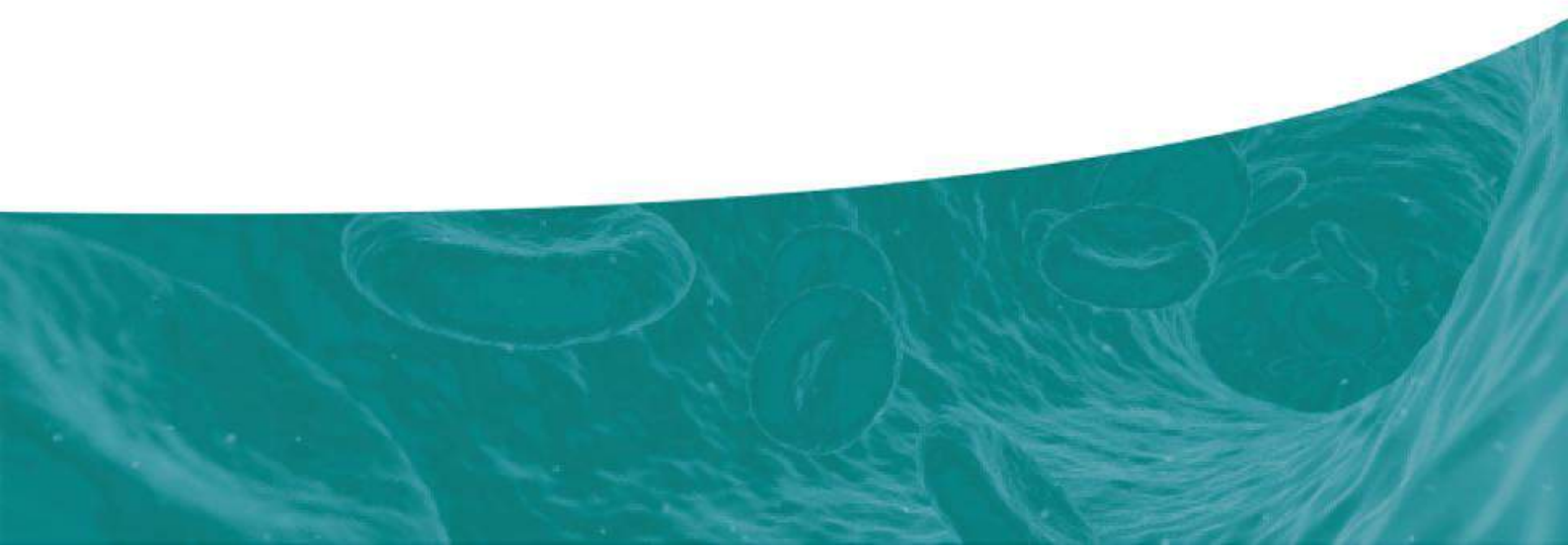
BanyanRR®

Auto Chemistry Analyzer

Instruction Manual



Contents

1 Preface

Thank you for purchasing our Auto Chemistry Analyzer. It is our honor for your trust. In order to know our product well, we offer you this operational manual which includes the features, appearance and dimension, using methods, usage instructions, maintenance, packing, storage and transportation, etc. We try our best to edit the operational manual to be easily understood so as to make sure you can know the instrument better. Please read the manual carefully before operation and it is great helpful for you to operate the instrument correctly.

Product full name： Auto Chemistry Analyzer, for short: Analyzer.

Model:Mini 60、CAS100、S120pro、CAS200、CAS300、AS400

Compone Product Power: <=300VA

Operation manual release date: 2024-07, Version: V1.01

Components:.Analyzing unit (Main unit), operation unit (PC), outputting unit (printer), accessories and other consumables.

Product applicable range:Used for quantitative analysis Serum, urine, cerebrospinal fluid or others Clinical chemical composition

Conventions Used in This Manual

This manual uses certain typographical conventions to clarify meanings in the text.

Safety Symbols

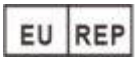
This chart explains the symbols used in this manual.

Symbol		Meaning
	WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	BIOHAZARD	In this equipment this sign is attached to exposed areas which are contacted by samples and may also be touched by the operator. If you have touched an area bearing this sign during a maintenance check,etc. ,be sure to wash your hands thoroughly.
	CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury for operator, or system damage or unreliable results.
	NOTE	Indicates reference information that enable more efficient use of the equipment.

Labels Used On the System

The labels attached to the panels of the system use symbols to clarify the meaning of the text. If any of the labels becomes vague or peels off, contact our Customer Service Department or your local distributor for replacement. The list below shows the symbols that are used on the analyzer.

	Serial Number
	Date of Manufacture
	Manufacturer
	In Vitro Diagnostic equipment
	Biohazard warning: risk of potentially biohazardous infection

	Warning： risk of personal injury or equipment damage
	Warning： the temperature of surface is very high, indicates personal injury or risk of burn
	Protective ground terminal
	ON（MAIN POWER）
	OFF（MAIN POWER）
	Warning： risk of electric shock
|O|O|	Serial Port
	CE marking. The device fully complies with the requirements of the European Council Regulation (EU) 2017/746 on in vitro diagnostic medical devices
	Authorized Representative in the European Community.

● Graphics

All graphics in this manual, including screens and printout, are for illustration purpose only and must not be used for any other purpose.

● Safety Precautions

Observe the following safety precautions when using the Chemistry Analyzer. Ignoring any of these safety precautions may lead to personal injury or equipment damage

	WARNING： If the system is used in a manner not specified by manufacturer, the protection provided by the system may be impaired, the risk of personal injury or equipment damage will be increased hardly.

● Preventing Electric Shock

Please observe the following instructions to prevent electric shock.

	WARNING: When the MAIN POWER (on the bottom of back board) is on, users

	must not open the rear cover or side cover. Spillage of reagent or sample on the analyzer may cause equipment failure and even electric shock. Do not place sample and reagent on the analyzer. In case of spillage, switch off the power immediately, remove the spillage and contact Customer Service Department of manufacturer or your local distributor. When two switches in the left side of this equipment are off, inside power cables still connect with outside power. Only after switching off MAIN POWER, the risk of electric shock from AC power will not be exist.

● Preventing Personal Injury Caused by Moving Parts

Please observe the following instructions to prevent personal injury caused by moving parts.

	WARNING: When the MAIN POWER (on the bottom of back board) is on, users must not open the rear cover or side cover. Spillage of reagent or sample on the analyzer may cause equipment failure and even electric shock. Do not place sample and reagent on the analyzer. In case of spillage, switch off the power immediately, remove the spillage and contact Customer Service Department of manufacturer or your local distributor. When two switches in the left side of this equipment are off, inside power cables still connect with outside power. Only after switching off MAIN POWER, the risk of electric shock from AC power will not be exist.

● Preventing Personal Injury Caused by Photometer Lamp

Please observe the following instructions to prevent personal injury caused by photometer lamp.

Preventing Infection

Please observe the following instructions to protect against the biohazardous infection.

	BIOHAZARD： Inappropriately handling samples, control liquid and calibrators may lead to biohazardous infection. Do not touch the sample, mixture or waste with your hands. Wear gloves and lab coat, if necessary, goggles.

● Handling Reagents and Wash Solution

	WARNING： Reagents and enhanced wash solution are corrosive to human skins. Exercise caution when using the reagents and enhanced wash solution. In case your skin or clothes contact them, wash them off with soap and clean water. In case the reagents or wash solution spill into your eyes, rinse them with much water and consult an oculist.

● Treating Waste Liquids

Please observe the following instructions to prevent environmental pollution and personal injury caused by waste.

	BIOHAZARD： Some substances in reagent, control enhanced wash solution and waste are subject to regulations of contamination and disposal. Dispose of the waste in accordance with your local or national code for biohazard waste disposal and consult the manufacturer or distributor of the reagents for details. Wear gloves and lab coat , if necessary, wear goggles.

● Treating Waste Analyzer

Please observe the following instructions to dispose of the waste analyzer.

	WARNING： Materials of the analyzer are subject to contamination regulations. Dispose of the waste analyzer in accordance with your local or national code for waste disposal.

● Treating Waste Parts

Please observe the following instructions to dispose of the waste parts such as reaction cuvette, sample tube or entire analyzer.

	BIOHAZARD： Dispose of the waste reaction cuvette, sample tube or the analyzer in accordance with your local or national guidelines for biohazard waste disposal.

● Prevent Fire or Explosion

Please observe the following instructions to prevent fire and explosion.

	WARNING： Ethanol is flammable substance. Please exercise caution while using the ethanol.

● Precautions on Use

To use the Chemistry Analyzer safely and efficiently, please pay attention to the following operation notes.

● System Intended Use

	WARNING： The system is an automated chemistry analyzer for in vitro diagnostic use in clinical laboratories and designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine or cerebrospinal fluid (CSF)samples. Please consult us first if you want to use the system for other purpose. To draw a clinical conclusion, please also refer to the patient's clinical symptoms and other test results.

● Operator

	WARNING： The Chemistry Analyzer is to be operated only by clinical professionals, doctors or experimenters trained by manufacturer or manufacturer authorized distributors.

● Equipment Repair

	WARNING： When malfunction for analyzer happens, Please inform of qualified professional to repair the equipment and eliminate the fault. The maintenance or repair of this equipment must be operated by qualified engineer from our company, and accessories must be qualified and provided by our company, otherwise the system's function and safety will be affected. Please do not change the inside structure of this equipment arbitrarily.

Environment

	CAUTION： The electromagnetic environment should be evaluated prior to operation of the device. Please install and operate the system in the environment specified by this manual. Installing and operating the system in other environment may lead to unreliable results and even equipment damage. To relocate the system, please contact our Customer Service Department or local distributor.

Preventing Interference by Electromagnetic Noise

	CAUTION： Electromagnetic noise may interface with operations of the system. Do not install devices generating excessive electromagnetic noise around the system. Do not use such devices as mobile phones or radio transmitters in the room housing the system . Do not use other CRT display around the system. Do not use other medical instruments around the system that may generate electromagnetic noise to interface with their operations. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. mobile phones or radio transmitters), as these may interface with the proper operation. The electromagnetic environment should be evaluated prior to operation of the device.

Operating the System

	CAUTION： (1) Operate the system strictly as instructed by this manual. Inappropriate use of the system may lead to unreliable test results or even equipment damage or personal injury. (2) Before using the system for the first time, run the calibration program and QC program to make sure the analyzer is in normal state. (3) Be sure to run the QC program every time you use the system, otherwise the result may be unreliable. (4) Do not open the cover of the sample/reagent disk when the system is in operation. (5) The RS-232 port on the analyzing unit is to be used for

	connection with the operation unit only. Do not use it for other connections. Only use the supplied cable by manufacturer for the connection. (6) The operation unit is a personal computer with the operating software installed. Installing other software or hardware on this computer may interfere with the system operation. Do not run other software when the system is working. Computer virus may destroy the operating software or test data. Do not use this computer for other purpose or connect it to the internet. Do not touch the display, mouse or keyboard with wet hands or hands with chemicals. Do not connect computer with mobile memory where virus may exist, such as U Disk or mobile HDD. (7) Do not switch the MAIN POWER within 10 seconds.

● Maintaining the System

	CAUTION： (1) Maintain the system strictly as instructed by this manual. Inappropriate maintenance may lead to unreliable results, or equipment damage or personal injury. (2) To wipe off dust from the system surface, use a soft, clean and wet(not too wet)cloth, soaked with soap water if necessary, to clean the surface. Do not use such organic solvents as ethanol for cleaning. After cleaning, wipe the surface dry with dry cloth. Switch off all the powers and disconnect the power plug before cleaning. Take necessary measures to prevent water ingression into the system, otherwise it may lead to equipment damage or personal injury. (3) Replacement of such major parts as lamp, photometer, sample probe, reagent probes, mixers and syringe plunger assembly must be followed by a calibration. (4) Replacement of lamp must be done after the MAIN POWER has been placed to off for at least 20 minutes. (5) Before maintaining the dust screen, be sure that the MAIN POWER is placed to OFF.

● Setting the Parameter

	CAUTION： To define such parameters as sample volume, reagent volume and

	wavelength, follow the instructions in this manual and the instructions of reagents.

● Samples

	CAUTION： Ethanol is flammable substance. Please exercise caution while using the ethanol. Use samples that are completely free of insoluble substances like fibrin, or suspended matter; otherwise the probe may be blocked. Hemolysis, icterus or lipemia in the samples may lead to unreliable test results, so sample blanks are recommended. Store the samples properly. Improper storage may change the compositions of the samples and lead to unreliable results. Do not leave the sample open for a long period. Sample volatilization may lead to unreliable results. Certain samples need to be processed before being analyzed by the system. Consult the reagent suppliers for details. The system has a specific requirement on the sample volume. Refer to this manual for proper sample volume. Load the sample to proper tube position on the sample disk before the analysis begins; otherwise you will not obtain correct results.

● Reagents, Calibrators and Controls

	CAUTION： Use proper reagents, calibrators and control liquid in the system. Select appropriate reagents according to performance characteristics of the system. Consult the reagents suppliers, manufacturer or its authorized distributor for details, if you are not sure about your reagent choice. Store and use the reagents, calibrators and control-liquid strictly as instructed by the suppliers. Otherwise, you may not obtain reliable results or best performance of the system. Improper storage of reagents, calibrators and control liquid may lead to unreliable results and bad performance of the system even in validity period. Perform calibration after changing the reagents. Otherwise, you may not obtain reliable results. Contamination caused by carryover among reagents may lead to unreliable test results. Consult the reagent suppliers for details.

Backing up Data

	Note： The system automatically stores the data to the built-in hard disk. However, data loss is still possible due to mis-deletion or physical damage of the hard disk. We recommend you to regularly back up the data to such medium as CDS.

Computer and Printer

	NOTE： Refer to their operation manuals for details.

Deion water bucket and waste water bucket

	NOTE： Deion water bucket bottle mouth diameter is 40 mm to 55 mm, volume is 25L, in order to guarantee the Deion water sensor and waste liquid sensor can use normally, bucket mouth is designed as flat.

External Equipment

	WARNING： External equipment connected to the system, such as computer, printer etc. all require to meet the requirements of GB4943 or GB 9254 (CLASS B). If you have any problem, consult the technical services department of manufacturer.

2 System Description

The system consists of the analyzing unit (Main unit), operation unit (PC), outputting unit(printer), accessories and other consumables.

2-1 Auto Chemistry Analyzer

The analyzing unit (Main unit) is composed of Testing system, sample and reagent system,Reaction system, Cleaning system （5 series instruments without this function）.

The operation unit (PC) is a personal computer with installed operating software which is forcontrolling, operating the analyzing unit and processing data.

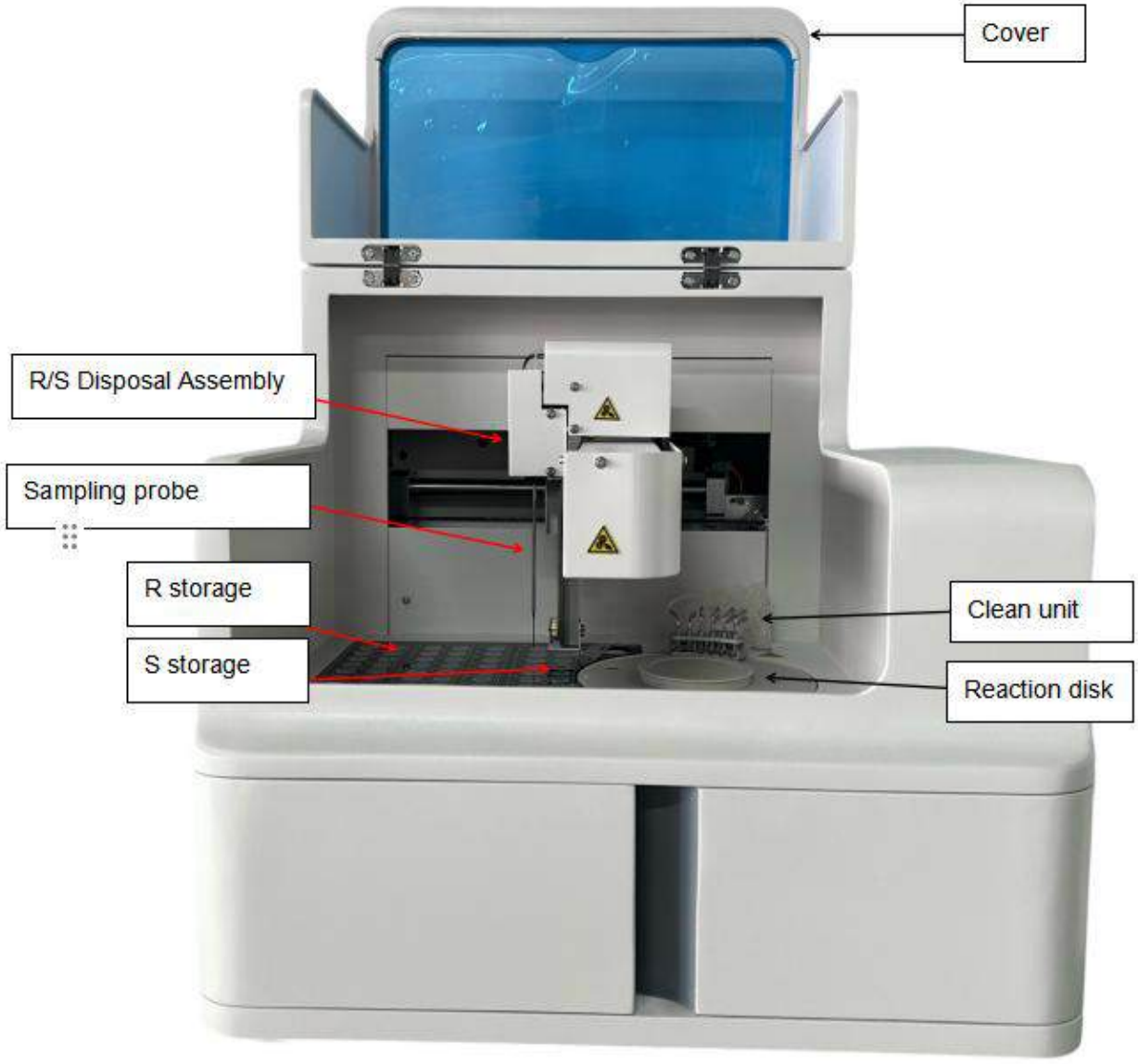
The outputting unit (printer) is a printer for printing out test reports.

The accessories and consumables include reaction cuvettes, photometer lamp, etc.

2.1 Analyzing Unit

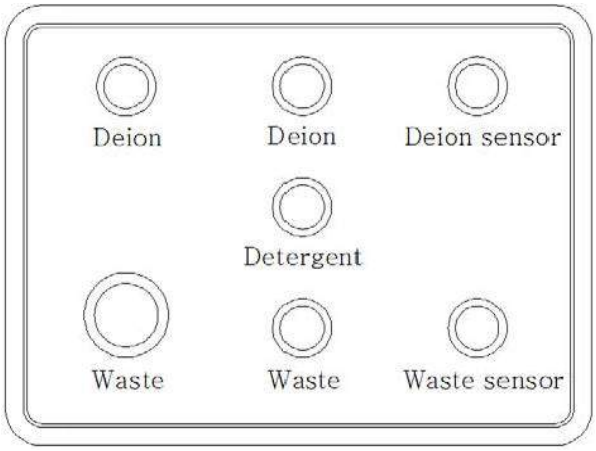
The analyzing unit consists of the following major parts:

Reagent & Sample Storage Assembly 、Reaction Disk Assembly 、Cuvette Auto-Cleaning Assembly （5 series instruments without this function）、Sampling & Mixing Assembly、Photometry Assembly

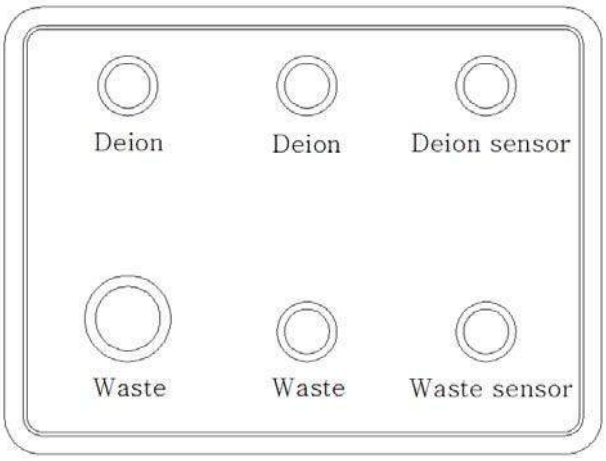


2-2 Front View of Analyzing Unit

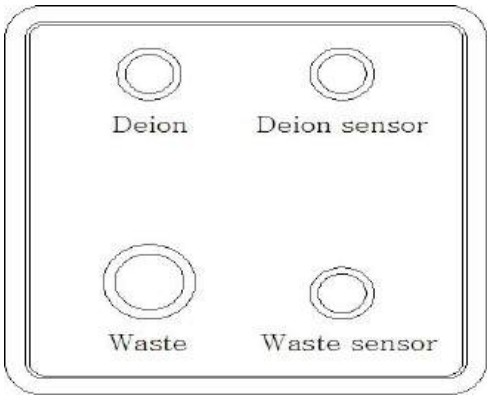
Analyzing unit side pipeline connector from left to right is shown as below, there are 3 types.



2-3 Analyzer side Liquid Tubing Connection 1

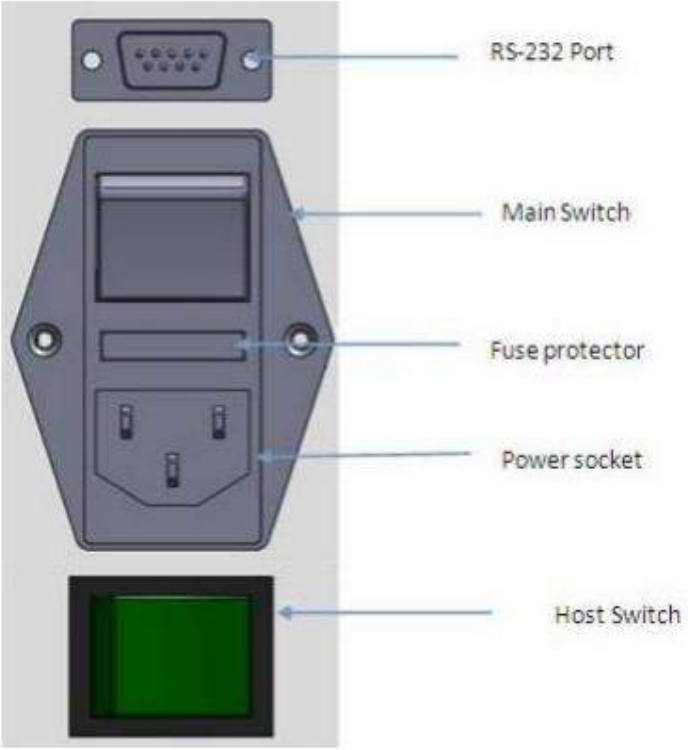


2-4 Analyzer side Liquid Tubing Connection 2



2-5 Analyzer side Liquid Tubing Connection 3

Deion sensor: Connector for customized sensor;
Waste sensor: Connector for customized sensor;
Deion: Connector for DI water tubing ; Detergent:
Connector for detergent tubing; Waste:
Connector for waste tubing;
Analyzing unit back side power supply interface is shown as the figure below:



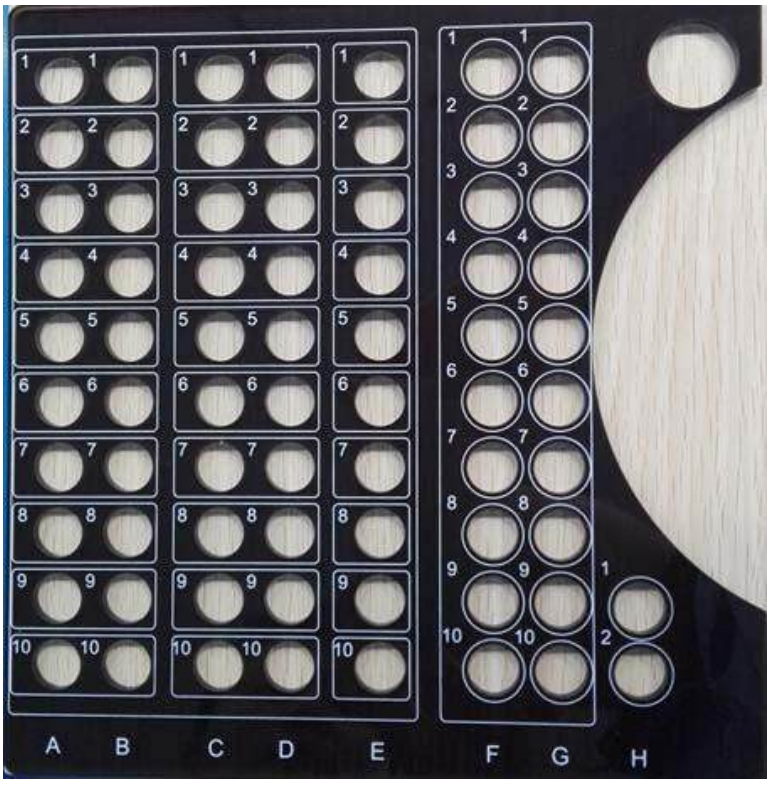
2-6 Back side socket of analyzing parts

RS-232 Port：Used for communication between data line and the operation unit
Main switch: Open this switch, the reagent storage starts cooling.
Host switch：Open the switch, instrument stay in standby state (this switch is optional for separate refrigeration function of reagent storehouse only)
Fuse protector: OCP (over-current protection)
Power socket: Used for connecting power line

2.2 Reagent Storage Assembly

The reagent storage assembly mainly consists of the reagent rack (including the cover door of reagent storage)

2-7 Reagent Storage



2-8 Panel for Reagent Storage

Reagent storage consists of 5 reagent racks, each rack with 10 reagent positions.

Please put First reagent (R1) or Second Reagent (R2) in A~E reagent racks place.. Please place reagent to the defined position which according to software setting, otherwise, reagent will not be normal aspirated.

The only specification of reagent bottle which reagent rack can be adopted is 20ml.

Reagent Rack Dismantlement

Open the cover door of reagent & sample storage.

Follow the path of guiding track, pick out the reagent rack.

Reagent Rack Assembling

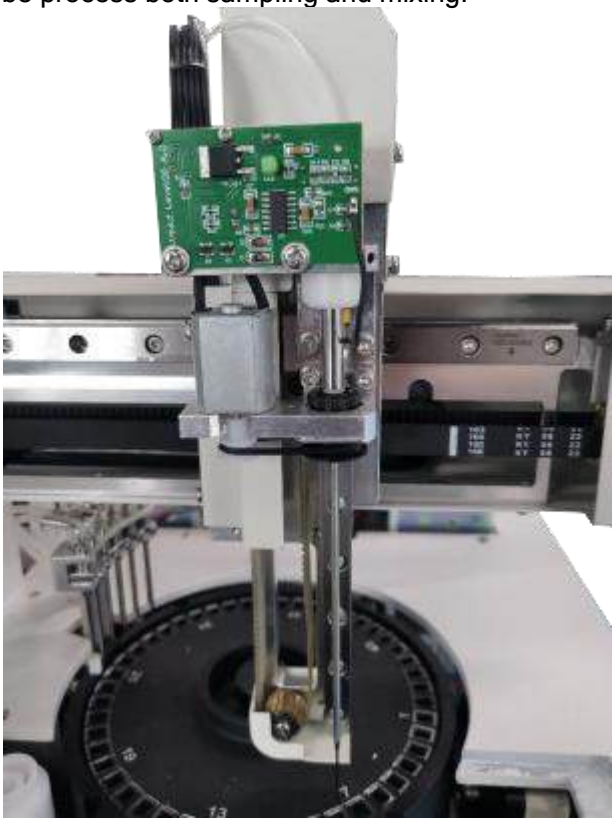
Follow the path of guiding track, push reagent rack into defined reagent place.

Well locking the door of reagent storage.

2.3 Sampling & Mixing Probe Assembly

Sampling & Mixing probe assembly consists of sampling probe, plunger pump, mixing component, DC motor and corresponding liquid tube.

Sampling & Mixing probe process both sampling and mixing.



2-9 Reagent & Sample Probe Assembly

⚠	WARNING: When the analyzing unit is in operation, do not place any part of your body or any obstacle in the route where the arm moves. Otherwise, it may lead to personnel injury or equipment damage.

After opening the cover of machine, user can see the sampling & mixing probe assembly, countertop panel, cleaning unit, clean cup. Reagent and sample adopt the same probe assembly to do aspiration and dispensing.

Sampling system is used for aspirating defined volume of sample from sample storage and dispensing it to reaction cuvettes.

The sampling range of probe; 2ul ~ 300ul, 0.1ul increasing.

The sampling system follows the sequence: Sampling probe -->-- Sample cup -->--- Reaction disk -->-- Clean cup to do repeated motion and finish sampling.

Cleaning Function

Sampling probe adopts “Fountain” method to do inner/outer wall cleaning. Probe processes inner wall cleaning by high pressure liquid flow from syringe. And the outer wall of probe is cleaned by gushing water from clean cup.

Mixing Function

Mixing system consists of DC motor, eccentric wheel, synchronous belt and probe itself.

The probe is controlled by DC motor and eccentric wheel, and process mixing reagent by elliptic circling.

2.4 Sample Storage Assembly

Sample storage assembly consists of sample rack (include cover door of sample storage).

2-10 Sample Storage Assembly

Sample storage consists of three sample racks. Among them, 2 racks with 10 sample positions for each.

Sample rack is used for loading sample cup or tube, there are three sample racks where placed side by side into sample storage.

Sample container (Specification)

Sample cup: Φ12×37mm、

Primary Tube: Φ12×100 mm;

Plastic Tube; Φ12×100mm;

Sample Rack Dismantlement

Open the cover door of sample storage.

Follow the path of guiding track, picks out the sample rack.

Sample Rack Assembling:

Follow the path of guiding track, push sample rack into defined sample place. Well locking the door of sample storage.

2.5 Reaction Disk Assembly

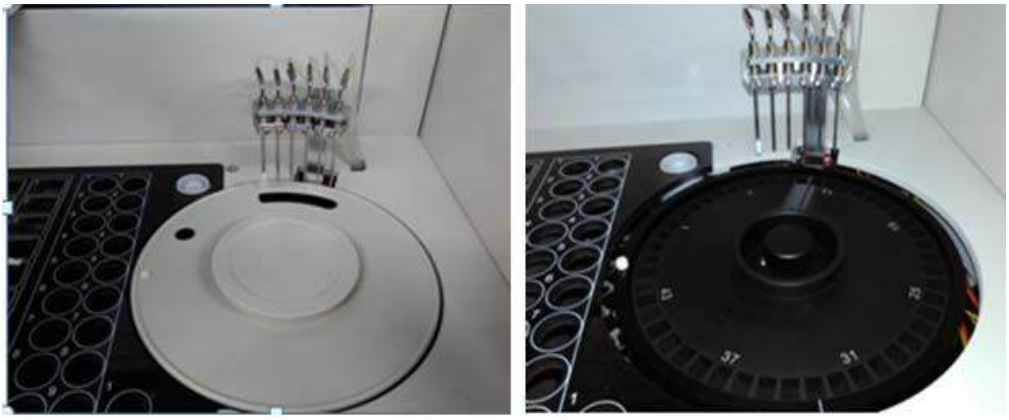
Reaction disk assembly consists of reaction disk, cuvette, heater and motion driving component.

Reaction disk is used for loading all cuvette.

Cuvette adopts high quality colorimetric cuvette, which use as the container both for reaction and colorimetric assay.

Heater is used for providing reaction disk an environment with steady temperature.

Motion driving component is used for carrying cuvette to appointed reagent position, mixing position, cleaning position.



2-11 Reaction Disk Assembly

Reaction disk is only processing contrarotation.

Reaction disk carry appointed cuvette to reagent dispensed position, sample dispensedposition, mixing position and cleaning position.

Reaction disk adopt single circle structure, 48 cuvettes can be placed.

Reaction volume: 180ul ~ 450 ul.

Cuvette Auto-Cleaning (5 series analyzer without this function) : In the end of each test, cuvette automatically process 6 steps cleaning and drying, then waiting for next test.

The controlled temp of reaction disk is 37 ℃.

2.6 Cuvette Auto-Cleaning Assembly(5 series analyzer without this function)

The cuvette auto-cleaning assembly consists of six cleaning probes, and place above the moving path of cuvette.

In the course of analyzing, all 48 cuvettes automatically process cleaning and drying.

1ST Step: Use detergent to clean cuvette(optional)

1ST Step: Use DI water to clean cuvette

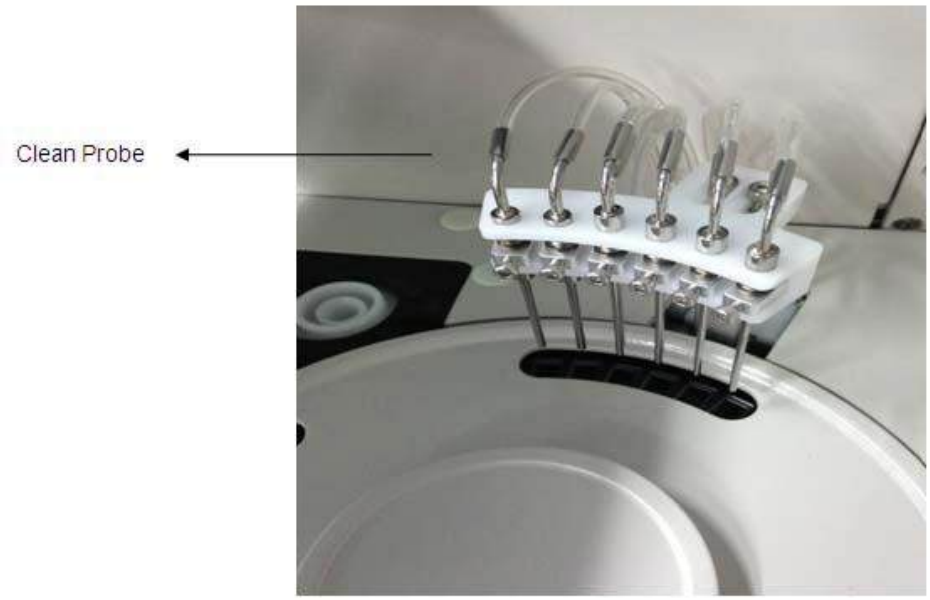
2nd Step: Use DI water to clean cuvette

3rd Step: Use DI water to clean cuvette

4th Step: Use DI water to clean cuvette

5th Step: Drying cuvette

6th Step: Drying cuvette



2-12 Cuvette Auto-Cleaning Assembly

2.7 Photometry Assembly

Photometry assembly is used for testing absorbance of reactant where inside the cuvette, photometry assembly is placed beside reaction disk.

