

# AUTOSTREAK S1800

# AUTOSTREAK S1800S

## Automated Streaking/processing System

## Operating Manual

2022-11-09

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This document can not be considered as substitute of official training of Autobio. Automated Streaking/processing System shall only be operated by personnel who has been authorized and trained by Autobio.

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## CONTACT

In the event of any questions or doubts related to using the Automated Streaking/processing System, please send an email with a short description of the question to the address below or contact the post-sales service. Any suggestions for improvements to products and services are gladly acceptable.

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## EC Representative



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1030 Brussels,  
Belgium

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## In Vitro Diagnostic Medical Device



This product is used for In Vitro Diagnostic purpose.

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## Waste Electrical and Electronic Equipment (WEEE)



In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), the presence of the left symbol on the product or on its packaging indicates that this item must not be disposed of in the way that normal unsorted municipal waste stream is mixed with other normal household-type waste. Instead, the responsibility should be taken by users to dispose of this element by returning it back to a collection area dedicated for recycling the waste of electrical and electronic equipment. The waste, which may be harmful to physical and potentially mental health or makes it impossible to keep a favorable environment, must be collected separately, observing the relevant legal regulations effective, which makes for recycling and minimizing the bad effect on human physical health and the environment. In order to acquire more information with respect to the correct disposal of this product, please contact your local authority or the dealer who supplied this product.

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The manual is mainly used for giving instructions to users for instrument related operation and general maintenance, which includes the following: general description, safety features, description and quality control of function and operation, measures taken in case of emergency, product labelling and maintenance, etc.,

# 1 General Description

## 1.1 Safety Information

### 1.1.1 Safety Features

Safety labels are affixed on the instrument to remind the user of safety. Please read the label and the operating manual carefully prior to operating the instrument. If any questions, please contact Autobio.

Prior to usage, user must be trained by Autobio to avoid risks caused by incorrect action.

### 1.1.2 Protective Device/Safety Equipment

The instrument has protective device to prevent user from danger.

#### 1.1.2.1 Instrument Failure or Unexpected Accident

**STOP button:** The STOP button is on the left side of the front panel of the instrument. Press this button to stop the operation of the instrument if the instrument fails or has other accidents during the test.

**Pressure symbol of opening and closing the cover:** Press the cover near the symbol to open and close the cover.

Please see the figure below:





### 1.1.2.2 UV Lamp

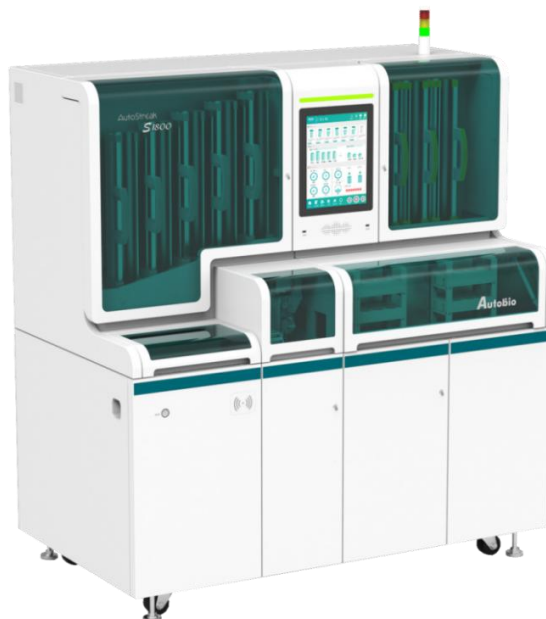
When the UV lamp is on, please ensure that the cover of the instrument is completely closed. Do not look directly at the UV lamp and keep a certain distance from the instrument.

### 1.1.2.3 Status Indicator

There is a status indicator above the touch panel of the instrument (or optional multi-layer signal light on the right side of the top of the instrument)

The status indicator (or multi-layer signal light) has three states: green, yellow, and red

Green: The instrument runs normally (See the figure below)



Yellow: The instrument is ready, paused or under commissioning(See the figure below)








Red: Other status(See the figure below)






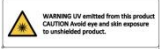


### 1.1.3 Safety Symbols and Others

This manual employs the following symbols and signal words to indicate hazards or instructions. The safety instructions are always placed before an action.

Symbol	Description
	<p>Biological Risks.</p> <p>Human serum or blood products with potential risk of infection may be present in certain areas of the instrument and related liquid treatment equipment. Materials in these areas should be disposed of in accordance with proper laboratory procedures or in accordance with local laws and regulations.</p>
	<p>Caution! Possibility of Electric Shock!</p> <p>Potential risk of electric shock, especially for the high voltage parts, such as power module. It's too dangerous to open these parts for checking and maintenance if operator is not trained professionally.</p>
	<p>Caution!</p> <p>Remind you of reading important information of the label or operating manual, and pay attention to potential danger existing along with another symbol nearby.</p>
	<p>Warning; Crushing of Hands!</p> <p>Watch your hand when opening or closing the cover of the instrument.</p>
	<p>Alternating Current.</p>
	<p>Protective Conductor Terminal.</p>
	<p>"OFF"(Power).</p>
	<p>"ON"(Power).</p>

	<p>Disposal of Electrical and Electronic Equipment:</p> <p>The equipment must not be processed according to the conventional waste disposal. It is the responsibility of the user to return it to the waste collection point of the electrical and electronic equipment for recycling.</p>
	<p>In Vitro Diagnostic Medical Device.</p>
	<p>Consult Instructions for Use or Consult Electronic Instructions for Use.</p>
	<p>Manufacturer.</p>
	<p>Authorized Representative in the European Community / European Union.</p>
	<p>European Economic Area Conformity.</p>
	<p>Country and Date of Manufacture.</p>
	<p>Catalogue/Reference Number.</p>
	<p>Serial Number.</p>
	<p>Temperature Limitation.</p>

	<p>Humidity Limitation.</p>
	<p>Model Number.</p>
	<p>Unique Device Identifier</p>
	<p>Pressure symbol of opening and closing the cover. Press the cover near the symbol to open and close the cover.</p>
	<p>Solid waste container</p>
	<p>Warning; Optical radiation Warning UV emitted from this product Caution Avoid eye and skin exposure to unshielded product.</p>

 **CAUTION:**

Failure to observe the content of symbols or operating manual, including the warnings, precautions and prompts, and using the damaged or missing safety symbols, will cause system damage or adverse impacts on system functionality; or may result in physical injury or deterioration in the state of health, damage to property or material!

### 1.1.4 General Safety

The operating manual gives important instructions for handling the system. Safety instructions must be observed at all times. Before or during the process of operation, the following items must be observed:

 **CAUTION:**

- 1) Do not perform any operations which are not described in the manual. If trouble occurs, please call post-sales service.
- 2) The operating manual must be accessible to the user at any time.

3) As for maintenance and service, it is forbidden to modify the Automated Streaking/processing System and replace the components or accessories of the instrument.

4) It is not allowed to use parts which are not provided by Autobio. It is not permitted to remove the protective device.

5) Personnel without authorization of Autobio can not install or maintain the Automated Streaking/processing System, nor make any changes during installation.

**NOTE:**

Improper connection between Automated Streaking/processing System and the peripheral devices with mains supply, as well as usage of damaged cables may result in severe personal injury even lethal consequences and property damage (e.g.fire).

**1.1.4.1 Liability**

It is the users' responsibility to comply with national and local law's regulations and laboratory procedures for installation and operation of the instrument. The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically.

Autobio is not liable for any loss or damage including consequential or special damages resulting from the misuse of the contained information or other faults of personnel and contractors. Additionally, the manufacturer assumes no liability for any damages, including those to the third parties, which are caused by improper use or handling of the system.

The instrument may only be used in accordance with its intended use. Only use the consumables and accessories described in the manual.

**1.1.4.2 Technical Condition**

Automated Streaking/processing System corresponds in its design and construction to the current state-of-the-art technology. Unauthorized modifications or changes, especially such that affect the safety of the staff and the environment, are generally not allowed.



**CAUTION:**

1) Any manipulation of the safety device is prohibited! In case of an accident manipulations of the safety equipment, it will be interpreted as deliberate!

2) The operator must only operate the device in a sound and operationally safe condition. The technical condition must always comply with the legal requirements and regulations.

3) Prior to every usage, the device must be checked to ensure its sound condition.

4) Any changes in the device affecting its safety must be reported to Autobio by the operator.

### 1.1.4.3 Requirements for the Operating Personnel

Automated Streaking/processing System must only be used by professional laboratory personnel taking into consideration the Automated Streaking/processing System operating manual and the instruction for use of corresponding IVD kits.

Apart from the information in the operating manual and instruction for use of the corresponding IVD kits, the regulatory requirements of the applicable country of use must be observed and complied with. The operator must ascertain the latest version of these regulations.



#### CAUTION:

- 1) The device must only be commissioned, operated and serviced by trained personnel instructed in technical safety.
- 2) The operation or servicing of the device by minors or individuals under the influence of alcohol, drugs or medication is not permitted.
- 3) It must be ensured that only authorized personnel works at the device. The operator must be familiar with the dangers arising from samples and excipients. Suitable personnel protection equipment must be worn.
- 4) Any changes in the device affecting its safety must be reported to Autobio by the operator. Prior to pauses or at the end of the work, appropriate skin cleaning and protection measures must be carried out.
- 5) Eating, drinking and smoking at the location of the device are prohibited!

### 1.1.5 Biological Risks

When operating the device or handling related liquid, such as reagent, human serum, blood products, etc., the user may be exposed to potentially infectious materials. Please strictly comply with Good Laboratory Practice when dealing with biological hazards or repairing and maintaining the Device.

Please take appropriate protective measures, such as wearing disposable gloves, waterproof lab coats and safety goggles.

Observe national and local laboratory standards and regulations. Forbid using the hoses or parts containing solution damaged or aged over time, and replace them by contacting with Autobio or local agent.

Materials used in the assays must be considered potentially infectious agents. They should therefore be decontaminated and disposed of in accordance with standard and regulations of laboratory specified by local government.

The following articles should be handled with as the potential biohazard:

All In vitro diagnostic instrument, pretreatment equipments, patient's specimen, petri dishes and and waste. such as tip, sampling cup, inoculation brush etc.

Exposure to these potentially biohazardous items: 4#Tip, sampling cup, inoculation brush, container, etc.

**NOTE:**

- 1) Inclusions in the solid waste container may be potential biological risks, and it may be infectious upon contact.
- 2) Please dispose the solid wastes in accordance with relevant procedure and applicable local regulation, and wear the appropriate personal protective equipment (PPE).
- 3) Please contact Autobio if the instrument needs to be scraped, and it can not be disposed as a regular article.

### 1.1.6 Electrical Hazards

The Automated Streaking/processing System does not pose uncommon electrical hazards to operators if it is installed and operated without alteration and is connected to a power source that meets required specifications. It is essential to the safe operation of any system to have basic electrical hazard awareness. So only personnel strictly observing the related national rules and local regulations for the safe electrical operation of the system should perform electrical servicing. Life threatening electrical voltages may occur in the interior of the Automated Streaking/processing System, and please strictly observe the elements of electrical safety, which include but are not limited to the following:

**CAUTION:**

- 1) Any work on the interior of the device may only be carried out by the service engineer of Autobio and specially authorized technicians.
- 2) Keep liquids away from all connectors of electrical or communication components.
- 3) Do not touch any switches with wet hands.
- 4) Do not replace the removable mains cable of the device by a mains cable that does not meet the specifications (without a protective ground conductor).
- 5) Any defects, such as loose connections, faulty or damaged cables, must be repaired without delay.
- 6) Do not put connecting cables at accessible place in order to avoid squeeze or damage.
- 7) Do not interrupt any electrical connection or service any electrical or internal components while the power is on.

**NOTE:**

Use an independent supply source to prevent device malfunction at site. It is strictly prohibited to add any other device to the socket of the Automated Streaking/processing System (if available) without the permission of Autobio.



**NOTE**

Severe personal injury or extensive damage to the device may occur. It will not trigger severe personal injury with lethal consequences and property damages unless not observing the rules and regulations for the safe electrical operation.

### 1.1.7 Physical Hazards

For most automated devices, there is potential physical injury or bodily harm from moving mechanical components whenever the system is running because of following hazards: radiation (laser light, etc.,), heavy objects, trip hazards, moving parts of the instrument and sharp units, etc.,.

Commissioning or installing the instrument must comply with the operating manual. Basic safety elements include but are not limited to the following (If applicable):

- 1) Do not touch directly with the sharp metal edges.
- 2) Do not overlook or ignore a safety equipment.
- 3) Keep all protective covers and barriers in right place.
- 4) Body part is not allowed to enter into the mechanical movement arrangement.
- 5) Do not contact with the probes that are contaminated with potentially infectious material.
- 6) UV lamp hazard warning.

**NOTE:**

Do not wear clothing or ornaments that could have an interference with the system.

### 1.1.8 Fluids Hazards

Users may be exposed to hazardous chemicals or agents when handling reagents, loading or removing the reagent kits, and disposing the liquid waste. Observing the instructions below can minimize the risks of fluids hazard.

- 1) Cleaning or decontamination shall not cause a direct hazard, such as an electrical hazard or a hazard arising from corrosion or weakening of structural parts.
- 2) Absorb the spill with absorbent material.
- 3) Observe the manual of IVD reagent kits.
- 4) Wear appropriate protective equipment, such as impervious gloves, protective goggles and clothing to protect eyes and skins from contacting with hazardous fluids.
- 5) Before handling IVD reagents, consult corresponding product-specific MSDS (Material Safety Data Sheets) for safe use instructions and precautions.
- 6) Seek medical attention if irritation or signs of toxicity occur after exposure.

### 1.1.9 Electromagnetic

Automated Streaking/processing System fulfills the corresponding requirements for transient emissions and interference resistance from IEC 61326 series. Only cables provided by Autobio can be used to minimize electromagnetic wave interference. Please read the following content carefully and ensure the ambient environment is appropriate:

- 1) This product conforms to the standard of CISPR 11 Class A equipment. Under some circumstances, it may cause radio interference, please take protective measures.
- 2) It is recommended that the electromagnetic environment should be evaluated before operation.
- 3) Do not operate the instrument near sources of strong electromagnetic radiation (such as unshielded, deliberately operated high frequency sources), as this may affect proper operation of the device.
- 4) Check the power supply cable periodically to avert it becoming loose.
- 5) It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
- 6) We declare that portable radio frequency communication equipment, including antennas, can affect medical electrical equipment. When the Product is in use, no part of [ME equipment or ME system], including the cable specified by the Manufacturer, shall approach 30 cm.
- 7) This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
- 8) This equipment is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in a home healthcare environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- 9) It has passed the electromagnetic compatibility test of medical electronic equipment. In case of interference, users can adopt the following measures:
  1. Open and close the device to confirm the interference source.
  2. Add an isolation device between the equipment and other equipment.
  3. Connect the equipment and other equipment to different power sockets.
  4. Consult relevant equipment suppliers and manufacturers.

Company Name:Autobio Labtec Instruments Co., Ltd.

Contacts:Autobio Labtec Instruments Co., Ltd.

Legal Address:No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China

Contact Information:Tel: [86]-371-6798-5313

10) This device cannot be stacked with other devices. If users really need to use this device, they must verify that the performance of the device is good in the use environment before it can be put into use.

11) Medical electronic equipment should pay special attention to the relevant matters stipulated in EMC, and its installation and use shall be based on the relevant information of EMC provided in this manual.

12) Unapproved accessories used in equipment may lead to EMC index exceeding the standard requirements, resulting in unpredictable damage.

13) The produce conforms to the basic safety and essential performance requirements.

14) This machine belong to medical treatment electronic equipment. The product has been evaluated, please refer to the risk assessment report 50410015-1.

#### **NOTE:**

1) Autobio is responsible for providing electromagnetic compatibility information of Automated Streaking/processing System

2) User is responsible for maintaining the electromagnetic compatibility environment where Automated Streaking/processing System can work properly as intended purpose.

### **1.1.10 Other Residual Hazards**

Notwithstanding the manufacturer has tried as possible as they can to reduce the risks to an acceptable level, such as inherent safe design and protective measures, users may be still at an unfavourable situation.

In regard of risk management, the system has been designed and manufactured based upon the standard ISO 14971.

The materials and components of the Automated Streaking/processing System are made and the reagents used on the instrument do not endanger the safety or health of users. Autobio has applied many principles for reducing risks, which include but are not limited to the following:

1) Eliminate or reduce risks as far as possible (an inherently safe design and construction);

2) Take the necessary protective measures related to the risks that cannot be eliminated, which can refer to the 1.1.5-1.1.9;

- 3) Inform users of the residual risks due to any defects of the protective measures adopted, indicate any particular training required, and provide operator with information of protective device/safety equipment;
- 4) Estimate the risks of hazardous situations, taking into account the severity of potential harm and the possibility of its occurrence by the application of an appropriate FMEA (Failure Mode Effect Analysis) methodology.

**NOTE:**

Autobio assumes no responsibilities concerning the losses or damages arising from the improper operations or maintenance by unauthorized personnel. It is recommended that users contact service engineer immediately in case emergency occurs.

### **1.1.11 Ergonomic**

Based on the ergonomic principles, the Automated Streaking/processing System is designed regarding to the user habits, interface layout, information prompts and software interface operation safety etc., to reduce discomforts fatigue, physical and psychological stress. If the user needs other functions, please contact customer service of Autobio.

The documents and materials related to safety operation are included in the accessory case, e.g. the operating manual, 4#Tip, sampling cup, inoculation brush, label paper etc.

## **1.2 Reporting Instrument Anomalies**

Users are encouraged by Autobio to report any anomalies observed in the performance, appearance, labelling or packaging of instrument. Autobio or its local representatives will carry out a thorough analysis of possible defects, and encourages users to report the anomalies in sufficient detail, e.g. serial number, UDI, product model or catalogue/reference number, along with a description of the relevant observations and supported with photographic or other descriptive material if available. It is advisable that products with suspected defects be quarantined and processed according to the advice of Autobio authorized representatives or local agents. Please preserve the whole product, together with the packaging material for further analysis.

## **1.3 Vigilance Information**

If the unlikely case of a suspected hazardous situation caused or affected by the use of the instrument of Autobio occurred, please contact Autobio or its local representatives directly and without delay, which can refer to the important contact information of chapter 1.4. Additionally, local competent authorities have standard reporting forms available for reporting possible adverse effects of IVD medical devices, and users should follow any local regulations or guidance provided by the local authorities.

