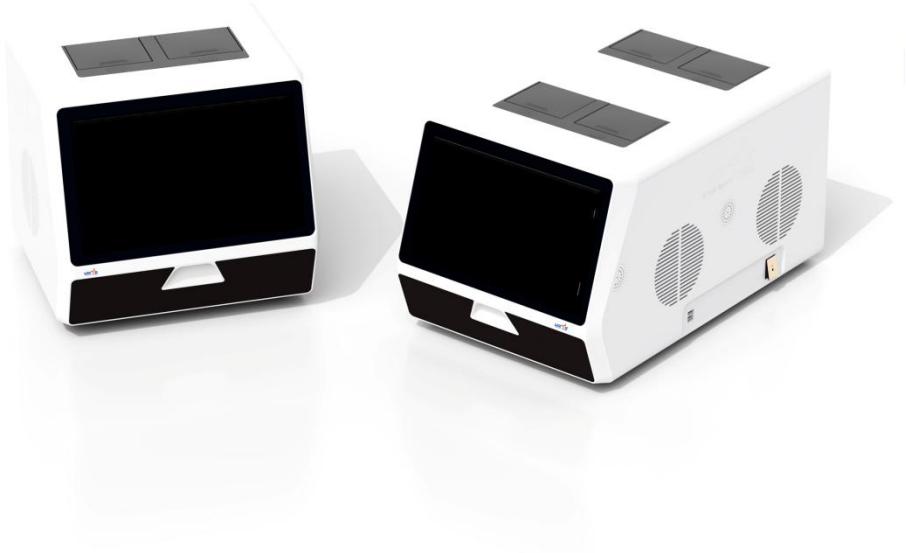
MultNAT Molecular Diagnostic Testing System



Operator Manual

Software: v1

Ustar Biotechnologies (Hangzhou) Ltd.

Catalog #:
U300002-2 (UP0102)
U300002-4 (UP0104)

03. 31, 2023
Document No.: SM-UP0104-ENG-CE
Version: A/1

Table of Contents

About the Manual

This Operator Manual provides detailed instructions on safe use of MultNAT Molecular Diagnostic Testing System. Please read this manual thoroughly and get familiar with relevant safety information before operating this instrument. Using the instrument without careful reading of the manual or without proper training may result in serious injury to the operator, damage to the instrument, invalid results, or loss of data.

Safety Information

- Thank you for purchasing MultNAT Molecular Diagnostic Testing System.

This product can only be used by licensed doctors and trained medical professionals.

Please read this manual carefully before operation and keep it properly for future use.

Please strictly comply with the procedures described in this manual for operation and maintenance.

Paragraphs marked with "Note", "Warning" and "Caution" should be read carefully and observed to avoid damage to the instrument or injury to the operator.

In case of problems when using the instrument, please contact your local dealer or Ustar, we will provide you with quality service.
Commitment: We promise to provide users with necessary and more detailed technical information to meet your needs when dealing with failures.

Due to continuous update on this instrument, we hereby inform you in advance that the actual appearance or specification of the instrument provided by Ustar may be different from that depicted in this manual. Ustar Biotechnologies (Hangzhou) Ltd. reserves the right to change this manual and the products without prior notice.

⚠Warning

1. Please do not use the instrument in fire hazard environments.
2. Please do not use the instrument in the environment with flammable anesthetic gases mixed with air, oxygen or nitrous oxide.
3. Given the precise components in the instrument, users shall not disassemble or refit it to avoid any damage to the internal components that may result in malfunction of the instrument.
4. A properly grounded power supply must be applied when using the instrument.
5. Please do not directly contact the inner part of modules to avoid scalding when using this instrument.
6. Make sure you wear disposable medical mask and rubber gloves during operation to avoid direct contact with biologically hazardous samples. Please refer to the standard operating procedure (SOP) in your lab for other protection items.
7. Protection provided by the instrument may be impaired if it is used in a manner not specified by the manufacturer.
8. Please do not direct the light of QR code scanning window to the eyes of operator or other personnel when using the instrument.

⚠Caution

1. Please do not directly expose this instrument to X-ray, γ-ray or ionizing radiation, or subject it to radio frequency interference or strong magnetic field/AlNiCo interference generated by diathermy apparatus or mobile phones in order to avoid any malfunction of this instrument.
2. Please use the power cord and data wire provided by Ustar in order to ensure the electrical safety and EMC performance of this instrument.
3. Please ventilate the instrument and irradiate it with ultraviolet lamp for 1 hour after it is stopped for use or prior to moving it to other places to minimize the biological hazards.
4. This instrument should be handled with care during transportation and operation to prevent it from impact, violent vibration and damp.
5. This instrument can only be repaired and maintained by professional personnel authorized by Ustar.
6. In case of any failure, please contact our customer service department in time.
7. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

⚠Precautions

1. This analyzer is only applicable to human biological samples detection.
2. The operator should understand how to operate the instrument and software and know all the safety issues through systematic training before use.

3. This analyzer can only be used with automatic cartridges provided by Ustar.
4. Please do not replace the original power cord and its built-in fuse. In case of power cord or fuse damage, please replace them with the parts provided by Ustar or authorized agent, so as not to affect the normal use of the analyzer and avoid damage to the instrument.
5. This analyzer is not waterproof, and its anti-immersion grade is IPX0. Please pay attention to waterproofing when cleaning the monitor parts.
6. In case of the following situations, please cut off the power supply immediately, pull out the power plug of the instrument from the power socket, and contact relevant after-sales service personnel:
   ①Liquid spilling into the instrument;
   ②Rain or water pouring on the instrument;
   ③Failure of the instrument, especially with any abnormal sound or smell;
   ④The instrument drops or the casing is damaged;
   ⑤Malfunction of the instrument.
7. Before being connected to the AC power supply, please ensure that the voltage of the power supply is consistent with that required in the manual, and the rated load of the power socket is not lower than the required rated load. The phase of the power socket must be consistent with the power cord plug of the analyzer, and there must be a good ground circuit.
8. The correct hand type should be used when the power cord is plugged in and out, please make sure that the plug is completely and firmly inserted into the socket when the plug is inserted. When pulling out the plug, do not pull or insert the power cord repeatedly.
9. This analyzer is a reusable instrument. Please wipe it with medical disinfectant (75% ethanol solution) before use. If the medical disinfectant (75% ethanol solution) entering into the module, please wipe it off before use. Do not immerse the product instrument in any liquid or contact it with strong organic solvents. In addition, the analyzer should not be sterilized by autoclave, steam, and ethylene oxide or placed at temperature higher than 45℃ (113℉). Any failure to comply with this precaution may cause serious damage to the analyzer.
10. Any leakage of hazardous substances on the surface or inside of the instrument should be treated in time and be cleaned by a soft cloth dipped with medical disinfectant (75% ethanol solution).
11. If you have any questions about the compatibility of disinfectants or cleaning agents with the components or materials in the instrument, please refer to the instructions of manufacturer.
12. Samples, kits and all consumables should be disposed of in accordance with the local Medical Waste Management Regulations.
13. Please turn off the power when the analyzer stops working. When it is not used for a long time, please cut off the power, pull out the power plug and cartridge and then close the module cover to avoid the dust or foreign matters.
14. The analyzer has a certain period of validity. There will be risks when it is used beyond the validity period. Please send it back to factory in time to confirm if it can continue to be used.
15. The analyzer can store up to 100,000 pieces of data. When the system memory is nearly saturated (less than 5% remained space), it will automatically prompt that the memory is saturated. At that time, please clean up the stored data in time, otherwise they will be automatically covered in order of time.

⚠Contraindication

None

Package Contents

Please check whether the following items are complete after opening the package.

No.	Name	Materials and specifications	Qty.
1	MultNAT Molecular Diagnostic Testing System	UP0102/UP0104	1
2	Power cord	AC250V 10A	1
3	Fuse wire	UP0102：T15AL250V UP0104：T20AL250V	2
4	USB drive	USB 2.0	1
5	Operator manual	/	1
6	Delivery inspection report	/	1
7	Certificate	/	1
8	Warranty certificate	/	1
9	Packing list	/	1

Symbols and Abbreviations

The following international symbols and abbreviations and the basic units of the international system of units may be used on the instrument and in this manual.