Light Source	Halogen Lamp， 6V/10W
Optical Component	Optics Filter
Photometry Module	Forward Optics
Optics Detector	Photodiode array
Measurement Wavelength	8 wavelength：340nm、405nm、450nm、510nm、546nm、578nm、 630nm、 700nm
Measurement range	0-3.8A

2.8 Operation System

The operation system is a computer with the operating software of Chemistry Analyzer. It manages the running of the analyzing unit, as well as operation and data processing.

2.9 Outputting unit

The outputting unit is a printer that prints out the test results and other data.

3 Installation

	WARNING: The system should be installed by our authorized personnel.

The system should be installed by our authorized engineer only, and you should prepare a proper site for installation.

If you need to move the system to another site, please contact manufacturer Customer Service Department or your local distributor, to designate the qualified engineer to finish the moving job.

3.1 Inspection before Installation

When you receive the system, you should carefully inspect the package. If you discover any signs of mishandling or damage, file a claim immediately with manufacturer Customer Service Department or local distributor.

After opening the package, check the delivered goods according to the packing list as well as the appearance of the system. If you find anything missing or damaged, contact our Customer Service Department or local distributor immediately.

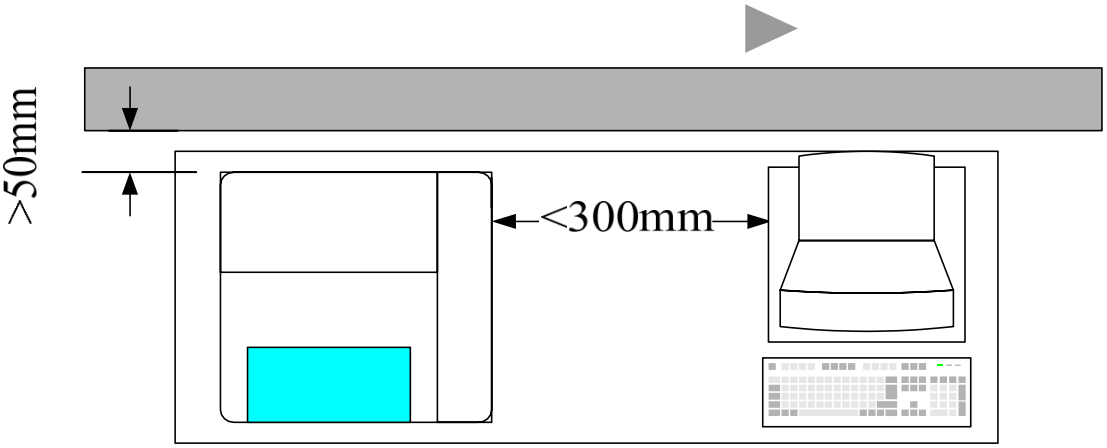
	CAUTION： In the course of moving the equipment, pressure points should be at the metal substrate.

Installation Requirements

	CAUTION： Make sure the system is installed to the place which meeting the following requirements. Otherwise, it will not perform as promised.

3.1.1 Environment Requirements

Installation spaces requirements



3-1 Space layout

The system is for indoor use only;

The bearing platform(or ground) should be level (gradient less than1/200);

The bearing platform(or ground) should be able to bear 50Kg weight;

The installation site should be well ventilated;

The installation site should be free of dust;

The installation site should get away from direct sun;

The installation site should not be near a heat or draft source;

The installation site should be free of corrosive gas and flammable gas;

The bearing platform(or ground) should be free of vibration;

The system should not be disturbed by large noise or power supply

The system should not be placed near brush-type motors and electrical contacts that are frequently turned on and off;

Do not use devices such as mobile phones or radio transmitters near the system. Electromagnetic waves generated by those devices may interface with operation of the system.

Altitude of the installation place should be less than 2000 m.

Reliable earth terminal for power supply

3.1.2 Power Requirements

Power supply: AC90V~ 264V, with fluctuation less than ±10%, 50Hz~60Hz;

Three-wire power cord, which should be grounded properly;

The system should be connected to a properly-grounded power socket;

The distance between the power socket and the equipment should be less than 2.5 meters;

Grounded voltage must be confirmed as the specified requirement;

⚠	WARNING: The installation site should be well ventilated to ensure radiating, taking ventilated devices if necessary, but to avoid direct airstream to the machine to affect the assurance of data.

	WARNING： Make sure the power socket is grounded correctly. Improper grounding may lead to electric shock or equipment damage. Be sure to connect the system to a power socket that meets the above-mentioned requirements and has a proper fuse installed.

3.1.3 Temperature and Humidity Requirements

Ambient temperature: 15℃～30℃, with fluctuation less than ±2℃/H;

Relative humidity: 35% ~ 80%RH, without condensation;

	CAUTION： Operating the system in an un-specified environment may lead to unreliable test results. If the temperature or relatively humidity does not meet the above-mentioned requirements, be sure to use air-condition equipment.

Water Supply and Drain Requirements

The water must meet requirements of CAP Ⅱ;

The water temperature should be between 5~32℃;

If use water purifier for providing water, the water purifier should meet follow requirement.

Continuous liquid flowing: > 5L/h

Peak flowing: < 0.08L/s

The water storing container should be large enough to meeting the largest continuous liquid flowing.

Pressure of water source: 100kPa ~ 392 kPa

The tube between water source and water inlet of machine should not longer than 1m.

The tube between drainage and water outlet of machine should not longer than 60mm, distance between drainage hole and floor should less than 80mm;

	BIOHAZARD： Be sure to dispose of the waste according to the local regulations. CAUTION： The water must meet requirements of the CAP Ⅱ. Otherwise, insufficiently purified water may lead to misleading measurement.

4 Basic Operations

4.1 General Operation Procedure

Preparation for Analysis

Before starting analysis, necessary works should be done to preparing test conditions for the system.

Analyzing

Samples are analyzed in correct test procedures, and the test results can be inquired, edit and output report, etc.

After Analysis

When all analysis are finished, necessary operations should be performed.

4.2 Preparing for Analysis

4.2.1 Checking before Power-On

You should do the following operations before starting the analyzer.

	BIOHAZARD： Wear gloves and lab coat in case of infection when performing the following operations. If necessary, wearing goggles to protect eyes.

1、Check the power supply and make sure that it can supply proper voltage for the analyzer.

2、Check the connections among the analyzing unit, operation unit and printer. Make sure the connections are right and secure. Check the power cords of the analyzing unit, operation unit and printer, make sure they are well connected to the power sockets.

3、Check and make sure sufficient paper is prepared for the printer.

4、Check the sampling probe and make sure the probe is not contaminated or bent. If the probe is contaminated, clean it as instructed by the manual. If the probe is bent, replace it as instructed by the manual.

5、Check the sampling probe whether place in the clean position (home position), If there are any deviations, removing the probe to clean position by hand.

4.2.2 Powering On

Power on the analyzer in the sequence presented as below:

1、Place the Main Power switch on the back side of machine to ON.

2、Press the Host Switch on to open the host of mainframe.

3、Press the power button on the monitor of the operation unit (PC).

4、Press the power button on the computer of the operation unit (PC).

5、Press the power button of the printer.

4.2.3 Starting the Operating Software

Should be configured with correct serial port and baud rate from configure document before start software.

Start the Windows operating system, then double clicks the icon <iChemManager>.

The login dialog interface of the operating software is displayed. Enter the username and password, and then select ok.

Self checking interface is displayed, then process self checking, after finish self-checking can user process corresponding operation.

4.2.4 Parameters Setting

Only setting proper parameter, user can apply test for sample or other operation.

In 1st using of system, user must set parameter. In daily using, user can set parameter according to requirement.

In 1st using of system, user must finish setting of follows parameters: item parameter, reagent position, calibrator information and calibrated rule, control liquid information and QC rule, hospital information, printer and printed module.

	CAUTION： Please use reagent from recommended manufacturer, and follow reagent manual to enter corresponding reagent information, otherwise, it may lead to improper test results.

Item parameter:	Within <Param>, <Item> interface, fills in all information according to reagent manual.
Reagent position:	Within <Reagent> interface, fills in reagent information and defining position for reagent.
Calibration Setting	Within < Calib.> interface, fills in calibrator information, setting calibrated rule.
QC Setting:	Within <QC> interface, fills in control fluid information, setting QC rule.
Hospital Info.	Within <Set.> interface, <System Set>, fills in corresponding hospital information.

Print Setting:	Within <Set.> interface, <System Set>, fills in corresponding hospital information.

4.2.5 Preparing Reagent/ Calibrator/ Control fluid/ Sample

Placing reagent to appointed position in reagent storage according to the setting in <Reagent> interface, take off the cap of reagent bottle, and checks the reagent whether is enough.

Placing calibrator, control fluid, sample to appointed position in sample storage according to corresponding setting.

	Warning： Please be careful of the operation, avoid hand scratch by the needle. Some agents may damage the skin, please be careful to use reagent. During the operation, please take on gloves, protective clothes, you'd better wear protective glasses.

4.2.6 Checking the remaining reagent volume

If you need to check the remaining reagent volume, please follow the instruction of 5.3 reagent remaining volume.

5 Advanced Operations

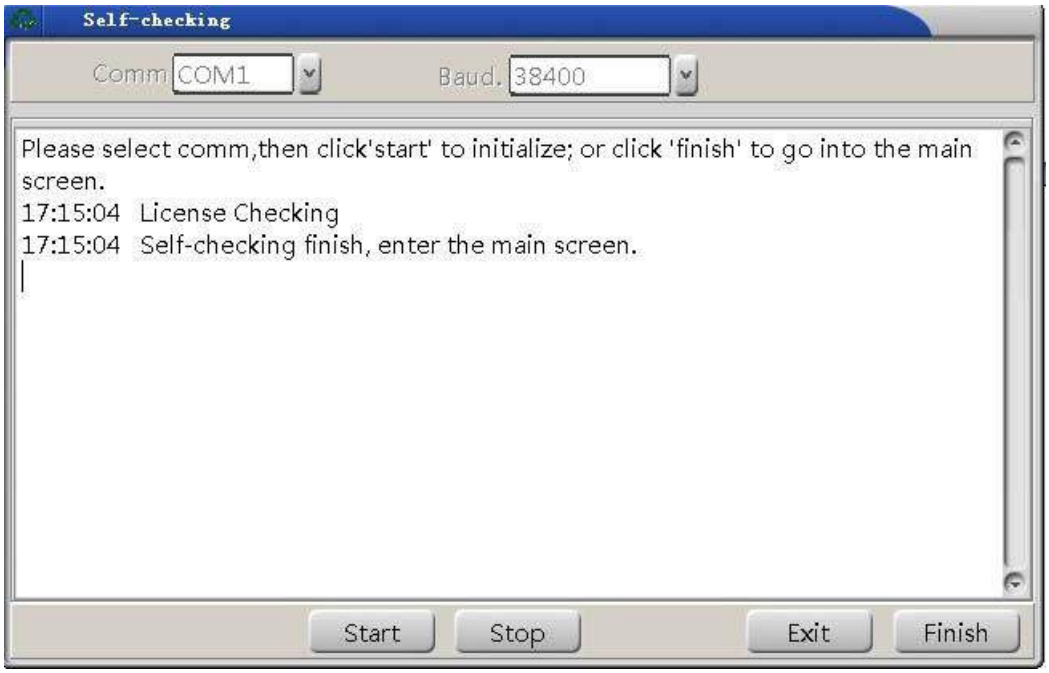
This chapter presents an introduction of the operating software of the analyzer by shortcut buttons and function buttons.

5.1 Start

Start the Windows Operating System, double-click the shortcut icon “iChemMini” on the Windows desktop. The **<Login>** interface of the operating software is displayed. (See Figure5-1)

5-1 Login Dialog Interface

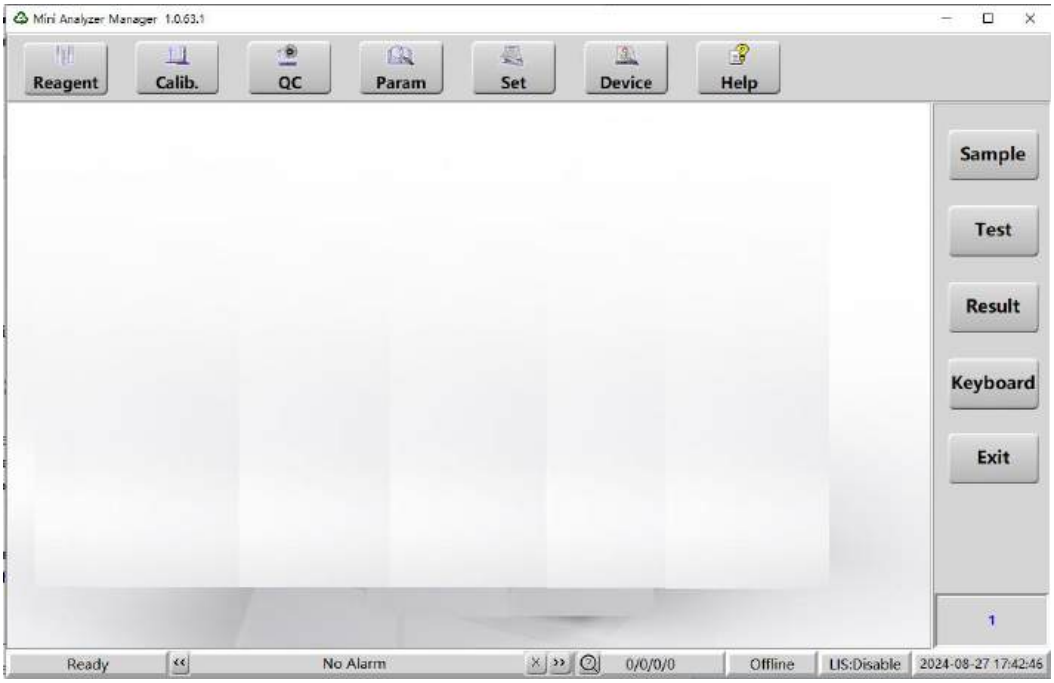
Select the *User Name* and enter the *Password*, the default username is “admin” and password is “ichem”. Click on 【OK】 to access **<Self-Checking>** interface after selecting the Language. (See Figure5-2)



5-2 Self-Checking

Click on 【Start】to start self-checking for machine. Self-checking process including: initialization, cleaning cuvettes, reading water blank and checking temperature. Click 【Finish】to access **<Main>** interface if user need skip self-checking.

After finish self-checking, system will auto-accessing **<Main>** interface. (See Figure 5-3)



5-3 Main interface

5.2 Sample

Sample preparation:

Use the serum which has been centrifuged, then dispense sufficient samples into the sample cup. Serum should without fibrinogen and hemolysis, and no air bubble in the sample cup.

Reagent preparation:

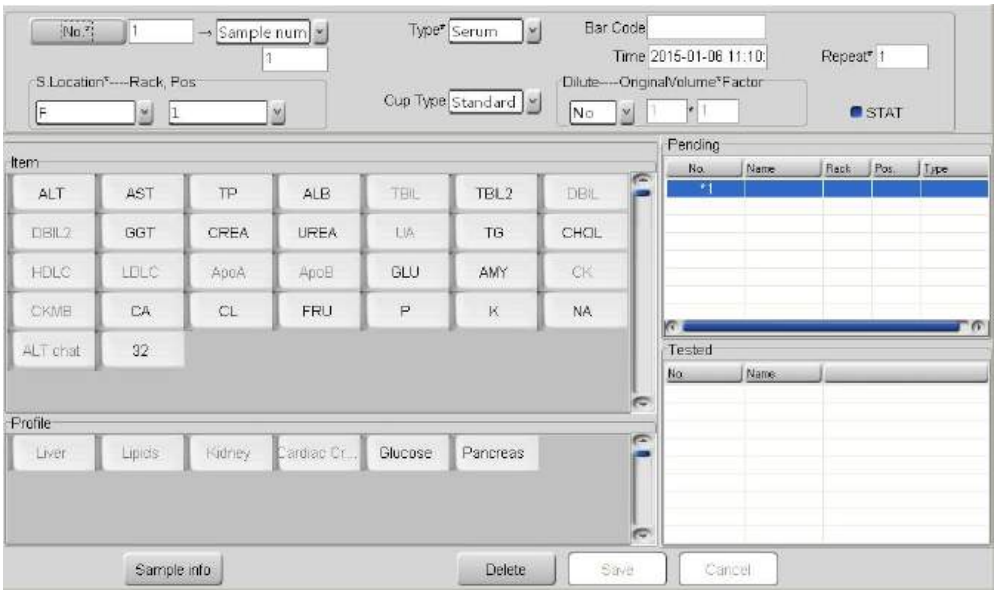
Put sufficient reagent into the reagent bottle. Make sure that the reagent is in the validity period with steady and reliable quality.

Washing water preparation: Use the DI water with conductivity less than 2.0us/cm. Make sure there are enough DI water in pure water tank.

⚠	Note: Before applying test for calibration and quality control, make sure that the parameter of requested item has already been set.

5.2.1 Sample Request

Click 【Sample】from the function buttons area of the **<Main>** interface. The **<Sample>** request interface is displayed as Figure 5-4



5-4 Sample Request

The interface of **<Sample>** is available to request and edit test information. Fill in patient's name, gender, and age into *Sample Information* column. The information of the patient could also be entered during reviewing result in **<Result>** interface.

The parameters of the sample interface are illustrated as below

Parameters	Description
No.	Daily default sample no. starting from No.1. Increases in sequence. Unrepeatable, editable, for typing the test report. When clink on this button, it will automatically create next sample no.
End/Sample	Use for Batch inputting, select End number module and enter end number; or select Sample Number module and enter total sample number.
Type	sample; control.
Bar Code	Each sample got a unique bar code. It can be entered manually. If connected LIS system, input scans or input bar code, click enter, the Lis corresponding test information, sample information will be obtained.
Rack/Cup no.	Sample put in sample rack, the positions accords with actual placing.
Application Time	Fill in the date when the sample is submitted. The default is the current date.
Pre-diluent	No dilution, manual dilution, automatic dilution.

Repeat	Select automatic dilution, you need to set up the dilution original content and dilution ratio, the dilution original content range is 2-100, the dilution original amount * dilution multiple values for the overall reaction volume, total reaction volume range is 180-500. Select manual dilution, input the dilution multiple, then the operator manually dilute the sample according to the dilution multiple set.
STAT	The default is No-dilution

The following table introduces the buttons on the <Sample> interface.

Buttons	Function
	Save sample request information, The request samples in *Pending* column will be displayed.
	Delete sample request with the item which did not starting the testing. Or delete sample with some of items tested and other item testing still not finish. The sample which is being tested cannot be deleted.
	Cancel request information without being saved.
	Select item from item list and profile item list. The item which been selected will be showed as highlighted
	Click on this button, user can edit the information of each sample.

The buttons of Item and Profiles column are introduced as below.

This interface includes all the test items that could be tested on the analyzer directly. After selecting an item, there are green dots displaying in the right corner, then user could continue to select other test item. (If the items are too much and the item interface is not large enough to display all of them, click the right corner button to go to next page and select other desired test items.)

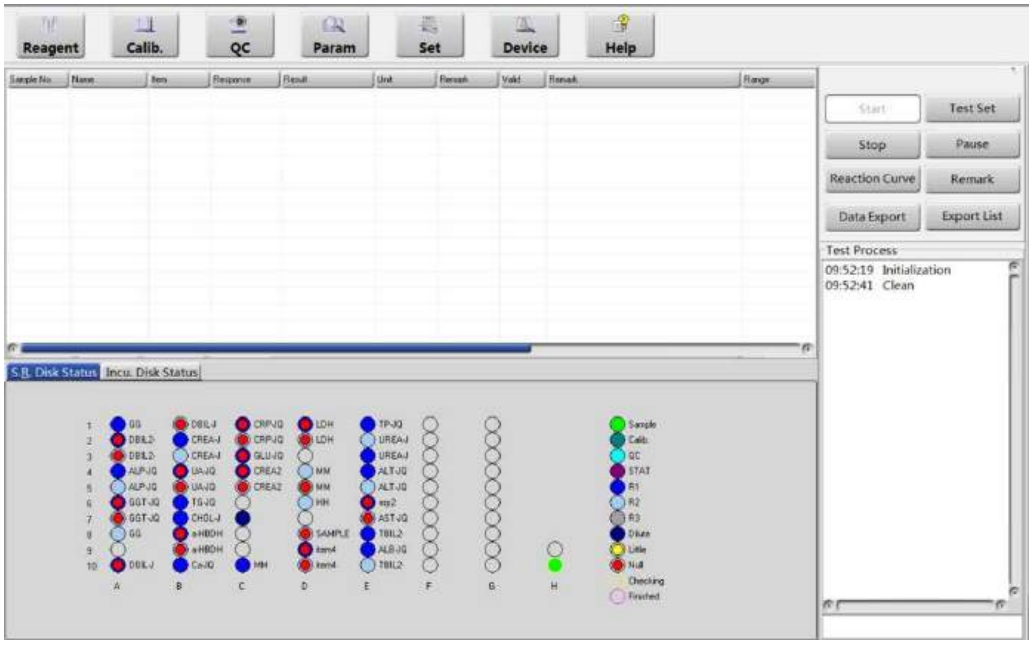
The columns of <Sample> interface are introduced as below.

Pending	It show all the samples which are waiting for being tested.
Tested	It show all the samples which are being tested.

	Note: If requested sample is submitted to test the same item again, all the items that had been requested originally but not requested this time, which are invalid no matter the requested tests are finished or not.

5.2.2 Sample test

Click 【Test】 to access testing interface after finishing sample requesting, the interface are shown as Figure 5-5



5-5 Sample Test

Click the【Start】button. Information bar will display corresponding reagent information, Then click【Yes】after make sure the indicated reagent is enough, test will starting. The following table introduces the buttons on the **<Test>** interface.

Buttons	Function
	After sample requesting, click this button to start test automatically. (Before clicking this button, please make sure the tube is clean, and re-checking all the samples, calibrators, quality control liquid and reagents are placed correctly).
	Setting Skip the invalid test and skip the invalid cuvette, skip the washing process before test. Tick off “skip the invalid test” button; testing will automatically skip this test to next test when reagent or sample insufficient Tick off “skip the invalid cuvette” button; skip the invalid cuvette automatically when reading water blank is abnormal. Tick off “skip washing before test after self-checking”, the next test will not washing cuvette if have finish self-checking. If abnormal stop for last test, need

	washing cuvette for next test. (5 series analyzer without this function)
	After starting test, click this button to cancel all the tests.
	Use to check the reaction curve of corresponding item.
	Alarmed remark for reagent, sample and absorbance.
	Export test result of appointed items.

The following table introduces meaning of different remark.

Remark	Meaning
S	Sample is not enough
R	Reagent is not enough
SR	Sample and reagent are not enough
OH	Higher than the linear range
OL	Lower than the linear range
OL	Lower than the linear range
RE	Reagent beyond expire date
BOE	Bottom liquid is exhaust
NL	No linear range
RC	Mark for result correction
MW	Mark for result may be wrong

Note:
Before starting the test, please re-check the samples, calibrators, quality control liquid and reagents whether are placed correctly. When stopping the test, all the unfinished tests will be voided. It is recommended that user only use this <STOP> button at last resort.

When test interface starting displayed data, real-time result, like sample No., Name, testing item, absorbance, testing result, unit, description and other information will be displayed in the result column. If all the testing results can't be displayed on one screen, there will be a vertical scroll bar on the right side of the interface, which use for observing all the testing data.

Related data of the **<Test>** interface will be introduced as below:

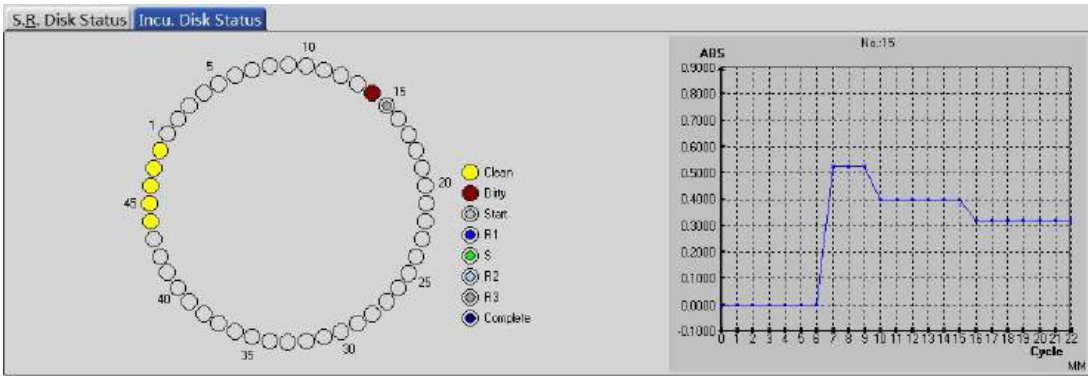
Parameters	Description
Sample No.	Specific Sample No. under testing.
Item	Show the name of the testing item.
ABS	Show absorbance of the testing item's wavelength.
Result	Concentration result.
Unit	The setting unit for corresponding item within <Param> interface.
Remark	It shows that whether the result is normal or not.
Valid	Availability for test result, valid indicate Y, or else indicate
Remark	N The description for test result
Range	Reference range is input when set the item parameter.
Retest	Indicating the retest results.
Request Time	Show the time of request.
Test Time	Show the time of test.

Click "Sample", allow to check test sample status while testing, display information of sample test status including: sample no. Item, Sample type and test status.

Detail sample test information will be introduced as below:

Sample no. Item Sample type	Sample no. of test Item of test Sample type of test
Retest	Repeat time and retest time
Test status	Including not start, testing and finished test.

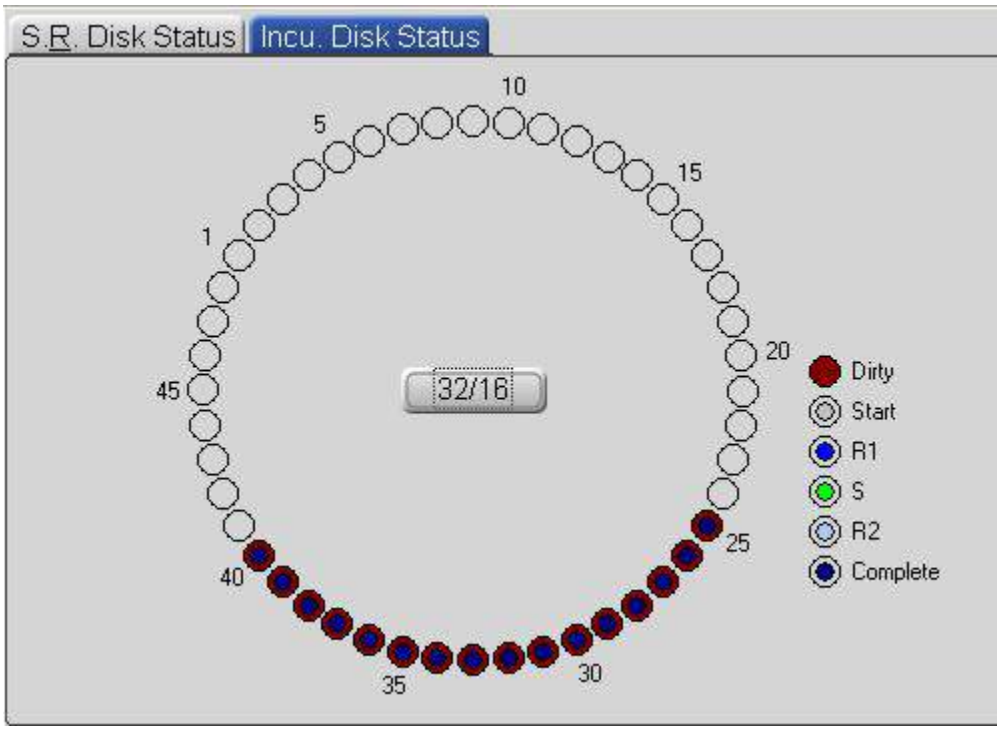
Click" Incu. disk status" for check status information and real time reaction curve for each cuvette. Real time display current cycle curve when click one of cuvette, the curve will not display if test result comes out.



5-6 Incubation disk interface

5.2.2.1 Replace cuvette (Applicable for 5 Series Analyzer）

5 series models, after used 48 cups, uses have to click on the cup state icon in the middle of incubation plate to replace cups, as shown in figure 5-7 Cup replace interface , 32/16 said: the current 32 cups are available cup, 16 sample cup has already been filled or dirty cups. Click the button, select the cup group that need to replace.



5-7 Cup replace interface

Select the cup group that need to be replaced in the software interface, click on the [sure], user will manually replace the corresponding cup group on the analyzer reaction tray.

5-8 change cup

Cup replace interface button shows as follows：

Button	Function
All	Click on this button, all cup groups are selected;
Clear	Click on this button, the selected cup groups will not be selected;
Read Blank	After replaced cups, user can read alone cup blank, if the cups in use appear dirty cup, dirty cup icon will be displayed in the interface;
OK	Select the cup group need to be replaced, then click the button to update the dirty cup state on interface;
Cancel	Select the cup group need to be replaced, then click the button, and the dirty cup state will not change on interface;

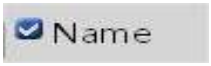
5.2.3 Result Review

Click on 【Result】 on the right side of the **<Main>** interface. **<Result>** interface is shown as Figure 5-9.

<Result> interface consists of **<Sample>** and **<Item>** interface.

5-9 Query Sample

Conditions column of **<Sample>** within **<Result>** interface is described as below

Parameters	Description
	Query tested result by selecting date. Select date range and right date.
	Query tested result by entering name. Entering name, if it is not the full name, it will show related name list for choosing.
	Click it to query results according with “date” and “name”.

Patient information column of <Sample> within <Result> interface is described as below:

Patient Information column shows all the information of the tested sample. The editing storage with “star” mark is required filling in necessary.

Parameters	Description
Patient	Enter patient name.
Gender	Select Male or Female in the combobox
Birth date	Enter patient’s birth date.
Pay type (Medical Insurance Card No.)	Enter Individual or social medical insurance card no..
Age	Enter Patient’s age.
Blood type	Select patient’s blood type in combobox
MRN	Enter patient’s medical record No.
Patient ID	Enter patient identification.
Sender	Select the sending nurse of sample.
Bed No.	Enter patient’s bed No.
Sample time	Enter sample collection time.

Send time	Enter samples submission time.
Tester	Operator who operate chemical analyzer to test sample.
Note	Enter note information
Save	Save the patient data to success

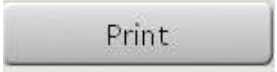
The Result column of <Sample> within <Result> interface is introduced as below:
Select a sample in the Result column, the items tested result will display on right column.

Parameters	Description
Sample No.	Sample serial number.
Name	Patient's name.
Request Time	The request time of tested sample

Parameters are introduced as below:

Parameters	Description
Item	Show the name of the item. eg.ALT
Retest	Indicating the retest results.
Final result	The result is final, allowed to be edited, which will display in test report.
Tip	Indicates the result value whether is too high or too low which compared with the standard value.
Range	Show reference range of tested item.
Unit	Unit of the parameters.
Test time	The tested time of the result.

Buttons on the <Sample> within <Result> interface are introduced as below:

Buttons	Function
	Delete the item which is selected.
	Edit the tested result
	Add calculative item composed by the items which displayed in the result column.
	Add manual item that need to print in the testing result of the report.
	Review reaction curve of the result.
	Abnormal result can be retested. One or more item could be chosen as retested. When click on retest button, these items will return to sample apply interface.
	Print patient's test report.

Data Export	Select one or batch item to export data.
Upload	Choose the samples which need to upload, and then upload the sample test information and patient information to the LIS server.

Click on 【Item】 within <Result> interface, <Item> interface shows as Figure 5-10

5-10 Query Item

Query Conditions column of <Item> within <Result> interface is introduced as below:

Parameters	Description
Date	Query tested result by selecting date. Select date range and right date.
Query	Review the result according to the condition “Date” and “item”

In the Item List column, select an item and add it to Query List column. Then select specific item from the Query List column and check the tested result within the selecting date, result will be displayed in the Sample List column.

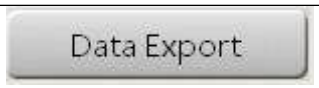
Buttons on the Item List column of <Item> interface are introduced as below:

Buttons	Description
>	Select an item from Item List column. Click this button to add it to the Query List column.
>>	Click this button to add all items from Item List column to the Query List column.
<	Select an item from the Query List column. Click this button to remove the selected item from the Query List to Item List.
<<	Click this button to select all the items from the Query List to Item List.

Parameters of <Item> interface are introduced as below:

Parameters	Description
Request Time	Show request time of the test
Sample No.	Show sample number of corresponding item.
Type	Show sample type of corresponding item
Retest	Indicates that the result is got from retesting
Actual Result	Show the result which tested by machine, it not allowed editing.
Final Result	Show the final result which display in test report, it is allowed editing.
Tip	Show the tip for tested result, like ↑, ↓.
Range	Show the referencing rang of tested result.
Unit	Show unit of tested result.
ABS	Show ABS data of tested result
Test Time	Show tested time of result.

Buttons of <Item>interface are introduced as below:

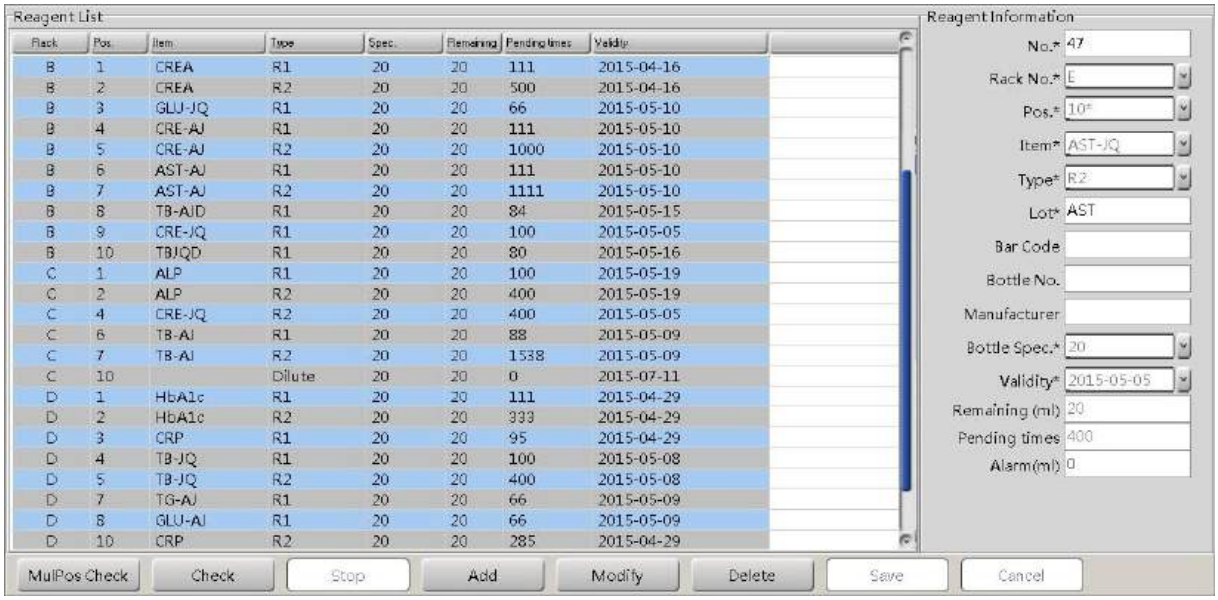
Buttons	Description
	After selecting tested result, click on this button, the reaction of the tested result will be displayed.
	Selecting one item or all items, click on this button, all tested result within the item or all items will be exported by EXCELL document.
	Selecting the results which you want to print, then clicks on this button.

