Linkor Signature

Multifunction Analyzer

by immunEC

User Manual

This User Manual describes its main structure, performance, specifications, installation, use, operation, servicing, and maintenance, as well as the safety measures to protect both the Analyzer and its operator.

Before using the Analyzer, the user must read this User Manual carefully to thoroughly understand its operating steps, function, performance and maintenance steps in detail.

All schematic diagrams given in these User Manual are for reference only, which may be slightly different from the interface actually shown on the Analyzer.

Content

Foreword

Safety Symbols and Labels

Safety symbols and labels are provided to remind you of any potential hazards during the operation and shall be comprehended together with explanatory notes.

Symbol	Meaning
	Watch your hand
	Biohazard
SN	Analyzer serial number
	Manufacturer
	Warning - an important warning message reminding you that it is especially necessary to refer to the User Manual
	This side up: It indicates that the transport package shall be placed with this side up
	In vitro diagnostic device
	ON (master switch)
	OFF (master switch)
	Avoid sunshine: the transport package shall be kept away from direct sun exposure
	USB port
	RJ45 network port

Safety Precautions

Please read the following safety precautions carefully in order to use the an Analyzer safely and effectively. Any operation violating the following safety precautions may cause damage to the Analyzer or personal injury.

⚠ ***Notes:***

- Any operation of the Analyzer without following this User Manual of ImmunEC may cause the provided preventive measures to fail. Please check visually to see if the Analyzer is up to standard.
- Do not put the Analyzer in any place where it is difficult to operate its disconnecting device.

Precautions for Electricity

Please observe the following precautions in order to prevent electric shock.

- When the Analyzer's main power supply is on, it's forbidden to remove its housing by any unauthorized maintenance personnel.
- Solution spilling into the Analyzer may cause its failure and electric shock. Do not place any articles on the Analyzer. In case of spills, disconnect the power supply immediately and contact ImmunEC.
- Do not plug or unplug the power supply with wet hands.
- Disconnect the Analyzer with all power supplies before opening it for any adjustment, modification, maintenance or servicing.
- If the above operations are necessary, they must be done by personnel who understand the risks and are skilled in handling them.
- At any time, if the Analyzer is probably damaged, it shall be powered off immediately, with no other operation performed.

Prevention of fire and explosion

Please observe the following precautions in order to prevent fire and explosion.
Since alcohol is inflammable, it must be used with extreme care.

Prevention of biohazards

Please observe the following precautions in order to prevent biohazards.

- Incorrect use of samples may lead to infection. Do not touch samples with bare hands. Before the operation, be sure to wear gloves; if necessary, wear safety goggles.
- If the sample or mixture gets on your skin accidentally, please handle it immediately in accordance with the User Working Standards and seek medical advice.

Others

- If you have any doubt about the compatibility of the disinfectants or cleaning agents with the parts or materials contained in the equipment, please do not hesitate to contact ImmunEC.
- Do not use cleaning agents or disinfectants that will cause hazards by chemical reaction with the parts or materials contained in the equipment;

Linkor Signature
Multifunction Analyzer

1. Introduction

Linkor Signature Multi-function Analyzer is an in vitro diagnostic device. The analyzer is composed of a software operating system, optical unit, mechanical system and electronic system. Fully automated in sampling, diluting, testing, analyzing, reporting and printing, simulated and replacing manual operation, it not only improves the work efficiency but also reduces test error and improves the accuracy and precision of the test results. According to the principle of Lambert-Beer law, the Analyzer collects and analyzes the photoelectric signal of blood samples to quantitatively analyze the tangible components of human blood and provide relevant information. Meanwhile, it can be matched with specific dry reagents based on fluorescence immunochromatography and colloidal gold immunochromatography for quantitative analysis of the tested substance in human samples.

This manual explains the installation steps, operation instruction, maintenance and precautions. Please make sure you understand this manual before startup. The product is provided for qualified medical staff with professional experience or well-trained and ready for operation.

1.1 Application Range of Analyzer

The Analyzer is used in conjunction with appropriate reagents to analyze the analytes in human body samples quantitatively.

1.2 Analyzer Specifications and Performance Indicators

Items	Parameter
Language	Chinese, English, French, German, Italian, Spanish, Portuguese
Display	10.1" touch screen, resolution, resolution: 800*1280
WIFI	Meet IEEE 802.11b/g/n standards
Input power	AC 100-240V 50/60Hz
Overall Dimensions	350mm*400mm*450mm
Printer	Built-in thermal printer
Test module	CBC analysis + Fluorescence immunochromatographic analysis + Colloidal gold immunochromatographic analysis + Biochemical test module
Noise	≤65 dBA
Analyzer service life	8 years
Production date	See the label
Software version	V1.0

1.3 Test Principle

1.3.1 CBC Analysis

Linkor Analyzer uses a digital camera to obtain a magnified image of cells in the blood cell counting chamber, differentiate and count the cells. Then collect and analyze the photoelectric signal of the blood sample through the spectrophotometer method (also known as colorimetric method) based on the Beer-Lambert Law, to quantitatively analyze the visible components in human blood and provide related information.

Red blood cell test:

Parameter	Abbreviation	International Units	Reference ranges
Total white blood cells	WBC	10^9/L	3.50~9.50
Total neutrophils	NEU#	10^9/L	1.80-6.30
Total neutrophil cytoplasmic granulocyte	NST#	10^9/L	0.04-0.50
Total neutrophilic granulocytes	NSG#	10^9/L	2.00-7.00
Total neutrophilic pleomorphic granulocytes	NSH#	10^9/L	0.00-0.30
Total lymphocyte	LYM#	10^9/L	1.10~3.20
Total monocytes	MON#	10^9/L	0.10~0.60
Total eosinophils	EOS#	10^9/L	0.02-0.52
Total basophils	BAS#	10^9/L	0.00-0.06
Total abnormal lymphocytes	ALY#	10^9/L	0.00-0.20
Neutrophil cytoplasmic granulocytes percentage	NST%	%	0.000-5.000
Neutrophilic granulocytes percentage	NSG%	%	50.00-70.00
Lymphocytes percentage	LYM%	%	20.00~50.00
Monocytes percentage	MON%	%	3.00~10.00
Eosinophils percentage	EOS%	%	0.40~8.00
Basophils percentage	BAS%	%	< 1.00
Neutrophils-to-Lymphocytes Ratio	NLR	/	1.25 ~ 3.5
Systemic Inflammation Index	SII	/	< 520.00
Systemic Inflammatory Response Index	SIRI	/	<1 .10

White blood cell test:

Parameter	Abbreviation	International Units	Reference ranges
Red Blood Cells	RBC	10^12/L	4.30~5.80
Hemoglobin	HGB	g/dL	12 ~16
Hematocrit	HCT	%	40.00~50.00
Mean Corpuscular Volume	MCV	fL	82.00~100.00
Mean Corpuscular Hemoglobin	MCH	pg	27.00~34.00
Red Cell Distribution Width - Coefficient of Variation	RDW_CV	%	12.00~14.30
Red Cell Distribution Width - Standard Deviation	RDW_SD	fL	37.00~50.00
Reticulocytes Count	RET#	10(9) /L	24.00~84.00
Reticulocytes Percentage	RET%	%	0.5-1.5 Adults/Children : 0.5-1,5 Newborns :0.02-0.06

Platelet test items:

Parameter	Abbreviation	International Units	Reference ranges
Platelets	PLT	10^9/L	100.00~350.00
Platelets Distribution Width	PDW	fL	6.00~14.00
Platelets Aggregate Count	PAg#	10^9/L	0.00~0.00
Platelets Large Cell Count	P_LCC	10^9/L	13.00~130.00
Platelets Large Cell Ratio	P_LCR	%	12.00~45.00

1.3.2 Fluorescence Immunochromatographic Analysis (FICA)

FICA is an irradiation of the fluorescence triggered by the fluorescence module onto the fluorescent test strip, and a stimulation of the cured immune complex and formation of a reflected light. The data processing system calculates the concentration value after transferring fluorescence signals into digital signals. Move the test strip to collect the test peak and quality control peak at the fixed positions on the reagent card. Then, it calculates the peak height or area of these two peaks to get the content of the pending test substance.

Fluorescence immunoassay:

Test indicators (abbreviated as)	Results	International Units	Reference ranges
25-OH-VD	Quantitative	ng/mL	30.0-100.0

1.3.3 Dry Biochemical Analysis

It uses an LED light source, which illuminates the specified wavelength of light to the dry biochemically tested reagent card through the filter. The sensor converts the reflected light intensity of the tested reagent card into a photoelectric signal, which is then converted into the corresponding concentration value or threshold value through the calibration information. Finally, it analyzes the measured object.

Biochemical testing items:

Test indicators (abbreviated as)	Results	International Units	Reference ranges
Glu	Quantitative	g/L	0.70～1.10
TG	Quantitative	g/L	< 1.50～1.70
TC	Quantitative	g/L	< 2.00
HDL-C	Quantitative	g/L	0.40～0.80
LDL-C	Quantitative	g/L	< 1.60

1.4 EMC Requirements

This equipment complies with the emission and immunity requirements of the GB/T 18268.1-2010 and GB/T 18268.26-2010.

1.5 Network Security Instruction

Data Interface: The analysis system is provided with a USB port and a wired network interface, which are compatible with the TCP/IP protocol and the USB 2.0 protocol.

User Access Control: Users are requested to enter the access passwords to operate the communication and maintenance of the Analyzer.

1.6 Contraindications: No.

2. Installation

2.1 Out-of-Box Audit (OBA)

Do not use a blade to open the box to prevent scratching the outer surface of the Analyzer. Lift the outer box upward, remove the sealing tape, open the package, and remove the Analyzer main unit and accessories.

Test Content

Please check if any accessory is missing in accordance with the Analyzer's packing list if all items are consistent with the packing list, and if the Analyzer or its accessories are damaged.

2.2 Storage and Transportation Conditions and Operating Environment

Storage and Transportation Conditions

Ambient temperature: 20°C - 55°C.
Ambient humidity: below 85%.

Operating Environment

The Analyzer shall be installed and operate in the following operating environment:

- The installation environment shall be as free of dust, mechanical vibration, pollution, loud noise sources, and electromagnetic interference as possible.
- It has to be used indoors in a place with good ventilation and away from direct sun exposure or contact with heat source or wind sources.
- Ambient temperature: 10°C - 30°C.
- Relative humidity: 20% - 80%.
- Power Requirements: The Analyzer is subject to functional grounding and the power socket must be well grounded. Make sure that the input voltage meets the requirements before powering the Analyzer on.

