Erba® Mannheim | TRANSASIA®
No.1 Diagnostic Company in India

Automated Glycohemoglobin Analyzer
VERTEX-Hb
Instruction Manual

Note

Thank you for purchasing VERTEX-Hb Automated Glycohemoglobin Analyzer.

FOR PROFESSIONAL USE ONLY.

For the proper use of the instrument, please be sure to read this instruction manual and fully understand its content prior to its operation. Even after you have read it, please keep the manual on hand so that you can consult it whenever necessary.

Model: VERTEX-Hb

Model Description: VERTEX-Hb Emergency position housing is gray; VERTEX-Hb Emergency position housing is white.

Term of Validity: 7 years

Content

Chapter 1 Preface

1.1 Intellectual Property

The intellectual property rights of this manual and its corresponding products are reserved by TRANSASIA BIOMEDICALS LTD.

1.2 Statement

Transasia Biomedicals Ltd. Company has the final explanation right of the manual of this VERTEX-Hb Automated Glycohemoglobin Analyzer (hereinafter referred to as the manual), and the contents of the manual are subject to change without notice. Regarding the manual, if you have any questions, please contact the following address directly, or contact your local dealer.

Our company is responsible for the safety, reliability and performance of products only if all the following requirements are met:

(1) Assembly operation, expansion, re-adjustment, improvement and repair are all carried out by professionals approved by the company;

(2) All parts, accessories and consumables involved in the maintenance are original or approved by the company;

(3) The relevant electrical equipment should meet the national standards and requirements in this manual;

(4) The operation of the analyzer should be carried out in accordance with this manual.

1.3 Revision History

Revisions	Date
1.1	2024.09.09

1.4 Basic Information

TRANSASIA BIO-MEDICALS LTD.,
Khatiyan No. 235, Khasra No. 24, Namthang Elaka, Mahakuma Namchi, South Sikkim - 737132. INDIA

1.5 Warranty

The warranty period of the purchased product is subject to the sales contract. Products manufactured by TRANSASIA BIOMEDICALS LTD. that fail under normal use by the customer during the warranty period will be repaired or replaced, at TRANSASIA BIOMEDICALS LTD.'s discretion, without charge.

Consumables: Here it refers to disposable materials that need to be replaced after each use or fragile materials that need to be replaced regularly. Consumables are not warranted.

This limited warranty does not extend to products for which any of the following situations apply. Even within the warranty period, in the situations listed below, a fee will be charged to repair the product:

(1) Artificial damage；

(2) Improper use；

(3) Product is operated or stored in grid voltage that exceeds the range specified for the product；

(4) Irresistible natural disasters；

(5) Replace or use parts, accessories and consumables that are not approved by the company or repaired by personnel not authorized by the company.

(6) Other faults irrelevant to product quality

Products with damage or failure caused by using reagents and other consumables that have not been approved by our company is not within the scope of warranty.

Repairs of TRANSASIA BIOMEDICALS LTD. products are available with charges after the end of the warranty period.

If the fees for maintenance service are not paid or paid late, our company will temporarily suspend repairs until paid.

1.6 Software Version

Version	Upgrade Date
V1.0	2025.06.31

1.7 Software Copyright

The software is used to control the VERTEX-Hb Automated Glycohemoglobin Analyzer, collect, display and analyze experimental data. The software is independently developed by the TRANSASIA BIOMEDICALS LTD. Company. The TRANSASIA BIOMEDICALS LTD. Company independently reserves all rights of the software in accordance with the law. No individual or organization may copy or modify this software without the authorization of the TRANSASIA BIOMEDICALS LTD. company.

1.8 After-sale Service

Service Name: TRANSASIA BIOMEDICALS LTD.

Service Address: Transasia House, 8, Chandivali Studio, Andheri(E), Mumbai 400 072

Website: www.transasia.co.in

Service Phone: 022-40309000

1.9 Conventional Identification Signs

The meaning of the label and screen on the Automated Glycohemoglobin Analyzer is explained as follows:

	Date of Production
	Manufacturer
	In Vitro Diagnostic Medical Device
	Warning: Risk of Biological Infection
	Notice: the Waste Liquid Bucket Watch Out Biological Contamination
	RFID
	Grounding
	Power, Network, USB

	Authorized representative in the European Community
	Temperature limit
	CE Mark
	Consult instructions for use
	Serial number
	Humidity limitation
	Atmospheric pressure limitation

The meanings of the labels contained in this manual are as follows.

 **Warning**	If the operator does not follow the instructions, it may cause injury.
 **Caution**	If the operator does not follow the instructions, the system may be damaged or the results may be inaccurate.
Notice	It prompts the operator of important information and guides the operator to use the analyzer correctly.
 **Risk of Biological contamination**	If the operator does not follow the instructions, it may cause biological contamination.

1.10 Intended Use

It is used to quantitatively test the percentage (%) and substance content (mmol/mol) of glycosylated hemoglobin (HbA1c) in human blood samples in vitro.

1.11 Performance indicators

Performance indicators	
Accuracy	Relative deviation within ±2%
Repeatability	The coefficient of variation CV is not greater than 1.0%.
Linearity	Linearity The linear correlation coefficient r of the test results should be not less than 0.9900 in the interval of 3.0%~20.0% (9mmol/mol ~195mmol/mol) for linear sample concentration.
Carrying Contamination Rate	The carry-over contamination rate should be no more than 1.5%.
Stability	Relative deviation not more than ±3.0%
Analysis speed	STD：1min/test；VAR：1.6min/test
Reporting range	3.0%~20.0%

1.12 Notes

For a safe use of this system, please read the following safety precautions carefully. Any operation that violates the following safety precautions may cause system damage and personal injury.

- **Use of the instrument**

Warning:

Anyone without operation training is strictly forbidden to use this instrument.

For the safe and effective use of this system, anyone is forbidden to operate the analyzer before reading the manual. If you do not follow the instructions on the manual, it may cause serious personal injury or damage to the instrument.

Moving units such as puncture parts may cause personal injury. Please do not touch any moving parts once the instrument is started, and keep hair, clothes, hands and other body parts a safe distance from the moving parts.

It is forbidden for non-trained personnel to disassemble the instrument for maintenance or repair, otherwise it may cause serious personal injury or damage to the instrument.

It is forbidden to carry out any operation not included in this manual, otherwise it may cause serious personal injury or damage to the instrument.

- **Power Connection**

Warning:

Please connect this instrument to a power supply with small voltage change and large power supply capacity.

If the power supply capacity connected to this instrument is insufficient or exceeds the rated voltage, it may cause fire.

This instrument should be installed on the correct ground wire.

- **Protection against biological hazards**

For effective protection against biological hazards, please observe the following precautions.

Risk of Biological Infection:

Blood samples may carry infectious pathogens, wrong operation may get operators infected with infectious pathogens. Glycosylated Hemoglobin (HbA1c) Chromatography Column（hereafter"Chromatography Column"), filters, sampling probes and sample cups used for blood samples may be contaminated. When operating, please wear gloves, overalls to prevent infection, and take goggles if necessary.

If the sample accidentally touches the skin, please immediately handle it according to the users' working standards and consult a doctor.

- **Protection against chemical hazards**

For effective protection against chemical hazards, please observe the following precautions.

Warning:

The reagent may hurt the skin. Please use reagents carefully to prevent direct contact with hands and clothes. If reagent spills on skin or clothes, please rinse immediately with clean water. If in eyes, rinse immediately with plenty of water and consult ophthalmologist for medical treatment.

- **Transportation requirements**

The outer packaging of instruments provided by our company are used for instruments transportation.

The whole transportation process needs to be in a dry environment.

This instrument should be transported through the highway and avoid severe bumps and impacts.

Warning:

Severe bumps and impacts may damage the equipment, please refer to the relevant requirements in GB/T 14710-2009 for transportation.

- **Prevent electromagnetic waves and noise**

Caution:

Before using this equipment, it is necessary to evaluate the electromagnetic environment.

Do not use this equipment in close proximity to sources of strong radiation (such as unshielded RF sources), as these may interfere with the proper operation.

This product meets the emission and immunity requirements specified in IEC 61326-1:2005 and IEC 61326-2-6:2005.

This equipment is designed and tested according to Class A equipment in CISPR 11:2016. In a home environment, this equipment may cause radio interference, and protective measures need to be taken.

Do not place other equipment that emits abnormal noise near this system. In the room where the system is installed, please turn off devices emitting electromagnetic waves, such as radio transceivers, and do not use other displays near the system. The interference of noise and electromagnetic waves may lead to system malfunction.

Do not use other medical instruments near this system. The electromagnetic waves emitted by this system may cause the malfunction of other medical instruments nearby.

Warning:

The manufacturer bears the responsibility to provide customers or users with EMC information of equipment.

Users have the responsibility to ensure the environment for electromagnetic compatibility of the equipment, so that the equipment can work normally.

- **Disposal of waste**

To prevent environmental pollution and personal injury caused by waste liquid, please observe the following precautions when disposing of waste.

Warning:

Scrapped analyzers must be disposed of according to local regulations.

Wastes such as used sample cups, blood collection tubes, filters, Chromatography Columns and waste liquid are under restraint of pollution regulations and emission standards. Please comply with local emission standards and contact our service department.

When disposing of waste liquid, please wear gloves and overalls to prevent infection, and take goggles if necessary.

- **Disposal of discarded instrument**

To prevent environmental pollution and personal injury caused by discarded analyzers, please observe the following precautions when disposing of instruments:

Warning:

Some substances in discarded analyzers are subject to pollution regulations. Please comply with local waste disposal regulations when disposing of discarded analyzers.

- **Prevent fire and explosion**

To prevent fire and explosion, please observe the following precautions:

Warning:

Alcohol is flammable. Be careful when using alcohol near the analyzer to avoid fire and explosion.

- **Emergency Stop**

If some abnormal phenomena occur in the use of the instrument, which may burn the instrument or threaten personal safety, please cut off the power urgently.

- **Environmental Conditions**

Caution：

The electromagnetic environment should be evaluated before operating the equipment.

Please install the system correctly according to the instructions specified in this manual. Installation and use of this system beyond the specified conditions may lead to unreliable test results and system damage.

- **Use of the system**

Caution：

The analysis results can only be a reference for doctors and cannot be directly used to diagnose diseases. When making clinical judgment, please combine the analysis with clinical symptoms or other test results together.

Please use the system according to the instructions in this manual. Improper use may lead to incorrect data, and even system damage or personal injury.

Before the initial use of the system, please calibrate it according to the requirements in the manual, and then carry out quality control to ensure the normal operation of the system.

When using the system, quality control procedures must be carried out as required, otherwise the reliability of the results cannot be guaranteed.

Do not touch the display screen of the instrument with wet hands or hands with chemicals.

Do not turn on the power switch again within 10 seconds after turning off the power supply, otherwise the system may enter into the protection state. If the system enters into protection state, please turn off the power supply and turn it on again.

System maintenance and repair

Caution：

Please maintain the system according to instructions in this manual. Improper maintenance may lead to incorrect analysis results, even system damage or personal injury.

If the system is idle for a long time, dust may accumulate on the surface. When cleaning, please use clean, soft cloth soaked with water and wring it dry, gently wipe its surface, and soak a small amount of soap liquid if necessary. Do not use organic solvents such as alcohol. After cleaning, please dry the surface with dry cloth.

Before cleaning, please turn off the power supply and unplug the system; During cleaning, take necessary measures to prevent liquid from entering the system, otherwise it may cause system damage or personal injury.

If the instrument needs to be repaired due to failure, please contact the service department of our company. During maintenance, it may be inevitable to stop using or transport the instrument. Please be careful to avoid biological hazards, electric shock hazards and moving units hazards caused by maintenance.

Samples

Caution：

Drugs, anticoagulants, preservatives, etc. in samples may affect analysis results. Hemolysis in the sample may affect the test results. It is not recommended to use such samples, re-drawing blood or other treatment is recommended instead.

Please adopt correct measures to store samples. Incorrect sample storage measures may change the composition or structure of samples and lead to incorrect analysis results.

To prevent the sample from volatilizing, do not leave the sample open for a long time. If the sample volatilizes, it may lead to incorrect analysis results.

This system has requirements for sampling amount when analyzing. When sampling, please ensure the appropriate sampling amount according to instructions in this manual.

Before analyzing, please make sure that the samples are placed in the correct position, otherwise the correct results cannot be ensured.

- **The use of reagents, calibrators and quality controls**

Caution：

When using this system for analysis, appropriate reagents, calibrators and quality controls are required.

Please choose the matching reagents of our company. If you are not sure whether the reagent is available, please consult our company or our distributor.

Please follow the instructions for the use and storage of reagents, calibrators and quality controls.

Improper storage of reagents, calibrators and quality controls may lead to incorrect test results and affect system performance even within the validity period.

Chapter 2 Working Principle

2.1 Overview

This instrument is based on the principle of ion exchange high performance liquid chromatography, which is used to quantitatively detect hemoglobin components in blood in clinic.

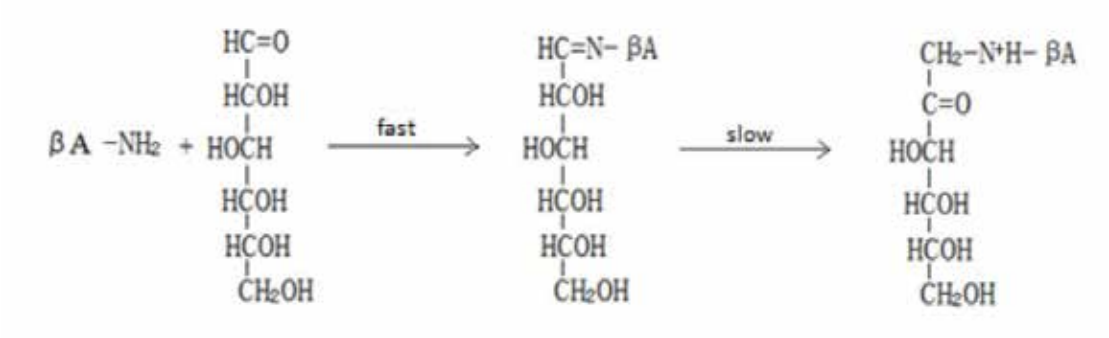
There are non-porous filling agents containing cation exchange groups in the Chromatography Column. Because of different electric charges in blood samples, hemolytic eluents with different concentrations can be used for gradient elution to separate components. By measuring the absorbance of each component, the instrument can provide the percentage (%, NGSP) and substance content (mmol/mol, IFCC) of HbA1c. Besides, it can also provide the detected values of FP, A1A, A1B, F, LA1c +, A0, etc.

2.2 Clinical Significance

HbA1c is a stable amino ketone compound, through a non-enzymatic combination reaction between the free aldehyde group of glucose and the amino group of the N-terminal valine of the β chain of HbA to form an unstable Schiff base, and then undergo rearrangement by Amadori (glucosamine). Finally, HbA1c is formed (as shown in the figure below). Its content depends on the blood glucose concentration and the contact time between blood glucose and hemoglobin, and has nothing to do with the time of blood drawing, whether the patient is in empty stomach, or whether insulin is used or not. It can objectively reflect the blood sugar control of diabetic patients in the past one to two months

GHb is composed of HbA1a, HbA1b, and HbA1c. Among which HbA1c accounts for about 70% with stable structure. The level of HbA1c is closely related to the risk of chronic complications of diabetes. In diabetes control, HbA1c level is the gold standard for blood sugar control and an effective indicator for evaluating diabetes treatment. In addition to being an indicator of blood sugar control, HbA1c can also be used for the diagnosis of diabetes. Currently, the World Health Organization (WHO) and many national diabetes societies have set HbA1c as an independent criterion for diabetes.

Figure the formation of HbA1c



2.3 Sample Requirements and Storage

To ensure the accuracy of the analysis, it is necessary to ensure that the sample volume is not less than 1mL when collected by tubes; when collected by sample cup, the blood volume is not less than 50μL, and the diluted sample is not less than 150μL.

It is applicable for anticoagulants EDTA, heparin, and anticoagulant NaF; If the whole blood samples are stored in cold storage for 7 days, the accuracy of test could be realized.

Chapter 3 Installation

3.1 Installation Requirements

3.1.1 Environment Requirements

Please install this instrument on a stable table without harmful gas, dust, vibration, direct sunlight and wind.

Notice:

Please do not use this instrument under the condition of huge temperature difference. The temperature difference will lead to condensation, which will cause electric leakage and affect the normal operation of the instrument.

Please use the instrument in the following environmental conditions:：

/	Indoor use
Altitude	Not exceeding 2000m
Power supply voltage fluctuation	Not more than ± 10% of nominal voltage
Transient overvoltage category	Class II
Rated pollution level	Level 2
Ambient temperature	10 ~ 30
Relative humidity	30% ~ 75%
Atmospheric pressure	85~106 kPa

Caution:

The analyzer must be operated within the specified ambient humidity and temperature, otherwise the results may be unreliable.

If the ambient temperature and humidity exceed the specified range, please use air regulator.

The working environment should be well ventilated to ensure heat dissipation, and ventilation equipment can be used when necessary. However, air flow should be kept from directly blowing into the system, otherwise the reliability of data may be affected.

- Only installed and used indoor;
- Keep on flat ground or table (inclination less than 1/200);
- The installed ground or table can bear no less than 100kg;
- Good ventilation;
- As dust-free as possible;
- Keep from direct sunlight;
- Be away from heat and wind source;
- No corrosive and combustible gases around;
- No vibration on the table;
- No noise and power interference;
- Keep away from brush engines, flashing fluorescent lamps and electrical equipment that is frequently switched on and off;
- Keep away from devices that emit electromagnetic waves, such as mobile phones and radio transceivers;

3.1.2 Space Requirements

Instrument size: 560 (L) × 590 (W) ×490 (H)mm Instrument weight: 45kg

When installing the instrument, please make sure to leave enough room(≥ 100mm) for it, and avoid the exhaust from other equipment blowing directly into the instrument.

3.1.3 Power Source Requirements

Warning：

This analyzer must be used under good grounding conditions. Incorrect grounding may lead to electric shock and damage the system.

Before turning on the analyzer, please make sure that the output voltage of the power junction box meets the specified requirements and that the appropriate fuse or circuit breaker has been installed.

- Required power：AC 100-240V；
- Frequency：50/60HZ；
- Maximum output power：360W；
- The electric supply input needs to have a protective ground which is well grounded；
- This instrument needs a specified power adapter. One end of the adapter is connected to electric supply, and the other end is connected to the instrument to supply power for the instrument.

3.1.4 Liquid discharge requirements

There are two ways to discharge waste liquid: using waste liquid bucket or directly discharging into waste liquid pipeline.

If a waste liquid bucket is used, please ensure that the table height for the analyzer is lower than that of the waste liquid barrel; If waste liquid is discharged directly to pipeline, please ensure that the pipeline is lower than the waste liquid outlet of the instrument.

3.2 Installation procedures

Warning：

It is forbidden to install by personnel who is not trained or authorized by our company, otherwise it may cause personal injury or damage to the instrument.

Caution：

Do not place the device in a position where it is difficult to unplug the adapter.

The installation of the instrument shall be carried out by the technical personnel of our company or has been authorized. Before installation, please ensure the specified environment and space requirements.

3.2.1 Pre-installation inspection

This instrument has been strictly inspected before entering to the market. In order to avoid damage to the instruments during transportation, the company has carefully packed the instruments. Upon receipt of this instrument, please check the package first. If there is any damage, please report it to our customer & service department or the distributor at your site immediately.

After unpacking, please carefully check the exterior appearance of the instrument and check the list of accessories (see appendix for the list of accessories). In case of damage or incomplete configuration, please report to our customer & service department or distributor at your site immediately.

3.2.2 System reset

When the instrument needs to be transported, please contact our customer & service department or the distributor at your site.

Chapter 4 System Introduction

4.1 Overview

This instrument uses three kinds of eluents in different concentrations to carry out gradient elution in the Chromatography Column on the samples entering the instrument, and the absorbance of the samples is measured in real time by the detector, and then the chromatogram will be output.

This chapter mainly introduces the system composition, functions and operation pages.

