General Description

Thank you for choosing the AyoTes Fully Automated HPLC Analyzer.
This operators' manual is provided to help you better understand and correctly use the analyzer. Read this manual carefully and make sure you thoroughly understand its contents before using the analyzer.
Refer to this manual whenever you encounter problems or unclear points.
The analyzer is referred to in this manual as AT-5600, AT-5610, AT-5620.

Product Name: AyoTes Fully Automated HPLC Analyzer
Model: AT-5600, AT-5610, AT-5620
Scope of application: This instrument is intended for the In Vitro quantitative detection of HbA1c content (%) and material content (mmol /mol).
Shelf Life: 5 years
Manufacturing Date: See product label

Manufacturer：Labnovation Technologies Inc.
Manufacturer's Address:102, 602, 702, 802, Sheng Hui Hongxing Chuangzhi Square, Tongren Road, Tianliao Community, Yutang Street, Guangming District, 518107 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Website: http://www.labnovation.com
After Service Provider: Labnovation Technologies Inc.
After Service Address: 102, 602, 702, 802, Sheng Hui Hongxing Chuangzhi Square, Tongren Road, Tianliao Community, Yutang Street, Guangming District, 518107 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Tel: 0755-86368328 Fax：0755-86667520-805
Release Date: November 23, 2023
Version Number: A3

Intellectual Property

Declaration

Labnovation shall not provide warranty of any kind for this information, including (but not limited to) any implied merchantability or suitability warranties for certain purposes.

The Fully Automated HbA1c Analyzer described in this manual is subject to continuous improvement and perfection. Labnovation shall reserve the right to modify the device structures, reagent types, and technical details at any time.

Labnovation shall not bear any responsibility for result errors, instrument failures, or other problems caused by the user's failure to adhere to the procedures and warnings.

Labnovation is only considered responsible for the safety, reliability, and performance of this instrument under the conditions as follows:

- All installation operations, modifications, and repairs of this product are conducted by the Labnovation authorized professionals;
- The instrument is operated in accordance with the instructions in the operation manual;
- The relevant electrical installation shall comply with the applicable national requirements.

Labnovation shall not be responsible for the safety, reliability, and performance of the product if any of the following occurs:

- The product has reached the expiration date;
- Any assembly has been removed and/or re-commissioned;
- The product has not been operated in accordance with the operation manual.

Warranty

Scope of the Free Maintenance Services:

Free service is provided for any devices that are within the scope specified by the Labnovation.

Scope of Paid Services

Labnovation offers paid service for any devices that are beyond the scope specified by the Labnovation warranty rules.

Even during the warranty period, Labnovation shall only offer paid services for the products that are in need of repair due to the following causes:

- Improper use;
- Human caused damage;
- Replacement of parts unapproved by Labnovation;
- Repair of the instrument by personnel unauthorized by Labnovation;
- Usage of grid voltage beyond the specified range of the device;
- Force majeure natural disasters.

Labnovation shall bear responsibility for the safety, reliability, and performance of this instrument only under the conditions as follows:

Warning:

- This instrument is only intended for use by the physicians or qualified professionals trained by Labnovation or Labnovation's agents.
- This instrument can only carry out the instrument inspection service or any spare parts service provided by Labnovation or Labnovation's agents.
- It is important for the hospital or organization that uses this instrument to execute a reasonable service/maintenance plan. Neglect of service/maintenance may cause instrument breakdown or injury to human health.
- If any problem occurs, please perform the troubleshooting procedures in accordance with Chapter 13. If the problem still exists, please contact the Labnovation service department for help.
- Please make sure that this analyzer is used under the conditions specified in the instruction manual. The incorrect instruction may result in abnormal operation of the analyzer, unreliable measuring results, and possibly cause damage to parts of the analyzer or even personal injury.
- The instrument should be inspected strictly before unpacking. In order to avoid breakage in transportation, the instrument is carefully packaged. When receiving the analyzer, please carefully check if there is physical damage in the packaging. If the packaging is damaged, please contact our services personnel.
- Please always keep it upward when unloading and delivering the instrument. Never tilt or roll the instrument. The foam inside the box can prevent shock to a certain extent during the handling of the instrument. Minimize the vibration during handling. After handling, perform checks and debugging.
- Do not use the device in close proximity to any sources of strong electromagnetic interference.
- Make sure the analyzer is properly grounded before switch on power.

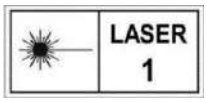
Note:

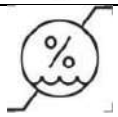
This user manual is intended for the following professionals:

- Personnel for daily operation of the system.
- Personnel for system maintenance and troubleshooting procedures.
- Personnel who learn system operation.

Symbols

The analyzer, reagent, quality control or calibration products may have the following symbols.

Symbols	Meaning
	Caution. To indicate that caution is necessary when operating the device or control close to where the symbol is placed. To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Biological risks. Indicates that there are potential biological risks associated with the medical device.
	To signify a general warning. Note that readers are advised to refer to the instruction manual in order to obtain important information related to safety.
	To warn of a sharp element. Taking care to avoid injury from sharp elements.
	To warn of a closing motion of mechanical parts of equipment. Taking care to avoid injury to hands when in the vicinity of equipment with closing mechanical parts.
	To warn of a biological hazard. Taking care to avoid exposure to a biological hazard.
	Caution, risk of electric shock.
	Class 1 Laser product.
	Universal Serial Bus (USB), port/plug To indicate that the device is plugged into a USB port or is compatible with a USB port.
	Computer network To indicate the connecting terminals of the computer network
	Stand-by To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption.
	"ON" (power) To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.
	"OFF" (power) To indicate disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.
	Protective earth; protective ground. To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
	Alternating current (AC). To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.

	In vitro diagnostic medical devices. Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Use-by-date Indicates the date after which the medical device is not to be used.
	Serial number Indicates the manufacturer's serial number so that the medical device can be identified.
	Date of manufacture. Indicates the date when the medical device was manufactured.
	Manufacturer. Indicates the medical device manufacturer.
	Importer Indicates the entity importing the medical device into the locale.
	Catalogue number. Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Temperature limitation. Indicates the range of temperature to which the medical device can be safely exposed.
	Humidity limitation. Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Consult instructions for use or consult electronic instructions for use. Indicates the need for the user to consult the instructions for use.
	Unique device identifier Indicates a carrier that contains unique device identifier information.
	Disposal in accordance with Directive 2002/96/EC （WEEE）
	Keep dry. Indicates a medical device that needs to be protected from moisture.

	Keep away from sunlight. Indicates a medical device that needs protection from light sources.
	Stacking limit by number. To indicate that the items shall not be vertically stacked beyond the specified specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
	This way up To indicate correct upright position of the transport package.
	FRAGILE To indicate that the contents of the transport package are fragile and the package shall be handled with care.

Table of Contents

Chapter 1 Brief Introduction

1.1 Intended use

AyoTes Fully Automated HPLC Analyzer is intended to use in conjunction with suitable reagents for the in vitro quantitative determination of the percentage (%) and substance content (mmol/mol) of glycosylated hemoglobin (HbA1c) in human blood. It is a fully automatic analyzer for the determination of glycated hemoglobin (HbA1c) in blood by liquid chromatography for all ages people.

This product is used in conjunction with glycated hemoglobin test reagent kits, glycated hemoglobin calibrator and glycated hemoglobin control produced by our company. It can be used for the determination of HbA1c in hospital laboratory departments and professional laboratories, etc., or used by trained and qualified medical personnel or under the direct supervision of trained and qualified medical personnel.

1.2 Principle

Using high performance liquid chromatography (HPLC), the stationary phase used is a weakly acidic cation exchanger. Glycosylation of hemoglobin will result in the loss of cations on the surface of hemoglobin without being charged, and non-glycosylated hemoglobin has a positive charge. According to the different charged properties of hemoglobin, eluents with different pH values and ionic strengths are used sequentially, and several hemoglobin components (HbA1a, HbA1b, HbF, HbA0, HbA2) including HbA1c are separated by high performance liquid chromatography. Each component is detected by a single-wavelength colorimeter, and the detected data is processed by a computer to calculate the percentage content of HbA1c in the total hemoglobin.

AT-5600, AT-5610, AT-5620 are fully automated HbA1c analyzers based on HPLC. They have two test modes: fast mode and variant mode. Automatic quantitative detection of HbA1c in fast mode; In variant mode, HbA1c and isolated variant hemoglobin (HbE, HbA2, HbD, HbS, HbC) are automatically detected. The test speed of the two modes is different, and the variation mode needs to add the matching eluent C.

1.3 Basic Parameters

Test modes: Fast mode and Variant mode.

Test Speed: Fast mode:90second/test

Variant mode:150 second/test

Autoloader Capacity: 20 tubes

Sample Type: Whole blood and pre-dilute blood.

Blood sampling volume: The sampling volume of whole blood samples shall not be less than 1.5ml. The sampling volume of pre-diluted samples shall not be less than 500ul. The EDTA-2K/3K and EDTA-2Na is the recommended anticoagulant.

Sample container: Whole blood/pre-diluted mode:(12.3/15 mm diameter) x (75 to 100 meter length)

Test specimen volume: 5ul in whole blood mode; 500ul in pre-dilution mode.

Dilution ratio (pre-dilution mode): Whole blood: Hemolysis = 1:300 (10ul Whole blood + 3000ul Hemolysis).

Analysis wavelength: 420nm.

1.4 Performance Parameters

Reporting unit: Glycosylated hemoglobin (HbA1c) is reported in NGSP (%) and IFCC units (mmol/mol).

Accuracy: The accuracy is tested with reference materials as samples, and the relative deviation of the test results should be within ±5%.

Repeatability: For samples with a test concentration of 4%-6%, the sample coefficient of variation (CV) of the test

results is not greater than 2.0%.

Linear range: Within the range of 3%-18% of glycosylated hemoglobin, within the range of 0%-15% of HbF, the linear correlation coefficient R value of the test results should not be less than 0.9900.

Stability: Within 8 hours after the analyzer is turned on and stabilized, the same normal sample is tested, and the relative deviation of the test results is not more than ±3.0%.

Carrying pollution: The carrying pollution rate of the analyzer should not be greater than 2.0%.

Basic function: Provides Chinese report and abnormal alarm.

The temperature accuracy and fluctuation of the chromatography column module: The temperature is within ±1°C of the set value, and the fluctuation is not more than 0.8°C.

1.5 Product Specifications

Equipment type of tested product: Laboratory

Equipment category: Fixed

Overvoltage category: Class II

Environmental conditions: Standard

Connection to grid power: Detachable power cord

Power supply type: AC

Input power: 300VA

Operating conditions: Continuous

Pollution level: Pollution level 2

Net weight: 28kg

Size: 378(L)×380(W)×510(H)mm

Storage environment: Temperature: -20℃～55℃; Humidity: 10%～93%; Atmospheric pressure: 75kPa～106kPa.

1.6 Reagents and Consumables

The analyzer is recommended to be used in conjunction with the AyoTes HPLC HbA1c Test Reagent Kit, AyoTes HPLC HbA1c control kit, AyoTes HPLC HbA1c calibrator kit, which produced by our company, which includes the following components:

AyoTes HPLC HbA1c Test Reagent Kit (high performance liquid chromatography) Specification: 100Tests, 200Tests, 300Tests, 400Tests, 600 Tests, 800Tests, 1200Tests, 1500Tests, 3000Tests.

Eluent A/Eluent B/Eluent C: Adjusts the pH of the solution for the elution of glycosylated hemoglobin and non-glycated hemoglobin.

Hemolysis Reagent: Used to dissolve red blood cells and release hemoglobin.

Chromatography column: Used for separation and elution of glycosylated hemoglobin and non-glycated hemoglobin.

Filter: Used to initially filter the sample after hemolysis.

Paper Rolls: Prints a report of the test results.

Usually, in order to maximize the utilization rate of reagents and avoid waste, it is recommended to choose 600T as the standard configuration as follows:

Reagents	QTY	Number of tests/Capacity	Total number of tests/Capacity
Eluent A	2 PCS	300T	600T
Eluent B	2 PCS	300T	600T
Hemolysis H	2 PCS	300T	600T
Hemolysis	1 PCS	100ml	100ml
Filter	1 PCS	600T	600T

Chromatography column	1 PCS	3000T	3000T

The Eluent C is optional reagent in Variant mode.

Reagents	QTY	Number of tests/Capacity	Total number of tests/Capacity
Eluent C	2 PCS	300T	600T

AyoTes HPLC HbA1c Control Kit: Level 1, Level 2.

Name	Spec.	Spec.	Spec.	Spec.	Spec.
HbA1c Control Level 1	0.1mL x 3	0.1mL x 4	0.1mL x 6	0.5mL x 6	1mL x6
HbA1c Control Level 2	0.1mL x 3	0.1mL x 4	0.1mL x 6	0.5mL x 6	1mL x6

Remark: The standard configuration is HbA1c Control Level 1: 0.1mL x 3, HbA1c Control Level 2: 0.1mL x 3.

AyoTes HPLC HbA1c Calibrator Kit: Level 1, Level 2.

Name	Spec.	Spec.	Spec.	Spec.	Spec.	Spec.
HbA1c Calibrator Level 1	0.1mL x 3	0.1mL x 4	0.1mL x 6	0.5mL x 2	0.5mL x 4	0.5mL x 6
HbA1c Calibrator Level 2	0.1mL x 3	0.1mL x 4	0.1mL x 6	0.5mL x 2	0.5mL x 4	0.5mL x 6

Remark: The standard configuration is HbA1c Calibrator Level 1: 0.1mL x 3, HbA1c Calibrator Level 2: 0.1mL x 3.

Caution:

You must use the specialized column, Hemolysis, Eluent, control, and calibrator dedicated to this system. Let us remind you that it is not our responsibility if you use any other column or reagent than ours on the system.

1.7 Contraindication

None

1.8 Accessories

No.	Name	QTY	Note
1	Test-tube tray	2 PCS	/
2	Waste liquid tube	1 Root	1*3m
3	Power cord	1 PCS	GB/EU/UK/AU
4	Fuse wire	2 PCS	/
5	Bag for liquid waste	1 PCS	5L
6	Operation Manual	1 PCS	/
7	Certificate of conformity	1 PCS	/
8	Packing list	1 PCS	/
9	Quick User Guide	1 PCS	/
10	Barcode scanner	1 PCS	optional

Chapter 2 System Description

This analyzer is a fully automated instrument used to analyze glycosylated hemoglobin. It has the characteristics of small sample amount and simple operation. It is suitable for the detection of glycosylated hemoglobin in medical institutions.

2.1 Main Parts

The analyzer consists of an auto sample injection module, a liquid chromatography separation module, a colorimetric detection and control module, a barcode scanning module, and a display printing module.

2.1.1 Product Overview

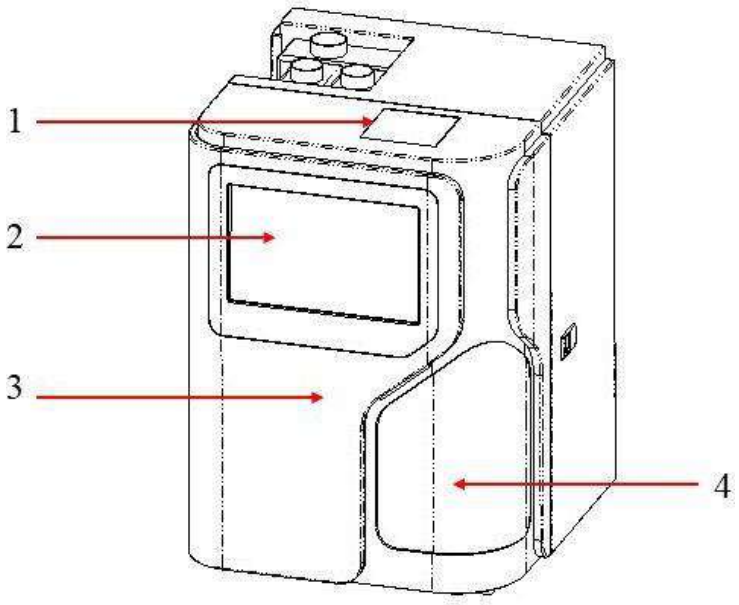


Figure 2-1

No.	Part	Function
1	Thermal printer	Used to print analysis results and graphics.
2	Touch screen	Touch the LCD screen to display the system operation interface. The operation of the instrument is performed on this screen.
3	Left door	After opening the door, you can replace consumables such as chromatography column.
4	Sample door	Samples can be placed after opening.

Open the front cover of the instrument, you can see the following parts:

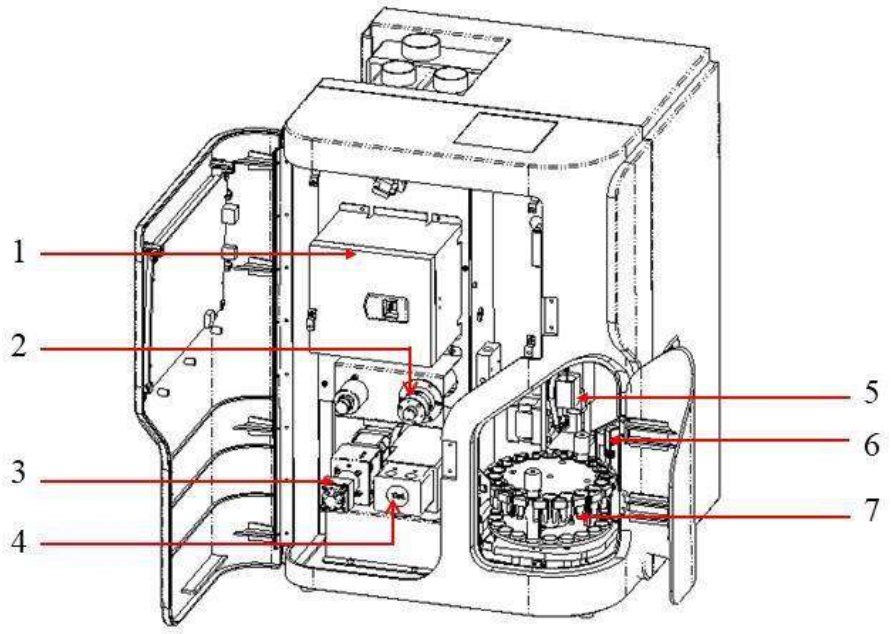


Figure 2-2

No.	Part	Function
1	Insulation box	Contains chromatography column module.
2	Optical component	Contains a 420nm colorimetric detection component, which is used to monitor the concentration change of the sample passing through the chromatography.
3	Six-way valve	Perform sample elution and switch sample loading.
4	High-pressure pump	A high-pressure pump with double plungers in series is used to provide power for elution.
5	Piercing component	Puncture and aspirate samples under program control.
6	Barcode scanner	Use laser to scan barcode on blood collection tube.
7	Sample tray	Place the samples and supports automatic sampling, and up to 20 samples at the same time.

