Labotronics

ELISA Workstation

LB-10ELISA

Index

1. Safety Measures

1.1 General Prevention

- Strictly observe Good Laboratory Practice (GLP) during use.
- DO NOT move the position of the test tube during sample addition to prevent testdata errors.
- Pay attention to the evaporation or concentration of the sample when running sensitive tests.
- Before routine use, experiment with distilled water and the final liquid.
- For easily foaming liquids, carry out liquid level detection first.
- Protect the instrument from sunlight and strong artificial light during operation.
- Use the instrument in a clean environment, free from contaminants or dust-producing products.
- Minimize interference from electromagnetic fields or static electricity, as theyaffect liquid-level detection.
- Avoid using the instrument in environments with flammable gases such asoxygen and nitrogen oxides.
- Use only the specified accessories and repair tools for the instrument.
- Ensure all mechanical units are in safe positions during repair or transport toavoid collisions.
- Ensure proper grounding during installation.
- Keep the instrument away from fire, and heat sources, and take waterproof measures (e.g., avoid placing vases or water glasses nearby).
- DO NOT halt the instrument for too long to prevent liquid loss in disposable tips, affecting results.
- DO NOT overfill the reagent slot or other liquid containers.
- Position the instrument with its back against a wall to prevent access to the workarea from the rear.
- Use an uninterruptible power supply (UPS) to prevent data loss during suddenpower outages.
- Ensure sufficient disk storage space to prevent computer failure.

1.2 Electrical Safety Precautions

- To prevent high-voltage or moving parts from endangering safety, operatorsshould not open the instrument's external housing without permission.
- Power off the instrument and disconnect the power cord before cleaning or disinfection.
- Never allow hands inside the instrument's internal cartridge while it is running.
- Untrained operators should not disassemble electrical and mechanical parts.
- Before removing any component or circuit board, power off the instrument and disconnect it from power sources.
- Monthly, press the electric leakage module indication button.

1.3 Biohazard Precautions

- Follow laboratory biosafety rules and dispose of waste according to hospital requirements.
- Take necessary safety measures and wear appropriate protective clothing andgloves.
- Place wastes in specified hospital positions, do not discard them carelessly ormix them with domestic wastes.
- DO NOT smoke, eat, or drink when using the instrument.
- Clean the instrument according to the maintenance procedure if contaminatedby biohazardous substances.
- Observe and execute maintenance procedures, especially for disinfection and decontamination.
- Wear gloves when handling the sample dispense arm, pipetting channel,container rack, containers, and disposable tips.
- Disinfect surfaces in contact with splashed liquids.
- Minimize contact with infectious samples and empty liquid waste and waste tip containers.
- DO NOT sprinkle destructive liquids onto the instrument, clean immediately if it occurs.

1.4 Mechanical Safety

- DO NOT lean on or tilt the instrument while it is running.
- Do not open the front door panel while the instrument is running to avoid injuryfrom moving parts.
- The instrument stops running when the door is opened (Open Stop). Do not operate the software until the front door is closed to avoid accidents.
- The Open Stop function has a service life of 100,000 times.

1.5 Fire Safety

- Establish, observe, and implement fire regulations specific to the medical field.Equip fire extinguishers for electrical and non-electrical fires.
- Operators should be trained to use fire extinguishers and other fire facilities.
- In case of fire, disconnect the power supply first to prevent electric shock injuries.

1.6 Emergency and Corrective Measures

- If the instrument fails during an experiment, power off the instrument.
- Save experiment samples and dispose of samples and waste according to rules.

1.7 Computer-related Preventive Actions

- To prevent computer viruses, use only approved software.
- Do not change the date and time in the computer system while the instrument is running to avoid affecting information processing.
- Use only approved software and hardware control protocols for the instrument.

1.8 Electromagnetic Compatibility (EMC)

- The instrument is subject to various electromagnetic disturbances conducted viapower sources, cables, or radiated in the environment. Do not use near-intense radiation sources such as non-shielded RF sources to avoid interference.
- The instrument conforms to the requirements on emission and immunity to interference as specified in relevant standards.
- Evaluate the electromagnetic environment around the instrument before use.

1.9 Safety signs and symbols

The following safety signs and symbols are used on the instrument, in this manual,and on the labels. They are crucial to the safe and reasonable use of the instrument.

Warning:

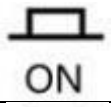
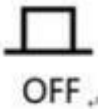
Symbols	Title	Description
	CAUTION, DANGER	• This symbol indicates a potential electric shock hazard. • Do not touch any electrical parts marked with this symbol usingyour hands or tools when the power source is connected.
	BIOHAZARD	• This symbol warns operators to wear protective equipment when handling infectious substances. • As this instrument is fully automated IVD equipment, wear gloves throughout theoperation. • Potential contamination sources include the tip ejector, sample dispensing positions, and incubator, necessitating medical rubber gloves for cleaning and sterilization. • Dispose of solid and liquid waste per local safety guidelines to avoid skin contamination.
	CAUTION, SCALDING	• This symbol indicates the instrument's surface may become very hot. • During operation, the incubation module can reachhigh temperatures. • Although double protection, including over-temperature protection components and a temperaturesensor, is pre-installed, if both fail simultaneously, these parts may overheat.

	CAUTION, HAND PINCHING HAZARD	• This symbol warns the operator to avoid placing hands in this area to prevent pinching. • Be cautious when opening orclosing the door cover.
	CAUTION, DANGER	• This symbol warns that ignoring the operation guide can damage the instrument and cause injury or death. • Always consult the document when this symbol is present. Do not open the housing when the power is connected or the door cover while the instrument is running. • Do not reach any part of your body into the instrument during the operation to prevent injury.
	PROTECTIVE CONDUCTOR TERMINAL	• Ensure proper earthing protection for the instrument duringoperation or maintenance. • Safely ground the baseplate and housing via earth wires. • Any break in grounding circuits, whether inside or outside the instrument, poses a danger.

Label Symbols

	Identification of in vitro diagnostic medical device

Other Marks

	Instrument Power Supply	The pushbutton switch is used as the power switch, it indicates the switch is in the **"ON"** position
	Instrument Power Supply	The pushbutton switch is used as the power switch, it indicates the switch is in the **"OFF"** position

2. Introduction

ELISA workstation LB-10ELISA is a fully automated immunoassay processor with a multifunctional liquid handling system. It is characterized with the unique module combination of pipetting, washing, incubating and reader functions. The dispense channels feature disposable tips to avoid contamination. The workstation employs dispensing-aspirating washing mode.

3. Features

1. Photometric microplate reader module
2. Air displacement pipetting system
3. Crosswise aspiration with selectable injection height
4. Liquid level, clot and empty tube monitoring
5. Barcode scanning (optional)-Manual
6. Multifunctional liquid handling (dilution, conjugation, aliquoting)
7. Multiple and diversified dispensing

4. Specifications

Model No.	LB-10ELISA
Assembly	Benchtop
Number of channels	2
Disposable tips	300 µL and 800 µL
Pipetting range	1 µL ~ 1000 µL
Pipetting increment	0.1 µL
Pipetting precision and accuracy (300 µLand 800 µL)	Volume: 100 µL
	Accuracy: ± 1%
	Precision: < 0.75 %
Total rails	12
Control positions	6 × 24 = 144
Reagent positions	6 × 4 = 24
Plate positions	4 + 1 ambient (optional)
Temperature range	RT ~ 60 °C
Temperature increment	0.1 °C
Temperature accuracy	± 0.5 °C
Washing channels	1 × 8
Selectable wash buffers	3
Wash volume	50 µL ~ 1000 µL per well
Residual volume	≤ 2 µL per well
Interface	USB and RS232
Dimensions	1270 × 785 × 1000 mm
Weight	180 kgs

5. Applications

Used to detect antigens or antibodies in serum, sputum, semen, urine, stool, and supernatant of culture in the fields of microbiology, genetic profiling, biotechnology, biochemistry, zoology, clinical trials, etc.

6. Instrument Introduction

6.1 Structural composition

The ELISA Workstation mainly consists of the main unit and control software. The main unit is the operation, reaction, and detection part of the instrument, mainly composed of a liquid-in system, microplate transfer system, oscillating incubation system, microplate washing system, and enzyme-labeled analysis system.

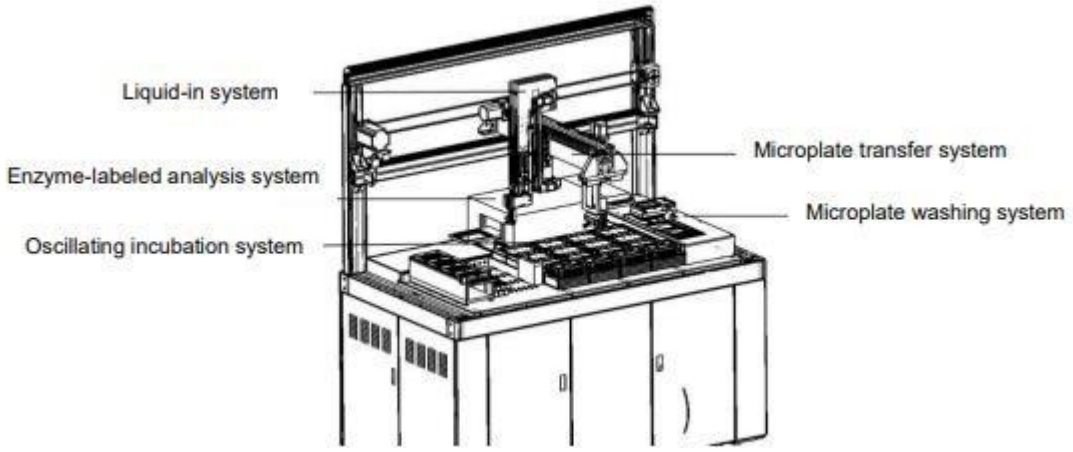


Figure-1 General Assembly Drawing of ELISA Workstation

(1) Liquid-in system

The liquid-in system consists of a sample dispense arm module, tip rack, sample rack, reagent rack, microplate rack, tip ejector, and consumables (tip tray, reagent kit, tip).

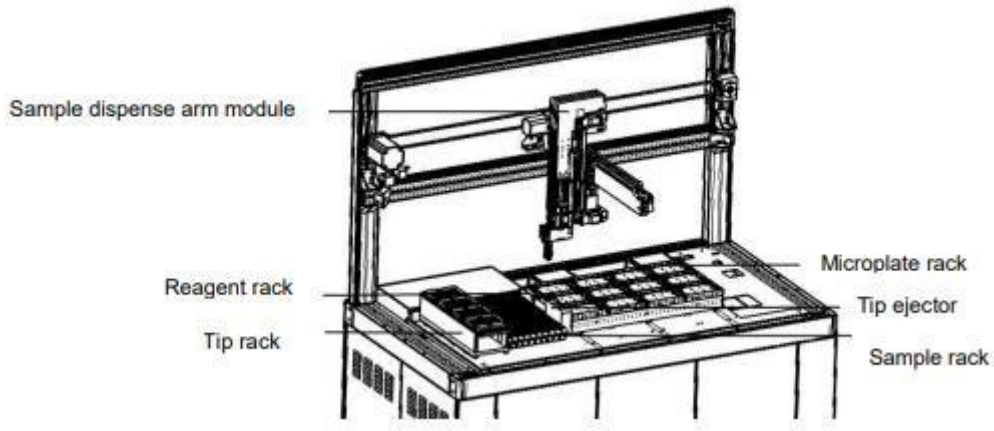


Figure-2 Layout of Sample-in system

1. **Sample Dispense Arm Module**
   The sample dispense arm module mainly consists of the circuit control part, mechanical control part and pressure sensor part.

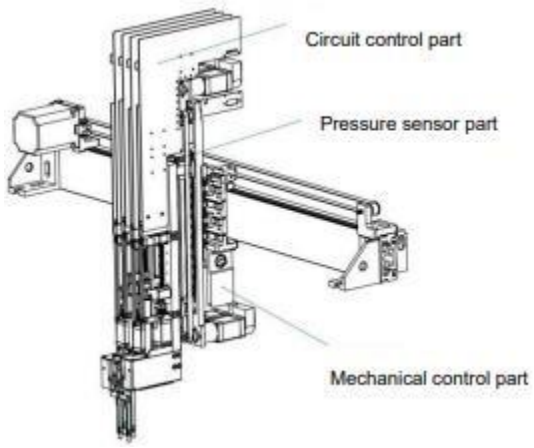


Figure-3 Layout of Sample Dispense Arm Module

Function of sample dispense arm module: The pressure detection principle and gas-liquid exchange principle are applied to realize liquid level detection, clot detection, empty tube detection and bubble detection and to complete absorption, discharge and transfer of liquid (including sample and reagent)

2. **Functions of Other Components**

Component	Function
Tip rack	For placing tip trays
Sample rack	For placing test tubes
Reagent rack	For placing reagent kits
Microplate rack	For placing microplates or deep-well plates
Tip ejector	For releasing disposable tips

3. **Consumables (Tip Trays, Reagent Kits, and Tips)**
   Tip Trays: For placing tips. Reusable.
   Reagent kits: For storing reagents. Reusable.
   Tips: This is for transferring reagents or samples and for single use only. Non-reusable**.**

(2) Microplate Transfer System

- The microplate transfer system consists of a mechanical structure part (X-axis motor, Y-axis motor and gripper motor) and a circuit control part.
- 96-well microplate (hereinafter referred to as “microplate”) is a transparent plastic plate for placing the sample to be tested.
- There are multiple rows of small wells of the same size on the plate, and the inside of each well is coated with the corresponding antigen or antibody. All experiments that can be performed on this instrument should be realized via microplates.

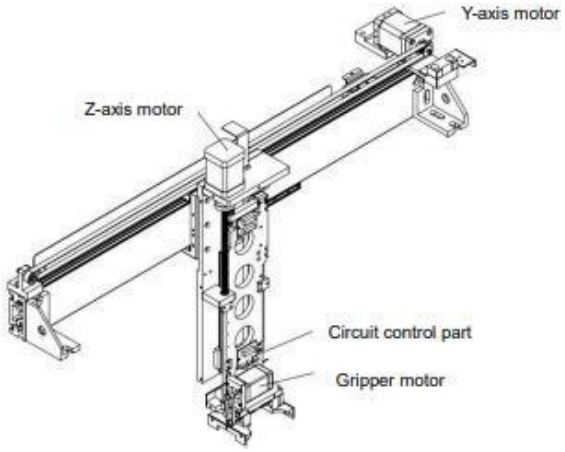


Figure-4 Layout of Microplate Transfer System

- **The Function of the Microplate Transfer System:** Transfer microplates from one component to another, thus correctly executing such functions as pipetting, incubation, microplate washing, and reading.

(3) Oscillating Incubation System

The oscillating incubation system consists of a heating element, temperature sensor, overheat protector, oscillating motor, and other components.

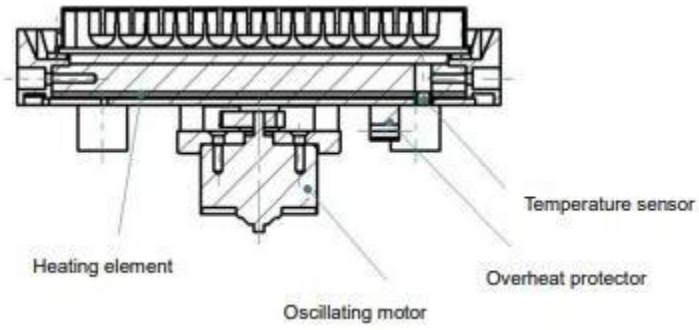


Figure-5 Layout of oscillating incubation system

(4) Microplate Washing System

The microplate washing system consists of a wash head, solenoid valve, motor, injection pump, liquid waste pump, liquid storage unit, and other components.

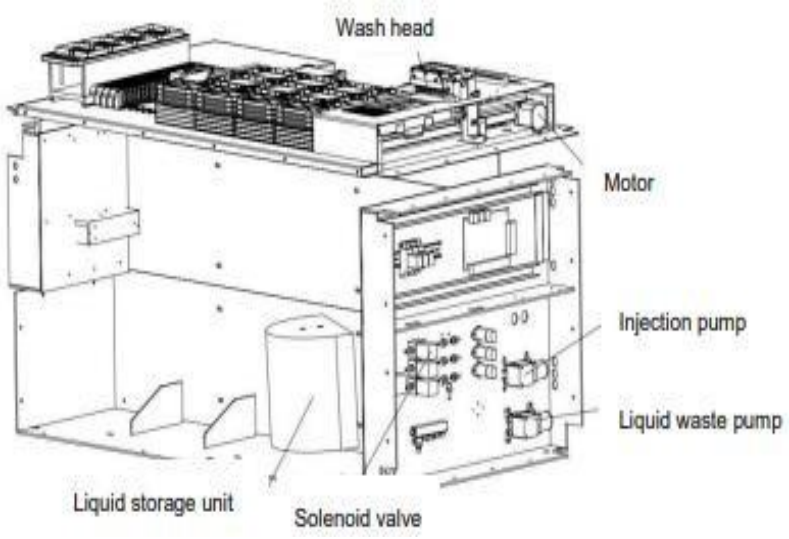


Figure-6 Layout of Microplate Washing System

The function of the Microplate Washing System: Through the movement of the wash head, the wash buffer in the liquid storage unit is transferred to the microwells,and the residual liquid is transferred to another liquid storage unit, thus, achieving the separation of free markers and immune complex markers.

(5) Enzyme-labeled Analysis System

The optical path detection module of the enzyme-labeled analysis system consists ofthe light source, optical filter, optical fiber, circuit control board, motor, etc.

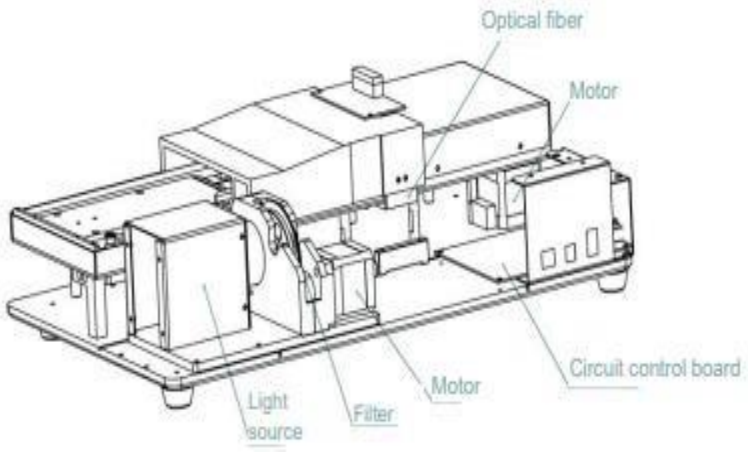


Figure-8 Enzyme-labeled Analysis System

The function of the Enzyme-labeled Analysis System: Liquid after processing by the sample-in system, microplate transfer system, oscillating incubation system, and microplate washing system is analyzed by the enzyme-labeled analysis system to obtain the test result and indicative judgment.

(6) Software

As a part of the ELISA Workstation, the software is the core part and control center of the instrument. It should be installed on a universal computer platform and is mainly used for program control, detection data analysis and data communication ofthe instrument.

7. Installation

This chapter briefly describes this product's transport and storage conditions and installation information.

7.1 Transport and Storage Conditions

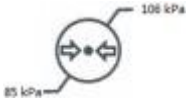
1) **Packaging:** Three-layer packaging is employed for the main unit, of which the outer layer is a carton for equipment packaging, marking, and protection, the medium layer is a plastic film for water and damp proofing, and the inner layer is bubble pad wrapping that is fixed by the stretch film for buffering.

2) **Transport:** The packaged instrument should be transported according to the requirements specified in the contract for goods and protected from violentimpact, rain, and sun exposure during transport.

3) **Storage:** The packaged instrument should be stored in a well-ventilated environment without corrosive gases, where the temperature is between - 40℃~55℃relative humidity not greater than 85%, and atmospheric pressure between 85kPa~106kPa.

The external packing for transport should contain the following signs:

Marking	Designation	Instruction
	Upward	Indicating the package should be upright during handling.
	Fragile, handle with care	Indicating the package contains fragile articles and should be handled with care.
	Keep it dry	Indicating the package should be kept dry.
	Do not roll	Indicating the package should not be rolled during handling.

	Temperature limitation	Indicating the range of temperature in which the package should be kept. This instrument should be stored and handled at a temperature between -40°C~55°C.
	Humidity limitation	This instrument should be stored and handled at relative humidity not greater than 85%.
	Atmospheric pressure limitation	This instrument should be stored and handled under barometric pressure of 85 kPa~106 kPa.

7.2 Installation Conditions and Environment Validation

Know the overall dimension and weight of the instrument to be installed, check in advance the user's location in the building, the elevator, and the width of doors which the instrument must go through, and prepare to handle equipment of the corresponding weight class.

1) Ventilation:

No special requirement is placed on ventilation if the following requirements are satisfied:

- DO NOT block the ventilation inlet.
- The horizontal spacing between the ventilation inlet and the surrounding walls and other obstacles should be no less than 5 cm.
- It is forbidden to place any objects in the air vent where the fan is installed.

2) Channel:

- An operation space of 50cm should be kept in front of the instrument to ensure convenient and safe operation.
- It is forbidden to pile up objects around the power switch.

 Prevent personal injury and damage to other objects due to crashing.

3) Operating environment:

Indoor use, normal ventilation environment.

Normal operating conditions:

1. **Supply voltage:** 200~240VAC, 50/60Hz
2. **Ambient temperature**: 10℃~30℃
3. Relative humidity: ≤85%
4. **Atmospheric pressure:** 85kPa~106kPa
5. Keep away from sources of strong electromagnetic interference.
6. Avoid direct radiation from strong light.
7. A good grounding environment should be available, at an altitude below2000m, if the altitude exceeds 2000m.

4) Handling and Installation Instructions

(1) Loading and Unloading:

1. Pay attention to the "Up" sign and do not roll over the instrument.
2. Handle with care due to sensitive electronic components and precise mechanical transmission unit.
3. Use a forklift, pallet truck, or other handling tools.
4. If unavailable, several people must handle it with safety measures.
5. Manual handling distance should not exceed 10m.

(2) Table-top Instrument Placement:

1. Place on an even table surface.
2. The table's upper surface should be 10-20cm larger than the instrument'sbase in both length and width.
3. Ensure the table surface's bearing capacity is at least 600 kg/m^2.
4. If using a support, install it on a fixed frame to minimize mechanical steploss from swinging.
5. Position the instrument with its back against a wall to prevent personnelfrom entering the work area from the rear.

(3) Computer Requirements:

1. Ensure sufficient disk storage space to prevent computer failure.
2. Meet at least the minimum configuration requirements for the computer.

(4) Maintenance and Transport:

1. Ensure all mechanical units are in collision-free positions.
2. Remove or secure all mobile components or containers.

(5) Use of Accessories and Consumables:

Only use accessories, repair tools, and consumables specifically provided for the instrument.

(6) EMC Information:

1. Users must ensure an appropriate EMC environment for the instrument to function normally.
2. Protective measures should be taken in household environments due to potential radio disturbances.
3. Evaluate the electromagnetic environment before using the instrument.
4. Avoid using the instrument near sources of intense radiation, such as unshielded RF sources.

(7) Professional Handling:

1. Only trained professionals should attempt to disassemble or install the instrument.
2. Installation must be supervised and guided by a professional engineer, strictly following the installation process.
3. Do not place the instrument where it is difficult to operate the disconnecting unit.

(8) Movement and Calibration:

1. The instrument should remain in a fixed location.
2. Any movement must be performed by a professional engineer, followed by recalibration before reuse.

