Labotronics



Operational Manual

ELISA Workstation

LB-12ELISA

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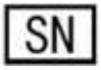
1. Safety Measures

The safety signs and symbols shown on the instrument, in this manual, and on the labels are essential for the safe and proper use of the instrument.

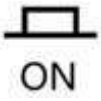
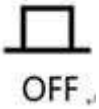
Warning Symbols		
Symbols	**Title**	**Description**
	CAUTION, DANGER	This symbol signifies a potential electric shock hazard during operation and serves as a warning to remain alert. Electrical components marked with this symbol must not be touched with hands or tools while the power source is connected.
	BIOHAZARD	• This symbol warns the operator to exercise caution and wear appropriate protective equipment when there is a risk of exposure to infectious substances during use. • This instrument is a fully automated IVD device. Protective measures, such as wearing gloves, should be taken throughout the entire operation. • Potential sources of contamination include the tip ejector, sample dispensing areas, and the incubator. To prevent biohazards, users should wear medical rubber gloves when cleaning and disinfecting these components. • The solid waste basket and liquid waste container may also pose contamination risks through skin contact. Waste should be disposed of in accordance with local safety regulations.
	CAUTION, SCALDING	This symbol indicates that the surface of the instrument may become very hot. During operation, the incubation module can reach high temperatures. To ensure safety, dual protection mechanisms—comprising over-temperature protection components and a temperature sensor control—have been pre-installed. However, if both systems fail simultaneously, these parts may still reach high temperatures.

	CAUTION, HAND	This symbol warns the operator to keep hands away from this area to prevent the risk of hand pinching.
	PINCHING HAZARD	Watch your hand when opening or closing the door cover.
	CAUTION, DANGER	• This symbol indicates that failure to follow the operating instructions or procedures may lead to damage to the instrument and could result in physical injury or even death. The relevant documentation must be consulted whenever this symbol appears. • The housing MUST NOT be opened while the power source is connected. Opening the door cover while the instrument is operating is strictly prohibited. • To avoid potential hazards from the dispensing arm and transfer arm, DO NOT insert any part of the body into the instrument during operation.
	PROTECTIVE CONDUCTOR TERMINAL	Ensure proper earthing protection for the instrument during operation or maintenance. The baseplate and housing must be securely grounded using earth wires. Any disruption to the grounding circuit, whether inside or outside the instrument, can pose a serious safety hazard.

Label Symbols

Symbols	Description
	Identification of in vitro diagnostic medical device
~	Alternating current
	Model Number
	Serial Number
	Consult Instructions for Use

CE	CE Mark
ISO 13485	ISO 13485
	WEEE

Other Marks		
	Instrument Power Supply	The pushbutton switch is used as the power switch; it indicates the switch is in “ON” position
	Instrument Power Supply	The pushbutton switch is used as the power switch; it indicates the switch is in “OFF” position

Prior to handling or transporting the instrument, remove all liquids and perform biohazard treatment to avoid corrosion or biohazard risks from spillage.

1.1 General Preventions

- Always adhere strictly to Good Laboratory Practice (GLP) during operation.
- Do not change the position of the test tube during sample loading, as this may lead to inaccurate test results.
- For sensitive test samples, monitor potential sample evaporation or concentration changes while running the method.
- Before routine use, perform a trial run using distilled water and the final liquid to ensure proper functioning.
- When handling foaming liquids, always conduct liquid level detection prior to use.
- During operation, shield the instrument from direct sunlight and intense artificial lighting.
- Operate the instrument in a clean environment, free from contaminants or dust-generating materials.
- Exposure to electromagnetic fields or static electricity may disrupt the liquid level detection function. Therefore, minimize such interference in the working environment.
- The instrument must not be operated in environments containing flammable gases like oxygen or nitrogen oxides.
- During maintenance or transportation, ensure all mechanical components are positioned to avoid collision. During installation, confirm that the instrument is properly grounded.

- Keep the instrument away from heat sources and open flames. Waterproofing precautions must be taken—do not place items like vases or water glasses near the instrument.

Note:

- Do not leave the instrument idle for extended periods, as evaporation of liquid in disposable tips may compromise test results.
- Do not overfill reagent trays or other liquid containers.
- Position the instrument with its rear against a wall to prevent entry into the work area from behind.
- A sudden power failure during operation may lead to data loss. To avoid this, use an uninterruptible power supply (UPS).
- Ensure sufficient disk storage space to prevent computer system failure. Do not overlook essential safety precautions.

1.2 Electrical Safety Precautions

- To ensure operator safety and avoid risks from the internal high-voltage module or moving parts, the external housing of the instrument must not be opened without proper authorization.
- Always power off the instrument and unplug it from the power source before performing any cleaning or disinfection.
- Never place your hand inside the instrument's internal cartridge while it is in operation.
- To prevent injury, untrained personnel must not attempt to disassemble any electrical or mechanical components.
- Before removing any parts or circuit boards, make sure the instrument is powered off and disconnected from both the backup power supply and the computer.
- The instrument does not contain a fuse, so fuse replacement is not required. Instead, press the leakage protection module's indicator button once a month as part of regular maintenance.

1.3 Biohazard Precautions

- Operators must follow applicable laboratory biosafety regulations and dispose of waste materials (such as liquid waste containers and waste tip containers) in accordance with hospital protocols. Since the instrument poses potential biosafety risks during sample testing, users must adopt appropriate safety precautions as per laboratory guidelines, including wearing suitable protective clothing and gloves. Waste materials should be placed in designated hospital disposal areas—do not discard them improperly or mix them with household waste. Smoking, eating, or drinking while operating the instrument is strictly prohibited.
- If the instrument becomes contaminated with biohazardous materials, it must be cleaned according to the maintenance procedures outlined in this manual. Failure to do so may compromise the instrument's reliability and normal operation.

- When handling biohazardous samples, strictly follow the maintenance procedures, with particular attention to proper disinfection and decontamination. Gloves must be worn when working with the sample dispensing arm, pipetting channels, container racks, containers, and disposable tips. Surfaces exposed to splashed liquids must be thoroughly disinfected.
- While adding infectious samples, avoid direct contact as much as possible, and be sure to promptly empty both the liquid waste container and the waste tip container.

Note: Do not spill any corrosive or damaging liquids on the instrument. If such a spill occurs accidentally, it must be cleaned up immediately.

1.4 Mechanical Safety

- Do not lean on or tilt the instrument while it is operating.
- To avoid injury from moving components, do not open the front door panel during instrument operation.
- For operator safety, the equipment is equipped with an interlock switch. The instrument will automatically stop when the cabin door is opened.
- When loading samples, reagents, or consumables, pull out the tip carrier, sample carrier, or reagent carrier to approximately 50% of their full length from the edge of the equipment.
- The instrument is equipped with an “Open Stop” feature, which halts operation if the door is opened during an experiment. While the door is open, do not use the computer software until the front door is securely closed, to prevent operational hazards.

1.5 Fire Safety

Fire safety regulations relevant to the medical field must be strictly established, followed, and enforced. Appropriate fire extinguishers for both electrical and non-electrical fires must be readily available. Operators must be familiar with fire extinguishers and other firefighting equipment and receive proper training. In the event of a fire, the power supply must be immediately disconnected to avoid secondary injuries due to electric shock.

1.6 Emergency and Corrective Measures

If a malfunction occurs during the experiment that prevents the instrument from operating normally, immediately Power off the instrument. In the meantime, experimenters should preserve the experimental samples and dispose of all materials, including waste, in accordance with relevant safety protocols.

1.7 Electromagnetic Compatibility (EMC)

- This instrument may be exposed to different types of electromagnetic interference (EMI), which can be transmitted through power sources, measurement or control cables, or emitted from the surrounding environment. The instrument **must not** be operated near high-intensity radiation sources such as unshielded RF devices, as this may disrupt normal operation.
- Appropriate precautions should be taken if the instrument is used in a residential environment.

Users are advised to assess the electromagnetic environment at the installation site before operating the instrument.

Essential performance specification provided by the manufacturer:

- Absorbance repeatability: The coefficient of variation (CV) for repeatability measurements should not exceed 1.0%.

Note: It is the user's responsibility to ensure that the electromagnetic conditions are suitable for the instrument to function properly.

2. Introduction

ELISA workstation LB-12ELISA is a fully automated immunoassay processor with 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

- Photometric microplate reader module
- Air displacement pipetting system
- Crosswise aspiration with selectable injection height
- Liquid level, clot and empty tube monitoring
- Barcode scanning (optional)- Automatic
- Multifunctional liquid handling (dilution, conjugation, aliquoting)
- Multiple and diversified dispensing

4. Specifications

Model No	**LB-12ELISA**
Assembly	Cabinet
Number of channels	4
Disposable tips	300 µL and 800 µL
Pipetting range	1 µL ~ 1000 µL
Pipetting increment	0.1 µL
Pipetting precision and accuracy (300 µL and 800 µL)	Volume: 100 µL
	Accuracy: ± 1%
	Precision: < 0.75 %
Pipetting speed (96 samples)	320 sec
Dispensing speed (96 wells)	45 sec
Total rails	16
Control positions	8 × 24 = 192
Reagent positions	8 × 4 = 32
Plate positions	9
Temperature range	RT ~ 60 °C
Temperature increment	0.1 °C
Temperature accuracy	± 0.5 °C
Washing channels	1 × 96 with 3 plate positions
Selectable wash buffers	3
Wash volume	50 µL ~ 1000 µL per well
Residual volume	≤ 2 µL per well
Interface	USB and RS232
Dimensions	1500 × 810 × 1735 mm
Weight	340 kgs

5. Applications

Used to detect antigens or antibodies in serum, sputum, semen, urine, stool, 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 primarily comprises the main unit and control software. The main unit handles the operations, reactions, and detection processes of the instrument and is mainly made up of the liquid-in system, microplate transfer system, oscillating incubation system, microplate washing system, and enzyme-labelled analysis system.

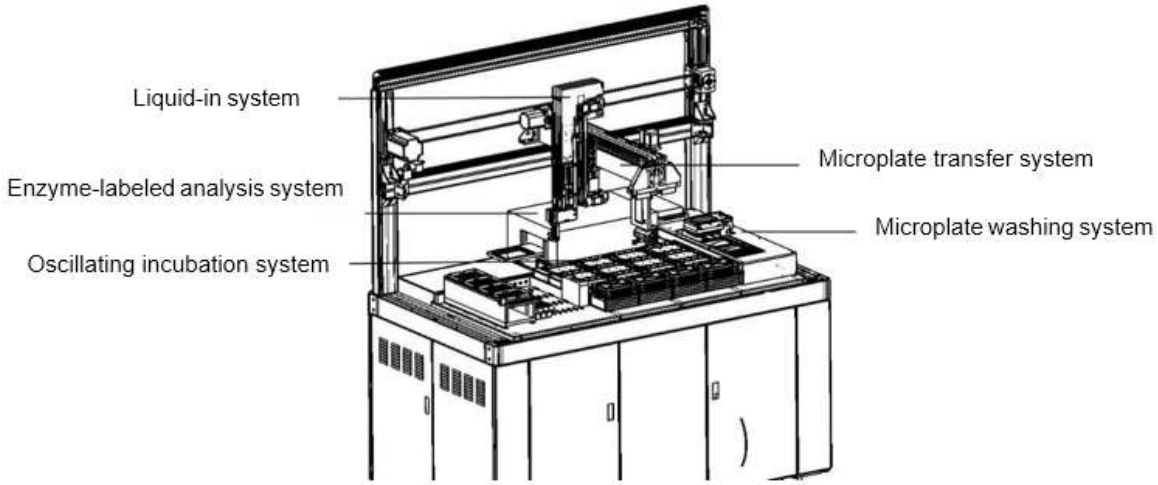


Figure-1 General Assembly Drawing of Fully Automated ELISA Workstation

6.1.1 Liquid In System

The liquid-in system is composed of the sample dispensing arm module, tip rack, sample rack, reagent rack, microplate rack, tip ejector, and consumables such as the tip tray, reagent kit, and tips.

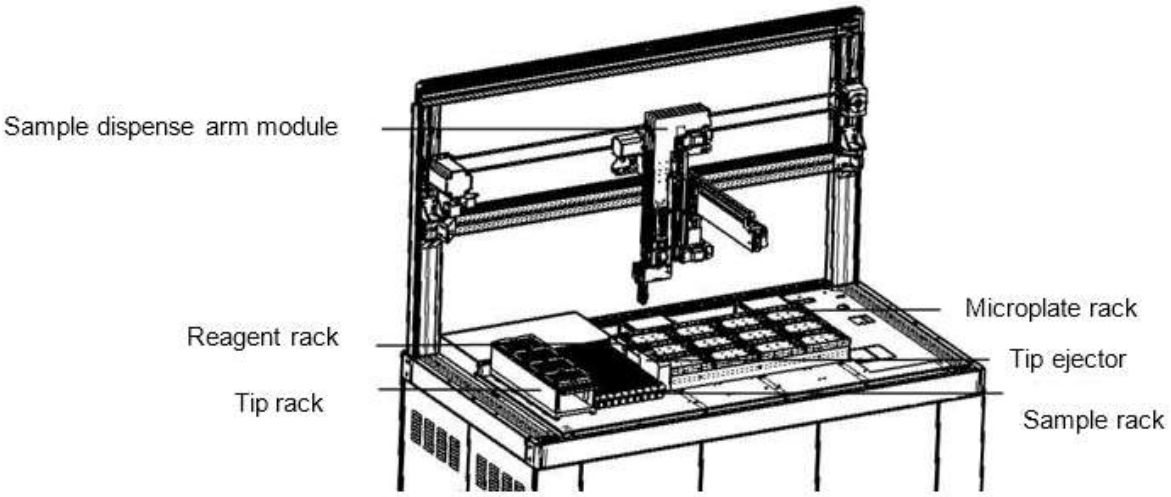


Figure-2 Layout of Sample in System

6.1.1.1 Sample Dispense Arm Module

The sample dispensing arm module primarily consists of the circuit control component, mechanical control component, and pressure sensor component.

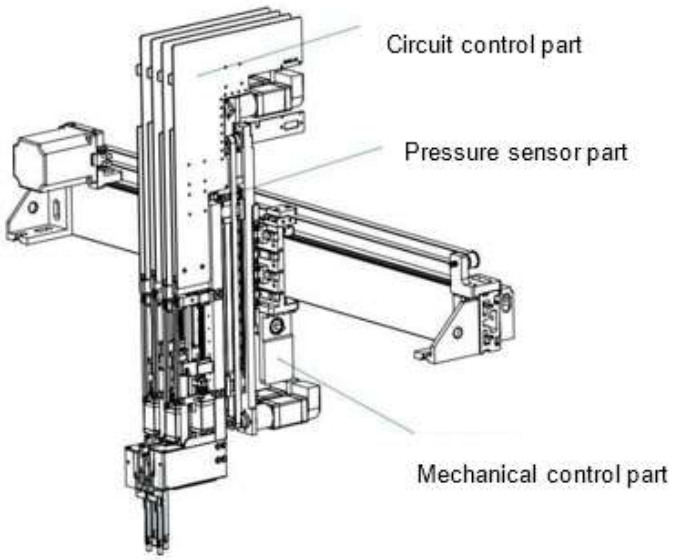


Figure-2 Layout of Sample Dispense Arm Module

Function of the sample dispensing arm module: It utilizes the principles of pressure detection and gas-liquid exchange to enable liquid level detection, clot detection, empty tube detection, and bubble detection, as well as to perform the absorption, dispensing, and transfer of liquids (including samples and reagents).

6.1.1.2 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

6.1.2 Microplate Transfer System

The microplate transfer system is composed of a mechanical structure section (including the X-axis motor, Y-axis motor, and gripper motor) and a circuit control section.

The 96-well microplate (hereinafter referred to as the "microplate") is a transparent plastic plate used to hold samples for testing. It contains multiple rows of uniformly sized wells, each coated with a specific antigen or antibody. All experiments performed on this instrument are conducted using microplates.

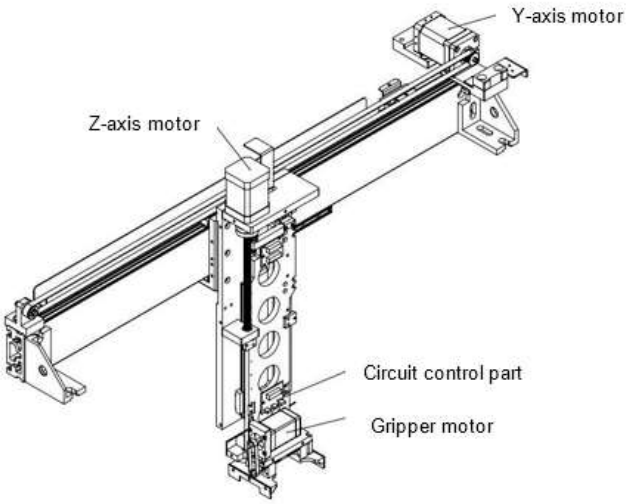


Figure-3 Layout of Microplate Transfer System

Function of the microplate transfer system: To move microplates between different components, thereby enabling the accurate execution of functions such as pipetting, incubation, microplate washing, and reading.

6.1.3 Oscillating Incubation System

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

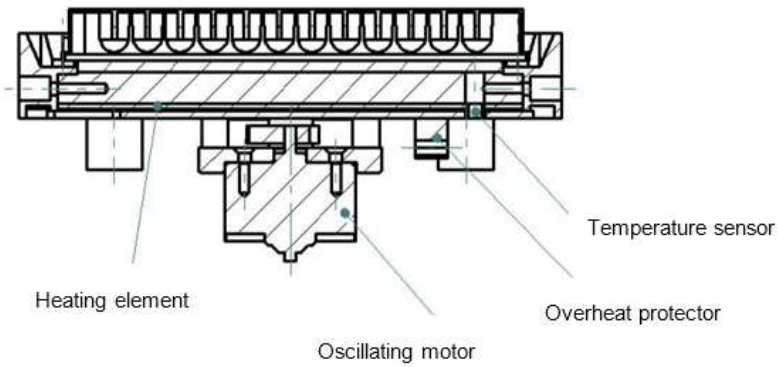


Figure-4 Layout of Oscillating Incubation System

Function of the oscillating incubation system: The oscillation function agitates the liquid in the microplate to ensure thorough mixing and reaction. The incubation function supplies the necessary experimental temperature and maintains it within a controlled range, ensuring safe operation of the instrument and meeting the requirements for incubating immunoreactions.

6.1.4 Microplate Washing System'

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

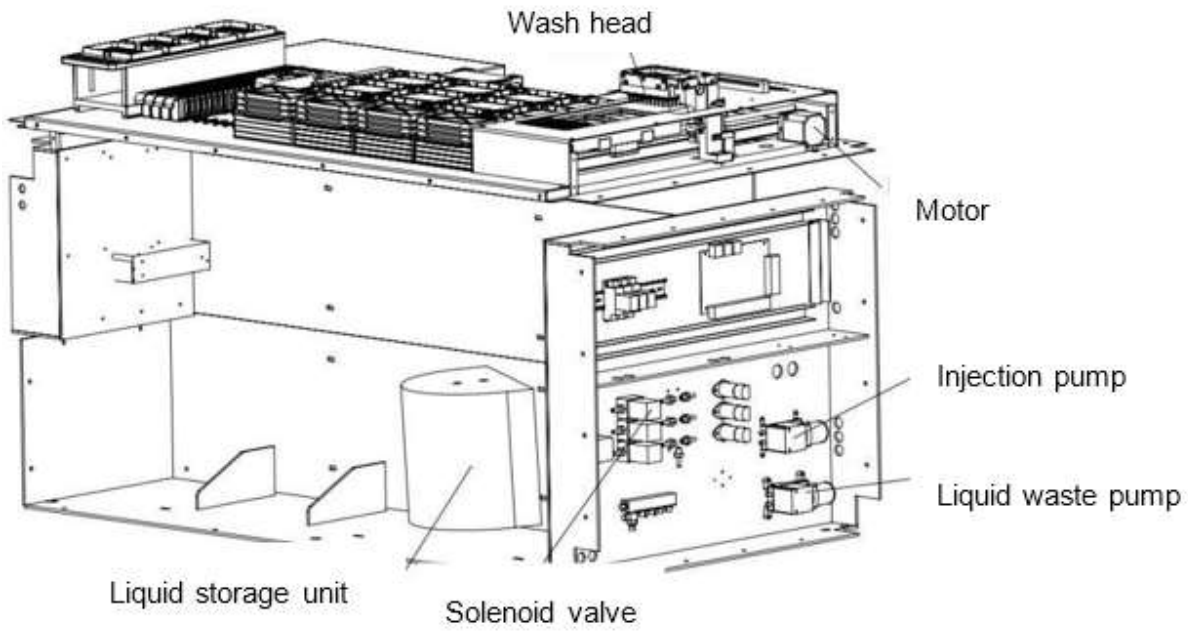


Figure-5 Layout Of microplate Washing System

Function of the microplate washing system: By moving the wash head, the wash buffer from the liquid storage unit is delivered into the microwells, and the residual liquid is then transferred to a separate liquid storage unit, thereby enabling the separation of free markers from immune complex markers.

6.1.5 Enzyme-labelled Analysis System

The optical path detection module of the enzyme-labeled analysis system comprises a light source, optical filter, optical fiber, circuit control board, motor, and other related components.

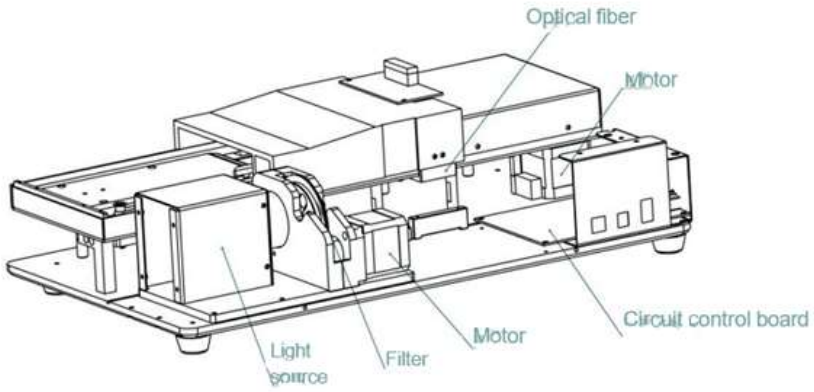


Figure-6 Enzyme-Labeled Analysis System'

Function of the enzyme-labeled analysis system: The liquid processed by the sample-in system, microplate transfer system, oscillating incubation system, and microplate washing system is analyzed by the enzyme-labeled analysis system to generate the test result and provide an indicative evaluation.

6.1.6 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 of the instrument.