5.3 Reagent

The interface of reagent is for setting the basic reagent information, arranging reagent position editing corresponding information, and checking the remaining volume of each reagent bottle and auto-calculating the remaining test time.

Click on 【Reagent】 on the main interface, Reagent List and Reagent Information column will shown as Figure 5-11.

Reagent List column displays the reagent information. Reagent Information column is used for edit corresponding information, and the parameter with " * " mark must be filled in.



5-11 Reagent

Parameters of Reagent Information column are introduced as below:

Parameters	Description
No.*	Serial number of the reagent, system auto arranging.
Disk No.*	Reagent loading shelf, “No.1” rank Is default.
Pos. *	Define the position of corresponding reagent.
Item *	From the drop-down box to select the corresponding item name. when set the diluent, do not need to set the item name;
Type *	define the reagent type is reagent 1, or reagent 2, or reagent 3, or diluent；
Lot *	Enter lot information for corresponding item.
Bar Code	Enter the barcode number of reagent bottle
Bottle No.	Bottle no. can be found within reagent manual.
Manufacturer	Enter manufacturer name for the reagent.
Bottle spec. *	Select the bottle specification, only 20ml can be selected.
Validity *	Enter the reagent validity period according to reagent instruction.
Remaining Vol.	Show the remaining volume. It could be edited by users.
Pending times	The system calculates pending times according to remaining volume and required volume automatically.
Alarm	The min Volume of alarm If the reagent volume is less than it, alarm will display.

Buttons of **<Reagent>** interface are described as below:

Buttons	Function

Check	Used for checking the remaining single reagent volume. Click on this button and fill in reagent position information according to indication.
MulPos Check	Used for checking the remaining volume of multiply reagent, when click on this button, total reagent volume and sample will be counted.
Stop	Stop checking remaining volume. The reagent disk reset.
Add	Add new reagent information for corresponding reagent item.
Modify	Modify reagent information for original reagent information.
Delete	Delete reagent information.
Save	Save the reagent information to database.
Cancel	Cancel editing current reagent information.

⚠	Warning Some reagent is harmful for skin. Please strictly follow reagent instruction. Keep hands and cloths in direct contact with the reagent. During the operation, if reagent accidentally contacts with eyes, please rinse immediately with plenty of water and consult with a doctor ASAP.

5.4 Calibration

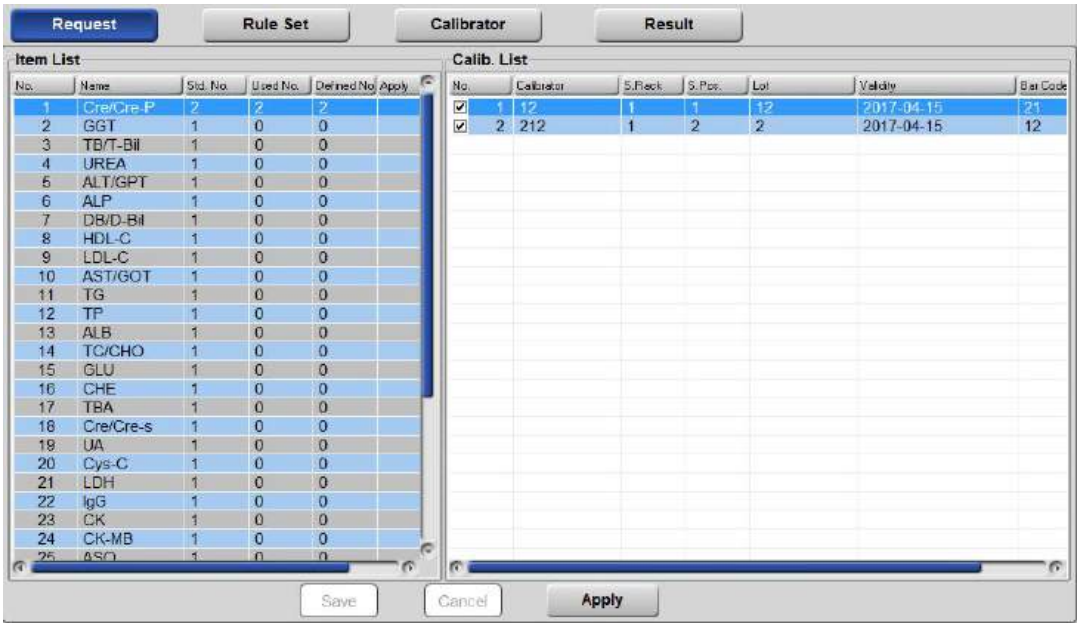
Before samples testing, user must process calibration. Click on【Calib】 to enter the Calibration interface .

There are four interfaces within <Calib.>:

5-12 Calibration

5.4.1 Calibration Request

<Request> interface is mainly used for applying calibrated tests.



5-13 Calibration request

All items will display in the Item List column, select certain items from Item List, the information of the testable calibrator for the item will display in the Calib List column. (The items within Item List should have been set parameter within <Param.> interface before Calibration. Request)

Parameters in the Item List column are described as below:

Parameters	Description
No.	Show the serial number of items.
Name	Show name of items.
Std. No.	Show the minimum number of calibrators for calibration request
Used No.	Show the number of calibrators which have been used for current item's calibration.
Defined No.	Show the number of calibrators have been defined parameter for the item
Apply	Show the current item whether have been applied for calibration, yes will indicates Y, NO will indicates N

Parameters of Calib . List column are described as below:

Parameters	**Description**
No.	Show the serial number of calibrator.
Calibrator	Show the name of calibrator.
S. Disk No.	Show the number of sample rack where calibrator placed.
S Position No.	Show the number of sample position where calibrator placed.
Lot	Show the lot of the calibrator.
Validity	Show the validity period of calibrator

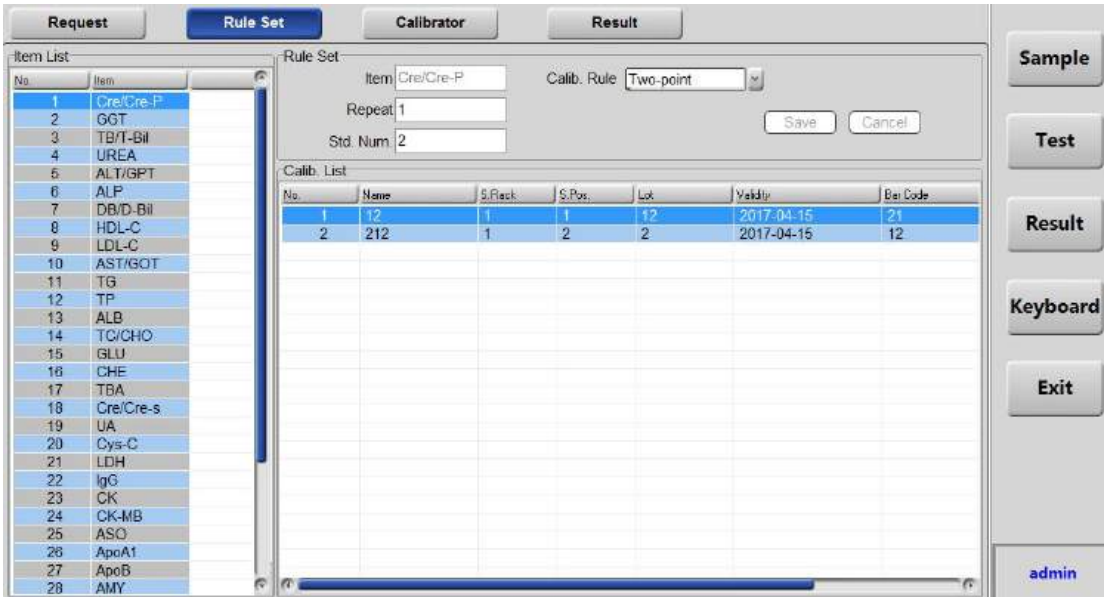
Bar Code	The barcode is self-set by user, the barcode scanned system is optional components.
Conc.	The concentration of corresponding items.

Buttons of <Request> interface are described as below:

Parameters	Description
Save	Select the item which you want to process calibration within a calibrator, then clicks on this button.
Cancel	Click on this button to cancel the calibration request which are editing
Apply	Apply calibration test, automatically add to Pending column within <Sample> interface.

5.4.2 Rule Set

<Rule Set> interface is mainly used for setting the calibrated rules, repeat times, K factor of the corresponding items, if user choose factor as calibrated rule, the factor should be entered.



5-14 Rule Set

Item List shows the item which can be measured, select a certain item, then the name of the item will displays in the Rule Set column, and corresponding calibrator information for the item will display in Calib. List column.

Buttons of Rule Set column are described as follow:

Buttons	Function
Save	Save the setting of the calibrated rule.
Cancel	Cancel the current editing.

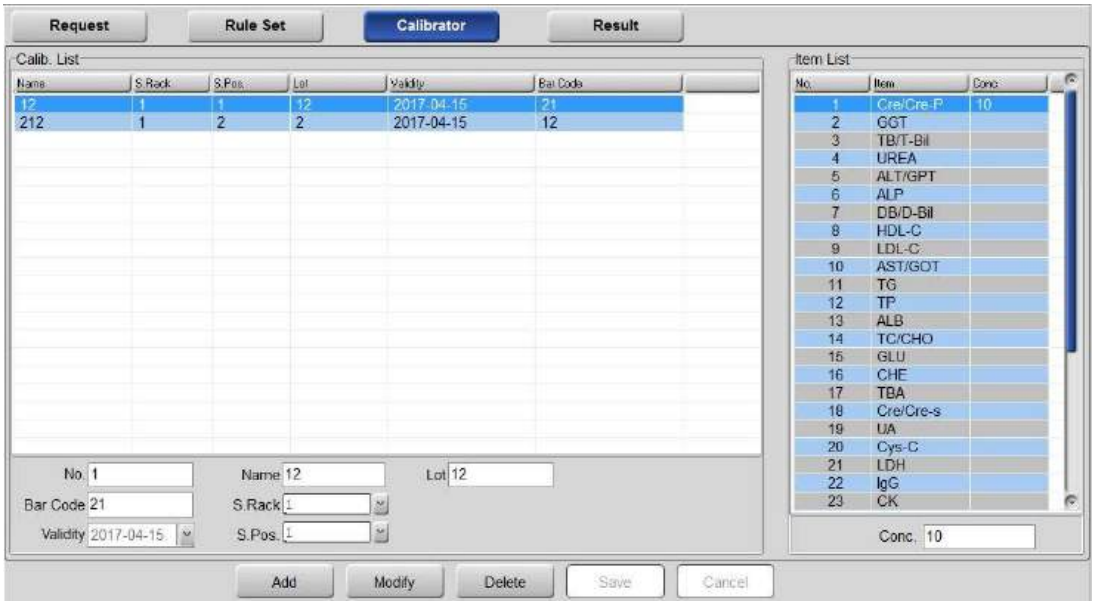
Textboxs of Rule Set column are described below:

Textbox	Description
Item	The item name will display after you selected an item from Item List column, it can be read but not edited.
Repeat	Enter the repeated times for calibration.
Std Num	The repeated time should not exceed 10, the calibrated result is the average of calibrated result. (The repeat time for K factor is empty. Default repeated time is 1)
Calib. Rule	For Factor rule, Std. Num. is empty.

Calibrator

Systems support one or more calibrator by dilution, allowing a calibrator dilute multiple different concentrations on the same item

<Calibrator> interface is mainly used for editing calibrator information.



5-15 Calibrator

Textbox of Calib. List column are described as follow:

Textbox	Description
No.	Enter the serial number of calibrator, each calibrator with a unique number. Default no. from No.1, stepping automatically plus 1.
S.rack No.	numbers of sample rack
Lot	Enter calibrator Lot. Same calibrator with different lot No.
Name	Enter calibration name
S.Pos.	Select the sample position where calibrator placed.
Barcode	Each sample cup can be set with unique barcode, barcode scanner is a optional component.
Pre-dilution type	The types of dilution include no dilution and automatic

	dilution.
One key dilution	Default not tick off “One key dilution” when add new sample and not need dilution calibrator. If tick off this button, need set “Gradient” and “Calib. Number” Gradient means multiple between current dilution calibractor and next dilution calibrator.

Parameters of Items list column are as follow:

Parameters	Description
No.	Show the series number of corresponding items, which according to <Param> setting.
Item name	Show the name of corresponding item
Conc.	Show concentration for corresponding item. Default concentration is empty. If concentration is 0, which represent that you have adopted the item, all un-linear items must adopt a 0 concentration calibrator.
	This textbox is used for entering concentration. Select item and fill in concentration.

	Caution: All un-linear items must adopt a calibrator which concentration is o.

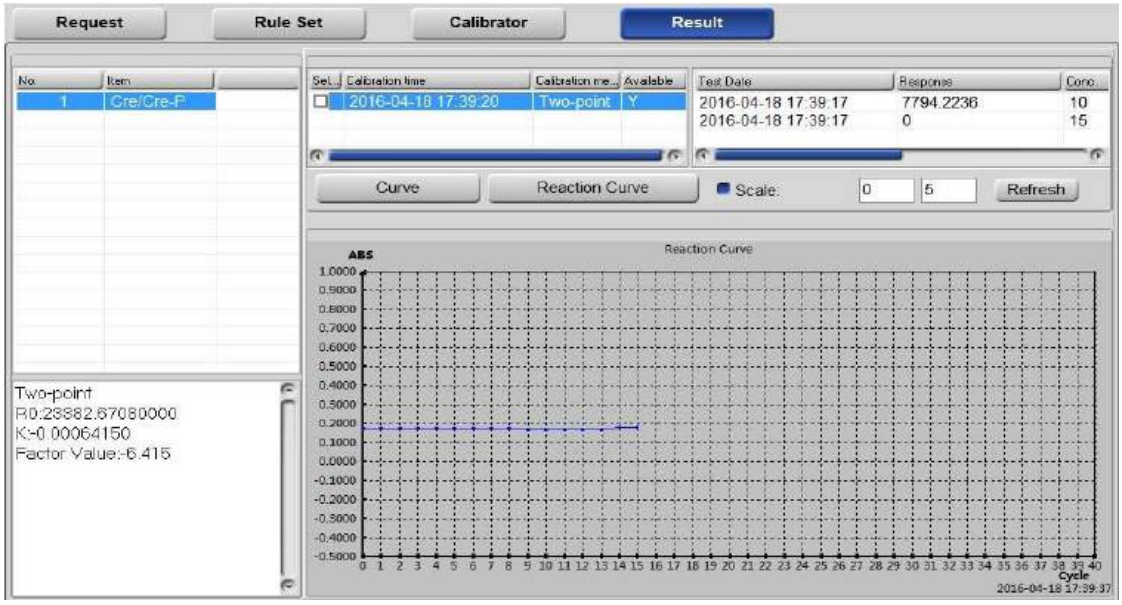
Buttons of <Calibrator> interface are described as follow:

Buttons	Description
	Click on this button, set the information for new calibrator, and concentration of corresponding items
	Select a calibrator in Calib. List column, click on this button, which can modify calibration information and item concentration for the calibrator.
	Select a calibrator in Calib. List column, click on this button, the information of the calibrator will be deleted from Calib.list.
	When finish entering calibrator information, click on this button to save. The calibrator’s information will display in Calib. List column, and concentration of corresponding item will display in Items list column.
	This button is used for given up current editing.

	CAUTION: User requires process calibration again once the reagent lots, test parameters, lamp or other analysis conditions was changed.

5.4.3 Result

On “Calibrate” interface, click ”result” as below figure 5-16 it is for checking the reaction curve , detailed calibration test each time and calibration result.



5-16 Calibrated Reault

<Result> interface is used for checking calibrated result. Left side is test item and calibrator factor display column, right side is calibrator information and calibrator result and above calibrated curve and reaction curve.

After entering **<Result>** interface, system displays the latest calibrate results of the item automatically.

Choose one item, then all related calibrator testing information is show on calibrator result column on right side. Click on 【Calibrated Curve】, user can check calibrated curve of corresponding items. Click on【Reacted Curve】, user can check the reaction curve of calibrator.

Customer can use every single success of calibration result. Latest calibration result will consider as default, if customer did not set calibration system.

We can check the validity of result by view the whole react curve.

⚠	Notice： Only manufactory has the access to choose iafoje calibrator result.

Parameters of <Result> interface are described as follow:

Parameters	Description
Test Date	Show the test data of calibrated test.

ABS	Show the ABS data of calibrated test.
Conc.	Show item's concentration of corresponding calibrator.
Valid	Show the valid of calibration, Y means valid, N means un-valid (require calibrating again)
Remark	Show the remark information of calibrator.

Buttons of <Result> interface are described as follow:

Parameters	Description
	Select item name, then clicks on this button, the calibrated curve of the item will display in Calibrated Chart column.
	Select item name and calibrated result, then clicks on this button, the reaction curve of the calibrated result will display.

5.5 Quality Control

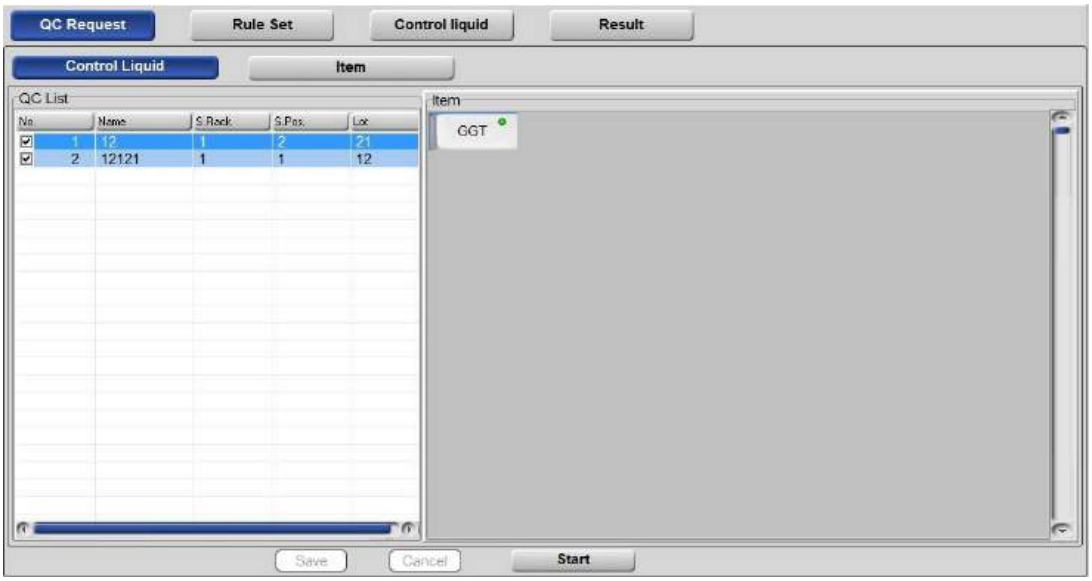
In order to monitor the accuracy of test results, sometimes it is necessary to test some quality control samples. Quality control testing can be done by several ways: one is general sample test, observed test results whether stay in the quality control range. Another way is to enter <QC> interface to execute quality control testing.

<QC> interface is mainly used for quality control testing, check quality control results. <QC> interface consists of four pages, see following Figure:

5-17 QC interface

5.5.1 Request

This interface is used for requesting testing for control fluid, which can be requested by <Control Liquid> or < Item>. As figure follow:



5-18 Request interface

5.5.1.1 Control Liquid

This interface is used for request QC testing by control liquid.

Within <Control Liquid> interface, all the control liquid will display in QC List column. Select a control liquid within QC List column, then all items within the control liquid will display in Item column, clicks on 【Start】, QC testing for the control liquid will adding to Pending column within <Sample > interface.

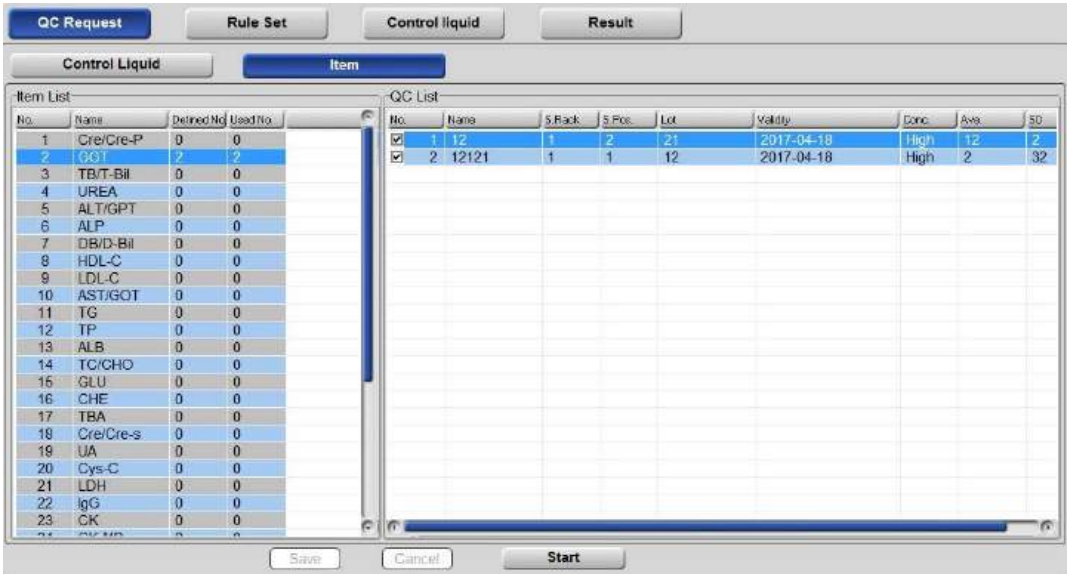
If user just wants to test several items within the control liquid, clicks on the item button within Item column, and green light will take off, then clicks on 【Save】and 【Start】.if user want to cancel this item, clicks on 【Cancel】.

Parameters of QC. List column are as follow:

Parameters	Description
No.	Show the serial number of control liquid.
Name	Show the name of control liquid.
S.Disk	Show number of disk where control liquid placed.
S.Posi.	Show number of sample position within sample storage where control liquid placed.
Lot	Show the lot number of control liquid.

5.5.1.2 Item

This interface is used for request QC testing by item name.



5-19 QC Request with item

Within <Item> interface, all items will display in Item List column.

Select a item within Item List column, all control liquid for the item will display in QC List column, then selects one or several control liquid for the item and clicks on 【Start】, QC testing for the item will adding to Pending column within <Sample > interface.

Parameters of Item List column are described as below:

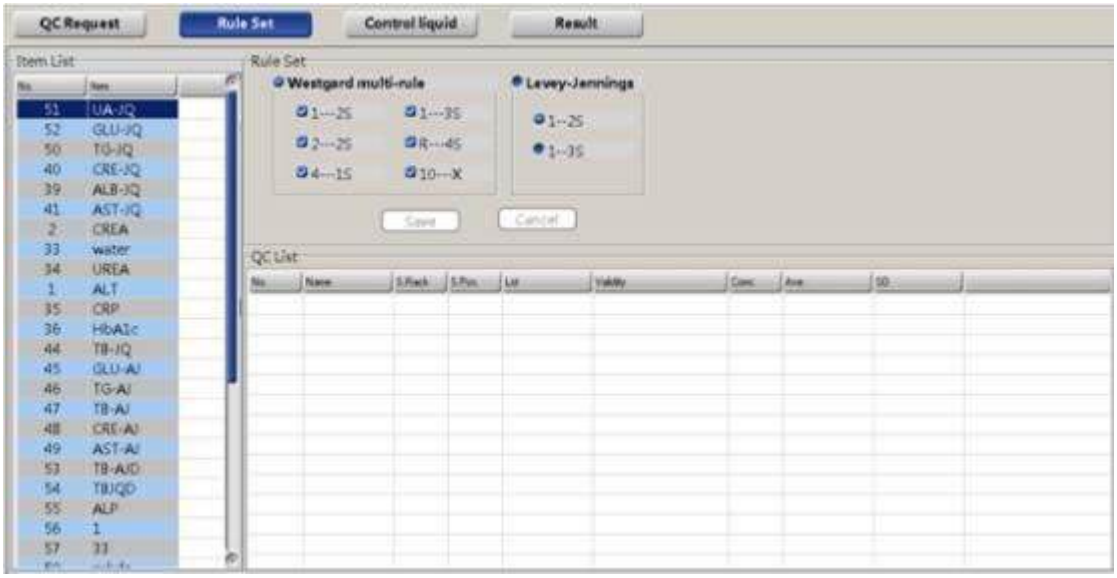
Parameters	Description
No.	Show the serial number of item.
Name	Show the name of item.
Defined No.	Show the number of control liquids which have been defined information for the item.
Used No.	Show the number of control liquids which have been applied QC test for the item.

Parameters of QC List column are described as below:

Parameters	Description
No.	Show the serial number of control liquid.
Name	Show the name of control liquid.
S.Rack	Show the numbers of sample rack where control liquid placed.
S.Pos.	Show the numbers of sample positions where control liquid placed.
Lot	Show lot number of control liquid.
Validity	Show validity period of control liquid.
Conc.	Show concentration level of control liquid.
Ave.	Show average concentration of corresponding item
SD	Show stand deviation of corresponding item

5.5.2 QC Rule Set

<Rule Set> interface is mainly used for setting the QC rules of the corresponding items



5-20 Rule Set

Parameters of Rule Set column are described as below:

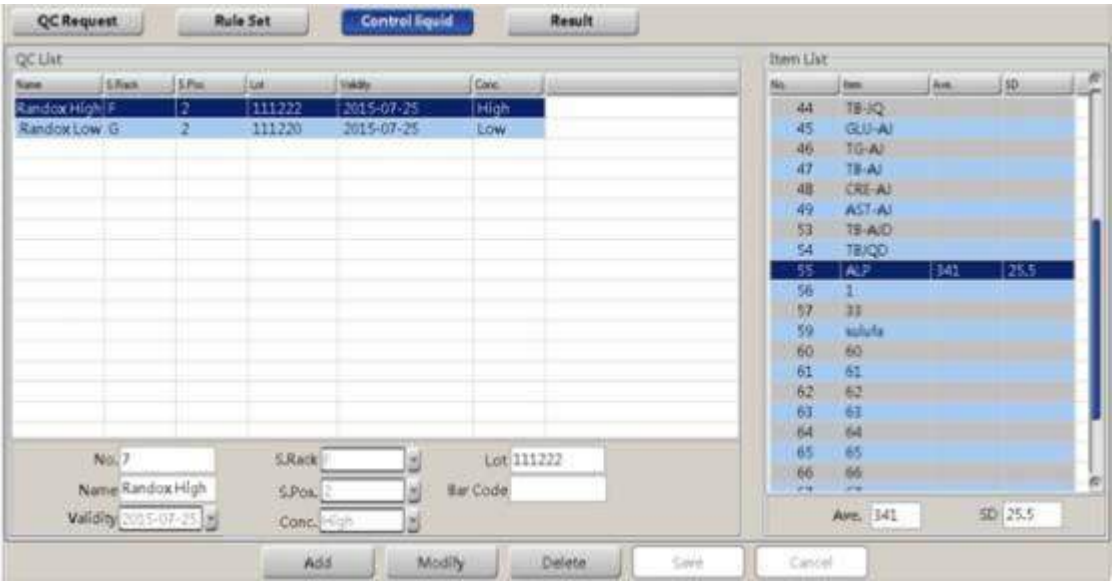
Parameters	Description
Westgard multi-rule	Show the range within Westgard Multi-Rule
Levey-Jennings	Show the range within Levery –Jennings Rule.

Buttons of ***Rule Set*** column are described as follow:

Buttons	Description
Save	Select item name from Item List column, and select QC rule for the item, then click on this button to save and the message will be showed on Control Liquid list.
Cancel	Cancel current QC rule setting.

5.5.3 Control Liquid

<Control Liquid> interface is mainly used for setting the information of control liquid.



5-21 Control liquid

Textbox of QC List column are described as follow:

Parameters	Description
No.	Enter the serial number of control liquid.
S. Rack	Select the number of sample rack where control liquid placed.
Lot	Enter lot number of control liquid.
Name	Enter name of control liquid.
S.Pos.	Select the number of sample position where control liquid placed.
Bar code	Enter unique bar code for each sample, bar code scanning part is optional equipment.
Validity	Enter the validity of control liquid, see from the reagent instruction.
Conc.	Select the concentration level of control liquid

Parameters of *Item List* column are described as follow:

Parameters	Description
No.	Show the serial number of item.
Item	Show the name of item
Ave.	Show the average concentration of item.
SD	Show the standard deviation of item
Ave. SD	Click on corresponding item from Item List column, then enter average concentration and SD data.

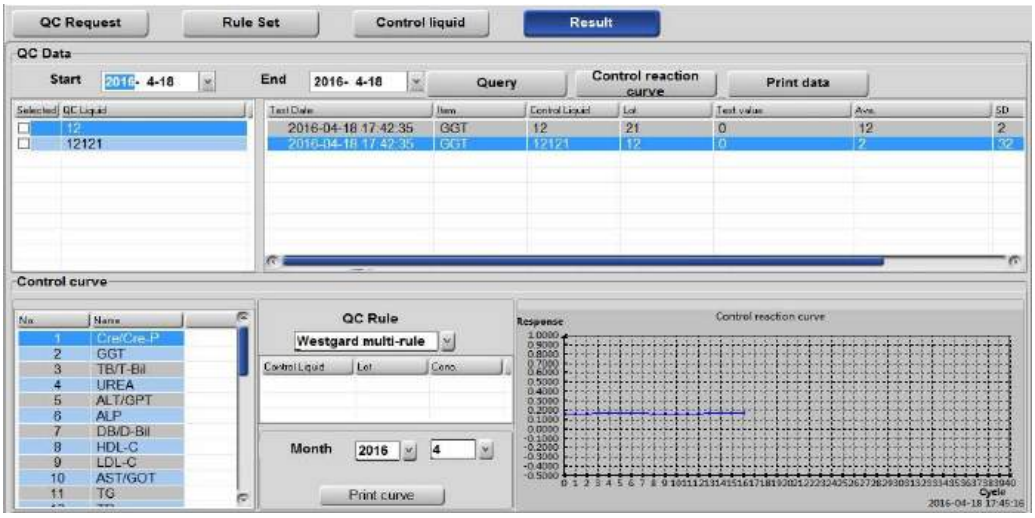
Buttons of <Control Liquid> interface are described as follow:

Buttons	Description
Add	Click on this button, set the information, average concentration and SD data for new control liquid.

Modify	Select a control liquid in QC List column, click on this button, which can modify the information of the control liquid.
Delete	Select a control liquid in QC List column and click on this button, information of the control liquid will not show on the QC list.
Save	When finish entering control liquid information, click on this button to save it to database. The information of the control liquid will display in QC List column, average concentration and SD data of the item will display in Items list column.
Cancel	This button is used for given up current editing.

5.5.4 QC Result

<Result> interface is mainly used for checking QC results, shown as Figure 5-22 Result.



5-22 QC Result

When entering in “QC Result” interface, left upper side is QC liquid name, left down side is test item, right side is the corresponding calibrator information

After selected the quality control liquid, then choose the time need to query, click on the "query", the corresponding QC result will show on list column including test date, test item, calibrator name, bath no. test value, average value, Standard deviation information and control liquid if beyond expiry date. Click on the list header to sort. Support data printing on the list.

After querying QC result, and select corresponding tested result, clicks on this button, user can check the reaction curve for the test result.

Control liquid list shows all the tested control liquid name and batch no. choose QC rule from ComboBox.

QC rule including Westgard multi-rule and Levery-Jennings.

Westgard rule is available with Control liquid or without Control liquid

Levery-Jennings need one Control liquid.

Parameters of<Result> interface are described as follow:

Parameters	Description
Test Date	Show the tested data of QC result
Item	Show the name of Item
Control Liquid	Show the name of control liquid
Lot	Show lot number of control liquid
Test Value	Show test value of corresponding item.
Mean	Show average concentration for the item.
SD	Show SD range for the item.

Buttons/Combobox of <Result> interface are described as follow:

Buttons/Combobox	Description
Query	After selecting date within combobox, then clicks on this button, user can check all QC tested result within the day.
Control reaction curve	After querying QC result, and select corresponding tested result, clicks on this button, user can check the reaction curve for the test result.
Print	After checking the control curve of corresponding item, click on this button, the control curve of the item within corresponding months can be printed.
Refresh	Selecting a certain item from the left side Item List column and selecting month from combobox of month, then click on this button, selecting QC rule and control liquid, the control curve of the item will display in Control Curve column.
2012- 7-26	This combobox is used for selecting date, and checking control tested data.
Levey-Jennings	This combobox is used for selecti8ng QC rule.
2012 7	This comboboc is used for selecting month, and checking control curve.

5.6 Parameter

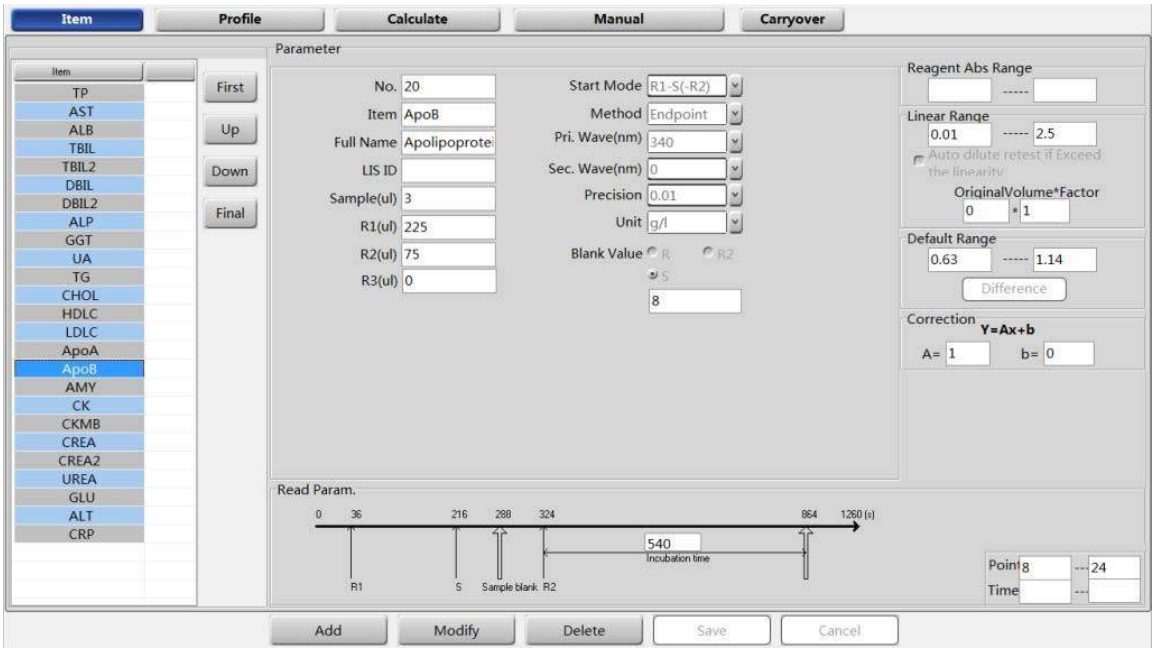
<Parameter> interface is used for setting parameter of reagent item, profile item, calculating item, manual item and carryover.