(9) Load Capacity:

1. The maximum load of a single caster is 300 kg.
2. The maximum load on each supporting foot is 1400 kg.

5) Connect power supply:

- The instrument should be installed at a position with earthing protection.
- Thepower port on the back of the instrument should be barrier-free so that the power cord can be disconnected rapidly in case of an emergency.
- Provide AC power input to the connecting plug, the supply voltage must be consistent with that indicated on the nameplate.
- The user shall provide a power supply that satisfies the local and application-specific safety requirements.
- During operation, keep the supply voltage at 220V, data loss willbe caused in case of a sudden power outage.
- To prevent data loss, it is suggested to use an uninterruptible power supply (UPS).
- Check to confirm that the plug is completely connected to the outlet.

7.3 Unpacking and Installation of Instrument

1) Visual Inspection of the Instrument

- Check whether the acrylic panel of the instrument is broken or cracked and whether any important components inside the instrument are damaged.
- Check whether the product is intact according to the Instrument Handover List.

2) Unpacking Steps

- First use a fork spanner to remove the upper cover after removing the screwsin the upper cover.
- After the removal of the upper cover, the four sides of the packing case can be removed in the same way.
- It is suggested that the removal operation should be done by two persons, and one of them should hold the wooden case to prevent injury caused by crashing. After removing the four sides of the packing case, the instrument is fixed to the base using hex socket screws.
- After removing the M6 hex socket screws above the four aluminum angle bars withan Allen key, the instrument will be separated from the base.
- At this moment,a forklift can be used to move the instrument to a level ground.
- When the forkenters the bottom of the instrument, first check whether there is any obstacleat the bottom of the instrument (whether the liquid waste container is pickedup, and whether the casters obstruct the entrance of the fork) to ensure a smooth entrance of the fork and avoid damage caused by collision.

1. If no elevator is available and the instrument must be moved to the designated floor by manpower, it would be better not to remove the base to facilitate handling.
2. During handling, protect the instrument from excessive shaking, after movement to the designated floor, the base of the instrumentcan be removed.
3. For a cabinet-type instrument with casters, use an adjustable spanner to screw upward the supporting feet of the instrument and let the four casters contact the ground, the supporting feet should be screwed to a certain height (about 2 cm over the ground) to ensure that theywill not contact the ground when pushing the instrument.
4. After lifting the caster brakes, push the instrument to the department needing it and place itin the specified position.
5. A table-top instrument is lighter than a cabinet-typeinstrument. When no elevator is available, first remove the housing of the instrument and retain the pallet.
6. Move the instrument to the designated floor by manpower, during transport, and protect the instrument fromexcessive inclination or collision.
7. If an elevator that is big enough is available, the base of the instrument can be directly removed from the hall.
8. For a cabinet-type instrument with casters,use an adjustable spanner to screw upward the supporting feet of the instrument and let the four casters contact the ground; push the instrumentinto the elevator, move it to the department needing it, and place it at the specified position.
9. For a table-top instrument, first confirm whether the size of the elevator can accommodate the instrument; if the size is big enough, simply move the instrument into the elevator.

10. During movement, handle with care to avoid collision.
11. When the instrument arrives at the department needing it, place it in the prearranged position (keep the rear of the instrument about 50-70cm awayfrom the wall, and ensure that all doors of the instrument can be opened to facilitate repair), tear off the protective film on the external surface of the instrument.
12. For a cabinet-type instrument with casters, after placing it at the specified position, putting down the supporting feet of the instrument, ensures the levelness of the instrument.
13. Adjust the levelness of the instrument via the supporting feet, the supporting feet must hold up the instrument and make the casters hang in the air.
14. For a table-top instrument, use a spanner to adjustthe four feet of the base until the instrument is level.

3) Moving the Instrument out of the Case

 Before moving the ELISA Workstation out of the case, kindly prepare thebase and place the measuring equipment. Improper installation will result in damage to the instrument.

Before taking out the ELISA Workstation, confirm that sufficient space is available to place this instrument and its accessories. The base of the instrumentmust meet the size requirement for the ordered model. Generally, it is requiredthat the upper surface of the table should be bigger than the base of theinstrument (its length and width should be respectively 10-20cm bigger than the base of the instrument).

Check the accompanying configuration according to the "Standard ConfigurationList" of the instrument. To prevent damage to the instrument, kindly follow thesteps below.

1. Move away the flexible package outside the packing case.
2. Shear off the strap at the top of the packing case.
3. Move away the top part of the packing case.
4. Take out the inside box.
5. Cut along the adhesive tape on the top of the inside box, take care to preventthe knife from contacting the ELISA Workstation.
6. Open the inside box, and make sure the four sides of the box are flush withthe ground.
7. Take out the small accessory box.

 The ELISA Workstation should not be lifted by only one person. Keep balance during movement, otherwise, the mobile mechanical units could get damaged.

8. Remove the panels on both sides of the instrument.
9. Four people should simultaneously grab the base beam of the instrument and lift it gently and slowly.
10. Securely and firmly place the ELISA Workstation on the prepared worktableor ground.
11. Open the small accessory box and place the parts taken out of it in an open area.
12. Check to confirm that all components on the packing list have been received.

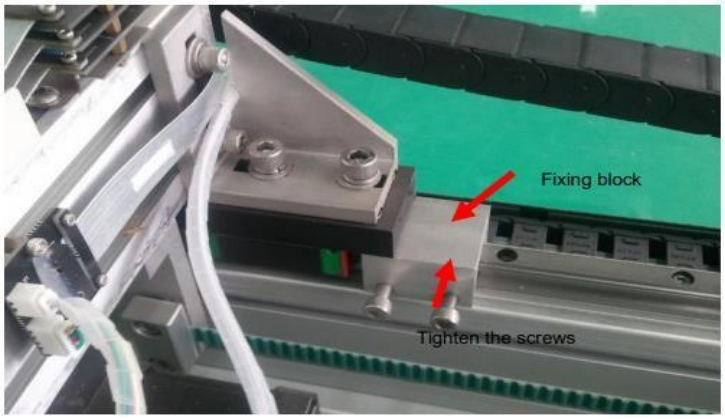
4) Removal of Fasteners inside the Instrument

To prevent the free movement of instrument components during transport, fasteners are used to fix the mobile components. Such fasteners must be removed before installation and operation of the instrument.

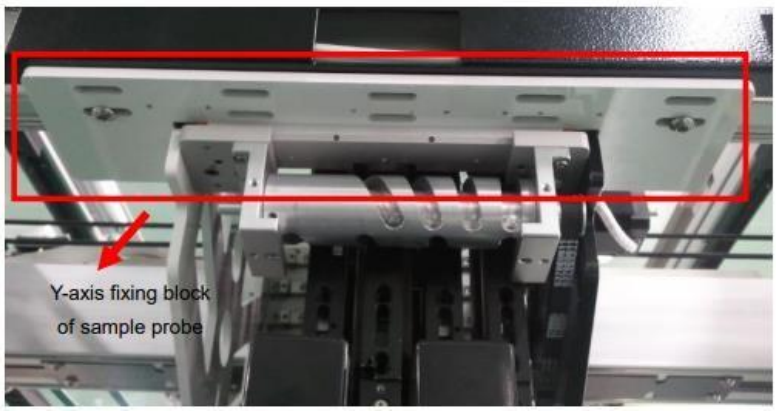
(1) Positions of and method for removal of fixing blocks:

The main components with fixing blocks include:

1. **X-axis track of sample probe:** 2 fixing blocks on each of the two guides,a total of 4 fixing blocks.



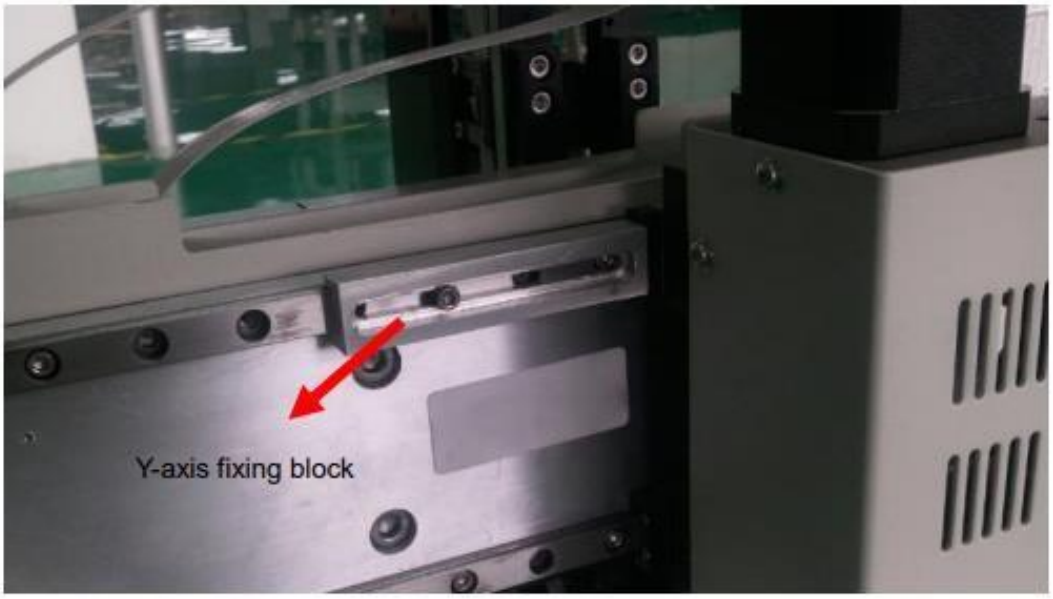
2. **Y-axis track of sample probe:**
   - 2 fixing blocks on each of the two beams of the sample probe of the 8-tip integrated instrument, a total of 4 fixing blocks.



- The 2- or 4-tip sample probe occupies a beam with 2 fixing blocks.

3. The 4-tip sample probe and the transfer arm use an integrated fixing block.

4. 1 fixing block on each of the upper and lower tracks in the Y-axis directionof the instrument, a total of 2 fixing blocks.
Method for removal of fixing blocks: Use an Allen key of the corresponding size to loosen the screw in the fixing block and slide the fixing block until it can be removed from the track.

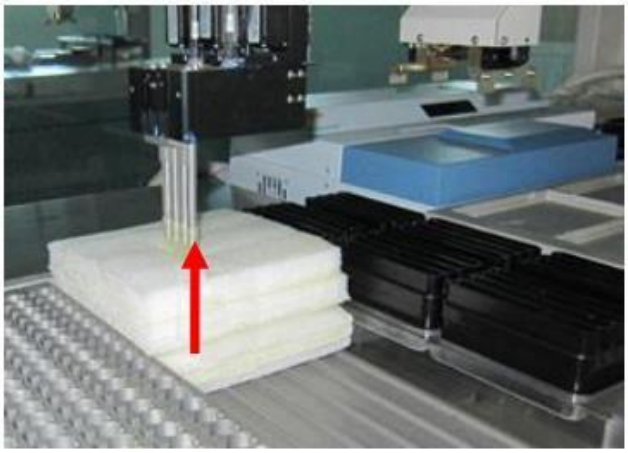


(2) Positions of and method for removal of fixing straps

Components with fixing straps include:

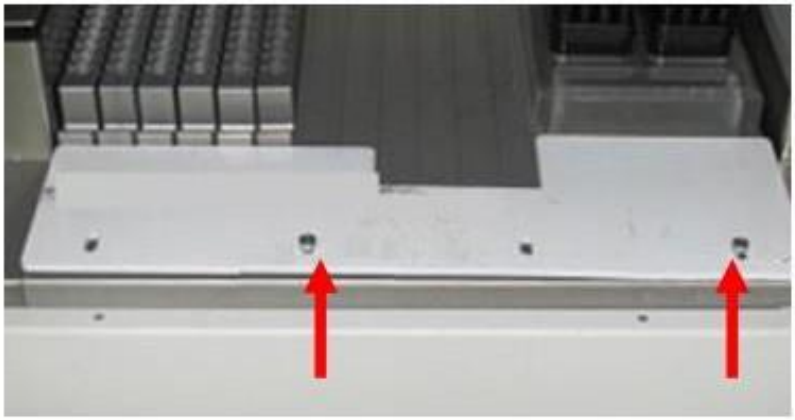
1. The Z-axis belt of each unit probe
2. Y-axis belt for plate washing

Removal method: Simply use diagonal pliers or scissors to cut the strapand take care to protect the belt. For the removal of the gun protective tip,after removing the strap, simply lift the unit probe and pull off the tip.



(3) Removal of fixing panel

To open the front cover of the instrument, first lift the Z-axis of the unit probe,after lifting, pull off the protective tip on the channel. On the tabletop of the instrument, you can see a piece of ABS panel fixing the sample rack and the reagent rack using hex socket screws. Use an Allen key to loosen the screws and then remove the ABS panel and install the spare screws to their originalpositions.



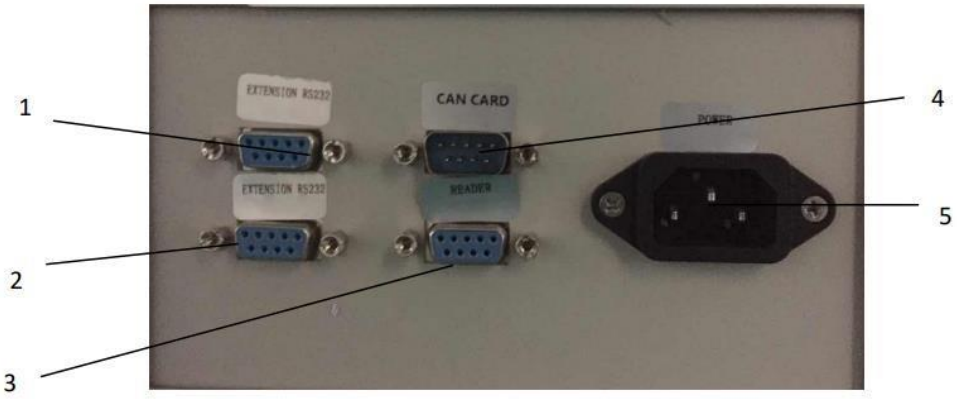
(4) Users can see that the handle on the front panel faces the inside of the instrument, which can prevent collision of the handle during transport. Use ascrewdriver to remove the handle, and then install it facing outward.

1. After removing the fixing blocks in the Y-axis direction of the pipetting system and the Y-axis direction of the transfer arm, the fixing screws must be installed back and tightened at the original positions. The two fixing blocks in the X-axis direction of the pipetting system can be directly removed.
2. The instrument cannot be powered up for operation before all fixing blocks and straps are removed.
3. For the typical instrument chosen for disassembly, kindly remove the fixing modules according to the actual model.

7.4 Connection of Instrument

1) Description of Ports on the Instrument

Ports on the instrument are shown in the figure below



1. Standby ports
2. Standby ports
3. Reader port
4. CAN card port
5. Power input port

Type of port	Description of port
Reader port	Port for connecting the computer and the reader
CAN card port	Port for connecting the main unit and the CAN card
Power input port	Port for inputting supply voltage

Note:
Can Card Line does not exceed 3M.
RS232 voltage is -15V ~ 15V
USB voltage is 5V

2) Position and Function of Power Switch

The power switch is positioned at the front left of the instrument, power is “ON” when the switch is pressed down, and “OFF” when the switch bounces up.

3) Connection of External Computer

Unpack the computer main unit and monitor and assemble the computer. Connect the power cord, CAN card DB9 cable, CAN card USB cable, reader serial cable, and scanner serial cable of the instrument in sequence to the rear panel of the instrument, jacks corresponding to the cables are provided on the panel.

8. Working Principle

According to the description of structural composition, the steps for the operation of this product are as follows: sample and reagent processing, immunoreaction (including oscillating incubation and microplate washing), optical detection, software control (instrument control, data analysis, and processing unit, and data transmission system), which will realize detection with ELISA and analysis of the result.

1) On the enzyme-labeled analysis module, the light wave emitted by the light source passes through the optical filter and changes to a single beam of monochromatic light which enters the sample to be tested in the microplate. This monochromatic light is partially absorbed by the sample, and the remaining light irradiates the photoelectric detector through the sample, the photoelectric detector converts the optical signals whose intensity varies with the sample to be tested to corresponding electric signals. After pre-amplification, log amplification, analog-digital conversion,and other signal processing, the electric signals are sent to the microprocessor for data processing and computation, thus, carrying out qualitative or quantitative analysis of the sample to be tested. ELISA is a solid-phase immunoassay technique, it first coats the surface of a solid-phase carrier with an antibody or antigen and maintains its immunocompetence. During the assay, add the sample to be tested andthe enzyme-labeled antigen or antibody according to the steps, which react with theantibody or antigen on the surface of the solid-phase carrier, remove the freeunbound ingredients by washing, and last, add the reaction substrate, according to the color of the substrate after enzymatic catalysis, carry out qualitative or quantitative analysis based on the value of absorbance (A).

2) Below are details of the immunoreaction methods: Immunoreaction methods include sandwich assay, competitive assay, capture assay, and indirect assay which are used depending on the immunoreaction mode.

(1) Sandwich assay

When determining antigen substances, generally use the specific antibody-coated reaction carrier and enzyme-labelled specific antibody to react with the specific antigen to be determined, thus forming the “solid-phase carrier antibody-antigen – enzyme-labelled antibody” complex. Wash off unbound sample and reagent; only retain the complex formed by the reaction. Apply the reaction substrate; use the optical detector to measure the absorbance; the measured concentration of specific antigen is directly proportional to the absorbance. Sometimes, the specific antibody is bridged to the reaction carrier; the step of binding between the specific antibody and the reaction carrier is added to the reaction process, and other steps remain unchanged. Antibody substance is determined following a similar principle; the steps are identical except that enzyme-labelled specific antigen and specific antigen-coated reaction carrier are used as the reactants to finally form the “solid-phase carrier antigen-antibody – enzyme-labelled antigen” complex.

(2) Competitive assay Generally, competitive assay includes two methods: enzyme-labeled antigen, and enzyme-labeled antibody. In the enzyme-labelled antigen method, the enzyme-labelled specific antigen and the sample react with the antibody coated on the reaction carrier, the specific antigen in the sample competes with the enzyme-labelled specific antigen for antibody-coated binding sites on the reaction carrier, which respectively form the "solid-phase carrier antibody-antigen" and "solid-phase carrier antibody – enzyme-labelled antigen"complexes. Wash off unbound sample and reagent, only retain the complex formed by the reaction. Apply the reaction substrate, and use the optical detector to measure the absorbance, the measured concentration of specific antigen is inversely proportional to the absorbance, which means if the concentration of specific antigen in the sample is low, most binding sites on the carrier antibody will bind with the enzyme-labelled antigen, and the reading of absorbance valuewill be high after the reaction. If the sample contains a high concentration of a specific antigen, most binding sites on the carrier antibody will bind with the antigen in the sample, and a few binding sites will bind with the enzyme-labelled antigen, the reading of absorbance value will be low after the reaction. Sometimes, the specific antibody is bridged to the reaction carrier, the step of binding between the specific antibody and the reaction carrier is added to the reaction process, and other steps remain unchanged. In the enzyme-labelled antibody method, the enzyme-labelled antibody and the sample react with the antigen coated on the reaction carrier, the specific antibody in the sample competes with the enzyme-labelled antibody for antigen-coated binding sites on the reaction carrier, which respectively forms the "solid-phase carrier antigen- antibody" and "solid-phase carrier antigen – enzyme-labelled antibody" complexes. Wash off unbound sample and reagent, only retain the complex formed by the reaction. Apply the reaction substrate, and use the optical detector to measure the absorbance, the measured concentration of a specific antibody is inversely proportional to the absorbance, which means if the concentration of aspecific antibody in the sample is low, most binding sites on the carrier antigen will bind with the enzyme-labelled antibody, and the reading of absorbance valuewill be high after reaction. If the sample contains a high concentration of a specific antigen, most binding sites on the carrier antibody will bind with the antigen in the sample, and a few binding sites will bind with the enzyme-labelledantibody, the reading of absorbance value will be low after the reaction.

(3) Capture assay

Capture assay is commonly used to determine the specific immunoglobulin M (IgM) antibody of certain antigens. This method generally uses the reaction carrier coated with anti-human specific IgM antibody and enzyme-labelled antigen to react with the sample, thus forming the "solid-phase carrier-anti-IgM antibody – IgM antibody – enzyme-labelled antigen" immune complex. Wash offunbound sample and reagent, and retain the complex formed by the reaction. Apply the reaction substrate, and use the optical detector to measure the absorbance, the measured concentration of a specific antibody is directly proportional to the absorbance.

(4) Indirect assay

Indirect assay is commonly used to determine the specific immunoglobulin M (IgM) antibody of certain antigens. This method generally uses the antigen-coated reaction carrier and enzyme-labelled anti-human specific IgM antibody to react with the sample, thus forming the "solid-phase carrier-antigen – IgM antibody – enzyme-labelled anti-IgM antibody" immune complex. Wash off unbound sample and reagent, and retain the complex formed by the reaction. Apply the reaction substrate, and use the optical detector to measure the absorbance, the measured concentration of a specific antibody is directly proportional to the absorbance.

9. Operations

Software operations

9.1 System Requirements

9.1.1 Operating Environment

1) Hardware configuration:

1. **CPU:** Intel P4
2. **Memory**: At least 1G memory
3. **Hard drive:** At least 100G hard drive
4. **Monitor:** Optimum resolution: 1024×768 pixels
5. **I/O device:** None

2) Software environment:

1. **System software:** Windows 7 or a higher version
2. **Supported software:** .Net Framework 4.0 or a higher version
3. **Prerequisite software:** Office 2003 or a higher version
4. **Optional software**: None
5. **Antivirus software:** None

3) Network conditions:

1. **Network type:** LAN
2. **CS** architecture
3. **Bandwidth:** At least 1M

9.1.2 Software Installation

Model: LB-10ELISA
Release version: V1.0
The instrument supports installation of the software to any drive under "My Computer",it is suggested to install it to D drive to facilitate uniform query of logs and other files.

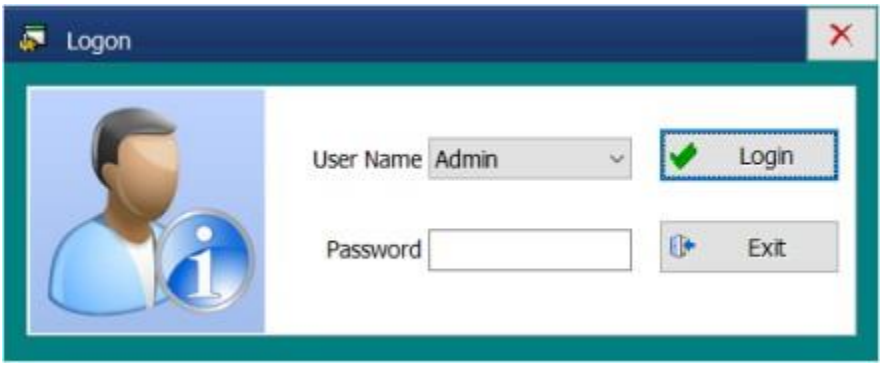
9.1.3 Description of Directory Files

The following directories will be shown under the installation directory. The functionand meaning of each directory are described here:
Conf: It contains system alarm files.
Database: It is the database folder. All operating data and parameters of the instrument are saved in the database. Change of data can be realized by replacing thedatabase.
Language: It is the file containing the language of the system settings interface.
Sample Barcode: This is the file containing the barcode of the sample tested.
Plate Barcode: This is the file containing the barcode of the microplate.
Raw Data: It contains raw data.
Traces: It is the file containing running logs and operation records of the instrument.

