

# User Manual

## Semi-auto Chemistry Analyzer (Drawell-Silver)



*Please read the manual before installation and operation.*

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## Preface

Thank you for purchasing Semi-auto chemistry analyzer Drawell- Silver.

**Product name:** Semi-auto chemistry analyzer

**Model:** Drawell- Silver

**Intended use:**

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

**Objects:**

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

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

### Versions

This document applies to the latest and later versions of the software listed.

Jan. 2021

Version: A/ 1

Main control board version number: V1.0.9

Screen software version number: V1.0.3

LIS software version number: V1.0

### Declaration of Conformity

This medical device has been assigned to class A according to Annex II + Annex III + Article 17 of IVDR (EU) 2017/746. It bears the mark



### whose single Authorized EU-Representative:

Name: Luxus Lebenswelt GmbH

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Email: info.m@luxuslw.de

## Statement and disclaimer

### Statement

Chongqing Drawell Instrument Co., Ltd. (hereinafter referred to as “our company” or “us”) has the final interpretation of this manual.

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

- Assembly operations, expansion, re-adjustment, improvement and repair are carried out by qualified personnel of our company.
- All repairs involving replacement parts and supporting accessories and consumables are original (original) or approved by our company.
- The product is operated in accordance with this instruction manual.

### Disclaimer

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

- Failure and damage caused by violation of the methods of use, precautions and use described in this manual.
- Due to the external company repair or modification caused by the failure and damage.
- Failure and damage caused by the use of external instruments at the same time.
- Fault and damage caused by inconsistency operating environment (power supply conditions, installation environment, etc.) specified by company.
- Due to earthquakes, floods and other natural disasters caused by failure and damage.
- After the installation of the equipment, due to unauthorized movement or transfer (transport) caused by the failure and damage.

## After-sales service and contact information

### After sales service

The warranty period of the purchased instrument is subject to the sales contract. During the warranty period, if there is any failure caused by the quality of the instrument itself, our company will provide free accessories (except consumables) and remotely guide users to repair. The warranty period starts from the date of shipment. After the warranty period expires, our company will continue to provide chargeable maintenance services.

Please contact our company's customer service center.

Note:

- If the ex-factory number provided by the customer is incorrect, the warranty will not be provided (our company uses the equipment ex-factory number to confirm whether the warranty is guaranteed).
- Consumables are not warranted. (Consumables: refers to disposable consumables that need to be replaced after each use or fragile materials that need to be replaced regularly.).

### Service

- Confirm the fault and repair method: First contact the customer service center to confirm the fault condition, and confirm that the repair method is home repair or return to the factory for repair.
- Maintenance costs are negotiated with our company according to the specific situation.
- Freight: If the instrument is shipped to our company for maintenance, the user must bear the freight (including customs fees).

### Return

- Obtain a return permission. Get in touch with our company's customer service center and inform the ex-factory number (see the instrument nameplate) to explain the reason for the return. If the number cannot be clearly identified, our company will not return the product.
- Under the premise of obtaining the right to return the goods, please follow our company's requirements to handle the relevant procedures.

### Contact information

**Name:Chongqing Drawell Instrument Co., Ltd.**

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Homepage : [www.drawell.com.cn](http://www.drawell.com.cn)

Tel : 0086-023-63268643

Email : [sales05@drawell.com.cn](mailto:sales05@drawell.com.cn)



## Chapter 1 Main Introduction

Drawell- Silver semi-auto chemistry analyzer is a microcomputer-based in-vitro diagnostics instrument uniting optics, mechanics and automation control in one. It is used together with the related reagents for quantitative determination of biochemical items, widely applied to hospitals and research institutes, with the characteristics of high precision, excellent repeatability, with LIS software and other features.

### 1.1 Configuration and Structure

Drawell- Silver mainly consists of control system, incubation system, optical and measuring system, peristaltic pump suction system, built-in thermal printer, etc.

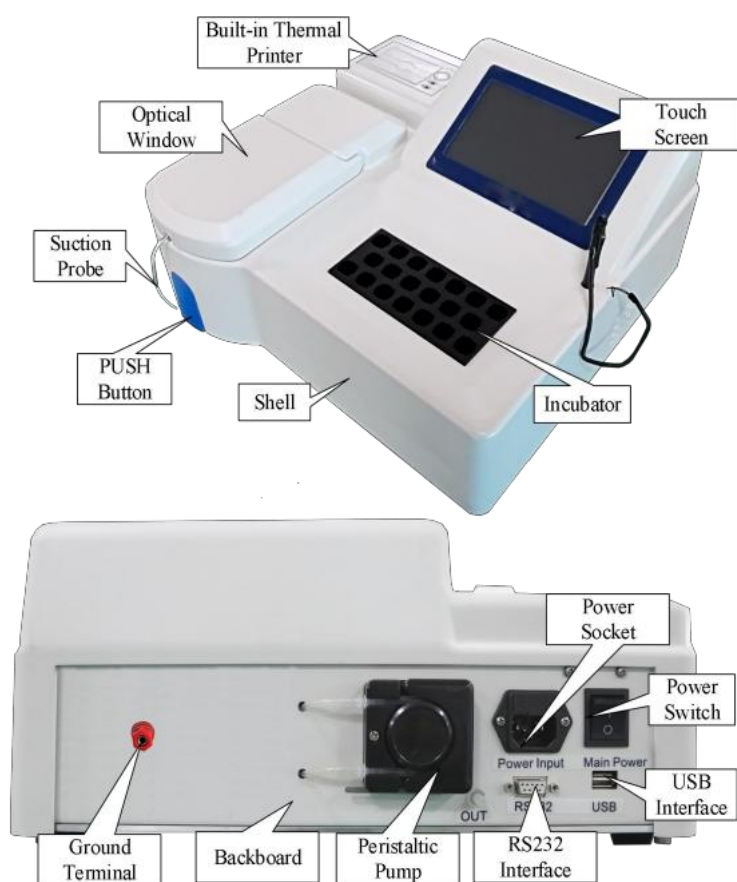


Figure 1- 1



## 1.2 Main Technical Parameters

Technical Parameter		Standard specifications		
Cuvette	Type of cuvette	Both through cell and direct reading cuvette		
Incubator	Incubator position	20 pcs		
	Temperature control	R.T., 25.0°C , 30.0°C , 37.0°C		
	Accuracy of temp control	±0.5°C		
	Temperature fluctuation	≤0.4°C		
Potometric System	Light source	6V, 10W halogen lamp		
	Wavelength of transmitted light	340/405/450/510/546/578/630nm wavelength, with two expandable positions		
	Accuracy of wavelength	±2 nm		
Measuring System	Measuring range	0~3.500 OD		
	Linear range	±2% from 0 to 2.500 OD		
	Absorbance accuracy	≤±0.02 OD		
	Zero drift	Less than 0.005 OD		
	Accuracy of linear absorbance	0.2~0.5 ODs	±5%	
		0.5~ 1.0 OD	±4%	
		1.0~ 1.8 OD	±2%	
	Repeatability of absorbency	Coefficient variance(CV) ≤ 1.0%		
Analysis method	End point method, fixed time method( two-point method), kinetic method( rate method), etc			
Instrument	Type of display	Touch screen		
	Type of printer	Built-in thermal printer		
	Power supply	220V/ 110V, 50Hz/60Hz		
	Interface	RS-232, USB		
	Machine weight	9kg		
	Gross weight	12kg		
	External size(W*D*H)	400*380*200 mm		
	Package size(W*D*H)	500*530*350 mm		

## Chapter 2 Installation

The installation and operation of this instrument is simple and easy to operate. In principle, no engineer is sent to install it. Before leaving the factory, commissioning and calibration by professionals, after the customer receives the equipment, install it according to the requirements of this chapter.

### **Attention**:

Violation of the installation operations in this chapter may cause problems or damage the equipment. Such problems or damages are not covered by the free warranty.

## 2.1 Requirement of Installation

Before the installation, user and engineer must check and confirm that the lab meets the requirements of space, power supply and working environment, etc.

### 2.1.1 Space Requirements

To ensure enough space for releasing heat, repairing, maintenance, keeping the pipeline not squeezed and ensure the fluid can flow freely, the space must meet the requirements as follows:

- Keep the analyzer not less than 100mm distance from wall and other objects for each side(left, right and back).
- Ensure enough space close to the instrument to place containers of pure water and waste.

### 2.1.2 Power Requirements

Power supply: 220V/ 110V, 50Hz/60Hz.

Power socket: a well-grounded socket within one meter of the instrument.

### **Attention**:

- The power supply socket should be within 1 m from the analyzer in order to pull out the plug timely when accident happens.
- Check if network voltage is the same to the analyzer voltage.

### 2.1.3 Environmental Requirements

- Working temperature: 15°C ~ 30°C
- Working humidity: 40% ~ 85%
- Working atmospheric pressure: 860hPa ~ 1060hPa
- Fuse: F3AL250V(5\*20mm)
- Input power: 150VA
- The environment should be in quiet and clean room and keep away from dust, noise, big equipment (X-ray machine, CT, centrifuge, etc) and radio interference.

- Avoid direct sunlight and ultraviolet rays and keep away from hot and cool source and outlet of air condition.

### **2.1.4 Computer Configuration Requirements**

The semi-automatic biochemical analyzer can be equipped with dedicated LIS software, which is convenient for users to edit and review test results, query and print reports. If you want to use the function, please contact our customer service center to install the LIS software on a computer, which meets the following requirements.

Computer host configuration requirements:

- It must be a branded machine with a CPU frequency of  $\geq 2.8$  GHz or above, a hard disk of 80 G or above, a partition  $\geq 2$  (C, D...), a memory  $\geq 2$  GB, and a stable USB interface.
- Install Windows 7 and above operating system, 32-bit or 64-bit version, Microsoft .NET Framework 4.0 and LIS software for semi-automatic chemical analyzer have been installed, and Microsoft Office Access software is recommended.

The display configuration requirements:

- 17 inches or more, the resolution is not less than 1366\*768.

## **2.2 Unpacking**

### **2.2.1 Unpacking Steps**

After the analyzer arrives, please carefully check the packaging of the instrument to see if there is any damage, such as broken or wet or polluted. If there is, please contact our company.



Figure 2- 1

After confirming that there is no external damage, open it by following steps:

- Open the box and according to the accessories list to check whether the object is complete, if missing, please contact our company.

