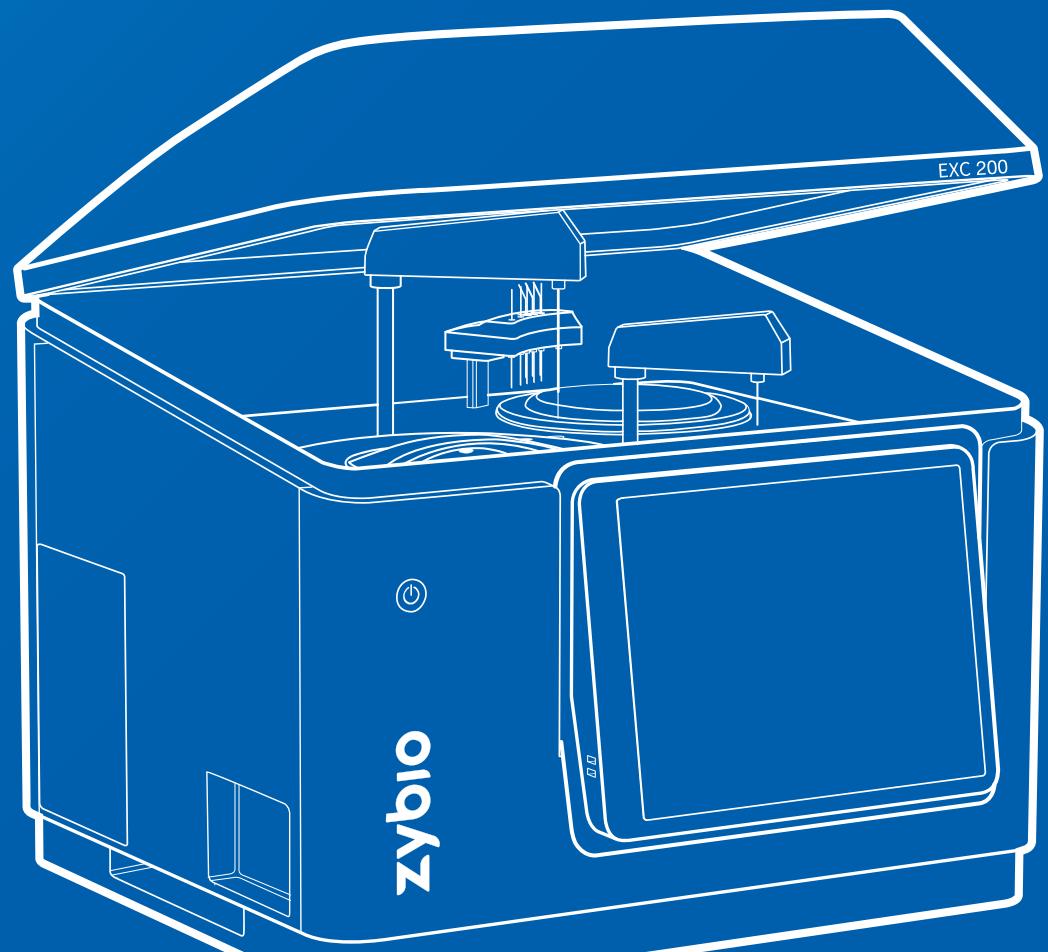




# EXC2X Series Chemistry Analyzer

Operation Manual



Chemistry

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The version of this manual is 1.0, and the release date is 2020.1. The manual may be amended without prior notice.

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The illustrations provided in the Operation Manual are only examples and may not be completely consistent with the actual display on the product. The actual items shall prevail and shall not be used for other purposes.

Only when all the following requirements are met can Zybio consider itself responsible for the safety, reliability and performance of the product, namely:

- 1) Assembly operation, re-commissioning, extensions, improvement and maintenance shall be carried out by personnel recognized by Zybio.
- 2) All replacement parts used in the repairs and all accessories and consumables used are products of or approved by Zybio.
- 3) The operation of the product shall be carried out according to this Operation Manual.
- 4) Relevant electrical equipment meets the requirements of national standard values and this Operation Manual.

## After-Sales Service

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Warning

- 1) This instrument can only be used by professionals, doctors and testers trained by Zybio or its Agents.
- 2) If each hospital or institution using this instrument cannot prepare a complete set of repair/maintenance plan, abnormal instrument failure may occur and personal safety may be endangered.
- 3) Please ensure that the analyzer is used under the operating conditions specified in the Operation Manual. If the operating conditions are exceeded, the analyzer may not operate normally, the measurement results will not be reliable, and the analyzer components may be damaged and personal safety may be endangered.



Attention

- 1) The readers of this Operation Manual are the following operators:
  - Personnel operating the system;
  - Personnel who maintain the system and handle system failures;
  - Personnel who learns the operating system.
- 2) When the instrument reaches the expiration date, it is recommended to stop using it or use it after comprehensive overhaul and maintenance by Zybio.

# Product Description

Thank you for purchasing Chemistry Analyzer by Zybio Inc. Hereby we would like to express our gratitude.

Before using the product, please read the contents of this Operation Manual carefully so that you can use it correctly.

The pictures in this instruction book are for illustration or example only and shall not be used for other purposes. The actual pictures are subject to the product.

Please keep this Operation Manual properly after reading, so that you can check it at any time in case of needing.

Product Name: Chemistry Analyzer

Model and Specification: EXC200, EXC220

Management Classification: The management category is Class II

Production License No.: YSYJXSCX20150016

Registration Certificate No. / Product Technical Requirement No.: YXZZ20202220024

The product structure consists of a reagent sample processing unit, a stirring unit, a reaction unit, a photoelectric detection unit, a control and data processing unit and software.

Scope of application: The product is based on the principle of spectrophotometry and is used with matched reagents in clinical applications for the quantitative detection of human serum, plasma, urine, cerebrospinal fluid and other samples.

Name of registered person/manufacturer: Zybio Inc.

Registered Person's Residence/Production Address: Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082.

Service life: 10 years. This service life is determined according to the lifespan test performed on the instrument. In the process of use, the user shall carry out maintenance and repair of the product according to the requirements of the Operation Manual. After maintenance and repair, the product that is confirmed to still maintain its basic safety and effectiveness can be used normally.

## **Warranty and Maintenance Services**

The warranty period of purchased products shall be subject to the sales contract.

Consumables: it refers to disposable consumable materials that need to be replaced after each use or vulnerable materials that need to be replaced regularly. Consumables have no warranty.

During the warranty period, faults caused by quality problems or design defects of products can be treated with free maintenance services. All you need to do is provide the "Warranty Card" to maintenance specialist of Zybio. The warranty period starts from the "Date of Installation" filled in the "Warranty Card" attached to the product. **The "Warranty Card" is your only warranty certificate and must not be lost.** If the "Warranty Card" and other relevant provisions of Zybio products conflict with relevant national laws and regulations, the provisions of relevant national laws and regulations shall be followed.

If the repair work required during the warranty period due to the following non-product problems does not fall within the scope of the free warranty:

- Voltage mismatch;
- Improper human use;
- Maintenance not approved by Zybio;
- Force majeure factors such as natural disasters;
- Other repair works caused by instrument or part itself.

We promise to provide corresponding technical support and technical cooperation for the products sold and guarantee after-service.

# Preface

This manual mainly helps users to understand the safety, installation, structure and function, analysis principle, operation process, maintenance, alarm and treatment of EXC2X Series Chemistry Analyzer (hereinafter referred to as EXC2X). In order to ensure its correct use, please strictly follow the instructions.

## Scope of Application of Operation Manual

This manual is suitable for medical inspection professionals or trained doctors, nurses or testers to read, and is used for:

- Understanding EXC2X hardware and software;
- Setting system parameters;
- Performing routine operations;
- Performing system maintenance and troubleshooting.

## Guide to Operation Manual

When you need ...	Please refer to ...
Learn about EXC2X safety information	Chapter 1 Safety Information
Learn about EXC2X system overview	Chapter 2 System Overview
Understand the basic test operation method of EXC2X	Chapter 3 Basic Operation Methods
Understand EXC2X software operation and software parameter setting	Chapter 4 Software System Operation
Understand the setting of EXC2X parameters and the principle of instrument analysis	Chapter 5 Analysis Principle and Calculation Method
Know how to maintain EXC2X	Chapter 6 Maintenance and Service
Understand the cause and treatment of EXC2X fault	Chapter 7 Alarm and Management
Understand the transportation and storage methods of EXC2X	Chapter 8 Transportation and Storage

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# 1. Safety Information

## 1.1. Overview

This chapter introduces the significance of the safety symbols, the labels related to the product, and silkscreen printing used in the Operation Manual, as well as the potential safety hazards and precautions when using the instrument.

Note: the following symbols are for reference only. For details, please refer to the Operation Manual.

## 1.2. Symbols used in the operation manual

Symbol	Meaning
 Warning	Prompt the operator to follow the instructions below the symbol. Failure to do so may result in personal injury.
 Caution	Prompt the operator to follow the instructions below the symbol, otherwise it may cause product failure, damage or affect the test results.
 Attention	Prompt the operator to follow the instructions below the symbol and emphasize important information or contents requiring special attention of the operator in the operation steps.
 Biological hazard	Prompt the operator to follow the instructions below the symbol, otherwise there is a risk of potential biological infectivity.

## 1.3. Silkscreen printing and labeling related to products

Various warning labels and silkscreen printing are used on the instrument to identify the characteristics of the instrument and remind operators to pay attention. Other marks related to the use of the instrument are also explained below. Please check the warning labels frequently to keep them clean and complete. If the label cannot be read normally due to blurring or falling off, please contact our customer service department for replacement.

**Note:** The following signs or symbols are for reference only, and the specific pictures are subject to the actual objects.

Symbol	Meaning
	Please refer to the specific files delivered with the instrument.
	Moving parts prompt label
	<p><b>Electric shock</b>  When the power is on, unauthorized maintenance personnel must not open the analyzer panel. Splashing liquid shall be avoided on the table. If liquid flows into the analyzer, please immediately turn off the analyzer and contact Zybio in time.</p>
	<p><b>Biohazard</b>  The background color of this symbol is yellow, and the symbol and outline are black.</p> <ol style="list-style-type: none"> <li>1) All test samples, calibrators, quality control, etc. Shall be considered infectious and gloves shall be worn when contacting;</li> <li>2) All waste liquid should be considered infectious and gloves should be worn when contacting. Parts in contact with the test sample, such as suction nozzle and measuring cuvette, shall be considered infectious, and gloves shall be worn during contact;</li> <li>3) All wastes are considered infectious and should be treated as medical wastes according to current regulations;</li> <li>4) When the instrument reaches its service life, it should be treated according to the requirements of the local environmental protection department, and should not be treated and discarded as ordinary wastes.</li> </ol>

Symbol	Meaning
	<p><b>High temperature</b> It may cause injury to human body.</p>
	<p><b>Corrosion</b> Cleaning fluid is chemically corrosive, and protective gloves should be worn during operation.</p>
	<p>Alternating current symbol</p>
	<p>This electronic information product contains some toxic and harmful substances. The environmental protection service period is 20 years, within which it can be used safely. After the environmental protection service period, it should be put into the recycling system.</p>
	<p>Only for in vitro diagnostic use</p>
	<p>Serial number</p>
	<p>Date of production</p>
	<p>Manufacturer</p>
	<p>Please refer to the Operation Manual</p>
	<p>On (power)</p>

Symbol	Meaning
○	Off (power)
DW1	Deionized water inlet
DW2	Deionized water outlet
HW	Concentrated waste liquid outlet
LW	Dilute waste liquid outlet
CW	Concentrated cleaning fluid inlet
DW-D	Pure water float sensor
CW-D	Float sensor for concentrated detergent
W-D	Waste liquid float sensor

## 1.4. Matters needing attention

### 1.4.1. Scope of application



Caution

- 1) EXC2X series Chemistry Analyzer is mainly used in medical institutions for quantitative examination of human serum, plasma, urine and other samples.
- 2) When making clinical judgment according to the test results, please consider the clinical examination results or other test results.

### 1.4.2. Operator



Caution

EXC2X series Chemistry Analyzer is only applicable to personnel trained by Zybio or its agents.

### 1.4.3. Application environment



Attention

- 1) Please install correctly according to the installation environment specified in this Operation Manual. Installing or using not under the specified conditions may lead to unreliable results and may damage the instrument.
- 2) If you need to change the working environment of the analyzer, please contact Zybio or the agent in your region.

### 1.4.4. Data backup



Attention

The system itself carries out backup processing on the data and stores the data in the industrial control board. If the industrial control board data is deleted or damaged due to some reasons, the data will be lost. Please back up the analysis data and analysis parameters to other mobile storage devices on a regular basis.

### 1.4.5. Analysis parameters



Attention

Incorrect analysis parameters will lead to incorrect test results, please consult Zybio or reagent supplier.

### 1.4.6. Electromagnetic interference



Attention

- 1) The analyzer is vulnerable to electromagnetic interference during operation, which may affect the test results and lead to misoperation. Please do not use electric drills, mobile phones, interphones and other devices that generate electromagnetic waves during operation.
- 2) During the operation of the analyzer, electromagnetic waves will be radiated to the outside. Do not install or use electromagnetic sensitive equipment near the analyzer.

### 1.4.7. Imperfect grounding



Attention

- 3) The power supply must be grounded correctly, otherwise there is danger of electric shock.
- 4) The grounding impedance must be less than 10mΩ. Poor grounding may lead to unstable test results and leakage of electricity from the casing, thus posing a risk of electric shock.

### 1.4.8. Label falling off



When the label of the instrument is fuzzy or falls off, please contact Zybio for replacement.

Attention

### 1.4.9. Leakage



Attention

- 1) Before testing, carefully check the manually tightened joints of each pipe to see if there is liquid leakage, which will lead to inaccurate suction and discharge capacity.
- 2) Do not place reagents or samples on the analyzer table to avoid liquid splashing and leakage.

### 1.4.10. Probe blocking



Attention

Carefully check the reagent and sample, which cannot contain insoluble floaters, such as cellulose, fibrin, etc. Otherwise, the reagent-sample probe will be blocked.

### 1.4.11. Ultraviolet transparent plastic cuvette



Attention

Ultraviolet transparent plastic cuvette (referred to as colorimetric cup or plastic cuvette) used by EXC2X series Chemistry Analyzer. Please use cuvette specified by Zybio, otherwise the expected use effect may not be obtained.

### 1.4.12. Water quality



Attention

The water quality shall meet the requirements of ISO3696 Class II, otherwise it will easily lead to valve and pump damage and not thorough cleaning.

### 1.4.13. System applicable

- 1) Please use the system according to the instructions in the Operation Manual. Incorrect use may lead to incorrect measurement results, and may even lead to system damage or personal injury.
- 2) Before using the system for the first time, calibration should be carried out before quality control to confirm that the system works normally.
- 3) When using the system on a daily basis, it is recommended to carry out quality control to ensure the reliability of the results.
- 4) Before analysis, please cover the reaction tray and reagent-sample tray.
- 5) Do not uncover the reaction tray during the analysis.
- 6) During the analysis, please ensure that there are no obstacles in the movement track of the probe and stirring rod.
- 7) When the reaction tray and reagent-sample tray rotate, do not touch them to prevent scratches.
- 8) Do not install any software or hardware other than those specified by Zybio on this system, or it may hinder the normal operation of this system. Please do not run other software during the operation of this system.
- 9) Do not use this system for other purposes. Incorrect use may cause the instrument to be infected with virus. Computer viruses may spread through USB, programs, networks, etc.



Warning

### 1.4.14. System maintenance

- 1) Please follow the instructions in this Operation Manual for system maintenance. Incorrect maintenance may lead to incorrect analysis results and even system damage or personal injury.
- 2) After replacing the main components, such as light source lamp, reagent-sample probe and syringe piston assembly, please carry out calibration analysis.
- 3) If you stop using the instrument due to malfunction or other reasons and needs repair or disposal, please contact Zybio or local agent in time. At the same time:

Warning



- Please take other measures, such as replacing the unfinished tests with other instruments or methods, so as not to cause delay in the results.
- Please take out the reagent on the instrument and store it separately according to the instructions for using the reagent in the kit. Put the reagent back in the refrigerator for cold storage to prevent it from deteriorating.

### 1.4.15. Sample

- 1) Please use a completely separated serum sample and a urine sample without suspended substances. If the serum sample contains fibrin or the urine sample contains suspended substances, the reagent-sample probe may be blocked, thus affecting the accuracy of the analysis results.
- 2) Drugs, anticoagulants, preservatives, etc. Present in the sample may interfere with some analysis results.
- 3) Lipemia, jaundice, hemolysis, etc. in the sample may affect the analysis results, and it is recommended to make blank analysis of the sample.
- 4) Please store the sample correctly. Incorrect sample storage conditions may change the composition content of samples, thus affecting the accuracy of analysis results.
- 5) Do not leave the sample tube open for a long time to prevent the sample from volatilizing, otherwise the accuracy of analysis results may be affected.
- 6) There is a requirement on sample volume in the analysis of this system. When sampling, please take appropriate sample volume according to the relevant instructions in this Operation Manual.

Warning



### 1.4.16. Reagent, calibrator and control

- 1) When using this system for analysis, please use appropriate reagents, calibrator and QC.
- 2) Please select suitable reagents according to this system. If you are not sure whether the reagent is available, please consult the manufacturer, agent of the reagent or manufacturer, agent of Zybio.
- 3) For the use and storage of reagents, calibrator and QC, please refer to the instructions of reagent manufacturers or distributors.
- 4) If reagents, calibrator and QC are not stored properly, even within the validity period, correct test results may not be obtained.
- 5) Please calibrate after replacing the reagent. Without calibration and quality control, correct analysis results may not be obtained.
- 6) Cross contamination of reagents may affect analysis results during analysis. For information on reagent cross-contamination, please consult the relevant reagent manufacturer or distributor.



Warning

### 1.4.17. Instrument discard



Some substances of waste analyzers are controlled by pollution regulations. Please follow the local waste disposal standard to dispose of the waste analyzer.

Warning

## 1.5. Picture

All the pictures in this Operation Manual are for illustration or example only and shall not be used for other purposes.

## 2. System Overview

This chapter gives a detailed introduction to the instrument about the installation, hardware, software and specifications, mainly including the following contents:

- Installation requirements and methods of instruments
- System structure of hardware
- Optional module
- Introduction and use of software interface

### 2.1. Installer



The installation of the instrument can only be carried out by Zybio's technicians or technicians authorized by Zybio.

Warning

EXC2X series Chemistry Analyzer can only be installed by Zybio or its authorized agent, and users need to provide corresponding environment and space. When the analyzer needs to be relocated, please contact Zybio or the local agent.

When you receive the analyzer, please inform Zybio and the local agent immediately.

### 2.2. Damage Examination

All analyzers have passed the strict inspection of Zybio before packaging and transportation. When you receive the analyzer, please check carefully before unpacking and pay attention to the following damages:

- 1) The outer package is inverted or deformed;
- 2) The outer package has obvious traces of being wetted by water;
- 3) The outer package has obvious marks of impact;
- 4) There are signs that the outer packing has been opened.

Once the above damages are found, please inform Zybio or its authorized local agent immediately. If the outer package is in good condition, please open the packing case and check it after unpacking in the presence of the designated staff of Zybio:

- 1) Check whether all components are complete according to the packing list in the packing box;
- 2) Carefully check the appearance of all devices for cracks, bumps or deformation.

After unpacking, please carefully inspect the appearance of the instrument and check the packing list. If there is any handling damage or the configuration is found to be incomplete, please immediately declare it to Zybio or its authorized local agent.

## 2.3. Installation Requirements

### 2.3.1. Site

- For indoor installation only;
- The installation table should be flat (inclination is less than 1/200);
- The mounting table can bear at least about 80kg of weight;
- Good ventilation;
- The environment should be as dust-free as possible;
- Avoid direct sunlight;
- Avoid heat sources and wind sources;
- No corrosive and flammable gases;
- No vibration on the table surface;
- No loud noise source and power interference;
- Keep away from brush-type engines and electrical contact equipment that are frequently switched on and off;
- Keep away from devices that emit electromagnetic waves, such as cell phones, radio transceivers, etc.

### 2.3.2. Power

- 100-240 V~, 50/60 Hz, properly grounded with grounding resistance of less than 10 mΩ
- Input power: ≤500 VA



Warning

Please ground the power socket correctly. Incorrect grounding may cause electric shock and system damage. Please confirm that the power outlet output voltage meets the system requirements.

### 2.3.3. Humidity and temperature

- Ambient temperature: 10°C-30°C
- Ambient humidity: 30%~85%, no frost



Caution

The system must be operated within the specified ambient temperature and humidity range, otherwise the test results may be unreliable. If the ambient temperature and humidity exceed the specified range, use air conditioning equipment.

### 2.3.4. Atmospheric pressure

- Atmospheric pressure: 70.0 kPa~106.0 kPa

### 2.3.5. Space

Please install the instrument according to the space requirements shown in the figure below.

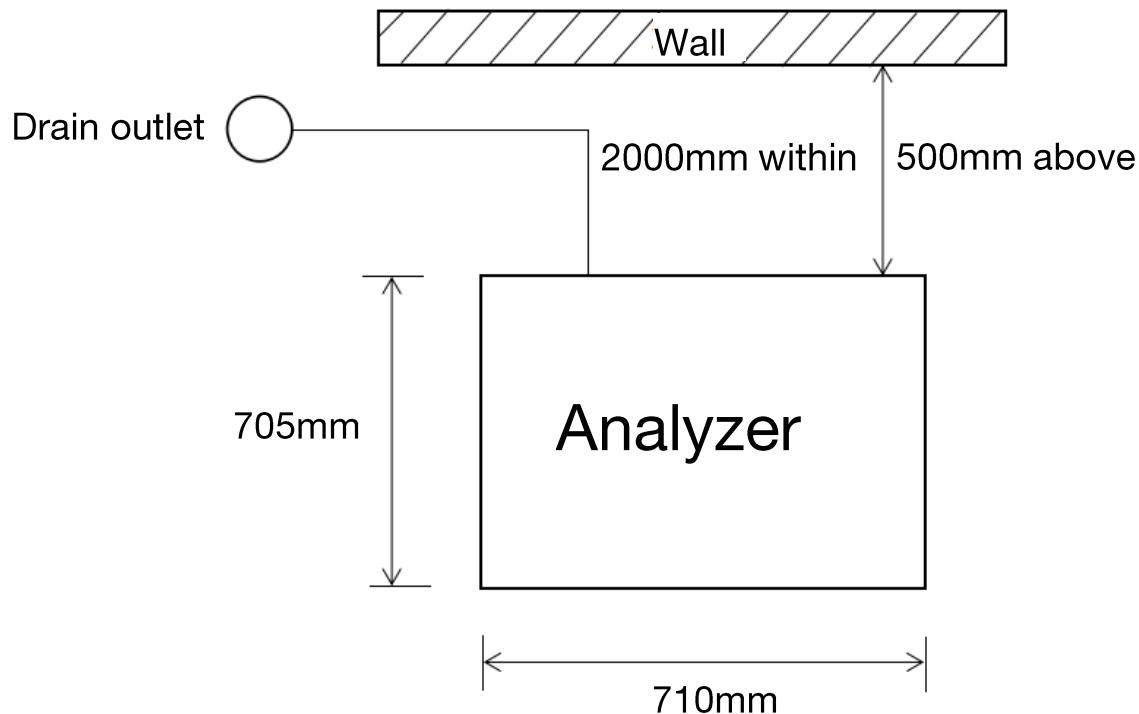


Figure 2-1 Installation Space Requirements

### 2.3.6. Water supply and drainage requirements

- The water quality of the water supply must meet the requirements of ISO3696 Class II;



The water quality must meet the water supply requirements. Otherwise, the water purity may affect the test results.

#### Caution

- Water supply volume: not less than 5L/h;
- The distance between the water supply device and the water inlet of the chemistry analyzer shall not exceed 10 meters;
- Waste container connection: the waste container shall be placed at the same level as the instrument or lower than the level of the instrument, and it must be ensured that its mouth is lower than the waste container outlet on the rear plate of the machine;
- Sewer connection: the height of waste liquid outlet from the ground shall not be higher than 12cm;
- The length of waste liquid pipe shall not be longer than 2m.



#### Biological pollution

Please wear gloves, work clothes to prevent infection and protective glasses as needed when operating.

#### Biological hazard

After installing the instrument, please connect the fluidic component correctly according to the following figure:

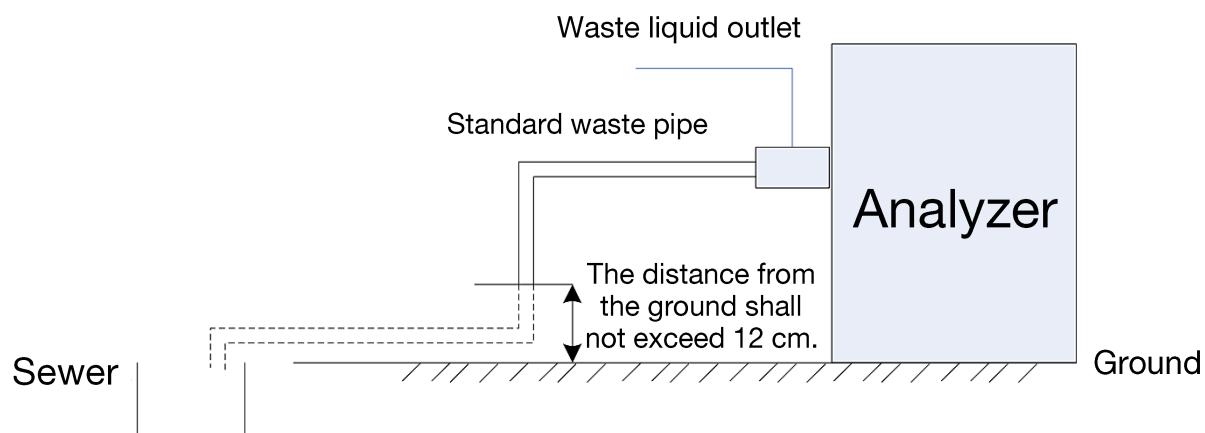


Figure 2-2 Requirements for Fluidic Component Connection

**Please treat the discharged waste liquid according to the local discharge standard.**



When connecting the drain pipes, be careful not to fold or flatten them.

Attention



Biological hazard

#### **Biological pollution**

Waste liquid is mainly consists of blood. Please treat the waste liquid discharged by the instrument according to the local discharge standard.

## **2.4. Product composition**

The Chemistry Analyzer consists of a reagent-sample processing unit, a mixing unit, a reaction unit, a photoelectric detection unit, a control and data processing unit and software.

### **2.4.1. Reagent-sample processing unit**

The reagent-sample processing unit mainly completes the whole operation process of loading reagent and sample, including adding the first reagent, adding the sample, adding the second reagent, etc.

### **2.4.2. Mixing unit**

The mixing unit mainly completes the mixing operation of reagents and samples.

### **2.4.3. Reaction unit**

The reaction unit mainly completes the reaction of reagent and sample, incubation and automatic cleaning of the reaction cuvette.

### **2.4.4. Photoelectric detection unit**

The photoelectric detection unit is mainly used to collect photoelectric signals and other functions.

### **2.4.5. Control and data processing unit**

The control and data processing unit mainly consists of touch screen, built-in main control board and industrial control board. It can be operated on the touch screen interface to control the operation of the instrument. The main control board and the industrial control board can process the photoelectric signal value and convert it into various results required for detection.

### **2.4.6. Software**

The name of the software is Chemistry Analyzer software, with functions of sample, result, reagent, status, calibration, quality control, setting and maintenance. Users can operate the software for sample application, results query, reagent management, online status checking, calibration application, quality control application, instrument settings, and

various maintenance operations.

### 2.4.7. Accessories and consumables

Accessories and consumables refer to the components necessary for sample testing of the instrument, which shall be checked frequently to ensure sufficient quantity, supplemented and replaced when necessary. Among them, the attachment is the content in A.4 except the host computer; consumables include the contents in A.3 and the matching reagents.

## 2.5. Instrument structure

### 2.5.1. Front view of instrument

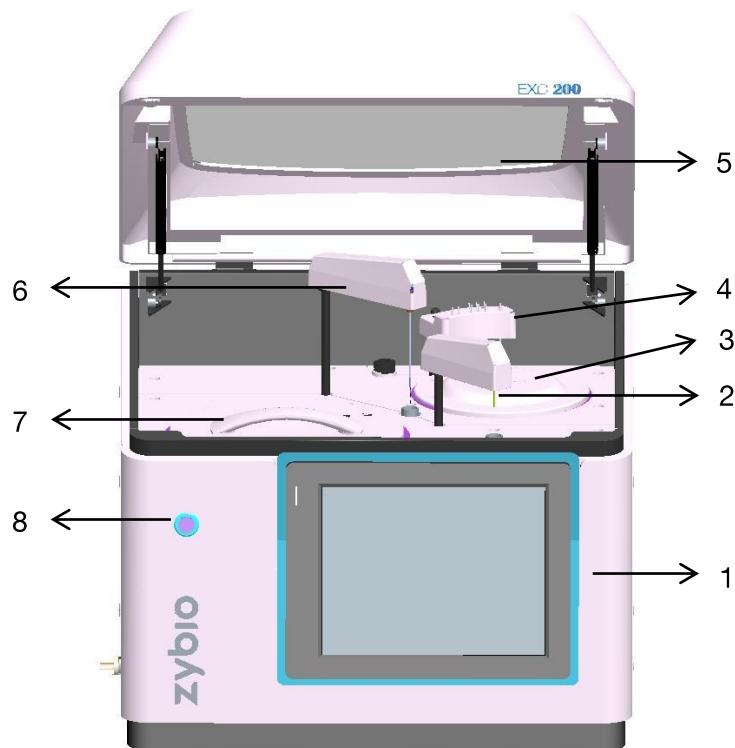


Figure 2-3 Front Structure

1-Touch Screen;

2-Stirring Rod; 3-Reaction Tray

4-Automatic Cleaning Mechanism;

5-Top Cover;

6-Reagent - Sample Probe

7-Reagent - Sample Tray;

8-Analysis Switch

## 2.5.2. Rear view of instrument

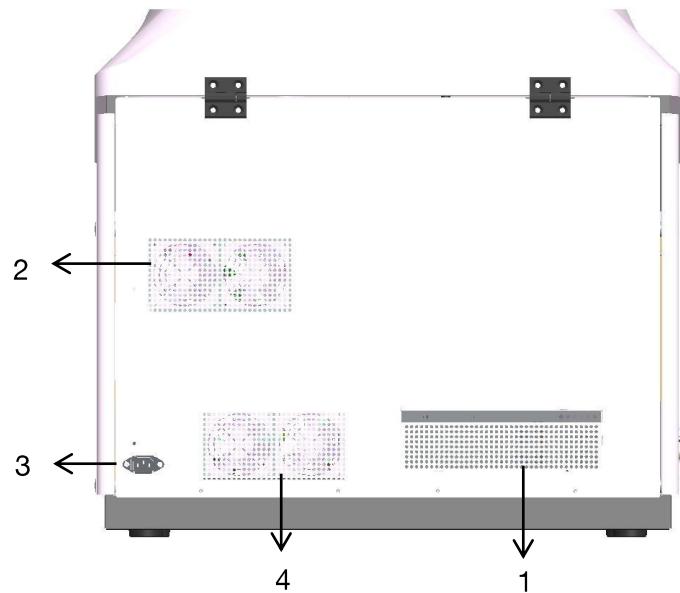


Figure 2-4 Rear Structure

1-Air Inlet;      2-Fan;      3-Power Socket  
4-Fan

## 2.5.3. Side view of instrument

- Left side

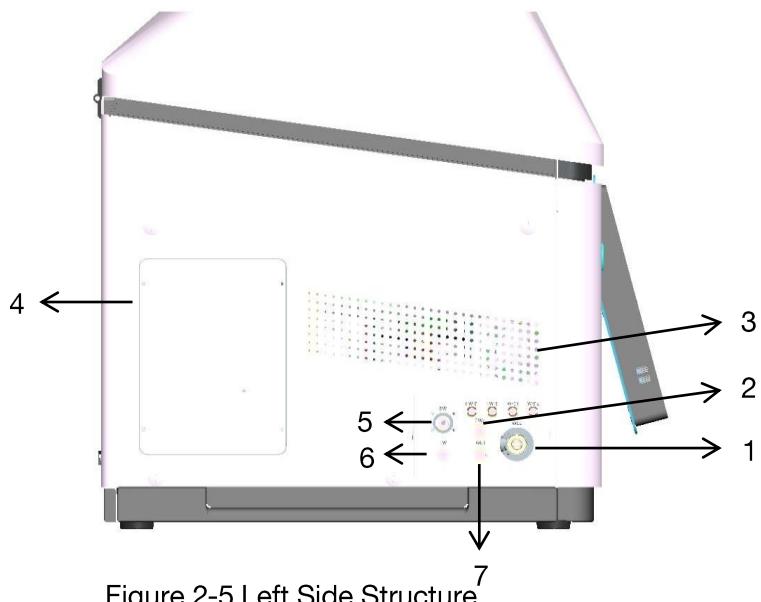


Figure 2-5 Left Side Structure

1-Waste Liquid Pipe Interface 2;      2-Purified Water Interface 2;      3-Air Inlet  
4-Maintenance Window;      5-Purified Water Interface 1;  
6-Acid-Base Detergent Interface      7-Waste Liquid Pipe Interface 1

- Right side

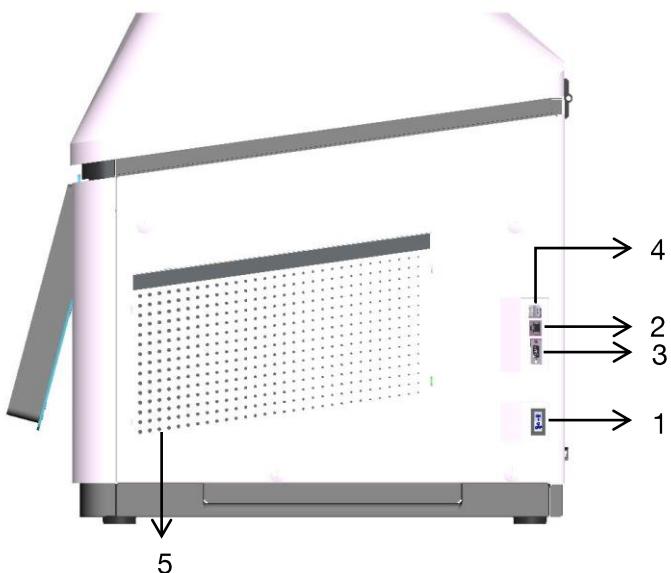


Figure 2-6 Right Side Structure

1-Main Power Switch;    2-Serial Port Interface;    3-Network Port Interface  
 4-USB Interface;                5-Air Inlet

The functions of each communication interface are as follows:

Network port: Use a network cable to connect the router for LIS data transmission.

Serial port: Can connect to printer or perform serial communication.

USB interface: Can be connected to a USB printer, or for U disk to insert data to copy.

#### 2.5.4. Reagent-sample processing unit

The reagent-sample processing unit is used for loading reagents and samples, sending each reagent and sample to a corresponding reagent absorption position and a sample absorption position respectively for absorption, then injecting into a reaction cuvette for reaction, and measuring the absorbance of the reaction liquid by the photoelectric detection unit. The reagent sample processing unit is mainly composed of the following components:

- Reagent-sample tray assembly
- Reagent-sample bar code scanning assembly
- Reagent-sample probe assembly
- Sample tube
- Reagent bottle

#### 2.5.4.1. Reagent-sample tray assembly

The reagent-sample tray assembly includes a reagent-sample tray (including a reagent-sample tray cover) and a reagent refrigeration system.

The reagent-sample tray is designed with a disc structure and is located on the left side of the analyzer table, which is used for loading sample tubes and reagent bottle. Each sample tube and reagent bottle is rotated to the corresponding sample suction position and reagent suction position respectively, waiting for the reagent-sample probe to suck.

The reagent refrigeration system is used to ensure that the reagents in the reagent bottle are always kept in a low temperature environment to keep the properties of the reagents stable and reduce volatilization. The reagent-sample tray has a 24-hour uninterrupted cooling function, which can ensure that the reagents in the reagent bottle are always stored in a low-temperature environment, ensure stable properties of the reagents, and reduce volatilization.

The following is the picture of reagent-sample tray:



Figure 2-7 Reagent-sample Tray

The reagent-sample tray is divided into inner, middle and outer circles, with a total of 80 reagent/sample positions. Among them:

- The inner circle contains 19 R1/R2 reagent positions +1 acid-base cleaning site
- The middle circle contains 19 R1/R2 reagent positions +1 acid-base cleaning site
- The outer circle is 40 sample positions

#### 2.5.4.2. Installation of reagent-sample tray

- 1) Hold the handle in the middle of the reagent-sample tray by hand, and vertically lower the alignment hole under the handle to the pin position of the base.

- 
- 2) Press the 2 panel fasteners on the reagent-sample tray.

#### 2.5.4.3. Disassembly of reagent-sample tray

- 1) Pull out the 2 panel fasteners on the reagent-sample tray.
- 2) Lift the handle of the reagent-sample tray up vertically and take it out.



Warning

Before loading or removing the reagent-sample tray, it must be confirmed that all moving parts of the analyzer have stopped, such as reagent-sample probe, stirring rod, cleaning mechanism, reaction tray and reagent-sample tray.



Biological hazard

#### Biological pollution

Please wear gloves, work clothes to prevent infection and protective glasses as needed when operating.

#### 2.5.4.4. Bar code scanning assembly

The barcode scanning assembly is mainly composed of a barcode scanner and decoding software. The main principle is: the laser emitted by the barcode scanner passes through its scanning system to form a scanning line, irradiates the barcode surface, and after being reflected by "bar" or "empty", it is received by the optical receiving system, and then undergoes photoelectric conversion, signal amplification and shaping and are finally decoded by the decoding software to identify the reagent or sample information corresponding to the barcode.

The barcode type supported by the instrument is CODE39 (standard 39)

#### 2.5.4.5. Reagent-sample probe assembly

The reagent-sample probe assembly consists of a probe, a probe rocker arm, a drive shaft, a probe syringe, a cleaning basin and related fluidic components. It is mainly used to suck a specified amount of sample or reagent from a sample tube or reagent bottle and inject it into a reaction cuvette to participate in the reaction.

#### 2.5.4.6. Reagent-sample probe

The reagent-sample probe integrates the functions of the sample probe, the first reagent probe and the second reagent probe, and the amount of sample or reagent to be sucked depends on the type of item.

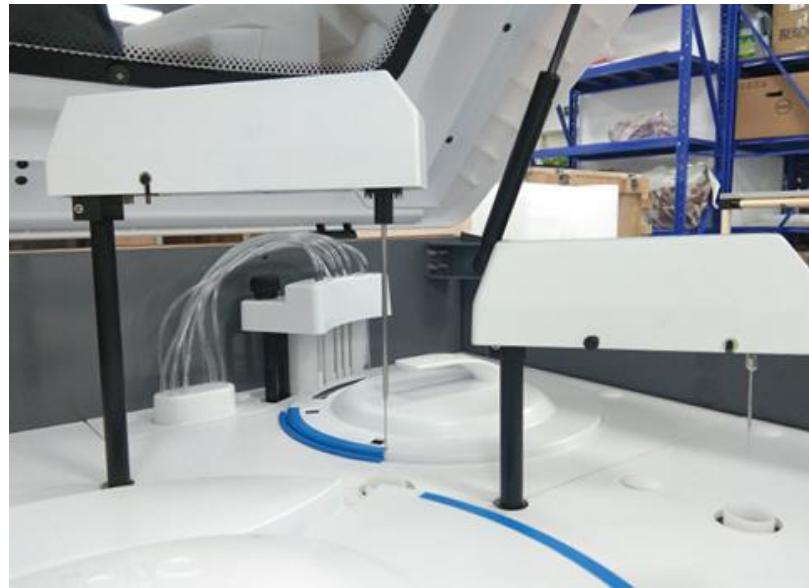


Figure 2-8 Reagent-sample Probe

1) Function

Absorb a specified amount of sample from the sample tube or R1/R2 reagent from the reagent bottle and place it in a cuvette (colorimetric cuvette).

2) Specifications

Samples: 2 ~ 50  $\mu\text{L}$ , increasing by 0.5  $\mu\text{L}$  each time;

Reagent: 10 ~ 400  $\mu\text{L}$ , increasing by 0.5  $\mu\text{L}$  each time.

3) Action

Move down and up at the following positions.

- Sample suction:

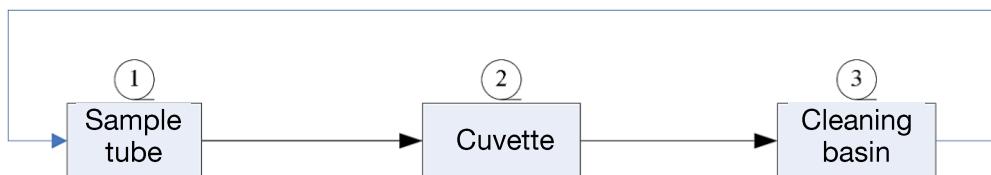


Figure 2-9 Sampling Position

- Suction reagent:

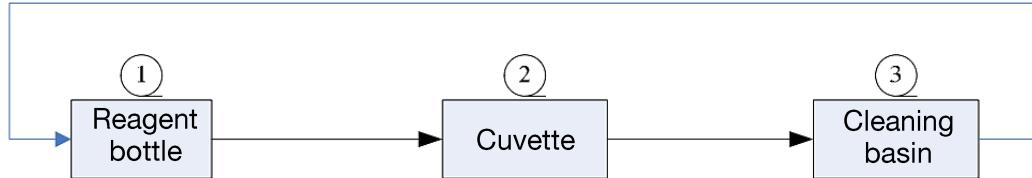


Figure 2-10 Reagent Aspiration Position

## 4) Fluidic component diagram

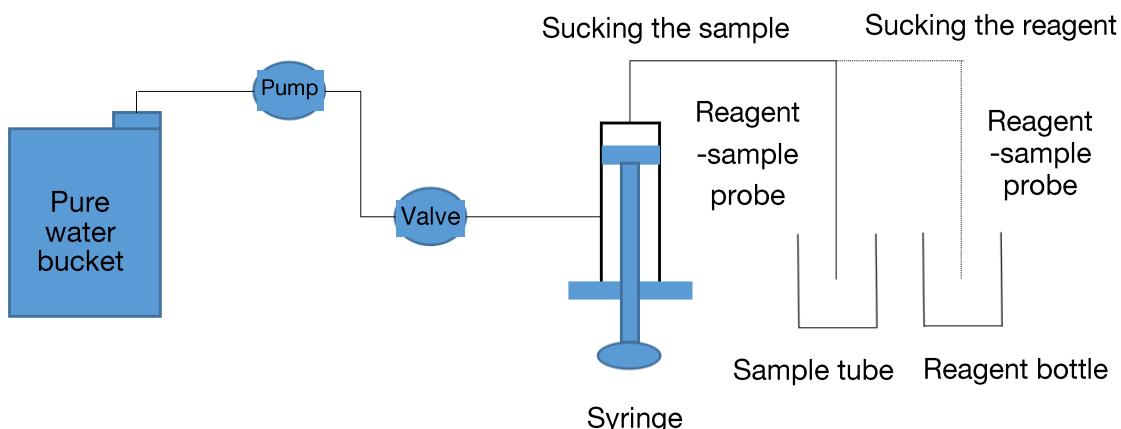


Figure 2-11 Fluidic Component Diagram

In addition to the basic sample /reagent suction functions, the reagent-sample probe also has the following functions:

- Vertical collision avoidance: it can detect obstacles in the vertical direction. In case of collision, the automatic protection system will be activated to prevent the reagent-sample probe from being damaged.
- Liquid level detection and tracking with quantity: the liquid level in the sample tube can be automatically detected and the depth falling below the liquid level can be determined according to the amount of liquid absorbed.



Warning

When the system is running, do not place your hands, other parts of your body or any obstacles on the swing path of the reagent-sample probe rocker arm, otherwise personal injury or system damage may occur.

#### 2.5.4.7. Cleaning of reagent-sample probe

Clean the interior and outer wall of the reagent-sample probe in the cleaning basin, and the reagent-sample probe syringe can be seen by opening the maintenance window at the left rear of the analyzer.

#### 2.5.4.8. Reagent cooling system

A cooling plate is installed at the bottom of the reagent sample cabin, which can absorb the heat inside the reagent sample cabin and radiate the heat to the outside through the air

duct to achieve the cooling effect. There is a temperature sensor at the cooling plate, which will monitor the temperature of the cooling plate in real time. When the temperature drops to  $(2 \pm 0.1)^\circ\text{C}$ , the control system will appropriately reduce the current flowing through the cooling plate according to the control algorithm, thereby reducing the power of the cooling plate. When the temperature rises, the control system will increase the current flowing through the cooling fins, thereby increasing the power of the cooling plate and stabilizing the temperature of the cooling plate at  $(2 \pm 0.1)^\circ\text{C}$ . At the same time, insulation foam is adhered around and at the bottom of the reagent sample pot for thermal insulation. As a result, the temperature around the reagent sample tray can be maintained at  $2\text{-}10^\circ\text{C}$ , which ensures that the detection reagents are always stored in a low temperature environment, so that the environmental temperature will not affect the reagent performance if the test time is long.

#### **2.5.4.9. Sample tube**

The sample tube is used for holding samples. The sample tray supports the following sample tube types.

- Micro measuring cuvette:  $\varphi 14*25\text{ mm}$ ,  $\varphi 12*37\text{ mm}$
- Original blood collection tube/plastic test tube:  $\varphi 12*68.5\text{ mm}$ ,  $\varphi 12*99\text{ mm}$ ,  $\varphi 12.7*75\text{ mm}$ ,  $\varphi 12.7*100\text{ mm}$ ,  $\varphi 13*75\text{ mm}$ ,  $\varphi 13*95\text{ mm}$ ,  $\varphi 13*100\text{ mm}$ ;

Different specifications of sample tubes require different minimum sample volume. The minimum sample volume of each sample tube must be guaranteed, otherwise sample suction errors may result. If the sample volume is less than the dead volume, transfer the sample to a smaller sample tube before testing. The minimum sample volume of the sample tube is the sum of the minimum sample volume required for the test and the dead volume of the sample tube.

#### **2.5.4.10. Reagent bottle**

Reagent bottle is used to contain reagents and is divided into 35mL and 20mL specifications.

### **2.5.5. Reaction unit**

The reaction unit mainly consists of a reaction system and an automatic cleaning system.

#### **2.5.5.1. Reaction system**

It comprises reaction tray, cuvette and heater, wherein the reaction tray is used for placing the cuvette, and plastic cuvette is used as the cuvette, which is used as a reaction container and used for colorimetric measurement.

The heater is used to provide a constant temperature environment for the reaction. The driving part turns the cuvette to the corresponding reagent adding position, sample adding position, stirring position and cleaning position respectively.

#### **1 Reaction tray**

In the analysis process of the reaction tray, place the designated cuvette at the reagent

adding position, sample adding position, stirring position or cleaning position.

The reaction tray is a single circle and can accommodate 63 plastic cuvettes.

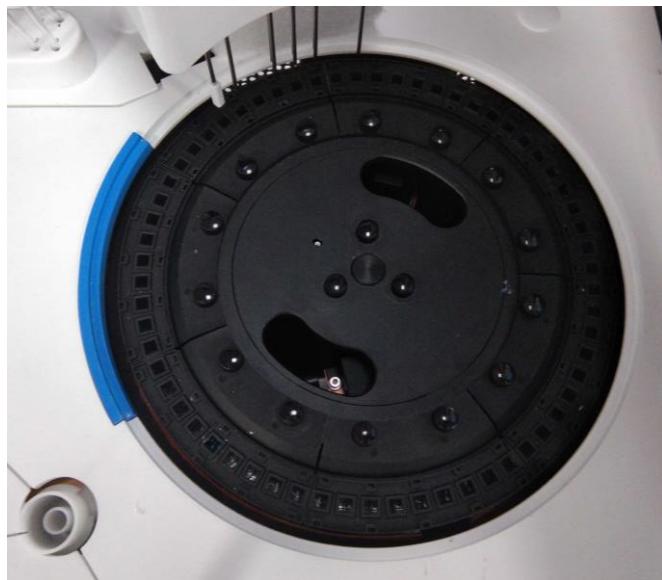


Figure 2-12 Reaction Tray

### 1) Function

Load cuvette, allowing a sample and a reagent to react in a constant temperature bath at 37°C, and directly conduct colorimetric measurement through the plastic cuvette.

### 2) Specifications

Number of cuvette: 63

Material of cuvette: Ultraviolet transparent plastic cuvette

### 3) Action

Rotate anti-clockwisely

## 2 Cuvette

The material is plastic, and the optical diameter of each reaction cuvette is 5 mm±0.03 mm.

After each test, the system automatically 6-steps cleans and dries the cuvette for the next test.

## 3 Temperature control tank

There is a heater in the temperature control tank. The heater will heat the temperature control tank before the test. There is also a temperature sensor. When the temperature is too high, the heater will automatically stop heating. When the temperature is too low, the heater will automatically continue to heat. In order to ensure that the entire temperature control tank maintains a constant temperature of 37 °C, it provides a constant temperature platform for the reaction, effectively simulates the temperature of the human body, and ensures the accuracy of the test results.

### 1) Function

Keep the reaction temperature at 37°C

2) Specifications

Setting temperature: 37°C

Temperature accuracy: 37°C±0.2°C

Temperature fluctuation: ±0.1°C

### 2.5.5.2. Automatic cleaning system

The system supports 6-step automatic cleaning. After the test is finished, the cuvette is automatically cleaned through 6-step cleaning.

The automatic cleaning system consists of a cleaning probe, a lifting motor and related fluidic components. The lifting motor controls the cleaning probe to move up and down in each cleaning stage to complete the cleaning of the reaction cuvette.



Figure 2-13 Cleaning System

1) Function

Clean the plastic cuvette after the test, suck out the reaction solution, inject purified water and concentrated detergent, and drain it.

2) Specifications

There are six cleaning heads in total, of which:

- Section 1 sucks the reaction liquid and injects purified water mixed with concentrated cleaning liquid;
- Sections 2 to 4 suck the purified water injected in the previous section and inject purified water again;
- Sections 5 and 6 suck out the remaining water droplets in the plastic cuvette.

3) Action

Move up and down in cuvette to complete the action of sucking the reaction liquid and

fill concentrated cleaning liquid and purified water.

### 2.5.6. Mixing unit

It is mainly composed of a stirring rod and a stirring rod cleaning basin. The stirring rod is driven by the motor to stir the mixed reaction liquid in the reaction cuvette to ensure a complete reaction. The stirring rod cleaning basin provides stirring after the reaction. The function of the rod cleaning avoids carrying pollution in the reaction or affects the accuracy of the measurement results.

1) Function

Mix the reagent and sample in the plastic cuvette (colorimetric cuvette).

2) Action

Move down, rotate and move up at the undermentioned positions.

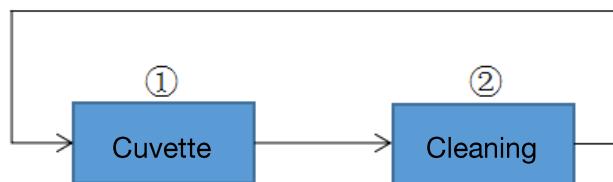


Figure 2-14 Mixing Position

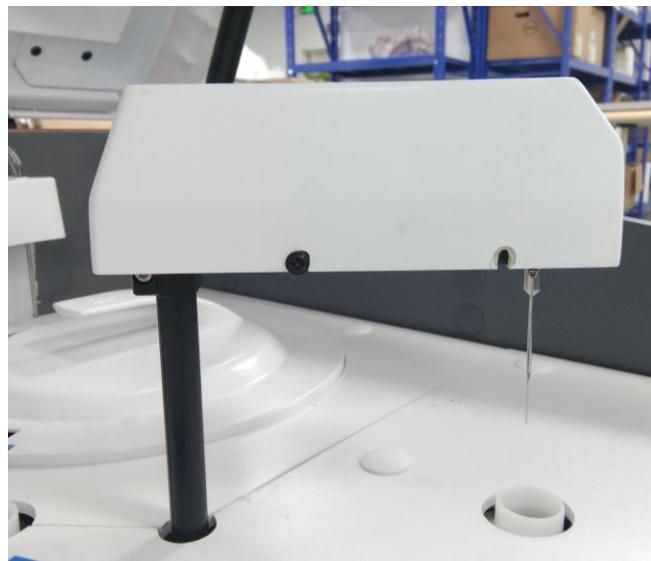


Figure 2-15 Stirring Rod

### 2.5.7. Photoelectric detection unit

The photoelectric detection unit is used for measuring the absorbance of the reaction liquid in the cuvette and consists of an optical system and a signal detection system. Its main function is to detect the change of light intensity of light-transmitting reactant, convert the

optical change signal caused by chemical reaction into electrical signal by photoelectric conversion method, and reflect the change of light intensity by detecting the change of electrical signal.

The optical system consists of a light source, an optical diameter colorimetric system and a light splitting component, and is used for providing monochromatic light with sufficient intensity and a stable and reliable colorimetric optical path structure.

The signal detection system includes photoelectric conversion part and AD acquisition and processing part. Its main function is to convert the light intensity signal of monochromatic light absorbed by the reactant and focused on the photoelectric conversion device into an electrical signal. The electrical signal is amplified and then collected by A/D to output photoelectric data reflecting the light intensity, which is then transmitted to the corresponding control unit for absorbance calculation.

1) Function

The absorbance of the reaction solution in the plastic cuvette was measured during the rotation of the reaction tray.

