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Jet-iStar 800 Analyzer Instructions for use (Model: Jet-iStar 800)

Joinstar Biomedical Technology Co., Ltd.

Contents

Chapter I. Information for Operation

Thank you for selecting the fluorescent immunoassay analyzer of Joinstar Biomedical Technology Co., Ltd. This product is a fluorescent immunoassay system based on the photoelectric testing principle, and the operation of which needs to have special-purpose fluorescent immunoreagents for supporting. This analyzer is high in testing accuracy, excellent in stability, fast in testing speed and low in costs. Its application in multiple fields such as disease detection, healthcare, epidemic monitoring, food inspection and quarantining is wide.

The present Operation Instructions apply to Model **Jet-iStar800** series. The specifics are subject to the actual interface operation.

The present Operation Instructions describes in detail the product characteristics and related information. The illustrated operating steps are convenient for use by you. Before using this analyzer, please read the present Operation Instructions in detail.

1.1 Introduction of the analyzer

1 Model number/specification: Jet-iStar800
2 Basic dimensions: 280*240*130 (length x width x height, unit: mm);

1.2 Scope of application

The fluorescent immunoassay analyzer needs to have a series of supporting fluorescent immunoreagent cards for common use. It is only available for medical laboratory test professional to do in vitro diagnostic experiments. It can be applied in the central laboratories, outpatient/emergency test laboratories, clinic sections and other medical service points (such as community medical points), physical examination centers, etc. of medical institutions, and also applied to scientific research laboratories.

Chapter II. System assemblies and main structure

After unpacking, please check according to the following standard configuration list for any missing or damaged assembly.

Note: When finding any missing or damaged assembly, please contact with Joinstar Biomedical Technology Co., Ltd. and your local sales representative. For contact details, please refer to Chapter X. of the Operation Instructions.

2.1 Standard configuration list of analyzer

S/N	Name	Qty.	Unit
1	Fluorescent immunoassay analyzer	1	Set
2	Power supply adapter	1	Set
3	Printing paper	1	Roll
4	Program disc	1	Piece
5	Data cable	1	Piece
6	Scanner	1	Set

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

Scanner

Barcode and QR code (on the package of the reagents)

Explanation to product symbols

Number	Symbol	Explanation
1		Attention, refer to the attached text
2		Vitro diagnosing apparatus
3		Biological risk

Chapter III. Basic parameters and operating conditions of analyzer

3.1 Basic parameters of analyzer

Interface RS232, USB, network interface

Printing Built-in thermal printer

Power AC100~240V,50/60Hz,48VA

Repeatability CV≤10%

Stability σ≤10%

Accuracy Δn ≤10%

Linearity r≥0.99

Measuring range 1000 times

3.2.1 Transportation and storage conditions of analyzer

After packaging, it should be stored in a well-ventilated environment free from condensation, corrosive gas and at -40℃～55℃, RH ≤93% and an atmospheric pressure (86~106) kPa.

Take care to prevent moisture, impact and strong vibration in transit.

3.2.2 Normal working condition of analyzer

1) Ambient temperature range: 5℃-40℃;

2) Relative humidity range: no more than 80%;

3 Atmospheric pressure range: 700hpa-1060hpa;

4) AC100~240V,50/60Hz,48VA.

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 Power supply voltage requirement

That analyzer uses power AC100~240V,50/60Hz supply. The input voltage is DC 12V. The power of the analyzer is 48VA. Take care to avoid short circuit and electric shock danger during operation! The analyzer connects to ground through power supply adapter.

Note: In all circumstances where that symbol is marked, it is imperative to consult relevant documents.

Chapter IV. analyzer installation

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

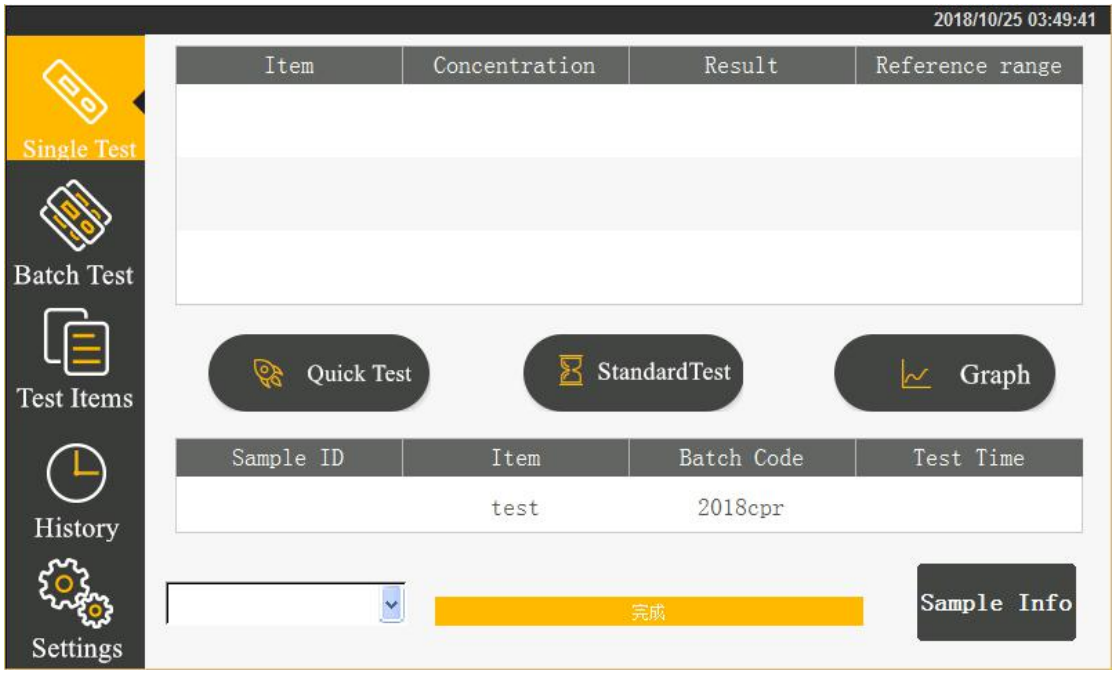
1 Place the fluorescent immunoassay analyzer on a stable operating table.

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.



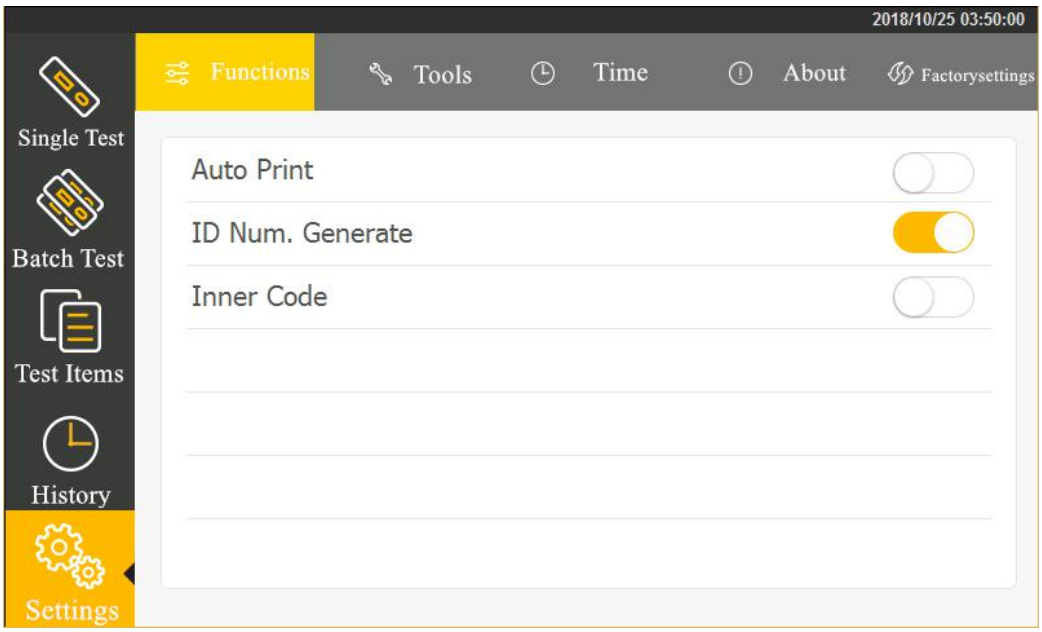
Complete system setup according to the practical operation need before operating the analyzer. After that, you can proceed to single sample testing, batch testing, project management and historic record operation.

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.