## 1.4 Product and Manufacturer Information

### **Product Information:**

Product Name: Automated Streaking/processing System

Product Model: AutoStreak S1800 and AutoStreak S1800S

Manufacturing Date: Refer to the nameplate label of the instrument.

Lifetime: 7 Years

Applicable Software Version: V1.0; Control instrument release version: V1

### **NOTE:**

The lifetime of the instrument is closely related to the operating environment and frequency of use. Regular maintenance can duly extend the lifetime. If there is any problem or alarming prompt, please call customer service or access the website of [en.autobio.com.cn/](http://en.autobio.com.cn/).

If the components mounted on the instrument were to be changed, the only way to purchase would be from Autobio other than other manufacturers. Do not open the cover of the instrument during running, otherwise it will cause damage to the instrument and user.

### **Manufacturer:**

Name: Autobio Labtec Instruments Co., Ltd.

Legal Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China

Tel: [86]-371-6798-5313

### **Post-sales Customer Service:**

Name: Autobio Diagnostics Co., Ltd.

Legal Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China

Tel: [86]-371-6798-5313

### **NOTE:**

Please prepare the serial number of the instrument before contacting post-sales service.

## 2 Product Description

### 2.1 Product Information

Product name: Automated Streaking/processing System

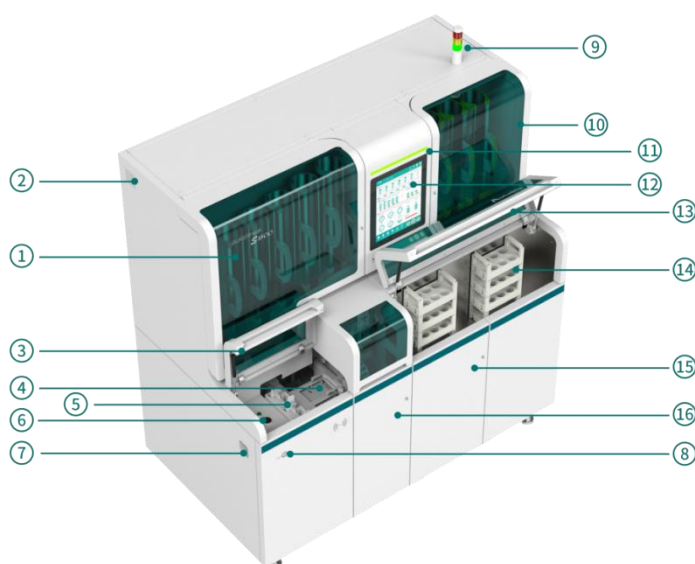
Model: AutoStreak S1800 and AutoStreak S1800S.

This manual takes AutoStreak S1800 as an example to describe and illuminate. Unless otherwise stated, the descriptions in this manual apply to both of the models.

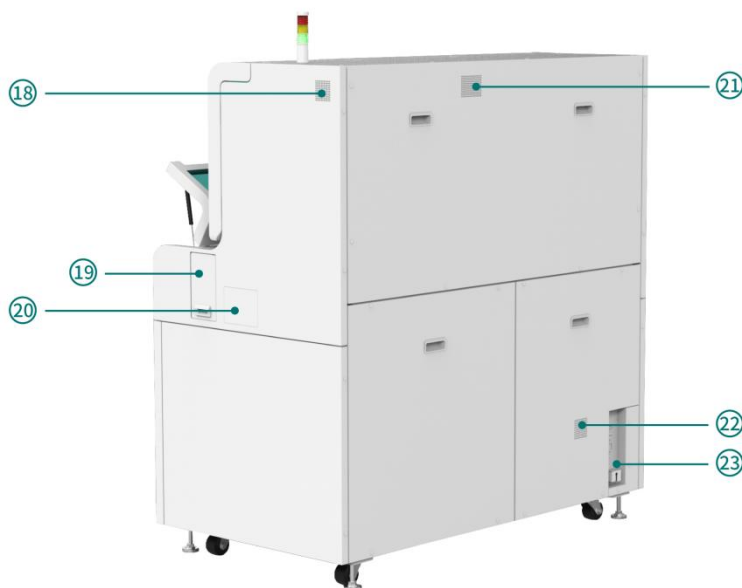
### 2.2 Structure Composition

Difference Model	Automatic mixing function
AutoStreak S1800	Yes
AutoStreak S1800S	No

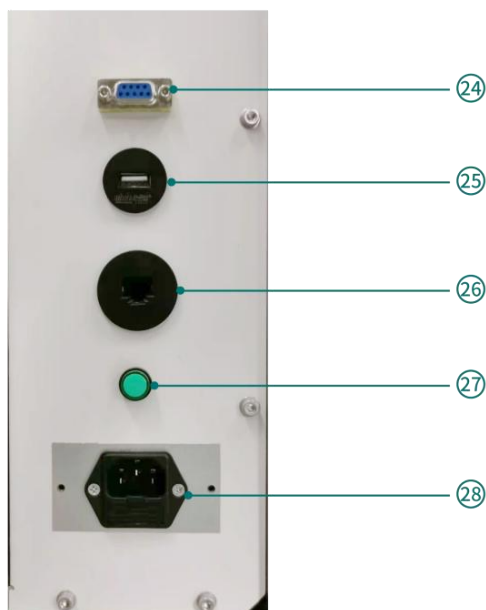
Product description: Automated Streaking/processing System is composed of instrument, software and accessories. The instrument is composed of sample adding module, transportation module, inoculating and streaking module, ultraviolet lamp module, automatic mixing module (only for AutoStreak S1800), air purification module, external vacuum module (optional) and electric module.



No.	Name	No.	Name
1	Plate loading cover	2	Cooling fan
3	Consumable cover	4	Tip position
5	Inoculation brush position	6	UV lamp timer
7	Power Switch	8	Stop button
9	Multi-layer signal light	10	Plate unloading covering
11	Status indicator	12	Panel screen
13	Sample rack cover	14	Sample rack position
15	Abnormal sample discharge gate	16	Solid discard gate



No.	Name	No.	Name
18	Cooling fan	19	Reagent bin
20	Interface for TLA	21	Air filter outlet
22	Cooling fan	23	Instrument interface panel (see figure below)



No.	Name	No.	Name
24	Serial port	25	USB interface
26	Internet port	27	Power indicator
28	Power outlet		

## 2.3 Intended Purpose

Automated Streaking/processing System is strictly intended for professional In-vitro Diagnostic use. It is an automated instrument which is clinically used for treating and processing the human sample before and after analysis.

Sample types: Sputum, urine, cerebrospinal fluid, alveolar lavage fluid and ascites.

Authorization: Automated Streaking/processing System must only be used by personnel with professional training. The operation of the instrument can be executed by observing this manual.

Contraindication: None.

## 2.4 Working Principle

The Automated Streaking/processing System can transfer the clinical samples to the instrument through the sample transfer system. The sample adding system automatically and sequentially aspirates the samples and transfers them to the culture plate. Then the



inoculation system performs the inoculation operation. The labelling system prints and pastes labels on the inoculated culture plates. Finally, the culture plate was unloaded and the whole clinical sample pre-treatment was completed.

## 2.5 Performance Parameter

Major function	It can inoculate and realize streak of sputum, urine, cerebrospinal fluid, alveolar lavage fluid and ascites
Sample loading	24 (in random)
Automatic opening and closing function of sampling cup	Support
Abnormal sample handling	Abnormal sample discharge function
Size of sample container	90 mm plate
Maximum loading capacity of sample container	185 pcs(can be supplemented without pause )
Inoculation speed	Maximum 180 pcs/h
Streaking mode	One time mode
Inoculation volume	11 $\mu$ l, 16 $\mu$ l, 21 $\mu$ l
Inoculation brushes	240 (can be supplemented without pause)
Tip (with filter element)	192 (can be supplemented without pause)
Barcode printing and pasting	Automatic pasting on the plate
Barcode scanning function	Support
Operation interface	Touch Panel
Air purification function	H14 High efficiency filter element
Ultraviolet function	UV lamp

## 2.6 Operation Environment

Automated Streaking/processing System must not be operated in an explosive environment, and it must not be operated with flammable, explosive or volatile substance.

The operating personnel must be familiar with the location of the fire-fighting equipment in the operating room of the device.

Automated Streaking/processing System must only be used in the room where the operation environment condition in the table below is sound:

Item	Requirement
Temperature	Normal operating environment temperature; 10 °C ~ 30 °C
Relative Humidity (RH) (non-condensing)	Normal operating environment humidity; ≅ 85 %
Altitude	≅ 2000 m
Ambient Brightness	Avoid direct sunlight
Atmospheric Pressure	85 kPa-106 kPa
Pollution Degree	Level 2
EMI	Stay away from sources with strong electromagnetic interference.
Interference from other Instruments or Equipment	Away from high power, strong amplitude, strong light illumination instrument and equipment.
Water requirements	Purified water for in vitro diagnostic reagent: Water pressure: ≅ 100 kPa. Water consumption: 10 L/h

The service life of the instrument is related to the operating environment and frequency of use of the instrument. Regular maintenance can extend the service life. If you have any questions, please contact the after-sales service provider.

## 2.7 System Specification and Feature

### 2.7.1 Weight

Item	Weight
Instrument (before adding supply materials and samples)	380 kg

## 2.7.2 Power Requirement

Component	Requirement
Instrument	1 kVA

## 2.7.3 Dimension

Instrument with All Covers and Drawer Open	Length: 2840 mm Height: 1700 mm Width: 1360 mm
Instrument with All Covers and Drawer Closed	Length: 1677 mm Height: 1700 mm Width: 890 mm
Clearance Required to Ventilation, Safety Operation and Maintenance	Back: 600 mm Top: $\geq 300$ mm Front: $\geq 800$ mm

## 2.7.4 Electronic Requirement

### 2.7.4.1 Power Supply

The power supply should meet the requirements of the following table in order to avoid damaging the instrument.

Item	Requirement
Circuit Power Supply	100-240 V, 50 Hz/60 Hz, single-phase power supply
Circuit Specific	Dedicated cable
Connector of Power Cord	AC 250V~, 10A
Power Cable Pug	AC 250V~, 10A
Power Cable	300-500V~
Circuit Outlet	Not more than 2 m away from the instrument, and compatible with the plug of the instrument
Voltage Fluctuation	It shall not exceed 10 % per cycle.

Maximum Resistance between Instrument Ground Wire and Safety Grounding of Lab	Not more than 0.1 Ohm
Overvoltage Category	II

### 2.7.4.2 UPS for the Instrument

If you need to use an uninterruptible power supply (UPS) as a backup power supply, Autobio recommends that you use a UPS with local ground isolation and a low battery indicator. You can contact the technical support department of Autobio Labtec Instruments Co., Ltd. to learn about the recommended backup power supply.

UPS power supply shall meet the following requirements:

Minimum output capacity	2400 VA
Output voltage	Range 100-240V~
Output frequency	50/60Hz
Output waveform	Sine wave
No-load operation time	Ensure that the instrument can run for at least 15 minutes in case of power failure
Certification	CE



#### CAUTION:

If power is anticipated to be cut off from all parts of the instrument, disconnect the equipment and the power supply providing the energy.

## 2.8 Used in Combination with Other Products

The instrument needs to be used in combination with the corresponding IVD kits designated by Autobio. End-user must read the manual of IVD kit carefully before usage to avoid unreliable assay result (such as expiration date, etc.,).



#### CAUTION:

- 1) Autobio shall not bear any liability due to non-observance of the IVD kit manual or using an IVD kit not designated by Autobio.
- 2) The instrument fulfills the safety requirements of IEC61010 series, and if it is anticipated to be used with a device certified in accordance with IEC60950, please contact engineers authorized by Autobio for a consultation to avert damages to the equipment.

## 3 Installation & Commissioning



The installation and commissioning of Automated Streaking/processing System must be executed by service engineers or personnel authorized by Autobio. Do not take out the instrument from the package without the engineer presenting at the site. After installation, any other device can not be plugged in the socket connected with the instrument.

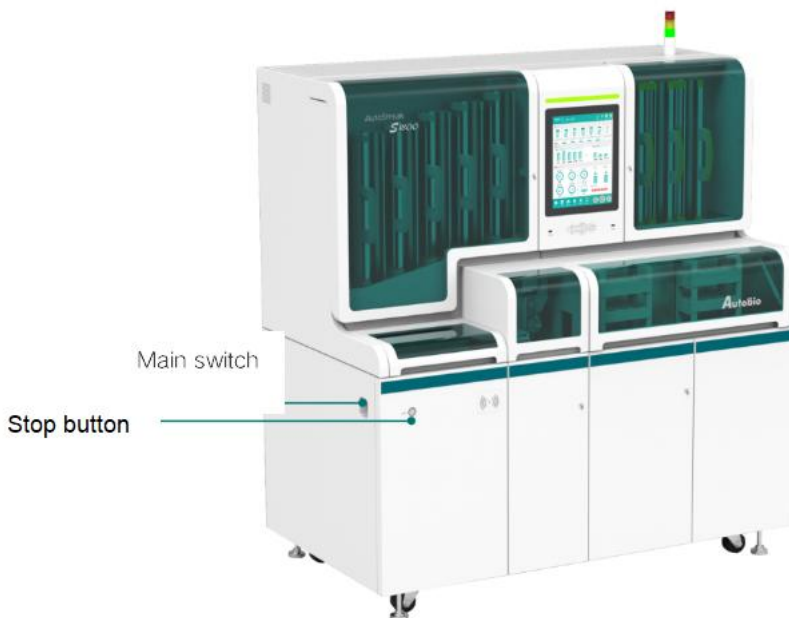
### 3.1 General

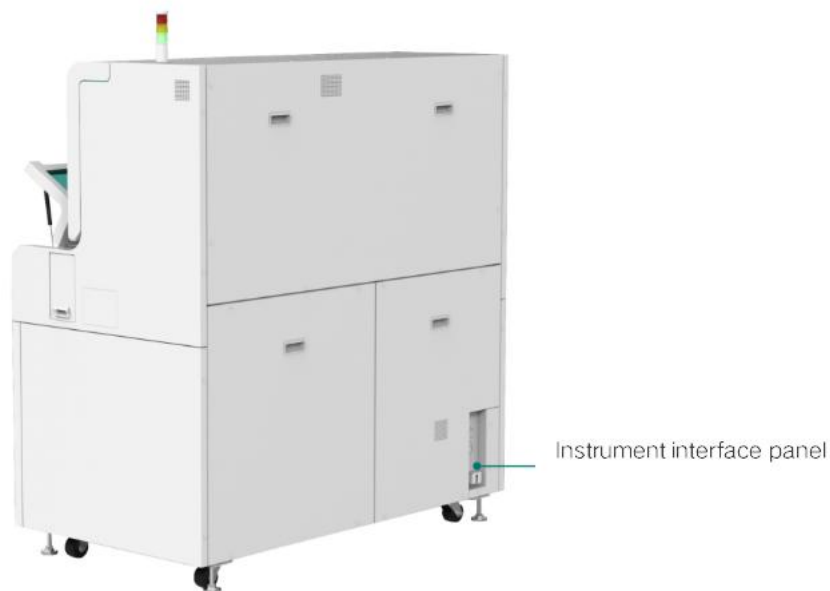
The instrument can not be installed and used in a laboratory with potentially explosive atmosphere. It can only be operated under the working conditions (temperature, altitude, no direct sunlight exposure and humidity) specified in this manual. End-user is obliged to assess whether the above requirement has been met.

### 3.2 Introduction of Instrument Connection

The technical data pertinent to instrument connection (power requirement, installation dimension, weight and environmental condition) can refer to chapter 2.5 - 2.6.

Connection between the instrument and other equipment is shown as the figure below:





### 3.3 Installation Precautions

- 1) The bottom of the instrument installation position is flat and hard, and the bottom bearing capacity is not less than 500kg/m<sup>2</sup>;
- 2) The instrument must be installed at the position where it is convenient to operate the main switch, stop button and instrument interface panel (see the figure below);
- 3) Contact the professional engineer when the instrument needs to be transported or moved;
- 4) Before powering on the instrument, ensure that the enclosure is installed completely;
- 5) The power cord shall be connected with the power supply with grounding protection function;
- 6) If the equipment cannot be used according to the method specified by the manufacturer, the protection provided by the equipment may be damaged;
- 7) The instrument needs to be leveled before use. Professional personnel should adjust it. Normal operation can only be carried out after the instrument level is confirmed.



#### **CAUTION:**

In no event shall Autobio bear any responsibilities for injuries and damages arising from operation performed by untrained or unauthorized personnel.

#### **NOTE:**

- 1) It is strictly forbidden to alter and / or modify the intended use conditions and functions

of the interlocked lid. When the state of the open lid is ignored, it is strictly forbidden to touch moving parts while running or getting closed to them with hands, arms, shoulders or face/ head.

If the AutoStreak S1800 moves within the plant, the authorized service personnel must perform a complete reinstallation.

Replaced instruments, packaging materials and all components must be handled in accordance with applicable local and national laws, regulations and laboratory procedures.

### **3.4 Commissioning**

The commissioning of the instrument must be performed by service engineers from Autobio or an agent.

Users are not allowed to perform the commissioning, please refer to the operating manual for details!

## 4 System Operation

The system can normally carry out a test from switching on the system to switching off the system provided that the operator definitely observes the operating manual when running the instrument.

**NOTE:**

Refer to chapters 1.1.5-1.1.10 for all potential safety hazards when performing the instrument. Do not perform any operations or functions not described in the operating instructions. If trouble occurs on the diagnostic system, contact Autobio or an authorized representative in the distributed area. In the case of unreasonable or unforeseeable usage, it will cause erroneous assay results, damage to the system or personal injury.

Prior to operation, the user should consult the operating manual, which must be followed strictly in case of damage to the analyzer.

