Fluorescence Immunochromatography Analyzer

(Models: EXR 100、EXR 110、EXR 120)

Service Manual

First edition (March, 2023)

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For customer service, please contact:

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Contents

1 General introduction

1.1 Revision history

Version	Revision Date:	Revised contents
01	March 31, 2023	First release

1.2 Scope of application

This service manual is for persons who:

- have a comprehensive knowledge of electrical circuits;
- supporting reagents and quality control and other related matters;
- troubleshooting;
- be able to operate and commission this analyzer proficiently;
- be able to use basic mechanical tools and understand relevant terminology.

1.3 Intended use

The Fluorescence Immunochromatography Analyzer is used with supporting reagents produced by Zybio to perform quantitative detection of analytes derived from human serum, plasma, and whole blood samples, helping clinical practice. Supporting reagents include: full-range C-reactive protein (hs-CRP + conventional CRP), serum amyloid A, myoglobin, creatine kinase isoenzyme, D-Dimer, calcitoninogen, cardiac troponin T, N-terminal brain natriuretic peptide precursor, glycosylated hemoglobin and interleukin-6.

1.4 About this manual

This Manual consists of 10 chapters. The readers may refer to the relevant chapter for the information needed.

Chapter	Content
1	This chapter mainly introduces the revision history of the instrument, scope of application, intended use, symbol description, precautions, return procedures, etc.
2	This chapter mainly introduces basic information, model differences, performance parameters, specification configurations, status alerts, etc. of the analyzer
3	This chapter mainly introduces installation requirements of the analyzer.
4	This chapter mainly introduces analyzer status confirmation and calibration.
5	This chapter mainly introduces the maintenance methods of the analyzer.

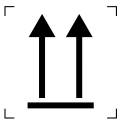
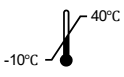
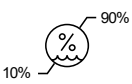
Chapter	Content
6	This chapter mainly introduces the common fault information of the analyzer and how to deal with it.
7	This chapter mainly introduces the basic functions of the analyzer software.
8	This chapter mainly introduces the composition of each part of the mechanical system of the analyzer.
9	This chapter mainly introduces the structure of the hardware system of the analyzer and the composition of each PCBA.
10	This chapter mainly introduces the analyzer's optical system and the main fault repair methods of the optical system.

1.5 Symbols

This chapter describes the symbols used on the Analyzer or in the Manual.

Table 1-1 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).
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.

Symbols	Explanation
	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.
	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.

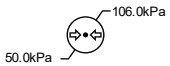
Symbols	Explanation
	Indicates that distribution packages shall be stored, transported, and handled within atmospheric pressure limitation.

Table 1-2 Symbols used in the 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.

1.6 Precautions on use

This section describes mainly the items that require special attention during analyzer maintenance. To use your Analyzer safely and effectively, observe the following precautions. If the Analyzer is used in a manner not specified by the manufacturer, it may damage the Analyzer or cause harm to the operator.

All items (samples, reagent cards, quality control cards, calibrators, etc.), as well as areas in contact with these items, have potential biological risks. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective clothing, gloves, etc.) when contacting relevant items and areas in the laboratory.

Warning

- It is important for the hospitals or institutes that employ this Analyzer to carry out a reasonable service/maintenance plan. Neglect of this may result in analyzer breakdown or personal injury.
- Do not use flammable gases (e.g. anesthetics) or flammable liquids (e.g. ethanol) in the vicinity of this product, as there is a risk of explosion.
- The power must be switched off when carrying out repairs. Performing repairs with the power on risks electric shock and damage to electrical components.
- Connecting the analyzer to a socket with a separate fuse and protective switch. Connecting the analyzer to the same fuse and protective switch with other equipment (e.g. life support equipment) may result in tripping if the machine malfunctions, if an overcurrent is generated, or if a momentary inrush current is generated when the machine is switched on.

- The clothing, hair, and hands of the service personnel must be kept at a distance from moving components, such as the motor, to prevent them from being caught in the moving parts during servicing.
- The operator is obliged to comply with local national and regional regulations on the discharge and disposal of reagents, liquid waste, waste samples, consumables, etc.
- Device disposal: some substances of the discarded analyzers are regulated by pollution regulations. Please observe the local regulations on disposal of discarded analyzers.
- The reagents can cause irritation to eyes, skin and mucous membranes. When contacting items related to reagents in the laboratory, the operator shall strictly abide by the laboratory safety regulations, and wear personal protective equipment (laboratory protective suit, gloves, etc.).
- Rinse immediately with plenty of water once the reagent contacts with skin or eyes. If necessary, please contact doctors for medical treatment.
- Be sure to operate the analyzer under the situation specified in the service manual; otherwise, the analyzer may not work properly and the analysis results will be unreliable, which may damage the analyzer components and cause personal injury.
- Data backup: the Analyzer saves the data in the computer hard disk. If the data on the hard disk is deleted, or if the hard disk has been damaged due to other reasons, the data cannot be recovered. If necessary, periodically back up the analysis data to other mobile storage devices.

1.7 Return procedure

For returns, please contact the after-sales service department of Zybio.

2 Product information

2.1 Product overview

Category	Basic Information
Product Name	Fluorescence Immunochromatography Analyzer
Model Type	EXR 100、EXR 110、EXR 120
Product structure and 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 a control software.
Intended purpose	The Analyzer is based on dry immunofluorescence technology and is used together with supporting reagents to perform immunoquantitative detection of analytes derived from human serum, plasma samples in clinical practice. The test items include myocardium-related, infection-related, and blood glucose.
Classification of device	Class A
Manufacturer	Zybio Inc.
Manufacturer address	Floor 1 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, PEOPLE’S REPUBLIC OF CHINA A
Registered address of the manufacturer	Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, PEOPLE’S REPUBLIC OF CHINA
Manufacturing date	Refer to the instrument nameplate.
Service life	5 years[1]
Contraindications	None

[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.

2.2 About the Analyzer

2.2.1 Models

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

Models	EXR 100	EXR 110	EXR 120
Channel (quantity)	1	3	3
Sample data storage (pcs.)	30,000 pieces of data	29,000 pieces of data	28,000 pieces of data
Software name	Fluorescence Immunochromatography Analyzer Software		
Software models	EXR 100	EXR 110	EXR 120
Software release version	V1		

2.2.2 Parameters and performance

This section introduces the parameters and performance of the Analyzer, as shown in the following table:

Item	Description
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 lower than 0.990.
Channel consistency	The relative range (R) of the measurement results for each channel should not exceed 5% (EXR 100 is not applicable)
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%.

2.2.3 Specifications and configuration

This section mainly describes the Analyzer’ s specifications and configuration, as shown in the following table:

Item	Description
Instrument Dimensions	• Length: 275 mm • Width:250 mm • Height:186 mm

Item	Description
Weight	• 3.7 kg (with battery) • 3.2 kg (without battery)
Input/output device	• Touch screen • Thermal printer • Buzzer
Main unit interface	• Power adapter interface: 1 • Network interface: 1 • USB interface: 2
power supply	• Adapter input: 100–240 V AC, 50/60 Hz, 1.4-0.7 A； • Machine input: 24 V⎓2.5 A, 60 W MAX； • Internal lithium battery (optional): 18 V, 4700 mAh, 84.6 Wh
Channel	3 Channel (EXR 110，EXR 120), single channel (EXR 100)
Sample type	Serum, plasma, whole blood
Select the test mode	• Single: standard test mode, quick test mode • Multi: standard test mode, quick test mode
Smart identification	Automatic identification of test items and reagent batches
Smart timing	Automatic calculation of the incubation time in standard test mode and automatically start the test when the incubation time is up.
Incubation temperature	The incubation area contains the temperature control system, with an incubation temperature of 27 °C to 37 °C.
Error alarm	Supports audible buzzer alarms
Control method	8.0-inch touch screen
Printing	The analyzer has a built-in thermal printer and supports external USB printers.
Storage capacity	More than 30,000 results.
Network Requirements	Network type is LAN, no required bandwidth.
Software name	Fluorescence Immunochromatography Analyzer Software
Software models	EXR 100，EXR 110，EXR 120
Software release version	V1

Item	Description
Data interfaces	• Wired network interface: The software performs two-way data transmission with the laboratory LIS via the HL7 transmission protocol and one-way data transmission to Zybio’ s maintenance system via the TCP/IP transmission protocol. • Wireless network interface: The software performs two-way data transmission with the User LIS via Wi-Fi using the TCP/IP transmission protocol, and it conducts one-way data transmission to Zybio’ s maintenance system via 4G communication, remotely transmitting equipment data such as instrument faults, etc. • USB interface: The software carries out electronic data exchange with storage media such as flash drives, etc. Data can be exported in “.xml” , “.pdf” , “.log” or “.csv” formats. The USB protocol version is USB 2.0; • RFID interface: The software communicates with the RFID reader through the Uart serial port, and users can enter the information of the reagent cards and quality control cards by placing the RF card close to the RFID reader.
User access control mechanism	A login password is required by the Analyzer software for user identification. The software should have a user control mechanism, including user identification method (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.)
Requirements related to software environment updates	No
Software Function	The software supports sample type selection, adding patient information, instrument status display, result query and printing, one-way or two-way transmission from the LIS system, system setup, and engineer maintenance functions.

2.2.4 Status

Buzzer

The buzzer sounds the alarm to remind the user that malfunctions occurred on the instrument. The buzzer alarm sound can be switched off automatically after a touch of the screen.

3 Installation

3.1 General introduction

The installation guide is the normative document that guides the engineer in the installation of a product on site, which includes: pre-installation preparation, installation, commissioning, verification, and acceptance.

3.2 Tools

This section mainly introduces the tools that may be used for installation and maintenance.

No.	Tools	Unit	Quantity	Remarks
1	M2 Hexagon socket screw 1.5 Inner hexagon wrench	piece	1	Fixing screws for RFID, 4G modules etc.
2	M2.5 inner hexagon socket head cap screws. #2 Inner hexagon wrench	piece	1	Optocoupler stopper fixing screw
3	M3 Hexagon socket screw #2.5 Inner hexagon wrench	piece	1	Upper case fixing screws (length to be greater than 90mm), accessories
4	M4 Hexagon socket screw #3 Inner hexagon wrench	piece	1	Motion assembly fixing screws, middle cover fixing screws, accessories
5	M2 Phillips screw Phillips screwdriver	piece	1	fixing screw for the incubation position on the mounting plate of the temperature control assembly (single channel models)
6	M3 Phillips screw Phillips screwdriver	piece	1	Fixing screws for PCBAs, etc.
7	Flexible ruler	piece	1	Installation space confirmation
8	Scissor	piece	1	Packing removal

3.3 Installation process

This section introduces the brief process of installing the analyzer.

No.	Content	Item
1	Quantity count of goods	The quantity of goods is correct.

No.	Content	Item
	and pre-opening checks	No inversion or deformation in the outer packaging.
		No signs of water in the outer packaging.
		No signs of crash in the outer packaging.
		No sign of unpacking in the outer packaging.
2	Inspection and detailed inventory of goods after unpacking	All goods listed in the packaging list are complete.
		No breakage, collision or deformation on the instrument, and no scratch on the screen.
3	Setting of the Analyzer	The site where the instrument is placed shall be flat and subject to no direct sunlight, and keeps away from radiology department, elevator room, brush motor or high-frequency high-power instruments as far as possible.
		Enough space left for instrument heat dissipation: 80mm for rear side.
4	Connecting the Analyzer	Check the power supply, which requires 220 V AC, 50Hz; stable voltage and good grounding; independent power supply.
5	Fixing removal	Remove tape on the card compartment and switches, and running part fixing screws.
6	For initial powering on, check the position of moving parts.	For initial powering on, enter the user name and password to login, and the Analyzer will reset when starting up. If the reset runs normally, it indicates the moving parts of the instrument free from the obstructions.
7	Status confirmation	Verify analyzer temperature, card reading, motion, light source, and bar code scanning status, and perform performance checks.
8	Parameter setup	Setup the parameter's detail on the software of the Analyzer.
9	Shutdown	Exit the software of the Analyzer and the shutdown runs normally. Take care to tidy up the site after installation.
10	Training	Training for customers in sample operation, instrument maintenance, switching on and off, and notes on instrument use.
11	Training assessment	Domestic: hands-on follow-up; International: hands-on training.
12	Acceptance procedures	Customer Acceptance Form, Service Order

3.4 Installation requirements

Prior to installation, only when requirements on installation space, power supply, and environment are met can the installation be made.

3.4.1 Installation space requirements

The space requirements for instrument installation are as shown in the figure below.

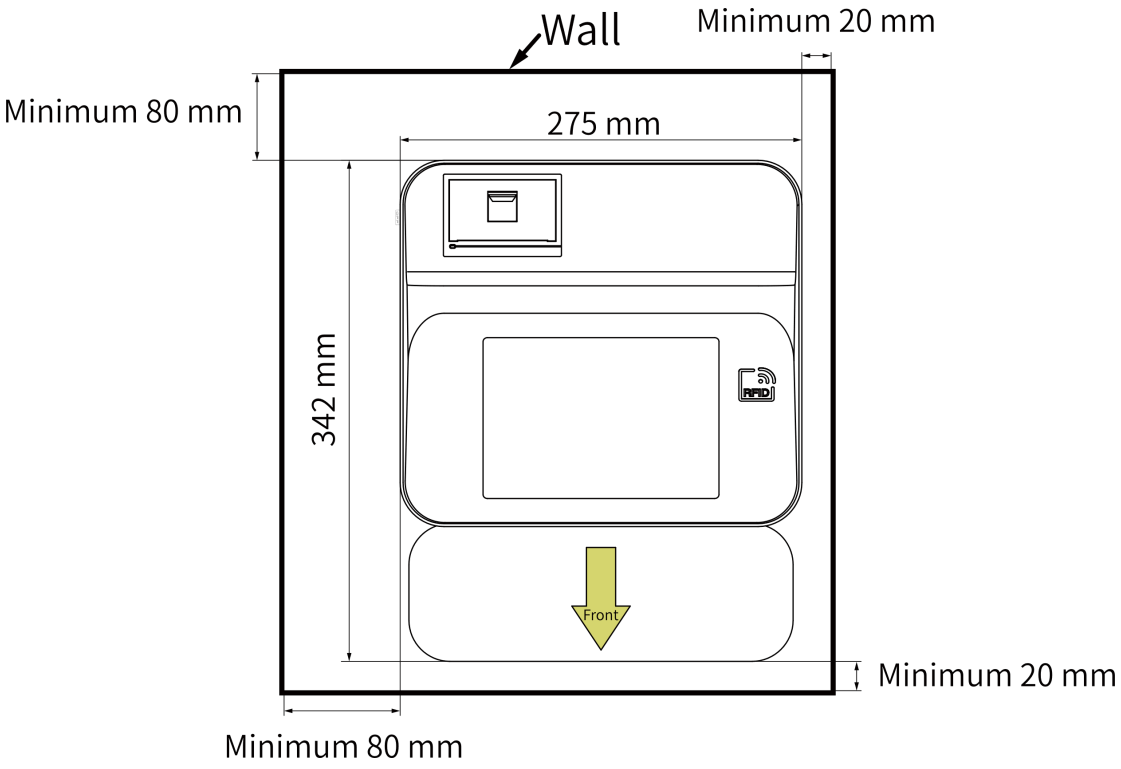


Figure 3-1 Installation space requirements

3.4.2 Environment requirements

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

Item	Working environmental requirements
Ambient temperature	10°C–30°C
Relative humidity	20%–85%, no condensation
Atmospheric pressure	700 hPa–1060 hPa
Altitude	⩽ 3000 m

- 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) has no 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 high noise source or power interference;
- Keep away from brush engines and electrical contacts that are often switched on and off;
- Keep away from the device that emits electromagnetic waves, such as mobile phones, radio transceivers, etc.;
- The site should be far away from strong electromagnetic field interference and well grounded.
- Please do not place the Analyzer in a site where it is difficult to be disconnected.

Note

The operating environment 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.

3.4.3 Power requirements

This section mainly describes the power supply requirements.

Power type	Specification
External power supply (power adapter)	Input: 100-240 V, 50/60 Hz, 1.4-0.7 A Output: 24 V⎓2.5 A, 60 W MAX.
Internal power supply (lithium battery, standard on EXR120)	18 V⎓, 4700 mAh, 84.6 Wh

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 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.

3.5 Unpacking

All analyzers packaging has gone through a strict inspection performed by Zybio before delivery. When you receive this analyzer, check carefully before unpacking and notice whether the followings exist:

3.5.1 Examination before unpacking

- Inversion or deformation in the outer packaging;

- Obvious signs of water in the outer packaging;
- Obvious signs of crash in the outer packaging;
- Signs of unpacking in the outer packaging;
- Carefully check whether cracks, bruises, or deformation occurs on all instruments and components' appearance.

3.5.2 Main unit unpacking

(1) Pull the package into place to ensure that there is enough space to unpack it.

(2) After unpacking, make sure that the whole package is complete and that the accessories are all provided according to the packing list. This way to ensure safety during the movement of the instrument and contact after-sales service if needed. Here are the main accessories on the packing list:

Accessories	Quantity
Power cable	1
Power adapter	1
Network cable	1
Waste card collection box	1
Instructions for use	1
Packaging list	1
User Acceptance Form	2
Certificate of conformity	1
Warranty	1
Quick guide	1
Battery (standard with EXR120)	1
Bar code scanner	1

3.5.3 Appearance inspection

(1) Check the face shell of the instrument for distortion and damage;

(2) Check the instrument screen for damage.

3.6 Main unit movement

Once unpacked, the instrument can be carried to the installation area by the portable handle on the top of the instrument or by holding its bottom with both hands, as shown in the diagram below.

Figure 3-2 Portable handle

Note

- If the Analyzer needs to be moved after installation, the card compartment must first be cleared, with no reagent cards left inside.
- Do not put the instrument upside down during movement.
- The movement needs to be smooth to prevent the center of gravity from leaning forward.

3.7 Fixing removal

3.7.1 Tape removal

Remove the tape from the card compartment and the switch.

3.7.2 Removal of motion component fixing screws

After unpacking, place the instrument on the table according to the installation environment requirements, do not turn the instrument upside down.

Move the instrument forward so that the two front feet are stuck to the edge of the table, the fixing screw holes at the bottom of the instrument are just exposed (be careful not to move the instrument forward too much, its center of gravity is too close to the edge of the table, in case the instrument fall off).

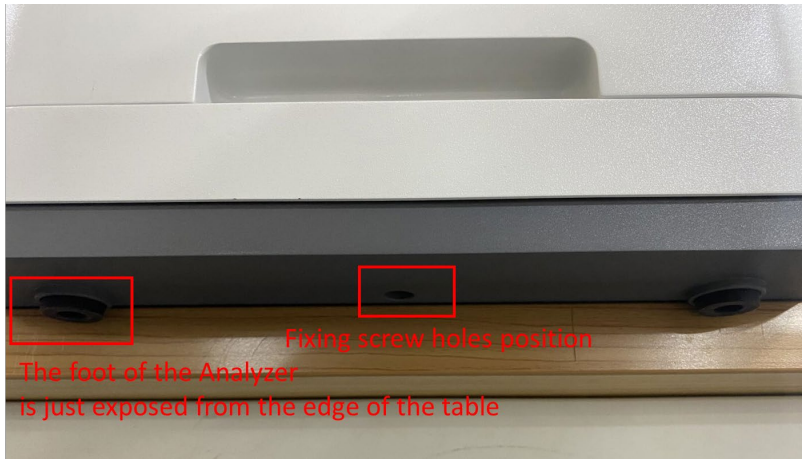


Figure 3-3 Fixing screw holes position

Loosen 1 x M4 x 30 hexagonal screw on the underside of the instrument from the round hole below and remove the screw. Take care to store the removed screw for next transport use.

3.8 Connecting instrument

This section introduces the connection of the instrument, including the connection of the power cord, power adapter, and the connection of the bar code scanner, and the installation of the waste card collection box and the printing paper.

3.8.1 Connection of the 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.

3.8.2 Connection of bar code scanner

An external bar code scanner can be connected to the instrument. It is recommended that users select or purchase a certified external 2D scanner (with CCC (S&E) compulsory certification) with a required USB interface. The applicable codes are one-dimensional barcode CODE128, CODE93, CODE39, CODEABAR, 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 center 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 reading is successful.

Note

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

3.8.3 Connection to external printer (user supplied)

The instrument supports external USB printers. USB protocol version is USB 2.0.

Please connect the barcode scanner as follows:

(1) Make sure the instrument and printer are turned off;

(2) Plug one end of the printer USB cable into the printer USB port;

(3) Plug one end of the printer USB cable into the USB socket on the left side of the instrument;

(4) Power on the instrument and printer, If the print icon in the instrument software interface light up, it indicates the printer is connected successfully;

(5) Go to “Manage” > “setup” > “Basic settings” > “Print Setup”, select “External printer” in the printer type field, click “OK” to save the settings, and then you can use the external printer to print.

Note

- External devices connected by the user should not cause the reduction of the safety and performance of the Analyzer.
- Recommended printer models: HP LaserJet P1008, HP LaserJet 1020 plus, HP LaserJet Pro M12a.

3.8.4 Installation of waste card collection box

Please connect 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 compartment, parallel to the two sides of the reagent card compartment.

Figure 3-4 Installation of waste card collection box

3.8.5 Installation of printer paper

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

See the following table for information about printer paper.

Paper size	Paper roll replacement method	Paper cutting method
The device uses thermal printer paper with the width of 57±0.5 mm and external diameter ≤Φ30 mm.	Front change, easy loading paper roll structure	Manually tearing

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 2cm) sticking out (as shown in the figure below).

Figure 3-5 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 to stuck or blurred printing.

3.9 Start up

This section introduces login of the analyzer.

3.9.1 Before startup check

The instrument should be checked before startup each time to ensure that it is in good status.

- Check the appearance of the instrument for any abnormalities, including whether the reagent card cabin is closed, whether the 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 of the instrument are undamaged and correctly connected.
- Check if the waste card collection box is in place.

3.9.2 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 into the login interface, as shown below:

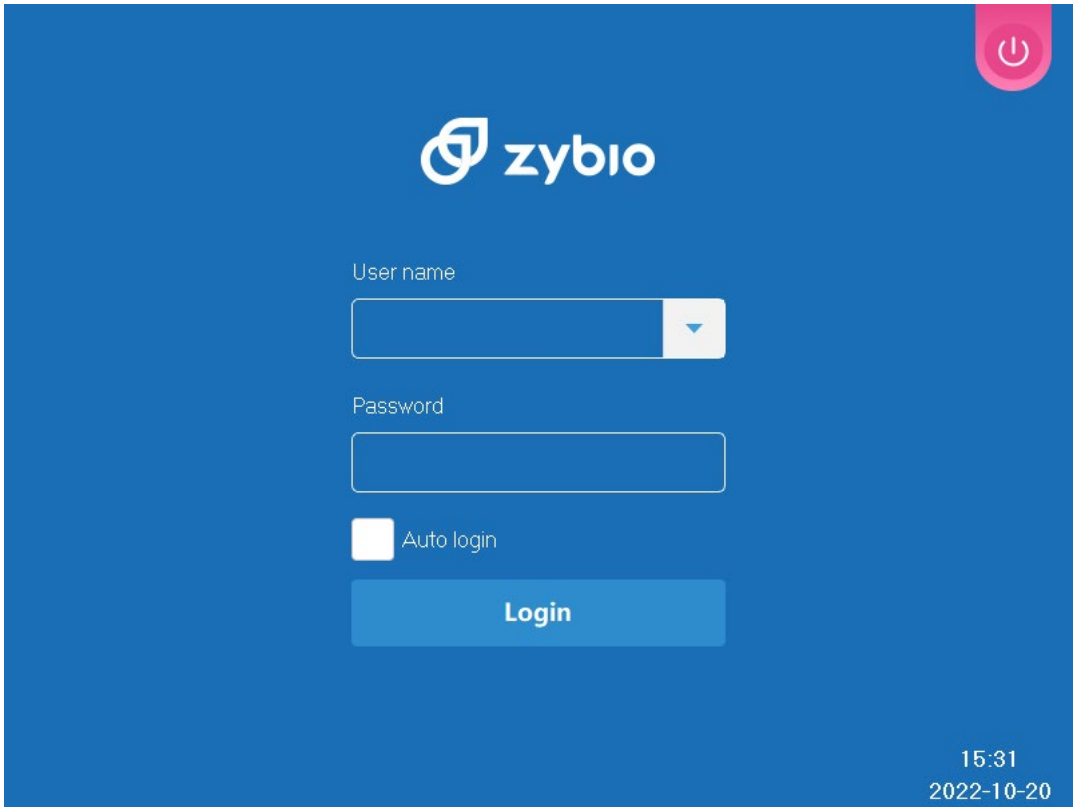


Figure 3-6 Software login interface

(2) Input the user name and password of the service account. (User name: service; password: ask an after-sales engineer for details)

(3) Click "Log in" to go to the main interface.

(4) After click "Auto login", auto log in to current login account when the device is started next time.

(5) The device can be shut down by clicking the shutdown key in the top right of the login interface.

3.10 Setup

This section describes the settings that need to be made to the analyzer software by the maintenance staff after installation, as listed below.

No.	Item	Remarks
1	Test settings	Set up according to test-related requirements.
2	Print settings	Set up according to the relevant requirements for printing report forms.
3	Hospital settings	Set up according to hospital related information.
4	Communication setup	Set up according to LIS requirements.
5	Language setting	Set up language accordingly.

3.10.1 Test settings

Select “Manage” > “Settings”, the default interface is “Basic settings”. Click on “Test” to set the settings according to the hospital's requirements, as shown below.

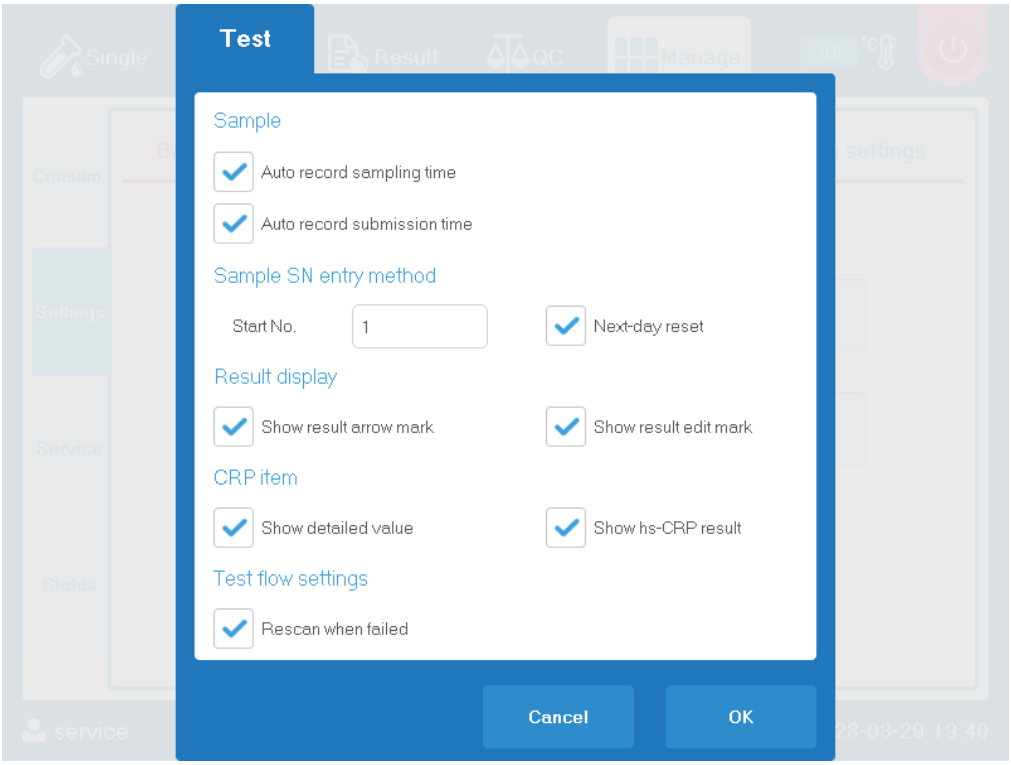


Figure 3-7 Test settings interface

3.10.2 Print setup

Select “Manage” > “Settings”, the default interface is “Basic settings”. Click “Print Setup”, In this interface, users can set the report title, select the template type, paper, printing template, import/export/delete templates, set up printing copies, auto print, and print options according to the requirements of the hospital.

