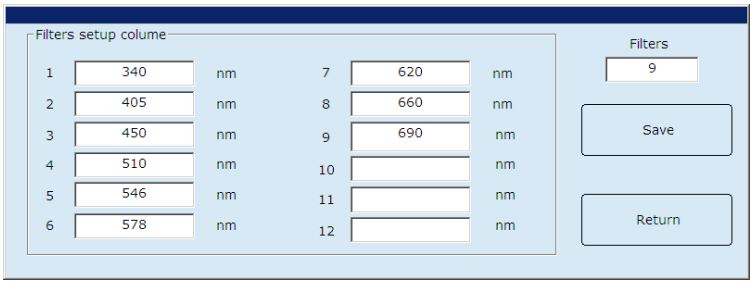
The following describes the parameters in this interface.

Parameters	Meaning
Sample tray and reagent tray settings	Set the parameters for the sample and reagent trays described below
Sample tray	The number of steps of initial position in the instrument sample tray.
Reagent tray	The number of steps of initial position in the instrument reagent tray.

Parameters	Meaning
Sample mechanical arm setting	Set the parameters of the following sample mechanical arm.
Cleaning position	With the sample arm in the cleaning position as a starting point.
Cleaning depth	The number of steps from the needle of the sample arm to the depth of the washing position.
Sample position	The number of steps of the sample arm needle from the washing position to the position of the sample cup in the sample tray.
Sample depth	The number of steps from the sample arm needle to the depth of the sample cup in the sample tray.
Reaction cup	The number of steps of the sample arm needle from the washing position to the cuvette position in the reaction tray.
Depth of reaction cup	The number of steps from the sample arm needle to the cuvette depth in the reaction tray.
Reagent arm setting	Set the parameters of arm for the following reagent
Cleaning position	With the reagent arm in the cleaning position as a starting point.
Cleaning depth	The number of steps from the needle of the reagent arm to the depth of the washing position.
Reagent outer ring	The number of steps of the reagent arm needle from washing position to the position of outer ring of reagent bottle in reagent tray.
Reagent inner ring	The number of steps of the reagent arm needle from washing position to the position of inner ring of reagent bottle in reagent tray.
Reagent depth	The number of steps from the reagent arm needle to the depth of the reagent bottle.
Reaction cup	The number of steps of the reagent arm needle from the washing position to the cuvette position in the reaction tray.
Depth of reaction cup	The number of steps from the reagent arm needle to the cuvette depth in the reaction tray.
Mixing arm setting	Set the parameters of the following mixing arm.
Cleaning position	With the mixing arm in the cleaning position as a starting point.
Cleaning depth	The number of steps from the mixing arm to the depth of the washing position.
Reaction cup	The number of steps of the mixing arm from the washing position to the position of the reaction cup in the reaction tray.
Depth of reaction cup	The number of steps from the mixing arm to the depth of the reaction cup in the reaction tray.
Cleaning arm setting	Set the parameters of washing arm.
Depth of reaction cup	The number of steps from the washing arm to the cuvette depth in the reaction tray.
Time setting	Set time of the following parameters.

Parameters	Meaning
Cup blank water level	The water level into the reaction cup when the testing cup is blank,it has been identified by factory.
Cleaning cup water level	The water level into the reaction cup when wash reaction cup,it has been identified by factory.
Cleaning needle time	The time required to clean the arm needle. it has been identified by factory.
Cuvette light path	The cuvette's light path,has been determined by the factory.

The following describes the button in this interface.

Button	Function
Confirm	Enter the password and click to enter the dialog box
Back	Click to return to the " Maintenance " Main page
Wavelength setting	Click to pop up the following dialog box, set the wavelength. 
Arm up	Click to move the mechanical arm up and down in the initial position.
Arm reset	Click to move the mechanical arm left and right and stop in the initial position.
Test	Select a motion parameter setting of the left arm, and click "Test" to check the correctness of the selected motion of the selected arm.
Save	Save the changed settings.

5.5.5.3. Instrument initialization

Click "Instrument Initialization" to get the following dialog box, then click "Instrument Initialization" to initialize the instrument. This is used when you are unsure that the instrument is return to the starting point.

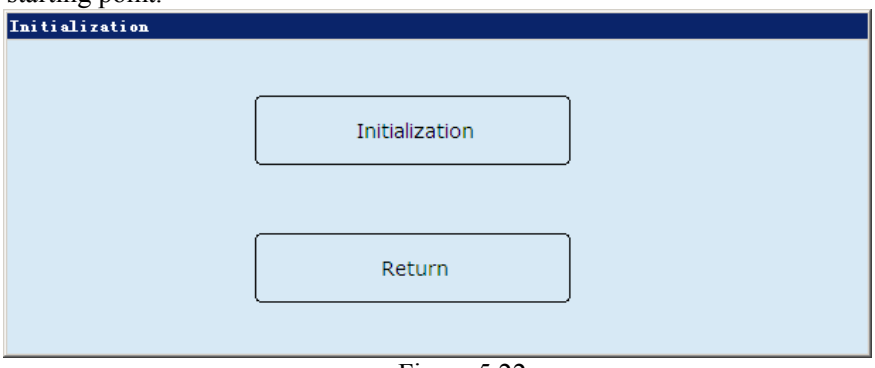


Figure 5.22

The following describes the button in this interface.

Button	Function
Instrument initialization	Click to initialize the instrument. Moving parts return back to the starting position.
Back	Click to return to the "Maintenance" main interface.

5.5.5.4. Moving parts inspection

Click "Moving Parts Detection" to get the following interface, which can detect moving parts.

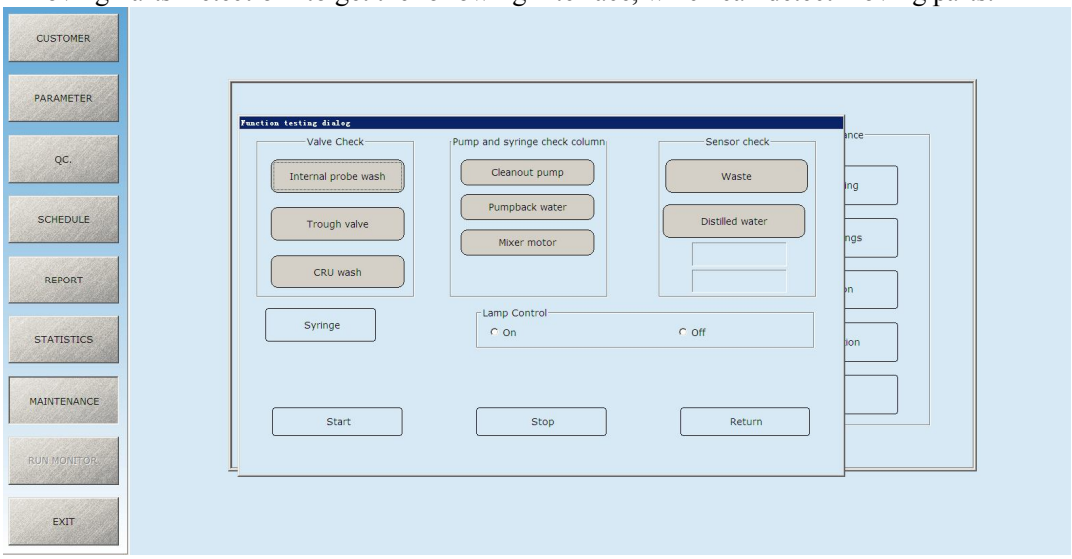


Figure 5.23

Warning

- When working in the system,do not touch the moving parts of the system.These moving parts include sample needle,mixing arm and washing arm.
- When working in the system, do not put your fingers or hands into the open parts.

The following describes the parameters in this interface.

Parameter	Meaning
Electromagnetic valve test bar	
Needle washing valve	Click "Needle Washing Valve",and then click "Test".Testing of Needle Washing Valve.
Reagent valve	Click "Reagent Valve",and then click "Test".Testing of reagent valve.
Watering valve	Click "Watering valve",and then click "Test". Testing of watering valve.
Pump and syringe test bar	
Washing pump	Click "Washing Pump",and then click "Test". Testing of washing pump.
Backwater pump	Click "Backwater Pump",and then click "Test". Testing of backwater pump.
Stirring motor	Click "Stirring Motor",and then click "Test". Testing of stirring motor.

The following describes the button in this interface.

Button	Function
Test	After selecting the moving parts, click "Test" to check the movement of the parts.
Stop	Moving parts reset.
Back	Click to return to the "Maintenance" main interface

5.5.5.5 Cuvette cleaning

Click "Cuvette Cleaning" to enter the following interface,the user can select the cuvette number to be cleaned, and click "Wash" at the right of "Clean all cuvettes", then clean all the cuvettes.

A total of 80 cuvettes,if click the second "Wash",then you can choose any cuvette between 1-80.

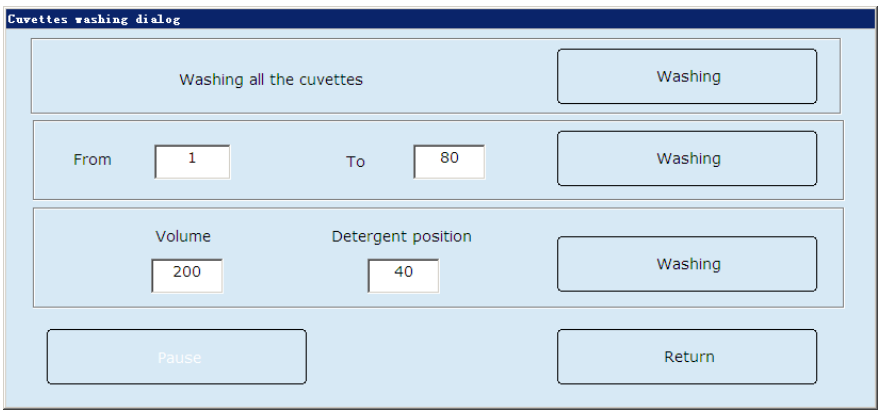


Figure 5.24

The following describes the button in this interface.

Button	Function
Clean	Clean all cuvettes.
Clean	The user chooses the cuvette to be cleaned.
Back	Click to return to the "Maintenance" main interface

5.5.5.6 Temperature and Pressure

Click the "Temperature and Pressure" to enter the following interface,the interface mainly displays temperature and pressure conditions of the reaction tray,if not correct,promptly improve by temperature calibration parameters setting.

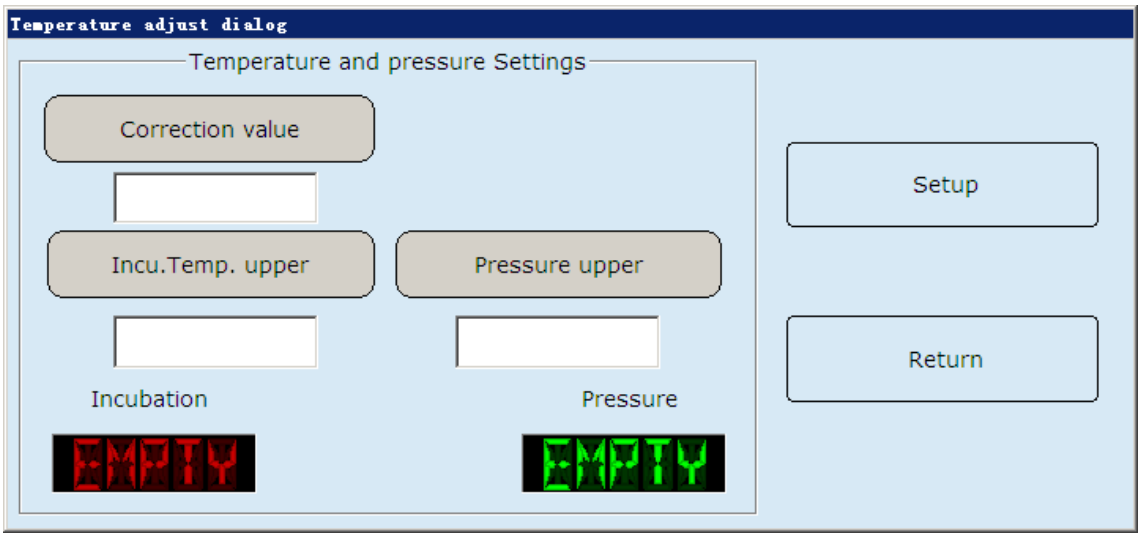


Figure 5.25

The following describes the button in this interface.