Caution:

- Do not look directly at the barcode scanner to prevent laser damage to your eyes. If you need to check the barcode scanner while it is turned on due to maintenance or other reasons, please wear anti-laser glasses.
- The user's clothes, hair and hands must be kept at a certain distance from the puncture assembly, the sampling tray assembly and other moving components, and must not be touched to prevent being pinched or stabbed by the moving parts.

2.1.2 Rear view of the analyzer

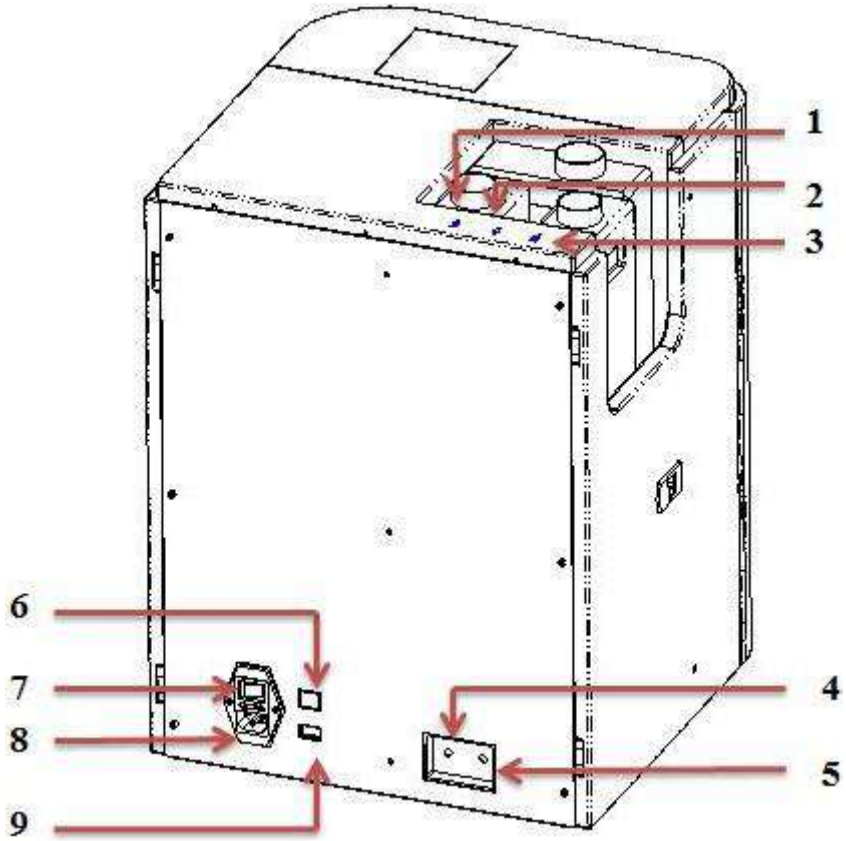


Figure 2-3

No.	Part	Function
1	Eluent C interface	Eluent C input
2	Eluent A interface	Eluent A input
3	Eluent B interface	Eluent B input
4	Tube interface for waste liquid	It is used to discharge waste liquid. One end of this tube should be connected to the analyzer, and the other end should be connected to a suitable waste liquid container.
5	Interface for Hemolysis reagent	Hemolysis reagent input.
6	Network connector	Used to connect the network cable and communicate with LIS.
7	Main power switch	When the top of the switch key(“ | ”) is pressed down, it is in the “ON” status.
8	Power connector	Connects the power cord.
9	USB connector	Used for software upgrade.

2.2 Model specifications

There are AT-5600, AT-5610 and AT-5620. The difference between the three is the difference in the color of the touch screen bezel, of which AT-5600 touch screen bezel color is black, AT-5600 touch screen bezel color is gray, AT-5620 touch screen bezel color is green, the other specifications are all exactly the same.

2.3 Software Interface and Function

2.3.1 Main Window

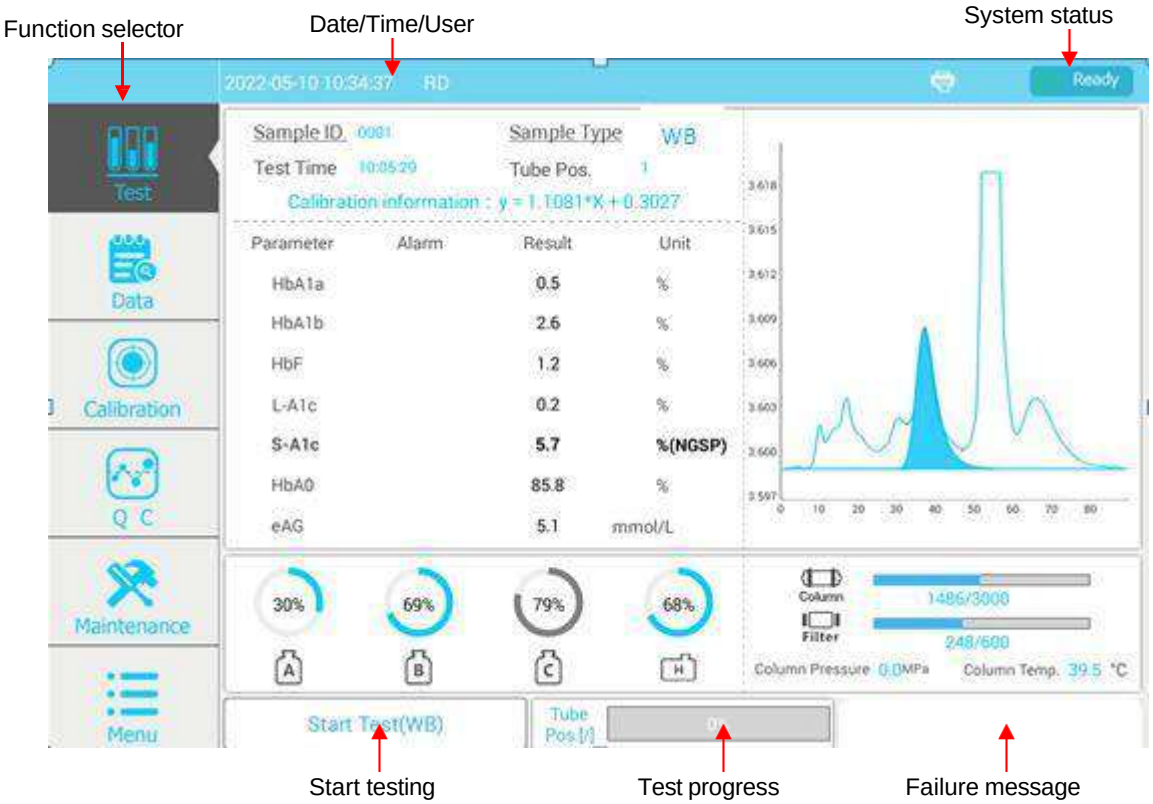


Figure 2-5a

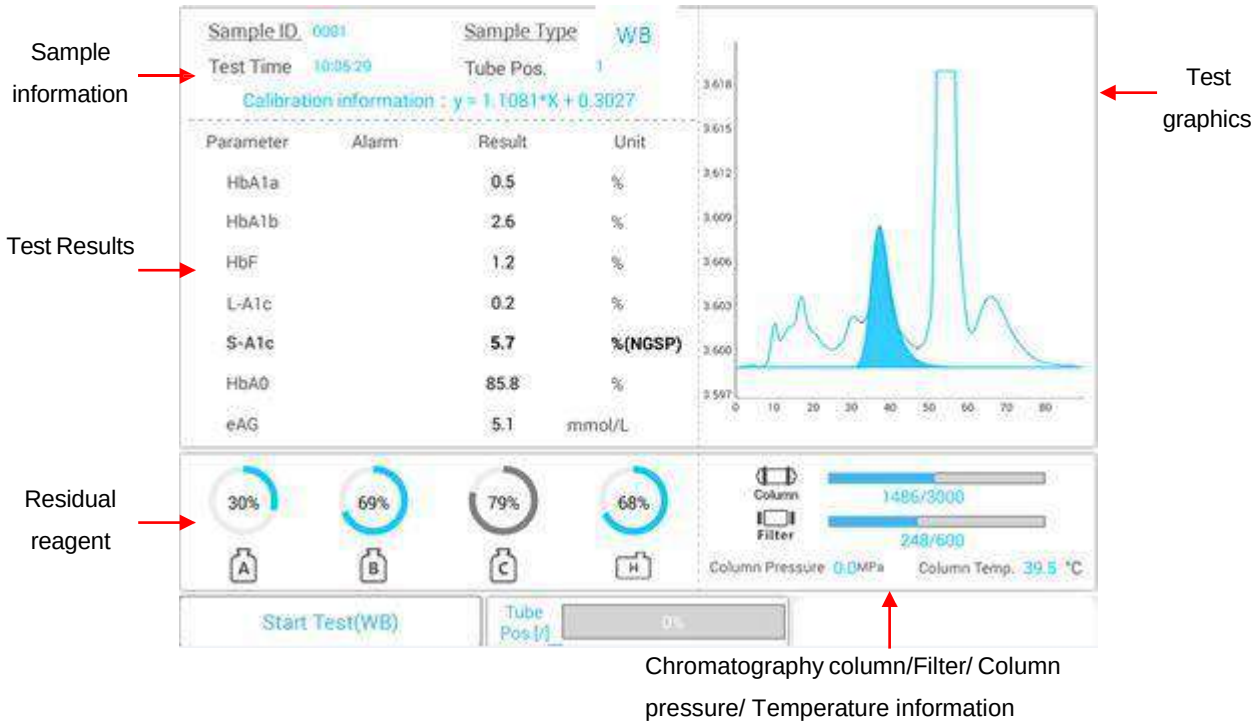


Figure 2-5b

2.3.2 Function Description

Click the left button on the main interface to enter the corresponding interface to perform the corresponding operation.

NO.	Main menu	Submenu	Function
1	Test	/	Enter the running interface and start the analyzer for sample testing.
2	Data	/	Enter the query interface to query the test results of the sample.
3	Calibration	/	Enter the calibration interface to calibrate the analyzer.
4	QC	/	Enter the quality control interface and set the quality control level, concentration, and batch number， and query quality control statistics.
5	Maintenance	/	Enter the maintenance interface to replace the eluent reagent and chromatography column.
6	Menu	Debugging	Enter the debugging interface to debug the bottom parameters of the analyzer.
		Capability	Enter the performance interface and perform repeatability, linearity, carryover, and aging tests.

		Settings	Enter the setting interface, set the date, authority, communication, language, printing and other parameters.
		Log	Display fault alarm information and usage log information.
		Logout	Enter the parameter management interface to export/import system parameters.
		Shutdown	The analyzer returns to the login interface.

Chapter 3 Installation

Warning:

Unpacking or installation by personnel who are not authorized or trained by Labnovation may cause personal injury or damage to the system. Persons who are not authorized by Labnovation are not allowed to unpack or install this product.

3.1 Installation Conditions

The analyzer needs to be installed under the following conditions:

1. Power supply: 100-240V～, 50/60Hz
2. Ambient temperature: 10℃～30℃
3. Relative humidity: ≤80%
4. Atmospheric pressure: 80kPa～106kPa
5. Overvoltage category: Class II
6. Pollution degree: Level 2
7. Input power: 300VA
8. Altitude: below 2000 meters

Due to the needs of installation and maintenance, do not place the analyzer in a location where it is difficult to operate the disconnecting unit.

Warning:

- The analyzer must be used under good grounding conditions.
- The power cord uses a three-phase connector. When the power socket is provided with a grounding function, just plug the plug into the socket.

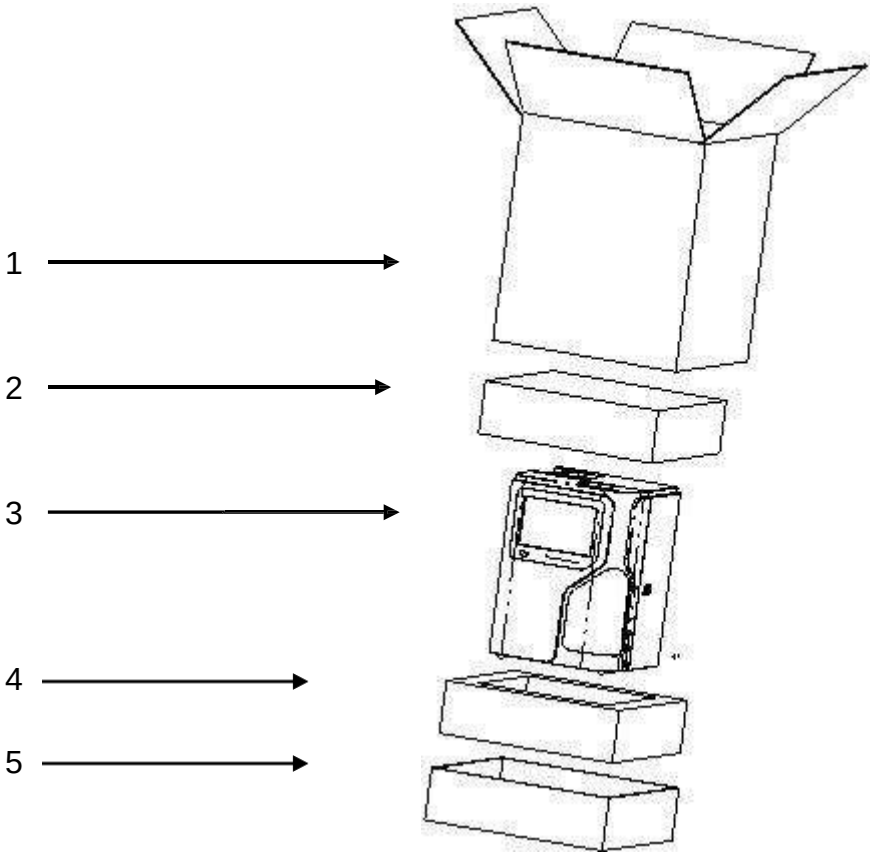
Caution:

- Please avoid using power strips. The use of power strips may cause additional electrical interference and lead to erroneous analysis results. Please choose a location close to the power socket to install the analyzer.
- Please use the included power cord. Using other power cords may damage the analyzer or cause erroneous analysis results.

Caution:

- Choose a location that is not exposed to direct sunlight and is relatively dust-free.
- There should be a horizontally stable table, and there should be no strong magnetic field and vibration within 1 meter. The desktop can bear a weight of at least 100kg.
- Considering the problem of heat dissipation, a clean space of at least 10cm should be provided behind the analyzer to allow air convection to dissipate heat.
- Due to the needs of maintenance and repair, try to provide a suitable space, and provide at least 30cm of space on the left and right sides, upper part and front of the analyzer.

3.2 Unpacking



1	Packaging box
2	Upper foam
3	Main unit
4	Lower foam
5	Base of carton

Remove the package as shown in the figure, check the main unit and accessories in the packing box according to the packing list, if there is any defect, please contact your dealer.

Caution:

- In order to avoid the impact of collision on the instrument during transportation, we have packaged the instrument professionally and carefully. When the analyzer arrives, please check its packaging carefully to observe whether it has physical damage. If any, please contact your dealer in time.
- The packaging must be opened by a qualified engineer approved by Labnovation. Do not open the packaging by yourself, otherwise the warranty terms of the instrument will not be protected.
- In order to prevent damage to the analyzer or accidents during moving or transportation, two people should cooperate to complete the work. Lift the machine from the special handle on the outer packaging and keep the machine upright and put down it carefully.

3.3 Tubing Connection and Reagents Installation

Insert the tube labeled A into the eluent A reagent bottle, the tube labeled B into the eluent B reagent bottle, and the tube labeled C into the eluent C reagent bottle, and then tighten the cap, and finally put the reagent bottles at the designated position on the upper right side of the analyzer.

At the back of the analyzer, insert the hemolysis agent tube into the interface marked H, tighten the cap and place it on the same level tabletop of the analyzer. Connect one end of the waste tube to the interface marked W on the back of the analyzer, and insert the waste bottle at the other end, and place the waste bottle on the ground.

Caution:

- The interfaces on the back of the analyzer are: Mark W for waste liquid, mark H for hemolysis agent; upper right of the analyzer: mark A for eluent A, mark B for eluent B, and mark C for eluent C.
- The hemolysis agent and eluent used in the analyzer must be specified by the manufacturer. If other unspecified reagents are used, the manufacturer does not assume any risks and consequences arising therefrom.
- Please dispose of waste in accordance with relevant local regulations.
- Make sure to use the reagents and chromatography columns specified by the manufacturer within the validity period.
- Carefully check the interface identification of the inlet tube and the waste tube to ensure that the reagents are installed correctly.

3.4 Chromatography Column Installation

The analyzer needs to be in an idle status when replacing the chromatography column.

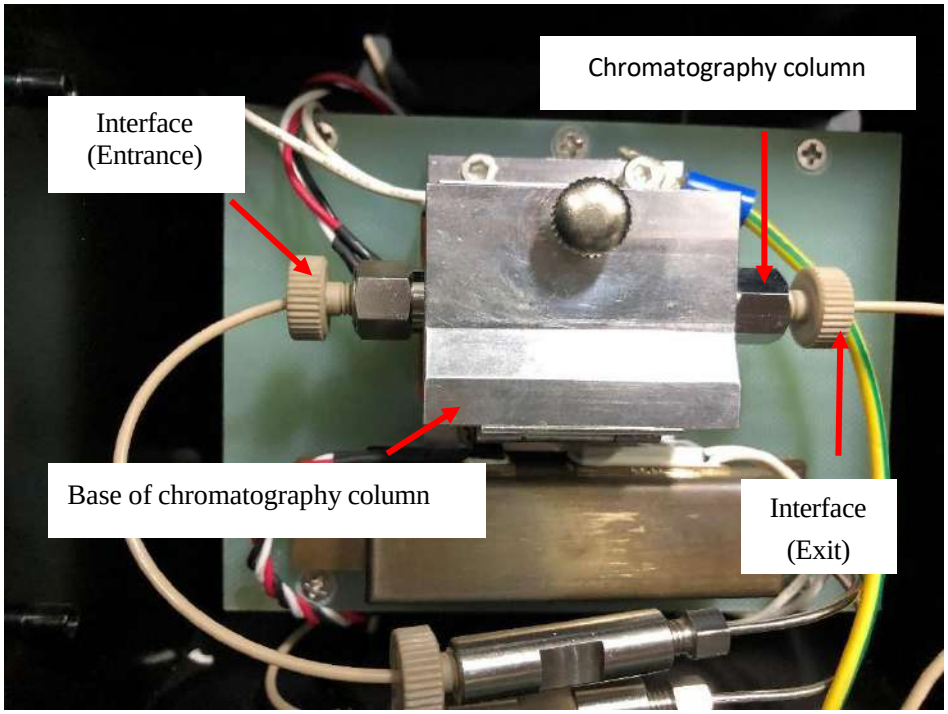


Figure 3-1 Temperature control box for chromatography column

The installation steps for chromatography column:

1.	Open the left front door of the analyzer, press the front lock of the temperature control box to the left and pull the temperature control box outward to expose the chromatography column (Figure 3-1).
2.	Take the dummy-column in the box out of the slot in the base of chromatography column.
3.	Loosen the connectors on the left and right sides of the dummy-column in turn, and remove the dummy-column.