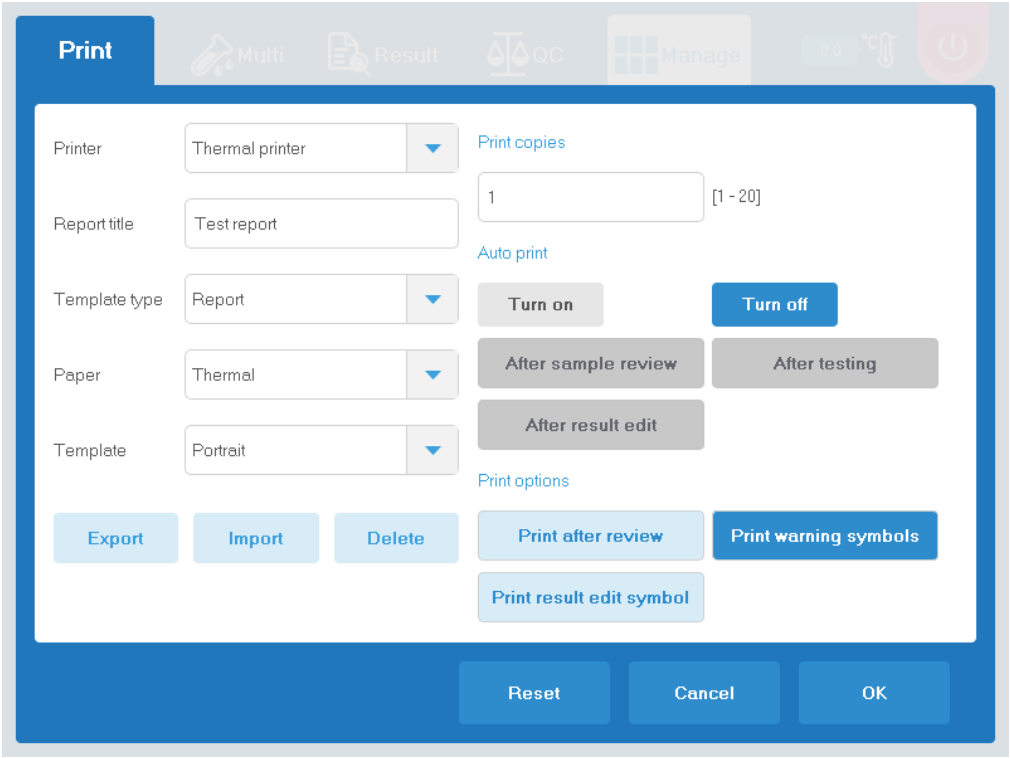


Figure 3-8 Print settings interface

3.10.3 Hospital settings

User can set up hospital-related information in this interface, including the hospital name, address, contact person and contact details. This screen shows the model, date of installation and serial number of the instrument 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 instrument when needed.

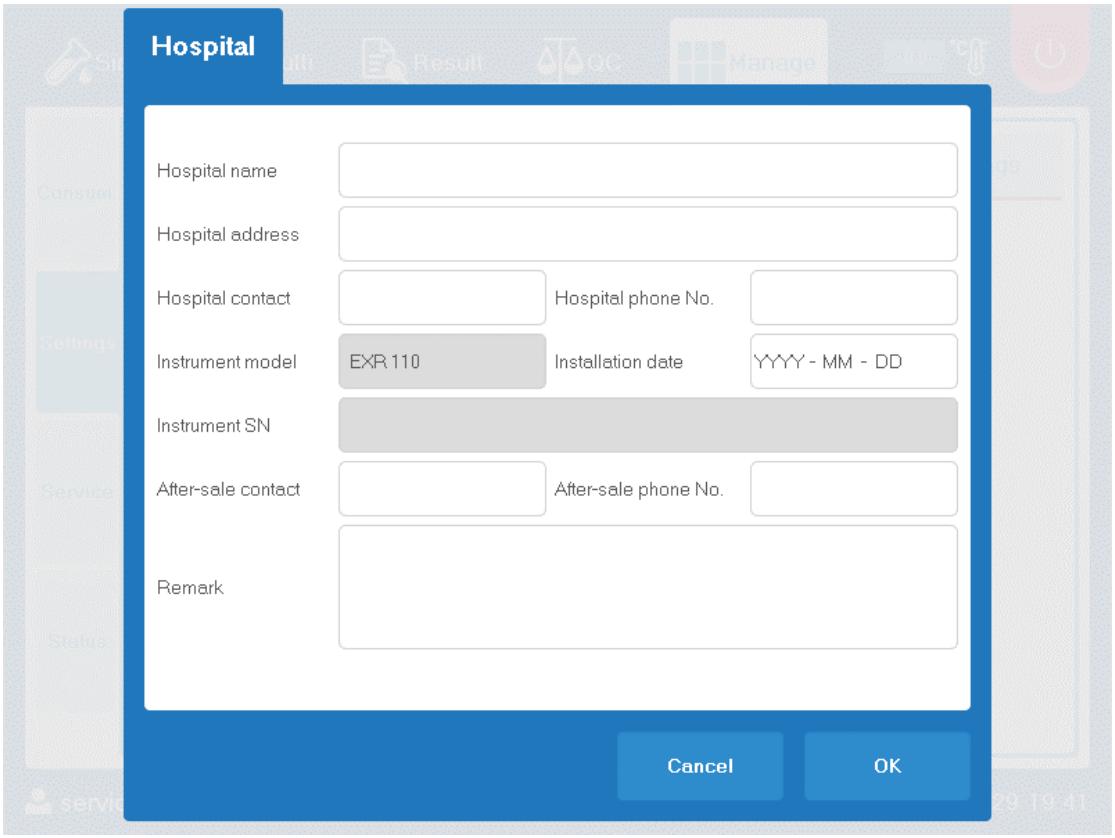


Figure 3-9 Hospital settings

3.10.4 Communication setup

Select “Manage” > “Settings” > “System settings” > “Communication”, and enter the following interface to edit information related to the communication of the Analyzer. This interface is mainly for LIS connection settings.

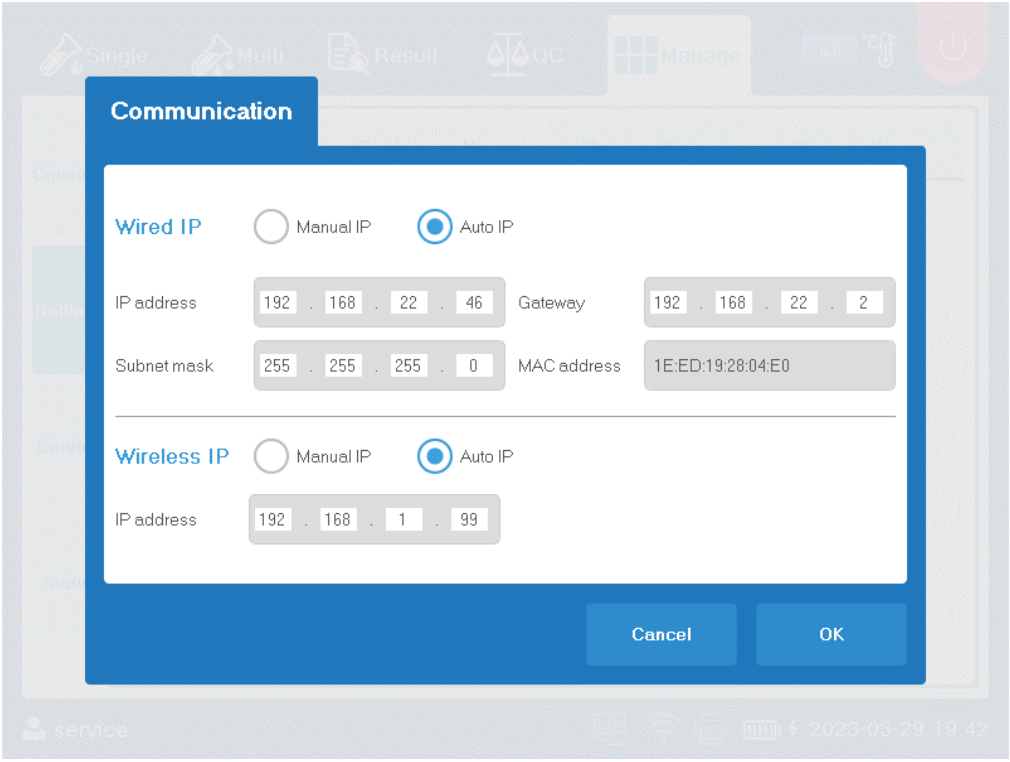


Figure 3-10 Communication settings interface

3.10.5 Language setup

Select “Manage” > “Settings” > “System settings” > “Language setting”, and enter the following interface to set the language of the Analyzer. After the language is confirmed, the new language will take effect when restart.

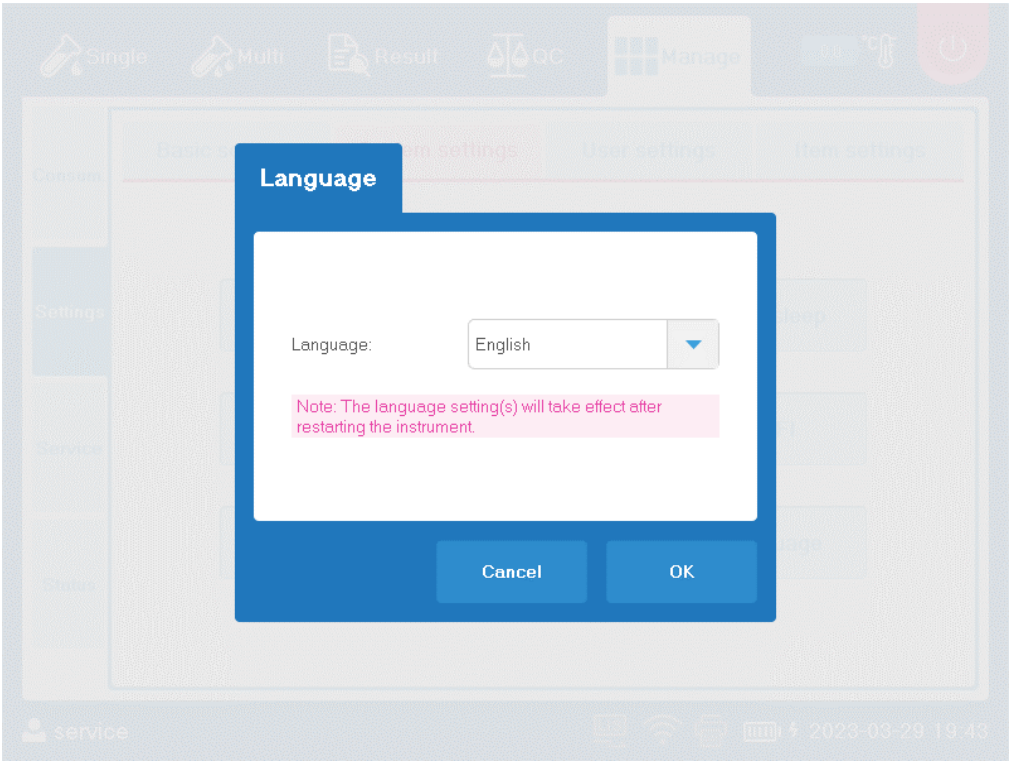


Figure 3-11 Language Setup interface

3.11 Status confirmation

This section describes the status of the analyzer that needs to be confirmed by the maintenance personnel after installation, as described below.

3.11.1 Temperature confirmation

After the instrument has been switched on for 5 min, check whether the temperature display in the upper right-hand corner of the main software interface is stable within the range of 30°C ± 1.5°C.

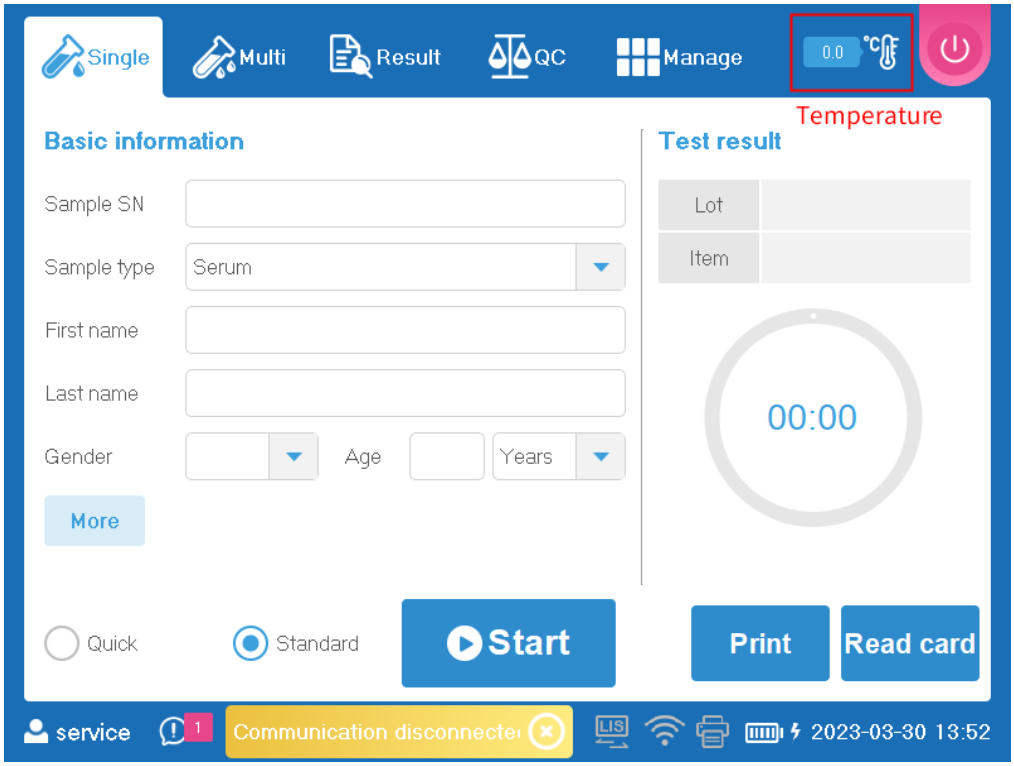


Figure 3-12 Temperature icon interface

3.11.2 Card reading confirmation

Place the ID card close to the instrument's radio frequency identification area and click on “Read Card” to see if the reagent card information has been entered successfully.

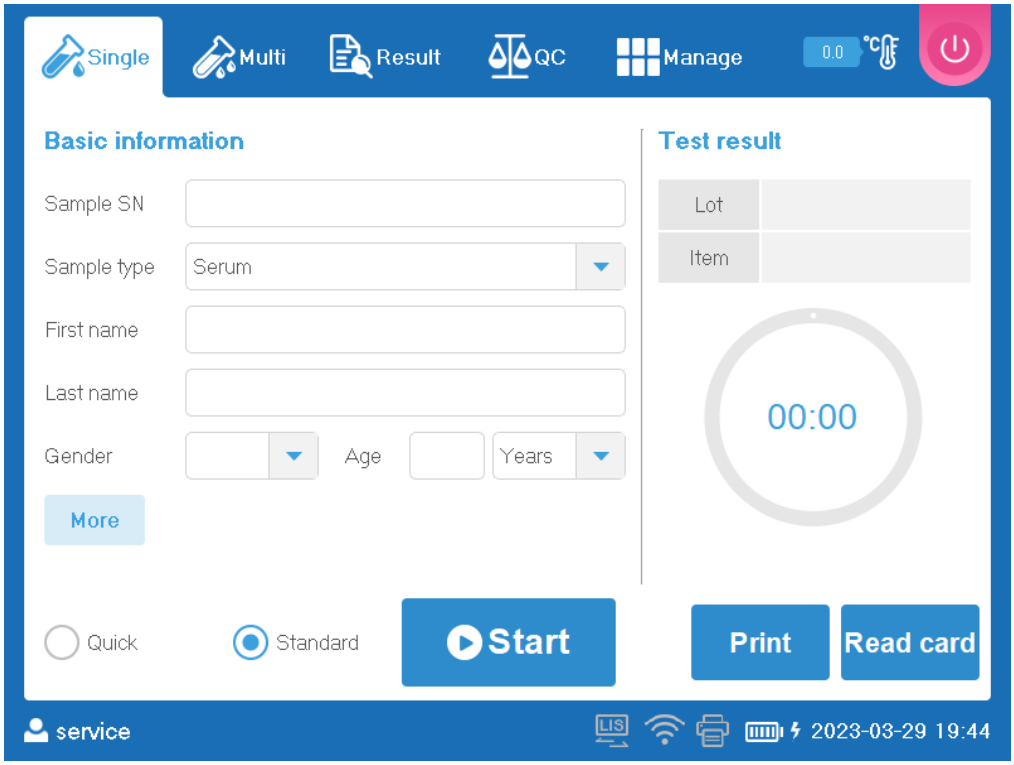


Figure 3-13 Card reading interface

3.11.3 Motion confirmation

Click on “Motor self-test” to see if the status of the in-situ optocoupler has changed from blocked->unblocked->blocked and to see if the motor self-test is successful.

Figure 3-14 Self-test interface

3.11.4 Light source status confirmation

(1) Click on the instrument “Manage” > “Service” > “Maintenance” > “Optical cal.” .

(2) Open the card compartment, place the reagent cards separately in channel 1 and close the card compartment.

(3) Click on “Position 1” to confirm that there is a signal value in the pre-built area of the reaction curve, indicating that the light source can be switched on properly.

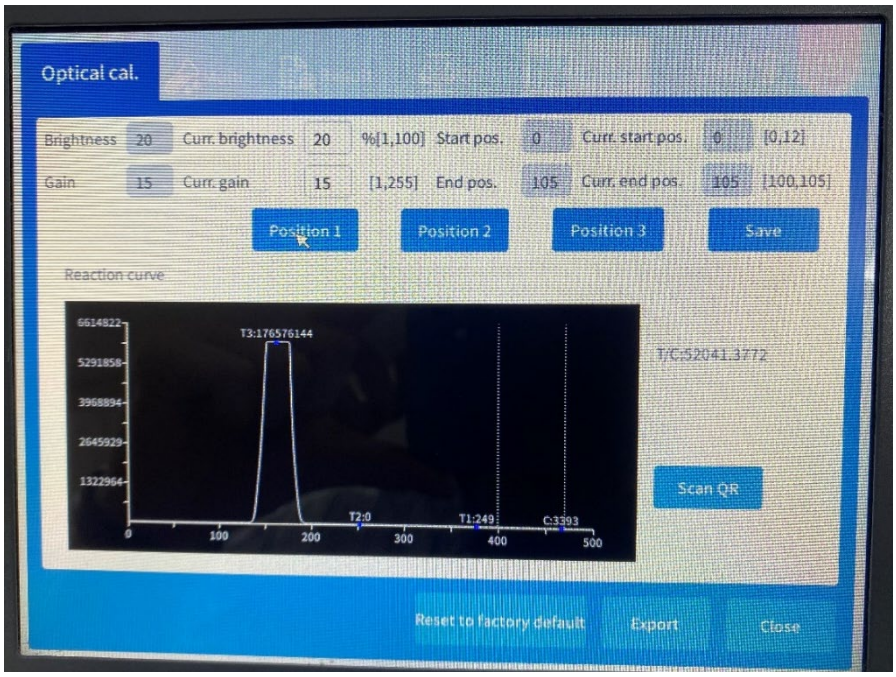


Figure 3-15 Light source status confirmation

3.11.5 QR code Scanning confirmation

(1) Click on the instrument “Manage” > “Service” > “Maintenance” > “Optical cal.” .

(2) Open the card compartment, place the reagent cards separately in 3 channels and close the card compartment.

(3) Click on “Scan QR” to see if the code is successfully scanned.

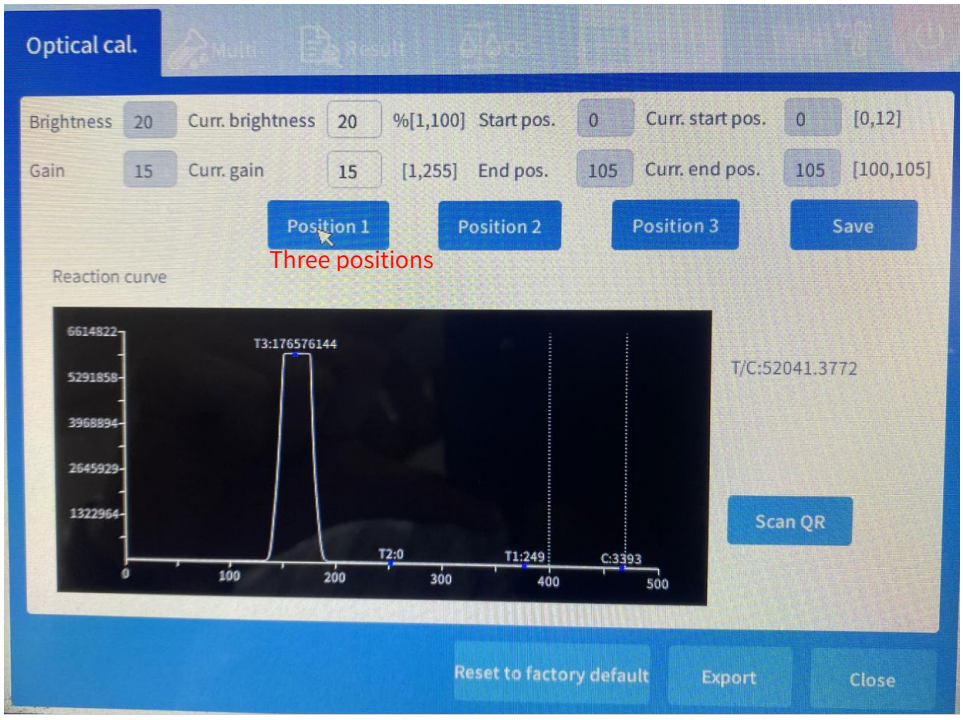


Figure 3-16 QR code Scanning confirmation Interface

3.11.6 Performance validation

QC card test

(1) Click on "QC" > "QC settings" to enter the calibration curve information of the QC card by scanning or reading the card.

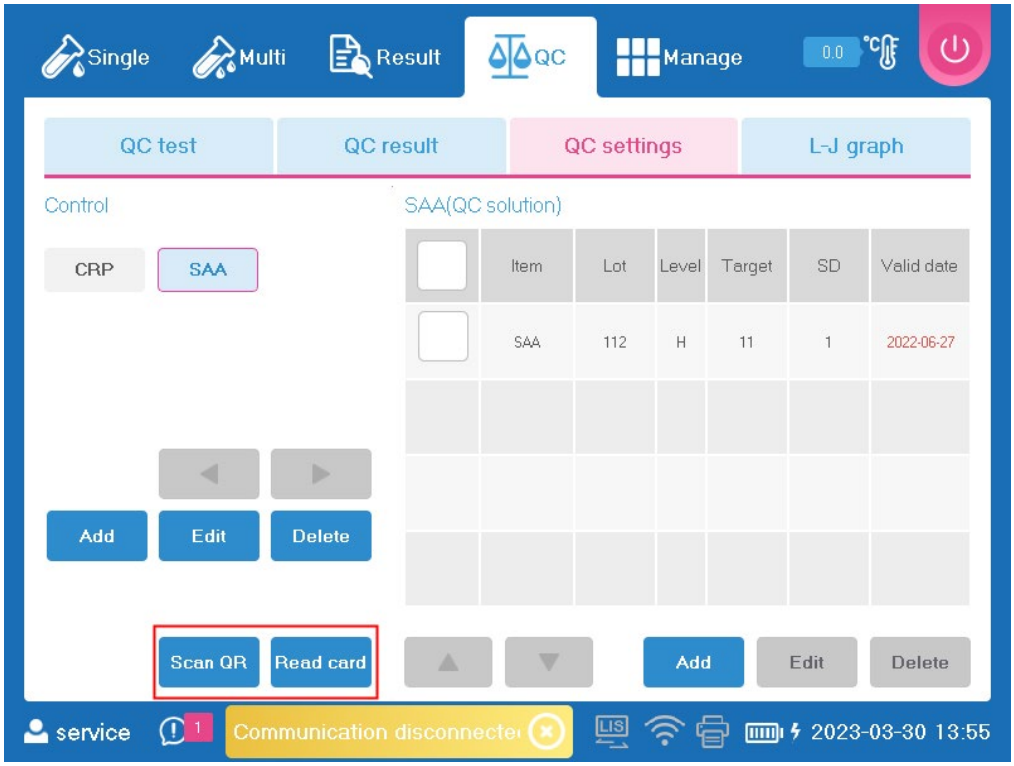


Figure 3-17 QC card information input interface

(2) You can edit the name of the QC card as required in the pop-up box for new QC items.

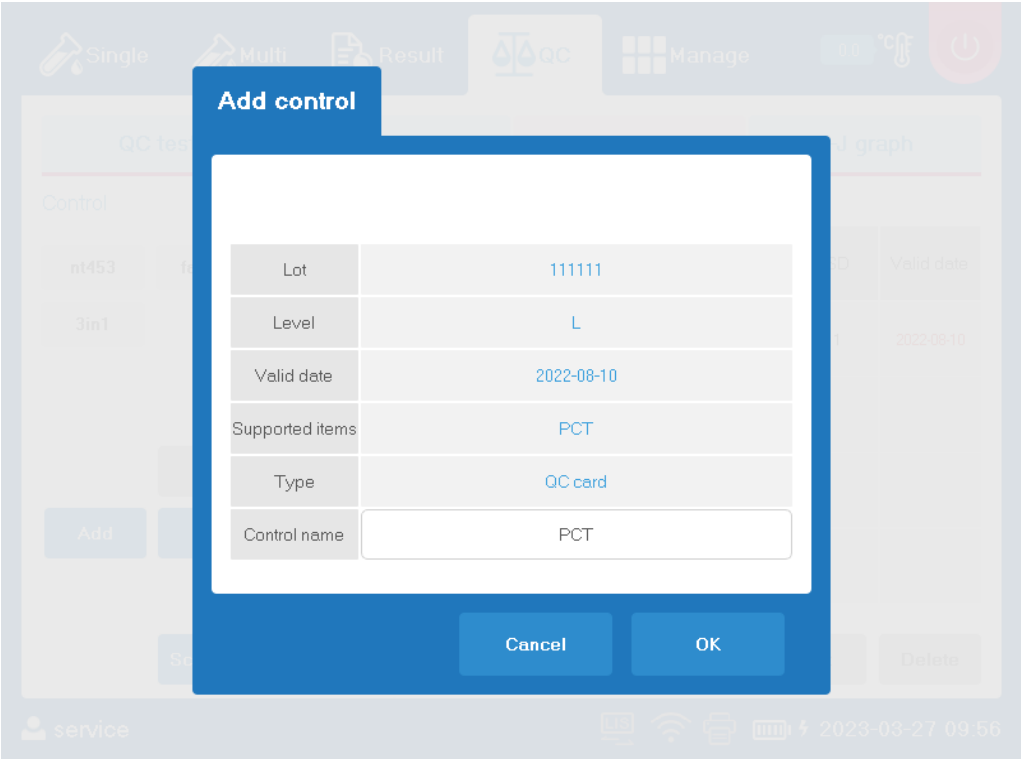


Figure 3-18 Add new QC item interface

(3) On the "QC test" interface, select "QC card" and in the "Control" drop down to select the name of the QC card you have just scanned or read.

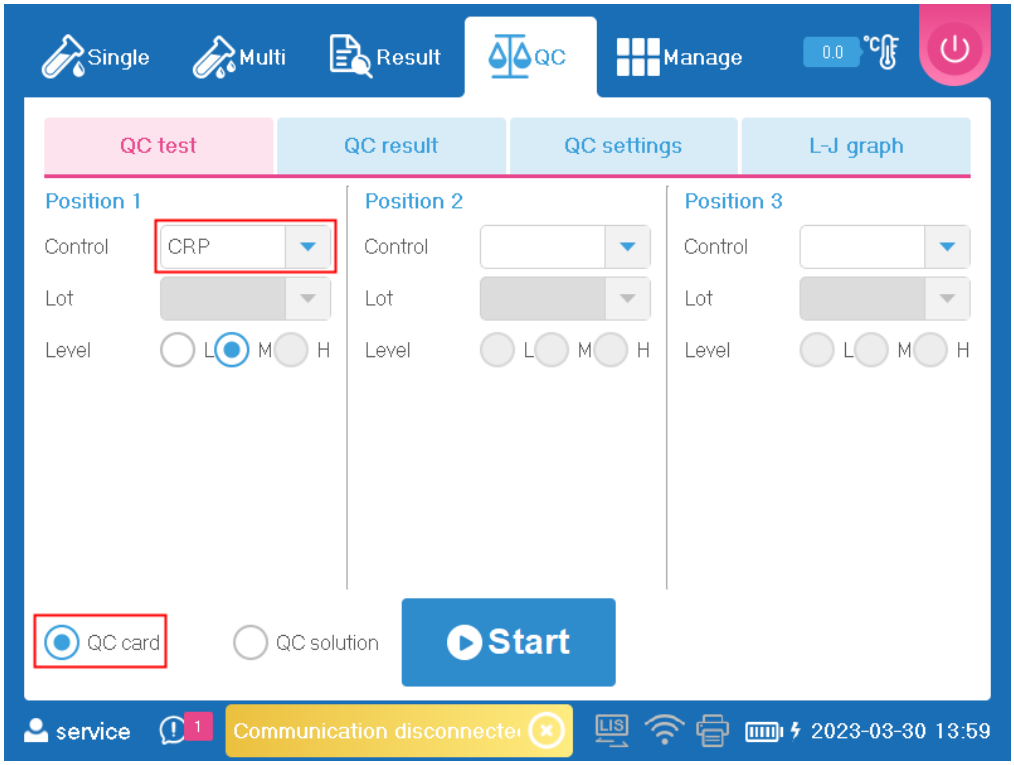


Figure 3-19 QC test interface

(4) Place the QC cards into the card slots according to the applied positions for QC test and make sure the door of the channel is closed tightly.

(5) Click "Start" to start test.

Click on “L-J graph”, select the name of the QC card you have just scanned or read by scrolling down the drop-down list of “Control”, click on “Query” and check the quality control display dots. If the color of the quality control display dot is green, the quality control result is normal. If the color is red, the quality control result is abnormal.