5.1.1 Function setup

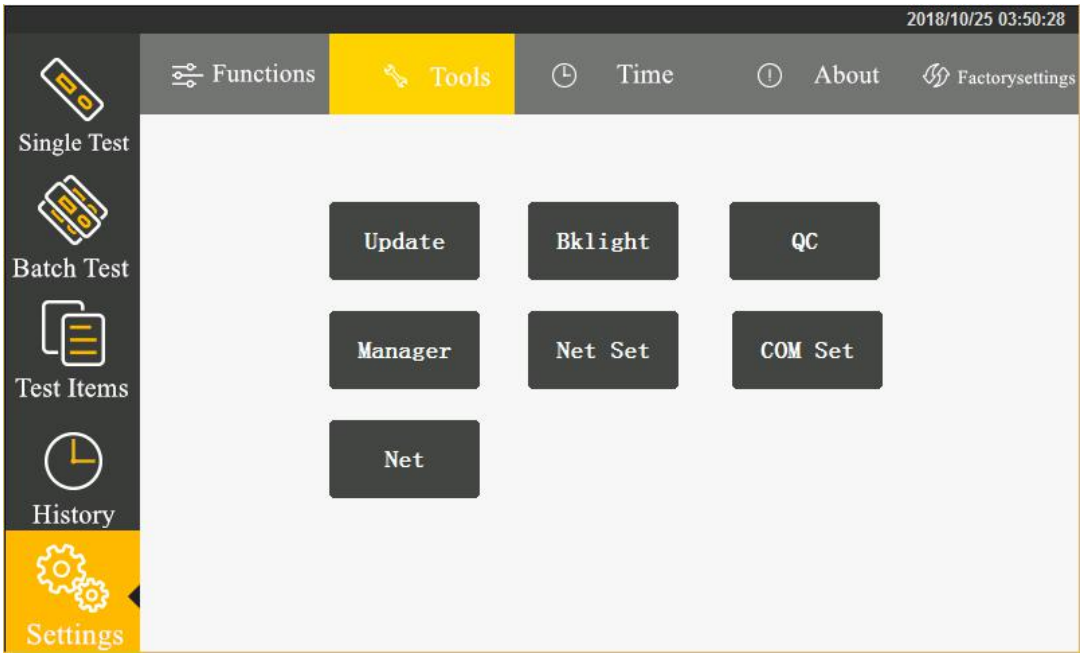
Click ”Function Setup” to enter the following interface. Click the icon  behind corresponding item to select the setup item.



1 Start auto printing:
on-print the result automatically after testing
off-print no result after testing
2 Automatic generation of ID number:
on-generate an ID number automatically according to the date encoding
off-input an ID number manually
3 Start the built-in barcode:
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

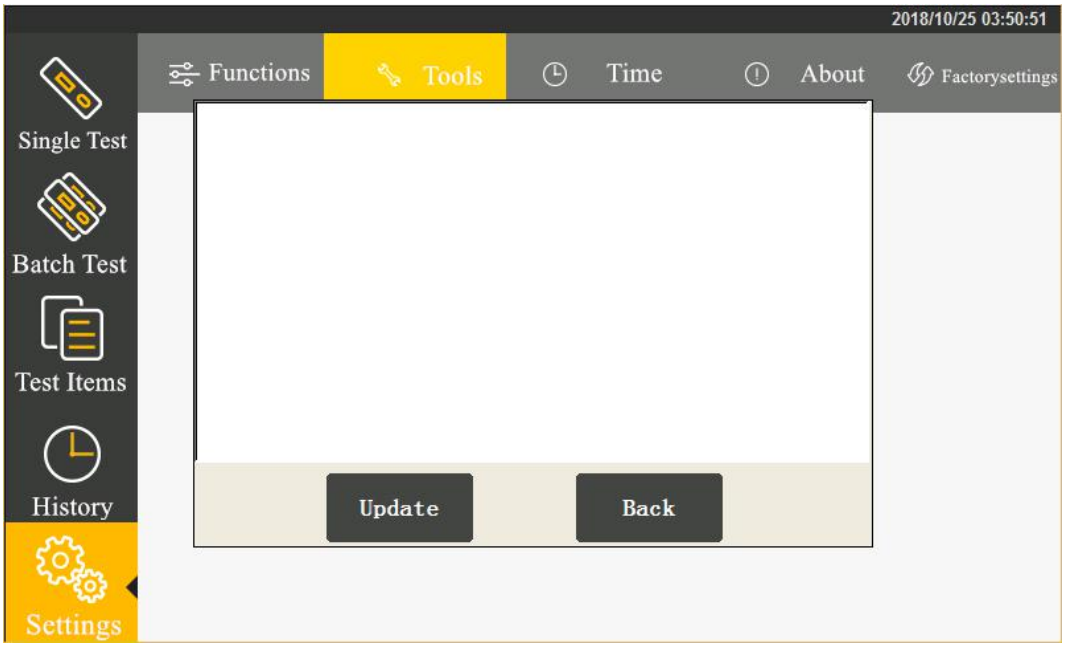
5.1.2 Tools

Click “Tools” to enter the follow interface. The main tools include: updating program, backlight adjustment, quality inspection, administrator, network configuration, port configuration and network connection.



I. Updating program

Click “Updating Program” to enter the following interface.



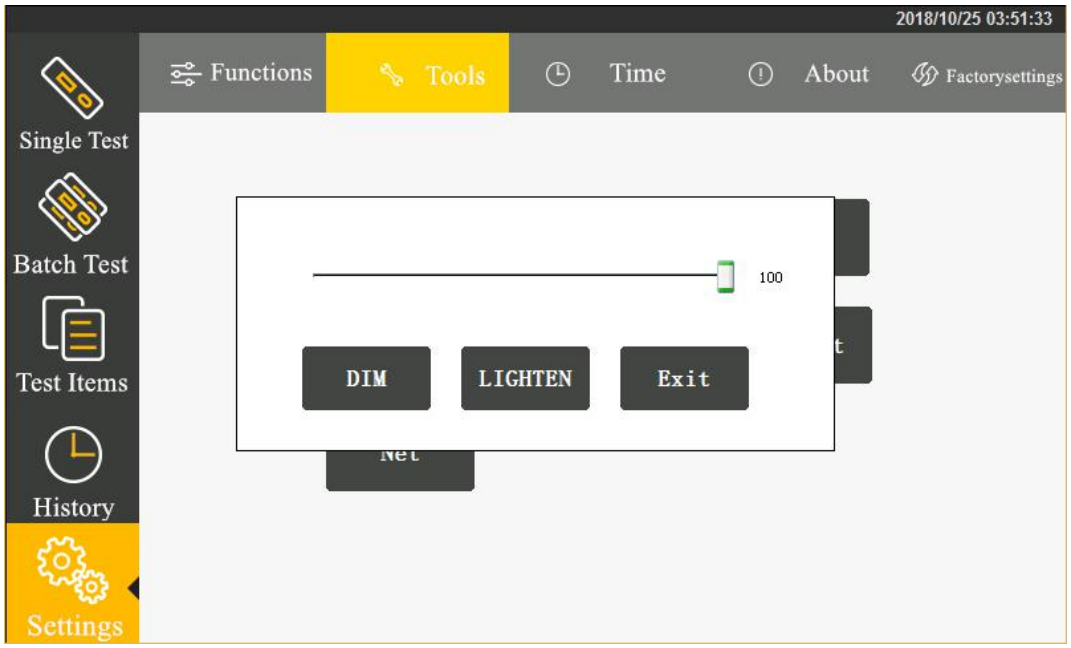
You can select network updating or u-disk updating.

Click Update 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

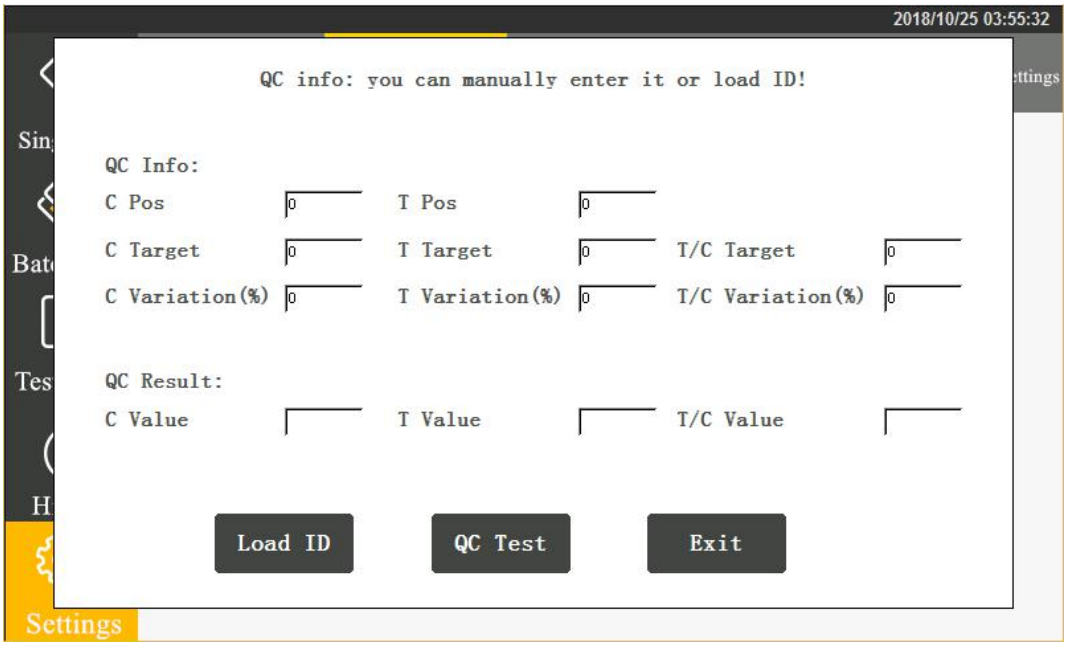
Click the “Backlight Adjustment” button to enter the following interface.



