Version number: 3.1.1

SuperTest 3000 Universal Biological Sample Drug Analyzer

Operation Manual

Supervised by Jiangsu Superbio Testing Technology Co., Ltd.

CATALOGUE

Chapter I. Instructions For Use

Thank you for choosing the SuperTest 3000 Universal Biological Sample Drug Analyzer of Jiangsu Superbio Testing Technology Co., Ltd. This product is a time-resolved immunofluorescence detection system based on the principle of photoelectric detection. It can perform fast quantitative and qualitative tests on common drugs in biological samples including hair, so as to complete the fast screening of suspicious drug users by multiple means. The instrument can also be used in the field of sewage drug testing and drug inspection. This operation manual is applicable to Supertest 3000, and the actual interface operation shall prevail.

This operation manual describes the features and relevant information of the product in detail, and the schematic operation steps are convenient for your use. Please read the manual carefully before using this analyzer.

1.1 Instrument Summary

1. Model / Specification: SuperTest 3000

2. Size: 306*357*367 (length * width * height, unit: mm);

1.2 Scope of Application

SuperTest 3000 Universal Biological Sample Drug Analyzer adopts advanced time-resolved fluorescence immunoassay technology, it needs to be used together with sample drug reagents. No longer limited to urine detection, the SuperTest 3000 can be widely used in the detection of drug content in hair, blood, dry blood spots, sweat, saliva, urine and other biological samples, and can complete the fast screening of suspicious drug users by multiple means.

The detection sensitivity of the analyzer for morphine, methamphetamine, ketamine and other common drugs can reach 0.001ng/mg, which can play a strong role in the field of drug detection. By swabbing the samples, the media such as luggage, parcels, fingers, vehicle steering wheel, room door handle and exhaust fan that have been exposed to drugs can be quickly detected on site, so as to quickly lock the suspects.

Meanwhile, the SuperTest 3000 has a strong specificity. It can complete on-site fast detection in the field of sewage drug monitoring. In a few minutes, the analyzer can quickly quantify the concentration of trace drugs in sewage, trace the source of drug pollution to the upstream, and provide case information clues in time.

Chapter II. System Components And Main Structure

After opening the package, please check whether the components are missing or damaged according to the following standard configuration list.

Note: if any missing or damaged components are found, please contact Suzhou Hemai Precision Instrument Co., Ltd. and local sales representative in time. For contact details, please refer to Chapter IX of this user manual.

2.1 Instrument Standard Configuration List

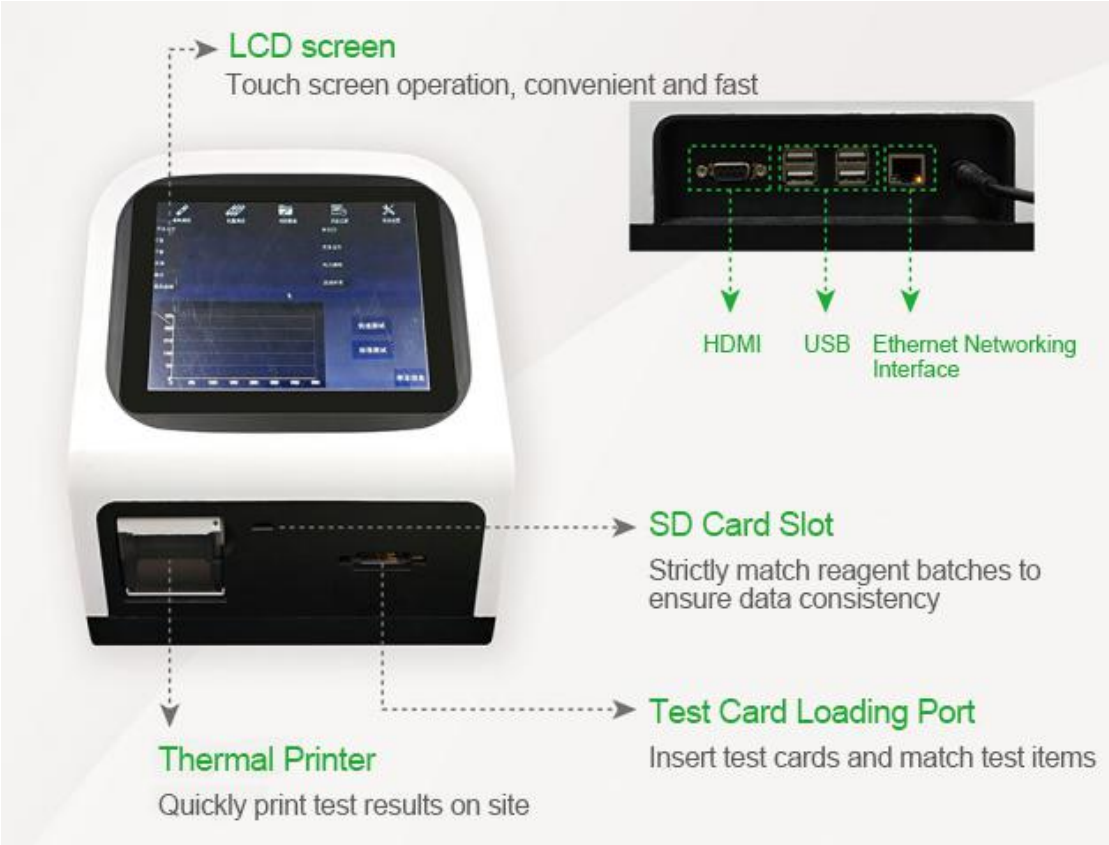
No.	Name	Quantity	Unit
1	Universal Biological Sample Drug Analyzer	1	Set
2	Power Adapter	1	Set
3	ID Card	1	Piece
4	Quality Control Card	1	Piece
5	Printing Paper	1	Roll
6	Compact Disc	1	Piece
7	Scanning Gun (optional)	1	Set

2.2 Main Structure

Note: the appearance of instrument and accessories shall be subject to the actual product.

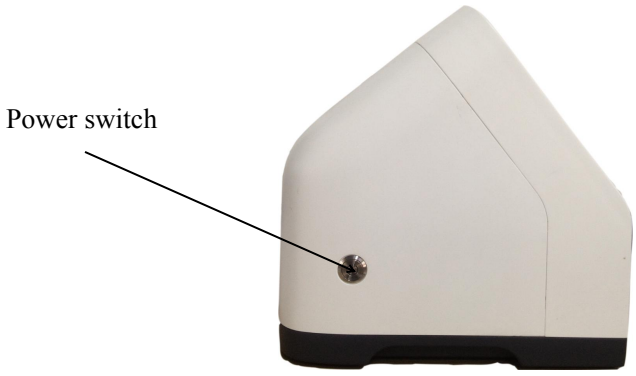
1. Instrument

Front structure:



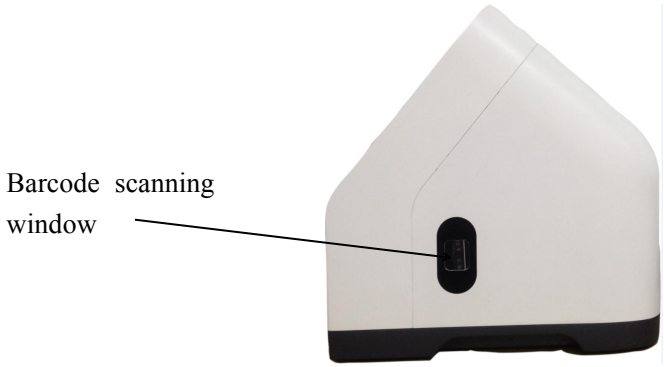
(Pic 1) Front structure of SuperTest 3000

Left side structure:



(Pic 2) Left side structure of SuperTest 3000

Right side structure:



(Pic 3) Right side structure of SuperTest 3000

Power adaptor

(Pic 4) Power adaptor

USB cable

(Pic 5) USB cable

ID card

(Pic 6) Note: this accessory is used with different testing reagents

Structure of test reagent card

Note: This accessory is a kind of consumable in reagent kits.

Product symbol description

No.	Symbol	Description
1		Be careful! Please refer to the accompanying text.
2		In vitro diagnostic equipment
3		Biohazard

Chapter III. Instrument Basic Parameters And Service Conditions

3.1 Basic Parameters

Excitation light source: LED

Excitation spectrum center wavelength: λ_0=365nm

Receiving spectrum center wavelength: λ_1=610nm

Interface: RS232, USB

Printer: Built-in thermal printer

Repeatability: CV≤10%

Stability: CV≤10%

3.2 Transportation and Storage Conditions

After being packaged, the SuperTest 3000 shall be stored in an environment of -10 ℃ ~ 40 ℃, relative humidity 20% ~ 90%, atmospheric pressure (86 ~ 106) kPa, no condensation, no corrosive gas, and good ventilation.

During transportation, attention should be paid to avoid moisture, shock and vibration.

3.3 Service Conditions

1. Positioning and placement requirements

1) The instrument shall be placed on a stable and horizontal workbench in a room without serious dust, direct sunlight and corrosive gas, and the worktable can bear a weight of more than 2.5kg.

2) There is no strong vibration source and strong electromagnetic field around.

3) The instrument should be placed in a well-ventilated place, and there should be more than 10cm space around the instrument to ensure the necessary space for operation and maintenance.

2. Power supply and voltage requirements

The instrument uses a 220 V/50 Hz AC power supply and the input voltage is 12 V DC. The power of the instrument is: 36VA. Care should be taken during use to avoid short circuits and electric shock!

Note: The file must be consulted in all cases marked with this symbol.
Instrument grounding instructions: Connect to the ground through an external power adapter.

Chapter IV. Instrument Installation

Please use the instrument under the service conditions. (Refer to 3.3 "Service Conditions" in Chapter III for details.)

