CE

Dry Fluorescence Immunoassay Analyzer

User Manual

Suzhou Helmen Precise Instruments Co., Ltd.

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Contents

Chapter I. Information for Operation

Thank you for selecting FIC-Q100 dry fluorescence immunoassay analyzer of Suzhou Helmen Precision Instruments Co., Ltd. The product is a dry type fluorescence immunoassay strip test system based on photoelectric detection principle which should support the use of reagent based on fluorescence immunochromatography principle. Please thoroughly read this User Manual before use so that you can refer to it when necessary.

This User Manual is applicable to FIC-Q100 dry type fluorescence immunoassay analyzer. For details, refer to actual interface operation.

1.1 Introduction to analyzer

【Product name】Dry Fluorescence Immunoassay Analyzer

【Product model】FIC-Q100

【overall dimensions】285mm×240mm×130mm (L×W×H)

【Weight】 2kg

【Software version】V1

【Date of manufacture】See the label at the bottom

1.2 Scope of application

It supports the use of specific dry reagent based on fluorescence immunochromatography and is used for immunofluorescence assay of human body samples. It is used for in vitro diagnosis and test by laboratory staffs of medical institutions only. It can be applied to central laboratories, outpatient/ emergency laboratories and clinical departments of medical institutions, as well as other medical service centers (such as community medical service center) and physical examination

centers and is also applicable to scientific research laboratories.

1.3 Contraindications

None.

Chapter II. System assemblies and main structure

After the product is unpacked, please check whether there are missing or damaged parts according to configuration list.

2.1 Standard configuration list of analyzer

S/N	Name	Qty.	Unit
1	FIC-Q100 host	1	Set
2	Power supply adapter	1	Set
3	Specification	1	Pcs.
4	Warranty Card	1	Pcs.
5	Certificate of Quality	1	Pcs.
6	Packing List	1	Pcs.
7	Scanner gun (optional)	1	Pcs.
8	ID card	1	Pcs.

2.2 Main structure

Note: The appearance of the analyzer and its accessories is subject to the physical object.

Front side structure diagram:

(Figure I) Front side structure of analyzer

Back side structure

(Figure II. Back side of analyzer)

Power supply adapter

(Figure III) Power supply adapter

ID card

(Figure IV) Notes: This accessory is used in coordination with different testing reagents

Explanation to product symbols

Symbol	Explanation
	Attention, refer to the attached text
IVD	Vitro diagnosing apparatus
	Biological risk
Reagent card slot	Test strip socket
ID card socket	ID card socket
Power switch	Power switch
LAN	LAN
COM	COM port
USB	USB port
Input ⎓12V	Input dc 12V

Chapter III. Basic parameters and operating conditions of analyzer

3.1 Basic parameters of analyzer

3.1 Parameter Performance

- Instrument interface： USB、Com、LAN、WiFi；
- Print Method： Thermal printer
- display：24-bit, 7-inch color LCD
- Power supply ： Host input DC12V 4A Adapter input AC100~240V、50Hz~60Hz
- Repeatability CV≤10%
- Stability σ≤10%
- Accuracy Δn ≤10%
- Linearity r≥0.99
- Measurement range 1000 times

3.2 Transportation and storage conditions of analyzer

After packaging, the product should be stored at the ambient temperature of -40℃～55℃, the relative humidity of no greater than 93% and the barometric pressure of 700hPa～1060hPa and should be free from toxic gases, inflammables, explosives and corrosive gases. Measures should be adopted against moisture, impact and violent vibration during transportation.

3.3 Operating conditions of analyzer

1 Positioning and placing requirements

1） The analyzer should be placed in a stable and leveled manner in a room free from heavy dust, direct sunlight and corrosive gas. The worktable is able to bear a

weight above 2.5kg.

2） No strong vibration source and electromagnetic field exist around;

3）It should be located in a well-ventilated place with a space over 10cm to be reserved around the analyzer to ensure the space necessary for operation and maintenance.

2 Normal working conditions

1) Ambient temperature range: 5℃-40℃;

2) Relative humidity range: 10%~80%;

3) Barometric pressure range: 700hpa~1060hpa.

4）Host input DC12V 4A　　Adapter input AC100~240V、50Hz~60Hz

3 Electromagnetic compatibility requirements

1) The product conforms to electromagnetic compatibility requirements of IEC61326-1/IEC6326-2-6, including emission and noise immunity requirements.

2) User should evaluate the electromagnetic environment before using the product, so as to ensure normal operation.

3) When the product is used in a dry environment, especially in a dry environment containing artificial materials (fabric and carpet, etc.), destructive electrostatic discharge may be caused and wrong conclusions may be drawn.

4) The product cannot be used near strong radiation source (such as unshielded radio source); otherwise normal operation of the instrument may be disturbed.

5) The product may cause radio disturbance in domestic situations, so protective measures should be adopted.

Chapter IV. analyzer installation

Please use this analyzer under the specified analyzer operating conditions. (Refer to Chapter III “Operating conditions of analyzer”)

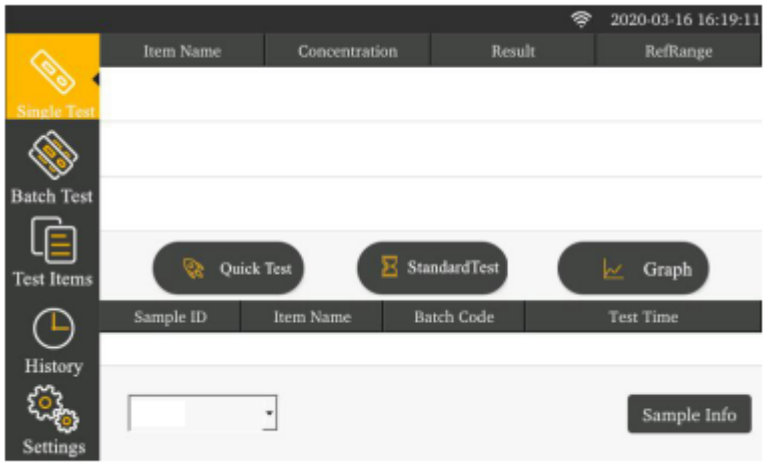
1 Place the fluorescent immunoassay analyzer on a stable operating table.

2 Connect the power supply adapter with the power supply interface of the fluorescent immunoassay analyzer.

3 Pull the power supply switch to the position “on” to start the analyzer.

Chapter V. Detailed operating steps of analyzer

The operation of this testing analyzer relies on fingers operating the touchscreen of the fluorescent immunoassay analyzer. Connect the power cord of the analyzer. Turn on the power supply switch of the analyzer to start it. The analyzer goes through starting initialization and booting. After successful booting, the analyzer displays its interface.