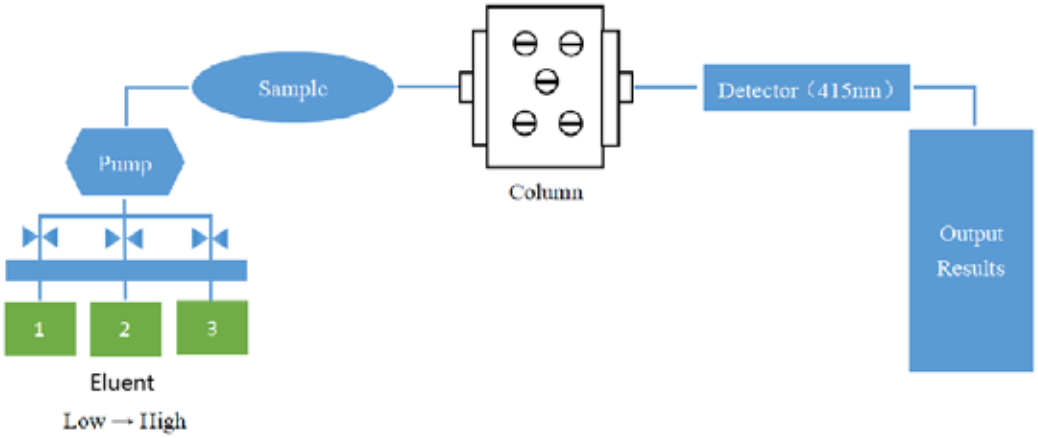


Figure 0-1 Working Principle of the system

4.2 System Units

The Glycohemoglobin analyzer consists of liquid chromatography separation system, liquid chromatography detection system, mechanical system, software and hardware.

4.2.1 Main components and modules

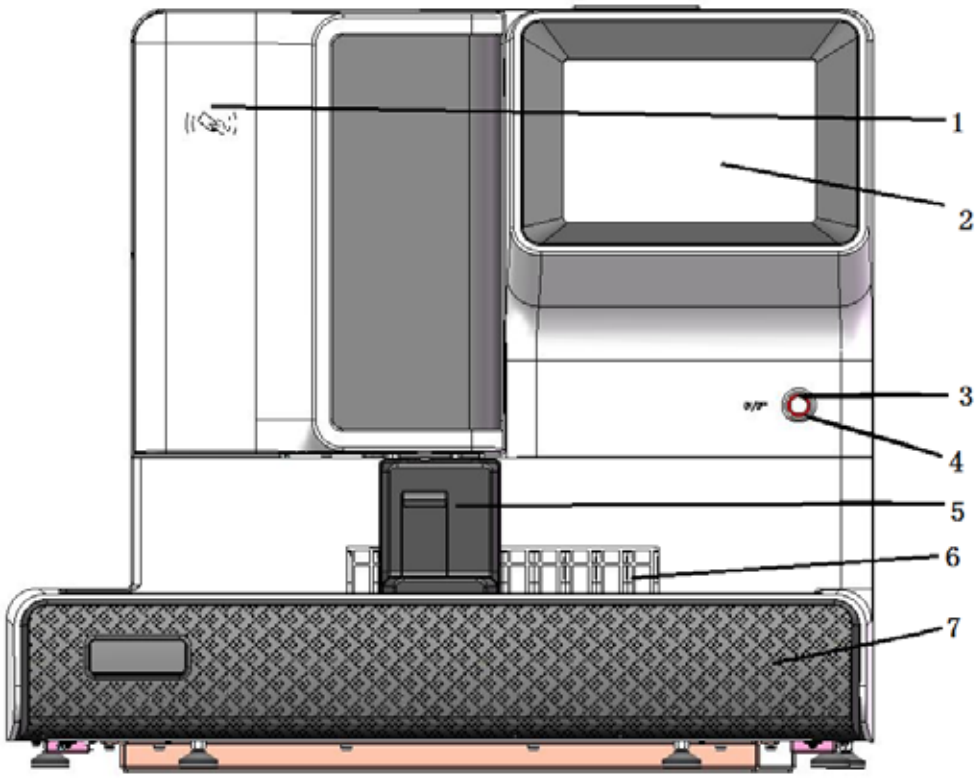


Figure 0-2 Front view of analyzer

1——RFID card swiping place　　2——Operation panel

3——Mode Indicator　　4——On/off

5——For emergency　　6——Test tube rack

7——Automatic sampler

- Operation panel: It is a LCD with touch panel. The operation panel can control various operations and display information.

Caution：

Do not click the operation panel with sharp objects or with force.

Clean the operation panel with a clean soft cloth. If necessary, use neutral detergent or alcohol, but do not use chemical solvent or acidic and alkaline liquid to wipe it.

- Mode indicator

The mode indicator light lies outside the on/off key of the instrument, it has 3 different colors to indicate the mode of the instrument.

Color	Mode
Green	Normal
Yellow	The instrument has a warning level fault, but it can continue to work.
Red	The instrument may stop working, and immediate troubleshooting is required.

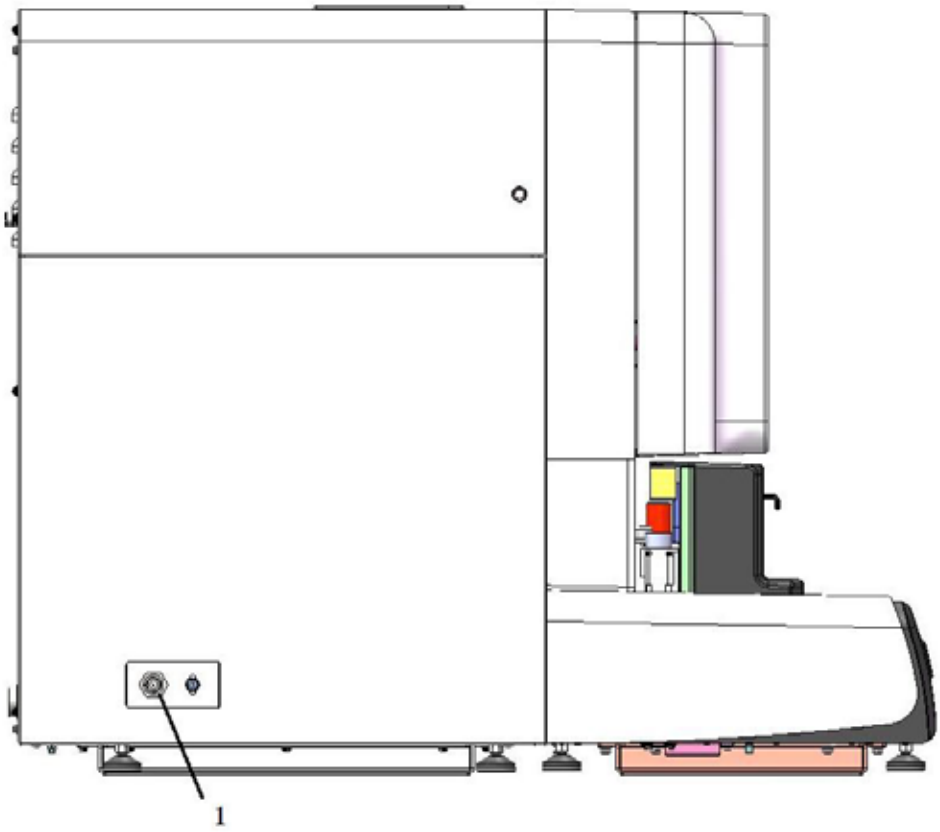


Figure 4-3 The left side view of the analyzer

1——Waste liquid circuit connector

- Waste liquid circuit connector

The connector lies at the lower left side of the analyzer, which is used to connect the waste liquid bucket or waste liquid pipe. Users can choose to discharge the waste liquid directly to pipeline or to a waste liquid bucket.

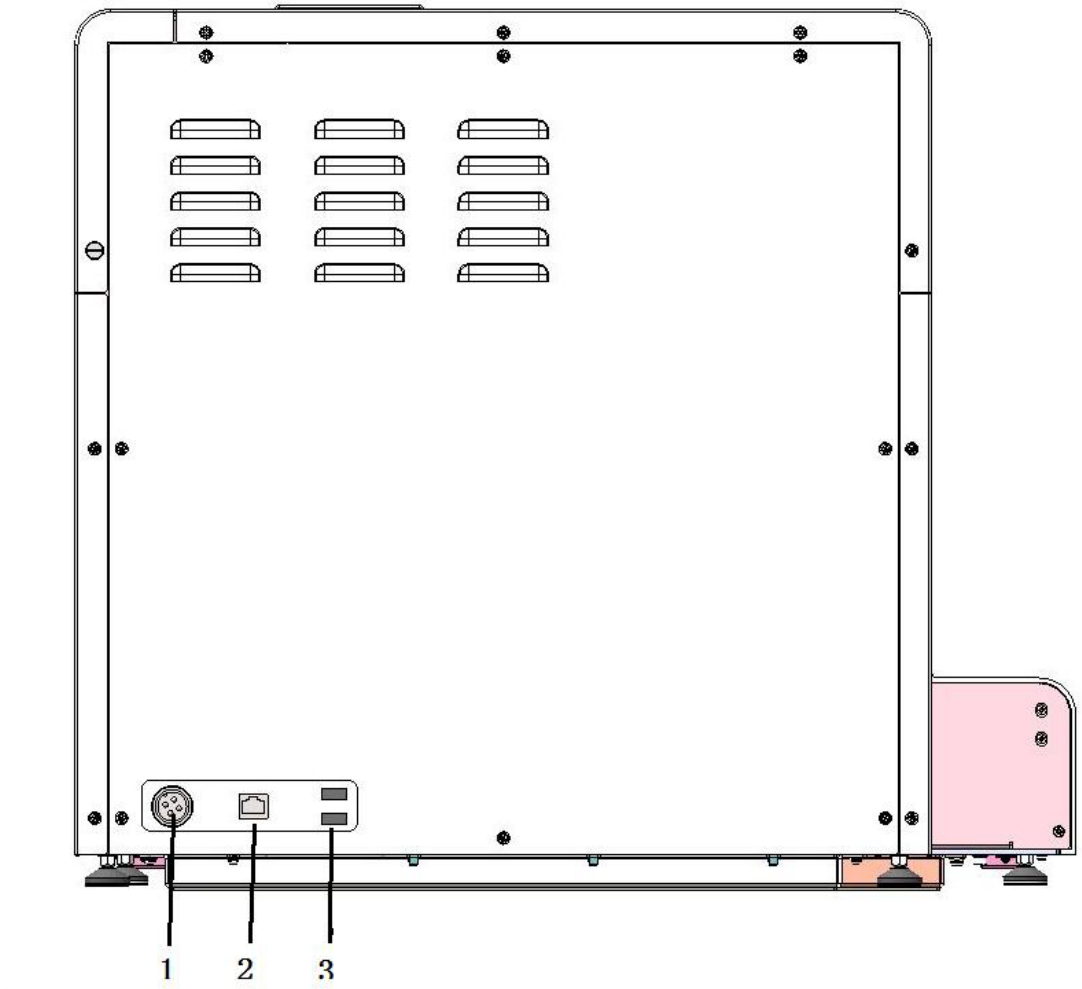


Figure 4-4 The rear view of analyzer

1——Power Input Socket　　2——Network Interface

3——USB interface

Warning：

The signal connector must be connected to the equipment conforming to GB4793.1-2007 standard.

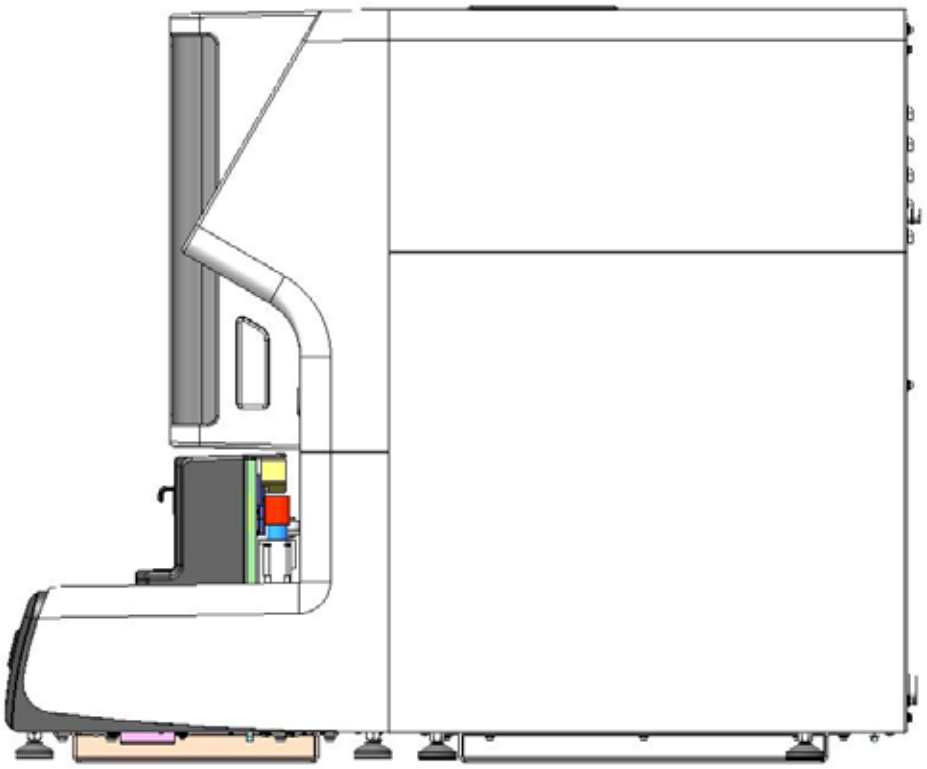


Figure 4-5 The right side view of this analyzer

4.2.2 Accessories

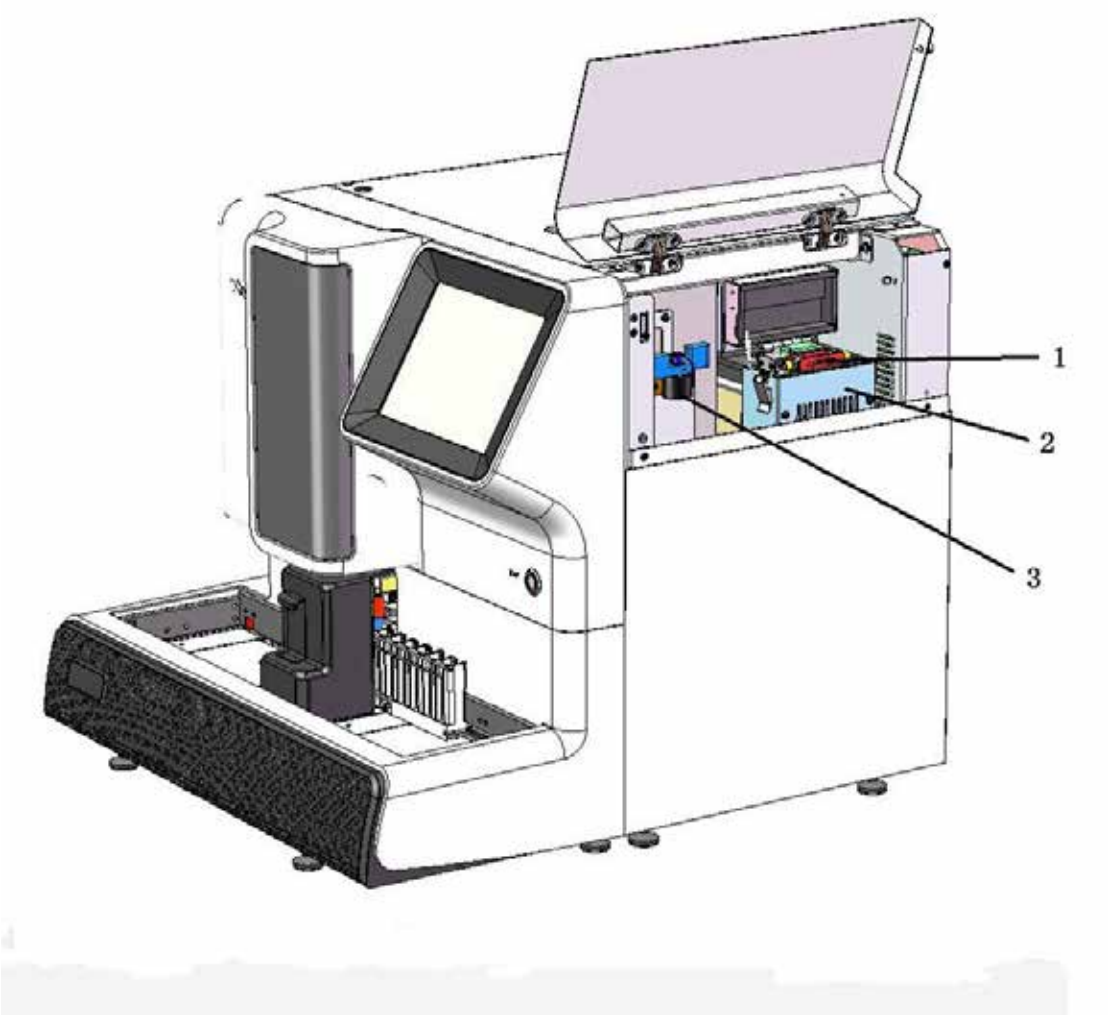


Figure 0-3 The side view of the analyzer

1——Chromatography Column　　2——Column temperature box

3——Filter

Chromatography Column

The Chromatography Column is installed in the column temperature box on the left side of main unit, which is an important measuring component of the analyzer.

Sample rack and adapter

Sample rack

Sample positions and sample racks: This instrument can load up to 9 sample racks, each sample rack has 10 positions, that is, 90 sample positions in total. Each rack can be placed or taken separately. Type of sample tube: It is compatible with vacuum collection tube (φ 12 ~ φ 15 × 75 ~ 100mm) and 2mL sample cup (12mm ×

38mm).

Adapter

When using a sample cup for samples, please choose the adapter that matches it.

Reagent cap assembly

Four sets of cap assemblies are attached, which are respectively connected with reagent bags of eluent A（green）, eluent B（pink）, eluent C/D（yellow）and a reagent bucket of hemolytic agent（orange).

4.3 System Functions

- **User management**

It is divided into general user mode and administrator mode. Users at different levels should carry out corresponding operations.

- **On and off functions**

It has the function of user startup and shutdown.

- **Detection**

It could take whole blood detection and hemolysis detection, and perform many functions including data collection (acquisition), storage, analysis, output (report), etc. It can fulfil the detection of sample parameters.

- **Quality control**

It has the function of quality control.

- **Calibration function**

It has the function of calibration.

- **Maintenance**

It can prompt and record maintenance, and prompt maintenance procedures.

- **Status display**

It has the display function of temperature, pressure, reagent residue, Chromatography Column and filter service times.

- **Fault alarm and handling**

It can prompt/alarm the abnormal state of the instrument and provide fault elimination

function.

- **Communication**

  It can carry out LIS communication.

- **Log**

  It has log function, which can record the operation and faults of the client-side, save and export these operations.

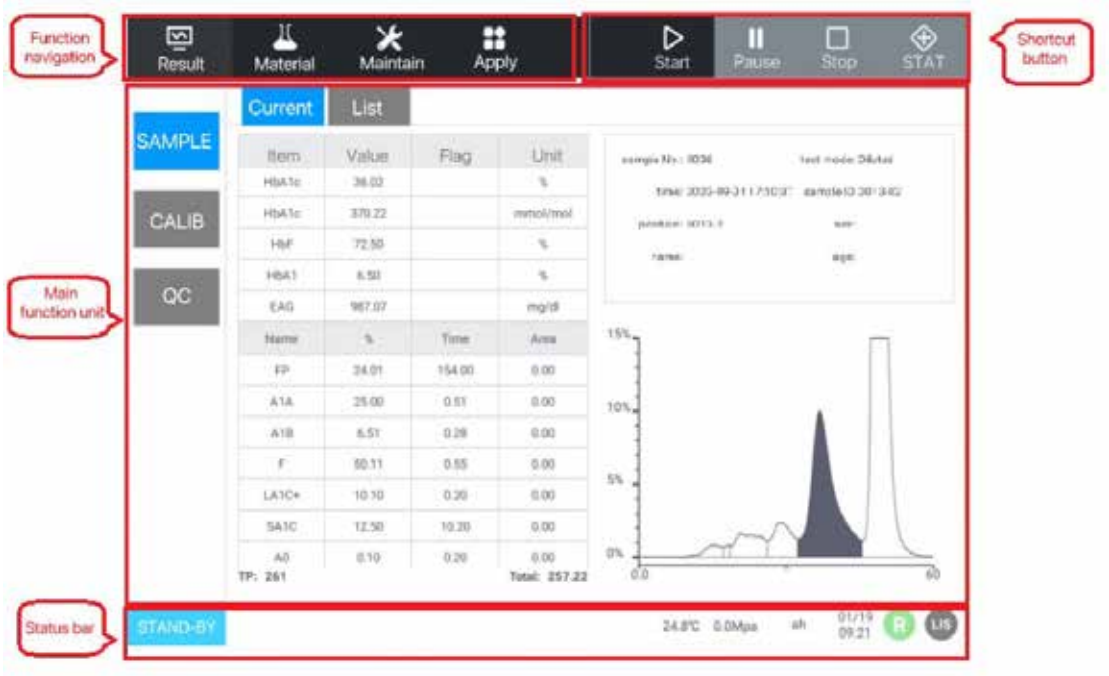
- **Print**

  It can print a report.