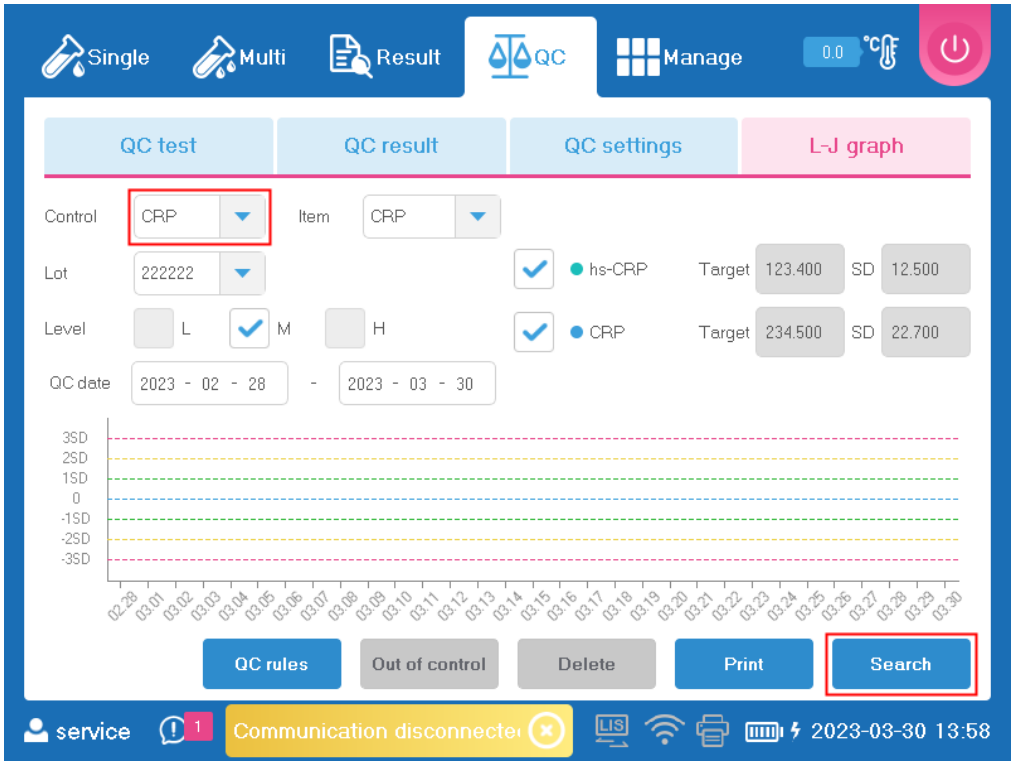


Figure 3-20 “QC result” Query interface

Sample repeatability

(1) Prepare three CRP test reagent cards and samples.

(2) Click on “Multi” to enter the test interface, place the RFID card of the CRP reagent card into the card reading area, click on the “Read card” button and input the reagent card information.

(3) If the sample is whole blood, the sample type is selected as “Whole blood” in all three positions, and if the sample is serum, the sample type is selected as “Serum” in all three positions.

(4) Select “Standard” test mode.

(5) Add 5 μl of sample to 995 μl of diluent and mix thoroughly. Pipette 60 μl of the mixed sample onto the reagent cards, again completing three cards in succession.

(6) Place the three reagent cards, with mixed samples on them, into the accordingly channels and close the cabin. Click “Start” to start the test.

(7) After the test is completed, the repeatability of the three results is calculated and should be no greater than 15%.

Note: if other items need to be selected for reproducibility testing, the difference is only in the process of pipette mixed samples onto the reagent cards in step 5, which should be done by referring to the contents of the reagent card instructions.

Once the test is complete, you can continue to confirm whether the print and return of reagent cards functions are working:

(1) Click on the selection box where the results are located and click on the “Print” button to print.

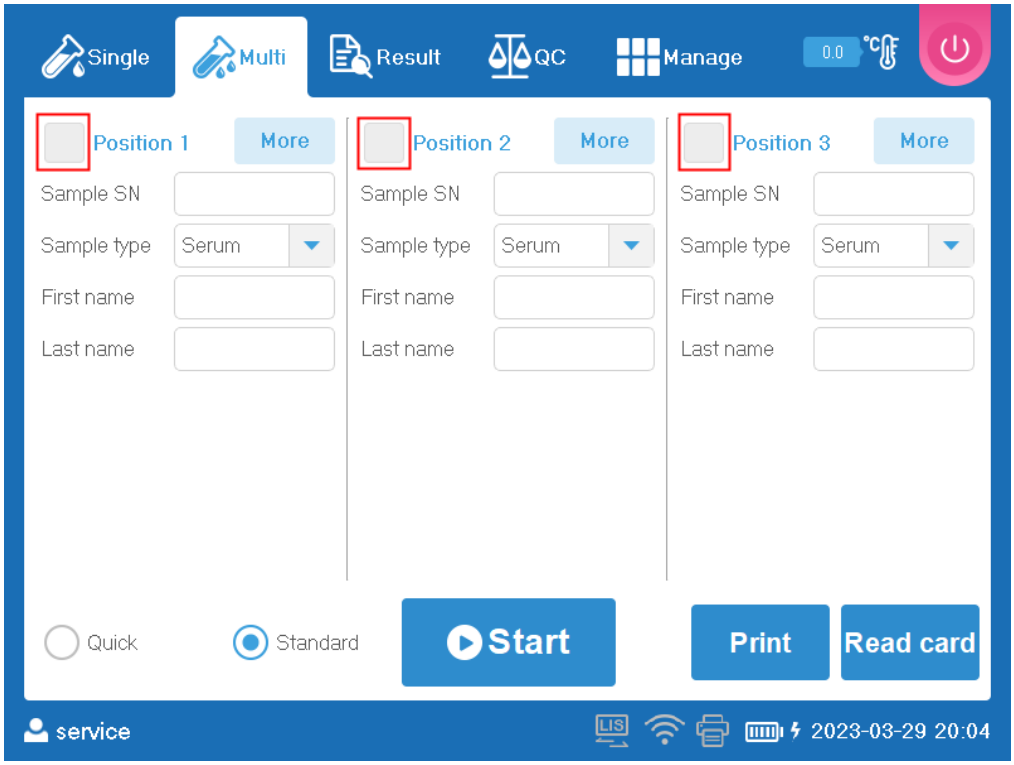


Figure 3-21 Print settings interface

(2) Ensure that the waste card box is in place, open the reagent card compartment door, and push the return toggle to drop the waste card into the recycling box.

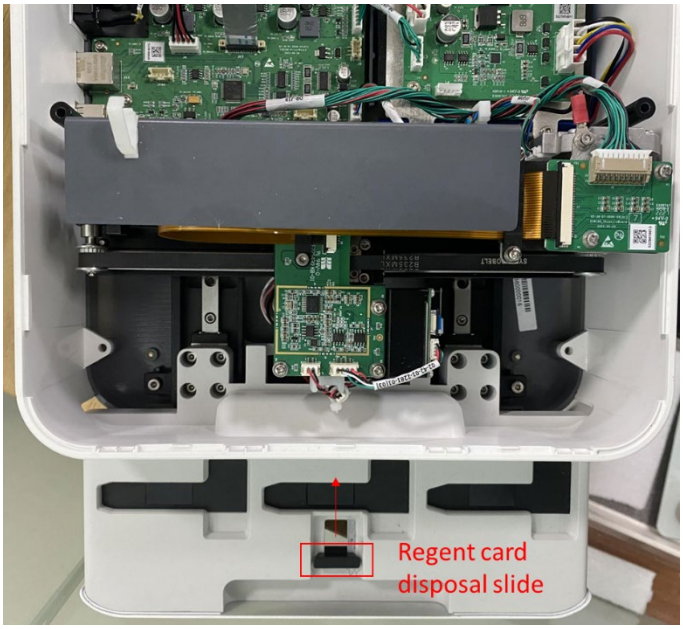


Figure 3-22 Return of reagent card

3.12 Exporting logs

Logs can be exported as needed. Insert the USB drive into the USB port, click on "Manage" > "Service" > "Log" > "One-click export", tick the items as shown and click "OK".

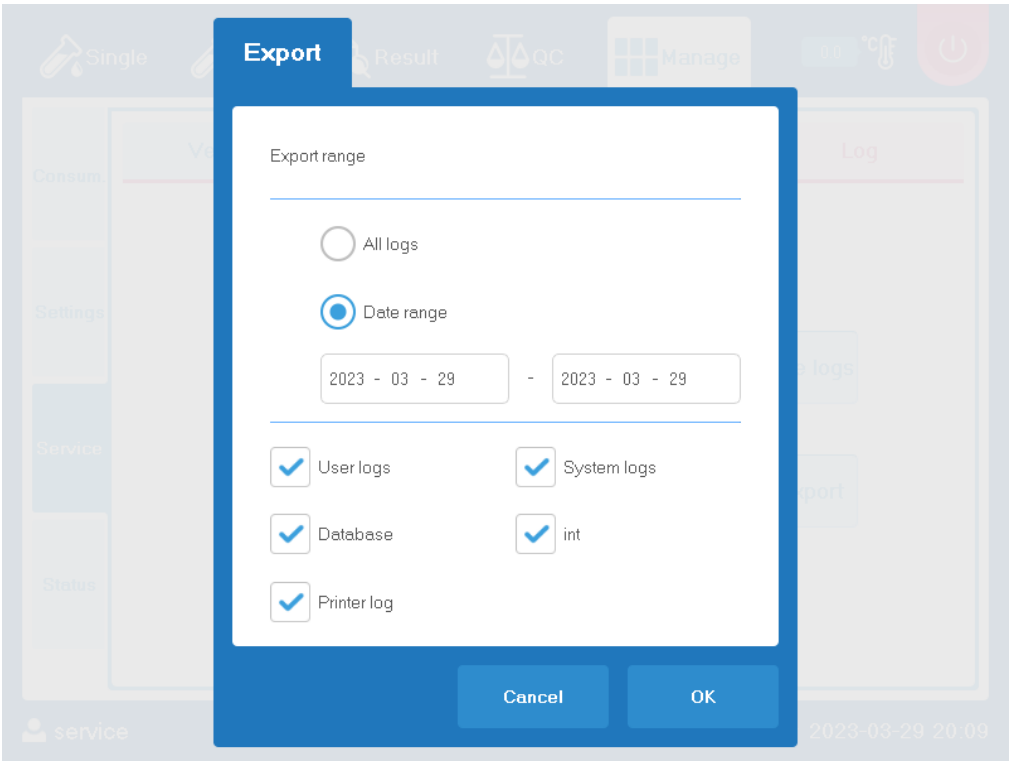


Figure 3-23 Exporting logs

4 Debugging and calibration

This chapter describes the Debugging and calibration of the instrument after troubleshooting such as repair or replacement of components.

4.1 Debugging

Module	Repaired or replaced component	Items needing confirmation or debugging
The temperature controller	Heating plates, temperature sensors	Temperature calibration
Optical component	LED Light source	Light spot status confirmation, optical calibration
	Optical PCBA	Optical calibration
	Entire optical module	Light spot status confirmation, optical calibration
QR code Scanning component	QR code Scanner	QR code Scanning confirmation
RFID component	RFID card reader	Card reading confirmation

4.2 Temperature calibration

(1) As shown in the figure, click on the instrument “Manage” > “Service” > “calibration” > “Temp. calibration” to enter the temperature calibration interface.

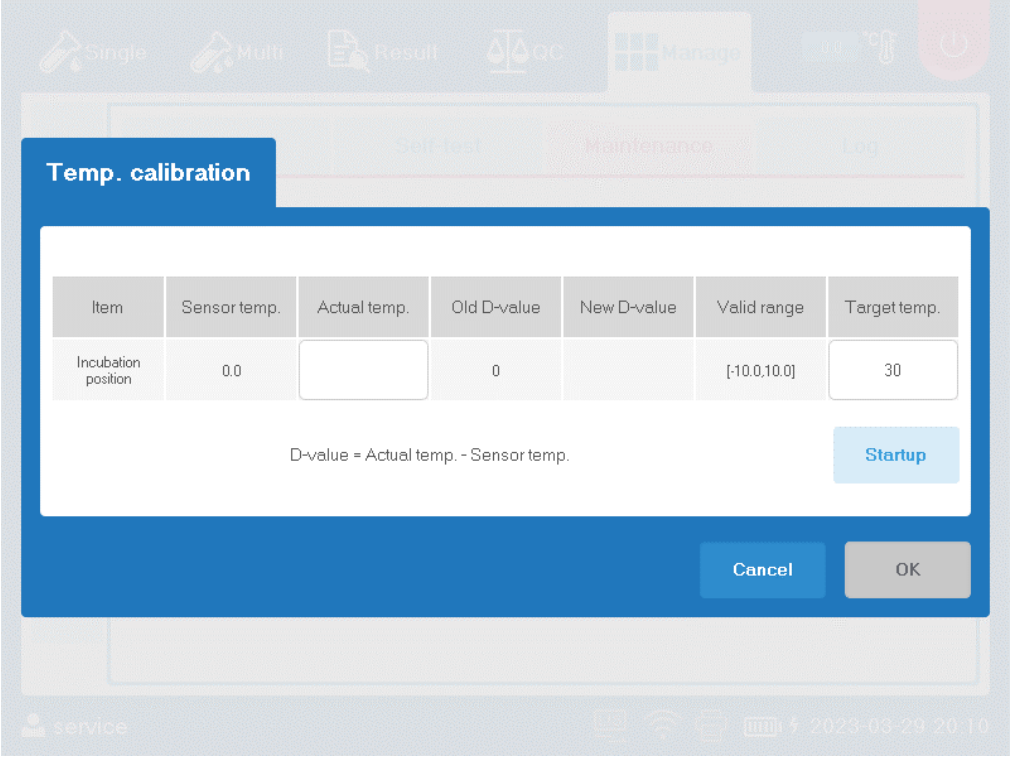


Figure 4-1 Temperature calibration

(2) Once the temperature has stabilized, apply heat-conducting silicone grease to the temperature probe of the Fluke meter and press up against the aluminum block at channel 2 to test the temperature, fill in the measured temperature, and click “Start” to calibrate the temperature.

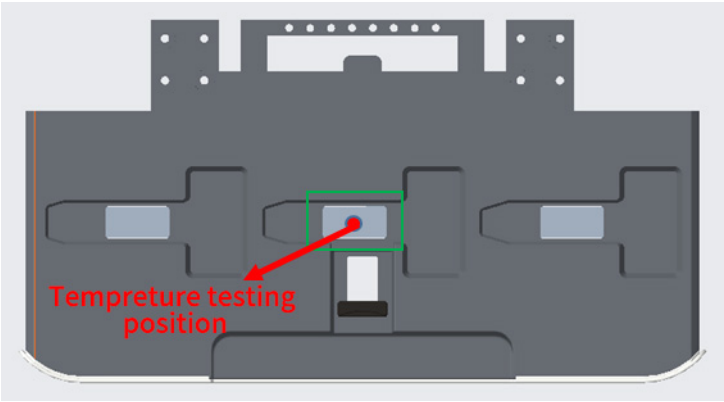


Figure 4-2 Temperature testing position

4.3 Light spot status confirmation

(1) Three channels: click on “Position 1”, “Position 2” and “Position 3” respectively. / Single channel: click on “Light spot”.

(2) Observe from the side each time whether the light spot on the chromatography strip hits a position in the middle of the strip. Click “ON” and observe the light spot pattern on the chromatography strip from the side. The normal light spot should be oval in shape and accompanied by a weak halo.

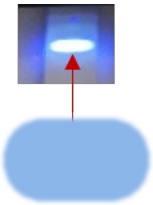


Figure 4-3 light spot shape

(3) Three channels: click on “Position 1”, “Position 2” and “Position 3” respectively. / Single channel: click on “Light spot”.

(4) Observe from the side each time whether the light spot on the chromatography strip hits a position in the middle of the strip.

Figure 4-4 Confirm if the light spot is in the middle position of the strip

4.4 Optical calibration

(1) Place the fluorescent standard card into channel 1 and click on position 1 to scan. After scanning, a curve will appear at the reaction curve position, and observe the horizontal coordinate position of the C-peak. Its horizontal coordinate should be between the two gray lines, and the horizontal coordinate position range is 400 to 470.

(2) In the optical calibration interface, check if the gain defaults to 1. If not, change it to 1 and click Save.

(3) Place the fluorescent standard card into channel 1 and click on position 1 to scan.

(4) Click on the reaction curve area, observe the curve shape near the peak in the scanned curve, increase the brightness. If the curve shape near the peak is flat, scan and observe again after decreasing the brightness by -1; if the curve shape near the peak is sharp, scan and observe again after increasing the brightness by +1. Repeat the above steps until the curve shape near the peak is flat, then decrease the brightness by -1 and click Save.

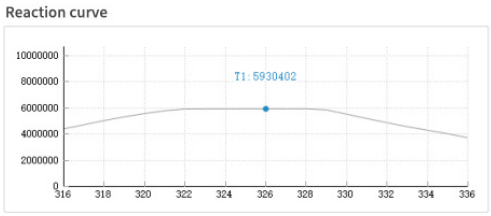


Figure a) Flat peak

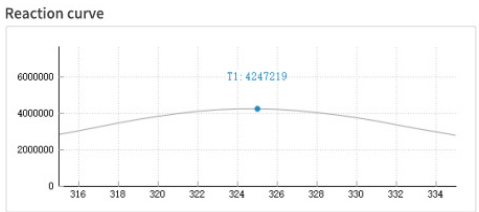


Figure b) Sharp peak

(5) After the brightness adjustment is completed, then adjust the gain so that the original AD value of the peak point of the test of the fixed-value fluorescent standard card is between 5500000 and 6000000, and the AD value should be adjusted as large as possible within the allowed range, and the value displayed at the peak point in the coordinate system can be viewed by clicking on the area of the response curve graph.

(6) As shown in the figure, observe the C-peak waveform, requiring left-right symmetry about its central axis.

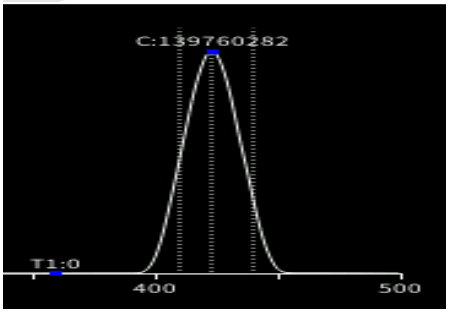


Figure c) peak waveform symmetry illustration

4.5 QR code Scanning confirmation

Refer to section 3.11.5 QR code Scanning confirmation.

4.6 Card reading confirmation

Refer to 3.11.2 Card reading confirmation.

5 Maintenance

The Analyzer is a precision analytical device. In order to keep the it in good operating condition, obtain reliable test results and reduce the frequency of failure, maintenance and servicing of the instrument is required.

5.1 Maintenance requirements

Frequency	Maintenance item	Refer to
Daily	Daily quality control of the Analyzer is required prior to sample test to ensure the reliability of the results.	Operation Manual
Monthly	Inspect the external power cable every month for any signs of damage and ageing to ensure electrical safety.	/
Every six months	Inspect whether the instrument casing is fixed and whether the fixing screws are loose every six months.	/
As needed	Perform screen calibration when the touch screen is unresponsive or inaccurate.	5.2
	After the test is completed, clear the waste cards and clean the waste card recycling box in time.	5.3
	The surface of the instrument and the surface of the card compartment need to be cleaned when there is contaminant to avoid possible biological contamination.	5.4
	If the thermal printer run out of printing paper or have insufficient paper left, you need to replace the thermal paper before printing.	5.5
	If the analyzer prompts other fault messages, please refer to the troubleshooting section of this manual to handle the operation accordingly.	6

Note

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

5.2 Screen calibration

Click “Manage” > “Service” > “Maintenance” > “Monitor cal.” and confirm it. After the calibration starts, you can finish the screen calibration by clicking the targeting point on the screen each time according to the prompt (refer to the figure below).

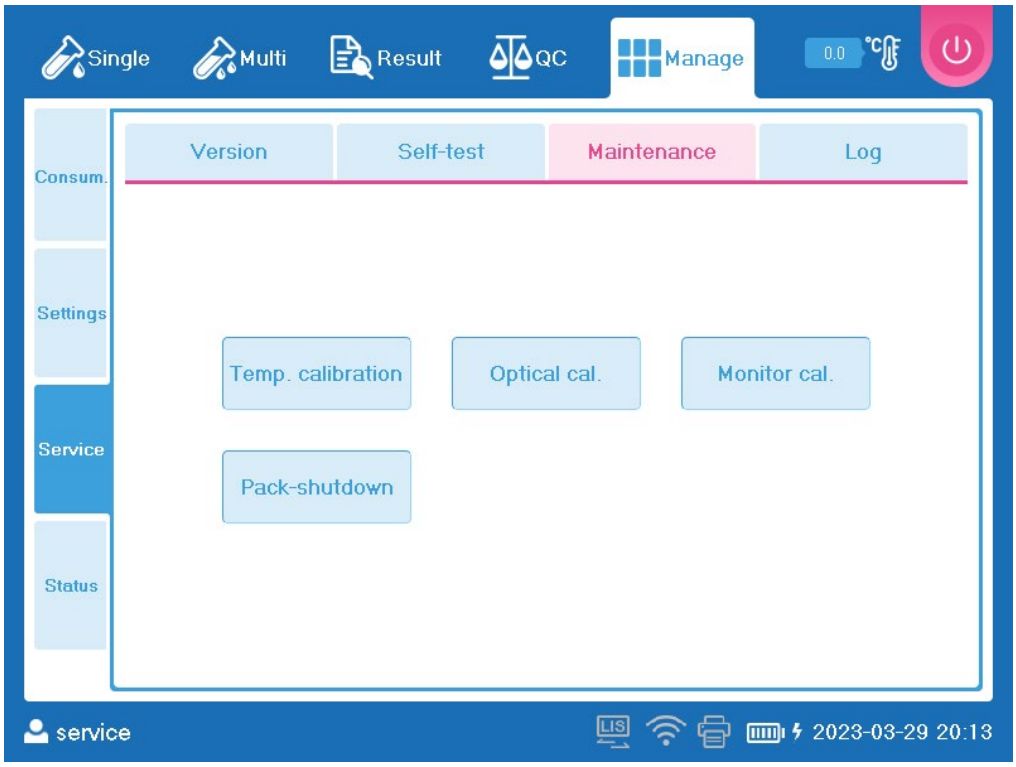


Figure 5-1 Monitor calibration

5.3 Emptying, cleaning and disinfection of waste card collection box

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

- Before each testing, check if the waste card collection box. 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 75% ethanol or 70% isopropyl alcohol and a cotton ball after all tests have been completed each day.

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.

5.4 Instrument cleaning

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.

Warning

- Do not clean the device with any solvents, grease, or corrosive substances. If the user has questions 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 testing port of the instrument.
- Please power off the instrument 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.

5.5 Printer paper replacement

When using the printing function, if the printer has run out of paper or if there is not enough paper left to print the testing report, the instrument 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 section “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.

6 Troubleshooting

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

6.1 Fault code and warning mechanism

The possible faults of the Analyzer and the corresponding causes are outlined in the following table.

Fault code	Fault name (User)	Description (Service personnel)	Warning mechanism
0x01000101	Incubation temperature sensor abnormal	Incubation temperature sensor abnormal	No data from temperature sensor. 1. Temperature sensor not connected. 2. Temperature sensor failure.
0x01000102	Incubation temperature abnormal	Incubation temperature exceeded upper limit	Done with real-time testing, the acquired results from continuous 5s, a total of 5 points, were all above the target temperature of 10 ℃ (after calibration).
0x01000103		Incubation temperature exceeded lower limit	1. Start testing after heating for more than the maximum heating time (normal heating time +1min). 2. The acquired results from continuous 5s, a total of 5 points, were all below the target temperature of 10 ℃ (after calibration).
0x01000202	Error: driver board 5V voltage abnormal	Error: driver board 5V voltage abnormal	Driver board 5V voltage out of range [4.50, 5.50] V
0x01000401	System clock abnormal	Error: system clock abnormal	The system clock is earlier than January 1, 2000
0x01000501	Motor assembly failure	Error: Optical detection motor assembly failure	Optocoupler are still blocked after the motor moves beyond the optocoupler position.

Fault code	Fault name (User)	Description (Service personnel)	Warning mechanism
0x01000502			The motor moves to the optocoupler position, moved all default steps, and the optocoupler is not blocked.
0x01000503			Abnormal number of remaining steps when motor triggers optocoupler.
0x01000504			Before the motor locate the optocoupler, the optocoupler status is abnormal.
0x01000505			While the motor is locating the optocoupler, false triggering of the optocoupler occurred.
0x01000506			Motor busy (serious out-of -step)
0x01000507			Motor running time out
0x01000601	Thermal printer has run out of paper.	Thermal printer has run out of paper.	Thermal printer has run out of paper.
0x01000605	Error: thermal printer failure	Error: thermal printer failure	Error: thermal printer connection failure
0x01001501	External printer run out of paper.	External printer run out of paper.	External printer run out of paper.
0x01001502	Error: external printer failure	Error: external printer failure	Other faults
0x01001503	External printer disconnected	External printer disconnected	External printer disconnected
0x01001504	External printer paper jam	External printer paper jam	External printer paper jam
0x01000701	Driver board communication abnormal	Error: driver board communication	MCU instruction analysis fault
0x01000702			MCU instruction parameter fault
0x01000703			MCU instruction: buffer overflows.
0x01000704			Driver board instruction has no response when timeout.

Fault code	Fault name (User)	Description (Service personnel)	Warning mechanism
0x01000801	Error: optical detection board communication	Error: optical board communication	1. MCU instruction analysis fault 2. MCU instruction parameter fault 3. MCU instruction: buffer overflows.
0x01000802			Optical board instruction has no response when timeout.
0x01000901	Error: RFID card reader communication	Error: RFID card reader communication	Error: RFID card reader communication failure
0x01001001	Error: QR code scanner communication	Error: QR code scanner communication	Communication with the decoder fails when scanning the QR code during the test process.
0x01001101	Communication disconnected	Communication disconnected	The user turns on automatic communication. The LIS connection disconnected when communicating automatically.
0x01001102	Communication error	Communication error	1. Fault in communication (protocol analysis fault, or protocol field is not supported) 2. LIS response times out when ACK synchronization is enabled.
0x01001201	Expired reagent card	Expired reagent card	The reagent card expiration date is earlier than the system time.

6.2 LIS connection failure

6.2.1 Fault code and warning mechanism

Fault code	Description (User)	Description (Service personnel)	Warning mechanism
0x01001101	Communication disconnected	Communication disconnected	The user turns on automatic communication. The LIS connection disconnected when communicating automatically.

Fault code	Description (User)	Description (Service personnel)	Warning mechanism
0x01001102	Communication error	Communication error	1. Fault in communication (protocol analysis fault, or protocol field is not supported) 2. LIS response times out when ACK synchronization is enabled.

6.2.2 Fault analysis and troubleshooting

When the LIS system fails to connect with the Analyzer, you can perform the following actions:

(1) Check whether the network cable is connected between the computer side of the LIS system and the instrument side. When the network cable is connected, the network port of the instrument will blink.

(2) Check whether the listening port of the LIS system and the instrument port are the same and whether the IP address of the LIS is correct.

1) LIS end port location: The listening port location is not consistent for different LIS systems, please confirm according to the actual situation.

2) Instrument Port Location: Click in the main interface of the software "Manage" > "Settings" > "System settings" > "LIS" to view the IP address and port number of LIS.

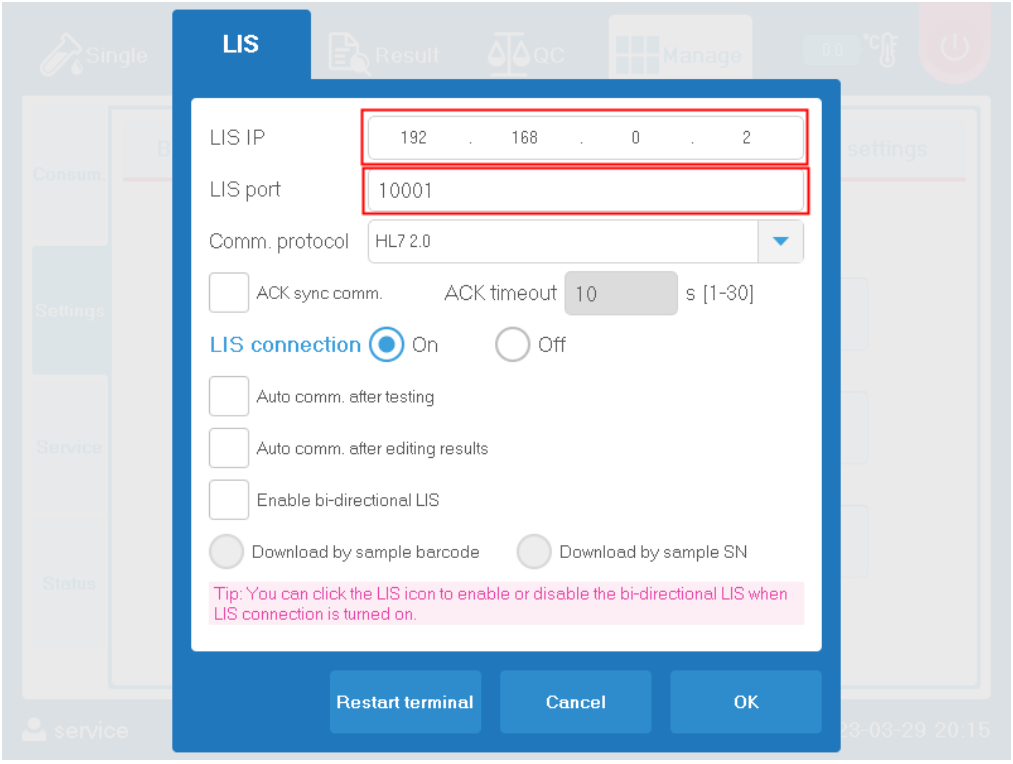


Figure 6-1 Check LIS port number

(3) Restart terminal Restarting the terminal can re-send connection commands to the LIS system. You can return to the main interface to check the LIS connection status after successfully restarting the terminal. Restart terminal: Click on the main screen of the

software “Manage” > “Settings” > “System settings” > “LIS” > “Restart terminal” to perform the restart terminal operation. After a successful restart of the terminal, a prompt will pop up.