7. Installation

7.1 Transport and Storage Conditions

Packaging:

The main unit is protected using three-layer packaging:

- The outer layer is a carton box used for labeling, equipment protection, and general packaging.
- The middle layer is a plastic film that provides moisture and water resistance.
- The inner layer consists of a bubble wrap cushion, secured with stretch film to offer shock absorption.

Transport:

During transportation, it must be protected from strong impacts, rain, and direct sunlight.

Storage:

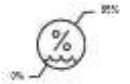
Store the packaged instrument in a well-ventilated area that is free from **corrosive** gases. The storage conditions must meet the following parameters:

- Temperature: **-40°C to 55°C**
- Relative humidity: **≤ 85%**
- Atmospheric pressure: **85 kPa to 106 kPa**

Labeling:

The external transport packaging must include the required handling and identification labels.

Symbol	Designation	Instruction
	Upward	Indicates the package should be kept upright during handling.
	Fragile, handle with care	Indicates the package contains fragile items and must be handled carefully.

	Keep dry	Indicates the package must be kept dry.
	Do not roll	Indicates the package must not be rolled during transport or handling.
	Temperature limitation	Indicates the acceptable temperature range is -40°C to 55°C.
	Humidity limitation	Indicates the relative humidity must not exceed 85%.
	Atmospheric pressure limitation	Indicates the acceptable atmospheric pressure range is 85 kPa to 106 kPa.

7.2 Installation Conditions and Environment Validation

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Determine the instrument's overall dimensions and weight prior to installation. Check the user’s site conditions in advance, including the building layout, elevator capacity, and doorway widths through which the instrument must pass. Prepare handling equipment suitable for the instrument’s weight.

7.3 Operating Environment

1) Designed for indoor use in a well-ventilated environment.
2) Normal operating conditions include:
   - Power supply: **200–240V~**, 50/60Hz
   - Ambient temperature: **10°C to 30°C**
   - Relative humidity: **≤85%**
   - Atmospheric pressure: **85 kPa to 106 kPa**
3) The instrument should be kept away from strong electromagnetic interference and protected from direct exposure to intense light.
4) A proper grounding system must be in place.
   - Suitable for use at altitudes below 2000 meters; for altitudes above 2000 meters, calibration must be carried out by authorized professional personnel.
   - **Transient overvoltage category:** Category II
   - **Pollution degree:** Level 2

7.4 Installation Requirements and Safety Precautions

- During loading and unloading, follow the "Up" orientation label and avoid rolling the instrument. As it contains delicate electronic and mechanical components, it must be handled with extreme care. Use appropriate handling tools such as a forklift or pallet truck. If mechanical aids are unavailable, the unit must be carried by multiple personnel using proper safety precautions, and manual transport must not exceed 10 meters.
- For table-top installation, place the instrument on a flat and stable surface. The table should be 10–20 cm larger than the instrument base in both length and width and have a load-bearing capacity of at least 600 kg/m^2. If using a support structure, it must be fixed to avoid mechanical drift caused by instability.
- Position the instrument with its rear against a wall to prevent access from behind during operation.
- Ensure the computer used meets the minimum system requirements and has adequate disk space to avoid operational failure.
- Before maintenance or transportation, set all mechanical components to safe, collision-free positions, and secure or remove all movable parts and containers.
- The manufacturer provides EMC compliance information. It is the user's responsibility to maintain an appropriate electromagnetic environment for reliable instrument performance.
- Only trained professionals are permitted to disassemble or install the instrument.
- Installation must be performed under the supervision of qualified personnel, strictly following the official installation procedures.
- Do not install the instrument in a location where it is difficult to access the power disconnecting unit.
- The instrument is intended for fixed-location installation. If relocation is required, it must be handled by a qualified professional, and recalibration is mandatory before resuming use.

7.5 Connect Power Supply

- The instrument must be installed in a location with proper grounding protection. Ensure that the power port at the rear remains unobstructed, allowing for quick disconnection of the power cord in case of an emergency.
- Connect the AC power supply to the designated plug, ensuring the input voltage matches the value indicated on the instrument's nameplate. Users are responsible for providing a power source that meets local and application-specific safety standards. The supply voltage should be maintained at 200–240V~ during operation. Since a sudden power outage may result in data loss, the use of an uninterruptible power supply (UPS) is recommended to safeguard data.
- Always verify that the power plug is fully and securely inserted into the outlet.

7.6 Unpacking and Installation of Instrument

7.6.1 Visual Inspection and Handover of Instrument

Inspect the acrylic panel of the instrument for any cracks or breakage, and check whether any critical internal components are damaged. If damage is found, promptly take photographs.

7.6.2 Unpacking Steps

- Begin by removing the screws from the upper cover, then use a #14 fork spanner to lift off the cover.
- Once the upper cover is removed, dismantle the four side panels of the wooden crate in the same manner. It is recommended that two people carry out this step—one of whom should hold the crate to prevent it from collapsing and causing injury.
- After removing the four sides, you will see that the instrument is secured to the base using hex socket screws. Use an Allen key to remove the M6 hex screws from the four aluminum angle brackets, thereby detaching the instrument from the base.
- At this stage, a forklift can be used to transfer the instrument to a level surface. Before inserting the forks underneath the instrument, inspect the bottom to ensure there are no obstructions—such as the liquid waste container or misaligned casters—that could hinder fork entry or cause damage during lifting.

1) When no elevator is available, it is recommended not to remove the base of the instrument, as this can aid in manual handling. During transportation, ensure the instrument is handled carefully to avoid excessive vibration. Once the instrument is moved to the intended floor, the base can then be removed.

For cabinet-type instruments with casters, use an adjustable spanner to raise the supporting feet, allowing all four casters to touch the ground. Adjust the supporting feet to a height of approximately 2 cm above ground level, ensuring they do not make contact during movement. After releasing the caster brakes, gently push the instrument to its designated location.

For table-top instruments, which are lighter, first remove the housing and keep the pallet in place. Manually transport the instrument to the correct floor, making sure to avoid tilting or collision during the move.

2) When an appropriately sized elevator is available, the base of the instrument can be removed beforehand in the building's entrance area.

For cabinet-type instruments, raise the supporting feet with an adjustable spanner so that the casters touch the floor, then push the instrument into the elevator. Move it to the assigned department and position it accordingly. For table-top instruments, confirm that the elevator dimensions are suitable. If they are, carefully move the instrument into the elevator, taking precautions to prevent any collisions during transit.

- Once the instrument reaches the designated department, place it in the prearranged location. Ensure that the back of the instrument is positioned 50–70 cm away from the wall and that all doors can open fully to allow easy access for maintenance. Remove the protective film from the outer surface of the instrument.

- For cabinet-type instruments with casters, lower the supporting feet after positioning the instrument, and adjust them to ensure the instrument is level. The supporting feet must bear the full weight of the instrument, ensuring the casters are lifted off the ground.
- For table-top instruments, use a spanner to adjust the four base feet until the instrument is properly levelled.

7.6.3 Moving the Instrument out of the case

Preparation Before Unpacking:

- Ensure the base or worktable is ready before unpacking the instrument.
- Confirm there is enough space to place the instrument and its accessories.
- The worktable surface should be 10–20 cm larger than the base of the instrument in both length and width.
- Check the "Standard Configuration List" to verify all items are included.

Unpacking Steps:

- Remove the flexible outer packaging.
- Cut the strap at the top of the packing case.
- Remove the top cover of the packing case.
- Take out the inner box from the packing case.
- Cut the adhesive tape on the top of the inner box (avoid touching the instrument with the knife).
- Open the inner box and ensure all four sides lay flat on the ground.
- Remove the small accessory box from the packaging.

Lifting and Placement:

- Do not lift the instrument by yourself — four persons should lift the instrument together by its base beam.
- Lift gently and steadily to avoid damaging internal mechanical components.
- Place the instrument securely on the prepared table or ground surface.

Final Checks:

- Open the small accessory box and arrange the parts in an open area.
- Verify that all components listed in the packing list are present.

7.6.4 Removal of Fasteners inside the Instrument

To prevent movement of internal components during transport, fasteners are applied to secure mobile parts. These fasteners must be removed before installing and operating the instrument.

Locations and procedures for removing the securing blocks:

Main components with fixing blocks include:

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

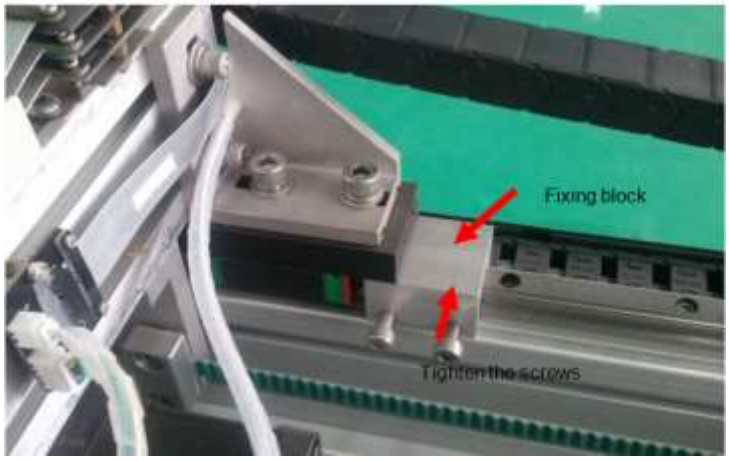


Figure-7

2) Y-Axis Track of Sample Probe

(1) 2 fixing blocks on each of the two beams of the sample probe of 8-tip integrated instrument, totally 4 fixing blocks.

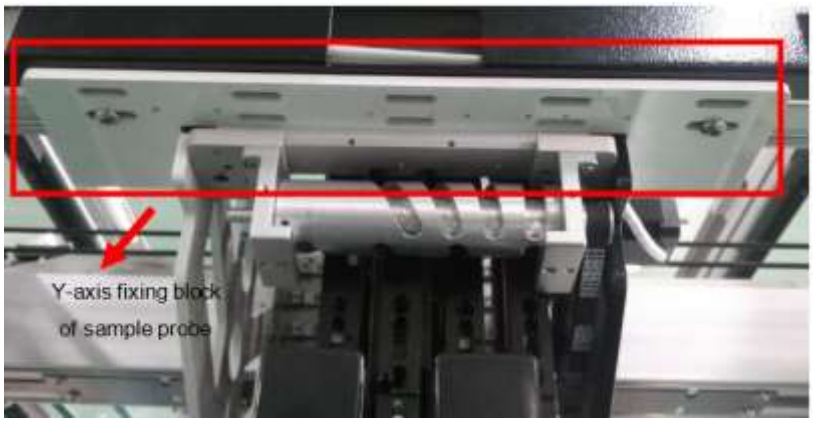


Figure-8

The 2- or 4-tip sample probe occupies a beam, and there are 2 fixing blocks.

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



Figure-9

4) There is one fixing block on each of the upper and lower tracks along the Y-axis of the instrument, making a total of two fixing blocks.
Removal method: Use a properly sized Allen key to loosen the screw securing the fixing block, then slide the block along the track until it can be taken out.

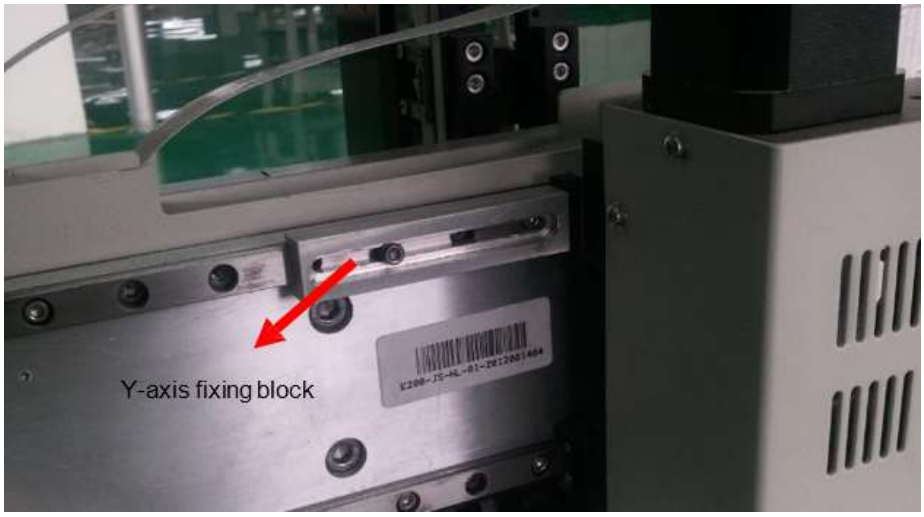


Figure-10

Locations and Removal Method for Fixing Straps
The components secured with fixing straps include:
① The Z-axis belts of each unit probe
② The Y-axis belt of the plate washing unit
Removal Method:
Use diagonal pliers or scissors to cut the straps, being careful not to damage the belts.
To remove the protective tip from the probe, first cut the strap, then gently lift the unit probe and detach the tip.

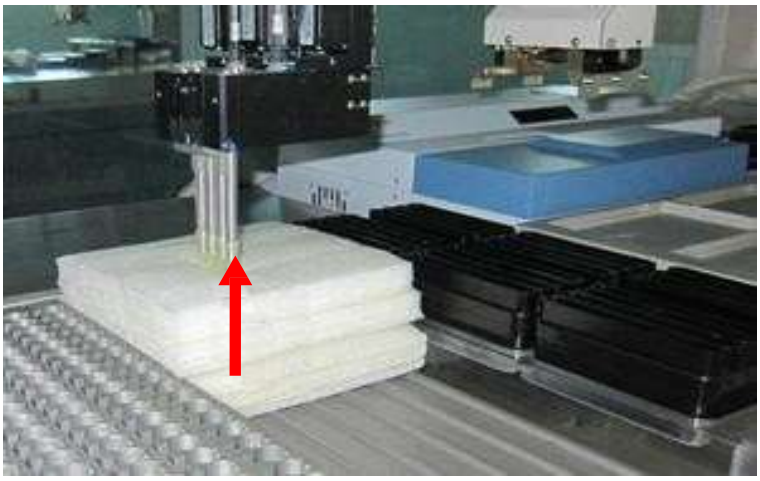


Figure-11

Removal of fixing panel

To open the instrument's front cover, first raise the Z-axis of the unit probe. Once elevated, remove the protective tip from the channel.

On the instrument's tabletop, an ABS panel secures the sample rack and reagent rack with hex socket screws. Use an Allen key to loosen and remove these screws, then take off the ABS panel. Reinstall the spare screws back into their original positions.'

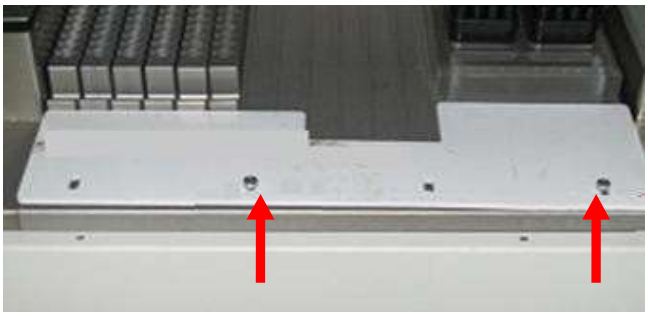


Figure-12

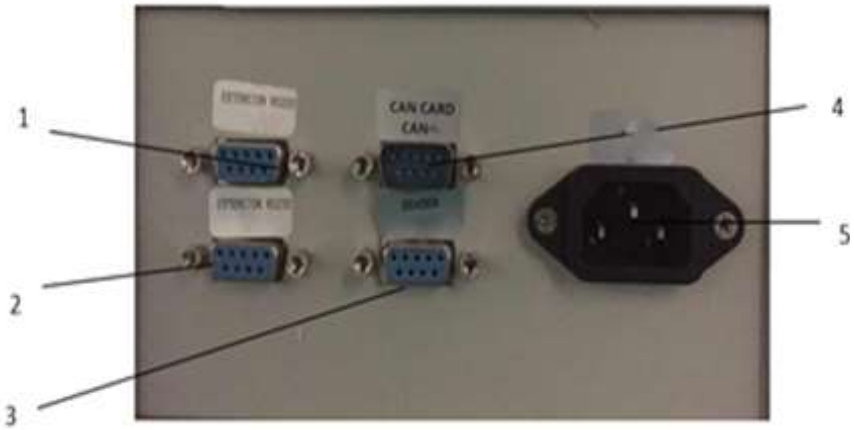
You can see that the handle on the front panel faces the inside of the instrument, which can prevent collision of the handle during transport. Use a screwdriver to remove the handle and then install it facing outward.

- After removing the fixing blocks located in the Y-axis direction of the pipetting system and the transfer arm, be sure to reinstall and securely tighten the screws in their original positions. The two fixing blocks on the X-axis of the pipetting system can be removed directly without reinstallation.
- The instrument must not be powered on or operated until all fixing blocks and fixing straps have been completely removed.
- For instruments selected for disassembly, ensure that the fixing modules are removed according to the specific model in use.

7.7 Connection of Instrument

7.7.1 Description of Ports on the Instrument

Ports on the instrument are shown in the figure below



1) Standby ports
2) Standard ports
3) Reader port
4) CAN Card port
5) Power input port

Figure-13

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

7.7.2 Position and Function of Power Switch

The power switch is located at the front left side of the instrument; pressing the switch down turns the power "ON," and when the switch springs up, the power is "OFF."

7.7.3 Connection of External Computer

Unpack the computer main unit and monitor, then proceed to assemble the computer.

Next, sequentially connect the instrument's power cord, CAN card DB9 cable, CAN card USB cable, reader serial cable, and scanner serial cable to the corresponding ports on the rear panel of the instrument, where clearly labeled jacks are provided for each connection.

7.7.4 Pipeline Connection

1) **Water Classification:** Fully automated enzyme immunoassays require a cleaning solution that is specifically provided by the reagent provider and must be compatible with the reagent kit.
2) **Bucket Classification:** The system includes both cleaning solution buckets and waste liquid buckets.

Important Notes:

1) Users must clearly identify the types of tanks and ensure that each tank is connected to its corresponding pipeline based on the color-coded labels. Incorrect connections are strictly prohibited.
2) Daily pre-use checks must include:
   Verifying that the cleaning solution tank is full; if not, it must be refilled.
   Ensuring the waste liquid tank is completely emptied; any remaining waste must be properly cleared.

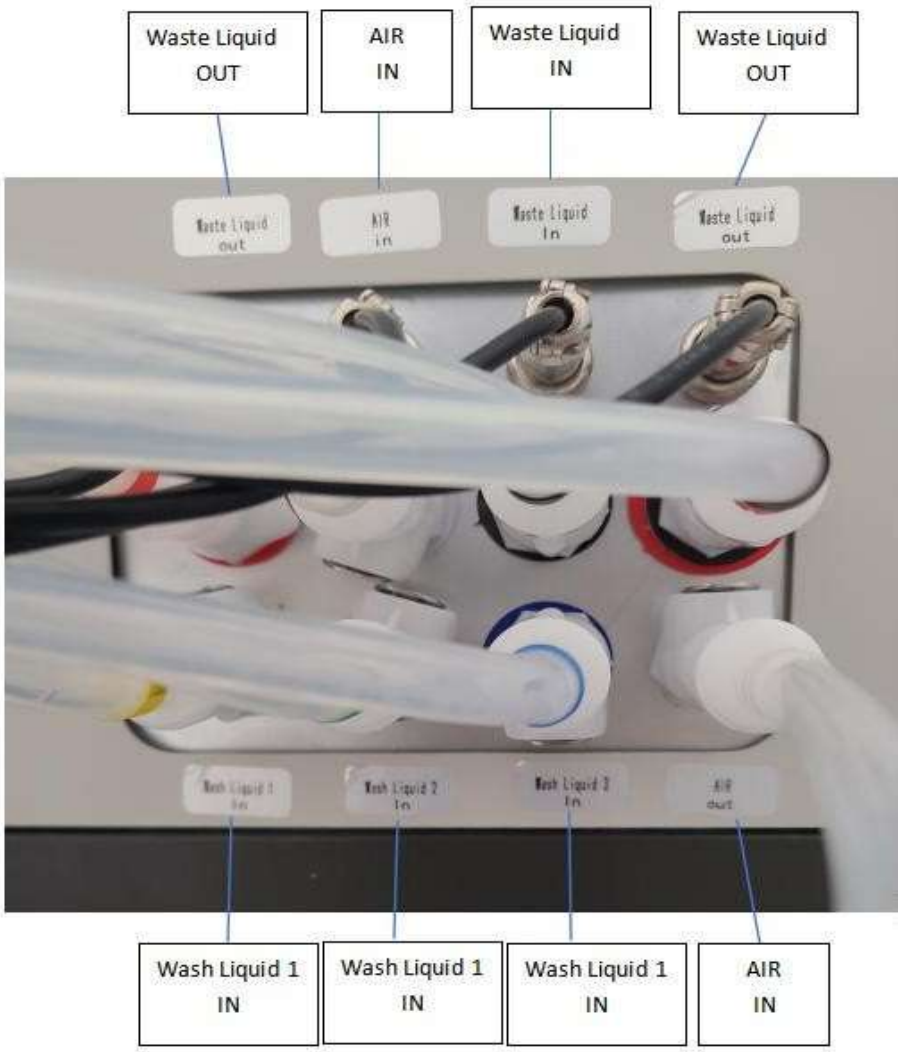


Figure-14

7.8 Commissioning

Operators are not permitted to modify software parameters without prior authorization. If adjustments are required, they must be made with professional personnel knowledge. The user shall bear full responsibility for any negative outcomes resulting from unauthorized modifications to the software parameters or functional settings.

7.9 Operating Environment-System Requirements

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

8. Software Installation

Model: ADC ELISA SOFTWARE
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. Working Principle

According to the structural composition, the operation steps of this product are as follows: sample and reagent processing, immunoreaction (including oscillating incubation and microplate washing), optical detection, and software control (which includes instrument control, data analysis and processing, and data transmission). These steps collectively enable ELISA detection and result analysis.

Enzyme-Labelled Analysis Module:

- Light emitted from the light source passes through an optical filter, converting it into a single beam of monochromatic light that enters the sample in the microplate. The sample partially absorbs this monochromatic light, while the remaining light passes through to the photoelectric detector. The detector converts the varying intensity optical signals into corresponding electrical signals. These signals undergo pre-amplification, logarithmic amplification, analog-to-digital conversion, and other processing before being sent to the microprocessor for data analysis and calculation, allowing for qualitative or quantitative analysis of the sample.
- ELISA is a solid-phase immunoassay technique. It involves coating the surface of a solid-phase carrier with antibody or antigen while preserving its immunocompetence. During the assay, the sample and enzyme-labeled antigen or antibody are added according to the protocol to react with the antibody or antigen on the carrier's surface. Free, unbound components are removed by washing, followed by the addition of the reaction substrate. Based on the color change of the substrate after enzymatic catalysis, qualitative or quantitative analysis is conducted using the absorbance (A) value.