2) Specifications

Wavelength: 340 nm ~ 800 nm, optional wavelength

Simultaneous determination of wavelengths: simultaneous determination of one or more wavelengths

Wavelength accuracy:  $\pm 2$  nm

Half wave width:  $8\pm 2$  nm

Inspector: photoelectric diode

Light source: tungsten halogen lamp, 12 V 20 W, 2000 h

3) Schematic diagram

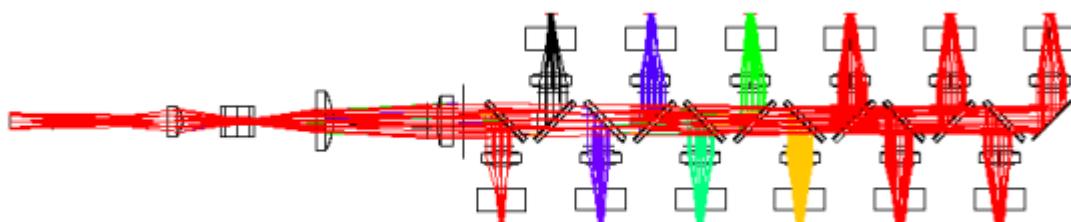


Figure 2-16 Optical Path Diagram

## 2.6. Software interface

### 2.6.1. Interface

The operation interface of EXC2X series Chemistry Analyzer includes toolbar, status bar and function display area, as shown in the following figure:

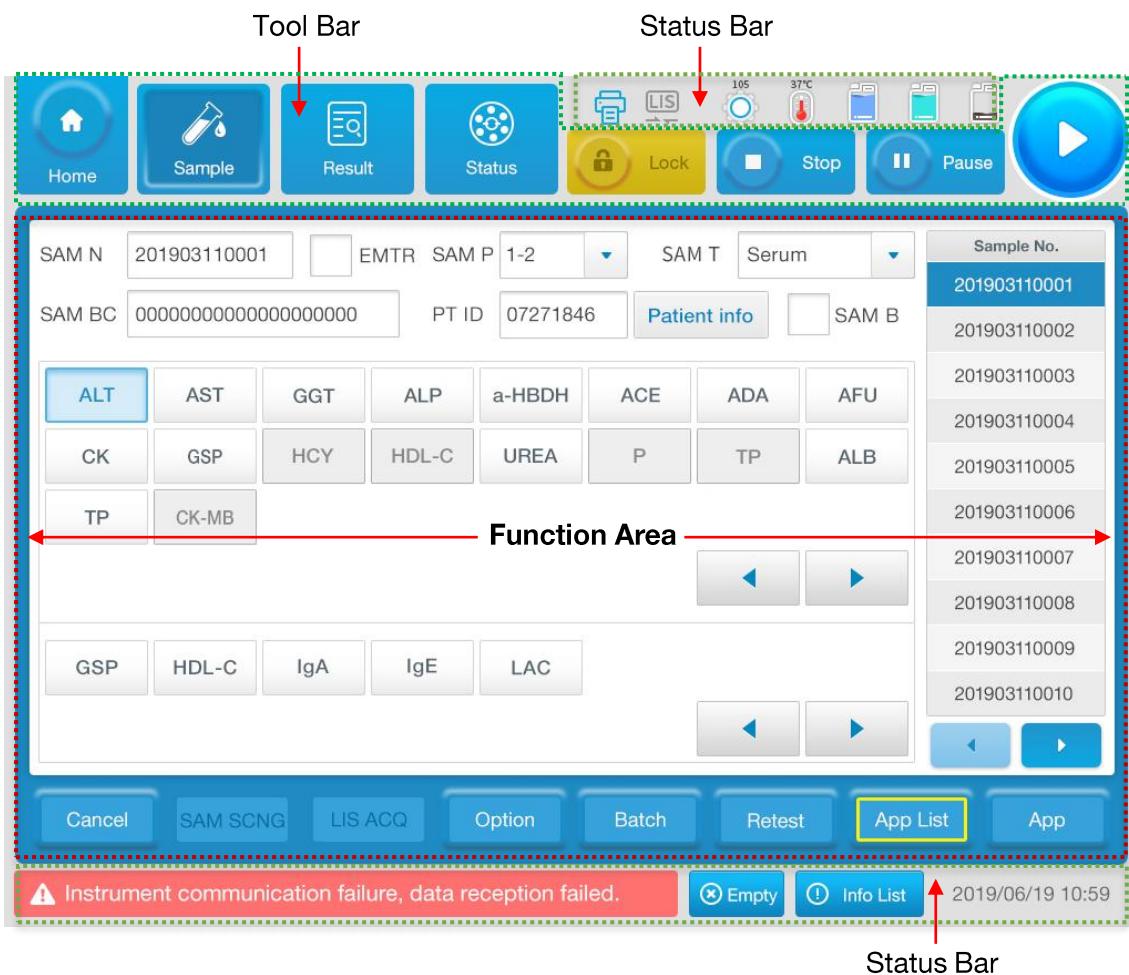


Figure 2-17 Software Operation Interface

#### ■ Status bar

Includes status display area and alarm information display area.

##### (1) Status display area

It displays system status, test period, reaction tray temperature, cleaning container status, pure container status, waste container status and system time.

- 1) System status: When the analyzer is in the test state, the gear in the upper right corner rotates, and the number on the gear indicates the total number of running cycles of the reaction tray in the most recent test (or ongoing test);
- 2) Reaction tray temperature: Indicates the actual temperature of the reaction tray;
- 3) Printer connection status: highlighted as connected printer and gray as

unconnected printer;

- 4) LIS connection status: highlighted as connected LIS system, and grayed out as unconnected LIS system;
- 5) Cleaning container, pure water container and waste liquid container: display the state of water container;
- 6) System date and time: date and time are displayed in the lower right corner;
- 7) User: the logged-in user name is displayed above the system date.

(2) Alarm information display area

When the system has error information, error information or alarm information will be displayed in the error information column. Click “**Clear**” in the function button area to clear the current error message or alarm message, and directly click “**Info List**” to enter the alarm information details page.

■ Toolbar

Includes various function buttons and shortcut buttons.

(1) Function button

Used to open various function pages of the system, mainly including the following buttons:

- 1) Sample: Carry out patient sample test (including batch application) and support functions such as patient information input, sample location setting and sample position release.
- 2) Calibration: You can set calibrator information, apply for calibration test and reagent blank test, and review calibration results and reagent blank results.
- 3) Quality control: You can set up QC information, apply for quality control tests, review quality control results and other operations.
- 4) Status: Displays information about the sample tray, reagent tray, and reaction tray. In sample tray interface, you can view the sample information, release the sample position, view the reaction curve, etc. In reagent tray interface, you can set the reagent position, check the reagent information, detect the reagent volume, etc. In reaction tray interface, you can check the state of the reaction tray, the test information, the reaction curve, etc. (Note: structurally, the sample tray and the reagent tray are combined into a reagent-sample tray, which is separated in software for easy operation. The sample tray on the software interface corresponds to 40 sample positions on the outer circle of the instrument reagent-sample tray; the reagent tray corresponds to 40 reagent positions in the middle circle and the inner circle. If there is something similar below, it will not be explained again).
- 5) Reagent: It can be used to query reagent information, scan reagent, detect remaining volume, load and unload reagent, etc.
- 6) Results: Patient sample results can be reviewed, reaction curves can be viewed,

and patient information can be viewed and edited.

- 7) Settings: Including test setting, system setting, user setting and item setting.
- 8) Maintenance: Including routine maintenance consisting of periodic maintenance, fault handling, data backup, temperature curve, fluidic component status and unit status and engineering maintenance consisting of maintenance and commissioning.

(2) Shortcut button

- 1) Start: Start all tests that have been applied for.
- 2) Pause: Pause the sample adding action.
- 3) Stop: Stop adding R1 reagent.
- 4) Lock: Lock the interface, and clicking other function keys is invalid.
- 5) Home page: Return to the home page interface with one key.



This figure shows the current alarm information before and after viewing.



This figure is to enter the fault processing and view the fault information

■ Function display area

The function interface displays after clicking the function button.

## 3. Basic Operation Method

### 3.1. Overview

This chapter describes the basic operation and daily operation process of the instrument, mainly including the following steps:

- Pre-startup check
- Startup
- Instrument status checking
- Reagent loading
- Calibration
- Quality control
- Routine testing
- Start
- Query
- Stop
- Daily maintenance
- Shutdown
- Operation after shutdown

## 3.2. Operation process

### Operational flow

Table 3-1

Operating steps	Description
1. Pre-startup check	Check the water source, power supply, waste liquid connection, reagent-sample probe/stirring rod, and the remaining amount of concentrated cleaning liquid.
2. Startup	Turn on the power switch and start the operating software.
3. Instrument status checking	Check system status, alarm status, reagent/calibration status and maintenance status.
4. Reagent loading	Prepare chemistry reagents, detergent and diluent.
5. Calibration	Apply for calibration items, prepare calibrator and start calibration tests.
6. Quality control	Apply for QC items, prepare QC and start QC test.
7. Routine testing	Apply for routine sample tests, prepare samples and start sample tests.
8. Start	Start testing the applied items.
9. Query	Query testing status and result
10. Stop	Stop testing the applied items.
11. Daily maintenance	Clean reagent-sample tray, analyzer panel, etc.
12. Shutdown	Perform shutdown operation.
13. Operation after shutdown	Turn off power supply, dispose chemistry samples, clean instruments, clean waste liquid, etc. to ensure safe operation.

### 3.3. Pre-startup check

#### 3.3.1. Water source check

- 1) Check whether there is enough deionized water in the external water storage container to ensure continuous water supply; if not, inject deionized water first;
- 2) Check that the water pipes between the water source, water inlet module and analyzer are firmly connected;
- 3) Check and confirm that the melt delivery tube is unblocked and free from bending, twisting, leakage, etc.

#### 3.3.2. Power supply check

- 1) Check the power supply to ensure it works and can provide correct voltage;
- 2) Check the power cord of the instrument to make sure it is firmly connected.

#### 3.3.3. Probe and stirring rod check

- 1) Check the reagent-sample probe to make sure it is free of dirt and bending.
  - If there is dirt, clean the reagent-sample probe.
  - If there is bending, replace the reagent-sample probe.
- 2) Check the stirring rod to make sure there is no dirt or bending.
  - If there is dirt, clean the stirring rod.
  - If there is bending, replace the stirring rod.

#### 3.3.4. Detergent volume check

- 1) For the remaining amount of cleaning liquid in the acid-base cleaning position, if it is insufficient, please add or replace it in time;
- 2) Open the external 5L concentrated cleaning liquid barrel and check the remaining amount of concentrated cleaning liquid. If the remaining amount is insufficient, please add or replace it in time.

#### 3.3.5. Waste connection check

- 1) Check whether the waste container is empty, if not, please empty the waste container;
- 2) Make sure that the waste pipe is not bent and the drain outlet of the sewer is not higher than 12CM.



Please dispose the waste according to the local discharge standard.

Biological hazard

### 3.3.6. Moving parts check

The movement of moving parts such as reagent-sample probe, stirring rod, cleaning mechanism, reaction tray, reagent-sample tray, syringe, etc. has no other interference and can operate smoothly and locate accurately smooth operation and accurate positioning.

## 3.4. Startup

### 3.4.1. Power on

Before plugging in the power cord, check whether the main switch of the instrument power supply is in the "off" state. If not, turn the switch state to the "off" state before plugging in the power cord safely.

After powering on, switch the main power switch to the "on" status, then after pressing the analysis switch, the indicator lamp will light up, and the system will be started and initialization and self-checking will be conducted. After the completion of the system startup, you will enter the login interface.

### 3.4.2. Login

1) Enter the user name and password in the **Login** dialog box, and click **OK**.

- 
- 1) The user name of the system administrator is "Admin" and the password is "Zybio" by default. It is recommended to change the password when using it for the first time to prevent others from using administrator privileges at will.

Caution

- 2) If the operator forgets his password, please contact Zybio User Services or the agent in the region.

2) Log in correctly and display the home page interface of the operating software after the instrument is normally turned on and tested. At this point, the startup process completes.



In order to ensure accurate test results, please start the test operation 30 minutes after startup to ensure stable light source and temperature control.

## 3.5. Instrument status check

After the startup is completed, please check the states of the instrument when necessary. Such as reagent status and maintenance alarm status. When the status of the instrument is abnormal, refer to "Maintenance and Service" and "Alarm and Treatment" for system maintenance and troubleshooting.

### 3.5.1. Reagent status check

1) Click the **Status-Reagent Tray** button in the homepage interface, then open the

covers of all reagents, and click **Residual Detection** on the software to select the corresponding reagent positions for detection.

- 2) When the reagent is deficient or exhausted, the corresponding reagent position is rosy.



Figure 3-1 Reagent Tray Status

- 3) Replace or replenish reagent according to the reagent state, and then refresh it.

### 3.5.2. Maintenance alarm status check

After starting up every day, it is necessary to check the maintenance status of the instrument to confirm whether any items have expired. If it expires, maintenance needs to be performed immediately to ensure the normal operation of the instrument.

Click **Maintenance-Daily Maintenance-Periodic Maintenance** to confirm whether any items have expired.

## 3.6. Reagent preparation

After checking the status of the instrument and performing the pre-test inspection, it is necessary to prepare the reagents used for the very day. Items that are not loaded with reagents can be applied for, but cannot participate in the test. In the standby mode, the instrument must be woken up before loading reagents.

### 3.6.1. Reagent preparation

When loading reagent, first open the reagent tray, and then put the reagent in correct position. There is no special requirements for reagents and the instrument is suitable for all biochemical reagents on the market. With the open system, users can set or import items by themselves.



Biological hazard

Please be sure to wear gloves and work clothes to prevent infection, wear protective glasses when necessary, and do not directly contact with reagents, otherwise skin damage or inflammation may occur.

### 3.7. Concentrated detergent preparation

The concentrated detergent is normally alkali with the PH more than 8.5 and is used to clean the cuvette and can only be loaded manually. When loading it, the bottle cap should be opened, the float sensor should be removed, and then the cap and sensor should be installed in the newly opened concentrated cleaning liquid barrel.

### 3.8. Probe detergent preparation

The acid and alkali detergent of reagent-sample probe is normally alkali with the PH more than 8.5 is used to clean the reagent-sample probe. It can only be loaded manually. When the detergent exceeds the validity period or the volume is insufficient, please add or replace the detergent immediately.



Attention

Before loading the detergent, make sure there are no bubbles in the reagent bottle to avoid affecting the cleaning effect.

### 3.9. Diluent preparation

For dilution items, sample diluent is required and can only be loaded manually. The sample diluent is normally saline. You only need to set the dilution ratio according to the dilution factor when testing.

### 3.10. Calibration

Calibration tests are used to calculate calibration parameters, thus participating in the calculation of sample results.

In general, calibration tests are recommended when any of the following occurs:

- Add a new item
- When reagents, calibrators and QC are still within the validity period, the QC test fails

- Change reagent lot number or bottle number
- The items has exceeded the validity period of calibration
- The calibration rules have been modified, including calibration method, number of repetitions, concentration of calibrators and calibrators used
- The light source lamp, syringe, reagent-sample probe, etc. have been replaced

Calibration must be performed if the following parameters are modified:

- Primary wavelength
- Sub-wavelength
- Blank time
- Reaction time
- Reagent volume
- Sample volume
- Analytical method
- Reaction direction
- Sample blank and result unit
- Intercept
- Two items tested in the same test



Repeated calibration tests are impossible to damage equipment and reduce protection against danger.

Warning

### 3.10.1. Calibrator preparation

Prepare the calibration solution in advance and only load it manually. The calibration solution has no special requirements and is suitable for calibration solutions produced by all manufacturers on the market. Note that the calibration solution must be within the validity period of the bottle opening.

### 3.10.2. Calibration application

#### Apply calibration according to the items

When any of the above occurs, please apply for calibration according to the following steps.

Before applying for calibration of chemistry items, ensure that the calibrators have been set correctly.

#### 3.10.2.1. Setting of calibrator

In the homepage interface, select **Calibration-Setting** to enter the setting interface shown

in the figure below, and set the information such as the location, concentration, validity period and batch number of calibrator.

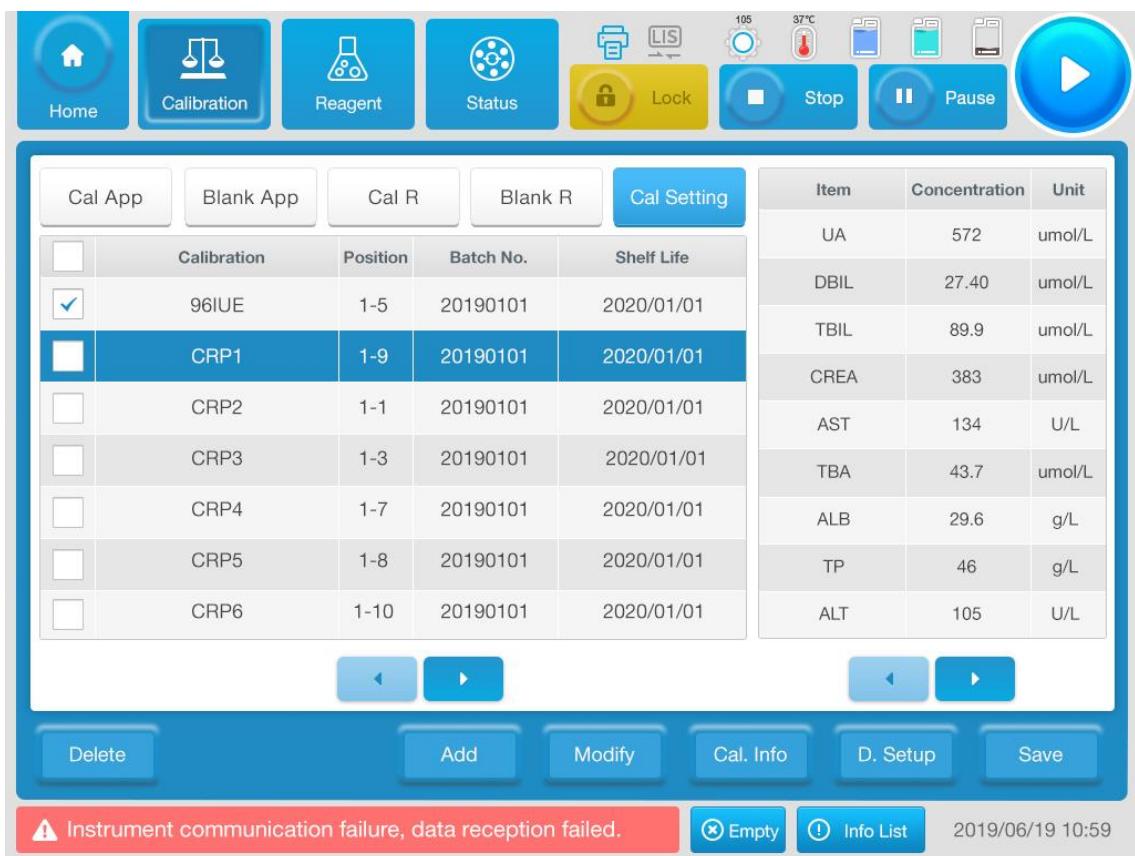


Figure 3-2 Calibration Setting

### Basic interpretation of parameters

Parameter	Meaning	Operation
Application for calibration	Apply for calibration	Click to enter the "Calibration Application" interface
Blank application	Apply for reagent blank	Click to enter the "Blank Application" interface
Calibration result	Review calibration results	Click to enter the "Calibration Result Review" interface
Blank result	Review blank test results	Click to enter the "Blank Result Review" interface
Calibrator setting	Set the parameter of calibrator	Click to enter the "Calibrator Setting" interface
Select	Select calibrator	Click once to select and click again to repeal
Calibrator	Name of calibrator	No operation required

Parameter	Meaning	Operation
Position	Tray number and position of calibrator	No operation required
Batch number	Batch number of calibrator	No operation required
Period of validity	Effective date of calibrator	No operation required
Item	Item name	No operation required
Concentration	Set the concentration of calibrator corresponding to the current item	Directly input
Unit	Concentration unit	No operation required
Add calibrator	Add calibrator	Click to enter the "Add Calibrator" interface
Modify calibrator	Modify calibrator setting information	Click to enter the "Modify Calibrator" interface
Delete calibrator	Remove the calibrator from the list	Directly click
Calibration information	Set calibrator information	Click to enter the "Calibration Information" interface
Dilution setting	Set calibration dilution parameters	Click to enter the "Dilution Setting" interface

### Basic operation

#### ■ Add calibrator

- 1) Click **Add** to open the "Add Calibrator" interface;

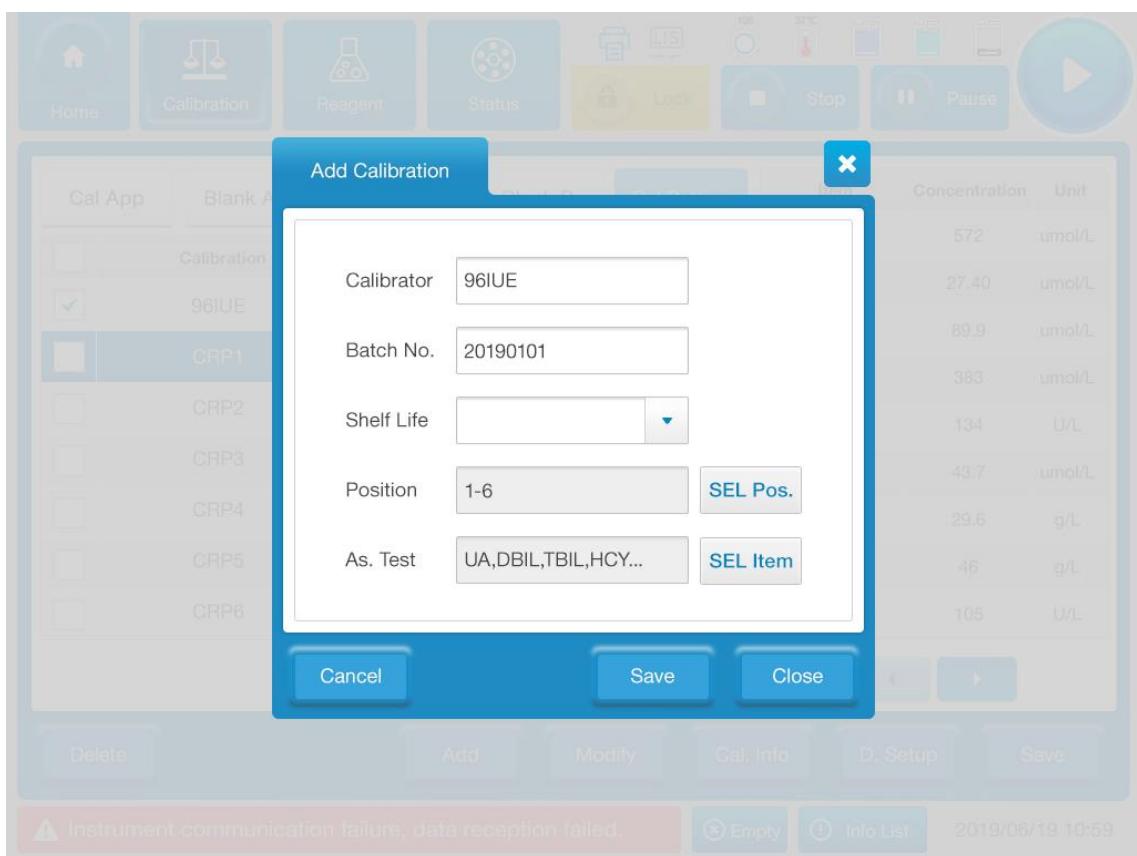


Figure 3-3 Add Calibrator

- 2) Enter the name and batch number of calibrator;
  - 3) Drop down to select the validity period of calibrator;
  - 4) Click **Position**, select the tray number and cuvette number in the pop-up dialog box, and click **OK**;
  - 5) Click **Item**, select the corresponding item in the pop-up dialog box, and then click **OK**;
  - 6) To save the added calibrator, click **Save**, otherwise, click **Cancel**.
- Set the concentration of calibrator
- 1) Select (click to select a row, not select some of them) the calibrator which needs to set concentration in the "Calibrator List";
  - 2) Enter the concentration value of calibrator in the concentration column behind the corresponding item name in the "Concentration List";
  - 3) To save the set calibrator concentration, click the **Save** button.
- Modify calibrator
- 1) Select the calibrator to be modified in the calibrator list, and calibrator information is not allowed to be modified during testing.
  - 2) Click **Modify** and enter the corresponding contents in the pop-up dialog box. The

- operation method is the same as "Add Calibrator";
- 3) To save the modified content, click **Save**, otherwise, click **Cancel**.
- Delete calibrator
    - 1) Check the calibrator to be deleted in the "Calibrator List";
    - 2) Click **Delete** to open a prompt box;
    - 3) If you are sure to delete it, click **OK**, otherwise click **Cancel**.
  - Calibration information
    - 1) Click **Calibration Information** to open the "Calibration Information" interface;

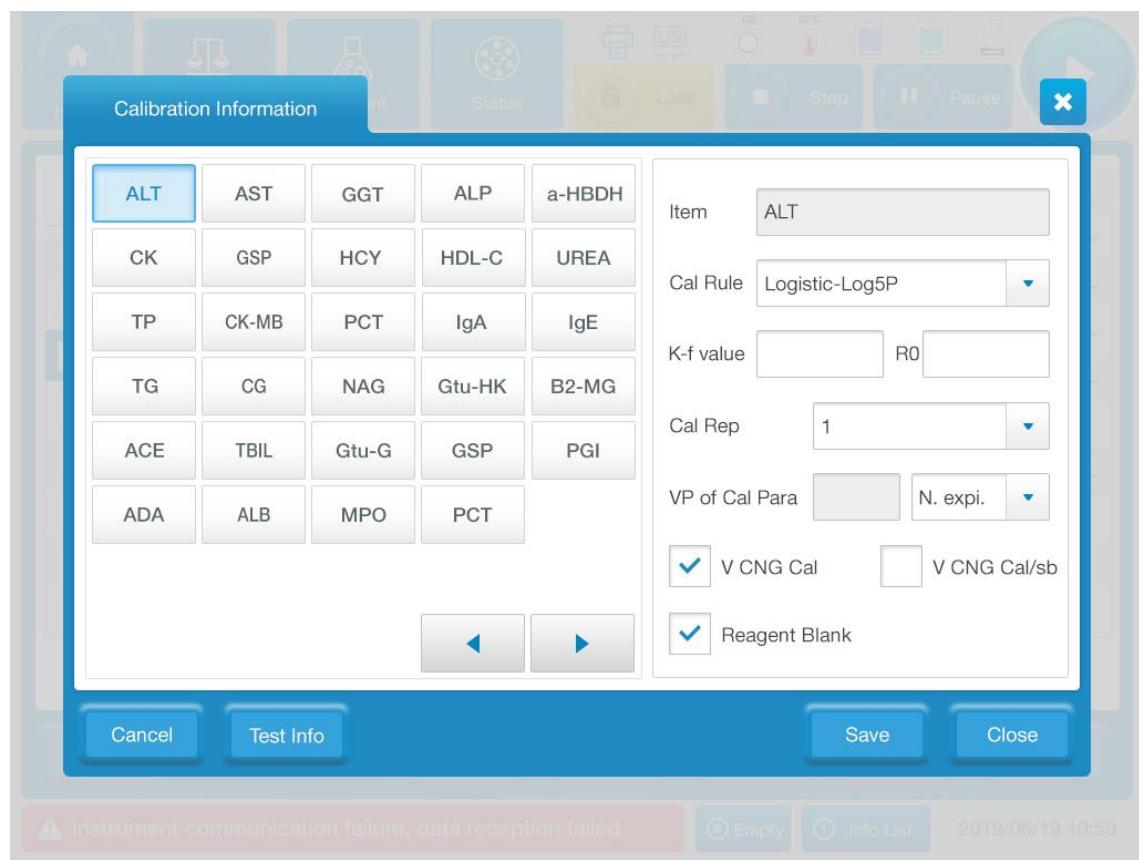


Figure 3-4 Calibration Information

- 2) Select the item to set calibration information in the item list;
- 3) Select the corresponding calibration rule from the "Calibration Rule" drop-down list, and select "Change Batch", "Change Bottle" or "Reagent Blank" as required;
- 4) Click the **Detection Information** button to set calibration detection information;
- 5) After confirming that the information is correct, click **Save**, otherwise click **Cancel**.

### 3.10.2.2. Calibration application

Click **Application** button to enter the calibration application interface shown in the figure below to perform calibration test application, reagent blank application and other operations.

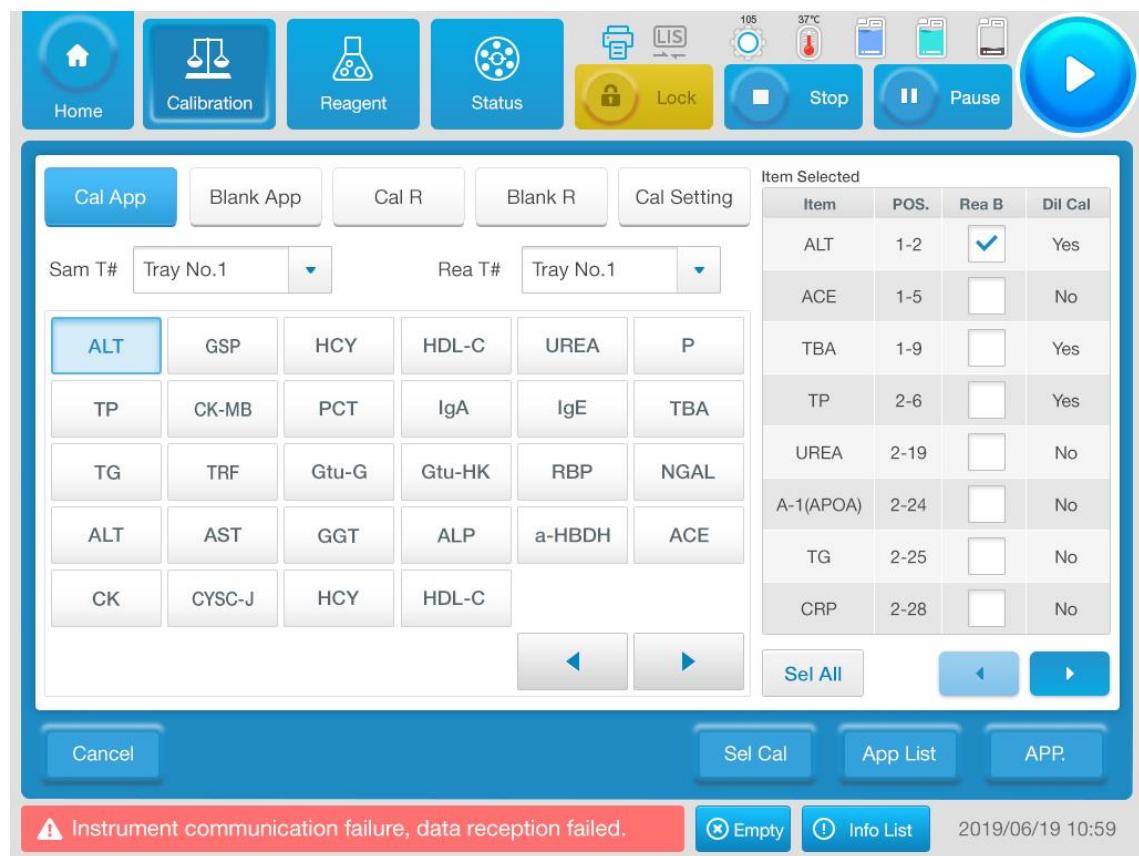


Figure 3-5 Calibration Application

#### Basic interpretation of parameters

Parameter	Meaning	Operation
Calibrator Tray No.	Select the tray number where the calibrator is located	Drop-down selection
Reagent Ray No.	Select the tray number where the reagent is located	Drop-down selection
Item	The name of the item selected in the “Item List”	No operation required
Reagent blank	Check for reagent blank	Click to check or uncheck

Parameter	Meaning	Operation
Diluent Calibration	Calibrate the diluent or not	No operation required
Select calibrator	Select the calibrator corresponding to a certain item	Click to enter the "Select Calibrator" interface
Application list	View the list of items for which calibration has been applied	Click to enter the "Calibration Application List" interface

### Basic operation

- Apply for calibration
  - 1) Click **Calibration-Calibration Application**;
  - 2) Drop down to select the tray numbers where the calibrator and reagent are located, respectively;
  - 3) Select the items to be calibrated in the list of items on the left, and check the "Selected Items" on the right if reagent blank test is required at the same time;
  - 4) Select a row in "Selected Items" and click **Select Calibrator** to open the "Select Calibrator" interface. You can check the calibrator required for calibration of this item and click **Save-Close** to return to the calibration application main interface;
  - 5) To save the applied calibration, click **Apply**, otherwise, click **Cancel**.
- Delete calibration application
  - 1) Click **Application List** to open the "Calibration Application List" interface:

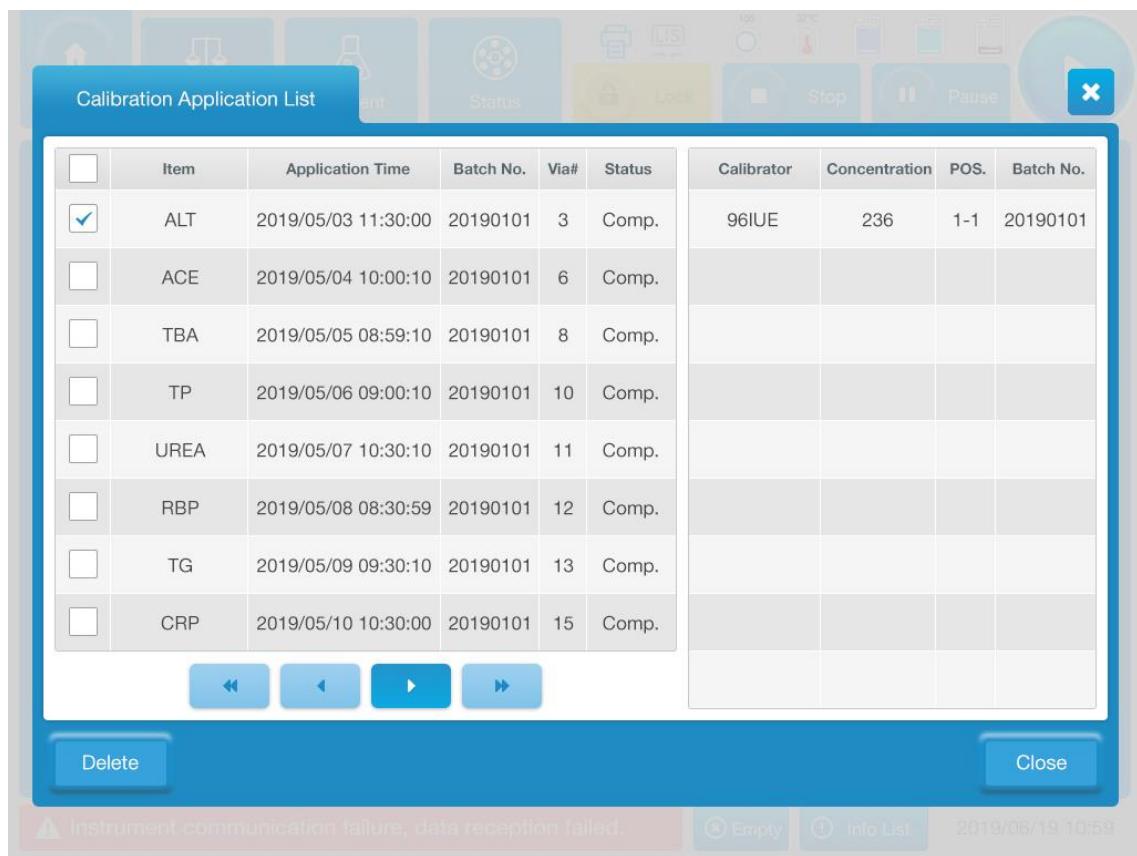


Figure 3-6 Calibration Application List

- 2) Select the calibration items to be delete, click **Delete**, otherwise, click **Close**.

### 3.10.2.3. Calibration results

Click the **Calibration Result** button to enter the calibration result interface, and perform operations such as querying calibration results and querying calibration curves.

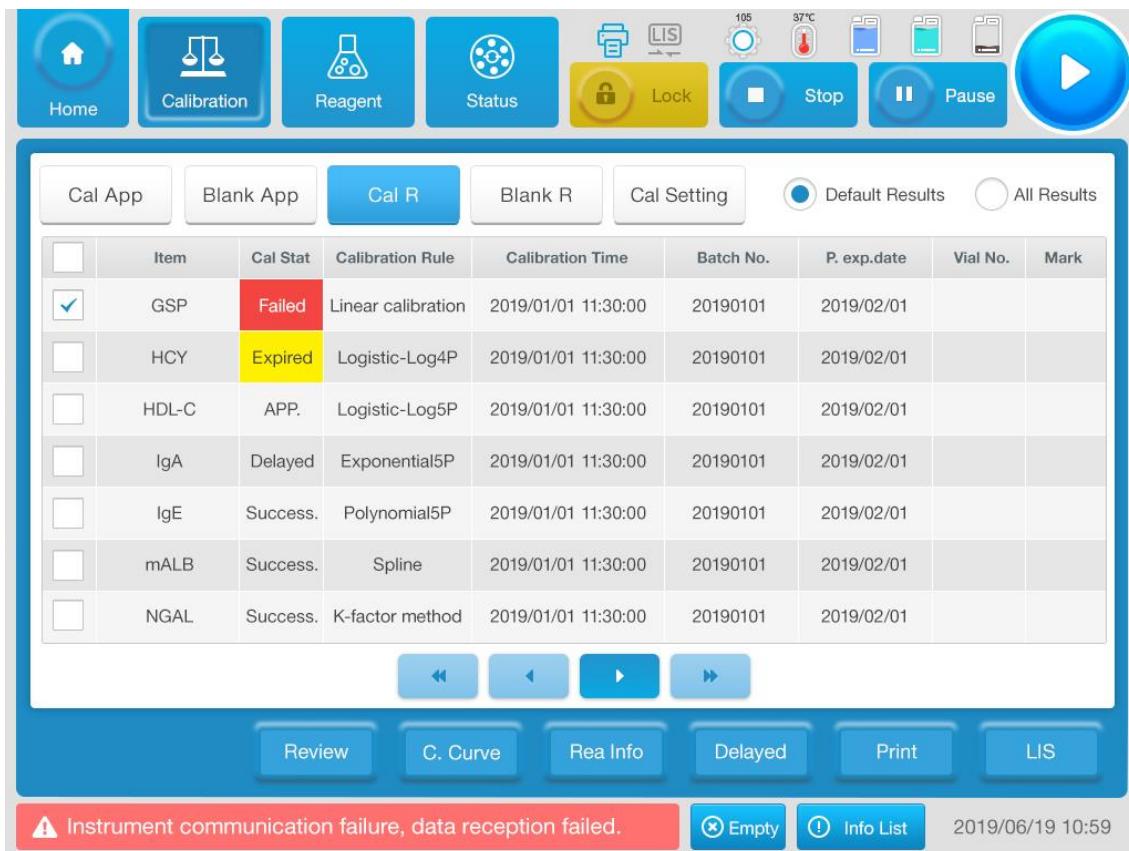


Figure 3-7 Calibration Results

#### Basic interpretation of parameters

Parameter	Meaning	Operation
Item	Name of calibration item	No operation required
Calibration status	Calibration status, including success, failure, expiration and extension	No operation required
Calibration rule	Mainly includes linear calibration, Logistic-Log4P, Logistic-Log5P, Exploratory 5P, Polynomial5P, Spline and K factor method	No operation required
Calibration time	The time when the calibration starts	No operation required
Validity period of parameters	Validity period of calibration parameters	No operation required

Parameter	Meaning	Operation
Default	The calibration result is default	No operation required
Marker	Marking of calibration items, including expired calibrator "ECF", expired reagent "ER" and recalculation of calibration results "#"	No operation required

### Basic operation

#### ■ Review calibration results

- 1) Click **Result-Review** to pop up the calibration result review interface;

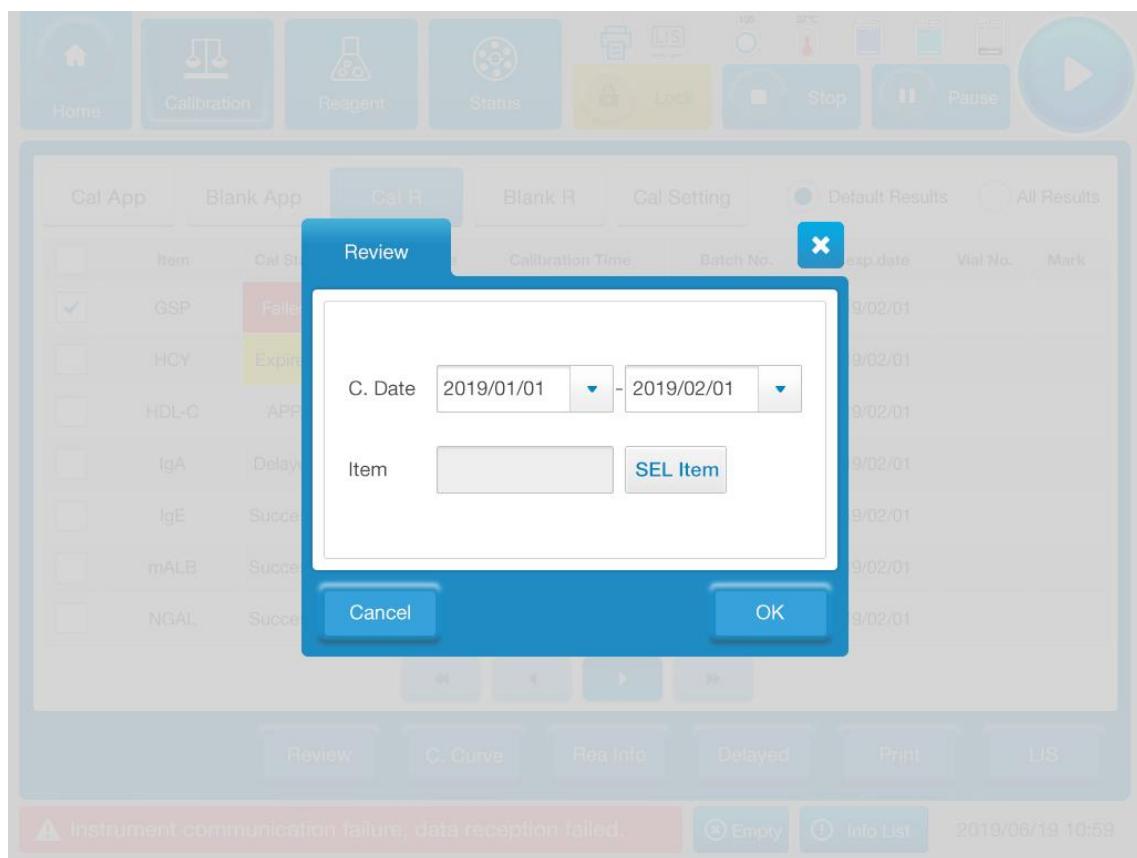


Figure 3-8 Calibration Result Review

- 2) Select the items to review results, and drop down to select the calibration date;
  - 3) Click the **OK** button.
- View calibration curve
- 1) Check the items need to view in the "calibration result" interface, and click **Calibration Curve** to enter the "Calibration Curve" interface, as shown in the following figure;

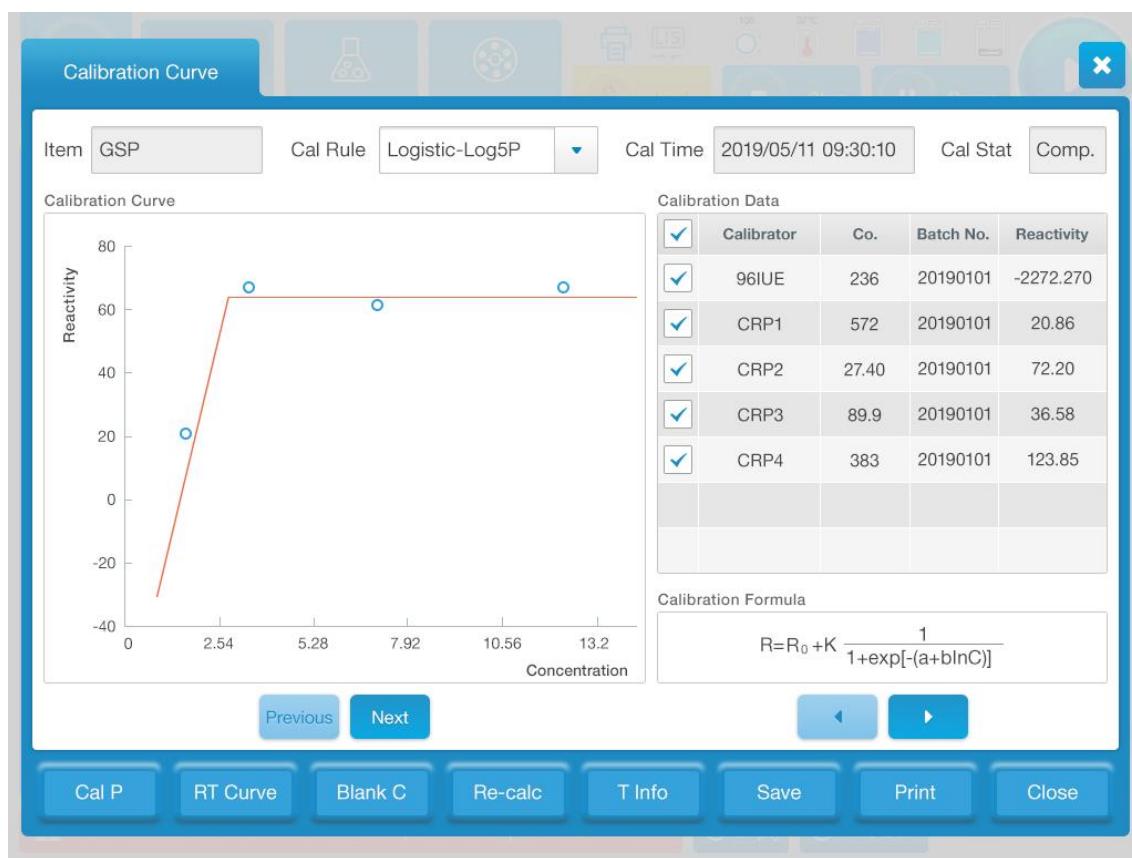


Figure 3-9 Calibration Curve

- 2) Check the calibration liquid in the "Calibration Liquid Data" on the right and click the **Reaction Curve** button to view the reaction curve of the calibration liquid;
  - 3) Click **Calibration Parameters** to view or modify the calibration parameters in the pop-up window;
  - 4) Click **Blank Calibration** to open the "Blank Calibration" interface, drop down to select the test date, click **Search**, then select the reagent blank required for the item, click **Calibration** to complete the calibration, otherwise click **Close**;
  - 5) After the calibration rule is changed or the selected calibrator is changed in "Calibrator Data", click the **Recalculate** button to refresh the calibration curve and recalculate the calibration parameters at the same time;
  - 6) If you want to view the calibration detection information, click the **Detection Information** button;
  - 7) Click the **Save** button to save the changes;
  - 8) Click the **Print** button to print the calibration curve;
  - 9) Click the **Close** button to close the calibration curve interface.
- View reagent information
- 1) Select an item;
  - 2) Click **Reagent Information** to view the reagent type, batch number, bottle

number and other information of the item.

■ Extension

- 1) Check one or more items;
- 2) Click **Extension** to open the "Extension of Calibration Parameters" interface:

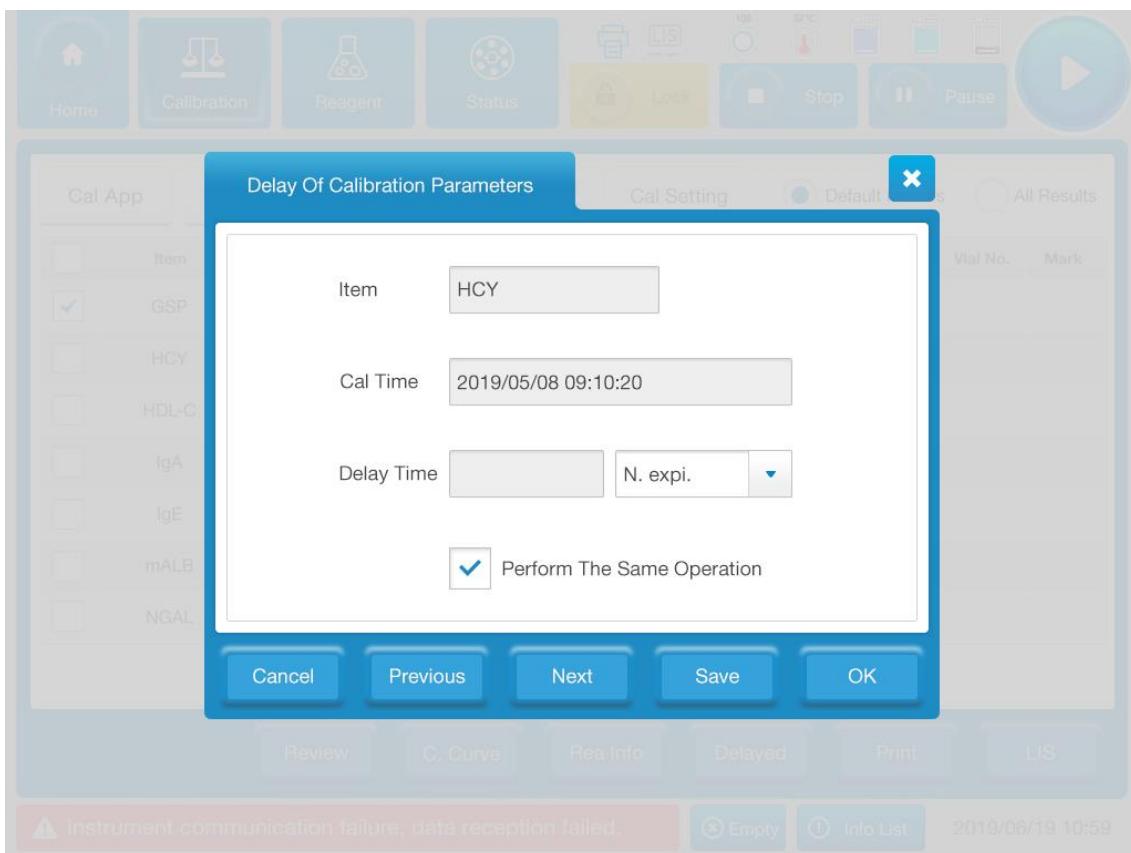


Figure 3-10 Calibration Parameter Extension

- 3) The extension time can be set by dropping down. The “Extension Time” plus the previously set “Calibration Parameter Validity Period” is the latest calibration parameter validity period.

■ Set default

- 1) Select an item;
- 2) Click **Default** to set the calibration result as the default result.

■ Print

- 1) Select an item;
- 2) Click **Print** to print the selected result or all the results in the pop-up dialog box.

■ LIS transmit

- 1) Select an item;

- 2) Click **LIS** to send selected results or all results in the pop-up dialog box.

### 3.10.2.4. Reagent blank

#### Basic operation

- Apply reagent blank

- 1) Select **Calibration-Blank Application** to enter the "Blank Application" interface, as shown in the following figure;

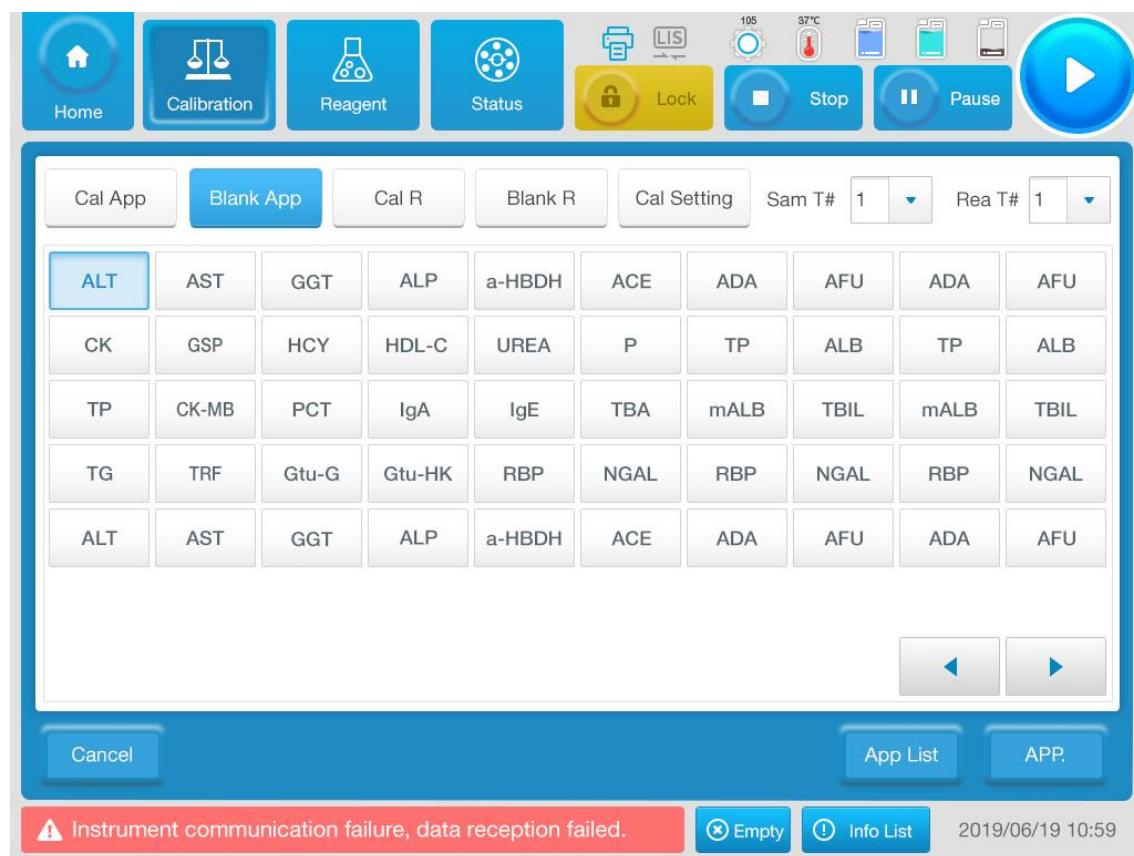


Figure 3-11 Blank Application

- 2) Select reagent blank test items from the list;
  - 3) To save the applied reagent blank test, click **Apply**, otherwise, click **Cancel**.
- Delete reagent blank
    - 1) Click **Blank Application-Application List** to open the following dialog box;

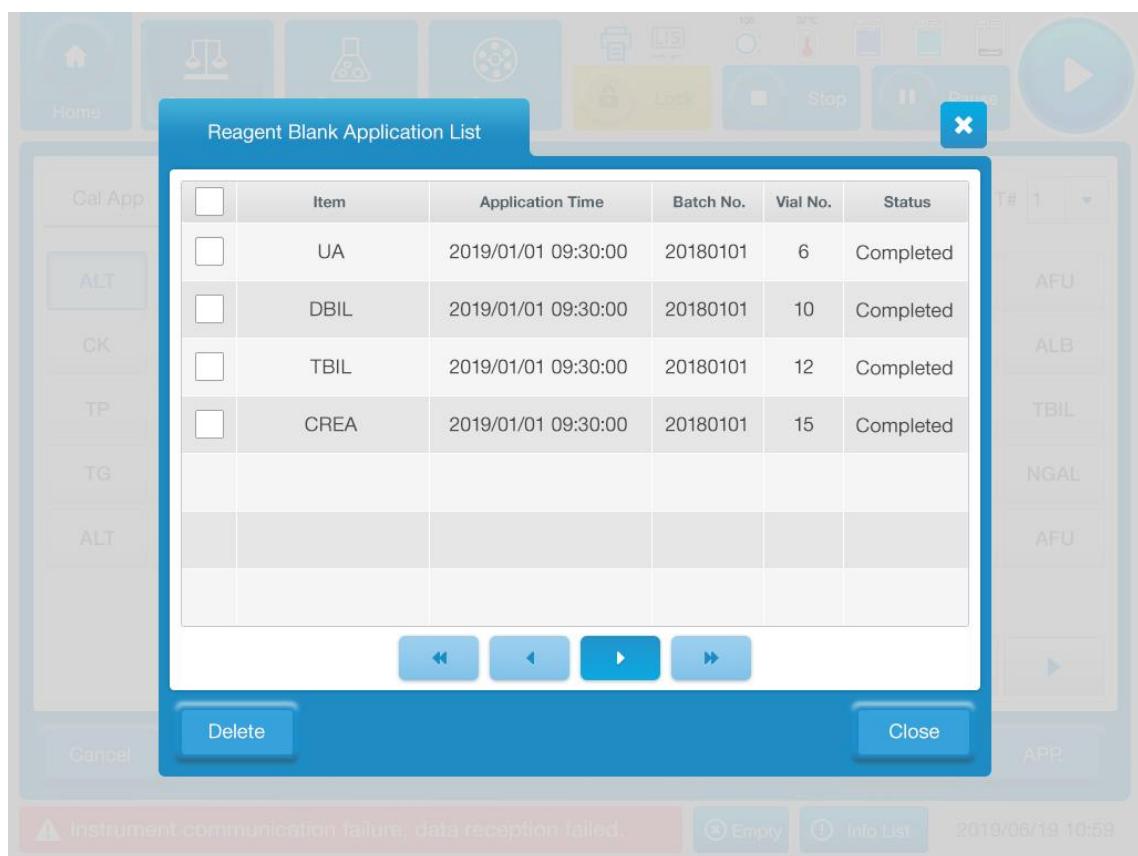


Figure 3-12 Reagent Blank Application List

- 2) Select the reagent blank items to be deleted;
- 3) If you are sure to delete the selected reagent blank items, click **Delete**, otherwise, click **Close**.