4.	Loosen the plugs at both ends of the new chromatography column (Figure 3-2), first extend the tubes connecting the outlet and inlet of the chromatography column by more than 3mm (Figure 3-3), and then respectively connect the tubes to the inlet and outlet of chromatography column by hand.

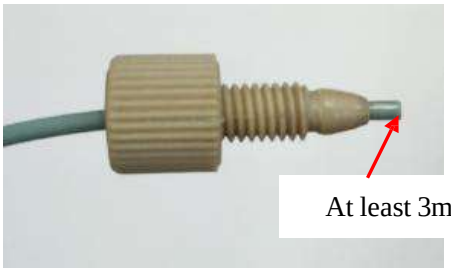


Figure 3-2 Remove the plus of new chromatography column Figure 3-3 Extend the tube

5.	After connecting the tubes, install the chromatography column back into its base, and then cover the temperature control box of chromatography column.

Caution:

- The installation direction of the chromatography column must not be reversed, and the liquid flow direction must be consistent with the column arrow.
- The removed dummy-column and plug need to be kept for future use.

3.5 Paper Roll Installation

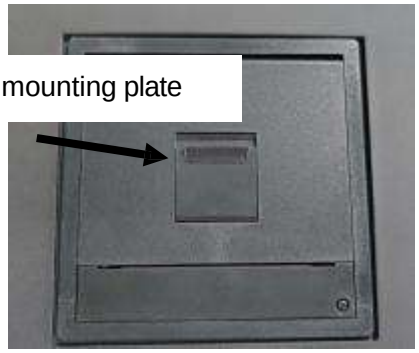


Figure 3-4 Figure 3-5

The installation steps for paper roll:

1.	Use your fingers to pull up the buckle mounting plate on the printer cover (as shown in Figure 3-4) to open the printer cover.
2.	Open the cover of the printer and put in the paper roll.
3.	Pull up a small part from under the paper roll and extend it out of the printer.
4.	Align both ends of the paper roll with the printer (Figure 3-5), and then press the printer cover down.

Caution:

- Paper roll width: 56mm.
- Do not open the cover of the printer while the analyzer is working.

3.6 Power Connection

1. Connect the power cord to the power socket. The socket should be a qualified product to ensure electrical safety.
2. Turn on the main switch of the power socket.
3. Press the switch key on the back of the analyzer to the < | > position.
4. The analyzer will initialize after it is turned on. When the status bar shows idle, you can start testing.

Caution:

- Reliable grounded power supply should be used, and a dedicated socket should be used separately.

3.7 Reagent Priming

1. Turn on the analyzer and log in as an administrator to enter the main interface (see section 4.3 for details), reagent H, eluent A, the eluent B, and the eluent C (variant mode) are primed in sequence. The specific prime process is as follows:

- Low-pressure hemolysis reagent prime: Click "Maintenance" > "Low-pressure priming" to perform hemolysis. The instrument automatically executes the prime procedure for about 100 seconds. After the prime is completed, click "Finish" to exit. .Figure 3-6 and 3-7

Figure 3-6 Prime interface

Figure 3-7 Low-pressure priming

2. High-pressure degassing (high-pressure priming): Click "High-pressure priming" on the maintenance interface > unscrew the high-pressure valve counterclockwise, click "Next" to perform high-pressure pump degassing > after degassing is completed, tighten the high-pressure valve clockwise, click "Next step", perform high-pressure perfusion> After the high-pressure priming is completed, the system will automatically perform a self-test. As shown in Figure 3-9, 3-10, 3-11, 3-12, 3-13.

When installing the instrument for the first time, in order to smoothly discharge the air bubbles of the high-pressure pump so that the Eluent ABC in the high-pressure part of the liquid circuit can be filled smoothly; please open the front door and find the high-pressure valve as shown in Figure 3-8.

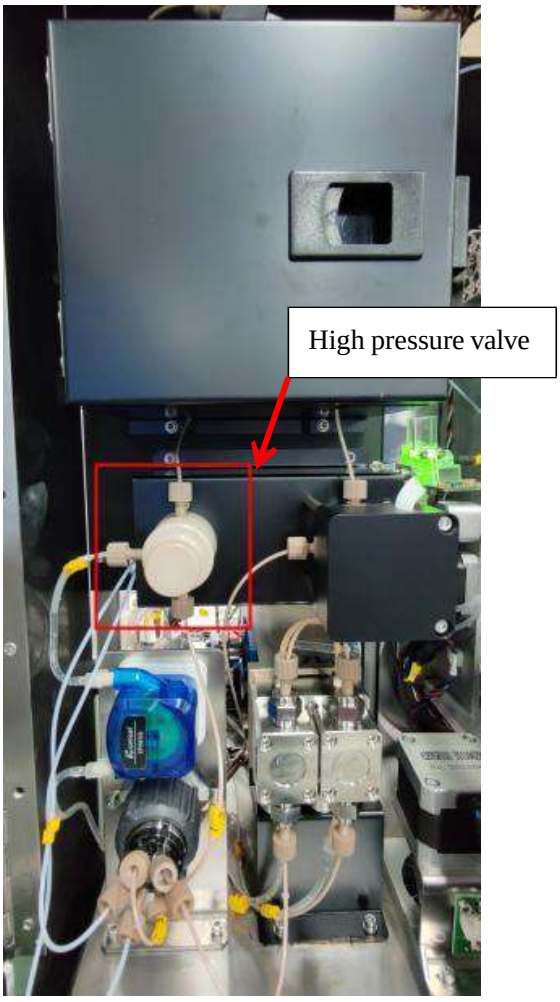


Figure 3-8 High pressure valve

Then, on the maintenance interface, click "High pressure de-bubbles" (Fig. 3-9), and follow the instructions on the software interface to complete the process of air removal by the high pressure pump.

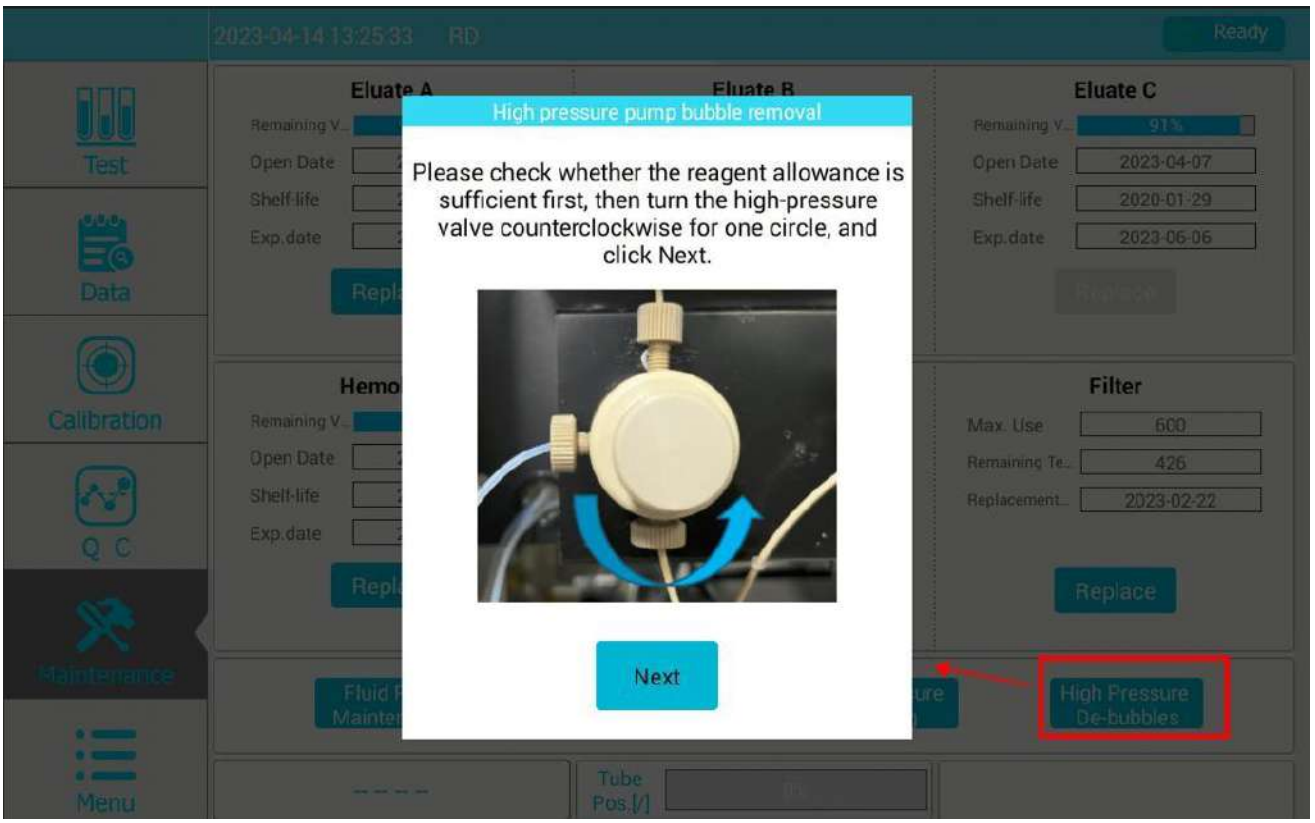


Figure 3-9 Unscrew the high pressure valve counterclockwise

After unscrewing the high-pressure valve counterclockwise for 3 turns, click "Next", and the instrument will start to exhaust air bubbles.

Fast mode:120s, variant mode: 180s.

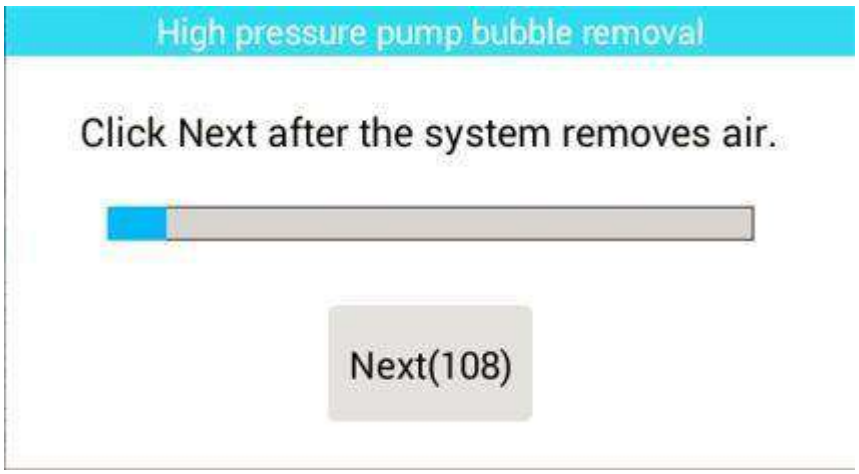


Figure 3-10 Countdown of high pressure pump bubble removal

After exhausting air bubbles, tighten the high-pressure valve clockwise, and then click "Next", the system will perform high-pressure liquid injection, as shown in Figure 3-11, 3-12

Fast mode:120s, variant mode: 180s.

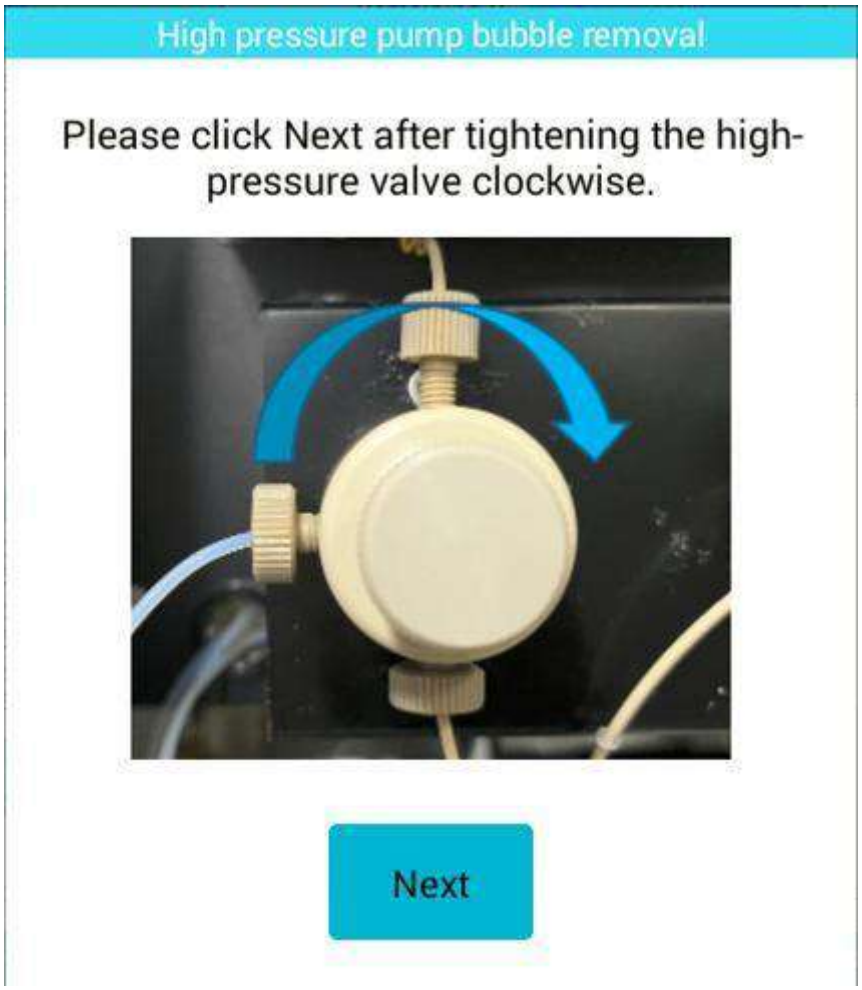


Figure 3-11 Tighten the high pressure valve clockwise

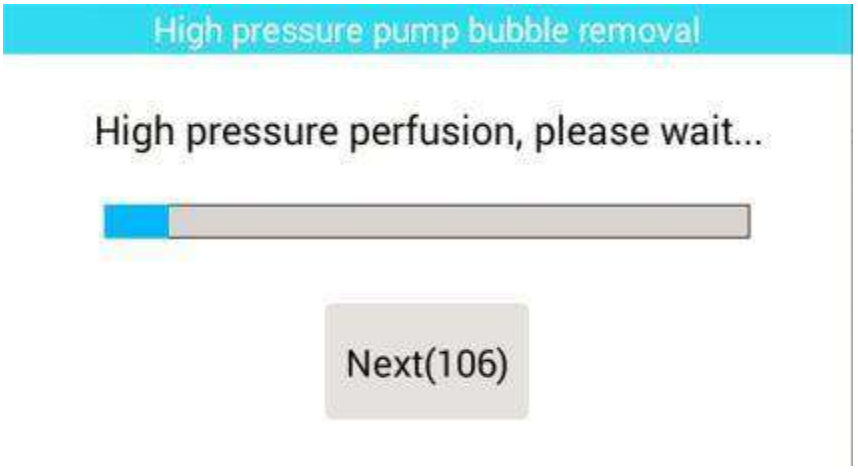


Figure 3-12 High pressure perfusion countdown

After the high pressure perfusion is finished, the system automatically maintains the liquid circuit, as shown in Figure 3-13; if the self-test alarms that the pressure of the liquid circuit is too low, it means that the high-pressure pump air bubbles have not been completely discharged, and you need to click the "High pressure de-bubbles" button to re-enter air bubble removal process.

Figure 3-13 Fluid Path Maintenance

Note: 1. When the Eluent ABC is empty, the instrument will alarm and display that the pressure of the high-pressure pump is too low, and air bubbles need to be removed, click the red fault bar in the lower right corner of the screen, select the fault, and then click fault repair, the instrument will automatically jump to the interface shown in Figure 3-9 , and continue to follow the prompts.

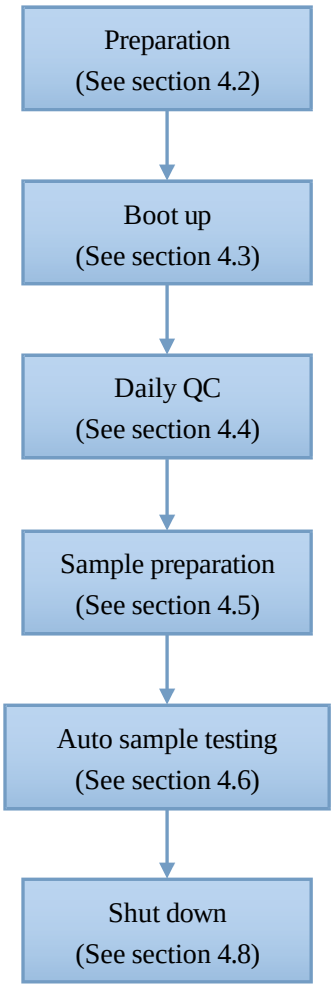
2. After the high-pressure pump removes air bubbles, the instrument will return to the idle state after the self-test is completed, and the sample analysis operation can be performed. It is recommended to prime for 3 minutes to replace different batches of reagents.

3. When installing the instrument for the first time, calibration and quality control are required. Please refer to Chapter 8 and Chapter 9 for calibration and quality control operations.

Chapter 4 Operation

Before operating this analyzer, please read the operation manual carefully to avoid malfunction or damage.
If the analyzer is used in a manner not specified by the manufacturer, the protection provided by the analyzer may be destroyed.

4.1 Operation Procedure

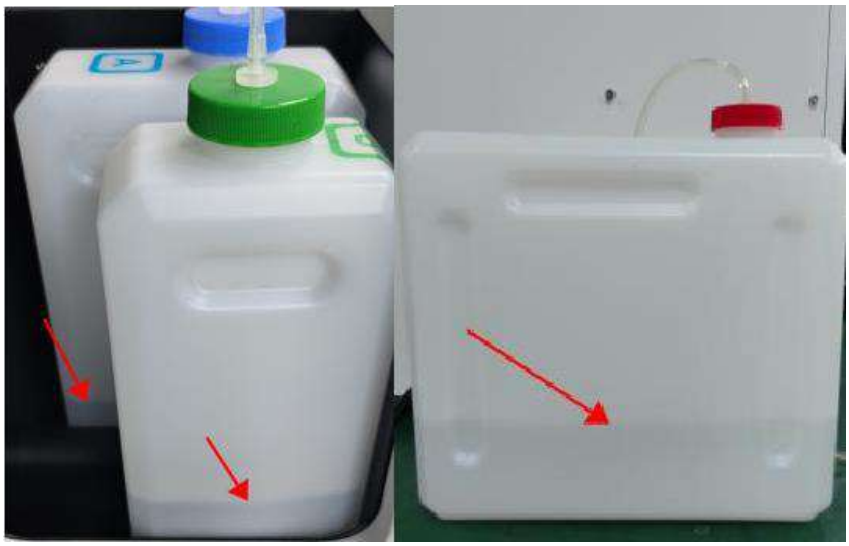


4.2 Preparation

Before turning on the analyzer, the operator must check the following requirements to ensure that the system is ready.

