Immunoassay Analyzer

FM-IA-A100

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1. Safety Measures

1.1 Safety Symbols

- This manual and the analyzer use various safety symbols to alert you to important considerations during operation.
- The table below provides an overview of these symbols.

No	Symbol	Signs	Explanation
1.		WARNING	In all instances marked with this symbol, you must consult the documentation to understand the potential hazard and the necessary countermeasures. Failure to use the instrument according to the instructions in this manual may invalidate the protective measures provided.
2.		IVD	Used in the nameplate position; indicates that the medical device is an in vitro diagnostic medical device.
3		Up	It indicates that the correct position of the transport package is vertical upward.
4.		Fragile	It indicates that the transport package contains fragile items, so it should be handled with care.
5.		Fear of Rain	It indicates that the transport package should be protected from rain.
6.		No Rolling	It indicates that the transport package cannot be rolled over.

7.		Stacking Layer Limit	Indicates that the maximum number of layers that can be stacked for the same shipping package is 3.

- The user engages with this product voluntarily and must adhere strictly to the safety precautions outlined below during operation, maintenance, repair, and transportation This product is designed with comprehensive protection against biological contamination, electrical hazards, and mechanical movement.
- Any actions that deviate from the safety precautions or other guidelines in this manual may lead to a failure of these protective measures or compromise the safety standards, design, and intended use of the instrument.

1.2 Safety Notes

- Fison Instruments Ltd will not be held responsible for any losses resulting from the user not reading this manual or failing to follow its instructions.
- To ensure the safe use of this instrument, review the following safety precautions thoroughly.
- Any actions that disregard these precautions could lead to personal injury or damage to the instrument.

Symbol	Sign	Explanation
	WARNING	• Whenever you see this warning sign, consult the instruction manual to understand the potential hazards and the necessary countermeasures. • Failure to use the instrument as instructed in this manual may render the protective measures ineffective.
	Biological Protection	**Risk of Biological Infection** • Improper handling of samples can cause infections. Always wear gloves, work clothes, and, if needed, protective glasses. • Avoid direct contact with reagent cards, samples, quality controls, and waste. • If a sample contacts your skin, follow your standard safety procedures immediately.
	Protection against chemical hazards	To prevent personal injury from hazardous chemicals, follow these precautions
	WARNING	• Some reagents can harm the skin. • Avoid direct contact with hands or clothing. • If contact occurs, wash with soap and water immediately. • For eye contact, rinse with plenty of water and seek medical advice.

	Waste liquid treatment	To prevent the waste liquid from causing environmental pollution and personal injury, observe the following precautions when disposing of the waste liquid.
	Risk of Biological Infection	• Certain substances in the reagent are subject to pollution regulations and discharge standards. Ensure compliance with local emission standards. • Dispose of used reagent cards according to "Medical Waste Management Regulations" to prevent biological hazards. • When handling waste liquid, always wear gloves, work clothes, and protective glasses if needed to prevent infection.
	Prevent Fire and Explosion	To prevent fire and explosion, observe the following precautions.
	WARNING	Alcohol is flammable and must be handled with great care.
	Disposal of waste Immunoassay Analyzer	Dispose of the discarded immunoassay analyzer according to the following requirements.
	WARNING	• Some of the substances in the discarded immunoassay analyzer are subject to pollution regulations. • Comply with the local waste disposal standard to dispose of the abandoned immunoassay analyzer.
	Instrument out of Use	To reduce or eliminate the risks involved in taking the equipment out of service, such as during service, transportation, or disposal, observe the following precautions.
	WARNING	• During equipment maintenance, transportation, or handling, clean and disinfect the instrument's surface and any other components with biological risks. Ensure that relevant personnel are informed about these risks to avoid biological hazards or other dangers during transportation or maintenance.
	Operation Precautions	To use the immunoassay analyzer correctly and effectively, read the following notes carefully.

	Instrument Use	• The instrument is designed for use with fluorescent immunochromatography reagents containing fluorescent microspheres and is intended for in vitro quantitative detection of analytes in human samples. • When making clinical decisions based on the analytical results, consider the patient's clinical symptoms and other test results.
	Instrument Installation	• Place the instrument on a stable surface to prevent it from falling. • Operate it in temperatures between 10°C to 30°C, with ≤70% humidity and 86kPa to 106kPa atmospheric pressure. • Avoid placing anything on or near the power cord and ensure the power cord is not a tripping hazard. • Keep the instrument accessible for emergency disconnection and away from the fire to prevent damage and fire risk.
	Use Environment	• Install the instrument according to the manual to avoid unreliable results or damage. • Ensure at least 5 cm of space around the instrument for air circulation and heat dissipation. • Keep the environment clean and free of dust. Assess the electromagnetic environment before use. For system status changes
	Protection against electromagnetic waves and noise	• Avoid placing the instrument near equipment that emits abnormal noise or strong magnetic fields, such as stereos and speakers, as they may damage data or displays. • Keep other medical equipment away to prevent interference from electromagnetic waves emitted by the instrument.
	Sample	• Use proper sample storage to avoid altering the sample composition and ensure accurate results. • To prevent volatilization, keep samples covered and do not leave them open for extended periods, as this can lead to incorrect results. Be aware that some samples may not be suitable for analysis with the test parameters and reagents used.
	Electromagnetic Compatibility Related Precautions	• This instrument meets Group 1 Class A standards in GB 4824 and may cause radio interference in domestic settings.

		• Keep it away from strong radiation sources (e.g., unshielded RF sources) to avoid operational interference. • Ensure the electromagnetic compatibility of the environment for proper functioning. • Evaluate the electromagnetic environment before use. The instrument complies with GB/T 18268.26 for immunity and emissions.
	Instrument use	• Use the instrument according to the manual to avoid inaccurate results, damage, or personal injury. • Unplug the power cord during thunderstorms to prevent electric shock or fire. • Do not place lit cigarettes or candles on the instrument to prevent fire or damage. • Keep the fan exhaust port clear to avoid fire or damage. • Avoid scratching the display to prevent damage. • The instrument is Class A equipment per GB 4824 and may cause radio interference in domestic settings. • Only trained professionals should operate the instrument.

2. Introduction

Immunoassay Analyzer FM-IA-A100 is designed for efficient and accurate testing. Operates with an excitation wavelength of 365 nm and a detection wavelength of 615 nm. Our analyzer supports versatile detection, allowing multiple items on one card. Features a 7-inch color touch screen for easy operation. Enhanced with a built-in thermal printer and connectivity options such as RS232, ensuring seamless integration.

3. Features

- ✓ Immunoassay analyzer with compact and portable design
- ✓ Connects to code scanner and LIS/HIS systems
- ✓ Leading flow system
- ✓ Supports instant test with random sample insertion function
- ✓ Detection time of up to 8 seconds per test
- ✓ Capability for multiple items on one card
- ✓ Sample types include serum, plasma, whole blood, and urine

4. Specifications

Model No.	FM-IA-A100
Excitation wavelength	$\lambda_0$365 nm
Detection wavelength	$\lambda_1$615 nm
Detection Channel	1
Detection Mode	Supports multiple items in one card
Display	7-inch color touch screen
Speed	<10 s/test
precision	CV ≤5%
Stability	σ ≤ ± 8%
Linear Correlation	(r) ≥ 0.98
Interface	RS232, USB , Ethernet port
Printer	Thermal printer
Power Supply	100 to 240 V , 50 /60 Hz
Exterior Dimension (L × W × H)	228 × 312 × 158 mm
Packing Dimension (L × W × H)	455 × 325 × 245 mm
Net Weight	3 Kg
Gross weight	4.5 Kg

5. Applications

Immunoassay analyzer are used in healthcare , Environmental monitoring , pharmaceuticals, biotechnology.

6. Instrument Introduction

Main Structural Composition

- The **FM-IA-A100** Immunoassay Analyzer consists of a host (including optical detection module (fluorescence), scanning module, data processing module, liquid crystal display module, information acquisition module, printer, shell), embedded software (software release version V1), power adapter, and power cord.
- Its structure diagram is shown in Figure 1& 3.
- The main component of the optical detection module is an optical path box, which is mainly composed of a light source, an optical path platform, and a detection component.
- The scanning module is mainly composed of a code scanner, a scanning head connecting
- plate, a scanning head mounting seat, and its fixing parts.
- The data processing module mainly comprises the measurement circuit board and its fixing parts.
- The LCD module mainly comprises an LCD screen and control board.
- The information collection module mainly refers to the ID card reader.