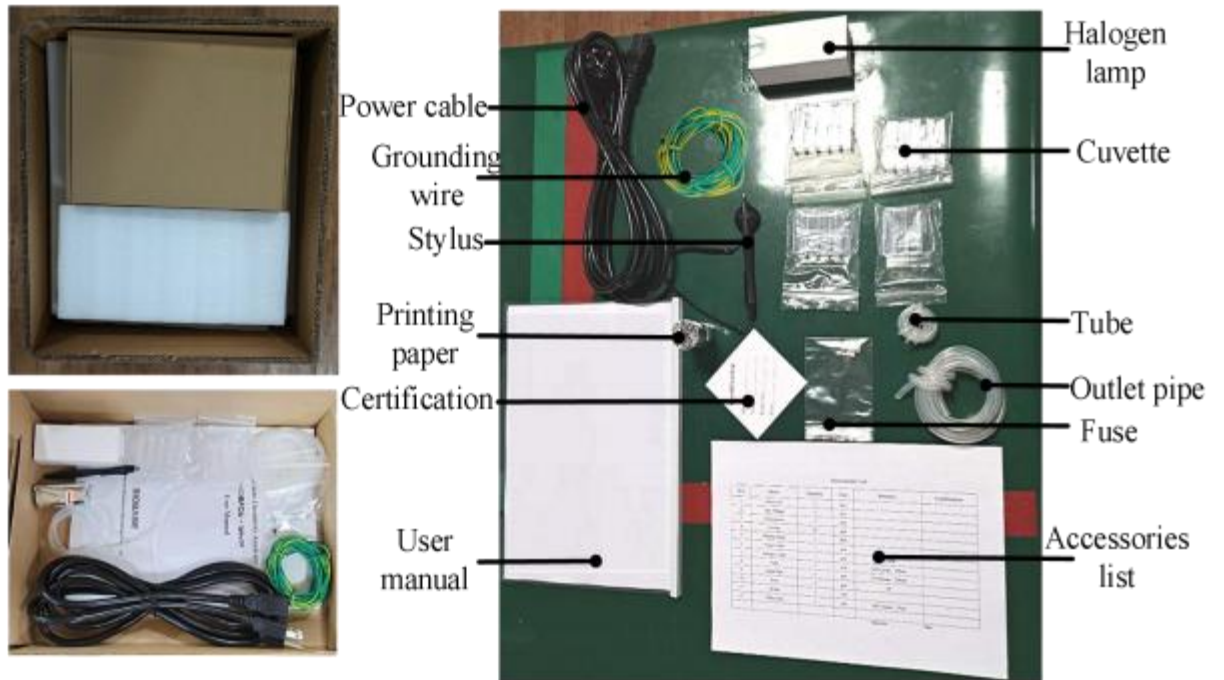


Figure 2-2

- Carefully check the appearance of the instrument, if damaged, please contact our company timely.
- Check whether the ex-factory number is in accord with outer package.
- As shown in figure below, open the optical window and pull out and rotate the suction probe to a appropriate position.

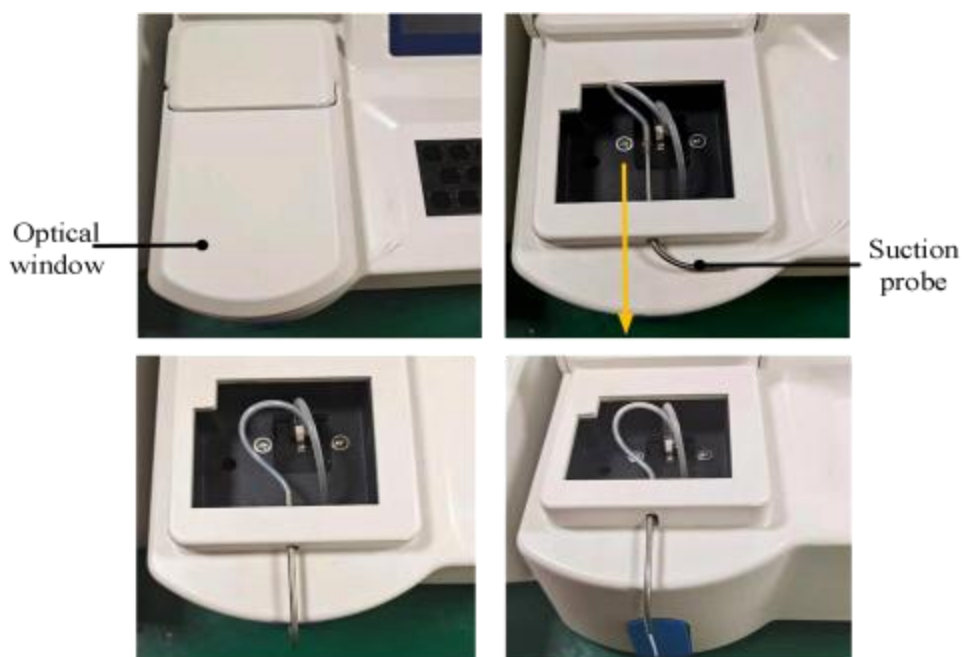


Figure 2-3

## 2.3 Installation Steps

1. Place the instrument on stable worktable.
2. Take out the power cable and outlet pipe from the accessory box, connect the power cord to the designated power supply according to the following figure, plug one end of the outlet pipe into the OUT joint and plug another end into the waste container. The instrument connect to a computer with a serial cable to use the LIS function( Contact our customer service center for details).

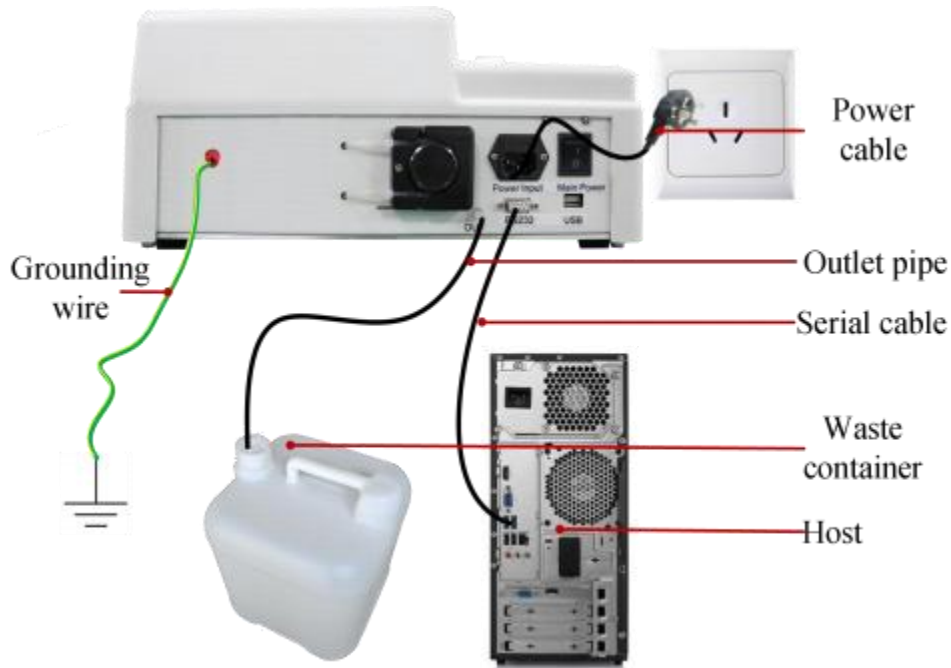


Figure 2-4

3. Switch on the main power before testing(“|”means connected, “O” means disconnected).
4. Install the thermal printing paper shows like below:



Figure 2-5

- Press the round button on the printer to open the printer cover.
- Load the printing paper into the paper slot.
- Put the paper to the feeding form and cover the cover.
- Click [Feed] on the main menu interface, make sure the paper running properly.

**Attention:**

- Installing a thermal printing paper, pay attention to the direction of the paper.
- Before installing the printing paper, do not print, or else it will cost system crash.
- The suction probe or waste fluid joint may carry some serum, control, calibrator and reagent, which is of potential biological risk. Therefore, it is dangerous to touch probe directly.



## 2.4 LIS Software Installation

Before using the LIS function, you need to install the LIS software.

### 2.4.1 LIS Software

Contact our customer service center to get the LIS software, and double-click Semi Automatic.exe to complete the installation.

### 2.4.2 Confirm the Port Number

Right-click on "This PC" - "Manage" - "Device Manager" to view the COM number of the serial cable connected to the instrument (Note: If the port is not found in the device manager, just plug and unplug the serial cable again).

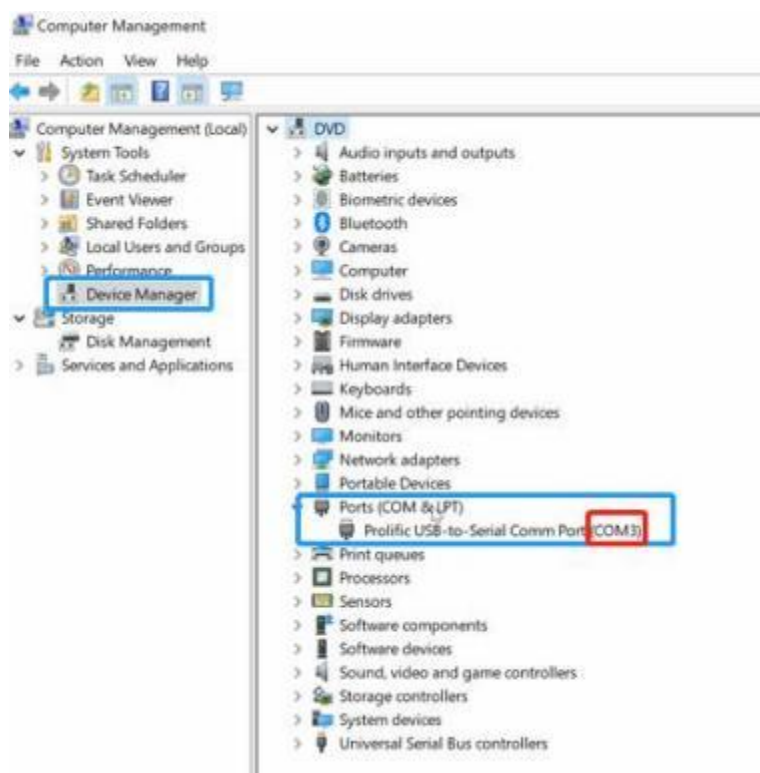


Figure 2-6

### 2.4.3 Go Online and Get Data

After opening the LIS software, select the port number and click [Open] to display "Open successfully!", which means the connection is successful.

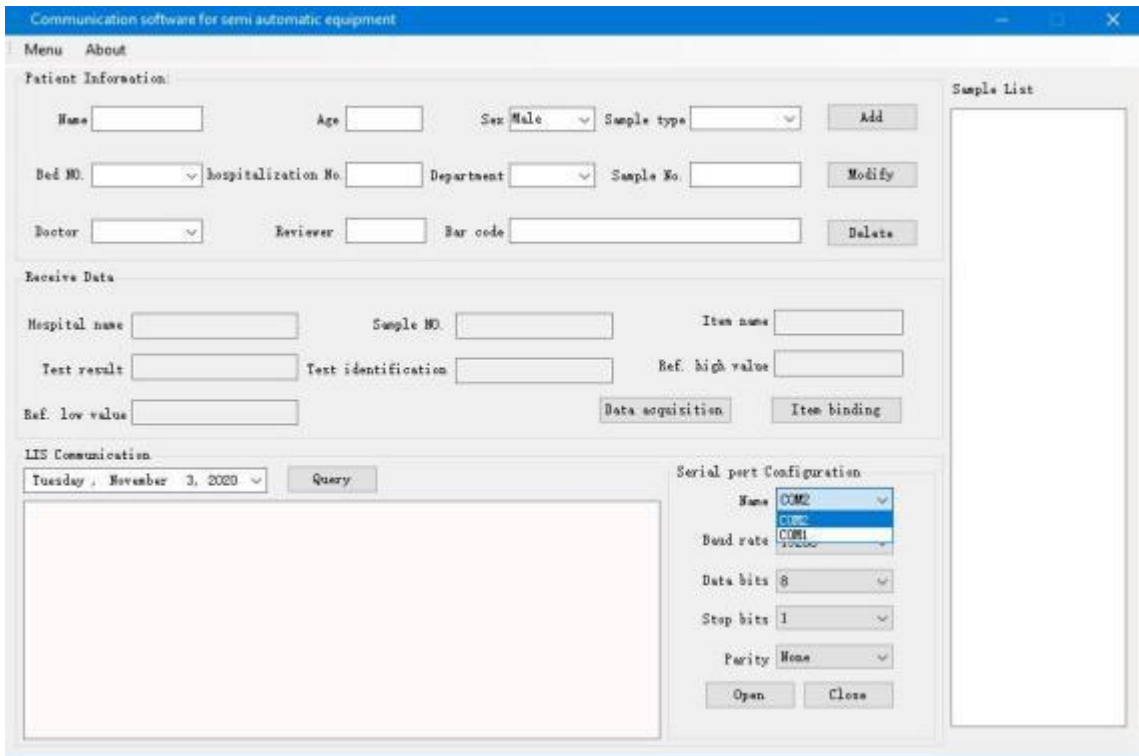


Figure 2-7

After the connection is successful, click [Data acquisition] to obtain the internal database of the instrument.

