Fluorescence Immunochromatography Analyzer

(Models: EXR 100, EXR 110, EXR 120)

Operation Manual

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First edition (Oct., 2022)

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If the warranty period and/or the warranty service described herein are conflict with the provisions of sales contract executed, the latter shall prevail.

For customer service, please contact:

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Tel: +86 (0) 23 6895 9999

Fax: +86 (0) 23 6869 9779

Web: https://www.zybio.com

E-mail: info@zybio.com

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1 General

The Fluorescence Immunochromatography Analyzer (hereinafter referred to as the "Analyzer") is used for the quantitative detection of analytes in human samples by measuring the fluorescence intensity of the strip in the reaction zone of the fluorescence immunochromatography reagent card.

This operation manual is intended to help readers understand the safety information, installation, structures, functions, operation principles, daily operation, maintenance and care, and error handling of the Analyzer.

This chapter describes the basic information about the Analyzer, the models of the Analyzer, the structure of the manual itself, the symbols on the Analyzer and its package, and safety and precautions related to the use of the Analyzer. Please strictly follow the instructions in this manual to ensure proper use.

Note

- Please carefully read and understand the contents of this manual before using the Analyzer to ensure the correct use of the instrument and the personal safety of the operator.
- The pictures in this manual are only used for illustration or example, but not for other purposes. Those in the actual product shall prevail.
- This manual is delivered together with the Analyzer. Please keep this manual properly after reading for reference at any time.

1.1 Basic Information

The basic information about the Analyzer is provided in this section.

Table 1- 1 Basic Information

Category	Basic information
Product name	Fluorescence Immunochromatography Analyzer
Model & REF No.	EXR 100: REF 02-11-03-0001-00 EXR 110: REF 02-11-03-0003-00 EXR 120: REF 02-11-03-0005-00
Product composition	The Analyzer is composed of the main unit, power adapter and software. The main unit includes a reagent card incubation module, a photoelectric detection module, a touch screen, a barcode scanning module, an RFID reading module, an internal battery (optional), and a control and data processing module. The software incorporated in the instrument is an embedded software.
Intended purpose	The Fluorescence Immunochromatography Analyzer is based on dry immunofluorescence technology and is used together with supporting reagents to perform quantitative detection of analytes derived from human serum, plasma, whole blood and urine samples in clinical practice.
Intended users	The device should only be operated by professionals, doctors and laboratory personnel trained by Zybio or its agents.

Category	Basic information
Intended use environment	The device is intended to be used in hospitals, clinics and other medical institutions.
Classification of device	Class A
Contraindications	None
Manufacturing address	Zybio Inc. Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Manufacturing date	Refer to the instrument nameplate.
Authorised representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Service life	5 years[1]

Note 1: In the process of use, the user shall maintain or repair the Analyzer according to this manual. The product which remains basic safety and performance after maintenance or repair can be used normally.

1.2 Models

The Analyzer covers three models: EXR 100, EXR 110 and EXR 120. The operation, working principle, main functions, and composition of the three models are the same. Refer to the following table for the difference among the three models.

Table 1- 2 Model differences

Model	EXR 100	EXR 110	EXR 120
Number of channels	1	3	3
Sample data storage	30,000 pieces of data	29,000 pieces of data	28,000 pieces of data
Software models	EXR 100	EXR 110	EXR 120
Released software version	V1		

1.3 About this manual

This manual consists of 9 chapters and 3 appendixes. Readers may refer to the relevant chapter for the information needed.

Table 1- 3 Manual guide

Chapter	Content
1. General	Introduces the basic information, models, manual guide, symbols, safety precautions and electromagnetic compatibility of the Analyzer.
2. Installation	Introduces information about the installation of the Analyzer, including installation requirements, connection, transportation and storage.

Chapter	Content
3. Instrument introduction	Introduces the working principle, composition, appearance, internal battery (optional), specifications and configuration, performance, cybersecurity requirements and main software interface of the instrument.
4. Daily operation	Introduces the routine operation process of the Analyzer, from start-up to shut-down, with a detailed description of the sample testing procedures.
5. Result query	Introduces the test result query function of the Analyzer.
6. Quality control	Introduces the quality control function of the Analyzer.
7. Management	Introduces the management function of the Analyzer.
8. Maintenance and care	Introduces the maintenance and care information of the Analyzer.
9. Troubleshooting	Introduces the errors that may occur and the corresponding troubleshooting measures.
Appendix A Related information	Introduces the list of accessories and list of miscellaneous materials.
Appendix B Report template	Gives an example of the test report template.
Appendix C Literature	Lists the reference documents to this manual.

1.4 Symbols

This section describes the symbols used in this manual and on the Analyzer and its package.

Symbols used in this manual are as follows:

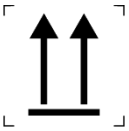
Table 1- 4 Symbols in this manual

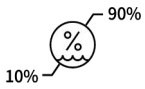
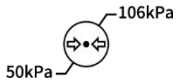
Symbols	Explanation
	Indicates a reference to substances that may be hazardous to men, animals, plants, or the environment based on biological activity.
Warning	Indicates a situation that, if not avoid, could result in hazards or other serious adverse consequences from the use of an IVD medical device.
Caution	Indicates a potentially hazardous situation which, if not avoid, could result in minor or moderate injury, or damage of the IVD medical device or incorrect results.
Note	Indicates the important information or content that requires the attention of the operator.

The symbols which may be used on the Analyzer and its package are as follows:

Table 1- 5 Symbols on the Analyzer and its package

Symbols	Explanation
	Indicates that there are potential biological risks associated with the medical device, necessary to consult instructions for use for details.
	Indicates the need of taking care regarding the hazard specified by the supplementary sign; the user needs to consult the instructions for use (yellow background).
	Indicates the need for the user to consult the instructions for use for important cautionary information (white background).

Symbols	Explanation
IVD	Indicates the instrument that is intended to be used as an in vitro diagnostic medical device.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
UDI	Indicates a carrier that contains unique device identifier information.
EC REP	Indicates the authorized representative in the European Community.
CE	Indicates CE marking of conformity.
	Indicates the date when the medical device was manufactured.
	Indicates the medical device manufacturer.
	Indicates the need for the user to consult the instructions for use.
	Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.
	Indicates that the device is suitable for alternating current only.
	Indicates that the device is suitable for direct current only.
OFF	Indicates disconnection from the mains.
ON	Indicates connection to the mains.
	Indicates the connecting terminals of the computer network.
	Indicates the USB interface.
	Indicates that distribution packages shall be kept away from rain and be kept in dry conditions.
	Indicates the correct upright position of the distribution package for transport and/or storage.
	Indicates that contents of the distribution package are fragile therefore it shall be handled with care.

Symbols	Explanation
	Indicates the maximum number of identical transport packages/items which may be stacked on the bottom package.
	Indicates that distribution packages shall not be rolled or turned over.
	Indicates that distribution packages shall be stored, transported, and handled within temperature limits.
	Indicates that distribution packages shall be stored, transported, and handled within humidity limits.
	Indicates that distribution packages shall be stored, transported, and handled within atmospheric pressure limitation.

1.5 Safety precautions

The safety precautions for use of the Analyzer are described in this section, so that the user can use the instrument safely and effectively. The following instructions should be followed strictly. Otherwise, inaccurate test results, instrument damage, personal injury, etc. may be caused.

Biological risk

- All test samples, calibrators, controls, quality control cards, reagent cards, waste cards, etc. should be considered infectious. Always wear protective gloves and clothes during operation to prevent infection, and wear safety goggles if necessary.
- The waste card collection box should be emptied on a regular basis to prevent the waste cards from falling onto the bench or desk to cause contamination.
- Parts that have been in contact with the test sample, such as suction nozzles, measuring cups, etc. should all be considered infectious and operators should wear protective gloves when using them.
- All wastes are regarded as infectious medical waste. Operators should wear protective gloves when handling them, and they should be disposed of according to local regulations.
- When the instrument reaches the end of its service life, it should be disposed of according to the requirements of the local environmental protection authority, and should not be disposed of or discarded as general waste.

Instrument use

Warning

- Please use the Analyzer in strict accordance with the requirements of the instructions. If the instrument is not used according to the instructions specified by the manufacturer, the protection provided by the instrument may be damaged.
- Please use the instrument under the conditions of use specified in this manual. Otherwise, the instrument may not operate normally, the test results may be unreliable, the instrument may be impaired and personal safety may be endangered.
- No body except the authorized service personnel may open the Analyzer housing while the power is on.
- Liquid spillage within the device may cause malfunction and electrical shocks. Do not place samples on the instrument. In case of spilling, please turn off the power immediately and contact the service engineer of Zybio.
- Do not use flammable or explosive hazardous materials near the Analyzer.
- It is prohibited to touch the moving parts, or put your fingers or hands into the open parts while the Analyzer is running.
- Some reagents and detergents may damage the skin. Please use them carefully to avoid direct contact with hands and clothing. In case of any reagent or detergent in contact with hands or clothes accidentally, rinse them with soap and water immediately. In case of contact with eyes, rinse with plenty of fresh water immediately and seek medical help.

Caution

- Please install, use and maintain the instrument in accordance with the requirements of this manual. Installation not following the specified conditions or improper use and maintenance may result in incorrect analytical results and may even cause instrument damage or personal injury.
- In case of any abnormal odour or smoke, cut off the power immediately, and remove the power plug from the socket. And contact the customer service engineer of Zybio or its authorized representative to check the device.
- When any liquid spills, or any foreign metal object falls inside the device, stop using the device and contact the customer service engineer of Zybio or its authorized representative to check the device.
- Do not touch the electrical circuits inside the device, especially with wet hands, which may cause electrical shock.
- Do not touch the display of the instrument with wet or chemical-stained hands.
- Do not replace any Analyzer part without authorization. Please contact Zybio or its authorized representative timely for replacement of any components.
- The presence of drugs, anticoagulants, preservatives, etc. in the sample may interfere with some analytical results.
- Lipemia, jaundice and hemolysis in the sample may affect the analytical results.
- Proper sample storage measures should be taken. Improper sample storage may lead to changes in the composition of a sample, resulting in incorrect analytical results.
- To prevent samples from volatilizing, do not leave the samples open for a long time. If

the sample volatilizes, it may lead to incorrect analytical results.

Note

- The Analyzer can only be operated and used by professional laboratory technicians, doctors or testers trained by Zybio or its authorized representative.
- Please use the reagent cards and QC cards produced by Zybio. Use of reagents cards and QC cards made by other manufacturers may cause test failures or inaccurate test results.
- Please use the QC solutions manufactured by Zybio or other companies for quality control of the Analyzer.
- Please pay attention to the storage conditions and validity period of reagent cards, QC cards and QC solutions. Using improperly stored or expired reagent cards, QC cards and QC solutions may result in incorrect test results.
- If users need information about the ordering or purchase of reagent cards, QC cards and QC solutions, please contact Zybio (see “Warranty statement” for details of contact) or its authorized representative.

1.6 Electromagnetic compatibility

The Analyzer complies with the emission and immunity requirements described in IEC 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 and IEC 61326-1:2020 - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.

- Radio frequency emissions of this equipment is very low and it is unlikely to cause interference to electronic equipment nearby.
- Portable and mobile radio frequency communication equipment may affect the device. Other equipment used near the device should meet relevant electromagnetic compatibility requirements.
- This instrument is suitable for use in non-domestic facilities and all facilities not directly connected to the public low-voltage power supply network for residences.
- The power socket should be reliably grounded, and the power cords, components and accessories provided with the device should be used.
- The floor should be of wood, concrete or ceramic tile. If the floor is covered with synthetic material, its relative humidity should be at least 30%.
- The grid power supply shall be of quality typically used in a commercial or hospital setting.
- If the user needs the device running continuously during power failure, it is recommended to use an uninterrupted power supply.
- This instrument has been designed and tested to CISPR 11 Class A.
- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
- This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic

interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

Warning

- Except for accessories and cables sold by the device manufacturer as spare parts of internal components, the use of other accessories and cables may lead to an increase in the emission or a decrease in immunity of the device.
- This device should not be positioned close to or stacked on other devices. If needed, please verify that the device can work normally in such situation.
- Do not use the Analyzer near sources of strong electromagnetic radiation, as these may interfere with the proper operation. Use of the Analyzer in a dry environment, especially if synthetic materials are at present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results.
- It is the user's responsibility to ensure that a compatible electromagnetic environment for the Analyzer can be maintained in order that the device will perform as intended. The electromagnetic environment should be evaluated prior to operation of the Analyzer.
- The calculation formula to determine the separation distance between this Analyzer and a mobile phone is given by $d = 6/E \cdot \sqrt{P}$, where d is the minimum separation distance in metres, *P* is the maximum power in watts, and *E* is the immunity test level in *V/m*.

1.7 Residual risk

The Analyzer is a dedicated medical device, the safe and effective operation of the system requires the correct use of hardware and software, as well as appropriate operating conditions.

The Analyzer shall be operated by persons who have undergone necessary trainings and have a good knowledge of its intended use and the safety warnings and precautions for its usage. Despite that risk mitigation measures are implemented to minimize various hazards as far as possible, risks including but not limited to biological hazards, electromagnetic compatibility cannot be completely excluded.

The Analyzer is used together with specified reagents as a detection system to provide quantitative detection of analytes in human-derived samples. The reagents shall be chosen and used according to the instructions for use to ensure the accuracy of results.

The test results produced by the Analyzer are for aiding to diagnosis only. Confirmation of clinical diagnosis shall be made based on the test results, the clinical symptoms, and other examination results.

Note

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.

2 Installation

This chapter mainly describes information about the Analyzer installation, including installation requirements, connection, transportation and storage.

2.1 Installation requirements

This section introduces the inspections before the instrument is installed, and the environment, space and power supply requirements for installation and use.

Warning

Do not unpack or install the instrument without the presence of Zybio authorized personnel. Unpacking and installation of the instrument by personnel not authorized or trained by Zybio may cause personal injury or instrument damage.

2.1.1 Check before installation

The device has been carefully inspected by Zybio before packaging and transportation. After receiving the Analyzer, please check carefully before unpacking to see if the package is upside down, damaged or opened. If any of the above problem is identified, please immediately notify Zybio or its authorized representative. If the package is intact, open the packaging carton and check the followings in the presence of personnel from Zybio or its authorized representative:

- Check whether all components are complete against the packing list in the packaging carton.
- Check the appearance of all components for any crack, bump or deformation, etc.

In case of any damage arising from transportation or any components missing, please immediately notify Zybio or its authorized representative.

2.1.2 Space requirements

The Analyzer is a portable device and can be used in different scenarios as needed. The space requirements for its installation are as follows:

- The distance between the back of the Analyzer and the objects/wall behind it or the edge of the desk or bench should be at least 80 mm.
- The distance between the front of the Analyzer and the edge of the desk or bench should be at least 220 mm.
- The space to the left or right of the Analyzer should be enough for the user to perform testing operations, such as preparing the reagent cards.

2.1.3 Environmental requirements

The working and operation environment of the device should meet the following requirements.

Table 2- 1 Environmental requirements

Item	Working environmental requirements
Ambient temperature	10℃～30℃
Relative humidity	20%～85%, no condensation

Item	Working environmental requirements
Atmospheric pressure	70kPa～106kPa
Altitude	≤3000m

- The device is for indoor installation and use only.
- Rated pollution degree: 2.
- The bench or desk on which the device is placed should be flat with a gradient of less than 1/200 and can withstand a weight of at least 16 kg; the bench or desk (or ground) is not subject to vibration.
- The environment should be with minimum dust, and free from corrosive and flammable gases.
- Avoid direct exposure to strong sunlight, and avoid placing the Analyzer near heat or wind source.
- There should be no loud noise source or strong power interference.
- Keep away from brush engines and electrical contacts that are often switched on and off.
- Keep away from devices that emit electromagnetic waves, such as cell phones and radio transceivers.
- The site should be far away from strong electromagnetic field interference and well grounded.
- Do not place the device in a position where it is difficult to operate the disconnecting unit.

Note

The operating environment of the Analyzer should be well ventilated to ensure heat dissipation. Ventilation equipment can be used where necessary. However, direct airflow to the Analyzer should be avoided, or it may affect the data reliability.

2.1.4 Power requirements

This section mainly describes the power supply requirements.

Table 2- 2 Power supply specifications

Power type	Requirements
External power supply (power adapter)	Input: 100-240V AC, 50/60Hz, 1.4-0.7A Output: 24V⎓2.5A, 60W MAX.
Internal power supply (lithium battery)	Output: 18V⎓, 4700mAh, 84.6Wh

Warning

- Make sure that the protective grounding of the power socket is good. Incorrect grounding may cause electric shock and damage to the Analyzer.

- The output voltage of the power socket must meet relevant requirements.
- Please use the power cord and power adapter supplied with the device. Using other power cords and power adapters may damage the instrument or cause erroneous test results.

2.2 Instrument connection

This section introduces the connection of the instrument, including the connection of the power cord, power adapter, barcode scanner and external printer, and the installation of the waste card collection box and thermal printer paper.

2.2.1 Connection of power cord and power adapter

Please connect the power cord and power adapter as follows:

(1) Confirm that the power switch on the left panel of the instrument is in the OFF state.

(2) Connect the power cord to the power adapter.

(3) Insert the circular plug of the power adapter into the power interface on the back of the instrument.

(4) Insert the three-pin plug of the power cord into the power socket.

2.2.2 Connection of barcode scanner (optional)

An external barcode scanner can be connected to the Analyzer. It is recommended that users select or purchase a certified external 2D scanner (with CCC (S&E) compulsory certification), and the interface required is a USB interface. The applicable codes are one-dimensional barcode CODE128, CODE93, CODE39, CODABAR, ITF, UPC, JAN, EAN and two-dimensional code QR code.

