新健康成®

IFP-2000 Fluorescent Immunoanalyzer

Instruction For Use

Important information!

Please read and understand this manual carefully before using the equipment. After reading, place this manual in an accessible place.

Sichuan Xincheng Biological Co., LTD

Catalog

Preface

- Dear users, thank you very much for purchasing the fluorescent immunoanalyzer of Sichuan Xincheng Biological Co.,LTD (hereinafter referred to as "Xincheng Bio").
- Please read the operation manual carefully before operation, so as to use the fluorescent immunoanalyzer correctly. Incorrect operation may affect the accuracy and precision of the test result of the instrument; if the equipment is not used according to the method specified by our company, the protection provided by the equipment may be damaged, or bring danger to your personal safety.
- This manual is only applicable to IFP-2000 fluorescent immunoanalyzer produced by Xincheng Bio.
- After reading, please take good care of this operation manual, which can be consulted at any time when necessary.

Important information!

It is forbidden to copy or reprint the contents of this manual in whole or in part without written permission.

Without prior notice to the user, the company has no legal obligation to inform if there is any change to the contents of this manual.

The content of this manual will continue to be improved. If you find any questions, description errors and unknown information, please inform us.

1. Safety precautions

Definition of safety precautions words

In this operation manual, the safety precautions are indicated with danger, warning, attention and other words. The meanings of each word are as follows. Please fully understand what these words mean when reading this article.

Precautions Words	Meaning
⚠ DANGER	Indicates a dangerous situation in which death or serious injury will occur if the warning is not followed.
⚠ WARNING	Indicates a dangerous condition that may result in death or serious injury if the warning is not followed.
⚠ BE CAREFUL	Indicates a dangerous situation in which minor or moderate injury will result if the warning is not followed.

Meaning of graphic mark

Graphic Mark	Meaning	Reason
	In this device, this mark indicates that it may cause damage or touch the part that may cause electric shock when the power is turned on.	During the operation of the instrument, avoid touching the reagent card slot in the process of movement, otherwise it will cause personal injury
	The samples and reagents in the device often touch the parts that the operator may also touch. Please take protective measures.	Samples and reagents used are considered to be potentially infectious
	There is a risk of electric shock. When the device is powered on, keep your face and hands away from the power device.	During the operation of the instrument, avoid touching the reagent card slot in the process of movement, otherwise it will cause personal injury
IVD	In vitro diagnostic device	The device belongs to in vitro diagnostic device

Safety precautions

Please follow the following safety precautions when using this equipment.

⚠ DANGER	• Avoid using inflammable and explosive dangerous goods around the instrument • Ignition may cause fire or explosion

⚠ WARNING	• The analyzer must be used under the condition of good grounding, independent power supply shall be used, and the input voltage shall meet the requirements of the instrument. • Do not step on, twist or pull wires and cables. If wires and cables are broken, it will cause fire. • Only touch the designated parts. • If the power is on and the circuit board is touched, it will be shocked. • Do not use wet hands to plug in the power supply, otherwise there is a risk of electric shock. • If any liquid enters the instrument, please turn off the power supply of the instrument immediately. • During the operation, operators shall wear work clothes, masks and latex gloves as much as possible. During the sample pretreatment, avoid direct contact with the sample, which shall be considered as potentially infectious. • If the sample splashes on the surface of the instrument, reasonable measures shall be taken immediately for disposal. • Dispose the reagent card according to the instructions provided by the reagent card manufacturer. • Waste treatment: used samples and reagent cards shall be considered as potentially infectious. Please handle according to relevant regulations of the hospital. • The instrument shall be operated, regularly maintained in strict accordance with the operation manual, otherwise it may cause instrument failure or affect the accuracy and precision of the instrument. • When using the instrument, it is necessary to monitor the status of the instrument.

⚠BE CAREFUL

- The instrument is matched with the reagent based on fluorescence Immunochromatography for immunofluorescence detection of human samples.
- Please note that the instrument is not suitable for other purposes.
- This instrument must be used by professional technicians or trained doctors and experimenters.
- The operation and maintenance of the instrument shall be carried out in the specified order. Do not touch other places.
- Please do not open the panel, touching the circuit board will damage the IC.
- When the instrument is running, please do not touch the reagent card bearing tank. Otherwise, the instrument will be damaged, resulting in the shutdown of the instrument, and may pose a threat to personal safety.
- Push all the reagent cards into the reagent card bearing tank until they can not be pushed. When pushing, use your thumb or index finger to push. Do not use too much force to avoid mechanical failure.
- If the instrument is placed for a long time, dust may accumulate on the surface. Clean the surface with a clean soft cloth or gauze, and use a small amount of detergent if necessary. Cut off the power before cleaning the instrument.
- Please use the instrument under the specified installation conditions.
- Do not make the instrument in the environment of mechanical vibration.
- Do not place heavy objects on the instrument to avoid mechanical damage or performance degradation of the instrument.

2. Product description

2.1 Product Classification

The product is classified according to the classification catalogue of medical devices issued by the State Food and drug administration, and belongs to the clinical test device (classification No.: 22-04-03), and the management category is class II.

2.2 Instrument Model Description

The model of fluorescent immunoanalyzer is IFP-2000. Full name is Auto High-Sensitive Fluorescent Immunoassay System IFP-2000.

3. Instrument Introduction

3.1 Summary

- **Brief introduction of the instrument**

The fluorescent immunoanalyzer is a simple, small and portable automatic analyzer, which is used to analyze the concentrations of various analytes in human samples quickly and quantitatively.

- **Application Scope**

Based on the principle of antigen antibody reaction and fluorescence immunoassay, the product is used in combination with the matching reagent produced by our company for the quantitative analysis of the substance to be tested in human samples.

- **Working principle**

The detected substance in the test sample forms immune complex with the fluorescent labeled antibody, and solidifies in the detection area and the quality control area respectively through the capillary surge process. When the reagent card is inserted into the immunofluorescence detector, the LED excitation light source irradiates the detection area and quality control area of the reagent card, excites the solidified fluorescent immune complex, and the emitted light is collected and converted into an electrical signal. The strength of the electrical signal is strictly related to the number of fluorescent molecules. The detector automatically calculates the content of the detected substance in the test sample according to the scanned signal.