Button	Function
Temperature calibration parameter setting	
Reaction tray calibration parameters	Calibrate the temperature of reaction tray
Set the maximum temperature and pressure	
Upper limit of reaction tray	Set the upper limit of reaction tray temperature
Pressure gauge upper limit	Set the pressure upper limit of pressure gauge.
Setting	Modify the parameter setting to confirm
Back	Click to return to the "Maintenance" main interface.

5.5.5.7. Cuvette check

1) Click "Cuvette Check" button,enter the following dialog box. In this dialog, you can determine whether the cuvette is good or bad by observing the absorbance of the water blank, and change the cuvette according to the absorbance observation.

2) There are two ways to check the cuvette: absorbance and signal value.

3) After "Fill distilled water",click "Test cup quality",if the individual cuvettes appear red,you need to detect whether the cuvette is abnormal,at this point,first wash the cuvette again and then check,if there is red, you have to replace the cuvette,if appear red wavelength,have to contact the company's after-sales service department

4) "Empty the cuvette" before daily testing,"Fill distilled water"after testing.

Figure 5.26

The following describes the button in this interface.

Button	Function
Fill distilled water	Add distilled water to the cuvette.
Empty the cuvette	Evacuate the distilled water in the cuvette.
Test cup quality	Click to detect the cuvette is good or bad,if necessary,be replaced.
Back	Click to return to the "Maintenance" main interface.

5.5.5.8. A/D signal testing

1) Click "A/D signal testing" button to enter the following interface.In this interface can detect the stability of each wavelength.

2) If the instrument is moved, the instrument signal value can be determined by the wavelength fluctuation on this screen.

3) This interface can also observe the linear range of different wavelengths of the instrument.

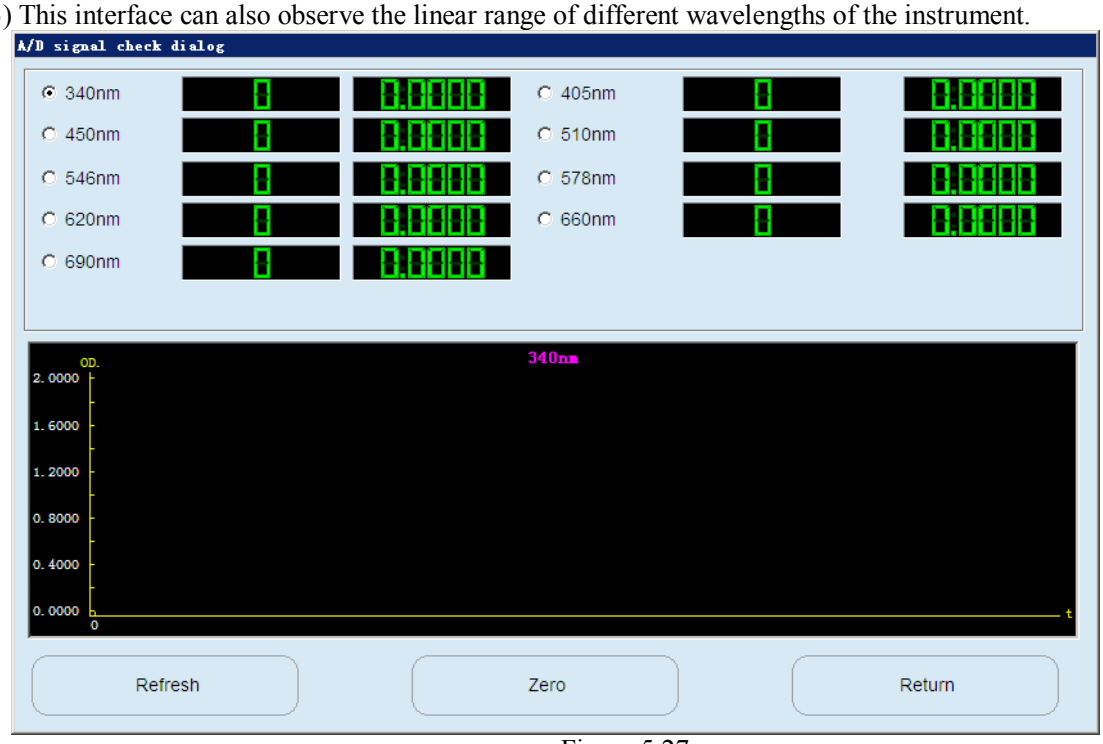


Figure 5.27

The following describes the button in this interface.

Button	Function
Refresh	Redraw the signal diagram.
Zero	Zero the signal value.
Back	Click to return to the "Maintenance" main interface.

5.5.6 Query statistics

Click "Query Statistics" button to enter the main interface. As shown below.
1) You can query the historical data under this menu.
2) The history data can be edited under this menu.
3) You can charge and make statistics to test items under this menu.
4) Has a variety of ways to query.
5) Print query and edit results.

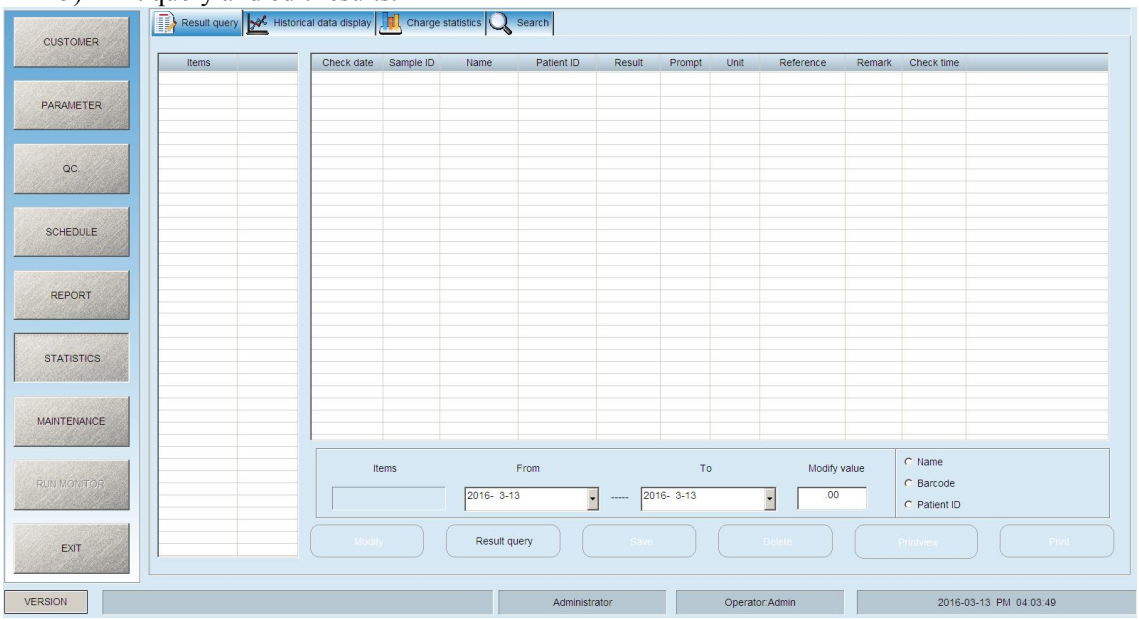


Figure 5.28

5.5.6.1. Results correction

1) Click on the "Correction" tab,you can enter the interface,as shown above,for the editing of results and other operations.

2) Select the item to be modified in the biochemical items bar,select the sample ID number to be modified in the side column,input the correction value you require,click "Correction" button.

3) Click the "Save" button as shown above to display the revised results.

The following describes the parameters in this interface.

Parameters	Meaning
Biochemical items	This bar shows all biochemical items,by selecting items to view and edit.
Items name	When selected in the biochemical item,it will be displayed in the item name.
Testing date	Display the biochemical items of the day according to testing date.
Correction value	Use it when editing a item,equivalent to the coefficient.

The following describes the button in this interface.

Button	Function
Modify	Click correction,the items need editing display revised results.
Save	The revised results will be saved.
Delete	The revised results will be saved.
Preview	Preview the test results.
Print	Print test results.

5.5.6.2. Historical data display

1) In the historical data, sample results and quality control results of different dates can be displayed. As shown below.

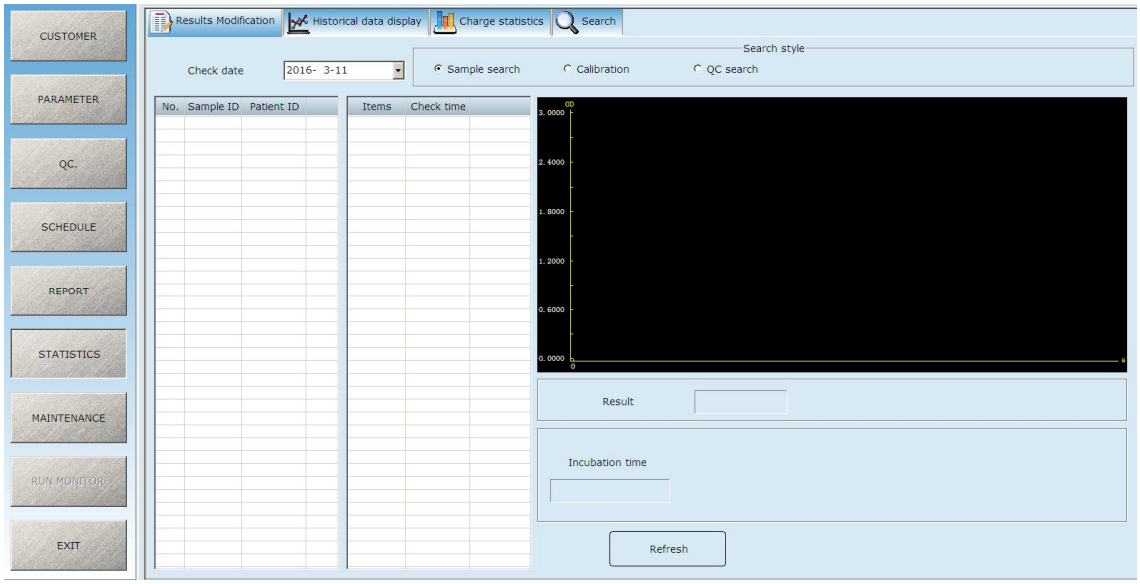


Figure 5.29

2)The reaction curve of the items results can be displayed.The reaction curve can be edited and computed.

The following describes the parameters in this interface.

Parameters	Meaning
Testing date	Only set the test date,can check the test items of the day.
Way of query	Two ways of sample query and quality control query.
ID Serial number and sample ID	Shows the serial number of the biochemical items and sample ID number done on the day.Select with the mouse.
Test item	After the sample ID number is selected,the test items are displayed.Selecting by mouse,shows the reaction curve of the test items.
Results of testing Result	After setting parameters,the test results from the analyzer. Show new results.

The following describes the buttons in this interface.

Button	Function
Refresh	Click "Refresh" to save the edited result.

5.5.6.3. Charge statistics

Can help the statistics of charges of the test items,click the "Statistics" button to get the total cost.