Please connect the barcode scanner as follows:

(1) Insert the USB cable of the scanner into the USB port on the left panel of the instrument.

(2) Press and hold the trigger button of the scanner, the light is activated, and the illumination area and focus line appear. Align the focus line with the centre of the barcode, move the scanner and adjust the distance between it and the barcode to find the best reading distance. When you hear a prompt sound and the focus line goes out, the barcode is read successfully.

Note

External devices connected by the user should not cause the reduction of the safety and performance of the Analyzer.

2.2.3 Connection of external printer (user-supplied)

An external USB printer can be connected to the Analyzer. The USB protocol version is USB2.0. Users are recommended to use HP LaserJet Professional p1108 Printer, HP LaserJet p1008 Printer, HP LaserJet Pro M14a-M17a Printer, HP LaserJet 1020 Printer and HP LaserJet 1020 Plus Printer.

Please connect the printer as follows:

(1) Make sure that the device and the printer are powered off.

(2) Insert one end of the printer's USB cable into the printer's USB interface.

(3) Insert the other end of the USB cable into the USB interface on the left panel of the device.

(4) Switch on the device and the printer. If the printer icon on the main software interface lights up, it means that the external printer is connected successfully.

(5) Click on “Manage” > “Settings” > “Basic settings” > “Print” to enter the print settings interface, select “External printer” in the “Printer” field, click on “OK” to save the settings, and the external printer can be used to print the test reports.

Note

External devices connected by the user should not cause the reduction of the safety and performance of the Analyzer.

2.2.4 Installation of waste card collection box

Please install the waste card collection box as follows:

(1) On the bench or desk where the instrument is positioned, please leave at least 200 mm of space in front of the instrument to place the waste card collection box.

(2) Place the waste card collection box close to the instrument in front of the reagent card cabin.

2.2.5 Installation of printer paper

This section mainly introduces information about thermal printer paper, paper roll installation and precautions.

- The device uses thermal printer paper with the width of 57±0.5 mm and external diameter of no more than Φ30 mm.
- It is easy to install.
- Users can manually tear off the paper.

Please install the printer paper as follows:

(1) Open the thermal printer cover gently.

(2) Insert the paper roll into the paper slot with the shiny side inward, and leave a tail of paper (about 2 cm) sticking out (as shown in the figure below).

Figure 2- 1 Installation of printer paper

(3) Close the printer cover.

Note

The printer paper should not be in a loose state, otherwise it may cause the printer jam or blurred printing.

2.3 Transportation and storage

To avoid damaging the Analyzer during transportation, it should be placed upright, and handled with care, avoiding shocks and bumps, and in accordance with labels such as fragile, upward, rain, and no rolling.

The device should be stored in the environmental conditions specified below:

Table 2- 3 Storage conditions

Ambient temperature	Relative humidity	Atmospheric pressure
-10℃～40℃	10%～90%, no condensation	50kPa～106kPa

3 Analyzer introduction

This chapter introduces the working principle, composition, appearance, internal power module (optional), specifications and configuration, performance indicators, cybersecurity requirements and main software interface of the Analyzer. This manual takes model EXR 110 as an example, but it's also applicable to other models. Note that the illustrations below may be inconsistent with the actual Analyzer due to the differences in device models and software versions.

3.1 Working principle

Immunochromatographic analysis is a membrane analysis method that combines antigen-antibody specific immune response and chromatography techniques. Fluorescence immunochromatography is an analytical technique that uses fluorescent substances as tracers to label antigens or antibodies for immunoreaction with the analyte, and determines the fluorescence intensity of the final product to obtain the concentration of the analyte. Fluorescent tracers mainly include fluorescein, quantum dots, and upconversion nanoparticles. A fluorescence analyzer is an instrument that interprets the detection results of fluorescence labelled reagent cards. Put the reagent card to be tested into the analyzer, and it analyses the analyte by converting the fluorescent signal of the reagent card into electrical signal via the sensor, and then converts the electrical signal into the corresponding concentration value through the calibration curve information.

3.2 Product composition

The Analyzer is composed of the main unit, power adapter and software. The main unit includes a reagent card incubation module, a photoelectric detection module, a touch screen, a barcode scanning module, an RFID reading module, an internal power module (optional), and a control and data processing module. The software incorporated in the instrument is an embedded software.

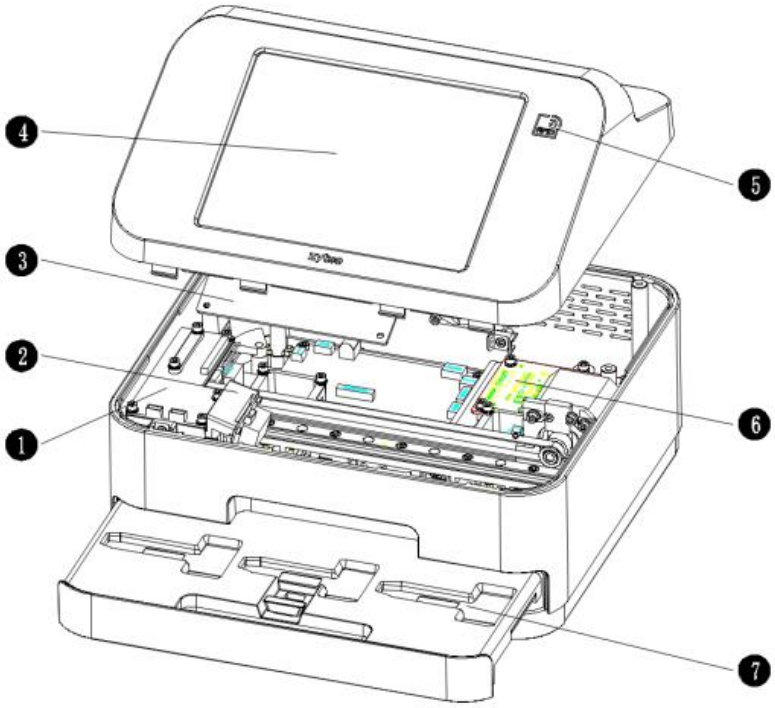


Figure 3- 1 Product composition

No.	Modules
1	Photoelectric detection module
2	Barcode scanning module
3	Control and data processing module, software
4	Touch screen
5	RFID reading module
6	Internal power module (optional)
7	Reagent card incubation module
Note: Model EXR 100 has only one card slot in the middle of the reagent card incubation module.	

3.3 Instrument appearance

This section briefly introduces the appearance of the Analyzer, including the front view, top view, back view, and the left view.

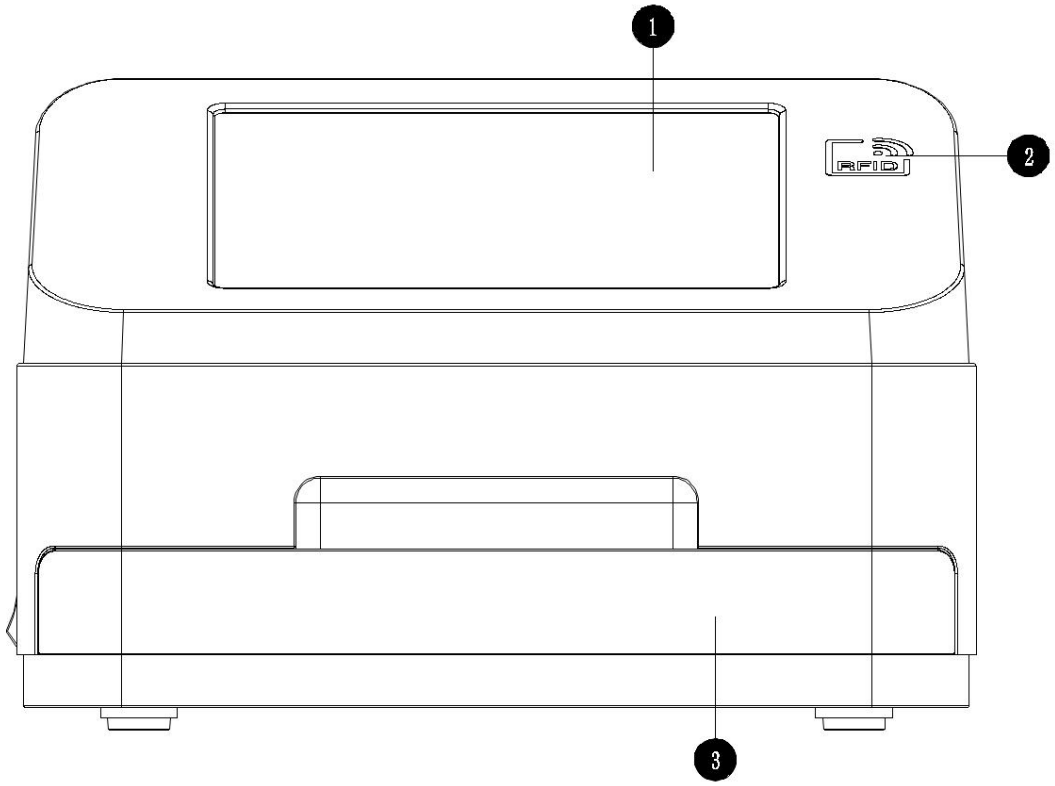


Figure 3- 2 Front view

No.	Parts
1	Touch screen
2	Card reading area
3	Reagent card cabin

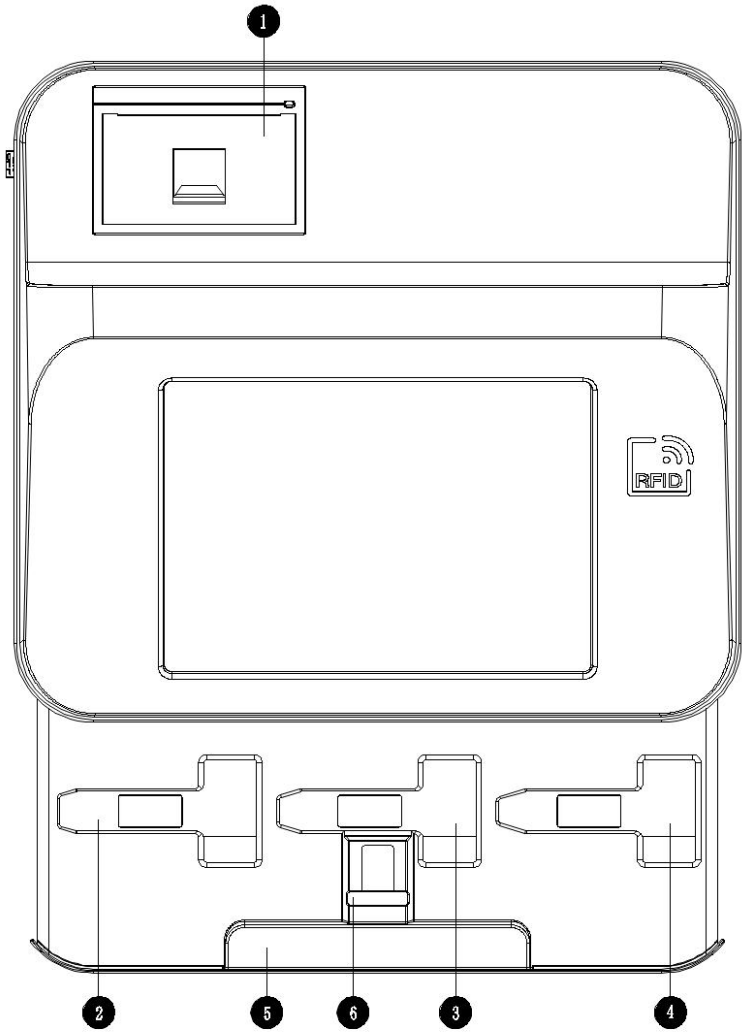


Figure 3- 3 Top view

No.	Parts
1	Thermal printer
2	Reagent card slot 1
3	Reagent card slot 2
4	Reagent card slot 3
5	Reagent card cabin handle
6	Regent card disposal slide
Note: Model EXR 100 has only one card slot in the middle of the reagent card cabin.	

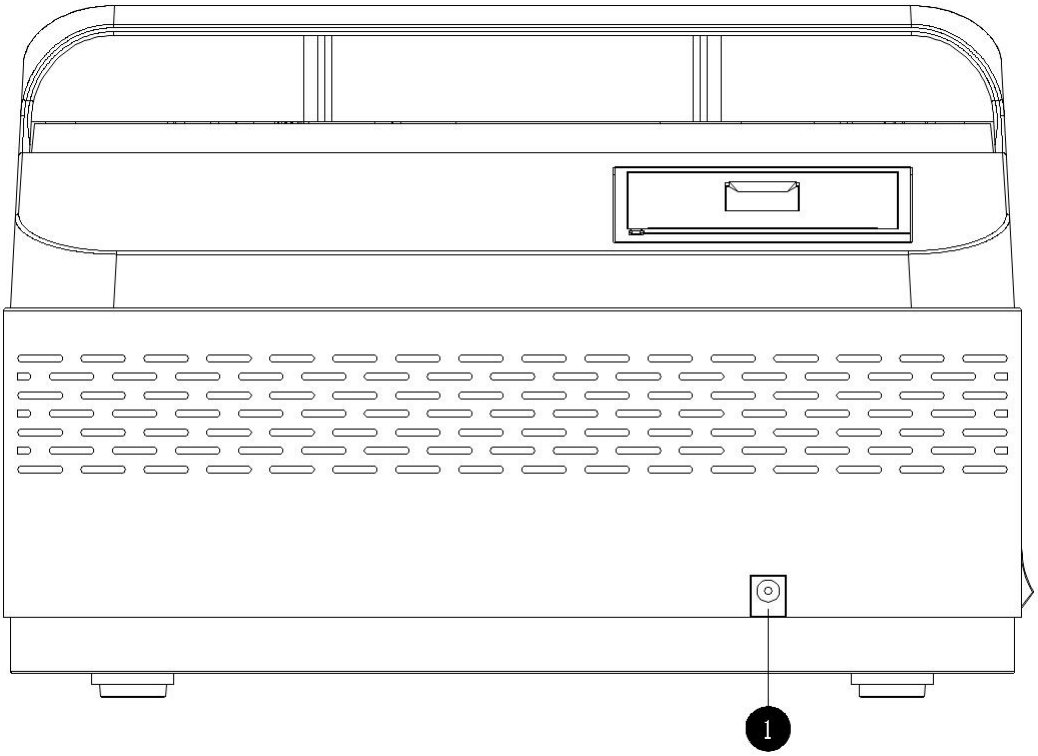


Figure 3- 4 Back view

No.	Parts
1	Power adapter interface

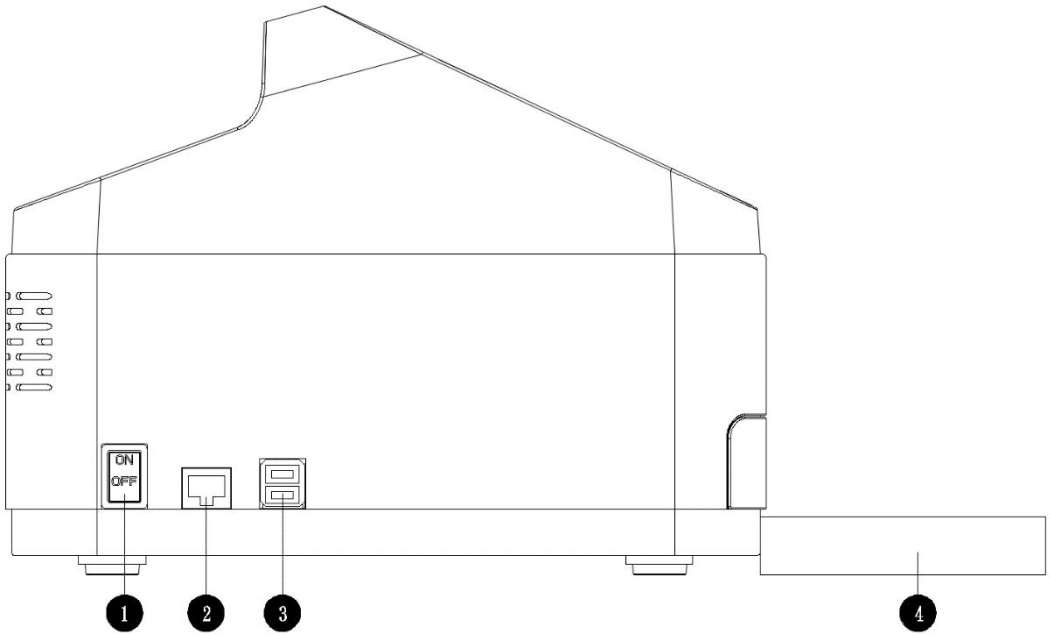


Figure 3- 5 Left view

No.	Parts
1	Power switch

No.	Parts
2	Network interface
3	USB interface
4	Waste card collection box

3.4 Internal power module (optional)

Users can opt to purchase an Analyzer equipped with battery (rechargeable lithium battery pack). The Analyzer with battery can be used when the power adapter is not connected. The batter icon will be displayed in the right lower corner of the main software interface, for example “  ”. The battery icon is divided into five bars which reflect the battery charge of the device and are distinguished by colour (see Table 3-1). Users can also choose to display the battery percentage through "Manage > Settings > System settings > Prompt". The battery percentage is displayed on the right side of the battery icon, for example “  ”。

Table 3- 1 Battery charge and corresponding icon

Battery percentage	Icon colour
100%-16%	Green
11%-15%	Yellow
6%-10%	Red
0%-5%	Red with an exclamation point

The Analyzer will not be powered by the battery when the power adapter is connected and will charge the battery if it is not full. When the battery is being charged, a charging icon will be displayed to the right of the battery icon, such as “” or “”.