9.2 File Menu

9.2.1 System Login and Logout

For secure use of the system, kindly log into the system before use. The login interface is shown in the figure. For the first login, the default username is "admin" and the password.



After clicking the "Login" button, the system will enter the main program interface. In case of login failure, a prompt message indicating the wrong password or username will appear.

9.2.2 Change Password

Click "Change Password", in the pop-up window, enter the old password and the new password, and then click OK. This menu allows the operator to change his/her password, if the operator has the user management permission, he/she can modify the information of all operators in the User Manage interface.

9.3 System Manage

9.3.1 User Manage

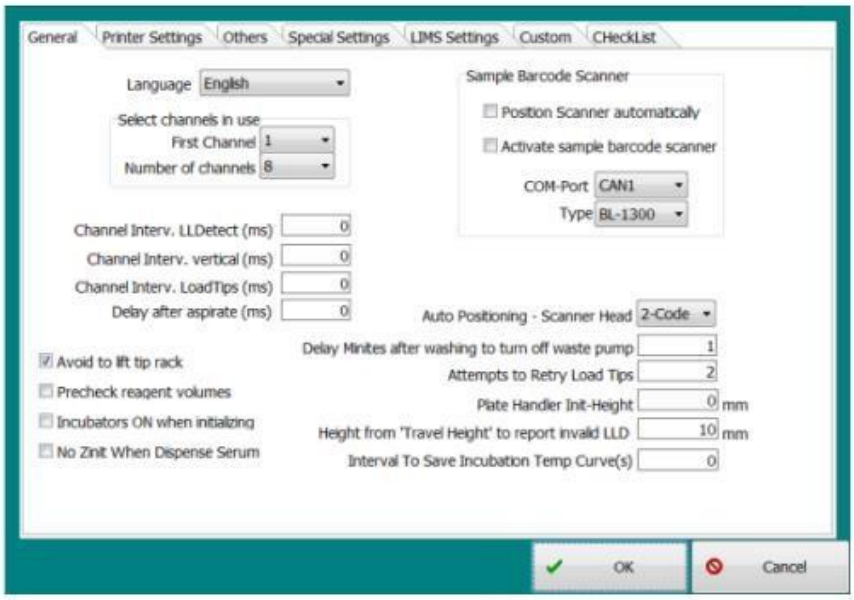
Click "User Manage" under "System Manage", and a new interface will pop up, where users can be added, changed, and deleted, and the user's password and permission can be specified. Each permission corresponds to a menu of the system. It is suggested that the general administrator should be set with all permissions and that the general operator only with routine operation functions.

9.3.2 System Settings

To meet different user requirements during the operation of the instrument, the user can adjust and set some operation parameters of the instrument in the "System Settings" menu so that its operation can better cater to the user's actual needs. The following describes parameters in the System Settings menu

If an option in this menu is modified, the specific function of the instrument will be modified according to the modified option.

1) "General" Tab



Language: Set the operation interface language of the software. Languages include Chinese, English, etc.; after a language is selected, it can take effect only after restarting the software.

Set channels in use: Set "First Channel" and "Number of channels". When a fault in a channel occurs, the faulty tip can be removed and left unused. For example, when the second tip on the instrument with four tips is faulty, "First Channel" can be set to "3" and "Number of channels" to "2". In such case, the 3rd and 4th tips will execute the pipetting process when rerunning the experiment, thus avoiding the delay of the experiment when waiting for the engineer

After repair, the default parameters should be changed by the engineer.

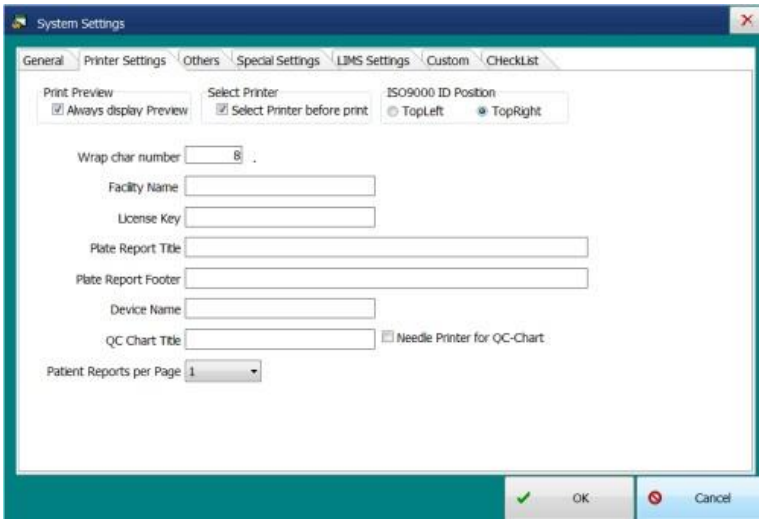
Incubators ON when initializing: It takes some time (about 3-5min) for the incubation temperature to rise. When this option is ticked, the temperature will rise when starting pipetting, if it is not ticked, the temperature will rise to 37℃at the beginning of the incubation step.

Delay after aspirate: After aspiration, the tip will stay in the liquid for a while to ensure sufficient aspiration.

Attempts to Retry Load Tips: The number of retries required when no tip is available or when a probe fails to get any tip.

Sample Barcode Scanner: Select the correct port and scanner type when the barcode scanning function is required.

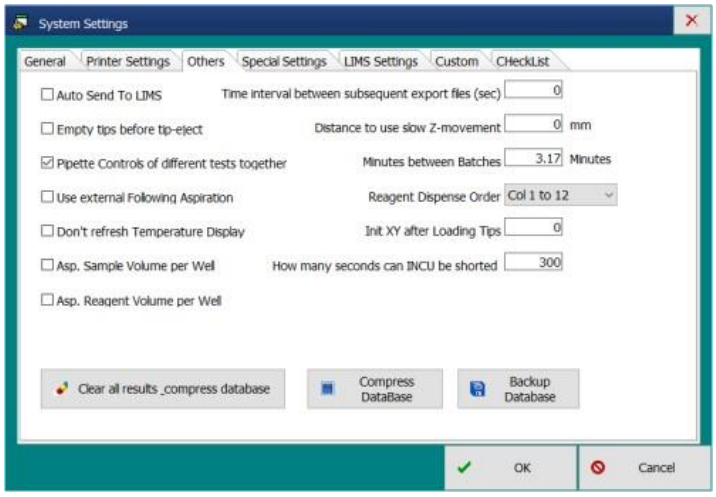
2) "Printer Settings" Tab



This interface allows the user to set some parameters for printing:

Always Display Preview:
It is needed to preview the microplate result when printing the result.
Select Printer before Print:
It is needed to select the printer when printing the experiment result.
ISO9000 ID Position: Position of the ID on the page when printing the microplate result.
Facility Name: Name of the facility using the instrument. After input, it will be displayed in the main interface of the software.
Plate Report Title: The title of the report is displayed as a result when printing the microplate result.
Plate Report Footer: Information which user wants to display at the bottom of the microplate result report to be printed.
QC Chart Title: The title of the report is displayed as a plate chart when printing the QC chart.
Patient Reports per Page: Number of reports that can be printed on one page when printing reports. Generally, a report occupies half a piece of A4 paper, if the paper is not torn in half, select "2", if A4 paper is torn in half in advance, select "1".
For other options, simply set them to their defaults.

3) "Others" Tab



Auto Send to LIMS: It is needed to automatically send the report to the specified folder after the experiment is finished.

Before using this function, first, it is needed to set the sending path of the result file in the Electronic Report Format menu.
The time interval between subsequent export HIS files (sec): Time interval for auto report sending. Generally, it is set to 5S.

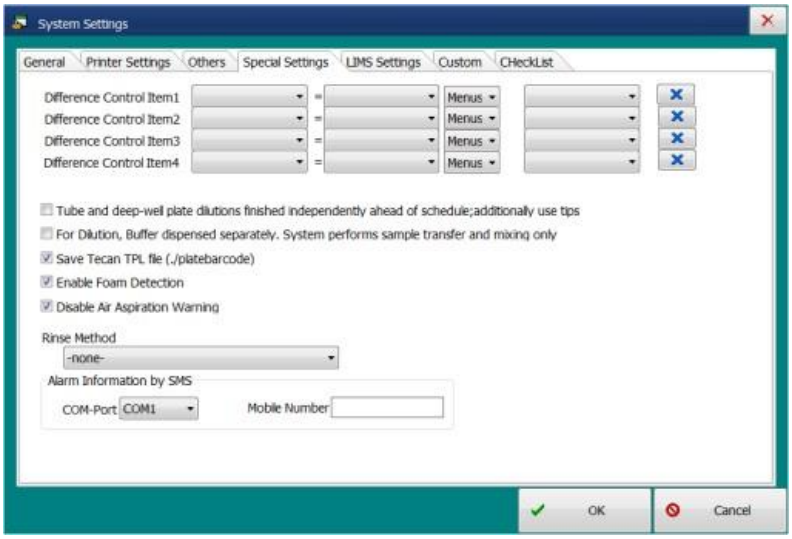
How many seconds can INCU be shorted: If the microplate washer has several positions, to save the running time of the experiment, the 3 microplate washing positions on the microplate washer should be fully used. When the difference in incubation time between microplates is less than this parameter and the microplate washer is to start washing, the microplates can be washed together ahead of time, the default values will be maintained according to the engineer's debugging parameters.

After installation, the engineer will adjust the parameters according to the user's actual needs.

Asp. Sample Volume per Well: The sample dispensing mode is "Asp. Sample Volume per Well". This parameter is used for the pre-delivery accuracy test.
Asp. Reagent Volume per Well: The reagent dispensing mode is "Asp. Reagent Volume per Well". This parameter is used for the pre-delivery accuracy test.
Clear all results _ compress database: Clear the database regularly to save hard disk space and increase the response speed of software. The test method is retained, but the test result is cleared.

Compress Database: Compress the historical data in the database to save hard disk space.
Backup Database: After parameter debugging on the instrument, back up the database to ensure the security of system data.
Reagent Dispense Order: On the instrument with 2 or 4 channels, reagent dispensing can be set to horizontal or vertical dispensing. Default settings are maintained for other parameters under this tab**.**

4) "Special Settings" Tab

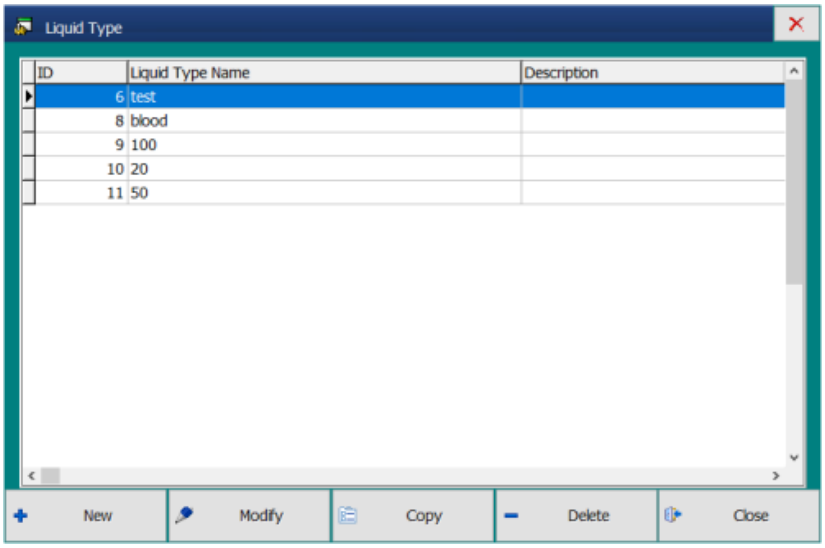


Difference Control Item: This option is an experimental function special for items with special applications. If there is no special item, this option will be left empty. **Remember Level of Repeated Reagents:** If this function is ticked, when the unit probe aspirates liquid again at the same reagent position, the liquid level will not be detected. The unit probe will take the liquid according to the memorized position of the previous item. This applies to the use of the same liquid for several items, which will increase the pipetting speed.
Tube and deep-well plate dilutions finished independently ahead of schedule, use tips: When tube dilution and plate dilution are required, the pipetting process will be executed after all sample dilutions are finished, and tips of the same number as the sample number will be additionally used. Immediately after adding diluent, the sample will be taken for dilution and pipetting will be carried out by default.

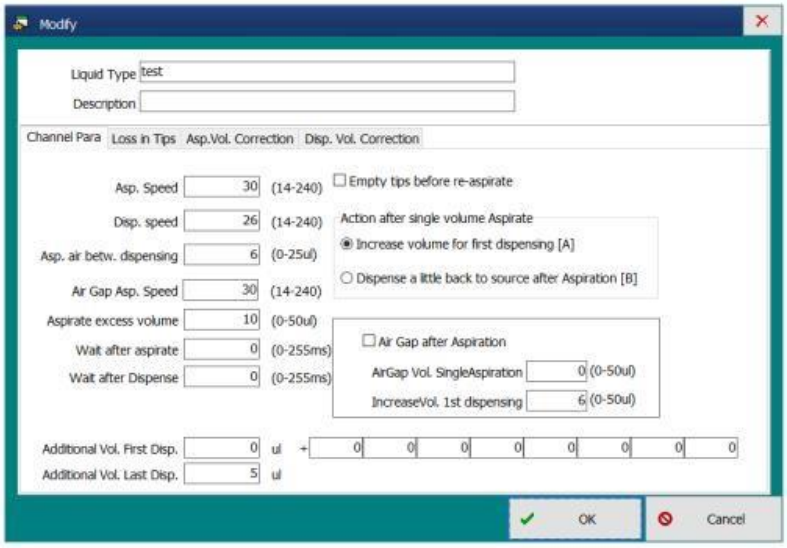
9.3.3 Liquid Type

Options in this menu are used to create and modify different liquid types such as QC and serum to ensure the pipetting accuracy of different viscosities of liquid. Kindly operate with care after modification by the engineer.

After clicking “Liquid Type”, the following interface will appear. In this interface, the user can create, modify, copy and delete different liquid types. In the method edition, select the proper liquid type according to the actual need.



Liquid type mainly includes a set of data and a setting of aspiration/dispensing speed and volume parameters:

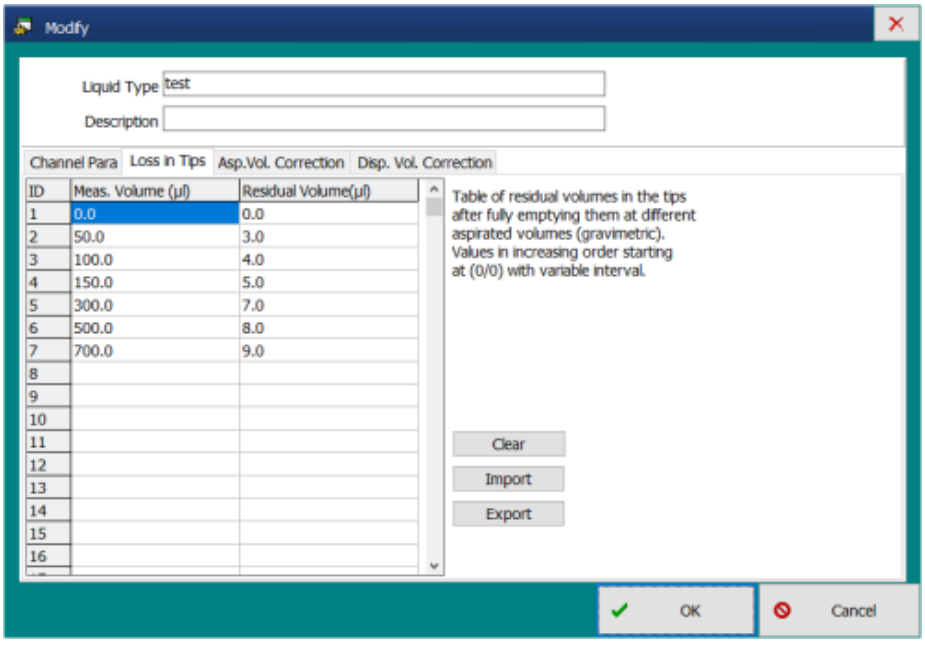


1) "Channel Para" Tab

Description of parameter meaning: For all speed settings in the software, the bigger the value is, the lower the speed will be.

Asp. Speed: The speed of the sample probe pump during aspiration. The accuracy of the sample probe can be corrected by reasonably setting this parameter. Generally, this parameter is set to 38-40.
Disp. Speed: The flow rate of liquid when dispensed by the sample probe. For serum QC, it is generally set to 27-30. This parameter is used to correct the accuracy of liquid dispensing.
Asp. air betw. dispensing: The volume of liquid aspirated back when dispensing is finished. Complete dispensing can be achieved and liquid drops adhering to the bottom of the tip after dispensing can be removed by reasonably setting this parameter. Generally, it is set to 2-3μl.
Air Gap Asp. Speed: The speed of back aspiration after dispensing. Based on the principle that the higher the liquid viscosity is, the lower the speed of back aspiration will be, it can be selected between 27-30.
Aspirate excess volume: Aspirate liquid of a volume enough for debugging. Generally, this parameter is set to 5-10μl.
Empty tips before re-aspirate: For multiple aspirations, the emptying action will be executed before each aspiration. Generally, it is not needed to tick this option since foam can be easily formed after several times of emptying.

2) "Loss in Tips" Tab

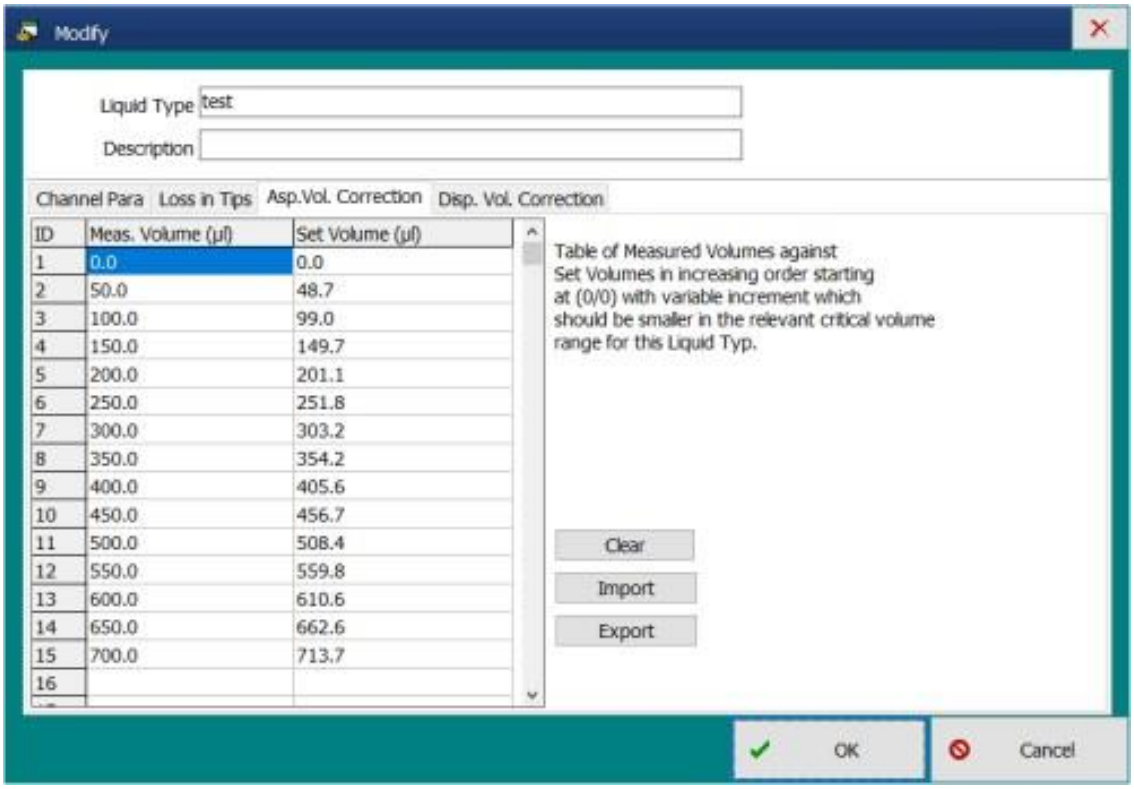


Parameters under this tab are mainly used to control the aspiration accuracy of the unit probe. It is the aspiration curve of the unit probe.

Meas. Volume: It is the target liquid volume and the theoretical volume of aspiration.

Residual Volume: The value for aspiration correction to offset the residual liquid volume on the inner wall of tips.

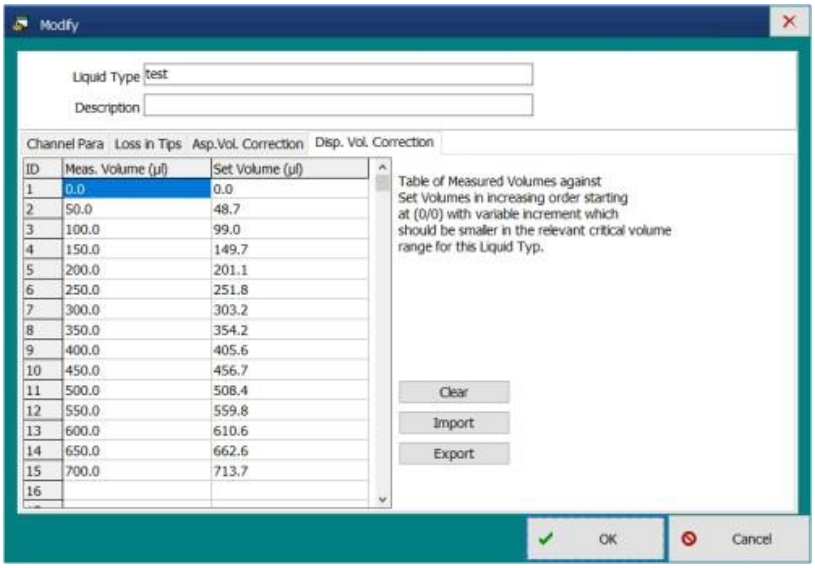
3) "Asp. Vol. Correction" Tab



The aspiration curve is used to autonomously correct the accuracy of aspiration volume.

This parameter is for auto adjustment according to the polyline formed by the parameters under Liquid Type when the software is running. It is unnecessary to add all aspiration volumes involved. Simply input a proper range.

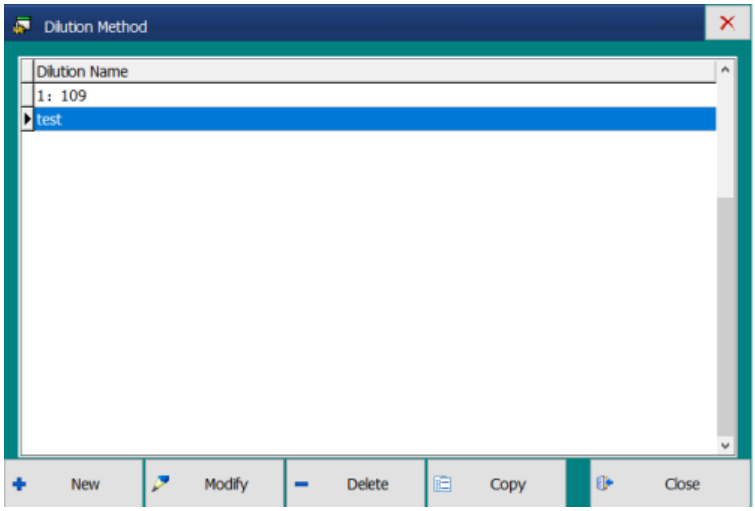
4) "Disp. Vol. Correction" Tab



The dispensing curve is used to autonomously correct the accuracy of dispensing volume.