Symbol	Meaning
	Off position
	On position
	Warning/Caution
	Date of manufacture
	Manufacturer
	Refer to the operator manual
	Serial No.
	Use-by date
	WEEE symbol
	Grounding
	*In vitro* diagnostic medical device
	Authorized representative in the European Community
	Warning scald
	Biohazard
	USB connection
	The product meets the provisons ofEuropean in vitro diagnostic medical devices REGULATION(EU)2017/746

A	Ampere	kPa	Kilopascal	μA	Microamp
AC	Alternating current	kW	Kilowatt	V	Volt
cm	Centimeter	mA	Milliampere	Ω	Ohm
Hz	Hertz	mm	Millimeter	°C	Centigrade
DVM	Multimeter	ms	Millisecond	mΩ	Milliohm

Basic units of International System of Units

Chapter 1 Introduction

1.1 Brief Introduction

Product Name: MultNAT Molecular Diagnostic Testing System

Model: UP0102, UP0104

UDI-DIs :

Model:UP0102,UDI-DI:06973492240619;

Model:UP0104,UDI-DI:06973492240626.

Scope of application: The MultNAT Molecular Diagnostic Testing System (hereinafter referred to as "the analyzer" or "the instrument"or"this product") is used together with matched test kits for *in vitro* quantitative detection of the nucleic acid sequence in samples of human pathogens based on three-stage magnetic conductivity extraction technology and fluorescence polymerase chain reaction (PCR)，this product is an in vitro diagnostic medical device,and is used for in vitro amplification and qualitative analysis of nucleic acid for sample genes.

Applicable of testing population： Nucleic acid virus infects people.

Intended user:Licensed doctors and trained medical professionals.

Test principle： This product is used together with our company's supporting nucleic acid diagnostic kit to achieve the integration and automation of sample preparation, nucleic acid extraction and amplification, and targeted sequence detection. In the whole operation process, the sample only needs to be dealt with simply pretreatment before adding the automatic detection tube. After the user inserting the automatic detection tube into the product, the user can run the equipment through the touch screen graphical user interface (GUI). The device will automatically conduct sample processing, amplification reaction and detection. During the user can also monitor the detection progress and view the data, and the instrument will automatically report and store the results after the detection

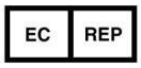
Ustar Biotechnologies (Hangzhou) Ltd.

Registered address: 6/F, Building 2, 611 Dongguan Road, Binjiang District, Hangzhou, Zhejiang, 310053 China

Web: en.bioustar.com

Tel: +86-571-88939358 (sale)
+86-4008707025 (after sale)

E-mail: sales@bioustar.com (sale)
service@bioustar.com (after sale)



Lotus NL B.V.

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

mail: peter@lotusnl.com

Tel: +31644168999

2.1 Potential hazards

This chapter describes potential hazards and corresponding measures, as well as safety features designed to minimize potential hazards. Familiar yourself with the following information before use.
Installation and operation of this analyzer should follow local laws and regulations.

Electrical hazards
There are high-voltage and moving parts inside the analyzer. Please do not open any shell parts of the instrument. Only professionals should conduct component replacement or inner adjustment of the instrument. **Please do not replace components when the power supply is turned on.**

Heat hazards
The analyzer contains a semiconductor temperature control system to make the kit at an appropriate operating temperature, and the maximum internal temperature is 95℃. See precautionary measures in **Maintenance**.

Biohazard
The diagnostic kit used with this analyzer may have biological hazards when loading samples. Protective devices should be worn when operating this instrument.

Eye safety
The QR code scanner of this analyzer adopts light-emitting diode (LED) rather than laser as the light source to form aiming indication graphics and lighting. Although the light wave generated by LED is safe if used in a correct manner, it is still recommended to avoid looking directly at the LED or shooting the light beam at human eyes in the process of use, so as to avoid any discomfort.

Electromagnetic compatibility hazards
This instrument has special preventive measures for electromagnetic compatibility (EMC) hazards. Please refer to the **EMC Declaration** in **Annex A** of this manual for installation and operation.

2.2 Safety features

This instrument provides some safety features to avoid mis-operation or accidental operation. All personnel involving in instrument or auxiliary operation must be familiar with the following safety features.

Error messages
When malfunction occurs, the system will shut down automatically and display error

code, error messages and repair measures. Please see **Error messages and troubleshooting** for the complete list of faults and failure analysis information.

Interlocking

The instrument is equipped with a cover interlock and a cartridge interlock. When the cover is opened or the cartridge is not put in, the interlock will be activated and the analyzer will not work.

Warning tone

When malfunction occurs, the instrument will sound a warning which can be turned on/off on the setting interface.

Security labels

The nameplate of this instrument is marked with a series of security labels, as shown in Figure 2.1 (take UP0102 for example) and Figure 2.2 below. Please ensure that all relevant personnel are familiar with these labels and their meanings. Please refer to the **Symbols and Abbreviations** for symbols that may be used on the instrument.

Figure 2.1 Instrument nameplate

Figure 2.2 Safety symbols position

Chapter 3 System Description

This chapter describes the main components and system specifications of this instrument.

3.1 Structure composition

This instrument is mainly composed of control components, drive components, transmission and thermal cycle components, photoelectric components, heating block, power supply system, shell and embedded software (release version number: 1).

A: Module A
B: Module B
C: Touch screen/User interface
D: Code scanner
E: Power button
F: USB interface

Figure 3.1 Operating area (UP0102)

A: Module A
B: Module B
C: Module C
D: Module D
E: Touch screen/User interface
F: Code scanner
G: Power button
H: USB interface

Figure 3.2 Operating area (UP0104)

3.1.1 External communication

This instrument is equipped with the following communication interfaces:

Port	Function
USB-A port (flat port)	Connect USB disk for software upgrade and data export

3.1.2 Power cord

Figure 3.3 Power cord

3.2 Technical characteristics and parameters

Specification	Parameters
Dimension (W×D×H）	UP0102: 370mm×350mm×340mm UP0104: 370mm×610mm×340mm
Weight	UP0102: 17kg UP0104: 31.5kg
Rated voltage	AC 100~240V，50/60Hz
Rated power	UP0102: 900VA UP0104: 1800VA
Fuse specification	UP0102：T15AL250V UP0104：T20AL250V
Controllable temperature range	40~95℃
Melting heating rate	0.1~1℃/s
Heating rate	Upper zone≥0.8℃/s Middle zone≥0.8℃/s Lower zone≥3.5℃/s
Cooling Rate	Lower zone≥2.5℃/s
Module temperature fluctuation	≤0.5℃
Precision of temperature control	≤0.5℃
Temperature uniformity	≤1℃
Excitation wavelength	Channel 1: 470nm; Channel 2: 520nm; Channel 3: 560nm; Channel 4: 625nm;
Detection wavelength	Channel 1: 520nm; Channel 2: 570nm; Channel 3: 625nm; Channel 4: 680nm;
Repeatability of fluorescent intensity test	CV value≤3%
Accuracy of fluorescent intensity test	CV value≤5%
Fluorescence detection time	≤15s

Specification	Parameters
Software interface	Chinese/English
Signal interface	USB
Print interface	External USB thermal printer
Ambient temperature during operation	5~40℃
Ambient humidity during operation	0%-95% (non-condensing)
Altitude	≤4000m
Atmospheric pressure for transportation and storage	≥56.0kPa
Ambient temperature during transportation and storage	-40~55℃
Relative humidity during transportation and storage	≤95% (non-condensing)

3.3 Standard

EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control，and laboratory use - Part 1: General requirements
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control and laboratory use-Part 2-101: Particular requirements for *in vitro* diagnostic (IVD)medical equipment
EN 61010-2-010:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use—Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN IEC 61326-1:2021	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment

Chapter 4 Special Requirements

This chapter mainly describes the special requirements for space, electricity, environment, warranty period, validity period and production date of the analyzer.

4.1 Space requirements

The dimensions of the product are shown in Table 4.1.

UP0102

Space requirements	Parameters
Height	340mm
Width	370mm
Length	350mm
Weight	17kg

UP0104

Space requirements	Parameters
Height	340mm
Width	370mm
Length	610mm
Weight	31.5kg

Note: Place the instrument on a hard, flat surface. Make sure the power cord connection and the power switch (on the back side) are easily accessible.

Provide at least 10 cm of clearance on each side of the instrument. Do not block the fan exhaust under the base plate or the air intake on the side of the instrument. The lack of proper ventilation can cause the instrument to malfunction.
Do not put the instrument in place where it is difficult to turn off the switch, so as to avoid personal injury caused by failure to turn off the power in time in case of danger.

