

H100Plus

Hemoglobin Analyzer(HPLC)

User Manual



Lifotronic

IVD Rx Only

Statement

Thank you for purchasing H100Plus Hemoglobin Analyzer(HPLC).

Before using the product, please read carefully the contents of this manual in order to handle the analyzer properly.

After reading, please keep this manual properly to consult at any time when needed.

Product name: Hemoglobin Analyzer(HPLC)

Product model: H100Plus

Product date: Refer to details in machine label

REF number: 012020702

User manual issuing date:2026-01

Version number : 1.0

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Chapter 1 Manual Introduction

1.1 Overview

This chapter introduces how to use the Instruction Manual for H100Plus. This manual is supplied with the analyzer, and describes the purpose, function and operation of H100Plus in details. Please read this manual before using H100Plus to ensure proper use and optimum performance of H100Plus and safety of the operator.

1.2 Scope of Application

This manual is intended for professional medical testers or trained doctors, nurses or laboratory technicians. It enables user to:

- know about hardware and software of H100Plus;
- perform routine operations;
- set system parameters;
- carry out system maintenance and troubleshooting.

1.3 Manual Guide

This manual consists of 11 chapters and 3 appendixes.

When you need...	Refer to ...
Understand the general overview and basic structure of the manual	Chapter 1 Manual Introduction
Understand the purpose, basic parameters, composition and operation interfaces of H100Plus	Chapter 2 Analyzer Introduction
Understand the measuring principle of H100Plus	Chapter 3 Operating Principle
Understand the requirements and steps for installation of H100Plus	Chapter 4 Analyzer Installation
Understand the process of routine operations of H100Plus	Chapter 5 Routine Operations
Review the sample analysis results	Chapter 6 Result Review
Review the error logs, operation logs and maintain logs	Chapter 7 Log Review
Understand the basic requirements and method	Chapter 8 Quality Control

for quality control of H100Plus	
Understand the basic requirements and method for calibration of H100Plus	Chapter 9 Analyzer Calibration
Understand the methods for maintenance and testing of H100Plus	Chapter 10 Service
Understand the causes of and solutions for malfunction of H100Plus	Chapter 11 Troubleshooting
Understand the basic features, performance indexes, input and output devices and other aspects of H100Plus	Annex A Specifications
Understand the communication protocol for H100Plus	Annex B Communication
Understand the electromagnetic radiation instructions for H100Plus	Annex C Electromagnetic Radiation Instructions

1.4 Notice

All illustrations in this manual are for reference only and may be inconsistent with actual situation.

1.5 Safety Information

In this manual we use the symbols below for the information that needs attention or is hazardous.

Symbol	Meaning
	Remind operator to follow the steps under this symbol, otherwise it will result in personal injury.
	Remind operator to follow the steps under this symbols, otherwise it will result in product failure, damage and inaccurate results.
	Remind operator to follow the steps under this symbols, emphasize important/critical information or steps in the manual.
	Remind operator to follow the steps under this symbols, otherwise it has bio-infectious risk.

	Alerts the operator to operate according to the instructions provided below this symbol, and emphasizes important information in operation steps or content requiring special attention from the operator.
---	--



- DO NOT operate in flammable and explosive environment.
- Make sure the switch is off ("OFF") before connecting power cord.
- Sampling needle, sample loader, column and filter are bio-hazard, operator should wear gloves and avoid direct contact.
- The cloths, hair and hands should keep a certain distance from moving parts components like sampling needle and sample loader in case of crushing or stabbing.
- Operators are in duty to local laws and regulations about disposing overdue reagents, waste liquid, waste samples and consumables.
- Reagents may irritate eyes, skin and mucous membranes. Operators ought to comply with safety regulations and wear on personal protective equipment (like protective clothing, gloves).
- Once the reagent contact with skin, wash immediately with plenty of water, if
- necessary, please seek medical treatment; Once the reagent contact with eyes, rinse immediately with plenty of water and seek medical treatment.
- DO NOT contact blood sample directly.
- DO NOT place sample or touch sample loader when sample loader is running or 2D arms are sampling.
- The power must be turn off during repair ! It may damage electrical components and cause injury.
- Operation of the instrument should be conducted by the personnel that received formal training, or master safe operation skills.
- To prevent electrical shock and / or equipment damage, operator should not open three covers of the instrument.
- Anomalies appear in the power-on or during operation, the operator should
- immediately turn off the power, and check by a qualified professional service personnel before re-power operation.



- It might damage the analyzer to unpack and install without authorized or trained personnel. So do not unpack or install the analyzer without present of one authorized or trained personnel.
 - The Analyzer must be used in a good grounding condition and equipped with reliable power outlet to ensure electrical safety.
 - Make sure input voltage meet the requirements.
 - If the room temperature exceeds the normal working temperature range of the analyzer, the test results will be unreliable.
 - Improper maintenance may damage the Analyzer. Operator must follow the guidance manual for maintenance.
 - If you encounter problems that there is no clear instructions, please contact the customer service of manufacturer and designated agent. Designated professionals will offer maintenance advises.
 - Must use components and parts that provided by manufacturer and designated agent for maintenance. Any questions, please contact manufacturer and designated agent' Customer Service Department.
-

NOTE

- This manual is for and only for :
 1. Daily operations personnel.
 2. System maintenance and troubleshooting personnel.
 3. Personnel that learn to use the system.
- H100Plus Hemoglobin Analyzer is a diagnosis analyzer that is used for disease screening. When diagnosing disease, clinicians should take clinical examination results or other test results into consideration.
- The device should not be used in patients during pregnancy for diagnosis of gestational diabetes.
- The device should not be used in newborns, pregnant patients, patients with heterozygous sickle cell trait, hemolytic diseases and recent significant or chronic blood loss.

- In cases of rapidly evolving type 1 diabetes the increase of HbA1c values might be delayed compared to the acute increase in glucose concentrations. In these conditions diabetes mellitus must be diagnosed based on plasma glucose concentration and/or the typical clinical symptoms.
- The device should not be used to diagnose or monitor patients with conditions that alter the life span of the red blood cells, such as: iron deficiency and hemolytic anemia, various hemoglobinopathies, thalassemia, hereditary spherocytosis, malignancies and severe chronic hepatic and renal disease.
- Refer to the user manual of reagent to see how to use and store reagent.
- After replacing Eluents, column, filter or Hemolytic Agent L, the operator should rinse the system to ensure ADC value in normal range.
- Ensure use reagents, column, filter before expiration date.
- Let reagents stand up at room temperature before use, to make it stable.
- The Analyzer must be placed on a sturdy and horizontal table, not placed on a slope.
- Please keep the packing box, in order to pack the Analyzer when moving a long distance.
- Only use reagents designated by the manufacturer and designated agent.
- After connecting the reagent and Analyzer, the bottle cap of reagent should be covered in case of contamination.
- Operator should execute system cleaning every day. Otherwise it may lead to wrong results.
- Reagents soaked in column or filters may drip onto the instrument or operating table prior to installation. Please prepare paper towels or handkerchief for cleaning in advance.
- The operator should use clean vacuum blood collection tubes with EDTA-K₂ and EDTA-K₃.
- It's recommended that operator should gently shake the blood collection tube or pre-diluted EP tube. Otherwise it may influence test results.
- If there are bubbles or lumps or floccules in the blood of blood collection tube, sampling needle can not aspirate blood sample. It might result in a test result of 0% . Once it appears, shake the tubes thoroughly and test it again.
- The maximum length of the sample ID number should be 20 digits, if it exceeds 20 digits, the Analyzer defaults the first 20 digits as current ID number. The length

of Lots No. is 15 digits. If exceeding, the system will default the first 15 digits as current Lots No.

- Once data has been deleted, they can't be recovered. It's recommended to print or keep data backup by connecting to computer with RS232 serial port line. Contact the manufacturer and authorized agents for backup software.
- QC chart supports to display 3 batches of information of QC in a month. It's recommended to print.
- Only after the Analyzer has been calibrated, the measured data can be used as valid data.
- If bubbles form during QC test, the system will set related parameter to invalid and give an alarm. See Chapter 12 for how to solve this problem.
- Refer to calibrator and QC material user manual for its usage and storage methods.
- Operator should use specific column, filters, reagent, calibrator and QC material designated by manufacturer and designated agent. Manufacturer and designated agent take no responsibility for inaccurate test result by using any other column, filters, reagent, calibrator and QC material.
- Before unsealing the column and filters , operator should check whether the packaging is damaged. If damage , please contact Service Department of manufacturer and designated agent immediately.
- Do not allow the sample to remain in the pipeline for a long time, especially in column. When not in use, plug both ends of the column and store at 2~8℃.
- DO NOT shut down the system during test. If abnormalities appear, clean the system before test !
- When the instrument is operating, DO NOT touch sensitive components such as optical systems and other part of the analyzer, otherwise it will cause wrong measurement results.
- The Hemoglobin Analyzer(HPLC) requires login with a username and password. When registering a new account, the password complexity must meet the following requirements: it must contain a combination of letters and numbers, and the password length must be no less than 8 characters.
- Place the device as far away as possible from other electronic devices that may cause interference.

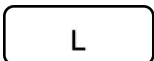
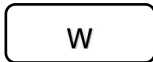
- The international universal Software Bill of Materials (SBOM) in SPDX format has been generated, supporting the conversion to other international and industry-wide common SBOM formats such as CycloneDX and SWID. If required, users can send an email to inform us, and our company will provide the latest SBOM list.
 - The software and firmware are updated and maintained by the manufacturer's engineers. Do not update or program the device software yourself.
 - When the device fails to authenticate during login, a pop-up will appear with a confusing prompt "Login Error". If the attempt fails 5 times, you can continue to enter after waiting for 30 seconds. After the Hemoglobin Analyzer(HPLC) is successfully installed, it can start working immediately, and users do not need to configure it.
 - During the effective period of the service, our company will provide continuous tracking and remediation for any security issues that may arise with the equipment. If the equipment exceeds its service life, our company cannot guarantee the provision of reasonable security patches and software updates for the user. Using the equipment after support has ended may pose certain security risks to the user, and it is recommended that the user discontinue use of the equipment.
 - After this device is deactivated and out of service, personal information will be handled in strict accordance with the American Data Privacy and Protection Act (ADPPA) and the Health Insurance Portability and Accountability Act (HIPPA), as well as security requirements.
-

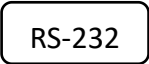
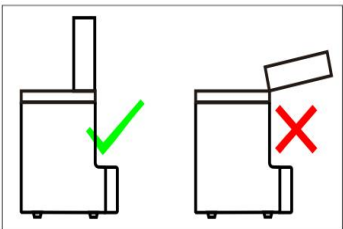
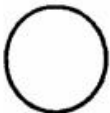


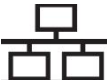
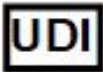
- Sample, QC material, calibrator, column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipment (safe clothing, gloves) when contacting lab articles.
- Surface of all the assembly units of analyzer are bio-hazardous, please take safe and protective measures when operating and maintaining.

- Sample loader, sampling needle, column, filter might be contaminated by blood. QC material and calibrator are bio-hazardous! Operator should wear on gloves while operating and avoid direct contact with sampling needle.

The following symbols may exist on analyzer body, label and packing box:

Symbol	Description
	Caution
	Biological hazard
	In vitro diagnostic medical device
	Serial number
	Use-by date
	Date of manufacture
	Manufacturer
	Temperature limit
	Humidity
	Atmospheric pressure limitation
	Consult instructions for use
	Dispose according to Waste Electrical and Electronic Equipment (WEEE) directive in European Union
Rx Only	Prescription use only
	USB port connection
	Hemolytic Agent L port connection
	Waste liquid port connection
	Waste Sensor port connection

	RS-232 port connection
	Protective ground
	Keep dry
	Fragile, handle with care
	This way up
	Stacking limit by number
	Be careful to avoid your hands from being pricked
	Correct and wrong operation diagram of opening the front cover of the instrument
	Beware of mechanical injury
Input: a.c.100-240V 50/60Hz,200VA Fuse:F5AL250VΦ5X20	Power input and fuse specifications
	Power on
	Power off
	The flow direction of the liquid in the column was marked

	The flow direction of the liquid in the filter was marked
	Network port connection flag
	Swipe RFID card
	Unique device identifier
	Reference Number
	Equipotentiality

1.6 Precautions

To ensure safe operation, please read the following precautions carefully before using and operating the analyzer.

During Installation



- **Connect an appropriate power source**
 - Connect to the power supply with sufficient power capacity and little voltage variation.
 - Fire may result if the power capacity is insufficient or the voltage exceeds the specific range.
- **Check the ground connection**
 - Electrical shocks may results if the grounding is incomplete.
 - Apart from prevention of electric shock, the ground also prevents loss of sensitivity caused by interference.

- Do not connect the grounding line to any gas pipes, water pipes, lightning rods or telephone ground lines.

Gas pipes :May causes explosions or fires.

Water pipes :provides no grounding.

Lightning rods or telephone grounding lines : Dangerous when struck by lightning.

ATTENTION

- **Choose an appropriate location for installation**
 - For installation location, please refer to “**Chapter 4 Analyzer Installation**”.
- **Do not change the power cord; do not use an extension cord or plug several power cords into the same socket; Use the fuse of the same specification while replacing it.**
 - The above operations may cause fires or electrical shocks.
 - Ensure that no dirt is on the plug and insert the plug firmly with no looseness.
 - Dirt on the plug or looseness between plug and socket may cause fires or electrical shocks.

During Using



- **Take great care of infections**
 - It is strongly recommended that the operator should have comprehensive clinical test knowledge and infection prevention awareness.
 - Blood samples to be tested may be contaminated by sources of diseases. Improper operations may result in infection of the operator and other working together. During operation, test sample should be handled with care. When checking the system unit, please wear personal protective equipment such as goggles, gloves and mask to prevent infection.
 - Used filter, column, sampling needle and sample cup may carry biological contamination, in order ensure personal and environmental safety, operators should wear protective equipment such as goggles, gloves and masks when handling these items. Also, operators should be equipped with applicable knowledge in order to handle these contaminated items.

ATTENTION

- **Do not perform operations not mentioned in this manual**
 - Otherwise, troubles may occur, such as disorder or injury or inaccurate results.
- **Please pay attention to liquid leakage**
 - Check for eluents leakage.
 - Eluents or Hemolytic Agent L leakage may cause fires, electrical shocks or corrosion.
 - When an eluent leakage is found, please stop the operation, wear proper protection, and then wipe off the eluent.
 - Make sure of no leakage in tube connections and measures should be taken to prevent recurrence.
 - Please contact manufacturer and designated agent' customer service when the leakage can not be stopped.
- **When any problem (e.g., smell of burning) occurs , please stop operation immediately, disconnect the power plug and contact manufacturer and designated agent**
 - Continuing the operation may cause fires or electrical shock.
- **During use, do not place fingers , rods or other objects into moving or driving unit**
 - Since the motor drive component is built-in and runs at a high speed, it is possible that the operator's finger or other object get hooked, rolled up or injured.
- **During operation, close the cover and door**
 - Since the drive and heating units and the high-voltage circuit are incorporated, it is possible that the operator gets hooked, rolled up, burnt or other injured.
 - During operation, do not try to add any samples or sample rack .
- **Do not touch the analyzer with wet hands**
 - Electrical shocks may result .
- **Routine maintenance of the analyzer should be performed by qualified personnel**

- During routine maintenance, if the operator is not familiar with the operation requirements, such as use of personal protective equipment (e.g., goggles, gloves, mask), injury or infectious diseases may be caused by contaminated blood samples.
- For operation and maintenance problems, please contact manufacturer and designated agent' customer service.
- **Dispose of wastes properly**
 - The wastes such as used sample tubes, column, filters and waste liquid should be disposed properly. Please wear protective equipment and do not touch the wastes directly, and dispose them according to applicable laws, in order to avoid harming personal or environmental safety.
- **Use personal protective equipment**
 - When disposing of samples, wastes or calibrators, please use personal protective equipment such as goggles, gloves and mask to prevent personal infection.
- **Place reagent container as designated**
 - If the reagent leaks into the analyzer, short circuit or poor electrical insulation or electrical shock may result.
- **Use the designated parts mentioned in the user manual**
 - Please use the consumables and spare parts listed in the user manual.

Other precautions

- The warning labels are attached to the analyzer. Please read thoroughly and follow the instructions.
- If the warning or caution labels are damaged, comes off or does not meet the requirement, please contact manufacturer and designated agent' Customer Service.
- Please keep this manual properly.
- Please hand over this manual when changing operators.

Chapter 2 Analyzer Introduction

2.1 Overview

2.1.1 Intended Use

H100Plus Hemoglobin Analyzer(HPLC) is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood using ion-exchange high-performance liquid chromatography(HPLC).

2.1.2 Analysis Results

After glycated hemoglobin in samples elutes from the column, the analyzer can provide the results of HbA1c (% , NGSP) and HbA1c (mmol/mol, IFCC). Meanwhile, the chromatogram can display HbA1a, HbA1b, HbF, LA1c, HbA1c, HbA0 and other components, like common abnormal hemoglobin (HbE, HbD, HbS , HbC or HbJ) or unknown hemoglobin. Based on the HbA1c result, the estimated average blood glucose is calculated by the conversion equation provided in ADA, EASD and IDF researches (Diabetes Care 2008; 31:1-6).

2.2 Product Composition

This analyzer mainly consists of a main unit, a sample introduction system, column, filters, and an analysis system.

The main unit mainly consists of a liquid chromatography separation system, a liquid chromatography detection system, a mechanical system and a hardware and software system.

The packing list of the analyzer is shown below, subject to the actual packing list.

Classification	No.	Name	Quantity	Unit
Entire analyzer	1.	Main unit	1	EA
Standard configuration	2.	Sample Loader	1	PCS
	3.	External Reagent Supply Module	1	EA
	4.	Sample Rack	11	PCS
	5.	Calibration Rack	1	PCS
	6.	QC Rack	1	PCS
	7.	Anemia Rack	1	PCS
	8.	Diluting Sample Holder	10	PCS
	9.	10L Waste Bottle	1	PCS
	10.	Liquid Path Accessory	1	PCS
	11.	Power Cord	1	PCS
	12.	Barcode Scanner	1	PCS
	13.	Thermal Paper	1	PCS
	14.	User Manual	1	PCS
	15.	Operation Guide	1	PCS
	16.	Reagent Tray	1	PCS
	17.	Connecting Plate	1	PCS
	18.	Protective Grounding Wire	1	PCS
	19.	Serial Port Connection Cable	1	PCS
	20.	Power Supply Cable	1	PCS
	21.	Clip	2	PCS
	22.	Reagent Connecting Tube	1	PCS
	23.	Head Screws M3*4mm	6	PCS
	24.	Pan Head Screw M6*20mm	8	PCS
	25.	Calibration Rack Label	6	PCS
	26.	QC Rack Label	6	PCS
	27.	Sample Rack Label	66	PCS
	28.	Anemia Rack Label	6	PCS
	29.	Spanner (8-10)	2	PCS
	30.	Spanner (1/4)	1	PCS
	31.	Spanner (Φ 3mm)	1	PCS

Chapter 2 Analyzer Introduction

	32.	Fuse Protector	2	PCS
	33.	Dilution Cup	2	PCS
	34.	Stirring Rod	2	PCS

2.3 Analyzer Configuration



Fig. 2-1 External Appearance

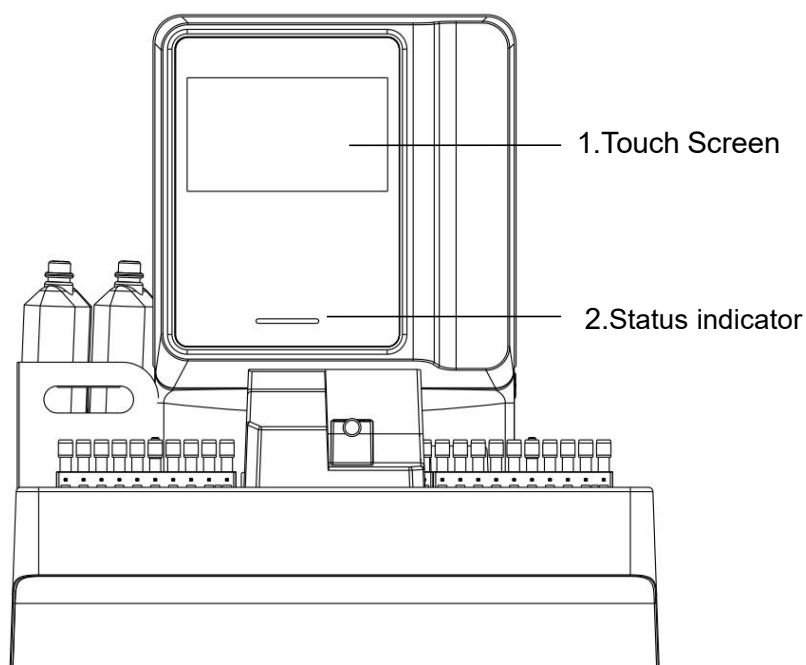


Fig. 2-2 Front View

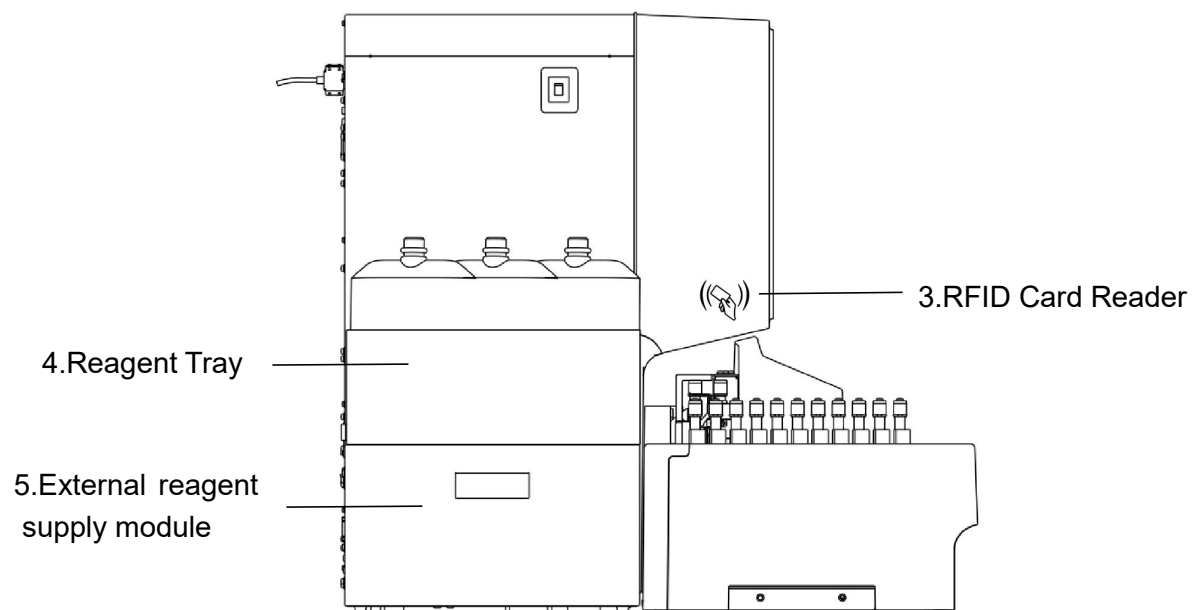


Fig. 2-3 Left Side View

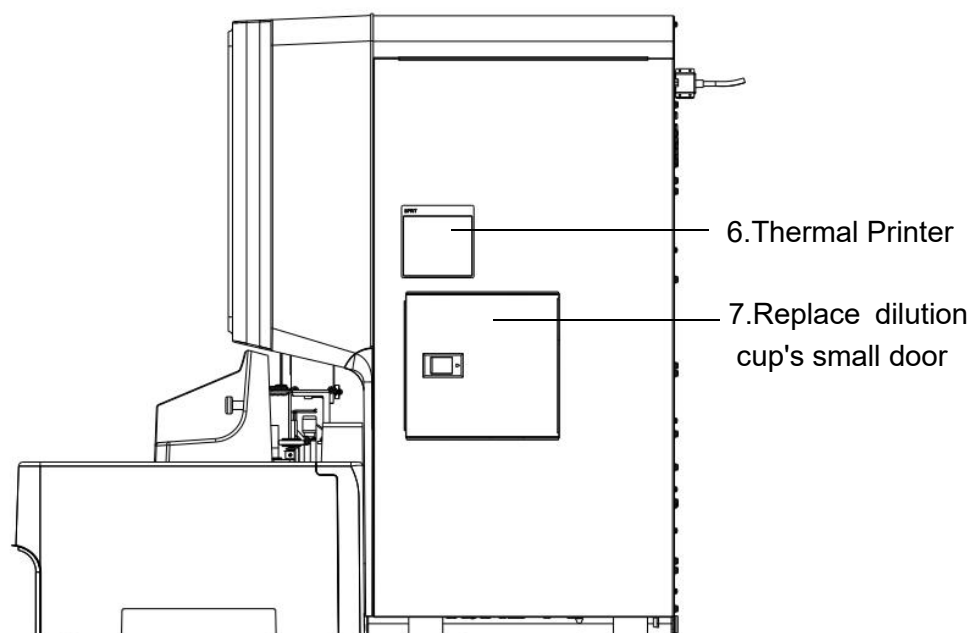


Fig. 2-4 Right Side View

1. Touch screen

The touch screen is in the front of the main unit of the analyzer. The analyzer uses a 10.1 inch capacitive screen for interface operation and information display.



- Do not use any sharp objects or apply too much force on the touch screen.
 - Use a clean, soft cloth to clean the touch screen; neutral cleanser or alcohol is recommended. It is forbidden to use chemical solvents or acid and alkali liquids.
-

2. Status indicator

The status indicator positioned directly below the touch screen is used to indicate statuses of the main unit. Refer to the table below for details.

Status of Indicator	Status of Device
Green light	Trouble-free ready
Yellow light	Sleep
Red light	Ready with fault or pause

3. RFID card reader

The RFID card reader is used to swipe RFID card when replacing the column.

NOTE

- FCC ID: 2BT5K-H100PLUS
- FCC Regulatory Compliance: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
- If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of

the following measures:

- Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.
 - This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
-

4. Reagent Tray

The reagent tray is used to place the eluent A/B/C.

5. External reagent supply module

The external reagent supply module is equipped with a connecting tube for linking to the instrument's In-line degasser. This module supports dual-channel reagents and enables the seamless replacement of reagents without stopping the analyzer.

6. Thermal printer

The thermal printer is used to print results of sample tests, fault information, device parameters, etc.

7. Replace dilution cup's small door

Open the small door, the operator could replace the dilution cup.

2.4 Units and Functions

This section shows the structure of the analyzer in front/rear/left/right view in perspective. Meanwhile, it also introduces the units and functions of the analyzer.

2.4.1 Front View

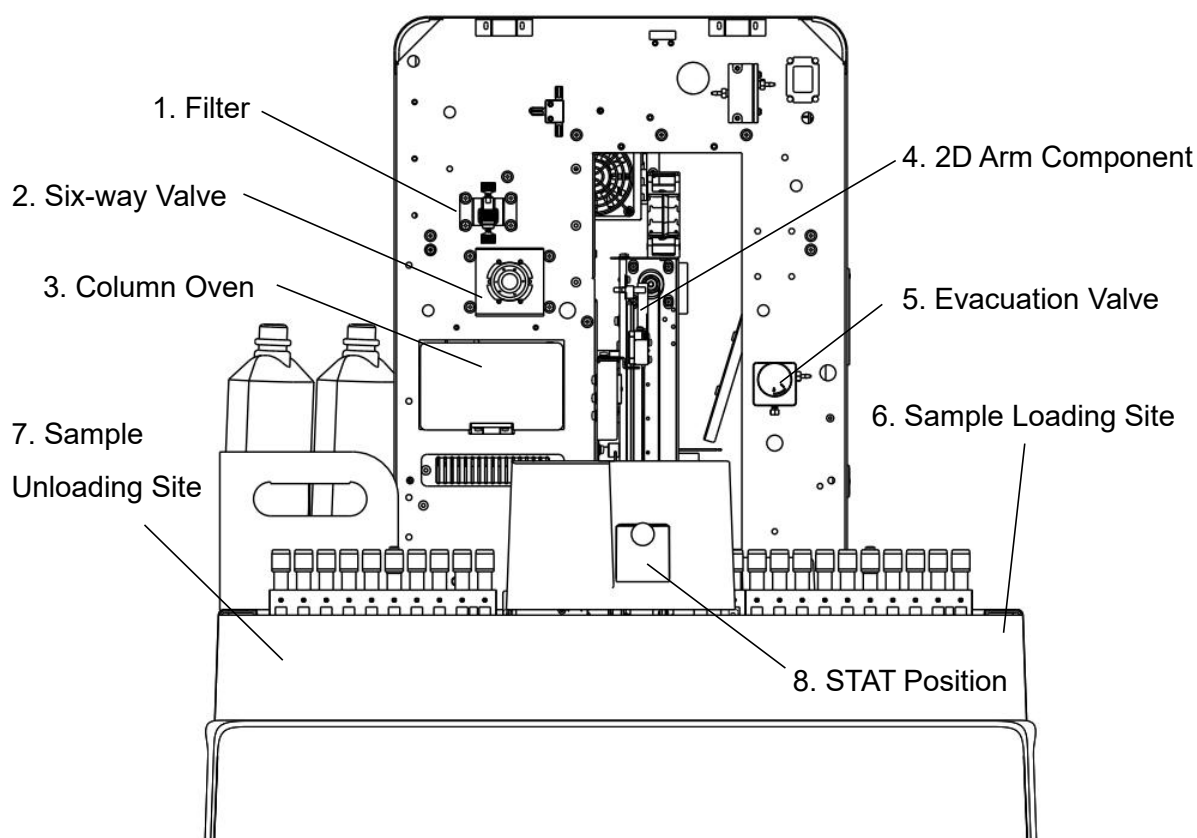


Fig. 2-5 Front View

1. Filter

The filter is used to intercept the filtrate lumps or floccules in blood samples, protect and prolong the life of column.

2. Six-way Valve

The six-way valve is mainly used to load the sample after hemolysis. After the sample is loaded into the six-way valve, the sample is pushed into the elution line through the switching action of the six-way valve, and finally enters the column for separation.

3. Column Oven

The column oven contains column that are critical in analytical test. The column should be kept at a certain temperature with the oven. The manually connected column can be easily replaced.

4. 2D arm component

The 2D arm component is for sample pre-treatment, including processes such as sample extraction and sample dilution.

5. Evacuation valve

Evacuation valve is for air evacuation. When air bubbles get into the pump or when changing reagents, open this valve for discharge. Do not open this valve during analysis.

6. Sample Loading Site

This site of the sample loader is for sample loading. Place the prepared sample rack on this site and start the test, the sample loader would automatically transfer the sample rack to the sample extraction spot.

7. Sample Unloading Site

This site of the sample loader is for sample unloading. When the test finishes, the sample loader would automatically transfer the sample rack to this site.

8. STAT Position

This position is designed for STAT test function, probe maintenance function and Hemolytic Agent L dispose function.