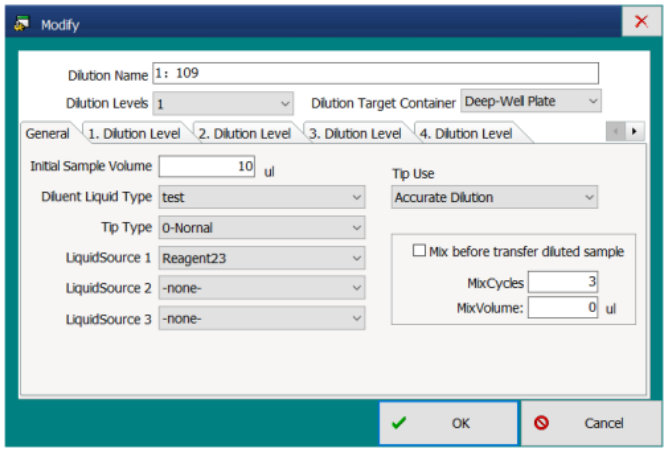
9.3.4 Tube Dilution

After login with administrator permission, click "Tube Dilution Edit" under "System Manage", the following interface will pop up, where the user can create, edit and modify the dilution level as per need. This dilution method is for multi-gradient big ratio dilution (small ratio dilution can be completed in a microplate). It supports dilution in right-side blank test tubes and dilution in special deep-well plates.

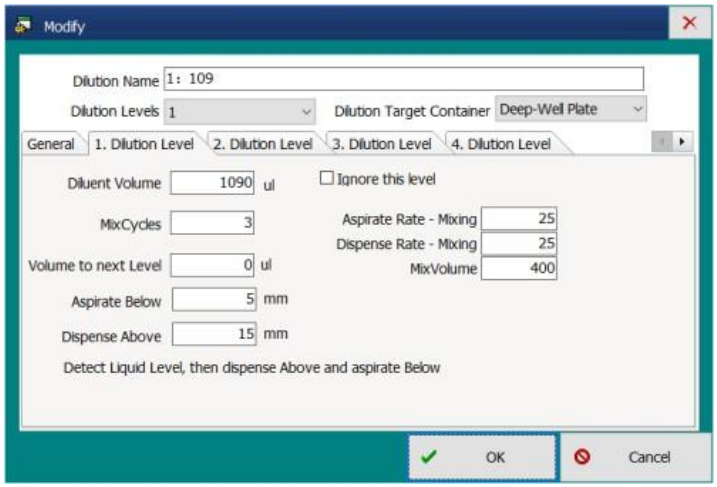


1) Edit Tube Dilution

After clicking "Edit", the following interface will appear:



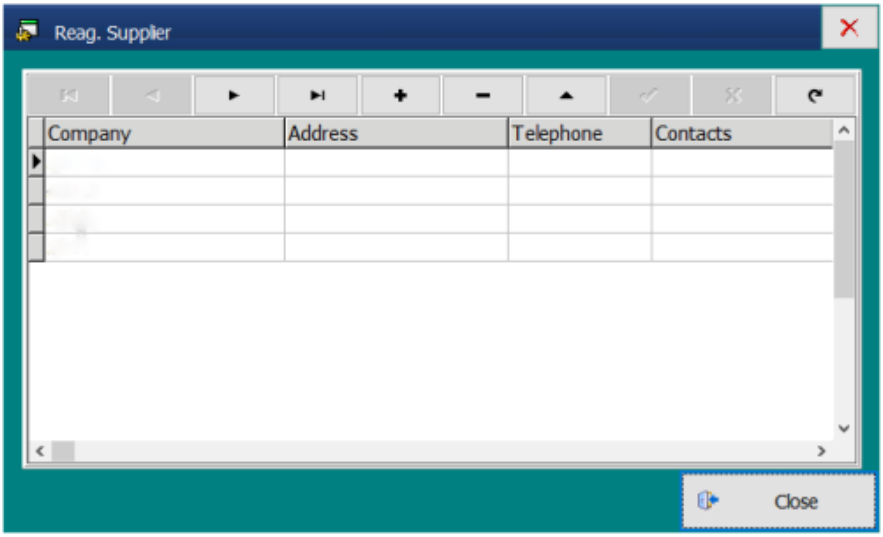
Dilution Name: The name of tube dilution, which is selected in the method step edition.
Dilution Levels: The established tube dilution level (gradient). Determine the dilution level to be established according to the dilution ratio.
Dilution Target Container: There are two options: Right-side Blank Test Tube, Deep-Well Plate.
Introduction of parameters under the "General" tab
Initial Sample Volume: Determine the volume of liquid to be diluted according to the dilution ratio.
Diluent Liquid Type: The type of diluent liquid used.
Tip Type: The type of tip used. Simply select the default type.
Liquid Source Position: The reagent chamber where diluent liquid is stored. The same diluent liquid is placed at positions 1, 2, and 3 to meet the requirement for the large volume of diluent liquid. Introduction of parameters under the "1. Dilution Level" tab:



Diluent Volume: The volume of diluent to be added according to the dilution ratio.
Mix Cycles: The number of mixing cycles after adding diluent.
Volume to Next Level: If the specified dilution ratio is not achieved after Level 1 dilution, based on the volume after dilution, aspirate liquid of the volume for the next level of dilution.
Take the dilution ratio of 1:1000 for example
Set the Initial Sample Volume to 10μl, place the diluent in reagent chamber 1, then click the "1. Dilution Level" tab. In the parameters under this tab, set Diluent Volume to 500 and Mix Cycles to 2, at this moment, the sample is only diluted 50 times, and it needs to be further diluted 20 times to achieve 1000-fold dilution. Therefore, the user needs to input 10μl to the "Volume to Next Level" field under the "1. Dilution Level" tab, and then click the "2. Dilution Level" tab. Under the "2. Dilution Level" tab, set Diluent Volume to 200 and Mix Cycles to 2 to finish the 1000-fold dilution process.

9.3.5 Reagent Supplier

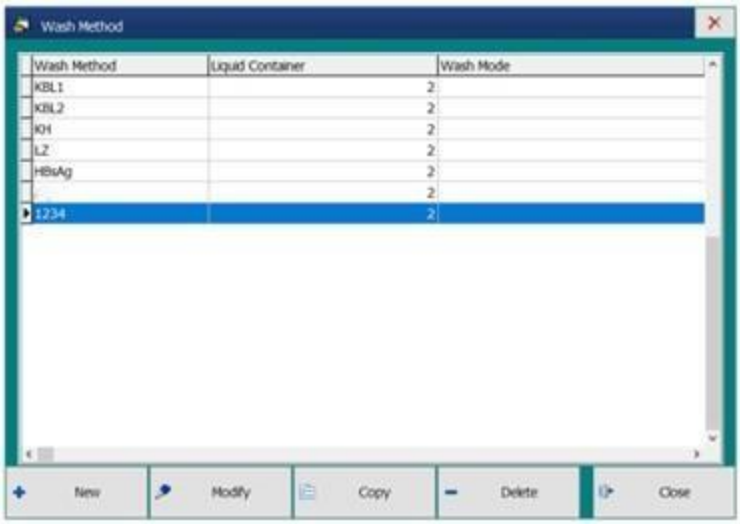
It is used to set the reagent supplier. Users can record the Address, Telephone, and Contacts of each supplier.



After clicking "Add", a blank line will appear, simply enter the information of the reagent supplier and click Save. Information of the reagent supplier can be modified in the same way as how a reagent supplier is added, simply change the information and click Save.

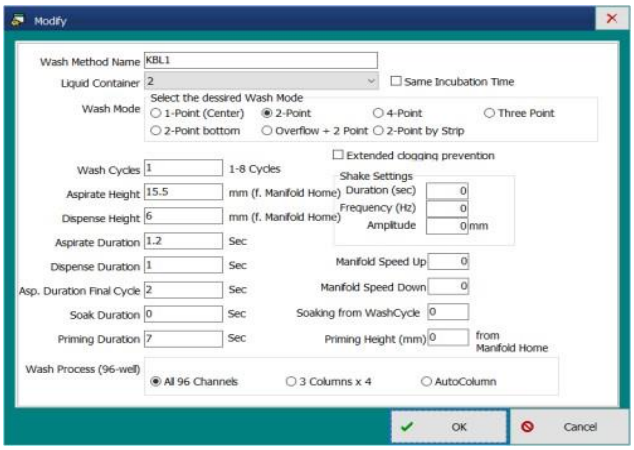
9.3.6 Wash Method Edit

After clicking "Wash Method Edit", the following interface will appear, where the user can create, modify, copy, and delete wash methods.



1) Modify the Wash Method

Click "Modify", the following window will appear:



Input the necessary wash parameters in the window and click OK. Below are the wash parameters:

Depending on the microplate type, different wash methods can be created to ensure the wash quality. The wash mode is also selected in the above interface, the wash parameters will take effect immediately after modification.

Wash Method Name: The name for differentiation when selecting a proper method during method edition.

Liquid Container: Wash liquid from different manufacturers can be placed separately. Select a proper liquid channel.

Wash Mode: Generally, the "2-Point" wash mode is selected, which means after aspiration at the first point, the Z-axis is lifted by 2mm and then aspiration is performed at the second point.

- **2-Point Bottom:** Different from the "2-Point" wash mode, the Z-axis is not lifted after aspiration at the first point, and it directly moves to the second point for aspiration.
- **2-Point by Strip：** Different from the "2-Point Bottom" wash mode, dispensing is performed while aspirating.
- **1-Point (Center):** Wash once at the central point, for the last wash cycle, use the "2-Point" wash mode.
- **4-Point:** A special microplate washer is needed; the wash head can be moved.

Aspirate Height: The distance of movement required for the long probe of the wash head to descend to the bottom of the microplate during aspiration. During debugging, prevent the long probe from pressing the microplate, and keep a 0.5-1mm clearance between the long probe and the bottom of the microplate.
Dispense Height: The distance of movement required for the long probe of the wash head to move to the upper edge of microplate wells during dispensing. The long probe is moved to the upper edge of microplate wells for timely absorption by the vacuum pump in case of excessive dispensing volume, thus avoiding contamination among the wells.
Aspirate Duration: The time of aspiration by the long probe at each point. Generally, it is set to 1s or 1.5s.
Dispense Duration: The time required to fill the microplate with wash buffer during dispensing by the short probe. Generally, it is set to 1s.
Asp. Duration Final Cycle: The time of aspiration by the long probe at each point during the last wash cycle. Generally, it is set to 2s.
Soak Duration: The time of soaking required after the short probe finishes dispensing, which varies with the reagent.
Priming Duration: When two methods use different wash buffer containers for plate washing, it is needed to flush out the wash buffer in the first container, and then fill the pipeline with the wash buffer in the second container. This parameter is the time required to complete the aforesaid action, which is generally set to 3-4s.
Priming Height: The height of the Z-axis from the origin when executing the priming action. **Wash Process (96-well):** All 96 Channels: The whole plate washing process is used, which means during dispensing, the wash head is also opened to inject liquid into the microplate wells. 3 Columns × 4: The liquid injection mode during plate washing is 3 Columns × 4, which means after completion of liquid injection of the first three columns, the following three columns are open, and so on. Auto Column: Automatic calculation is performed according to the number of experiments, and the wash head is opened taking 3 columns as the base.

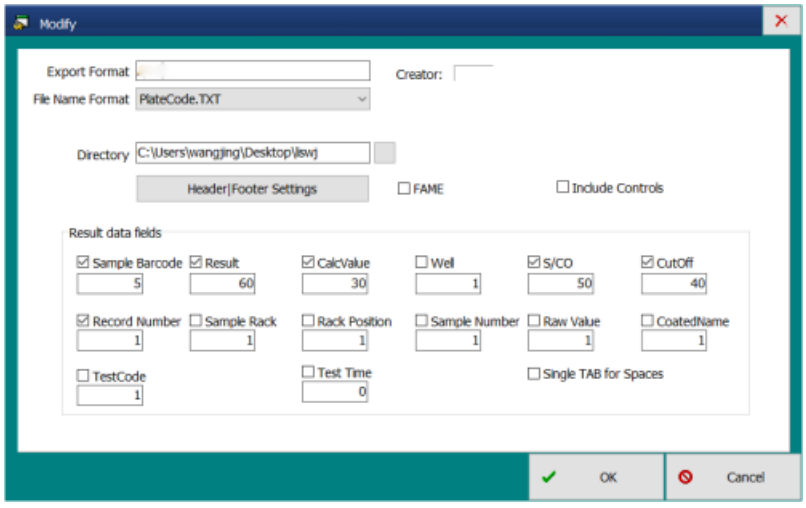
The three wash processes require different pressures of the pressure tank. Our default parameters are used, which should not be changed.

Number of Shakes: The shake function can be added to the wash process to achieve shaking after dispensing. The value is adjustable. It is set to 0 by default or when this function is not used.
Frequency: Adjust the shake frequency during plate washing. It is set to 0 by default or when the shake function is not used.
Amplitude: Adjust the shake amplitude during plate washing. It is set to 0 by default or when the shake function is not used.
Manifold Speed Up: Allow the wash head to move up with the liquid surface, thus achieving the follow-up dispensing function. It is set to 0 when this function is not used.
Manifold Speed Down: Allow the wash head to move down with the liquid surface, thus achieving the follow-up aspiration function. It is set to 0 when this function is not used.

Add wash buffer during plate washing: Generally, wash liquid should be configured and added before the experiment. If the wash buffer is inadequate during plate washing, the software will generate an alarm. Since the pressure in the wash buffer container is too high, pressure relief (i.e., opening the quick connector) is needed before opening the container cover.

9.3.7 Electronic Format Setting

After clicking Electronic Format Setting, the following interface will appear:

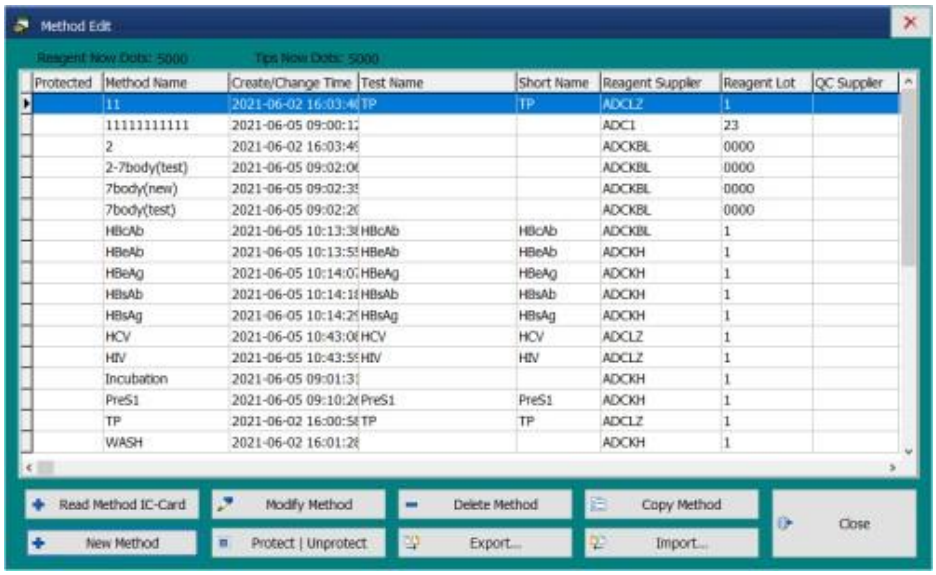


This menu provides the electronic report format for communication with LIS/HIS. Users can perform creation, modification, copying, deletion and other operations. Before completion of installation, the engineer will communicate with the LIS manufacturer to determine the electronic report format which does not need to be further modified thereafter.

Export Format: The name of the report format. After creating a proper name, it is selected during the method edition.
File Name Format: After an experiment is finished, the result will be exported in a certain format. Generally, the default format is used: PlateCode.TXT.
Directory: The path for export of experiment result. After establishing a result folder, simply select the directory in this interface.
Header Footer Settings: Whether the result file in PlateCode.TXT format contains header/footer information. After clicking "Header|Footer Settings", the user can set the header/footer information of the report.
Result data fields: Tick to select the experiment result information to be sent to LIS.

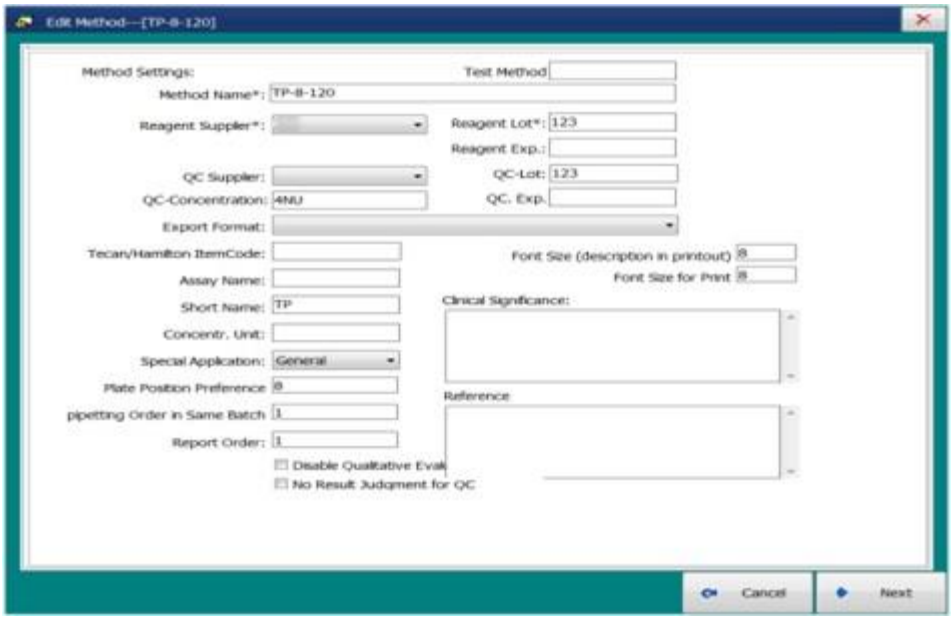
9.3.8 Method Edit

The Method Edit menu allows the user to edit the experiment method according to the Instruction Manual for reagents. After clicking Method Edit, the following interface will appear, where the user can create, edit, copy and delete methods, also, import, export and shield operations can be performed.



1) Create and Edit Method

1. Set basic parameters such as method name, reagent used, and QC. "*" representsthat it is a required field.



Information such as Reagent Supplier, QC Supplier and Export Format are all pre-established in the "Reagent Supplier" and "Electronic Report Format" menus, which can be simply selected and called when establishing the method.
Assay Name: The assay name of the new method.
Short Name: The short name of a new method in English, for example, the short name of surface antigen is HBsAg.
Concentr. Unit: The unit of concentration value in the ELISA experiment result.
Clinical Significance: Clinical explanation of different concentration values in the result.
Pipetting Order in Same Batch: The pipetting order of the experiment in the batch if the batch experiment is performed (i.e., several experiment items are simultaneously performed in each batch).

 It is suggested to completely input the above information, thus, providing sufficient data for report printing and result reception by LIS.

2. **After entering the basic information, click "Next" to set the plate chart. When setting the plate chart, the user can design the plate chart according to requirements.**

   To meet the requirements, the system provides several basic well types. Their meanings are described as follows:

   NU: It stands for null well, indicating that there is nothing and the system will not calculate this well.

   BL: It stands for blank correction well, which is used when calculating the blank correction value.

   NC: It stands for negative control. It has no special application and is for formula calculation only.

   PC: It stands for positive control. It has no special application and is for formula calculation only.

   H: It stands for high-value standard. It has no special application and is for formula calculation only.

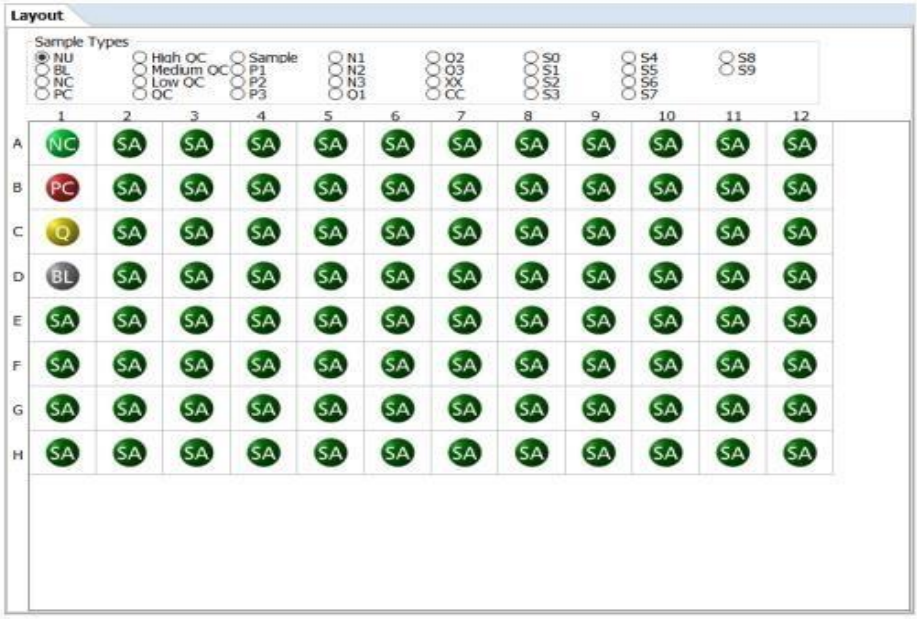
   M: It stands for medium-value standard. It has no special application and is for formula calculation only.

   L: It stands for low-value standard. It has no special application and is for formula calculation only.

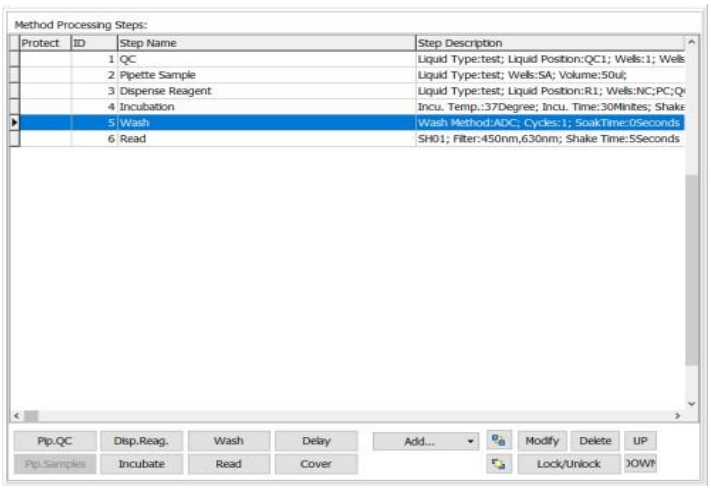
   QC stands for QC material: It has no special application and is for formula calculation only.

   SA: It stands for sample, indicating the sample-adding position.

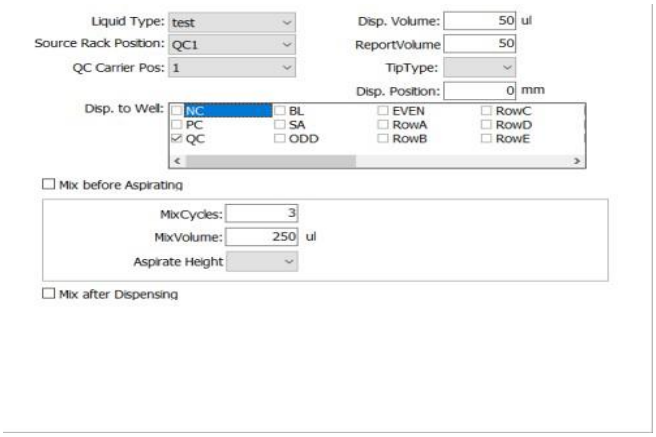
   S0-S9: These are calibrator-adding positions, which are used to calculate the calibrator curve and obtain the sample concentration value.



