沃文特
ORIENTER

使用说明书
USER MANUAL

LA3000
全自动化学发光免疫分析仪

Automatic Chemiluminescence Immunoassay Analyzer

服务热线/Service 400 823 6886

Table of Contents

Foreword

Thank you for using Automatic Chemiluminescence Immunoassay Analyzer (hereinafter referred to as the "System") of Sichuan Orienter Biotechnology Co., Ltd. (hereinafter referred to as the "Company"). Before using the system, please read and understand the contents of this manual carefully and keep it properly.

Product information

Product name: Automatic Chemiluminescence Immunoassay Analyzer

Specification & model: LA3000, LA3000S

Manufacture date: see nameplate

Service life: 10 years

Name of registrant/manufacturer: Sichuan Orienter Biotechnology Co., Ltd.

Domicile of registrant/manufacturer: No.9, Kangqiang 4th Road, Hi-tech Zone, Chengdu

Production address: W2, No.9, Kangqiang 4th Road, Hi-tech Zone, Chengdu

Tel: 028-87808620

Medical Device Manufacturing License No.: CYJXSCX No. 20150063

Medical Device Registration Certificate No./Product Technical Requirements No.: CXZZ 20222220095

Manual approval date: June 21, 2022

Version: 1.0

Intellectual Property Declaration

The Company has:

- the right of final interpretation of this manual;
- the right to modify the content of this manual without prior notice;
- the right to change technology without prior notice; and
- the right to modify product specifications without prior notice.

The Company disclaims all warranties of any kind with respect to this manual, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

The Company is only responsible for the safety, reliability and performance of this system if:

- assembly operations, extensions, readjustments, improvements and repairs are carried out by personnel approved by the Company;
- the relevant electrical equipment conforms to the national standards; and
- the product operation is carried out according to the instructions of this manual.

Maintenance service

Free service scope:

All products that meet the scope of our warranty service can enjoy the free service.

Paid service scope:

- Products beyond the scope of the Company's warranty service, to which the Company will provide paid service;
- Even during the warranty period, the products that need to be repaired due to the following reasons: man-made damage; improper use; the grid voltage exceeding the specified range of the product; irresistible natural disasters; replacement of the parts and consumables without the permission of the Company or repair and disassembling of the machine by the personnel not authorized by the Company.

For after-sales service, please contact:

Company Tel: 028-87808620

Order Tel: 028-87820207

Order Fax: 028-87820370

Company E-mail: scwwt@scwwt.com

After-sales Tel: 400-823-6886

Company address: No.9, Kangqiang 4th Road, Hi-tech Zone, Chengdu

Electromagnetic Compatibility Declaration

- This system complies with GB/T18268.1-2010 (IEC61326-1:2005, IDT), Electrical Equipment for Measurement, Control, and Laboratory Use - EMC Requirements - Part 1: General Requirements and GB/T18268.26-2010 (IEC61326-2-6:2005, IDT), Electrical Equipment for Measurement, Control, and Laboratory Use - EMC Requirements - Part 26: Particular Requirements - In Vitro Diagnostic (IVD) Medical Equipment (see Table 1-Table 3).
- The following requirements shall be strictly observed during use, otherwise electromagnetic interference may be caused to other equipment or the anti-electromagnetic interference capability of this system may be reduced, or even the basic performance may be lost.
- The system is designed and tested as per Class A equipment in GB4824.The system is not expected to be directly connected to the public power grid, and it is not permanently installed equipment, nor life supporting equipment.
- Description of possible effects of portable and mobile RF communications equipment on medical electrical equipment: Portable and mobile RF communication equipment may affect the normal operation of the system. It is necessary to ensure that the portable and mobile RF communication equipment and the system meet a certain distance requirement. See Table 4 for details.
- It is recommended that the electromagnetic environment be evaluated prior to use of the system.The system shall not be used close to or stacked with other equipment. Except for the cables, connecting wires and other accessories sold by the manufacturer as spare parts of internal components, the components shall not be replaced or repaired without permission, otherwise it may cause excessive electromagnetic interference or increased immunity requirement.
- Do not use the system near strong radiation sources (e.g., unshielded RF sources) as this may interfere with normal system operation.

Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The system is intended for use in the electromagnetic environment specified below and the purchaser or user shall ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Guidance
Conducted emission, GB 4824	Group 1 Class A	The equipment uses RF energy only for its internal function. As a result, its RF emissions are low and there is little chance of interference with electronic equipment.
Radiated emission, GB 4824	Group 1 Class A	The equipment is suitable for use in all establishments other than domestic facilities and not directly connected to the public low-voltage power supply network for domestic use.
Harmonic emission, GB 17625.1	N/A	
Voltage fluctuation/Flicker emission GB 17625.2	N/A	

Table 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The system is intended for use in the electromagnetic environment specified below and the purchaser or user shall ensure that it is used in such an environment.			
Immunity test	GB/T 18268.26 Test level guide	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge GB/T 17626.2	±4 kV contact discharge ±8 kV air discharge	±4 kV contact discharge ±8 kV air discharge	Floors shall be of wood, concrete or ceramic tile and if covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient burst, GB/T 17626.4	±1 kV to power line	±1 kV to power line	The mains supply shall be of a quality typical for use in a commercial or hospital environment.
Surge GB/T 17626.5	±1 kV line-to-line ±2 kV line-to-ground	±1 kV line-to-line ±2 kV line-to-ground	The mains supply shall be of a quality typical for use in a commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, GB/T17626.11	0%U_T for 1 cycle (100% dip on U_t) 40% U_T for 5 cycles (60% dip on U_T) 70% U_T for 25 cycles (30% dip on U_t) 5%U_T for 5s (95% dip on U_t)	0%U_T for 1 cycle 40% U_T for 5 cycles 70% U_T for 25 cycles 5%U_T for 5s	The mains supply shall be of a quality typical for use in a commercial or hospital environment. If the user of the equipment requires continuous operation during power interruptions, it is recommended that the equipment be powered by an uninterruptible power supply or a battery.
Power frequency magnetic field (50Hz) GB/T 17626.8	3A/m	3A/m	If abnormal operation occurs, it is necessary to keep the equipment away from the power frequency magnetic field or install magnetic shielding in that place. The power frequency magnetic field in the intended installation site shall be measured to meet the requirements below the compliance level.
Note: In the voltage dip and short interruption test, U_T refers to the AC grid voltage before voltage application, and 1 cycle is 20 ms.			

Table 3

<table>
<tr><td colspan="4">Guidance and Manufacturer's Declaration-Electromagnetic Immunity</td></tr>
<tr><td colspan="4">The system is intended for use in the electromagnetic environment specified below and the purchaser or user shall ensure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>GB/T 18268.26
Test level</td><td>Compliance level</td><td>Electromagnetic environment-Guidelines</td></tr>
<tr><td>RF conduction
GB/T 17626.6</td><td>3V (effective value)
150 kHz~80 MHz</td><td>3 V (effective value)</td><td rowspan="2">Portable and mobile RF communications equipment shall not be used closer to any part of the equipment including cables than the recommended separation distance, which shall be calculated using the formula corresponding to the frequency of the transmitter.
Recommended separation distance
$d=1.2\sqrt{P}$
$d=1.2\sqrt{P}$ 80 MHz～800 MHz
$d=2.3\sqrt{P}$ 800 MHz～2.0 GHz
where:
P-Maximum output power rating of the transmitter provided by the transmitter manufacturer, in watt (W);
d-Recommended separation distance, in meter (m).
The field strength of fixed RF transmitters, as determined by a survey [a] of the electromagnetic site, and each frequency scope [b] shall be lower than the compliance level.
Interference may occur near equipment marked with the following symbol:
  </td></tr>
<tr><td>RF radiation
GB/T 17626.3</td><td>3 V/m
80 MHz~2.0 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800MHz, the formula for the higher frequency band should be used.
Note 2: These guidelines may not be suitable for all cases. Electromagnetic propagation is affected by absorption and reflection of buildings, objects, and the human body.</td></tr>
<tr><td colspan="4">a. The field strength of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur radio, AM/FM radio broadcasts, and television broadcasts, cannot be predicted theoretically with accuracy.To assess the electromagnetic environment of fixed RF transmitters, a survey of the electromagnetic site should be considered.If the measured equipment is located in an area with field strengths above the above RF compliance levels, the system should be observed to verify normal operation.If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.
b. The field strength shall be less than 3 V/m over the frequency range of 150 KHz to 80 MHz.</td></tr>
</table>

Table 4

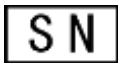
Recommended Separation Distances between Portable and Mobile RF Communications Equipment and this Equipment			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. According to the maximum output power of communication equipment, the purchaser or user of this system can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitter) and this system.			
Maximum rated output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter/m		
	150 kHz~80 MHz $d=1.2\sqrt{P}$	80 MHz～800 MHz $d=1.2\sqrt{P}$	800 MHz～2.0 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the transmitter's maximum rated power not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where p is the transmitter's maximum rated output power provided by the transmitter manufacturer, in watts (w). Note 1: At 80 MHz and 800MHz, the formula for the higher frequency band should be used. Note 2: These guidelines may not be suitable for all cases. Electromagnetic propagation is affected by absorption and reflection of buildings, objects, and the human body.			

Signs

Please pay attention to and strictly observe all the following warning labels affixed to the Automatic Chemiluminescence Immunoassay Analyzer. Do not cover or remove these labels. If it falls off or is damaged, please inform the technical service department of our company to replace it.

	**Caution, Danger:** It means that if the content or operation of the warning is not guarded, it may cause serious harm to users or others. **Caution:** Operators are forbidden to touch without training. If they do not follow the prompts, it may lead to injury to the operators or instrument damage, data loss or low system performance.
	**Biohazard:** It indicates that this part involves biological risks, which may cause biological harm to users or others.
	**High Voltage:** It indicates that this part contains high voltage, and contact with high voltage will cause serious injury.
	**Caution, Sharp Objects:** It indicates that this part contains sharp objects that may pose a hazard.
	**Caution, Mechanical Injury:** It indicates that the area has moving parts and that physical contact with the area during operation may result in mechanical injury.

The following signs may also be seen on the internal and outer packages of instruments, kits and related consumables produced by the Company:

Signs	Meaning
	**Protective earthing:** It indicates the terminals connected to the outer protective conductor that prevent electric shock in the event of a fault.
	**Alternating current:** It indicates the terminals used for AC power, indicating that the equipment is only suitable for AC power.
	**Manufacturer:** It indicates the manufacturer or producer of the product.
	**Manufacture date:** It indicates the manufacture date of the product.
	**Instructions for Use:** The reader is advised to read the Instructions for Use for information on proper use.
	**Serial Number:** Used with the instrument serial number.
	**Temperature limits:** It indicates the upper and lower storage and transport temperature limits of the product.
	**Service life:** It indicates that the product shall be used before the indicated year, month or day.
	**Fragile, handle with care:** It indicates that the product or some of its components are fragile, and the handling personnel are reminded to handle it with care.
	**Avoid rain:** It indicates that the product is afraid of rain and should be kept dry
	**This side up:** It indicates that the transport package should remain upright during transport.

	**Hooking prohibited:** It indicates that hooks are prohibited when handling transport packages.
	**Stacking prohibited:** It indicates that the package can only be stacked in a single layer.
	**Relative humidity limits:** It indicates the upper and lower relative humidity limits for storage and transportation of this product.

Note: The above warning labels, packaging, storage and transportation signs and graphical symbols of electrical products meet the requirements of relevant laws and regulations. For more detailed interpretation, please refer to GB/T191-2008, YY/T0466.1-2016/ISO15223-1:2016 、GB/T5465.2-2008/IEC60417 DB:2007, ISO7000:2019 and other relevant standards.

Chapter 1 System Overview

1.1 System introduction

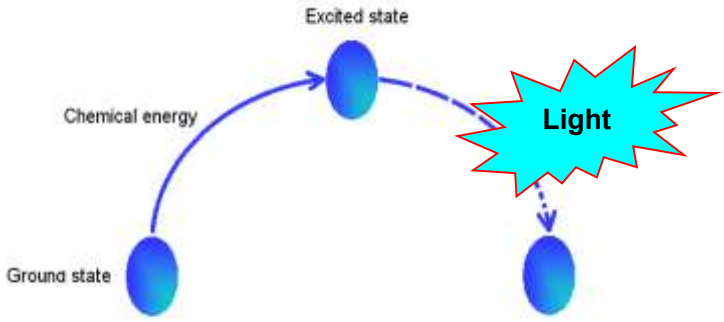
LA3000 and LA3000S Automatic Chemiluminescence Immunoassay Analyzer is a chemiluminescence enzyme immunoassay system based on magnetic particles. Chemiluminescence immunoassay is a new labeled immunoassay technology which combines chemiluminescence system with immune reaction and is used to detect trace antigens or antibodies.Its detection principle is similar to that of radioimmunoassay (RIA) and enzyme immunoassay (EIA), but the difference is that it uses luminescent substances instead of radionuclides or enzymes as markers, and directly determines with its own luminous intensity. It not only utilizes the specificity of antigen-antibody immune reaction, but also utilizes the high sensitivity of chemiluminescence. It is more sensitive than the previous radioimmunoassay (RIA) and enzyme immunoassay (EIA). Its dynamic range is wider and its result is more accurate. This system is used for quantitative or qualitative determination of different analyte concentrations in human body fluids. It is widely used for the determination of eugenics, thyroid function, tumor markers, inflammatory markers, infectious diseases and other items.

1.2 Working principle

Chemiluminescence is a kind of light radiation phenomenon accompanying in the process of chemical reaction. The difference between chemiluminescence and fluorescence is that the luminescence of fluorescent dye needs external excitation light. The energy of excitation light makes the molecule undergo energy transition to form an excited state, and then returns to the ground state from the excited state, thus releasing photons. However, chemiluminescence is a chemical reaction to generate chemical energy. Chemical energy makes molecules undergo energy transition, forming an excited state, and then returning from the excited state to the ground state, thereby releasing photons, as shown in the following figure:

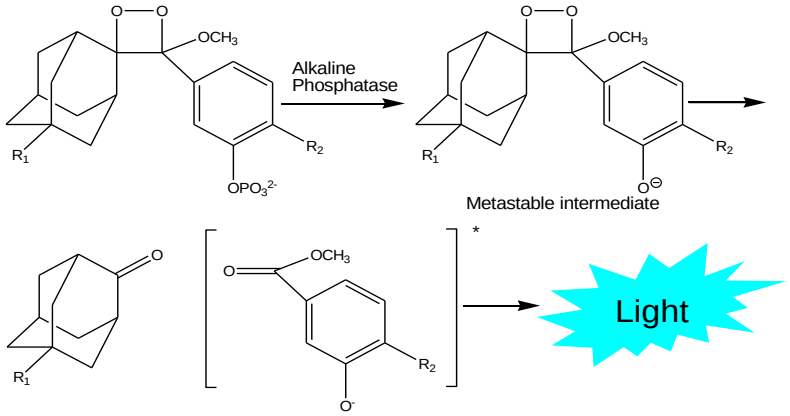
$$A + B \rightarrow C^* + D$$

$$C^* \rightarrow C + h\nu$$



Luminols and 1,2-dioxetanes are two typical chemiluminescent substrate groups.

The LA3000 and LA3000S Automatic Chemiluminescence Immunoassay Analyzer adopts the principle of indirect chemiluminescence immunoassay based on AMPPD and alkaline phosphatase. An enzyme involved in chemiluminescence reaction, such as alkaline phosphatase (ALP), is used to label an antibody or antigen, and after an immune reaction with the antigen or antibody in the sample to be detected, a complex of magnetic particle coated antibody (or antigen) -antigen (or antibody) to be detected -enzyme labeled antibody (or antigen) is formed. After washing, AMPPD is added to catalyze or decompose the substrate to emit light with a wavelength of 470nm, and the light intensity reaches the peak in 15min, and the light signal intensity remaines stable within 15~60min, with little change. Under the catalysis of ALP, the light intensity of ALP with the same concentration is very consistent after 4min under the condition of consistent reading time. The light signal is received by a highly sensitive photomultiplier tube, converted into an electrical signal and amplified, and finally converted into a digital signal, which is transmitted to a computer system for calculation of the analyte.According to the different patterns of immune reaction, it can be divided into sandwich method, competition method, capture method and so on.AMPPD luminescence mechanism is shown in the following figure:



1.3 Reaction principle

LA3000 and LA3000S Automatic Chemiluminescence Immunoassay Analyzer use the principle of enzyme-catalyzed chemiluminescence immunoassay to detect human serum, plasma, urine or other body fluid samples. The chemiluminescence reagent is adamantane (AMPPD). The immune complex is separated from other substances not involved in the reaction by magnetic separation of magnetic particles in heterogeneous reaction mode.

According to the different patterns of immune reaction, it can be divided into sandwich method, competition method, indirect method, capture method and so on.

1.3.1 Sandwich method

According to the different detection objects (antigen or antibody), it can be divided into double antibody sandwich method and double antigen sandwich method.

The basic principle of double antibody sandwich method is that the specific antibody and ALP-labeled specific antibody connected to the solid-phase magnetic particles are respectively combined with two different antigenic determinants on the antigen to be detected to form "antibody-antigen-antibody" immune complex, and the magnetic particles are adsorbed by magnetic field, and the immune complex is directionally aggregated under the magnetic field, and then other substances not involved in the reaction are removed by washing.The substrate is added, the ALP on the immune complex and the substrate generate a chemiluminescence reaction, the luminescence signal is measured by an instrument, and the luminescence signal value is positively correlated with the concentration of the antigen to be detected in the sample.

The basic principle of the double antigen sandwich method is that the specific antigen and ALP-labeled specific antigen connected to the solid-phase magnetic particles are respectively combined with two different sites on the antibody to be detected to form an "antigen-antibody-antigen" immune complex, and the magnetic particles are adsorbed by the magnetic field, and the immune complex is directionally aggregated under the magnetic field, and then other substances not involved in the reaction are removed by washing.The substrate is added, the ALP on the immune complex and the substrate generate a chemiluminescence reaction, the luminescence signal is measured by an instrument, and the luminescence signal value is positively correlated with the concentration of the antibody to be detected in the sample.

1.3.2 Competition method

According to the different test objects (antigen or antibody), the competition method can be divided into double antigen competition method and double antibody competition method.

Double antigen competition method is used for antigen detection. Its basic principle is that the antigen labeled by ALP and the antigen to be detected in the sample compete with the antibody connected to the solid-phase magnetic particles to form two immune complexes of

"ALP-antigen-antibody" and "sample antigen-antibody". The magnetic particles are adsorbed by magnetic field, and the two immune complexes are directionally aggregated under the magnetic field, and then other substances not involved in the reaction are removed by washing.The substrate is added, the ALP on the "ALP-antigen-antibody" immune complex and the substrate undergo a chemiluminescence reaction, and the luminescence signal is measured by the instrument, and the luminescence signal value is negatively correlated with the concentration of the antigen to be detected in the sample.

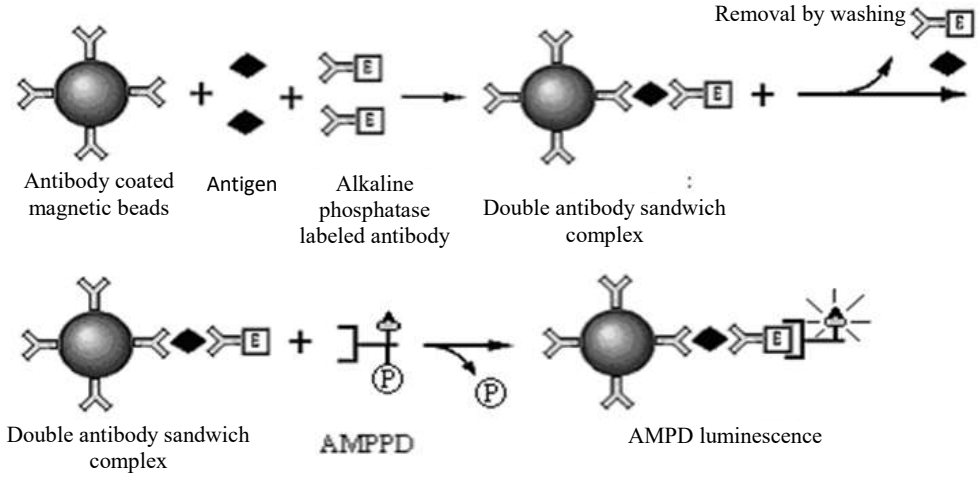
Double antibody competition method is used for antibody detection. Its basic principle is that ALP-labeled antibody and the antibody to be tested in the sample compete with the antigen connected to the solid-phase magnetic particles to form two immune complexes of "ALP-antibody-antigen" and "sample antibody-antigen". The magnetic particles are adsorbed by magnetic field, and the two immune complexes are directionally aggregated under the magnetic field, and then other substances not involved in the reaction are removed by washing.The substrate is added, and the ALP on the "ALP-antibody-antigen" immune complex and the substrate undergo a chemiluminescence reaction, and the luminescence signal is measured by the instrument, and the luminescence signal value is negatively correlated with the concentration of the antibody to be detected in the sample.

1.3.3 Capture method

The capture method is divided into capture method and reverse capture method (indirect method).