(1) Check the remaining amount of reagents

Check whether the remaining amount of eluent A, eluent B, eluent C and hemolysis agent is sufficient.



Eluent A, Eluent B Hemolysis H

(2) Check the waste liquid barrel

Check whether the bag for liquid waste has been emptied before starting the analyzer every day.

Bag for liquid waste

(3) Check the liquid tubes and power supply

Check whether the tubes of reagent and waste liquid are bent and whether the connections are reliable.

Check the analyzer for fluid leakage.

Check whether the power plug of the analyzer is securely inserted into the power socket.

Power cord plug

(4) Check the printer

Check whether the paper roll is sufficient and whether it is installed in correct place. Install the paper roll, as shown in the figure. For detailed operation methods, see 3.5.

- Samples, quality control products, calibrators, chromatography columns, waste liquids, etc. are potentially biologically infectious. Operators should abide by safe operation regulations and wear protective equipment when touching related items in the laboratory.

Warning:

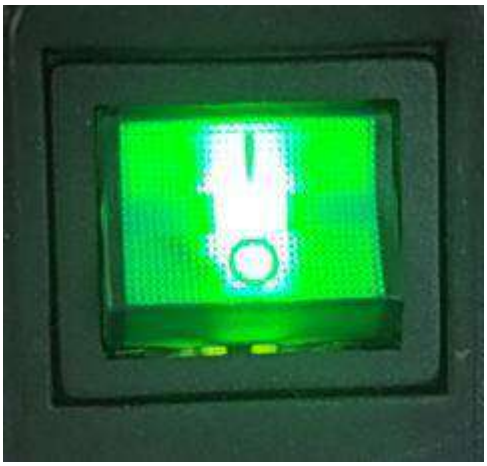
- Operators are obliged to comply with local regulations regarding the discharge and disposal of reagents, waste liquids, waste samples, consumables, etc.
- If you find any abnormal smell or smoke, please turn off the power immediately and unplug the power plug, otherwise it may cause fire, electric shock or other hazards.
- Do not touch the internal power cord of the analyzer, and keep your hands dry during operation to avoid electric shock.
- Before operating the system, be sure to check that all doors/covers/plates are closed, and make sure that they will not open or loosen during operation.
- Do not touch the moving parts, and clothes, hair, hands, etc. must be kept a certain distance from the moving parts.

Caution:

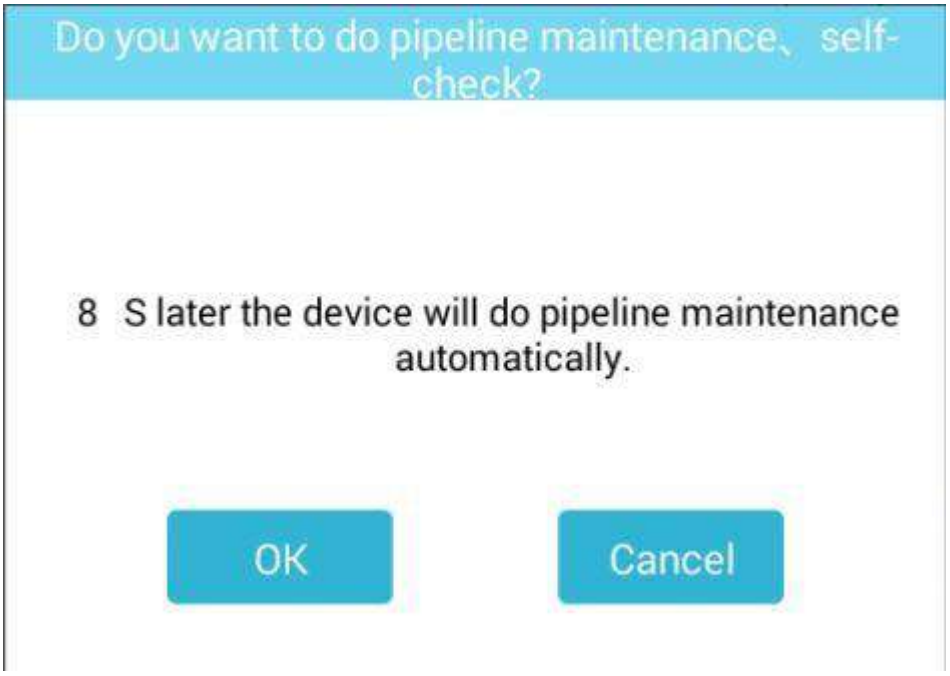
- Please use this analyzer strictly in accordance with the operation manual.
- Please avoid blood, liquid reagents, and any other metal materials from entering the analyzer, otherwise it may cause a short circuit and produce smoke.
- Do not damage the power cord, place heavy objects on it, or pull the power cord forcibly.
- When connecting peripheral equipment (such as a computer), please turn off the power first, otherwise it may cause a fire or electric shock.
- Please handle all alarms and fault messages in time.
- During the use of the analyzer, if any tubes or parts with liquids are found to be aged or worn, please stop using them immediately and contact the after-sales service engineer for inspection or replacement in time.

4.3 Boot up

The power switch is located on the back of the instrument. When the switch key (“ | ”) is pressed down, it is in the “ON” status. After the analyzer is turned on, the self-check will be performed first, and then you can choose whether to start cleaning. As shown in the figure:



Power switch



Whether to start cleaning

4.3.1 System login

After the initialization is completed, the dialog box shown in Figure 4-1 will pop up. After entering the user information, click "OK" to enter the main window.

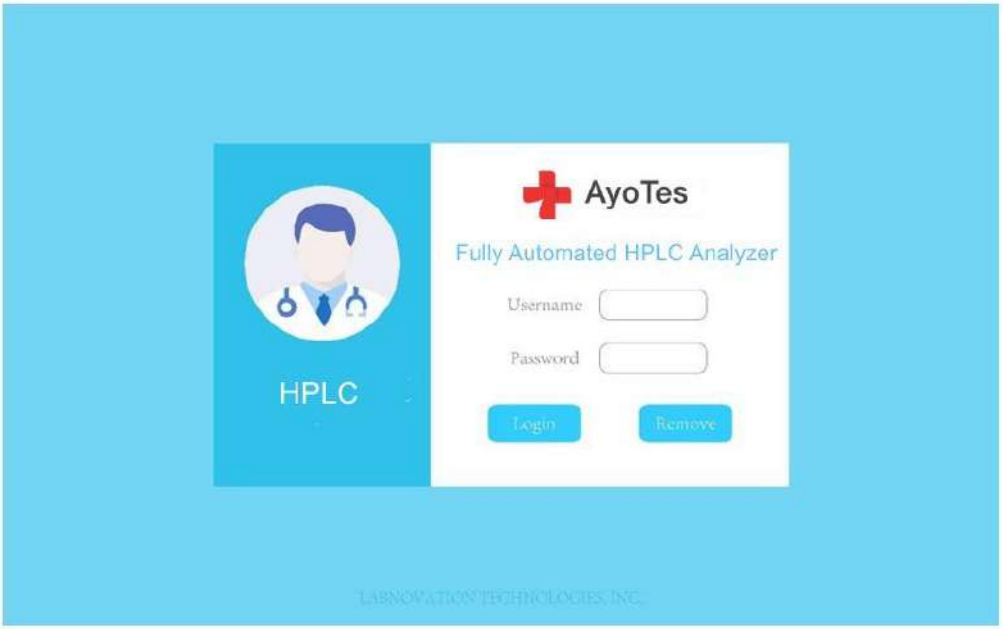
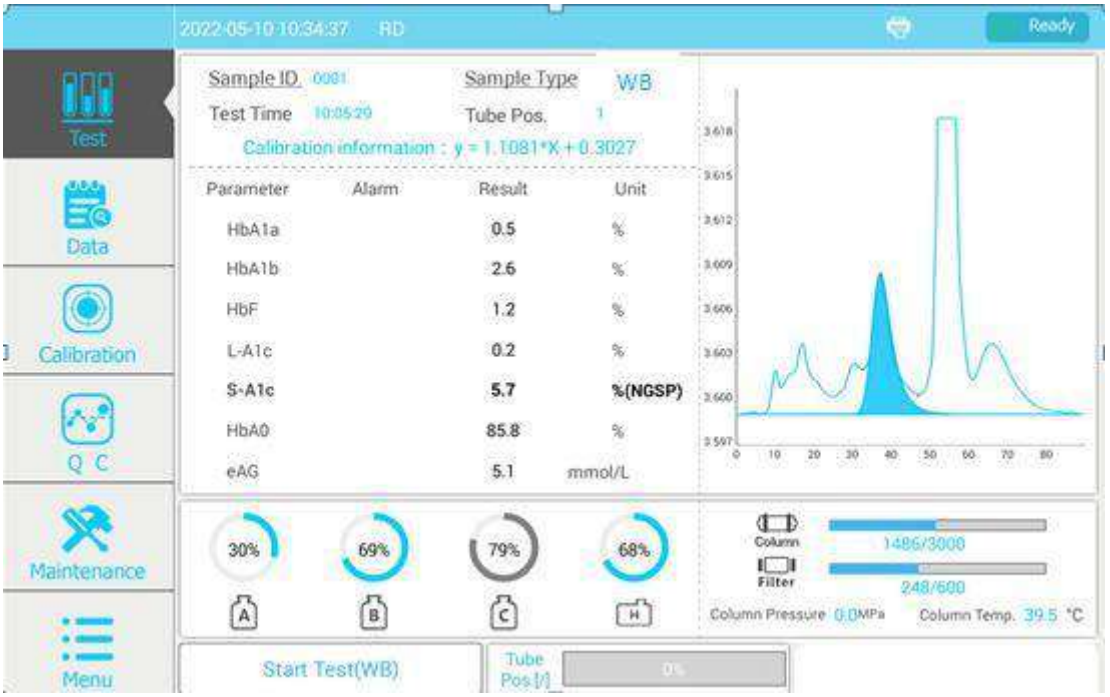


Figure 4-1



Main interface

Caution:

- It is necessary to perform self-check and start-up initialization at the first startup every day, otherwise the analyzer may malfunction and fail to test or the test results will be wrong.

4.4 Daily QC

Before sample testing, the analyzer needs to be subjected to quality control analysis daily to ensure that the analyzer obtains reliable results. See Chapter 7 for specific quality control analysis operation methods.

4.5 Samples Preparation

Samples include whole blood samples and pre-diluted samples.

The whole blood samples refer to the blood samples that has not been treated with a hemolysis agent, mainly refers to fresh blood samples from patients, which was collected using a vacuum blood collection tube containing EDTA-2K/3K and EDTA-2Na anticoagulant.

Pre-diluted samples are treated with hemolysis agents, including calibrators, quality control products, or pre-diluted forms of whole blood samples.

4.5.1 Barcode label

In order to read the barcode correctly, the barcode must be pasted correctly. The operator needs to paste the barcode according to the X range shown in Figure 4-3:

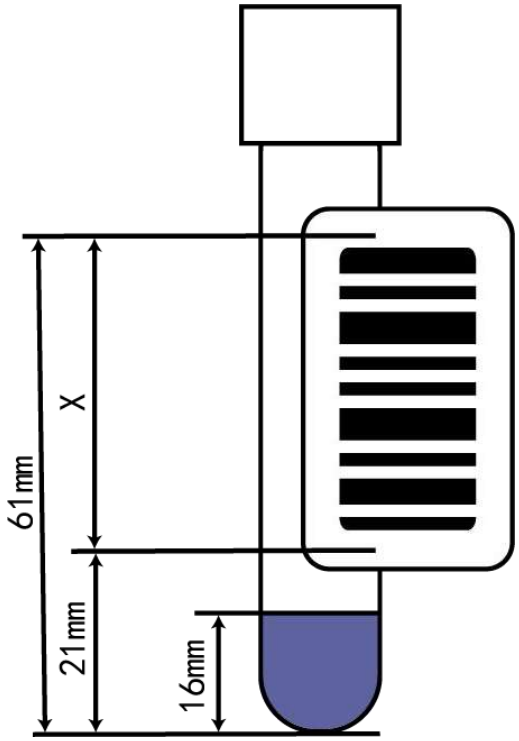


Figure 4-3

Caution:

When labeling, please pay attention to the following points:

- The barcode is affixed to the appropriate position as required.
- Do not paste multiple barcodes on the same test tube.
- The surface of the barcode must not be wrinkled.
- The barcode cannot be pasted obliquely.
- Make sure that the test tubes with the barcodes can be easily taken out or put back in the test-tube rack.

4.5.2 Processing of whole blood samples

1.	Use EDTA-2K/3K or EDTA-2Na (1.5~2.2mg/mL) anticoagulant vacuum blood collection tube to collect venous blood samples.

2.	Quickly mix the venous blood and anticoagulant thoroughly in the tube
3.	Put the blood collection tube into the sample holder and test on the analyzer.

Caution:

- Samples that have been refrigerated (2°C-8°C) should be placed at room temperature for at least 30 minutes before testing.
- To ensure the accuracy of the test results, please ensure that the volume of whole blood sample is not less than 1.5ml.
- If the whole blood sample has been placed for a period of time, it needs to be shaken before testing.

4.5.3 Processing of pre-diluted samples

1. Take 3000uL of hemolysis reagent into the empty blood collection tube of the pre-diluted sample.

2. Add 10uL of venous whole blood/finger blood/reconstituted quality control product/reconstituted calibrator and mix gently.

Caution:

- To ensure the accuracy of the test results, please ensure that the sample volume in the pre-dilution mode is not less than 0.5ml.
- Make sure to test the diluted sample within 30 minutes, otherwise the result will be unreliable.
- Samples that have been stored for a period of time need to be re-mixed before testing.

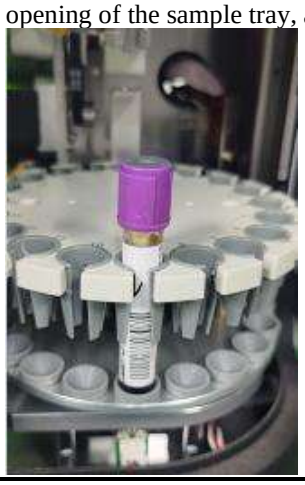
4.6 Auto Sample Testing

The steps for auto sample testing are as follows:

1.Make sure that the analyzer is in the test-ready status (the status bar in the upper right corner of the main window is displayed as "Ready").

2. Enter the sample number (this step can be skipped, and the number will automatically start from 0001 after the analyzer is turned on every day).

3. Put the prepared samples into the sample tray in order, align the barcode of the sample with the opening of the sample tray, and then prepare for testing.



4.After checking that the sample type on the start test button is consistent with the sample type to be tested, directly click the "Start" button to start the test.
If the sample type is inconsistent with the test button, click the “Sample Type" button to re-select the current sample type.

5.The test result of each sample will be displayed on the main interface, and a list will be formed on the "Data" interface.

6.After tests are completed, the status bar changes back to the "Ready" status, and the operator can take away the samples at this time.

The test results will form a reviewable list in the "Data" interface, which can be inquired or printed out sample by sample. See Chapter 5 for details.

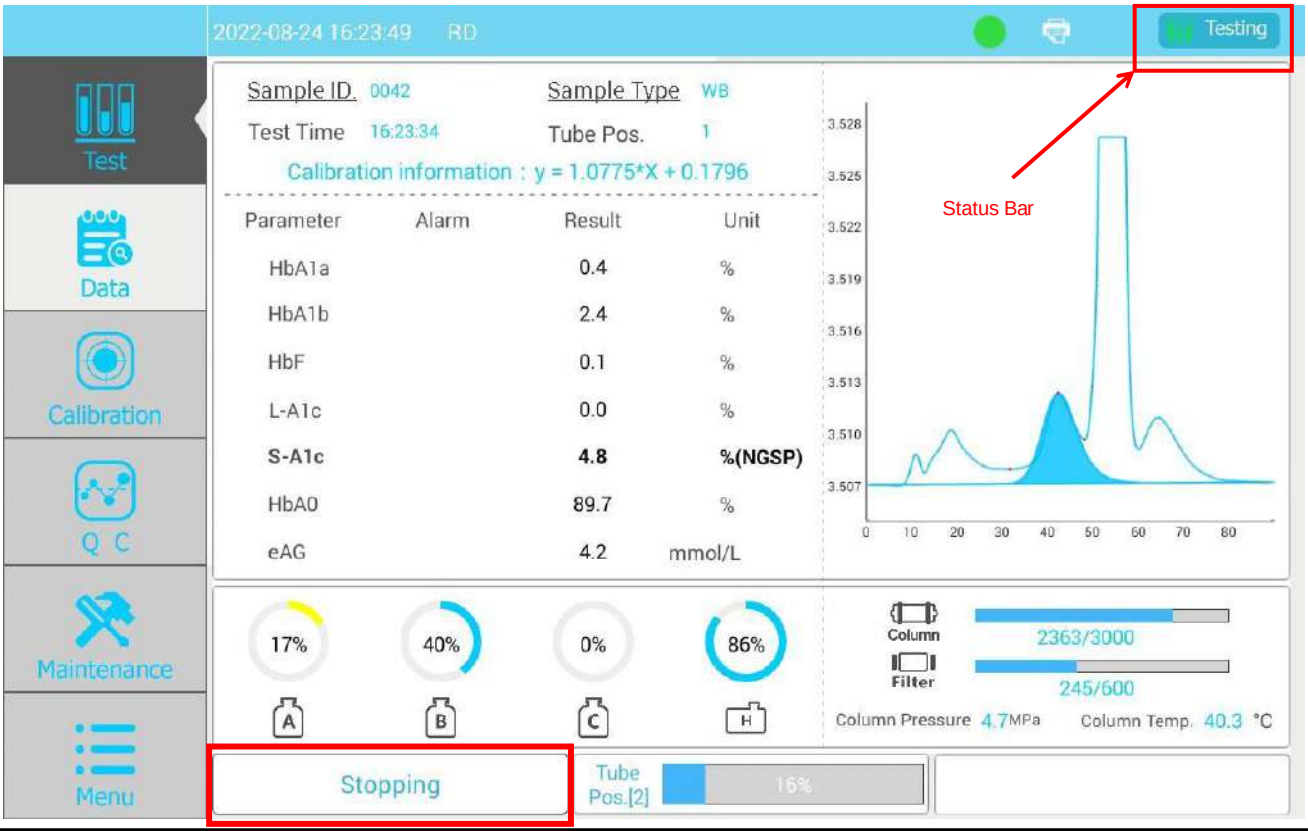
Caution:

- The operator should not open the front cover while the analyzer is running. Their clothes, hair and hands must be kept at a certain distance from the puncture assembly, sampling tray and other moving parts, and must not be touched to prevent being pinched or stabbed.