1. Place the universal biological sample drug analyzer on a stable workbench.

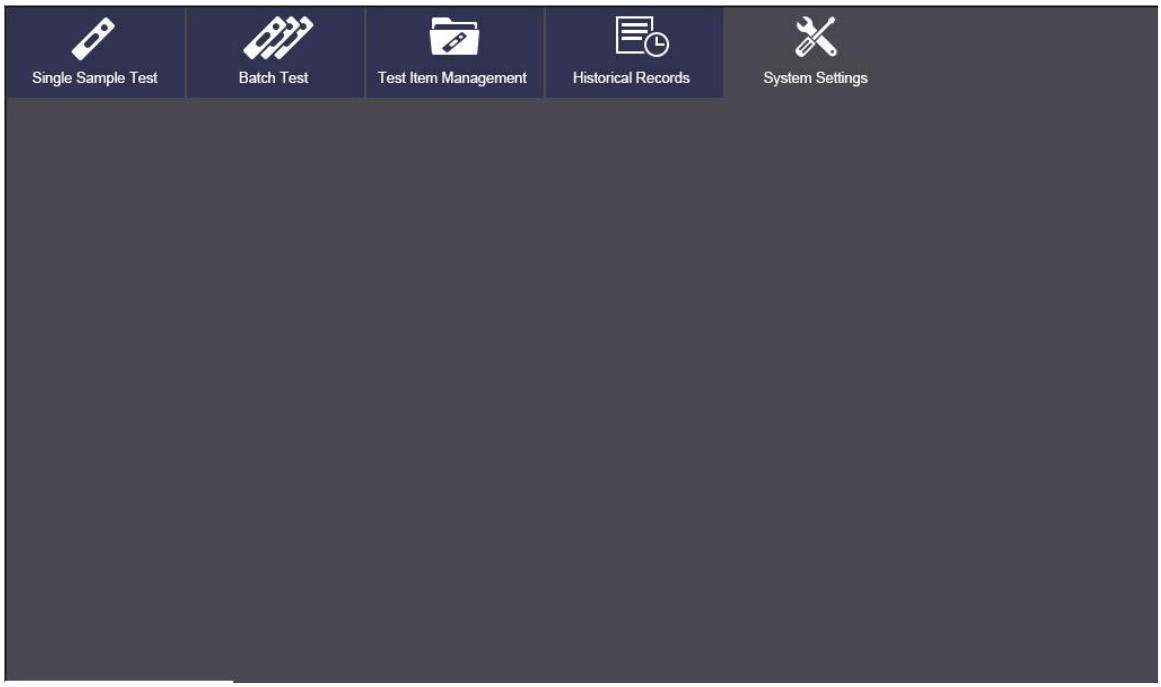
2. Connect the power adapter with the power interface of the universal biological sample drug analyzer.

3. Turn the power switch to the "On" position and start the instrument.

Chapter V. Detailed Operation Steps

The analyzer is operated by finger operation of the touch screen of the universal biological sample drug analyzer. Connect the power cord of the instrument, turn on the power switch on the left side of the instrument, and start the instrument. The instrument is powered on and starts self-check.

After the self-check is successful, this interface will be displayed.



Before using the instrument, please set the system according to actual needs. After the system setting is completed, users can perform fast test and standard test, and operate on historical records.

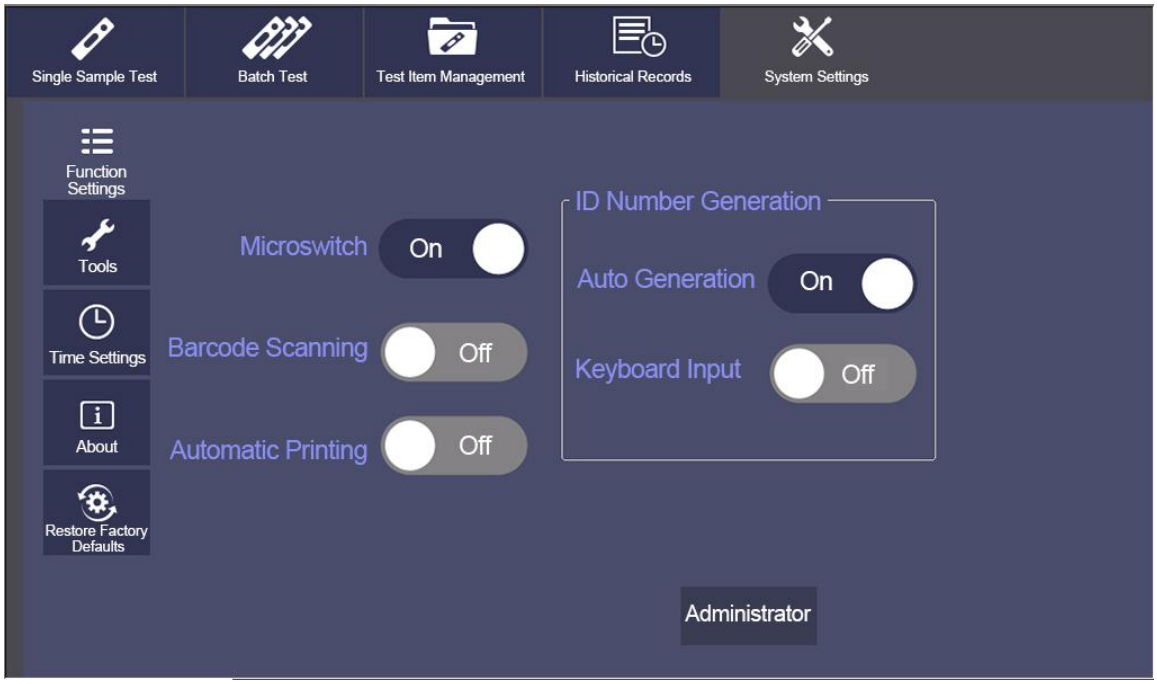
5.1 System Settings

Click [System Settings] to enter this interface, and the secondary menu will appear: Function Settings, Tools, Time Settings, About, and Restore Factory Defaults.

5.1.1 Function Settings

Click [Function Settings] to enter the following interface. Click the 

icon after the corresponding item to select the item to be set.



1. Enable micro-switch: On - when the test strip is inserted in place, the detection will be started automatically.

Off - Manually click the “Test” button to start the test process.

2. Enable barcode scanning: On - scan the barcode before each test and automatically match the test information.

Off- uses the currently selected test information of the instrument, and does not need to start barcode scanning and matching test information.

At this time, the test item defaults to the System Settings - > selected item in the Test Item Management interface.