The Analyzer will be powered by the battery when the power adapter is not connected. If the battery icon becomes yellow, the user should connect the power adapter timely. If the battery is low, the device will prompt the user (as shown in the following figure), and use of the Quick or Standard test mode will be limited.

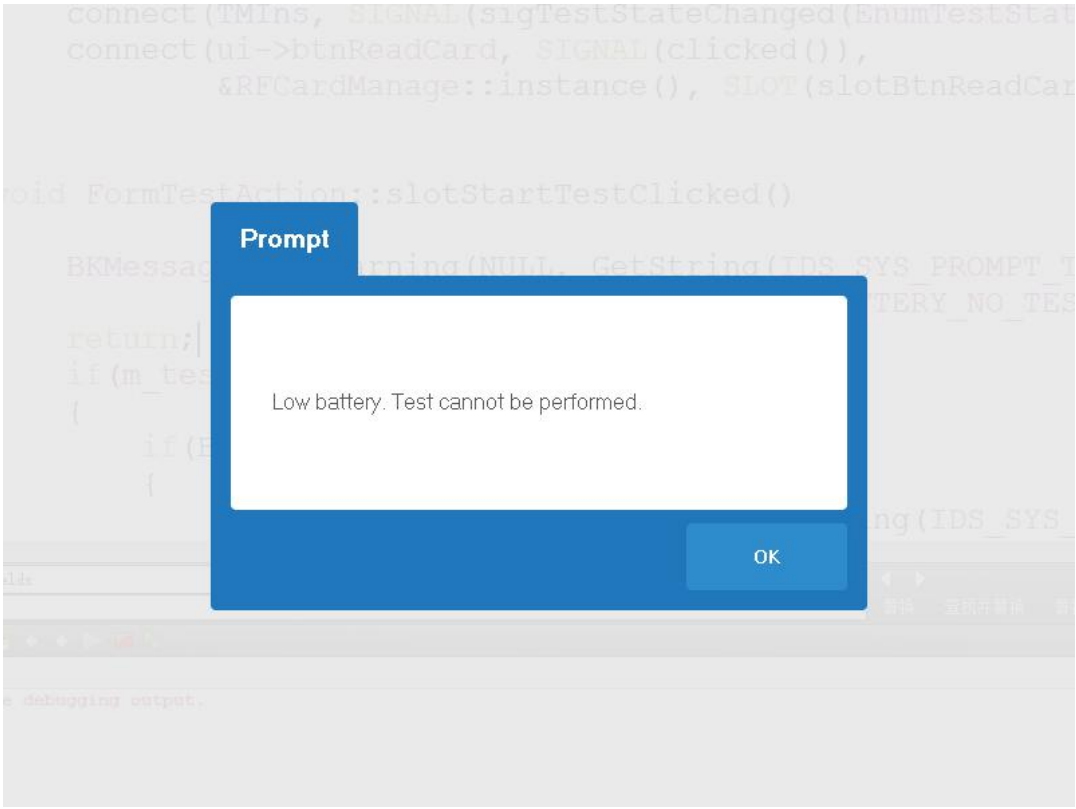


Figure 3- 6 Prompt for limitation of testing

When the battery is depleted, a prompt will be displayed and the device will automatically switch off after a 3s countdown.

Note

- The power adapter supplied with the instrument must be used.
- The power adapter must be connected in time to charge the battery according to the battery status and prompts.
- When the battery runs out, please power off the device timely according to the prompts.
- If the battery is damaged, please contact the after-sales service department of Zybio.

3.5 Specifications and configuration

The specifications and configuration of the device are shown below.

Table 3- 2 Specifications and configuration

Item	Description
Dimensions (length*width*hight)	275 mm*250 mm *186 mm
Weight	3.9 kg (with battery) 3.4 kg (without battery)
Noise grade	Noise peak (except alarm tone) ≤ 65 dBA
Input/output device	● Touch screen

Item	Description
	● Buzzer ● Printer and barcode scanner
Error alarm	Audio alarm
Control method	8-inch touch screen
Overvoltage category	II

3.6 Performance indicators

The performance indicators of the Analyzer are as shown in the following table.

Table 3- 3 Performance indicators

Parameter	Content
Accuracy	The relative deviation should not be more than ± 15%.
Repeatability	The coefficient of variation (CV) should not be greater than 1%.
Linearity	The linear correlation coefficient (r) should not be less than 0.990.
Channel consistency	The relative range (R) of the measurements on the three channels should not be greater than 5%.
Stability	The relative deviations between the measurements at 4 h and 8 h after the device is started and in a stable status and those at the beginning of the stable working status should not be greater than 5%.

Note: The indicator “Channel consistency” is applicable only to models EXR 110 and EXR 120.

3.7 Software and cybersecurity

The Analyzer software is an embedded software component.

Software name	Fluorescence Immunochromatography Analysis Software
Software models	EXR 100, EXR 110, EXR 120
Released version	V1
Software runtime environment	● Hardware configuration CPU: single-core 800 MHz and above RAM: 512 MB and above ROM: 8 GB and above Operating system: Linux operating system and compatible versions ● Network conditions: The network architecture is CS and the network type is LAN. There is no need to connect to the Internet and no bandwidth requirements.
Data interfaces	● Wired network interface: The software performs bi-

	directional data transmission with the LIS via the HL7 transmission protocol. ● Wireless network interface: The software performs bi-directional data transmission with the LIS via WIFI using the TCP/IP transmission protocol. ● USB interface: The software carries out electronic data exchange with storage media such as mobile hard disks, USB flash drives, etc. Data can be exported as ".xml", ".pdf", ".log" or ".csv" formats. The USB protocol version is USB2.0. ● RFID interface: The software communicates with the RFID reader via the Uart serial port, and users can record the information of reagent cards and quality control cards by placing the RF card close to the RFID reader.
User access control	A login password is required by the Analyzer software for user identification. The software has a user access control mechanism, including user identification (user name and password), user type and permissions (ordinary user, administrator, equipment maintenance personnel). Among them, the ordinary user can change the login password; the administrator can manage ordinary users (create, delete, change password), manage sample results (delete, review, cancel review) and perform system settings; the equipment maintenance personnel have all permissions (sample results management, user management, system settings and maintenance, etc.)
Security software	None
Requirements related to software environment and security software updates	None

3.8 Main software interface

The main software interface includes five modules, namely Single, Multi, Result, QC and Manage, as shown in the following figure. See Chapters 4 to 9 for detailed descriptions.

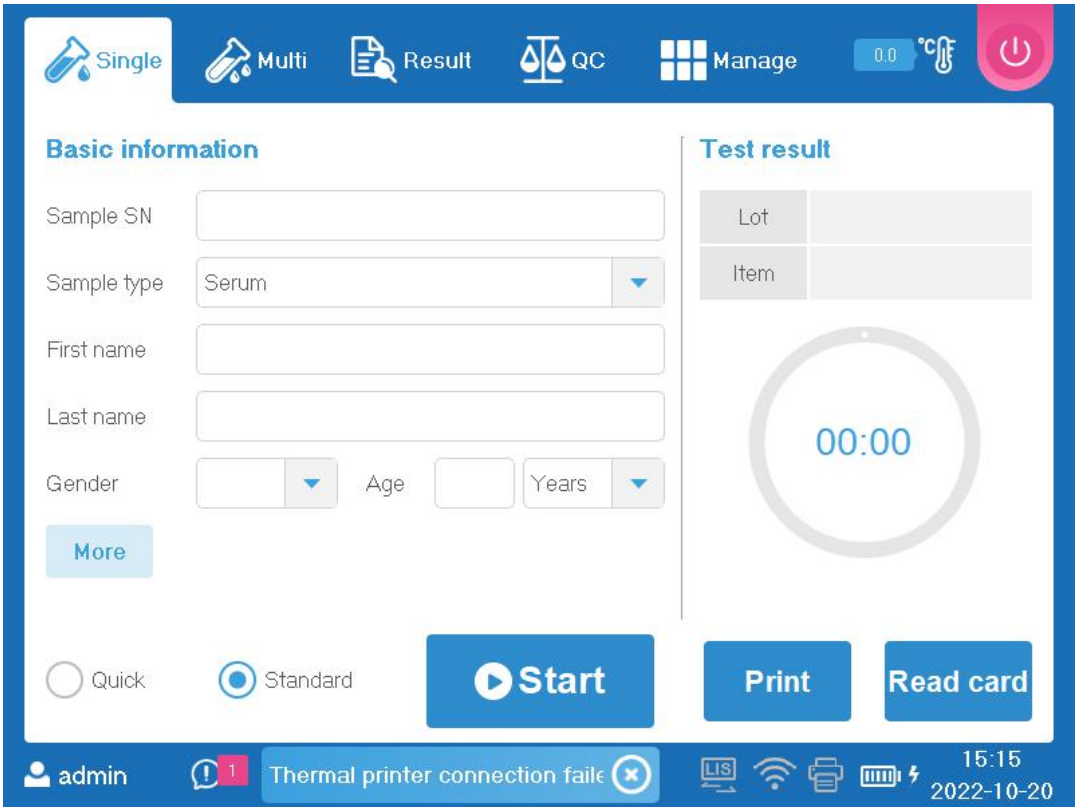
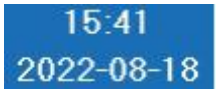


Figure 3- 7 Main software interface

Function buttons and icons	Name	Description
	Single	Click “Single” to enter the single card testing interface. One reagent card can be placed into any of the channels for testing.
	Multi	Click “Multi” to enter the multiple cards testing interface. One to three reagent cards can be placed into the channels for testing.
	Result	Click “Result” to enter the results interface to view the results of completed tests and perform operations such as printing or exporting the results, or sending the results to the LIS.
	QC	Click “QC” to enter the quality control interface to perform QC tests, view QC results, etc.
	Manage	Click “Manage” to enter the device management interface to record information about consumables, change or set device functions, etc.

Function buttons and icons	Name	Description
	Incubation temperature	Shows the real-time incubation temperature in the channels.
	Fault prompt	Indicates instrument faults. The number in the top right corner indicates the number of fault messages and the specific fault message is displayed to the right side, such as "Thermal printer connection failed". When several faults are present, they will be shown one by one.
	LIS icon	Indicates the connection status of the LIS. It is highlighted when the LIS is connected, and then users can click it to perform bi-directional LIS settings.
	WIFI icon	Indicates the connection status of WIFI. It is highlighted when the WIFI is connected.
	Printer icon	Indicates the connection status of the printer. It is highlighted when the printer is connected. And then users can click it to manage the printing tasks.
	Battery icon	When the device is equipped with a battery, a battery icon will be shown on the main interface of the software to indicate the current remaining battery charge.
	System time	Shows the current system time.
	Current user	Indicate the user logged onto the software.

4 Daily operation

This chapter introduces the routine operation process of the Analyzer, from device start-up to shutdown, with a detailed description of the sample testing procedure.

The daily operation procedure is as follows:

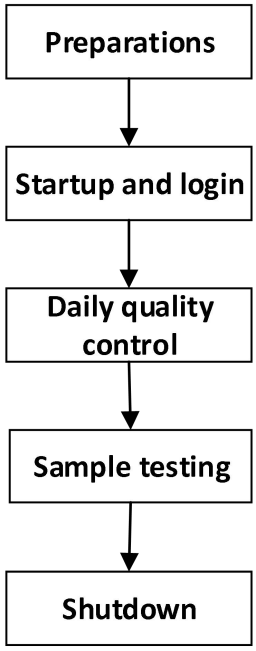


Figure 4- 1 Daily operation procedure

4.1 Preparations

The Analyzer should be checked before each use to ensure that it is in good status.

- Check the appearance of the device for any abnormalities, including whether the reagent card cabin is closed, whether the reagent card disposal slide is blocked, whether there is paper in the thermal printer and whether the printer cover is closed, etc.
- Check if the power cable and power adapter (if connected) are undamaged and correctly connected.
- Check if the waste card collection box is in place.

4.2 Start-up and login

(1) Turn the power switch of the device on the left panel to the “ON” position. The device will start up and run initialization and self-test, and then enter the login interface, as shown below:

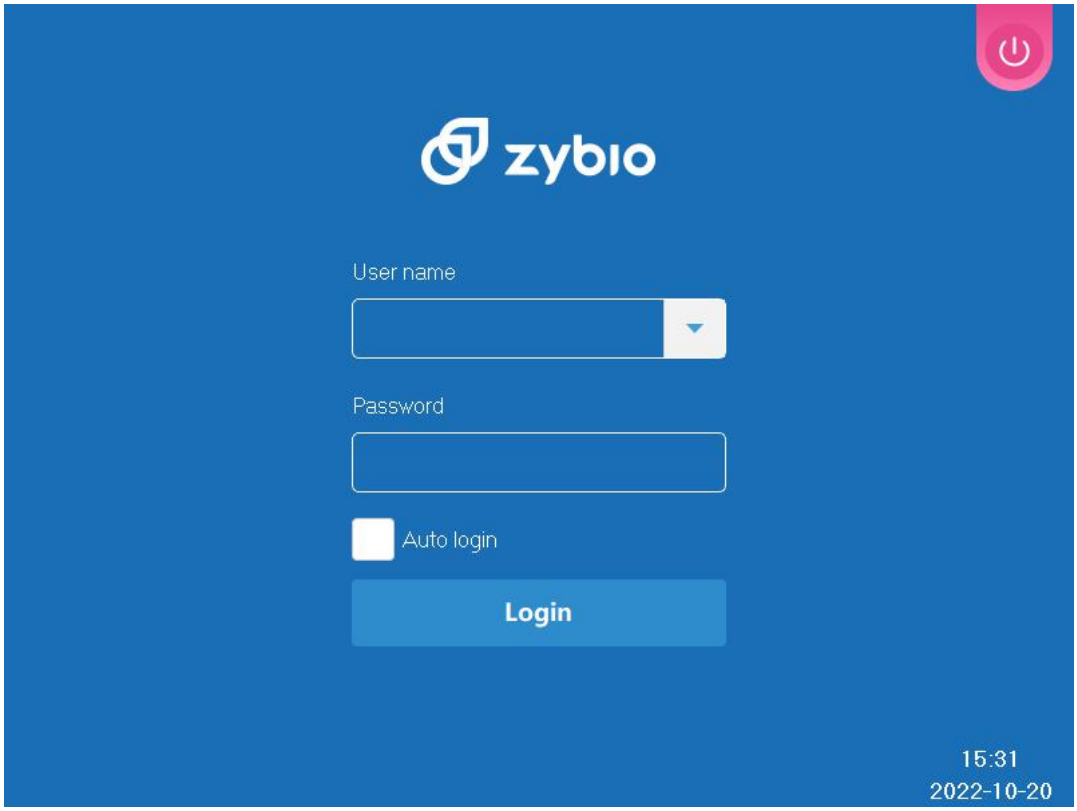


Figure 4- 2 Software login interface

(2) Input the user name and password.

(3) Select “Auto login” if you want to log into the software automatically next time.

(4) Click “Login” to enter the main interface.

4.3 Daily quality control

Daily quality control of the Analyzer is required prior to sample testing to ensure the reliability of the results. See "6 Quality Control” for details.

4.4 Sample testing

This section introduces the sample testing process. Users can perform sample testing on the “Single” interface (see Figure 3-7) or “Multi” interface (as shown below).

Note

- Please use the reagent cards produced by Zybio. Use of reagent cards made by other manufacturers may cause test failures or inaccurate test results.
- The types of samples that can be tested by the Analyzer are human serum, plasma, whole blood and urine samples.
- Please follow the instructions for use of reagents for the conditions for collection, handling, and preparation of samples.

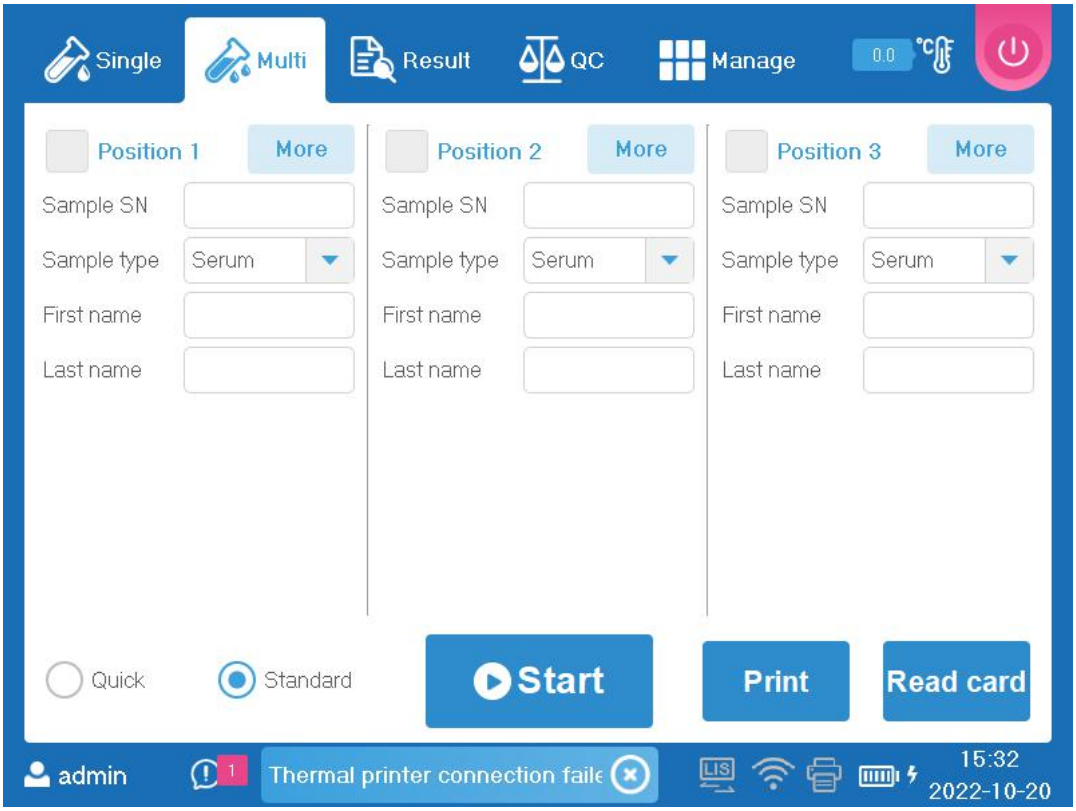


Figure 4- 3 Multi card testing interface

Please perform sample testing according to the following steps:

(1) Record reagent card information.