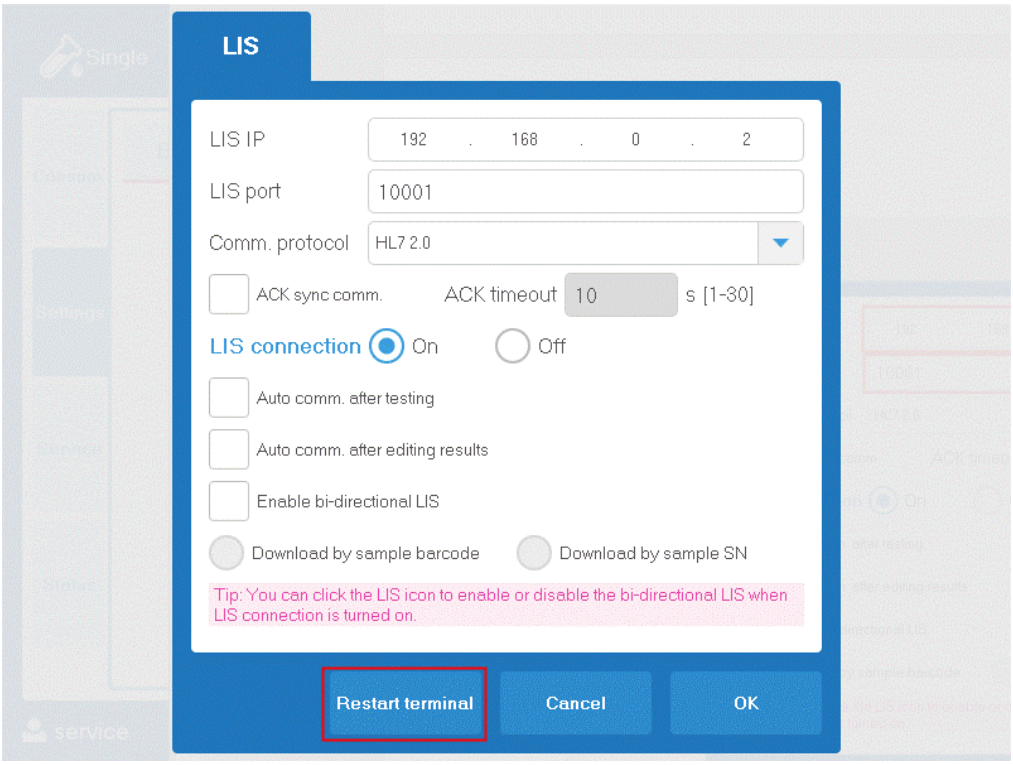


Figure 6-2 Restart terminal

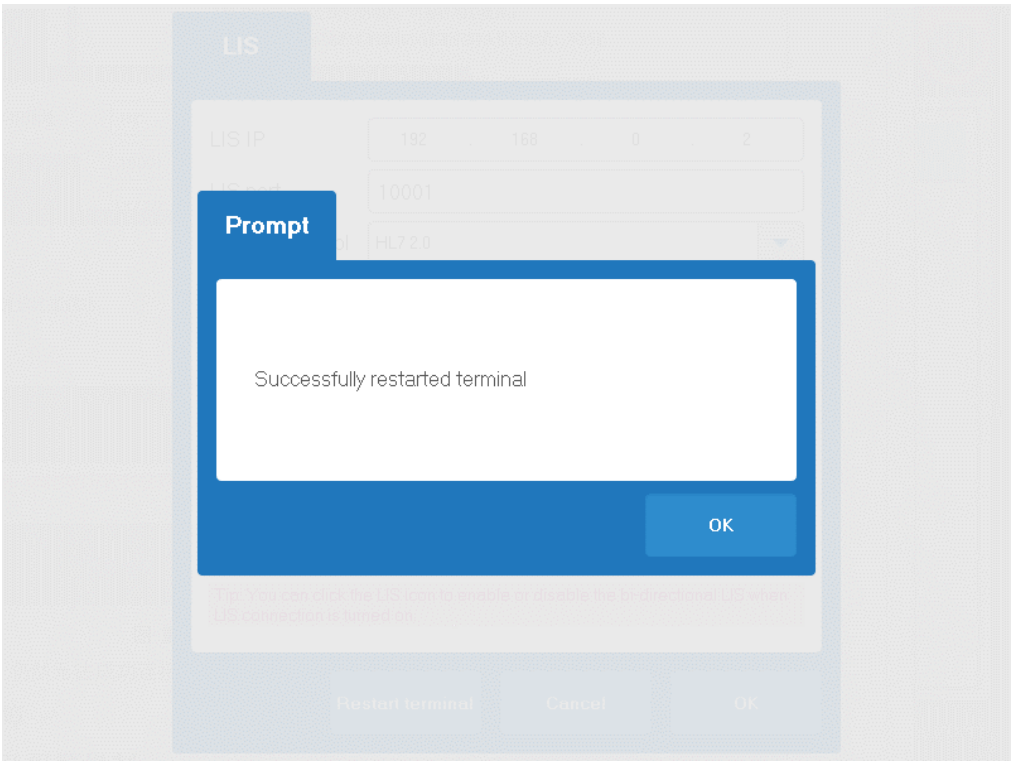


Figure 6-3 Restart terminal prompt

(4) If you perform the above actions and still cannot connect LIS successfully, turn off your computer's anti-virus software/firewall.

6.3 External printer failure

6.3.1 Fault code and warning mechanism

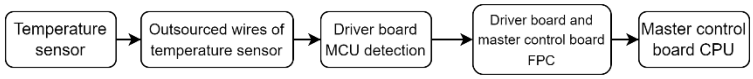
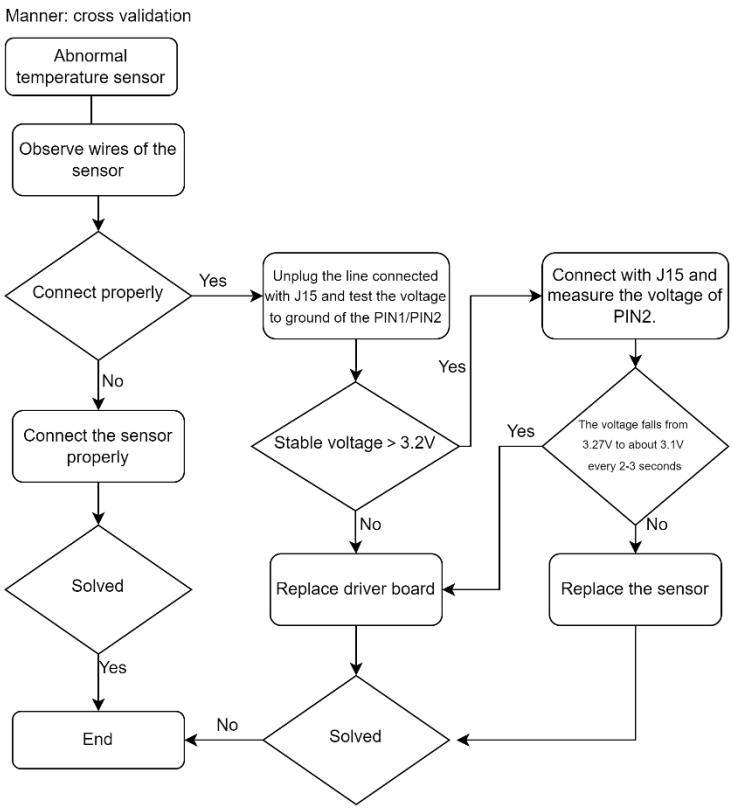
Fault code	Description (User)	Description (Service personnel)	Warning mechanism
0x01001501	External printer run out of paper.	External printer run out of paper.	External printer run out of paper.
0x01001502	Error: external printer failure	Error: external printer failure	Other faults
0x01001503	External printer disconnected	External printer disconnected	External printer disconnected
0x01001504	External printer paper jam	External printer paper jam	External printer paper jam

6.3.2 Fault analysis and troubleshooting

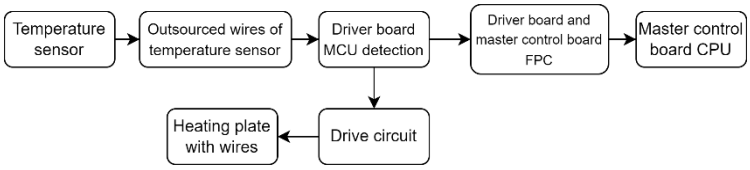
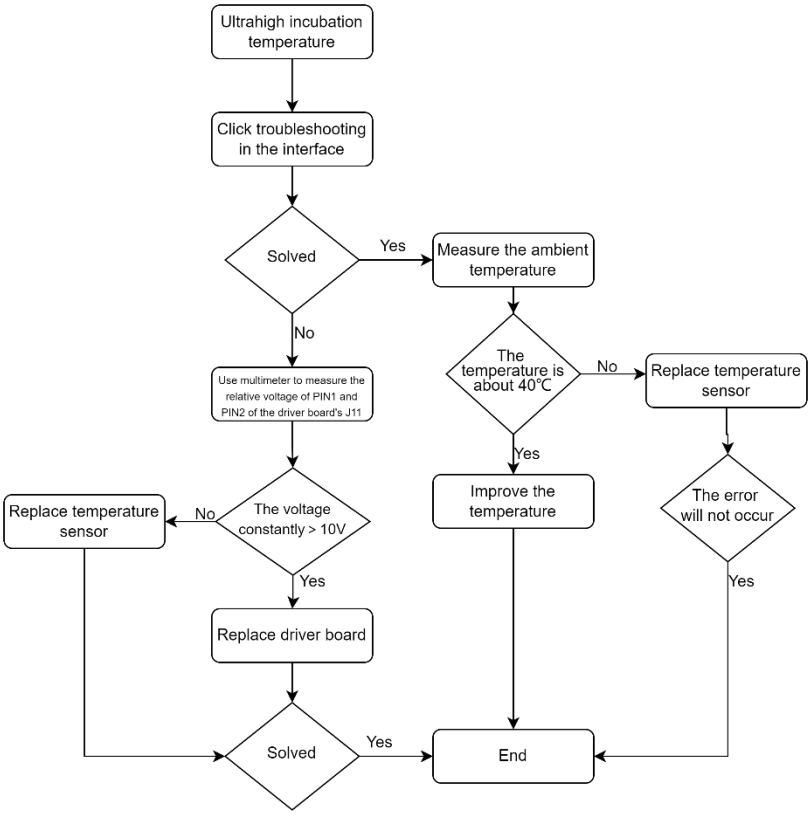
No.	Possible cause	Method	Troubleshooting
1	Printer model not supported or printer quality problems.	Check the printer model and make sure the printer is fault-free.	Change to the printer that the Analyzer supports.
2	USB interface problems	The printer icon in the instrument interface is not lit; the fault is “External printer not connecting”.	Connect the printer to other USB ports to see if it works properly, and contact the R&D team for further confirmation.
3	External printer failure	The printer icon on the instrument interface is normal; no response when clicking “Print”.	1. Turn off the printer, disconnect the printer from the USB interface of the instrument. 2. Click “Print Setup” > “Reset”, and restart the Analyzer one minute after the reset. 3. Plug in the printer USB after the Analyzer restarted, and then turn on the printer.

6.4 Temperature related failure

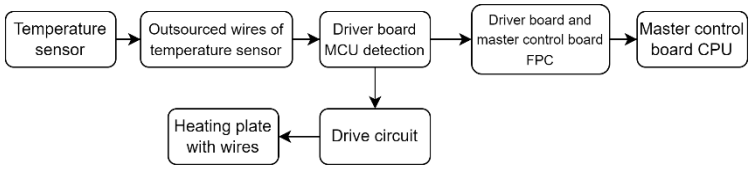
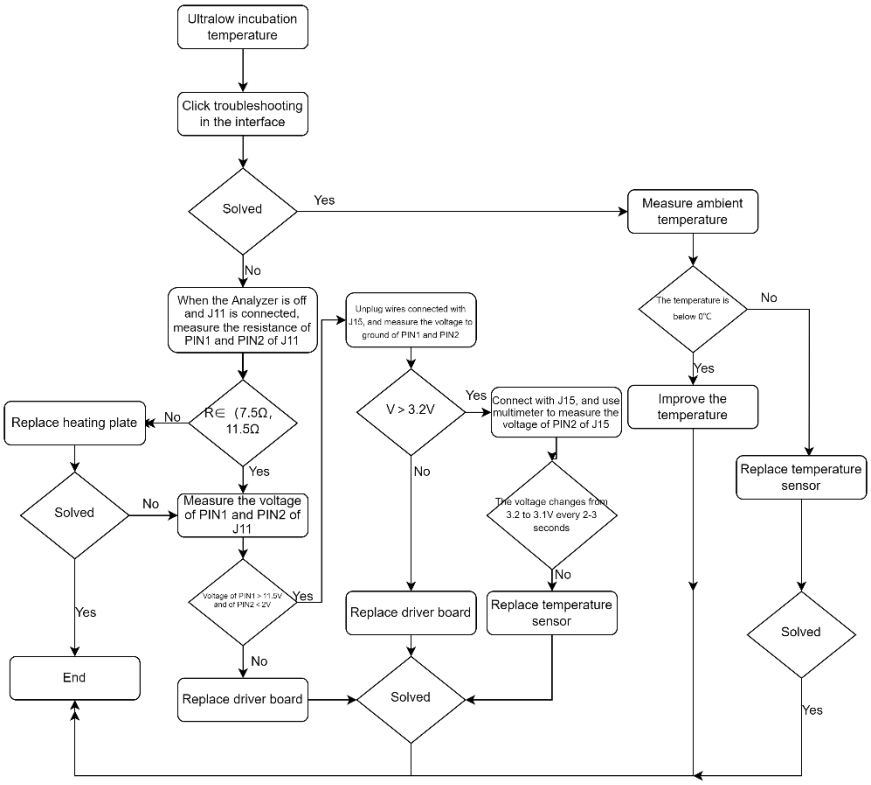
Incubation temperature sensor abnormal	
Trigger condition	MCU detects once a second. MCU communicates with a digital temperature sensor through the uni-bus. If no response, the sensor is abnormal.

Incubation temperature sensor abnormal	
Trigger time	MCU detects once a second.
System block diagram	
Troubleshooting steps	
Tool preparation	When customer service encounters sensor abnormalities, it is recommended to prepare in advance the temperature sensor, driver board, multimeter, and screwdriver;

Incubation temperature exceeded upper limit	
Trigger condition	Done with real-time testing, the acquired results from continuous 5s, a total of 5 points, were all above the target temperature of 10 °C (after calibration).
Trigger time	1. Sampling rate ⩾ 10 Hz 2. Real-time detection and alarm after power on. Alarm trigged if the results from the continuous collection of all 5 points exceed the limit. 3. Interface refresh rate: 2SPS

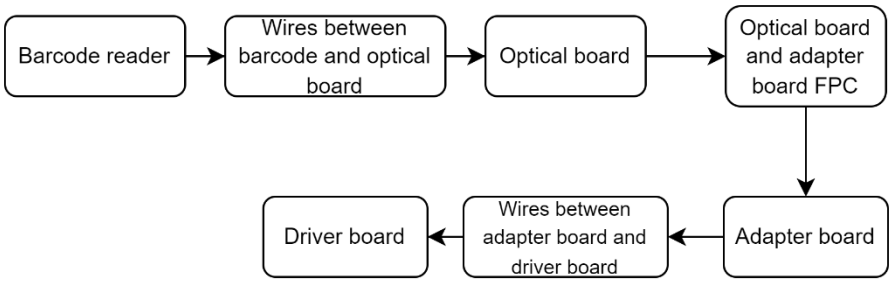
Incubation temperature exceeded upper limit	
System block diagram	
Troubleshooting steps	
Tool preparation	When customer service encounters sensor abnormalities, it is recommended to prepare in advance the temperature sensor, driver board, multimeter, and screwdriver;

Incubation temperature exceeded lower limit	
Trigger condition	Start testing after heating for more than the maximum heating time (normal heating time + 1 min). The acquired results from continuous 5s, a total of 5 points, were all below the target temperature of 10 °C (after calibration).
Trigger time	Start testing after heating for more than the maximum heating time (normal heating time +1min). Alarm trigged if the results from the continuous collection of all 5 points exceed the limit.

Incubation temperature exceeded lower limit	
System block diagram	
Troubleshooting steps	
Tool preparation	When customer service encounters sensor abnormalities, it is recommended to prepare in advance the temperature sensor, driver board, multimeter, and screwdriver;

6.5 Communication fault

Error: QR code scanner communication abnormal	
Trigger condition	Communication with the decoder fails when scanning the QR code during the test process.
Trigger time	Detect when scanning the QR code.

Error: QR code scanner communication abnormal	
System block diagram	

7 Software

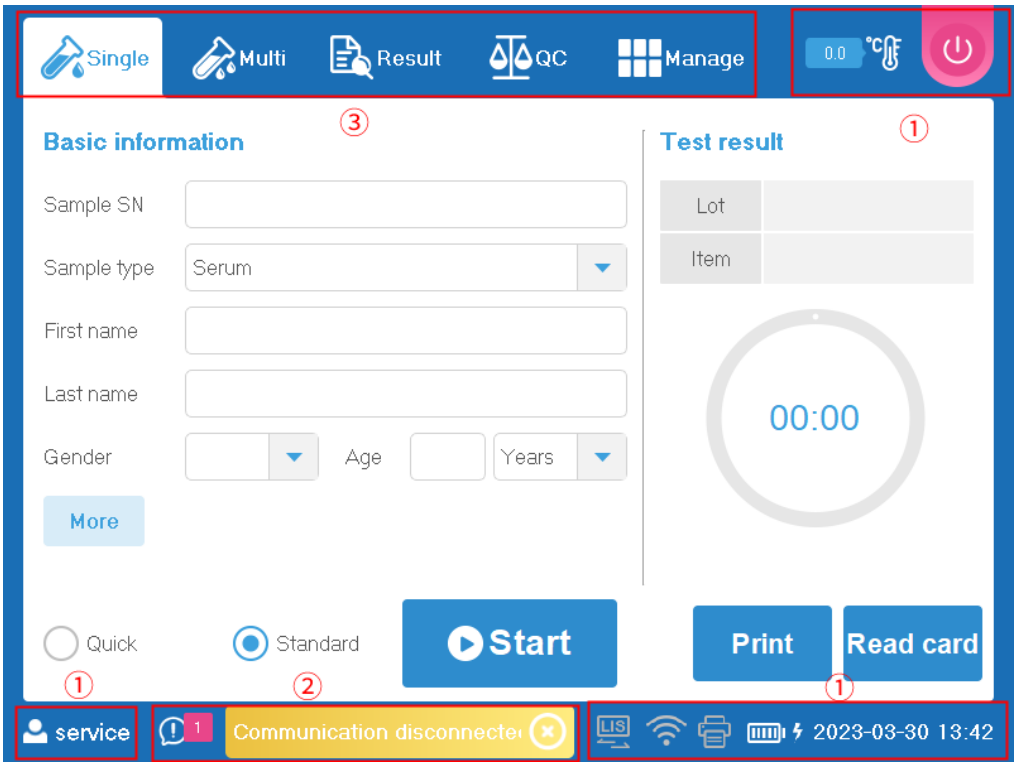
7.1 Login

- Administrator’ s user name: admin
- Administrator’ s password: admin
- Service personnel user name: service
- Service personnel password: ask the after-sales engineer for details

Note

The login password is case-sensitive.

7.2 Software interface introduction



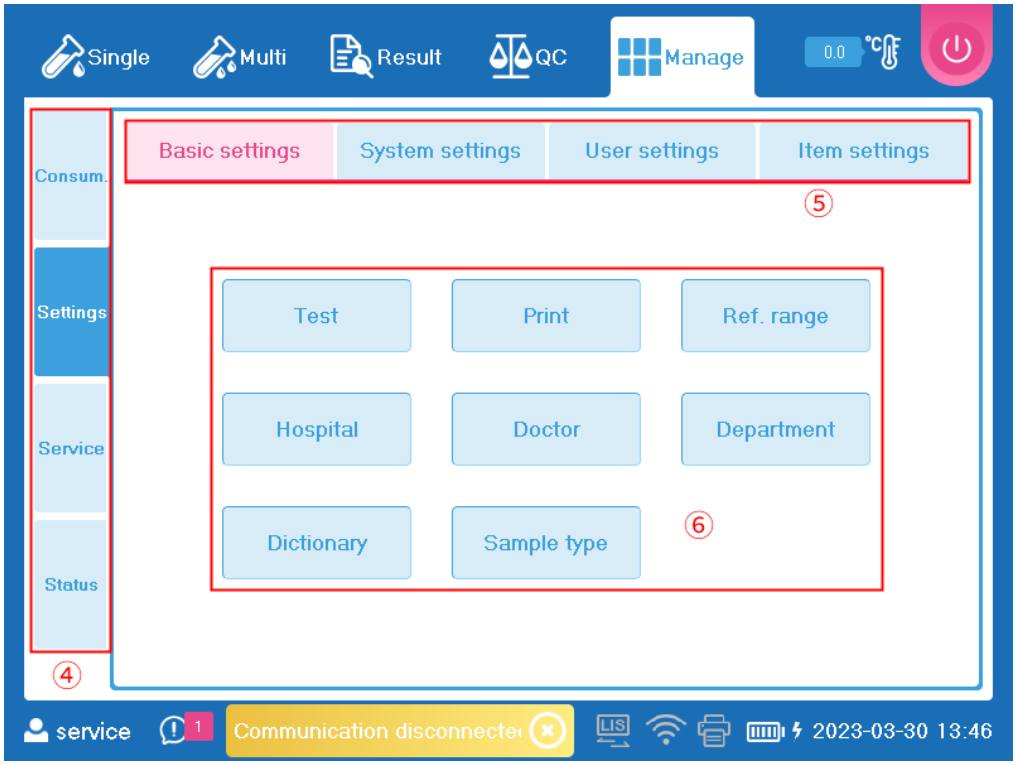


Figure 7-1 Software interface introduction

No.	Description
①	Information display area: 1. Display temperature, logout, and shutdowns; 2. Display user name, LIS, WIFI, printing, battery level, system time.
②	Auxiliary information area: When there is a fault in the instrument, the fault message is displayed here.
③	Function quick switch area: Single, Multi, Result, QC, and Manage.
④ ⑤	Navigation bar
⑥	buttons

7.3 Function list and authority category

No.	First level function	Second level Function	Third level Function
1	Single	/	
2	Multi	/	
3	Result	/	/
4	Quality control	QC test	/

No.	First level function	Second level Function	Third level Function
		QC result	/
		QC settings	/
		L-J graph	/
5	Consumables	/	
6	Settings	Basic settings	Test settings (administrator, service engineer)
			Print settings (administrator, service engineer)
			Reference range settings (administrator, service engineer)
			Hospital settings (administrator, service engineer)
			Doctor settings (administrator, service engineer)
			Department settings (administrator, service engineer)
			Dictionary settings (administrator, service engineer)
			Sample type settings (administrator, service engineer)
		System settings	System time settings (administrator, service engineer)
			Screen brightness settings (administrator, service engineer)
			Auto sleep settings (administrator, service engineer)
			Communication settings (administrator, service engineer)
			LIS settings (administrator, service engineer)
			Wi-Fi settings (administrator, service engineer)
			Prompt settings (administrator, service engineer)

No.	First level function	Second level Function	Third level Function
			Language settings (service engineer)
		User settings (administrator, service engineer)	/
		Item settings (service engineer)	/
7	Service	Version	Upgrade (Service personnel)
		Self-test	Motor-Optocoupler (administrator, service engineer)
			RFID recognition (administrator, service engineer)
			Monitor self-test (administrator, service engineer)
			Light (administrator, service engineer)
			Light spot confirmation (administrator, service engineer)
		Maintenance	Monitor calibration (administrator, service engineer)
			Optical calibration (Service personnel)
			Temperature calibration (Service personnel)
			Pack-shutdown (Service personnel)
		Log	All logs (administrator, service engineer)
			Operation logs (administrator, service engineer)
			Para. change logs (administrator, service engineer)
			Fault logs (administrator, service engineer)
			One-click export (Service personnel)
			Clear logs (Service personnel)

No.	First level function	Second level Function	Third level Function
8	Status	Monitoring	5V Power supply voltage (administrator, service engineer)
			Incubation temp. (administrator, service engineer)
		System information (administrator, service engineer)	/

7.4 Settings

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

7.4.1 Basic settings

Select “Manage” > “Settings” > “Basic settings” and the following interface is displayed. You can set up relevant settings as needed.

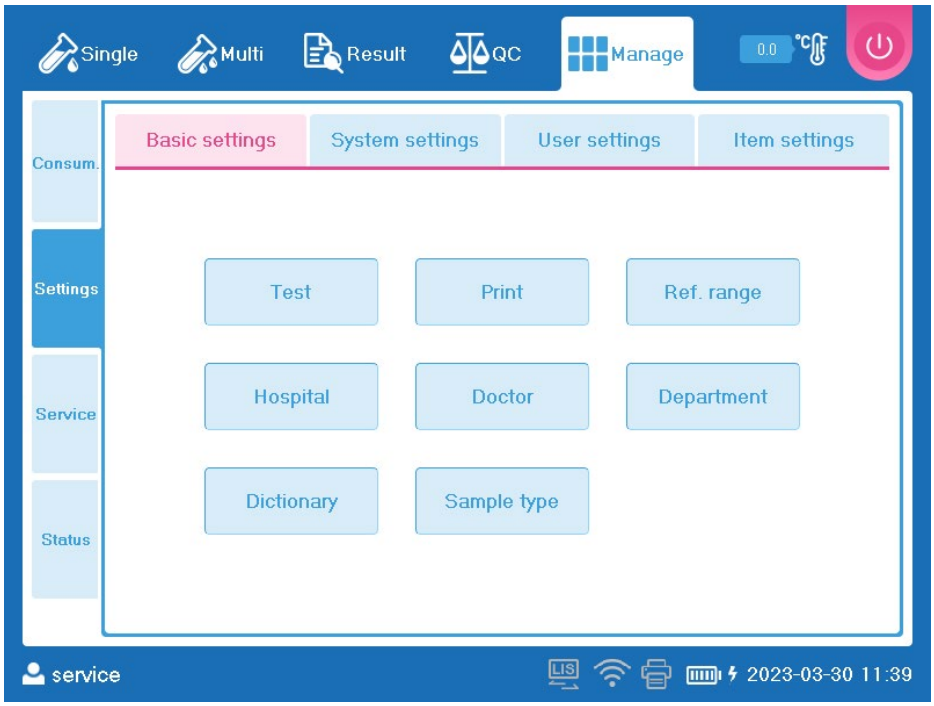


Figure 7-2 Basic settings interface

- **Test settings**

  Click on “Test” to set the settings according to the hospital's requirements, as shown below.

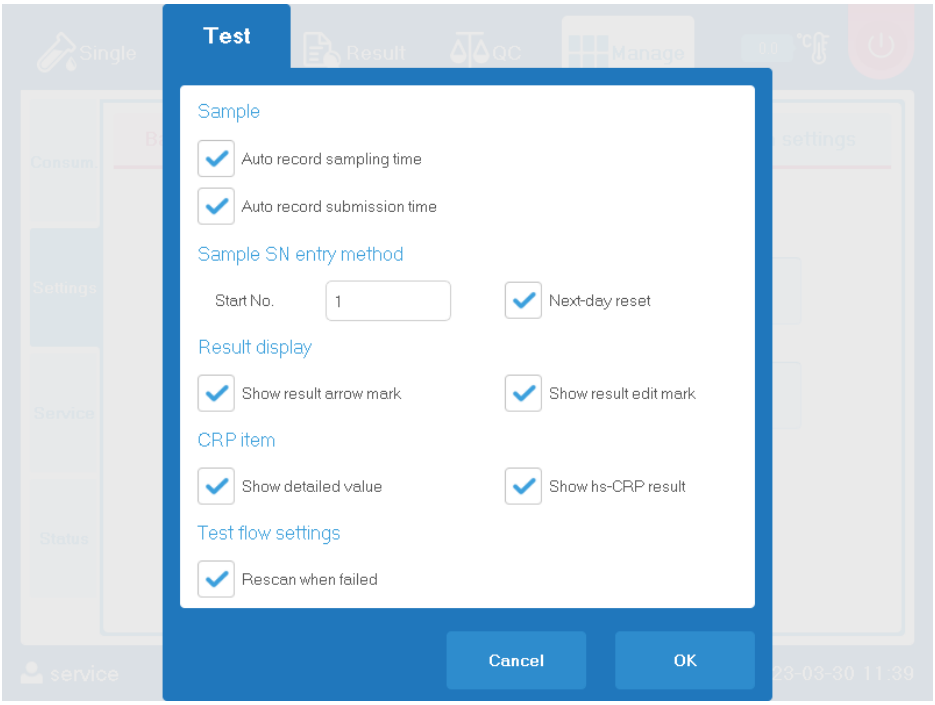


Figure 7-3 Test settings interface

Users can perform settings of the samples, sample SN entry method, result display and CRP item. See the following table for details.

Parameters	Explanations
Auto record submission 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 new start No.
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 outside the reference range
Show detailed value	Whether to display the detailed value of CRP test results
Show hs-CRP result	Whether to display the hs-CRP result in the test results of CRP item
Rescan when failed	The decoder rescans the QR code on the reagent card after it fails to recognize it.

- **Print settings**

  Refer to section 7.9 Printer Connection for printer connection procedures.