<Parameter> interface consists of five branching interface, as follow picture Parameter inter interface is default.

5-23 Parameter Interface

5.6.1 (Reagent) Item

<Item> interface is used for setting test parameters for reagent items, such as usage, analysis method, reading point, linear range.



5-24 tem interface

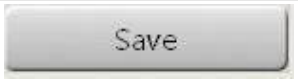
Textbox of Parameter column are described as follow:

Textbox	Description
No.	Enter the serial number for item, used serial number is available for new item.
Item	Enter item name, eg.ALT.
Full Name	Enter the full name of the item.
Lis ID	Input Lis ID, acquire the test information on the LIS server and upload test information.
Sample (ul)	Enter the using volume of sample. The range is (2~100μl) stepping from 0.1μL.
R1 (ul)	Enter the using volume of reagent one. The range is (180~350μl).
R2 (ul)	Enter the using volume of reagent one. The range is (0~200μl). If the reaction doesn’t need the second reagent, enter 0.（notice: Minimum reagent volume R1+R2+S is 182μL）
R3(ul)	If don't set reagent 3, please input "0" or keep empty in this column;（Note：the maximum reaction volume of R1+R2+R3+S is 650μL）
Reaction direction	The ABS change direction while reaction. Positive direction: ABS increase with the extension of time.

	Negative direction: ABS lower with the extension of time. Reaction direction support Two-point and Kinetic only.
Bottom liquid is exhaust	For Two-point and kinetic item, reaction curve and ABS is linear Within reaction time, if reagent is exhaust will lead to wrong Test result. The system will caluate linear range of test time, Checking ABS linear range if its linear, the exhaust range is -1~5.
Method	Select the monitoring method, like Endpoint, Fixed-time , Kinetic and so on.
Pri. Wave (nm)	Select the primary wavelength, 340nm、405nm、450nm、510nm、546nm、578nm、630nm、700nm；
Sec. Wave. (nm)	Select the second wavelength, 0nm、340nm、405nm、450nm、510nm、546nm、578nm、630nm、700nm
Precision	Select the precision of test result, that is digit capacity after decimal, choose the data among 0.1,0.01, 0.001;
Unit	Select unit of the result, such as U/L、IU/L、mmol/L、umol/L. set as [data dictionary-result unit]
Blank value	Choose the end point method item need to set up the blank value, the single reagent end point method, the default used is reagent blank, for double reagent end point method, using the sample blank by default.
Default Range	Enter referencing normal range of the item. When test result is beyond than the normal range, the machine will give notice. Typing in the upper limit and lower limit of normal reference range, When test concentration is higher than upper limit, then output test result will with a upper sign. When test concentration is lower than lower limit, then output test result will with a lower sign.
Linear Range	Enter the linearity range obtaining from reagent instruction Click【Auto dilution and retest if over linear】means it will Auto dilution and retest as per dilution multiple when the test Result over linear range value. If the sample do different test, Dilution within max multiple; not support retest for finished dilution Sample.

Correction	Enter the correction number. Recommend as A=1, B=0
Reading parameters	Users will read according to the incubation time and reading time on the reagent instruction.

Buttons of <Item> interface are described as follows.

Buttons	Function
	Click on this button, and edit parameter for new item.
	Select a certain item from Item List column, clicks on this button, and modify parameter for original item.
	This button is used for deleting parameter of corresponding items from database.
	This button is used for saving item's parameter to database.
	This button is used for canceling current parameter editing.
	To select an item, then click this button, the current item will move to be the first test order;
	To select an item, then click this button, the current item will move one test up in the test sequence.
	To select an item, then click this button, the current item will move one test down in the test sequence.
	To select an item, then click this button, the current item will move to be the last test order;

Profile (the Compounding Project Parameters Setting)

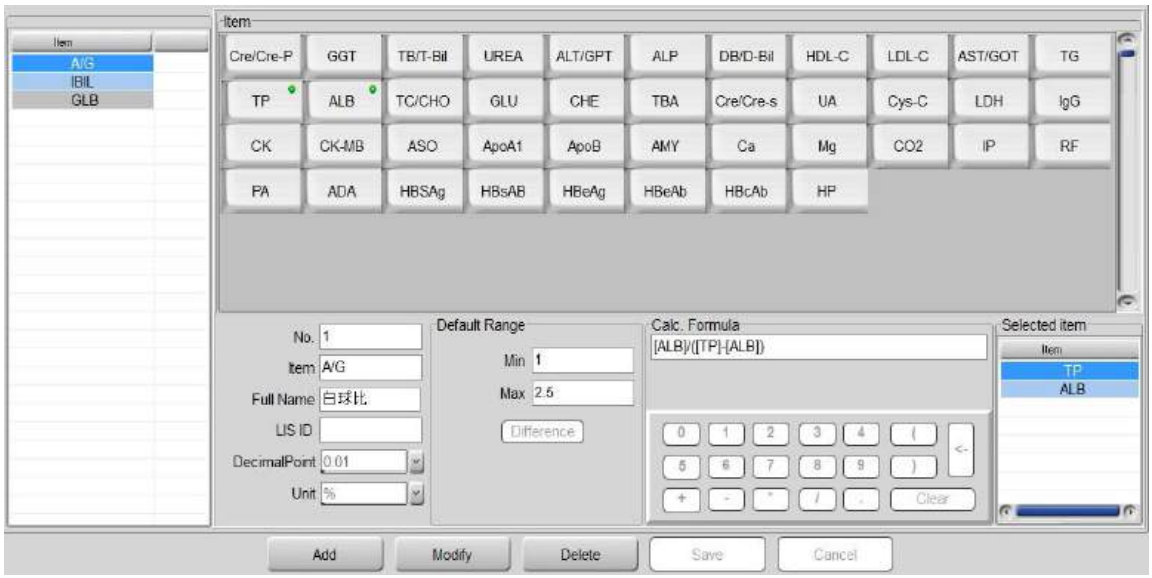
<Profile> interface is used for setting profile (setting the related Compounding Project parameters) with Clinical significance which is for quick typing when apply the compounding item, such as liver function, renal function User can request profile tests quickly by simply selecting a profile button in <Sample> request interface. The profile is applicative for both the sample request and QC request.

5-25 Profile Item

5.6.2 Calculate Item Parameter Set

<Calculate> interface is used for setting calculated item which use the relationship of tested items to calculate new items. It is indirect item. Such as A/G, TBil-DBil.

On the parameter interface, click “calculate item” button, enter into “calculate item parameter set” as show in Fig 5-26 below:



5-26 Calculate

Textbox of <Calculate> interface are described as follows:

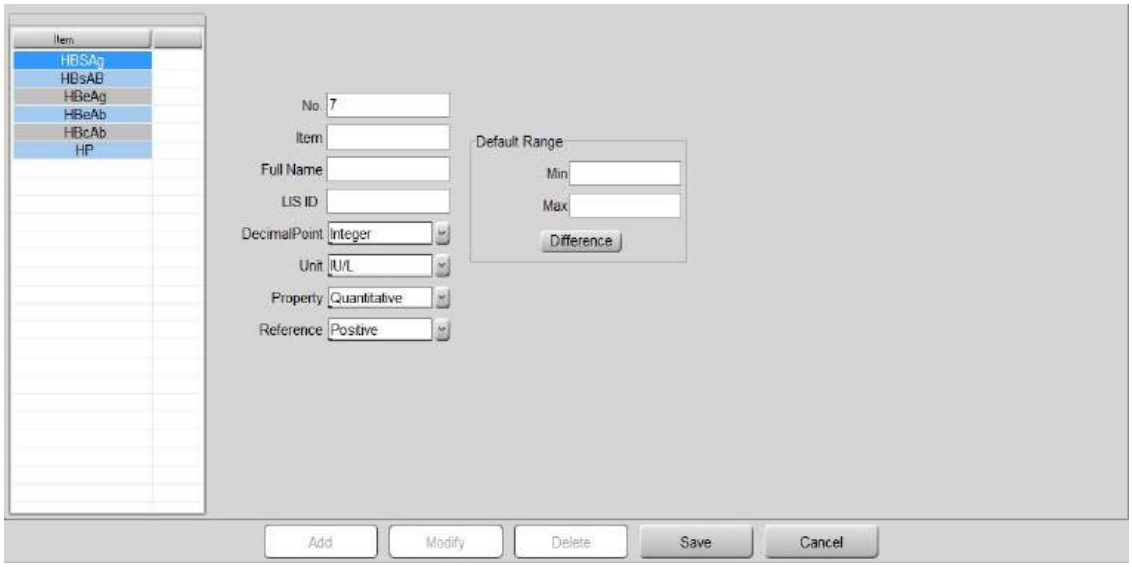
Textbox	Description
No.	Enter the serial number of calculated item.
Item	Enter name of calculated item.
Full Name	Enter full name of calculated item, allowed to be

	empty.
Precision	Select the precision of test result.
Unit	Select the unit of the calculated item: U/L、IU/L、mmol/L、umol/L and so on. Set as [data dictionary-result unit],
High Value Normally	Upper limit of normal reference. When test concentration is higher than upper limit, then output test result will with a upper sign. Lower limit of normal reference. When test concentration is lower
Lower Value Normally	than lower limit, then output test result will with a lower sign.
Calc. Formula	Take IBIL for example: 1st step, click on 【Add】button. 2nd step, follow the formula as IBIL=TBIL-DBIL, clicks on the button as the sequence.  3rd , click on 【Save】button to save setting to database. Then the setting for IBIL calculated item will finish, user can see the IBIL calculated item name within Item column

5.6.3 Manual Item

<Manual> interface is used for setting manual item, such as HIV.
Manual item defined as the item which cannot be tested in analyzer but need to type with analyzer items. Or the item need to be typed by analyzer printer.

On the parameter interface, click “manual item” button, chose “manual item parameter set” as show in Fig 5-27 below:



5-27 Manual Item

Textbox of <Manual> interface are described as follow:

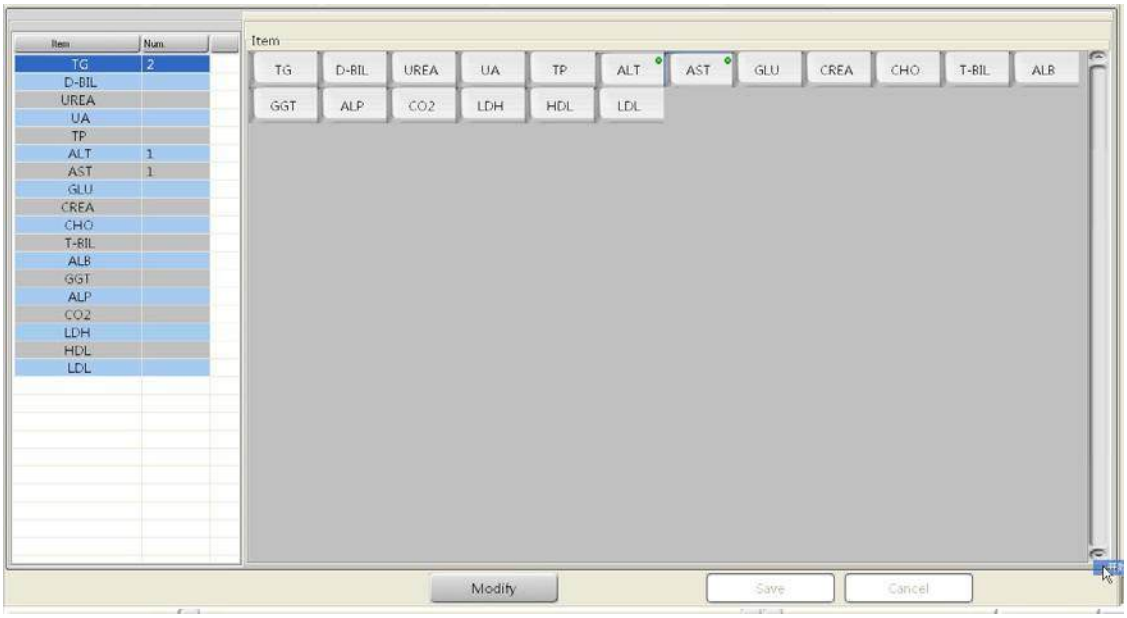
Textbox	Description
No.	Enter the serial number of manual item.
Item	Enter the name of manual item.
Full Name	Enter the full name of manual item.
Precision	Select precision of test result, qualitative item is not required select precision.
Result Unit	Select unit of test manual item: U/L、IU/L、mmol/L、umol/L and so on. Set as [data dictionary-result unit],
Property	Select quantitative item or qualitative item
Qualitative Reference	Select the referenced remark for qualitative item from positive, negative, weakly positive
High Value Normally	Upper limit of normal reference. When test concentration is higher than upper limit, then output test result will with a upper sign.
Lower Value Normally	Lower limit of normal reference. When test concentration is lower than lower limit, then output test result will with a lower sign.

⚠	Notice： When delete item, that should be deleted in print item simultaneously, otherwise it will go wrong. Print report item should be maintained in manual item interface. The item could not be printed without maintaining here.

5.6.4 Carryover

<Carryover> interface is used for setting carryover parameter:

System will auto dividing the items which will lead to carryover in the course of testing, if there are not enough item for dividing tested sequence, system will add a special cleaning procedure between the carryover items.



5-28 arryover

The method of setting carryover:

Select a certain item within *Item List* column and clicks on 【Modify】button, then click on the items button which will be leaded to carryover by the selected item, click on 【Save】button.

Example: TG has carryover influence with ALT and AST:

1st step，select TG from *Item List* column.

2nd step, click on 【Modify】button.

3rd step, click 【ALT】and 【AST】button, the green light of ALT and AST will lighting.

4th step, click on 【Save】button to save setting to database, finishing carryover setting.

5.7 Set

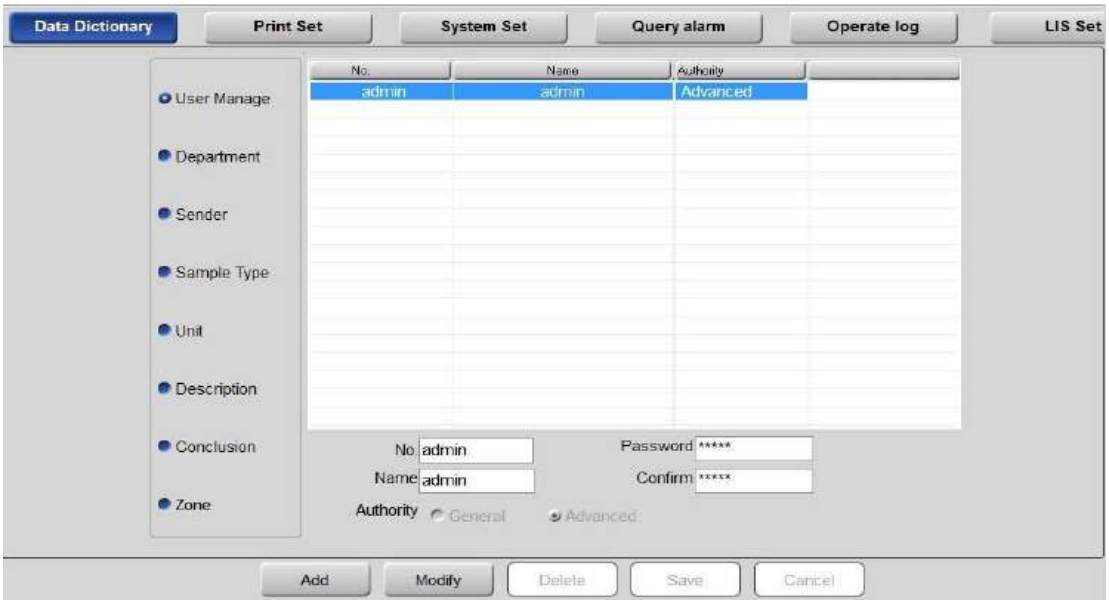
<Set> interface consists of 6 branching interface, as show in Figure 5-29 below, <Data Dictionary> interface is default.

5-29 Set interface

5.7.1 Data Dictionary

<Data Dictionary> interface is used for setting user managing information, bottle specification and corresponding parameter of test report.

Press “set” enter into acquiescent “data dictionary” as shown in Fig 5-30 below Data Dictionary.



5-30 Data Dictionary

Textbox of <User Manager> interface are described as follows:

Textbox	Description
No.	Enter number as the serial number for corresponding user, each user with one unique number.
Name	Enter the name of user
Password	Enter the password for the user
Confirm	Confirm the password for the user
Authority	Select authority for different user： Admin(advanced), manufacturer(manufacturer), service(super) can be selected

Parameters of <Data Dictionary> interface are described as follow:

Parameters	Description
Department	Enter the name, no. of department, like Clinical laboratory, editable and undeletable.
Sender	Enter the name, No. Sexuality, Department of sender, editable and undeletable.
Sample Type	Enter the type of sample, like Serum, Plasma, Urine, and CSF, editable and undeletable.
Unit	Enter the unit of corresponding items, set as U/L、IU/L、mmol/L、umol/L, editable, addable and undeletable.
Description	Enter the description for test result, user defined and

	added , like low, high, ↓, ↑.
Conclusion	Enter the conclusion for test result. user defined and added
Zone	Enter the zone name, like inpatient department. user defined and added
Reagent Bottle	Enter the specification of reagent bottle, set size is 20ml

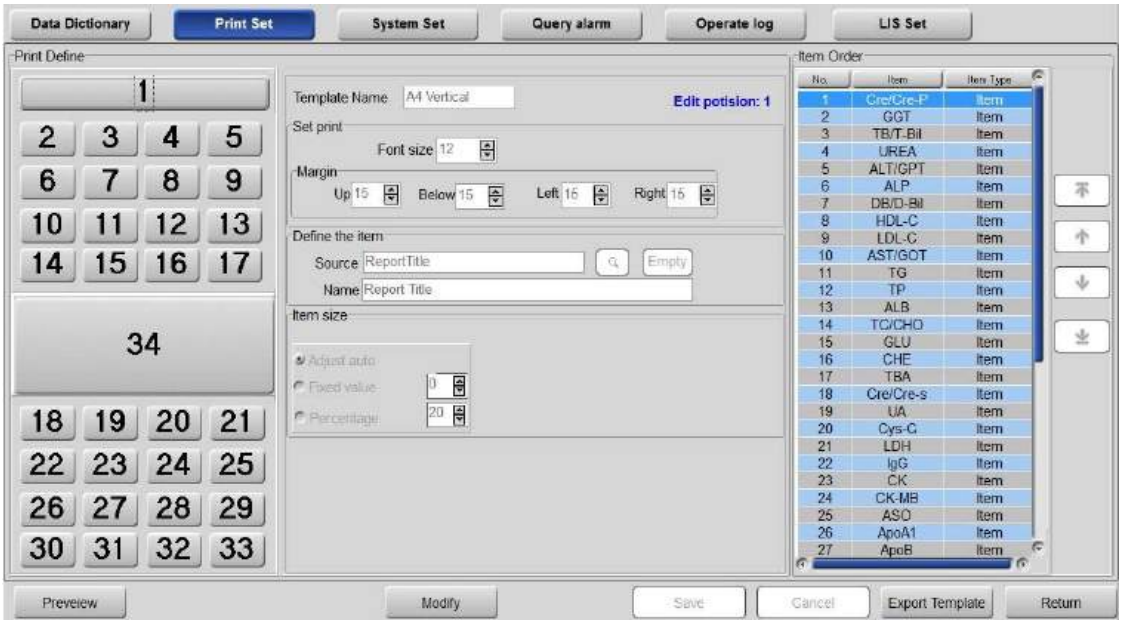
Note: 1. all the items must be included when arranging print order, including calculation items and manually added item. Otherwise the item cannot be printed if one item is not included.

Buttons of <Data Dictionary> interface are described as follows.

Buttons	Function
Add	Select a certain item, and click “Add” to input relevant parameters.
Modify	Select a certain item, and click this button to modify the relevant parameters
Delete	Select a certain item, and choose the related parameters need be deleted, click this button, and then it will pop-up dialog prompting "delete data, whether to continue?" Click "yes" to delete the item, click "no" to abandon deletion operation;
Save	This button is used for saving setting of corresponding parameter. After you finished inputting information, then click this button for save.
Cancel	This button is used for canceling current parameter editing. If you inputted wrong information, then click this button to cancel.

5.7.2 Print Setting

<Print Set> interface is used for editing test report format, after a test is completed, we need to print the test report, and we can self-define a print report format, click "Settings", then select "Print Set" interface, and then select a template, click on the【Edit】 button, enter into the print format defined interface, as shown in figure 5-31



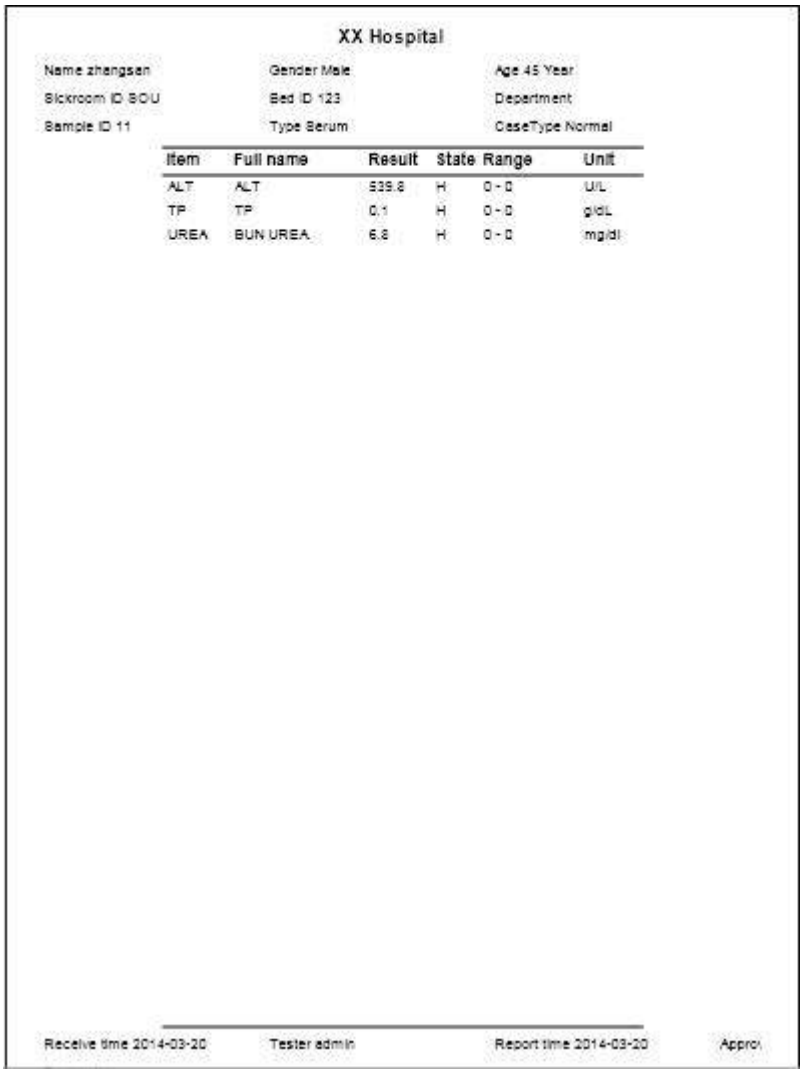
5-31 Print setting

The left area is the self-defined area for printing format. User can print test report by self-defined format. On the right side is the definition for item print order. The default order is basic item, calculation item and manually inputted item, and this order can be changed according to the user's requirements.

Items print order definition buttons are described as follows.

First	Select one item, then click this button, the current item will move to the first in print order.
up	Select one item, then click this button, the current item will move one item ahead in print order.
Down	Select one item, then click this button, the current item will move one item down in print order.
Final	Select one item, then click this button, the current item will move to the last in print order.

The default print report format is as follows:



5-32 Print Report Format

5.7.3 System Setting

<System Set> interface is used for setting machine model, hospital information, report title, test result statement, AD value and so on. Every hospital have their own uniform format, these information can only be modified but not deleted.

Click【Setting】，select <System Set>，shown as figure 5-33

5-33 System set

<System Set> interface are described as follow:

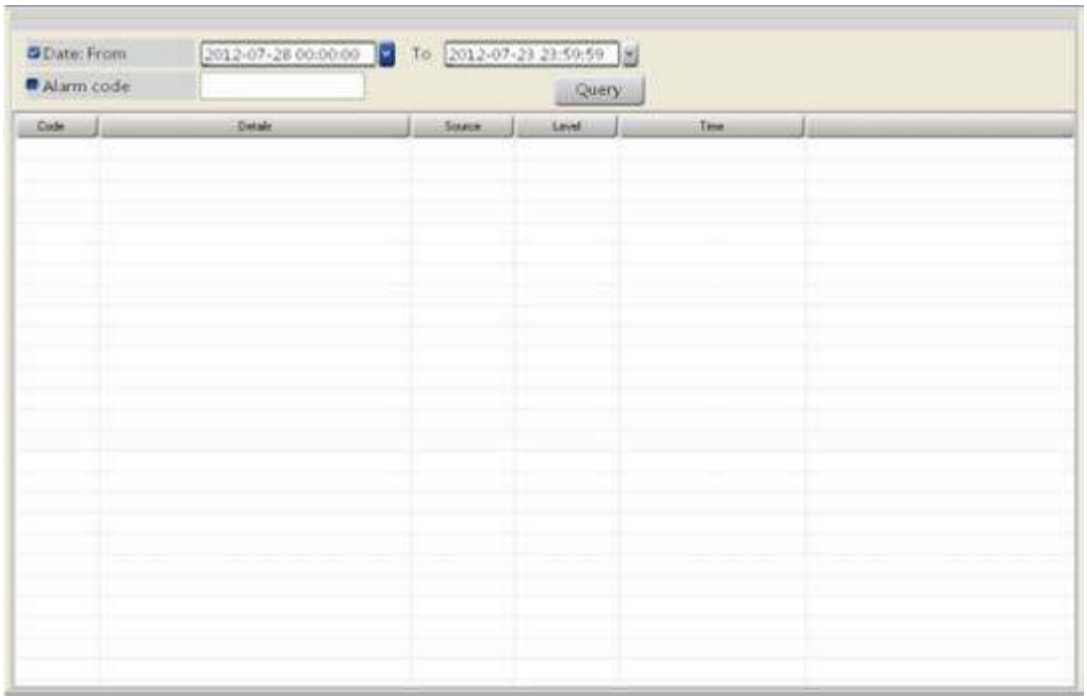
Machine Model	Show the model of the instrument.
Hospital Name	The name of hospital
Report Title	Edit the title of test report.
Test Declaration	Edit the test result statement

Buttons of <System Set> interface are described as follow:

Buttons	Description
Modify	Click on this button and modify corresponding parameters.
Save	This button is used for saving system setting to database after finished information inputting.
Cancel	This button is used for cancelling current edit if input some wrong information.

5.7.4 Alarm Query

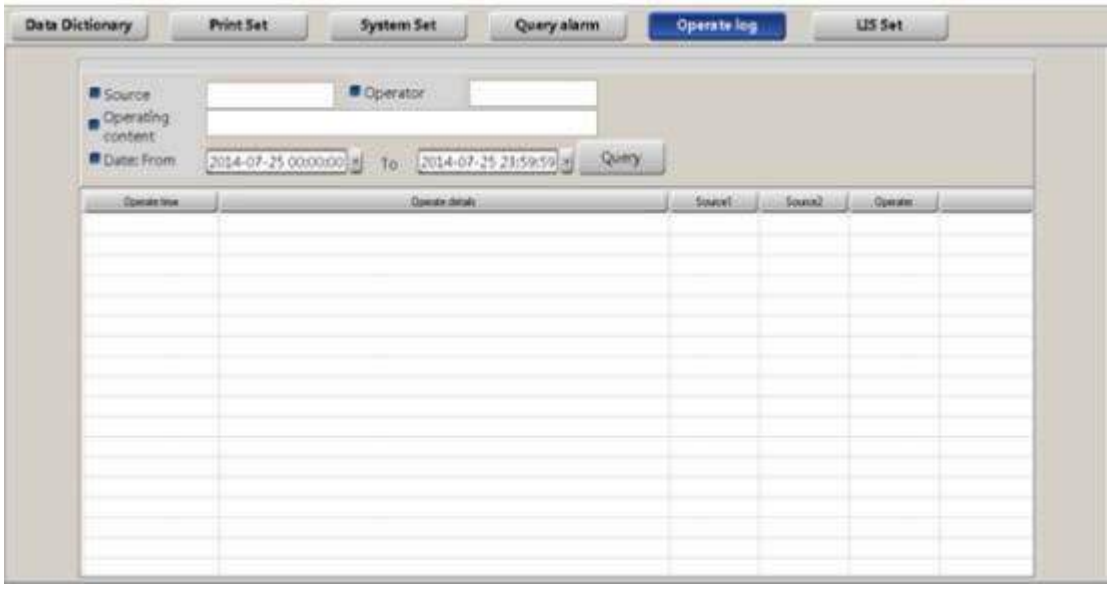
< Alarm Query > interface is used for querying alarm information by date or alarm code. Click 【Setting】， select < Alarm Query >， then will enter in to < Alarm Query > interface, shown as figure 5-34



5-34 Alarm Query

5.7.5 Operation log

<Operation log> interface is used for querying operation log by source, operator, operation content and date. Click【Setting】，select <operation Log>，then will enter in to < operation Log > interface, shown as figure 5-35

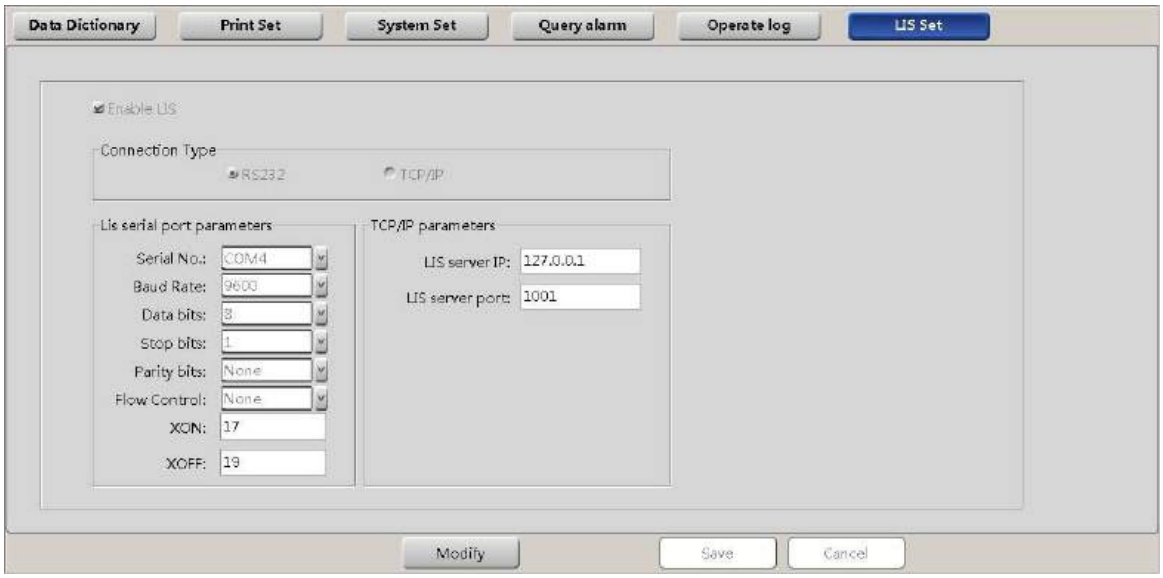


5-35 Operation Log

5.7.6 LIS Setting

LIS is an external host, through the fixed interface connected to the analyzer, used to download sample application information from analyzing unit, and receive sample test results from the analyzing unit. Before using LIS to download sample application information and transmit sample results, you need to set up the LIS communication parameter and results input mode. Before using LIS function, make sure that already selected the LIS. If not, please contact with the company's customer service or contact area agents.

Users can set whether to enable the LIS and set the LIS connection mode and parameters. Click "Settings", select "set the LIS", enter "LIS Settings" interface, as shown in figure 5-36



5-36 LIS Setting

The LIS setting interface parameter specifies as the followings:

Enable the LIS set whether to enable the LIS, the LIS is not enabled by default.

Connection mode set the connection mode of the LIS, there are RS232 and TCP/IP connection respectively (currently only supports the RS232 connection for Lis)

The LIS serial port parameters Settings:

Serial port Choose the serial port which attached LIS server computer.

Baud rate Allowed set to 300, 1200, 2400, 4800, 9600 and 19200, the default is 9600.

Data bits Allowed set to 7 or 8, the default is 8.

Stop bits Allowed set to 1 or 2, the default is 1.

Check bit Allowed set to black and white check or parity checking, the default is no.

Flow control bit Allows set to no, RCS/TCS or XON/XOFF, the default is no.

XON XON default setting is 17.

XOFF XOFF default Settings is 19.

TCP/IP parameters settings

The LIS server IP Set the LIS server's IP address.