The lot number and calibration curve on the reagent card kit must be entered before the sample is tested, so that the test items can be recognized during the testing and the results can be identified later. There are two ways to record the reagent card information.

- Recording via the “Read card” button: Place the RF card from the reagent card kit onto the FRID card reading area of the Analyzer and click on the "Read card" button in the “Single” or “Multi” interface. After the RF card is read successfully, a window will pop up, showing the recorded reagent card information.
- Recording via the consumables management interface: Select “Manage” > “Consum.” to enter the consumables management interface, and record the reagent card information by scanning the QR code, reading card or importing. See “7.1 Management of consumables (reagents)” for details.

(2) Enter the sample information corresponding to the reagent cards to be tested.

The sample information corresponding to the reagent cards to be tested can be input in the “Basic information” section of the “Single” interface or the “Multi” interface, including the sample SN, sample type, patient name, etc., and other information can also be entered by clicking on the “More” button, as shown in the following figure.

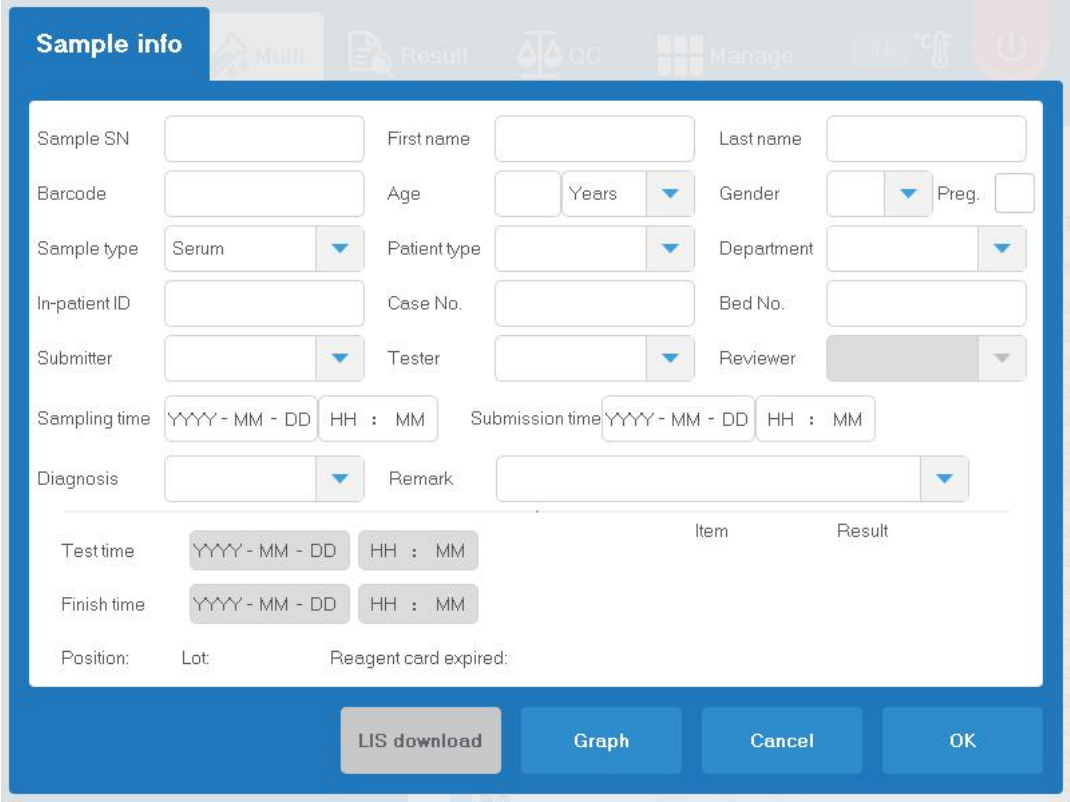


Figure 4- 4 Sample information

Sample information can also be obtained by clicking the “LIS download” button if the by-directional LIS is connected.

(3) Select the testing mode. Two sample testing modes are available: Quick mode and Standard mode. The colours of the two interfaces are different.

- **Quick mode**: If the reagent card is spotted and incubated outside the Analyzer, select the Quick mode to test it directly.

Note

- If the spotted reagent card is incubated outside the Analyzer, it should be placed in an environment with stable temperature and protected from tilting or violent shocks.
- The user should set a proper incubation time for the spotted reagent card if it is incubated outside the Analyzer according to the test items.
- The reagent card should be put into the Analyzer for testing timely after incubation outside the Analyzer is completed.

- **Standard mode**: If the reagent card is spotted outside the Analyzer but needs to be incubated inside, select the Standard mode. It will be tested after incubation completed.

(4) Place the reagent cards to be tested into the card slot and close the cabin.

(5) Click “Start” to begin sample testing. Note that the testing mode cannot be switched during testing.

(6) When the testing is completed, the results are displayed in the "Test result" area to the right of the "Single" interface or below the corresponding positions in the "Multi" interface.

(7) After all tests are completed, manually open the reagent card cabin, and push the reagent card disposal slide inward so that the tested reagent cards fall into the waste card collection box.

(8) Click on the “Next” button to continue testing other samples if needed.

Note

- Ensure that the reagent card cabin is closed tightly before starting the testing.
- After starting a test, it is forbidden to open the reagent card cabin until all reagent cards in the Analyzer are tested, otherwise it may damage the device or lead to inaccurate testing results.
- Do not operate the reagent card disposal slide, except when all the tests have been completed, to avoid wasting reagent cards by accidentally dropping them into the waste card collection box.

4.5 Cancellation of testing

Once the test is started, the 'Start' button switches to the 'Cancel' button, which can be used to stop all ongoing tests in the event of an emergency.

After the tests are cancelled, open the reagent card cabin to take out the cards. Click on the “Next” button to continue testing if needed.

Note

The test results may be inaccurate after the emergency stop.

4.6 Printing of results

When the test is completed (whether it is a normal test, an abnormal test or manually cancelled), click on the "Print" button to print the information and results of the tested sample.

If there are no test results, the user will be prompted, for example "No results, printing is not available.” after clicking the "Print" button.

4.7 Shutdown

When all tests are completed, the device will go into the idle state. If you do not need to continue using it, please shut it down.

The device shutdown procedure is as follows:

(1) Click on the shutdown icon on the upper right corner of the software interface, and the “Shutdown and logout” window will display. Click “Shutdown” and the device will prompt the operator whether to shut it down.

(2) Click “Yes” to shut down the operating system (software deactivated but power is still connected), and the device will prompt the operator to disconnect the power supply.

(3) Turn the power switch on the left panel to the OFF position to turn off the device completely.

Note

- The device can only be shut down when it is idle.
- Do not turn off the power switch or disconnect the power supply while the Analyzer is performing shutdown.

5 Result query

This chapter introduces the test result query function of the Analyzer. Click on 'Result' in the main interface to enter the results interface, where users can view existing test results and perform related operations.

5.1 Result display

The “Result” interface is as follows:

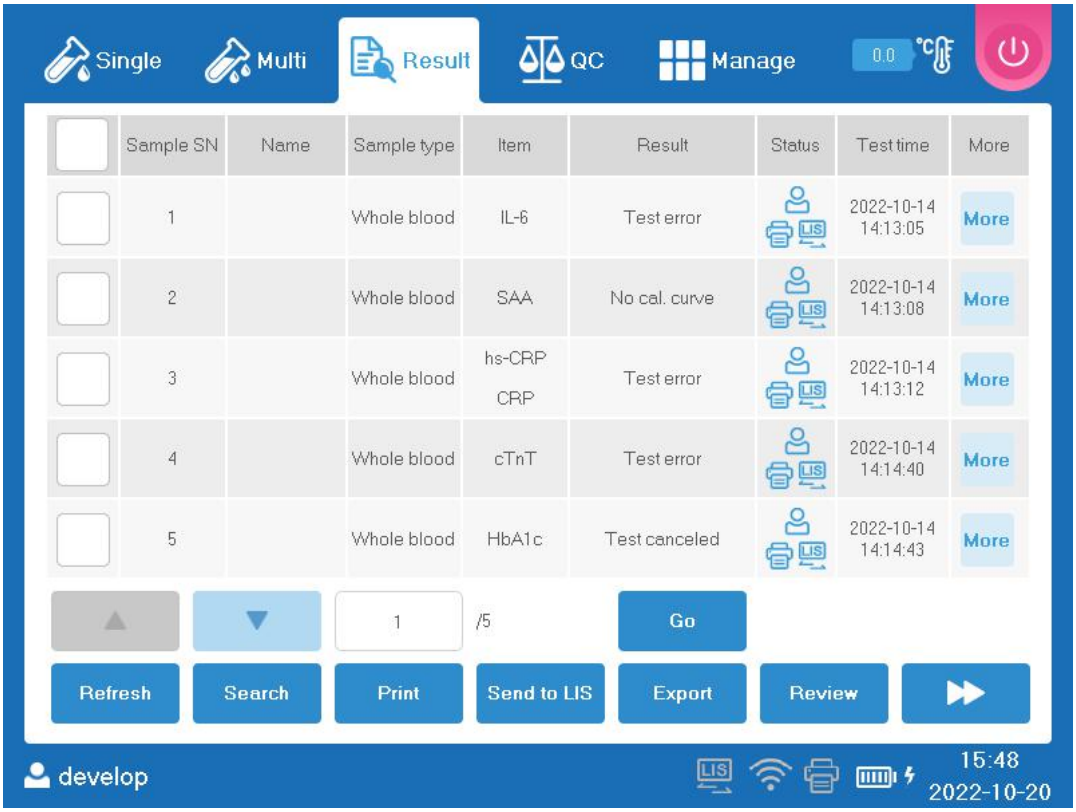


Figure 5- 1 “Result” interface

Up to 5 sample test results can be shown on each page of list of results, each containing the sample SN, patient name, sample type, test item, test result, status (Printed/Sent to LIS/Reviewed) and test time. Users can click on the “More” button to view other information related to the test result.

5.2 Operations related to results

Users can perform a variety of operations on the test results, including refreshing, searching, printing, exporting, reviewing, cancelling reviewing, deleting and statistics, as well as sending the test results to the LIS.

5.2.1 Refresh

Click on the "Refresh" button to refresh the data displayed in the results list to its current state.

5.2.2 Search

By clicking on the “Search” button, users can search the results by different conditions to quickly find what they need. Searching by one or several conditions is supported. Click on the “OK” button after entering the conditions to get the results.

5.2.3 Print

Select one or more results and click on the “Print” button to print these results as a report. After printing is finished, the printer icon will show in the “Status” column.

5.2.4 Send to LIS

Select one or more results and click on the “Send to LIS” button to transmit these results to the LIS. After sending is finished, the LIS icon will show in the “Status” column.

5.2.5 Export

The "Export" function is used to export the selected results to a specified directory on a mobile device. There are two types of exporting: exporting selected results and exporting results generated in a specific time range.

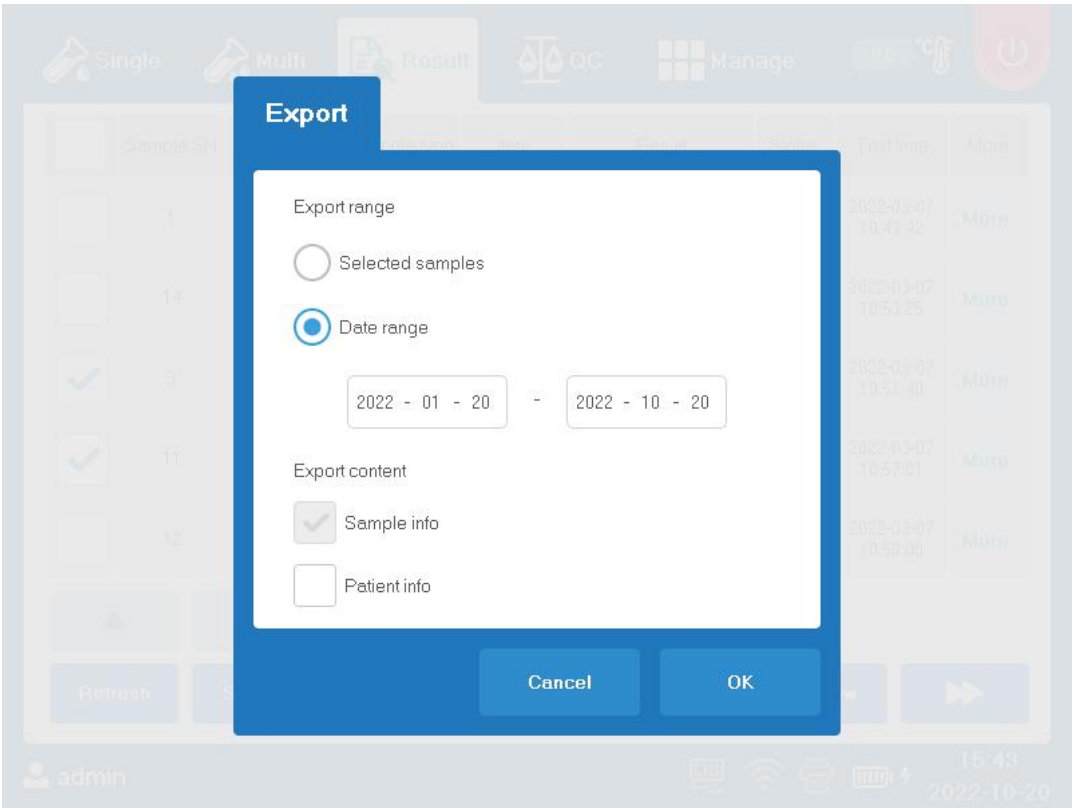


Figure 5- 2 Result export

5.2.6 Review

Select one or more results and click on the “Review” button to review the results. After reviewing is finished, the review icon will show in the “Status” column.

5.2.7 Cancel review

Select one or more reviewed results and click on the “Cancel review” button to cancel the review of these results. After cancelling the review, the review icon in the “Status” column will disappear.

5.2.8 Delete

Select one or more results, click on the “Delete” button, and click on the “Yes” button in the pop-up window to delete these results.

Note

Results cannot be recovered after deletion, please confirm if you want to permanently delete the selected results.

5.2.9 Statistics

The results can be sorted by conditions via the “Statistics” function. The statistics interface is as shown below.

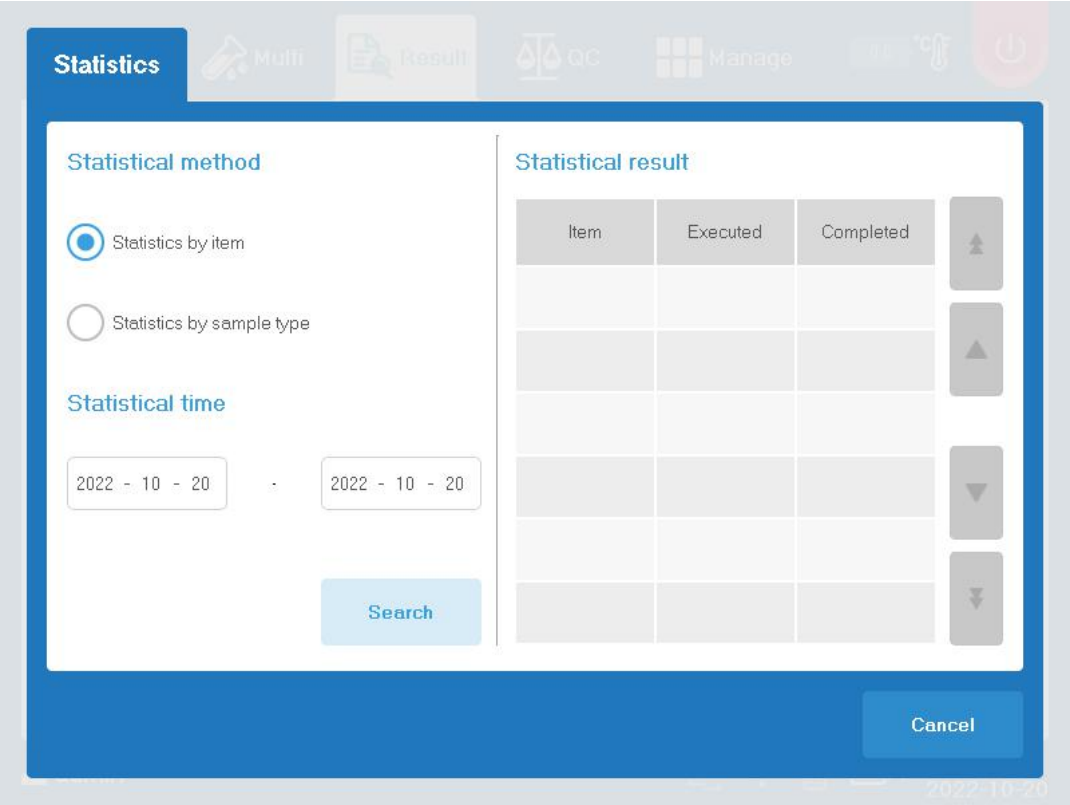


Figure 5- 3 Statistics interface

Two statistical methods are available: “Statistics by item” and “Statistics by sample type”.