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

III. Quality inspection

Click the “Quality Inspection” button to enter the following interface.



By scanning the quality inspection 2D code, you can obtain the quality control information. Click “QC Test” to start analyzer quality inspection.

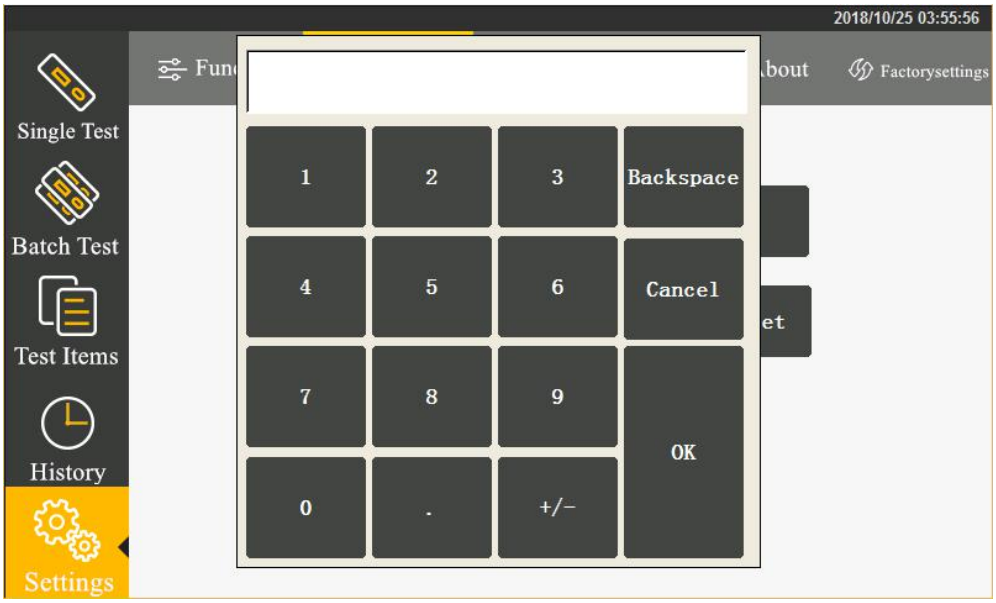
When passing the quality inspection, “Quality inspection successful!” will display.

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. Administrator

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

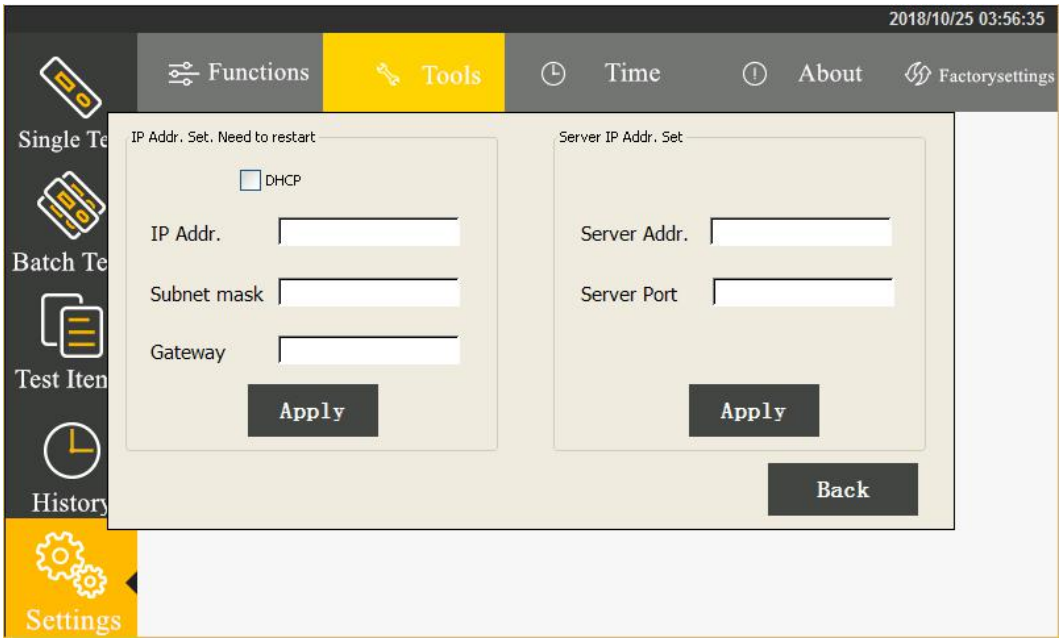


After entering the password, you can set up automatic testing, automatic testing interval, uploading cloud and uploading Lis.

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

V. Network configuration

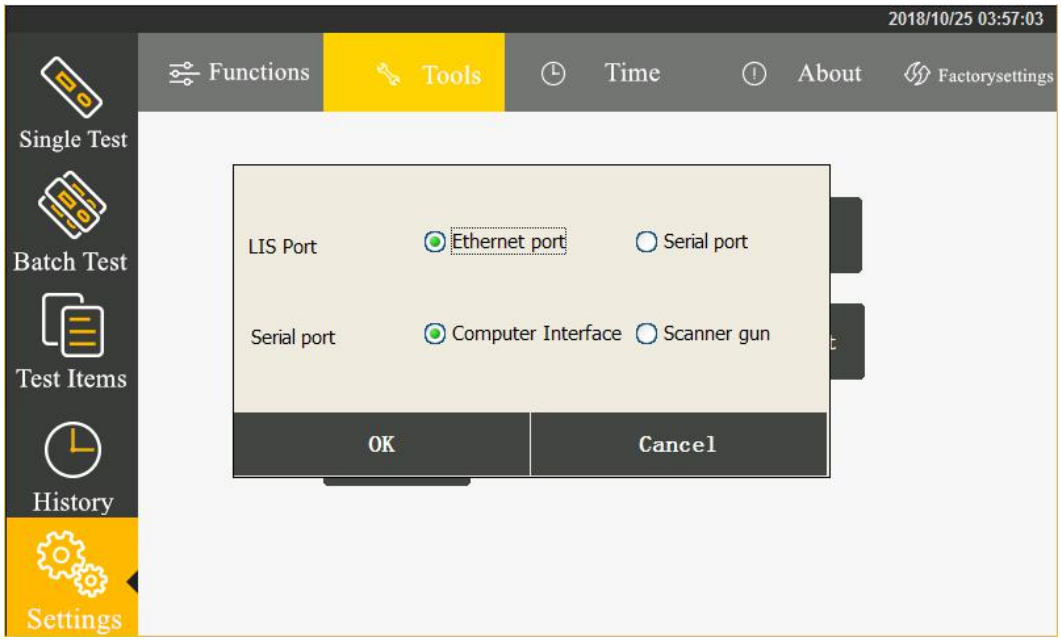
By clicking “Network Configuration”, you can set up the analyzer IP.



The analyzer IP setup will come into effect after restarting.

