GH-900Plus

HbA1c Analyser

User Manual

Lifotronic

Statement

Thank you for buying GH-900Plus HbA1c Analyser .

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: HbA1c analyser
Product model: GH-900Plus
Production date: see details in machine label
REF number：0120210
Shelf life: 5 years
User manual issuing date: 2022-05
Version number: A3

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WARNING

- The system is operated and used by Lifotronic or designated agents trained professionals, doctor or lab assistant;
- If hospitals or institutions can not achieve a satisfactory repair /maintenance plan, it may cause abnormal instrument failure, and may endanger human health.
- Ensure to run the instrument under the conditions that are written in this manual. If not, it may fail to run, result in inaccurate results, or even damage the components and injure humans.

NOTE

This manual is for the following clinical laboratory professionals:

1. Daily operations personnel;
2. System maintenance and troubleshooting personnel;
3. Personnel that learn to use the system.

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Chapter1 Manual Introduction

1.1 Overview

This chapter introduces how to use the Instruction Manual for GH-900Plus. This manual is supplied with the analyzer, and describes the purpose, function and operation of GH-900Plus in details. Please read this manual before using GH-900Plus to ensure proper use and optimum performance of GH-900 Plus 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 GH-900Plus;
- 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 GH-900Plus	Chapter 2 Analyzer Introduction
Understand the measuring principle of GH-900Plus	Chapter 3 Operating Principle
Understand the requirements and steps for installation of GH-900Plus	Chapter 4 Analyzer Installation
Understand the process of routine operations of GH-900Plus	Chapter 5 Routine Operations
Review the sample analysis results	Chapter 6 Result Review
Review the error logs, using logs and maint logs	Chapter 7 Log Review

Understand the basic requirements and method for quality control of GH-900Plus	Chapter 8 Quality Control
Understand the basic requirements and method for calibration of GH-900Plus	Chapter 9 Analyzer Calibration
Understand the methods for maintenance and testing of GH-900Plus	Chapter 10 Service
Understand the causes of and solutions for malfunction of GH-900Plus	Chapter 11 Troubleshooting
Understand the basic features, performance indexes, input and output devices and other aspects of GH-900Plus	Annex A Specifications
Understand the communication protocol for GH-900Plus	Annex B Communication
Understand the electromagnetic radiation instructions for GH-900Plus	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 symbols, 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.



- DO NOT operate in flammable and explosive environment.
- The Analyzer must be used in a good grounding condition.
- Make sure input voltage meet the requirements.
- Make sure the switch is off ("OFF") before connecting power cord of adapter.
- Operator should wear on gloves and avoid direct contact with sampling needle. Because sampling needle is sharp, sample loader, sampling needle, Chromatography Column and filter may carry with blood and QC material and calibrator is bio-hazard.
- 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 equipments (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.
- When repairing and fixing, shut down the power ! It may damage electrical components with Analyser on!
- Operation of the instrument should be conducted by the personnel that received formal training, or master safe operation skills. For clinical trials, the instrument should be used in charge of personnel management or clinical management personnel.

- To prevent electrical shock and / or equipment damage, operator should not open three covers of the instrument. Only maintenance staff can be allowed to complete instrument maintenance or repair.
- If the instrument's door open, DO NOT repair with the instrument power on. Powered touch internal circuit will cause injury.
- Instrument installation must be equipped with reliable power outlet to ensure electrical safety.
- 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.
- DO NOT reuse disposable supplies.
- 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 Service Department of Lifotronic. Designated professionals will offer maintenance advises.
- Must use components and parts that provided by Lifotronic for maintenance. Any questions, please contact Service Department of Lifotronic.

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.

- GH-900Plus Analyser 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.
- Refer to the user manual of reagent to see how to use and store reagent.
- After replace eluent, Chromatography Column, filter or hemolytic agent, the operator should rinse the system to ensure ADC value in normal range.
- Ensure use reagents, Chromatography Column, filter before expiration date.
- Stand the reagents before use, to make it stable.
- If room temperature exceeds normal operating temperature range, the obtained results will be inaccurate.
- The Analyser must be placed on a sturdy and horizontal table, not placed on a slope.
- Please keep the packing box, in order to pack the Analyser when moving a long distance.
- Only use reagents designated by the manufacturer.
- After connecting the reagent and analyser, 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.
- Operator should wear on gloves for safety operation due to the potential biohazard of column and filter.
- Reagents soaked in chromatography columns 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 K2EDTA, K3-EDTA, NA2-EDTA and sodium fluoride anticoagulant.
- It’s recommended that operator uses oscillator to shake the blood collection tube or prediluted EP tube. Otherwise it may influence testing result.
- 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 is 20 digits, if it exceeds 20 digits, the Analyser defaults the first 20 digits as current ID number.
- Samples should be placed consecutively (one by one). DO NOT leave space

between Start and End position. Otherwise, the result of blank position will be shown as 0%.

- 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.
- The length of Lots No. is 15 digits. If exceeding, the system will default the first 15 digits as current Lots No.
- QC chart supports to display 3 batches of information of QC in a month. It's recommended to print or keep data backup by connecting to computer with RS232 serial port line. Contact the manufacturer and authorized distributors for backup software.
- Operator should use specific QC material designated by Lifotronic. Lifotronic takes no responsibility for inaccurate QC result by using any other QC materials.
- Refer to QC material user manual for its usage and storage methods.
- If bubbles form during QC test, the system will set related parameter to invalid and give an alarm. See Chapter 11 for how to solve this problem.
- If the room temperature exceeds the normal working temperature range of the analyzer, the test results will be unreliable.
- Only after the Analyser has been calibrated, the measured data can be used as valid data.
- Operator must use specific calibrator designated by Lifotronic. Lifotronic takes no responsibility for inaccurate calibration results by using any other calibrators.
- Refer to the user manual of calibrator for its usage and storage method.
- Operator must use specific Chromatography Column and filter designated by Lifotronic . Lifotronic takes no responsibility for inaccurate test results by using any other Chromatography Columns and filters .
- Before unsealing the chromatography column and filter , operator should check whether the packaging is damaged. If damage results in Chromatography Column and filter are not available, please contact Service Department of Lifotronic immediately.
- Do not allow the sample to remain in the pipeline for a long time, especially in chromatography columns. Liquid Line Priming after every test. DO NOT shut down the system during test. If abnormalities appear, clean the system before test ! When not in use, lines and chromatography must be filled with reagents.

- When the instrument is operating, DO NOT touch sensitive components such as optical systems and other analyzers, otherwise it will cause error measurement results.



- Sample, QC material, calibrator, Chromatography Column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipments (safe clothing, gloves) when contacting lab articles.
- Surface of all the assembly units of GH-900Plus are bio-hazard, please take safety and protective measures when operating and maintaining.
- Sample loader, sampling needle, Chromatography Column, filter might be contaminate by blood. QC material and calibrator are bio-hazardous! Operator should wear on gloves while operating and avoid direct contact with sampling needle.

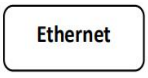
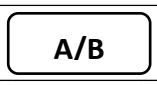
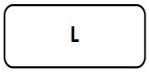
1.6 Symbols

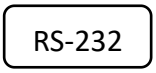
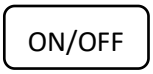
Symbols in this manual:

Symbol	Meaning
	Alerts the operator to operate according to the steps provided below this symbol; otherwise personal injury may result.
	Alerts the operator to operate according to the steps provided below this symbol; otherwise product failure or damage may result, or the test result may be affected.
	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.

	Alerts the operator to operate according to the steps provided below this symbol; otherwise potential biohazard may result.

The following symbols may exist on labelling of the analyzer, reagents, QC materials or calibrators:

Symbol	Description
	Max. pressure at liquid inlet: ≤0.25MPa
	Biohazard
	In vitro diagnostic medical device
	Serial number
	Batch code
	Use-by date
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community
	Indicates this analyzer is in compliance with Europe Directive
	Storage temperature
	Refer to the Product Instruction Manual
	Compliance with WEEE Standard
	Network port connection
	USB port connection
	Eluent A and B port connection
	Reagent L port connection

	Waste liquid port connection
	RS-232 port connection
	DC Power input port connection
	ON/OFF switch
	Protective ground
	Keep dry
	Fragile, handle with care
	This way up
	Stacking limit by number
	Be careful to avoid your hands from being pricked
	Do not turn the lever of evacuation valve more than 90° to the left
	Remove the cap of tube before testing

1.7 Precautions

To ensure safe operation, please read the following precautions carefully before use and operation of the analyzer.

The meaning of  and  are as follows:

During Installation

WARNING

- **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.**
  - 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

WARNING

- **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 column, filter, sampling needle and sample cup have been contaminated, in order not to damage personal health or environment, personal protective equipment such as goggles, gloves and mask must be used when handling these items. Please observe applicable laws on discharge of medical waste to properly handle them.

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 eluent leakage.
  - Eluent or Hemolysis 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 local maintenance personnel 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 local maintenance personnel**
  - 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 start the operation or stop the test by plugging and unplugging the power**
  - Otherwise, fires or electrical shocks may result.
  - Never fail to use the main power switch at the back of the analyzer.
- **Do not damage the power cord**
  - When unplugging the power cord, must pull on the plug itself.
- **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 does not know the operation requirements, such as use of personal protective equipment (e.g., goggles, gloves, mask), infectious diseases may be caused by injury or contaminated blood samples.
  - When replacing the sampling needle, if it is moved away forcibly instead of pulled out, the analyzer may get damaged. Maintenance can be carried out only after it is pulled out.
  - For operation and maintenance problems, please contact local maintenance personnel.
- **Dispose of wastes properly**
  - The wastes such as used sample cups, filters, columns and buffers accompanied with test shall be disposed of properly. Please wear protective equipment and do not touch directly, and dispose of them according to applicable laws, not to damage health and environment.
- **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 maintenance manual**

- Please use the consumables and spare parts listed in the maintenance manual .

Other precautions

- The warning labels are attached to the analyzer. Read the instruction thoroughly and follow them.
- When the warning or caution labels are damaged, comes off or does not meet the requirement, please contact your local agent.
- Avoid loss of this user manual.
- Please hand over this manual when changing operators.

Chapter 2 Analyzer Introduction

2.1 Overview

GH-900Plus HbA1c Analyser uses ion exchange liquid chromatography for quantitative determination of the content of glycated hemoglobin (HbA1c) in human whole blood.

After glycated hemoglobin in samples elutes from the chromatography column, the analyzer can provide the results of HbA1c (%, NGSP) and HbA1c (mmol/mol, IFCC). Meanwhile, the chromatogram can display HbA1a, HbA1b, HbF, LA1c, SA1c (HbA1c), A0 and other components, and the estimated average blood glucose can be calculated by the conversion equation provided in ADA, EASD and IDF researches (Diabetes Care 2008; 31:1-6). Also, common abnormal haemoglobin can be reported.

ATTENTION

- This analyzer is a clinical examination equipment used for screening. During clinical judgment based on the result of analysis, the doctor will be required to also consider the result of clinical examination or other test result.

2.2 Product Composition

This analyzer mainly consists of a main unit, a sample introduction system, chromatography columns, filters, a power adapter 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	PCS
Standard configuration	2	Sample Rack	1	PCS
	3	Diluting Sample Holder	5	PCS
	4	5L Waste Bottle	1	PCS
	5	Bottle cap component	2	EA
	6	Reagent L Connecting Tube	1	EA
	7	Waste Liquid Connecting Tube	1	EA
	8	Power Cord	1	PCS
	9	Power Adapter	1	PCS
	10	Barcode Scanner	1	PCS
	11	Spanner	2	PCS
	12	Sampling needle	1	PCS
	13	Thermal Paper	1	PCS
	14	User Manual	1	PCS

2.3 Analyzer configuration

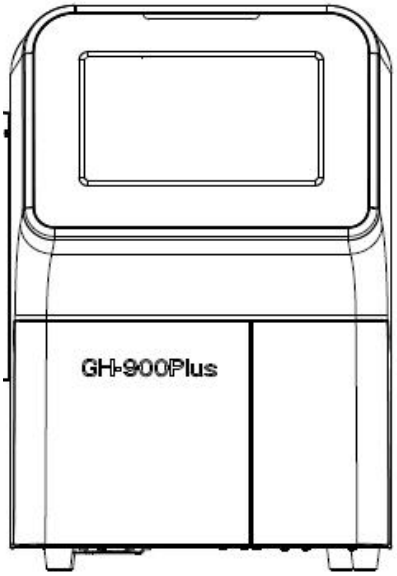


Fig. 2-1 External Appearance

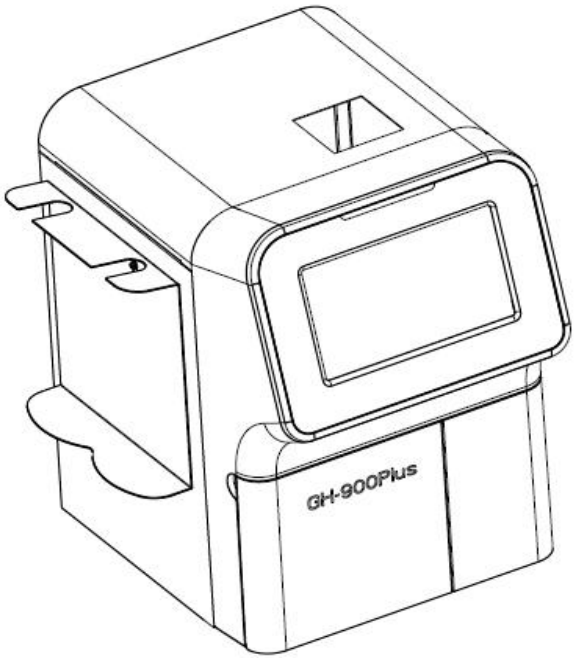


Fig. 2-2 External Appearance

2.4 Units and functions

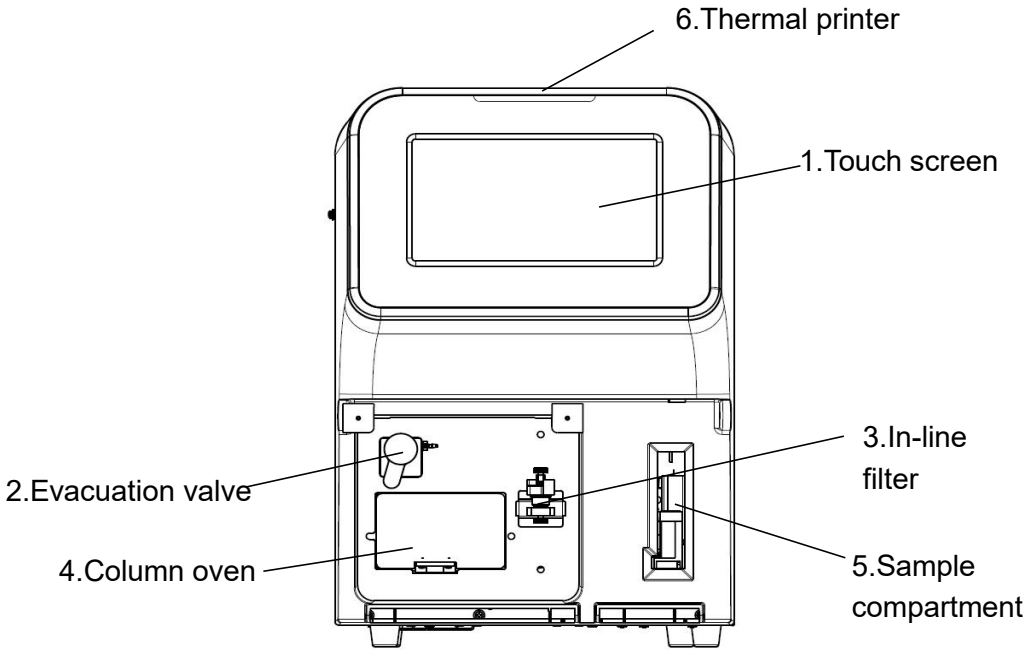


Fig. 2-3 Front Side View

1. Touch screen

The touch screen is in the front of the main unit of the analyzer. The analyzer uses a 10.1'' TFT color LCD screen for interface operation and information display.

CAUTION

- 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. Evacuation valve

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

3. In-line filter

Prevent samples, fragments of the pump sealing cover and other rubbish from entry into the chromatography column. The manually installed filter can be easily replaced.

4. Column oven

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

5. Sample compartment

The Sample introduction compartment is used to place the sample rack; the analyzer supports introduction of **5** samples at a time. Do not open the Sample introduction compartment door during analysis.

6. Thermal printer

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

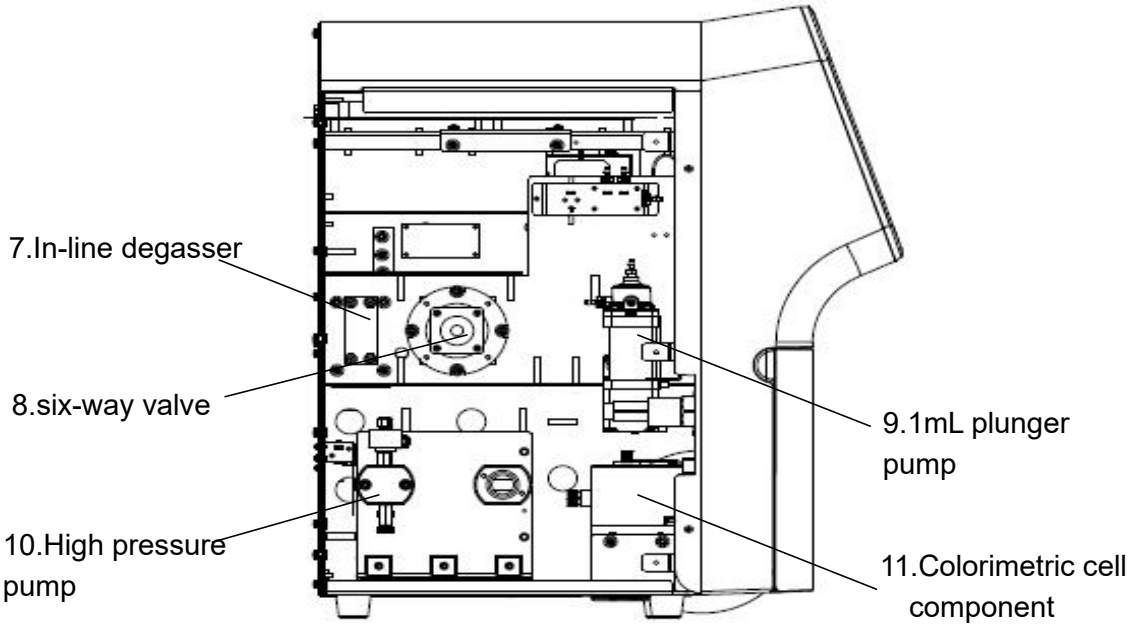


Fig. 2-4 View after Opening the Left Door

7. 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.

8. 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 chromatography column for separation.

9. 1mL plunger pump

1mL plunger pump is mainly used for the extraction, mixing and sampling of whole blood/diluted blood samples, as well as the cleaning of liquid path.

10. 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 chromatography column is used to separate different components of hemoglobin.

11. Colorimetric cell component

The colorimetric cell component is used to detect the absorbance change of hemoglobin in the sample after separation by the chromatography 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.

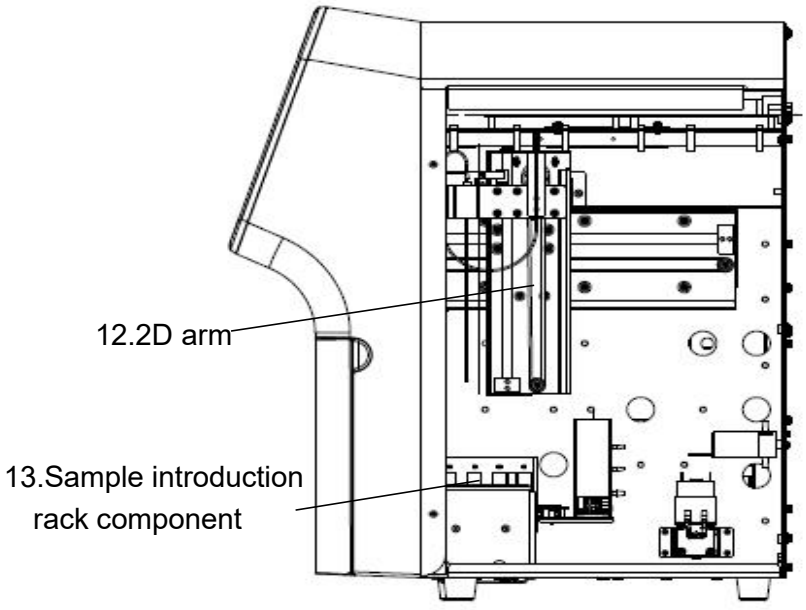


Fig. 2-5 View after Opening the Right Door

12. 2D arm component

The 2D arm component is for pretreatment of samples, including such steps as sampling and sample dilution.

13. Sample introduction rack component

The sample rack component is used to convey and place the sample rack.

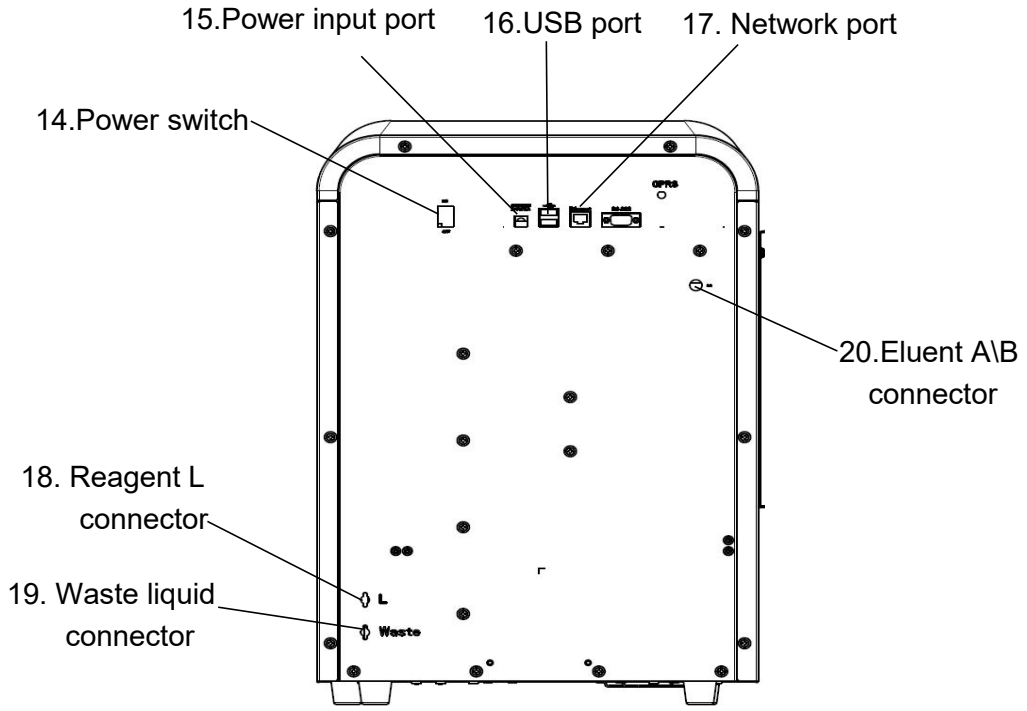


Fig. 2-6 Rear View

14. Power switch

Control power input of the analyzer. “ON” means power-on; “OFF” means power-off.

