



# FLUORESCENCE IMMUNOASSAY ANALYZER

BANA-1203

# INDEX

Product Instruction	3
<hr/>	
1. Product Overview	12
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1.1. Instrument introduction	12
1.2. Main structural composition	12
1.3. Scope of application	15
1.4. Basic principle	15
1.5. Software	17
1.6. Network Security	17
1.7. Contraindications	18
2. The basic parameters and the conditions of use	18
<hr/>	
2.2. Function	19
2.3. Transport and storage conditions of the instrument	20
3) Instrument installation	21
<hr/>	
3.1. Package	21
3.2. Unpack	21
3.3. Packing List	22
3.4. Installation requirements	23
<hr/>	
4. Operation interface instructions	27
<hr/>	
4.1. Item interface function description	28
4.2. Test interface function description	28
4.3. Record interface function description	32
4.4. User interface function description(Administrator permissions)	34
4.5. System interface function description	34
4.6. Pwr	37
5. Item Test Operation Procedures	38
<hr/>	
5.1. Power On	38
5.2. Sample Test Information Settings	38
5.3. Read item ID information	39
5.4. Sampling	40

5.5. Using a pipetting gun, add the mixed sample to the reagent card.	41
5.6. Detect	41
5.7. Result Output	42
6. Cleaning and Disinfection	43
.....	
7. Instrument Care and Maintenance	44
.....	
7.2. Maintenance Weekly	45
7.3. Keep air circulation	46
7.4.Keep the power supply stable	46
7.5. Overheating protection	47
7.6. Other maintenance	47
7.7. The key to maintenance of System Hardware	48
8. Quality Control and Calibration	48
.....	
8.1. Quality Control	49
8.2. Calibration	49
9. Troubleshooting Guidelines	50
.....	
9.1. Analysis and treatment of the reasons why the whole machine does not work	50
9.2. The instrument is turned on, but the display is black	51
9.3. The instrument failed to obtain ID information	51
9.4. Instrument cannot print test results	52
9.5. Individual test results show that no sample has been added	52
10. Accessories list	54
.....	
11. After Sales Service, Repair and Destruction	55
.....	

# Product Instruction

Thank you for choosing Fluorescence Immunoassay Analyzer. This instrument is an immunofluorescence automatic detection system based on the principle of photoelectric detection, which needs to be used with special fluorescent immunoreagents. It is widely used in many fields such as disease detection, medical care, epidemic monitoring, food inspection and quarantine. To reduce the risk of fire, electric shock and personal injury, please read and understand all instructions, follow the warnings and instructions indicated on the instrument itself, and always follow basic safety precautions. The protection provided by the equipment may be impaired if the equipment is used in a manner not specified by the manufacturer. In all cases marked with a warning sign, the instruction manual should be consulted to clarify the nature of the potential hazard and any countermeasures that must be taken.

This instruction manual is applicable to the model BKP2000, and the actual interface operation shall prevail.

Date of preparation/revision of the manual: Apr., 2024

Manual version number: V1.3

This manual gives the following two safety warning signs to guide the instrument operator to avoid injury or damage to the instrument and to obtain wrong test results. In order to remind the operator to avoid potentially dangerous and hazardous conditions, we have given different prompt signs depending on the degree of hazard of the operation.



**WARNING:** Failure to follow the operating procedures may result in greater harm to the operator, the environment, or both.



**NOTE:** Emphasizes the operation method that must be followed to avoid possible danger or damage to the instrument and possible erroneous test results.



**NOTE:** Emphasize important information.

All personnel who may use, maintain, move and maintain the instrument should read this manual carefully. If any unexpected failure occurs during the operation and use of the instrument, please refer to the contact information in this manual and call the company for technical support.

## Intellectual property rights

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Without the prior written consent of the company, no individual or organization may copy (including any means of photography, reprint, transcription, etc.), copy, modify or translate any part of this instruction manual.

If the contents of this manual are changed, the user will not be notified separately.

## Statement

Bioscientific Lab has the final right to interpret this instruction manual.

The company believes that it is responsible for the safety, reliability and performance of the product only when all the following requirements are met, namely:

- Assembly operation, expansion, readjustment, improvement, maintenance and replacement of parts are all carried out by professionals recognized by the company;

- All repairs involve the replacement of parts and the accessories and consumables used for them are the original equipment (original) of the company or approved by the company;
- The relevant electrical equipment conforms to the national standards and the requirements of this instruction manual;
- The operation of the product is carried out in accordance with this instruction manual.

### Use Objects

The audience of this instruction manual is the following:

Personnel who carry out the daily operation of the system; Personnel who perform system maintenance and troubleshooting; Personnel who learn system operation.

Before using the product, please read the contents of this instruction manual carefully and use the product correctly. Please keep this instruction manual in a safe place for reference at any time. Warranty is voided if the precautions described in this instruction manual are not followed during use.






In order to keep the protection provided by the equipment effective, the experimenter or operator should consult and operate according to the requirements of this instruction manual.



**WARNING:** This instrument is limited to the operation and use of inspection professionals, doctors or laboratory personnel trained by the company or its agents.

### Safety Symbols

Various safety symbols are used in this manual and the analyzer to remind you of matters needing attention during operation. As shown in the table below:

NO.	Symbol	Signs	Explain
1.		WARNING	Documentation must be consulted in all cases marked with this symbol in order to ascertain the nature of the potential hazard and any countermeasures that must be taken. If you do not use the instrument in accordance with the instructions in this manual, the protective measures provided by this instrument may become invalid.
2.		IVD	Used in the nameplate position; indicates that the medical device is an in vitro diagnostic medical device.
3.		Risk of biological infection	Used in the card carrier to indicate a biological contamination hazard, which may be present if instructions are not followed.
4.		This way up	It indicates that the correct position of the transport package is vertical upward.
5.		Fragile	It indicates that the transport package contains fragile items, so it should be handled with care.


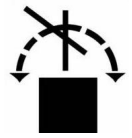
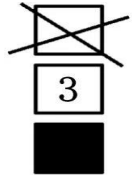

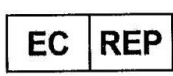

6.		Keep away from rain	It indicates that the transport package should be protected from rain.
7.		Do not roll	It indicates that the transport package cannot be rolled over.
8.		Stacking Layer Limit	Indicates that the maximum number of layers that can be stacked for the same shipping package is 3.
9.		CE mark	At the nameplate position. Indicates this medical device has been assigned to class A according to Annex II + Annex III + Article 17 of IVDR (EU) 2017/746.
10.		European Authorized Representative	At the nameplate position. Represents the authorized representative of the European Union.
11.		Marking of WEEE	Indicates the waste electrical and electronic equipment (WEEE), which designed for use with a voltage rating not exceeding 1000V for alternating current and 1500V for direct current, when marked with this marking the waste management should be in accordance with Directive 2002/96/EC(WEEE).

Table 1

The user uses this product voluntarily, and the operation, maintenance, repair and transportation of this product must strictly follow the safety precautions listed below. The design of this product fully considers biological pollution protection, electrical safety protection and mechanical movement protection. Any operation that does not comply with the safety precautions or other prompts in this manual may cause protection failure, or may undermine the safety standards of design and manufacture and the intended range of use of the instrument.

### Safety Notes

Bioscientific Lab does not assume any responsibility for any loss caused by the user not reading this manual or operating in accordance with the contents of this manual! To use this instrument safely, please read the following safety precautions carefully. Any operation that violates the following safety precautions may cause personal injury or damage to the instrument.



**WARNING:** In all cases marked with this warning sign, the instruction manual should be consulted in order to clarify the nature of the potential hazard and any countermeasures that must be taken. If you do not use the instrument in accordance with the instructions in this manual, the protective measures provided by this instrument may become invalid.

### Biological Protection

For effective protection against biological hazards, please observe the following precautions.



#### Risk of biological infection

- Improper use of samples can lead to infection. Do not touch reagent cards, samples, quality controls, and waste cards with bare hands. Be sure to wear gloves, work clothes to prevent infection, and protective glasses if necessary.
- If the sample accidentally comes into contact with the skin, please handle it according to the user's work standards immediately and consult a doctor.

#### Protection against chemical hazard

In order to prevent personal injury caused by dangerous chemicals, please observe the following precautions.



#### WARNING:

Some reagents may damage the skin. Please use reagents carefully to prevent direct contact between hands and clothes. In case of contact with hands or clothes, wash immediately with soap and water. In case of eye contact, rinse immediately with plenty of water and consult an ophthalmologist.

#### Waste liquid treatment

To prevent the waste liquid from causing environmental pollution and personal injury, please observe the following precautions when disposing of the waste liquid.



#### Risk of biological infection:

Some substances in the reagent are regulated by pollution regulations and discharge standards. Please comply with local emission standards and consult the relevant reagent manufacturer or distributor.

Please dispose of used reagent cards in accordance with the "Medical Waste Management Regulations" to avoid biological hazards.

When handling waste liquid, be sure to wear gloves, work clothes to prevent infection, and protective glasses if necessary.

#### Prevent Fire And Explosion

To prevent fire and explosion, please observe the following precautions.



#### WARNING:

Alcohol is flammable and must be handled with great care.

#### Disposal of waste immunoassay analyzer

Please 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. Please 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 processing, please clean and disinfect the surface of the instrument and other components with biological risks, and remind relevant personnel of the risks of the instrument to avoid biological risks or other hazards during transportation or maintenance.

**Operation precautions**

In order to use the immunoassay analyzer correctly and effectively, please read the following notes carefully.

**Instrument use**



**WARNING:**

- The instrument is used in conjunction with fluorescent immunochromatography reagents labeled with fluorescent microspheres, and is used for in vitro quantitative detection of analytes in human samples.
- When making clinical judgments based on analytical results, please also consider clinical symptoms or other test results.

**Instrument installation**



**WARNING:**

- Please place the instrument firmly in a stable and safe place to prevent the instrument from falling.
- Please operate the instrument in an environment where the ambient temperature is within the range of 10°C~30°C, the humidity is within the range of ≤70%RH, and the atmospheric pressure is within the range of 86kPa~106kPa.
- Do not place anything on the power cord, and place the instrument in a place where the power cord will not be stepped on or tripped over.
- Do not place the device in a location where it is difficult to access the disconnect device.

Please keep the instrument away from the source of fire, otherwise the instrument may be deformed and there is a risk of fire.

**Use environment**



**WARNING:**

- Please install the instrument correctly according to the installation environment specified in the instruction manual. Installation and use of this instrument outside the specified conditions may give unreliable results and may result in damage to the instrument.
- At least 10cm of space should be left around the instrument to ensure air circulation and facilitate the heat dissipation of the instrument.
- Please keep the environment where the instrument is used clean and avoid dust, otherwise there will be a danger of destroying the instrument.
- Electromagnetic environment should be assessed before operating equipment.
- If you need to change the system status, please contact the company customer service center or the distributor in your area.

**Protection against electromagnetic waves and noise**



Be careful:

- Do not place equipment that emits abnormal noise near the instrument. Keep the instrument away from other electrical equipment, such as stereos; speakers in stereos may generate strong magnetic fields, and open magnetic fields may cause damage to data or displays.
- Do not use other medical equipment near this instrument. Electromagnetic waves emitted by this instrument may cause malfunctions of other medical instruments in its vicinity.