The principle of capture method is to use secondary antibody to capture antibody and form "secondary antibody-antibody-antigen" immune complex with antigen. The difference between the two sub-methods is that the solid phase magnetic particles in capture method are connected with secondary antibody and the ALP marker is connected with antigen, while the solid phase magnetic particles in reverse capture method are connected with antigen and the ALP marker is connected with secondary antibody.The magnetic particles are adsorbed by the magnetic field, the immune complex is directionally aggregated under the magnetic field, and other substances not participating in the reaction are removed by washing.The substrate is added, the ALP on the immune complex and the substrate generate a chemiluminescence reaction, the luminescence signal is measured by an instrument, and the luminescence signal value is positively correlated with the concentration of the antibody to be detected in the sample.The reaction process of the reverse capture method (indirect method) is shown in the following figure:

The whole analytical reaction steps of this system are shown in the following figure (taking sandwich method as an example):



1.4 Scope of application

This product is an enzyme-catalyzed chemiluminescence immunoassay system, which adopts heterogeneous reaction mode and indirect chemiluminescence method based on AMPPD and alkaline phosphatase. It is used with the supporting reagents of the Company and is clinically used for qualitative or quantitative detection of analytes derived from human serum, plasma, urine or other body fluid samples;including tumor associated antigen, infectious immunology, myocardial disease, liver disease, kidney disease, osteoporosis, immune function, allergen, hormone, enzyme, protein, blood lipid and lipoprotein, sugar and its metabolite, vitamin, amino acid and blood drug concentration, autoimmune disease and blood coagulation item examination.

This manual is applicable to the Automatic Chemiluminescence Immunoassay Analyzer, including the following specifications and models:

LA3000 Automatic Chemiluminescence Immunoassay Analyzer

LA3000S Automatic Chemiluminescence Immunoassay Analyzer

1.5 System composition

1.5.1 Structure composition

The product is composed of analysis unit, control module, supporting software (release version V1) and accessories (optional).The analysis unit consists of a sample module, a reagent module, an incubation module, a magnetic separation module and a detection module;The control module consists of electronic hardware and embedded system;Accessories include computer host and handheld barcode scanner.

1.5.2 Appearance and composition of analyzer

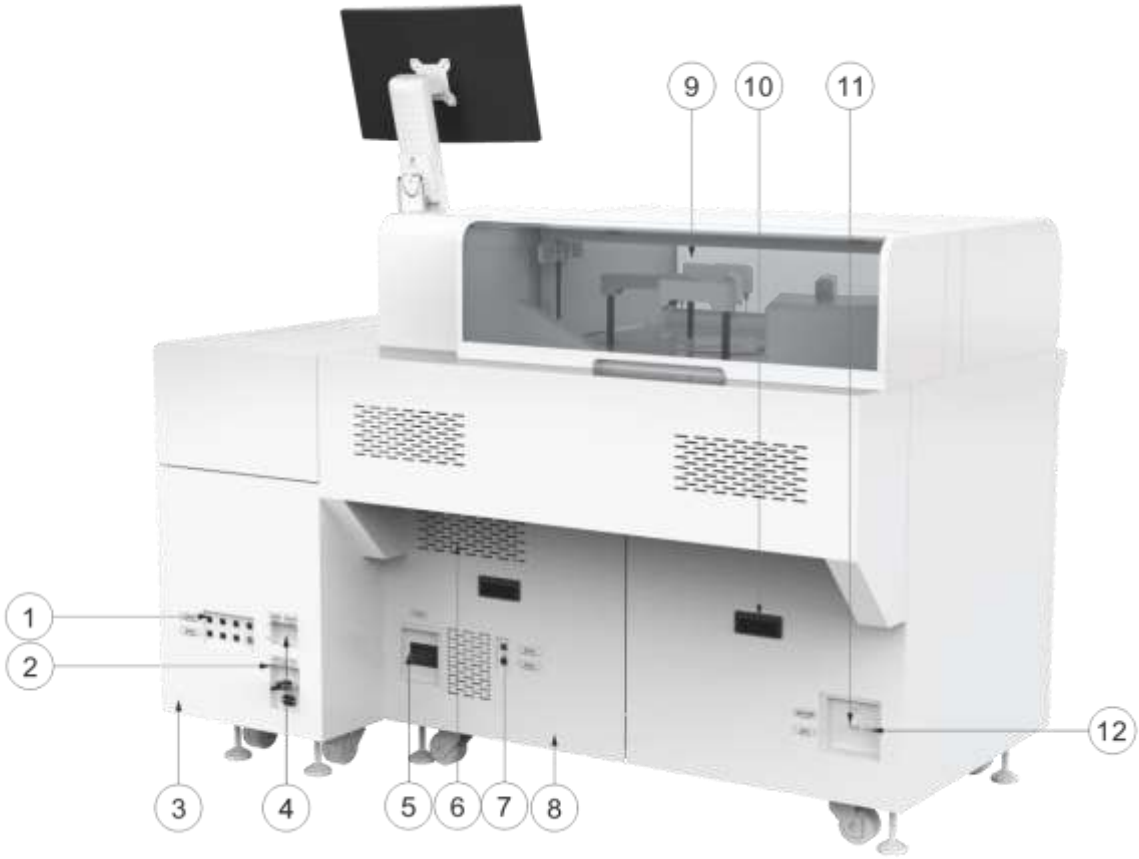
1.5.2.1 Front view of analyzer

1: Consumables indicator	2:Analysis unit front cover	3: Status indicator	4: RV loading cap
5: Display (schematic)	6: Computer stand	7: Sample management unit (schematic)	8: Tablet PC (schematic)
9: Right front door	10: Middle front door	11: Left front door	12: Substrate cabin door

1.5.2.2 Front view of open panel

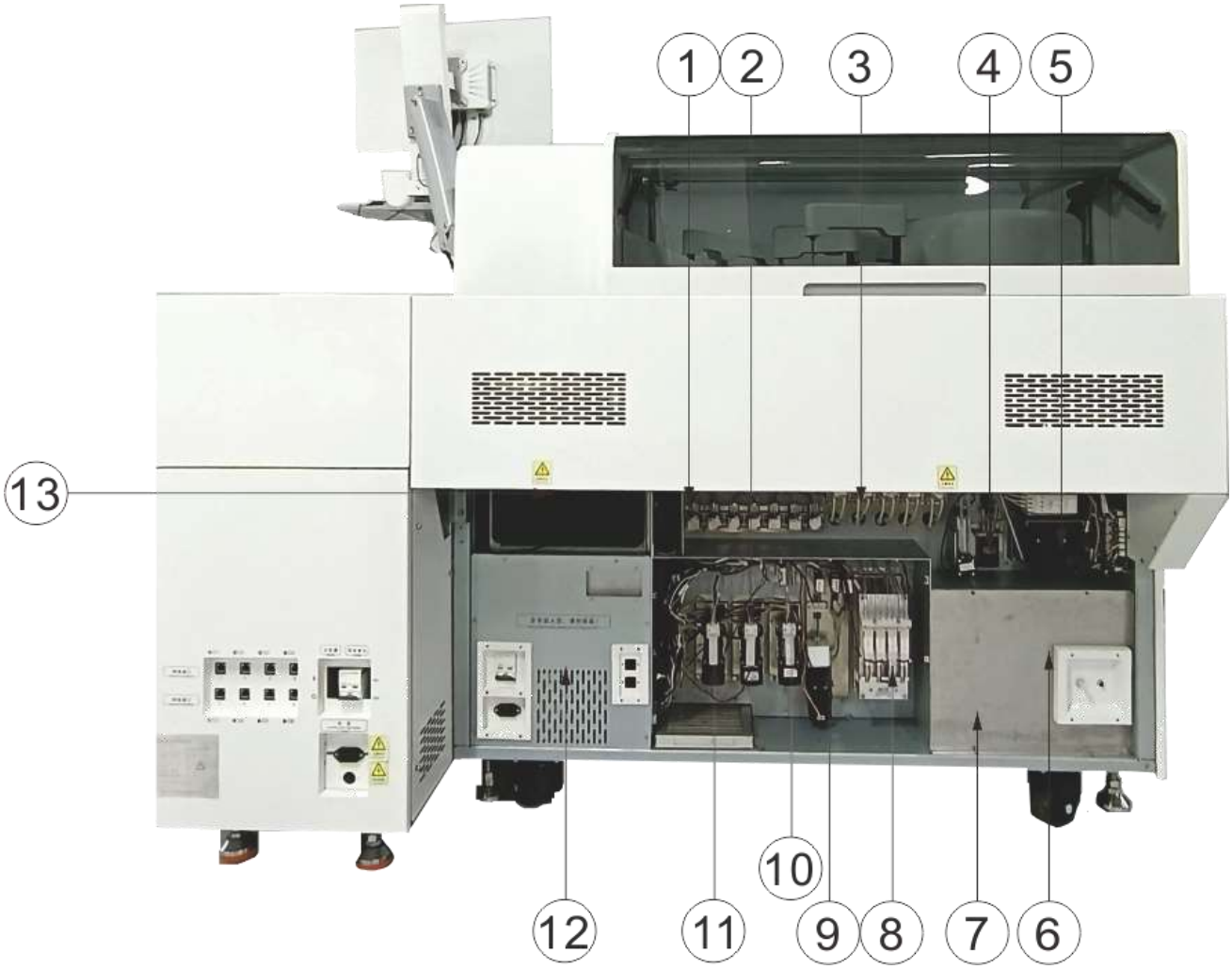
1: Substrate placement cabin	2: S probe wash buffer loading button	3: Wash buffer cabin	4: Wash buffer tray
5: Solid waste basket tray	6: S probe wash buffer	7: Solid waste basket	8: Weak current electric control box
9: Solid waste emptying button	10: Automatic tube feeding module		

1.5.2.3 Rear view of analyzer



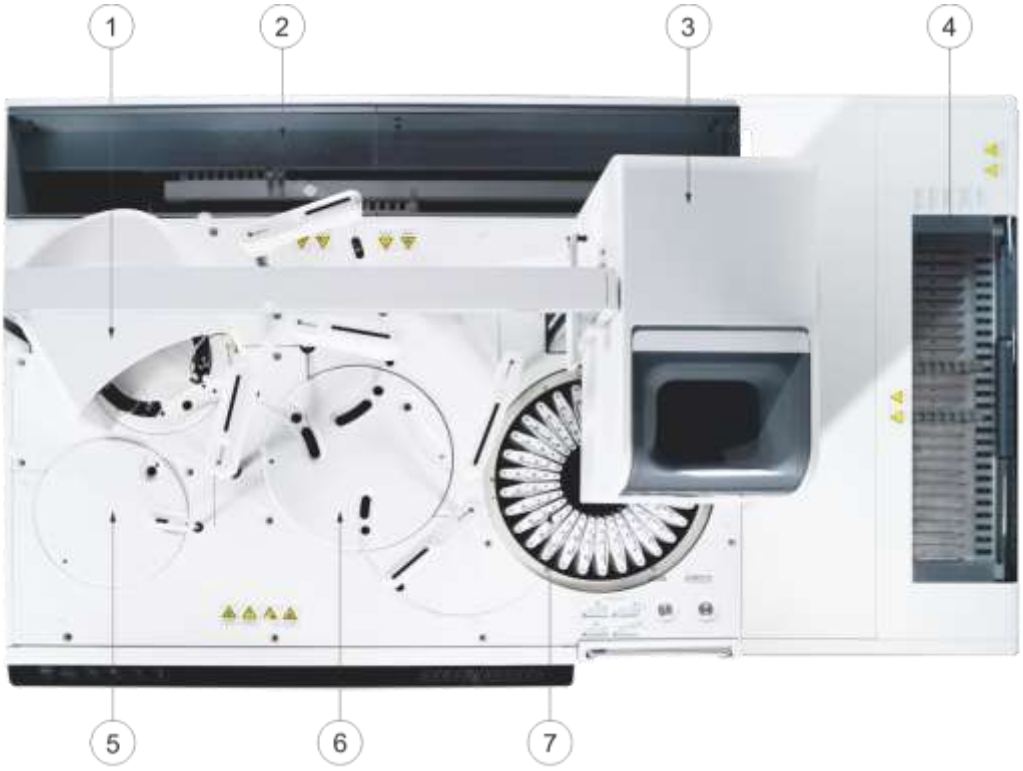
1: Network interface	2: Sample management unit power plug	3: Sample management unit (schematic)	4:Sample management unit switch
5: Analysis unit power plug and power switch	6: Vent	7: Network interface	8: Filter screen
9: Instrument rear cover	10: Back panel handle	11: Waste liquid outlet	12: Waste liquid sensor

1.5.2.4 View of the analyzer after opening the cover



1:Diaphragm pump assembly	2: Probe pump assembly	3: Peristaltic pump assembly	4: Wash buffer pump valve assembly	5: Multi-channel peristaltic pump assembly
6: Waste liquid nozzle assembly	7: Waste liquid diaphragm pump assembly	8: Quadruple syringe assembly	9: Substrate pump valve assembly	10: Probe pump assembly
11: Probe pump assembly	12: Power supply assembly	13: Water cooling radiator		

1.5.2.5 Top view of analyzer



1: Magnetic separation module	2: Sample transport track	3: Automatic tube feeding module	4: Sample management unit (schematic)
5: Detection module	6: Incubation module	7: Reagent compartment module	

1.6 Product performance

Indicators	Content	
Module innterconnection	Supported	
Intra-lot precision for clinical items	Intra-lot precision of procalcitonin (PCT) should be ≤8%	
Analyzer stability	Relative bias not more than ±10%	
Carrying pollution rate	$\leq 10^{-5}$	
Reaction type	One-step or two-step process	
Sample cabin	≥250	
Sample volume [μl]	10~200	
Reagent cabin	An analysis module	30
	Two analysis modules	60
Reagent volume [μl]	25~200	
Reagent refrigeration [℃]	2~8	
Incubation temperature [℃]	37±0.5	
Consumables balance prompt	Supported	
On-board wash buffer capacity [L]	20	
On-board substrate capacity [mL]	260	
On-board RV capacity [unit]	About 2000	
On-board solid waste capacity [unit]	About 2000	

1.7 Notice

Please read this manual carefully before using the system.

Follow the relevant instructions in the manual. If those instructions are neglected, it may cause injury to human body and damage the instrument.

For safety consideration, please do not use parts and devices modified by third parties or privately on the instrument.

This system is applicable to the immunological test using human serum, plasma, urine or other body fluids as samples. If other types of samples are used, this instrument may not work normally.

Before using the system, monitor the system for proper operation by measuring the Quality Control.Incorrect measurement results may lead to wrong diagnosis.

When the newly installed instrument or the instrument is energized for the first time after being moved, the person in charge of the equipment shall check the grounding of the equipment. Under normal use, the person in charge of the equipment shall also check the grounding of the equipment regularly to ensure good grounding. Unreliable grounding may damage the equipment and reduce the protection against hazards, resulting in safety risks.

Please refer to the relevant instructions for use for the storage methods (including before and after opening) and usage methods of reagents, Quality Controls and standard solutions.

Do not open the protective enclosure of the instrument or touch the inside of the instrument in any other way while the instrument is powered on. Opening the protective enclosure of the instrument may result in damage to the internal components of the instrument, exposure to high pressure and mechanical damage.

The system shall remain in the stopped state when the Sample Reagent Module and Wash Incubation Module are performing weekly and monthly maintenance.Contact with these modules may result in injury or infection and therefore requires proper protection and proper laboratory procedures should be followed in case of inadvertent contact with parts that may contain potentially infectious substances.

Due to the risk of infection in contact with samples/waste liquid, it is necessary to wear protective gloves for proper protection when using samples and cleaning solid waste baskets and waste liquid barrels. In case of accidental contact with potentially infectious substances, correct laboratory procedures should be followed.

Due to the risk of injury caused by contact with wash buffers/reagents, it is necessary to wear protective gloves for proper protection when loading wash buffers and reagents. In case of accidental contact with substances that may cause injury, correct laboratory procedures should be followed.

The solid waste and waste liquid of this system are infectious waste, which shall be disposed according to corresponding laws and regulations, and shall not be discarded together with domestic garbage.

This system must be used by medical laboratory professionals or professionally trained doctors and laboratory personnel.

Repeated performance of any of the experiments of this standard may damage the equipment and reduce protection against hazards.

The user shall maintain, service and repair the system according to the requirements of the product manual. The system can be used for a long time if it is confirmed that the product can still maintain basic safety and effectiveness after maintenance, service or repair.

The precautions described in this system are special circumstances that may still occur after full discussion and research. In case of special circumstances, please comply with relevant laws and regulations of the country or region where you are located and contact our after-sales service in time.

1.8 Contraindications

None

Chapter 2 System Installation

2.1Installation condition

Environmental requirement

Instrument size	1710mm (L) x 1020mm (W) x 1225mm (H) (This size includes the sample management unit.)
Requirements for installation clearance	Left: 300mm Right: 500mm Rear: 500mm Front: 800mm Top: 800mm Do not place the device in a position where it is difficult to operate the disconnecting device.
Temperature	10℃~30℃
Humidity	30%～85%
Power supply voltage	AC220V; 50Hz; Good grounding
Power	2000VA
Atmospheric pressure	61.6kPa~106.0kPa (less than 79.5kPa; external pressurization equipment can be used normally)
Air switch	A9F18210
Pollution level	Level 2
Electromagnetic compatibility requirements	The instrument should be kept away from centrifuges, ultrasound, X-ray, MRI and other magnetic field sources.
Ground bearing	The weight that the mounting table can bear shall be greater than 540kg.
Weight of instrument	About 540kg (The analyzer cannot be separated into several independent parts, so there is no individual weight of main components, and this weight includes the sample management unit.)
Protective earthing	The socket connected to the power cord must be reliably grounded.
Other environmental requirements	The environment shall be dust-free, free from mechanical vibration, large noise source and power supply interference, and well ventilated. Avoid direct sunlight or avoid placing it in front of heat source and wind source. The installation ground shall be flat and the surface shall be made of hard material. Carpet, plastic foam and other similar materials are prohibited. If the equipment may not meet all safety requirements after transportation or storage under humid conditions, the equipment shall be allowed to dry and recover for at least 24 hours.

Software environment

Operating system	Windows 10 and above compatible versions
CPU	Intel i3 10100@3.6GHz or higher
Memory space	8GB or more
Hard disk space	250GB or more

2.2 Instrument installation

Packing list

S/N	Description	Quantity	Remarks
1	Instrument host	1	
2	Solid waste basket	1	
3	Waste-discharging probe	4	
4	Peristaltic pump tube	4	
5	Discharge pipe	1	5 meters
6	Cleaning brush	10	
7	Manual	1	
8	Syringe	2	Adding alcohol/weekly maintenance
9	Maintenance bottle	2	
10	Wash buffer barrel supporting sheet	2	
11	Network cable	2	
12	Simplified Operation Guide	1	
13	Daily Maintenance Operation Guide	1	
14	Waste liquid sensor assembly	1	
15	Innterconnection locating pin	2	
16	M12 bolt	2	
17	M20 bolt	2	

2.2.1 Installation preparation

Prior to installation, please provide a site that meets the requirements of installation conditions in the previous section of this manual. The system must be installed by professionally trained personnel. Before removing the packing box, it is necessary to check the packing box. After removing the packing box, it is necessary to check whether the items in the package are complete according to the packing list, and check whether the appearance of the instrument is intact. If any abnormal sign is found in these inspection links, please contact the supplier or the Company.

Note: If the installation position of the instrument needs to be adjusted during use, please contact the supplier or the Company. Do not disassemble it without permission.

	**Caution, Danger:** Care should be taken when removing the box, as shock and impact can cause internal damage to the instrument or displacement of moving parts. After removing the packing box, be careful during the transportation of the instrument to avoid collision between the instrument and other articles, which may damage the instrument. If any of the modules of the instrument are visibly damaged, do not energize the instrument but contact the supplier or the Company. If any of the moving parts of the instrument are not moving smoothly or are blocked after removing the protective material from the instrument, please contact the supplier or the Company.

	**High Voltage:** The power supply part involves high voltage. Please connect the power cord reliably.

2.2.2Connection of power supply

	**Caution, Danger:** Please ensure that the sample management unit switch and power switch are off before connecting power.

Plug one end of the supplied power cord into the power connector of the analyzer and connect the other end to the wall outlet.

2.2.3 Connection of peripheral devices

(1) Install and connect the monitor, printer, and check:

a) Whether the printer driver is installed.

b) The size of the paper used by the printer.

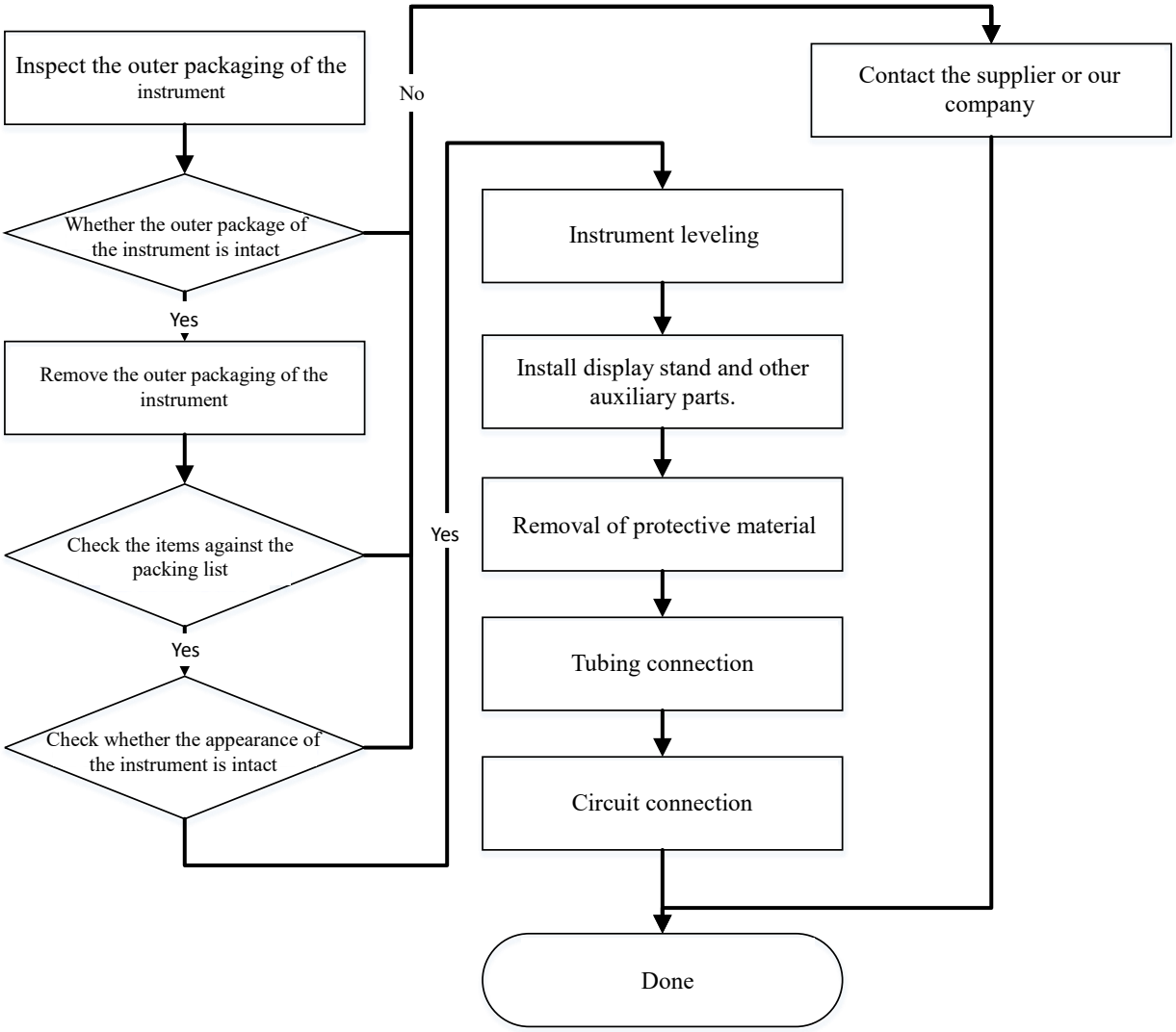
(2) Connect one end of the communication cable to the USB port under the monitor and the other end to the printer port.