4.4 Software Interface and Operation

4.4.1 Software Interface

After logging in, the software will be shown as below, and the user can click to enter the corresponding function interface.



The software interface can be divided into four sections: function navigation, shortcut buttons, status bar and main function unit.

- Function navigation contains the following buttons: results, consumables, maintenance and application. Press the corresponding buttons and the functions are displayed in the main function unit.

Toolbar Level

Number	The first level	The second level	The third level
1	Results (The results can be viewed and edited)	General (ordinary sample)	current
			current
		Calibration	current
			list
		Quality control	current
			list
2	Consumables	General	Eluent A,B,C/D, hemolytic agent, Chromatography Column (you can see the surplus of the above consumables and see the detailed information)
		Calibration	In this interface you can register and fill calibrator
		Quality control	In this interface you can register and fill quality controls
3	Maintenance	In this interface, you can carry out the replacement, filling, degassing, reset and other operations of consumables.	/
4	Application	Settings	Lis
			Print
			Detection
			Result mark
			User
		Log	Fault log
			Operation log
		Statistics	In this interface, you can view all the test quantities tested so far
		Data	You can back up data in this interface.
		About	View software version in this interface.

- Shortcut button: It can control the instrument for detection, pause, stop and emergency treatment.
- The status bar is used to display the LIS connection status, instrument status, fault information, log on user, current temperature and pressure of the instrument, system date and time.

4.4.2 Software Operation

Keyboard

By clicking the edit box, you can call up the soft keyboard for editing operations.

Table

A table will appear in the history results interface, and the operator can browse the information in the table by clicking the button at the bottom of the table. These buttons are: (homepage), (previous page), (next page), (last page).

Date edit box

The following figure shows the date edit box, where the operator can edit the date according to the current date format. The default valid range is: Year [0, 9999]; Month [1, 12]; Day [1,31].

Check box

Click the check box item you want to select, and a "√" mark appears in the box on the left side of the item, indicating that the item is selected. Click the item again, and the "√" mark disappears, indicating that the item is restored to the unselected state.

4.5 Reagents

The operator must use the reagents specified by our company, otherwise, the instrument may be damaged and fail to meet the performance index stated in the manual. "Reagents" in this manual refers to the matching reagents used in this instrument.

The packaging of each reagent must be checked before use. Damage to the packaging may affect the quality of the reagent. Confirm whether the package shows signs of damp or leakage. If this happens, do not use the reagent.

Notice：

Please refer to the manual for the use and storage of reagents.

Ensure that the reagent is used within the validity period indicated on the description.

The reagent shall be allowed to stand for a period of time to stabilize before use.

4.5.1 Matching reagents

- Eluent A,B,C/D for glycohemoglobin analysis

It is used in combination with glycohemoglobin analysis system to detect the content of glycohemoglobin in samples.

- Glycohemoglobin hemolytic agent

It is used for pretreatment of blood samples in glycohemoglobin detection.

4. 5. 2 Quality controls and calibrators

Quality controls and calibrators are used to calibrate analyzers and control its quality.

Quality control is an industrial whole blood product, which is used to monitor and evaluate the precision of analyzer detection results. There are two kinds of quality control products: low value one and high value one. Running 2 different levels of quality control every day can monitor the analyzer's operation and ensure the reliability of the analysis results.

Calibrator is also an industrial whole blood product, which can be used to calibrate some parameters of the analyzer, so as to establish the metrological traceability of the measurement results of the analyzer. Please refer to the instructions for use and storage methods of quality controls and calibrators.

The "quality control" and "calibrator" mentioned in this manual refer to the special quality control and calibrator designated by our company, and the user needs to purchase them from our company or the agent designated by our company.

Chapter 5 Operation Procedures

5.1 Overview

This chapter introduces the whole detection process of analyzer in routine operations.

The complete routine operation process is as follows:

5.2 Check Before Startup

Warning.

Do not touch the moving parts of the instrument and keep your head, hands, clothing, etc. at a safe distance from them.

The following items need to be checked before the instrument starts to test in order to avoid inaccurate testing results or damage to the instrument system.

Check the surplus amount of reagent

Make sure that there are sufficient hemolysis reagent and eluent A, B and C/D, otherwise it will cause an alarm and accurate test results will not be obtained.

Error messages caused by insufficient volume of reagents include: insufficient hemolysis reagent, unabsorbed samples, low total area, etc.

Check the pipelines and connection lines

Check that the connection lines between reagents and waste liquids are connected reliably and ensure that there are no bends.

Check that the system's power plug is securely inserted into an electrical outlet.

Check waste Liquid bucket

Please empty the waste liquid bucket before starting the measurement.

Notice:

The waste liquid contains blood components. Never handle waste liquid buckets or waste liquid tubes directly by hand. Protective gear (goggles, gloves, masks, etc.) must be worn carefully to prevent infection. Waste liquids must be disposed and destroyed in designated facilities in accordance with the relevant regulations.

Check the surplus of printing paper

Check the surplus printing paper and replace it timely if found insufficient. See *9.4.5 Replacement of printing paper* for specific replacement procedures.

Others

Please pay attention to whether there is any leakage. If the Chromatography Column, filter, etc. are found to leak, you should promptly stop the machine, and perform the infusion or eliminate the malfunction after tightening the joint.

5. 3 Power on

5.3.1 Turn on the main power supply

The main power switch of the instrument is located directly under the display screen in its front and functions as a circuit breaker. If the main power supply turns off immediately even though the power switch is on, there is a possibility of power failure inside the instrument. Be careful not to touch the metal part of the instrument, immediately cut off the main power supply, unplug the power lead and contact our after-sale service department.

Notice:

Do not touch the power supply, buttons, and screen with wet hands otherwise it may cause electric shock.

5.3.2 Power-on initialization

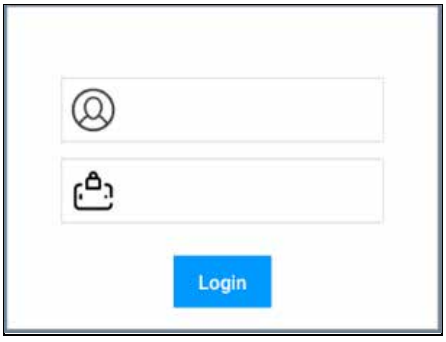
After turning on the main power, the instrument will automatically initialize itself, including system check, power-on check, and mechanical initialization. If a fault message appears during the self-check, please follow the prompts for fault elimination. See *Chapter 10 Troubleshooting* for more details.

Notice:

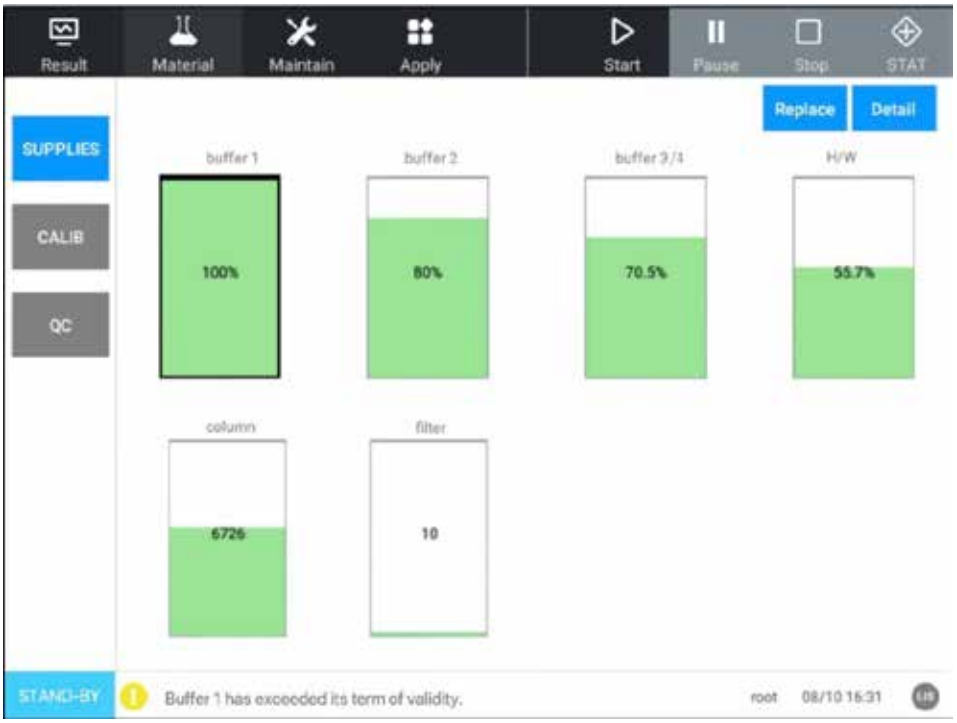
Faults need to be eliminated in time, if not, the next step cannot be performed.

5.3.3 Login and status check

After the initialization, the login dialog box will be shown. After entering username and password in the dialog box, click "Login" button to log in and enter the main interface.



Check the consumables interface to make sure that the surplus amount of each reagent is sufficient.



5. 4 Daily Quality Control

Daily quality control analysis of the instrument is required prior to sample analysis to ensure a truly controllable testing result. See *Chapter 7* **Error! Reference source not found.***Control* for details.

5. 5 Sample Preparation

Two kinds of sample containers are permitted for use in this instrument, the blood collection tubes and special sample cups, which are respectively used in whole blood and hemolysis mode. The user can set the detection operation through "Application" <"Settings" <"Detection" button to select the sampling mode and the corresponding container (see ***Error! Reference source not found.***).

Blood collection tubes with silicone caps can be placed directly on the sample rack. When sample cups are filled with diluted samples, calibrators, and normal samples, they need to be placed on a test tube rack with adapters.

Risk of biological infection.

The blood samples, reagents, waste liquids and areas in contact with these substances used in the test are potentially biologically infectious. when touching relevant items and areas in the laboratory, operators should follow laboratory safety operation rules and wear protective equipment (e.g. laboratory protective gowns, gloves, etc.)

Warning

Do not touch the patient's blood samples directly.

Caution:

Don't reuse disposable products.

Samples should be prepared according to the procedures recommended by the test tube manufacturer.

Notice:

The operator should use clean anticoagulated vacuum blood collection tubes (recommended anticoagulants: K2EDTA, K3EDTA, lithium heparin, sodium citrate, potassium oxalate/sodium fluoride), silicone glass/plastic tubes, centrifuge tubes, and borosilicate glass capillaries.

The operator should use disposable products such as vacuum blood collection tubes and sample cups specified by the manufacturer.

To ensure the accuracy of the analysis results, make sure that the sample volume is not less than 1 mL when using a blood collection tube and not less than 150μLwhen using a sample cup

5. 5. 1 Whole blood samples

Caution.

Don't reuse disposable products.

Use the recommended anticoagulated vacuum tubes to collect venous blood samples.

Quickly mix the venous blood in the tube with the anticoagulant thoroughly.

Make sure that the sample volume in whole blood mode is not less than 1mL to ensure the accuracy of the analysis results.

Samples that have been refrigerated (2°C-8°C) should be left at room temperature for at least 30 minutes before analysis.

Samples that have been left for a period of time need to be re-mixed before analysis.

5. 5. 2 Hemolysis Samples

In the whole blood mode testing, results from the analyzer may be inaccurate if the blood sample volume is too small. The sample can be diluted as required and analyzed again in hemolysis mode.

- Add a certain amount of sample (10μL recommended) to the blood collection tube or sample cup as required by laboratory quality management practices.
- When the sample volume is not sufficient for a whole blood mode testing, the sample can be diluted with a hemolytic agent and mixed thoroughly.
- When measuring blood dilution, the optimal measurement area (total area) is within the range of 700-2500. Higher or lower than this range will not guarantee the reliability of the results. According to the test results, the dilution factor can be adjusted reasonably to enable the total area to fall between the range of the testing.

Caution.

Pre-prepared hemolytic agents should be protected from being mixed with dust, which will result in analytical errors.

Make sure that the analysis is conducted within 30 minutes of sample dilution, otherwise the results will be unreliable.

Blood samples should be mixed by gentle shaking. Intense or mechanical mixing is not allowed.

Samples that have been left for a period of time need to be re-mixed before analysis.

Each laboratory should assess the stability of the analysis results of hemolysis sample based on their specific sample size, sample collection method and technology.

Make sure that the sample volume in the hemolysis mode is not less than 150μL to ensure the accuracy of the analytical results.

5. 6 Analysis of Automated Sample Injection

Risk of biological infection:

All items (samples, control materials, calibrators, reagents, waste liquids, etc.), as well as areas in contact with these substances, have the potential of biological infections. when touching relevant items and areas in the laboratory, operators should follow laboratory safety operation rules and wear protective equipment (e.g., protective gowns, gloves, etc.)

Avoid touching the sampling probe, which has a pointed tip and may carry blood samples, control materials and calibrators that have the potential of biological infections.

Caution:

Don't reuse disposable products.

Samples that have been left for a period of time need to be re-mixed before analysis.

Repeated punctures of vacuum blood collection tubes can damage the rubber cap and the resulting debris may lead to inaccurate analysis. It is recommended that each vacuum blood tube will conduct no more than three punctures.

Verify that the entered sample number, tube rack number, tube number and measurement mode correspond exactly to the sample to be analyzed.

Notice:

You need to select the appropriate parameter reference range in the "Settings" - "Parameter Settings" interface prior to sample analysis, otherwise incorrect alarm prompt will appear when analyzing the sample.

When placing the sample rack, the recess of the sample rack should correspond to the protruding part on the right side of the sample injector.

5. 6.1 Sample Testing Procedures

No barcode mode

1、After confirming that the instrument is in standby state, gently shake the whole blood sample or diluted hemolyzed sample from side to side to thoroughly mix the sample.

2、If the sample is filled in a blood collection tube, place the blood collection tube directly into the tube rack; if the sample is filled in a sample cup, place the sample cup into the adapter and then place them on the tube rack.

3、Place the sample on the sample rack, then place the sample rack in the sample injection area with the open side of the tube rack facing the host machine.

4、 Follow "Application" <"Settings" <"Detection", check whether the set Automated sample injection mode matches the container currently filled with the sample and the injection mode. Please refer to *9.4 Detection Settings* for details.

5、Click the "ON" button and the instrument begins to perform sample analysis.

6、The test results are automatically saved after each sample is tested, and

can be viewed in the results screen.

7、After all samples are tested, the instrument automatically performs a wash function and the tube rack is automatically transferred to the left side of the injector, so please take away the samples promptly.

Barcode mode

1、Place a barcode properly on the blood collection tube.

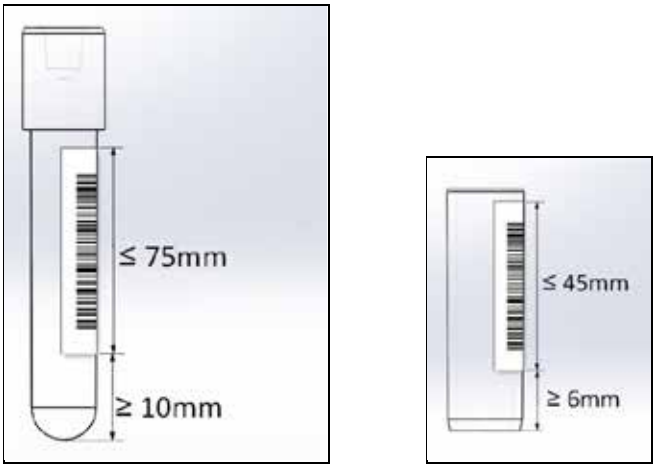
2、Load the sample in the blood collection tube, and shake the whole blood sample or diluted hemolysis sample gently to mix the sample thoroughly.

3、Put the blood collection tube in the test tube rack with the barcode facing the open end of the test tube rack to make sure the barcode can be scanned.

4、Click the "ON" button and the instrument begins to perform sample analysis.

5、The test results are automatically saved after each sample is tested, and can be viewed in the results screen.

6、After all samples are tested, the instrument automatically performs a wash function and the tube rack is automatically transferred to the left side of the injector, so please take away the samples promptly.



blood collection tube sample cup

Figure 5-1 Barcode Pasting Area

Caution:

The barcode label should be horizontal or vertical after pasting, and the inclination angle of the barcode should not be greater than 9°.

Barcode labels should be pasted in strict compliance with the recommended positions.

Barcode labels should be pasted by spreading them flatly from one end to prevent creases.

If the corners of the barcode label are raised, the barcode should be replaced or other remedies should be taken.

It is strictly forbidden to touch liquids in the barcode area, such as blood samples, water, etc.

The barcode area should be protected from scrawling by pen and ink and from scratching by hard objects.

Please use the barcode specifications that are clearly supported in the manual.

The label must be affixed correctly in order to read the barcode accurately. The operator must put the barcode within the area shown in Figure 5-1 and properly affix the barcode according to the rule shown in Figure 5-2.

Figure 5-2 Barcode pasting method

Notice:

In general, it is required to carry out the initialization process, the cleaning of the pump and the heating process of the chromatography column before the testing every day. The whole process takes about 6.1 minutes, please do not cancel.

5. 7 Special Functions

5. 7.1 Pause

Click the "Pause" button in the software interface to pause the sampling process during detection. After the pause, the instrument will no longer inject samples, which will not affect the samples already in measurement.

Click the "Start" button to resume sampling if you need to end the pause after a successful pause; if there is no other operation after 10 minutes of pause, the instrument will resume testing.

5. 7. 2 Stop

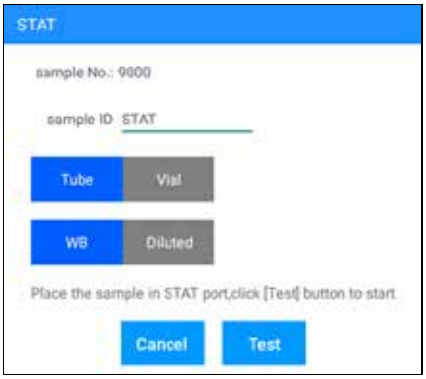
Click the "Stop" button at the top of the software interface to stop the detection, all detection processes can be manually triggered to stop, and can also be stopped after a pause. After testing the current sample, no subsequent samples will be tested and the cleaning process will be performed.

5. 7. 3 Emergency

If an emergency sample is to be prioritized for analysis during the Automated sample injection analysis, please follow the steps below:

Emergency registration

1) Click the "Emergency" button, the following emergency registration dialog box will pop up to register the emergency sample information.



2) Open the emergency sample bank, put the emergency sample into the bank, and close it.

Emergency detection

1) After the current auto-injected samples are sampled, the registered emergency samples will be tested.

2) The system automatically resumes Automated sample testing after sampling the emergency sample.

Emergency Results View

Emergency results can be viewed in "Results" < "Routine".

Notice:

Emergency sample testing requires a specified sample bay for emergency and cannot be conducted in a test tube rack.

Emergency test can only be conducted while the machine is in a testing mode.

Only one emergency sample can be added at a time, and barcode scanning is not available for emergency samples.

Please choose the sample container and testing mode carefully according to the actual use when registering emergency samples, otherwise it will cause damage to the sampling probe or inaccurate test results.