4.2 Electrical requirements

Please consider the electrical requirements shown in Table 4.2 below before installing this instrument.

Electrical requirements	Parameters
Voltage	AC 100~240V
Current	UP0102: ≤15 A UP0104: ≤20 A
Frequency	50/60Hz

Note: This instrument shall not share the same cable with other electric load

equipment (such as air conditioner or elevator). If conditions permit, independent cable with circuit breaker should be used.

⚠Warning

To avoid electrical hazards, the power supply connected to the instrument must be grounded.

4.3 Operating environment

For safe use of the analyzer, please follow the following requirements:

- It should be ensured that the air is free of corrosive substances, such as salts and acids that may damage the surface of cables and instrument.
- Relative humidity: ≤ 95%, non-condensing.
- Operating temperature: 5℃~40℃. If the temperature ≤5℃ or≥40℃, the performance deduction of the instrument may occur.
- Operating altitude: 0-4,000m
- Do not place the instrument in the vent of heating, other heat sources or places where the temperature is easy to change. Place the instrument away from the heating vent, other heating sources or places where the temperature is easy to change.
- Do not use it in the environment where flammable anesthetic gas is mixed with air, oxygen or nitrous oxide.

4.4 Operator training requirements

This manual cannot be used as the comprehensive guide for operation. It is recommended that all relevant personnel involving in operation should firstly receive the training including but not limited to：

- Biological safety
- Electrical safety
- Instrument operation procedure
- Instrument setting procedure
- Potential hazards
- Practical training

The training related to this analyzer is available from Ustar Biotechnologies (Hangzhou) Ltd.

4.5 Storage and transportation requirements

To store and transport this analyzer properly, please follow the following requirements:

- Maintain the ambient temperature between -40℃~55℃.
- Maintain the relative humidity ≤95%, non-condensing.

- Maintain the air free of corrosive substances such as salt and acid in the place where the instrument is stored.
- Please minimize shock and vibration during transportation.
- Do not drop the instrument.
- Storage life(Storage life of the instrument without being powered on): no more than 12 months

4.6 Moving and transporting the instrument

⚠Warning

Any operation violating the following instructions may cause instability and damage to the product.

Movement

When moving the instrument, please keep the instrument **upright**, lift it away from the ground and do not drag it.

Transportation

If the instrument is transported by vehicles, it should be put into the packing box. Please ensure that the packing box is not upside down, nor lies down.

4.7 Product recycling (end-of-life solution)

The analyzer and the accompanied accessories are non-degradable objects.
Disposal advice: the expired instrument and accessories should be recycled or disposed of by the special environmental protection department.

4.8 Warranty period

The whole product is guaranteed for 12 months from the date of sale.

4.9 Production date and service life

Production date: Please see instrument nameplate Service life: 5 years.
Note: The service life of the analyzer is determined according to the accelerated aging test. During the use of the analyzer, the user should maintain and repair the instrument according to this operator manual. If it is confirmed that it can still maintain safety and effectiveness after maintenance and repair, it can continue to be used normally.

4.10 Network security instructions

The original data is stored in the instrument, which can only be exported, not imported; the user can only log in through the touch screen interface.

4.10.1 Operating environment

Hardware configuration: CPU: IMX6Q; RAM: 1G; ROM: 8G.
Embedded software operating system: Linux real time operating system.
Data storage medium: we recommend you to use the provided USB disk.

4.10.2 Security software

Name: Microsoft Defender
Supplier: Microsoft

4.10.3 Data and instrument (system) interface

USB A interface (USB2.0)

4.10.4 User access control mechanism

The users need to enter the correct account and password to log in.

4.10.5 Software environment

System software (computer system): win7 / win10

4.10.6 Update of software environment and security software

Update through the software upgrade function

Chapter 5 Installation

This chapter mainly describes how to install the instrument.

5.1 Instrument installation

5.1.1 To connect power cord

Insert the terminal female of the power cord into the power socket rear the base plate, and install it in place without loosening, as shown in Figure 5.1.

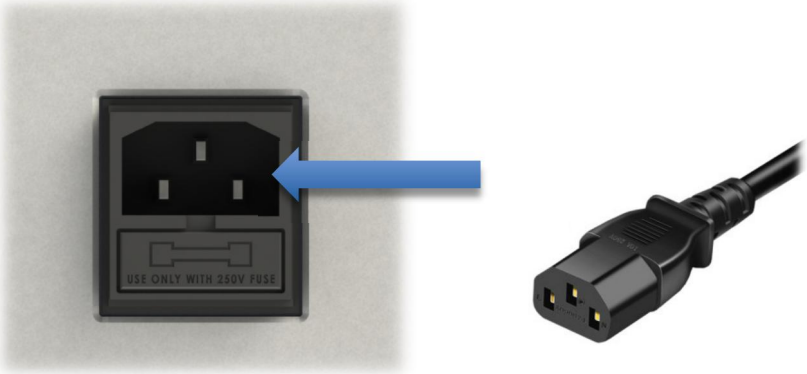


Figure 5.1 Power cord installation

5.1.2 To connect thermal printer

Insert the USB plug of thermal printer into the USB socket on the side or the back of the analyzer and install it in place without loosening.

Note: When using the thermal printer function of the analyzer, it is recommended to use the thermal printer recommended by Ustar, otherwise it may affect the normal functioning of printing.

Chapter 6 Operating Instructions

This chapter describes in detail how to operate the instrument.

6.1 Standard test procedures

6.1.1 Starting the instrument

Connect the instrument to the power supply, turn on the power switch on the rear right side of the instrument, and enter into the initialization page, as shown in Figure 6.1.
Note: Leave at least 10 cm of clearance on each side of the instrument for power connection and switching.

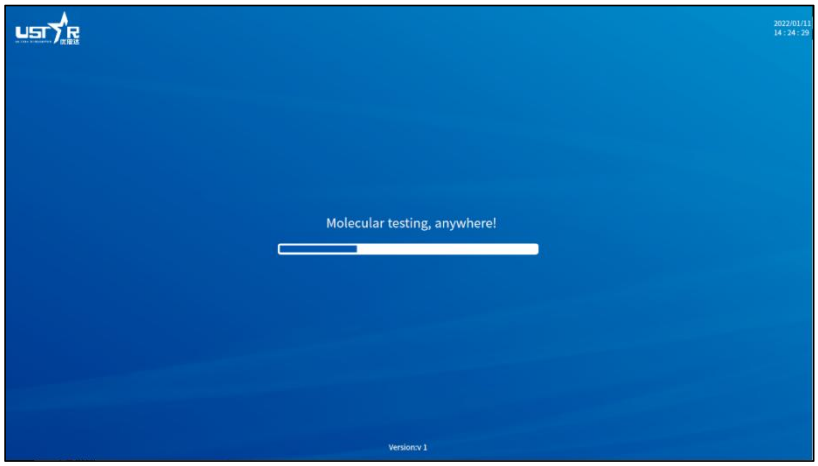


Figure 6.1 Initialization

6.1.2 Logging on

As the instrument is turned on, enter the user name and password, click "LOGIN" to enter the detection interface, as shown in Figure 6.2 (Admin account: user name: admin; password: 123).

If you forget your account or password and cannot log on, please contact the administrator. If you need to apply a new account, please contact the administrator.

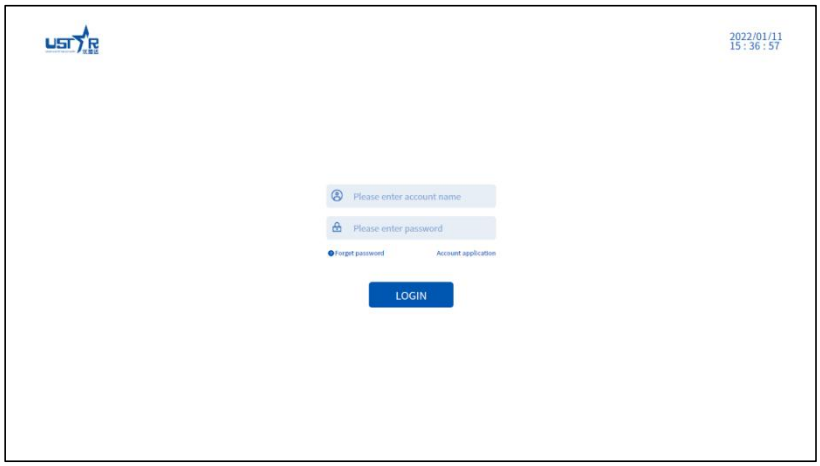


Figure 6.2 Login

6.1.3 Running a test

The "TEST" page will be displayed after successful login. Click "Module A", "Module B" in UP0102, or "Module A", "Module B", "Module C", "Module D" in UP0104 to select corresponding test module, as shown in Figure 6.3 and 6.4.