(3) Waste liquid level sensor connection:

Connect the supplied level sensor to the terminal of the waste liquid level sensor interface.

Display parameter requirements:

Maximum resolution	1920 x 1080
Touch screen supported or not	Supported
Number of USB input ports	1
Number of USB output ports	4
Display input	HDMI/VGA
Installation mode	VESA

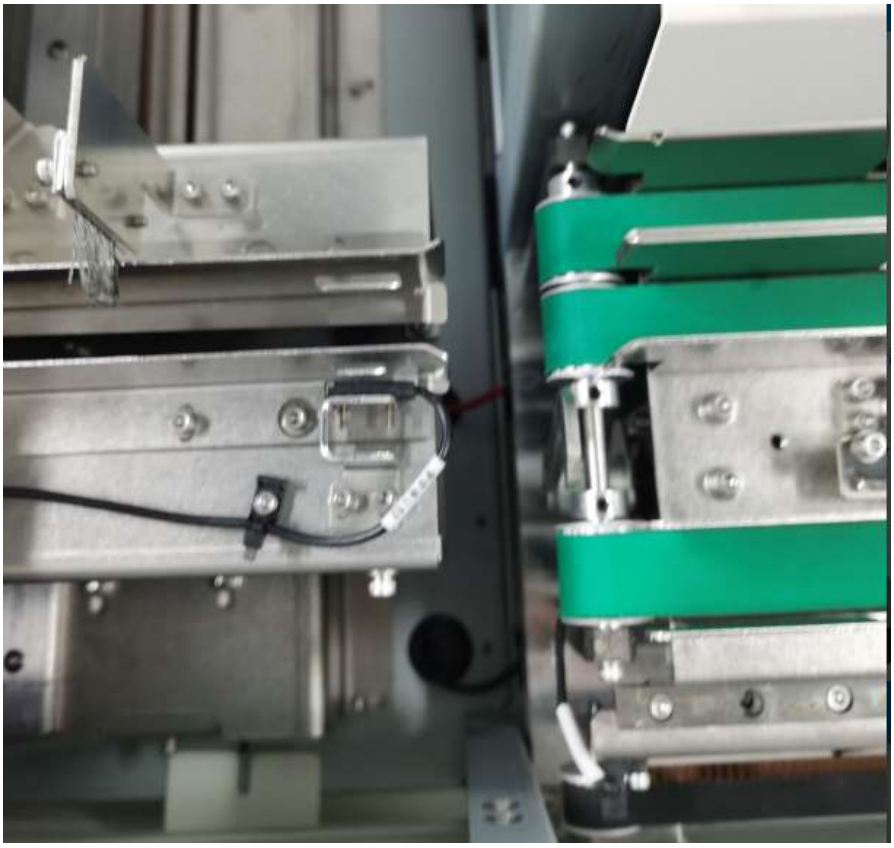


Instrument Installation Process

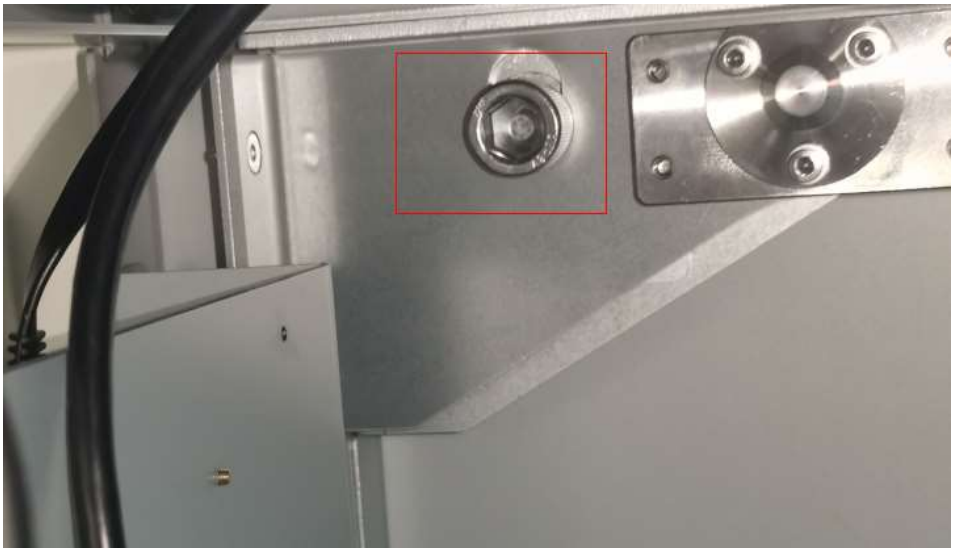
2.2.4Connection and installation of analyzer and sample management unit (SDM)

The sample management unit is filed as an independent non-medical device product and used in combination with this product.

(1) Level the height of the analyzer and SDM;

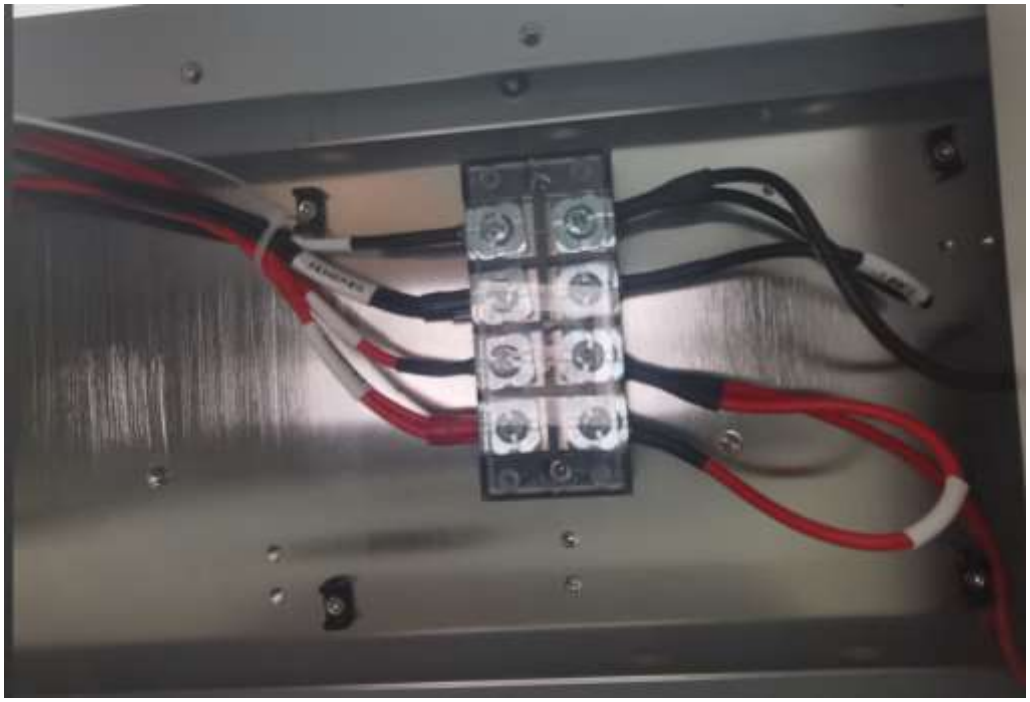


(2) Fasten screws connecting analyzer to SDM



(3) Connect the analyzer with the communication network cable of SDM;

(4) Connect the power cord



2.2.5 Multi-analyzer interconnected installation

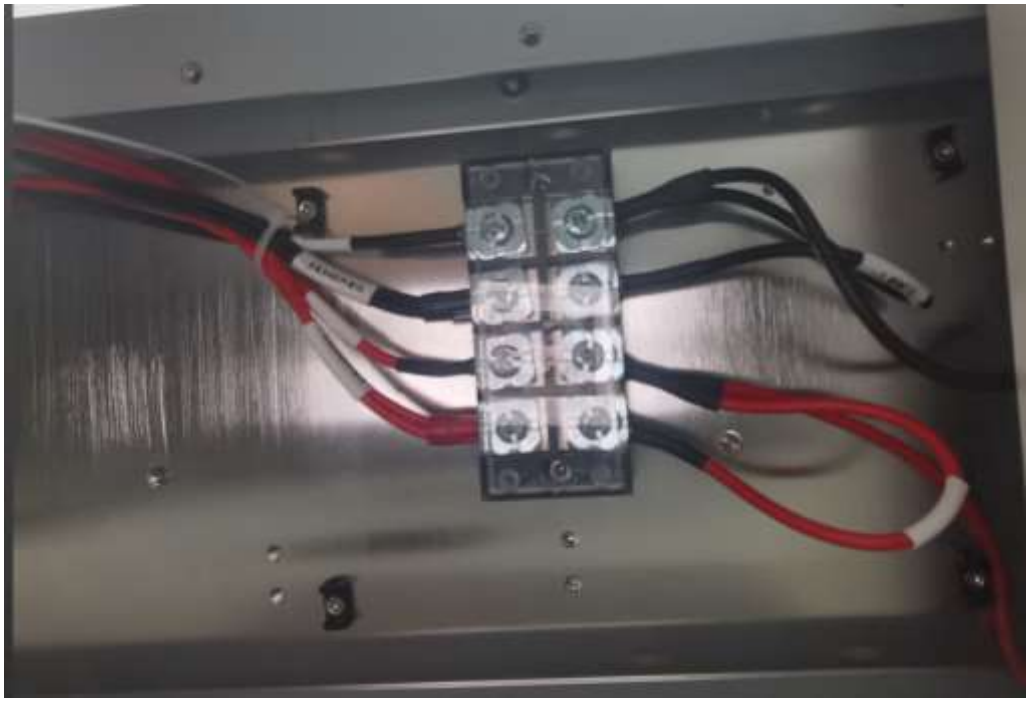
(1) Level the analyzer height

(2) Insert the locating pin on the left side of the analyzer into the locating hole on the right side of the next analyzer, as shown in the red box below;

(3) Connect the fastening screws between analyzers.

(4) Connect the network cable

(5) Connect the power cord



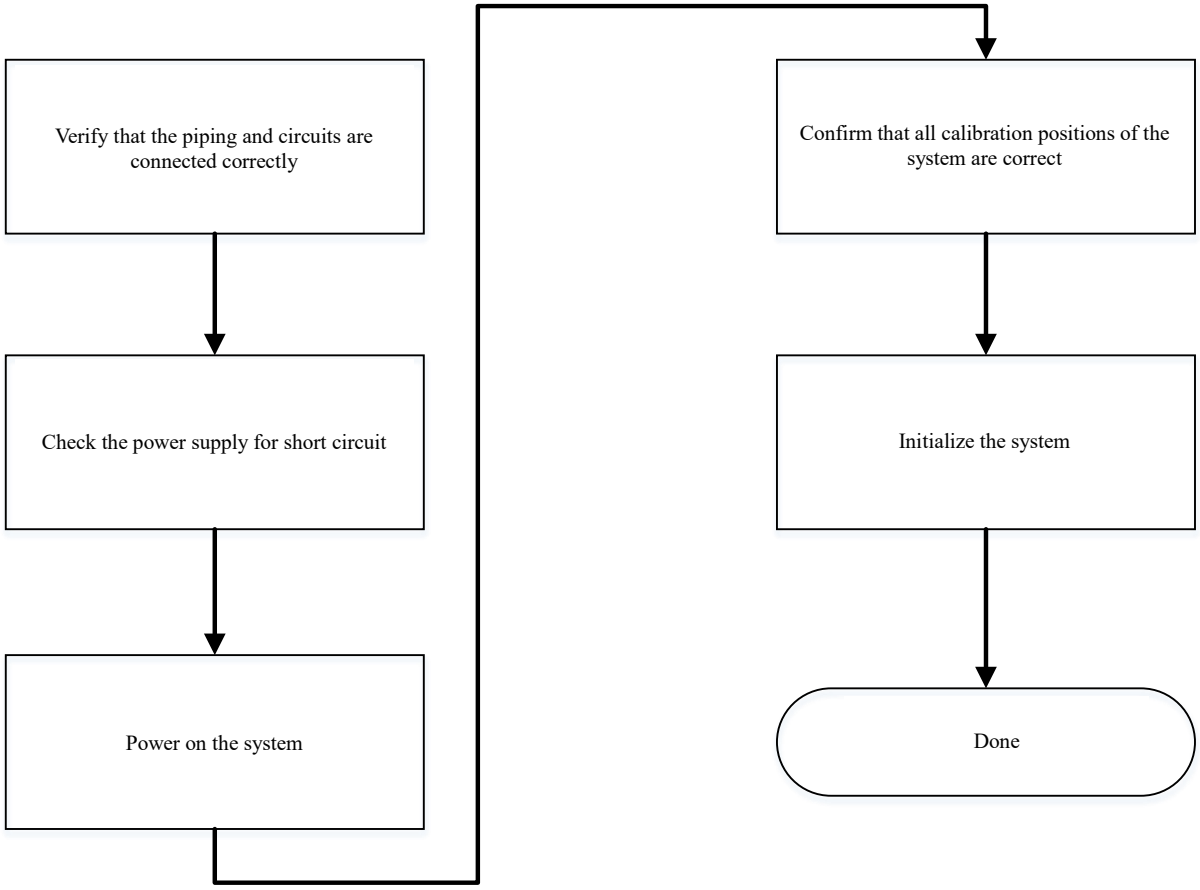
2.3 Software installation

After the instrument is installed and normally powered on, the computer is turned on. The computer is pre-installed with software.

2.4 Debugging

After installation of the instrument and software, debugging is required before normal operation.Before debugging, it is necessary to confirm that the piping connection and circuit connection during the installation of the instrument are correct.During the whole debugging process, only trained professionals shall use the debugging function of the supporting software of the system.

	**Caution, Danger:** Do not hot-plug the wiring and the circuit board when the machine is turned on. Do not force a part by hand when the machine is turned on. Do not touch any circuit board with conductive objects when the machine is turned on. In case of smoke, overheating of the circuit board or an electronic device, or abnormal power indication, shut down the machine immediately for inspection, and restart the machine after troubleshooting.



System Debugging Process

The following table lists all calibration positions for this system.The column title corresponding to the horizontally ticked cell of the calibration position is the motion module associated with the calibration position, and when there are multiple ticked cells in the row corresponding to the calibration position, it indicates that there are multiple motion modules associated with that position.

Module name / Calibration position	Automatic tube feeding	Sample transfer tray	Sample arm	Sample track	Sample gripper	Reagent transfer tray	Reagent arm	Magnetic bead arm	Kit tray	Incubation tray	Detection gripper	Wash tray	Cleaning & mixing motor	Waste liquid probe	Test tray
Sampling position			√	√											
Loading position		√	√												
S probe alkaline wash position			√												
S probe common wash position			√												
Sample transfer tray tube pick-up position		√			√										
Reagent transfer tray tube inlet/outlet position					√	√					√				
First reagent pick-up position							√		√						
Second reagent pick-up position							√		√						
Reagent loading position						√	√			√					
R probe alkaline washing position							√								
R probe common cleaning position							√								
Magnetic bead pick-up position								√	√						
Magnetic bead adding position						√		√							
M probe washing position								√							
Incubation tray tube inlet position					√					√	√				

Incubation tray tube outlet position					√					√	√				
Wash tray tube inlet position for cleaning											√	√			
Washing & mixing height position													√		
Waste liquid suction height														√	
Mixing position after adding the second-step reagent											√				
Detection tray tube inlet and outlet position											√				√
Sample gripper tube-drop position					√										
Detection tray gripper tube-drop position											√				

Chapter 3 System Usage

3.1 Preparation before starting up

If the equipment is not used in accordance with the method specified by the manufacturer, the protection provided by the equipment may be damaged; before powering on the instrument, please perform the following checks to ensure that the system is functioning properly.

Power supply

Check that the power cord on the back of the instrument is properly connected. Check whether the external power supply works normally;

Instrument

Ensure that there is no obstacle on the probe arm on the instrument table, the RV transfer gripper or the cleaning module running track;

Ensure that the video cable, power cable and touch screen cable of external monitor are connected correctly, and the mouse and keyboard cable are connected correctly;

S probes, R probes, and M probes

Ensure that the front end of each probe is free from water droplets and dirt; the probe sees no bending deformation;Check whether there is any obstacle on the running track.

Chemiluminescence RV

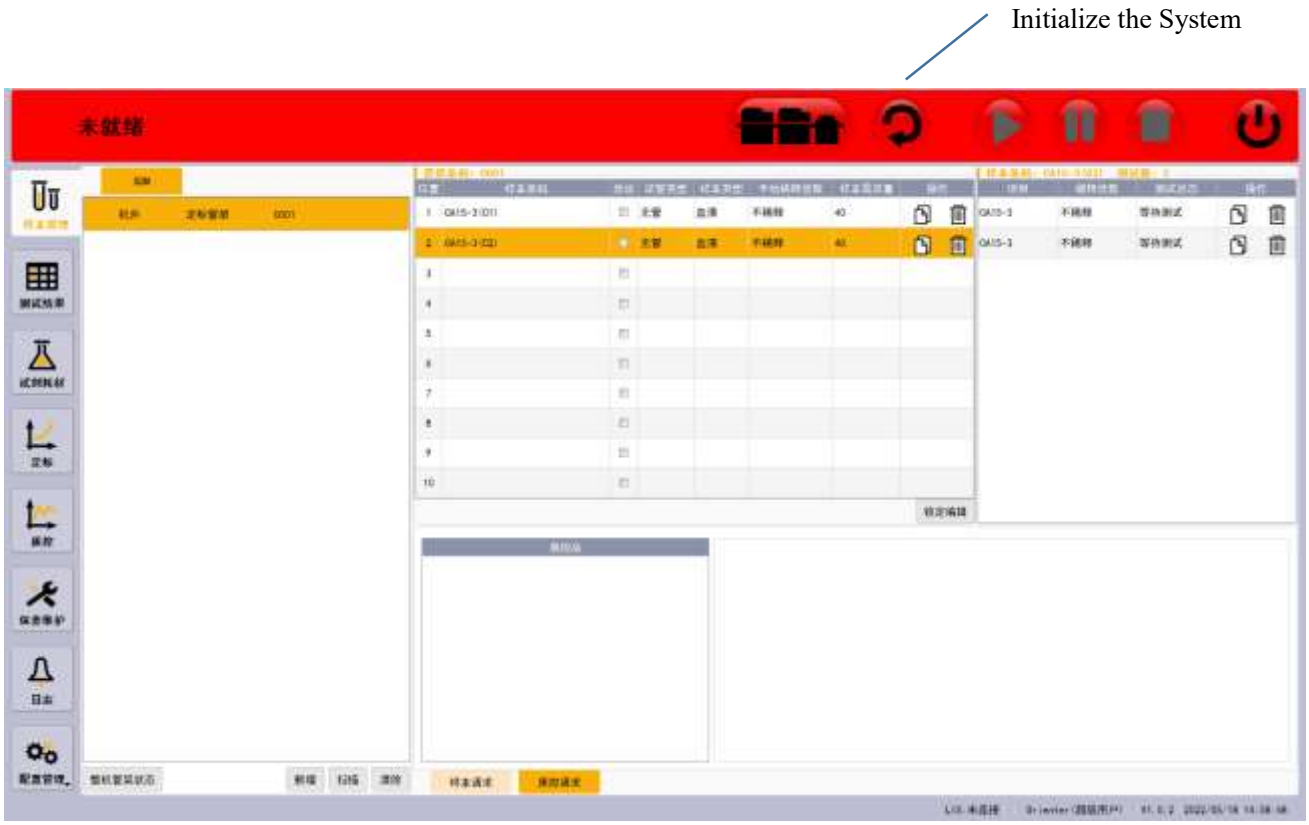
Ensure sufficient chemiluminescence RVs to meet the requirements of instrument operation and sample detection.

For other inspections and the addition, loading and replacement of consumables, see the corresponding sections of this chapter.

3.2 Startup process

3.2.1. Turn on the Sample Management Unit Switch, power switch and Perform Module Switch of the instrument. After the instrument is turned on and the computer is started, double-click the "  " on the desktop of the computer supporting the instrument. After the software is started, the login interface as shown in the figure below will pop up:

3.2.2 After entering the correct user name and password, click the "Login" button to enter the software correctly, and then click the Initialize System button to detect whether each part of the instrument works normally and return the moving parts to their original positions.