15. Power input port

Power input port for 24V/5A adapter.

16. 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..

17. Network port

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

18. Reagent L connector

For connection with the external 5L hemolytic agent bucket.

19. Waste liquid connector

For connection with the waste liquid tube to discharge waste liquid.

20. Eluent A\B connector

For connection with the eluent A and eluent B.

2.5 Software System

Using the Qt graphical user interface application framework, the Linux-based application provides beautiful and friendly operation interfaces, and also supports one-click switch of system language between Chinese and English.

2.6 Reagents, Chromatography Columns, Filters, QC Materials and Calibrators

The analyzer, reagents, chromatography column, filter, QC materials and calibrators constitute together a system which must be used as a whole to ensure its performance. The operator must use reagents designated by Lifotronic (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 packing prior to use of the reagent as damage of the packaging may affect the reagent quality. Confirm that the packaging is free from moisture or leakage. Otherwise, it is forbidden to use the reagent.

2.6.1 Reagents

The volumes of eluent and hemolytic agent to be used are calculated based on at least 4 samples each run; if less than 4 samples are tested each run, the eluent and hemolytic agent may have been run out of before warning information occurs.

Before each run, the volumes of eluent and hemolytic agent should be checked to ensure enough volumes for the test. Sample testing is not supported when the number of available tests of reagent 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, chromatography column, filter or hemolytic agent, 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, chromatography column and filter 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 low temperature (15~25℃) to avoid failure caused by evaporation, it is forbidden to expose the analyzer and reagents to direct sunlight;
  - Do not use the reagent if it is frozen;
  - It is forbidden to perform the test with the bottle cap opened; otherwise the reagent will lose efficacy within one day.

■ Eluents A and B

The analyzer uses two different concentration eluents , forming a 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

It is used to dissolve red blood cells and release glycated hemoglobin molecules.

2.6.2 Chromatography Column

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

Sample testing is not supported 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 chromatography column, please read the following precautions carefully:

- The chromatography column should not be subject to impact or vibrate，therefore, it is necessary to prevent the chromatography column from dropping or violent collision.

- If the pressure increases during detection (About 4.0Mpa higher than the initial pressure), the in-line filter should be replaced immediately. If the pressure does not drop, it is necessary to replace the chromatography column.

2.6.3 Filter

The filter screen plate inside is to filtrate impurities in the liquid path and in the blood, prevent decrease of liquid path flow rate and increase of pressure caused by obstruction of the chromatography column, and ensure the stability and reliability of the system.

The filter has a service life for 400T. When system pressure is too high and alarm occurs, please replace the filter promptly. Sample testing is not supported 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 respectively used for quality control and calibration of the analyzer. 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 Lifotronic; please purchase them from Lifotronic or agents designated by Lifotronic.

Chapter 3 Operating Principle

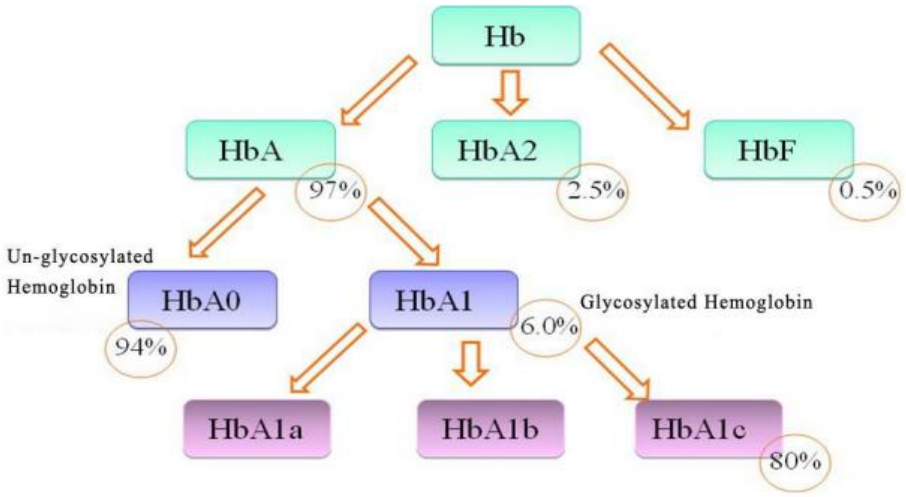
3.1 Overview

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 HbA1c 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.

GH-900Plus Analyser adopts Liquid Chromatography method to measure the level of HbA1a, HbA1b, LA1c, HbA1c and HbA0. And the Analyzer calculates the rest items.

3.2 Aspirating Samples

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

In the case of testing venous whole blood, the analyzer aspirates about 10μl of whole blood sample to the dilution tank , mix thoroughly and then inject for testing.

In the case of testing diluted sample , it is suggested that the sample should be diluted according to the default ratio of whole blood: L liquid = 1: 75. As the analyzer aspirates 400μl of sample at a single time , the dilution ratio is 1:75. The requirement of the analyzer for the volume of diluted blood sample ≤ 5μl.

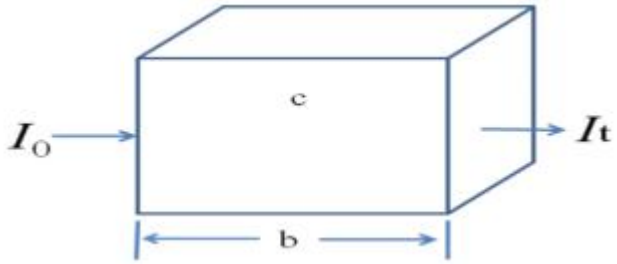
3.3 Measurement

3.3.1 Ion Exchange Theory

The glycosylation of hemoglobin will lose cation on hemoglobin surface. The ion concentration increases and (or) PH decreases in low level cation-exchanger. When passing through cation-exchange column, the hemoglobin will be absorbed by resin which was balanced by acidic buffer. Since the charges of different glycosylated hemoglobin and un-glycosylated hemoglobin, absorbing forces will be different. The less cation of glycosylated hemoglobin means the less absorbing force. On the contrary, the cation level of un-glycosylated hemoglobin is high. Elute those glycosylated hemoglobin with different buffer solutions in sequence, as HbA1a, HbA1b, HbA1c. The strongest absorbing force of HbA0 will be eluted in the end.

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 I0, the transmission light intensity as It, the solution concentration as c, and the thickness of liquid as b. See the absorbing schematic diagram below.



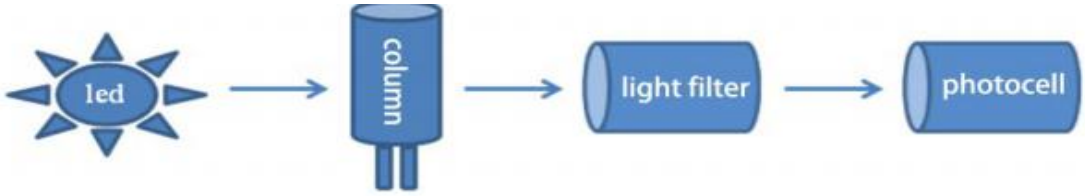
Picture 3-2 Absorbing Schematic Diagram

Written as：

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

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 transmit a cuvette, it will be absorbed by photocell after passing through a 415nm band pass filter. 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:

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

In the equation above, E0 means incident light potential; Et 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 column automatically.

Chapter 4 Analyzer Installation

4.1 Overview



- Unpacking or installation should be performed by personnel authorized or trained by Lifotronic; 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 Lifotronic's Customer Service personnel or the local agent immediately.

4.2 Installation Requirements

4.2.1 Environmental Requirements



- 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℃~30℃	0℃~55℃
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 ≥50cm between the wall and the left and right doors of the analyzer;
- Reserve a spacing ≥50cm between the wall and the rear door of the analyzer;
- Reserve a spacing of at least 60cm above the analyzer;
- The surface where the analyzer is placed should have a bearing capacity of at least 60kg;
- 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 there are major hidden dangers.
- If the operator repeatedly switches the power switch of the analyzer for a short time, the hardware circuit of the analyzer may be damaged.

CAUTION

- 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~	50Hz/60Hz	120VA

4.3 Handling Method

- Remove all reagents prior to handling and transportation.
- If the analyzer has been used, confirm that the liquid path is emptied prior to handling.
- A trolley or other transportation means can be used for short-distance transportation on a smooth road.
- During handling and transportation, take care to protect the display screen and the sampling needle from external force and ensure that they will not come into contact with other objects.
- During handling and transportation, keep the analyzer upright and avoid vibration; do not tilt the analyzer. After handling, check and debug the analyzer before use.
- During handling, put your hands at the bottom of the analyzer; apply uniform force to hold the analyzer, and gently place it at the specified position.

ATTENTION

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

4.4 Installation Steps

WARNING

- The sampling needle is sharp. Bio-contaminated blood samples may remain on the sample compartment, sampling needle, chromatography 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 Cable Tie Fixing the 2D arm

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

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

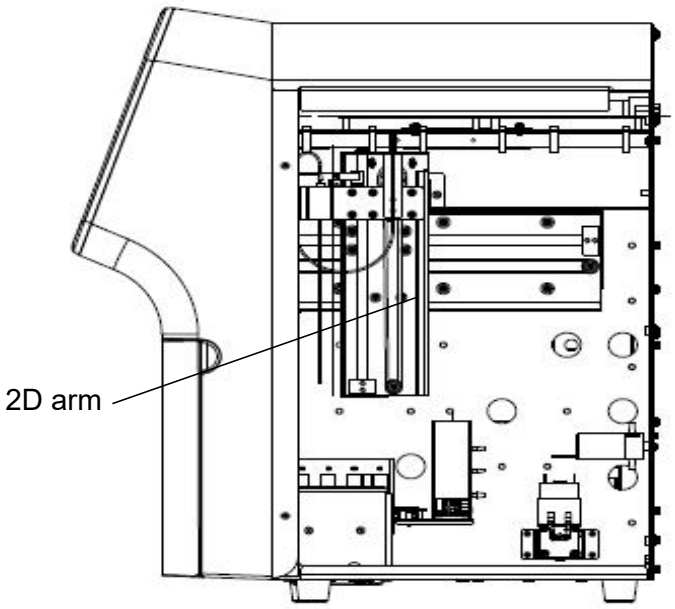


Fig. 4-1 View after Opening the Right Door

2.Use a pair of cutting pliers to cut the cable tie which fixing the 2D arms, and remove the cable tie.

4.4.2 Reagent Connection

Take the bottle cap components from the accessories and insert them to eluents A and B respectively, Tighten the cap firmly .

WARNING

- The operator is obliged to comply with the local and national regulations on discharge and disposal of expired reagents, liquid waste, waste samples, consumables, etc.
- Reagents may irritate eyes, skin and mucosa . When contacting reagent-related articles 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 regent, 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

- Only use reagents designated by the manufacturer.
- Different batches of reagents can not be mixed to use.
- The reagents should be shelved before use.
- Ensure that the reagent and chromatography column are used within shelf life.
- After the reagent is connected to the analyzer, 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 reagent component from the accessories; connect one end to the hemolytic agent connector on the back of the analyzer and insert the other end into the hemolytic agent bucket;

Take the Waste Liquid Connecting Tube 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 Filter and Chromatography Column

ATTENTION

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

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

Procedure

1) Take the chromatography column out of the packaging box, and remove the retaining plugs connected at both ends of the column. Please keep the retaining plugs properly for future use;
2) Open the chromatography column oven after confirming that the analyzer has stopped delivering liquid; open the hand-tight connectors connected at both ends of the chromatography column; take out the used chromatography column;
3) Enter the System -> Maintenance interface; open SV1, and start the high pressure pump; confirm that the pump stops working after liquid flows out of the connecting pipe of chromatography column. At this moment, use rags or other items to block liquid flowing out of the tube; take care to avoid liquid leaks to the main unit of the analyzer.

4) Confirm the liquid delivery direction of the chromatography column (the arrow direction -> indicated on the label attached to the chromatography column) the same with the label on the column oven ; connect the pipe to the inlet end of the column; start the high pressure pump through interface operation to confirm whether any liquid flows out of the outlet end of the chromatography column; stop the pump, and connect the tube at the outlet end of the chromatography column.

5)Start the high pressure pump; check that the pressure gradually increases till it reaches a steady state and that no leakage is detected at the pipe connection; stop the high pressure pump and close SV1.

6) In the Reset Counter area of the maintenance interface, reset the chromatography column counter by scanning the code with a barcode scanner or manually entering the serial number refer to the label attached to the packaging box of the chromatography column.

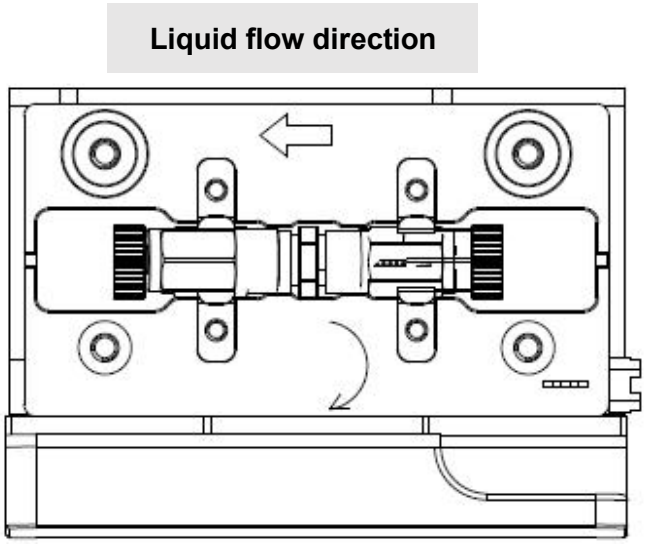


Fig. 4-2 Installation of chromatography column

Turn open the filter knob; place the filter in the holder with its smaller end facing downward; tighten the knob clockwise; then open SV1 at the system maintenance interface, and start the high pressure pump. Carefully observe whether the filter leaks; if yes, tighten the knob again until liquid leakage disappears.

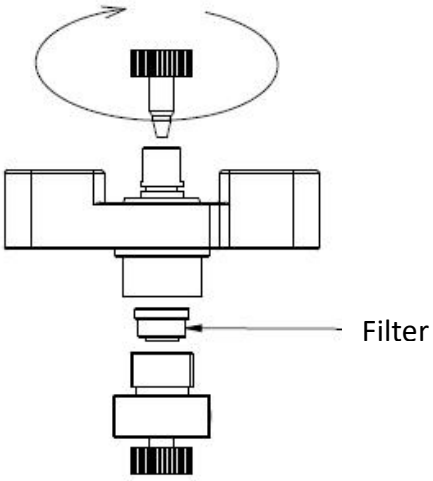


Fig. 4-3 Installation of filter

4.4.5 Loading of Recording Paper

Pull open the printer lever outward to open the printer door. Load recording paper into the paper cavity in the direction shown in **Fig. 4-4**, with the paper end positioned outside the paper outlet. Close the printer door; check the position of recording paper to ensure that the recording paper is aligned with the paper outlet.

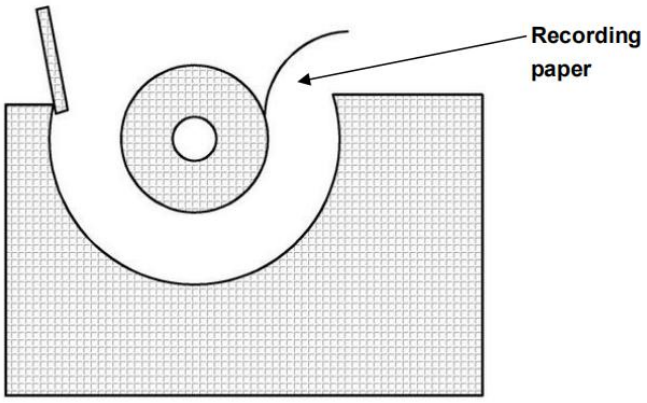


Fig. 4-4 Loading of Recording Paper

4.4.6 Installation of Power Adapter

Take the three-wire power adapter out of the accessory box; insert one end of the power cord into the power socket of the power adapter, and the other end to the power outlet; insert the output terminal of the power adapter into the power input socket on the back of the analyzer.

4.5 Initial Startup

Switch on the power switch on the back of the analyzer. The system will enter the

login interface after executing the self-check and cleaning process. And the user logs in, then enters the test interface:

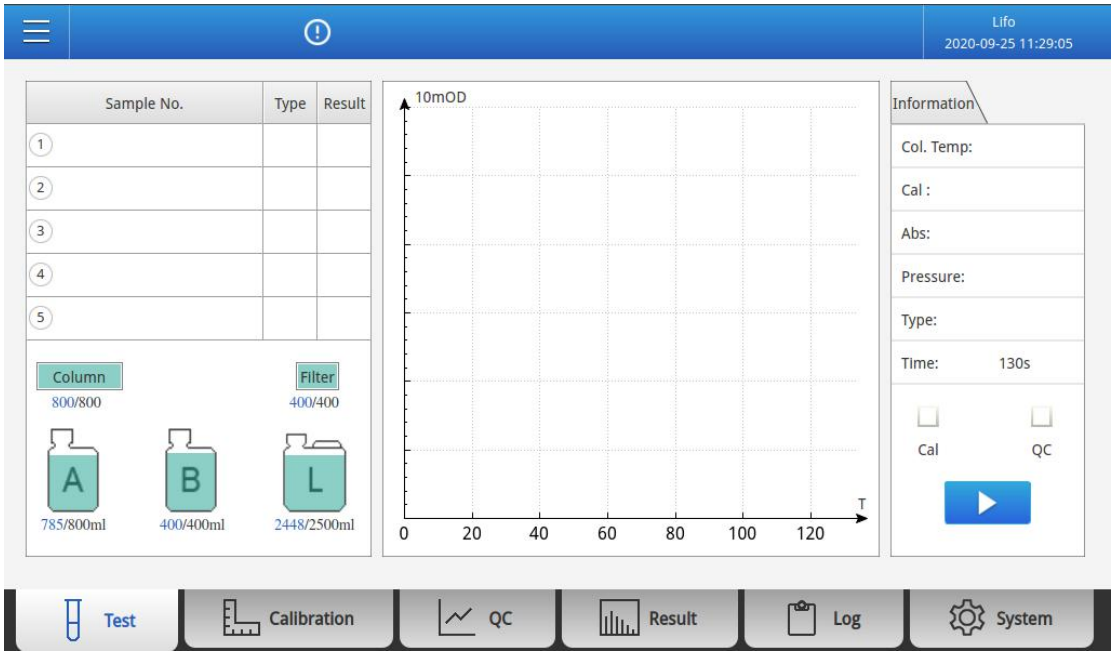


Fig. 4-5 Test Interface

Enter the test interface, this page shows the remaining volumes of the two eluents and hemolytic agent L, the number of available tests of the chromatography columns and filters.

■ Number of Tests of Chromatography Column

Chromatography columns are consumable materials; the number of available test is 800T (not cover calibration analysis and QC analysis) . Every time a sample is analyzed, the number of available test by the chromatography column automatically decreases by one. If the number of available test by the chromatography column reaches the lower limit, the chromatography column should be replaced by a new one. Otherwise the test cannot be started.

■ Number of Tests per Filter

Filters are consumable materials; the number of available test is 400T (not including calibration analysis and QC analysis). Every time a sample is analyzed, the number of available test by the filter automatically decreases by one. If the number of available test by the filter reaches lower limit, the filter should be replaced. Otherwise the test cannot be started.

Click “**System”** button to enter the system interface:

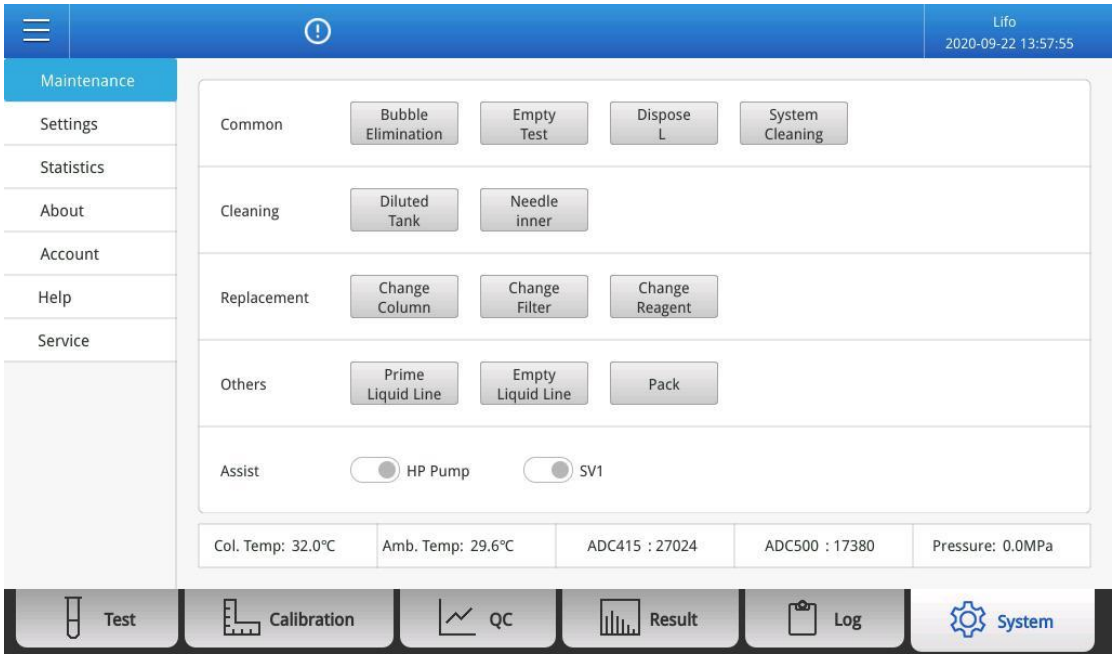


Fig. 4-6 System Interface

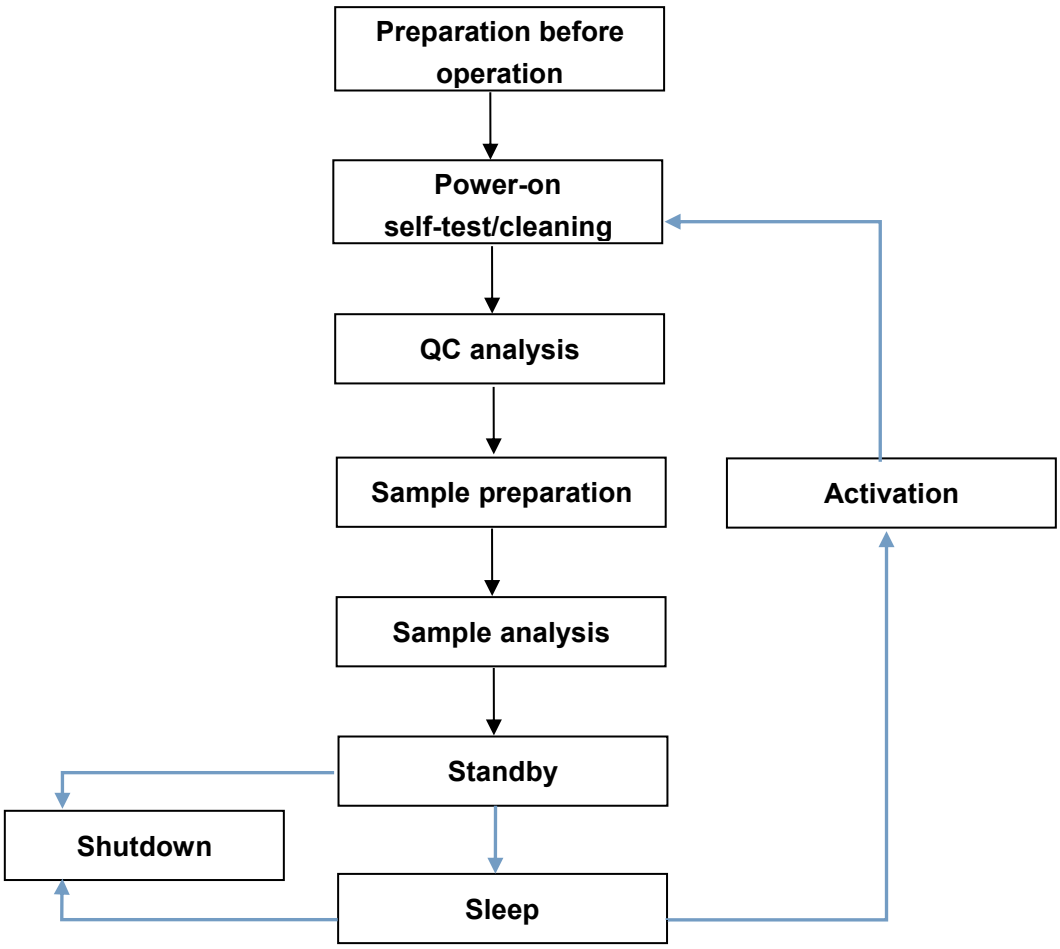
Click the "**Prime Liquid Line**" button,when liquid path perfusion is completed, click the "**Bubble Elimination**" button to eliminate air bubbles in the high pressure pump; execute the "**Empty Test**" operation. In case of other malfunctions during operation, please see "**Chapter 11 Troubleshooting**" in this manual.