1) Query statistics-Charge statistics-Patient Charge Statistics(Display after click Statistics button)

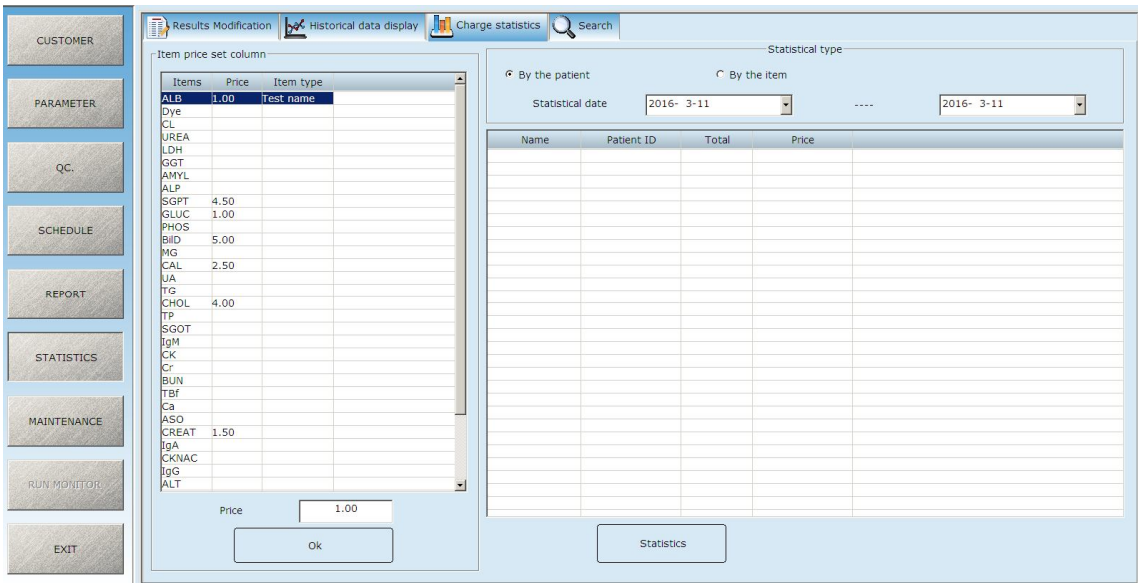


Figure 5.30

2) Query Statistics-Charge Statistics-Items Charge Statistics(Display after click Statistics button)

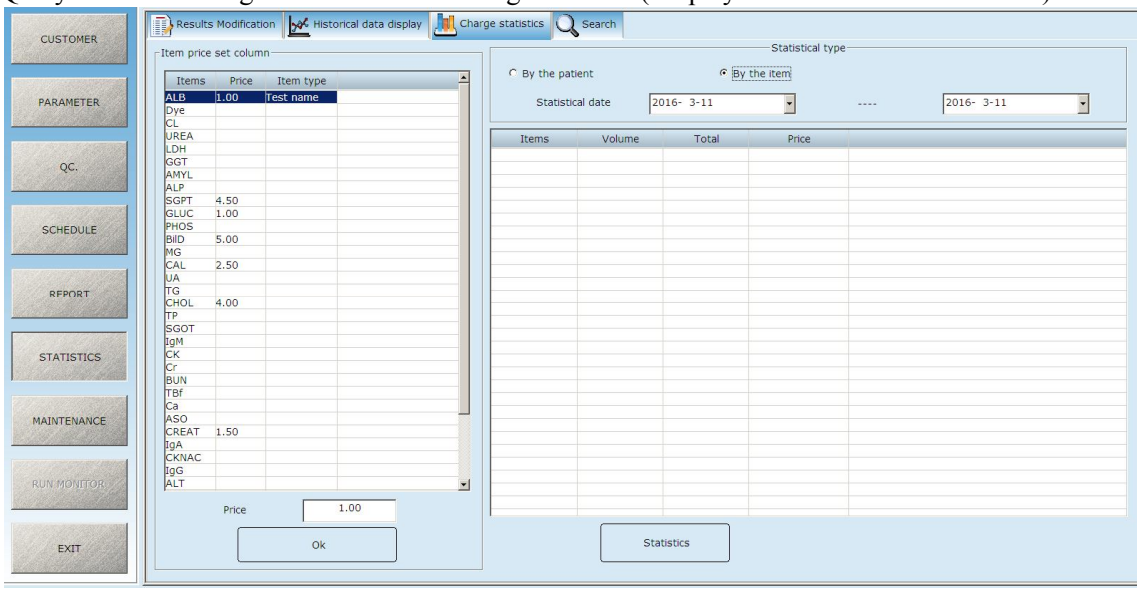


Figure 5.31

The following describes the parameters in this interface.

Parameters	Meaning
Item price setting	According to the items,can enter the required price for testing the item.
Patient Charge Statistics	Can display test items of a patient,and the fees charged for these items.
Items Charge Statistics	Charges of a item during date computed.
Date computed	Query charges statistics as date computed.
Price	Enter the price of the selected item in the price bar.

The following describes the buttons in this interface.

Button	Function
Confirm	Confirm the price entered.
Statistics	Make statistics on prices.

5.5.6.4 Query

Select the appropriate way of query,click the "Query" button,you can get the test results.

1）Query Statistics-Query-Query as date of testing(Display after click Query button.),as shown below:

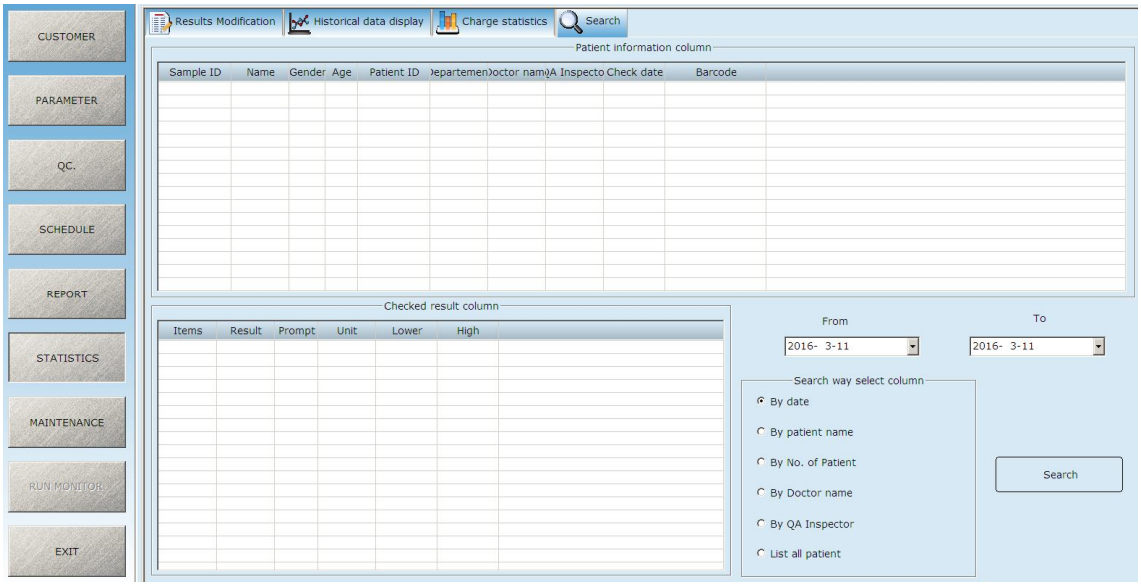


Figure 5.32

2) Query Statistics-Query-Query as doctors conducting testing(Display after click Query button.)

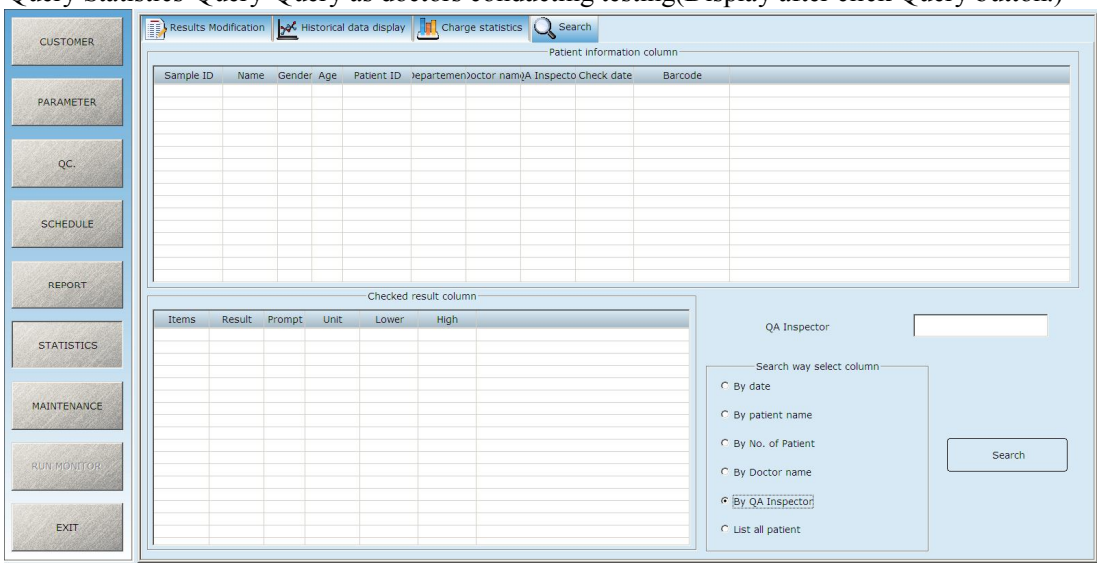


Figure 5.33

The following describes the parameters in this interface.

Parameter	Meaning
Query result bar	Click the item in the query result bar to display it in the display column of test results.
Showing bar of test results	Display the results in the query results bar.

Parameter	Meaning
Doctor conducting testing	You can choose the test results from a doctor.
Query mode selection bar	You can choose a way of query in the query way selection bar,by date,patient name,Medical record No.,doctor conducting testing or all the test results and so on.

The following describes the buttons in this interface.

Button	Function
Query	After selecting "Query Conditions",click this button to search for the result that meets the conditions.

5.5.6.5. Query as patients name

Patient history data can be displayed for easy analysis of the patient's condition.

Query Statistics-Query as patient's name,as shown below:

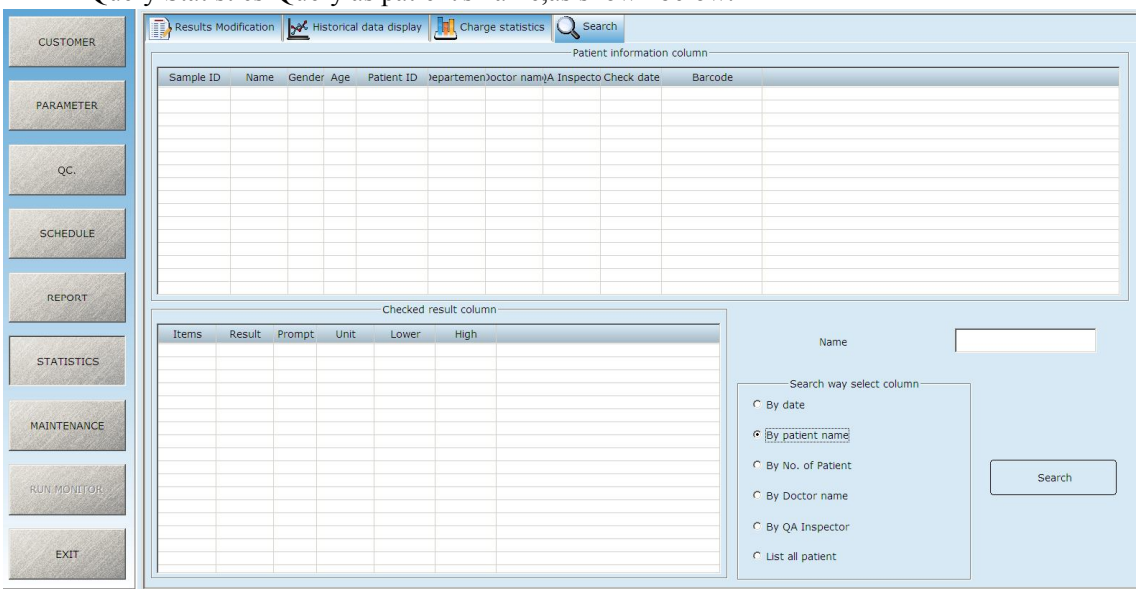


Figure 5.34

The following describes the parameters in this interface.

Parameter	Meaning
Patient's name	Display bar shows the patient's name and other information
List of test items	Display the results in the query results column.
Date of testing	You can choose the date of testing.

The following describes the buttons in this interface.

Buttons	Function
Query	After selecting "Query Conditions",click this button to search for the result that meets the conditions.

5.5.7 Test Report

Click the "Test Report" button to enter the interface,enter the patient details, "Save" the input information,the user can "Preview" printing format,select the appropriate style,"Print",you can get the patient's test report.

5.5.7.1 Patient information registration

Generally,input detailed information after testing is finished and before printing the report,click the

"Patient Information" button,pop-up "Patient Information Input Bar" dialog box,as shown.This dialog box is used to display and edit the sample details.