4.7 Special Functions

4.7.1 To stop testing

During the test, click the "Stop" button on the main window. The analyzer will stop testing and enter the “Ready” status after the current sample was tested and cleaning actions were finished. The status bar will change from "Testing" to "Ready".



Caution:

- When the status bar in the upper right corner of the main window displays "Ready", it indicates that the analyzer is in the ready status.

4.7.2 Parameter alarm

"H" or "L" is displayed on the right side of the corresponding result parameter (Figure 4-4), which means that the test result exceeds the preset reference value range but is still within the display range. If the test result is "***", it means the test result is invalid or out of the display range. Please refer to section 6.5 for parameter setting.

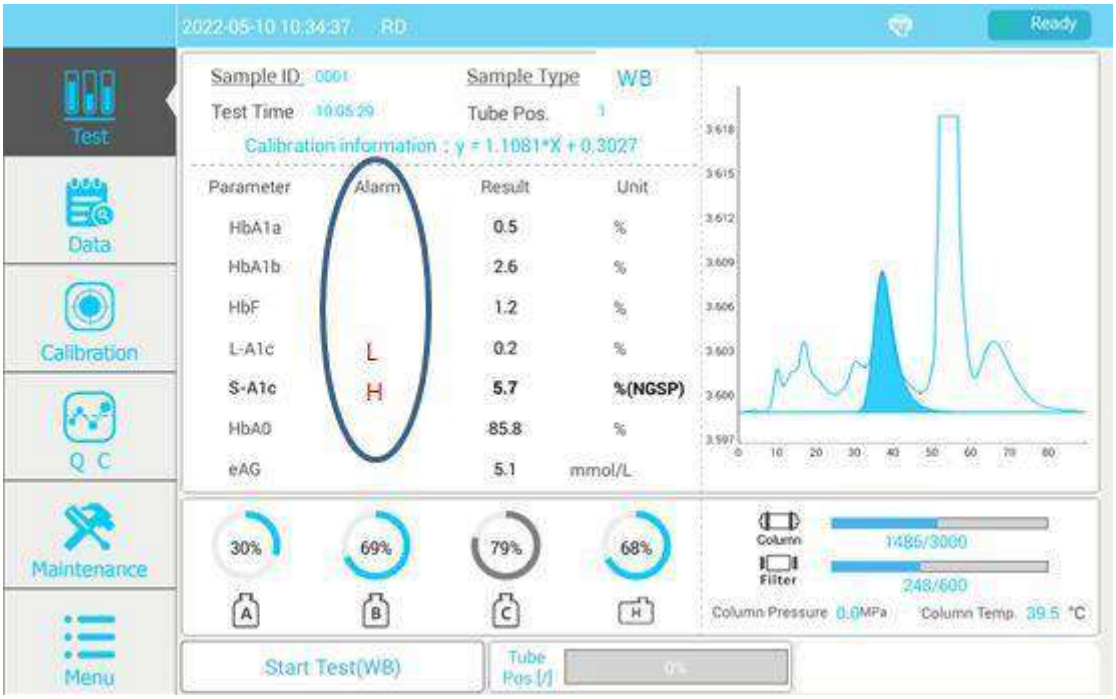


Figure 4-4

4.8 Shut Down

Take away the samples, press the power switch on the back of the analyzer, and the analyzer will shut down when it is in the "0" status.

Chapter 5 Data Management

Click the "Data" button in the main window to enter the query interface (Figure 5-1), and you can query the sample testing data.

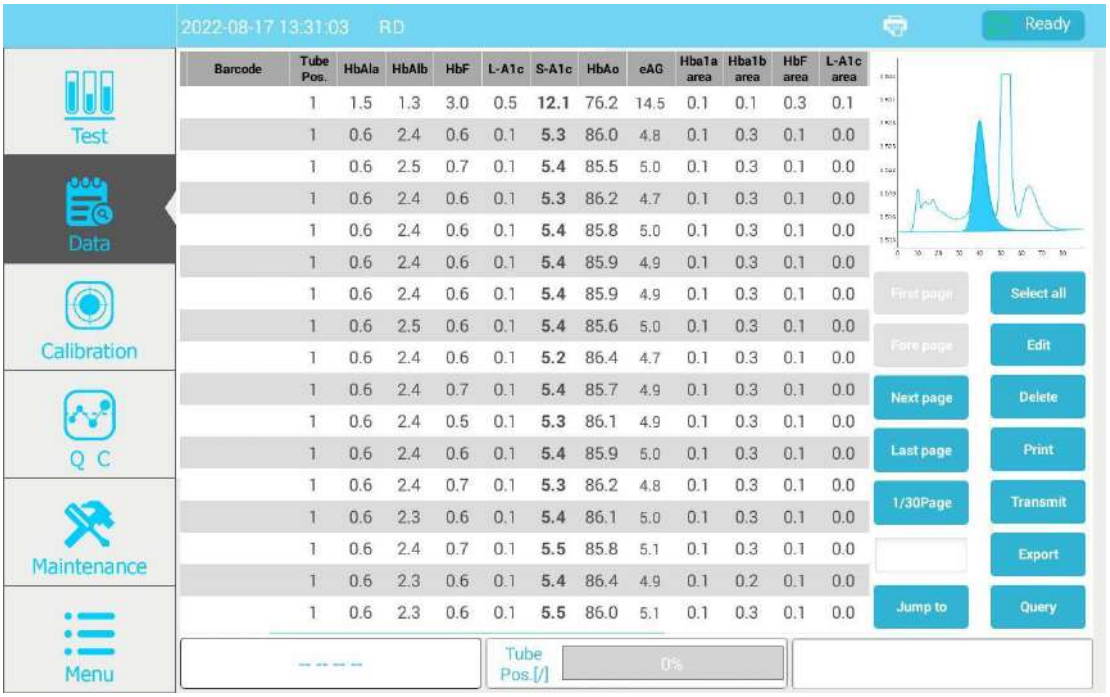


Figure 5-1 Query interface

Button	Description
Query	Query sample data and chromatograms.
Select all/ Select all cancel	Select or unselect all the test results of the current page.
First page	Return to the first page of test results.
Fore page/Next page	Turn to previous/next page.
Last page	Turn to the last page.
Jump to	Jump to the specified page.
Delete	Delete the selected test result and chromatogram.
Print	Print the selected result and chromatogram.
Transmit	Transfer selected testing data or all data.
Export	Export all data via USB.
Edit	Edit the relevant information such as the barcode or sample number of the currently selected sample.

5.1 Data Query

The upper right corner of the interface is the sample search option (Figure 5-2), which supports 3 query methods by time interval, serial number interval, and sample number.

Figure 5-2

5.1.1 Query all test results

If the check button "□" of all options is not clicked, click the "Query" button directly, and the test results of all samples will be displayed in the list according to the test time sequence (it takes different time according to the amount of data stored. If The amount of data is large, please be patient).

5.1.2 Query test results by time interval

1) Click the check button "□" in front of the "Date" option.
2) Click the blank boxes behind "Date" to select the start date and due date.
3) Click the "OK", and the test results within a certain period of time will be displayed on the left side of the interface in the order of the test time.

5.1.3 Query test results by sample number interval

1) Click the check button "□" in front of the "NO." option.
2) Click the blank boxes behind "NO." and enter the Start and end sequence numbers.
3) Click the "OK", and the test results of the sample serial number segment will be displayed on the left side of the interface.

5.1.4 Query the test result of the specified sample

1) Click the check button "□" in front of the "Sample ID" option.
2) Click the blank box behind "Sample ID" and enter specific information.
3) Click the "OK" button in the data interface, and the test result will be displayed on the left side of the interface.

5.2 Data Deletion

In the test result list, select the record to be deleted, and then click the "Delete" button, the following dialog box will pop up (Figure 5-3), click "OK" to delete the selected record.

Figure 5-3

5.3 Export Results

Click the "Export" button in the query interface to export all the current test results of the instrument to the U disk in the form of an excel file. The operation is as follows: connect the U disk to the USB interface, and then click the "Export" button on the query interface, and a pop-up box prompts "Save successfully, please view the exported xls file under the U disk", and then all the current test results of the instrument can be exported.

5.4 Data Printing

In the test result list, select several test results, and then click the "Print" button to pop up a print dialog box (Figure 5-4), you can select "print selected" or "Print by range", and finally click "Yes" to start printing.

Figure 5-4

Chapter 6 System Setting

6.1 Overview

Click the "Menu" > "Settings" button in the main window to enter the settings interface (Figure 6-1).

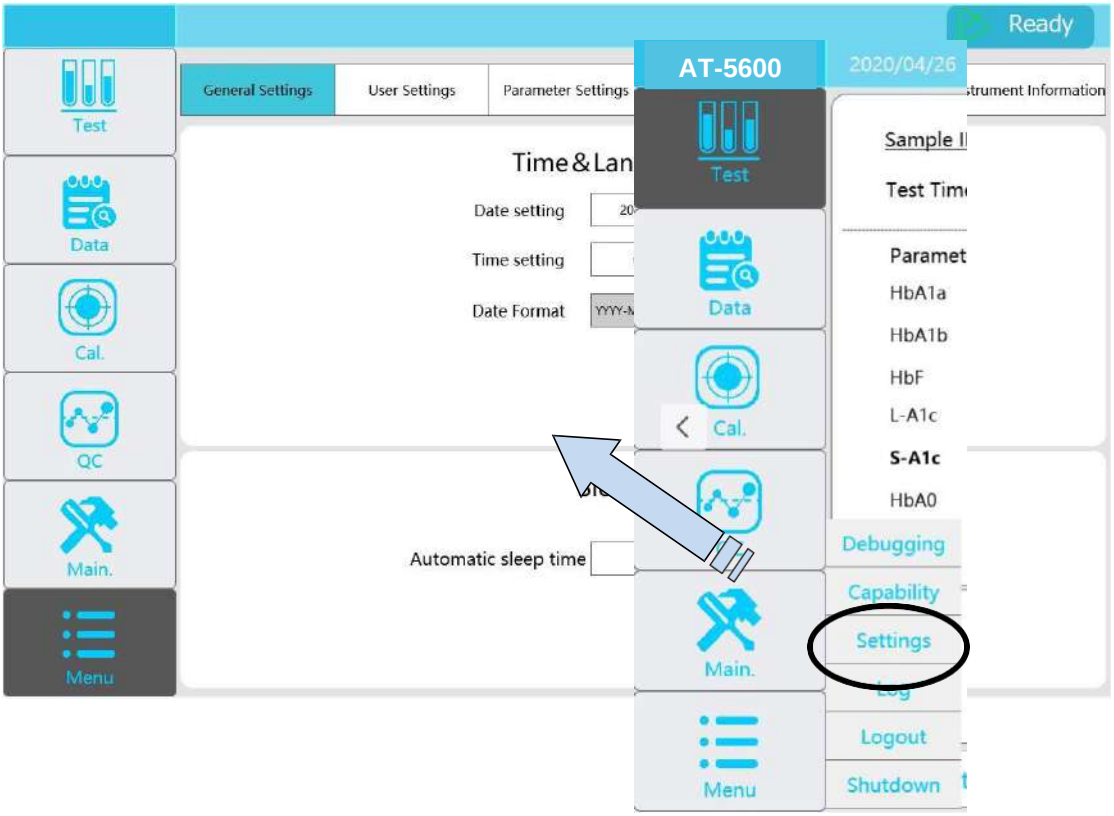


Figure 6-1

General Settings: Time setting, language setting and sleep setting.

User Settings: User authority settings.

Parameter Settings: Result parameter setting.

Print Settings: Print the setting interface.

Communication Settings: Communication setting interface.

Instrument Information: System information.

6.2 General Settings

On the setting interface, click "General Settings" to set the time and Sleeping setting (Figure 6-2).

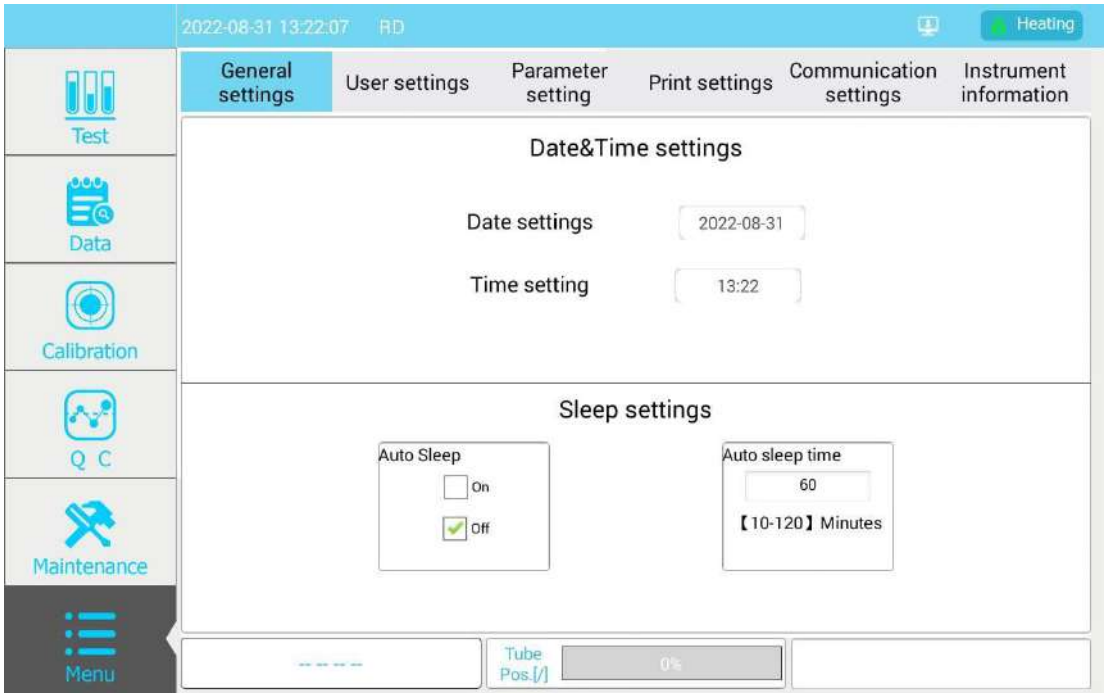


Figure 6-2

Set the date, time, and select the date format. The settings will be saved after exiting this interface.

Select the language type and save the settings after exiting this interface.

6.3 User Settings

In the settings interface, click "User Settings" to add or delete users (Figure 6-3)

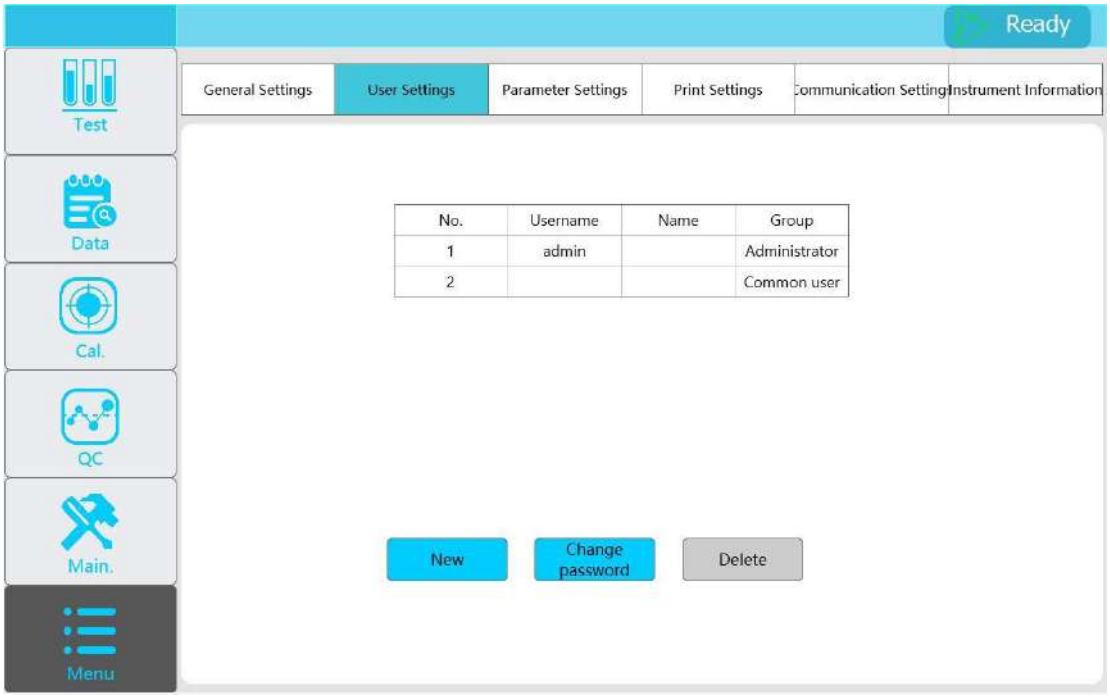


Figure 6-3

Click on the new user in the interface to assign corresponding permissions. The settings will be saved after exiting this interface.

6.4 Parameter Settings

Click the "Parameter Settings" on the setting interface to set laboratory information (Figure 6-4).

Parameter setting steps:

1) Make sure the box shown in 1 is unchecked.

2) Click the input box shown in 2 and input the corresponding parameter warning range.

3) Check the box of 1, the parameter range setting is successful.

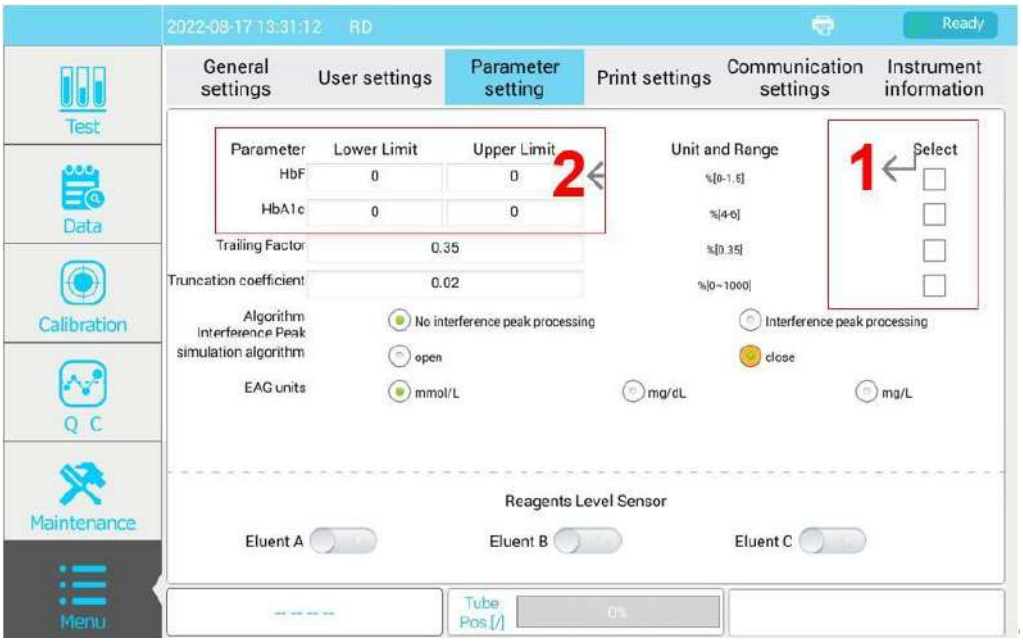


Figure 6-4

6.5 Print Settings

Click the "Print Settings" on the setting interface to set the print mode and report template (Figure 6-5).