3.2 System Composition

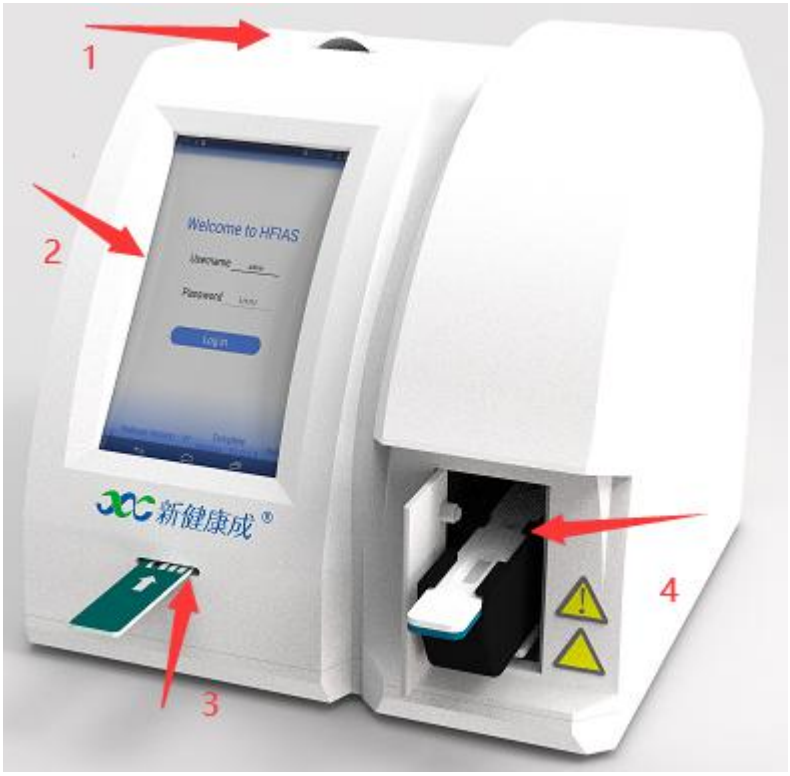
- List of standard accessories

No.	Name	Quantity	Unit
1	fluorescent immunoanalyzer	1	set
2	Power adapter	1	set
3	RJ45 network cable	1	pc

4	Instruction manual	1	set
5	Warranty card	1	pc
6	Quality certificate	1	pc

3.3 Instrument structure

The instrument is mainly composed of optical detection module (fluorescence), data processing module, power adapter and software (software release version: V1). Front of instrument:



As shown in the above figure:

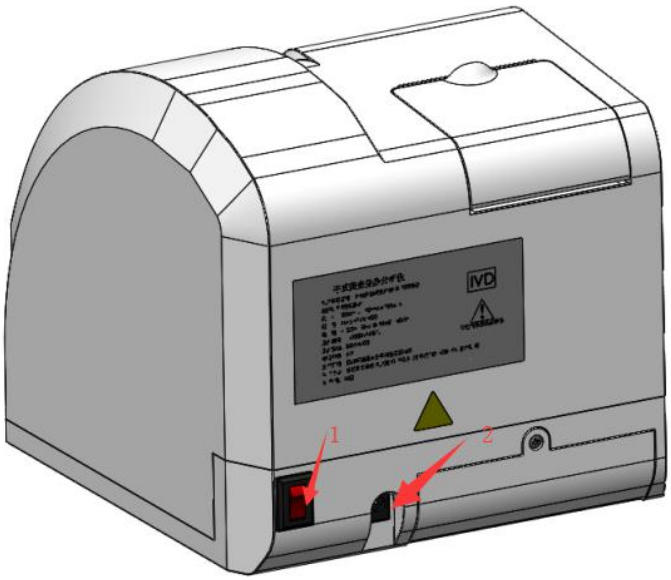
1. Printing area: pull out the printing cover to load the printing paper, and take out the report printing from here.

2. LCD screen, human-computer interface.

3. Chip insertion port.

4. Card slot: Put the reagent card into manually.

Backside of instrument：



As shown in the above figure:

1. Power switch.

2. Power connector.

3.4 Basic parameters of the instrument

Excitation light source: LED

Excitation spectrum: center wavelength λ 0 = 470nm

Receiving spectrum: center wavelength of λ 1 = 525nm

Software system: Chinese and English input method and self-defined intelligent management module are provided.

Release software version number: v1

Interface: RS232 serial port, Ethernet port, USB interface

Printing: built-in thermal printer

Size: 200mm * 190mm * 180mm (L * W* H)

Weight: about 2kg

Repeatability: CV less than or equal to 15%

Stability: CV less than or equal to 8%

3.5 Operation conditions of instrument

Ambient temperature: 10 ℃ ~ 30 ℃ (Note: the operating temperature of reagent shall be subject to the instruction)

Relative humidity: 10% ~ 70%

Power supply: voltage 1A / 115VAC 0.5A / 230VAC

Power frequency: 47 ~ 63Hz

Power of the whole machine: less than 40W

Storage conditions: dry, clean and flat horizontal surface, avoiding direct sunlight, violent vibration and strong electromagnetic interference

3.6 Installation, commissioning and use instructions

3.6.1 Unpacking and inspection

-Take the instrument and accessories out of the box with care, and keep the packaging materials for future transportation or preservation of the instrument. Check the accessories according to the packing list.

-Check the instrument and accessories for damage.

-After the user's acceptance, connect the adapter and tester.

Note: in case of any problem, contact our sales department or agent immediately.

3.6.2 Installation and commissioning steps

-The instrument shall be placed in a clean and ventilated room with a temperature of 10 ℃ ~ 30 ℃ and a relative humidity of no more than 70% to avoid direct sunlight.

-Make sure that the vent is not blocked and that there is a gap of at least 5cm around the instrument.

-Connect the power adapter with the power interface of the fluorescent immunoanalyzer, and turn on the power to start it.

-The instrument has been debugged before leaving the factory and can be used directly by the user.

-In order to ensure the normal operation of the instrument, do not place articles on the instrument at any time.

3.6.3 Operation instructions

Please use the instrument in the environment with the ambient temperature of 10 ℃ ~ 30 ℃ (please note: the operating temperature of the test reagent shall be subject to its instructions) and the relative humidity of less than 70%. And operate in strict accordance with the operation precautions in this manual. If the equipment is not used in

accordance with the method specified by the manufacturer, the protection provided by the equipment may be damaged.

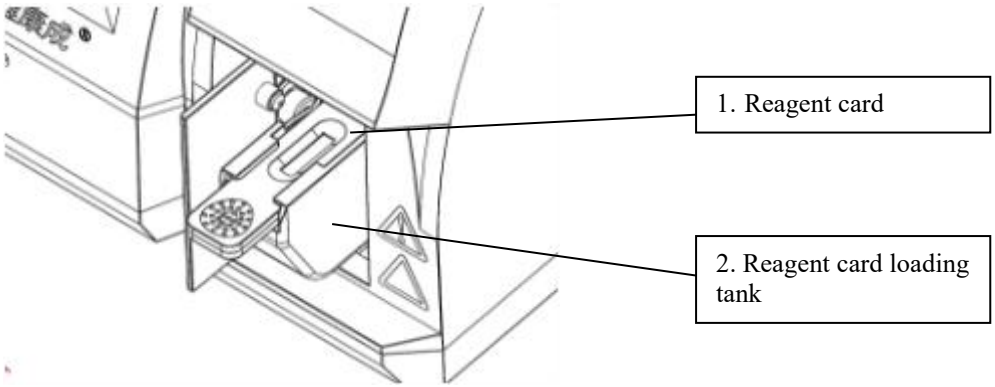
3.7 Operation steps

3.7.1 Preparation before use

1) Please make sure that the host is placed in a stable place without direct sunlight and strong electromagnetic interference.

2) Connect the power adapter cable: insert one end of the power adapter cable equipped with the instrument into the power socket of the instrument, and the other end into the standard well grounded power socket; if you need to connect HIS / LIS, please connect the RJ45 network cable to the network interface of the instrument and the RJ45 wall base.

3) Turn on the power switch of the instrument, the instrument will carry out self-inspection, and the reagent card bearing groove will reciprocate once (as shown in the figure below);



4) The test software starts automatically and the main interface appears automatically.