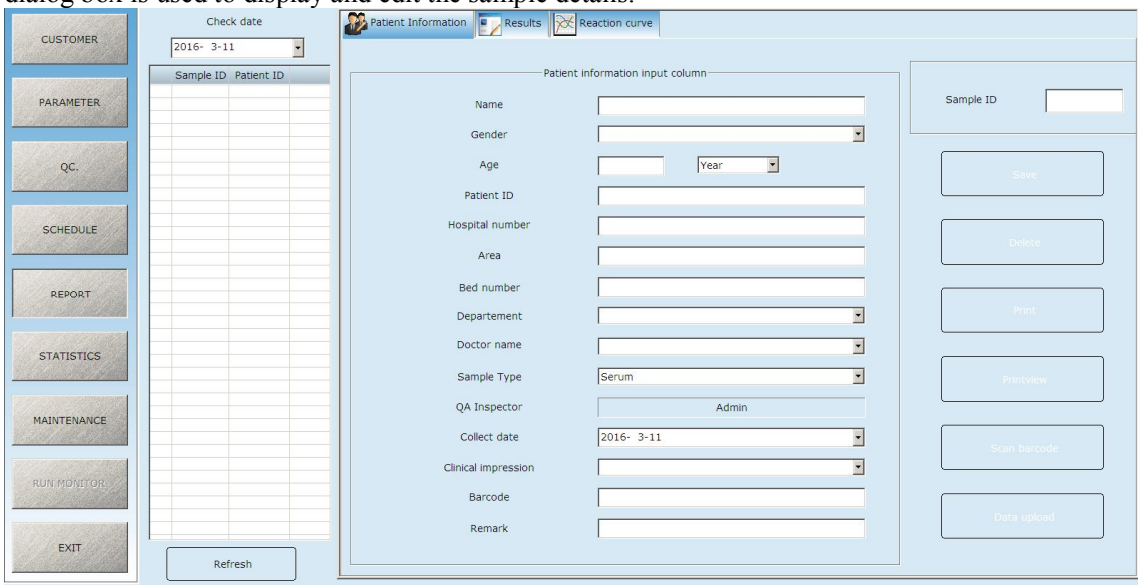


Figure 5.35

In this interface you can also view the patient's test results, and display the measured chart.

The following describes the parameters in the "Sample Information" dialog box.

Parameter	Meaning
Sample No.	Sample ID
Name	Name of patient
Gender	Gender of patient
Age	Age of patient
Medical record number	Medical record number of patient
Hospitalization No.	Hospitalization No.of patient
Ward No.	The patient's ward number
Department where the sample is from.	The department where the person sent the sample for inspection is.
The person who sent the sample for inspection	Name of the person who sent the sample for inspection.
Sample type	Divided into "serum","plasma","urine","other".
Test physician	Operator
Clinical diagnosis	Doctor's description of the patient's clinical diagnosis
Barcode	Sample barcode information

5.5.7.2 Results editing

Here you can see the patient's test results, and modify.

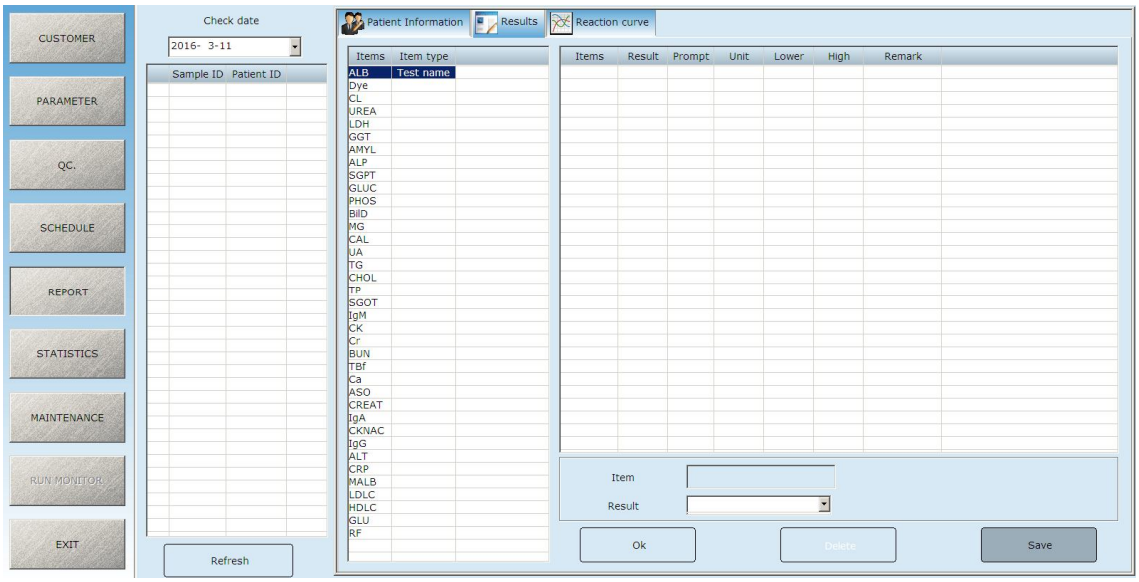


Figure 5.36

5.5.7.3 Reaction curve

1) The inspector can see the test chart here and determine if there is a problem with the instrument or reagent according to the test chart,and whether the patient's test result is reliable.

2) Inspectors can check the actual measurement chart to see if the reagent parameters are set correctly. If incorrect, the test points can be changed and reset.

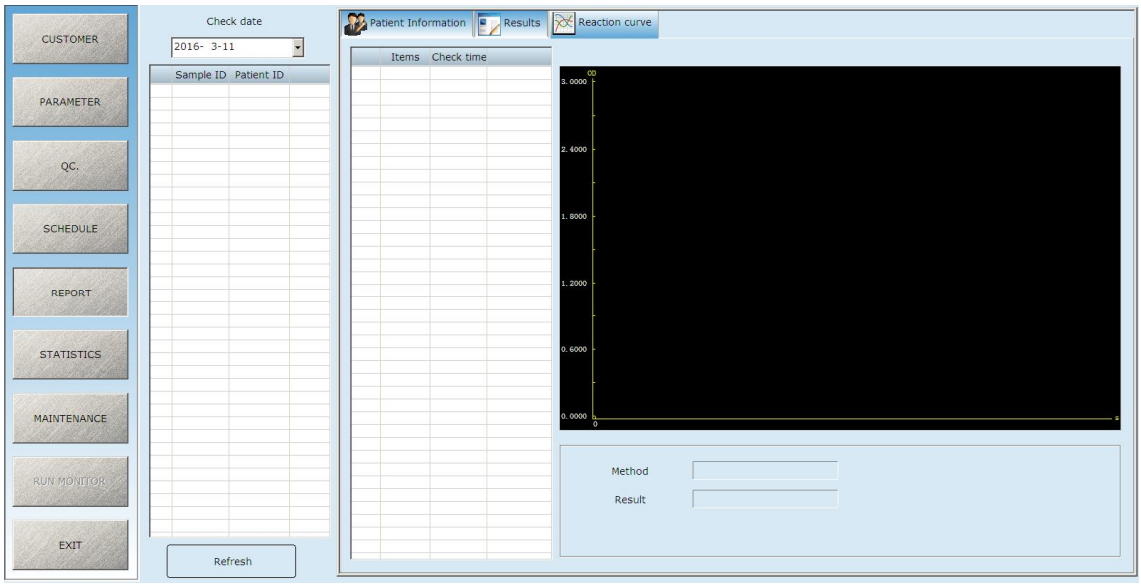


Figure 5.37

5.5.8 Calibration

Click the "biochemical test" button, enter the interface as shown. This interface is mainly used for biochemical testing and calibration.

5.5.8.1 Determine the calibration item

Firstly select biochemical items,choose the items to be tested,click"Save&Modify" button,in the work list,select the item to be calibrated,click the "Reagent Amount Measurement",the instrument will be calibrated before doing biochemical tests.

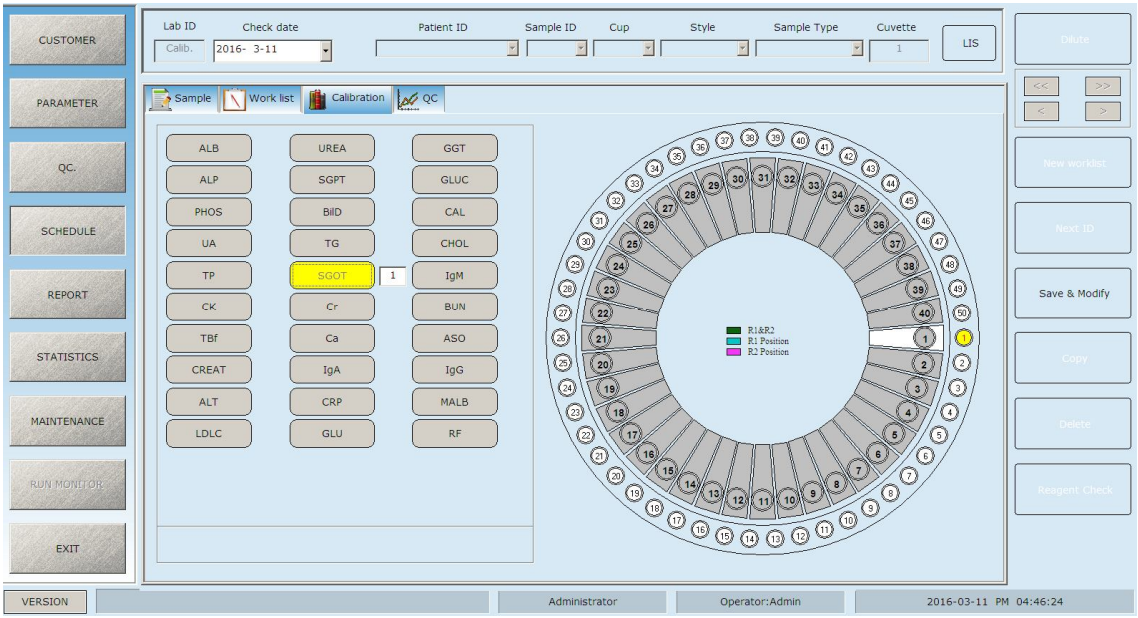


Figure 5.38

5.5.8.2 Calibration fluid settings

Calibration fluid position settings are made in the "Parameter Settings" function.

Click the "Parameters Setting" button,select "Biochemical Items Settings",click on the "Item Basic Parameters"option,the following interface appears.

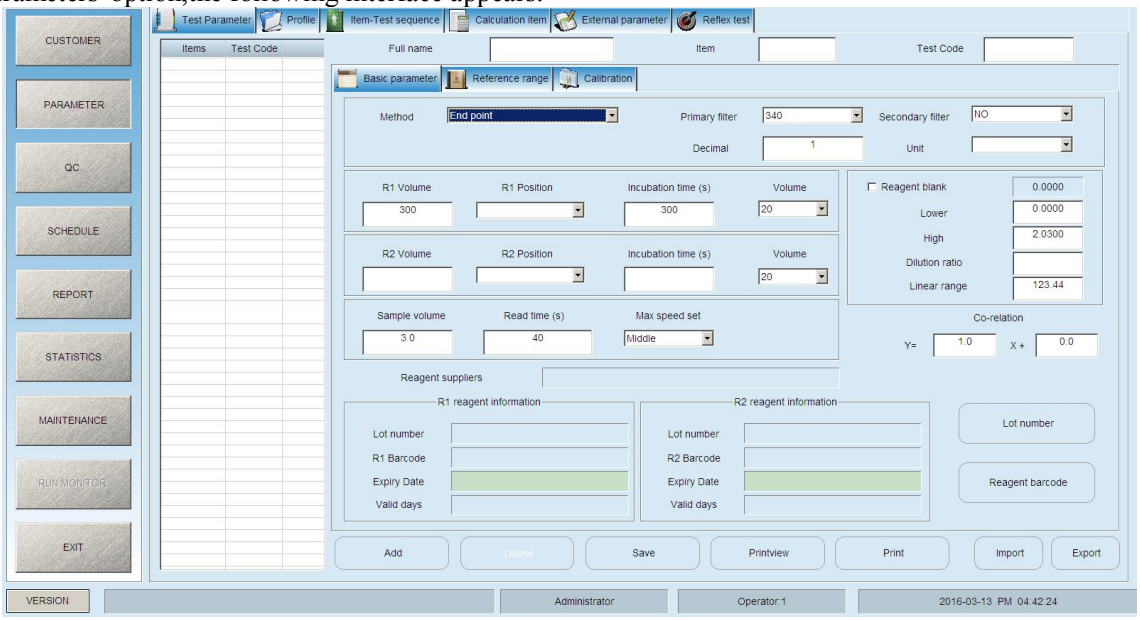


Figure 5.39

Select an item in the "Item" list,and then set the standard number and standard liquid position of items,"Save".When doing the calibration test,the standard solution should be placed in the set position.If you need to modify the calibration fluid position also through the above steps to change.