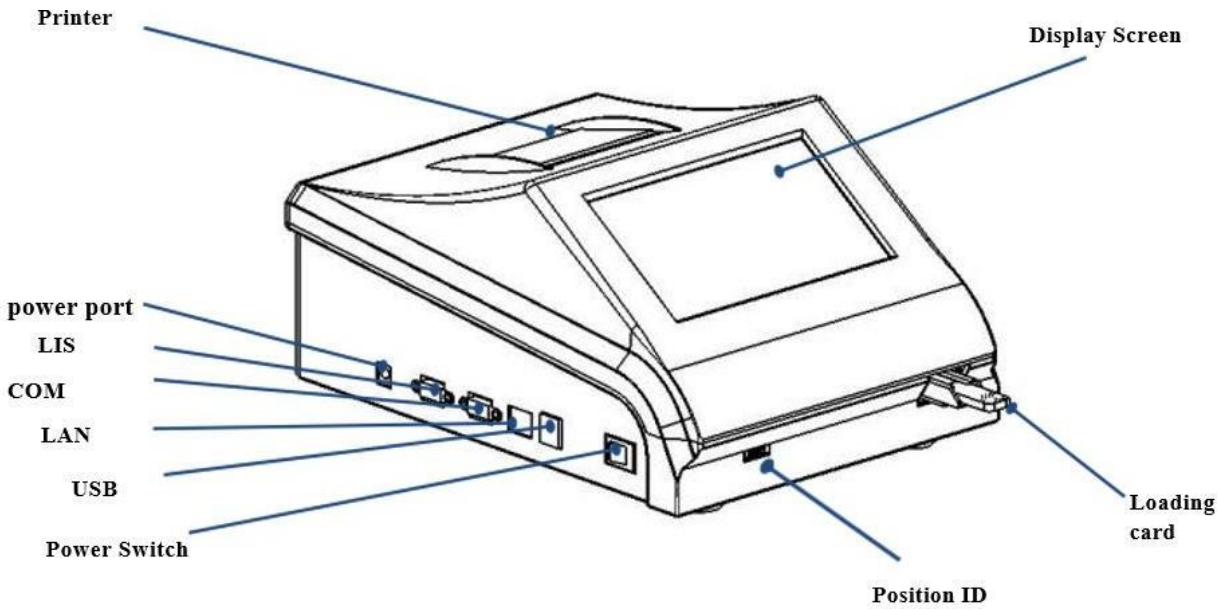

Fig.1

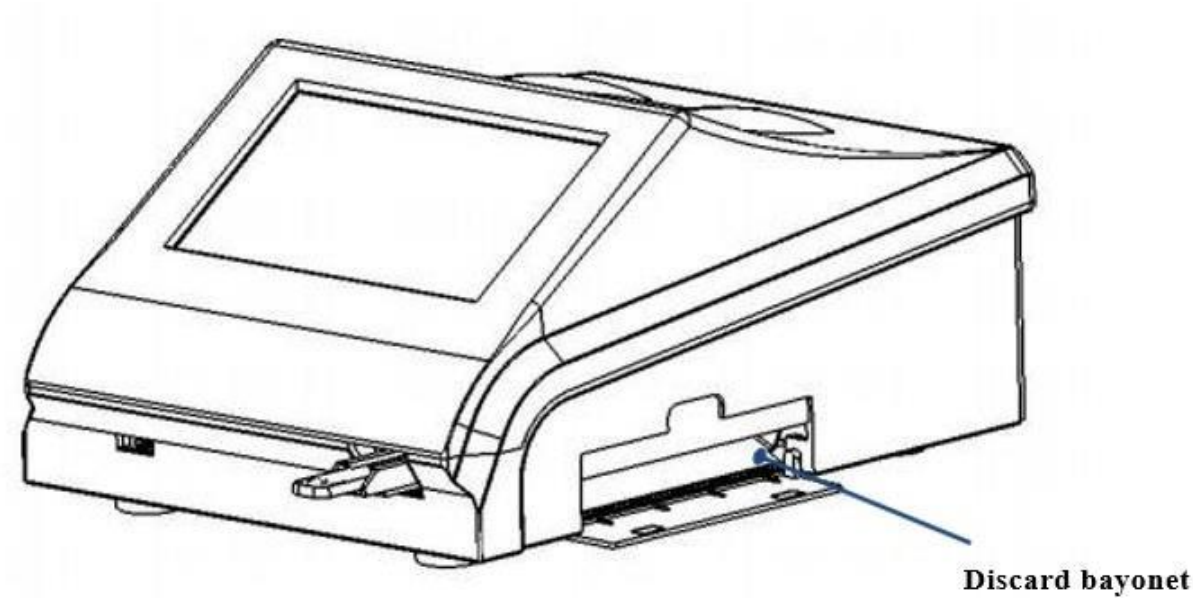

Fig.2

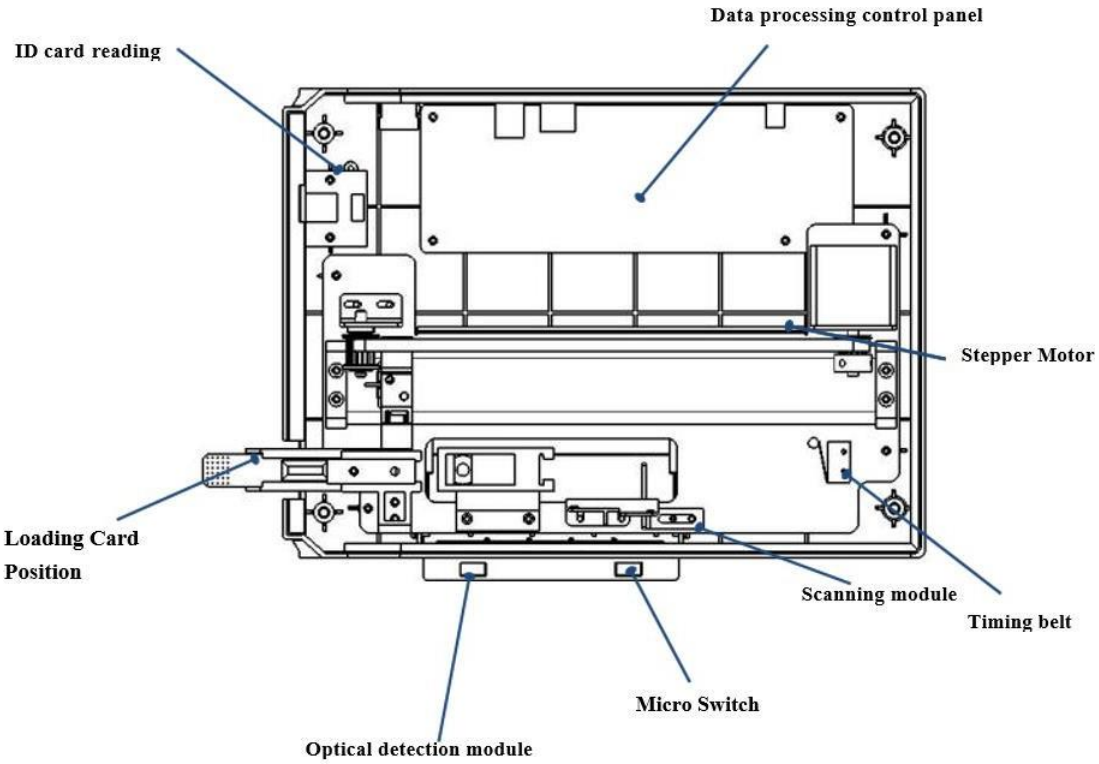

Fig.3

Note: The appearance of the instrument is subject to the actual product.

7. Installation

Use this instrument under conditions that meet the environmental requirements of the instrument.

7.1 Package

- If the package is damaged after receiving the instrument, or the instrument is damaged
- If it's well packed without any damage, then follow the steps below to remove the packaging materials and install the instrument.

7.2 Unpack

- Carefully remove the instrument and accessories from the box, saving the packing material for future shipping or storage.
- Count the random accessories item by item according to the packing list.
- Check the instrument and accessories for mechanical damage.
- When handling the instrument, should be handled with care, and it is strictly forbidden to force the front case directly to avoid damage to the instrument.
- Place the instrument's main body on a stable flat operating table.

7.3 Installation Requirements

7.3.1 Installation Environment

- The instrument should be placed in a stable and level room with no serious dust, no direct sunlight and no corrosive gas, and the work surface can carry a weight of more than 5kg
- There are no strong vibration sources and strong electromagnetic fields around
- Do not place the instrument in a position where it is difficult to operate the disconnect the device, with a clearance of at least 5 cm around the instrument
- Do not cover the instrument with anything to prevent the vents from being blocked
- Try not to use parallel sockets to avoid fire caused by overload
- A 24V/2.5A power adapter and an effectively grounded socket must be used
- The instrument should be placed in a clean and ventilated room with a temperature of 10°C to 30°C and a relative humidity of not more than 70%.
- To ensure the normal operation of the instrument, do not place objects on the instrument at any time.