5) For the use and storage of reagents, please refer to the instructions provided with the reagents.

6) Place the reagent card containing the sample to be tested on the card carrying position stably, and test according to the software operation instructions.

7) According to the different test items, select the appropriate parameter settings (the technical personnel shall guide and train the operators).

3.7.2 Start the test

To control instrument action through software, to test.

Be careful:

- At this time, the card carrying position shall not be close to the exit of it
- It is not allowed to operate the software during the test.

3.7.3 Finish the test

1) When the test is finished, the reagent card slot automatically moves outside the instrument;

2) Turn off the power and end the test.

3) The waste produced in the use of the instrument shall be disposed uniformly by professionals in accordance with the regulations on the management of medical waste (Order No. 380 of the State Council) and other relevant regulations.

WARING:

- Through the above operation inspection, if there is any sign that the function of the instrument is damaged or there is an error message, it is forbidden to continue the test, and please contact the after-sales service department of the company

3.8 Warning tips

The text marked with ⚠ is warning.

3.8.1 Precautions for use place

WARING:

- Please try not to use parallel socket to avoid fire caused by overload.
- 12V / 5A power adapter and effectively grounded socket must be used.
- Use of damaged or non-original (modified) power cord may cause fire and electric shock; do not over bend or roll the power cord to avoid fire and electric shock accidents.
- If the instrument is loose or parts fall or damaged, please contact our company in time.
- Do not use the instrument in unstable environment such as tilt, vibration and impact.
- Do not put the equipment in the position where it is difficult to operate the disconnection device.

- There shall be no water or sundries in the instrument. Please contact our company in time if there are foreign matters in the instrument.

WARNING:

- When moving the instrument, the power must be cut off and the power plug must be unplugged;
- When moving the instrument, try to avoid vibration;
- The instrument is placed on the desktop, and the load-bearing requirement of the desktop is more than 15kg;
- The instrument shall be placed in a stable place with at least 5cm of space around to ensure air circulation and heat dissipation of the instrument;
- It is not allowed to cover anything on the instrument to prevent the vent from blocking;
- Avoid using the instrument in the following environments: sunlight; high humidity environment; near water environment; places with vibration and inclination; strong magnetic field environment; places where electromagnetic wave and impulse voltage occur; places where chemicals are kept, places with corrosive gas;
- The instrument shall not be placed near the interference signal source of radio, television, copier, fax machine, etc.
- It shall not be used together with other instruments (such as microwave and other high-frequency equipment) to avoid electromagnetic interference and wrong operation.

3.8.2 Precautions during use

WARNING:

- Before starting the machine, the operator must carefully read the operation manual. The operator must pass the professional training and be familiar with the operation manual and method. The instrument must be managed by a specially assigned person.
- Please set the test parameters under the guidance of professionals.
- When dealing with potential infectious substances (such as human body samples or reagents), if it is possible to contact the skin, protective gloves or other protective measures shall be used;

CAUTION:

- Confirm whether the instrument is in normal operation before use;
- It is necessary to confirm whether all wires have been connected correctly and safely;
- When using together with other instruments, it is necessary to read and clarify the operation precautions, otherwise there may be danger, please pay attention.
- The instrument shall be used correctly by professional operators, and personnel other than non-professional operators shall not use the instrument.
- After the test, confirm that the reagent card has been taken out, reset the card carrying tongue, and then turn off the power supply.

3.8.3 Precautions for failure, storage and inspection

WARNING:

- In case of any abnormal condition of the instrument, the use shall be terminated immediately. In case of smoke and burning smell, there is a risk of fire and electric shock if you continue to use. Please turn off the power supply quickly, unplug the power plug, and contact our company or the dealer immediately;
- Except for the company's maintenance personnel and the company's authorized maintenance personnel, other personnel are not allowed to dismantle, modify and repair the instrument. If there is any violation, the company will not be able to carry out normal maintenance and repair of the instrument, and the company will not bear any responsibility for the possible personal injury and fire and electric shock risk.

CAUTION:

- The instruments and components shall be inspected regularly. In case of damage, crack and other abnormal conditions, please inform the company to repair or replace them;
- Clean the surface of the instrument with clean soft cloth and non-corrosive detergent to prevent scratching the instrument shell and panel;

3.8.4 Electromagnetic compatibility precautions

WARNING:

- This instrument is designed and tested according to class A equipment in GB 4824. In the home environment, this equipment may cause radio interference, so protective measures shall be taken.
- It is forbidden to use the equipment beside the strong radiation source (such as the unshielded RF source), otherwise it may interfere with the normal operation of the equipment.

CAUTION:

- The user has the responsibility to ensure 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.

3.9 Spare parts replacement instructions

Spare parts replacement instructions

Printing paper:

1. Printing paper specification 57mm × 40mm;

2. To replace the printing paper, turn off the power supply, open the printer cover from bottom to top, place the printing paper in the printer slot correctly (the output head of the printing paper is below), and leave a length of at least 2cm, press the printer cover firmly, and confirm that the cover is installed in place.

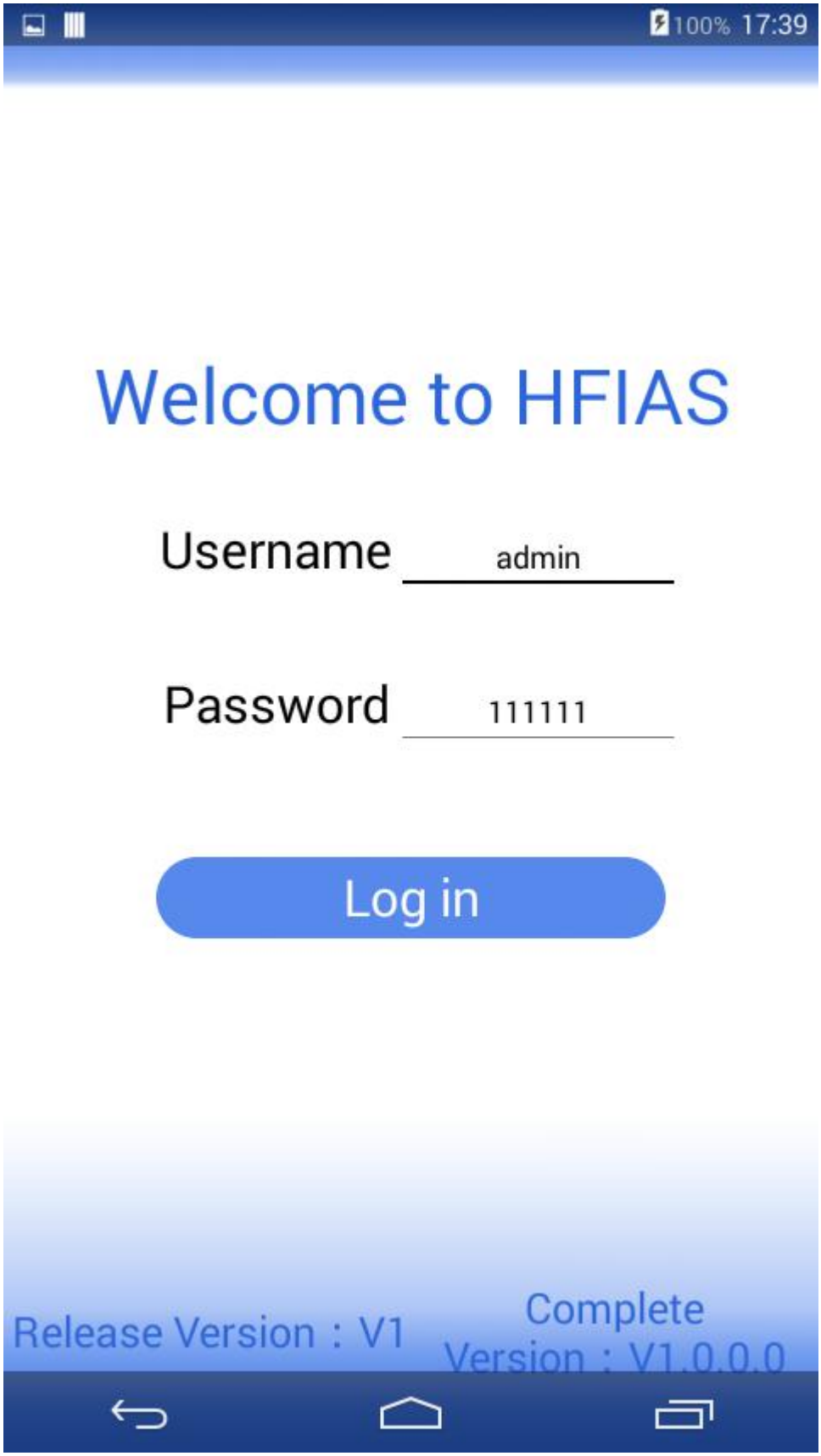
3. The printing paper shall be kept away from high temperature and direct sunlight.