3. Click "Next" to set the method steps. Add steps according to the pipetting order in the Instruction Manual for reagent.



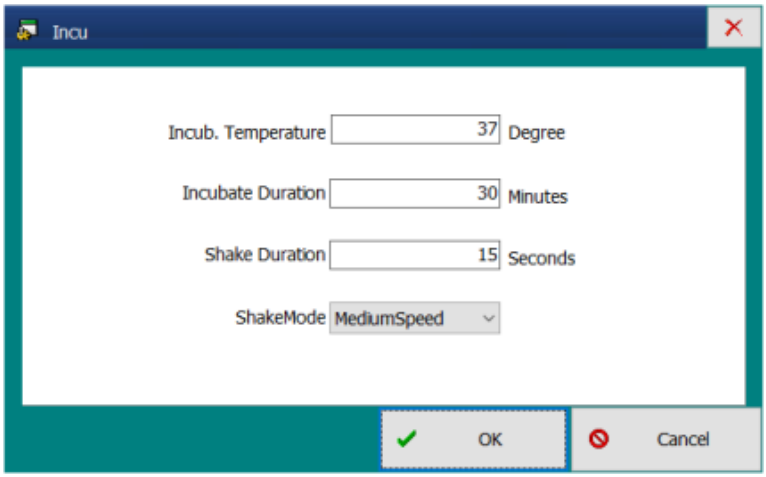
(1) **QC dispensing method:** Click Dispense QC to enter the following interface



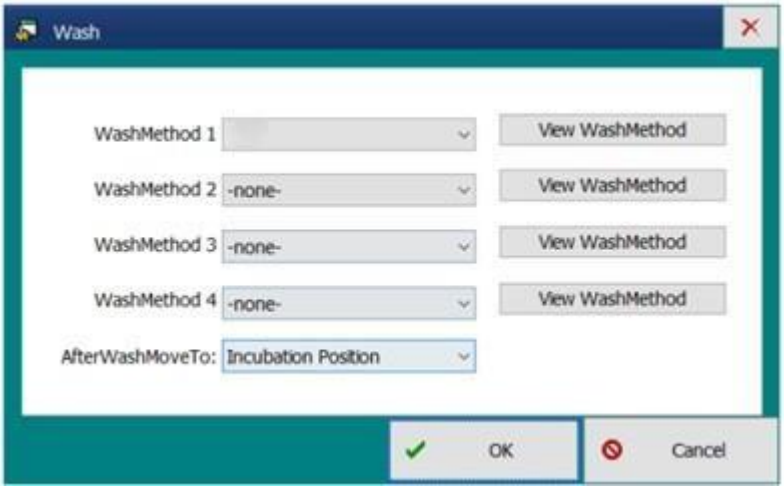
Liquid Type: The type of liquid to be dispensed.
Disp. Volume: The volume of liquid to be dispensed.
Source Rack Position: The No. of QC rack where QC is placed.
QC Carrier Pos: The No. of well on the QC rack where QC is placed.
Disp. to Well: The well of the microplate to which the liquid is to be dispensed. Refer to the plate chart.
Disp. Position: When Disp. Position is set to 0, it indicates dispensing will be performed above the microplate (at the Travel high value). If the digit (7) is input to the field, it indicates dispensing will be performed 7mm below the microplate (7mm below the Travel high value). The default is 0.

(2) Liquid, sample, and QC are dispensed by the same method. Refer to the QC dispensing method.

(3) **Add/Incubation:** Set incubation parameters for the sample

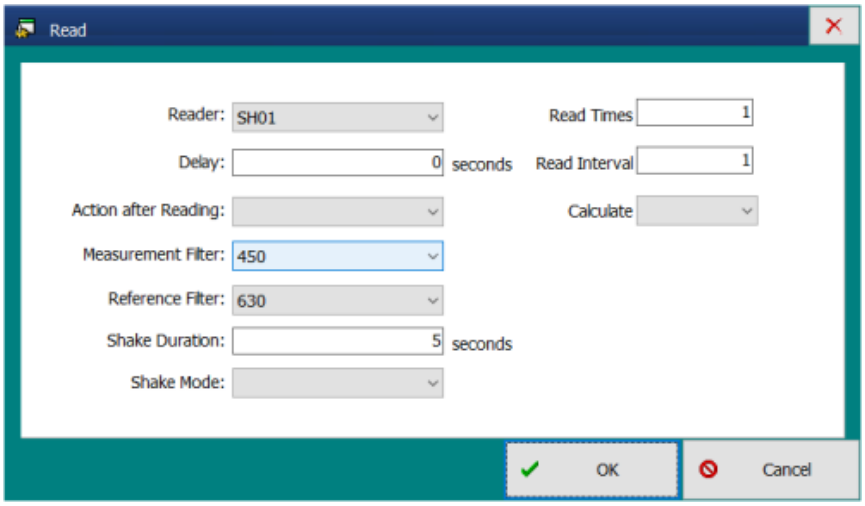


(4) **Add/Wash:** Set wash parameters for the sample. Set the wash process in the Wash Method Edit interface, and simply select the wash method in the method edition.



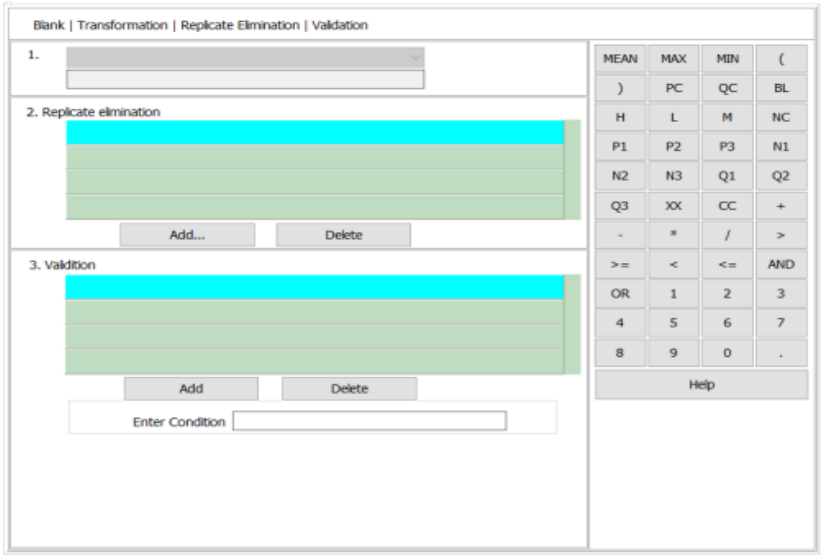
(5) **Add/Read:** Simply set to the defaults and click OK.

ELISA analyzer:



ELISA experiment is performed. Correctly input the wavelength and shake intensity of the optical filter as required in the Instruction Manual for reagent.

4. After adding the experiment steps, click Next to enter the following interface: set the reading interpretation rule and the experiment's effectiveness.

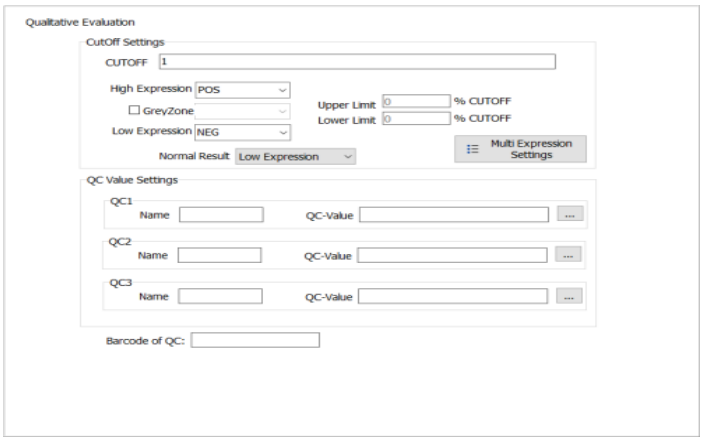


- For the ELISA experiment, select blank control and select the blank well calculation method. Generally, the user can simply select mean (BL).
- Input the experiment effectiveness condition according to the Instruction Manual for reagent. The right side of the above figure shows the common calculation commands. In the "Enter Condition" field, input the calculation

formula by clicking in the right-side area. For example, input "mean(nc)<=0.05 and mean(pc)>=1.5" to the condition field and click "Add".

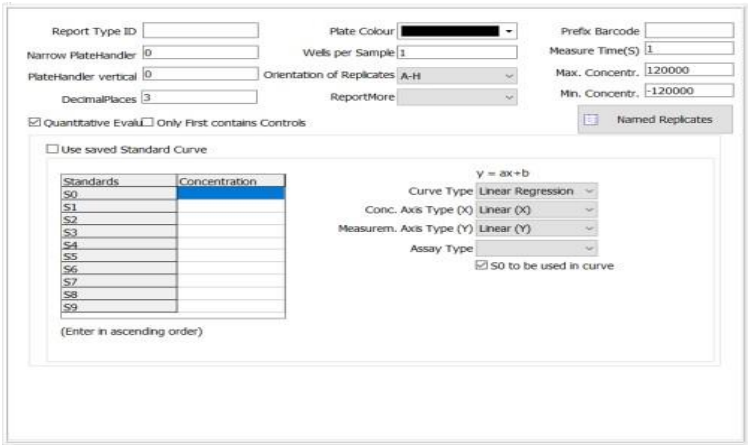
5. Next, input the reference values from the Instruction Manual for the reagent to the "High Expression" and "Low Expression" fields of CUTOFF.

b.



- For CUTOFF input, edit the formula or calculate directly as required in theInstruction Manual for reagent. Click to edit the formula.
- **High Expression/Low Expression:** The result expression (negative or positive)of the sample is higher/lower than the cutoff. For example, the high expressionof HBsAg is positive, and the high expression of HBeAb is negative.
- **Grey Zone:** After the Grey Zone is ticked, the weakly positive range will be defined. Range setting depends on the user's actual condition. The upper Limit/Lower Limit is the percentage relative to the cutoff.
- **QC Value Settings:** If the user requires QC of some items, the QC well should be set during layout. Input the QC "Name", then click on the right side of"QC-Value" and input the method for calculation of QC value.

6. Select the Quantitative Evaluate checkbox, input Calibrator Concentration, Curve Type, and other parameters necessary for calculation according to the InstructionManual for reagent, then click Finish.



7. Edit Method

The method can be edited similarly to the creation of a new method. First, select the method to be edited, and click "Edit Method". Modify the information item by item according to the wizard. Method edition will not affect existing experiment results, it will only affect future result judgment. The microplate result contains a description of the then-current method. If the experiment is terminated unexpectedly and then restarted after the method edition, it is needed to click "Refresh".

8. Copy Method

This function allows the quick creation of an experiment method same as the existing method. First, select the method to be copied, and click "Copy Method". In the pop-up window, simply input a method name.

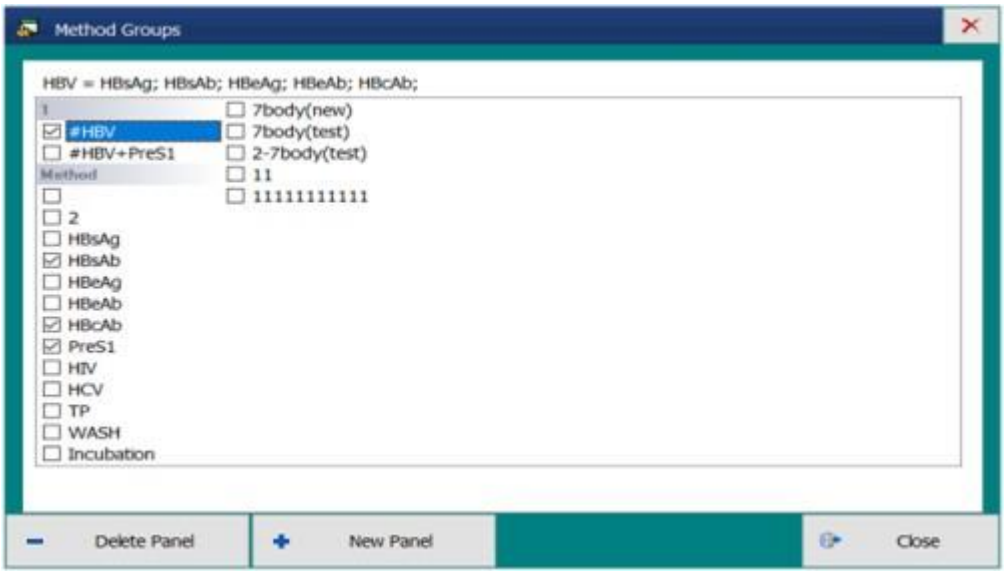
9. Shield Method

In the process of method edition, method steps can be shielded. When the experiment is restarted after shielding, the instrument will not execute the shielded steps. Click "Shield/Un shield Method" to shield or un shield the experiment method.

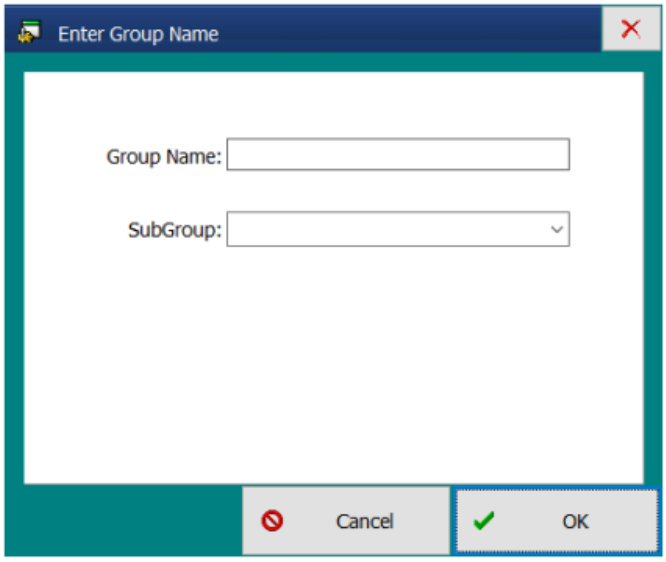
9.3.9 Method Group Manage

Method group management is mainly for the management of common experiment items, which facilitates the user's operation, before the start of the experiment, the user simply needs to group the common methods without the need to select experiment methods in sequence.

After clicking “Method Group Manage”, the following interface will appear:



1) Create Method Group After selecting the experiment methods for grouping, click “Methods Selected for New Group”, and the following interface will appear:



Input “HBV” and click “OK” to save as a method group named “HBV”. To perform the HBV experiment, simply select the group name.

2) Delete Selected Group

After selecting the method group to be deleted, simply click “Delete Selected Group” to delete this group.

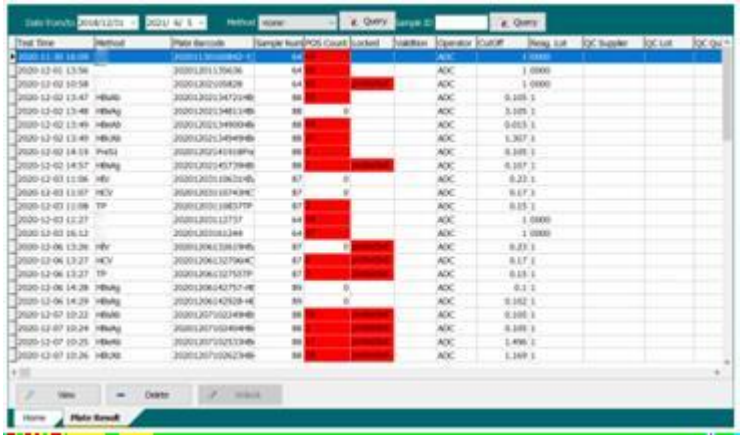
9.4 Routine Work

In this menu, the user can view routine experiment operations and experiment results.

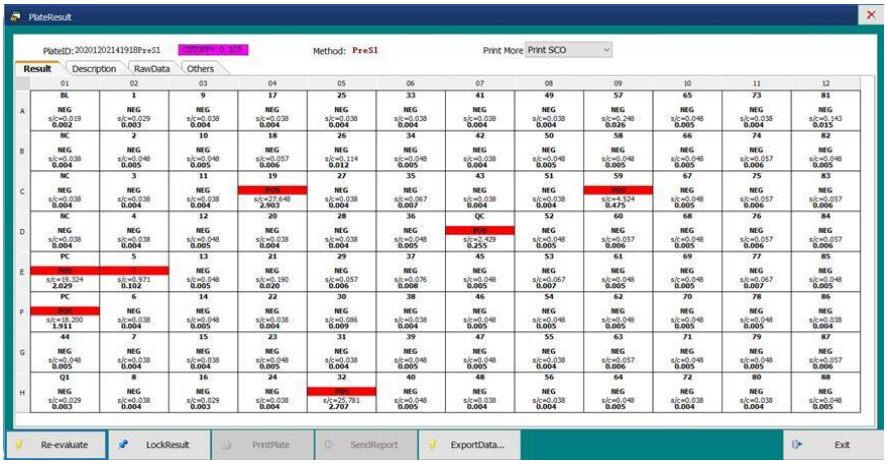
1) Kindly refer to the test process.

2) Experiment Results

In this menu, the user can view and query the experiment results. After clicking "Experiment Results", the following interface will appear:



Test Time: The user can query results within a specific time range.
Method: The user can query a specific experiment method.
Print: Print the experiment results within a certain time range using a certain method.
View: View details of the experiment results of a certain lot.
Delete: Delete the experiment results of a certain lot.
Unlock: Unlock the sample results of this lot so that the user can modify the results.
After selecting an experiment item in the above interface, the user can click "View" to view the experiment result, as shown in the figure below:



3) **"Plate Result" Tab:**

Re-evaluate: Re-save and check the result information.

Lock Result: Lock the result to prevent the operator from deleting the experiment result.

Print Plate: Print the plate chart information for backup, query, etc. This operation can be performed only after locking.

Send Report: Manually send the experiment result to LIS. This operation can be performed only after locking.

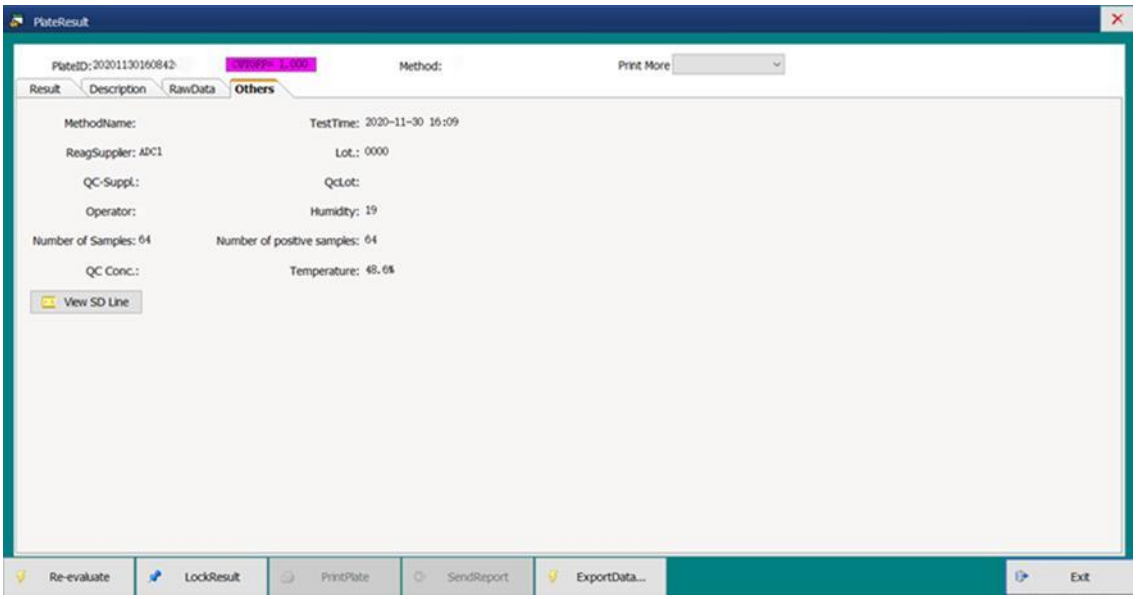
Export Data: Save result data in Excel format, which can be used only for commissioning by the engineer.

"Description" Tab: It covers the whole process of the experiment method, including such information as experiment steps and aspirate/dispense volume.

"Raw Data" Tab: It is used when the operator or engineer needs to view the raw reading of a calibrator or sample during the experiment.

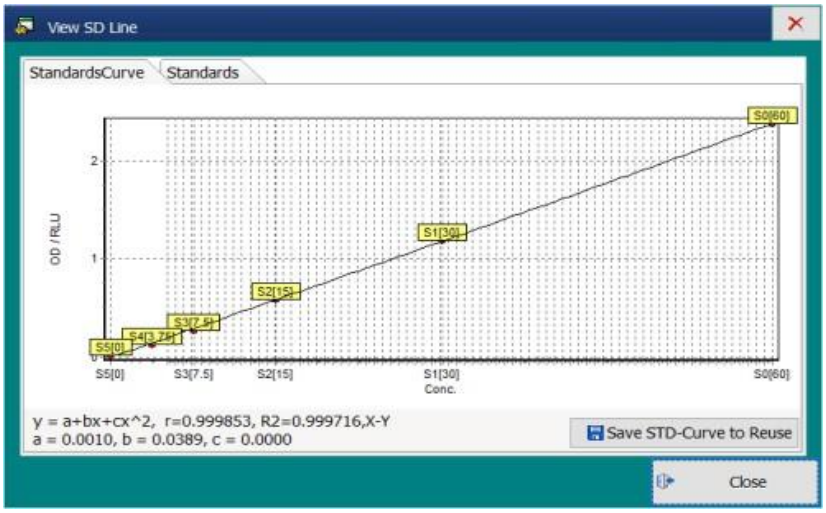
"**Others" Tab:**

⚠ Content under the "Others" tab mainly includes key parameters in a test method, which are used as the header of the printed microplate result. If a backup needs to be saved, kindly correctly fill in the parameters in the Method Edit interface.



⚠ Under the "Others" tab of the ELISA test method and result, click "View SD Line" to View the calibrator curve of this experiment. The operation is detailed as follows:

4) Click "View SD Line" to enter the following interface:

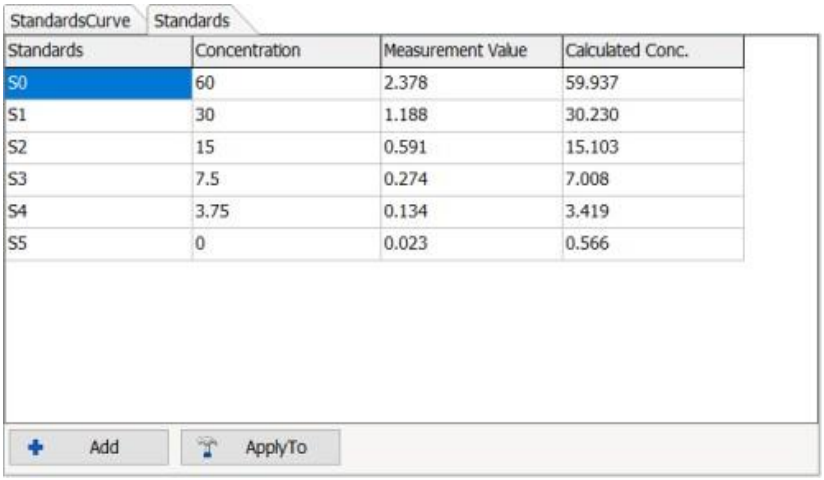


In the Standards Curve interface, the user can view the linearity of the standard curve, the curve calculation method and other parameters.