7.3.2 Power Supply Voltage Requirements

- **Power supply**: AC 220V, 50Hz
- **Rated input power**: 60VA.
- During use, be careful to avoid short circuits and the risk of electric shock
- **Note**: The documentation must be consulted in all cases marked with a ⚠ symbol.

7.3.3 Accessories Connection

Install the related accessories configured with the machine to the corresponding interface of the instrument.

7.3.4 Connect the Power Cord

- Ensure the analyzer's power switch is in the off (O) position.
- Connect one end of the provided power adapter cable to the instrument's power socket (marked accordingly), and plug the other end into a standard, well-grounded power outlet.
- If connecting to HIS/LIS, attach the serial cable to the LIS port on the instrument.

7.3.5 Thermal Printing Paper Installation Procedures

- Open the printer compartment door, then place the thermal printer paper configured with the printer into the printer compartment and close the door.
- **Notes**: ⚠
  Thermal printing paper size (width 57mm±0.05mm, outer diameter ≤30mm).
  The paper is installed with the thermally coated side facing up. Before closing the door, extend the printing paper 2-5cm outwards.

7.4 Transport and Storage Conditions of the Instrument

7.4.1 Transport

- The instrument under the packaging condition is suitable for road, railway, air, and water transportation.
- During loading, unloading, and transportation, it should prevent severe vibration and shock, should not be affected by moisture, and should not be mixed with flammable and corrosive substances. Requirements according to the order contract.

7.4.2 Storage

- When storing the instrument, it should be placed in the original packaging box, placed in a well-ventilated room, the packaging box should be padded, the ambient temperature should be -40°C ~ 55°C, and the relative humidity should not be greater than 70%.
- Harmful gases, flammable, explosive substances, and corrosive gases are not allowed.

8. Working Principle

8.1 Principles of Immune Response

Basic Principle

1. **Competition Method**
   - The detection area (T line) on the NC membrane of the detection card is coated with antigen, and the quality control area (C line) is coated with goat anti-mouse IgG.
   - After the sample is added to the sample well, the liquid is chromatographed upward under the capillary effect.
   - The analyte (antigen) in the sample competes with the antigen in the detection area (T line) on the NC membrane to bind the antibody labeled with fluorescent microspheres during the chromatography process.
   - Then continues to be chromatographed upward, at the C line, a solid-phase goat anti-mouse IgG-fluorescent microsphere-labeled antibody complex is formed fluorescent microspheres emit visible light signals under excitation light.
   - The more analytes in the sample, the less complexes accumulate on the T line.
   - The signal intensity of the fluorescently labeled antibody on the T line is inversely proportional to the content of the analyte in the sample.

2. **Sandwich Method**
   - The detection area (T line) on the NC membrane of the detection card is coated with coating antibody, and the quality control area (C line) is coated with goat anti-mouse IgG.
   - After the sample is added to the sample well, the liquid is chromatographed upward under the capillary effect.
   - During the chromatography process, the analyte in the sample is first combined with the labeled antibody labeled with fluorescent microspheres to form the analyte-fluorescent microsphere labeled antibody complex and then continues to be chromatographed upwards.
   - Then the complex will be bound by the coated antibody coated on the T line and a solid-phase coated antibody-antigen to be tested-fluorescent microsphere-labeled antibody complex will be formed at the position of the T line.
   - At the position of the C line, a solid-phase anti-mouse IgG-fluorescent microsphere-labeled labeled antibody complex was formed.
   - The fluorescent microspheres emit fluorescent signals under excitation light.
   - The more analytes in the sample, the more complexes accumulate on the T line.
   - The signal intensity of the fluorescently labeled antibody reflects the amount of the analytes captured.

8.2 Working Principle

- Drop the sample containing the antigen (antibody) to be tested in the sample application area.
- If you use the fast mode, you need to wait for the antigen and antibody to react completely before putting it into the instrument, and the instrument will directly read the data.
- If you choose the normal mode, you need to directly put the reagent card that has just added the sample on the loading card position.
    - When the instrument detects that a card is inserted, it will start the
    - countdown.
    - After the predetermined time is over, the instrument will read the data.
- The read procedure is as follows: The instrument automatically turns on the LED light source and scans the reaction area of the reagent card horizontally.
- The LED will gradually irradiate the detection area, and then irradiate to the quality control area, and the fluorescent immune complexes solidified on the reagent card will be excited under the specific wavelength of the LED.
- The excited light is collected by the silicon photocell and converted into an electrical signal.
- The strength of the electrical signal is strictly related to the number of fluorescent molecules.
- The fluorescence signal of the reagent card will be converted to the corresponding voltage signal, and the software calculates the signal value of the reagent card by the highest peak area method.
- Substitute this value into the calibration curve to calculate the concentration, and the reading process ends.
- Finally, discard the reagent card after the test is completed.

9. Operations

9.1 Specific Operation Steps

9.1.1 Preparation Before Use

- Turn on the power switch of the instrument, the instrument will perform a self-check and the loading tab will reciprocate once
- The test software starts automatically, and the main interface appears automatically
- For the use and storage of reagents, refer to the instructions that come with the reagents
- Put the reagent card containing the sample to be tested smoothly on the loading tab, and test according to the software operation instructions
- According to the different test items, select the appropriate parameter settings (the technician will guide and train the operator).

9.1.2 Start Testing

- The instrument action is controlled by the software to carry out the test.
- **Notice**: ⚠
  At this time, the loading tab is moving, do not approach the outlet of the loading tab; the software cannot be operated during the test.

9.1.3 End of the Test

- After the project test is completed, the instrument will automatically save the test results, and the operator can output the results through the built-in printer, external printer, or Lis system.
- When the test is over, the reagent card is dropped from the discarding port to the outside of the instrument
- The loading tab is automatically reset to the loading position
- Turn off the power to end the test.
- The waste generated during the use of the instrument should be handled uniformly by professionals by the "Medical Waste Management Regulations" and other relevant regulations.

9.2 Quality Control and Calibration

9.2.1 Quality Control

- The instrument has been quality controlled before leaving the factory.
- After the instrument is debugged and installed, it can be directly tested with reagents.
- If you need to perform quality control on the instrument again, you can perform quality control by testing the quality control strip.
- Quality control is implemented in the same way as when testing normal samples, that is, directly using the Analyzer to test the concentration of the quality control strip.
- If the reading value of the instrument is compared with the target value of the quality control product, if the reading value meets the target value range requirements of the quality control product, the instrument can be tested.

9.2.2 Calibration

- After 1 year of normal use, the user needs to use the standard for calibration.
- The calibration method is the same as when testing ordinary samples, that is, directly using the Fluorescence Immunoassay Analyzer to test the concentration of the reagent card (with the standard added).
- If the reading value meets the target value range of the standard, it can continue to be used.

9.3 Start-up Operation Procedures

- Power on the instrument, then turn on the power switch and enter the username and password after the instrument is turned on.
- Enter the software experiment operation interface, and enter the equipment self-check program, and the loading card reciprocates once.
- The test software starts automatically, and the main interface appears automatically.

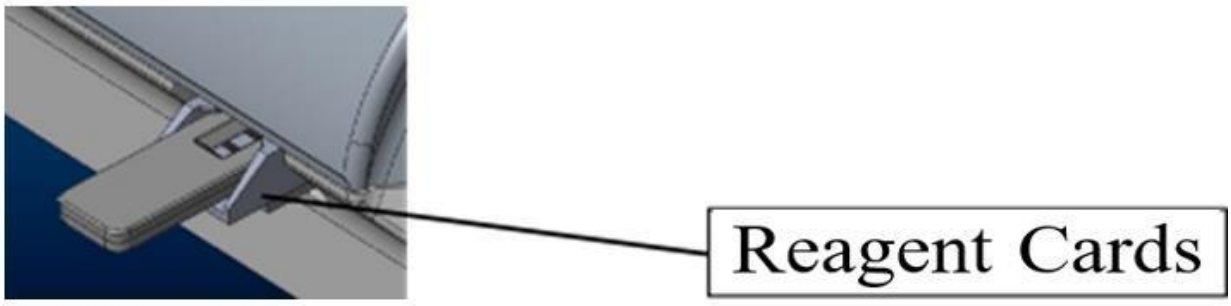

Fig.4

9.4 Function

1. The analyzer should have an ID card information reading function.
2. The analyzer has a data display function: after testing with the analyzer, the test results can be inquired.
3. The analyzer has a touch operation function.
4. The analyzer has the function of automatic printing. After the test is over, it can automatically print the test results.
5. The analyzer has a self-checking function.
6. The analyzer has a fault prompt: the analyzer has corresponding prompts for operation errors.
7. The analyzer has a LIS data interface.
8. The analyzer has user access control: it is divided into two levels: administrator and common user.
9. Common user authority: can only access the test data of this user
10. administrator authority: can access the test data of all users.