2.4.2 Left View

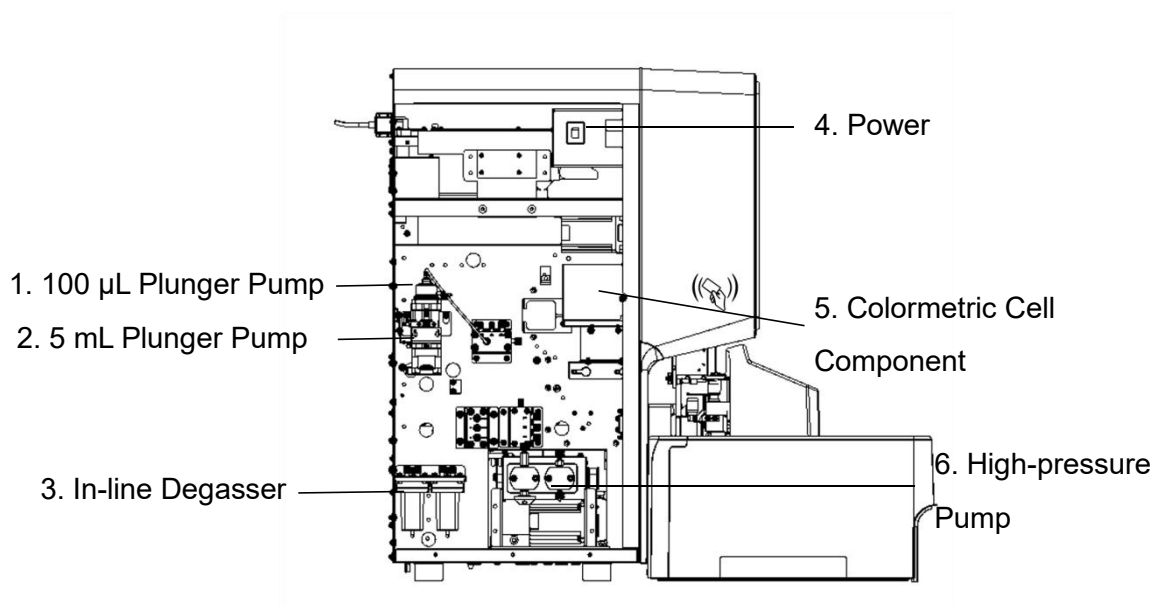


Fig. 2-6 Left View

1. 100 µL Plunger Pump

The 100 μ L plunger pump is majorly designed for sample extraction of whole blood/pre-diluted blood.

2. 5 mL Plunger Pump

The 5 mL plunger pump is majorly designed for sample dilution and the cleaning process of the liquid path.

3. In-line Degasser

This unit is used to degas eluents delivered by the pump. In order to maintain a certain vacuum pressure in the degassing container, the vacuum pump works intermittently.

4. Power switch

Controls power input of the analyzer. “I” means power-on; “O” means power-off.

5. Colorimetric cell component

The colorimetric cell component is used to detect the absorbance change of hemoglobin in the sample after separation by the column. Blue LED (light emitting diode) is used as the light source, and the detector applies dual-wavelength (415nm/500nm) detection, which improves the anti-interference capability of the system.

6. High-pressure Pump

The single-piston tandem-type high pressure pump is used to deliver eluent. Generally, the pump remains in working condition during analysis. In the analysis period, two eluents with different salt concentrations are delivered by switching of the solenoid valve to form a gradient (concentration gradient); the column is used to separate different components of hemoglobin.

2.4.3 Right View

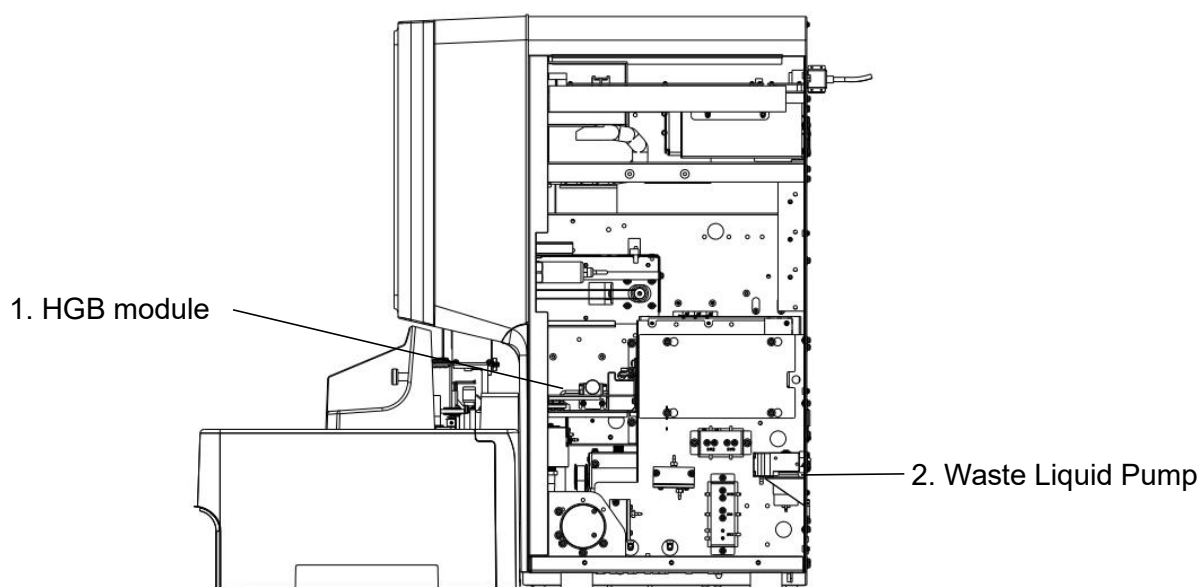


Fig. 2-7 Right View

1. HGB Module

HGB module is majorly designed for sample dilution and the cleaning process of the liquid path. By measuring the hemoglobin concentration of the pre-diluted blood samples and performing a secondary dilution, the hemoglobin concentration of the samples entering the high-pressure chromatography system can be maintained within a relatively stable range.

2. Waste Liquid Pump

Waste liquid pump is majorly designed for waste liquid discharge.

2.4.4 Rear View

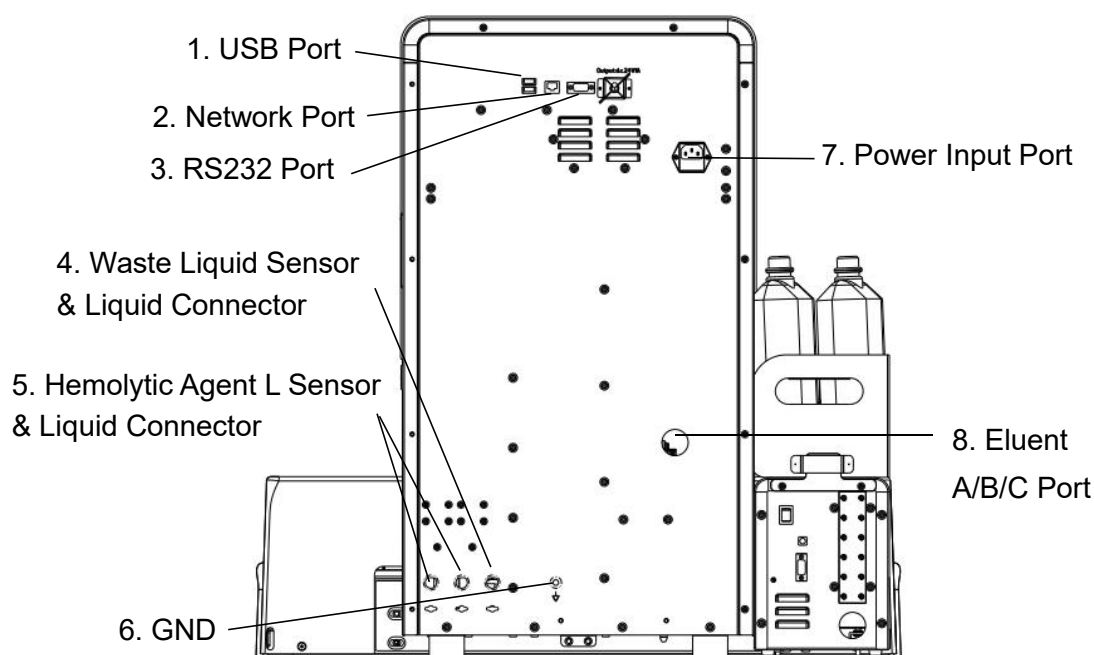


Fig. 2-8 Rear View

1. USB Port

The double-layer USB port can be used for upgrade of system application and external connection with USB scanner gun, mouse, keyboard, laser printer, etc.

2. Network Port

The network port can be used for online debugging, and the networking function of LIS/HIS system.

3. RS232 Port

Connection port for RS232 serial port line.

4. Waste Liquid Sensor & Liquid Connector

For connection with the external 10L waste liquid bottle and the sensor.

5. Hemolytic Agent L Sensor & Liquid Connector

For connection with the external 5L Hemolytic Agent L bottle and the sensor.

6. GND

Establish a unified reference ground potential for all devices connected to the system, thereby eliminating the interference voltage introduced by the ground potential difference between different devices and ensuring the accuracy and stability of measurement results.

7. Power Input Port

100-240V AC Power input port.

8. Eluent A/B/C Port

Connect to the ABC connectors on the back of the external reagent supply module.

2.5 Software System

Using the Qt graphical user interface application framework, the Linux-based application provides beautiful and friendly operation interfaces and the system language can be selected.

2.6 Consumables

The analyzer, reagents, column, filter, QC materials and calibrators constitute together a system which must be used as a whole to ensure the performance. The operator must use reagents designated by manufacturer and designated agent (see Annex A Specifications), otherwise, analyzer damage and bad performance may result. Use of reagents not specified may result in unreliable analysis data. “Reagent(s)” mentioned in this manual refer to reagent(s) matched with the analyzer. Check the packaging prior to using the reagent, as damage of the packaging may affect the reagent quality. DO NOT use the reagent if there is any moisture or leakage of the packaging.

2.6.1 Reagents

Before each run, the volumes of eluent and hemolytic reagent should be checked to ensure that there are enough reagents for the test. DO NOT start sample testing when the number of available tests of reagents is less than the number of sample applications required.

ATTENTION

- For use and storage of reagents, please refer to the reagent operation instructions.
- After the operator replaces the eluent, column, filter or Hemolytic Agent L, system cleaning should be carried out to ensure that the ADC value is within a normal range, so as to get ready for sample analysis.
- Ensure that the reagent, filter and column are within shelf life.
- The reagent should be shelved for a while before use.
- Precautions for use of reagent.
 - Reagents should be maintained at a lower temperature (4~30℃) to avoid failure caused by evaporation, DO NOT expose the analyzer and reagents to direct sunlight;
 - DO NOT use the reagent if it is frozen;
 - DO NOT perform the test with the bottle cap opened, otherwise the reagent will lose efficacy within one day.

■ Eluents A\B\C

They're different concentrations of eluents, form an ascending gradient of ion concentration. Due to the difference in electric charges carried by target proteins, the adsorbability against eluents varies. Therefore, when the concentration of eluent increases gradually, the target proteins HbA1a, HbA1b, HbF, LA1c, HbA1c and HbA0 are eluted off in sequence.

■ Hemolytic Agent L

Hemolytic Agent L is used to dissolve red blood cells and release glyated and other hemoglobin molecules.

2.6.2 Column

Cation exchange resin inside the column can adsorb glyated and other hemoglobin molecules. As the ion concentration of the eluent increases, the glyated hemoglobins HbA1a and HbA1b, fetal hemoglobin HbF, unstable glyated hemoglobin LA1c, stable glyated hemoglobin HbA1c and non-glyated hemoglobin HbA0 are eluted off, respectively.

DO NOT start sample testing when the remaining usage of the column is 0 and the number of available tests of column is less than the number of sample applications required.

Before using the column, please read the following precautions carefully:

- The column should not be subject to impact or vibrate, therefore, it is necessary to keep the column from dropping or violent collision.
- If the pressure increases during detection (About 4.0Mpa higher than the initial pressure), replace the filter immediately. If the pressure does not drop after the replacement, it is necessary to replace the column.

2.6.3 Filter

The filter is used to filtrate lumps or floccules in blood samples and the liquid path, in order to prevent decrease of liquid path flow rate and increase of pressure caused by obstruction of the column, and ensure the stability and reliability of the system.

When system pressure is too high and alarm occurs, please replace the filter immediately. DO NOT start sample testing when the remaining usage of the filter is 0 and the number of available tests of filter is less than the number of sample applications required.

2.6.4 QC Materials and Calibrators

QC materials and calibrators are used for quality control and calibration of the analyzer, respectively. QC materials are whole blood products and can be classified into low-value and high-value ones. Run the QC program daily to monitor the performance of the analyzer to ensure the reliability of analysis results. Calibrators are also whole blood products and are used for calibration of the analyzer. For use and storage of QC materials and calibrators, please see the instructions for QC materials and calibrators.

“QC materials” and “calibrators” mentioned in this manual refer to specific QC materials and calibrators designated by manufacturer and designated agent; please purchase them from manufacturer and designated agent or agents designated by manufacturer and designated agent.

Chapter 3 Operating Principle

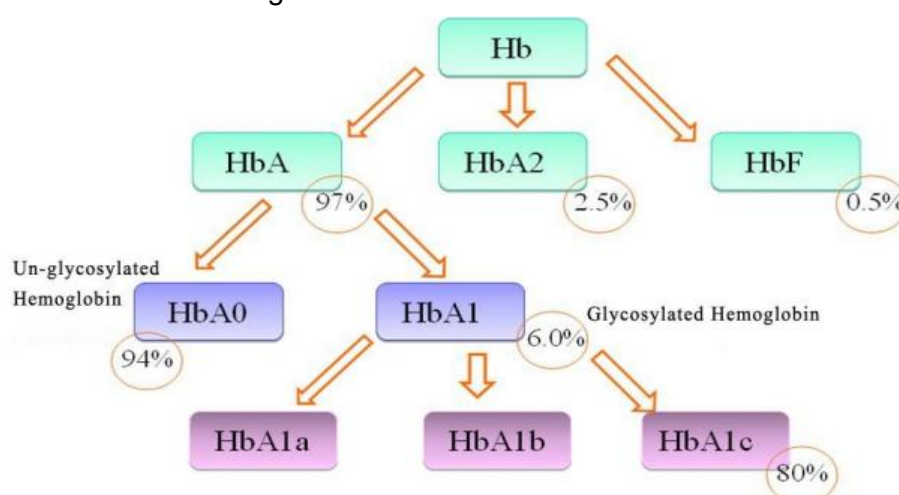
3.1 Overview

In human blood, there are three kinds of hemoglobin (Hb): hemoglobin A (HbA), hemoglobin A2 (HbA2) and hemoglobin F (HbF).

For adult, the level of HbA consists 97% of total hemoglobin, and HbA includes 2 subfractions: glycosylated hemoglobin (HbA1)(6%), un-glycosylated hemoglobin (HbA0)(94%).

Glycosylated hemoglobin is a compound that is formed in the non-enzymatic reaction between hemoglobin and carbohydrate. Glycosylated hemoglobin is called HbA1 and un-glycosylated hemoglobin is called HbA0. On the basis of combination with different carbohydrate compound, glycosylated hemoglobin is divided into HbA1a1, HbA1a2, HbA1b and HbA1c. Among of which, HbA1c is about 80% of HbA1, a stable addition compound formed by one or two strips of β -chain amino terminal and glucose carbonyl.

See constituent of hemoglobin below.



Picture 3-1 Constituent of Hemoglobin

Synthesis process of HbA1c is slow and irreversible. And it accumulates in the 120 days lifetime of erythrocytes. The synthesis rate is proportional to the concentration of blood glucose and its structure is stable. Therefore, the level of HbA1c reflects the average level of blood glucose in the past 2-3 months. As the average amount of blood glucose increases, the fraction of glycated hemoglobin increases in a predictable way, which is not related to blood drawing time, whether it is fast or not and whether use insulin or not. It's a reliable marker to indicate the control of blood glucose levels.

3.2 Aspirating Samples

The analyzer supports 2 types of sample testing, including whole blood sample and pre-diluted blood sample.

In the case of testing venous whole blood, the analyzer aspirates about 4 μ L of whole blood sample to the dilution cup, mix thoroughly and then inject for testing.

In the case of testing pre-diluted blood sample, it is suggested that the sample should be diluted according to the default ratio of whole blood: L liquid = 5: 1500. The analyzer aspirates 300 μ L of pre-diluted blood sample at a single time. The requirement of the analyzer for the volume of pre-diluted blood sample ≥ 1 μ L.

3.3 Measurement

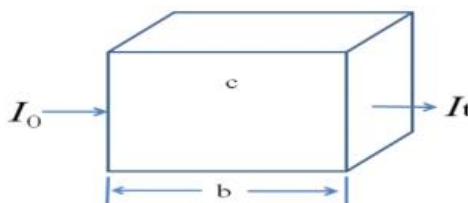
3.3.1 Ion Exchange Theory

The principle of separating glycosylated hemoglobin (HbA1c) from un-glycosylated hemoglobin using a weak cation-exchange column is based on the difference in their net surface charges caused by glycosylation. Glycosylation of hemoglobin reduces the number of positively charged cationic groups on its surface. As a result, when a blood sample is applied to a cation-exchange column pre-equilibrated with an acidic buffer, the un-glycosylated hemoglobin, which retains more cations and thus carries a higher net positive charge, binds more strongly to the negatively charged functional groups of the resin. In contrast, glycosylated hemoglobin, with fewer cations and a lower net positive charge, exhibits weaker electrostatic interaction with the resin. By sequentially eluting the column with buffers of increasing ionic strength and/or varying pH, the differently charged hemoglobin variants are selectively displaced: the less positively charged glycosylated hemoglobin elutes earlier under milder conditions, while the more positively charged un-glycosylated hemoglobin requires a higher ionic strength or pH change to be eluted. This stepwise elution allows for the separation and quantification of hemoglobin variants based on their differential adsorption affinities.

3.3.2 Colorimetric Analysis Principle

According to Lambert-Beer law, when a collimated monochromatic light transit a even solution medium, part of this light will be absorbed and the other part will be reflected by container. Define the incident light intensity as I_0 , the transmission light

intensity as I_t , the solution concentration as c , and the thickness of liquid as b . See the absorbing schematic diagram below.



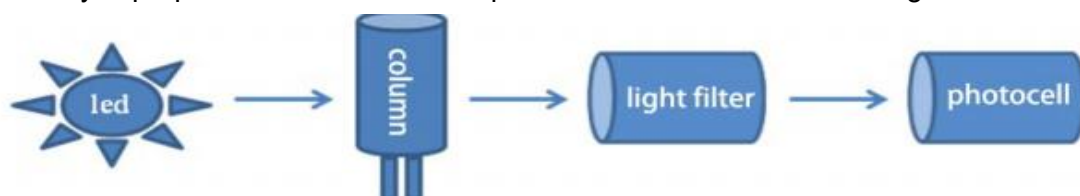
Picture 3-2 Absorbing Schematic Diagram

Written as:

$$A = kbc = \lg \frac{I_0}{I_t}$$

In the equation above, A means absorbance; K is absorption coefficient. The equation means that the absorbance of solution is in direct proportion to the product of solution concentration and liquid thickness.

The absorption peak wavelength of glycosylated hemoglobin is 415nm. So when 415 nm LED light passes through a cuvette, it will be absorbed by photocell after passing through a 415nm band pass filter. The 500 nm LED light also passes through the cuvette, and absorbed by photocell after passing through the 500 nm band pass filters. This wavelength is mainly used for corrects the background absorbance. Light intensity is proportion to the converted potential. See the schematic diagram below.



Picture 3-3 Colorimetric Analysis Principle

Therefore, absorbance could be also written as:

$$A = \lg \frac{I_0}{I_t} = \lg \frac{E_0}{E_t}$$

In the equation above, E_0 means incident light potential; E_t means transmission light potential.

Through amplifying and acquiring photocell signal by computer, measure real-time absorbance of the eluates continuously.

3.4 Column Balance

After last sample result in a batch, system will clean and balance the column automatically.

Chapter 4 Analyzer Installation

4.1 Overview



- Unpacking or installation should be performed by personnel authorized or trained by manufacturer and designated agent; otherwise, personal injury or system damage may result.

The analyzer has been tested and packed carefully prior to delivery. Upon receipt of the analyzer, please carefully check its packaging to see if there is any physical damage; if any, please contact manufacturer and designated agent' Customer Service immediately.

4.2 Installation Requirements

4.2.1 Environmental Requirements

ATTENTION

- Please store and use the analyzer under specified environmental conditions.
- If the room temperature is beyond the range of normal operating temperature for the analyzer, the analysis result obtained will be unreliable.

	Operating conditions	Storage conditions
Ambient temperature	10°C~30°C	0°C~55°C
Relative humidity	≤80% (non-condensing)	≤93%
Atmospheric pressure	75kPa~106kPa	75kPa~106kPa

- The ambient environment should be free from dust, mechanical vibration, pollution, noise sources and power interference.
- Evaluate the electromagnetic field in the laboratory before running the analyzer.
- Keep the analyzer away from sources of strong electromagnetic field to ensure optimal performance.

- Do not place the analyzer near brush type motors, flashing fluorescent lights and electrical equipment that is frequently turned on and off.
- Avoid direct exposure to strong light and keep the analyzer away from sources of heat and wind.
- Keep the analyzer at a well-ventilated place.
- Do not place the analyzer on an inclined plane.
- Good grounding should be available.
- Indoor use.

4.2.2 Space Requirements

To guarantee space required for repair and maintenance; In consideration of the heat dissipation of the analyzer and the liquid path behind the analyzer will not be squeezed to affect the normal flow of the reagent, the analyzer should be installed with the following requirements satisfied:

- Reserve a spacing $\geq 65\text{cm}$ between the wall and the left and right doors of the analyzer;
- Reserve a spacing $\geq 50\text{cm}$ between the wall and the rear door of the analyzer;
- Reserve a spacing of at least 70cm above the analyzer;
- The surface where the analyzer is placed should have a bearing capacity of at least 100kg ;
- Do not place the analyzer at a position where it is difficult to operate the disconnecting unit.

4.2.3 Power Requirements



- The analyzer must be well grounded before use.
- Before starting the system, please confirm that the input voltage conforms to the analyzer requirement.
- Before connecting the power adapter cable, confirm that the analyzer switch is in “OFF” status.
- The operator must use the built-in adapter of the analyzer. If use other adapters , it may affect the normal operation of the analyzer, and it might cause safety problems.

- If the operator repeatedly switches the power switch of the analyzer for a short time, the hardware circuit of the analyzer may be damaged.
-



- Use of an extension socket may introduce extra electrical interference and lead to wrong analysis results. Please place the analyzer close to the power socket to avoid using any extension socket.
 - Please use the power cord shipped with the analyzer. Use of other power cords may damage the analyzer or lead to wrong analysis results.
-

Voltage	Frequency	Input power
100V-240V	50/60Hz	200VA

4.3 Transportation Method

- Remove all reagents prior to transportation.
 - If the analyzer has been used, confirm that the liquid path is emptied prior to transportation.
 - A trolley or other tools can be used for short-distance transportation on a smooth road.
 - During transportation, keep the touch screen and the sampling needle from any kinds of violent impact or collision and avoid direct contact with other objects.
 - During transportation, DO NOT tilt the analyzer, keep the analyzer upright and avoid vibration.
 - When lifting the analyzer, put your hands at the bottom of it; hold it tenderly, and gently place it at the specified position.
-

ATTENTION

- Properly keep the packaging box for future long-distance transportation.
-

4.4 Installation Steps



- The sampling needle is sharp. Bio-contaminated blood samples may remain on the sample compartment, sampling needle, column and filter. The operator should wear gloves during installation to avoid direct contact with the above components.
- The operator's clothes, hair and hands must be kept at a safe distance from the sampling needle, 2D arms and other moving parts to prevent injury.

4.4.1 Removal of Metal Slice Fixing the 2D arm

In order to avoid damage of the 2D arm during transportation, a metal slice is used to fix the 2D arm before delivery. Prior to use, the metal slice must be removed following the steps below:

1. Open the right door, as shown in **Fig. 4-1**:

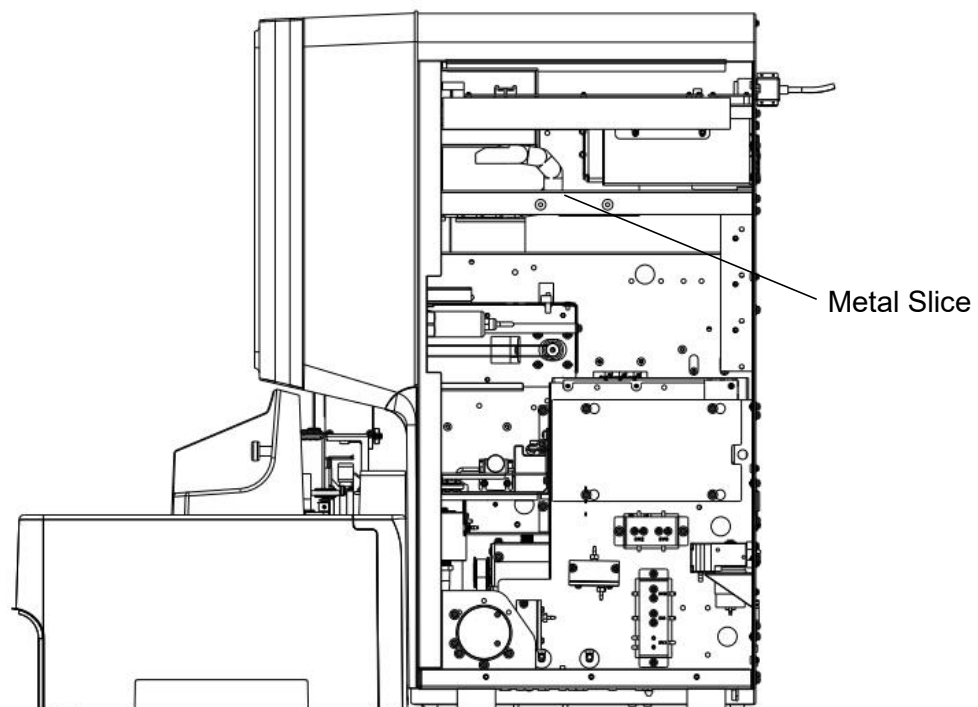


Fig. 4-1 View after Opening the Right Door

2. Use a screwdriver to unscrew the two screws that fixed the 2D arm to the metal slice, and then, remove the metal slice.

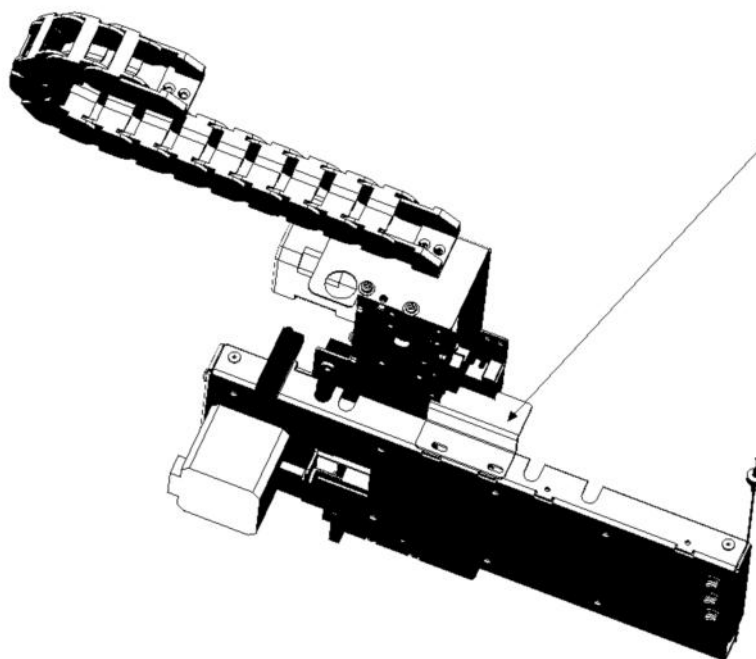


Fig. 4-2 View of the Metal Slice and Fixed 2D Arm

4.4.2 Reagent Connection

Take the bottle cap components from the accessories. Connect one end to the reagent A/B/C connector on the back of the external reagent supply module and insert the other end into the eluents A, B, and C respectively, then tighten the cap firmly.



- Reagents may irritate eyes, skin and mucosa. When contacting reagent-related materials in the laboratory, the operator should comply with the requirements for safe operation in the laboratory and wear personal protective equipment (e.g., laboratory protective clothing and gloves).
 - If your skin comes into contact with any reagent, flush immediately with plenty of water, and seek advice from a doctor if necessary. If in eye, please flush immediately with plenty of water, and seek advice from a doctor.
-
-

ATTENTION

- DO NOT mix different batches of reagents together.
 - Ensure that the reagent and column are used within shelf life.
 - After the reagent is connected to the analyzer, firmly cap the reagent bottle to prevent contamination of the reagent.
-

4.4.3 Connection of Hemolytic Agent L and Waste Liquid

Take the Hemolytic Agent L connecting component from the accessories; connect one end to the hemolysis reagent connector on the back of the analyzer and insert the other end into the Hemolytic Agent L bucket;

Take the waste liquid connecting component from the accessories; connect one end to the waste liquid connector on the back of the analyzer and insert the other end into the waste liquid bucket.

ATTENTION

- Two modes are available for connection of waste liquid: use of waste liquid bucket, or direct discharge.
 - Ensure that the waste liquid bucket is placed at a height not above the surface where the analyzer is placed. If direct discharge of waste liquid is selected, make sure the position of waste liquid pipe is below the waste liquid outlet of the analyzer.
-

4.4.4 Installation of the Filter and Column

ATTENTION

- When tightening the hand-tight connectors at both ends of the column, do not leave any gap at the connection part of conduit and column; the inlet conduit should be straightly and tightly inserted to the bottom of the connection part.
- The filter and column may contain biological contamination; the operator must wear protective gloves to ensure operation safety.
- When installing the filter or column, there may be reagent drops on the analyzer or console. Please prepare tissue or a handkerchief for cleaning.

4.4.4.1 Installation of the Column

Before installing the column, please read relevant chapters in the instructions, and then follow the steps below:

Procedure

- 1) Take the column and filter out of the packaging box, and remove the retaining plugs connected at both ends of the column and filter. Please keep the retaining plugs properly for future use. Open the column cover after confirming that the analyzer has stopped delivering liquid, take off the plastic hose which both sides are connected to the plugs and connect the both sides of the column with the plugs. Make sure that the liquid delivery direction of the column (Align the column arrow “” with the column oven arrow “”) is consistent with the label on the column oven, then tighten the plugs on both sides and close the column cover.

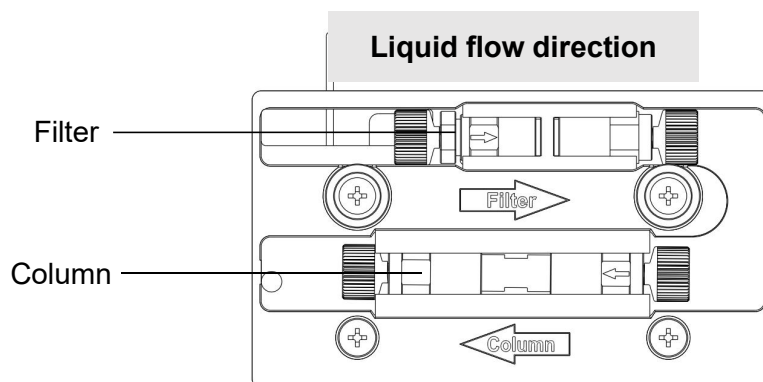


Fig 4-3 the Liquid Delivery Direction of the Column

- 2) Enter the “Test” interface, press the “Column” icon, a prompt will show as **Fig 4-4** below. Press “Replace”, a prompt will show as **Fig 4-5**.