#### Electromagnetic Compatibility Related Precautions



Be careful:

- This instrument is designed and tested according to Group 1 Class A equipment in GB 4824. In a domestic environment, this equipment may cause radio interference, requiring precautions.
- Do not use this device near strong radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the device.
- Users are responsible for ensuring the electromagnetic compatibility environment of the equipment so that the equipment can work normally.
- It is recommended to evaluate the electromagnetic environment before using the equipment.
- This instrument complies with the immunity and emission requirements specified in this part of GB/T 18268.26.

#### Instrument use



Be careful:

- Please use the instrument according to the relevant instructions in the instruction manual. Improper use may result in inaccurate test results and may even cause instrument damage or personal injury.
- Please unplug the power cord on the instrument during thunderstorms, otherwise there is a danger of electric shock or fire.
- If your instrument falls, please unplug the power cord and seek help from the company's customer service center, otherwise there will be a risk of electric shock or fire.
- Please do not put lit cigarettes or candles on the instrument, otherwise there will be a risk of fire or damage to the instrument.
- Please do not block foreign objects in the fan exhaust port of the instrument, otherwise it will cause the risk of fire or damage to the instrument.
- Please do not scratch the display with sharp objects, otherwise the display may be damaged.
- This instrument is designed and tested according to the Class A equipment in GB 4824. In a domestic environment, this equipment may cause radio interference, requiring precautions.
- Non-professional medical laboratory personnel of medical institutions should not operate it.

#### Instrument maintenance



Be careful:

- Please maintain the instrument according to the relevant instructions in the instruction manual. Improper maintenance measures may result in incorrect analytical results and may even result in instrument damage or personal injury.

- If the instrument is placed for a long time, dust may accumulate on the surface. When cleaning, please use a clean soft cloth soaked in water and wring it out, gently wipe the surface, and dip a small amount of 75% ethanol if necessary. After cleaning, dry the surface with a dry cloth. Please use mild instrument-specific products to clean the instrument, and do not use the instrument until the instrument is completely dry, otherwise there will be a risk of electric shock or fire. If in doubt about the compatibility of disinfectants or cleaning agents with equipment parts or materials contained within the equipment, the manufacturer should be consulted.
- Before cleaning, please turn off all power of the instrument and unplug the power cord; during the cleaning process, please take necessary measures to prevent water droplets from entering the instrument, otherwise it may cause damage to the instrument or personal injury.
- If the instrument needs to be repaired due to failure, please contact the company's customer service center. When repairing or suspending use, please confirm that there is no reagent card left in the instrument; before the instrument is repaired, please carry out routine sterilization and disinfection.
- During the maintenance period, the instrument may need to be stopped or transported. Please operate with care to avoid the risk of biological infection, electric shock, and moving parts due to maintenance.
- After completing any inspection or repair, ask a technical service engineer to perform a safety test. Neglecting the safety test may result in electric shock or fire.

#### Sample



Be careful:

- Please use the correct sample storage measures. Improper sample storage practices may alter the composition of the sample and lead to incorrect analytical results.
- To prevent the sample from volatilizing, do not leave the sample open for a long time. If the sample volatilizes, it may lead to incorrect analytical results.
- Some samples may not be analyzed based on test parameters and reagents used. For these samples, please consult the relevant reagent manufacturer or distributor.

#### Other Notes


- Please do not use loose or damaged power sockets, otherwise there will be danger of electric shock and fire.
- Use the correct grounding. If the socket is not properly grounded, there is a danger of electric shock and damage to the instrument.
- Do not touch the power socket when your hands are wet, otherwise there will be a risk of electric shock
- Please use your instrument under the appropriate voltage/current standard. Working under the unsuitable voltage/current will result in the danger of electric shock, fire or damage to the instrument.
- If you hear noise from the power cord and power interface, please unplug the power cord immediately and seek help from your company's customer service center, otherwise there will be a risk of fire or electric shock.
- Please keep the power socket and power interface in close contact, loose contact may cause fire hazard.
- Do not bend the power cord or place heavy objects on the power cord to avoid damage to the power cord by persons and animals. Damaged power cords may cause electric shock or fire.
- Please keep the power cord and plug clean, otherwise there will be a risk of fire.
- If foreign objects or liquids enter the instrument, please remove the power cord and any other cables from the instrument, and seek help from the company's customer service center, otherwise there will be

danger of electric shock, fire and damage to the instrument.

j. Limit requirements for toxic and hazardous substances

k. This instrument complies with the limit requirements of toxic and hazardous substances stipulated in SJ/T11363-2006.

NOTE:

In all cases marked with a warning sign  the instruction manual should be consulted to clarify the nature of the potential hazard and any countermeasures that must be taken.

### Warranty and Maintenance Services

The warranty period of the purchased instrument is subject to the sales contract. Consumables: Refers to disposable consumable materials that need to be replaced after each use or fragile materials that need to be replaced regularly. Consumables have no warranty service.

The warranty period starts from the "purchase date" filled in the "Warranty Card" attached to the instrument. The "Warranty Card" is the only proof for calculating the warranty period. In order to protect your rights, please fill in the warranty card after the instrument is installed, and hand over the second copy ("B") of the warranty card to the installer or mail it back to the company's customer service center. Please note that the following situations will not be covered under warranty:

- The customer fails to fill in and return the equipment warranty card within 30 days after the completion of the installation and acceptance;
- The factory number of the instrument provided by the customer is incorrect (our company confirms whether the warranty is guaranteed by the factory number of the instrument);
- The company is not responsible for the failure and damage of the instrument in the following circumstances, or for direct or indirect damage during use:
  - Failure and damage caused by violation of the method of use, precautions and purpose of use described in this instruction manual;
  - Failure and damage caused by the operation of inspection professionals, doctors or laboratory personnel not trained by the company or the agent designated by the company;
  - Failure and damage caused by maintenance or modification by companies other than those designated by the company;
  - Failure and damage caused by the use of instruments other than those designated by the company;
  - Failure and damage caused by the inconsistent operating environment and the operating environment (power conditions, installation environment, etc.) specified by the company;
  - Failure and damage caused by irresistible natural disasters;
  - Failure and damage caused by the company's unknowing movement or transfer (transportation) after the instrument is installed;
  - Instrument failure caused by the use of reagents and other consumables not approved by the company does not belong to the scope of maintenance services provided by the company;
  - Other faults not caused by the instrument itself.

During the warranty period, if the fault is caused by the design and manufacturing defects of our company, it will be repaired free of charge, and our company will take corresponding countermeasures according to the fault content.

After the expiration of the warranty period, the company can continue to provide fee based maintenance services.

After-sales service

Please contact our after-sales service department.

#### Repair

- Confirm failure and repair method: First, contact the company's after-sales service department to confirm the fault situation and confirm whether the repair method is on-site repair or return to the factory for repair.
- Repair fees: Negotiate with the company according to the specific situation.
- Freight: If the immunoassay analyzer is shipped to the company for repair, the user shall bear the freight (including customs fees).

#### Return

- Get permission to return goods. Contact after-sales service department of the company and inform product serial number (see the nameplate of immunoassay analyzer for details), explain the reason for return. If the product serial number cannot be clearly identified, the company will not return the goods.
- On the premise of obtaining the right to return goods, please go through the relevant procedures according to the requirements of the company.

## 1. Product Overview

### 1.1. Instrument introduction

(1) Instrument Name: Fluorescence Immunoassay Analyzer

(2) Model: BKP2000

(3) Specification: 1 unit/box

(4) Software Name: Fluorescence Immunoassay Analyzer Software

(5) Software release version: V1

(6) Software full version: V1.0.0

(7) Production date: See the nameplate

(8) Service life: The service life of the immune analyzer is 8 years from the date of installation of the instrument (NOTE: excluding man-made damage). The expected service life of the instrument is determined according to the high temperature and high humidity accelerated life test. The instrument should be maintained, serviced and repaired in accordance with the instructions. Instruments that have been confirmed to maintain their basic safety and effectiveness after maintenance, upkeep and repair can be used normally.

### 1.2. Main structural composition

Fluorescence Immunoassay Analyzer consists of host (including optical detection module (fluorescence), scanning module, data processing module, liquid crystal display module, incubation module, information acquisition module, printer, housing) and embedded software (software release version V1), power cord . 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 is mainly composed of the measurement circuit board and its fixing parts.

The LCD module is mainly composed of LCD screen and control board.

The incubation module includes structures such as a stepping motor, a pulley, a dial-card turntable, a

disc, a spindle module, a clip-card module, and a turntable detection switch assembly. It can carry 12 reagent cards at one time.

The information collection module mainly refers to the ID card reader.

### 1) Appearance diagram



Figure 1



Figure 2

### 2) Internal structure layout

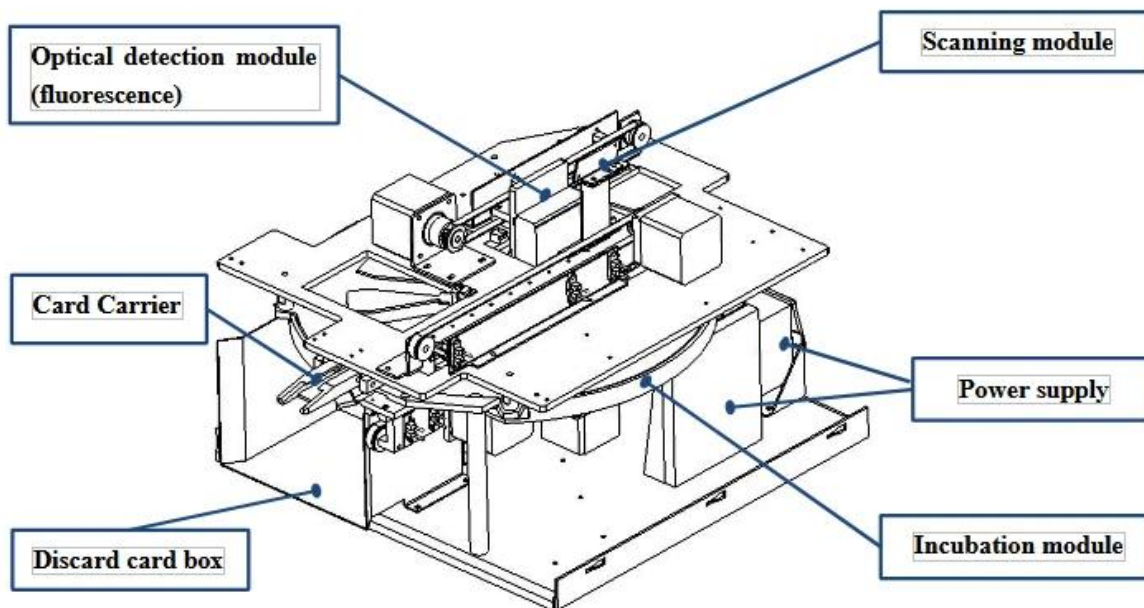


Figure 3

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

## 1.3. Scope of application

### 1.3.1. Intended Uses

Fluorescence Immunoassay Analyzer is used in conjunction with fluorescent immunochromatography reagents labeled with fluorescent microspheres for in vitro quantitative detection of analytes in human samples.