3. ID Number Generation

Auto generation: On - automatically generate ID number according to date code

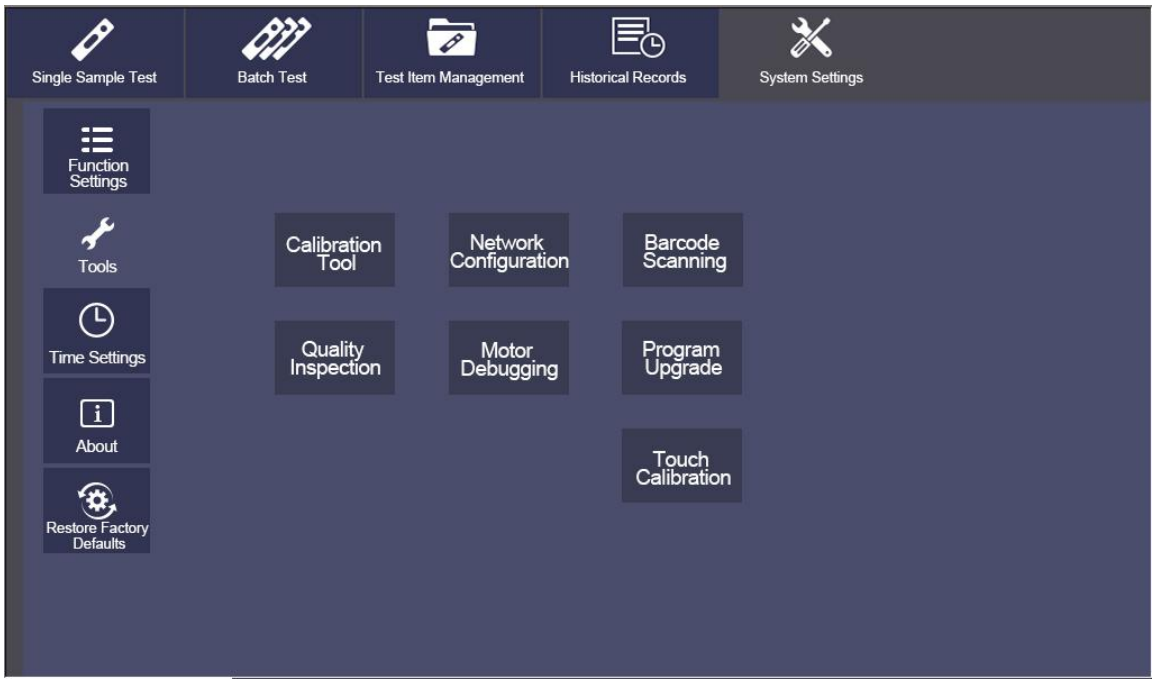
Off - enter ID number manually

Keyboard input: On - input ID number with soft keyboard

Off - automatically generate ID number

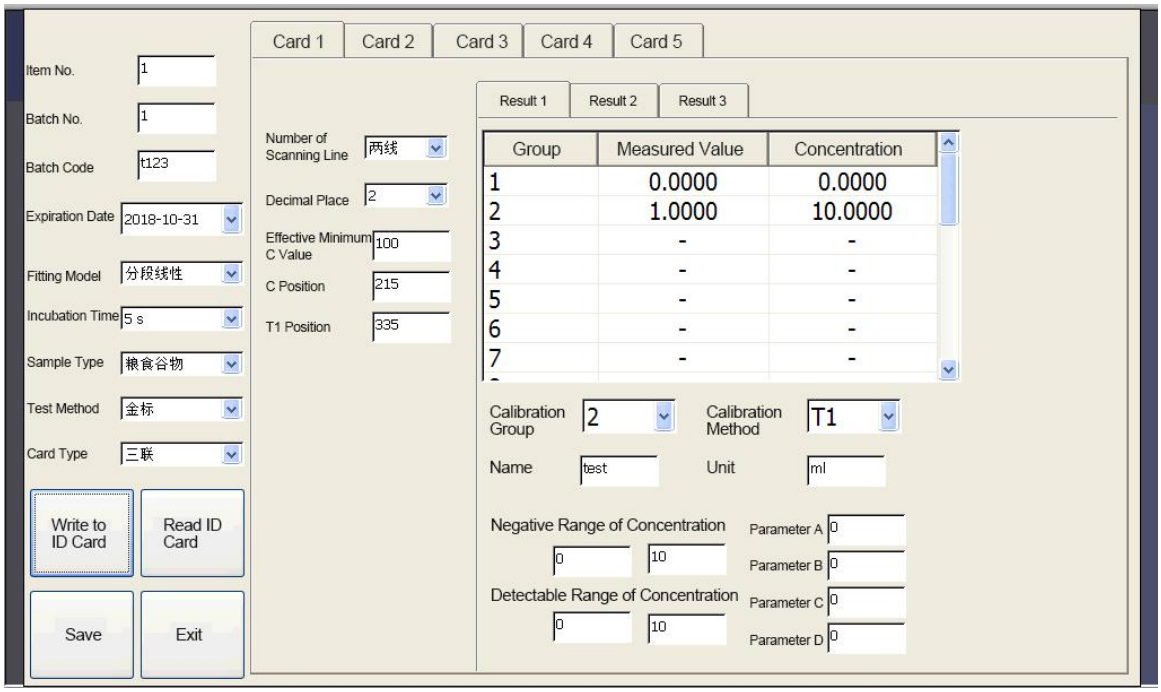
5.1.2 Tools

Click [Function Settings] to enter the following interface. Main tools include: calibration tool, network configuration, touch calibration, quality inspection, motor debugging, program upgrade, barcode scanning. Among them, the functions of quality inspection, motor debugging, program upgrade and barcode scanning have not been realized.



(1) Calibration tool

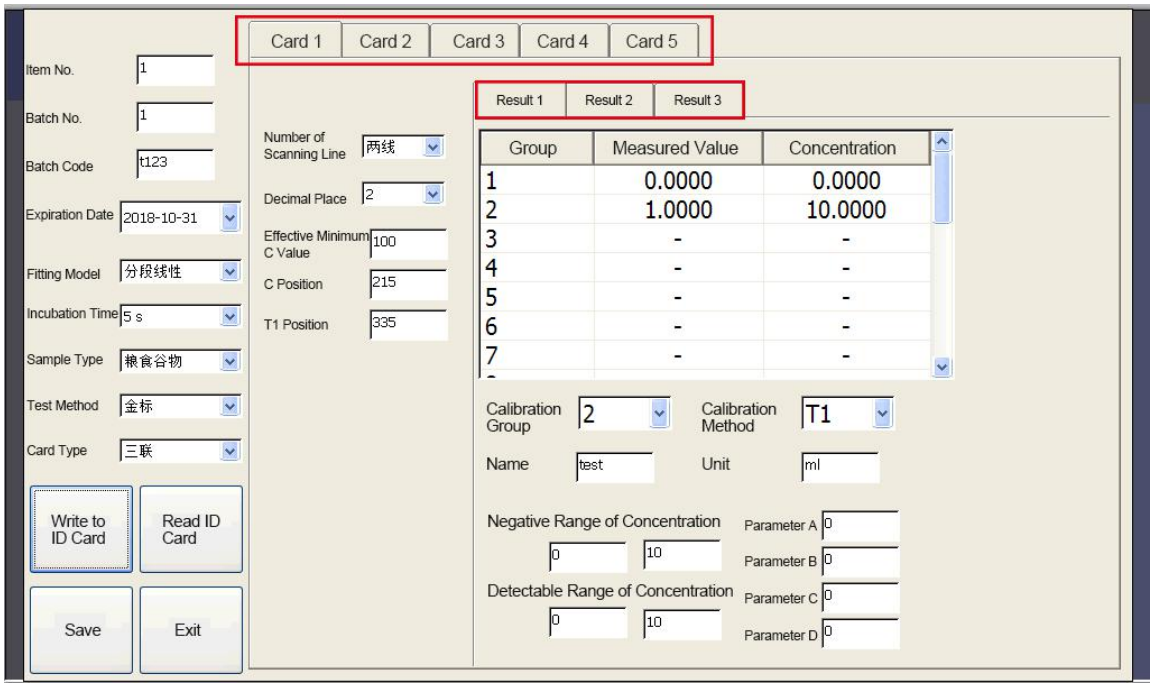
Click [Calibration Tool] to enter the following interface.



1 Fill in the overall parameters: fill in the item number, batch number and corresponding batch code, select the expiration date, fitting model, incubation time, sample type, detection method and card type.

Each item number and batch number has a unique corresponding test information and calibration curve. Reset will overwrite the original settings.

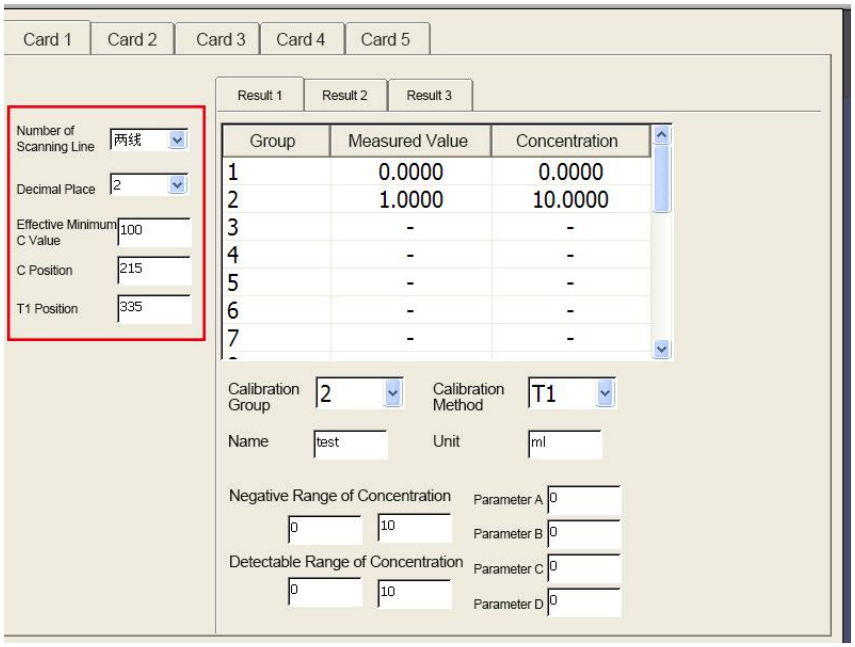
2 Multi-card standard curve setting



Note: 1) Card 1, Card 2 ... Card 5

This corresponds to the number of test strips on the multi test card. For example, if the detection card is a 3-way card, then selects 3-way card. Card 1 corresponds to the first strip on the left of

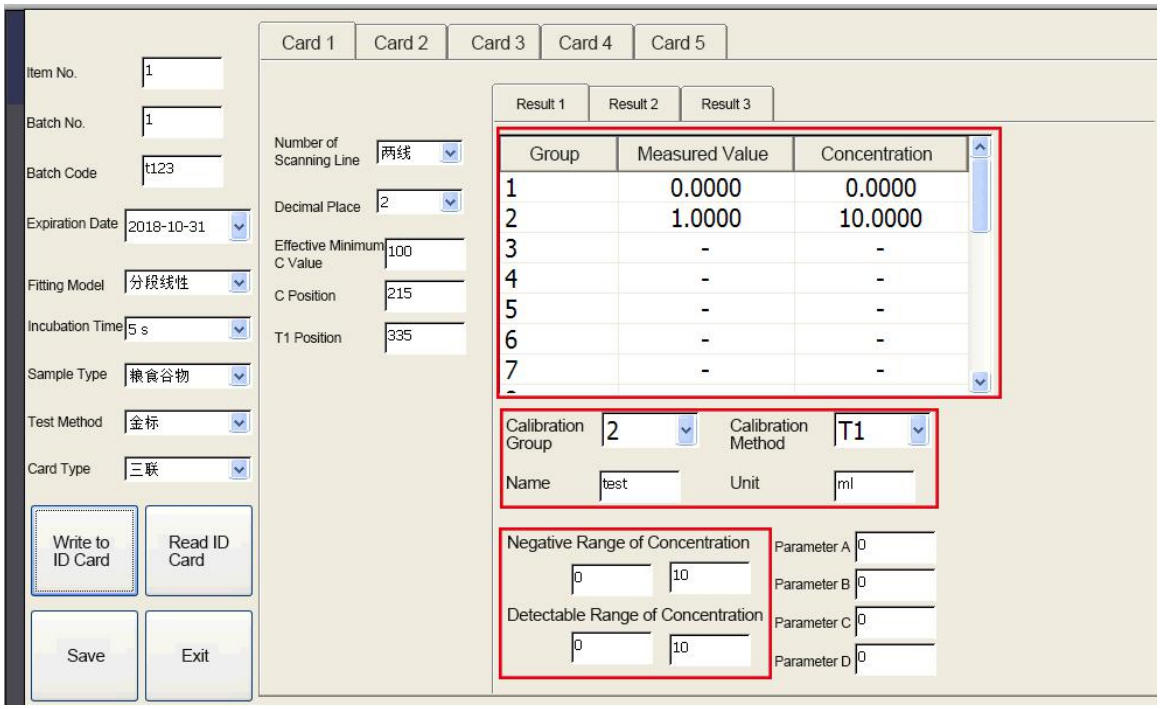
3-way card, card 2 corresponds to the middle strip, and so on. Each card can set the number of scan lines, decimal places, effective minimum value of C value, and CT position.