Immunoreaction Methods:

The immunoreaction methods include sandwich assay, competitive assay, capture assay, and indirect assay, selected based on the immunoreaction type.

1) **Sandwich Assay:**
   Used for antigen detection, this method typically employs a specific antibody-coated carrier and enzyme-labelled specific antibody that react with the antigen to form a “solid-phase carrier antibody – antigen – enzyme-labelled antibody” complex. Unbound samples and reagents are washed away, leaving only the formed complex. The reaction substrate is applied, and absorbance is measured by the optical detector. The antigen concentration is directly proportional to the absorbance. Sometimes, a step to bind the specific antibody to the carrier is added; other steps remain unchanged.
   Antibody detection follows a similar principle, except enzyme-labeled specific antigen and antigen-coated carriers are used to form a “solid-phase carrier antigen – antibody – enzyme-labelled antigen” complex.
2) **Competitive Assay:** There are two common methods: enzyme-labeled antigen and enzyme-labelled antibody.
   In the enzyme-labeled antigen method, enzyme-labeled antigen and sample compete for antibody-coated binding sites on the carrier, forming either “solid-phase carrier antibody – antigen” or “solid-phase carrier antibody – enzyme-labeled antigen” complexes. Unbound materials are washed away, and absorbance is measured.

The antigen concentration is inversely proportional to absorbance: low antigen concentration results in more enzyme-labeled antigen binding and higher absorbance, while high antigen concentration leads to more sample antigen binding and lower absorbance. Sometimes, a step to bind the antibody to the carrier is added; other steps remain the same.

In the enzyme-labeled antibody method, enzyme-labeled antibody and sample compete for antigen-coated binding sites on the carrier, forming either "solid-phase carrier antigen – antibody" or "solid-phase carrier antigen – enzyme-labeled antibody" complexes. Washing removes unbound components, and absorbance measurement shows that antibody concentration is inversely proportional to absorbance. The binding pattern mirrors that of the enzyme-labeled antigen method.

3) **Capture Assay:**
   Commonly used to detect specific immunoglobulin M (IgM) antibodies. The reaction carrier is coated with anti-human specific IgM antibody and enzyme-labeled antigen to form the "solid-phase carrier – anti-IgM antibody – IgM antibody – enzyme-labeled antigen" complex. After washing unbound components, the complex remains. The substrate is added, and absorbance measurement reflects the antibody concentration, which is directly proportional to absorbance.
4) **Indirect Assay:**
   Also used for detecting specific IgM antibodies. The carrier is coated with antigen, and enzyme-labeled anti-human specific IgM antibody reacts with the sample, forming the "solid-phase carrier antigen – IgM antibody – enzyme-labeled anti-IgM antibody" complex. After washing unbound materials, the complex remains. Substrate addition and absorbance measurement enable quantitative analysis, with antibody concentration directly proportional to absorbance.

10.Operations

10.1 Description of Directory Files

The following directories are located within the installation folder. Each serves a specific purpose as described below:

- **Conf:** Stores system alarm files.
- **Database:** Contains the system database, where all operational data and instrument parameters are saved. You can modify data by replacing this database.
- **Language:** Holds language files used for the system settings interface.
- **Sample Barcode:** Stores barcodes of tested samples.
- **Plate Barcode:** Contains barcodes of microplates.
- **Raw Data's**: Includes raw data collected by the system.
- **Traces:** Keeps logs and records of instrument operations and running history.

10.2 File Menu

10.2.1 System Login and Logout

To ensure secure system usage, Kindly log in before operating the system. The login screen is shown in the figure. For the initial login, the default username is "admin" and the default password is "addcare"

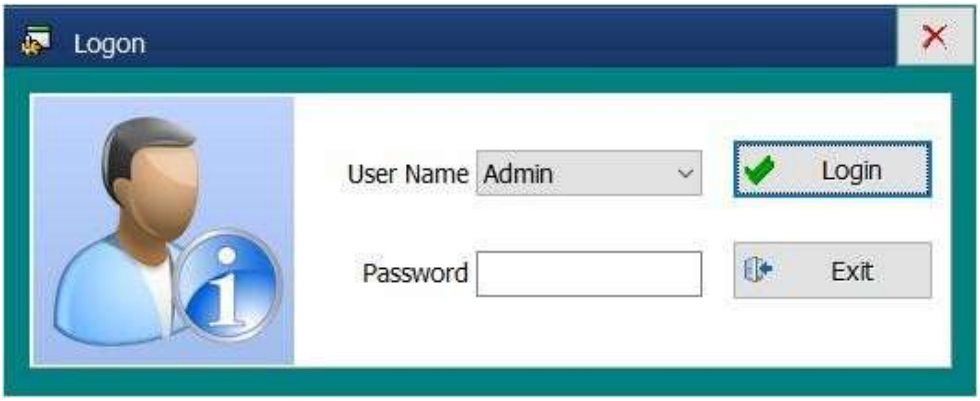


Figure-15

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

10.2.2 Change Password

Click **"Change Password"**, then enter the old password and the new password in the pop-up window and click **OK** to confirm. This option allows an operator to change their own password. If the operator has user management permissions, they can also edit the information of all users through the **User Manage** interface.

10.3 System Manage

10.3.1 User Manage

Click "**User Manage**" under the "**System Manage**" menu to open a new interface where users can be added, modified, or deleted. In this interface, you can also set each user's password and assign permissions. Each permission corresponds to a specific menu within the system. It is recommended that the general administrator be granted full permissions, while general operators should have access only to routine operational functions.

10.3.2 System Settings

To meet different user requirements during operation of the instrument, user can adjust and set some operation parameters of the instrument in the "System Settings" menu so that its operation can better cater to 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. The operator attempting to modify an option

10.3.2.1 General Tab

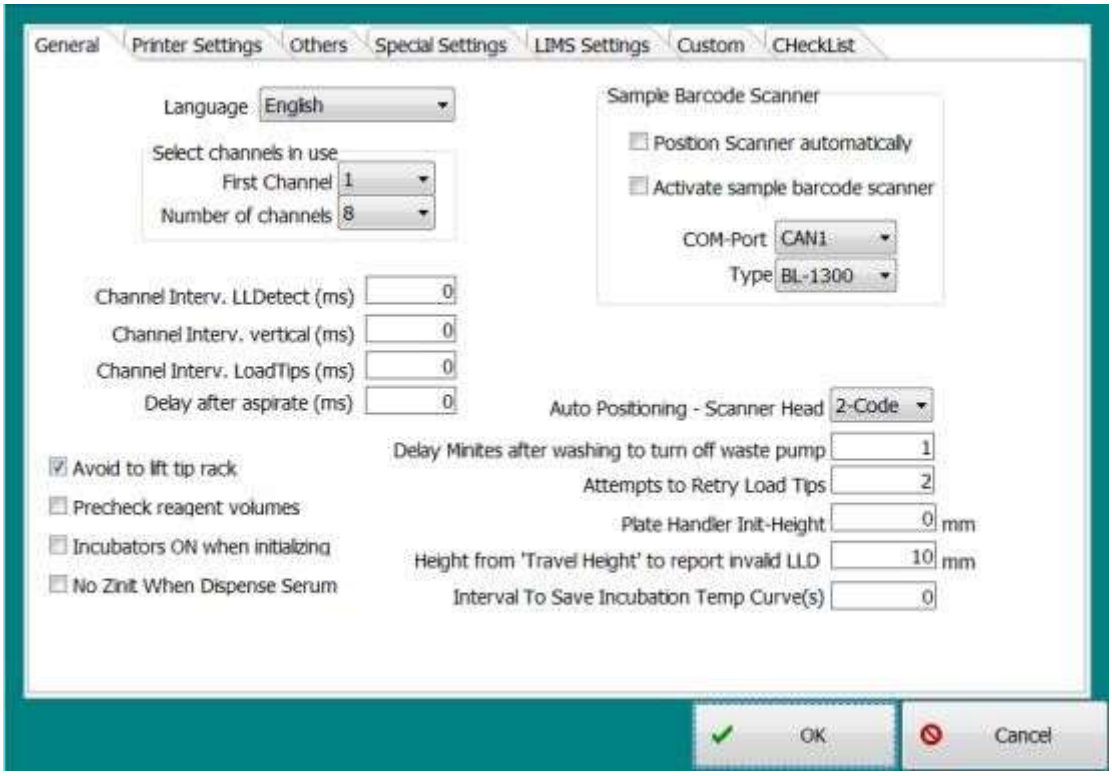


Figure-16

Language: Allows you to set the software's interface language. Available options include English, and others. The selected language will take effect only after restarting the software.

Set Channels in Use: Configure the First Channel and Number of Channels. If a channel malfunctions, the corresponding tip can be excluded from use. For example, if the second tip on a four-tip instrument is faulty, you can set First Channel to "3" and Number of Channels to "2". In this configuration, only the 3rd and 4th tips will perform the pipetting tasks during the rerun of the experiment, thereby avoiding delays while waiting for technician support.
After repairs, default parameters should be adjusted by an authorized personnel.

- **Incubators ON During Initialization**: It typically takes 3–5 minutes for the incubator to reach the desired temperature. When this option is enabled, the system will begin heating during the pipetting step. If left unchecked, the temperature will rise to 37°C only at the start of the incubation phase.
- **Delay After Aspirate**: After aspirating, the tip remains in the liquid briefly to ensure accurate and sufficient aspiration.
- **Attempts to Retry Load Tips**: Specifies the number of retry attempts when no tip is detected or when the probe fails to pick up a tip.
- **Sample Barcode Scanner**: When using the barcode scanning feature, select the appropriate port and scanner type.

10.3.2.2 Printer Setting Tab

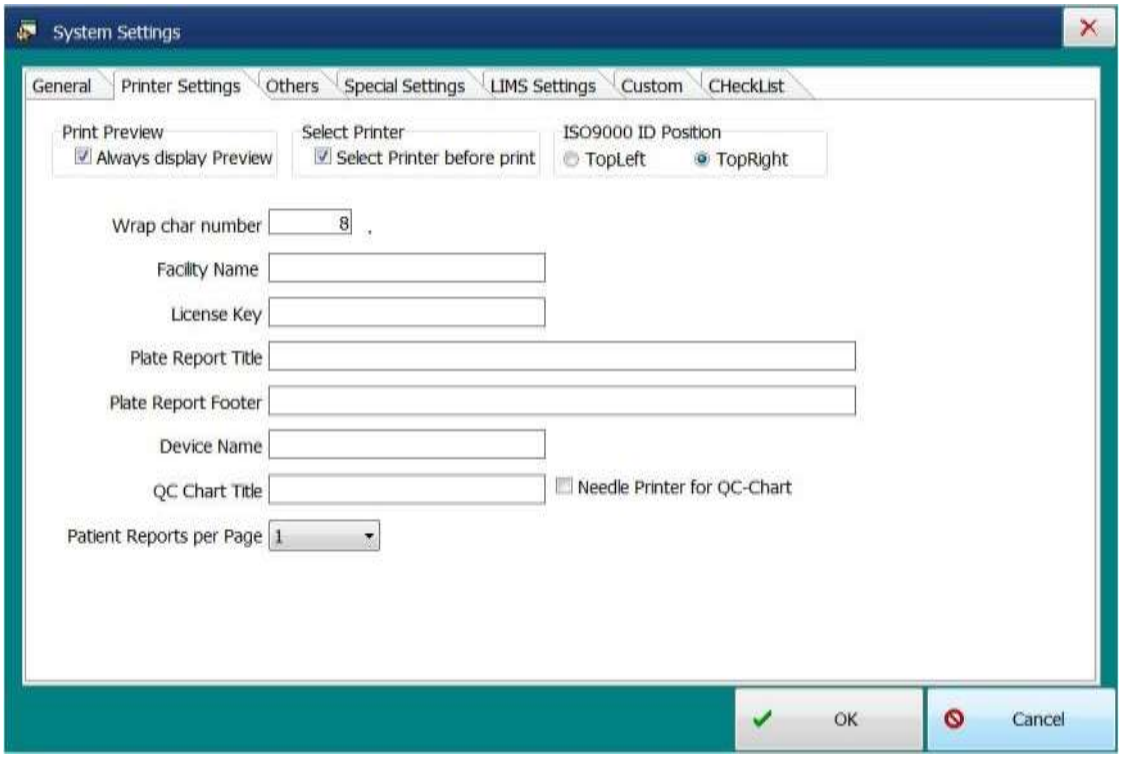


Figure-17

This interface allows the user to configure various printing parameters:

- **Always Display Preview**: Enables or disables the preview of microplate results before printing.
- **Select Printer before Print**: Specifies whether the user needs to select a printer each time an experiment result is printed.

- **ISO9000 ID Position**: Defines the position of the ISO9000 ID on the printed microplate result page.
- **Facility Name**: Enter the name of the facility using the instrument. This name will appear on the software's main interface.
- **Plate Report Title**: Sets the title displayed on the printed microplate result report.
- **Plate Report Footer**: Allows the user to add custom information that will appear at the bottom of the printed microplate report.
- **QC Chart Title**: Sets the title shown on the QC chart when printed.
- **Patient Reports per Page**: Determines how many patient reports are printed on each page. Typically, one report takes up half of an A4 sheet. Select "2" if using full A4 sheets, or "1" if the A4 paper is pre-cut in half.
- **Other Options**: These can generally be left at their default settings.

10.3.2.3 Others Tab

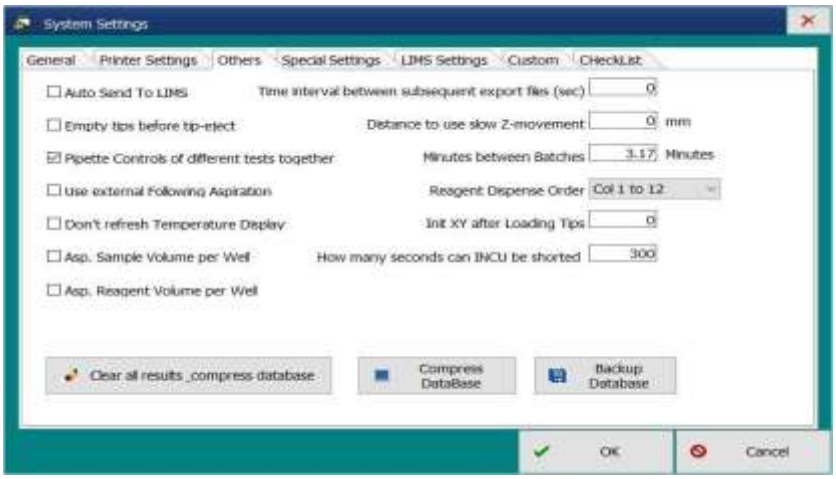


Figure-18

10.3.2.4 Tab

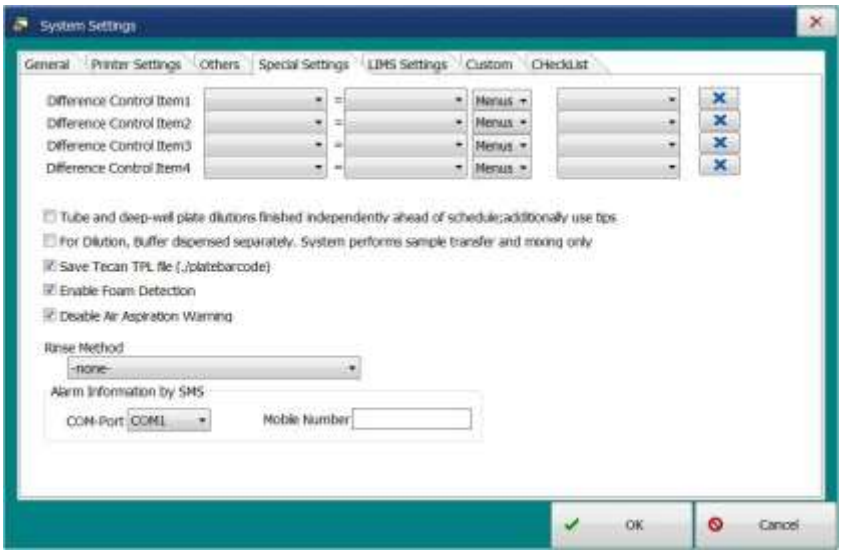


Figure-19

Difference Control Item

This is an experimental feature intended for specific items with special application requirements. If no such items are used, this option should be left unselected.

Remember Level of Repeated Reagents

When enabled, the unit probe will skip liquid level detection if it returns to the same reagent position. Instead, it will aspirate based on the previously recorded liquid level. This is useful when the same reagent is used for multiple items, as it increases pipetting efficiency.

Tube and Deep-Well Plate Dilutions Completed Independently in Advance; Additional Tips Used

When both tube and plate dilutions are needed, all sample dilutions are completed first, before beginning the pipetting process. Additional tips—equal in number to the samples—will be used. By default, pipetting begins immediately after adding the diluent.

10.3.3 Liquid Type

The options in this menu are used to create and modify various liquid types—such as QC and serum—to ensure accurate pipetting based on the viscosity of each liquid. These settings should only be adjusted with caution.

When you click on **"Liquid Type"**, an interface will appear that allows you to create, modify, copy, or delete different liquid types. During method setup, be sure to select the appropriate liquid type based on the actual requirements.

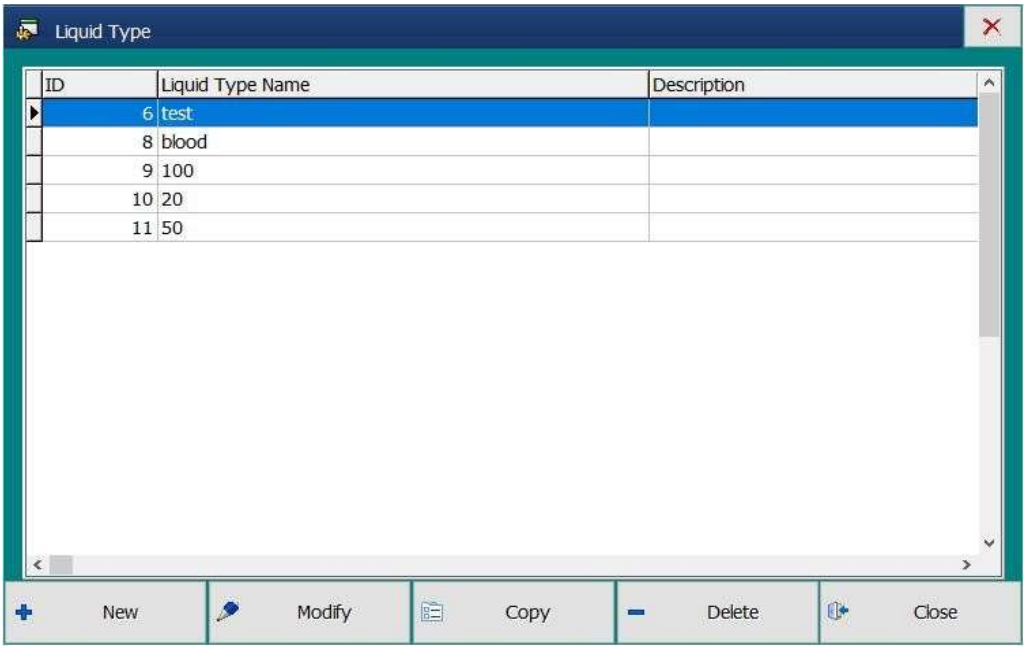


Figure-20

A liquid type primarily consists of a set of data along with configured parameters for aspiration and dispensing speeds and volumes.

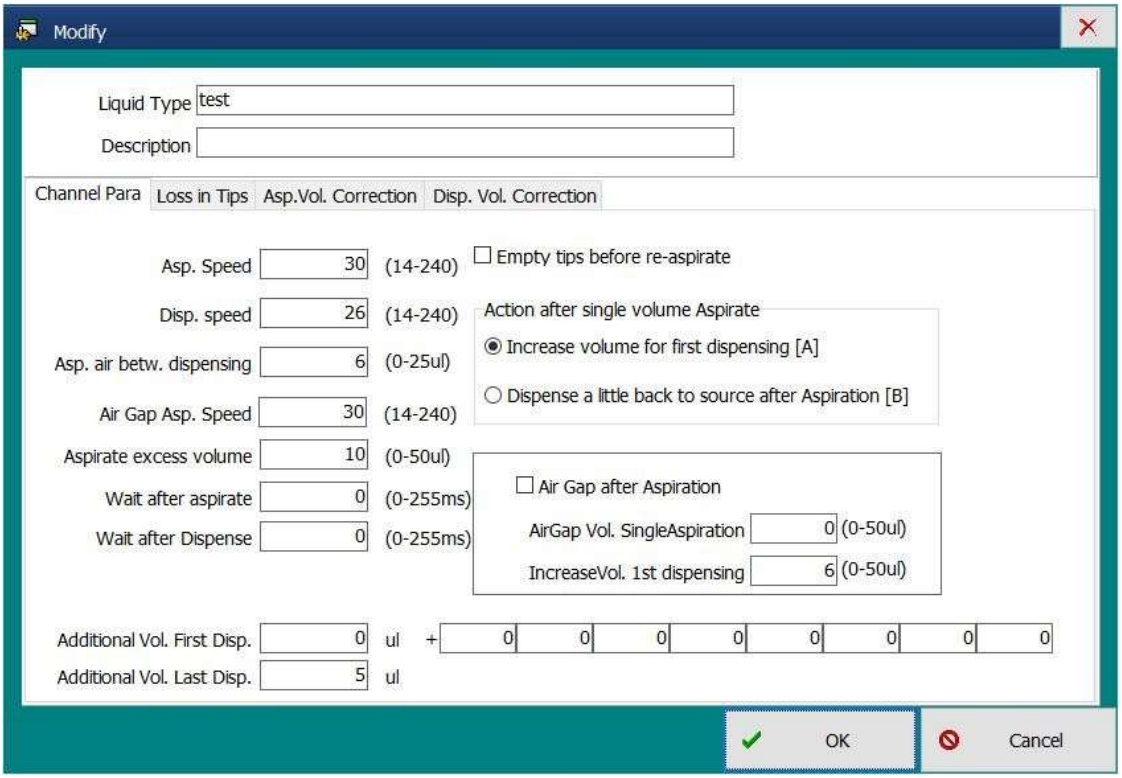


Figure-21

10.3.3.1 "Channel Para' 'Tab

Parameter Descriptions

Note: For all speed-related settings in the software, a higher value corresponds to a slower speed.