The main interface of the system is shown in the following figure:



The modules and functions are described in the table below:

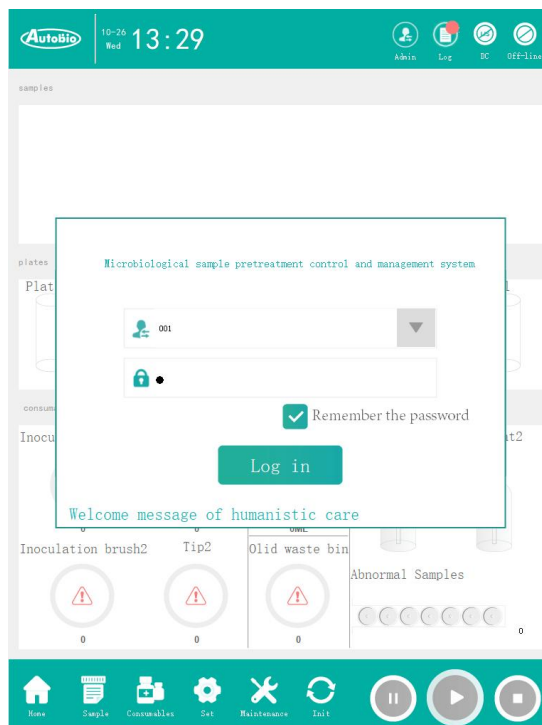


No.	Corresponding module name	Function introduction
1	Information display	Including Autobio LOGO and instrument time and date
2	System shortcut button	Home page, sample allocation, consumables, settings, maintenance, initialization, user switching and login
3	Detailed display area of each functional module	Detailed display of each functional module and sub functional module
4	System operation button	Start, pause and stop buttons
5	Instrument status display	Including instrument real-time status and LIS connection status

## 4.1 System status and control

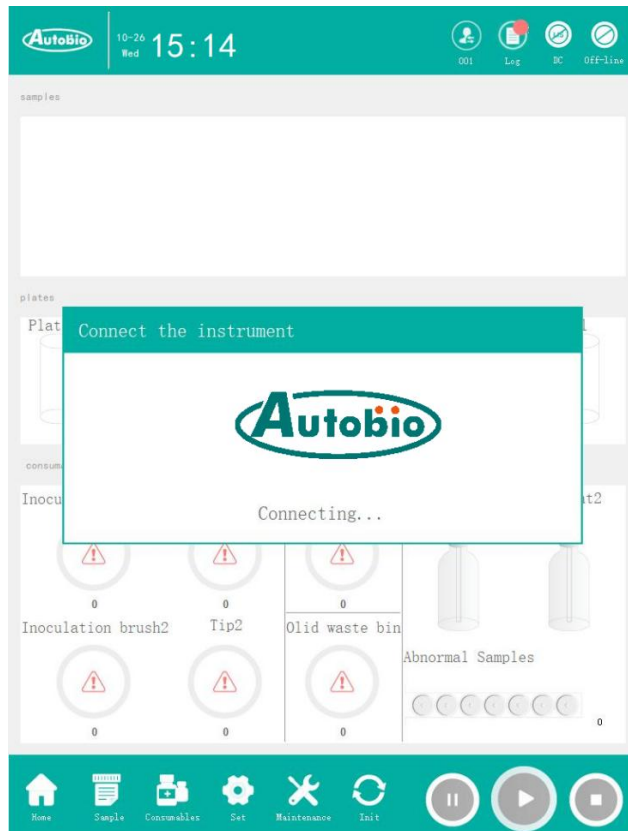
### 4.1.1 System login

When the system starts, the login module pops up on the top level, as shown in the following figure:



## 4.1.2 Connect the instrument

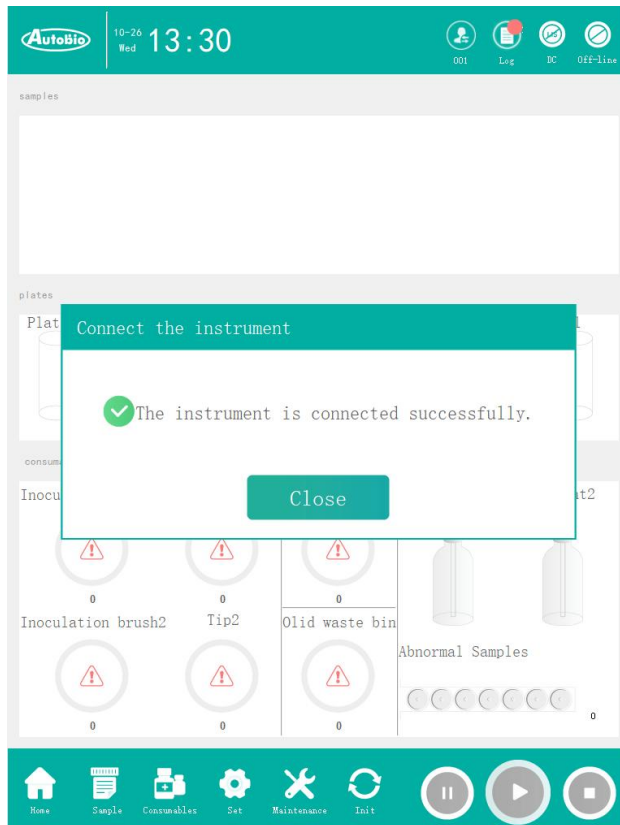
After logging in to the main interface, the Connect Instrument window will pop up automatically to connect the instrument. The interface for connecting the instrument is shown in the figure below:



After the instrument is connected, the current operation status of the instrument will be displayed on the main interface. The instrument status includes offline, not-ready, ready, running, and suspended. Each status reflects the current working condition of the instrument, and the user judges the operation according to the displayed status.

After the equipment status changes, the operation buttons on the main interface will change accordingly according to different statuses.

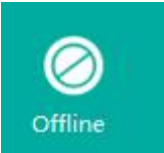
The successful connection between the system and the instrument is shown in the figure below:







### 4.1.3 Status prompt

After the instrument is connected, the current operation status of the instrument will be displayed on the main interface. The instrument status includes offline, not-ready, ready, running, and suspended. Each status reflects the current working condition of the instrument, and the user judges the operation according to the displayed status.



The system status list and description are shown in the following table:







System status	Description
	<p>Offline status:</p> <p>The status of the controller when it is not connected or disconnected from the client. If the network is abnormal, it will enter the offline status.</p>

 <p>Not ready</p>	<p>Not-ready status:</p> <p>The network connection between the controller and the client has been established, but the controller has not reset the motor, so the task cannot be started.</p>
 <p>Ready</p>	<p>Ready status:</p> <p>The system has established a network connection with the instrument, and the instrument has been reset. The task can be started at any time.</p>
 <p>Running</p>	<p>Running status:</p> <p>The instrument is executing the task issued by the client. The task is suspended due to an exception.</p>
 <p>Pause</p>	<p>Pause status:</p> <p>When the client actively pauses or executes a task, the instrument will enter the pause status if it is abnormal.</p>

#### 4.1.4 System shortcut button

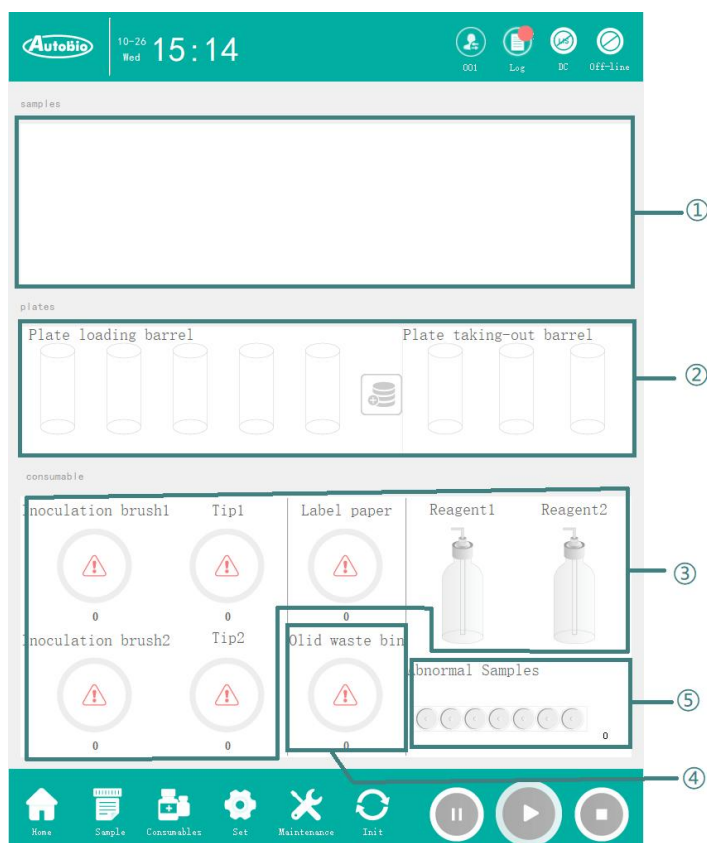
The system has 8 shortcut command buttons, which are Home Page, Sample Allocation, Consumables, Settings, Maintenance, Overall Initialization, User Switching, and Log. Select a button to view the related interface.

Shortcut buttons	Description
 <p>Home</p>	<p>On the homepage, you can view the real-time processing progress of the samples, the type and status of the plates loaded into the plate barrels, the incubation type and status of the plates loaded out, all the consumables information, and the status of the discarded boxes and samples.</p>
 <p>Sample allocation</p>	<p>The main purpose of sample allocation is to add test information of samples and print barcode information of samples.</p>

 <p>consumable</p>	<p>The main function of consumables is to replace consumables, including replacing the Tip and inoculation brush that need to push out the tray, replacing the label paper, cleaning the waste box, and adding digestive juice.</p>
 <p>Setting</p>	<p>The setting interface mainly includes system settings and instrument component parameter settings, including panel group settings, plate barrel settings, sensor KB value settings, marking reference line settings, fan settings, etc.</p>
 <p>Maintenanc</p>	<p>Maintenance mainly includes daily cleaning and daily maintenance of instruments, monomer adjustment, sensor list display, motor parameter modification, database backup and recovery, log cleaning, etc.</p>
 <p>Overall Initiatio</p>	<p>Overall initialization is the necessary processing before the instrument starts to test the samples, including database initialization, instrument connection, LIS connection, data inspection and repair, sending system parameters, sample rack discharge, and instrument reset.</p>
	<p>Switching users can switch users who use the instrument.</p>
	<p>Log is used for viewing the system use information in the corresponding time, the log generated by the instrument operation, the user's operation information, etc.</p>

## 4.2 Homepage


The homepage module includes the sample progress display of the current test, the information display of the currently loaded plate barrel and the loaded plate barrel, and the quantity display of various types of consumables. The homepage interface is shown as follows:



No.	Name of corresponding area	Function introduction
1	Sample status area	Display sample weight, current sample barcode, progress and corresponding step name
2	Plate barrel status area	Loading plate barrel status and plate type name, loading out plate barrel status and incubation type name
3	Consumable status area	Inoculation brush, tip, label paper, reagent
4	Waste box status area	Status of waste box
5	Abnormal sample area	Number of abnormal samples

### 4.2.1 Sample status area

The sample status area can display up to 7 sample details in the instrument at the same time. After the sample rack is injected, the instrument first scans the barcode on the sampling cup to obtain test information. If the test information is normal, weigh it, and the sample details will display different sampling cups according to different sample weights. Whenever a sample changes its status, the sample status area is updated to display the corresponding samples in sequence according to the injection sequence, the sample barcode number, the current progress and the corresponding progress name.



No.	Name	Function introduction
1	Progress	Sample injection, weighing, mixing, inoculation, completion
2	sample size From left to right: 1g-3g 3g-6g 6g-9g 9g-12g 12g-15g	

### 4.2.2 Plate barrel status area

The plate barrel status area contains the status of loading and loading-out plate barrels.




There are 5 loading plate barrels, corresponding to the detailed information of the 5 plate barrels on the left side of the display instrument, including the plate type of each barrel and the status of the number of plates in the barrel. There are three loading plate barrels, corresponding to the three plate barrels on the right side of the display instrument, including the incubation type of each barrel and the status of the number of plates in the barrel.

No.	Name	Function introduction
1	Bottom information of plate barrels	Loading plate barrel: plate type abbreviation Loading-out plate barrel: incubation type abbreviation


<p>2</p>	<p>Status of number of loading plate barrels Corresponding to (taken out, normal, few, none)</p>	
<p>3</p>	<p>Status of number of loading-out plate barrels Corresponding to (taken out, normal, excessive, full)</p>	

### 4.2.3 Consumables status area

The consumables status area includes four types: inoculation brush, Tip, label paper and reagent.

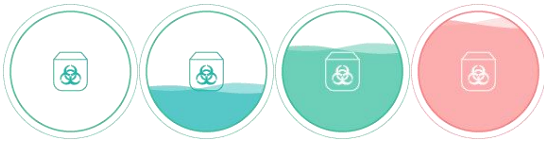
No.	Name	Function introduction
<p>1</p>	<p>Inoculation brush (unknown, normal, few, alert)</p>	
<p>2</p>	<p>Tip (unknown, normal, few, alert)</p>	
<p>3</p>	<p>Label paper (unknown, normal, few, alert)</p>	



4	Reagent (unknown, normal, few, alert)	
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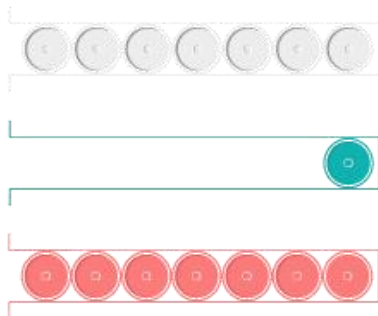
#### 4.2.4 Status of waste box

There are four statuses of waste boxes: empty, few, many and full. The display icons of each status in the system are shown in the following table.

No.	Name	Function introduction
1	Waste box (empty, few, many, full)	

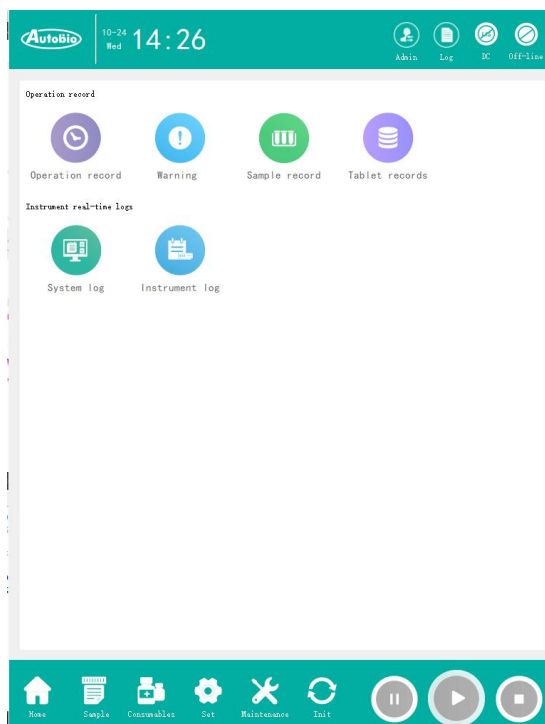
#### 4.2.5 Abnormal sample area

Abnormal samples are discharged due to abnormality during the test of the instrument, and the interface displays the number of abnormal samples.

No.	Name	Function introduction
1	Abnormal samples (empty, 1, 7)	

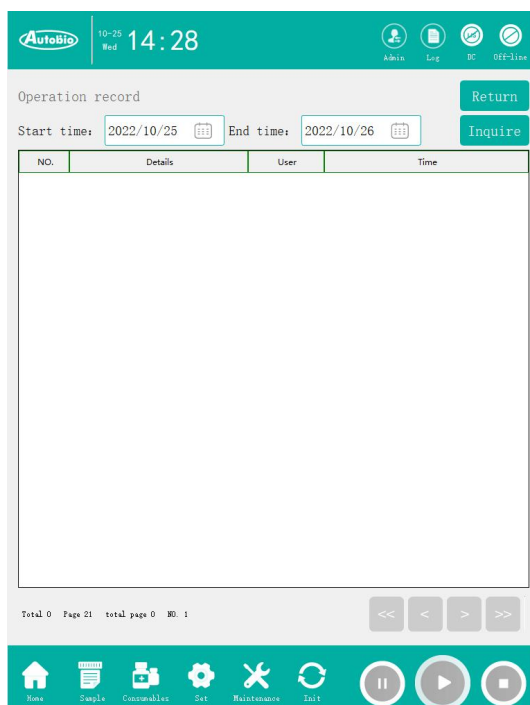
### 4.3 Log

The log module, as shown in the figure below, contains three functions: operation record, warning information and sample record.



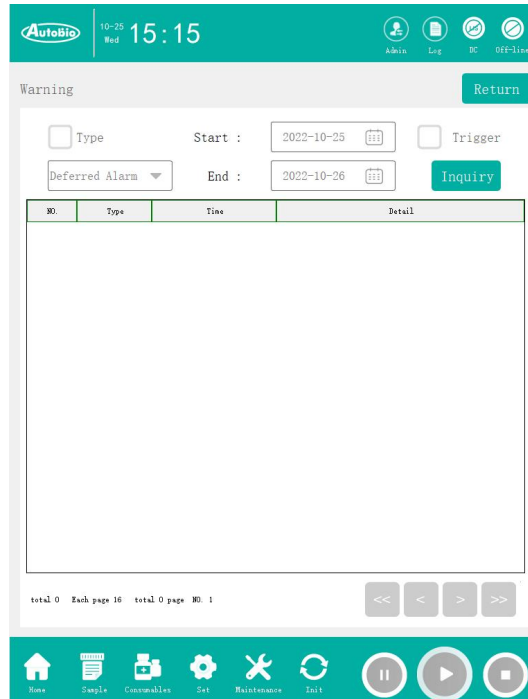
### 4.3.1 Operation record

The operation record is shown in the following figure. It's the operation record information of the main user.



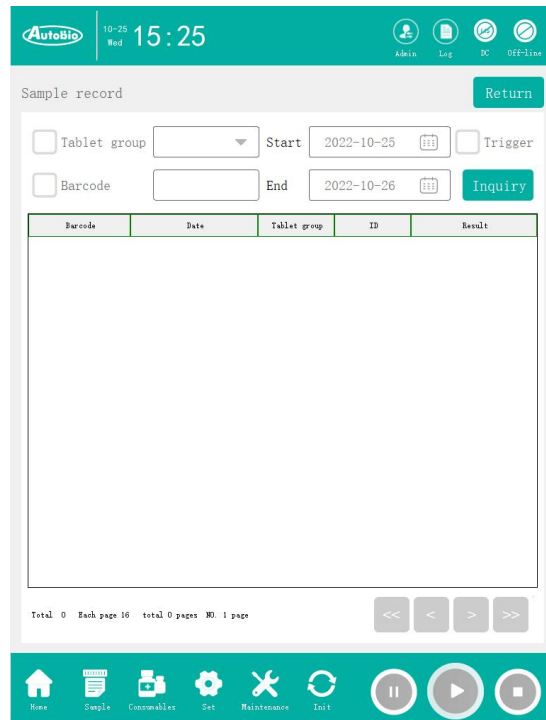
### 4.3.2 Warning message

The warning information mainly records the general warning, serious warning, fault and other information fed back by the instrument.