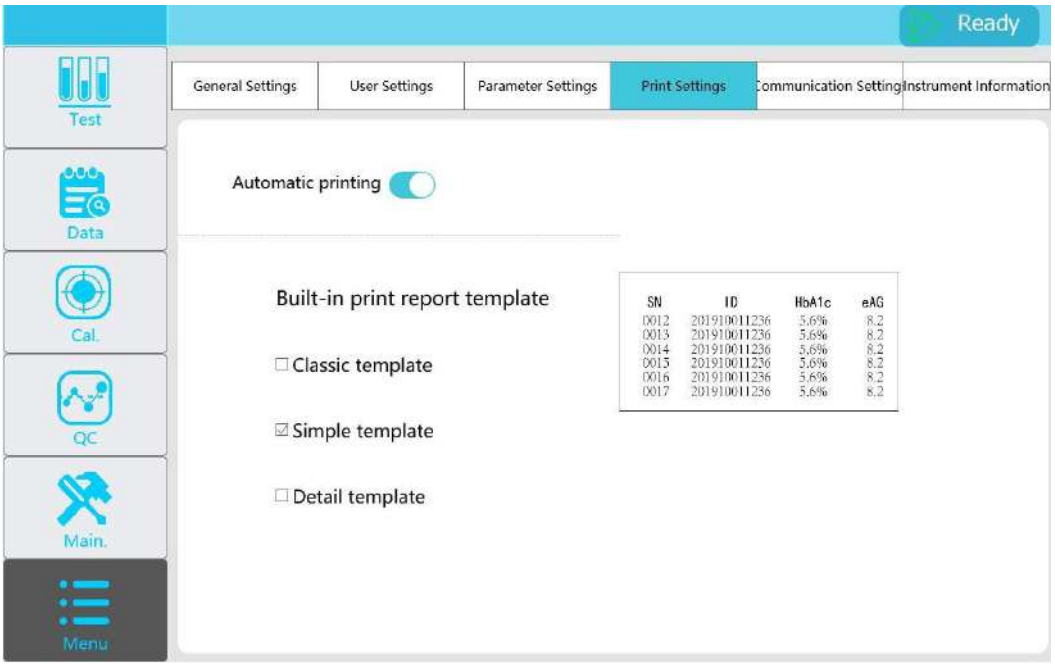


Figure 6-5

6.6 Communication Settings

Click the "Communication Settings" on the setting interface to set the communication protocol and transmission mode, etc. (Figure 6-6).

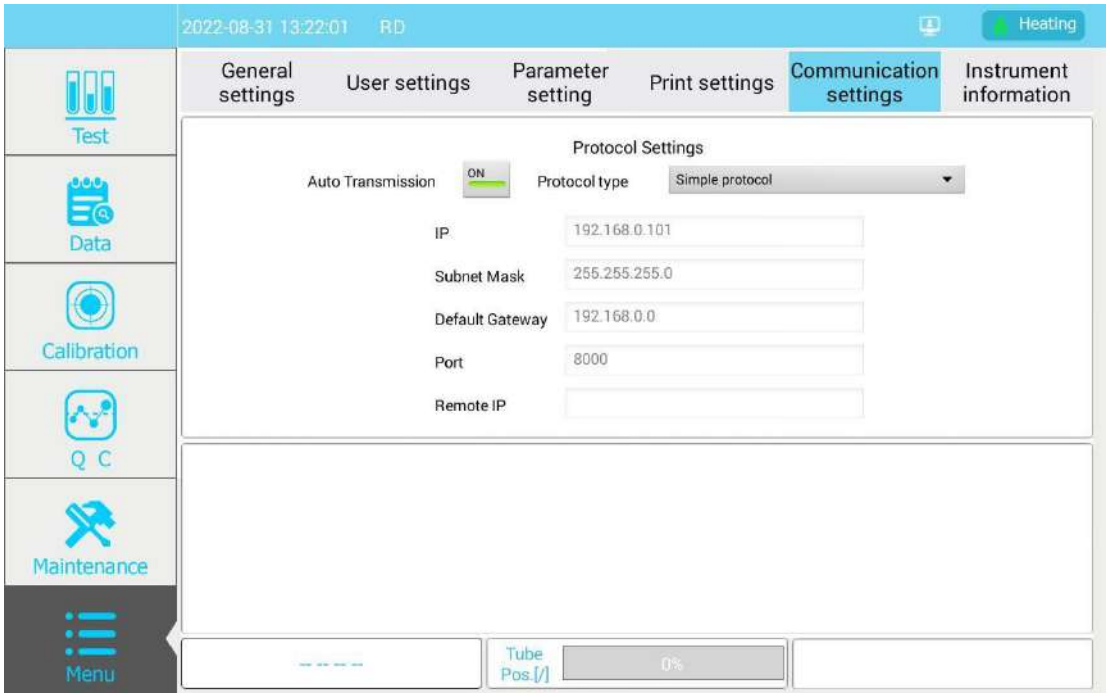


Figure 6-6

6.7 Instrument Information

Click "Instrument Information" on the setting interface to query the instrument serial number, model, software version and other information (Figure 6-7).

Figure 6-7

Chapter 7 Quality Control

The Glycated hemoglobin may produce a certain degree of error during the test, which may lead to false or unreliable test results. In order to ensure the reliability of the test results, it is recommended that operators use low-value and high-value quality control substances to perform quality control tests for the glycosylated hemoglobin test every day.

7.1 QC Interface

In fast mode (no variation mode), click the "QC" button on the main interface to enter the quality control interface, as shown in Figure 7-1-1.

Figure 7-1-1

In the variation mode, click the "Quality Control" button on the main interface to enter the quality control interface, as shown in Figure 7-1-2.

Figure 7-1-2

Editing information: Quality control product file number, batch number, level, expiration date, target value type, target value and standard value, etc.

Delete: Delete the selected quality control file or all quality control files.

Start QC: Start the quality control test.

Export: Export quality control files.

Print: Print quality control information.

Communication: Upload and communicate information about quality control.

Click "Edit" and enter the quality control information, then click "Yes" to save or click "No" to cancel the modification (Figure 7-2).

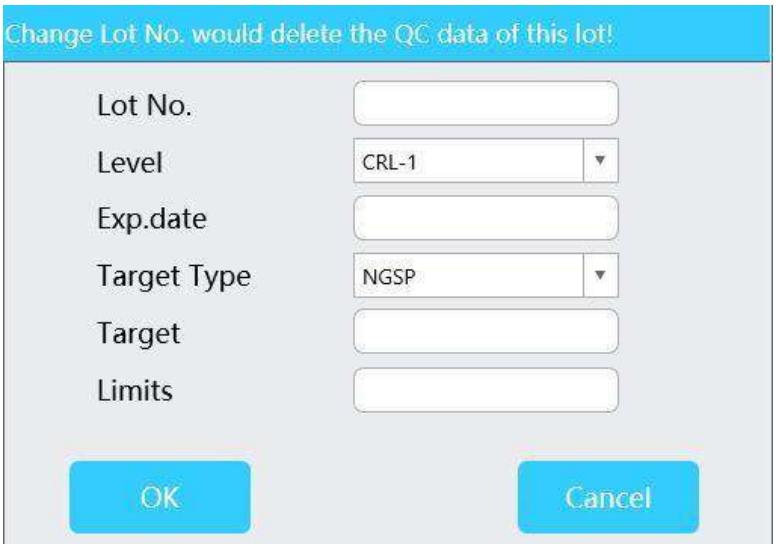


Figure 7-2

7.2 QC Procedures

1.	Respectively add 100ul of distilled water to low-concentration and high-concentration quality control products to reconstitute, and shake gently to avoid foaming.
2.	Take two clean and empty blood collection tubes numbered 1~2, and then add 3000ul of hemolysis agent to each tube.
3.	Add 10ul of reconstituted low-concentration and high-concentration quality control products to the No. 1 and No. 2 blood collection tubes respectively, and mix them with a pipette.
4.	Put No. 1~2 blood collection tubes into the 1# and 2# of the sample tray in order.
5.	On the QC interface, click "Star (QC)" to run the quality control test.

7.3 QC Results Query

In the QC result interface (Figure 7-3), select a file in the QC data list on the left, and the QC result and QC statistics chart of the corresponding file will be displayed on the right.

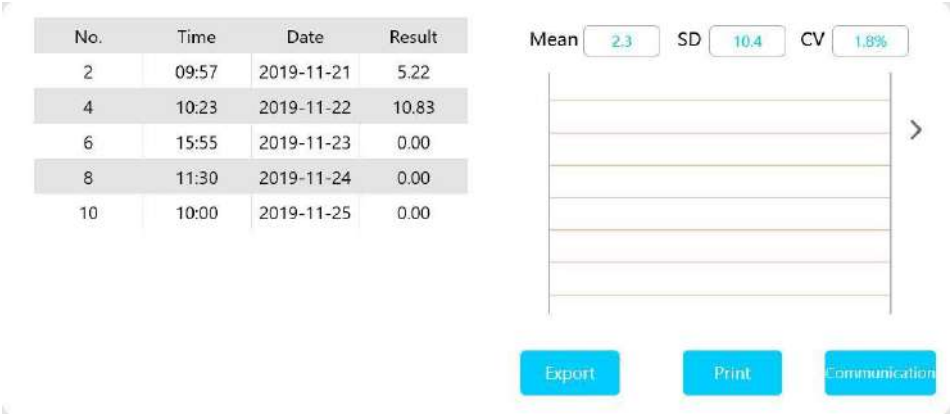


Figure 7-3

Caution:

- When there are more than 3 QC results of the same batch number and the same level, the average value, standard deviation and coefficient of variation will be calculated and displayed in the table on the upper left of the query interface.

7.4 QC Results Export

There are 3 options on the QC query interface: "Export", "Print" and "Communication".

Export: Click "Export" to export all the data of the current QC file and file information in CSV file format to a U disk.

Print: Click "Print" to print all the data of the current QC file and file information.

Communication: Click "Communication" to communicate all data of the current QC file and file information to the LIS/HIS terminal.

Chapter 8 Calibration

The purpose of calibration is to ensure the accuracy of test results. In order to obtain accurate test results, the analyzer should be calibrated according to the requirements and procedures in this chapter.
The analyzer should be calibrated and run within the specified temperature range, otherwise the accuracy and precision will be reduced. After replacing reagents and chromatography column, the analyzer should be calibrated or re-input the calibration parameters given by the manufacturer.

Caution:

- The analyzer must be calibrated, so that the test results can be used as valid data.

8.1 Calibration Situations

In the following situations, the operator needs to calibrate the analyzer:

- First installation
- After replacing the chromatography column or filter;
- When the high-pressure pump is replaced or the column pressure changes greatly;
- After replacing reagents with different batch numbers;
- When the analyzer is not used for a long time and is used again;
- When running quality control, there is a significant deviation in the system.

8.2 Calibration Method

The analyzer provides a calibration method. All mathematical calculations related to calibration are automatically completed by the analyzer. The latest calibration coefficient after calibration is automatically displayed on the calibration interface, and the system automatically saves the current calibration coefficient and the last calibration coefficient.

Caution:

- The analyzer must be calibrated after first installation, so that the test results can be used as valid data.

8.2.1 Calibration operation

In fast mode (no variation mode), Click "Cal." on the main interface to enter the calibration interface (Figure 8-1).

Figure 8-1

In the variation mode, Click "Cal." on the main interface to enter the calibration interface (Figure 8-2).

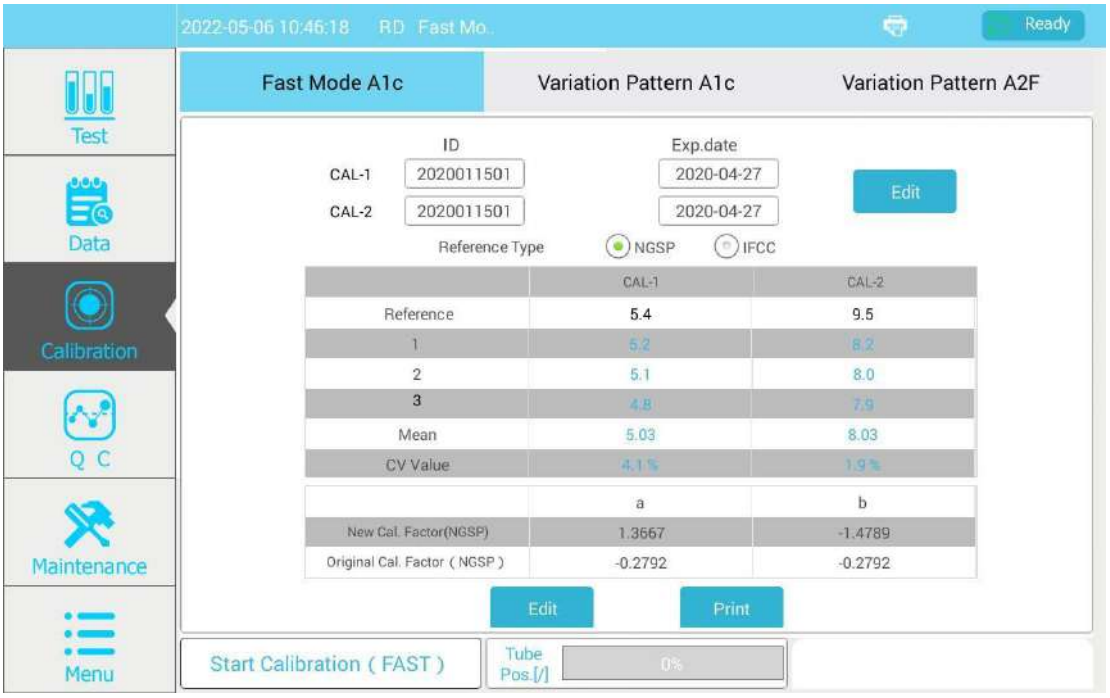


Figure 8-2

Click "Edit Information" and enter the serial number, expiration date and reference value of the low and high value calibrators (as shown in Figure 8-3). After editing the relevant information, click "Yes" to save the calibrator information; click "No" to not save the calibrator information.

Figure 8-3

After confirming that the input information is correct, click "Start (Cal.)", a dialog box will pop up (Figure 8-4), prompting the location of the calibrator (see section 8.2.2 for details), and then click "Yes" to run the automatic calibration program.

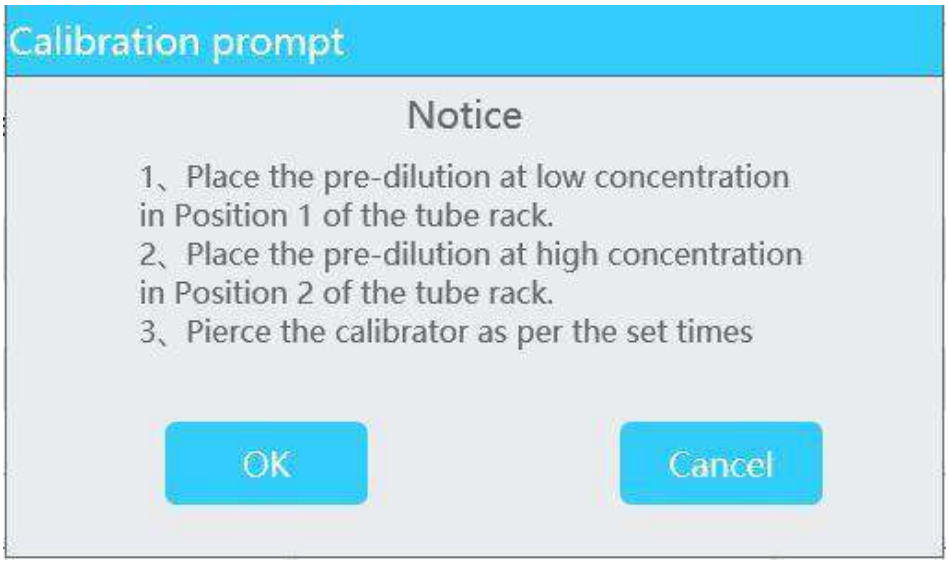


Figure 8-4

Caution:

1. The variant mode version needs to be calibrated twice (after the quick mode A1c calibration is completed, the variant mode A1c calibration is performed) to prevent inaccurate results when the variant mode version of the instrument is switched to the quick mode test. To obtain accurate A2 and F variant protein values, please contact the distributor/ manufacturer to purchase specific calibrators, calibrate and then measure.
2. In the variant mode, the same calibrators used for the two A1c calibrations are used in the fast mode (no variant mode).

- The calibrators have a potential hazard of biological infection. Operators should abide by the safety operation regulations and wear protective equipment (such as laboratory protective clothing, gloves, etc.) when touching related items in the laboratory.

Caution:

- The operator should use the calibrator specified by Labnovation. Labnovation should not be responsible for any erroneous test results from the use of other calibrators.
- For the usage and storage method of the calibrator, please refer to its instructions.

8.2.2 Calibration procedures

1.	Respectively add 100ul of distilled water to low-concentration and high-concentration calibrators to reconstitute, and shake gently to avoid foaming.
2.	Take two clean and empty blood collection tubes numbered 1~2, and then add 3000ul of hemolysis agent to each tube.
3.	Add 10ul of reconstituted low-concentration calibrator to No. 1 blood collection tube, and add 10ul of reconstituted high-concentration calibrator to No. 2 blood collection tube, and then mix them with a pipette.
4.	Put No. 1~2 blood collection tubes into the 1# and 2# of the sample tray in order.
5.	Click "Yes" on the calibration prompt interface (Figure 8-2) to start the calibration analysis. After the analysis is completed, the new calibration coefficients a and b are automatically calculated.

Caution:

- If the difference between the low or high test value and the input low or high value exceeds 20%, and the CV value of the three calibration values exceeds 10%, it will prompt the calibration failure.

8.3 Edit calibration

The operator clicks the "Calibration Edit" button to edit the current calibration coefficients a and b. Click "Yes" to save the calibration coefficients a and b. Click "No" to not save the calibration coefficients a and b (as shown in Figure 8-5).