Complete system setup according to the practical operation need before operating

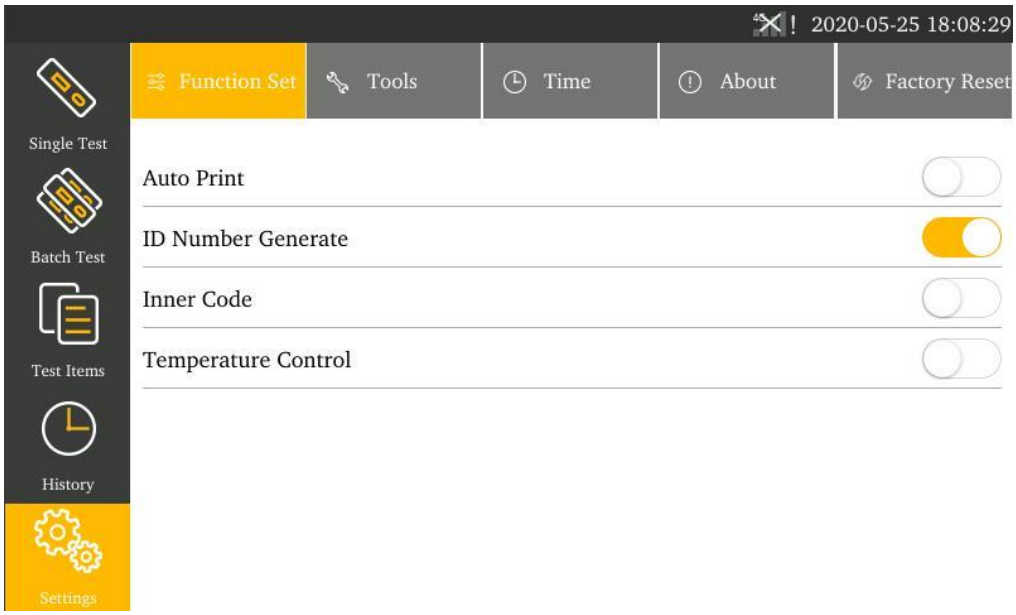
the analyzer. After that, you can proceed to single sample testing, batch testing, project management and historic record operation.

5.1 System setup

Click the “System Setup” button for a second-level menu to appear after entering the interface: function setup, tools, time setup, about, factory reset.

5.5.1 Function setup

Click ”Function Setup” to enter the following interface. Click the icon  behind corresponding item to select the setup item.



1 Auto printing:
on-print the result automatically after testing
off-print no result after testing
2 f ID number Generate:
on-generate an ID number automatically according to the date encoding
off-input an ID number manually
3 Inner Code:
on-scan built-in barcode to identify the testing item and batch number information before test
off-test directly without scanning the built-in barcode

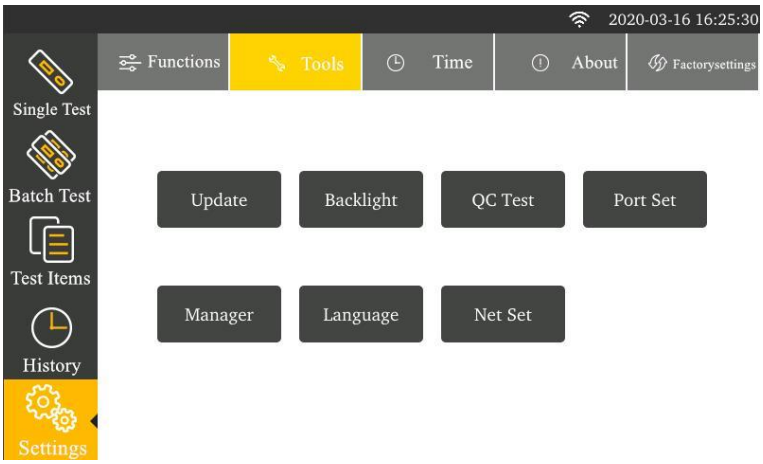
4 .Temperature Control :

On-Open temperature contro

Off--Turn off temperature control

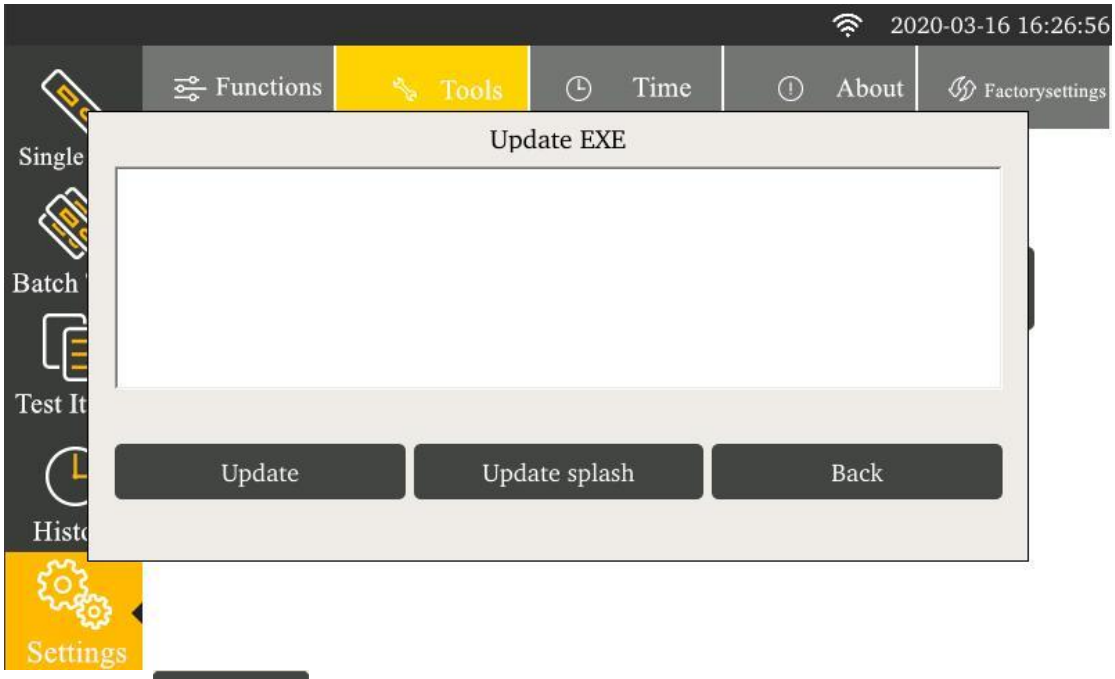
5.1.2 Tools

Click “Tools” to enter the follow interface. The main tools include: update, backlight 、QCtest, Port Set, Manager, Language and Net set.



I. Updating program

Click “Update” to enter the following interface.