### 1.3.2. Applicable Items

Including pathogenic pathogen antigens/antibodies, proteins, carbohydrate, vitamins, kidney disease, myocardial disease, immune function and other items.

### 1.3.3. Intended use environment

It can be applied to central laboratories, outpatient/emergency laboratories, clinical departments and other medical service points (such as community medical points), physical examination centers, etc. in medical institutions, as well as scientific research laboratories. For laboratory medicine professionals to perform in vitro diagnostic experiments only.

## 1.4. Basic principle

### 1) Principles of Immune Response:

#### 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, and 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.

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 continue 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 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.

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.

## 1.5 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.

## 1.6. Network Security

Software operating environment requirements:

Embedded software, 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 USB data interface, the storage medium is U disk, and the exported test data is in .xls format.

Access Control: Deny any unauthorized external access. The software can log in to the software after the user enters the user name and password for verification.

It is divided into two levels: administrator and ordinary user. Ordinary user authority: can only access the test data of this user; administrator authority: can access the test data of all users.

## 1.7. Contraindications

No

# 2. The basic parameters and the conditions of use

### 2.1. The basic parameters

Host size and weight	336mmx410mmx400mm(L*W*H);17KG;
Sample type	Whole Blood, Serum, Plasma, Urine
Detection speed	Single detection time <10s
Detection method	Supports multiple items in one card
Printer	Built-in thermal printer,57mm
Display screen	10.1-inch 24-bit true color LCD screen (screen can be customized)
Interface Language	English
Data storage	Unlimited
Excitation light source	LED
Working wavelength range	Excitation spectrum Center wavelength $\lambda_0=365\text{nm}$ ; Receive spectrum Center wavelength $\lambda_1=615\text{nm}$ ;
Detection channel	1
Reaction channel (Card Carrier)	12

Power-on warm-up time	After powering on, set the required temperature, and the temperature can be tested when the temperature meets the requirements.
Power consumption	108VA
Power Specifications	power supply:AC 100-240V, 50Hz/60Hz;
Normal working conditions	Indoor use; The altitude is below 2000m; Ambient temperature: 10°C~30°C; Relative humidity: ≤70%; Atmospheric pressure: 86.0kPa~106.0kPa The power supply voltage fluctuation should not exceed ±10% of the nominal voltage; Transient overvoltage is category II of facility category (overvoltage category); The rated pollution degree is 2.
Storage and transportation environment	The ambient temperature is -40°C ~ 55°C, and the relative humidity is not more than 70%
Performance indicators	Repeatability: CV≤5%. Stability: $\sigma \leq \pm 8\%$ . Linear correlation: $(r) \geq 0.98$ . Accuracy: $\Delta n \leq \pm 8\%$ .

Table 2

## 2.2. Function

- (1) The analyzer should have 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 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 monitors the temperature of the reaction zone in real time. The set temperature range should be between 10°C and 40°C. The analyzer will prompt when the temperature is not within the set range. (applicable to BKP2000)
- (8) The analyzer has the function of prompting when the discarded card bin is full. (applicable to BKP2000)
- (9) The analyzer has a LIS data interface.
- (10) The analyzer has user access control: it is divided into two levels: administrator and common user. Common user authority: can only access the test data of this user; administrator authority: can access the test data of all users.

## 2.3. Transport and storage conditions of the instrument

### 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, and should not be affected by moisture, and should not be mixed with flammable and corrosive substances. Requirements according to the order contract.

### 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  $-40^{\circ}\text{C} \sim 55^{\circ}\text{C}$ , and the relative humidity should not be greater than 70%. Harmful gases, flammable, explosive substances and corrosive gases are not allowed.

## 3) Instrument installation

Please use this instrument under conditions that meet the environmental requirements of the instrument.

### 3.1. Package

If the package is damaged after receiving the instrument, or the instrument is obviously damaged, please contact the carrier immediately and file a claim according to the degree of damage. At the same time, please contact your supplier to confirm that the instrument is well packaged, and then follow the steps below to remove the packaging materials and install the instrument.

### 3.2. Unpack

Carefully remove the instrument and accessories from the box, saving the packing material for future shipping or storage.

- (1) Count the random accessories item by item according to the packing list.
- (2) Check the instrument and accessories for mechanical damage.
- (3) When handling the instrument, it should be handled with care, and it is strictly forbidden to force the front case directly to avoid damage to the instrument.
- (4) Place the instrument main body on a stable flat operating table.

If there are any problems please restore the packaging and contact your supplier immediately.

### 3.3. Packing List

No.	Name	Quantity	Unit	Remark
1.	Host (including packing box, pearl cotton pad)	1	Set	Standard accessories
2.	Instruction Manual	1	PCS	Standard accessories

3.	Certificate	1	PCS	Standard accessories
4.	Power cable	1	PCS	Standard accessories
5.	Network Cable	1	PCS	Standard accessories
6.	Fuse	2	PCS	Standard accessories
7.	Clean cloth	1	PCS	Standard accessories
8.	Barcode Gun	1	PCS	Standard accessories
9.	Printer paper	1	PCS	Standard accessories
10.	Customer Satisfaction Survey	3	PCS	Standard accessories

Table 3

## 3.4. Installation requirements

### 3.4.1. Installation Environment

- 1) 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 20kg;
- 2) There is no strong vibration source and strong electromagnetic field around;
- 3) Do not place the instrument in a position where it is difficult to operate the disconnect device, where the distance between the back of the instrument and the wall is at least 10cm;
- 4) Nothing should be covered on the instrument to prevent the ventilation openings from being blocked;
- 5) Please try not to use parallel sockets to avoid fire caused by overload;
- 6) A 100-240V filter and an effectively grounded socket must be used;
- 7) The instrument should be tested in an environment of 10°C-30°C, and operate in strict accordance with the operation precautions in this manual.

### 3.4.2. Supply Voltage Requirements

Power supply: AC 100-240V, 50Hz/60Hz. Rated input power: 108VA. During use, be careful to avoid short circuit and risk of electric shock!

NOTE: Documentation must be consulted in all cases marked with a symbol 

### 3.4.3. Accessories connection

Install the randomly configured related accessories on the corresponding interface of the instrument (such as: AC power cord, mouse, keyboard, etc.), according to needs, you can also directly touch the screen without using the mouse and keyboard.

### 3.4.4. Connect the power cable

Make sure that the power switch on the rear panel of the analyzer is in the off (O) state, insert the female end of the power cord plug into the power socket of the instrument, and insert the other end of the power cord into the power socket.

### 3.4.5. Thermal printing paper installation rules

Open the printer door, then place the thermal printer paper configured with the printer into the printer compartment and close the door.

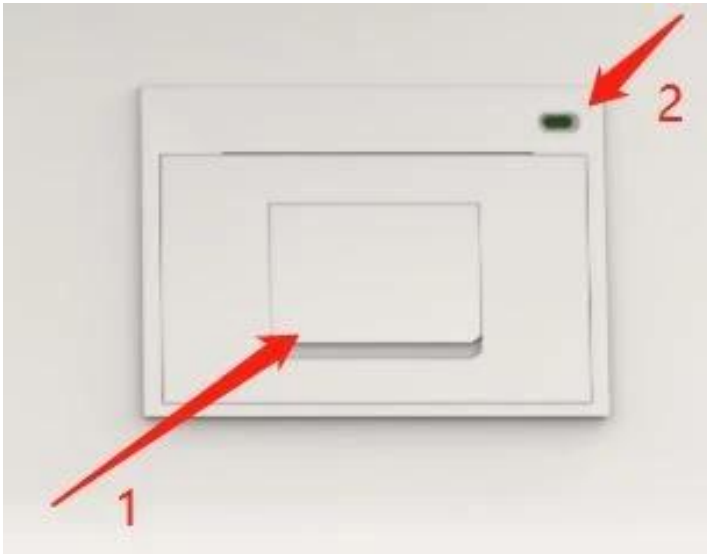


Figure 4  
Thermal Printer Diagram  
1.Door button 2.Indicator light



Notes

Thermal printing paper size (width is  $57 \pm 0.5\text{mm}$ , outer diameter is  $30 \pm 0.5\text{mm}$ ). The paper is installed with the thermally coated side facing up.

Before closing the door, please extend the printing paper 2-5cm outwards.

3.4.6.Start-up Procedure

Power on the instrument, then turn on the AC power switch and the PC power switch in sequence. After the instrument is turned on, enter the user name and password, enter the software experiment operation interface and enter the equipment self-check program(The position of the switch is shown in Figure 5 and Figure 6 below).

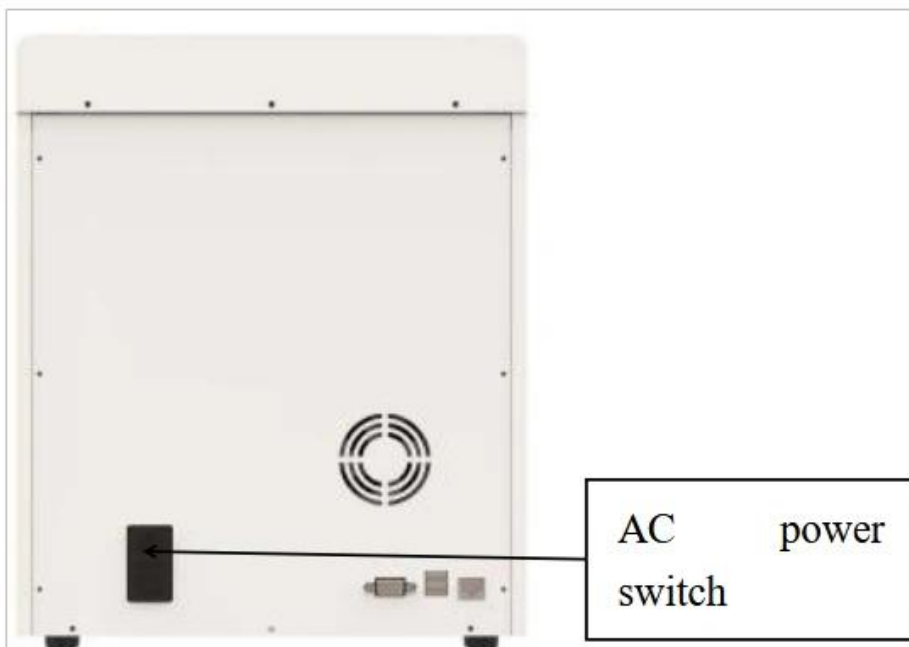


Figure 5

## AC power switch location diagram

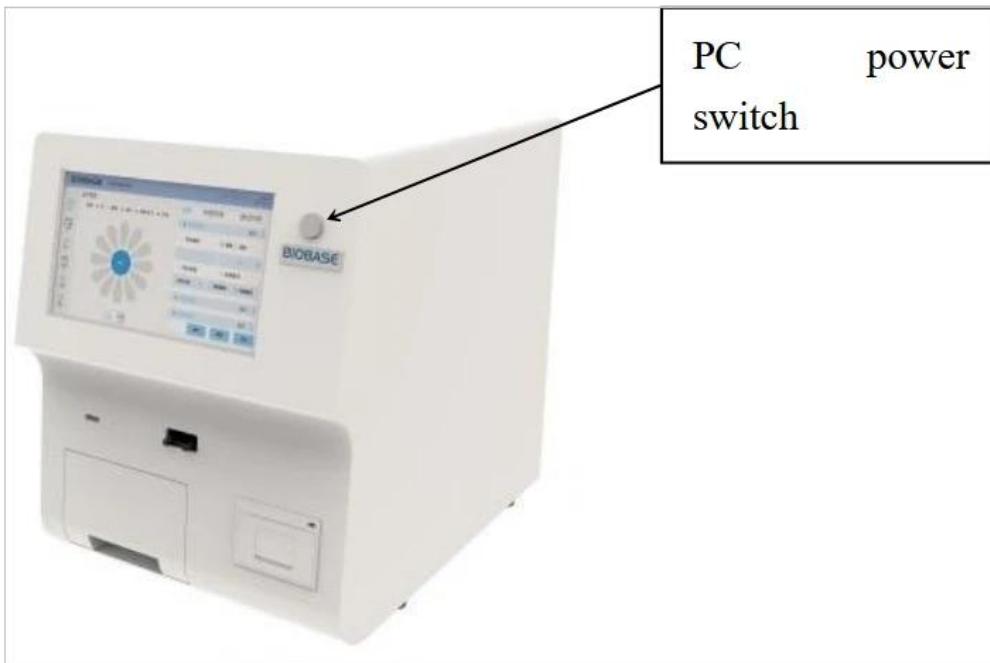


Figure 6  
PC power switch location diagram

### 3.4.7. Shutdown Procedure

In the experimental operation and test interface of the instrument, click the "Pwr" button on the left, and then press the power button on the front to shut down, as shown in Figure 7 below