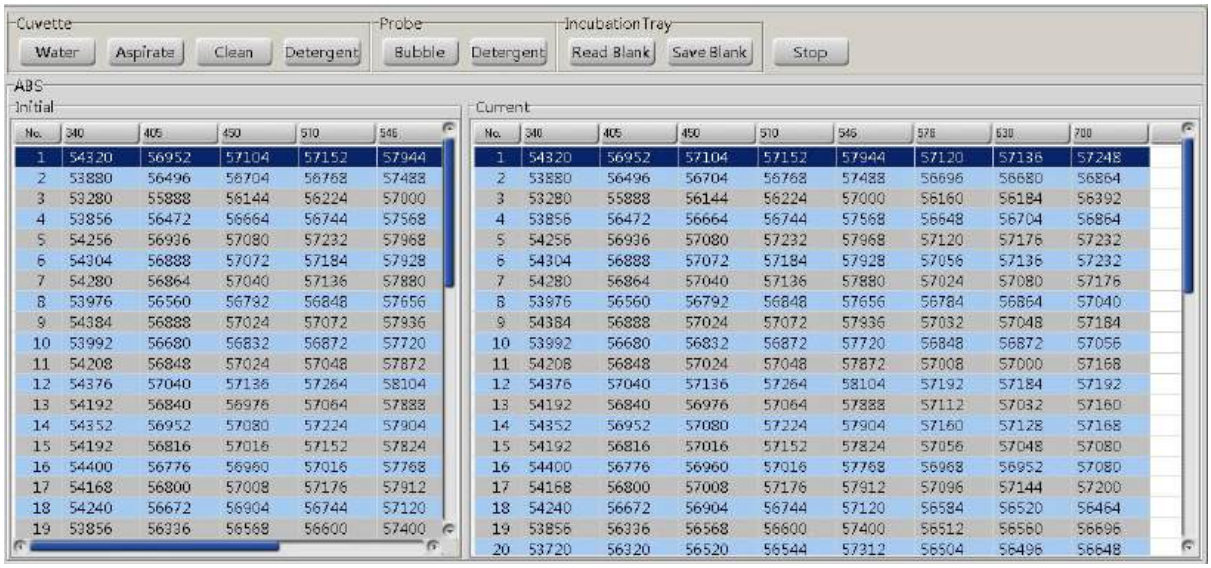
The LIS server port Set the LIS server port/

5.8 Maintenance

Click “Maintenance” button in the main operation interface, and enter into the <maintenance> interface, which is mainly used for daily maintenance, maintenance debugging, etc. <Maintenance> interface are divided into three pages, namely, <daily maintenance>, <instrument detection> and <absorbance test>, the default interface is <daily maintenance>.

5.8.1 Daily Maintenance

Click on the 【Maintenance】button, then will enter the <daily maintenance> interface, Shown as figure 5-37. It will run such daily maintenance as cleaning, aspirating, etc. We can check the cleaning status of all cuvettes by reading the absorbance of the 48 cuvettes.



5-37 Daily Maintenance

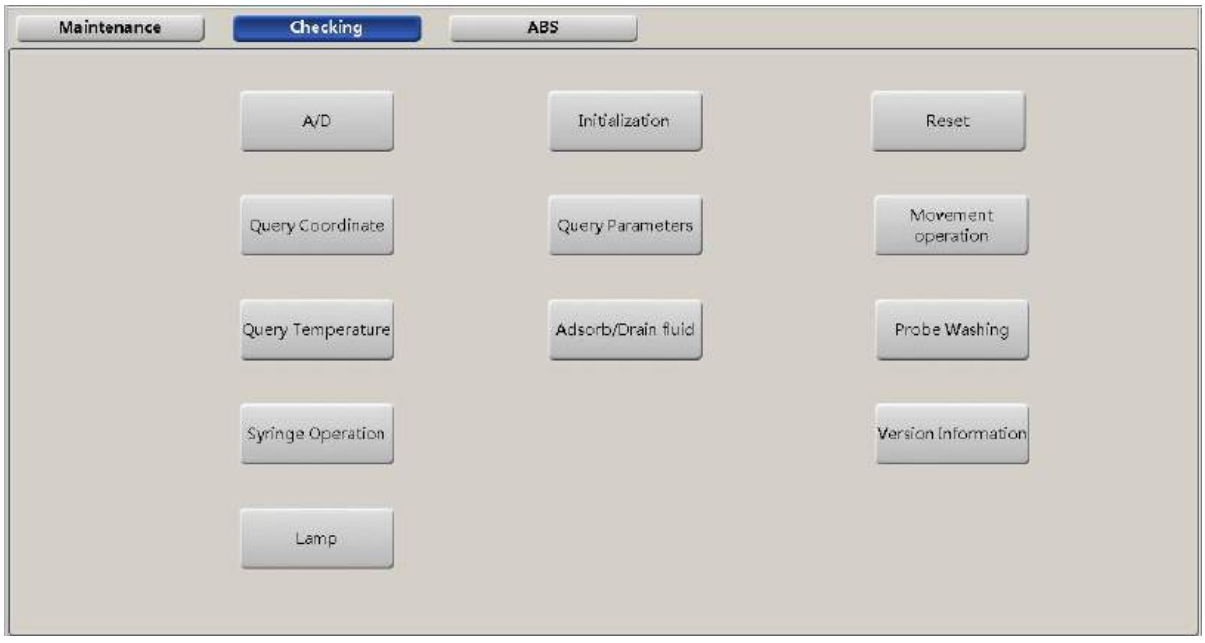
Buttons of **<Daily Maintenance> i**nterface are described as follow:

Buttons	Function
Add Water	This button is used for adding water to cuvettes, click STOP, then will stop the operation and reaction disk will reset to Zero. (5 series analyzer without this function)
Aspirate	This button is used for aspirating water or detergent from reaction cuvettes, click STOP, then the operation will be stopped and reaction disk reset to Zero. (5 series analyzer without this function)
Clean	This button is used for cleaning all cuvettes, click STOP,, then the operation will be stopped and reaction disk reset to Zero. (5 series analyzer without this function)
Add detergent	Set the position for two kinds of wash solution, and then wash the cuvettes. (5 series analyzer without this function)

Bubble	This function will remove out bubble from syringe, the user should put Bubble exhaust tool in G-10 position if need.
Special solution	Set position for wash solution to do probe cleaning
Read Blank	This button is used for reading absorbance of the cuvettes filled with water.
Save Blank	After reading ABS data of the cuvettes filled with water, click on this button to save the current ABS data as initial blank.
Stop	Click on this button to stop reading the blank data.

5.8.2 Checking

When the machine happens malfunction, user can test the status of corresponding motional components by **<checking >** interface to find out the cause of failure. Click on the【Maintenance】button, then will enter into the < checking > interface, shown as figure 5-38



5-38 Checking

Each buttonare describedas below:

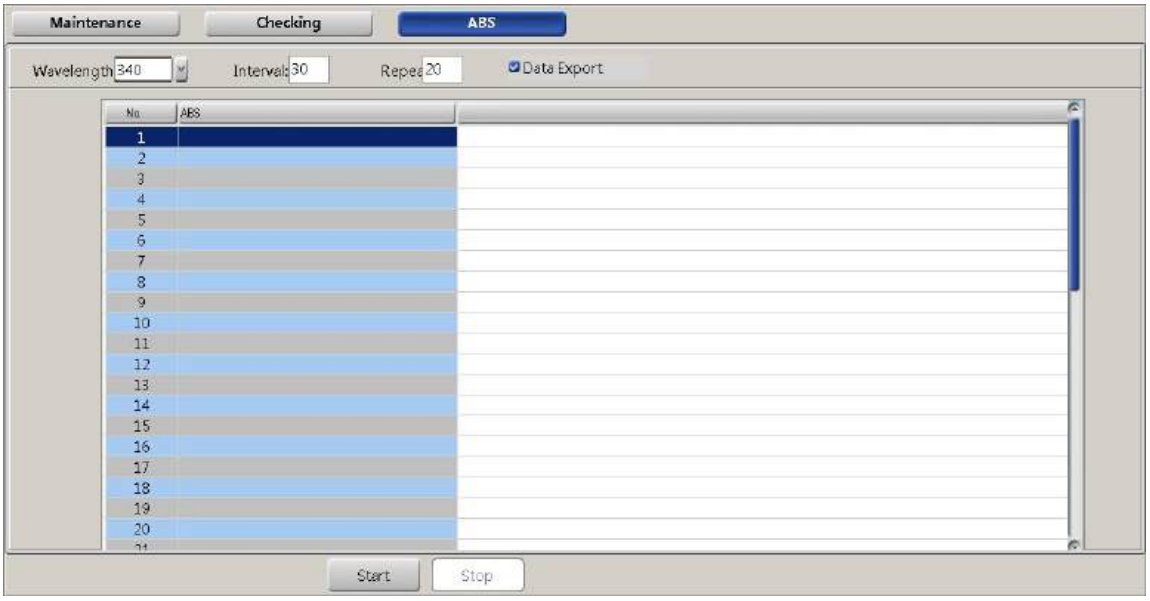
ButtonName	Description
A/Dreading	Each wavelength signal readings
Initialization	Systemreset forinstrument wholeparts
Reset	Mechanical reset for instrumenteachparts, reset to current position,checking the zero position calibration.
Coordinate query	Querythe coordinate value of instrument parts

Parameter Query	Query the parameter value of instrument parts
Movement operation	Movement checking for instrument each part
Temp. Query	Click【Temp Query】button,reactionplate temperature will be displayed at thesoftware interface upper right position.
Aspirate/Dispense	Aspirate and dispense at the appointed target position, then do mixing and checking.
Needle washing	Click【Neddle washing】button,willprocess needle washing checking.
Syringe operation	Operating through a syringe, can check if the syringe aspirating and dispensingvolumeaccurate or not.
Version	Queryversion info, including:software version, Mechanical Version and firmware version
Lamp info	Query the lamp usage time
Parameter backup	The backup and restore of parameters

Details please refer to the service manual.

5.8.3 Absorbance test

According to machine performance test requirements, the user can enter into this program module and check the absorbance test. Shown as figure 5-39



5-39 Absorbance test

6 Analysis Method

6.1 Analysis Method

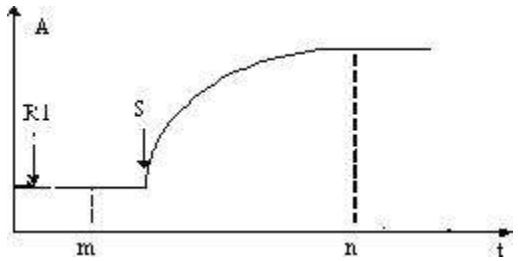
The system provides three reaction analysis methods for measurement:
Endpoint method
Fixed-time method
Kinetic method

6.1.1 Endpoint Method

Endpoint method means the reaction reaches equilibrium after a period of reaction time. Because the equilibrium constant is very large, it can be considered that all substrates have changed into outcomes, and absorbance of the reactant will not change any more. The absorbance change is directly proportional to the sample concentration. This kind of method is often called "endpoint" method, or rather it shall be called "balance" method, this is the most ideal type of analysis.

The endpoint method is insensitive to minor changes of such reaction conditions as amount of enzyme, pH value and temperature; as long as the changes do not affect the reaction reaching to equilibrium within a certain time.

6.1.1.1 Single-reagent Endpoint method



6-1 Single-reagent Endpoint reaction curve

As Figure 6-1 indicates, R1 is the time adding the first reagent, S is the time adding the sample. M,n is the reaction test time.

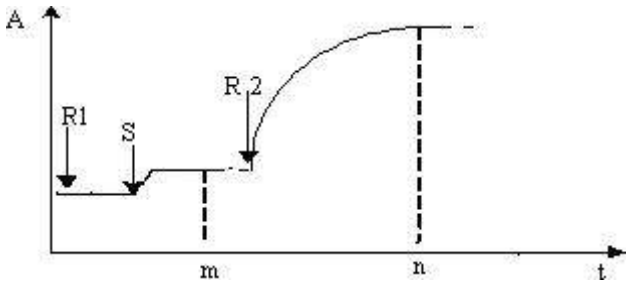
◇ Input reaction time in the **<Item Set>** interface as follow:

Reaction time: m and n	1≤m≤5, m<n, 10≤n≤35

Am is reagent blank, and the An is the final sample absorbance;

The calculation of absorbance：A=An-Am；

6.1.1.2 Double-Reagent Endpoint method



6-2 Double-reagent Endpoint reaction

As Figure 6-2 indicates, R1 is the time adding the first reagent, S is the time adding the sample. R2 is the time adding the second reagent. M,n is the reaction test time..

◇ Input reaction time in the **<Item Set>** interface as follow::

Reaction time: m and n	7≤ m ≤ 9 When 1≤ m ≤5 is reagent blank, 7≤ m ≤9 is sample blank

Am is sample blank, and the An is the final absorbance;

The calculation of absorbance：A=An-Am；

6.1.2 Fixed-Time Method

Fixed-time method (namely, first-order kinetic method), the reaction velocity (v) within a specific period, is directly proportional to the substrate concentration [C], namely, v=k[C]. As the substrate is consumed continuously, the reaction velocity decreases accordingly, it shows as the absorbance increase or the declining velocity comes down. It takes much time for such reaction to reach equilibrium. Theoretically, the absorbance reading can be taken at any time. The reaction can, however, become steady only after a delay because the reaction is complicated in the beginning and there are miscellaneous reactions due to complex serum compositions.

For any first order reaction, the substrate concentration [S] at a given time after the start of the reaction is given by the following:

$[C]=[C_0]\times e^{-kt2}$

[C0] - -initial substrate concentration

e- -base of the natural log

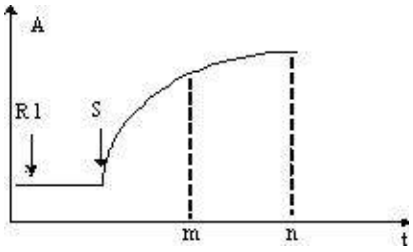
k- -velocity constant

The change in substrate concentration -Δ[C] over a fixed time interval, t1 to t 2, is related to $[C_0]$ by the following equation:

$$[C_0]=\frac{-\Delta[C]}{e^{-kt1}-e^{-kt2}}$$

That is to say, within a fixed time interval at T_m~T_n, the change in substrate concentration is directly proportional to its initial concentration. This is the general property of first-order reactions. Within this interval, absorbance change (increase or decrease) is directly proportional to the sample concentration. The fixed-time method is also known as the Initial rate method; first order kinetic method, two point kinetic method etc.

6.1.2.1 Single-reagent Fixed Time Method



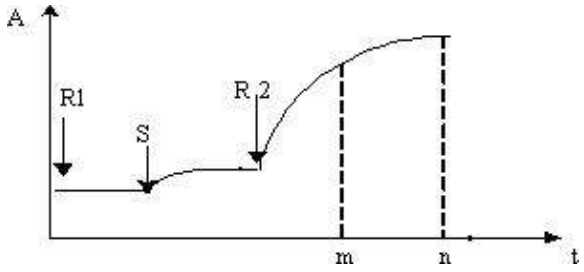
6-3 Single-reagent Fixed-time Reaction Curve

As figure 6-3 indicates, R1 is the time adding the first reagent, S is the time adding sample. M, n is the reaction test time.

◇ Input reaction time in the **<Item Set>** interface as follow:

Reaction time: m and n	7 ≤m<n ≤35

6.1.2.2 Double-reagent Fixed Time Method



6-4 Double-reagent Fixed-time Reaction Curve

As figure 6-4 indicates, R1 is the time adding the first reagent, S is the time adding sample. M, n is the reaction test time.

◇ Input reaction time in the **<Item Set>** interface as follow:

Reaction time: m and n	10<m<n ≤35

6.1.3 Kinetic Method

Kinetic method (namely, zero-order kinetic method), the reaction velocity is not related to substrate concentration and remains constant during the reaction process. As a result, for a given wavelength, the absorbance of the analytes changes evenly, and the change rate (ΔA/min) is directly proportional to the activity or concentration of the analytes. The kinetic method is usually used to measure enzyme activity.

In fact, it is impossible for the substrate concentration to be high enough, and the reaction will be no longer a zero-order reaction when the substrate is consumed to a certain degree during reaction period. Therefore, the theory only stands within certain period. In addition, the reaction can become steady only after a certain period of delay time, because the reaction is complicated at the beginning and there are miscellaneous reactions due to complex serum compositions. Therefore, all reagent manufacturers are regulating strictly with this two period time.

In Kinetic reaction, the concentration or activity is obtained according to absorbance change among specified measuring points.

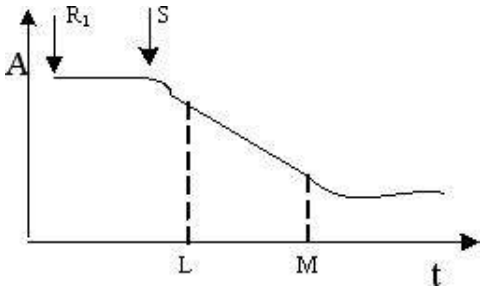
The Kinetic method is available in single-interval Kinetic and double-interval Kinetic according to input mode of measuring points.

Determination of Linearity Range

The absorbance linearity range should be determined based on the substrate depletion limitation.

You should determine the linearity range within the reaction time, but not during reagent blank period.

6.1.3.1 Single-reagent Kinetic Method



6-5 Single-reagent Kinetic Reaction Curve

As figure 6-5 indicates, R1 is the time adding the first reagent, S is the time adding sample, m and n are the reaction test time.

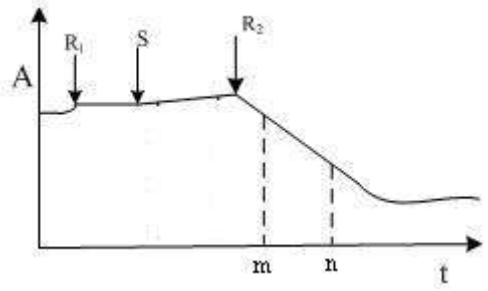
◇ input the reaction time in **<Item Set>** interface as follow:

Reaction time: m and n	5 < m < n ≤ 35

Absorbance calculation: R = ⊿ A_{mn}

⊿ shows the absorbance changing rate per minute between the photometry point (m, n) (response curve slope).

6.1.3.2 Double-reagent Kinetic Method



6-6 Double-reagent Kinetic Reaction Curve

As figure 6-6 indicates, R1 is the time adding first reagent, S is the time adding sample, R2 is the time adding second reagent, m and n are the reaction test time.

◇ input reaction time in the **<Item Set>** interface as follow:

7 System Specification

Test Speed	Constant speed from 100 to 120 Test/Hour
Configuration	Host + PC
System	Discrete, Multi-channel, Multi-item
Test Method	End Point, Kinetic, Fixed Time
Test Item	Defined by software, Request one by one, provide profile, calculate item and manual item.
Sample Volume	2～100uL,0.1μl stepping
Sample Rack	3 sample racks, the first two racks can hold 10 cups for each, the last rack can hold 2 cups
Sample Position	22 sample cups or tubes, position can be defined by operator.
Probe	Liquid level detect and vertical collide protect.
Probe Wash	Both inside and outside
Reagent 1	180～350μl, 1μl stepping
Reagent 2	0~200μl, 1μl stepping
Reagent Rack	5 sample racks, each sample rack can hold 10 cups
Online Reagent	50 positions, suit for our 20ml special bottle.
Reagent	All open, can choose any qualified reagent brands at home and abroad.
Cuvette	Optical diameter is 5.8 mm, recyclables.
Reaction Volume	180~450μl
Incubation	48 cuvettes
Wavelength	340nm，405nm，450nm，510nm，546nm，578nm，630nm，700nm,
AD Range	0~3.8Abs
Calibration	Linear / Non-linear, single point/ multi-point calibration
QC	Westgard multi-rule, L-J plot
Mix mechanism	Sample probe mix with eccentric wheel.
Wash mechanism	6 steps auto washing the cuvettes
Sample Probe	Intelligence sample probe liquid level detection, with the amount of tracking, allowance alarm collision protection, the needle inside and outside wall cleaning to prevent cross contamination.
Reaction curve	real-time reaction curve, within fixed time to read an absorbance.
STAT	Support emergency at any time to give automatic priority detection.
Light Source	6V/10W halogen tungsten lamp.

Spectral Method	by filters, then spectroscope with forward method
Half Wave Width	≤10nm
Reaction Temperature	37±0.1℃, solid direct heat mode
Data processing	Storage and output of various types of data and charts, items calculation.
Dimensions	Length×Width×Height: 520×512×440mm
Weight	37kg
Operating system	Windows system
Interface	RS-232
Printer	Decided by Windows system, optional
Power Source	AC 90/264V, 50/60Hz
Power	≤300VA
Work Environment Temperature	15℃～30℃
Relatively Humidity	35%～80%.
Water Consume	3L/H
Detergent Dosage	0.5ml/cuvette (Optional accessories)
bucket	Length330mm/width200mm/height400mm Capacity 25L, Mouth Diameter 45mm

8 Maintenance and Service

To ensure reliability, good performance and life span of the system, regular maintenance is required. Be sure to follow the instructions which given below to maintain the system. Even there is only one operator, it's very important for you to learn this chapter. Your thorough understanding will help you obtain the best performance of the system.

In case of problems beyond your ability or not covered in this chapter, be sure to contact our Customer Service Department or your local distributor.

	WARNING: Do not perform any maintenance procedures that are not described in this chapter. Do not touch the components other than the ones specified in this chapter. Performing unauthorized maintenance procedures can damage your system, void any applicable warranty or service contract and even cause personal injury. After performing any maintenance actions or procedures, ensure that the system runs normally. Do not spill water or reagent on the mechanical or electrical components of the system.

	BIOHAZARD: Wear gloves and lab coat and, if necessary, goggles during maintaining process.

8.1 Maintenance Preparation

The following tools may facilitate your maintenance. Such as intensity detergent and alcohol and so on.

8.1.1 Tools

Hex wrenches (M1.5, M3 and M4)
Cross-headed screwdrivers (large, medium and small)
Needle tube
Tweezers
Clean gauze
Scissor

8.1.2 Other

Clean with water-free alcohol except the syringe.
Forbid using alcohol to clean syringe assembly.
Disinfector

8.2 Weekly Maintenance

8.2.1 Clean Sampling Probe

	CAUTION： To prevent injury, exercise caution when working around the sample probe.

	BIOHAZARD: Wear gloves and lab coat and, if necessary, goggles. Dispose of the used gauze in accordance with your local or national regulations for biohazard waste disposal

1. Confirm the Power is OFF.
2. Use ethanol-dipped gauze to gently clean the exterior of the sample probe until it is clean and smooth, especially for the probe tip cleaning。
3. Wipe the sample probe with DI water-dipped gauze。
4. Power on, Wait for about 30 seconds and then execute <Initialization> on the <Maintenance> interface. The system will reset the sample probe and rinse probe with DI water。

	CAUTION: The tweezers may scratch the probe, Exercise cautiously when using it to clean the probe. Avoid direct contact between the tweezers and the probe. Do not use excessive force when cleaning the probe. Otherwise it may bend.

	NOT: We recommend the acid and alkaline detergents be used alternately for this purpose. For instance, if the acid detergent has been used for last maintenance, the alkaline detergent had better be used for this time.

8.2.2 Clean Sample Rack/ Storage

	CAUTION： To prevent injury, exercise caution when working around the sampling probe.

	BIOHAZARD: Wear gloves and lab coat and, if necessary, goggles. Dispose of the used gauze in accordance with your local or national regulations for biohazard waste disposal

1. Confirm the Power is OFF.
2. Open the cover door of sample rack, then follows the guiding track to take out sample rack.
3. Clean sample rack by pure water and wipe it by gauze.
4. Clean interior of sample storage by gauze. If necessary, adopt detergent or sanitizer to do the cleaning.
5. Re-assembling sample rack, follow the guiding track to put sample rack into sample storage, then close the cover door of sample storage.

8.2.3 Clean Reagent Rack/ Storage

	CAUTION： To prevent injury, exercise caution when working around the sampling probe.

	BIOHAZARD: Wear gloves and lab coat and, if necessary, goggles. Dispose of the used gauze in accordance with your local or national regulations for biohazard waste disposal

1. Confirm the Power is OFF.
2. Open the reagent storage gate, and then follows the guiding track to pick out reagent rack.
3. Clean reagent rack by pure water and wipe it by gauze.
4. Clean the drops interior of reagent storage by gauze. If necessary, adopt detergent or sanitizer to do the cleaning
5. Re-assembling reagent rack, follow the guiding track to put reagent rack into reagent storage, then close the cover door of reagent storage.

8.2.4 Clean Cover Panel of Analysis Unit

	CAUTION： To prevent injury, exercise caution when working around the sampling probe.

	BIOHAZARD: Wear gloves and lab coat and, if necessary, goggles. Dispose of the used gauze in accordance with your local or national regulations for biohazard waste disposal

1. Confirm the Power is OFF.
2. Clean the cover panel of analysis unit by gauze, if necessary, adopting some water or sanitizer to do cleaning.

9 Common Faults and Troubleshooting

When finding any abnormality in the analyzer, the operator should check the following:
Reagent configuration and preservation methods
Sample preparation and preservation methods;
Equipment operating procedures; Maintenance.
Common faults phenomenon and simple troubleshooting as follows:

	Faults	Troubleshooting
1	No power after turn on the machine	Check the power plug and instrument fuse.
2	Lamp does not light	Check whether the lamp is burned out, the power of lamp is 6V. If the lamp is broken, please replace the lamp.
3	The probe doesn't rinse water	Check if the connection pipeline is loose or blocked, or if syringe pump doesn't work. Fasten or clean the pipeline if it is loose or blocked; replace the syringe pump if it doesn't work.
4	The volume of sampling is not accurate	Check whether the syringe is leaking, or the connection tube leaks, or the probe is blocked. If it is, please deal with the connection tube and replace the syringe.
5	The position of sampling probe is not correct	Check/adjust the position of sampling probe.
6	Test results of an item is not correct	Check the condition of sample and reagent, observe the other items within the same wavelength whether is normal, if all the results are not correct, may need to replace the filter.

	Attention: Non-professional maintenance personnel are forbidden to move or dismantle the machine. If the faults can't be solved, please contact with service engineers.

10 Packaging, Storage, Transportation

Instrument net weight: 37kg, gross weight: 56kg.

The package of instrument is adopting hard carton box, and the interior part adopts high-quality EPE foam, which is rugged, and shockproof.

The instrument package features a simple shockproof facilities, suitable for shipping by air, rail, road and ship, but should be avoid of rain and snow splashing, inversion and collision

If the instrument storage humidity is more than 85%, it should be removed from the storage, power on at least 4 hours, then follows the direction by the storage to place machine in the warehouse.

In normal storage condition, every three months the instrument should be removed from the storage, power on at least 4 hours, then follows the direction by the storage to place machine in the warehouse.

Machine should not be stacked, or close to the ground, walls and roofs.

Transportation environment should be conformed to: Temperature: -20 ℃ ~ +55 ℃; Relative humidity: ≤ 85%.

Storage environment should be conformed to: Temperature: -10 ℃ ~ +40 ℃; Relative humidity: ≤ 85%.

Remark of package :

FRAGILE

THIS WAY UP

KEEP AWAY FROM RAIN

KEEP AWAY FROM SUNLIGHTS

DO NOT ROLL

TEMPERATURE LIMIT

CE

The device fully complies with the requirements of the European Council Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Manufacturer: Dezhou Guoke Medical Technology Co., Ltd.

Add: 28-31 axis.1 and 2 span.No.2 workshop, (Zhongyuan Science and Technology Innovation Park) No.6596 Dongfanghong East Road, Yuanqiao Town, Economic and Technological Development Zone, Dezhou City, Shandong Province, China

EU- Representative: **RIOMAVIX SOCIEDAD LIMITADA**

Add: Calle de Almansa 55, 1D, Madrid 28039 Spain

Tel: +34 658 396 230

Email: riomavix@gmail.com

SRN: **ES-AR-000001202**

Banyan RR®

To achieve more accurate detection results.

CE

User Manual

Semi-auto Chemistry Analyzer

CATALOGUE

Introduction

Welcome to use the Semi-auto Chemistry Analyzer of our company.

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

All contents of this manual have been prepared in strict accordance with relevant national laws and regulations and our company's technical specifications.

Safety inspection requirements are based on IEC 61010-1:2001 "Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1 General Requirements".

The environmental test requirements are grouped and selected according to the environmental test conditions in Table 1 of GB/T14710-2009 "Environmental Requirements and Test Methods for Medical Electrical Equipment". The climatic environmental test is group I and the mechanical environment is group Ⅱ.

Product Name: Semi-auto Chemistry Analyzer

Model：CAS60,CAS70,CAS80,CAS90

This product is for professional use only！

The company will continue to improve product functions and quality, so it reserves the right to improve the technical performance of products, software programs and the contents of this manual without prior notice.

The pictures in this manual are schematic diagrams and are for reference only. If it is not the same as the actual product, the actual product shall prevail.

The instruments, Biochemistry analyzers mentioned in this manual refer to Semi-auto Chemistry Analyzer.

The company has the intellectual property rights and final interpretation rights of this instruction manual and its corresponding products.

Semi-auto Chemistry Analyzer sold directly by our company or sold by authorized

distributors have a warranty period of one year from the date of installation. However, consumables, wearing parts and damage caused by abnormal use are not covered by the warranty. For details of replacement of spare parts and out-of-warranty maintenance, please refer to the sales contract and the relevant provisions of our after-sales service.

If the instrument fails, please keep the relevant samples and contact our after-sales service department immediately. Only our company or distributor can inspect or provide any parts of the instrument. If the failure of the instrument cannot be solved through telephone guidance, our company will send professional engineers or authorized professional engineers to provide you with services.

NOTE

- This instrument must be a qualified medical laboratory professional with clinical biochemical training or a trained medical staff or laboratory operator. And all users can use or provide maintenance after they are trained by qualified engineers authorized by our company.
- The user must ensure that the instrument is used under the conditions specified in the instruction manual. If the usage conditions are exceeded, the instrument may not operate normally, the measurement results will be Unreliable, and other accidents.
- The user must calibrate and maintain • the instrument in accordance with the requirements of the manual during use. If calibration and maintenance are not performed in accordance with the regulations, causing instrument failure or other problems, our company will not assume corresponding responsibility.
- If the user does not use the instrument according to the method specified in the instruction manual, the protection provided by the instrument may be damaged.
- The company considers it responsible for the safety, reliability and accuracy of the product only when all the following requirements are met, namely:
  1. Users need to operate and maintain strictly in accordance with the provisions in this instruction manual;
  2. The installation, upgrade and maintenance of the Semi-auto Chemistry Analyzer are performed by our company's engineers or engineers authorized by our

company;

3. Users can choose reagents, controls and calibrators from other vendors. And these matching supplies are confirmed to be suitable for our company's instruments without accidental errors;
4. The user should test the controls before the formal testing of the sample daily, and confirm that the controls test meets the controls requirements before the clinical sample testing.

- The company will not bear free warranty service even if the following situations occur:
  1. Not using the power supply (voltage, frequency) specified by the company, and failure caused by abnormal power supply;
  2. Failure caused by corrosion and deterioration of pipelines caused by impure substances mixed in pure water used by customers;
  3. Circuit corrosion and obvious aging of optical components caused by strong corrosive gas in the air;
  4. Failure caused by using hardware, software, etc. not provided by the company;
  5. Failures caused by usage methods other than those described in this manual;
  6. Failure caused by the non-our company or unauthorized maintenance;
  7. Failure caused by maintenance not performed in accordance with company regulations;
  8. Malfunctions caused by unauthorized disassembly or modification;
  9. Accidents caused by fire, earthquake, flood, lightning strike, crime, riot, war, harmful substances and other irresistible natural disasters;
  10. Malfunctions due to computer viruses.

Safety and Precautions:

To use the instrument safely, please read the following safety precautions carefully. Any operation that violates the following safety precautions may cause system damage and personal injury.

 **Warning：**

- If the user does not follow the instructions of XXX Company, the protection measures provided by this system may be invalid.

Prevent electric shock

To prevent electric shock, observe the following precautions.

 **Warning：**

- Back and side covers mustn't be opened when the power is on, except by authorized service personnel.
- If liquid enters the instrument or leaks from the instrument, immediately turn off the power and contact the company's after-sales service department or the distributor timely. Improper handling of liquids can cause electric shock and damage to the system.

Prevent personal injury from light sources

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

 **Warning：**

- When the instrument is working, do not look directly into any beams to prevent possible damage to your eyes.
- Before replacing the light source, disconnect the power source and wait at least 30 minutes until the light source cools down. Do not touch the light source before it cools down to avoid burns.

Prevent biochemical hazards

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

 **Biohazard:**

- Incorrect use of samples may cause contamination. Do not touch samples, mixtures and waste liquid directly with your hands. Always wear gloves and work clothes to prevent contamination during operation, and wear protective glasses if necessary.
- If the sample accidentally comes into contact with the skin, please immediately dispose of it according to the working standards of the user and consult a doctor.
- Some reagents are strongly acidic or alkaline. Handle reagents carefully to prevent direct contact with hands and clothing. If hands or clothes accidentally come into contact with the reagents, immediately wash them off with soap and water. If the reagent accidentally gets into the eyes, immediately rinse with plenty of water and consult an ophthalmologist.

Dispose of waste liquid

To prevent environmental pollution and personal injury caused by waste liquid, please

observe the following precautions when handling waste liquid.

 **Biohazard:**

- Some substances in reagents, quality control solutions, calibration solutions, cleaning solutions, and waste solutions are subject to pollution regulations and discharge standards. Please reach out to local emission standards and consult with the relevant reagent manufacturer or distributor.

Prevent fire and explosion

To prevent fire and explosion, observe the following precautions.

 **Warning：**

- Do not use flammable or hazardous materials near the instrument.

Precautions for use:

In order to use this system correctly and effectively, please read the following precautions carefully.

Use environment

 **Caution：**

- Install the instrument correctly in accordance with the installation environment specified in this instruction manual. Installation and use of the instrument outside the specified conditions may yield unreliable results and may cause system damage.
- If you need to change the system status, contact our company's service department or dealer.

System maintenance

 **Caution：**

- Follow the instructions in this instruction manual to maintain the instrument. Improper maintenance may lead to incorrect analysis results and may even cause damage to the instrument or personal injury.
- If the instrument is left for a long time, dust may accumulate on the surface. When cleaning, use a clean soft cloth soaked in water to wring, and gently wipe the surface. Do not use organic solvents such as alcohol. After cleaning, wipe the surface with a dry cloth.

- Before cleaning, please turn off the power of the instrument and unplug the power cord. During the cleaning process, take necessary measures to prevent water droplets from entering the instrument, otherwise it may cause system damage or personal injury.
- Replacement of main components, such as light source, must be calibrated and analyzed.

Chapter 1. Instruction Manual

This chapter introduces how to use the “Instruction Manual for Semi-auto Chemistry Analyzer”. The "Instruction Manual for Semi-auto Chemistry Analyzer" is included with the machine. It explains the principle, purpose, function, operation and maintenance of the instrument in detail. Before using the instrument, please read this manual carefully to ensure that the instrument can be used correctly to achieve its best performance, and to ensure the safety of the operator.

 **Note：**

- Please strictly follow the instructions in the manual.
- This manual is a comprehensive introduction to the Semi-auto Chemistry Analyzer produced by our company. Some of these contents may not be applicable to the model of the instrument you have purchased. Therefore, users are advised to pay attention to the purchased model when reading and using this manual.

1.1 Who Should Read This Manual

This manual is intended for medical laboratory professionals or trained medical staff or laboratory personnel. Used to understand the working principle of Biochemistry analyzer, hardware and software installation, biochemical parameter setting, daily operation, instrument maintenance and handling of common faults.

1.2 Symbols

The symbols used in the description are shown in Table 1-1 below:

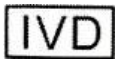
Table 1-1

Symbols	Meaning
 **Warning**	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may cause personal injury or damage to the instrument.
 **Caution**	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may lead to analyzer damage or unreliable analysis results.
 **Note**	Alerts the operator to follow the statement below the symbol, which emphasizes the important information or special attention to be paid while in operation.