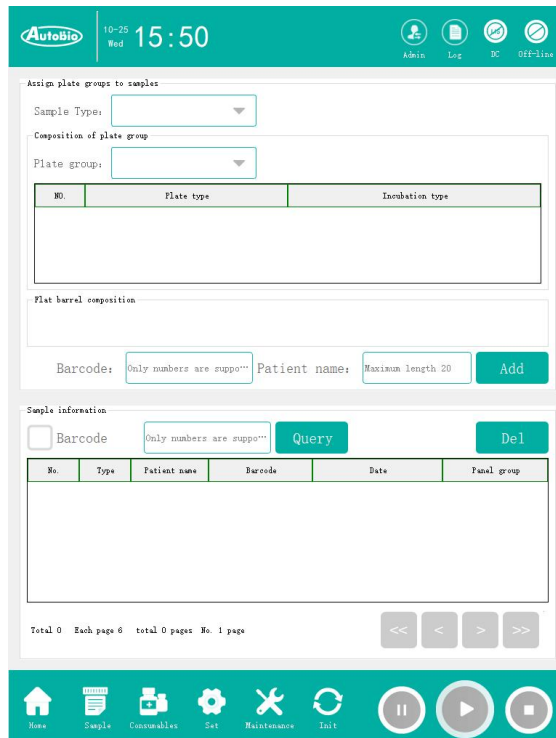
### 4.3.3 Sample record

The sample record is shown in the figure below, which mainly displays the sample information of the test conducted by the current instrument, and can intuitively feedback the time when the sample was tested and the test results.



## 4.4 Sample allocation

The main function of the sample allocation module is to allocate tests for user-defined barcodes and barcodes without test information. Click the panel group drop-down button to display all test items in the test list in the database, and click the panel type drop-down button to display all panel items in the panel type table in the database. All the allocated sample information is stored in the sample information data table and displayed in the sample allocation interface in order. The sample allocation interface is shown below:



Manual input: input the barcode manually at the sample barcode input control, select the panel group and panel type, and click the Add button to save the test information into the database.

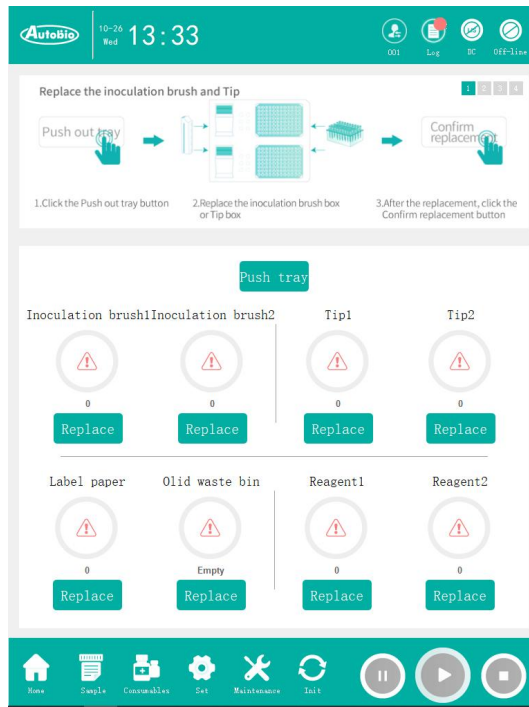
Handheld barcode scanner: Length of the barcode scanner cable: < 3m.

Use the hand-held barcode scanner to scan the sample with barcode attached, select the panel group and panel type, click the Add button, and store the test information in the database.

Note: The minimum amount of non-sputum samples shall not be less than 500  $\mu$  L. Otherwise, the instrument may not be inoculated normally.

## 4.5 Consumables

The consumables module interface is shown in the figure below. It is an interface for users to display the current consumables quantity information and replace consumables. Tip, inoculation brush, label paper, waste box and digestive juice can be replaced.

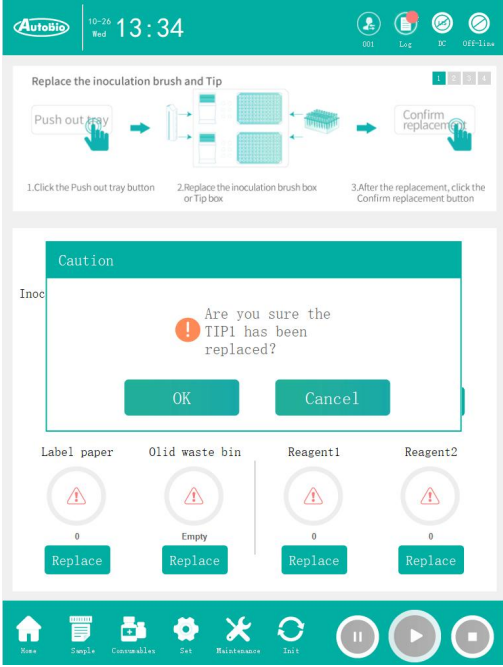
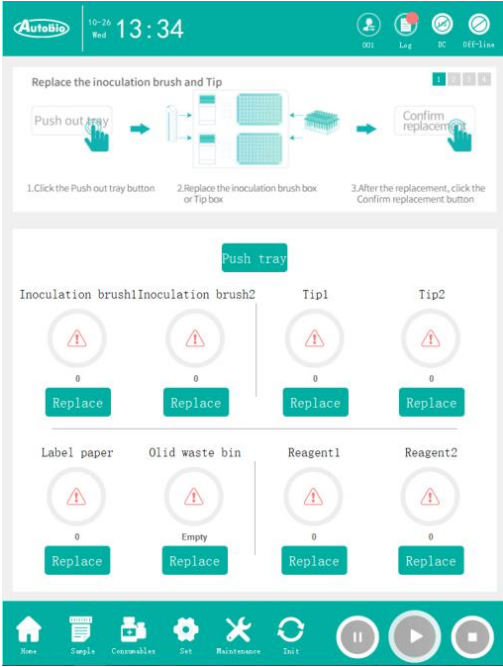


### 4.5.1 Replace the inoculation brush and Tip

The replacement steps of inoculation brush and Tip are as follows:

No.	Corresponding instrument position	Description
1		<p>After the instrument is initialized, the tray can be pushed out.</p> <p>After the tray is pushed out, the button for replacing the inoculation brush and Tip becomes clickable.</p> <p>Click the button to replace Tip Box I, and the barcode scanning box will pop up.</p>

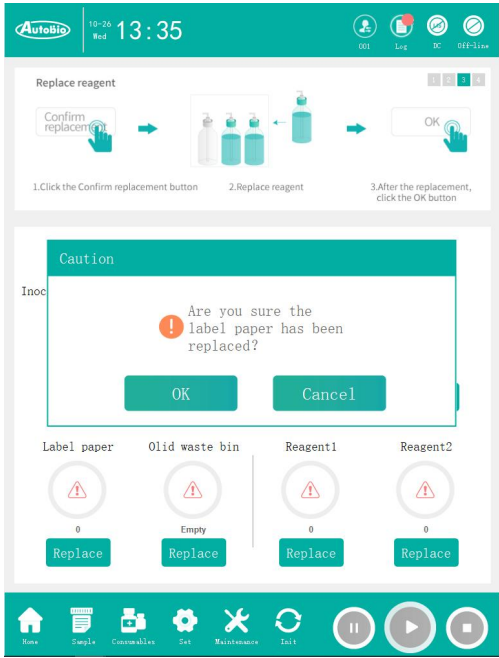
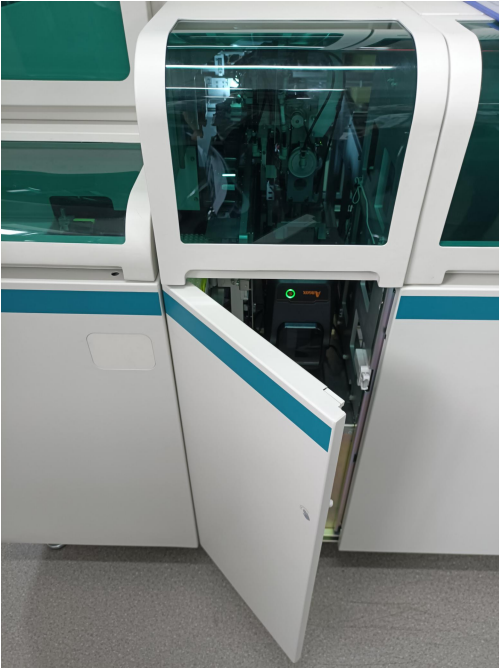
<p>2</p>		<p>Open the instrument cabinet door.</p>
<p>3</p>		<p>After the tray is pushed out, the corresponding positions of the inoculation brush (left) and Tip (right) can be seen.</p> <p>Take out the used inoculation brush box or Tip box.</p> <p>Unpack new consumables.</p> <p>Put new consumables into the instrument.</p>

<p>4</p>		<p>Select the button corresponding to the consumables placed in the corresponding position (if it is a Tip, the pop-up window will display as shown in the figure).</p> <p>Click OK to replace.</p>
<p>5</p>		<p>Click the Enter Tray button, and the instrument will send the replaced consumables.</p> <p>After the tray is fed in, the button for replacing the inoculation brush and Tip becomes non-clickable.</p>

### 4.5.2 Replace label paper

The replacement steps of label paper are as follows:



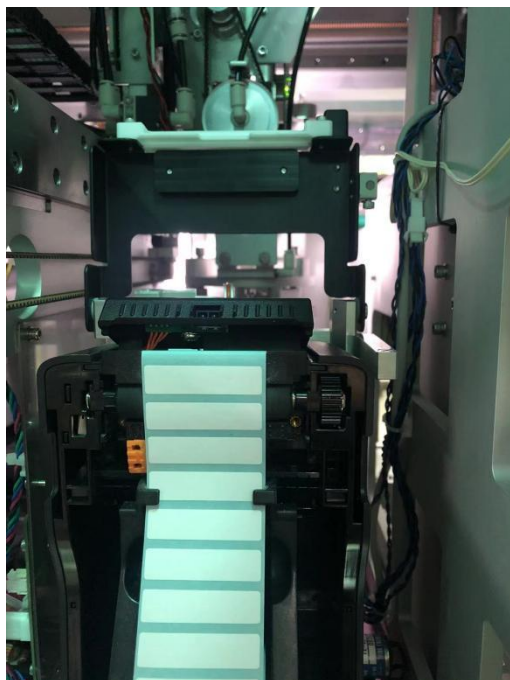
No.	Corresponding instrument position	Description
1		<p>Click the button to replace the label paper, and the prompt box to confirm the replacement of the label paper pops up.</p>
2		<p>Open the instrument cabinet door and turn off the printer power switch (on the right side of the rear end of the printer).</p>

3

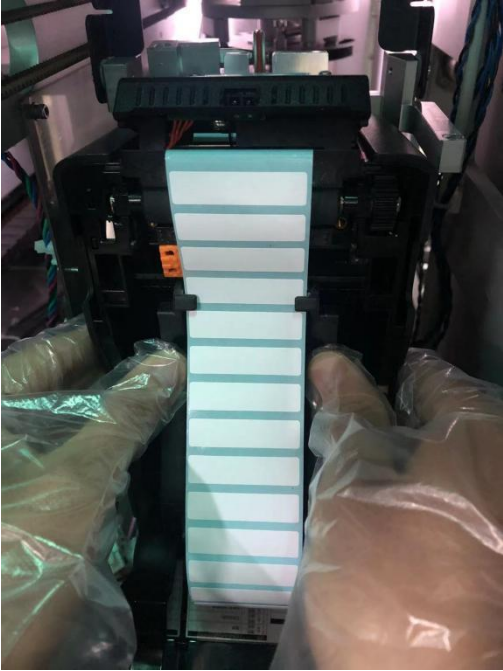




Place both hands on the orange buttons on the left and right sides of the printer, pull up the buckle of the orange button cover, and open the front cover of the printer.

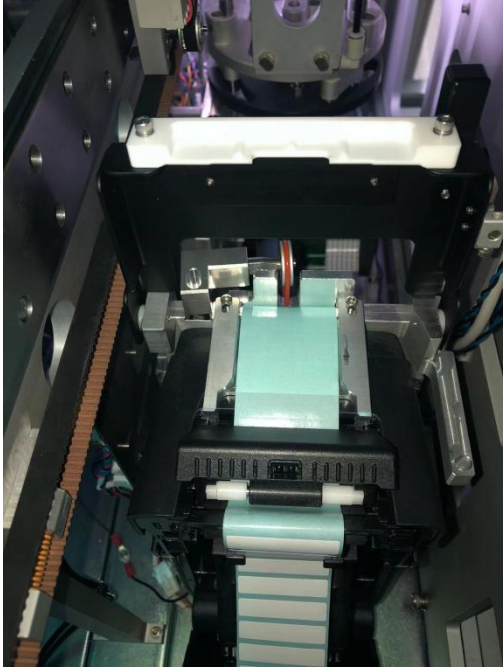

4

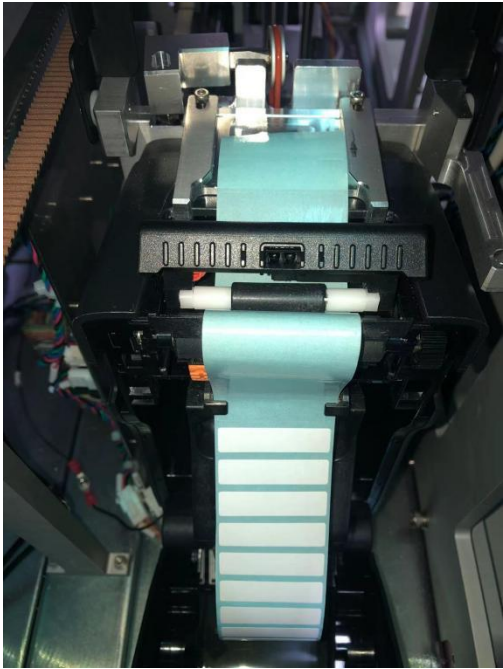
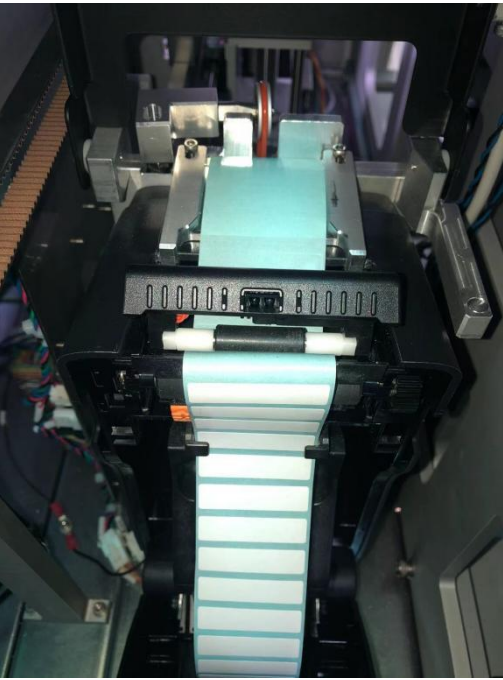




Open the label interaction board and the stripper on the upper side of the printer upward.



<p>5</p>		<p>Pull the paper roll support to both sides and take out the used label paper roll.</p>
<p>6</p>		<p>Take out a new roll of label paper and tear off the identification label of the roll.</p> <p>Please remove the first 10 labels of the paper roll and ensure that the distance from the open end of the bottom paper to the first label (this length is critical) is 130mm-143mm.</p> <p>If you need to tear the blue backing paper from the middle, you need to ensure that:</p> <ol style="list-style-type: none"> <li>1. Tearing joint shall be straight without obvious burr;</li> <li>2. The distance from the open end of waste</li> </ol>

		<p>paper to the first label (this length is critical) is 130mm-143mm (about the length of 10 labels torn off).</p> <p>Note: When tearing the label, make sure that the blue backing paper has no obvious creases.</p>
7		<p>Pull the paper roll support bracket to both sides, put the label paper into the bracket, and confirm that the side to be printed faces up and the paper roll support bracket that bounces back is firmly attached to the paper roll.</p>

<p>8</p>		<p>After the length of the blue background paper is confirmed, the part of the blue background paper without label passes through 1. The guide bayonet in the printer; 2. Roller at the lower side of the paper stripper; 3. Finally enter the paper take-up guide system.</p>
<p>9</p>		<p>Refer to Clause 8 in detail: 1. Go through the guide bayonet in the printer.</p>

10		<p>Refer to Clause 8 in detail: 2. The roller passing through the lower side of the paper stripper.</p>
11		<p>Refer to Clause 8 in detail: 3. Finally enter the paper take-up guide system.</p>

<p>12</p>		<p>The length of the blue backing paper is as shown in the figure, the label just reaches the position shown in the figure, and the label needs to be parallel to the paper stripper.</p>
<p>13</p>		<p>Sequence: close the upper paper stripper from top to bottom, and close the front cover of the printer from front to back.</p>

14		<p>Close the label interaction board from top to bottom.</p>
15		<p>After confirming that the replacement is completed, turn on the printer power switch (on the right side of the rear end of the printer), click the paper feed button to execute the label paper self-inspection. At this time, a blank label is exported. Please remove the label and close the instrument cabinet door.</p>