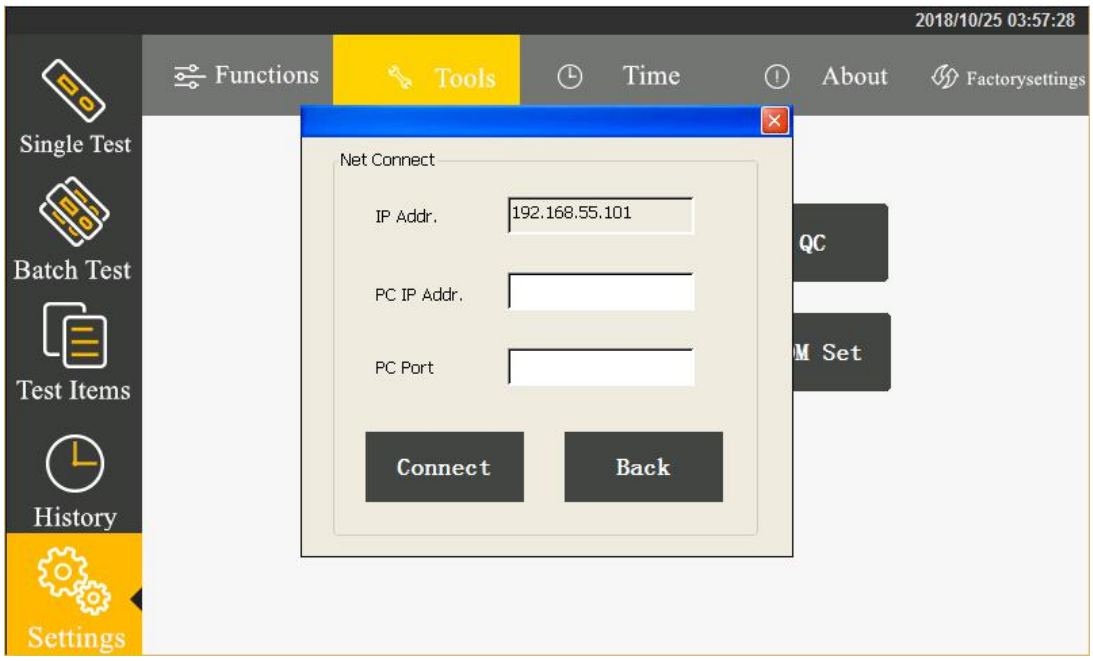
VI. Port configuration

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



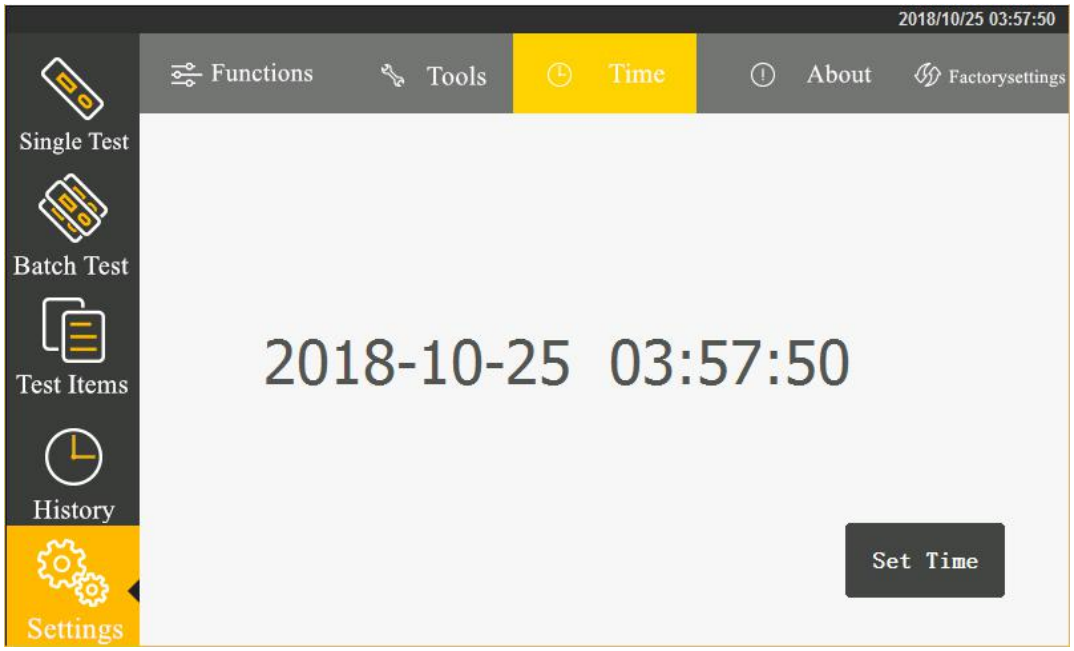
VII. Network connection

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”.

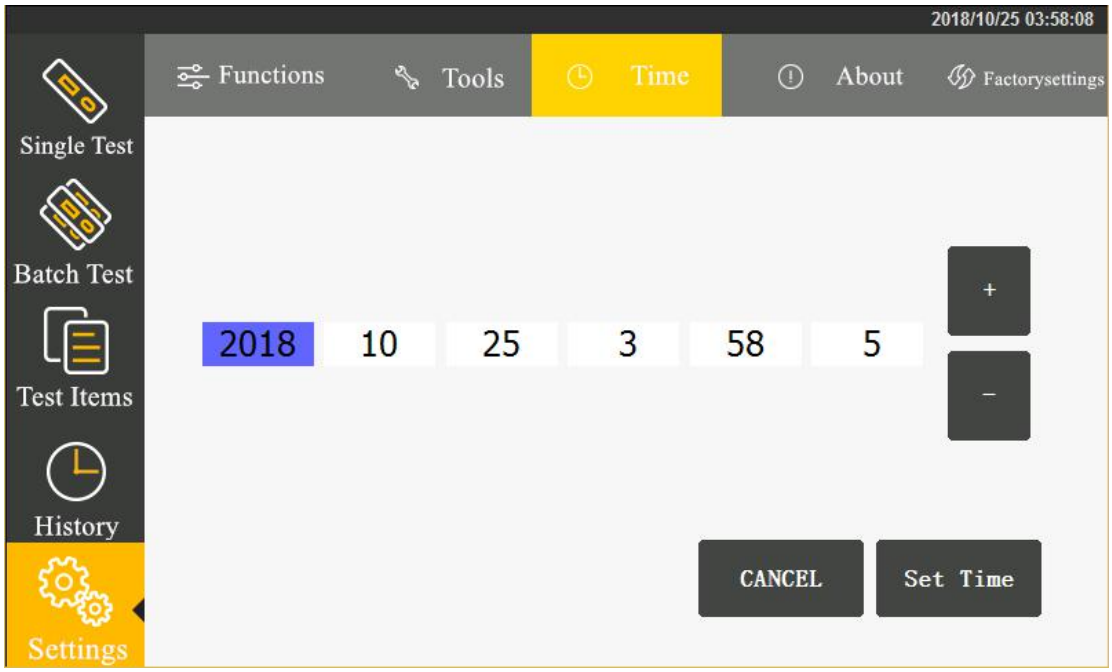


5.1.3 Time setup

Click “Time Setup” to enter the following interface.

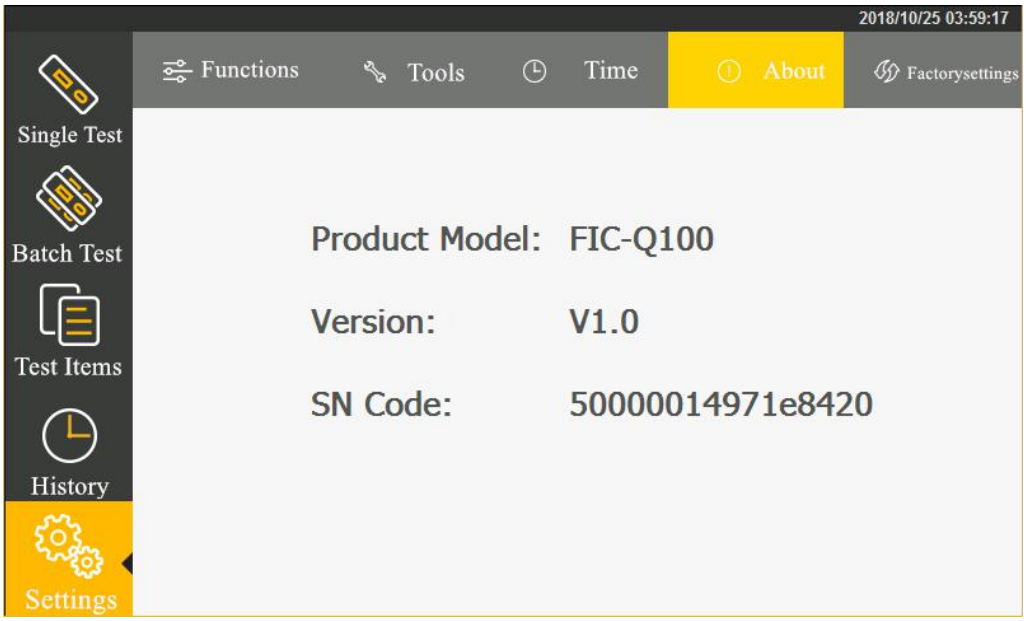


By clicking “Time Setup”, you can set up time. Click the field to be modified and press the signs +, - for adjustment. After modification, click “Time Setup” to confirm the modification. Clicking “Cancel” can cancel time modification.



5.1.4 About the analyzer

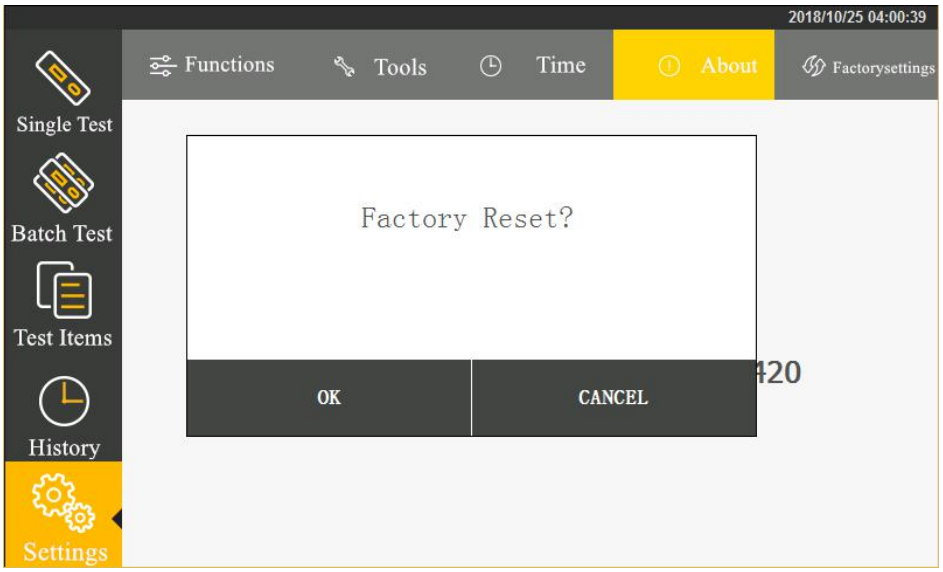
Click “About” to enter the following interface and display the model number and version information of the fluorescent immunoassay analyzer.