 **Biohazard**	Alerts the operator to follow the statement below the symbol, otherwise it may take the risk of potential biohazard.

The symbols used in the Semi-auto Chemistry Analyzer are shown in Table 1-2 below:

Table 1-2

Symbols	Meaning
	On(Power)
	Off(Power)
	serial number
	Biological Risks
	Caution
	Alternating current
	in vitro diagnostic ,medical device
	CE marking. The device is fully in conformance with the Directive 98/79/EC on in vitro diagnostic medical devices
	Date of manufacture

Chapter 2. Instrument Introduction

2.1 Product introduction

Semi-auto Chemistry Analyzer is an in vitro diagnostic equipment that is suitable for the detection of human proteins, lipids, sugars, enzymes and inorganic elements in samples under laboratory environmental conditions. It is used for clinical diagnostic reference and scientific research.

2.2 Principles

The principle of the Biochemistry analyzer mainly uses the Beer-Lambert Law to mix the reagent with the serum sample of the patient to be tested in a certain ratio, and the mixed solution is incubated in a cuvette at a certain temperature, and it continuously measures the absorption. Finally, the concentration or time of the measured substance is calculated automatically based on the absorbance value.

2.3 Instrument composition

The instrument is mainly composed of circuit control system, optical system, colorimetric incubation system, sampling system, LCD screen, touch screen, built-in printer, keyboard, and mouse, of which keyboard and mouse are optional accessories.

2.4 The main technical parameters

Analysis methods: endpoint method, rate method, two-point method, multi-standard method, dual-wavelength method, two-point endpoint method.

Optical system: The light source is a halogen lamp (6V 10W), and the wavelength range (340nm ~ 630nm).

Channel: The detection channel is a single channel.

Storage: The host of the Biochemistry analyzer can store more than 100,000 test results.

Output: built-in thermal printer or external printer

Reaction volume: The minimum reaction volume is 200 μL.

Linear range: 0～3.0A.

Temperature control: pre-incubator 37° C, colorimetric incubation system 25°C, 30°C, 37°C and room temperature.

Sleep function: Set the sleep time of the halogen lamp to extend its service life.

Interface: Equipped with standard USB interface.

Colorimetric mode: cuvette.

Absorbance range: 0 ～ 4.0A.

Absorbance accuracy: 0.0001A.

Note：

- The company can appropriately modify the configuration according to user requirements, and the manual may not be updated in time.

Chapter 3. Introduction

This chapter introduces the installation process and precautions of the instrument.

In order to ensure the normal operation of the instrument after installation, the installation of the instrument at the time of delivery must be installed and debugged by an engineer of China String Company or an engineer authorized by China String Company. The instrument must be installed and used according to this installation procedure when it is moved or used in another place.

Note：

- Any unauthorized or untrained personnel to install the instrument may cause damage to the instrument. Such damage is not covered by XXX's free warranty.

3.1 Installation Requirements

Before installation, the operator must meet the requirements of the following places, power supply and temperature and humidity before installation.

3.1.1 Site requirements

In order to ensure the normal use, repair and maintenance of the instrument, and the pipeline behind the instrument is not squeezed to ensure the normal flow of liquid, the installation of the instrument must meet the following conditions:

1. The instrument is only used indoors;
2. Bearing platform needs level;
3. The bearing platform must not be shaken;
4. The installation site needs good ventilation;
5. Install the instrument as clean as possible;
6. Avoid direct sunlight at the installation site;
7. The installation place should not be close to the heat source;
8. Keep the installation place away from corrosive gas and flammable gas;
9. The installation place must not be disturbed by loud noise or power;
10. The instrument should not be near brushed motors and equipment with frequent switching;
11. Do not use, for example, a mobile phone or radio near the instrument. Devices that emit electromagnetic waves may interfere with the operation of the instrument;
12. The altitude of the installation site of the instrument should be lower than 2000 meters;
13. For example, when placing the computer, there should be enough space on the plane

of the operation platform, and the distance between the computer and the instrument should be kept at least 100mm;

14. Make sure there is enough space behind the instrument or under the instrument to place the distilled water bucket and waste liquid collection device.
15. Do not place the instrument where it is difficult to operate the disconnect device.

Caution：

- Make sure that the instrument is installed in a qualified environment, otherwise it will not be allowed to run.
- The instrument generates thermal energy during operation. A good ventilation environment can keep the room temperature stable. If necessary, use a ventilation device.

3.1.2 Power Requirements

1. frequency 50～60Hz; input power 50W; rated current 4A.
2. Within 1m around the instrument, there is a well-grounded three-hole power socket to provide the power required by the instrument.

Note：

- The instrument needs to be connected to a power socket within 1m, so that the power can be removed in time in an emergency.
- Check that the power grid voltage is consistent with the instrument's voltage before use.
- Before turning on the power, make sure that the instrument power switch is turned off.

3.1.3 Temperature and humidity requirements

1. Normal working temperature range: 10 ℃ ~ 30 ℃;
2. Relative humidity range: ≤80%;
3. Atmospheric pressure range: 75KPa ~ 106 KPa;

Caution：

- Failure of the instrument to operate in the specified environment may result in unreliable results.
- If the temperature and relative humidity cannot meet the above requirements, use an air-conditioning device.

3.2 Open the package

Unpacking steps：

When the analyzer arrives, please carefully check the analyzer's outer packaging for physical damage. If there is any damage, please contact the XXX's after-sales service department or the local dealer immediately; after confirming that there is no external damage, follow the steps below to unpack:

1. Gently open the box, check the items, and check whether the items are complete according to the attached list. If there are any missing items, please immediately notify XXX's after-sales service department or the local distributor;
2. Select a good water platform;
3. Take out the instrument, remove the fixed foam and the instrument packaging film, and place the instrument on the surface of the water platform.

3.3 Installation steps

Warning：

- Blood samples, quality controls, calibrators, and reagents that may be carried on the pipette have potential biological risks. Avoid touching the probe directly with your hands.

3.3.1 Pipelines connection

Take one end of the waste pipe from the accessory and connect it to the waste connector on the back of the instrument, and connect the other end to the waste bottle or waste tank.

Note：

- Before connecting the pipes, make sure there are no foreign objects in the joints.
- Do not bend the waste pipe or immerse the tail end in the waste liquid. If it is too long, it must be cut short, otherwise it will cause poor drainage

Biohazard:

- It is recommended that the instrument waste liquid be discharged after being harmlessly treated, and not directly poured into the sewer.

3.3.2 Device connection

The specific steps for device connection are as follows:

1. Remove the power adapter from the accessory box;
2. Connect the output end of the power adapter to the instrument, and the other end to the network power supply;
3. Connect an external printer (provided)
4. Connect the mouse and keyboard to the instrument (optional).

Note：

- If the installed printer does not support graphic text printing, please install a higher-level version of the driver.

Warning：

- The power supply voltage of the network must be consistent with the input voltage identification of the power adapter, otherwise the instrument will be damaged.
- Do not plug or unplug serial communication cables and other wires with power on at any time.

Chapter 4. System description

This chapter describes the functions and precautions of the instrument.

In order to ensure the normal operation of the instrument after installation, the installation of the instrument at the time of delivery needs to be installed and set by engineers or engineers authorized by China String Company.

4.1 Function introduction

The Semi-auto Chemistry Analyzer is suitable for the quantitative analysis of clinical biochemical items of serum, plasma, Urine and cerebrospinal fluid samples in medical units. The working principle of the instrument is to apply the principle of light absorption to make monochromatic light pass through the mixed liquid of human body fluids and reagents, and then measure its absorbance value to determine whether the physiological indicators of the human body are normal.

Caution：

- The instrument may not be able to measure due to samples and reagents. For the availability and conditions of the measurement, please follow the instructions of the reagent vendor.

Note：

- When using this instrument, please use quality control products to monitor whether the instrument is operating normally. Incorrect measurement results may cause incorrect diagnosis.
- For the storage methods of reagents, quality controls and calibrators (including before opening and after opening), and usage methods, please refer to the instructions of the reagent dealer.
-

4.2 Screen operation introduction

4.2.1 Main interface

The main interface is shown in Figure 4-1 below:

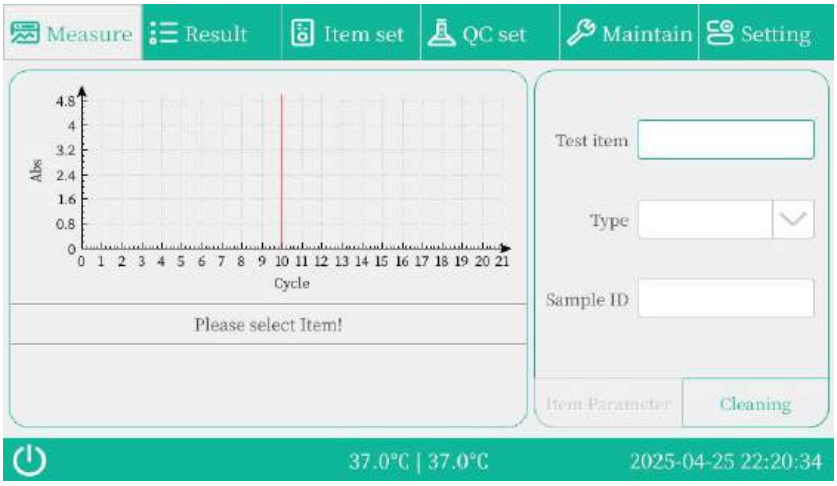


Figure 4-1

The main interface includes a top menu bar, a middle function area, and a bottom status bar. The main functions of the main interface are shown in Table 3 below.

Table 3 main functions

No.	Function	Description
1	Measure	Test samples, controls, calibrators, reagent blank and water blank for biochemical items
2	Result	Query samples, QC and calibration results
3	Item set	Set the test item parameters
4	QC set	Set quality control parameters
5	Adjust	Perform pump adjust, optical adjust, filter wheel adjust, and temperature adjust
6	System setting	Setting up the printer, temperature, dictionary, and system
7	System shutdown	Exit system
8	Fault messages	Display system fault information, click to display fault details
9	Temperature display	Display system incubation temperature
10	Time display	Display the current system date and time

4.2.2 Interface description

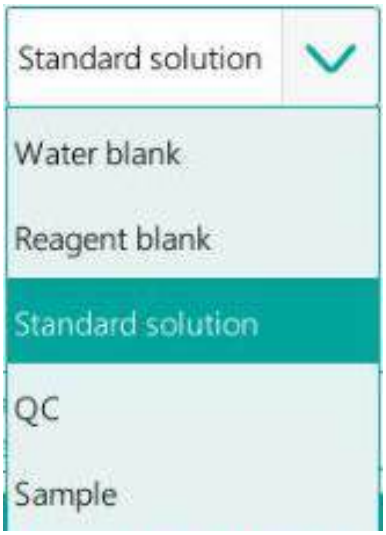
4.2.2.1 Input box

You can enter characters from the touch screen or a USB keyboard in the edit box.

4.2.2.2 Button

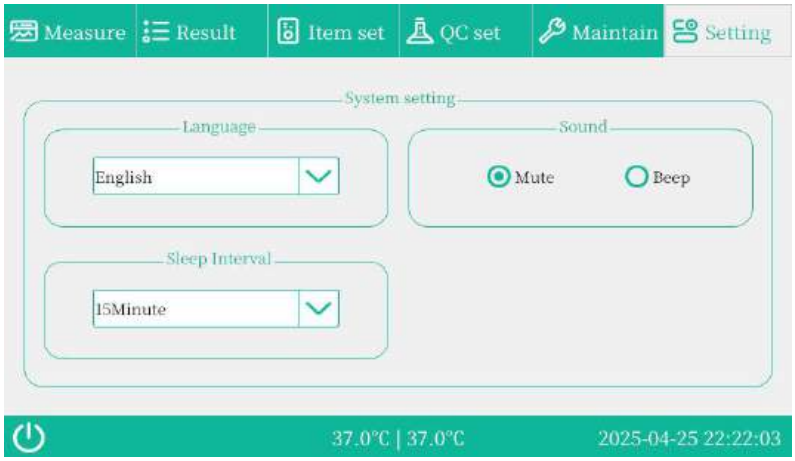
With a click of a button, you can access its functions.

4.2.2.3 Combo Box



Clicking on list  will display as shown. Click to select the desired item.

4.2.2.4 Radio button



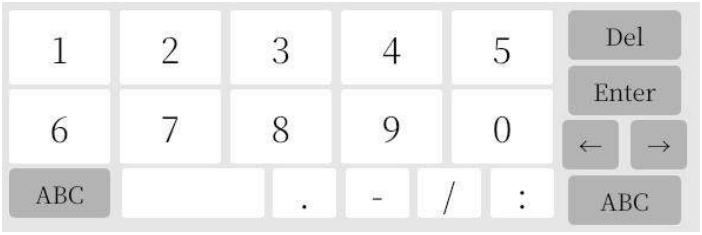
Click the radio button to select the option it represents.

Note that for a given set of radio buttons, you can only select one of them.

4.3 Soft keyboard

The input panel can pop up automatically when you enter characters, as shown in the figure below.

English soft keyboard



Numeric soft keyboard

Click the Tab key to select the next edit box, and click the Close key to close the input panel.

4.4 External USB mouse and USB keyboard

The instrument can be connected to an external USB keyboard and USB mouse of a traditional computer. Simply connect the USB mouse or USB keyboard to the USB port of the instrument and use it normally. The USB keyboard and mouse are shown in Figure 4-2 below.

Figure 4-2

Note：

- Do not use the right button of a USB mouse, it does not have this function.

4.5 External USB printer

Built-in thermal printer and external USB printer are used to print various types of test

reports. External USB printer in addition to the printer recommended by the company, other external printers need to support the PCL 3 printing language. The USB printer is shown in Figure 4-3 below.

Figure 4-3

The company recommends the following printer models:

HP Color LaserJet Pro M252n
HP LaserJet Professional P1108
HP LaserJet Professional P1106
HP LaserJet Professional P1102

External USB printer installation steps:

- Connect the printer cable to the USB port of the instrument;
- Enter the system main interface [System setting], then select [Printer setting], and then select the [Printer] or [PCL Printer] option.

Note:

- PCL printers need to support the PCL 3 printing language. Otherwise it will not work, if there is any problem, please contact the printer manufacturer or get technical support.

Chapter 5. Software function

5.1 System boot

Connect the power, turn on the power switch of the instrument, and the system enters the startup initialization interface, as shown in Figure 5-1 below:

Figure 5-1

This interface will be initialized at startup, and automatically enter the measure interface after the initialization is completed.

5.2 Measure

Click the [Measure] button on the main interface to enter the measure interface, as shown in Figure 5-2 below:

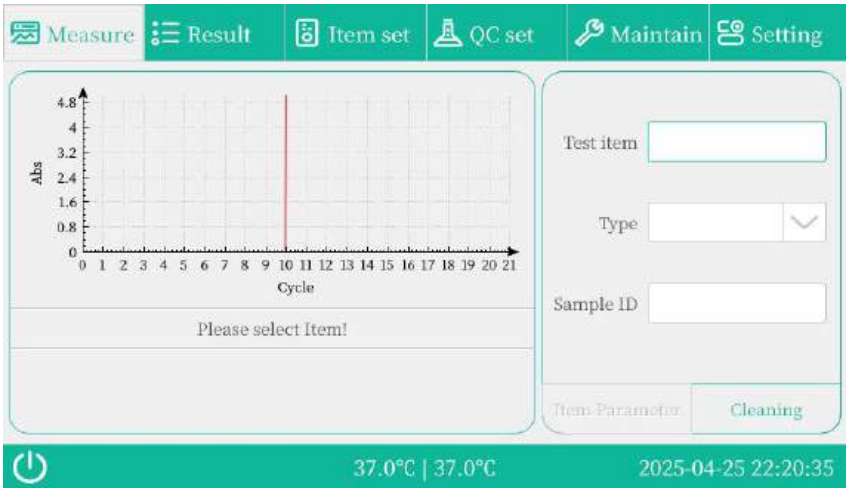


Figure 5-2

This measure interface can test water blank, reagent blank, standard solution, QC and sample, and display the reaction curve and data in real time.

- Reaction curve: The instrument reads one absorbance per second during the incubation and test time. The absorbance during incubation is displayed to the left of the red line, and the absorbance at the test time is displayed to the right of the red line. The X axis is the period and the Y axis is the absorbance.
- Test Tip: Prompt test status and user operations
- Test item: Click the input box to pop up the [Apply for item] dialog box. This dialog box

can apply for a test item.

- Test Type: Click the drop-down box to select the test type: Water blank, Reagent blank, Standard solution, QC and sample.
- Test information: Click the input box to pop up the [Sample editing] or [QC info] dialog box. The dialog box can set sample information and select test QC.
- Item parameter: Click this button to pop up the [Item parameters] dialog box, displaying the parameters of the item being tested.
- Cleaning: Click this button to enter the manual cleaning mode, insert the sample pipette into the cleaning solution, and then hold down the aspirate key to aspirate in the cleaning solution, and the instrument will start cleaning the cuvette and tubing.
- Cuvette temperature: Displays the temperature of the cuvette in real time.

5.2.1 Apply for item

The [Apply for item] interface is shown in Figure 5-3 below:

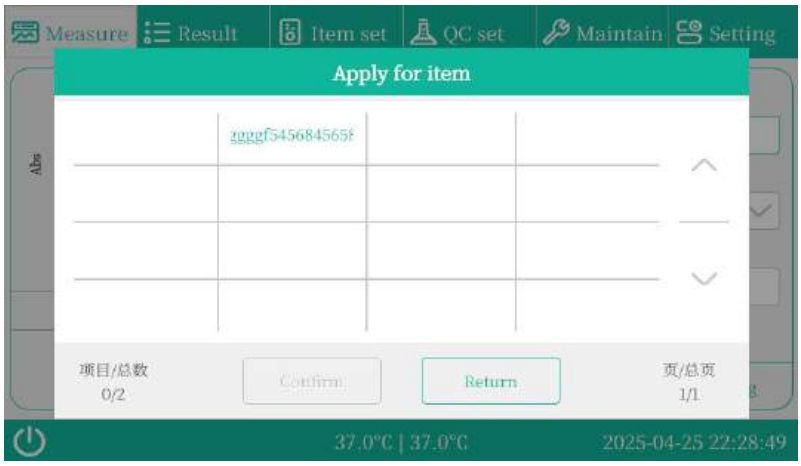


Figure 5-3

This dialog allows you to select a test item.

- Test item: Select the test item entered by the user, and enter the item information in the [Item set] interface.
- Page up / down buttons: When the number exceeds one page, click the page up / down buttons to view the pages.
- Total: Shows the total number of test items.
- Confirm: Click this button to switch the item and return to the [Measure] interface.
- Return: Click this button to return to the [Measure] interface.

5.2.2 Water blank test

The water blank test interface is shown in Figure 5-4 below:

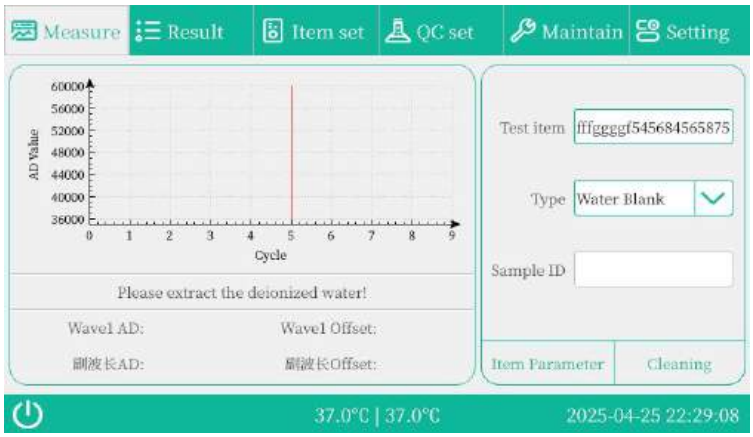


Figure 5-4

This test interface can test the AD value and Offset value of distilled water. This value will be saved as the zero absorbance.

- Test procedure: Insert the sample pipette into distilled water, and then hold the aspirate key to aspirate in the distilled water, the instrument will start to test the AD value and Offset value.
- Wave1 AD: The AD value of the tested filter is displayed.
- Wave1 Offset: The Offset value of the tested filter is displayed.

Note：

- The normal AD value range is 36000-52000, and the offset value range is 0-2000. If it is out of range, a warning dialog box will pop up when clicking the reagent blank, standard, QC and sample buttons.

5.2.3 Reagent blank test

The reagent blank test interface is shown in Figure 5-5 below.

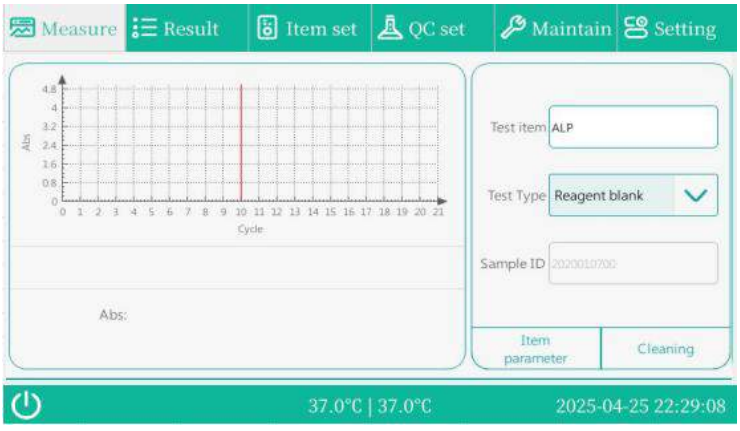


Figure 5-5

This test interface can test and save the reagent blank, and the instrument will subtract the absorbance of the blank reagent when calculating the results.

- Test procedure: Insert the pipette into the reagent, and then hold down the aspirate key to aspirate in the reagent, and the instrument will start testing the reagent blank absorbance.
- Abs: The reagent blank absorbance is displayed after the test.

Caution：

- When using a new batch of reagents, it is necessary to determine the reagent blank again. Using the previous reagent blank may lead to unreliable test results.

Note：

- If there is no reagent blank option in the test type when "Item set"-"Blank Type" is water.

5.2.4 Standard solution test

The standard solution test interface is shown in Figure 5-6 below:

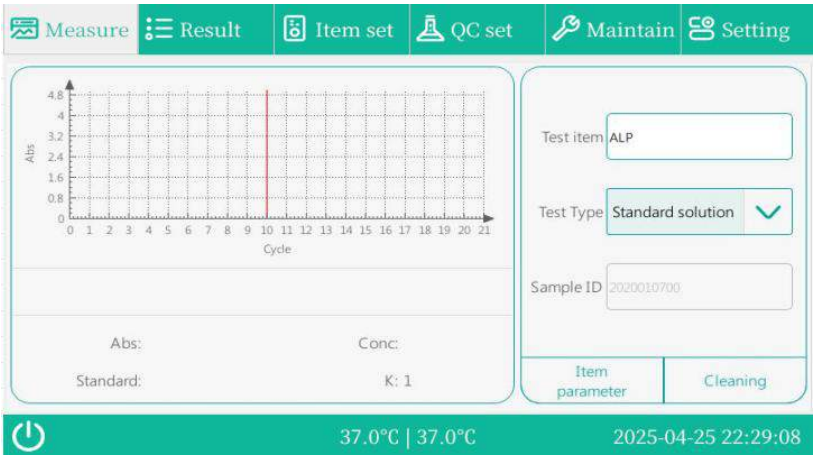


Figure 5-6

This test interface can test the absorbance of standard solutions. If it is a multi-standard adjust, test each standard solution from low concentration to high concentration.

- Test procedure: Insert the sample pipette into the standard solution, and then hold down the aspirate key to aspirate in the standard solution, the instrument will start to test the absorbance of the standard solution.
- Abs: The test solution shows the absorbance of the standard solution after the test.
- Conc: The test concentration of the standard solution is displayed after the test.

- Standard: Displays the input concentration of the standard solution after the test.
- K: The K value stored and displayed is before the test, and a new K value will be generated after the test.

Caution：

- It is recommended that users perform standard tests regularly. Incorrect standard results or K values will lead to unreliable results.

Note：

- If "Item set "-"Type" is 1 point linear, there is no standard solution option for the test type.

5.2.5 QC test

The QC test interface is shown in Figure 5-7 below:

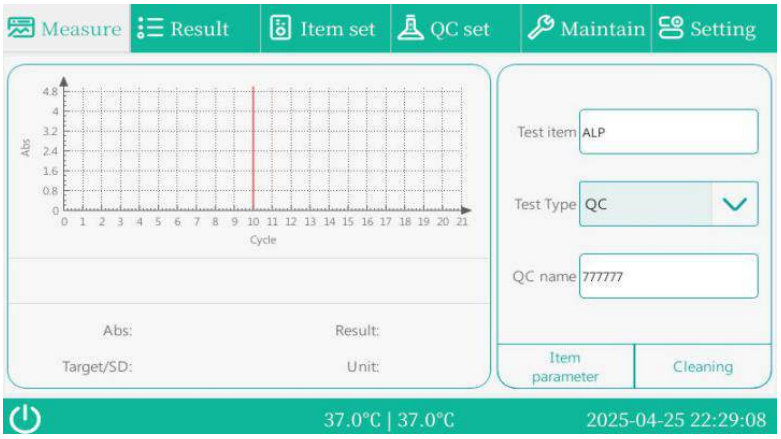


Figure 5-7

This test interface can test the QC absorbance and calculation results.

- QC name: Click the input box to pop up the QC Information dialog box, and select a QC you want to test.
- Test procedure: Insert the sample pipette into the quality control, then press and hold the aspirate key to aspirate in the QC, and the instrument will start to test the absorbance of the QC.
- Abs: The test absorbance for QC is displayed after the test.
- Result: The test result of QC is displayed after the test.
- Target/SD: The input target value and standard deviation of the QC are displayed after the test.

- Unit: The unit of the input item that shows the QC after the test.

Note：

- If there is no QC information in the “QC set”, there is no QC option for the test type.

5.2.6 QC information

The QC information dialog box is shown in Figure 5-8 below:

Figure 5-8

This dialog allows you to select test QC information.

5.2.7 Sample test

The sample test interface is shown in Figure 5-9 below:

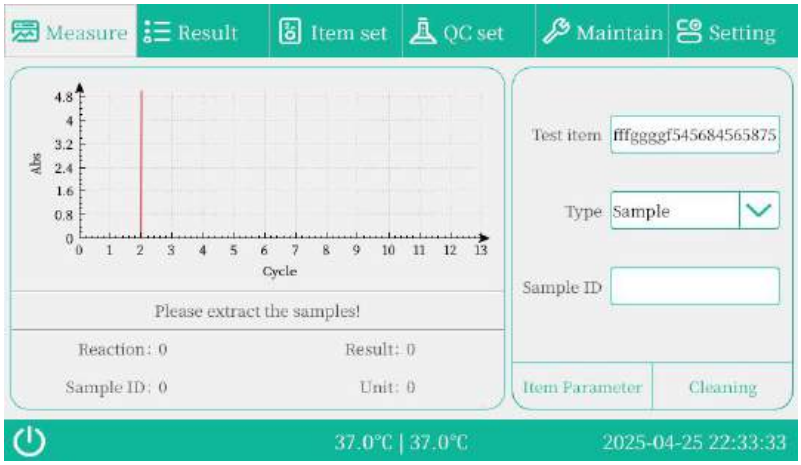


Figure 5-9

This test interface can test the absorbance and calculation results of the sample.

- Sample ID: Clicking this button will bring up the sample editing dialog box. In this dialog box, you can edit the sample ID, Name, Gender, Age, Doctors and Department.
- Test procedure: Insert the pipette into the sample, and then hold down the aspirate

key to aspirate in the sample.

- Abs: The absorbance of the sample is displayed after the test.
- Result: The result of the sample is displayed after the test.
- Sample ID: Shows the sample ID of the most recently completed test.
- Unit: The unit for displaying the test results of the sample.

Caution：

- YYYYMMDD0001 is the default value of the first sample of the day. The sample ID can be edited through the sample editing dialog.
- After the test, the sample ID number will automatically increase by 1. If you want to test the previous ID, you can test it after editing through the sample editing interface before testing.
- Click the "Cleaning" button to clean the cuvette with distilled water.
- After the test, the instrument will be automatically cleaned. If the current sample result is abnormal, it is necessary to manually flush the cuvette before testing the next sample to prevent cross-contamination.

5.2.8 Sample editing

The sample editing dialog is shown in Figure 5-10 below:

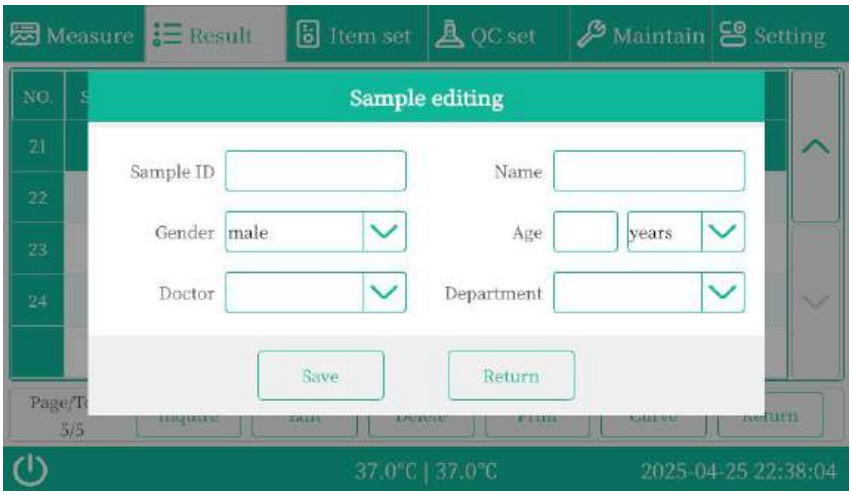


Figure 5-10

This dialog box allows you to edit the Sample ID, Name, Gender, Age, Doctors and department.

5.3 Result

Click the [Result] button on the main interface to display the interface as shown in Figure 5-11 below:

Figure 5-11

This interface provides access to Sample result, QC result and Calibration result.

5.3.1 Sample result

The sample result interface is shown in Figure 5-12 below:

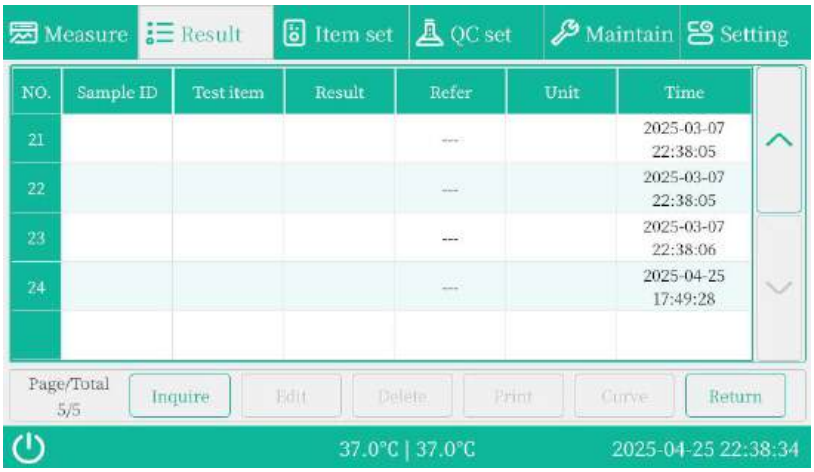


Figure 5-12

This interface can view sample information and query historical test samples.

- Sample list: Display the latest or historical test sample information.
- Page up/down: When the number exceeds one page, click the page up /down buttons to view the pages.
- Page/Total: Displays the current and total pages of the list.
- Inquire: Click this button to pop up the sample query dialog box, in which you can query the historical sample test.
- Edit sample: Click this button to pop up the sample edit dialog box, in which you can edit the sample information.
- Delete sample: Click this button to delete sample information and test results.
- Result: Click this button to enter the result interface.

- Return: Click this button to return to the result interface.

5.3.1.1 Sample query

The sample query dialog is shown in Figure 5-13 below:

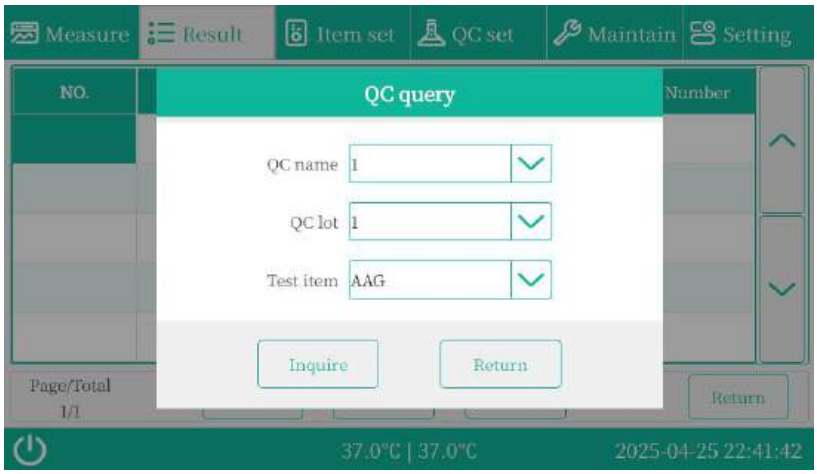


Figure 5-13

This dialog box can query sample information based on the entered query conditions.

- Name: Search by name.
- Sample ID: Search by sample ID.
- Date: query by date or date range, default is today's date.
- Inquire: Query the sample according to the selected conditions and return to the sample result interface.
- Return: Click this button to return to the sample results interface.

5.3.1.2 Sample editing

The sample editing dialog is shown in Figure 5-14 below.

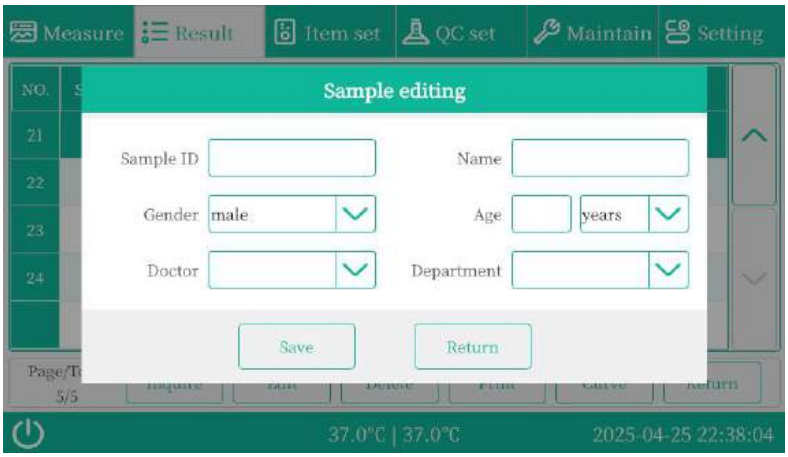


Figure 5-14

This dialog box can edit the information of the selected sample.