2) Result 1, Result 2, Result 3

Each card can get different results according to different calibration methods of T1, T1 / C and T1 / T2.

Different test results can be set with item name, unit, corresponding calibration data, negative range of concentration and detectable range of concentration. The calibration data must be arranged in the table according to the measured value from small to large.

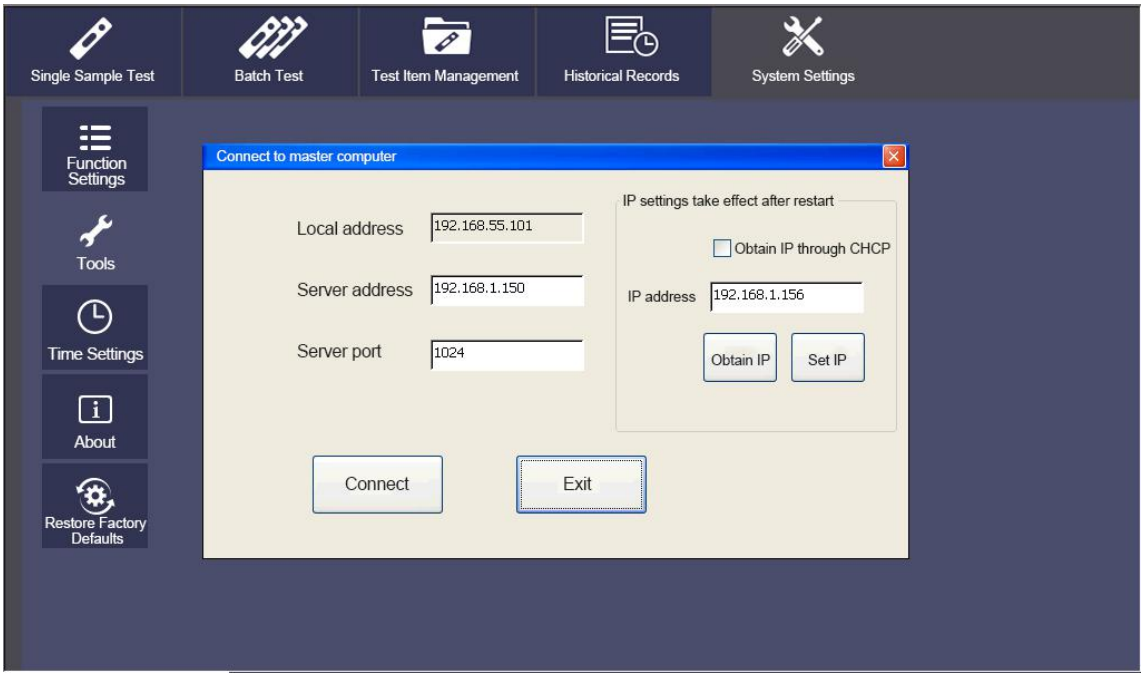


As shown in the figure, when the test result T1 is 11, the test result is positive. When the test result

is 11, the test result is > 10.

(2) Network configuration

Click [Network Configuration] to enter the following interface.

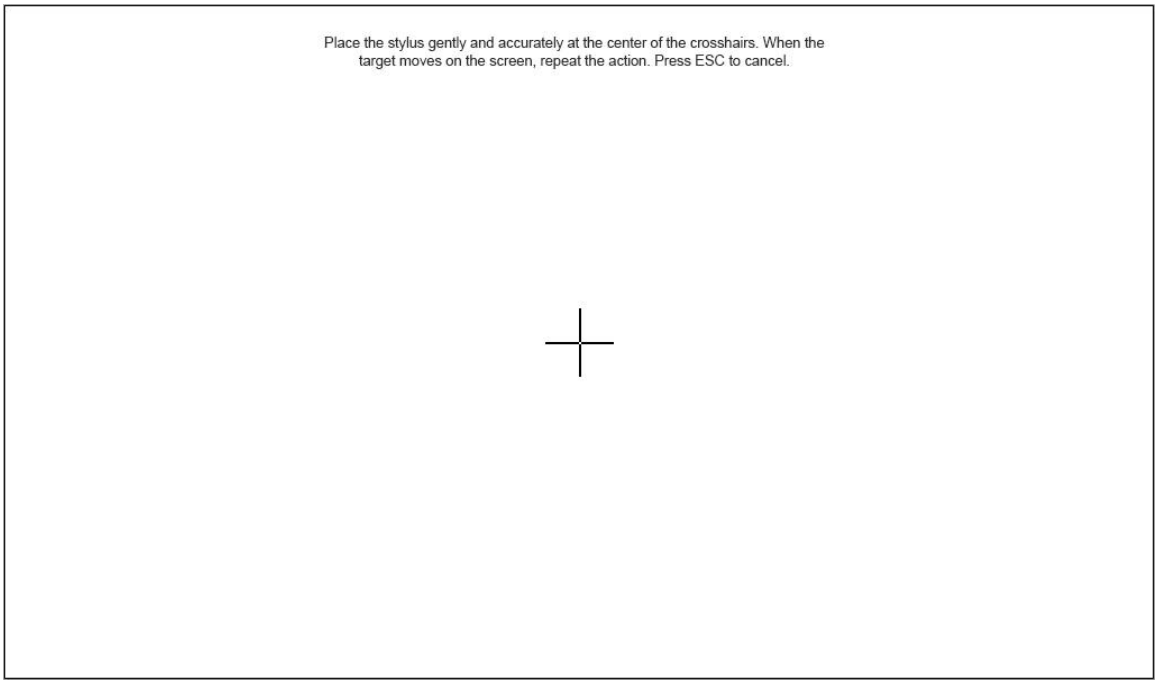


Local address: users can select "Obtain IP through CHCP" or enter the IP address directly.

Server address / port: input the address information of the master computer software installed on the network.

(3) Touch calibration

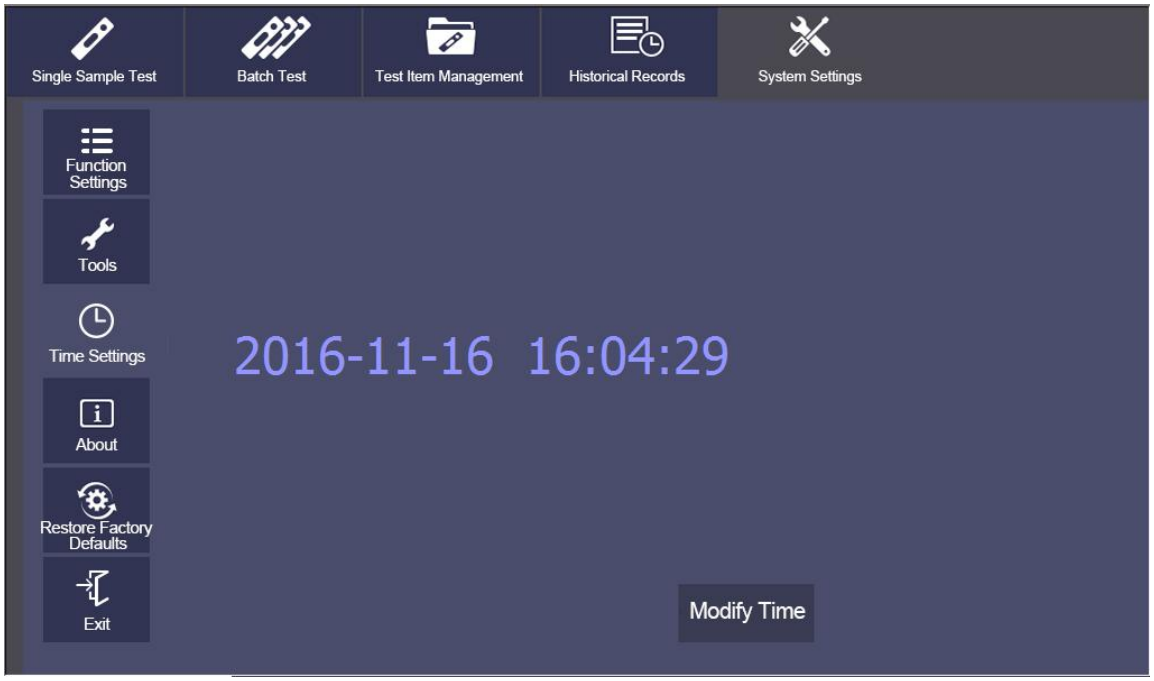
Click [Touch Calibration] to enter the following interface.



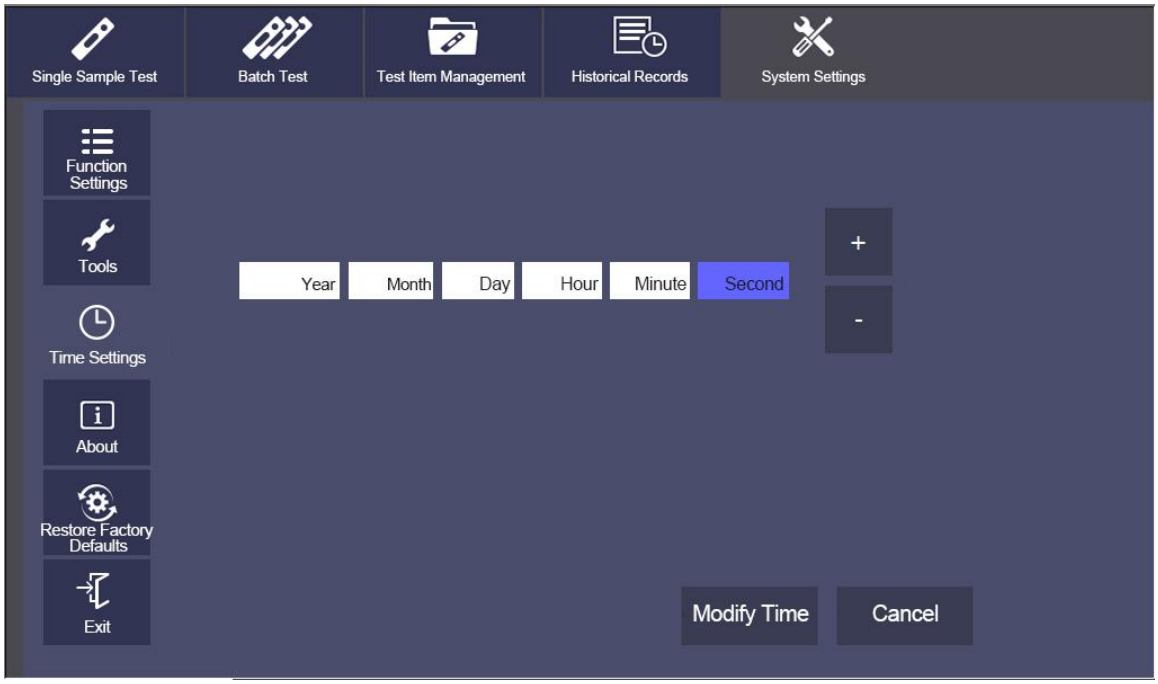
Use the stylus or fingernail tip to accurately click the center of the crosshairs. When the target moves on the screen, repeat the action.

