HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số

Người đại diện hợp pháp của cơ sở

Giám đốc
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Dear user,

Thank you for choosing our product!

This user manual will guide you through the safe and proper use of the MQ-3000 Glycated hemoglobin analyzer. Please read this user manual carefully before using this instrument to get the most out of it.

After reading, please keep this manual in a safe place for future reference at any time.

Medconn's "star service" will accompany you all the time. Please contact us at the number of the global service center. We are always glad to be at your service.

Thanks again for your support!

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Foreword

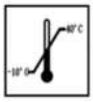
This user manual that comes with the MQ-3000 Glycated hemoglobin analyzer details the use, function, and operation of the instrument. It is intended for medical laboratory professionals or trained nurses and laboratory technicians to:

- Understand the software and hardware of MQ-3000 ;
- Perform daily operations and maintenance;
- Perform system maintenance and troubleshooting.

Common Symbols

Caution: Be careful! Risk of electric shock. Check the user manual when seeing this symbol.	
Caution: Be careful! Danger. Check the user manual when seeing this symbol.	
Caution: Biohazard. This warning alerts you to a potential dangerous condition of biological infection.	
Caution: Mechanical Injury. This warning alerts you to a potential dangerous condition of mechanical injury.	
AC symbol	Grounding symbol
In vitro diagnostic product	Refer to the instruction manual
Manufacturer	Instrument serial number
| Power on	○ Power off
Date of Manufacture	Authorized Representative in the Eurporean Commiunity
CE Mark	Caution
Separate collection	Expiration Date

Meaning of symbols on packaging boxes

 This way up	 Keep dry
 Fragile,handle with care	 The stacking limit is 2
 Temperature	 Humidity

Warnings and Precautions

Safety Precautions

Please read the following safety precautions carefully to avoid personal injury and to prevent damage to this product or any product connected to this product:

- To avoid possible hazards, be sure to use this product in accordance with the instructions in this manual.
- Do not open the housing of this instrument to prevent danger. There are no user-adjustable parts inside the instrument.
- MQ-3000 Glycated hemoglobin analyzer is designed and guaranteed to meet the safety standards of GB 4793.1/IEC/EN 61010-1, GB 4793.6/IEC/EN 61010-2-010, GB 4793.9/IEC/EN 61010-2-081, and YY 0648/IEC/EN 61010-2-101. Follow this user manual to ensure safe operation of this product. This safety guarantee does not extend to other equipment or ancillary facilities not covered by the above standards, even when they are connected to the MQ-3000 Glycated hemoglobin analyzer.
- This instrument should not be modified or altered in any way. Changes to this instrument will void the guarantee in GB 4793.1/IEC/EN 61010-1, GB4793.6/IEC/EN 61010-2-010, GB 4793.9/IEC/EN 61010-2-081, and YY 0648/IEC/EN 61010-2-101, and may lead to potential safety hazards.
- Only the personnel trained and authorized by our company can perform the repair. Shanghai Medconn Medical Technology Co., Ltd. is not responsible for any damage caused by the modification to the equipment not performed by our company or other authorized institutions.
- IEC/EN 61010-1, IEC/EN 61010-2-010, IEC/EN 61010-2-081, and IEC/EN 61010-2-101 are internationally accepted safety standards for laboratory devices — *in vitro* diagnostic medical devices. GB 4793.1, GB 4793.6, GB 4793.9, GB 7247.1, and YY 0648 are national and industry standards derived from the above standards.

Prevention of the Hazard of Electric Shock

Please read the following precautions against electric shock carefully to avoid personal injury and to prevent damage to this product or any product connected to this product:

- Use a qualified outlet: It is required to use a separate and dedicated outlet.
- The ground terminal of the power outlet should be grounded: The ground terminal of the power outlet should be connected to the ground wire of the power supply system instead of the ground wire of public facilities such as water pipes, gas pipes and lightning rods.
- The power switch is located on the side of the instrument and can be easily turned on and off. Do not block the power switch; it must be accessible to the user at any time.

Prevention of Mechanical Injury

Please read the following precautions against mechanical injury carefully to avoid personal injury:

- Do not open the front panel and the housing of the instrument while the instrument is running. There are moving parts inside the machine.
- Do not place your fingers under the sampling needle to prevent finger injury.
- Do not place your fingers between the sample tray and the front panel of the instrument while operating it to prevent damage.