- **Asp. Speed:** Refers to the aspiration speed of the sample probe pump. Adjusting this parameter can help improve aspiration accuracy. It is typically set between 38–40.
- **Disp. Speed:** Indicates the flow rate during liquid dispensing by the sample probe. For serum or QC samples, this is usually set to 27–30. Adjusting this value helps ensure accurate dispensing.
- **Asp. Air Between Dispensing:** Defines the volume of air aspirated after dispensing is completed. Proper adjustment (usually 2–3 µL) ensures complete dispensing and helps remove any liquid adhering to the tip.
- **Air Gap Asp. Speed:** Controls the speed of air aspiration after dispensing. For higher-viscosity liquids, a slower speed is recommended—typically set between 27–30.
- **Aspirate Excess Volume:** Specifies an additional volume of liquid to be aspirated for debugging purposes. Commonly set between 5–10 µL.
- **Empty Tips Before Re-aspirate:** When enabled, the system empties the tip before each aspiration during multiple aspiration cycles. This option is generally left unchecked, as repeated emptying can create foam.

10.3.3.2 ‘‘Loss In Tips’ ‘Tab

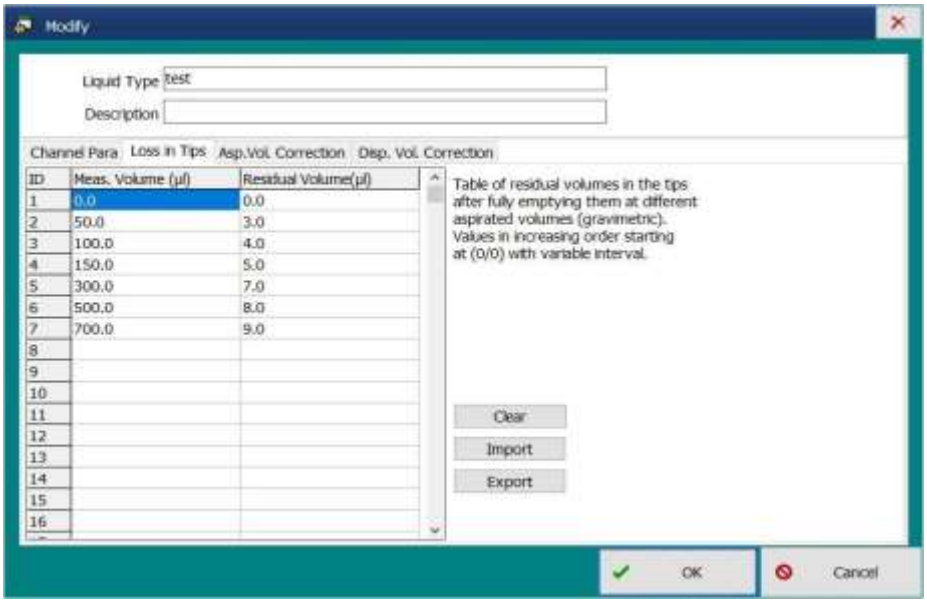


Figure-22’

The parameters in this tab are primarily used to control the aspiration accuracy of the unit probe. They define the aspiration curve for the unit probe.

- **Meas. Volume:** Represents the target liquid volume, which is also the theoretical aspiration volume.
- **Residual Volume:** A correction value used to compensate for any residual liquid left on the inner wall of the tips after aspiration.

10.3.3.3 ‘‘Asp. Vol. Correction’’ Tab

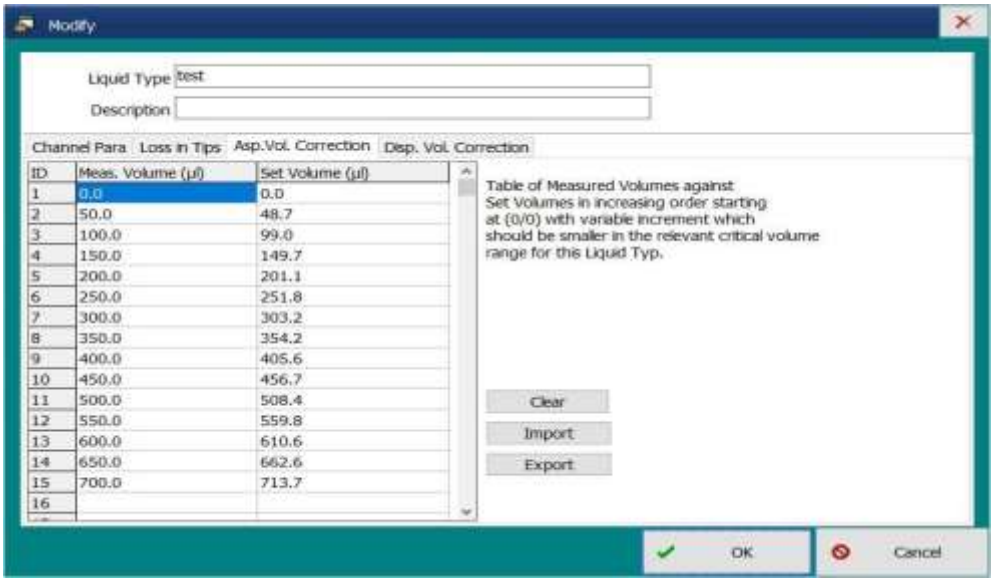


Figure-23’

The aspiration curve is used to automatically correct the accuracy of the aspirated volume.
This parameter enables automatic adjustment based on the polyline defined by the settings under Liquid Type during software operation. It is not required to enter every aspiration volume—just provide an appropriate range.

10.3.3.4 "Disp. Vol. Correction" Tab

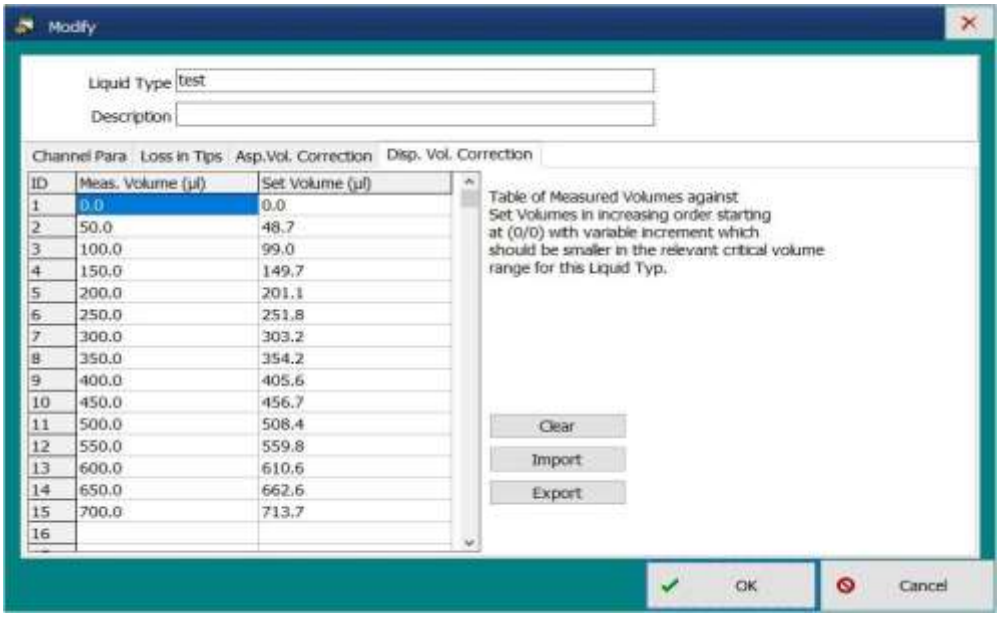


Figure-24

The dispensing curve is used to automatically correct the accuracy of the dispensed volume.
This parameter enables automatic adjustment based on the polyline generated from the Liquid Type settings during software operation. It is not necessary to include every dispensing volume—just enter an appropriate range.

10.3.4 Tube Dilation

After logging in with administrator privileges, click **"Tube Dilution Edit"** under the **"System Manage"** menu. The corresponding interface will appear, allowing users to create, edit, and modify dilution levels as needed. This dilution method is designed for multi-gradient, large-ratio dilutions (small-ratio dilutions can be performed directly in a microplate). It supports dilution using blank test tubes on the right side as well as in specially designed deep-well plates.

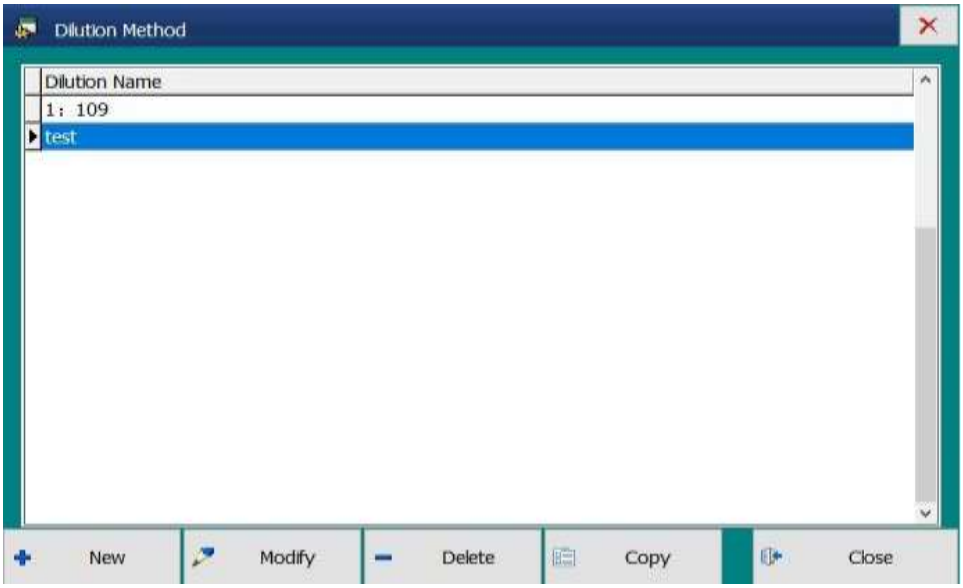


Figure-25

10.3.4.1 Edit Tube Dilution

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

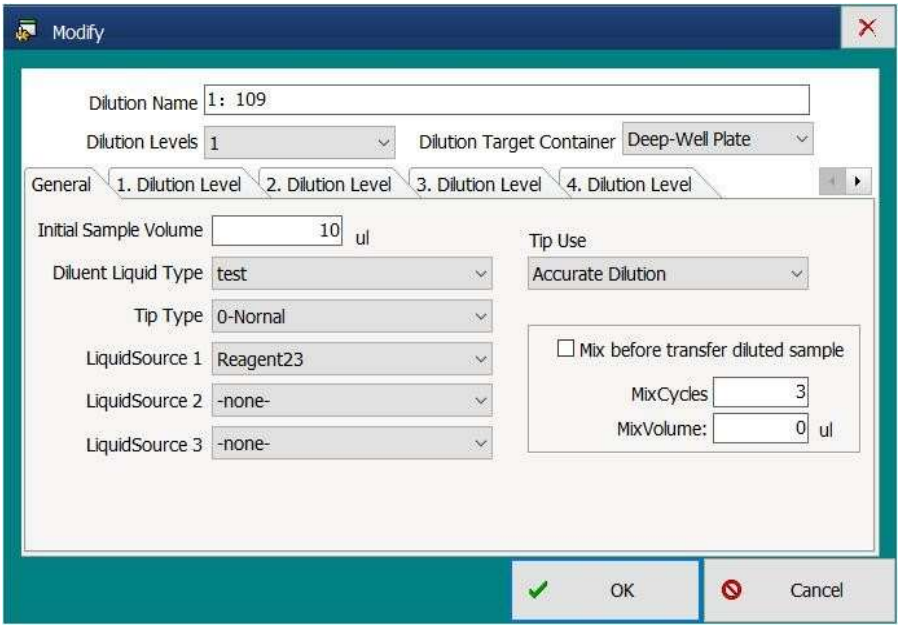


Figure-26

Dilution Name

Specifies the name of the tube dilution, which will be selected during method step editing.

Dilution Levels

Indicates the defined dilution levels (gradients). Set the appropriate levels based on the required dilution ratio.

Dilution Target Container

Two options are available: Right-side Blank Test Tube and Deep-Well Plate.

Parameters Under the "General" Tab

- **Initial Sample Volume:** Specifies the volume of sample to be diluted, determined by the desired dilution ratio.
- **Diluent Liquid Type:** Defines the type of diluent used.
- **Tip Type:** Select the tip type to be used—generally, the default type is sufficient.
- **Liquid Source Position:** Refers to the reagent chamber containing the diluent. The same diluent is placed in positions 1, 2, and 3 to ensure sufficient volume for the dilution process.

Parameters Under the "1. Dilution Level" Tab

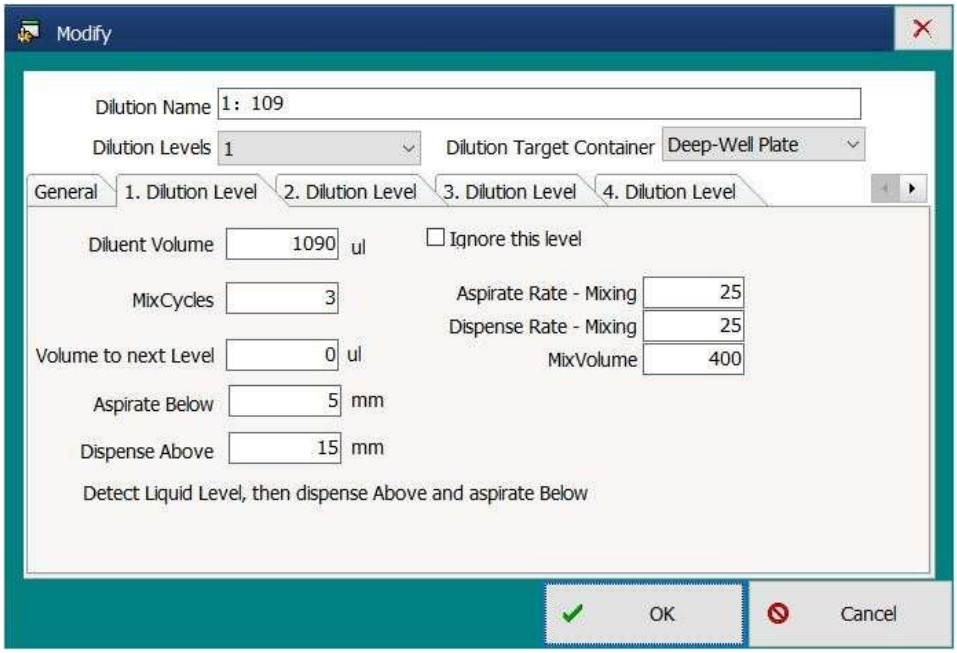


Figure-27

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 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, 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.

10.3.5 Reag. Supplier

It is used to set the reagent supplier. User can record the Address, Telephone.

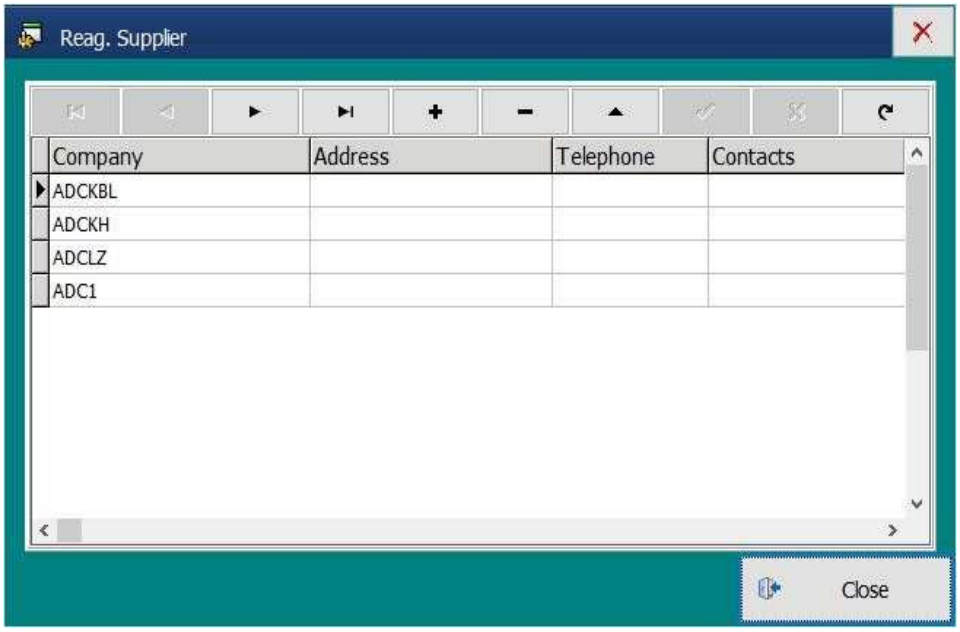


Figure-28

After clicking "**Add**", a blank line will appear. Enter the reagent supplier information and click Save.

To modify existing supplier information, follow the same steps as adding a new one-edit the details and click **Save**.

10.3.6 Wash Method Edit

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

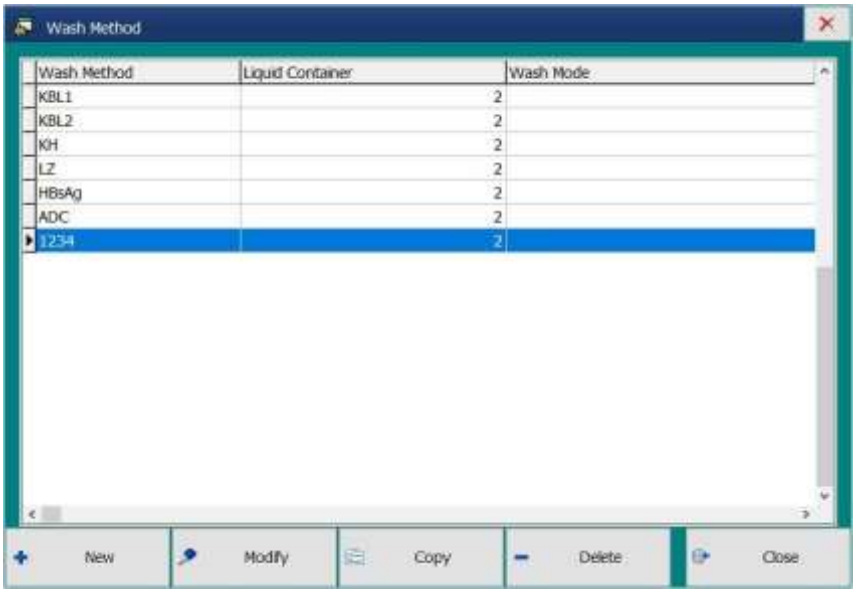


Figure-29

10.3.6.1 Modify Wash Method

Click "**Modify**"; the following window will appear:

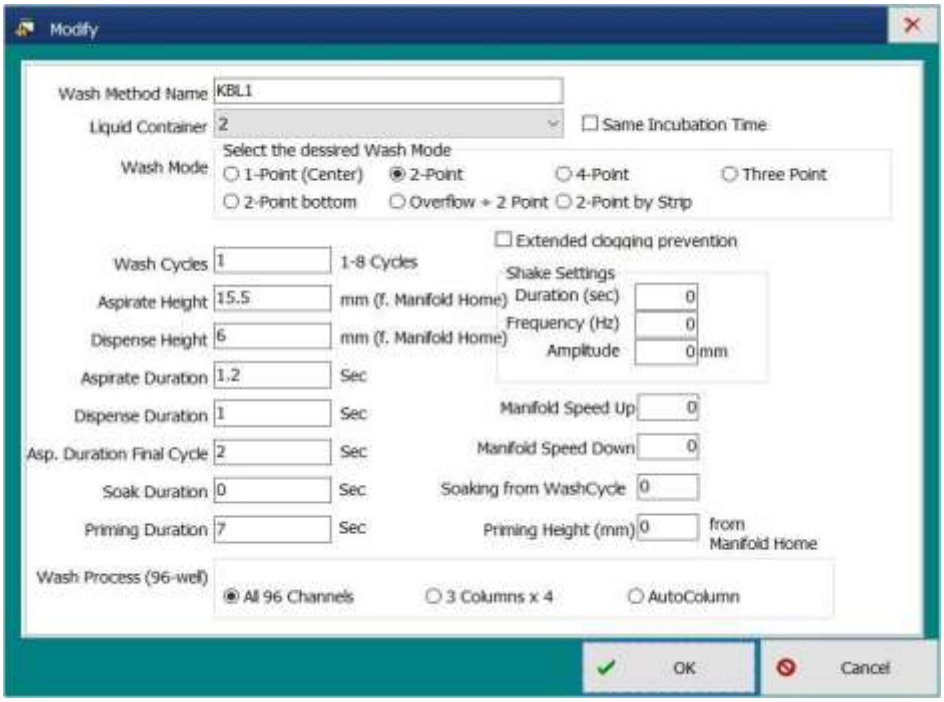


Figure-30

- **Wash Parameters Overview**
  Depending on the type of microplate used, different wash methods can be configured to ensure optimal cleaning performance. The wash mode is selected within the same interface, and any changes made to the wash parameters will take effect immediately.
- **Wash Method Name:** Used to distinguish between wash methods when selecting during method editing.
- **Liquid Container:** Wash liquids can be stored separately. Select the appropriate liquid channel.
- **Wash Mode Options:**
  - **2-Point:** After aspiration at the first point, the Z-axis lifts by 2 mm before aspirating at the second point.
  - **2-Point Bottom:** Like the 2-Point mode, but the Z-axis does not lift between aspiration points—it moves directly to the second point.
  - **2-Point by Strip**: In this mode, dispensing occurs simultaneously with aspiration.
  - **1-Point (Center):** Performs a single wash at the center point. For the final wash cycle, the 2-Point mode is used.
  - **4-Point:** Requires a specialized microplate washer with a movable wash head.
- **Aspirate Height:** Sets how far the long probe descends during aspiration. During system setup, ensure a 0.5–1 mm gap between the probe and the microplate bottom to avoid contact.

- **Dispense Height:** Sets how far the long probe moves to reach the upper edge of the wells during dispensing. This ensures that any excess liquid is quickly removed by the vacuum pump, helping prevent cross-contamination between wells.
- **Aspirate Duration:** Duration the long probe aspirates liquid at each point—typically set to 1 to 1.5 seconds.
- **Dispense Duration:** Time required for the short probe to completely fill the wells with wash buffer—typically 1 second.
- **Asp. Duration Final Cycle:** Aspiration time for each point during the final wash cycle—commonly set to 2 seconds.
- **Soak Duration:** Time the liquid is allowed to soak after dispensing by the short probe. This varies depending on the reagent used.
- **Priming Duration:** When switching between wash buffer containers in different methods, this is the time needed to flush out the previous buffer and fill the lines with the new one. Typically set to 3–4 seconds.