5.1.5 Factory reset

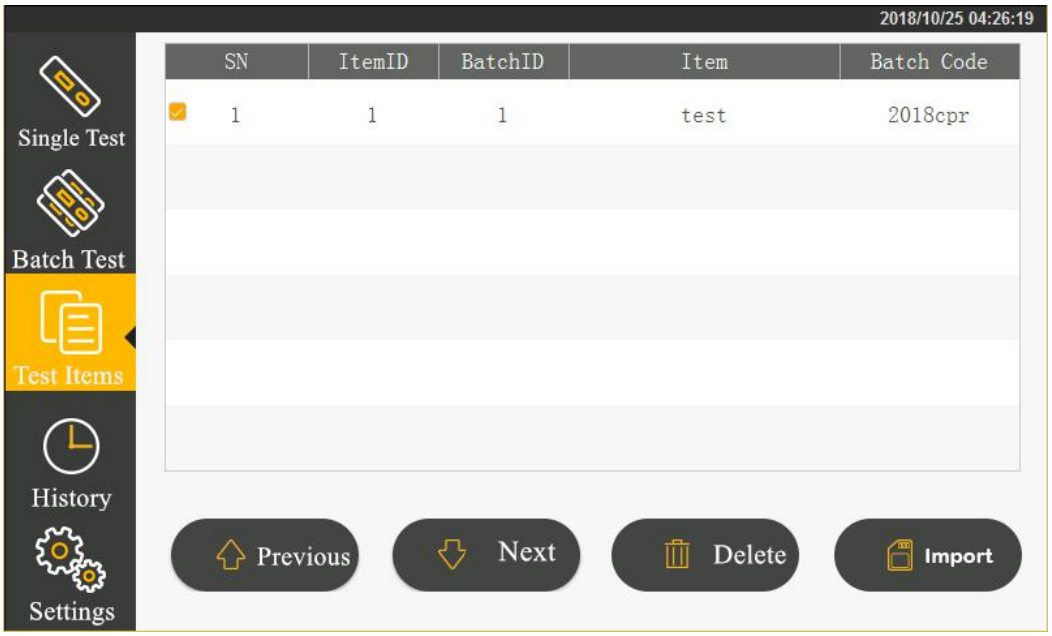
When clicking “Factory Reset”, a dialogue box will appear. You can clear all data to resume the ex-factory setup.

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



5.2 Project management

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



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

Click “Delete the Selected” to cancel the selected inspecting item information.

How to import test items:

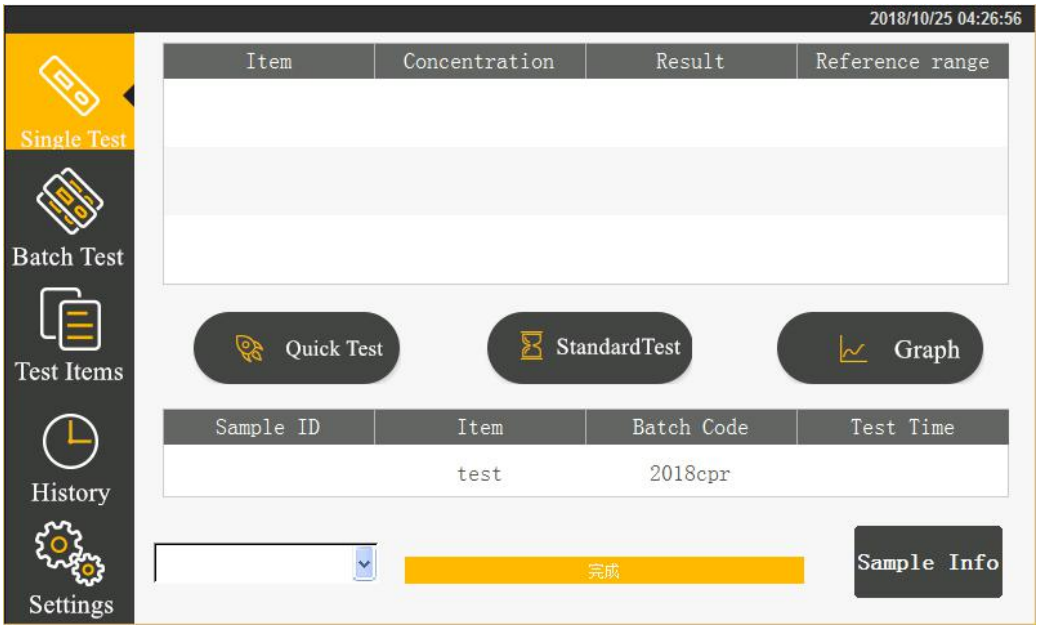
Step 1: Connect the scanner to the USB-COM port of the analyzer.

Step 2: Scan the QR code on the reagent package.

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.

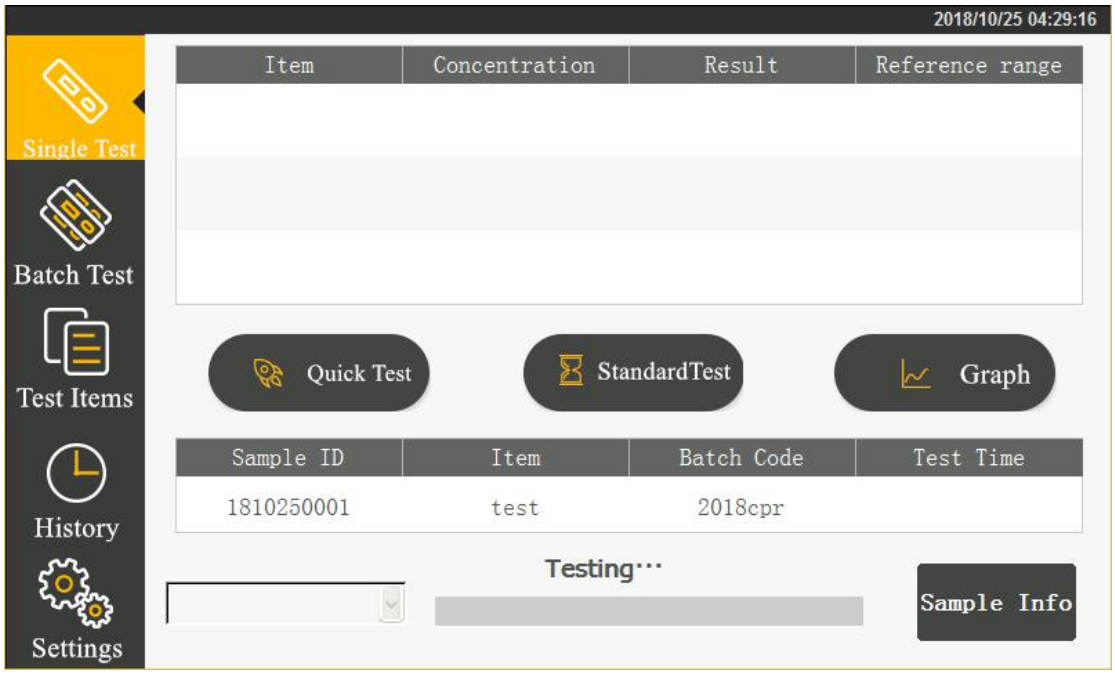
Step 4: Confirm the inspecting item and batch number information.

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.