Prevention of Infectious Pathogen Contamination

Please read the following precautions carefully to prevent infectious pathogen contamination:

- Waste can only be disposed of by trained personnel.
- All reference materials (e.g., calibrators, quality control substances) and patient samples should be considered as biohazards and should be handled with care.
- The remaining samples, waste after analysis, expired reagents and scrapped accessories shall be disposed of in accordance with the provisions in the local "Management Measures for Medical Wastes of Medical and Health Institutions" to avoid damage to health and environment.
- All personnel using the instrument should wear protective clothing (such as safety glasses, gloves, masks, protective clothing, etc.) to prevent infection.

Chemical Safety Precautions

The reagent used with this instrument contains 0.02% sodium azide, and skin or eye contact with or ingestion of the reagent should be prevented.

- In case of inadvertent skin or eye contact, wash the site of contact thoroughly with water.
- In case of inadvertent ingestion, wash the mouth thoroughly with water and drink plenty of water.

1. Overview

1.1 Product Introduction

In the report published on November 16, 2011, the International Diabetes Federation estimated that there were 346 million people with diabetes worldwide, and more than 80% of death cases were in developing countries. Based on factors such as population aging and demographic changes, there may be 552 million people with diabetes worldwide over the next 20 years. Currently, the incidence rate of diabetes is third only to cerebrovascular diseases and tumors.

Since the blood glucose measurement only represents the level of blood glucose at the time of patient sampling, it cannot be used as an indicator for evaluating the degree of disease control and treatment efficacy. In recent years, Glycated hemoglobin (HbA1c) receives increasing clinical attention. The International Diabetes Federation recommends the test of HbA1c as a long-term evaluation indicator for blood glucose control within 2–3 months.

The measurement result of Glycated hemoglobin is expressed as a percentage and refers to the ratio of glucose-bound hemoglobin in the total hemoglobin. The level of HbA1c in non-diabetic patients is 4%–6%. Many studies have found that if diabetic patients can reduce their HbA1c level to below 8%, the complications of diabetes will be greatly reduced. If the HbA1c level is > 9%, it indicates that the patient has persistent hyperglycemia and may develop complications such as diabetic nephropathy, arteriosclerosis, and cataract, as well as acute complications such as ketoacidosis.

This instrument also provides converted reporting units of IFCC and eAG.

The MQ-3000 analyzer is an automated instrument for measuring the content of HbA1c in the blood. It can be used to monitor the HbA1c level in diabetic patients and can provide clinicians with information on the glycemic control of diabetic patients, so that a scientific diagnosis and treatment plan can be formulated for diabetic patients.

1.2 Definitions and Abbreviations

GHb The hemoglobin (Hb) bound to any form of carbohydrate;
Hb Hemoglobin;
HbA1c Hemoglobin A1c;
RS232 Standard for serial data communication interface;
ID Sample identification number;
CV Coefficient of variation, used to evaluate the stability of test parameters of analytical instruments;
NGSP National Glycohemoglobin Standardization Program;
IFCC International Federation of Clinical Chemists;
eAG Estimated average glucose;
LIS Laboratory Information System;

1.3 Result Reporting Units

HbA1c: NGSP unit (%), IFCC unit (mmol/mol), eAG unit (mmol/L).
Conversion formula of reporting units:
NGSP = (0.09148 * IFCC) + 2.152
IFCC (mmol/mol) = 10.93 * NGSP − 23.50
eAG (mmol/L) = 1.59 * A1c − 2.59

1.4 Working Principle

The MQ-3000Glycated hemoglobin analyzer detects HbA1c based on the principle of high-performance liquid cation exchange. HbA1c can be separated from non-HbA1c due to the difference in their charges, since non-HbA1c is positively charged, while HbA1c is almost uncharged. A cation-exchange stationary phase is used based on the different charge properties. This stationary phase has a group with exchangeable cations, which can bind to positively charged non-HbA1c by electrostatic action. Since HbA1c is uncharged, it cannot bind to the stationary phase. The analyzer first equilibrates the chromatography column with an ultra-low concentration reagent , and then rinses the chromatography column with a low concentration reagent . The HbA1c of the sample adsorbed on the chromatography column polymer is first eluted. The non-HbA1c is then eluted with a high-concentration reagent . For each separated hemoglobin component, the detector continuously obtains the absorbance of each component by photoelectric colorimetry (Appendix A) and generates a chromatographic curve. The micro-control unit performs peak identification (including peak/valley search) and integral calculation of each peak area on the chromatographic curve, and calculates the percentage of the

peak area of HbA1c to the total area. The value calibrated by the slope and intercept of the calibration curve serves as the HbA1c value of the sample. The results are presented on the display or the results and chromatograms are output by the printer.