3.2.3 If the instrument has been turned on but the internal computer needs to be restarted (e.g., the system supporting software does not respond correctly), only restart the computer through the operating system.

	**Caution, Danger:** Before the first start-up operation after the instrument has been transported or moved, always ensure that the instrument has been subjected to the debugging process.

3.3 Shutdown process

The motion module of the instrument can be powered off by pressing the Perform Module Switch. If the whole system is powered off, the instrument needs to stop working and exit the software. After the computer is shut down through the operating system, press the Perform Module Switch of the instrument, and finally press the power switch of the instrument and the sample management unit switch to cut off the overall power supply of the system.If the operation of the instrument is abnormal or unexpected, which may damage the parts of the instrument, please immediately turn off the Perform Module Switch.

	**Caution, Danger:** If the whole system is powered off, be sure to exit the software first, and then turn off the power switch and sample management unit switch after turning off the computer through the operating system, otherwise the database or computer operating system may be damaged.

3.4Status indicators

The status indicators are divided into two types: instrument status indicators and consumables indicators, as shown in the following figure:

1: Waste liquid barrel 2: Solid waste basket 3: Wash buffer 4: S probe wash buffer

5: Substrate 6: RV

Schematic Diagram of Instrument Status Indicator Position

The instrument status indicator indicates the current status of the entire instrument, with the following meanings:

Indicator status	System status
Red light on	Not ready
Green light on	Standby
Green light flashing	Running
Yellow light on	Paused

The consumable indicator indicates the current consumable status. For some consumables, there is a channel number, and there are auxiliary lights 1 and 2 corresponding to the indicator for indication purpose. The specific meaning is as follows:

Indicator status	System status
Red light on	Consumable allowance or waste space allowance is less than or equal to 5% or the critical sensor is triggered.
Yellow light on	Consumable allowance or waste space allowance is greater than 5% and less than or equal to 20%.
All lights off	Consumable allowance or waste space margin is greater than 20%.

3.5 System configuration

Click the "Configuration Management" button in the navigation bar to configure the software interface language, user account, project parameters, etc., and also configure the project package and define the sample type, department and other options.

Function	Configuration content	Detailed description
System setup	System setup	Configure the interface language, hospital name and other information
	Analysis unit	Configure the current system analysis unit composition and other information
	Account management	Configure and manage current system account information
Item configuration	Configuration	Configure the basic parameters of the item, such as item name, code, sample volume, result unit, number of decimal places of the result and default dilution factor
	Fitting	Configure the item to be a qualitative item or a quantitative item. If it

		is a qualitative item, configure the calculation formula of Cutoff value. If it is a quantitative item, configure the fitting formula and calibration curve calculation method.
	Scope	Configure information such as review range, detection range and reference range of the item.
	Combination of items	Add or delete a package, configure the package ID, package name and items of the package

System configuration interface

3.6 Consumables management

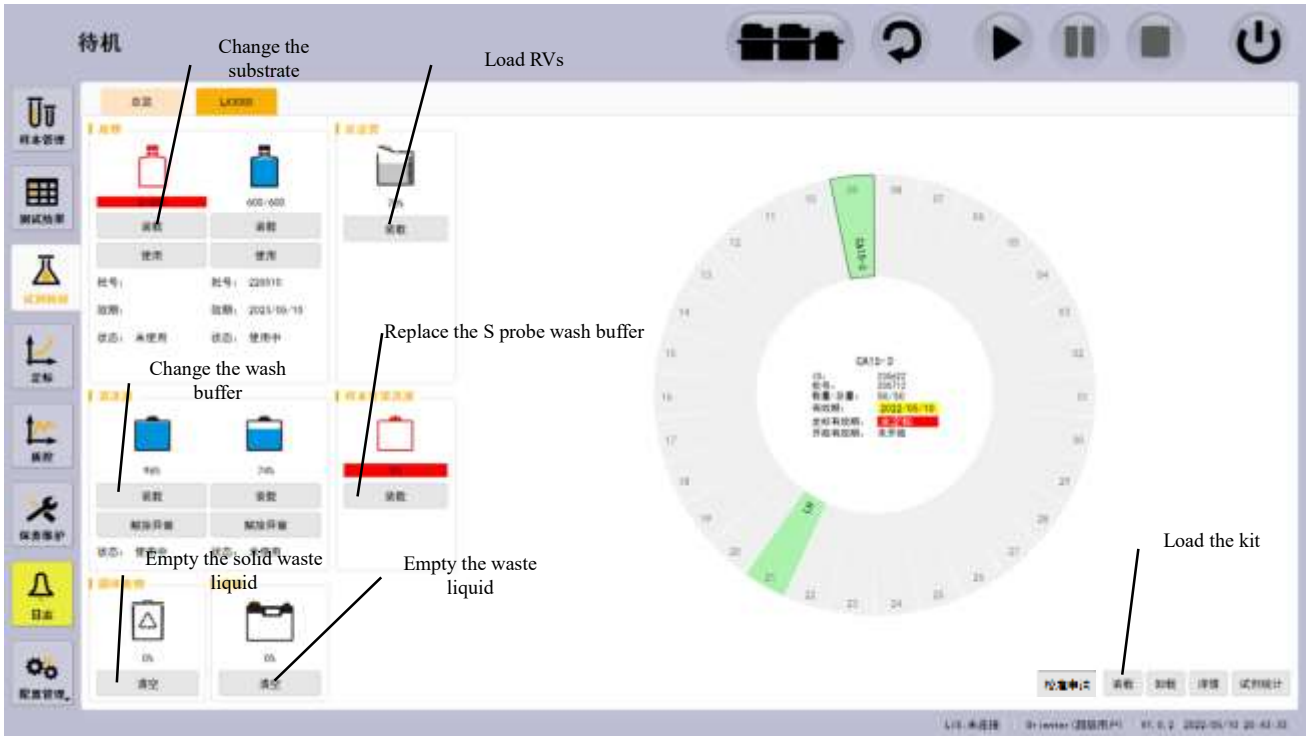
3.6.1 Regional distribution of consumables

In the process of specimen testing, the consumables required by the system are: Chemiluminescence RV (hereinafter referred to as RV), reagent, S probe wash buffer, wash buffer and substrate solution for automatic immunoassay system (hereinafter referred to as substrate). The wastes generated include solid waste and liquid waste. The location distribution of various consumables and wastes in the instrument is shown in the following figure:

1: Substrate loading area	2: Sprobe wash buffer loading button	3: Wash buffer loading area	4: Wash buffer observation area
5: Sprobe wash buffer loading area	6: Solid waste basket	7: Solid waste emptying button	8: RV loading area

Before running the test, load enough RVs, reagents, wash buffer, S probe wash buffer and substrate, and leave enough space in the solid waste basket and waste liquid barrel.

Note: The waste liquid barrel is optional. Please check it when the instrument is equipped with a waste liquid barrel.



Consumables Management Software Operation Interface

Consumables Loading Interface

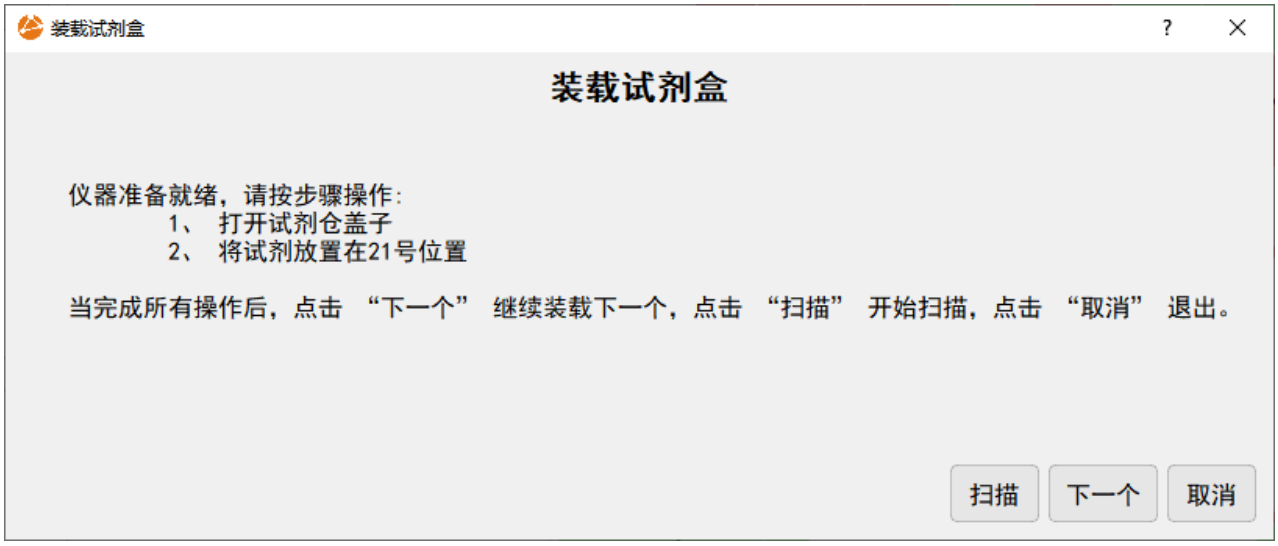
3.6.2 Load the kit

When the reagents required for the test item are insufficient or do not exist, the corresponding kit needs to be loaded.Before the current system uses a Lot No of reagent for the first time to test patient samples, the Lot No of reagent must be calibrated with calibrators, otherwise the system cannot calculate the concentration.

	**Biohazard:** Due to the risk of damage from contact with reagents, calibrators, quality controls, etc., proper protection is required when loading reagents. In case of inadvertent contact with substances that may cause injury, follow proper laboratory procedures for handling.

3.6.2.1 Click the "Reagent Consumables" button in the navigation bar to enter the Consumables Management Software Operation Interface, and select the position where the reagent kit needs to be loaded;

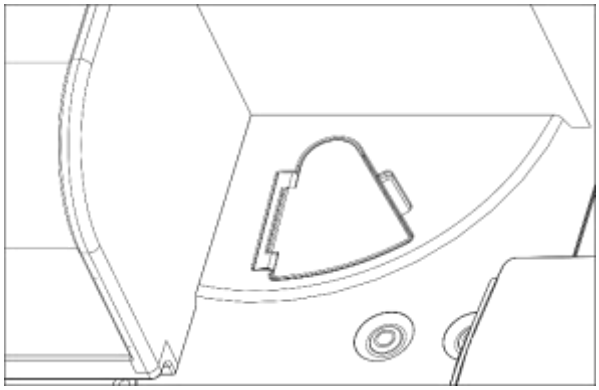
3.6.2.2 Click the "Load" button, the software controls the designated position of the kit tray to rotate to the reagent loading area, and the software pops up the loading reagent kit interface;



3.6.2.3 The user loads the reagent kit to the corresponding position of the reagent compartment, and then clicks the "Scan" button. The instrument automatically recognizes the reagent kit information and successfully loads it.

3.6.2.4 After the reagent is loaded, the software will display the number of remaining tests, expiration date, whether the reagent is calibrated, whether the calibration is expired, and the number of days of opening the bottle. If the above information is abnormal, the test result may be affected.

Remarks:

	Before loading, it is necessary to confirm that the reagent is within the validity period. Before loading a new reagent, please check the fluidity of reagent magnetic beads by manual mixing, and check whether there are magnetic beads at the coating, so as to avoid drying of magnetic beads caused by inversion of reagent during transportation and storage, which may affect reagent performance.For the used reagent kit, it shall be confirmed that the reagent does not spill out during storage, and the reagent shall be loaded in the correct position of the reagent compartment during loading. The reagent loading area is located at the front right corner of the instrument table as shown in the figure. Open the small fan-shaped cover on the reagent compartment cover during loading.

3.6.3 Change the substrate

The system is configured with two substrate channels, which can load two bottles of substrate simultaneously. The software will automatically switch according to the usage of the two bottles of substrate, or specify the substrate of a certain channel through the software. When the system is using one bottle of substrate, it can switch to another bottle of substrate, which ensures that the substrate can also be replaced during the process operation. If the two bottles of substrate are used up, the software will stop the process operation and give an alarm.

Note: The substrate should be allowed to equilibrate at room temperature for at least 18 hours before use.

	**Biohazard:** Proper protection when loading substrates is required due to the risk of injury from contact with the substrate. In case of inadvertent contact with substances that may cause injury, follow proper laboratory procedures for handling.

	**Caution, Danger:** Because the contamination of the substrate will affect the test results, during the process of replacing the substrate, the inner surface of the substrate stopper and the tubing below the stopper that will contact the substrate should be avoided from contacting the articles that may contaminate the substrate.

3.6.3.1 Click the "Reagent Consumables" button in the navigation bar to enter the Consumables Management Software Operation Interface, click the "Load" in the corresponding area of substrate channel, and the software pops up the "Consumables Loading Interface";

3.6.3.2 Scan the barcode of the substrate bottle with a handheld barcode scanner or manually input the barcode of the substrate, and the substrate information will be automatically displayed on the "Consumables Loading Interface";

3.6.3.3 Open the substrate door of the instrument and unscrew the cap of the warmed substrate bottle;

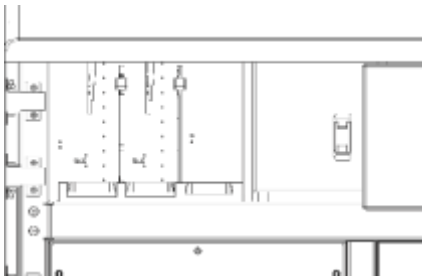
3.6.3.4 Take out the substrate bottle cap of the corresponding channel on the substrate piping from the used substrate bottle;

3.6.3.5 Put the substrate bottle cap and the piping below it into the substrate bottle to be loaded;

3.6.3.6 Take out the empty substrate bottle from the instrument and put a new substrate bottle into the corresponding substrate channel position;

3.6.3.7 Then click the "OK" button in the "Consumables Loading Interface", and the "Consumables Management Software Operation Interface" will automatically display the newly loaded substrate information.

Remarks:

	Open the upper left front door of the instrument and you will see the substrate loading area as shown on the left, where the first channel is on the left and the second channel is on the right. Before loading, it is necessary to confirm that the newly loaded substrate is within the expiration date. Before loading, use a handheld barcode reader to read the barcode on the substrate bottle. The software will automatically update the Lot No, expiration date and remaining test number of the substrate according to the read barcode content.

3.6.4 Change the wash buffer

The software Consumables Management screen displays the status of the on-machine wash buffer. The wash buffer shall be replaced in time according to the interface prompt. If there is not enough wash buffer, the problems of inaccurate sample addition and unclean cleaning will be caused, which will seriously affect the results.The wash buffer inside the instrument is divided into two channels, and when one channel is in use, the other channel can be replaced, which ensures that the wash buffer can also be changed during the running process.

	**Biohazard:** Proper protection is required when loading wash buffers due to the risk of injury from contact with wash buffers. In case of inadvertent contact with substances that may cause injury, follow proper laboratory procedures for handling.

3.6.4.1 Click the "Reagent Consumables" button in the navigation bar to enter the Consumables Management Software Operation Interface, and click the "Load" button in the corresponding area of the wash buffer channel, and the software pops up the "Consumables Loading Interface";

3.6.4.2 Scan the barcode of wash buffer with a handheld barcode scanner or manually input the barcode of wash buffer, and the "Consumables Loading Interface" will automatically display the information of wash buffer;

3.6.4.3 Move the new wash buffer to the instrument, open the bottle cap and take out the bottle stopper;

3.6.4.4 Open the left front door of the instrument, and drag the wash buffer tray to the outer end of the instrument;

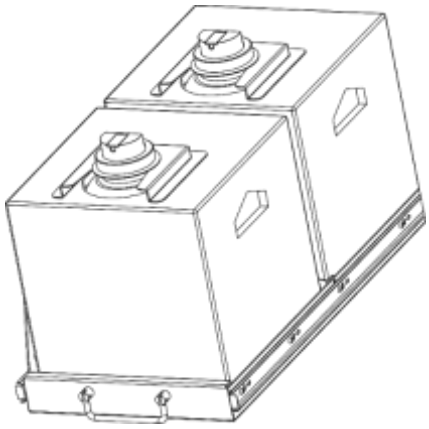
3.6.4.5 Take out the bottle cap of wash buffer and the piping on it from the wash buffer barrel to be replaced and put it into a new wash buffer barrel;

3.6.4.6 Remove the empty wash buffer bucket from the inside of the instrument and place the new wash buffer barrel on the instrument wash buffer tray;

3.6.4.7 Push the wash buffer tray back into the instrument and close the front left door of the instrument;

3.6.4.8 Then click the "OK" button in the "Consumables Loading Interface", and the "Consumables Management Software Operation Interface" will automatically display the newly loaded wash buffer information.

Remarks:

	Open the front door on the left side of the instrument, and the lower part is the wash buffer loading area as shown in the figure. The front part is the first wash buffer channel and the back part is the second wash buffer channel. During loading, the wash buffer and carton shall be correctly loaded into the rectangular area of the wash buffer channel, and the bottom of the box shall not be placed on the frame or vertical beam. After loading, the quick-connect connector on the bottle cap of the wash buffer barrel shall be correctly connected. After loading, the consumable interface of the software will display the volume proportion of wash buffer.

3.6.5 Replace the S probe wash buffer

In order to ensure the cleaning efficiency and avoid carry-over contamination, the S probe wash buffer should be replaced in time to ensure that there is sufficient S probe wash buffer in the instrument.

	**Biohazard:** Proper protection is required when loading the S probe wash buffer due to the risk of injury from contact with the S probe wash buffer. In case of inadvertent contact with substances that may cause injury, follow proper laboratory procedures for handling.

3.6.5.1 Click the "Reagent Consumables" button in the navigation bar to enter the Consumables Management Software Operation Interface, click the "Load" button in the corresponding area of S probe wash buffer, and the software pops up the "Consumables Loading Interface";

3.6.5.2 Scan the barcode of the S probe wash buffer with a handheld barcode scanner or manually input the barcode of the S probe wash buffer, and the "Consumables Loading Interface" will automatically display the information of the S probe wash buffer;

3.6.5.3 Unscrew the cap of the S probe wash buffer bottle that needs to be replaced inside the instrument;

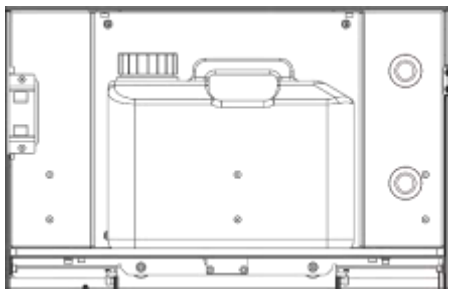
3.6.5.4 Open the front door in the middle of the instrument, and unscrew the bottle cap of the S probe wash buffer bottle inside the instrument;

3.6.5.5 Take out the S probe wash buffer bottle cap and tubing inside the instrument, and put them into the S probe wash buffer bottle to be placed inside the instrument;

3.6.5.6 Take out the empty S probe wash buffer bottle from the instrument, and place the S probe wash buffer with the bottle cap and tubing in the corresponding position of the instrument;

3.6.5.7 Then click the "OK" button in the "Consumables Loading Interface", and the "Consumables Management Software Operation Interface" will automatically display the newly loaded S probe wash buffer information.

Remarks:

	The S probe wash buffer is located in the upper half of the front door in the middle of the instrument.

3.6.6 Load RVs

RVs are disposable consumables and should not be touched by hand. Do not load dusty, dirty or used RVs into the instrument. RVs must be used with the instrument, otherwise it may cause system failure or inaccurate test results.

	**Caution, Danger:** Do not load dusty, dirty, or used RVs into the instrument. The RV supplied with the instrument must be used, otherwise mechanical failure or incorrect test results may result.

3.6.6.1 Click the "Reagent Consumables" button in the navigation bar to enter the Consumables Management Software Operation Interface, and click the "Load" button in the corresponding area of the RV, and the software pops up the "Consumables Loading Interface";

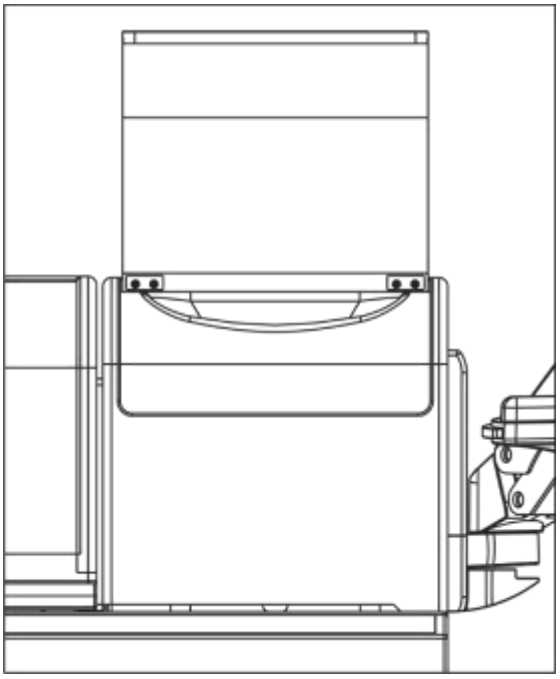
3.6.6.2 Scan the barcode of the RV with a hand-held barcode scanner or manually input the barcode of the RV, and the "Consumables Loading Interface" automatically displays the

information of the RV;

3.6.6.3 Open the cover of the instrument RV compartment, pour in a new RV, and close the cover of the instrument RV compartment;

3.6.6.4 Then click the "OK" button in the "Consumables Loading Interface", and the "Consumables Management Software Operation Interface" will automatically display the newly loaded RV information.