Priming Height

Refers to the height of the Z-axis from the origin point during the priming process.

Wash Process (96-well)

- **All 96 Channels**: Performs a full-plate wash. During dispensing, all channels of the wash head are activated to inject liquid into the wells simultaneously.
- **3 Columns × 4**: In this mode, liquid is injected into 3 columns at a time. Once dispensing into the first 3 columns is complete, the next 3 columns are activated, continuing in this sequence.
- **Auto Column**: The number of active wash head channels is automatically calculated based on the experiment's requirements, using 3 columns as the base unit.

Shaking Parameters

- **Number of Shakes**: Defines how many shaking motions occur after dispensing. Set to **0** by default or when not in use.
- **Frequency**: Adjusts how fast the shaking occurs during plate washing. Default is **0** when unused.
- **Amplitude**: Sets the intensity of shaking during washing. Default is **0** when the function is not active.

Manifold Movement Settings

- **Manifold Speed Up**: Enables the wash head to rise along with the liquid surface, allowing follow-up dispensing. Set to **0** if this function is disabled.
- **Manifold Speed Down**: Enables the wash head to descend with the liquid surface for follow-up aspiration. Also set to **0** when not used.

Wash Buffer Management

- **Add Wash Buffer During Plate Washing**: Wash buffer should typically be prepared and loaded before starting the experiment. If the buffer runs low during washing, the software will issue an alarm.

Important: Due to the high internal pressure of the wash buffer container, pressure must be released before opening the lid. This is done by opening the quick connector to relieve the pressure.

- **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, to achieve 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, to achieve the follow-up aspiration function. It is set to 0 when this function is not used.

10.3.7 Electronic Format Setting

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

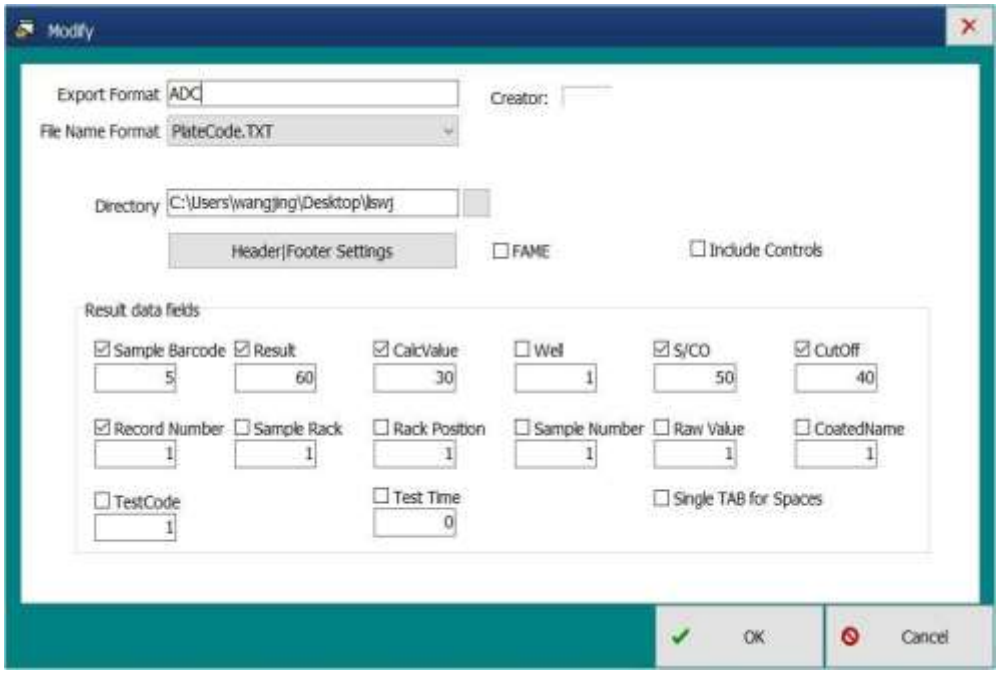


Figure-31

This menu allows users to configure the electronic report format for communication with LIS/HIS systems. Users can create, modify, copy, delete, and manage report formats as needed.

Before installation is finalized, the professional personnel will coordinate with the LIS provider to define the appropriate electronic report format, which typically does not require further modification afterward.

- **Export Format**: The name assigned to the report format. This name will be selected during method setup.
- **File Name Format**: Defines how the result file is named after the experiment is completed. The default format is usually **PlateCode.TXT**.

- **Directory**: Specifies the file path where experiment results will be exported. Once a results folder is created, simply select its path within this interface.
- **Header|Footer Settings**: Determines whether the exported file (e.g., PlateCode.TXT) includes header and footer information. By clicking **"Header|Footer Settings,"** users can customize the content of these sections.
- **Result Data Fields**: Allows selection of specific experimental result fields to be transmitted to the LIS by checking the appropriate boxes.

10.3.8 Method Edit

The Method Edit menu enables users to configure experimental methods based on the reagent's instruction manual. After clicking **Method Edit**, an interface will appear where users can create, edit, copy, and delete methods, as well as perform import, export, and disable (shield) operations.

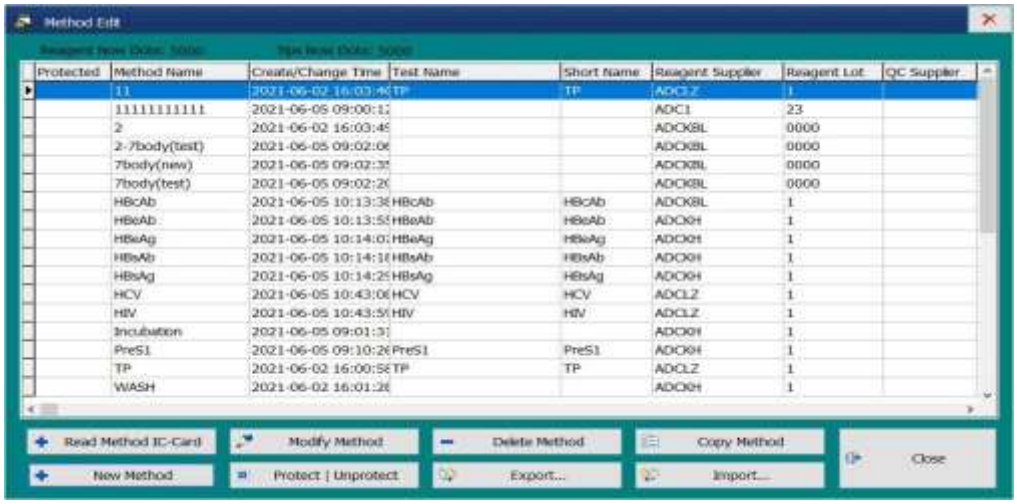


Figure-32

10.3.8.1 Create and Edit Method

1) Configure the basic parameters, including the method name, reagent used, and QC settings. Fields marked with "*" are mandatory.

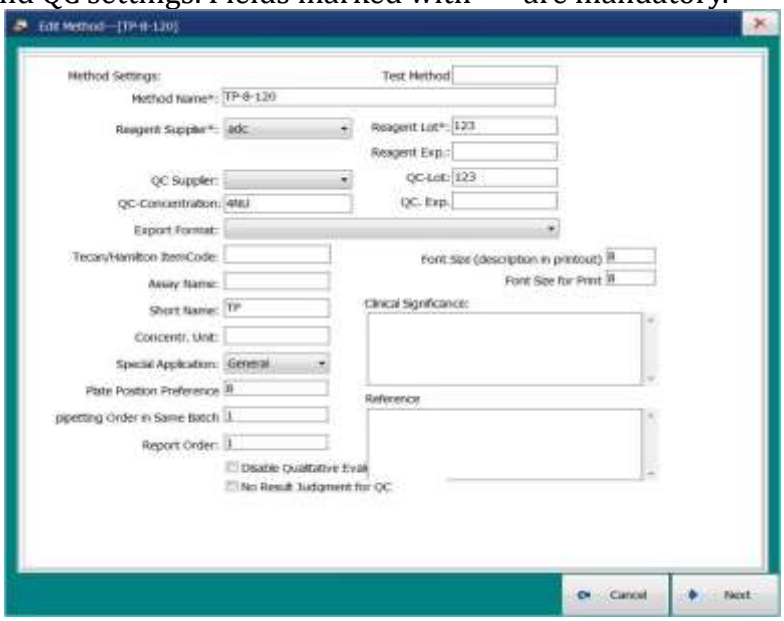


Figure-33

Information such as Reagent Supplier, QC Supplier, and Export Format is pre-configured under the Reagent Supplier and Electronic Report Format menus. These can be easily selected and applied when setting up a new method.

- **Assay Name**: The full name of the new assay method.
- **Short Name**: The abbreviated English name of the method; for example, the short name for surface antigen is **HBsAg**.
- **Concentr. Unit**: The unit used to represent concentration values in ELISA test results.
- **Clinical Significance**: Provides clinical interpretation for different concentration values in the result.
- **Pipetting Order in Same Batch**: Defines the pipetting sequence for experiments conducted in batches (i.e., multiple assay items processed simultaneously within the same batch).

2) After entering the basic information, click **"Next"** to configure the plate chart. Users can customize the plate layout according to specific requirements.

To support this, the system offers a variety of predefined well types, described as follows:

- **NU**: Null well – indicates an empty well; no calculations are performed.
- **BL**: Blank correction well – used for calculating the blank correction value.
- **NC**: Negative control – used solely for formula calculations; has no special function.
- **PC**: Positive control – used solely for formula calculations; has no special function.
- **H**: High-value standard – used only in formula calculations.
- **M**: Medium-value standard – used only in formula calculations.
- **L**: Low-value standard – used only in formula calculations.
- **QC**: Quality control material – used only in formula calculations.
- **SA**: Sample – indicates the position for sample addition.
- **S0–S9**: Calibrator positions – used for establishing the calibration curve to determine sample concentrations.

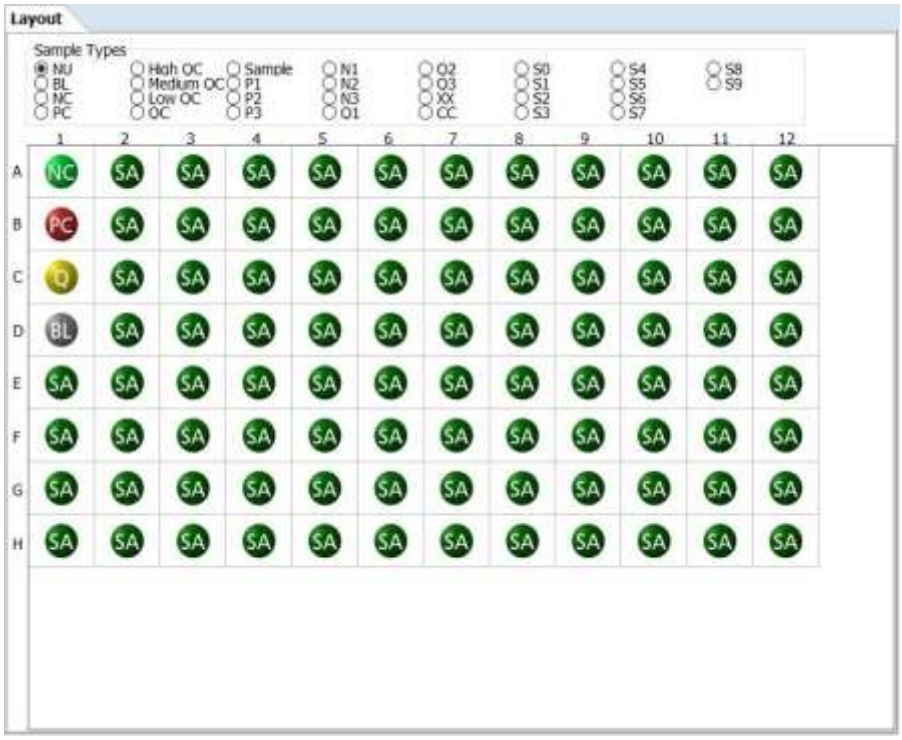


Figure-34

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

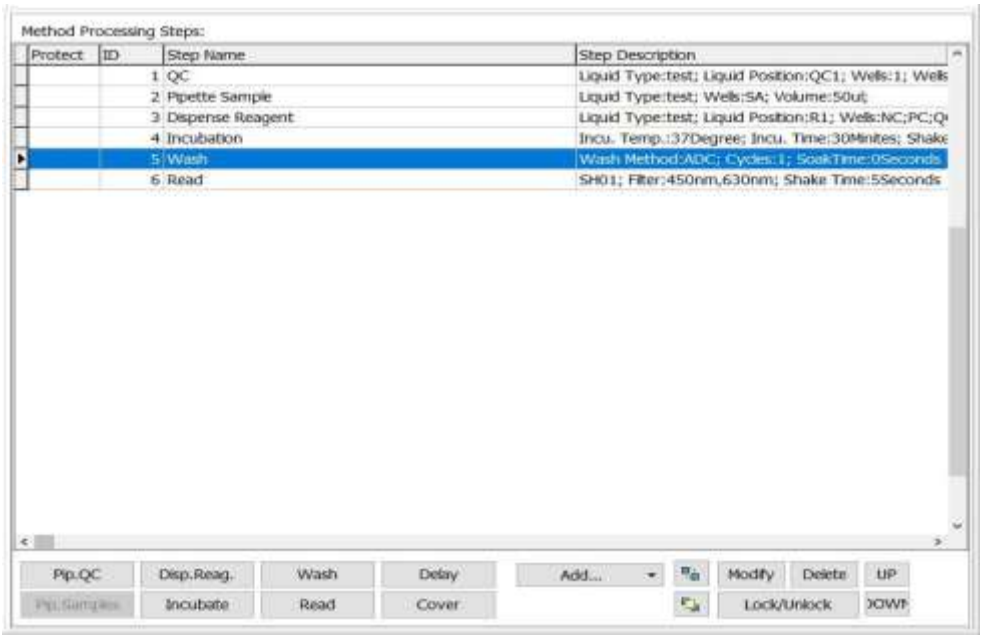


Figure-35

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

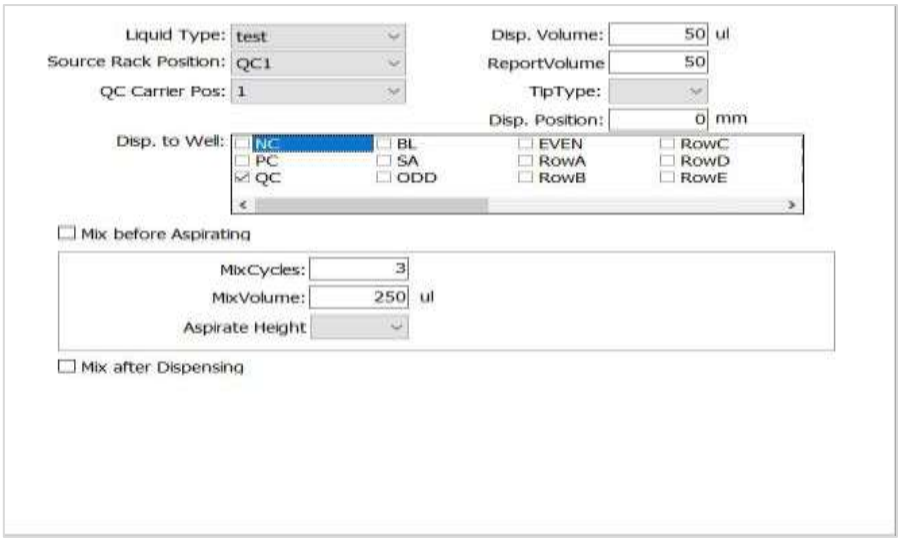


Figure-36

Liquid Type: Specifies the type of liquid to be dispensed.
Disp. Volume: Indicates the volume of liquid to be dispensed.
Source Rack Position: Identifies the QC rack number where the QC is located.
QC Carrier Pos: Refers to the well number on the QC rack that holds the QC.
Disp. to Well: Denotes the well on the microplate where the liquid should be dispensed (refer to the plate chart for guidance).
Disp. Position: A value of 0 indicates dispensing will occur above the microplate, at the Travel Hight level. If a number such as 7 is entered, it means dispensing will take place 7mm below the microplate (i.e., 7mm below the Travel Hight level). The default setting is 0.

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

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

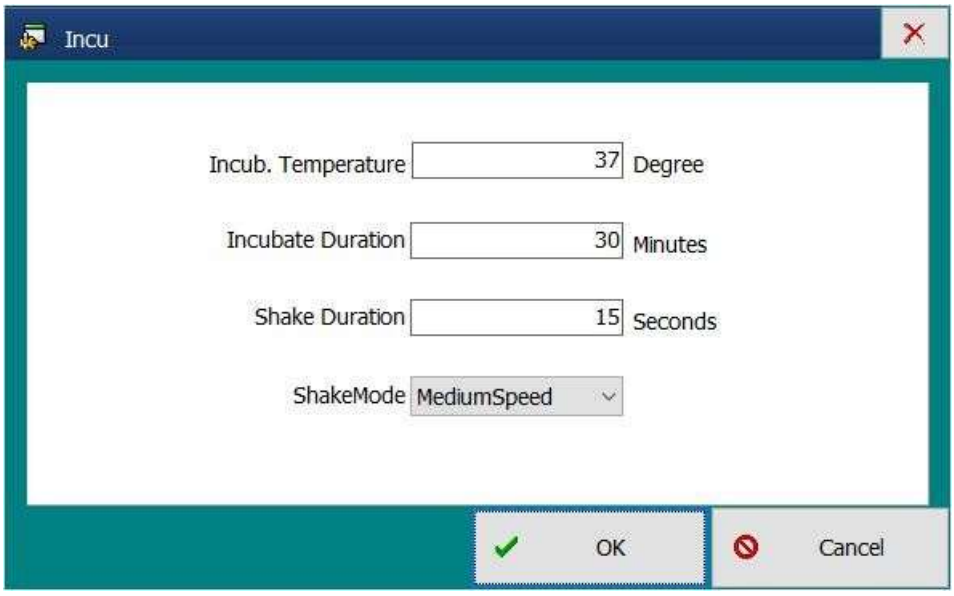


Figure-37

(4) **Add/Wash:** Configure the wash parameters for the sample. Define the wash process using the Wash Method Edit interface, then select the desired wash method during method setup.



Figure-38

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

ELISA analyzer:

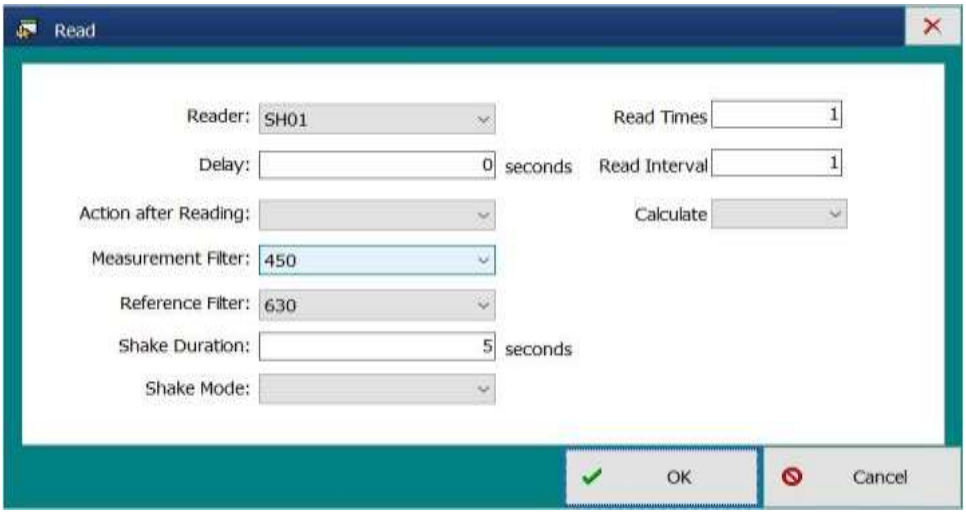


Figure-39

Perform the ELISA experiment by accurately entering the wavelength and shake intensity of the optical filter as specified in the reagent Instruction Manual.

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

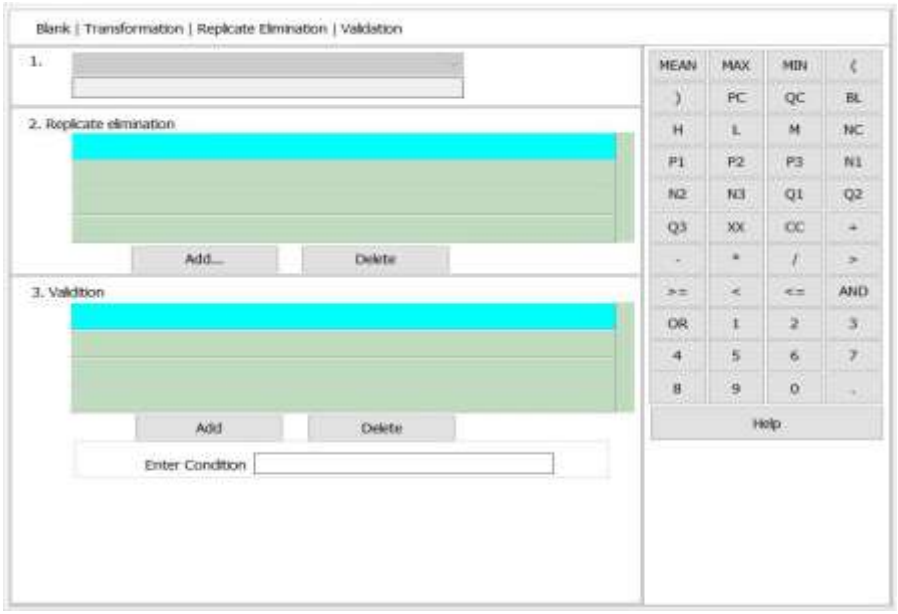


Figure-40

(1) For the ELISA experiment, choose the blank control and select the method for blank well calculation. Typically, users can simply choose to mean (BL).

(2) Enter the experiment validity criteria as outlined in the reagent Instruction Manual.

The right side of the above figure displays common calculation commands. In the "Enter Condition" field, enter the calculation formula by clicking in the area on the right. For example, input "mean(nc) <= 0.05 and mean(pc) >= 1.5" into the condition field, then click "Add."