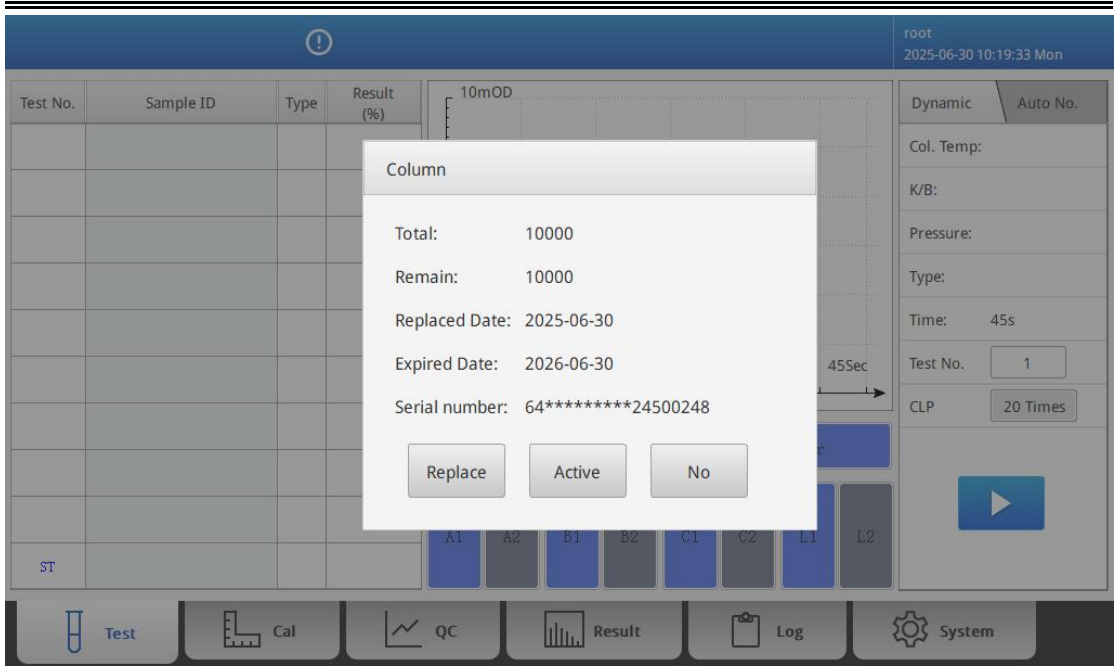


Fig 4-4 View of Column Installation Procedure(1)

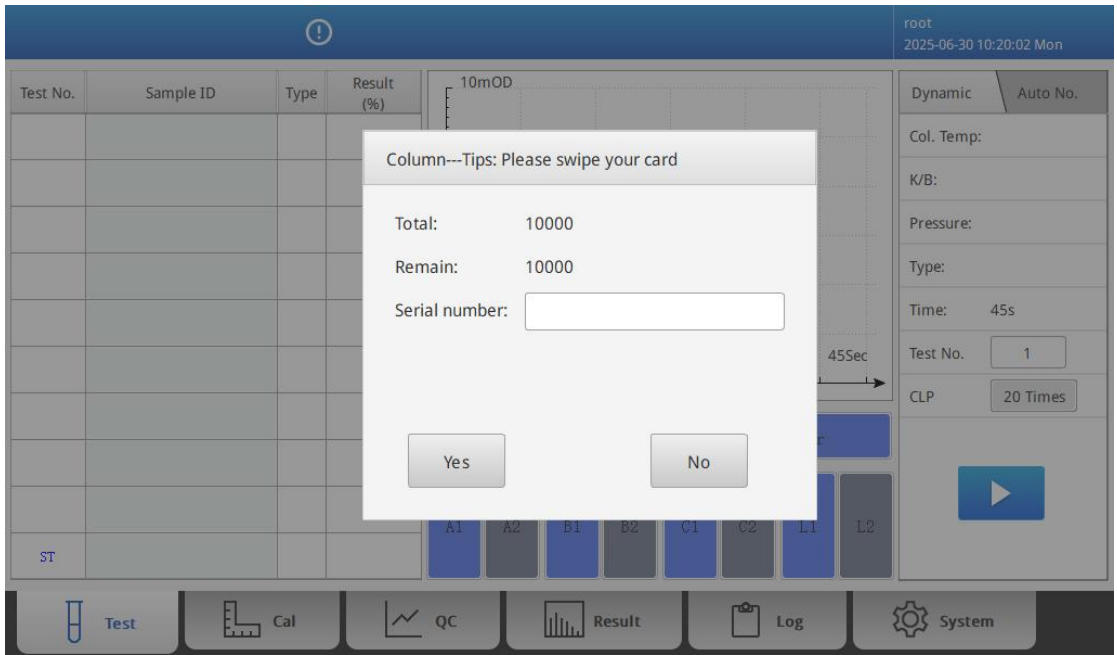


Fig 4-5 View of Column Installation Procedure(2)

- 3) Take the RFID card out of the packaging box and swipe the card on the left side of the analyzer to read the new serial number. A prompt will show as **Fig 4-6**. Then press “**Yes**”. A prompt will show as **Fig 4-7**.

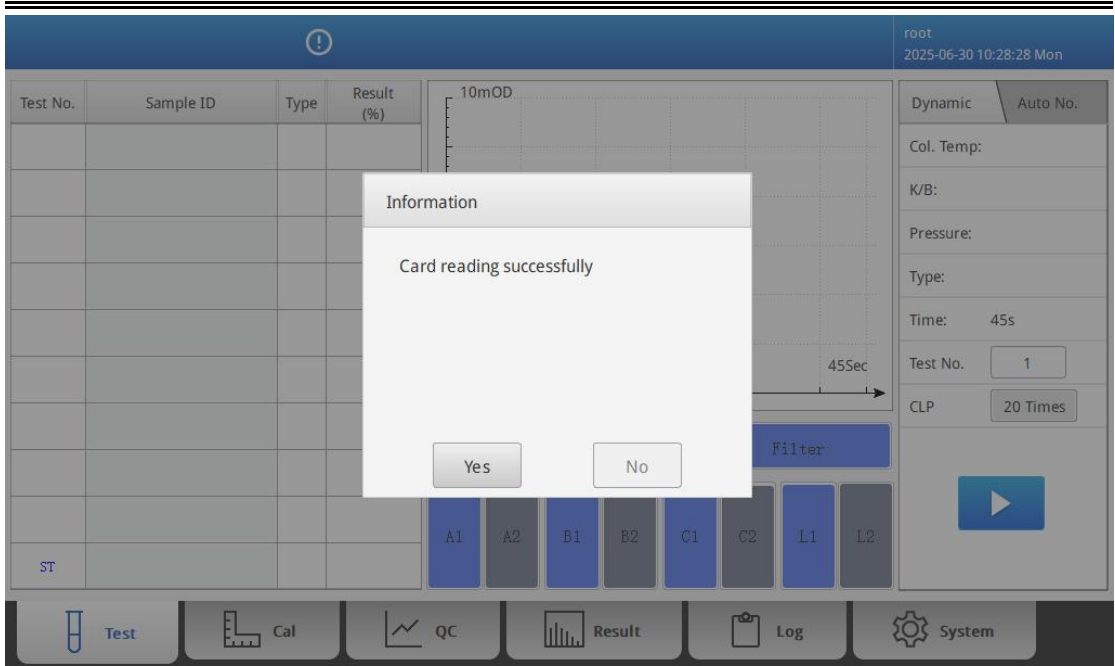


Fig 4-6 View of Column Installation Procedure(3)

- 4) Input the temperature for the column, press “Yes” and a prompt will show as Fig 4-8.

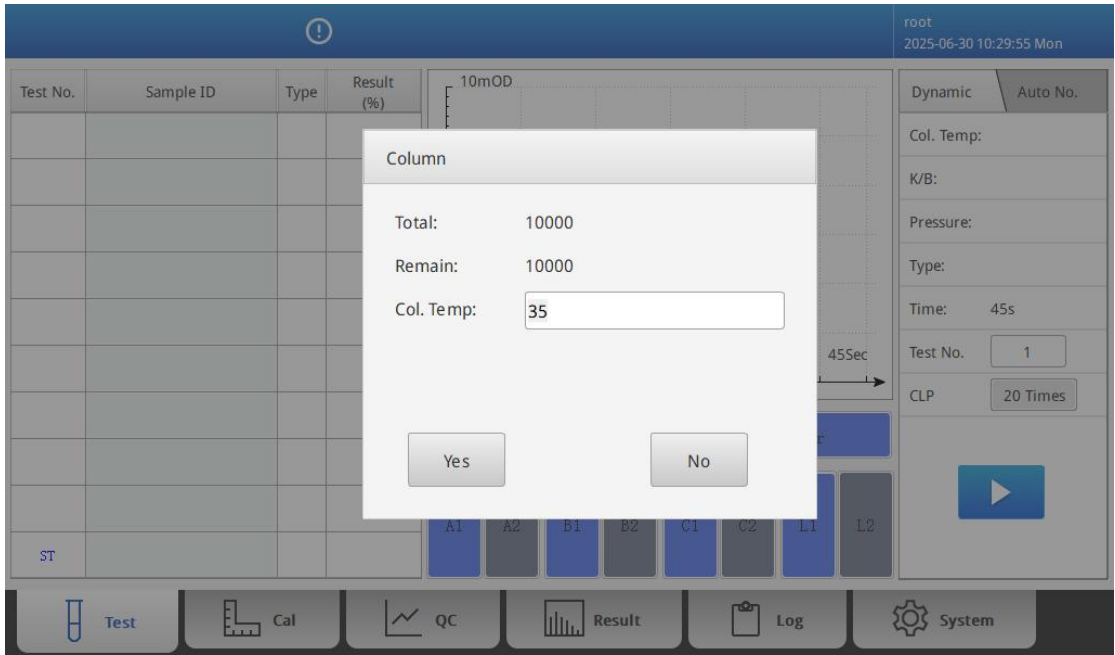


Fig 4-7 View of Column Installation Procedure(4)

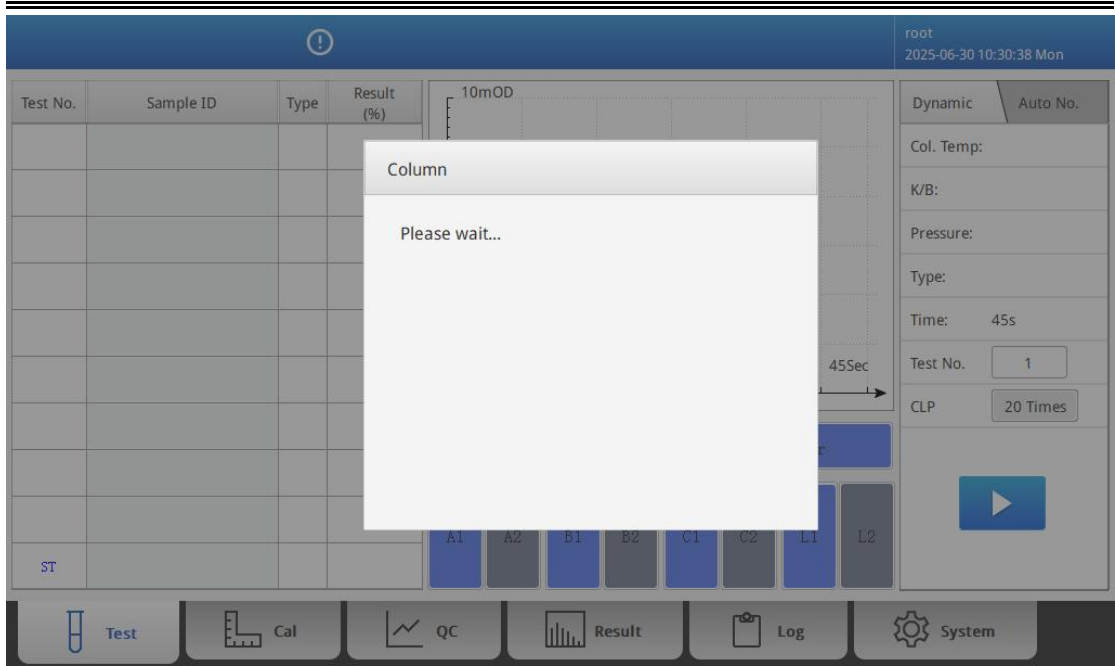


Fig 4-8 View of Column Installation Procedure(5)

5) Waiting about 10 minutes, the replacement process is completed. Simultaneously, the operator may sequentially prepare the calibrators, controls and test samples in the loading area.

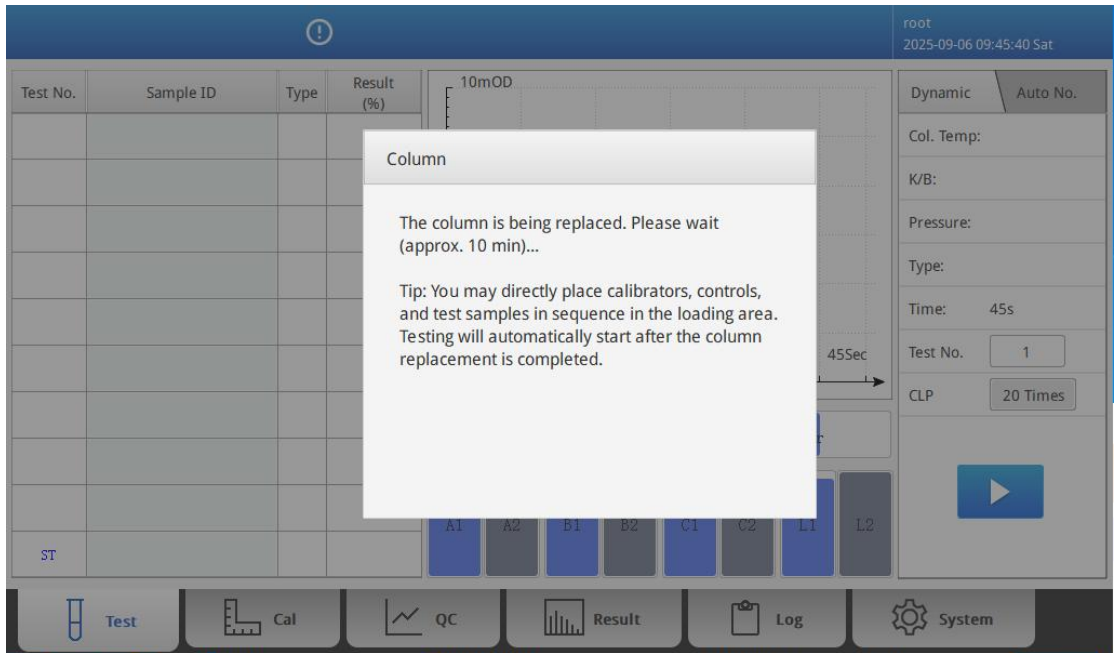


Fig 4-9 View of Column Installation Procedure(6)

4.4.4.2 Installation of the Filter

Procedure

1) The filter needs to be installed at two positions, as shown in the fig 4-10.

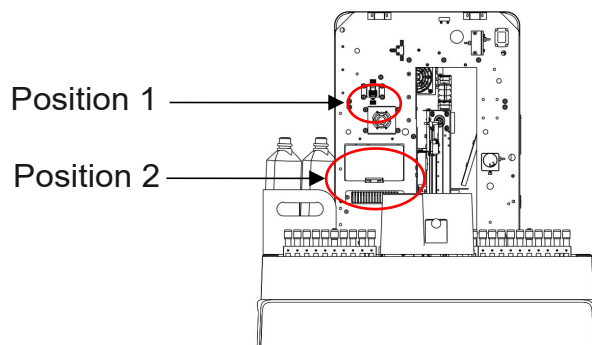


Fig 4-10 the Installation steps of the filter(1)

2) As shown in Fig 4-11, unscrew the tight joints at both ends of the filter, then take out the old filter, follow the prompt label on the instrument to install the new filter and screw the tight joints.

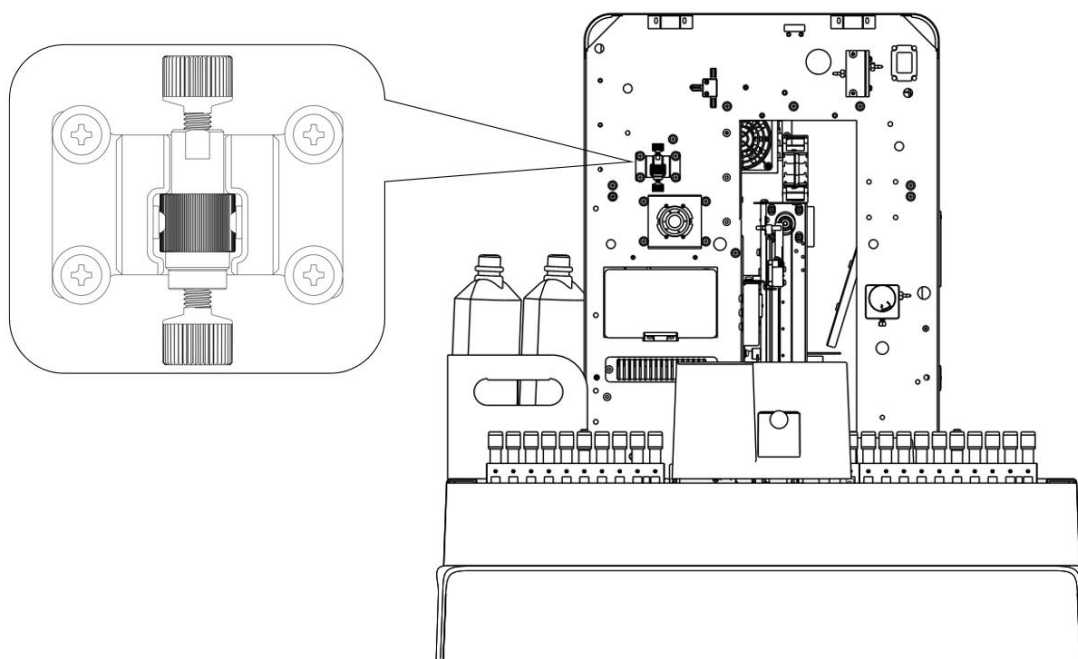


Fig 4-11 the Installation steps of the filter(2)

3) As shown in Fig 4-12, refer to step 1 of the column installation. Make sure that the liquid delivery direction of the filter (Align the filter arrow "  " with the column over arrow "  "), then tighten the plugs on both sides and close the column oven.

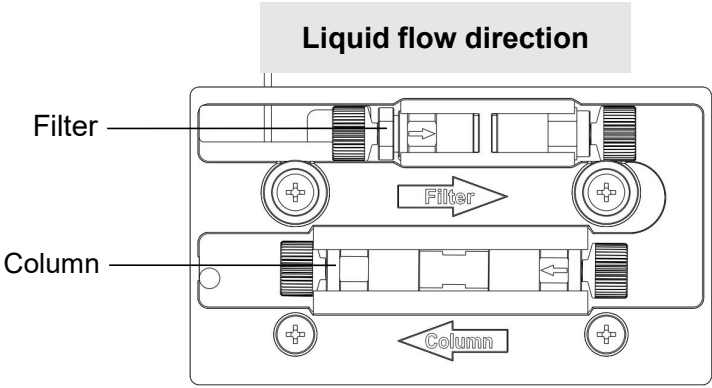


Fig 4-12 the Installation steps of the filter(3)

4) Enter the “**Test**” interface, press the “**Filter**” icon, a prompt will show up as **Fig 4-13**.

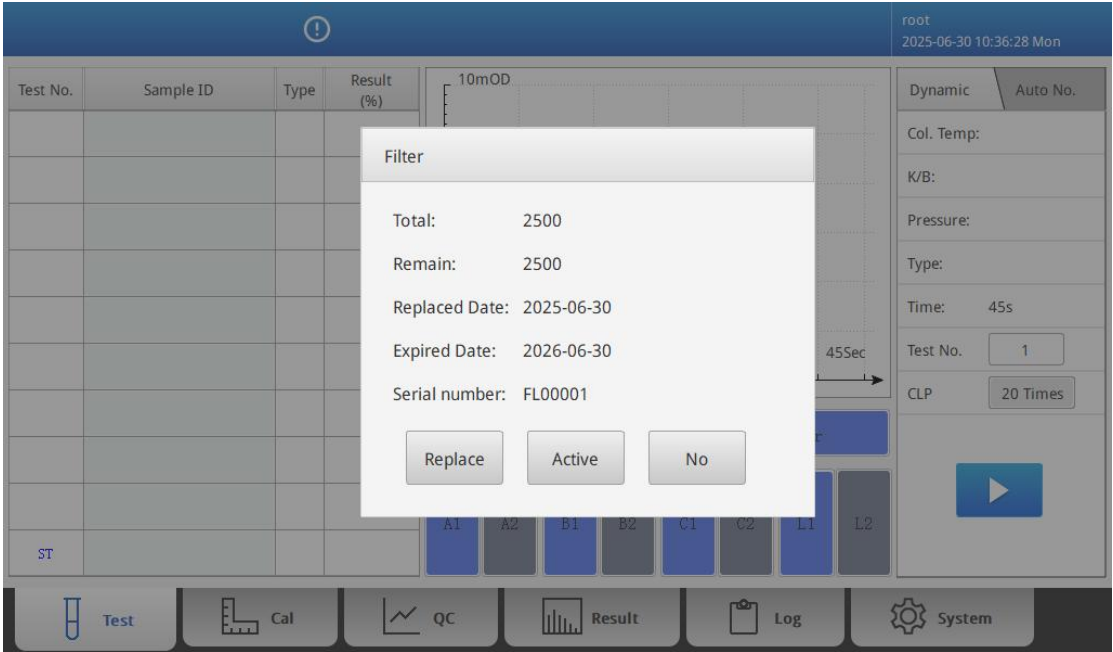


Fig 4-13 View of Filter Installation Procedure(1)

5) Press “**Replace**”, a prompt will show up as **Fig 4-14**.

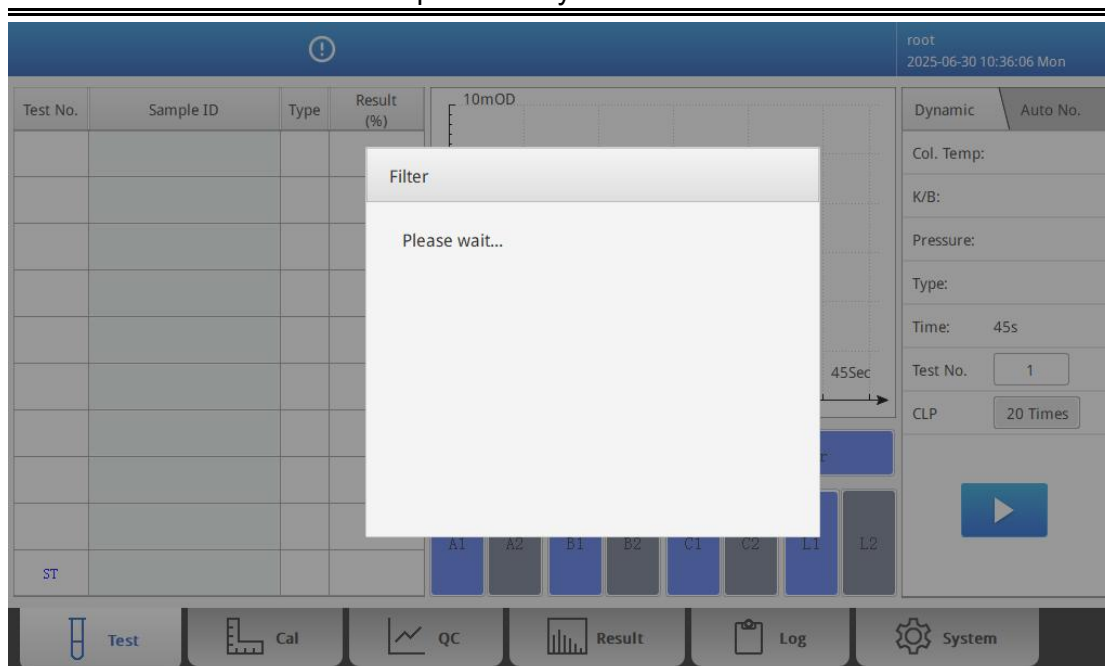


Fig 4-14 View of Filter Installation Procedure(2)

6) Waiting about 10 minutes, the replacement process is completed. Simultaneously, the operator may sequentially prepare the calibrators, controls and test samples in the loading area.

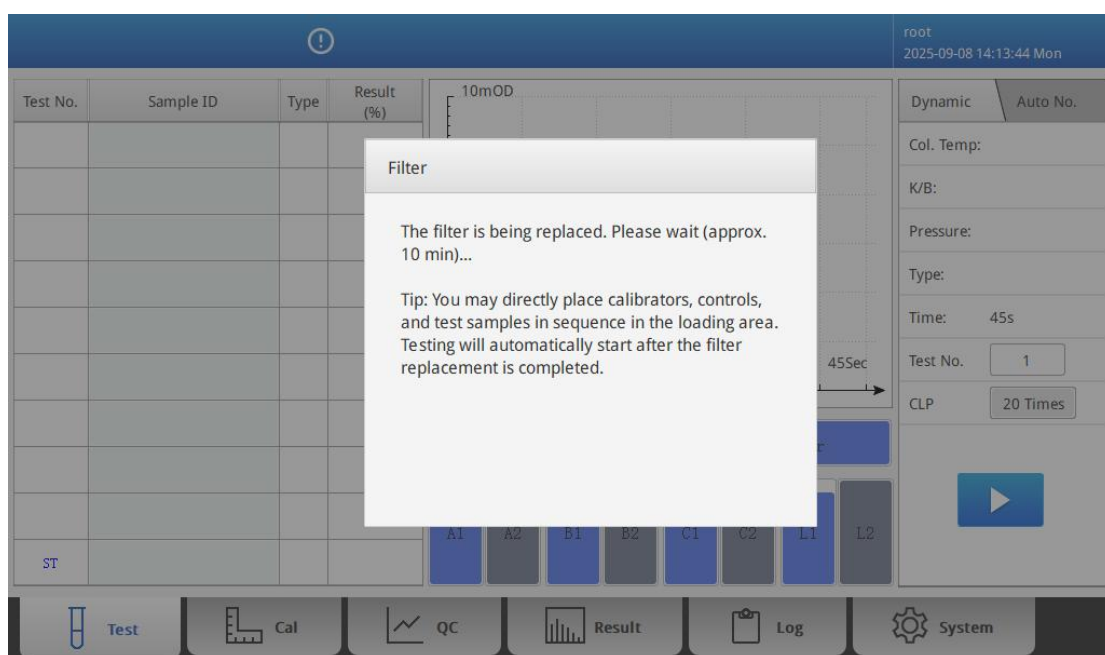


Fig 4-15 View of Filter Installation Procedure(3)

4.4.5 Loading of the Thermal Paper

Pull the printer lever outward to open the printer door. Load thermal paper into the paper cavity in the direction shown in **Fig. 4-16**, with the paper end positioned

outside the paper outlet. Close the printer door; check the position of thermal paper to ensure that is aligned with the paper outlet.

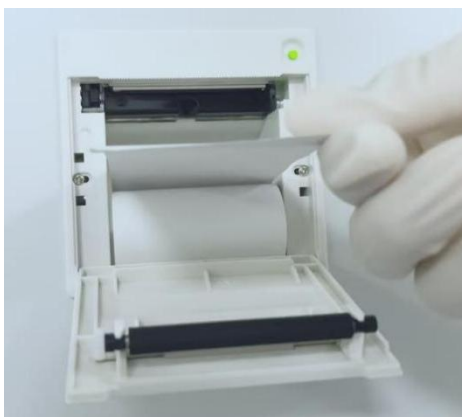


Fig. 4-16 Loading of Recording Paper

4.4.6 Installation of the Power Cord

Take the power cord from the accessory package, insert one end of the power cord into the power input port on the back of the analyzer, and the other end into the power outlet.

4.5 Initial Startup

Switch on the power switch on the back of the analyzer. The system will enter the login interface (**Fig 4-17**). Enter the account and password, then press “**Login**”, the analyzer will automatically execute self-check and system cleaning process, and then enters the test interface (**Fig 4-18**).

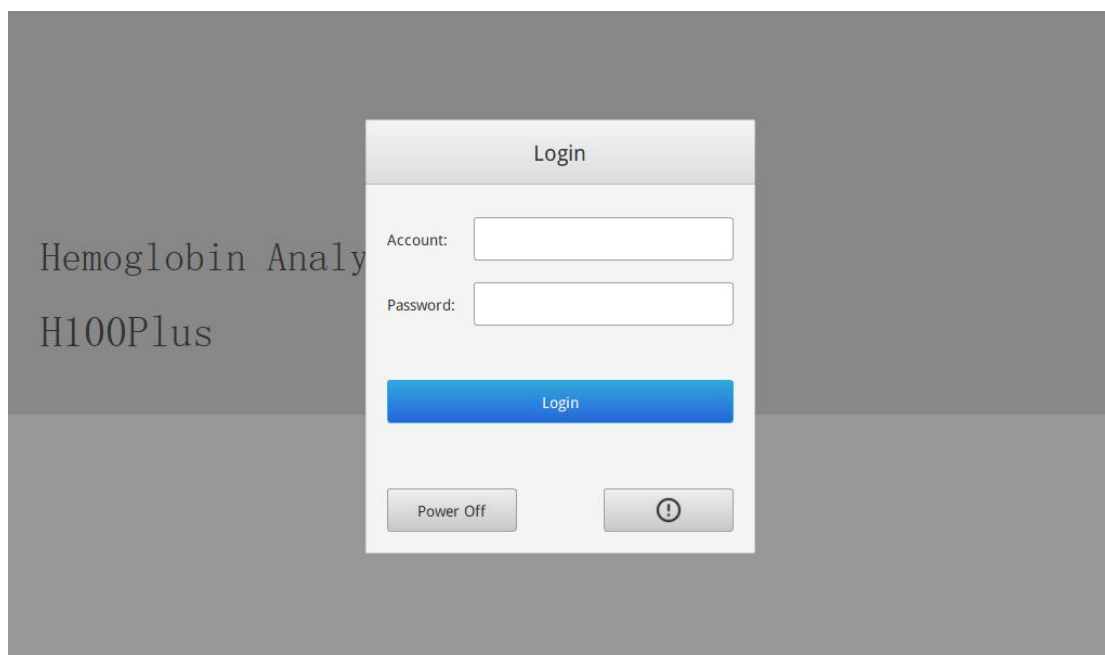


Fig 4-17 View of Login Interface

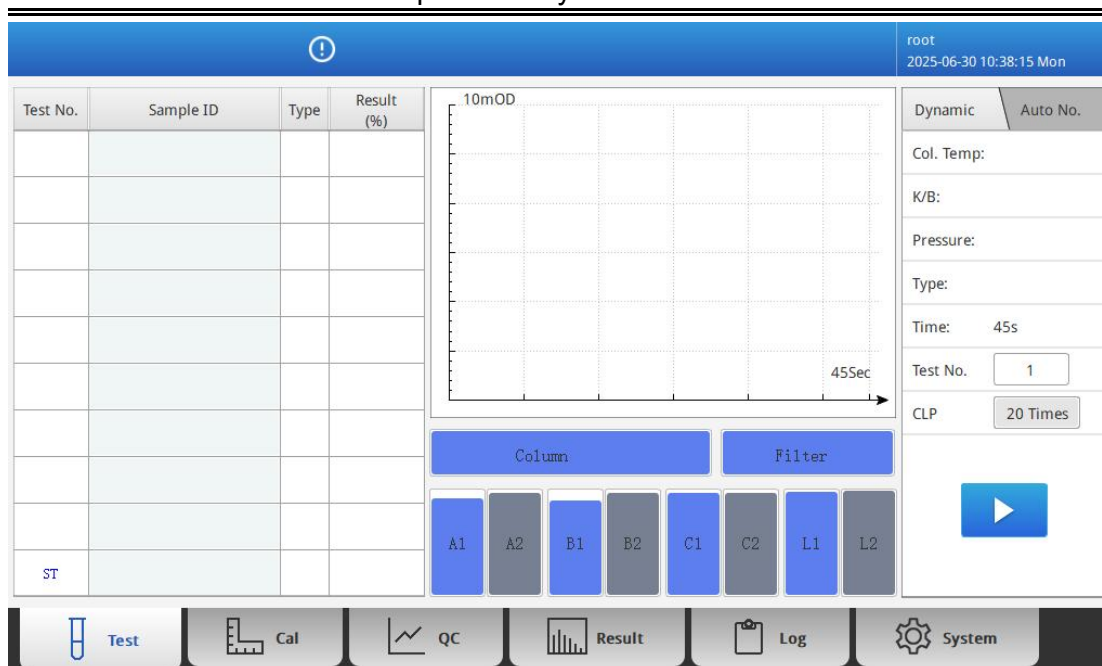


Fig. 4-18 View of Test Interface

In the test interface, the remaining volumes of the eluents A/B/C and Hemolytic Agent L, the number of available tests of the column and the filter are displayed.