9.5 Software Interface Operation Introduction

9.5.1 Main Interface

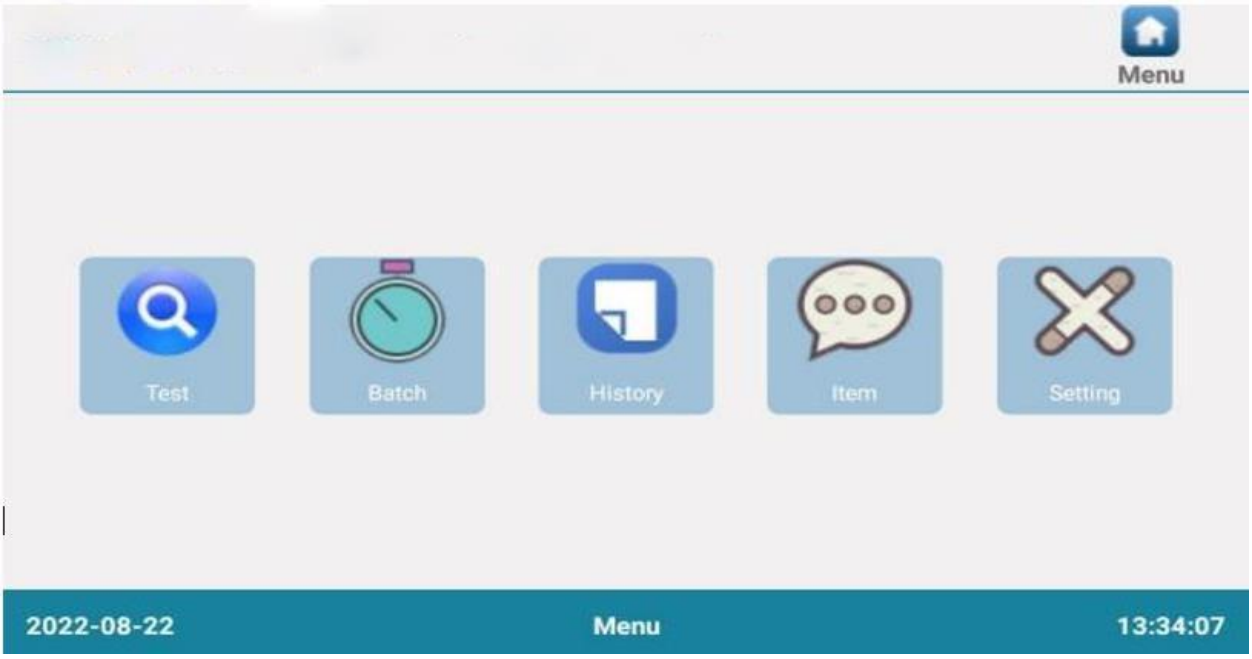

Fig.5

1. As shown in Figure-5, there is a main menu button at the bottom of all display interfaces; after clicking, it will return to the interface of Figure-5.
2. From left to right are the [Test], [Batch], [History], [Item], and [Setting] buttons.
3. Click one of the buttons to enter the corresponding function operation interface.

9.5.2 Test Interface

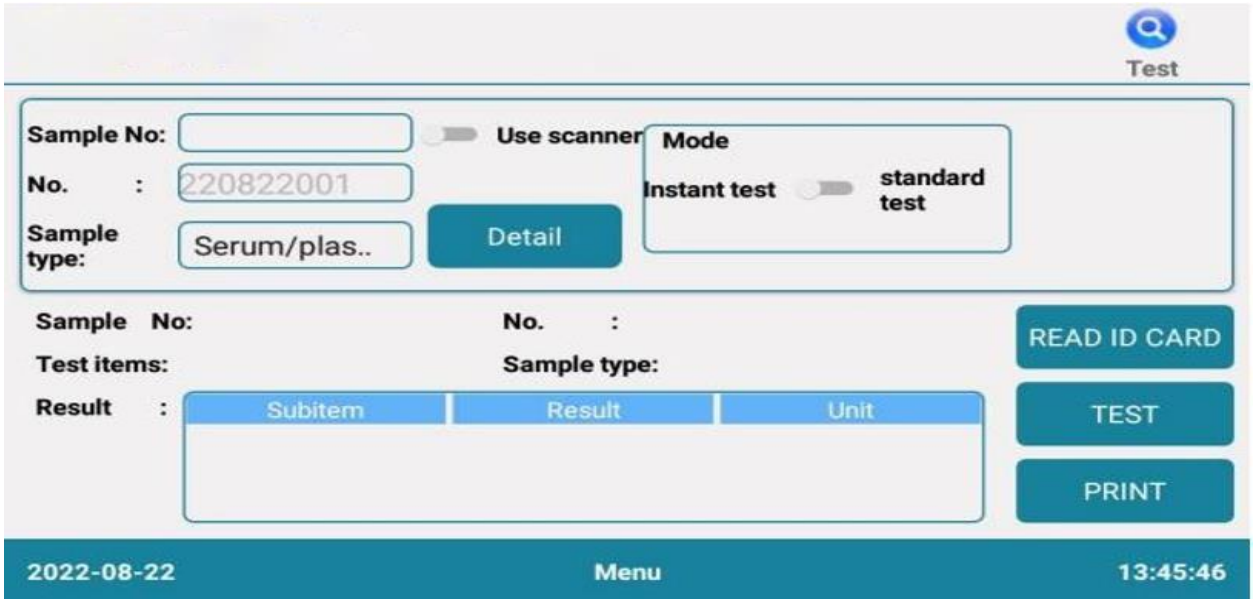

Fig.6

1. First select [Test] on the main interface, after selecting, as shown in Figure-6
2. Before each batch of reagent cards is tested, there is no corresponding test item in the system, so the ID card needs to be inserted to read; the user can manually select the [Read ID card] button in Figure-6 to read the data
3. When the ID card data has been read, the sample type can be selected, and the sample number can be manually entered as needed
4. Users can also click [Detail] to enter detailed patient information
5. After all the information is entered, the user can select [Standard Test] or [Instant Test] to test.
6. The standard test refers to scanning the reagent card and calculating the result after the reaction time of the item is counted down.
7. The instant test refers to the instant test scan and the result calculation
8. The user code is used to count the number of user tests and the distribution of test items.
9. After the corresponding information is input, the user can select the [Test] button in Figure-6 to test, and the test value result will be displayed in the corresponding value box in Figure-6
10. After testing each reagent card, the user can select the [Print] function in Figure 6 to print the test report.