A biochemical test can have multiple criteria,enter the number in the standard number,for example input 3,the following interface appears:

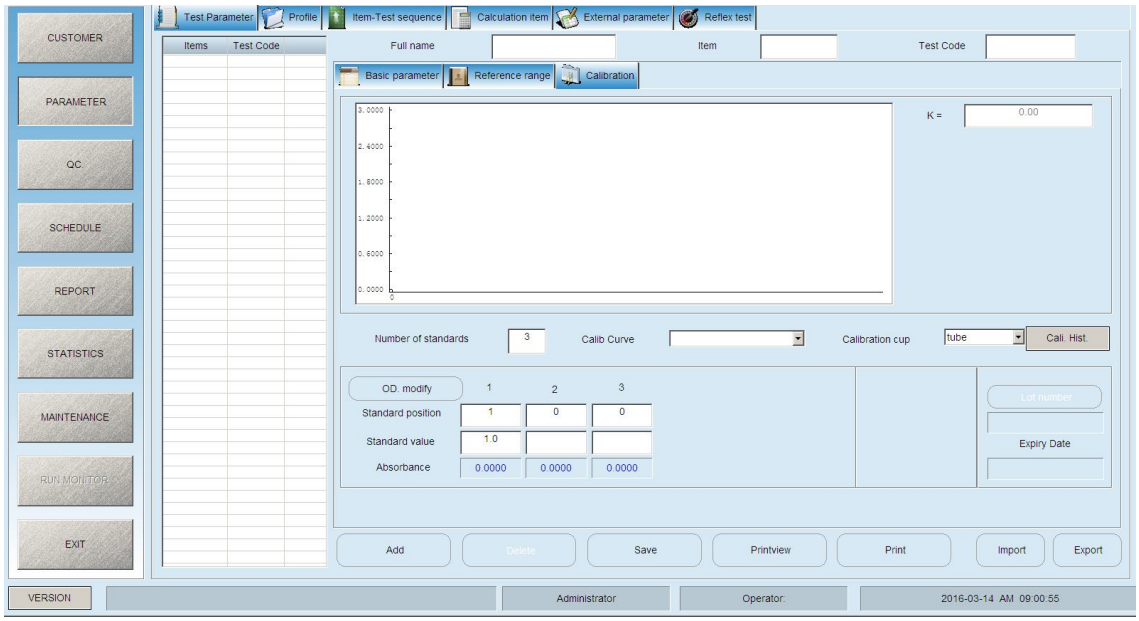


Figure 5.40

In the "Standard Liquid Position" edit box fill in the location of each standard solution,and in the "Standard Value" edit box to fill in the appropriate standard value. Click the drop-down box to the right of "Calibration Rule" to pop up the calibration formula and select the correct calibration method:

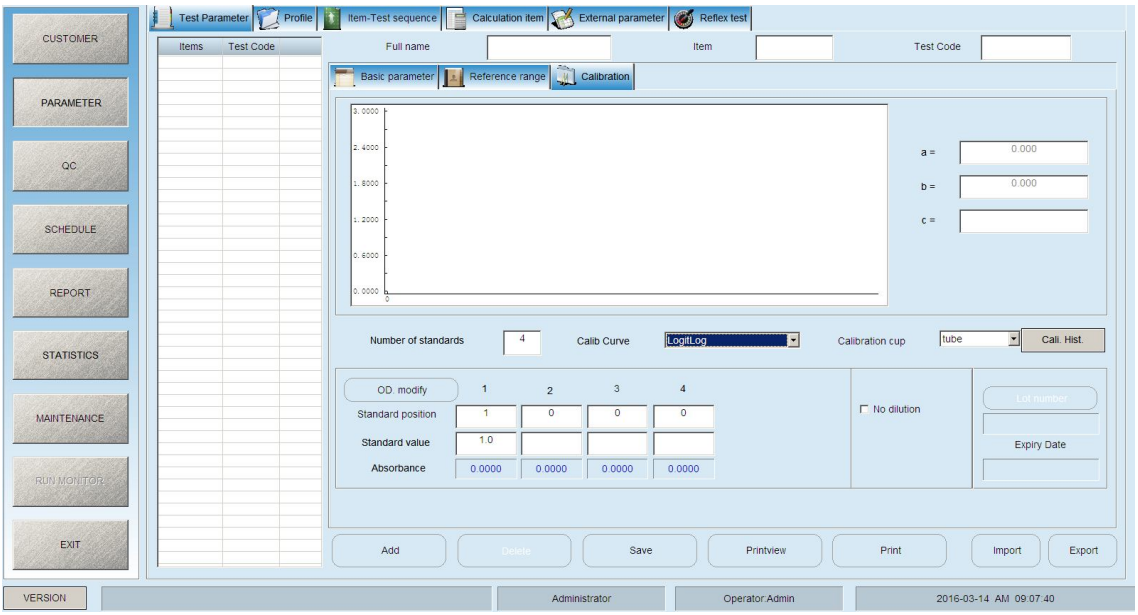


Figure 5.41

The following describes the parameters in this dialog box.

Parameter	Meaning
Standard number	Input the standard number of the item,which can be multiple.
Standard solution position	Set the calibration fluid position on the sample plate.
Standard value	The standard value corresponding to calibration solution.
Calibration formula	When there is multiple calibration fluids,the computational relationship between every standard values.

The following describes the buttons in this dialog box.

Button	Function
Save	Save the settings you made.

5.5.8.3 Results view

The result after calibration is the standard factor obtained and still be viewed in the "Parameters" function. The value of "Standard Factor" as the following picture is the results of calibration.

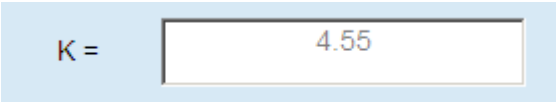


Figure 5.42

Remark

- The system uses the current default calibration factor as a basis for computing the sample concentration.
- The system will automatically take the current calibration factor (including calibration factors from calibration test and calibration editor) as the current default calibration factor.

5.5.9 Biochemical parameters

Click the "Parameter Settings" button,enter the interface as shown in the figure, mainly used for biochemical test items parameter settings. This is the most important step in using the instrument to produce the correct result.

Because biochemical testing has many items,in the process of inputing parameters, should set one by one carefully.

The following tabs are introduced one by one.

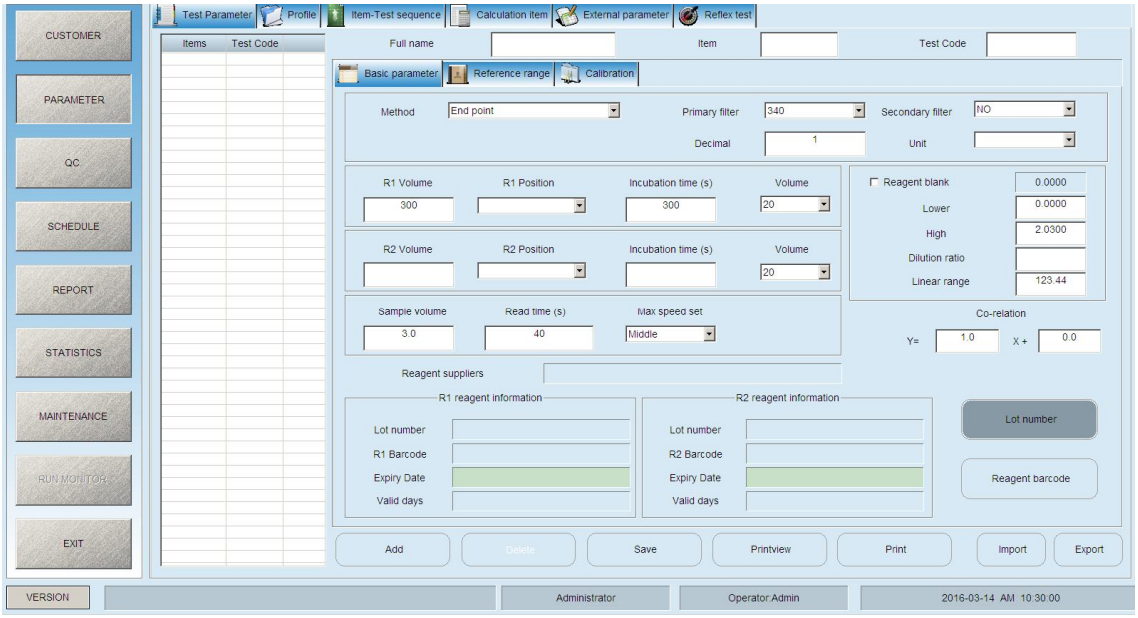


Figure 5.43

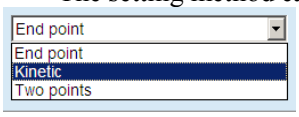
5.5.9.1 Biochemical items parameters seting

"Biochemical Items Settings" interface as shown above,used to set the basic parameters of biochemical test items,reagents and samples,reference range and so on.

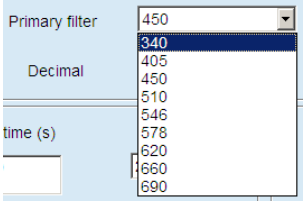
1) Basic parameters

Here you can set the test method,main wavelength,sub wavelength,reagent position, reagent bottle capacity,stirring speed,decimal places and unit.

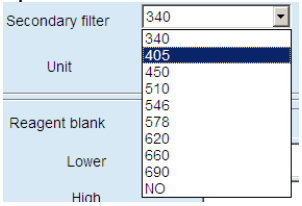
The setting method can refer to the parameter setting of instruction manual.



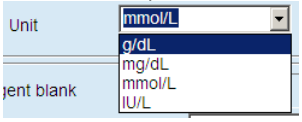
Click the drop-down box on the right side of the test method to pop up this interface to choose the right method.



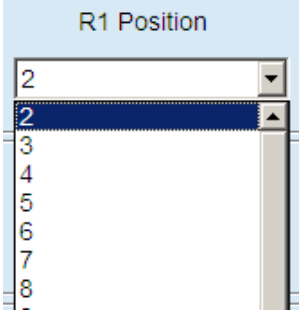
Click the drop-down box on the right side of the main wavelength to pop up this interface to choose the correct wavelength.



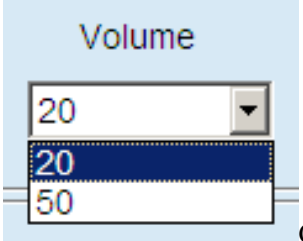
Click on the right side of the sub-wavelength drop-down box to pop up this interface, select the correct sub-wavelength..



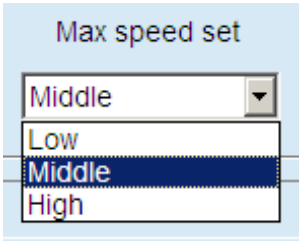
Click on the right side of the unit drop-down box to pop up this interface,select the correct unit.



Click the drop-down box on the bottom of the first reagent position,the second reagent position to pop out this interface,select the correct reagent position.



Click the drop-down box under the capacity to pop-up the interface,select the correct reagent bottle capacity.



Click the drop-down box on the bottom of the stirring speed to pop out this interface,select the correct stirring speed.

The following describes the parameters in this dialog box.

Parameter	Meaning
Test method	According to the test items,select the appropriate test method through the drop-down menu.Such as: ALT is the rate method.
Main wavelength	Refers to the main wavelength and must be set.
Sub wavelength	Refers to the wavelength removed interference,set according to need.
Decimal places	Refers to the value of the decimal place that the result should retain Such as: set "0" means not retain the number behind the decimal places.
Unit	Refers to the unit of test item.
Blank absorbance	Refers to the maximum blank absorbance value of test items.
Standard solution number	Set the standard number,and some adopt multiple standard solutions.
Standard position	During calibration,the place value where the standard solution is placed at the sample position.
Standard value	Marked value of standard solution.