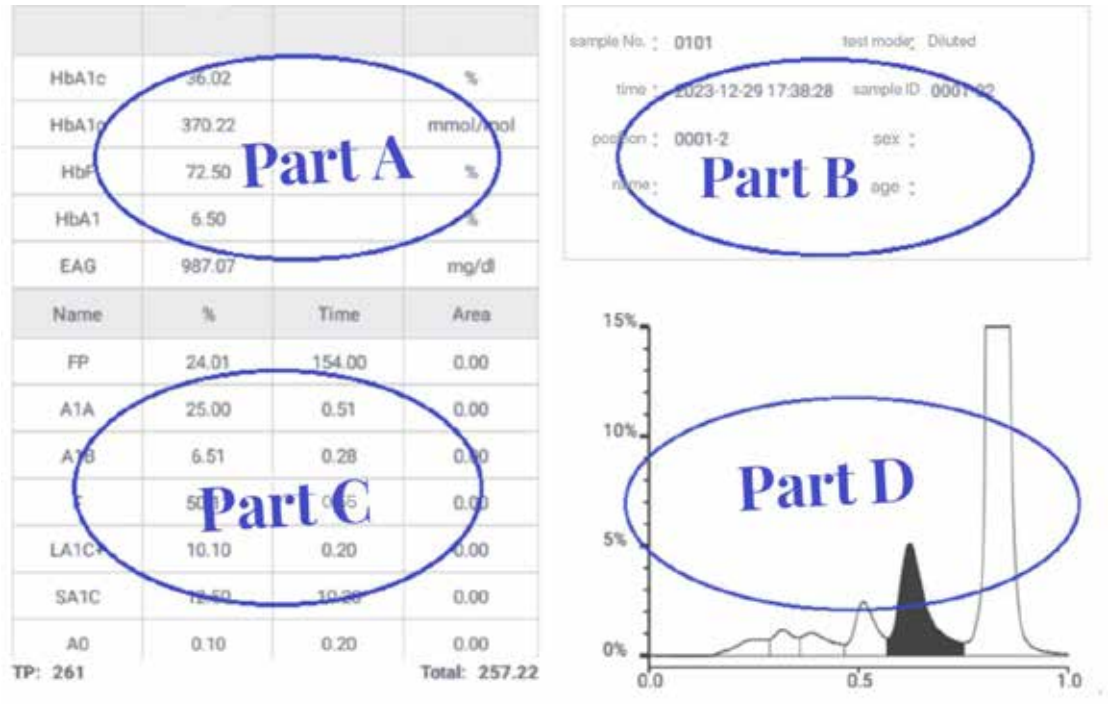
---

5. 8 Analysis Results

Click "Results < Routine" to enter the results view screen. You can view the current sample testing results and a list of historical sample testing results.

5. 8. 1 Current results

The results section is divided into four parts, as shown below:



Part A: You can view the NGSP value (%) and IFCC value (mmol / mol) of HbA1c, HbF (%), HbA1 (%) and EAG (mg/d1); and, when the result does not fall within the set parameter ranges, it will be marked in Part A with " " or " ".

Part B: Sample information can be viewed.

Part C: You can view the percentage content, retention time (S) and peak area of the 7 components of GHb (FP, A1A, A1B, F, LA1C+, SA1C, A0), as well as the number of plates and total area of the current testing result.

Part D: You can view the chromatogram of the sample results. 6-7 peaks can generally be seen in Part D in the order of FP peak, A1A peak, A1B peak, F peak, LA1C+ peak, SA1C peak, A0 peak, which can correspond to the results in the table in Part C. The peak in the darkened part is the SA1C peak.

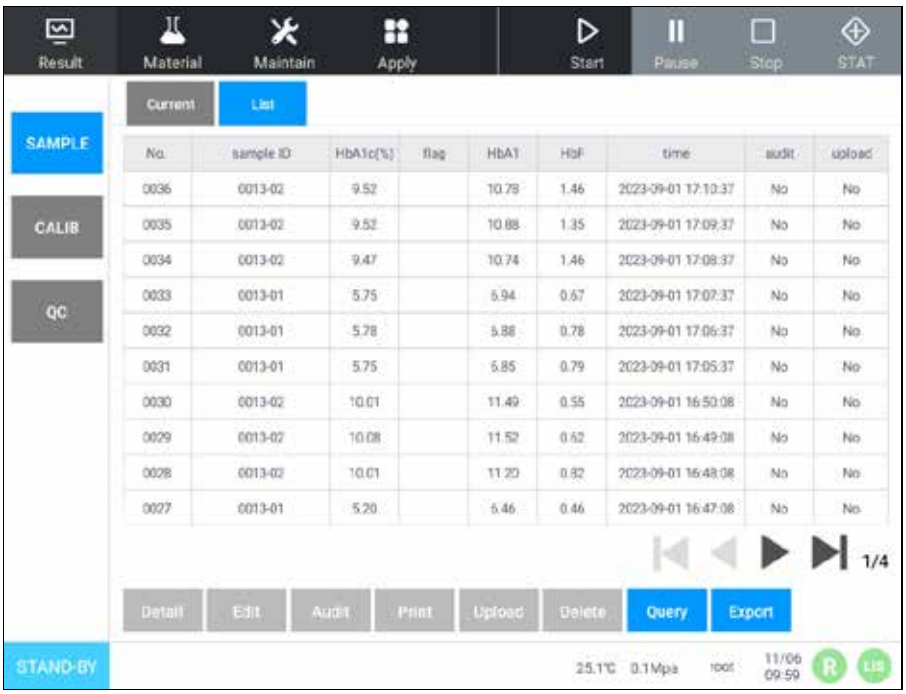
The software excludes peaks eluting after the A0 peak when calculating the Total Area. The HbA1c % is usually not affected in such situations though chromatograms should be carefully reviewed. HbD, HbS and HbC elute after the A0 peak as H-VAR peak. The HbA1c % is generally reportable on the VERTEX-HB when these hemoglobins are present in the heterozygous state with HbA.

If a hemoglobin variant peak elutes independently of the s-A1c peak, but before the A0 peak, it will cause a false decrease in the s-A1c result. However the analyzer detects the presence of a P-HV3 peak where the glycated form of HbE typically elutes .

5. 8. 2 List of Historical Results

In "Result" < "Routine" < "History", the historical results data can be seen, which is ordered by testing time from the near to the distant. 10 results are displayed on each page and you can turn pages by clicking the first page, previous page, next page, and last page below.

The historical data in a list displays the sample number, sample ID, HbA1c (%), mark, HbA1, HbF, testing time, review(yes/no), and upload(yes/no) in sequence. In addition, you can view detailed data, edit, review, print, upload, search, delete, export, and export original data for historical data.

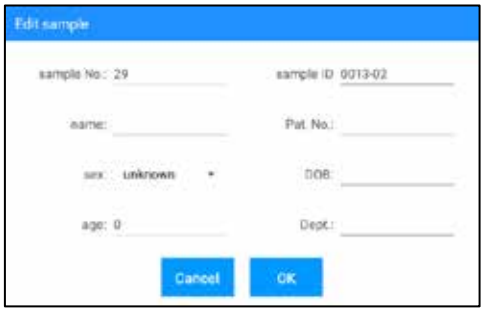


View detailed data

Select the sample row you wish to view and click the "Details" button below to view the detailed information of the sample.

Edit sample information

Select the sample row to be edited and click the "Edit" button, the dialog box will be shown as below, where you can edit the sample number, sample ID, patient name, medical record number, gender, date of birth, age, clinical department and other information.



Review

Select the sample rows to be audited and click the "Review" button to confirm that the "Review" column changes to "Yes" to complete the review.

Print

Select the detection results to be printed and click the "Print" button to print the detection results. Only one detection report is supported to be printed at a time.

Upload

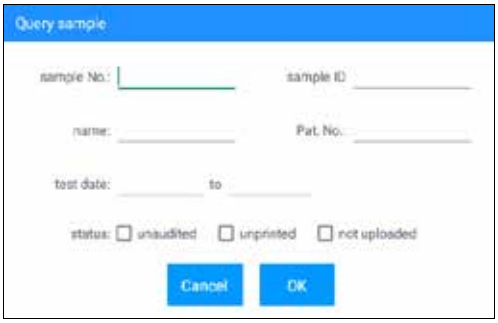
Select the detection results to be uploaded and click the "Upload" button to upload the selected results to LIS.

Notice：

Before uploading, you need to ensure that LIS is on, and you can set it in "Settings < LIS".

Search

Click the "Search" button，a dialog box will be shown as below. Fill in the information and click "OK" to search for a specific sample.



Delete

Select the sample rows to be deleted and click the "Delete" button to delete the selected sample rows.

5. 9 Processing Analysis Results

5. 9. 1 Saving analysis results

The analyzer can automatically save the analysis results.

5. 9. 2 Processing abnormal results

If the analysis result is higher than the pre-defined parameter reference range (see *8.2.4* **Error! Reference source not found.** for the settings of parameter reference range), " " is displayed in the result marker column.

If the analysis result is lower than the pre-defined parameter reference range, " " is displayed in the result marker column.

5. 10 Shutdown

When the instrument is in standby or fault state, short press the power button to shut down the instrument.

If the instrument is not in standby state, short press buttons to pop up a dialog box prompting "The instrument is currently in XXX state, do you want to perform a shutdown?". Click the "OK" button and the instrument will be shut down.

During the detection process, if an emergency situation happens and requires a shutdown of the instrument right away, then long press the power button long to force the machine to shut down.

Notice:

Long press on the power button should last more than 3s.

Chapter 6 Calibration

6. 1 Overview

Calibration aims to obtain accurate measurement results and determine the deviation correction factor for blood sample analysis under specified conditions. In order to obtain accurate blood sample analysis results, the analyzer should be calibrated according to the procedures given in this chapter when necessary.

6.2 Timing of Calibration

Calibration is required in the following cases.

- When quality control results are poor

Calibration is required when the quality control result falls outside the target range; and after calibration, the quality control result needs to be reconfirmed as normal before testing the sample.

- When replacing chromatography columns

After replacing the chromatography column with a new one, please calibrate the instrument promptly.

- When maintaining the instrument

Calibration is required when replacing chromatography column gaskets, etc., or when maintaining the instrument.

- When the instrument parameters change

Calibration is required when instrument parameters change.

Notice:

The calibration frequency is based on quality control results as well as chromatograms.

The operator should use the calibrators and reagents specified by the company, and store and use them in strict accordance with the instructions for their use.

6.3 Calibration Process

Notice:

Repeated punctures of vacuum blood collection tubes may damage the rubber cap and the resulting debris may lead to inaccurate analytical results. It is recommended that each vacuum blood tube will conduct no more than three punctures.

6.3.1 Calibrator Preparation

Please check that the instrument is in order and that there is sufficient reagent left to complete the whole process before calibration. If the reagents are used up during the calibration process, you will need to recalibrate them.

It is recommended that the operator create a log file and file it after making a record sheet. The record sheet are recommended to contain the following items: date, source of calibrator, lot number and reference value.

For calibrator preparation, please refer to the instructions of the calibrator.

Notice

Notice:

Please read the instructions of the calibration kit carefully.

Unopened calibrators need to be stored in refrigerators and used before the indicated expiration date.

The amount of calibrator taken out should be more than 400 μL, otherwise the accuracy of the calibration results cannot be guaranteed.

Use them immediately as the calibrators dissolve and avoid prolonged exposure to room temperature. For leftover solutions after use, they should be sealed with a rubber stopper and screw cap, and preserved in refrigerator.

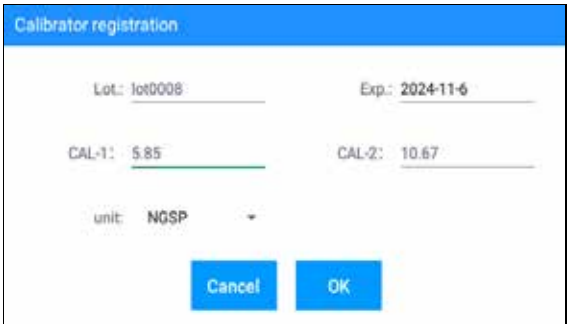
Calibrators can be stored for approximately one week after dissolution.

6.3.2 Calibration operation

1) Prepare one CAL-1 and one CAL-2 calibrator according to the steps in *7.3.1.1 Preparation of calibrators.*
2) Calibration information can be registered by swiping the RFID card or by manually entering it.

a）Swipe calibration RFID card to register calibration information.

Place the corresponding RFID card for the calibration item on the swiping area and the following interface will pop up when you hear a beep.



b) Manual enter to register calibration information

Click "Consumables < Calibration < Registration" , the interface will be shown as below. Enter the lot number, expiration date, CAL-1 and CAL-2 values according to the calibrator instructions or bottle information, and select the type of the test value (either NGSP value or IFCC value).

3) Check the calibrator information, click the "OK" button to pop up "Calibrator Registration Complete", then click "OK" to complete the calibration registration.

4) Place the calibrators in the tube rack with calibrator CAL-1 (low concentration) in tube position 1 and calibrator CAL-2 (high concentration) in tube position 2, and place the tube rack on the Automated sampler.

5) Click "Consumables < Calibration < Test Tube Rack" to view the rack label number and determine if the calibration rack number matches the rack currently in use.

6) Click the "Start" button to start the calibration analysis.

7) After calibration, the calibration results are automatically displayed in the "Results < Calibration" interface.

Notice

Notice:

Calibrators, waste liquids, etc. have the potential of biological infections. when touching relevant items in the laboratory, the operator should follow the laboratory safety operation regulations and wear protective equipment (such as laboratory protective clothing, gloves, etc.).

The operator must use the calibrator specified by the company for this analyzer; the use of other calibrators may result in inaccurate analytical results.

Refer to the instructions for use and storage of the calibrators.

The operator should use a clean 2mL sample cup.

If the room temperature is higher or lower than the normal operating temperature of the analyzer, it will cause the instrument temperature (the temperature measured by the sensor inside the instrument) to exceed its limit, thus making the analysis results unreliable. At the end of the analysis, a temperature abnormality alarm message will be displayed in the fault message. See *Chapter 10 Troubleshooting* for instructions.

Caution.

Don't reuse disposable products.

6.3.3 Validation of calibration results

After completing calibration, please test and analyze the remaining two levels of calibrators once again, and check whether the analysis result is within the allowable range of the target value. Please refer to *Analysis of Automated sample injection* for procedures of the testing analysis.

If the analysis result is not within the range of target value of the calibrator, please recalibrate the instrument. If the problem cannot be solved, please contact our after-sales & service department.

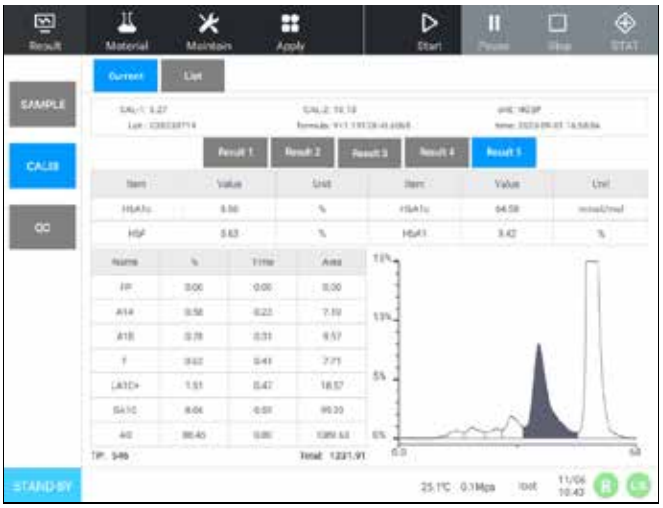
6.4 Calibration results

Current calibration results and historical calibration results can be viewed in Calibration Results.

6.4.1 Current

Click "Results < Calibration" button to view the current calibration results.

You can view the latest results in this interface. 2 levels of calibrators need to be tested in one calibration. They need to be calibrated for 5 times in total, 3 times for calibrator level 1 and 2 times for calibrator level 2. The calibration results of these 5 tests are displayed in the order of Calibrator 1, Calibrator 2, Calibrator 3, Calibrator 4 and Calibrator 5 in the current calibration results interface. Click to view the corresponding calibration results, and the selected calibration results are highlighted.



In the Results column, you can view the sample information of the current calibration.

- Calibration parameter 1 (C_1, reference value for calibrator level 1)
- Calibration parameter 2 (C_2, reference value for calibrator level 2)
- Reference type: including NGSP (%) and IFCC (mmol / mol)
- Calibration formula: Y=AX+B

$$A = \frac{C_2 - C_1}{S_2 - S_1}$$

$$B = C_2 - S_2 \times A$$

C1 - calibration parameter 1.

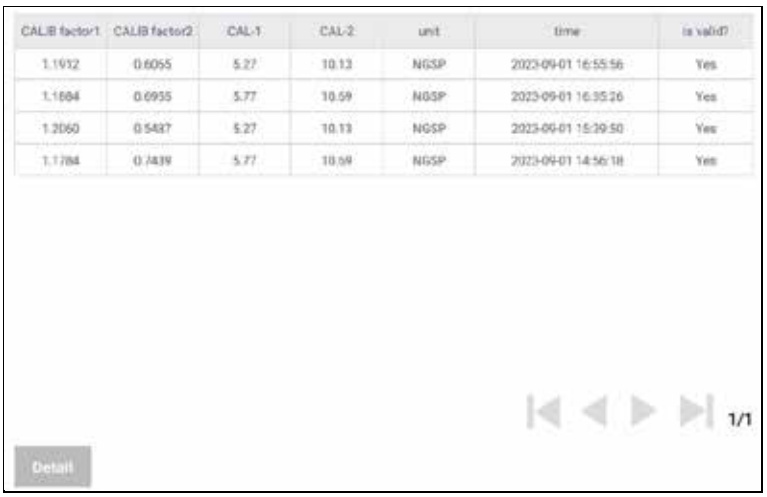
C2 - calibration parameter 2.

S1 - mean of the second and third HbA1c of calibrator 1.

S2 - mean of the first and the second HbA1c of calibrator 2.

6.4.2 List

Click "Results < Calibration < List" button to view historical calibration results.



The displayed content includes calibration coefficient 1, calibration coefficient 2, parameter 1, parameter 2, reference type, time and successful(yes/no). 10 results are displayed on each page and you can view historical calibration results of the first page, previous page, next page, and last page by turning pages.

Select any result data and click "Details" to view more detail information.

6.5 Calibration Failure

When the calibration fails, the detection will automatically be terminated, and the instrument will conduct cleaning command and enter standby state. After ruling out the possibility of the calibration failure, please carry out the calibration again.

The system will regard the following conditions as calibration failure:

1. When the difference between the second and third SA1C% values exceeds 0.3%;

2. When the difference between the fourth and fifth SA1C% values exceeds 0.3%;

3. When the label values respectively corresponding to the second to fifth SA1C% values exceed ±30%.

If any of the above conditions are met, the system will regard that the calibration fails.

The possibilities for these errors are roughly as follows:

1. After dissolving the calibrator, leave it for more than one week, or leave it at room temperature for a long time.

2. The filter and the chromatography column are blocked, making the pressure increase.

3. Liquid leakage.

4. Samples instead of calibrators are used for the testing.

Remedy:

If a calibration failure occurs, replace the chromatography column or filter, or prepare a new calibrator, reinforce the connecting pipeline, etc., and perform the calibration again.

Chapter7 Quality Control

7.1 Overview

A certain degree of deviation may occur during the long-term use of the analyzer, which may lead to wrong or unreliable analytical results. Quality control can monitor the performance of the analyzer to ensure that its performance meets the measurement requirements. So each laboratory must perform quality control in accordance with laboratory specifications. VERTEX-Hb instrument requires daily quality control to ensure accurate and controllable results.

The operator detects the control materials on the analyzer and compares the results according to a specific statistical method. If it is judged to be out of control according to laboratory practices, certain measures need to be taken.

Quality control refers to the daily monitoring of analyzer performance by certain control materials. Quality control procedures provide an effective method for standardized measurements in the laboratory. Only when the operator is familiar with the theory of quality control and masters the actual operation methods, can the stability of the analyzer be effectively monitored.

In order to ensure the reliability of the sample analysis results, it is recommended to use 2 levels of control materials with different HbA1c values for experiments. Please use the control materials provided by our company for corresponding operations.

7.2 Quality Control Process

The operator can perform quality control on the parameter HbA1c. The analyzer provides a total of 20 quality control files to allow the operator to save quality control parameters and results, with each file recording results for one control materials.

7.2.1 Control Materials Preparation

Please refer to the instructions of the control materials for the preparation of control materials.