Chapter 5 Routine Operations

5.1 Overview

This chapter introduces the whole process of routine operations from startup to shutdown of the analyzer, and focuses on description of the operation process of sample analysis in whole blood sample mode and pre-diluted blood mode.

Below is the process of routine operations:



5.2 Preparation before Operation

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



- Samples, QC materials, calibrators, chromatography columns, filters and waste liquid can be biologically infectious. When contacting relevant articles 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, liquid waste, waste samples, consumables, etc.
- Use of the analyzer without following the methods specified by the manufacturer may damage the analyzer.

■ **Check the residual volume of reagent**

Check whether the residual volumes of eluents A and B and hemolytic agent L are sufficient.

■ **Check the waste liquid bucket**

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

■ **Check the liquid tube and power supply**

Check that the reagent and waste liquid tubes are not bent and the connection is reliable.

Check the analyzer for liquid leakage.

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

■ **Check the printer**

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

5.3 Power on

Turning main power on which is at the back of analyzer.

The side marked “ON” indicates power on,and the side marked “OFF” indicates power off.

Procedure

1) Turn on the main power and messages on the **Fig. 5-1** will appear.



Fig. 5-1 Just after turning on the Main Power

2) The analyzer will enter the self-check and cleaning process.

3) After executing the self-check and cleaning process, the login interface will be displayed, then user logs in.

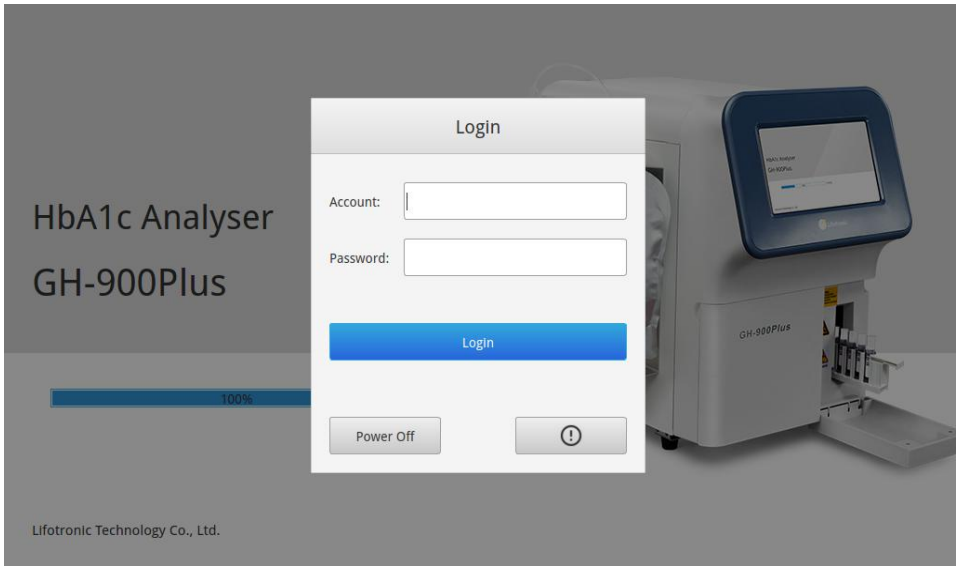


Fig. 5-2 Login Interface

4)Then enter the Test interface after logging in and **Fig. 5-3** is displayed.

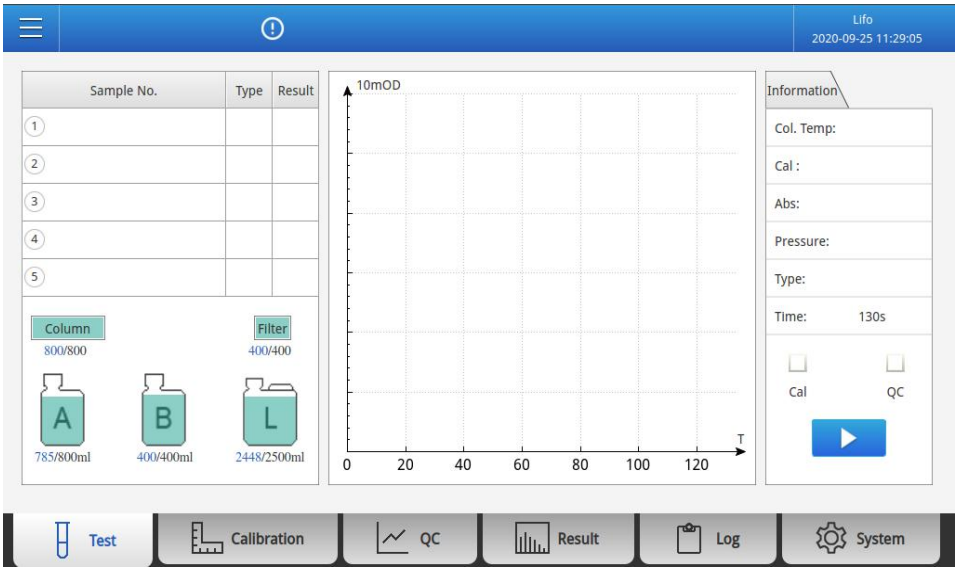


Fig. 5-3 Test Interface

5.4 Daily QC

Before sample analysis, the analyzer should be subject to QC analysis every day 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, chromatography columns, filters and waste liquid can be biologically infectious. When contacting relevant articles 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 patients' 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 K2EDTA,K3-EDTA,NA2-EDTA and sodium fluoride anticoagulant.
- For blood collection, use only disposable products with specifications specified by the manufacturer, such as vacuum blood collection tubes, centrifuge tubes, and capillary tubes.

5.5.1 Whole Blood Samples

The blood collection tubes with rubber caps can be directly placed on the sample rack but must remove the rubber caps of tubes before performing the test. The dimensions of blood collection tubes available are Φ12~15 wide and 75~100mm high.

Whole blood samples are prepared as follows:

Procedure

1)Use recommended vacuum tubes with anticoagulant to collect venous blood samples.

2)Rapidly and fully mix venous blood and anticoagulant in each tube.

3)Place the blood collection tubes in the sample rack after mixing it upside down for three times (if conditions permit, the oscillator is recommended), then remove the rubber caps of the tubes and perform the test on the analyzer.

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℃~8℃) 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 deviation, bending or fracture of the sampling needle during sampling. Please use blood collection tubes with diameters within the recommended range.
- **Make sure to remove the rubber cap of the blood collection tube before performing the test.**
- If blood in the venous blood collection tube contains air bubbles, lumps or floccules, the sampling needle cannot aspirate the sample and retest if the test result is <3%.

5.5.2 Pre-diluted Samples

If the blood sample volume is too small or the haematocrit is low, the error (e1) indicating the area of chromatogram determined by the analyzer is too small will occur. If the result marked “e1” , dilute the sample as required, and analyze the sample again in the pre-diluted mode.

Pre-diluted samples are prepared including two ways as follows:

About the first way

Procedure

1) As required in the Laboratory Quality Management Practices, add a certain volume of sample (10μL recommended) to a 1.5 mL EP tube.

2)Use a pipette to add 750μL of hemolytic agent L to the EP tube (i.e. a dilution ratio of 1:75 between the sample and hemolytic agent L); then mix them evenly.

3)Before performing the test on the analyzer, the cap of EP tube should be cut off.

About the second way

Procedure

1)As required in the Laboratory Quality Management Practices, add a certain volume of sample (10μL recommended) to a 1.5 mL EP tube.

2)Press ”**Dispose L**” button in the System interface and **Fig. 5-4** is displayed.

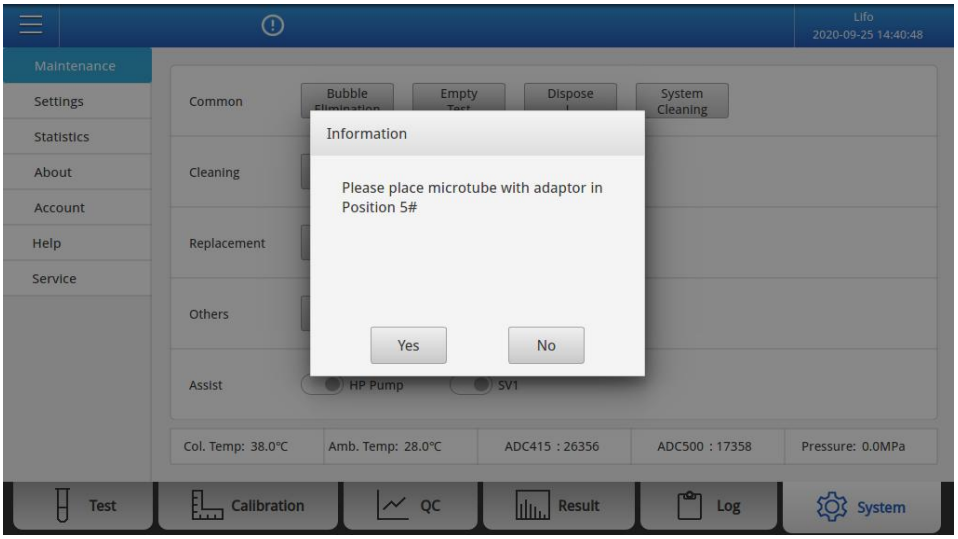


Fig. 5-4 System Interface

3)According to the information , place the EP tube with holder on position 5# of the sample rack.Then click “**Yes**” button.

4)The analyzer will automatically aspirate 750 μL of hemolytic agent L to the EP tube (i.e. a dilution ratio of 1:75 between the sample and hemolytic agent); then mix them evenly.

5)Before performing the test on the analyzer, the cap of EP tube should be cut off.

ATTENTION

- When there is not enough sample for the test in whole blood mode, which leads to the “Small Total Area” alarm, use a pipette to dilute the sample with hemolytic agent to a ratio of 1:75; then mix them evenly and retest.
- When the “ Small Total Area” alarm is generated due to low haematocrit , dilute the sample at a reduced ratio (e.g., at a ratio of 1:50 between the blood sample and hemolytic agent); then mix them evenly and retest.
- 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 method and technical level.
- In order to ensure the accuracy of analysis results, the residual volume of diluted sample in the pre-dilution mode should not be less than 0.5mL.

5.6 Sample Analysis

Sample request is required before sample analysis .

Sample request is including two ways,manual input and barcode scanner reading.

When manual input selected, edit the sample ID in the test interface. Only edit the sample ID for the position where sample has been placed. When barcode scanner reading selected, use the scanner to read the label on the blood collection tube and the sample ID will be automatically read into the ID field.

After the analysis process is completed, the analyzed results will be displayed on the test interface and will not be emptied. If user needs to retest, there is no need to delete the sample ID one bye one, only need to edit the new ID correspondingly; then start. The analyzer will automatically update the status of each sample with different color. When the sample rack is pulled out, all information on the interface will be cleared.

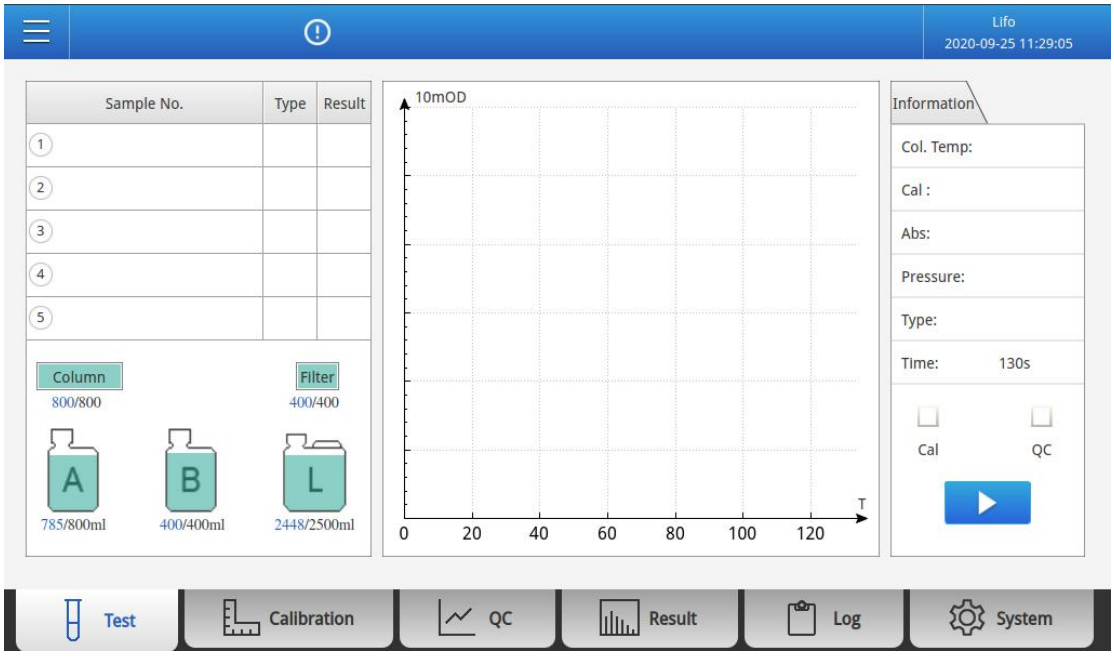


Fig. 5-5 Test Interface

Procedure

1)Input the sample ID (manually edit or barcode scanner reading) in the "Sample No." column of the test interface.

2)Select the corresponding sample type (Whole blood sample or Diluted sample) in the "Type" column. The sample type information input must be consistent with the actual sample type placed in the sample rack. The meaning of "W" indicates Whole blood sample, and the meaning of "D" indicates Diluted sample.

3)Place samples in the sample rack. For whole blood samples, make sure to remove the caps of tubes before test.

4)Open the sample compartment door and place the sample rack.

5)Then close the compartment door.

6)Press the ""key on the right bottom of the test interface (first screen).

7)The analyzer automatically performs sample analysis after the sample is aspirated by the sampling needle.

8)A single sample analysis is taken 130s to complete and the result will be displayed on the interface and stored.

About the status of sample

- "Orange" indicates testing
- "Green" indicates test completed
- "Red" indicates test failed
- "Blue" indicates test waiting

About the alarms

When the system detects low pressure, high pressure, insufficient consumable and fan broken , the alarm will occur, and this symbol "" will keep flashing and generate a "**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. 5-6**).

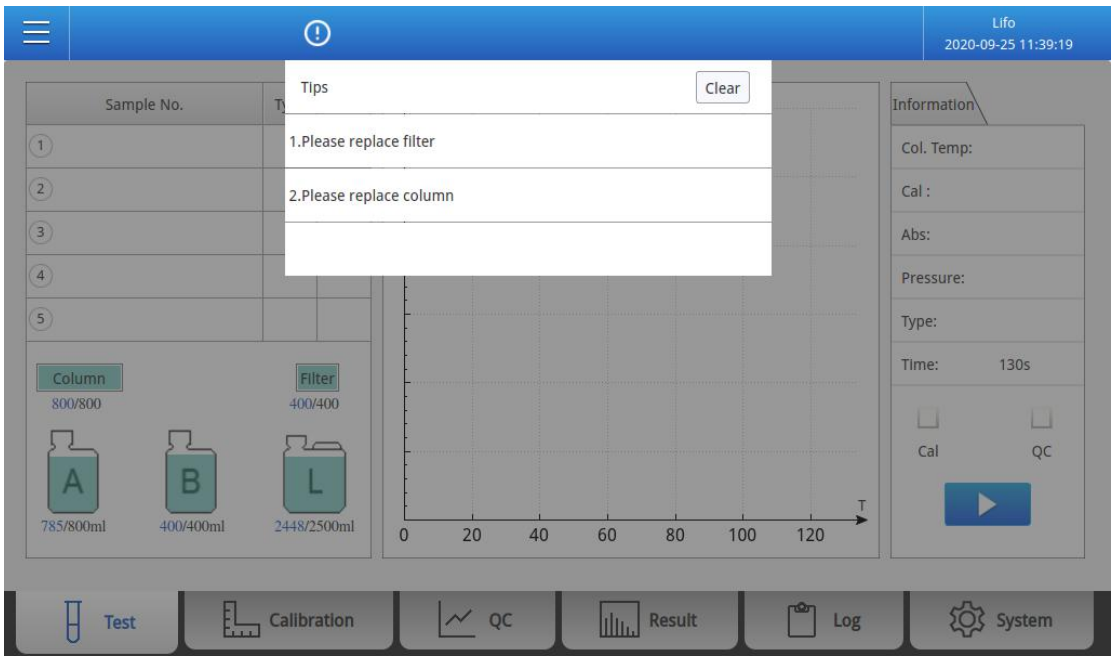


Fig. 5-6 alarm Interface

■ **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 current test is executed.

■ **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 and B, hemolytic agent L , filter and chromatography column. Consumable insufficient alarms include : A insufficient, B insufficient, L insufficient, Filter count insufficient and Column count insufficient. When the remaining amount of reagent is less than or equal to 10% of the total and chromatography column or filter are equal to 0 , an alarm will be given. If the available remaining amount is greater than the amount of reagents consumed when applying for samples, the test can be started normally. If the remaining amount of reagent is less than the amount required by the applied sample, the alarm will also be occurred and the test can not be started until the reagent

amount is reset .

ATTENTION

- When doing a whole blood sample test, the cap of whole blood tube must be removed.
- The maximum length of the sample ID number is 20 digits, if it exceeds 20 digits, the Analyser defaults the first 20 digits as current ID number.
- Do not reuse disposable products.
- Prior to test, please ensure that the sample has been mixed evenly. If the improperly mixed sample is used, the peak area may exceed the given range, which will affect the reproducibility and accuracy of results.
- Samples having been shelved should be remixed evenly prior to analysis.
- If the room temperature is beyond the range of normal operating temperature for the analyzer, the analysis result obtained will be unreliable.



- Samples, QC materials, calibrators, chromatography columns, filters and waste liquid can be biologically infectious. When contacting relevant articles 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 use barcode scanner,Do not look straightly at the light source of the scanner .
- Avoid direct contact with patients' 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 personal injury.
- When the automatic sampler is rotating or the 2D arms are aspirating a sample, it is forbidden to place the sample 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 and 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 and 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 when turn 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, liquid waste, waste samples, etc.

5.8 Replacement of consumables

Sample testing is not supported when the number of tests of remaining reagent is less than the number of sample applications required. Meanwhile, Sample testing is not supported when the remaining usage of the column or filter is 0 and the number of available tests of column or filter is less than the number of sample applications required.

The replacement operation of consumables are as follows:

■ Replacement of column

1)Click the icon of the column in the test interface and relevant information of column will pop up.

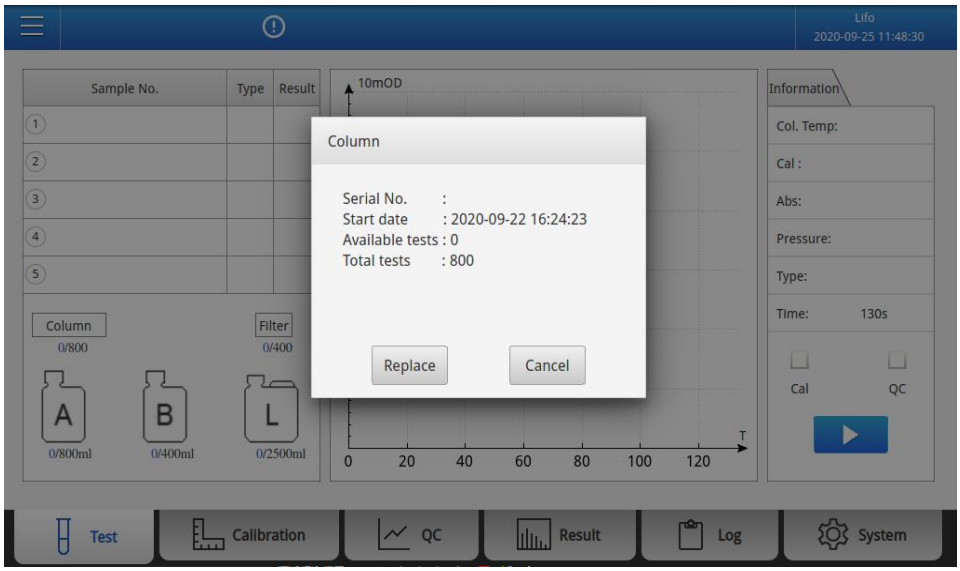


Fig. 5-7 Information of column

2)Click “**Replace**” button, input new serial number and click “**Yes**” button, it prompts “Column reset successfully”, then click “**Yes**” button.The **Fig. 5-8** is displayed.

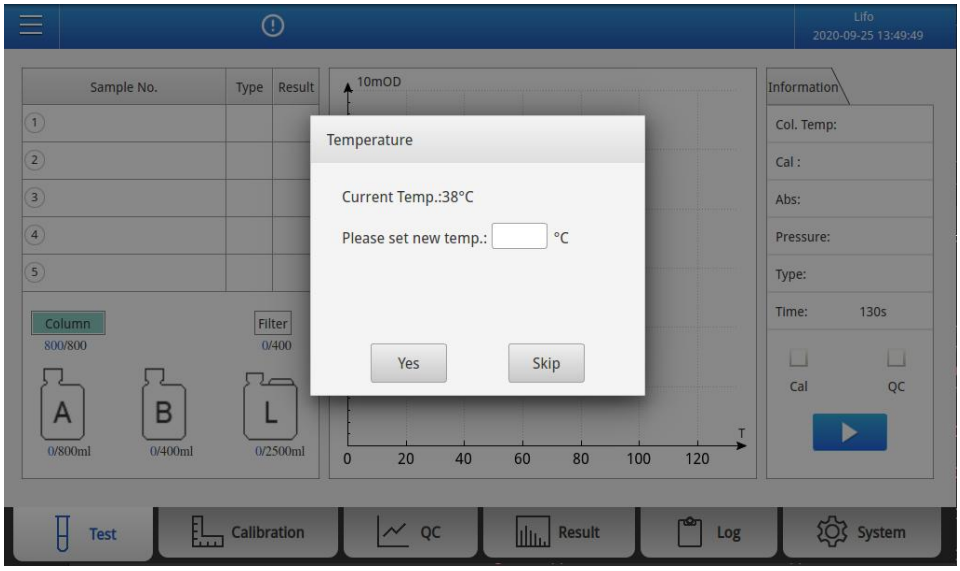


Fig. 5-8 Temperature setting interface

3)According to operating instruction, set the temperature of the new column which refer to the information of label printed on chromatography column packing, then click “**Yes**” button. The **Fig. 5-9** is displayed.