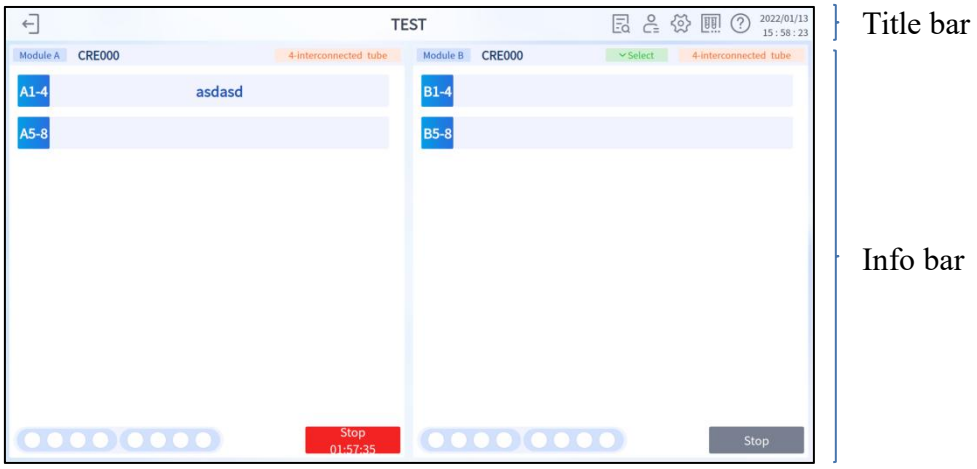


Figure 6.3 Test (UP0102)

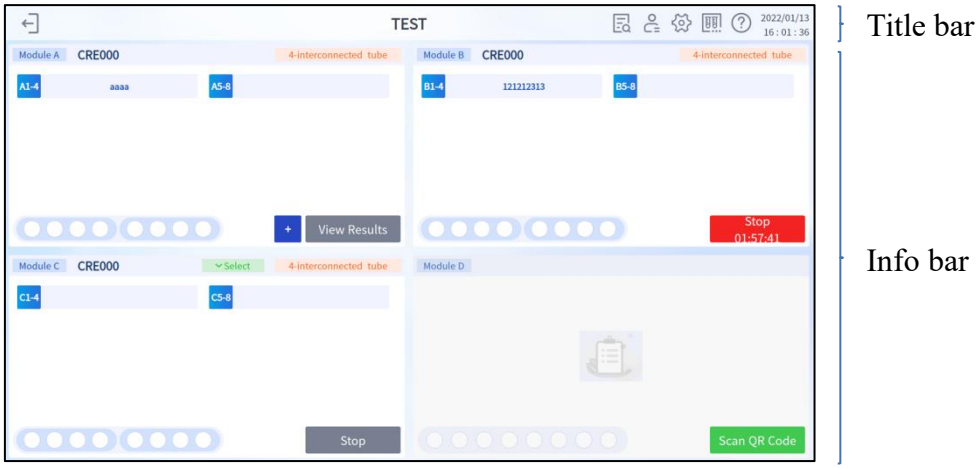


Figure 6.4 Test (UP0104)

The test page is composed of a title bar and info bar. The info bar has two display types respectively for UP0102 and UP0104, as shown in Figure 6.3 and 6.4.

- Title bar includes:
  a) "⇦" : return to the login page;
  b) Test;
  c) "📋" : click to check detailed test results;
  d) "👤" : click to enter user management page;
  e) "⚙" : click to enter system settings page;
  f) "?" : click to enter help page;
  g) Date and time

Info bar includes:

a) Module number
b) Test target;
c) Sample type;
d) Cartridge type;
e) Sample information;
f) Cartridge sketch;
g) Buttons.

Note: If a module fails, it is marked with an "x". In this case, the module cannot run and cannot be selected.

(1) Select a test module, and the module will be highlighted. Click "SCAN" button, scanner in the front of the instrument flashes. Place the QR code parallel in front of the scanner (make sure the QR code in the center of the scanning spot) to input the cartridge information, as shown in figure 6.3. After successful input, the blank position on the upper side of the module will display the test item.

Note: If scanning fails due to incomplete or damaged QR code, click the prompt box "Scan the QR code on cartridge" to enter the cartridge information manually.

(2) Scan sample barcode. The method is the same as QR code scanning. After successful scanning, the sample ID will be displayed in the corresponding sample ID box.

Note: If the scanning fails due to incomplete or lack of barcode , click the barcode to input sample ID manually. Any incorrect barcode can be deleted by clicking "×" on the top right corner.

(3) If you want to add or modify sample type, click "Select sample type" to check the pull-down list, as shown in Figure 6.5.

Note: This step is optional. If the required sample type is not displayed in the list, set it on the System Settings page. For details, see Section 6.2.

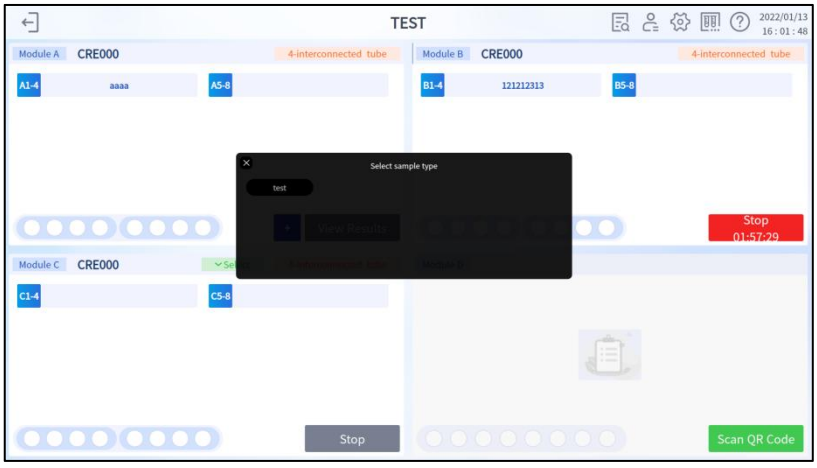


Figure 6.5 Select sample type

(4) After the sample type is selected, open the module cover. Insert a cartridge into a module, and the icon displayed on the screen corresponding to this module will be lit up.

Note: Please put the cartridge into the module from left to right successively. Do not leave vacancy between each cartridge. Cartridges tested in the same module should be in the same test item.

(5) After all cartridges are loaded, cover the module cover.

(6) Click "STOP SCAN" button, it will turn to be "START TEST" and turn blue.

Note: If cartridge is not loaded or module is not closed, the test program cannot start, and a reminder will prompt accordingly when clicking the "START TEST" button.

(7) Click "START TEST" , the test program will start. A countdown timer will be displayed on the screen; A red "STOP TEST" button will be displayed in the lower right corner. If click it when a test is in progress, the system will prompt whether to stop the test. Click "Confirm", the test will be forcibly terminated, as shown in Figure 6.6.

Note: Do not open the module cover during the test. After the termination of a test, all the cartridges and samples in the module will be invalid. Please use this operation with caution!

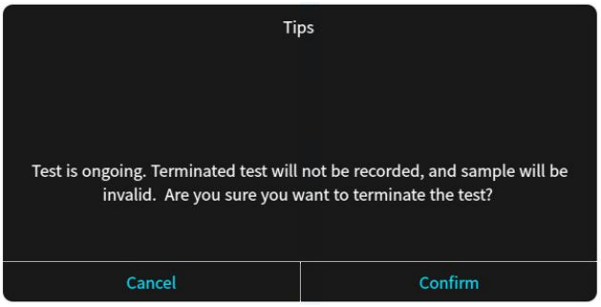


Figure 6.6 Terminate the test

(8) After the test in selected module starts, another module can be selected for a new test. The operation procedure is the same.