Remarks:

	The RV loading area is located at the right rear of the top of the large cover of the instrument. During the loading process, ensure that all RVs are poured into the bin of the automatic tube feeding module, and shall not spill to other areas of the instrument. After loading, a new bag of RVs should be set on the "Consumables" interface of the software to correctly remember the number of RVs in the instrument. If the setting is not made, the software cannot correctly remember the current number of RVs in the instrument.

3.6.7 Empty the solid waste liquid

The "Consumables Management" interface of the software will display the status of solid waste. When the solid waste is full, the instrument will suspend the operation process and give an alarm. In order not to affect the normal operation of the process, please empty the solid waste in time.

	**Biohazard:** Due to the risk of infection from contact with solid waste, proper precautions should be taken when emptying solid waste and proper laboratory procedures should be followed in case of inadvertent contact with potentially infectious substances. The solid waste of this system is infectious waste, which should be disposed according to relevant laws and regulations.

3.6.7.1 Pull out the solid waste basket tray and remove the waste bag from the solid waste basket;

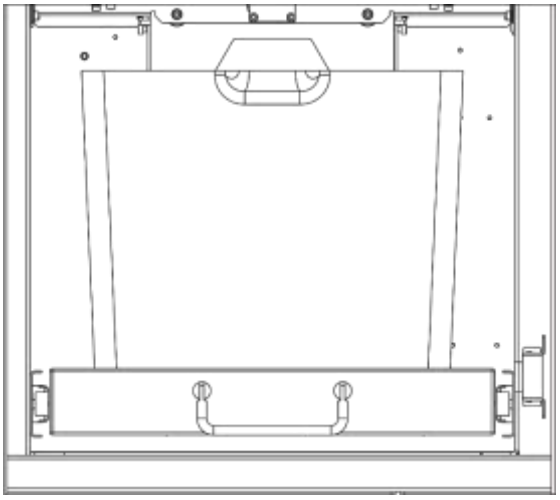
3.6.7.2 Put the new waste bag on the solid waste basket;

3.6.7.3 Push back the solid waste basket tray and close the front door of the instrument;

3.6.7.4 Click the "Reagent Consumables" button in the navigation bar to enter the Consumables Management Software Operation Interface, click the "Empty" button in the corresponding area of

solid waste, and the software will automatically refresh the solid waste information.

Remarks:

	The solid waste area is located in the lower half of the left front door, from which the solid waste basket tray can be pulled out by opening the left front door. After removing the solid waste and putting on a new waste bag, be sure to push the solid waste basket tray back into the instrument, otherwise the used waste RVs will not fall into the waste basket correctly.

3.6.8 Empty the waste liquid

Before running the process, please check the waste liquid status and empty it. When the external waste liquid barrel (not direct discharge) of the instrument is full, the instrument will suspend sample addition and give an alarm. If the waste liquid is discharged directly, this step is not required.

	**Biohazard:** Due to the risk of infection from contact with waste liquid, proper precautions should be taken when emptying waste liquid, and in case of inadvertent contact with potentially infectious substances, proper laboratory procedures should be followed. The waste liquid of this system is infectious waste, so please dispose it according to the corresponding laws and regulations.

3.6.8.1 Take out the waste discharge piping from the current waste liquid barrel and put it into a new waste liquid barrel;

3.6.8.2 The waste liquid of the replaced waste liquid barrel is treated according to corresponding laws and regulations;

3.6.8.3 Click the "Reagent Consumables" button in the navigation bar to enter the Consumables Management Software Operation Interface, click the "Clear" button in the corresponding area of waste liquid, and the software will automatically refresh the waste liquid information.

3.7 Test flow

3.7.1 General test flow

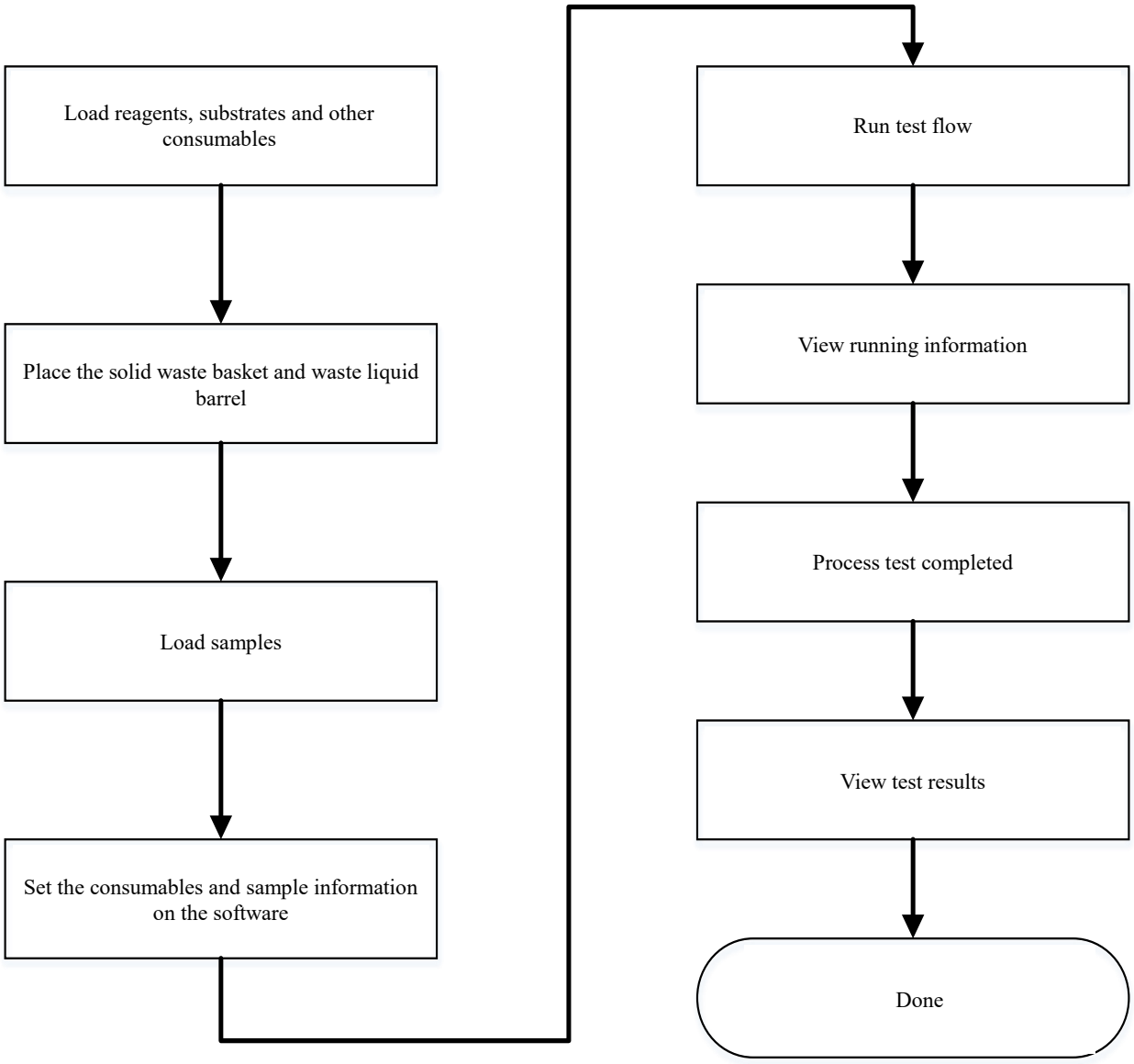
The list of reagents/consumables to be prepared prior to testing is as follows:

Instrument supporting reagents/consumables	Project reagents/calibrators/quality controls
	Wash buffer

	S probe wash buffer
	Substrate solution
	RV
	Sample tube (cup)
	Sample rack

Load the above consumables into the instrument (see the section on consumables management for the specific loading method of consumables), place the solid waste basket and waste liquid barrel (if the waste liquid is not directly discharged), then put the sample tube (cup) containing calibrators, quality controls or patient samples and compatible with the instrument into the sample rack provided by the manufacturer, set the correct information on the software, and run the test process.Operation information, test results and printing can be viewed through the software.When there are calibrators, quality controls and patient samples being tested at the same time, the software will give priority to the calibrator test, followed by the control test, and the patient samples will be tested in the manner of "emergency first, then ordinary cases".

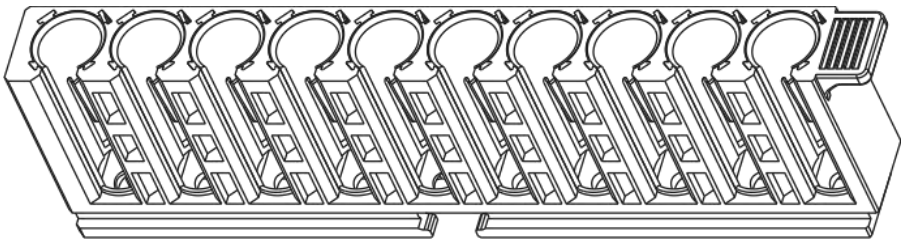
	Please pay attention to sample or reagent volatilization: Volatilization of the sample or reagent may result in erroneous test results. ● Do not leave samples, calibrators, or quality controls that have been pipetted into sample containers for an extended period of time. ● Do not use expired reagents.



General Test Flow

3.7.2Sample loading

A sample rack supporting the instrument can be loaded with 10 sample tubes (cups). The position serial numbers of the 10 sample cabins in the sample rack are arranged in sequence from left to right, with the leftmost position being sample cabin 1 and the rightmost position being sample cabin 10. The sample rack and compatible sample tubes (cups) supporting the system are as follows:

Sample rack: 10 sample cabins, numbered from 1 to 10 from left to right.	

Sample tube type		Picture description	Sample tube type		Picture description
12/13 X 75mm glass blood collection tube Spec: 12/13 X 75			12/13 X 75mm plastic blood collection tube Spec: 12/13 X 75		
Dead space volume	1500μl		Dead space volume	1500μl	
13X100mm blood collection tube Spec: 13X100			Calibrator and quality control cup Spec: 13X50		
Dead space volume	1500μl		Dead space volume	150μl	

Calibrators, quality controls, and patient specimens are loaded onto the rack as samples. For calibrators, quality controls and patient specimens, sufficient sample volume shall be allocated to the sample tubes (cups) according to the sample volume of the test item to be run, the number of tests and the dead space volume of the sample container. The calculation formula of the minimum sample volume is as follows:

$$\text{Minimum sample volume} = \text{Sample volume of test item} * \text{Number of tests} + \text{Dead space volume of sample container}$$

3.7.2.1 Allocate a sufficient number of samples into the sample tubes (cups);

3.7.2.2 Load the sample tubes (cups) into the sample rack in the required order;

3.7.2.3 After the sample tubes (cups) are loaded onto the sample rack, click the "Scan" button on the "Sample Management" interface of the software to load the sample rack onto the sample management unit;

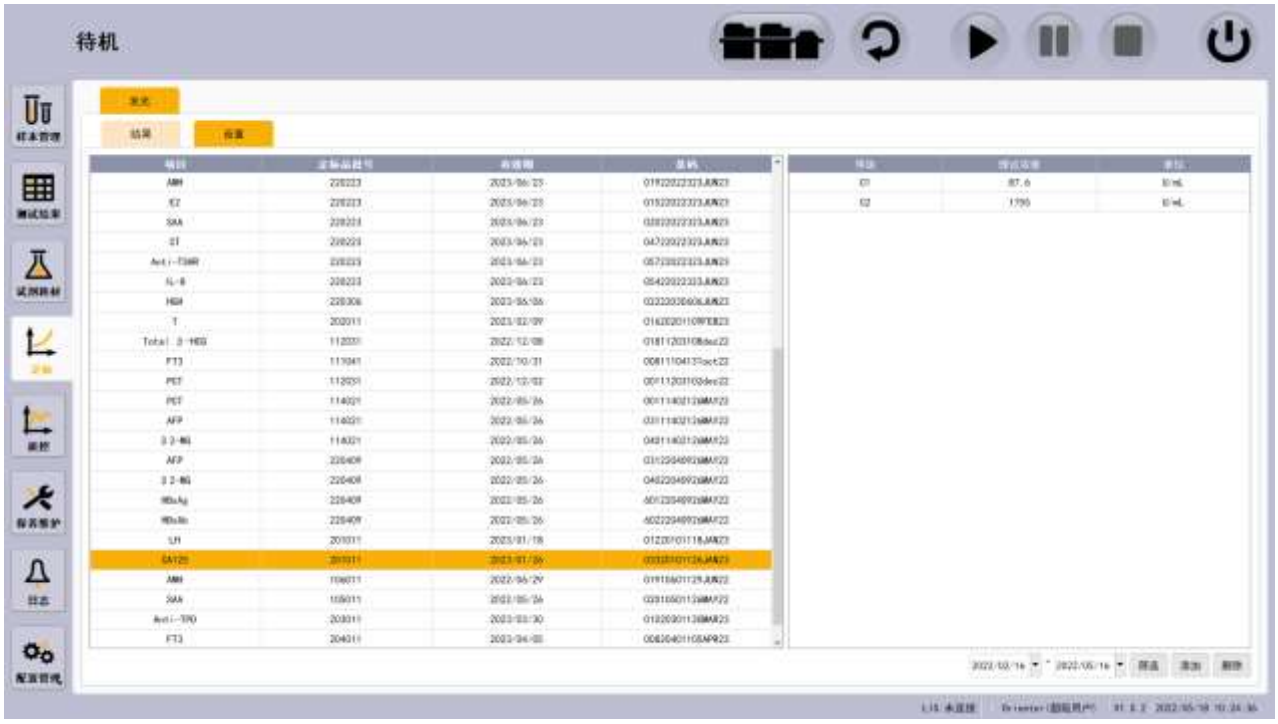
3.7.2.4 After successful scanning, the SDM area will display the cabin number of the sample rack in the sample management unit, otherwise it will still be displayed as "off-board".

3.7.3 Calibrator test flow

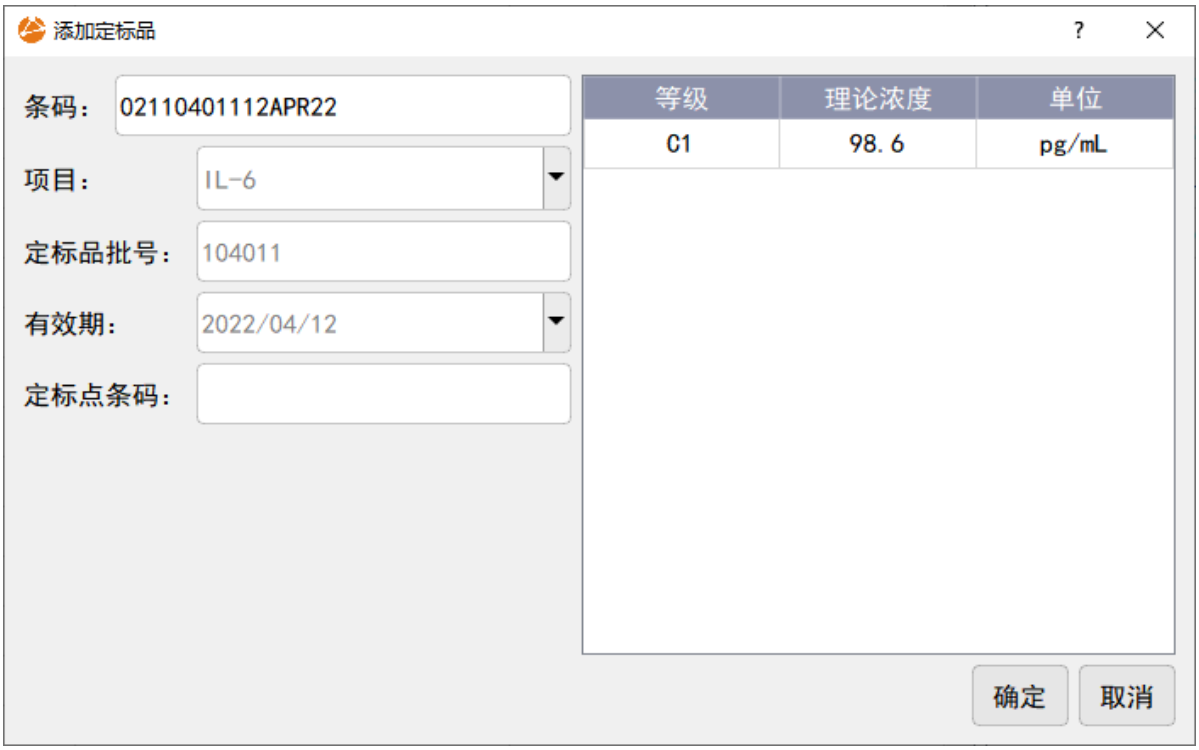
If a new Lot No. of reagent is put on the machine or the validity period of calibration is exceeded, the calibrator supporting the project shall be used for calibration. Before calibration, it is necessary to set the item information, calibration reagent information and corresponding calibrator information. The calibrator information can be set in the "Setting" interface of "Calibration". After setting, it is necessary to confirm whether the "Item","Lot No." and "Expire Date" of the calibrator are correct on the interface, and then load the reagent, calibrator and other consumables to start the calibration process.

	**Biohazard:** Due to the risk of injury to calibrators and reagent consumables, protect them during loading. In case of inadvertent contact with substances that may cause injury, follow proper laboratory procedures for handling.

3.7.3.1 Click the "Calibration" button in the navigation bar of the software interface, click the "Setting" button at the top of the displayed interface to enter the calibrator setting interface, and then click the "Add" button at the bottom right to add the calibrator information.

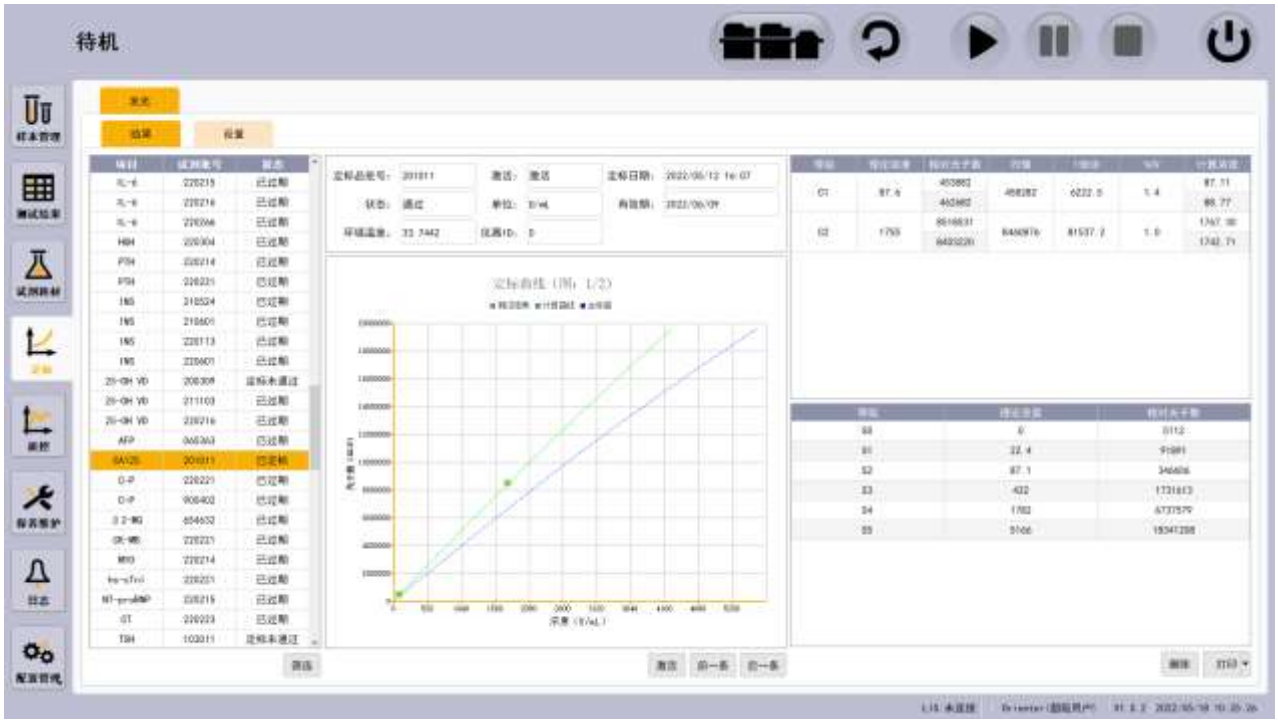


3.7.3.2 Enter the barcode number in the “Add Calibrator” interface or scan the calibrator barcode with a handheld barcode scanner to automatically obtain the calibrator information, and then click "OK".



3.7.3.3 After obtaining the calibrator information, select the reagent kit in the "Reagent Consumables" interface to perform "Calibration Application", and then click the "▶" button in the software control column to run the calibrator test process.

3.7.3.4 After the completion of the calibrator test process, you can view the calibration results in the "Results" interface of the software "Calibration". The calibration result interface will display the measured luminescence value and calculated concentration value of each concentration calibrator, and will display the calibration curve, reagent Lot No., pass or not, activation or not and other information.The calibration curve generated by the calibration of a kit is valid for all kits with the corresponding reagent Lot No of the kit.The user can also manually activate a calibration curve to specify that calibration curve to be used, but caution must be exercised when manually specifying a calibration curve as it is directly related to the concentration calculation.