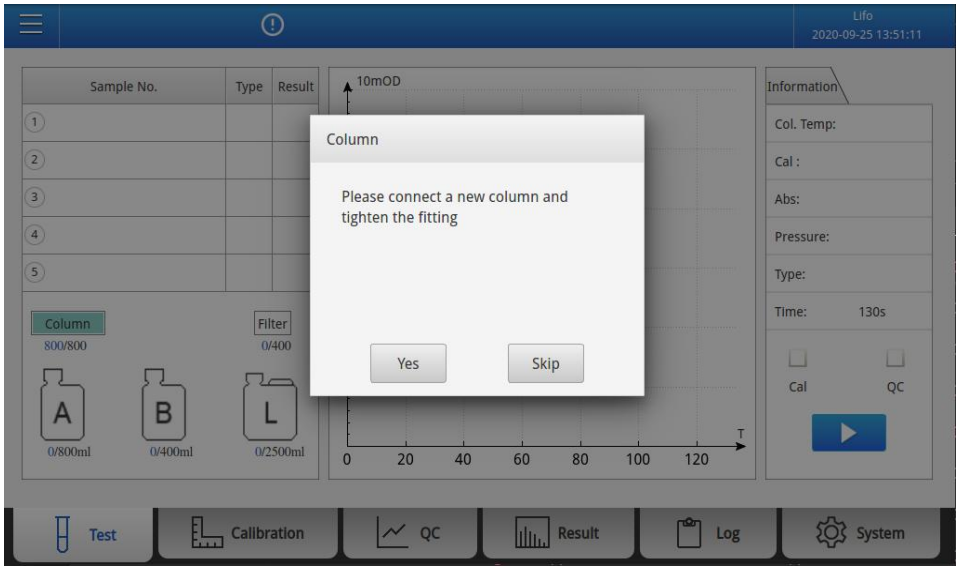


Fig. 5-9 Replacement interface

4)Connect a new column and tighten the fitting, then click ”**Yes**” button .The **Fig. 5-10** is displayed.

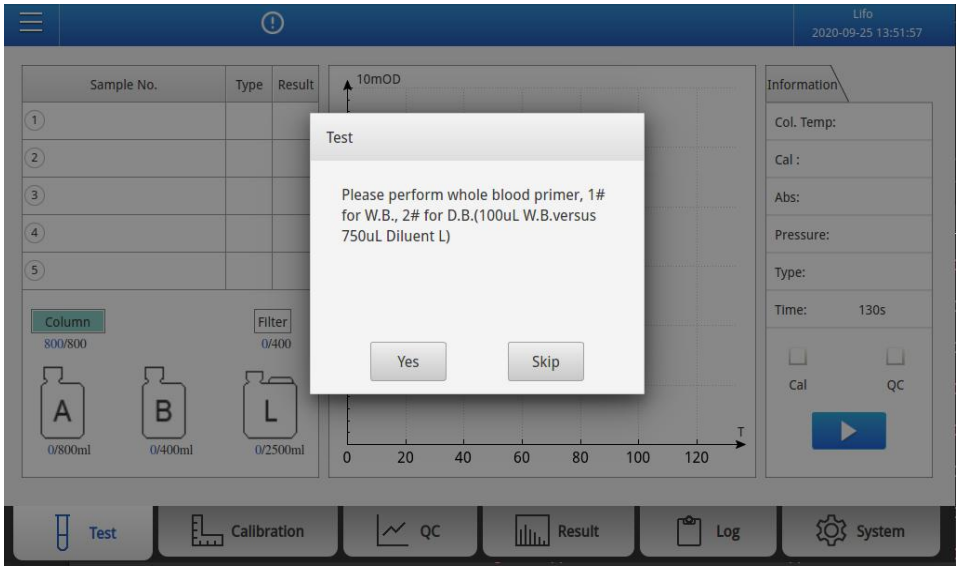


Fig. 5-10 Whole blood perfusion reminder interface

5)According to the operating instruction, perform whole blood primer, position 1# for W.B., position 2# for D.B.(100ul W.B. versus 750ul Diluent L) , then remove the cap of whole blood tube and click **”Yes”** button. The **Fig. 5-11** is displayed.

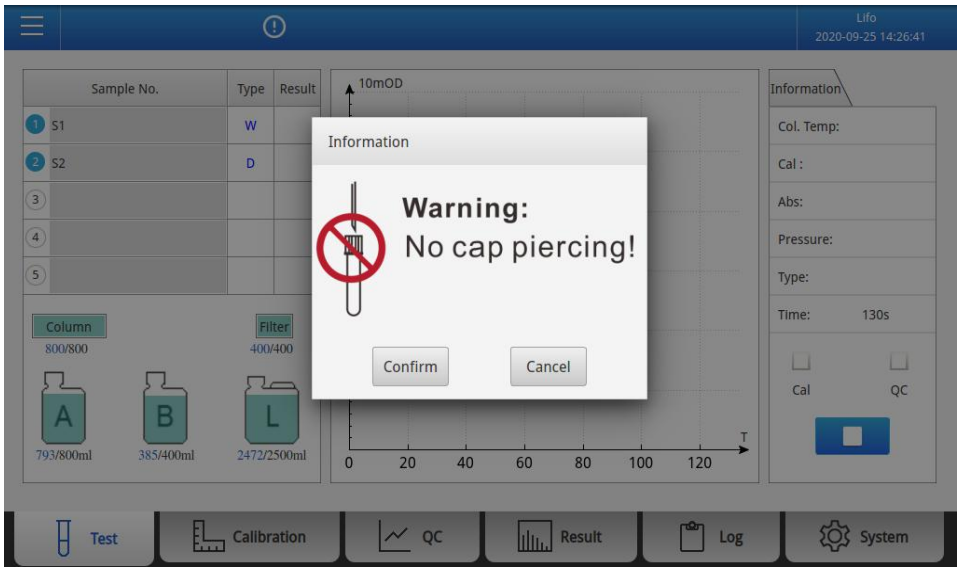


Fig. 5-11 Warning interface

6)Confirm the caps have been removed ,then click "**Confirm**" button to start testing.

■ Replacement of filter

1)Click the icon of the filter in the test interface and relevant information of filter will pop up.

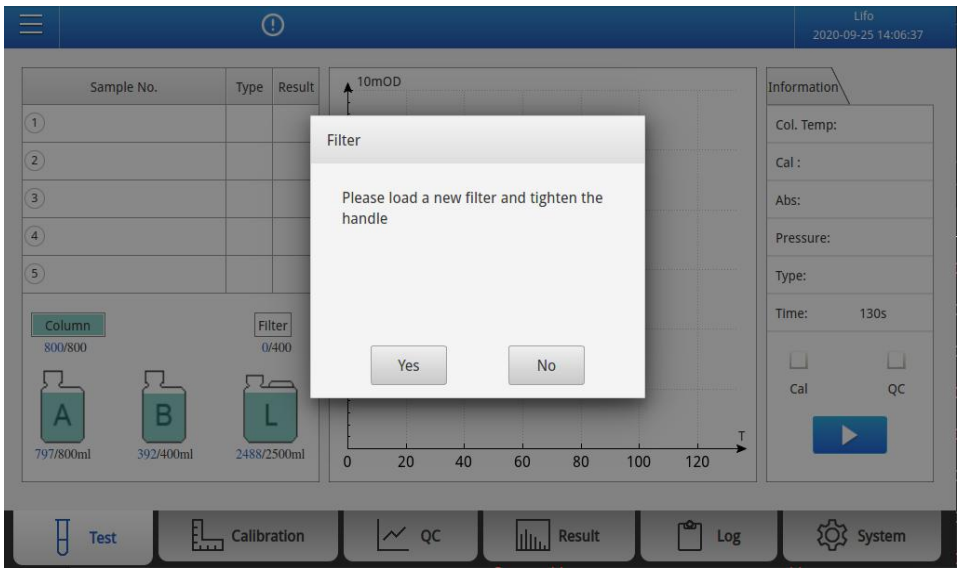


Fig. 5-12 Information of filter

2)Click "**Replace**" button, and according to the operating instrutions, load a new filter and tighten the handle , then click "**Yes**" button.

3)The analyzer will enter system cleaning procedure of about 10minutes.

4)After the completion of system cleaning, the number of the available test of filter will be reset to 400T.

■ Replacement of eluent A

1)Click the icon of the A in the test interface and relevant information of eluent A will pop up.

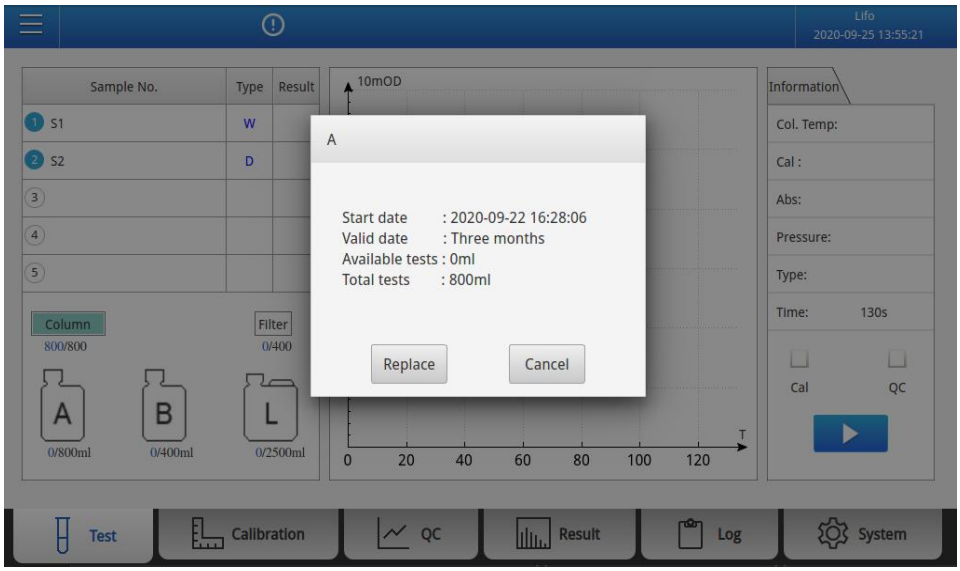


Fig. 5-13 Information of eluent A

2)Replace with new eluent A and click “**Replace**” button. The **Fig. 5-14** will be displayed.

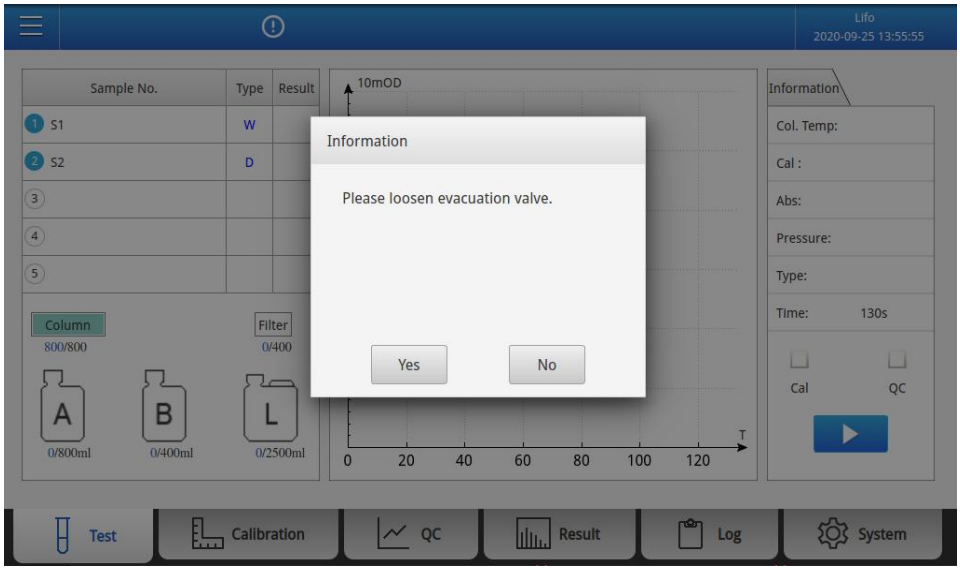


Fig. 5-14 After click “Replace”button

3)According to the operating instrutions, loosen evacuation valve, then click “**Yes**” button. The **Fig. 5-15** is displayed.

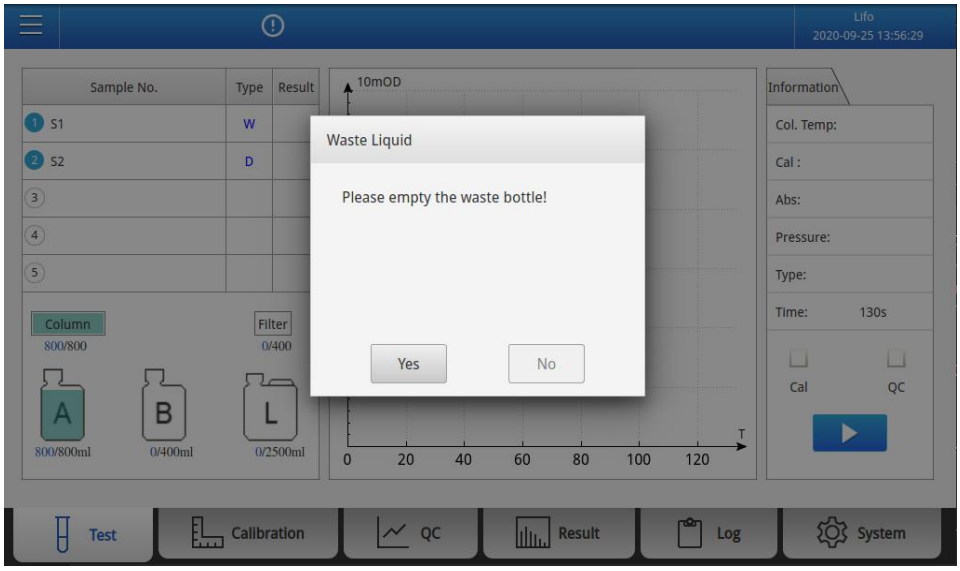


Fig. 5-15 After click "Yes"button

4)Empty the waste bottle, then click "**Yes**" button. (A waste bottle can only hold a single load of reagents). The **Fig.5-16** is displayed.

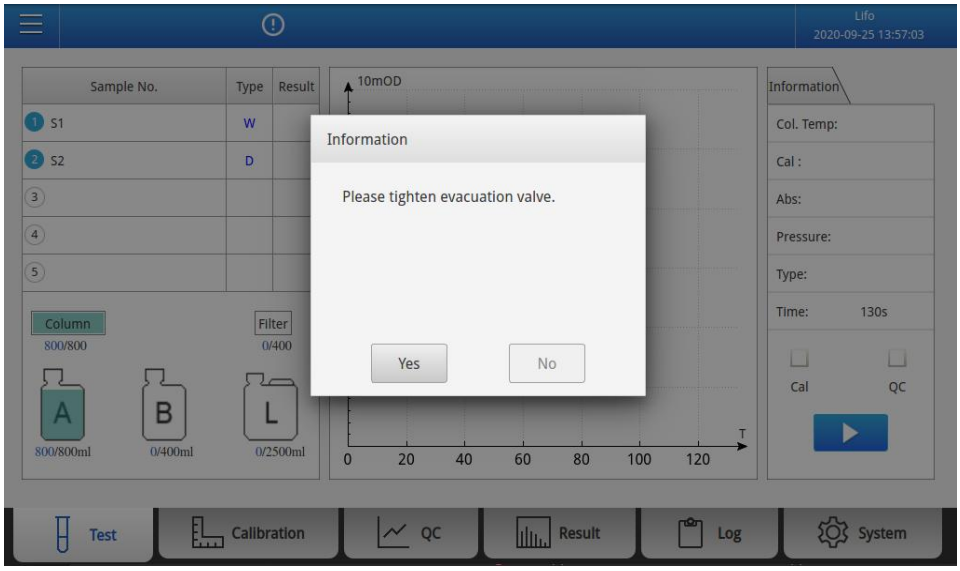


Fig. 5-16 After click "Yes"button

5)According to the operating instruction ,tighten evacuation valve and remainning capacity will be filled out .

■ Replacement of eluent B

1)Click the icon of the B in the test interface and relevant information of eluent B will pop up.

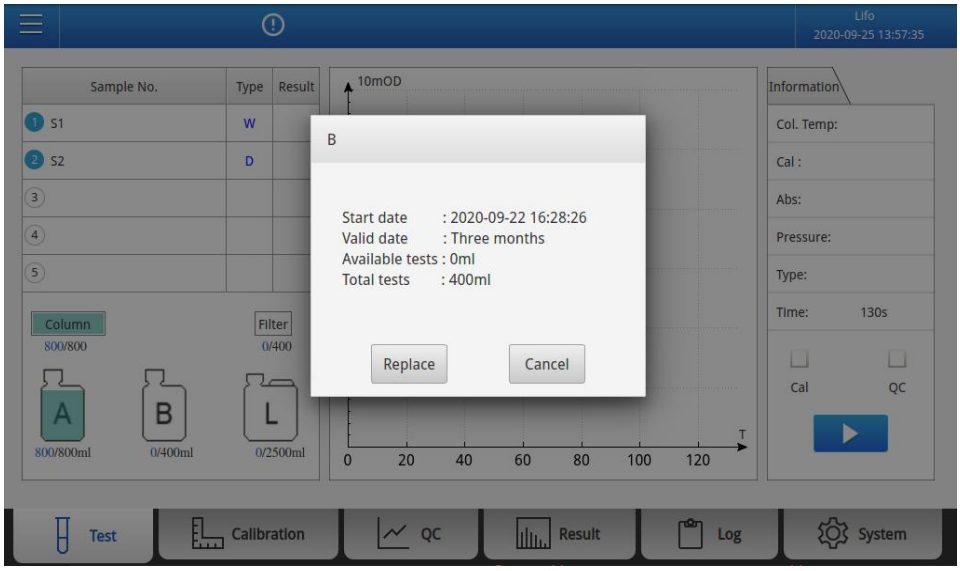


Fig. 5-17 Information of eluent B

2)Replace with new eluent B and click “**Replace**” button. The **Fig. 5-18** will be displayed.

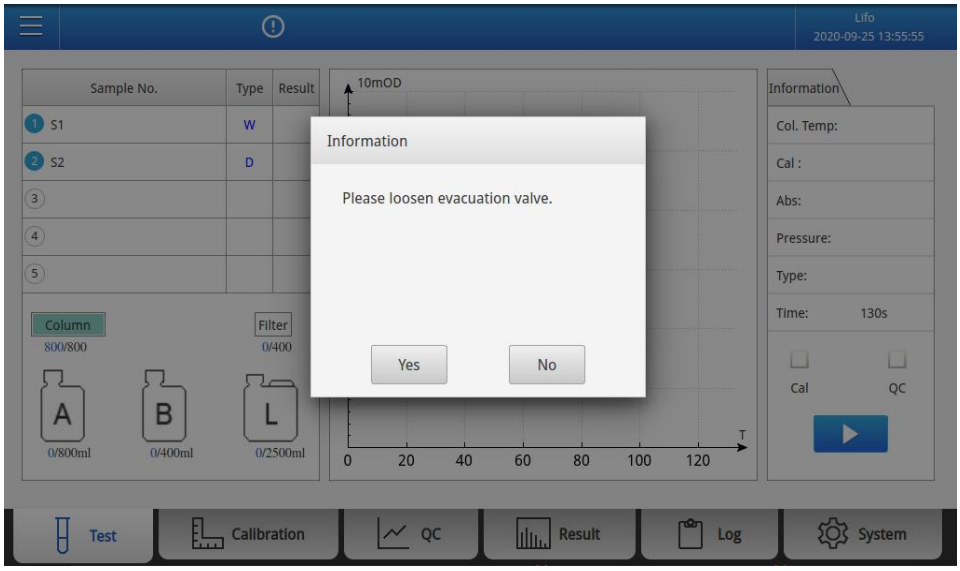


Fig. 5-18 After click “Replace”button

3)According to the operating instrutions, loosen evacuation valve, then click “**Yes**” button. The **Fig. 5-19** is displayed.

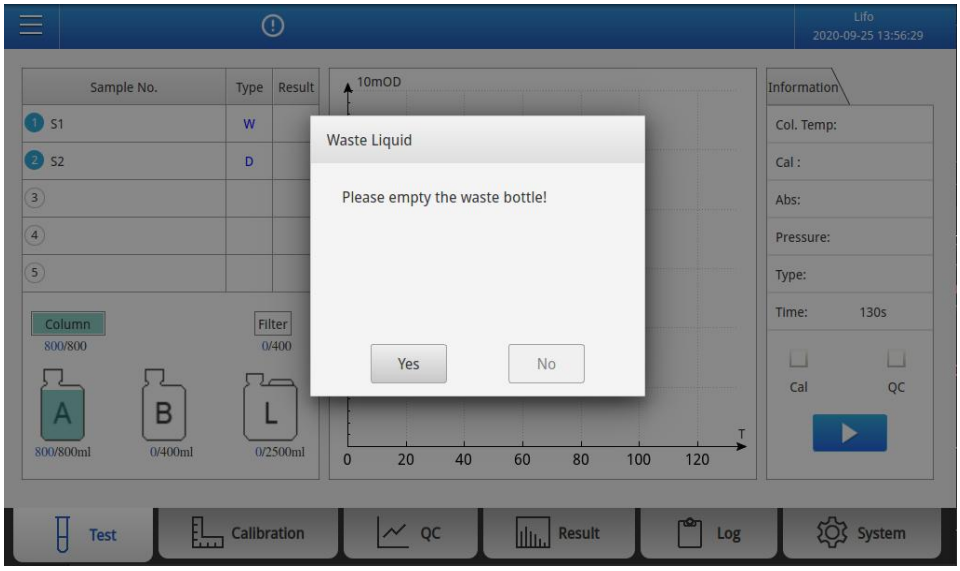


Fig. 5-19 After click "Yes"button

4)Empty the waste bottle, then click "**Yes**" button. (A waste bottle can only hold a single load of reagents). The **Fig.5-20** is displayed.