9.5.3 Batch Test

J

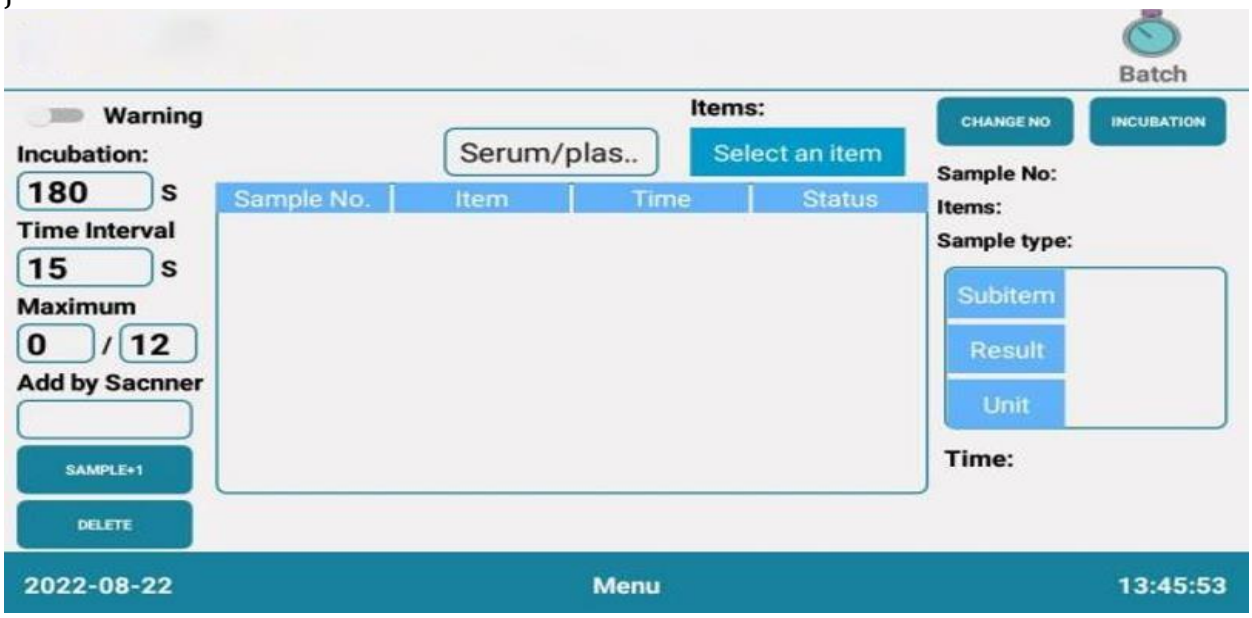

Fig.7

1. The interface of [Batch Test] is shown in Figure-7, the user can select the sample type, and test items, and add and delete items to be tested
2. First, select the detection item to determine the time.
3. Select [SAMPLE+1] to add test samples, if you want to delete redundant test samples, the user needs to select the corresponding samples, and then click the delete button
4. After the sample is added, the sample code is automatically assigned. If you want to customize the code, select the sample, and click [CHANGE NO.] to modify the code.
5. Click [INCUBATION], and the instrument will start the countdown, and will also count down the interval time for the next sample

9.5.4 History View Interface

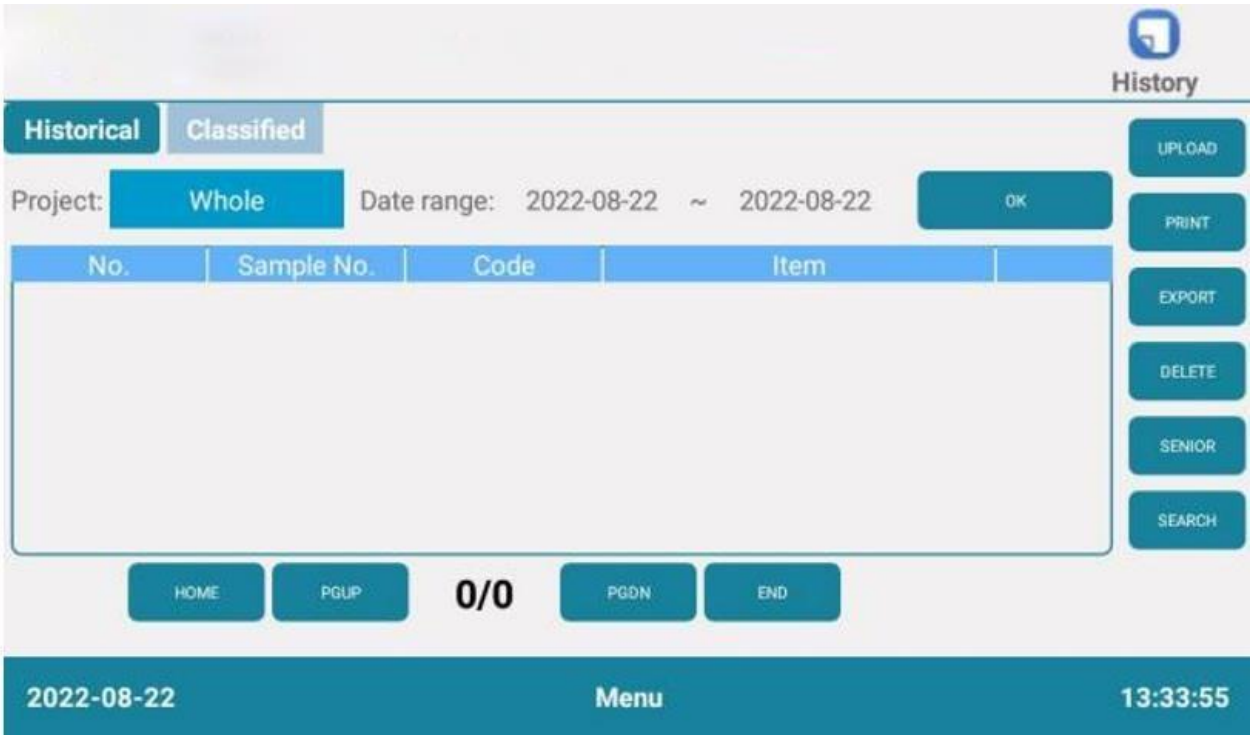

Fig.8

1. In the [History] interface, the user can perform historical viewing, classification and statistics operations
2. After each test result comes out, the system will automatically save the data locally, and the user can select [Historical] to view it
3. Click [Date] in Figure-8, select the date range to be viewed, and click [OK] to view the record
4. After selecting the item code to be viewed, click [OK] to filter out the corresponding item record
5. Click [Upload] in Figure-8 you can choose to upload the selected records or upload them all
6. Click [Print] in Figure-8, you can choose to upload the selected records or print them all
7. Click [Export] in Figure-8, you can choose to upload the selected records or export them all
8. Click [Senior] in Figure-8, and then select a single history record to view detailed information.