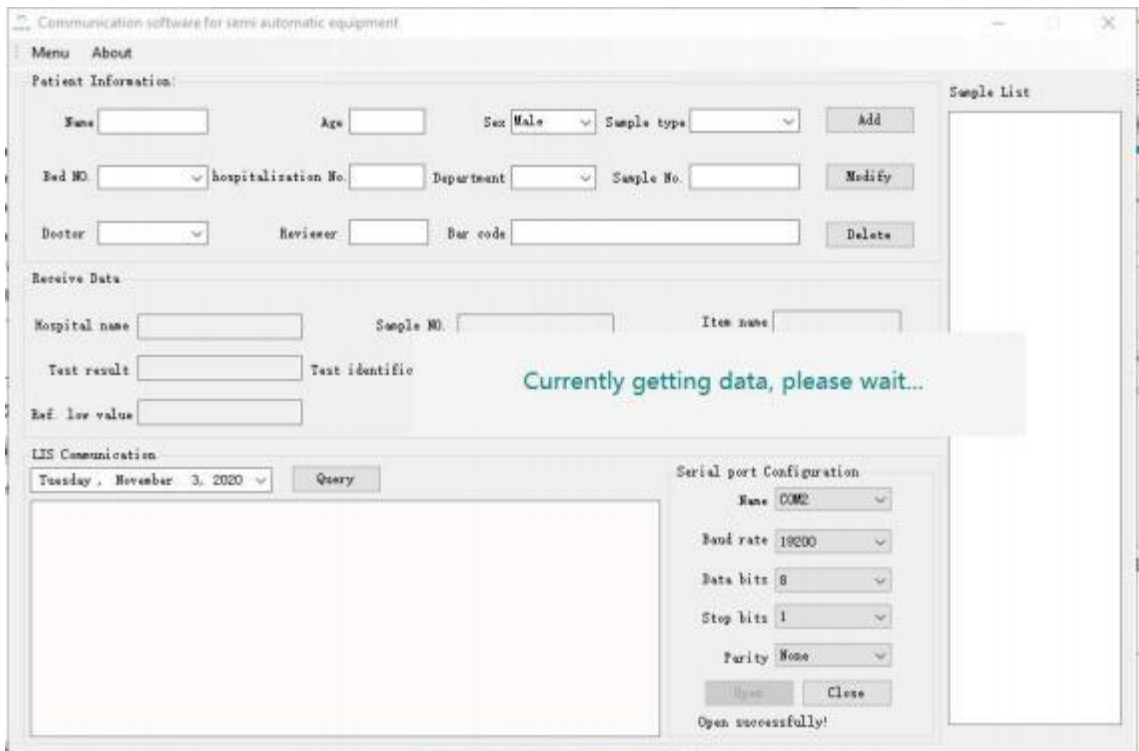


Figure 2-8

After selecting the test date and clicking [Query], all test results of the day will be automatically filtered out.

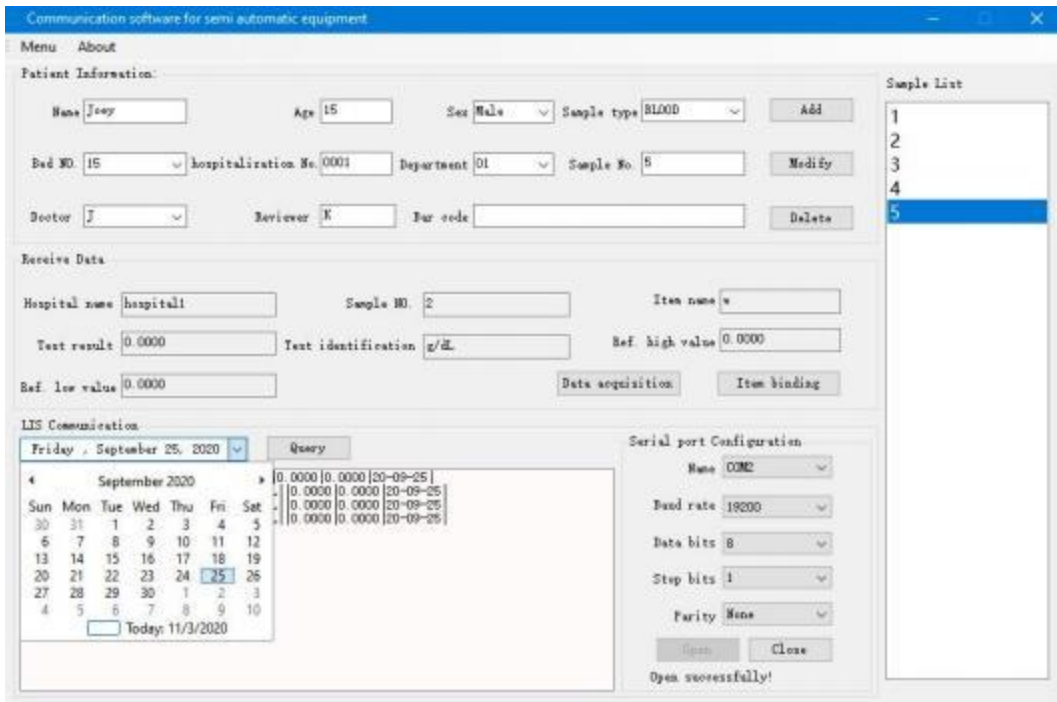


Figure 2-9

Click [Add] to automatically generate a sample number, enter patient information on the left, and click [Save] to save the sample information.

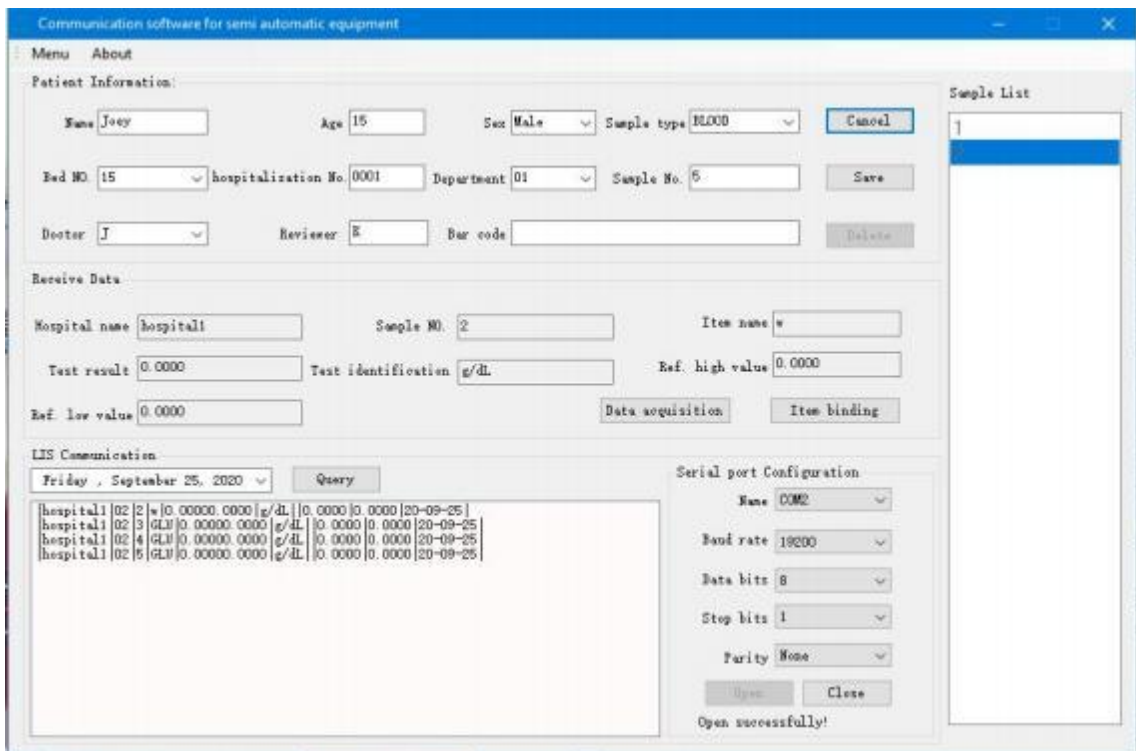


Figure 2- 10

After selecting a sample, click to select the test result, and click [Item binding] to bind the test result to the sample information, as shown in the figure below, displaying “Successfully added item for sample !” means that the test result is successfully bound.



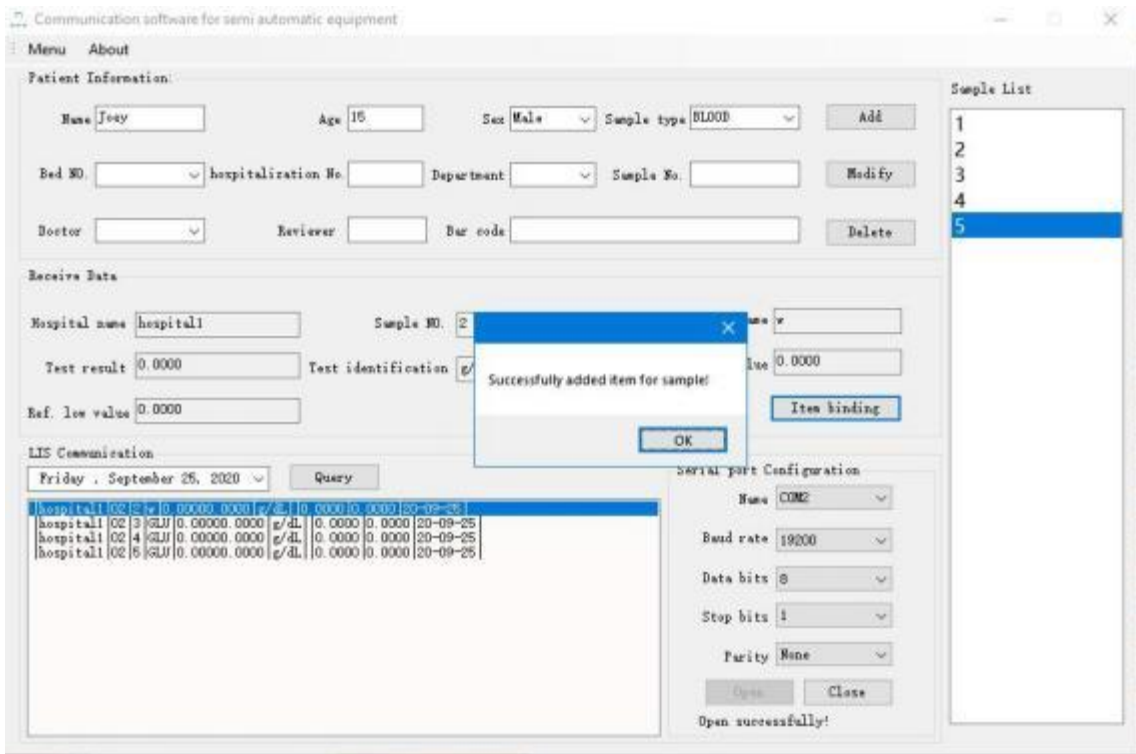


Figure 2- 11

In the [Sample List] column, double-click a group of samples to pop up all the test items and results of the sample, click [Preview] to preview the report printing results, and click [Print] to print the report of the group of samples.