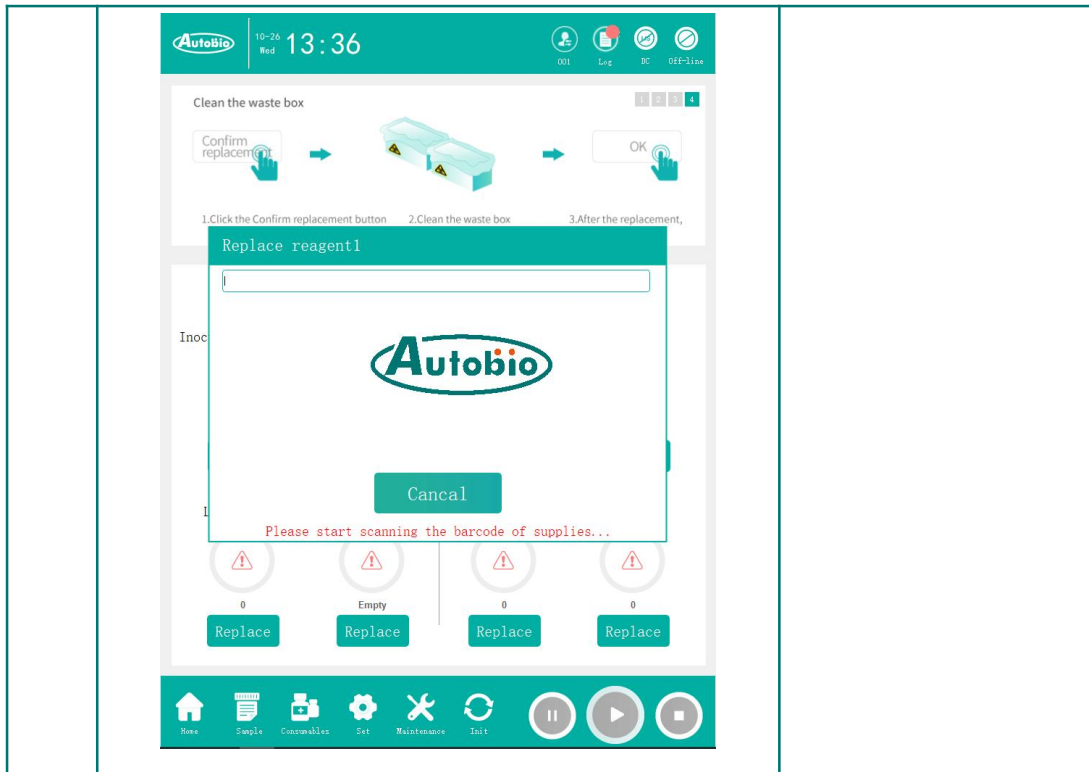


16		<p>Click the Confirm button to complete the replacement of consumables and refresh the quantity.</p>
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### 4.5.3 Replace reagent

Reagent replacement steps are as follows:

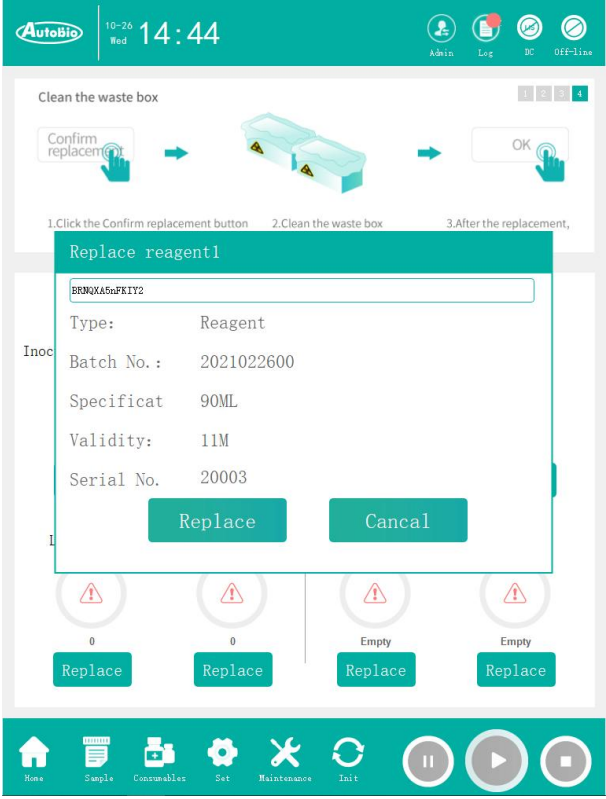
No.	Corresponding instrument position	Description
1		Click the reagent replacement button, and a prompt box for reagent replacement confirmation pops up.



2

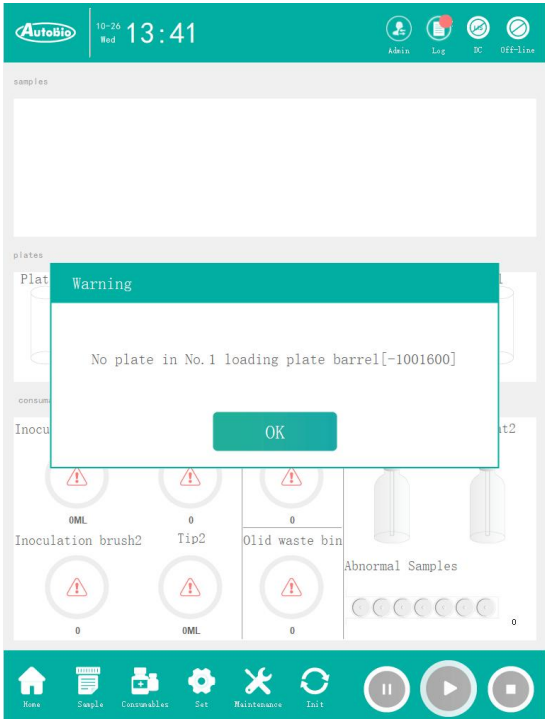
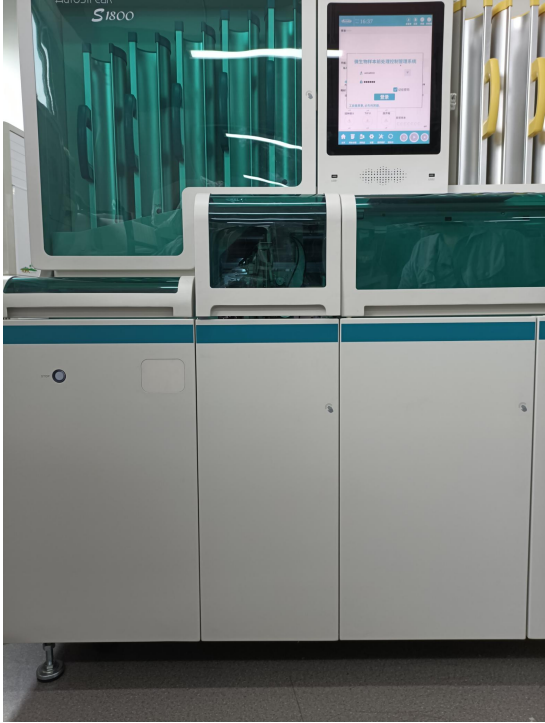


Find the handle of the reagent storage position on the right side of the instrument.

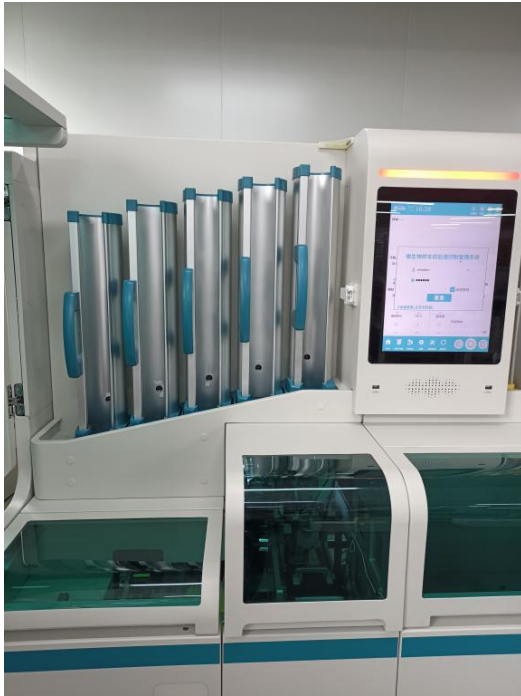
<p>3</p>		<p>Extract out the instrument cabinet door and replace the reagent at the corresponding position.</p>
<p>4</p>		<p>Click the Confirm button to complete the replacement of consumables and refresh the quantity.</p> <p>Note: Before the initialization of the complete machine, it is necessary to confirm whether the reagent margin in the reagent bottle is sufficient. If the margin is insufficient, it is necessary to replace a new reagent before initialization.</p>

### 4.5.4 Add plate

The steps to add a plate are as follows:

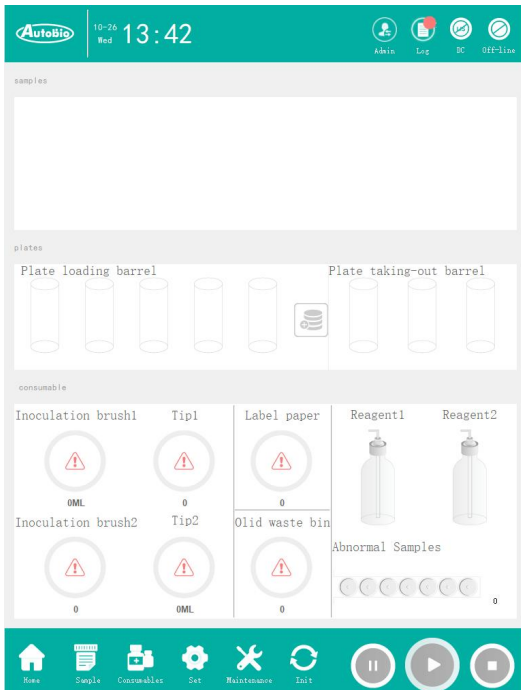
No.	Corresponding instrument position	Description
1		<p>When the instrument is running, it is detected that there is no plate in No. 1 loading plate barrel, and the pop-up window as shown in the figure is displayed.</p>
2		<p>Open the cabinet door in the loading plate barrel area on the left side of the instrument.</p>

3



The cabinet door is opened as shown in the figure (note: the agar plate is on the top).

4



Click the button to replace the plate in the home page, and the pop-up window to replace the plate pops up.

<p>5</p>		<p>Use a hand-held barcode scanner to scan the barcode on the consumables package. The interface displays the type and number of plates. Unpack the consumables and put them into the corresponding type of plate barrel.</p>
<p>6</p>		<p>Note 1: When replacing the plate, keep the agar side up and do not put it upside down.</p> <p>Note 2: Please place the corresponding type of plate in the plate set by the instrument. If the placement is wrong, the experimental results may be affected.</p>

7

After scanning the code successfully, the panel details and confirmation button will be displayed.

Click the Confirm button to complete the replacement.

### 4.5.5 Clean the waste box

The steps of waste box cleaning are as follows:

No.	Corresponding instrument position	Description
1		Click the button to clear the waste box, and a prompt box to confirm the cleaning will pop up

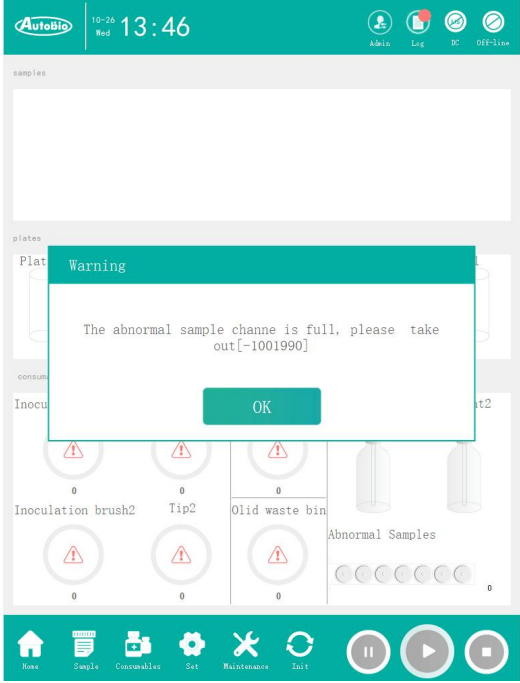

		
<p>2</p>		<p>Open the instrument cabinet door, extract the waste box and dispose the waste.          Note: Discarded consumables pose a risk of biosafety hazards, please handle with caution.</p>


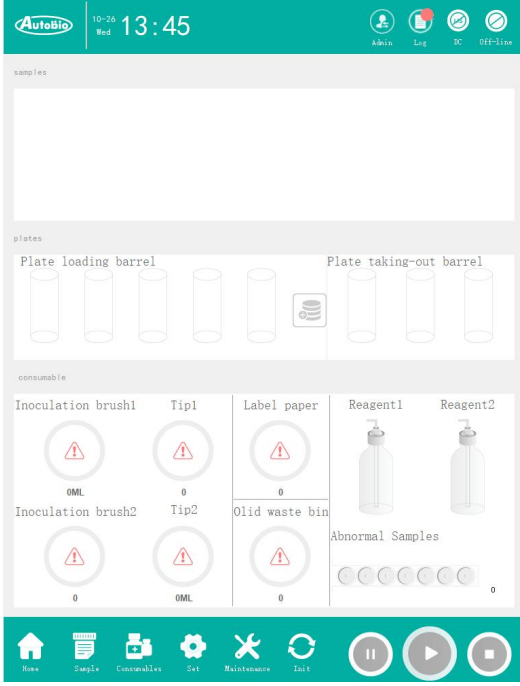


<p>3</p>		<p>After disposing the waste, put the waste box back in place, push it into the instrument, and close the cabinet door.</p>
<p>4</p>		<p>Click the Confirm button to complete the cleaning and refresh the status of discarded containers.</p>

### 4.5.6 Take out abnormal samples

Steps for taking out abnormal samples are as follows:

No.	Corresponding instrument position	Description
1		<p>When the number of abnormal samples in the abnormal sample channel is full, the system will pop up a window to prompt.</p>
2		<p>Open the instrument cabinet door and find the handle of the abnormal sample channel.</p>

<p>3</p>		<p>Draw out the abnormal sample channel, push the channel into the instrument after taking out the abnormal sample, and close the cabinet door.</p>
<p>4</p>		<p>After the exception sample is taken out, the exception sample status is refreshed.</p> <p>Note: The state of the abnormal sample channel will change during extraction. Please be sure to take out the abnormal sample.</p>

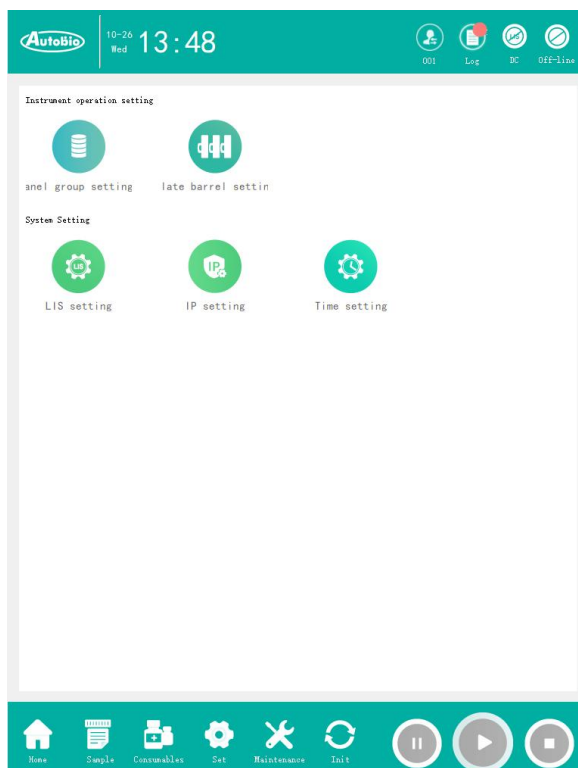
## 4.6 Settings

Interface of setting module, including instrument operation setting, system setting and

other modules.

The user can modify the system parameters by the setting module to ensure the normal operation of the instrument.

The setting module interface is shown below:

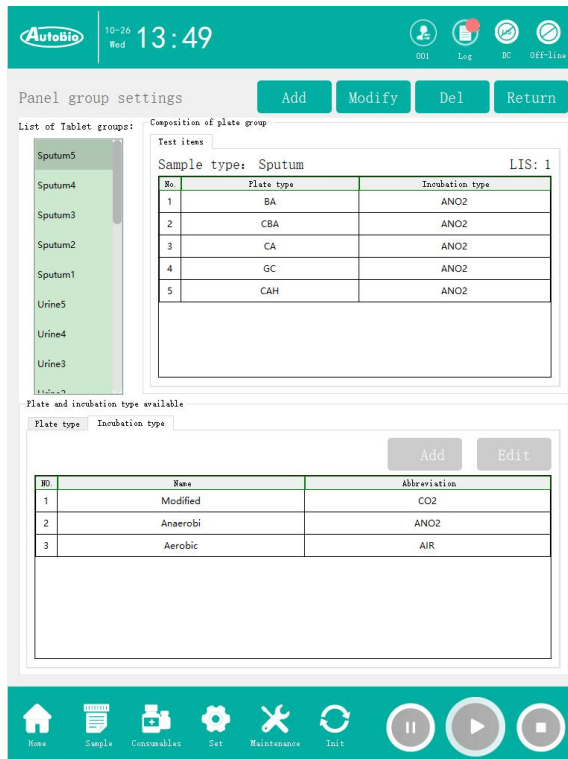


The instrument operation setting has two functions: panel group setting and plate barrel setting.

System settings include instrument IP settings, LIS settings, time settings, and concerning.

### 4.6.1 Panel group settings

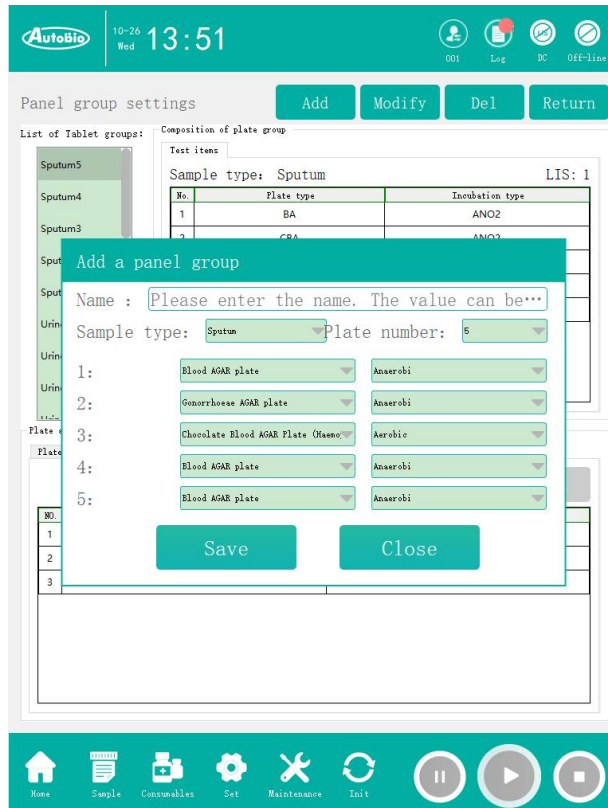
The panel group setting is shown in the figure below, which is used to set the test information of the sample. Including the type of plate to be inoculated for the sample, and the incubation type corresponding to the plate after inoculation. It also includes adding and deleting available plate types and incubation types.