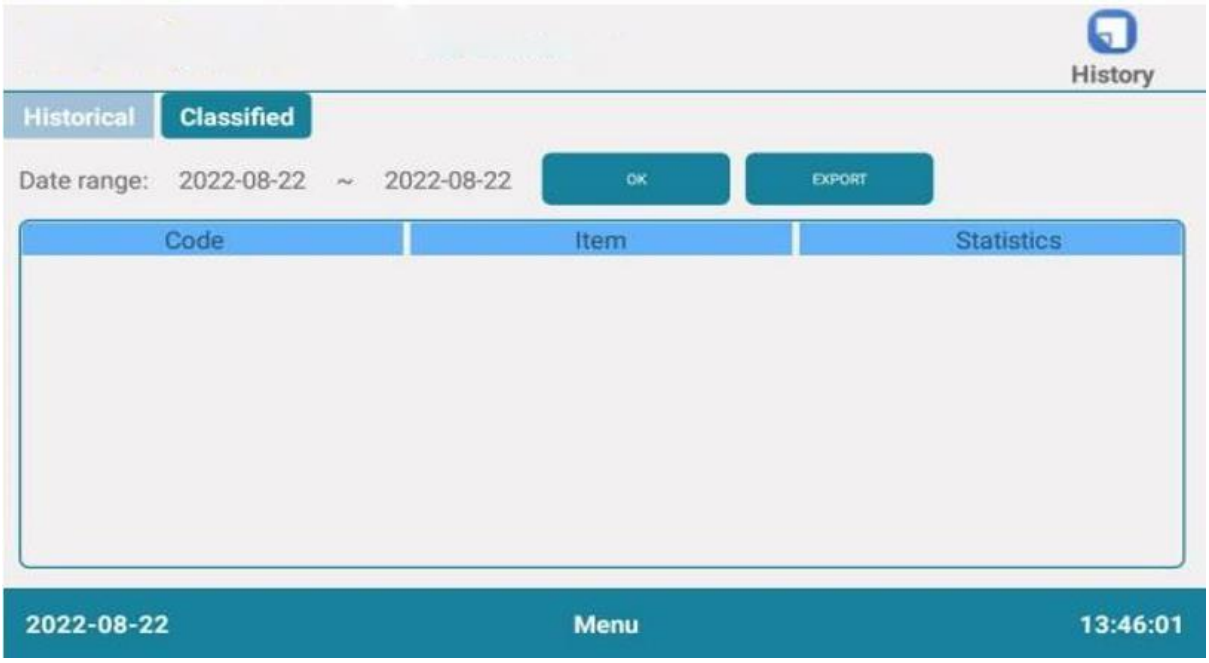

Fig.9

9. Click [Classified] in Figure-9, select the date range to be viewed, and click [OK] to view the statistical results.

9.5.5 Project View Interface

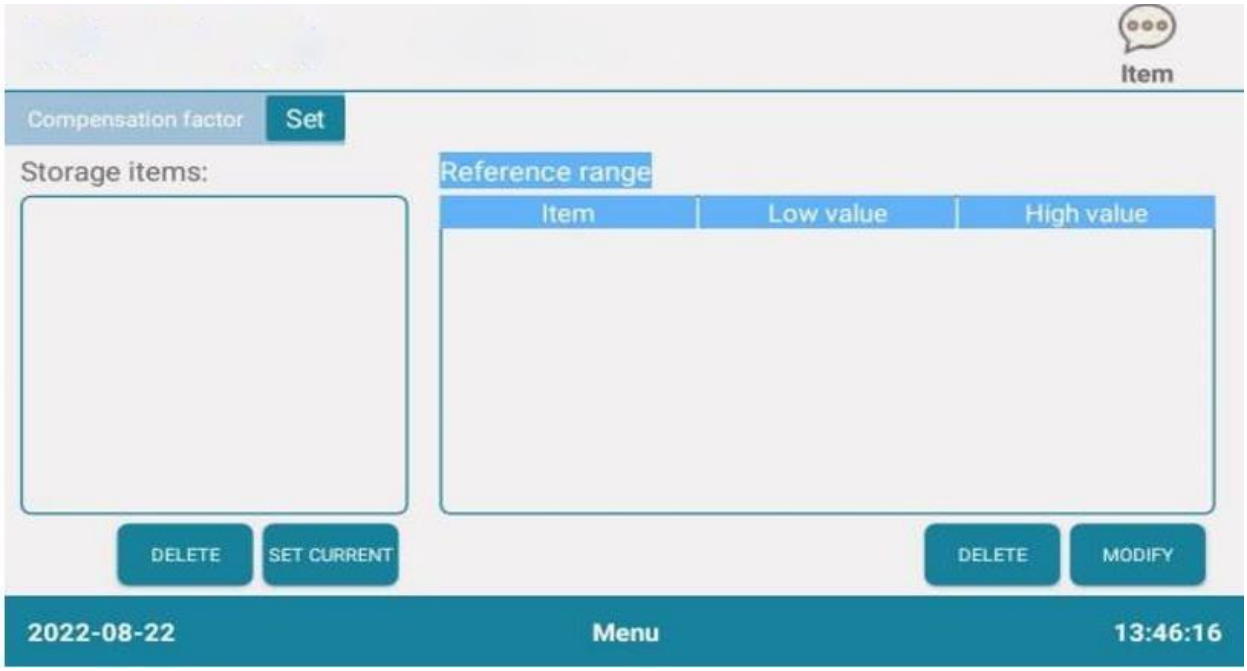

Fig.10

1. As shown in Figure 10, the project list can be viewed in the project settings, and the project reference value can be set
2. The system supports viewing the list of items stored in the system and can replace items.
3. The user can modify and delete the project reference value.

Fig.11

1. As shown in Figure-11, in the "coefficient" item of the compensation coefficient, "symbol + number" can be input
2. The symbols supported by the system are "+", "-", "*", "/", etc., which can represent addition, subtraction, multiplication, and division respectively
3. The function of the compensation coefficient is when there is a deviation in the test value due to the influence of external factors, the user can manually eliminate the deviation through the correction coefficient

9.5.6 Setting

In [Setting], users can view institutional information, LIS/HIS link parameter setting, test setting, system setting, about, and user management.

1. **[Institutional Info]:** Users can view the institution name, institution address, and re-register the institution name.

Fig.12

2. [**LIS/HIS link parameters]:** To set the LIS upload parameters, first select the upload method, and then set the corresponding parameters.

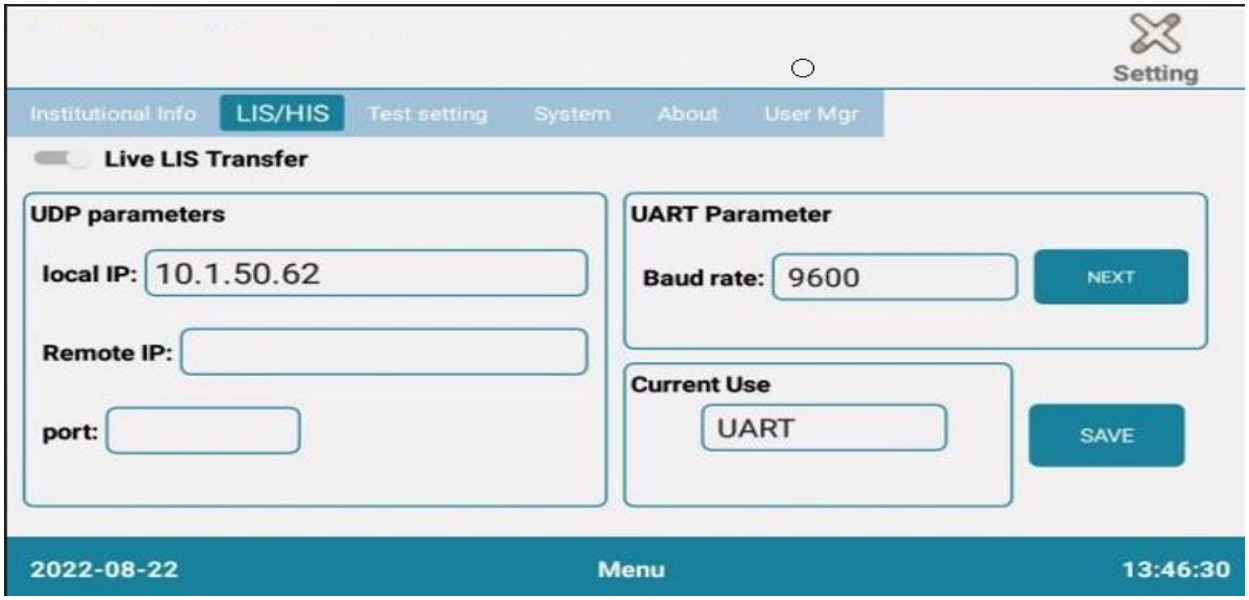

Fig.13

3. **[Test Setting]:** Set the initial value, length, and alignment of the sample serial number.
   - Set real-time printing results, if selected, the report will be automatically printed after each test.
   - Set the record-keeping days, when the record-keeping days exceed the set days, they will be automatically deleted.
   - Set weather to test automatically. If this option is selected, once the system detects that a reagent card is inserted, the system will automatically perform

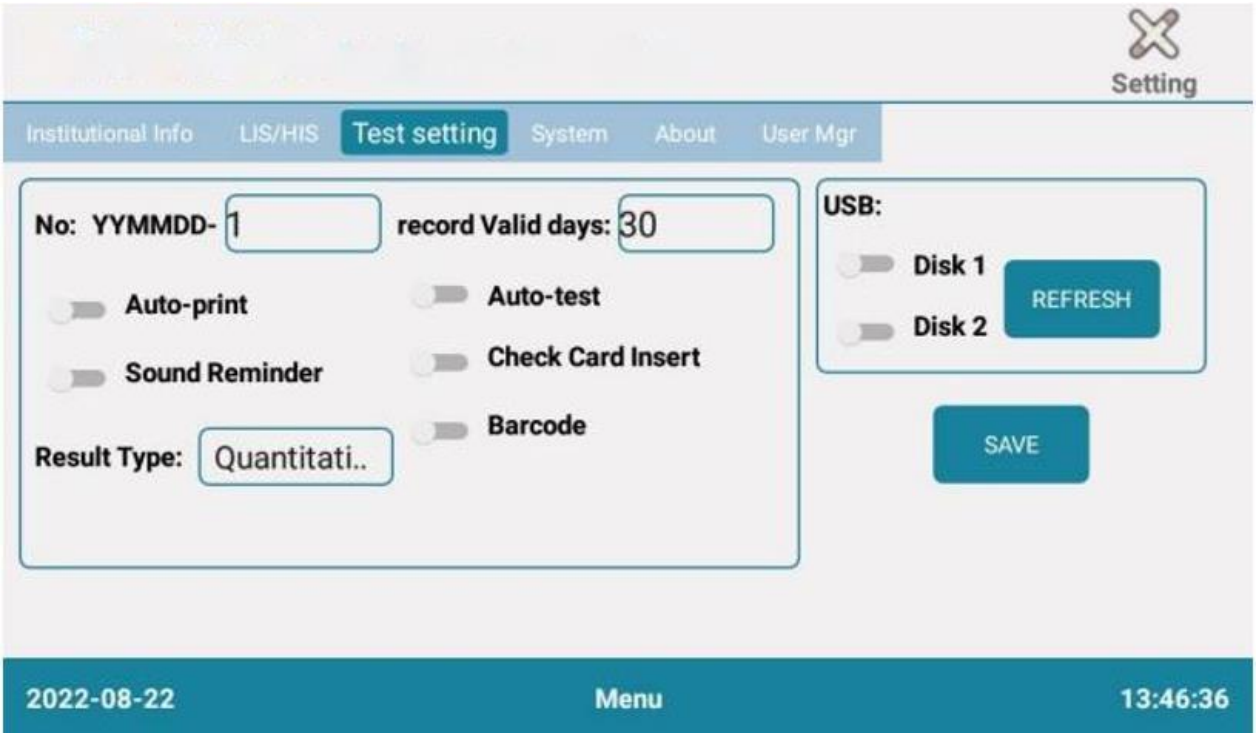

Fig.14

4. **[System Setting]:** Set the system time. After setting the system time, you need to save it to take effect.