1.5 Reference Value

Take NGSP unit (%) as an example:
Healthy population: 4.0% to 6.0%
It is recommended that each laboratory set its own reference value according to the characteristics of its own population.
The MQ-3000 analyzer automatically recognizes the various peaks of hemoglobin. After calculation, the test results are displayed on the screen and printed automatically. The reported range of HAb1c is 3% to 20% (NGSP).

1.6 Methodological Limitations

In fresh blood samples, there is no interference with the measurement result of HbA1c when the concentration of bilirubin F is lower than 18 mg/dL, the concentration of bilirubin C is lower than 18 mg/dL, the concentration of chyle is lower than 1400 FTU, the concentration of hemolytic hemoglobin is lower than 450 mg/dL, the concentration of ascorbic acid is lower than 50 mg/dL, the concentration of glucose is lower than 1200 mg/dL, and the concentration of acetaldehyde is lower than 60 mg/dL.

1.7 Working Conditions

- Ambient temperature: 10 °C ～ 30 °C;
- Relative humidity: ≤ 80%;
- Altitude: ≤ 2000 m;
- Power supply voltage: AC 100~ 240 V;
- Power frequency: 50/60 Hz;
- Rated power: 150 VA;
- Other: Avoid direct sunlight, dust, corrosive gases, and vibration and interference from strong electromagnetic field.

1.8 Performance Indicators

- Accuracy: The relative deviation should be within ± 5.0%;
- Repeatability: CV ≤ 2.0%;
- Linear range: The linear range of HbA1c is 3.0% to 20%, and the correlation coefficient r is ≥ 0.9900;
- Carryover rate: ≤ 3.0%;
- Stability: Within 8 h after boot-up and stabilization of the instrument, the relative deviation of the results from the same normal sample should be within ± 3.0%.

1.9 Network Security

- Data interface:

1) Network port (RJ45): The network port of the analyzer outputs the sample analysis results to the user's terminal device through the UDP protocol.
2) USB port: The USB port of the analyzer performs database backup, database import, and software upgrade using the USB2.0 protocol.
3) SD card port: The SD card port of the analyzer performs factory setting backup and restore factory settings using the SD bus protocol after insertion of an SDXC card.
4) RS232 port: The RS232 port of the analyzer outputs the sample analysis results to the user's terminal device through the RS232 protocol.

- Storage format:

1) Local: The test result file MQ-3000.db is stored in the flash drive of the motherboard of the analyzer in the SQLite DB file format.
2) Export: The MQ-3000.db file may be exported in the SQLite DB file format using a USB flash drive or SD card.

- User access control

User identification authentication: On the login interface, ordinary users may enter their user name and tap Login to directly enter the system. System admins must enter their user name and password before tapping Login to enter the system.
Different user types and permissions are described as follows:
Ordinary users: Analysis, query, quality control, calibration, service (maintenance and settings), and log operations.
System admins: Diagnosis operations in the service module in addition to all the permissions of ordinary users.

- Minimum hardware configuration:

Cortex-A9 quad-core processor: 1 GHz.
RAM: 2 GB.
Flash: 8 G (up to 100,000 test results can be stored).
Display: A touchable display device with a resolution of 800 × 600.

- Software configuration: operating system arm-Linux 2.0 and its compatible versions.

2. Instrument Overview

2.1 Scope of Application

The MQ-3000 Glycated hemoglobin analyzer ("MQ-3000analyzer") is used in conjunction with the HbA1c assay kit (HPLC), HbA1c haemolyser, and HbA1c column kit (HPLC) produced by Shanghai Medconn Biotechnology Co., Ltd. to detect the content of Glycated hemoglobin in blood samples as a percentage of total hemoglobin.