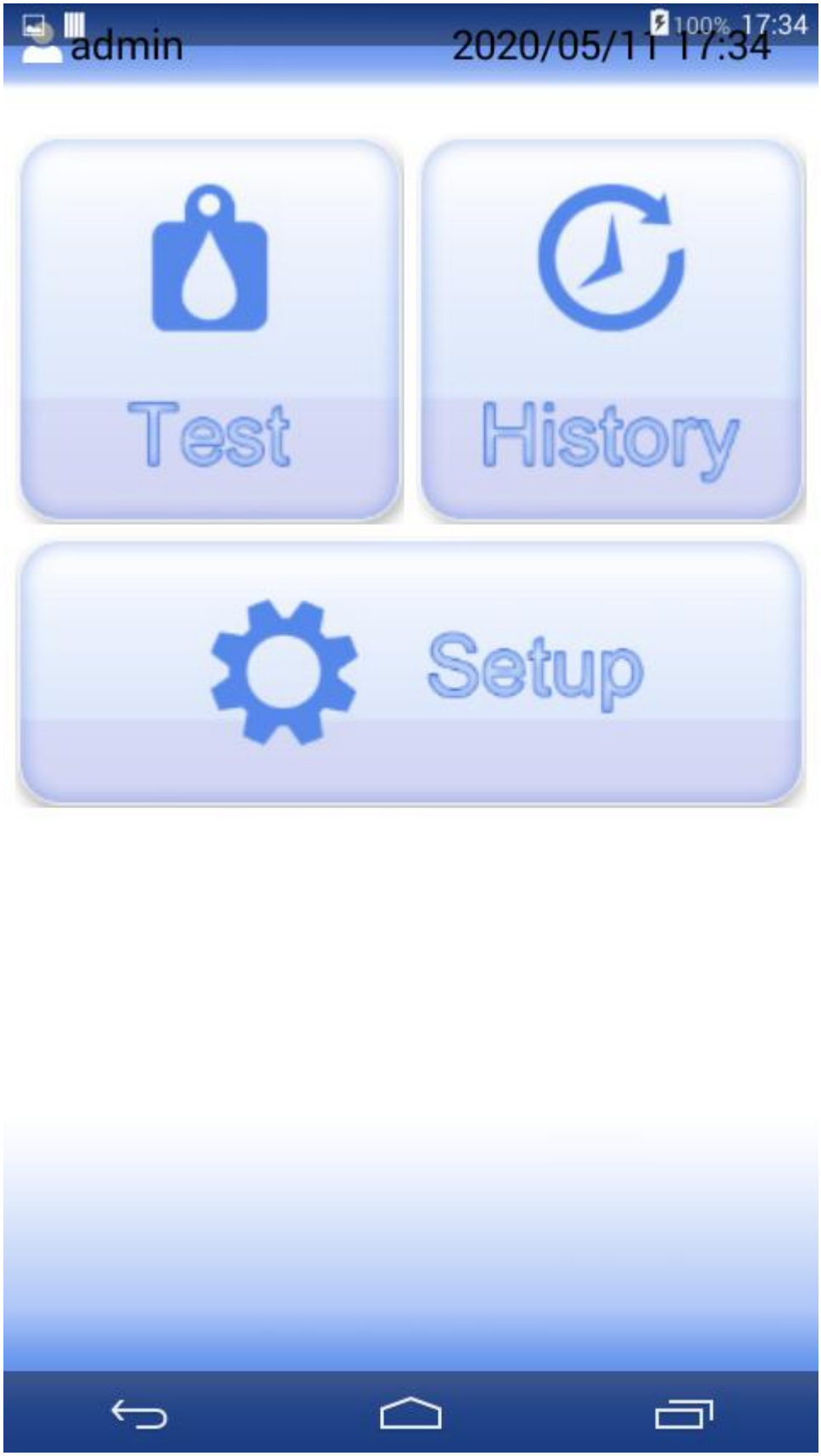
4. Replacement cycle: the printing paper can be replaced after use.

4. Software instructions

The instrument is operated by light touch screen.