After selecting the statistical method, enter the statistical time range and click on the "Search" button, and the corresponding statistical results will be displayed on the right side of the interface. When there are many statistical results, users can view them via the next/previous or page up/down buttons.

6 Quality control

Daily quality control of the Analyzer is required prior to sample testing to ensure the reliability of the results. In the QC function module, users can apply for QC test, search and send QC results, perform QC settings and L-J graph related operations.

6.1 QC test

Select “QC” > “QC test” and the following interface will be displayed.

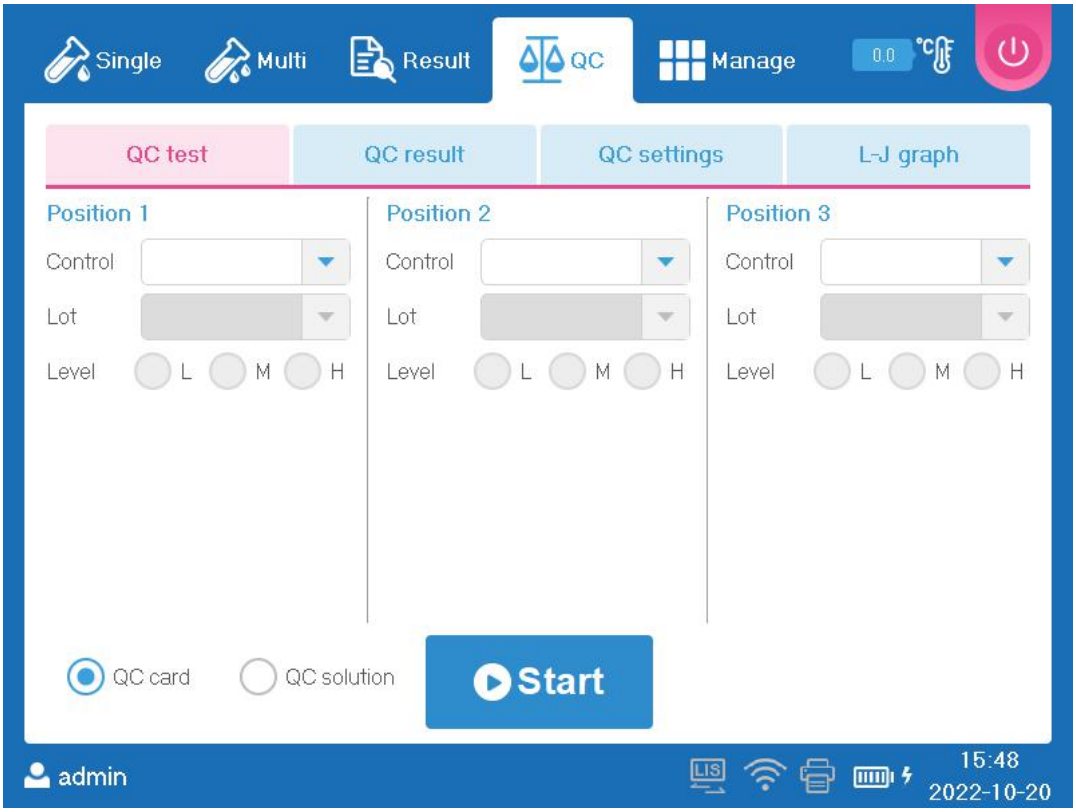


Figure 6- 1 QC test interface

Users can perform quality control with QC card or QC solution.

QC card

Perform quality control with QC cards as follows:

(1) Ensure that information about the corresponding consumables is available on the "Consum." interface, or enter it first if it is not (see 7.1 "Management of consumables (reagents)" for details).

(2) Select “QC card” in the “QC test” interface, and select the control, lot number and level (L=Low, M=Middle, L=High) under the corresponding positions of the reagent cards.

(3) Place the QC cards into the card slots of the Analyzer according to the applied positions for QC test.

(4) Click on the “Start” button to perform quality control.

Note

Please use the QC cards produced by Zybio. Use of QC cards made by other manufacturers may cause test failures or inaccurate test results.

QC solution

Users are recommended to use the QC solutions manufactured by Zybio or other companies for quality control. The procedure for conducting quality control with QC solution is as follows:

(1) Ensure that information about the corresponding consumables is available on the "Consum." interface, or enter it first if it is not (see 7.1 "Management of consumables (reagents)" for details).

(2) Click on “QC settings” (see 6.2 “QC settings”) to enter the interface, and use the barcode scanner to scan the QR code on the control to record the information automatically.

(3) Select “QC solution” in the “QC test” interface, and select the control, lot number and level under the corresponding positions of the reagent cards.

(4) Transfer the QC solution onto the regular reagent cards with a pipette and place them into the card slots of the Analyzer according to the applied positions for QC test.

(5) Click on the “Start” button to perform quality control.

Note

If users need information about the ordering or purchase of reagent cards, QC cards and QC solutions, please contact Zybio (see “Warranty statement” for details of contact) or its authorized representative.

6.2 QC settings

Select “QC” > “QC settings” to enter the following interface:

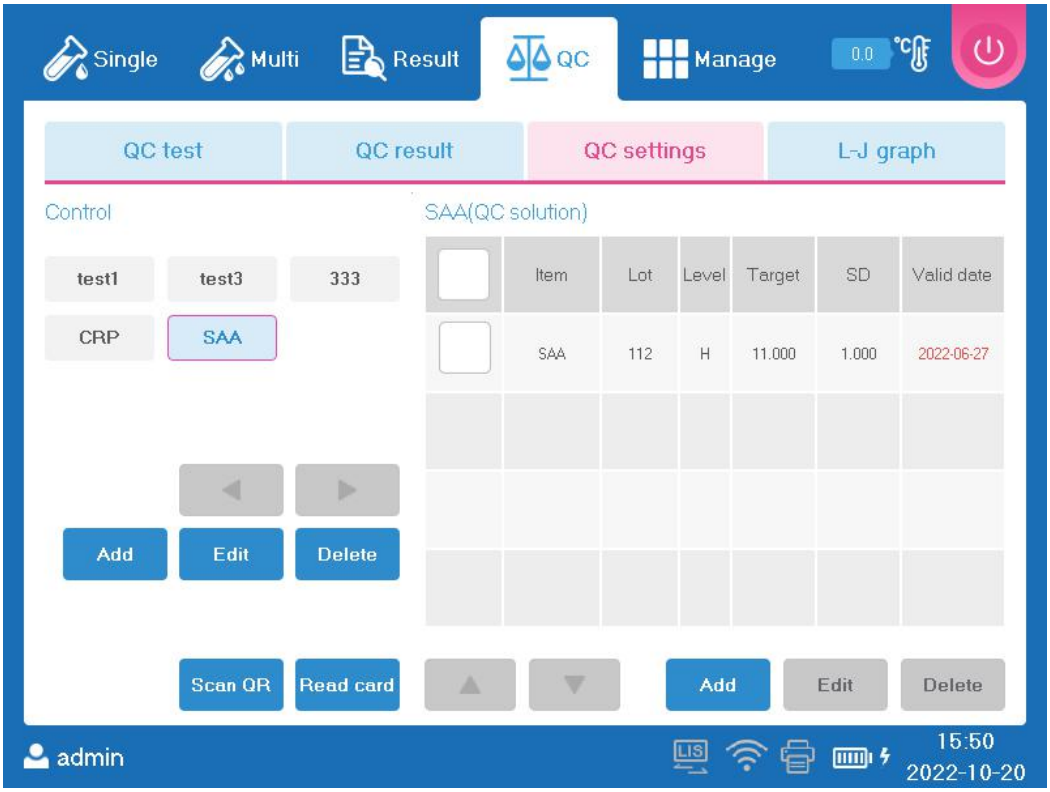


Figure 6- 2 QC settings interface

Information related to the control and relevant buttons are displayed on the left side of the interface, and information about the quality control items and relevant buttons are shown on the right side.

Users can manually modify the information about the control or quality control items via the "Add", "Edit" and "Delete" buttons, and automatically obtain the RF card information in the reagent card kit via the "Read card" button. If a barcode scanner is connected, information about the QC solution can be recorded by scanning the QR code of the QC solution.

Note

Information about the quality control items cannot be edited or changed during testing.

6.3 QC result

Select “QC” > “QC result” to enter the following interface:

Figure 6- 3 QC result interface

The QC result interface shows the name of the QC items, lot number of reagent cards, control, lot number of the QC items, target value, specific QC result, and test time.

Users can search for QC results, delete selected QC results, send selected QC results to the LIS, or export selected QC results to a specified directory on a mobile device.

Note

QC results cannot be recovered after deletion, please confirm if you want to permanently delete the selected results.

6.4 L-J graph

Select “QC” > “L-J graph” to enter the following interface:

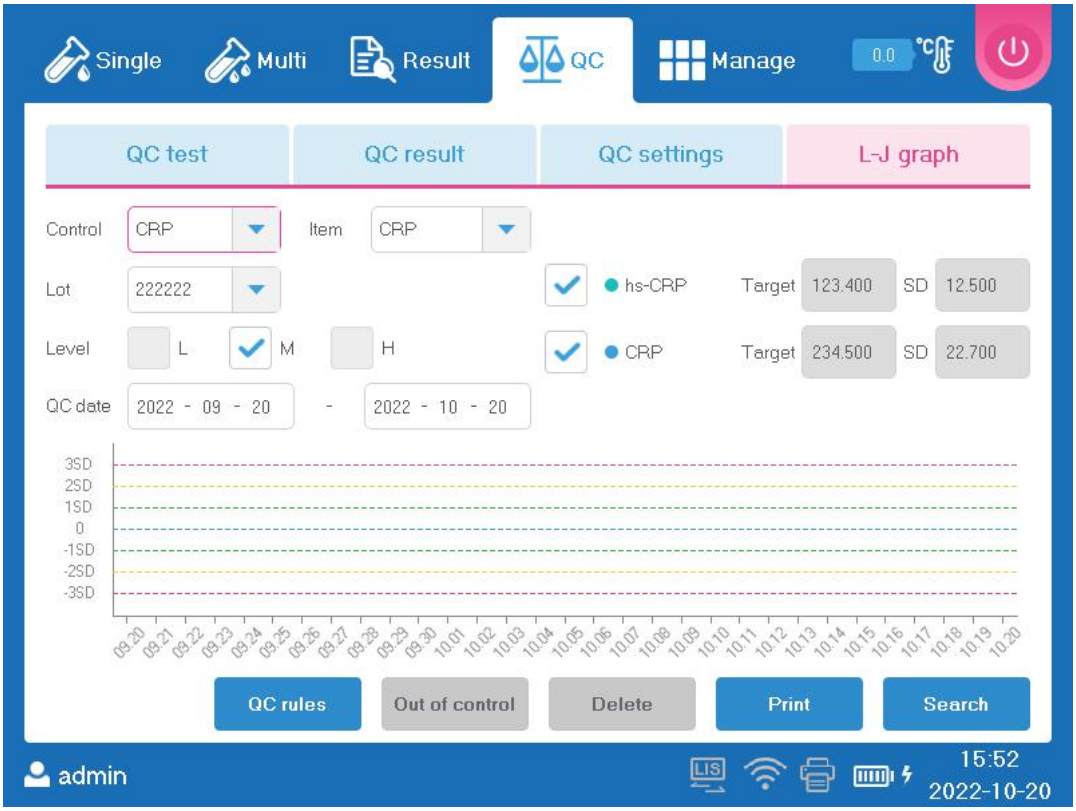


Figure 6- 4 L-J graph interface

Operations:

- Search for L-J graph

(1) Select the control.

(2) Select the item.

(3) Select the lot (after selecting the control, item and lot, the Analyzer automatically obtains the target value and standard deviation entered in the "QC settings" interface for this batch of quality control items).

(4) Select the level.

(5) Enter the QC date to be queried (note that the start time cannot be greater than the end time).

(6) Click on the "Search" button to find the L-J QC graphs for the parameters set. If there are no QC results under the set conditions, no L-J graph will be found.

- Print L-J graph

After querying the L-J graph, click on the "Print" button to print it.

- Delete L-J graph data

After querying the L-J graph, select the quality control results to be deleted and click on the "Delete" button to remove these L-J quality control data.

- Out of control

Users can click on the "Out of control" button to go into the interface and mark the results in the L-J graph as out of control and enter the causes.

- Set QC rules

Users can click on the "QC rules" button to go into the interface and set the QC rules.

7 Management

The management module includes four sub-modules: Consum., Settings, Service and Status, which are used to manage the reagents (consumables) required for testing, set the parameters of the Analyzer to make it more user-friendly, view and set the information related to the device service, and view the status of the device and software.

7.1 Management of consumables (reagents)

Select “Manage” > “Consum.” and the following interface will be displayed.

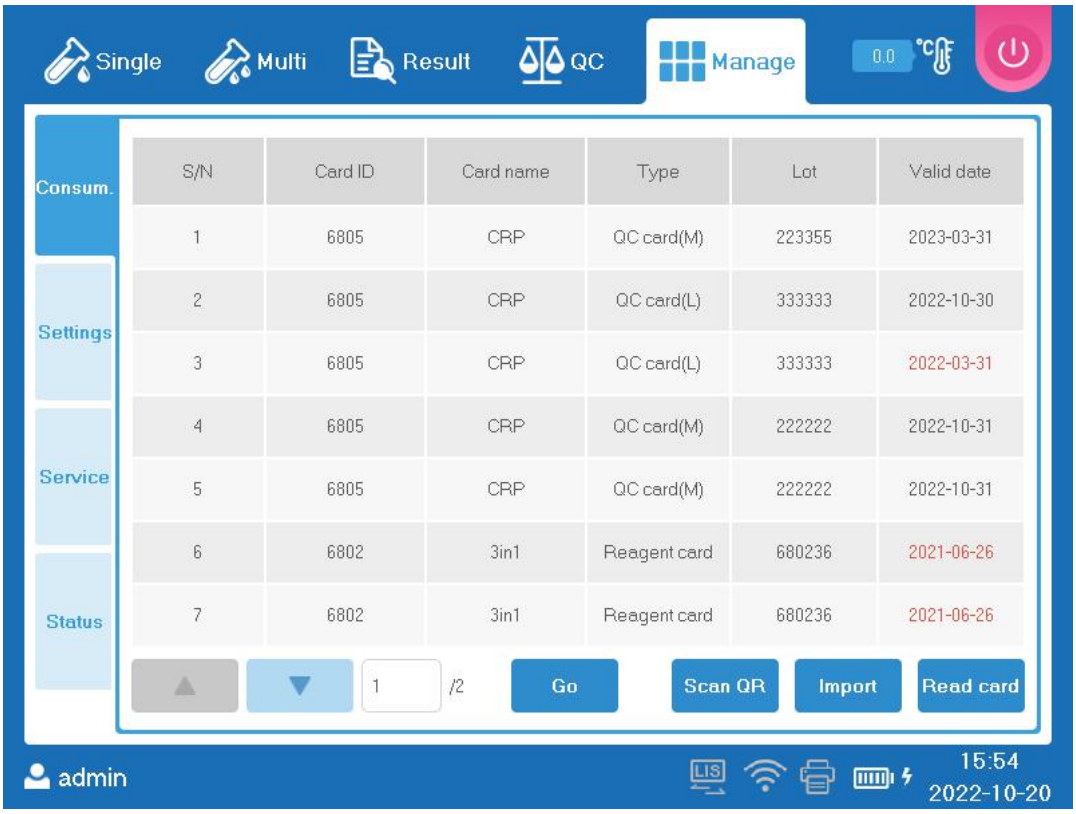


Figure 7- 1 Consumables interface

Users can check the information of consumables already recorded, or enter information of new consumables via the “Scan QR”, “Import” or “Read card” function.

- **Scan QR code**

(1) To use this function, a barcode scanner must be connected to the device first.

(2) Click on the “Scan QR” button and the corresponding interface pops up.

(3) When the cursor flashes in the input box, aim the scanner at the QR code on the reagent card to recognize it.

- **Import**

(1) Store the QR code file as .bmp format into a USB flash disk.

(2) Insert the USB flash disk into the USB interface on the left panel of the device and click on the “Import” button.

(3) Once the file manager pops up, select the file to parse it.

- **Read card**

(1) Click on the "Read card" button and place the RF or QC card from the reagent card kit close to the RFID reader.

(2) After the card is read successfully, the reagent card or QC card information will be shown on the interface.

7.2 Settings

Users can set up the basic settings, system settings and user settings in this sub-module.

7.2.1 Basic settings

Select “Manage” > “Settings” > “Basic settings” and the following interface will be displayed.