### 3.10.2.5. Blank result

Click **Blank Result** to enter the blank result interface for querying reagent blank results and querying reagent blank reaction curves.

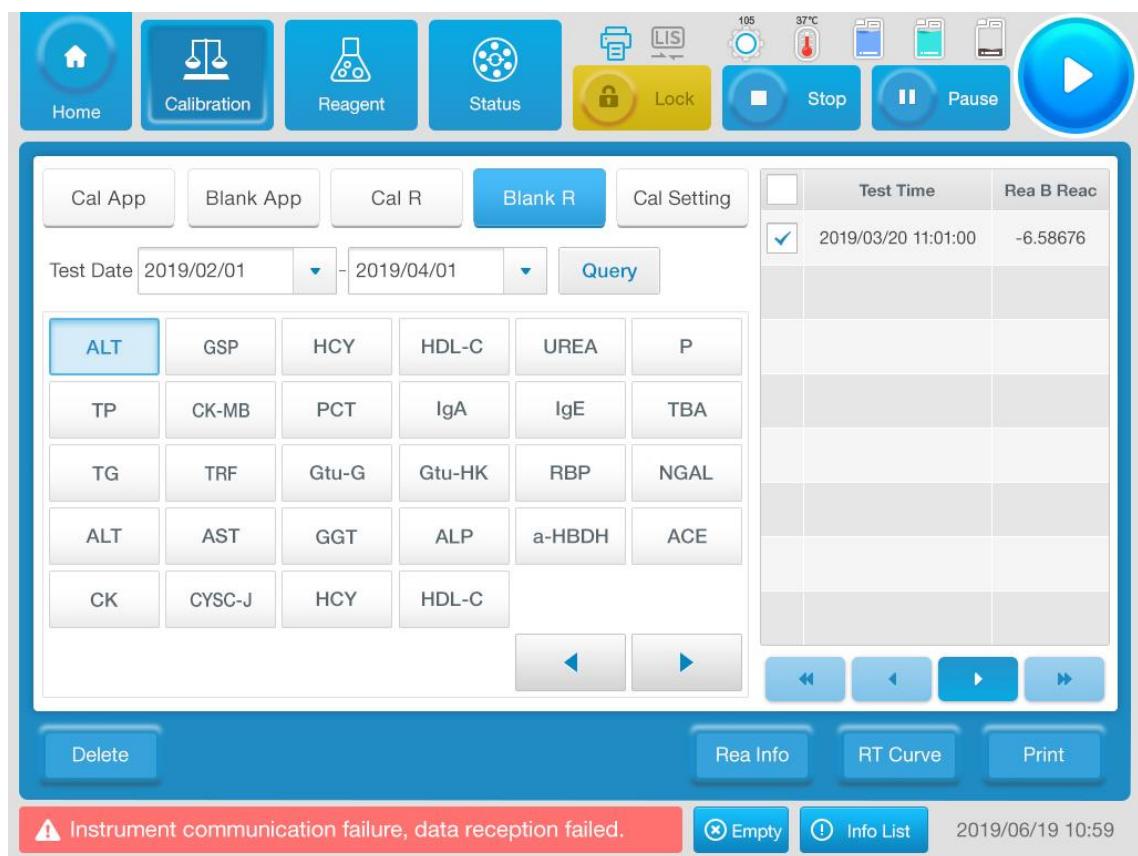


Figure 3-13 Blank Result

### Basic operation

- Review blank result
  - 1) Select the test date from the drop-down list, and click **Review**;
  - 2) If an item is selected in the list on the left, the test time and reagent blank reactivity of the item will be displayed on the right.
- Reagent information
  - 1) Check one item in the list on the right of blank result;
  - 2) Click **Reagent Information** to view the reagent type, batch number, and bottle number of the item in the pop-up reagent information interface;
  - 3) Click **Previous** or **Next** to switch to display different reagent information.
- Review blank reaction curve
  - 1) Check the blank result of a reagent on the right;
  - 2) Click **Reaction Curve** to open the blank reaction curve interface.

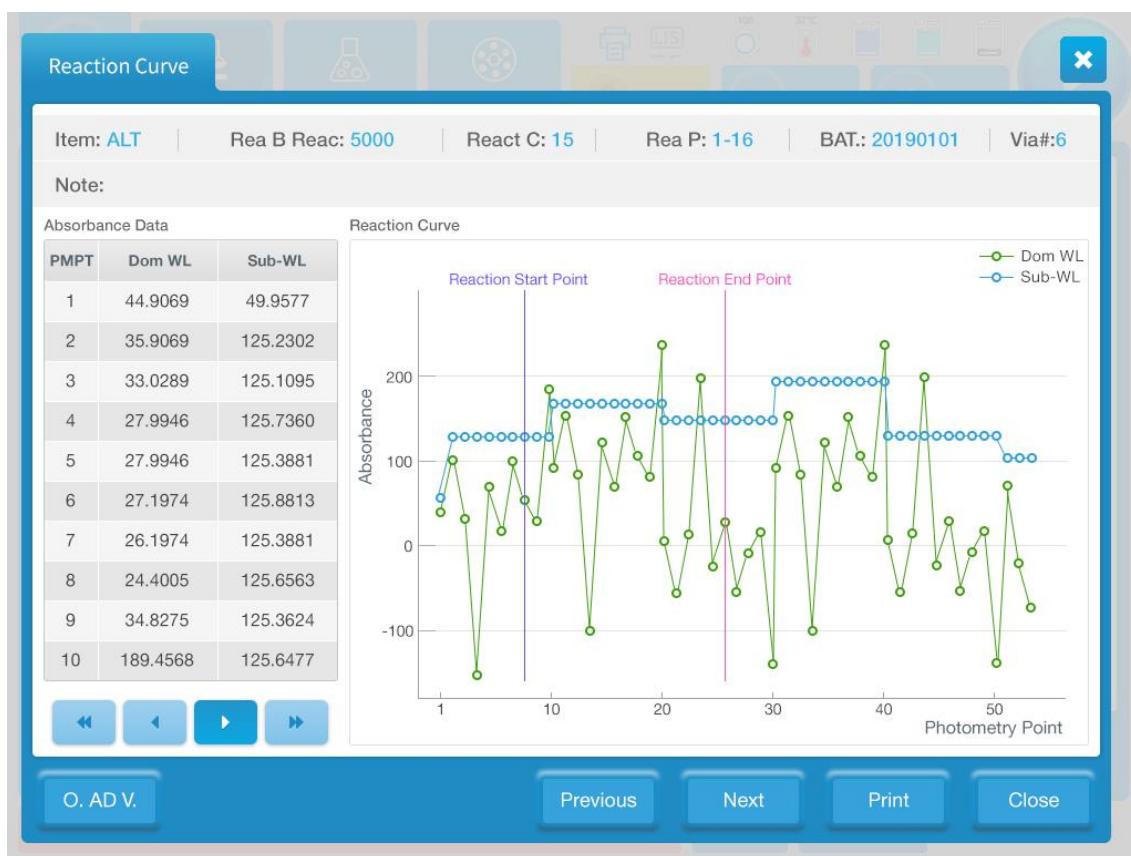


Figure 3-14 Blank Reaction Curve

- Delete reagent blank results
  - 1) Select the blank result of a reagent on the right;
  - 2) Click the **Delete** button.
- Print reagent blank results
  - 1) Select the blank result of a reagent on the right;
  - 2) Click the **Print** button.

## 3.11. Quality control

As the quality control results can ensure the accuracy of the sample test results, it is recommended to carry out quality control tests every day.

### 3.11.1. Quality control preparation

Prepare quality control in advance and it can be only be loaded manually. There is no special requirement for the quality control, and it is suitable for the quality control produced by all manufacturers on the market. Note that the quality control must be used within its expiration date.

### 3.11.2. Quality control application

It is allowed to apply for quality control tests according to the QC. You can apply for quality control tests through items or combined items. You may select at least one item, otherwise it is not allowed to apply. If you don't set the mean and standard deviation, it is not allowed for QC test.

#### 3.11.2.1. Setting of control

Select **QC- QC Setting** to enter the following interface:

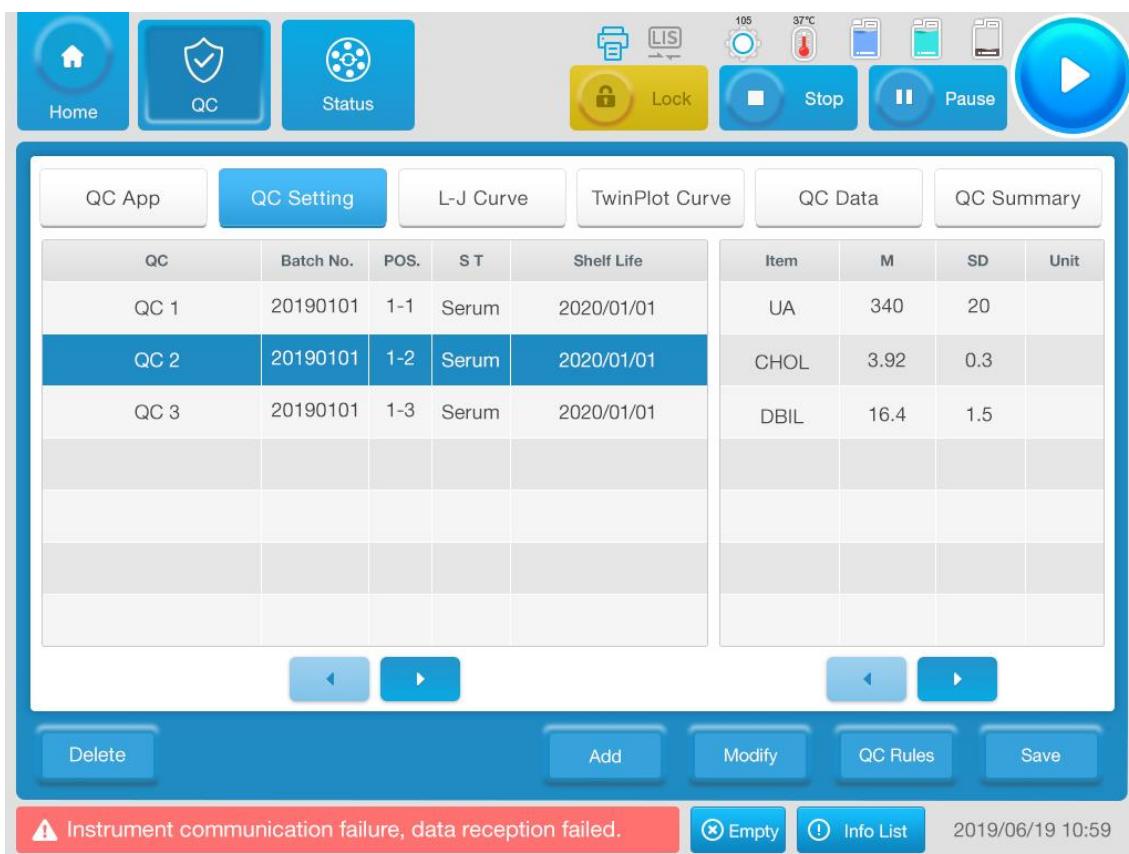


Figure 3-15 Quality Control Setting

**Basic interpretation of parameters**

Parameter	Meaning	Operation
QC	Name of QC	No operation required
Batch number	Batch number of QC	No operation required
Position	The tray number and cuvette number of the sample	No operation required
Sample type	Type of sample	No operation required
Period of validity	Validity period of QC	No operation required
Item	Item name	No operation required
Mean value	The QC corresponds to the mean value of each item that QC corresponds to	Enter directly in the box
Standard deviation	Standard deviation of each item that QC corresponds to	Enter directly in the box
Save	Save QC information	Directly click
Add new QC	Add QC	Directly click
Modify QC	Modify QC settings	Directly click
Delete QC	Remove the QC from the list	Directly click
Quality control rules	Set up control rules for the item	Directly click

**Basic operation**

- Add new QC
  - 1) Click **Add** to open the ‘Add QC’ interface:

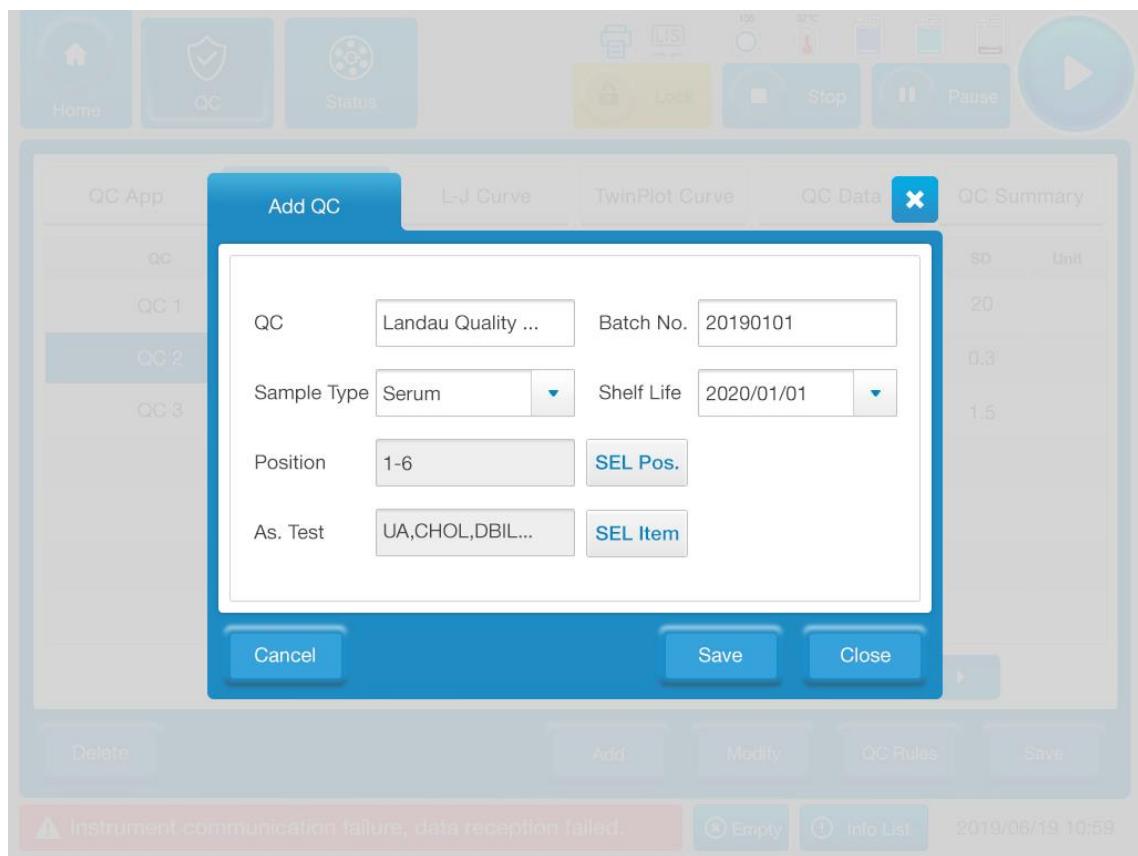


Figure 3-16 Add QC

- 2) Enter the name and batch number of the QC;
  - 3) Drop down to select the sample type and validity period of the QC;
  - 4) Click **Position**, select the tray number and cuvette number in the pop-up dialog box, and click **OK**;
  - 5) Click **Select Item**, select the corresponding items in the pop-up dialog box, and then click **OK**;
  - 6) To save the added QC, click **Save**, otherwise, click **Cancel**.
- Set the mean and standard deviation of the QC
- 1) Select a row in the "QC List" on the left;
  - 2) Enter the mean value of the QC in the mean value column after the corresponding item name in the "Concentration List" on the right, and enter the standard deviation of the QC in the standard deviation column;
  - 3) To save the set QC mean and standard deviation information, click the **Save** button.
- Modify quality control
- 1) Select the QC to be modified in the "QC List" and it is not allowed to modify the information of the QC during the instrument test;

- 2) Click **Modify** and enter the corresponding contents in the pop-up dialog box. The operation method is the same as "Add QC";
  - 3) To save the modified content, click the **Save** button.
- Delete QC
    - 1) Select the QC to be deleted from the QC List;
    - 2) Click the **Delete** button to pop up a prompt box;
    - 3) If you are sure to delete, click **OK**, otherwise, click **Cancel**.
  - Set quality control rules
    - 1) Click on the "**QC Rules**" to enter the quality control rules setting interface:

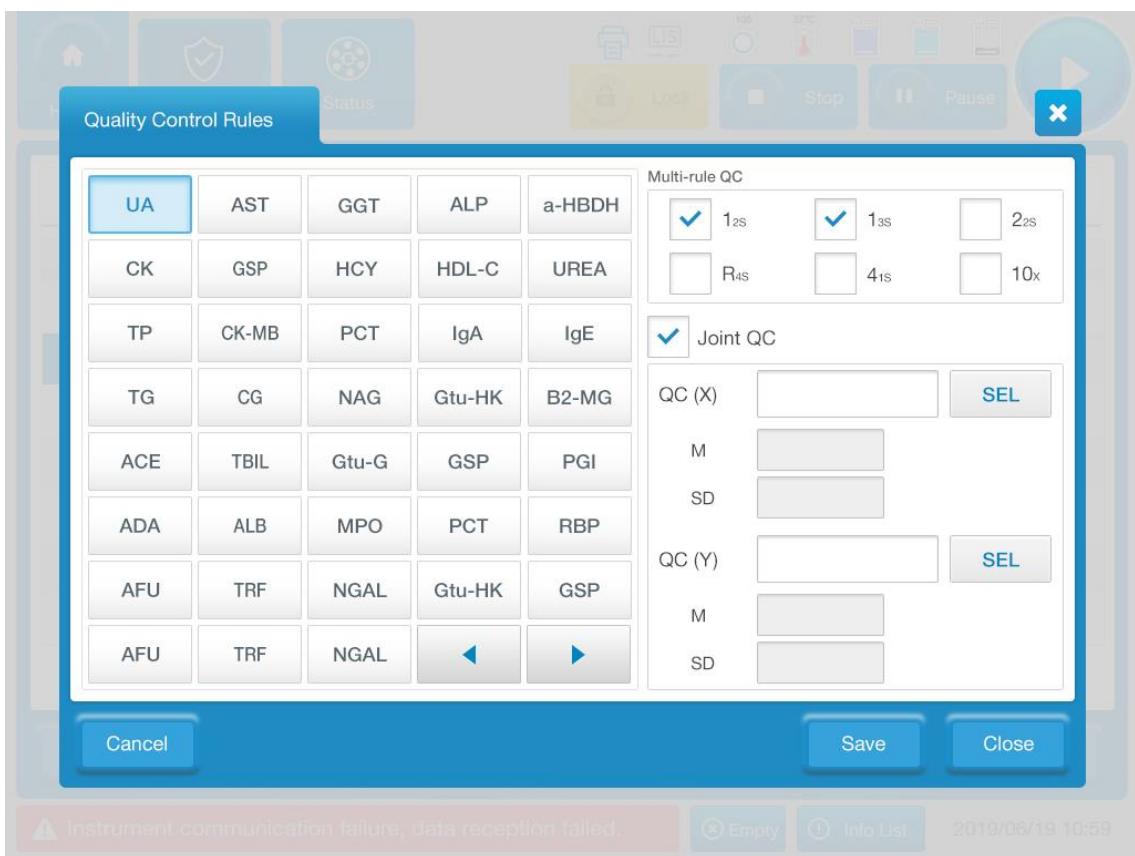


Figure 3-17 QC rule

- 2) Click to select an item on the left, and check the quality control rules in the "multi-rule quality control" on the right;
- 3) If you want to carry out joint quality control, you need to select both QC X and QC Y;
- 4) If you don't want to carry out joint quality control, you don't need to select either QC X or QC Y, and you can directly click the **Save** button;
- 5) Click **Close** to exit the interface.

### 3.11.2.2. Application for quality control

Click the **QC Application** button to enter the following quality control application interface:

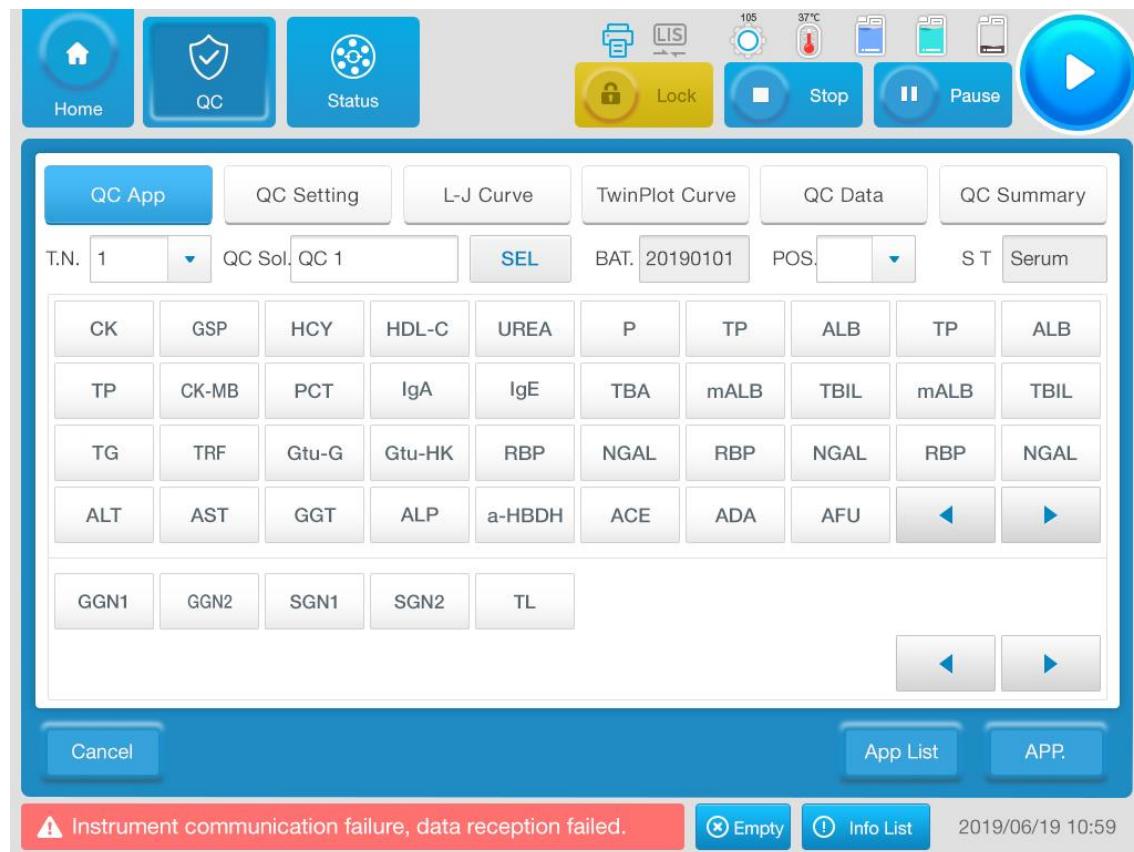


Figure 3-18 Quality Control Application

#### Basic interpretation of parameters

Parameter	Meaning	Operation
QC	Name of QC set up	Click <b>Select</b> to enter the "select quality control solution" interface
Batch number	Batch number of QC has been selected	No operation required
Position	The tray number and cuvette number of the QC	Select from the drop-down box
Sample type	Selected sample type	No operation required
Application list	List of QC samples applied	Directly click
Cancel	Cancel quality control application	Click to return to the previous menu
Apply	Apply for quality control after selecting items	Directly click

#### Basic operation

- Apply for quality control
  - 1) Click **QC Application** to enter the "Quality Control Application" interface;
  - 2) Click **Select QC** to confirm its batch number and sample type;
  - 3) If the position of QC has not been selected, the tray number and cuvette number can be determined in the **Position** drop-down menu;
  - 4) Select the quality control item in "Regular Item" or "Combination Items";
  - 5) Click the **Apply** button.
- Delete QC apply
  - 1) Click **Application List** to enter the "Application List" interface:

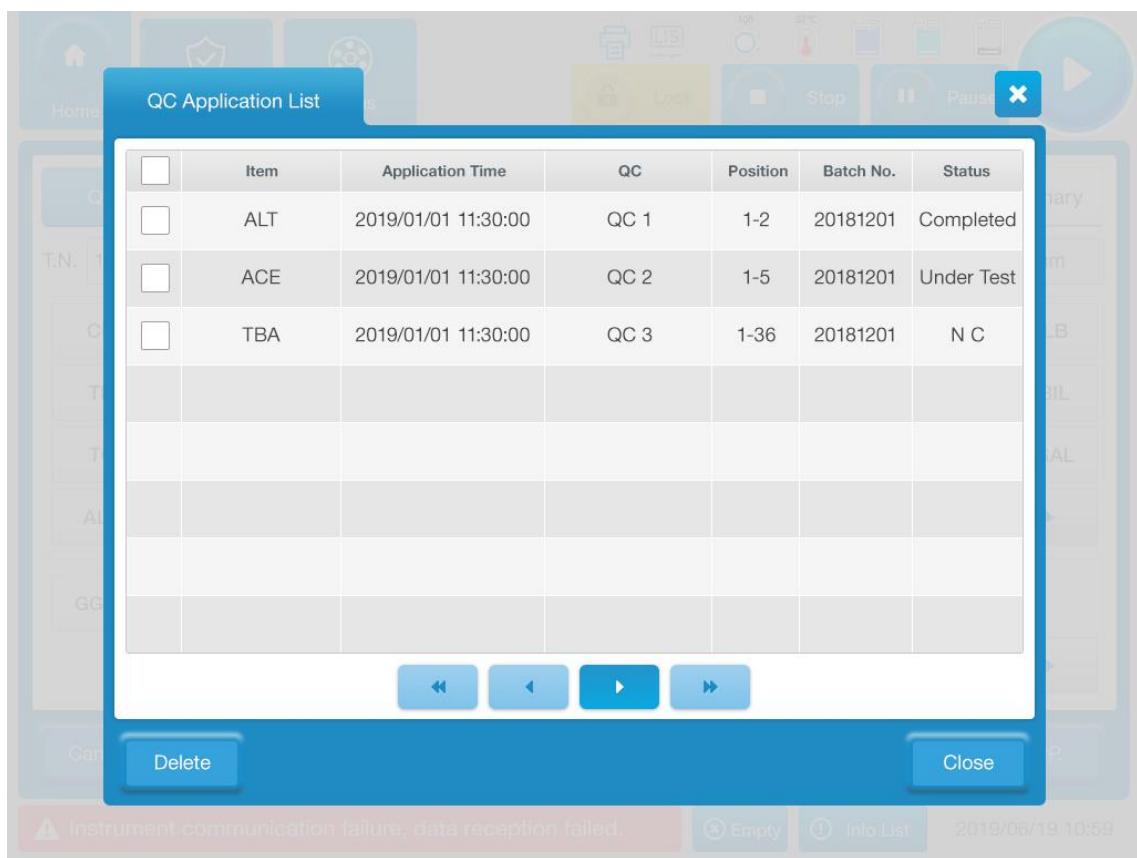


Figure 3-19 Control Application List

- 2) Check the control application to be deleted;
- 3) Select the quality control application that needs to be deleted, and click the **Delete** button to confirm deletion; otherwise, click the **Close** button.

### 3.11.2.3. Quality control data

Click **QC Data** to enter the quality control data interface, as the following:

## Basic Operation Method

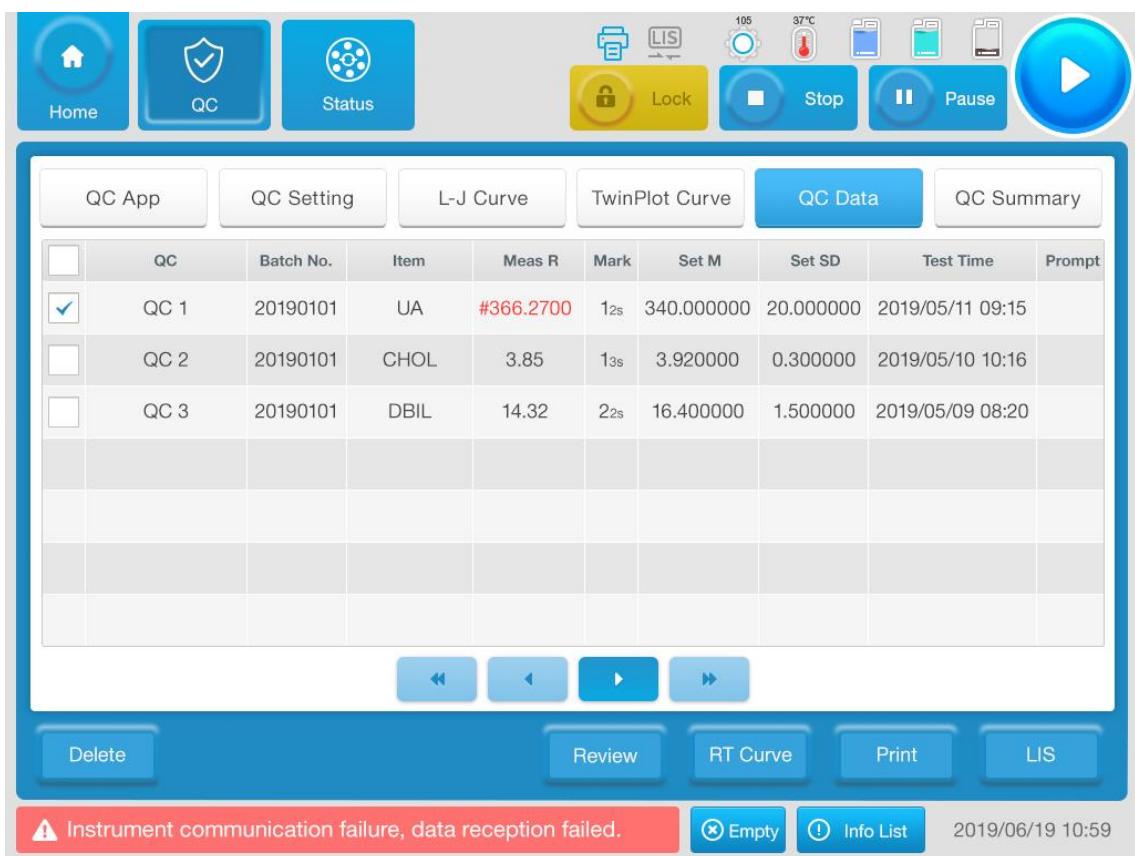


Figure 3-20 Quality Control Data

### Basic interpretation of parameters

Parameter	Meaning	Operation
QC	Name of QC	No operation required
Batch number	Batch number of QC	No operation required
Item	The items corresponding to the QC	No operation required
Measured results	Quality control results and out-of-control symbols	No operation required
Set mean value	Mean value set in quality control settings	No operation required
Set standard deviation	Standard deviation set in quality control settings	No operation required
Marker	Marking symbols, including: use of Quality control rules "1 <sub>2s</sub> , 1 <sub>3s</sub> , 2 <sub>2s</sub> , R <sub>4s</sub> , 4 <sub>1s</sub> , 10 <sub>x</sub> "	No operation required
Prompt	Marking symbols, including: use of expired QC "EQC", use of expired reagent "ER"	No operation required
Test time	The time when the quality control test starts	No operation required

### Basic operation

- 1) Click the **Review** button, in the pop-up dialog box to select items and QC, and drop-down to select quality control date, click **OK** to view the quality control results;
- 2) Select a certain quality control result and click **Reaction Curve** to view the reaction curve of the quality control result;
- 3) Select a certain quality control result and click **Delete** to delete the quality control result;
- 4) Select a certain quality control result and click the **Print** button. In the pop-up dialog box, you can choose to print only the selected quality control result or all the quality control results;
- 5) Select a certain quality control result and click the **LIS** button. In the pop-up dialog box, you can choose to send only the selected quality control result or all the quality control results.

#### 3.11.2.4. Quality control summary

Click **QC Summary** to enter the Quality control summary interface, as the following:

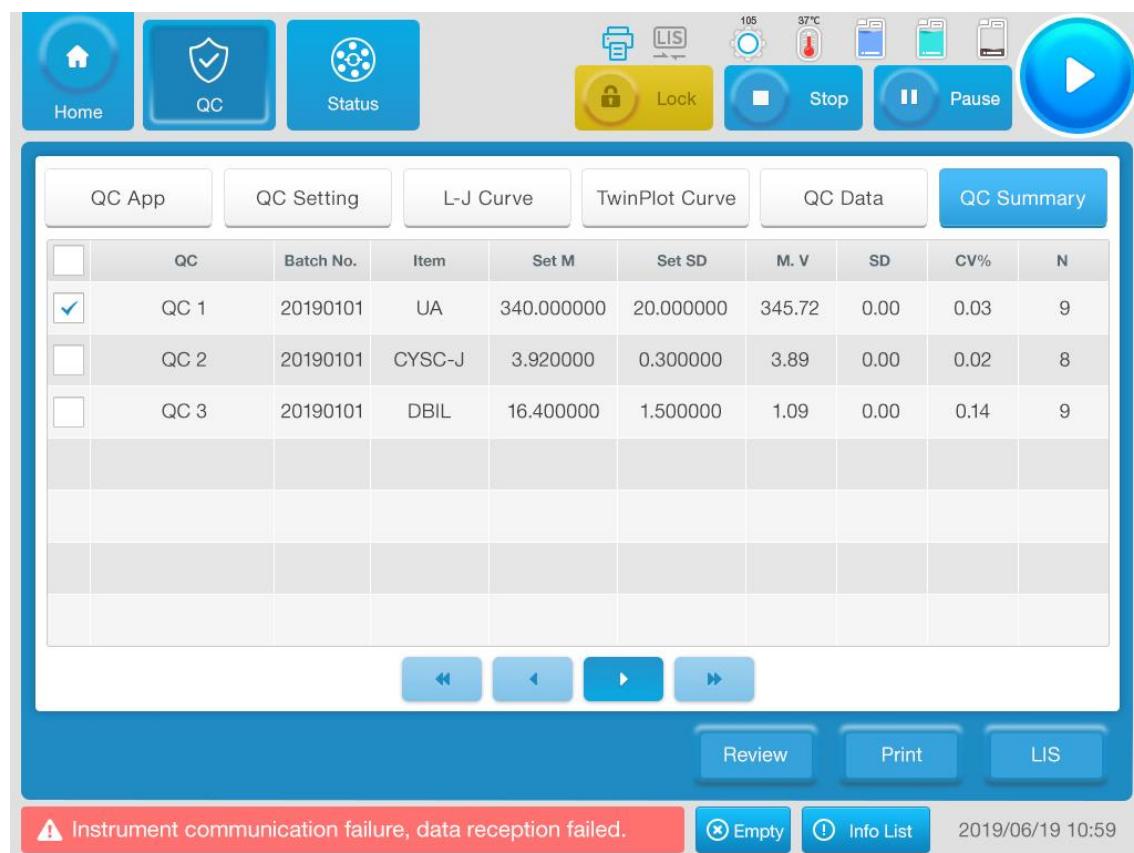


Figure 3-21 QC Summary

### Basic interpretation of parameters

Parameter	Meaning	Operation
Summary mean	The arithmetic mean value of all control results of the same QC and the same item	No operation required
Summary standard deviation	Standard deviation of all control results of the same QC and the same item	No operation required
Summary CV%	Repeatability CV of all control results of the same QC and the same item	No operation required
Summary N	The total number of quality control tests conducted for the same item in the same QC	No operation required

### Basic operation

- 1) Click the **Review** button, in the pop-up dialog box to select items and QC, and drop-down to select quality control date, click OK to view the quality control results;
- 2) Select a certain quality control result and click the **Print** button in the pop-up dialog

- box, you can choose to print only the selected quality control result or all the quality control results;
- 3) Select a certain quality control result and click the **LIS** button. In the pop-up dialog box, you can choose to send only the selected quality control result or all the quality control results.

### 3.11.2.5. L-J chart



Figure 3-22 L-J chart

#### Basic operation

- 1) Click to select item , drop down to select quality control date, click select QC 1, and then click **Review** to view the L-J chart of quality control results;
- 2) To view the quality control results of other QC at the same time, click to select QC 2 and QC 3;
- 3) To display the deleted quality control results in "Quality Control Data", click "Display Deleted Value";
- 4) Click **Previous** or **Next** to view the quality control result of the previous item or the quality control result of the next item in the item list;
- 5) Click **Print** to print the quality control results;

- 6) Click **LIS** to send the quality control results.

### 3.11.2.6. Twinplot

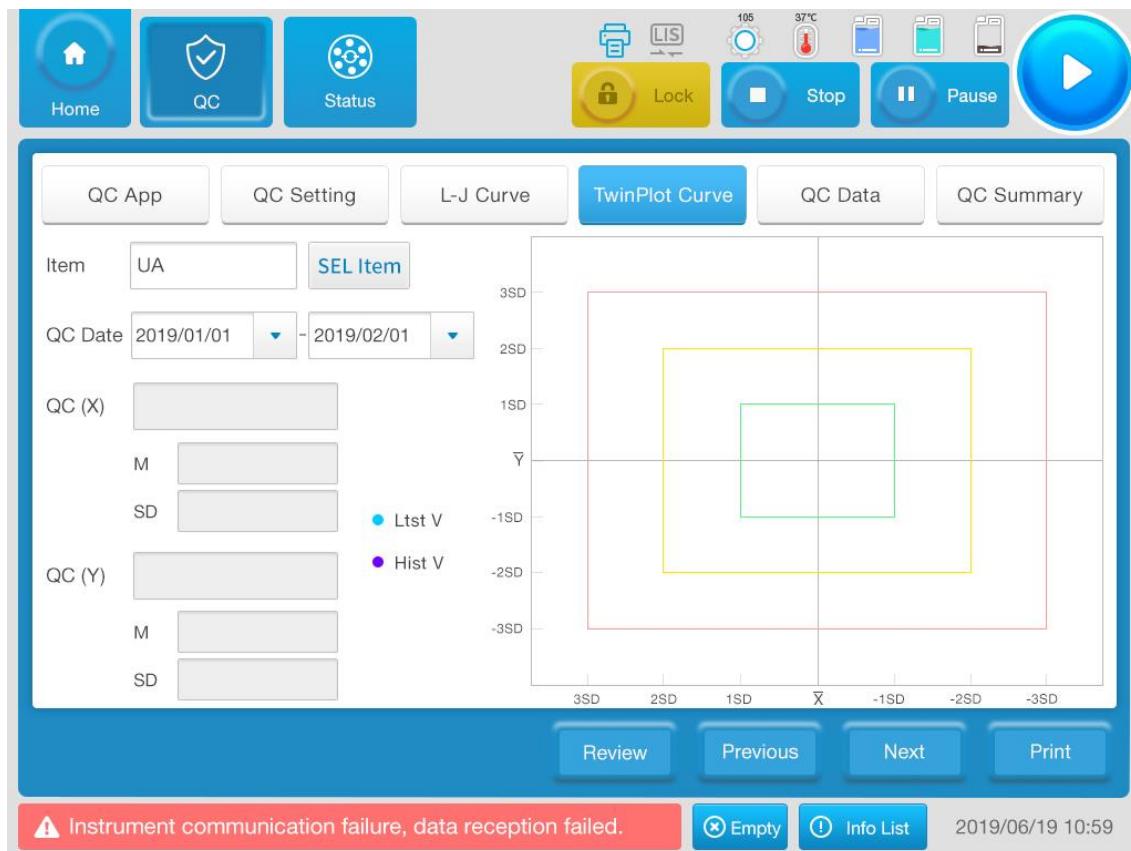


Figure 3-23 TwinPlot

#### Basic operation

- 1) Click to select item, drop down to select the quality control date, and click the **Review** button to view the quality control results. At the same time, the names, mean and standard deviation of QC X and QC Y will be displayed at the bottom left;
- 2) Other operations are the same as "L-J chart".

## 3.12. Routine test

This section describes how to apply for routine testing of samples.

### 3.12.1. Sample application

In the sample application menu, users can apply for samples, and can choose test applications for functions such as emergency samples, batch sample applications, and repeated tests according to actual needs; they can also view the application list and enter patient information.

Click **Sample** in the main interface. The sample application interface is as follows:



Figure 3-24 Sample Application

### Basic interpretation of parameters

Parameter	Meaning	Operation
Sample number	Number of test sample	Enter directly in the box
Emergency	Set the current sample as emergency	Selecting the previous radio box indicates that the emergency is selected
Sample position	Select the location of the sample	Select the tray number and cuvette number from the drop-down box
Sample type	Select sample type	Select from the drop-down box
Sample barcode	Bar code of test sample	Enter directly in the box
Patient information	Enter patient information	Click <b>Patient Information</b>
Blank test	Test sample blank	Click to choose and click again to cancel

Parameter	Meaning	Operation
Sample scanning	Perform sample barcode scanning	Click <b>Sample Scan</b>
LIS acquisition	LIS acquisition content selection	Click to enter the setting interface
Options	Select test method	Click <b>Options</b> interface
Batch	Apply for batches of sample test	Click <b>Batch Application</b> interface
Retest	Retest sample	Click <b>Retest</b>
Application list	Check the list of applied samples and items	Click <b>Application List</b>
Cancel	Cancel this sample application	Click <b>Cancel</b>
Apply	Apply for testing	Click <b>Apply</b>

**Note:**

- 1) The sample position consists of tray No. and cup No. Conventional samples support virtual tray setting, which can be set up to 5 at most. The default for the current day is from the 1st position of the 1st tray. The occupied sample position cannot be used for reapplication before release.
- 2) The numbering can be composed of numbers. The sample numbering is prefixed by time. For each sample number starting from 0001, the user can enter 1-9999, and the system will automatically jump to the default format. If the input data exceeds this range, an error will be reported. You can re-enter it again. You cannot set a duplicate sample number after releasing the sample position. You can set it only after deleting the sample.

**Basic sequence of operations**

- Apply for a single sample
  - 1) Select the sample tray number and cuvette number from the sample position drop-down box;
  - 2) Drop down to select sample type;
  - 3) If it is an emergency test, select the emergency radio box, otherwise not select;
  - 4) Enter interface contents such as sample number;
  - 5) Click the item to be measured in the measurement item selection area, click once

for selection, and click again to cancel;

- 6) Click the **Apply** button.

■ Batches application

- 1) Select the sample tray number and cuvette number from the sample position drop-down box;

- 2) Drop down to select sample type;

- 3) If it is an emergency test, select the emergency radio box, otherwise not select;

- 4) Click the **Batch** button, enter the start number and end number in the pop-up window, or enter the start number and batch number, and then click **OK** to close the popup window;

- 5) Click the item to be measured in the measurement item selection area, click once for selection, and click again to cancel;

- 6) Click the **Apply** button.

- 1) During batch application, the sample number and cuvette position on the sample tray are increased in sequence according to the number of the starting sample and the cuvette position of the starting sample.

- 2) The starting sample for batch application must be the sample that has not yet been applied. If the sequentially increasing sample positions contain samples with the status of "Application", "Under Test", "Incomplete" or "Complete", the sample positions will be skipped and will continue to be set from the next sample position.
- 3) Batch application and single application can be carried out at the same time.

Attention

■ Delete sample application

- 1) Click **Application List** to enter the "Application List" interface:

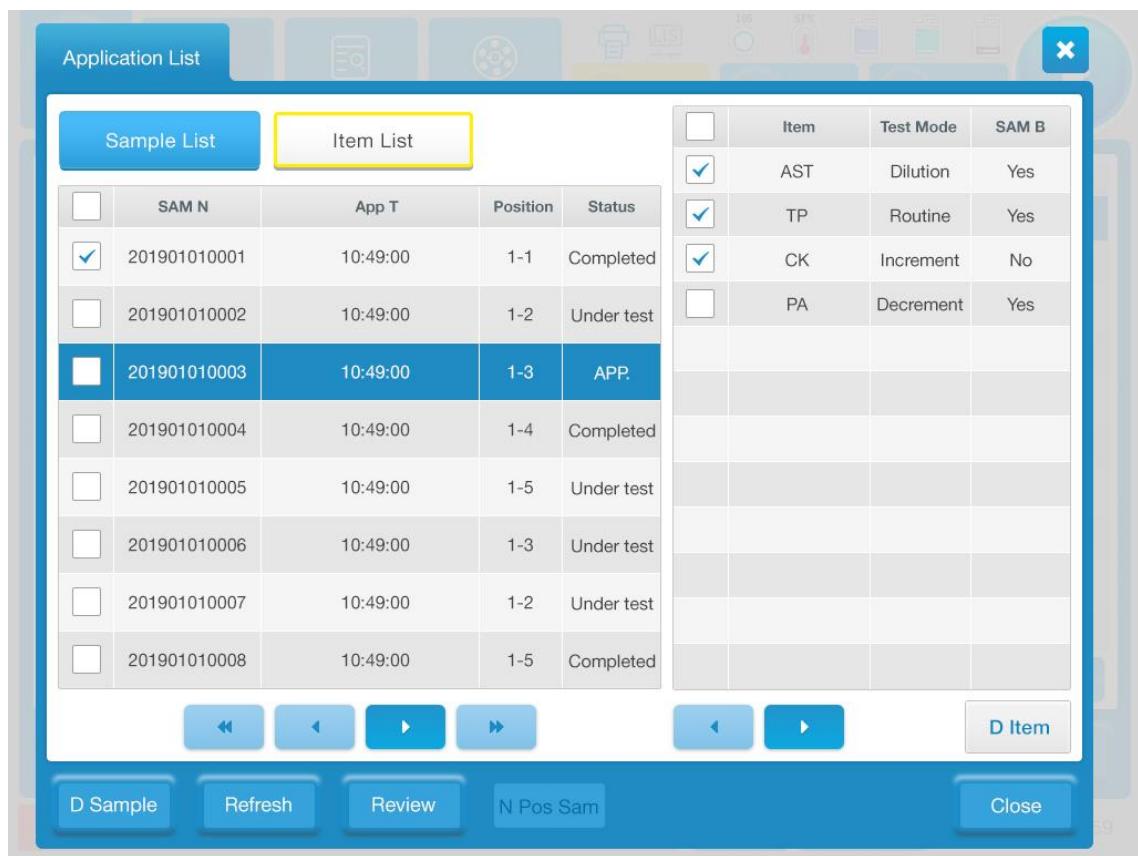


Figure 3-25 Sample Application List

- 2) Check the sample application to be deleted under "Sample List";
  - 3) After clicking on the **Delete** button, you can select to delete the selected samples, the specified tray, the specified samples or all samples in the pop-up window, then click the **OK** button;
  - 4) To delete an item, first select a row in the sample list on the left, select the item to be deleted on the right, click **Delete**, or click **Item List**, select a row, and then click **Delete**.
- Apply for increase/decrease volume
    - 1) After selecting the applied item, click **Options**;
    - 2) Set the test method in the pop-up "Options" interface;
    - 3) Click the **Save** button.
  - Re-test basic operation sequence
    - 1) Click **Retest** and select the content to be retested in the pop-up window:

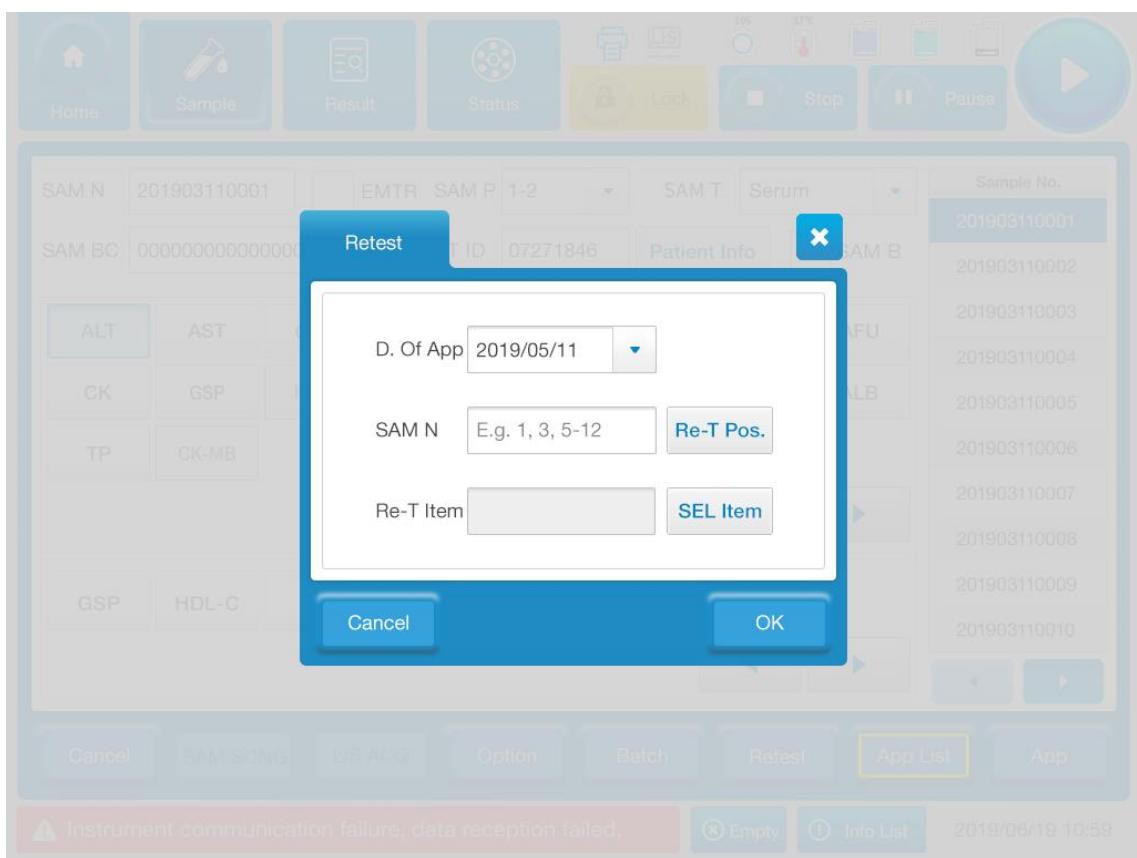


Figure 3-26 Sample Retest

- 2) Select the application time, number and item to be retested in the popup window;
  - 3) Click **OK** and the instrument will start retesting.
- Patient information registration
- Patient information interface are as follows:

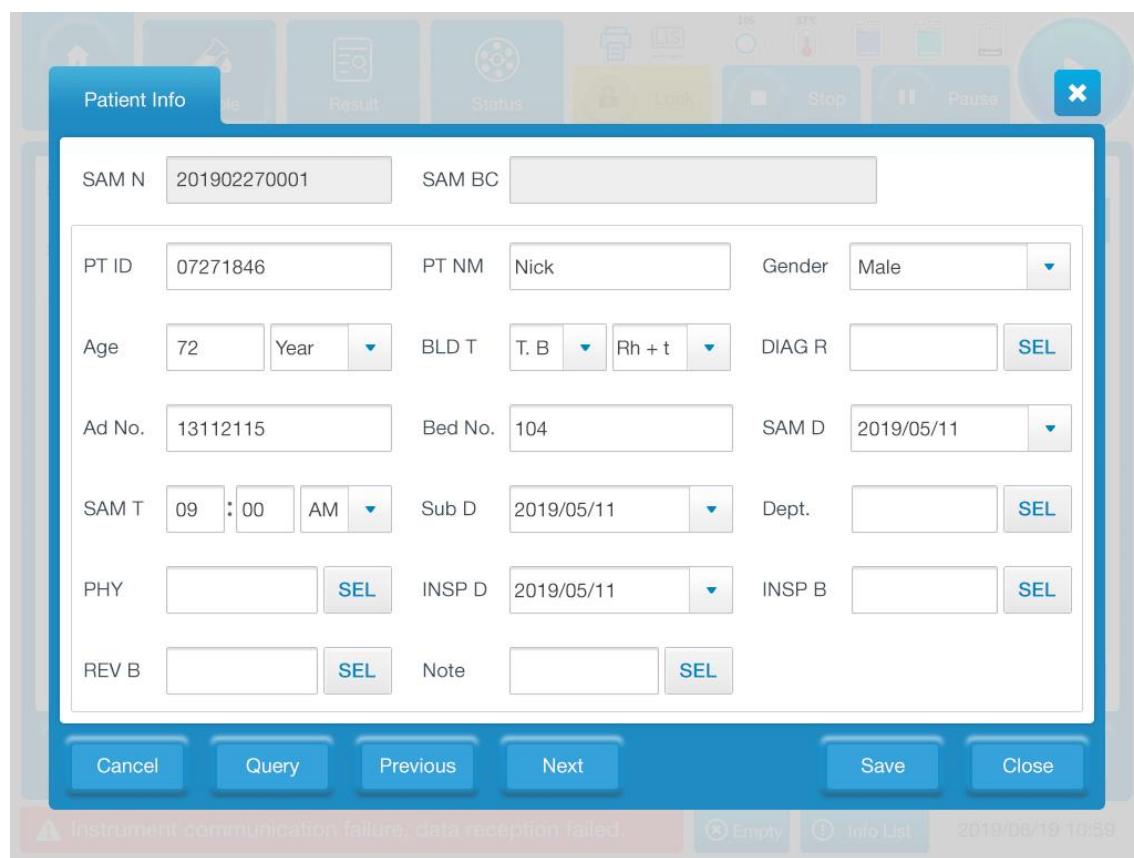


Figure 3-27 Patient Information Registration Form

**Basic interpretation of parameters**

Parameter	Meaning	Operation
Sample number	Number of samples	No operation required
Sample barcode	Barcode of samples	No operation required
Patient ID	Patient number	Input directly
Patient name	Name of the current patient	Enter directly in the box
Gender	Gender of the current patient	Select one from the drop-down box
Age	Age of the current patient	The first box is directly entered, and the second box is selected from the drop-down box
Blood type	Blood type of the current patient	Select from the drop-down box
Inpatient No.	Number of inpatient	Enter directly in the box
Bed No.	Patient bed number	Enter directly in the box
Sampling date	Date of sampling	Direct input or drop-down selection
Sampling time	Time of sampling	Direct input or drop-down

Parameter	Meaning	Operation
		selection
Submission date	Date of sample submission	Direct input or drop-down selection
Department	Department where the current patient is located	Enter directly or click to select
Doctor	The doctor who issues a test application form to the current patient	Enter directly or click to select
Date	Date of sample test	Direct input or drop-down selection
Clinical diagnosis	Clinical diagnosis results of the current patients	Enter directly or click to select
Operator	The doctor who tests a patient sample	Enter directly or click to select
Authority	The person who reviews the inspection report	Enter directly or click to select
Remarks	Indicating the special situation of the current patient or other relevant contents	Enter directly or click to select
Search	Search sample number and barcode	Click directly
Previous	View previous patient information	Click directly
Next	View next patient information	Click directly
Cancel	This entry information is not saved	Click directly
Save	Save this entry information	Click directly
Close	Close the pop up patient information	Click directly

### Basic operations

- Enter patient information
  - 1) Click **Patient Information** to enter the "Patient Information" input interface;
  - 2) Enter all relevant information and click the **Save** button to save.