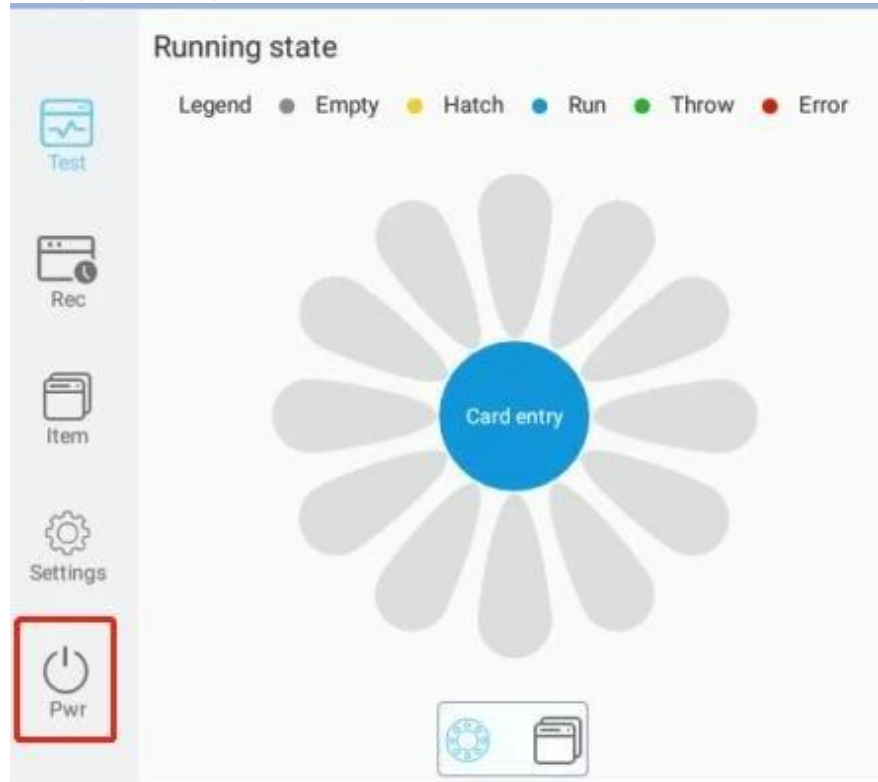



Figure 7  
 Notes

- a. During the normal testing process, it is strictly forbidden to turn off the instrument or force the power off.
- b. When the instrument is normally shut down, it is strictly forbidden to force power off the instrument directly.
- c. When the instrument does not work for a long time, the external power supply should be completely cut off.

3.4.8.LIS connection operation procedures

- a. Connect the instrument to the PC through the network cable, and connect in the following way, as shown in Figure 8

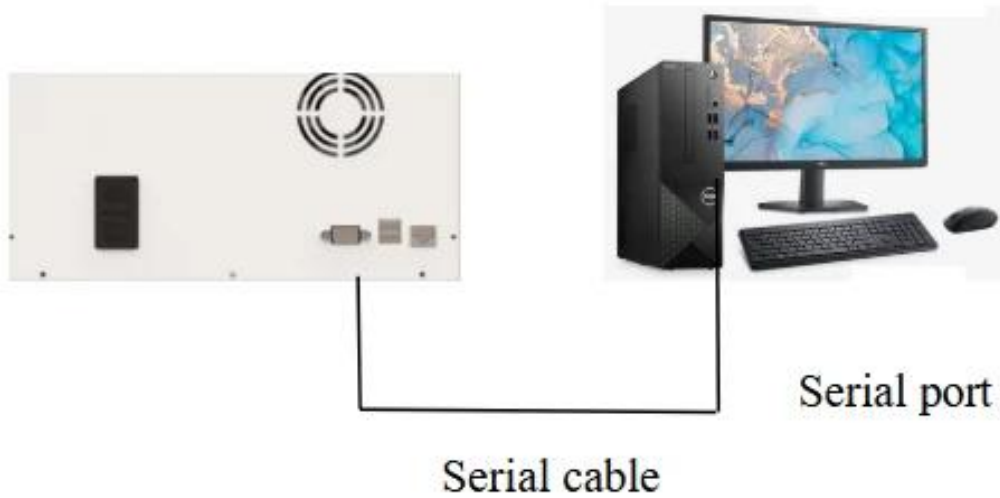


Figure 9

- b. Enter the "Test Set" page in the system settings page of the main system menu, and configure the "Enable Send Lis" option to configure whether to automatically upload Lis after the test is completed.

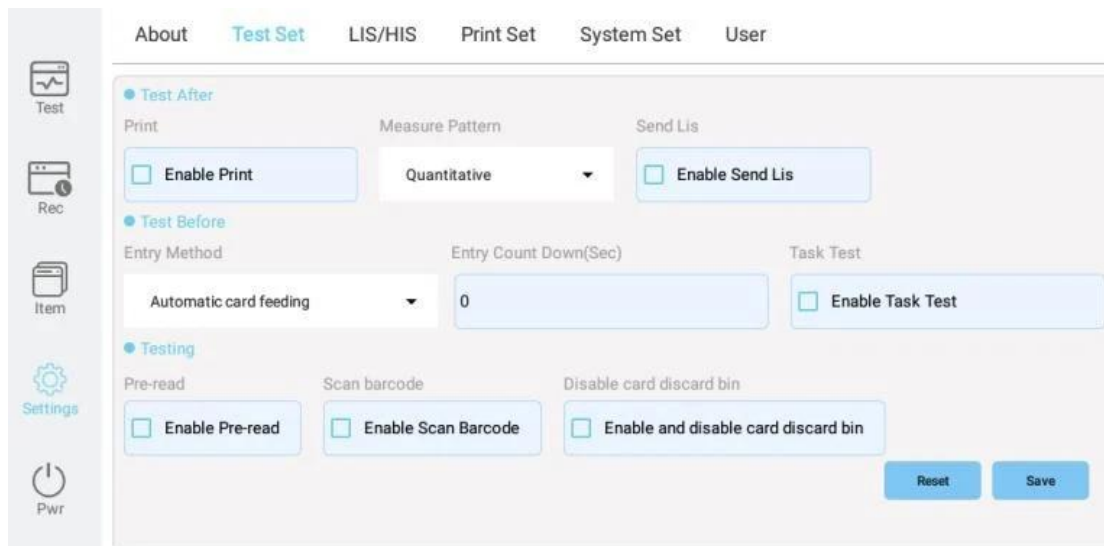


Figure 10

## 4. Operation interface instructions

Start the instrument, initialize the instrument and perform self-test. After the self-test is completed, the display interface is shown in Figure 10. Software system functions include [Test], [Rec], [Item], [Settings], [Pwr].

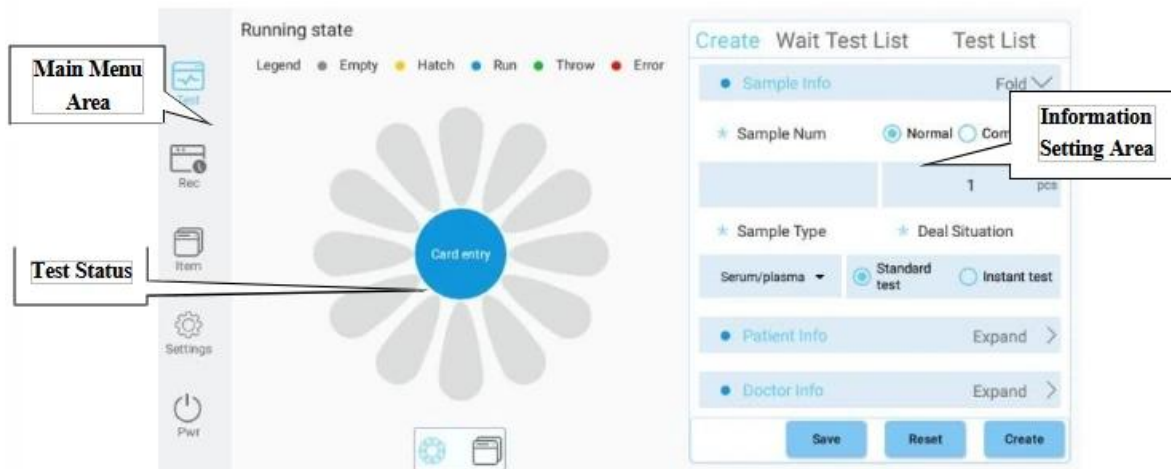


Figure 10

### 4.1. Item interface function description

Before testing, you need to read the Item card information. Insert the ID card, click to read the Item card, after the reading is successful, you can set the default Item card. And set the reference range etc. as needed.