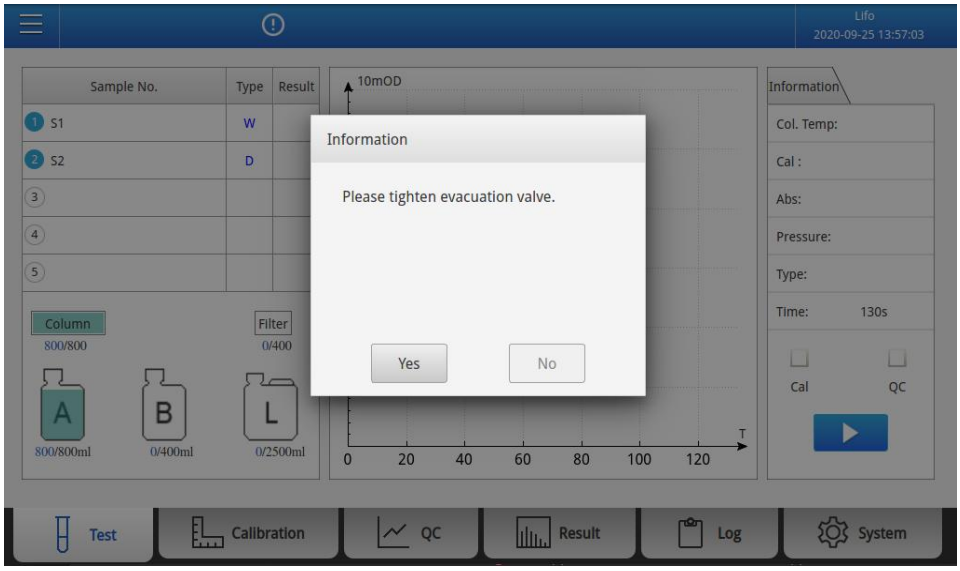


Fig. 5-20 After click "Yes"button

5)According to the operating instrutions , tighten evacuation valve and remainning capacity will be filled out .

■ Replacement of hemolytic L

1)Click the icon of the L in the test interface and relevant information of hemolytic L will pop up.

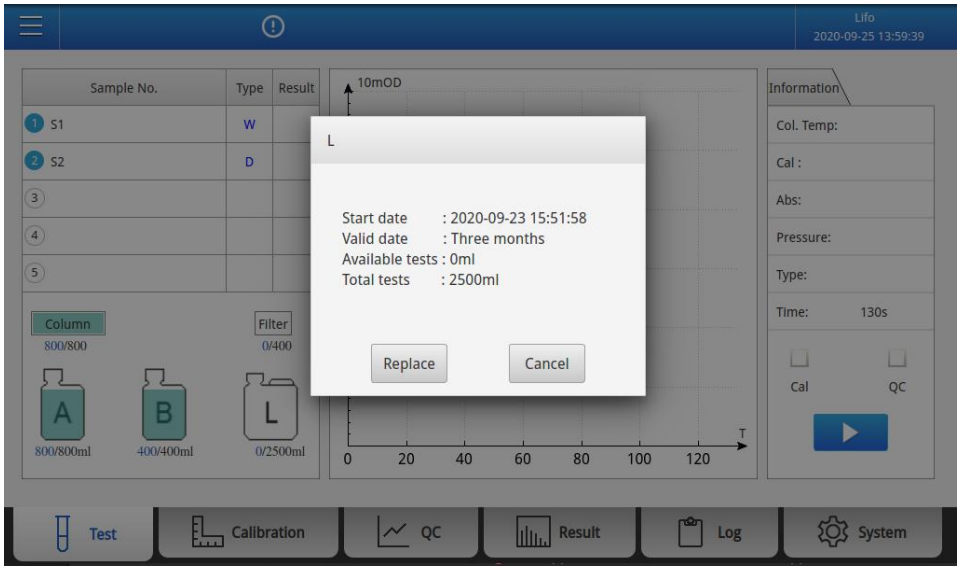


Fig. 5-21 Information of hemolytic L

2)Replace with new hemolytic agent L and click “**Replace**” button.The **Fig. 5-22** will be displayed.

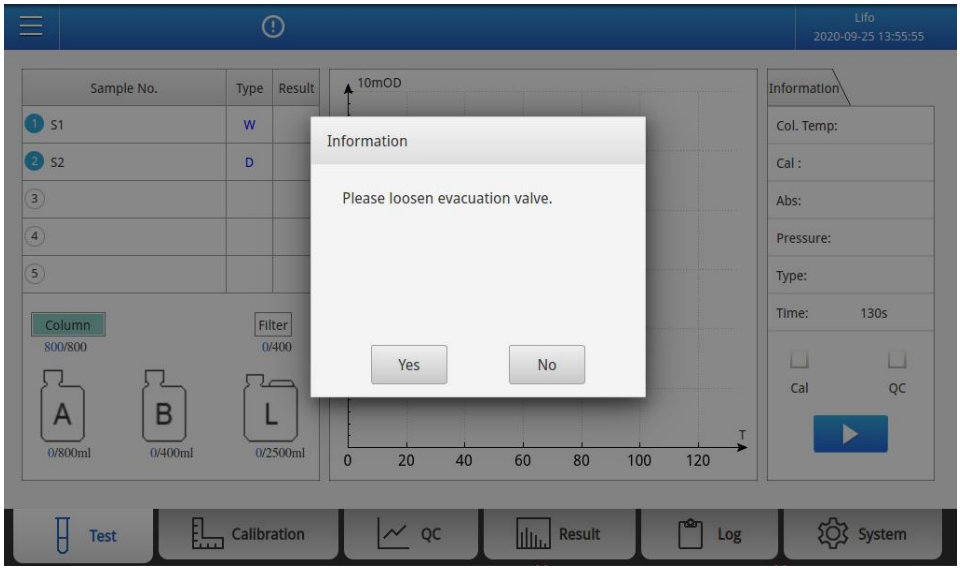


Fig. 5-22 After click “Replace”button

3)According to the operating instrutions, loosen evacuation valve,then click “**Yes**” button.The **Fig. 5-23** is displayed.

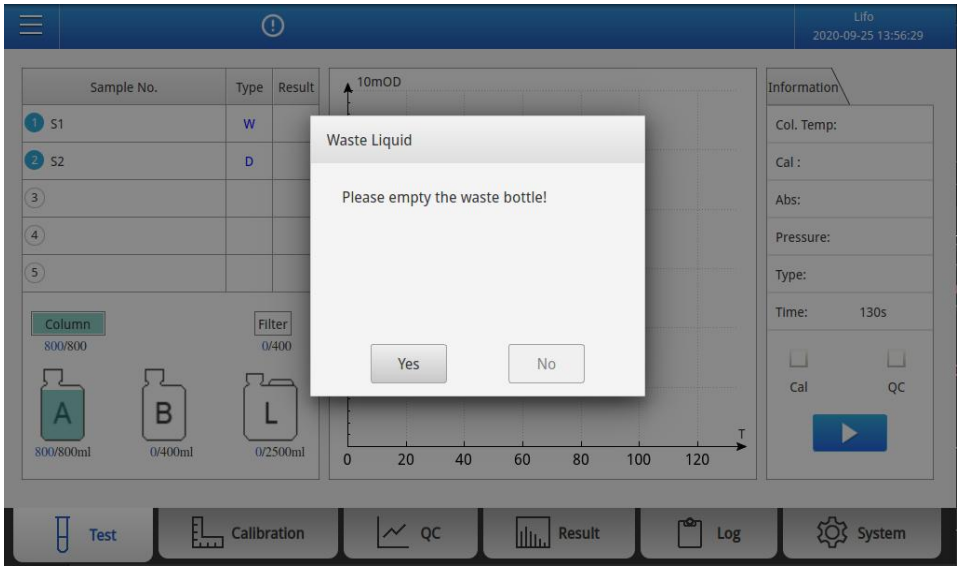


Fig. 5-23 After click "Yes"button

4)Empty the waste bottle then click "**Yes**" button. (A waste bottle can only hold a single load of reagents). The **Fig. 5-24** is displayed.

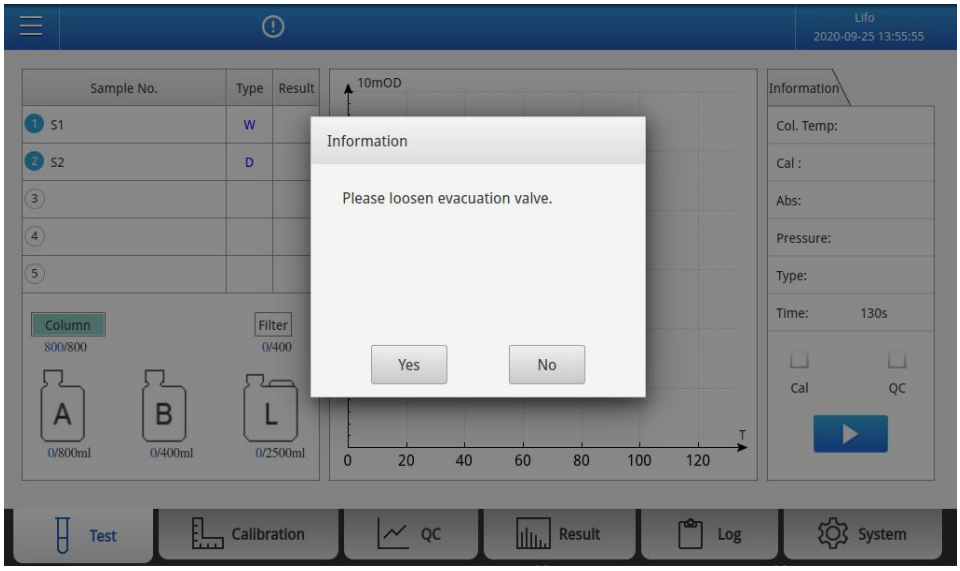


Fig. 5-24 After click "Yes"button

5)According to the operating instrutions, tighten evacuation valve and remainning capacity will be filled out.

5.9 Cleaning and Disinfection of Analyzer

Daily cleaning method: Use a clean cloth dipped in clean water or soapy water to clean the analyzer.

If you are in doubt about the compatibility of disinfectants or cleaning solution with analyzer components or materials contained in the analyzer, please contact the manufacturer or agent.

The detailed cleaning and disinfection methods are shown in **table 5-1.**

No.	**Part**	**Prepare before cleaning**	**Disinfectant Recommended**	**Steps**	**Precautions**	**Disinfection cycle**
1	Host shell, Touch screen	Turn off the power switch ,unplug the power cord	Neutral disinfectants Recommended : alcohol disinfectants (containing ethanol, isopropanol, n-propanol, or a combination of two components), chlorhexidine.	1. The external routine cleaning main unit and components shall be executed in general first ; 2. According to the operating instructions of the disinfectant to mix the concentration of disinfectant ; 3. Use a clean cotton cloth dipped in a small amount of neutral solution (only slightly wet) to wipe and disinfect; 4. Please disinfect according to the operating instructions and	1. Disinfection method is not recommended: boiling disinfection (high temperature), strong oxidizing disinfectant, strong acid and alkaline disinfectant and other corrosive liquids ; 2. The surface of the main unit and components should not be wiped with	weekly
2	Near evacuation valve, colu-mn oven and In-line filter	Turn off the power switch and disconnect the socket,use a clean cotton cloth to wipe off the dirt near the evacuation valve,column oven and In-line filter				monthly

				duration requirements of the cleaning solution; 5. Replace the clean cotton cloth to wipe off the residual disinfectant after disinfection ,and ensure that the wiping part is dry before power on .	hard and rough goods; 3. Do not dip too much cleaning solution; 4. It is forbidden to use flushing method.	

Chapter 6 Result Review

6.1 Overview

The analyzer will automatically store the analysis result in the database once a sample analysis is completed. The analyzer database can store up to 10000 samples (including all testing parameters and chromatograms) 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:

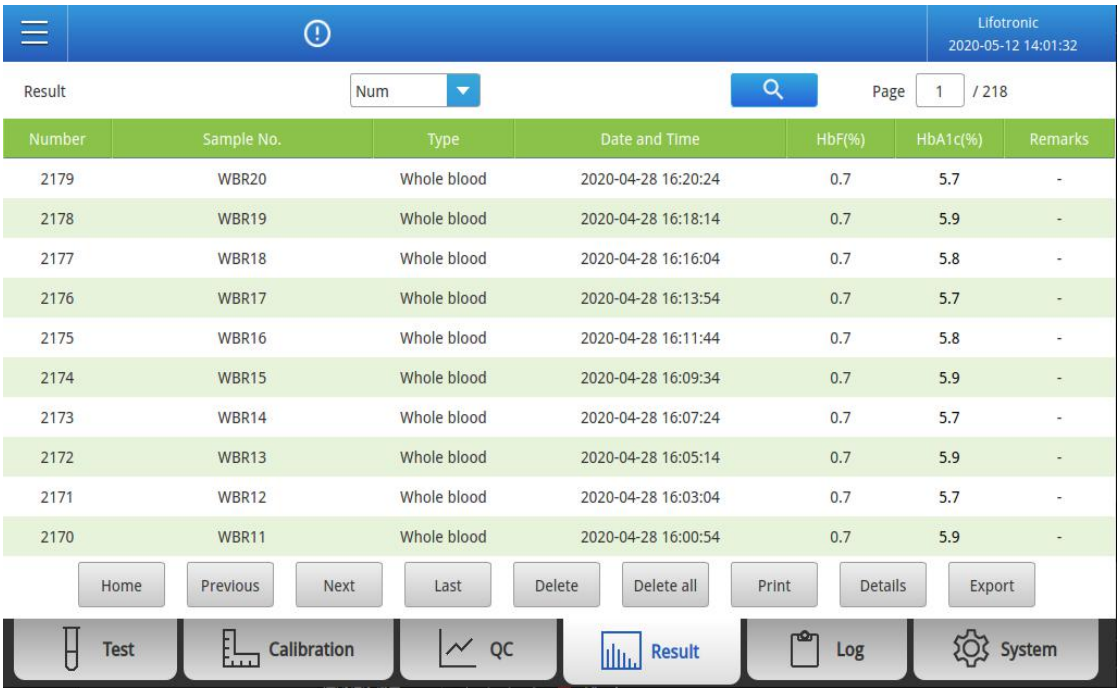


Fig. 6-1 Result Interface

Display content

1.Number → Test SN
2.Sample No. → Sample ID
3.Type → Sample type
4.Date and time → Analysis time
5.HbF(%) → HbF ratio

6.HbA1c(%) → HbA1c ratio

7.Remark → Remark

Key Functions

Home	:	Return to result interface
Previous	:	Displays the previous page
Next	:	Displays the next page
Last	:	Displays the last page
Delete	:	Delete the selected result
Delete all	:	Delete all results
Print	:	Print the selected result
Details	:	Displays the details of selected sample result
Export	:	Export sample results to U-disk

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 and date.

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 ~ e8).

The meaning of the codes are as follows：

e1：Total area less than 50,000;

e2：Total area more than 300,000;

e3：Result more than 15%;

e4：Result less than 4%;

e5：Variants detected;

e6：ADC415 value reach max value during testing;

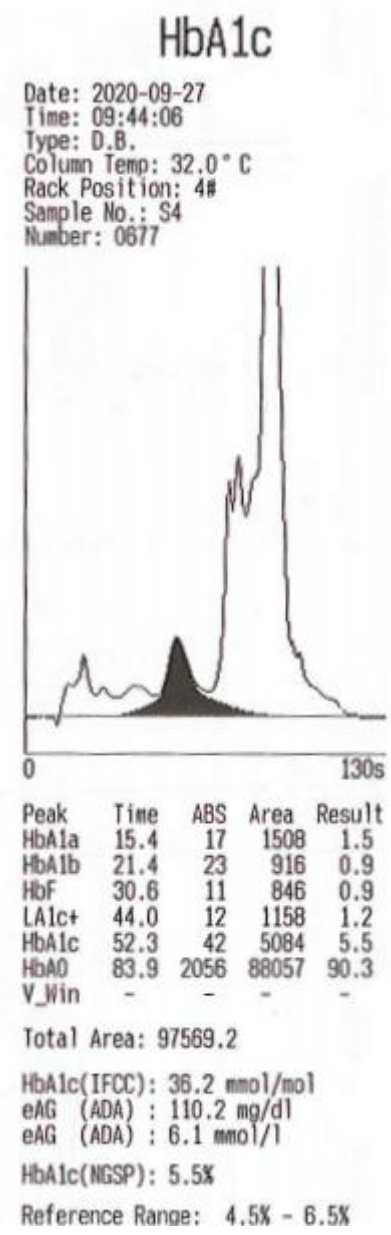
e7：A0 Total area less than 80%;

e8：Target peak is out of range.

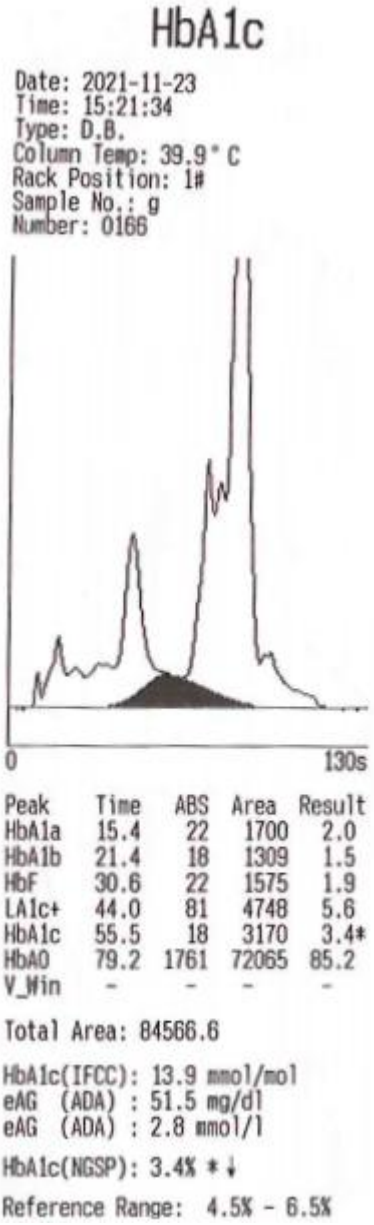
About the explanation of abnormal chromatogram

The following are abnormal chromatogram situations:

normal chromatogram:



(1)The target peak exceeds the recognition range



HbA1c

Date: 2021-11-23
Time: 15:21:34
Type: D.B.
Column Temp: 39.9°C
Rack Position: 1#
Sample No.: g
Number: 0166

0 130s

Peak	Time	ABS	Area	Result
HbA1a	15.4	22	1700	2.0
HbA1b	21.4	18	1309	1.5
HbF	30.6	22	1575	1.9
LA1c+	44.0	81	4748	5.6
HbA1c	55.5	18	3170	3.4*
HbA0	79.2	1761	72065	85.2
V_Win	-	-	-	-

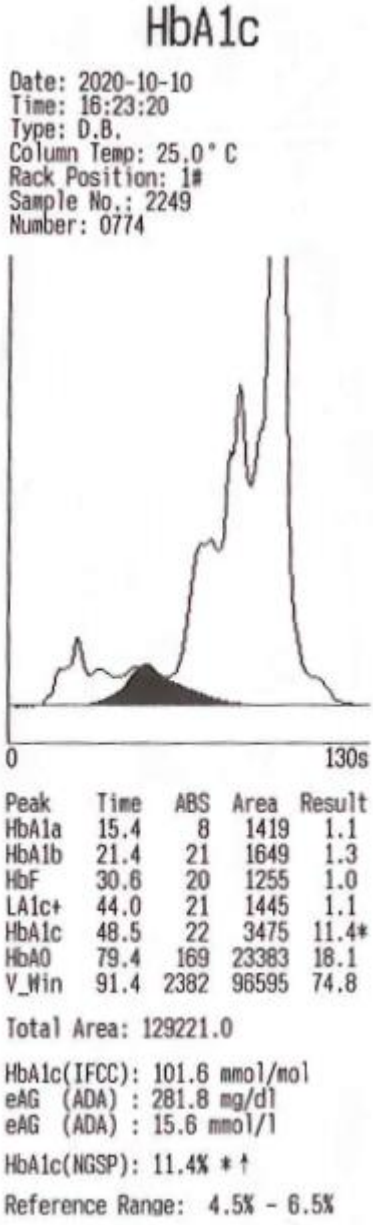
Total Area: 84566.6

HbA1c(IFCC): 13.9 mmol/mol
eAG (ADA) : 51.5 mg/dl
eAG (ADA) : 2.8 mmol/l

HbA1c(NGSP): 3.4% *↓

Reference Range: 4.5% - 6.5%

(2)The target peak exceeds the recognition range



HbA1c

Date: 2020-10-10
Time: 16:23:20
Type: D.B.
Column Temp: 25.0°C
Rack Position: 1#
Sample No.: 2249
Number: 0774

0 130s

Peak	Time	ABS	Area	Result
HbA1a	15.4	8	1419	1.1
HbA1b	21.4	21	1649	1.3
HbF	30.6	20	1255	1.0
LA1c+	44.0	21	1445	1.1
HbA1c	48.5	22	3475	11.4*
HbA0	79.4	169	23383	18.1
V_Win	91.4	2382	96595	74.8

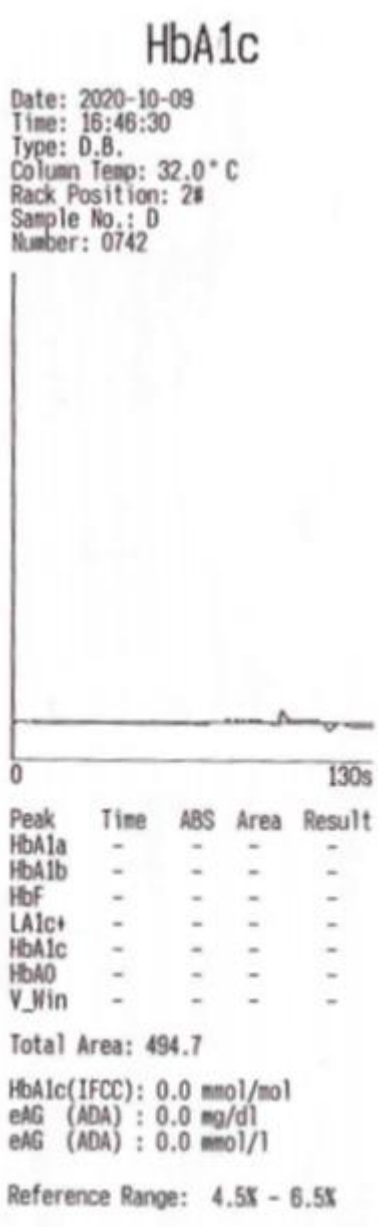
Total Area: 129221.0

HbA1c(IFCC): 101.6 mmol/mol
eAG (ADA) : 281.8 mg/dl
eAG (ADA) : 15.6 mmol/l

HbA1c(NGSP): 11.4% *↑

Reference Range: 4.5% - 6.5%

(3)Aspirated an empty sample



HbA1c

Date: 2020-10-09
Time: 16:46:30
Type: D.B.
Column Temp: 32.0°C
Rack Position: 2#
Sample No.: D
Number: 0742

0 130s

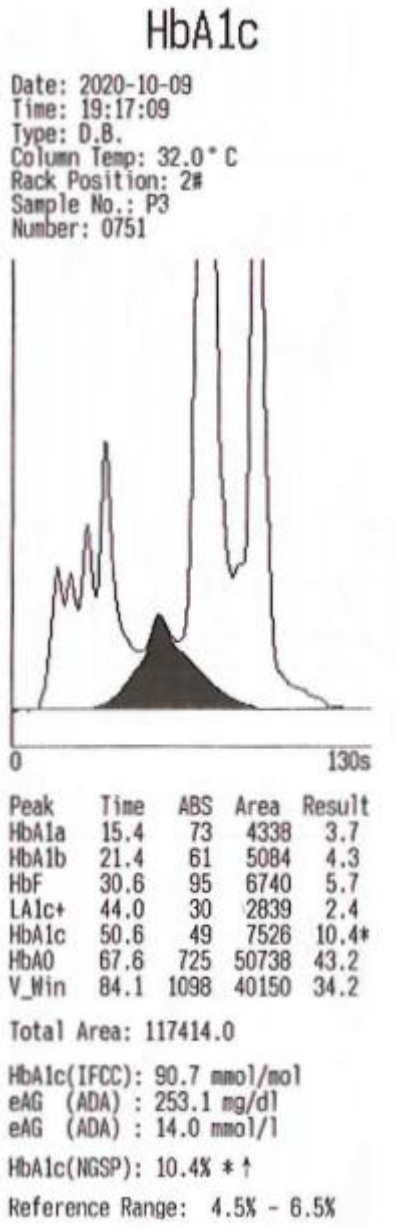
Peak	Time	ABS	Area	Result
HbA1a	-	-	-	-
HbA1b	-	-	-	-
HbF	-	-	-	-
LA1c+	-	-	-	-
HbA1c	-	-	-	-
HbA0	-	-	-	-
V_Win	-	-	-	-

Total Area: 494.7

HbA1c(IFCC): 0.0 mmol/mol
eAG (ADA) : 0.0 mg/dl
eAG (ADA) : 0.0 mmol/l

Reference Range: 4.5% - 6.5%

(4)A0 peak degradation



HbA1c

Date: 2020-10-09
Time: 19:17:09
Type: D.B.
Column Temp: 32.0°C
Rack Position: 2#
Sample No.: P3
Number: 0751

0 130s

Peak	Time	ABS	Area	Result
HbA1a	15.4	73	4338	3.7
HbA1b	21.4	61	5084	4.3
HbF	30.6	95	6740	5.7
LA1c+	44.0	30	2839	2.4
HbA1c	50.6	49	7526	10.4*
HbA0	67.6	725	50738	43.2
V_Win	84.1	1098	40150	34.2

Total Area: 117414.0

HbA1c(IFCC): 90.7 mmol/mol
eAG (ADA) : 253.1 mg/dl
eAG (ADA) : 14.0 mmol/l

HbA1c(NGSP): 10.4% * ↑

Reference Range: 4.5% - 6.5%

About the influence of interference on the test results

The following concentrations of interferences have no effect on the test results:

1. The glucose concentration is less than 10g/L;
2. The bilirubin concentration is less than 0.6g/L;
3. The triglyceride concentration is less than 20g/L;
4. HbF is less than 10%.