■ Number of Tests per column

Column are consumable materials. Every time a sample is analyzed, the available test number of the column automatically decreases by one(not including calibration analysis). If the number of available tests by the column reaches the lower limit, the column should be replaced by a new one. Otherwise the test cannot be started.

■ Number of Tests per filter

Filters are consumable materials. Every time a sample is analyzed, the available test number of the filter automatically decreases by one(not including calibration analysis). If the number of available tests by the filter reaches lower limit, the filter should be replaced. Otherwise the test cannot be started.

Press **“System”** to enter the system interface:

Chapter 4 Analyzer Installation

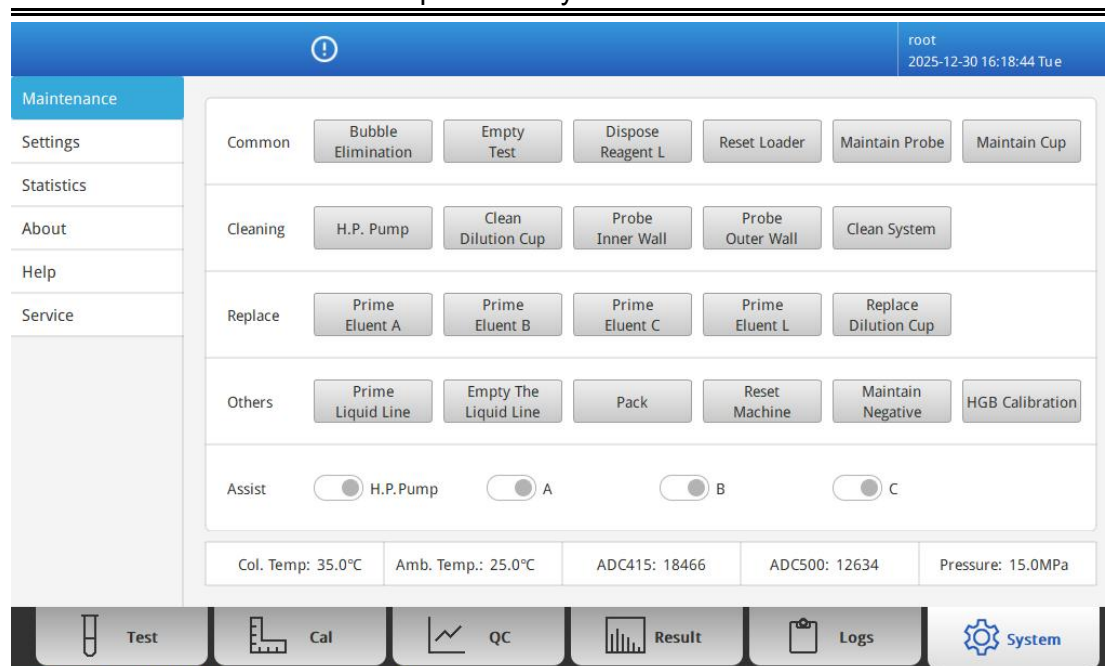


Fig. 4-19 View of the System Interface

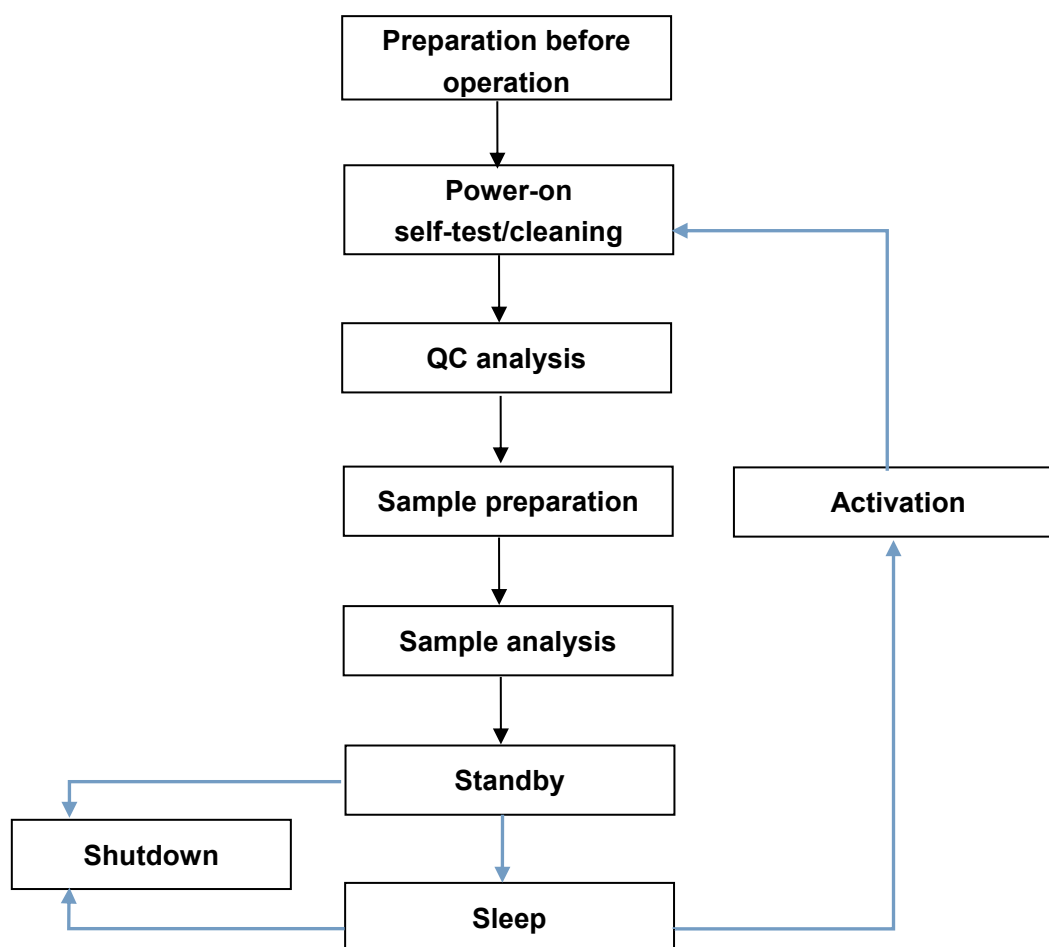
Press **“Prime Liquid Line”** and wait, when the priming process is completed, Press **“Bubble Elimination”** to eliminate air bubbles in the high pressure pump. In case of other malfunctions during operation, please see **“Chapter 11 Trouble shooting”** in this manual.

Chapter 5 Routine Operations

5.1 Overview

This chapter introduces the whole process of routine operations from start up to shutdown of the analyzer, and especially focuses on the operation process of analysis of whole blood sample and pre-diluted blood sample.

Below is the process of routine operations:



5.2 Preparation Before Operation

Before powering on the analyzer, the operator should check it according to the following requirements to ensure that the system is ready.



- Samples, QC materials, calibrators, columns, filters and waste liquid may carry biological contamination. When contacting relevant materials and areas in the laboratory, the operator should comply with the requirements for safe operation in the laboratory and wear personal protective equipment (e.g., laboratory protective clothing and gloves).
-



- The operator is obliged to comply with the local and national regulations on discharge and disposal of expired reagents, waste liquid, waste samples and consumables, etc.
 - Use of the analyzer without following the methods specified by the manufacturer may damage the analyzer.
-

■ Check the remaining volume of reagents

Check whether the remaining volumes of eluents A/B/C and Hemolytic Agent L are sufficient.

■ Check the waste liquid bucket

Check the waste liquid bucket to ensure that it is emptied prior to start up every day.

■ Check the liquid tube and power supply

Check if the reagent and waste liquid tubes are bent.

Check if the connection of reagent and waste liquid tubes are reliable.

Check if there is any liquid leakage of the analyzer.

Check if the power plug of the analyzer is properly inserted into the socket.

■ Check the printer

Check if the recording paper is sufficient and the printer is properly installed.

■ Check the Probe Rinse Solution

Check if the Probe Rinse Solution is sufficient and place in STAT position.

5.3 Power On

Turn on the main power switch which is at the left of the analyzer.

The side marked “I” indicates power on, and the side marked “O” indicates power off.

Procedure

- 1) Turn on the main power switch, the Login interface will show as **Fig 5-1**.

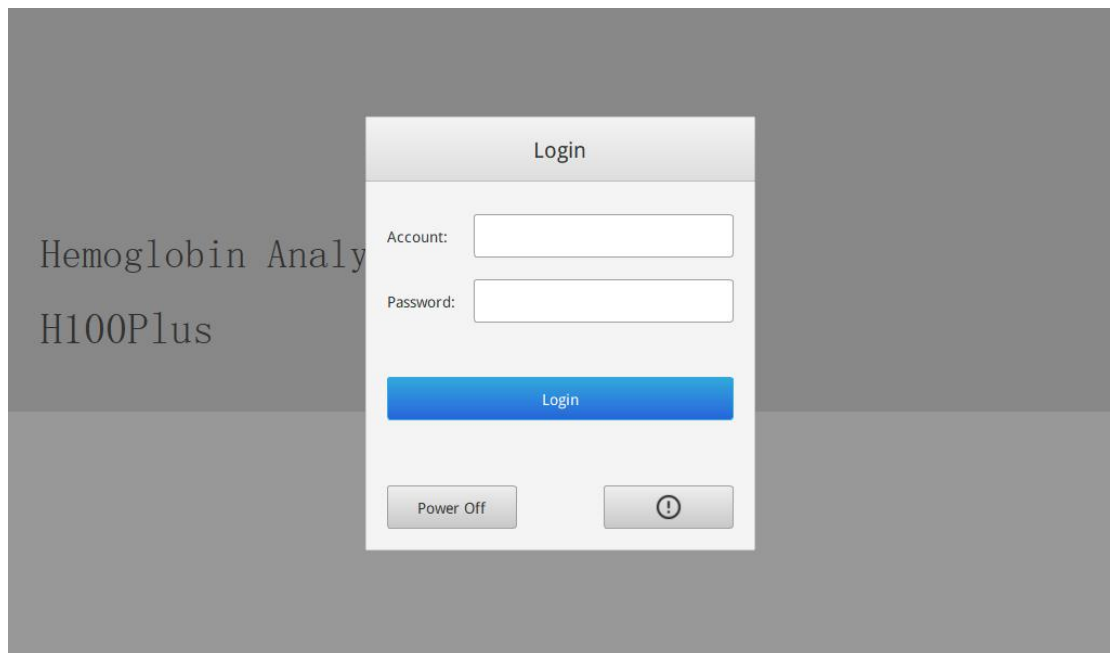


Fig. 5-1 View of Login Interface after powered on

- 2) Enter the account, password, and select “Login”. If login successfully, the analyzer will execute the self-check process as **Fig 5-2**. After the self-check process is completed, the analyzer will automatically run system cleaning process, and a prompt will show up as **Fig 5-3**. Please wait patiently till the system cleaning process ends.

The screenshot displays the 'Test' screen of a software interface. At the top, there is a status bar with a warning icon and the text 'root' and '2025-06-30 10:41:40 Mon'. Below this is a table with the following columns: 'Test No.', 'Sample ID', 'Type', and 'Result (%)'. A pop-up window titled 'Information' is centered on the screen, displaying the message 'System pressure detecting... (00:00:24)'. The background interface includes a graph area with a 10mOD scale, a 45Sec timer, and a 'Filter' button. The bottom navigation bar contains icons for 'Test', 'Cal', 'QC', 'Result', 'Log', and 'System'.

3) After the system cleaning process is completed, if sample rack is detected in the sample loading site, the analyzer will automatically start the test. A prompt will display as **Fig 5-4** .

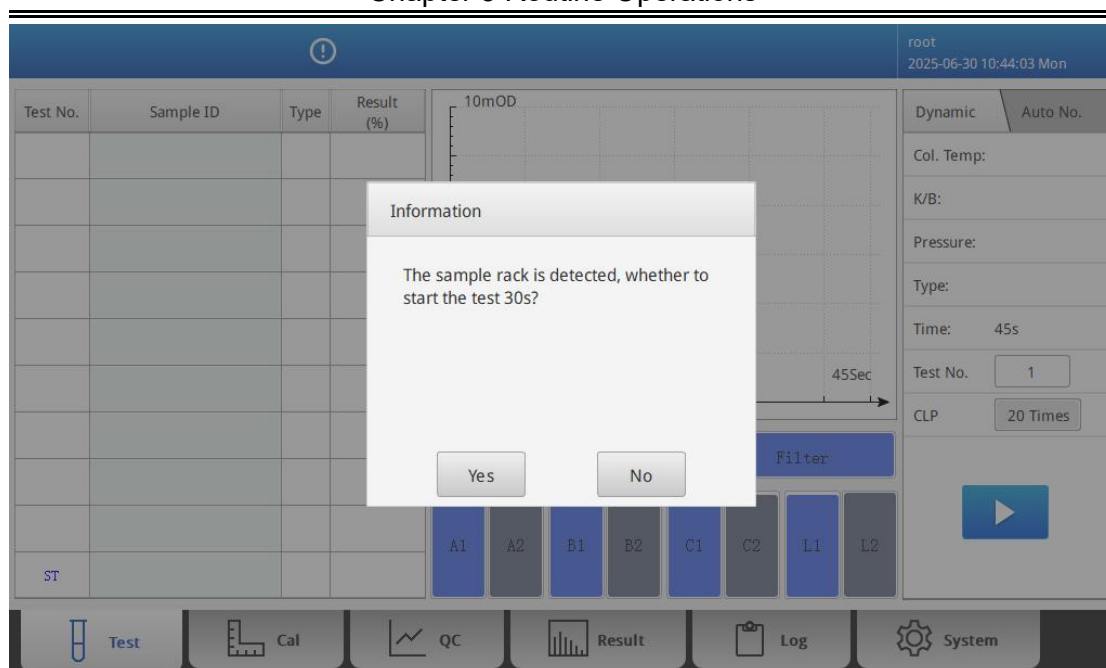


Fig. 5-4 View of Test Interface

5.4 Daily QC

Quality control process should be carried out by the operator every day after the analyzer is powered on, to ensure that the analyzer provides reliable analysis results. For QC analysis method, see “**Chapter 8 Quality Control**”.

5.5 Sample Preparation



- Samples, QC materials, calibrators, column, filters and waste liquid may carry biological contamination. When contacting relevant materials and areas in the laboratory, the operator should comply with the requirements for safe operation in the laboratory and wear personal protective equipment (e.g., laboratory protective clothing and gloves).



- Avoid direct contact with blood samples.



- Do not reuse disposable products.
 - Prepare samples according to the procedure recommended by the test tube manufacturer.
-

ATTENTION

- The operator should use clean vacuum blood collection tubes with EDTA-K₂ and EDTA-K₃.
 - For blood collection, use only disposable products with specifications specified by the manufacturer, such as vacuum blood collection tubes, centrifuge tubes, and capillary tubes.
-

When the user collects the sample solution, the recommended specification of the disposable vacuum collection vessel is Φ 12-15mm in width and Φ 75-85mm in height.

The instrument can automatically read the barcode label ID pasted on the blood collection tubes. The pasting position and the label size of the barcode label are shown in Figure 5.5.

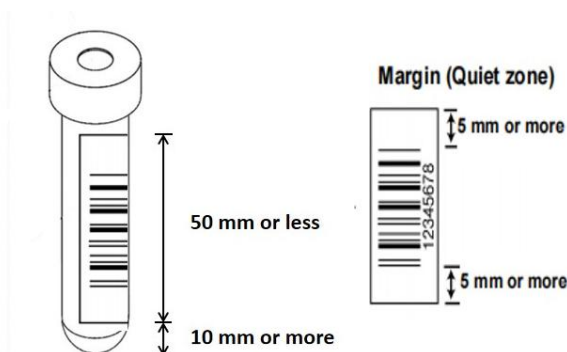


Fig. 5-5 Barcode labels position and size

ATTENTION

- The specifications and dimensions of barcode labels, printing specifications, pasting methods and other reasons will lead to the failure of instrument identification. The operator shall stick the barcode ID label in the way specified by

our company, and our company will not be responsible for the instrument's failure to recognize the ID or recognition error due to other ways.

- You should leave a margin(quiet zone) of 5 mm or more on the left and right of the barcode. In addition, the barcode labels should leave a margin(quiet zone) of 10 mm or more on the bottom of the vacuum blood collection tube.
- If the label is pasted at an angle, the bar code can not be read correctly, and if the label is wrinkled or overlap multiple or broken, instrument failure may occur because the tube can not drop back properly to the sample rack.
- When the analyzer enter system cleaning process, please don't open the STAT. door ! Also, ensure place a 5mL tube with cleaning solution in STAT position.

5.5.1 Whole Blood Samples

The blood collection tubes with rubber caps can be directly placed on the sample rack. The dimensions of available blood collection tubes should be $\Phi 12\sim 15\text{mm}$ in width and $75\sim 100\text{mm}$ in height. Whole blood samples should be prepared as follows:

Procedure

- 1) Use recommended vacuum tubes with anticoagulant to collect venous blood samples.
- 2) Place the blood collection tubes in the sample rack. DO NOT remove the rubber cap, since the automatic mixing up method and the puncture method are applied on the analyzer for sample extraction.

ATTENTION

- In order to ensure the accuracy of analysis results, the sample volume in the whole blood mode should not be less than 1mL.
- Refrigerated ($2\sim 8^{\circ}\text{C}$) samples should be placed at room temperature for at least 30 min prior to analysis.
- Samples having been shelved should be remixed evenly prior to analysis.
- Smaller blood collection tubes are too loose when placed in the sample rack, which may result in malposition, bending or fracture of the sampling needle during sample extraction. Please use blood collection tubes with dimensions within the recommended range.

- Blood samples that contain air bubbles, lumps or floccules may cause malfunction of the sampling needle in sample extraction. Please retest if the test result is less than 3%.
-

5.5.2 Pre-diluted blood Samples

The following three situations where the dilution sample mode is recommended:

1. Anemia samples
2. Peripheral blood samples
3. Whole blood sample not enough

Pre-diluted blood samples should be prepared as follows:

Procedure

- 1) Use a pipette to accurately add 5 μ L(Peripheral blood samples and whole blood samples) or 10 μ L(Anemia samples) whole blood to a 1.5 mL EP tube.
- 2) Use a pipette to add 1500 μ L Hemolytic Agent L to the EP tube and mix them evenly.
- 3) Place the EP tube on the sample rack with the diluting sample holder, and the caps of EP tube must be securely fastened into the slots of the diluting sample holder before performing the test.

When the test result of the whole blood samples is marked with "e1" that means total area is less than 30,000 (see chapter 6) and at the same time the analyzer has no other malfunctions ,it is suggested to dilute the sample(10 μ L + 1500 μ L) or place the whole blood sample to the anemia rack and retest again.

ATTENTION

- Ensure that analysis is conducted within 30min after sample dilution, otherwise the analysis result obtained may be inaccurate.
- Samples having been shelved should be remixed evenly prior to analysis.
- Each laboratory should evaluate the stability of sample analysis results obtained in the pre-dilution mode according to sample size, sample collection methods and technical level.
- In order to ensure the accuracy of analysis results, the remaining volume of pre-diluted blood sample in the pre-dilution mode should not be less than 0.5mL.

5.5.3 Emergency Samples

If you want to get the result of an emergency sample test quickly during the process of batch sampling test, the STAT. function is recommended. Please consider that automatic barcode scanning is not available in STAT position.

Procedure

1) Click “**Settings**” -> “**Maintain Probe**” button on the System interface, then click “**STAT**” button. A prompt will display as **Fig 5-6**.

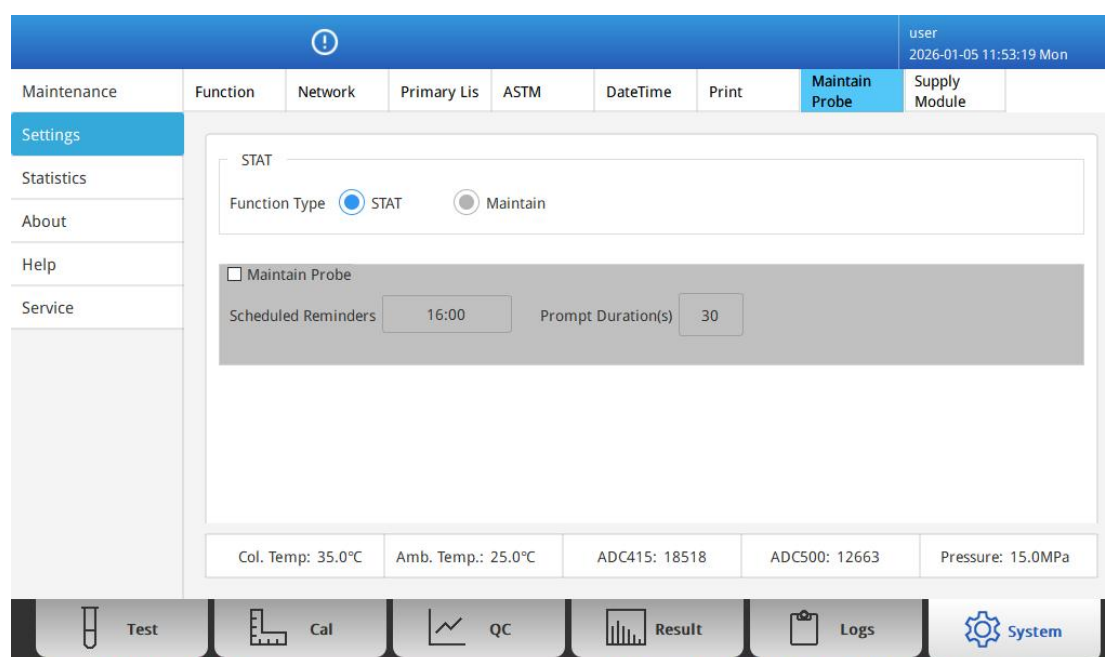


Fig. 5-6 View of Settings Interface

2) Open the STAT. door and put the prepared sample (i.e. a whole blood sample or a pre-diluted blood sample) into the STAT. position.

3) Return the Test interface, click the “**STAT.**  ” button to turn on the STAT. function when the batch sampling test is running. A prompt will display as **Fig 5-7**.

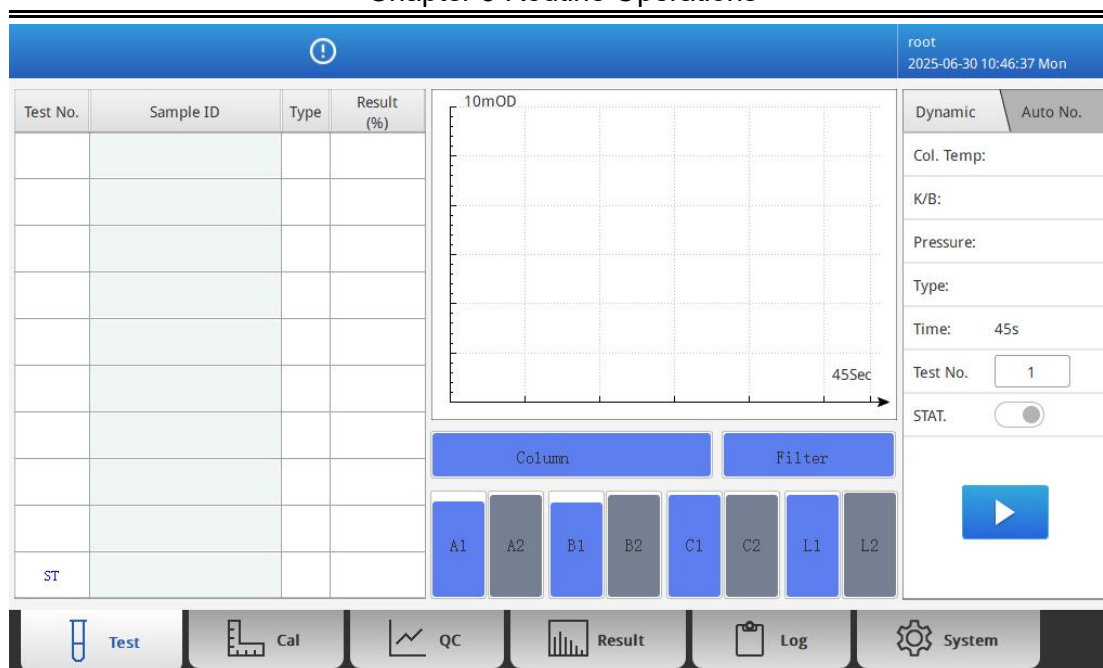


Fig. 5-7 View of Test Interface

- 4) Open the STAT. door and take out the emergency sample when the sample test is completed.
- 5) The test result of the emergency sample will be displayed on the left bottom of the test interface which is marked with "ST".

5.6 Sample Analysis

The analyzer is equipped with automatic barcode scanning module. Therefore, there is no need to manually input the sample No. of whole blood samples.

The operator need to input the sample No. of pre-diluted blood samples or sample tubes without barcode before test ,or the corresponding sample No. on the result interface will be displayed as empty. As alternative, empty ID samples can be filled in Result menu.

After the analysis process is completed, the 9 newest results will be displayed on the left of the test interface and the newest result on the last line.

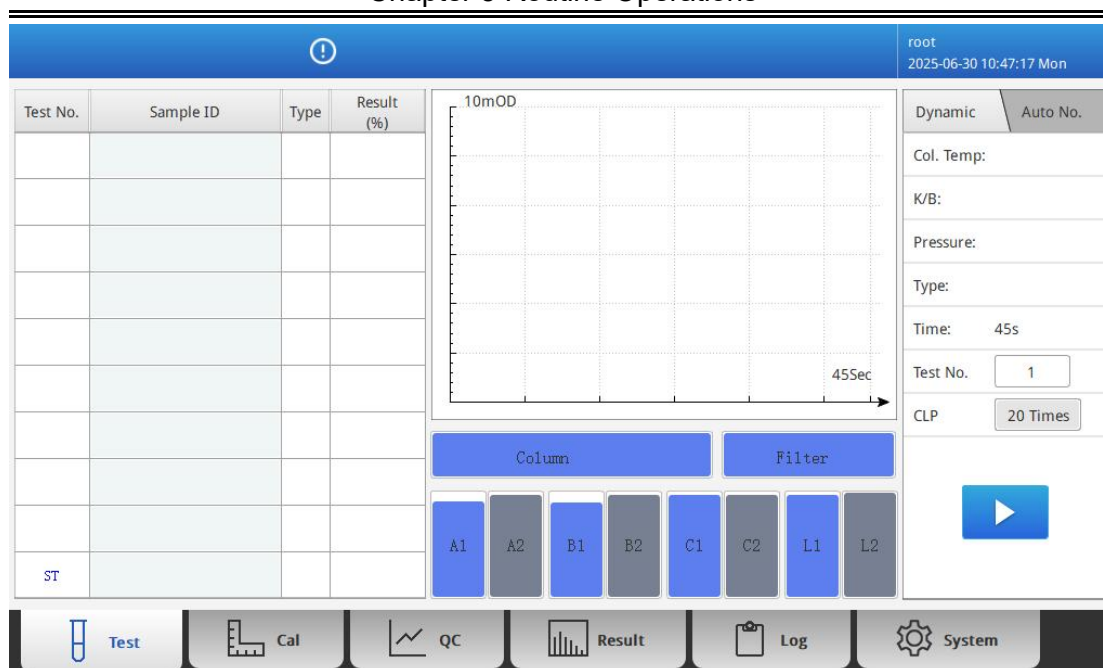


Fig. 5-8 Test Interface

Procedure

- 1) Place sample tubes with barcode in the sample rack.
- 2) Click the “▶” button on the right bottom of the test interface.
- 3) The analyzer automatically performs sample analysis after the sample is aspirated by the sampling needle.
- 4) The result will be displayed on the interface and stored.
- 5) When the system cleaning process is completed, if sample rack is detected in the sample loading site, the analyzer will automatically start the test.

About the sample type

“W” means whole blood sample;

“D” means Pre-diluted blood;

When the system detects low pressure, high pressure, insufficient consumable and fan broken, the alarm will occur. This symbol “ⓘ” will keep flashing and the analyzer will generate “**beep, beep, beep**” alarm sound. In this case, you should click “**Clear**” button after the completion of current test and eliminate the fault according to the tips (as e.g. of **Fig. 5-9**).