2.2 Instrument Appearance

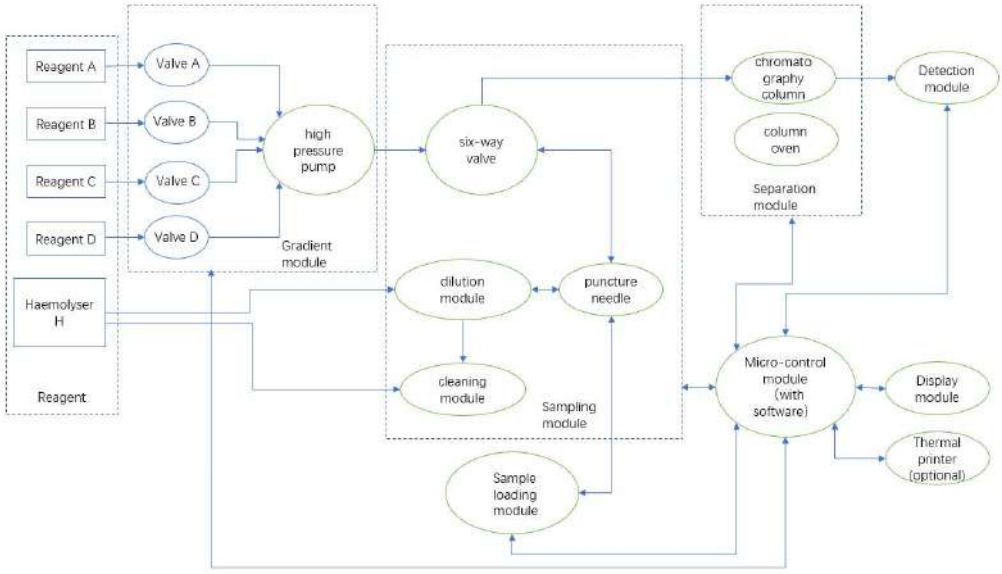
Front view of the analyzer

Side view of the analyzer

The size of the instrument is: 460mm×340mm×525mm

2.3 Main Structure of the Instrument

- This instrument is mainly composed of a micro-control module including the MQ-3000 Glycated hemoglobin analyzer system software (release version 1), sample loading module, sampling module, separation module, detection module, display module, Gradient module and thermal printer (optional).



- **Micro-control module:** The micro-control module of the instrument uses an embedded computing module. The instrument acts as required under the control of the MQ-3000 Glycated hemoglobin analyzer system software (release version 1) on the embedded computing module. The software collects and calculates photoelectric signals, temperature, and pressure signals and stores and queries sample assay data (approximately 100,000 test results).
- **Sample loading module:** This module rotates at the start of the test to send the sample directly under the puncture needle to retrieve and identify the sample type. After the test for the current sample is completed, the next sample is sent under the puncture needle until the 18-bit rotation is completed. The instrument can hold up to 18 test tubes.
- **Sampling module:** The sampling module is mainly composed of a puncture needle, a dilution module, and a cleaning module. When the sample loading module sends the sample under the puncture needle in the sampling module, the puncture needle is driven by the motor to the bottom of the sample. The plunger pump and the solenoid valve in the dilution module work together to draw 4 μL of whole blood sample. Then the sample and 1000 μL of haemolyser are injected into the hemolysis cell of the dilution module to dilute the sample by 1:250 hemolysis. The puncture needle runs to the bottom of the hemolytic pool and the diluted sample is drawn by the plunger pump, which works with the metering valve to send 6 μL of hemolyzed and diluted sample to the high-pressure elution pipeline. Meanwhile, the plunger pump extracts haemolyser and cleans the puncture needle and the hemolytic pool by working with the solenoid valve and the liquid waste

pump in the cleaning module.

- **Separation module:** After the sampling module completes the above operations, the diluted sample is pushed by the micro constant flow pump to the chromatography column installed in the column oven. The diluted sample is first adsorbed on the filler of the chromatography column, and then the chromatography column is rinsed with a low concentration reagent . The HbA1c of the sample adsorbed on the chromatography column polymer is first eluted. The non-HbA1c is then eluted with a high-concentration reagent for separation.
- **Detection module:** This module is composed of a 415 nm blue LED, a detection cell, and a signal receiving board welded to a photodiode. It is a unit component used to detect the changes in hemoglobin absorbance as the sample passes through the separation module. The requirements for interference filters in the detection module are as follows:
- **Peak transmittance:** The nominal center wavelength is 414 nm, and the peak transmittance is not less than 30%.
- **Half width: 8 nm.** The deviation between the actual half width and the nominal half width should not exceed ± 2 nm.
- **Center wavelength:** The nominal center wavelength is 414 nm, and the deviation between the center wavelength and the nominal center wavelength should not exceed ± 2 nm.
- **Display module:** This module consists of a 10.4-inch LCD screen and a resistive touch screen, which are used to display the system operation interface as well as test results and chromatograms, so that the analyzer operation can be controlled by touch input.
- **Gradient module:** This module is mainly composed of a gradient solenoid valve and a constant-flow high-pressure pump. After the micro-control unit commands the gradient solenoid valve to switch the reagent according to the preset gradient, the constant-flow high-pressure pump will send the reagent to the chromatography column for elution.
- **Thermal printer (optional) :** Thermal printer (80mm paper width) , auxiliary module, can print test results and diagrams.