	Voltage	Electric current	Frequency
Input	220V AC	1.2A	50Hz

2.3 Analyzer Installation

1) Place Linkor Signature Analyzer on workbench
2) Connect the power adapter to the power cord
2) Plug the power adapter into the DC power port at the rear of the Analyzer
4) Connect the power cord to the network power supply that meets the requirements.

Installation of Printing Paper

1) Open the back housing of the printer of the Analyzer outward
2) Pull the door handle outward to open the upper housing of the printer
3) Take out the printing paper and then put it into the paper channel
   Take care to keep the thermosensitive side of the printing paper facing up
4) Pull out the printing paper a little from the upper cover of the printer and the paper outlet on the back cover of the printer, and close the upper cover of the printer.

2.4 Outline and Structure

Linkor Signature Analyzer is mainly composed of a main unit and a power adapter. It comes with a black ImmunEC tray for reagents' disposal.
The main unit consists of a integrated module of fluorescent vision, microcamera module, photovoltaic module, high-precision X/Y mobile platforms, automatic sample-loading module, display module, print module, measurement analysis module, systems software and power system.

Outside view of
Linkor Signature Analyzer

Structure Description

No.	Name	Function
1	Light source module	To provide a light source for the camera
2	Microimaging module	To realize the movement of the microimaging component, as well as the guiding function and microimaging function
3	Traditional imaging module	To realize the shotting and transfer of visible images at a traditional viewing angle
4	Pipette module	To realize the pipetting, mixing and transfer functions of samples
5	Housing display module	Analyzer housing and touch screen
6	Main control module	Main controller circuit to realize overall machine control
7	Optoelectronic reading module	To realize the optoelectronic test and reading functions for hemoglobin
8	DC port	RJ45 port is used to connect the network cable
9	USB port	to connect the printer or other external devices such as U-disk

2.5 Start-up

After proper Analyzer installation, turn on the rocker-type power switch at the rear of the Analyzer to start it.
If the Analyzer is stopped with the start/stop button and the rocker-type power switch has not been turned off, it can be started by long pressing the start/stop button.

First start

1) Plug the power adapter into the DC power port at the rear of the Analyzer and connect it to power supply.
2) Switch on the machine by pressing the power switch at the back
3) A window opens for language selection. Select the desired language.
4) A window opens for time and date settings.
5) Connect with the following account :
   ID : immunec
   Password : linkor
6) A window open for an update, click on “Update now”.
7) Once update is done, the machine restart.

It is now ready for use.

2.6 Shutdown

1) Turn off the rocker type power switch at the rear of the Analyzer to disconnect the power supply
2) Unplug the power cord.

3. Basic Software Functions

3.1 Description of Start-up/Shutdown Menus

Start Up Interface

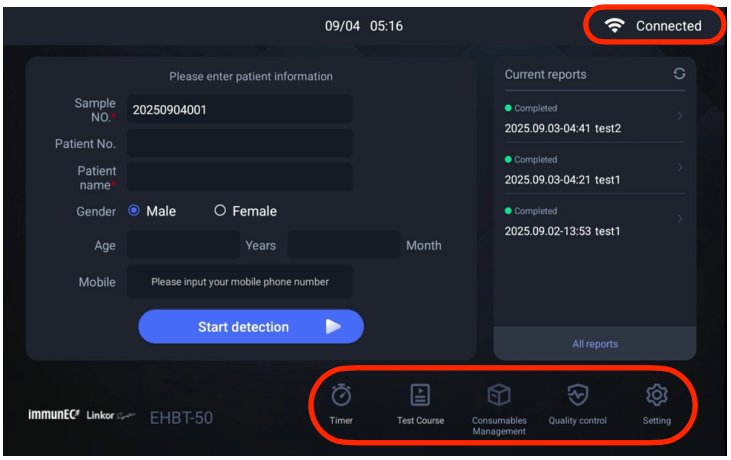
Boot & Initialization Interface

3.2 Operations on the Settings Menu

Home Page

Click the corresponding positions on the screen to enter fhe following sub-menus :
“Start detection”
“Timer”
“Test Course”
“Consumables Management"
“Quality control"
“Setting”

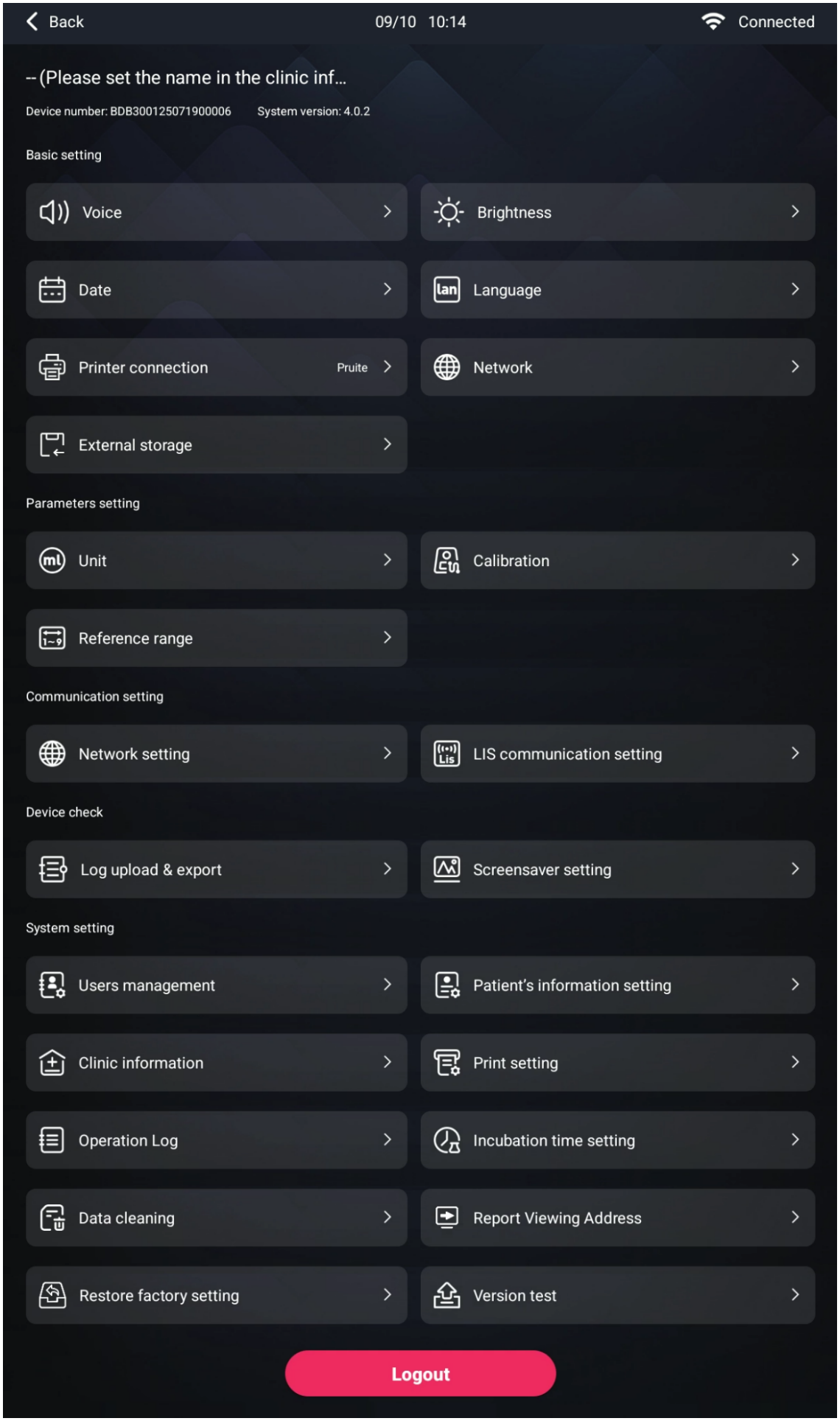
The Analyzer's network connection state is shown on the page's top right
(an icon for network connected/disconnected is shown depending on the current network connection state).



Home Page

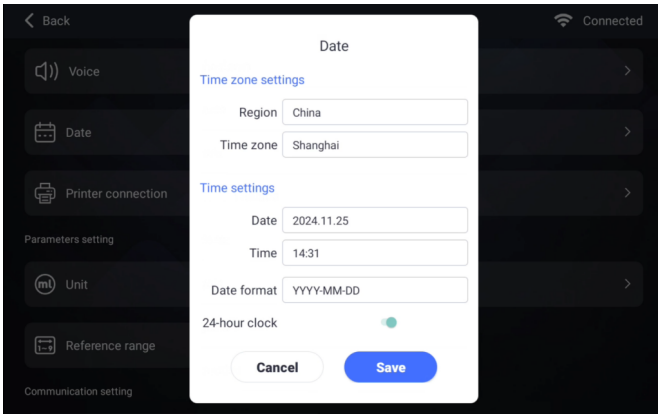
Setting Menu

Click the corresponding positions on the screen on this page to select:
Basic settings : “Voice” - “Brightness” - “Date” - “Language” - “Printer connection” - “Network” - “External storage”
Parameters settings : “Unit” - “Calibration” - “Reference range”
Communication settings : “Network Setting” - “LIS communication setting”
Device check : “Log upload & export” - “Screensaver setting”
System setting : “Users Management” - “Patient’s Information Setting” - “Clinic Information” - “Print Setting”
“Operation Log” - “Incubation time setting” - “Data cleaning” - “Report Viewing Address”
“Restore factory setting” - “Version test”

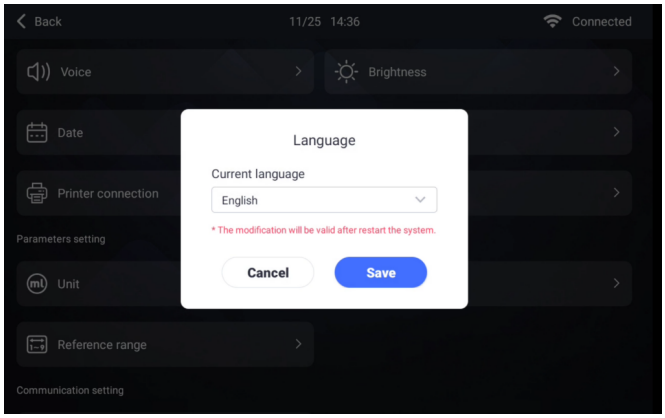

Back
09/10 10:14
Connected
-- (Please set the name in the clinic inf...
Device number: BDB300125071900006
System version: 4.0.2
Basic setting
Voice
Brightness
Date
Language
Printer connection
Pruite
Network
External storage
Parameters setting
Unit
Calibration
Reference range
Communication setting
Network setting
LIS communication setting
Device check
Log upload & export
Screensaver setting
System setting
Users management
Patient's information setting
Clinic information
Print setting
Operation Log
Incubation time setting
Data cleaning
Report Viewing Address
Restore factory setting
Version test
Logout

3.2.1. Basic Setting

- Click “Voice” to adjust the volume level by dragging its corresponding slider on the screen.
- Click “Brightness” to adjust the brightness of the display by dragging its corresponding slider on the screen.