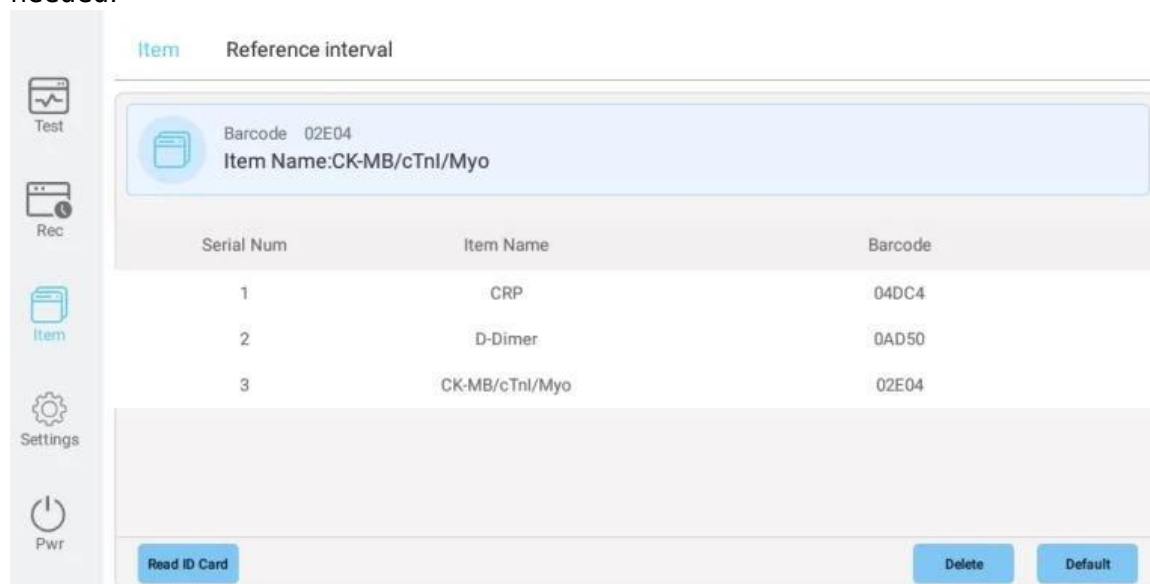


Figure 11

## 4.2. Test interface function description

After entering the Item information, you need to enter the sample information before the sample test. Select the sample type, enter the sample number, the number of samples, select the processing situation, and enter the sample information. Enter patient information and doctor information, click Generate, it will be displayed in the test list, insert the reagent card, start the test, and you can view the test progress in the test list. In the running status bar, it displays the status of the reagent card storage tray, incubation/progress/completed/discarded/abnormal.

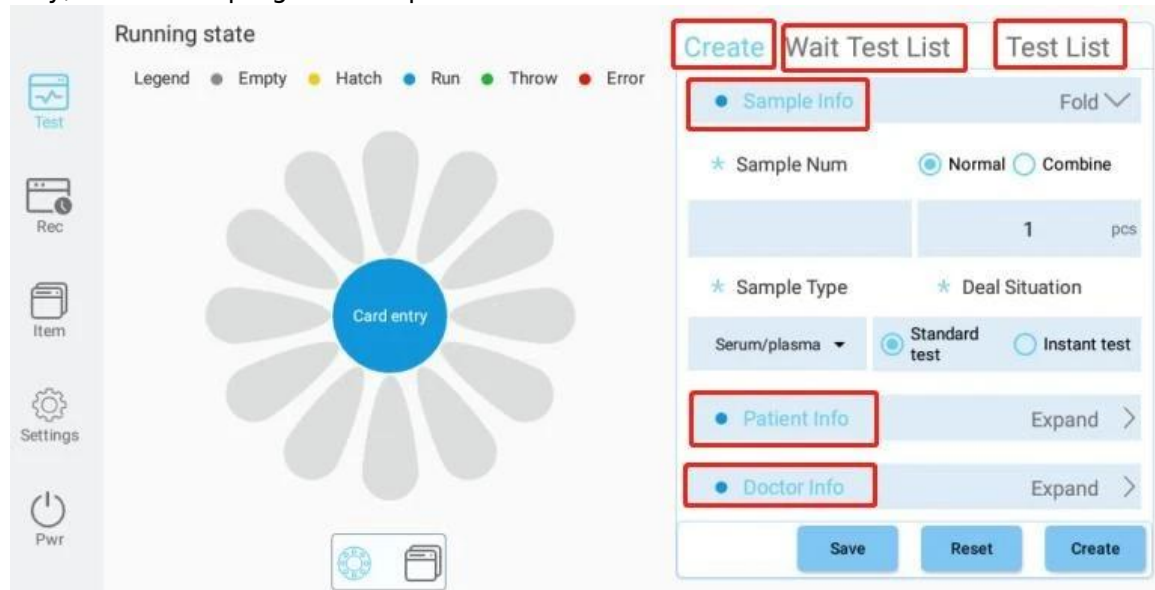



Figure 12

### 4.2.1. Temperature control range setting operation procedure

Click the temperature display area in the upper right corner of the interface, and then set the desired temperature range in the dialog box.

**Temp Set**

 Current Temp  
**27.0 °C**

\* Min Temp(°C)  
15

\* Max Temp(°C)  
30

**Confirm** **Cancel**

Figure 13

4.2.2. Sample type setup procedure

Click the "Drop-Down" button in the red area in the figure below, and select the sample type according to the experimental requirements.

**Create** **Wait Test List** **Test List**

● **Sample Info** Fold ▾

\* **Sample Num**  **Normal**  **Combine**

pcs

\* **Sample Type** \* **Deal Situation**

Serum/plasma ▾  **Standard test**  **Instant test**

Figure 14

4.2.3. Patient information, doctor information setting operating procedures

You can fill in the relevant information of the patient and doctor according to the test needs.

Patient Info		Fold	
Patient Name	Gender		
	<input checked="" type="radio"/> Male <input type="radio"/> Female		
Patient Num	Age		
		Year ▾	
Bed Num	Diagnosis		
Inpatient Num			

Figure 15

Doctor Info		Fold	
Checker	Doctor		
Department	Collection Time		
	07-31-2023 11:20:24		
Remarks			

Figure 16

#### 4.2.4. Quick Test Operating Procedure

Select the number of the required quick test in the sample number to be tested, and then click the "Up" button.

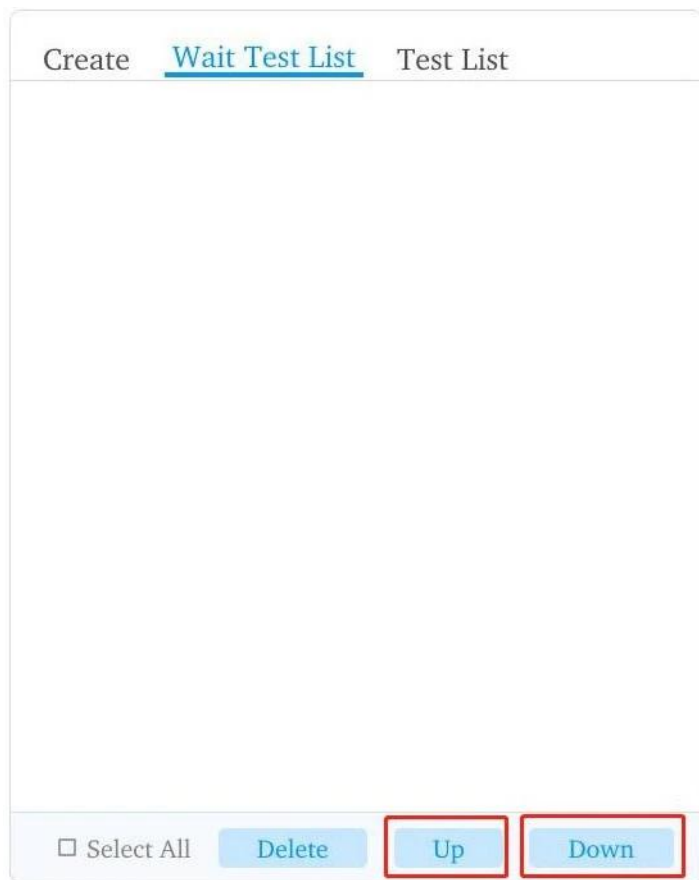


Figure 17

### 4.3. Record interface function description

Click the [Rec] button, the interface is displayed as shown in Figure 18.

The historical test records of the completed tests are displayed on the record page. The test results can be filtered according to the sample type and time. Select the test results to view the details, delete, export, Lis, and print.

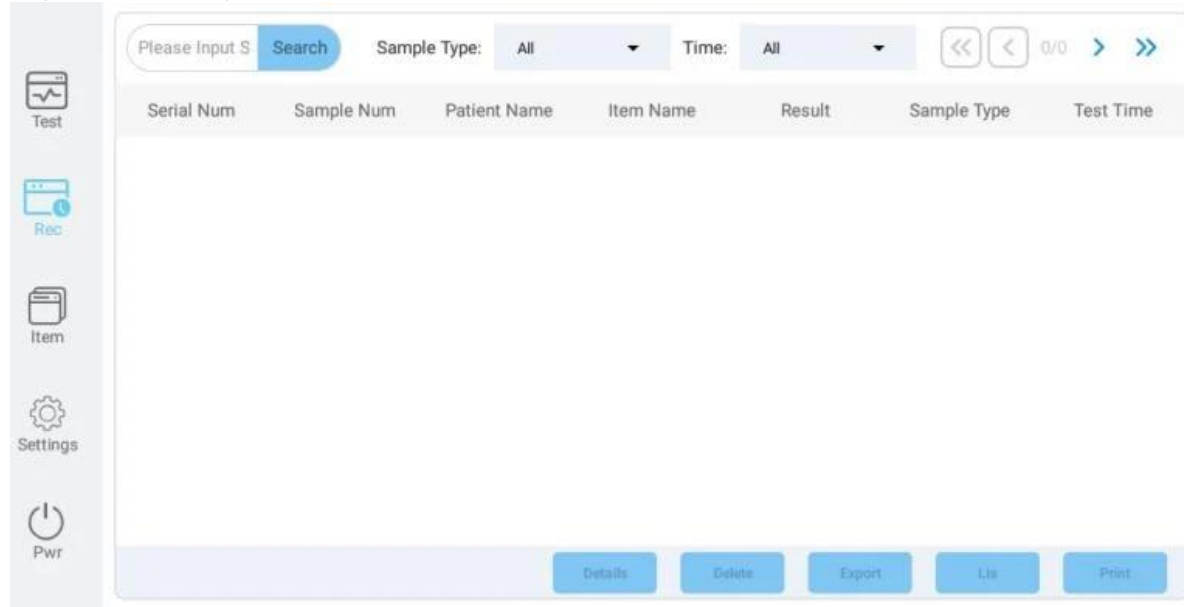


Figure 18

### 4.3.1. Test Record View Details

Select the object in the record interface and click the "Details" button in the interface to view the detailed information.

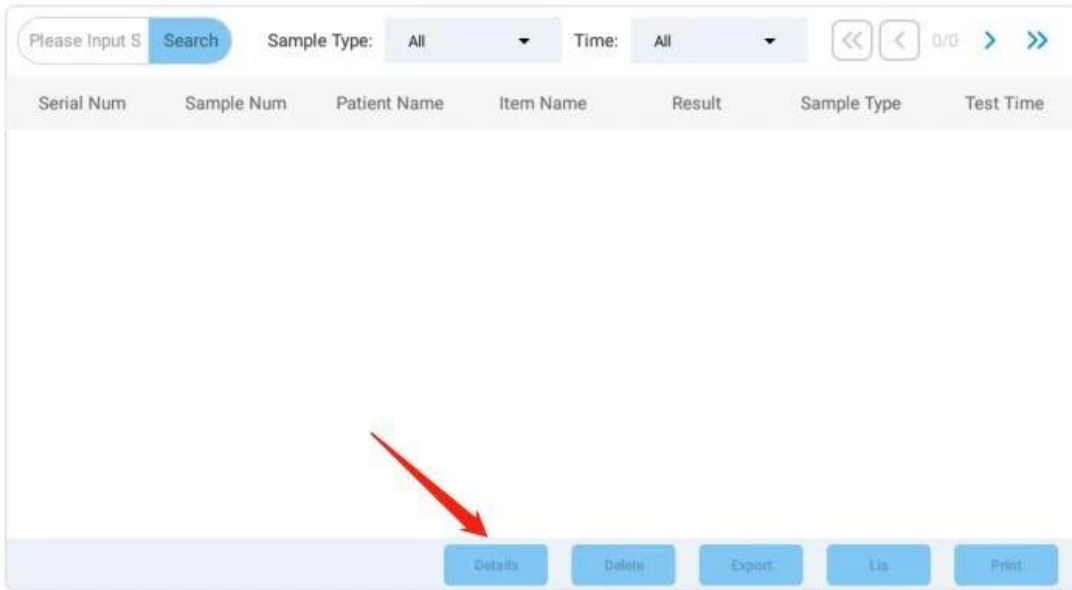


Figure 19

### 4.3.2. Manual printing procedure for test records

Select the print object in the record interface, and click the "Print" button in the interface.