5.1.3 Time Settings

Click [Time Settings] to enter the following interface.

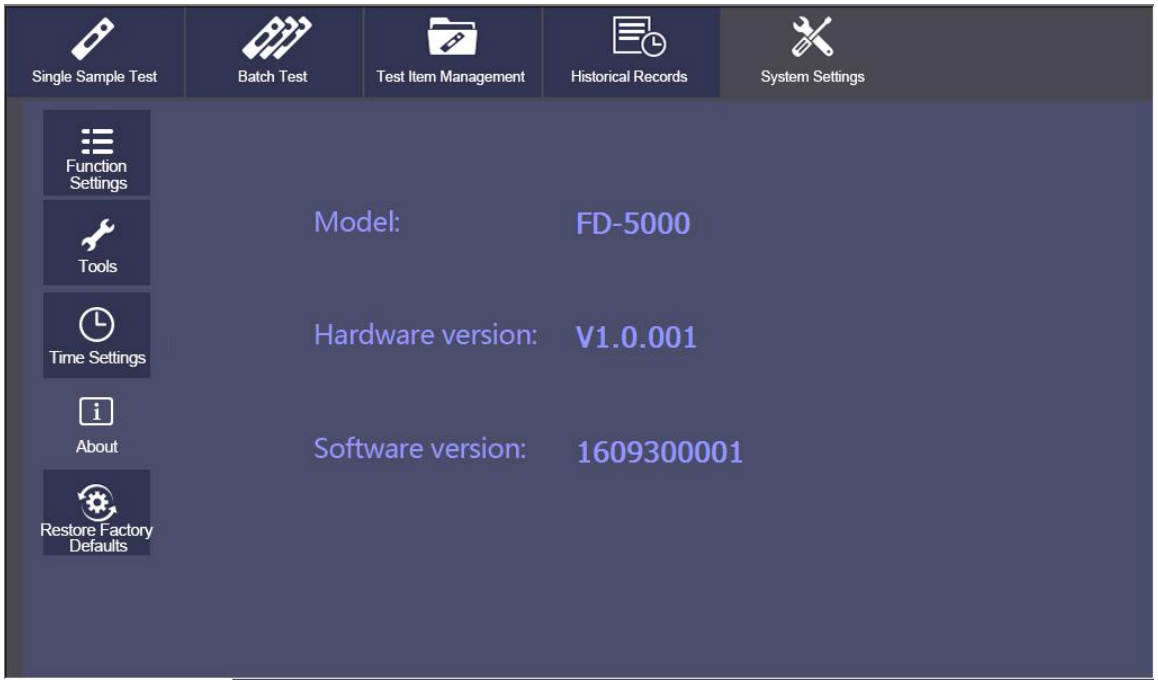


Click [Modify Time] to set the time. Click the field you want to modify, and then press + or - to adjust. After modification, click [Modify Time] again to confirm the modification.



5.1.4 About

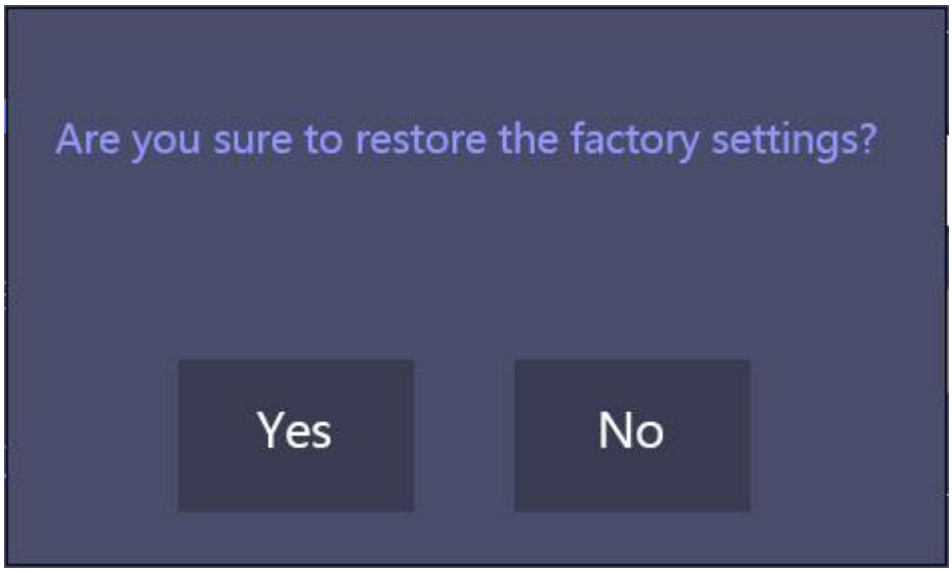
Click [About] to enter the following interface to display the model and version information of the analyzer.



5.1.5 Restore Factory Defaults

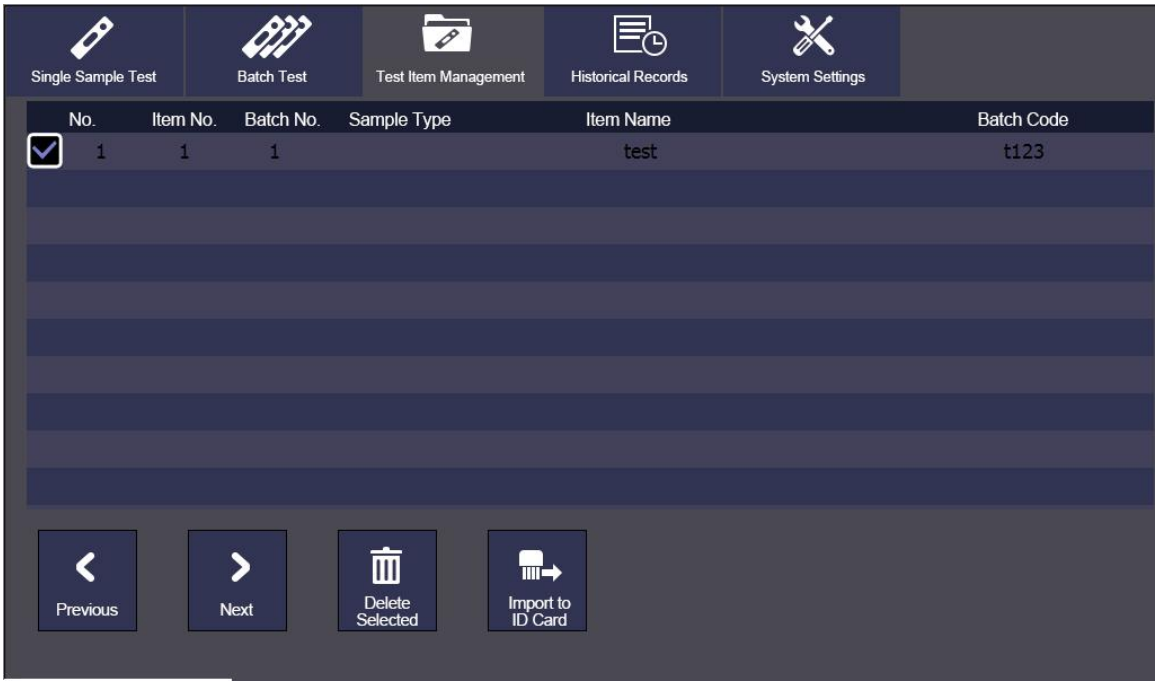
Click [Restore Factory Defaults] to open the dialog box. All data will be cleared and all settings will be restored to defaults.

After restoring to default settings, the instrument will restart automatically.



5.2 Test Item Management

Click [Test Item Management] to enter the following interface. Click the corresponding item to select the test information suitable for the current test.



Click [Previous] and [Next] to browse the inspection items saved by the instrument.
Click [Delete Selected] to delete the selected test item information.

The ID card is imported as follows:
Step 1: Insert the ID card into the ID card socket at the front of the instrument.
Step 2: In the test item management interface, click the [Import ID Card] button to complete the import of test information.

Additional instructions for ID card import:

1) Each item number and batch number has a unique corresponding test information and calibration curve. Reset will overwrite the original settings.
2) When the ID card is inserted, the instrument scans the matched barcode, and after a test, the test items of the current ID card will be added to the list.

Instructions for the user to change the test items:
1) When "Start Barcode Scanning" is turned off, the user can determine the current test information by manually selecting test items in this interface. The test information is not read from the ID card at this time.
2) When "Start Barcode Scanning" is turned on, the user can scan the barcode through the side window to obtain the current test information.
3) If there is a barcode on the test strip shell, the instrument will automatically obtain the current test information when the “Built-in Barcode” is turned on.

5.3 Single Sample Test

In the following operation instructions, it takes disabled "Microswitch", enabled "Start Barcode Scanning" and disabled "Automatic Printing" in the System Settings -> Function Settings as an example.