Click “Print Setup”, In this interface, users can set the report title, select the template type, paper, printing template, import/export/delete templates, set up printing copies, auto print, and print options according to the requirements of the hospital.

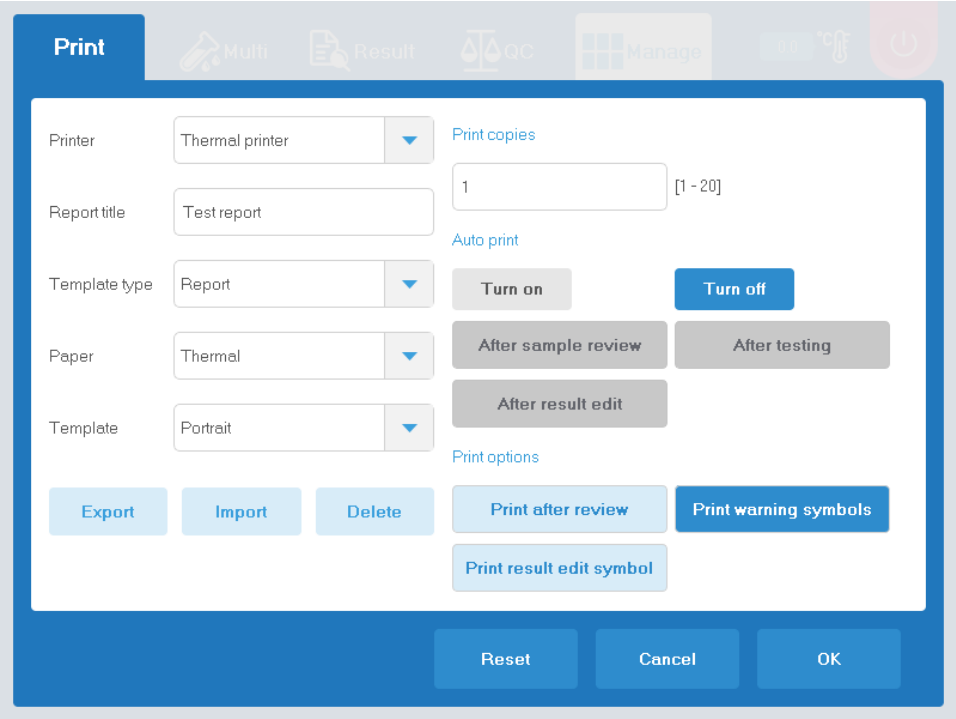


Figure 7-4 Print settings interface

- **Reference range settings**

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

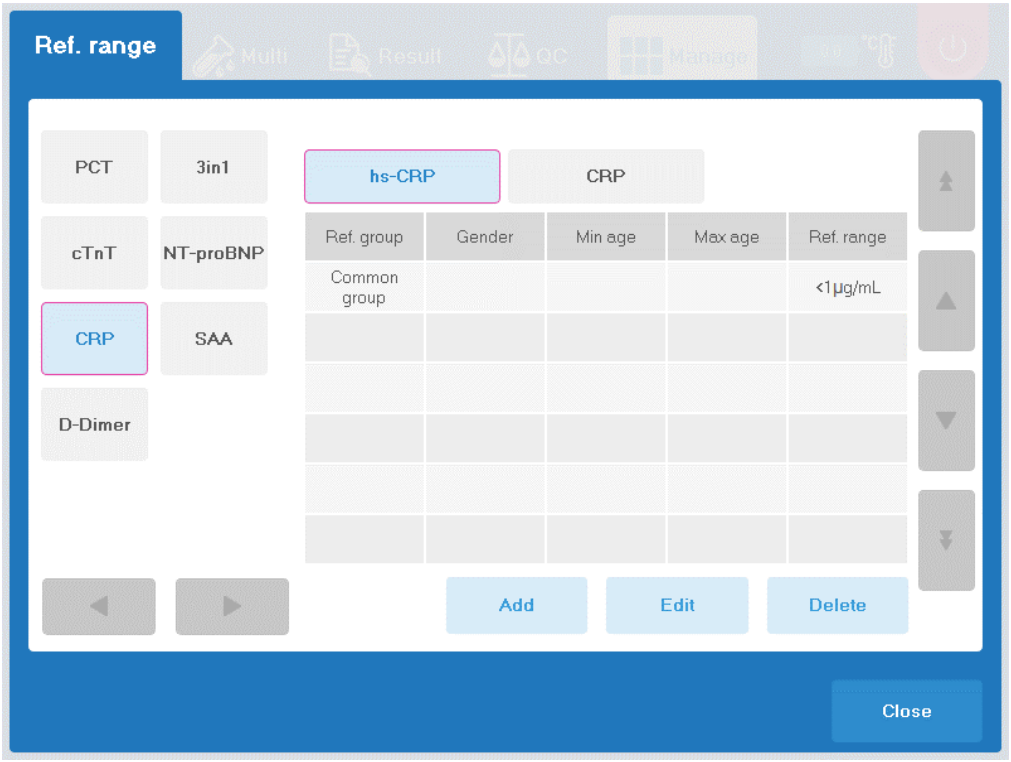


Figure 7-5 Reference range settings interface

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

- Hospital settings

  User can set up hospital-related information in this interface, including the hospital name, address, contact person and contact details. This screen shows the model, date of installation and serial number of the instrument 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 instrument when needed.

- Doctor settings

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

- Dictionary settings

  Click on the button to enter the dictionary settings interface which includes three parts: 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 types are shown. Both include for types: whole blood, plasma, serum, and urine. Uses can choose the sample types according to actual testing needs.

7.4.2 System settings

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

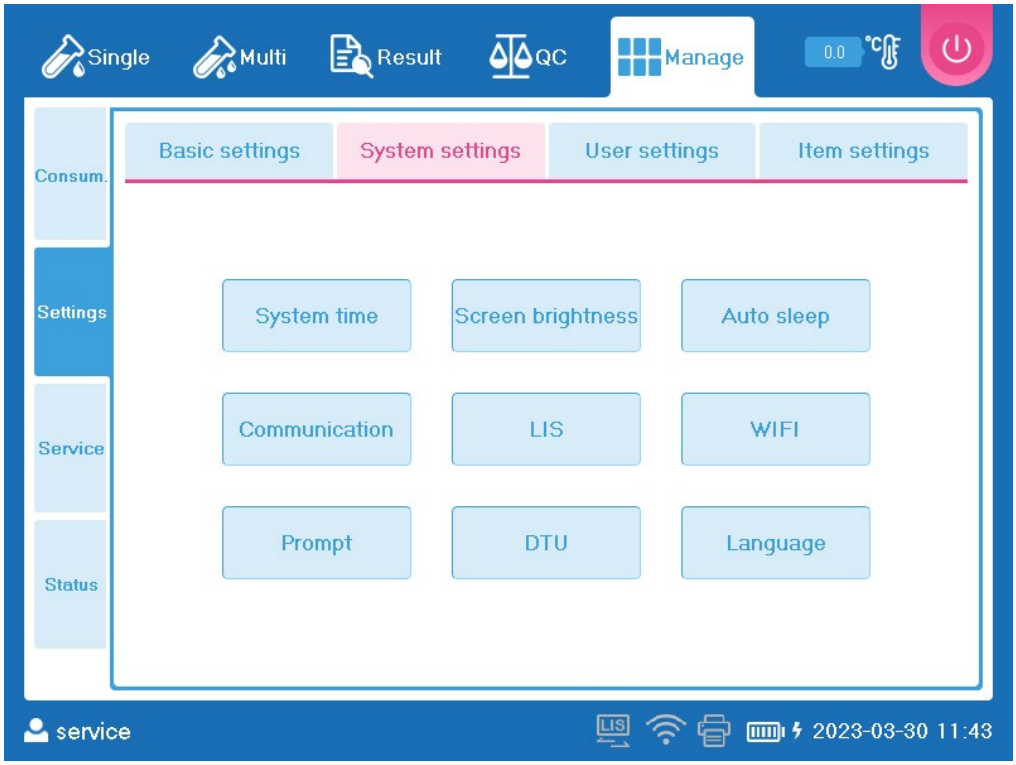


Figure 7-6 System settings interface

- **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 both adapter-powered and battery-powered instruments (only for instruments with batteries), respectively.

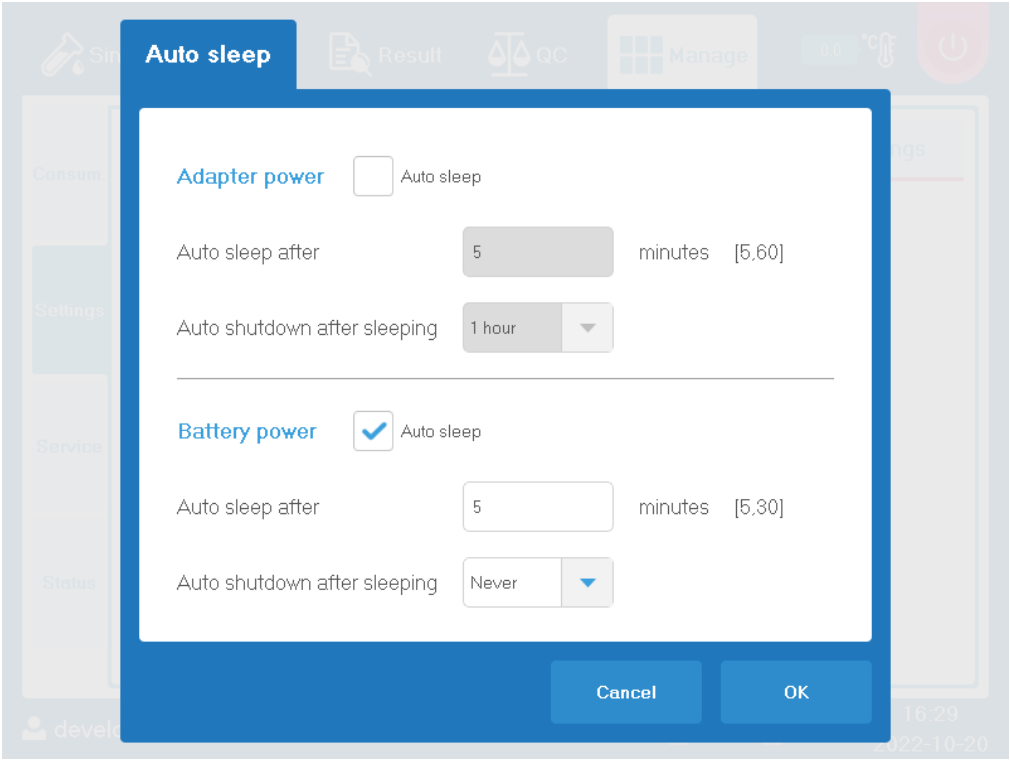


Figure 7-7 Auto sleep settings interface

- Communication

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

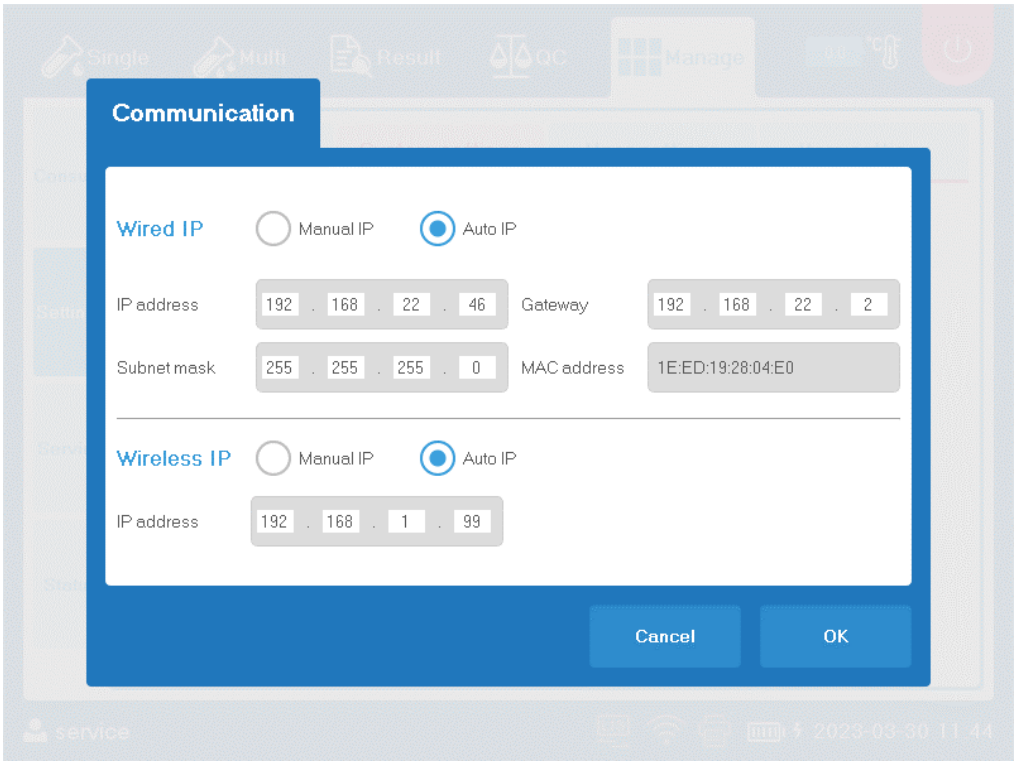


Figure 7-8 Communication settings interface

- **LIS**

  Click on the "LIS" button and enter into the following interface to set up the connection of the Analyzer to the LIS.

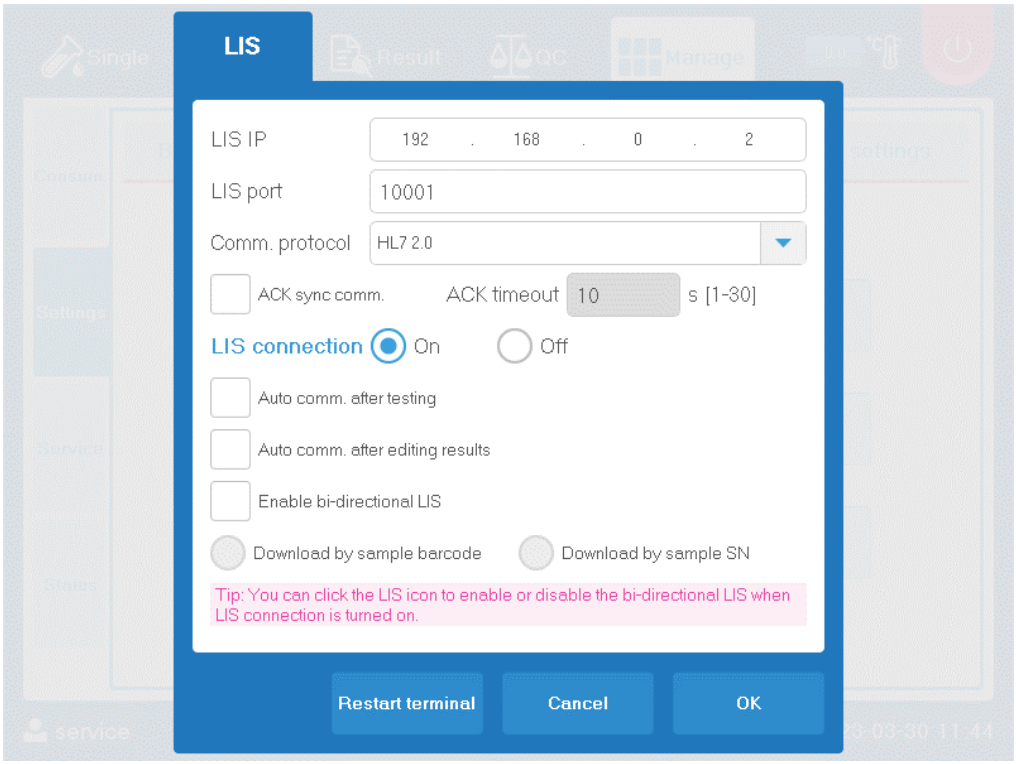


Figure 7-9 LIS settings interface

- **Wi-Fi**

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

  Note: "Display battery percentage" is only applicable to Analyzers equipped with battery.

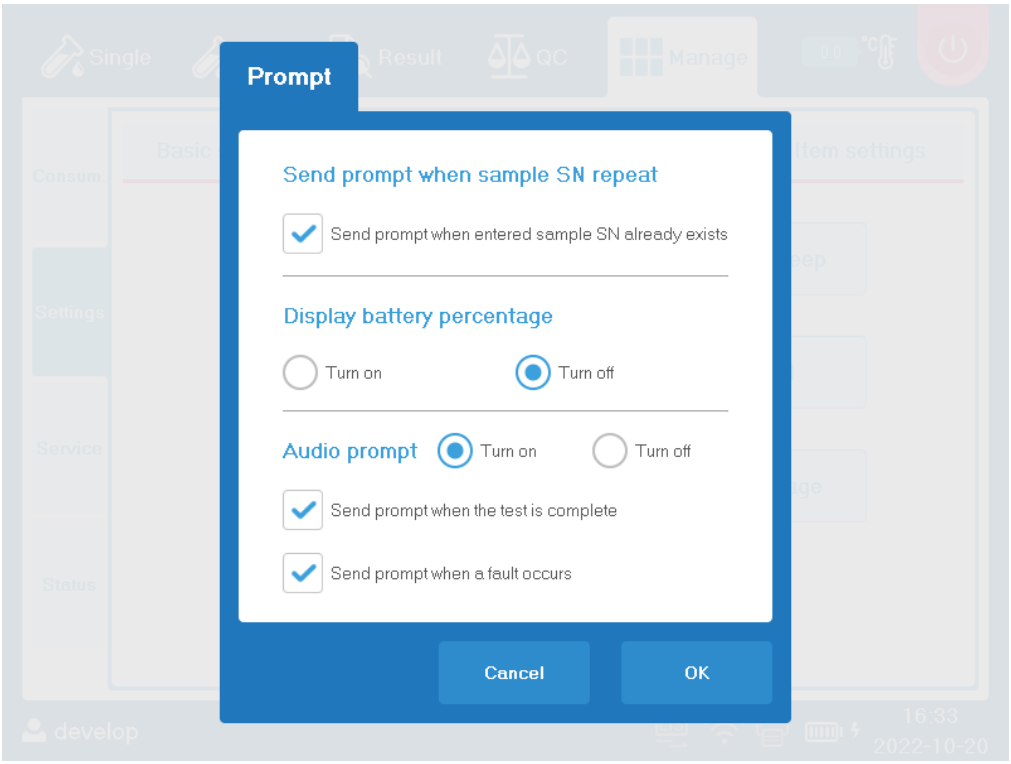


Figure 7-10 Prompt settings interface

- **Language**

  The language can be switched via the drop-down box and takes effect after restarting the instrument.

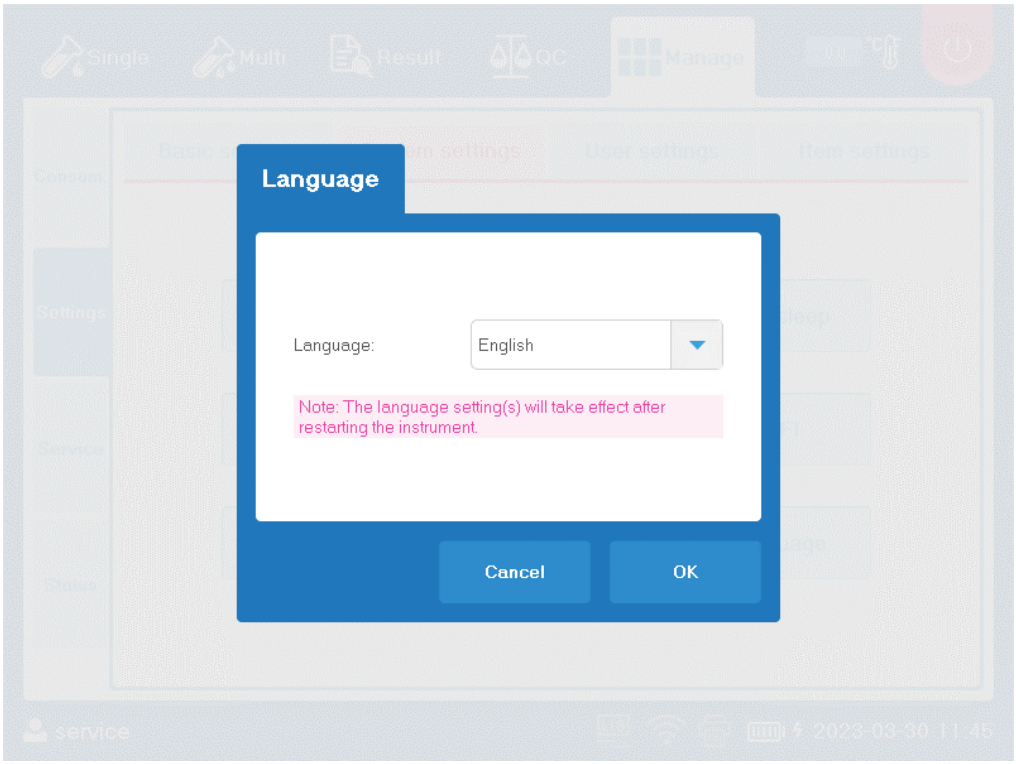


Figure 7-11 Language setup interface

7.4.3 User settings

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

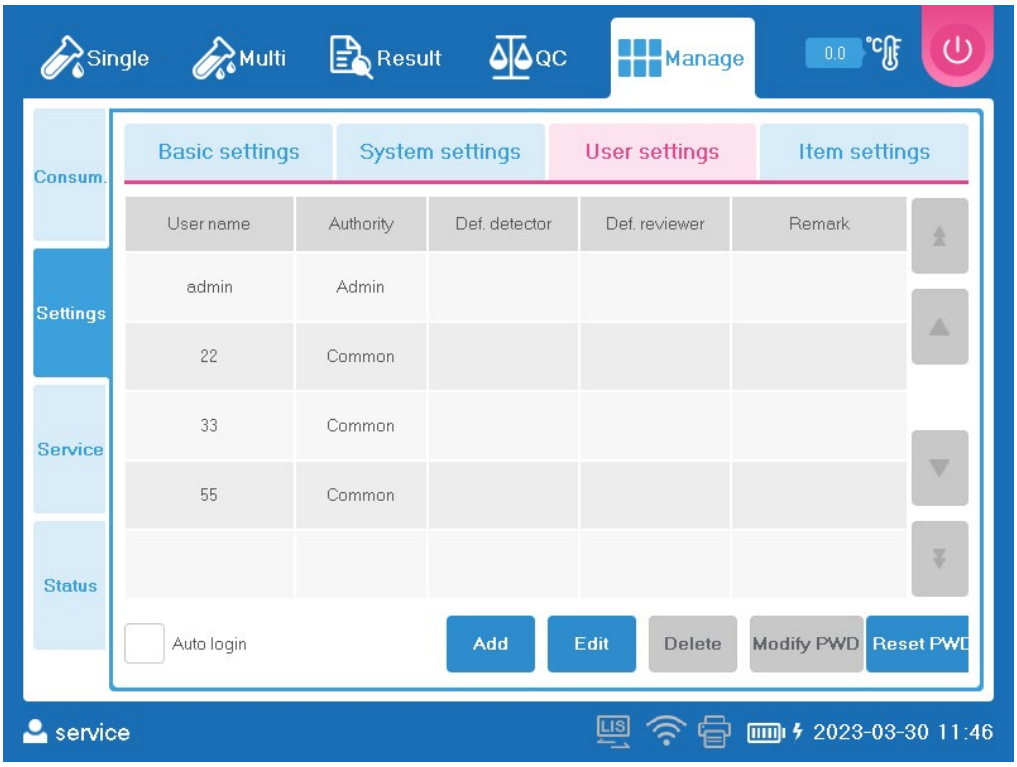


Figure 7-12 User settings interface

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).

7.5 Service

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

7.5.1 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.

Figure 7-13 Version information interface

7.5.2 Self-test

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

Figure 7-14 Self-test interface

7.5.3 Maintenance

In the “Maintenance” interface, you can perform screen calibration, optical calibration, temperature calibration and packing shutdown operations.

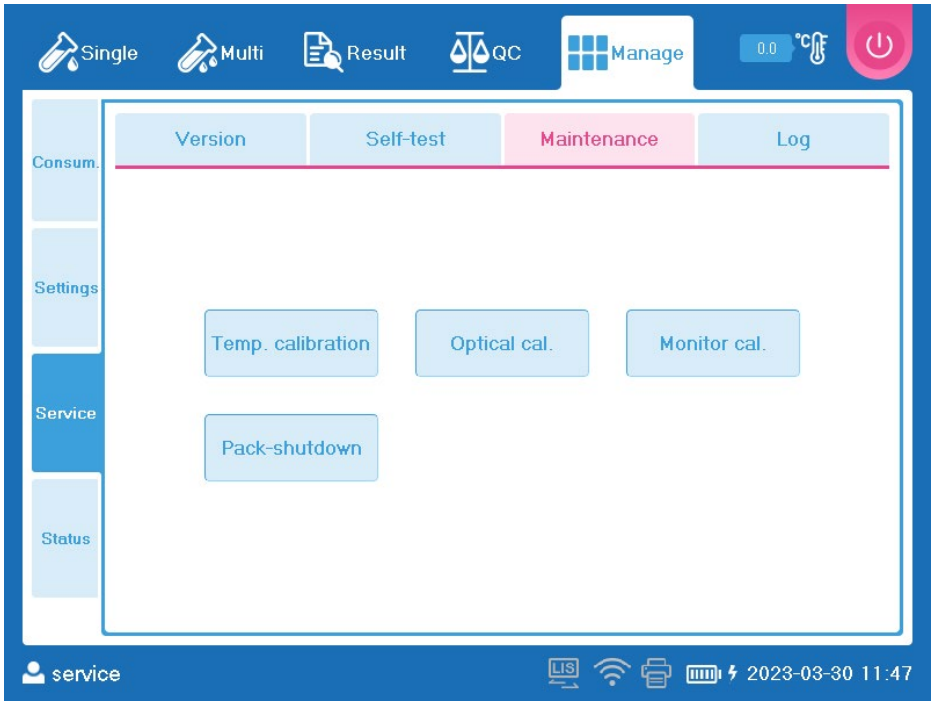


Figure 7-15 Maintenance interface

7.5.4 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” button and the following screen will be displayed:

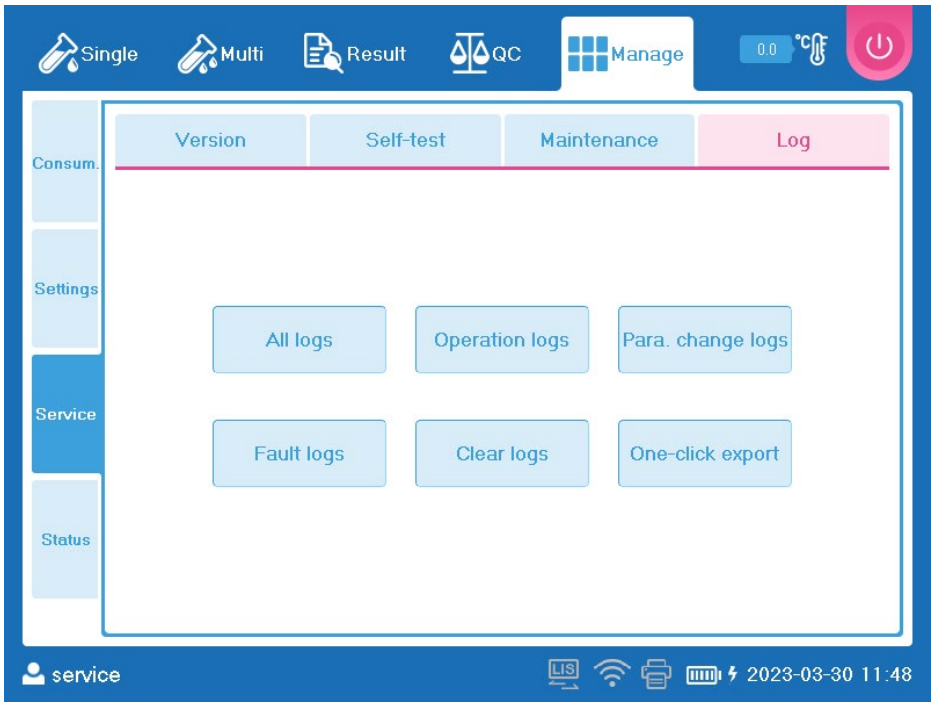


Figure 7-16 log interface

The log includes all logs, operation logs, parameter change logs, and fault logs. All logs show all logs that the currently logged-in user can see, which are the sum of the logs described below; operation logs record the daily operation logs of the machine, including: power on, power off, login, logout, sample analysis, sample management, other important business operations, etc.; parameter modification logs show data of all major parameter modification categories, including various settings in setup items, system configuration changes caused by certain functions, and fault logs show fault-related logs, including fault reporting, fault troubleshooting, fault resetting, etc. All can be queried and exported.

- **Searching for logs**
  (1) Choose the type of logs 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 (format FAT32) into the USB port;
  (2) Choose the type of logs need to enter the corresponding interface;
  (3) Click on the “Export” button to go to 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).