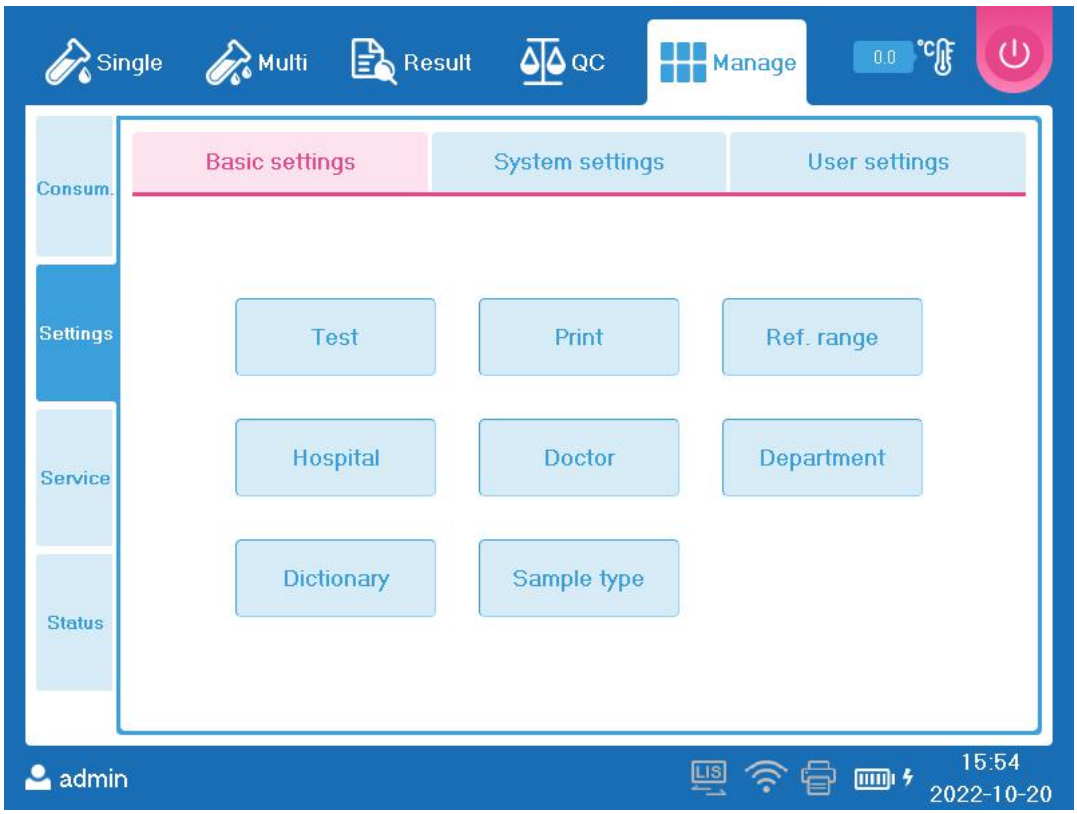


Figure 7- 2 Basic settings interface

- **Test settings**

Click on the “Test” button and the following screen will be displayed.

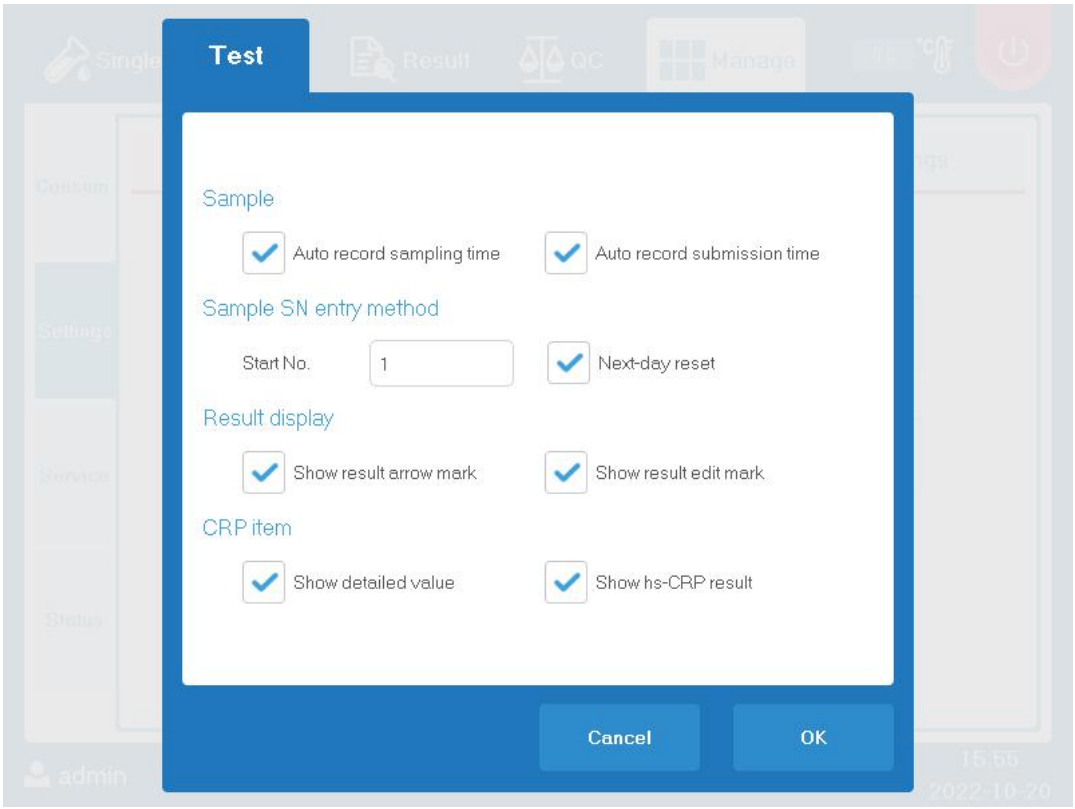


Figure 7- 3 Test settings interface

Users can perform settings of the samples, sample SN entry method, result display and CRP item. See the following table for explanation of the parameters in this interface.

Table 7- 1 Parameters for test settings

Parameter	Explanation
Auto record sampling time	The start time of testing will be automatically regarded as the sampling time.
Auto record submission time	The start time of testing will be automatically regarded as the test submission time.
Start No.	Starting number for automatic incremental numbering of new samples
Next-day reset	The following day the samples will be numbered incrementally from the start No already set up.
Show result edit mark	Whether to display the "E" mark after the result is edited
Show result arrow mark	Whether to display the "↑, ↓" mark if the test result is outs of the reference range
Show detailed value	Whether to display the specific value of the test results of CRP item
Show hs-CRP result	Whether to display the hs-CRP result in the test results of

Parameter	Explanation
	CRP item

- **Print settings**

Click on the “Print” button and the following interface will be displayed.

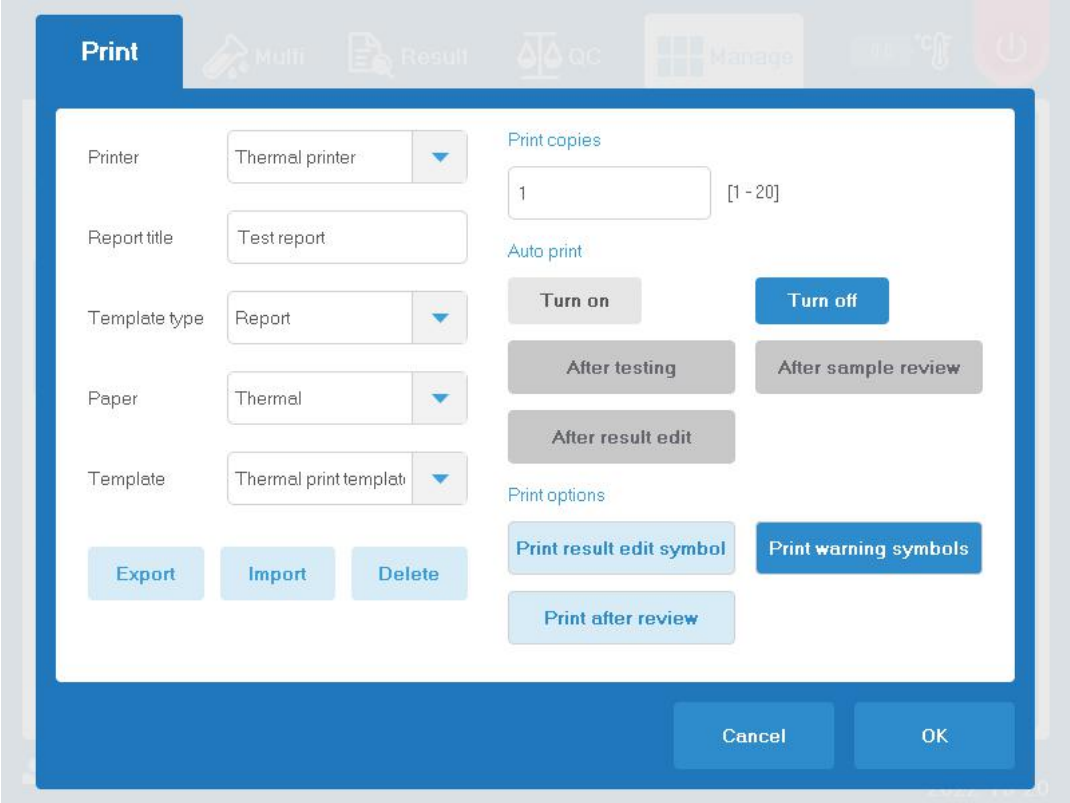


Figure 7- 4 Print settings interface

Users can set the report title, select the template type, paper, printing template, import/export/delete templates, enter printing copies, and set up auto print and print options.

- **Reference range settings**

Click on the “Ref. range” button and the following interface will be displayed.

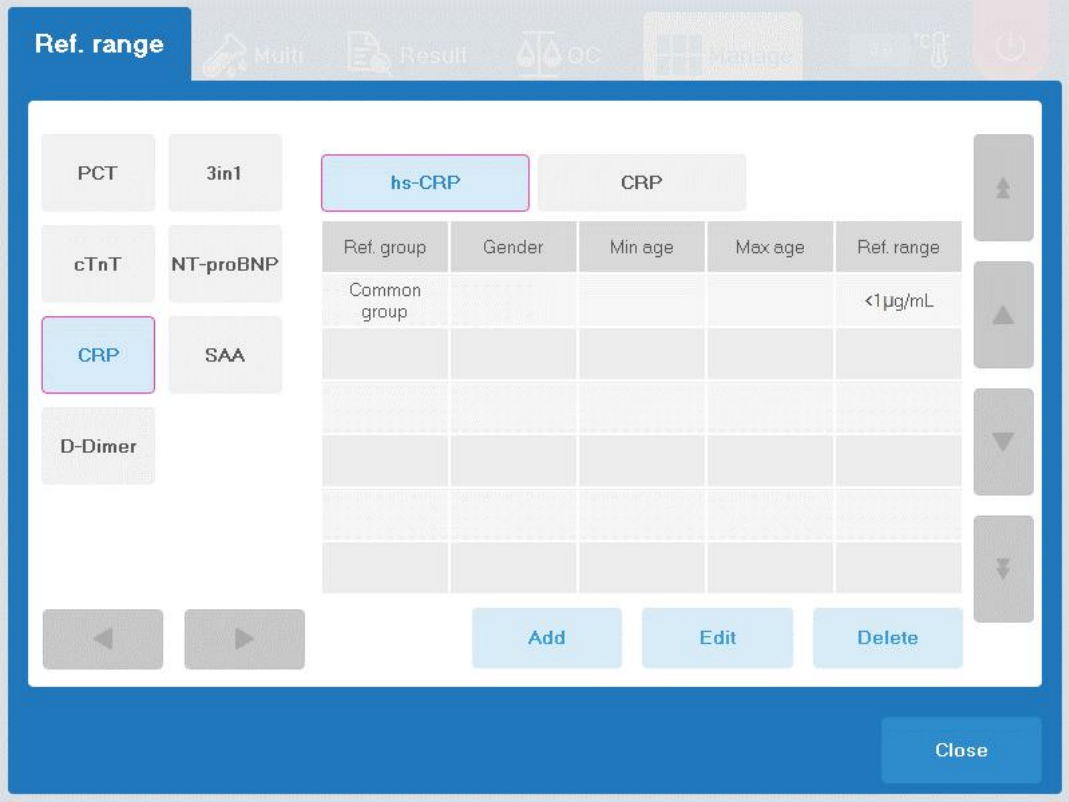


Figure 7- 5 Reference range settings interface

In this interface, users can view the reference range for each test item, and add, edit or delete reference groups.

- **Hospital settings**

Click on the “Hospital” button to enter the hospital settings interface. User can set up hospital-related information, including the hospital name, address, contact person and contact details. This interface also shows the model, date of installation and serial number of the Analyzer by default. Users can set the contact person, contact details and notes for after-sales service, so that they can contact the after-sales service engineers for maintenance and repair of the Analyzer when needed.

- **Doctor settings**

Click on the “Doctor” button to enter the doctor settings interface. Users can add new doctors, edit or delete information about selected doctors, including doctor's name, the department they work for, whether they are test submitters, testers or reviewers, and add or modify the remarks.

- **Department settings**

Click on the “Department” button to enter the department settings interface. Users can add new departments, edit or delete information about selected departments, including the name, person in charge and the remarks.

- **Dictionary settings**

Click on the “Dictionary” button to enter the dictionary settings interface which includes three tabs: Clinical diagnosis, Patient type and Remark. Users can add, edit or delete relevant information.

- **Sample type settings**

Click on the “Sample type” button to enter the sample type settings interface where the sample types to be displayed and the default sample type are shown. Both include four types: whole blood, plasma, serum and urine. Uses can choose the sample types according to actual testing needs.

7.2.2 System settings

In the “System settings” interface, users can change the settings of the system time, screen brightness, sleep mode, communication, LIS, WIFI and prompt. Select “Manage” > “Settings” > “System settings” to enter the following interface.

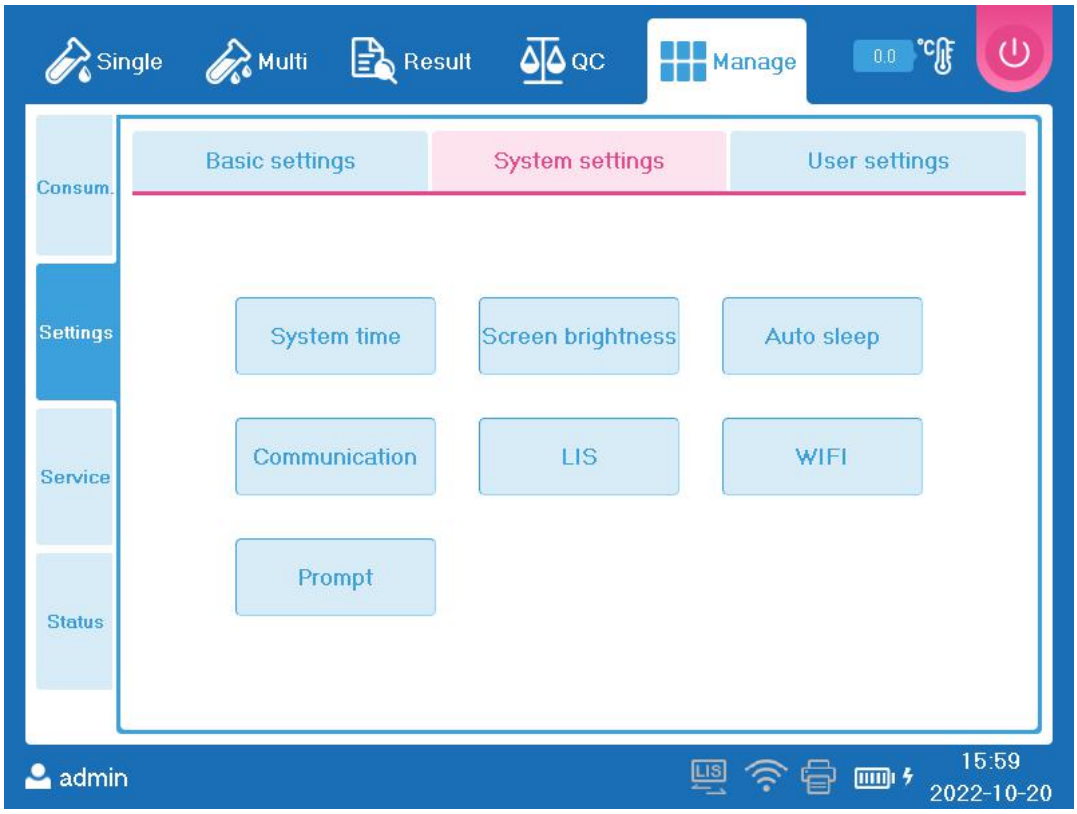


Figure 7- 6 System settings interface

- **System time**

Click on the “System time” button to enter the system time settings interface to set up the date, time and date format of the Analyzer.

- **Screen brightness**

The "Screen brightness" interface allows users to adjust the brightness of the Analyzer's screen.

- **Auto sleep**

Click on the “Auto sleep” button and the following screen will be displayed. In this interface, users can set auto sleep and automatic shutdown after a period of idling, for the adapter-powered and battery-powered Analyzers (only for Analyzer with batteries), respectively.