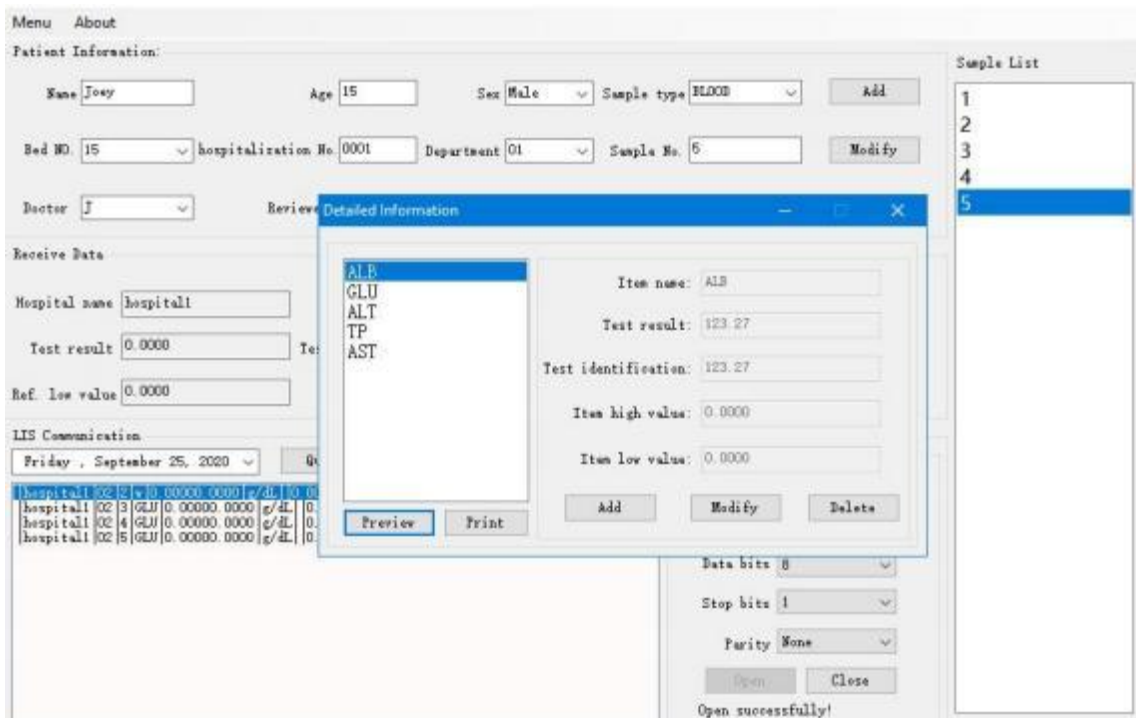


Figure 2- 12

# Chapter 3 Main Menu Functions

## 3.1 Working Principle

The principle of analyzer is based on Lambert-Beer Law.

## 3.2 Introduction of Main Menu Functions

Turn on the instrument, the interface looks like the left figure. Click on the screen, it will enter function menu as shown in the right figure:



Figure 3- 1

The menu functions are shown in the table. Touch screen to select the functions you need and enters the sub-menu.

No.	Menu name	Function	Operation
1	Test	To select the program to do sample test, after testing, the instrument will show the test results and print it automatically.	See 4.2.3
2	Edit	To add, modify, delete or print test programs.	See 4. 1.6
3	Result	Sample test results and QC test results view, delete and print, etc.	See 4.2.4
4	Wash	The shortcut key for cleaning, aspiration volume is 1.5ml per keystroke, used to clean cuvette.	See 4.2.2
5	Feed	The printer automatically feeds and prints a blank piece of paper.	See 5.3.2
6	Pump	Calibration for Peristaltic pump aspiration volume.	See 4. 1.5
7	Blank	AD Check to confirm whether the instrument is in the regular test status.	See 4. 1.4
8	Filter	Measure and adjust each filter's AD value, blank value and absorbance.	See 4. 1.3
9	Setup	Show temperature of cuvette and incubator, print settings, standby settings, screen brightness settings, time format and date/time Settings, hospital settings, view version information, etc.	See 4. 1. 1
10	Reserved	Contains settings for temperature calibration, aspirate format, plate calibration, ect.	See 4. 1.2



# Chapter 4 Operations

## 4.1 Parameter Setting

Proper parameter setting is the basic work before the daily testing. Only when the parameters are correct and reasonable can the instrument get accurate results. Parameter setting is mainly used to set parameters of temperature, aspiration, filter, program and other system parameters.

### 4.1.1 System Setup

Click [Setup] on the main menu to enter the sub-menu [System Setup].



Figure 4- 1

We can click the key shows above to enter the sub- menu for checking or setting corresponding system parameters. After changing the parameters, click [System Setup] for return, Pop up the interface shows like that, click [YES] to save changes.



Figure 4-2

#### 1 Temperature Display

Click [Temp Display] on the [System Setup] menu to enter the interface as shown below. The interface displays the preset temperature and real-time temperature of the cuvette and incubator measured by thermal sensor. The cuvette can be preset to four temperature levels. Note that when the room temperature is higher than the preset temperature, the temperature preset function will be invalid. Please adjust the room temperature first.

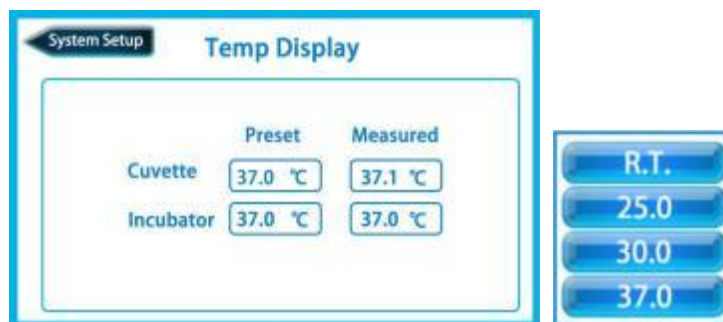


Figure 4-3

## 2 Print Setup

Click [Print Setup] on the [System Setup] menu to enter the interface as shown below. We can choose the print mode and whether to print the result or curve.

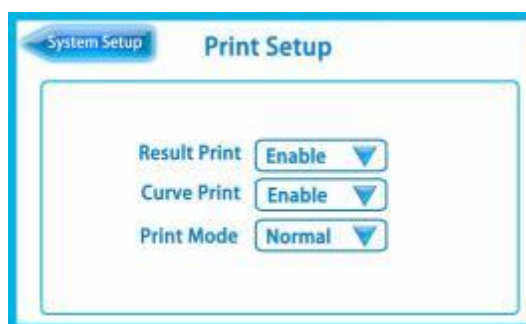





Figure 4-4

[Result Print]: Click , choose [Enable] or [Disable] to decide whether to print the test result. If we choose [Enable] indicates that printing function is turned on, and the test result will be automatically printed during the test. [Disable] indicates that the printing function is turned off. The instrument will prohibit automatic printing of test results during testing, but the test results can be manually printed in [Result] menu.

[Curve Print]: Click , choose [Enable] or [Disable] to decide whether to print the curve result.

[Print Mode]: Click , choose [Normal] or [Concise] to decide the print mode.

[Normal mode] means that during the test process, the instrument will print the test results and curves one by one. Take the end point method test as an example as shown in below:

- Printing of AD auto zero test:

2020-02-18 09:42:53  
Program Name: TP  
Program Method: End Point  
Main Filter: 546 nm  
Linearity Low: 0.0000  
Linearity High: 0.0000  
AD Auto Zero  
AD: 47265 M  
AD Range: 45000-60000

- Printing of Blank Test:

2020-02-18 09:43:39  
Blank:  
Program Name:TP  
Blank:0.0068

- Printing of STD Test:

2020-02-18 09:43:39  
Program Name:TP  
STD 1  
CONC:46.1  
Factor:160.692  
OD:0.0195

- Printing of QC Test:

2020-02-18 09:45:20  
Program Name:TP  
Control  
Control value: 47.3  
OD: 0.0977  
Control: 240.7506

- Printing of Sample Test:

2020-02-18 09:47:46  
Nr:001  
Program Name:TP  
Result: 78.5371  
OD: 0.1552  
Normal Low: 60  
Normal High: 88

[ Concise mode] means that to printing the test results one by one in line with the principle of saving paper to facilitate the results to be counted, saved and consulted. Take the end point method test as an example as shown in below:

- Printing of AD auto zero test:

2020-02-18 09:55:30  
Program Name: TP  
Program Method: End Point  
Main Filter: 546 nm  
Linearity Low: 0.0000  
Linearity High: 0.0000  
AD Auto Zero  
AD: 50196 M  
AD Range: 45000-60000

- Printing of Blank Test:

Blank:0.0068

- Printing of STD Test:

CONC:46.1  
Factor:160.692  
OD:0.0195

- Printing of QC Test:

Control  
Control value: 47.3  
OD: 0.0977  
Control: 240.7506

- Printing of Sample Test:

Result: 78.5371  
OD: 0.1552

### 3 Standby Setup

Click [Standby Setup] on the [System Setup] menu to enter the interface as shown below. Click the box after [Wait Time], pop up a soft keyboard for entering the wait time.

If the instrument has no operation in excess of wait time, it will enter the standby interface as shown below. You can touch the screen to wake up the instrument.



Figure 4-5

### 4 Date Format

Click [Date Format] on the [System Setup] menu to enter the interface as shown below. Click ▼, pop up a soft keyboard for changing the format of

date.

There are three date formats: YY-MM-DD, DD-MM-YY and MM-DD-YY. (YY represents year, MM represents month and DD represents day.)



Figure 4-6

### ⑤ Date& Time

Click [Date& Time] on the [System Setup] menu to enter the interface as shown below.

Click the box after Date, pop up a soft keyboard for entering numbers. The date is entered in the order set in [Date Format].

The setting of time is the same as that of the date.



Figure 4-7

### ⑥ System Info

Click [System Info] on the [System Setup] menu to check the system version information.



Figure 4-8

### ⑦ Hospital Setup

Click [Hospital Setup] on the [System Setup] menu to enter the interface. Click the box, pop up a soft keyboard and input the hospital name.



## 8 Language Setup

The default language is English.

## 9 Screen Setup

Click [Screen Setup] on the [System Setup] menu. Click ▼ or ▲ to adjust the screen brightness.

### 4.1.2 Reserved Setting

Click [Reserved] on the main menu, pop up a soft keyboard and then input the password "666666" to enter the sub-menu [Reserved Setting].

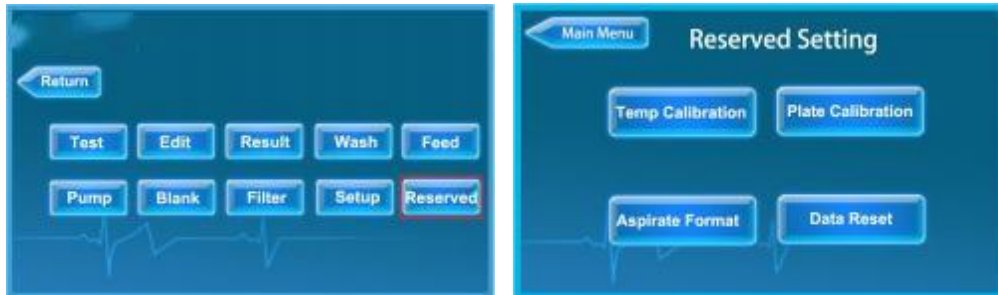


Figure 4-9

#### 1 Temperature Calibration

Temperature calibration includes the temperature calibration of cuvette and incubator. Click [Tem Calibration] to enter the interface as shown below.



Figure 4- 10

[Set Temp]: System preset temperature.

[Temp]: Display value of temperature which measured with the temperature sensor.

[Actual Temp]: Temperature measured with the thermometer, click the box to enter the measured value.