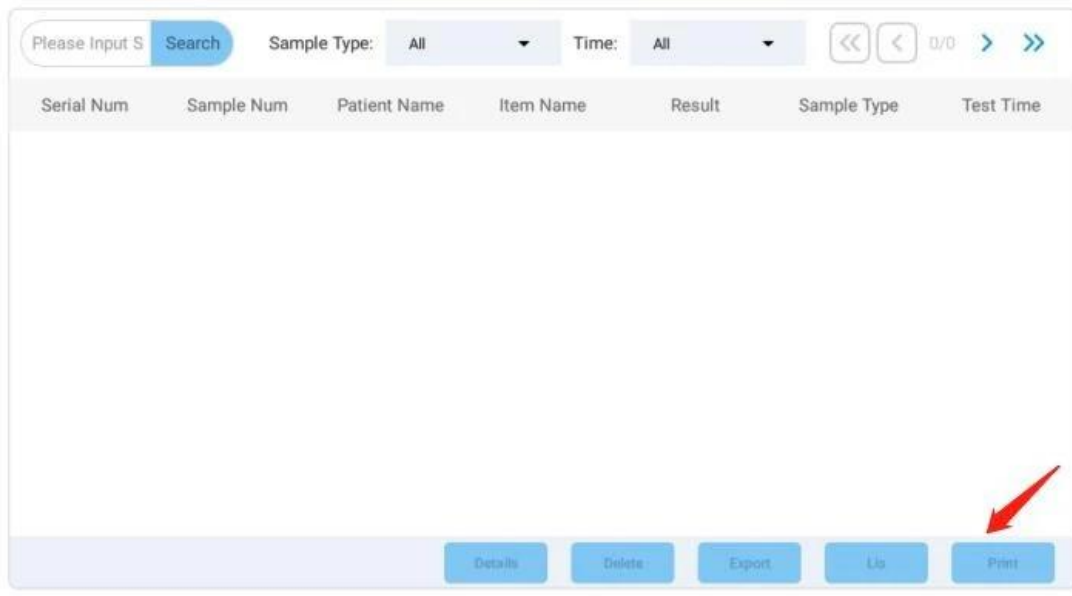


Figure 19

## 4.4. User interface function description(Administrator permissions)

Display the user list, add or delete users.

User List

Serial Num	Account	User Name	User Right
1	admin	administrator	Advanced User

Add

Delete

Figure 20

## 4.5. System interface function description

### 4.5.1. About

Click the [About] button, the user can view the software version information

### 4.5.2. Test Set

Click the [Test Set] button, the interface is displayed as shown in Figure 21. Test Before: Entry Method, Entry Count Down, Task Test.

Testing: Pre-Read, Scan Barcode.

Test After: Print, Measure Pattern, Send Lis.

About Test Set LIS/HIS Print Set System Set User

Test

Rec

Item

Settings

Pwr

● Test After

Print Measure Pattern Send Lis

Enable Print Quantitative  Enable Send Lis

● Test Before

Entry Method Entry Count Down(Sec) Task Test

Automatic card feeding 0  Enable Task Test

● Testing

Pre-read Scan barcode Disable card discard bin

Enable Pre-read  Enable Scan Barcode  Enable and disable card discard bin

Reset Save

Figure 21  
4.5.3. Lis/His

Click the [Lis/His] button, the interface is displayed as shown in Figure 22. Lis/His Set: Lis Connection, Code, Remote IP, Remote Port ,  
Lis/His Test: Sample Number, Result, Test Time, Item Name.

The screenshot shows a web interface with a navigation bar at the top containing 'About', 'Test Set', 'LIS/HIS', 'Print Set', 'System Set', and 'User'. The 'LIS/HIS' tab is active. Below the navigation bar, there are two main sections. The first section, titled 'LIS/HIS Set', contains four input fields: 'Lis Connection' (a dropdown menu with 'UART' selected), 'Code' (a dropdown menu with 'utf-8' selected), 'Remote IP' (a text input field with '192.168.1.1'), and 'Remote Port' (a text input field with '8080'). Below these fields is a blue 'Settings' button. The second section, titled 'LIS/HIS Test', contains four text input fields: 'Sample Num' (with 'Filed 1'), 'Result' (with 'Filed 1'), 'Test Time' (with 'Filed 1'), and 'Item Name' (with 'Filed 1'). Below these fields is a blue 'Send Test Data' button.

Figure 22

4.5.4. Print Set

Click the [Print Set] button, the interface is displayed as shown in Figure 23. Set up the printer, define the company name and prompt information.

The screenshot shows a web interface with a navigation bar at the top containing 'About', 'Test Set', 'LIS/HIS', 'Print Set', 'System Set', and 'User'. The 'Print Set' tab is active. Below the navigation bar, there are three main sections. The first section, titled 'Printer', contains a dropdown menu with 'printer' selected. The second section, titled 'Corporate Name', contains a text input field with 'BIOBASE POCT CO.,LTD'. The third section, titled 'Tip', contains a text input field with 'This result is only responsible for this specimen!'. Below these sections is a large empty text input field for 'Company address' and a blue 'Save' button.

Figure 23

4.5.5. System Set

Click the [System Set] button, the interface is displayed as shown in Figure 24. Clock Set: Set the clock pattern and time.

IP Set: Set IP acquisition method, automatic acquisition/manual setting, input IP and mask.

System Set: Input Method Pattern (virtual/physical) ,Language Pattern (English).

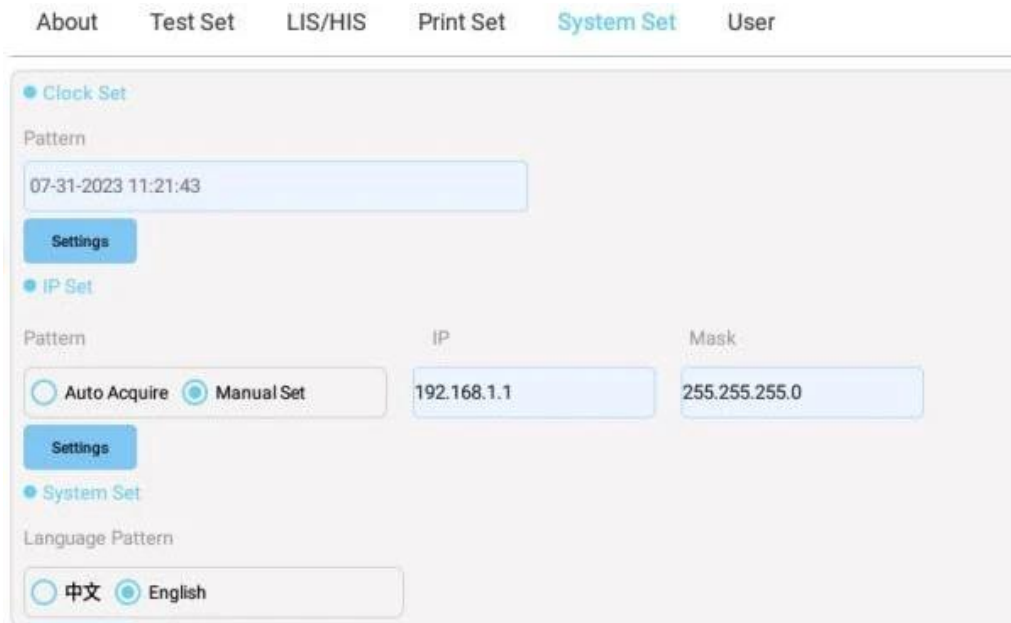


Figure 24

#### 4.5.6. User

Click the [User] button, the interface is displayed as shown in Figure 25.

Display the current user, view the account number and user name. Change the password and log out.

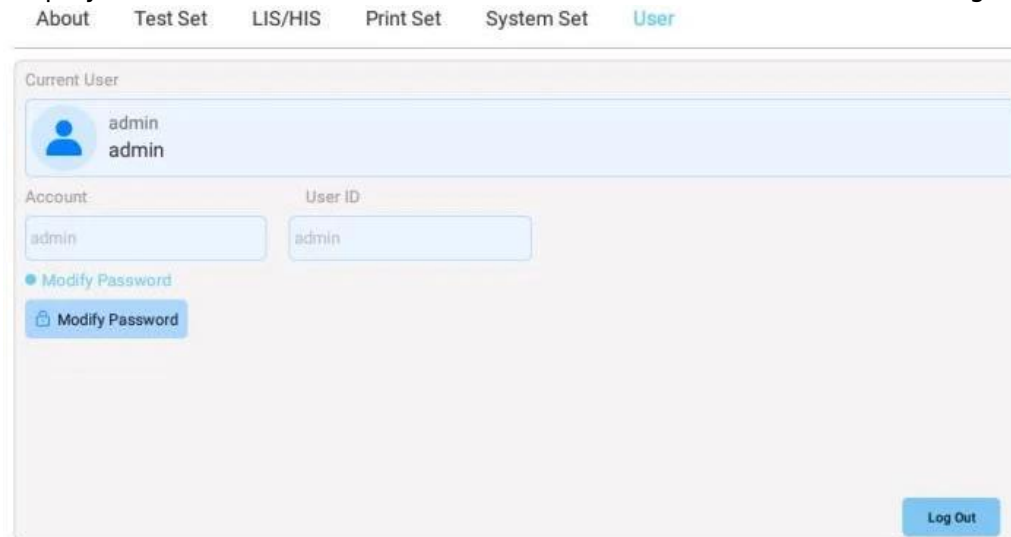


Figure 25

## 4.6. Pwr

Click the [Pwr] button, a window for confirming shutdown will pop up, and the software will execute the shutdown procedure, prompting to turn off the power.

# 5. Item Test Operation Procedures

## 5.1. Power On

Turn on the external power of the instrument and turn on the power switch of the PC. After the instrument is fully turned on, it will enter the Item test interface (the waiting time for booting is about 30 seconds)

## 5.2. Sample Test Information Settings

In the test interface, edit the sample number, sample type, patient information, doctor information, etc., and select the processing situation (Normal Test, Quick Test).