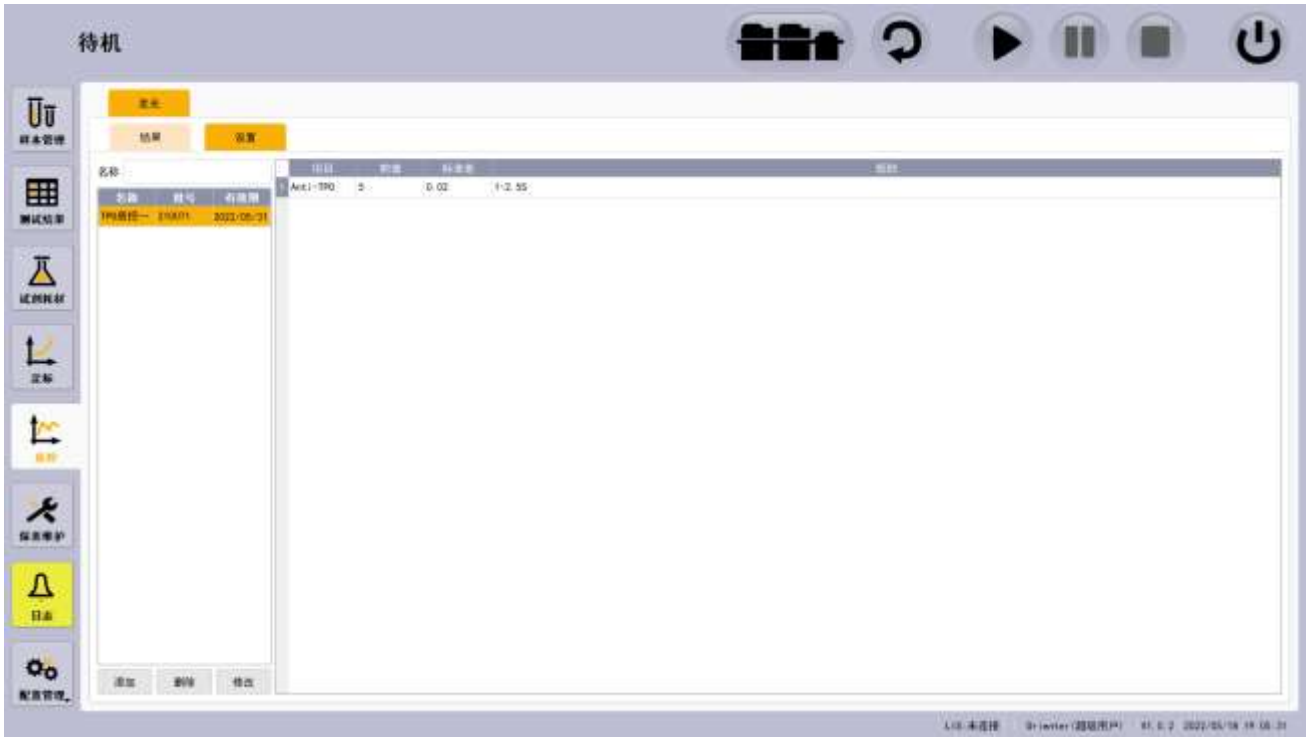
Calibration Result Interface

3.7.4 Quality control test flow

According to the quality management manual of each department, regularly run the quality controls to control the reagents in service and the whole system.Before running the quality control test, set the quality control information, and then assign the quality control at the relevant control level to control the corresponding items.Check the quality control results after the quality control test process is completed.

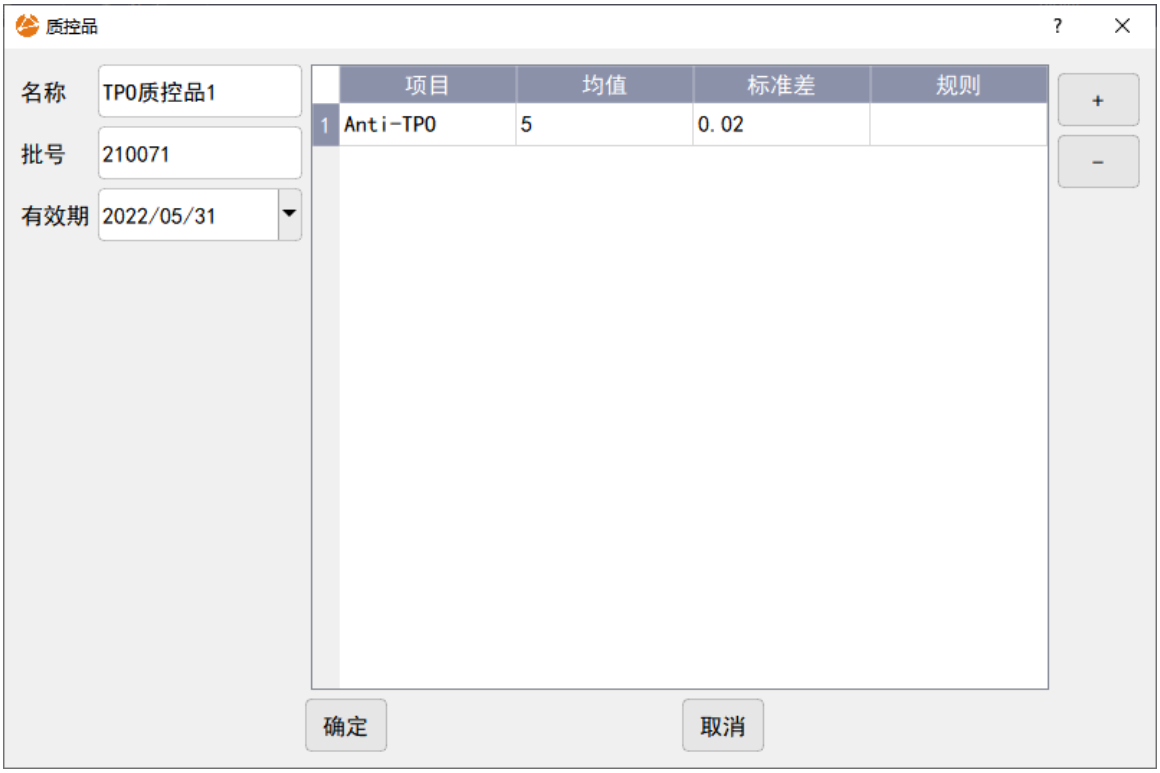
	**Biohazard:** Quality controls and reagent consumables should be protected during loading due to the risk of injury. In case of inadvertent contact with substances that may cause injury, follow proper laboratory procedures for handling.

3.7.4.1 Click the "QC" button in the navigation bar of the software interface, click the "Setting" button at the top of the displayed interface to enter the QC setting interface, and then click the "Add" button to add the quality control information.

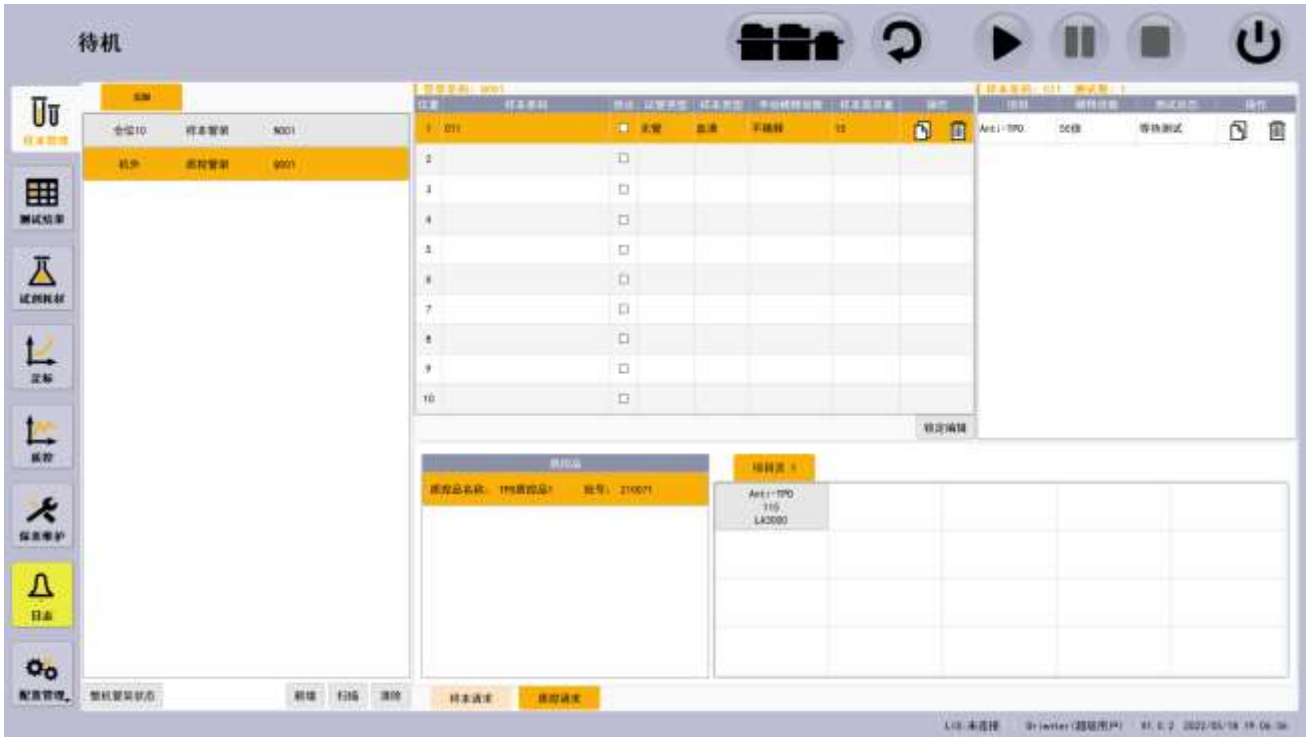


Quality Control Settings

3.7.4.2 Enter the quality control information in the quality control interface and click the "OK" button.



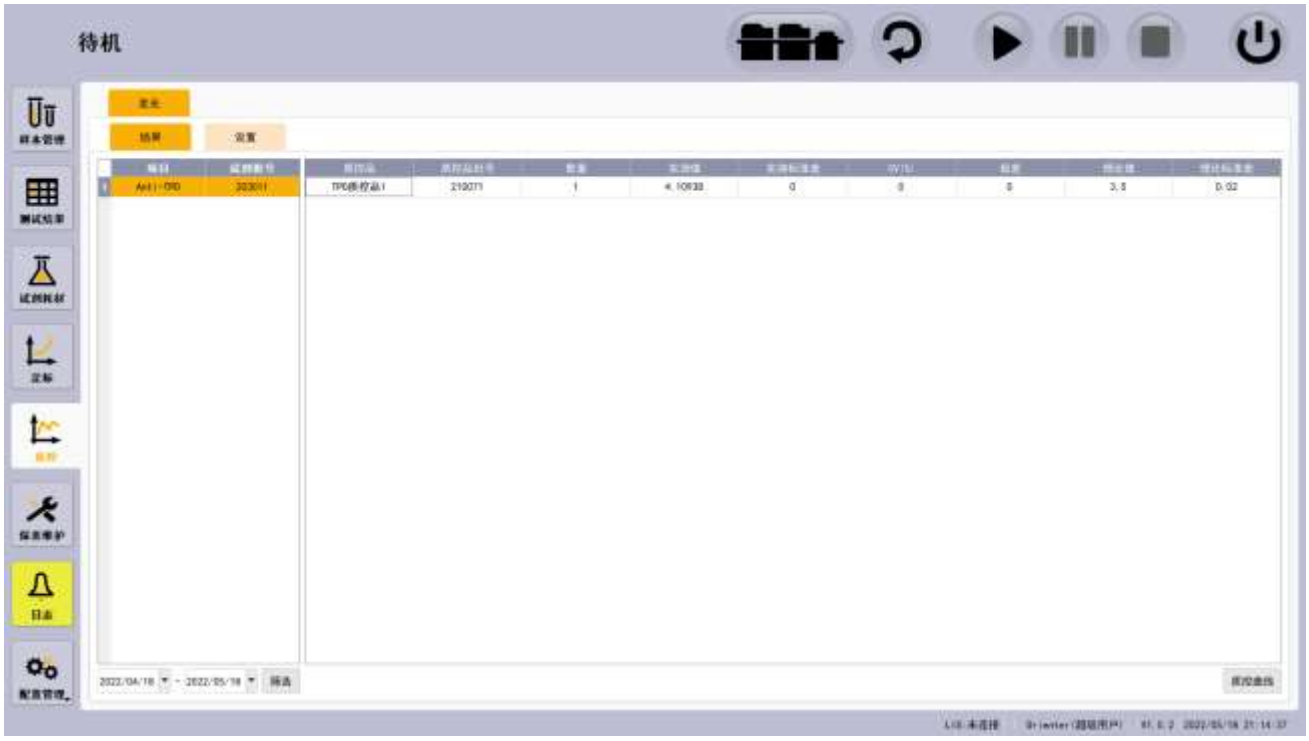
3.7.4.3 After the quality controls are set, click the "Sample Management" button in the navigation bar of the software to enter the sample management interface, and then click the "QC Request" button to select the items and controls to perform QC on the specified reagents.



Sample Management-QC Request

3.7.4.4 After selecting items and quality controls, click the "▶" button in the software control bar to run the control test process.

3.7.4.5 After the quality control test process is completed, the QC results can be viewed in the "Results" interface of the software "QC".In the "Results" interface of "QC", you can view the latest QC results, and also view the QC mean value and calculated standard deviation within a certain date, and view the out-of-control situation.



QC Results

3.7.5Patient sample test flow

The system supports the testing of emergency samples and routine samples, and the emergency samples are preferentially tested. Samples are loaded into the instrument using a system-compatible sample container. Sufficient sample volume shall be loaded according to different tube types, and the samples shall not contain air bubbles.

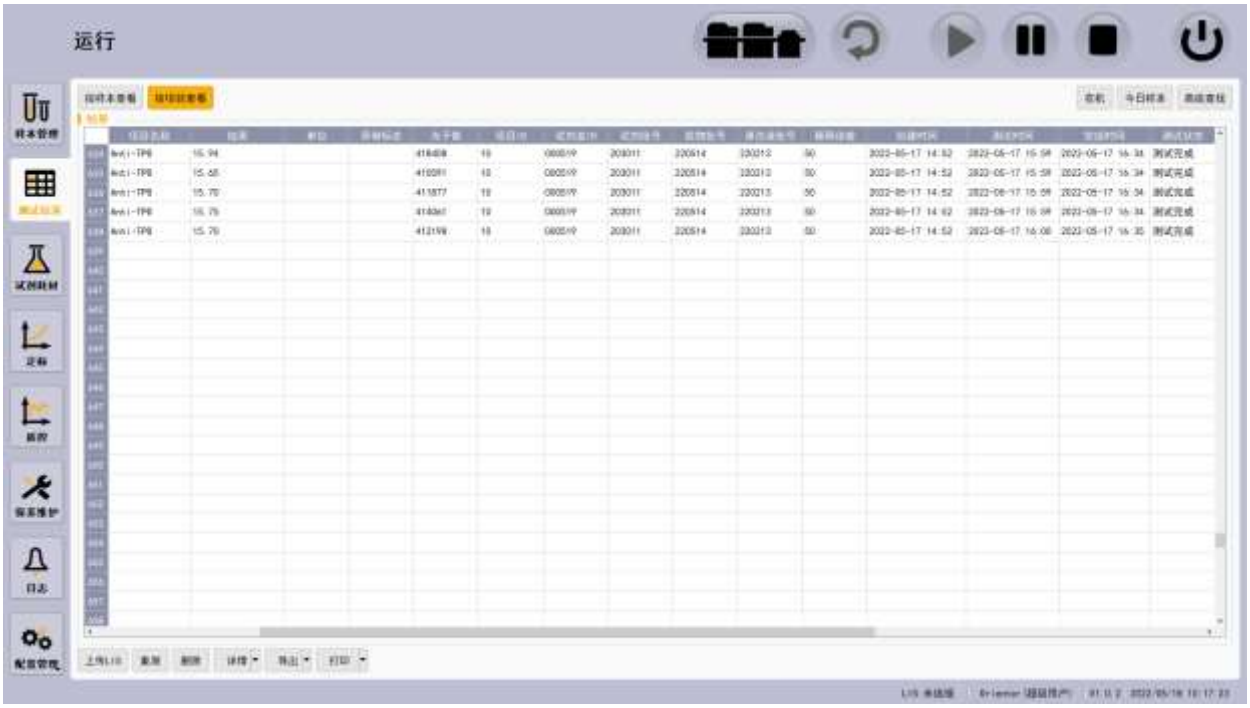
	**Biohazard:** Due to the risk of infection of patient samples and the risk of damage to reagent consumables, it is necessary to take precautions during loading of patient samples and reagent consumables. In case of inadvertent contact with potentially infectious material, follow proper laboratory procedure for handling.

3.7.5.1 Click the "Sample Management" button in the navigation bar of the software interface to enter the "Sample Management" interface, and click the "Scan" button in the "SDM" area to scan the samples in the "Sample Management Unit". After scanning, the software will automatically obtain the sample information and test items from the LIS (Laboratory Information Management System), or select the item combination and test items in the "Combination Item Page" and "Luminous Item Page" interfaces, and click the "Save" button to manually add test items.The specific interface for setting sample information is as follows:

Sample Management Interface

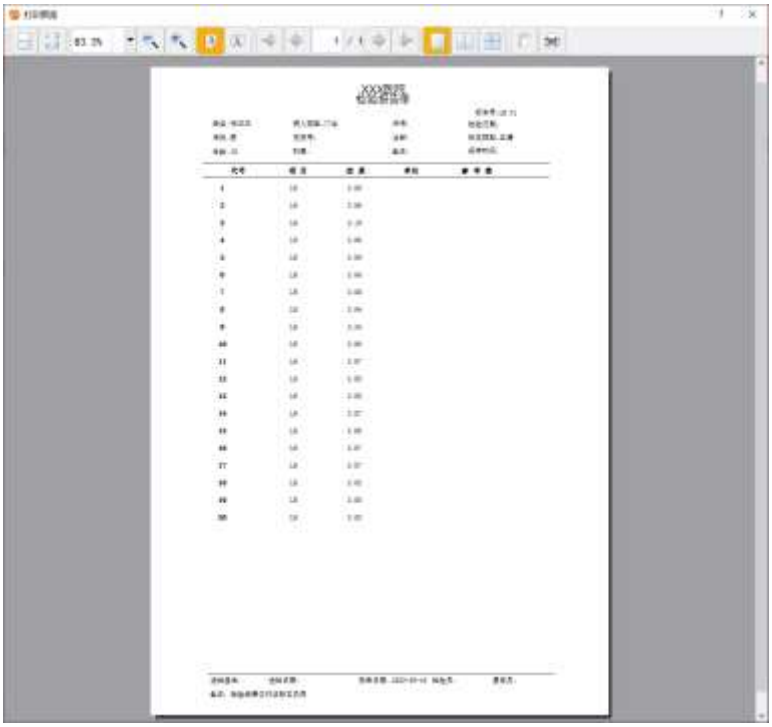
3.7.5.2 After the sample information is set, click the "▶" button in the software control bar to run the sample test process.

3.7.5.3 During the operation of patient sample test flow, you can view the status of each sample and test items included in the "Test Result" interface of the software. After the operation is completed, you can view the test results of each test item of the sample in the "Test Result" interface.You can also query the test results within a certain date according to certain conditions in the "Test Results" interface, and you can query the test results of some items within a certain date by using the test items as query criteria.



Test Results

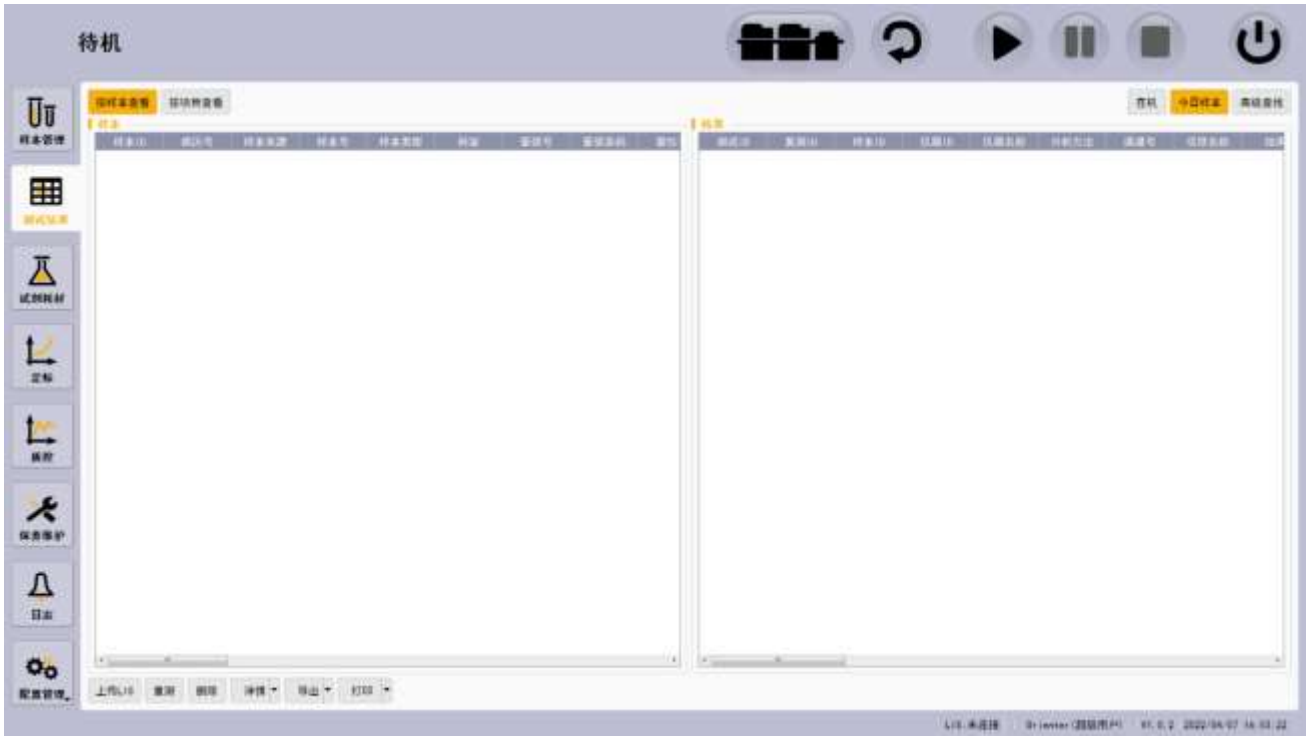
3.7.5.4 In the "Test Results" interface, you can also set the "Medical Record No.","Name","Gender","Department" and other information of the patient corresponding to the sample, so as to output the corresponding information when printing the result.