Click 

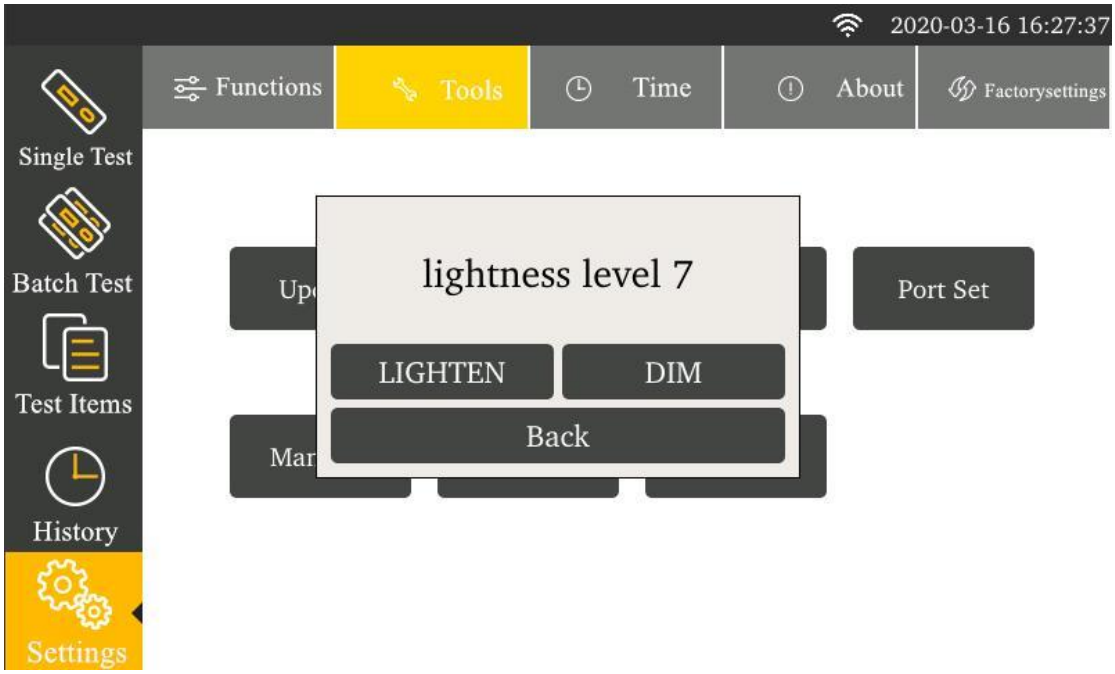
to copy the updating program package to a U-disk and insert

it into the USB port behind the analyzer. The analyzer obtains the program of a new version from the U-disk and updates the system.

After updating, the analyzer restarts.

II. Backlight adjustment

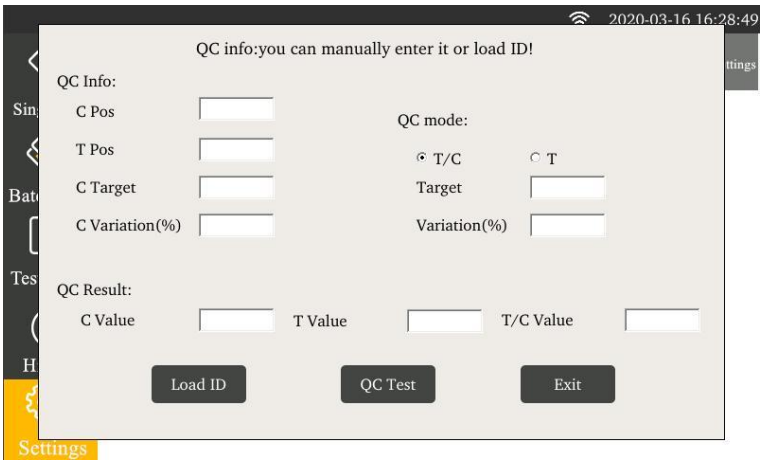
Click the “Backlight ” button to enter the following interface.



Click  or  to adjust the backlight brightness. Click  to complete the setup. Close the dialogue box.

III. QCTest

Click the”QC Test” button to enter the following interface.



Enter or insert the quality control ID card, you can obtain the quality control information. Click “QC Test” to start analyzer quality inspection.

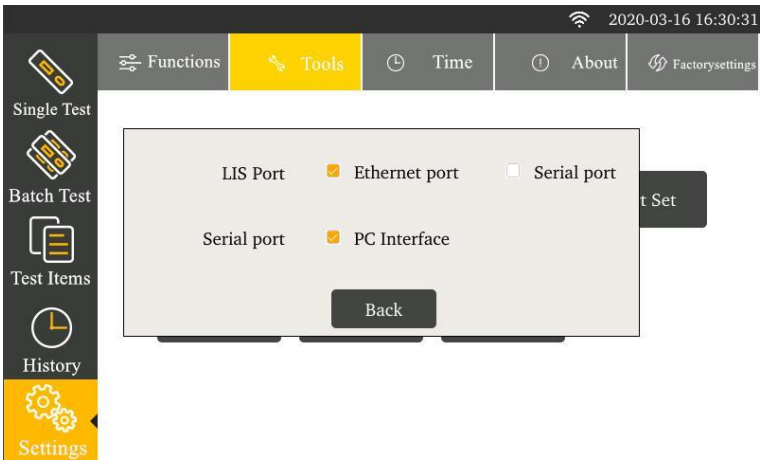
When passing the quality inspection, “quality Inspection Successful!” will display.

When not passing the quality inspection, “quality inspection failed!” will display.

If the quality inspection fails, you have to contact the manufacturer for analyzer commissioning and the testing result is invalid.

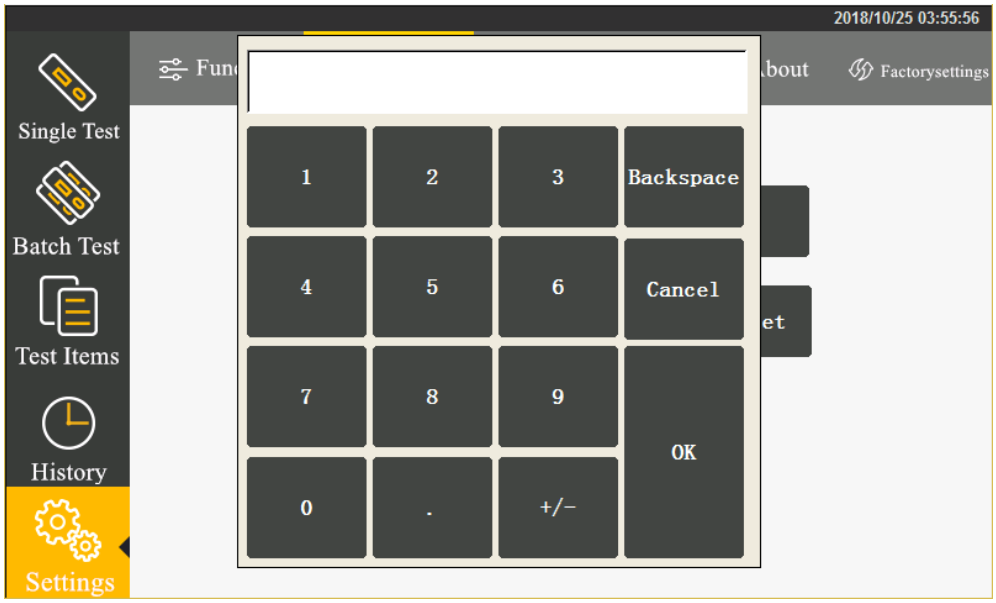
IV. Port set

By clicking “Port set”, you can set up the port of the analyzer connecting Lis. There is also a serial interface function.