7.6 Status interface

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

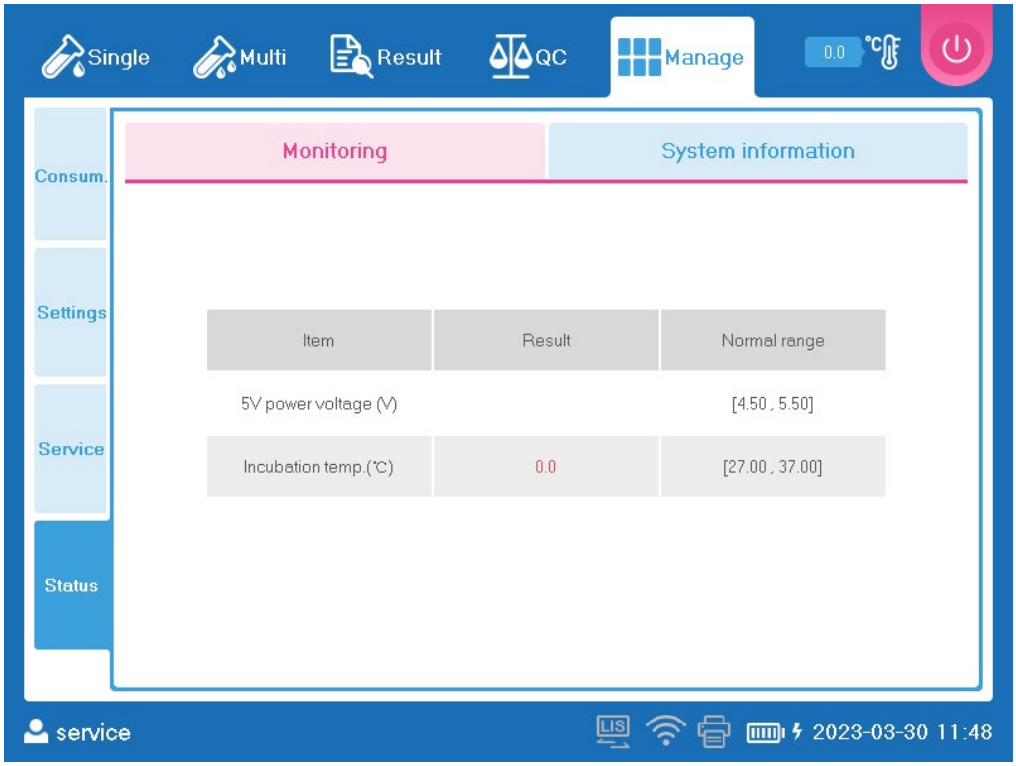


Figure 7-17 Status interface

7.6.1 Monitoring

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

7.6.2 System information

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

7.7 Status prompt

7.7.1 battery percentage

The battery icon can appear in eight states depending on how much power is available, with the icon mark for charging under adapter power, and the percentage display of power can be turned on or off in the settings. Shown as figure below:

Status	Color	Battery icon
81%-100%	White, 5 bars	
61%-80%	White, 4 bars	
41%-60%	White, 3 bars	
21%-40%	White, 2 bars	
16%-20%	White, 1 bar	
11%-15%	Yellow, 1 bar	
6%-10%	Red, 0 bars	
0%-5%	Red with an exclamation point, 0 bars	
Powered by battery		
Powered by battery - display percentage		
Powered by adapter		
Powered by adapter - display percentage		

Figure 7-18 battery status icon

- The percentage is displayed/not displayed to the right of the battery icon according to the setting in Prompt Settings - Power Percentage Display.
- During charging, the charging icon is displayed to the right of the battery icon or percentage.

7.7.2 Buzzer

The buzzer indicates the current status of the system. The buzzer’ s status varies with the status of the instrument, as shown in the following table:

Condition	Buzzer state
Test completed	3 beeps
Instrument failure	Continuous beeping

- Tap on the touch screen to stop the beeping;
- If a mouse is connected externally, click on the event with the mouse stops the beeping alarm;

7.8 Printer connection

7.8.1 Recommended printer models

- HP LaserJet P1008
- HP LaserJet 1020 plus
- HP LaserJet Pro M12a

7.8.2 Print setup

- Click “Manage” > “Settings” > “Basic Settings” > “Print” to enter the print settings interface.
- You can select “Thermal printer” (default) or “External printer” for printing as required.
- Select the print paper type required by the hospital.
- Select a print template.
- Other auxiliary functions can be set as needed, usually the default is sufficient and no additional settings are required.

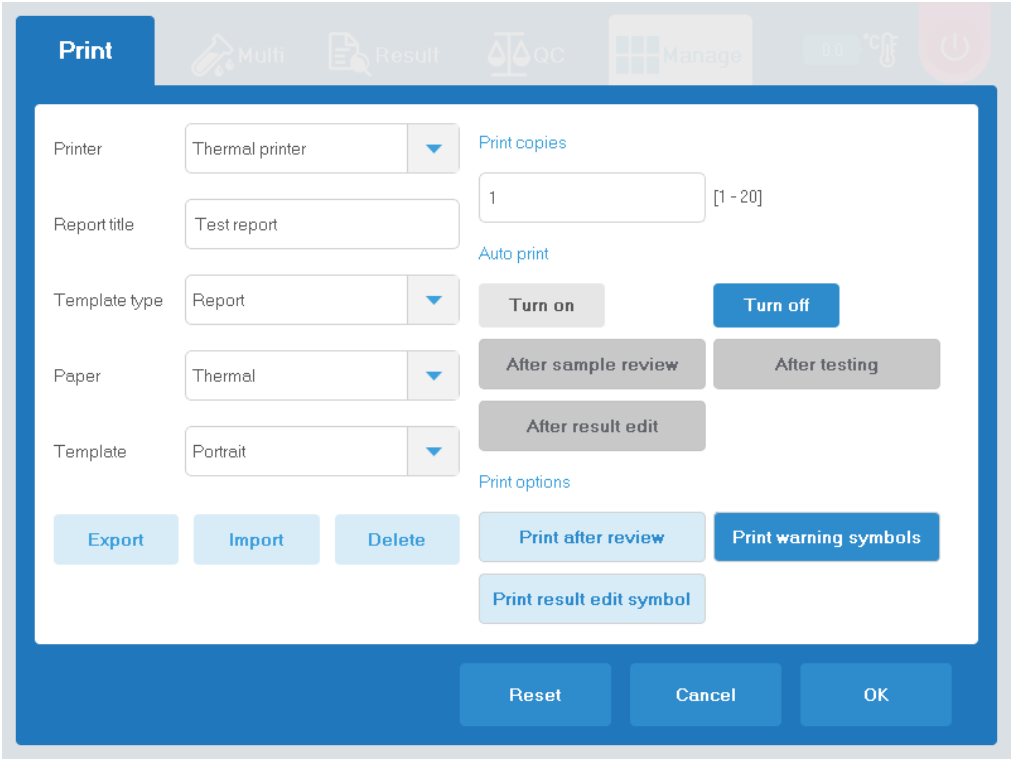


Figure 7-19 Print setup interface

7.8.3 Connect External printer

(1) Select a printer and plug it into the analyzer USB port.

(2) The printer is plugged in and powered on.

(3) The icon will light up when the connection is successfully marked, and the icon can also be clicked to view print tasks.

7.8.4 Print the report

Go to the “Result” interface, select the samples to be printed, click “Review” (can be turned off at print settings), and then click “Print”.

7.8.5 Troubleshooting

- If the printer in same model has the problem in recognizing, you can restore by “Reset” button.
- If a malfunction occurs during connection or printing, it can be handled by the “External Printer Troubleshooting Method”.

7.9 Upgrade

7.9.1 Preparation

Copy “update_Q3.tar.gz” to the root directory of the formatted USB drive.

Note

- The USB drive has been formatted into FAT32 format.
- The USB flash drive has enough storage left.
- The root directory of the USB drive contains only the file “update_Q3.tar.gz”. Change of file name is prohibited. No unzipping is required.

7.9.2 Steps

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

(2) Login with service personnel user name;

(3) Click “Manage” > “Status” > “Version”, enter the version interface, and click “Upgrade”;

(4) After entering the upgrade interface, select the programs that need to be upgraded (by default, all programs that support upgrade are selected) and click “Update” to start the upgrade.

7.9.3 Upgrade status verification

After the upgrade is completed, restart the instrument, log in with your service personnel user name, enter “Manage” > “Status” > “Version”, check whether the software information version number is the upgrade version number, if it is the same, then the upgrade is successful.

7.9.4 Upgrade process abnormal handling

If the upgrade prompt fails, you can try to upgrade again.

8 Hardware system

8.1 About hardware System

This chapter describes the hardware subsystems of the Fluorescence Immunochromatography Analyzer.

8.2 Hardware system composition

The hardware subsystem of the fluorescence immunochromatography analyzer can be divided into power subsystem, human-computer interaction subsystem, temperature control subsystem, reagent containment subsystem, motion control subsystem, and measurement subsystem according to the functional modules, and its schematic block diagram is shown below:

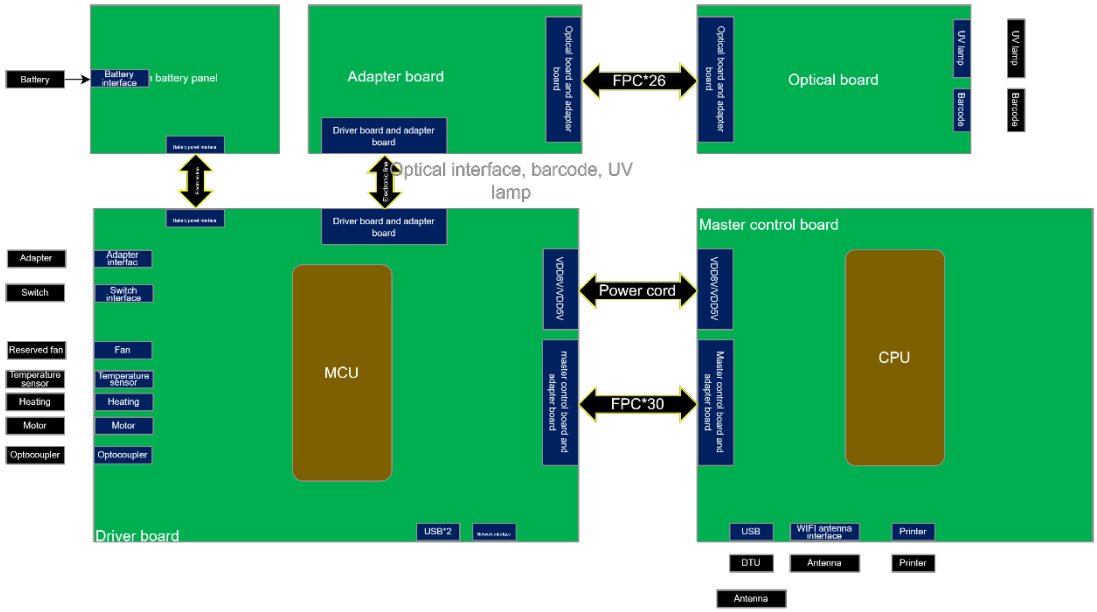


Figure 8-1 Hardware system diagram

The power subsystem diagram is shown in the following figure:

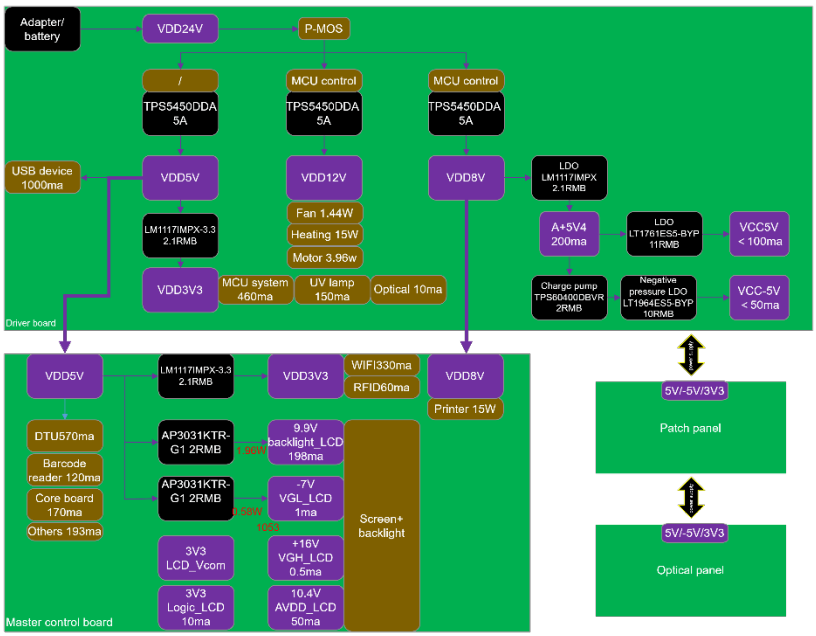


Figure 8-2 Hardware system-power subsystem diagram

8.2.1 Hardware subsystem components of the complete machine accessories

The list of the components of the complete hardware subsystem of the Fluorescence Immunochromatography Analyzer is shown in the following table.

No.	Name	Description
1	Master control board	It acts as the brain of the system in the hardware subsystem and is responsible for the control unit and human-machine interface for the operation of the complete machine.
2	Driver board	In the hardware subsystem, it is the driver for motors, heating, and system power topology, etc.
3	Adapter board	/
4	Optical PCBA	Optical signal acquisition
5	Lithium battery charging pad	Lithium battery charging
6	RFID card reader	/
7	8 inch capacitive screen module	/
8	QR code Scanner	/
9	Outsourced leaded NTC resistors	/
10	Rechargeable lithium battery pack	/

No.	Name	Description
11	Thermal printer Zybio grey1	/
12	Thermal printer Zybio grey2	/
13	DC power adapter	/
14	Outsourced terminal UV LED lamp aluminum substrate	/
15	SWITCH	/
16	4G antenna	/
17	Wi-Fi antenna	/
18	Magnetic ring	/
19	Outsourced terminal OPB880P51Z optocoupler	/
20	SZ18 driver board outsourced temperature sensor	/
21	Heating disk	/

8.2.2 PCBA card layout for the hardware subsystem

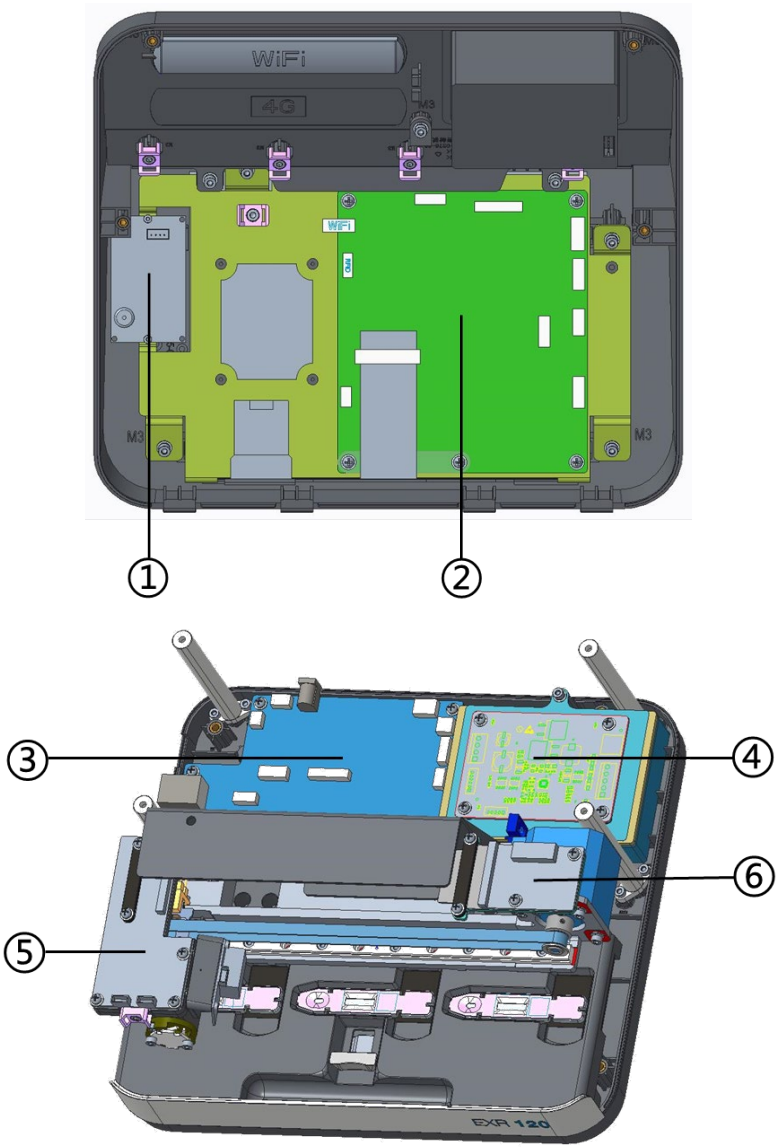


Figure 8-3 PCBA cards diagram

No.	Description
1	RFID card reader
2	Master control board
3	driver board
4	Lithium battery charging board
5	Optical board
6	Adapter board

8.3 Functions of the circuit board

8.3.1 Master control board

Shown in the figure below is the diagram of the main control board of the Analyzer. It works as the control unit of the complete machine to control its operation and testing. The main control board is mainly composed of USB interfaces, a 100 Gigabit network PHY interface, a CPU minimum system, a thermal printer, Wi-Fi, DTU, human-computer interaction, and other interface circuits.

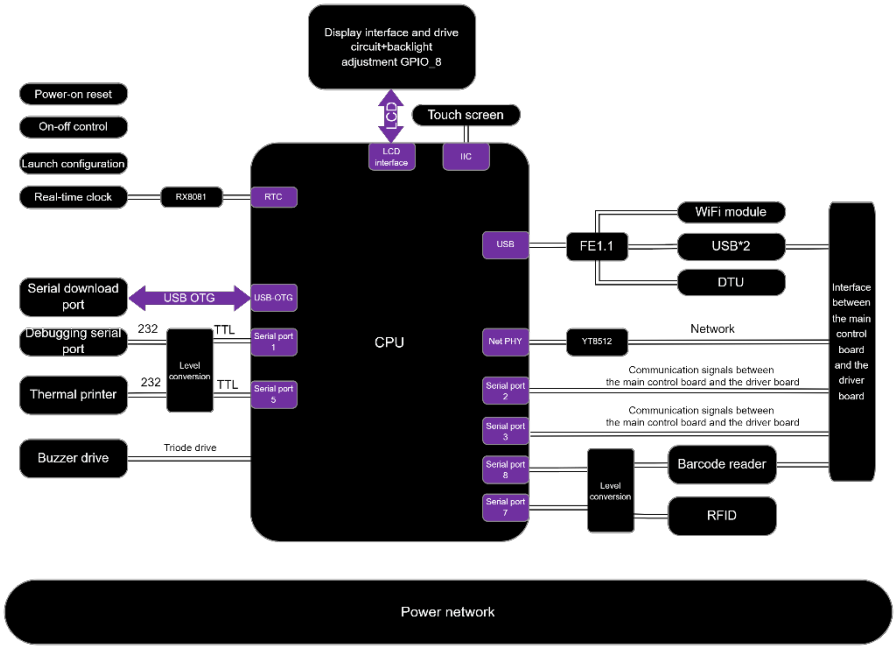


Figure 8-4 Master control board principle diagram

The symbols on it are shown in the following figure:

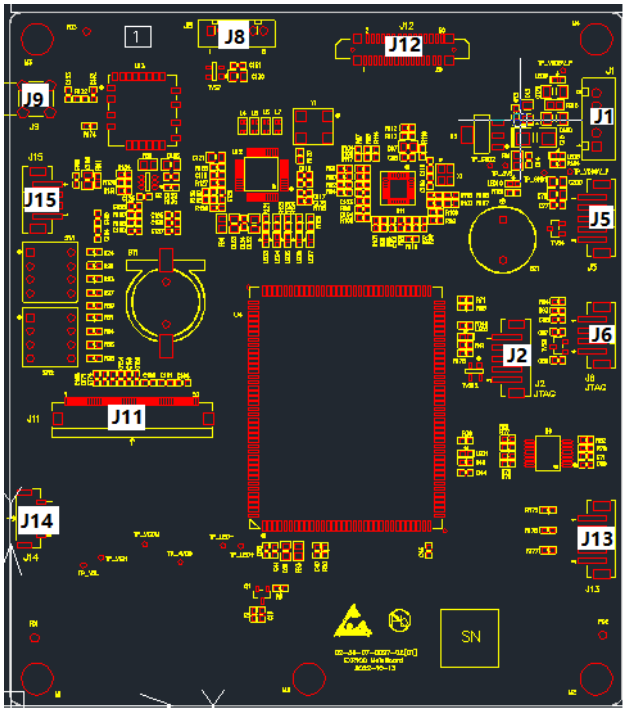


Figure 8-5 Master control board symbols

Connection port interface definition description:

J8 main control board DTU module interface definition description		
Terminal number	Definition	Description
J8.1	DP2	DTU module communication signal
J8.2	DM2	
J8.3	VDD_USB	DTU module power supply
J8.4	DGND	
J8.5	NC	/
J8.6	NC	/

J12 main control board driver board communication port definition description		
Terminal number	Definition	Description
J12.1	DGND	/
J12.2	DGND	/
J12.3	DGND	/
J12.4	MCU_Usart1_RX	The communication signal of the main control board and the driver board
J12.5	MCU_Usart1_TX	
J12.6	DGND	/
J12.7	MCU_Usart3_RX	The communication signal of the main control board and the driver board
J12.8	MCU_Usart3_TX	
J12.9	DGND	/
J12.10	RS232_CPU_RX8	Bar code scanner communication signal
J12.11	RS232_CPU_TX8	
J12.12	DGND	/
J12.13	DGND	/
J12.14	DP3	USB3
J12.15	DM3	
J12.16	DGND	/

J12 main control board driver board communication port definition description		
J12.17	DP4	USB4
J12.18	DM4	
J12.19	DGND	/
J12.20	LED0_PHYAD0	Network port indicator light
J12.21	LED1_PHYAD1	
J12.22	DGND	/
J12.23	RMII_RX_N	NET Differential Signal Line
J12.24	RMII_RX_P	
J12.25	DGND	/
J12.26	RMII_TX_N	NET Differential Signal Line
J12.27	RMII_TX_P	
J12.28	DGND	/
J12.29	DGND	/
J12.30	DGND	/

J1 main control board power supply port definition description		
Terminal number	Definition	Description
J1.1	DGND	/
J1.2	VDD8V_P	/
J1.3	DGND	/
J1.4	VDD5V_P	/
J1.5	DGND	/

J5 main control board thermal printer port definition description		
Terminal number	Definition	Description
J5.1	VDD8V_P	Thermal printer power supply
J5.2	DGND	

J5 main control board thermal printer port definition description		
J5.3	RS232_CPU_TX5	Thermal printer communication signal
J5.4	RS232_CPU_RX5	
J5.5	DGND	/

J6 main control board serial debug interface definition description		
Terminal number	Definition	Description
J6.1	/	232 debug serial port
J6.2	DGND	
J6.3	RS232_CPU_TX1	
J6.4	RS232_CPU_RX1	

J2 master control board USB download interface definition description		
Terminal number	Definition	Description
J2.1	CPU_USB_VBUS1	USB download interface
J2.2	DGND	
J2.3	CPU_DM1	
J2.4	CPU_DP1	
J2.5	CPU_USB_OTG1_ID	

J13 main control board reserved interface definition description		
Terminal number	Definition	Description
J13.1	/	Reserved interface
J13.2	/	
J13.3	/	
J13.4	/	
J13.5	/	

J14 main control board touch screen interface definition description		
Terminal number	Definition	Description
J14.1	VDD3V3	Touch screen interface
J14.2	CPU_TP_INT	
J14.3	CPU_IIC2_SDA	
J14.4	CPU_IIC2_SCL	
J14.5	CPU_TP_RST	
J14.6	DGND	

J11 main control board touch screen interface definition description		
Terminal number	Definition	Description
J11.50	LCD_LED+	Touch screen interface
J11.49	LCD_LED+	
J11.48	LCD_LED-	
J11.47	LCD_LED-	
J11.46	DGND	
J11.45	LCD_VCOM	
J11.44	LCD_VDD	
J11.43	LCD_MODE	
J11.42	LCD_DE	
J11.41	LCD_VSYNC	
J11.40	LCD_HSYNC	
J11.39	LCD_DATA7	
J11.38	LCD_DATA6	
J11.37	LCD_DATA5	
J11.36	LCD_DATA4	
J11.35	LCD_DATA3	
J11.34	LCD_DATA2	

J11 main control board touch screen interface definition description		
J11.33	LCD_DATA1	
J11.32	LCD_DATA0	
J11.31	LCD_DATA15	
J11.30	LCD_DATA14	
J11.29	LCD_DATA13	
J11.28	LCD_DATA12	
J11.27	LCD_DATA11	
J11.26	LCD_DATA10	
J11.25	LCD_DATA9	
J11.24	LCD_DATA8	
J11.23	LCD_DATA23	
J11.22	LCD_DATA22	
J11.21	LCD_DATA21	
J11.20	LCD_DATA20	
J11.19	LCD_DATA19	
J11.18	LCD_DATA18	
J11.17	LCD_DATA17	
J11.16	LCD_DATA16	
J11.15	DGND	
J11.14	LCD_PCLK	
J11.13	DGND	
J11.12	LCD_L/R	
J11.11	LCD_U/D	
J11.10	LCD_VGH	
J11.9	LCD_VGL	
J11.8	LCD_AVDD	
J11.7	LCD_RST	

J11 main control board touch screen interface definition description		
J11.6	NC	
J11.5	LCD_VCOM	
J11.4	LCD_DITHB	
J11.3	DGND	
J11.2	NC	
J11.1	NC	

J15 master control board RFID interface definition description		
Terminal number	Definition	Description
J15.1	DGND	RFID interface
J15.2	RS232_CPU_RX7	
J15.3	RS232_CPU_TX7	
J15.4	VDD5V	
J9 master control board Wi-Fi antenna interface definition description		
Terminal number	Definition	Description
J9.1	RF-S0	Wi-Fi antenna interface
J9.2	DGND	
J9.3	DGND	
J9.4	DGND	
J9.5	DGND	

J12 main control board driver board communication port definition description		
Terminal number	Definition	Description
J17.30	DGND	/
J17.29	DGND	/
J17.28	DGND	/

J17.27	MCU_Usart1_RX	The communication signal of the main control board and the driver board
J17.26	MCU_Usart1_TX	
J17.25	DGND	/
J17.24	MCU_Usart3_RX	The communication signal of the main control board and the driver board
J17.23	MCU_Usart3_TX	
J17.22	DGND	/
J17.21	RS232_CPU_RX8	Bar code scanner communication signal
J17.20	RS232_CPU_TX8	
J17.19	DGND	/
J17.18	DGND	/
J17.17	DP3	USB3
J17.16	DM3	
J17.15	DGND	/
J17.14	DP4	USB4
J17.13	DM4	
J17.12	DGND	/
J17.11	LED0_PHYAD0	Network port indicator light
J17.10	LED1_PHYAD1	
J17.9	DGND	/
J17.8	RMII_RX_N	NET Differential Signal Line
J17.7	RMII_RX_P	
J17.6	DGND	/
J17.5	RMII_TX_N	NET Differential Signal Line
J17.4	RMII_TX_P	
J17.3	DGND	/
J17.2	DGND	/
J17.1	DGND	/

8.3.2 Driver board

Shown in the figure below is the diagram of the main control board of the Analyzer. It works as the control unit of the complete machine. The driver board is mainly composed of a stepper motor driver, UV lamp driver, fan driver, heating driver, temperature detection, optocoupler detection, connector adapter, and other interface circuits.