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 also view the sample chromatogram, and the elution time, area, result and other information of each eluted protein components.The message on the the **Fig. 6-2** is displayed as below.

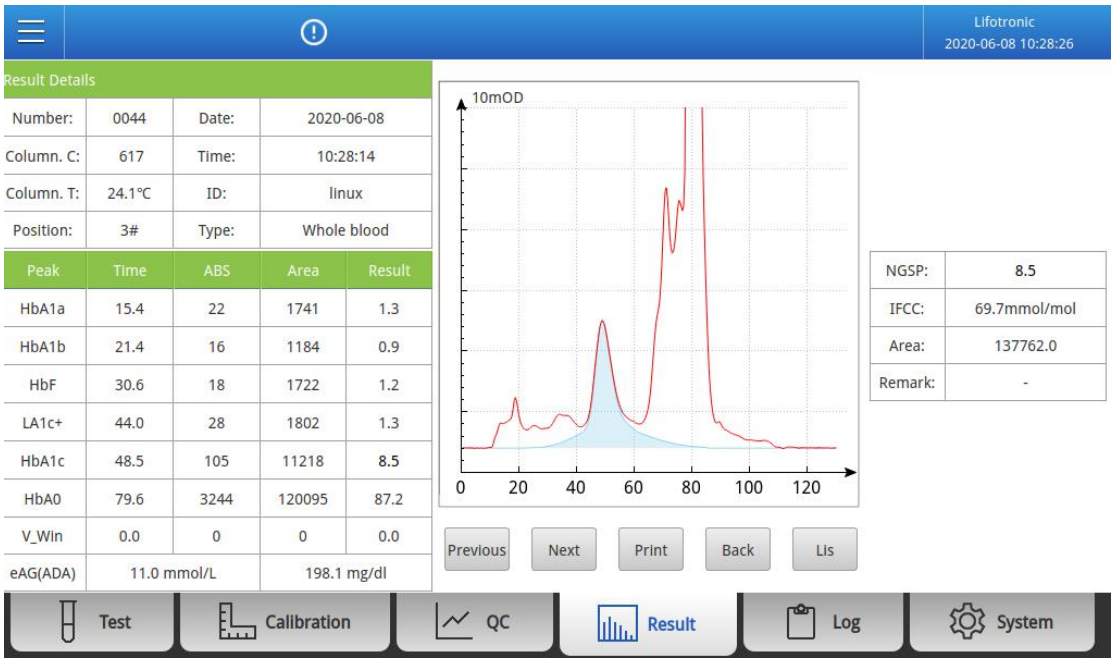


Fig. 6-2 Details of Single Sample Result interface

About the detection of variants

The analyzer can detect 4 kinds of variants, including HbE, HbD, HbS, HbC . When a variant is detected, the result is shown in the " **V_Win** " window and the result of HbA1c will be marked with * and marked red. At this time, the result of HbA1c cannot be directly reported. It is recommended that the operator combine with other indicators to make judgments. Example of variant detected is as e.g. **Fig. 6-3 test result of variants.**

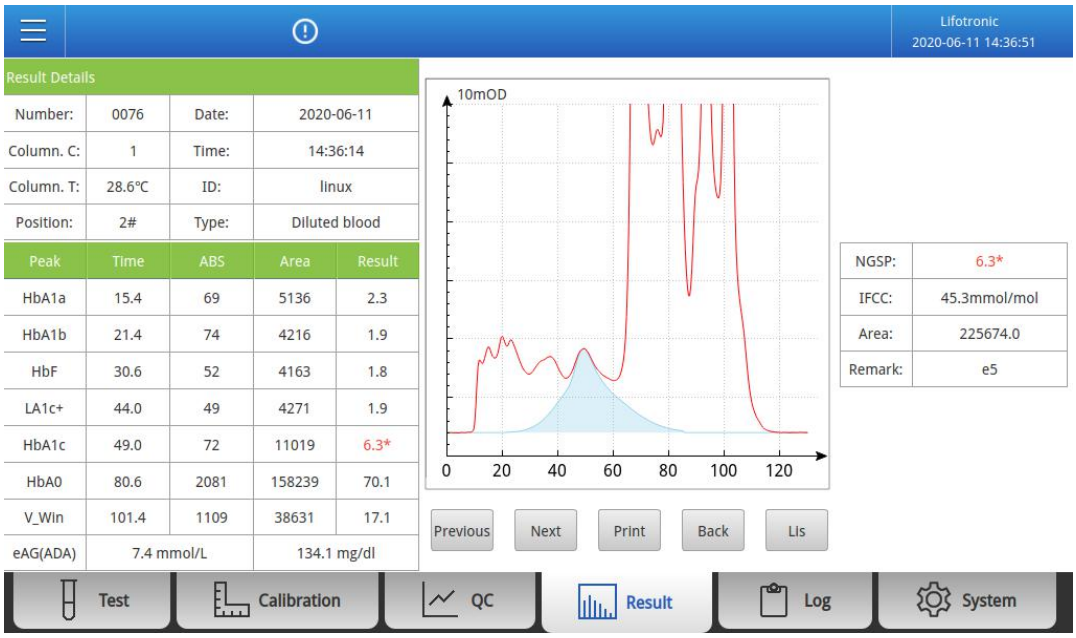


Fig. 6-3 test result of variants

6.4 Deleting Data

The operator can delete the sample test results. Select any result entry, 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 connection to a PC via the LIS prior to deletion. For computer software, user can contact the manufacturer or the agent specified by the manufacturer.

6.5 Printing Data

The operator can print the test result of the current sample. Select any result entry, then click the "**Print**" button; the analyzer will automatically print sample information.

Chapter 7 Log Review

7.1 Overview

The analyzer will automatically store the logs (error log, using log, maint log) in the database once a operation is completed. The analyzer database support each type of log can store up to 1000 datas. 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:

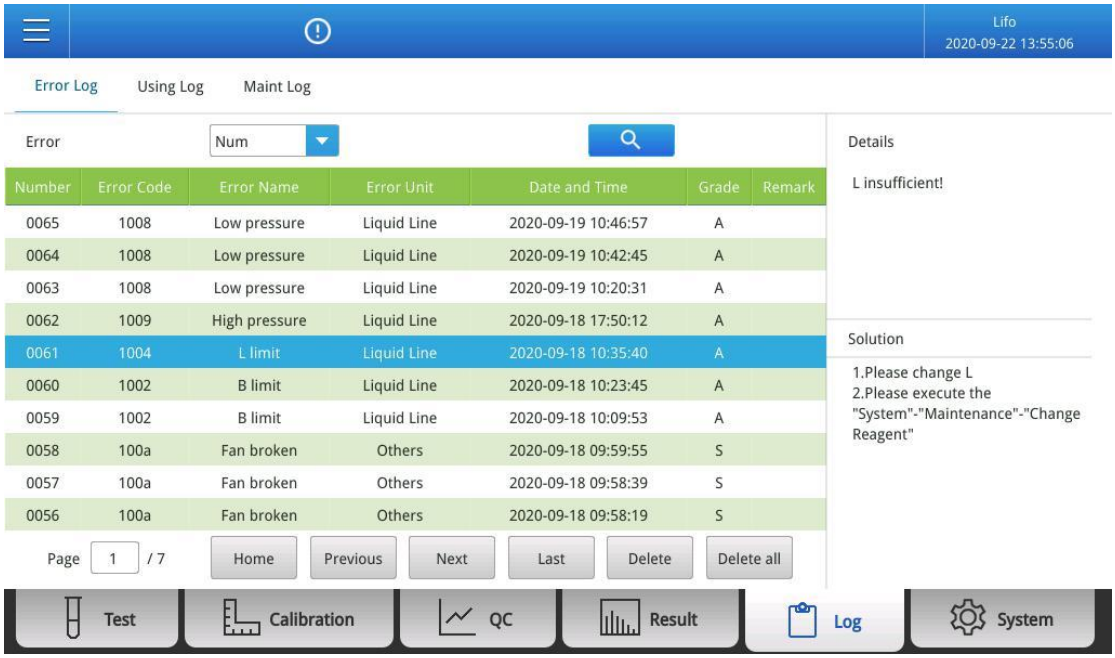


Fig. 7-1 Error Log interface

■ Error Log

The operator can review the error logs.The lointerface shows information of the error log, such as test SN, 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 left side of the interface.

■ Using Log

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

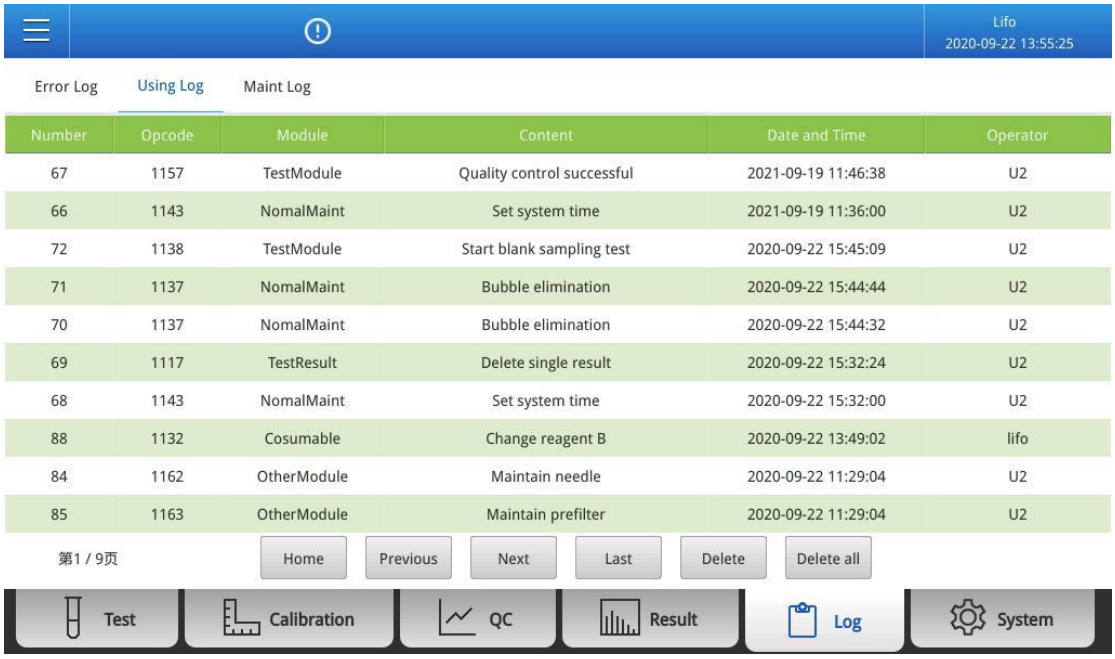


Fig. 7-2 Using Log interface

Each operation is recorded in the using log interface.The interface shows information of the using log, such as SN, operation code, module, content, date and time and operator .The operator can click “**Previous**” or “**Next**” button to review using logs in the form of list.

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

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



Fig. 8-1 QC Interface

In the upper left of the QC interface, input the Lots No. of QC material, target values and deviations of high and low values; then return to the test interface to start

the QC sample test. Lots No. must be input correctly according to the information printed on QC bottle body label.

■ QC Data area

"QC Data" area is used to input the information of QC materials.

■ QC Info area

"QC Info" area is used to display the latest information of QC.

■ 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 Level, Target value, Deviation and Result.



Fig. 8-2 QC Interface

ATTENTION

- The length of Lots No. is 15 digits. If exceeding, the system will default the first 15 digits as current Lots No.
- The QC chart supports to display 3 batches of QC information in a month. 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 the agent specified by the manufacturer.

8.3 QC Analysis



- Samples, QC materials, calibrators, chromatography columns, filters and waste liquid can be biologically infectious. When contacting relevant articles 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).

WARNING

- Infectious blood sample, QC material or calibrator may remain in/on the automatic sampler, sampling needle, chromatography column and filter. The operator should wear gloves during operation to avoid direct contact with the sampling needle.
- 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 material 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 our Company; 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 double distilled water or deionized water; take the QC material 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 0.1mL of double distilled water or deionized water, and slowly inject it into the bottle, tighten the bottle cap and carefully shake the brown bottle for several seconds, and then keep it shelved for 10min and meanwhile gently shake the brown bottle to ensure full dissolution of the content;

2)After re-dissolution, add 10μL of the QC material to the EP tube for dilution; then close the EP tube cap, and gently hold the tube upside down to ensure full mixing.

3)Click the "**QC**" button on the test interface, and be sure to input QC information on the QC interface before that. See **Fig. 8-3 test interface**.

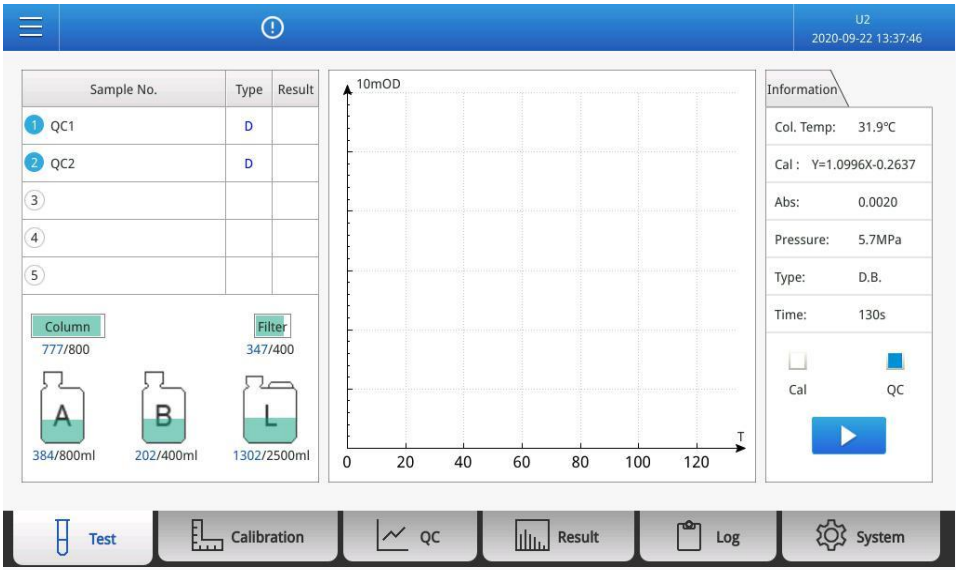


Fig. 8-3 test interface

4) Click the "▶" button and the **Fig.8-4** will be displayed.

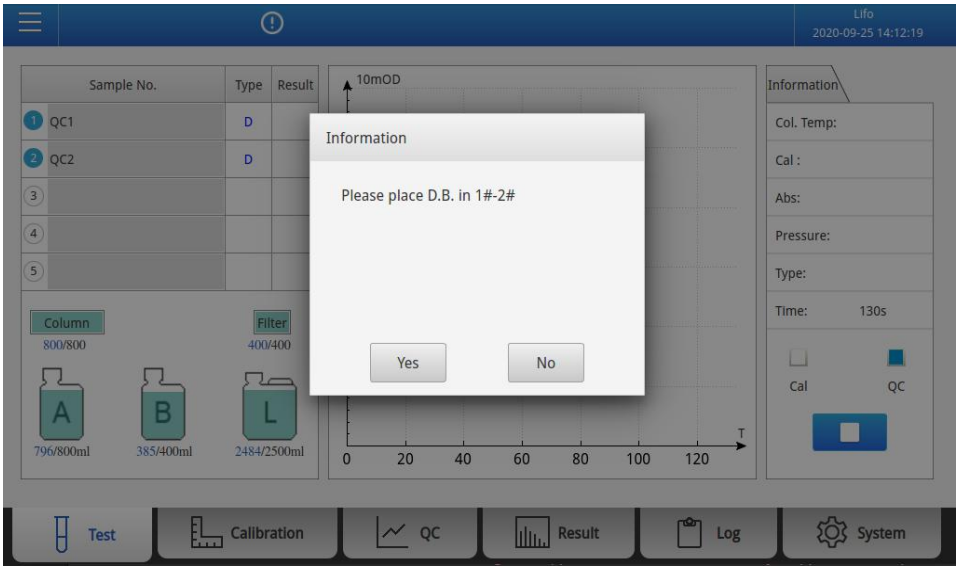


Fig. 8-4 test interface

5)According to operating instruction, cut off the EP tube cap; place the low-value EP tube in Position 1# of the sample rack and high-value EP tube in Position 2# of the sample rack.

6)Click "**Yes**" button and **Fig. 8-5** is displayed.

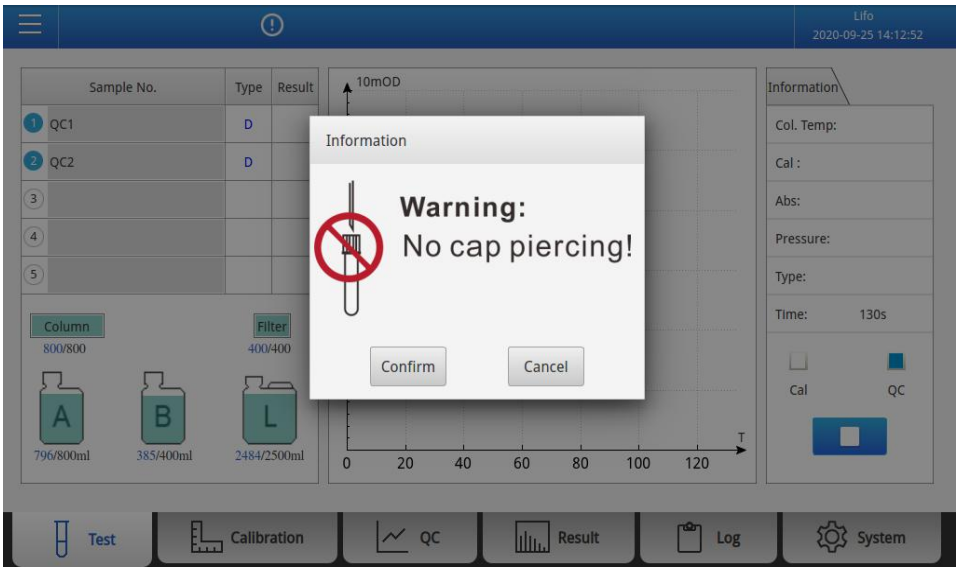


Fig. 8-5 test interface

7)According to the operating instruction, make sure the cap of the tubes have been removed .Then click "**Confirm**" button, the system start to do QC analysis.

ATTENTION

- Put the QC material after re-dissolution in 1.5mL EP tubes (10μL in each tube),

and keep them at a 2~8℃ for 7 days. Take one EP tube every time and restore it to room temperature between 10℃~30℃ before use to avoid repeated re-dissolution.

- Every time a bottle of QC material is uncapped, the uncapping date should be recorded on the bottle, and the QC material should be used within its shelf life.
- Before starting analysis, make sure the cap of tubes have been removed.

Chapter 9 Analyzer Calibration

9.1 Overview

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

Chromatography columns, filters, calibrators and reagents specified by our Company 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 chromatography column or filter is replaced;
- the analyzer is reused after it is shelved for long;
- obvious inaccuracy of analysis results are detected during QC or clinical trial and comparison;
- a new batch of reagents are to be used.

ATTENTION

- Measured data can be used as valid data only when the analyzer has been calibrated.
- Apart from the above five situations, it is suggested that weekly calibration should be executed to ensure the accuracy and reliability of results.

9.3 Calibration Methods

This analyzer provides three calibration modes: Diluted Blood Calibration ,Manual Calibration and Whole blood Calibration. In all modes, all mathematical calculations related to calibration are automatically completed by the analyzer. The calibration factor obtained after calibration will be automatically saved to the calibration query 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 Lifotronic if necessary.

- Check the analyzer and the reagent to ensure that the amount of reagent is adequate to complete the whole calibration process. Please recalibration if the reagent is used up in the calibration process.
- Upon startup, check and ensure that there remains enough chromatography columns and filters.
- It is suggested that one whole blood sample should be tested for 4~5 times before calibration; proceed to calibrate if proper results are obtained.

9.4 Calibrator Info Input

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

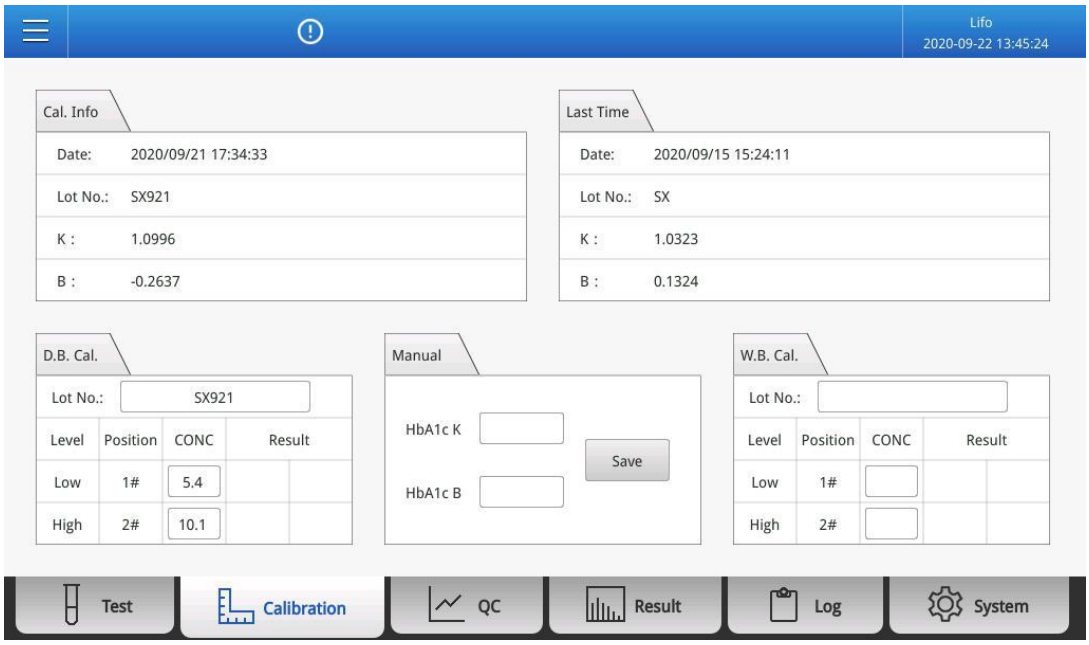


Fig. 9-1 Calibration Interface

■ Cal Info area

The "Cal Info" area is used to display the current calibration time, Lots No. of calibrator , K-value and B-value .