When adding a panel group, the window for adding a panel group as shown below pops up:



When modifying the panel group, the window to modify the panel group as shown in the following figure pops up:

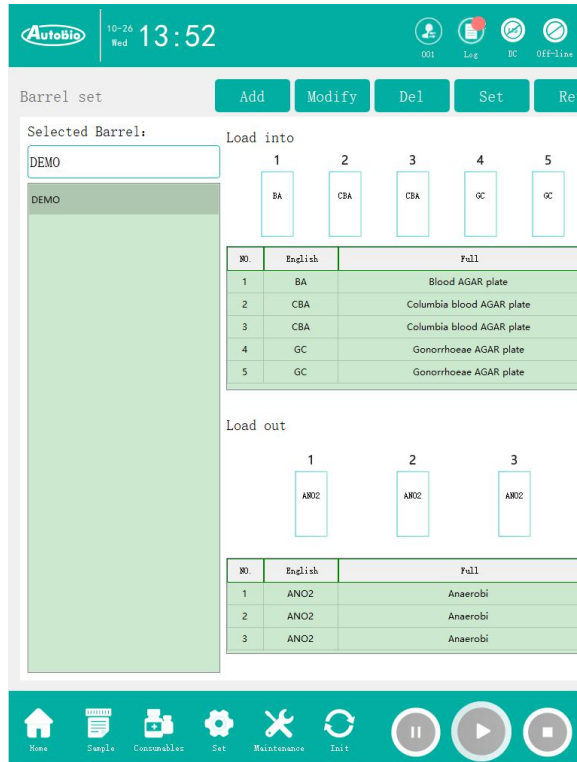


## 4.6.2 Plate barrel setting

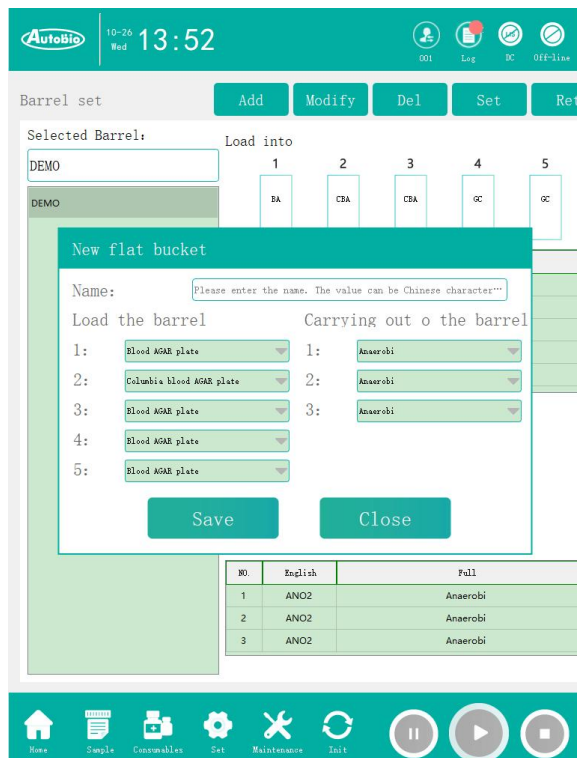
The plate barrel setting is shown in the figure below, which is the setting window for setting the plate type loaded into the plate barrel and the incubation type loaded out of the plate barrel. Users can add, modify and delete plate barrel settings, and each operation will save the results to the database.

Click the Set to System button, and the system will send the setting result to the instrument, informing the instrument of the change of the plate barrel.

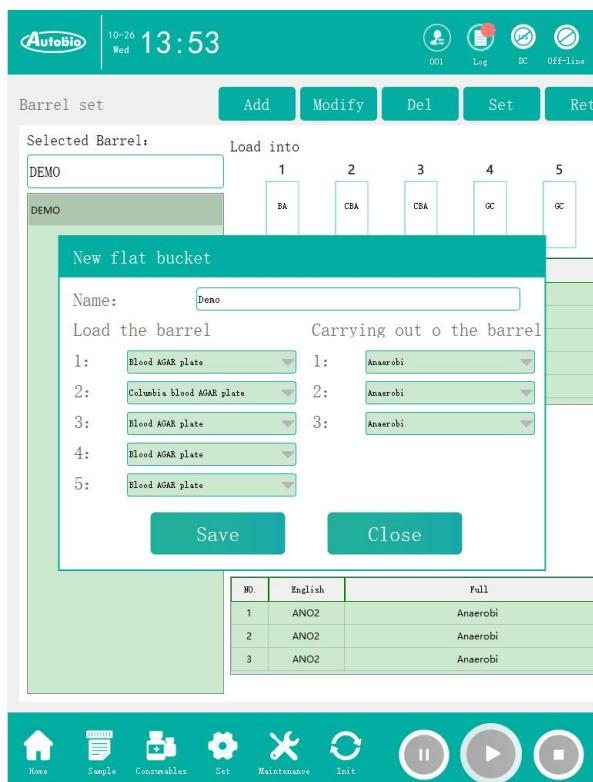
Plate barrel set to the system cannot be modified or deleted.



When adding plate barrel, the window of adding plate barrel as shown below pops up:



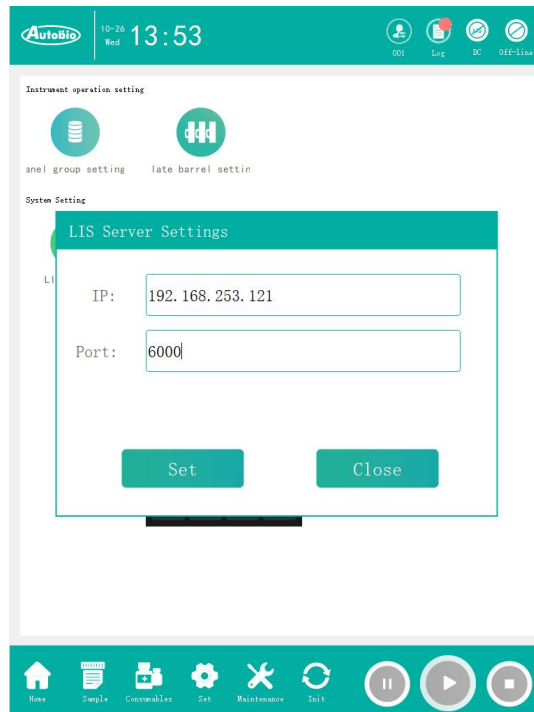
When modifying the plate barrel, the window for modifying the plate barrel as shown below pops up:



### 4.6.3 LIS Server Settings

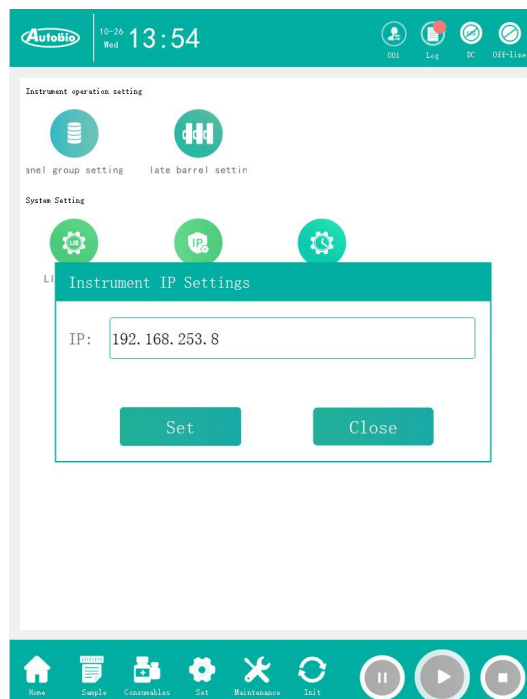
LIS server settings can be used to set the IP and port number of the LIS server to which the system is connected. The interface is shown below:





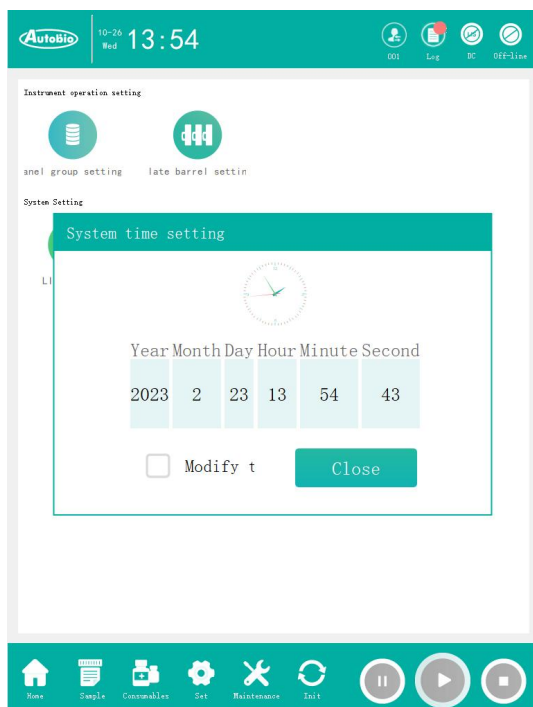
#### 4.6.4 Instrument IP Settings

Instrument IP setting can set the IP of the instrument connected to the system, and the interface is shown as follows:



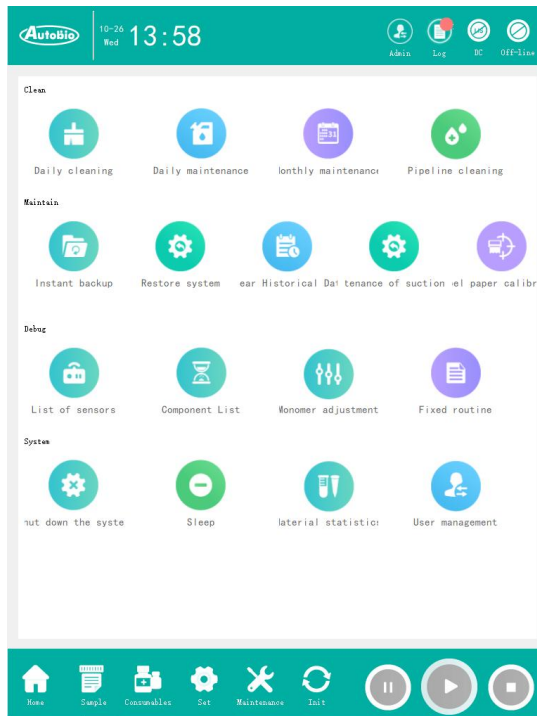
## 4.6.5 System time setting

The system time setting can be used to set the current time of the system. The interface is shown in the following figure:



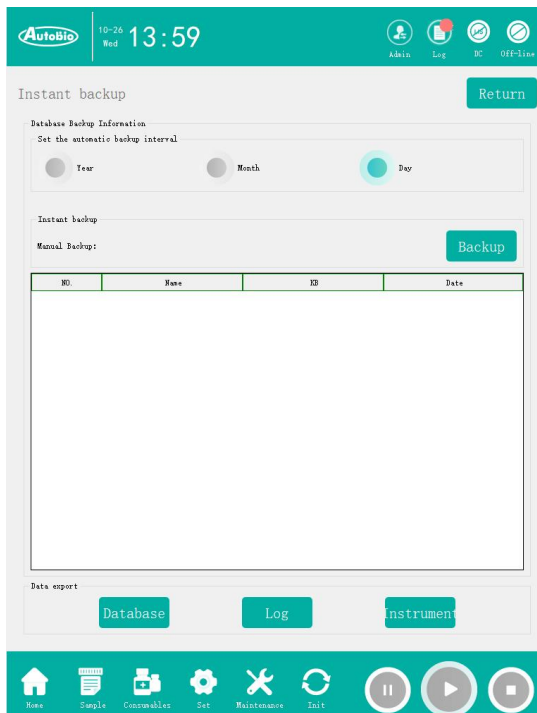
## 4.7 Maintenance

Maintenance mainly involves the restoration and backup of instruments, as well as cleaning, maintenance management. The maintenance interface is shown below:



### 4.7.1 Instant backup

Instant backup is shown in the figure below, including three functions: display of database backup information, automatic backup interval setting, and manual backup.



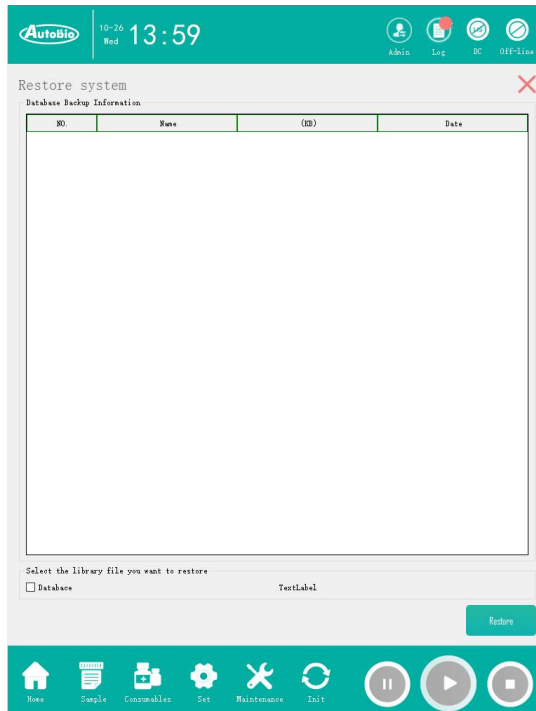
The database backup information shows the user the serial number, name, file size and file date of the database backup. The backup database can be used to recover data.

The automatic backup interval setting is used to tell the user the current automatic backup interval, which can be set by the user. It is divided into three levels: year, month, and day.

Manual backup is used to immediately back up the database. If a backup record already exists on that day, it will delete and back up the database again.

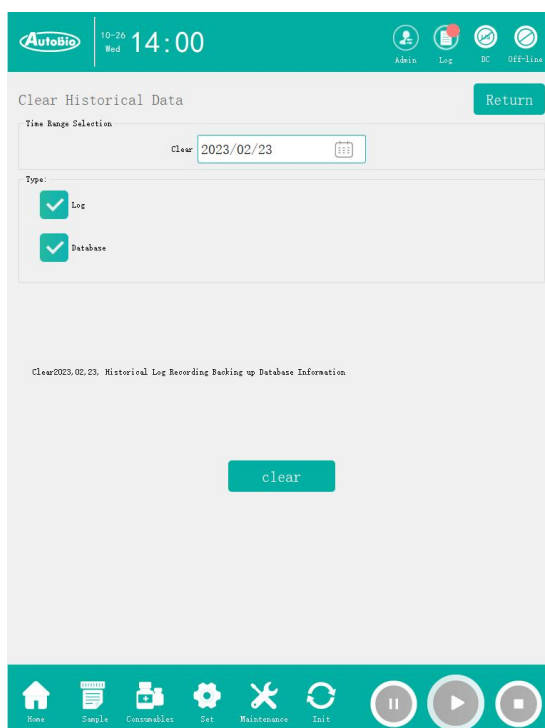
## 4.7.2 Restore system

The interface shown in the following figure is the function of system restoring, which can restore the database files of the system.



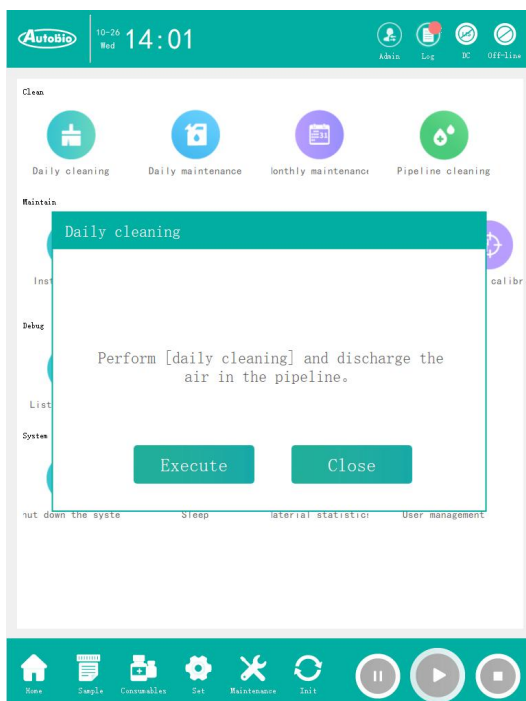
## 4.7.3 Clear Historical Data

To clear historical data, you can select to clear log information and database backup information before a certain date.



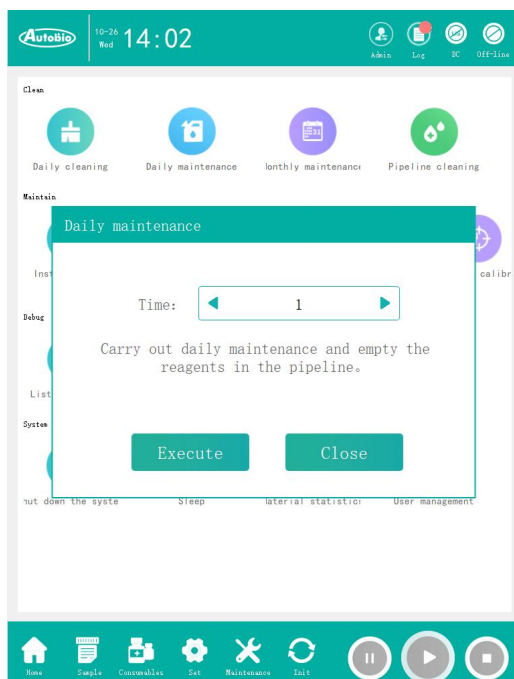
#### 4.7.4 Daily cleaning

The daily cleaning function is as shown in the figure below. Click Execute "daily cleaning" before the experiment starts, and the instrument will empty the air in the pipeline (the instrument will automatically execute without manual operation. Daily maintenance is required before manual daily cleaning, otherwise repeated daily cleaning will lead to reagent overflow, causing serious risks such as short circuit of the instrument).