## 3.13. Start

### Basic operation

- 1) Select the type and position of the sample, and click the **Start** button after confirmation;
- 2) Set the content of test;

- 3) Click **OK**.

## 3.14. View testing status and result

- View testing status
  - 1) Click **Status-Sample Tray**, select the sample position to be viewed on the sample tray status interface, and then view the test status of all items of the specified sample in the test list.
  - 2) Click **Status-Reaction Tray**, you can view the current status of each cuvette on the reaction tray status interface; click **Reaction Curve** on the reaction tray interface to observe the effective test (sample, calibration, quality control, sample blank, reagent blank).
- View test result

Click **Results-Current Results / Historical Results** on the homepage, and view the current sample test results or previous sample test results on the results interface.

## 3.15. Pause

- Function description
  - 1) Suspend the tests that have not been added with R1 in all ongoing tests, and the tests that have been added with R1 will continue to complete the actions of adding S (samples) and R2, and continue the tests;
  - 2) When sample addition is suspended, the reaction tray will continue to work. After all the application items that have started testing have finished adding samples or R2 reagent (in case of dual reagent items) and the reagent-sample tray and reagent-sample probe stop rotating, the operations of adding samples and adding reagents can be performed.
- Step
  - 1) Click the **Pause** button at the top right of the interface, and the analyzer will stop sample loading status.
  - 2) After the suspension of sample addition, click the **Start** button on the right side of the interface to resume the test.

## 3.16. Stop

Stop all ongoing tests without adding S (single reagent items) or R2 (dual reagent items). This function will only be performed if the user needs to stop the current work for various reasons. Click the button **Stop**, and click **OK** in the pop-up dialog box, then only the single reagent item added with S and the dual reagent item added with R2 will continue, and other tests will stop immediately.

## 3.17. Daily maintenance

After the test is finished every day, the instrument shall be maintained according to the maintenance items in the daily maintenance list and the yellow maintenance items displayed. The daily maintenance items include:

- Check deionized water connection
- Check waste connection
- Check the remaining amount of concentrated detergent
- Check if the reagent-sample probe syringe leaks
- Check the balance of acid-base detergent
- Check whether the probe outlet water is normal (verify whether the probe inner wall is blocked)
- Check and clean the cleaning basin

## 3.18. Shutdown

- 1) Confirm that the system is in a non-test state;
- 2) Select **Shutdown-OK** at the bottom right of the homepage interface to wait for the shutdown process to complete;
- 3) Turn off the power supply of the instrument after the software is turned off.

## 3.19. Emergency shutdown

This function is only performed when the analyzer fails during operation and cannot exit normally. In case of emergency exit, the analyzer does not execute any shutdown process and exits directly. Click the button **Emergency Shutdown**, and directly click **OK** in the pop-up dialog box to exit the software immediately. If you do not want to shut down the software urgently, click **Cancel**.

## 3.20. Operation after shutdown

- 1) Open the reagent-sample tray and take out the calibrator, QC, etc.
- 2) Check the analyzer table for stains. If so, please wipe the stain clean with a clean soft cloth.
- 3) Check the high-concentration waste container. If there is any waste liquid, please empty the waste container.
- 4) Cover the reagent-sample tray and close the upper cover.

## 4. Software System Operation

This chapter mainly introduces the system status, reagents, results, and setting functions in detail.

### 4.1. Home page

After normal startup, enter the homepage interface. As shown in the following figure:

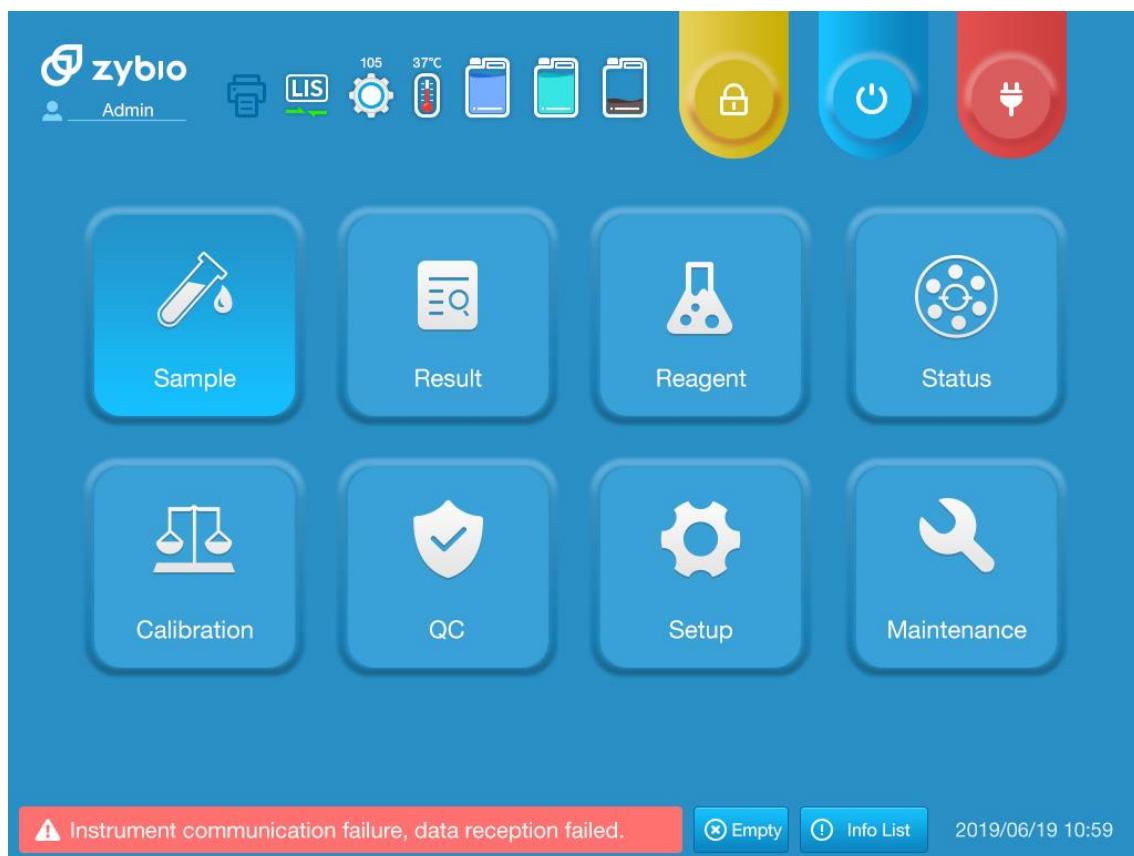


Figure 4-1 Home Page

Description of interface function keys:

Function key	Name	Function
	Sample	Enter the sample application function page to apply for a sample test. Support batch application, patient information entry, sample location setting, sample scanning and other functions.

Function key	Name	Function
	Result	Enter the results review function page to view the test results. It has the functions of retest, recalculation, reaction curve checking, printing, LIS sending, etc.
	Reagent	Enter the reagent management function interface and have the functions of reagent scanning, reagent loading, reagent unloading, residual quantity detection, reagent information inquiry, etc.
	Status	Enter the online status viewing function page of the instrument to display relevant information of the sample tray, reagent tray and reaction tray.
	Calibration	Enter the calibration function page to set calibrator information, set reagent position, apply for calibration test and reagent blank test, and query calibration results.
	QC	Enter the quality control function page, you can set up QC information, apply for quality control tests, query quality control results and other operations.
	Setting	Enter the setting function page. It mainly includes test settings, system settings, user settings, items settings and other functions.
	Maintenance	Enter the maintenance function page. It mainly includes routine maintenance and engineering maintenance. Daily maintenance includes periodic maintenance, fault handling, data backup, temperature curve, consumables maintenance and unit status. Engineering maintenance includes maintenance and debugging.

Function key	Name	Function
	Lock	Lock the interface and clicking other function keys is invalid.
	Emergency shutdown	Exit the system directly.
	Shutdown	Exit the system normally according to the shutdown process.

## 4.2. Status

Including the online status of the sample tray, reagent tray and reaction tray, respectively described below.

### 4.2.1. Sample tray

Check the test status of the applied samples on each sample tray.



Figure 4-2 Sample Tray Status

### Basic interpretation of parameters

The meaning of each sample color in the “Sample Tray Status” interface is as follows:

Status	Color	Interpretation
Free	Blank	Clean cuvette
Occupied	Gray	Sample positions have been occupied by diluent, QC and calibration, and a routine test cannot be applied
Applied	Blue	Applied test, ready for test
Testing	Green	Sample is under testing
Finished	Yellow	Testing is finished
Not enough	Rosy	Sample is not enough
Not finished	Purple	The sample did not complete the test due to abnormalities, failures, etc.
Collision	Red	Probe collision during the test

The meaning of the shape of each sample position in the “Sample Tray Status” interface is as follows:

Shape	Interpretation
Round	Normal sample
Triangle	Emergency sample
Square	Calibrator
Pentagon	Water
Hexagon	QC

### Basic operation

- Sample tray status review
  - 1) Click trays 1 to 5 to view the test status of the samples on the corresponding sample trays respectively;
  - 2) In the sample tray on the left, different sample types and test states are represented by different shapes and colors;
  - 3) After selecting a sample on the sample tray, its information (QC or Calibrator information) is displayed in the sample information area on the right side of the interface, and the test list area displays the items applied for the sample position.



When the sample size is not enough, the "Refresh" operation must be performed after the sample is replenished before starting the test.

#### Attention

- Release Immediately

Select a sample on the sample tray and click **Release Immediately** to release the current sample position.

- Release

Click **Release** to release the position where the sample is located. In the pop-up window, you can choose to release the sample status at the specified position or all positions..

- Refresh

Click **Refresh** to refresh the test status of the sample tray. In the pop-up window, you can choose to refresh the sample status at the specified position or all positions.

- Reaction Curve

Click **Reaction Curve** to view the reaction curve of the selected sample that has completed the test.

### 4.2.2. Reagent tray

The online status interface of reagent tray is shown in the following figure:



Figure 4-3 Reagent Tray Status

#### ■ Reagent tray status review

- 1) Click on trays 1 to 5 at the left, and then click on the cup position in the tray to view the reagent information on different reagent trays and the items corresponding to the current reagent position.
- 2) The status of the reagent position on the reagent tray is divided into 6 types: Empty, R1, R2, common reagent position, detergent and diluent, which are respectively marked with different colors.
- 3) There is a circle in the middle of each reagent position, and different colors show different states of reagents, namely default reagent, expired reagent, expired bottle opening period, insufficient reagent and striker.
- 4) In the list of items displayed on the right, gray indicates that reagents have not been associated, and blue indicates that reagents have been associated. Click on the item and a brown box will appear at the corresponding reagent position in the reagent tray.
- 5) Click on a reagent position in the reagent tray, and the reagent information will be displayed on the lower right.

#### ■ Residual detection

- 1) Click the button **Residual Detection** to open the " Residual Detection" interface:

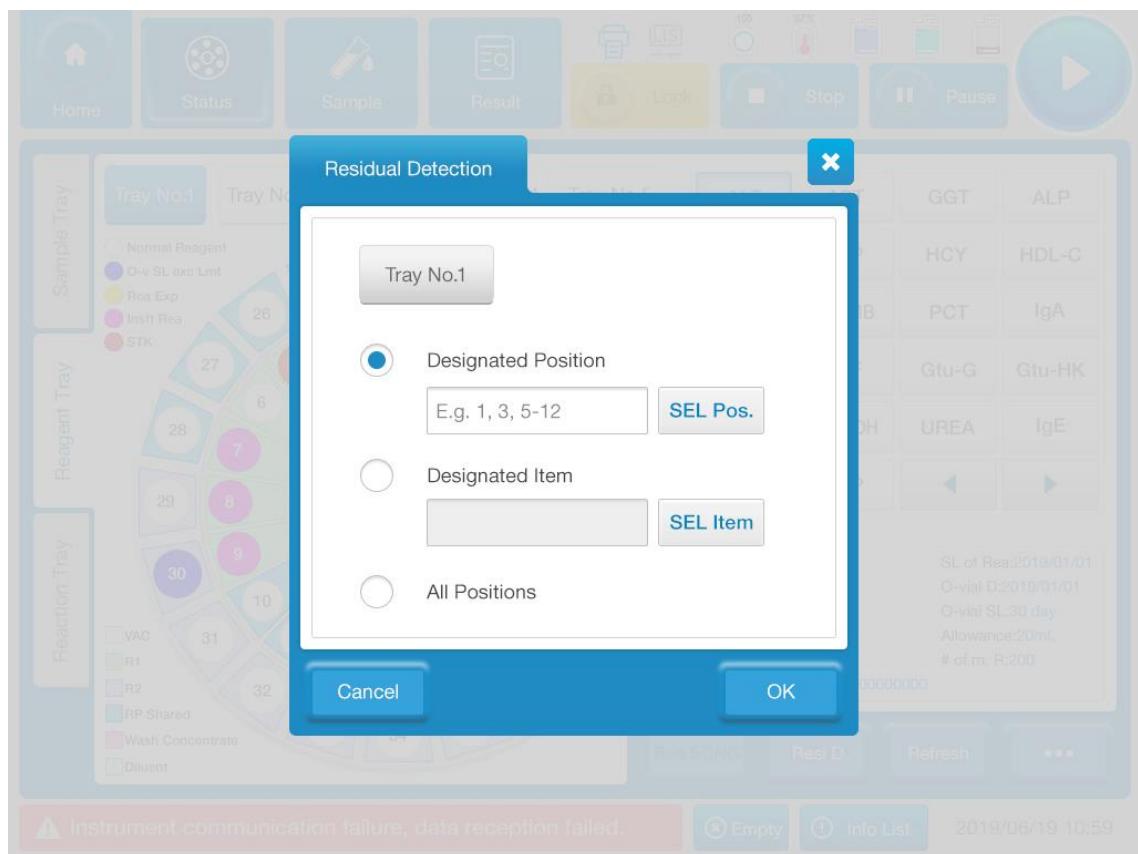


Figure 4-4 Residual Detection

- 2) Set the content that needs residual detection. You can select the cup position at the specified position, the specified item or all positions for residual detection;
- 3) To start residual detection, click **OK**, otherwise, click **Cancel**.



Attention

- 1) R1 and R2 for dual reagent items must be set on the same reagent tray.
- 2) The remaining amount detection operation can be performed only in the standby mode.

■ State refresh

- 1) Click the button **Refresh** to enter the "status refresh" interface;
- 2) Click to select the specified position or all positions to refresh the status.



Attention

When there is a lack of reagent for a certain item, a refresh operation must be performed after the reagent is replenished to start the test of the reagent item, and the state must be refreshed after the striker is restored, as well.

■ Shared reagent position

- 1) Click **Shared Position** to open the "Shared Reagent Position" interface:

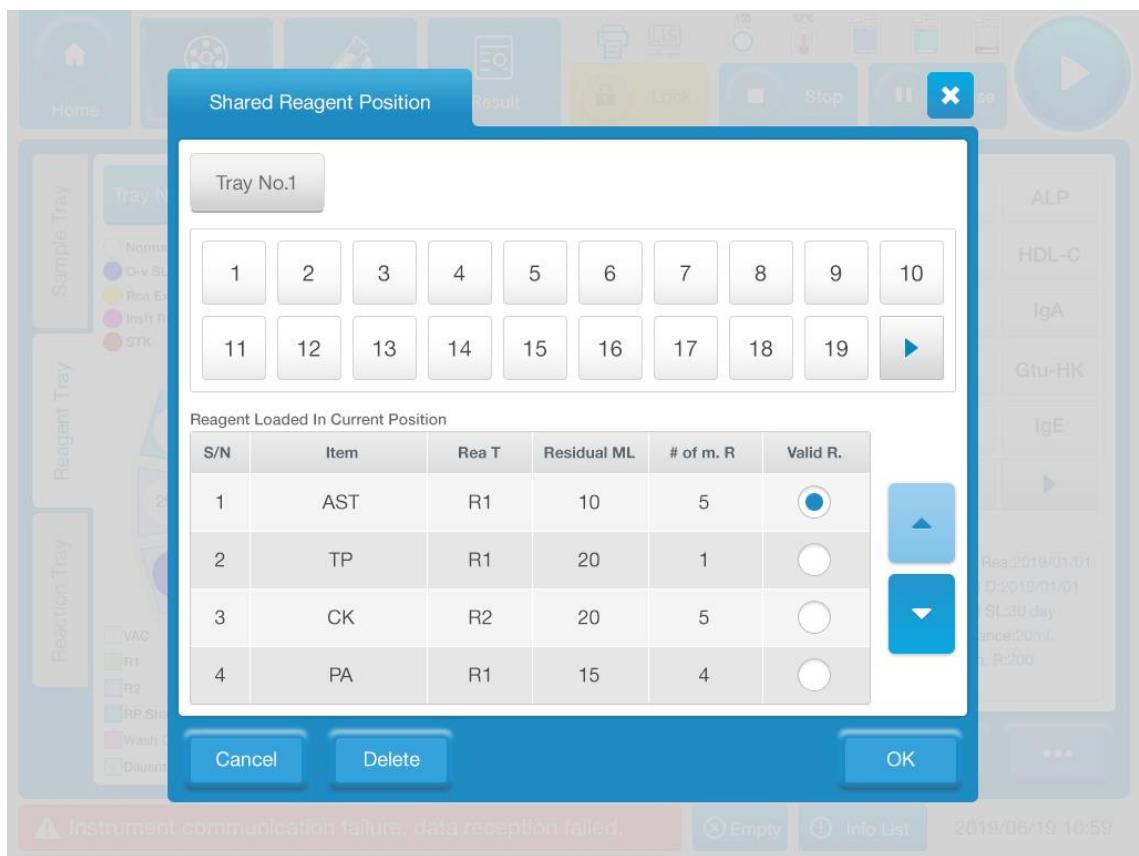


Figure 4-5 Shared Reagent Position

- 2) Click on the cup number to view the reagent information loaded at the current cup position;
- 3) Click "Effective Reagent" to switch the reagent currently preferred for this cup.

#### ■ Reagent loading

Click the **Loading** button to enter the reagent loading interface, enter the corresponding reagent information and click save.

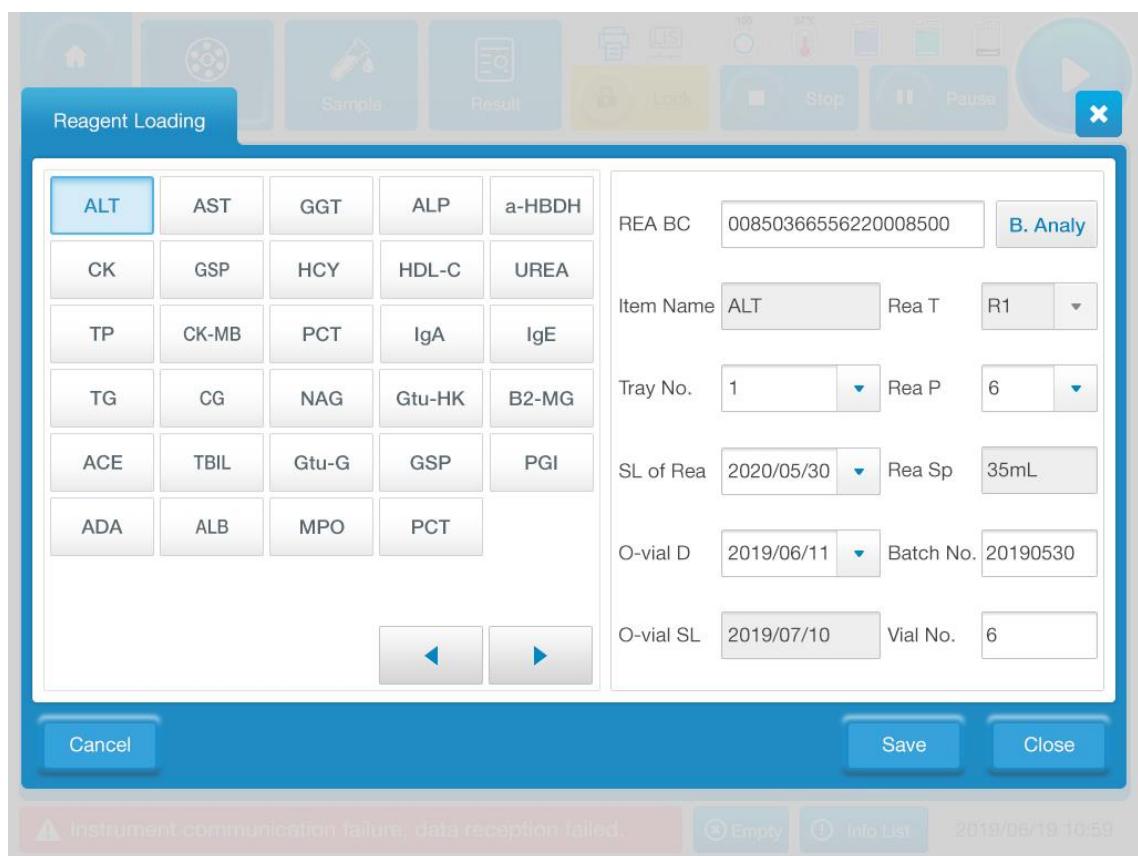


Figure 4-6 Reagent Loading

**Basic interpretation of parameters**

Parameter	Meaning	Operation
Reagent barcode	Barcode corresponding to reagent	Directly input
Barcode analysis	Analyzing reagent information corresponding to the bar code	Directly click
Item name	Displays the name of the item	No operation required
Reagent type	Types of reagents	Drop-down box selection
Tray No.	Set the tray number where reagent locates	Drop-down box selection
Reagent location	Set the cup position where the reagent is located	Drop-down box selection
Production validity period	Effective days after reagent production	Drop-down box selection

Parameter	Meaning	Operation
Reagent specification	Reagent bottle specification Inner circle: fixed to 35ml, not optional. Middle circle: fixed to 20ml, not optional.	No operation required
Batch number	Lot number information of reagent kit	Directly input
Opening date	The date of reagent bottle opening shall be calculated from the date when the reagent position is set.	Drop-down box selection
Bottle number	Reagent kit bottle number information	Directly input
Validity period of bottle opening	The effective time after the reagent is opened is calculated from the days after the reagent position is set.	No operation required

■ Reagent unloading

- 1) Click on a reagent to be unloaded on the reagent tray, and then click **Unloading**, and click **OK** in the pop-up window.
- 2) You can also click **Unloading** directly, click **Specified Position-Select Position** in the pop-up window to select the position, and click **OK** to unload.
- 3) Click **Select Item** in the pop-up window to unload the reagent of the corresponding items, and click **Unload All** to unload all the loaded reagents on the reagent tray.

■ Reagent replacement

- 1) Click **Replace Reagent** and enter the corresponding reagent information in the pop-up window;
- 2) Click **Save**.

### 4.2.3. Reaction tray

The online state interface of the reaction tray is shown in the following figure:

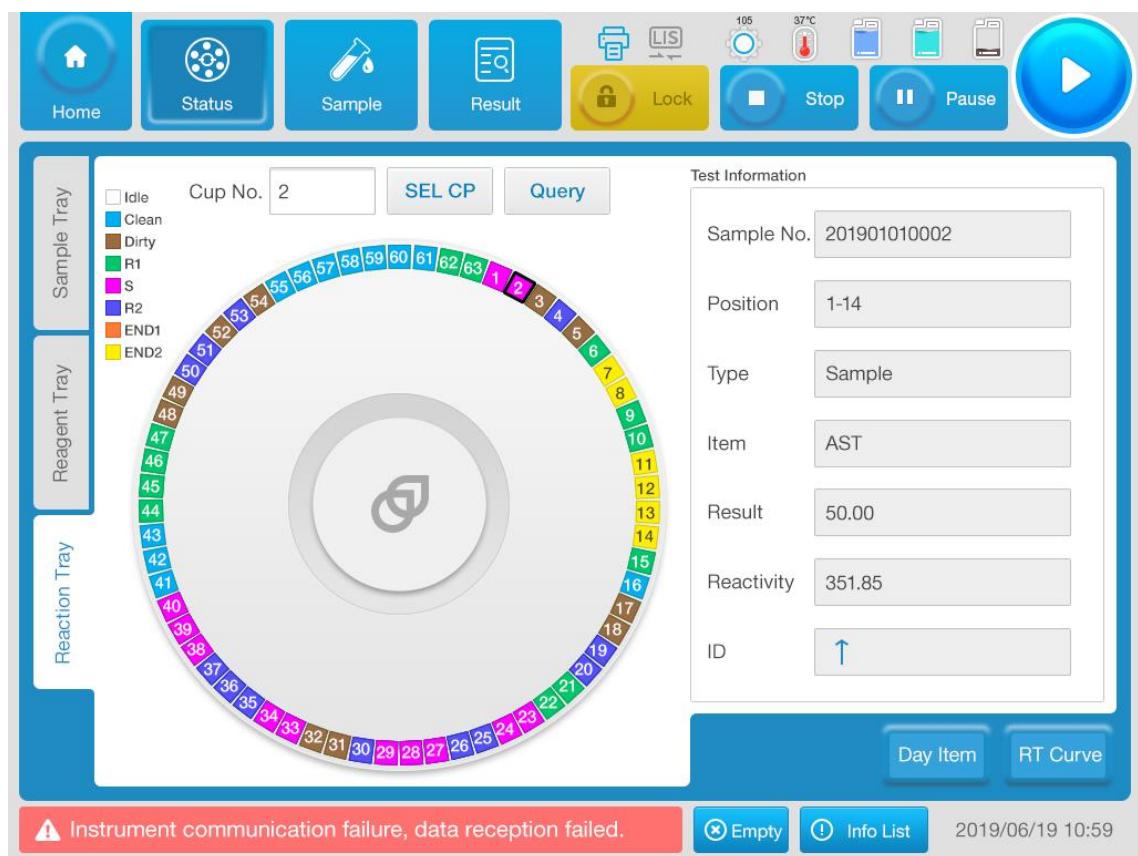


Figure 4-7 Status of Reaction Tray

### Basic interpretation of parameters

Parameter	Meaning	Operation
Cuvette number	Number of reaction cuvette	Select cup position and click <b>Query</b> to view the test information of the corresponding cuvette number
Sample No.	Number of the sample	Showed automatically
Type	Testing type	Showed automatically
Item	Testing item	Showed automatically
Result	Test result	Showed automatically
Reaction curve	View the real-time absorbance curve of each item in the test	Choose the item and click <b>Reaction Curve</b>

#### ■ Review of reaction tray status

- 1) Click **Cuvette Position**, select the cuvette number and click the **OK** button to return to the reaction tray interface; click **Query** to view the test information of the corresponding cuvette number.
- 2) The state of the reaction cuvette on the reaction tray is marked with 9 different

colors, Namely, Empty, Clean, to be Washed, Dirty, R1, S, R2, END1 and END2, wherein R1, S and R2 respectively indicate that R1, S and R2 are being added, END1 indicates that the test is finished, but no result has been calculated, and END2 indicates that the test is finished and the result has been calculated.

■ Day item

- 1) Click **Cuvette Position**, select the cuvette number and click the **OK** button to return to the reaction tray interface;
- 2) Click **Day Item** to view all status of the current cuvette number on the day;
- 3) Click **Previous** or **Next** to switch between different status information.

■ View reaction curve

- 1) During the periodic test, select one of the cuvettes under test on the reaction tray;
- 2) Click the **Reaction Curve** button to pop up the “Reaction Curve” interface, showing the reaction curve.

### 4.3. Result

Click the button **Review** in the homepage interface to enter the result query interface, as shown in the following figure:

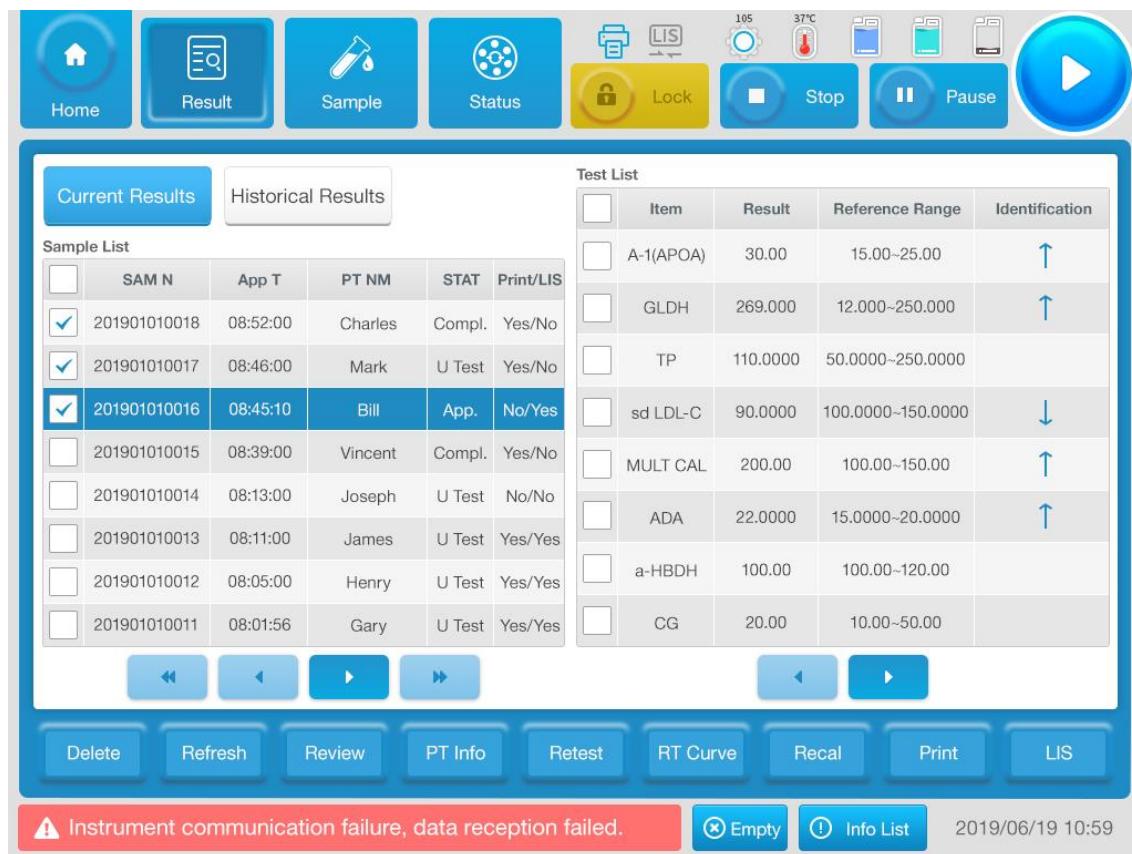


Figure 4-8 Current Results

Including current results and historical results, the basic operations are the same, as follows:

■ Refresh

- 1) Click the button **Refresh** to refresh the current test results.

■ Query

- 1) Select a row in the sample list on the left, and the test list on the right will display the test results of all items corresponding to the sample;
- 2) Click the button **Search**, enter the search criteria in the pop-up dialog box, and click **OK** to display the corresponding results in the sample list.

■ Patient information

- 1) Select a sample in the sample list and click **Patient Information** to open the "Patient Information" interface:

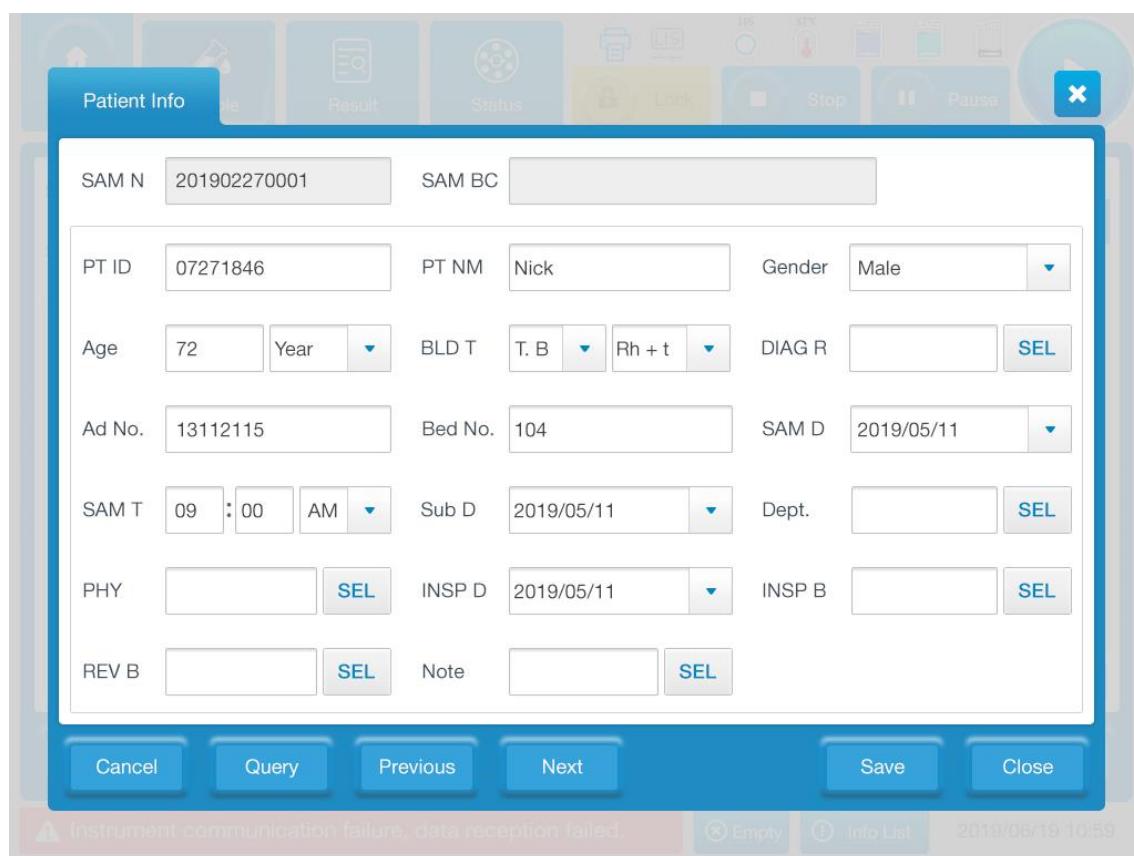


Figure 4-9 Patient Information

- 2) Enter the corresponding patient information and click **Save**.

■ Retest

- 1) After checking the test result, select the items to be retested in the "Test List";
- 2) Click the button **Retest** to set the retest method and retest position (if the retest sample position changed);

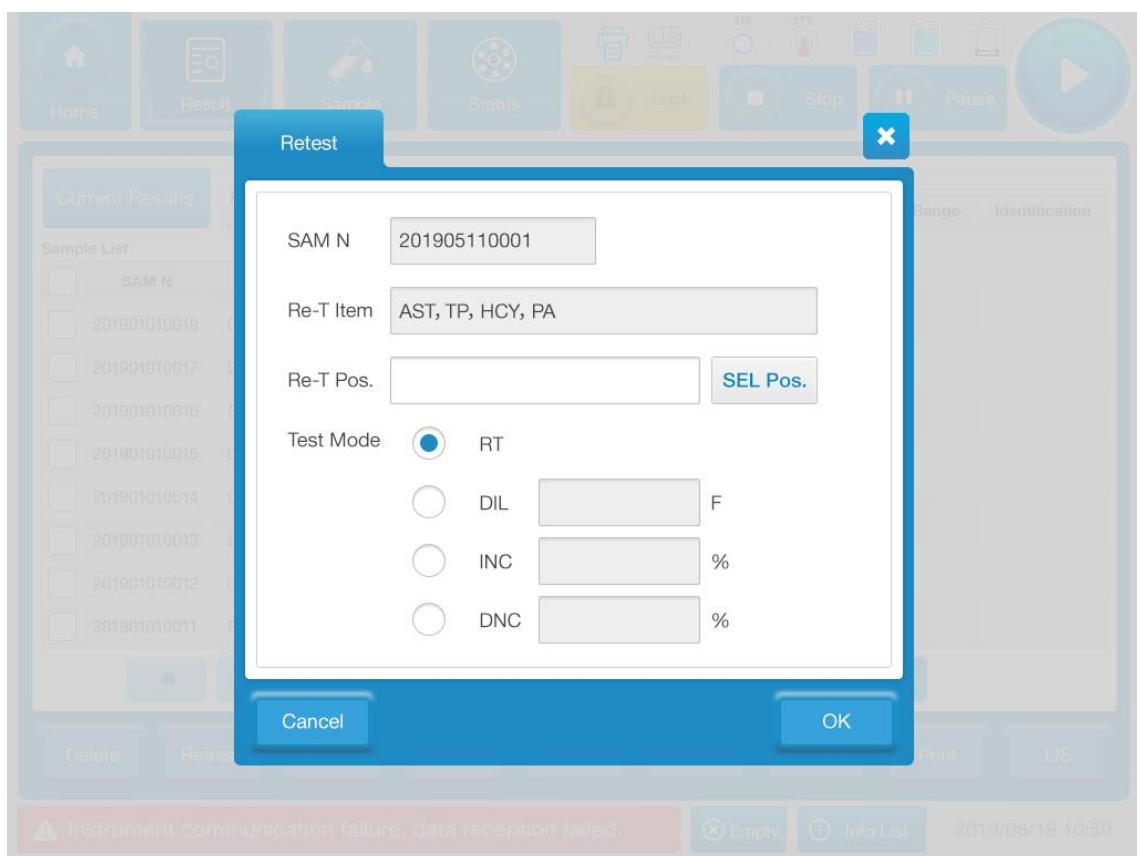


Figure 4-10 Retest

- 3) Click **OK** to start the retest.
- Reaction curve
    - 1) Check the items in the test list and click the button **Reaction Curve** to open the "Reaction Curve" interface;
    - 2) You can also click to view the original AD value and the reaction curve of sample blank.
  - Recalculation
    - 1) After the results are found, check the items to be recalculated;
    - 2) Click **Recalculation** to start recalculation.
  - Delete result
    - 1) After the result is found, check a sample in the "Sample List", click the button **Delete**, and select **Delete Selected Sample** in the pop-up window to delete all tests of the sample;
    - 2) Check the test to be deleted in the "Test List", click the button **Delete**, and click **Delete Selected Item** in the pop-up window to delete the test;
    - 3) If you need to delete all results, directly click **Delete Results** and select **Delete All** in the pop-up window.

■ Print

- 1) After checking the results, select the sample/item to be printed and click **Print** to display the printing interface.
- 2) You can choose to print the currently selected or all the results. You can choose whether to ignore the printed samples or whether to print double rows. You can set the printing order, print preview, etc.
- 3) After the setting is completed, click **OK** to print the results.

■ LIS send

After checking the results, click **LIS** in the "Sample List" column to jump out of the interface, set the content to be transmitted, and select **OK** to start LIS sending.

## 4.4. Reagent

"Reagent" interface can view detailed information of all reagents, and can perform basic functions such as reagent loading, reagent unloading, remaining amount detection, reagent scanning, etc.

Click **Reagent** in the homepage interface to enter the reagent management interface, as shown in the following figure:

The screenshot shows the Reagent Management interface with the following components:

- Top Bar:** Home, Reagent, Calibration, Status, Lock, Stop, Pause, and a large blue circular button.
- Table Headers:** Tray No.1, Tray No.2, Tray No.3, Tray No.4, Tray No.5, Item, and Meas Ite.
- Data Table:** A grid of reagent information across five trays. The first tray has 10 rows of data, while the others have fewer. Columns include Item, Rea T, Position, # of m. R, Cal Stat, C. val. Period, Batch No., Via#, and VD of Rea.
- Bottom Buttons:** Cle Sol., Search, Rea SCNG, Rea Load, Resi D, Rea UNLD, Rea Info, and navigation arrows.
- Status Bar:** A red bar at the bottom left indicates "Instrument communication failure, data reception failed." Other status icons include Empty, Info List, and the date/time 2019/06/19 10:59.

Figure 4-11 Reagent Management

### Basic interpretation of parameters

Parameter	Meaning	Operation
Reagent type	Types of reagents	No operation required
Position	Tray number and cup position of reagent	No operation required
Reagent measurable number	Number of tests that reagent can perform	No operation required
Calibration status	If the reagent calibrated	No operation required
Calibration effective time	Validity period of calibration parameters	No operation required
Batch number	Batch number of the reagent	No operation required

Parameter	Meaning	Operation
Bottle number	Bottle number of the reagent	No operation required
Reagent effective days	Remaining effective days of the reagent	No operation required
Measurable number of items	Number of items that reagents can perform	No operation required

## Basic operation

- Search
  - 1) Click the button **Search** to open the "Search" interface;
  - 2) Select the tray number and item and click **OK** to view the loaded reagent information.
- Reagent loading
  - 1) Click the button **Reagent Loading** to open the "Reagent Loading" interface;
  - 2) Enter the corresponding reagent information and click **Save**.
- Residual detection
  - 1) Click the button **Residual Detection** and select the tray number in the pop-up window.
  - 2) Click **Select Position** at the 'Specified Position' to select a specific cup number for residual detection;
  - 3) Click **Select Item** at "Specified Item" to carry out residual detection on all reagent positions of the specified items;
  - 4) To carry out residual detection for all positions on the reagent tray, select "All".
- Reagent unloading
  - 1) Click on the button **Reagent Unloading**, in the pop-up window drop-down select tray number;
  - 2) Similar to the "Residual Detection" function, reagents can be unloaded according to the specified location, specified items or all.
- Search reagent information
  - 1) Click the button **Reagent Information** to enter the "Reagent Information" interface to view the detailed information of the reagent;

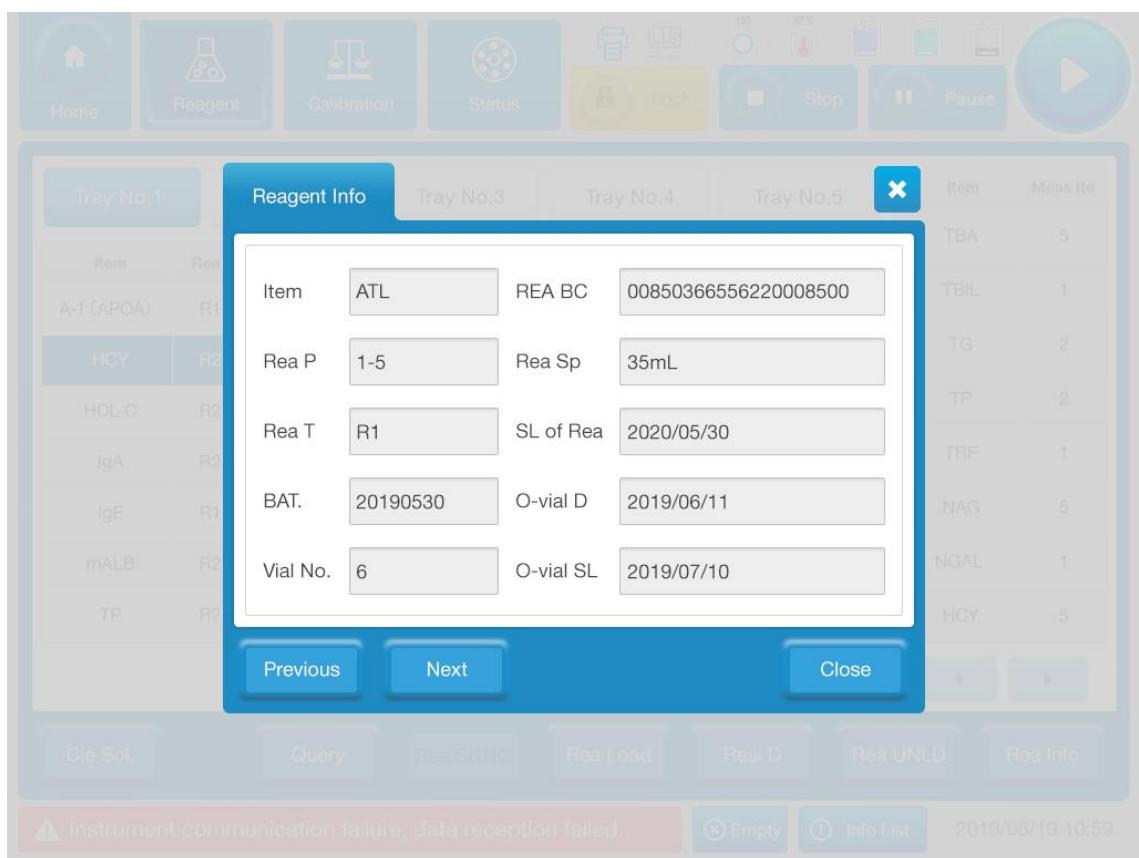


Figure 4-12 Reagent Information

- 2) Click **Previous** or **Next** to switch to display different reagent information.

## 4.5. Setting

Including test settings, system settings, user settings, user management and item settings, which are described separately below.

### 4.5.1. Test setting

The test settings are divided into upper and lower pages, including basic settings, cleaning settings, result marking, automatic retest settings and alarm settings.

As the following figure:



Figure 4-13 Test Settings

#### 4.5.1.1. Basic setting

##### Basic interpretation of parameters

Parameter	Meaning	Operation
Target temperature of reaction tray	Target temperature during reaction	Enter directly in the box, the default is 37 celsius degrees
Wait for the light source to stabilize	Choose whether to wait for the light source to stabilize	Check or uncheck, the default is check

Parameter	Meaning	Operation
Wait for the temperature to stabilize	Choose whether to wait for stable temperature control	Check or uncheck, the default is check
Automatic acquisition of sampling and inspection time	Automatic acquisition time	Check or uncheck, the default is uncheck
Sample validity period	Set the sample valid time	Enter directly in the box
Default sample type	Set the default sample type for the sample application interface	Select directly from the drop-down box
Automatic serum index	The serum index will be automatically tested when the sample type is serum or plasma	Check or uncheck, the default is uncheck
Still calculate the result when exceeding the maximum concentration calibration reactivity	Choose if the result needs to be calculated	Check or uncheck, the default is uncheck
Re-test results	Decide whether the retest result will overwrite the original result or be added to the result list	Click <b>Append or Overwrite</b>

### Basic operation

- 1) Enter the parameters and click **Save**.
- 2) If you need to modify, directly modify and then click **Save**.  
The basic settings, cleaning settings, result marking, automatic retest settings, and alarm settings are the same.

#### 4.5.1.2. Cleaning setting

Parameter	Meaning	Operation
Ordinary cleaning times before testing	Ordinary cleaning times of reagent-sample probe and stirring rod before testing	Enter directly in the box
Number of intensified cleaning before testing	Number of intensified cleaning of reagent-sample probe and stirring rod before testing	Enter directly in the box
Ordinary cleaning times after test	Ordinary cleaning times of reagent-sample probe and stirring rod after testing	Enter directly in the box

Number of intensified cleaning after testing	Intensified cleaning times of reagent- sample probe and stirring rod after testing	Enter directly in the box
--	--	---------------------------

#### 4.5.1.3. Result marking

Parameter	Meaning	Operation
Exceed upper limit of reference range	The test result exceeds the maximum value of the reference range.	Set the color identification of the test results
Exceed the upper limit of critical value	The test result exceeds the maximum value of the critical value range.	Set the color identification of the test results
Below the lower limit of the reference range	The test result is lower than the minimum value of the reference range.	Set the color identification of the test results
Below the lower limit of critical value	The test result is lower than the minimum value of the critical value range	Set the color identification of the test results

#### 4.5.1.4. Automatic retest setting

Parameter	Meaning	Operation
Exceeding upper limit of reference range	The test result exceeds the maximum value of the reference range	Check or uncheck, the default is uncheck
Below the lower limit of the reference range	The test result is lower than the minimum value of the reference range	Check or uncheck, the default is uncheck
Exceeding the upper limit of critical value	The test result exceeds the maximum value of the critical value range	Check or uncheck, the default is uncheck
Below the lower limit of critical value	The test result is lower than the minimum value of the critical value range	Check or uncheck, the default is uncheck
Exceeding upper limit of linearity range	The test result exceeds the maximum value of the linearity range	Check or uncheck, the default is uncheck
Below lower limit of linearity range	The test result is lower than the minimum value of the linearity range	Check or uncheck, the default is uncheck
Test results have no linearity	The test results do not have linearity characteristics	Check or uncheck, the default is uncheck

No calculation interval	If the number of photometric points within the delay time and within the substrate depletion limit is less than 2, no calculation interval mark is given.	Check or uncheck, the default is uncheck
Substrate depletion	The substrate was exhausted during the reaction	Check or uncheck, the default is uncheck
Abnormal prozone	Abnormal prozone inspection	Check or uncheck, the default is uncheck
Exceeding calibration reactivity of maximum concentration	The test results exceed the calibration reactivity of maximum concentration	Check or uncheck, the default is uncheck

#### 4.5.1.5. Alarm setting

Parameter	Meaning	Operation
Bulb alarm limit	The period of the bulb from turn on till alarm	Enter time data directly in the box
Reagent volume alarm limit	The alarm will start if the reagent residual is less than specified volume	Enter directly in the box
Increase the alarm limit of the detergent remnant	Increase the alarm limit of the detergent remnant that triggers the alarm	Enter directly in the box
Alarm in case exceeding the validity period of the reagent	Whether to prompt for alarm when exceeding the validity period of the reagent	Check or uncheck, the default is check
Critical value alarm	Alarm or not if the test results exceed the critical value	Check or uncheck, the default is check
Alarm volume	The volume of the alarm	Enter a volume percentage value in the box
Alarm type	Types of alarm	Import from the folder to conduct alarm choice
Show the marking of edited result	Marking after editing a result	Check or uncheck, the default is check

## 4.5.2. System setting

System setting includes five parts: Instrument Setting, Print Setting, LIS Setting, Barcode Setting and Data Dictionary, which are described below.

### 4.5.2.1. Instrument setting

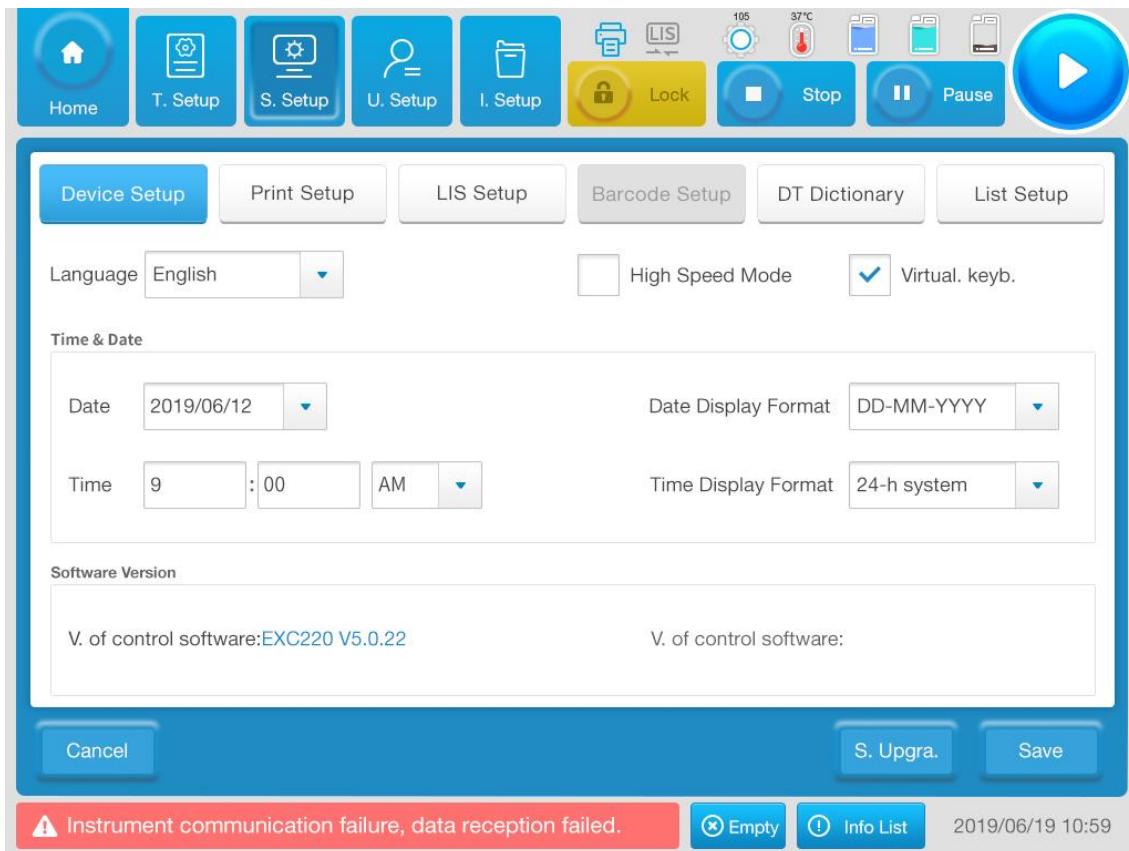


Figure 4-14 Instrument Settings

### Basic interpretation of parameters

Parameter	Meaning	Operation
Language	Software interface display language	Drop-down selection
Speed mode	Testing mode is high speed	Check or uncheck, the default is uncheck
Virtual keyboard	Show virtual keyboard at the bottom of the interface	Check or uncheck, the default is check
Date	The date is displayed in the lower right corner of the instrument interface	Select directly from the drop-down box
Date display format	Select the date to display the sort of year, month and day	Select directly from the drop-down box

Parameter	Meaning	Operation
Time	Set time	Select directly from the drop-down box
Time display format	12 h or 24 h system	Select directly from the drop-down box
Operating software version number	Current operating software version number	No operation required
Control software version number	Current control software version number	No operation required
Software upgrade	Upgrade current software	Click software upgrade to import the new installation package

### Basic operation

- 1) Directly enter the information and click **Save**.
- 2) After modifying the data, you can click **Cancel** to restore.