V. Manger

The Manager function is available for professional technicians to commission the machine only.

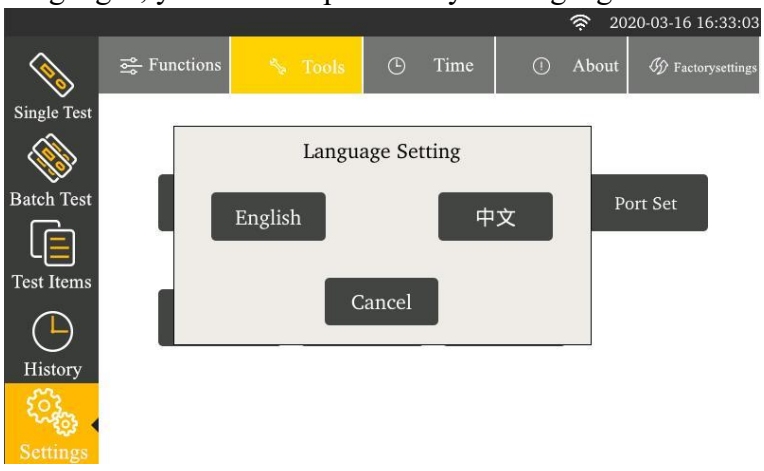


After entering the password, you can set up automatic testing, automatic testing interval, uploading cloud and uploading Lis.

Besides, the analyzer provides the following new tools: calibration tool, gain adjustment, save data, clear records and about the analyzer.

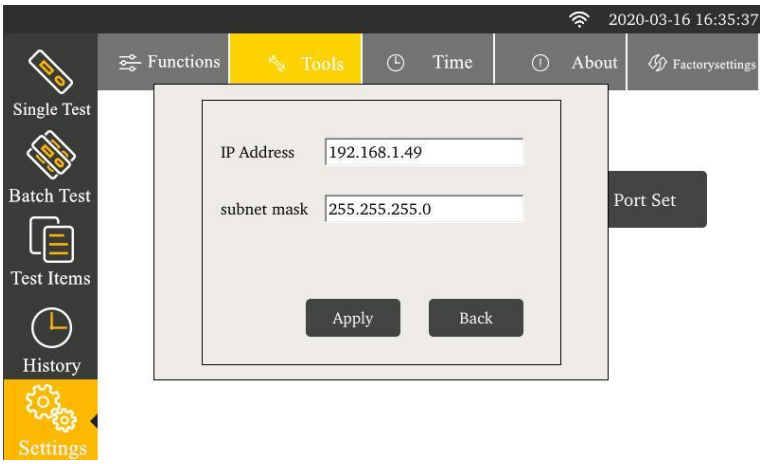
VI languge

By clicking “Language”, you can set up the analyzer language.



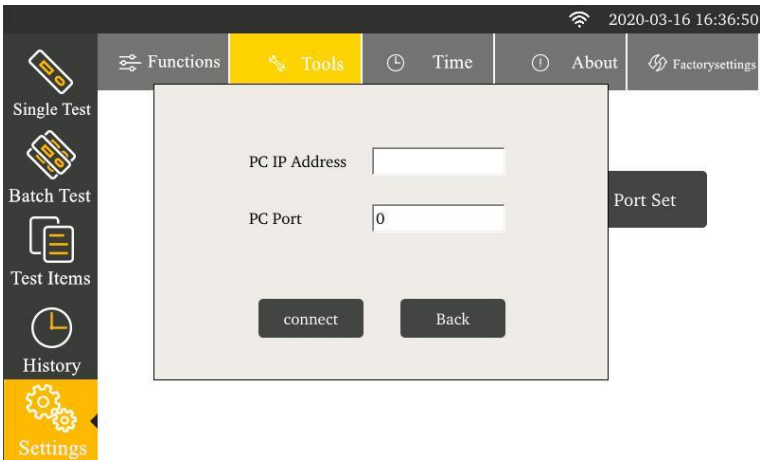
VII. Net Set

By clicking “Net Set”, you can set up the analyzer IP.

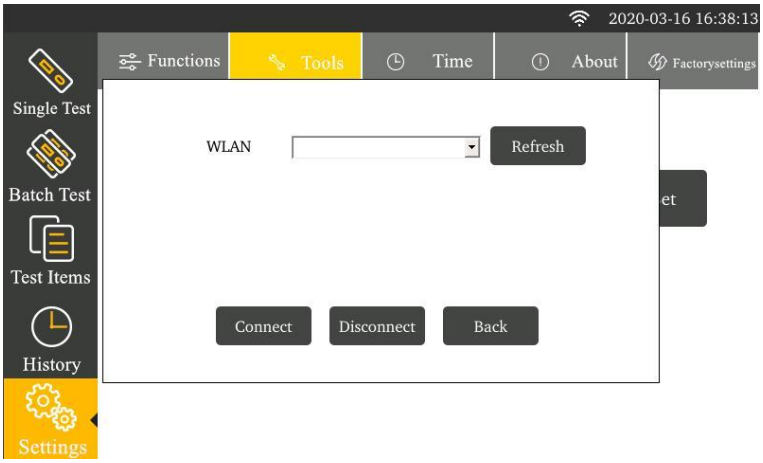


The analyzer IP setup will come into effect after restarting.

By clicking “Network Connection”, you can set up the computer IP address. After proper setup, you can connect the upper computer software by clicking “Connection”.

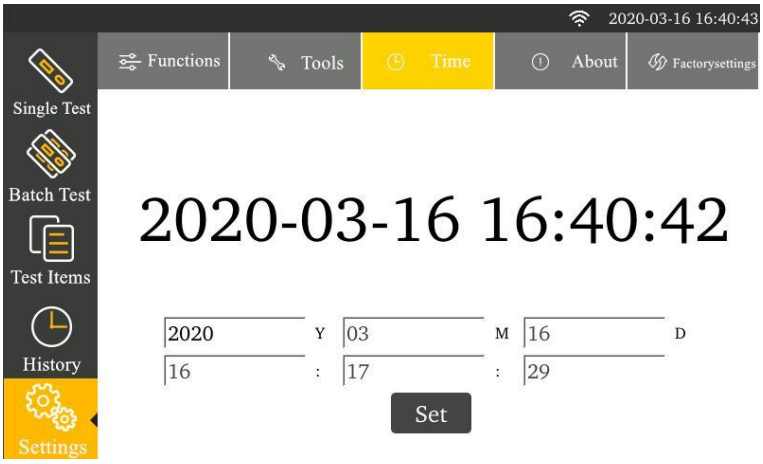


By clicking “WlAN”, Enter the following interface,Select the network, click connect, and enter the password.