■ Last Time area

The “Last Time” area is used to display the last information of calibration .

■ D.B. Cal. area

The “D.B. Cal” area is used to input the information of calibrator (Lots No., target values of high-value and low-value calibrators).

■ Manual area

The “Manual area” area is used to input K-value and B-value.

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

Manually input the K-value and B-value as required, and click “**Save**” button; the analyzer will automatically calculate the result by the equation of Y=KX+B, where X is the initial result measured by the analyzer. Meanwhile, the “**Cal Info”** area will display the K-value and B-value currently input and show the calibrated lots No. as Manual.

■ W.B. Cal. area

The “**W.B. Cal**” area is used to input the information of calibrator (Lots No., target values of high-value and low-value calibrators).

Lots No. must be input correctly according to the information printed on Calibrator bottle body label.

9.5 Starting Calibration



- Samples, QC materials, calibrators, chromatography columns, filters and waste liquid can be biologically infectious. When contacting relevant articles 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 sample, QC material or calibrator may remain in/on the sample compartment, sampling needle, chromatography column and filter. The operator

should wear gloves during operation to avoid direct contact with the sampling needle.

- 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 our Company; 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 calibrator:

Procedure

1)Re-dissolution: Prepare an appropriate amount of double distilled water or deionized water; take the calibrator 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 0.1mL of double distilled water or deionized water and inject it into the bottle, tighten the bottle cap and carefully shake the brown bottle for several seconds, then keep it shelved for 10min and meanwhile gently shake the brown bottle to ensure full dissolution of the content;

2)After re-dissolution, add 20 μL to the EP tube, and then add 1500 μL of

hemolytic agent L for dilution; close the EP tube cap, and gently hold the tube upside down to ensure full mixing.

3)Click the "**Cal**" button on the test interface, and be sure to input the information of calibrators on the QC interface before that. See **Fig. 9-2 test interface**.

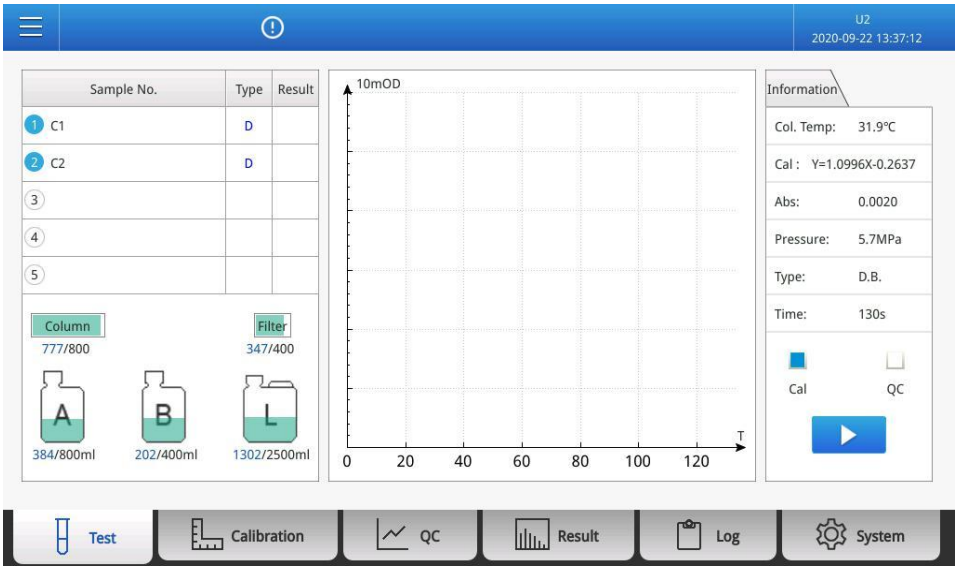


Fig. 9-2 test interface

4)Select the corresponding type according to the type of calibrator ("D" for diluted blood ,"W" for whole blood). Then Click the "▶" button and the **Fig.9-3** will be displayed.

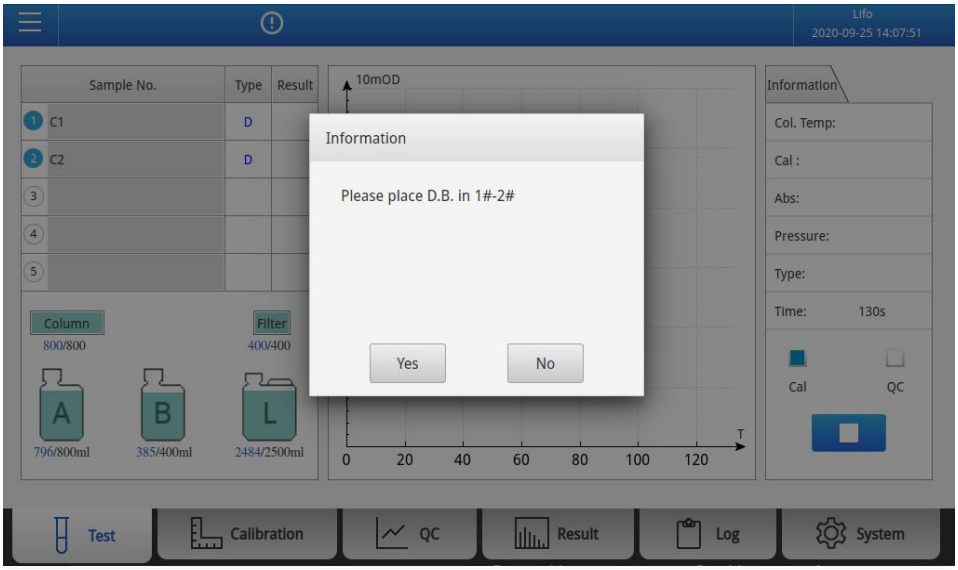


Fig. 9-3 test interface

5)According to operating instruction, cut off the EP tube cap; place the low-value EP tube in Position 1# of the sample rack and high-value EP tube in Position 2# of the sample rack.

6)Click “**Yes**” and **Fig. 9-4** is displayed.

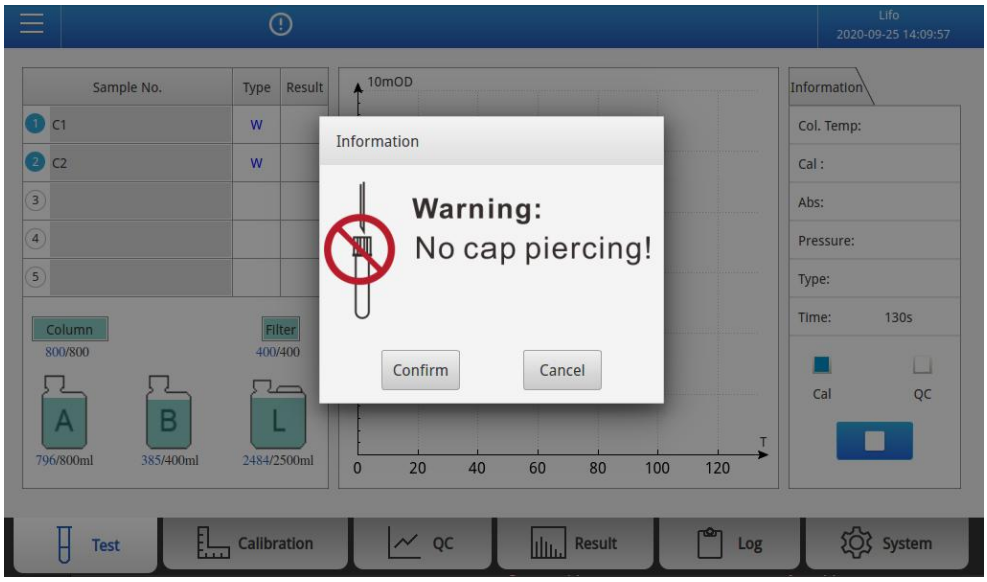


Fig. 8-4 Warning interface

7)According to the operating instruction, make sure the cap of the tubes have been removed .Then click “Confirm” button,the system start to calibrate.

■ Verification of calibration result

After calibration, analyze the high-value calibrator and low-value calibrator in the sample analysis interface, and check whether the analysis results are within range. If not, please recalibrate. If the problem cannot be solved, please contact Lifotronic.

ATTENTION

- Put the QC material after re-dissolution in 1.5mL EP tubes (20μL in each tube), and keep them at a 2~8℃ for 7 days. Take one EP tube every time and restore it to room temperature between 10℃~30℃ before use to avoid repeated re-dissolution.
- Every time a bottle of calibrator is uncapped, the uncapping date should be recorded on the bottle, and the calibrator should be used within its shelf life.
- For the Lots No., shelf life and reference value of the calibrator, please see the instructions and the target value list of the calibrator.
- If analysis starts before complete calibrator info is input, a dialog box indicating “Invalid input” will pop up; in such case, the operator should click “**OK”** and re-enter complete calibrator info before starting calibration analysis.

Chapter 10 Service

10.1 Overview

In order to ensure accurate and effective performance of the analyzer, the operator should carry out routine maintenance of the analyzer as required in this chapter. This analyzer provides several maintenance functions to facilitate operator's maintenance.

This chapter introduces the maintenance functions of the analyzer and some measures that can be taken in case of malfunction.



- The surfaces of all components of the analyzer are potentially infectious; therefore, safety protection measures should be taken during operation and maintenance.
- Infectious blood sample, QC material or calibrator may remain in/on the sample compartment, sampling needle, chromatography column and filter. The operator should wear gloves during operation to avoid direct contact with the sampling needle.



- Improper maintenance may damage the analyzer. The operator must maintain the analyzer in accordance with the guidance provided in the Product Instruction Manual.
- In case of any problem not mentioned in this manual, please contact Lifotronic's Customer Service personnel.
- Repair and maintenance must be performed by trained personnel.
  - Before repair and maintenance; please wear personal protective equipment (e.g., goggles, gloves and mask). Otherwise, injury or infection by infectious sample may result.
  - Replace the sampling needle after cutting off the main power supply; otherwise, damage to the analyzer or personal injury may result. In addition, take extreme care when replacing the sampling needle as it has a sharp tip.

- For repair and maintenance problems, please contact our After-sales Service personnel.

- Instructions on repairing, handling, discarding and destruction
  - Please wear personal protective equipment such as goggles, gloves and mask as the analyzer can be infectious. Use the 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. After removing the contaminants, spray alcohol onto the analyzer for sterilization purpose.
  - You can also contact Lifotronic's After-sales Service personnel.
- Please use parts provided by Lifotronic to repair the analyzer.

10.2 Maintenance Guide

Check before analysis

Exterior of analyzer	The exterior of the analyzer is free from dust and scratches; the tube is connected properly; the printer does not lack of recording paper; there is no liquid leak or physical damage.
Safety	The power supply is grounded and connected properly, and the adapter indicator is on.
Chromatography column	≥1.
Filter	≥1.
Reagent	Use specified reagents; hemolytic agent L and eluents A and B are sufficient ; the waste liquid bottle is emptied.
Operation	The date and time are correct; the displayed temperature is consistent with the target temperature; the ADC value is within normal range.

ATTENTION

- The operator must use chromatography columns and filters specified by Lifotronic; otherwise, incorrect analysis results may result.
- Before unsealing a chromatography column or a filter, check whether its packaging is damaged. Please contact Lifotronic's Customer Service personnel promptly in case of any serious damage which results in failure to use the filter or chromatography column.

10.3 System Maintenance

Click the "**Maintenance**" button on the system interface below to enter the system maintenance interface：

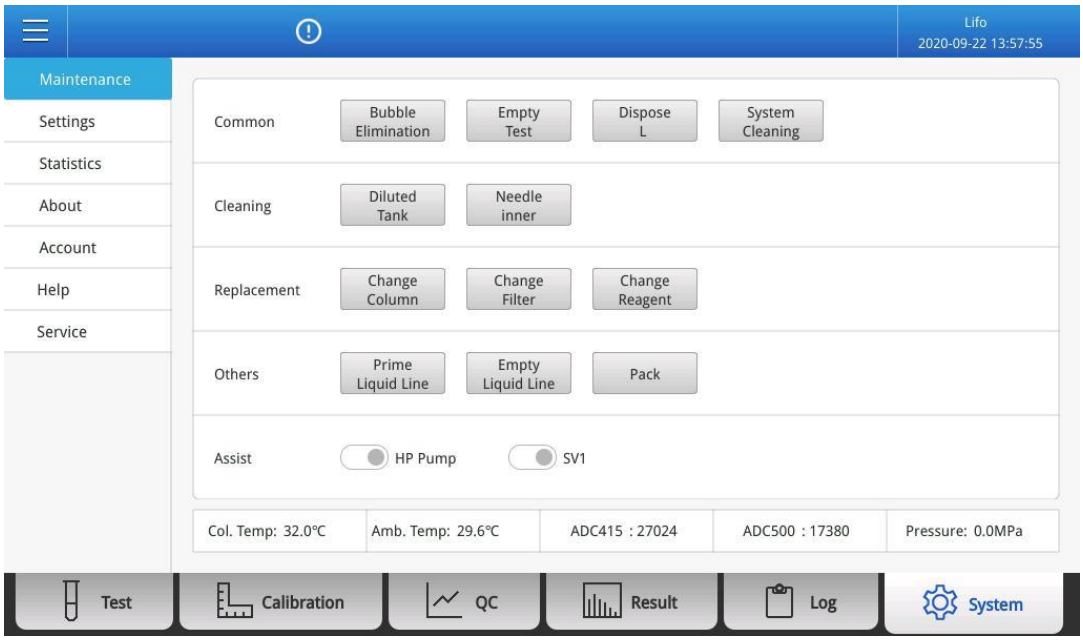


Fig. 10-1 System Maintenance Interface

10.3.1 Bubble Elimination

When air bubbles appear in the high pressure pump, the system pressure cannot increase to the normal range of 3-10MPa; meanwhile the eluent cannot flow; the analyzer will generate an error alarm indicating low pressure of the high pressure pump. At this moment, bubble elimination should be performed; click "**Bubble Elimination**", and turn on the evacuation valve in the maintenance compartment as prompted in the interface. The analyzer will execute bubble elimination; after air bubbles are eliminated, re-tighten the evacuation valve.

If it fails to reach system pressure after this step, the connector on the main pump head of the high pressure pump should be unscrewed; place clean rags below the main pump head. Click the "**Bubble Elimination**" button again; you can see a lot of air bubbles coming out of the main high pressure pump. When the bubble elimination procedure is finished, re-tighten the connector, and execute the eluent A procedure.

Open SV1, and turn on the high pressure pump; wait for the pressure to increase to a normal range between 3-10MPa.

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

other.

Before executing empty test, please remove the sample from the sample compart-ment.

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

10.3.3 Dispose L

Before disposing hemolytic agent, please place a EP tube with holder at 5# sample rack position. The analyzer will automatically aspirate 750μl from the hemolytic agent bucket, and inject the hemolytic agent into the EP tube via the sampling needle for future use during calibration or QC operation.

10.3.4. System Cleaning

“system cleaning” button is used to system cleaning. It takes 5 minutes approximately.

The operation steps are as follows:

Procedure

1)Click “**System cleaning**” button on the System interface and **Fig. 9-2** is displayed .

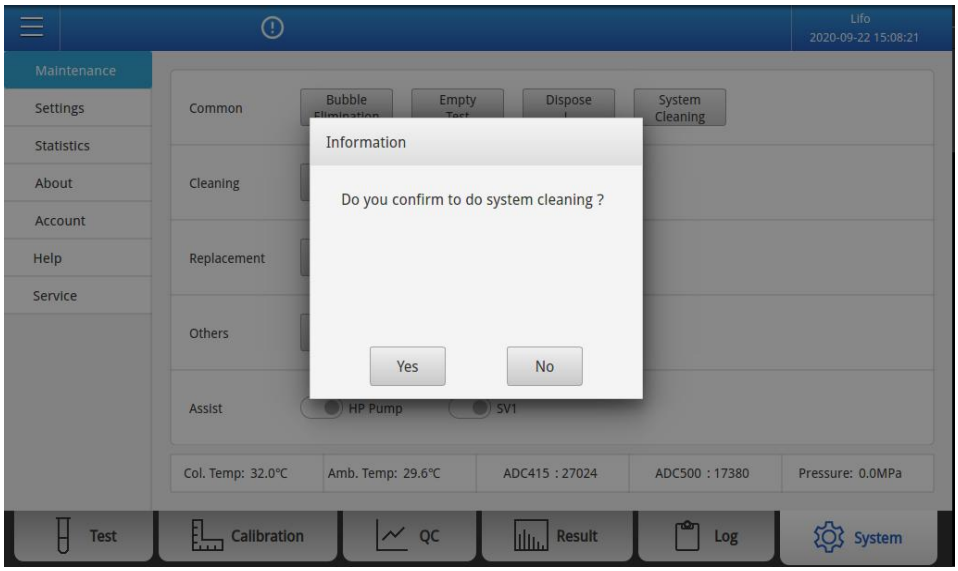


Fig. 10-2 system cleaning interface

2)After clicking “**Yes**” button ,the system will enter the cleaning procedure.The whole process will take about 5 minutes. After the

cleaning, it will automatically return to the system interface .

10.3.5 Diluted Tank

When cleaning the dilution Tank, the 1ml plunger pump will push 2ml of hemolytic agent to clean the cavity of the dilution Tank.

10.3.6 Needle Inner Wall

When cleaning the inner wall of the needle, the 1ml plunger pump will push 1ml of hemolytic agent L to clean the sampling tube, including the inner wall of the needle.

10.3.7 Change Column

“ **Change Column** ” button is used to the replacement of column.

The operation steps are as follows:

Procedure

1)Click”**Change Column**” button and **Fig. 10-3** is displayed. After input new serial number and click “**Yes**” button, it will prompt “Column reset successfully”, and the number of available test will be reset to 800T.

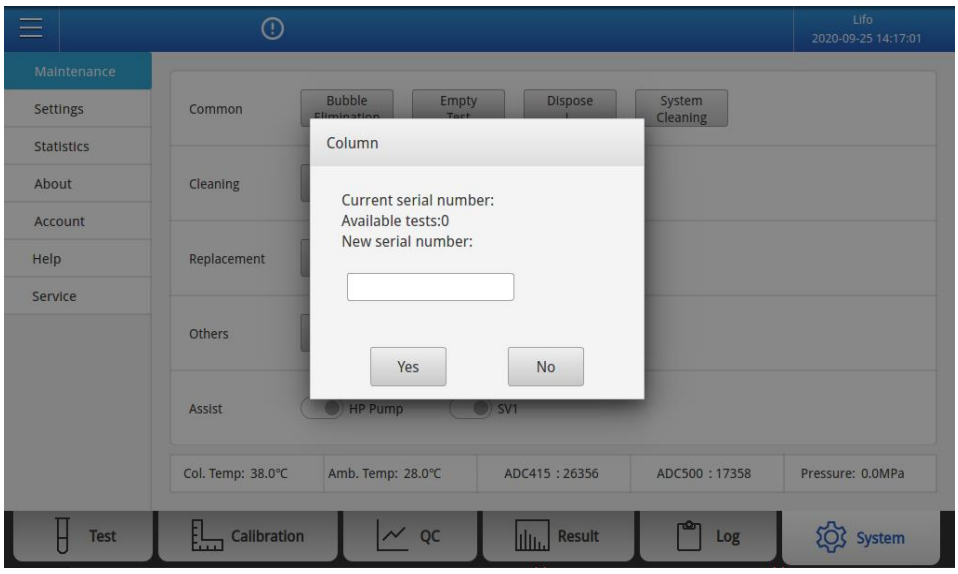


Fig. 10-3 After Clicking”Change Column”

2)Set the temperature of the new column which refer to the the information of label printed on chromatography column packing, then click “**Yes**” button.

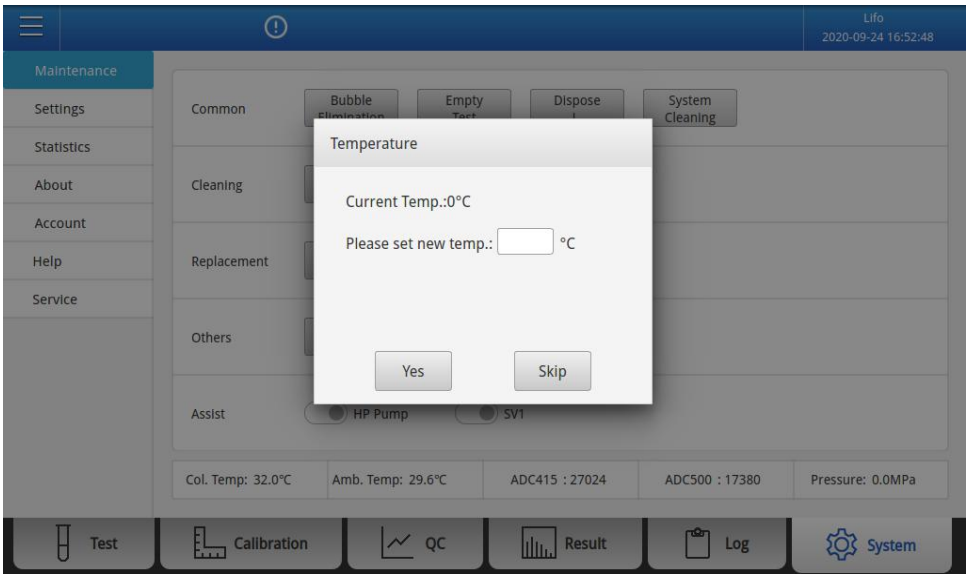


Fig. 10-4 Temperature input interface

3)According to the operating instrcutions,connect a new column and tighten the fitting, then click ”**Yes**” button.

4)According to the operating instrcutions, perform whole blood primer, position 1# for W.B., position 2# for D.B.(100ul W.B. versus 750ul Diluent L) , then remove the cap of whole blood tube and click ”**Yes**” button. The interface will automatically return to the test interface and **Fig. 10-5** is displayed.