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

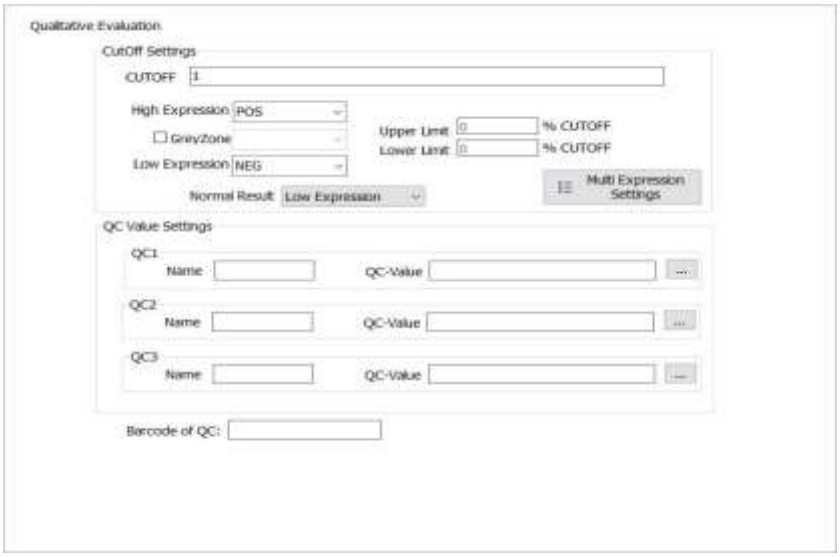


Figure-41

(1) For CUTOFF input, either edit the formula or calculate it directly as instructed in the reagent Instruction Manual. Click to modify the formula.

(2) **High Expression/Low Expression:** Indicates whether the sample result is negative or positive based on being higher or lower than the cutoff. For example, a high expression of HBsAg is positive, while a high expression of HBeAb is negative.

(3) **Grey Zone:** When the Grey Zone option is selected, the weakly positive range is defined. The range settings should be based on the user's specific conditions. The Upper Limit and Lower Limit are set as percentages relative to the cutoff.

(4) **QC Value Settings:** If QC is required for certain items, the QC wells must be assigned during the layout setup. Enter the QC "Name," then click next to "QC-Value" to input the calculation method for the QC value.

6) Check the Quantitative Evalu box; enter the Calibrator Concentration, Curve Type, and any other parameters required for calculation as specified in the reagent Instruction Manual; then click **Finish**.



Figure-42

10.3.8.2 Edit Method

A method can be edited in the same way as creating a new method. First, select the method you want to edit and click "**Edit Method**." Then, modify each information item step-by-step following the wizard. Editing a method will not impact existing experiment results; it will only affect the evaluation of future results. The microplate result includes a description of the method used at that time. If the experiment is interrupted and then resumed after editing the method, be sure to click "**Refresh**.

10.3.8.3 Copy Method

This function enables fast creation of a new experiment method identical to an existing one. First, select the method you want to copy and click "**Copy Method**." Then, in the pop-up window, enter a name for the new method.

10.3.8.4 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/Unshielded** Method" to shield or unshielded the experiment method.

10.3.9 Method Group Manage

Method Group Manage is primarily used to manage common experiment items, making operation easier for the user. Before starting an experiment, the user only needs to group the common methods, eliminating the need to select experiment methods one by one.

After clicking "**Method Group Manage**," the following interface will appear:

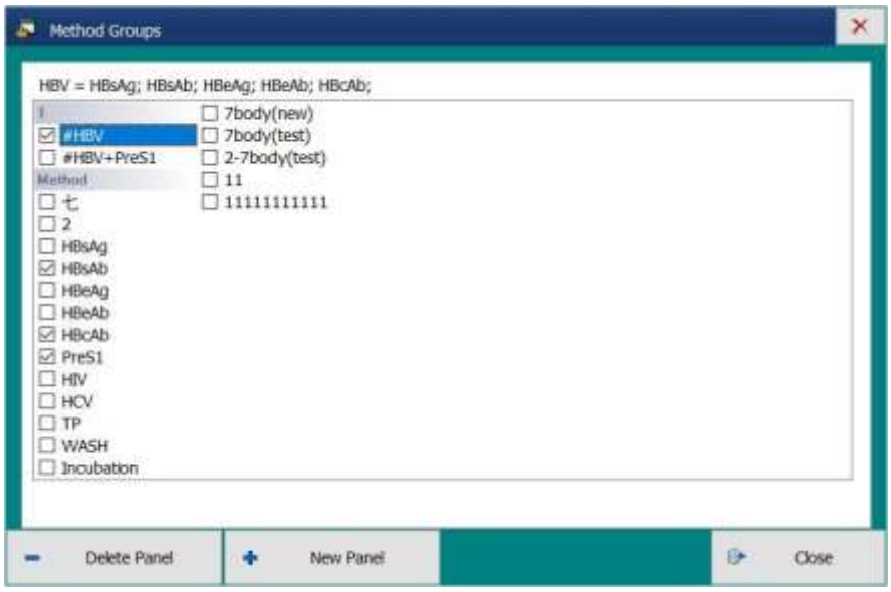


Figure-43

10.3.9.1 Create Method Group

After selecting the experiment methods for grouping, click "**Methods Selected for New Group**"; the following interface will appear:

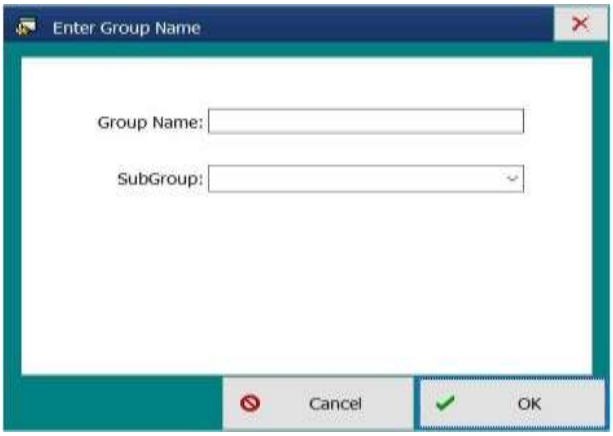


Figure-44

Here's a reframed version of your sentence without changing the meaning: Enter "HBV" and click "**OK**" to save it as a method group named "HBV." To run the HBV experiment, just select this group name.

10.3.9.2 Delete Selected Group

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

10.4 Routine Work

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

10.4.1 Start Experiment

Refer Chapter

10.4.2 Experiment Results

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

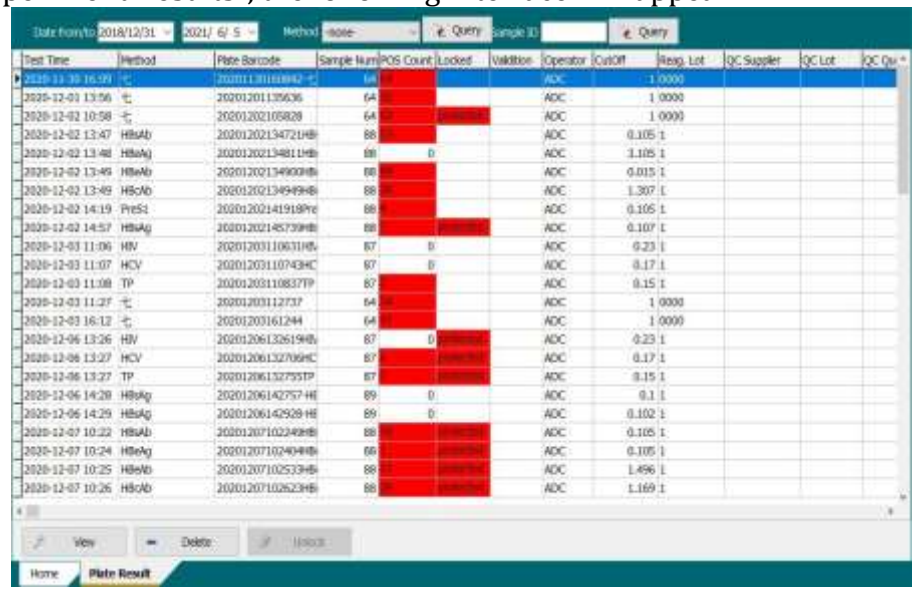


Figure-45

- **Test Time:** Allows the user to query results within a specified time range.
- **Method:** Enables the user to search for results from a specific experiment method.
- **Print:** Prints experiment results from a selected time range and method.
- **View:** Displays detailed experiment results for a specific lot.
- **Delete:** Removes the experiment results for a specific lot.
- **Unlock:** Unlocks the sample results for the selected lot, allowing the user to modify them.

After selecting an experiment item in the interface above, the user can click "**View**" to see the experiment results, as illustrated in the figure below:



Figure-46

"Plate Result" Tab:

- **Re-evaluate:** Re-save and verify the result information.
- **Lock Result:** Locks the result to prevent the operator from deleting the experiment data.
- **Print Plate:** Prints the plate chart information for purposes such as backup or review. This option is only available after the result is locked.
- **Send Report:** Manually sends the experiment results to the LIS system. This function can only be used once the result is locked.
- **Export Data:** Saves the result data in Excel format, intended for use by professional personnel during system commissioning.

"Description" Tab:

Provides a complete overview of the experiment method, including steps, and aspirate/dispense volumes.

"Raw Data" Tab:

Used by the operator to view raw readings of calibrators or samples during the experiment.

"Others" Tab:

Contains key parameters of the test method, which serve as headers in the printed microplate result. If a backup is required, ensure these parameters are correctly entered in the Method Edit interface.

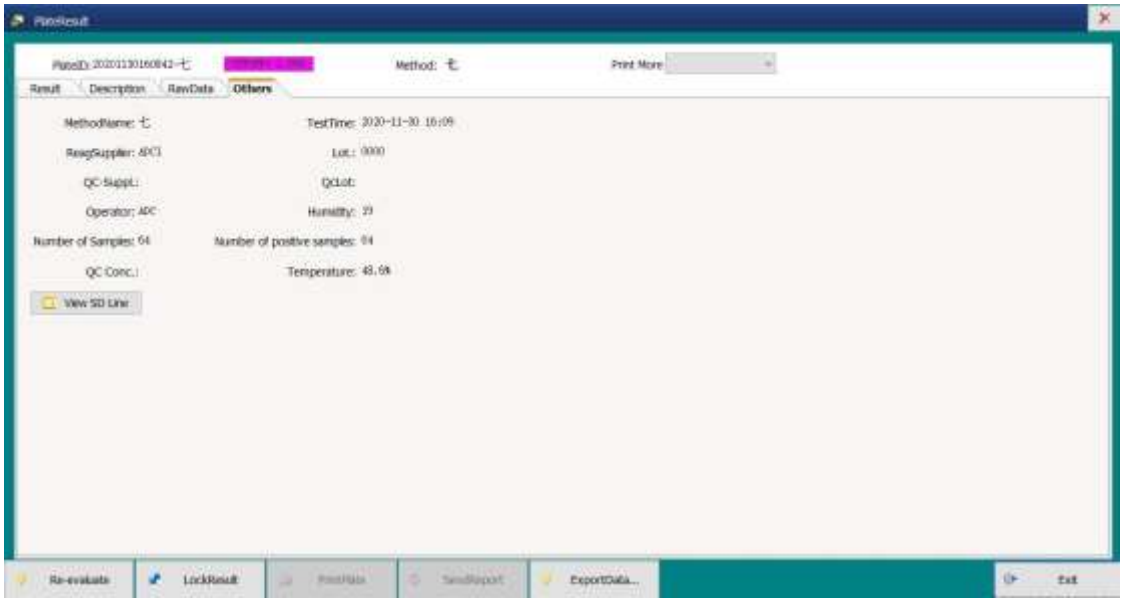


Figure-47

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

(1) Click "**View SD Line**" to enter the following interface

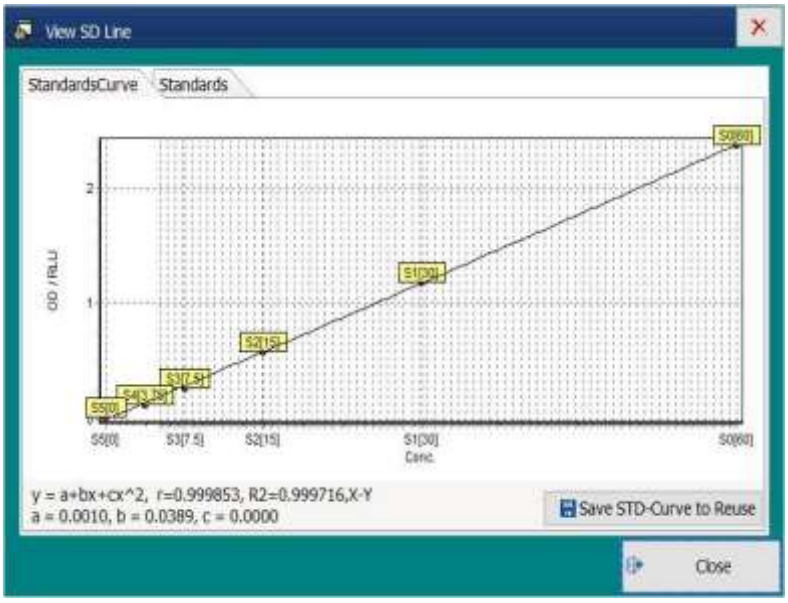


Figure-48

In the Standard Curve interface, users can view the linearity of the standard curve, the calculation method used, and other related parameters.

Save STD-Curve to Reuse: This button allows the same calibrator curve to be reused for the same reagent lot and test item. The saved curve template can be directly applied in subsequent experiments.

(2) Click the Standards tab to enter the following interface

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

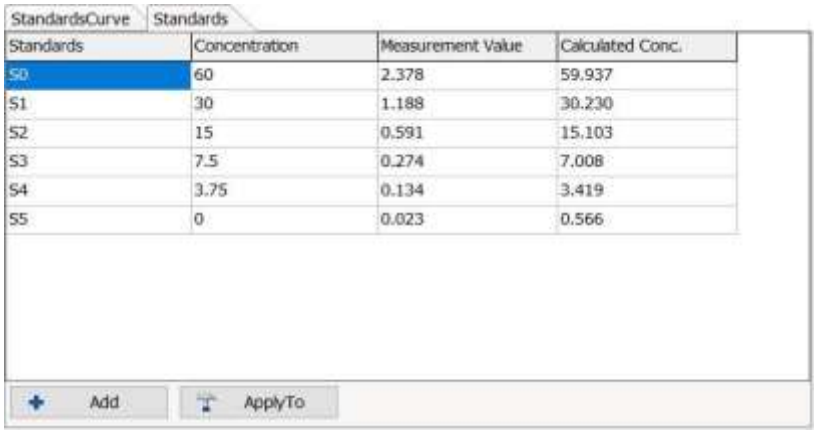


Figure-49

10.4.3 Quick Reading

The Quick Reading menu offers an independent reading step. In manual experiments, the instrument can be used to read and transmit results. Quick Reading is available if it does not conflict with any ongoing reading operations on the instrument.

1) Click"**Quick reading**" to enter the following interface

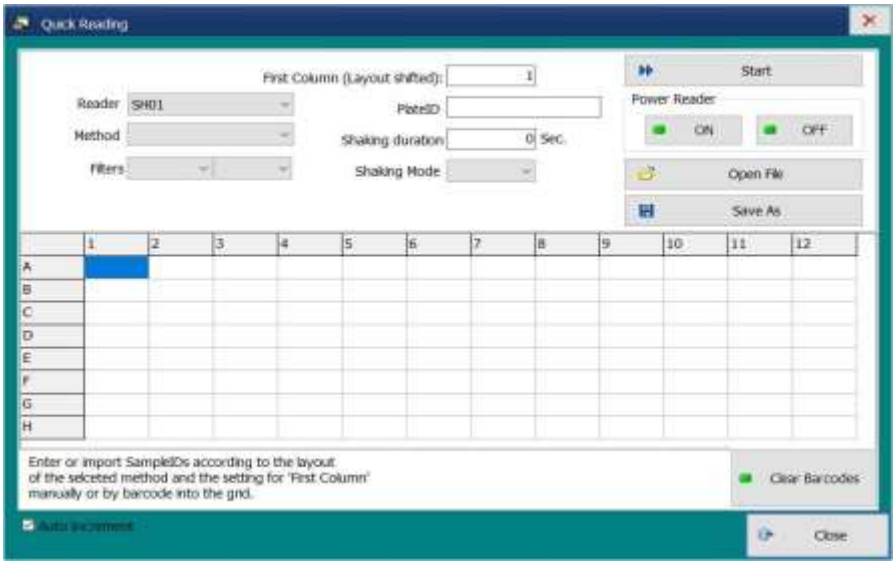


Figure-50

2) After selecting the method name, click "**ON**" under Power Reader. Once the sample layout is entered, click "**On**" again.
3) After initiating the process, place the microplate and click "**Close**."
4) Once the cabin door of the ELIASA instrument is closed, click "**Start**" to begin the reading.
5) After the reading is complete, the result will be automatically saved in the test results.

10.4.4 QC Chart manager

The QC Chart Manager menu enables the consolidation of QC values for all experiment items and displays them as charts. Users can edit and print the QC chart for each item from this menu.

1) Click "**QC Chart Manager**" to open the interface shown below:

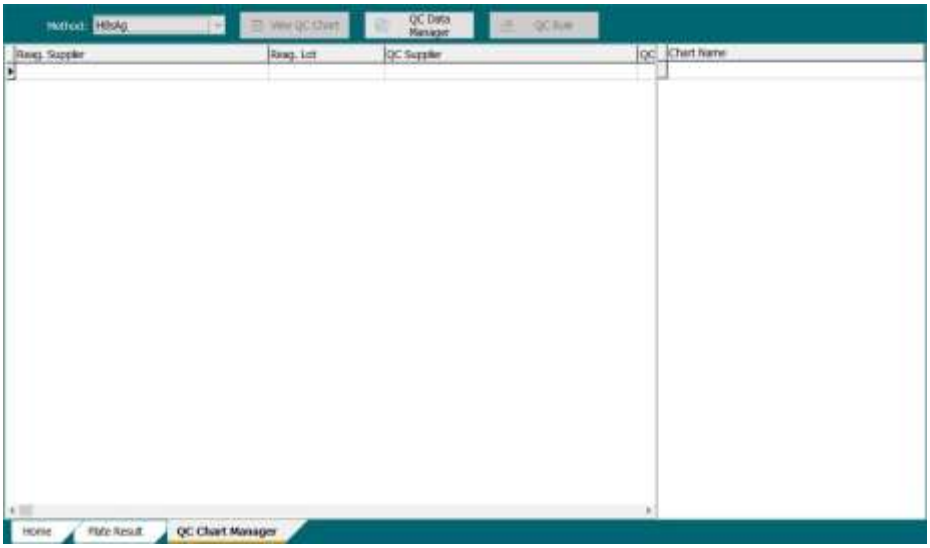


Figure-51

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

To view 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.

10.4.5 Result Summary

The Result Summary menu enables querying and summarizing of results within a specified time range. Searches can be conducted using sample ID or result values. There are two summary types: Single-item Summary and Multi-item Summary.

Multi-item Summary provides a summary of results for multiple items across different samples within a given period.

Single-item Summary provides a summary of results for one specific item across different samples within the same time frame.

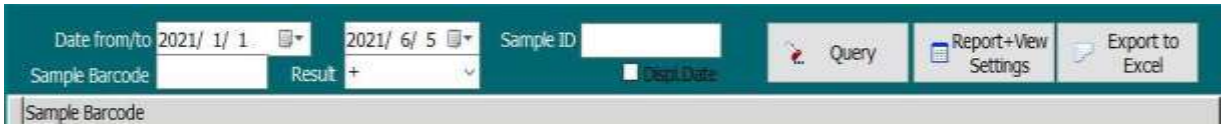


Figure-52

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

10.5 Report Manager

This menu serves as the primary window for entering patient information. For routine sample testing, patient details must be entered before printing the corresponding laboratory test report. This menu is mainly intended for users who do not use an LIS system to manage patient reports.

10.5.1 Dictionary Setting

Dictionary Setting is a quick-access feature that helps eliminate repeated input when entering patient information. Users can configure commonly used details such as Department Info, Doctor Info, and Doctor Advice. Once set, these options can be quickly selected during patient data entry.

10.5.2 Report Format

The Report Format section provides a report template tailored to the user's requirements. Once established, it typically does not need modification. The template should be designed based on user needs.

Sample Information is used for printing laboratory test reports; patient details can be entered into the system either in advance or after the experiment is completed.

1) Click "**Sample Information**" to access the following interface:



Figure-53

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**.

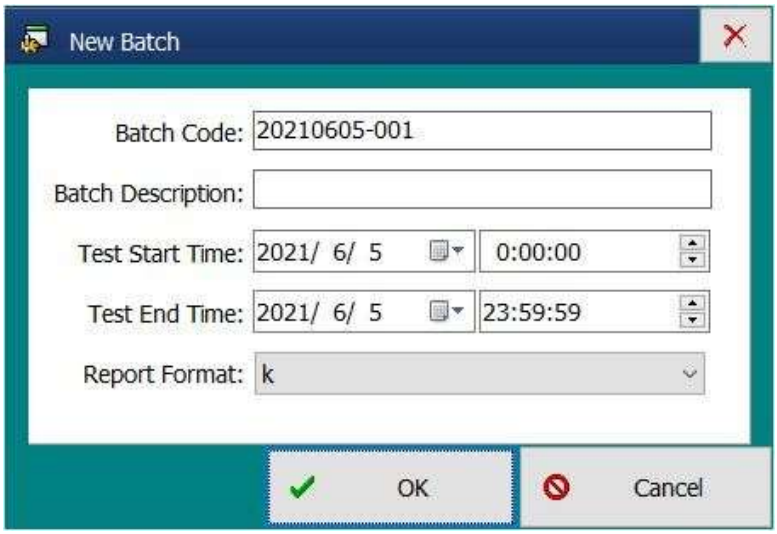


Figure-54

3) Click Enter Patient Information. In the window that appears, input the patient details based on the actual sample order. Once the information is entered, simply click Close.