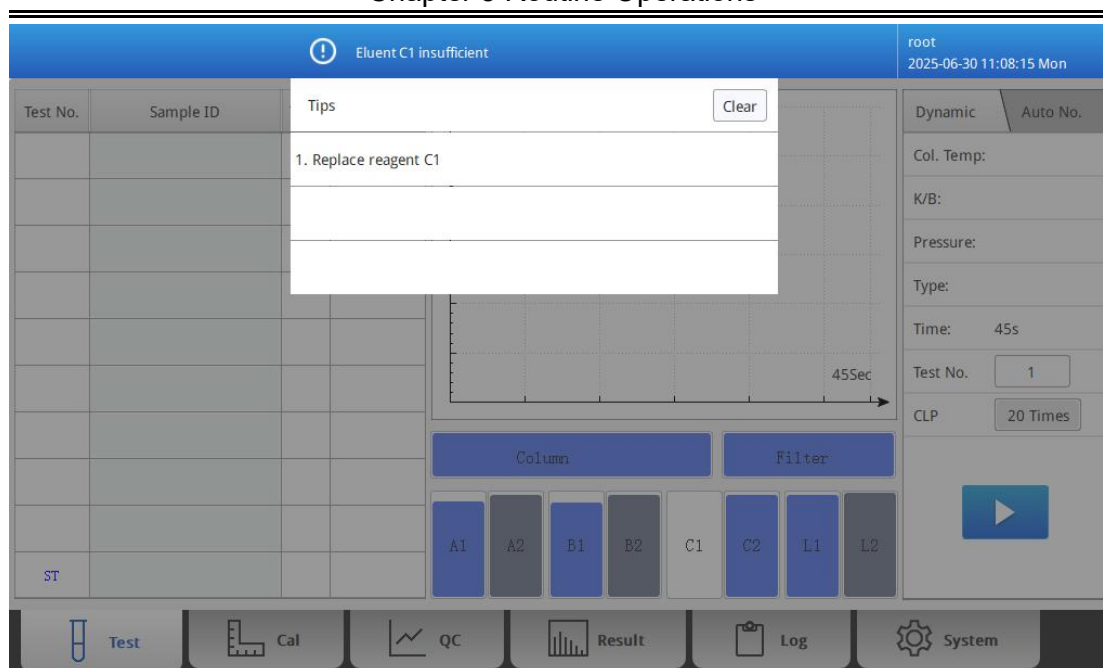


Fig. 5-9 Alarm Interface

- **High pressure alarm:** After starting the test, the pressure will be detected immediately. If the pressure is too high and reaches the upper limit of the set pressure, the high pressure pump will be stopped and an alarm will be given. At the same time, after the current sample test is executed, the pop-up box prompts that “Alarm occurred,result invalid ! ”
- **Low pressure alarm:** when the system detects low pressure, an alarm will be given and the pop-up box will prompt that “Alarm occurred, result invalid! ” after the end of the current test.
- **Fan broken alarm:** When the system detects the fan is abnormal, an alarm will be given. The tester can eliminate the fault by checking whether the fan is running normally and checking the fan connection.
- **Consumable insufficient alarm:** Consumables include eluent A ,eluent B ,eluent C, Hemolytic Agent L , filter and column. The details of consumable insufficient alarms are as below:

No.	Error Name	Probable Cause	Impact on test	Suggested Solution
1	Eluent A/B/C insufficient	Eluent A/B/C are empty	Not affected	Replace eluent A/B/C
2	Eluent A/B/C less than 5%	total eluent A/B/C less than 5%	Not affected	Replace eluent A/B/C

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3	Eluent A/B/C is empty	Eluent A/B/C is empty	Forbidden to test	Replace eluent A/B/C
4	Hemolytic Agent L insufficient	Hemolytic Agent L is empty	Forbidden to test	Replace Hemolytic Agent L
5	Filter count insufficient	Available number is 0	Forbidden to test	Replace In-line filter
6	Column count insufficient	Available number is 0	Forbidden to test	Replace column

ATTENTION

- The maximum length of the sample ID number is 20 digits. If it exceeds 20 digits, the analyzer defaults the first 20 digits as current ID number.
- Do not reuse disposable products.
- Wait for 30 minutes after the samples are taken out from a refrigerator.



- If using barcode scanner, do not look straightly at the light source of the scanner.
- Avoid direct contact with blood samples.
- The operator's clothes, hair and hands must be kept at a safe distance from the sampling needle, automatic sampler and other moving parts to prevent injury.
- When the automatic sampler is rotating or the 2D arms are aspirating a sample, it is forbidden to place samples into the analyzer or touch the automatic sampler in order to prevent sampling error or damage of the analyzer.

5.7 Shut Down

Every time a sample analysis is completed, the analyzer will automatically execute the cleaning procedure. The operator can turn off the power switch to shut down the analyzer only if the analyzer enters the standby or sleep state. Then the operator should clear up waste liquid in the waste bottle and dispose of waste liquid properly.

Before shutdown, please read the following precautions carefully:

- The operator can turn off the power switch to shut down the analyzer only if the analyzer enters the standby or sleep state.
 - If the analyzer is not shut down in standby or sleep state, the system cleaning process must be carried out after power on.
 - It is recommended to perform system cleaning every time turning on the analyzer (do not manually skip this operation).
-



- The operator is obliged to comply with the local and national regulations on discharge and disposal of reagents, waste liquid, waste samples, etc.
-

5.8 Replacement of Consumables

Sample testing is not available when the remaining volume of the column, filter, reagent A/B/C or the Hemolytic Agent L is less than the volume of sample applications required.

The replacement operation of column and filter please refer to chapter 4.4.4 on page 38.

The replacement operation of reagents can be done by scanning the reagent QR code or using the Test menu:

5.8.1 Replace with scanning the reagent QR code

■ Replacement of eluent A(as example)

1) Replace it with new eluent A and use the external barcode reader to scan the QR code on the label of the reagent. **Fig. 5-10** will be displayed.

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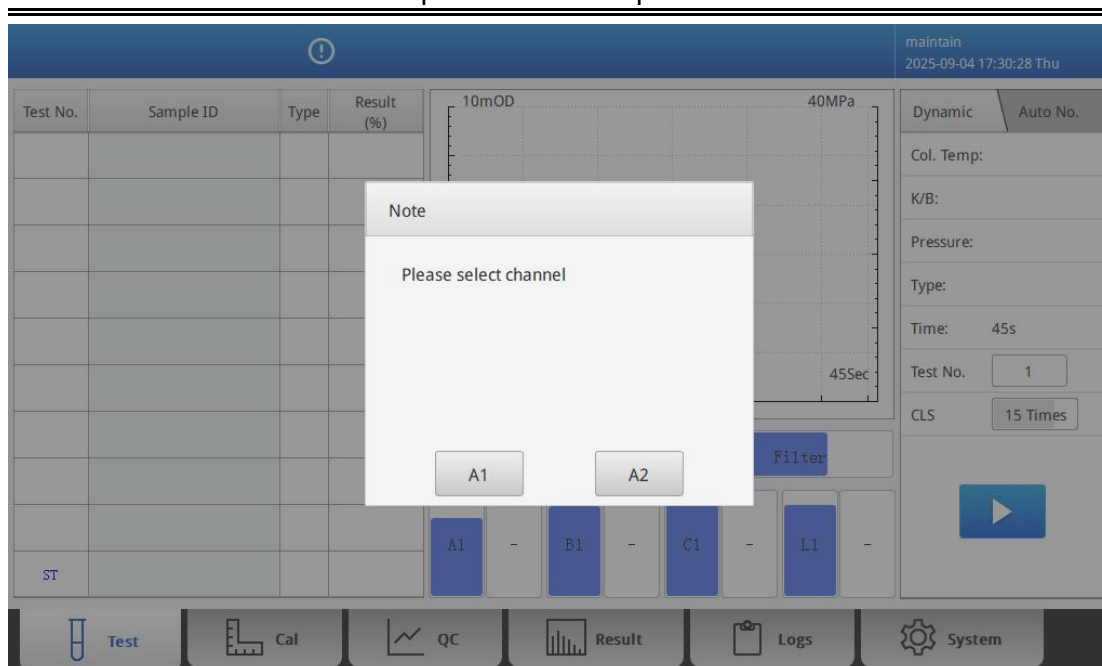


Fig. 5-10 Information of Eluent A

2) Click "A1", then click "Yes" button. The **Fig. 5-11** will be displayed.

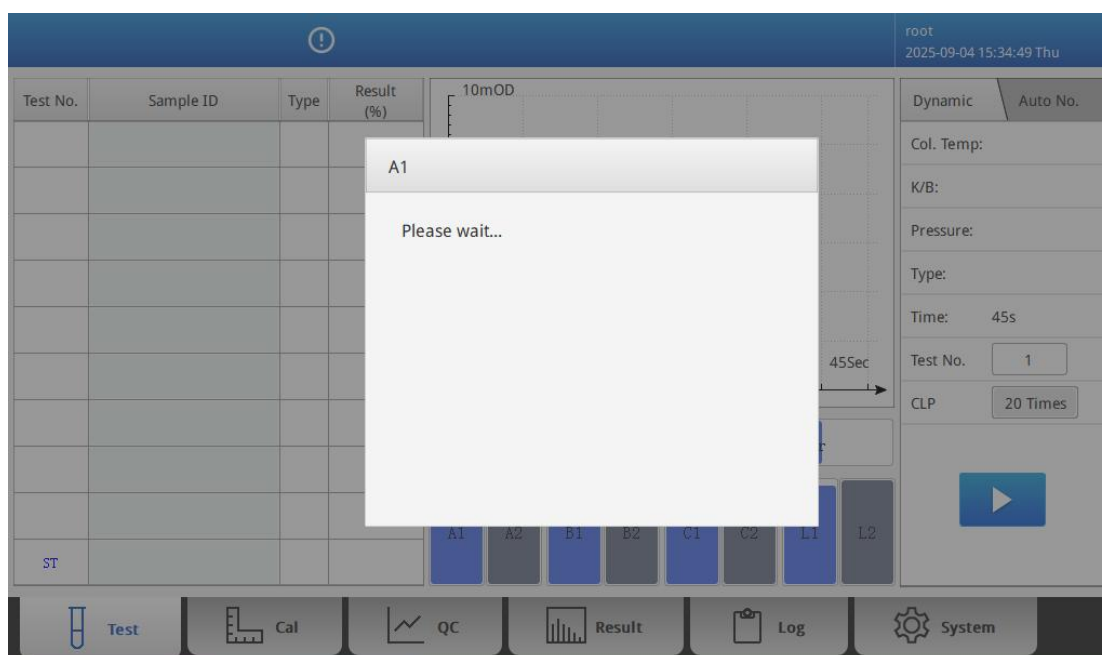


Fig. 5-11 After Clicking "Yes" Button

3) When the procedure ending, the replacement of eluent A is completed. The same goes for the replacement of eluent B, C and also Hemolytic Agent L.

5.8.2 Replace by Test Menu

■ Replacement of Hemolytic Agent L

1) Replace it with new Hemolytic Agent L and click the icon of the Hemolytic Agent L

in the test interface. The **Fig. 5-12** will be displayed..

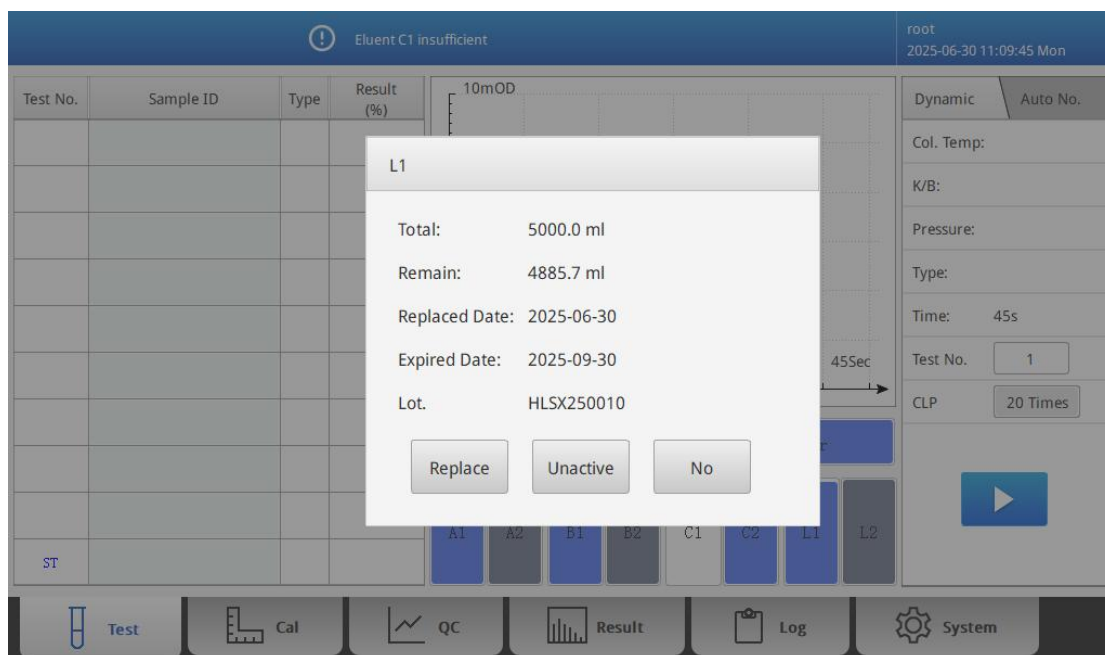


Fig. 5-12 Information of Hemolytic Agent L

2) Click **“Replace”** button. The **Fig. 5-13** will be displayed.

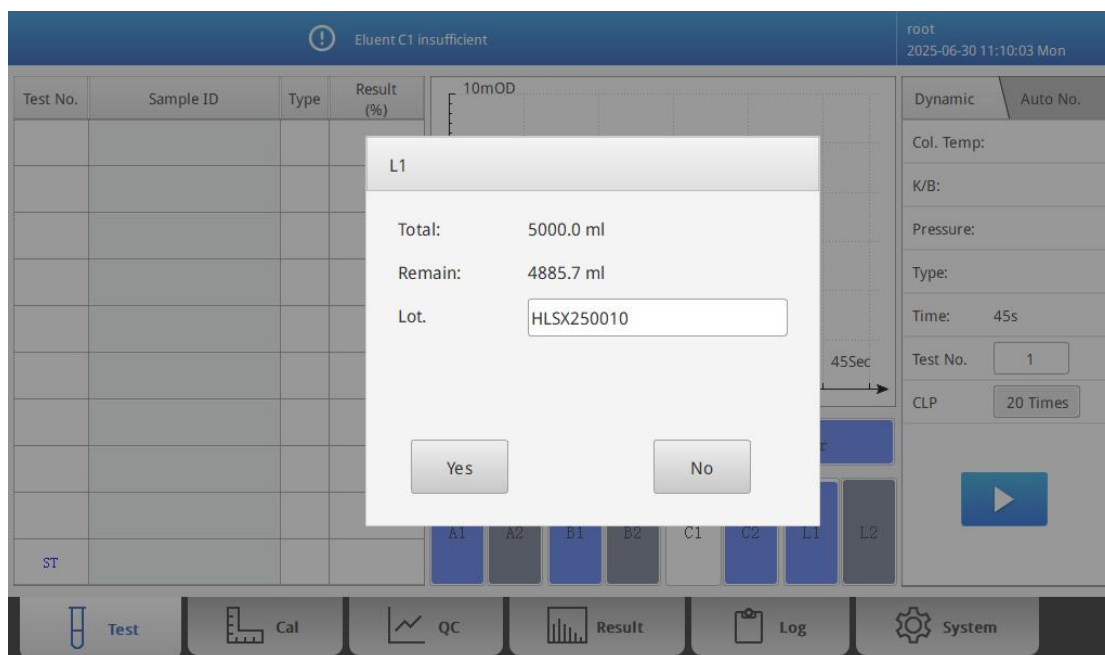


Fig. 5-13 After Clicking “Replace” Button

3) Enter manually the lot number on the label of the Hemolytic Agent L, then click **“Yes”** button. The **Fig. 5-14** is displayed.

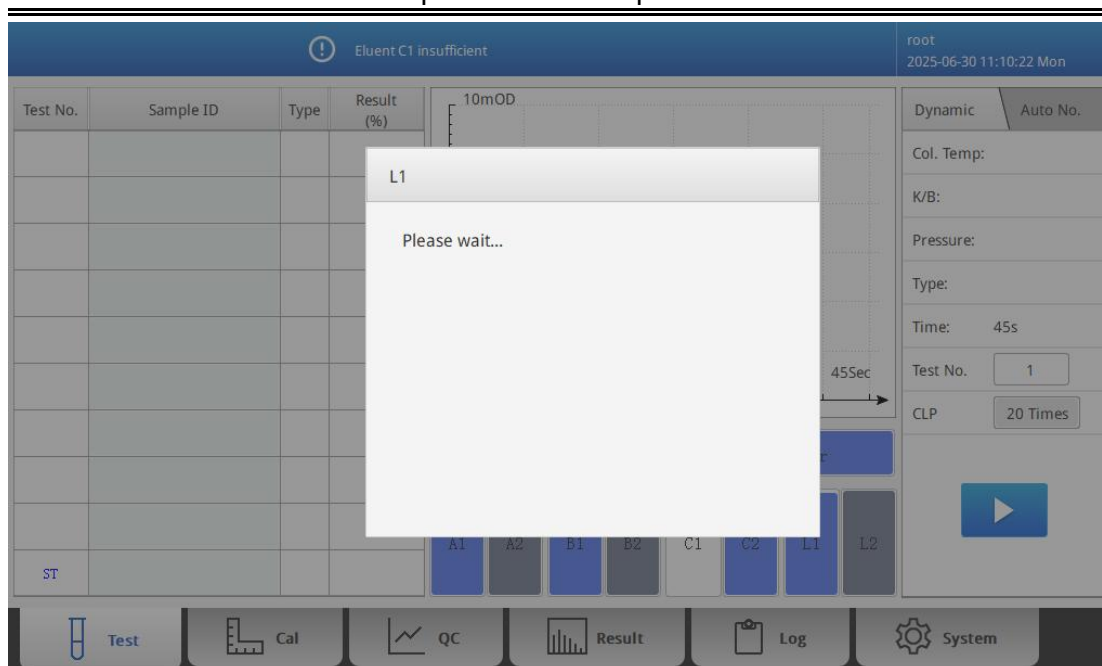


Fig. 5-14 After Clicking “Yes” Button

4) When the procedure ending, the replacement of Hemolytic Agent L is completed. The same goes for the replacement of eluent A, eluent B, eluent C.

5.9 Cleaning and Disinfection of Analyzer

A daily cleaning method: Use a clean cloth dipped in deionized water or 75% ethanol to clean the analyzer.

If you are in doubt about the compatibility of disinfectants or cleaning solution to analyzer components or materials contained in the analyzer, please contact manufacturer and designated agent' Customer Service.

Detailed cleaning methods are shown in Table 5-1. Detailed disinfection methods are shown in Table 5-2.

Table 5-1 Cleaning methods

Part	Host shell, touch screen, evacuation valve, column oven
Preparation	Operator should wear gloves and protective clothing
Recommended cleaning agent	Deionized water
Steps	1. Turn off the power switch and unplug the power cord. 2. Use the clean cloth dipped in deionized water (slightly wet) to wipe. 3. Replace the clean cloth to wipe off the remaining deionized

Chapter 5 Routine Operations

	water, and ensure that the analyzer is dry before powering on.
Precautions	1. Do not dip too much cleaning agent; 2. It is forbidden to use flushing method. 3. The power must be turned off during cleaning.
Cleaning period	It is recommended to clean it every day or when there is obvious dirt on the analyzer

Table 5-2 Disinfection methods

Part	Host shell, touch screen, evacuation valve, column oven
Preparation	Wiped the dirt on the analyzer with deionized water
Recommended Disinfectant	75% ethanol
Steps	1. Turn off the power switch, disconnect the socket. 2. Match the concentration according to the recommended disinfectant instructions; 3. Use a clean cloth dipped in disinfectant (slightly wet) to wipe. 4. Please disinfect them according to the operating instructions and duration requirements of the cleaning solution. 5. Replace the clean cloth to wipe off the remaining disinfectant and ensure that the analyzer is dry before powering on.
Precautions	1. Prohibited disinfection methods: boiling disinfection (high-temperature), strong oxidizing disinfectants, strong acid and alkaline disinfectants and other corrosive liquids. 2. The surface of the main unit and components should not be wiped with the hard and the rough. 3. Do not dip too much disinfectant. 4. It is forbidden to use flushing method.
Disinfectant period	Host shell and touch screen recommended weekly disinfection. Evacuation valve and column oven recommended monthly disinfection.

Chapter 6 Result Review

6.1 Overview

The analyzer will automatically store the analysis results in the database once a sample analysis is completed. The analyzer database can store up to 20000 samples (including all testing parameters and chromatograms with TF card) analysis results.

6.2 Review of Results

This system allows review of analysis results in the form of list; 10 samples are listed on each page. Click the “**Result**” button on the menu interface below to enter the list result query interface.

!

Eluent A is empty!

maintain

2025-12-29 17:54:35 Mon

Num

-

Q

Page

3

/ 2000

No.	Test No.	Sample ID	Type	Date and Time	HbF(%)	HbA1c(mmol/mol)	Remark
9063	0013	770244101900	W.B.	2025-08-22 17:27:02	0.33	32.17	-
9062	0012	770244122400	W.B.	2025-08-22 17:26:17	0.44	27.83	-
9061	0011	770244103700	W.B.	2025-08-22 17:25:31	0.56	38.55	-
9060	0010	770244075100	W.B.	2025-08-22 17:24:46	0.75	27.42	-
9059	0009	770243811300	W.B.	2025-08-22 17:24:01	0.30	22.26	-
9058	0068	WBR20	W.B.	2025-08-22 17:12:46	0.47	35.35	-
9057	0067	WBR19	W.B.	2025-08-22 17:12:01	0.47	35.81	-
9056	0066	WBR18	W.B.	2025-08-22 17:11:16	0.46	35.34	-
9055	0065	WBR17	W.B.	2025-08-22 17:10:31	0.48	35.48	-
9054	0064	WBR16	W.B.	2025-08-22 17:09:45	0.46	35.89	-

Home

Previous

Next

Last

Delete

Details

Upload

Batch upload

Print

Batch print

Test

Cal

QC

Result

Logs

System

Fig. 6-1 Result Interface

Display content

- | | | |
|-----------------|--------|---------------|
| 1.No. | —————> | Sample number |
| 2.Test No. | —————> | Test SN |
| 3.Sample ID | —————> | Sample No. |
| 4.Type | —————> | Sample type |
| 5.Date and Time | —————> | Analysis time |
| 5.HbF(%) | —————> | HbF ratio |
| 6.HbA1c(%) | —————> | HbA1c ratio |

Key Functions

Home	: Return to result interface
Previous	: Display the previous page
Next	: Display the next page
Last	: Display the last page
Delete	: Delete the selected result
Details	: Display the details of selected sample result
Upload	: Upload the selected result
Batch upload	: Upload the day or all results
Print	: Print the selected result
Batch print	: Print Export sample results to U-disk all results

The operator can click “**Previous**” or “**Next**” button to review analysis results in the form of list. Data shown in the list includes sample SN, sample ID, sample type, analysis date, analysis time, HbF ratio, HbA1c ratio, and remark. After selecting a result entry, click for Details. Also, the system allows query of results by sample ID, date and remarks.

During the testing, only the results of the current page are allowed to be viewed, and no other actions are allowed.

About the explanation of abnormal results

If the test results are abnormal, the “Remark” column will display the corresponding code (e1 ~ e12).

The meaning of the codes are as follows:

e1: Total area less than 50,000;

e2: Total area more than upper 270,000;

- e3: Result more than 15%;
- e4: Result less than 4%;
- e5: Variants detecte;
- e6: Chromatogram abnormal or ADC abnormal;
- e7: A0 Total area less than 80%;
- e8: Target peak is out of range;
- e9: Pressure is abnormal;
- e10: TP is too low;
- e11: HbF Result more than 5%;
- e12: Minor Peak more than upper limit.

About TP

TP: Theoretical plate

Function: TP value is to indicate the theoretical plate of the column by calculating the target peak to show the column efficiency.

Meaning: The theoretical plate depends on the type and nature of the column stationary phase, like particle size and its distribution, column length, column type, flow rate. To analyze the column efficiency during the test of the device, it is monitored the target peak by calculating its peak sharpness, symmetry, height, whether the elution is complete, etc. which will help the user understand more about the column state and column efficiency during the tests.

6.3 Details of Single Sample Result

The operator can review the sample analysis results. Click “**Previous**” or “**Next**” button to view sample results one by one. The sample detail interface shows information of the sample such as test SN, sample ID, test time, and sample type. The operator can change the sample ID in the sample detail interface. The operator can also view the sample chromatogram, and the elution time, area, result and other information of each eluted protein components. If the “Remark” column display the code (e1/e2/e6/e9/e10), the HbA1c result will be hidden. The operator can click HbA1c column to view the results. The message on the **Fig. 6-2** is displayed as below.

Chapter 6 Result Review

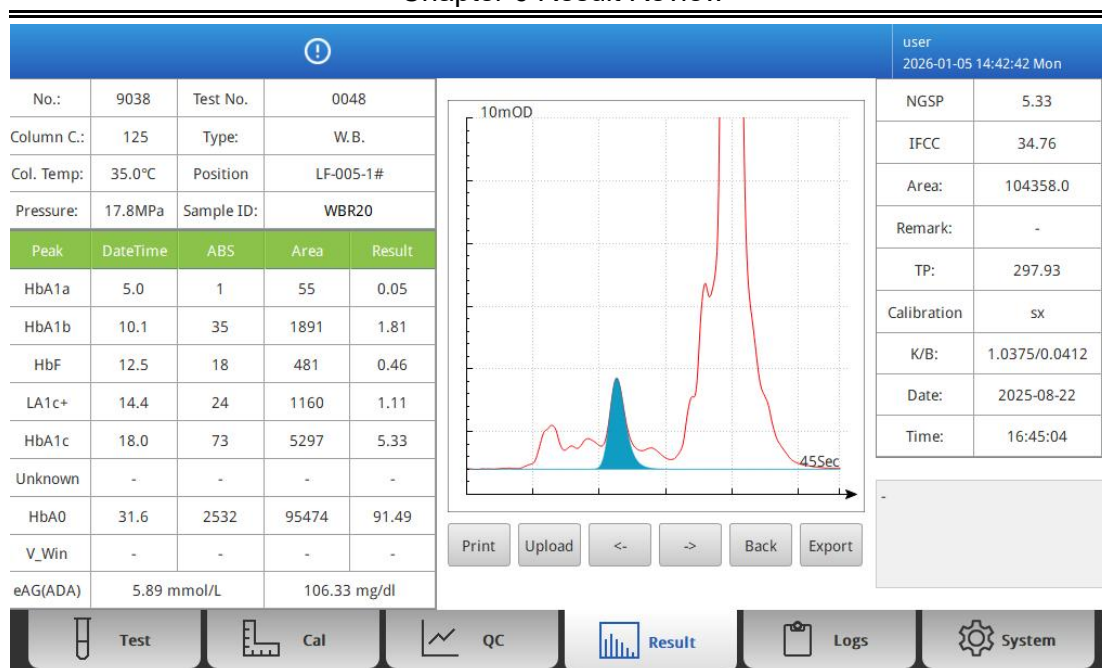


Fig. 6-2 Details of Single Sample Result Interface

Click on the chromatogram area to enlarge it and the full chromatogram of the selected sample will be displayed.

6.4 Deleting Data

The operator can delete the sample test results. Select any result entry, and then click the **"Delete"** button; when a dialog box pops up, click **"OK"** button.

ATTENTION

- Data cannot be recovered once deleted. It is suggested that data should be printed or backed up by connecting to a PC via the LIS prior to deletion. For computer software, users can contact the manufacturer or the agent specified by the manufacturer.

6.5 Upload Data

The operator can upload the sample test results. Enter the result interface, select any result entry, and then click the **"Upload"** button to upload a single test result, or enter the details interface and click the **"Upload"** button below the chromatogram to upload. Click the **"Batch upload"** button, you can choose to upload the test results of the same day or all.

6.6 Printing Data

The operator can print the test results of the current sample. Select any result entry, and then click the **Print** button. The analyzer will automatically print sample information. Automatic printing is also possible to setup in Settings on System menu.

The analyzer has three ways to print the test results. Enter the “System” - “Settings” - “Print” interface, setting the printer.

- (1) Select “Thermal”, the operator can print the test results on paper.
- (2) Select “Laser”, the operator needs to connect external printing equipment.
- (3) Select “PDF”, the operator needs to insert a USB stick into the back of the analyzer.

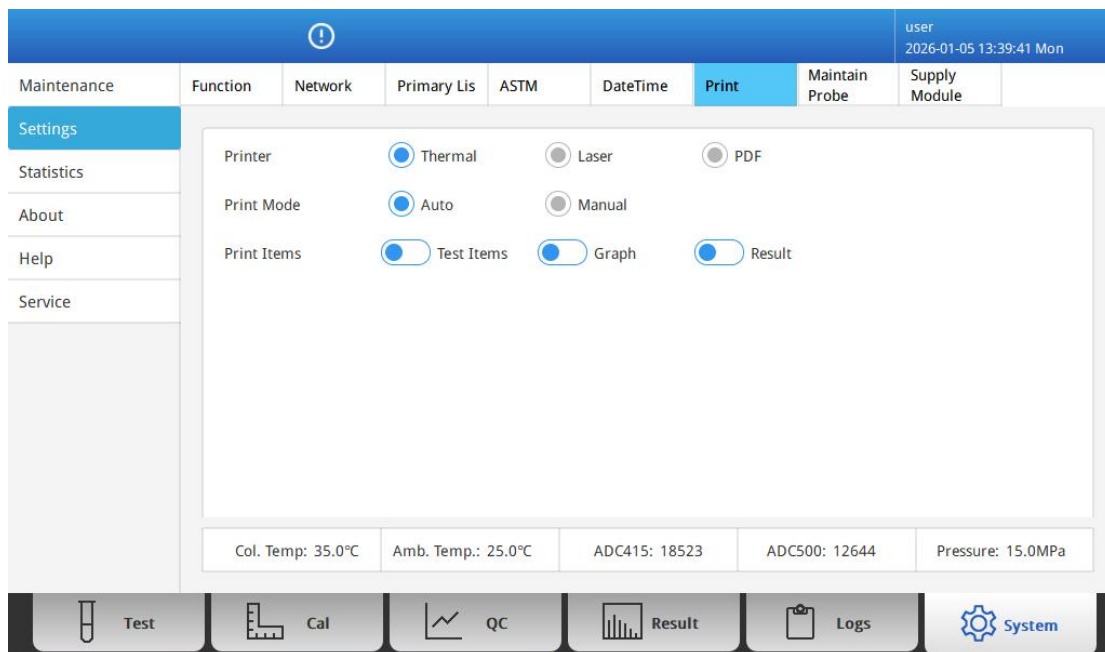


Fig. 6-3 Print Setting interface

Chapter 7 Log Review

7.1 Overview

The analyzer will automatically store the logs (Error log, Operation log, Maintenance log) in the database once an operation is completed. The analyzer database support that each type of log can store up to 1000 records. Users can view the log but deletion is not supported.

7.2 Review of Log

This system allows review of logs in the form of list ; 10 logs are listed on each page. Click the “**Log**” button on the menu interface below to enter the list log query interface:

The screenshot displays the 'Error Log' interface. At the top, there is a blue header bar with a warning icon and the text 'root 2025-06-30 11:23:15 Mon'. Below the header, there are tabs for 'Error Log', 'Operation Log', and 'Maintenance Log'. The 'Error Log' tab is selected. The main area shows a table of error logs. The table has columns: No., Error Code, Error Name, Error Unit, Date and Time, and Grade. The table lists 10 error records. To the right of the table, there are sections for 'Details' and 'Solution'. At the bottom, there is a navigation bar with buttons for Test, Cal, QC, Result, Log, and System.

No.	Error Code	Error Name	Error Unit	Date and Time	Grade
0010	0003	Eluent C1 insufficient	Liquid Line	2025-06-30 11:07:12	B
0009	1007	Waste container full	Liquid Line	2025-06-30 09:39:30	A
0008	1007	Waste container full	Liquid Line	2025-06-30 09:01:26	A
0007	1007	Waste container full	Liquid Line	2025-06-30 09:00:38	A
0006	1005	Filter Usage Limit	Liquid Line	2025-06-30 08:50:17	A
0005	1005	Filter Usage Limit	Liquid Line	2025-06-30 08:48:58	A
0004	0006	Eluent A2 insufficient	Liquid Line	2025-06-30 08:48:58	B
0003	1001	Eluent A limit	Liquid Line	2025-06-30 08:46:30	A
0002	1001	Eluent A limit	Liquid Line	2025-05-29 11:03:11	A
0001	1001	Eluent A limit	Liquid Line	2025-05-29 11:01:14	A

Fig. 7-1 Error Log Interface

■ Error Log

The operator can review the error logs. The log interface shows information of the error logs, such as No., error code, error name, error unit, date and time, grade and remark. The operator can click “**Previous**” or “**Next**” to review error logs in the form of list.