3.7.6 Software function

The supporting application software has the functions of "sample management","test result","reagent consumables","calibration","QC","maintenance","log" and "configuration management".

1)The software interface mainly includes control bar and navigation bar.



Control bar: Located at the top of the interface, this control bar is used for basic instrument control, including instrument start, stop, pause, software shutdown, initialization, etc.

Push button	Description	Function
	**Software shutdown button**	**Software exit**
	**Stop button**	**Control instrument stop**
	**Pause button**	**Control instrument pause**
	**Start button**	**Control instrument startup**
	**Initialization button**	**Initialize the system**
	**Device status button**	**View device status**

The navigation bar is located on the left side of the interface, and is used for window switching of function modules, including sample management, test results, reagent consumables, calibration, quality control, maintenance, log and configuration management;

Push button	Description	Function
	**Sample management button**	**Sample management module switching window**
	**Test results button**	**Test result module switching window**
	**Reagent consumables button**	**Reagent consumables module switching window**
	**Calibration button**	**Calibration module switching window**
	**QC button**	**QC module switching window**
	**Maintenance button**	**Maintenance module switching window**
	**Log button**	**Log module switching window**
	**Configuration management button**	**Configuration management module switching window**

2) Sample management interface

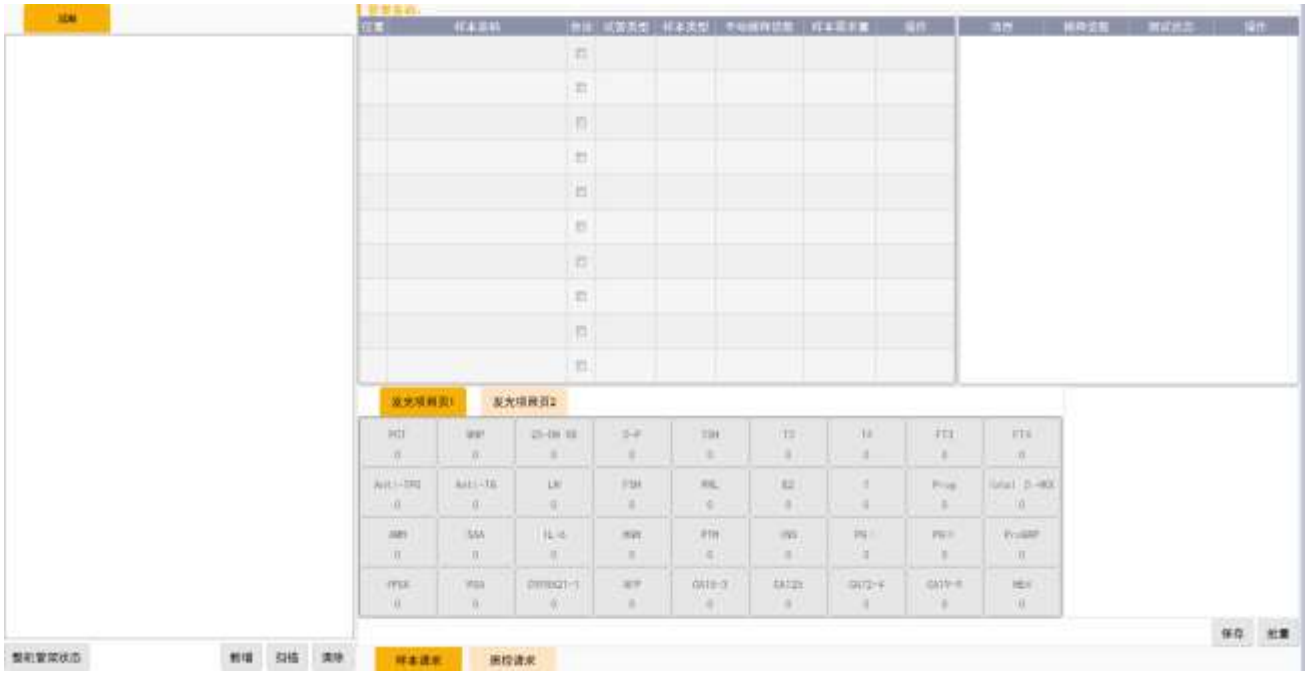
When the Sample Management navigation button is selected, the interface will be switched to the Sample Management interface, which mainly includes:

Pipe rack display area: for displaying the pipe rack edited on or off the machine;

Sample editing area: for editing sample numbers and test items;

Item selection area: for displaying the available items and their number;

Item display area: for displaying all test items selected by a sample;



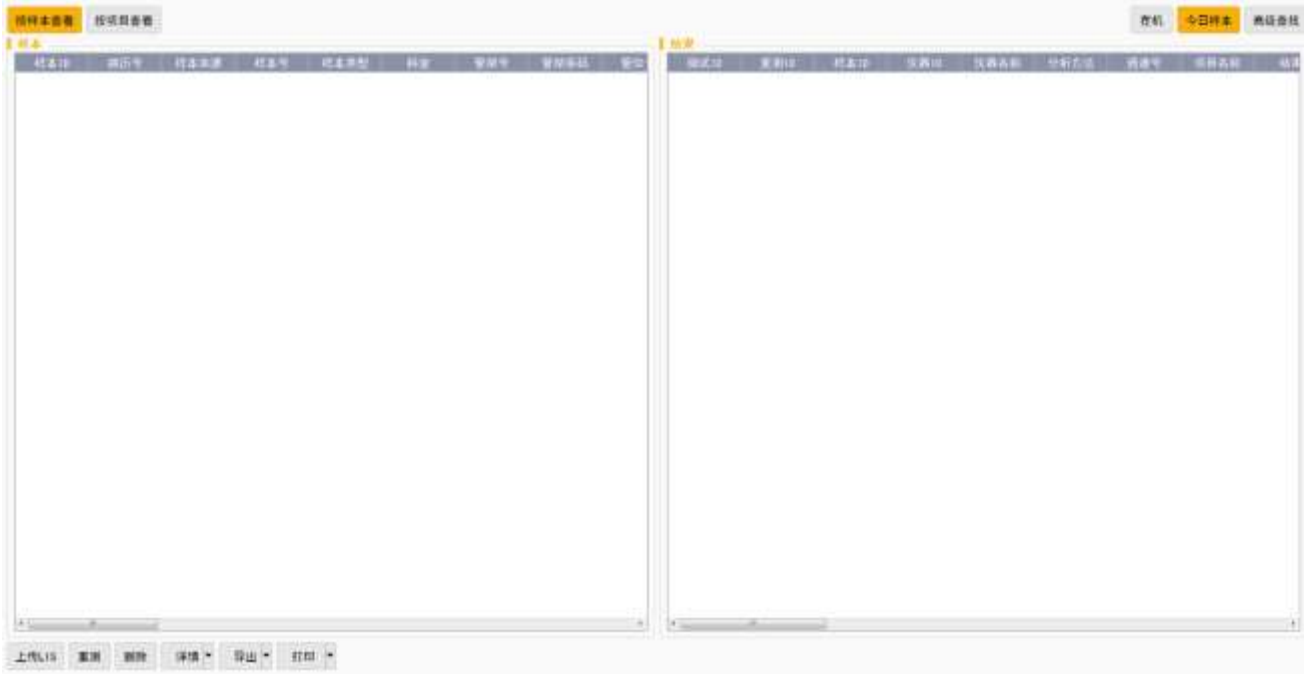
3) Test results screen

When the test result button is selected, the screen is switched to the test result interface, which mainly includes:

Result display area: for displaying the information of a test result, which can be viewed by sample or item;

Screening area: for screening the results by conditions using the function button at the upper right corner;

Operation area: The function buttons below can operate the results, such as upload, retest, or export, etc.;

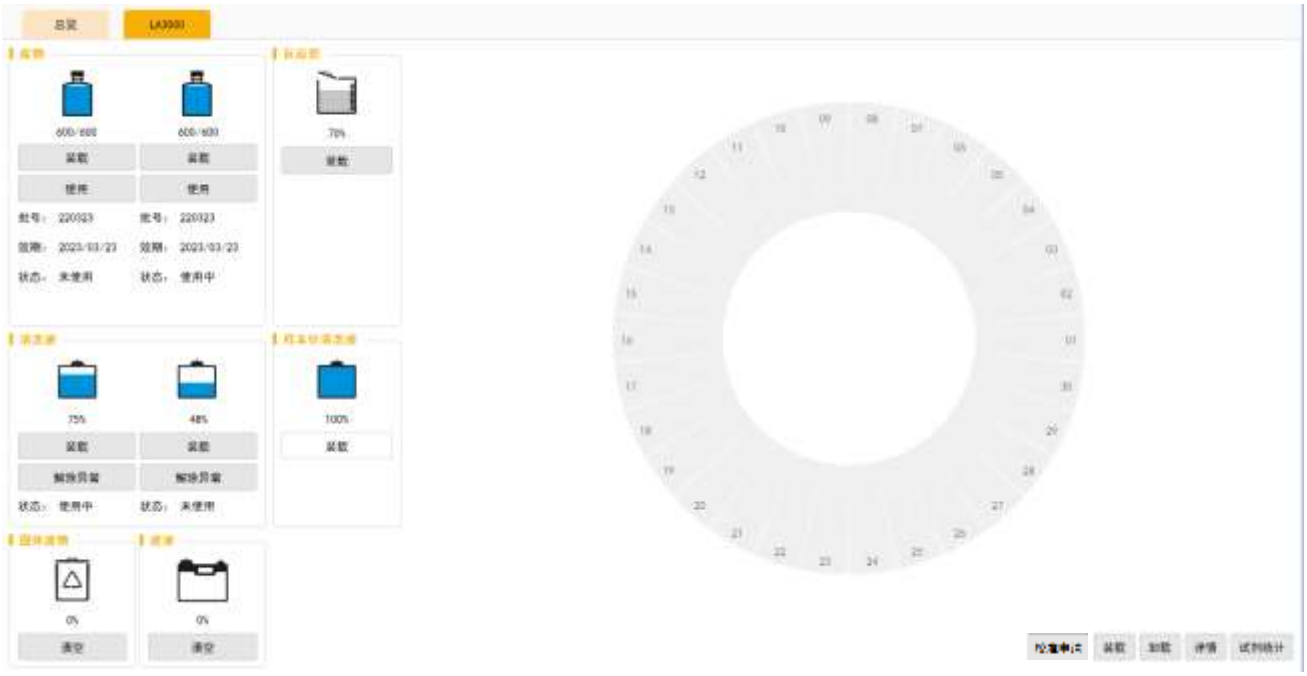


4) Reagent consumables interface

When the reagent and consumables button is selected, the screen is switched to the reagent and consumables interface, which mainly includes:

Consumables display area: for displaying all consumables information on the instrument and corresponding consumables operation buttons;

Reagent display area: for displaying all reagent information on the instrument, as well as function buttons such as loading and unloading;



5) Calibration interface

When the calibration button is selected, the screen is switched to the calibration interface, which mainly includes:

Calibration solution setting: for adding calibration solution information to the software;

Calibration result: for viewing the calibration results, and screening them by conditions;

6) QC interface

When QC button is selected, the screen is switched to the QC interface, which mainly includes:

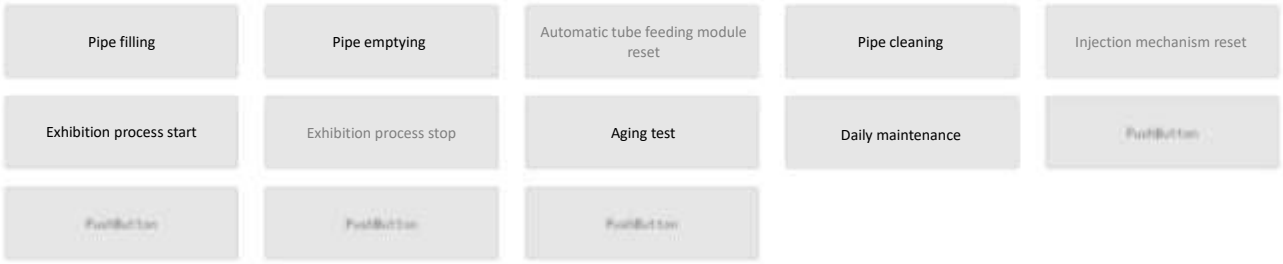
Quality control settings: for adding quality control information to the software;

QC results: for viewing the QC results, and screening them by conditions;

7) Maintenance

When the Maintenance button is selected, the maintenance interface is switched to, which mainly includes:

Maintenance: common maintenance functions, such as piping filling, pipe cleaning, pipe emptying, etc.;



8) Log

When the Log button is selected, the screen is switched to the Log interface, which mainly includes:

Alarm: for display of all alarm information of the instrument;

Operation: for filtering, clearing and viewing details of alarm information;

9) System configuration

Select the Configuration Management to enter the system configuration interface, which mainly includes:

Maintenance appointment: appointment of automatic maintenance time;

Instrument setting: for setting the waste liquid discharge mode, voice prompt, etc.;

Account management: for adding and modifying users and permissions;

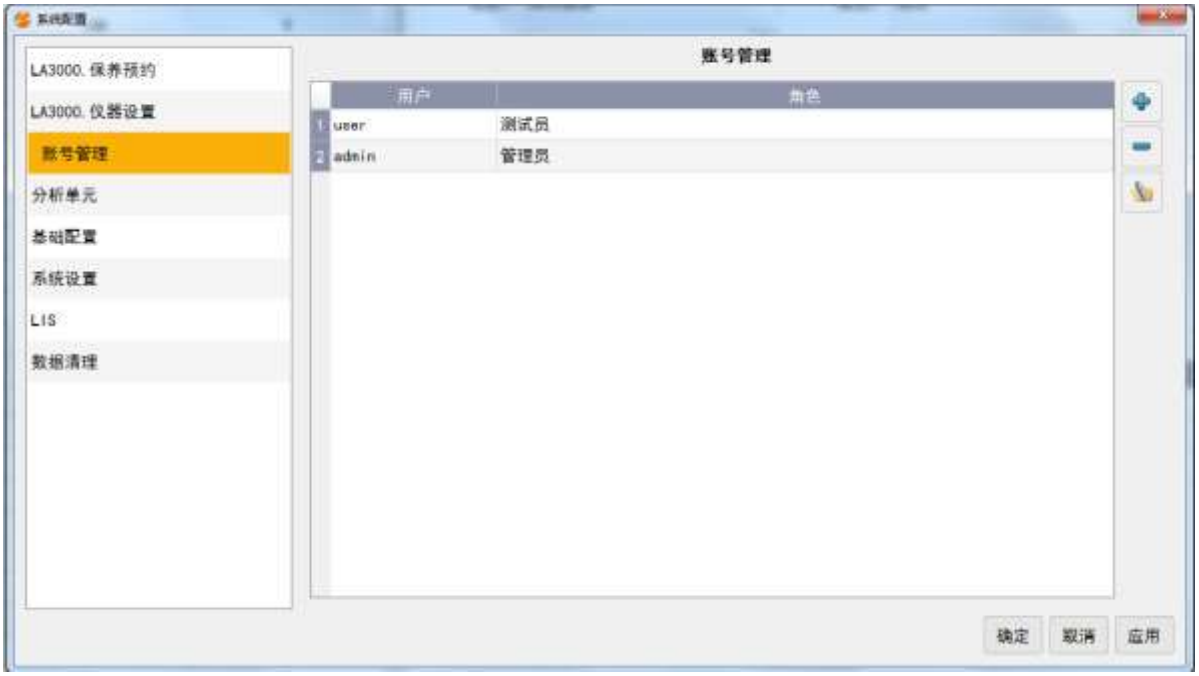
Analysis unit: for setting the innterconnection function;

Basic settings: for setting the basic information field of the sample;

System settings: for setting language, style, software version, etc.;

LIS: for setting the information related to lis;

Data cleaning: for setting the periodic data cleaning period;



10) Equipment diagnosis

Select the Configuration Management to enter the equipment diagnosis interface, which mainly includes: Diagnostic function and hardware test flow of each unit;

Chapter 4 Maintenance

4.1 Daily maintenance

In order to ensure the normal operation of the instrument and not affect the test results, the operator shall complete the daily maintenance and fill in the maintenance record as required.

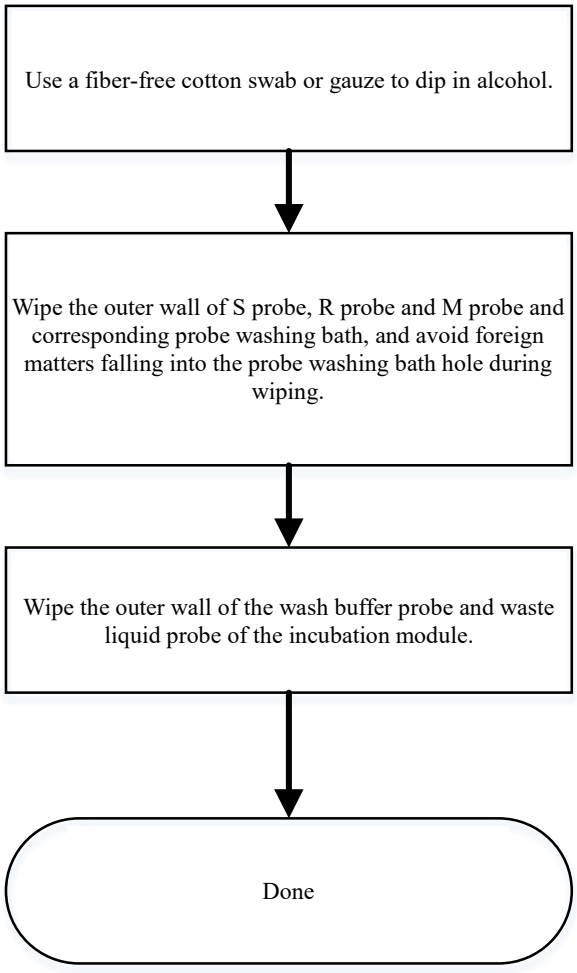
4.1.1 Check system status

Check the temperature of the temperature-controlled area, the supply of consumables and the status of waste containers during routine maintenance. If the instrument is preheated, the temperature of the "Washing Cabin","Incubation Cabin" and "Substrate" shall be within the allowable ranges. If the temperature control is out of range for a long time, please contact the after-sales personnel.

4.1.2 Cleaning fluid path system

To avoid crystallization of relevant parts of the fluid path system affecting the test results, the fluid path system should be cleaned.

	**Biohazard:** Since the fluid path system may have the risk of contamination of patient samples, the wash buffer component contains chemical reagents, so take precautions during the process of performing fluid path cleaning. In case of inadvertent contact with potentially infectious material, follow proper laboratory procedure for handling.

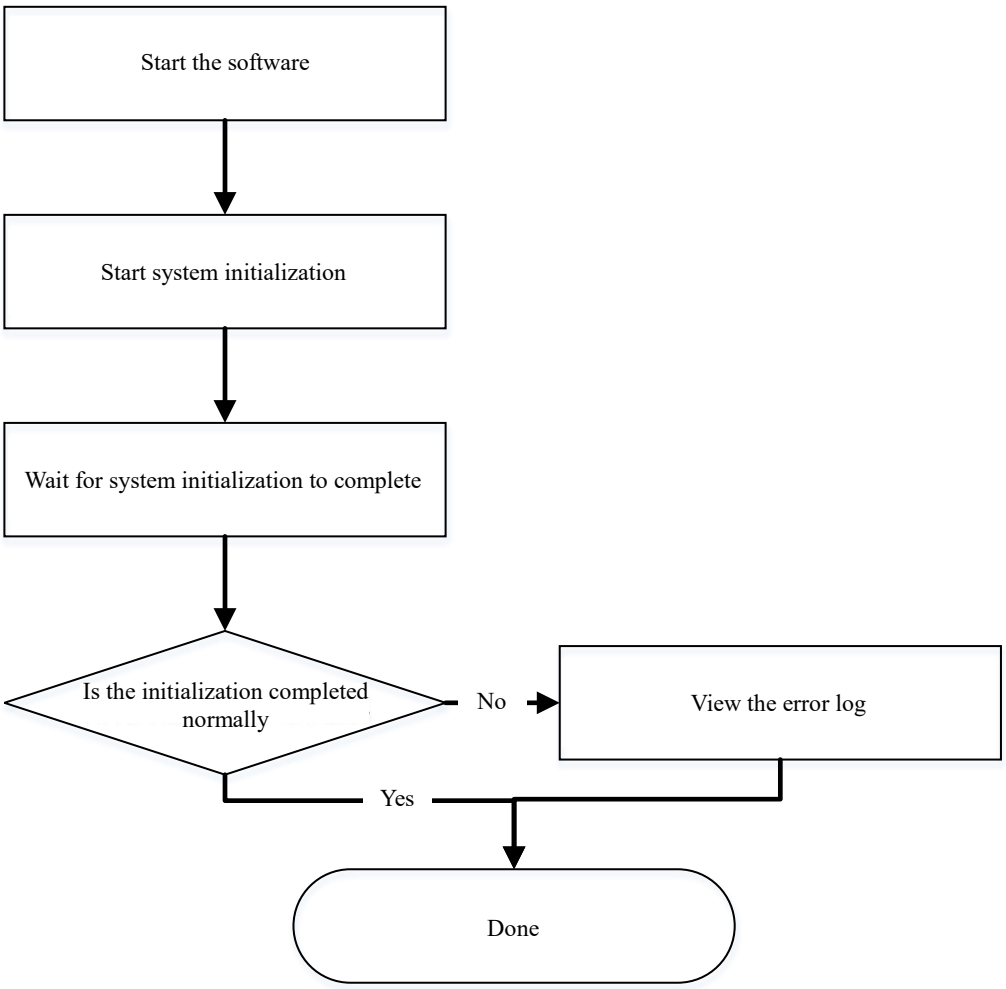


Fluid Path System Cleaning Process

4.1.3 System initialization

Initialize the system and check whether all parts of the instrument are normal and run to the initial position.