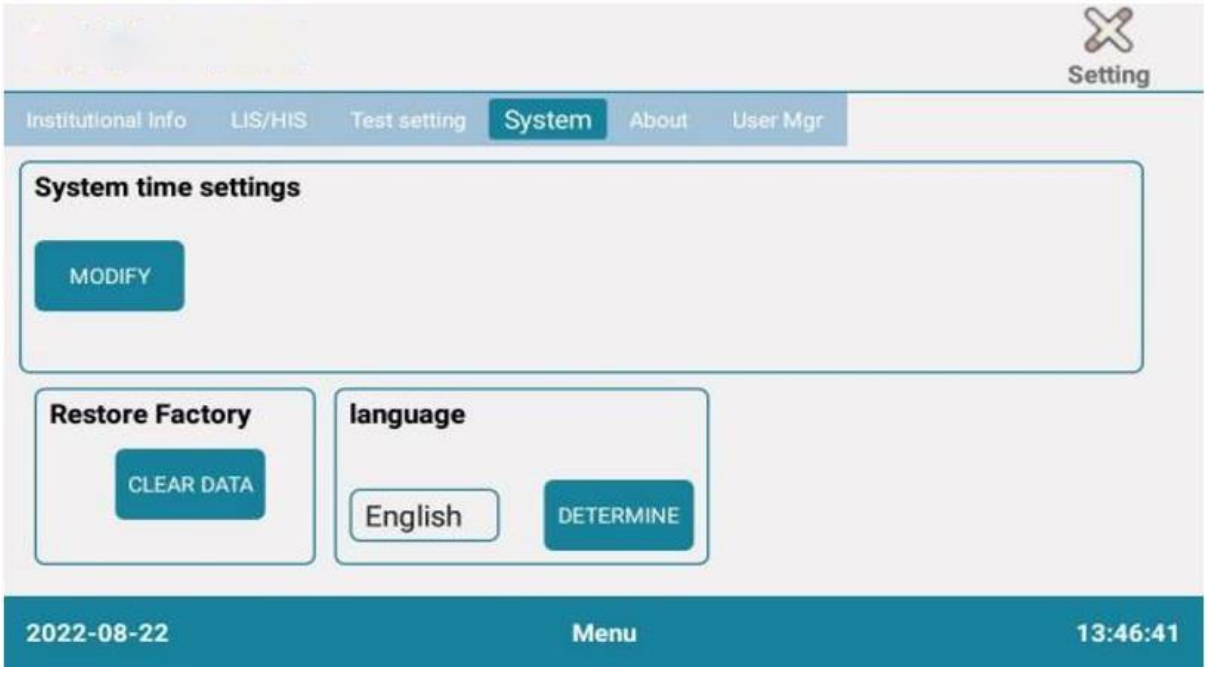

Fig.15

5. **[About]:** To check the software version, you can put the software upgrade package into the U disk and insert it into the USB port of the instrument. After the system detects the upgrade program, the software can be upgraded.

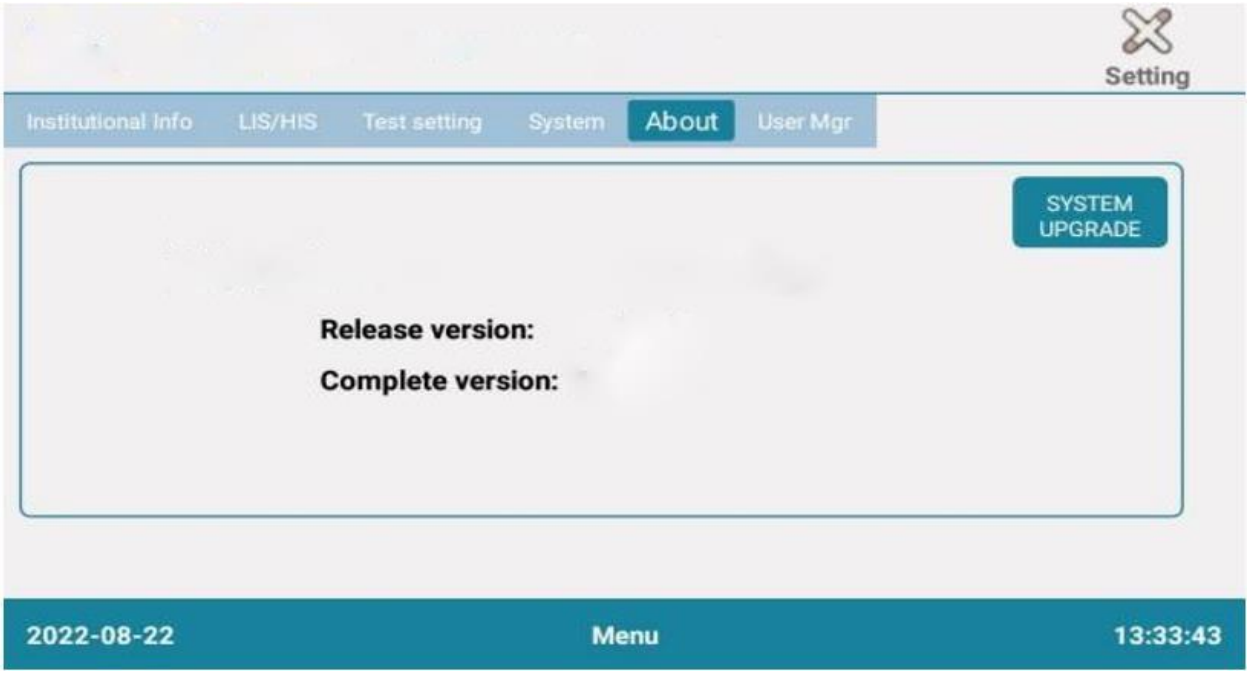

Fig.16

6. **[User Mgr]:** User management, logout, modify, add, and delete users.

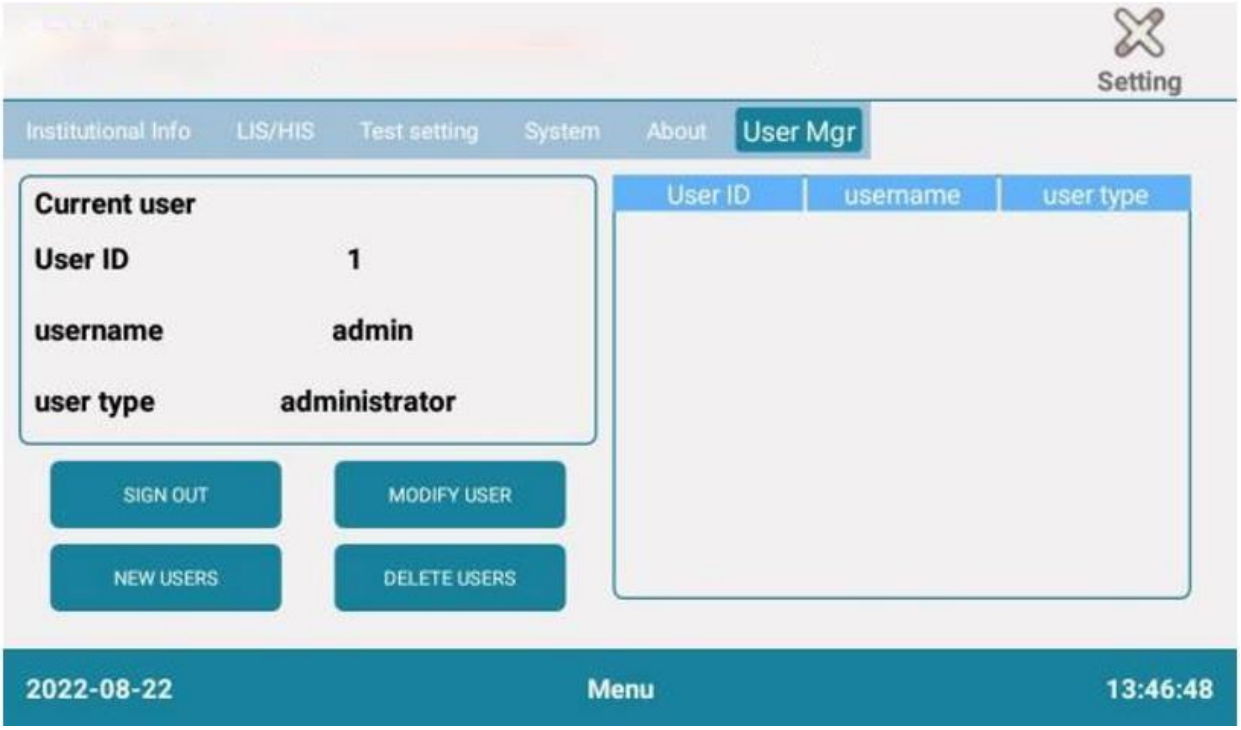

Fig.17

9.6 Software

Software interface: wizard-style interface, intuitive layout, and program settings, easier to operate and edit.
Language support: English.
Data storage: The instrument can store experimental data files.
Data transmission: The experimental data can be printed out through the printer, or the experimental data can be exported to the U disk through USB.