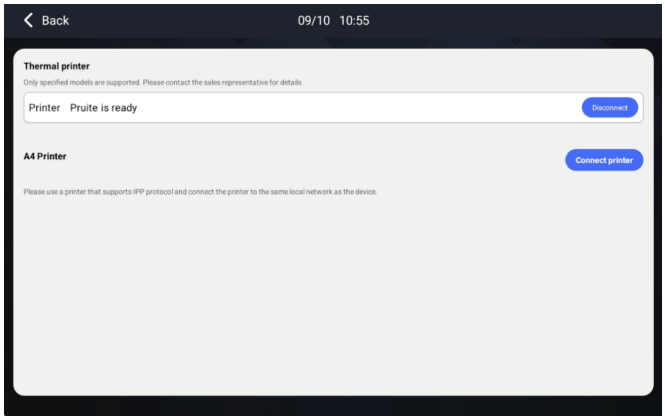
“Date” setting
You can set the date, time, time display format and date display format.
This time setting will influence the report display time.



“Language” setting
You can select the machine language among Chinese, English, French, German, Italian Spanish & Portuguese.

“Print Connection” setting
Click the “Connect Printer” button to enter the “Connect Printer” page

“Printing device” refers to the device that can be queried nearby and identified as being available for printing.

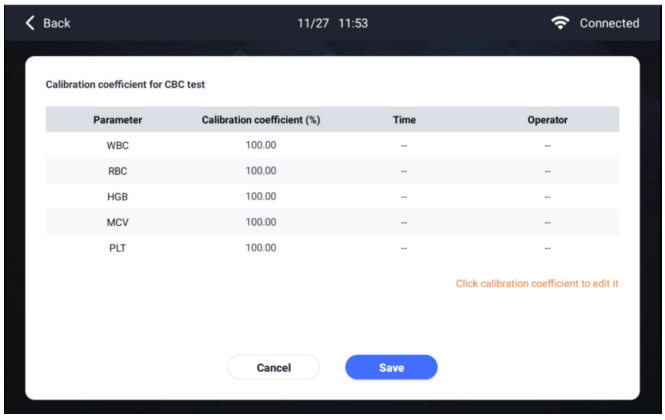


- Click “Back” to return to the Home Page.
- Click “Logout” to log out of the current account. It will skip back to the “Login Page”.

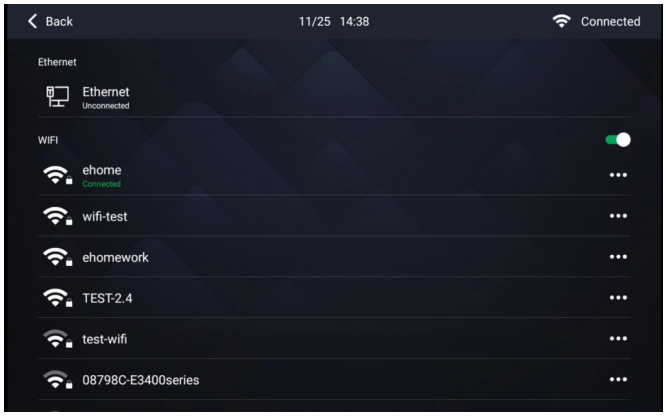
3.2.2 Parameters setting

“Calibration” setting
This page displays the blood routine's calibration factor. It includes the parameter, calibration factor, time, and operator. The initial calibration factor is 100%, and the boxes of time and operator display “–“ by default.

You can edit the value by clicking "Calibration Coefficient”. The edited calibration factor will take effect after being saved by clicking the "Save" button. The equipment will process the test results according to the new calibration factor.



3.2.3 Communication setting

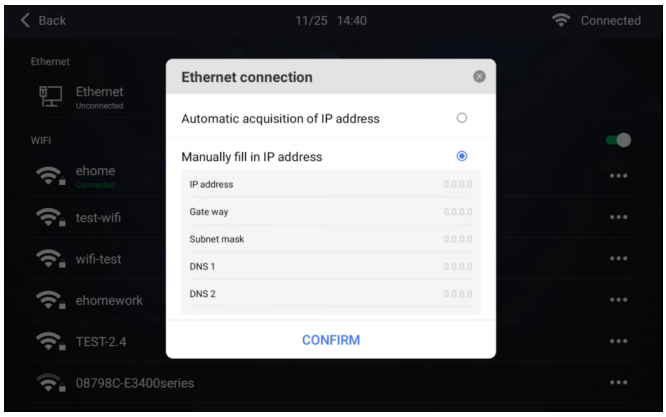


“Network setting”

[Ethernet Connection]: Click Ethernet on the top to modify the wired network connection mode.
Connection via a network cable is available, and network configuration can be adjusted by clicking.
When the network cable is connected on the back of the Analyzer, "Connected" will be displayed on the Ethernet.

[WIFI]: Select a wireless network to connect, and click “ON/OFF” on the right to turn on or off the wifi connection. After turning on the switch, the interface displays all the wireless network names that can be searched, and you can select any wifi to connect.
By clicking “… (More)” on any wireless network, you can select to connect/disconnect and cancel, saving the network.

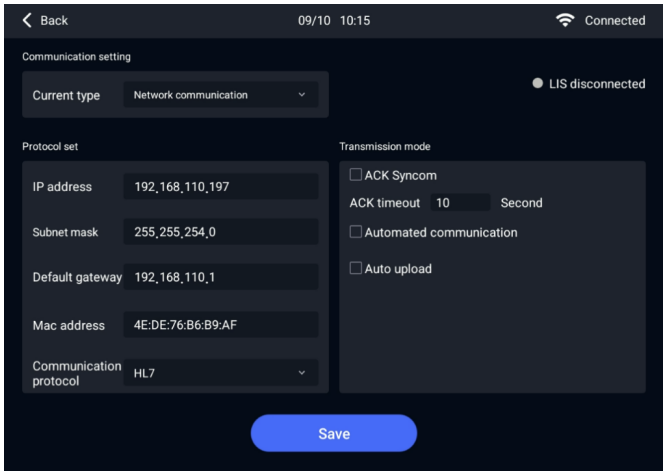
“Ethernet Connection” menu



[Automatic Acquisition of IP Address]:
With this option checked, an IP address of the Ethernet to which the Analyzer has been connected will be automatically acquired via Android, which is unmodifiable. “Automatic Acquisition of IP Address" is selected by default.

[Manually Fill-in IP address]:
With this option checked, the following information needs to be filled in manually to adjust the IP address of the Ethernet to which the Analyzer has been connected.

“LIS Communication Setting” menu



Click “LIS communication setting” to set the IP address.

[IP address]: Click the text box on the right, then enter the IP address on the pop-up keyboard.

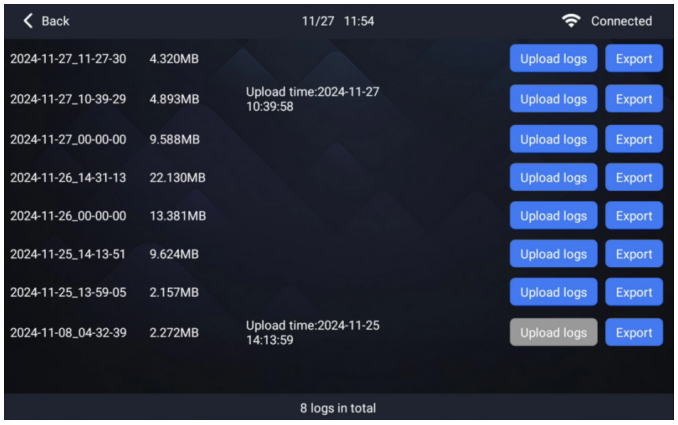
[Subnet mask]: Click the text box on the right, then enter the subnet mask on the pop-up keyboard.

[Default Gateway]: Click the text box on the right, then enter the default gateway on the pop-up keyboard.

[Mac Address]: Click the text box on the right and enter the domain name on the pop-up keyboard.

Click “Save” to save and make the above settings valid.

3.2.4 Device check setting



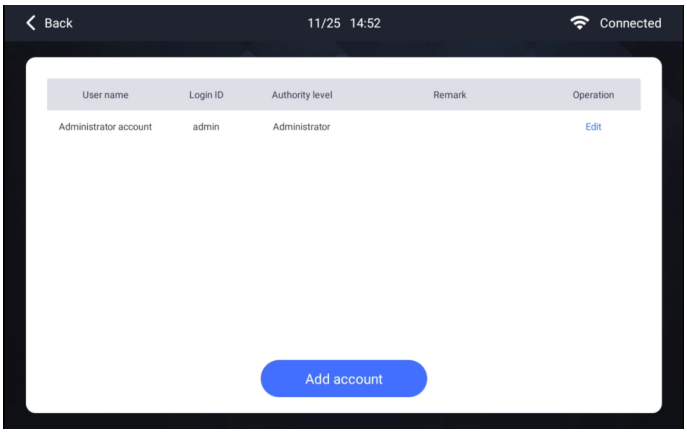
“Log upload & export”

The running log of equipment will be saved daily and can be uploaded manually.

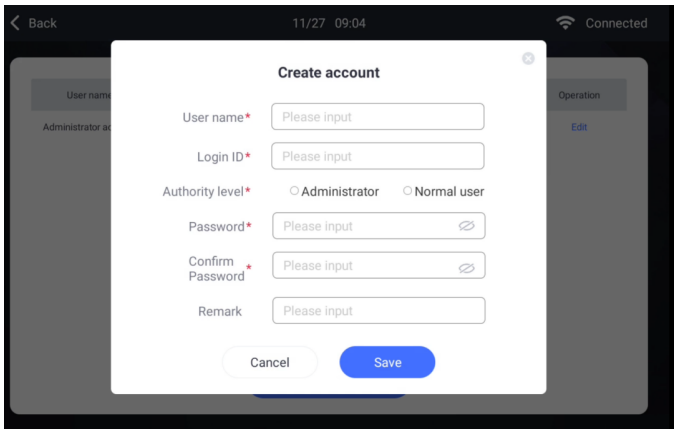
“Upload Log” means that the log record generated in the current day is uploaded to the management background.