### 4.5.2.2. Print setting

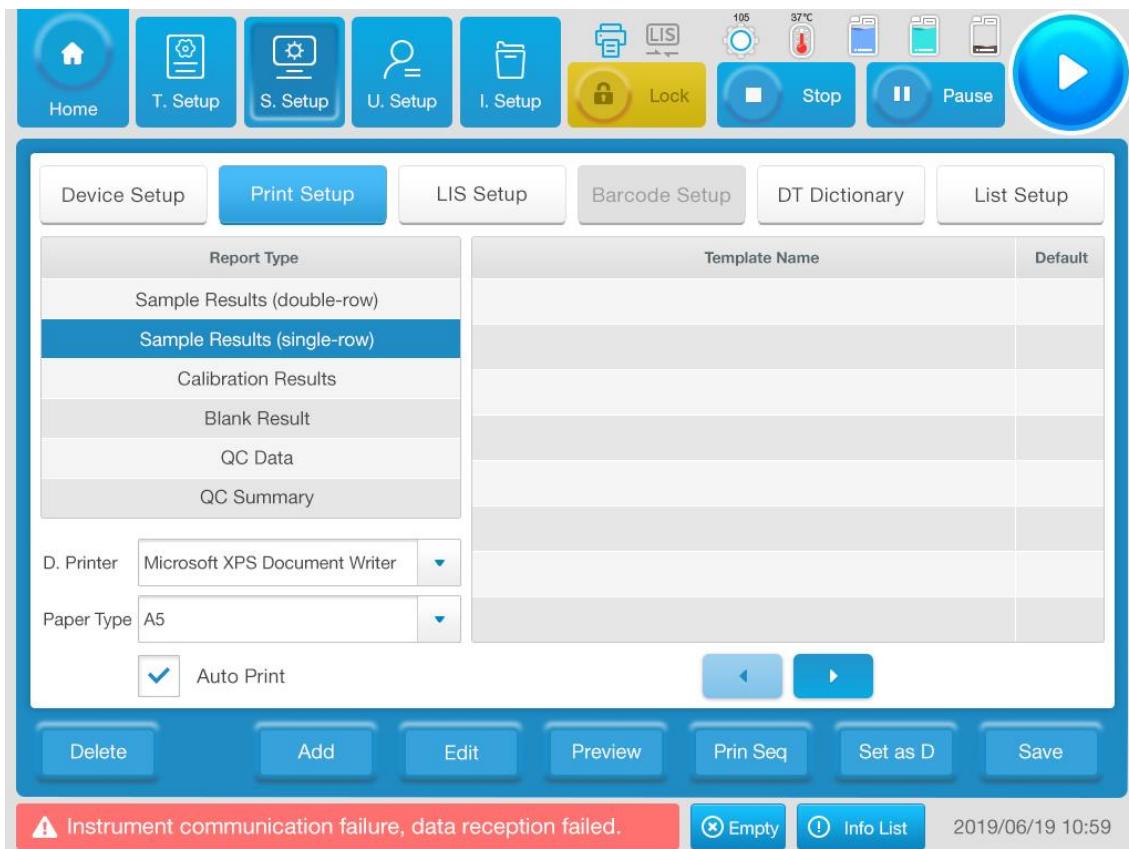


Figure 4-15 Print Settings

### Basic operation

### ■ Print operation

- 1) The system has 6 report types corresponding to 6 default report templates, which cannot be deleted or edited;
- 2) Select the report type to add a template, and click **Add** to add a template that is the same as the default template. This template can be edited. After editing, you can click **Preview** to preview. Click **Save** to save; to delete, click **Delete**;
- 3) You can select the default printer from the drop-down list in the "Default Printer" line; select the printing paper type from the "Paper Type" line; and determine whether automatic printing is required through checking;
- 4) Click **Printing Sequence** to set the item printing order;
- 5) Select any template under "template" and click the button **Set as Default** to set the template as the default template.

### ■ Edit template

Select the new template to edit, and click **Edit** to open the following report designer interface, which can be used for simple report design, including font, content, typesetting, etc.

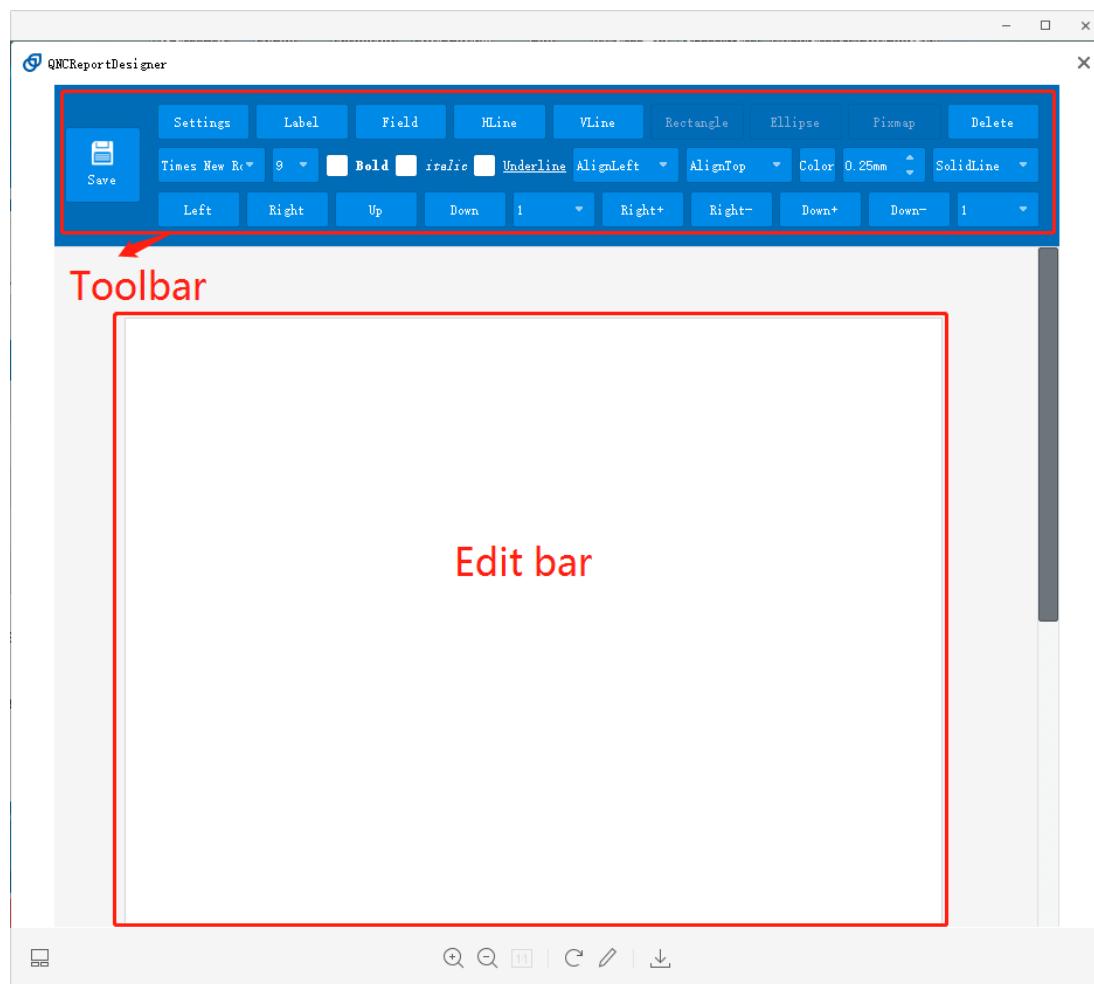


Figure 4-16 Report Designer

The report designer shown above includes toolbar, edit bar and save button.

- 1) "Settings" can be used for simple general settings and page and margin settings. General settings include report name, file code, default font and default font size. Page and margin settings include setting page size, margin and page orientation.
- 2) Click **Label** to add a label text box in the editing column below and enter a text description in the text box. If the text box needs to import relevant data, it needs to be associated with the name of the relevant data. Select it in the drop-down box, and the data will be imported automatically when printing. If you want to get the ID of the patient in a text box, double-click to the text box and select the ID of the associated patient in the associated drop-down box.
- 3) Click **Field** to add a field text box in the editing column below. Double-click the text box to enter the field setting dialog box, where you can set the input text type, field type, value, character format, number and date display.
- 4) Click **Horizontal** or **Vertical** to add horizontal line or vertical line in the editing column below, and you can stretch the length freely.
- 5) As shown in the figure, the left area of the second line is a tool only applicable to text boxes, which can set font, size, bold, italic, underline and alignment.
- 6) As shown in the figure, the right area of the second row is a tool only applicable to line segments, and the type and width of line segments can be set.
- 7) To set the color of the text box and line segments, select the text box, click on the color setting interface to select; select a text box or line segment and click **Delete** to delete. After the operation is completed, click **Save** to save the modified template.

#### ■ Printer setting

Select the new template to be set up for printer, and click **Preview** to open the template preview interface as shown in the following figure. Simple printer settings can be made, including page printing settings such as margins.

## Software System Operation

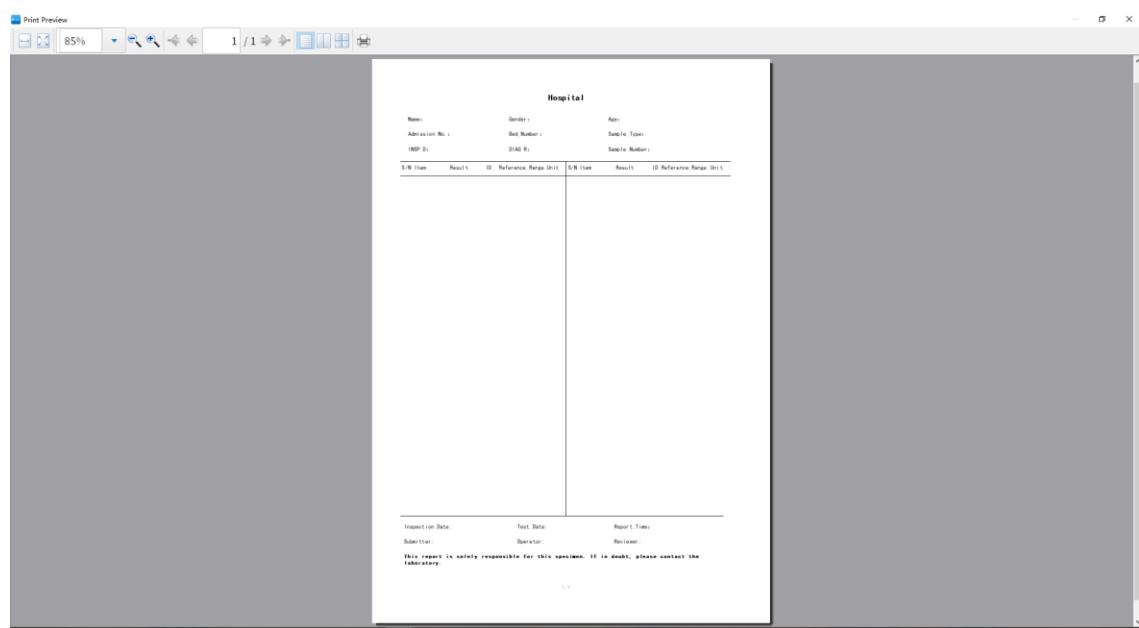


Figure 4-17 Template Preview

### 4.5.2.3. LIS setting

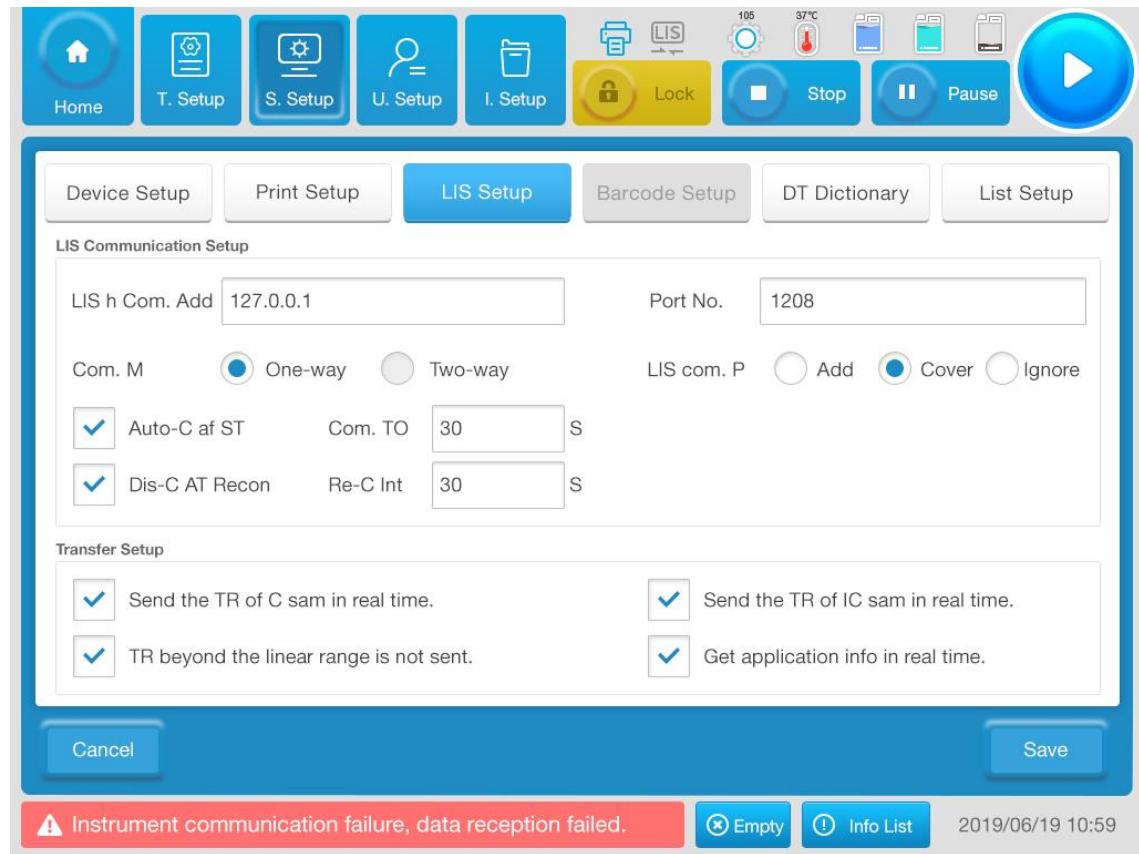


Figure 4-18 LIS Settings

### Basic interpretation of parameters

Parameter	Meaning	Operation
LIS host communication address	Host communication IP address of LIS	Enter directly in the box
Port number	Port number of the communication host (the port number entered is the same as that of the communication host)	Enter directly in the box
Communication method	Select a communication method	Select "one-way" or "two-way"
LIS communication	Choose to manage LIS communication	Select "Append", "Overwrite" or "Ignore"
Automatic connection for startup	Choose whether to automatically connect to communication when startup	Check or uncheck, the default is check
Communication timeout	Set the time to reconnect automatically after timeout	Enter directly in the box
Automatic reconnection after disconnection	Choose to automatically reconnect or not after disconnection	Check or uncheck, the default is check
Reconnection interval	Set the period before connecting automatically	Enter directly in the box
Send test results of completed samples in real time	Select whether to send test results in real time	Check or uncheck, the default is check
Send the test results of incomplete samples in real time	Select whether to send incomplete sample test results in real time	Check or uncheck, the default is check
Not to send test results beyond the linearity range	Select whether to send test results beyond the linearity range	Check or uncheck, the default is check
Obtain application information in real time	Select whether to send sample application information in real time	Check or uncheck, the default is check

### Basic operation

- 1) Enter the parameters and click **Save**.
- 2) If you need to modify, directly modify and then click **Save**.

#### 4.5.2.4. Data dictionary

The results unit, sample comments, clinical diagnosis and patient information can be set.

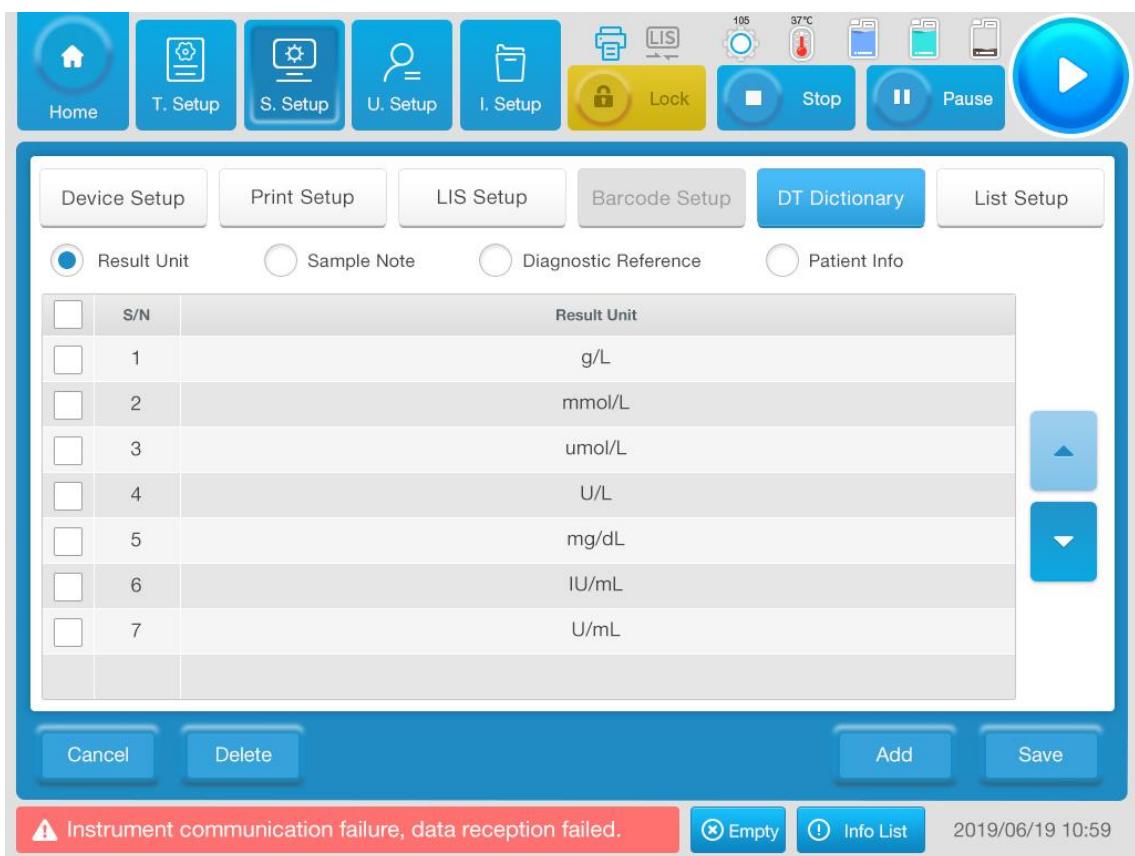


Figure 4-19 Data Dictionary

### Basic operation

- 1) To add a type, select a data dictionary type, click **Add** and enter it in the blank line, and then click **Save**.
- 2) If you need to delete data under a data dictionary type, select the type and click **Delete**.
- 3) If you need to modify a type under a data dictionary type, select the type and modify it directly. Click **Save** after completion.
- 4) If you do not want to save the changes made, click **Cancel**.

#### 4.5.2.5 List setting

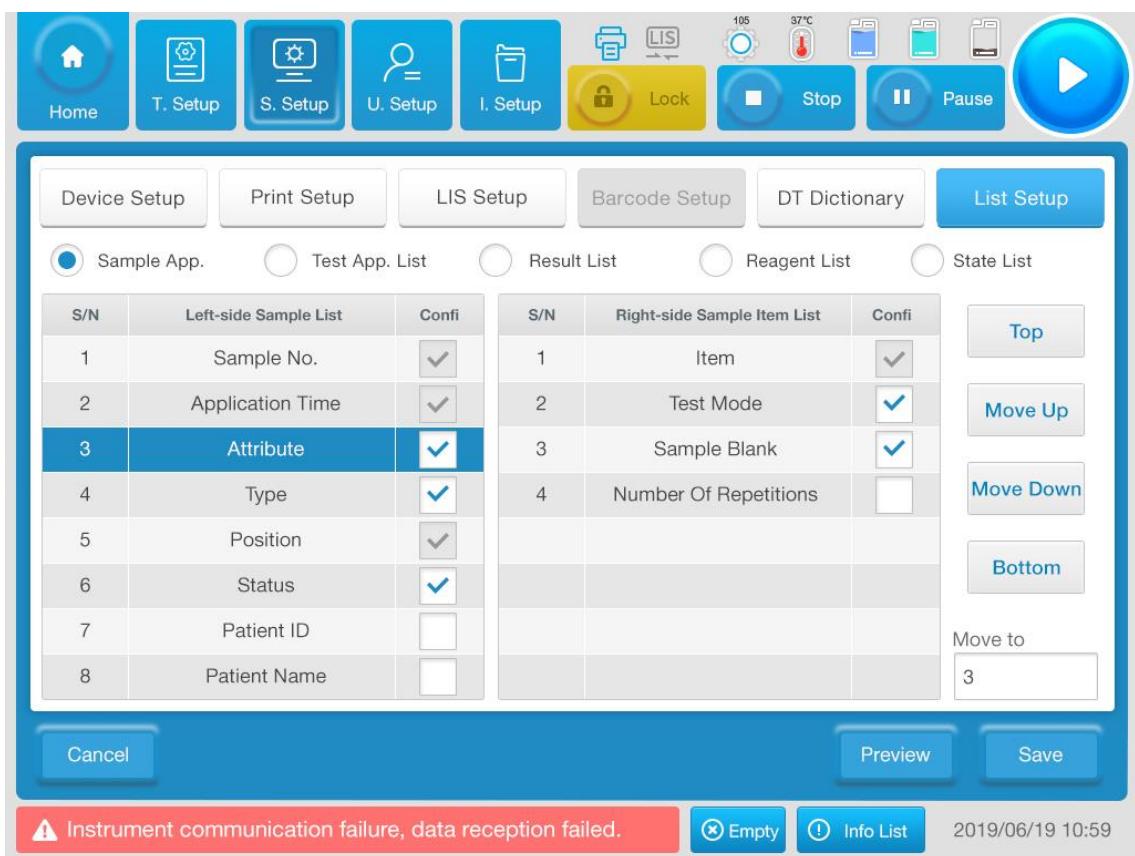


Figure 4-20 List Setting

### Basic operation

- 1) Check or uncheck a configuration to set the display format of the list, and then click the **Preview** button to preview the list format;
- 2) Click **Save** to save the setting, click **Cancel** to cancel the setting.

### 4.5.3. User setting

User setting mainly includes user management, hospital setting, department setting and doctor setting, which will be described separately below.

#### 4.5.3.1. User management

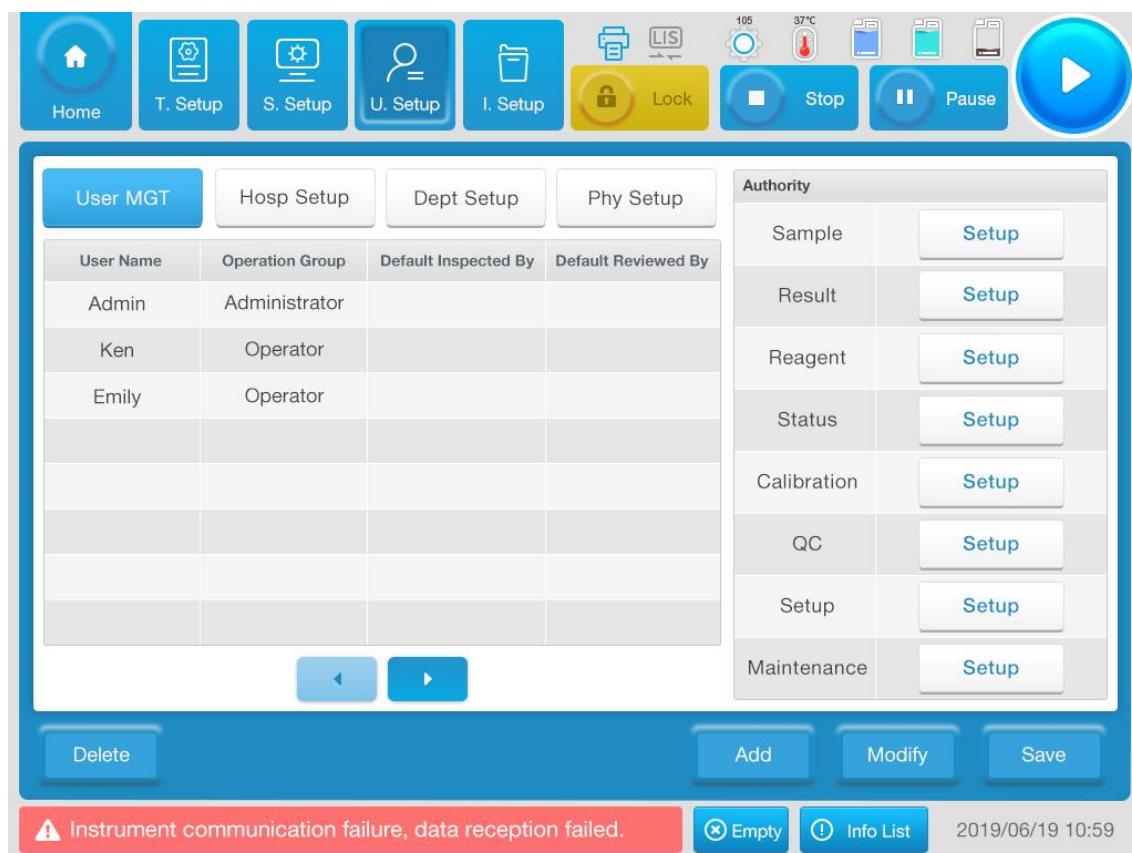


Figure 4-21 User Management

### Basic interpretation of parameters

Parameter	Meaning	Operation
Add	Add user account	Click directly
Modify	Modify user information	Click directly
Authority	The interface contents that the corresponding account can view	Click <b>Setup</b> to enter the "Authority Setting" interface

### Basic operation

- 1) If you need to add users, click **Add** to open the "Add User" interface, and set the contents of the new account. First set the associated doctor, click **Associated Doctor** to select the test physician and reviewer, it can be set as the default. Click **Save** after setting, and click **OK** after all the contents are set;
- 2) To delete a user name, select the line, click **Delete** to open the interface, and click **OK-Save**.
- 3) To modify, select the line to be modified, click **Modify** to open the modify user interface, enter the modified content, and then click **Save**.
- 4) If you need to change authority, click **Setup** to open the "Authority Setting" interface, check or uncheck a permission directly, then click **Save**.

#### 4.5.3.2. Hospital setting

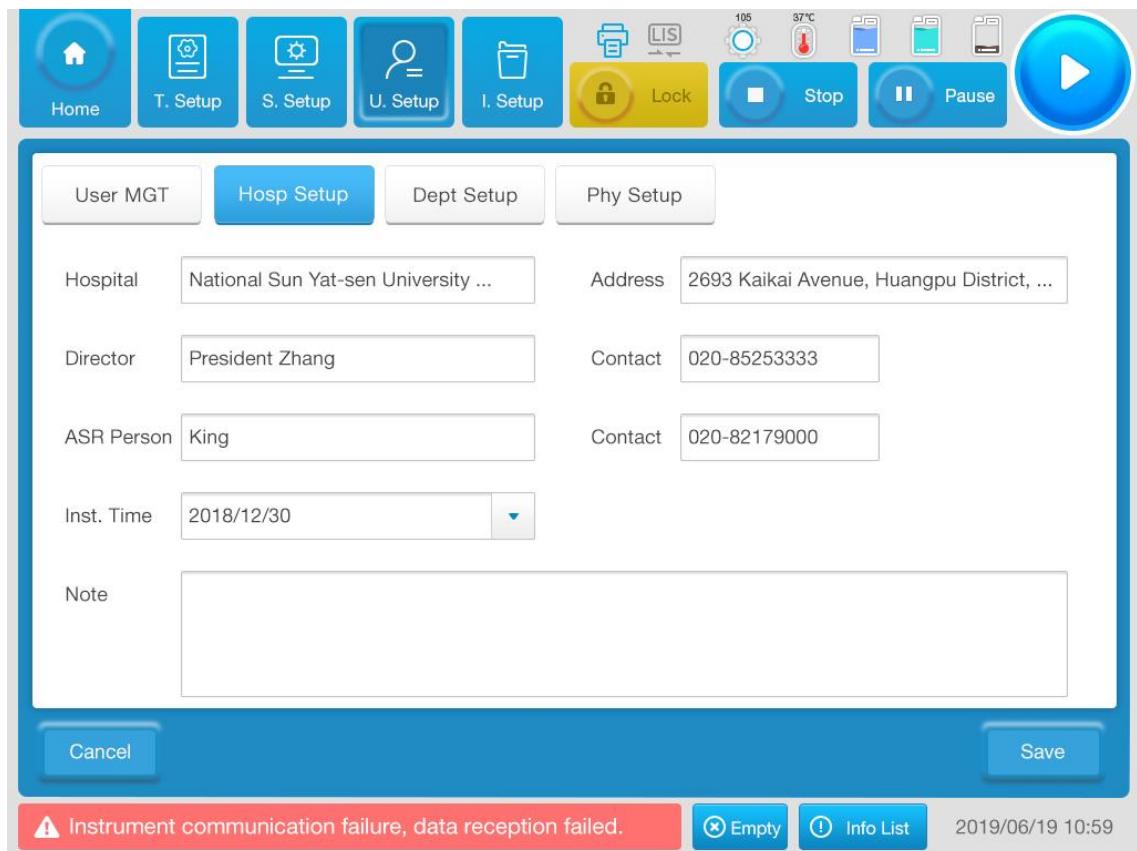


Figure 4-22 Hospital Settings

#### Basic interpretation of parameters

Parameter	Meaning	Operation
Hospital name	Name of hospital	Directly input
Hospital address	Address of the hospital	Directly input
Hospital director	The director of the hospital	Directly input
Contact number	The contact number of the person in charge of the hospital or after-sales service	Directly input
After-sales person in charge	Designated person in charge of after-sales of the product	Directly input
Installation time	Date when this instrument is installed	Select from the drop-down box
Remarks	Remarks	Directly input

#### Basic operation

- 1) Enter the parameters and click **Save**.

### 4.5.3.3. Department setting

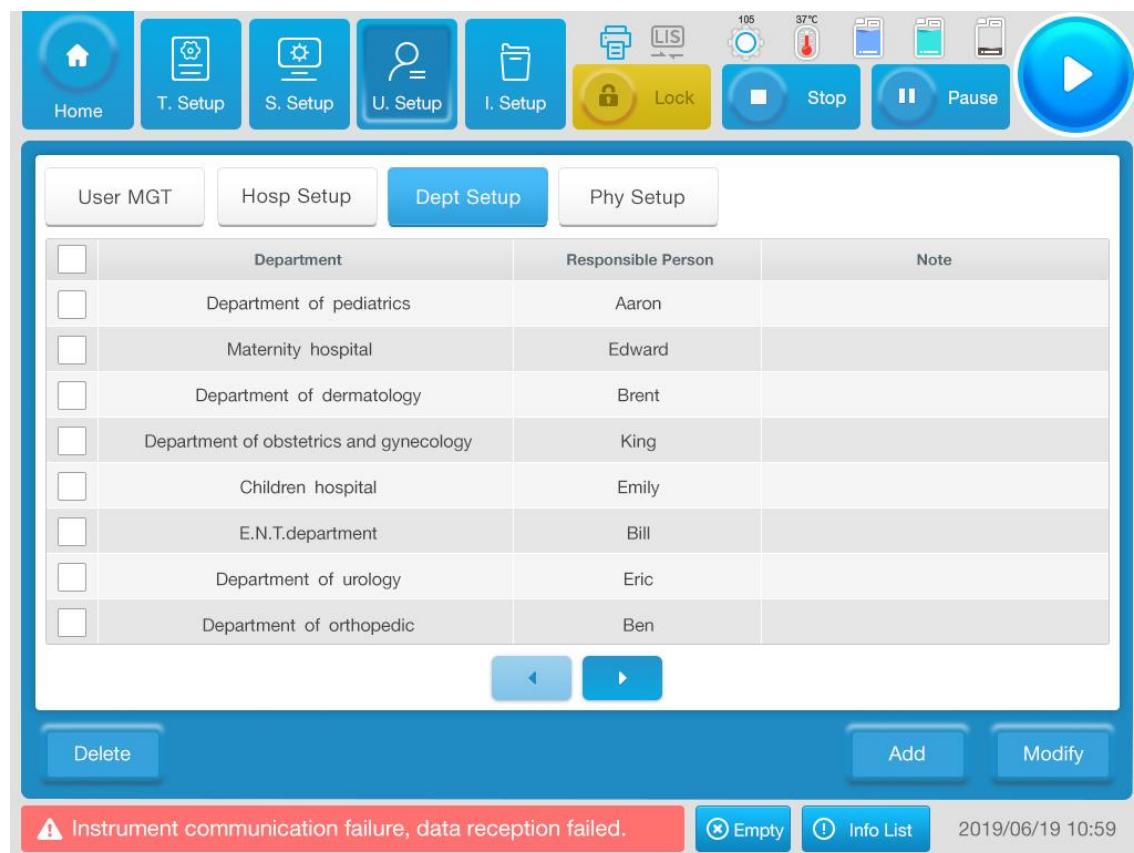


Figure 4-23 Department Settings

#### Basic interpretation of parameters

Parameter	Meaning	Operation
Department	Displays the name of the department	No operation required
Person in charge	The person who in charges of the department	No operation required
Remarks	Show comments	No operation required
Add	Add department information	Directly click
Modify	Modify department information	Directly click
Delete	Delete department information	Directly click

#### Basic operation

- 1) Add: click **Add** to enter the parameter content in the pop-up window.
- 2) Modify: check the content to be modified, click **Modify** and enter the parameter content in the pop-up window.
- 3) Delete: check the content to be deleted and click **Delete**.

#### 4.5.3.4. Doctor setting

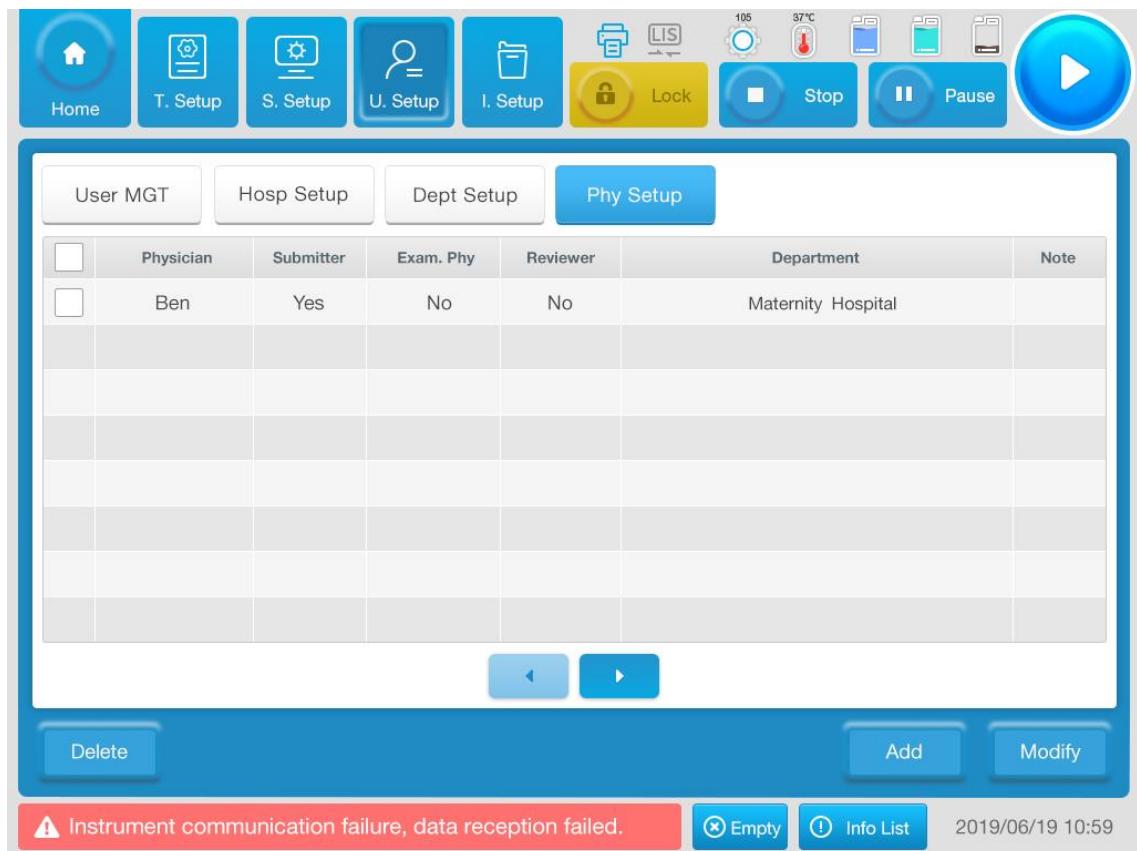


Figure 4-24 Doctor Settings

#### Basic interpretation of parameters

Parameter	Meaning	Operation
Doctor	Doctor's name	No operation required
Operator	Operator or not	No operation required
Doctor	Doctor or not	No operation required
Approval	Approval	No operation required
Department	The department to which the doctor belongs	No operation required
Remarks	Remarks	No operation required
Add	Add doctor information	Directly click
Modify	Modify doctor information	Directly click
Delete	Delete doctor information	Directly click

#### Basic operation

- 1) Add: click **Add** to enter the parameter content in the pop-up window.

- 2) Modify: check the content to be modified, click **Modify** and enter the parameter content in the pop-up window.
- 3) Delete: check the content to be deleted and click **Delete**.

#### 4.5.4. Item setting

It mainly includes routine items, serum index, calculation items, combination items, manual items and cross contamination, which will be described separately below.

##### 4.5.4.1. Regular items



Figure 4-25 Regular Items

##### Basic operation

- Add new item
  - 1) Click **Add** to open the "Add Regular Item" interface;
  - 2) Enter the item parameters and click **Save**.

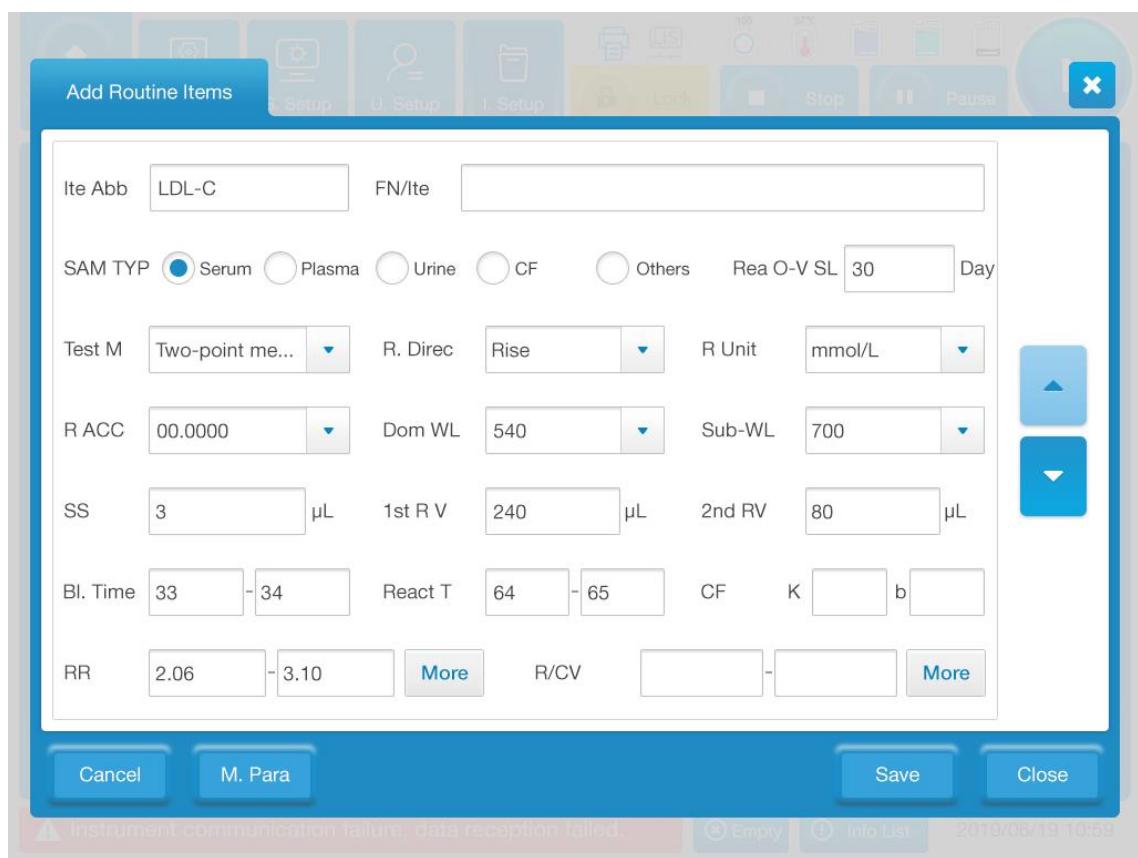


Figure 4-26 Add Regular Items

### Basic interpretation of parameters

Parameter	Meaning	Operation
Abbreviation	Short name of the item	Directly input
Number	Item number	Directly input
Full name	Full name of the item	Directly input
Sample type	Select the type of the sample	Click the radio box to select
Validity period of reagent bottle opening	The validity period after the reagent is opened	Directly input
Item method	Set test methods for items include endpoint method, two-point method and kinetic method	Select from the drop-down box
Reaction direction	Test reaction direction	Select from the drop-down box
Result unit	Unit of results	Select from the drop-down box

Parameter	Meaning	Operation
Result precision	Number of decimal places reserved for results	Select from the drop-down box
Primary wavelength	Primary wavelength to be measured	Select from the drop-down box
Sub-wavelength	Sub-wavelength to be measured	Select from the drop-down box
Sample volume	The amount of sample added to the test, in microliters	Directly input, range is 2~50 ul
R1 vol.	R1 volume added in the test	Directly input, range is 90~350 ul
R2 vol.	R2 volume added in the test	Directly input, range is 10~250 ul
Blank time	The time before a test initiates a reaction. Single reagent item refers to the time between adding reagent and adding sample, while dual reagent item refers to the time between adding sample and adding R2	Directly input
Reaction time	The period of time used to calculate the starting and ending photometric points	Directly input
Correction factor	Correct the result according to $y=kx+b$ , where x is the measured result, y is the corrected result, k is the slope in the correction formula, and b is the intercept in the correction formula	Enter a specific number in the box, k defaults to 1 and b defaults to 0
Reference range	Reference range of sample concentration for test results	According to the reference range provided by the kit instructions or professional reference books, enter the specific value in the box
Critical value range	Critical value range of test result	Directly input
More	Set the upper and lower limits of the sample concentration reference range or critical value range for more conditions, including gender, sample type, age, etc.	Click to enter the interface of "setting reference range/critical value range"

Parameter	Meaning	Operation
Monitoring parameters	Set monitoring parameters for various conditions, including detection linearity limit, substrate depletion limit, linearity range, reaction degree range, absorbance of working solution, R1 blank absorbance, prozone inspection parameters, etc.	Directly input
Cancel	Do not save the input information	Directly click
Close	Close the interface	Directly click
Save	Save the current parameters	Directly click

- Modify item
  - 1) Select the item to be modified in the item list, and click **Modify** to enter the "Modify Regular Item" interface;
  - 2) Enter the modified parameters and click **Save**.
- Delete item
  - 1) Select the item to be deleted in the item list, and click the button **Delete**.
- Item sequence
  - 1) Click **Sequence** to open the "Item Sequence" interface, and select the item/test of which the sequence needs to be changed;
  - 2) Click **Top** to put the chosen item/test to the first place, and click **Bottom** to put the chosen item/test to the last place.
  - 3) Click **Move up** to move up one position of the chosen item/test, and click **Move Down** to move down one position of the chosen item/test.
  - 4) If you need to move to a specified position, directly enter the specified number in the box on the right of **Move to** and press enter.
  - 5) To save the settings, click the button **Save**. Click **Close** to return to the main interface of the regular item, otherwise click the **Cancel** button
- Import
  - 1) Click the button **Import** to open the import item dialog box;
  - 2) Select the excel file in the local folder to import the item parameters into the item list.
- Export
  - 1) Select the item to export from the item list;
  - 2) Click the button **Export** to open the export item dialog box;

- 3) Select the file path to export the item parameters in the item list to the local folder.

#### 4.5.4.2. Serum index

Serum index refers to the degree of hemolysis, jaundice and lipemia in serum samples.

“Serum index” interface is as follows:

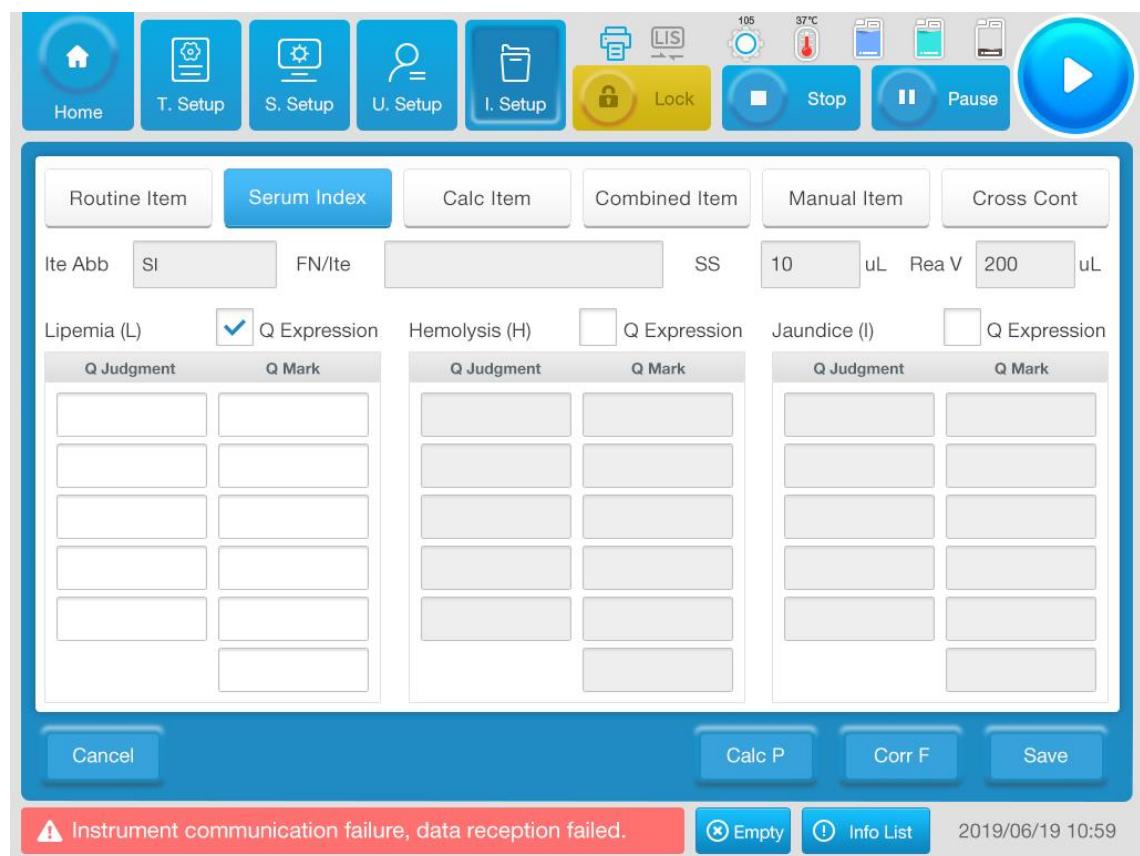


Figure 4-27 Serum Index

#### Basic interpretation of parameters

Parameter	Meaning	Operation
Item abbreviation	Abbreviations for the items	No operation required
Full name	The full name of the items	No operation required
Sample volume	The sample is serum, and the sample volume is fixed at 10μl	No operation required
Reagent volume	The reagent is normal saline and the test volume is fixed at 200 μl	No operation required

Parameter	Meaning	Operation
Qualitative representation	Whether the test results are expressed according to qualitative marks	Check or uncheck
Qualitative judgment	The qualitative marker is determined by comparing the test value of hemolysis, jaundice or lipemia with the threshold value of qualitative judgment	Enter manually. The qualitative judgment threshold is 5 positive integers or decimals that increase in sequence from top to bottom. Any symbol can be entered in the 6 input boxes of the qualitative mark. Taking lipemia (l) as an example, qualitative judgment inputs L1 to L5 required to be $0 < L1 < L2 < L3 < L4 < L5$ . when the result l satisfies $L < l1$ , the corresponding qualitative marker 1; in case of $L1 < L < L2$ , it corresponds to qualitative marker 2, and so on
Qualitative marker	The test results will be displayed as this mark	
Calculation parameters	Six parameters, A, B, C, D, E and F, are set to calculate the serum index results	Enter manually. Among them, B, E and F are not adjustable, being 1.42, 1.31 and 4.55 respectively. A, C and D are adjustable with default values of 2.20, 1.45 and 250 respectively
Correction factor	Set the slope and intercept of the correction	Enter manually

### Basic operation

- 1) To qualitatively express the serum index test results, tick the corresponding selection box.
- 2) Input five ascending positive integer or decimal numbers from top to bottom in that five input boxes for qualitative judgment, and customizing input symbol in the qualitative mark input box;
- 3) If you want to change the calculation parameters, click **Calculation Parameters** and enter the values of A, C and D in the pop-up window.
- 4) If you want to change the correction factor, click **Correction Factor** button and enter the slope and intercept values in the pop-up window.
- 5) After completing the parameter setting, click **Save**.

#### 4.5.4.3. Calculation items

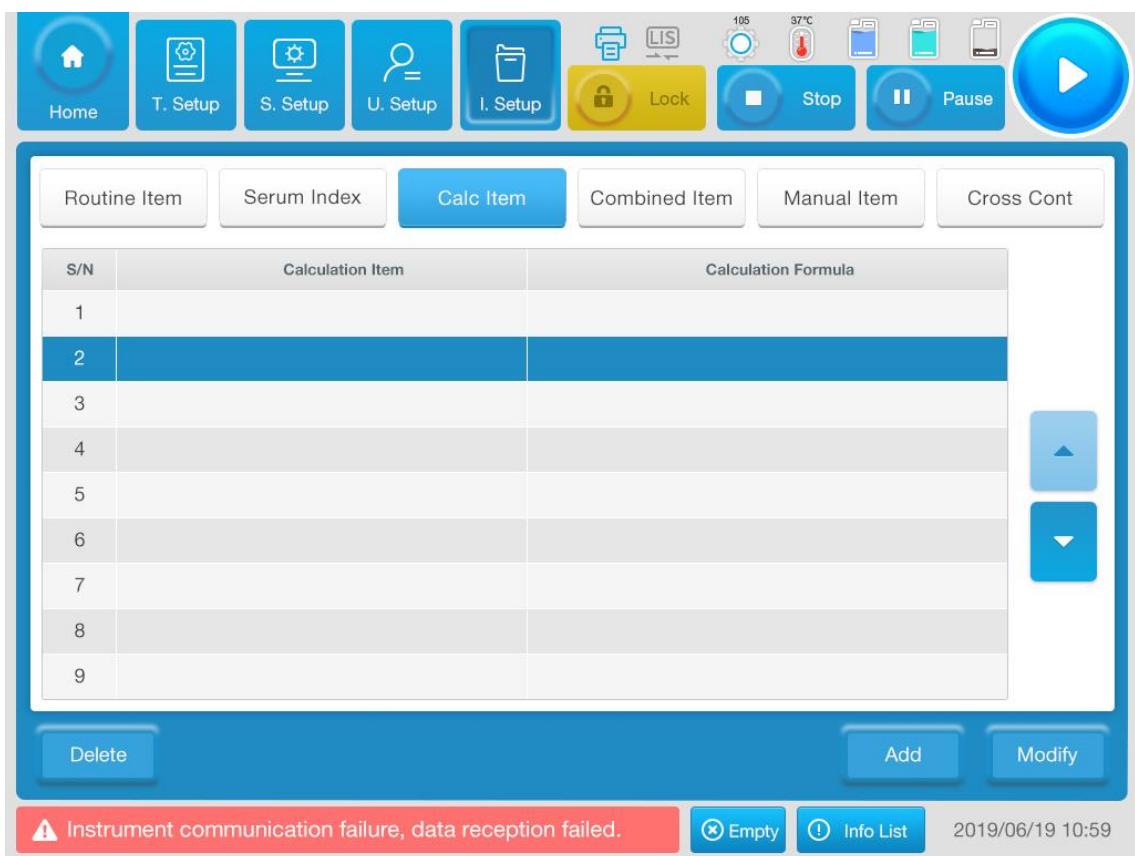


Figure 4-28 Calculation Items

### Basic interpretation of parameters

Parameter	Meaning	Operation
Serial number	Sequence of the calculation items	No operation required
Calculation item	Abbreviations of calculation items	No operation required
Computational formula	Formulas for calculation items	No operation required
Add	Add new calculation items	Click directly
Modify	Modify calculation items	Click directly
Delete	Delete calculation items	Select the item first, and then click <b>Delete</b>

### Basic operation

- Add calculation items
  - 1) Click **Add**;
  - 2) Enter or select the corresponding content in each box;
  - 3) After clicking an item in the "Item List", click the numeric value and the calculation

symbol in the calculation button selection area to form an expression of the calculation item. The input expression can be seen in the "calculation formula" area.

- 4) To save added calculation items, click **Save**, otherwise click **Cancel**.

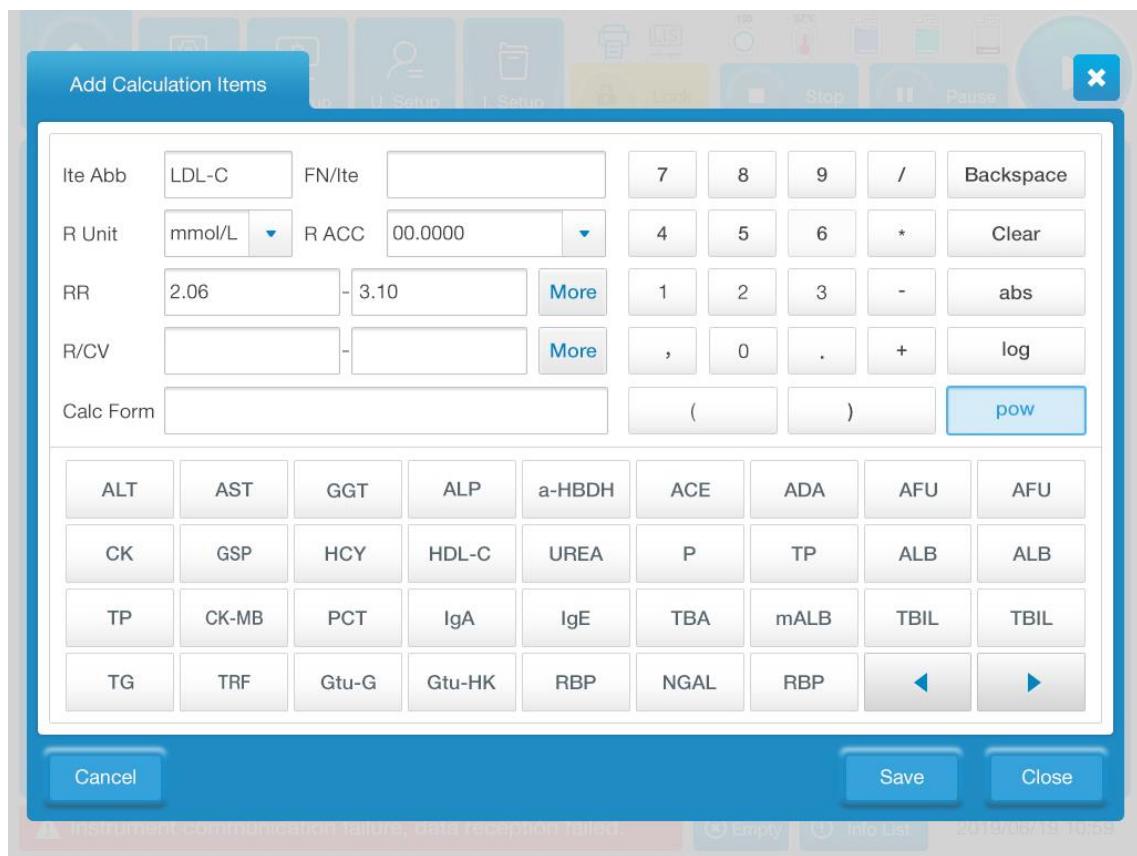


Figure4-29 Add Calculation Item

### Basic interpretation of parameters

Parameter	Meaning	Operation
Item abbreviation	Abbreviations of calculation items	Enter directly
Full name	Full name of the calculation items	Enter directly
Result unit	Unit of results	Select from the drop-down box
Result precision	Number of decimal places reserved for results	Select from the drop-down box, there are five types: 0,0.0,0.00,0.000,0.0000
Reference range	Reference range of test results	Enter directly

Parameter	Meaning	Operation
Critical value range	Critical value range of test result	Enter directly
More	Set the upper and lower limits of the sample concentration reference range or critical value range for more conditions, including gender, sample type, age, etc.	Click to enter the interface of "Setting Reference Range/Critical Value Range"
Calculation formula	Displays the expression for the calculated item	No operation required

■ Modify calculation items

- 1) In the calculation item list display area, select the calculation item to be modified and click **Modify**.
- 2) Enter or select the corresponding content in each box;
- 3) To change the calculation formula, click **Clear** in the calculation area to delete the formula and re-enter the expression;
- 4) To save the modified content, click **Save**, otherwise click **Cancel**.