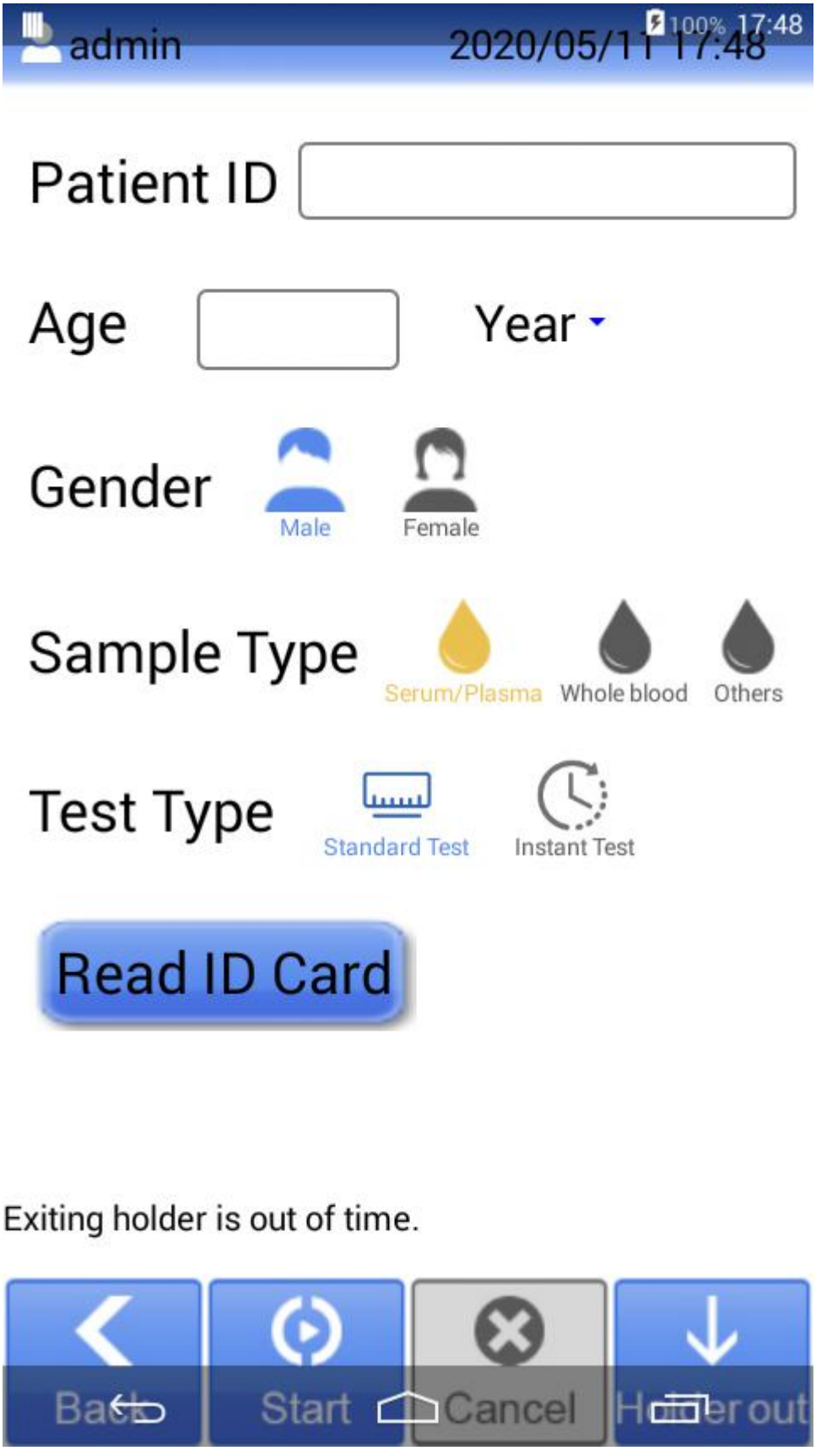
After starting the instrument, the instrument will automatically enter the login box, enter the user name and password, and click the login button to enter the main test interface.


100% 17:39
Welcome to HFIAS
Username
admin
Password
111111
Log in
Release Version : V1
Complete Version : V1.0.0.0



- The main interface includes test, history and settings. Click each module to enter the corresponding interface.

4.1 To do the test



- **Test process**

Click to input the patient ID, age, gender, select the sample type, test mode, put in the card with the sample added, insert the ID card of the item to be

tested, after the ID data is read successfully, the corresponding test can be carried out.

- **Test mode and process**

Standard test procedures:

1. Select standard test.
2. Take out the reagent card and add the processed sample into the sample hole of the reagent card.
3. Click "card out" to pop up the reagent card bearing tank.
4. Put the reagent card into the reagent card carrying tank.
5. Click "test" and the instrument will automatically start scanning the reagent card information.
6. The reagent and sample start to react, and the instrument enters the countdown.
7. After the countdown, the instrument starts to calculate the test results.
8. After calculating the result, the result will be saved automatically and displayed in the interface.
9. Click "print" to print the result.
10. Take out the reagent card.
11. Repeat if the next test is required
12. After the test, click "exit" and turn off the power switch.

Instant test steps:

1. Select instant test.
2. The instrument shall carry out self-inspection first.
3. Take out the reagent card and add the processed sample into the sample hole of the reagent card.
4. Click "card out" to pop up the reagent card bearing tank.
5. Put the reagent card into the reagent card carrying tank.
6. The instrument starts directly, loads the reagent card into the instrument, and starts the test.
7. After the test, the instrument starts to calculate the test results.
8. After calculating the result, the result will be saved automatically and displayed in the interface.
9. Click "print" to print the result.
10. Take out the reagent card.
11. Repeat if the next test is required.

12. After the test, click "exit" and turn off the power switch.

During the test, click the "test cancel" button to end the test.

- **Test results**

After the test, the interface will automatically pop up the test result interface. You can click OK to close the interface, or click Print to print the result directly.

- **Function description of each key:**

Return: return to the main interface. You cannot click this button during the test.

Test: after the task is issued, click this button, the instrument will enter the test automatically.

Cancel: click this button to cancel the test when there is no action for the component during the test.

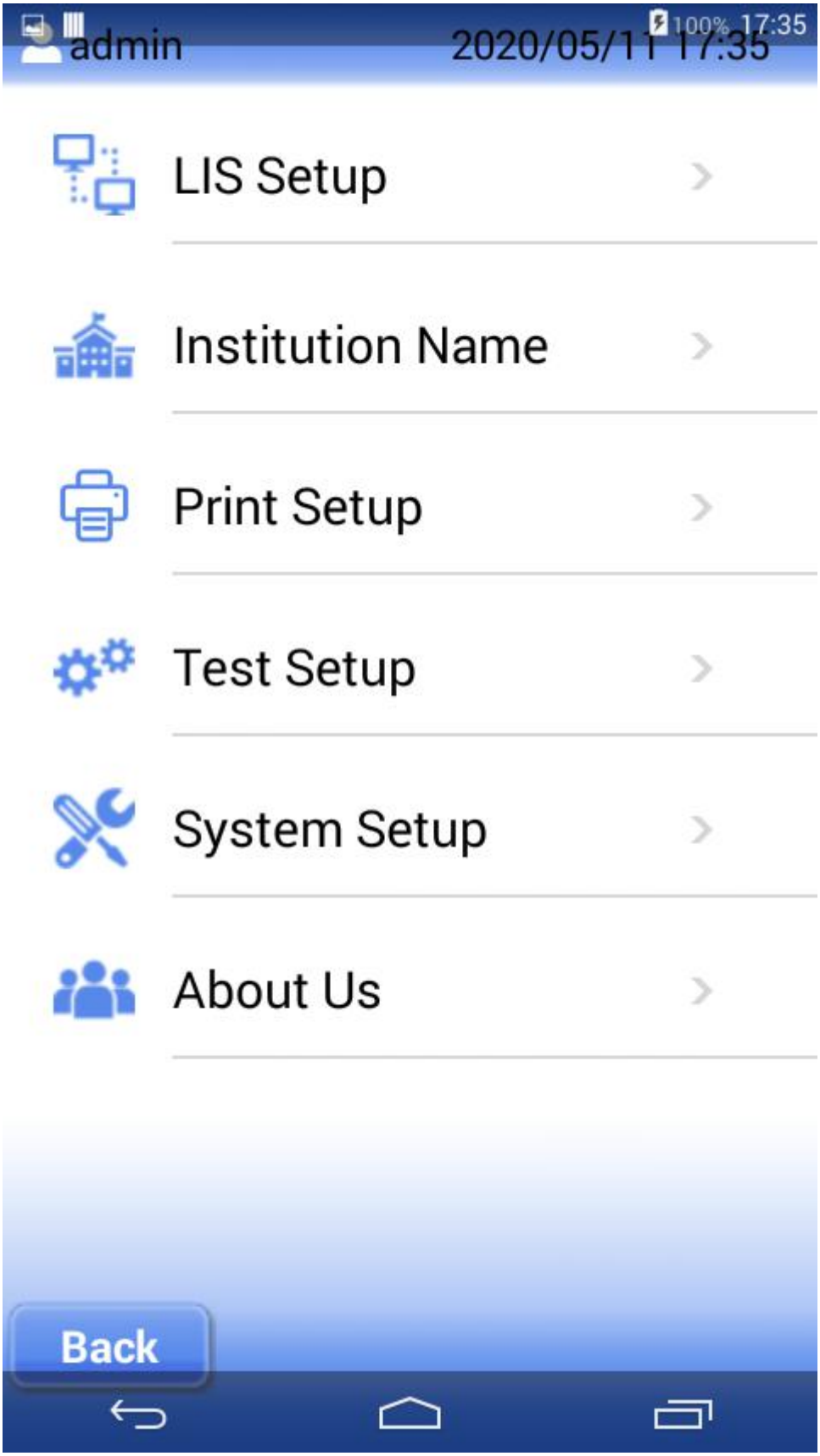
Card out: when not entering the test, click this button to open the bin door and the reagent card carrying tank will exit automatically.