Save STD-Curve to Reuse: This button can realize the use of the same calibrator curve for the same lot of reagents used for the same item, the curve template can be directly used in the next experiment.

5) Click the "Standards" tab to enter the following interface:

In this interface, the user can compare the standard concentration of the calibrator with the actual test concentration, thus, to determine the effectiveness of this experiment.

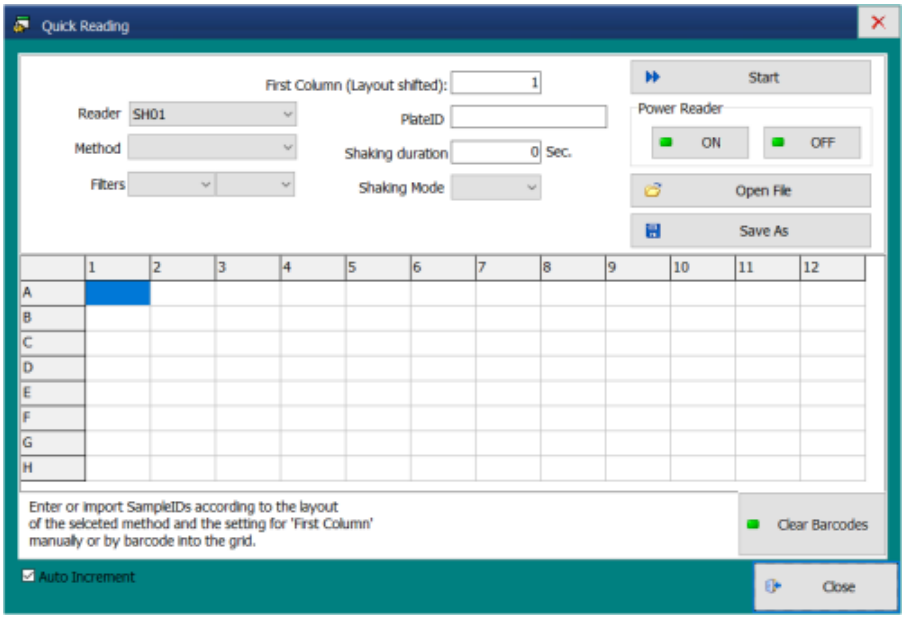


Standards	Concentration	Measurement Value	Calculated Conc.
S0	60	2.378	59.937
S1	30	1.188	30.230
S2	15	0.591	15.103
S3	7.5	0.274	7.008
S4	3.75	0.134	3.419
S5	0	0.023	0.566

6) Quick Reading

The Quick Reading menu provides a separate reading step. For manual experiments, the instrument can be used to read and transmit the result. Quick Reading can beused if there is no conflict with the reading running on the instrument.

1. Click “Quick Reading” to enter the following interface:

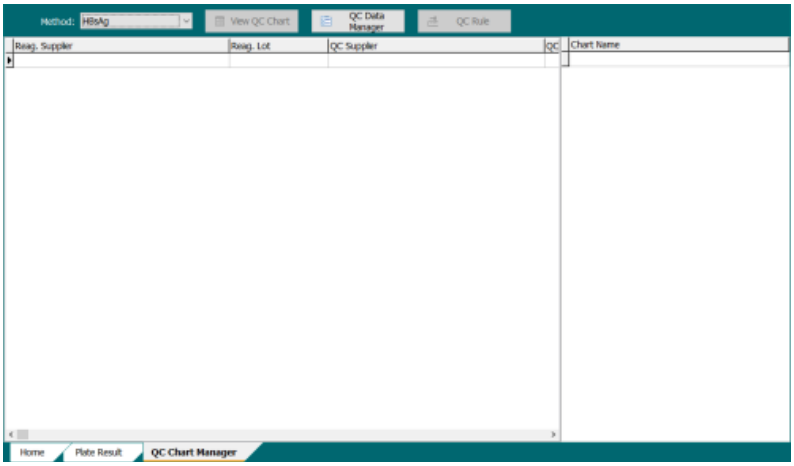


2. After selecting the method name, click “ON” under Power Reader, after inputting the sample layout, click “On”.
3. After start, place the microplate, and click “Close”.
4. When the cabin door of the ELISA instrument is closed, click “Start”, the instrument will start reading.
5. After reading, the result will be saved in the test result.

7) QC Chart Manager

The QC Chart Manager menu allows the summarization of QC values of all experiment items and shows them in the form of a chart. Users can modify and print the QC chart of each item in this menu.

1. Click “QC Chart Manager” to enter the following interface:



2. After selecting an experiment method under "Method", the user can manage QC chart data with the "View QC Chart", "QC Data Manager" and "QC Rule" buttons.

   To view the QC data of an experiment item or allow the recording of such data into the software database, it must be guaranteed that the QC well and QC well calculation method have been set in the corresponding experiment method. See the process in Method Edit.

8) Result Summary

1. The Result Summary menu allows query and summarization of results within a certain period.
2. The query can be performed by sample ID or result value. There are:
   - Single-item Summary and Multi-item Summary.
   - Multi-item Summary allows a multi-item summary of the results of differentsamples within a certain period.
   - Single-item Summary allows a single-item summary of the results of different samples within a certain period.

Date from/to: Select the time range for the query.
Sample Barcode: Enter the barcode for the query.
Result: Select the expression corresponding to the negative/positive result in the experiment method.
Sample ID: Enter the Sample ID for the query. It is the Sample ID prepared by the operator before the experiment.
Query: Click it to query based on the entered information.
Print: Print the query result.

9.5 Report Manager

This menu is the main window for entering patient information. For daily sample tests, it is needed to enter the patient information of the sample before printing the corresponding laboratory test report. This menu is mainly for users without LIS to manage patient reports.

9.5.1 Dictionary Setting

Dictionary Setting is a quick action that avoids repeated input when entering patient information. Users can set Common Dept. Info, Doctor Info, Doctor Advice, etc., after setting, quick selection can be achieved when entering patient information.

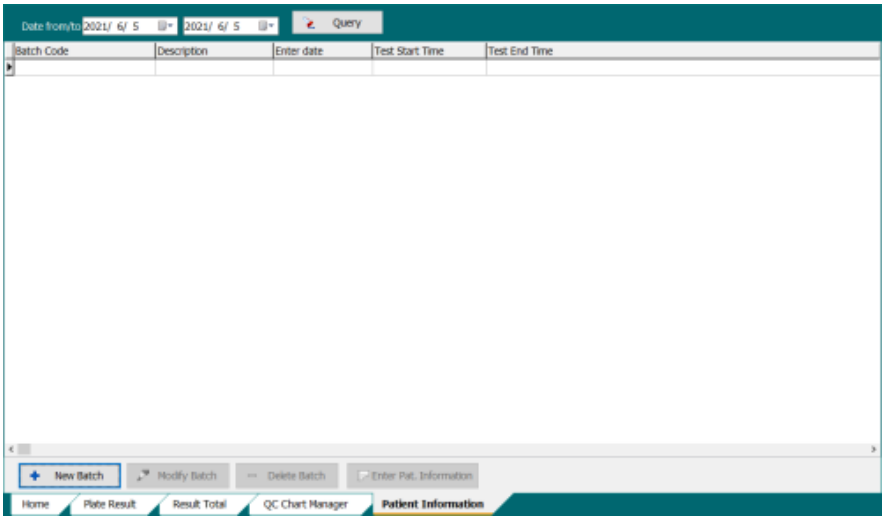
9.5.2 Report Format

Report Format provides a report template, which is created according to user requirements and generally does not need to be changed after establishment. Before handover by the engineer, it should be designed according to user requirements, if change is required.

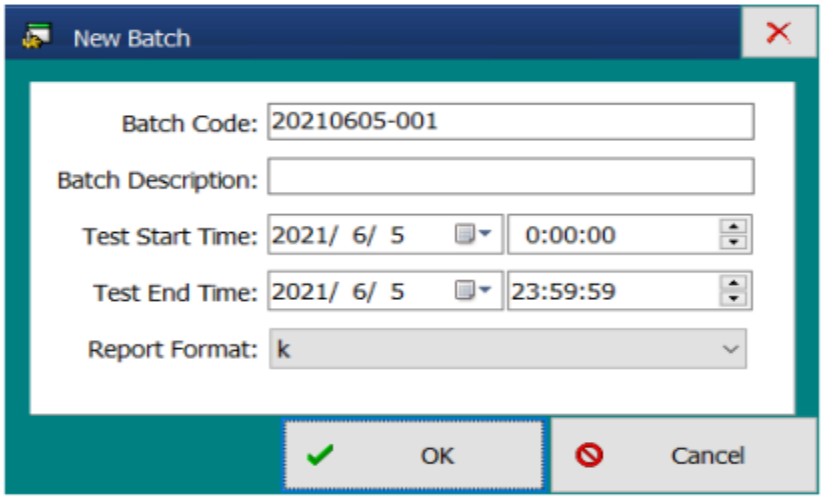
9.5.3 Sample Information

Sample Information is for printing laboratory test reports, and patient information is entered into the system ahead of time or when the experiment is finished.

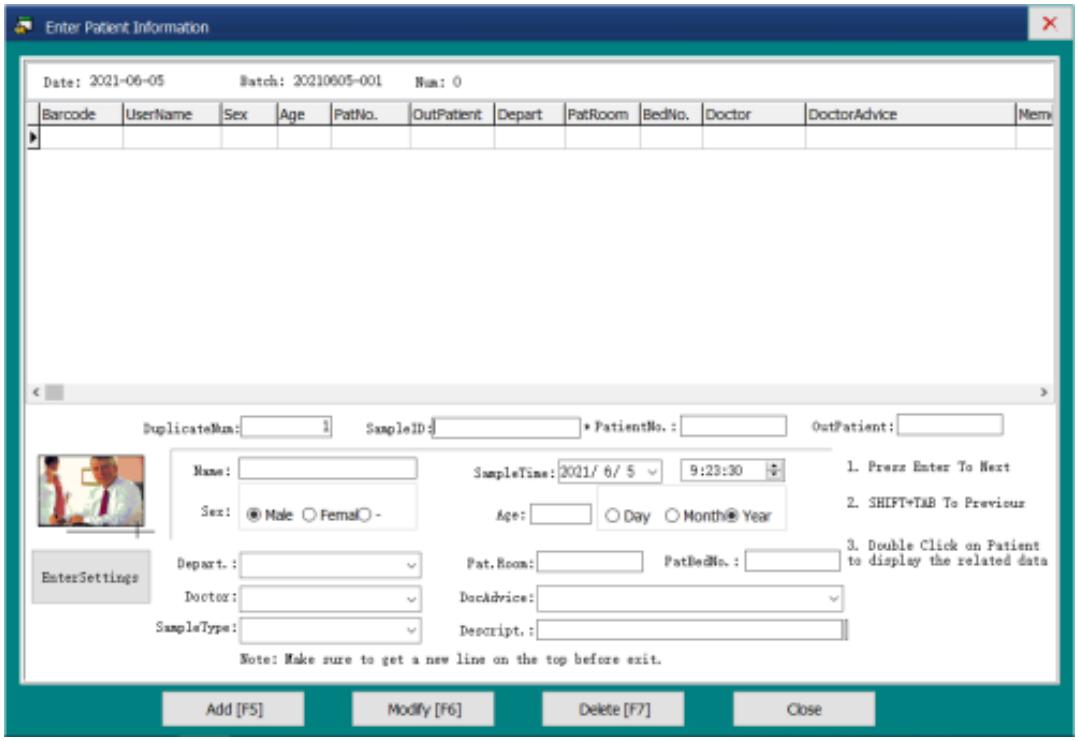
1. Click "Sample Information" to enter the following interface:



2. After creating a new batch, the following interface will appear. After a brief description of the batch, select the Report Format, and click OK.



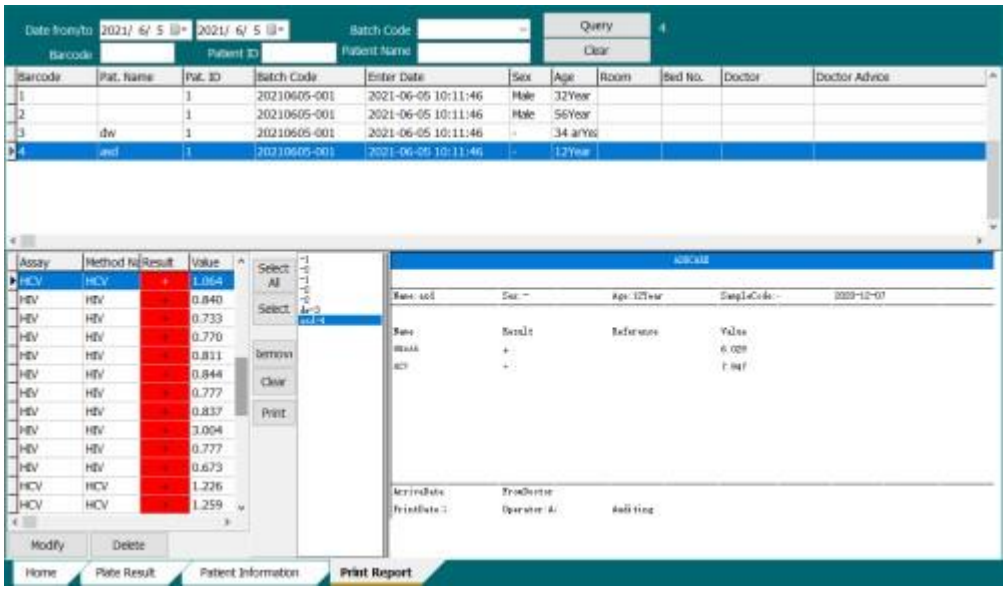
3. Click Enter Patient Information, as shown in the window below, and enter the patient information according to the actual sample order. After entering the information, simply click Close.



4. For a new batch, the batch No. should be associated, and the associated batch No. can be modified in the Batch Edit interface. Enter the patient information item by item according to the sample. Patient information items can be input quickly using the [Enter Settings] button. Sample barcodes can be added automatically.

5. Print Report

Print Report is to print experiment results in the format of the laboratory test report. Click “Print Report” to open the following window, where the user can print all or selected microplate results.



The above figure shows the Print Report interface:

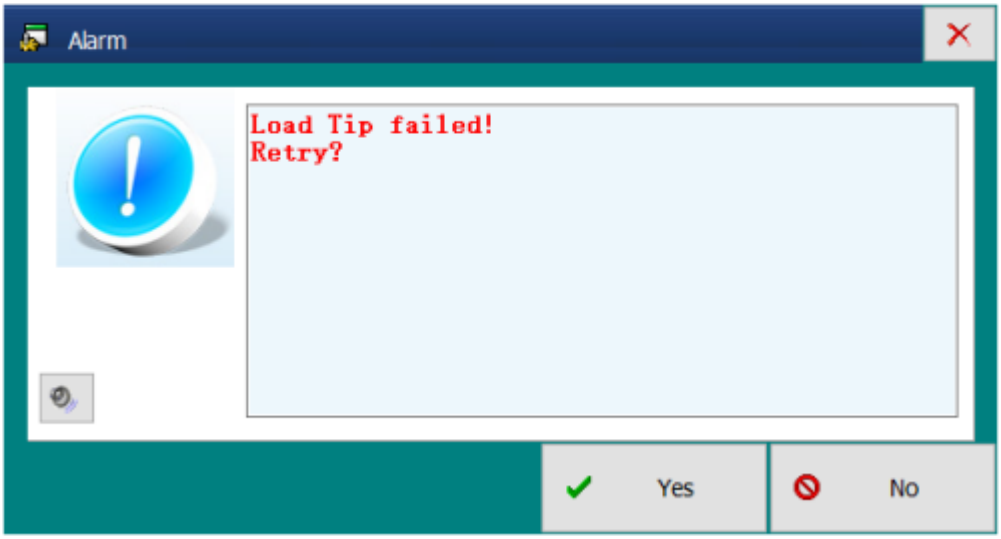
1. The upper part of the interface shows information entered in Patient Information.
2. The lower left part of the interface shows the result data of each patient, which can be modified by the operator before printing the report.
3. The lower right part of the interface shows the report of the patient in the form of a simulative report.

9.6 About Interface

9.7 Alarm Messages and Handling

9.7.1 Load tip failed:

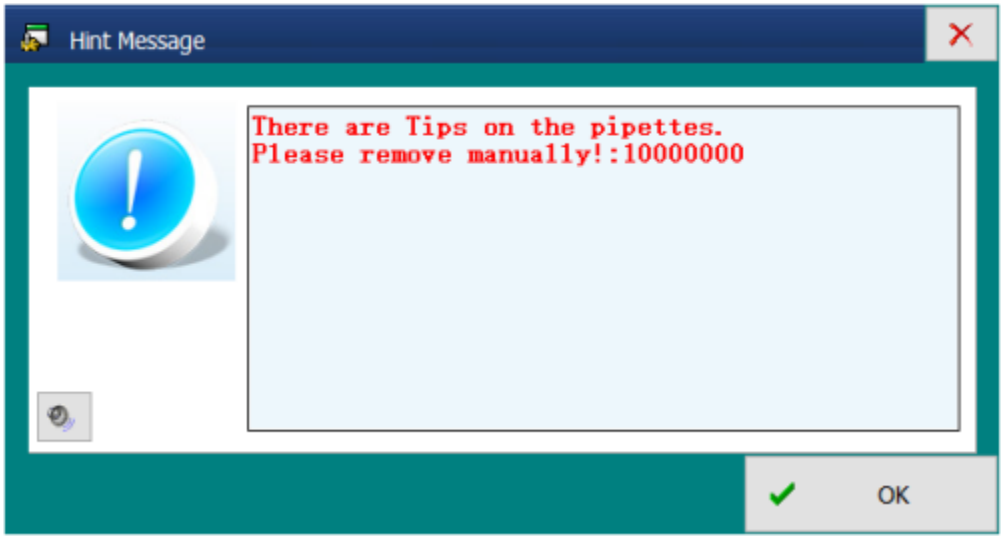
Cause: No tip is available or the tips loading detection sheet is too short.



Solution: Check whether there are tips in the tip box. If any, click "Yes". If this problem occurs frequently.

9.7.2 There are tips on the pipettes:

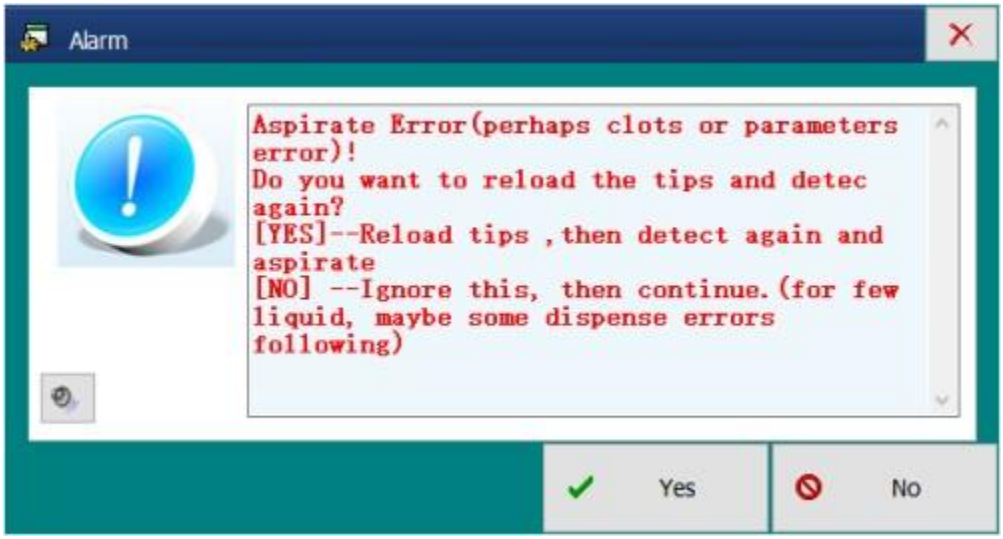
Cause: After the experiment is terminated unexpectedly, the tip is not removed when re-running the experiment.



Solution: Remove the tip.

9.7.3 Aspirate Error (perhaps clots or parameters error):

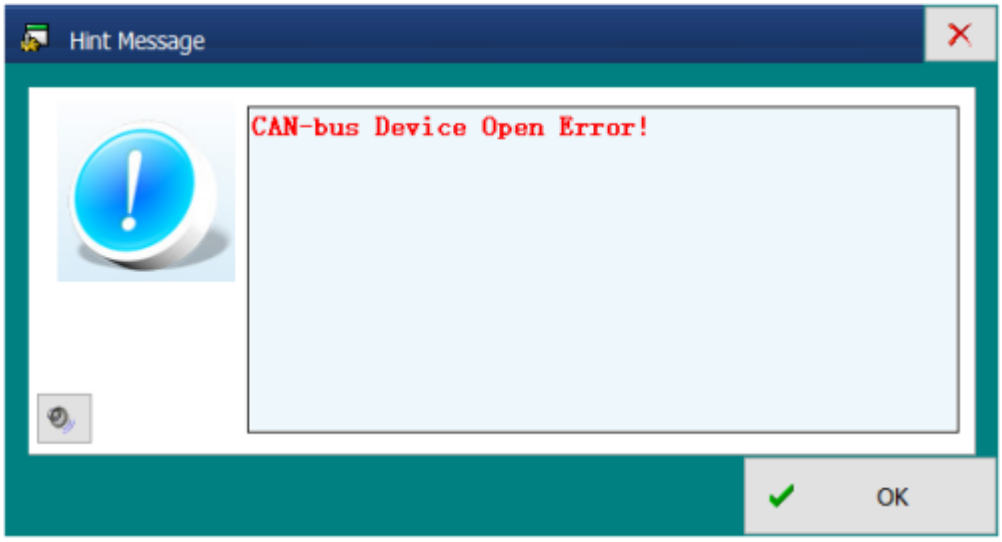
Cause: Grume or fibrous protein is contacted during aspiration, or the tip is clogged.



Solution: Replace the tip after re-treatment of serum, click "Yes" or replace the tip for re-detection.

9.7.4 CAN-bus Device Open Error

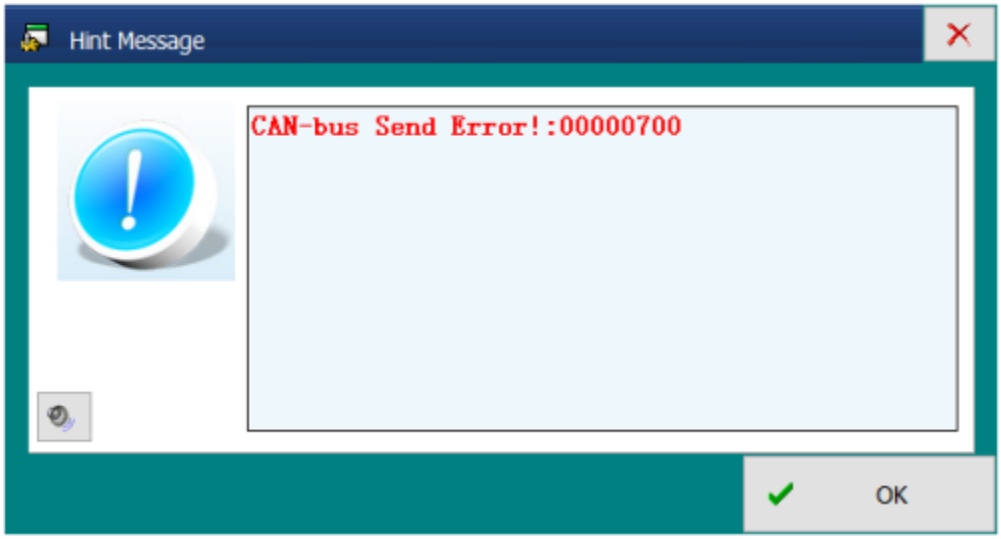
Cause: The CAN card is not connected to the computer, a wrong type of CAN card is selected, or the instrument is not powered up.