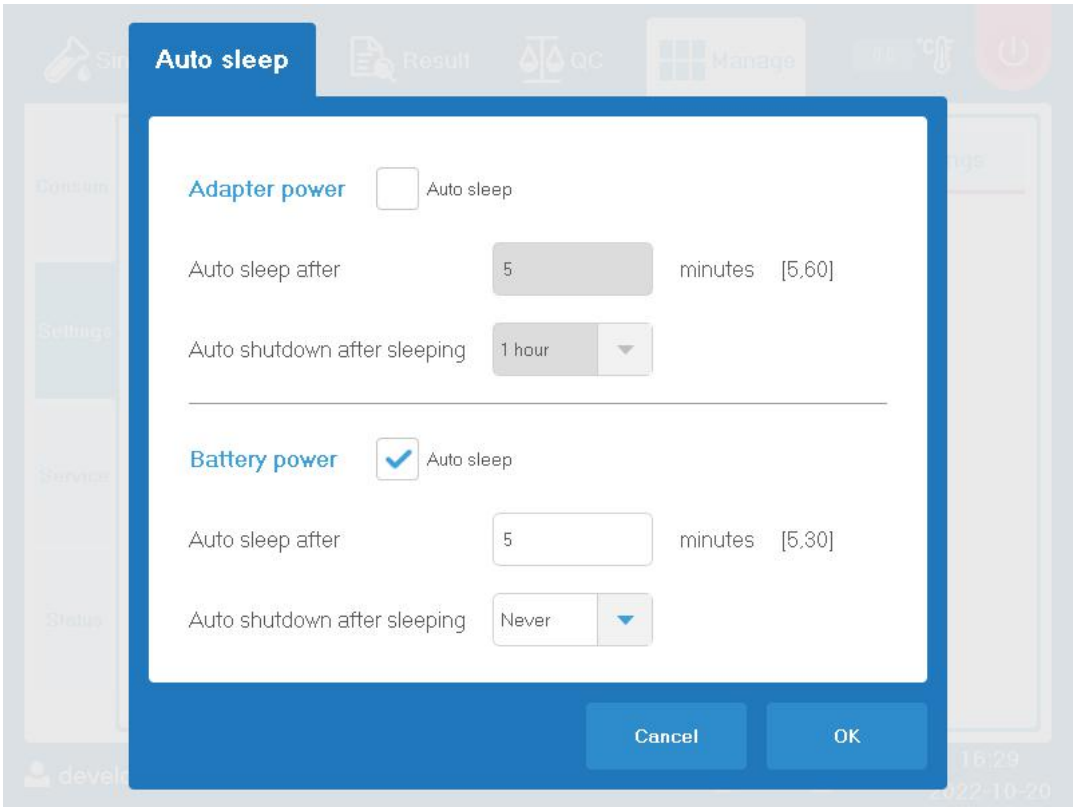


Figure 7- 7 Auto sleep settings interface

- **Communication**

Click on the "Communication" button and enter the following interface to edit information related to the communication of the Analyzer.

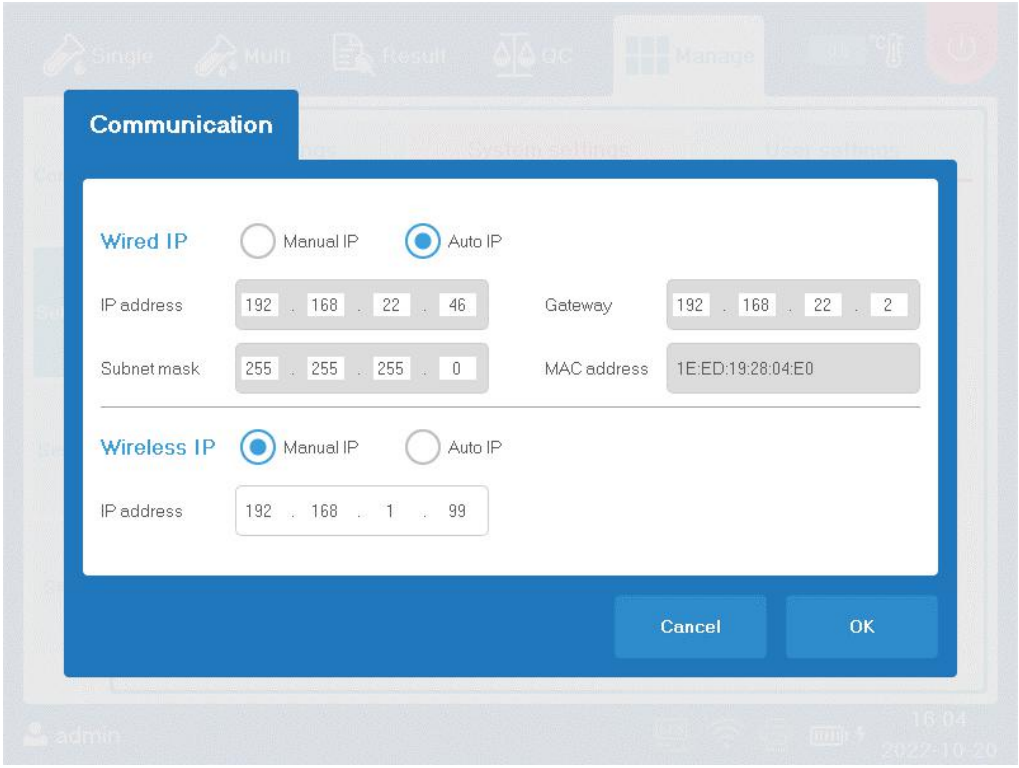


Figure 7- 8 Communication settings interface

- **LIS**

Click on the “LIS” button and enter the following interface to set up the connection of the Analyzer with the LIS.

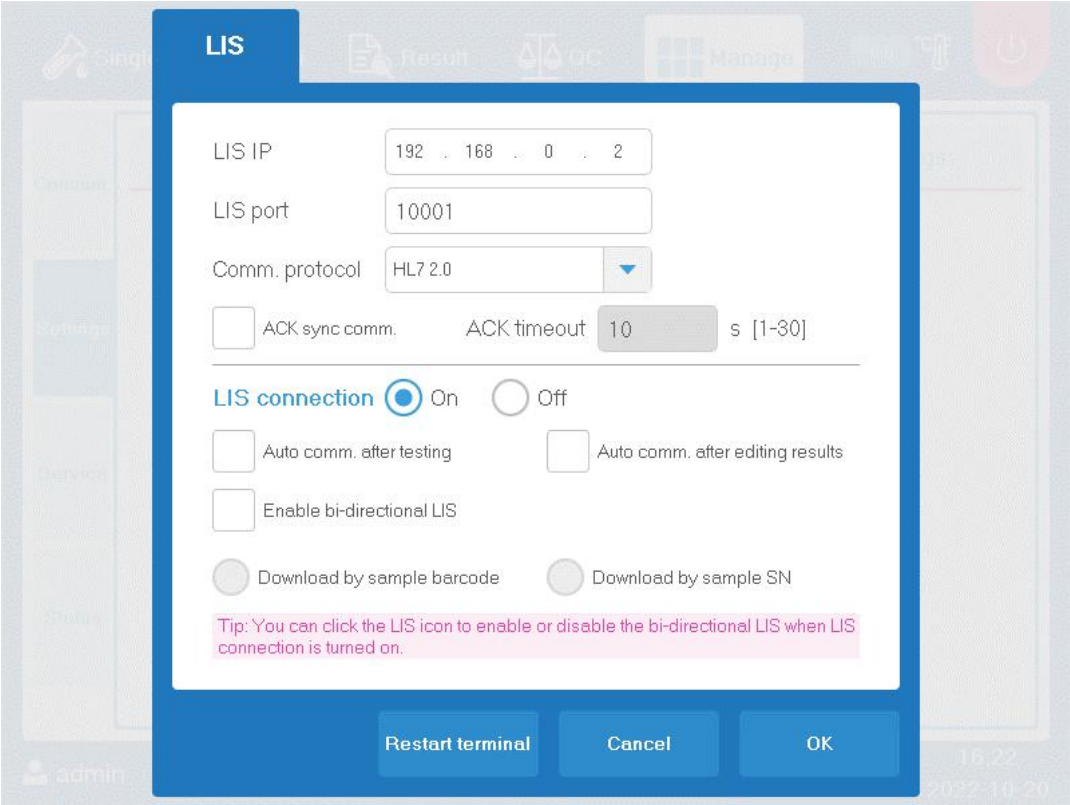


Figure 7- 9 LIS settings interface

- **WIFI**

Click on the “WIFI” button to enter the WIFI settings interface. Users can set up the WIFI communication of the Analyzer.

- **Prompt**

Click on the “Prompt” button and enter the following interface to edit the way the Analyzer send prompts.

Note: “Display battery percentage” is only applicable to devices equipped with battery.

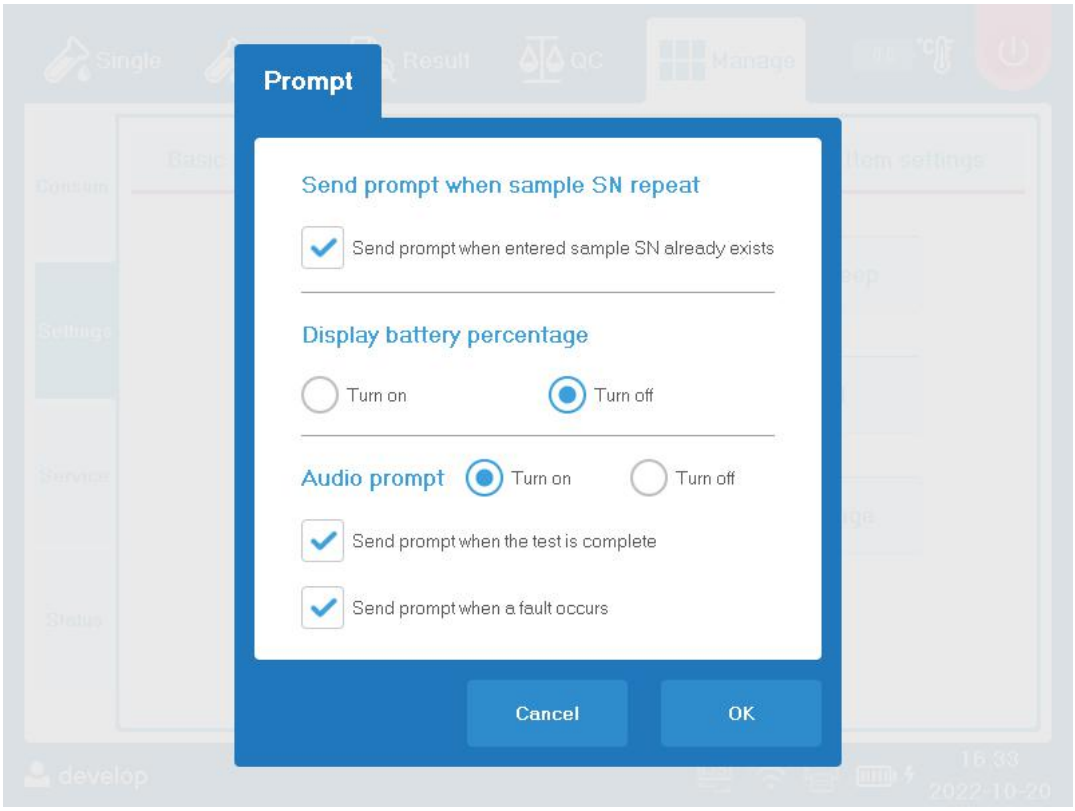


Figure 7- 10 Prompt settings interface

7.2.3 User settings

In the "User settings" interface, user roles and permissions can be set and differentiated to improve the security of the device. Select “Manage” > “Settings” > “User settings” to enter the following interface.

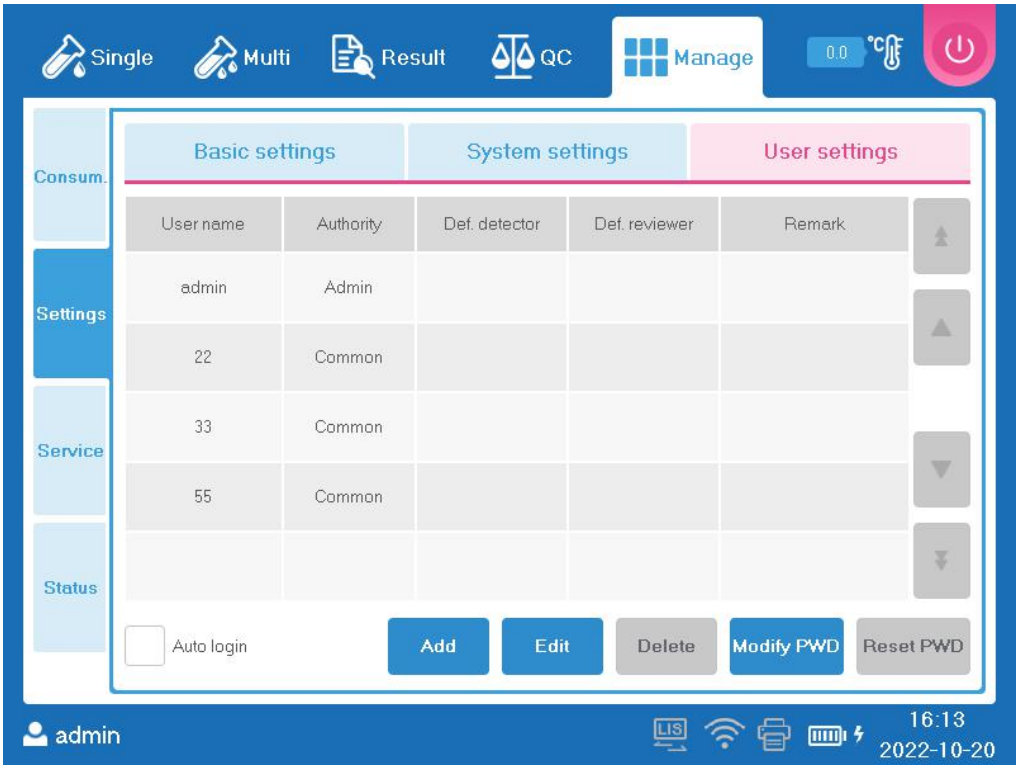


Figure 7- 11 User settings interface

You can add, edit or delete users, and change or reset their passwords in this interface. Select “Auto login” if you want to log into the operating software automatically (same as that in the login interface).

7.3 Service

The "Service" sub-module contains four sections: Version, Self-test, Maintenance and Log.

7.3.1 Version

Select “Manage” > “Service” > “Version” to enter the version information interface where the software name, released software version, software model and device model are shown.

7.3.2 Self-test

Click on the “Self-test” tab to enter the following interface where users can perform self-test of all components to check their status and operational conditions.

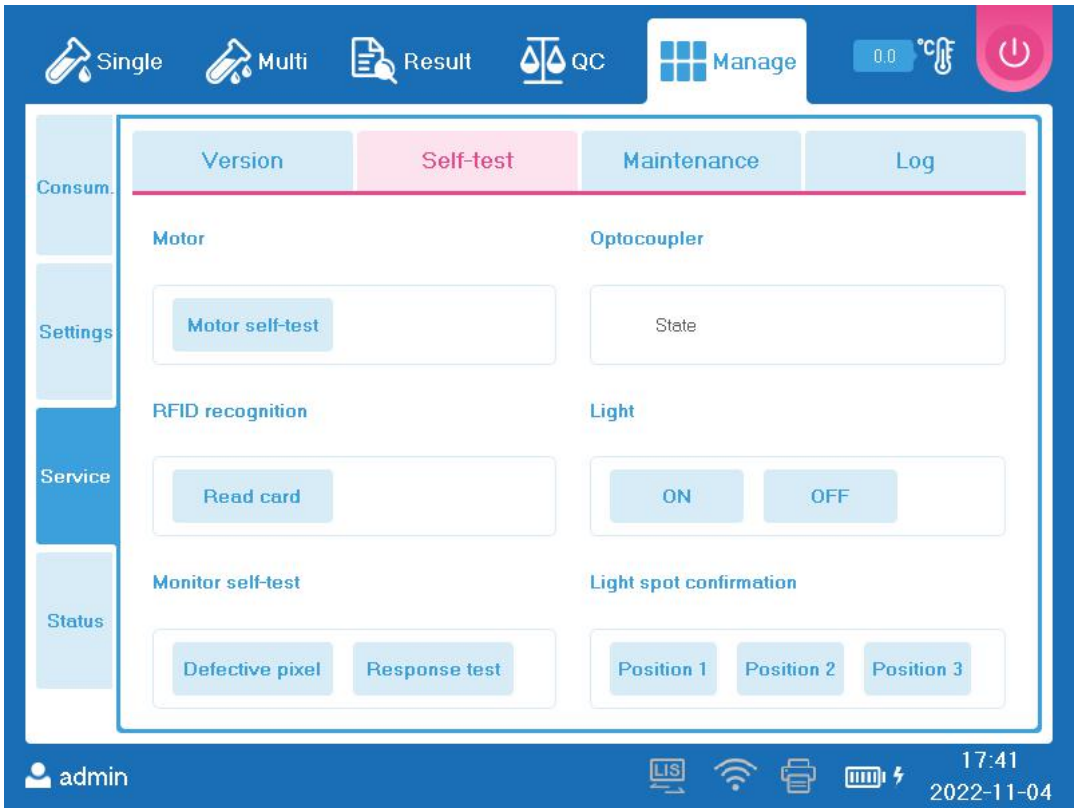


Figure 7- 12 Self-test interface

7.3.3 Maintenance

The monitor can be calibrated in this interface via the “Monitor cal.” function.

7.3.4 Log

Logs are used to record the usage of the Analyzer and are important for the user to check the usage history and for maintenance personnel to conduct troubleshooting. Click on the “Log” tab and the following screen will be displayed.