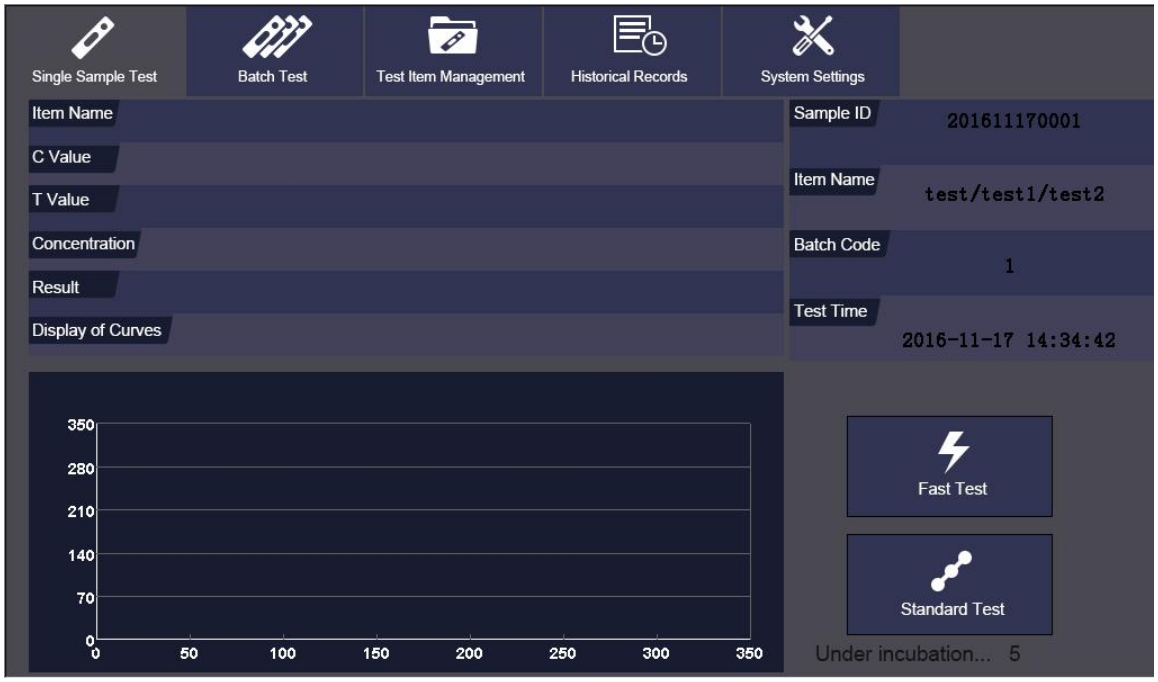
Step 1 Install the instrument, turn on the power switch, and start the instrument.
Step 2 Click [Single Sample Test] to enter the following interface.

Step 3 Scan the barcode to obtain test items and batch information.

The instrument adopts the default test information in the test item management directory. If the test information is not the current item to be tested, place the barcode in front of the scanning window and keep 10cm ~ 20cm away from the scanning probe, and the infrared ray will scan the whole barcode.

Step 4 Click on the [Fast Test] button.

If clicking on the [Standard Test] button, the incubation time countdown will be displayed, and the test will not be started until the countdown is over.



After the test, the results will be displayed.

Step 5. Check test results.

Select the boxes of different colors to view the test results of different card strips.

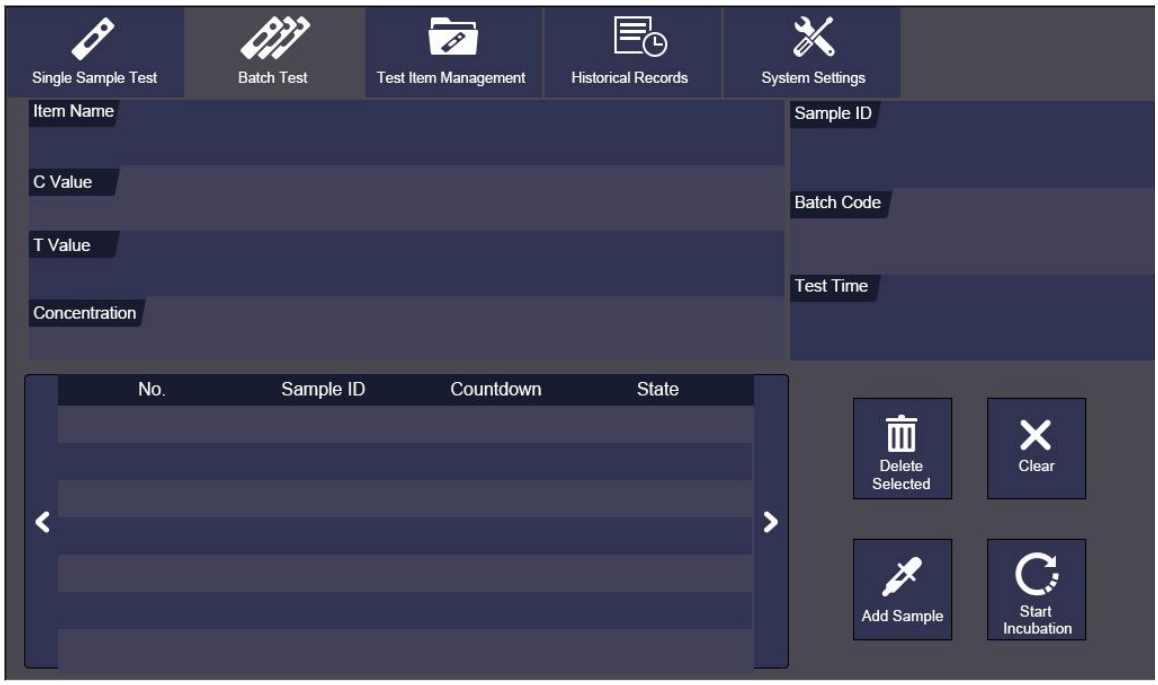
5.4 Batch Test

In the following instructions, the "Microswitch" is turned on.

The batch test status changes as follows:

Start Incubation - In Incubation - Please Insert Reagent Strip - Under Test - Please Pull Out Reagent Strip

Click [Batch Test] to enter the following interface.

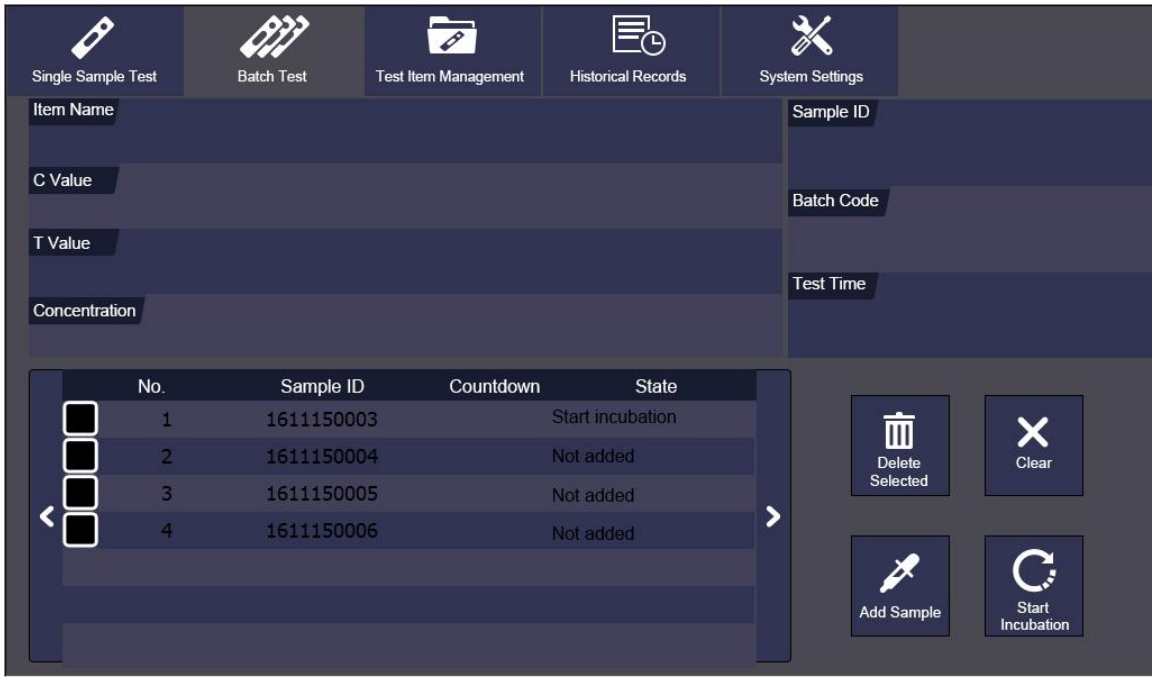


Step 1. Input sample ID

Method 1: scan sample barcodes with the scanning gun, and then add samples.

Method 2: click 

to add the IDs of all samples to be tested.