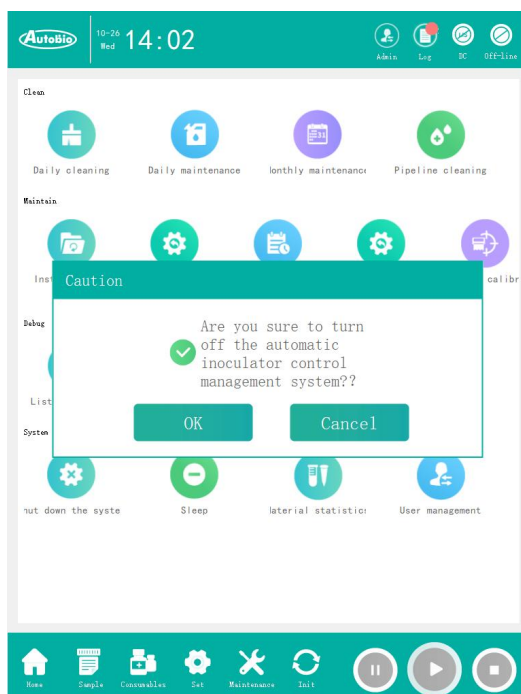
### 4.7.5 Daily maintenance

The daily maintenance function is as shown in the figure. After the experiment, execute the "Daily maintenance", and the instrument will discharge the reagent in the pipeline into the reagent bottle (the instrument will automatically execute without manual operation).



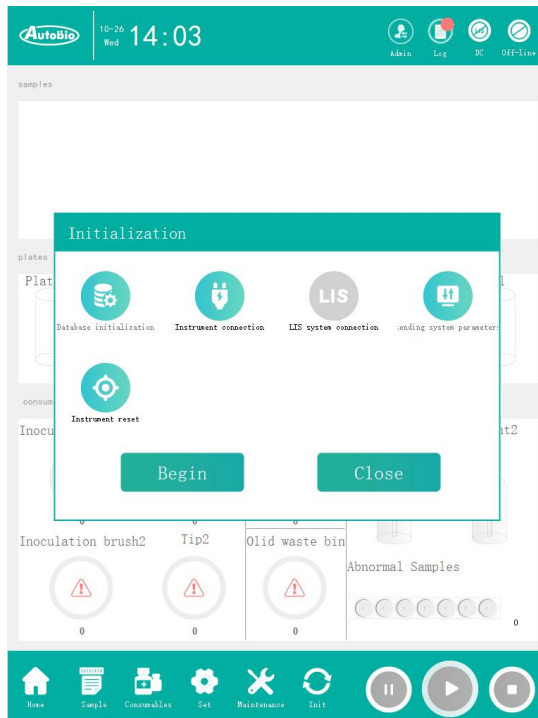
## 4.7.6 Shut down the system

As shown in the figure below, the system closing function needs to be reconfirmed before execution, and a window to confirm the closing will pop up. The database will be backed up automatically before the system is shut down.

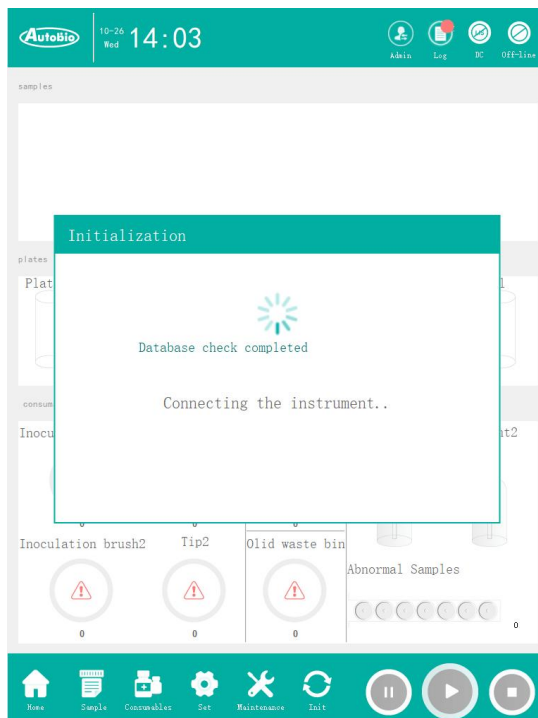


## 4.8 Overall initialization

When users use the instrument, they need to perform overall initialization. The functions selected by default include database initialization, instrument connection, sending system parameters, and instrument reset. The interface is shown in the following figure:

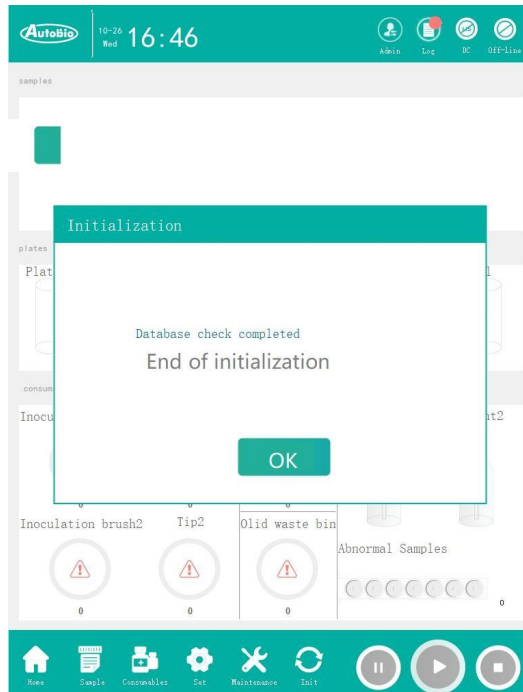


The Send Parameter option is required. Each time an overall initialization operation is performed, system parameters must be sent. Click Start to execute, and the interface is as shown below:





The overall initialization includes six functions: database initialization, instrument connection, LIS system connection, data check and repair, sending system parameters, and instrument reset. During initialization, these functions are executed sequentially. After the instrument is reset, the interface is shown in the figure below. Click the OK button to complete the initialization and start the test.

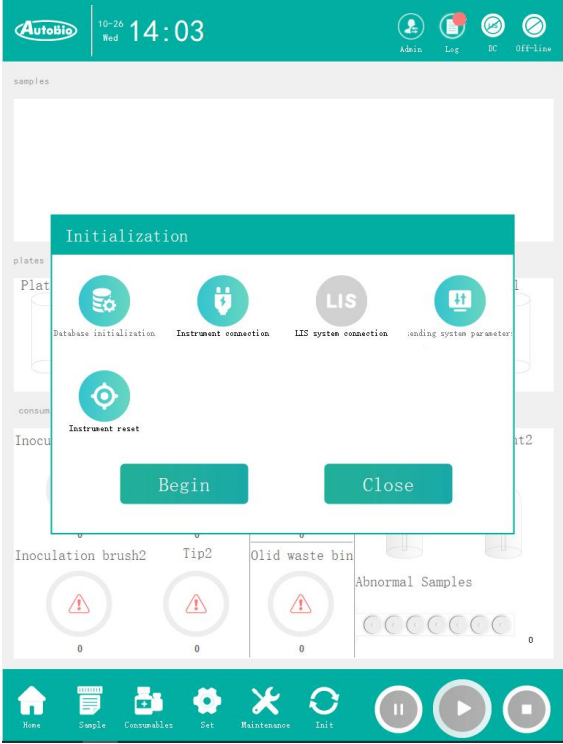


## 5 Test Operation

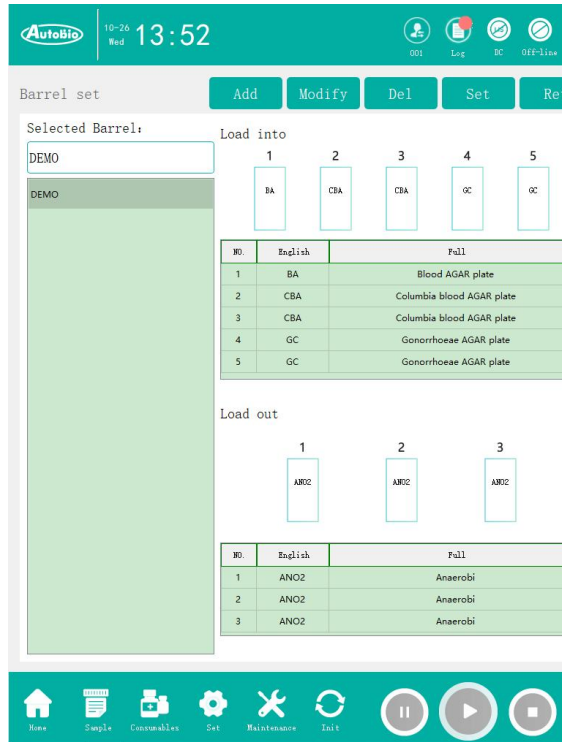
The Automated Striking/processing Control and Manage System supports both local distribution testing and obtaining sample testing information from LIS server, which can be configured according to the actual situation and requirements of the hospital.

### 5.1 Assign sample test information by manual

The flow of manually allocating sample test information is as follows:

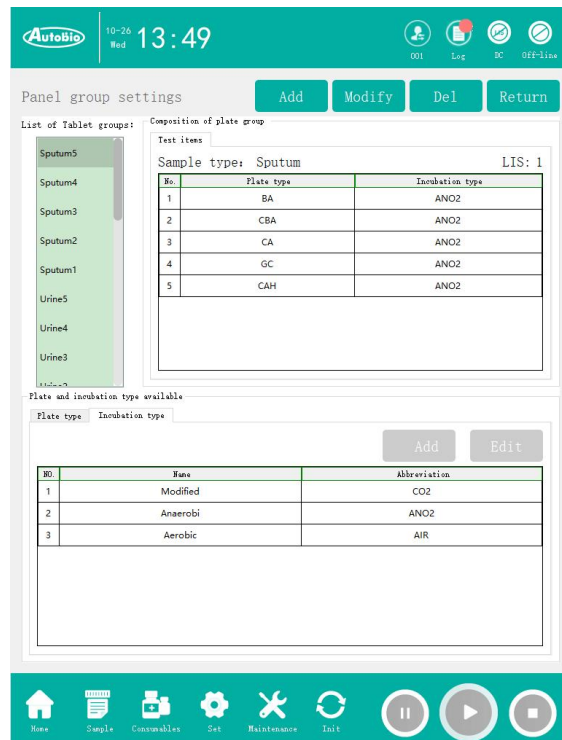
No.	Display	Description
1		<p>Initialize the instrument, and do not select the Connect LIS option during initialization.</p>

2

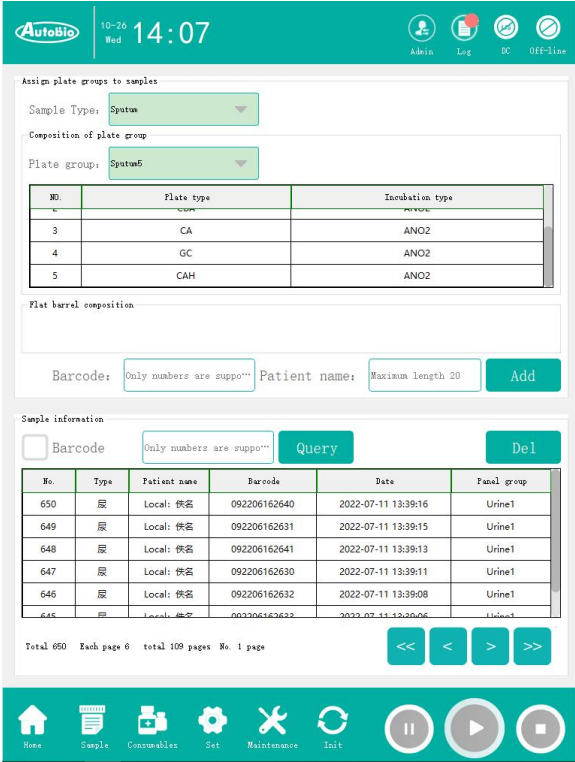


After initialization, check whether the flat barrel setting exists. If not, refer to the chapter “4.6.2 Plate barrel setting”, add a new plate barrel setting and set it to the instrument.

3



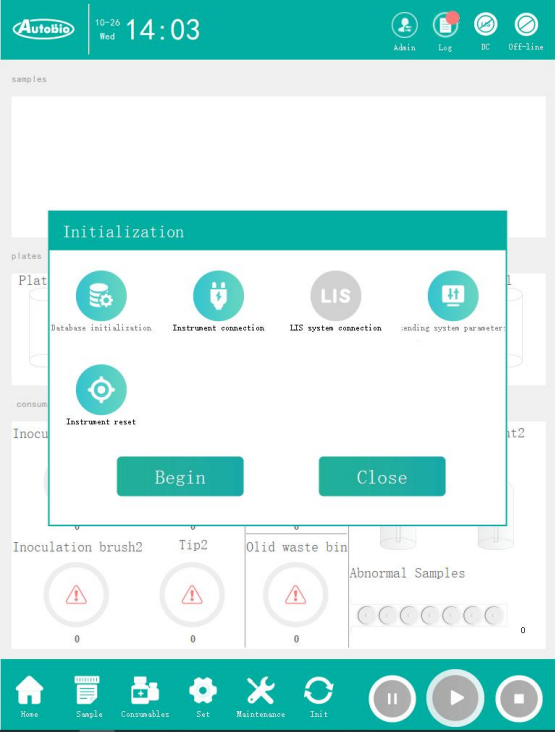
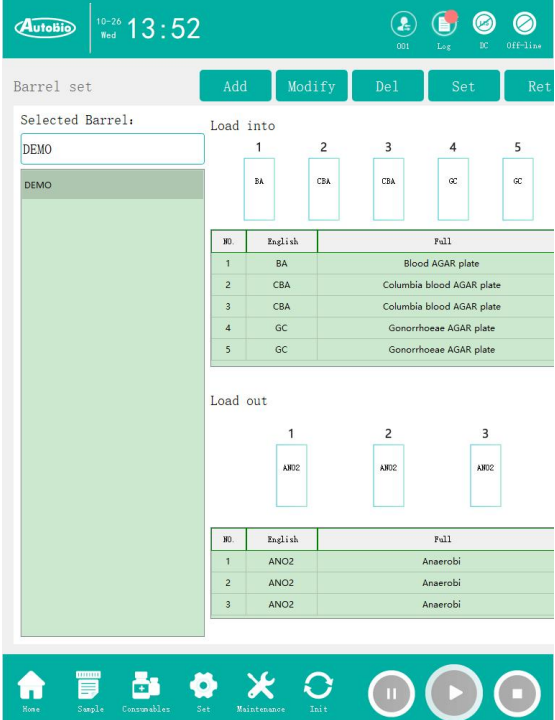
Select Setting - plate group setting function. Refer to the section “4.6.1 Plate group setting” to add a new panel group.

<p>4</p>	 <p>The screenshot shows the 'Assign plate groups to samples' screen. At the top, it displays the date '10-26 Wed' and time '14:07'. Below this are navigation icons for Admin, Log, DC, and OFF-line. The main section is titled 'Assign plate groups to samples' and includes a 'Sample Type' dropdown set to 'Sputum' and a 'Composition of plate group' section with a 'Plate group' dropdown set to 'Sputum5'. A table lists plate types and incubation types:</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Plate type</th> <th>Incubation type</th> </tr> </thead> <tbody> <tr> <td>3</td> <td>CA</td> <td>ANO2</td> </tr> <tr> <td>4</td> <td>GC</td> <td>ANO2</td> </tr> <tr> <td>5</td> <td>CAH</td> <td>ANO2</td> </tr> </tbody> </table> <p>Below the table is a 'Flat barrel composition' section. At the bottom of this section are input fields for 'Barcode' (with a note 'Only numbers are supported'), 'Patient name' (with a note 'Maximum length 20'), and an 'Add' button. The 'Sample information' section below has a 'Barcode' input field, a 'Query' button, and a 'Del' button. A table lists sample information:</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Type</th> <th>Patient name</th> <th>Barcode</th> <th>Date</th> <th>Panel group</th> </tr> </thead> <tbody> <tr> <td>650</td> <td>尿</td> <td>Local: 佚名</td> <td>092206162640</td> <td>2022-07-11 13:39:16</td> <td>Urine1</td> </tr> <tr> <td>649</td> <td>尿</td> <td>Local: 佚名</td> <td>092206162631</td> <td>2022-07-11 13:39:15</td> <td>Urine1</td> </tr> <tr> <td>648</td> <td>尿</td> <td>Local: 佚名</td> <td>092206162641</td> <td>2022-07-11 13:39:13</td> <td>Urine1</td> </tr> <tr> <td>647</td> <td>尿</td> <td>Local: 佚名</td> <td>092206162630</td> <td>2022-07-11 13:39:11</td> <td>Urine1</td> </tr> <tr> <td>646</td> <td>尿</td> <td>Local: 佚名</td> <td>092206162632</td> <td>2022-07-11 13:39:08</td> <td>Urine1</td> </tr> <tr> <td>645</td> <td>尿</td> <td>Local: 佚名</td> <td>092206162622</td> <td>2022-07-11 13:39:06</td> <td>Urine1</td> </tr> </tbody> </table> <p>At the bottom of the screen are navigation icons for Home, Sample, Consumables, Set, Maintenance, and Init, along with control buttons for back, forward, and play/pause.</p>	No.	Plate type	Incubation type	3	CA	ANO2	4	GC	ANO2	5	CAH	ANO2	No.	Type	Patient name	Barcode	Date	Panel group	650	尿	Local: 佚名	092206162640	2022-07-11 13:39:16	Urine1	649	尿	Local: 佚名	092206162631	2022-07-11 13:39:15	Urine1	648	尿	Local: 佚名	092206162641	2022-07-11 13:39:13	Urine1	647	尿	Local: 佚名	092206162630	2022-07-11 13:39:11	Urine1	646	尿	Local: 佚名	092206162632	2022-07-11 13:39:08	Urine1	645	尿	Local: 佚名	092206162622	2022-07-11 13:39:06	Urine1	<p>Select the sample allocation function to allocate test information to the samples to be tested. Use the hand-held barcode scanner to scan the barcode of the sample or manually input the barcode number of the sample, select the panel group and sample type assigned to the sample, and refer to “4.4 Sample Allocation” in chapter to complete the addition of test information.</p>
No.	Plate type	Incubation type																																																						
3	CA	ANO2																																																						
4	GC	ANO2																																																						
5	CAH	ANO2																																																						
No.	Type	Patient name	Barcode	Date	Panel group																																																			
650	尿	Local: 佚名	092206162640	2022-07-11 13:39:16	Urine1																																																			
649	尿	Local: 佚名	092206162631	2022-07-11 13:39:15	Urine1																																																			
648	尿	Local: 佚名	092206162641	2022-07-11 13:39:13	Urine1																																																			
647	尿	Local: 佚名	092206162630	2022-07-11 13:39:11	Urine1																																																			
646	尿	Local: 佚名	092206162632	2022-07-11 13:39:08	Urine1																																																			
645	尿	Local: 佚名	092206162622	2022-07-11 13:39:06	Urine1																																																			
<p>5</p>	<p>Place the sample into the sample rack, and put the sample rack into the sample loading position. Click the Start button to start the test. The sample information is obtained from the local database.</p>	<p>Place the sample into the sample rack, and put the sample rack into the sample loading position. Click the Start button to start the test. The sample information is obtained from the local database.</p>																																																						