3.2.3. System Setting

"User Management" setting



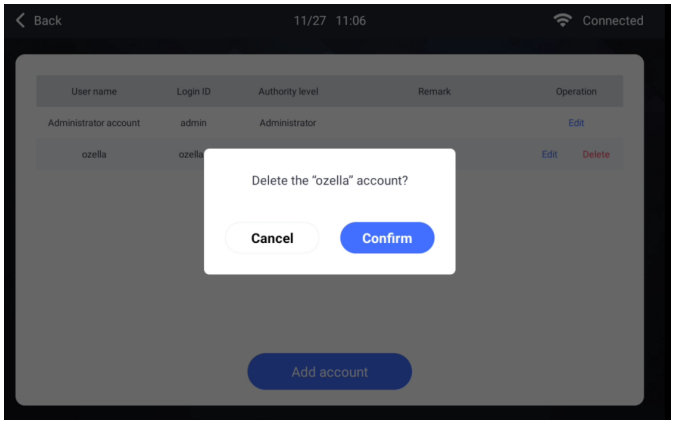
The user management list will display the account information for logging in to the Analyzer, including the account user's name, account number, access level and remark.



By clicking the "Add account" button, a window will pop up.
You can edit the user's name, login account, access level, password, and remarks.

Click the "Edit" button at the end of each record to edit the information of the account.
Click the "Delete" button at the end of each record to delete the account.
You can delete the account by clicking the "Confirm" button in the confirmation box for deleting.

The admin account cannot be deleted.

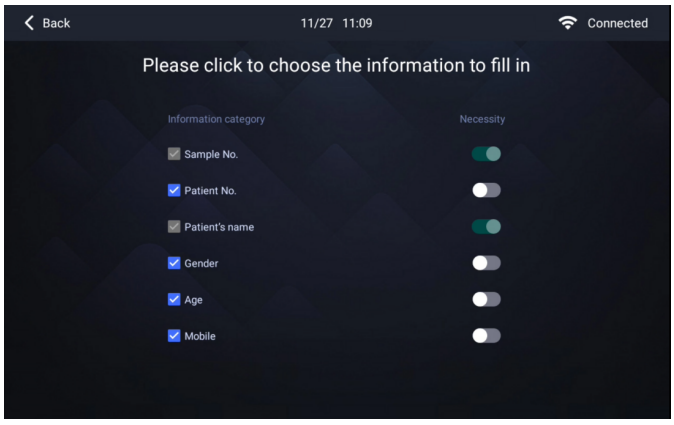


Access Description:
You can operate all the functions of the Linkor Analyzer through the administrator account.
The general user has the same access to the functions as the administrator except that he cannot operate the "Restore Factory Setting", "Edit Clinic Information", "Data Deletion," and "Equipment Calibration" modules in the "Setting" Menu.

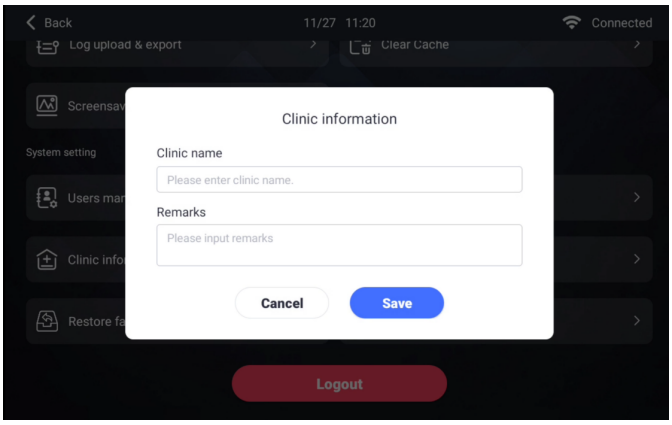
"Patient's Information" setting
This page will display the patient's information list.
The patient's information list contains six items:
Number - Name - Gender - Age - Mobile Phone Number

You can control if the entry box is displayed when entering the patient's information by checking the checkbox at the beginning of each information line.

You can control whether each selected option is a required option with the "Required or not" switch.

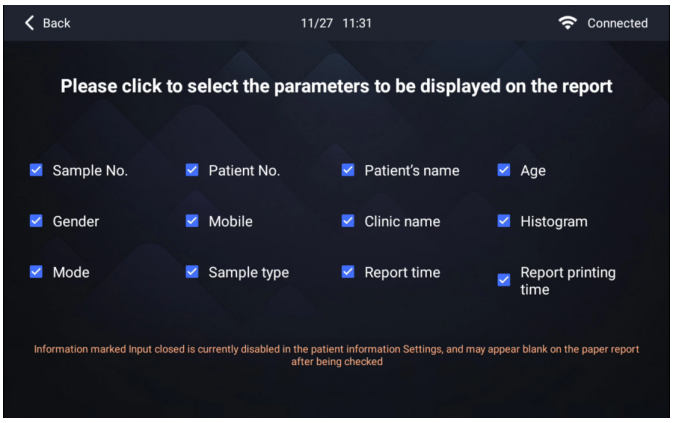


The number, gender, and age are checked and required by default and cannot be unchecked by the user but can be released from the required item. The patient's name is checked by default and cannot be unchecked by the user but can be released from the required item. These operations take immediate action.



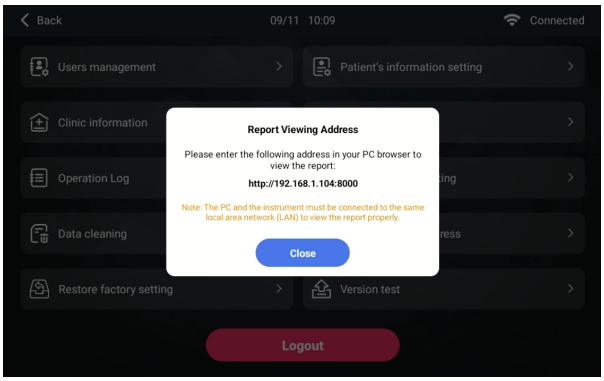
“Clinic Information” setting

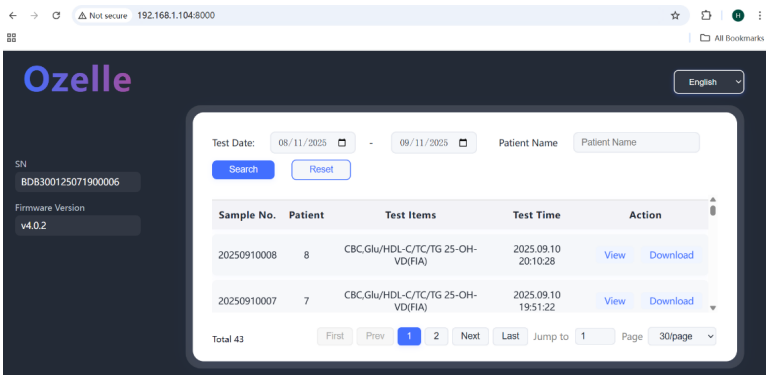
Enter this menu to modify the current clinic's name.
This may affect the institution displayed on the report.



“Print Setting”

Click to check/uncheck check boxes which information needs to be displayed on the printed report.
Unchecked information will not be displayed on the report.





“Report Viewing Address” setting

The “Report Viewing Address” window will pop up.
Enter the address in you PC browser to view the report.
Note: PC and Analyzer must be connected to the same local area network (LAN) to view the report properly.

“Version test” setting

The “Version Upgrade” window will pop up

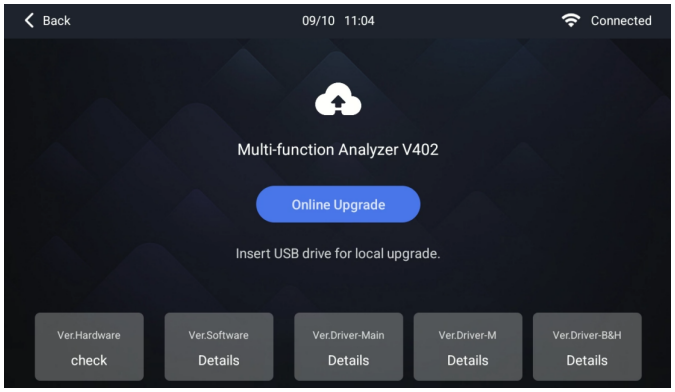
Click “Online Upgrade” to upgrade online.
In this case, the Analyzer must be connected to internet.

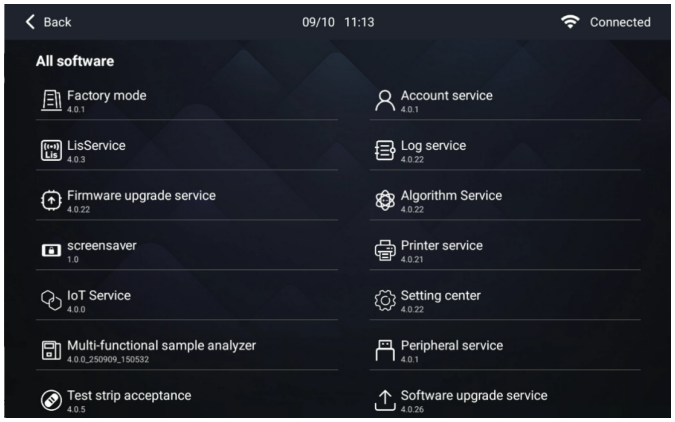
“Hardware Version” : Current Hardware version

“Software Version”: Versions of the current Analyzer's software, in detail, one by one.
All software versions include: "Factory Mode", "Account Service”, "LisService", "Log Service", "Firmware Upgrade Service", "Algorithm Service", "Screensaver", "Printer Service”, "IoT Service", "Setting center", "Multi-functional sample Analyzer”, "Peripheral service", "Test strip acceptance" and "Software Upgrade Service", 14 in total.

“Driver Version”: Versions of the current Analyzer's drivers. Click to check the versions of the main control board drive and motor drive.