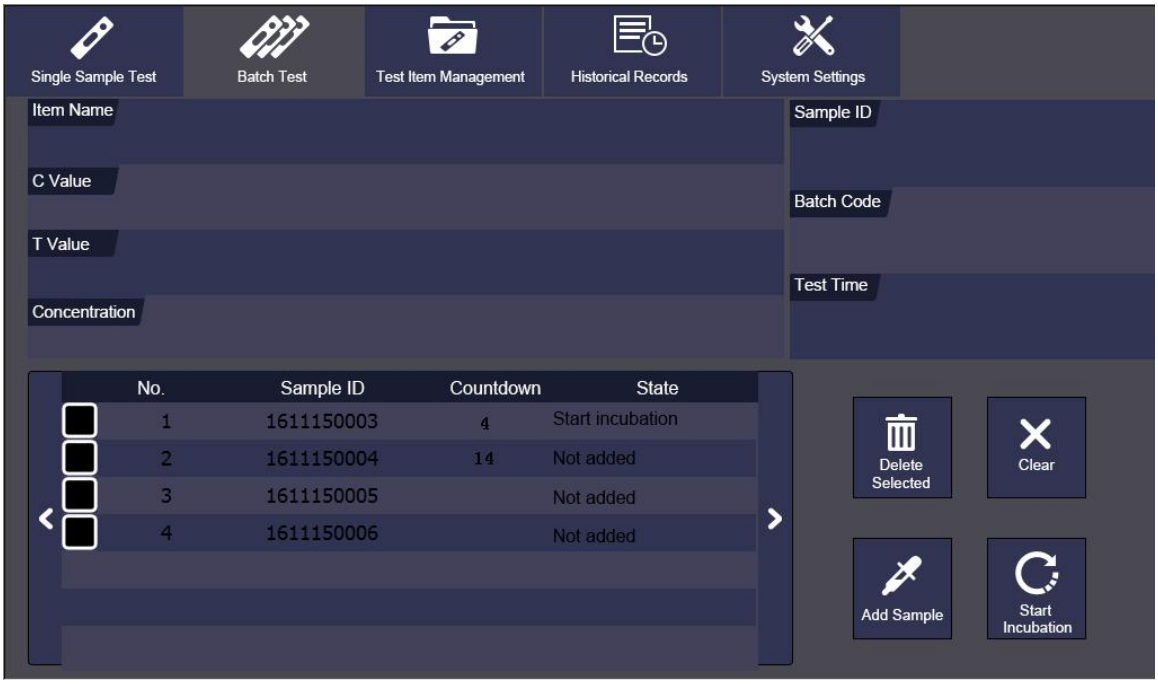


Step 2. Start incubation

Add samples to the test strip, and click 

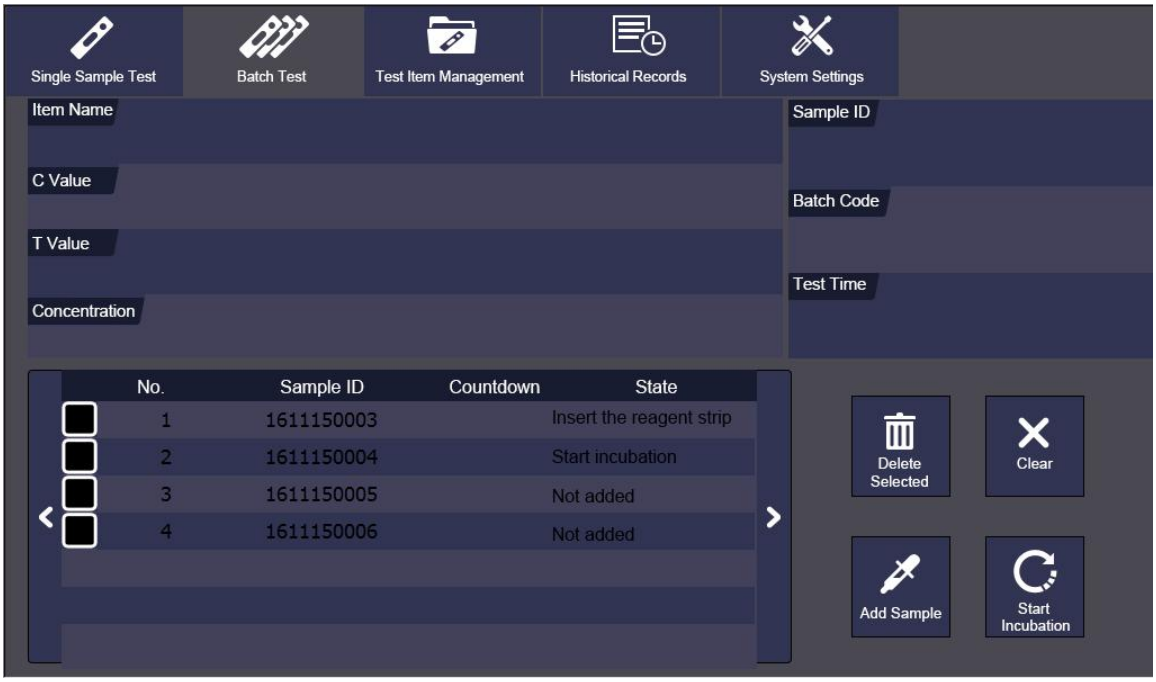
. The current state changes and the incubation countdown begins.

Follow up samples shall wait for sample addition according to the countdown of sample adding interval (15s).

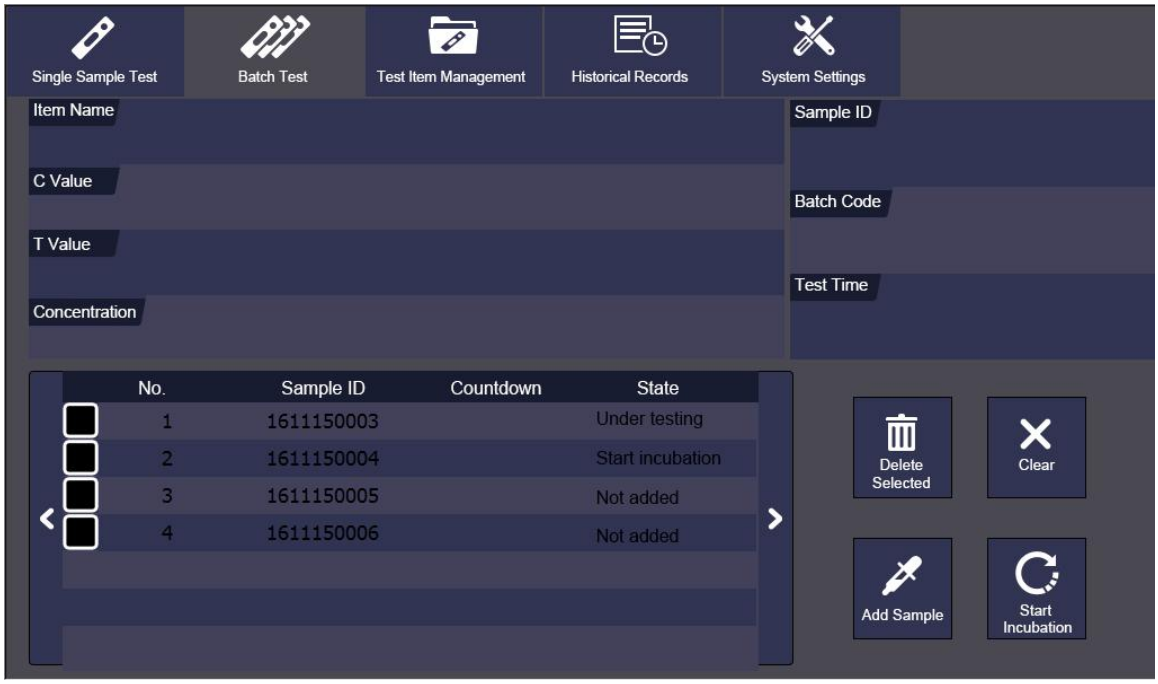


Step 3. Start test.

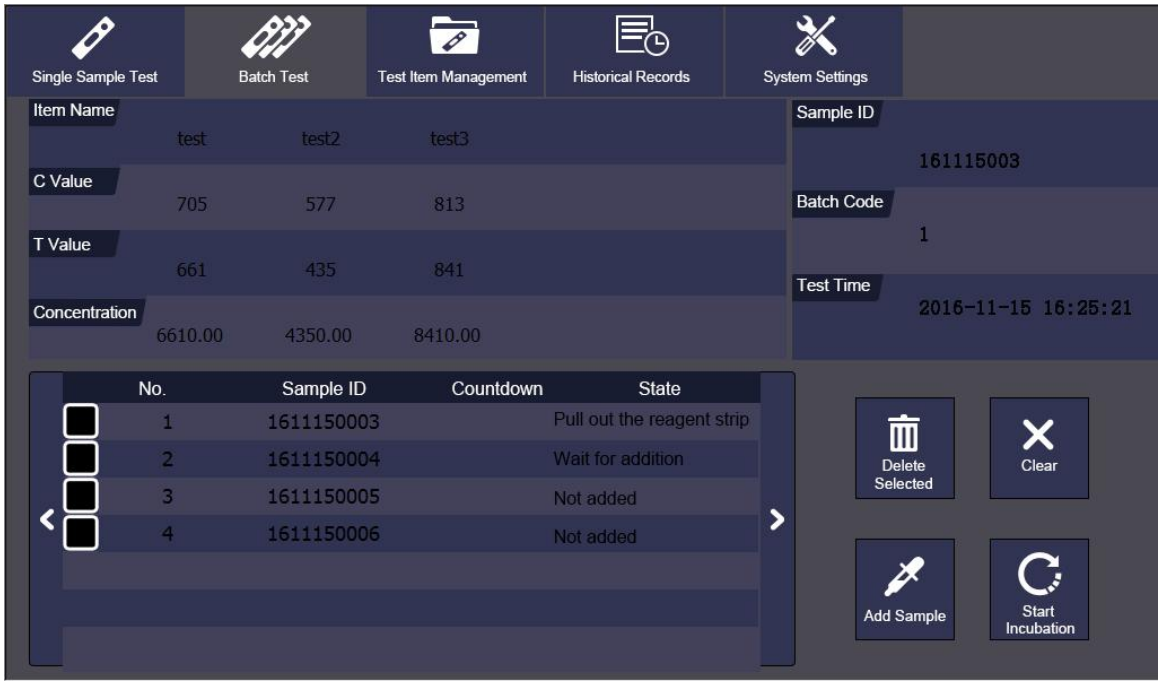
When incubation time is over, the system prompts "Please Insert Reagent Strip".



Insert the incubated reagent strip according to the prompt and then start test.



At the end of the test, the test results will be displayed. Sample status: please pull out the reagent strip.