Figure 8-5

Chapter 9 Reagents and Consumables

9.1 Maintenance

Click the "Main." on the main interface to enter the maintenance interface (Figure 9-1) to replace various reagents, chromatography columns and filters:

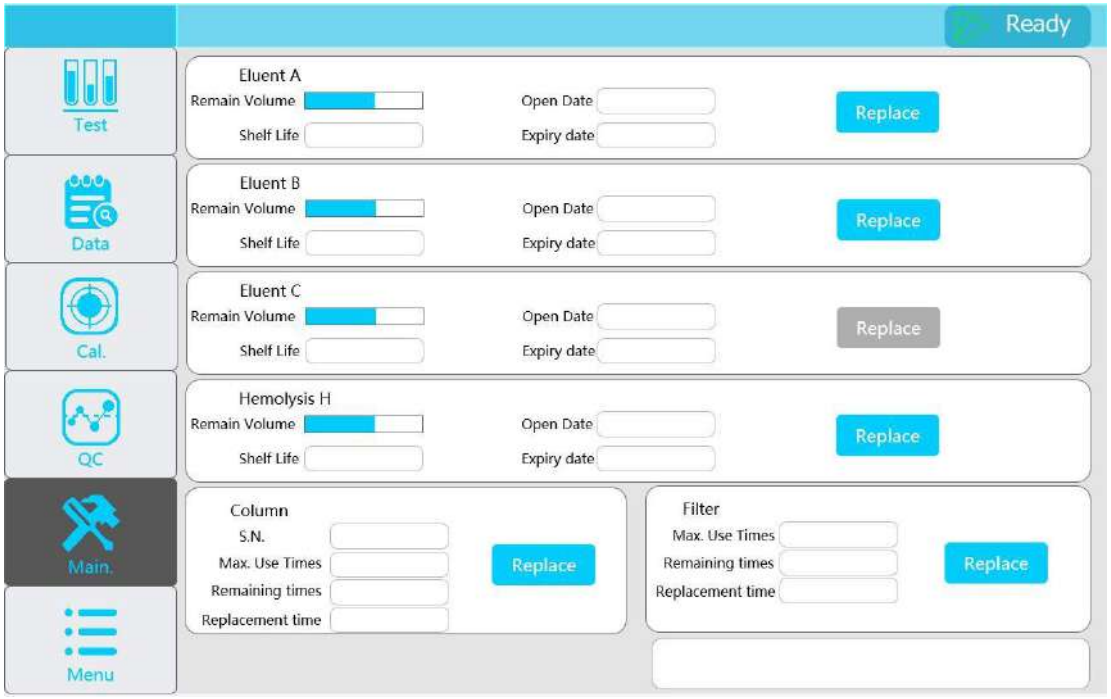


Figure 9-1

9.2 Reagents Replacement

When you need to change the reagent, click "Replace" to replace the corresponding reagent (Figure 9-2); you can manually enter or identify the relevant reagent information through RFID, including: Reagent name, Lot No., expiry date, and calculate the bottle opening date and expiration date based on the current time, and then click "Yes" to execute the reagent replacement process.

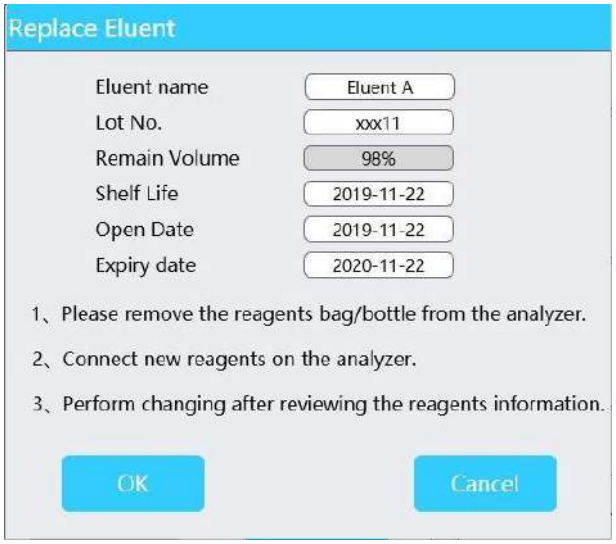


Figure 9-2

Caution:

- After replacing the reagent, check the connected tubes to make sure they are not bent.
- The agent can irritate the eyes, skin and mucous membranes. When contacting reagent-related items in the laboratory, the operator should abide by the safe operation regulations and wear protective equipment (such as protective clothing, gloves, etc.).
- Use large quantity of water to wash in case your skin or eyes has touched reagents, and ask doctors for help.

9.3 Consumables Replacement

9.3.1 To replace chromatography column

The analyzer needs to be in "Ready" status when replacing the chromatography column.

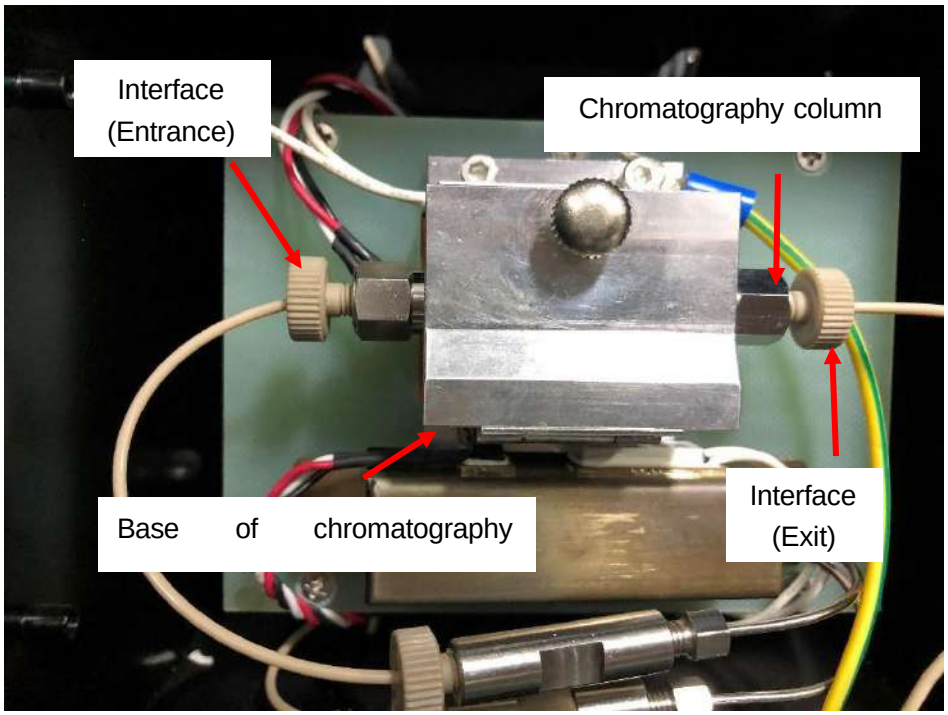


Figure 9-3 Temperature control box for chromatography column

The installation steps for chromatography column:

1.	Open the left front door of the analyzer, press the front lock of the temperature control box to the left and pull the temperature control box outward to expose the chromatography column (Figure 9-3).
2.	Take the old chromatography column out of the slot in the base of chromatography column.
3.	Loosen the connectors on the left and right sides of the chromatography column in turn, and remove the chromatography column. A small amount of liquid may flow out of the interface when removing the old chromatography column. It is recommended to put a paper towel at the bottom of the old chromatography column when removing it.
4.	Firstly extend the tubes connecting the outlet and inlet of the chromatography column by more than 3mm (Figure 9-4), and then respectively connect the tubes to the inlet and outlet of chromatography column by hand.

Figure 9-4 Remove the plus of new chromatography column

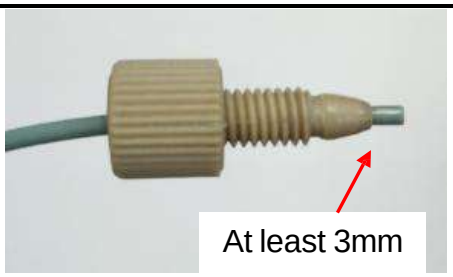


Figure 9-5 Extend the tube

5. After connecting the pipeline, install the column back into the column holder, and then cover the column temperature control box.

Caution:

- The installation direction of the chromatography column must not be reversed, and the liquid flow direction must be consistent with the arrow of chromatography column.

6. After connecting the tubes, wrap the outlet and inlet connectors of the chromatography column with paper towels, and then click the main window "Menu"> "Priming & Packing"> "Combined priming", and check whether the connector on both sides of the chromatography column are leaking, otherwise tighten the connectors again.

7. If there are no leakage, wipe clean the connectors with paper towels and install the chromatography column back into the base of chromatography column, then wipe clean the base of chromatography column with paper towels, finally cover the temperature control box of chromatography column.

8. Click "Main."> " Column"> "Replace" on the maintenance interface (Figure 9-6) , enter the serial number, the max use times, and set the number of used times to 0, finally click "Yes", the software will automatically generate the first-used date.

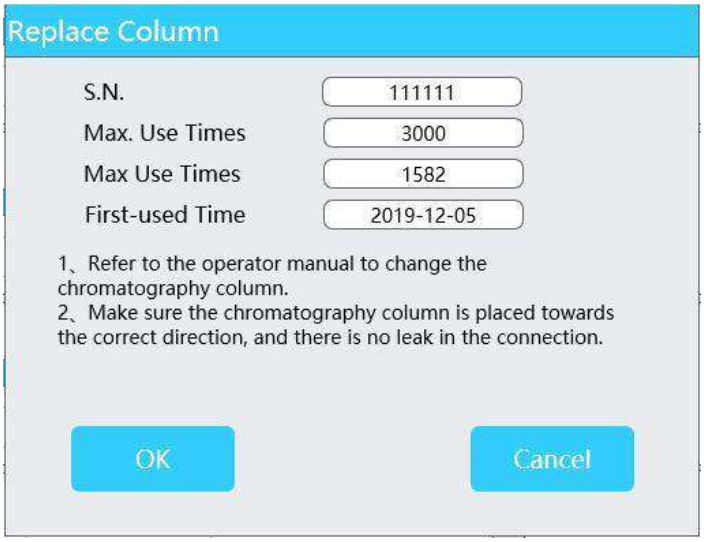


Figure 9-6

9.3.2 To replace paper roll

When a red bar appears on the edge of the paper roll, it means that the paper roll is about to be used up and needs to be replaced. Please see Chapter 3.5 for details.

9.3.3 To replace filter

The filter needs to be replaced (Figure 9-7). The analyzer should be in a non-operating status before replacement.

Figure 9-7

The replacement steps are as follows:

1. Open the right front door and take out the pre-column filter (as shown in Figure 9-8) from the holder.

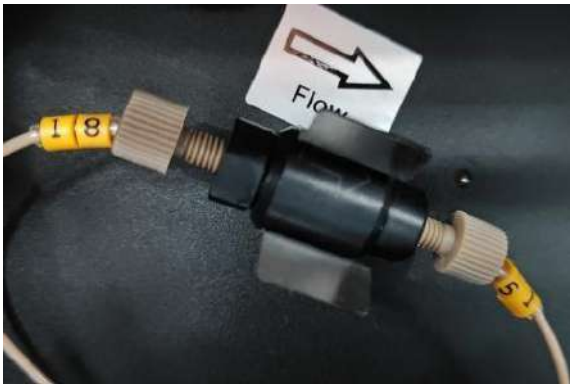


Figure 9-8 filter

2. Unscrew the connectors at both ends and remove the old filter.

3. Install the new filter and tighten the connectors at both ends.

4. Click "High Pressure Priming" > "Eluent A Priming" on the maintenance interface and check whether there is leakage at both ends of the filter joint. Otherwise, the joint needs to be re-tightened.

5. Click "Main."> " Filter"> "Replace" on the maintenance interface (Figure 9-9) , enter the max use times and set the number of used times to 0, then click "Yes", the software will automatically generate the first-used date.

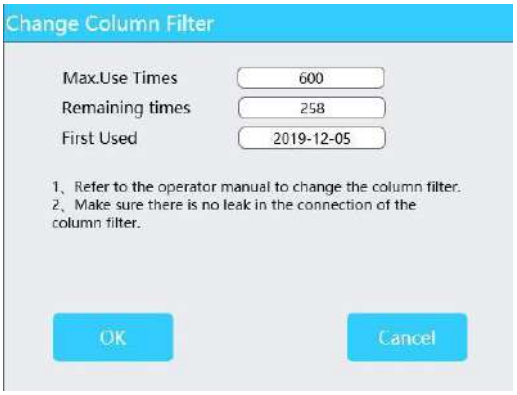


Figure 9-9

Caution:

- A small amount of liquid may flow out of the connector when removing the filter cover and priming inspection. It is recommended to put a paper towel under the filter.

9.4 Minimum Sales Unit and Replacement Cycle of Consumables

9.4.1 Minimum sales unit (600Tests)

Reagents	QTY	Number of tests	Total number of tests
Eluent A	2 PCS	300T	600T
Eluent B	2 PCS	300T	600T
Hemolysis H	2 PCS	300T	600T

Consumables	QTY	Number of tests	Total number of tests
Filter	1 PCS	600T	600T
Chromatography column	1 PCS	3000T	3000T

9.4.2 Replacement cycle (600Tests)

Consumables	Number of tests	Replacement cycle
Eluent A	300T	300 tests are used up or two months after opening
Eluent B	600T	600 tests are used up or two months after opening
Hemolysis H	300T	300 tests are used up or two months after opening
Filter	600T	600 tests are used up or the pressure alarm of the liquid pipeline appears
Chromatography column	3000T	3000 tests are used up

- The maximum number of uses of chromatography columns and reagents is calculated based on the amount of 10 samples per day. The instrument will consume consumables for daily startup cleaning and pre-test cleaning. If the number of samples tested per day is less than 10, the maximum number of uses may not be reached.
- Two months after opening the cap, it is recommended to replace with a new reagent.

Chapter 10 Log Management

10.1 Log Management Interface

Click the "Menu"> "Log" button on the main window (Figure 10-1) to enter the log management interface to review calibration logs, fault logs and other operation logs.

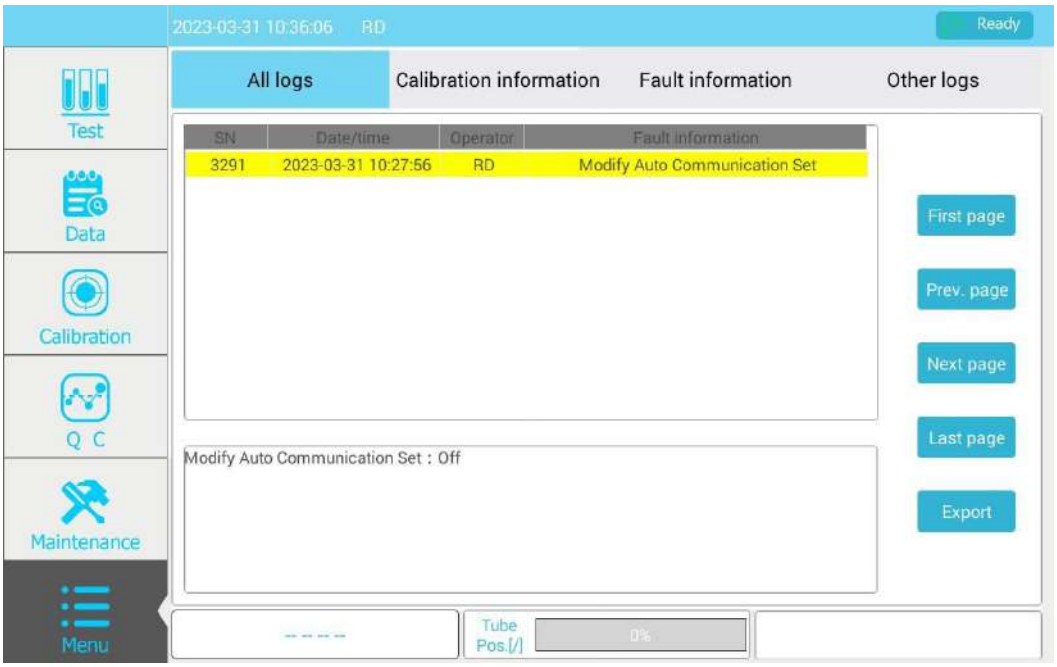


Figure 10-1

10.2 Calibration Logs

Click the "Calibration Information" on the log management interface (Figure 10-2) to review the calibration logs.

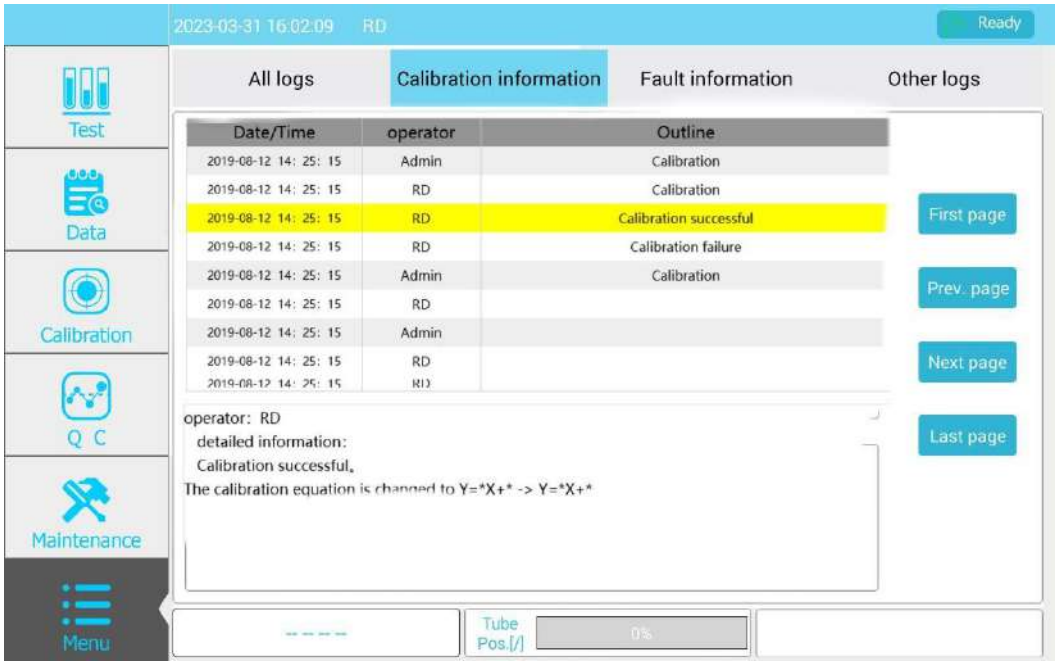


Figure 10-2

10.3 Fault Logs

Click the "Fault Information" on the log management interface (Figure 10-3) to review the fault message logs.