5.1.3 Time setup

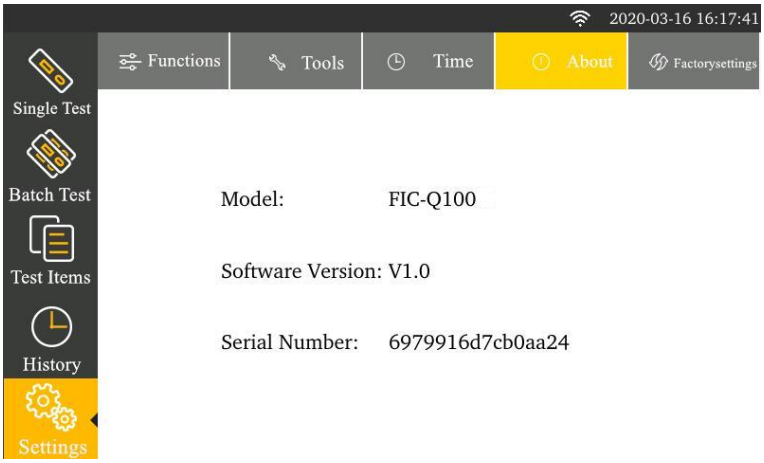
Click “Time Setup” to enter the following interface.



Enter the correct year, month, day, minute, second, to set the time.

5.1.4 About the analyzer

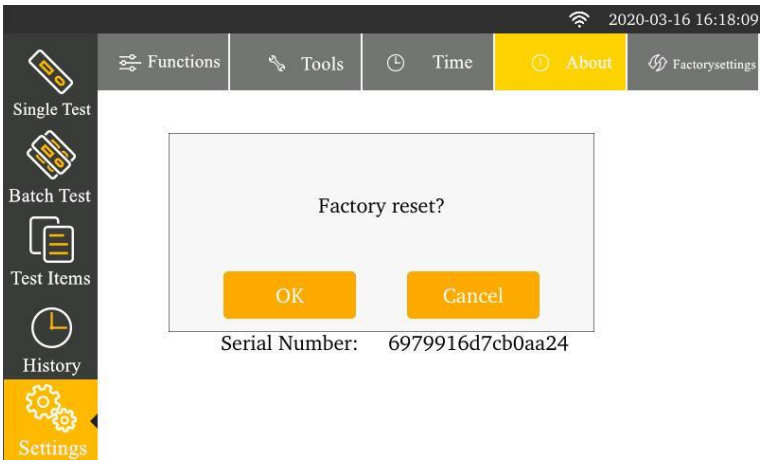
Click “About” to enter the following interface and display the model number and version information of the fluorescent immunoassay analyzer.



5.1.5 Factory reset

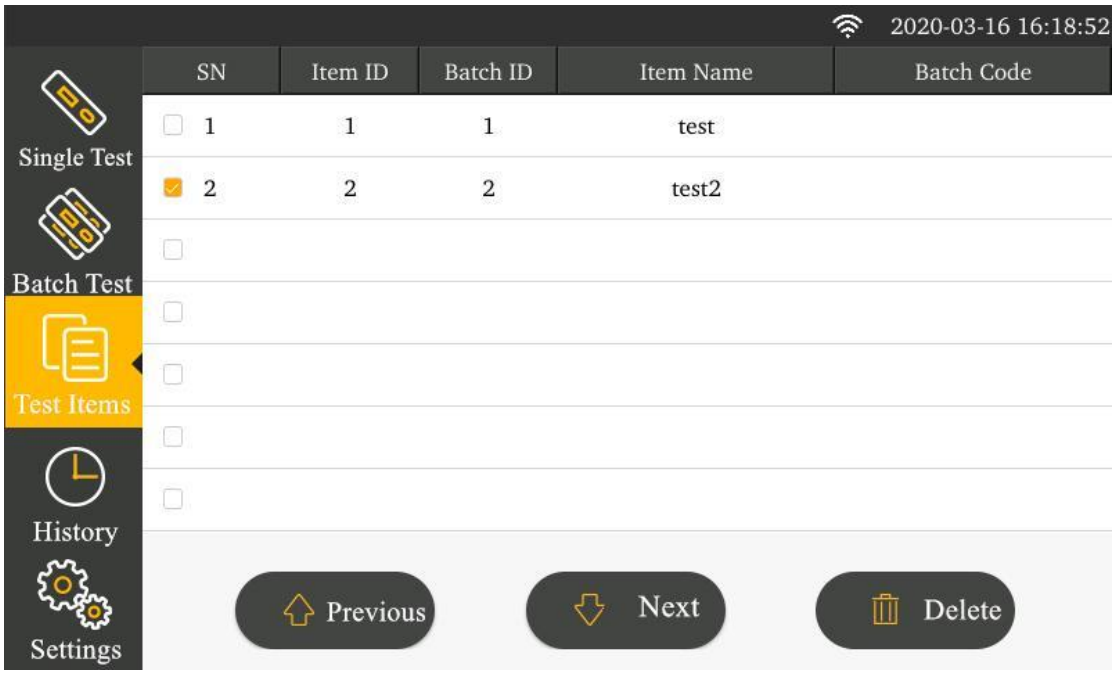
When clicking “Factory Reset”, a dialogue box will appear. You can clear all data to resume the ex-factory setup.

After resuming the ex-factory setup, the machine restarts automatically.



5.2 Test Items

Click “Test Items” to enter the following interface. Clicking corresponding item can select the examination information appropriate for current inspection.



Click “Previous ”, “Next ” to browse the inspecting items saved by the analyzer.

Click “Delete ” to delete the selected inspecting item information.

Here is the ID card import method:

Step 1: Insert the ID card into the ID card socket of the analyzer.

Step 2: The analyzer automatically reads the information in the ID card

Supplementary notes to ID card import:

1) Each item number and batch number have a unique corresponding examination

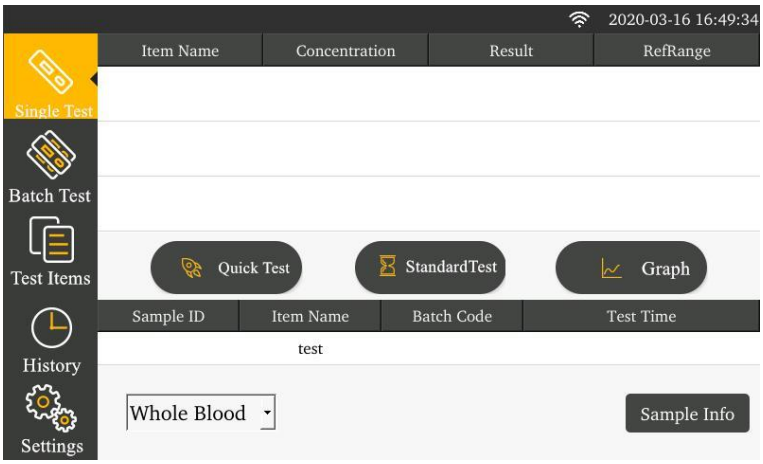
information data. Setting again will overwrite the original setup.