	**Caution, Danger:** During system initialization, do not open the upper cover of the instrument and extend your hands or other parts of your body into the range of motion, otherwise it may cause movement injuries.



System initialization process

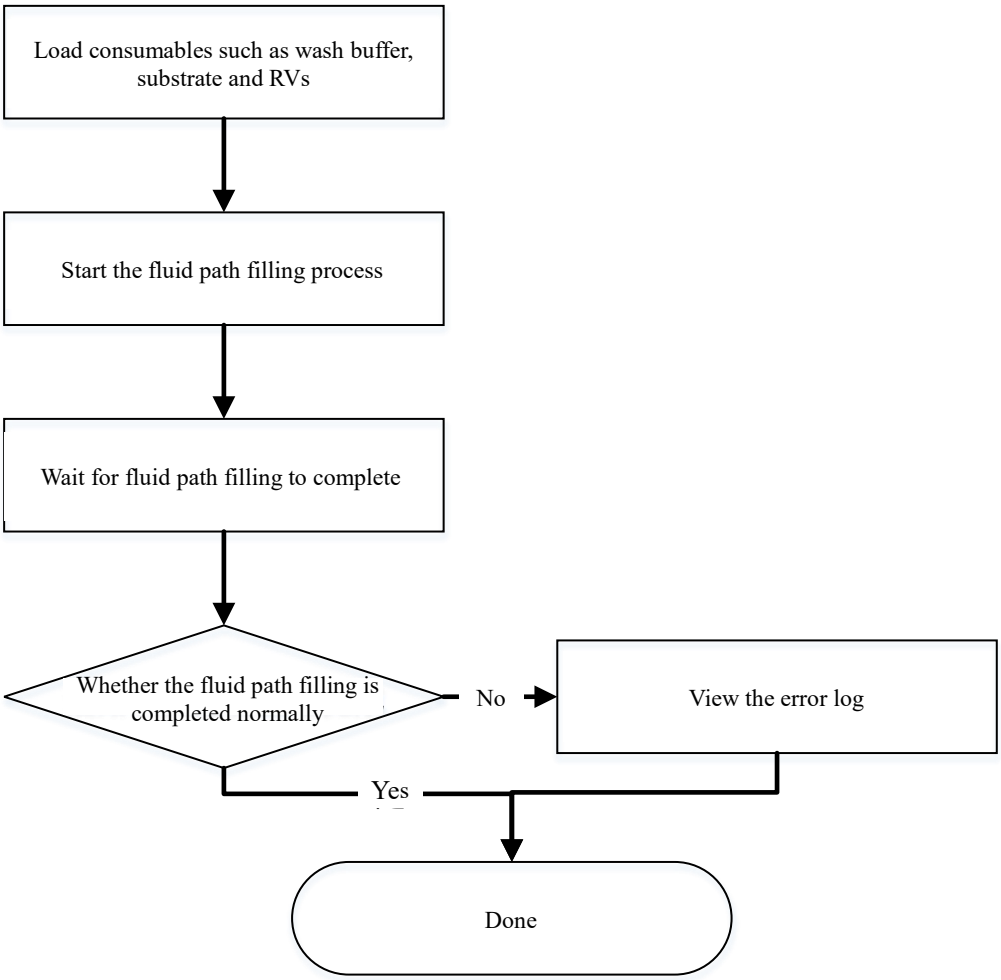
4.1.4 Fluid path filling

Fill the piping in the "Maintenance" interface. If the instrument has not run the test or eliminated the tubing bubbles for more than 4 hours, fill the fluid path before running a new test.Before running the filling fluid path, check whether the connectors of "wash buffer","S probe wash buffer" and "substrate" piping are detached or loose, and whether the piping is damaged. If they are detached or loose, please reconnect them. If the connectors are damaged, please contact the technical support. If the piping is damaged, please replace them; During the operation of filling fluid path, observe whether there is leakage at the tubing connector. If there is leakage, stop filling fluid path immediately and reconnect the connector with leakage.

	**Caution, Danger:** Do not open the upper cover of the instrument and extend your hands or other parts of your body into the range of motion during fluid path filling, otherwise it will cause movement injury. Do not interrupt the fill fluid path process except in an emergency.

Materials required:

- Wash buffer
- S probe wash buffer
- Substrate solution
- RVs



Fluid Path Filling Process

4.2 Weekly maintenance

The system shall be maintained weekly every seven days, and if it is not used for more than two days (inclusive of two days), it shall also be maintained weekly. For weekly maintenance, in addition to routine maintenance, the waste liquid probes need to be cleaned.

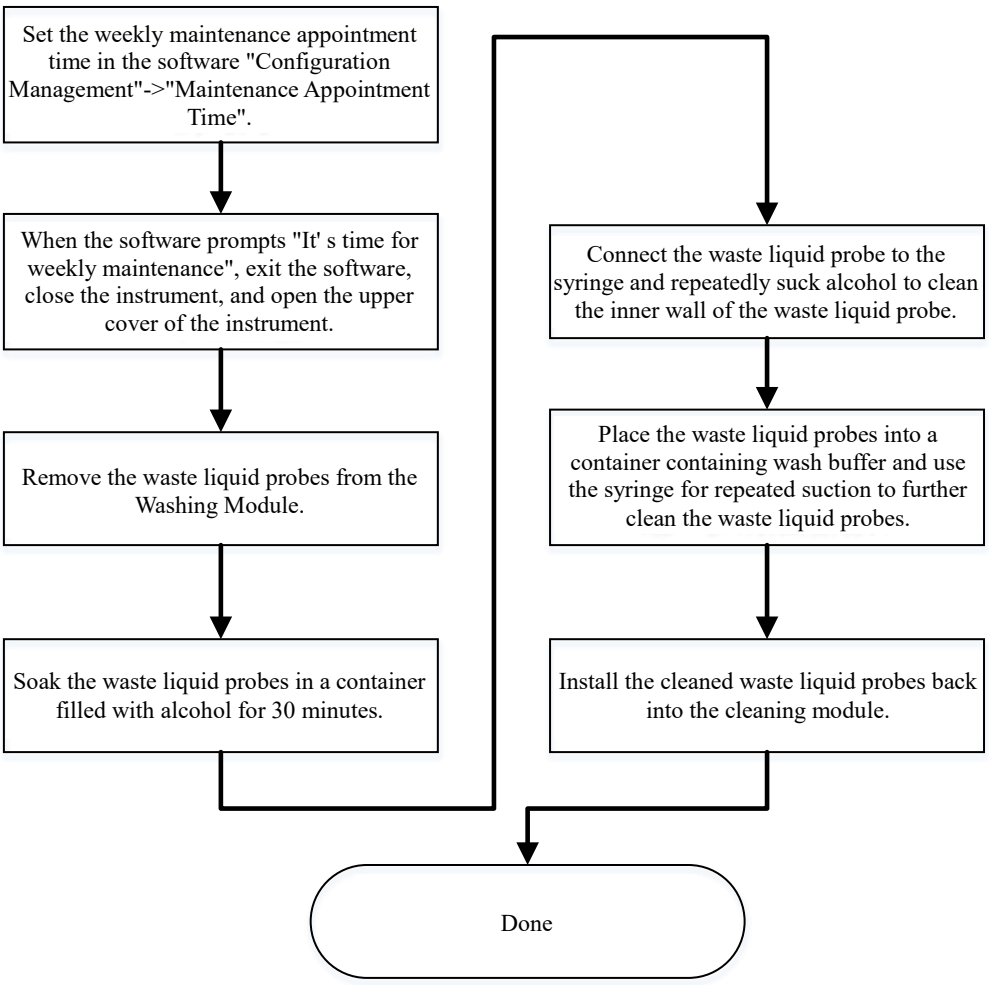
4.2.1 Waste liquid probe cleaning

	**Biohazard:** Since the waste liquid probe may come into contact with infectious substances during cleaning, it is necessary to carry out correct protection. In case of accidental contact with potentially infectious substances, correct laboratory procedures should be followed.

	**Caution, Danger:** Use extreme care during removal, cleaning, and installation of the waste liquid probes to prevent mechanical damage. Probes are fragile and should be protected from bending during cleaning.

Materials required:

- 75% alcohol
- Wash buffer
- Syringe



Waste Liquid Probe Cleaning Process

4.3 Monthly maintenance

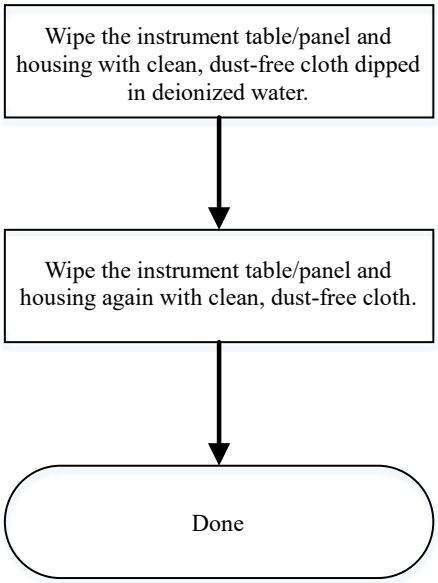
The system shall be cleaned and disinfected at least once a month.

4.3.1 Equipment cleaning

	**Biohazard:** During the cleaning process of the equipment, it may be exposed to infectious substances, so it is necessary to carry out correct protection. If it is accidentally exposed to potentially infectious substances, it should be handled according to the correct laboratory procedures.

Materials required:

- Deionized water
- Clean dust-free cloth



Equipment Cleaning Process

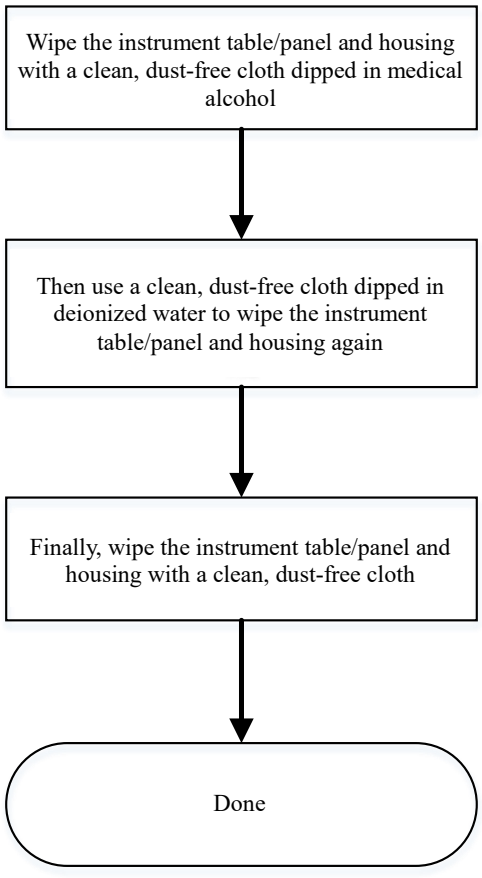
4.3.2 Equipment disinfection

	**Biohazard:** During equipment disinfection, infectious substances may be contacted, and proper protection shall be carried out. In case of accidental contact with potentially infectious substances, correct laboratory procedures shall be followed.

	**Caution, Danger:** When waste liquid and sample are splashed on the equipment, the relevant area of the equipment shall be disinfected.

Materials required:

- 75% alcohol
- Deionized water
- Clean dust-free cloth



Equipment Disinfection Process

During cleaning and disinfection, do not use cleaning agents and disinfectants that cause chemical reactions with equipment parts or materials contained in equipment. If there is any doubt about the compatibility of disinfectants or cleaning agents with equipment components or materials contained in equipment, consult the manufacturer or its agent.

4.4 Components and parts for system maintenance

Caution, Danger:

The protection provided by the analyzer may be reduced if the analyzer is used with accessories not provided or recommended by the manufacturer, or if the analyzer is not used in the manner specified by the manufacturer.

4.4.1Regular cleaning, inspection and replacement of parts

See Table 4-3-1 for regular cleaning, inspection and replacement of parts (calculated assuming the analyzer for 4 hours per day):

Table 4-3-1 List of Parts to be Cleaned, Inspected and Replaced Regularly (○: Regular cleaning and inspection ●: Regular replacement and addition)

No	Item	Frequency				Reference
		Daily	Timely	Weekly	Monthly	
1	S probe	○				
2	R probe	○				
3	M probe	○				
4	Wash buffer probe	○				
5	Waste liquid probe			○		
6	Probe washing bath				○	
7	Solid waste basket	○				
8	External waste liquid barrel	○				
9	Quick connector for wash buffer barrel		○			
10	Substrate bottle cap connector		○			
11	Wash buffer		●			
12	S probe wash buffer		●			
13	RV		●			
14	Substrate		●			
15	Probe plunger pump		○			

No	Item	Frequency				Reference
		Daily	Timely	Weekly	Monthly	
16	Incubation cabin, test cabin		○			
17	Reagent cold storage cabin				○	
18 (Note a)	Sample cabin		○			
19	Cooling fan and dust cover				○	
20	Water cooling liquid		●			
21 (Note b)	Printing paper and printer ribbon, ink, toner cartridge		●			
22	Thermal fuse				○	
23	Waste liquid sensor				○	

Notes:

a) The sample cabin is located in the sample management unit (optional) module.

b) The analyzer can be equipped with stylus, inkjet and laser printers. The user can choose the printer consumables according to the printer.

4.4.2 Spare parts list for regular replacement or maintenance by the user

Please prepare the following parts regularly so that the analyzer can be repaired in time in case of failure, as shown in Table 4-3-2:

Table 4-3-2 List of Spare Parts for Maintenance

No.	Component name	Remarks	Recommended stock/year
1	Peristaltic pump tube	Considering that the hose is under stress even when not in use, its replacement period is 12 months.	4 pieces
2	Waste liquid probe	Unintended damage may occur due to routine maintenance requiring cleaning of the waste liquid probes.	4
3	O-ring and silicone tube for mixing	It is recommended to replace them once every 12 months due to wear caused by long-time reciprocating & mixing.	6 sets

4.5 Maintenance method

Caution, Danger:

- Do not spill water, reagents, wash buffers and other liquids on the mechanical or electrical parts of the analyzer so as to avoid damage to the analyzer.
- Do not touch the probe mechanism and manipulator mechanism during the operation of the analyzer, otherwise there is a risk of infection or injury.
- In the process of work, the operator should take precautions, and need to wear protective gloves and work clothes.Otherwise, there is a risk of infection due to contact with contaminated areas, contaminated liquids, or contact with corrosive liquids that damage the skin.If contaminated or corrosive liquids come into contact with the body, rinse immediately with water and disinfect.
- Care should be taken during maintenance to check for hazards that may arise from the failure of any hose or fluid-containing parts.
- Operators should be trained before being allowed to operate and maintain the analyzer.

4.6 Instructions for maintenance and storage of the analyzer before decommissioning

Before the analyzer is stopped from use due to maintenance or disposal, or is not used for a long time, the analyzer should be treated as follows:

(1) Take out all reagents/consumables and samples.

(2) Empty piping.

(3) Remove all cables and store them properly to avoid twisting and damaging the cables.

(4) Remove the tubing connected to the wash buffer barrel/substrate bottle and place them in a clean container to avoid contamination.

Chapter 5 Troubleshooting and Treatment

In case of any failure during the operation of the instrument, the operator shall stop using the instrument and contact the engineer for treatment in time;

Fault phenomenon	Analysis	Solutions
Instrument has no power supply.	● Instrument switch is not turned on. ● One end of the power cord is loose. ● Faulty power supply.	● Turn on the instrument power switch. ● Confirm that the power cord is securely connected to the socket and instrument. ● Contact the Technical Support.
Connection failure between computer and instrument	● The connection between the computer and the router is disconnected or unreliable; ● The connection between the router and the instrument is disconnected or unreliable; ● The network connection between the circuit boards of the instrument is disconnected or unreliable; ● Instrument is not powered on.	● Confirm that the connection between the computer and the router is correct and reliable; ● Confirm that the connection between the router and the instrument is correct and reliable; ● Confirm that the connection between circuit boards is correct and reliable; ● Power on the instrument; ● Contact the Technical Support.
System initialization fails.	● System does not power up properly. ● The computer is not properly connected to the instrument or the internal network cable of the instrument ● Instrument internal wiring fault ● Failure of a component of the instrument	● Check the power cord of the instrument and power on the instrument correctly; ● Check the computer and instrument, as well as the internal network cable of the instrument, so that the network cable is connected correctly; ● Contact the Technical Support.
Pipe filling fails.	● Substrate bottle is not loaded correctly or no substrate is in substrate bottle. ● Wash buffer barrel is not properly loaded or no wash buffer is in the machine. ● Pump valve system is not powered up. ● Pump valve system failure	● Inspect the substrate bottle and confirm that there is sufficient substrate in the substrate bottle and that the substrate bottle is loaded correctly. ● Check the wash buffer barrel and confirm that there is sufficient wash buffer in the wash buffer barrel and that the wash buffer barrel is

	● Probe arm system failure	loaded correctly.
Many bubbles are in the fluid path.	● Unreliable connection of fluid path connector, with leakage. ● Faulty pump valve	● Check the fluid path connector to ensure reliable connection without leakage. ● Contact the Technical Support.
The sample tube barcode cannot be read correctly by the internal barcode reader.	● The barcode of sample tube is not applied correctly. ● The sample tube barcode format is not supported. ● The barcode reader fails.	● Apply the sample tube barcode correctly. ● Replace the unsupported tube barcode. ● Contact the Technical Support.
Sample tube specification cannot be judged correctly.	● Unsupported tube specification is loaded on the sample rack. ● Sample rack is not loaded correctly. ● Sample disk specification judgment sensor fails.	● Check the sample tubes on the sample rack and replace the unsupported sample tubes; ● Reload an incorrectly loaded sample rack. ● Contact the Technical Support.
Abnormal kit tray rotation after loading the kit	● The kit is not loaded correctly. ● A kit that is not part of the system is loaded. ● Kit tray fails.	● Check kits, and reload kits that are not loaded correctly ● Replace the kit in the machine that does not belong to this system. ● Contact the Technical Support.
Kit information cannot be read correctly.	● Incorrect position of kit tray to read kit information ● The kit electronic label is damaged. ● Reagent reader fails.	● Correct the position where the kit tray reads the kit information. ● If only some of the kits cannot be read, the e-tag of the kit is damaged and needs to be replaced. If all the kit information cannot be read, the reagent reader is faulty. Please contact the Technical Support.
Analysis failure		
Calibration fails.	● Calibration information is set incorrectly. ● Calibrators are not placed in the same position as the setting. ● Failure to perform necessary	● Ensure calibrator information is set correctly. ● Ensure that the calibrator is placed in the same position as the setting. ● Recalibrate after necessary

	maintenance ● Calibrator expires. ● Calibrator is contaminated during storage or handling. ● Reagent is contaminated during storage or handling. ● Substrate is contaminated during storage or handling. ● Fluid path system fails. ● Failure of mechanical structure	maintenance. ● Replace calibrators, reagents and substrates and recalibrate. ● Contact the Technical Support.
QC fails.	● Quality control information is set incorrectly. ● The placement position of quality control is inconsistent with the setting. ● Failure to perform necessary maintenance ● The quality control expires. ● Quality control is contaminated during storage or handling. ● Reagent is contaminated during storage or handling. ● Substrate is contaminated during storage or handling. ● Fluid path system fails. ● Failure of mechanical structure	● Ensure that the quality control information is set correctly. ● Ensure that quality controls are placed in the same position as setting. ● Re-perform QC after necessary maintenance. ● Re-perform QC after replacement of quality controls, reagents and substrates. ● Contact the Technical Support.
Patient sample results are abnormal.	● Incorrect patient sample type ● Improper handling of patient samples ● Patient sample contains clots. ● Insufficient patient sample size ● Wrong reagent loaded ● Reagent expires or reagent calibration expires. ● Reagent or substrate is contaminated due to improper storage or handling. ● Normal service or maintenance is not performed. ● Unsupported rack or sample	● For the sample type of each test item, please refer to the instructions for use of the corresponding reagent. ● Follow proper laboratory procedures for storage and handling of cached samples. ● Use the sample filter to filter the clots in the sample or centrifuge the sample again, and then re-test. ● Please calculate the required sample size according to the sample size, retest times and dead volume of the corresponding sample container specified in the instructions for use of each

	container is used.	test item, and then load enough samples for retest. ● Replace with correct reagent within the validity period for testing. ● Change the substrate for testing. ● Test after performing normal maintenance and repair. ● Test after replacing with supported rack or sample container.

Chapter 6 Transport and Storage

6.1 Transport

The transport of analyzer shall be specified in the contract. The analyzer shall be protected from severe collision, rain and exposure, and shall not be mixed with corrosive materials.

6.2 Storage

The packaged analyzer shall be stored in a clean, chemical-free and corrosive-gas-free room with good ventilation and an ambient temperature of -40℃~55℃ and a relative humidity of 10%~85%.

Appendix

Accessories List

Accessories List (including fittings, accessories and consumables)

Part name	Location	Replacement cycle	Replacement method	Remarks
Waste-discharging probe	Fluid path system	Timely	Contact the Technical Support.	This part can be replaced as instructed by the support technicians.
Wash buffer probe	Fluid path system	Timely	Contact the Technical Support.	This part can be replaced as instructed by the support technicians.
Peristaltic pump tube	Fluid path system	Timely	Contact the Technical Support.	This part can be replaced as instructed by the support technicians.
Sample rack	Sample Management Unit	Timely	/	/
Solid waste basket	Waste system	Timely	/	/
Waste liquid barrel	Fluid path system	Timely	/	/

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