Risk of biological infection:

All items (samples, control materials, calibrators, reagents, waste liquids, etc.), as well as areas in contact with these substances, have the potential of biological infections. when touching relevant items and areas in the laboratory, operators should follow laboratory safety operation rules and wear protective equipment (e.g., laboratory protective gowns, gloves, etc.).

Notice:

Don't reuse disposable products.

The control materials should be mixed gently and manually upside down. To avoid air bubbles, mechanical mixer is not allowed.

Notice.

The operator should use the control materials and reagents specified by our company, store and use them in strict accordance with the instructions for use of the control materials and reagents. Please read carefully the instructions of control materials before using them.

7.2.2 Quality control operations

1) After completing the quality control registration, the operator can prepare the control materials of one CRL-1 and one CRL-2 according to **Error! Reference source not found.***Preparation of control materials*

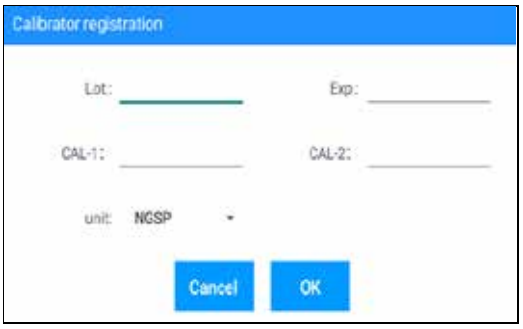
2) The quality control information can be registered by swiping the RFID card or by manually entering.

a) Swipe quality control RFID card to register quality control information.

Place the corresponding RFID card for the control materials on the swiping area and the following interface will pop up when you hear a beep.

b) Manual enter to register quality control information

Click "Consumables < Quality Control < Registration" button, the following interface will be shown. Enter the lot number, expiration date, reference value and deviation value according to the instructions of control materials or bottle information, and select the type of the test value (either NGSP value or IFCC value) and quality control level (L means low-value control materials, H means high-value control materials).



3) Confirm that the information of control materials is consistent with that on the quality control bottle, click "OK" to select the quality control document. When "Registration Completes" pops up, the registration of the quality controls is completed.

4) Place the control materials in the tube rack with control material CAL-1 (low value) in tube position 1 and control material CAL-2 (high value) in tube position 2, and place the tube rack on the Automated sample injector.

5) Click "Consumables < Quality Control < Test Tube Rack" to view the tube rack number and check whether it matches the current rack in use.

6) Click the "Start" button to start the quality control analysis.

7) Once quality control is completed, the results are automatically displayed in the "Results < Quality Control" interface.

Notice

Notice:

The remaining quality controls can be stored at a low temperature of 2～8 for

7 days, frozen at -20 for 30 days. You need to take it out from cryogenic environment and rewarm it to the temperature of 10-32°C for use.

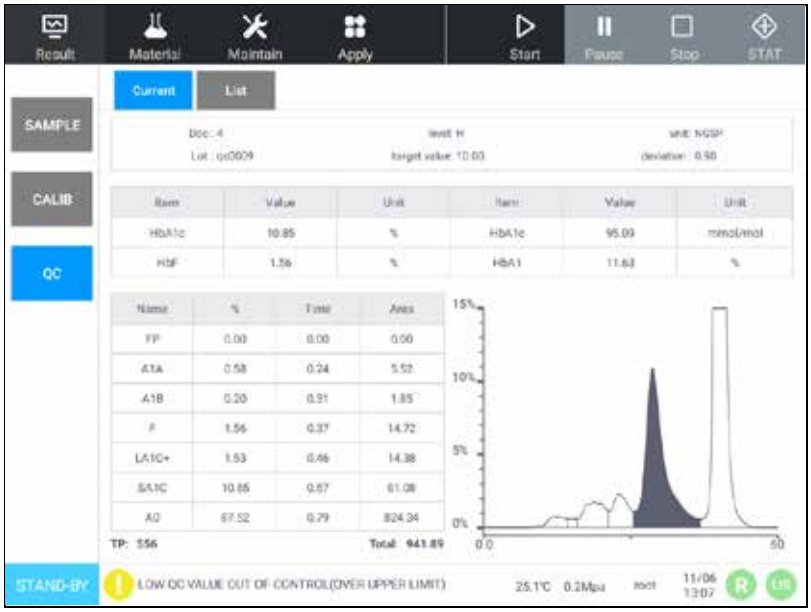
The opening date is required to be recorded on the bottle.

7.3 Quality Control Results

The quality control results are divided into current and historical ones.

7.3.1 Current

You can click "Results <Quality Control < Current" to view the results of the latest quality control.



The detection result of the latest quality control sample is displayed on the current result interface, with each quality control sample measured three times and displayed as Results 1, Results 2, and Results 3.

Detailed information of quality control results includes:

- Quality control file: quality control file number, corresponding to the number column in "Consumables < Quality Control".
- Level, reference type, reference value, deviation value.
- Mean: the average of three quality control testing results of the same control materials in the same batch.

$$Mean = \frac{\sum_{i=1}^{n} X_i}{n}$$

n is the number of quality control analysis; X_i is the ith quality control result of the specified parameter.

- SD: The standard deviation of the three quality control testing results of the same control materials in the same batch.

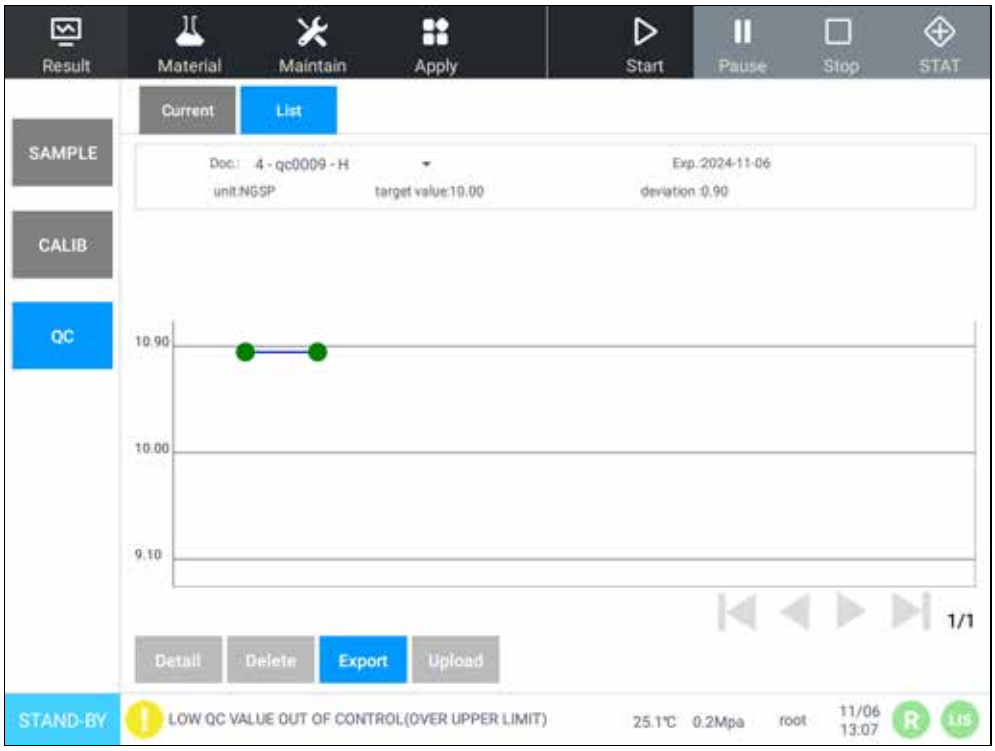
$$SD = \sqrt{\frac{\sum (X_i - Mean)^2}{n-1}}$$

- CV: The index of variation of the three quality control testing results of the same control materials in the same batch.

$$CV\% = \frac{SD}{Mean} \times 100$$

7.3.2 List

Click "Results < Quality Control < List" button to view historical quality control results.

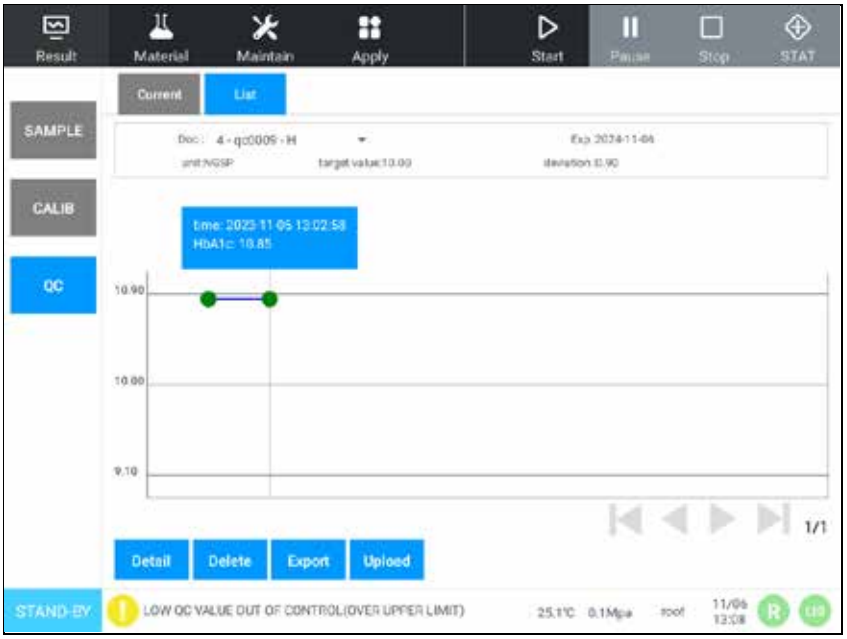


The quality control information that can be viewed in the history interface

includes files, expiration date, reference types, reference values, and deviation values.

- File: In the file drop-down list, you can select the quality control document number to switch to view the historical results of different quality control documents. A total of 20 historical files can be viewed. A quality control file records the test results of one level of one type of control material.
- See **Error! Reference source not found.Error! Reference source not found.**for the meaning of expiration date, reference types, reference values, and deviation values.

Quality control chart



The historical results are displayed in the form of a line chart in the quality control chart. The points that are above or below the upper and lower limits are marked on the horizontal line and flagged in red. 10 points are displayed on each page.

- The meaning of each point in the quality control chart is explained as follows:

  Green point: the point is within the control range.

  Red point: the point is beyond the control range.

- The vertical data on the left side correspond to the three horizontal dividing lines in the chart. The data indicate the upper limit, target value and lower limits of the parameters from top to bottom.

  Upper limit: reference value of the quality control + deviation value.

  Target value: reference value of the quality control.

  Lower limit: reference value of the quality control – deviation value.

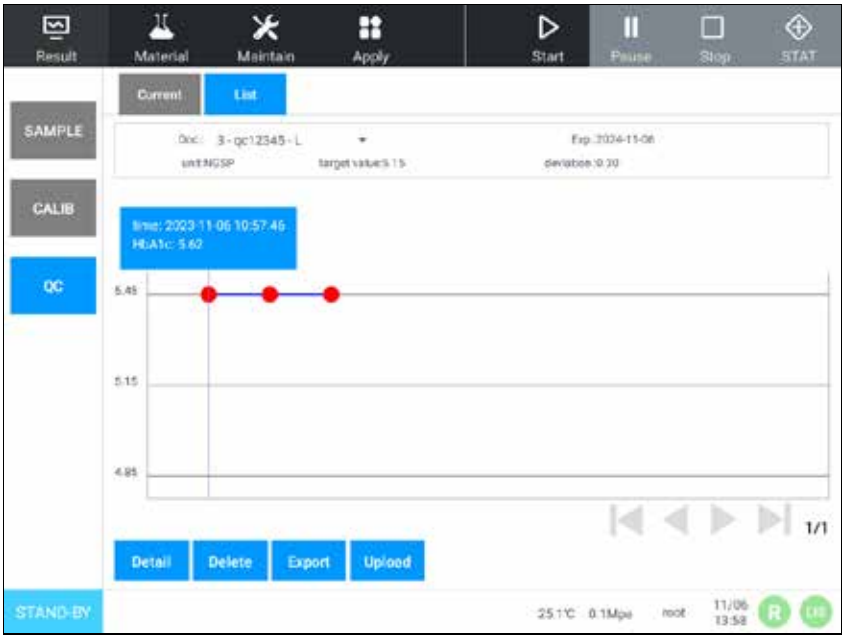
- View Details: Select the quality control point and click the "Details" button to

display the detailed data of the three quality control tests, including the testing time, mean, SD and CV values.

- Delete: Delete the selected quality control point and its associated data.
- Export: Export data from the current quality control file to external storage equipment.
- Upload: Upload the data of the selected quality control point to LIS.

7.4 Quality Control Failure

After completing the quality control analysis, if the result is out of the range, it means that the quality control fails. In this case, the quality control results in the chart are shown in red points.



If the quality control results are out of the control range, it is recommended to follow the steps below until the problem is resolved. If the problem cannot be solved after completing the steps below, please contact our after-sales & service department.

1. Check the fault message on the screen, if there is a fault, refer **Error! Reference source not found.***10* **Error! Reference source not found.**troubleshooting.

2. Check the range of the settings values of quality control and modify them if they are incorrect.

3. Re-conduct quality control analysis.

4. If the quality control result remains out of the control range, perform the quality control analysis again with another bottle of control materials; if the result is the same as previous ones, recalibrate the instrument.

Chapter 8 Application

8.1 Overview

The user can set up the instrument to meet the testing requirements as described in this chapter, and, with the guidance of this chapter, the testing data of the current instrument can be viewed.

8.2 Settings

8.2.1 LIS settings

The user can change LIS settings and communication settings via clicking "Application < Settings < LIS" button.

LIS IP Address:192.168.7.66

LIS Port: 1001

Enable LIS: If enabled, it will automatically connect with the device when booting

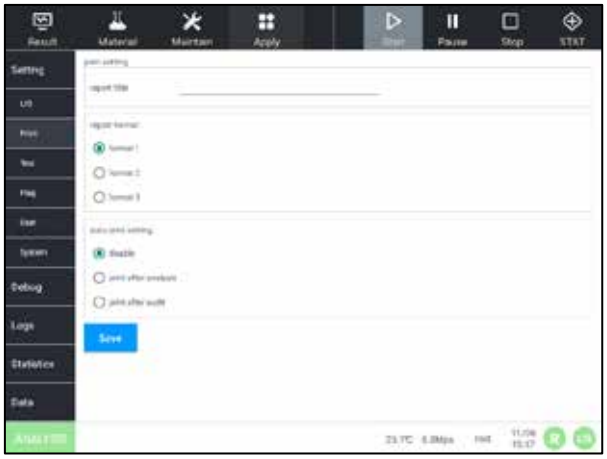
Bi-directional: If a barcode is required during Automated sample injection, select Bi-directional

- Click to edit IP address and the port of the LIS server.
- By checking the checkbox in the communication settings below, the user can set whether to enable LIS, whether to be bi-directional, and whether to upload result markers.
- The local IP can be set.

- Click "Set" after making changes to save the changes and complete the settings.

8.2.2 Print settings

The user can set printing via clicking "Application < Settings < Print" button.

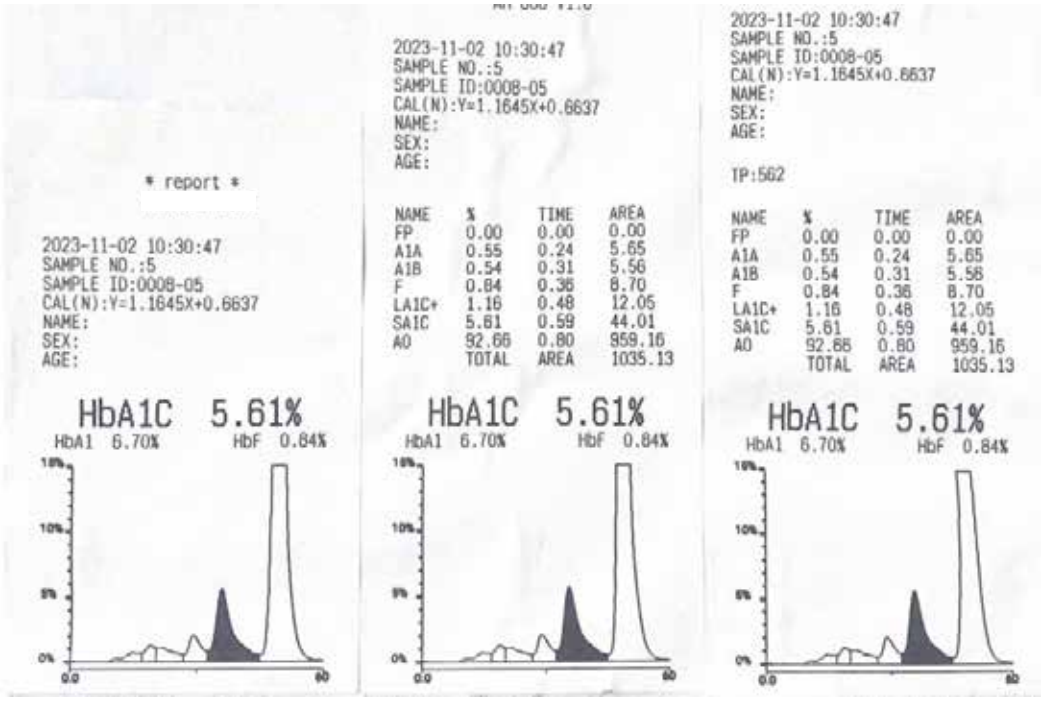


- Click to edit the report sheet title.
- Three printing formats are available.

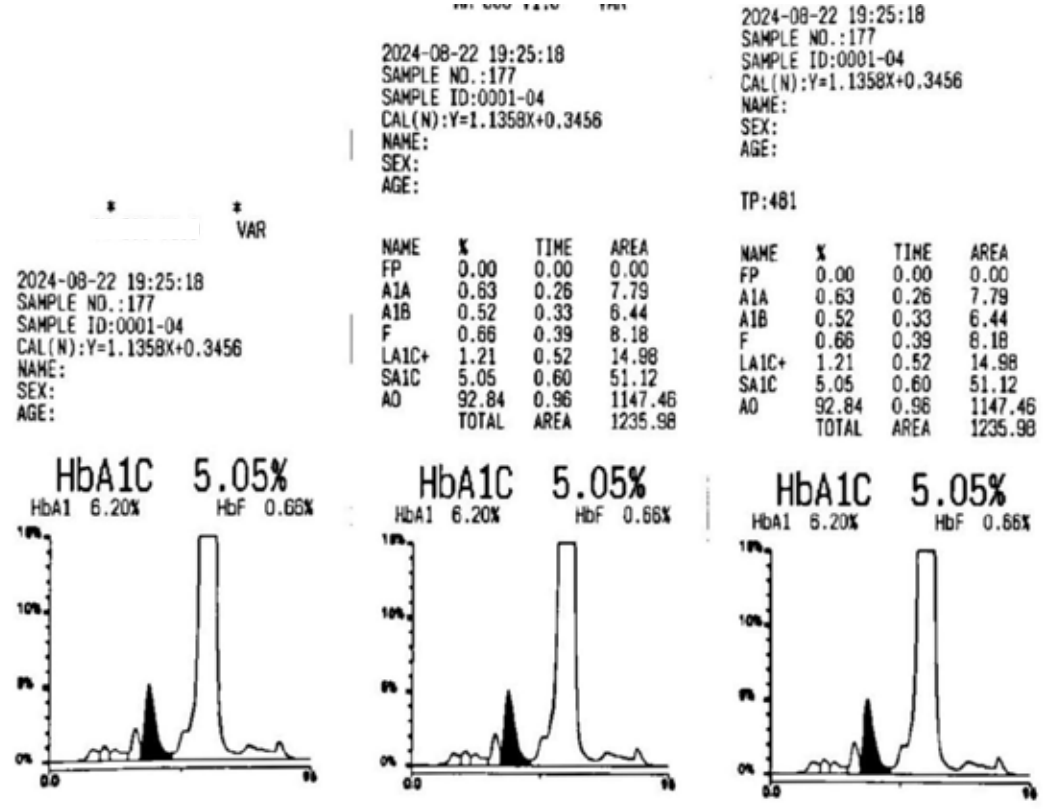
Format 1: Simplified format. The exported information includes: report sheet title, instrument specifications and software version, basic sample information (testing time, sample number, sample ID), patient information (name, gender, age) calibration formula, testing results (HbA1c, HbF), and chromatogram.