■ Delete calculation assay

- 1) Select item;
- 2) Click **Delete** and then click **OK** in the pop-up window, otherwise click **Cancel**.

#### 4.5.4.4. Combination item

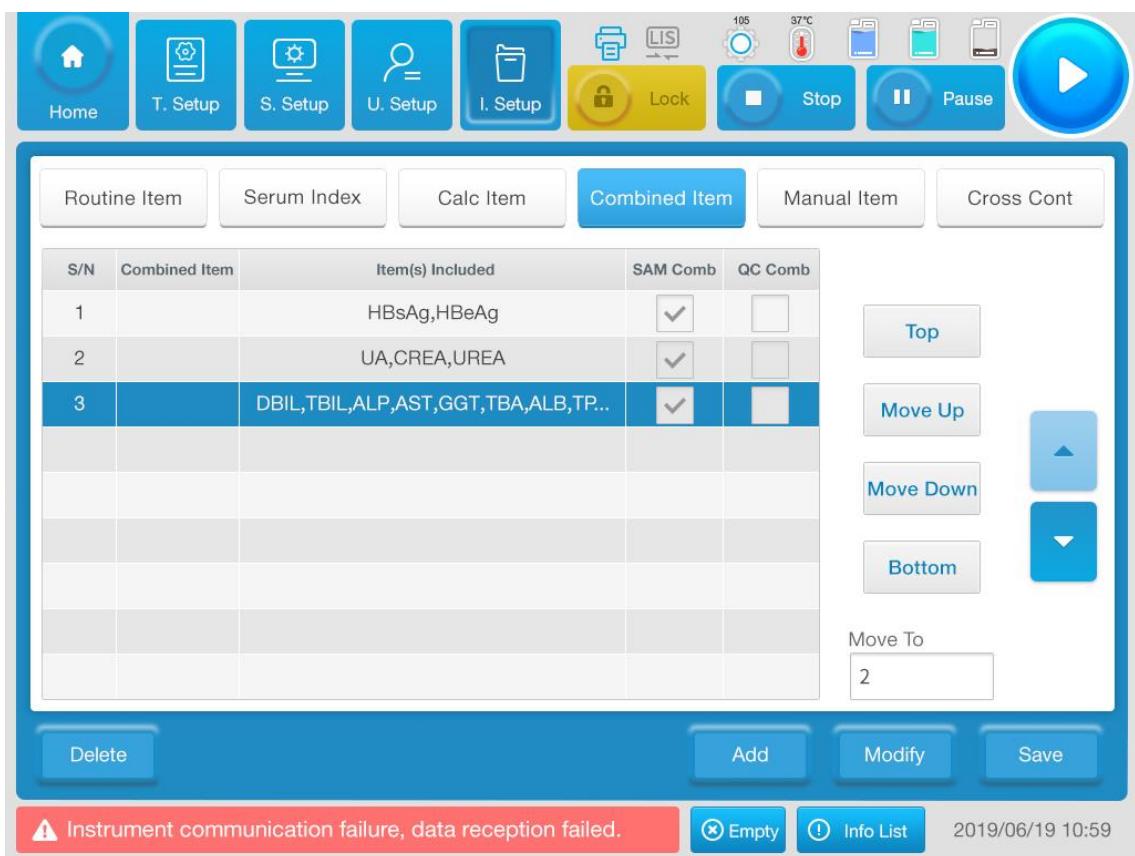


Figure 4-30 Combination Item

### Basic interpretation of parameters

Parameter	Meaning	Operation
Combination item	Abbreviations for combination items	No operation required
Contains regular item	Regular items included in this combination items	No operation required
Sample combination	If the combination items displayed in the sample application list	No operation required
Quality control combination	If this combination items displayed in the QC application list	No operation required
Top	The selected calculation items will be displayed at the top	Select the item first, and then click <b>Top</b>
Move up	Move the selected calculation items up one position to display	Select the item first, and then click <b>Move Up</b>

Parameter	Meaning	Operation
Move down	Move the selected calculation items down one position to display	Select the item first, and then click <b>Move Down</b>
Bottom	Place the selected calculation items in the last position for display	Select the item first, and then click <b>Bottom</b>
Move to	Move the selected calculation items directly to the specified location for display	Select the item first, enter the specified serial number in the box, and then press <b>Enter</b>

### Basic operation

#### ■ Add combination item

- 1) Click **Add**, the “Add combination item” interface will pop up:

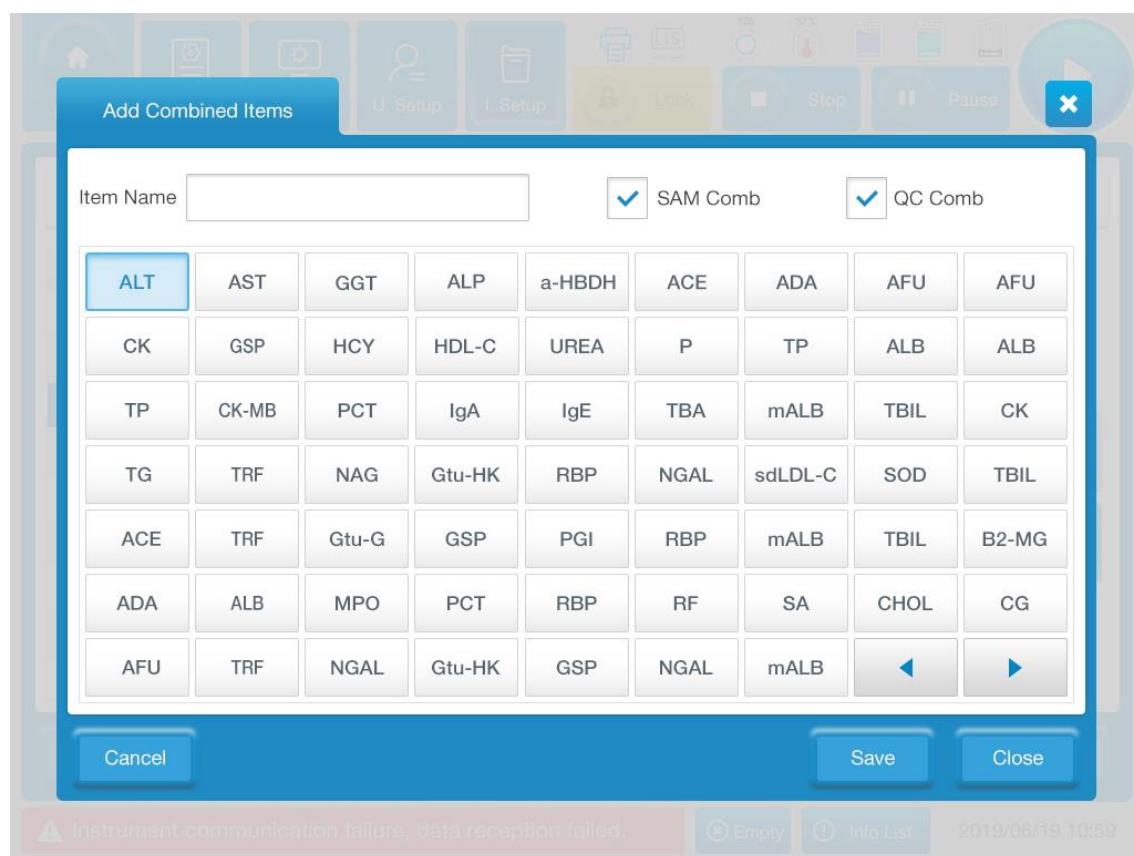


Figure 4-31 Add Combination Item

- 2) Enter the short name and full name of the item;
- 3) Click on the corresponding item in the regular item list, clicking once indicates selection, and click again to cancel;

4) To display the combination item in the sample application list, check the selection box to the left of **Sample Combination**;

5) To display the combination item in the quality control application list, check the selection box to the left of **Quality Control Combination**;

6) To save the added combination item, click **Save**.

■ Modify combination item

1) Select the combination item;

2) Click **Modify**;

3) Enter the modified content to delete or add items in the "Item List";

4) To save the modified content, click **Save**.

■ Delete combination item

1) Select the combination items;

2) Click **Delete**.

#### 4.5.4.5. Manual items

Manual items are items where users manually input item parameters and test results. They do not participate in the test but only save, display and print the test results.

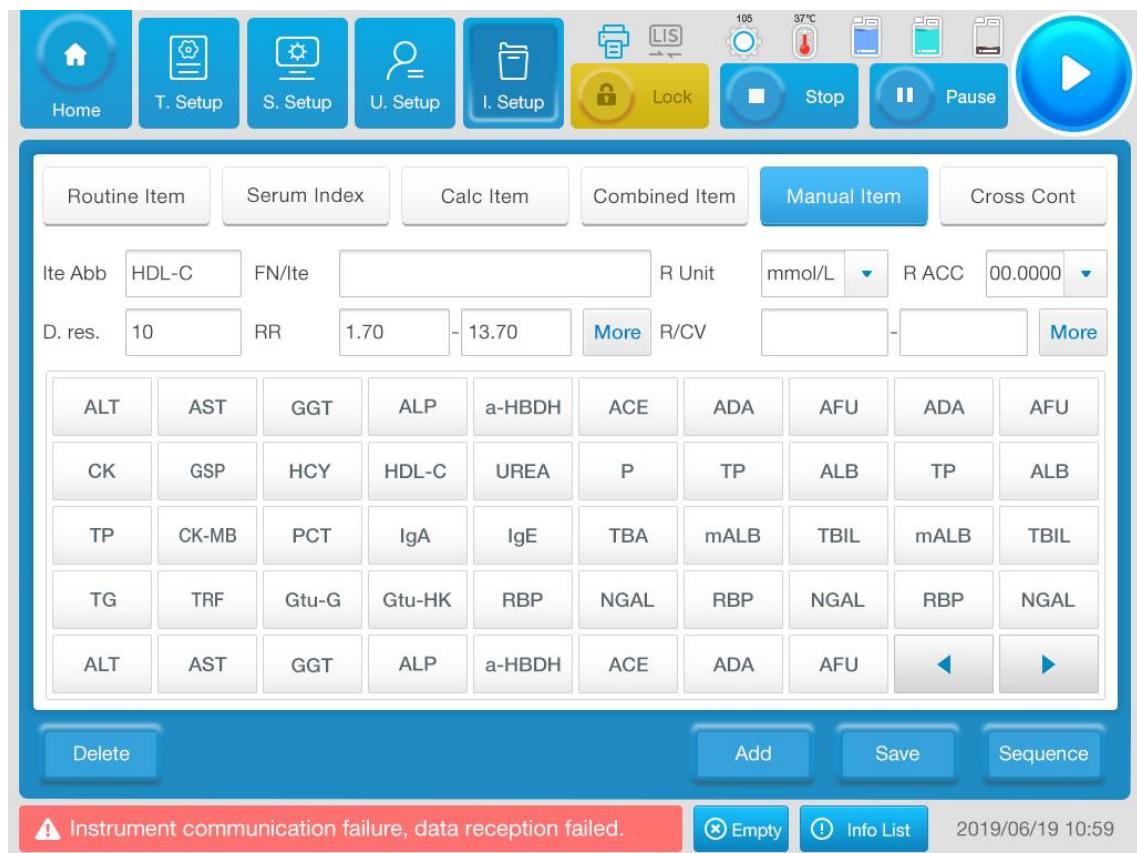


Figure 4-32 Manual Items

### Basic operation

- Add manual item
  - 1) Click **Add**;
  - 2) Enter or drop down in the box to select the input content, add the entered parameter items to the manual item display area below;
  - 3) Click **Save**.
- Modify manual item
  - 1) Select the items to be deleted;
  - 2) Modify or pull down the content directly in the box;
  - 3) Click **Save**.
- Delete manual item
  - 1) Select the items to be deleted;
  - 2) Click **Delete**;
  - 3) Click **Save**.
- Manual item sequence
  - 1) Click **Sequence**;
  - 2) Sort the items;
  - 3) Click **Save** to return to the manual item main interface.

#### 4.5.4.6. Cross-contamination

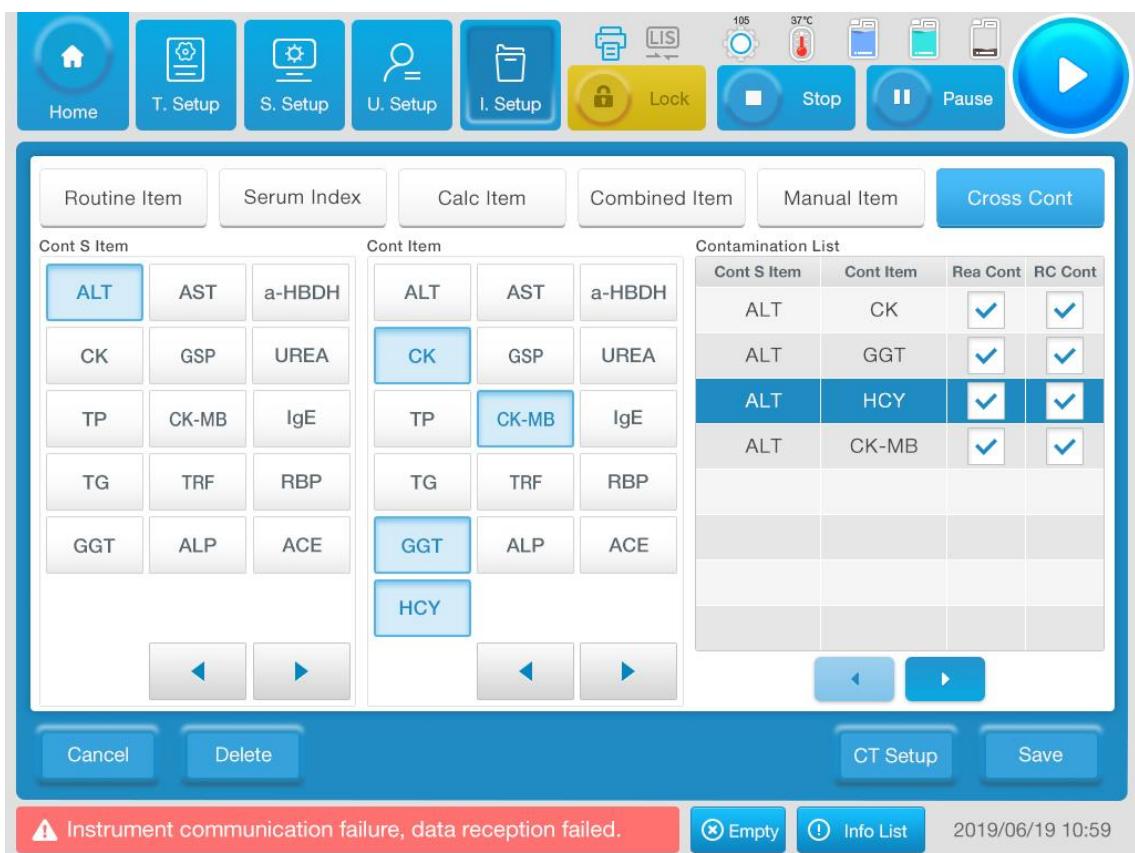


Figure 4-33 Cross-Contamination

### Basic operation

- 1) Select a contamination source item in "Contamination Source Item";
- 2) Select the contaminated item in "Contaminated Item" and you can select multiple items. For the item, click once is selected and click again is deselected;
- 3) Check **Reagent Contamination** or **Reaction Cuvette Contamination** under "Contamination List" on the right;
- 4) Click **Save**, otherwise, click **Cancel**;
- 5) Click the **Cleaning Times Settings** and select the number of times of intensive cleaning and normal cleaning from the pop-up window, and click **Save**.
- 6) To delete the set cross-contamination items, select them in the "Contamination List" and click **Delete**.



Attention

Please set up the cross-contamination among the analysis items according to the reagent composition provided by the reagent manufacturer, otherwise the analysis results of the items may be affected by cross-contamination.

## 4.6. Maintenance

### 4.6.1. Daily maintenance

This function includes periodic maintenance, fault handling, data backup, temperature curve, consumables maintenance, and unit status. Daily maintenance is the default maintenance interface. Click the button **Maintenance** in the main menu to display the following page:

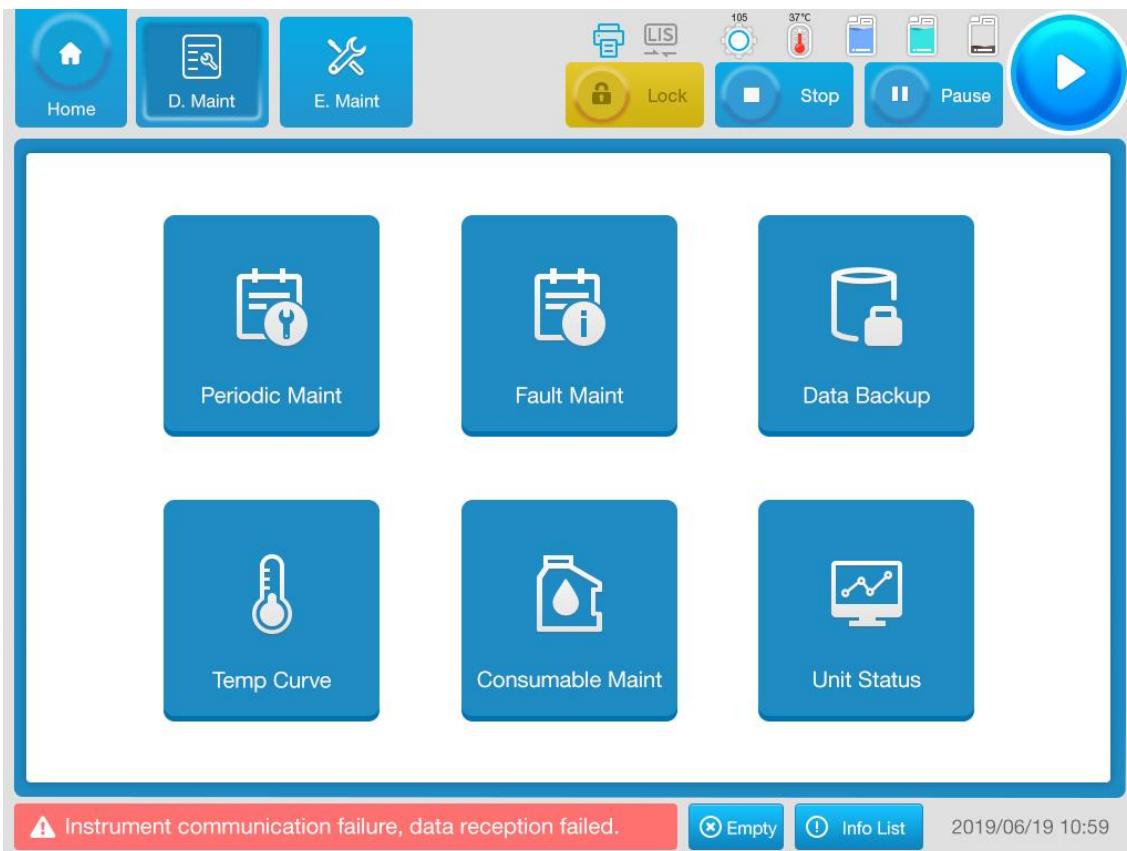


Figure 4-34 Maintenance Interface

#### 4.6.1.1. Periodic maintenance

**Periodic maintenance** divides the items requiring maintenance by users into daily, weekly, monthly and other (irregular) items according to the maintenance cycle, and also carries out maintenance according to instructions.

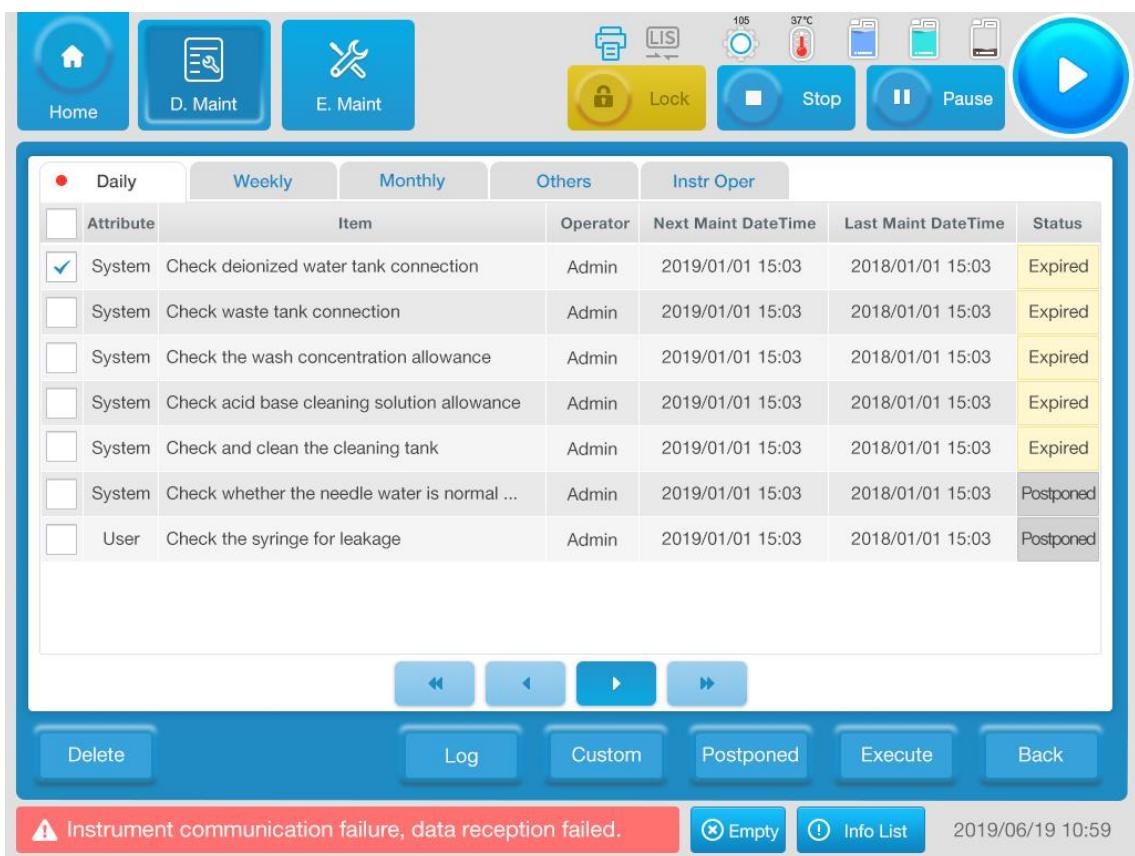


Figure 4-35 Periodic Maintenance

The periodic maintenance list is divided into the following maintenance periodic units:

- Daily-1 day
- Weekly-7 days
- Monthly-30 days
- Other-irregular
- Order operation

#### 4.6.1.2. Fault handling

When the instrument fails during operation, the failure code, failure source, failure unit, failure level, failure time, detailed failure description, failure reason and failure handling method can be viewed on the failure handling page. Users can simply handle the instrument failure according to the failure description, which is convenient for users to solve the failure occurred during operation, and at the same time, failure recovery function is available.

Click on the fault handling interface as shown in the following figure:

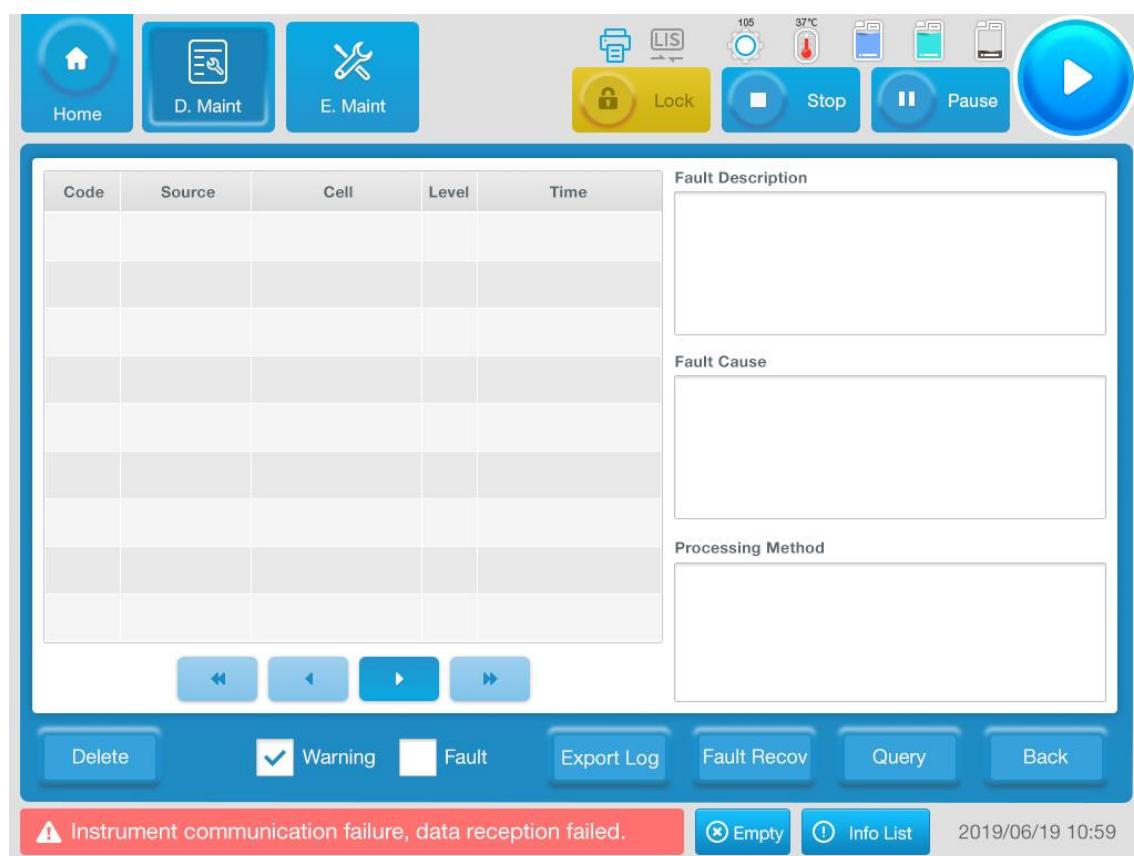


Figure 4-36 Fault Handling

### Basic interpretation of parameters

Parameter	Meaning	Operation
Code	Failure code	/
Source	Failure source component	/
Unit	Failure source unit	/
Level	Failure level	/
Time	Time of failure occurs	/
Failure description	Description of fault phenomenon	/
Cause of failure	Preliminary analysis of failure causes	/
Handling	Suggestions on fault handling	/
Failure recovery	Restore the machine from a fault state to a normal state	/
Query	Query failure	Click to open the query interface
Warning	Level 0 failure	Mark ✓ for selection

Parameter	Meaning	Operation
Failure	Non-level 0 failure	Mark √ for selection
Export log	Export fault records	Click directly
Delete	Delete the selected fault information	After selecting the information to be deleted, click <b>Delete</b>
Back	Close the log query window	Click directly

#### 4.6.1.3. Data backup

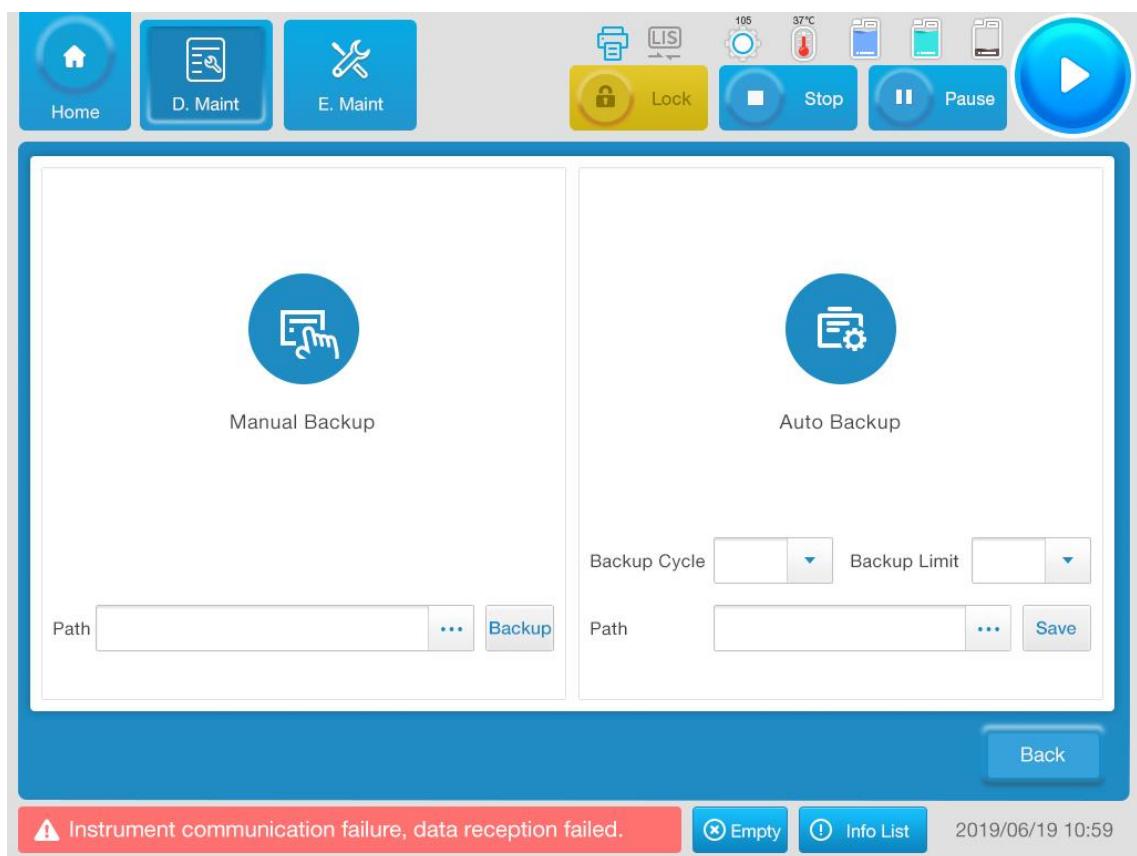


Figure 4-37 Data Backup

#### Basic operation

- Automatic backup
  - 1) Backup cycle: backup interval time;
  - 2) Backup limit: number of backup package;
  - 3) Path: enter or select the backup path manually, that is, the storage location;
  - 4) Set the backup period, backup limit, and path and click **Save**. When the set time is up, it will remind you to backup all data on the software and power off the analyzer.

- Manual backup

Enter or select the backup path manually, that is, the storage location, and click **Backup** to start the backup immediately.

#### 4.6.1.4. Temperature curve

The temperature control system includes temperature control (heating) of the reaction tray and reagent refrigeration. The reaction tray carries out temperature sensing and data feedback by a single temperature sensor. The refrigeration module of reagent tray includes a refrigeration unit composed of two refrigeration plates, which work independently of each other, and one temperature sensor carries out temperature sensing and data feedback respectively.

Click **Temperature Curve** to enter the temperature status interface, where you can view three temperature statuses, including reaction tray temperature, reagent tray temperature 1 and reagent tray temperature 2. Low temperature, normal temperature and high temperature are respectively expressed in blue, green and red. The temperature display includes data and status display.

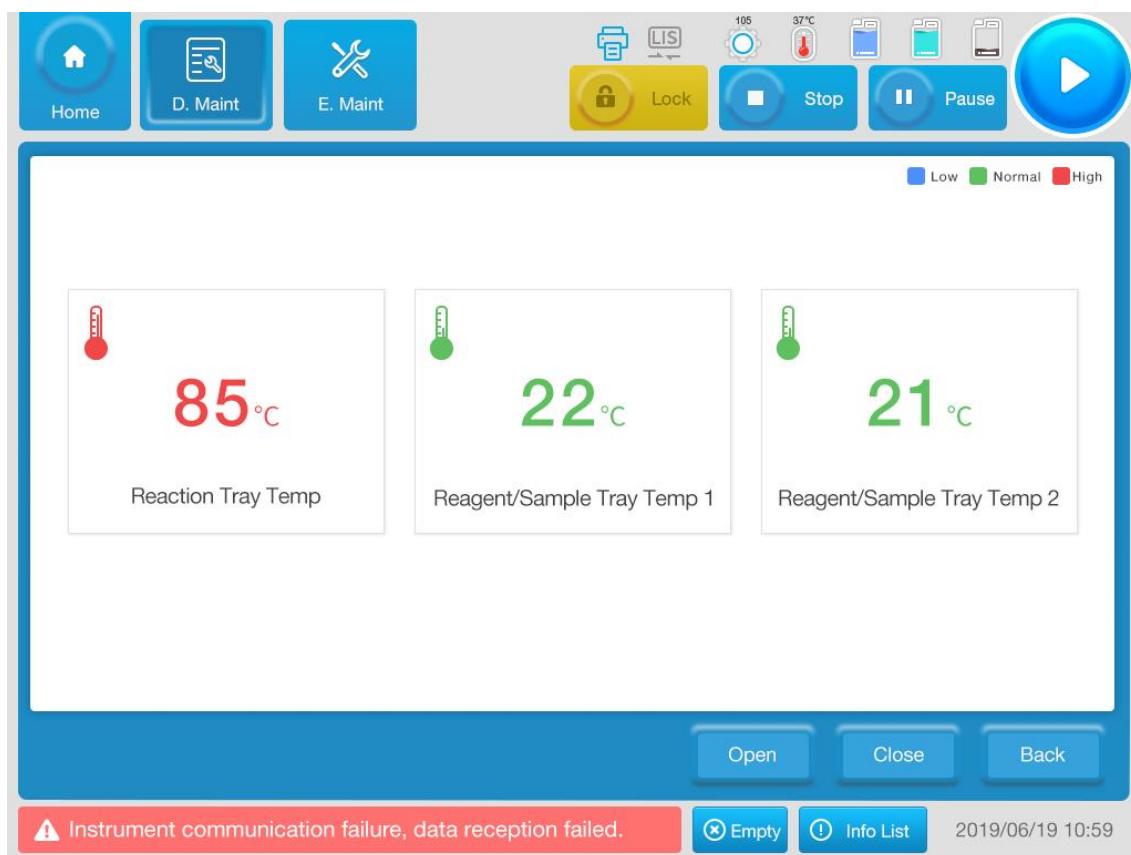


Figure 4-38 Temperature Status

#### Basic operation

- 1) "On/Off Temperature Control" refers to open or close the temperature control for the reaction tray;

- 2) Click **Back** to return to the daily maintenance main interface.

#### 4.6.1.5. Consumables maintenance

Use to check the status of pure water bucket, waste container, concentrated cleaning liquid bucket, acid-base cleaning liquid and deionized water.

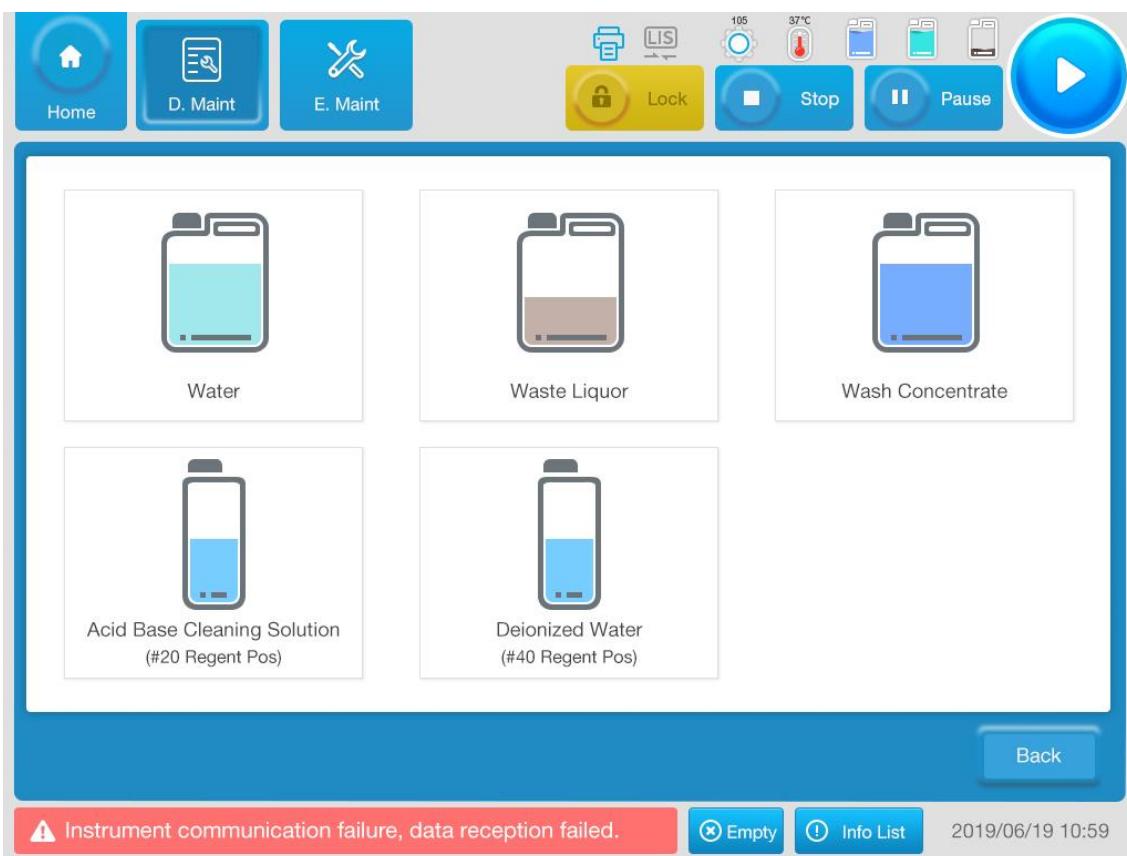


Figure 4-39 Consumables Maintenance

##### ■ Setting

Set the interval inquiry time of liquid level status and whether to inquire regularly, and only refresh the status of 2 water tanks; the remaining amount of acid-base detergent is indicated during the operation of the instrument.

##### Basic operation

Click **Daily Maintenance-Consumables** to judge directly according to the status displayed in the software interface.

- 1) Each state of the water tank has a corresponding color reminder:

Container	State		Liquid level color display	
Waste bucket	Full	Not full	Red	Sepia
Pure water bucket	Empty	Not empty	Red	Cyan

- 2) In particular, the acid-base detergent displays the liquid residual in the bottle by percentage. A red alarm will be given in case of below 10%, a yellow alarm for above 10% and below 25%, and a normal blue alarm for above 25%.

#### 4.6.1.6. Unit status

It is mainly divided into the following units: photoelectric unit, temperature control unit, reaction tray unit, reagent-sample probe unit, stirring rod unit, automatic cleaning unit, sample bar code unit, reagent bar code unit and fluidic component unit. The temperature control unit includes temperature control of the reaction tray and refrigeration of the reagent-sample tray.

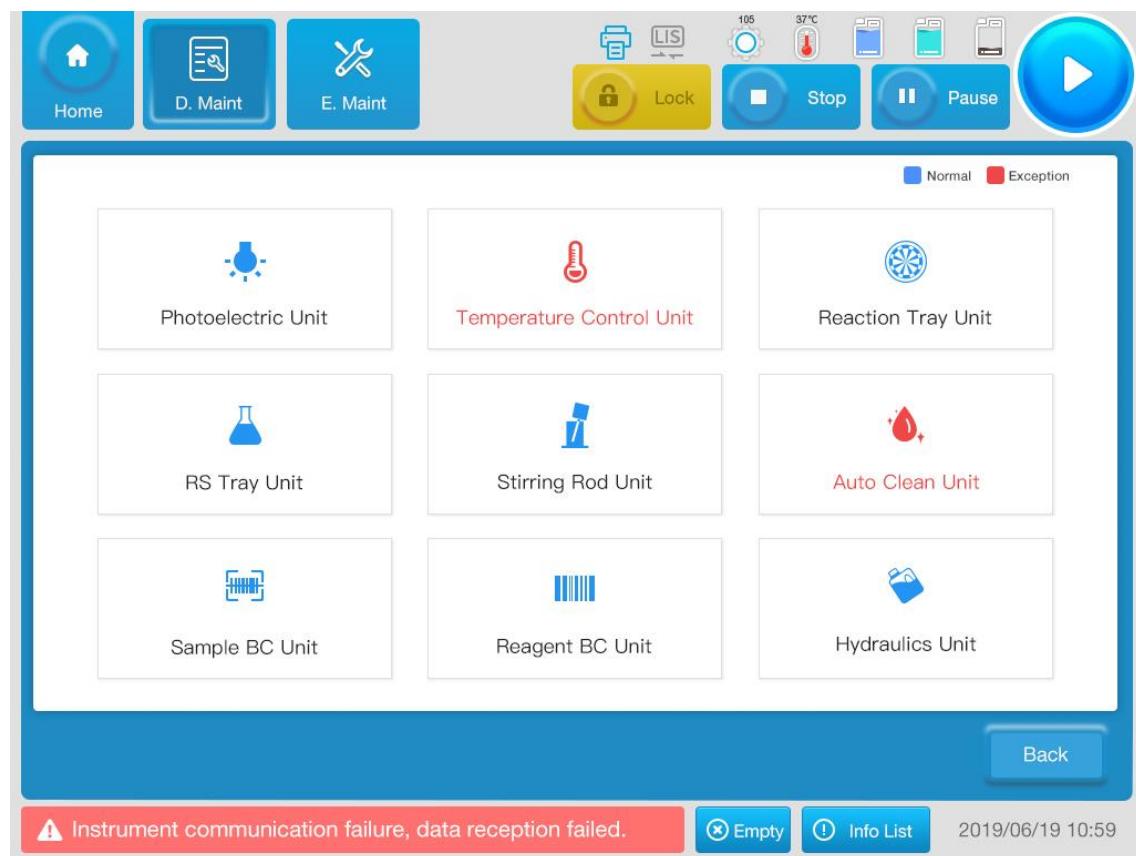


Figure 4-40 Unit Status

#### Basic operation

Click **Daily Maintenance-Unit Status** to judge directly according to the status displayed in the software interface. Blue means normal while red means abnormal.

# 5. Analysis Principle and Calculation Method

This chapter briefly introduces the measuring principle of the instrument, including:

- Analytical method
- Calibration type and measurement principle
- Prozone inspection

## 5.1. Analytical method

Using the absorption law of solution to light or the transmission law of suspension to light, the absorbance of each photometric point in the reaction process is monitored, and the concentration or activity of the measured substance is calculated according to the change of absorbance before and after the reaction or the change rate of absorbance in the reaction process, combined with corresponding calibration parameters or calculation factors.

## 5.2. Analysis process

It includes action process, action position, test process, and photometric points.

### 5.2.1. Action process

EXC2X series Chemistry Analyzer completes all tests by performing the following actions in a loop:

- 1) Turn the cuvette under the cleaning head in step 1 for automatic cleaning;
- 2) After the cleaned cuvettes rotate to the position for first reagent R1 is called the first cycle or the first photometric points, add sample S and the second reagent R2 at the 10th and 23rd cycles, respectively. The absorbance measurement is performed once in each cycle, and the reaction test is completed in the 52nd cycle, that is, the 52th photometric point, and then automatic cleaning is performed.
- 3) After cleaning, the cuvette rotates to the bottom of the cleaning head in step 1, and starts the next cycle after cleaning.

### 5.2.2. Testing process

EXC2X series Chemistry Analyzer performs a fixed test process, with a total of 52 test cycles per reaction.

### 5.2.3. Photometric points

For the same reaction, metering is performed once per cycle, with a total of 52 photometric

points periods. In high-speed mode, the time interval between two adjacent photometric points is 15 seconds; in normal mode, the time interval between two adjacent photometric points is 22.5 seconds.

\*The above time period is for reference only. The specific time period is subject to the software setting after the instrument is installed.

## 5.3. Analysis method and reactivity calculation

In EXC2X series Chemistry Analyzer, the calculation formula of absorbance is as follows:

$$\text{Absorbance of solution} = \lg (\text{AD water-AD dark}) / (\text{AD dissolved-AD dark})$$

Among them:

- 1) "Lg" means carrying out common logarithmic operation with 10 as the base;
- 2) "AD" means the value of transmitted light intensity after photoelectric conversion and digital-to-analog conversion;
- 3) "AD dark" means the AD value when the bulb is not turned on, "AD water" means the AD value of purified water in the cuvette, "AD dissolved" means the AD value when the solution to be tested in the cuvette;
- 4) The absorbance data on the reaction curve of EXC2X series Chemistry Analyzer is a value that is magnified 20,000 times of the absorbance value.

According to the characteristics of reaction speed in the reaction process, EXC2X series Chemistry Analyzers classify all reactions into three categories: endpoint method, two-point method and kinetic method, which are described respectively below.

- Analysis methods: endpoint method, two-point method and kinetic method.
- Reaction time **N** **P**: a period of time from the start of a test to the end of reaction monitoring. For a single reagent item, the reaction time refers to the time after adding S while for dual reagent item, it refers to the time after R2 is added. Such interval includes two input boxes, which respectively input the start time and end time of the reaction monitoring, and are respectively replaced by using N and P.
- Blank time **L** **M**: the time before a test starts a reaction. For a single reagent item, blank time refers to the duration between adding R1 and adding sample S while for dual reagent item, it refers to the duration between adding sample S and R2. The interval also includes two input boxes, which input start time and end time of blank monitoring respectively, and are respectively replaced by using L and M.
- For a dual-wavelength item, A is the difference between the absorbance of dominant wavelength and that of the secondary wavelength; For a single wavelength item, A is the absorbance of the dominant wavelength.

### 5.3.1. End-point method

After a certain period of time, the reaction reaches the equilibrium point, at which time the absorbance no longer changes, and the increase (or decrease) amplitude of absorbance

caused by the reaction is proportional to the concentration of the measured substance. Also known as the "Balance" method.

### 5.3.1.1. Single reagent endpoint method

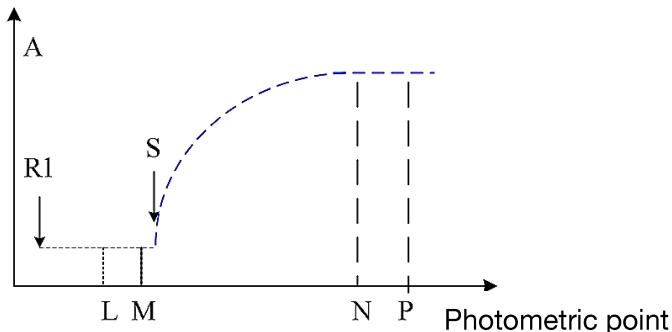


Figure 5-1 Reaction Curve of Single Reagent Endpoint Method

Reaction time  $[N] [P]$ ,  $10 \leq N \leq P \leq 51$ , where  $N+4 \geq P$ ;

Blank time  $[L] [M]$ ,  $0 \leq L \leq M \leq 8$ , where  $L+4 \geq M$ .

- Calculation of absorbance  $A_i$  participating in the calculation of reactivity in the reaction time interval.
  - 1) If  $N=P$ , input  $[P]$   $[P]$  and use only one point, then  $A_i = A_N$ .
  - 2) If  $P=N+1$ , input  $[N]$   $[N+1]$ , and use two points for  $A_i = \frac{A_N + A_{N+1}}{2}$ .
  - 3) If  $P=N+2$ , i.e. Input  $[N]$   $[N+2]$  and use 3 points, then  $A_i$  is the absorbance values after the maximum and minimum values are removed.
  - 4) If  $P=N+3$ , i.e. Input  $[N]$   $[N+3]$ , and use 4 points, then  $A_i$  is the average of the remaining 2 absorbance values after removing the maximum and minimum absorbance values.
  - 5) If  $P=N+4$ , i.e. Input  $[N]$   $[N+4]$ , and use 5 points, then  $A_i$  is the average of the remaining 3 absorbance values after removing the maximum and minimum absorbance values.
- Absorbance participating in the calculation of reactivity in the blank time interval  $A_b$ : the calculation method is the same as that of absorbance participating in the calculation of reactivity  $A_i$  in the reaction time interval.
- Calculation of reactivity:  $R = A_i - KA_b$ .
- Where  $k = \frac{V_{R1}}{V_{R1} + V_S}$  is the single reagent volume correction factor,  $V_{R1}$ ,  $V_S$  represents the first reagent and sample volume respectively. The second item  $KA_b$  in

the above R formula represents the reagent blank correction value, and reagent blank can be deducted in real time, but sample blank cannot be deducted. If sample blank correction is required, a sample blank test must be applied separately. The calculation method of sample blank reactivity  $R_{sb}$  is the same as that of R above, that is

$$R_{sb} = A_i - kA_b, \text{ so the reactivity after sample blank correction is } R' = R - R_{sb}.$$

### 5.3.1.2. Dual reagent endpoint method

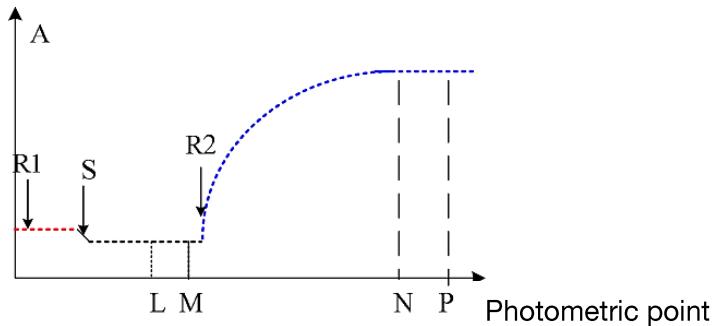


Figure 5-2 Reaction Curve of Dual Reagent Endpoint Method

Reaction time  $[N] [P], 22 \leq N \leq P \leq 51$ , where  $N+4 \geq P$ ;

Blank time  $[L] [M], 10 \leq L \leq M \leq 21$ , where  $L+4 \geq M$ .

- Calculation of absorbance  $A_i$  participating in the calculation of reactivity in the reaction time interval: same as single reagent endpoint method.
- Calculation of absorbance  $A_b$  participating in the calculation of reactivity in blank time interval: same as single reagent endpoint method.
- Calculation of reactivity R:  $R = A_i - k' A_b$

1) The second term  $k' A_b$  in the formula represents the correction value of the mixed

blank of the first reagent and the sample, and  $k' = \frac{V_{R1} + V_s}{V_{R1} + V_s + V_{R2}}$  is a dual reagent volume correction factor.

2) The mixed blank of the first reagent and the sample blank can be deducted in real time, but R2 (second reagent) blank cannot be deducted. If R2 correction is required, a reagent blank test must be applied separately. The calculation method of blank reactivity  $R_2$  is the same as that of r above, that is  $R_{R2}$ , which means

$$R_{R2} = A_i - k' A_b, \text{ so the reactivity after sample blank correction } R' = R - R_{R2}.$$

### 5.3.2. Two-point method

1) The two-point method is also called the first-order kinetic method, the two-point rate

method and the fixed-time method. It means that the reaction rate is proportional to the one-power of the substrate concentration within the specified reaction time, i.e.  $V=K[S]$ . Due to the constant consumption of substrate, the whole reaction speed is continuously decreasing, which shows that the increasing (or decreasing) speed of absorbance is smaller and smaller. The increase (or decrease) ( $\Delta A/\text{min}$ ) of absorbance of the reaction solution within the specified reaction time is proportional to the concentration of the measured substance.

- 2) According to whether the sample blank needs to be deducted, the two-point method is divided into single interval two-point method and dual interval two-point method. The dual interval two-point method can deduct the sample blank in real time, that is, the absorbance change rate between two points in the sample blank period is used as the sample blank deduction.
- 3) The two-point method can be used to check substrate depletion. If substrate depletion occurs, the corresponding mark will be given on the result.

#### 5.3.2.1. Single reagent two-point method

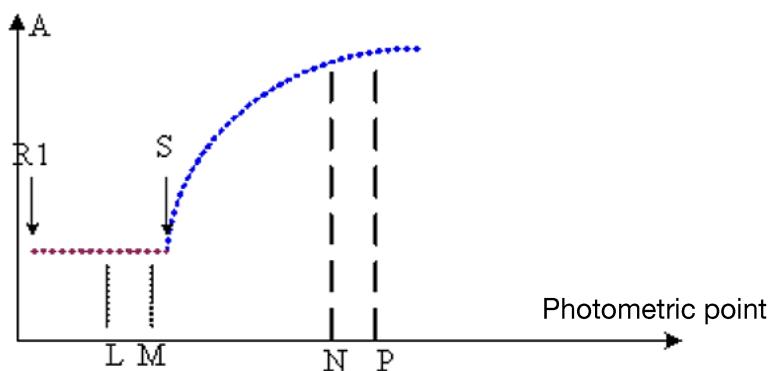


Figure 5-3 Reaction Curve of Single Reagent Two-Point Method

Reaction time  $[N] [P]$ ,  $10 \leq N < P \leq 51$ ;

Blank time  $[L] [M]$ ,  $0 \leq L < M \leq 8$ , L and M are blank by default without performing blank correction.

- Reactivity  $R$  calculation:  $R = \frac{A_P - A_N}{t_P - t_N}$  ( $R$  needs to be converted into  $R$  per minute);
- Blank reactivity  $R_b$  : the algorithm is the same as the above reactivity  $R$  ,  

$$R_b = \frac{A_M - A_L}{t_M - t_L}$$
 ( $R_b$  needs to be converted into  $R_b$  per minute);
- If blank time is set, blank correction must be carried out. After blank correction, the reactivity  $R' = R - KR_b$  , where  $K$  is the single reagent volume correction factor,

$$K = \frac{V_{R1}}{V_{R1} + V_S}.$$

### 5.3.2.2. Dual reagent two-point method

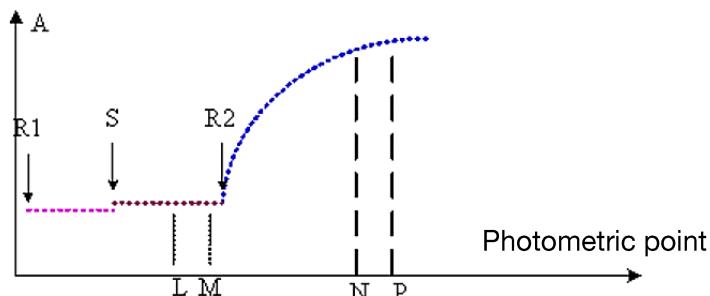


Figure 5-4 Reaction Curve of Dual Reagent Two-Point Method

Reaction time  $[N] [P], 22 \leq N < P \leq 51$ ;

Blank time  $[L] [M], 10 \leq L < M \leq 21$ , L and M are blank by default without performing blank correction.