2) When inserting the ID card for the analyzer to scan for the matched barcode and complete one test, it will add the current ID card inspecting item to the list.

5.3 Single sample testing

Step 1: Install the analyzer properly and power on to start the same.

Step 2: Click “Single Sample Testing” to switch to the following interface



Step 3: select the sample type to be tested.

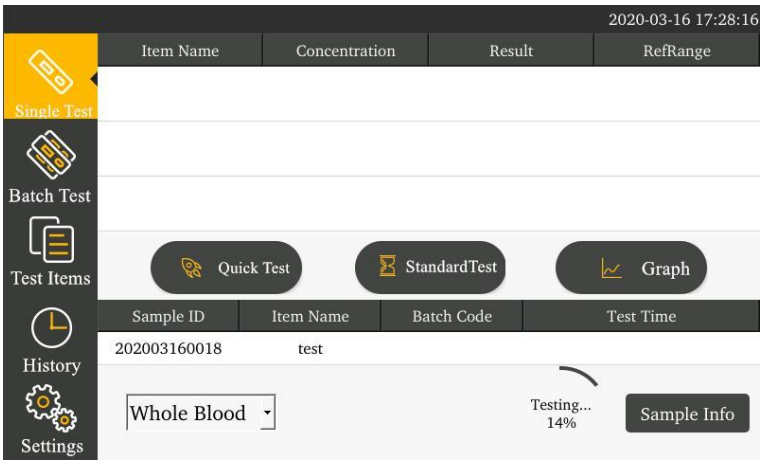
Step 4: Confirm the inspecting item and batch number information.

The current inspecting item and batch number information are set up in the project management. Refer to 5.2 Project Management when it is necessary to change.

Step 5: After obtaining the confirmation information, begin to test.

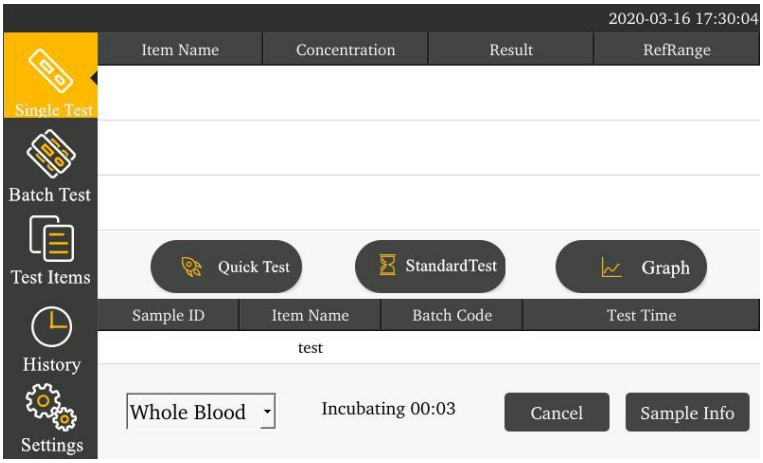
Click 

for the analyzer to start the motor scanning reagent card and begin to test.

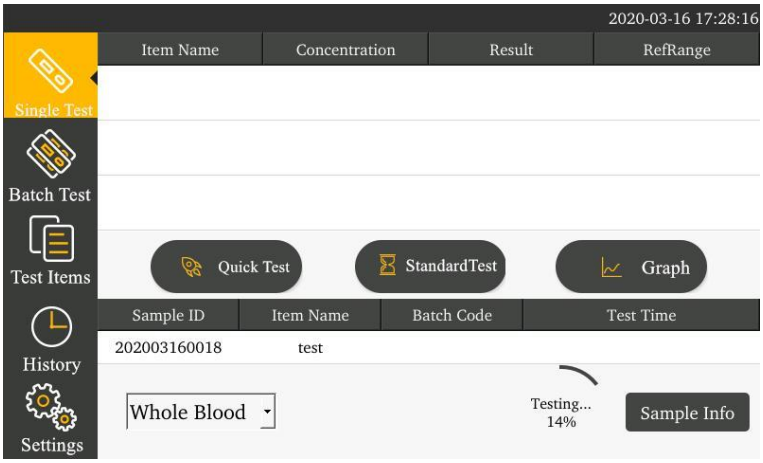


In case of clicking , 

the incubation time countdown will appear. The test will start only after countdown is finished.



After inspection is finished, the result will display.



Step 7: Result inspection operation

When the test is complete, the result will display on the interface list. By clicking 

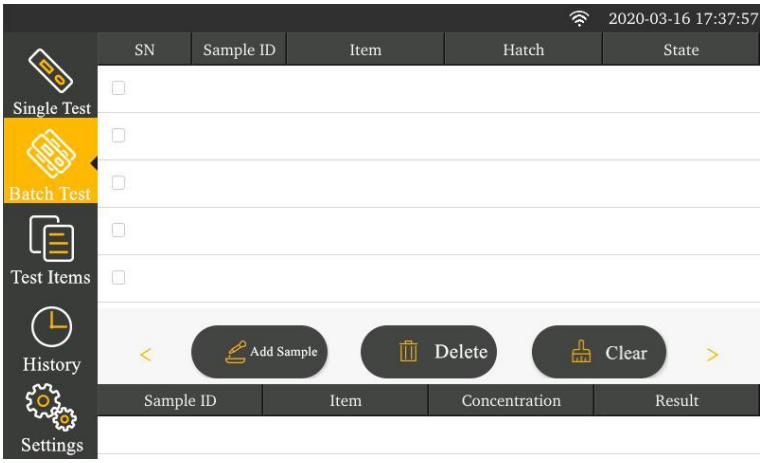
, you can check the detailed test result.

5.4 Batch testing

Here is the change in the batch testing state:

Begin to incubate－〉incubation under progress－〉please insert a reagent strip －〉 testing under progress –〉 please pull out the reagent strip

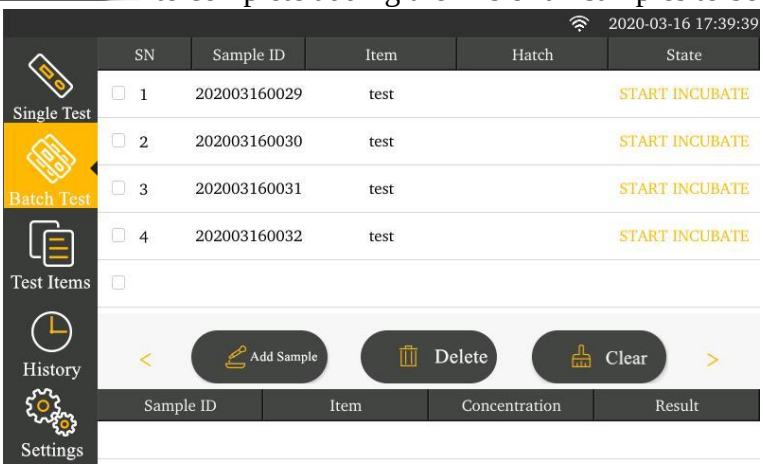
Click “Batch Testing” to switch to the following interface.