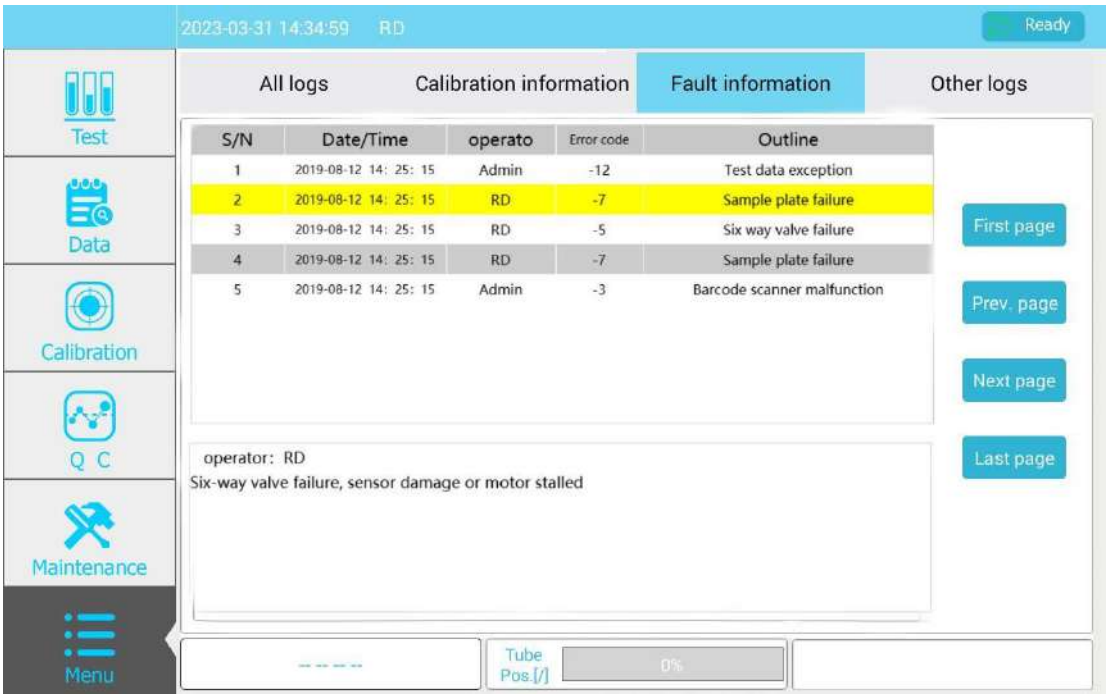


Figure 10-3

10.4 Other Operation Logs

Click the "Other logs" on the log management interface (Figure 10-4) to review other operation logs.

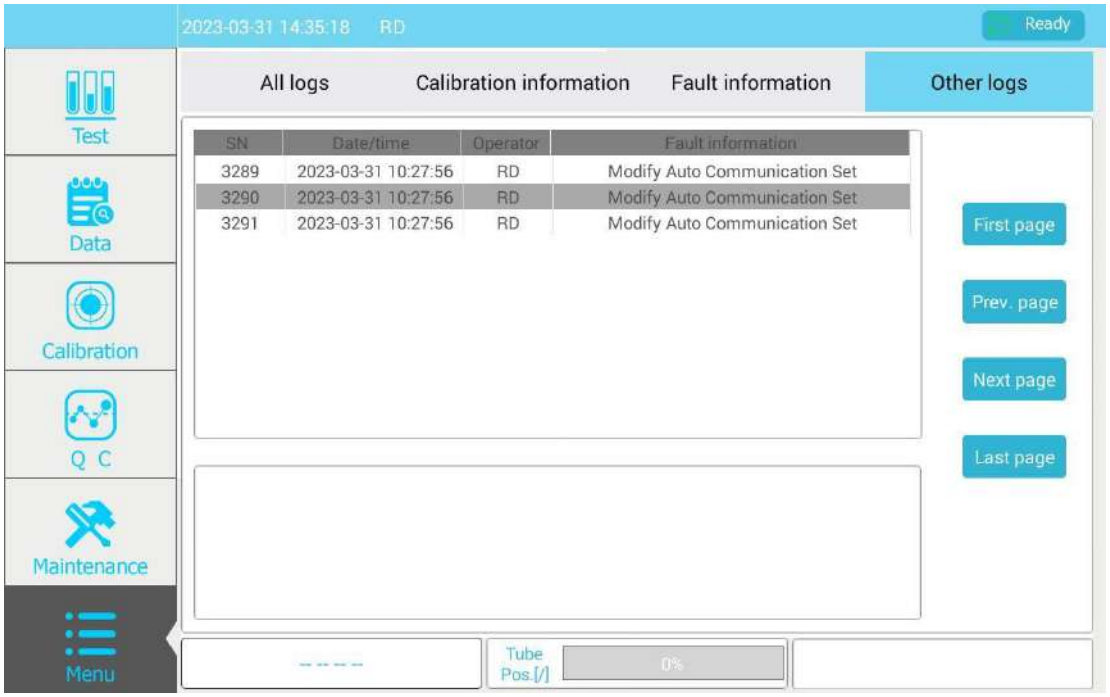


Figure 10-4

Chapter 11 Usage Precautions

The analyzer should be used strictly in accordance with the operating requirements, and the main points in this chapter should be paid attention to.

11.1 Hazard Notices

1. The liquids such as samples and waste liquid have a potential hazard of biological infection. Operators should abide by safe operation regulations and wear protective equipment (such as protective clothing, gloves, etc.) when touching related items in the laboratory.
2. The operator is obliged to abide by the local regulations regarding the disposal of reagents, waste liquids, waste samples, consumables, etc.
3. The reagent can irritate eyes, skin and mucous membranes. Use large quantity of water to wash in case your skin or eyes has touched reagents, and ask doctors for help. If you eat it accidentally, rinse your mouth with plenty of water and drink plenty of water, and then seek medical help.
4. Do not touch the moving parts when the analyzer is running, and clothes, hair, hands, etc. must keep a certain distance from the moving parts.

11.2 Operation Cautions

Caution:

1. 100V~240V, 50Hz~60Hz AC power supply must be used.
2. The equipment connected to the external port of the analyzer must pass safety certification and have a safety certification mark.
3. Do not use expired reagents and chromatography columns.
4. The filter elements and chromatography columns must not be used beyond the recommended number of use, otherwise the pressure in the system will exceed the limit, resulting in deviations in test data.
5. When the analyzer is in normal use, various reagents, waste liquids, etc. will not leak. If leakage is found, it should be checked and eliminated in time, and the leaked liquid should be wiped clean by wear medical gloves to prevent biological infection.

11.3 Sample Requirements

1. The sample can be venous blood or peripheral blood.
2. The EDTA-2K/3K and EDTA-2Na is the recommended anticoagulant. The anticoagulated whole blood samples can be stored at 2℃~8℃ for 7 days.

Caution:

- It is recommended to use the vacuum blood collection tubes containing EDTA-2K/3K and EDTA-2Na anticoagulant, with size of 13mm×75mm.

11.4 Calibration and QC Requirements

The "QC reagents" and "calibrators" mentioned in this manual refer to the special quality control products and calibration products designated by Labnovation. Users need to purchase them from authorized agents or Labnovation.
For the use and storage method of the calibrator, please refer to its instruction.
For the use and storage method of the QC product, please refer to its instruction.

11.5 Contraindication

None

Chapter 12 Maintenance

Caution:

The trained medical professionals, doctors, nurses or laboratory workers can replace the filters, chromatography column, reagents, paper roll and fuses produced by Labnovation by themselves. Users are not allowed to use other substitutes by themselves, otherwise Labnovation will not be responsible for any problems.

12.1 System Maintenance

12.1.1 Daily maintenance

1. After turning on the analyzer, visually check for liquid leakage during the system self-test. If leakage is found, please contact the after-sales engineer.
2. Check whether the paper roll is enough. If the paper roll appears red on one side, it means that the paper roll is almost used up, and it should be replaced.
3. Check whether the reagent is sufficient and the waste liquid is full. It is recommended to empty the waste liquid bottle every day.

- The liquids such as samples and waste liquid have a potential hazard of biological infection. Operators should abide by safe operation regulations and wear protective equipment (such as protective clothing, gloves, etc.) when touching related items in the laboratory.
- The operator is obliged to abide by the local regulations regarding the disposal of reagents, waste liquids, waste samples, consumables, etc.

12.1.2 Preventive maintenance

Please refer to the table below for regular maintenance:

Items	Period
Cleaning the puncture needle.	Weekly
Cleaning the outer surface of the analyzer.	Monthly
Cleaning the sample test-tube rack.	Monthly
Cleaning auto sample injection module.	Monthly
Check whether the over-temperature protection switch is off.	Monthly

Caution:

- The operator must wear gloves and clean the analyzer with gauze dipped in 75% ethanol. Please avoid the liquid flowing into the analyzer when wiping, so as not to damage the analyzer.

12.1.3 Reagents and Consumables Maintenance

Please refer to the table below for regular maintenance:

Items	Time
Replace Eluent A.	When the system prompts for replacement.
Replace Eluent B.	
Replace Eluent C.	
Replace Hemolysis H.	
Replace the chromatography column.	
Replace the filter .	
Replace the paper roll.	When red lines appear on the edge of the paper roll.

- The liquids such as samples and waste liquid have a potential hazard of biological infection. Operators should abide by safe operation regulations and wear protective equipment (such as protective clothing, gloves, etc.) when touching related items in the laboratory.
- The operator is obliged to abide by the local regulations regarding the disposal of reagents, waste liquids, waste samples, consumables, etc.

12.1.4 Stop working for a long time

1. When the analyzer is not used for a long time, the chromatography column should be removed. The two-way connector or dummy-column (removed during the first installation, see section 3.4 for details) should be installed back to the position of the chromatography column.
2. Block the two ends of chromatography column with plugs, and then store it at 2°C ~ 8°C and avoid direct sunlight.
3. Put all external reagent tubes into the deionized water bottle, click "Menu"> "Priming & Packing"> "Packing", and follow the prompts on the interface to complete the operation.
4. After observing that no waste liquid comes out of the waste tube for one minute, turn off the power switch and unplug the power socket.

12.2 Cleaning and disinfection Operation

1. The power must be turned off before cleaning and disinfection.
2. Use a soft cloth dipped in 75% ethanol or 70% isopropanol to wipe the surface of the analyzer. Please use cotton swabs to clean the parts which are not easy to clean until no obvious residues on the surface of the analyzer.
3. After cleaning and disinfection, reconnect the power supply and turn it on for use.

Users can clean the analyzer daily according to the equipment cleaning method specified by the laboratory, but do not use disinfectants that have corrosive effects on metals, such as 3% hydrogen peroxide. Labnovation does not provide any guarantee for damages and accidents caused by the use of corrosive disinfectants.

Caution:

- If dangerous substances leak on the surface of the equipment or enter the equipment, the equipment should be disinfected.
- Cleaning agents or disinfectants that react chemically with equipment parts or materials shall not be used.
- If there is any doubt about the compatibility of disinfectants or cleaning agents with equipment parts and materials, consult the manufacturer or your agent.

Chapter 13 Troubleshooting

Before or during the use of the analyzer, if there are any failures listed in the following table, please refer to the relevant troubleshooting steps for handling. If the failure still exists, please contact the after-sales service department of Labnovation for helps.

Caution:

- This analyzer can only be repaired by Labnovation or an engineer approved by Labnovation.

13.1 Software and Hardware Failures

Problem	Possible causes	Measurement
Turn on the power switch, but the analyzer is not running and its LCD screen doesn't light up.	Power cut.	
	Main power fuse failure.	Replace the fuse (see section 13.1.1).
	Main power switch failure.	Seek technical support from the manufacturer.
Software failure.	System initialization failed or error during operation.	Turn off the power and restart it. If the problem persists, please seek technical support from the manufacturer.
Print failed or display is not clear.	Printing heads are not lined up or need to be replaced.	Seek technical support from the manufacturer.
	The paper roll does not match the printer.	Use the paper roll supplied by Labnovation.
	The paper roll is installed reversely.	Reinstall the paper in the correct direction.
Abnormal system high pressure. High pressure pump doesn't work.	The pressure is too high and the filter is blocked.	Replace the filter
	The pressure is too high, the heating tube or other tubes are blocked.	Seek technical support from the manufacturer.
	The pressure is lower, there is air in the liquid path.	Check whether there is any remaining reagent, manually remove the air bubbles in the high-pressure pump.
Abnormal temperature.	Software failure.	Restart the analyzer, if there is still abnormal, please seek manufacturer technical support.
	The temperature has been too low and the heater is damaged.	Seek technical support from the manufacturer.
	The temperature sensor is faulty.	

13.1.1 To replace the fuse

1. Unplug the power cord first, and then open the fuse box.
2. Insert a screwdriver into the edge of the fuse box, and gently pry open and take out the fuse box.
3. Take out the failed fuse and replace it with a new one.

Warning:

- Please use the fuse provided by the manufacturer to avoid fire.

13.2 Abnormal Chromatographic Peaks

Problem	Possible causes	Measurement
No peak in chromatogram. No data on the report.	There is air in the sample syringe tubing or the system is not primed properly.	Perform one or two system priming.
	The sample has clumped or is missing.	Check whether the sample is condensed or has a low volume. Re-prepare the sample and retest.
	The pipelines are leaked.	Seek technical support from the manufacturer.
	The sampling needle is blocked.	
	The switching of the six-way valve is not in place.	Use the six-way valve operation to test in the test interface, if the fault cannot be eliminated, seek technical support from the manufacturer.
Abnormal peak shape.	Expired, contaminated or damaged reagent kit.	Replace the reagent kit.
	Expired or damaged chromatography column.	Replace the chromatography column.
Failed calibration.	Input data error.	Correctly enter the setting value of the calibrator.
	The wrong calibrator is used.	Correctly use the calibrator.
	The calibrator was placed in the wrong position on the test-tube rack.	Check the position of the calibrator on the test-tube rack.
	The calibrator has too little capacity.	Check whether the capacity of the calibrator is sufficient.
	Air bubbles in the detector or pump system.	Perform system priming and cleaning procedures.

Chapter 14 Declaration of EMC

Warning:

- The analyzer meets the emission and immunity requirements specified in part of IEC 61326-2-6.
- The user is responsible for ensuring a good electromagnetic compatibility environment so that the analyzer can work normally.
- It is recommended to evaluate the electromagnetic environment before using the analyzer.
- Using cell phone or microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance, which means that the accuracy will be affected.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, transducers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Caution:

- The analyzer is designed and tested according to CISPR 11 Class A equipment. This device may cause radio interference in the home environment, so protective measures need to be taken.
- It is forbidden to use this device near strong radiation sources (such as non-shielded RF sources), otherwise it may interfere with the normal operation of the device.
- Security, antitheft, and radiofrequency identification (RFID) devices. Some electromagnetic anti-theft systems and metal detectors may affect the monitor. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, may also affect the monitor. Please do not use monitor near these places. If you have to go through one of these devices, turn off your monitor. Before each usage, checking the status of your monitor to ensure it can operate normally.

Table I:

Guidance and manufacture's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The device is suitable for use in all medical settings, including hospitals and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table II:

Guidance and manufacturer's declaration — Electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Phenomenon	Basic EMC standard or test method	Professional healthcare facility environment
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact discharge: ±2kV, ±4kV Air discharge: ±2kV, ±4kV, ±8kV
RF electromagnetic field	IEC 61000-4-3	3V/m, 80MHz～2.0GHz, 80%AM
Pulse train	IEC 61000-4-4	Power cord:±1kV(5/50ns,5kHz)
Surge	IEC 61000-4-5	Line-to- ground: ±2kV Wire-to-wire: ±1kV
RF conduction	IEC 61000-4-6	Power cord: 3V, 150kHz～80MHz, 80%AM
Power-frequency magnetic field	IEC 61000-4-8	3A/m，50/60Hz
Voltage sags, voltage interrupts	IEC 61000-4-11	1 cycle 0%; 5/6 cycle 40%; 70% for 25/30 cycle; 250/300 cycle 5%
Performance judgment: A. The performances are normal within the specification limits during the test, B. The functions or performances are temporarily reduced or lost during the test, but it can recover by themselves. C. The functions or performances are temporarily reduced or lost during the test, t, but interventions of operator or system reset are required.		

Chapter 15 Network Security

The analyzer is equipped with a USB interface and a network port. The USB interface is used for software upgrades by after-sales engineers, and the network port is used to transmit test data to the hospital LIS system.

The system provides two different login accounts: engineer and ordinary user. You can log in by entering the corresponding user name and password. Only when you log in with an engineer account, you can read the U disk data through the USB connector to upgrade software. The USB type is Host (host device), and the internal data of the analyzer cannot be accessed through the connector.

The analyzer communicates with the external LIS system through the network port, and the one-way transmission mode is adopted. The LIS system cannot access the internal data of the analyzer. If you need to understand the communication protocol, message definitions and examples, please contact after-sales service department of Labnovation for details.

Name of software:
AyoTes Fully Automated HPLC Analyzer AT-5600, AT-5610, AT-5620 software
Software release version:
V1.1920220714R
Software operating environment:
The software runs on the Android Tablet, which is equipped with the Android 4.4.4 system. The main frequency is 2.0GHz, the memory is 2GB, and the storage capacity is 8GB.

Chapter 16 Disposal

The specimens used for instrumental analysis and testing are whole blood samples from human body, which may have biological hazards. There may be a risk of infection to the operator. Therefore, it is necessary to take protective measures (wear gloves, etc.)
when operating the instrument or replacing the corresponding accessories.
Replaced medical waste, such as used chromatography columns, filters, sampling needles, sample cups, etc., should be disposed of in accordance with relevant laws and regulations to protect the surrounding environment and health.

Chapter 17 Warranty

Warranty Description:

Respected user:

Thank you very much for choosing the products of Reynolds. In order to get timely maintenance and repair services, please read the following terms carefully:

1. Please keep this warranty card properly for future warranty use.

2. Only within one year from the date of installation, if there is a fault under normal use, you can enjoy the free warranty service provided by us.

3. The failure of the instrument caused by any of the following conditions is not covered by the warranty:

A. The reagents are not original reagents produced by Reynolds or the reagents used have expired.

B. Man-made damage caused by unauthorized unpacking, dismantling and repair by personnel not authorized by Reynolds.

4. After-sales service department of Labnovation Technologies, Inc.:

Toll free service number: 400-860-2589

Address: 102, 602, 702, 802, Sheng Hui Hongxing Chuangzhi Square, Tongren Road, Tianliao Community, Yutang Street, Guangming District, 518107 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Tel: +86 755 86368328 Fax: +86 755 86368318 www.labnovation.com

Postcode: 518107

Appendix

1 Power supply

Voltage	Frequency	Rated power
115/250VA (±10%)	50/60/Hz	300VA

Note: Do not use detachable MAINS power cord with inadequate RATING.

2 Temperature protection switch

Overload temperature	Maximum voltage	Rated current
65°C (±5°)	220V	7-15A

2 Rating and characteristics of fuse

Fusing characteristics	Fusing time	Maximum voltage	Rated current
Slow disconnect	150ms～3s	AC 250V	2A

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