- Reactivity  $R$ : the algorithm is the same as the single reagent two-point method.
- Reactivity  $R_b$ : the algorithm is the same as the single reagent two-point method.
- If blank time is set, blank correction must be carried out. The reactivity after blank correction is  $R' = R - K' R_b$  where  $K'$  is the dual reagent volume correction factor,

$K' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$ . By setting the blank time, the instrument can only automatically deduct the mixed blank of the first reagent and the sample, but cannot deduct the blank of the second reagent. If the blank of the second reagent needs to be deducted, the reagent blank test shall be applied separately. The reactivity algorithm of the second reagent blank  $R_{R2}$  is the same as the above-mentioned reactivity R, and the

reactivity corrected by the blank of the second reagent  $R'' = R - R_{R2}$ .

### 5.3.3. Kinetic method

- 1) Also called zero-order rate method, rate method and continuous monitoring method, it refers to that the reaction speed is proportional to the zero square of the substrate concentration, i.e. Independent of the substrate concentration. Therefore, during the whole reaction process, the reactant can generate a certain product at a uniform speed, resulting in the absorbance of the measured solution uniformly decreasing or increasing at a certain wavelength. The decreasing or increasing speed ( $\Delta A/\text{min}$ ) is proportional to the activity or concentration of the

measured substance (catalyst). It is mainly used for the determination of enzyme activity.

- 2) In practical application, as the concentration of substrate cannot be infinite, the reaction will no longer be zero-order after the substrate is consumed to a certain extent as the reaction progresses. Therefore, the zero-order rate method is aimed at a specific time period, and the zero-order reaction time period must be selected for monitoring to ensure the accuracy of the results.
- 3) According to whether the sample blank needs to be deducted, the kinetic method is divided into single interval two-point method and dual interval two-point method. The dual interval two-point method can deduct the sample blank in real time, that is, the absorbance change rate in the sample blank period is used as the sample blank deduction.
- 4) Kinetic method can be used to check substrate depletion. If substrate depletion occurs, corresponding prompt marks will be given on the results.
- 5) The dynamic method can be used to check the linearity limit. If the situation of exceeding the linearity limit occurs, the corresponding prompt mark will be given on the result.

### Calculation of reactivity

In the zero-order kinetic reaction interval, the least square method is used to calculate the reactivity, and the least square method calculation formula is as follows:

$$R = \frac{\sum_{i=N}^P (t_i - \bar{t}) \cdot (A_i - \bar{A})}{\sum_{i=N}^P (t_i - \bar{t})^2}$$

Where N is the starting point of the zero-order kinetic reaction interval and P is the end point of the zero-order kinetic reaction interval,  $A_i$  is the absorbance at point i,  $\bar{A}$  is the average absorbance from point n to point P,  $t_i$  is the time at point i, and  $\bar{t}$  is the average time from point L to point M.

### 5.3.3.1. Single reagent kinetic method

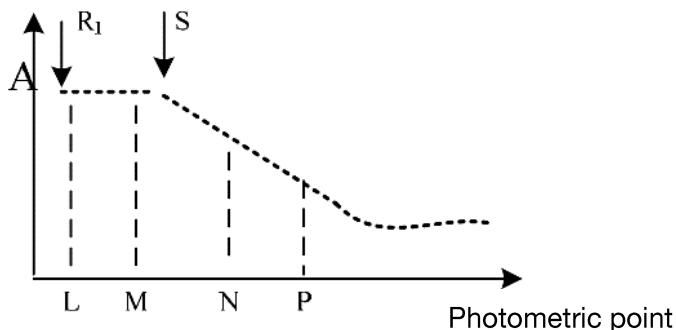


Figure 5-5 Reaction Curve of Single Reagent Rate Method

The reaction time  $[N]$   $[P]$ , same as that of the single reagent two-point method, but  $N+2 \leq P$ , i.e. At least 3 photometric points are required;

The blank time  $[L]$   $[M]$ , same as the single reagent two-point method, but  $L+2 \leq M$ , i.e. there must be at least 3 photometric points; the default values of L and M are blank, and no blank correction is performed.

- Reactivity  $R : R = \Delta A_{NP}$ ,  $\Delta$  means the change rate of absorbance per minute between photometric points (N, P) obtained by least square method.
- Blank reactivity  $R_b$ : the algorithm is the same as the above reactivity  $R$ ,  $R = \Delta A_{LM}$ .
- If blank time is set, blank correction must be carried out. After blank correction, the reactivity  $R' = R - KR_b$ , where K is the single reagent volume correction factor,

$$K = \frac{V_{R1}}{V_{R1} + V_S}.$$

### 5.3.3.2. Dual reagent kinetic method

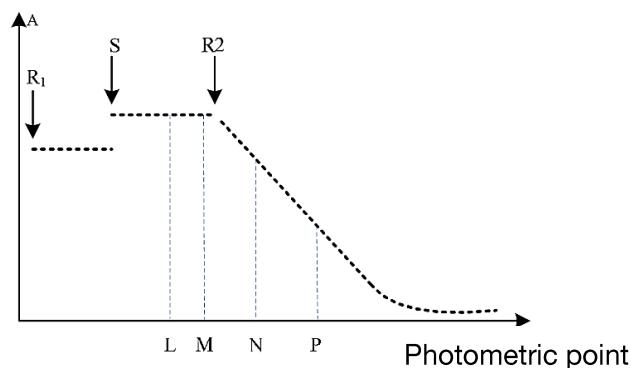


Figure 5-6 Reaction Curve of Dual Reagent Rate Method

The reaction time  $[N]$   $[P]$  is the same as that of the dual reagent two-point method, but  $N+2 \leq P$ , i.e. there must be at least 3 photometric points;

The blank time  $L$   $M$  is the same as the dual reagent two-point method, but  $L+2 \leq M$ , i.e. There must be at least 3 photometric points;  $L=0, M=0$  by default without performing blank correction.

- Reactivity  $R$  :  $R = \Delta A_{NP}$ ,  $\Delta$  means the change rate of absorbance per minute between photometric points (N, P) obtained by least square method.
- Reactivity  $R_b$  : the algorithm is the same as the single reagent kinetic method.
- If blank time is set, blank correction must be carried out. The reactivity after blank correction is  $R' = R - K' \times R_b$  where  $K'$  is the dual reagent volume correction factor,

$$K' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}. \text{ By setting the blank time, the instrument can only automatically}$$

deduct the mixed blank of the first reagent and the sample, but cannot deduct the blank of the second reagent. If the blank of the second reagent needs to be deducted, a reagent blank test shall be applied separately. The reactivity algorithm of the blank of the second reagent  $R_{R2}$  is the same as the above-mentioned reactivity  $R$  and the reactivity corrected by the blank of the second reagent is  $R'' = R - R_{R2}$ .

## 5.4. Calibration

### 5.4.1. Calibration type

In EXC2X series Chemistry Analyzer, calibration is divided into linear and non-linear calibration. The linear calibration includes single point, two points and multi-point linear calibration, which is mainly applicable to items where the reactant is solution; non-linear calibration mainly includes Logistic-Log4P, Logistic-Log5P, Exponential-5P, Polynomial-5P and Spline. It is mainly applicable to items where the reactant is turbid liquid, such as immunoturbidimetry, etc.

### 5.4.2. Calibration parameter

The number of calibration parameters and calculation methods are different for different calibration types, which are described respectively below.

#### 1) Single point linear calibration

Formula  $C = KR$ , where there is one calibration parameter, namely  $K$ .

$$K = \frac{C_{\text{Standard}}}{R_{\text{Standard}}}$$

Where: C is the concentration of the standard value and R is the reaction range of the

standard value.



Attention

When performing single-point linear calibration, reagent blank test must be performed at the same time.

## 2) Two-point linear calibration

Formula  $C = K(R - R_0)$ , where there are 2 calibration parameters, namely K and  $R_0$ .

$$K = \frac{C_2 - C_1}{R_2 - R_1}$$

$$R_0 = R_1 - \frac{C_1(R_2 - R_1)}{C_2 - C_1}$$

Where,  $C_1, C_2$  are the concentration of standard 1 and 2 respectively, and  $R_1, R_2$  are the reaction ranges of standard 1 and 2 respectively.

## 3) Multipoint linear calibration

Formula  $C = K(R - R_0)$ , where there are 2 calibration parameters, namely K and  $R_0$ .

According to multi-point linear regression, the calibration parameters are calculated.

## 4) Logistic-Log4P

The calibration formula  $R = R_0 + k/[1 + e^{-(a+b\ln C)}]$  has four parameters, namely,  $R_0$ , K, a and b. It is required to provide at least 4 standard values, in which the concentration (activity) of the first standard value is zero, and its corresponding R is equal to  $R_0$ , and the rest parameters are determined by iteration method.

## 5) Logistic-Log5P

The calibration formula  $R = R_0 + k/[1 + e^{-(a+b\ln C+c\ln C^2)}]$  has five parameters, namely  $R_0$ , k, a, b and c. It is required to provide at least 5 standard values, of which the concentration (activity) of the first standard value is zero, and its corresponding R is equal to  $R_0$ , and the rest parameters are determined by iteration method.

## 6) Exponential-5P

The calibration formula  $R = R_0 + Ke^{[a\ln C+B(\ln C)^2+C(\ln C)^3]}$  has five parameters, namely  $R_0$ , k, a, b and c. It is required to provide at least 5 standard values, of which the concentration (activity) of the first standard value is zero, and its corresponding R is equal to  $R_0$ , and the rest parameters are determined by iteration method.

## 7) Polynomial-5P

The calibration formula  $\ln C = a + b(R - R_0) + c(R - R_0)^2 + d(R - R_0)^3$  has five parameters, namely  $R_0$ , a, b, c and d. It is required to provide at least 5 standard values, of

which the concentration (activity) of the first standard value is zero, and its corresponding R is equal to  $R_0$ , and the rest parameters are determined by iteration method.

### 8) Spline

The calibration formula  $C - C_i = R_{0i} + a_i(C - C_i) + b_i(C - C_i)^2 + c_i(C - C_i)^3 - R$  has  $4i$  parameters, namely  $R_{0i}$ ,  $a_i$ ,  $b_i$  and  $c_i$ . It is required to provide at least 2 standard values and use iterative method to find the parameters of each interval.

## 5.5. Concentration calculation

- When the calibration method of the item is K factor method, the calibration is not required, and the theoretical calculation factor K can be directly input. The calculation formula of the concentration is as follows:

$$C = KR/10000$$

Where: K is the input calculation factor and R is the reactivity of the sample to be tested.

- If the calibration type is linear calibration, Logistic-Log4P or Polynomial-5P, the concentration can be calculated by directly using the calibration parameters and the reactivity amplitude R.
- If the calibration type is Logistic-Log5P, Exponential-5P or Spline, according to the reaction degree amplitude R and calibration parameters, the positive real root is obtained by dichotomy to calculate the concentration.

## 5.6. Quality control

### 5.6.1. Quality control rules

The default quality control rule for EXC2X series Chemistry Analyzer is Westguard multi-rule. Users can select one or more rules to judge the quality control status for different items according to actual needs.

The Westguard multi-rule quality control rule includes 6 sub-rules, and the judgment significance of each sub-rule is as follows:

Representative symbol	Definition	Judgment of quality control
$1_{2s}$	One point falls outside $+2 SD$ or $-2 SD$ of the mean value	Give a warning
$1_{3s}$	One point falls outside $+3 SD$ or $-3 SD$ of the mean value	Out of control (random error, systematic error)
$2_{2s}$	Two consecutive points fall outside $+2 SD$ or $-2 SD$ of the mean value	Out of control (random error)

Representative symbol	Definition	Judgment of quality control
$R_{4s}$	The difference between the two values in the same batch exceeds 4 SD	Out of control (random error)
$4_{1s}$	Four consecutive points fall outside +1 SD or -1 SD of the mean value	Out of control (random error)
$10_x$	Ten consecutive points fall on the same side of the mean value	Out of control (random error)

The judging flow chart of EXC2X series Chemistry Analyzer for the above sub-rules is as follows:

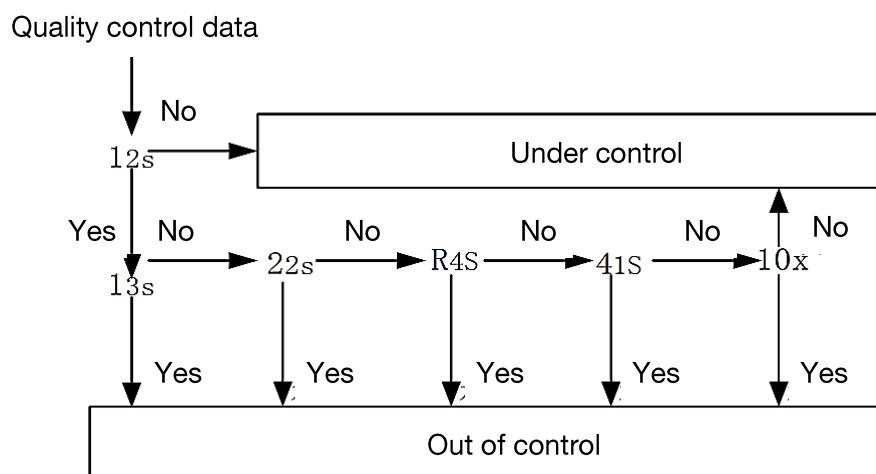


Figure 5-7 Quality Control Rule Judgment Flow Chart

### 5.6.2. Quality control type

EXC2X series Chemistry Analyzers have three types of quality control, namely real-time quality control, intra-day quality control and inter-day quality control. Quality control status is judged according to the set quality control rules.

- Real-time quality control: to judge the quality control status of 10 consecutive quality control data in one day;
- Intra-day quality control: carry out quality control status judgment on all quality control data in one day;
- Inter-day quality control: to judge the quality control status of all quality control data in different days.

### 5.6.3. Quality control chart

EXC2X series Chemistry Analyzer has two types of quality control charts, L-J and Twin Plot respectively.

### 1) L-J quality control chart

Taking the measured quality control data value as the vertical ordinate, draw a horizontal line from the quality control target value, draw 6 lines parallel to the mean line on the top  $+1\text{ SD}$  (standard deviation, abbreviated as SD),  $+2\text{ SD}$ ,  $+3\text{ SD}$  and the bottom  $-1\text{ SD}$ ,  $-2\text{ SD}$  and  $-3\text{ SD}$ , and mark the values of the quality QC sample measured each time on the quality control chart, and connect the adjacent points with fine lines.

### 2) Twin Plot quality control chart

Twin Plot QC chart can be displayed when one item simultaneously determines two concentrations of QC. According to the target value and standard deviation SD of each QC liquid (input by the user in the quality control setting), the measured value of one QC liquid is taken as the horizontal coordinate (generally low-concentration QC liquid), the measured value of the other QC liquid is taken as the vertical coordinate (generally high-concentration QC liquid), the average value is taken as the center line, and mark  $\pm 1\text{ SD}$ ,  $\pm 2\text{ SD}$  and  $\pm 3\text{ SD}$  lines, and the same measurement results of the two QC liquids form a point on the coordinate, as shown in the following figure:

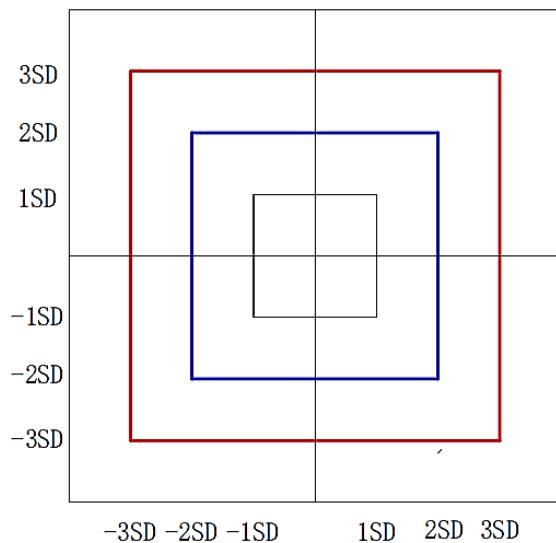


Figure 5-8 Twin Plot Control Chart

The chart can sensitively reflect the system and random errors. The data falling within the blue circle ( $\pm 2\text{ SD}$ ) indicates control. The first or third quadrant between the red circle and the blue circle indicates systematic error. The second or fourth quadrant falling between the red circle and the blue circle indicates random error, while falling outside the red circle indicates random error.

## 5.7. Other relevant calculations

### 5.7.1. Relevant calculation of calibration curve

#### 1) Calibration sensitivity

In the specified calibration process, the difference between the reactivity of the maximum concentration calibrator and the minimum concentration calibrator is judged to be unqualified if it is less than the set value.

## 2) Blank liquid reactivity

Refers to the reactivity of calibrator with zero concentration. If it is higher than the set value, it is judged as unqualified.

## 3) Calibration repeatability

The difference between the maximum and minimum values of the reactivity measured 3 times for each calibrator is judged to be unqualified if it is higher than the set value.

## 4) Standard deviation of calibration curve

Only applicable to multi-point linear and non-linear calibration curves. It refers to the square sum of the difference between the reactivity ( $R$ ) of each calibrator and the reactivity ( $R_i'$ ) calculated according to the calibration curve, divided by the degree of freedom, and then squared. The specific calculation method is as follows:

- Multipoint linear calibration

$$SD = \sqrt{\frac{\sum_{i=1}^N \sum_{j=1}^n (R_{ij} - R_i')^2}{Nn - 2}}$$

In the formula:  $R_{ij}$  is the reactivity (effective determination times) of a certain determination of the calibrator  $i$ ,  $R_i'$  is the reactivity of the calibrator  $i$  calculated according to the calibration curve,  $N$  is the number of calibrators, and  $n$  is the effective number of repeated determinations.

- Logistic-Log4P

$$SD = \sqrt{\frac{\sum_{i=1}^N \sum_{j=1}^n (R_{ij} - R_i')^2}{Nn - 4}}$$

In the formula:  $R_{ij}$  is the reactivity (effective determination times) of a certain determination of the calibrator  $i$ ,  $R_i'$  is the reactivity of the calibrator  $i$  calculated according to the calibration curve,  $N$  is the number of calibrators, and  $n$  is the effective number of repeated determinations.

- Logistic-Log5P

$$SD = \sqrt{\frac{\sum_{i=1}^N \sum_{j=1}^n (R_{ij} - R_i')^2}{Nn - 5}}$$

In the formula:  $R_{ij}$  is the reactivity (effective determination times) of a certain determination

of the calibrator i,  $Ri'$  is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated determinations.

- Exponential-5p and polynomial-5p

$$SD = \sqrt{\frac{\sum_{i=1}^N \sum_{j=1}^n (Rij - Ri')^2}{Nn - 5}}$$

In the formula: Rij is the reactivity (effective determination times) of a certain determination of the calibrator i,  $Ri'$  is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated determinations.

- Spline

$$SD = \sqrt{\frac{\sum_{i=1}^N \sum_{j=1}^n (Rij - Ri')^2}{Nn - 4}}$$

In the formula: Rij is the reactivity (effective determination times) of a certain determination of the calibrator i,  $Ri'$  is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated determinations.

## 5) Correlation coefficient of calibration curve

Only applicable to multi-point linear and non-linear calibration curves, and the calculation formula is as follows:

$$R^2 = \frac{\sum_{i=1}^N \sum_{j=1}^n (Cij - \bar{C})^2 (Rij - \bar{R})^2}{\sum_{i=1}^N \sum_{j=1}^n (Cij - \bar{C})^2 \sum_{i=1}^N (Rij - \bar{R})^2}$$

Where: C is the concentration of the calibrator, R is the reactivity, N is the number of calibrators, and n is the effective number of repeated determinations.

### 5.7.2. Substrate depletion judgment

It is only applicable to kinetic method and two-point method. Some high-concentration (active) samples make the substrate run out quickly, so that the reaction speed is no longer the desired speed (grade 0 or grade 1 reaction). In order to correctly reflect the determination result, the substrate run-out limit judgment is required. The specific judgment method is as follows:

### 1) Increasing reaction

If the absorbance at any point or points in the period between start and end time is greater than the set value, it is judged as substrate depletion.

### 2) Descending reaction

If the absorbance at any point or points in the starting and ending time periods is less than the set value, it is judged as substrate depletion.

## 5.7.3. Linearity check

It is only applicable to the kinetic method, judging whether the straightness of the reaction curve meets the set value within the time period of the reaction between start and end points according to the data of each photometric point. The specific calculation method is as follows:

- 1) There are more than 9 photometric points in the starting and ending time periods;

Linear limit = (change rate of absorbance at the first 6 points-change rate of absorbance at the last 6 points)/change rate of absorbance at all points

- 2)  $4 \leq$  Photometric points from the start to the end  $\leq 8$ ;

Linear limit = (change rate of absorbance at the first 3 points-change rate of absorbance at the last 3 points)/change rate of absorbance at all points

- 3) Linearity is not calculated in the following cases:

- Photometric points  $\leq 3$ ;
- The absorbance change rate is less than 0.006/ min or the difference between absorbance change rates is less than 0.006/ min;
- Reagent blank test, sample blank test and zero concentration calibrator test.

## 5.7.4. Prozone inspection

In the reaction of antigen and antibody, the insoluble antigen-antibody complex generated is closely related to the proportion of antigen and antibody. When the proportion is appropriate, the insoluble antigen-antibody complex generated is the largest, and the light transmitted at this time is the least, which is equivalent to the maximum absorbance. When the ratio is greater than or less than this ratio, the amount of insoluble antigen-antibody complexes generated will decrease, the transmitted light will increase, and the absorbance will decrease, as shown in the following figure. If two samples with very different concentrations are not examined by the prozone, the amount of insoluble antigen-antibody complexes generated can be equal, and the same determination results will be obtained.

Ag/Ab compound

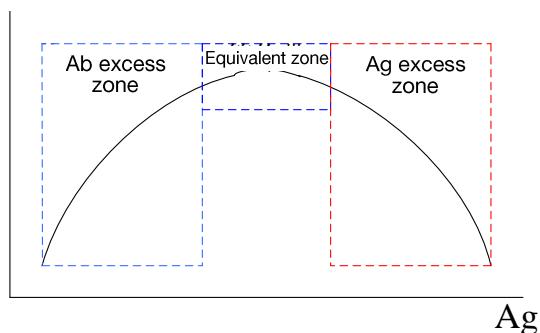


Figure 5-9 Prozone Inspection

In EXC2X series Chemistry Analyzer, perform prozone inspection according to the following methods.

- Dual reagent endpoint method

As shown in the following figure, L is the start point of the reaction, M is the start point of the reaction time interval, N and P are the prozone checkpoints, and L, M, N and P satisfy the following relationship:  $22 \leq L < N < P < M \leq 51$ .

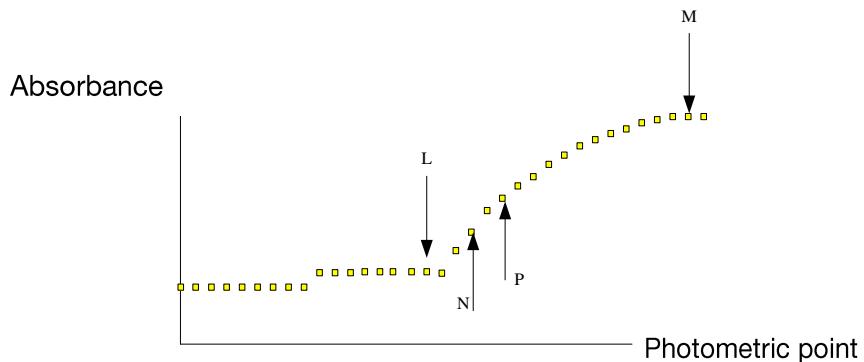


Figure 5-10 Prozone Inspection of Dual Reagent Endpoint Method

The prozone check value (PC) is equal to:

$$PC = \frac{\frac{A_M - A_P}{M - P} \times 100\%}{\frac{A_P - A_N}{P - N}}$$

If  $PC >$  set prozone check limit, it is judged that prozone phenomenon exists.

- Single reagent endpoint method

As shown in the following figure, L is the start point of the reaction, M is the start point of the reaction time interval, N and P are the prozone checkpoints, and L, M, N and P satisfy the following relationship:  $8 \leq L < N < P < M \leq 52$ .

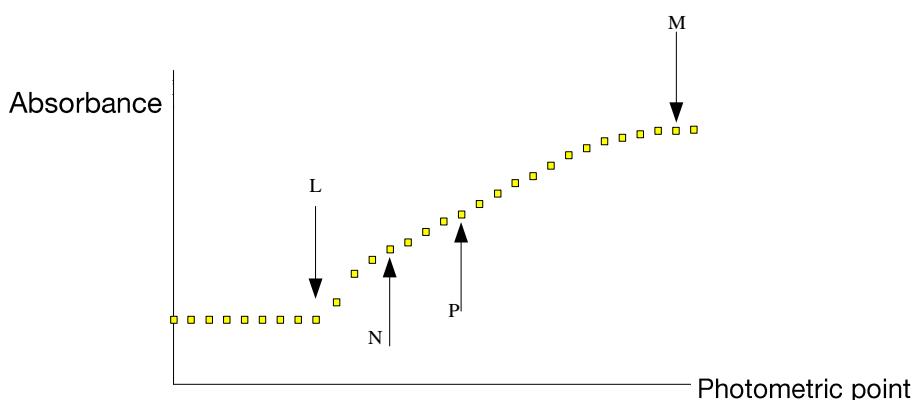


Figure 5-11 Prozone Detection for Single Reagent Endpoint Method

The prozone check value (PC) is equal to:

$$PC = \frac{\frac{A_M - A_P}{M - P}}{\frac{A_P - A_N}{P - N}} \times 100\%$$

If  $PC >$  set prozone check limit, it is judged that prozone phenomenon exists.

### 5.7.5. Reaction equilibrium judgment

It is only applicable to endpoint method. According to the data of each photometric point, it is determined whether the reaction has reached equilibrium at the endpoint time of the reaction. The specific calculation method is as follows:

- 1) Calculate the difference of absorbance between the endpoint and 3 consecutive photometric points in the future;
- 2) If all the differences are less than 0.01, it is judged that the balance has been reached, otherwise it has not been reached;
- 3) If the end point of the reaction is greater than 49, the reaction equilibrium judgment will not be carried out.

### 5.7.6. Bulb status judgment

After each startup and before starting the test, the reaction tray rotates the reaction cuvette until the light spot stays in the middle of the 63 # to 1 # cuvettes, and then carries out photoelectric collection of all wavelengths, collects data for 10 times at each wavelength, removes the maximum and minimum values, and takes the average value of the number of 8 in the middle as the photoelectric data collected at this time at each wavelength as the basis for judging the luminous intensity of the bulb. When the photoelectric data of any wavelength at all cuvette positions is lower than 18000, the alarm prompts the user to "Please Replace the Bulb Due to Insufficient Luminous Intensity of The Light Source" and allows the user to continue the test. However, a prompt box pops up before each test to prompt the user to "Continue the Test or not because Insufficient Luminous Intensity May

Affect the Result". When the photoelectric data of any wavelength in all cuvette positions is lower than 12000, the alarm prompts the user to "Please Replace the Bulb Immediately Due to Seriously Insufficient Luminous Intensity of the Light Source" and the user is prohibited from continuing the test. The user can only continue the test after replacing the bulb and passing the luminous intensity test of the light source as required.

## 6. Maintenance and Service

This chapter introduces the maintenance methods of the instrument, including common maintenance instructions and regular maintenance. The purpose, use timing, required supplies, instrument status, precautions and operation steps of each maintenance item are introduced in detail.

### 6.1. Overview

In order to ensure the system reliability and good working condition and service life, please operate and regularly maintain the system in strict accordance with this Operation Manual.

#### 6.1.1. Maintenance tools

- A set of hex wrench
- Cross screwdriver (large, medium and small)
- Stainless steel wire (inner diameter 0.3 mm and 0.5 mm, respectively)
- Plastic syringe (approx. 10 ml, without probe)
- Clean gauze
- Clean cotton swabs
- Brush (for cleaning the barrel)
- Non-ionic surfactant detergent
- Anhydrous ethanol
- 84 disinfectant
- Medical latex gloves

## 6.2. Regular maintenance items

Regular maintenance items are defined according to the conditions of various parts of the instrument and actual use. Trained personnel are required to strictly implement the items according to the specified cycle to ensure the performance of the instrument and reduce unnecessary service calls. Before performing maintenance, please make sure to read the maintenance procedures in this section thoroughly.

The system provides the customization function. You can customize the required maintenance items through the customization function except the system-defined maintenance items that are not allowed to be edited. After the maintenance operation is completed, the maintenance log can be filled in according to the maintenance situation to record the abnormalities and other necessary information during maintenance.

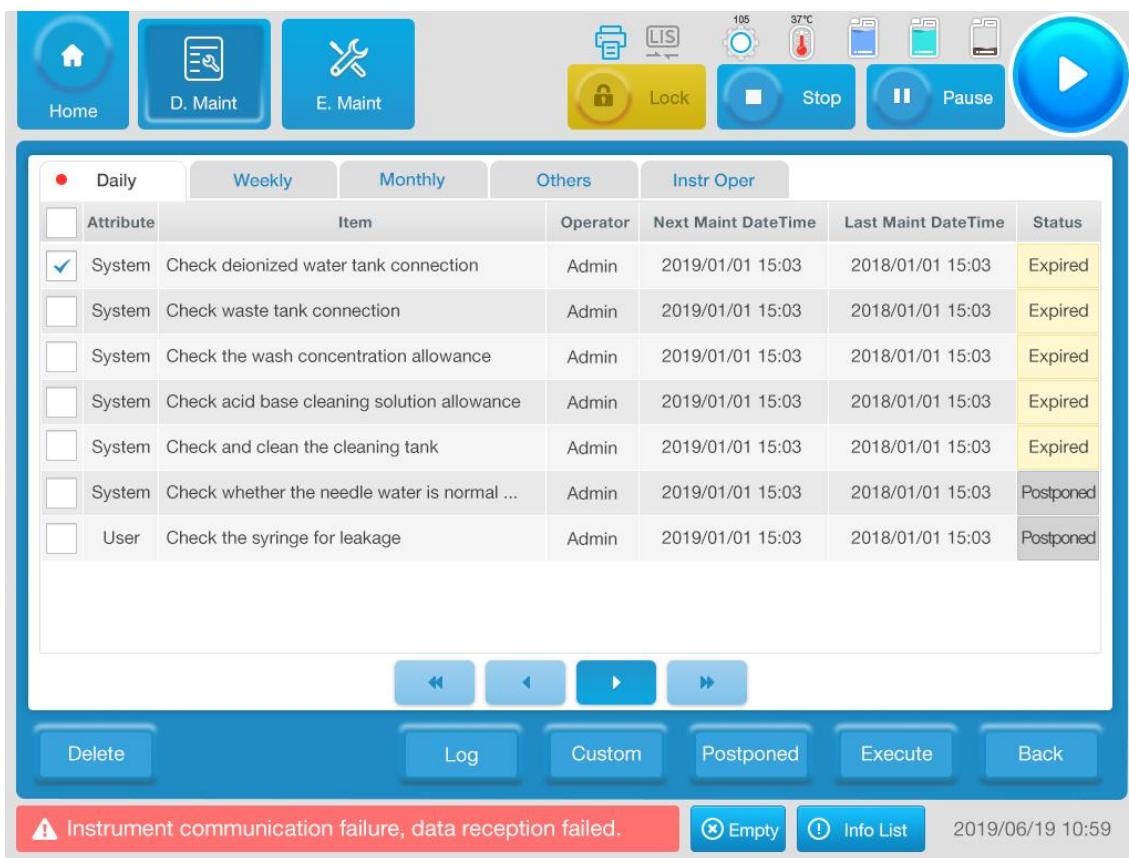


Figure 6-1 Periodic Maintenance

### 6.2.1. Maintenance cycle

The periodic maintenance list is divided into the following maintenance periodic units:

- Daily-1 day
- Weekly-7 days
- Monthly-30 days
- Other-irregular

■ Order operation

The system starts with the current maintenance time of each maintenance item and counts down the maintenance items.

### 6.2.2. Maintenance content

Maintenance cycle	Maintenance items (Arranged in order)	
Daily	1	Check deionized water connection
	2	Check waste connection
	3	Check the balance of concentrated detergent
	4	Check the reagent-sample probe syringe for leaks
	5	Check the balance of acid-base detergent
	6	Check whether the probe outlet water is normal (Verify whether the probe inner wall is blocked)
	7	Check and clean the cleaning basin
Weekly	1	Clean the reagent-sample storehouse
	2	Clean the reagent sample barcode scanning window
	3	Clean the analyzer panel
	4	Check and clean the automatic cleaning mechanism and stirring rod (Outer wall)
	5	Check and clean reagent -sample probe (Outer wall)
	6	Intensified cleaning
	7	Reaction cuvette (Dirty) detection-cuvette pollution (Including light source lamp detection)
	8	Reaction cuvette (Residual) detection-scraping of cuvette inner wall
Monthly	1	Clean ball spline
	2	Clean the cleaning basin for reagent -sample probe and stirring rod
Other	1	Fluidic component emptying

### 6.2.3. Maintenance interface

- Attribute

Displays the definition properties of the maintenance item. There are two values, "system" and "user". The system indicates that the maintenance item has been set before the instrument leaves the factory, and the user is the maintenance item which the user adds through the "customization" function.

- Item

Displays all system pre-defined items and user-defined maintenance items for the current maintenance cycle.

- Operator

Displays the operator for the current execution of the corresponding maintenance item, i.e. the user ID of the current software login.

- Time to be maintained

Displays the time the item needs maintenance next time.

- Maintained time

Displays the last maintenance time of the item.

- State

Displays whether the current item has expired or been postponed and the date to be maintained.

- Log

Record exceptions and other necessary information generated during maintenance.

- Customization

Customization function is used to customize the required maintenance items according to the reagent usage of the instrument. The system also allows adding and deleting custom maintenance items.

- Delete

If a maintenance item is not needed, the system allows it to be deleted. Please note that only custom maintenance items are allowed to be deleted, and system pre-defined maintenance items are not allowed to be deleted.

- Delay

The maintenance of the item is delayed by one cycle.

- Execution

After selecting one or more maintenance items, click this button to start the inspection of maintenance items.

## 6.2.4. Daily maintenance

The daily maintenance items shall be carried out before the test starts every day, and the reagent -sample probe, cleaning basin, syringe, deionized water connection, waste liquid connection and the remaining amount of concentrated cleaning liquid shall be checked.

### 6.2.4.1. Connection of deionized water check

Abnormal connection of the deionized water will result in the insufficient water supply or water leakage, which may cause the machine works improperly.

- Purpose

Check the connection of deionized water to ensure normal water supply.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

- Operating steps

- 1) Check whether the switch of the water purification system or other water storage module is on;
- 2) Check and confirm that the liquid guide pipe is dredged and free from bending, twisting and leakage of liquid;
- 3) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
- 4) Click the check box corresponding to checking deionized water connection;
- 5) Click **Execute** to perform maintenance;
- 6) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 7) Click **Save** to save the log.

### 6.2.4.2. Waste connection check

Improper connection of waste lines, or full high-concentration waste liquid barrel without emptying in time, will cause waste liquid overflow, environmental pollution, cross-contamination and even damage to instruments. Therefore, it is necessary to check the waste liquid connection of the instrument frequently.

- Purpose

Check whether the waste liquid pipeline connection and high-concentration waste liquid container are empty to avoid overflow of waste liquid.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

---

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

#### Operating steps

- 1) Check whether the waste liquid discharge system is normal, keep the waste liquid pipeline free from bending, discharge smoothly, and discharge high-concentration waste liquid properly (waste liquid shall be discharged as per local regulations);
- 2) Empty the waste liquid in the high-concentration waste liquid barrel;
- 3) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
- 4) Click the check box corresponding to the connection of waste liquid;
- 5) Click **Execute** to perform maintenance;
- 6) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 7) Click **Save** to save the log.

#### 6.2.4.3. Enhanced detergent volume check

Inadequate balance of enhanced detergent will cause the instrument to fail continuous testing. It is recommended to check the balance of concentrated detergent or intensified detergent before starting the test every day. If it is insufficient, please add it in time.

- Purpose

Check the remaining amount of the enhanced detergent to avoid the test being unable to continue due to insufficient remaining amount.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

#### Operating steps

- 1) Open the reagent-sample tray and observe whether the intensified detergent is sufficient. If it is insufficient, add it in time.
- 2) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
- 3) Click the check box corresponding to checking the balance of acid-base detergent;
- 4) Click **Execute** to perform maintenance;
- 5) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 6) Click **Save** to save the log.

#### 6.2.4.4. Probe syringe check

Reagent-sample probe syringe is a device for precisely distributing samples and reagents.

If the syringe leaks, the dispensing amount will be inaccurate and even damage the syringe. Before starting the analysis every day, be sure to check whether the reagent -sample probe syringe leaks.

■ Purpose

Check the reagent-sample probe syringe for leakage and internal air bubbles.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Maintenance supplies

Clean gauze.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

**Operating steps**

- 1) Open the analyzer maintenance window to see the reagent -sample probe syringe;
- 2) Select **Maintenance-Periodic Maintenance-Daily Maintenance**;
- 3) Click the check box corresponding to checking whether the reagent-sample probe syringe leaks;
- 4) Observe whether the syringe leaks liquid, wipe the joints between the syringe and the manually tightened joints with clean gauze, and check whether the gauze is wet to judge whether the liquid leaks:
  - If not, proceed to the next step.
  - If there is leakage, tighten the hand-tight joint.
  - Check again. If there is any leakage, please tighten the hand tight joint to confirm whether its gasket is in good condition.
- 5) Check whether there are air bubbles inside the syringe. If there are air bubbles, please perform the maintenance operation of "remove air bubbles from the syringe".
- 6) Close the analyzer maintenance window;
- 7) Click **Execute** to perform maintenance;
- 8) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 9) Click **Save** to save the log.

**6.2.4.5. Acid and alkali detergent volume check**

Insufficient balance of acid-base detergent will cause the instrument to be unable to continuously test. It is recommended to check the balance of acid-base detergent before starting the test every day. If it is insufficient, please add it in time.

■ Purpose

Check the remaining content of acid-base detergent to avoid that the test cannot be preceded due to insufficient of it.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

#### Operating steps

- 1) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
- 2) Select the check box corresponding to checking the balance of acid-base detergent, click **Execute**, and then click **Continue** to execute the rotation of reagent-sample probe and drop to the acid-base cleaning position, record the drop in the liquid level of the current cleaning position, and then mechanically reset.
- 3) Click **Execute** to perform maintenance;
- 4) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 5) Click **Save** to save the log.

#### 6.2.4.6. Probe water discharging check

If there are foreign matters or abnormalities in the reagent-sample probe, the test may be affected, leading to inaccurate results. Therefore, please check whether the water outgoing state of the probe is normal before testing every day.

■ Purpose

Check whether the water outgoing state of reagent-sample probe is normal.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

#### Operating steps

- 1) Open the upper cover of the analyzer;
- 2) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
- 3) Select the check box corresponding to check whether the probe outlet water is normal;
- 4) Click **Execute**, and then click **Continue** to clean the inner wall of reagent-sample probe.
- 5) Observe the water outgoing condition when cleaning the inner wall of reagent-sample

probe (as shown in the following figure). If the cleaning water is sprayed or not vertically discharged from the probe tip, the probe may be blocked. Firstly, carry out "intensified cleaning" maintenance operation; if it is still abnormal, it is necessary to carry out the maintenance operation of "replacing reagent-sample probe" or contact the service engineer.

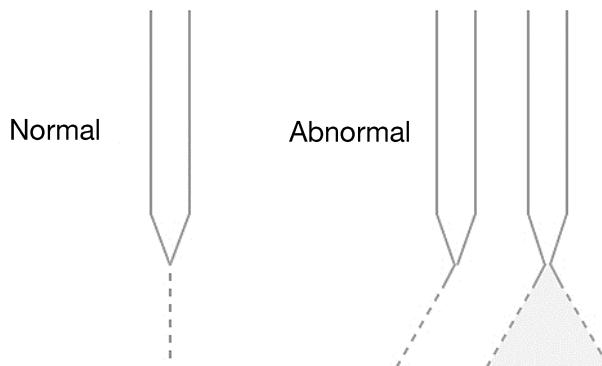


Figure 6-2 Water Outgoing From Probe Inner Wall Cleaning

- 6) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 7) Click **Save** to save the log.

#### 6.2.4.7. Cleaning basin check and cleaning

Foreign matters or abnormalities in the cleaning basin may affect the test and lead to inaccurate results. Therefore, please check whether the outlet state of the outlet tank is normal before testing every day.

■ Purpose

Check whether the outgoing state of the outlet tank is normal.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Instrument status

Before performing maintenance, please ensure that the instrument is powered off or idle.

#### Operating steps

- 1) Open the upper cover of the analyzer;
- 2) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
- 3) Check and clean the check box corresponding to the cleaning basin.
- 4) Click **Execute**, and then click **Continue** to clean the outer wall of reagent-sample probe. Refer to the following figure to observe the water output of the cleaning basin.

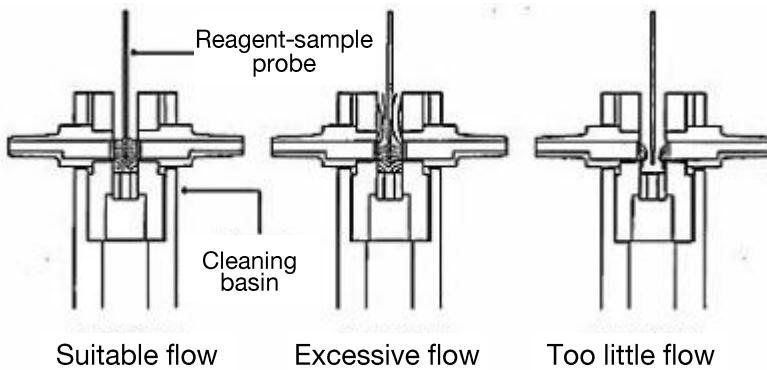


Figure 6-3 Water Outgoing From Probe Outer Wall Cleaning

- 5) If the flow rate is too small, click **Exit** and clean the cleaning basin before performing the operation of the maintenance item;
- 6) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 7) Click **Save** to save the log.

## 6.2.5. Weekly maintenance

Mainly for cleaning reagent-sample storehouse, cleaning sample/reagent bar code scanning window, cleaning analyzer panel, cleaning stirring rod/reagent-sample probe, intensified cleaning (cleaning reagent-sample probe inner wall and reaction cuvette), reaction cuvette detection and light source lamp detection.

### 6.2.5.1. Reagent-sample tray cleaning

When the reagent is accidentally spilled in the reagent-sample tray, or dust is accumulated on the inner wall through visual inspection, it should be cleaned in time to reduce the risk of cross contamination.

#### ■ Purpose

Clean the reagent-sample storehouse assembly, keep the working environment and table clean and tidy, so as to reduce the risk of cross contamination.

#### ■ Maintenance timing

It is recommended to perform this maintenance operation weekly.

#### ■ Maintenance supplies

Clean gauze, deionized water, alcohol, cotton swab.

#### ■ Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.



#### Biological pollution

Biological risk The table surface should be considered infectious and protective gloves

should be worn during operation.

#### Operating steps

- 1) Please confirm that the instrument is in shutdown or idle state;
- 2) Uncover the reagent-sample storehouse, remove the reagent-sample tray and place it in a safe and reliable place;
- 3) Wipe the inner tray with gauze dipped in a small amount of deionized water or alcohol. When necessary, a small amount of neutral detergent can be dipped into gauze to wipe it.
- 4) Put the reagent-sample tray back into the storehouse and cover the tray.
- 5) Select **Maintenance-Daily Maintenance-Weekly Maintenance** to check the corresponding options of cleaning reagent-sample storehouse.
- 6) Click **Execute** to perform maintenance;
- 7) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 8) Click **Save** to save the current log content.

#### **6.2.5.2. Sample/Reagent Barcode Scan Screen Cleaning**

When dust or stains are accumulated in the barcode scanner through visual inspection, it should be cleaned in time to reduce the risk of cross contamination.

■ Maintenance timing

It is recommended to perform this maintenance operation weekly.

■ Maintenance supplies

Clean gauze, deionized water, cotton swab.

■ Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.



#### **Biological pollution**

The table surface should be considered infectious and protective gloves should be worn during operation.

Biological risk

#### **Operating steps**

- 1) Please confirm that the instrument is in shutdown or idle state;
- 2) Uncover the reagent-sample storehouse, remove the reagent-sample tray and place it in a safe and reliable place;
- 3) Wipe the barcode scanning window with gauze dipped in a small amount of deionized water or alcohol;
- 4) Put the reagent-sample tray back into the storehouse and cover it
- 5) Select **Maintenance-Daily Maintenance-Weekly Maintenance** to check the clean sample/reagent barcode scanning window.

- 
- 6) Click **Execute** to perform maintenance;
  - 7) Click **Log** to record the exceptions or other information to be filed during maintenance;
  - 8) Click **Save** to save the current log content.

### 6.2.5.3. Analyzer table cleaning

Reagents, reaction solutions and serum are easy to drip on the analyzer table, which should be removed in time. In order to ensure a clean working environment and reduce biological risks, exposed parts such as analyzer table and tray cover should be cleaned in time.

- Purpose

Clean the analyzer table and tray cover and keep the working environment and table clean and tidy, so as to reduce the risk of cross contamination.

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, cotton swab.

- Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.



#### Biological pollution

Biological risk      The table surface should be considered infectious and protective gloves should be worn during operation.

#### Operating steps

- 1) Please confirm that the instrument is in shutdown or idle state before opening the upper cover of the analyzer.
- 2) Wipe the analyzer table and tray cover with gauze dipped in a small amount of alcohol.
- 3) Cover the upper cover of the analyzer;
- 4) Select **Maintenance-Daily Maintenance-Weekly Maintenance**, and check the relevant options of cleaning analyzer panel;
- 5) Click **Execute** to perform maintenance;
- 6) Click **Log** to record the exceptions or other information to be filed during maintenance;
- 7) Click **Save** to save the current log content.

#### 6.2.5.4. Reagent - sample probe/stirring rod (outer wall) check and cleaning

If the reagent-sample probe and stirring rod are dirty, cross-contamination between samples or reagents may occur and correct analysis results cannot be obtained. To prevent cross contamination, clean reagent-sample probes and stirring rods weekly.

- Purpose

Keep the outer wall of the reagent-sample probe free of contaminants to reduce cross contamination between samples or reagents.

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, cotton swab.

- Instrument status

Before performing maintenance, please ensure that the instrument is in shutdown or idle state.



#### Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Biological risk

#### Operating steps

- 1) Click **Maintenance-Daily Maintenance-Weekly Maintenance** to check and clean the corresponding options of reagent-sample probe/stirring rod (outer wall).
- 2) Click **Execute-Continue** to perform reagent-sample probe reset operation, click **Continue** to reset the stirring rod, and then descend to the cleaning basin to clean the outer wall. Reset the stirring rod vertically after 5 seconds. Click **Continue** to reset the reagent-sample probe, click **Continue** to lower the cleaning basin to be cleaned for outer wall cleaning after reset, and then reset vertically after 5 seconds.

#### Operating steps for cleaning the outer wall of reagent-sample probe

Step	Process prompt
1	Click <b>Continue</b> and the reagent-sample probe will be in the state to be maintained
2	Please use clean gauze to dip in alcohol and wipe the outer wall of reagent-sample probe until it is clean and smooth
	After cleaning, click <b>Continue</b> to proceed to the next step. Please stay away from the movement area of reagent-sample probe
3	This maintenance has been completed
	Click <b>Continue</b> to exit the maintenance status

- 3) After cleaning, click **exit**.

### 6.2.5.5. Intensified cleaning

Use acid-base detergent to clean reagent-sample probe.

■ Purpose

Keep the outer wall of the reagent-sample probe free of contaminants to reduce cross contamination between samples or reagents.

It is recommended to perform this maintenance operation weekly.

■ Instrument status

Before performing maintenance, please ensure that the instrument is in shutdown or idle state.

#### Operating steps of intensified cleaning

Step	Process prompt
1	Preparation: place a bottle of acid-base cleaning agent (cleaning dose > 50 ml) at the acid-base cleaning position
	Check the option to directly perform dirty cuvette detection after intensified cleaning
	Click <b>Continue</b> , the system will start to perform intensified cleaning
2	Please wait while the system performs reaction cuvette testing
	After completion, the next step will be automatically entered
3	This maintenance has been completed
	Click <b>Continue</b> to exit the maintenance status

### 6.2.5.6. Dirty cuvette detection

Judging whether the reaction cuvette is dirty or not and whether the light source lamp is too weak by testing the water blank of each reaction cuvette.

#### Dirty reaction cuvette detection operation steps

Step	Process prompt
1	First, make sure that the startup time is more than 30 min so that the light source is stable. Otherwise, please exit the detection process
	Select whether to proceed with "residual cuvette detection"
	Click <b>Continue</b> to start the reaction cuvette (dirty) test
2	Please wait while the system detects the reaction cuvette (dirty)
	After completion, the next step will be automatically entered
3	This maintenance has been completed
	Click <b>Continue</b> to exit the maintenance status

### 6.2.5.7. Cuvette residual detection

On the premise of completing the dirty cuvette test, whether the reaction cuvette is a

residual cuvette is judged by testing the water blank dynamic AD fluctuation of each channel wavelength of each reaction cuvette.

#### Operating steps for residual cuvettes in reaction cuvettes

Step	Process prompt
1	First, make sure that the startup time is more than 30 min so that the light source is stable. Otherwise, please exit the detection process
	Place a box of deionized water (>20 mL) at # 1 reagent position
	Click <b>Continue</b> to start the reaction cuvette test
2	Please wait while the system performs reaction cuvette testing
	After completion, the next step will be automatically entered
3	This maintenance has been completed
	Click <b>Continue</b> to exit the maintenance status

#### 6.2.6. Monthly maintenance

- Maintenance item
 

Clean ball spline and reagent-sample probe and stirring rod cleaning basin
- Operational flow
  - 1) Manual maintenance items
 

Clean the ball spline (to be done with the analysis part switch off)
  - 2) Semi-automatic maintenance item
 

Clean the cleaning basin for reagent-sample probe and stirring rod

Purpose: to prevent dust from depositing in the cleaning basin and blocking the cleaning basin after a long time.

#### Operating steps for cleaning the cleaning basin

Step	Process prompt
1	Click <b>Continue</b> to clean the cleaning basin for reagent-sample probe and stirring rod according to the following prompts
2	Manually remove the reagent-sample probe and the rocker arm of the stirring rod from the cleaning basin
	Use the label to dip NaClO and wipe each cleaning basin
	After cleaning is completed, Click <b>Continue</b> to proceed to the next step. Please keep away from the moving area of reagent-sample probe and stirring rod pair
3	This maintenance has been completed
	Click <b>Continue</b> to exit the maintenance status

## 6.3. Irregular maintenance items

### 6.3.1. Yearly maintenance

#### 6.3.1.1. Overheating protection device

In order to ensure the effective operation of the equipment, the safety inspection of the overheating protection device should be performed once a year. Methods as below:

Put the plastic sealing part of the temperature protection switch in 90 ~ 100 °C water (or boiled water) for 5 minutes. If the heating wire which measured by a multimeter breaks, the overheat protection device is normal, otherwise it will fail.



Repeated tests in this section may damage equipment and reduce protection against danger.

Caution

#### 6.3.1.2. Cleaning basin cleaning



##### Biological pollution

All stains should be considered infectious and protective gloves should be worn during operation.

Biological risk

- 1) Turn off the analysis unit;
- 2) Dip a cotton swab into the detergent, gently wipe the inner and outer walls of the cleaning basin of the reagent-sample probe and stirring rod until there is no obvious stain, and then dry with clean gauze.

#### 6.3.1.3. Cuvette cleaning

- 1) Turn off the analysis unit;
- 2) Remove the cleaning head and remove the reaction tray cover.
- 3) Loosen the reaction tray fixing screw;
- 4) Hold the two sides of the reaction tray with both hands respectively, and evenly exert upward force to remove the reaction tray;
- 5) Dip clean gauze or cotton swab into the supernatant lotion, clean all parts of the inner wall of the reaction tank until there is no obvious stain, and then dry with clean gauze;
- 6) Install the reaction tray and fix the fastening screws;
- 7) Cover the reaction tray, and then install the cleaning head.



#### Biological pollution

All stains should be considered infectious and protective gloves should be worn during operation.  
Biological risk

#### 6.3.1.4. Drive rod wipe

- 1) Turn off the switch of the analysis unit;
- 2) Move the stirring rod so that its driving rod rotates to an angle suitable for wiping;
- 3) Wipe the drive rod up and down lightly with clean gauze until there are no obvious dust or stains, then apply lubricating oil, and pull the drive rod up and down to evenly distribute the lubricating oil on the drive rod;
- 4) Wipe the driving rod of the reagent-sample probe by same method ;
- 5) Move the reagent-sample probe and stirring rod above the corresponding cleaning basin.

#### 6.3.1.5. Check pure water bucket

On the left side of the analyzer, a pure water bucket will be placed.

Check the pure water bucket: check whether the bottom of the pure water bucket is clean. If it is dirty, clean the pure water bucket thoroughly before use.

#### 6.3.1.6. Clean probe tube/suction nozzle of cuvette

If the probe tube of the cuvette cleaning mechanism is not clean, there will be adhesion of reaction liquid, moisture and the like, which should be checked in time after daily shutdown. In case of the above situation, please refer to the following steps for cleaning:

- 1) Dip a clean cotton swab with absolute ethyl alcohol and gently wipe the drainage probe tube and probe tip until there is no obvious adherent
- 2) Dip a clean cotton swab with absolute ethyl alcohol, and gently wipe the suction probe tube and probe tip until there is no obvious adherent.
- 3) Clean cotton swabs with purified water and gently wipe the four sides and upper and lower parts of the suction nozzle until there is no obvious adherent.
- 4) Dip a clean cotton swab with absolute ethyl alcohol and gently wipe the four sides and upper and lower parts of the suction nozzle until there is no obvious adherent.



Attention

When cleaning, attention should be paid to the possibility that cotton fibers on cotton swabs may be clamped between the drainage probe tube and the suction probe tube, and the cotton fibers should be removed in time if necessary.



Biological risk

**Biological pollution**

All parts shall be considered infectious and protective gloves shall be worn during operation.

**6.3.1.7. Waste container cleaning**

This step can be omitted if the waste liquid is directly discharged into the sewer; otherwise, it will be carried out according to the following step:

- 1) Unscrew the waste liquid container cover and take out the waste liquid sensor and waste liquid pipe;
- 2) Take out the waste liquid container, wash it thoroughly with a brush and then put it in.