The following describes the buttons in this dialog box.

Button	Function
Delete	Click to delete the set item.
Save	Save the set item.
Preview	To preview.
Print	To print.

Reagent dosage and sample size

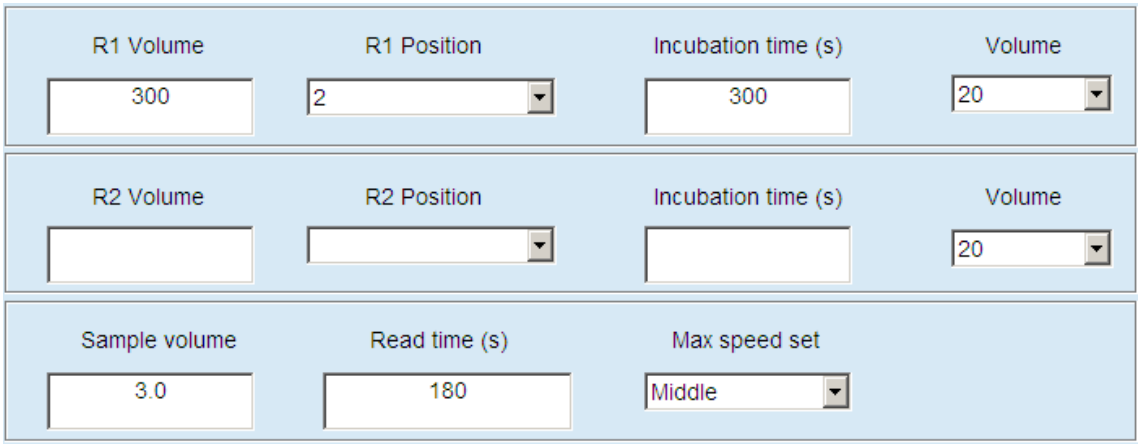


Figure 5.44

Here, set the dosage and location of the first reagent,the dosage and location of the second reagent,the respective incubation time and reagent bottle capacity,the sample size,the test time,and the stirring speed. The following describes the parameters in this dialog box.

Parameter	Meaning
The first reagent	R1 reagent required amount.The range is 10-300μl,in 0.5μl increments.
Position of the first reagent	The location of R1 reagent on reagent position.
Incubation time	Incubation time after adding R1 reagent into sample.
The second reagent	R2 reagent required amount. The range is 10-300μl,in 0.5μl increments. If no need a second reagent,input "0".
Position of the second reagent	The location of R2 reagent on reagent position.
Incubation time	Incubation time after adding R2 reagent into sample cup.
Sample size	The amount of sample required.The range is 1 to 50μl,in 0.1μl increments.
Test time	The time used to test.
Volume	Select the volume of the reagent bottle

2) Reference range

Select a biochemical item,click on the "Reference Range",the reference range of the item appears,and can be edited.

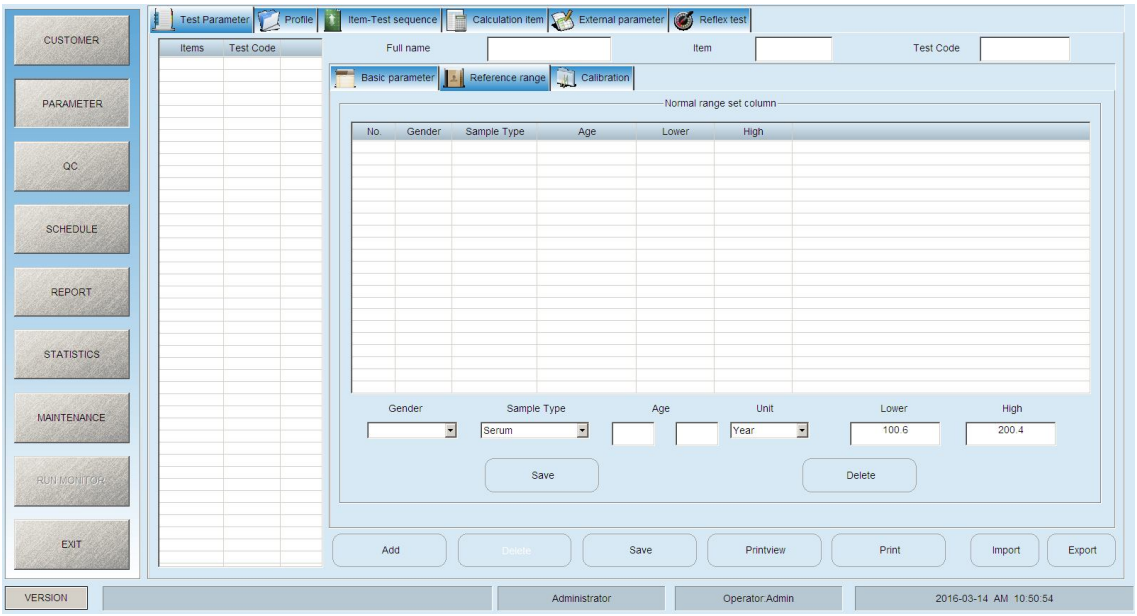


Figure 5.45

The following describes the parameters in this dialog box.

Parameter	Meaning
Gender	Gender of patient.
Sample type	Type of specimen to be tested. Such as,serum or urine.

Parameter	Meaning
Age	Age of patient.
Unit	Unit of specimen concentration or activity.
Value of lower limit	The lower limit of normal value.
Value of upper limit	The lower limit of normal value.

The following describes the buttons in this dialog box.

Button	Function
Delete	Click to delete the set item.
Save	Save the set item.
Preview	To preview.
Print	To print.

3) Calibration rule

If more than one standard is set in "Basic Parameters" and the corresponding calibration method is selected,the calibration curve is displayed here.

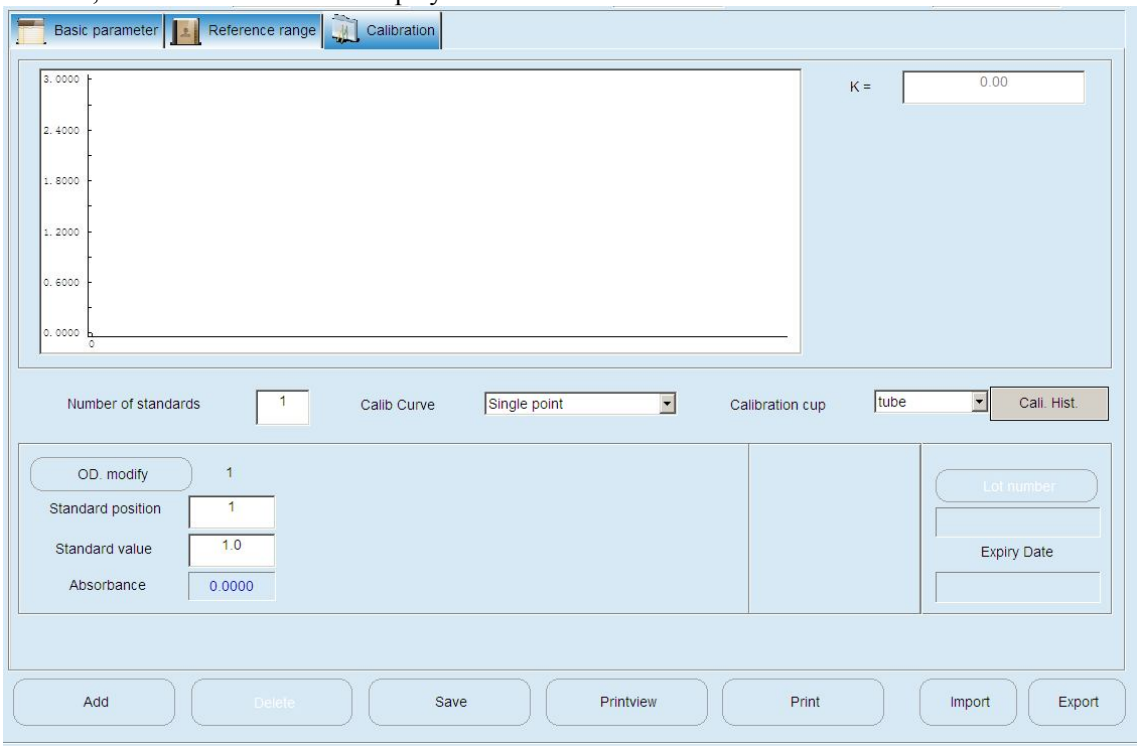


Figure 5.46

The following describes the parameters in this dialog box.

Parameter	Meaning
Standard solution position	The location of the required standard solution on the sample position.
Standard value	Marked value on standard solution.
Absorbance	Absorbance value of the standard solution testing.

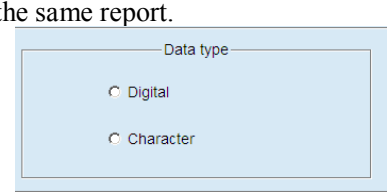
The following describes the buttons in this dialog box.

Button	Function
Delete	Click to delete the set item.
Save	Save the set item.
Preview	To preview.
Print	To print.

5.5.9.2 External items settings

Click "External Items Settings" to enter the following interface to view or edit other items.

This is primarily for patients who test other results on other instruments and need to print the results on the same report.



For results, you can choose quantitative or qualitative items.

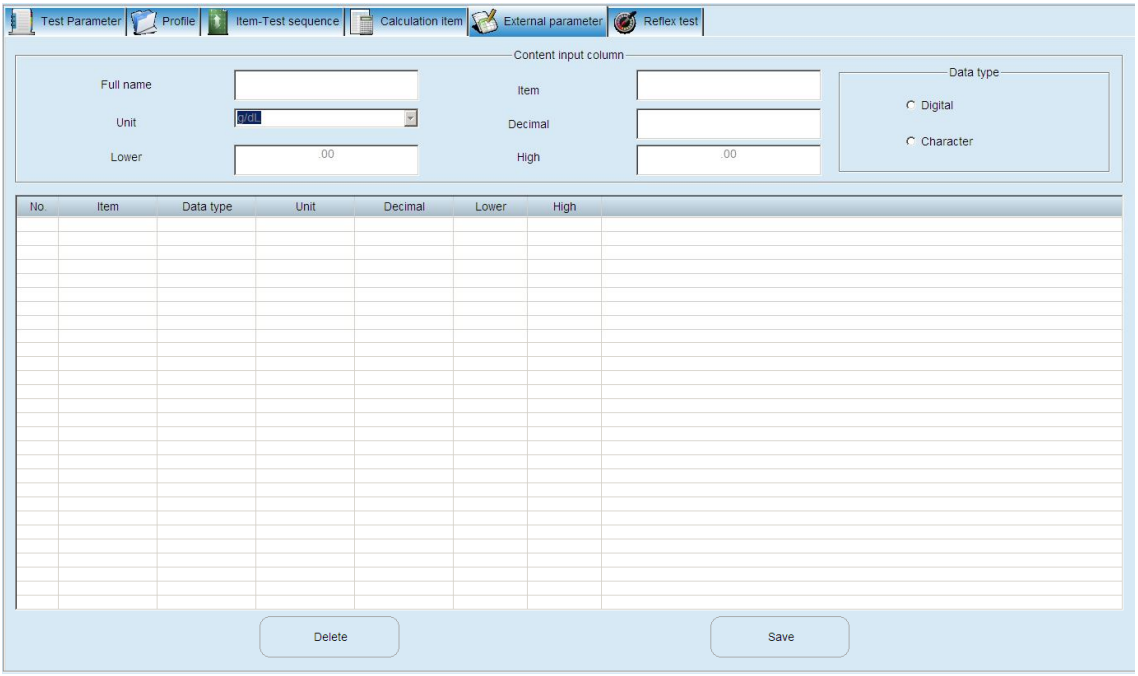


Figure 5.47

5.5.9.3 Computed Items Settings

Some biochemical items do not need to be tested and can be computed using other test results such as "Globulin=Total protein-Albumin".