9.6.1 Network Security

Software operating environment requirements.
Embedded software and its operating environment requirements are as follows:

- **Android platform:** PowerVR SGX544MPI, 8G (EMMC), android6.0 or above.
- **Motherboard hardware configuration**: Control board main control chip: GDF205VCT6
- **Memory**: AT24C64
- **Network type**: none
- **Security software**: none
    - **Data interface**: LIS port, LAN port, USB port.
    - LIS port and LAN port are used to connect LIS.
- The USB port is used for keyboard and mouse access, data export, and system upgrade.
- The LIS port transmission protocol is the RS232 communication protocol. The LAN port transmission protocol is TCP/IP or UDP/IP protocol, and the USB interface protocol is USB protocol.
- **Data type**: Export data through a USB data interface, the storage medium is U disk, and the exported test data.
    - **Access Control**: Deny any unauthorized external access.
- The software can log in to the software after the user enters the user's name and password for verification.
- It is divided into two levels: Administrator and ordinary user. **Administrator authority**: can access the test data of all users. **Ordinary user authority:** can only access the test data of this user

10. Maintenance

The instrument requires minimal maintenance under normal use. However, regular cleaning and minor maintenance are necessary for long-term operation. Before cleaning, carefully review this chapter to ensure proper procedures. Proper maintenance and cleaning will extend the instrument's service life.

Consider the following during maintenance:

1) Assign a responsible person for machine upkeep.
2) Ensure the maintainer educates all users on the importance of maintenance.
3) Wear gloves, work clothes, and protective glasses if needed during maintenance. Dispose of used cleaning materials according to relevant regulations.

1. Daily Maintenance

When the instrument is turned on every day, it can automatically complete an initialization and perform a self-test reset.

1) Check the Printing Paper

Check whether there is printing paper in the printer, and replenish it in time, so as not to affect the printing of the experimental results.

2) Check the Loading Tab

Check whether there is any foreign object at the loading tab, whether the operation is smooth, and whether there is a stuck phenomenon.

2. Weekly Maintenance

1) Clean up the Printer

- Check the printer to see if the print roller is glued.
- When cleaning, turn off the printer, slide the upper cover limit block, and open the upper cover assembly position of the printer; turn the printing roller, and at the same time use a 75% ethanol cotton swab (should be wrung out) to wipe off the dust and stains on the surface of the printing roller; wait 5- 10 minutes and close the lid when it evaporates completely.

2) Cleaning the Discarded Bayonet

- The reagent card after the test is discharged from the discarding port.
- After a long time, there will be a risk of biological infection hazards.
- It should be cleaned and disinfected in time.
- When cleaning, wear gloves and use a piece of lint-free gauze and 75% ethanol to clean only the surface.
- After cleaning, dry it with a dry cloth.

3) Clean the loading tab

- The reagent card enters from the loading tab, and there is a risk of biological infection. It should be cleaned and disinfected in time.
- When cleaning, wear gloves, and use a piece of lint-free gauze, cotton swab, and 75% ethanol to clean only the surface.
- After cleaning, dry with a dry cloth

4) Clean the outside of the instrument

- The analyzer casing or frequently touched places are very easy to become dirty. To keep the working environment clean and reduce biological risks, the exposed parts of the analyzer should be cleaned promptly.
- When cleaning, turn off the switch of the immunoassay analyzer, wear gloves, and use a piece of lint-free gauze and 75% ethanol to clean only its outer surface.
- After cleaning, dry it with a dry cloth.
- **Warning**: 
  Do not spill liquid on the analyzer to avoid liquid immersion and damage to the immune analyzer.
- **Biological Infection Hazard**: 

1. During Maintenance Work, Be Sure to Wear Gloves and work clothes to prevent Infection, And Protective Glasses If Necessary.
2. Do Not Throw Away the gauze used for wiping, dispose of it properly according to Relevant Regulations.

3. Keep Air Circulation

This instrument requires air circulation, so periodically check the area where the instrument is placed to ensure that there is adequate ventilation and that no other objects are interfering with the airflow around the instrument.

4. Keep the power supply stable

- The normal operation of this instrument requires a stable power supply, so check the power supply of this instrument regularly to ensure that the power supply voltage is consistent with the voltage required by the instrument (±10% deviation is allowed).
- Ensure that the rated load of the power socket is not less than the requirements of the instrument.

5. Other Maintenance

- Use the parts provided by our company.
- For daily cleaning and maintenance of the immunoassay analyzer, clean the surface of the immunoassay analyzer with lint-free gauze after the power is turned off and use 75% ethanol to clean the parts of the immunoassay analyzer.
- After use in a clinical setting, if the instrument does need to be repaired or replaced, it should be decontaminated before repackaging and shipping.
- Thoroughly scrub the outer surfaces of the instrument with an inorganic laboratory disinfectant (containing less than 0. 1% bleach) and lint-free gauze.
- Do not spray the instrument with disinfectant or clean any internal parts and surfaces.
- **Warning:**
  Hazardous radiation exposure may result if control or adjustment devices are not used, or procedures are performed by this specification.

6. The key to Maintenance of System Hardware

- Warning: ⚠
  1) Do not switch the immune analyzer on and off frequently, and the interval between switching on and off should be more than 1 minute.
  2) Regularly clean and disinfect the discarding bayonet.
  3) Do not place items on top of the immunoassay analyzer.
  4) When moving the immunoassay analyzer, avoid vigorous shaking.
- The equipment contains no operator-serviceable components and regular maintenance must be performed by an authorized service technician to avoid electric shock.

7. Instrument Maintenance

Maintain the instructions in the manual carefully. Incorrect maintenance can lead to inaccurate analytical results, damage to the instrument, or personal injury.

- **Cleaning**: If the instrument is not used for an extended period, dust may accumulate on its surface.
- Use a clean, soft cloth dampened with water to gently wipe the surface. For more thorough cleaning, you can use a small amount of 75% ethanol. Ensure that the instrument is completely dry before using it again, as residual moisture can pose a risk of electric shock or fire.
- Avoid using harsh chemicals, if you are unsure about the compatibility of cleaning agents with the instrument.
- **Power Off Before Cleaning**: Always turn off the instrument and unplug it before cleaning. Protect the instrument from water droplets during cleaning to prevent damage or injury.
- **Repair**: Remove any reagent cards from the instrument and perform routine sterilization and disinfection before sending it for repair.
- **Handling During Maintenance**: During maintenance, transport, or when the instrument is stopped, handle it with care to prevent biological contamination, electric shock, or damage from moving parts.
- **Post-Repair Safety:** After any inspection or repair, have a technical service engineer perform a safety test to ensure the instrument is safe to use. Skipping this step could result in electric shock or fire hazards.

11. Troubleshooting

Fault	Analysis of Causes	Exclusion Method
The instrument can't be turned on	The power switch is not turned on.	Turn on the power switch
	The power adapter is not connected.	Reconnect the power adapter.
The display does not start	Screen cable failure	
	Problem with the operating system	
Software system failure	Operating system malfunction	
	The test analysis software cannot be started.	
	Other prompts appear during the operation of the test analysis software.	Record the complete error message code and error message prompt.
Abnormal sound during testing	Possibly the carrier tab is stuck.	Turn the analyzer power off and on, let it rest Automatically and start working again.
	Mechanical movement failure.	
The testing process stopped suddenly	Possible analyzer power outage.	Turn the analyzer switch back on and test again.
	There is a communication failure.	Turn the analyzer switch back on and test again.
Abnormal test results	Abnormal measurement results.	
	Pollution problem.	Reduce pollution
Other faults	When other failures occur.	

Note:

- The above daily failure analysis and handling methods are for reference only, if necessary.
- When the instrument fails, but the displayed error code is not in the above table, stop the operation immediately.