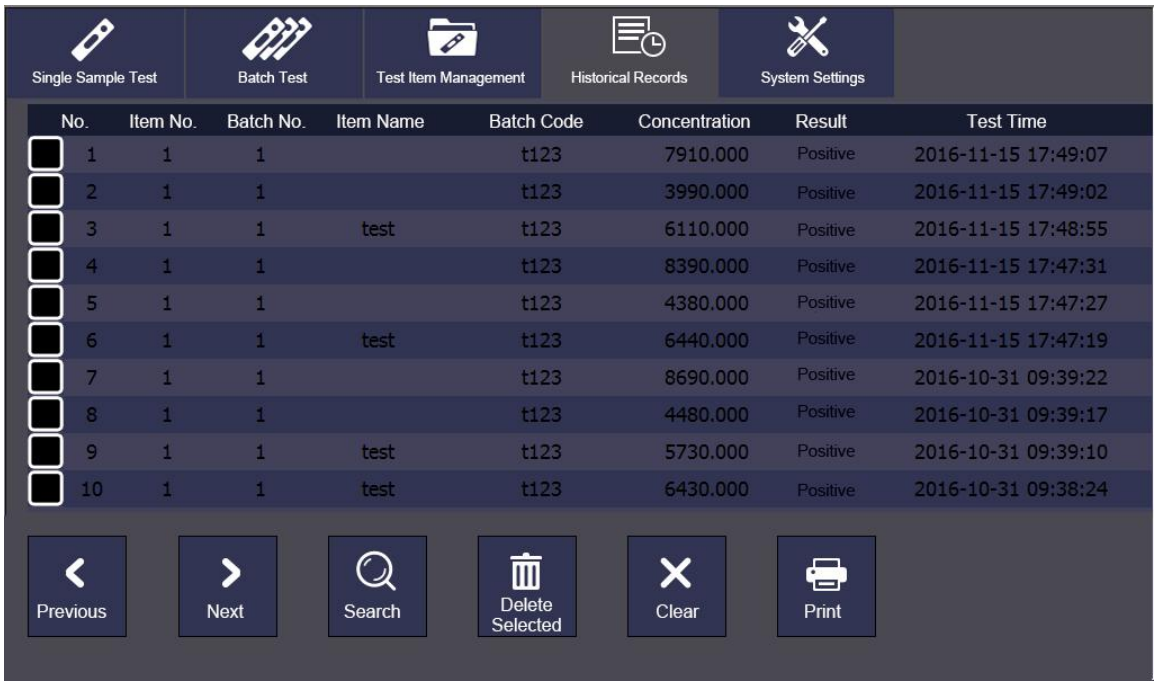


Step 4. Pull out the reagent strip according to the prompt, and the list will no longer show the tested samples.

Step 5. Repeat the previous operation to test the next reagent strip.

5.5 Historical Records

Click on the "Historical Records" button on the main menu page to switch to the following interface. Users can browse and manage the records.



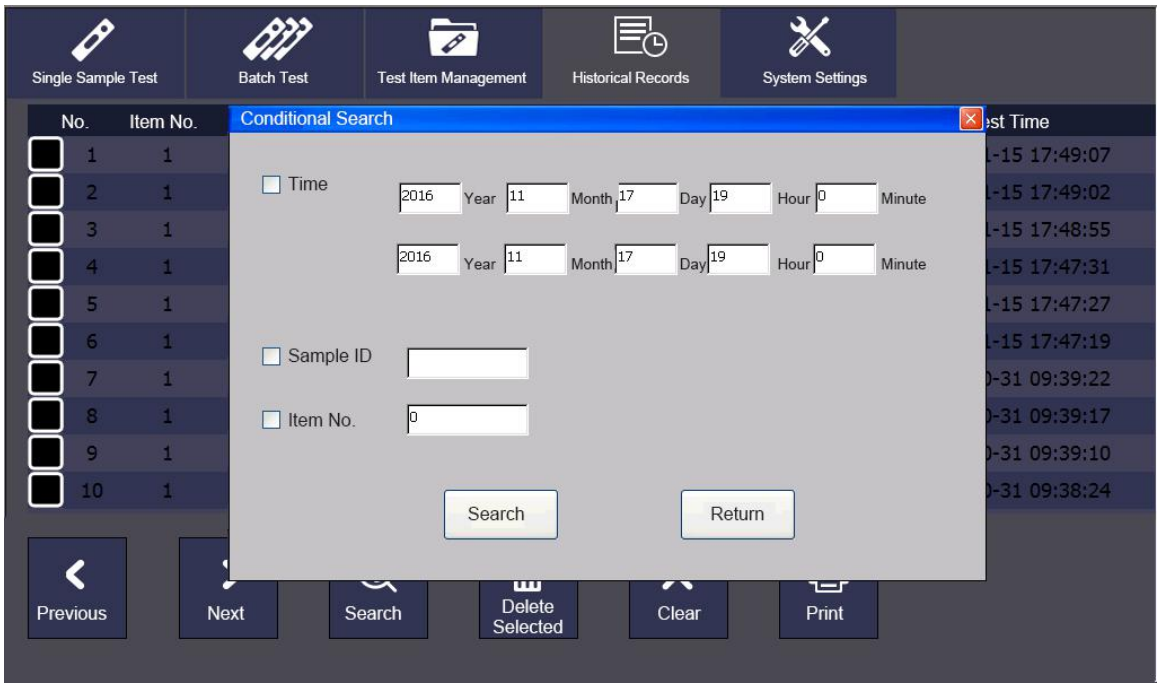
Click  or  to view test records.

Click  to print the selected test results through the built-in printer;

Click  to delete the selected test records.

Click  to clear all test records.

Click  . Users can enter various filter conditions to search test records.



Select the time, sample ID, item number, enter the search field, and click on the [Search] button to find the corresponding record.

Chapter VI. Instrument Maintenance

6.1 Maintenance

The universal biological sample drug analyzer only needs to keep the exterior clean.

External cleaning and maintenance method: use wet cloth and 70% ethanol to clean the external surface of the instrument, and do not use strong bleaching agent (≥ 0.5% solution), because the oxidant and solvent may damage the outer case and touch screen. Take care not to clean any internal parts or internal surfaces.

Before cleaning the instrument, turn off the power switch to ensure that the power cord plug is disconnected and avoid short circuit and electric shock!

6.2 Maintenance Plan

Maintenance Item	Weekly	Quarterly	On Demand
Dust Elimination	×		
Replace printing paper			When the printing paper runs out

6.3 Precautions For Instrument Use

1. Do not place the instrument where it is difficult to operate or disconnect the device.
2. Except for the reagent cards provided by the manufacturer, do not put any other items into the test strip holder.
3. If the test sample of reagent card has potential infectivity, please use protective gloves or other protective measures to avoid skin contact with the sample adding port of reagent cards.
4. The used reagent cards should be disposed of in accordance with the *Regulation on the Administration of Medical Treatment Wastes.*
5. Please use the instrument in strict accordance with the instructions provided by the manufacturer. Otherwise, the protection provided by the instrument will be destroyed.
6. Instructions for data storage and recovery procedures: The instrument can save the calibration curves related to the items and batches imported by the manufacturer as well as the detection records. When the manufacturer imports the calibration curves through ID card or the master computer transmits directly, the instrument will save automatically. The instrument can save calibration data of up to 16 items at the same time, and each item has 3 batches of calibration data. The test results during normal use will be automatically saved to the instrument in the form of records, and the instrument can save up to 50,000 records. The saved data can be recovered automatically after power failure, and will not be lost. Data will be cleared when the user selects " Restore Factory Defaults".
7. The personnel who use and operate the PC software supporting the universal biological sample drug analyzer need to have relevant knowledge: be familiar with the use of Windows XP and Windows 7 operating systems, and the installation and uninstallation of the software package on Windows XP and Windows 7.

Chapter VII. Troubleshooting Guide

Handling Steps For System Crash

1. When clicking the button on the interface or the instrument button does not respond, the machine crashes. Please restart the instrument according to the following steps:
   1) Turn off the power switch;
   2) Re-connect the power cord;

3) Turn on the power switch.

2. If the PC software does not respond and continues to crash, please restart the software as follows:

1) Use Ctrl-Alt-Del to open the Windows Task Manager to end the task and turn off the PC software;

2) Restart the PC software；

3) If the PC software is not working properly, restart the computer that controls the instrument and then run the PC software.

Description of common errors:

1. If there is an error in the user interface, the instrument may not be able to perform the "Test" function, while the data backup and transmission functions will not be affected. At this time, the backup records can be uploaded to the master computer software, and then the instrument can be sent to the factory for maintenance.

2. The logic error of the application program itself has a very low probability of occurrence. When it occurs, the current test data will be lost, but the historical data backed up in the instrument will not be lost. At this time, the instrument should be powered off and restarted for continued use.

3. When the system or network resources are not available, the test function and data backup function can continue to be used, but it may affect the upload of records to the master computer software. After the system or network resources are stable, the function will be restored automatically.

Chapter VIII. Service, Repair and Destruction

As long as the instrument is kept clean and the printing paper is replaced, the universal biological sample drug analyzer generally does not need special maintenance. For service or repair, please call the company.

If for some reason, the user needs to destroy the universal biological sample drug analyzer, it is recommended that the user destroy it according to the regulations of Class B electronic instruments.

The technical support and maintenance provided by the company for the software include functional maintenance, corrective maintenance and software error change or upgrade.

The company declares that the above service guarantee can be obtained only when the manufacturer's operation instructions are fully complied with. The company will not be responsible for any other damages.

Contact Information

Manufacturer: Jiangsu Superbio Testing Technology Co., Ltd.
Address: 11F, Block B, Sino-Danish Ecological Life Science Industrial Park, No. 3-1 Xinjinhu Road, Pukou District, Nanjing
Tel: 025-58277529
QQ: 834729327
E-mail: subotest@superbio.cn
Website: http://www.subotest.com
Postal code: 261000