Click “Restore Factory Setting” to restore the current Analyzer to its ex-factory state.





3.3. All reports

All reports are shown by clicking “All reports” button on the home menu.

Click "DD/MM/YYYY filter" to select the start and end date of the period to be searched in the input box to the left and right of the timebar. You can now filter the test records based on such a period.

Click Search Box of "Patient Name" to enter the name, then click on the search box on the right to query corresponding test records based on the name entered.

“Print status”: Refers to print is ready or not.

“LIS status”: Refers to reports is uploaded to LIS or not.

“Patient Name”: Refers to the patient's name filled in during the test.

“Parameter”: Refers to the name of the test item recorded in this test.

“Report time”: Refers to the time of the current test in the format of YYYY/MM/DD hh: mm: ss.

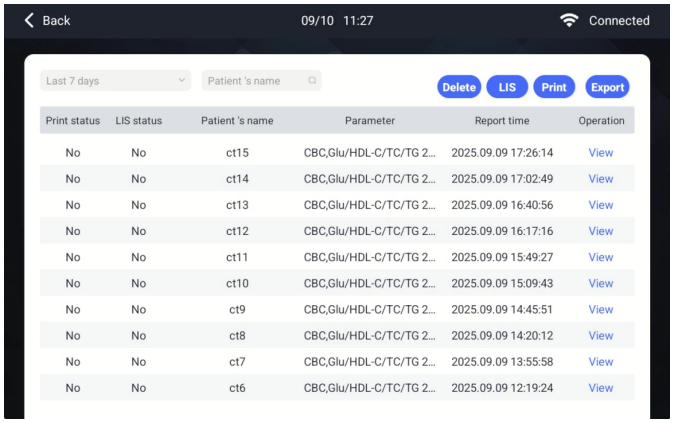
Click “View” to skip to the details page of the report.

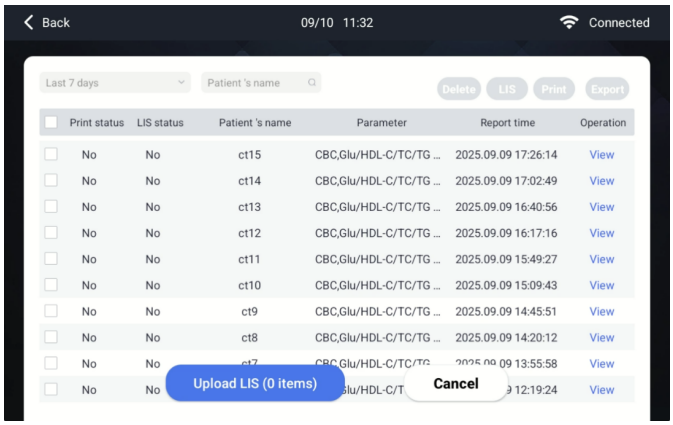
Click “Delete” to delete record. Selected items will no longer be displayed.

Click “Print” to print the selected items.

Click “Export” to export selected items to USB flash disk.

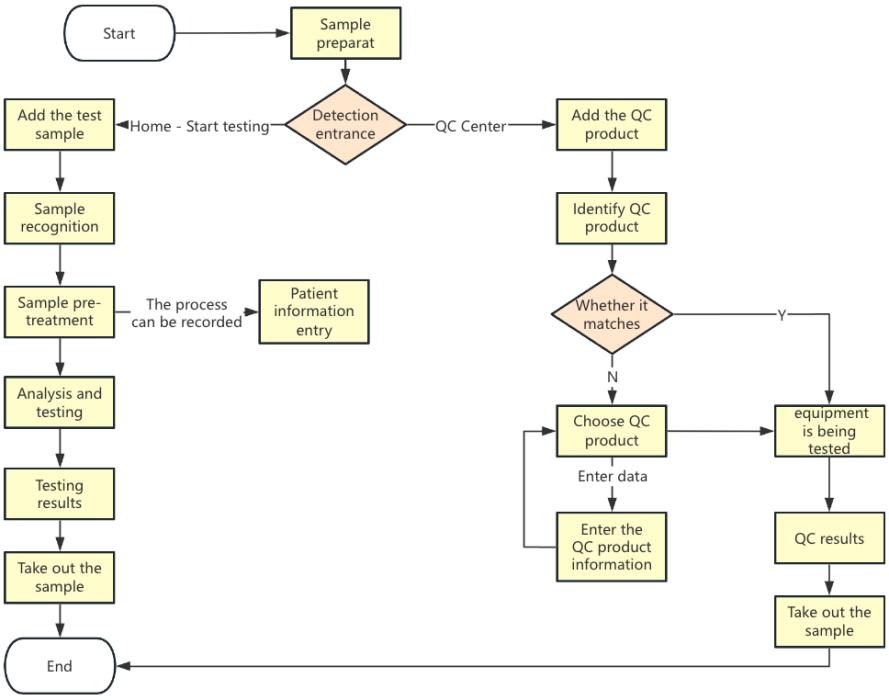
Click “LIS” to upload reports to LIS.
Select items need to be uploaded on the left.





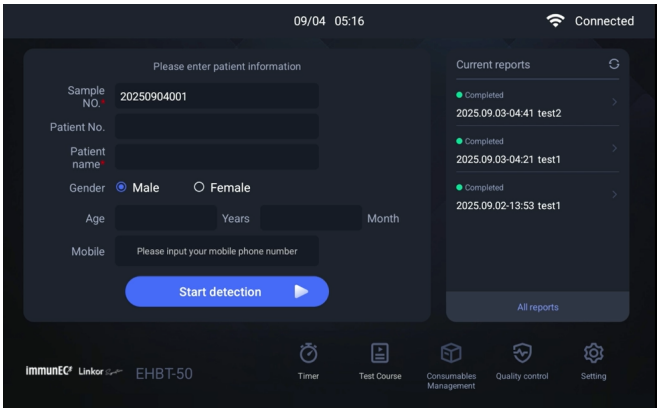
4. Testing

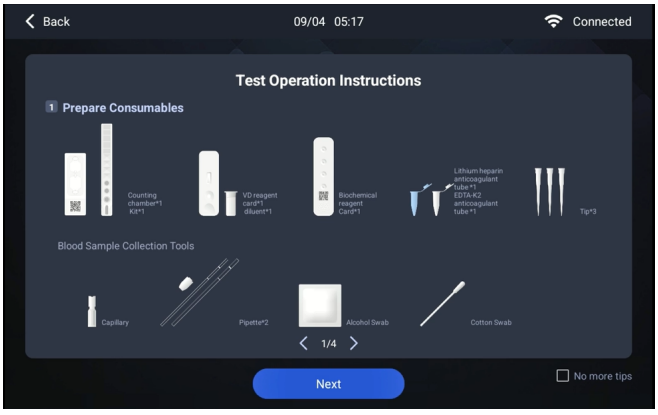
4.1 Sketch of Test Process

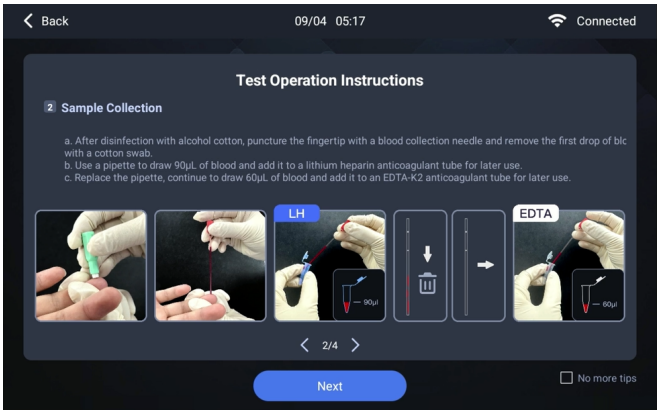


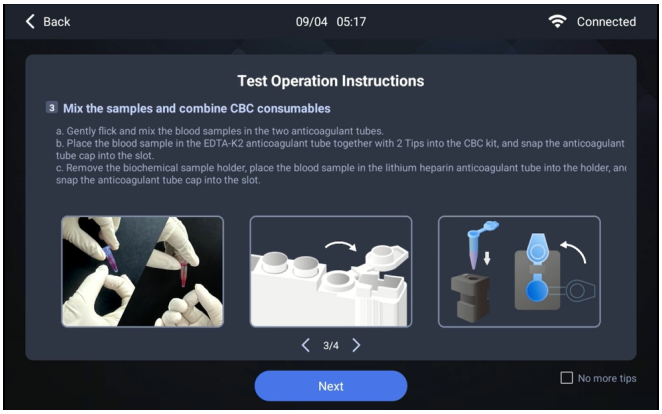
4.2 Test Preparation

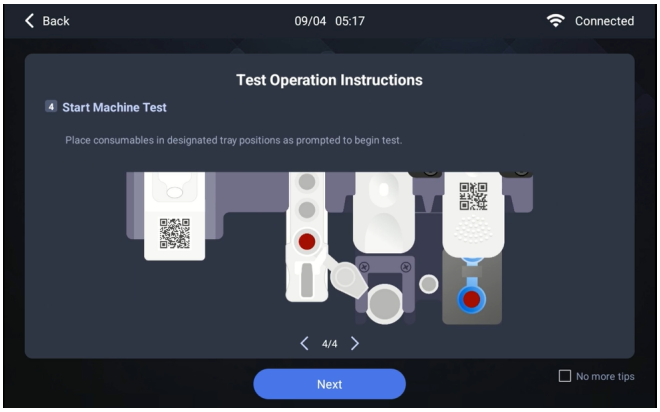
1) Start and log into the Analyzer
2) Enter patient information in the Home Page
3) Click “Start Detection”
4) Operation tutorial guide interface will appear
5) Prepare auxiliary supplies for the test:
   disposable gloves, alcohol pad, swab and lancet
6) Unpack the disposable reagent kit
7) Take blood and fill the 2 samples.
   Avoid direct sun exposure on the samples.