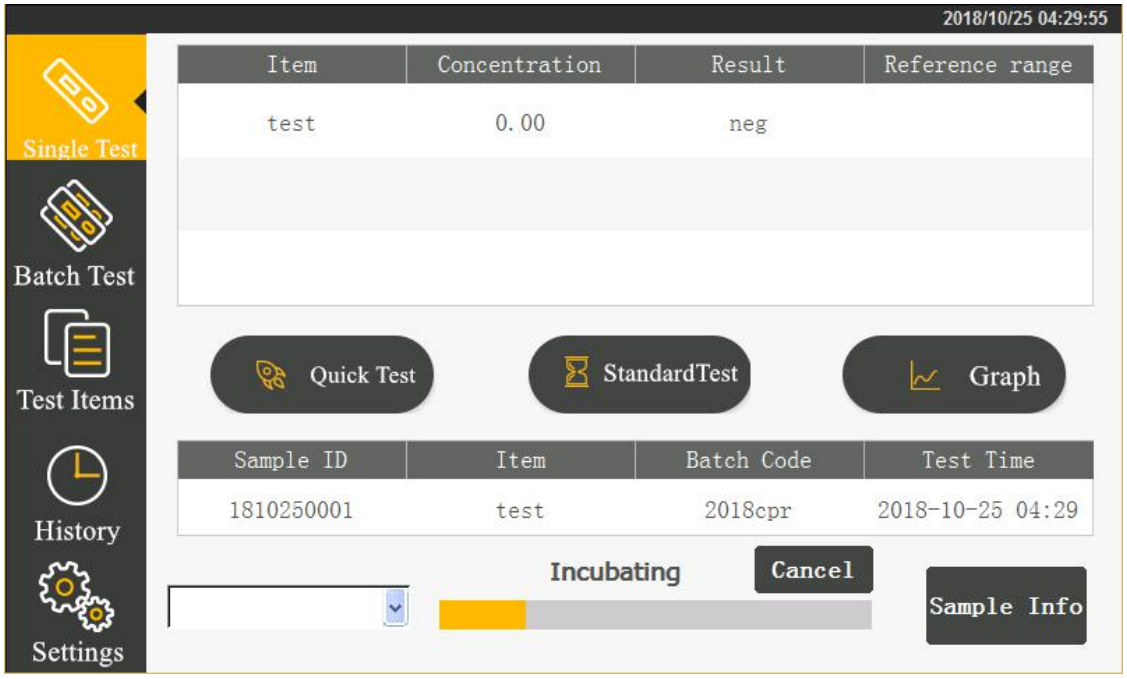
Click 

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

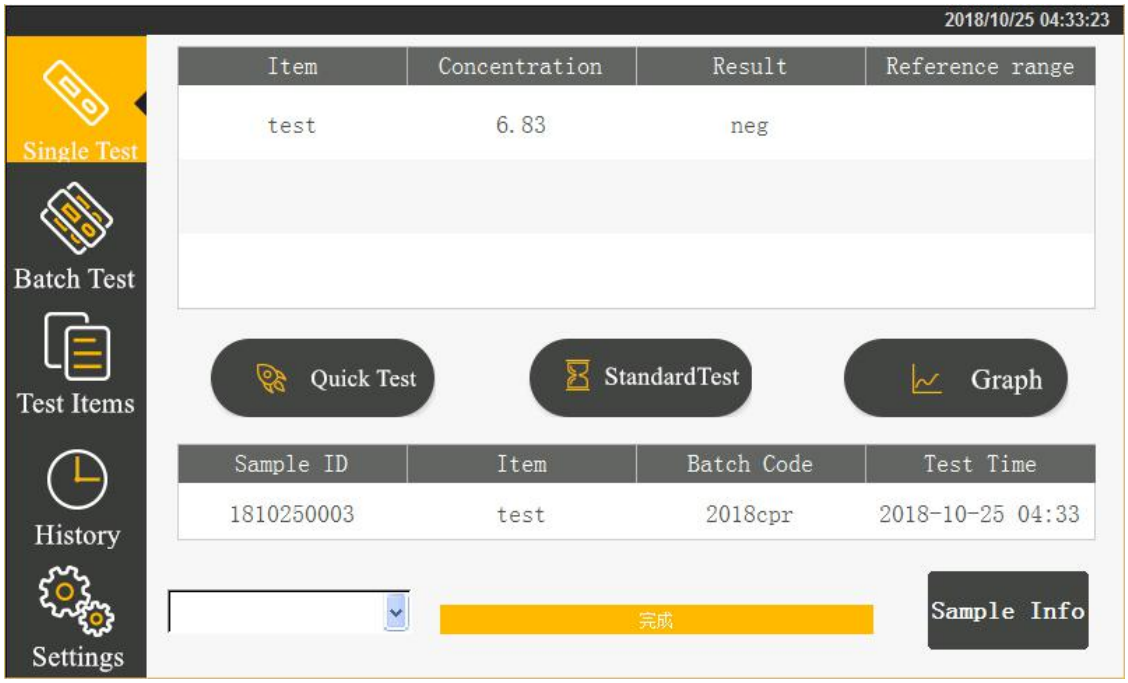


In case of clicking , 

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



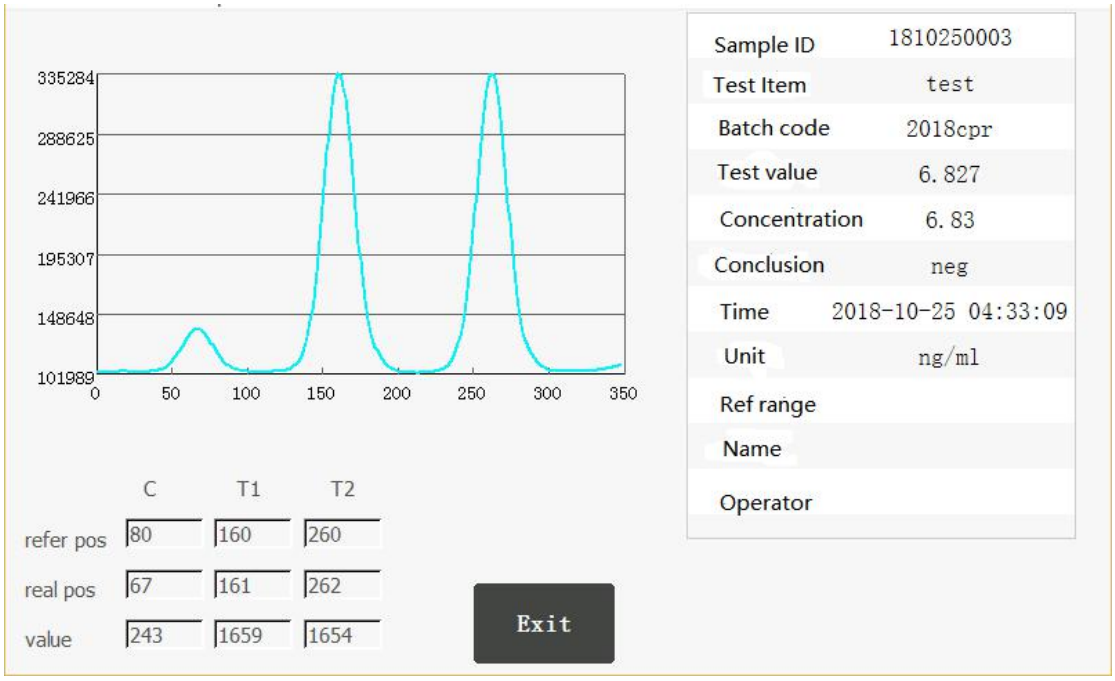
After inspection is finished, the result will display.



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.