Temp calibration of cuvette:

- Insert the temperature measuring rod into the tube containing distilled water, Note that the tip of the rod should not touch the tube wall or the bottom of the tube, as shown in the figure:



Figure 4- 11

- As shown, rotate the sheet metal, take out and place well the cuvette



Figure 4- 12

- Put the tube into the cell shows like below:

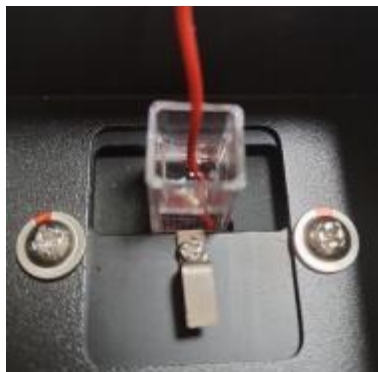


Figure 4- 13

- When the value of the thermometer is stable, click the input box of [Actual Temp] and enter the measured value.
- Click [Calibrate], the displayed temp value will be calibrated to the measured one. If the displayed temp is lower than the set temp, the heating system will work and heat the cuvette. Otherwise, the heating system will not work and will cool to the set temp slowly.

Temp calibration of incubator:

Put the tube into the cell shows like below, the steps of temp calibration is the same as that of cuvette.



Figure 4- 14

**Attention:**

- This function can only provide the confirmation on whether temperature monitoring is right or not. When testing sample, the temperature will be shifted according to the test program.
- If the displayed temp is lower than the preset temp, meanwhile the actual temp is higher than the preset temp and continues to increase, consider some wrong with the temperature sensor.

**2 Aspirate Format**

Aspirate format includes the settings of aspirate format and air gap. Click the [Aspirate Format] on the [Reserved Setting] menu, the interface shows as below.

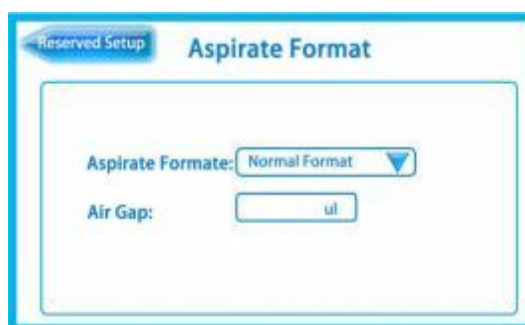


Figure 4- 15

Click ▼ to choose the format of aspirate:

[Normal Format]: Only absorb samples with set volume during normal format.

[Express Format]: After the instrument has absorbed the set volume of the sample, pause and then continue to absorb the sample that set volume in the [Air Gap].

In order to avoid the interference of the air in the suction probe to the sample absorption accuracy, we can choose express aspirate format. Click the box after [Air Gap], pop up a soft keyboard to enter the compensated volume of air.

### 3 Plate Calibration

Plate calibration is used to set the optimum position of filter plate. Click the [Plate Calibration] on the [Reserved Setting] menu, the interface shows as below.

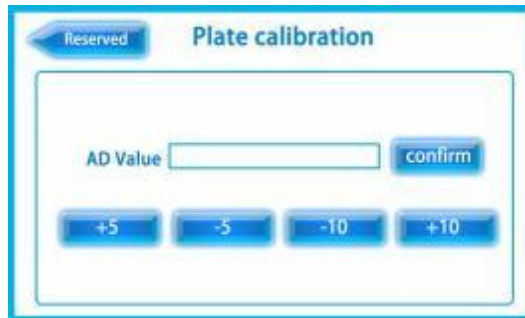


Figure 4- 16

Drive the stepping motor through the button [+5], [-5], [+10], [- 10] to adjust the position of the filter plate. When the [AD Value] is the maximum value, click [Confirm] to save the position parameters of filter plate.

#### **Attention**:

Click the [Data Reset] on the [Reserved Setting] menu will restore factory settings, which means that all the parameter settings will be restored to the default values and all the programs and results will be delete. Use the function with caution. The interface shows like that:



Figure 4- 17

### 4.1.3 Optical Paths Calibration

Click [Filter] on the main menu and enter the sub-menu [Filter Test].



Figure 4- 18

[Filter]: Click ▼ or ▲ to choose different optical paths for calibration, if the

filter is 0, it represents the detection of background value.

[Gain]: Set the target value of light path amplification, the instrument will automatically enlarge AD value. If the AD value is equal to the target value, it will display [Success]. If the target value cannot be reached, it will display [Fail].

The calibration steps show like that :

- Choose the filter and set amplification target value.
- Insert the suction probe into the distilled water, press PUSH button to aspirate water.
- Click [AD Test] for calibration. The difference between [Gain] and [AD0] need to be no more than 1000.
- Click [Continue] to enter the interface as shown below:



Figure 4- 19

- Insert the suction probe into the sample, press PUSH button to aspirate sample for absorbance testing.
- Click [Print] to print the calibration result of the filter.
- Click [Return] to redo the calibration.

#### 4.1.4 AD Blank Check

When we finished the calibration of optical paths, click [Blank] on the main menu and enter the sub-menu [AD Check] for AD blank check.

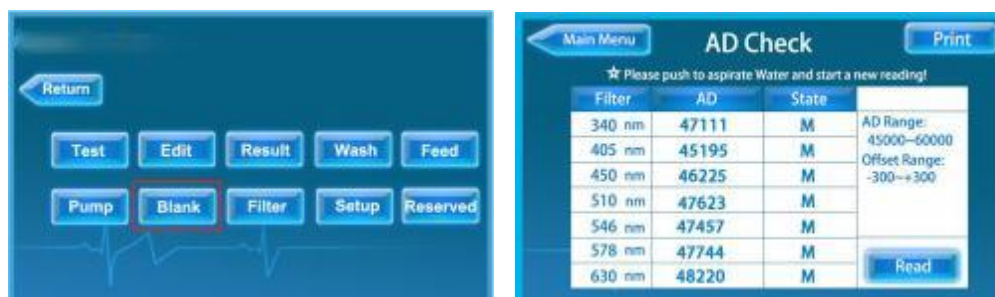


Figure 4-20

- Insert the suction probe into the distilled water, press PUSH button to aspirate water.
- Click [Read] in the interface to read the AD value of all optical paths at

one time. In the [State] bar, use letter H, M, L and No to judge the result is high, medium or low.

- Click [Print] can print the test result.

### 4.1.5 Pump Calibration

When the aspiration volume of the instrument is not accurate, we can calibrate the pumping steps as follows:

- Click [Pump] on the main menu and enter the sub-menu [Pump Calibration].



Figure 4-21

- Input calibration volume and take the same volume of distilled water in tube. Insert the suction probe into the bottom of the tube and then push the PUSH button to aspirate distilled water.
- Press the PUSH button immediately when the distilled water is exhausted, and the number of pumping motor steps has been calibrated. (For example, when the volume is 400ul, the motor steps is about 12000 to 12500.)
- Click [Main Menu] to save and return to main menu, it will pop up an interface to ask if you want to save the changes, click [YES] to save changes.
- If the aspirate volume is still not accurate during the sample testing process, you can repeat the above operations or directly modify the current motor step of the instrument through the soft keyboard.

### 4.1.6 Program Process

Click [Edit] on the main menu and enter the sub-menu [Program Process] as shown below.

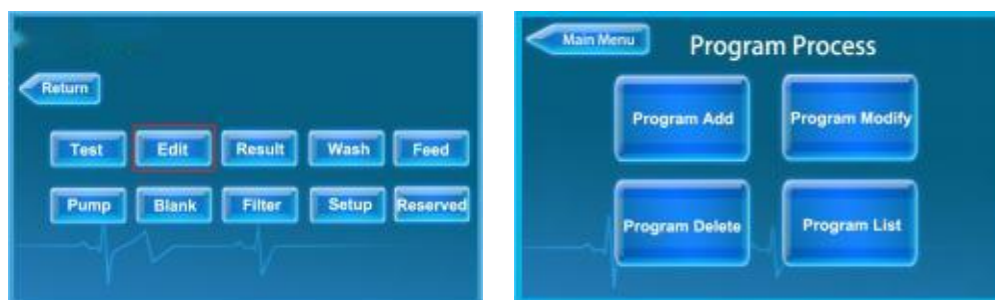


Figure 4-22

We can click the keys show above to enter the sub-menu for adding, modifying, deleting or printing program.

### 1 Program Add

Before adding a new program, it's necessary to set parameters according to the reagent specification. The program must choose the right analysis method. The commonly used analysis methods are kinetic method, two-point method and End point method. Usually, enzymes programs adopt kinetic method. Creatinine and urea programs adopt fixed time method, and others are used by the end point method. Take program ALB as an example, the operation steps of program parameter setting shown as below:

- Click [Program Add] to enter the interface as shown follow:



Figure 4-23

[Program Name]: Input the program name through the soft keyboard.

[Program Method]: Click ▼ to choose analyse method between [End Point], [Fixed Time] and [Kinetic].

[Program Unit]: Click ▼ to choose the program unit.

[Aspirate Volume]: 100 to 1000 ul, input the volume of sample to be absorbed during the test through the soft keyboard.

[Main Filter]: Click ▼ or ▲ to choose light path.

[Sub Filter]: None nm.

[Delay Time]: Delay time before test, 1 second to 999 seconds, refer to reagent specification to enter value through soft keyboard.

[Test Time]: 1 second to 999 seconds, refer to reagent specification to enter value through soft keyboard.

- Click [Next] to enter next page:

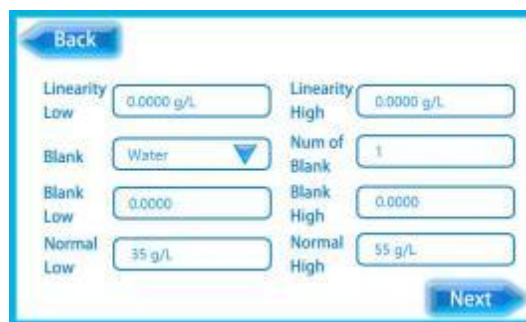


Figure 4-24

[Linearity Low]: Refer to reagent specification to enter value through soft keyboard.

[Linearity High]: Refer to reagent specification to enter value through soft keyboard.

[Blank]: Click ▼ to select the type of blank test in [Water], [Reagent] or [Serum], in order to checking and correcting the optical path system.

[Num of Blank]: The number of blank tests, which can be entered through the soft keyboard 0~7, the default number is 1.

[Blank Low]: Refer to reagent specification to enter value through soft keyboard.

[Blank High]: Refer to reagent specification to enter.

[Normal Low]: Refer to reagent specification or clinical reference value to enter value through soft keyboard.

[Normal High]: Refer to reagent specification or clinical reference value to enter value through soft keyboard.

- Click [Next] to enter next page:



Figure 4-25

[Num of STD]: Quantity of standards, which is depends on calibration method.

Num. of STD	Calibration Method
1	End- point Method ( Factor Method)
2	Fixed Time Method ( Two- point Method)
6	Kinetic Method ( Rate Method)



[STD]: Standard No., which is used in fixed time method and kinetic method, click ▼ or ▲ for choice.

[CONC]: Concentration, represents the standard concentration corresponding to the STD No., enter value through soft keyboard.

[Factor]: Standard factor, which is entered through soft keyboard according to the reagent specification. The standard factors can also be obtained by STD test.

[Control]: Click ▼ or ▲ to choose the type of QC, such as high value QC, median value QC and low value QC.

[Control Value]: Set the target value of QC through soft keyboard.

[Cuvette Temp]: The preset temperature of cuvette, the default value is 37°C.

[Dilution Factor]: The sample dilution factor, by default, is 0, which can be entered by soft keyboard, and the test result is multiplied by the corresponding dilution factor.

- Click [Done] to enter the interface as shown below, click [YES] to add the program, click [No] to back to the main menu interface, click [Cancel] to back to the interface of parameters edit.



Figure 4-26

## 2 Program Modify

Modify and view the parameters of the added program. When the reagent type or batch number is changed, the corresponding parameters need to be modified. The modification steps of the program are as follows:

- Click [Program Modify] to enter the interface as shown follow:



Figure 4-27

- Choose the program you need to modify, click > to enter the interface of program parameters, and then modify the parameter need to be modified.
- Click [Done] to enter the edit saving interface, and click [YES] to save the edit of the program.