- Sample ID: Displays the sample ID.
- Name: Enter the sample name.

- Gender: Select the gender of the sample.
- Age: Select the unit of age after entering the age of the sample.
- Doctors: Click the drop-down button to select a doctor.
- Department: Click the drop-down button to select the department.
- Save: Click this button to save the sample information and return to the sample results interface.
- Return: Click this button to return to the sample results interface.

5.3.1.3 Result

The result interface is shown in Figure 5-15 below:

Figure 5-15

This interface can view and edit sample test results.

- Sample information: display sample information.
- Result list: display the sample test results.
- Page up/down: When the number exceeds one page, click the page up /down buttons to view the pages.
- Page/Total: Displays the current and total pages of the list.
- Edit result: Click this button to pop up the result edit dialog box, in which you can edit the test results.
- Delete result: Click this button to delete the selected test result.
- Print report: Click this button to print a sample report.
- Return: Click this button to return to the sample result interface.

5.3.1.4 Result Edit

The result edit dialog is shown in Figure 5-16 below.

Figure 5-16

This dialog box allows you to edit the results of the selected sample.

- Test item: Display the selected test item.
- Result: Display and edit the selected test result.
- Save: Save the edited results and return to the result interface.
- Return: Click this button to return to the result interface.

5.3.2 QC result

The QC result interface is shown in Figure 5-17 below:

Figure 5-17

This interface can view the QC information, as well as query historical QC tests.

- QC List: Display QC information of recent or historical tests.
- Page up/down: When the number exceeds one page, click the page up /down buttons to view the pages.
- Page/Total: Displays the current and total pages of the list.
- Inquire: Click this button to pop up the QC query dialog box, in which you can query the historical QC test.
- QC table: Click this button to switch to the QC table interface, and view the QC test results on this interface.

- QC chart: Click this button to switch to the QC chart interface, where you can view the QC trend chart and status.
- Return: Click this button to return to the result interface.

5.3.2.1 QC query

The QC query dialog box is shown in Figure 5-18 below:

Figure 5-18

This dialog box can query QC information according to the entered query conditions.

- QC name: Search by QC name.
- QC lot: query according to QC lot.
- Test item: query according to test item.
- Inquire: Query according to the selected conditions and return to the QC result interface.
- Return: Click this button to return to the QC result screen.

5.3.2.2 QC table

The QC table interface is shown in Figure 5-19 below:

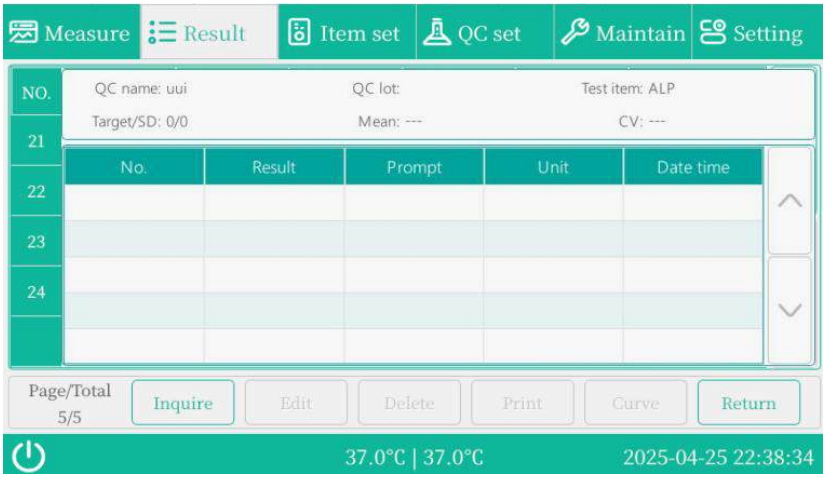


Figure 5-19

This interface can view the QC test results.

- QC info: Displays the QC information that is viewed.

- Results list: display and check the QC results.
- Page up/down: When the number exceeds one page, click the page up /down buttons to view the pages.
- Page/Total: Displays the current and total pages of the list.
- Date: Select a date range. The matching test results will be displayed in the results list. The default is the results of the current day.
- Delete result: Click this button to delete the QC result.
- QC chart: Click this button to switch to the QC chart interface.
- QC info: Click this button to switch to the QC result interface.

5.3.2.3 QC chart

The QC chart interface is shown in Figure 5-20 below:

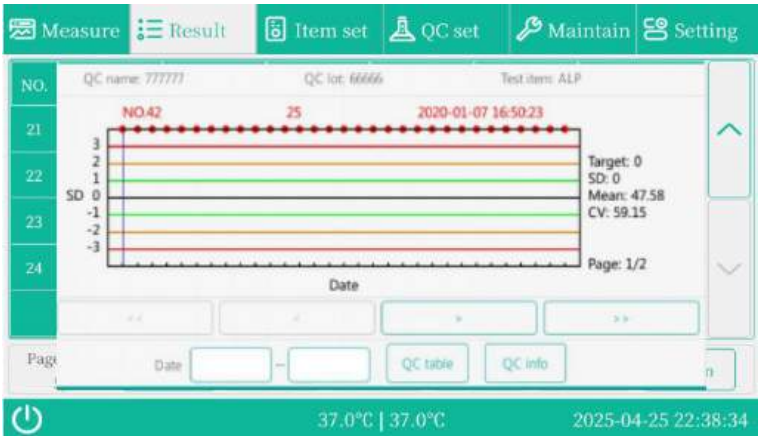


Figure 5-20

This interface allows you to view QC charts and check QC status. QC is based on multi-rule QC.

- QC info: Displays the QC information that is viewed.
- QC chart: Displays the QC chart that is viewed.
- ▲Current result: The first line displays the result of the currently selected point.
- ▲Coordinate description: The abscissa indicates the test number, and the ordinate indicates the target value ± 3 times SD.
- ▲Information on the right: display Target, SD, Mean and CV.
- ▲Page: Displays the data page.
- Turn left and right: When there are more than one page, turn left and right to view.
- Date: Select a time range to view the QC chart.
- QC table: Click this button to switch to the QC table interface
- QC info: Click this button to switch to the QC result interface.

The rules for multi-rule QC are shown in Figure 5-21 below:

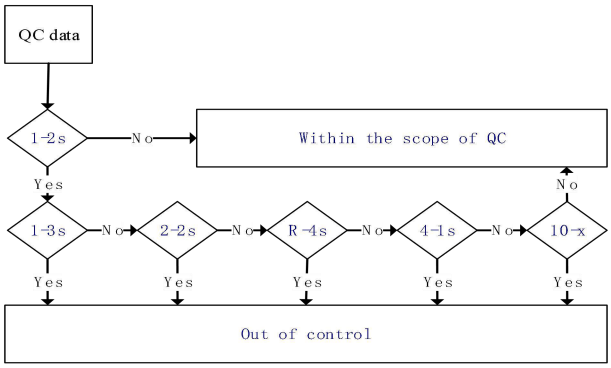


Figure 5-21

- **1-2s:** One QC result crossed the limit ± 2 standard deviation.
- **1-3s:** One QC result crossed the limit ± 3 standard deviation.
- **2-2s:** Two consecutive QC results crossed the limit ± 2 standard deviation.
- **R-4s:** Two different continuous QCs crossed the standard by 4 standard deviations.
- **4-1s:** Continuous QC results crossed the standard line 1, with a ± 1 standard deviation.
- 10-x: 10 consecutive QC results are on the same side of the mean line.

5.3.3 Calibration result

The calibration result interface is shown in Figure 5-22 below.

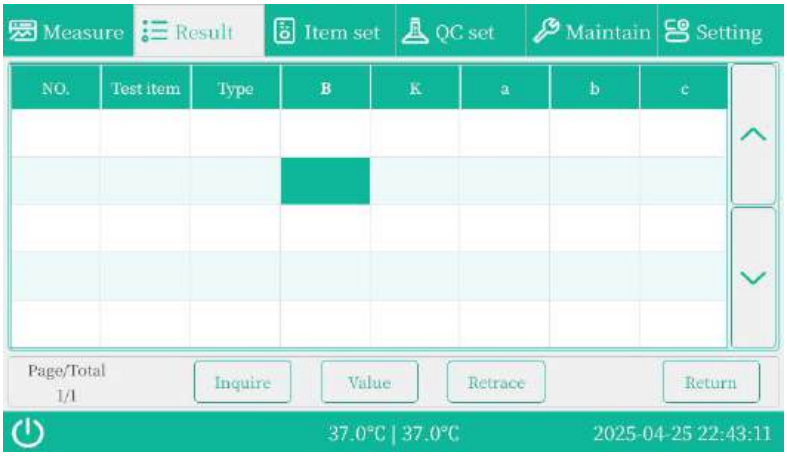


Figure 5-22

This screen displays the calibration parameters for each test.

- Results list: display the calibration information currently used in the test.
- Page up/down: When the number exceeds one page, click the page up /down buttons to view the pages.
- Page/Total: Displays the current and total pages of the list.
- Inquire: Click this button to pop up the calibration query dialog box, in which you can query the historical calibration information.
- Calibration value: Click this button to enter the calibration value interface. In this

interface, you can see detailed calibration parameters and reaction curves.

- Calibration trace: Click this button to enter the calibration trace interface. In this interface you will see the historical absorbance, reagent blank, and each standard.
- Return: Click this button to return to the result query interface

5.3.3.1 Calibration query

The calibration query dialog box is shown in Figure 5-23 below:

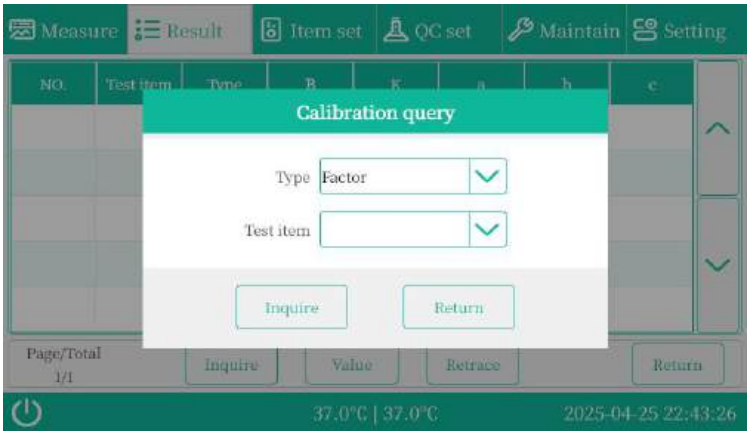


Figure 5-23

This dialog box can query the calibration information according to the entered query conditions.

- Type: query according to the calibration type.
- Test item: query according to test items.
- Inquire: Query according to the selected conditions and return to the calibration result interface.
- Return: Click this button to return to the calibration result interface.

5.3.3.2 Calibration value

The calibration value interface is shown in Figure 5-24 below:

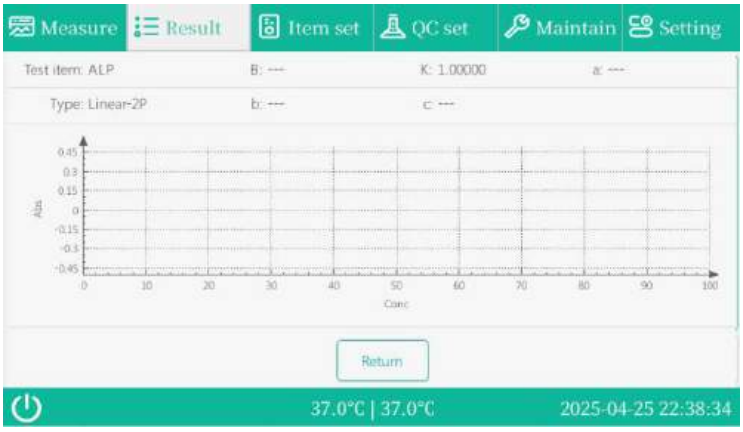


Figure 5-24

In this interface, you can view detailed calibration parameters, reaction curves, and the absorbance and blank absorbance of each standard.

- Test item: display test item name.
- B: 1-point linear or 2-point linear. If the blank type is reagent, here is the reagent blank absorbance. If the blank type is water, this is 0. For other calibration types, this is a parameter that automatically calculates the calibration curve.
- K: For 1-point calibration, the K value is entered in the item set dialog box. For 2-point linear, the K value is automatically calculated after the calibration is completed. For other calibration types, this is a parameter that automatically calculates the calibration curve.
- abc: This is a parameter that automatically calculates the calibration curve, and is only used for non-linear calibration types.
- Type: The calibration type is displayed.
- Calibration curve: display the calibration curve.

  ▲Coordinate description: The abscissa indicates the test concentration, and the ordinate indicates the test absorbance.

  ▲View value: After clicking to select a point, its concentration and absorbance will be displayed in the indicator label.
- Return: Click this button to return to the calibration result interface.
- For B, K, a, b, and c, please refer to the calibration types in Appendix 2.

5.3.3.3 Calibration trace

The calibration trace interface is shown in Figure 5-25 below:

Figure 5-25

This interface can view the standard absorbance and blank absorbance of each selected item.

- Test item: display test item name.
- Type: The calibration type is displayed.

- Blank Conc: Displays the standard 0 concentration.
- Standard Conc: Display standard 1-5 concentration.
- Result list: display all calibration results.
- Page up/down: When the number exceeds one page, click the page up /down buttons to view the pages.
- Page/Total: Displays the current and total pages of the list.
- Delete: Click this button to delete the selected calibration test result.
- Return: Click this button to return to the calibration result interface.

5.4 Item set

Click the [Item set] button on the main interface, and the interface shown in Figure 5-26 will be displayed:

Figure 5-26

This interface can add and edit test items and combined item.

- Item list: display test items information.
- Page up/down: When the number exceeds one page, click the page up /down buttons to view the pages.
- Page/Total: Displays the current and total pages of the list.
- Types: Click the drop-down box to select the item type: Regular item and combined item.
- Add: Click this button to pop up the add item dialog box. This dialog box can add new items.
- Edit: Click this button to pop up the editing item dialog box. This dialog box can edit the item information.
- Delete: Click this button to delete the selected item information.

5.4.1 Regular item

Select [Regular item]-[Add], the add item dialog box pops up, as shown in Figure 5-27 below:

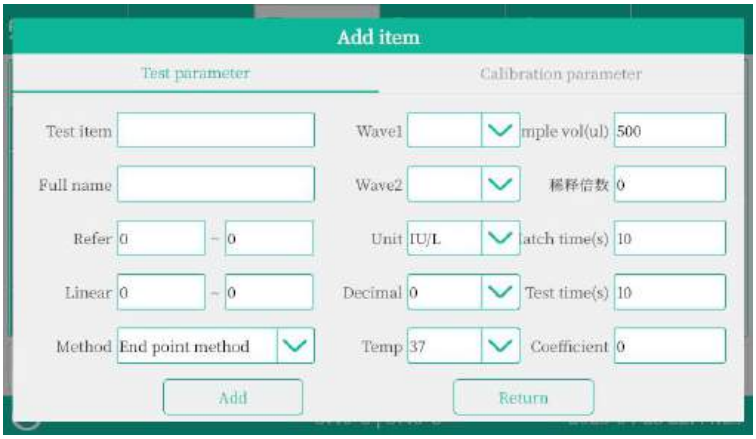


Figure 5-27

5.4.1.1 Test parameter

Select the test parameters and set the test parameters for the item.

- Test item: Enter the test code, not the full name.
- Full name: Enter the full name of the test item. It can be empty.
- Method: Select the test method, including End point method, Rate method, Two point method, and Two-point end method.
- Unit: Select the unit of the result, and set more units in [System setting]-[Dictionary setting].
- Wave1: Select the Wave1 of the test item.
- Wave2: Select the Wave2 of the test item. It cannot be set to the same wavelength as the Wave1.
- Decimal: Set the decimal places (0-4) of the result.
- Reference: Set the reference range. If the test result exceeds this range, it will be marked with " ↑ " or " ↓ ".
- Linear: Set the linear range. If the test result exceeds this range, “≥” or “≤” will be marked.
- Hatch time(s): Enter the incubation time (1 second-999 seconds).
- Time: Enter the test time (1 second-999 seconds).
- Temp: Set the reaction temperature according to the reagent instructions, including 25°C, 30°C, 37°C and room temperature. The default is 37 ° C.
- Sample vol(ul): Set the aspiration volume (1μl -5000μl) according to the reagent instructions. The default aspiration volume is 500μl.
- Add: Add a new item and return to the item set interface.
- Return: Return to the item set interface.

Caution：

- End point method

Mix the sample and reagent first, and then insert the test tube or other container into the incubator. When the incubation time is over, remove the test tube or other container and suck it into the cuvette. Generally, the incubation time is 3-5 seconds, and the test time is 3-5 seconds.

- Rate method and Fixed time method

The incubation time of the above two methods is usually set to 60 seconds. After the sample and reagent are mixed, it is sucked into the cuvette and does not need to be placed in an external incubator. The incubation time is set to 60 seconds and the test time is set to 30 or 60 seconds.

5.4.1.2 Calibration parameter

Select the calibration parameter and set the calibration parameters for the item. As shown in Figure 5-28 below.

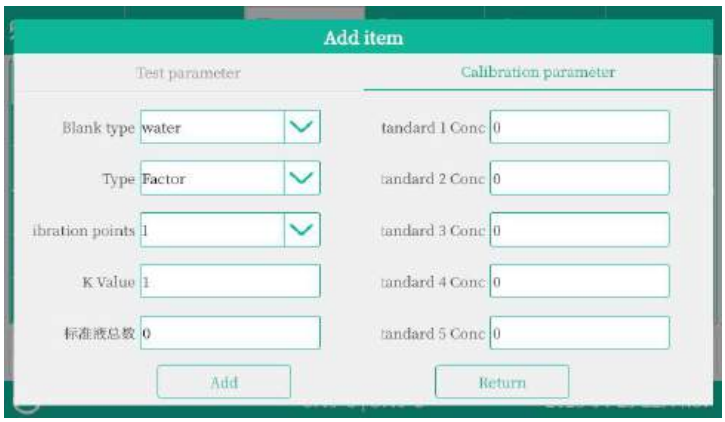


Figure 5-28

- K Value: Enter the K value of the test item.
- Type: Click the combo box to select the calibration type.
- Calibration points: Displays the standard quantity.
- Blank type (standard 0): Click the combo box to select the blank type including water and reagent.
- Standard 1-5 Conc: Set the standard 1-5 concentration.
- Add: Add a new item and return to the item set interface.
- Return: Return to the project setting interface.

Caution：

- Set the reagent parameters step by step according to the reagent manual. The Semi-auto Chemistry Analyzer is different from the auto Biochemistry analyzer. Many preparations need to be done manually. If you have any questions, please contact technical support.

5.4.2 Combined item

Select the [Combined item]-[Add] button, and the add combination dialog box will pop up, as shown in Figure 5-29 below:

Figure 5-29

- ◆ Single item: display a list of regular items.
- ◆ Sub item: Display a list of combined items.
- ◆ Move button: you can add and delete left and right list items
- ◆ Name: Enter a combination name.
- ◆ Add: Add a new combination and return to the item set interface.
- ◆ Return: Return to the item set interface.

5.5 QC set

Click the [QC set] button on the main interface, and the interface shown in Figure 5-30 will be displayed:

Figure 5-30

This interface can set QC information and QC test information, and set the average value and SD value of QC test.

- Add QC: Click this button to pop up the Add QC dialog box. This dialog box can add QC.
- Delete QC: Click this button to delete the selected QC information and QC test.
- Add test: Select one of the QCs in the QC list, and then click this button to pop up the Add QC test dialog box. In this dialog box, you can edit the mean and standard deviation of the QC and add them to the test List.
- Edit test: Select one of the tests in the test list and click this button to display the Edit QC test dialog box. In this dialog box, you can edit the mean and standard deviation of the QC.
- Delete test: Click this button to delete the QC test in the test list.

5.5.1 Add QC

The Add QC dialog box is shown in Figure 5-31 below:

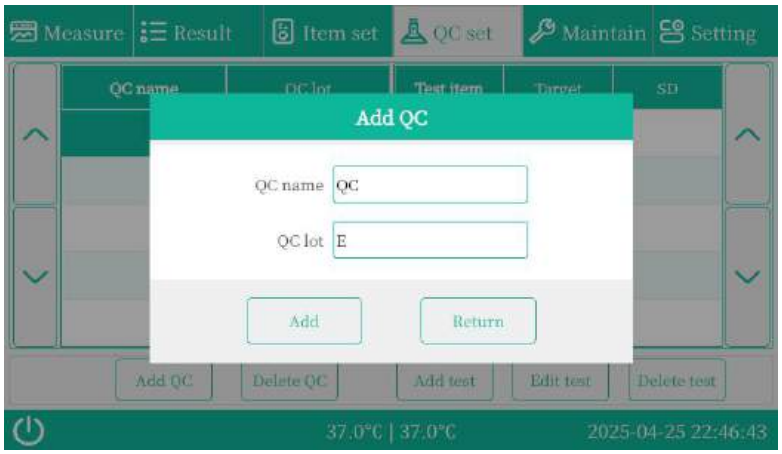


Figure 5-31

This dialog box can add a new QC to the QC list.

- QC name: Enter the QC name.
- QC lot: Enter the QC lot number.
- Add: Click this button to add a new QC, and return to the QC set interface.
- Return: Click this button to return to the QC set interface.

5.5.2 Add test

The Add QC test dialog is shown in Figure 5-32 below:

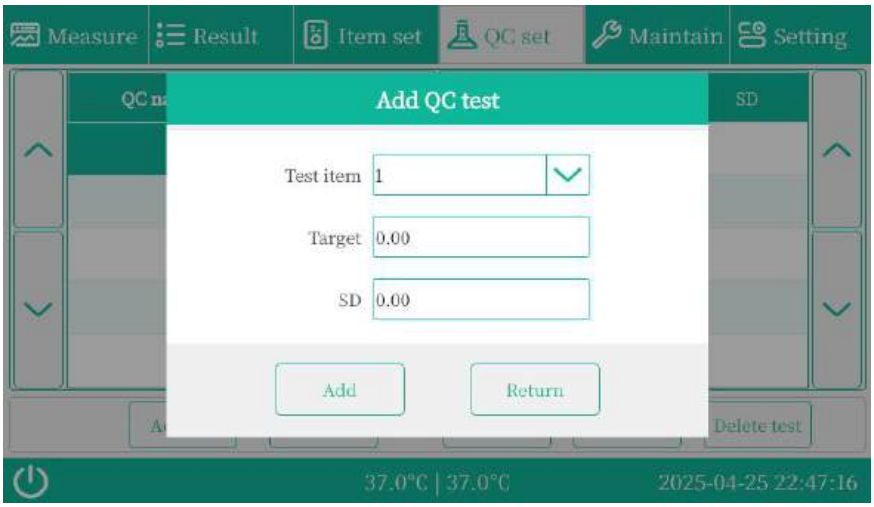


Figure 5-32

This dialog box can add a new QC test to the test list.

- Test item: Enter the test name.
- Target: Enter the QC target value.
- SD: Enter the standard deviation of QC.
- Add: Click this button to add a new QC test, and return to the QC set interface.
- Return: Click this button to return to the QC set interface.

5.6 Adjust

Click the [Adjust] button on the main interface, the interface as shown in Figure 5-33 will be displayed:

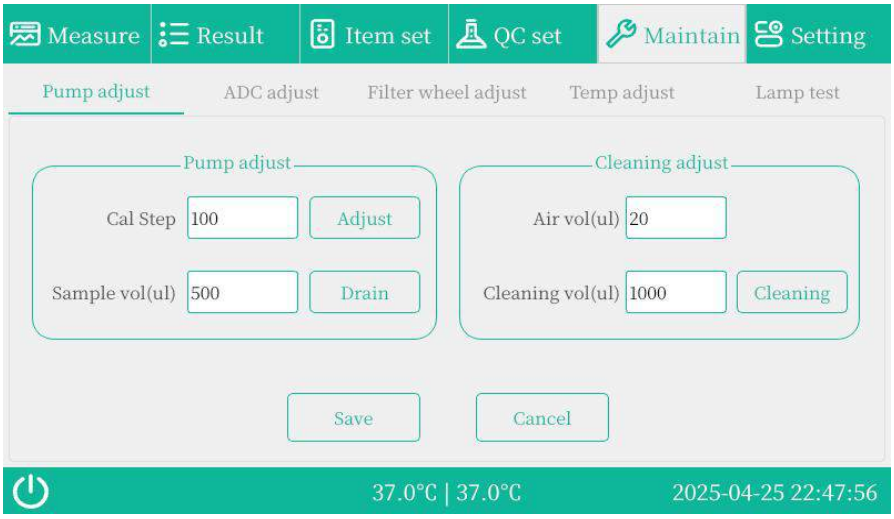


Figure 5-33

5.6.1 Pump adjust

Select the pump Adjust, the interface shown in Figure 5-34 will be displayed:

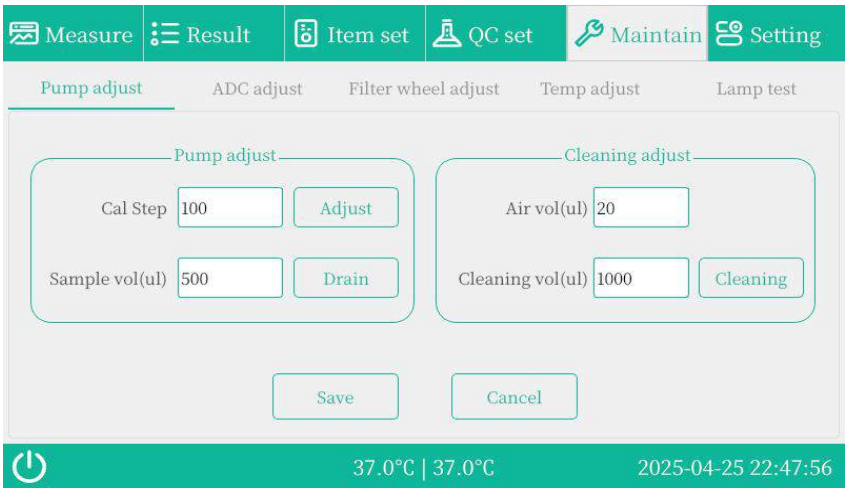


Figure 5-34

This interface can perform peristaltic pump adjust and fluid cleaning adjust.

- Pump adjust steps: Select the Sample vol(ul), press the Adjust button to enter the calibration mode, insert the sample tube into the distilled water measuring cup, and then press and hold the aspirate key. The instrument will start to sample, wait until the measuring cup has finished pumping the distilled water, press the aspirate key, the calibration is complete.
- Cleaning adjust: Enter the Cleaning vol(ul), press the Cleaning button to enter the calibration mode, insert the sample tube into distilled water, and then press and hold the aspirate key to start cleaning.
- Save: Save the parameters for pump adjust and setting.
- Cancel: Cancel pump adjust and setting parameters.

5.6.2 ADC adjust

Select ADC adjust, the interface shown in Figure 5-35

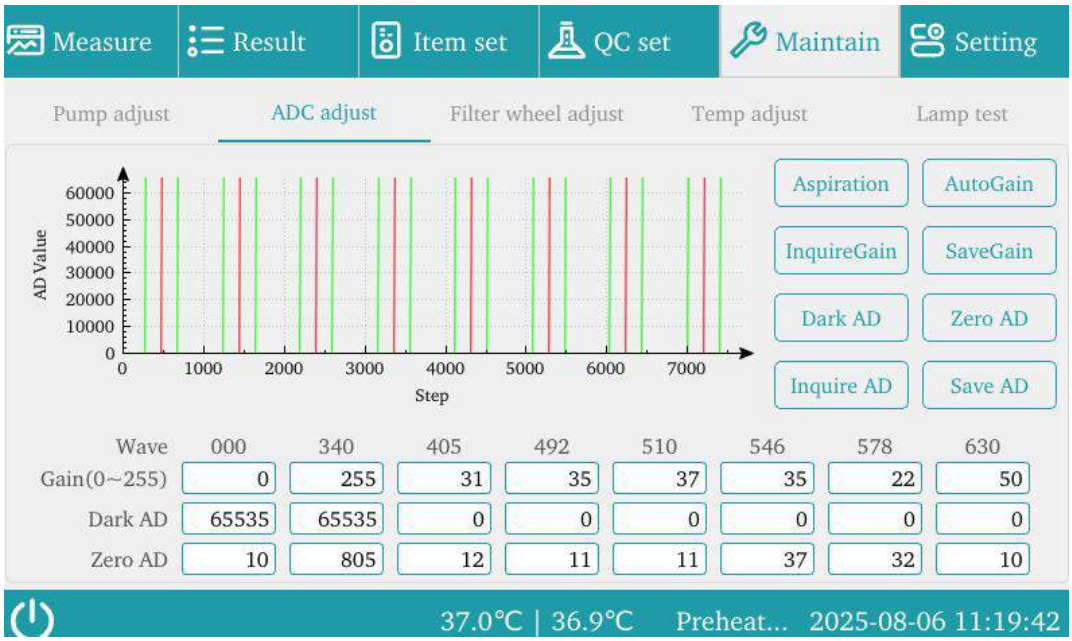


Figure 5-35

This interface can be used for ADC adjust and setting.

- Adjust steps:

  ▲Select the adjust wavelength and input gain.

  ▲Insert the pipette into the distilled water, and then click the Aspiration button to aspirate in the distilled water.

  ▲Press the aspirate key to perform ADC acquisition. The AD input box displays the AD value.

  ▲Press the Aspiration button again to exit the acquisition, and click the Drain button to empty the fluid path.

- Wavelength: Click the drop-down box to select the calibration wavelength.
- Gain: Save automatically after inputting the channel gain.
- Cleaning vol(ul): Set the cleaning amount of the cleaning pipeline system.
- AD: Display the collected AD.
- Aspiration: press this button to aspirate.
- Drain: Press this button to empty.

Caution：

- The AD value range of each filter is 35000-60000 and the Offset value range is 0-4000. If the value exceeds the range, please contact technical support.

5.6.3 Filter wheel adjust

Select the filter wheel adjust, the interface as shown in Figure 5-36 will be displayed:

Figure 5-36

This interface can be used to adjust and set the filter wheel.

- Step: Enter the number of steps for the filter wheel Adjust.
- Read: Click this button to read the step value from the configuration file.
- Write: Click this button to write the interface step value to the configuration file.
- Reset: Click this button to reset the filter wheel and verify the number of steps

5.6.4 Temp adjust

Select Temp adjust, and the interface shown in Figure 5-37 will be displayed:

Figure 5-37

This interface can be used for temperature adjust and setting.

- Target temperature: Enter the target temperature.
- Adjust temp: Enter the adjust temperature.
- Read: Click this button to read the value from the configuration file
- Write: Click this button to write the interface value to the configuration file

5.7 System setting

Click the [System setting] button on the main interface, and the interface shown in Figure 5-38 will be displayed:

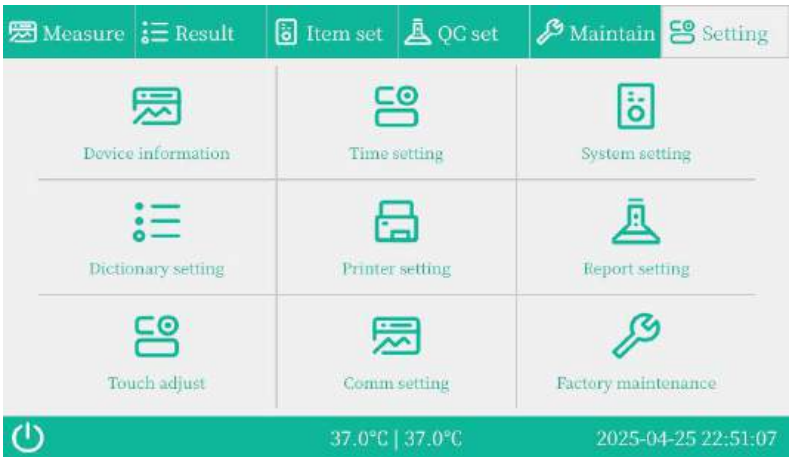


Figure 5-38

5.7.1 Device Information

The device information interface is shown in Figure 5-39 below:

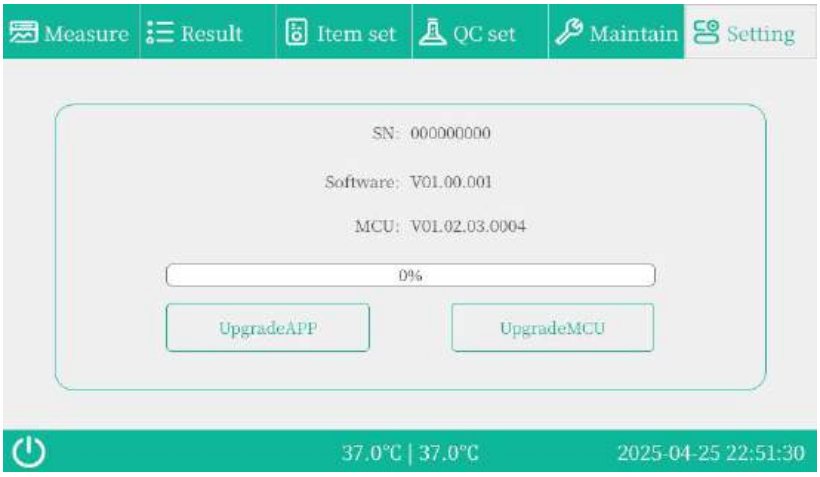


Figure 5-39

This interface can view system version information and update programs.

- Instrument serial number: Displays the serial number of the instrument.
- System software version: Displays the current system software version.
- Core software version: Displays the current core software version.
- Driver board software version: Displays the current driver board software version.
- Program update: After inserting the upgrade U disk, click this button to perform automatic upgrade and update.

5.7.2 Date time

The date time interface is shown in Figure 5-40 below:

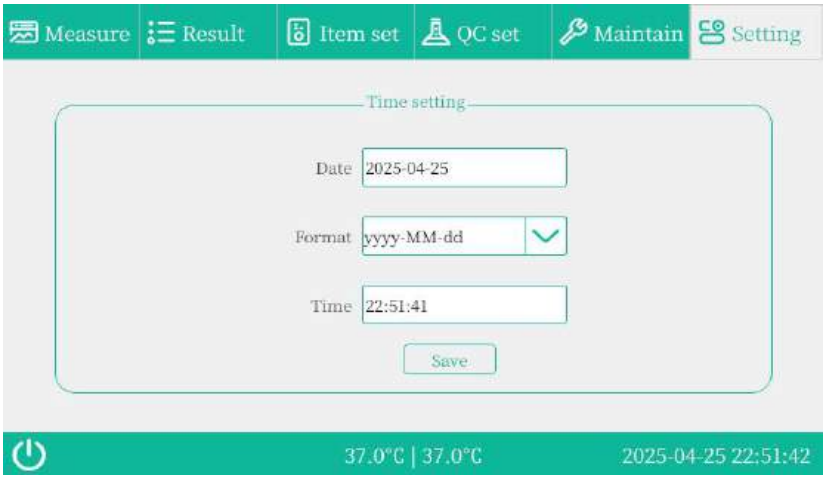


Figure 5-40

This interface can set the system date time and date format.