Format 2: Detailed format. In addition to the information in Format 1, it also includes details about the percentage value, retention time, and retention area of each component.

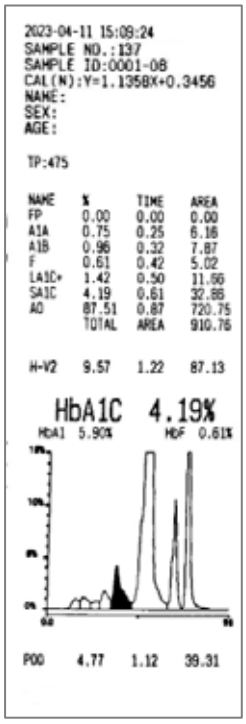
Format 3: Adds the number of plates on the basis of Format 2.

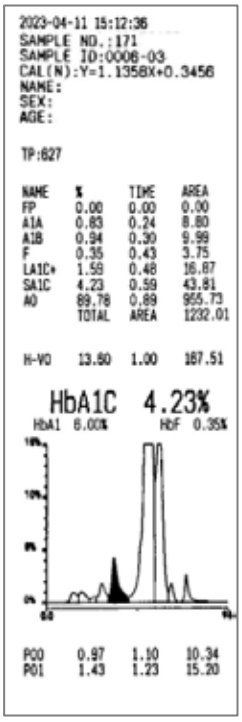


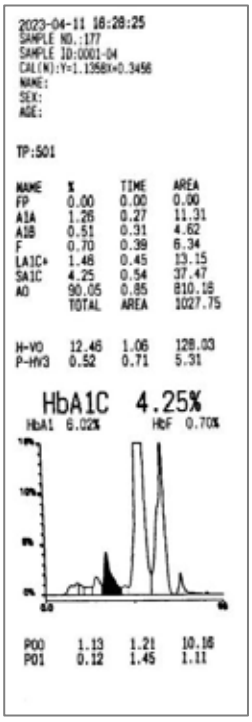
Format 1 Format 2 Format 3

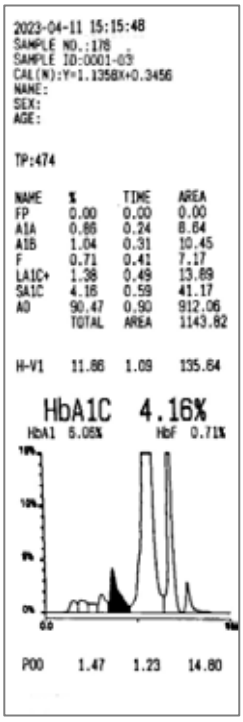


Format 1 Format 2 Format 3









HbC HbD HbE HbS

- By checking the checkbox, the user can choose whether to print automatically, 3 modes are available:

  Mode 1: Off

  Mode 2: Automated printing after sample analysis.

  Mode 3: Automated printing after review

8.2.3 Detecting setting

The user can set detection via clicking "Application <Settings <Detection".

- Click to edit the starting number of the normal sample rack.
- Tick the check box to select Automated sample injection mode recognition, namely, two loading containers of blood collection tube and sample cup, which

can be combined freely with the whole blood mode and hemolysis mode for detection.

- Click "Settings" to complete the change.

8.2.4 Parameter settings

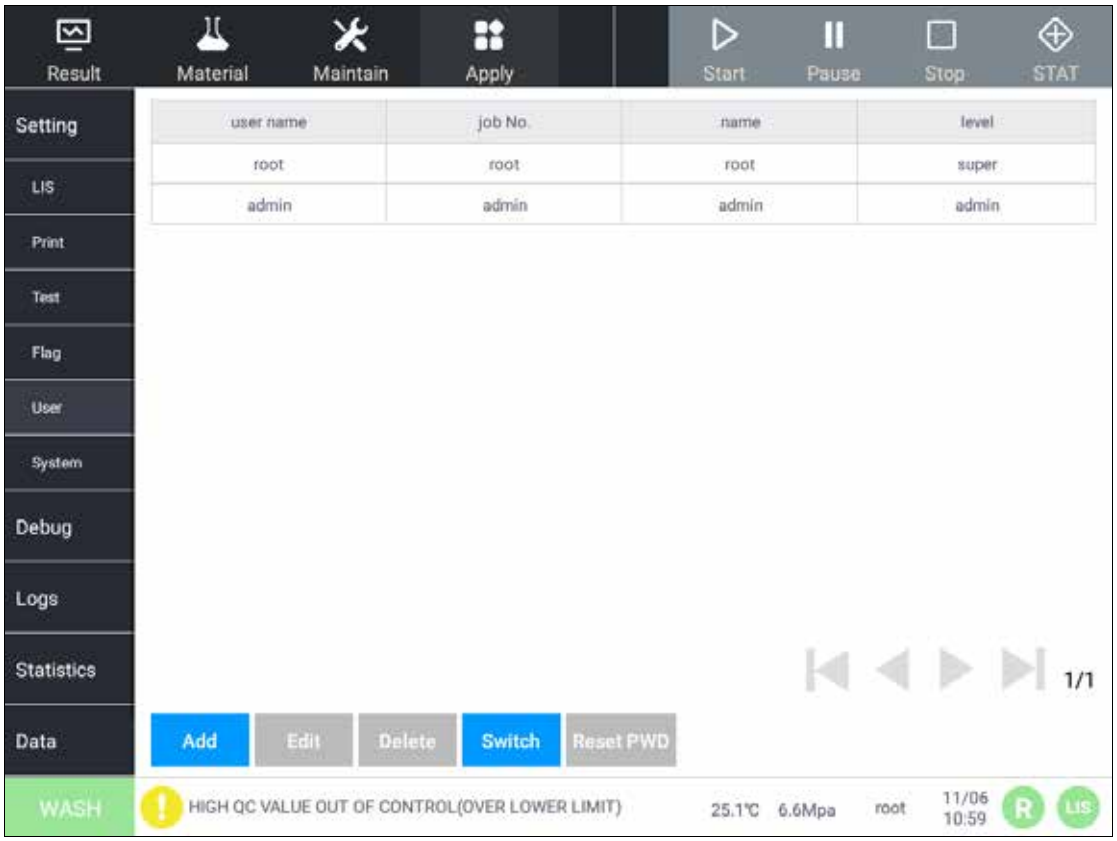
The user can click "Application <Settings <Result Mark".

The user can set the reference range of each parameter (HbA1c (unit %), HbA1c (unit mmol/mol), HbF, HbA1) on this interface, and choose whether to apply the parameter settings.

8.2.5 User settings

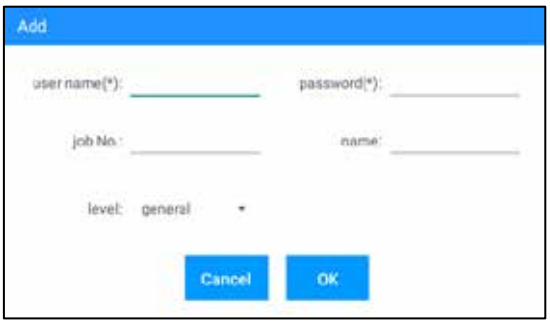
The users can perform user management via clicking "Application<Settings <Users".

The users can add, edit, delete, change Users ID and reset passwords in the user management interface. General users can only view their own user list and modify their own information and passwords; administrator users can add, modify, delete, and reset other users' information.



8.2.5.1 Add user

- Click the "Add" button on the user interface, and the "Add User" edit box will be shown as below.

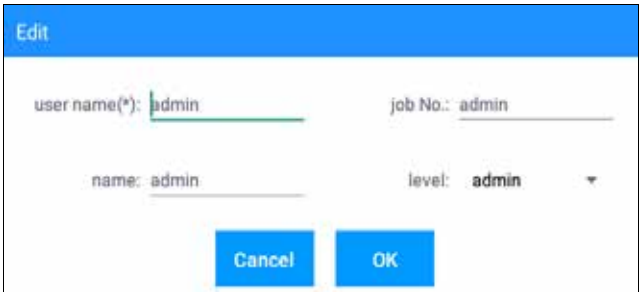


- Enter the user name, password, employee number, and name in the edit box. Administrator-level accounts can select "Administrator" or "General User" identity; general users can only select "General User" identity.
- Click "OK".

8. 2. 5. 2 Edit user

Administrator-level users can modify passwords and user permissions on this interface.

- Select the user information that needs to be modified, click "Edit", and the dialog box will be shown as below.



- Enter the new password, then click "OK" to complete the password modification.
- Administrator-level users can change user permissions in the "Permissions"

8.2.5.4 Delete user

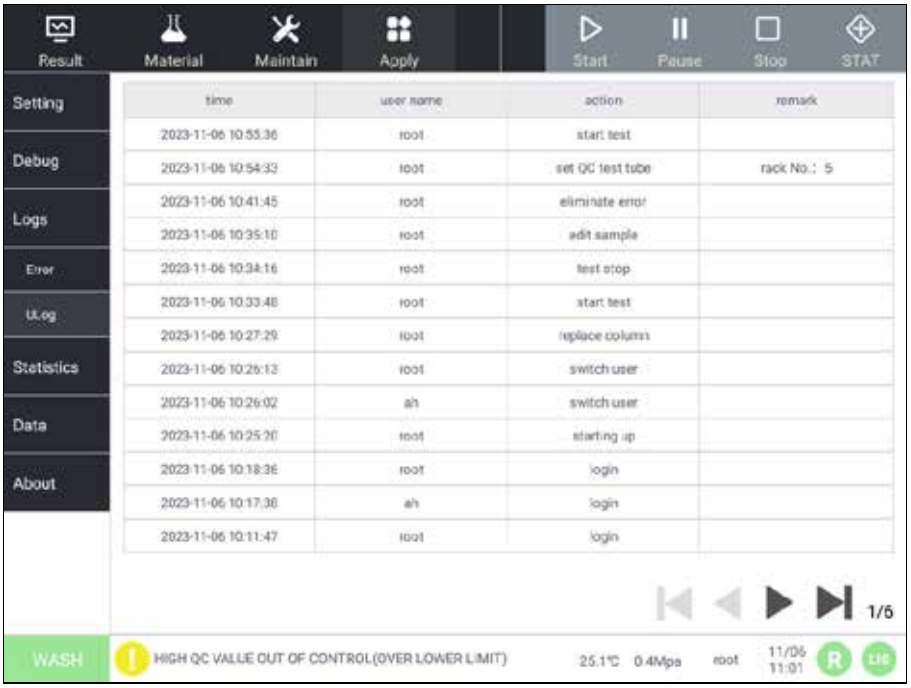
Administrator-level users can select user information and click the "Delete" button in the user interface to delete users.

8.2.5.5 Reset password

General users can reset their own passwords while administrator users can reset the passwords of both administrator and general users on this interface.

8.3 Log

The users can view the fault log and operation log via clicking "Application <Log".

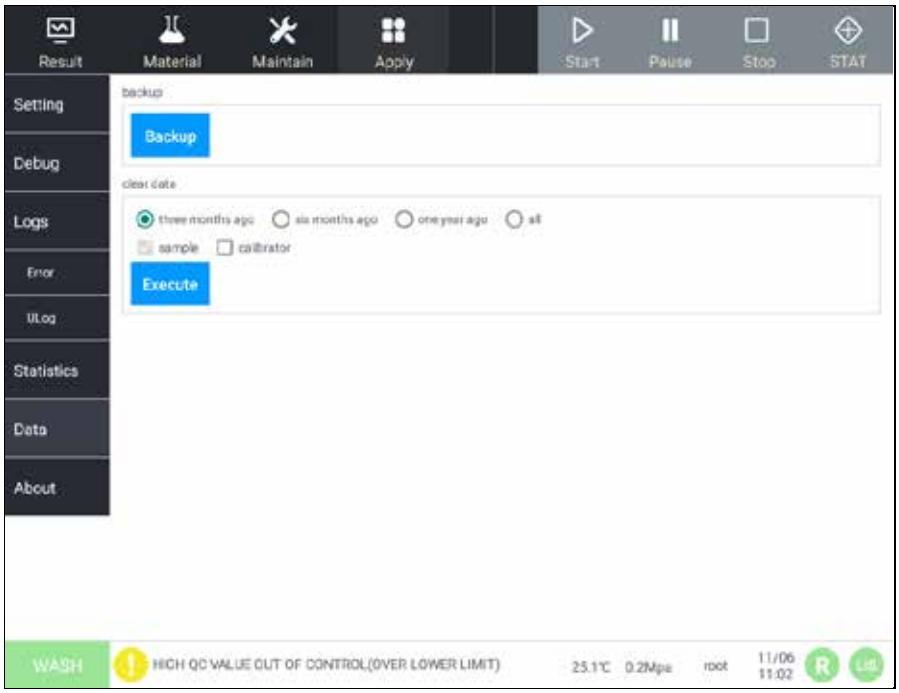


8.4 Statistics

The user can view all the previous test quantities of the analyzer and query by time period via clicking "Apply <Statistics".

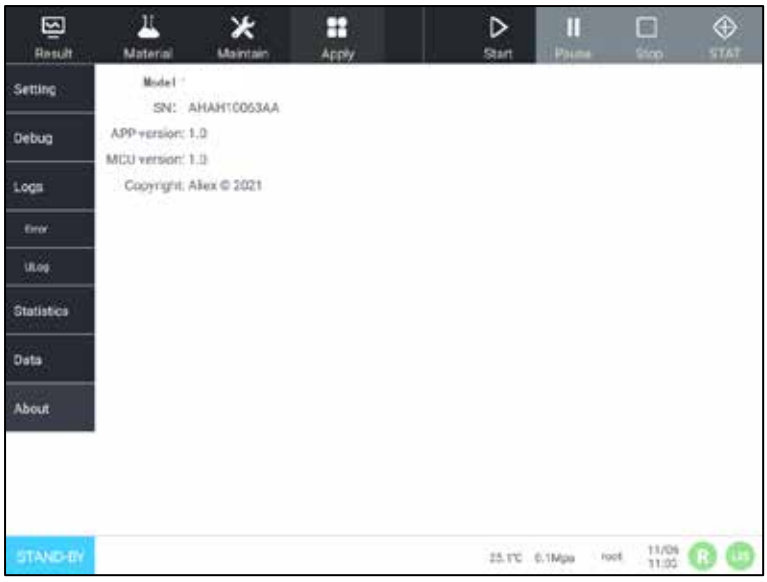
8.5 Data

Click "Application <Data" for data backup.



8.6 Version Information

Click "Application <About" to view the analyzer model, SN, software version and more help information.



Chapter 9 Maintenance

9.1 Overview

To ensure the normal operation of the instrument, the user should perform maintenance operations in accordance with the requirements of this chapter.

9.2 Cleaning

The user can clean the instrument shell according to the equipment cleaning method specified by the laboratory when necessary. The materials listed in this section can be used for cleaning. For damage or accidents caused by the use of other cleaning materials not listed in this section, the company does not provide any guarantees. The user can use a cloth dampened with a neutral detergent to wipe the resin part (sampling probe cover, etc.) on the front of the instrument. If the conveyor belt, display, and keyboard sealing surface of the auto sampler are dirty, please wipe gently with an alcohol-containing cloth. If the metal part is dirty, please wipe it with a cloth containing neutral detergent after wringing it dry; if it is seriously dirty, please wipe it with a cloth containing alcohol.

Notice：

Do not clean the resin part of the instrument with organic solvents such as alcohol, otherwise it will deform and discolor the resin part. Please keep the surface of the instrument dry, otherwise it may cause rust.

If dangerous substances leak on the surface of the equipment or enter the inside of the equipment, proper disinfection should be taken.

The cleaning operation may cause some damage to the instrument. It is recommended to perform the cleaning operation only when deemed necessary.

Available cleaning materials: 70% ethanol, 70% isopropanol, Cidex 2% glutaraldehyde + activator.

Unavailable cleaning materials: 3% hydrogen peroxide, Aerodes in 2000, Cidex OPA, phthalaldehyde.

If you have any questions about the compatibility of disinfectants or cleansing

agents with equipment units or materials contained in the equipment, you can consult the company's customer service department or local distributors.

Warning:

Do not use cleansing agents or disinfectants that will cause danger by chemically reacting with equipment units or materials contained in the equipment.

9.3 Maintenance and Inspection Items

Inspection items before measurement

Inspection item	Inspection content
Calibration settings	the display of the calibration key
Chromatography Column	the number of uses
Filter	the number of uses
Eluent	the remaining amount
Hemolytic agent	the remaining amount
Print paper	the remaining amount
Waste Liquid bucket	the remaining amount of the waste bucket
Pipeline Leakage	the pipeline system

Replacement Frequency

Inspection/Replacement Items	Maintenance Frequency
Eluent suction filter	every 6 months
Sampling probe	Broken or bent
Needle O-ring	Every year

Inspections required by after-sales service personnel

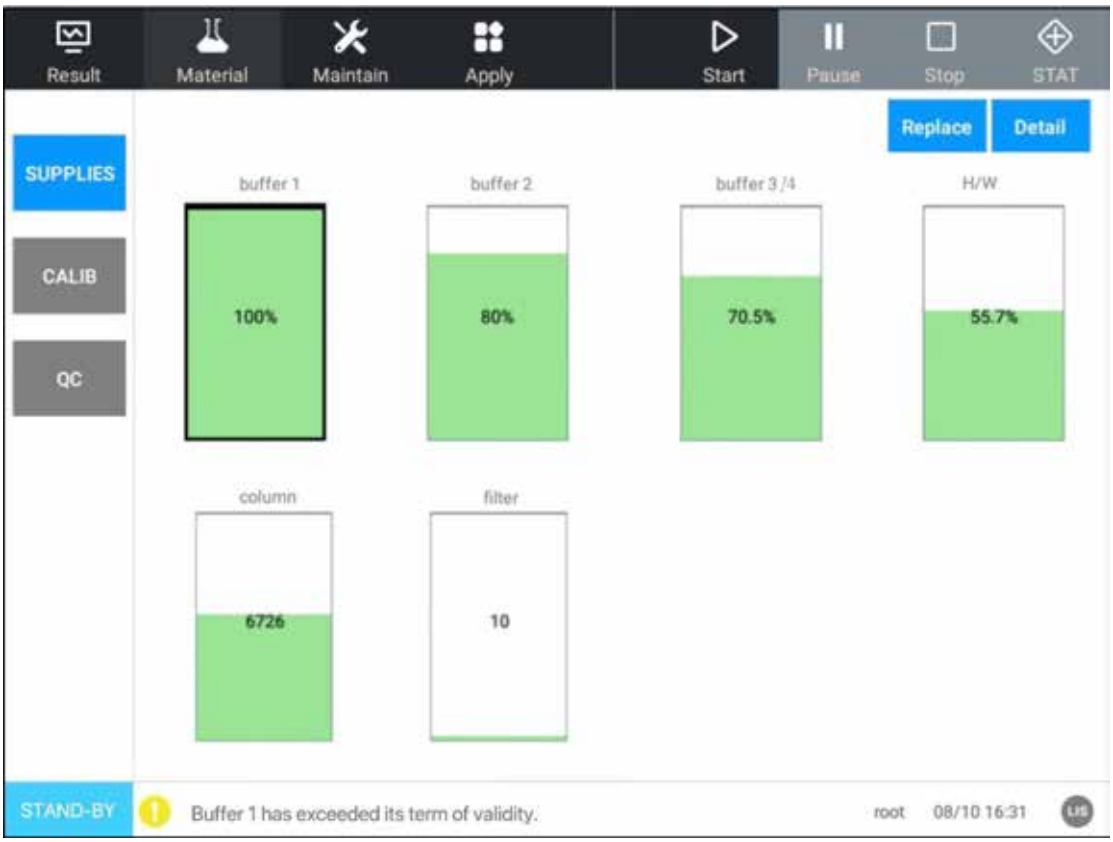
Maintenance/replacement items	Maintenance Frequency
Barcode reader	Every year
Result mark	
Tube rack and test tube rack	
Sample holder sensor	
The position where the sampling probe descends	
Clean the hemolysis cavity, cleaning device	
the fixing screws of the sampling unit	
the temperature of the column temperature box	
the function of solenoid valve	
the function of the vacuum pump	
Inspection or replacement of the rotor seal of the distribution valve	
Inspection or replacement of sample valve rotor seals	
Sample loop inspection or replacement	
Cleaning or replacement of pump detection valve	

Check or replace plunger seal	
Lubricate the pump drive part	
Check or replace the valve fixing surface	When dirty or worn
inspection or replacement of Exhaust sealing valve	When worn

9.4 Replacement of Consumables

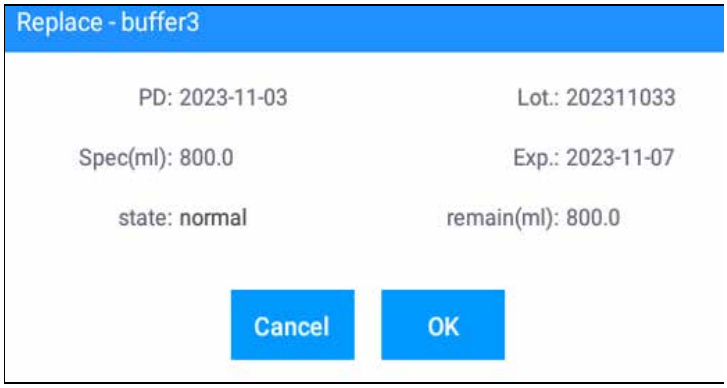
9.4.1 Replacement of eluent/hemolytic agent

When it is found that the remaining amount of the eluent is insufficient, it should be replaced immediately.