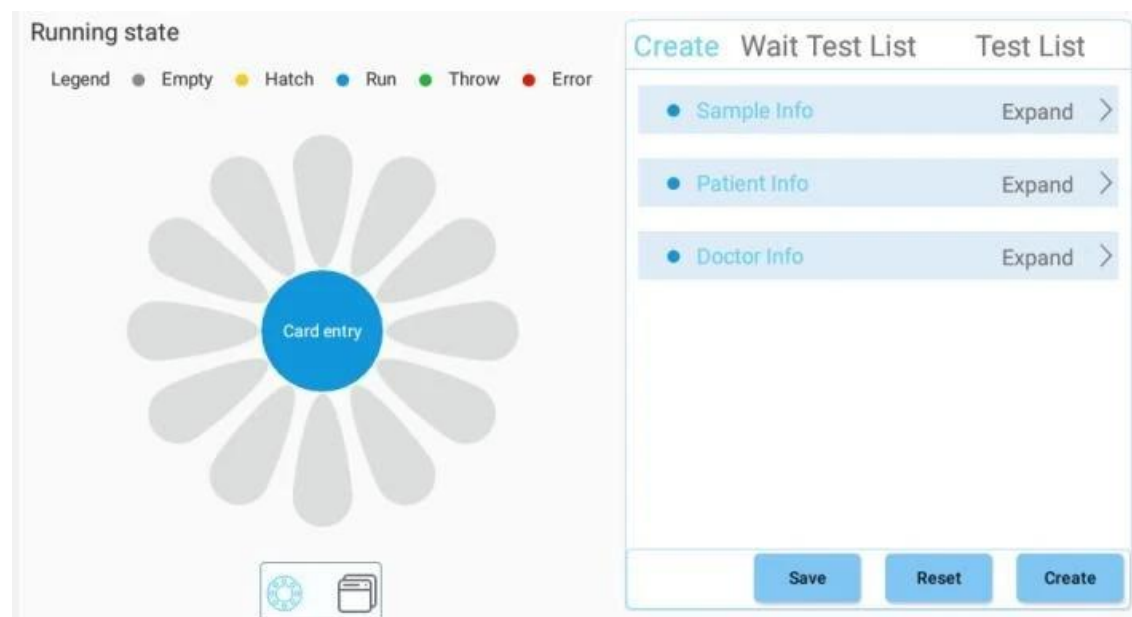


Figure 26

## 5.3. Read item ID information

Insert the Item ID chip into the ID card slot, and click the "Read ID" button on the test interface to obtain Item information.

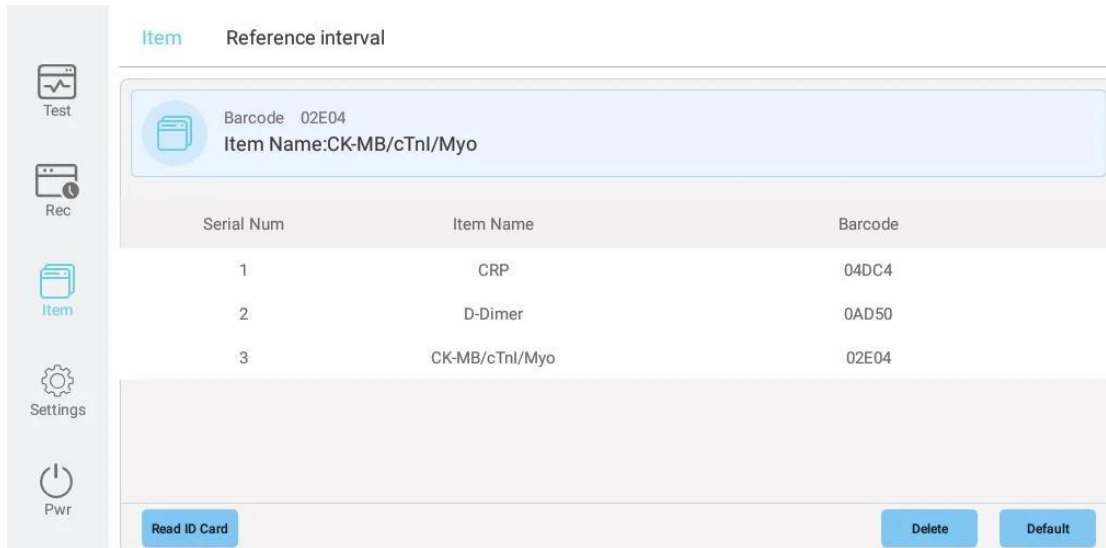


Figure 27

Note: The same sample ID information does not need to be read twice!

## 5.4. Sampling

Aspirate the blood sample, add it to the buffer, and mix well.



Figure 28

## 5.5. Using a pipetting gun, add the mixed sample to the reagent card.

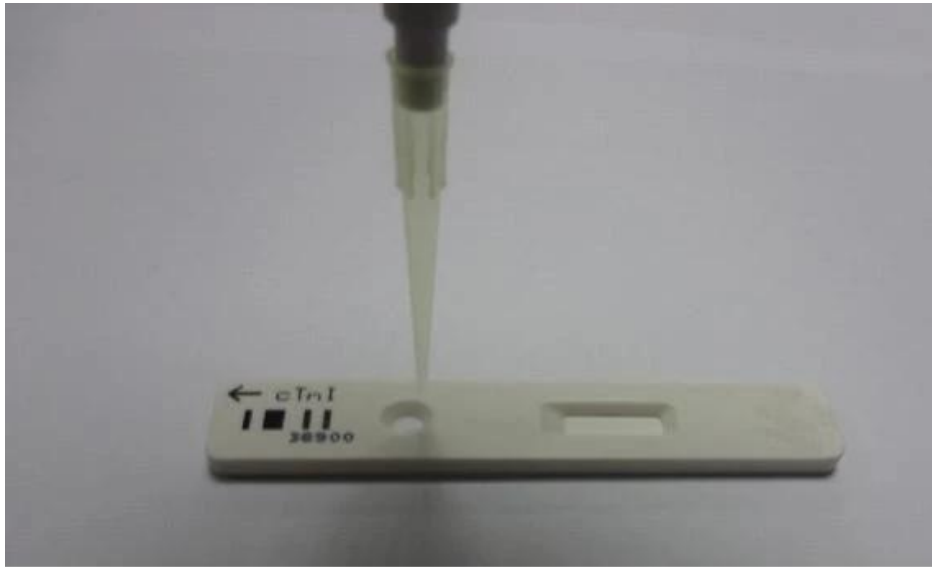


Figure 29

## 5.6. Detect

Insert the reagent card into the "Loading card position" (be careful not to use too much force when inserting or pulling out the reagent card), the instrument will automatically test the sample after detecting the reagent card.

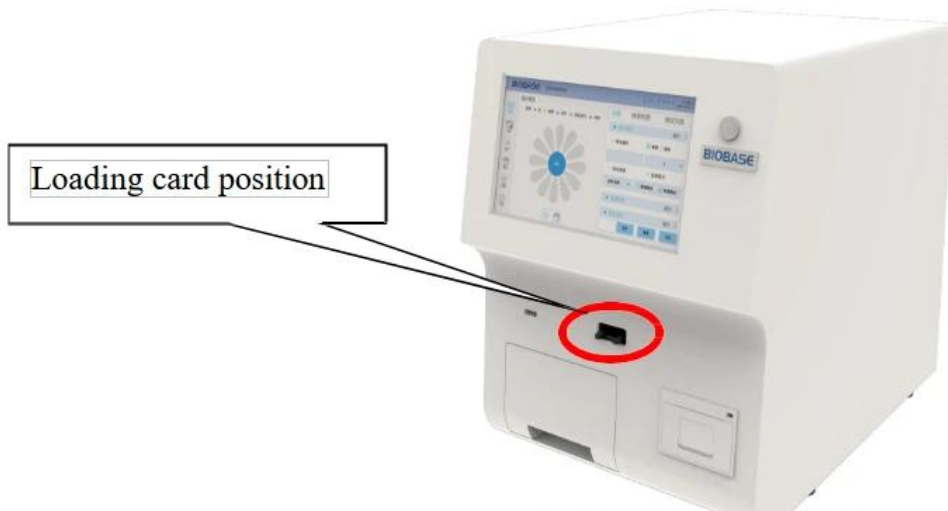


Figure 30

## 5.7. Result Output

After the Item 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.

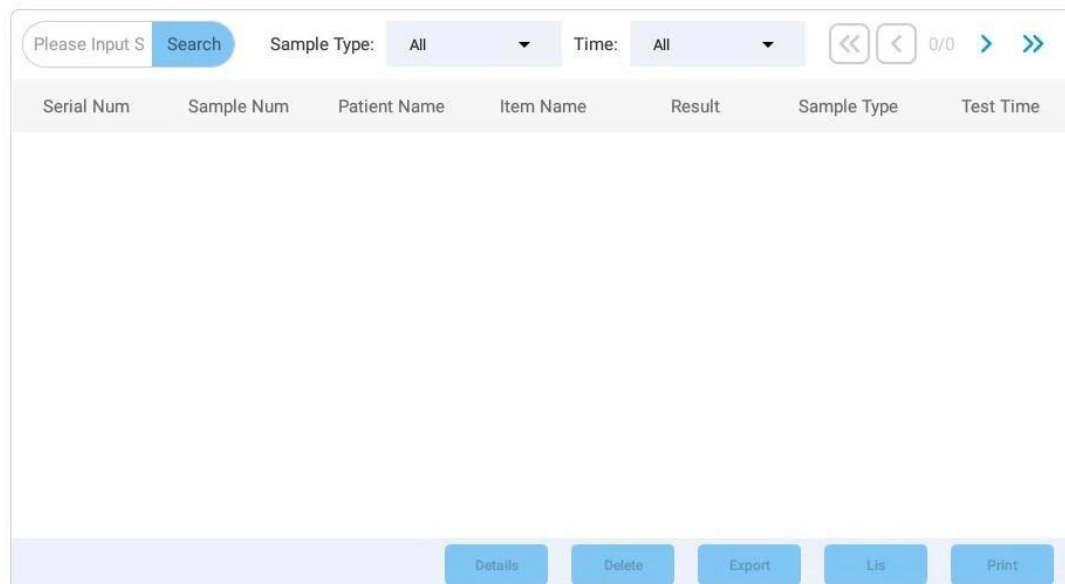


Figure 31

## 6. Cleaning and Disinfection

"Fluorescence Immunoassay Analyzer" is an inspection instrument, which is a non-sterile medical device and does not require sterilization. It only needs to be maintained and maintained according to ordinary medical equipment, and the outside can be kept clean.

Recommended cleaning and disinfection methods: The analyzer casing or frequently touched places are very easy to become dirty. In order to keep the working environment clean and reduce biological risks, the exposed parts of the analyzer should be cleaned in a timely manner.

External cleaning and maintenance method: Use lint-free gauze and 75% ethanol to clean the outer surface of the instrument. After cleaning, please dry the surface with a dry cloth. Be careful not to clean any internal parts or interior surfaces with cleaning agents.