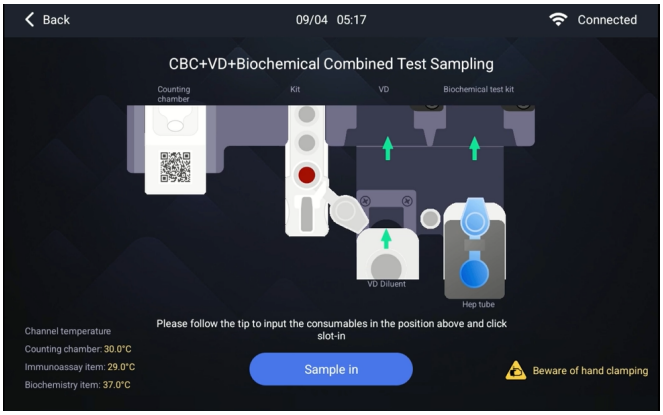


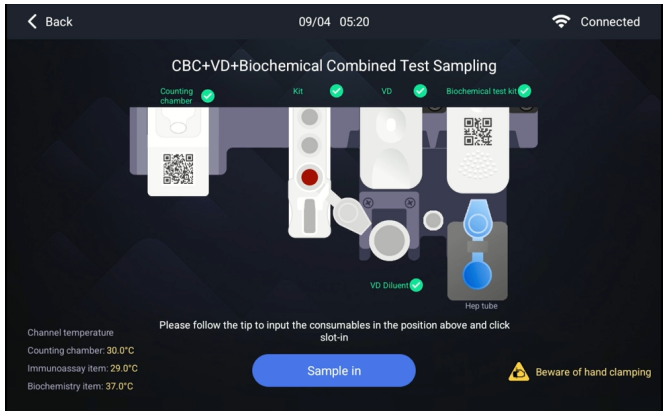
4.3 Sample Load

After tutorial, click “Next” to enter the Sample Load page, the Analyzer's cabin door will pop up automatically. The Analyzer can accommodate a counting plate, a reagent kit for blood routine, a reagent card and a diluent for fluorescence test, and a reagent card, a lithium heparin anticoagulant tube and a EDTA-K2 anticoagulant tube for biochemical tests.

Place the counting chamber, blood reagent, VD cartridge, VD diluent, Glucose&lipid cartridge, 3*tips, EDTA-K2 tube and Heparin tube into the corresponding slots according to the instructions on the interface.

After all the consumables are placed correctly, a green √ will appear in the corresponding position.





4.4 Sample Identify

Click “Sample in”, the Analyzer door will be closed, and the device will identify each consumable placed.

If the identification is unsuccessful, an error message will pop up and test will not proceed.

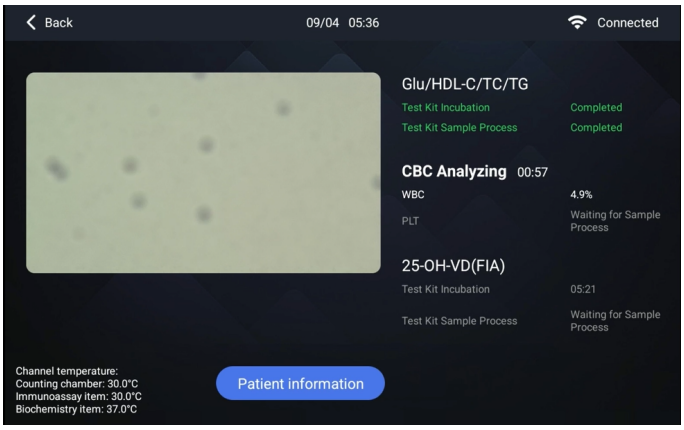
It is necessary to place correct consumable that meets the requirements according to the instructions.

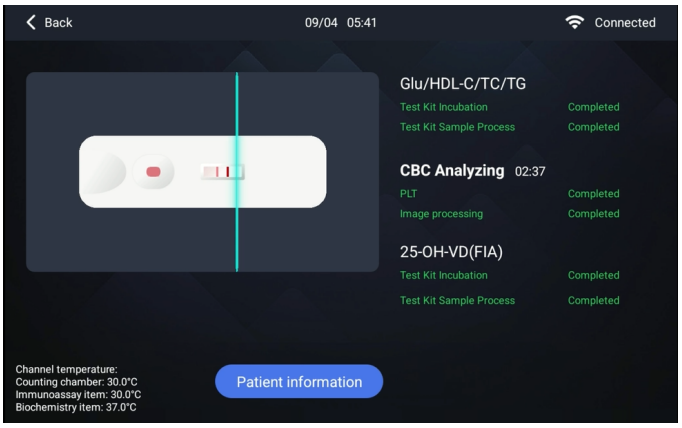
4.5 Sample Blending

After all the consumables are identified successfully, Analyzer enter the sample blending stage.

4.6 Sample Testing

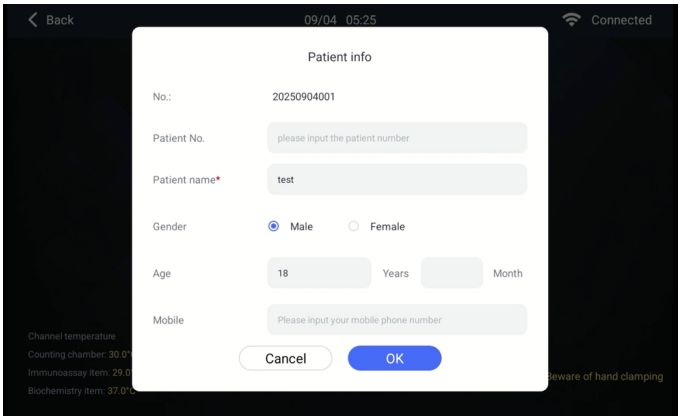
After the sample has been mixed and loaded,
the Analyzer will launch the test procedure automatically.
The testing items are displayed in the interface,
as well as its current sub-item testing progress.





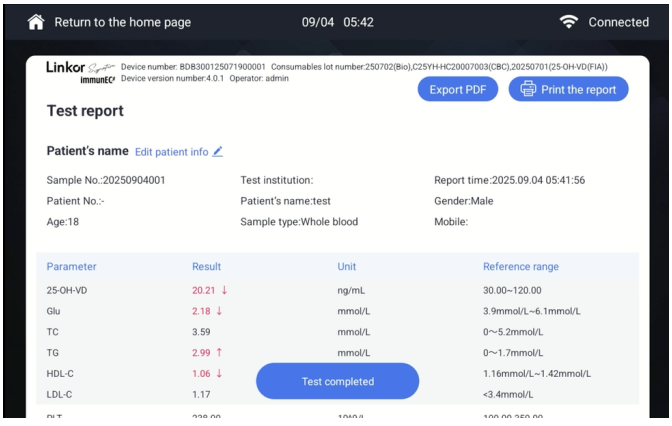
You can open the filling/editing popup window of the patient's information by clicking the “Patient Information” button and entering the patient's basic information.

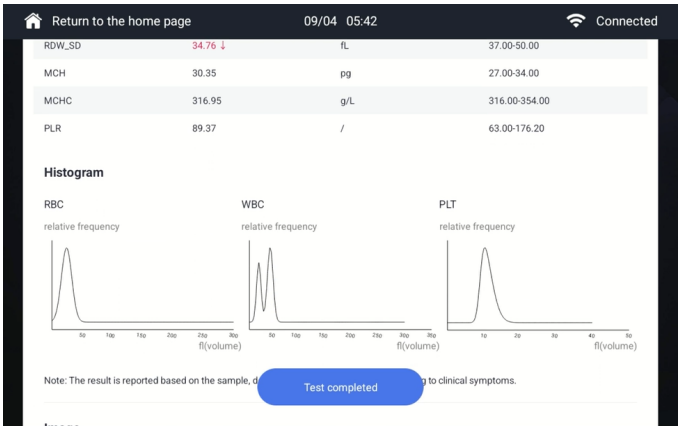
If the user is requested to confirm the patient’s information/sample information in the test process, a window will pop up automatically.

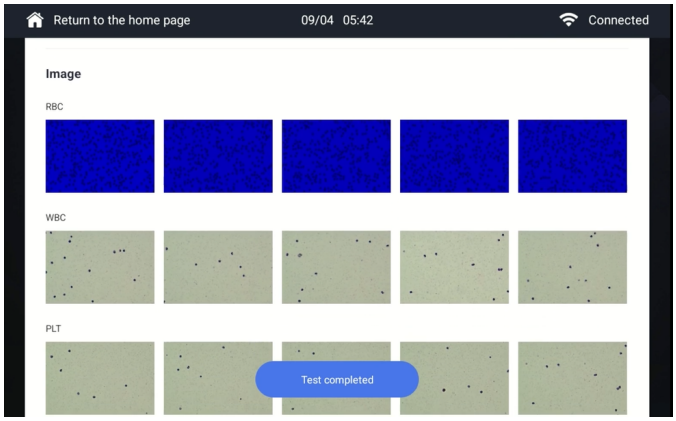


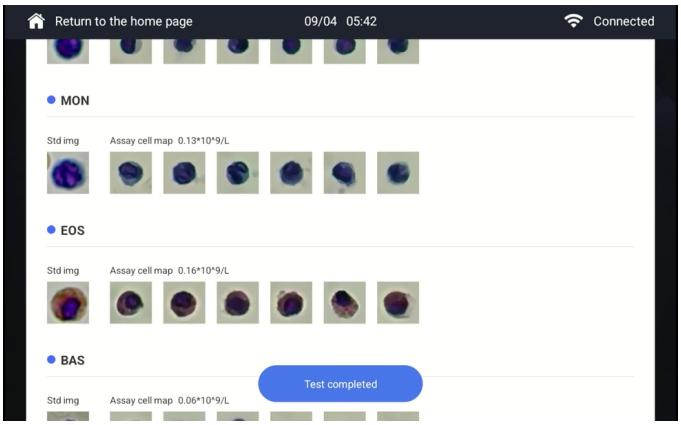
4.7 Test completed

When the test is completed, the test report will be directly displayed on the interface. You can view the report on screen, print or export it as a PDF document.
The report details page will display the patient's information, detailed results of the test item, test curve of blood routine and cell image of blood routine.



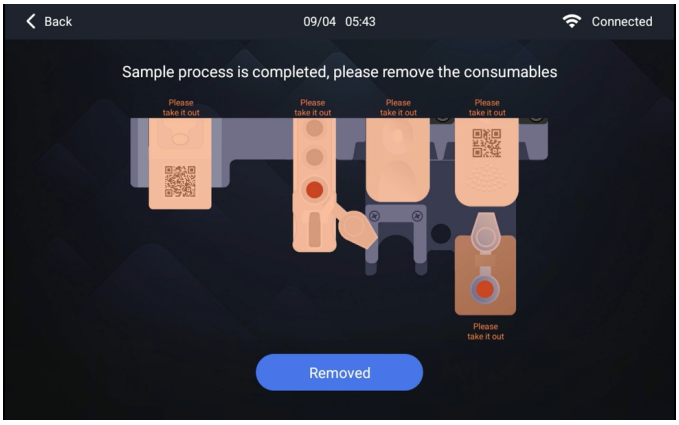






4.7 End of the test

Click [Test complete] on the bottom of the page, the Analyzer will exit the report page, open the cabin door and prompt the operator to pull out and discard the consumables.