Biological risk

**Biological pollution**

All waste liquid shall be considered infectious and protective gloves shall be worn during operation.

**6.3.1.8. Probe dredge**

When the probe is blocked, it needs to be dredged immediately.

- 1) Turn off the analysis unit;
- 2) Turn the reagent-sample probe to the appropriate position and open the upper cover of the reagent-sample probe rocker arm;
- 3) Pull off the connection line with the liquid level detection plate;
- 4) Loosen the teflon tube connecting the reagent-sample probe;
- 5) Loosen the compression spring piece;
- 6) Take out reagent-sample probe upwards;
- 7) Use stainless steel wire with an inner diameter of 0.3 mm to dredge the reagent-sample probe upwards from the probe tip, and dredge repeatedly back and forth for many times;
- 8) Connect a disposable syringe with a reagent-sample probe through a matching hose, draw water into the probe tube through the syringe, and make sure that water is ejected from the probe tip in a straight line, which indicates that the probe tube has been dredged;
- 9) Install the reagent-sample probe and close the cover of the rocker arm in the reverse sequence of the above operation;
- 10) Move the reagent-sample probe above the cleaning basin.



#### Biological pollution

Biological risk

Reagent-sample probes should be considered infectious and protective gloves should be worn during operation.

#### 6.3.1.9. Probe replacement

When the probe is broken, bent or cannot be dredged after being blocked, it needs to be replaced immediately. Refer to "Sample Probe Dredge" in the previous section for the operation process.

- 1) Turn off the analysis unit;
- 2) Move the reagent-sample probe to a suitable position, open the upper cover of the reagent-sample probe rocker arm, loosen the teflon tube, and pull off the lead of the liquid level detection sensor;
- 3) Loosen the compression spring piece and take out the reagent-sample probe;
- 4) Install the new probe on the rocker arm, press on the spring leaf, connect the teflon tube, insert the lead of the liquid level detection sensor, and close the upper cover of the rocker arm;
- 5) Move the reagent-sample probe above the cleaning basin.



#### Biological pollution

Biological risk

Reagent-sample probe should be considered infectious and protective gloves should be worn during operation.

#### 6.3.1.10. Stirring rod replacement

When the stirring rod is broken, bent or frequently hung, it needs to be replaced immediately.

- 1) Turn off the analysis unit;
- 2) Move the stirring rod to a suitable position;
- 3) Loosen the two top screws fixed on the rotating shaft of the stirring motor;
- 4) Take off the stirring rod;
- 5) Install the new stirring rod upward into the rotating shaft of the motor until it touches.
- 6) Fix the stirring rod on the rotating shaft of the stirring motor by using two jacking screws.



#### Biological pollution

Biological risk

Mixing rod shall be considered infectious and protective gloves shall be worn during operation.

### 6.3.1.11. Bulbs replacement

When the bulb is used for more than half a year, or when the analyzer prompts that the bulb needs to be replaced, it needs to be replaced immediately.

Note: before replacing the bulb, make sure that the power supply of the analysis unit is turned off; otherwise the light beam emitted by the light bulb will cause damage to eyes.



Caution

#### Screw falls off

When loosening or fixing the bulb screws, be careful not to fall off the screws.

- 1) Turn off the switch of the analysis unit and carry out the following steps after half an hour;
- 2) Take off the automatic cleaning head, and then remove the reaction tray cover;
- 3) After removing the reaction tray, loosen the fixing screws on the bulb base with M3 hexagonal screwdriver;
- 4) After the light source lamp is removed, loosen the power cord of the light source lamp on the binding post;
- 5) Take out the old bulb;
- 6) Install the new bulb, screw in the fixing screw, and plug in the power cord of the new bulb;
- 7) Install the reaction tray and screw on the fixing screw;
- 8) Close the cover of the reaction tray and install the cleaning head.



High temperature

#### High temperature, scald

Before replacing the bulb, please turn off the power switch and wait at least 30 minutes until the lamp has cooled down.



Strong light

Before replacing the bulb, make sure that the power of the analysis unit is turned off, otherwise the light beam from the lamp will cause eye damage.

### 6.3.1.12. Syringe replacement

- 1) Open the maintenance window on the left rear of the analyzer to see the reagent-sample probe syringe;
- 2) Firstly, loosen up the fixing screws at the piston end of the syringe, and then loosen up the two fixing screws of the tee joint;
- 3) Take out the syringe and tee joint, pinch the metal part on the upper part of the syringe,

rotate counterclockwise to separate the syringe from the tee joint, and take off the syringe;

- 4) Push the metal thread on the upper part of the new syringe into the thread opening of the tee joint and rotate clockwise to fix it;



#### **Sealing washer**

Caution

There is a sealing gasket in the threaded opening of the tee joint, be careful not to lose it when disassembling.

- 5) Place the syringe in the installation position, and sleeve the piston end of the syringe into the drive screw; screw on the tee joint and the fixing screw of the syringe piston end.

#### **6.3.1.13. Peristaltic pump head replacement**

- 1) Turn off the switch of the analysis unit and open the maintenance window at the left rear of the analyzer to see the peristaltic pump;
- 2) Pull out the peristaltic pump head which is connected with rubber tube from the pipe. Then press the snap on both ends of peristaltic pump head and pull out the pump head. Replace a new pump head;
- 3) Replace the new peristaltic pump head, connect the pipeline and install the maintenance window.

#### **6.3.1.14. Cleaning and replacing liquid tubes**

The liquid tubes need irregularly maintenance every six months or one year by engineers. The instrument casing needs to be disassembled to check whether the pipeline is dirty or blocked. If there is, remove it and wash it with 84 disinfectant and water or replace it directly.

## 6.4. Replacement parts list

### 6.4.1. Components for users replacement

- Reagent-sample probe, stirring rod
- Injection syringe
- Bulb
- Peristaltic pump tube

### 6.4.2. Components for engineers replacement

- Main power switch
- Power switch of analysis unit
- Overheating protection device
- Other devices

## 6.5. Maintenance log

The following table lists the components to be maintained and gives the recommended maintenance schedule. Please copy these tables monthly and make records in the column corresponding to the maintenance date after the maintenance is completed.

Table 6-1 Daily Maintenance Items

\_\_\_\_ yy \_\_\_\_ mm

	Maintenance items (daily)	Maintenance records																															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
1	Check deionized water connection																																
2	Check waste connection																																
3	Check the remaining amount of concentrated detergent																																
4	Check the reagent-sample probe syringe for leaks																																
5	Check the balance of acid-base detergent																																
6	Check whether the probe outlet water is normal																																
7	Check and clean the cleaning basin																																

Table 6-2 Weekly Maintenance Items

--yy--mm

	<b>Maintenance items (weekly)</b>	<b>Maintenance records</b>																															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
1	Clean the reagent-sample storehouse																																
2	Clean reagent sample barcode scanning window																																
3	Clean the analyzer panel																																
4	Check and clean the stirring rod (outer wall)																																
5	Check and clean reagent-sample probe (outer wall)																																
6	Intensified cleaning																																
7	Reaction cuvette (dirty) detection-cuvette pollution (including light source lampdetection)																																
8	Reaction cuvette (residual) detection-scraping of cuvette inner wall																																

Table 6-3 Monthly Maintenance Items

\_\_\_\_ yy \_\_\_\_ mm

	Maintenance items (monthly)	Maintenance records																														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Clean ball spline																															
2	Clean reagent-sample probe and stirring rod cleaning basin																															

Table 6-4 Other Maintenance Items

\_\_\_\_ yy \_\_\_\_ mm \_\_\_\_ dd

	Maintenance items (other)	Maintenance records																														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	System reset																															
2	Mechanical reset																															
3	The reagent-sample probe syringe exhausts air bubbles																															
4	Routine cleaning of reaction cuvettes																															

## 7. Alarm and Management

### 7.1. Data alarm interface

Data alarm is a kind of mark for abnormal test results, and the corresponding mark is displayed on the software interface to prompt.

1. The remarks column of the interface **Status-Sample Tray** displays all the marks indicating that the test result of the current sample/standard value/QC is abnormal in the current item. If it is blank, the test result is normal. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Calibration	Quality control	Sample
1	ADE	$Adi \leq Adid$ $Adi \leq ADid$	Applicable	Applicable	Applicable
2	RBK	R1 blank absorbance exceeds the limit	Applicable	Applicable	Applicable
3	ABS	Absorbance of working fluid exceeds the limit	Applicable	Applicable	Applicable
4	RCE	Incorrect calculation of reactivity	Applicable	Applicable	Applicable
5	RCT	Reactivity of working fluid exceeds the limit	Applicable	Applicable	Applicable
6	PRO	Abnormal examination of prozone	Applicable	Applicable	Applicable
7	PROE	Error in prozone inspection calculation	Applicable	Applicable	Applicable
8	BOE	Substrate depletion	Applicable	Applicable	Applicable
9	NLN	Non-linearity interval	Applicable	Applicable	Applicable
10	ENC	No calculation interval	Applicable	Applicable	Applicable
11	EXP	Enzyme linearity expansion calculated result reactivity	Applicable	Applicable	Applicable
12	LIN	Linearity is less than the limit	Applicable	Applicable	Applicable
13	MBK	Mixed blank absorbance exceeds limit	Applicable	/	/
14	BLK	Blank reactivity exceeds limit	Applicable	/	/

15	RRN	Check if the sample reactivity exceeds that of maximum concentration calibrator	/	Applicable	Applicable
16	RRNE	The concentration calculation failed after exceeding the reactivity of the maximum concentration calibrator	/	Applicable	Applicable
17	LOW	The sample reactivity is lower than the minimum concentration standard reactivity check	/	Applicable	Applicable
18	LRG	Sample concentration exceeds the upper limit of linearity range	/	Applicable	Applicable
19	LRL	Sample concentration exceeds the lower limit of linearity range	/	Applicable	Applicable
20	↑!	Sample concentration exceeds the upper limit of critical value range	/	/	Applicable
21	↓!	Sample concentration exceeds the lower limit of critical value range	/	/	Applicable
22	↑	Sample concentration exceeds the upper limit of normal reference range	/	/	Applicable
23	↓	Sample concentration exceeds the lower limit of normal reference range	/	/	Applicable

2. The "Mark" in the result query interface indicates that the sample test result is abnormal. The result is normal in case of blank display. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Identification	Prompt
1	ADE	$AD_{is} \leq AD_{id}$		Applicable
2	RBK	R1 blank absorbance exceeds the limit		Applicable
3	ABS	Absorbance of working fluid exceeds the limit		Applicable
4	RCE	Incorrect calculation of reactivity		Applicable

5	RCT	Reactivity of working fluid exceeds the limit		Applicable
6	PRO	Abnormal examination of prozone		Applicable
7	PROE	Error in prozone inspection calculation		Applicable
8	BOE	Substrate depletion		Applicable
9	NLN	Non-linearity interval		Applicable
10	ENC	No calculation interval		Applicable
11	EXP	Reactivity of enzyme linearity expansion calculation results		Applicable
12	LIN	Linearity is less than the limit		Applicable
13	RRN	Sample reactivity exceeds maximum concentration standard reactivity examination		Applicable
14	RRNE	The concentration calculation failed after exceeding the maximum concentration standard reaction degree		Applicable
15	LOW	The sample reactivity is lower than the minimum concentration standard reactivity check		Applicable
16	LRG	Sample concentration exceeds the upper limit of linearity range		Applicable
17	LRL	Sample concentration exceeds the lower limit of linearity range		Applicable
18	↑!	Sample concentration exceeds the upper limit of critical value range	Applicable	
19	↓!	Sample concentration exceeds the lower limit of critical value range	Applicable	
20	↑	Sample concentration exceeds the upper limit of normal reference range	Applicable	
21	↓	Sample concentration exceeds the lower limit of normal reference range	Applicable	
22	ER	Use expired reagent		Applicable
23	DCP	Use deferred calibration parameters		Applicable

3. The "Mark" in **Calibration-Calibration Result** indicates that the calibration test result is abnormal. The result is normal in case of blank display. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Prompt
1	DMON	Non-linear calibration data is not monotonous	Applicable

2	CDE	Concentration divided by 0 (reactivity 0)	Applicable
3	COV	Nonlinear calibration iteration does not converge	Applicable
4	CMON	The nonlinear calibration curve is not monotonous	Applicable
5	ER	Use expired reagent	Applicable

4. The "Mark" in the interface of **Quality Control-Quality Control Data** indicates that the quality control test result is abnormal. The result is normal in case of blank display. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Prompt
1	ADE	ADi≤ADid	Applicable
2	RBK	R1 blank absorbance exceeds the limit	Applicable
3	ABS	Absorbance of working fluid exceeds the limit	Applicable
4	RCE	Incorrect calculation of reactivity	Applicable
5	RCT	Reactivity of working fluid exceeds the limit	Applicable
6	PRO	Abnormal examination of prozone	Applicable
7	PROE	Error in prozone inspection calculation	Applicable
8	BOE	Substrate depletion	Applicable
9	NLN	Non-linearity interval	Applicable
10	ENC	No calculation interval	Applicable
11	EXP	Reactivity of enzyme linearity expansion calculation results	Applicable
12	LIN	Linearity is less than the limit	Applicable
13	RRN	Check whether the reactivity of QC exceeds the maximum concentration of standard value	Applicable
14	RRNE	The concentration calculation failed because of exceeding the reactivity of maximum concentration calibrator	Applicable
15	LOW	The reactivity of the QC sample is lower than that of the minimum concentration standard value	Applicable
16	LRG	The concentration of the QC sample exceeds the upper limit of the linearity range	Applicable
17	LRL	The concentration of the QC sample exceeds the lower limit of the linearity range	Applicable
18	ER	Use expired reagent	Applicable
19	DCP	Use deferred calibration parameters	Applicable

## 7.2. Instrument alarm and management

### 7.2.1. Overview

When the analyzer gives an alarm, according to the alarm level, the system will automatically process it in the following 7 ways, and display it with a high-brightness red bar at the bottom of the operation software interface. After clicking on the red bar, detailed fault information, possible causes and solutions will pop up.

1) Prohibit testing

Only diagnosis and maintenance are allowed, and no tests are allowed to start.

2) Shutdown

Stop all current tests; the analyzer is in standby state, waiting for wake up.

3) Stop the new test

Stop all tests that have not yet started, and continue the tests that have been added.

4) Stop testing related samples

Stop testing some samples and continue other tests.

5) Stop testing related reagents

Stop testing some reagents and continue other tests.

6) Warning

Only the warning message pops up, and the analyzer does not make any processing.

7) Prompt

Only the prompt message pops up, and the analyzer does not make any processing.

This chapter lists all the fault alarm information of the system and their corresponding treatment measures. Please deal with the system in a timely manner according to the treatment measures provided. If the alarm state cannot be released after the measures are taken, please contact Zybio.

### 7.2.2. Alarm information inquiry

EXC2X series chemistry analyzer instrument operation error query, click **Maintenance-Alarm** to enter the following figure:

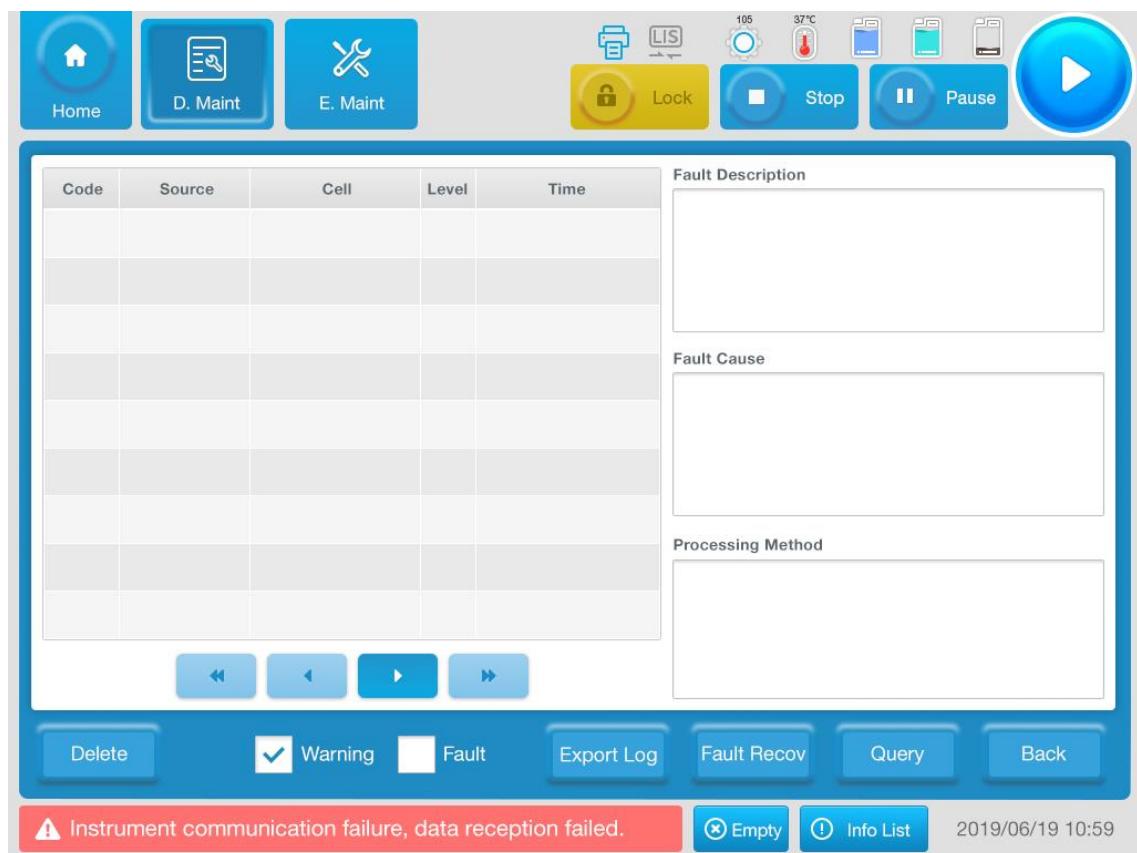


Figure 7-1 Alarm

### 7.2.3. Instrument Operation Error Table

Malfunction code	Error Description	Error Explanation	Troubleshooting
F00001	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00002	A unit malfunctioned during the recovery period, recovery failed, but the photoelectric data collection can continue.	A unit malfunctioned during execution	Log out and reboot the host computer, start Power On Self Test
F00003	A unit malfunctioned during period recovery, recovery failed, and the host computer is interrupted	A unit malfunctioned during execution	Log out and reboot the host computer, start Power On Self Test
F00004	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00005	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00006	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00007	A unit malfunctioned during periodic test	Error in execution of a unit	Execute the periodic recovery command

F00008	The sampling probe is not in the vertical start position and cannot be rotated	<ul style="list-style-type: none"> <li>1. The sampling probe is not in the vertical start position;</li> <li>2. Malfunction of the vertical start position sensor of the sampling probe or wire malfunction.</li> </ul>	<p>Check the wires and connectors, execute the vertical reset command of the sampling probe first, and then execute the corresponding rotation command. If the error persists, please contact the Technical Support Department of Zybio Inc.</p>
F00009	During the lowering of the sampling probe, the surface of the enhanced cleaning solution can be detected, but the enhanced cleaning solution is insufficient (the sampling probe will touch the bottom of the reagent cup in the following 5 steps or less)	<ul style="list-style-type: none"> <li>1. Insufficient enhanced cleaning solution.</li> </ul>	<p>1. Replenish the enhanced cleaning solution. If the problem persists, please contact the Technical Support Department of Zybio Inc.</p>
F00010	During the lowering of the sampling probe, the surface of the enhanced cleaning solution cannot be detected, indicating malfunction of the liquid surface sensor of the sampling probe or no enhanced cleaning solution in the cleaning container.	<ul style="list-style-type: none"> <li>1. No enhanced cleaning solution;</li> <li>2. Malfunction of the liquid surface sensor.</li> </ul>	<p>1. Replenish reagents, 2. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc.</p>

F00011	During the vertical movement of the sampling probe to the start position, no signal for the start position sensor was detected till it completes its maximum number of steps.	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor wire connection of stepper motor leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00012	Collision occurred during the vertical downward movement of the sampling probe.	<ol style="list-style-type: none"> <li>1. The reagent bottle cap is not open;</li> <li>2. The sample tube cover is not open;</li> <li>3. Reagent/sample tray cover or reaction tray cover is not positioned correctly;</li> <li>4. Strong electromagnetic interference;</li> <li>5. The collision sensor is broken or poor wire connection.</li> </ol>	<ol style="list-style-type: none"> <li>1. Check whether the reagent bottle cap is open and whether the reagent is misplaced;</li> <li>2. Check whether the sample tube cover is open and whether the sample is misplaced;</li> <li>3. Place the reagent/sample tray cover and the reaction tray cover in the correct positions;</li> <li>4. Eliminate possible electromagnetic interference.</li> </ol> <p>If the problem persists, please contact the Technical Support Department of Zybio Inc.</p>

F00013	During the vertical downward movement of the sampling probe from the start position, the sampling probe did not leave the start position before the specified number of steps is completed, indicating malfunction of the start position sensor of the sampling probe or lost steps.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00014	The liquid surface is detected before the sampling probe reaches the mouth of the reagent bottle during its lowering process, indicating malfunction of the liquid surface sensor of the sampling probe or water droplets on the sampling probe tip.	1. The dirty tip of the sampling probe leads to water droplets hanging on the tip; 2. Insufficient cleaning solution in the container leads to water hanging on the sampling probe tip; 3. The sensitivity of the liquid surface sensor increases; 4. Strong electromagnetic interference.	1. Check the surface level of the cleaning container. If the cleaning solution is insufficient, replenish it immediately. 2. Check the sampling probe tip. If it is dirty, wipe it lightly with absorbent cotton swab dipped in absolute ethanol. 3. Eliminate possible electromagnetic interference. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00015	During the lowering of the sampling probe, the liquid surface of the reagent can be detected, but the amount of reagent is insufficient, the sampling probe will touch the bottom of the reagent cup in the following 5 steps or less.	1. Insufficient reagent	1. Add reagents. If the problem persists, please contact the Technical Support Department of Zybio Inc.

F00016	During the lowering of the sampling probe, the surface of the reagent cannot be detected, indicating malfunction of the liquid surface sensor of the sampling probe or no reagent in the reagent bottle.	1. No reagent; 2. Reagent misplaced; 3. Malfunction of the liquid surface sensor.	1. Check the position of the reagent; 2. Add reagent 3. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00017	The sampling probe is not in the vertical start position and cannot reach the specified position. If operate by force, the sampling probe will be damaged, so the operation cannot be carried out.	The sampling probe is not in the vertical start position	1. Execute the vertical reset command of the sampling probe, and then execute the related lowering command. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00018	Although there was no intake of the sample in the current period, when moving down to the reaction cup, it was detected that the sampling probe was not in the vertical start position.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00019	There was intake of the sample in the current period, but when moving down to the reaction cup, it was detected that the sampling probe was not in the vertical start position.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00020	Although there was intake of the sample before, when cleaning the sampling probe, it was found that the sampling probe was not in the start position and could not be lowered to complete the cleaning.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00021	Although there was no intake of the sample before, when cleaning the sampling probe, it was found that the sampling probe was not in the start position and could not be lowered to complete the cleaning.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00022	The sampling probe is not in the start position and cannot be lowered to the specified position to complete the enhanced cleaning	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00023	There was intake of the sample, but the sampling probe was not in the start position, and the sampling probe could not be lowered to the cleaning container to release the cleaning solution and complete cleaning	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00024	Although there was no intake of the sample, the sampling probe was not in the start position and sampling probe could not be lowered to the cleaning container and complete cleaning process.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3. The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00025	During the horizontal rotation of the sampling probe to the start position, the start position sensor did not be detected by the sampling probe before the maximum number of steps is completed, the start position sensor may be broken or there is step loss.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00026	The sampling probe was originally at the start position. To rotate horizontally to the start position, it must rotate counterclockwise for a certain number of steps before rotating clockwise to the start position. The sampling probe did not leave the start position after a specified number of steps had been completed. The start position sensor may be broken or there is step loss.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00027	During the horizontal rotation of the sampling probe to the cleaning position, the cleaning position was not found before the specified number of steps were completed. The encoding disk sensor may be broken or there is step loss of the motor.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00028	The sampling probe could not rotate to the position of the specified reagent cup, and the horizontal encoding disk sensor of the sampling probe may be broken or there was step loss.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00029	The sampling probe could not rotate to the specified sample cup, the horizontal encoding disk sensor may be broken or there was step loss.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00030	Unable to find the position of the sampling probe before rotation. The problem may be that the horizontal rotation reset of the sampling probe was not performed prior to the rotation, or there was an error during the rotation reset. Please complete the horizontal rotation reset of the sampling probe first.	1. No rotation reset command is executed	1. Execute the rotation reset command of the sampling probe, and then execute the rotation command. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00031	During the horizontal rotation of the sampling probe to the position of the reaction tray, the position of the reaction tray was not found before the specified number of steps was completed	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00032	The liquid surface is detected before the sampling probe reaches the mouth of the sample cup during its lowering process, indicating malfunction of the liquid surface sensor of the sampling probe or water droplets on the sampling probe tip.	<ul style="list-style-type: none"> <li>1. The dirty tip of the sampling probe leads to water droplets hanging on the tip;</li> <li>2. Insufficient cleaning solution in the container leads to water hanging on the sampling probe tip;</li> <li>3. The sensitivity of the liquid surface sensor increases;</li> <li>4. Strong electromagnetic interference.</li> </ul>	<p>1. Check the surface level of the cleaning container. If the cleaning solution is insufficient, replenish it immediately.</p> <p>2. Check the sampling probe tip. If it is dirty, wipe it lightly with absorbent cotton swab dipped in absolute ethanol.</p> <p>3. Eliminate possible electromagnetic interference.</p> <p>If the problem persists, please contact the Technical Support Department of Zybio Inc.</p>
F00033	When cleaning the inner wall of the sampling probe, the electromagnetic valve cannot be opened correctly to complete cleaning	<ul style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. The cleaning solution valve is broken or poor wire connection;</li> <li>3. The valve driver board is broken.</li> </ul>	<p>After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.</p>
F00034	When the liquid pump is working in a long time or cleaning the outer wall of the sampling probe, the liquid pump cannot be opened.	<ul style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. The cleaning fluid pump is broken or poor wire connection;</li> <li>3. The pump driver board is broken.</li> </ul>	<p>After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.</p>

F00035	When cleaning the inner and outer walls of the sampling probe, the electromagnetic valve was first opened, but the liquid pump could not be normally turned on after 0.8 seconds. Therefore, the electromagnetic valve needs to be closed, but the electromagnetic valve could not be normally closed.	<ol style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. The inner wall cleaning fluid valve is broken or poor wire connection;</li> <li>3. The cleaning pump is broken or poor wire connection;</li> <li>4. The pump valve driver board is broken.</li> </ol>	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00036	After cleaning the sampling probe, neither the liquid pump nor the electromagnetic valve can be turned off or closed correctly.	<ol style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. The inner wall cleaning fluid valve is broken or poor wire connection;</li> <li>3. The cleaning pump is broken or poor wire connection;</li> <li>4. The pump valve driver board is broken.</li> </ol>	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00037	The electromagnetic valve cannot be normally closed after cleaning the sampling probe.	<ol style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. The inner wall cleaning fluid valve is broken or poor wire connection;</li> <li>3. The valve driver board is broken.</li> </ol>	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00038	After cleaning the sampling probe, the liquid pump cannot be normally turned off.	<ol style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. The cleaning pump is broken or poor wire connection;</li> <li>3. The pump driver board is broken.</li> </ol>	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00039	When cleaning the inner and outer walls of the sampling probe, the cleaning valve on the inner and outer walls of the sampling probe cannot be normally opened.	1. Strong electromagnetic interference; 2. The inner wall cleaning fluid valve is broken or poor wire connection; 3. The valve driver board is broken.	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00040	The sampling syringe could not reach the start position before the maximum number of steps is completed. The start position sensor of the sampling syringe may be broken or there is step loss.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00041	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00042	Checksum error in the command frame received by the sampling probe unit.	1. Strong electromagnetic interference; 2. Loose serial line; 3. Poor serial line connection.	1. Check and fix the serial line after shutdown the machine; 2. After eliminating strong electromagnetic interference. Restart the machine.  If the error persists, please contact the Technical Support Department of Zybio Inc.

F00043	During the lowering of the sampling probe, the liquid surface of the sample can be detected, but the amount of sample is insufficient (the sampling probe will touch the bottom of the sample cup in the following 5 steps or less).	1. Insufficient sample ;	1. Add sample. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00044	During the lowering of the sampling probe, the liquid surface of the sample can not be detected, indicating the liquid surface sensor of the sampling probe may be broken or there is no sample in the sample bottle.	1. No samples; 2. Misposition of the sample; 3. Malfunction of the liquid level sensor.	1. Check the position of the sample; 2. Add samples and; 3. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00045	Before rotating the sampling probe to the specified reagent cup position, it was found that the reagent cup position code transmitted in the command was not a number between 1 to 60(for 100 series it should be 1 to 40), and could not rotate in the specified reagent cup position.	The issued command contains illegal cup position number	The command issued by the user must contain legal cup position number.
F00046	When the sampling probe moves to the vertical start position, it reaches the vertical start position too early.	The possible reasons are that the vertical start position sensor of the sampling probe is broken or there is external light interference.	Check whether there is light interference, if the problem persists, contact the manufacturer.

F00047	When the sampling syringe moves to the vertical start position, it reaches the vertical start position too early	The possible reasons are that the vertical start position sensor of the sampling syringe is broken or there is external light interference.	Check whether there is light interference first, if the problem persists, contact the manufacturer.
F00048	During the vertical reset of the sampling syringe, it cannot leave the vertical start position.	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor wire connection of stepper motor leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00049	Before rotating the sampling probe to the specified sample cup position, it was found that the sample cup position transmitted in the command was not a number between 1 to 60 (for 100 series it should be 1 to 40), cup and the sampling probe could not be rotated to the specified position.	The issued command contains illegal cup position number	The command issued by the user must contain legal cup position number.
F00050	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command

F00051	Invalid unit command for the sampling probe	The command issued by the host computer is an illegal unit command for the sampling probe	Check whether the issued command are correct
F00052	This indicates that the horizontal encoding disk of the sampling probe is broken or lost step.	<ul style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the stepper motor wires leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. the horizontal encoding disk sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ul>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00053	This indicates that the horizontal encoding disk of the sampling probe is broken or lost step.	<ul style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the stepper motor wires leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. the horizontal encoding disk sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ul>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00054	This indicates that the horizontal encoding disk of the sampling probe is broken or lost step.	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the stepper motor wires leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The horizontal encoding disk sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	<p>After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.</p>
F00055	During online dilution, the liquid surface of the sample can be detected during the lowering process of the sampling probe, but the amount of sample is insufficient (the sampling probe will touch the bottom of the sample cup in the following 5 steps or less).	<ol style="list-style-type: none"> <li>1. Insufficient sample.</li> </ol>	<p>1. Add sample. If the problem persists, please contact the Technical Support Department of Zybio Inc.</p>
F00056	During online dilution, the liquid surface of the sample cannot be detected during the lowering process of the sampling probe, indicating that the liquid surface sensor of the sampling probe is broken or there is no sample in the sample bottle.	<ol style="list-style-type: none"> <li>1. Insufficient sample;</li> <li>2. Misposition of the sample;</li> <li>3. The liquid surface sensor is broken.</li> </ol>	<p>1. Check the position of the sample; 2. Add samples and; 3. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc.</p>

F00057	The start position sensor for of the sampling probe for horizontal rotation is broken or lost steps	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor wire connection of stepper motor leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00058	Insufficient sample in the reaction cup, and there is a risk of damaging the sampling probe when it moves downward	<ol style="list-style-type: none"> <li>1. The amount set by the software is greater than the maximum amount allowed in the reaction cup.</li> </ol>	Please contact the Technical Support Department of Zybio Inc.
F00066	During the rotation of reagent or sample tray, the encoding disk malfunctioned or lost step.	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the step motor wires leads to step loss;</li> <li>3. The step motor is broken;</li> <li>4. The encoding disk is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00067	Indicates malfunction of the start position sensor or lost step	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor connection of the step motor wires leads to step loss;</li> <li>3. The step motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00068	Indicates malfunction of the encoding disk of the reagent tray or lost step	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the step motor wires leads to step loss;</li> <li>3. The step motor is broken;</li> <li>4. The encoding disk is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00069	Indicates malfunction of the encoding disk of the reagent tray or lost step	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the step motor wires leads to step loss;</li> <li>3. The step motor is broken;</li> <li>4. The encoding disk is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00070	The stirring rod did not stop moving until the maximum number of steps was completed, indicating malfunction of the start position sensor of the stirring rod or lost step	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection; 5, motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00071	The stirring rod did not leave the start position until the specified number of steps in the vertically downward direction is completed	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection; 5, motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00072	The stirring rod is not in the start position, and cannot correctly be lowered to the specified position, and lowering by force may damage the stirring rod, so the operation cannot be carried out.	1. The stirring rod is not in the vertical start position; 2. The stirring rod vertical start position sensor malfunction or wire defect.	Check the wire or plug and execute the vertical reset command to the stirring rod. If the problem persists, please contact the Technical Support Department of Zybio Inc..

F00073	The stirring motor cannot be turned on correctly.	<ul style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. Poor wire connection;</li> <li>3. The driver board is broken.</li> </ul>	After eliminating the strong electromagnetic interference, check the wires and boards and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00074	The stirring motor cannot be correctly turned off.	<ul style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. Poor wire connection;</li> <li>3. The driver board is broken.</li> </ul>	After eliminating the strong electromagnetic interference, check the wires and boards and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00079	During the horizontal rotation of the stirring rod to the start position, the start position was not found before the maximum number of searching steps was completed.	<ul style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor connection of the step motor wires leads to step loss;</li> <li>3. The step motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection;</li> <li>5. motor driver board problem;</li> <li>6. sensor wire or plug problems.</li> </ul>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00080	The stirring rod was already in the start position. To rotate horizontally to the start position, it must first leave the start position and then rotate to the start position again. After the specified number of steps, the stirring rod never left the start position. The start position sensor may be broken or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection; 5. motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00081	During the horizontal rotation of the stirring rod to the cleaning position, no cleaning position was found before the maximum number of searching steps was completed. The encoding disk may be broken, or lost step, or encoding disk signal error happened.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00082	During the horizontal rotation of the stirring rod to the cleaning position, the cleaning position was not found before the maximum number of searching steps was completed in the deceleration system. The encoding disk may be broken, or lost step	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the stepper motor wires leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The horizontal encoding disk sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00083	During the horizontal rotation of the stirring rod to the position of the reaction tray, the reaction tray was not found before the maximum number of searching steps was completed, and the encoding disk may be broken or lost step.	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the stepper motor wires leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The horizontal encoding disk sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00084	During the horizontal rotation of the stirring rod to the position of the reaction tray, the reaction tray was not found before the maximum number of searching steps was completed during deceleration. And the encoding disk may be broken, or lost step.	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the stepper motor wires leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The horizontal encoding disk sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00085	The horizontal position of the stirring rod is unknown before the rotation.	It may be that the horizontal rotation reset for the stirring rod was not done before the rotation or an error occurred during the rotation.	To complete the operation correctly, please complete the horizontal rotation reset of the stirring rod first.
F00086	When the stirring rod moves to the vertical start position, it reaches the vertical start position too early	It maybe that the vertical start position sensor of the stirring rod is broken or there is external light interference.	Check whether there is light interference, if the problem persists, contact the manufacturer.
F00087	The stirring rod is not in the vertical start position and cannot rotate.	1. The stirring rod is not in the vertical start position; 2. Malfunction of the vertical start position sensor of the stirring rod or wire malfunction.	Do the vertical reset command of the stirring rod first, check the wires and connectors, and then execute the rotation command. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00088	Checksum error in the command frame received by the stirring rod unit	1. Strong electromagnetic interference; 2. Loose serial line; 3. Poor serial line connection.	1. Check and fix the serial line after shutdown the machine; 2. After eliminating strong electromagnetic interference. Restart the machine.  If the error persists, please contact the Technical Support Department of Zybio Inc.

F00089	The cleaning head is not in the vertical start position and the reaction tray cannot be rotated	<ul style="list-style-type: none"> <li>1. The cleaning head is not in the vertical start position;</li> <li>2. Cleaning head vertical start position sensor malfunction or wire malfunction.</li> </ul>	Execute the vertical reset command of the cleaning head first, check the wires and connectors, and then execute the corresponding command. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00090	Error in validating the unit command received by the reaction disk Checksum filed of the command frame is different from the calculated checksum, and the returned command has responded to the incorrect frame. Or invalid command	<ul style="list-style-type: none"> <li>1. Strong electromagnetic interference;</li> <li>2. Loose serial line;</li> <li>3. Poor serial line connection.</li> </ul>	<ul style="list-style-type: none"> <li>1. Check and fix the serial line after shutdown the machine;</li> <li>2. After eliminating strong electromagnetic interference. Restart the machine.</li> </ul> <p>If the error persists, please contact the Technical Support Department of Zybio Inc.</p>
F00091	No signal from the encoding disk is detected before the maximum number of steps to a cup position (the cup before the one that has been stopped) in the reaction tray was completed.	<ul style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor contact of the step motor wires leads to step loss;</li> <li>3. The step motor is broken;</li> <li>4. The encoding disk is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ul>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.

F00092	The start position of the reaction tray is not found after the reaction tray is rotated one round during the process when it rotates to the specified cup position by reaction try start position rotate, indicating the start position sensor of the reaction tray malfunctioned or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00093	While rotating to the static sampling position, no signal was detected by the encoding disk before the maximum number of steps to the position of the stop cup on the reaction tray was completed. Indicates the encoding disk of the reaction tray malfunctioned or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the step motor wires leads to step loss; 3. The step motor is broken; 4. The encoding disk is broken or poor wire connection; 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00094	The stopping position of the stopped cup on the reaction tray cannot be found before the rotation, and the rotation cannot be completed.	The possible reason is that the rotation reset operation of the reaction tray has not been performed before, or the operation of directly rotating the reaction tray motor has been performed after rotation reset of the reaction tray, which makes it impossible to know the current cup position stopped on the reaction tray.	First, perform the rotation reset operation of the reaction disk, then perform other operations. If the problem persists, please contact the Technical Support Department of Zybio Inc.

F00102	Malfunction of the start position sensor or lost step	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor wire connection of stepper motor leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	<p>After eliminating strong light or strong electromagnetic interference, check whether the sensor plug is loose, or whether the sensor wire is broken, and restart the machine. If the error still recurs, please contact the Technical Support Department of Zybio Inc.</p>
F00103	Malfunction of the start position sensor	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor wire connection of stepper motor leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection.</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	<p>After eliminating strong light or strong electromagnetic interference, check whether the sensor plug is loose, or whether the sensor wire is broken, and restart the machine. If the error still recurs, please contact the Technical Support Department of Zybio Inc.</p>

F00104	The cleaning head did not leave the start position until the specified lowering steps is completed	<ol style="list-style-type: none"> <li>1. Strong light or strong electromagnetic interference;</li> <li>2. Poor wire connection of stepper motor leads to step loss;</li> <li>3. The stepper motor is broken;</li> <li>4. The start position sensor is broken or poor wire connection;</li> <li>5. Motor driver board problem;</li> <li>6. Sensor wire or plug problems.</li> </ol>	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc.
F00105	The cleaning head is not in the start position before moving to the cleaning position	Vertical reset of cleaning head is not performed	Perform the vertical reset of the cleaning head before other operations, if the problem persists, please contact the Technical Support Department of Zybio Inc.
F00106	The cleaning head reaches the start position before completing the 185 steps of moving upwards, and cannot continue	The cleaning head was not in the correct position to perform the operation, or the start position sensor of the cleaning head malfunctioned	First, reset the cleaning head vertically, then lower the cleaning head to the cleaning position, and then perform the operation. If the error still recurs, please contact the Technical Support Department of Zybio Inc.
F00107	The waiting time plus the running time of the peristaltic pump exceeds the allowable range.	Illegal waiting time setting for the peristaltic pump	Reset the waiting time of the peristaltic pump

F00108	When the cleaning head is vertically reset, it goes to the vertical start position too early	The problem may be that the start position sensor of the cleaning head malfunctioned or the signal of the start position sensor of the cleaning head is interfered by external light.	Check the sensor, plug and wires of the cleaning head, and then perform this operation. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00111	The current temperature of the reaction tray exceeds the specified temperature value by 10 degrees.	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00112	The reaction tray is not in the normal temperature range (target temperature +/- 2) for the first time after the time for establishing the specified temperature has passed (about 14 minutes).	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00113	When the temperature is normally controlled, the current temperature value deviates from the normal range (target temperature +/- 2) after the time for establishing the specified temperature has passed (about 14 minutes).	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc.

F00114	When the temperature is normally controlled, the temperature exceeds the specified temperature by at least 10 degrees during 10 consecutive temperature detection.	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc.
F00115	The system is currently in a state where parameters cannot be changed.	The analyzer is running	Stop the analyzer and put it in standby.
F00116	When setting the target temperature, its value is higher than 95 degrees.	The target temperature value has been set incorrectly.	Reset the target temperature value.
F00119	The temperature maintains at least 10 degrees higher than the target temperature, and the temperature control automatically shut down. The AD value of the static temperature of 0 may be FF, resulting in a negative value in the result calculation, which may be caused by the failure of the 0 degree reference resistor;	1. The AD value of static temperature 0 may be FF, resulting in a negative value in the result calculation thus resulting in incorrect temperature value, which may be caused by the failure of the 0 degree reference resistor; 2. Temperature AD jumps caused by grid interference.	Contact the Technical Support Department of Zybio Inc. in a timely manner.
F00127	The command received by the master control unit is illegal.	The command received by the master control unit is illegal.	Check whether the command is correct.

## 8. Transportation and Storage

### 8.1. Shipping instructions

The analyzer shall be transported in the packaged state according to the requirements of the order contract, and shall be protected from severe impact, vibration, rain and snow splash and exposure during transportation.

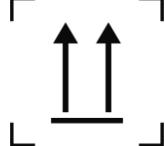
### 8.2. Storage condition

The packaged analyzer shall be stored in a clean room with ambient temperature of -20°C ~ +55°C, relative humidity of 10% ~ 90%, atmospheric pressure of 50.0 Kpa ~ 106.0 Kpa, no corrosive gas and good ventilation.

### 8.3. Package Symbol Explanation



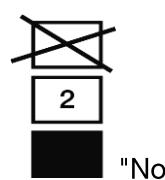
"Fragile": Handle the transport package with care.



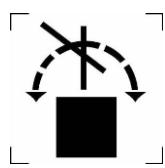
"Upward": The transport package shall be vertically upward during transportation.



"Keep Dry": This transport package cannot be wetted by rain.



"No Stacking": This transport package can only be placed in two layers.



"No Rolling": This transport package cannot be rolled.



"Storage Temperature".

Note: The diagram is for reference only, and the picture of the outer packing box of the product shall prevail.

# Appendix A

## A.1. Product Classification

According to the Classification Catalogue of Medical Devices (2017 Edition), the Chemistry Analyzer belongs to the chemistry analysis equipment in the subdirectory of clinical examination equipment. The management category is class II and the classification code is 22-02.

## A.2. Commonly Used Terminology

### A.2.1. AD value

The photocurrent generated by the light reaching the detector flows through the fixed resistor and is amplified and converted into an optical voltage (analog signal), and the voltage is converted into a value with a corresponding size (the size is related to the number of AD positions selected) through AD conversion (digital-to-analog conversion), and the value is the AD value.

### A.2.2 Dark Current

The value output by the circuit when the light source is not turned on (i.e. when there is no signal light) is expressed in AD value. Dark current is equivalent to circuit background and must be deducted when calculating absorbance.

### A.2.3 Water Blank

Absorbance value when the reaction cuvette is filled with purified water. Because absorbance values are relative, i.e. based on a certain absorbance value, the absorbance of water blank is defined as 0 in EXC2X series Chemistry Analyzer, i.e. the absorbance value of reaction water blank should be subtracted from any other absorbance.

### A.2.4 Photometric Points

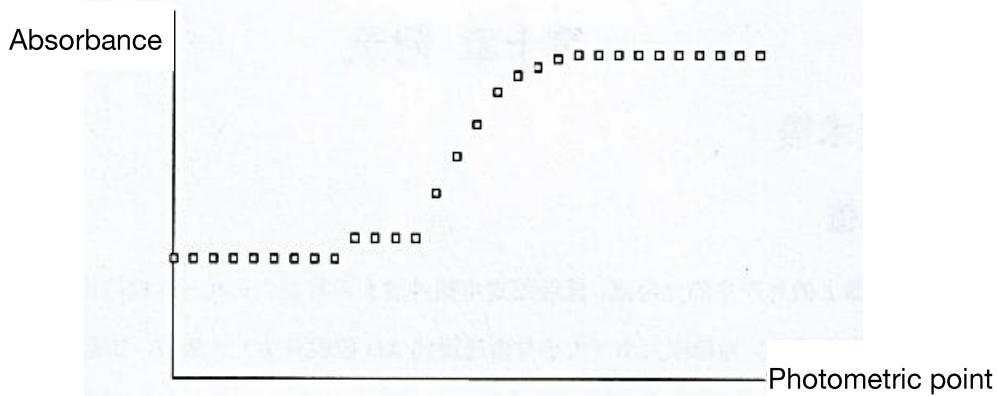
The specific time for photoelectric color comparison is generally expressed in specific numerical values, and there is a strict and fixed time relationship between each photometric point.

### A.2.5 Absorbance

The negative common logarithm of the transmitted light intensity divided by the incident light intensity. In EXC2X series Chemistry Analyzer, the incident light intensity is AD value when the reaction cuvette is filled with deionized water, and the absorbance value displayed is calculated absorbance value  $\times 10000$ .

## A.2.6 Reaction Curve

A series of points consisting of photometric points as horizontal coordinate and absorbance as vertical coordinate. The typical reaction curve of EXC2X series Chemistry Analyzer is as follow:



## A.2.7 Reaction Range

Changes or rates of absorbance before and after the reaction or during the reaction.

## A.2.8 Calibration

Also known as calibration. One or more samples with known concentration (or activity) (also known as calibrators) are measured for their reactivity. According to the calibration method (linear or non-linear) selected by the user, an optimal curve is used to fit the data set (concentration, reactivity) and the mathematical expression of this curve is calculated. Using this curve, the reactivity of the sample with unknown concentration (or activity) can be measured, that is, the concentration (or activity) of the sample can be calculated.

## A.2.9 Calibration Curve

For a series of points consisting of concentration (or activity) as horizontal coordinate and reactivity as vertical ordinate, the curve is fitted with the best mathematical equation.

## A.2.10 Calibration Parameters

Specify other items in the standard curve expression except concentration and reactivity.

## A.3. Consumables List

Serial number	Name of consumables	Specifications/units
1	Detergent	5 L/ barrel
2	Detergent	35 mL/ bottle
3	Detergent	20 mL/ bottle

## A.4. Packing List

Serial number	Name	Quantity
1	Host	1
2	Manual	1
3	Warranty card	1
4	Packing list	1
5	Easy operation guide	1
6	User acceptance form	1
7	Waste liquid drain assembly 1	1
8	Waste liquid drain assembly 2	1
9	Purified water inlet pipe assembly	1
10	Cleaning solution inlet pipe assembly	1
11	Pure water float sensor assembly	1
12	Cleaning solution float sensor assembly	1
13	Waste liquid container level sensor assembly	1
14	Power cord	1

## A.5. Basic Parameters

Model	EXC200	EXC220
Instrument type	Discrete	
Light source	Halogen lamp 12 V, 20 W	
Analytical method	End point method, two-point method, kinetic method, supporting single/dual reagent, single/dual wavelength	
Reaction tray	63 cuvettes with optical diameter of 5mm	
Reagent capability	40	
Sample capability	40	
Sample volume	(2 ~ 50) µL, step by 0.5 µL	
Reagent volume	(10 ~ 400) µL, step by 0.5 µL	
Wavelength	(340~800) nm	
Light splitting method	Post-splitting 12 wavelength	
Power	Not more than 500VA	
Minimum reaction volume (µl)	90	100
Water consumption	≤5 L/H	
Test speed	Constant speed 160 T/H	
Reagent-sample probe	It has the functions of liquid level detection, volume tracking and vertical collision avoidance	
Dimensions (width × depth × height)	710 mm×705 mm×635 mm	

Printing function		Supports HP, EPSON and other printers	
Software component	Name	Software of Chemistry Analyzer	
	Model	EXC200	EXC220
	Release Version	V5	

## A.6. Performance Parameters

Parameter name	Parameter content			
Stray light	Absorbance shall not be less than 4.5 A			
Temperature accuracy and fluctuation	The temperature value is within $\pm 0.2^{\circ}\text{C}$ of the set value, and the fluctuation degree is less than $\pm 0.1^{\circ}\text{C}$			
Carryover	$\leq 0.005\%$			
Linearity range of absorbance	The maximum absorbance of relative bias within $\pm 5\%$ should not be less than 4.0			
Absorbance accuracy	Absorbance value A		Allowable error $\Delta A$	
	0.5		$\pm 0.02$	
	1.0		$\pm 0.04$	
Accuracy and repeatability of sample addition	Category	Adding volume ( $\mu\text{L}$ )	Accuracy error	Coefficient variation
	Sample	2	$\pm 4\%$	$\leq 2\%$
		5	$\pm 4\%$	$\leq 2\%$
		50	$\pm 4\%$	$\leq 1\%$
	Reagent	10	$\pm 3\%$	$\leq 2\%$
		400	$\pm 3\%$	$\leq 1\%$
Clinical intra-item precision	Item name		Concentration range	
	ALT (alanine aminotransferase)		30 U/L~50 U/L	
	UREA (urea)		7.0 mmol/L~11.0 mmol/L	
	TP (total protein)		50.0 g/L~70.0 g/L	

## A.7. Input and Output Equipment



Warning

External equipment such as printers must pass CCC (S&E) mandatory authentication. Using unqualified external equipment may cause abnormal system operation and personal injury.

- External barcode scanner (Optional)
- Printer (Optional)
- Power supply

Voltage	100-240 V~, 50/60 Hz
Input power	≤500 VA

## A.8. Electromagnetic Compatibility

- The radio frequency emission of this equipment is very low and the possibility of interference to nearby electronic equipment is very small.
- Portable and mobile radio frequency communication equipment may affect this equipment, and other equipment used in the vicinity of this equipment at the same time shall meet the relevant requirements of electromagnetic compatibility.
- It is suitable for use in non-domestic and all facilities that are not directly connected to the public low-voltage power supply network of domestic houses.
- The power socket shall have reliable protective grounding measures and shall use the matched power cord, components and accessories that come with it.
- The floor shall be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity shall be at least 30%.
- Network power supply shall have the quality used in typical commercial or hospital environment.
- If the user needs to keep the equipment running continuously during power interruption, it is recommended that the user use uninterruptible power supply.
- The power frequency magnetic field in the expected installation site shall be measured to ensure it is low enough. This equipment should be far away from power frequency magnetic field source. Under special circumstances, magnetic shielding materials should be installed to ensure the normal operation of the equipment.
- This IVD equipment meets the emission and anti-interference requirements specified in GB/T 18268.



Warning

In addition to accessories and cables sold by the manufacturer of this equipment as spare parts for internal components, the use of accessories and cables other than those specified may lead to an increase in equipment emission or a decrease in anti-interference.



Warning

This equipment should not be used close to or stacked on top of other equipment. If it has to be used close to or stacked on top of other equipment, it should be observed and verified that it can operate normally under its own configuration.



Warning

Do not use this equipment near strong radiation sources (e.g. Unshielded RF sources), otherwise it may interfere with the normal operation of the equipment.



Warning

This equipment is designed and inspected as per the Glass 1 Category A in GB4824. In the family environment, this equipment may cause radio interference, which requires protective measures.



Warning

It is recommended that the electromagnetic environment be evaluated before the equipment is used, and the user is responsible for ensuring the electromagnetic compatibility environment of the equipment to enable normal operation.

## A.9. Contamination Levels

Rated pollution level: level 2

## A.10. Working Environment

Working environment	Ambient temperature: 10°C ~ 30°C Environmental relative humidity: 30% ~ 85% Atmospheric pressure: 70.0 KPa ~ 106.0 KPa Altitude: Below 3000m
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Attention

Please be sure to store and use the analyzer under the specified environmental conditions.

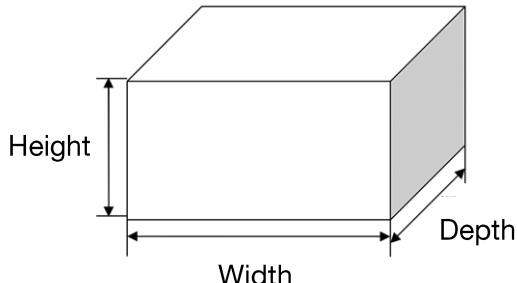
## A.11. Storage Environment

Storage environment	Ambient temperature: -20°C ~ 55°C Relative humidity: 10% ~ 90% Atmospheric pressure: 50 Kpa ~106 Kpa
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## A.12. Transport Environment

Transportation environment	Ambient temperature: -20°C ~ 55°C Relative humidity: 10% ~ 90% Atmospheric pressure: 50 KPa ~106 KPa
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## A.13. Overall Dimensions and Weight



<b>Analyzer</b>	<b>Overall dimensions and weight</b>
Dimensions (Width × Depth × Height)	710 mm×705 mm×635 mm
Weight (Gross Weight)	80 kg

## A.14. Communication Interface

Test port	RS-232 communication serial port (only for engineers for commissioning)
Computer and network interface	Net port

## A.15. Training

In order to use this product correctly and give full play to its performance, Zybio will send its internal after sales service engineers or agents designated by Zybio to train users.

## A.16. Contraindications

None

## A.17. Names and Contents of Toxic and Harmful Substances or Elements

Part name	Toxic and harmful substances or elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr(V)	Polybrominated biphenyl (PBB)	Polybrominated diphenyl ether (PBDE)
Reaction tray assembly	○	○	○	○	○	○
Reagent-sample tray assembly	○	○	○	○	○	○
Reagent-sample probe+stirring rod assembly	○	○	○	○	○	○
Syringe assembly	○	○	○	○	○	○
Rack	○	○	○	×	○	○
Metal casing	○	○	○	×	○	○
Plastic casing	○	○	○	○	○	○
Pumps, valves	○	○	○	○	○	○
Liquid pipeline and joint	○	○	○	○	○	○
Liquid bottle	○	○	○	○	○	○
Heater	○	○	○	○	○	○
Refrigeration module	○	○	○	○	○	○
Fan	○	○	○	○	○	○
Circuit board	○	○	○	○	○	○
Switch	○	○	○	○	○	○
Motor	○	○	○	○	○	○
Wire rod	○	○	○	○	○	○
Optical system	○	○	○	○	×	×
Packaging materials	○	○	○	○	○	○

○: Indicates that the content of the toxic and harmful substances in all homogeneous materials of the component is below the limit specified in SJ/T 11363-2006.

×: Indicates that the content of the toxic and harmful substances in at least one homogeneous material of the component exceeds the limit requirements specified in SJ/T 11363-2006.

Hexavalent chromium is used in the surface coating of metal stamping parts during processing.



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## Chemistry