### ③ Program Delete

- Click [Program Delete] to enter the interface as shown follow:

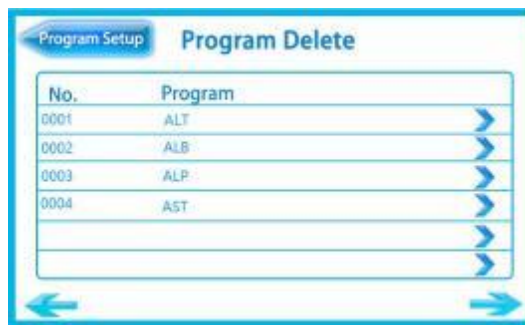


Figure 4-28

- Choose the program and click >, then pop up an interface like that:

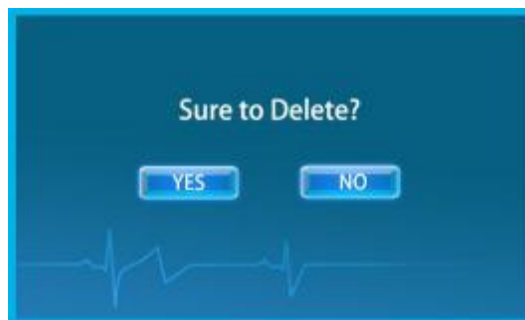


Figure 4-29

- Click [YES] to delete the program, click [No] to back to the interface of parameters edit.

### ④ Program List

- Click [Program List] to enter the interface as shown follow :

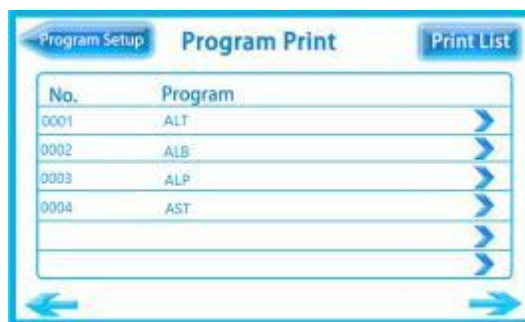



Figure 4-30

- Click the , the instrument will print the program information.
- Click [Print List], the instrument will print the program list, including the program number and program name, for users to query for program numbers.

## 4.2 Daily Operation Process

### 4.2.1 Instrument preheating

Connect to the power and turn on the switch, the instrument should be preheated in 30 minutes.

### 4.2.2 Pipeline Washing

Clean the cuvette and pipe line before testing, insert the suction probe into distilled water, and then click [Wash] on the main menu to start washing, last 5- 10 times.

#### **Attention**:


- Pay attention to use environmental dustproof, moisture proof, and installation air conditioning is better, environment temperature in 18-25 °C is the best working temperature.
- When external power is not stable, instruments must connect regulated power supply.
- Instruments in the process of operation shall not open the cover, so as not to cause damage to equipment or operator.
- Leakage and electrostatic prevention, the instrument should be in good grounding. Line power socket must have a reliable grounding line to guarantee in a steady state and security.
- After work, wash the instrument 3 times at least immediately to keep the cuvette and pipeline from liquid waste.
- After finish the testing, the used should be collected and disposed according to the medical waste.
- The waste pipe end should not be dipped into the waste to avoid poor drainage.
- Use qualified reagent within the period of validity.

## 4.2.3 Program Test

Click [Test] on the main menu to enter the sub-menu [Test] as shown below:



Figure 4-31

Take program ALB for example to show the test progress. Click  to enter the interface as shown below:

### 1 Temperature Calibration



Figure 4-32

- [Skip]: Go to the next step.
- [Wait]: When the cuvette reaches the set temperature, it will automatically proceed to the next step.
- [Exit]: Return to main menu.

After calibrate the temperature, click to proceed to the next step.

### 2 AD Auto Zero



Figure 4-33

Confirm that the suction probe is inserted into distilled water and click [YES] to enter the interface as shown below:

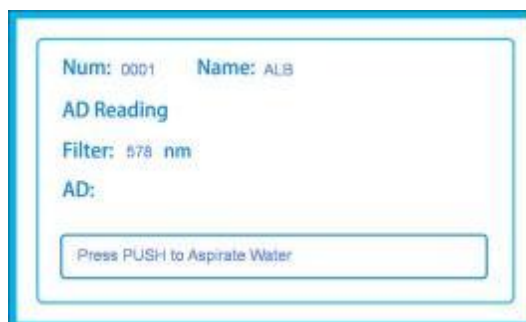


Figure 4-34

Push the PUSH button to aspirate distilled water, the instrument will automatically calibrate AD value and enter the interface as shown below:



Figure 4-35

- [Num]: The number of program.
- [Name]: The name of program.
- [Filter]: The main filter of testing optical path.
- [AD]: AD value for water blank.
- [AD Range] Reference range of AD value.

After calibrate the AD value, click [Continue] to proceed to the next step.

### 3 Water Blank Calibration



Figure 4-36

Water blank means the absorbency of cuvette with distilled water. Confirm that the suction probe is inserted into distilled water and click [YES] to enter the interface as shown below:



Figure 4-37

- [Blank Low]: The same as that we setted in progress parameters.
- [Blank High]: The same as that we setted in progress parameters.

Push the PUSH button to aspirate water, enter the interface as shown below:



Figure 4-38

- [OD]: Absorbency in blank.
- [Return]: Do water blank test again.
- [Continue]: Go to the next step.

After calibrate the water blank, click [Continue] to proceed to the next step.

#### 4 STD Test



Figure 4-39

- [Factor]: Standard factor. We can set it in program parameter.
- [No]: Skip STD test, go to the next step.
- [YES]: Start STD test.

Confirm that the suction probe is inserted into STD and click [YES] to enter the interface as shown below:

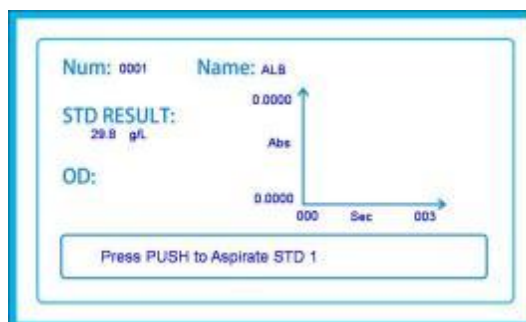


Figure 4-40

- [STD Result]: Concentration of the STD. We can set it in program parameters.

Push the PUSH button to do STD test, the test result shows like that:

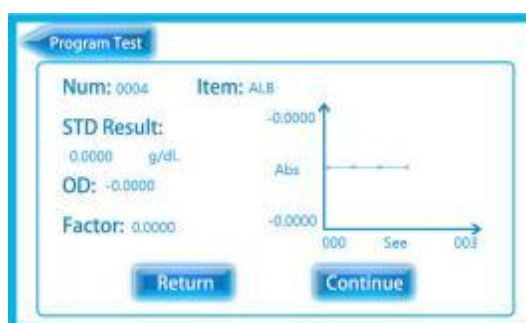


Figure 4-41

- [Return]: Do STD test again.
- [Continue]: Go to the next step.

After finished the STD test, click [Continue] to proceed to the next step.

## 5 QC Test



Figure 4-42

Confirm that the suction probe is inserted into QC product and click [YES] to do the test of QC which is same as STD test.

After finished the QC test, confirm that the suction probe is inserted into sample and click [Continue] to proceed to the next step.

## 6 Sample Test

Figure 4-43

- [Feed]: The same as the [Feed] button in main menu.
- [Wash]: The same as the [Wash] button in main menu.
- [Continue]: Test the sample.

Input the patient's name in the box and then click [Continue] to do sample test.

**Attention:**

- After each sample test, click [Wash] to clean the pipeline. Avoid cross contamination to affecting the accuracy of test results.
- The STD test is used to calculate the factor, so as to participate in the calculation of sample test results. Generally, it is necessary to do the STD test when any of the following situations occurs:
  - a. Add a new item or edit the item parameters.
  - b. When the reagent, QC product and standards are still within its validity, the QC results are out of tolerance.
  - c. Switched to another batch or bottle number reagent.
  - d. Replaced the halogen lamp or cuvette.
- QC results as an important tool to monitor whether the instrument runs well. In order to ensure the accuracy of sample test results, it is recommended to do QC test every day.

#### 4.2.4 Result Process

The instrument can store 5, 600 sample test results by time for users to query. When the storage is full. All or some results need to be removed. We can search, edit, delete, print or synchronize the sample test results and QC results through the [Result Process] menu as shown below:

Click [Result] on the main menu and enter the sub-menu [Result Process].





Figure 4-44

#### 4.2.4.1 Sample Result Process

##### 1 Result List

Click [Result List] on the [Result Process] menu, the interface shows like that:

ID	Date	Time	Action
0001	02-15-20	17:38:43	>
0002	02-15-20	18:18:16	>
0003	02-15-20	18:19:28	>
0004	02-15-20	18:37:33	>
0005	02-15-20	18:39:04	>
0006	02-15-20	18:40:41	>
0007	02-15-20	19:02:33	>

Figure 4-45

- [Search]: To query the test result, click to enter the interface as shown below:

Figure 4-46

- [No.]: Input program number, search for the program with that number.
- [Name]: Input patient's name, search program for all patients with the same name.
- [Date]: Input the testing date, search all the program done on that day.

We can use the key words to searching sample testing results, the query list shows like that:

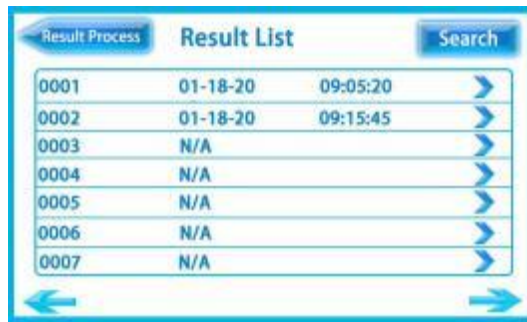


Figure 4-47

Choose one result in [Query List], click > to enter the interface shows like that:



Figure 4-48

- [Edit]: Input patient's name.
- [Print]: Print this testing result.
- [Delete]: Delete this testing result.
- [Data Sync]: Synchronize this test result to the database.

## 2 Delete All Result

Click [Delete All] on the [Result Process] menu, the interface shows like that:



Figure 4-49

Click [YES] to delete all test results.

## 3 Data Synchronization

Click [Data Synchronization] on the [Result Process] menu, the interface shows like that:



Figure 4-50

Click [YES] to synchronize all test results.

#### 4.2.4.2 QC Result Process

Click [Control Manage] on the [Result Process] menu and enter the sub-menu [Control Manage].



Figure 4-51

##### 1 QC Statistic List

Click [Control Statistic] on the [Control Manage] menu, the interface shows like below. Choose one QC program, click ➤ to choose control type like that:



Figure 4-52

Click the control type to query, the types H, M and L are same as the control type set in program parameters.

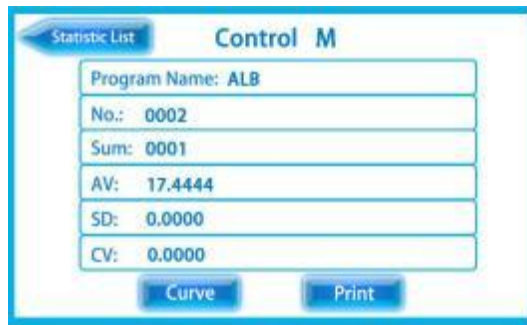


Figure 4-53

- [Print]: Print this QC results.
- [Curve]: Analyze the QC results in curve, but if the QC results are less than 3 pieces, that doesn't work.