Note: Users can click the "⑦" button at the upper right corner of the test page to enter the help page to view the detection instructions, as shown in Figure 6.7. Here UP0102 is taken as an example.

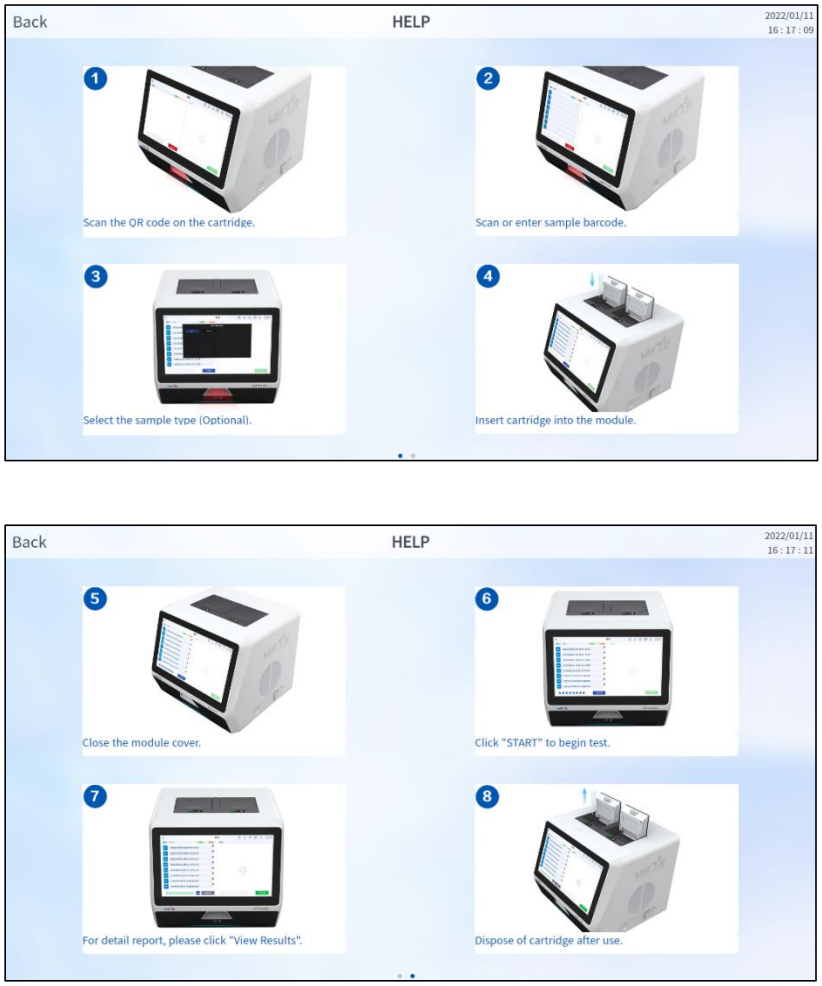


Figure 6.7 Help

6.1.4 Viewing the test results

Once the test is completed, "STOP TEST" will change to "VIEW RESULT". "Negative" result is in green font, other results in red font, as shown in Figure 6.3. For detailed result, please click "VIEW RESULT" for detailed results. For another new test, click "+" in the lower right corner of the module.

The detail results page is mainly divided into title bar and info bar, as shown in Figure 6.8.

Click "" to export result (a USB and permission required); Click "" to print result (a printer and permission required).

Figure 6.8 Detail report

Info bar includes: test module, test item, sample information, amplification and dissolution curves of each fluorescence channel, test result, test date, and analyzer number. The amplification dissolution curve of each fluorescence channel can be viewed on the left side of the info bar; the result of each sample and Ct value of each leg can be viewed on the right side of the info bar, and the status and final result of each cartridge can be observed at the bottom of the info bar.

6.1.5 Turning off the instrument

Press the power switch on the right side of the instrument to shut down.

6.2 System settings

Click" ⚙ " in the upper right corner of the "TEST" page to enter "SYSTEM SETTINGS", as shown in Figure 6.9.

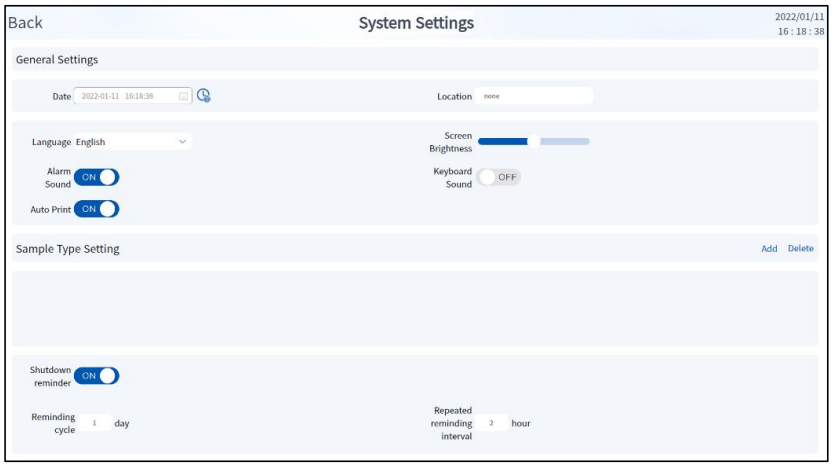


Figure 6.9 System settings

The "General Settings" include:

Back: return to the previous page

Date: date and time setting
Location: test location setting
Keyboard sound: keyboard sound switch
Screen brightness: screen brightness adjustment
Alarm sound: alarm sound switch
Language: interface language switch
Auto print: automatic printing switch

The "Sample Type Setting" includes:

View, add or delete sample types

The "Software Upgrade" includes:

Current version: display the current version number of the system software
Search for new version: detect whether there is a new system version available to update

6.2.1 Date and time setting

Click the blank box next to the "Date" and set the current date on the left side of the pop-up box and the current time on the right side. Click "Confirm" to save the setting, as shown in Figure 6.10.

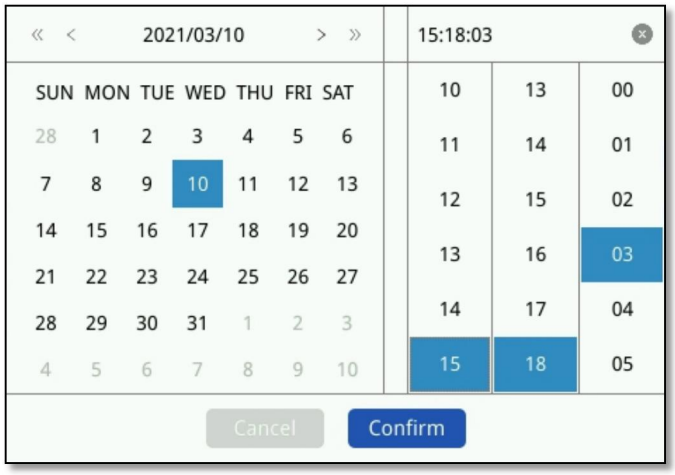


Figure 6.10 Date and time settings

6.2.2 Test location setting

Click the blank box next to the "Location" and enter or modify the test location with a screen keyboard.

6.2.3 Keyboard sound setting

Click the button to the right of the "Keyboard Sound" to select "Off" or "On" for the keyboard sound.

6.2.4 Screen brightness adjustment

Click or drag the progress bar to the right of the "Screen Brightness" to adjust the brightness. Move to the far left for the minimum brightness, and move to the far right for the maximum brightness.

6.2.5 Alarm sound setting

Click the button to the right of the "Alarm Sound" to select "Off" or "On" for the alarm sound.

6.2.6 Language switch

Click on the drop-down menu next to the "Language" to select the system language.

6.2.7 Auto print setting

Click the blue button to the right of the "Auto Print" to select "On" or "Off" for the auto print function. When the automatic printing function is turned on and connected with a printer, the analyzer will print out the test results immediately after each sample test is completed.

6.2.8 Sample type setting

If you need to add a sample type, click the "Add" on the right side of "Sample Type Setting" to add a new sample type. At this time, the system will pop up a dialog box, please enter the "Sample Type" and "Abbreviation of the sample type" as prompted. Then, click "YES" to save them. If you do not need to save them, click "CANCEL". As shown in Figure 6.11.

Figure 6.11 Add sample type

If you need to delete a sample type, click the "Delete" on the right side of "Sample Type Setting", then click "⊗" in the upper right corner of the sample type you want to delete, and confirm to delete the sample.