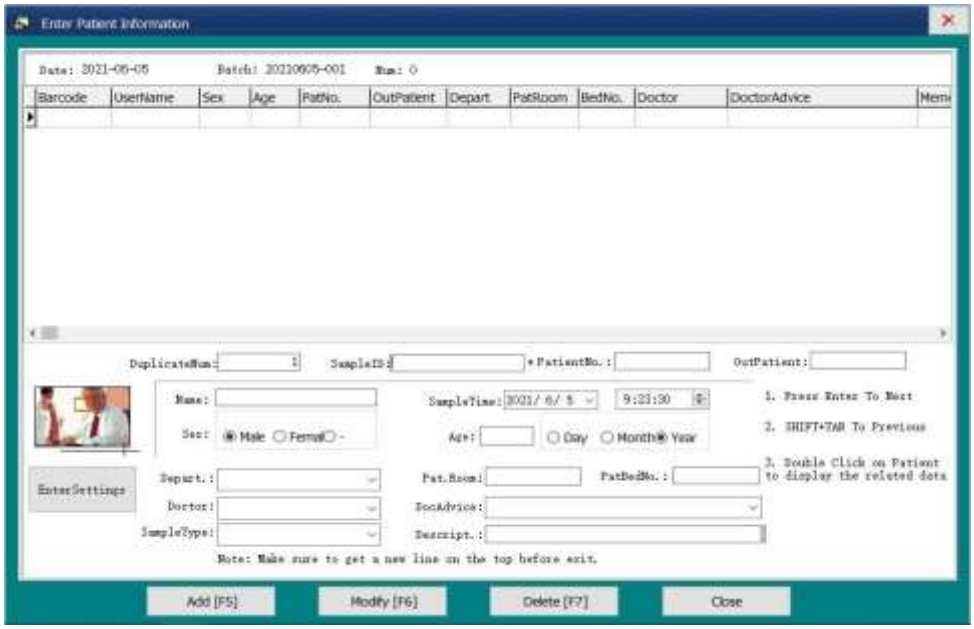


Figure-55

For a new batch, the batch number must be associated, and it can also be modified later in the Batch Edit interface. Enter patient information for each sample individually. The [Enter Settings] button allows for quick input of patient information items. Sample barcodes can be added automatically.

10.5.3 Print Report

Print Report is used to print experiment results in the format of a laboratory test report. Click "**Print Report**" to open the window shown below, where users can print all or selected microplate results.



Figure-56

The above figure shows the Print Report interface:

- The top section of the interface displays the information entered in Patient Information.
- The lower left section shows each patient's result data, which can be edited by the operator before printing the report.
- The lower right section presents a preview of the patient report in a simulated report format.

10.6 About Interface



Figure-57

10.7 Alarm Messages and Handling

1) **Load tip failed:**
Cause: No tip is available or the tips loading detection sheet is too short.

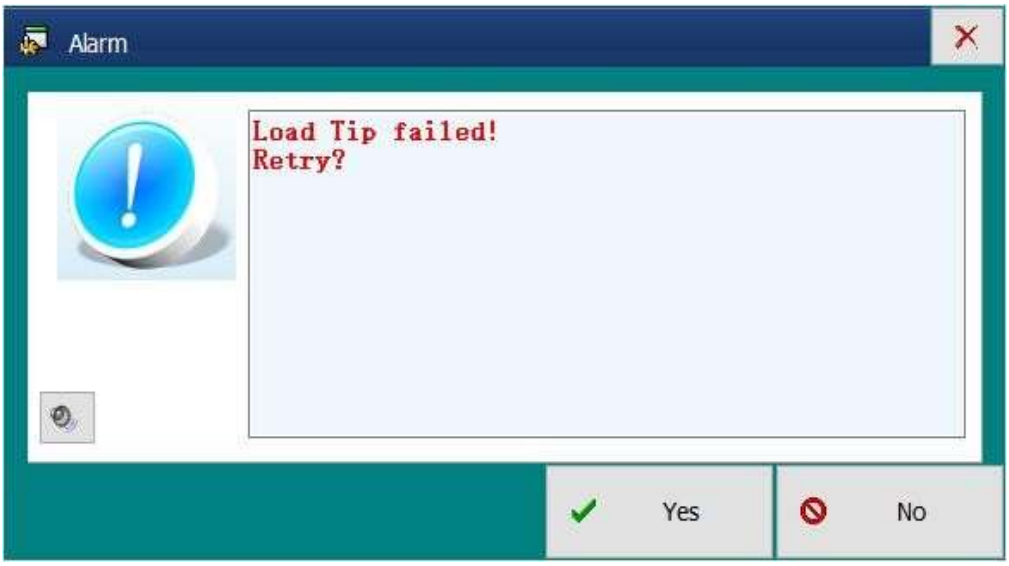


Figure-58

Solution: Check whether there are tips in the tip box. If any, click "**Yes**".

2) **Tips remain on the pipettes:**
Cause: The experiment was unexpectedly terminated, and the tips were not removed before re-running the experiment.

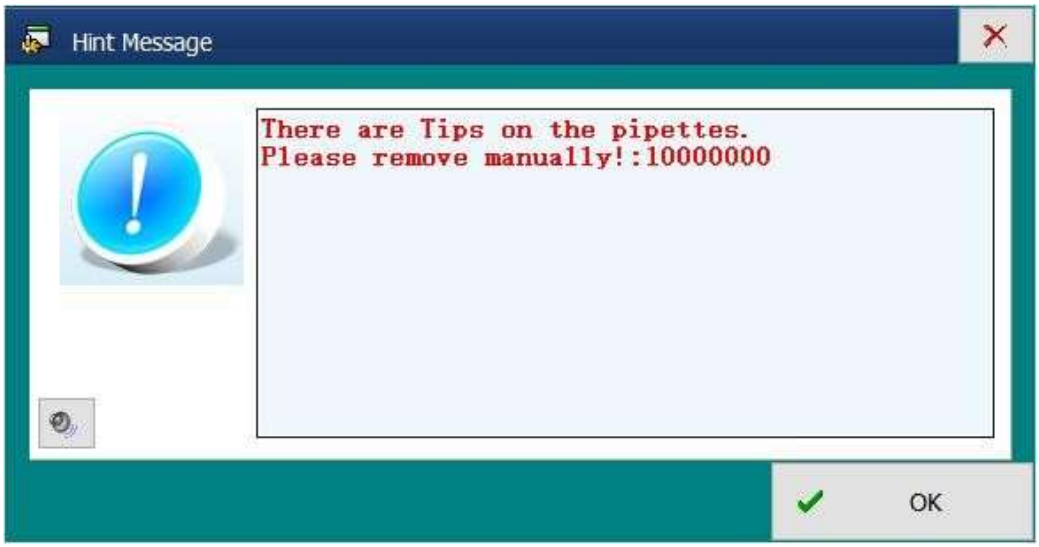


Figure-59

Solution: Remove the tip.

3) **Aspirate Error (perhaps clots or parameters error):**
Cause: Grume or fibrous protein is contacted during aspiration, or the tip is clogged.

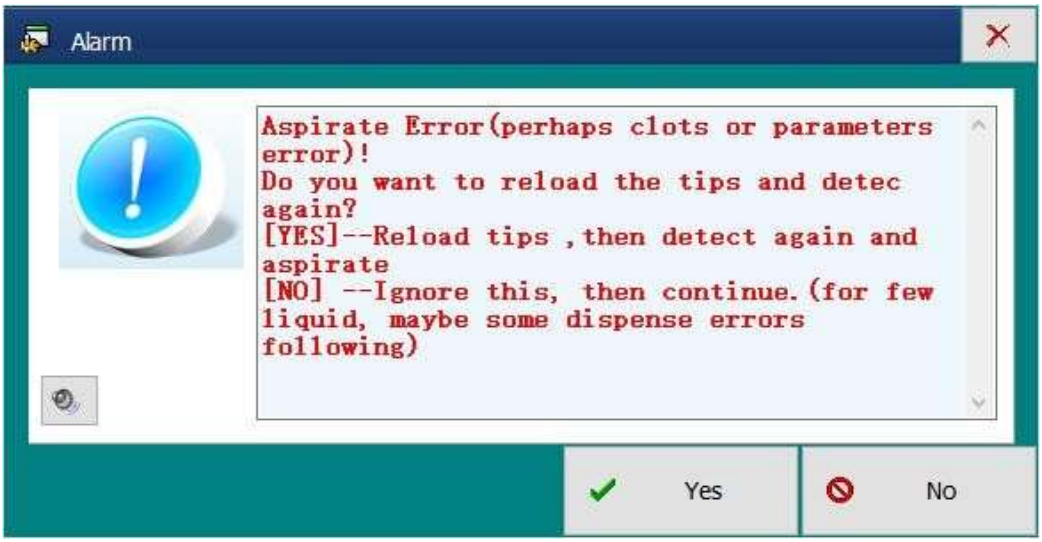


Figure-60

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

4) **CAN-bus Device Open Error**

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



Figure-61

Solution: Power up the instrument after checking the connection.

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.

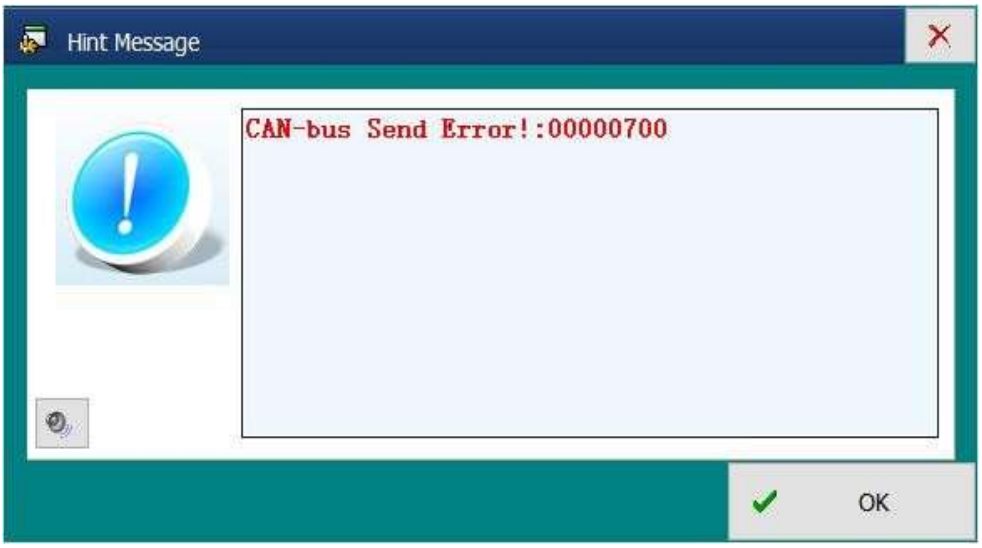


Figure-62

Solution: Check the connection.

6)**Serial port failed to open**

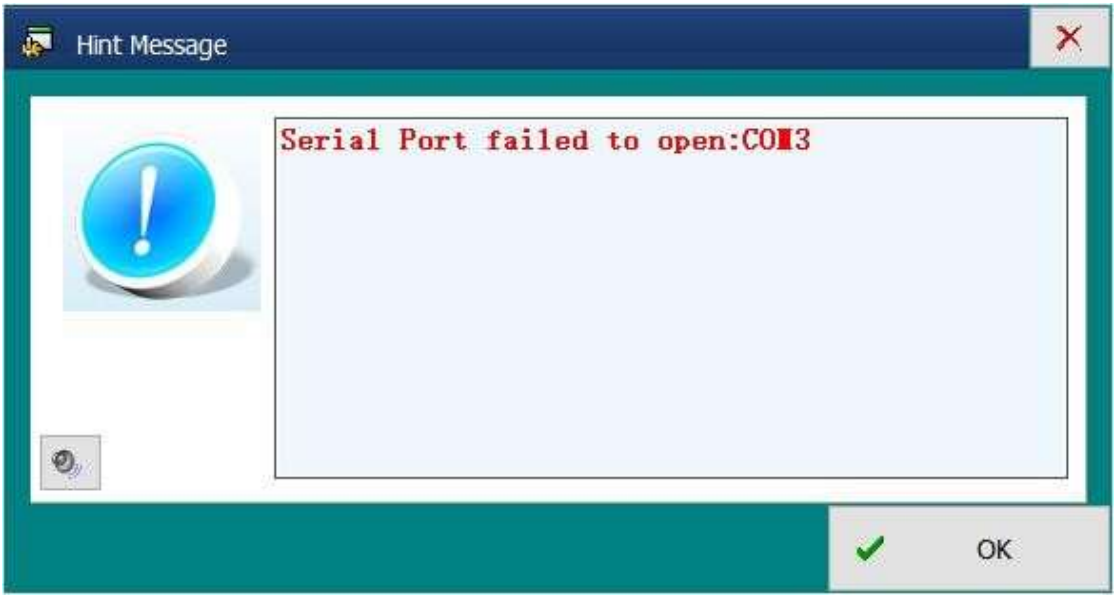


Figure-63

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

7) **Liquid level detection:**

Cause of Error: The container is overfilled with liquid. During detection, the liquid level descends less than the system-defined distance (10mm below the Travel light).

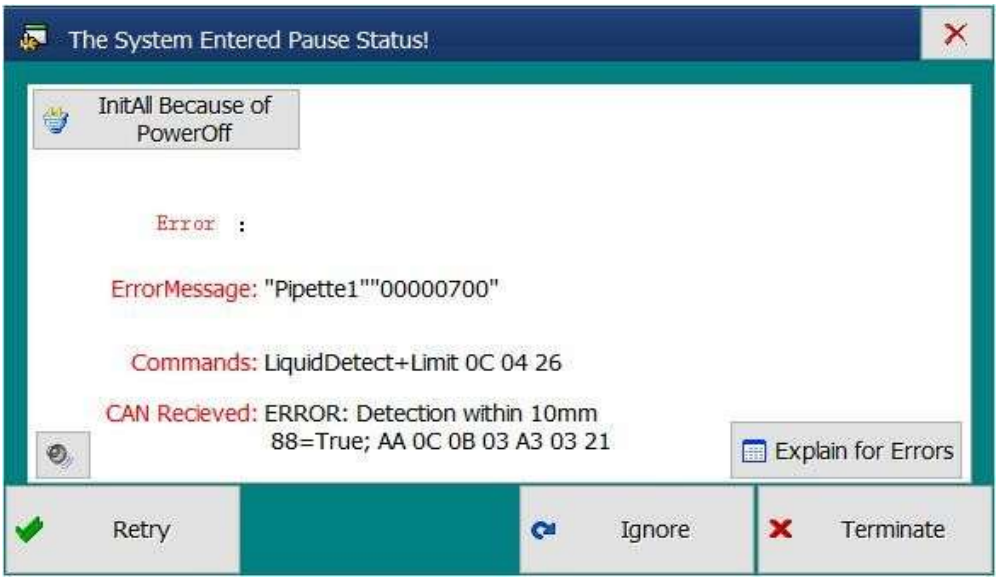


Figure-64

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

8) **The liquid level between channels is different:**

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

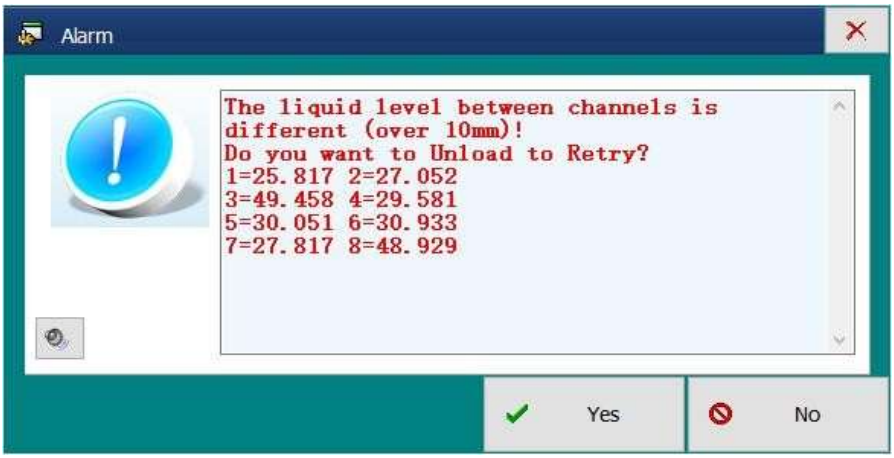


Figure-65

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

9) **Liquid Level Cannot Be Detected**
Cause: The corresponding liquid is missing, the pressure detection is not sensitive, or the pressure sensor is damaged. Click **Retry** to attempt detection again. If ignored, aspiration will proceed from the Z-axis initialization position. After the experiment is complete, inspect the hardware or verify the detected pressure value.

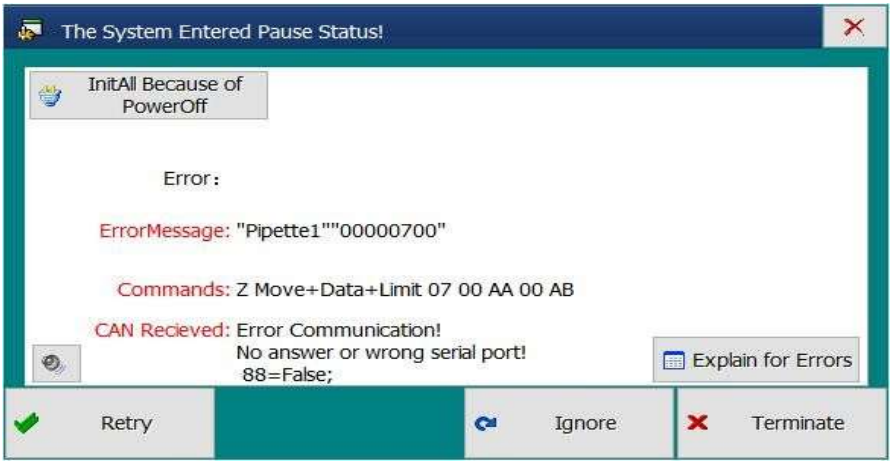


Figure-66

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

10.8 Test Process

10.8.1 Instrument Power-On and Balancing

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

10.8.2 Pre-Experiment Preparation

1) **Check Consumables Status:** Verify whether the tips, wash buffer, and system maintenance liquid are sufficient for the test volume. If not, replenish the consumables as needed.
2) **Check Waste Status:** Inspect the liquid waste container and the waste tip container for any residues. Dispose of any waste promptly.
3) **Check Wash Head Condition:** Launch the software, perform "Power-on/off Maintenance," and run the washing process. Inspect the wash head's dispensing performance and the presence of any liquid residue in the microplate. Proceed with the test only after confirming that there are no issues such as uneven dispensing, interruptions, or probe blockages, and that no significant residue remains in the microplate wells.

10.9 Test Operation

10.9.1 Check Settings

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

10.9.2 Add Reagent

Add all the reagents to be used in the test.

10.9.3 Add Sample

Place the test tubes in the test tube rack.

10.9.4 Start Experiment

1) Click "**Start Experiment**" in the menu bar to open the following interface, where users can add experiment batches.

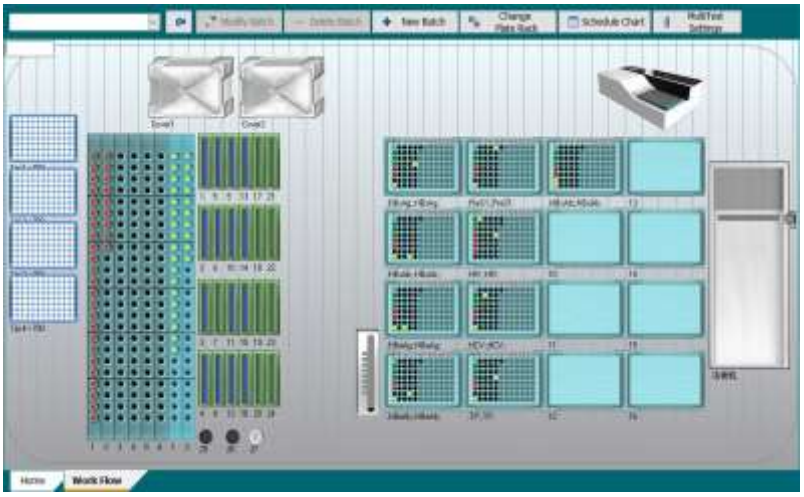


Figure-67

2) Click **"New Batch"** to add experiment batches; the following interface will appear. Enter the sample ID based on the sample position. To enable automatic increment of the sample ID, press and hold the **Enter** key. If barcode scanning is needed, insert the sample rack into this window to initiate scanning.

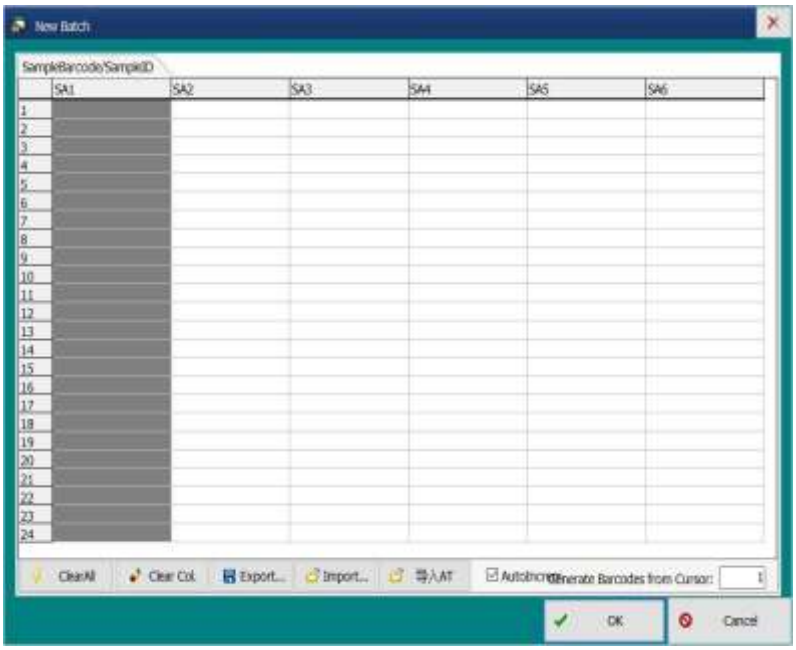


Figure-68

3) After entering the sample ID, click "**OK**" in the interface shown above. The following window will appear, where the user should select the experiment method to be used. If there are special samples, select the default group first, then click "Special Samples" to edit them accordingly.