Back to home page

By clicking “Removed”, cabin door will close again, and screen will turn to home page.
The whole test procedure is completed.

4.8 Disposal of the Tested Samples and Reagent Kits

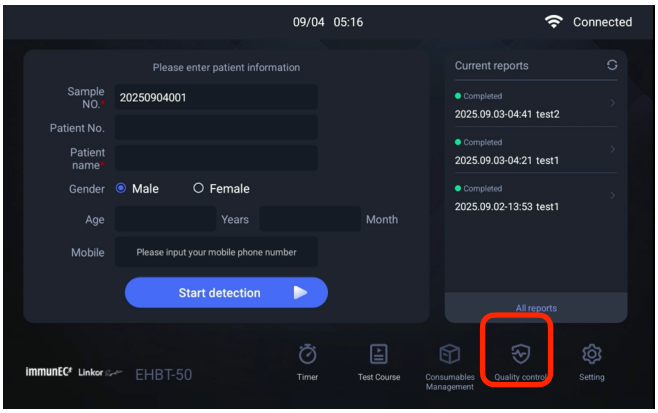
All the tested samples and reagent kits having done testing shall be thrown into designated medical garbage bags or properly disposed of in accordance with local and national laws & regulations.

4.9 Precautions

- Do not put reagents or samples irrelevant to the Analyzer on the workbench, to avoid affecting operation.
- After the Analyzer is finished using or left idle for a long time, it shall be turned off and unplugged.
- Operation of the Analyzer without following specified methods may cause an increase in the chance of its damage, as well as the chance of inaccurate test results.
- The manufacturer cautions that the Analyzer's all parts may contact with test samples directly, and must be treated as potentially infectious agents.
- During the test, the operator must put on the lab gown and wear disposable medical gloves and masks to avoid spilled or splashed infectious fluid.
- The test results need to be considered in combination with other clinical and laboratory data. If they are inconsistent with the clinical assessment, further examination will be needed.
- In case of any fault, power the Analyzer off immediately, then contact its dealer. Do not disassemble it arbitrarily. Without the fault test by the manufacturer, do not power the Analyzer on or open its power supply for the avoidance causing secondary damage to it or causing personal injury.
- The Analyzer's related kit is disposable and must not be used repeatedly.
- The Analyzer can only be used together with its related kit. Do not mix them with other company's products, or the manufacturer's products of other models.
- During the operation, please keep more than 10cm away from the cabin door to avoid impeding the door's normal opening/closing.

5. Quality Control Process and Operation

Click the “Quality Control” button on the Home Page to enter the quality control center interface.
There are 2 areas in the interface: The top function entrance buttons area and the quality control chart area.



Top function entrance area
Click “Start detect” to start the quality control testing.

Click "Add QC product” to enter the quality control product addition process.

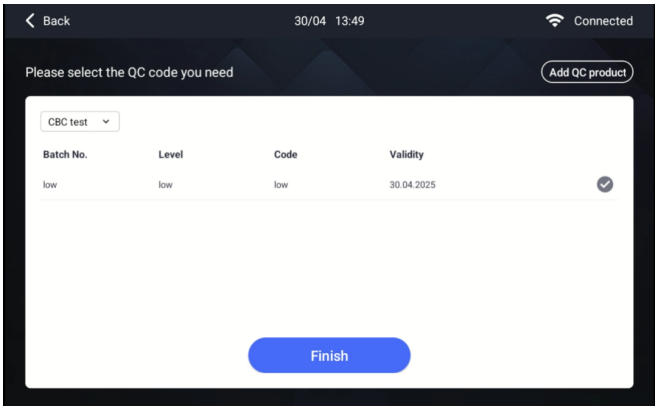
Click "QC management” to enter the quality control product management list page.

Click “QC record” to enter the quality control record list page.

It is advised to do a full-function QC after every 200 tests.
A counter displayed on the screen will show the number of tests already performed. When 200 tests have been reached, a reminder message will appear on the screen to inform you that a QC test is required.
QC tests are reusable for life if no scratches, damages and dirty, stored at room temperature

5.1 Quality Control Testing

Click the top button "Start QC test".
You will enter the quality control product information selection page.



The list will display the information list of all quality control products under the selected type.
Select the quality control product that you will put into the Analyzer for quality control test in the list, and the record of the quality control product will be marked with "✔".

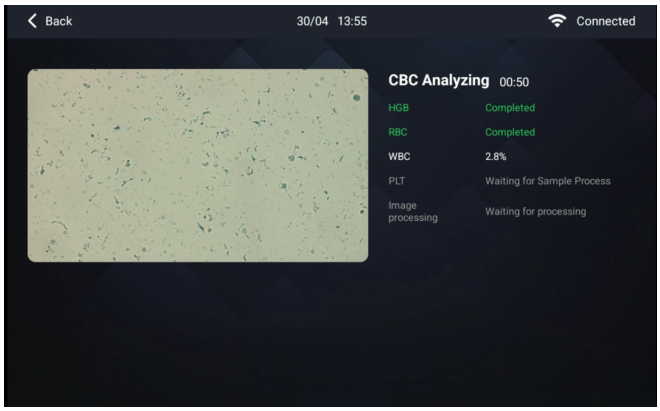
After selection, click the “Finish" button below.
If the information of the quality control product you are about to put into the Analyzer is not entered in advance, click the "Add QC product" button in the upper right corner.

Put in the sample
When the sample page is entered, the Analyzer's bin door will pop up automatically.

During quality control testing, the Analyzer only supports one quality control sample at a time.
Follow the prompts to put the quality control product into the corresponding card slot.
After completing the placement, click the “Sample in" button. The Analyzer will close the chamber door and begin identifying the quality control sample while matching it with existing data. Once a match is found, the system will automatically initiate the quality control test.

Testing procedures

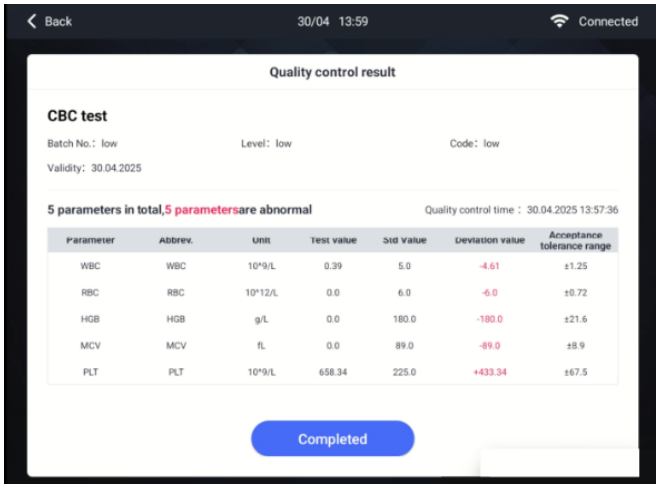
In the detection process, the interface will display the detection items and the current progress of the sub-item detection of the item.
After the test is completed, the system will automatically enter the quality control result report viewing page.



View the report

The result report viewing page will display the basic information of the quality control test (name, batch, level and code), the parameter value of the test result and the comparison information with the standard value.

Click the "Completed" button at the bottom, and the system will jump to the sample retrieval page to complete this quality control.



Take out the sample

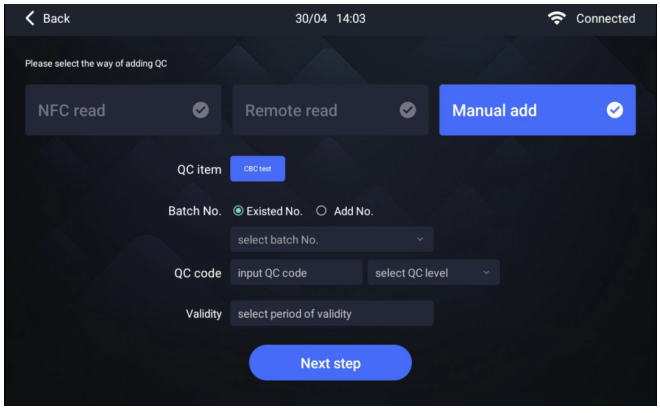
After the completion of the test, the sample discarding prompt page is entered. The Analyzer will automatically open the bin door. After taking out the sample, click the "Removed" button, and the system will close the bin door and return to the Analyzer homepage.

5.2 Add Quality Control Product

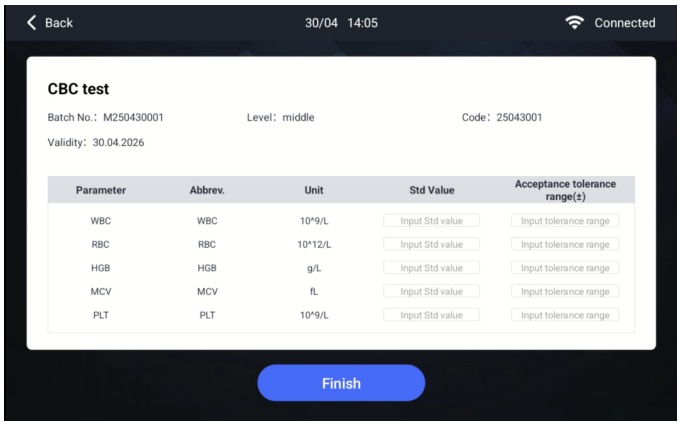
“Manual add”

The interface will display the basic information and edit content of the quality control product (type of quality control product, batch, level, code and validity period).

After entering the information, click “Next step" below, and the system will check the basic information of the quality control product.
If the check fails, if the input quality control information is not conform to the system input rules or is empty, the system will give a prompt and ask the operator to re-enter the content.
If the verification is passed, the system will jump to the page of input of standard value information of quality control product.



In the quality control standard value information input page, the basic information of quality control products and the input list of standard value information of quality control detection parameters entered by the superior interface will be displayed.