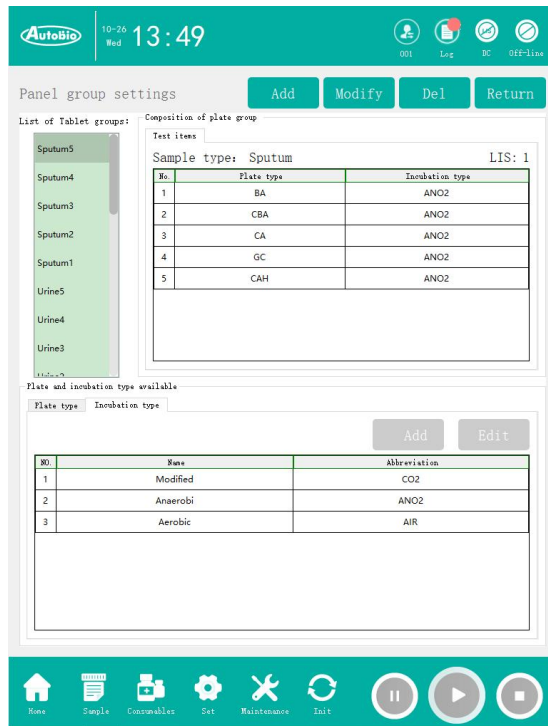
<p>6</p>		<p>After the test, refer to “6.1 Ultraviolet lamp disinfection requirements” for ultraviolet disinfection inside the instrument. Turn off the main switch on the left side of the instrument after disinfection.</p>

## 5.2 Obtain sample test information from LIS server

The flow of obtaining sample test information from LIS is as follows:

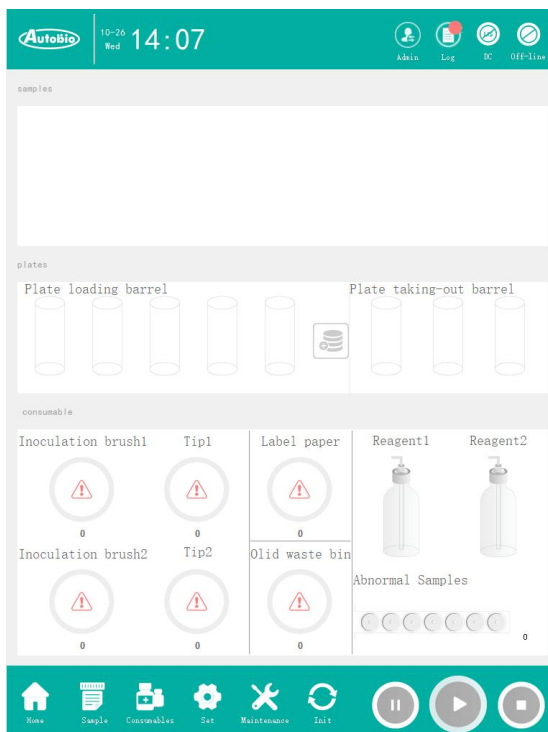
No.	Display	Description
1		<p>Initialize the instrument, and select the Connect LIS option during initialization.</p> <p>After the LIS connection is successful, the LIS connection status in the upper right corner of the screen is displayed as connected.</p>
2		<p>After initialization, check whether the plate barrel setting exists. If not, refer to the chapter "4.6.2 Plate barrel setting", add a new plate barrel setting and set it to the instrument.</p>

3



Select the setting - panel group setting function. Refer to the section "4.6.1 Panel group setting" to add a new panel group.

4



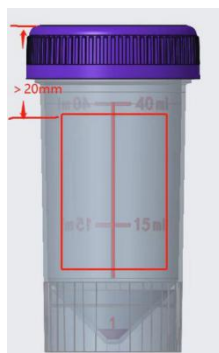
Place the sample into the sample rack, and put the sample rack into the sample loading position. Click the Start button to start the test. The sample information is obtained from the LIS server.

5		<p>After the test, refer to "6.1 Ultraviolet lamp disinfection requirements" for ultraviolet disinfection inside the instrument. Turn off the main switch on the left side of the instrument after disinfection.</p>
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### 5.3 Suggestions on pasting barcode information of sampling cup

The sampling cup barcode is the only identification for accurately recording the sample information. The standardized pasting of the sampling cup barcode can facilitate the barcode scanner to scan. The following suggestions are made for pasting the barcode label on the sampling cup:

1. The barcode label must be firmly pasted, flat and free of wrinkles;
2. The width edge of the barcode shall be pasted parallel to the scale horizontal line. It is required to ensure that the barcode position is pasted within the range below 40mL characters of the sampling cup and above the thread line (red box area);
3. Paste the barcode length edge parallel to the vertical line of the scale;





4. An example of correct pasting is shown below:



**CAUTION :**

1. The edge distance between the left and right blank areas of the barcode setting should be more than 2.5 mm;
2. The barcode setting width is recommended to be larger than 8 mm.

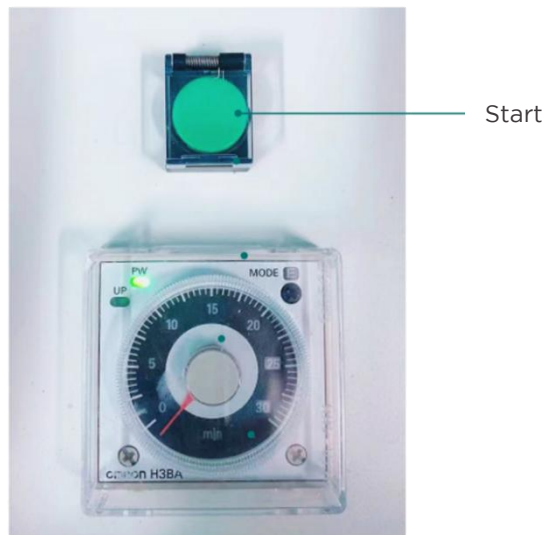


## 6 Ultraviolet Lamp Disinfection

### 6.1 Disinfection requirements of UV lamp

It is recommended that ultraviolet disinfection should be executed inside the instrument after completing the test every day.

Press the green “Start” button (as shown in the figure below), the instrument will automatically turn on the UV lamp for disinfection for 30mins by default.



#### CAUTION:

1. Please do not turn on the UV lamp during the operation of the instrument;
2. When the UV lamp is turned on, please ensure that the instrument cover is completely closed. Do not look directly at the UV lamp and keep a certain distance from the instrument.

### 6.2 Timer setting method

To change the timer time, follow the steps below:

1. Set the action mode of the timer, which is E mode by default. Before setting the timer,

please confirm whether it is E mode (see the figure below);

2. Set the time unit. The time unit switch can be selected from sec, 10s, min, 10m, hrs and 10h (see the figure below);

3. Set the time range, and select the time range switch from 1.2, 3, 12 and 30 (see the figure below);

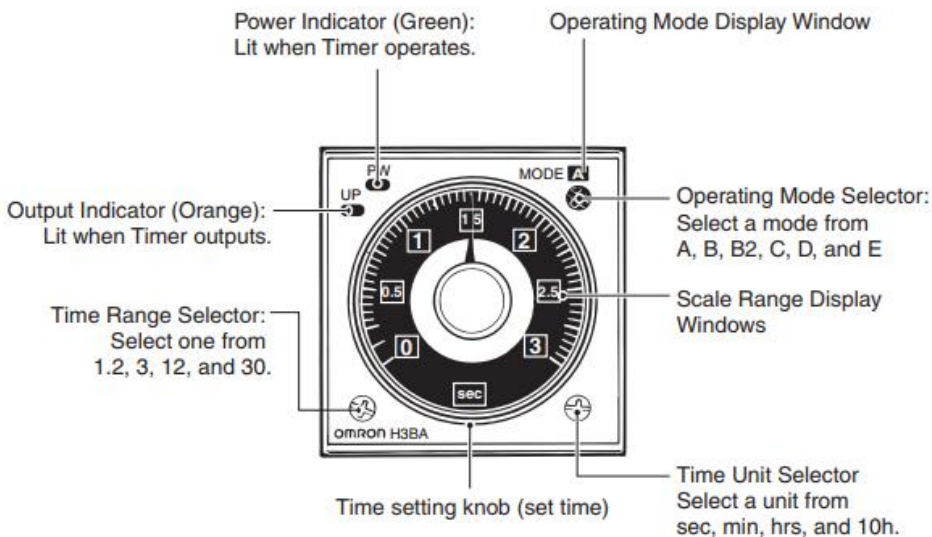
For example, when the timer is 30min, set the action mode to E, set the time unit to min, and set the time range to 30.



**CAUTION:**

The pointer of the timer does not rotate with the time change, so after setting the timing time, it is not necessary to reset it next time.

## H3BA-N



## 7 Instrument Internal Cleaning

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Turn off the power switch on the lower left side of the instrument, open the instrument chamber door, and use 75% medical alcohol and gauze to clean the inner surface of the instrument, including the metal surfaces such as the plate entry area, plate exit area, sample entry area, sample exit area, Tip box placement area, inoculation brush placement area, and the interior of the reagent chamber.

Use a clean non-woven cloth to soak in water and wring it dry, then gently wipe the surface of the instrument suckers. If necessary, soak a small amount of soap solution (do not use alcohol or other organic solvents). After cleaning, please dry the surface with a dry cloth.

Use a dry soft cloth dipped in neutral detergent to wipe the surface of the protective casing of the moving parts inside the instrument.

Check whether there is any waste in the abnormal sample channel and waste box. If there is, please clean it in time.



### **CAUTION:**

Make sure the instrument is powered off, otherwise electric shock may occur.

Please take protective measures to prevent sharp parts from being scratched when cleaning.

Cleaning cycle of sucker: clean every six months or 60000 tests (whichever comes first).

After cleaning, confirm whether the suckers are damaged or skewed.

## 8 Instrument External Cleaning

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Turn off the power switch at the lower left of the instrument, and wipe the instrument shell with a dry soft cloth dipped in neutral detergent.



**CAUTION:**

Do not wipe the window of the instrument shell with alcohol! To avoid damage to the window!

## 9 List of Accessories

No.	Name of accessories	Quantity
1	Sample rack	6
2	Handheld barcode scanner	1
3	Scanner bracket	1
4	Power cord (1.5 m)	1
5	Multilayer signal lamp	1
6	M3 × 8 Hexagon socket cylinder head combination screw	2

## 10 List of Wearing Parts

No.	Name	Replacement cycle	Replacement method
1	Vacuum filter	6 months	It shall be replaced by Auto customer service personnel.
2	High efficiency filter without partition	6 months	
3	Grab the spring plate of sampling cup	12 months	
4	sampling cup opening/closing cover grab	24 months	
5	Mixing sample rack	12 months	
6	Paper cutting blade	36 months	
7	The spring piece for pressing-block and breaking-off of the inoculation brush	24 months	
8	Fuse ( 32V 10A )	None (replace if damaged)	
9	Fuse ( 48V 1.3A )	None (replace if damaged)	
10	Fuse ( 250V 10A )	None (replace if damaged)	

# 11 Transportation and Storage

## 11.1 Transportation requirements

The requirements of temperature and humidity should be fulfilled, that is to say, the instrument should be water-proof and damp-proof during transportation and handling, and free from serve vibration and force,squeezing. A status indicator may be installed by the manufacture to show if the instrument is in a favorable condition, whether the Tilt indicator, Vibration-proof indicator . Thus it is prohibited that the instrument will be transported without packages that will prevent abnormal wear and tear.

Please check indicator status of package, vibration proof and tilt. The following figure shows right status of indication.



### NOTE:

- 1) The product can be unpacked and installed only by authorized service personnel.
- 2) Please verify that the delivery is complete on receipt of the AutoStreak S1800 and check for possible transport damage. If the delivery was incomplete or the device was damaged during transport, please contact Autobio.

## 11.2 Storage requirements

The non-open or indoor storage that keeps the instrument with package at the temperature of - 40 °C ~ + 55 °C and with relevant humidity no more than 90% should meet with the following conditions:



- 1) Be clean, tidy without accumulated water, grass, chemical medicine and corrosive gas;
- 2) Good ventilation without pollution source;
- 3) Safeguarding the instrument from direct sunlight and humidity.

The storage of unpacked instrument should also meet the temperature and humidity requirements above. Precautions of dust-proof and water-proof should be taken, such as heat shrinkable film and plastic bags. Besides, there should be enough clearance between the instruments and floor, wall, ceiling and etc to prevent unnecessary damage.

If the instrument is kept for more than three months, please contact with post-sales engineers to evaluate the instrument before reuse.

Please retain the packaging material if possible so that you can reuse it if it is necessary to return the device.

## 12 Troubleshooting

The following solutions are for simple errors. Please contact service engineer or technical personnel authorized by Autobio if there are any other problems or errors not indicated in the following table.

Description	Reason	Recovery Solutions
Operation fault	1. Alarm of failure to take Tip	Check whether the Tip margin is sufficient and consistent with that displayed on the client, and resume the test. If the Tip taking still fails, please contact the local engineer for maintenance
	2. Alarm of failure to take inoculation brush	Check whether the inoculation brush box is installed in place, confirm whether the margin is consistent with the margin displayed on the client, and resume the test. If the inoculation brush is still failed, please contact the local engineer for maintenance
	3. Inoculated plate without label	Check whether the margin of label paper is sufficient and resume the test. If the label still fails to stick, please contact the local engineer for maintenance

	4. Paste one more blank label on the inoculated plate	Check whether the label paper is spliced, and continue to test if there is splicing; If there is no splicing, please contact the local engineer for maintenance
Consumables alarm	1. Insufficient Tip margin	Continue the test after adding the Tip in time
	2. Insufficient inoculation margin	Continue the test after adding the inoculation brush in time
	3. Insufficient printer label margin	Continue the test after replacing the label paper in time
	4. Insufficient reagent margin	Continue the test after replacement of digestive juice in time
	5. Excessive waste in solid waste bin	Clean the waste in the solid waste bin in time
Instrument not ready	1. The instrument is not initialized	Perform initialization and reset of the instrument
	2. Moving parts reset failed	After the instrument is restarted, the complete machine is initialized again. If it is not ready, contact the local engineer for maintenance
Unable to start test	1. The instrument chamber door is not closed	Close the back cover of the instrument and click Start to run the test

	<p>2. Unable to connect to instrument</p>	<p>Restart the instrument, perform the initialization of the complete machine after connection, and click Start to run the test after the instrument is ready. If the test is still unavailable, please contact the local engineer for maintenance</p>
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**CAUTION:**

Please contact the technical service department of Autobio before carrying out the above diagnostic procedures to determine whether you can diagnose and debug some items.

The accuracy of the test results cannot be guaranteed under the condition of instrument failure!

Before contacting the manufacturer, do not attempt to open the chassis shell. The manufacturer is responsible for the instrument only when the instrument is checked and adjusted by qualified maintenance personnel approved by the manufacturer.

Cut off the power before opening the chassis shell!

If the instrument needs to be returned to the factory for maintenance, please contact the professional engineer and use the complete packing box.

## 13 Relevant Description of Cybersecurity

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### 13.1 Operating system

Linux operating system.

### 13.2 Runtime environment

Kernel version: 4.1.15 and above;

QT version: Qt5.9.7 and above.

### 13.3 Network conditions

TCP/IP protocol.

### 13.4 Data and equipment interface

The computer and equipment communicate through network port. The communication protocol is TCP/IP, and the data is stored in the Sqlite database.

### 13.5 User access mechanism

Access Control: Deny any unauthorized external access.

Access records: The system provides user access records and operation log records for review and tracking.

Permission control: The system has the function operation permission control. The viewing software system settings should conform to the identity category and permission management of maintainer, administrator and operator to ensure the security of software and data.

## Appendix 1- Backtracking Authorization

Company:		Company: Autobio Diagnostics Co., Ltd.	
Address:		Address: No.199, 15th Ave National Eco & Tech Zone, Zhengzhou 450016, China	
Contact		Contact	
Tel		Tel	
Fax		Fax	

Fault description:

The accessories sent back together with the instrument are:

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### NOTE:

1. Please pack the instrument with the original packing box if it still exists.
2. Please pack the instrument with double layer packing if the original packing box does not exist.

Put the instrument in a box with foam in the bottom, and fill the side and top with foam, then seal the box to prevent damages caused by shocking during transportation.

- b. After the first layer is finished, put it in a larger packing box and fill its four sides and top with foam.
  - c. Seal the outer packing box.
-

## Appendix 2- Disinfection Statement

Product Name:	Serial No.:
Model:	Backtracking Authorization:
Purchase Date:	No. of Warranty Certificate:

A

Does the internal or external of the product have ever been exposed to the following environment?

Please mark “yes” or “no” with X, then answer each of the questions below and give a detailed description in the B column.

	Yes	No		Yes	No
1 Pathological blood and body fluid			4 Chemical or material may endanger health		
2 Any other bio-hazardous substance			5 Radioactive material (please provide detail information below, including name, quantity and residual activity of the isotope)		
3 Substance that can decompose into dangerous substance			6 Other hazards		

B

Inform detailed information about the harmful substances in the environment that the product has been exposed to, including the name, quantity and related safety analysis table:

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**NOTE:** If harmful substances have been used, disinfection treatment must be done.

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C

Your disinfectant method (table can be attached) is :

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D

Whether are the substances mentioned in part A or B likely to remain contaminated?

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**I guarantee the truth and efficiency of the information provided above.**

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Sign:

Date:

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Name:

Title:

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Company:

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Address:

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Tel:

E-mail:

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