Click any of logs, the details of this log and the solution is displayed on the right side of the interface.

■ Operation Log

Click the **“Operation Log”** button on the Log interface below to enter the list log interface:

						root 2025-06-30 11:23:38 Mon
Error Log	Operation Log	Maintenance Log				
No.	Code	Function	Details	Date and Time	Operator	
88	1164	Consumables	Change reagent C1	2025-06-30 11:22:22	root	
87	1133	Consumables	Change reagent L1	2025-06-30 11:10:25	root	
86	1131	Consumables	Change reagent A1	2025-06-30 11:09:03	root	
85	1202	Maintenance	Full reagent C1	2025-06-30 11:07:38	root	
84	1202	Maintenance	Full reagent C1	2025-06-30 11:07:24	root	
83	1202	Maintenance	Full reagent C1	2025-06-30 11:07:12	root	
82	1202	Maintenance	Full reagent C1	2025-06-30 11:07:04	root	
81	1202	Maintenance	Full reagent C1	2025-06-30 11:06:58	root	
80	1202	Maintenance	Full reagent C1	2025-06-30 11:06:47	root	
79	1202	Maintenance	Full reagent C1	2025-06-30 11:06:35	root	
Page 1 / 9		Home	Previous	Next	Last	Delete Delete all
Test	Cal	QC	Result	Log	System	

Fig. 7-2 Operation Log Interface

Each operation is recorded in the operation log interface. The interface shows information of the operation logs, such as No., Code, Function, Details, date and time and operator. The operator can click **“Previous”** or **“Next”** button to review operation logs in the form of list.

■ Maintenance Log

Click the **“Maintenance Log”** button on the Log interface below to enter the maintenance log list interface:

Chapter 7 Log Review



root
2025-06-30 11:24:02 Mon

Error Log Operation Log Maintenance Log

No.	Code	Function	Details	Date and Time	Operator
24	1164	Consumables	Change reagent C1	2025-06-30 11:22:22	
23	1133	Consumables	Change reagent L1	2025-06-30 11:10:25	
22	1131	Consumables	Change reagent A1	2025-06-30 11:09:03	
21	1164	Consumables	Change reagent C1	2025-06-30 10:48:16	
20	1135	Consumables	Change Filter	2025-06-30 10:36:05	
19	1135	Consumables	Change Filter	2025-06-30 10:34:18	
18	1134	Consumables	Change Column	2025-06-30 10:29:53	
17	1134	Consumables	Change Column	2025-06-30 10:28:21	
16	1134	Consumables	Change Column	2025-06-30 10:21:41	
15	1134	Consumables	Change Column	2025-06-30 10:15:00	

Page 1 / 3 Home Previous Next Last Delete Delete all

 Test

 Cal

 QC

 Result

 Log

 System

Fig. 7-3 Maintenance Log Interface

Chapter 8 Quality Control

8.1 Overview

A certain degree of inaccuracy may occur after long-term use of the analyzer and may lead to incorrect or unreliable analysis results.

QC is to perform routine testing of analyzer performance with matched QC materials. The operator should perform testing on the analyzer with QC materials; the results obtained can be compared according to specific statistical methods. Remedial measures are recommended if the judgment is “Out-of-control” according to the laboratory operation practices.

The QC procedure provides an effective method for standardized laboratory QC measurement. The operator can effectively monitor the analyzer stability after getting familiar with the QC theory and acquiring the actual operation method.

To ensure the reliability of sample analysis results, it is suggested that the operator should perform quality control of the analyzer respectively with low-value and high-value QC materials every day.

8.2 QC Material Info Input

This analyzer provides two input info modes: scan the QR code or manually input:

Scan the QR code input: the Lot, target values and deviations of high and low values can be automatically input by scanning the QR code on the external box of the QC materials with the external barcode reader. A prompt will show up as **Fig 8-1**, Then click “Yes”.

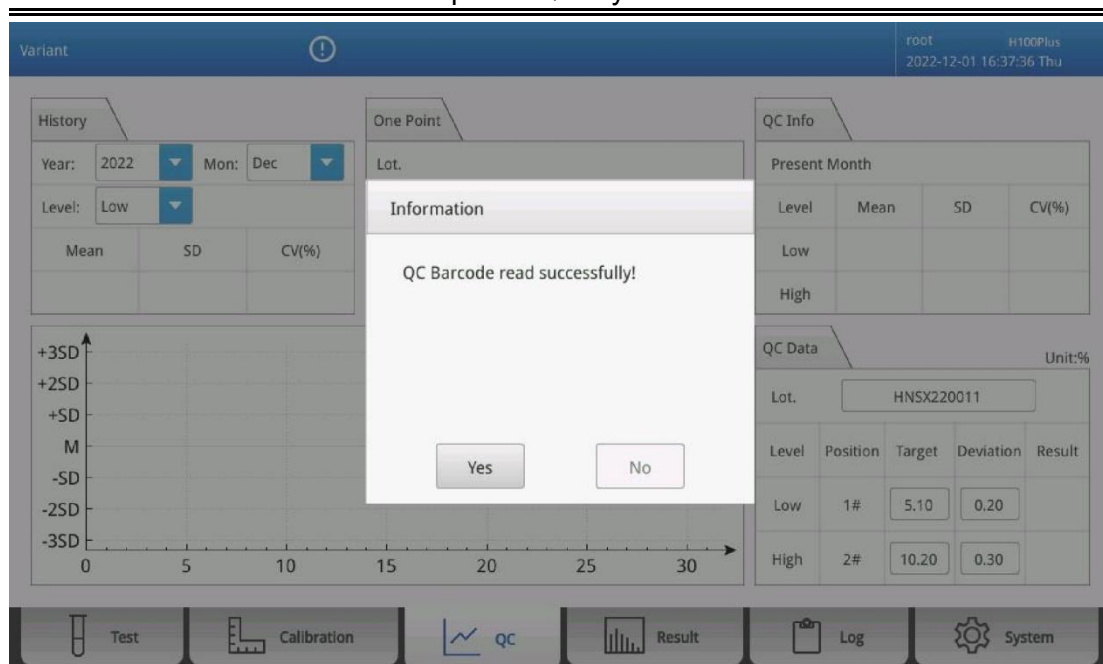


Fig. 8-1 After scanning the QR code

Manually input: Click the “QC” button on the menu interface below to enter the QC interface:

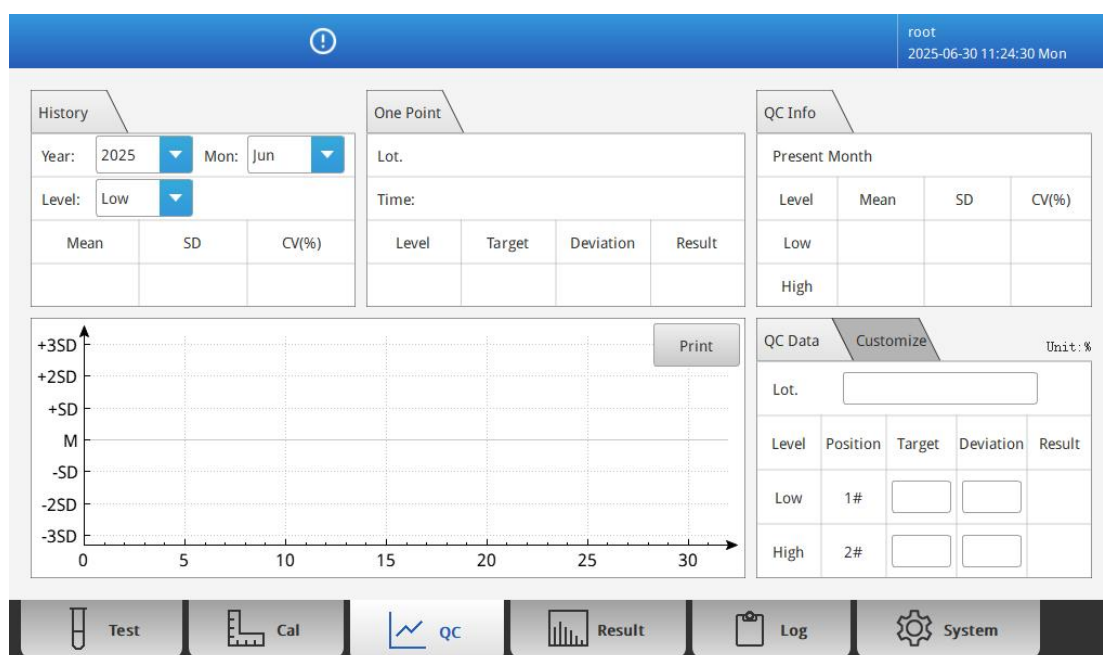


Fig. 8-2 QC Interface

On the bottom right of the QC interface, input the Lots No. of QC materials, target values and deviations of high and low values and then return to the test interface to start the QC sample test. Lots No. and target values must be input correctly according to the information printed on QC bottle body label or specific datasheet supplied.

■ History area

Year, Month and QC Level can be selected as needed. The corresponding values

of Mean,SD,CV(%) and QC graph will be displayed in the “History” area.

■ One Point area

The QC chart supports to display 3 batches of QC information in a month. After clicking a corresponding point on the QC chart, the “**One Point**” area will show the corresponding QC Lot.,Test time,Level, Target value, Deviation and Result.

■ QC Info area

“QC Info” area displays the latest information of QC.

ATTENTION

- The length of Lots No. is 15 digits. If exceeding, the system will default the first 15 digits as current Lots No.
- It is suggested that data should be printed or backed up by connection to a PC via the LIS prior to deletion. For computer software, user can contact the manufacturer or designated agent.

8.3 QC Analysis



- Samples, QC materials, calibrators, column, filters and waste liquid may carry biological contamination. When contacting relevant materials and areas in the laboratory, the operator should comply with the requirements for safe operation in the laboratory and wear personal protective equipment (e.g., laboratory protective clothing and gloves).



- Infectious blood samples, QC materials or calibrators may remain in/on the sample loader, sampling needle, column and filters. As a result, the operator should wear gloves to avoid direct contact during operation.
 - The sample may splash out of the uncapped EP tube and lead to biological contamination. Be careful when handling the uncapped EP tube.
-

ATTENTION

- Use QC materials of uniform lots No.
 - Do not reuse disposable products.
 - The QC materials should be mixed gently in an upside-down manner to avoid air bubbles; do not use a mechanical mixer for mixing.
 - The operator should use QC materials and reagents specified by manufacturer and designated agent;
 - QC materials and reagents should be stored and used strictly in accordance with their respective instructions.
 - If the room temperature is beyond the range of normal operating temperature for the analyzer, the analysis result obtained will be unreliable.
-

Use of QC materials:

Procedure

- 1) Re-dissolution: Prepare an appropriate amount of Hemolytic Agent L; take the QC materials stored at 2~8℃ and restore it to room temperature, gently knock the bottle cap to ensure that the freeze-dried sample completely drops to the bottom of the bottle, carefully unscrew the bottle cap and avoid loss of the content; accurately pipette 100μL of Hemolytic Agent L, and slowly inject it into the bottle, screw the bottle cap and carefully shake the brown bottle for several seconds to ensure full dissolution of the content;
- 2) Subpackage: After re-dissolution, use pipette to take 5μL QC materials from brown bottle into EP tube one by one and store 14 days at 2~8 ℃ or 30 days -20℃.
- 3) Dilution: Take out 5μL subpackaged QC materials from the freezer, pre-dilute the QC materials and hemolytic agent L at a ratio of 5μL:1500μL(the dilution ratio can be slightly adjusted according to the acceptance criterion of a total area ranging from 80,000 to 120,000). At last, close the EP tube cap, and gently shake the tube upside down to ensure it fully-mixed.
- 4) Check: Click the “**QC**” button and be sure to input QC data on the QC interface.
- 5) QC test: Put the EP tube with diluted QC materials into the 1# and 2# position of

the QC rack which is labeled with a QC barcode. The caps of EP tubes must be securely fastened into the slots of the diluting sample holder. Place the QC rack into the sample loading site. Click the “” button to start the QC test.

ATTENTION

- Put the QC materials after re-dissolution in 1.5 mL EP tubes (5μL in each tube), and it is effective for 14 days at 2~8℃ or 30 days at -20℃ .
 - Take one EP tube every time and restore it to room temperature between 10℃~30℃ before use to avoid repeated re-dissolution.
 - Diluted QC materials should be used up in 30 minutes.
 - The uncapping date should be recorded on the QC materials bottle, and the QC materials should be used within its expiration date.
 - Before starting tests, make sure the cap of tubes are securely fastened into the slots of the diluting sample holder.
-

Chapter 9 Analyzer Calibration

9.1 Overview

To obtain accurate sample analysis results, the analyzer should be calibrated according to the steps given in this chapter.

Column, filters, calibrators and reagents specified by manufacturer and designated agent are recommended. Calibrators and reagents should be stored and used strictly in accordance with instructions.

9.2 Calibration Frequency

This analyzer has been calibrated prior to delivery. Please calibrate the analyzer upon occurrence of any of the occasions below:

- the analyzer is installed for the first time;
- the column or filter is replaced;
- the analyzer is reused after it is shelved for a long time;
- obvious inaccuracy of analysis results are detected during QC or clinical trial and comparison.

ATTENTION

- Measured data can be used as valid data only when the analyzer has been calibrated.
-

9.3 Calibration Methods

This analyzer provides two calibration modes: Pre-diluted blood Calibration and Manual Calibration. The K and B factors of the calibration are automatically completed by the analyzer. The calibration factor obtained after calibration will be automatically saved on the calibration interface, and the system will automatically save the current and previous calibration factors.

- Check according to the following steps prior to calibration. Do not perform calibration if any problem is found. The operator should find out the cause and decide whether calibration is necessary after the problem is solved. Please

contact manufacturer and designated agent' Customer Service if necessary.

- Check the status of analyzer to ensure that it has no errors.
- Check the amount of the reagent to ensure that it is adequate to complete the whole calibration process.
- Check the remaining column and filters to ensure that they are enough.

9.4 Calibrator Info Input

This analyzer provides two input info modes: scan the QR code or manually input:

Scan the QR code input: the Lot and target values can be automatically input by scanning the QR code on the external box of the calibration with the external barcode reader. A prompt will show up as **Fig 9-1**. Then click "Yes".

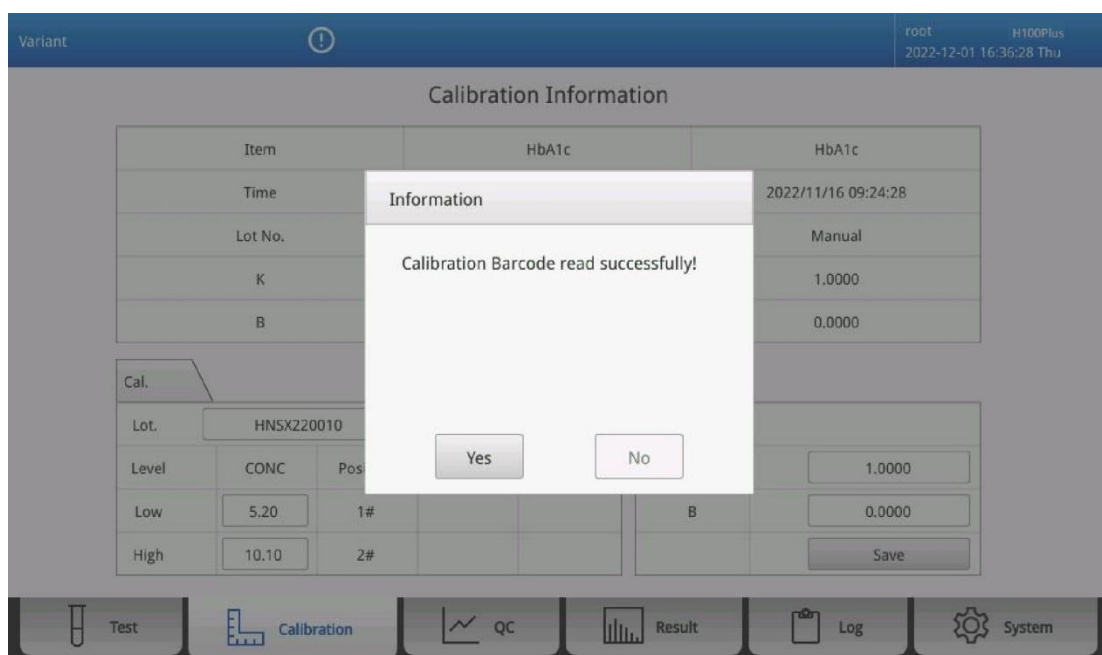


Fig. 9-1 After scanning the QR code

Manually input: Click the "Calibration" button on the menu interface below to enter the calibration interface:

The screenshot displays the 'Calibration Information' form. At the top, there is a status bar with a user icon, the text 'root', and the timestamp '2025-06-30 11:24:59 Mon'. Below this, the title 'Calibration Information' is centered. The main content area contains a table with calibration data and two input tabs: 'Cal.' and 'Manual'.

Item	HbA1c	HbA1c
DateTime		
Lot No.	Manual	Manual
K	1.0000	1.0000
B	0.0000	0.0000

Below the table, there are two tabs: 'Cal.' and 'Manual'. The 'Cal.' tab is active and shows a 'Unit: %' label. It contains a 'Lot.' input field, a 'Level' dropdown menu with options 'Low' and 'High', and a 'CONC' input field. There are also 'Position' dropdowns for '1#' and '2#', and 'Result 1' and 'Result 2' input fields. The 'Manual' tab is also visible, showing 'K' and 'B' input fields and a 'Save' button. At the bottom of the interface is a navigation bar with icons for 'Test', 'Cal', 'QC', 'Result', 'Log', and 'System'.

Fig. 9-2 Calibration Interface

■ Calibration Information Form

The “Calibration Information” form displays the latest two calibration values. of Item, calibration time, calibrator Lot No. , calibration factors of K and B. Lots No. and reference values must be input correctly according to the information printed on bottle body label or specific datasheet supplied.

■ Cal. tab

The “Cal.” tab supports to input the information of calibrator (Lots No., target values of high level and low level).The calibration results will also be displayed on this tab when the calibration test is completed.

■ Manual tab

The “Manual ” tab supports to input the calibration factors of K and B.The valid range of the calibration factor K is 0.8000~1.4000 and the factor B is -2.0000~2.0000.

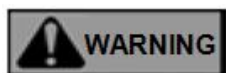
The analyzer allows the operator to manually input the calibration factors for calibration. The operator can manually modify the calibration parameters in “Manual” tab.

Enter the calibration factors of K and B. as required, and click “**Save**” button. The analyzer will automatically calculate the result by the equation of $Y=KX+B$, which X is the original result measured by the analyzer. Meanwhile, the “**Calibration Information**” form will display the values of K and B, and Calibration Lots No.which is manually entered.

9.5 Starting Calibration



- Samples, QC materials, calibrators, column, filters and waste liquid may carry biological contamination. When contacting relevant materials and areas in the laboratory, the operator should comply with the requirements for safe operation in the laboratory and wear personal protective equipment (e.g., laboratory protective clothing and gloves).
-
-



- Infectious blood samples, QC materials or calibrators may remain in/on the sample loader, sampling needle, columns filters. As a result, the operator should wear gloves to avoid direct contact during operation.
 - The sample may splash out of the uncapped EP tube and lead to biological contamination. Be careful when handling the uncapped EP tube.
-
-

ATTENTION

- Use calibrators of uniform lots No.
 - Do not reuse disposable products.
 - The calibrator should be mixed gently in an upside-down manner to avoid air bubbles; do not use a mechanical mixer for mixing.
 - The operator should use calibrators and reagents specified by manufacturer and designated agent; calibrators and reagents should be stored and used strictly in accordance with their respective instructions.
 - If the room temperature is beyond the range of normal operating temperature for the analyzer, the analysis result obtained will be unreliable.
-

■ Usage of calibrators:

Procedure

- 1) Re-dissolution: Prepare an appropriate amount of Hemolytic Agent L; take the calibrators stored at 2~8℃ and restore it to room temperature, gently knock the bottle cap to ensure that the freeze-dried sample completely drops to the bottom of the bottle, carefully unscrew the bottle cap and avoid loss of the content; accurately pipette 100uL of Hemolytic Agent L, and slowly inject it into the bottle, screw the bottle cap and carefully shake the brown bottle for several seconds to ensure full dissolution of the content;
- 2) Subpackage: After re-dissolution, use pipette to take 5uL calibrator materials from brown bottle into EP tube one by one and store 24 hours at 2~8 ℃ and freezing is prohibited.
- 3) Dilution: Take out 5μL subpackaged calibrator materials from the freezer, pre-dilute the calibrator materials and hemolytic agent L at a ratio of 5μL:1500μL (the dilution ratio can be slightly adjusted according to the acceptance criterion of a total area ranging from 80,000 to 120,000). At last, close the EP tube cap, and gently shake the tube upside down to ensure it fully-mixed.
- 4) Check: Click the “Calibration” button and be sure to input the calibration concentration of the calibration materials on calibration interface.
- 5) Calibration test: Put the EP tube with diluted calibration materials into the 1# and 2# position of the calibration rack which is labeled with a calibration barcode. The caps of EP tubes must be securely fastened into the slots of the diluting sample holder. Place the calibration rack into the sample loading site. Click the “▶” button to start the calibration test.

■ Verification of calibration result

If the calibration is passed, the K and B value after calibration will be displayed automatically on the calibration interface. If not, please check whether the calibration is within the expiration date. If the problem cannot be solved, please contact manufacturer and designated agent' Customer Service.

ATTENTION

- Put the calibration materials after re-dissolution into 1.5mL EP tubes (5μL in each

tube), and it is effective for 24 hours at 2~8 °C .

- Take one EP tube every time and restore it to room temperature between 10°C~30°C before use to avoid repeated re-dissolution.
- Diluted calibration materials should be used up in 30 minutes.
- The uncapping date should be recorded on the calibration materials bottle, and the calibration materials should be used within its expiration date.
- Before starting test, make sure the cap of tubes are securely fastened into the slots of the diluting sample holder.

Chapter 10 Service

10.1 Overview

In order to ensure accurate and effective performance of the analyzer, routine maintenance should be carried out as required. This chapter introduces its maintenance functions and some measures that can be taken in case of malfunction.



- All components of the analyzer surfaces are potentially infectious. Therefore, safety protection measures should be taken during operation and maintenance.
- Infectious blood samples, QC materials or calibrators may remain in/on the sample loader, sampling needle, column and filters. As a result, the operator should wear gloves to avoid direct contact during operation.



- In case of improper maintenance damage, the analyzer must be maintained in accordance with the guidance provided in the Product Instruction Manual.
- If any problem and measures are not involved in this manual, please contact manufacturer and designated agent' Customer Service.
- Repair and maintenance must be performed by trained personnel.
 - Before repair and maintenance, please wear personal protective equipment (e.g., goggles, gloves and masks). Otherwise, injury or infection by infectious samples may result.
 - Please replace the sampling needle after cutting off the main power supply. Otherwise, damage to the analyzer or personal injury may result. In addition, please take extreme care at the sharp tip of sampling needle.
 - For any repair and maintenance problems, please contact manufacturer and designated agent' Customer Service.
- Instructions on repairing, handling, discarding and destruction
 - Please wear personal protective equipment such as goggles, gloves and

masks as the analyzer may be infectious.

- Please use hydrolytic enzyme detergent whose main components are protein, fat and sugar, as this type of detergent can dissolve blood and other secretions, especially those on dry surfaces.
- Please spray alcohol onto the analyzer for sterilization purpose after removing the contaminants.
- You can also contact manufacturer and designated agent' Customer Service.
- Please use parts provided by manufacturer and designated agent to repair the analyzer.

10.2 Check Guide

(Please check the elements as follows before analysis)

Elements	Criteria
Exterior	Dust-free
Tubes	Properly-connected
Printer	Recording paper available
Liquid leakage	No leakage
Physical damage	No physical damage
Power supply	Grounded and connected properly
Adapter indicator	On
Column	≥1
Filter	≥1
Hemolytic Agent L	Sufficient
Eluents A/B/C	Sufficient
Waste liquid bottle	Empty
Date/Time	Correct
Displayed temperature	Consistent with the target temperature
ADC value	Within normal range

ATTENTION

- Column and filters specified by manufacturer and designated agent must be used

in case of incorrect analysis results.

- Before unsealing a column or a filter, please check whether its packaging is damaged.
- Please contact manufacturer and designated agent's Customer Service immediately in case of any serious damage which results in failure to use the filter or column.

10.3 Maintenance

Click “**Maintenance**” button to enter system maintenance interface:

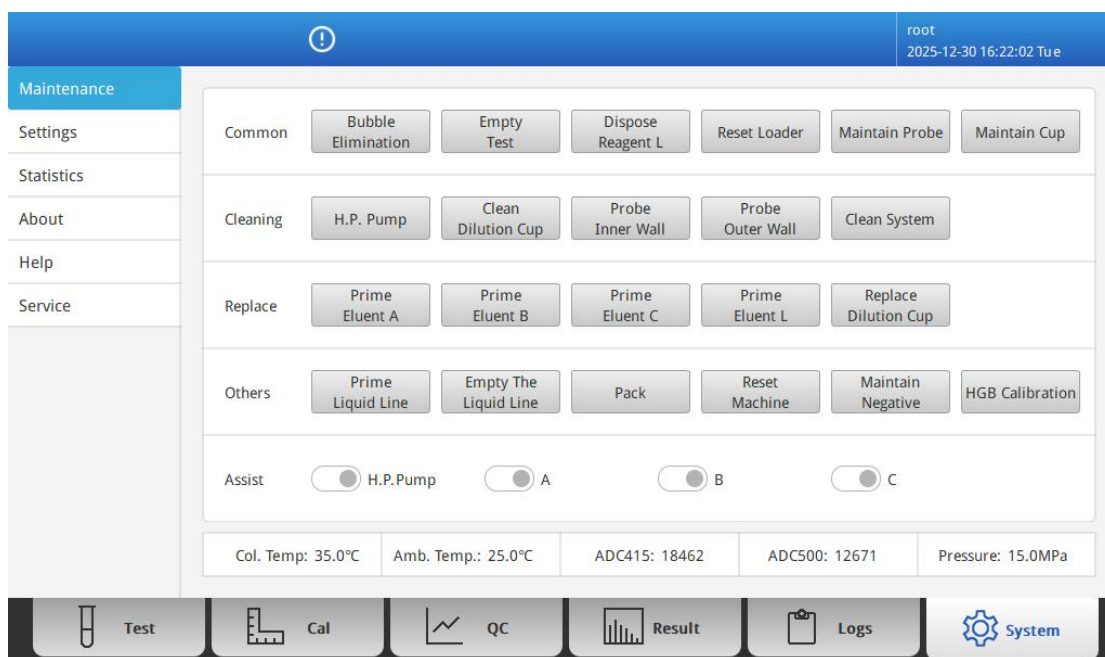


Fig. 11-1 System Maintenance Interface

10.3.1 Bubble Elimination

When air bubbles appear in high pressure pump, system pressure cannot increase to the normal range of 14-20MPa and meanwhile eluents cannot flow. The analyzer will activate an error alarm indicating low pressure of the high pressure pump. At this moment, bubble elimination should be performed. Please click “**Bubble Elimination**”, and turn on the evacuation valve as prompted on the interface. The analyzer will execute bubble elimination then. After air bubbles are eliminated, please re-tighten the evacuation valve.

10.3.2 Empty Test

Empty Test is used to test whether the elution process of the analyzer is correct. Meanwhile, empty test can also eliminate reagent peaks. Please click “**Empty Test**” to perform the procedure after removing the sample from the sample loader. The

acceptance criterion for empty test is that the red and blue lines are smooth and highly coincide with each other.

When the pump speed of the analyzer, reagent and column change, empty test should be executed again.

10.3.3 Dispose Reagent L

Reagent L is Hemolytic Agent L. Before disposing Hemolytic Agent L, please place an EP tube with holder at STAT. position. After that, please click “**Dispose Reagent L**” to perform the procedure. The analyzer will automatically aspirate 1500µL from the Hemolytic Agent L bucket, and inject the Hemolytic Agent L into the EP tube via the sampling needle for future use during calibration or QC operation or to pre-dilute samples.

10.3.4 Reset Loader

Please click “Reset Loader” to reset the sample loader to original situation after removing the sample rack from the sample loader.

10.3.5 Maintain Probe

If the probe need to be maintained, please click “**Maintain Probe**” button and a prompt will show “Confirm to maintain probe?”. Click “**Yes**”, and a prompt will show “please place a W.B. tube with 5 ml cleaning solution in STAT Port”. Place 5mL Probe Rinse Solution specified by manufacturer and designated agent as required and start the probe maintenance procedure. The instrument automatically absorbs the cleaning fluid and carry out the probe maintenance operation. The sampling probe automatically resets after the completion of the maintenance. Finally, dispose of used cleaning solution complying with local laws and regulations.

■ **The Probe Rinse Solution can not be reused.**

10.3.6 Maintain Cup

If the dilution cup need to be maintained, please click “**Maintain Cup**” button and a prompt will show “Confirm to maintain cup?”. Place 5 mL of Probe Rinse Solution in the STAT position as prompted by the instrument. Then start the maintenance procedure.

10.3.7 Cleaning

Cleaning function helps to the cleaning of **H.P. pump, diluted cup, probe inner wall, probe outer wall and (liquid line) system**. This section takes “Clean Diluted Cup” cleaning as an example to introduce this function. The operation steps are as follows:

Procedure

- 1) Click "**Clean Diluted Cup**" on the System interface.
- 2) Click "**Yes**" button and it will enter the cleaning procedure.
- 3) After cleaning, it will automatically return to the system interface .
- 4) The same goes for the cleaning of H.P. pump, probe inner wall, probe outer wall and (liquid line) system cleaning function.

10.3.8 Prime

- Prime function helps to eliminate the bubbles from the reagent pipeline.
- This section takes the prime of eluent A as an example to illustrate this function.
The operation steps are as following:

Procedure

- 1) Prepare aluminum foil bag with eluent A, connect the liquid line and screw up the lid of the bag.
- 2) Click "**Prime Eluent A**" button, it will display interface.
- 3) Select the eluent channel.
- 4) Click "Yes".
- 5) If not, click "No" to quit the procedure.

10.3.9 Replace Dilution Cup

When the consumable dilution cup reaches its usage limit, the instrument will prompt you to replace the cup promptly and perform the "Replace Dilution Cup" operation. The system will automatically reset the remaining usage count of the dilution cup.

10.3.10 Prime Liquid Line

When installing the analyzer , please prime the liquid line to ensure proper sample sucking during sample analysis. Please click "Prime Liquid Line" and open the evacuation valve as prompted on the interface.

Please execute this step with caution as it consumes much hemolysis reagent and may lead to a lack of hemolysis reagent in the following operation.

10.3.11 Empty The Liquid Line

Before emptying the liquid line, please disconnect Hemolytic Agent L and eluents A、B and C. After emptying the liquid line, the liquid path of the entire analyzer is empty.

10.3.12 Pack

- 1) Empty the liquid path;
- 2) Perfuse the liquid path with deionized water;
- 3) Empty the liquid path again.

This operation applies when the analyzer is to be left unused for a long period or be transported for a long distance.

10.3.13 Maintain Negative

When the negative pressure less than lower limit, the instrument will prompt, then perform the "Maintain Negative" operation. The system will automatically re-establish the negative pressure.