Solution: Power up the instrument after checking the connection.

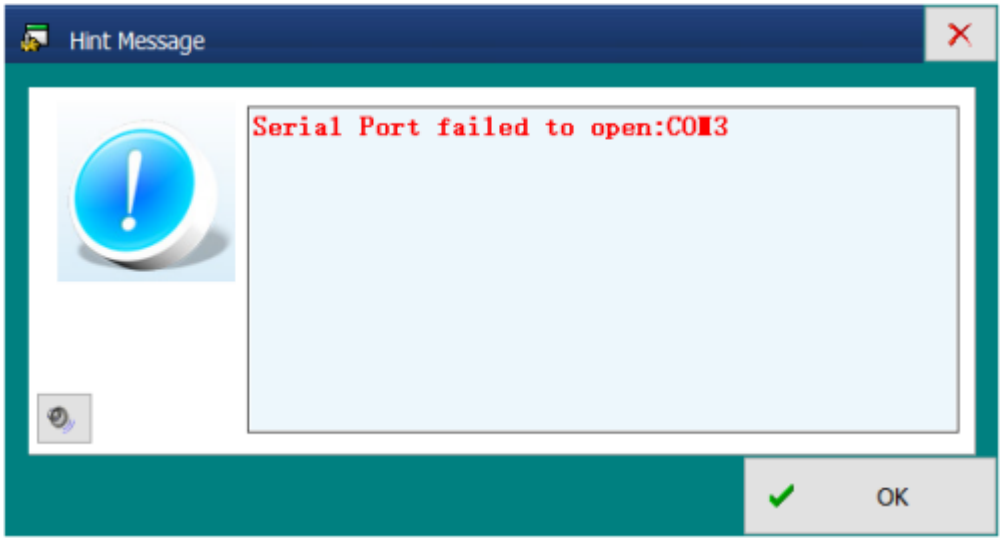
9.7.5 CAN-bus Send Error

When the CAN card is disconnected unexpectedly or the HL line is broken, the main control board where the problem exists can be analyzed according to the error content.



Solution: Check the connection and notify the engineer to make judgments.

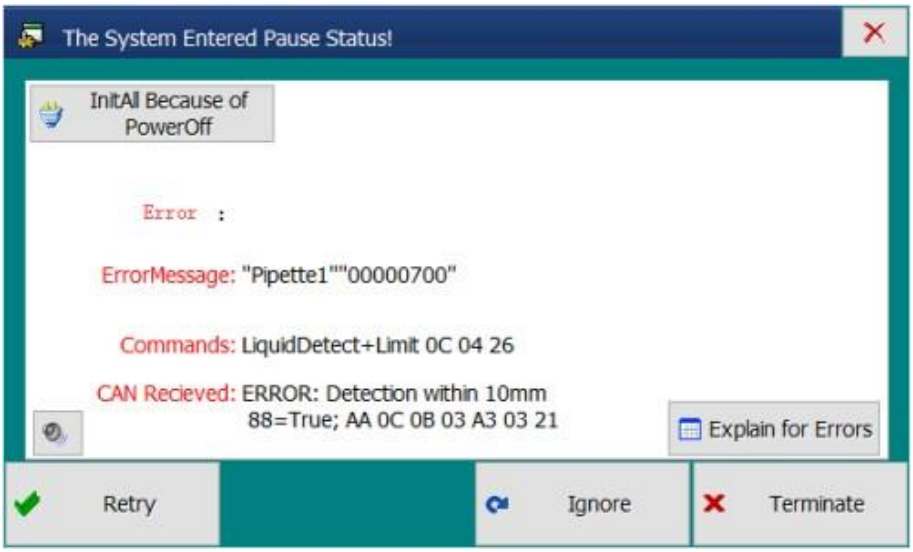
9.7.6 Serial port failed to open



Solution: Check whether the serial cable is connected properly. Software parameters should not be changed at random.

9.7.7 Liquid level detection:

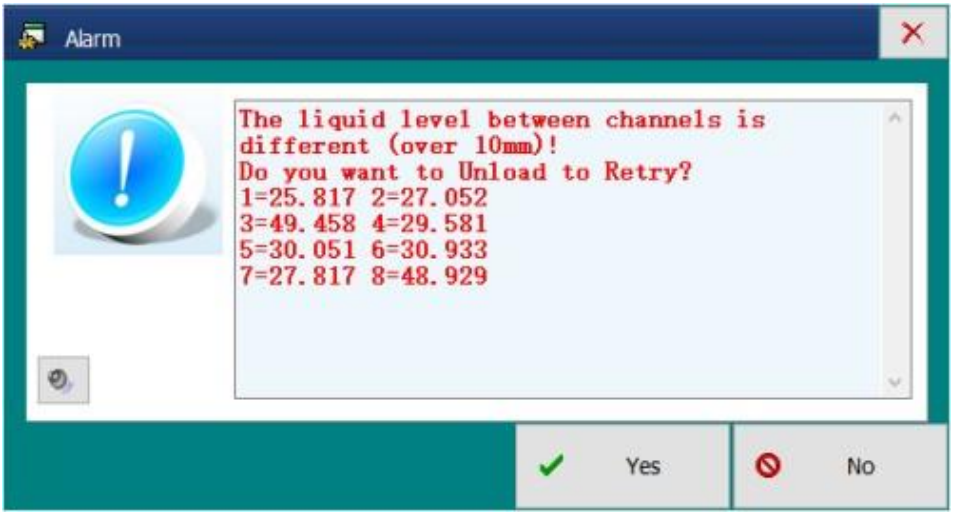
Cause of error: The container is overfilled with liquid; during detection, the descending distance of the liquid level detected is shorter than the system set distance (10mm lower than the Travel height).



Solution: Reduce the liquid in the container or increase the Travel height, then click Retry.

9.7.8 The liquid level between channels is different:

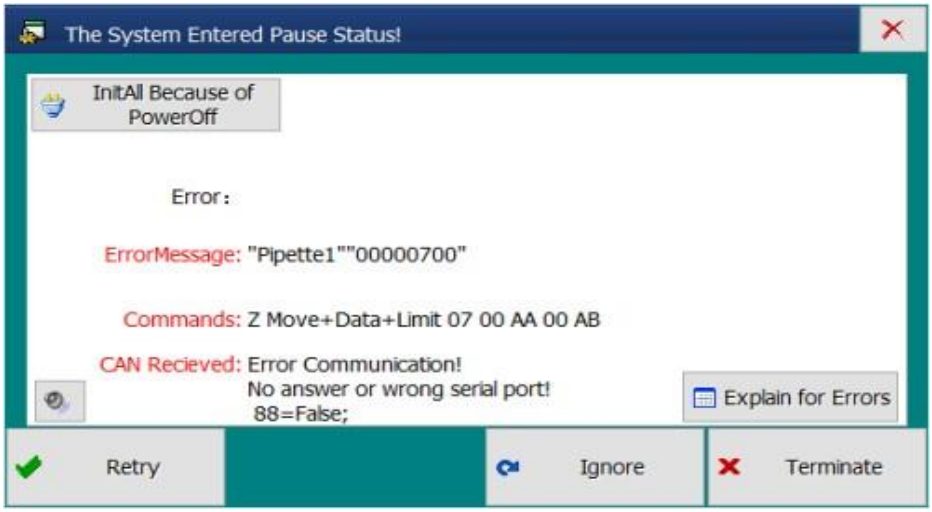
Cause: Detection error occurs during reagent detection by a unit probe.



Solution: Click “Yes” to reload the probe for detection. Click “No” and carry out aspiration after lowering the Z-axis of the unit probe with an error to Z data consistent with a normal unit probe. When the experiment is finished, whether the faulty tip detects pressure normally.

9.7.9 Liquid level cannot be detected

Cause: Corresponding liquid is not placed, pressure detection is insensitive, or the pressure sensor is damaged. Click Retry to carry out detection again, after ignoring, perform aspiration at the Z-axis initialization position. When the experiment is finished, check the hardware or the detected pressure value.



Solution: Check whether the reagent or sample is placed at the specified position.

9.8 Test Process

9.8.1 Instrument Power-on and Balancing

Power up the instrument (by pressing the left switch), and balance the instrument temperature for about 30 minutes, power on the computer (the instrument and the computer can be powered on without sequential order) and carry out pre-experiment maintenance during the instrument balancing period.

9.8.2 Pre-experiment Preparation

1) **Check the state of consumables:** Determine whether the tips, wash buffer and system maintenance liquid meet the test needs according to the test volume, if not, add the consumables as per need.

2) **Check the state of waste:** Check whether there are any residues in the liquid waste container and the waste tip container. If any, dispose of them in time.

3) **Check the state of the wash head:** Launch the software, execute "Power-on/off Maintenance", and carry out the washing. Check the dispensing condition of the wash head and the liquid residue condition in the microplate. Normal tests can be performed after confirming that the wash head has no problems like dispensing inclination, interruption, and probe blockage and there is no obvious residue in the microplate wells.

9.8.3 Test Operation

1) Check Settings

Check whether there is any expired setting in the Reagent and QC Manage interface of the software.

2) Add Reagent

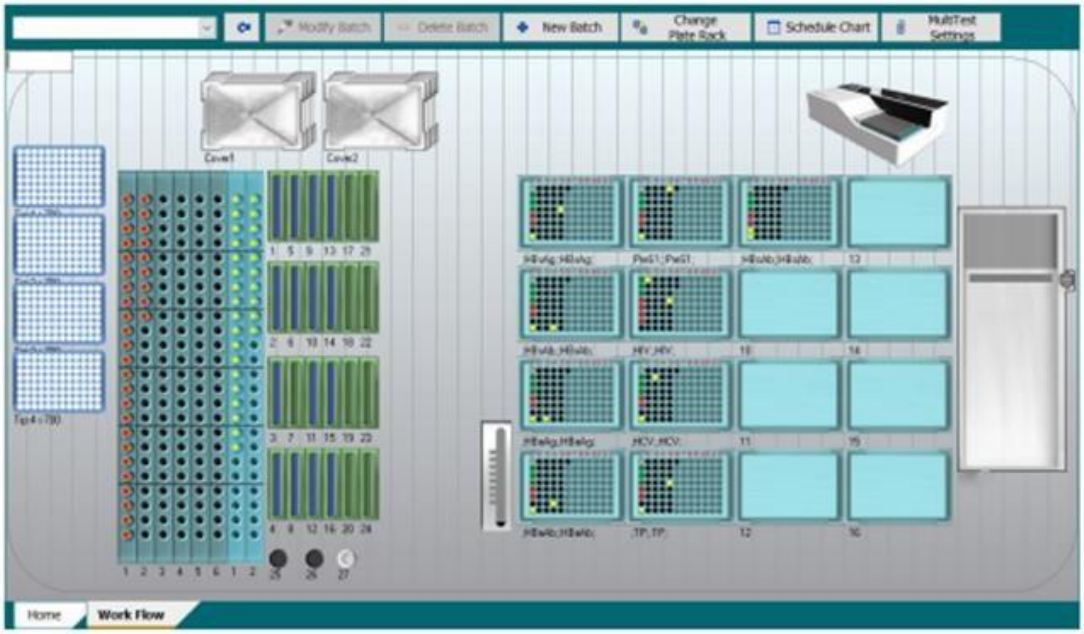
Add all reagents to be used in the test.

3) Add Sample

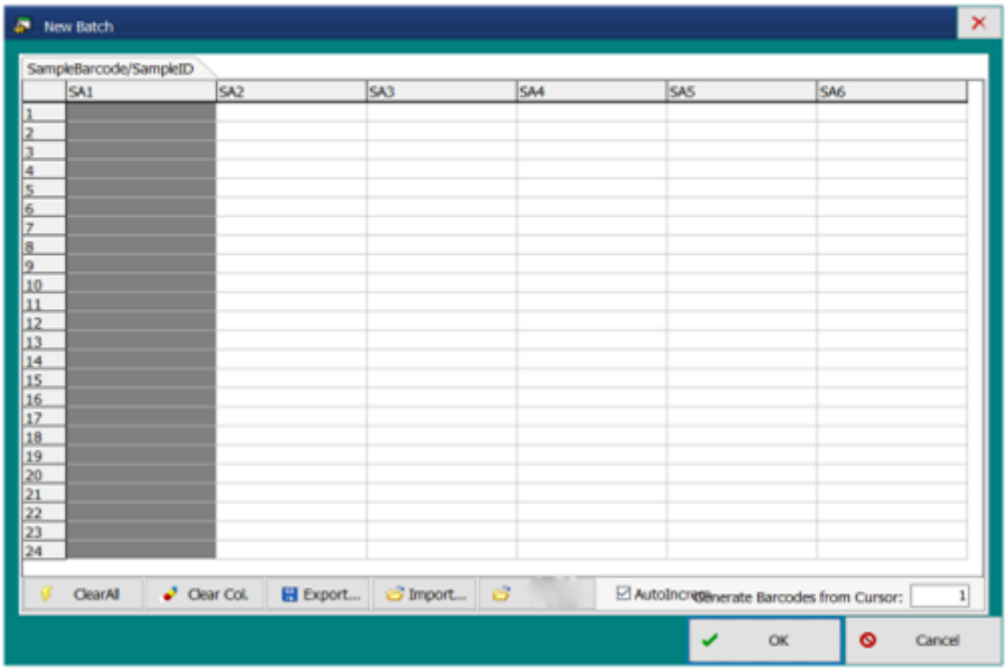
Place the test tubes in the test tube rack.

9.8.4 Start Experiment

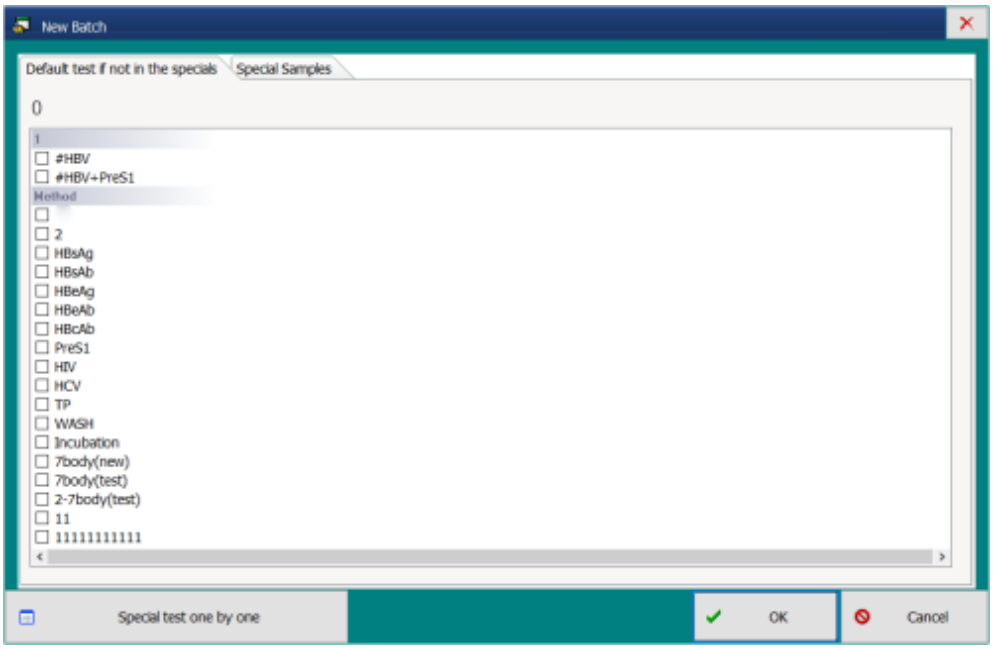
1) Click “Start Experiment” on the menu bar, and the following interface will appear,where the user can add experiment batches.

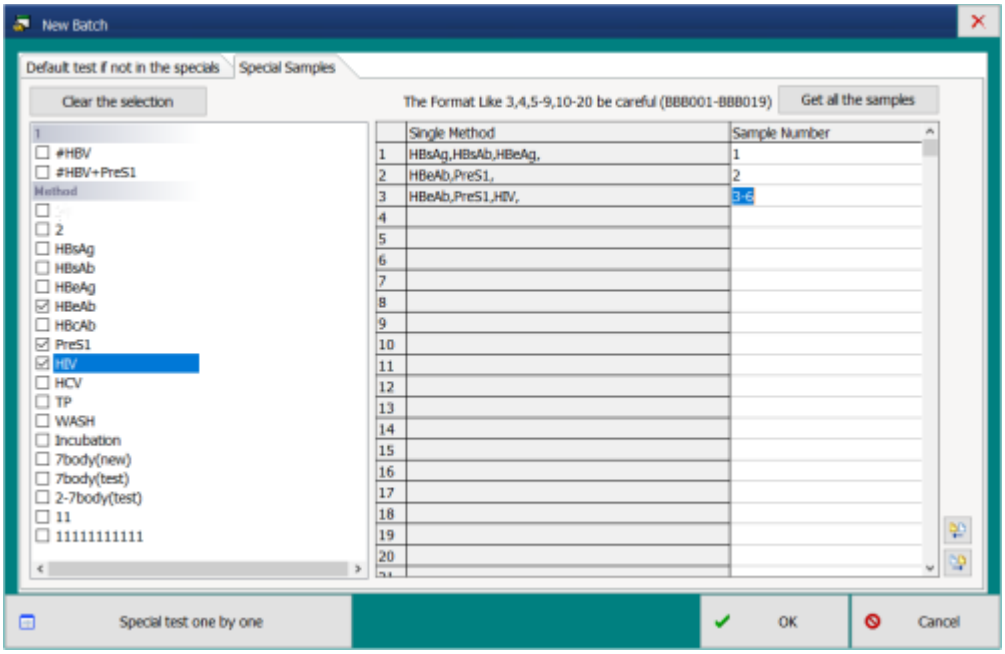


2) Click “New Batch” to add experiment batches, and the following interface will appear. Input the sample ID according to the sample position, press and hold the Enter key for auto increment of sample ID. If barcode scanning is required, insert the sample rack into this window for scanning.

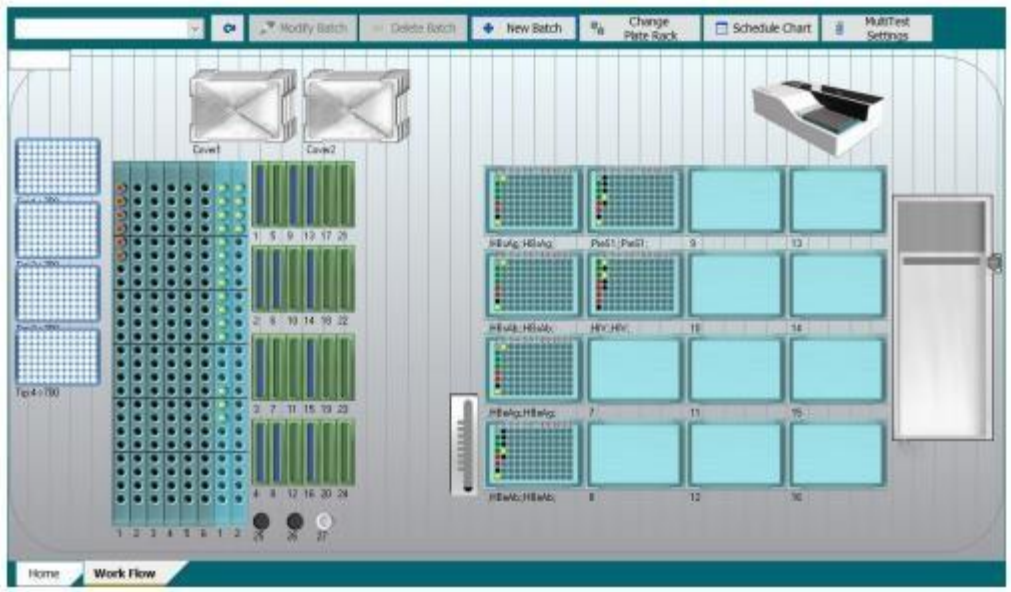


3) After entering the sample ID, click “OK” in the interface shown above, the following interface will pop up, where the user should select the experiment method to be used. If there are special samples, after selecting the default group, click “Special Samples” to edit special samples.



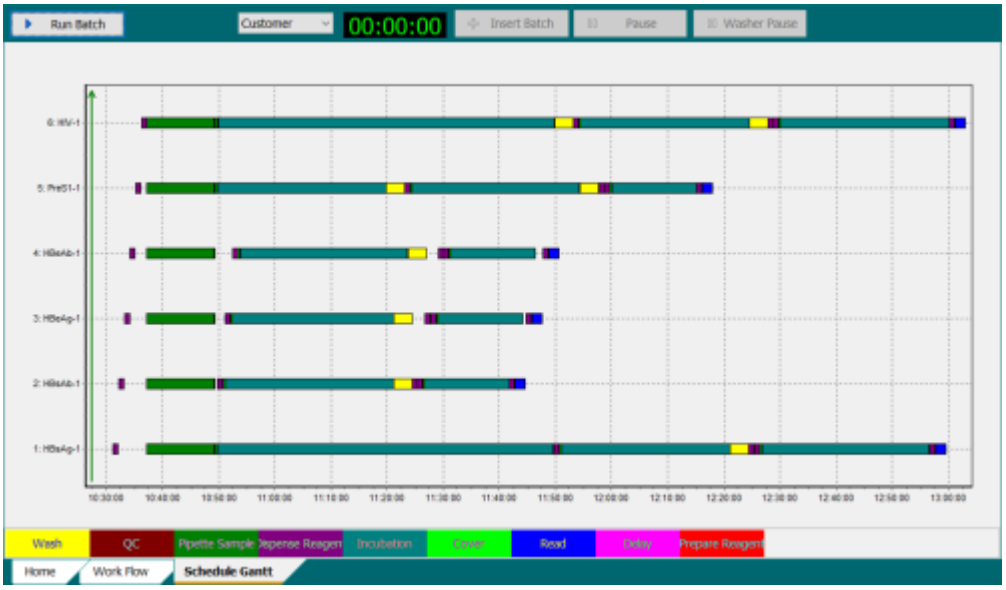


4) After selecting the experiment items in the above interface, click “OK”, and the following interface will appear:



5) When a batch is added, the position of the reagent rack or sample rack to be used will be colored, remember to confirm the correctness of the reagent position and microplate position to avoid delay in the experiment progress. Right-click the bar rack at the used positions, the reagent placement information will be displayed, kindly check the information.

6) After adding an experiment batch, click "**Schedule Chart**" to enter the following interface.