## 2 QC Result

Click [Control Result] on the [Control Manage] menu, the interface shows like that:

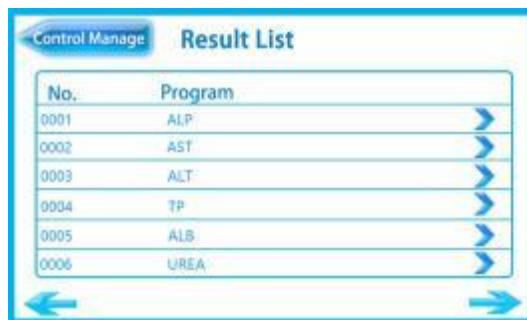


Figure 4-54

Choose one QC program, choose one QC program, click > to choose control type to query all QC results of the control type in the program, the interface shows like that:

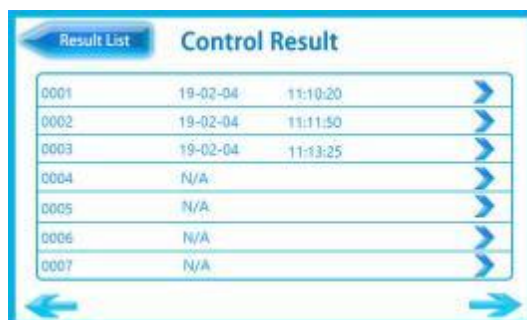


Figure 4-55


Click > to see the control result, shows like that:



Figure 4-56

- [Print]: Print this QC result.
- [Delete]: Delete this QC result.

### 3 Delete QC Result

Select a program and click  to delete all QC results of the program.

### 4 Delete All Result

Click to delete all QC results.

# Chapter 5 Maintenance

## 5.1 Overview

In order to ensure the reliable performance, good working condition and service life of the system, the system should be operated and maintained regularly according to the requirements of this user manual. Even if you are only an operator, it is very important to understand the knowledge of maintenance and repair in this chapter. In-depth study will enable the instrument to achieve the best operating state and performance in use. For unsolvable problems encountered in use and maintenance problems not covered in this chapter, please contact our company customer service center or the distributor in the area.



### Warning:

- Do not perform maintenance work that is not explicitly stated in this chapter. Failure to do so may result in system damage and personal injury.
- Do not touch parts that are clearly documented and can be operated and maintained by the user.
- Unauthorized repairs to the system can result in system damage and personal injury, and the terms promised in the repair contract are no longer valid.
- After the maintenance work is completed, please confirm that the system is working properly.
- Do not spill liquids such as water or reagents on the mechanical or electrical parts of the system.

---

### Biological infection risk:



During maintenance work, be sure to wear gloves, work clothes to prevent infection, and wear protective glasses if necessary.

---

### 5.1.1 Accessories Information

To ensure personal safety and system performance, please use the accessories manufactured or recommended by our company. If you need instrument repair or replacement of accessories and consumables, please contact our customer service department or distributor in your area.

Accessory Name	Location	Note
Halogen Lamp	Light box	6V 10W
Tube	Peristaltic pump	2*4
Fuse	Power Socket	F3AL250V(5*20mm)
Thermal Printing Paper	Thermal Printer	56mm*28mm

## 5.1.2 Maintenance Materials and Tools

Materials & Tools	Applicable range
Clean gauze	Cleaning the surface of housing and screen, ect.
Cotton swab	Cleaning incubator.
Alcohol	Cleaning the outer surface of the instrument.
Neutral detergent	Cleaning the surface of housing and screen, ect
Fiber-free gloves	Protecting operator in maintenance process.
Phillips screwdriver $\phi 3.3 \times 75$	Removing and installing the housing.
Slotted screwdriver $\phi 3.3 \times 75$	Removing and installing the power line of halogen lamp.

## 5.2 Regular Maintenance

### 5.2.1 Daily Maintenance

#### 5.2.1.1 Cuvette Washing

If there are contaminants or bubbles attached to the cuvette, it will affect the absorbance, so it is necessary to wash cuvette frequently.

#### Purpose

Wash the cuvette and pipelines to avoid contamination by samples or reagent residues, which may affect the test results.

#### Maintenance opportunity

- Before testing, 10 times washing are necessary.
- After each test, wash 4~5 times is essential.
- When all tests done, please use distilled water flush.
- If there are bubbles in cuvette, you may aspirate neutral detergent to flush, and then wash it by distilled water again and again.

#### Operation steps

- Insert the suction probe into enough distilled water to avoid bubbles due to insufficient distilled water during the aspiration process.
- Press the PUSH button to clean once, and repeat the operation several times.

#### Instrument status

When performing this maintenance operation, make sure the instrument is in standby.

#### 5.2.1.2 Check Waste Connection

The improper connection of the waste liquid pipeline, full of the waste liquid barrel, and empty barrel not in time, all of them will cause the waste liquid

overflow, environmental pollution and cross-infection, and even damage the instrument.

Therefore, it is necessary to check the waste connection of the instrument frequently.

### **Purpose**

Check the connection of waste liquid pipeline and whether the waste liquid barrel is not emptied to avoid waste liquid overflow.

### **Maintenance opportunity**

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

### **Instrument status**

When performing this maintenance operation, make sure the instrument is in standby or out of power.

### **Precautions**



Biological infection risk:

During maintenance work, be sure to wear gloves and work clothes to prevent infection and wear protective glasses if necessary.

When disposing of waste liquid, dispose of waste liquid in accordance with local regulations.

---

### **Operation steps**

- Click [Wash] on the main menu to check whether the discharge system is normal, keep the waste pipeline not bent and discharge smoothly.
- Make sure that the waste pipe is not immersed in the waste water. Otherwise, the accuracy of aspiration may be affected due to poor drainage.

## **5.2.2 Weekly Maintenance**

Weekly maintenance is on washing the flowing cuvette by detergent. Keep detergent in cuvette for 5 to 10 minutes before draining. Then flush it by distilled water again and again.

Recommended detergents:

- 20% sodium hypochlorite solution
- Dedicated detergent for chemistry analyzer

## **5.2.3 Monthly Maintenance**

Monthly maintenance is mainly about calibrating the aspiration accuracy of peristaltic pump.



## 5.3 Unscheduled Maintenance

### 5.3.1 Cleaning housing

Instrument housing, printer cover, touch screen and other frequently touched places, are very easy to become dirty. In order to keep the working environment clean, reduce biological risk, clean them timely.

#### Purpose

Remove dust or other contaminants for keeping clean.

#### Maintenance opportunity

Perform this maintenance when dust or other contaminants accumulate on the exposed parts.

#### Instrument status

When performing this maintenance operation, make sure the instrument is out of power.

#### Precautions



#### Warning:

Do not spill liquid on the analyzer to prevent liquid from immersing and causing damage to the instrument.

---



#### Biological infection risk:

- During maintenance work, be sure to wear gloves and work clothes to prevent infection and wear protective glasses if necessary.
  - Do not discard the gauze used for wiping. Please dispose of it in accordance with relevant regulations.
- 

#### Operation steps

- Confirm the analyzer is out of power.
- Gently wipe the touch screen, housing and printer cover with gauze dipped in neutral detergent.
- Wipe the PUSH button and suction probe with gauze dipped in alcohol.

### 5.3.2 Replacement of Printing Paper

#### Maintenance opportunity

Perform this maintenance when the printing paper run out or jam.

#### Instrument status

When performing this maintenance operation, make sure the instrument is in standby.

## Precautions

---



### Warning:

If the printing paper installation direction is reversed, can only print white paper.

---

## Operation steps

- Push the round button on the printer to open the printer cover and take out the old paper core (Some types of paper has no paper core).
- Load a new roll of printer paper in the slot, pay attention to the direction as shown in the figure:



Figure 5- 1

- Cover the printer cover, click [Feed] on the main menu of the screen, make sure the paper running properly.

## 5.3.3 Replacement of Fuse

### Maintenance opportunity

This maintenance can be performed when the instrument switch does not respond and is judged to have blown a fuse.

### Instrument status

When performing this maintenance operation, make sure the instrument is out of power.

## Precautions

---



### Warning:

The operator must use fuse of appointed specification.

---

## Operation steps

- Turn off the power of analyzer and pull out the power line from the power socket.
- Take out the fuse seat and replace the fuse.



Figure 5-2

- Plug the fuse seat into original position.

### 5.3.4 Replacement of Pump Tube

#### Maintenance opportunity

Replace the tube in the peristaltic pump when the aspiration accuracy gets worse due to tube broken or wear on the inner wall.

#### Instrument status

When performing this maintenance operation, make sure the instrument is out of power.

#### Precautions



#### Warning:

Before replacing the pipeline, click [Wash] on the main menu for several times to empty the pipeline.

#### Operation steps

- Open the peristaltic pump housing counterclockwise as shown in the figure.



Figure 5-3

- Take out the worn water pipe, unplug it from the joint, take out the new pipe from the accessory box, cut the appropriate length, connect it to the joint and install it into the peristaltic pump as it is.

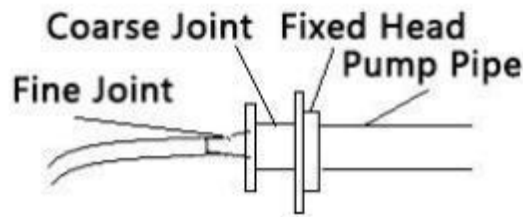


Figure 5-4

- Close the casing of the peristaltic pump and install it in place when you hear a click.
- Click the [Wash] function on the main menu interface of the touch screen, confirm that the suction and discharge function is good, and calibrate the suction volume according to 4. 1.5.

### 5.3.5 Replacement of Halogen Lamp

If light source lamp aging, light energy will deviate from the light measurement range. During the sample test, it won't test correctly because of interfere.

#### Maintenance opportunity

When the AD value of all optical path are less than 45, 000, click [Filter] on the main menu to do gain. If the gain fails, consider replacing the halogen lamp.

#### Instrument status

When performing this maintenance operation, make sure the instrument is out of power.

#### Precautions



#### Warning:

Do not touch the surface of the halogen lamp, otherwise it will affect the amount of light. If the surface is found to have smudges such as fingerprints, wipe it with a gauze dampened with alcohol.

---

#### Operation steps

- Prepare a new halogen lamp.
- Turn off the power switch, wait 20 minutes for cooling down.
- Open the optical window, remove the silicone tube shown in the figure from the suction probe, then withdraw the pipette from the suction probe and remove the suction probe.



Figure 5-5

- Remove seven M4\*12 screws with cross recess from the bottom with a phillips screwdriver, hold the shell with both hands and lift it 15 cm upwards, then turn the shell assembly to the right, as shown in the figure, open the FFC fixing seat shown in the figure, pull out the FFC, and remove the shell assembly.

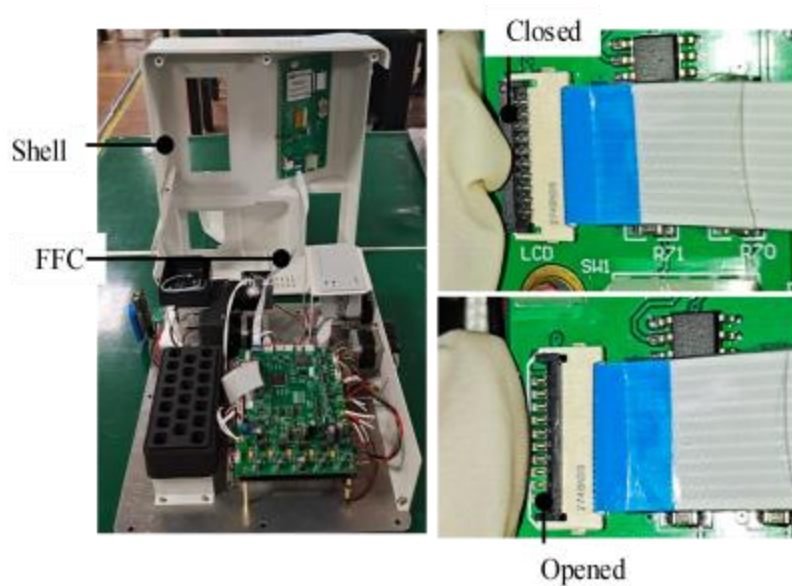


Figure 5-6

- Loosen the screw at the indicated position with a slotted screwdriver and pull out the halogen lamp wire.