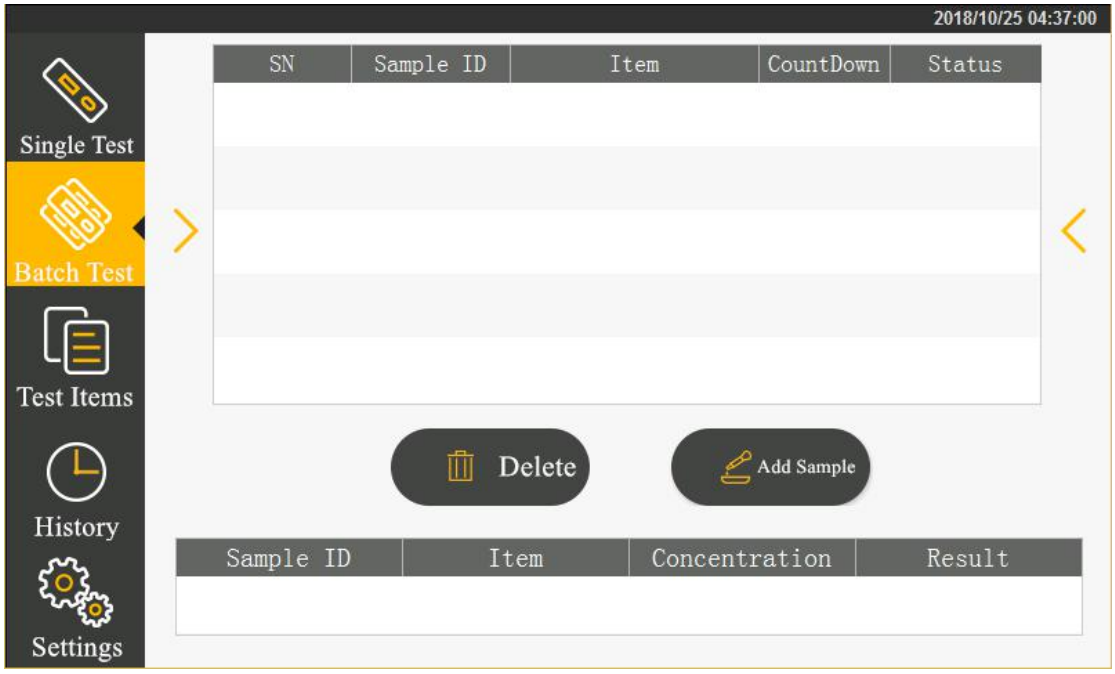


5.4 Batch testing

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

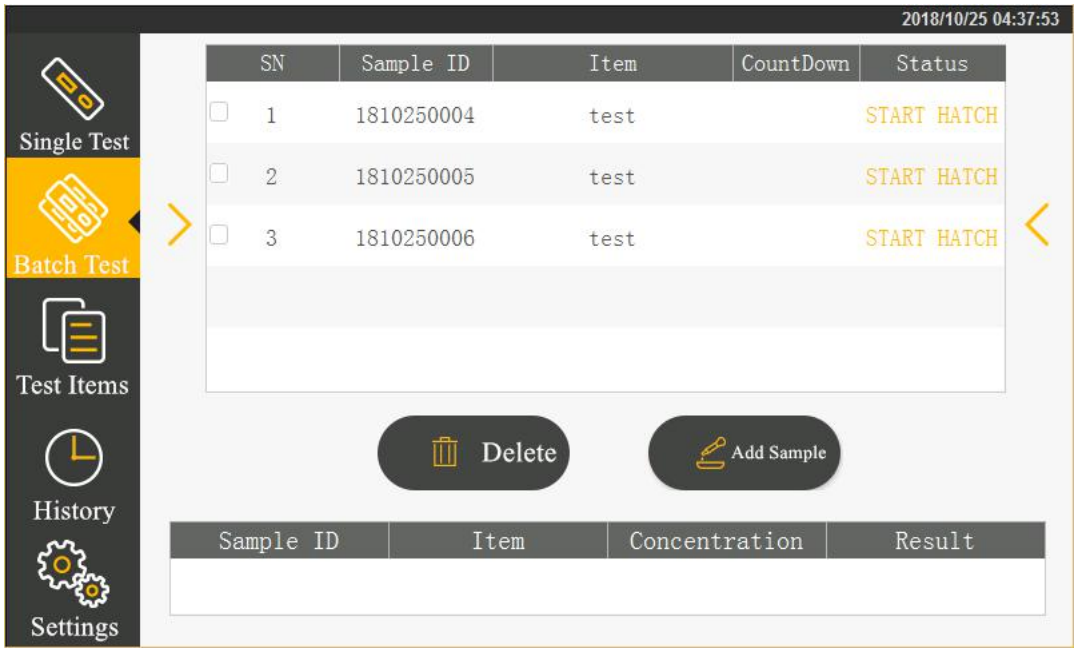
Click “Batch Testing” to switch to the following interface.



Step 1: Add samples.

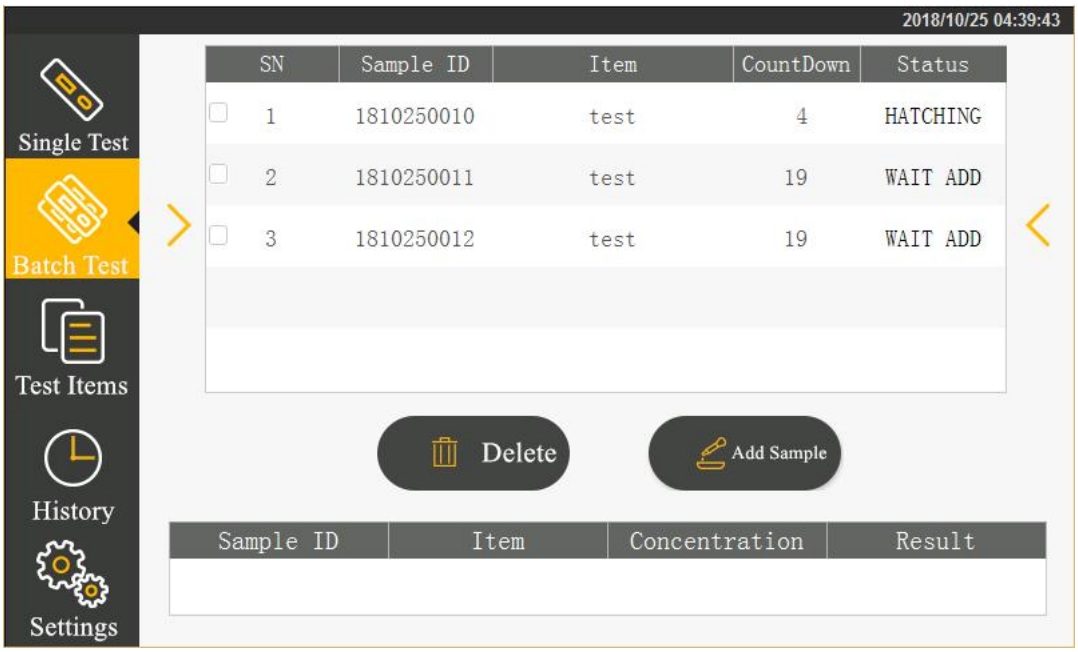
Click 

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



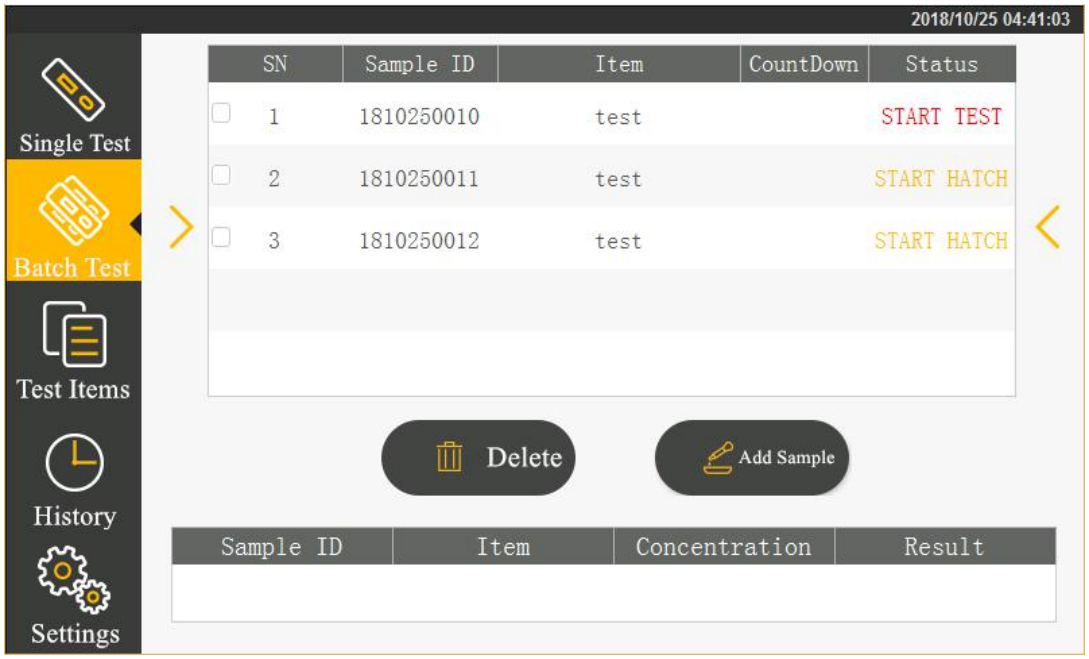
Step 2: Begin to incubate

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.