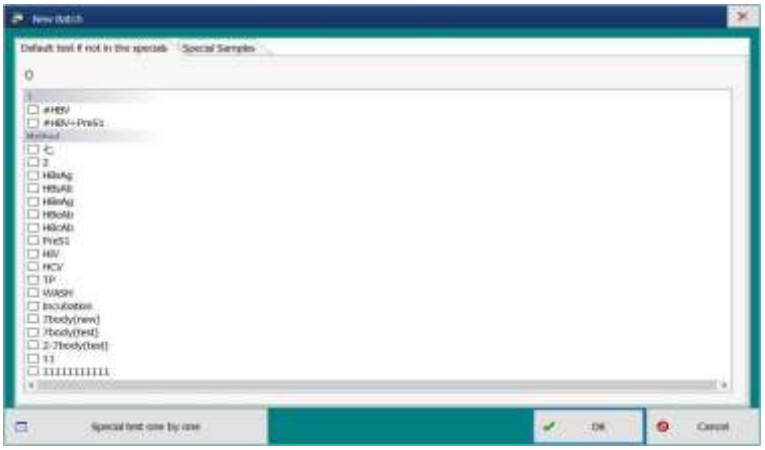


Figure-69

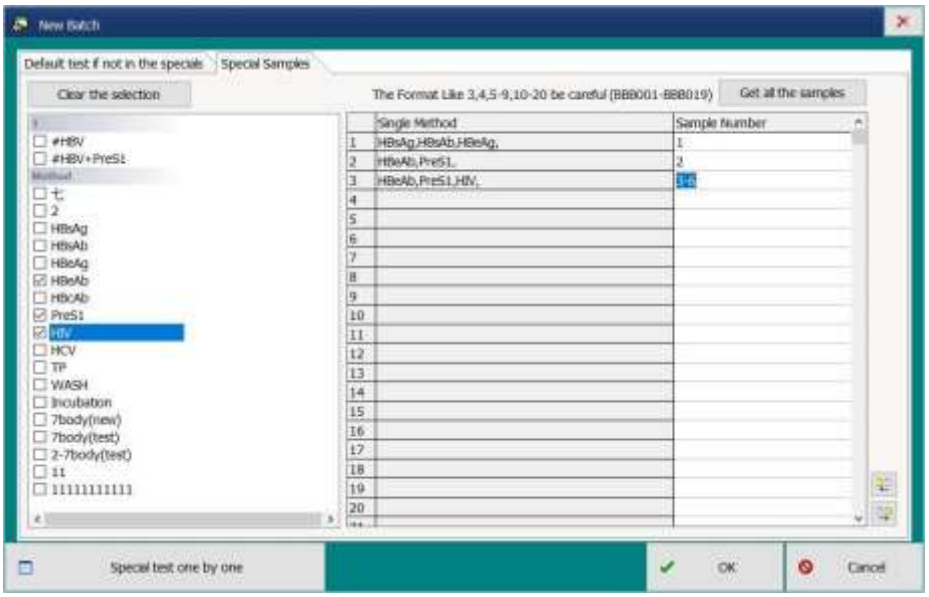


Figure-70

4) After selecting the experiment items in the above interface, click "OK"; the following interface will appear:

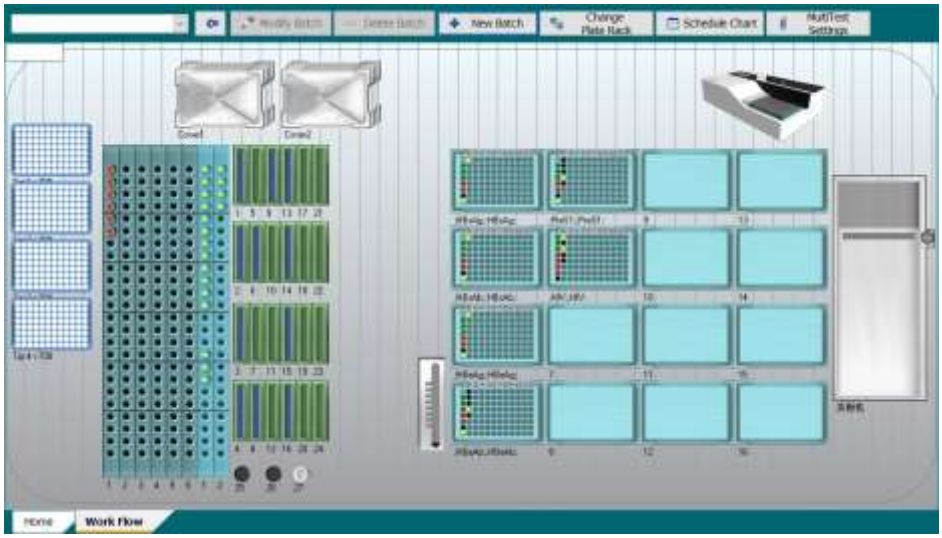


Figure-71

When a batch is added, the positions of the reagent rack or sample rack to be used will be highlighted. Make sure to confirm that the reagent and microplate positions are accurate to avoid any delays in the experiment. Right-click on the highlighted rack positions to display the reagent placement details and review the information carefully.

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



Figure-72

6) Click'' **Run Batch''** in the above Figure: After Selecting proper tip Position Click **''OK''** to start running the experiment.

10.10 Post-experiment Maintenance

Power-on/off Maintenance" should be performed both before and after the experiment to rinse the wash head and prevent crystallization.

This is a key maintenance procedure for the instrument and must be carried out as instructed. The maintenance parameters, as set by the manufacturer, typically do not require adjustment. Also, ensure that the distilled water container has an adequate liquid level.

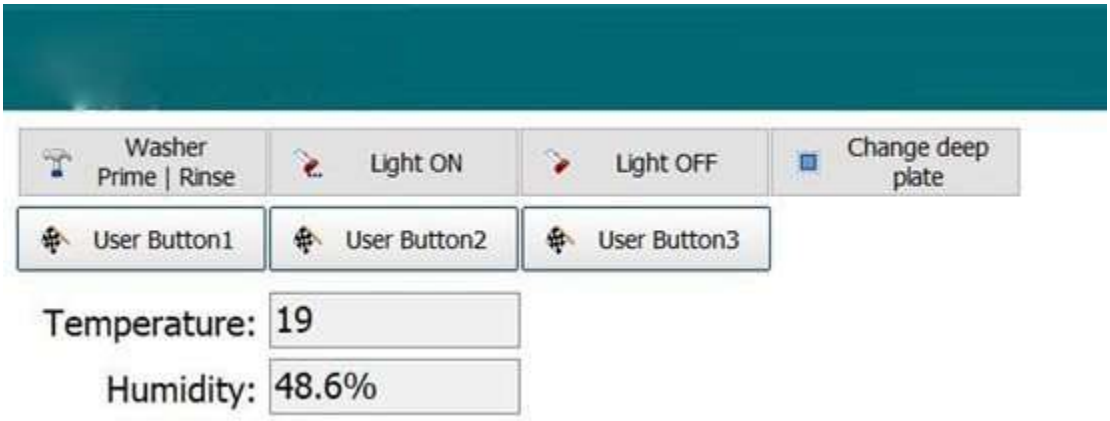


Figure-73

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

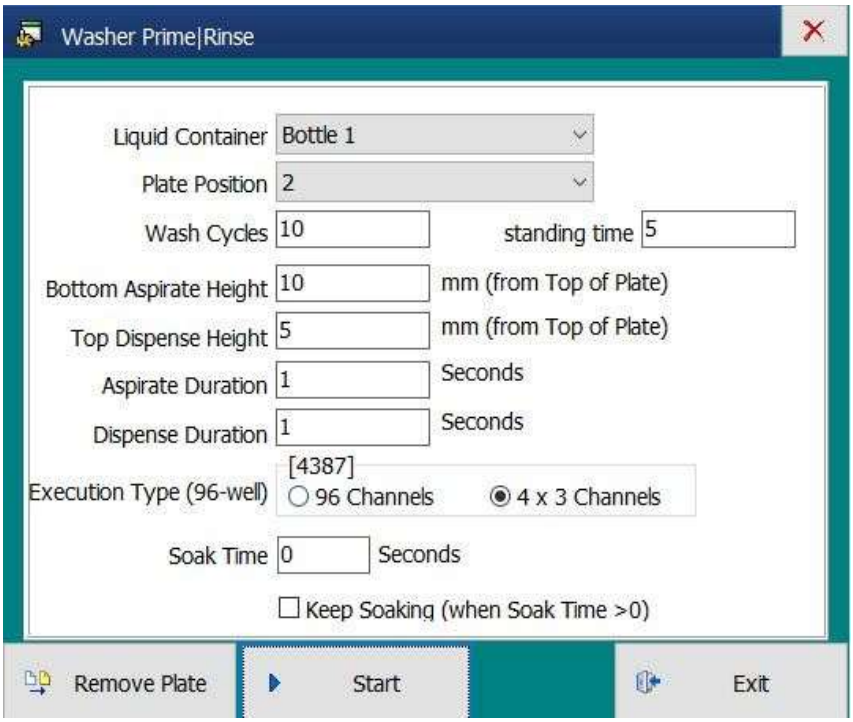


Figure-74

2) Switch on the liquid waste valve to completely discharge the liquid waste; switch it off once the discharge is complete.
3) Turn off the instrument and shut down the computer.
4) Clean the exterior of the wash probe with alcohol. (Perform this step weekly.)
5) Dispose of wastewater, leftover reagents, probe cleaning solution, and plate cleaning solution, or handle them in accordance with hospital protocols.
6) Remove any dust from the instrument surface.

10.11 Precautions for Daily Experiment

1) Ensure complete separation of serum. Perform sample centrifugation strictly to achieve thorough separation; to prevent probe blockage, make sure there are no clots on the sample surface or within the usable sample volume.
2) Prevent the use of blood samples containing fibrinogen at the source.
3) Carefully screen serum samples; do not test blood samples exhibiting lipemia, haemolysis, or other abnormalities on the instrument.
4) Do not add reagents or samples during the sample loading process to prevent potential hazards.

Note: Failure to operate the instrument as outlined in the manual may compromise the protection it provides.

11. Maintenance

1) **Daily Maintenance Tasks:**
   - Perform system maintenance at the beginning and end of each experiment using the software interface.
   - Regularly empty both the liquid waste container and the waste tip container.
   - Clean the instrument's working area promptly after completing the experiment. Ensure the power supply is disconnected before cleaning. Use a soft cloth dampened with diluted detergent to wipe the instrument housing, followed by a dry cloth. Do not use organic solvents. If reagents remain on the surface, use tissue paper or cotton balls to clean them. If a sprayer is necessary, do not aim it at the auto-loading unit, circuit boards, connectors, or similar components.
2) **Weekly Maintenance Tasks:**
   - Use 75% alcohol to clean the bottom of the stainless-steel needle of the unit probe to prevent blockage by foreign objects.
   - Inspect the liquid waste outlet of the plate washing trough for blockages. If blocked, clean it to avoid water damage that could lead to circuit board failure.
   - Apply lubricating oil to the plate washing guide rails to prevent rust, which could impair instrument performance.
3) **Preventive Maintenance:**
   The instrument should undergo preventive maintenance, including volume calibration, twice per year.
4) **Usage Frequency:**
   As an electrical device, the instrument should not remain unused for more than 3 months. Extended disuse may cause electrical malfunctions. If unused for long periods, start the instrument at least once a month to complete a standard initialization cycle.
   The user assumes responsibility for any damage caused by failing to follow this guideline.
5) **Storage and Shutdown Procedure:**
   - Before discontinuing use, remove all liquids from the instrument and perform biohazard treatment. Liquids must not be left inside the device for extended periods. Disconnect the power cord.
   - Once a week, power on the instrument, allow it to complete initialization of moving parts, and keep it powered for 30 minutes to 1 hour to prevent malfunction or aging of electronic and mechanical components.
6) **Safe Sample Handling:**
   When handling infectious samples, always use protective equipment and promptly empty the waste tip and liquid waste containers.
7) **Electromagnetic Interference:**
   If exposed to electromagnetic fields or static electricity, the instrument's liquid level detection and plate washing system may be affected. Take precautions to minimize electromagnetic and static interference in the working environment.

8) Calibration and Maintenance Guidelines:

- After the initial setup, the instrument will be calibrated by professional personnel
- The company provides calibration tools for volume verification, using the gravity measurement method (Gold Standard Volume Calibration).
- Extended use of the instrument may result in **positional deviation**; if this occurs, recalibration is required to maintain accuracy.
- As a standard, calibration should be conducted once every year.
- This product has an expected useful life of **10 years**.

12.Troubleshooting

12.1 General Faults

Symptom	Cause	Solution
Continuous rattle sound can be heard during Z-axis initialization of sample probe	1) Power cord of Z-axis proximity switch is open-circuited 2) Signal line of Z-axis proximity switch is open-circuited 3) Z-axis proximity switch is damaged	The experiment may proceed after isolating the faulty tip.
During Z-axis initialization in the experiment, 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	Belt of corresponding unit probe is loosened	Experiment can be continued after shielding the faulty tip.
During pump (S) initialization in the experiment, the pump motor drives the syringe to continuously move downward and makes continuous "click" sound; the "click" sound can also be heard during pump (S) initialization in the component console.	• The power cable of the S-axis proximity switch is disconnected (open circuit). • The signal cable of the S-axis proximity switch is disconnected (open circuit). • The S-axis proximity switch is malfunctioning or damaged.	Experiment can be continued after shielding the faulty tip.

During the experiment, the X, Y, or Z axis fails to stop upon reaching the zero position and simultaneously produces a "click" sound; this same issue also occurs during X, Y, or Z-axis initialization in the component console.	• The metal block component of the sensor is bent, preventing it from being inserted into the sensor (typically occurs during transport). • The sensor's power cable is disconnected (open circuit). • The sensor's signal cable is disconnected (open circuit). • The sensor is faulty or damaged.	• Align the bent metal block component of the sensor to allow proper insertion into the sensor. • Examine the circuit and proceed with replacement as needed. • Check the circuit and carry out the required replacement.
During experiment or operation in the component console, a component cannot reach the designated position, and there is no abnormal sound **Note:** This situation may occur to transmission parts of all motors	• A loose belt causes the corresponding motor to lose steps. • Slippage of the pulley connected to the motor bearing leads to step loss in the corresponding motor.	• Find the faulty belt connection and tension the belt. • Tighten the fastening jackscrew of pulley.
During experiment or operation in the component console, a component cannot arrive at the specified position, and abnormal "click" sound is heard **Note:** This situation may occur to transmission parts of all motors	• There is external force interference (guide deformation) during movement. • The motor runs with open phase.	Use the continuity mode of a multimeter to test the A+, A– and B+, B– phases of the motor; identify which phase is open. Locate the break point and perform soldering or replacement as needed. (If the open circuit is located within the drag chain, replacement is recommended to avoid recurrence due to extended operation.)
During experiment or operation in the component console, a component stops after running an additional distance when the designated position is reached	Step excess of motor	Replace the faulty motor

During liquid level detection, the unit probe stops after a slight move when it drops to the Travel Hight, and the error message “Liquid level detection error” is generated	• The tip is blocked (the tip is unperforated, or the perforation is too small). • There is too much liquid in the container. • Contaminants in the sample probe cavity block the cavity. • Liquid level sensor or circuit board is damaged.	• Replace the tip and retry the operation. • Lower the liquid level in the container or increase the Travel Height setting in the software. • After aspirating liquid in the component console, verify that the current sensing value decreases steadily. If not, use a heating wire or acupuncture needle to clear the sampling cavity. • Replace the sensor or circuit board.
During liquid level Retention, liquid level is detected by mistake in the halfway of detection	• Detection value of the faulty tip is too small. • The sensor or circuit board is damaged.	• Increase the detection value in the component console. • Replace the component.
During liquid level detection, the probe moves down continuously and does not stop when touching the liquid surface till the extreme position, and error is reported.	• Detection value of the faulty tip is too big. • The sensor or circuit board is damaged.	• Decrease the detection value in the component console. • 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	• The spring on the tips loading detection sheet is too loose, causing it to fail to press down the detection sheet properly. • The tips loading detection sheet is bent, leading to hindered or stuck vertical movement.	Remove and tighten the tip release spring or manually or remove and straighten the detection sheet to make 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 obviously more than that in other tips	The dispensing speed is too high, causing the pump motor to stall during operation.	Reduce the dispensing speed.

12.2 How to Dredge the Wash Head

Kindly exercise caution when clearing the wash head after removing the right-side panel of the instrument to avoid injury to maintenance personnel caused by the door panel closing unexpectedly.

Type I

1) First remove the thick silicone tube for aspiration as shown in the figure



Figure-75

2) Remove the wash head from the support as illustrated: (Hold the wash head, slide the tube backward, then lower it downward).



Figure-76

After removing the washed head, withdraw it according to the figure below:



Figure-77

3) Use an acupuncture needle or other hard object that can be inserted into the wash probe for dredging:

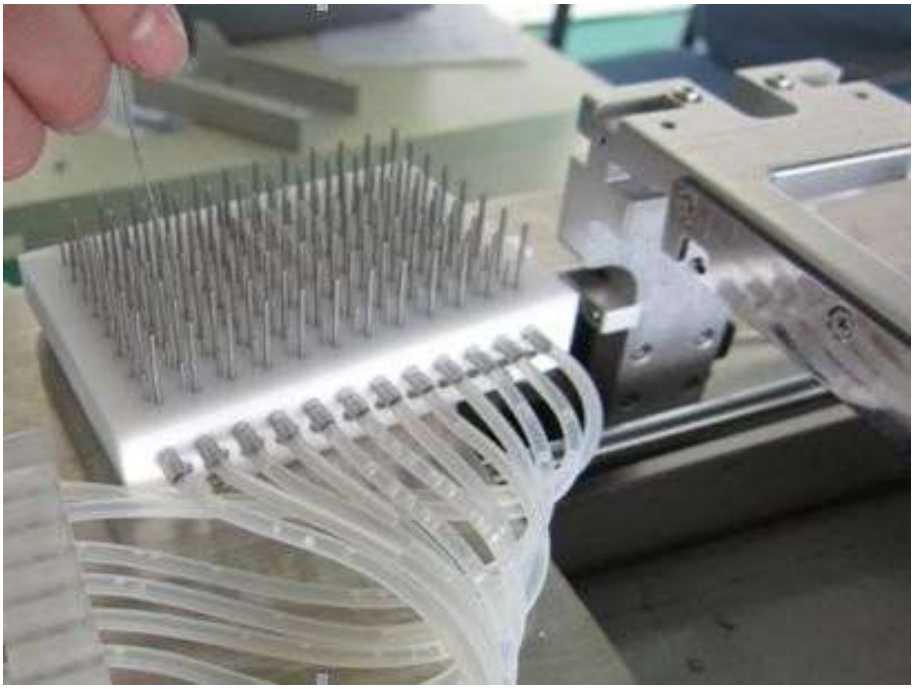


Figure-78

Type II

1) Type II is shown in the figure below:



Figure-79

2) First remove the silicone tube for aspiration



Figure-80

3) Lift the wash head
Lift in the Position shown in the figure

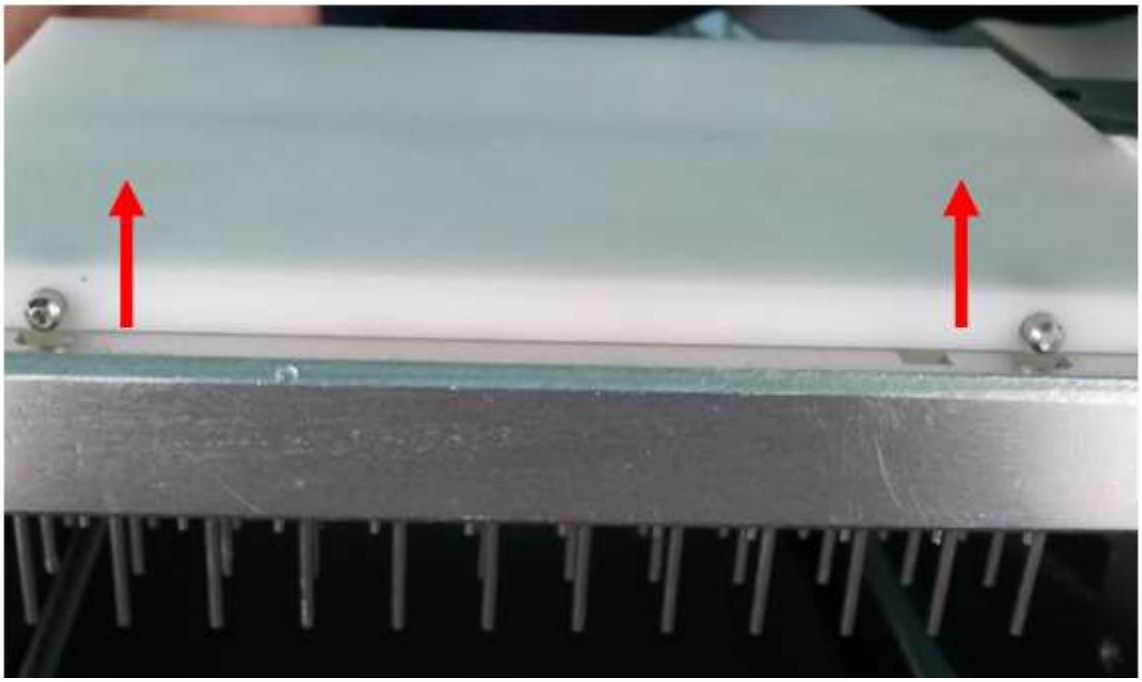


Figure-81

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

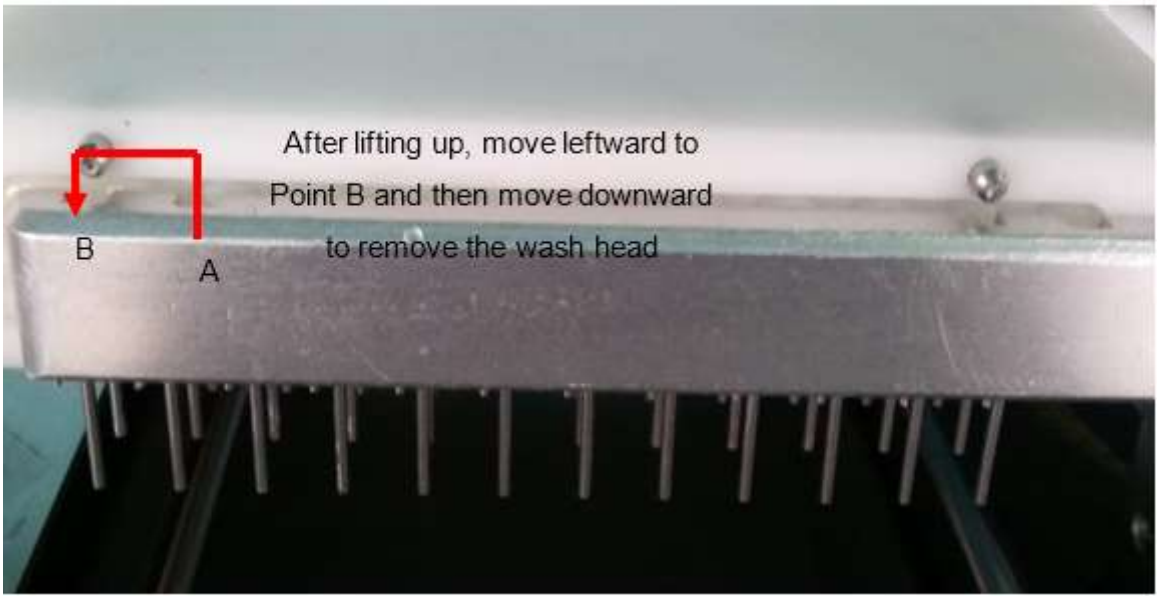


Figure-82

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