The basis for the determination of the disinfection process: due to the common dust on the surface of the equipment shell, use a cloth dipped in water to wipe the dust directly to complete the removal of dust. Ethanol is used for product disinfection because ethanol is a medium-effective disinfectant, which is medium-effective, quick-acting, non-toxic, irritating to skin and mucous membranes, and non-corrosive to metals. This method is formulated according to WS/T 367-2012 "Technical Specifications for Disinfection in Medical Institutions" and GB/T 27949-2011 "Technical Requirements for Disinfectants for Medical Devices".

Prohibited: Do not clean or maintain the instrument while it is powered on or in operation.

Prohibited: Never pour water or other solutions into any of the instrument parts. When the instrument is energized, inflow of liquid may cause electric shock!

NOTE: Ethanol is a flammable and volatile liquid.

NOTE: Ethanol is a flammable and volatile liquid. Exposure can irritate eyes, skin and respiratory tract and may cause central nervous system hypofunction and liver damage. Wear suitable protective eyewear, clothing, and gloves when cleaning with ethanol.

High surface temperature: During instrument operation, the incubation module may be exposed to high temperatures. Before cleaning or maintaining the instrument, pay attention to the temperature to avoid burns.

Biohazard: Please treat and handle all samples as potentially biohazardous. If a liquid sample is spilled or splashed, immediately sterilize with an appropriate disinfectant to avoid spreading contaminants that contaminate instruments or cause injury to laboratory personnel.

Biohazard: Do not handle or manipulate any potentially biohazardous samples without taking any safety precautions.

## 7. Instrument Care and Maintenance

The instrument does not require extensive maintenance under normal use. If the instrument is used for a long time, regular cleaning and a small amount of maintenance are required to ensure the normal operation of the instrument. Before cleaning the instrument, please read this chapter carefully. Correct maintenance and cleaning of the instrument will help prolong the service life of the instrument.

We should pay attention to the following issues in the maintenance process:

- 1) Arrange someone to be responsible for maintaining the machine;
- 2) The specific maintainer of the machine should emphasize the importance of maintenance to all users of the machine in their daily work;
- 3) During the maintenance work, be sure to wear gloves, work clothes to prevent infection, and protective glasses if necessary. Do not throw away the gauze used for wiping, please dispose of it properly in accordance with relevant regulations.

### 7.1.1. Check the loading card position

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

### 7.1.2. Check the discard bin

Check whether there are multiple or full cards in the discarded card bin, and clean it up in time. If the discarded card bin is full or there are too many cards, the software will prompt that the discarded card bin is full, affecting the experiment process.

### 7.1.3. 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.

## 7.2. Maintenance Weekly

### 7.2.1. Clean 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.

### 7.2.2. Clean the discard bin

The discarded card bin is mainly used to store discarded reagent cards. After a long time, there will be

the risk of biological infection hazards. It should be cleaned and disinfected in time. When cleaning, please wear gloves, use a piece of lint-free gauze and 75% ethanol to clean only its surface, after cleaning, please dry it with a dry cloth.

#### 7.2.3. Clean the loading card position

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

#### 7.2.4. Clean the outside of the instrument

The analyzer casing or frequently touched places are very easy to become dirty. In order to keep the working environment clean and reduce biological risks, the exposed parts of the analyzer should be cleaned in a timely manner. 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, please dry it with a dry cloth.

NOTE:



**WARNING:**

Do not spill liquids on the analyzer to avoid liquid immersion and damage to the immunoanalyzer.



**Risk Of Biological Infection:**

During Maintenance Work, Be Sure To Wear Gloves, Work Clothes To Prevent Infection, And Protective Glasses If Necessary.

Do Not Throw Away The Gauze Used For Wiping, Please Dispose Of It Properly In Accordance With Relevant Regulations.

## 7.3. 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 air flow around the instrument.

## 7.4. Keep the power supply stable

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

## 7.5. Overheating protection

The heating system of the instrument is equipped with an overheat protection device. When the heating system fails and the temperature value exceeds the upper limit of the allowable range, the protection device will automatically disconnect and cannot be restored; at this time, the heating system cannot continue to rise and fall normally. After the above failure occurs in the heating system, the user should stop using the instrument and contact the manufacturer for maintenance in time.

NOTE:

Heating maintenance: Since the heating source is inside the instrument, it cannot be sensed by touch. Therefore, you can actually set the temperature through the software and observe the displayed temperature to judge whether the heating of the instrument is normal. If the heating source fails, the software will also have a temperature reminder. It is recommended to perform temperature calibration once a year, which can be calibrated by our company or by the Metrology Institute.

## 7.6. Other maintenance

- Please use the parts provided by our company.
- For daily cleaning and maintenance of the immunoassay analyzer, please 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.
- Users can contact the customer service center of the company if they have any questions.
- 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 the control or adjustment device is not used in accordance with this specification.

## 7.7. The key to maintenance of System Hardware



WARNING:

Do not switch the immune analyzer on and off frequently, and the interval between switching on and off should be more than 1 minute.

Regularly clean the discarded card compartment.

Do not place items on top of the immunoassay analyzer.

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.

# 8. Quality Control and Calibration

## 8.1. 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 card. The implementation of quality control is the same as when testing ordinary samples, that is, directly testing the concentration of the quality control card with the Fluorescence Immunoassay Analyzer.

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; if it does not meet the target value range requirements, it is forbidden to use! And contact the company's customer service center in time to return to the factory for calibration or maintenance.

## 8.2. 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 use 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. If the reading value is deviated, do not use it! And contact the company's customer service center in time for processing.

# 9. Troubleshooting Guidelines

## 9.1. Analysis and treatment of the reasons why the whole machine does not work

- Cause Analysis:

- (1) No power at the power outlet
- (2) The main switch of the instrument is not turned on
- (3) Fuse open circuit
- (4) No voltage output of switching power supply

- Treatment Method

- (1) Check whether the indicator light of the power socket is displayed normally or use a multimeter to measure the output voltage of the power socket.
- (2) Turn on the main switch of the instrument.
- (3) Replace the fuse (Specifications and models: BANA-1203)
- (4) Change the switching power supply

## **9.2. The instrument is turned on, but the display is black**

- Cause Analysis:

- (1) PC PCB failure
- (2) Data line failure
- (3) Display failure

- Treatment Method

- (1) Externally connect the display function of the instrument to eliminate the fault of the PC PCB (if the external display function of the instrument cannot be displayed, it is judged as a fault of the PC PCB)
- (2) Replace the display line.
- (3) Replace the display.

## **9.3. The instrument failed to obtain ID information**

- Cause Analysis:

- (1) ID card is invalid
- (2) ID card slot failure

- Treatment Method

- (1) Replace the ID card and obtain it again.
- (2) Replacing the ID card slot.

## **9.4. Instrument cannot print test results**

- Cause Analysis(Built in):

- (1) No paper or paper turned over.
- (2) Printer failure.

- Treatment Method

- (1) Install the paper and confirm the paper installation orientation.
- (2) Replace the printer.

- Cause Analysis(External):

- (1) Driver installation is abnormal.
- (2) USB line connection is abnormal.
- (3) External printer not turned on

- Treatment Method

- (1) Check whether the printer connection cable is abnormal or replace the data cable.
- (2) Install the paper and confirm the paper installation orientation.
- (3) Replace the printer.

## **9.5. Individual test results show that no sample has been added**

- Cause Analysis:

- (1) The reagent card is not loaded with the test sample or the sample volume is insufficient.
- (2) The sample is not immersed in the reagent card test area within the predetermined time.
- (3) The reagent card is leaking.

- Treatment Method

- (1) Select the unsampled item and click "Throw" on the test interface to retest the sample by adding sample.
- (2) Wait for the instrument to test the sample for a second time.(If the second test still shows that no sample has been added, click "Throw" to re-add the sample for testing.)
- (3) Replace the reagent card and reload the tes(t Liquid leakage judgment method: take out the reagent card and dissect it, and check whether there are obvious traces of sample liquid leakage at the lower part of the sample hole)

Instrument daily failure analysis and processing summary table:

Fault phenomenon	Cause Analysis	Exclusion method
The instrument does not respond when turned on	The corresponding power switch is not turned on	View the instruction manual
	The power fuse is blown	Please replace the fuse
	The power cord is not connected properly	Reseat the power cord
	Other hardware instrument is faulty	of the Please contact the customer service center company
Test results cannot be printed	Internal printing and external enabled at the same time or other hardware failure	One of the built-in printing and external printing is turned off. If it cannot be ruled out, please contact the company customer service center
Individual reagent card barcodes cannot be read	Reagent card barcode is fuzzy or other faults	Manually select "Modify Barcode" or contact the company customer service center
The built-in printout has no content	paper turned over	Change the paper installation orientation
The instrument cannot read the ID card information	ID chip is abnormal	Replace the ID chip or contact the company customer service center
The results of individual test items indicate "no sample added"	Sample test area signal is low	Select the item and click "Continue Test" or click "Throw" to re-test the item

Table 4

Note: The above daily failure analysis and Treatment Method are for reference only, if necessary, please contact the company's customer service center. When the instrument fails, but the displayed error code is not in the above table, stop the operation immediately and contact the company customer service center.

- Fuse replacement

Fuse burnt will cause the instrument to fail to power on

Maintenance supplies:

A flat-blade screwdriver

Instrument status:

Make sure the instrument is turned off when performing this maintenance operation.

Note:



WARNING:

It cannot be replaced with a fuse of a different specification.

Steps:

1. Confirm that the instrument is turned off and unplug the power cord;
2. Prepare a new fuse (F3AL250V);
3. Use a flat-blade screwdriver to lift out the fuse socket at the power male head of the rear panel of the instrument, and take out the fuse;
4. Observe whether the fuse is blown, burnt black and other abnormal phenomena;
5. If the fuse is blown or burnt black, replace the new fuse to the current position;
6. Install and tighten in the reverse order of removal.

## 10. Accessories list

To ensure personal safety and ensure the performance of the immunoassay analyzer, please use accessories manufactured or recommended by Bioscience Lab. If necessary, please contact Bioscience Lab or your regional distributor. Please order all kinds of consumables and accessories from our company one month in advance. Do not use consumables from any other company. Some of the chemical components in them will speed up the damage of your instrument and cause greater losses. If the accessories are damaged, please contact our company or the local distributor in time for replacement.

Name	Replacement Period and Method
Power Cable	In case of aging or damage, please contact the manufacturer or agent
Network Cable	In case of aging or damage, please contact the manufacturer or agent
Fuse	In case of damage, please contact the manufacturer or agent
Mouse And Keyboard Set	If necessary, please contact the manufacturer or agent
Barcode Gun	If necessary, please contact the manufacturer or agent
Printer Paper	If necessary, please contact the manufacturer or agent

Table 5

## 11. After Sales Service, Repair and Destruction

When the Fluorescence Immunoassay Analyzer fails, please call Bioscience Lab for consultation first, and we will provide telephone technical support to help guide customers to troubleshoot.

If the instrument needs to be recalled for repair, please send the instrument back for repair as required.

The general repair cycle does not exceed seven working days.

If the instrument really needs to be scrapped, the company will provide a new instrument during the warranty period.

If for some reason the user needs to destroy the Fluorescence Immunoassay Analyzer, it is recommended that the user do so in accordance with the Class B Electronic Instrument Regulations. The company declares that the above service guarantee can only be obtained if the manufacturer's

instruction manual is fully complied with, and the company will not be responsible for any damage caused by this.



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