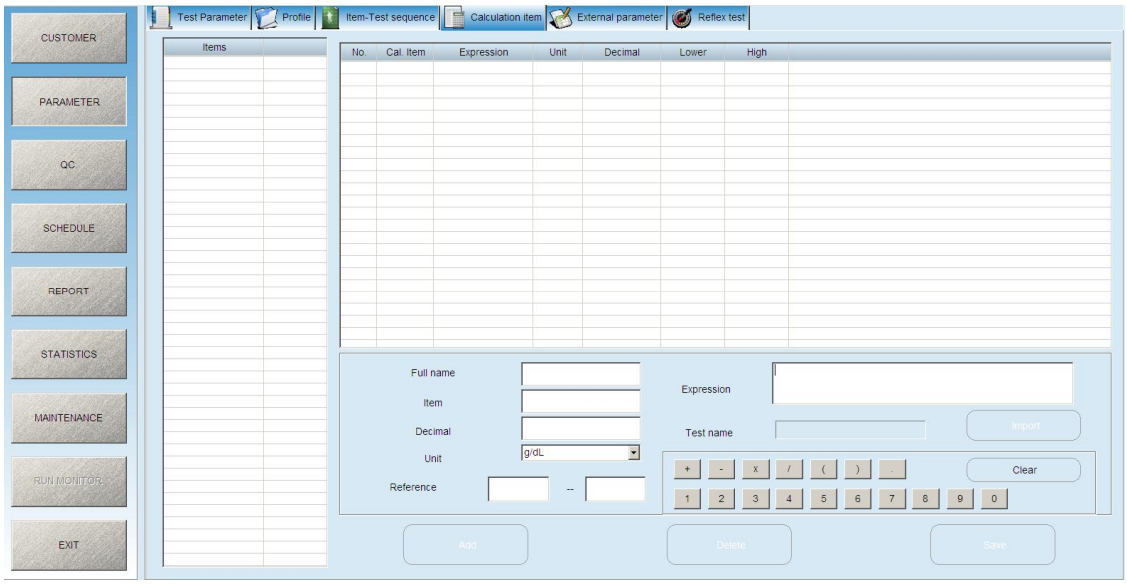


Figure 5.48

The following describes the parameters in this dialog box.

Parameter	Meaning
Chinese name	计算项目的中文名称。
English name	English name of the computed item.
Decimal places	Decimal places of the saved result of computed item.
Unit	Unit of the computed item.
Reference range	Normal reference value of computed item.
Expression	Computed formula.
Biochemical items	In the biochemical item list,select the item related to the selected computed item and import it.
Clear	Click this button to clear the current formula.
Import	After selecting the item in the box above the button,click this button to import the item into the formula.
0~9	Click these buttons to enter figures in the formula.
+ - * /	Click these buttons to input add,subtract,multiply and divide operational symbol.
.（）	Click these buttons to input the decimal point and parentheses in the formula.

The following describes the buttons in this dialog box.

Button	Function
Save	Save the set result.
Add	Add parameters of patient.
Delete	Delete the set result.

5.5.9.4 Combinations items settings

1) Click "Combinations Items Settings" to enter the following interface,where you can edit combinations items.

2) After click "New" button,input item names need to be combined in the "Combination Item Name",then click the items to be combined in the items column,click "Save" to display it in the biochemical combinations items.

3) Biochemical items combination,you can simplify the operation,in the biochemical test,just click the biochemical items combinations to dispay the items to be tested, see "Biochemical Testing" specifically.

Figure 5.49

5.5.9.5 Items Testing Order Setting

1) Here you can set the test order of the items.The left list shows all the biochemical items,and the right shows the list of available biochemical tests.

2) Select one item on the left and click "Add" to add the item to the bottom of the list on the right. If you want to set the order of the items in the list on the right, select one and click "Up", "Down", " Top "and" Last "buttons move," Up "and" Down "buttons move one by one.

3) According to the order set,will start to test from the No.1.

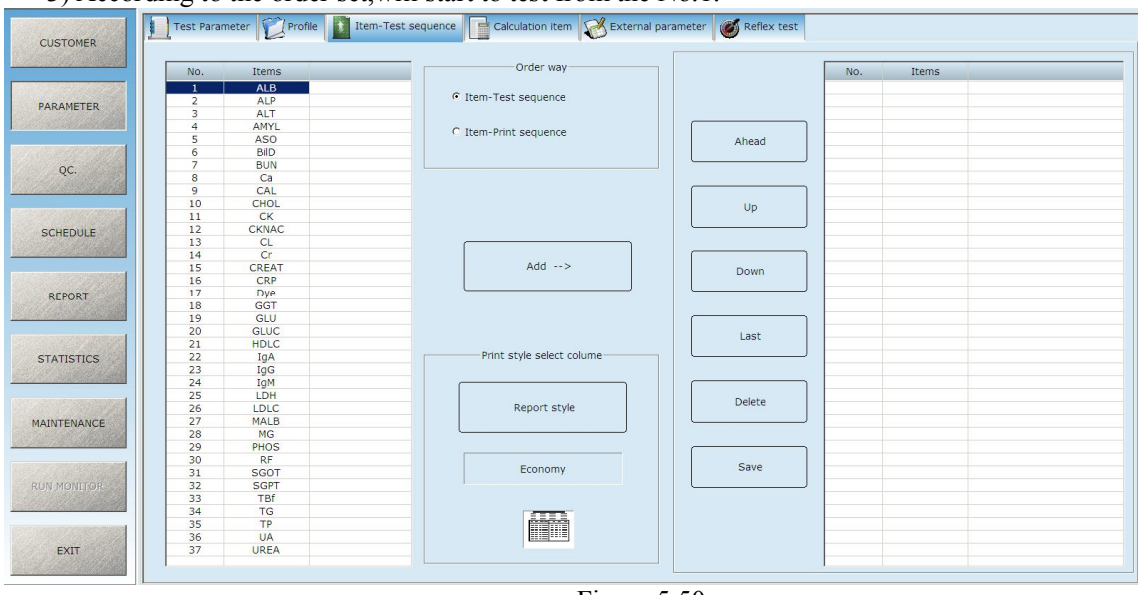


Figure 5.50

5.5.10 Reagent

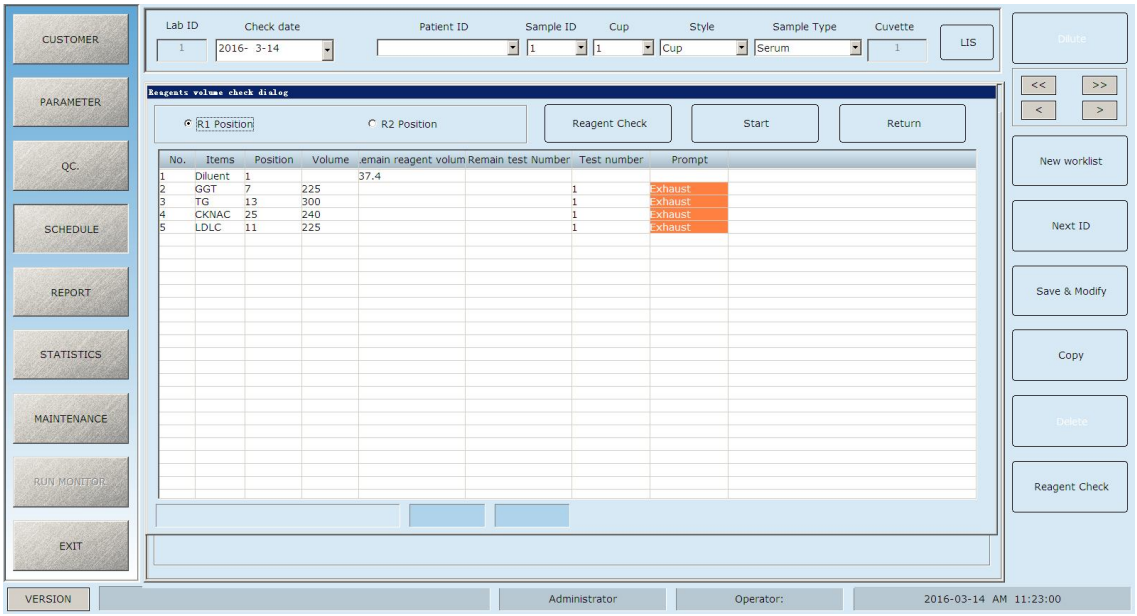
Reagent is an integral part in biochemical equipment,the quality of reagents directly affect the test results.

5.5.10.1 Reagent parameter settings

In the "Parameter" setting has been written in detail.

5.5.10.2 Inquiry of reagent amount

1） When test reagent,click " Reagent Amount Measurement',a dialog box appears,here is a reagent amount testing column as shown below:



Fiture 5.51

2) Click the Reagent Amount Measurement column, the following figure is shown.

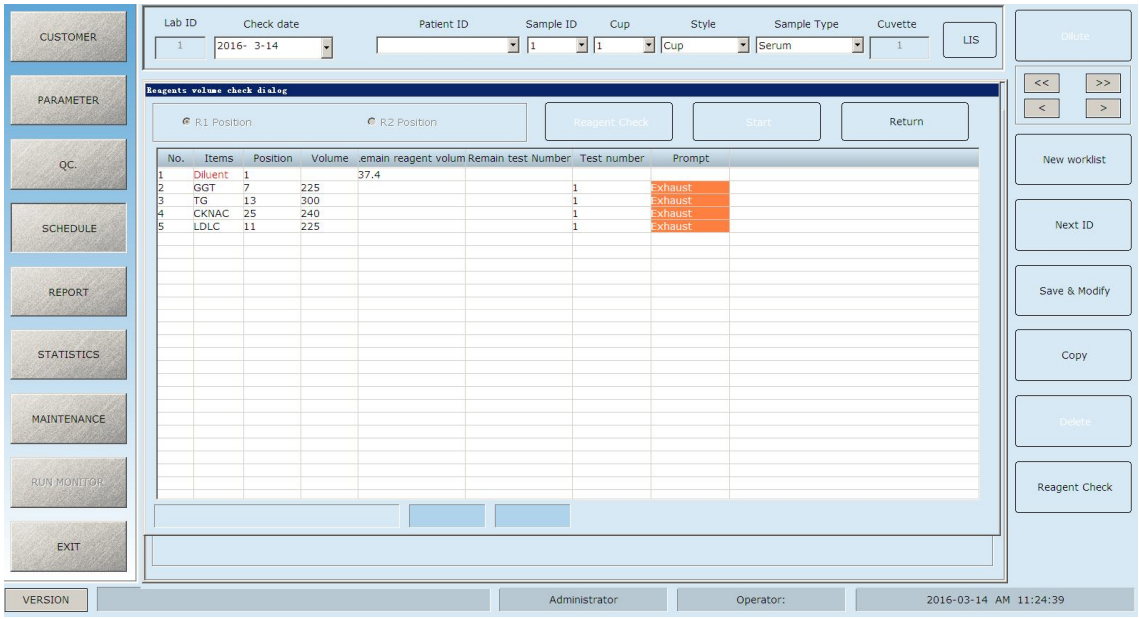


Figure 5.52

3) After the first reagent is selected, the first reagent amount of the set parameters can be viewed in the display column. After the second reagent is selected, the second reagent amount of the set parameters can be viewed in the display column.