- Date: Set the system date.
- Date format: Select the date format.
- Time: Set the system time.

5.7.3 System setting

The system setting interface is shown in Figure 5-41 below:

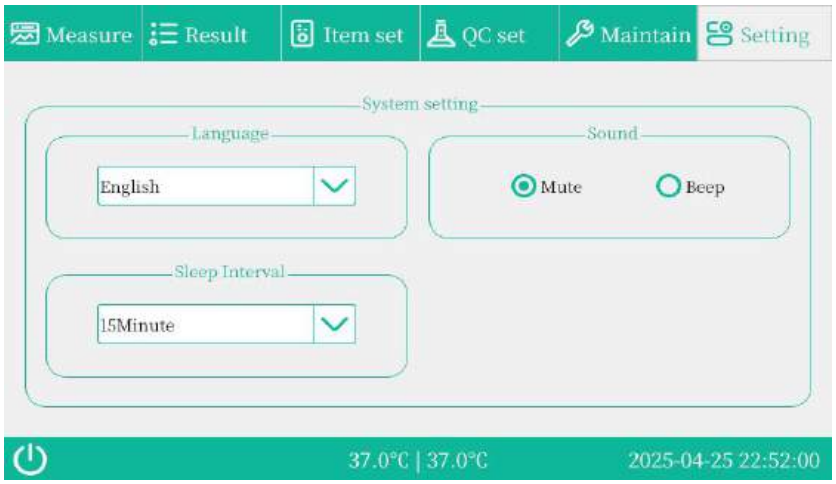


Figure 5-41

This interface can set Language setting, Sound setting, Display brightness and Sleep interval.

- Language setting: Set the system language. The system will restart automatically after setting the language.
- Sound setting: Set the system prompt sound, Mute close the honey pot prompt and Beep turn off the honey pot prompt.
- Display brightness: Set the screen backlight brightness.
- Sleep interval: Set the system sleep interval time.

5.7.4 Dictionary setting

The dictionary setting interface is shown in Figure 5-42 below:

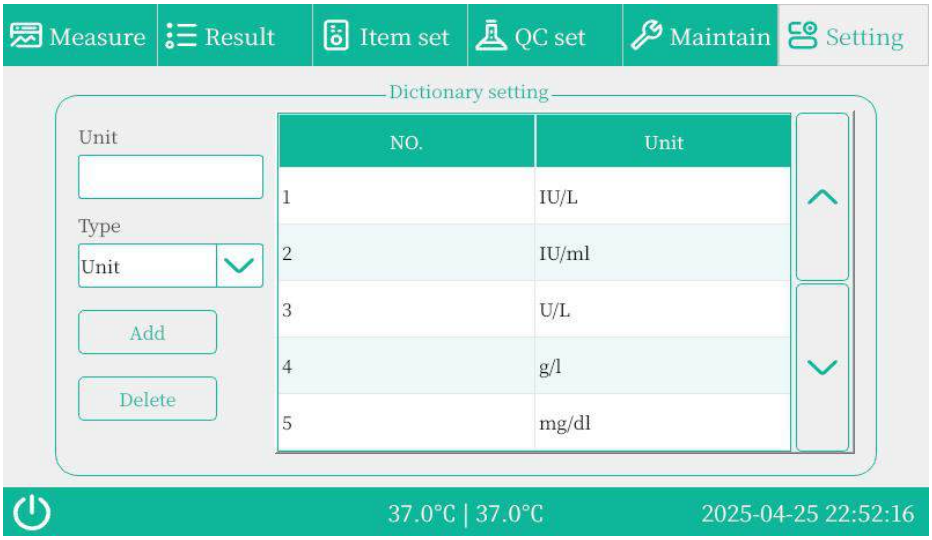


Figure 5-42

This interface can set the content of the combo box.

- Unit: Set the unit list.
- Department: Set the department list.
- Doctor: Set the doctor list.
- Add: Add a new item in the data list.
- Delete: Delete the data in the selected data list.

5.7.5 Printer setting

The printer setting interface is shown in Figure 5-43 below:

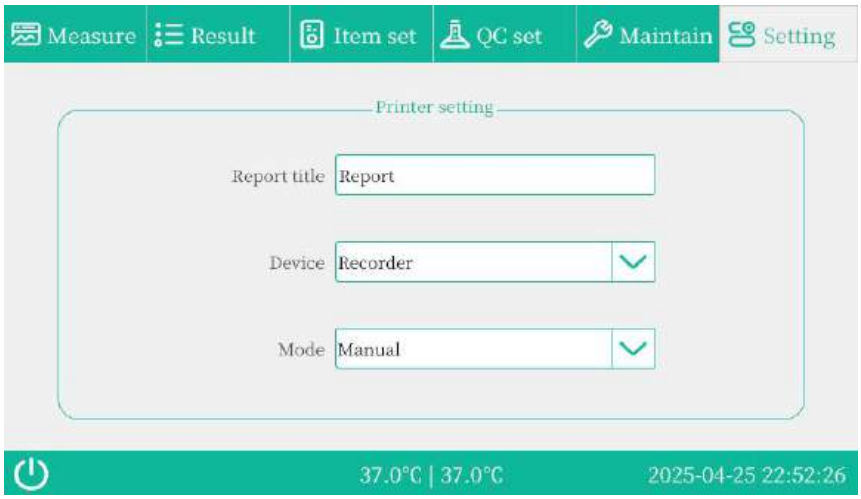


Figure 5-43

This interface can set the system to print.

- Report title: Enter the title of the printed report.

- Print Device: Select the print device type: Recorder, Printer, and PCL Printer.
- Print Mode: Select the print mode: Manual printing and Real-time printing.

5.7.6 Report setting

The report setting interface is shown in Figure 5-44 below:

Figure 5-44

This interface can set the recorder report direction.

- Horizontal display: The recorder prints horizontally.
- Vertical display: The recorder prints vertically.

5.7.7 Touch adjust

Generally, the touch screen is adjusted at the factory, but it needs to be adjusted again after the motherboard is replaced and the software is upgraded.

Figure 5-45

This screen confirms whether to adjust the screen.

- Confirm: Click this button to perform touch screen adjust. The asjust interface is shown in Figure 5-46 below:

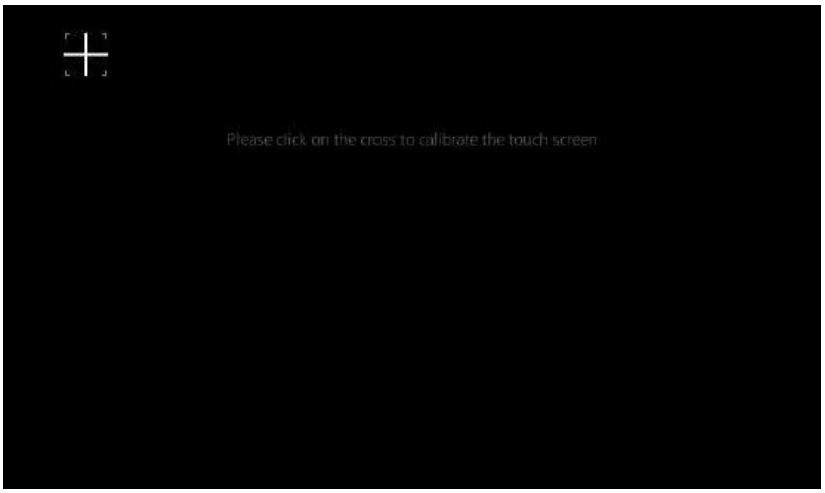


Figure 5-46

Adjust method: Click the five cross icons on the screen in sequence to complete the screen adjust.

Caution：

- If the touch screen does not work, use an external mouse to enter the above dialog box.

5.7.8 Comm setting

The communication setting interface is shown in Figure 5-47 below:

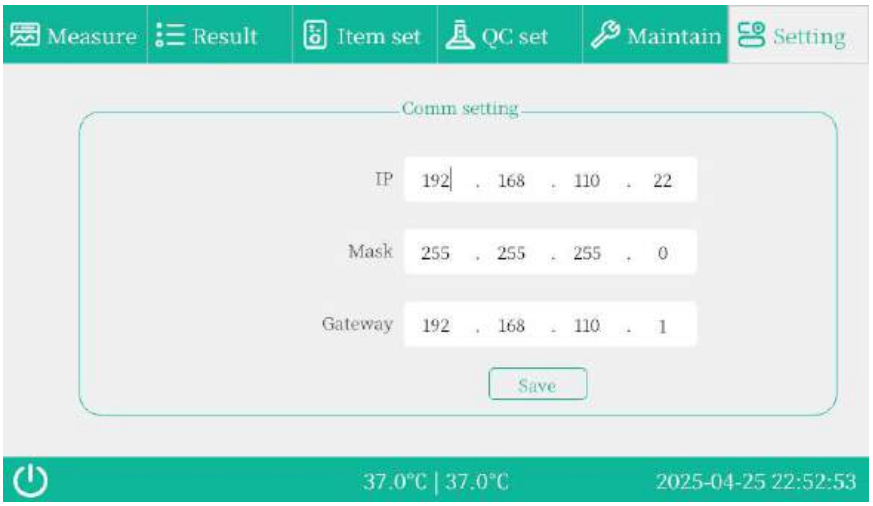


Figure 5-47

This interface can set the system network settings.

- IP Address: Set the system network IP address.
- Subnet mask: Set the network subnet mask of the system.
- Default gateway: Set the system network default gateway.

5.7.9 Factory maintenance

Enter the factory maintenance interface needs to verify the password. The password input interface is shown in Figure 5-48 below:

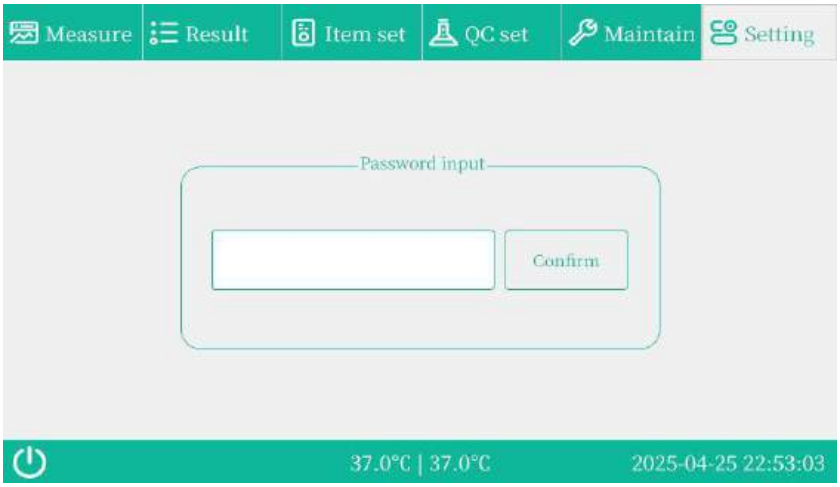


Figure5-48

This interface can enter the authority password.

- Input box: Enter the password.
- Confirm: After clicking this button, the system verifies the input password, prompt an error if the password is wrong, and enter the interface if the password is correct.

5.8 System sleep

The system will enter sleep mode without any operation during the sleep interval. The sleep interface is shown in Figure 5-49 below:

Figure 5-49

Caution：

- When the instrument enters the sleep state, the light bulb will be turned off protectively. Clicking on the touch screen, moving the external USB mouse or tapping the USB

keyboard will wake up the instrument and the light bulb, and enter the detection state after the light bulb is stable for 1 minute.

5.8.1 System shutdown

Click the [Shutdown] button on the main interface, and the dialog box shown in Figure 5-50 will pop up.

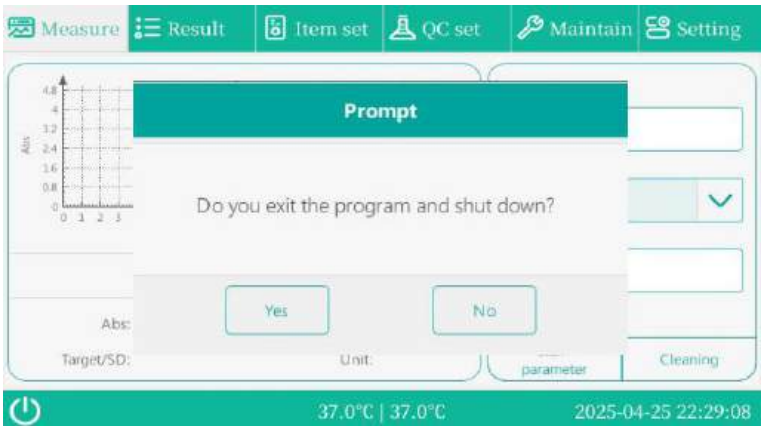


Figure 5-50

- Yes: Click this button to enter the shutdown interface.
- No: Click this button to cancel the shutdown and close the dialog box.

5.8.2 Shutdown interface

The shutdown interface is shown in Figure 5-51:

Figure 5-51

This interface can be configured to save and close the program.

Chapter 6. Maintenance and replacement

6.1 Care and maintenance

Daily maintenance: Optical adjust is required before the start of the daily test. After the test, the pipeline is cleaned and the surface of the instrument is wiped.

Weekly maintenance: Pump and touch screen adjusts are performed weekly.

Monthly maintenance: Soak and clean the cuvette with detergent every month.

Warning：

- When using cleaning agents, follow the precautions on each cleaning agent bottle, and use protective glasses and rubber gloves.

Biohazard:

- It is recommended that the instrument waste liquid be discharged after being harmlessly treated, and not directly poured into the sewer.
- Blood samples, controls, calibrators, and reagents that may be on the pipette have potential biological risks. Avoid touching the probe directly with your hands.

6.2 Cleaning the cuvette

Caution：

- Before working on the instrument, the cuvette must be cleaned with distilled water.
- At the end of each test, the cuvette and peristaltic pump should be rinsed with distilled water immediately to remove any dirt deposited in the cuvette.
- After the user finishes a week of work. Rinse the cuvette with distilled water, then aspirate sodium hypochlorite or detergent and wait 1-5 minutes in the cuvette. Finally, rinse repeatedly with distilled water to ensure that the sodium hypochlorite or detergent is thoroughly washed.
- It is not good for any liquid to remain in the cuvette for a long time. Please clean and drain any liquid in the cuvette.

6.3 Paper installation

If you select "Recorder" in the system setting, it is necessary to install thermal printing paper, otherwise the recorder will warn when it works, as shown in Figure 6-1 below.

Figure 6-1

Installation steps:

- Open the recorder cover as shown above.
- Place the thermal paper in the recoder slot with the carbon film side of the thermal paper facing down.
- Close the recorder cover.

Caution：

- Pay attention to the direction of the printing paper. If the direction is wrong, the printing paper will not display information when the printer is working.

6.4 Display adjust

See [Touch adjust] method.

6.5 Pump pipe replacement

If the sample suction is abnormal, the pump pipe may need to be replaced, as shown in Figure 6-2 and 6-3 below.

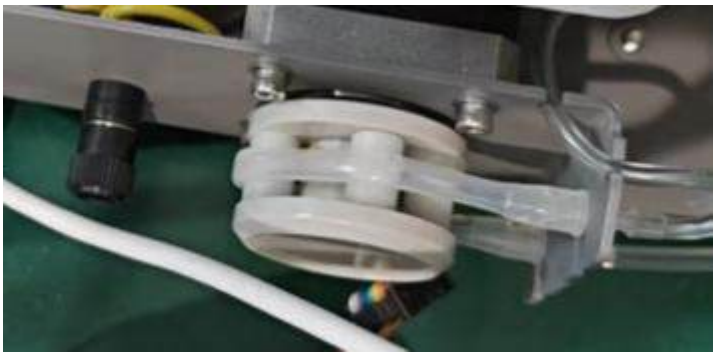


Figure 6-2

Figure 6-3

 Biological:

- Improper disposal of biological waste liquid may lead to infection. Don't touch the waste liquid with your hand. If necessary, wear gloves, goggles and a coat.
- If your skin is exposed to waste liquid, follow standard laboratory safety procedures or consult a doctor

Chapter 7. Reagents, cleaning agents, controls and calibrators

7.1 Reagents

The Semi-auto Chemistry Analyzer is all open design, which can choose any qualified biochemical reagents and set the parameters.

 **Note：**

- For the use and storage method of the reagent, please refer to the instruction manual of the reagent.
- When setting biochemical item parameters, please read the reagent instruction manual carefully, and combine the item parameter settings of the instrument.
- When changing the reagent, the operator should pay attention to the setting of biochemical item parameters.
- Make sure reagents are used within the expiration date.

7.2 Cleaning agents

The cleaning agent is used for daily cleaning and maintenance of the Biochemistry analyzer, and decomposes and removes organic stains in the cuvette and pipeline.

 **Note：**

- The immersion time of the cleaning agent is 1-5 minutes. After the immersion, clean it immediately with distilled water to prevent the instrument from being damaged for too long.

 **Warning：**

- When using cleaning agents, follow the precautions on each cleaning agent bottle, and use protective glasses and rubber gloves.

Chapter 8. Common faults and troubleshooting

Before or during the use of the analyzer, if any of the faults listed in the table below occur, please refer to the corresponding troubleshooting steps for troubleshooting. If the fault persists, please contact China String Bio's after-sales service department or your local distributor. Common faults and troubleshooting are shown in Table 4 below.

Table 4

Fault Description	**Cause analysis→Troubleshooting**
Instrument or bulb is not working	1. The socket is loose or poorly connected → Fix and connect socket 2. The power socket is loose or poorly connected → Fix and connect the power socket
Not aspirate	1. Pump tube life has expired or is damaged → Replace pump tube 2. Pipe blocked → clear the blockage
Built-in printer does not work	1. The printer has no paper → install the paper
External USB printer does not work	1. The printer socket is loose or the connection is unstable → Fix and connect the socket 2. USB socket is loose → Fixed USB socket 3. The printer does not support PCI 3 GUI printing language → Replace the printer that supports PCI 3 GUI printing language
No response from touch screen	1. Touch screen is not adjusted after software update → readjust touch screen 2. Touch screen is not adjusted after replacing motherboard → readjust touch screen
AD value is out of range (35000-60000).	1. Air bubbles in the cuvette → clean the cuvette with a cleaning agent 2. The bulb does not work → replace the bulb
Abnormal result or Poor repeatability	1. Air bubbles in the cuvette → clean the cuvette with a cleaning agent 2. Sample hemolysis or expired reagent

 **Biohazard:**

- Improper disposal of waste fluids can lead to biohazardous infections. Do not touch the waste liquid with your hand. If necessary, wear gloves and goggles and a coat.
- If your skin comes in contact with waste fluid, follow standard laboratory safety procedures or consult a doctor.

Chapter 9. Calculation method and adjust mode

9.1 Calculation method

The Semi-auto Chemistry Analyzer has four biochemical analysis methods: End point method, Rate method, two point method, and Two-point end method.

9.1.1 End point method

After aspiration, the instrument reads the absorbance (one absorbance per second) during the hatch time and test time, and then calculates the average absorbance during the test time. The reaction curve is shown in Figure 9-1 below:

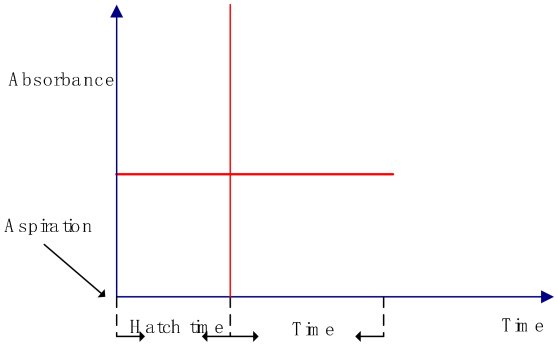


Figure 9-1

Absorbance calculation formula:

$$A_X = \frac{\sum_{i=1}^{N} A_i}{N}$$

In the formula: N——test time.

9.1.2 Rate method

After aspiration, the instrument reads the absorbance (one absorbance per second) during the hatch time and test time, and then calculates the average absorbance during the test time. The reaction curve is shown in Figure 9-2 below:

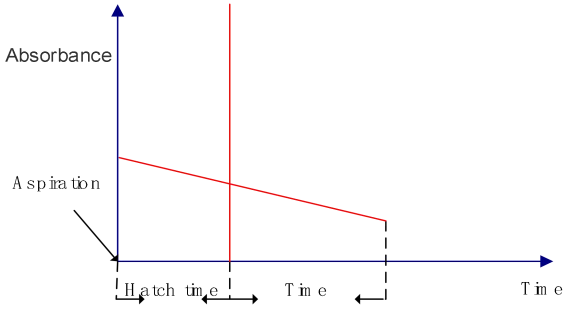


Figure 9-2

Absorbance calculation formula:

$$A_X = \Delta A/\text{min}$$

9.1.3 Two point method

After aspiration, the instrument reads the absorbance (one absorbance per second) during the hatch time and test time, reads the A1 initial absorbance, and then reads the A2 end absorbance to calculate the difference between A2 and A1. The reaction curve is shown in Figure 9-3 below:

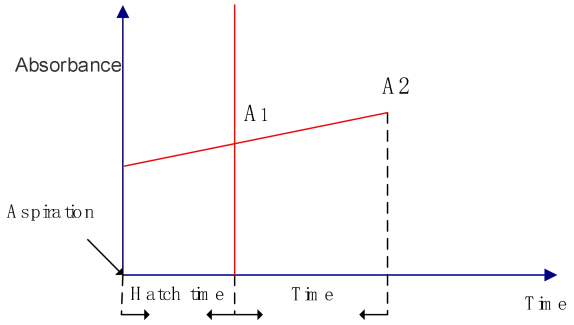


Figure 9-3

Absorbance calculation formula:

$$A_X = A_2 - A_1$$

9.1.3.1 Two-point end method

The two-point end method requires 2 steps and requires 2 aspiration.

In the first step, after aspiration, the instrument reads the absorbance (one absorbance per second) during the hatch time and test time, and then calculates the average absorbance A1 during the test time.

The second step is after the first step. After the reaction solution is aspirated, the instrument reads the absorbance (one absorbance per second) during the hatch and test time, and then calculates the average absorbance A2 during the test time. Calculate the difference between A2 and A1. The reaction curve is shown in Figure 9-4 below:

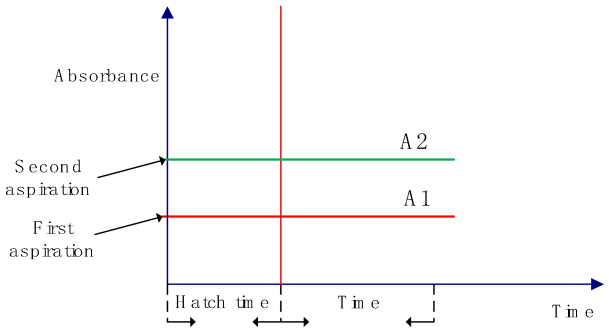


Figure 9-4

Absorbance calculation formula:

$$A_1 = \frac{\sum_{i=1}^{N} A_i}{N}$$

$$A_2 = \frac{\sum_{i=1}^{N} A_i}{N}$$

$$A_X = A_2 - A_1$$

In the formula: N——test time.

9.2 Adjust mode

9.2.1 Glossary

Calculated value: the value automatically calculated by the instrument

Measured value: the value measured by the instrument

Input value: the value entered by the operator

AX:

End point method, the measured absorbance at single wavelength and the difference in absorbance at dual wavelength.

Rate method: The rate of change in absorbance per minute during the test time.

Two point method: The difference in absorbance between the last point and the first point in the test time.

Two-point end method: the difference between the absorbance of the sample and the absorbance of the sample blank.

Immunoturbidimetry: The ratio of absorbance in the first and second steps.

9.2.1.1 Point linear

The 1-point linearity is shown in Figure 9-5 below.

Figure 9-5

Adjust formula:

$$C_X = K \times (A_X - B)$$

In the formula:

C_x : (Calculated value) sample concentration

A_x : (Measured value) Sample absorbance

B : (Measured value) reagent blank absorbance, blank is water, here is 0

K : (Input value) The value entered in the item set dialog

B, K will be displayed in the calibration value

9.2.1.2 -point linear

The 2-point linearity is shown in Figure 9-6 below.

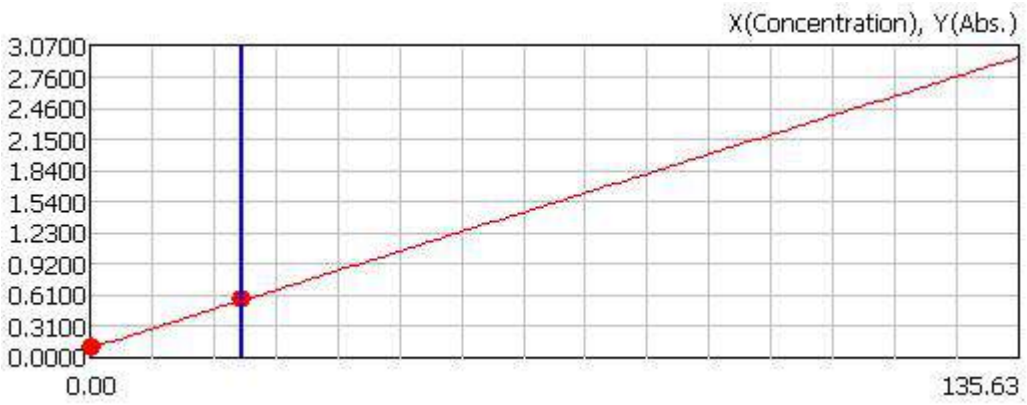


Figure 9-6

Adjust formula:

$$C_X = K \times (A_X - B)$$

$$K = \frac{C_1}{A_1 - B}$$

In the formula:

C_x : (Calculated value) sample concentration

A_x : (Measured value) Sample absorbance

B : (Measured value) reagent blank absorbance, blank is water, here is 0

K : The value entered in the item set dialog

C_1 : (Input value) Concentration of standard 1

A_1: (Measured value) Absorbance of standard 1

B, K will be displayed in the calibration value

9.2.2 Multipoint linear

Multipoint linearity is shown in Figure 9-7 below.

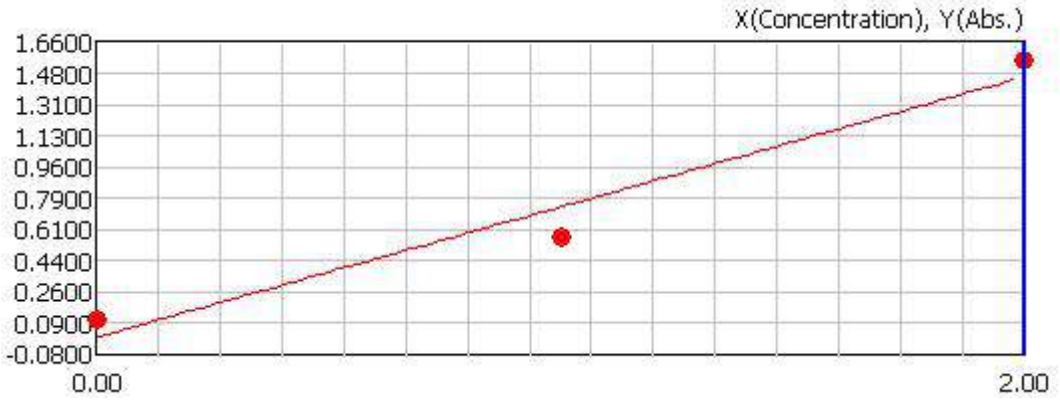


Figure 9-7

Adjust formula:

$$B = \overline{A} - \frac{X \times \overline{Cr}}{Y}$$

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

$$X = \sum_{i=0}^{n-1}\left(Cri - \overline{Cr}\right) \times \left(Ai - \overline{A}\right)$$

$$Y = \sum_{i=0}^{n-1}\left(Cri - \overline{Cr}\right)^2$$

$$\overline{A} = \left(\sum_{i=0}^{n-1} Ai\right) / n$$

$$\overline{Cr} = \left(\sum_{i=0}^{n-1} Cri\right) / n$$

$$C_X = K \times \left(A_X - B\right)$$

In the formula:

C_x: (Calculated value) sample concentration

A_x: (Measured value) Sample absorbance

B: (Calculated value) Parameters of the adjust formula

K: (Calculated value) Parameters of the adjust formula

C_{ri}: (Input value) Concentration of standard i

A_i: (Measured value) Absorbance of standard i

n: (Input value) Enter the number of calibrations in the item set dialog box, the range must be 3-8

9.2.3 B, K will be displayed in the calibration value-point nonlinear

The 3-point non-linearity is shown in Figure 9-8 below.

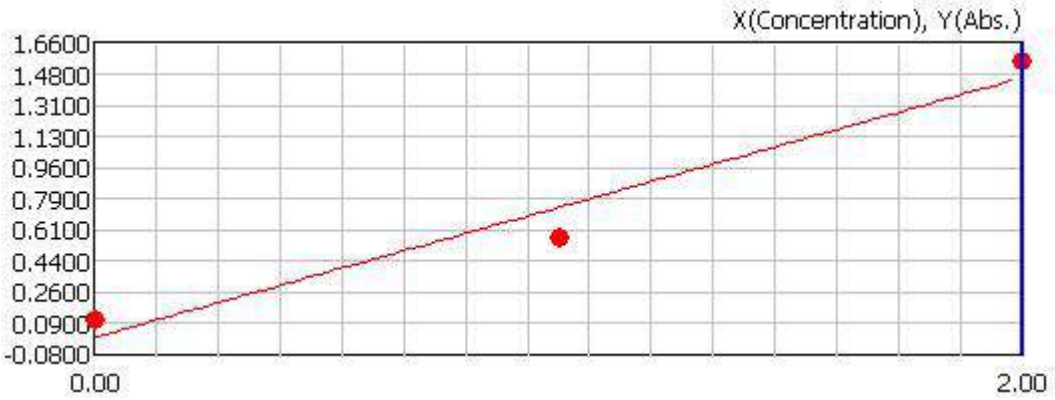


Figure 9-8

Adjust formula:

$$A_X = B + \frac{K}{1 + aC_x}$$

In the formula:

C_x: (Calculated value) sample concentration

B: (Calculated value) Parameters of the adjust formula

K: (Calculated value) Parameters of the adjust formula

a: (Calculated value) Parameters of the adjust formula

B, K, a will be displayed in the calibration value.

9.2.4 Point non-linear

The 4-point non-linearity is shown in Figure 9-10 below.

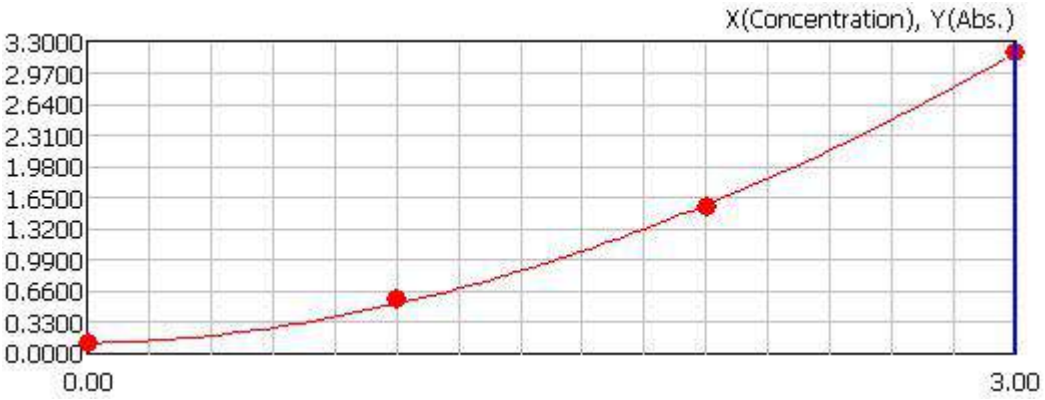


Figure 9-10

Adjust formula:

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

In the formula:

C_x: (Calculated value) sample concentration

A_x: (Measured value) Sample absorbance

B: (Calculated value) Parameters of the adjust formula

K: (Calculated value) Parameters of the adjust formula

a: (Calculated value) Parameters of the adjust formula

b: (Calculated value) Parameters of the adjust formula

B，K，a，b will be displayed in the calibration value

9.2.5 -point non-linear

The 5-point non-linearity is shown in Figure 9-11 below.

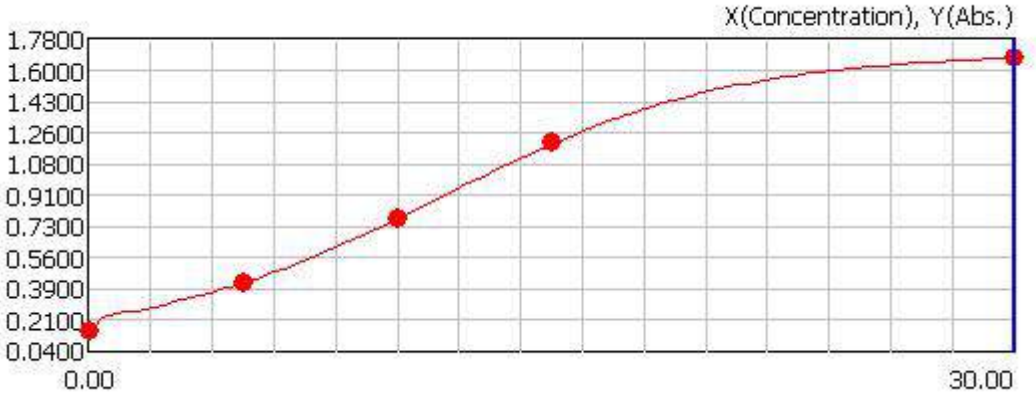


Figure 9-11

Adjust formula:

$$Ax = B + \frac{K}{1 + \exp\left(-a - b \times l\,\mathrm{n}\,C_x - c \times C_x\right)}$$

In the formula:

A_x : (Measured value) Sample absorbance

B : (Calculated value) Parameters of the adjust formula

K : (Calculated value) Parameters of the adjust formula

a : (Calculated value) Parameters of the adjust formula

b : (Calculated value) Parameters of the adjust formula

c : (Calculated value) Parameters of the adjust formula

B，K，a，b，c will be displayed in the calibration value

Chapter 10. Transportation and Storage

10.1 Transportation

The Biochemistry analyzer is transported in accordance with the requirements of the order contract in the packaged state, and must be protected from severe impact, rain and exposure during transport. Not to be transported with toxic, harmful and corrosive substances.

10.2 Storage

The packed Biochemistry analyzer should be stored at -20 ℃ ～ 55 ℃, the relative humidity should not exceed 85%, no corrosive gas, and well ventilated environment. Do not mix with toxic, harmful and corrosive substances.

Date of preparation: April 28, 2025

Version：A0