10.3.14 HGB Calibration

After replacing the dilution cup, it's necessary to recalibrate the sample HGB signal value and the sample HGB concentration. Place a whole blood sample 1# position of the sample rack and initiate HGB calibration. The instrument dilutes the sample at different concentration ratios and calculates the calibration curve by comparing the measured sample HGB signal value with the sample HGB concentration.

10.3.15 (Col.Temp)Temperature of Column

It is suggested that the column temperature should be set 30~40°C. If the analyzer is at an abnormal operating temperature, it may affect the column temperature and further the peak appearance time of HbA1c. The higher the temperature is, the sooner the peak appearance will be, vice versa. The column temperature is suggested to be adjusted to make the peak appearance time fall within the specified range to ensure accurate test results.

10.3.16 (Amb.Temp) Ambient Temperature

The ambient temperature for normal operation of the analyzer is between 10~30°C, and 25°C is recommended. Beyond this range, the analysis results may be affected.

10.3.17 ADC415

The analyzer uses a high-precision photoelectric sampling system, and also employs the dual-wavelength detection technique to eliminate system interference and non-specific absorption of hemoglobin. In normal status, the ADC415 value is within the range of 50000~54000; the ADC value is determined by the LED value and the gain. The ADC value is in direct proportion to the LED value — the higher the LED

value is, the higher the ADC value will be. The ADC value is inversely proportional to the gain — the higher the gain is, the smaller the ADC value will be.

If the ADC value cannot fall within the normal range after adjusting the LED value and the gain, please confirm whether there are air bubbles in the cell and whether the illuminating surface of the cell is dirty under the precondition that the system pressure is normal.

10.3.18 ADC500

Similar to ADC415, the ADC500 value in normal status is within the range of 34000~38000. It is also affected by the LED value and the gain; the ADC value debugging method is identical to that for ADC415.

10.3.19 Pressure

The system pressure can reach above 14-20MPa, which increases as the number of test increases. If the pressure increases during detection (About 4.0MPa higher than the initial pressure), please first replace the filter. If the pressure does not drop, please replace the column. The analyzer will activate an alarm and the test will be interrupted if the system pressure is beyond the set range.

10.4 System Settings

Click “**Settings**” button on the system interface below to enter system settings interface.

The screenshot displays the 'System Settings' interface of a laboratory instrument. The interface has a blue header bar with a user profile 'user' and the date/time '2026-01-05 13:43:27 Mon'. Below the header is a navigation menu with tabs: Maintenance, Function (selected), Network, Primary Lis, ASTM, DateTime, Print, Maintain Probe, and Supply Module. The 'Function' tab is active, showing a 'Settings' sidebar on the left with options: Settings, Statistics, About, Help, and Service. The main content area contains various settings:

- Screen Brightness(%): 100
- Curve Range(MOD): 300
- Target Temp.(°C): 35
- Sample Interval(Min): 15
- Waste Discharge: ☒ Barreled, ☐ Direct Discharge
- Reagent: ☐ Double, ☒ 1st Channel, ☐ 2nd Channel
- Sarstedt: ☒ On, ☐ Off
- Custom Rack: ☐ On, ☒ Off
- Auto-Generate ID: ☐ On, ☒ Off
- Sample Results: ☐ Export

At the bottom of the settings area, there is a status bar showing: Col. Temp: 35.0°C, Amb. Temp.: 25.0°C, ADC415: 18507, ADC500: 12639, and Pressure: 15.0MPa. The bottom of the interface features a row of icons for Test, Cal, QC, Result, Logs, and a 'System' button with a gear icon.

Fig. 11-2 System Settings Interface

10.4.1 Screen Brightness/Target Temperature

The range of screen brightness is 0~100%. Users can adjust it as needed.

Temperature setting is used to set the temperature in the column oven. Peak appearance time of target proteins relates to the temperature. It is suggested that target temperature should be set 30~40°C. For specific setting rules, please contact manufacturer and designated agent' Customer Service.

10.4.2 Waste Discharge

- **Barreled:** please ensure that a waste barrel is connected before clicking "Barreled". Please dispose of the waste in the waste liquid barrel when the analyzer activates the alarm that the barrel is full.
- **Direct Discharge:** please obey the laws and regulations about direct discharge to implement this procedure.

10.4.3 Reagent

The reagents can be configured as dual channels, channel 1 and channel 2, according to the requirements.

10.4.4 Sarstedt

The system allows the enabling and disabling of the blood collection tubes shaking function, and allowing operators to make selections according to their specific requirements.

11.4.5 Custom Rack

This function can support different dimensions of blood collection tubes for sample testing. The operator can choose according to the need. For details, please contact manufacturer and designated agent' Customer Service.

11.4.6 Auto-Generate ID

If the sample barcode information cannot be scanned or recognized, you may enable the "Auto-Generate ID" function. Once activated, the instrument will automatically assign an ID to such samples.

11.4.7 Sample Results

You can export test result for any selected time period through this operation.

10.4.8 Network

This function is used to set the IP address and network port of the analyzer and realize LIS/HIS transmission. Please refer to **Annex B**.

10.4.9 DateTime

This operation is used to set system time. After resetting, the system time will be updated at the upper right of the screen. Because QC data are stored according to the

current system time and the analyzer only records one-year QC data, if system time is set wrong and the QC operation is executed, the correct QC data will be deleted. Please operate with caution.

10.4.10 Print

The analyzer supports thermal, laser, and PDF printing. Before printing test results, please prepare a printer. Two print modes are available: Auto Print and Manual Print. If you click “**Auto**”, test results selected will be printed automatically after each sample test. If you click “**Manual**”, test results selected can be printed only in the result interface.

To save printing paper, users can selectively print the following three items in thermal printing mode:

- **Test Items:** print the peak appearance time, absorbance, total area and results in percentage of each hemoglobin component.
- **Graph:** print the chromatogram of the current sample.
- **Result:** print the IFCC concentration in the analysis result of the current sample and the estimated blood glucose level expressed in two units.

10.4.11 Maintain Probe

- **Maintain Position:** you can only execute sampling needle cleaning process at the test end of each round. It is forbidden to use emergency functional test samples.
- **STAT Position:** you can only test samples that need results quickly in the STAT position.

10.4.12 Eluent Supply Module

This function supports dual-channel reagents and enables the seamless replacement of reagents without stopping the testing. The operator can choose according to the need.

10.5 Statistics

The statistics function could record the number of times the analyzer was tested and the number of times the consumables were used. The operator can check the number of samples tested by selecting different types and times.

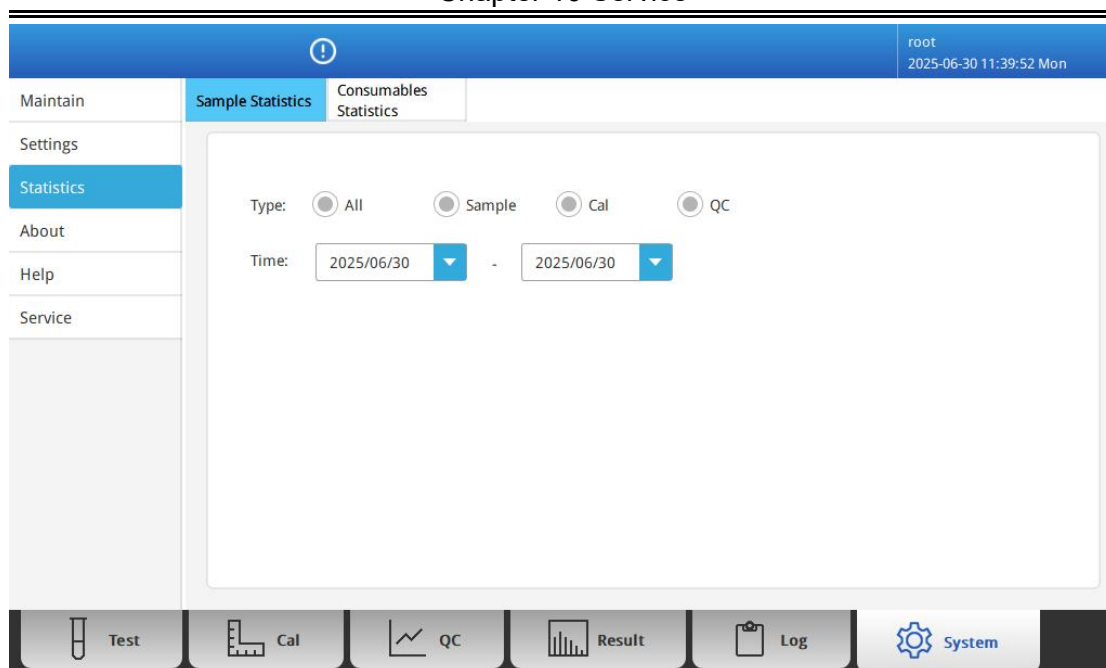


Fig. 11-3 Statistics Interface

■ Number of tests

Select one type that you want to check. If “Sample/Cal/QC” is selected, only the corresponding test times will be calculated. If “All” is selected, the test times of sample, calibration and QC will be calculated. Select a period as needed. The sum and the average for the number of tests will be display.

■ Usage count of spare parts

Select one spare part that you want to check. “**Maintenance**” shows the cumulative usage count during maintenance interval and the test times of recommended maintenance spare parts. “**Replace**” shows the cumulative usage count of spare parts during the service life and the test times of recommended replacement of spare parts. If the number of tests during maintained or replaced is reached, operator can perform maintenance or replacement according to the instrument prompts or contact manufacturer and designated agent’ Customer Service.

10.6 About

The “About” interface displays information of software, version and copyright.

Chapter 10 Service

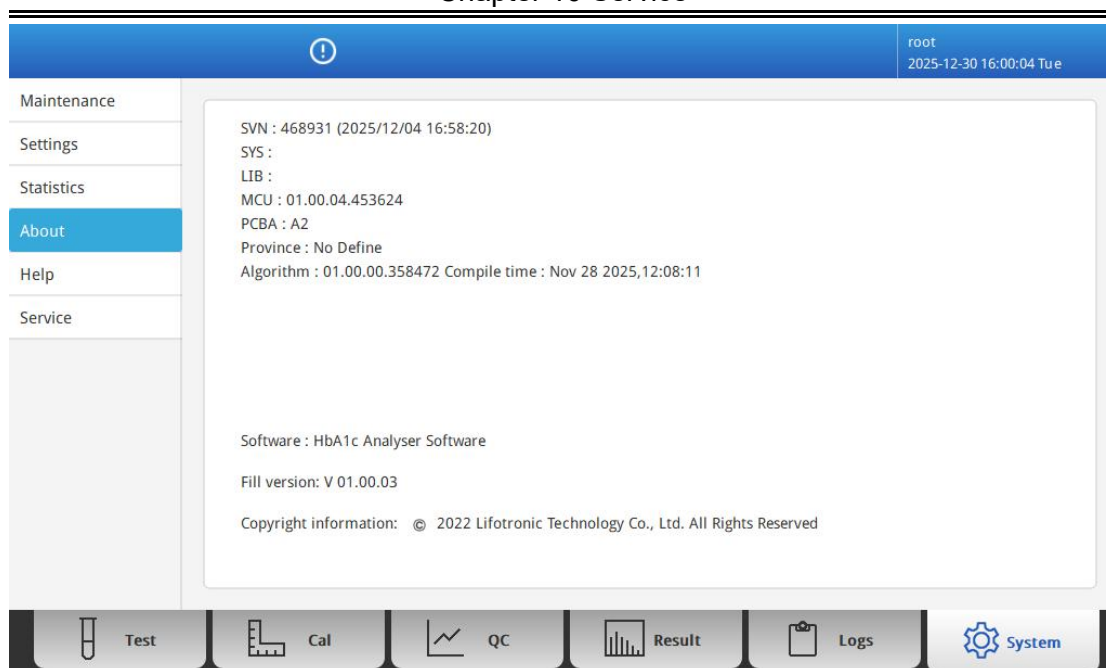


Fig. 11-4 About Interface

10.7 Help

The Help interface only displays the operating principle of the analyzer and the list of admitted sample remarks. More content will be provided in the future.

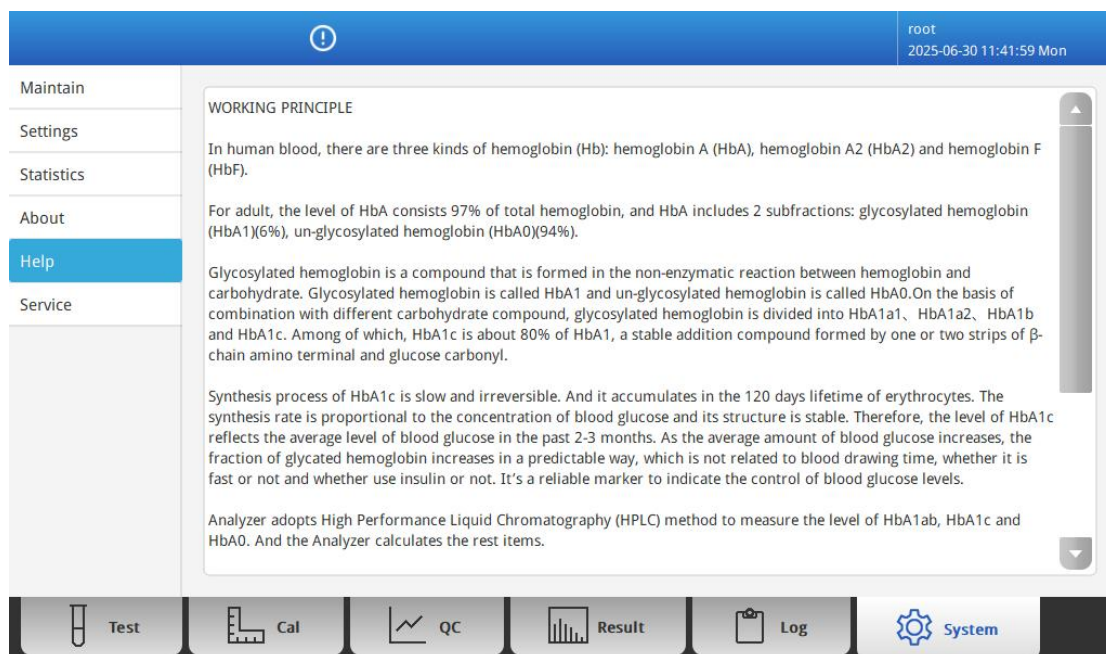


Fig. 11-5 Help Interface

10.8 Service

User needs an account and a password to log into the Service interface. For details, please contact manufacturer and designated agent' Customer Service.

Chapter 10 Service

Variant

!

rootH100Plus
2024-12-16 11:39:53 Mon

Maintenance

Settings

Statistics

About

Help

Service

Account:

Password:

Login

Test

Calibration

QC

Result

Log

System

Fig. 11-6 Service Interface

Chapter 11 Troubleshooting

11.1 Overview

This chapter introduces possible malfunctions of the analyzer and provides corresponding solutions.



- Power off the analyzer before repairing; otherwise electrical components damage and personal injury may result.



- If sample analysis is carried out in the presence of any malfunctions, the analysis result obtained may be incorrect. In case of a malfunction alarm during sample analysis, please eliminate the malfunction before continuing sample analysis.



- This Product Instruction Manual provides solutions to malfunction alarms.



- Samples, QC materials, calibrators, column, filters and waste liquid may carry biological contamination. When contacting relevant materials and areas in the laboratory, the operator should comply with the requirements for safe operation in the laboratory and wear personal protective equipment (e.g., laboratory protective clothing and gloves).
-

11.2 Malfunctions and Solutions

If any malfunction described in the list below occurs, please eliminate the malfunction following relevant troubleshooting steps. If the malfunction still exists, please contact manufacturer and designated agent's Customer Service.

Problem	Possible causes	Solution
The analyzer does not work after the power switch is turned on	1. The power cord is improperly connected. 2. The adapter is damaged. 3. The AC socket has no power supply.	1. Check the connection of the power cord. 2. Check whether the blue indicator light on the adapter is on. 3. Check whether the power socket has power supply.
The analyzer leaks liquid	1. The connector of high pressure tube gets loose. 2. The front filter is blocked. 3. The 6-way valve is blocked.	1. Identify the liquid leakage point. 2. Tighten the connector. 3. Replace the front filter. 4. Disassemble the 6-way valve for cleaning.
The printer does not work	1. The printer is out of paper. 2. Paper jam. 3. Circuit problem.	1. Change the printing paper. 2. Remove the jammed paper. 3. Upon startup, enter the System Maintenance interface to perform a printing test. If the test result is not OK, replace the circuit board or printer.
The sample rack does not move smoothly in the sample compartment.	1. The motor position is not properly adjusted, resulting in improper force of rollers pressing the sample rack. 2. The motor motion parameters are not properly adjusted. 3. The motor malfunctions.	1. Readjust the motor installation position. 2. Readjust the motor motion parameters. 3. Check the motor and optocoupler connecting cable, or replace the motor.
The touch screen input is abnormal.	1. The touch screen responds irregularly. 2. The touch screen is installed too tightly. 3. The touch screen is damaged.	1. Recalibrate the touch screen. 2. Slightly loosen the screw fixing the touch screen. 3. Replace the touch screen.
The high pressure pump does	1. The motor signal cable is improperly connected. 2. The drive module	1. Replug the signal cable. 2. Replace the drive module. 3. Replace the motherboard.

Chapter 11 Troubleshooting

not work	malfunctions. 3. The motherboard is damaged.	
The test result is beyond the range of 3%~20%	1. The sampling volume is set incorrectly. 2. The whole blood sample is not mixed evenly.	1. Reset the sampling volume. 2. Shake the venous blood collection tube before performing the test.

11.3 Classification of System Detection Info

In case of any abnormality detected during use of the analyzer, the analyzer will continuously generate a “beep, beep, beep” alarm sound. If any of the following malfunctions occurs, please contact manufacturer and designated agent's Customer Service.

Problem	Possible cause
0X0001	Unknown command.
0X0002	Command parameter error
0X0003	In execution
0X0005	Insufficient memory
0X0006	X-axis movement is disturbed by Z axis
0X0007	Instruction queue cleared
0X0008	Z-axis interferes with sample rack withdrawal
0X0009	Door interferes with sample rack withdrawal
0X0102	Attempt to operate the running sample introduction motor
0X0103	Step loss of sample introduction motor encoder
0X0104	The target position of sample introduction motor is beyond the maximum limit
0X0105	Error of reset sensor of sample introduction motor
0X0106	Timeout when the sample introduction motor waits for the end of movement
0X0107	The controller of sample introduction motor is not initialized
0X0202	Attempt to operate the running high pressure pump motor
0X0203	Step loss of high pressure pump motor encoder
0X0204	The target position of high pressure pump motor is beyond the maximum limit
0X0205	Error of reset sensor of high pressure pump

	motor
0X0206	Timeout when the high pressure pump motor waits for the end of movement
0X0207	The controller of high pressure pump motor is not initialized
0X0302	Attempt to operate the running 1ml plunger pump motor
0X0303	Step loss of 1ml plunger pump motor encoder
0X0304	The target position of 1ml plunger pump motor is beyond the maximum limit
0X0305	Error of reset sensor of 1ml plunger pump motor
0X0306	Timeout when the 1ml plunger pump motor waits for the end of movement
0X0307	The controller of 1ml plunger pump motor is not initialized
0X0502	Attempt to operate the running X-axis motor
0X0503	Step loss of X-axis motor encoder
0X0504	The target position of X-axis motor is beyond the maximum limit
0X0505	Error of reset sensor of X-axis motor
0X0506	Timeout when the X-axis motor waits for the end of movement
0X0507	The controller of X-axis motor is not initialized
0X0602	Attempt to operate the running Z-axis motor
0X0603	Step loss of Z-axis motor encoder
0X0604	The target position of Z-axis motor is beyond the maximum limit
0X0605	Error of reset sensor of Z-axis motor
0X0606	Timeout when the Z-axis motor waits for the end of movement
0X0607	The controller of Z-axis motor is not initialized

11.4 Malfunctions of Optical System and Solutions

If irregular ADC value is detected, please follow relevant troubleshooting steps provided in this chapter. If the problem persists, please contact manufacturer and designated agent's Customer Service.

Problem	Possible cause	Solution
The ADC value is 0	1. The signal line of sampling board or LED board is in poor connection.	1. Replug the signal line. 2. Replace the sampling board. 3. Replace the LED board.

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	- The sampling board malfunctions. - The LED board malfunctions.	
The ADC value is 65535	- The channel gain value is too small. - The LED value is set too high. - The sampling board malfunctions. - Air bubbles exist in the colorimetric cell.	- Increase the gain value. - Decrease the LED value. - Replace the data sampling board. - Execute perfusion of eluent A for 4-5 times; where necessary, take out the colorimetric cell during perfusion. Gently flick with your finger several times to help quickly eliminate air bubbles.
The ADC415 value cannot be stabilized between 50000 and 54000	Air bubbles exist in the colorimetric cell.	System -> Maintenance, click 'A' and turn on the high pressure pump, observe whether the ADC value is stable. Where necessary, take out the colorimetric cell in this process. Gently flick with your finger several times to help quickly eliminate air bubbles.

11.5 Malfunctions of External Connections and Solutions

If abnormal communication of external components is detected, please follow relevant troubleshooting steps provided in this chapter. If the problem persists, please contact manufacturer and designated agent's Customer Service.

Problem	Possible cause	Solution
Communication failure	- The communication connecting cable is loose. - The network IP address does not match. - The LIS transmission switch in the analyzer interface is not turned on.	- Check whether the analyzer is properly connected to the receiving end. - The IP address on the computer should be consistent with that on the analyzer. - Turn on the LIS transmission switch in the analyzer interface.
Communication failure of Bar code scanner	- The Bar code scanner is not properly connected. - The connecting cable is loose.	- Check whether the Bar code scanner is properly connected. - Check whether the connecting cable is properly connected.

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Invalid Bar code	1. The Bar code model is inconsistent. 2. Invalid Bar code data are scanned.	Please contact manufacturer and designated agent' Customer Service personnel.
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11.6 Problem and Solution

If any abnormality of reagents, column or filters occurs, please follow relevant troubleshooting steps provided in this chapter. If the problem persists, please contact manufacturer and designated agent's Customer Service.

Problem	Possible cause	Solution
Absence of hemolysis reagent	1. The hemolysis reagent connecting pipe is not inserted into the liquid. 2. The hemolysis reagent is used up.	1. Check whether the hemolysis reagent pipe is properly connected. 2. Add hemolysis reagent.
Absence of eluent A	1. Eluent A is used up 2. The count of eluent A is not reset.	1. Add eluent A. 2. Reset the count of eluent A.
Absence of eluent B	1. Eluent B is used up 2. The count of eluent B is not reset.	1. Add eluent B. 2. Reset the count of eluent B.
Absence of eluent C	1. Eluent C is used up 2. The count of eluent C is not reset.	1. Add eluent C. 2. Reset the count of eluent C.
Air bubbles occur in the reagent tube	Eluent A\B\C is used up, or the connecting pipe is not inserted into the liquid	Check the connecting pipe and the reagent; then execute perfusion of eluent A\B\C to eliminate air bubbles
Abnormality of chromatogram	1. The liquid path is blocked. 2. The column or filter malfunctions. 3. The reagent loses efficacy. 4. Sample analysis is carried out before the column temperature is stable. 5. Air bubbles are generated.	1. Carry out system cleaning after replacing the filter. 2. Replace the column or filter. 3. Replace the reagent. 4. Carry out sample analysis only when the column temperature is stable. 5. Eliminate air bubbles.
The result is beyond the range of 3%-20%	1. The sample volume aspirated is too small. 2. Lack of whole blood sample 3. The column or filter malfunctions. 4. The reagent loses efficacy.	1. Increase the sample volume aspirated. 2. Replace the whole blood sample or use the pre-diluted mode. 3. Replace the column or filter.

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	5. No system pressure	4. Replace the reagent. 5. Eliminate air bubbles.
Error code e1	Total area less than 50,000	1. Confirm that the sampling needle is not blocked and the sampling tube is not leaking; 2. If it is a anemia sample, reduce the dilution ratio.(e.g., it was 1:150 before, reduced to 1:75)
Error code e2	Total area more than 270,000	Increase the dilution ratio, such as 1:75 before, increase to 1: 150
Error code e3	Result more than 15%	None
Error code e4	Result less than 4%	None
Error code e5	Variants detected	None
Error code e6	Chromatogram abnormal or ADC abnormal	Adjust the value of ADC415 to between 50,000 and 54,000
Error code e7	A0 Total area less than 80%	None
Error code e8	Target peak is out of range	1. Confirm that the temperature of column is set correctly and the flow rate of the instrument is 1.5ml/min; 2. Confirm that the target peak recognition window is set correctly
Error code e9	Pressure is abnormal	It indicates that the analyzer may be abnormal, and the operator is recommended to check the analyzer after finishing test.
Error code e10	TP is too low	It indicates that the analyzer may be abnormal, and the operator is recommended to check the analyzer after finishing test. Then try to run those sample again.
Error code e11	HbF Result more than 5%	None
Error code e12	Minor Peak is greater than upper limit	It indicates that the sample may be abnormal, and the operator is recommended to make a comprehensive judgement based on other clinical indicator.

Please contact manufacturer and designated agent's Customer Service for more.

Appendix A Specifications

A.1 Matched Reagents

Eluents A\B\C, and Hemolytic Agent L.

A.2 Matched Columns and Filters

Columns and filters specified by Lifotronic.

A.3 Calibrators

Calibrators specified by Lifotronic.

A.4 QC Materials

QC materials specified by Lifotronic.

A.5 Cleaning Solution

Cleaning solution specified by Lifotronic.

A.6 Power Supply

- Voltage: AC 100V-240V
- Frequency: 50/60Hz
- Input power: 200VA

A.7 Operating Environment

- Ambient temperature: 10°C~30°C
- Relative humidity: ≤80% (no condensation)
- Atmospheric pressure: 75kPa~106kPa
- No frost, condensation, water seepage, moisture or direct sunlight.

A.8 Storage Conditions

- Ambient temperature: 0°C~55°C
- Relative humidity: ≤93%

- Atmospheric pressure: 75kPa~106kPa
- Storage location: The analyzer should be stored in a well-ventilated indoor warehouse free from acid, alkali and other hazardous gases.

A.9 Package Dimensions

- Length : 923mm
- Width : 818mm
- Height : 897mm

A.10 Analyzer Dimensions

- Length: 775mm
- Width: 730mm
- Height: 730mm

A.11 Weight

Net Weight: 67.5kg Gross Weight: 105.0kg

A.12 Valid Period

The product has a service life of 5 years. The service life of this product is determined based on the aging test of the product. During use, users should maintain, preserve and repair the product in accordance with the requirements of the product manual. After maintenance, preservation and repair, if the product can still maintain its basic safety and effectiveness upon confirmation, it can be used normally.

A.13 Contraindications

None.

Appendix B Communication

B.1 Communication Setting

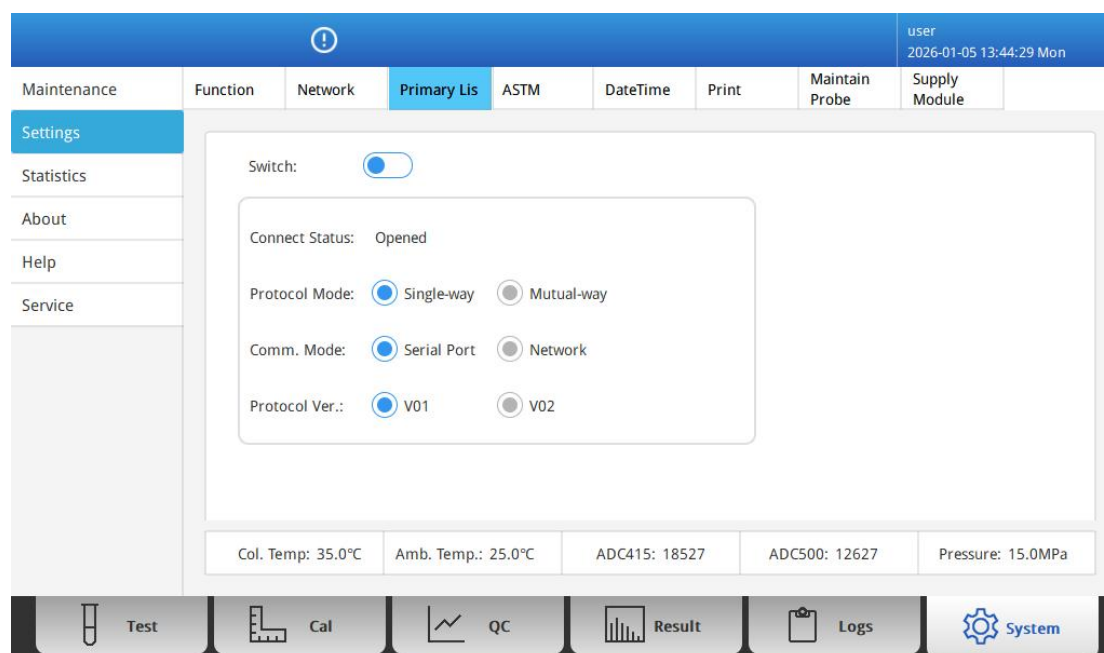
The analyzer LIS supports two communication protocols: Lifotronic and ASTM. Both protocols are described in detail in later sections.

B.1.1 Communication Parameters

- Analyzer IP Addr: 192.168.5.55
- Analyzer Port: 8080
- PC IP Addr: 192.168.5.56
- TCP Communication Mode on PC: TCP Server
- TCP Port on PC: 8080

B.1.2 Lifotronic Communication Protocol Settings

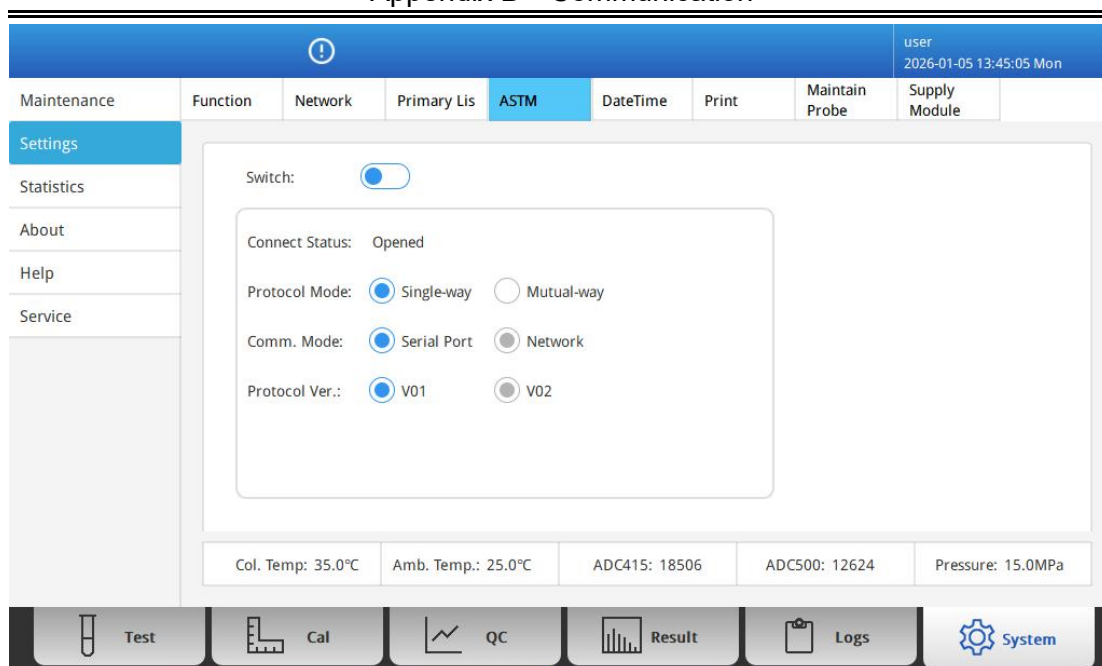
Please checked "System" -> "Settings" -> "Primary Lis" -> "Switch".