5.5.11

5.5.11.1

Click "Biochemical Test", then click "Sample Application" to select test items, click "Reagent Amount Measurement",click "Test" and then click the "Start" in the following picture;

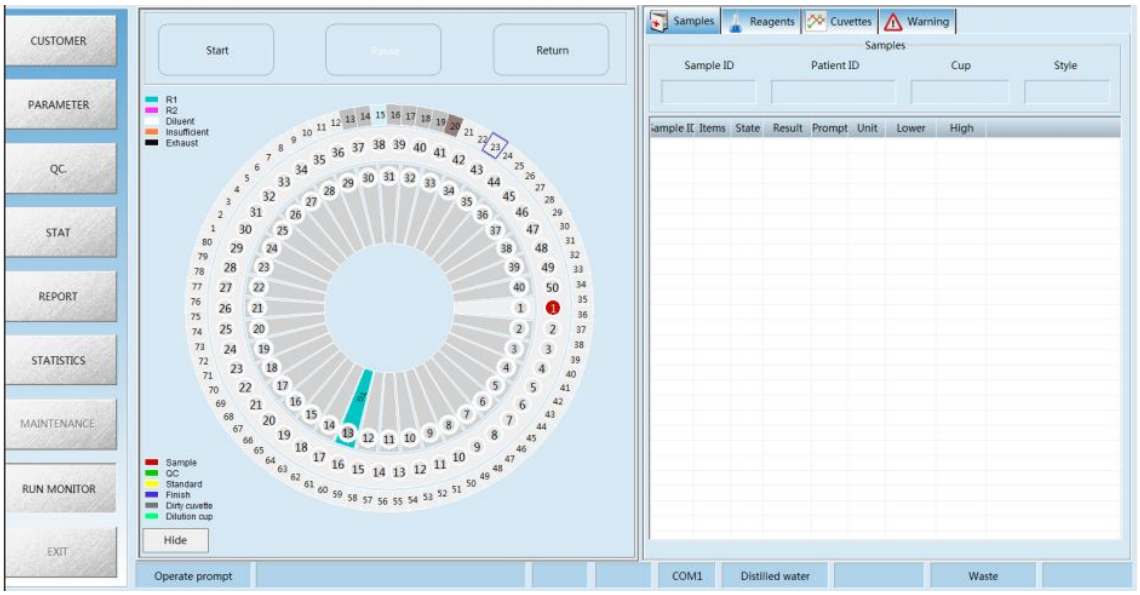


Figure 5.53

2) The instrument begins to test. As shown below.

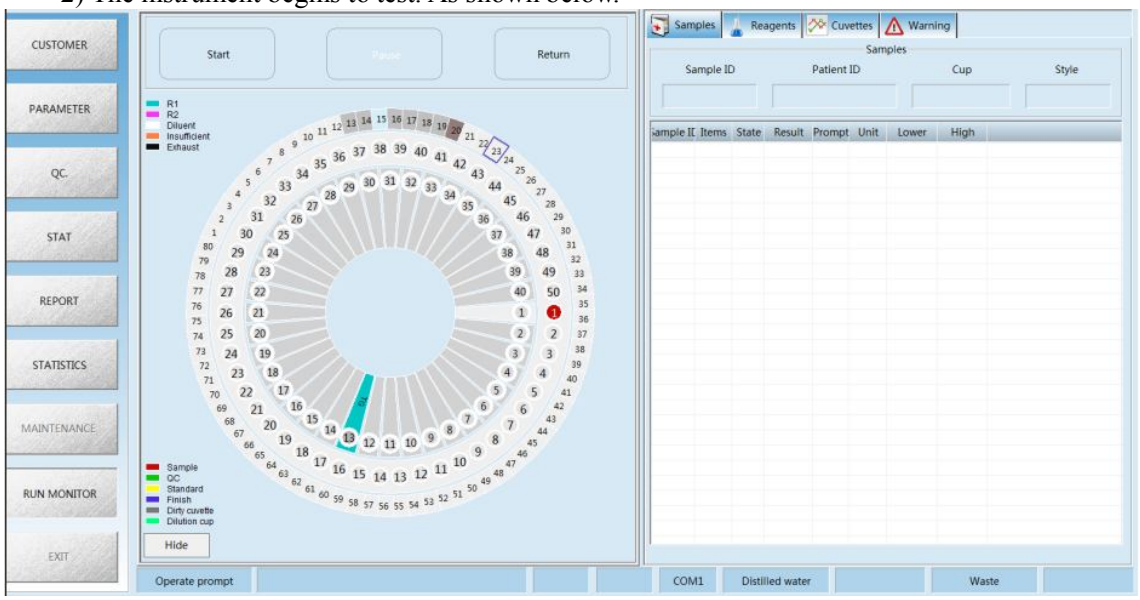


Figure 5.54

- The outermost circle on the above chart represents the reaction tray;
- The second ring from outside-to-inside of the above circular disc represents the sample tray;
- The third ring from outside-to-inside of the above circular disc represents the reagent tray;

The innermost ring of the above circular disc make identify on different states of reagent,sample and color of reaction process.

When a mouse clicks on a reaction cup in the reaction try of the disk,a information list bar of the reaction cup appears on the left side of the menu,and the reaction status of the reaction cup and various parameters information of the reaction are displayed;When the reagent tray in the disk is clicked,the reagent information list bar will appear on the left of the menu, and the parameter setting and reaction process of the reagent will be displayed. When the sample tray in the disk is clicked, the sample information list will appear on the left side of the menu and display parameter setting and reaction process of the sample.

5.5.11.2.Emergency testing

The operation is similar as biochemical testing.

5.5.12 Exit

Click the "Exit" button on the main menu,you can exit the entire operating system. There are also "Exit" buttons in each submenu.If you click the "Exit" button on the submenu,you will be taken back to the previous menu.

Chapter 6 Maintenance

To ensure the reliability,good working condition and life expectancy of the system performance,the system should be operated and regularly maintained in strict accordance with the requirements of this manual.

6.1 Maintenance

6.1 Methods and precautions of correct use and maintenance of biochemical analyzer:

1) Every morning,firstly let the machine run for 30 minites before testing.

2) Before testing,check if reagent and serum are sufficient.

3) After the daily sample test is completed,the reagents,standard solution and quality control serum should be stored in the refrigerator in time.

4) Do not touch the arm (moving parts) while the instrument is in testing to prevent accidents.

5) After finishing testing,add distilled water to the cuvette to keep the cuvette wet.

6) Every day,check if distilled water, cleaning solution,and waste bucket are sufficient or spillage.

7) Regularly check if the needle is clogged. Method:Click "Moving Parts Detection" in the "Instrument Maintenance" menu (Figure 6.1)

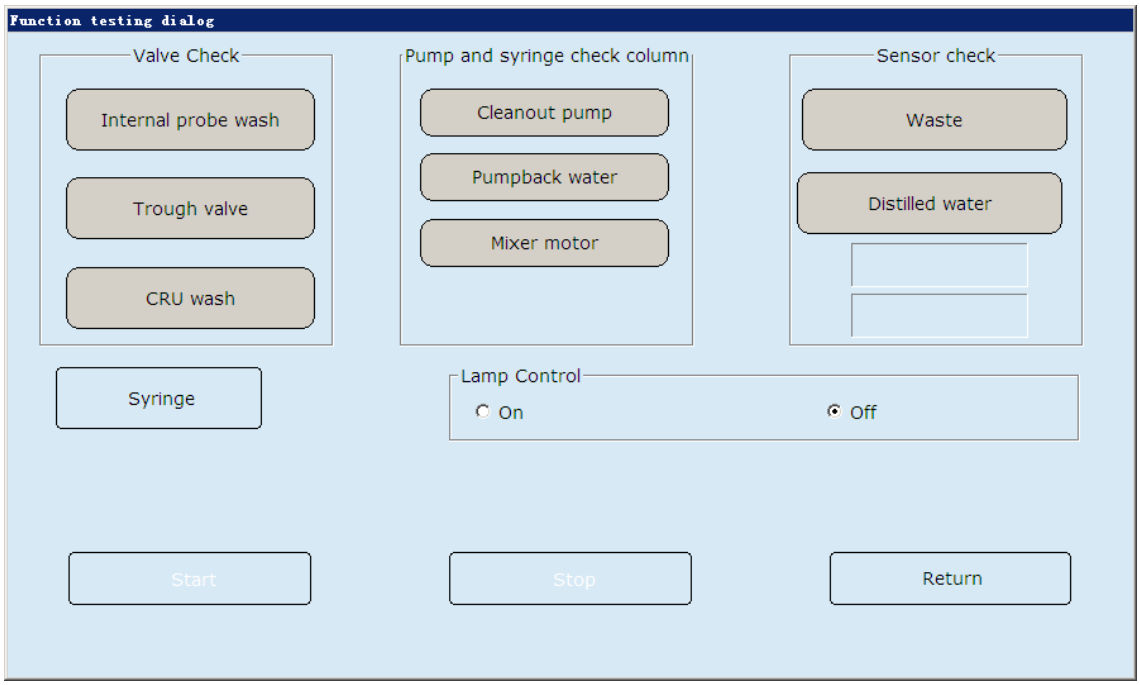


Figure 6.1

Click on "Reagent Valve" and click "Test". If there is no water spray on the sampling needle,apply acupuncture,if there is no effect,contact us.We will send someone to process it as soon as possible.

8) If it is found that the washing arm can not be drained of water or not poured water into the cuvette,contact us.

9) If you find the reaction cup scratched surface, affecting the determination of absorbance, should be promptly replaced.

10) The instrument requires regular testing of the quality control serum to calibrate the instrument for accuracy.

11) It is recommended that the instrument set the reaction cup at the beginning of the test from Cup No. 40 because the No. 40 cup has been dried after cleaning.

12) During the use of the instrument,can not frequently switch machines,frequent power will damage the instrument power supply.

13) If the grid voltage is unstable or the voltage is low, you should use a regulated power supply.

14) Before testing by anallyzer,firstly take reagent out of the refrigerator and await it **recover to room temperature.**

15) When the instrument is stationary (without testing), the reagents should be sealed and need to be opened when testing.

16) The instrument's 3 electronic valves should be regularly checked in the "Moving Parts Inspection" menu in the "Maintenance" menu. Select "Needle Valve", "Reagent Valve", "Water Valve" and then "Test" in Figure 6.1 respectively. If you hear a "pop" sound, the electronic valve is good and contact us if you can not hear the sound.

17) Select the "Mixing System",click test in Figure 6.1 to check if the paddle is rotating. If the stirring blade can not rotate,should contact us.

18) Can not strike the "ENTER" and "SPACE" keys of the keyboard while testing,otherwise the analyzer will directly exit the test.

19) If the cleaning fluid runs out, you can use distilled water instead. Pipette should be placed in a distilled water bucket.

Chapter 7 Maintenance and troubleshooting

The following table lists some simple troubleshooting methods. Users can follow the steps below, if you can not solve, please contact the Hightop Biotech or local dealer.

Maintenance

Notice

- All inspection and repair of the instrument should be responsible by technical staff from or authorized by Hightop Biotech,the user may not open the case without permission, otherwise may result in damage to the system or personal injury,at customer's own risk.
- All parts of the instrument are provided by Hightop Biotech or agents authorized by Hightop Biotech,do not use other parts without permission of Hightop Biotech,or it may cause system damage or personal injury, at customer's own risk.

7.1 Maintenance and usual troubleshooting

Symptoms	Possible cause → Troubleshooting
The instrument can't work or the power switch is off.	1. Loose receptacle or unreliable connection→Reconnect and secure the receptacle 2. The power cord is loose or unreliable connection→ Reconnect and secure the power cord
Communication error	1. The serial communication cable is loose or unreliable connection→ Reconnect and secure the serial communication cable

	2. Strong electromagnetic interference→Re-plug the serial communication cable and restart the operating software
Sample needle drip	Bubble into the liquid path→Perform instrument infusion in the maintenance interface.
Cleaning tank overflow	1. Waste collection device is full→Empty the waste collection device 2. The waste tubing is bent or clogged→Reprocess the waste tubing and make sure it is free from bending and clogging.
Mean value of reaction cup is wrongly checked.	1. The reaction cup is dirty→Perform the cuvette cleaning in the maintenance interface 2. The cuvette scratches serious→Replace the new cuvette
Absorbance of reaction cup is wrongly checked.	1. The reaction cup is dirty→Perform the cuvette cleaning in the maintenance interface. 2. The cuvette scratches is serious→Replace to new cuvette
Detecting abnormal of liquid level of sample needle.	Ground connection is poor or not grounded → make sure the ground is good.
Software abnormality	In the event of a user interface error,the application's own logic error,system or network resource availability error,please shut down the current running software, restart the software before use,also could contact with the service department of Hightop Biotech or your local distributor.

HIGHTOP 汉唐

Registered person and manufacturing enterprises:Qingdao Hightop Biotech Co., Ltd.

Address of manufacturer: No.369,Hedong Road,High-tech Industrial Development Zone,Qingdao City,China.

After-sales service unit: Qingdao Hightop Biotech Co., Ltd.

Tel:0086 532 58710707 Fax: 0086 532 58710706

Medical Device Registration Number: Lu Mechanical Registration Guideline 20142400027

Production License No.: Shandong Food and Drug Administration Device Production Permit No.20120133