2.4 Instrument Interface

- **Reagent port:** Connecting reagent s A, B, C, and D and haemolyser H.
- **Port for the pipe of liquid waste:** Used to discharge liquid waste generated during the analysis.
- **Network port (RJ45):** Used to connect network cables and output the sample analysis results to the LIS system through the Ethernet (one-way data exchange).
- **USB:** Two USB ports are used to connect USB drives for database backup, database import, and software upgrade.
- **SD card slot:** Used to insert an SD card for factory setting backup,and restore factory settings .
- **RS232 (serial port):** It is abbreviated as the serial port, which is also known as the serial communication port (usually referred to as the COM port) and can be used to output the sample analysis results to the LIS system (one-way data exchange).
- **Power socket:** Used to plug in the Power cableand connect the instrument to a power source.

3. Instrument Installation

3.1 Installation Environment

The MQ-3000 analyzer requires the following environment for installation:

- Do not install the instrument at the following places: places with high fluctuations of voltage and temperature, places close to air outlets, places with a high amount of dust and dirt, places with vibration, places with high humidity, places close to flames, places with poor ventilation, and places with strong magnetic fields and high frequency.
- Do not install the instrument on a table that is exposed to direct sunlight, airflow and harmful gases, dust, or vibration.
- The table on which the instrument is installed should be able to withstand a weight of more than 40 kg.
- Keep a space of 400 mm on both sides of the instrument and keep a space of 100 mm to the left and behind the instrument for air convection by the fan.
- Make sure the Power cableis connected to the instrument's power outlet. Before plugging the power plug into a power outlet, check and make sure that the instrument's power switch is at the "O" position. The current capacity of the power supply outlet should not be less than 6 A and should have a grounding wire. Do not place the device where it is difficult to disconnect the power cord.

3.2 List of Accessories

Serial Number	Name	Unit	Quantity
1	20 mL syringe	Pcs	1
2	COM serial port cable with 9 pins	Pcs	1
3	Sample cup	Pcs	10
4	Fuse 2 A/250 V	Pcs	2
5	Power cable3GTJ1/3GTJA	Pcs	1
6	Two-way PEEK connector	Pcs	2
7	user manual	Pcs	1
8	waste container	Pcs	1

- The above list of accessories is for reference only. Please refer to the accompanying packing list for the details.

3.3 Unpacking

After unpacking the paper carton, two people should hold the bottom of the instrument with both hands to remove the analyzer. Please handle with care to avoid accidental damage or accident.

3.4 Connection

Waste pipe

Insert the waste liquid tube firmly into the liquid waste discharge port on the back of the analyzer. The waste pipe should be fixed firmly so that it cannot be easily pulled out. Insert the other end of the waste pipe into the connector on the liquid waste container lid.

Precautions:

- Please place the waste container under the liquid waste discharge port so that the liquid waste can be discharged to prevent backflow.
- Avoid bending the waste pipe.
- After the analyzer is relocated, the waste pipe tube should be checked for signs of loosening or breakage, so as not to clog the discharge of liquid waste.

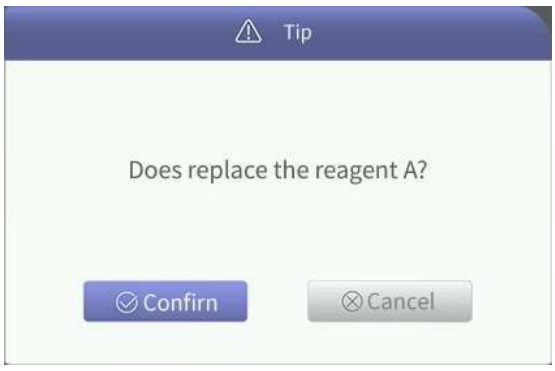
Reagent pipe

Connect the Teflon tube marked H to H on the back of the instrument. Insert the reagent pipe corresponding to A, B, C, and D into the reagent bags and seal the bags. Insert the reagent pipe H into the haemolyser H bottle and tighten the bottle cap.