Step 1: Add samples.

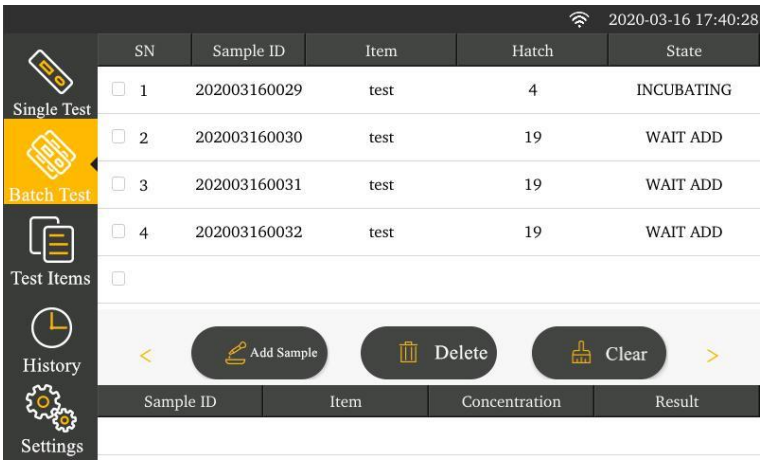
Click 

to complete adding the IDs of all samples to be tested.



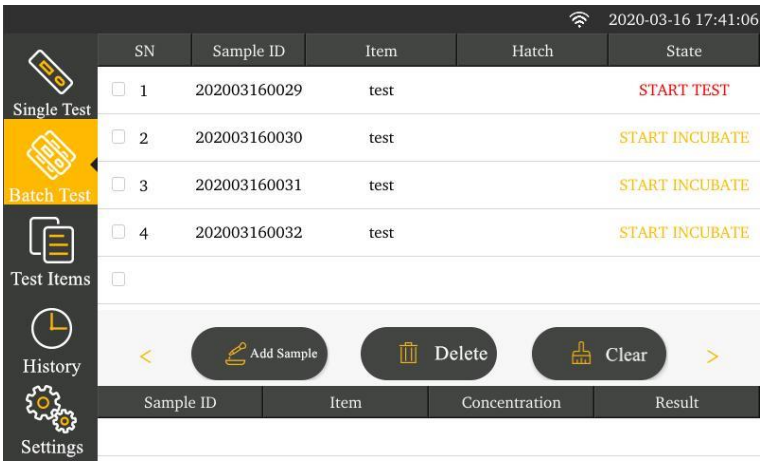
Step 2: Begin to incubate

Apply samples for the test paper strip. As soon as the sample application is complete, click “Begin to Incubate”. The current state changes and incubation countdown begins.

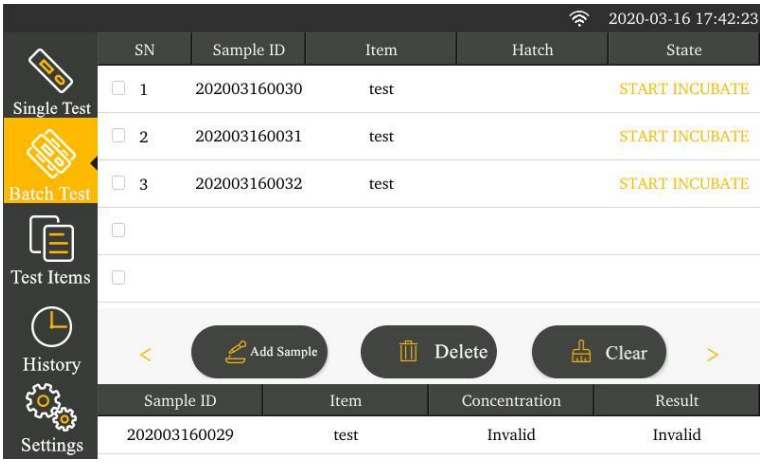


Step 3: Begin to test

When incubation timing is finished, click “Begin to Test”.



When the test is finished, the test result will display. No list will display and the sample test is completed.

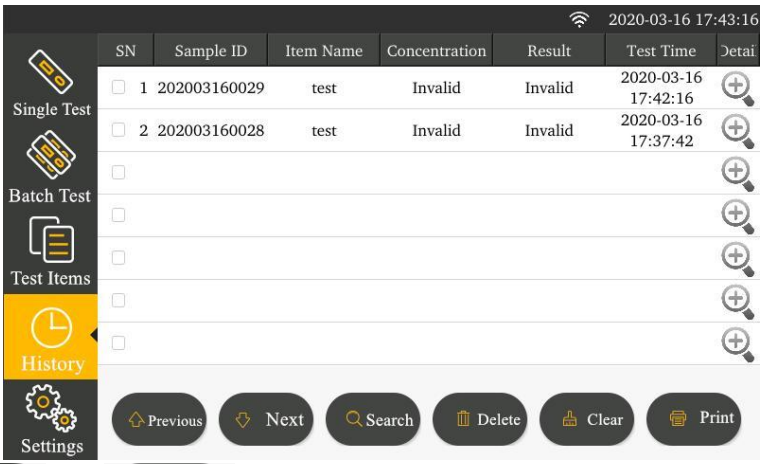


Step 4: Repeat the above operations for testing the next reagent strip.

5.5 History

Click the “History” button on the main menu page to switch to the following interface.

Provide record browse and record operation.



Click 

or 

to browse the inspection records.

Click 

to print the selected inspection result through the built-in printer;