Please follow the steps below to replace the eluent/hemolytic agent:

- Put the instrument in standby mode.
- Click the "Replace" button under the corresponding reagent to replace the eluent/hemolytic agent.
- Follow the prompts on the operation panel and swipe the RFID code to update the reagent information.



- Click "OK", then the dialog box will be shown as below.

- When replacing the eluent, gently loosen the bottle cap of the eluent to be replaced, carefully remove the eluent bottle cap assembly, remove the old eluent, and insert the bottle cap assembly into the new eluent and make sure to insert the bottom end of the reagent bag. After gently squeezing out the air in the bag, tighten the bottle cap.
- If you need to replace the hemolytic agent, unscrew the cap of the hemolytic agent bottle to be replaced, replace the cap assembly connected to the instrument. Make sure that the liquid tube is inserted into the bottom of the hemolytic agent, and tighten the cap.
- Put the replaced bottle caps on the used reagent bags/barrels, and properly dispose of the used reagent bags/barrels.
- Click "OK" and the reagent will start to infuse.

- Pay attention to whether the pressure of the instrument is normal, after the filling is completed, click "OK" to complete the replacement.

Notice

Notice：

When replacing with a new eluent, carefully squeeze the eluent bag to empty the air in the bag and tighten the cap. After the replacement is completed, check whether the pipe connected to the bottle cap assembly is bent.

Please use the eluent and hemolytic agent specified by our company.

Replaced the eluent and hemolytic agent according to the actual remaining volume.

When the reagents are almost used up, it is forbidden to add new reagents, otherwise the test results will be unreliable.

9.4.2 Replacement of Chromatography Column

9.4.2.1 Replacement Timing

1. When the pressure is higher than the initial pressure (displayed on the column pressure test gauge) + 4Mpa, even if the filter is replaced, there will be no improvement.

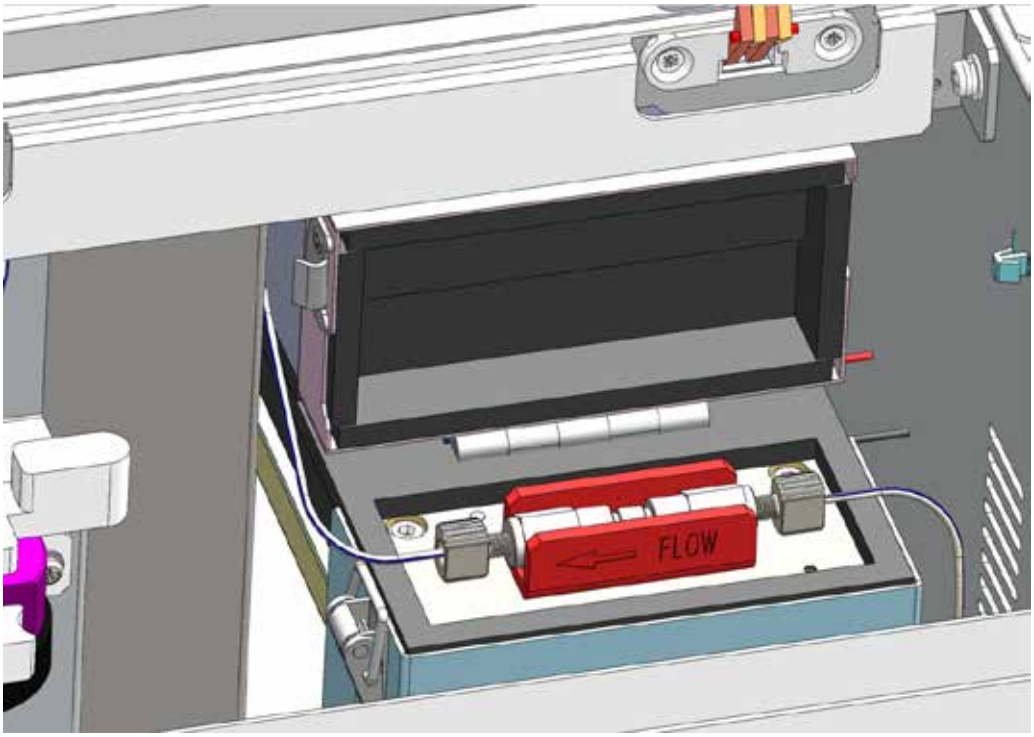
2. When the peak of the chromatogram (especially the SA1C peak) becomes broad or becomes double peak. (Note: If this split occurs only when testing one sample, it may not be the problem of column deterioration, but other problems, such as hemoglobin variation)

3. When the test results of the control materials are continuously inconsistent with the reference value, and they are still inconsistent after re-calibration.

4. Calibration failures continue to occur.

If the above problems still exist after the chromatography column is replaced, please contact the after-sales service personnel.

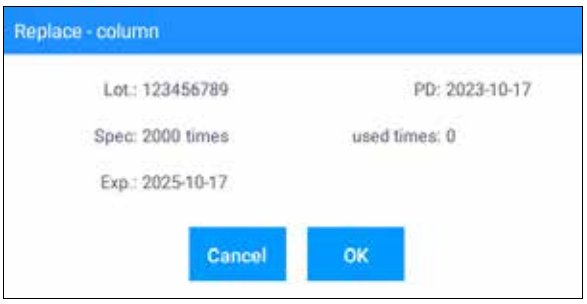
9.4.2.2 Procedures



1、Make sure the instrument is in the standby mode.

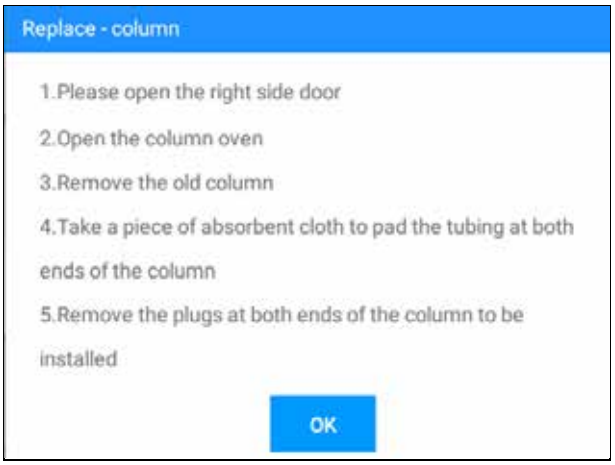
2、Enter the "Maintenance <Chromatography Column" interface, click "Replace", a prompt box will be shown to prompt you to swipe the RFID card.

3、Scan the RFID for chromatography column to be installed to check whether the scanning information is wrong.



4、After confirming that the chromatography column information is correct, remove the old chromatography column according to the steps prompted on the

interface.



Content on the image：

Replace chromatography column

1. Open the upper panel on the right side of the analyzer
2. Open the temperature control box cover of chromatography column
3. Remove the chromatography column from the instrument
4. Take a piece of absorbent cloth to pad the tubing at both ends of the chromatography column
5. Remove the plugs at both ends of the chromatography column to be installed

1) Open the upper panel on the right side of the analyzer.

2) Lift the inner lock catch on the top of the chromatography column temperature box, loosen the outer lock ring, remove the fixed lock, and open the temperature box cover.

3) Put a layer of absorbent cloth under the column.

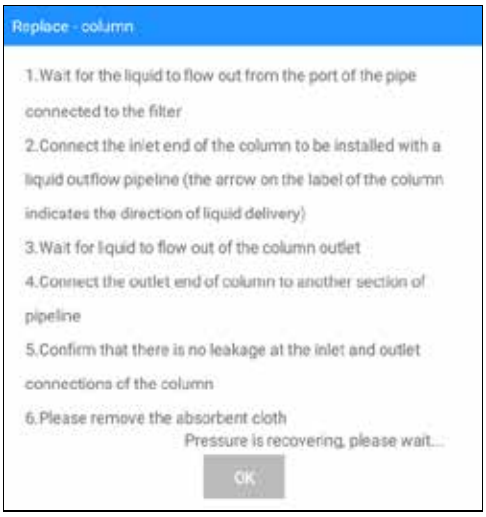
4) Take out the chromatography column located above the box from the card slot.

5) Loosen the nuts and pipes on the right and left sides of the chromatography column in turn and remove the old chromatography column.

6) Extend the pipeline connecting the inlet and outlet of the chromatography column by more than 3mm from the joint.

7) Remove the plugs at both ends of the new chromatography column (be careful not to throw away the removed plugs, and use them when storing the chromatography column), and save the old chromatography column.

5、Install the new chromatography column according to the information prompted on the interface.



Content on the image：

Replace chromatography column

1. Wait for the liquid to flow out of the port of the pipe connected to the filter

2. Connect the inlet end of the chromatography column to be installed with a liquid outflow pipeline (the arrow on the label of the chromatography column indicates the direction of liquid delivery)

3. Wait for liquid to flow out from the outlet end of the chromatography column.

4. Connect the outlet of the chromatography column to another pipeline.

5. Confirm that there is no leakage at the inlet and outlet connections of the chromatography column

6. Please remove the absorbent cloth

Pressure is recovering, please wait…

OK

1）Wait for the liquid to flow out from the connection of the chromatography column.

2）Connect the inlet end of the new chromatography column to the pipeline with the liquid outlet end. Note that the liquid delivery direction of the column label arrow should be consistent with the liquid flow direction.

3）Wait for liquid to flow out from the outlet end of the chromatography column.

4）Connect the outlet of the chromatography column to the pipeline.

5）Observe whether there is any leakage at the outlet end.

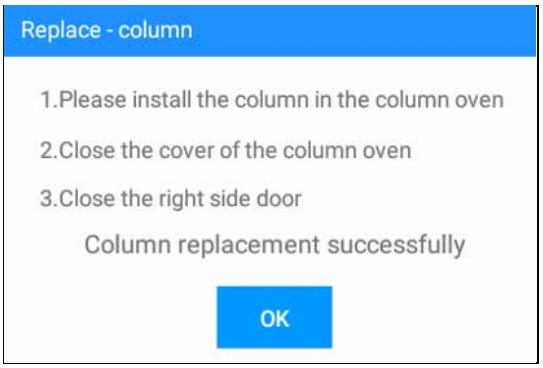
6）After confirming that there is no leakage, remove the absorbent cloth under the chromatography column, and wipe off the leakage of the chromatography column.

7）Confirm whether the pressure is normal (the delivery pressure is within the initial pressure + 4Mpa).

Notice：

If there is continuous leakage or abnormal pressure at the outlet end, the chromatography column needs to be replaced.

6、Complete the replacement.



Content on the image：Replace chromatography column

1.Install the chromatography column in the temperature box.

2.Please cover the lid of the temperature box of the chromatography column

3.Please close the upper panel on the right side of the instrument

Column Replacement succeeds

OK

1）Close the column temperature box and relock the lock.

2）Close the upper panel on the right side of the instrument.

3）The replacement is completed.

7、The new chromatography column needs to be activated. After processing 3-30 whole blood samples and confirming that the resulting chromatogram is normal and stable with 6 waves, perform calibration and quality control operations.

8、Recalibrate the instrument and perform quality control on the instrument.

Risk of biological infection:

Do not touch the sample with the replaced old chromatography column, and fully prevent infection. Wear protective equipment (goggles, gloves, masks, etc.) and treat it as infectious waste. Please handle it in accordance with relevant regulations at each facility.

Notice：

Please do not use chromatography columns other than those provided.

Do not leave a gap in the connecting part between the piping and the column, and plug the inlet piping straight and tightly to the bottom of the continuous part.

9.4.3 Replacement of Filter

9.4.3.1 Replacement Timing

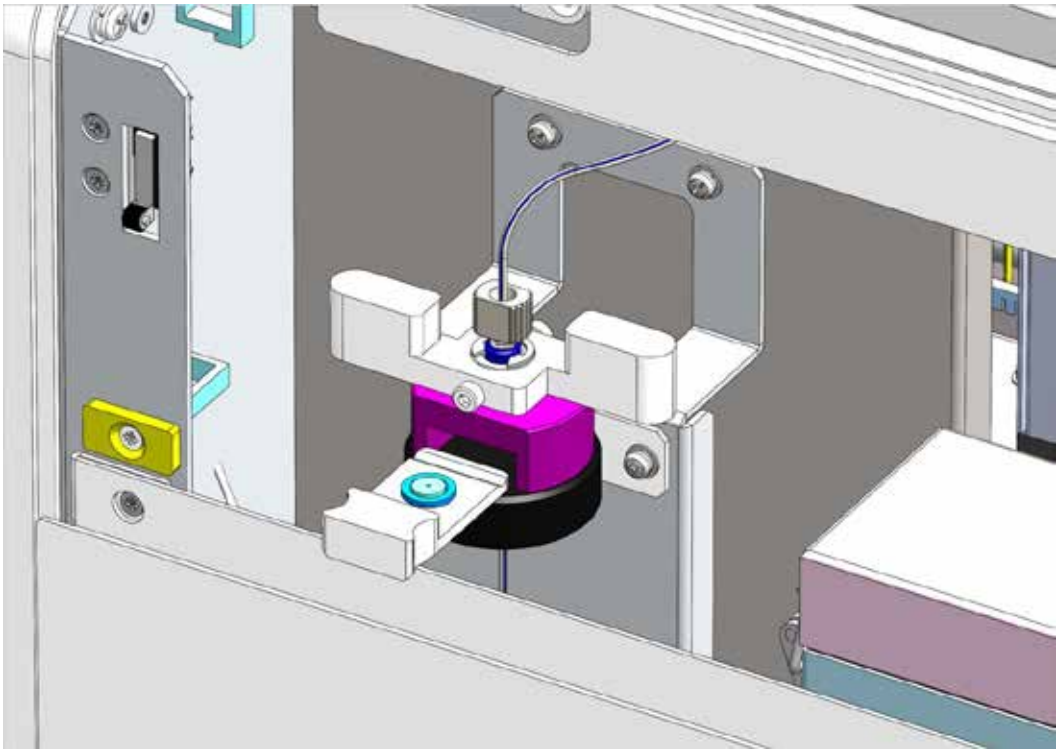
1、When the liquid delivery pressure is higher than the initial pressure + 4Mpa.

2、When blockage occurs.

Risk of Biological Infection：

The inside of the filter has been in contact with the blood sample. Be careful to prevent infection when replacing, please wear protective equipment (goggles, gloves, masks, etc.).

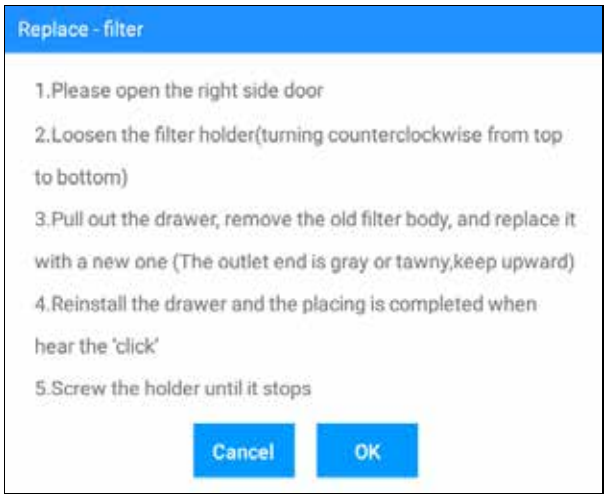
9.4.3.2 Replacement procedures



1、Make sure the instrument is in the standby state.

2、Click "Consumables" <"Filter" to enter the filter replacement interface. Click "Replace"

3、Replace the filter according to the prompts on the interface:



1）Open the upper panel on the right side of the instrument.

2）Unscrew the outlet pipe of the filter (the arrow on the filter label indicates the direction of liquid delivery).

3）Loosen and remove the filter holder (turn it counterclockwise from top to bottom).

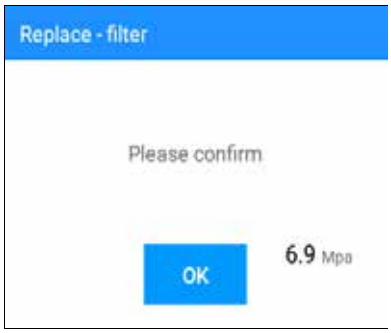
4）Gently push the upper part of the cage, remove the old filter, and replace it with a new one (note that the gray or brown side is the outlet end, facing upwards).

5）Reinstall the filter holder and tighten it by hand until it stops.

6）Take a piece of absorbent cloth and place it under the holder.

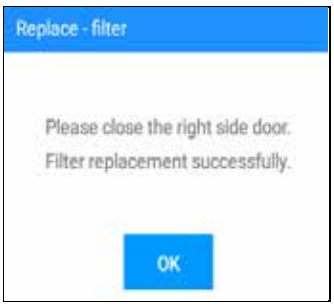
7）After all the above steps are completed, click "OK".

4、After clicking "OK", the prompt box will be shown as below, connect the outlet end of the filter according to the prompt:



1) Wait for the liquid to flow out from the outlet end of the bracket, and observe whether there are bubbles in the outflowing liquid. After there are no bubbles, proceed to the next step.
2) Connect the pipeline at the outlet end of the bracket.
3) Observe whether there is any leakage at the outlet of the filter. If so, please check whether the outlet is tightened.
4) Observe whether the pressure is normal. If not, you need to perform the filter replacement procedure again.
5) Wipe the leaking liquid with an absorbent cloth.

5、Close the instrument panel and complete the replacement.



Please close the upper panel on the right side of the instrument. Successful filter replacement!

OK

Risk of Biological Infection ：

All used filters that have been replaced have come into contact with blood samples. Full attention should be paid to prevent infection, and protective equipment (goggles, gloves, masks, etc.) should be worn during handling. At the same time, it should be destroyed as an infectious waste at the designated location of each unit.

9.4.4Replacement of waste liquid filter

9.4.4.1Replacement Timing

Replacement when the instrument alarms ‘Waste pool full’.

Risk of biological infection:

Take care to prevent infection when changing, wear protective gear (glasses, gloves, mask, etc.)

9.4.4.2Procedures

1) Wait for the instrument to enter the STAND BY state or switch off.
2) Remove the lower left side sheet metal of the instrument.
3) Unscrew the waste liquid filter and take off the old waste liquid filter.
4) Screw the new waste liquid filter into the line according to the direction marking, ‘IN’ is the waste liquid inlet.
5) Attach the lower left side sheet metal of the instrument.

Notice

Notice：

When replacing the new waste liquid filter, it must be accessed according to

the filter direction marking, 'IN' is the waste liquid inlet. After replacing the filter, check if the waste liquid filter is tightened..

Please use the waste liquid filter specified by us..

9.4.5Replacement of eluent suction filters

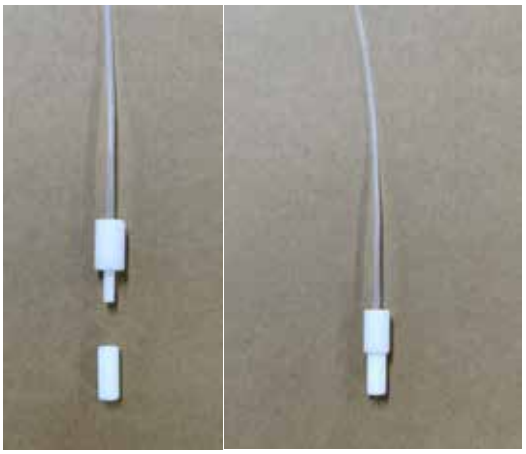
9.4.5.1Replacement Timing

When the eluent suction filter is clogged.