4.2 History record of the test

The instrument saves the test results and provides the function of querying, retrieving and printing the historical test results. Steps to view historical data:

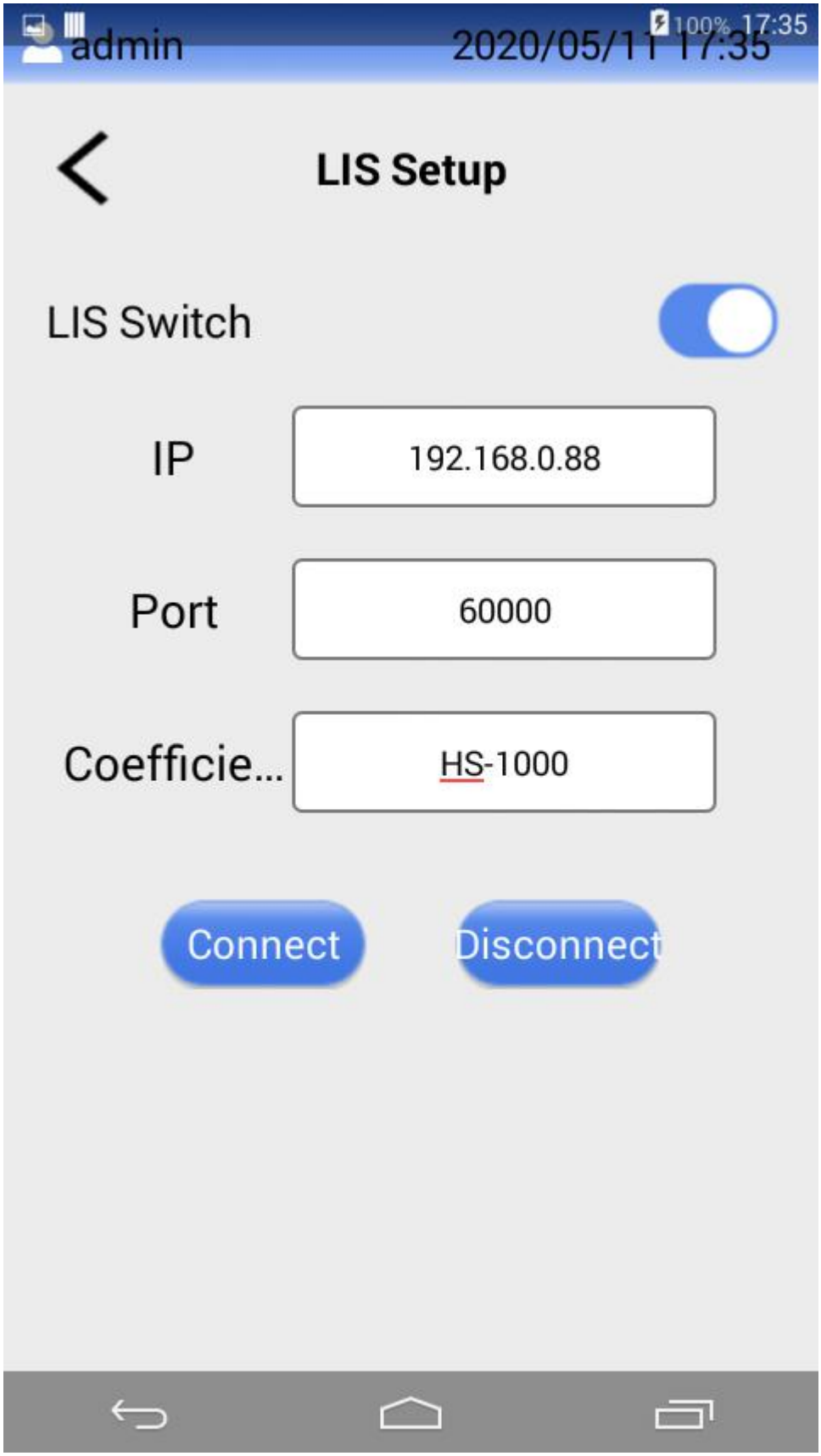
- Click "history" in the software interface;
- To query the detailed information of inspection results at a specific time, click "search" to input the time or item to be searched, then the detailed information can be queried;
- Click the tick before each record to select the record;
- Click Print to print the selected record.