6.2.9 Upgrading the software

Insert the USB storage medium containing the upgrade files at the UBS interface on the right or rear of the instrument, and click "Search for new version" on the right of "Current Version" to automatically detect a new software version available to update. If there is a new software version available to update, click "Upgrade" to get the latest version, as shown in Figure 6.12.

During the upgrade process, please keep the instrument power supply normal until the system pops up the upgrade completion prompt box. After the upgrade is complete, please restart the instrument. If it displays "Your Software is the Latest Version", no upgrade operation is required, as shown in Figure 6.13.

Note: Please store the upgrade package folder (named as "update", if it is a compressed package, unzip it) in the root directory of the USB storage medium.

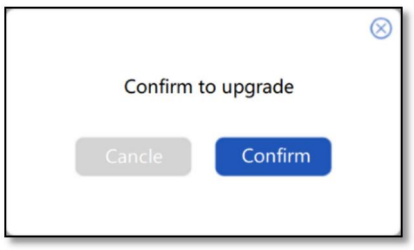


Figure 6.12 Upgrade confirmation

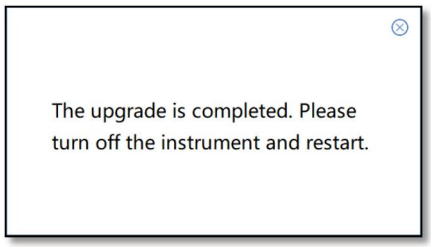


Figure 6.13 Upgrade completion

6.3 Managing test records

Click"" on the "TEST" interface to enter the "TEST RECORDS" interface. You can view the "Test Item", "Test Date", "Sample ID", " Samply Type" and "Test Result" of each test record on this interface. "Test Result" shows "Positive" or "Negative" or "Invalid". Click the "" button on the far right of a record to view the detailed information of the current record. Click "Test item", "Test Date", "Sample ID", "Type" or "Test Result", corresponding test records can be arranged in positive or reverse order. "TEST RECORDS" interface is shown in Figure 6.14.

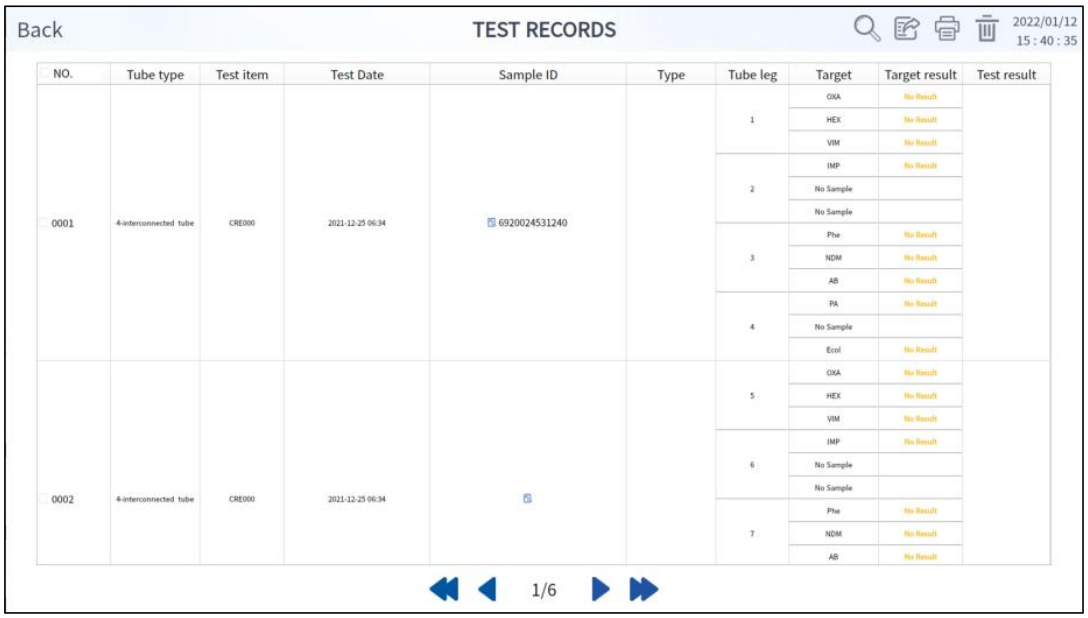


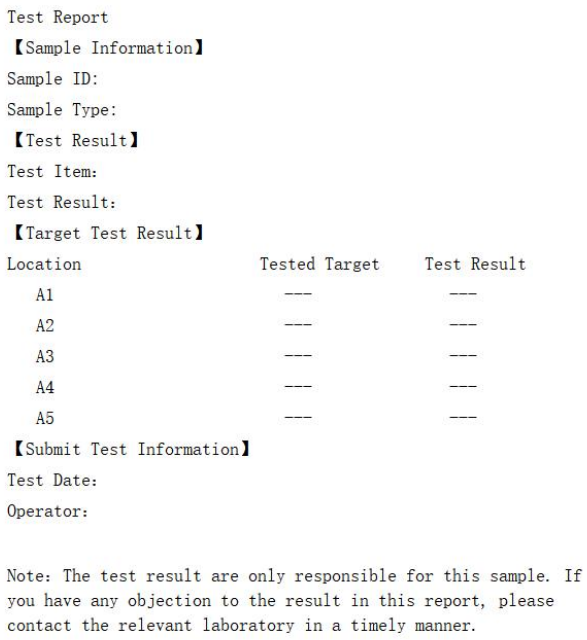
Figure 6.14 Test records

The function of each function key in Figure 6.14:
<Back: Return to the previous page.
: View the test results of the selected test record (only valid when one test record is selected).
: Use USB to export the checked test records.
: Print the checked test records.
: Search records by conditions
: Delete the checked test records (only available in administrator account)
Warning: the deleted test records cannot be restored, please make a backup.
and : Turn the page forward and backward.
and : Turn to the first page and turn to the last page.
Note: You can click the triangle arrow on the right side of the page to turn the page forward and backward. Ordinary users cannot delete the records.

6.3.1 Printing test results

Click the blank box on the left side of the test record on the "TEST RECORDS" interface, and select the test records that need to be printed (multiple selections are available. Click the blank box before the "NO." will select all test records). Click "" to print the selected test results, or click "" on the "RESULT DETAILS" interface to print the current test results,as shown in Figure 6.14 and Figure 6.8. The printed test report is shown in Figure 6.15.

Note: Results printing requires a printer connection and corresponding permissions that can be granted or eliminated by the administrator.



Test Report
【Sample Information】
Sample ID:
Sample Type:
【Test Result】
Test Item:
Test Result:
【Target Test Result】

Location	Tested Target	Test Result
A1	---	---
A2	---	---
A3	---	---
A4	---	---
A5	---	---

【Submit Test Information】
Test Date:
Operator:

Note: The test result are only responsible for this sample. If you have any objection to the result in this report, please contact the relevant laboratory in a timely manner.

Figure 6.15 Test report

The meanings of letters in the test report shown above as follows:
A: Site name (“Location” in General Settings)
B: Sample ID
C: Test date
D: Test number (auto-generated serial number)
E: Test item
F: Test result (Positive, Negative, Invalid）
G: Operator (login user)

6.3.2 Exporting test results

On the "TEST RECORDS" interface, click the blank box on the left side to select the test records that need to be exported (multiple selections are available. Click the blank box before "NO." to select all records). Click "" to export the selected test results or click "" on "DETAIL RESULTS" interface to export current test result, as shown in Figure 6.14 and Figure 6.8.

Note: Results export requires corresponding permissions which can be granted or eliminated by the administrator. This operation requires a USB storage medium; The exported results are stored in the root directory of the USB storage medium, such as "H:\XXXX.csv".

6.3.3 Deleting test records

Click "" in the upper right corner of the page on the "TEST RECORDS" page to delete the checked test results.

Warning

Data cannot be restored after deletion, please use them with caution. Ordinary users cannot delete records.

6.4 User management

With an administrator access role, click "" in the upper right corner on the "TEST" interface to enter the "USER MANAGEMENT" interface, as shown in Figure 6.16.