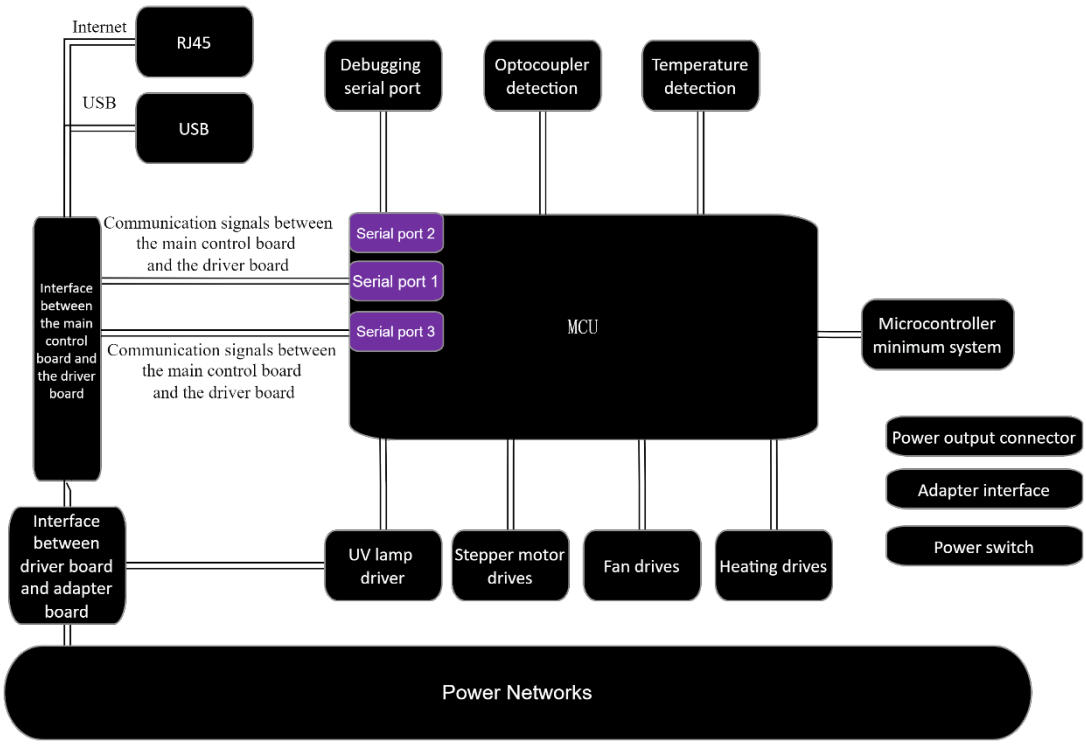


Figure 8-6 Driver board principle diagram

The symbols on it are shown in the following figure:

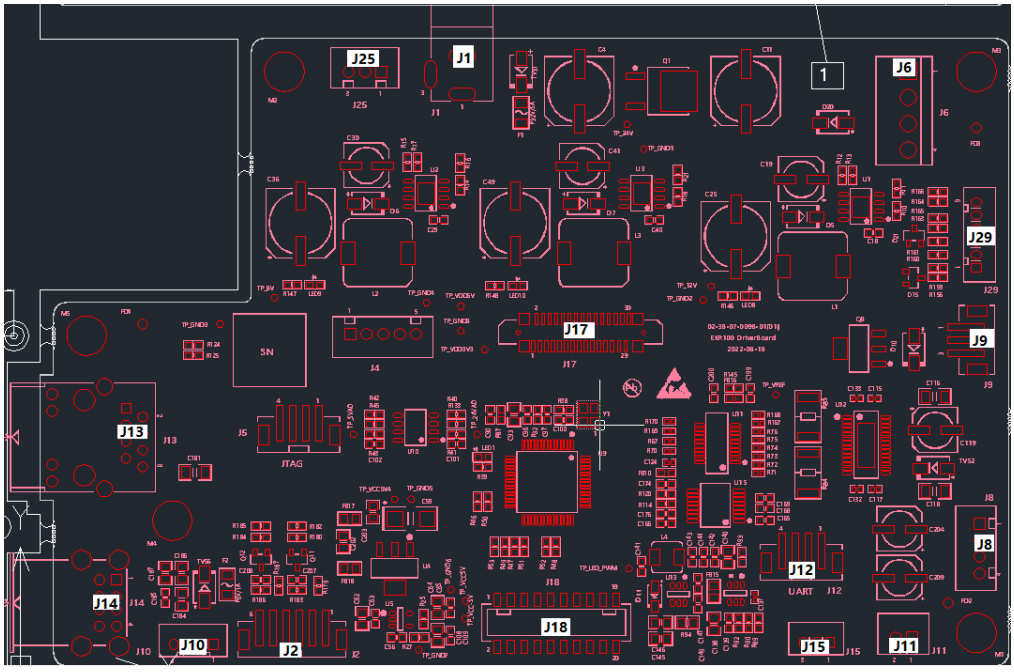


Figure 8-7 Driver board symbols

Plugin interface definition description:

J25 driver board power switch interface definition description		
Terminal number	Definition	Description
J25.1	Push Button	Power switch interface
J25.2	GND	
J25.3	GND	

J1 Driver board adapter interface definition description		
Terminal number	Definition	Description
J1.1	VDD_24V	Adapter power input
J1.2	GND	
J1.3	GND	

J6 Driver board and lithium battery charging board interface definition description		
Terminal number	Definition	Description
J6.1	VDD_24V	Driver board output to Li-ion battery board
J6.2	GND	
J6.3	VDD24V_IN	Lithium battery board output to driver board
J6.4	GND	

J29 driver board and lithium battery board communication interface definition description		
Terminal number	Definition	Description
J29.1	BAT_PG	Driver board and lithium battery board communication interface
J29.2	BAT_STAT1	
J29.3	BAT_STAT2	
J29.4	BAT_SCL	
J29.5	GND	
J29.6	BAT_SDA	

J9 driver board reserved fan interface definition instructions		
Terminal number	Definition	Description
J9.1	VDD_12V	Reserved fan interface
J9.2	FAN_FG	
J9.3	DrvFAN	

J8 driver board stepper motor interface definition description		
Terminal number	Definition	Description
J8.1	Motor_AOUT1	stepper motor interface
J8.2	Motor_AOUT2	
J8.3	Motor_BOUT1	
J8.4	Motor_BOUT2	

J11 Driver board heating interface definition description		
Terminal number	Definition	Description
J11.1	VDD_12V	Driver board heating interface
J11.2	Drv_Heat1	

J15 Driver board temperature detection interface definition description		
Terminal number	Definition	Description
J15.1	VDD3V3_SYS	Detection wire connection port
J15.2	MCU_DS18B20_1	
J15.3	GND	

J12 driver board debug serial port interface definition instructions		
Terminal number	Definition	Description
J12.1	RS232_MCU_TX2	Driver board debug serial port interface definition instructions
J12.2	RS232_MCU_RX2	

J12 driver board debug serial port interface definition instructions		
J12.3	GND	
J12.4	/	

J18 Driver board and adapter board interface definition description		
Terminal number	Definition	Description
J18.1	Light_VR_CS	Driver board and adapter board interface
J18.2	VCC5V	
J18.3	GND	
J18.4	VCC-5V	
J18.5	Light_SPI2_CLK	
J18.6	AGND	
J18.7	GND	
J18.8	VDD5V_SYS	
J18.9	Light_SPI2_MOSI	
J18.10	GND	
J18.11	Light_SPI2_MISO	
J18.12	VDD3V3_SYS	
J18.13	Light_N_DRDY	
J18.14	RS232_UART_TX8	
J18.15	Light_SPI2_CS	
J18.16	RS232_UART_RX8	
J18.17	Light_ADC_RST	
J18.18	GND	
J18.19	UV+	
J18.20	UV	

J2 driver board reserved interface definition instructions		
Terminal number	Definition	Description
J2.1	/	Driver board reserved interface definition instructions
J2.2	/	
J2.3	/	
J2.4	/	
J2.5	/	
J2.6	/	

J10 Driver board optocoupler interface definition description		
Terminal number	Definition	Description
J10.1	SENSOR1	Driver board optocoupler interface
J10.2	GND	
J10.3	SENSOR_LED1	
J10.4	GND	

J14 driver board USB interface definition description		
Terminal number	Definition	Description
J14.1	VBUS_USB	USB interface 1
J14.2	DM3	
J14.3	DP3	
J14.4	GND	
J14.5	VBUS_USB	USB interface 2
J14.6	DM4	
J14.7	DP4	
J14.8	GND	

J13 driver board USB interface definition description		
Terminal number	Definition	Description
J13.1	RMII_TX_P	
J13.2	RMII_TX_N	
J13.3	RMII_RX_P	
J13.4	TD_CT	
J13.5	RD_CT	
J13.6	RMII_RX_N	
J13.7	NC	
J13.8	GND	
J13.9	GREEN_LED+	
J13.10	GREEN_LED-	
J13.11	YELLOW_LED-	
J13.12	YELLOW_LED+	

8.3.3 Optical detection board

The following figure shows the principle diagram of the optical detection board of the Fluorescence Immunochromatography Analyzer. Its optical detection board converts the detected fluorescence signal to a digital signal and uploads it.

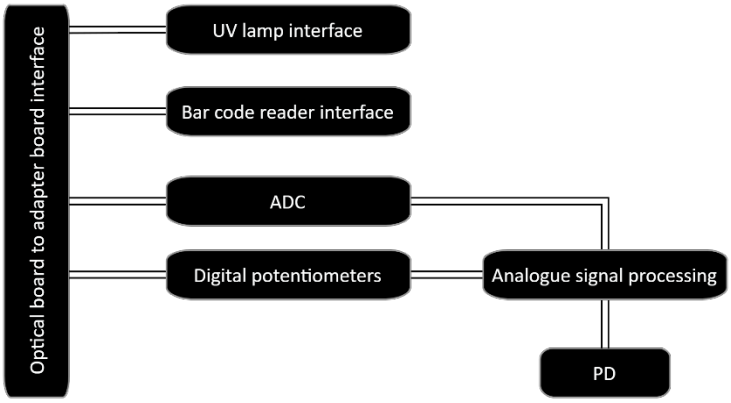


Figure 8-8 Optical detection PCBA principle diagram

Its PCB symbol is shown in the following figure:

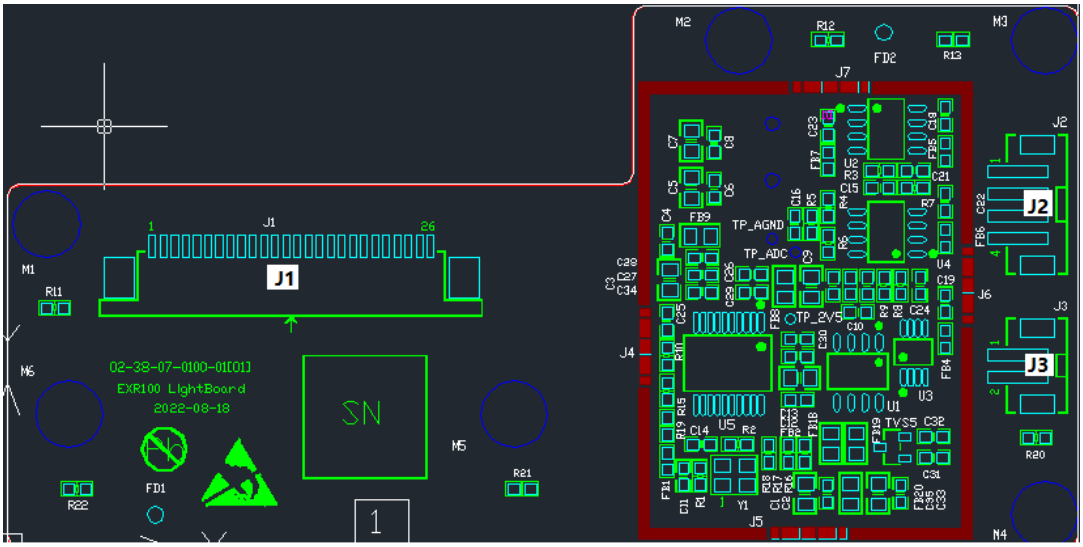


Figure 8-9 Optical detection PCBA symbols

Plugin interface definition description:

J1 optical detection board and adapter board interface definition description		
Terminal number	Definition	Description
J1.1	GND	Optical detection board and adapter board interface
J1.2	Light_SPI2_MISO	
J1.3	GND	
J1.4	Light_SPI2_MOSI	
J1.5	GND	
J1.6	Light_SPI2_CLK	
J1.7	GND	
J1.8	Light_VR_CS	
J1.9	GND	
J1.10	Light_N_DRDY	
J1.11	Light_SPI2_CS	
J1.12	Light_ADC_RST	
J1.13	GND	
J1.14	VDD3V3_SYS	
J1.15	VDD5V_SYS	

J1 optical detection board and adapter board interface definition description		
J1.16	GND	
J1.17	RS232_UART_TX8	
J1.18	RS232_UART_RX8	
J1.19	GND	
J1.20	UV+	
J1.21	UV	
J1.22	GND	
J1.23	AGND	
J1.24	VCC5V	
J1.25	VCC-5V	
J1.26	AGND	

J2 optical detection board UV lamp interface definition instructions		
Terminal number	Definition	Description
J2.1	VDD5V_SYS	Optical board barcode reader interface
J2.2	UVRS232_UART_RX8	
J2.3	RS232_UART_TX8	
J2.4	GND	

J3 optical detection board UV lamp interface definition instructions		
Terminal number	Definition	Description
J3.1	UV-	Optical detection board UV lamp interface definition instructions
J3.2	UV+	

8.3.4 Lithium battery charging pad

The following diagram shows the principle diagram of the Analyzer’ s lithium battery charging board, which can manage the charge and discharge of rechargeable lithium batteries.

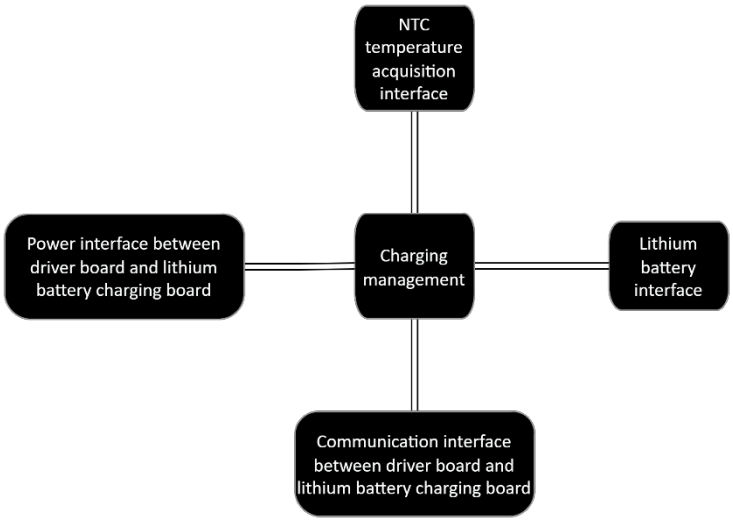


Figure 8-10 Lithium battery charging pad principle diagram

Its PCB symbol is shown in the following figure:

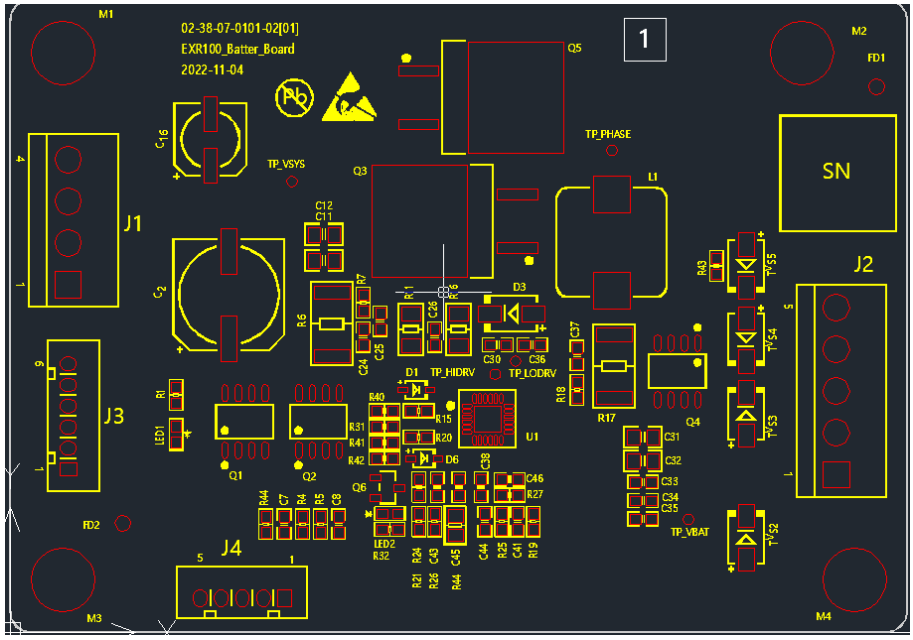


Figure 8-11 Lithium battery charging pad symbols

Plugin interface definition description:

J1 Driver board and lithium battery charging board interface definition description		
Terminal number	Definition	Description
J1.1	VDD_24V_IN	Driver board output to Li-ion battery board
J1.2	GND	
J1.3	VDD_SYS	Lithium battery board output to driver board
J1.4	GND	

J2 Driver board and lithium battery charging board interface definition description		
Terminal number	Definition	Description
J2.1	VBAT+	Driver board and lithium battery charging board interface
J2.2	BAT_SCL	
J2.3	BAT_SDA	
J2.4	BAT_NTC	
J2.5	GND	

J3 Driver board and lithium battery charging board interface definition description		
Terminal number	Definition	Description
J2.1	VBAT+	Driver board and lithium battery charging board interface
J2.2	BAT_SCL	
J2.3	BAT_SDA	
J2.4	BAT_NTC	
J2.5	GND	

J4 lithium battery charging board temperature detection interface		
Terminal number	Definition	Description
J4.1	/	Lithium battery charging board temperature detection interface
J4.2	GND	
J4.3	BAT_TS	
J4.4	GND	
J4.5	/	

8.4 Indicator light status of the PCBAs:

Name	Normal operation indicator status
Master control board	Voltage status indication • LED8 (8V) does not light up while start-up and is always on after start-up is completed; • LED9(5V) light always on when start-up; • LED10(3V3) light always on when start-up. • Core board Red light is always on, blue light flashes once a second.
Driver board	• LED8 (12V), LED9 (8V), LED10 (5V) always on when start-up (voltage status indication); • LED1 blinks once in 200 ms when starting and once per second when started (MCU working status indicator).
Lithium battery charging pad	• LED1 always on when connected to the adapter, LED2 on when charging; • LED1/ LED2 does not light up when not connected to the adapter.

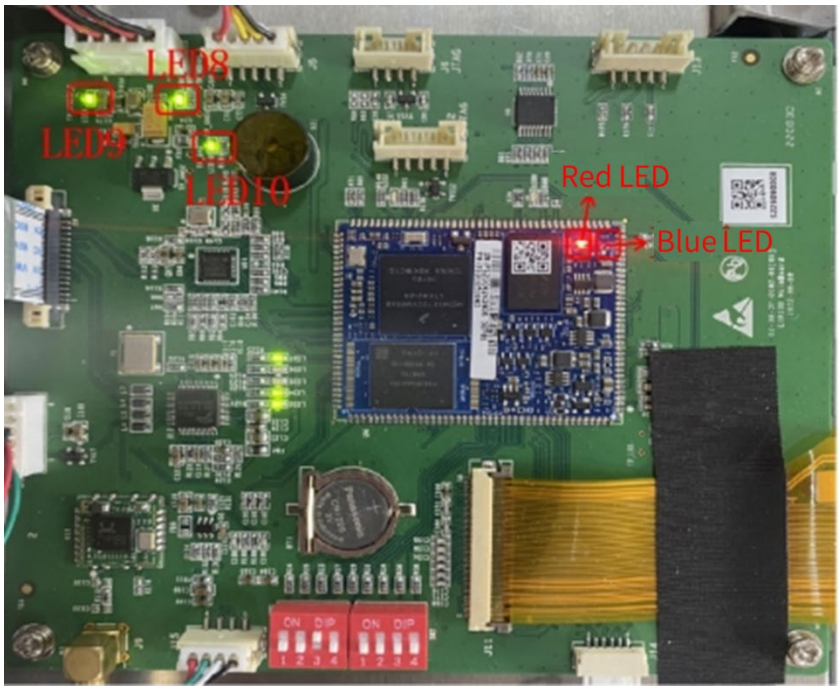


Figure 8-12 Master control board indicator light

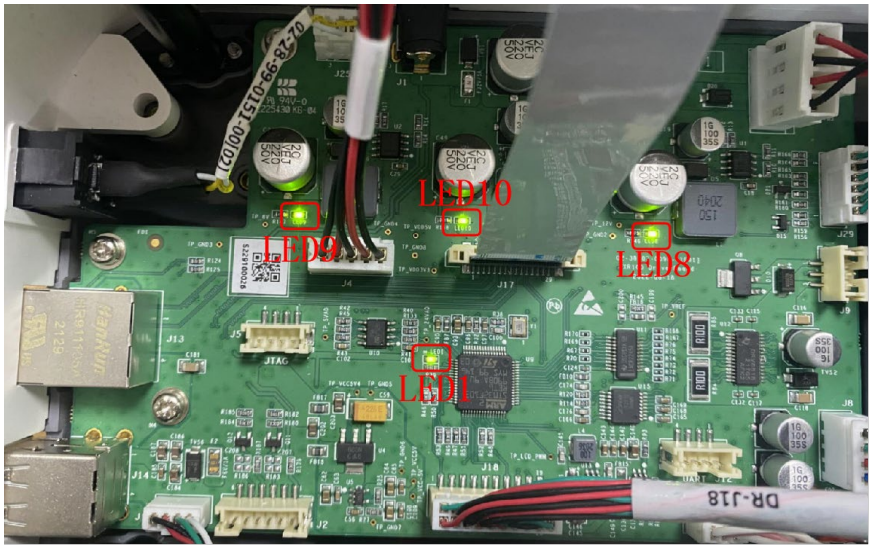


Figure 8-13 Driver board indicator light

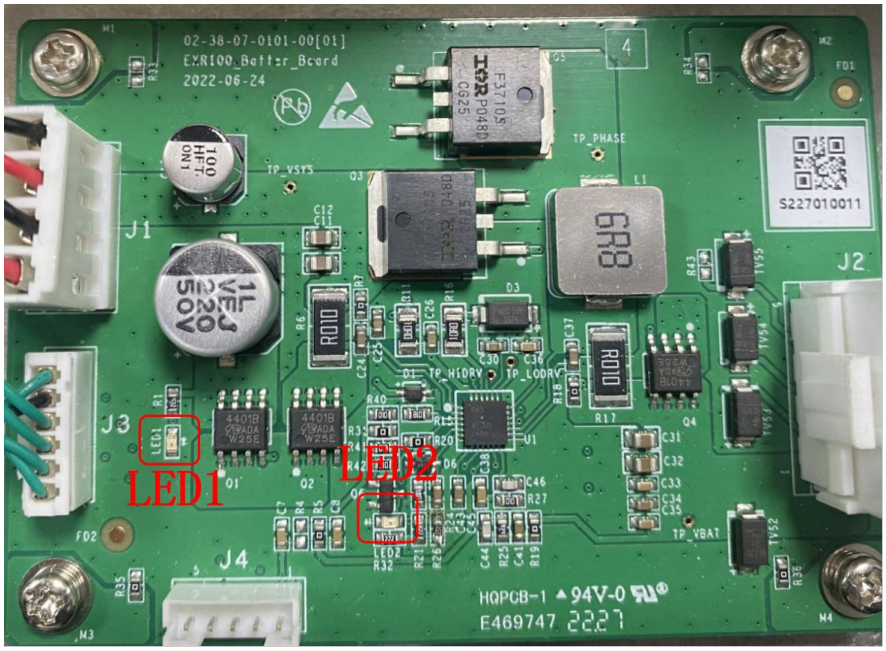


Figure 8-14 Battery board indicator light

9 Mechanical system

9.1 About mechanical system

The complete structure of the Analyzer is mainly composed of the following parts: top shell assembly, middle shell, bottom shell assembly, bottom board assembly, card compartment assembly, hardware boards, wires, etc.

9.2 Appearance:

The front view of the Analyzer is as shown in the figure below.

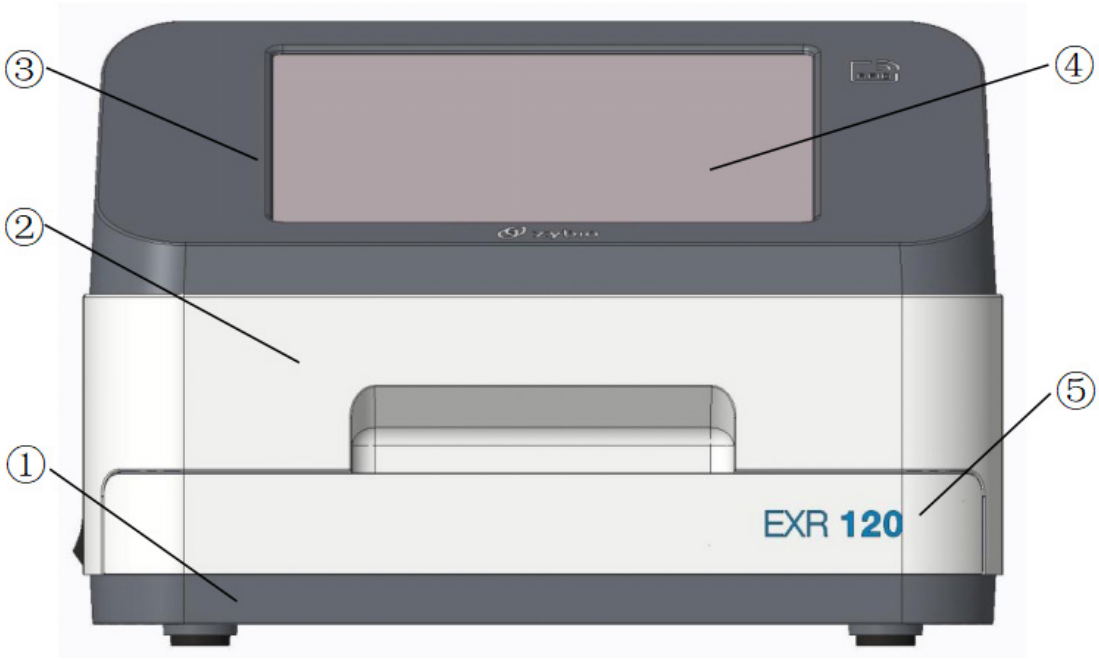


Figure 9-1 Front view

Parts breakdown:

No.	Name
1	Bottom panel assembly
2	Middle panel assembly
3	Top panel assembly
4	Monitor assembly
5	Card compartment exterior dressing part-EXR120

The back view of the Analyzer is as shown in the figure below.

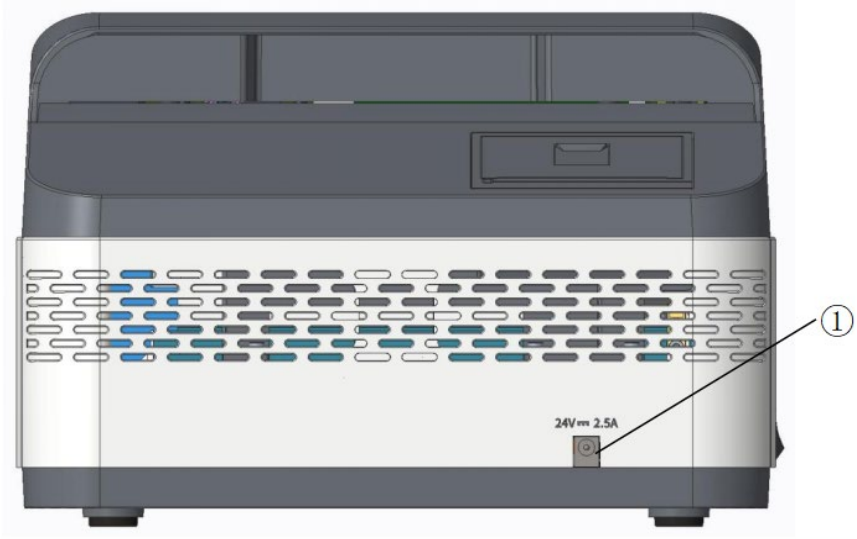


Figure 9-2 Back view

Parts breakdown:

No.	Name
1	Power interface

The left view of the Analyzer is as shown in the figure below.

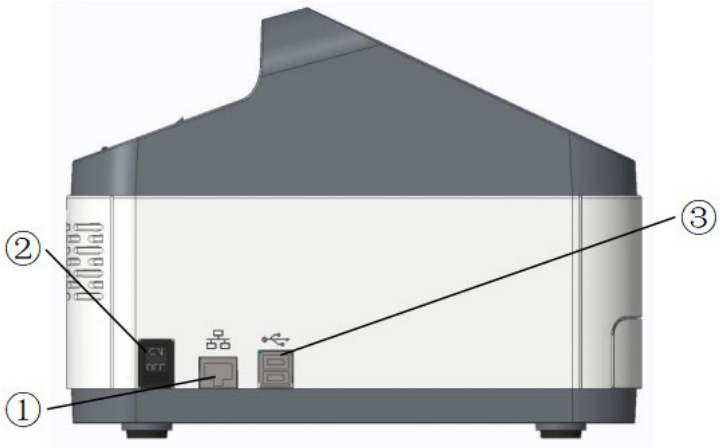


Figure 9-3 Left view

Parts breakdown:

No.	Name
1	Network interface
2	Switch
3	USB interface

The top view of the Analyzer is as shown in the figure below.

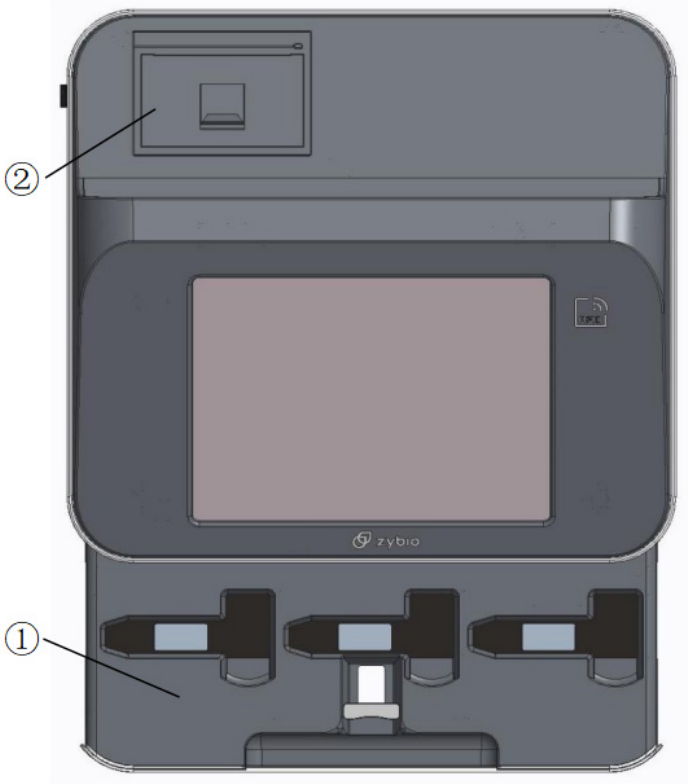


Figure 9-4 Top view

Parts breakdown:

No.	Name
1	Card compartment assembly
2	Printer

The bottom view of the Analyzer is as shown in the figure below.