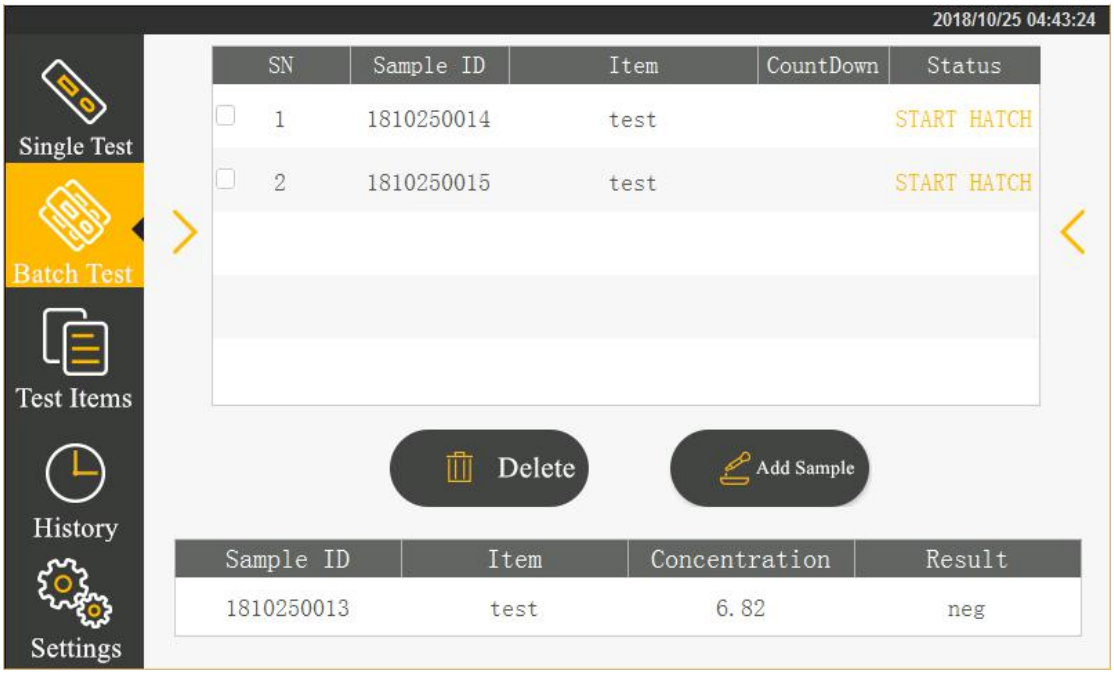


Step 3: Begin to test

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



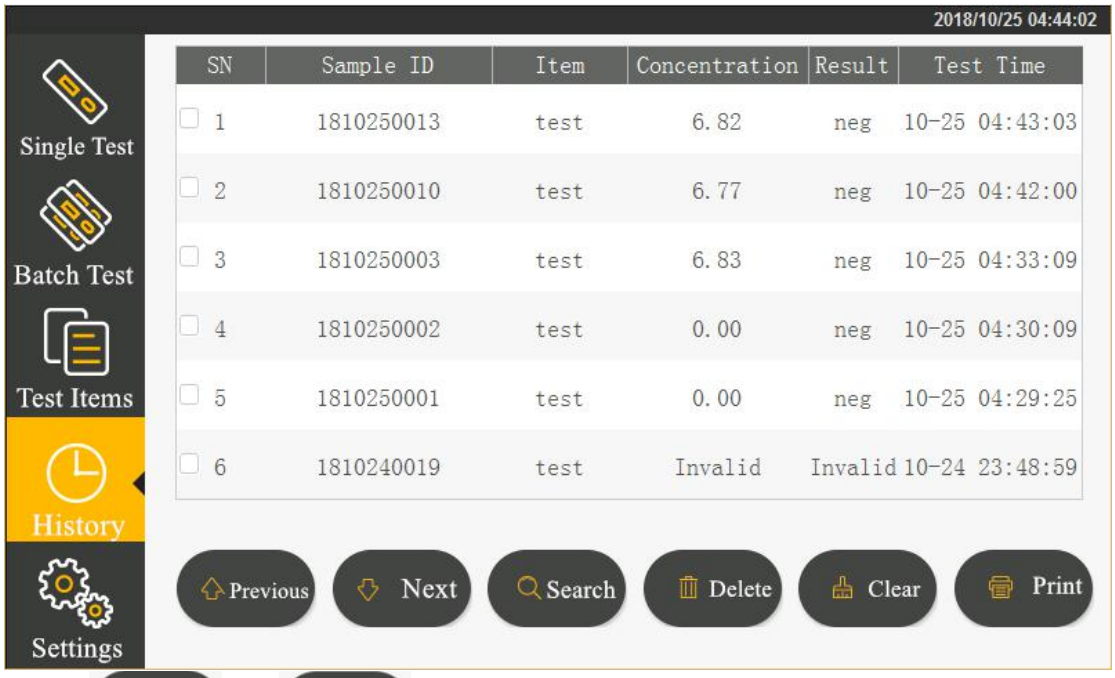
When the test is finished, the test result will display. No list will display and the sample test is completed.



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

5.5 Historic records

Click the “Historic Records” 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 

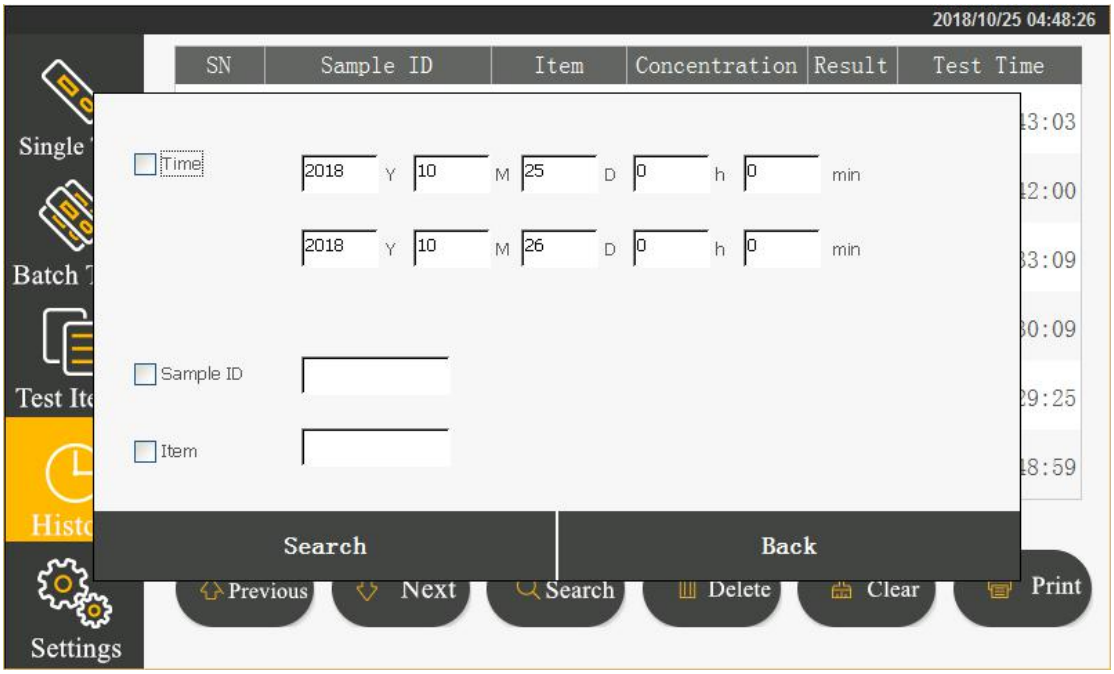
to delete a selected inspection record.

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. Maintenance and Service

6.1 Maintenance and Service

What you have to do only is to keep the external part of the fluorescent immunoassay analyzer clean.

External cleaning and service method: Clean the outer surface of the analyzer with wet cloth and 70% ethanol. Do not use any strong bleaching agent (≥0.5% solution), as oxidants and solvents may deface the housing and touch screen of the testing analyzer. Note: do not use the same to clean any internal component or surface.

⚠ Before cleaning the analyzer, switch off the power and ensure that the power cord plug is in a disconnected state to avoid short circuit and electric shock!

6.2 Maintenance plan

Maintenance item	Weekly	Three months	When necessary
analyzer dust collection	X		
Change printing paper			When the printing paper is used up

6.3 Attentions for analyzer operation

1. Do not place the analyzer in a place where it is hard to operate or inconvenient to disconnect the device.
2. Except the reagent card as provided by the manufacturer, do not place anything else into the test paper strip card holder.
3. If any reagent card testing sample has any potential for infection, please use protective gloves or take other protective measures to avoid skin contacting with the opening of the reagent card for adding samples.
4. Please dispose any used reagent card according to Medical Waste Management Regulations to avoid any biological hazard arising.
5. Please use the analyzer strictly according to the Operation Instructions from the manufacturer. Otherwise, the protection as provided by the analyzer will be destroyed.
6. Notes to analyzer data saving and restoring procedures: In the analyzer, the calibration curves relating to item, batch as imported by the manufacturer and the testing records of users can be saved. When the manufacturer transmits through an upper computer any calibration curve directly, the analyzer will save automatically. The analyzer can save the calibration data for a maximum of 16 items with each item having 3 batches simultaneously. The testing results during normal operation by users will be saved automatically in the analyzer in the record form. The analyzer can save a maximum of 50,000 records. The data saved can resume automatically after power-off without loss. When users select “Factory Reset”, data will be cleared.
7. Those using and operating the supporting PC software for the fluorescent

immunoassay analyzer need to have relevant knowledge: be familiar with such operating systems as windows XP, windows7 and with the installation, unloading of the software installation package in windows XP, windows7.

8. Replacing detachable MAINS or supply cords by inadequately RATED cords is prohibited

9. The power plug must be connected to a grounded socket.

10. The consumables used for supporting the instrument must be used within the validity period

Chapter VII. Troubleshooting guide

Steps dealing with crash

When there is no response in clicking the analyzer interface buttons or analyzer press keys, crash occurs. Please restart the analyzer by following the steps below:

1) Switch off the power;
2) Plug and unplug the power cord again;
3) Switch on the power.

Notes to common errors:

1. A user interface error may result in the analyzer being unable to perform the “testing” function. This will not influence the data backup and transmission function. At this point, you can upload the records backed up to the upper computer software and then return the analyzer to the factory for repairing.

2. The application logic itself errs. The possibility for this error is very low. When it occurs, the testing data this time will lose. However, the historic data backed up in the analyzer will not lose. At this point, have the analyzer power off and restart to use continually.

3. The system or network resources cannot be used and the testing function and data backup function of the analyzer itself can be used continually. This may influence the record uploading to the upper computer software. As the system or network resources

become stabilized, that function will resume automatically.

Chapter VIII. Service, Repair and Destroy

As long as you keep the analyzer clean and change printing papers, the fluorescent immunoassay analyzer needs no special maintenance normally. In case of needing any service or repair, please email to market@joinstar.cn.

The internal structure of the fluorescent immunoassay analyzer, including such important spare parts and components as circuit boards, optical testing modules, display screen, printer and 1D scanning modules, can be inspected and replaced by our company only. No repair by any third party is supported.

When the fluorescent immunoassay analyzer has any trouble or the upper computer software operates abnormally, please email to market@joinstar.cn first for consultation. We will provide technical support on the telephone to help customers troubleshoot. If any analyzer needs recall for repair, please send the analyzer back for repair according to relevant requirements. Normally, the repair period is not beyond one week. If any analyzer does have to be scrapped, the company will provide a new analyzer within the warranty period.

If any user needs to destroy the fluorescent immunoassay analyzer due to some reason, it is suggested that the user should destroy the same according to the regulations relating to class B electronic analyzers.

This company provides technical support and maintenance to the software, including functional maintenance, corrective maintenance and software error correction or upgrading.

The company states that the above service guarantees will be available only subject to fully complying with the Operation Instructions from the manufacturer. For any damage other than this, the company will not take any liability.

Date of Manufacture: See the label

Validity Period: See the label

Effective date and version

Effective Date: 2020-05-25

Version: 0

Contact information

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Website: www.joinstar.cn

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