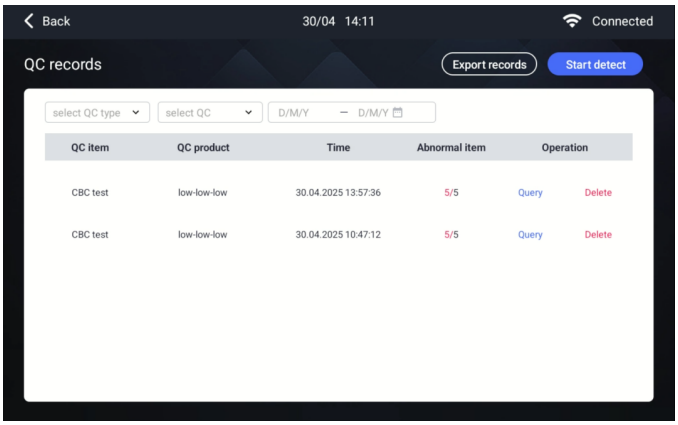
After the input is completed, click the "Finish" button at the bottom of the page, and the system will verify the standard value information of the quality control product.

If the check fails, if the standard value information of the input quality control product is not conform to the input rules of the system or is empty, the system will give a prompt and ask the user to re-enter the content.
If the check is passed, the system will save the quality control information and jump back to the previous page before adding the quality control information.

5.3 Quality Control Record

List

The page will display a list of quality control test records performed by the Analyzer, and support query and search by various conditions.

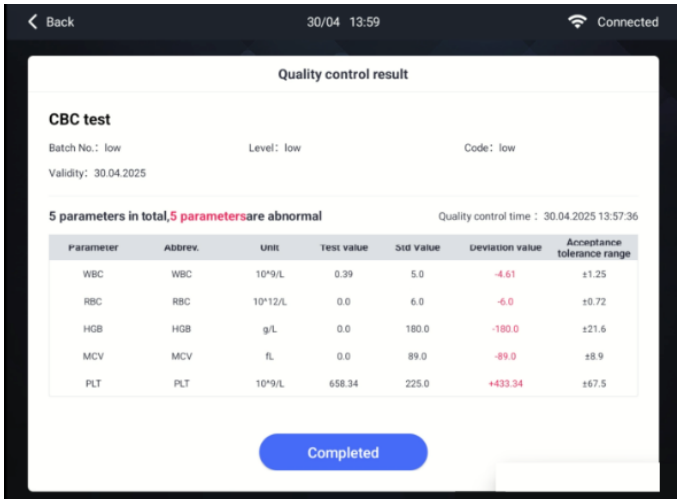


The list will display the qualified quality control records according to the search conditions, and all quality control records will be displayed when there is no search conditions. The list field includes the type of quality control item, quality control item, quality control time, and statistics of abnormal items (meaning how many parameters in the quality control result are beyond the quality control allowable deviation range).

At the end of each quality control item line, there will be a "Query" and "Delete" button.
Click "Query" to enter the quality control record details page.
Click "Delete", the system will pop up a second confirmation box, click confirm to delete the record.

Details

When viewing the results report page, it displays the basic information of the quality control test, test result parameters, and comparison with standard values.



For routine blood tests, the interface also shows the test curve. If there are abnormalities in the quality control results, the top of the page will display a prompt for operators to report the abnormal quality control information to the cloud.

The basic information will display the type name of the quality control test, batch of quality control product, level of quality control product, code of quality control product and validity period of quality control product.

At the top of the parameter detection value list, the number of items in the parameter detection value and the number of items exceeding the deviation range are displayed.
The test results will display the parameter values of this quality control, as well as the corresponding unit, standard value, deviation value and allowable deviation range. The deviation value will be displayed with different color marks according to whether it is within the allowable deviation range, with black font for within the allowable deviation range and red warning mark for beyond the allowable deviation range.

6. Troubleshooting

Fault Name Displayed in the Pop-up Window	DTCs	Solution
Fail to turn on the camera	CAMERA-004	Restart the device. If the screen keeps displaying this kind of functional failure prompt, please contact customer service.
Initialization failure of the printer	PRINT-001	Restart the device. If the screen keeps displaying this kind of functional failure prompt, please contact customer service.
Exception during test	BLOOD-002	Restart the device. If the screen keeps displaying this kind of functional failure prompt, please contact customer service.
Test algorithm exception	BLOOD-003	It may be caused by operational errors such as sample preparation errors or counting board card errors. Please retest.

Cautions: Failure to follow the steps in this User Manual or neglect of the fault condition reported by the Analyzer for a long time may cause erroneous test results.
If the fault cannot be rectified through the solutions listed in this section or is not covered in this section, please contact ImmunEC user service department or its local service representative.

6.1 Fault List

1	The motor equipment cannot be started; the motor is not connected the motor fails.	Restart the device. If the screen keeps displaying this kind of functional failure prompt, please contact customer service.
2	Failure to enable the motor	Restart the device. If the screen keeps displaying this kind of functional failure prompt, please contact customer service.
3	spi communication failure of motor equipment	Restart the device. If the screen keeps displaying this kind of functional failure prompt, please contact customer service.

6.2 Examples of Power-on Exception Handling

Periodic test			
Inspection Item	**Inspection Period**	**Inspection Contents**	**Inspection Purpose**
Power	Daily	Plug, socket and power cord	Avoid bad contact or even electric leakage that may cause personal injury
Quality control	Daily	Blood cell, colloidal gold, fluorescence and biochemical test system of Analyzer	Avoid displaying incorrect values

7. Maintenance & Warranty

7.1 Daily Maintenance and Precautions

- In order to guarantee the Analyzer's working stability and test accuracy, please do not place it in an environment with high magnetic interference. Keep it in a place with good ventilation and air permeability.
- When the Analyzer is running, do not move or hit it or spill any liquid into it.
- Do not unplug/plug the Analyzer's power cord or signal plug when it is powered on.
- If the Analyzer is left idle for a long time, power it off and unplug its power cord.
- This Analyzer is a precision analyzer and users cannot open the Analyzer without authorization.

7.2 Preventative Maintenance

During maintenance and servicing, even in cases where spillage is not found and is not suspicious of having occurred, the following preventive specifications must be observed.

Cleaning:

- Perform cleaning in accordance with the user institution's cleaning process if appropriate.
- Warnings: Before cleaning, power the Analyzer off and unplug its power cord.
- Wear disposable gloves, and use a clean dry duster cloth to wipe off the liquid remaining in the Analyzer.
- Wear disposable gloves, and use a soft disposable duster cloth dipped with a little water or 75% medical alcohol to clean the Analyzer housing weekly.
- Do not clean the Analyzer's LCD with water. Use a clean soft and dry cloth (or soft paper) and wipe it gently.
- Do not immerse the Analyzer in the liquid.
- Do not directly spray alcohol or other liquid into the Analyzer.
- Do not let any liquid enter any opening of the Analyzer.

Disinfection:

- Perform disinfection in accordance with the user institution's disinfection process if appropriate.
- Warning: Before disinfection, unplug the Analyzer's power cord.

7.3 Warranty

The standard warranty period for this Analyzer is 15 months. Within the warranty period, free after-sales services will be offered. However, it should be noted that ImmunEC will charge for the repair services (including expenses for repair and accessories) for any of the following reasons even within the warranty period:

- Man-made damage;
- Incorrect use;
- The grid voltage exceeds the acceptable standard range of the Analyzer;
- Irresistible natural disasters;
- The components (hose of plunger pump, optical fiber etc.), accessories or consumables that ImmunEC has not approved are replaced with or used, or the personnel repairs the Analyzer without authorization.
- Other faults that do not result from the Analyzer itself;
- Disassembly/assembly of the Analyzer without permission.

8. EMC Statement

Table A-1 Guidelines and Manufacturer Statements - Electromagnetic Emission

Electromagnetic emission		
Emission Test	Basic Standard	Conformance
Conducted Emission (CE)	GB4824	Group 1-Class B
Radiated Emission (RE)	GB4824	Group 1-Class B
Harmonic Distortion	GB17625.1	Class A
Voltage Fluctuations and Flickering	GB17625.2	Conformance
To ensure that they meet or exceed the specified minimums, the actual RF shielding effectiveness and RF filtering attenuation of the shielding place must be verified.		

Table A-2 Guidelines and Manufacturer Statements -Electromagnetic Immunity (EMI)

Port	Test items	Basic Standard	Test values	Performance criterion
Housing	Electrostatic discharge (ESD)	GB / T 17626. 2	Air discharge: 8kV: Contact discharge: 4kV:	A
	Radiated electromagnetic field	GB / T 17626. 3	3V/m (80MHz～2.0GHz), 80%AM Modulation frequency1kHz	A
	Rated power frequency magnetic field	GB / T 17626. 8	3A/m, 50Hz	A
AC power supply (including protective grounding)	Voltage interruption	GB / T 17626. 11	0%, 1 cycle	A
			40%, 5 cycle	A
			70%, 25 cycle	A
	Voltage interruption	GB / T 17626. 11	5% duration; 250 cycle	C
	Pulse Group	GB / T 17626. 4	1kV(Repetition frequency: 5kHz)	A
	Surge	GB / T 17626. 5	Line to line:2KV, line to ground:1KV	A
	RF conduction	GB / T 17626. 6	3Vrms,150kHz~80MHz,80%AM, Modulation frequency1kHz	A

Performance criterion:

A. During the test, the performance is normal within the specified limits.

B. During the test, the function or performance is temporarily reduced or lost, yet can be restored on its own.

C. During the test, the function or performance is temporarily reduced or lost and requires operator intervention or system reset.

Before, during and after the test, the Analyzer works normally according to its established procedures, with the software interface displaying normally and no messages of exceptions or errors.

Manufacturer: Hunan Ehome Health Technology Company Limited

Registrant/manufacturer name: Hunan Ehome Health Technology Company Limited
Service address: Room 103 and 104, No.13 Building, Country Garden Wisdom Garden, Xueshi Street, Yuelu District, Changsha, Hunan, P. R. China
Production address: Room 301/302/303/401/402/403/503, Building 3, Liandong Yougu Industrial Park, No. 32 Yulian Road, Xueshi Street, Yuelu District, Changsha City, Hunan Province
After-sales service unit name: Hunan Ehome Health Technology Company Limited
Contact：400-803-0907
Postcode: 410000
Production Permit No.: Producing Certificate Number 20210117 of Hunan Food & Drug Analyzer Administration
Registration Certificate No. of Medical Device/Technical Requirement No. of Product:
Approval Date or Revision Date of Instructions:28 November 2024