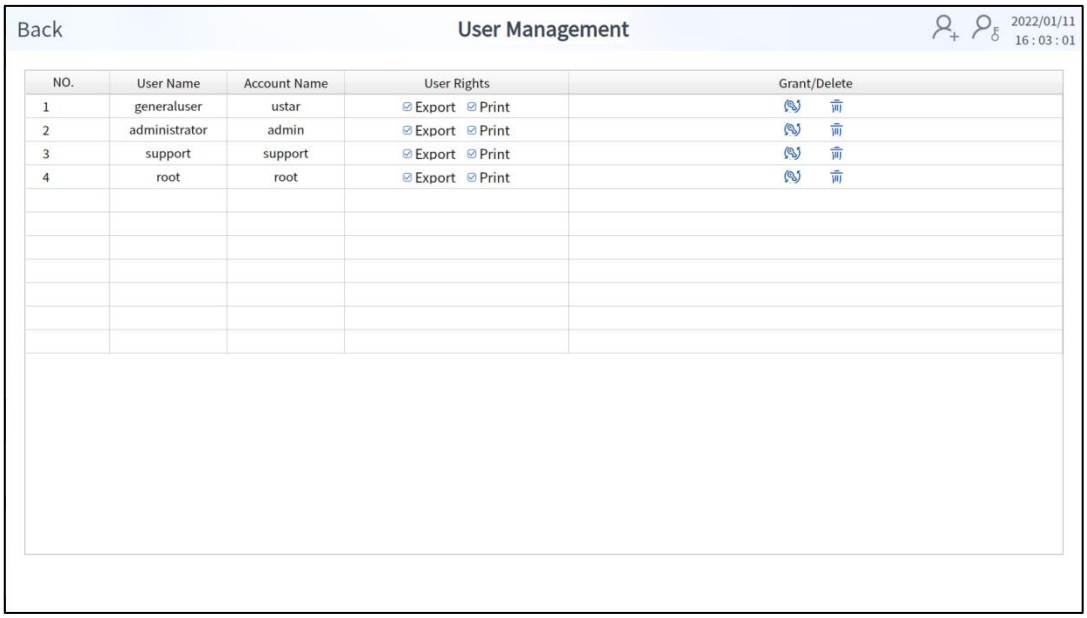


Figure 6.16 User Management (admin account)

Note: There are two types of user accounts: administrator user and ordinary user. Admin users have an access to editing, deleting, and adding accounts. Ordinary users can only edit their own accounts (*i.e.*, it is only allowed to modify the password of their own accounts).

6.4.1 Adding new users

Click"" on the "USER MANAGEMENT" interface with the administrator account to open the "Add new account" dialog box.

Enter "Account Name", "User Name" (optional), "Password" and "Confirm Password" in sequence. Select user permissions: "Export Results" and "Print Results" (Tick the blank box to grant corresponding permissions. Multiple permissions are available), as shown in Figure 6.17.

Click "YES" to save the setting.

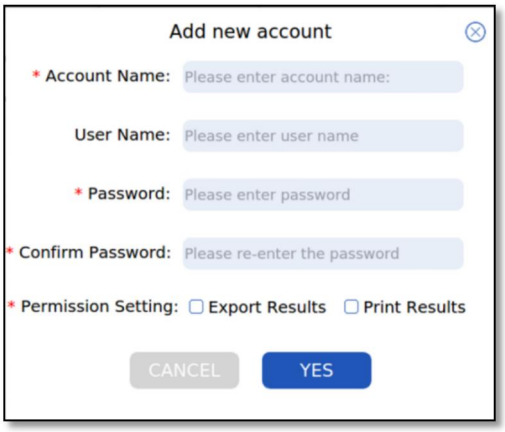


Figure 6.17 Add new account

6.4.2 Permission management

To grant permissions for a new account, the administrator can check corresponding permission setting boxes of "Export Results" and "Print Results" on the “USER MANAGEMENT” interface, and click "YES" to save such setting.

To change a permission, the administrator can check or uncheck the permission setting boxes of “Export Results” and “Print Results” on the “USER MANAGEMENT” interface.

6.4.3 Password management

To reset the password of an existing user, please enter the "USER MANAGEMENT" interface with the administrator account.

Click"" to the right of the user name whose password is to be reset. Then, the password will be reset to "123456", as shown in Figure 6.18.

If you need to change the password, please enter the corresponding account to modify it.

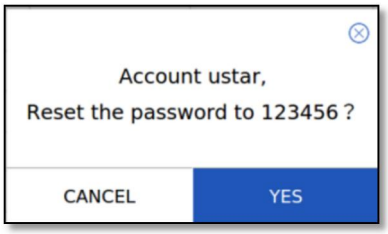


Figure 6.18 Reset password with admin account

To change the password of ordinary user account, click "" in the upper right corner on the “TEST” interface, as shown in Figure 6.19.

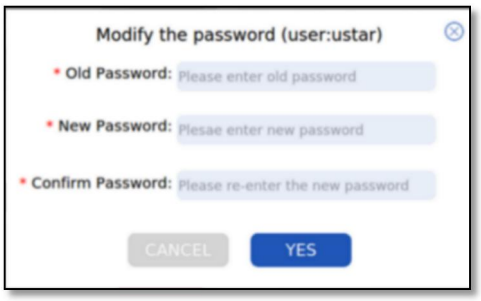


Figure 6.19 Change password (ordinary users)

If you need to change the password of admin account, please click "🔑" on the "USER MANAGEMENT" interface (admin user), enter old password, new password, and confirmed new password in the prompt box, and then click "YES", as shown in Figure 6.20.

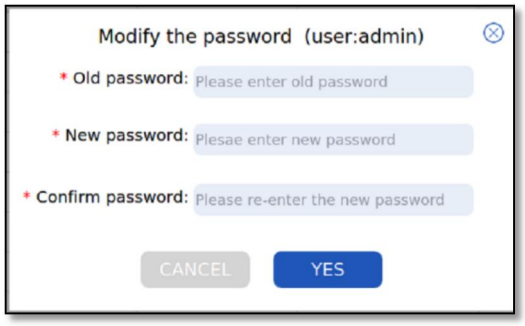


Figure 6.20 Change password (user admin)

6.4.4 Removing users

On the "USER MANAGEMENT" interface with the admin account, click"🗑" of the users to be deleted and confirm to delete. **Be cautious for this operation!**

Chapter 7 Maintenance

This chapter provides maintenance methods, replacement of spare parts and troubleshooting of the instrument.

7.1 Maintenance

Please clean and disinfect the instrument regularly in order to ensure normal function and test result accuracy of the instrument. During the clean procedure, please turn off the analyzer.

Task	Maintenance interval	Method
Display screen cleaning	Once a month	Clean the screen with a dry and soft cloth. **Warning: DO NOT use any organic solvents, acidic or alkaline solutions, otherwise the display screen may be damaged.**
Instrument surface cleaning	Once a month	Disinfect the analyzer surface with a soft cloth dipped with medical disinfectant (75% ethanol solution).
Cartridge socket cleaning	Once a month	Disinfect and clean the cartridge socket with a soft cloth dipped with medical disinfectant (75% ethanol solution). **Warning: DO NOT let the fluid flow into the socket!**
Verify the effectiveness of the over-temperature protection device	Once every 5 years	The manufacturer or a qualified technician should conduct an on-off test on the over-temperature protection equipment.
Calibration	Once a year	Please contact Ustar after-sale staff.

Table 7.1 Instrument maintenance

Note:

1. Please close module cover after pulling out the cartridge to prevent dust and particles from entering into it.

2. Wipe dry or air dry the cartridge after cleaning it. There should be no water accumulated in the module, sockets and power sockets.

3. If the instrument is not used for a long time, please cut off the power supply.

7.2 Fuse replacement

a) Remove the fuse holder under the power socket.

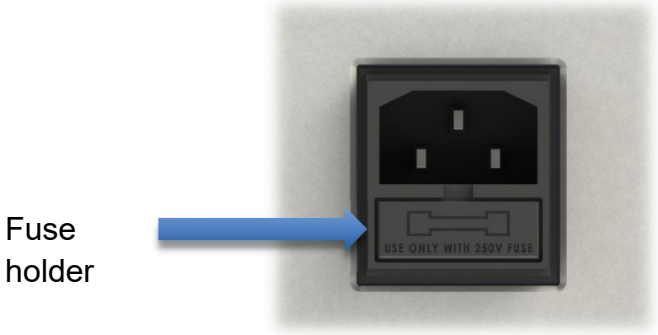


Figure 7.1 Remove the fuse holder

Figure 7.2 Fuse holder

b) Take out the fuse to be replaced and scrap it.