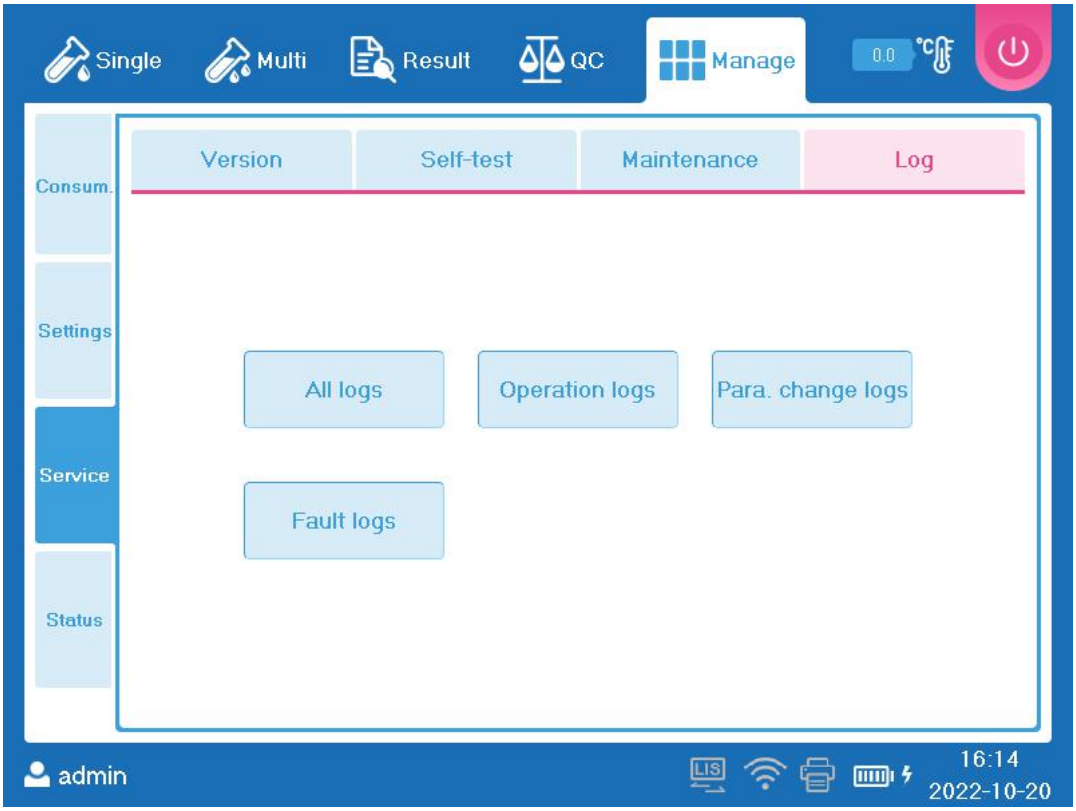


Figure 7- 13 Log interface

Four options are available: All logs, Operation logs, Para. change logs and Fault logs. All can be queried and exported.

- **Searching for logs**

(1) Choose the type of logs you need to enter the corresponding interface.

(2) Input the range of date.

(3) Click on the “Search” button and all logs within the date range will be shown.

- **Exporting logs**

(1) Insert the USB flash drive into the USB port of the Analyzer.

(2) Choose the type of logs you need to enter the corresponding interface.

(3) Click on the “Export” button to enter the log exporting interface.

(4) Select the type of log you want to export (current log or all logs) and click "OK" to export the log(s).

7.4 Status

The “Status” sub-module includes two tabs: Monitoring and System information. Select “Manage” > “Status” to enter the following interface.

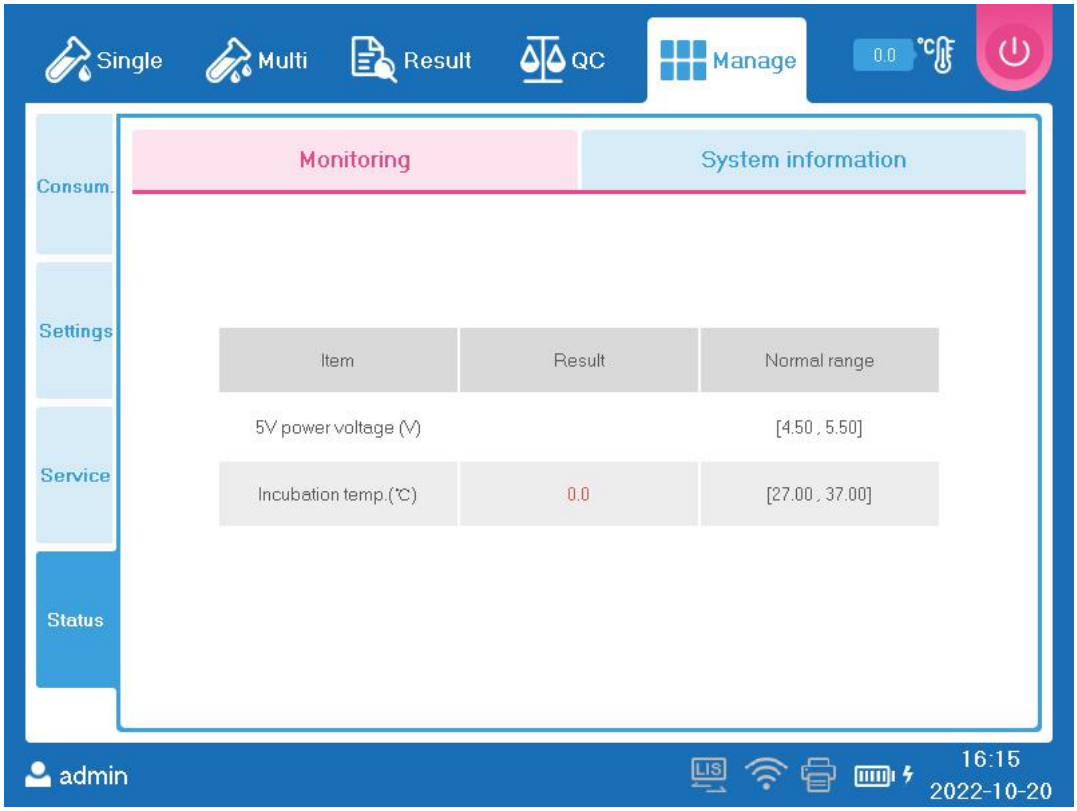


Figure 7-14 Status interface

7.4.1 Monitoring

Users can check the voltage and incubation temperature of the Analyzer in this interface.

7.4.2 System information

Users can check the information related to the disks of the Analyzer in this interface.

8 Maintenance and care

The Analyzer is a precision analytical device. In order to keep it in good operating condition, produce reliable test results and reduce the frequency of failure, maintenance and servicing is required, including emptying, cleaning and disinfection of the waste card collection box, cleaning of the Analyzer surface and preventive maintenance and inspection.

8.1 Emptying, cleaning and disinfection of waste card collection box

The waste card collection box can be reused, but it must be cleaned, sanitised and disinfected after each day of use.

- Before each testing, check if the waste card collection box is full. If it is, empty it timely to prevent the waste cards from falling onto the bench or desk and cause biological contamination.
- Clean the waste card collection box by wiping it with water, 75% ethanol or 70% isopropyl alcohol and a cloth after all tests have been completed each day.
- If necessary, disinfect it with 75% ethanol or 70% isopropyl alcohol.

Note

- Protective gloves must be worn to avoid biohazards when emptying, cleaning and disinfecting the waste card collection box.
- Obsolete waste card collection boxes may still be biohazardous and should not be disposed of indiscriminately. Please dispose of them in accordance with the relevant regulations.

8.2 Cleaning and disinfection of Analyzer

Clean the Analyzer by wiping its surface with water, 75% ethanol or 70% isopropyl alcohol and a cloth after all tests have been completed each day. If necessary, disinfect it with 75% ethanol or 70% isopropyl alcohol.

Warning

- Do not clean the Analyzer with any solvents, grease or corrosive substances. If the user has doubts about the compatibility of the disinfectants or detergents with the device components or the materials contained in the device, please consult the after-sales service department of Zybio.
- Please wear protective gloves during cleaning and disinfection to avoid contact with samples left or dripped on the surface of the Analyzer.
- Please power off the Analyzer and remove the power plug from the socket before cleaning and disinfecting it. Please take necessary measures to prevent liquids from entering the device during cleaning and disinfection, otherwise it may cause damage to the device or personal injury.

8.3 Preventive maintenance and inspection

- Inspect the external power cable every month for any signs of damage and ageing to ensure electrical safety.
- Inspect whether the device housing is fixed and whether the fixing screws are loose

every six months.

- Do not clean the device with 84 disinfectant, or strong acid, strong alkali or other strong solutions, otherwise it may cause corrosion of the surface and electronic components of the Analyzer.

Note

Please wear protective gloves during preventive maintenance and inspection to avoid biohazards.

8.4 Replacement of printer paper

When using the printing function, if the printer has run out of paper or if there is not enough paper left to print the test report, the Analyzer will report a fault and the user will need to replace the paper and remove the fault manually.

Please replace the printer paper as follows:

(1) Open the thermal printer cover gently.

(2) Take out the paper roll and the remaining paper.

(3) Insert the paper roll into the paper slot with the shiny side inward, and leave a tail of paper (about 2 cm) sticking out.

(4) Close the printer cover.

(5) Clear the fault manually as described in Chapter 9 "Troubleshooting".

Note

Please use thermal printer paper that meets the requirements, otherwise it may lead to problems such as printer failure, poor printing quality or print head damage.

9 Troubleshooting

This chapter introduces the errors or faults that may occur and the corresponding troubleshooting measures.

9.1 Fault prompts

If an abnormal condition is detected during the use of the Analyzer, a fault icon will be displayed at the bottom of the interface (the number in the upper right corner indicates the number of fault messages) and the specific fault message will be shown to the right of the icon and a beeping alarm will sound.

Click on the fault icon or fault message and the fault management interface will be displayed.

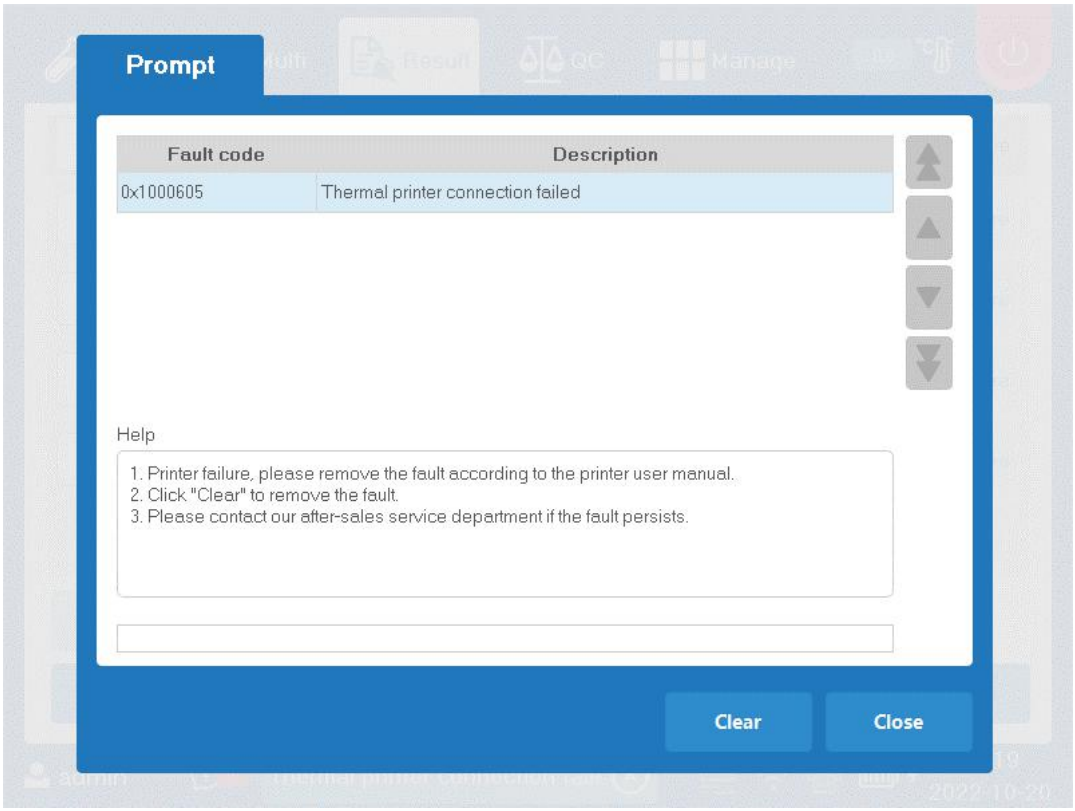


Figure 9- 1 Fault prompt

It shows the fault code, fault description and help information. Users can troubleshoot the fault according to the help information. Click on the “Clear” button to remove the fault.

9.2 List of fault messages

The possible faults of the Analyzer and the corresponding troubleshooting measures are outlined in the following table. Refer to the measures provided for troubleshooting. If the fault persists after measures are taken, please contact the after-sales service department of Zybio.

Table 9- 1 Fault messages and troubleshooting

Fault code	Description	Troubleshooting
0x01000101	Incubation temperature sensor abnormal	1. Click "Clear" to remove the fault. 2. If the fault persists, contact our after-sales service.
0x01000102	Incubation temperature exceeded upper limit	1. Click "Clear" to remove the fault. 2. If the fault persists, contact our after-sales service.
0x01000103	Incubation temperature exceeded lower limit	1. Click "Clear" to remove the fault. 2. If the fault persists, contact our after-sales service.
0x01000202	Error: driver board 5V voltage	1. Click "Clear" to remove the fault. 2. If the fault persists, contact our after-sales service.
0x01000401	Error: system clock	1. Please shut down the instrument and restart it. 2. If the fault persists, contact our after-sales service.
0x01000501	Error: optical detection motor assembly	1. Click "Clear" to remove the fault. 2. If the fault persists, contact our after-sales service.
0x01000502		
0x01000503		
0x01000504		
0x01000505		
0x01000506		
0x01000507		
0x01000601	Thermal printer has run out of paper.	1. Thermal printer is running out of paper, please change. 2. Click "Clear" to remove the fault. 3. If fault still exists, please remove the fault according to the printer user manual. 4. Please contact our after-sales service department if the fault persists.
0x01000605	Error: thermal printer	1. Click "Clear" to remove the fault. 2. If fault still exists, please remove the fault according to the printer user manual. 3. If the fault persists, contact our after-sales

Fault code	Description	Troubleshooting
		service.
0x01000701	Error: driver board communication	1. Please shut down the instrument and restart it. 2. If the fault persists, contact our after-sales service.
0x01000702	Error: driver board communication	
0x01000703	Error: driver board communication	
0x01000704	Error: driver board communication	
0x01000801	Error: optical board communication	
0x01000802	Error: optical board communication	
0x01000901	Error: RFID card reader communication	1. Click "Clear" to remove the fault. 2. If the fault persists, contact our after-sales service.
0x01001001	Error: QR code scanner communication	1. Click "Clear" to remove the fault. 2. If the fault persists, contact our after-sales service.
0x01001101	Communication disconnected	1. Communication is disconnected, please check network connection. 2. This fault cannot be cleared at one click, but can be automatically eliminated after LIS re-connected. 3. If the fault still exists, please contact the after-sales service department.
0x01001102	Communication error	1. Please check whether the network is connected normally. 2. Click "Clear" to remove the fault. 3. If the fault still exists, please contact the after-sales service department.
0x01001201	Expired reagent card	1. This message intends to remind the user that the reagent card has expired, which may affect the testing results. The user is advised to use reagent cards that are within the expiry date. 2. Click "Clear" to remove the fault.

Appendix A Related information

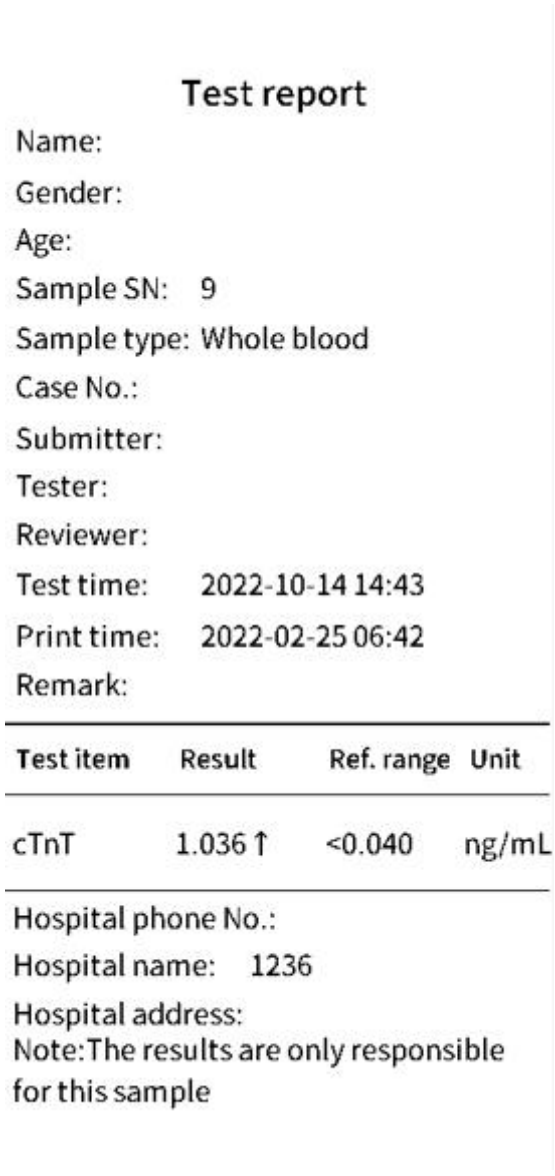
Table A-1 List of accessories

No.	Name
1	Power cable
2	Power adapter
3	Network cable
4	Internal power module (optional)
5	Barcode scanner (optional)
6	Waste card collection box

Table A-2 List of miscellaneous materials

No.	Material name
1	Protective suit
2	Latex gloves
3	Surgical mask
4	Medical alcohol
5	Centrifugal tube
6	Pipette
7	Pipette tip
Note: Users shall prepare the materials above, and the list may not be exhaustive.	

Appendix B Test report template



Test report

Name:

Gender:

Age:

Sample SN: 9

Sample type: Whole blood

Case No.:

Submitter:

Tester:

Reviewer:

Test time: 2022-10-14 14:43

Print time: 2022-02-25 06:42

Remark:

Test item	Result	Ref. range	Unit
cTnT	1.036 ↑	<0.040	ng/mL

Hospital phone No.:

Hospital name: 1236

Hospital address:

Note:The results are only responsible for this sample

Figure B-1 Test report template

Appendix C Literature

1. ISO 20916:2019 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice
2. EN ISO 18113-1:2011, In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1: Terms, definitions and general requirements
3. EN ISO 18113-3:2011, In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 3: In vitro diagnostic instruments for professional use