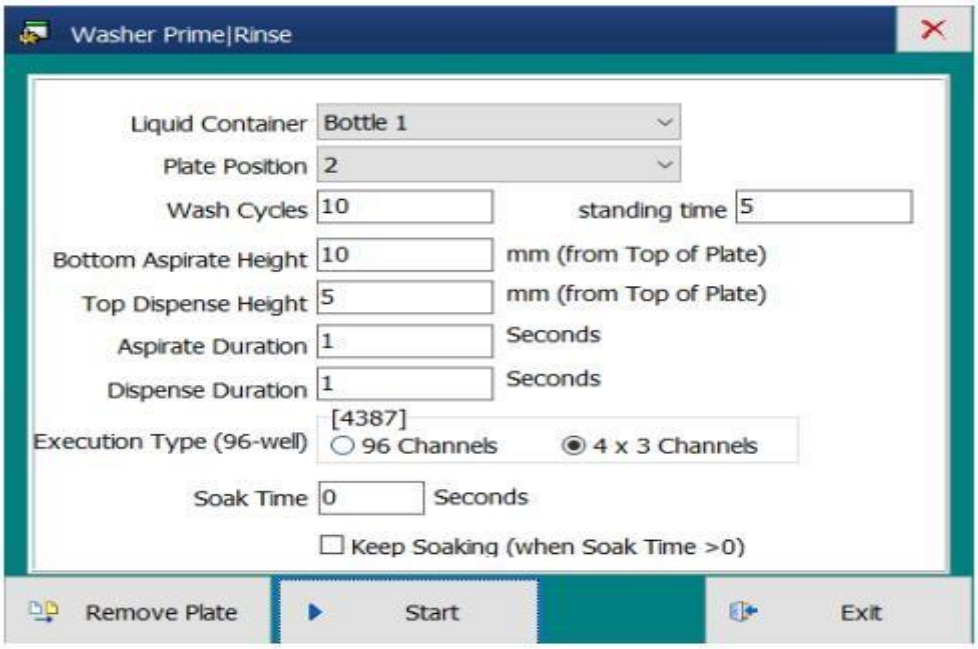
7) Click "Run Batch" in the above figure; after selecting the proper tip position, click "OK" to start running the experiment.

9.8.5 Post-experiment Maintenance

Before and after the experiment, "Power-on/off Maintenance" should be carried out, and the wash head should be rinsed to prevent crystallization.

⚠ "Power-on/off Maintenance" is a major maintenance procedure of this instrument. Kindly carry out maintenance as required. After a determination by the engineer, this maintenance parameter does not need to be changed. Check whether the liquid in the distilled water container is adequate.

1) Click "Power-on/off Maintenance" to enter the following interface, and simply click "Start".



2) Turn on the liquid waste switch to fully discharge the liquid waste, turn off the switch after full discharge.
3) Power off the instrument and shut down the computer.
4) Use alcohol to wipe the outside of the wash probe. (This step is executed once a week).
5) Pour out waste water, excess reagents, probe washing liquid, and plate washingliquid, or dispose of them according to the hospital's requirements.
6) Wipe off any dust on the instrument.

9.8.6 Precautions for Daily Experiment

1) The serum should be separated thoroughly. Sample centrifugation should be performed strictly to ensure thorough centrifugation, to avoid probe blockage, no clots should exist on the sample surface and in the effective utilization space.
2) Avoid blood samples containing fibrinogen from the source.
3) Screen serums strictly; blood samples with lipoidemia, hemolysis or other abnormalities are forbidden to be tested on the instrument.
4) During sample adding, it is forbidden to add reagents or samples to avoid danger.


The protection provided by the instrument could be impaired if the instrument is not used according to the methods specified in the manual.

10. Maintenance

1) Daily Maintenance Items:

- Before and after each experiment, use the software system for on/off maintenance.
- Empty the liquid waste container and the waste tip container promptly.
- Clean and wipe the working area of the instrument after each experiment.
- Disconnect the power supply before cleaning. Use a soft cloth dampened with diluted suds to wipe the instrument housing, followed by a dry cloth.
- Avoid using organic solvents. Use tissue paper or cotton balls to clean any residual reagent. If using a sprayer, avoid directing it at the auto-loading unit, circuit board, or connectors.
- Maintain the equipment with the recommended cleaning solution before and after each experiment.

2) Weekly Maintenance Items:

- Wipe the bottom of the steel needle of the unit probe with 75% alcohol to prevent blockages.
- Check the liquid waste hole of the plate washing trough for blockages and clean if necessary to prevent circuit board damage from water ingress.
- Lubricate the plate washing guide with lubricating oil to prevent rust that could affect the experiment.

3) Biannual Preventive Maintenance:

Perform preventive maintenance, including volume correction, twice a year.

4) Long-Term Use Guidelines:

- Do not leave the instrument unused for more than 3 months.
- Electrical failures canoccur if the instrument remains idle for extended periods.
- Start the instrument atleast once a month to perform normal initialization.
- Users are responsible for any electrical failure resulting from prolonged idleness without following these instructions.

5) Before Stopping Use:

- Remove all liquid from the instrument and store it properly.
- Carry out biohazard treatment.
- Do not leave liquid in the instrument for long periods and disconnect the power cord.
- Power on the instrument weekly, initialize moving parts and keepit on for 0.5-1 hour to prevent malfunction or aging of electronic and mechanicalparts.

6) **Handling the Instrument:**
   - Before handling, remove all liquid from the instrument, store it properly, and perform biohazard treatment to prevent corrosion or biohazards from liquid splashes during transport.
   - Confirm that all mechanical units are in their initial positions, remove all containers, and disinfect them before repairs.

7) **Handling Infectious Samples:**
   Use protective measures when handling infectious samples. Promptly empty the waste tip container and the liquid waste container.

8) **Electromagnetic and Static Interference:**
   Minimize exposure to electromagnetic fields and static electricity in the experiment environment to prevent interference with liquid level detection and the plate washing pipeline.

9) **Use of Cleaning Agents**:
   Avoid using decontamination or cleaning agents that could react with parts of the equipment, or the materials contained within it, causing hazards.

11. Troubleshooting

1) General faults

Symptoms	Cause	Solution
A continuous rattle sound can be heardduring the Z-axis initialization of the sample probe	1) The power cord of theZ-axis proximity the switch is open-circuited. 2) The signal line of theZ-axis proximity the switch is open-circuited. 3) The Z-axis proximityswitch is damaged.	1) The experiment can be continued after shielding the faulty tip, notifyingthe engineer to check the circuit, and carry out the replacement. 2) The experiment can be continued after shielding the faulty tip notify the engineer to check the circuit and carry out replacement. 3) The experiment can be continued after shielding the faulty tip Notify the engineer to replace the proximity switch.
During Z-axis initialization in theexperiment, the Z-axis cannot be fully lifted, or drops when lifted a little, at the same time,the Z-axis motor runs continuously and produces the “click”sound	The belt of the the corresponding unit probeis loosened	1) The experiment can be continued after shielding the faulty tip. 2) Notify the engineer to tighten theZ-axis belt.
During pump (S) initialization in the experiment, the pump motor drives the syringe to continuously move downward and makesa continuous “click” sound, the “click”sound can also be heard during pump (S) initialization in the component console	1) The power cord of theS-axis proximity the switch is open-circuited. 2) The signal line of theS-axis proximity the switch is open-circuited. 3) The S-axis proximityswitch is damaged.	1) The experiment can be continued after shielding the faulty tip. Notify the engineer to check the circuit and carry out a replacement. 2) The experiment can be continued after shielding the faulty tip. Notify the engineer to check the circuit and carry out a replacement. 3) The experiment can be continued aftershielding the faulty tip and notifying the engineer to replace the proximity switch.
During the experiment, the X, Y, or Z axis of the product does not stop when reaching zero and meanwhile makes the “click” sound,	1) The metal block pieceof the sensor is bent, failing to insert it intothe sensor (during transport)	1) Straighten the metal block piece of the sensor so that it can be inserted into the sensor. 2) Notify the engineer to check the circuit and carry out a replacement

the same phenomenon is observed during X, Y, or Z-axis initialization in the component console	2) The power cord of the sensor is open-circuited 3) The Signal line of the sensor is an open circuit. 4) The sensor is damaged.	3) Notify the engineer to check the circuit and carry out a replacement 4) Notify the engineer to check the circuit and carry out a replacement
During an experimentor operation in the component console, a component cannot reach the designated position, and there isno abnormal sound **Note:** This situation may occur to transmission parts of all motors	1) The belt is loosened, resulting in step loss of the corresponding motor. 2) Pulley at the connection with the motor bearing slips, resulting in step lossof the corresponding motor.	1) Find the faulty belt connection and tension the belt. 2) Tighten the fastening jackscrew ofthe pulley.
During an experimentor operation in the component console, a component cannot arrive at the specifiedposition, and an abnormal “click” soundis heard **Note:** This situationmay occur to transmission parts ofall motors	1) There is external force interference (guide deformation) during movement. 2) The motor runs with an open phase.	1) Periodic inspection and maintenance should be performedby the engineer. 2) Use the on-off position of the multimeter to measure the A+, A-and B+, B- phases of the motor, check which phase is open, find theopen position, and carry out soldering or replacement (if theopen position is within the drag chain, replacement is suggested to prevent second openness afterlong-time operation)
During an experimentor operation in the component console, a component stops afterrunning an additional distance when the designated position is reached	Step excess of motor	Notify the engineer to replace the faulty motor.
During liquid level detection, the unit probe stops after a slight move when it	1) The tip is blocked (the tip is unperforated, or the perforation is too small)	1) Replace the tip and try again. 2) Reduce liquid in the container or increase the Travel height settingin the software.

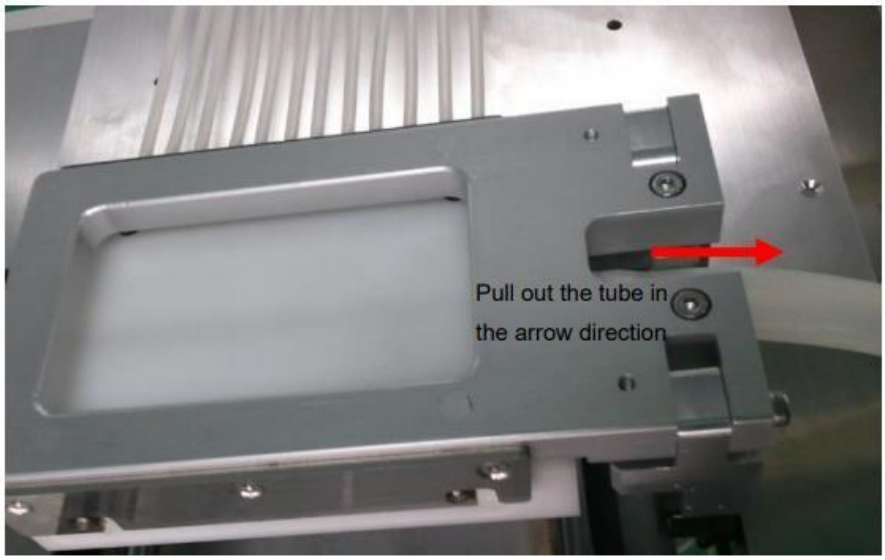
drops to the travel height, and the error message "Liquid leveldetection error" is generated	2) There is too much liquid in the container. 3) Contaminants in the sample probe cavity block the cavity. 4) Liquid-level sensors or circuit boards are damaged.	3) After liquid aspiration in the component console, check to confirm the current sensing value decreases continuously, and use a heating wire or acupuncture needle to dredge the sampling cavity. If the problem still exists,notify the engineer of the solution. 4) Notify the engineer to replace the sensor or circuit board.
During liquid level detection, the liquid level is detected by mistake the halfway through detection	1) The detection value ofthe faulty tip is too small. 2) The sensor or circuit board is damaged.	1) Increase the detection value in the component console 2) Notify the engineer to replace the component
During liquid-level detection, the probemoves down continuously and doesnot stop when touching the liquid surface till the extremeposition, and error is reported.	1) The detection value ofthe faulty tip is too big 2) The sensor or circuit board is damaged	1) Decrease the detection value in the component console 2) Notify the engineer to replace the component
A false alarm is given during tip release, after the tip is unloaded, the alarm message "Tip release failed. Do you want to try again?" is still generated.	1) The spring on the tips loading detection sheet is too loose, failing to spring downthe tips loading detection sheet. 2) The tips loading detection sheet is bent, resulting in unsmooth or stuckup-and-down movement.	1) Remove and tighten the tip release spring or notify the engineer to place it. 2) Manually or remove and straighten the detection sheet tomake it move up and down smoothly.
During liquid dispensing, there is no or little liquid in a well,and the residual in the corresponding tip is more than that in other tips	The dispensing speed istoo high, and the pump motor gets struck whilerunning	Reduce the dispensing speed

2) How to Dredge the Wash Head

Kindly take care when dredging the wash head after lifting the right-side panel of the instrument, thus, to prevent injury of maintenance personnel due to collision when the door panel is pressed down

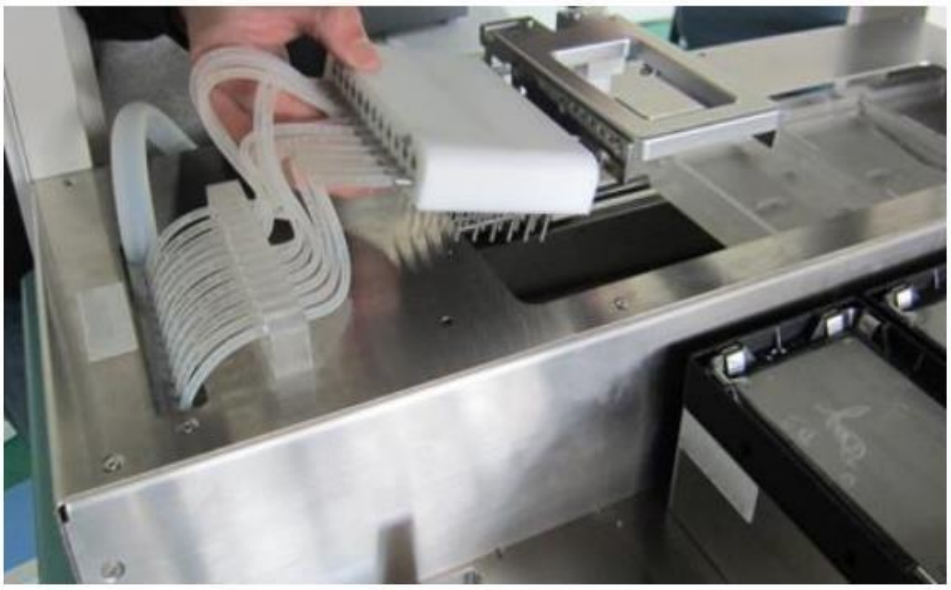
(1) Type I

- First remove the thick silicone tube for aspiration, as shown in the figure.

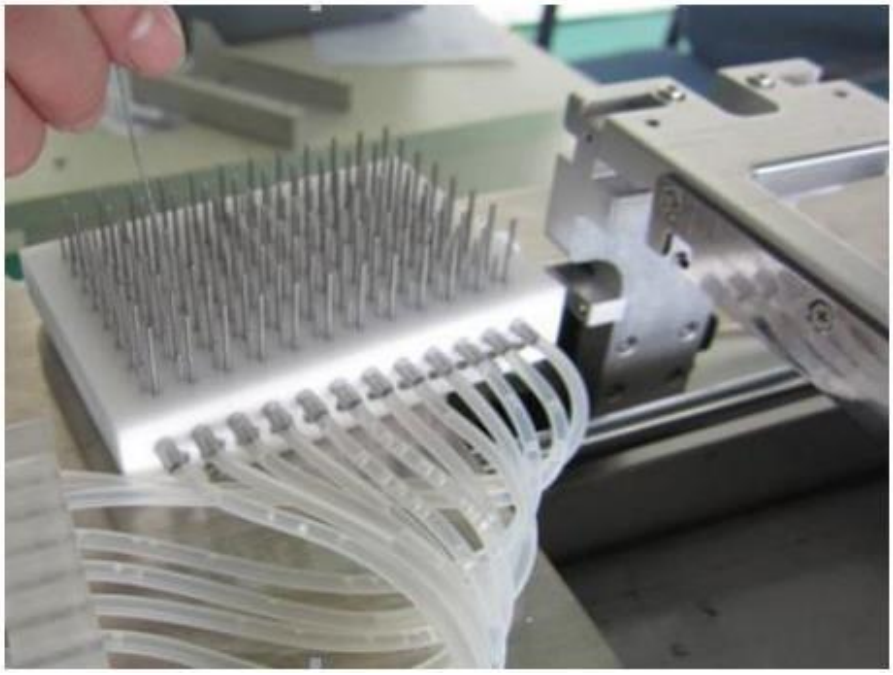


- Remove the wash head from the support, as shown in the figure: (After holding the wash head, move the tube backward and then move it downward)

- After removing the wash head, withdraw it according to the figure below.

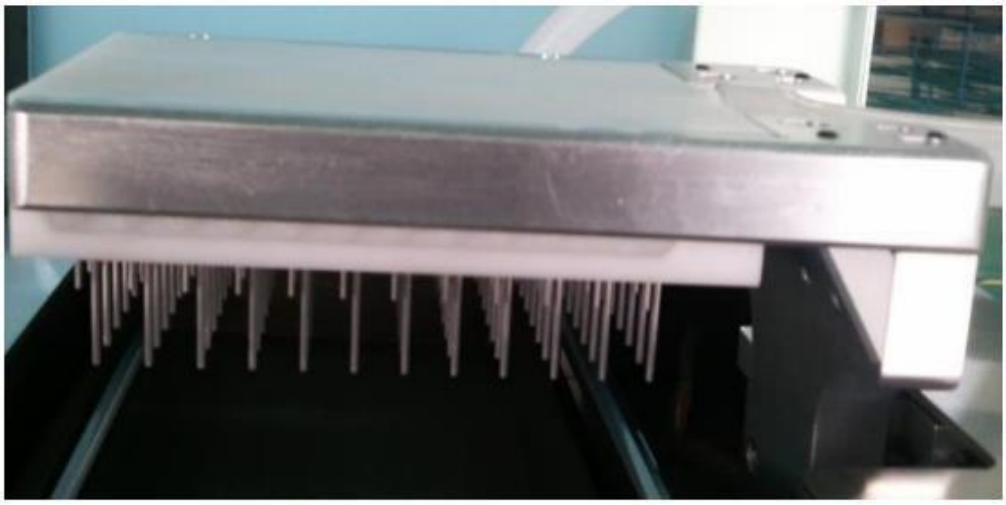


- Use an acupuncture needle or other hard object that can be inserted intothe wash probe for dredging.

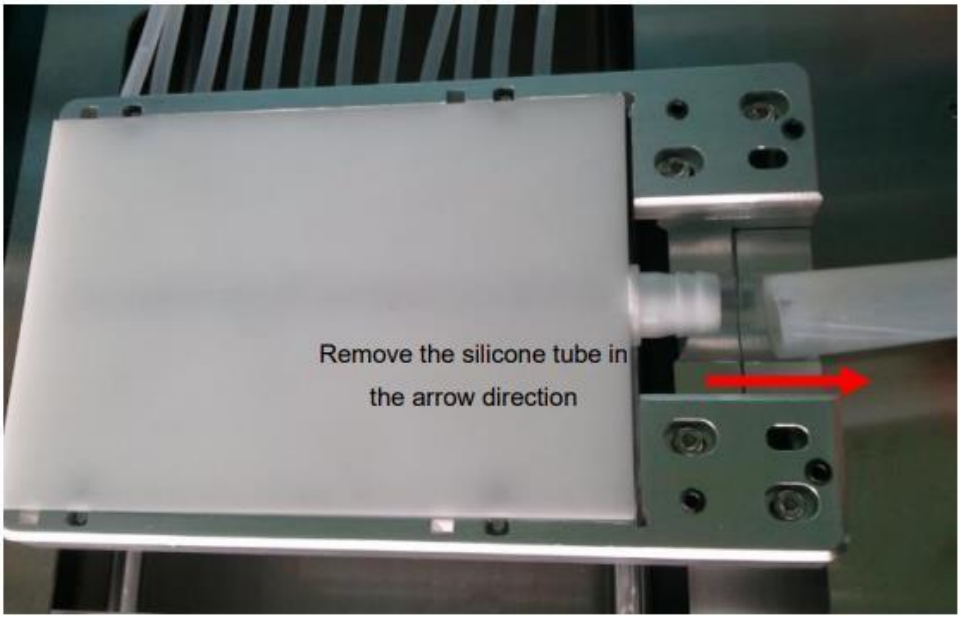


(2) Type II

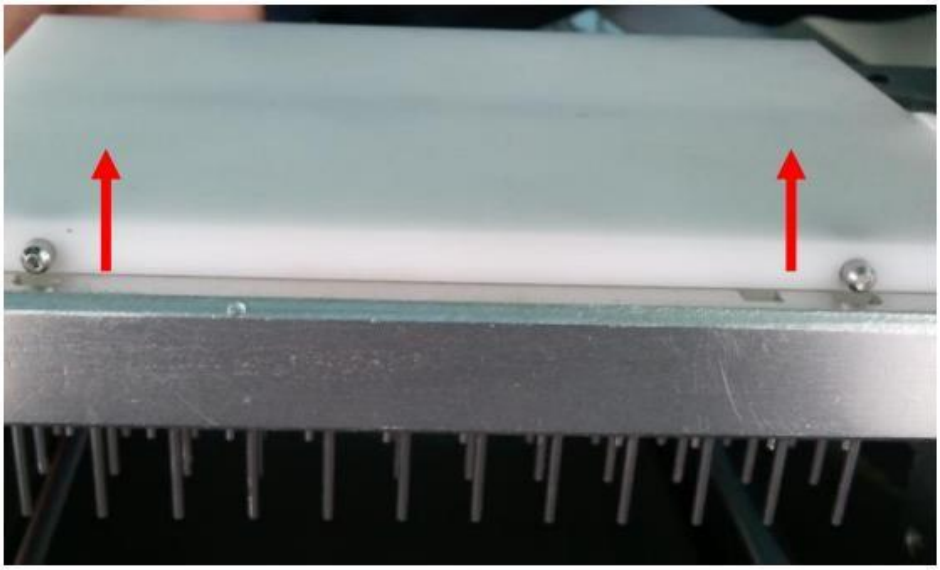
- Type II is shown in the figure below



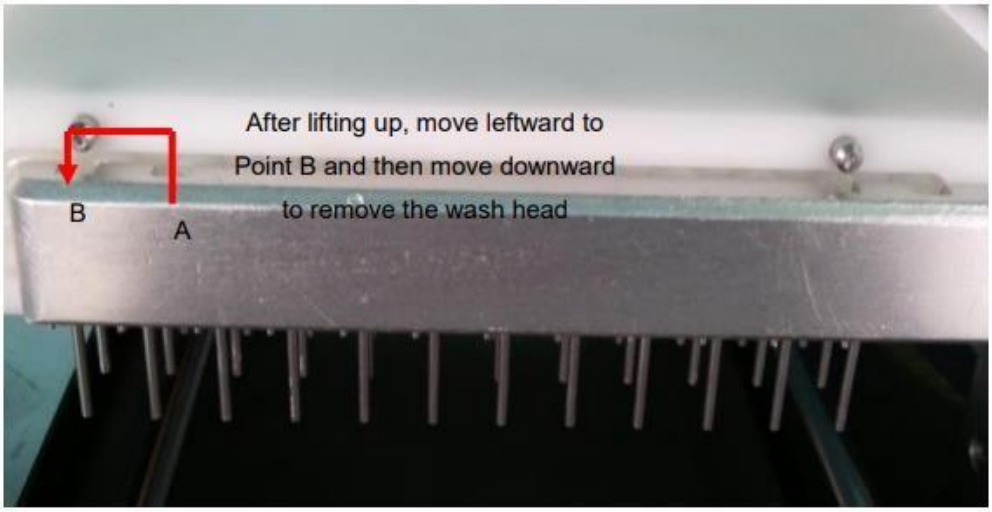
- First, remove the silicone tube for aspiration:



- **Lift the wash head:** Lift to the position shown in the figure.



- Remove the wash head according to the trajectory marked in the figure below.



- Insert a steel needle or other hard object into the steel needle of the wash head to dredge the wash head.

⚠ This option involves the auto curve correction process of the software.