Click 

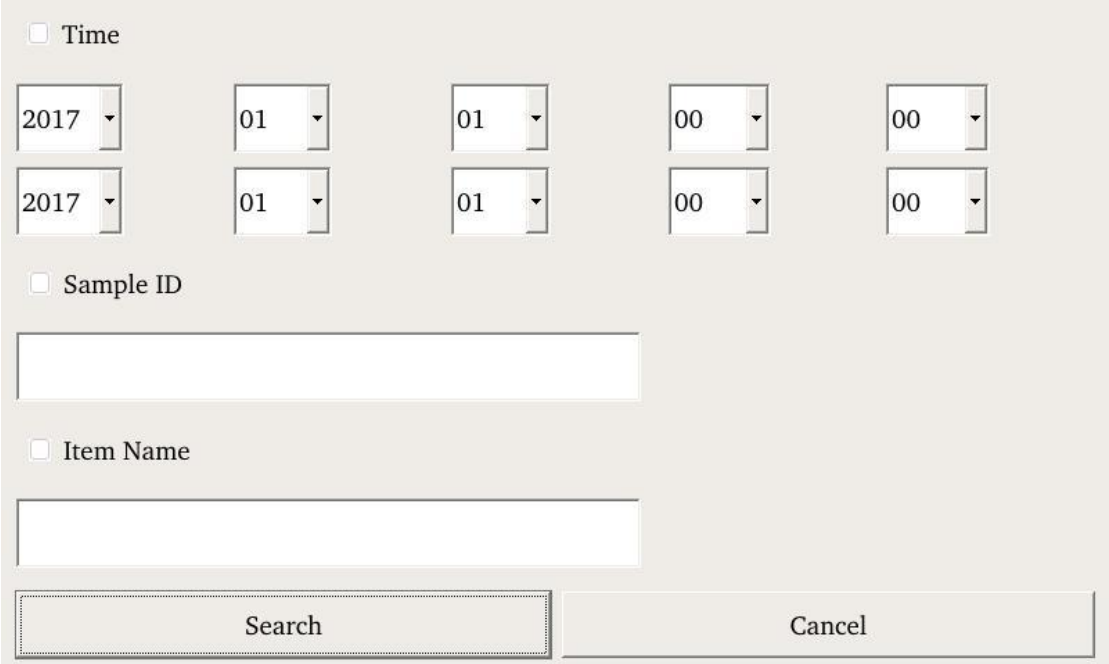
to delete a selected inspection record.

Click 

to clear all records.

Click 

to enter various screening conditions for record searching.



Check time, sample ID, item number and enter the retrieval field. By clicking the "Search" button, you can find corresponding record.

Chapter VI Quality Control

Upon first power on or each power on, test quality control product from reagent to control the quality. For quality control method, please refer to Chapter V 【System Settings】-【Quality Inspection】.

Attention:

The instrument can be tested after passing quality inspection. If quality control conditions are dissatisfied or quality control fails, the use of the instrument is prohibited! Contact after-sales service engineer timely and return the instrument for calibration or repair. If the instrument is tested upon failed quality inspection and consequently an improper diagnosis is caused, the Company assumes no liability.

Chapter VII Repair and Maintenance

7.1 Repair

1) Managerial personnel must inspect the instrument and parts regularly.
2) Inspect whether power line is deformed or broken visually. If any, a fire may be caused by electric leakage. Please contact service engineer about replacement of power line immediately.

7.2 Maintenance

1) The product just requires external cleaning and dust removal instead of special maintenance in daily use

2) Before cleaning and dust removal, turn off the power switch and disconnect USB cable.

3) While cleaning the product, clean the external surface using wet cloth and 70% ethyl alcohol instead of strong decolorizer (≥0.5% solution), because oxidizer and solvent may damage casing and touch screen of the instrument. Do not clean any internal part or internal surface.

 **Attention:**

Before cleaning the instrument, turn off the power switch and disconnect USB cable so as to avoid short circuit and electric shock!

7.3 Common Fault and Elimination Method

Fault Phenomenon	Possible Cause	Elimination Method
The instrument cannot be powered on	Dead battery	Charge the battery
	Battery failure	Contact after-sales engineer
The screen fails to display	The screen connecting line is loose	Contact after-sales engineer
Test result is invalid	Transmission part of the reagent card is invalid	Contact after-sales engineer

	The reagent card is invalid	Contact after-sales engineer
	Test part of the instrument is invalid	Contact after-sales engineer
The motor makes abnormal sound and gets stuck during test	Mechanical movement failure	Contact after-sales engineer
Other faults	Other faults	Please contact after-sales engineer timely

Chapter VIII Precautions

1) User;

a. Professionals of medical institutions
b. People trained by manufacturer

 **Attention**

Other people than the above mentioned are not allowed to operate the instrument; otherwise the Company assumes no liability for faults thus incurred.

2) Limits of toxic and harmful substances;

The content of toxic and harmful substances in all homogeneous materials of the parts should be below the specified limits of SJ/T 11363-2006 *Requirements for concentration limits for certain hazardous substances in electronic information products*.

3) Potential safety maintenance and use restrictions;

Potential biohazards which exist when the sample is tested using the product should be disposed of according to safety requirements for test species of hospitals when the sample is disposed of and operated. Please do not put hand or any article into a moving part during test.

4) If an accident occurs when the product is used correctly, adopt protective measures for operator and user and appropriate emergency and corrective measures;

The probability that an accident occurs when the product is used correctly is very low. If an

accident occurs, please cut off the power immediately.

5) Necessary monitoring, evaluation and control methods;

Please inspect the quality of the instrument using quality control card every month so as to evaluate whether the instrument works normally. User may reduce the quality control cycle according to actual service condition.

6) Potential mutual interference with other products and potential hazards;

 **Attention**

1. Whereas the product may be affected by electromagnetic interference during operation and consequently the test result may be invalid, please keep the product far away from strong electromagnetic interference in use.

2. Whereas the product may emit electromagnetic wave during operation, please keep the product far away from electromagnetic sensitive equipment in use.

7) Potential adverse events

The product is an in vitro diagnostic device and adverse events have not been observed yet. Whereas the tested specimen may be biologically infective, please avoid direct skin contact with the reagent card and the sample inlet.

The instrument should be cleaned and disinfected in use or before transportation, maintenance and storage, so as to prevent pollution and potential biohazard.

8) Other notices

a. Diagnosis and treatment cannot be based on the test result only, please consider clinical history and other test results simultaneously.

b. Be sure to use the kit provided by the manufacturer and attached to the instrument and confirm the applicability before use.

c. Be sure to import the standard curve using ID Card attached to the reagent and conduct a

test.

d. Normal use of the instrument will be automatically saved in the instrument in the form of at most 4000 records. Data will not be lost in case of power failure and can be cleared by “Factory Reset”.

Chapter IX Service, Maintenance and Destruction

The product just requires cleaning instead of special maintenance. When necessary, please consult 0512-67508871for service or maintenance.

Key parts of the product such as circuit board, optical detection model and display screen must be detected and replaced by our company and cannot be maintained by third parties.

If the product breaks down and consequently works abnormally, please consult 0512-66806823. We will provide technical support and guide customers to eliminate faults. If recall is needed, please post the product back. If obsolescence is needed during the warranty period, we will provide a new product.

If destruction is needed for some reason, user may destruct the product according to regulation on class B electronic instrument.

Hereby we declare that the aforesaid service guarantees are available only for full compliance with the User Manual. The Company assumes no liability for other damages.

Registrant/Manufacturer/After-sales Service: Suzhou Helmen Precision Instruments Co., Ltd.

Domicile: 4th floor, building 5, 8 jinfeng road, high-tech zone, suzhou city

Production Address: 4th floor, building 5, 8 jinfeng road, high-tech zone, suzhou city

Tel: 0512-67508871

Fax: 0512-67508871

Post Code: 215163

Website: www.helmence.com

EC Authorized Representative

Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail：peter@lotusnl.com

Tel：+31644168999

Date Prepared: Marcht, 2020

Date of Manufacture: See the label

Validity Period: See the label