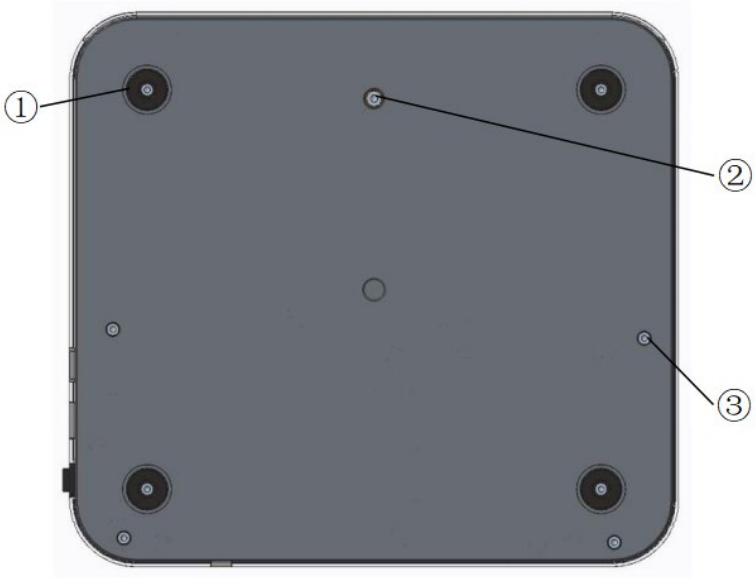


Figure 9-5 Bottom view

Parts breakdown:

No.	Name	Quantity	Remarks
1	Foot	4	/
2	Knurled hexagon socket cheese head screws	1	Remove after opening the box
3	Top shell fixing screws	4	Remove when dismantle top panel

9.3 Mechanical component structure

9.3.1 Top panel assembly

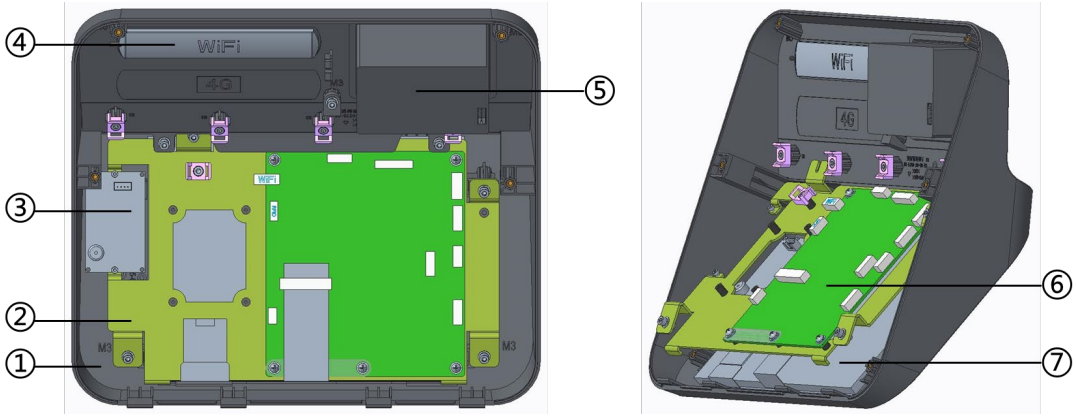


Figure 9-6 Exploded view of the instrument housing

Parts breakdown:

No.	Accessories name
1	Top panel assembly
2	Screen plate
3	RFID card reader
4	Wi-Fi module antenna
5	Thermal printer
6	Master control board
7	8 inch capacitive touch screen module

9.3.2 Bottom panel assembly

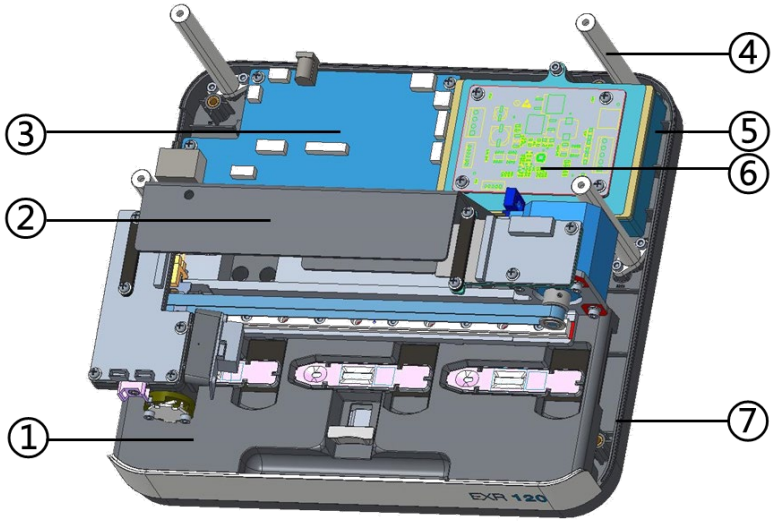


Figure 9-7 Bottom panel assembly

Parts breakdown:

No.	Accessories name
1	Card compartment assembly
2	Bottom panel assembly
3	Driver board
4	Top panel connection bar
5	Rechargeable lithium battery pack
6	Lithium battery charging pad
7	Bottom panel assembly

9.3.3 Bottom panel assembly

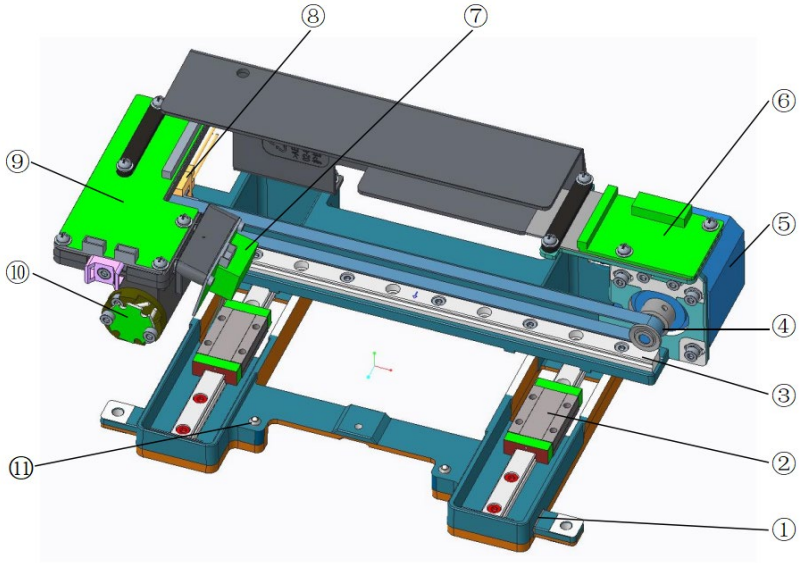


Figure 9-8 Bottom panel assembly

Parts breakdown:

No.	Accessories name
1	Motion component mounting base plate
2	Linear guide
3	Linear guide
4	Synchronous belt
5	42 stepper motor
6	adapter board
7	QR code scanner
8	Sensor
9	Optical PCBA
10	Outsourced terminal UV LED lamp aluminum substrate
11	Ball plunger

9.3.4 Card compartment assembly

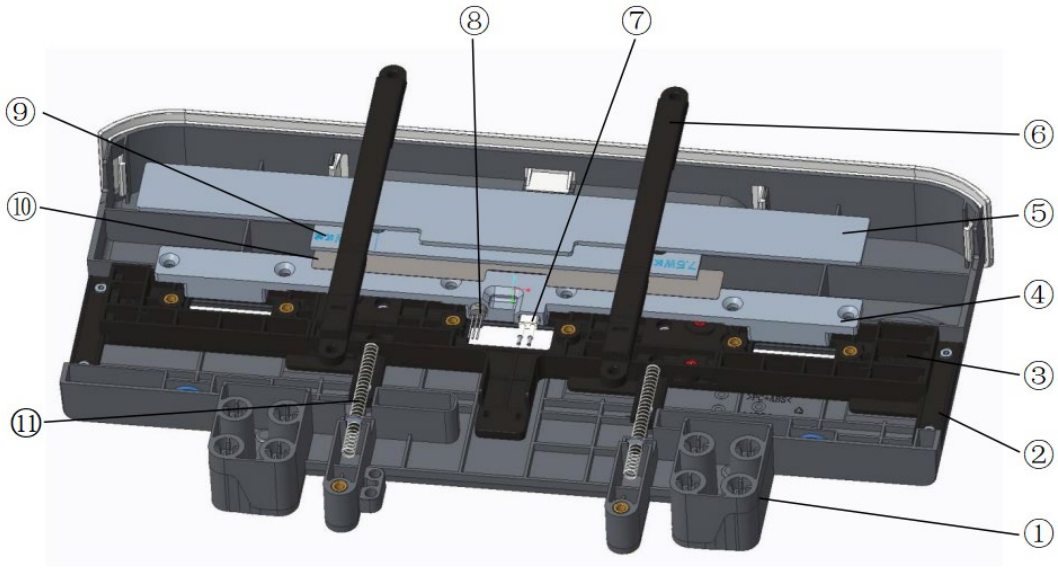


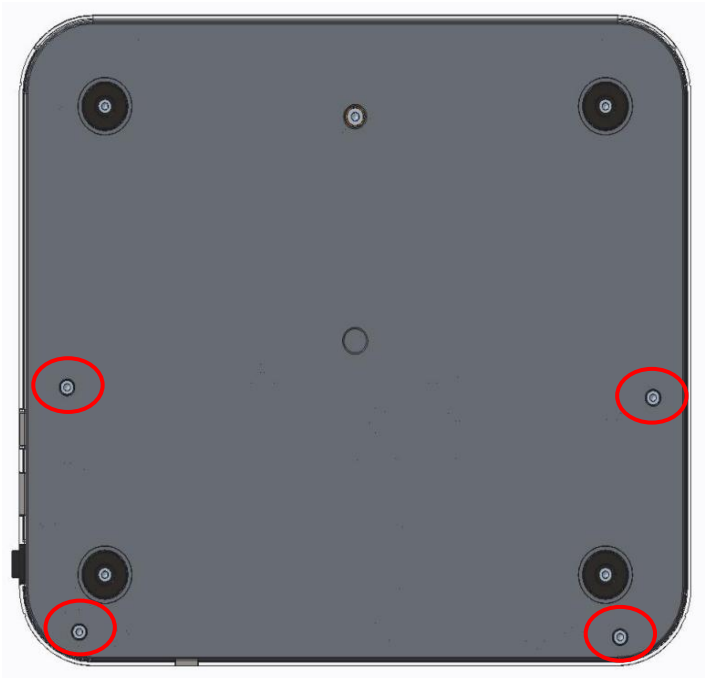
Figure 9-9 Explosion diagram of the card compartment assembly

Parts breakdown:

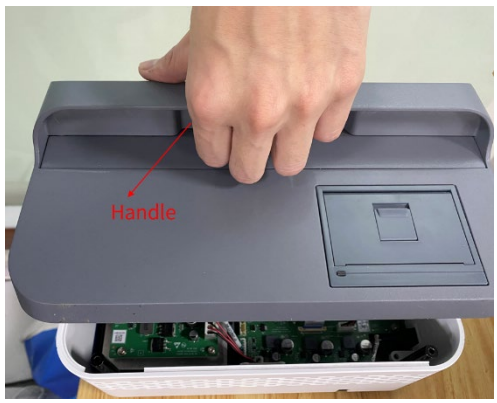
No.	Accessories name
1	card compartment
2	Temperature control component motion guide block
3	Temperature control component mounting plate
4	Incubation module heating plate
5	Heater insulation foam
6	Movement damping plate of the card compartment assembly
7	Temperature protection switch
8	Digital temperature sensor
9	Ceramic heating plate
10	Ceramic heating plate fixing adhesive layer
11	Temperature control assembly reset spring

9.3.5 Top panel removal

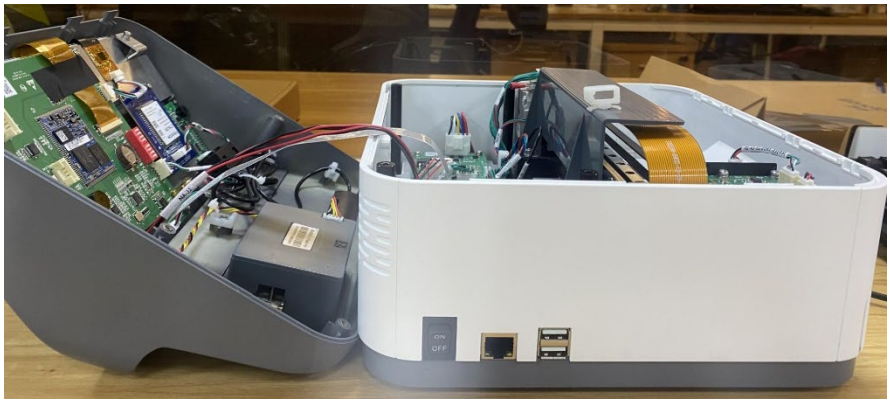
(1) Unscrew four M3*8 socket head cap screws from bottom to top.



(2) Hold the handle of the instrument and turn it counterclockwise on the axis of the front of the top panel.

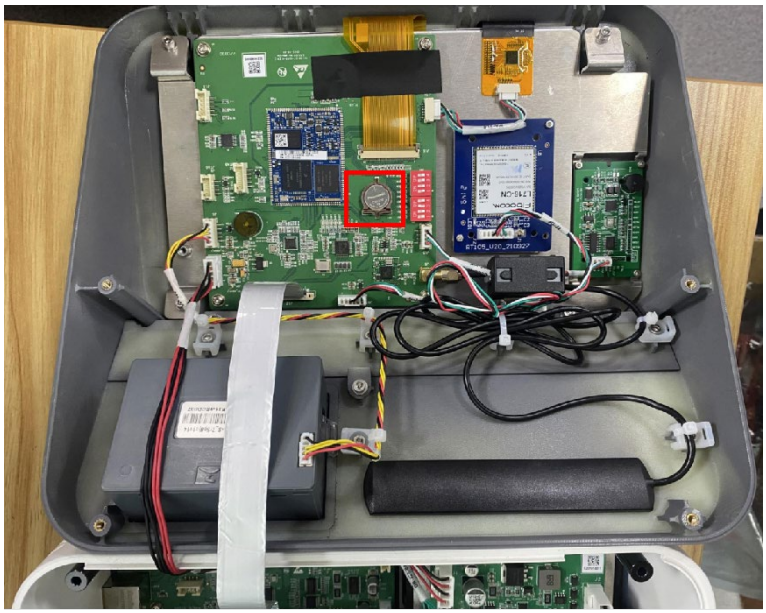


(3) Remove the upper case and place it in the following way, taking care not to tilt the top panel too much and pull the SZ18 main control board power input line and connection line of SZ18 main control board and driver FPC during the process.



9.3.6 Coin cell battery disassembly (mainly for customs inspection)

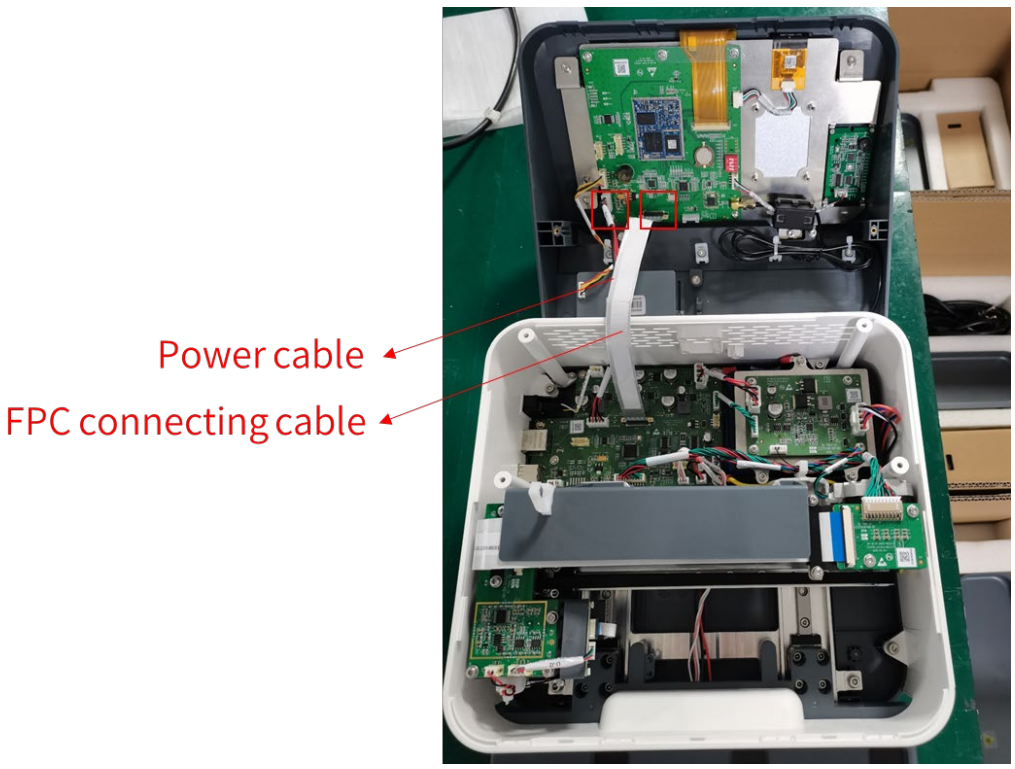
(1) After removing the top panel in accordance with section 9.3.5 above, you can observe the coin cell battery on the main control board in the following position.



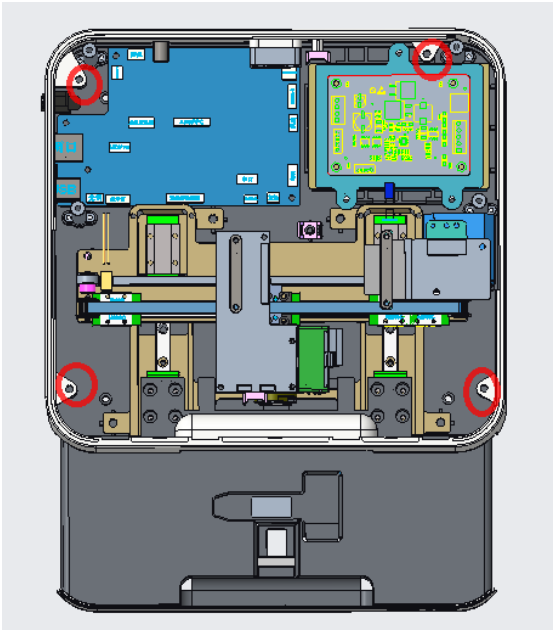
(2) The coin cell battery can be removed by toggling the lateral tab outward.

9.3.7 Middle panel removal

(1) Unplug the main control board power input cable and the main control board-driver FPC connection cable from the main control board.

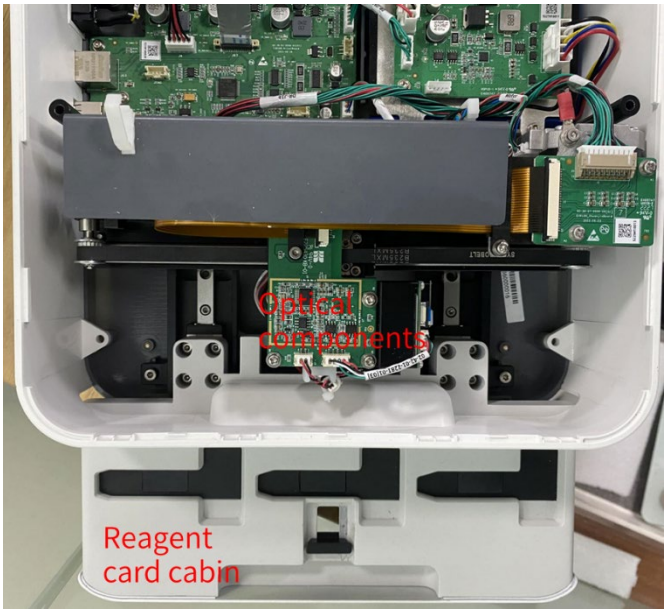


(2) Pull out the card compartment in order to unscrew the fixing screw of the middle panel.



(3) Unplug the J25 port switch connection cable.

(4) Make sure you have pulled out the card compartment. Remove the middle panel by moving the optical assembly to the center and then lifting the middle panel.



10 Optical system

This chapter introduces the information about the optical system, including the principle and composition of the optical system, identification of the optical system status, maintenance of optical system, and replacement of the optical system.

10.1 Principle of optical system

After antigen and antibody reactions are generated in the detection and quality control line areas of the reagent card, microsphere-antibody-antigen-antibody sandwich complexes are formed and immobilized, and detected by scanning the detection area with excitation light, and fluorescent nanospheres emit fluorescence on the detection and quality control lines. The concentration of the substance to be measured in the sample can be analyzed by detecting the fluorescence emitted by the photodetector.

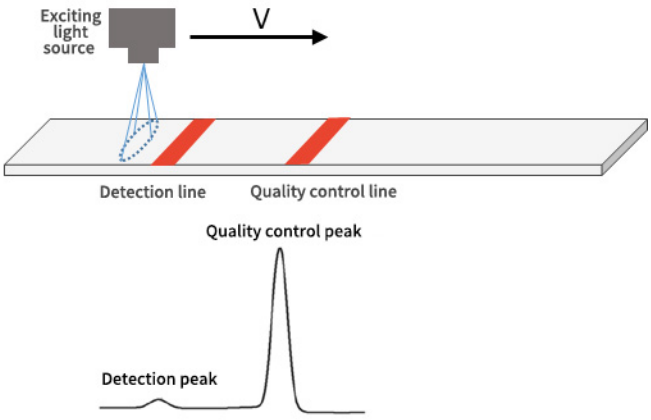


Figure Basic principle of optical system

10.2 Optical system structure

This section presents information related to the composition of the optical system, including a general introduction and an introduction to the core components.

10.2.1 General introduction

The optical system mainly includes light source driver and signal acquisition board, sealing foam pad, lens set module, and LED light source.

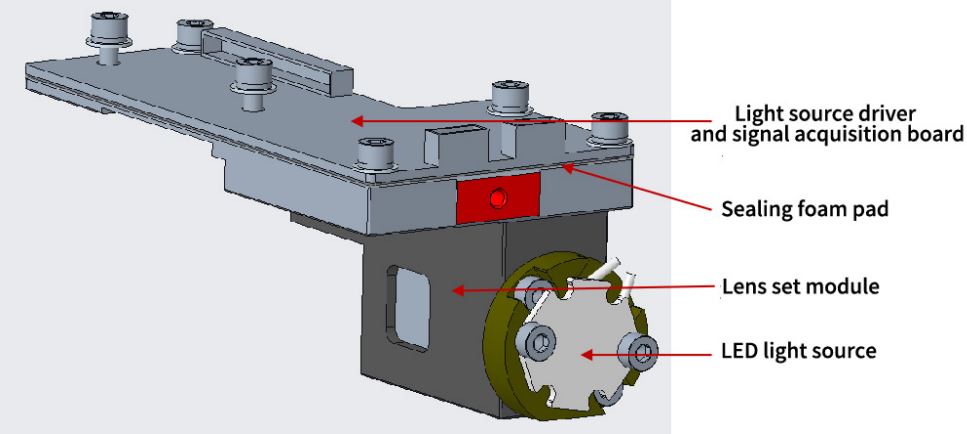


Figure Optical component structure

10.2.2 Introduction to the optical path of optical systems

The optical path in the optical system is shown as follows. The UV LED lamp emits UV light, which is shaped by the lens and diaphragm, and is reflected and focused on the test strip by the two-way beam splitter to excite fluorescence, and the red fluorescence is focused on the PD through the two-way beam splitter by the lens to collect the fluorescence signal.

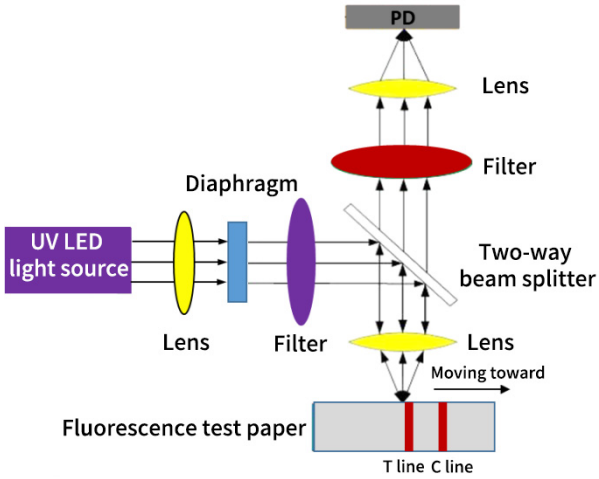


Diagram of the internal optical path of the lens assembly

10.3 Optical system maintenance and replacement

This section describes how to maintain and replace the optical system.

10.3.1 Precautions

Warning

- When touching the optical components in an emergency, touch the analyzer's door or metal grounding object with your hand to draw the static electricity away from your body.
- Do not use bare hands to directly touch the optical components, detector light-sensitive surface.
- The whole process should be careful of dust, oil and fingerprints contaminating the optics and PD photosensitive surface.

- When opening the instrument housing for optical system testing, the optical system should be shaded to prevent ambient glare from hitting the detector within the optical system.

Caution

- It is strictly prohibited to unplug the power cord of LED light source under charged condition.
- Be aware of UV radiation and do not look directly into the beam at any moment.

10.3.2 Optical system maintenance

10.3.2.1 LED maintenance

- **Steps**

(1) Check the internal wiring of optical system and if the laser path is blocked by wires;

(2) Check if the light source driver board is normal.

(3) If the light source driver board is confirmed to be damaged, the laser driver board can be replaced separately.

(4) If you confirm that the light source driver board is intact, and the LED light source does not light, you can replace the LED light source alone. At the same time, the light source brightness and gain need to be calibrated a second time.

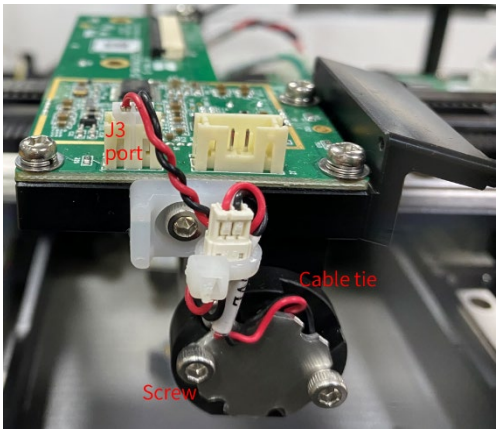
10.3.2.2 Lens maintenance

If the light spot morphology confirmation result is abnormal spot, the lens inside the lens assembly may be contaminated, use a dust-free cloth with anhydrous alcohol to gently wipe them. The method of wiping is: wipe from the center of the lens spiral outward (not recommended, the more you wipe, the greater the possibility of making it dirtier).

10.3.3 Replacement of optical system assembly

10.3.3.1 Replace the LED light source

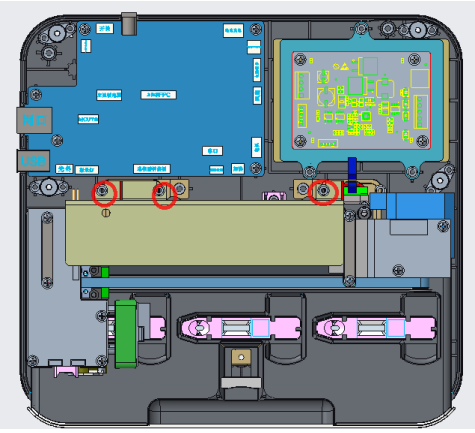
If the UV LED light source is determined to be faulty, it can be replaced. First, power off the instrument, then disassemble the top panel and the middle panel, cut the light source wire fixing tie, unplug the UV light source power supply interface J3, and use the hexagonal screwdriver to remove the LED light source from the module to replace it. You need to perform optical recalibration after replacing the light source.



a) light source

10.3.3.2 Replace the light source driver and signal acquisition board

If it is confirmed that the light source driver and signal acquisition board is faulty, it can be replaced. First, disconnect the instrument's power supply, open the top panel, take off the three M3 * 8 hexagonal combination of screws that fix the guard plate installed on the bottom, and then unplug all the interfaces on the board, and then unscrew the board and cable holding plate fixing screws, unplug the adapter plate and the optical board FPC connection cable on the board, replace the corresponding circuit board. Wear plastic gloves during the replacement process to prevent fingerprints, dirt pollute PD detection surface, if the board is removed after a long period of time without operation, the optical module detection light outlet should be covered with black tape or paper to prevent dust contamination of the lens. The light source driver and signal acquisition board should be rechecked or calibrated after replacement.

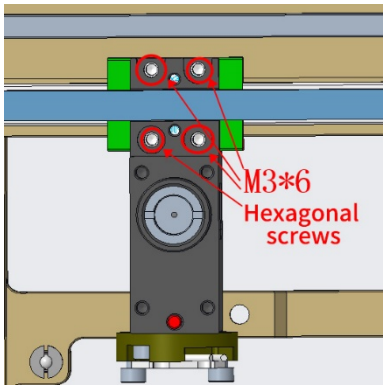


a) Wire guard fixing screw

b) Adapter board and optical board FPC connection cable

10.3.3.3 Replace the entire optical assembly

If it is confirmed that the optical lens set has failed, the entire optical assembly needs to be removed. First, disconnect the instrument's power supply, open the top panel, take off the three M3 * 8 hexagonal combination of screws that fix the Wire guard installed on the bottom, and then unscrew the board and wire plate fixing screws, unplug the adapter plate and the optical board FPC connection cable on the board. The optical module assembly can be removed by unscrewing the hexagonal screw that connects the optical assembly to the slide rail and synchronous belt. You can first gently shake the optical components to see if the internal lens is fixed properly. If there is a shaking sound, you can remove the circuit board and light source to fix screws with a flat-blade screwdriver. If there is no shaking sound, the cause needs further analysis. After replacing the entire optical assembly, the Analyzer needs to perform optical calibration.



a) Fixing screws

b) Fixing screws

Appendix Complete machine wiring diagram