4.3 Settings

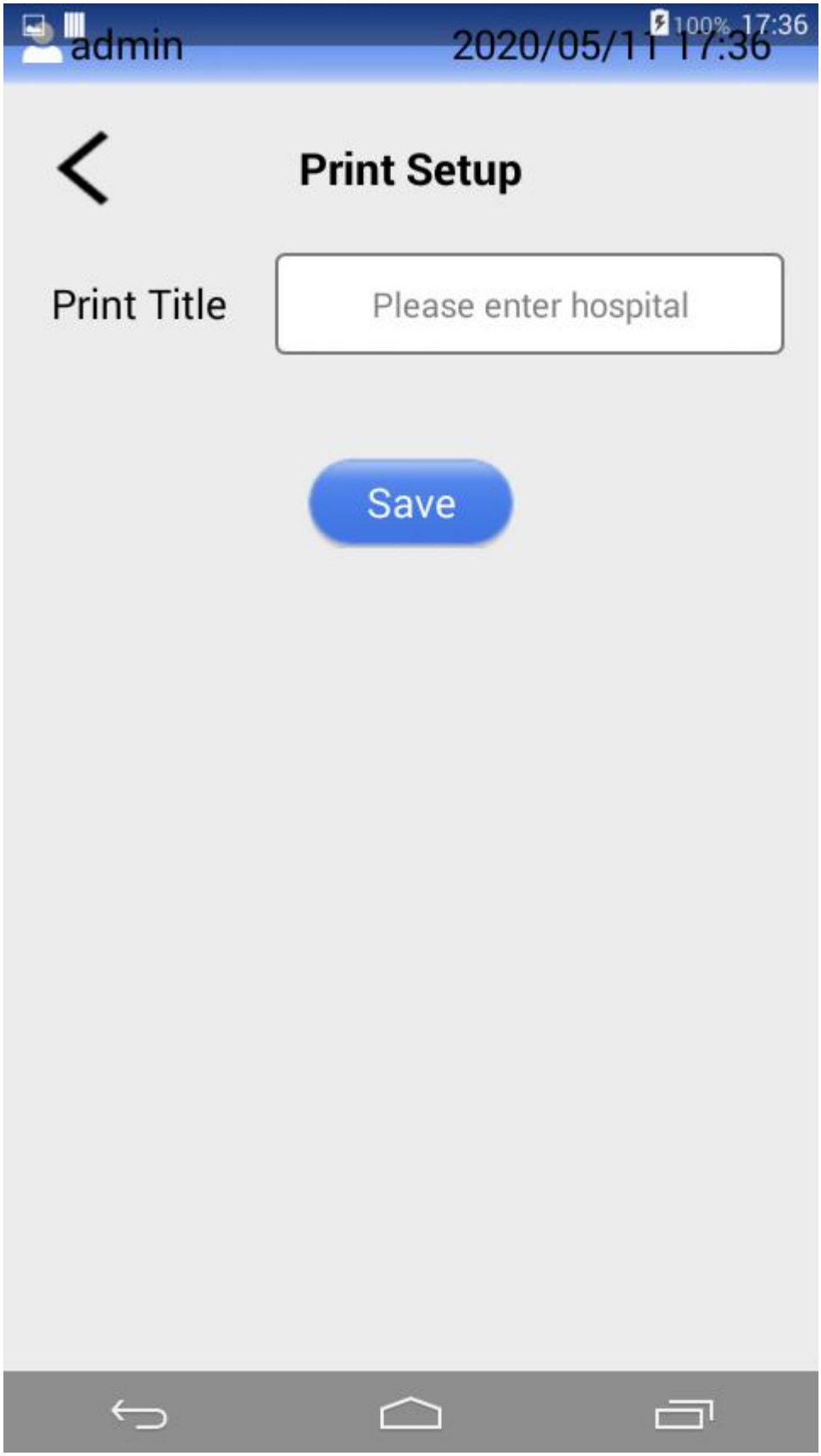


Settings include LIS settings, organization name, print settings, test settings, system settings and about us.

- Test setting: maintain relevant operation interface for use by customer service engineer;
- System settings: provide the function of restoring factory settings;
- Organization Name: record instrument information;
- About us: record software version information;
- LIS settings: PC’s IP and network port settings. After the configuration with the PC, click "connect" and the connection is successful. When the LIS switch is on, the test data will be automatically transmitted to the LIS end. When the LIS switch is off, the test data will not be automatically transmitted to the LIS end, but can be transmitted manually.



- Print settings: after entering and saving the hospital name, the name of the hospital will be displayed on the print report.



5. Maintenance

5.1 Daily Maintenance

After the daily clinical test, the external surface of the instrument shall be thoroughly scrubbed with inorganic laboratory disinfectant and rag.

⚠CAUTION	● Strong bleach (> 0.5% solution) can not be used, because oxidants and solvents may damage the analyzer's shell and touch screen. ● It is not allowed to scrub any internal devices and internal surfaces of the instrument.

5.2 Regular Maintenance

The instrument does not provide an automatic maintenance process. Maintenance shall be performed with the instrument power off. The bearing tank area of the reagent card should be scrubbed regularly to prevent splashing liquid residue.

6. After sales service

6.1 services and destruction

Dear user,

Thank you for purchasing Sichuan new healthy fluorescent immunoanalyzer. You can get the following services provided by our company:

Provide technical consultation at any time.
The complete machine's maintenance is free of charge for one year from the date of purchase. 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. All components of the equipment can only be inspected and provided by our company or designated agent.

Provide paid services for:

- Products that is out of the warranty period (free warranty period of 1 year, recommended service life of 5 years);
- Damage caused by not using according to the instructions;
- Damage caused by unexpected factors and improper use;
- The damage caused by self-repair without the permission of our company;

With the improvement of technology, our company will provide the upgrading service of the analyzer. If you need service or repair, please call 400-6550770 028-87822789

If the user wants to destroy the instrument for any reason, it is recommended that the user destroy the instrument according to the regulations of class B electronic instrument.

6.2 Common Faults and Treatment of Instruments

Fault phenomenon	Reason Analysis	Elimination method
The entire device cannot be turned on	The power switch is not turned on	Turn on the power switch
	The power adapter is not connected	Please reconnect the power adapter
The display screen does not start	Screen line failure	Contact the maintenance department
	Operating system problems	Contact the maintenance department
Software system failure	Operating system malfunction	Contact the maintenance department
	Test analysis software cannot be started	Contact the maintenance department
	Other prompts appear during the running of the test analysis software	Please record the complete error message code and error message prompt, and then contact the maintenance department
Abnormal sound during the test	The carrier tongue may be stuck	Restart the test unit,let it reset automatically and start working again
	Mechanical motion failure	Please contact the maintenance department
The test process suddenly stopped	It may be that the power supply of the tester is interrupted	Reopen the analyzer switch and retest
	There is a communication failure	Reopen the analyzer switch and retest
	The problem still exists	Contact the maintenance department
Abnormal test results	Abnormal measurement results	Contact the maintenance department

	pollution problem	Reduce pollution
Other faults	When other faults occur	Please contact the after-sales service department in time

6.3 Transportation and Storage of Instruments

Transportation

- The analyzer shall be transported in the packaging state. During the transportation, the analyzer shall be placed horizontally, and shall be protected from severe collision, rain and exposure to the sun, and shall not be stored with corrosive materials;
- Transportation environment temperature: 0 ℃ ~ 40 ℃, relative humidity: 10% ~ 85%, atmospheric pressure: 86kpa ~ 106kpa;

- Transport packages contain fragile products, so handle them with care. Once the package is exposed to rain, it will completely deteriorate or be damaged;
- It is not allowed to roll the transport package;
- The number of stacking layers shall not exceed 5.

Storage

- The indoor environment temperature is 0 ℃ ~ 40 ℃, and the relative humidity is 10% ~ 85%;
- During storage, the objects directly contacted by the packing box shall be dry and clean without oil pollution, dust and other pollution;
- The number of stacking layers shall not exceed 5;
- No chemicals, corrosive gases and well ventilated environment.

6.4 Description of Electromagnetic Compatibility and Risk Warning

The fluorescent immunoanalyzer has passed the electromagnetic compatibility test and meets the requirements of GB / T 18268.26-2010 electromagnetic compatibility requirements of electrical equipment for measurement, control and laboratory use Part 26: special requirements in vitro diagnostic (IVD) medical equipment and GB / T 18268.1-2010 electromagnetic compatibility requirements of electrical equipment for measurement, control and laboratory use part 1: General requirements.

The following requirements shall be strictly followed in use, otherwise electromagnetic interference may be caused to other equipment or the anti-electromagnetic interference ability of the fluorescent immunoanalyzer may be reduced, or even the basic performance may be lost.