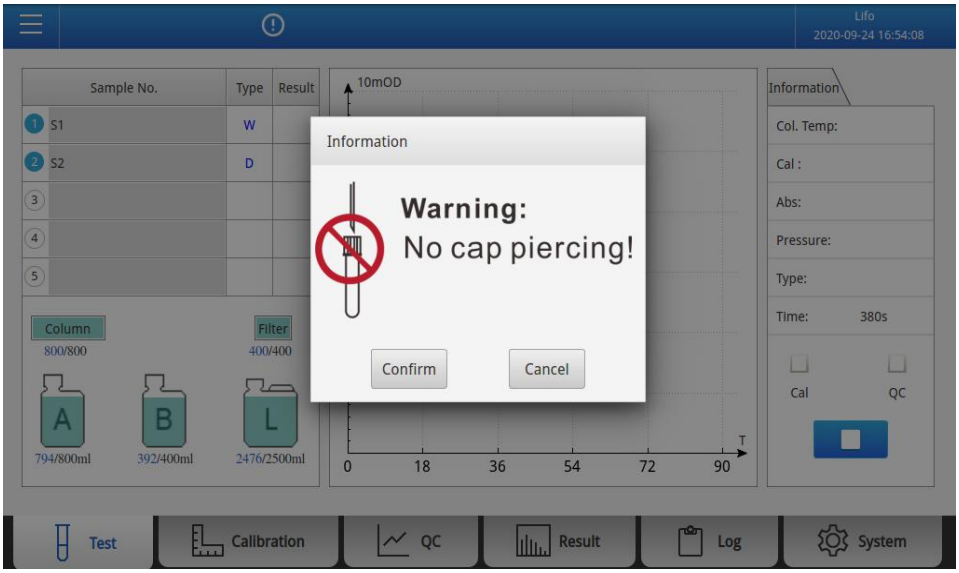


Fig. 10-5 Test interface

5)Confirm the caps have been removed ,then click “**Confirm**” button to start testing.

10.3.8 Change Filter

“ **Change Filter** ” button is used to the replacement of filter.

The operation steps are as follows:

Procedure

1)Click “**Change Filter**” button and **Fig.10-6** is displayed. According to the operating instrcutions, load a new filter and tighten the handle , then click “**Yes**” button.

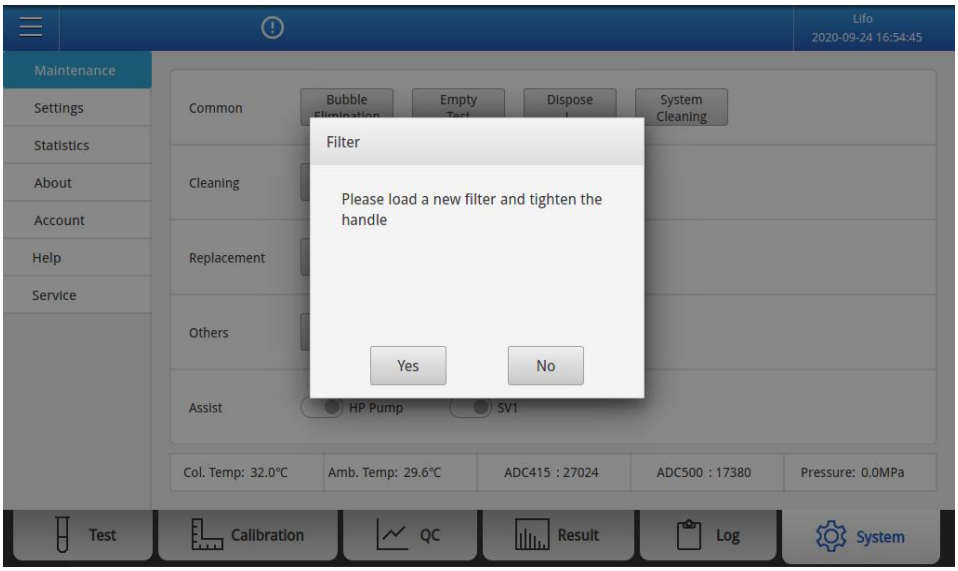


Fig. 10-6 After clicking “Change Filter”

2)The analyzer will enter system cleaning procedure of about 10minutes.

3)After the completion of system cleaning, the number of the available test of filter will be reset to 400T.

10.3.9 Change Reagent

“ **Change Reagent** ” button is used to the replacement of reagents .This function is used to replace all reagents at once, including eluent A, eluent B and hemolytic agent L.

The operation steps are as follows:

Procedure

1)Replace with new reagents and click ”**Change Reagent** “ button and **Fig. 10-7** is displayed. Loosen evacuation valve, then click “**Yes**” button.

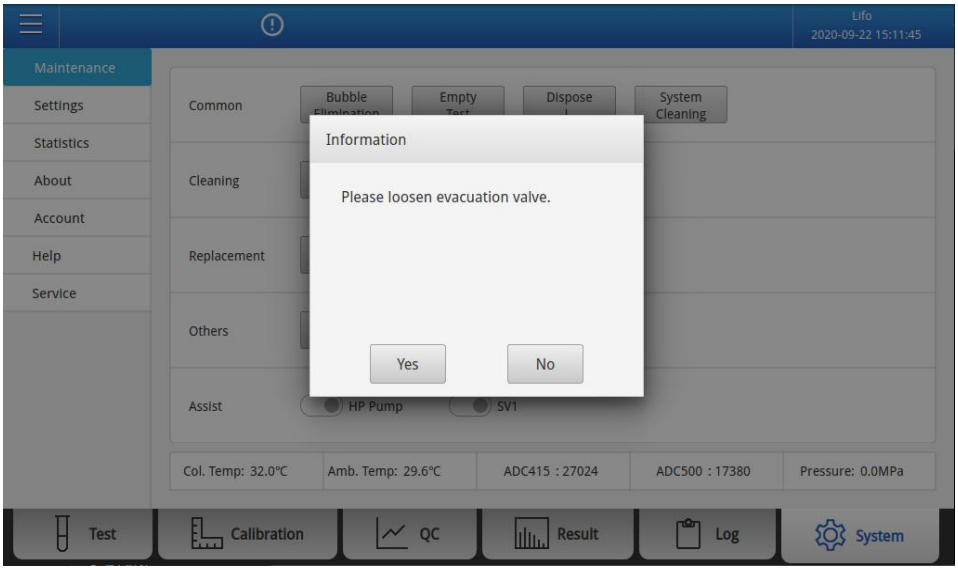


Fig. 10-7 After clicking “Change Reagent”

2))According to the operating instruction, empty the waste bottle then click ”**Yes**” button. (A waste bottle can only hold a single load of reagent).

3)Tighten evacuation valve and the remaining capacity will be filled out.

10.3.10 Prime Liquid Line

When installing the analyzer , please prime the liquid line to ensure proper sample sucking during sample analysis. Please execute this step with caution as it consumes much hemolytic agent and may lead to lack of hemolytic agent in the following operation.

10.3.11 Empty Liquid Line

Before emptying the liquid line, please disconnect hemolytic agent L and eluents A and B. After emptying the liquid line, the liquid path of the entire analyzer is empty. This operation applies when the analyzer is to be left unused for a long period of time or before long-distance transportation.

10.3.12 Pack

1) Empty the liquid path;

2) Perfuse the liquid path with deionized water;

3) Empty the liquid path again.

10.3.13 (Col.Temp)Temperature of Chromatography Column

It is suggested that the column temperature should be set within the range of 25~40℃. If the analyzer is at an abnormal operating temperature, it may affect the column temperature and further affects the peak appearance time of HbA1c; the higher the temperature is, the sooner the peak appearance will be, vice versa. The column temperature can be adjusted to make the peak appearance time fall within the specified range to ensure accurate test results.

10.3.14 (Amb.Temp) Ambient Temperature

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

10.3.15 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 24000~28000; 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.

10.3.16 ADC500

Similar to ADC415, the ADC500 value in normal status is within the range of 16000~20000. It is also affected by the LED value and the gain; the ADC value debugging method is identical to that for ADC415.

10.3.17 System Pressure

The system pressure can reach above 12MPa, which increases as the number of test increases. If the pressure is 4MPa above the pressure indicated on the product

delivery identification of the chromatography column, first replace the in-line filter. If the pressure does not drop, please replace the chromatography column. The analyzer will generate an alarm if the system pressure is beyond the set range, and the test will be interrupted.

10.4 System Settings

Click the "**Settings"** button on the system interface below to enter the system setting interface.

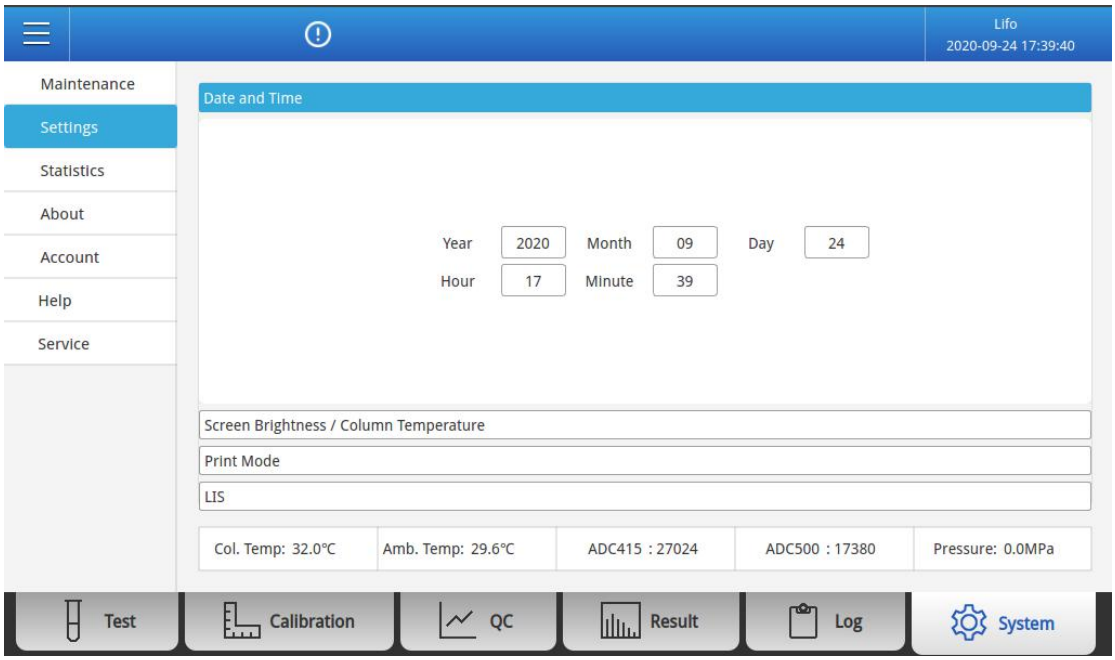


Fig. 10-8 system setting interface

10.4.1 Date and Time

This operation is used to set the system time; after resetting, the system time will be updated at the upper right of the screen. Since QC data are stored according to the current system time and the analyzer only records one-year's QC data, if the system time is set to a wrong year and the QC operation is executed, QC data in the correct year will be deleted. Please operate with caution.

10.4.2 Screen Brightness/Column Temperature

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

Temperature setting is used to set the temperature in the column oven, i.e., the temperature setting will affect the peak appearance time of target proteins. It is suggested that the setting range should be 25~40℃. For specific setting rules, please contact Lifotronic's after-sales personnel.

10.4.3 Print Mode

Two print modes are available: Auto Print and Manual Print. If Auto Print is selected, the test result will be printed automatically after each sample test. If Manual Print is selected, the test result selected can be printed only in the result interface.

To save printing paper, user can selectively print the following three options:

Analysis Item: Select this option to print the peak appearance time, absorbance, total area and result in percentage of each hemoglobin component.

Chromatogram: Select this option to print the chromatogram of the current sample;

Analysis Result: Select this option to print the IFCC concentration in the analysis result of the current sample and the estimated blood glucose level expressed in two units.

10.4.4 LIS

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

10.5 About

The about interface displays information of software, version and copyright.

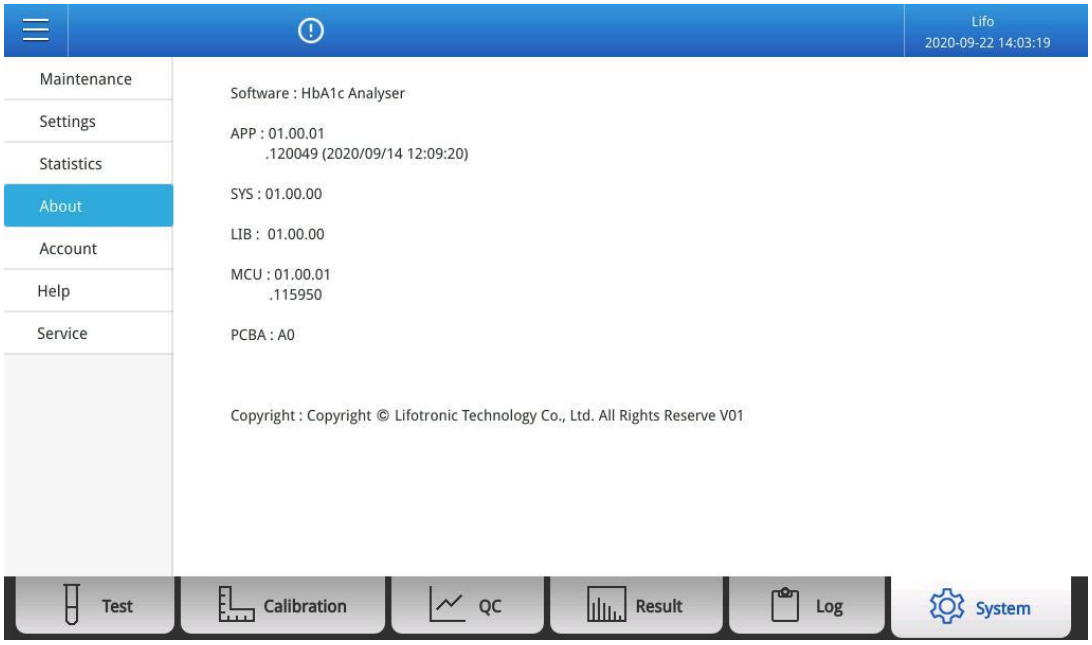


Fig. 10-9 About Interface

10.6 Account

In the account interface, users can view the information of current login account , register the account and change the password.

10.7 Help

The Help interface only displays the operating principle of the analyzer currently. More content will be provided in the future.

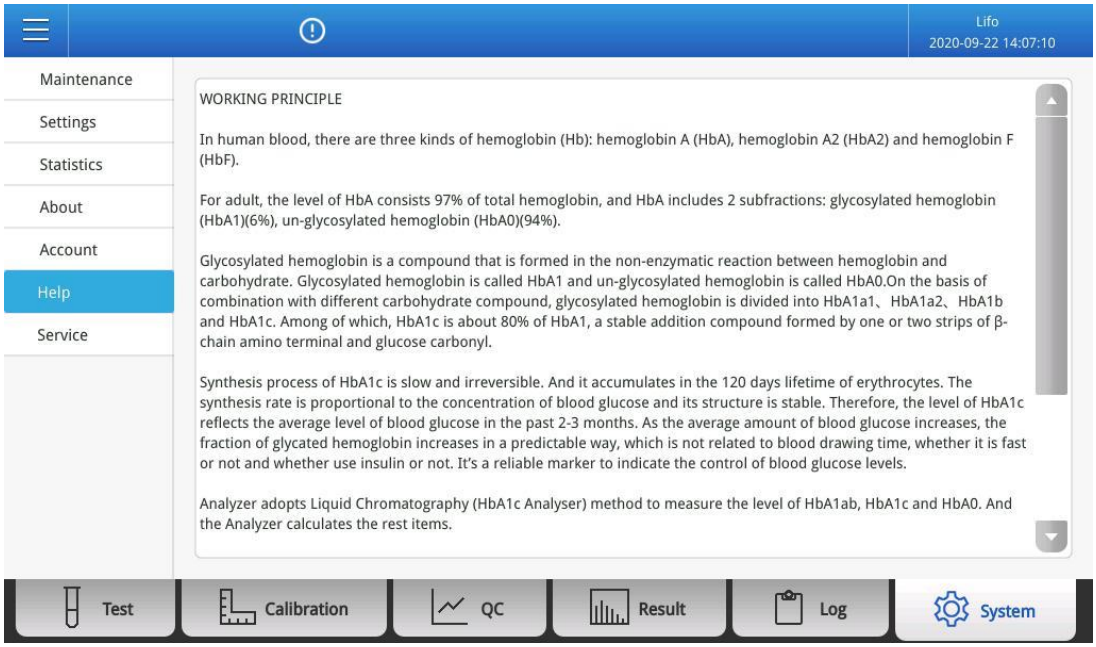


Fig. 9-10 Help Interface

10.8 Advanced Maintenance

User needs an account and a password to log into the Advanced Maintenance interface. For details, please contact Lifotronic's after-sales service personnel.

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, chromatography columns, filters and waste liquid can be biologically infectious. When contacting relevant articles 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 des cribed in the list below occurs, please eliminate the malfunction following relevant troubleshooting steps. If the malfunction still exists, please contact Lifotronic's Customer Service personnel.

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. Tighten the connector. 2. Replace the front filter. 3. 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.

not work	malfunctions. 3. The motherboard is damaged.	
The test result is beyond the range of 3%~18%	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 Lifotronic's Customer Service personnel.

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 Lifotronic's Customer Service personnel.

Problem	Possible cause	Solution
The ADC value is 0	1. The signal line of sampling board or LED board is in poor connection. 2. The sampling board malfunctions. 3. The LED board malfunctions.	1. Replug the signal line. 2. Replace the sampling board. 3. Replace the LED board.
The ADC value is 32767	1. The channel gain value is too small. 2. The LED value is set too high. 3. The sampling board malfunctions. 4. Air bubbles exist in the colorimetric cell.	1. Increase the gain value. 2. Decrease the LED value. 3. Replace the data sampling board. 4. 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 24000 and 28000	Air bubbles exist in the colorimetric cell.	Open SV1, 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 Lifotronic's Customer Service personnel.

Problem	Possible cause	Solution
Communication failure	1. The communication connecting cable is loose. 2. The network IP address does not match. 3. The LIS transmission switch in the analyzer interface is not turned on.	1. Check whether the analyzer is properly connected to the receiving end. 2. The IP address on the computer should be consistent with that on the analyzer. 3. Turn on the LIS transmission switch in the analyzer interface.
Communication failure of barcode scanner	1. The barcode scanner is not properly connected. 2. The connecting cable is loose.	1. Check whether the barcode scanner is properly connected. 2. Check whether the connecting cable is properly connected.
Invalid barcode	1. The barcode model is inconsistent. 2. Invalid barcode data are scanned.	Please contact Lifotronic's Customer Service personnel.

11.6 Problem and Solution

If any abnormality of reagents, chromatography columns or filters occurs, please follow relevant troubleshooting steps provided in this chapter. If the problem persists, please contact Lifotronic's Customer Service personnel.

Problem	Possible cause	Solution
Absence of hemolytic agent	1. The hemolytic agent connecting pipe is not inserted into the liquid. 2. The hemolytic agent is used up.	1. Check whether the hemolytic agent pipe is properly connected. 2. Add hemolytic agent.
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	3. Eluent B is used up 4. The count of eluent B is not reset.	3. Add eluent B. 4. Reset the count of eluent B.
Air bubbles occur in the reagent tube	Eluent A and B 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 to eliminate air bubbles
Abnormality of chromatogram	1. The liquid path is blocked. 2. The chromatography	1. Carry out system cleaning after replacing the filter.

	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.	2. Replace the chromatography 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%-18%.	1. The sample volume aspirated is too small. 2. Lack of whole blood sample 3. The chromatography column or filter malfunctions. 4. The reagent loses efficacy. 5. No system pressure	1. Increase the sample volume aspirated. 2. Replace the whole blood sample or use the diluted blood mode. 3. Replace the chromatography column or filter. 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 1:75 before, reduced to 1:50)
Error code e2	Total area more than 300,000.	Increase the dilution ratio, such as 1:75 before, increase to 1: 100
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	ADC415 value reach max value during testing	Adjust the value of ADC415 to between 24,000 and 28,000
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 chromatography 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

Please contact our customer service personnel for more.

Appendix A Specifications

A.1 Matched Reagents

Eluents A and B, and hemolytic agent L .

A.2 Matched Chromatography Columns and Filters

Chromatography columns and filters specified by Lifotronic.

A.3 Calibrators

Calibrators specified by Lifotronic.

A.4 QC Materials

QC materials specified by Lifotronic.

A.5 Power Supply

- Voltage: AC 100V~240V
- Frequency: 50Hz/60Hz
- Input power: 120VA

A.6 Operating Environment

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

A.7 Storage Conditions

- Ambient temperature: 0℃~55℃
- 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.

- Storage period: Not longer than one year.

A.8 Package Dimensions

- Length : 615mm
- Width : 530mm
- Height : 790mm

A.9 Analyzer Dimensions

- Length: 450mm
- Width: 361mm
- Height: 540mm

A.10 Weight

Net Weight: 28.9kg, Gross Weight: 32.8kg

A.11 Valid Period

The product has a service life of 5 years. A analyzer beyond its service life shall be disposed of according to applicable laws and regulations. For more information, please contact the manufacturer or its agent.

A.12 Contraindications

None.

Appendix B Communication

B.1 LIS Communication Parameters

- Analyzer IP Addr: 192.168.5.55
- Analyzer Port: 8000
- PC IP Addr: 192.168.5.56
- TCP Communication Mode on PC: TCP Server
- TCP Port on PC: 8000

B.2 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	Venous Blood
0x31	Diluted Blood
0x32	QC Material
0x33	Calibrator

Error codes have the following meanings:

Code	Meaning
0x31	E1 error code,Total area less than 50,000
0x32	E2 error code,Total area more than 300,000
0x33	E3 error code,Result more than 15%

0x34	E4 error code,Result less than 4%
0x35	E5 error code,Variants detected
0x36	E6 error code,ADC415 value reach max value during testing
0x37	E7 error code,A0 Total area less than 80%
0x38	E8 error code,Target peak is out of range

B.3 Sample Data Format

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	##
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	###.#
Average blood glucose concentration in ADAG(mmol/L)	##.#
Average blood glucose concentration in ADAG(mg/dl)	###.#
Sent chromatographic curve number	###
Sent chromatographic curve values	#.####
Test error code	#
Data end flag	【ETX】

Appendix C Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic emissions		
The analyzer is intended for use in the electromagnetic environment specified below,Thecustomer 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 emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The analyzer is suitable for use in all establishments,including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Group A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic Discharge(ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV 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	±2kV for power Supply lines ±1 kV for input/output lines	±2kVfor power Supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or a hospital environment.

Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or a hospital environment.
Voltage dips,short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95%dip in U_T) FOR 0,5cycles 40% U_T (60% dip in U_T) for 5 cycles <5% U_T (>95%dip in U_T) for 5 sec	<5% U_T (>95%dip in U_T) FOR 0,5cycles 40% UT (60% dip in U_T) for 5 cycles <5% U_T (>95%dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or a hospital 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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

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 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC	3Vms 150kHz to 80	3 V	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**

61000-4-6 Radiated RF IEC 61000-4-3	MHz 3Vms 80MHz to 2.5 GHz	3 V/m	**d=1.2√ P** **d=1.2√ p 80MHz to 800MHz** **d=2.3√ p 800MHz to 2.5 GHz** where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter distance in metres(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 [V_1] 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 $d = [\frac{3.5}{V1}]\sqrt{P}$	80MHz to 800MHZ $d = [\frac{3.5}{E1}]\sqrt{P}$	800MHz to 2.5 GHz $d = [\frac{7}{E1}]\sqrt{P}$
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 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 an reflection from structures,objects and people.

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