B.1.3 ASTM Communication Protocol Settings

Please checked "System" -> "Settings" -> "ASTM" -> "Switch".

Appendix B Communication



B.2 Lifotronic Communication Protocol

B.2.1 Communications Instructions

Code

【STX】	0x02
【ETX】	0x03
"S"	0x53
"Q"	0x51
"C"	0x43
"#"	0x30-0x39
"*"	0x2A
"_"	0x2D
"+"	0x2B
."	0x2E

Blood type codes have the following meanings:

Code	Meaning
0x30	Whole blood
0x31	Pre-diluted blood
0x32	QC Material
0x33	Calibrator

Error codes have the following meanings:

Code	Meaning
------	---------

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0x31	e1 error code, Total area less than 50,000.
0x32	e2 error code, Total area more than upper 270,000.
0x33	e3 error code, Result more than 15%.
0x34	e4 error code, Result less than 4%
0x35	e5 error code, Variants detecte.
0x36	e6 error code, Chromatogram abnormal or ADC abnormal
0x37	e7 error code, A0 Total area less than 80%.
0x38	e8 error code, Target peak is out of range.
0x39	e9 error code, Pressure is abnormal
0x41	e10 error code, TP is too low
0x42	e11 error code, HbF Result more than 5%
0x43	e12 error code, Minor Peak more than upper limit

B.2.2 Sample Data Format(V01)

Data start flag	【STX】
Data block specifier	"S"
Version No.	##
Number of parameters	##
Parameter description format number	##
Code length	##
Sample ID.	#####
Test Temperature(T*10).	####
Sample rack position	##
Series No.	####
Blood type	#
Year	##
Month	##
Day	##
Hour	##
Minute	##

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Second	##
HbA1a appearance time	##
HbA1b appearance time	##
HbF appearance time	##
LA1c appearance time	##
HbA1c appearance time	##
HbA0 appearance time	##
HbA1a absorbance	#.####
HbA1b absorbance	#.####
HbF absorbance	#.####
LA1c absorbance	#.####
HbA1c absorbance	#.####
HbA0 absorbance	#.####
HbA1a peak area	##.###
HbA1b peak area	##.###
HbF peak area	##.###
LA1c peak area	##.###
HbA1c peak area	##.###
HbA0 peak area	##.###
HbA1a peak area ratio	##.##
HbA1b peak area ratio	##.##
HbF peak area ratio	##.##
LA1c peak area ratio	##.##
HbA1c peak area ratio	##.##
HbA0 peak area ratio	##.##
HbA1c content in IFCC(mmol/mol)	###.#
Average blood glucose(mmol/L)	##.#
Average blood glucose(mg/dl)	###.#
Sent chromatographic curve number	###
Sent chromatographic curve values	#.####
Test error code	#
Data end flag	【ETX】

B.2.3 Sample Data Format(V02)

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Data start flag	【STX】
Data block specifier	"S"
Version No.	##
Number of parameters	##
Parameter description format number	##
Code length	##
Sample ID.	#####
Test Temperature(T*10).	####
Sample rack position	##
Series No.	####
Blood type	#
Year	##
Month	##
Day	##
Hour	##
Minute	##
Second	##
HbA1a appearance time	##.#
HbA1b appearance time	##.#
HbF appearance time	##.#
LA1c appearance time	##.#
HbA1c appearance time	##.#
HbA0 appearance time	##.#
V-Win appearance time	##.#
HbA1a absorbance	#.####
HbA1b absorbance	#.####
HbF absorbance	#.####
LA1c absorbance	#.####
HbA1c absorbance	#.####
HbA0 absorbance	#.####
V-Win absorbance	#.####
HbA1a peak area	###.####
HbA1b peak area	###.####
HbF peak area	###.####

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LA1c peak area	###.####
HbA1c peak area	###.####
HbA0 peak area	###.####
V-Win peak area	###.####
HbA1a peak area ratio	##.# or ##.##
HbA1b peak area ratio	##.# or ##.##
HbF peak area ratio	##.# or ##.##
LA1c peak area ratio	##.# or ##.##
HbA1c peak area ratio	##.# or ##.##
HbA0 peak area ratio	##.# or ##.##
V-Win peak area ratio	##.# or ##.##
HbA1c content in IFCC(mmol/mol)	###.#
Average blood glucose(mmol/L)	##.#
Average blood glucose(mg/dl)	###.#
Sent chromatographic curve number	###
Sent chromatographic curve values	#.#####
Sent chromatographic fit curve values	#.#####
Test error code	#
Procotol version	###
Precision(NGSP)	#
Variant type	#
Data end flag	【ETX】

B.3 ASTM Communication Protocol

B.3.1 Interface specifications

H100Plus adopts the communication protocol compliant with ASTM-1381. The ASTM communication protocol supports RS232 and TCP transmission.

B.3.2 Instrument Settings

We have two methods to send LIS data. Click the LIS button(Result Detail) or upload automatically.

B.3.3 Frame structure and control code

This tabel shows the frame structure:

STX	FN	Transmission data	CR	ETB	CSH	CSL	CR	LF
-----	----	----------------------	----	-----	-----	-----	----	----

Frame control code have the following meanings:

Code	Hex	Description
STX	02H	Start of text (frame)
FN		Fram No. Begin with "1" and incremented by one. Return to "0" after reaching "7"
Transmission data		Communication text
ETB	17H	End of transmission block
CSH	Note 1)	Checksum high
CSL		Checksum low
CR	0DH	Carriage return
LF	0AH	Line feed

ATTENTION

Checksum is calculated by adding up the bytes from after STX through ETX or ETB and dividing the sum by 256 to express its remainder in 2-digit hexadecimal form. The first and second characters of the checksum represent "CSH" and "CSL", respectively.

➤ Example

the sum of the bytes after STX to ETX = 1000

$1000 \bmod 256 = 232 = \text{E8H}$

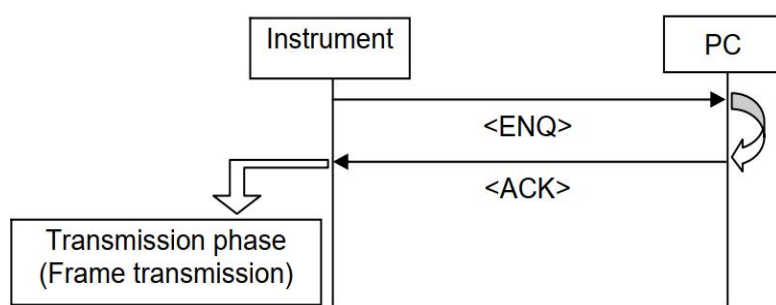
CSH = "E" (45H), CSL = "8" (38H).

B.3.4 Communication Format

H100Plus communication format including query message (Instrument -> PC), response message (PC -> Instrument) and measurement result message (Instrument -> PC). But query message is not supported.

The instrument transmits <ENQ> when it has a message to send. If the instrument receives a response other than <ACK> and <ENQ>, it performs the same process as when it receives <NAK>. If the instrument receives <ACK>, it moves on to the transmission phase. - If the instrument receives <NAK>, it retransmits <ENQ> after waiting for 10 seconds. If the instrument does not receive <ACK> after transmitting <ENQ> 6 times (including the first transmission), it sends <EOT> before

giving a trouble message.



B.3.4.1 Communication control code

Code	Hex	Description
ENQ	05H	Enquiry (Request for start)
ACK	06H	Acknowledgement
NAK	15H	Negative acknowledgement
EOT	04H	End of transmission and request for receive interrupt

B.3.4.2 Common record

All the above messages include common records (header / end records). This section provides information about the header and end records.

Header record is composed of 14 fields.

No.	Field	Description	Remark (Example)
1	Record type	Set character	"H"
2	Delimiter setting	Set characters Field delimiter Repeat delimiter Component delimiter Escape delimiter	" \${^&"
5	Sender name	1. Instrument name: Set characters 2. Instrument No. (S/N): 12-digit number 3. APP version: Characters / digits 4. MCU version: Characters /	1. "H100Plus" 2. "100001011500" 3. "V01.00.01.223119" 4. "V01.00.00.204568"

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		digits 5. Surplus: Space	5. “ ”
14	Communication date / time	Communication date / time (YYYYMMDDHHMM): 12-digit number (Year, Month, Date, Hour, Minute)	“202108161536”
	End of record	End of record (set characters)	<CR> (0x0D)

➤ Example

H|\$^&|||H100Plus^100001011500^V01.00.01.223119^V01.00.00.204568|||||||20
2108161536<CR>

End record is composed of 3 fields.

No.	Field	Description	Remark (Example)
1	Record type	Set character	“L”
2	Sequence No.	Set digit	“1”
3	End code	Indicates whether measurement has been normally completed. (Normal end : Set character)	“N”
	End of record	End of record	<CR> (0x0D)

➤ Example

L|1|N<CR>

B.3.4.3 Query message

This section describes the structure of query message.

1) Query message structure (Instrument->PC)

Appendix B Communication

Message header segment	H
Query message segment	Q
Message tail segment	L

2) Query message segment

No.	Field	Description	Remark (Example)
1	Record type	Set character	“Q”
2	Sequence No.	Set digit	“1”
3	Patient ID	Barcode ID: 18-digit number/character/symbol (*1) 2. Port No.: 5-digit number 3. Rack ID : Characters 4. Cup No. : 2-digit number 5. Test Mode -1. Fast mode	1. “WBR19-----” 2. “004925” 3. “LF-002” 4. “01” 5. -1. “F”
13	Query code	1. Query content(command or statement): character	1) “O”
	End of record	End of record	1) <CR> (0x0D)

➤ Example

Q|1|WBR19-----^004925^LF-002^01^F| | | | | | | | O<CR>

Or

Q|1|WBR19-----^004925^LF-002^01^T| | | | | | | | O<CR>

B.3.4.4 Response Message (PC->Instrument)

1) Patient information

No.	Field	Description	Remark (Example)
1	Record type	Set character	1) “P”
2	Sequence No.	Sequence number starting with “1”	1) “1”
	End of record	End of record	1) <CR> (0x0D)

2) Test order message

Test order message is composed of 16 fields, which are different from those of the response message.

➤ Example

B.3.4.5 Measurement result message (Instrument -> PC)

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record.

1) Patient information record is composed of the same fields as those of the response message.

No.	Field	Description	Remark (Example)
1	Record type	Set character	"P"
2	Sequence No.	Sequence number starting with "1"	"1"
	End of record	End of record	<CR> (0x0D)

➤ Example

P|1<CR>

2) Test order record is composed of 20 fields, which are different from those of the response message.

No.	Field	Description	Remark (Example)
1	Record type	Set character	" O"
2	Sequence No.	Set digit	" 1"
3	Patient ID	1. Barcode ID: 18-digit number/character/symbol (*1) 2. Port No.: 5-digit number 3. Rack ID : Characters 4. Cup No. : 2-digit number 5. Test Mode -1. Fast mode	1. "WBR19-----" 2. " 4925" 3. " LF-006" 4. " 02" 5. -1. " F"
4	Measurement No.	Measurement number: 4-digit number	" 0020"
5	Measurement item	Measurement item name (*2) 1. HbA1c: Set characters 2. HbF: Set characters 3. No Measurement: No output	1. "^^^HbA1c" 2. "^^^HbF" 3. NULL(No output)

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6	Priority	Measurement type (one of below) 1. Normal sample: Set character 2. STAT sample: Set character 3. Control: Set character 4. Calibrator: Set character	1. " R" 2. " S" 3. " Q" 4. " C"
16	Sample type	Sample type (either of below) 1. Whole blood: No output 2. Hemolysis: Set character 3. Anemia: Set character	1. NULL (No output) 2. " H" 3. " A"
20	Additional comment	1. HbA1c measurement error information 8-digit number (Hexadecimal) 2. Reserve 8-digit number (Hexadecimal) 3. Column degradation information: Normal Column degradation 4. Measurement mode: Variant mode 5. Eluent A: Lot, Expiry 4. Eluent B: Lot, Expiry 7. Eluent C: Lot, Expiry 8. Eluent D: Lot, Expiry 9. Hemorisisys: Lot, Expiry 10. Calibrator: Lot, Expiry 11. QC: Lot, Expiry 12. Column : Lot, Expiry	1. " 00000000" (*1) 2. " 00000000" 3. " 0" " 1" 4. " V" 5. "1SX0023100A""2024-08-16" 6. "1SX0023100B""2024-08-16" 7. "1SX0023100C""2024-08-16" 8. "1SX0023100D""2024-08-16" 9. "HHSX210020""2023-07-21" 10. "Manual""2024-05-16" 11. "SX0023100""2024-05-16" 12. "1E*****225456

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		13. Align: K, B 14. TP: value	78""2025-05-16" 13. "1.0871""0.3762" 14. "281.191"
	End of record	End of record	<CR> (0x0D)

➤ Example

O|1|WBR19-----^4925^LF-006^02|0020|^HbA1c^HbF|R|||||H||||000
00000^00000000^0^F^1SX0023100A^2024-08-16^1SX0023100B^2024-08-16^1SX0
023100C^2024-08-16^1SX0023100D^2024-08-16^HHSX210020^2023-07-21^Manu
al^2024-05-16^SX0023100^2024-05-16^1E*****22545678^2025-05-16^1.0871^0.
3762^281.191<CR>

Barcode ID:

QC1V、QC2V、C1V、C2V - QC and Calibration(Variant mode)

This is HbA1c measurement error information,the last digit indicates the result flag(Fast mode).

00000000 - : Normal

00000001 - e1: Total area less than 50,000;

00000002 - e2: Total area more than upper 270,000;

00000003 - e3: Result more than 15%;

00000004 - e4: Result less than 4%;

00000005 - e5: Variants detecte;

00000006 - e6: Chromatogram abnormal or ADC abnormal;

00000007 - e7: A0 Total area less than 80%;

00000008 - e8: Target peak is out of range;

00000009 - e9: Pressure is abnormal;

00000010 - e10: TP is too low;

00000011 - e11: HbF Result more than 5%;

00000012 - e12: Minor Peak more than upper limit;

3) Result record

Result record (Sequence No.1) of Fast mode is shown in the follwing table. One result record is composed of 12 fields.

No.	Field	Description	Remark (Example)
1	Record type	Set character	"R"

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2	Sequence No.	Sequence number starting with "1"	"1"
3	Measurement item	Item name: Set characters (one of below) 1. HbA1c measurement value 2. IFCC measurement value 3. HbF measurement value 4. Total area 5. HbA1a peak 6. HbA1b peak 7. HbF peak 8. L-A1c peak 9. HbA1c peak 10. Unknown peak 11. A0 peak 12. Variant peak (one of below) V_Win peak E_Win peak D_Win peak S_Win peak C_Win peak J_Win peak 13. Bottom time 14. Baseline contact position (start/end) time 15. Bottom retention time HbA1c peak 16. Bottom retention time HbF peak 17. Bottom retention time HbS peak 18. Bottom retention time HbC peak 19. Time for chromatogram scale adjustment 20. Value for chromatogram scale adjustment 21. A/D count value 22. A/D count value	"^^^ValueHbA1c" 2. "^^^ValueIFCC" 3. "^^^ValueHbF" 4. "^^^AreaTotal" 5. "^^^PeakHbA1a" 6. "^^^PeakHbA1b" 7. "^^^PeakHbF" 8. "^^^PeakLA1c" 9. "^^^PeakSA1c" 10. "^^^PeakUnknown" 11. "^^^PeakA0" 12. "^^^PeakVWin" "^^^PeakEWin" "^^^PeakDWin" "^^^PeakSWin" "^^^PeakCWin" "^^^PeakJWin" 13. "^^^TimeBottom" 14. "^^^TimeBase" 15. "^^^TimeSA1c" 16. "^^^TimeHbF" 17. "^^^TimeHbS" 18. "^^^TimeHbC" 19. "^^^TimeGain" 20. "^^^ValueGain" 21. "^^^ADCount1" 22. "^^^ADCount2"

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		... 40. A/D count value	... 40. “^^^ADCount0”
4	Measurement value	Data: digits/symbols(For Item name) 1. HbA1c measurement value (Area ratio) 2. IFCC measurement value (Concentration) 3. HbF measurement value (Area ratio) 4. Total count value 5. HbA1a peak appearance time,area value, area ratio, abs 6. HbA1b peak appearance time,area value, area ratio, abs 7. HbF peak appearance time,area value, area ratio, abs 8. L-A1c peak appearance time,area value, area ratio, abs 9. HbA1c peak appearance time,area value, area ratio, abs 10. Unknown peak appearance time,area value, area ratio, abs 11. A0 peak appearance time,area value, area ratio, abs 12. Variant peak appearance time,area value, area ratio, abs 13. Bottom time 14. Baseline contact position (start/end) time	1. “5.15” 2. “32.77” 3. “0.12” 4. “108648.0” 5. “10.0^318^0.29^14” 6. “11.8^1146^1.05^37” 7. “14.8^131^0.12^23” 8. “17.7^2148^1.97^48” 9. “23.1^5601^5.15^83” 10. “36.1^8269^7.61^245” 11. “39.5^92395^85.04^3714” 12. “0.0^0^0.0^0” 13. “” 14. “”

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		15. Bottom fractionation time HbA1c peak 16. Bottom fractionation time HbF peak 17. Bottom fractionation time HbS peak 18. Bottom fractionation time HbC peak 19. Time for chromatogram scale adjustment 20. Chromatogram minimum scale, baseline, scope 21. A/D count value 22. A/D count value ... 40. A/D count value	15. "" 16. "" 17. "" 18. "" 19. "0^58" 20. "10^20^300" 21. "1234^2345^.." 22. "1234^2345^.." ... 40. "1234^2345^.."
5	Unit	Unit: Symbol (For Item name) 1. Area ratio 2. Concentration (mmol/mol) 3. Area ratio 4. Total count value 5. Peak appearance time, area value, area ratio , abs 6. Peak appearance time, area value, area ratio, abs 7. Peak appearance time, area value, area ratio, abs 8. Peak appearance time, area value, area ratio, abs 9. Peak appearance time, area value, area ratio, abs 10. Peak appearance time, area value, area ratio, abs 11. Peak appearance time, area value, area ratio, abs 12. Peak appearance time, area value, area ratio, abs	"%" 2. "mmol/mol" 3. "%" 4. "count" 5. "sec^count^%^10mOD" 6. "sec^count^%^10mOD" 7. "sec^count^%^10mOD" 8. "sec^count^%^10mOD" 9. "sec^count^%^10mOD" 10. "sec^count^%^10mOD" 11. "sec^count^%^10mOD" 12. "sec^count^%^10mOD"

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		13. Bottom time 14. Baseline contact position (start/end) time 15. Bottom fractionation time HbA1c peak 16. Bottom fractionation time HbF peak 17. Bottom fractionation time HbS peak 18. Bottom fractionation time HbC peak 19. Time for chromatogram scale adjustment 20. Value for chromatogram scale adjustment 21. A/D count value 22. A/D count value 40. A/D count value	13. "sec" 14. "sec" 15. "sec" 16. "sec" 17. "sec" 18. "sec" 19. "sec" 20. "mOD" 21. "count" 22. "count" 40. "count"
7	Abnormal flag	1. Normal 2. Abnormal	1. NULL (No output) 2. "ERR." (Set characters)
9	Test result status	Set character	"F"
12	Measurement start date/time	Measurement start date / time (YYYYMMDDHHMM): 1. Year, Month, Date, Hour, Minute: 12-digit number After 2. No output	1. "200607191010" 2. NULL (No output)
	End of record	End of record	<CR> (0x0D)

➤ Example

R|1|^^^ValueHbA1c|5.15|%|||F|||202312051014<CR>

R|2|^^^ValueIFCC|32.77|mmol/mol|||F<CR>

R|3|^^^ValueHbF|0.12|%|||F<CR>

R|4|^^^AreaTotal|108648.0|count|||F<CR>

R|5|^^^PeakHbA1a|10.0^318^0.29^14|sec^count^%^10mOD|||F<CR>

```
^0036^0035^0034^0033^0032^0031^0030^002F^002E^002D^002C^002C^002B^00
2A^002A^0029^0029^0029^0029^002A|count||||F<CR>
```

```
R|28|^^^ADCount8|002A^002C^002D^002F^0031^0034^0037^003A^003E^004
2^0047^004B^0050^0054^0058^005C^005F^0062^0064^0066^0067^0067^00
66^0065^0063^0061^005F^005C^0059|count||||F<CR>
```

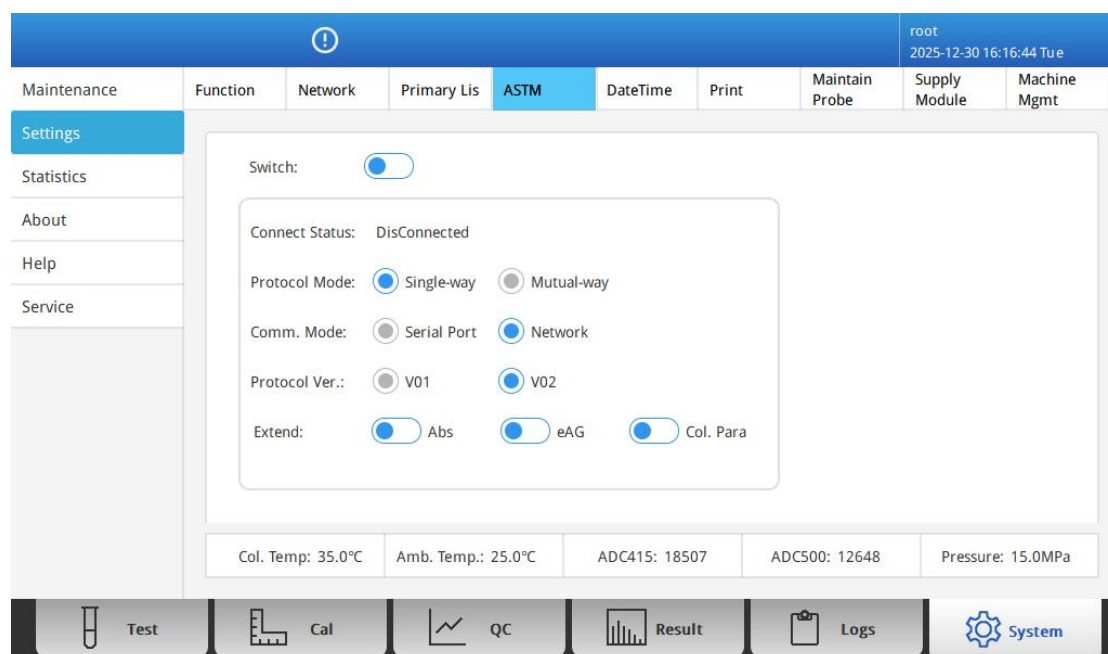
```
R|29|^^^ADCount9|0056^0053^0050^004D^004A^0047^0044^0042^003F^003D
^003B^0039^0036^0035^0033^0032^0030^002F^002E^002D^002C^002B^002B^00
2A^0029^0029^0028^0028^0028^0027|count||||F<CR>
```

```
R|30|^^^ADCount0|0027^0027^0027^0027^0027^0028^0028^0028^0028^0029^
002A^002A^002B^002B^002C^002C^002C^002D^002D^002D^002D^002D^0
02C^002C^002C^002C^002C^002D|count||||F<CR>
```

...

B.3.4.6 Measurement result Option (Instrument -> PC)

Add configuration options to extend the information of Measurement results.



(1) Abs

Absorbance value of the measurement item.

(2) eAg

Estimated average glucose.

(3) Col.Para

Chromatography column parameters (column temperature, column pressure).

➤ Example

```

R|1|^^^ValueHbA1c|6.1|%|F|202102012058<CR>
R|2|^^^ValueIFCC|43.0|mmol/mol|F<CR>
R|3|^^^ValueHbF|1.3|%|F<CR>
R|4|^^^AreaTotal|87077.0|count|F<CR>
R|5|^^^PeakHbA1a|8.0^99^0.1^28|sec^count^%^10mOD|F<CR>
R|6|^^^PeakHbA1b|11.0^420^0.5^1095|sec^count^%^10mOD|F<CR>
R|7|^^^PeakHbF|13.0^1173^1.3^436|sec^count^%^10mOD|F<CR>
R|8|^^^PeakLA1c|17.0^628^0.7^105|sec^count^%^10mOD|F<CR>
R|9|^^^PeakSA1c|24.0^2716^3.1^1031|sec^count^%^10mOD|F<CR>
R|10|^^^PeakUnknown|36.1^8269^7.61^245|sec^count^%^10mOD|F<CR>

R|11|^^^PeakA0|39.0^82038^74.2^1553|sec^count^%^10mOD|F<CR>
R|12|^^^PeakVWin|0.0^0^0.0^0|sec^count^%^10mOD|F<CR>
R|16|^^^TimeBottom|sec|F<CR>
R|17|^^^TimeBase|sec|F<CR>
R|18|^^^TimeSA1c|sec|F<CR>
R|19|^^^TimeHbS|sec|F<CR>
R|20|^^^TimeHbC|sec|F<CR>
R|21|^^^TimeGain|0^60|sec|F<CR>
R|22|^^^ValueGain|10^20^300|mOD|F<CR>
R|23|^^^ADCount1|0014^0014^0014^0014^0014^0014^0014^0014^
0013^0013^0013^0013^0013
^0013^0013^0013^0013^0013^0013^0013^0013^0014^0014^0013^0013^0013^
0014^0014|count|F<CR>
R|24|^^^ADCount2|0014^0013^0014^0013^0014^0014^0014^0014^0013^
0013^0013^0013^0013^0013
^0013^0013^0013^0013^0013^0013^0013^0013^0013^0013^0013^0013^
0013^0013|count|F<CR>
R|25|^^^ADCount3|0013^0013^0013^0013^0013^0013^0014^0014^0014^0014^
0015^0015^0017^0019^001D
^0021^0027^002E^0036^003E^0046^004D^0054^0059^005C^005D^005C^005
A^0056^0052|count|F<CR>
R|26|^^^ADCount4|004E^0049^0045^0041^003E^003C^003B^003B^003C^003
D^003E^0040^0042^0044^0046

```

```

^0048^004B^004C^004E^004F^0050^0051^0052^0052^0053^0054^0055^0058
^005A^005E|count||||F<CR>
R|27|^^^ADCount5|0061^0064^0067^0069^006A^006B^006A^0068^0064^0060
^005C^0058^0054^0050^004C
^0049^0047^0045^0043^0041^0040^003F^003E^003D^003D^003D^003D^003
E^003F^0041|count||||F<CR>
R|28|^^^ADCount6|0043^0045^0047^0049^004B^004C^004C^004C^004B^004
A^0048^0047^0045^0043^0041
^003F^003D^003B^003A^0039^0038^0037^0037^0036^0036^0036^0036^0036
^0037^0037|count||||F<CR>
R|29|^^^ADCount7|0037^0038^0038^0039^0039^0039^0039^0039^0039^0039^
0039^0039^0039^0039^0039
^0039^0039^0039^0039^0039^0038^0038^0038^0038^0038^0037^0037^0037^
0036^0036|count||||F<CR>
R|30|^^^ADCount8|0036^0036^0036^0036^0036^0036^0037^0038^003A^003C
^003E^0040^0043^0047^004B
^004F^0054^005A^005F^0065^006B^0071^0076^007C^0080^0084^0087^008A
^008B^008C|count||||F<CR>
R|31|^^^ADCount9|008C^008C^008B^0089^0087^0084^0081^007D^0079^0074
^0070^006B^0066^0062^005D
^0059^0055^0051^004E^004A^0047^0044^0041^003F^003D^003B^0039^0037
^0036^0035|count||||F<CR>
...
R|56|^^^Press|16.0|MPa||||F<CR><ETB>25<CR><LF>
R|57|^^^ColumnTemp|308.15|K||||F<CR><ETB>D5<CR><LF>
R|56|^^^ColumnNum|437|count||||F<CR><ETB>BE<CR><LF>
R|58|^^^ValueeAG|5.76|mmol/L||||F<CR><ETB>3D<CR><LF>
R|59|^^^ValueeAG|104.01|mg/dl||||F<CR><ETB>36<CR><LF>

```

Appendix C Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic emissions		
The analyzer is intended for use in the electromagnetic environment specified below, The customer or the user of the analyzer should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The analyzer uses RF energy only for its internal function. Therefore, its RF radiation is very small and unlikely to cause any interference in nearby electronic equipment. The analyzer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity			
The analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the analyzer should ensure that it is used in such an environment.			
Immunity test	IEC 61326 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic Discharge(ESD) IEC 61000-4-2	±4kV contact ±8kV air	±4kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±1kV for power supply lines, ±0.5 kV for input/output lines	±1kV for power supply lines, ±0.5kV for input/output lines	Mains power quality should be that of a typical commercial or a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.

Appendix C Electromagnetic Compatibility

Surge IEC 61000-4-5	$\pm 0.5\text{kV}$ line-to-line, $\pm 1\text{kV}$ line-to-ground	$\pm 0.5\text{kV}$ line-to-line, $\pm 1\text{kV}$ line-to-ground	Mains power quality should be that of a typical commercial or a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.
Voltage dips, short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T during 0,5 cycles, 0 % U_T during 1 cycle, 70 % U_T during 25/30 cycles	0 % U_T during 0,5 cycles, 0 % U_T during 1 cycle, 70 % U_T during 25/30 cycles	Mains power quality should be that of a typical commercial or a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. If the user of the analyzer requires continued operation during power mains interruptions, it is recommended that the analyzer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The magnetic field with the frequency of the power supply network should correspond to the characteristics of a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.
NOTE U_T is the a.c. mains voltage prior to application of the test level. "25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test".			

Appendix C Electromagnetic Compatibility

Guidance and manufacturer's declaration-electromagnetic immunity			
The analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the analyzer should ensure that it is used in such an environment			
Immunity test	IEC 61326 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vms 150kHz to 80 MHz 3Vms 80MHz to 6GHz	V1=3 Vrms E1=3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the analyzer ,including cables,than the recommended separation distance calculate from the equation applicable to frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{p}$ 80MHz to 800MHz $d=2.3\sqrt{p}$ 800MHz to 6GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter distance in meters(m). Field strengths from fixed RF transmitters,as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz,the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations.Electromagnetic propagation is affected by absorption and reflection from structures,objects and people.			
^a Field strengths from fixed transmitters,such as base stations for radio(cellular/cordless)telephones and land mobile radios,amateur radio,AM and FM radio broadcast and TV broadcast cannot be predicated theoretically survey should be considered.If the measured field strength in the location in which the analyzer is used exceeds the applicable RF compliance level above,the Medical analyzer should be observed to verify normal operation.If abnormal performance is observed,additional measures may be necessary,such as reorienting or relocating the analyzer. ^b Over the frequency range 150 kHz to 80 MHz,field strengths should be less than 3 V/m.			

Recommended separation distances between Portable and mobile RF communications equipment and the Medical analyzer			
The analyzer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical analyzer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the analyzer as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80 MHz $d = \left[\frac{3.5}{\sqrt{P}} \right] \sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3.5}{E1} \right] \sqrt{P}$	80MHz to 800MHz $d = \left[\frac{7}{E1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.37
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 AT 80 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

P/N:XXX-XXXXXXXXXX-XX(1.0)

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