Risk of Biological Infection ：

Be careful to prevent infection when changing, wear protective gear (glasses, gloves, mask, etc.).

9.4.5.2Procedures



1) Wait for the instrument to enter STAND BY state or switch off.
2) Loosen the cap of the eluent bottle.
3) Remove the eluent tube and take off the old eluent suction filter.
4) Install the new eluent suction filter, insert the tube into the bag of eluent and cover the bottle.
5) The three eluent tubes need to replace the eluent suction filters at the same time, and after all of them have been replaced, you need to perform the filling process of eluent A, eluent B, and eluent C/D.

Notice

Notice：

When replacing the eluent suction filter with a new one, carefully squeeze the eluent bag to evacuate air from the bag and tighten the cap. After replacement is complete, check for bends in the lines connected to the cap assembly.

If three eluent suction filters are to be replaced at the same time, use the eluent suction filters specified by us..

9.4.6 Venting of High pressure pump

When it is observed that the eluent is sufficient, but the pressure of the instrument is low or the pressure is unstable, it is likely that air has been mixed in the high-pressure pump module, and it is time to vent the high-pressure pump.

High pressure pump venting procedures

1、Confirm that the instrument is in the standby state.

2、Click the "Maintenance <Vent high-pressure pump " button.

3、A dialog box "Please open the front cover of the instrument and open the venting valve" will be shown as below. At this time, please open the front cover of the instrument and loosen the venting valve counterclockwise. After completing this operation, click "OK" on the panel.

4、A dialog box "The high-pressure pump is venting, please wait..." will be shown as below. Please wait at this time.

5、After venting, a dialog box "Please close the pressure venting valve and close the front cover of the instrument" will be shown as below. Please turn the pressure venting valve clockwise until it is tight, and close the front cover of the instrument. After completing this operation, click "OK" on the panel.

6、Complete the venting of the high-pressure pump.

7、Please continue to observe whether the pressure is stable. If not, perform the venting operation again.

9.4.7 Replacement of printer paper

Please use special printer paper for this instrument.

Replacement procedures:

1. Open the printer cover.

2. Take out the remaining printer paper.

3. Put the new printing paper in, and carefully thread the print paper through the overpressure strip.

4. Cover the printer cover and complete the replacement.

9.4.8 Replacement of waste liquid bucket

Replacement procedures:

1）Take an empty waste liquid bucket and open the lid for use.

2）Rotate the lid of the old waste bucket counterclockwise and carefully remove the lid assembly.

3）Put the old waste bucket lid assembly into the new waste bucket

vertically, and tighten the lid clockwise.

4）Put the lid of the new waste bucket on the old waste bucket, and properly dispose of the old waste bucket.

Warning：

The operator is obliged to comply with the relevant regulations of the region and country on the discharge and disposal of reagents, waste liquids, waste samples, consumables, etc.

The waste bucket can only be replaced when the instrument is in standby mode, otherwise the waste liquid may be sprayed out.

Chapter 10 Troubleshooting

10.1 Overview

This chapter introduces the possible failure information of the instrument and provides corresponding solutions

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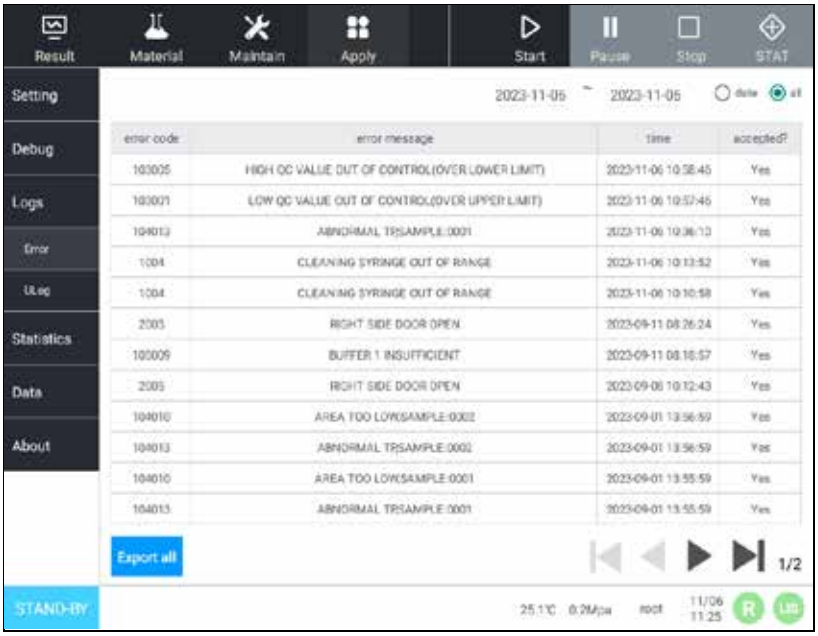
Notice：

This instruction manual is not the maintenance manual, and only provides the corresponding handling measures for the operator when the instrument malfunctions and alarms.

10.2 Fault log

Click the fault exclamation mark under the status bar of the software interface to view the fault information; or click "Application <Log <Fault Log" to view the fault information, and the user can also select the date to query the corresponding fault information.

When the fault information appears in the status bar, the user can click on the fault information and perform the fault elimination operation. After the fault is eliminated successfully, the instrument returns to the standby state. During the troubleshooting process, please do not perform other operations.



10.3 Fault Information and Solutions

Error code	Description	Solution
101001	Online timeout	Power off, check the circuit or main control board
101002	The instrument cannot be connected	Check the communication line; re-plug the connection line; check whether the power of the instrument is turned on; re-execute the initialization process; restart the instrument; after failure for 3 consecutive times, contact the customer service department or the distributor in your area .
101003	Printer is not connected	Check the printer power; check the data connection line;
101004	Printer is out of paper	Add paper to the printer
101005	An abnormal command occurs	Contact customer service department or local distributor
103001	Low value quality control out of control, exceeding upper limit	No processing required
103002	Low value quality control out of control, exceeding the lower limit	No processing required
103004	High value quality control out of control, exceeding the upper limit	No processing required
103005	High value quality control out of control, exceeding the lower limit	No processing required
103003	Calibration abnormal	No processing required
104001	No calibrator found	Place the calibrator and recalibrate
104002	No low-value quality controls found	Place low-value quality control products and re-control
104006	No high-value quality controls found	Place high-value quality control products and re-control
104003	The calibrator is not registered	Enter calibration information
104004	Low-value quality controls are not registered	Enter low-value quality control information
104007	High-value quality controls are not registered	Enter high-value quality control information
104008	Calibration test does not support whole blood mode	Please check the corresponding relationship between the blood collection tube/sample cup and the detection mode.
104009	Quality control testing does not support whole blood mode	Please check the corresponding relationship between the blood collection tube/sample cup and the detection mode.
105001	Eluent A has exceeded the production expiration date	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105002	Eluent B has exceeded the production expiration date	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105003	Eluent C/D has exceeded the expiry date of production	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105004	The hemolytic agent has exceeded the expiry date of production	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105015	Chromatography column has exceeded the expiry date of production	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105005	Eluent A the bottle opening period has expired	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.

105006	Eluent B the bottle opening period has expired	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105007	c 3/4 the bottle opening period has expired	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105008	The hemolytic agent has exceeded the expiration date of opening	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105009	Insufficient reagent for eluent A	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105010	Insufficient reagent for eluent B	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105011	Insufficient reagent for eluent C/D	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105012	Insufficient hemolytic agent	The user replaces the reagent with a new one, or contacts the reagent supplier for replacement.
105013	The number of times of the column has been used has exceeded the upper limit	The user replaces the column with a new one, or contacts the supplier for replacement.
105014	The number of times the filter has been used has exceeded the upper limit	The user replaces the filter with a new one, or contacts the supplier for replacement.
106001	LIS communication abnormal	Reconnect; if it happens multiple times, consult the LIS supplier, or contact the user service department or local distributor.
106002	Failed to send sample results. Barcode: %s, location: %s	Occasionally it can be ignored, just resend or receive; if it happens multiple times, consult the LIS supplier, or contact the user service department or local distributor.
106003	Failed to apply for sample from lis, barcode: %s, location: %s	Check LIS connection

Error code	Description	Solution
1001	Sample injector failed to initialize	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1002	Sample syringe is out of stroke	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1003	Cleaning syringe failed to initialize	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1004	Cleaning syringe is out of stroke	Perform fault recovery, and If the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1005	The injection valve failed to initialize	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1006	The left side of the injection valve failed to rotate	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1007	The injection valve failed to rotate on the right side	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1008	The switching valve failed to initialize	Perform fault recovery, and if the problem cannot be

		solved 3 times in a row contact the customer service department or the distributor in your area
1009	The high-pressure pump failed to initialize	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
1011	The pressure of Chromatography Column pipeline is abnormal (too low)	1. Perform the high-pressure pump bubble discharge process 2. If after the bubbles are discharged, the alarm still occurs, contact the customer service department or the distributor in your area
1012	The pressure of Chromatography Column pipeline is abnormal (too high)	1. Perform the process of replacing the chromatography column. 2. Perform the process of replacing the filter. 3. Perform fault recovery. If the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
1013	Waste liquid bucket is full	1. Empty the waste liquid bucket 2. If the alarm still remains after emptying, contact the customer service department or the distributor in your area
1014	Failed to calibrate sample syringe zero calibration	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department of Transasia Biomedical Company or the distributor in your area
1015	Failed to calibrate the cleaning syringe zero point	Perform fault recovery, and the problem cannot be solved 3 times in a row. Contact the customer service department of Transasia Biomedical Company or the distributor in your area
2001	The communication between the Main Control Unit (MCU) and the main control board FPGA is abnormal	Restart the instrument and the client software. If it can not be solved 3 times in a row, please contact the customer service
2002	The communication between the Main Control Unit MCU and the drive board is abnormal	Restart the instrument and the client software. If it can not be solved 3 times in a row, please contact the customer service
2003	The communication between the main control board MCU and the power startup board is abnormal	Restart the instrument and the client software. If it can not be solved 3 times in a row, please contact the customer service
2005	The right door of the instrument is detected to be open	1. Check whether the right door of the instrument is open; 2. If it is confirmed that the right door of the instrument is closed and there is no accidental failure, please contact customer service;
2006	The front door of the instrument is detected to be open	1. Check whether the front door of the instrument is open; 2. If it is confirmed that the front door of the instrument is closed and there is no accidental failure, please contact customer service;
2011	The driver board received an incorrect command	Restart the instrument and the client software. If it can not be solved 3 times in a row, please contact the customer service
2012	Launchpad received incorrect instructions	Restart the instrument and the client software. If it can not be solved 3 times in a row, please contact the customer service
2013	Error occurs during scanning the barcode of the sample rack	Restart the instrument and the client software. If it can not be solved 3 times in a row, please contact the customer service

Error code	Description	Solution

3001	The ambient temperature inside the whole machine is abnormal	1. Check whether the ambient temperature is between 10°C and 30°C (including 10°C and 30°C) 2. The instrument will be shut down for half an hour and restart the instrument. If this happens 3 consecutive times, contact the customer service department or the distributor in your area.
3002	Abnormal temperature control of optical module	1. Check whether the ambient temperature is between 10°C and 30°C (including 10°C and 30°C) 2. If the instrument has been restarted for 3 consecutive times and there are still problems, please contact the customer service department or local distributor
3004	The ambient temperature sensor in the whole machine is short-circuited or disconnected	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3005	Optical module temperature sensor short circuit or open circuit	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3006	Drive board +24V voltage is abnormal	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3007	Drive board +15V voltage is abnormal	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3008	Drive board -15V voltage is abnormal	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3009	Drive board +5V voltage is abnormal	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3011	The Peltier current of the drive board is abnormal.	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3012	The optical module cooling fan (internal) is blocked	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
3013	The optical module cooling fan (external) stalled	If the instrument has been restarted three times in a row and there are still problems, please contact the customer service department or the distributor in your area.
4001	Failed to initialize vertical movement of puncture sampling (position uncertain)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4002	Failed to initialize the vertical movement of the puncture sampling (above the emergency department)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4003	Failed to initialize the vertical	Perform fault recovery, and if the problem cannot be solved 3

	movement of puncture sampling (above the sampler)	times in a row, contact the customer service department or the distributor in your area
4004	Failed to initialize vertical movement of puncture sampling (above hemolysis)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4005	Failed to initialize the vertical movement of the puncture sampling (above the needle washing)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4006	Failed to initialize vertical movement of puncture sampling (above the origin)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4007	Failed to initialize vertical movement of puncture sampling (other positions)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4013	Failed to calibrate the vertical movement zero point of the puncture sampling (above the emergency department)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4014	The zero-point calibration of the vertical movement of the puncture sampling failed (above the sampler)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area
4015	The zero-point calibration of the vertical movement of the puncture sampling failed (above hemolysis)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.

Error code	Description	Solution
4016	The zero-point calibration of the vertical movement of the puncture sampling failed (above the needle washing)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4017	The zero-point calibration of the vertical movement of the puncture sampling failed (above the origin position)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4019	Failed to initialize the horizontal motion of the puncture sampling	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4021	The current vertical state of the puncture sampling does not allow horizontal movement (above the emergency department)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4022	The current vertical state of puncture sampling does not allow horizontal movement (above the sampler)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.

4023	The current vertical state of puncture sampling does not allow horizontal movement (above hemolysis)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4024	The current vertical state of puncture sampling does not allow horizontal movement (above the needle washing)	Perform fault recovery, if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4025	The current vertical state of puncture sampling does not allow horizontal movement (above the origin)	Perform fault recovery, if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4027	The current horizontal state of the puncture sampling does not allow vertical movement (above the emergency department)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4028	The current horizontal state of puncture sampling does not allow vertical movement (above the sampler)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4029	The current horizontal state of puncture sampling does not allow vertical movement (above hemolysis)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4030	The current horizontal state of puncture sampling does not allow vertical movement (above the needle washing)	Perform fault recovery, and the problem cannot be solved 3 times in a row. Contact the customer service department or the distributor in your area
4031	The current horizontal state of puncture sampling does not allow vertical movement (above the origin)	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4033	The puncture sampling horizontal movement zero-point calibration failed	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4034	Failed to initialize the transport track	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4035	Failed to calibrate the zero point of the conveyor track	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4037	Failed to initialize recovery track	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4038	Failed to calibrate the zero point of the recovery track	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4040	No test tube rack is detected at the entrance of the conveyor track	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4042	No test tube rack is detected at the exit of the conveyor track	Perform fault recovery, andif the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4043	No test tube rack was detected at the entrance of the recovery track	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.

4044	No test tube rack was detected at the exit of the recovery track	Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4045	Sample injector is full	1. Remove the sample rack on the recovery track 2. Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4046	Transport track is blocked	1. Remove the sample rack on the track 2. Perform fault recovery, and if the problem cannot be solved 3 times in a row, contact the customer service department or the distributor in your area.
4047	Emergency department is not closed	The front door of the emergency room needs to be closed during emergency testing

Chapter 11 Appendix

11.1 Product Classification

VERTEX-Hb Automated Glycohemoglobin Analyzer is classified according to Indian medical device management:

It belongs to the hemoglobin analyzer in the clinical laboratory analysis instrument (6840), and the management category is Class II.

Classification by electrical safety:

Overvoltage category: Class II

Pollution level: Level 2

according to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL:

Class A

11.2 Host specifications

Main specifications

Test items	In STD mode:HbA1c（S-A1C）、HbF、HbA1 In VAR mode: adding HbS, HbC, HbD, separating HbE(unknown peak flag)
Test object	Whole blood, hemolysis sample
Detection principal	Ion exchange high performance liquid chromatography
Analysis speed	STD：1min/test；VAR；1.6min/test
Detection method:	Dual-wavelength absorption (detection wavelength 415nm,subwavelength 500nm)
Screen size	8 inches

Sampling characteristics

Sample injection volume:	3μL whole blood, 80μL hemolysis
Sample installation method:	Tube rack method with 10 samples as a unit
Maximum sample load:	90 samples
Suction method:	Nozzle suction
Injection method:	injection loop (4μL)
Dilution method:	Dilute with glycosylated hemoglobin hemolytic agent in the dilution tank
Sample container:	Φ12~Φ15×75~100mm vacuum blood collection

	tube
	2mL sample cup (12mm × 38mm) (use adapter)
Barcode recognition:	The length of the sample ID number is not more than 18 digits

11.3 Matching reagents of the product

Glycosylated Hemoglobin (HbA1c) Assay Kits （HPLC）.

11.4 Barcode specifications

The barcode contains the sample information, the barcode label is pasted on the sample container, and the barcode label can be automatically read by the instrument when the test tube rack automatically samples. The barcode information will establish a corresponding relationship with the results of the tested samples, and finally shown in the test report.

When using barcodes, you need to ensure that the ID barcode specifications of this instrument are met. This section will clearly specify barcode labels.

11.4.1 Compatible barcode

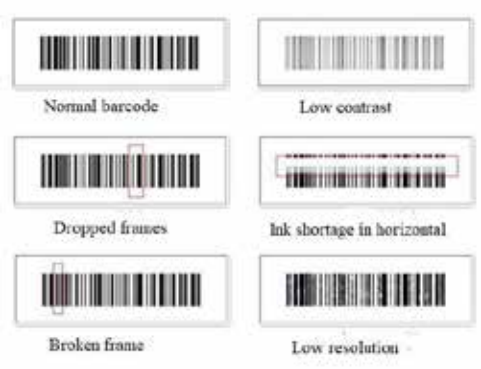
The scanner equipped with this instrument can be compatible with the following barcode standards:

2/5Interleaved、Code 39、Code 93、Code 128、EAN 128、EAV/UPC、EAN Addendum、Codabar。

The length of the sample ID number is not less than 4 digits and not more than 18 digits.

11.4.2 Barcode defects

The use of defective barcodes will increase the error rate of label identification. Please use normal barcodes when scanning.



11.4.3 Barcode size

Barcode label width：A ≤ 75mm

Barcode height：B ≥ 10mm

Blank areas on both sides of the barcode：C ≥ 5mm

Barcode label size

Barcode wide-to-narrow ratio：2.5:1 to 3.0:1

Narrow strip width： ≥0.127mm

Barcode quality: According to ANSI MH10.8M standard, greater than or equal to C level

11.5 Input and output devices

Notice：

The external equipment of the specified model and specification of our company must be used.

11.5.1 Touch screen

HDMI capacitive touch high-definition screen (resolution 1024*768).

11.5.2 Buzzer

It can prompt instrument failure.

11.6 Host interface

1 network interface

2 USB interfaces

11.7 Working environment

Power requirements: AC 100-240V;

Frequency: 50/60HZ;

Ambient temperature: + 10 ~ + 30 ;

Relative humidity: 30% ~ 75% (no condensation);

Atmospheric pressure: 85kPa ~ 106kPa.

11.8 Storage environment

Ambient temperature	0 ~ + 50
Relative humidity	~ 80% (no condensation)
Other	Keep dry and store indoors

Notice：

Please store the instrument under the specified conditions

11.9 Inspection sheets

11.9.1 Inspection sheet for instruments

Serial number	Accessories description	Specification model	Quantity
1	Power Adapter	PC-240150	1
2	cable	CAT-703H	1
3	Printer paper (thermal paper)	/	1
4	wrench	88-000-1-22	1
5	Ligature	/	5
6	Phillips screwdriver	63611	1
7	Allen wrench	SKH-9/64	1
8	Allen wrench	82307	1
9	Allen wrench	82306	1
10	Φ12 tube adapter	/	1
11	Parts plastic box	E8413	1
12	Buffer fluid mounting bracket assembly	VERTEX-HB	1
13	Instruction manual	/	1
14	Operation card	/	1
15	Inspection certificate	/	1
16	Warranty Bill	/	1
17	Inspection sheet	/	1

11.9.2 Inspection sheet for the injector

Serial number	Accessories description	Specification model	Quantity
1	Warranty Bill	/	1
2	Inspection certificate	/	1
3	Sample injector rack	/	1
4	Sample adapter	/	1
5	Inspection sheet	/	1