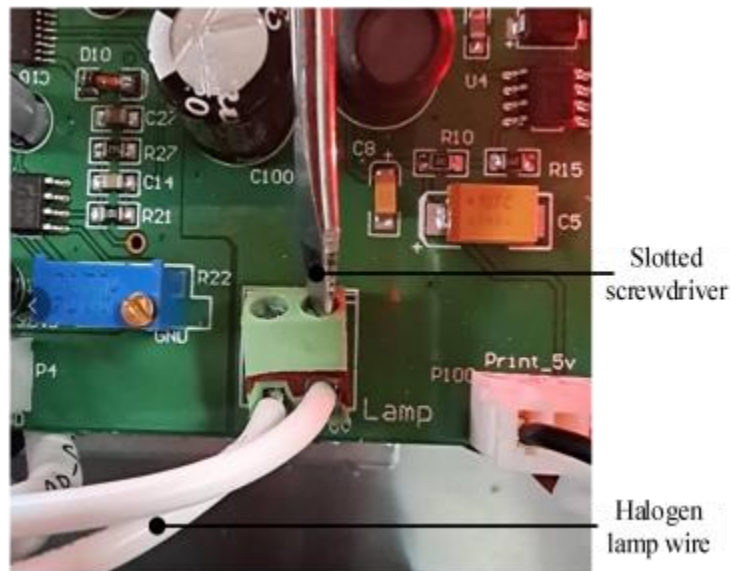


Figure 5-7

- Unscrew the knurled screw shown as below and take out the halogen lamp by hand.

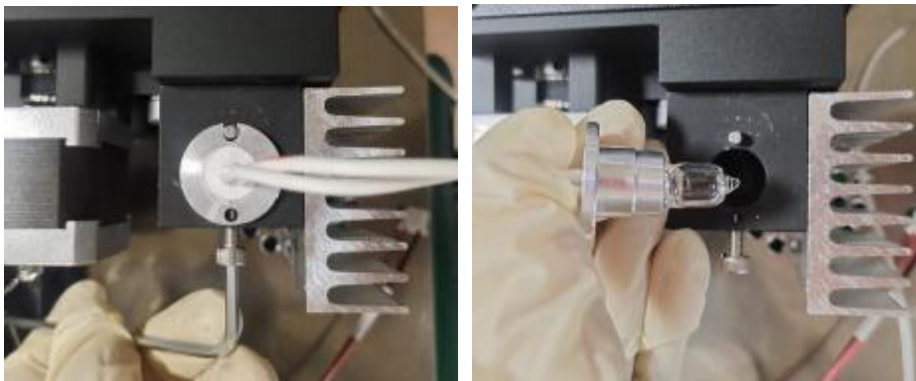


Figure 5-8

- Replace with a new halogen lamp, fix with knurled screws and install the housing.
- Remove the two screws fixing the cover of the OCB( optical circuit board) from the front of the instrument, remove the OCB cover, remove the two screws fixing the OCB, remove the OCB, turn on the power of the instrument, choose 510 wavelength on the [Filter] interface, install the cuvette into the cell, fine-tune the positioning screws at both sides of the assembly, so that the light source passes through the light-transmitting hole of the cuvette.

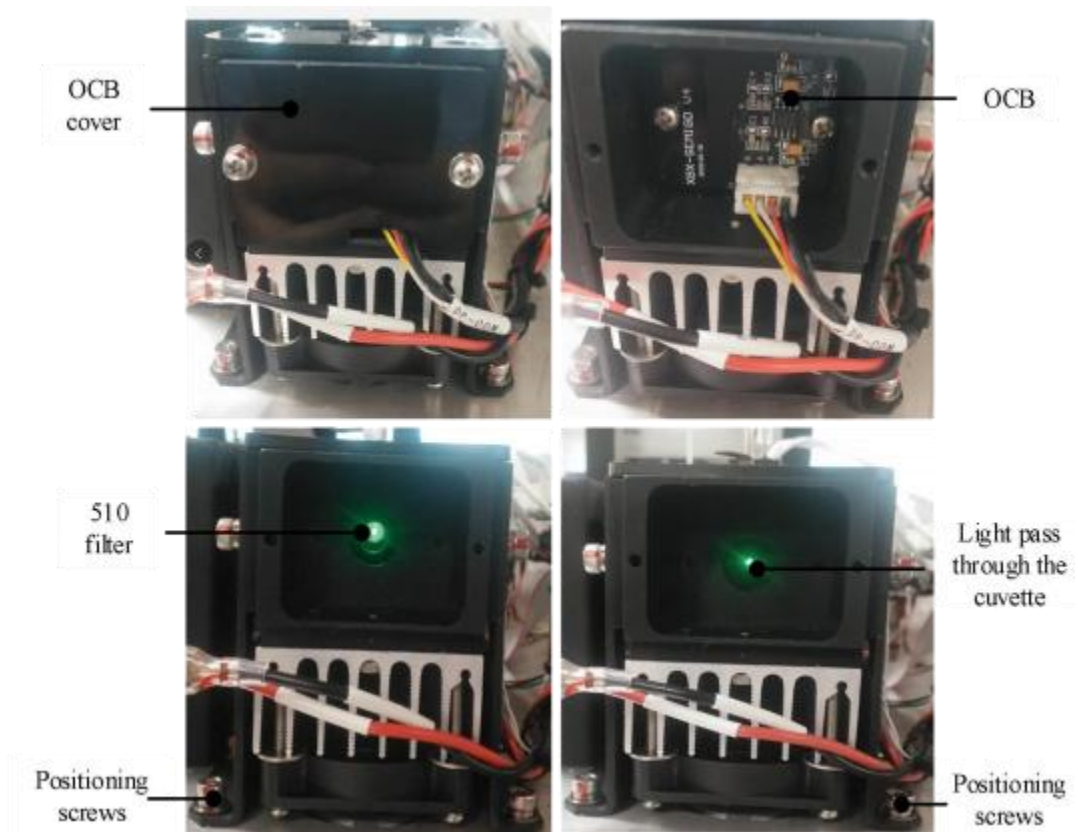


Figure 5-9

- Install the housing and other parts in reverse order, and perform optical path calibration and optical path test. The test can only be performed when the AD value of each optical path is above 52000.

## Chapter 6 Troubleshooting

This chapter explains all kind of malfunctions, which often happen in the routine operations. Besides, it analyzes the related reasons about malfunctions and supplies some methods against the malfunctions.

Please take measures to eliminate the malfunctions which occur in use or before use according to relevant troubleshooting. If the malfunctions still exist, please contact our company customer service center or the distributor in the area as soon as possible.




### **Warnings:**

- You must turn off the analyzer, cut off the power, and then remove the power plug from the socket. The repair work must be taken by our company professional trained staff.
- The analyzer must use suited power supply and voltage. Or else, the damage which is caused against this order is out of our responsibility.



### **Caution:**

- Analysis of samples may give incorrect test results in the case of instrument malfunction. If there is a fault detected in the sample, be sure to troubleshoot before use.
-  Sample, QC product, STD, wasted liquid and so on have potential biochemistry risk. The operator must comply with the laboratory regulations about the safety operator to wear personal protective device (like: laboratory protective clothing, gloves etc.), and accordance with local government regulations to dispose the waste materials generated by the instrument detection.

### **6.1 Instrument Faults and Handling**

The failure analysis and solution for common faults are shown in the following table:



Accident details	Main reason	Solution
The instrument doesn't work	Fuse burn-out.	Replace the fuse.
	Power socket is poor connected.	Check the power interface.
Preheating time is too long	Effect of ambient temperature ( Especially in winter).	Use air conditioner to keep the environment temperature to 15°C~30°C .
	The heating voltage is insufficient could lead to a longer heating time.	Please remove the housing, use the digital multimeter to test the voltage of incubator heating rod, if there is no voltage, and replace the Peltier.
The heating system continues to heat up which is beyond the preset temp.	Careless error of the temperature sensor.	Please contact us for replacement of the temperature sensor.
Insufficient suction	Pipeline leak.	Check and replace pipe, joints or suction probe.
	The waste barrel is placed too high or too low.	Place the waste barrel lower than the instrument.
	During the suction process, the suction probe exposed the liquid level and caused the air to be suction	Insert the suction probe into the bottom of the sample tube.
Abnormal or no suction	Pump pipe worn out.	Replace pump pipe.
	Pipeline is blocked.	Check for clots in cuvette or pipelines.
	Pipeline is leaking due to joint broken or loosen.	Check the joints and pipes.
	Peristaltic pump motor is not working properly.	Please contact us for motor replacement.
There are mistakes with auto zero	There is no distilled water in cuvette.	Cuvette washing.
	Cuvette is dirty.	Cuvette washing.
	There is air bubble in Cuvette.	Cuvette washing.
	Pipeline leak.	Check and replace pipe, joints or suction probe.
	Pump pipe is worn out.	Replace the pump pipe.
	Halogen lamp burned out.	Replace halogen lamp.
All or some filters have a high AD value.	There is air bubble in Cuvette.	Cuvette washing.
	Halogen lamp burned out.	Replace halogen lamp.

Accident details	Main reason	Solution
	The filters are damaged.	Please contact us for plate replacement.
Wrong Blank result	The light source fault.	Adjust or replace halogen lamp.
	The cuvette is empty or blocked.	Check and wash cuvette.
	Too much light.	No filter or filter problem, check the filter plate.
Control value is too low.	Standard factor is too high.	Check the standard factor, check whether the STD concentration is correct, check whether the STD test is correct
	The absorbance of the reactant is out of linear range	Use a new reagent or dilute the sample.
Poor repeatability of test results.	There is air bubble in Cuvette.	Cuvette washing.
	Pipeline leak.	Check and replace pipe, joints or suction probe.
	The inaccuracy of the aspirate volume causes cross contamination in the test.	Recalibrate aspirate volume or replace pump pipe.
	Halogen lamp burned out.	Replace halogen lamp.
	The working environment is poorly ventilated or temperature is too high.	The temperature of the laboratory working environment must meet the requirements of the analyzer.
	The reagent is unstable or may contain suspended particles.	Use a qualified reagent.
	Whether the sample is hemolytic or whether the reagent is invalid.	Check and replace the sample or reagent.
	Voltage is not stable.	connect regulated power.
The results are uniformly low or high.	The aspirate volume of STD is wrong.	Add standard accurately.
	Standard out of date.	Change the standard.
	Reagents ( especially enzymatic reagents) are spoiled by contamination.	Use a qualified reagent.
	Wrong temperature.	Temperature calibration.
	The ratio of sample to reagent is incorrect.	Add samples and reagents exactly as required in the reagent specification.
Print white paper	The printing paper installation direction is reversed.	Reinstall thermal printing paper.



# Chapter 7 Transportation and Storage

## 7.1 Transportation

Transport should be in accordance with the regulations implementing of order contract, Away from the toxic, harmful, corrosive substances.

It should be to prevent severe shocks, rain and exposure, overturned not be permitted in transportation.

## 7.2 Storage

It should be stored in environment temperature  $-5^{\circ}\text{C} \sim 50^{\circ}\text{C}$  , relative humidity no more than 80%, well-ventilated indoor. It shouldn't storage with toxic, harmful, corrosive materials stored.



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