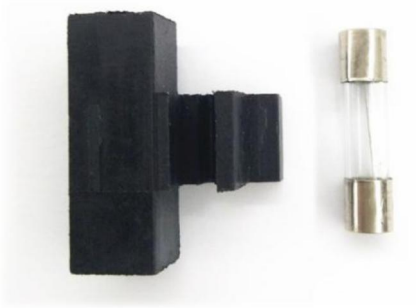


Figure 7.3 Take out scrapped fuse

c) Take out the spare fuse in the accessories.

Figure7.4 Spare fuse

d) Install spare fuses.
e) Insert the fuse holder back into the lower part of the power socket.

7.3 Error messages and troubleshooting

Error messages

No.	Error Code	Error message	Possible causes	Solution
1	error1	Cartridge information is wrong, please scan the correct QR code.	Kit information error	Check the verification code of the kit and contact supplier
2	error2	Cartridge has expired, please use a new cartridge.	The cartridge has expired.	Use a cartridge that has not expired
3	error3	Cartridge has already been used, please use a new cartridge.	Secondary use of the cartridge	Use a new cartridge
4	error4	Kit information is wrong, please scan the correct QR code.	Kit information error	Check the verification code of the kit and contact the supplier
5	error5	Kit information already exists, please scan the matching QR code.	Kit information error	Check the verification code of the kit and contact the supplier
6	error6	Kit information does not match the	The cartridge	Use the kit that

No.	Error Code	Error message	Possible causes	Solution
		input cartridge information, please scan the matching QR code.	information does not match the verification code of the newly entered kit information.	matches the cartridge
7	error7	Module cover is opened, test fails.	The cover is opened during the test.	Retest
8	error8	Module cover is opened, the cartridge is taken out, and the test fails.	The cover is opened during the test and the cartridge is taken out.	Retest
9	error11	Temperature sensor short circuit of module X upper zone	The resistance value of the temperature sensor of the module X upper zone is 0, causing the short circuit. X is A~D.	Contact customer service
10	error12	Temperature sensor short circuit of module X middle zone.	The resistance value of the temperature sensor of the module X middle zone is 0, causing the short circuit. X is A~D.	Contact customer service
11	error13	Temperature sensor short circuit of module X lower zone.	The resistance value of the temperature sensor of the module X lower zone is 0, causing the short circuit. X is A~D.	Contact customer service
12	error14	Break of temperature sensor of module X upper zone.	Temperature sensor short circuit of module X upper zone. X is A~D.	Contact customer service
13	error15	Break of temperature sensor of module X middle zone.	Temperature sensor short circuit of module X middle zone. X is A~D.	Contact customer service
14	error16	Break of temperature sensor of module X lower zone.	Temperature sensor short circuit of module X lower zone. X is A~D.	Contact customer service.

No.	Error Code	Error message	Possible causes	Solution
15	error23	Module X cannot be used, please use other modules or contact after sale service.	Module X fault. X is A~D	Contact customer service.
16	error25	Please insert USB disk.	USB disk is not inserted when exporting test data.	Insert the USB disk.
17	error29	File reading error.	Incorrect update file established by USB disk when updating USB disk software.	Establish update file with correct name.
18	error30	Module X optical path fault.	Module X optical path fault. X is A~D.	Contact customer service.
19	error31	Module X motor fault.	Module X motor fault. X is A~D.	Contact customer service.
20	error32	Temperature control fault in (upper/middle/lower) Module X.	Temperature control fault in (upper/middle/lower) Module X. X is A~D.	Contact customer service.
21	error36	Magnetic steel motor X fault.	Magnetic steel motor X fault. X is A~D.	Contact customer service.
22	error37	Linear motor unit 1/2 fault.	Linear motor unit 1/2 fault.	Contact customer service.
23	error38	Repeated barcode scanning.	Repeated barcode scanning.	Check the barcode.
24	error39	Sample ID has reached to the upper limit for current module. Please load cartridge and start the test.	All sample IDs have been input.	Load cartridges and start testing.
25	error40	Please scan the correct QR code.	QR code cannot be read correctly.	Check the verification code of the kit and contact the supplier.
26	error41	Scan QR code on the kit card.	QR code cannot be read correctly.	Check the verification code of the kit and contact the supplier.

No.	Error Code	Error message	Possible causes	Solution
27	error42	Module cover is not closed.	The cover is open.	Check the cover.
28	error43	It is detected that module cover is not closed, please close it and click to start the test.	The cover is not closed or the sensor is faulty	Check the cover.
29	error44	Scan the correct barcode.	The barcode is too long.	Check the barcode.
30	error45	Cartridge information has been input in the module. Delete it or wait until the end of test if you want to change tube type and test item.	QR code has been scanned, cartridge information has been input.	Check the barcode or follow the instruction.
31	error46	There is cartridge not loaded. Still start the test?	The number of inserted cartridges does not match that of filled barcode.	Follow the instruction.
32	error47	There is barcode not input. Still start the test?	The number of inserted cartridges does not match that of filled barcode.	Follow the instruction.

Troubleshooting

No.	Problem	Possible causes	Solution
1	Fail to start up,	The fuse is blown out,	Replace the fuse.
2	Unable to press button,	The button is mechanically stuck,	Contact customer service.
3	No response to screen taps	Circuit fault	Contact customer service.
4	Three consecutive “Invaild” results, displaying N. A as the result.	Circuit fault	Contact customer service.
5	Unable to automatically stop working.	Circuit fault	Shut down and restart; if the problem still exists, contact customer service.

Annex A EMC Declaration

This instrument complies with the emission and immunity requirements specified in **EN 61326-2-6:2020**.

⚠Warning

The user is responsible for ensuring the electromagnetic compatibility environment of the instrument so that it can work normally.

It is recommended to evaluate the electromagnetic environment before using the instrument.

⚠ Warning

DO NOT operate this instrument in close proximity to sources of strong electromagnetic fields (*e.g.* unshielded intentional RF sources), as they may interfere with proper operations.

⚠Warning

This instrument is designed and tested to AS CISPR 11:201 Class A standard. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Basic electromagnetic compatibility performance

Prior to, during and after the test, the instrument can run in accordance with the established procedures, and each module can work normally, without abnormal interruptions, crashes or errors.

Temperature accuracy

The absolute value of the difference between measured value and set temperature should be ≤0.5℃.

Minimum immunity requirements for *in vitro* diagnostic (IVD) medical device				
Port	Test item	Basic standard	Test value	Performance grade
Shell	Electrostatic discharge (ESD)	EN 61000-4-2	Air discharge: 2kV, 4kV, 8kV Contact discharge: 2kV, 4kV	B
	Radiated electromagnetic field	EN 61000-4-3	3V/m，80MHz～2.0GHz，80%AM	A
	Rated power frequency	EN 61000-4-8	3A/m，50/60Hz	A

	magnetic field			
AC power	Voltage dip	EN 61000-4-11	1 cycle 0%; 5/6 cycle 40%; 25/30 cycle 70%	B
	Voltage interruption	EN 61000-4-11	5%, duration: 250/300 cycles	C
	Pulse cluster	EN 61000-4-4	1kV (5/50ns, 5kHz)	B
	Surge	EN 61000-4-5	Line to ground: 2kV Line to line: 1kV	B
	RF conduction	EN 61000-4-6	3V, 150kHz～80MHz，80%AM	A
DC power supply	Pulse cluster	EN 61000-4-4	1kV (5/50ns, 5kHz)	N.A.
	Surge	EN 61000-4-5	Line to ground: 2kV Line to line: 1kV	N.A.
	RF conduction	EN 61000-4-6	3V, 150kHz～80MHz，80%AM	N.A.
I/O port	Pulse cluster	EN 61000-4-4	0.5kV (5/50ns, 5kHz)	N.A.
	Surge	EN 61000-4-5	None	N.A.
	RF conduction	EN 61000-4-6	3V, 150kHz～80MHz，80%AM	N.A.
I/O port for main power supply	Pulse cluster	EN 61000-4-4	1kV (5/50ns，5kHz)	N.A.
	Surge	EN 61000-4-5	None	N.A.
	RF conduction	EN 61000-4-6	3V, 150kHz～80MHz，80%AM	N.A.

[INSTRUCTION VERSION AND MODIFICATION DATE]

Approved on 03. 31, 2023. Version: A/1