This equipment is designed and tested according to group I class B equipment in GB 4824-2013. In the home environment, this equipment may cause radio interference, and precautions need to be taken.

Description of portable and mobile radio-frequency communication equipment that may affect medical electrical equipment: portable and mobile radio-frequency communication equipment may affect the normal operation of the fluorescence immunoanalyzer. It shall be ensured that the portable and mobile radio-frequency communication equipment and the fluorescence immunoanalyzer meet certain space distance. See Table 4 for specific requirements.

Warning 1: In addition to the cables sold by the manufacturer of the equipment or system as the spare parts of the internal components, the use of accessories and cables other than those specified may lead to the increase of the emission or decrease of the immunity of the equipment or system.

Warning 2: The equipment or system shall not be close to or stacked with other equipment. If it must be close to or stacked, it shall be observed and verified that it can operate normally in its used configuration.

Warning 3: It is forbidden to use the equipment near the strong radiation source, otherwise it may interfere with the normal operation of the equipment.

6.5 Network Security Instructions

Please make sure that the instrument is used in a network security environment.

6.5.1 Data Interface

1. Ethernet port is reserved for the instrument, UDP protocol is used for network layer communication, ASTM protocol is used for data exchange, which is used for LIS communication.

2. The DB9 interface is reserved for the instrument, and the protocol is RS232, which is used

for instrument debugging and communication.

3. USB interface is reserved for the instrument, which can be used for program upgrading and data transmission.

6.5.2 User Access Control

1. After the instrument is powered on, you need to enter the user name account and password.

2. The instrument needs to enter the password to enter the "test setting" interface for parameter setting.

Table 1

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">The fluorescent immunoassay analyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment</td></tr>
<tr><td>Launch experiment</td><td>Compliance</td><td>Electromagnetic environment — Guide</td></tr>
<tr><td>Radio frequency emission
GB 4824</td><td>1 set</td><td>The fluorescent immunoassay analyzer uses radio frequency energy only for its internal functions. Therefore, its radio frequency emission is very low, and the possibility of interference to electronic equipment is very small</td></tr>
<tr><td>Radio frequency emission
GB 4824</td><td>A Class</td><td rowspan="3">The fluorescent immunoassay analyzer is suitable for all facilities that are not household and not directly connected to the residential public low-voltage power supply network for domestic use</td></tr>
<tr><td>Harmonic emission
GB 17625.1</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuation /
Flashing emission
GB 17625.2</td><td>Not applicable</td></tr>
</table>

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The fluorescent immunoassay analyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment			
Immunity test	IEC 61326 Test Level Guidelines	Coincidence level	Electromagnetic environment — Guide
Electrostatic discharge GB / T 17626.2	± 4 kV contact discharge ± 8 kV air discharge	± 4 kV contact discharge ± 8 kV air discharge	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%
Electrical fast transient pulse group GB / T 17626.4	± 1 kV to power line	± 1 kV to power line	The grid power supply should have the quality used in a typical commercial or hospital environment
surge GB / T 17626.5	± 1 kV line-to-line ± 2 kV line to ground	± 1 kV line-to-line ± 2 kV line to ground	The grid power supply should have the quality used in a typical commercial or hospital environment
Voltage dips, short interruptions and voltage changes on the power input line GB / T17626.11	0% UT for 1 cycle (on Ut , 100% dip) 40% UT, continued 5 cycles (Ut , the 60% of sag) 70% UT, continuous 25 cycles (Ut , the 30% of sag) 5% UT, sustained 5S (in Ut , the 95% of sag)	0% UT for 0.02s 40% UT for 0.1s 70% UT for 0.5s 5% UT for 5s	The grid power supply should have the quality used in a typical commercial or hospital environment. If the user of the fluorescence immunoassay analyzer needs to run continuously during the power interruption, it is recommended that the LuxScan Dx24 microarray scanner be powered by an uninterruptible power supply or battery
Power frequency magnetic field (50 / 60Hz) GB / T 17626.8	3A / m	3A / m	If abnormal operation occurs, it is necessary to keep the fluorescent immunoassay away from the power frequency magnetic field or install a magnetic shield in the place. The power frequency magnetic field in

			the intended installation site shall be measured to meet the requirements below the compliance level.
Note: In the voltage sag and short-term interruption test, UT refers to the AC grid voltage before the voltage is applied, one cycle is 20ms .			

Table 3

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</td></tr>
<tr><td colspan="4">The fluorescent immunoassay analyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment</td></tr>
<tr><td>Immunity test</td><td>IEC 61326 test level</td><td>Coincidence level</td><td>Electromagnetic environment - guide</td></tr>
<tr><td>Radio frequency conduction
GB / T 17626.6</td><td>3V (effective value)
150 kHz to 80 MHz</td><td>3 V (effective value)</td><td rowspan="2">Portable and mobile RF communication equipment should not be closer to any part of the fluorescent immunoassay analyzer than the recommended isolation distance. Use including cables. The distance should be calculated using the formula corresponding to the transmitter frequency.
Recommended isolation distance
d = 1.2
d = 1.2 80 MHz to 800 MHz
d = 2.3 800 MHz ～2.0 GHz
In the formula:
P—— The maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W);
d—— Recommended isolation distance, in meters (m).
The field strength of a fixed RF transmitter is determined by surveying a of the electromagnetic site, and each frequency range b should be lower than the compliance level.
Interference may occur near equipment marked with the following symbol</td></tr>
<tr><td>Radio frequency radiation
GB / T 17626.3</td><td>3 V / m
80 MHz to 2.0 GHz</td><td>3 V / m</td></tr>
<tr><td colspan="4">Note 1 : At 80 MHz and 800 MHz , the formula for the higher frequency band should be used.
Note 2 : These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.</td></tr>
<tr><td colspan="4">a Fixed transmitters, such as: wireless (cellular / cordless) telephones and terrestrial mobile radio base stations, amateur radios, AM and FM radio broadcasts, and television broadcasts, the field strength of which cannot be predicted theoretically accurately. To assess the electromagnetic environment of fixed RF transmitters, surveys of electromagnetic sites should be considered. If the measured field strength of the fluorescent immunoassay analyzer is higher than the above RF compliance level,
the LuxScan Dx24 fluorescent immunoassay analyzer should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or relocating the fluorescent immunoassay analyzer.
b In the entire frequency range from 150 KHz to 80 MHz , the field strength should be less than 3 V / m .</td></tr>
</table>

Table 4

Recommended isolation distance between portable and mobile RF communication equipment and fluorescent immunoassay analyzer			
The fluorescent immunoassay analyzer is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. Depending on the maximum output power of the communication equipment, the purchaser or user of the fluorescent immunoassay analyzer can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment (transmitter) and the fluorescent immunoassay analyzer			
Maximum rated output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter / m		
	150 KHz to 80 MHz d = 1.2	80 MHz to 800 MHz d = 1.2	800 MHz to 2.0 GHz d = 2.3
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	twenty three
For the maximum rated power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the transmitter provided by the transmitter manufacturer Maximum rated output power in watts (W) . Note 1 : At 80 MHz and 800 MHz frequency points, the formula for the higher frequency band should be used. Note 2 : These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.			

[Basic Information]

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