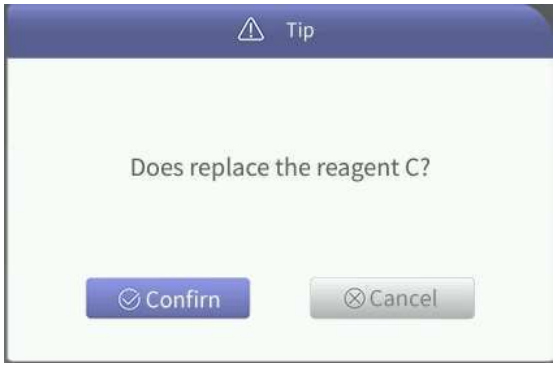
Reagent A、Reagent B、Reagent C、Reagent D

Reagent H

A, B, C, D, H icons of the reagent at the bottom of the instrument interface. After installing the reagent, click on the corresponding reagent icon. The system will pop up the corresponding dialog box and click [Confirn]




Tip
Does replace the reagent B?
Confirn
Cancel


Tip
Does replace the reagent C?
Confirn
Cancel


Tip
Does replace the reagent D?
Confirn
Cancel


Tip
Does replace the reagent H?
Confirn
Cancel

Power cable

The Power cable that comes with the analyzer should be connected to the AC input terminal tightly. After confirming that the power switch of the instrument is on the Off (O) side, insert the plug into the outlet. The power capacity of the outlet should be above 6 A, and it should have a grounding terminal.

Precautions:

- **Do not place additional items in front of the power switch so that it can be turned off quickly in case of an emergency.**
- **Do not share the power supply with high-powered electrical equipment (refrigerators, compressors, etc.).**
- **The grounding wire must be connected.**

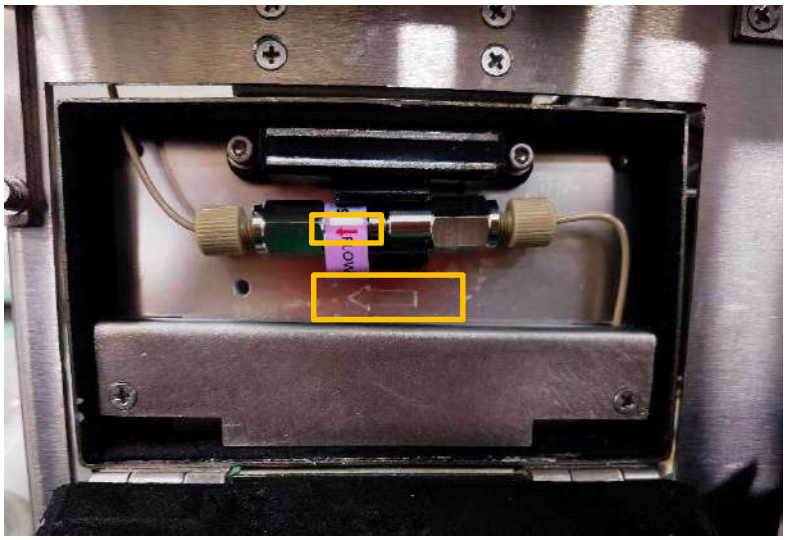
Data cable

Before connecting the data cable, make sure the instrument power is off to protect these ports against damage caused by current surge.

For all equipment that is to be connected to this instrument, they must pass the safety certification approved by the local competent authority and should carry a safety certification sign.

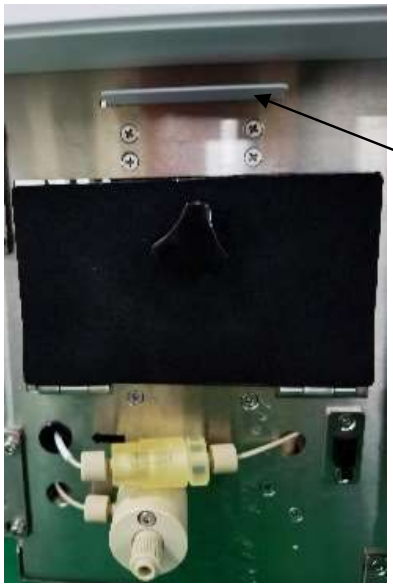
Chromatography column

Open the left door of the instrument. Take the column out of the box of the column kit and unscrew the sealing plugs at both ends. Connect the column along the direction of the liquid flow indicated by the arrow on the label, which should match the direction marked on the column base.



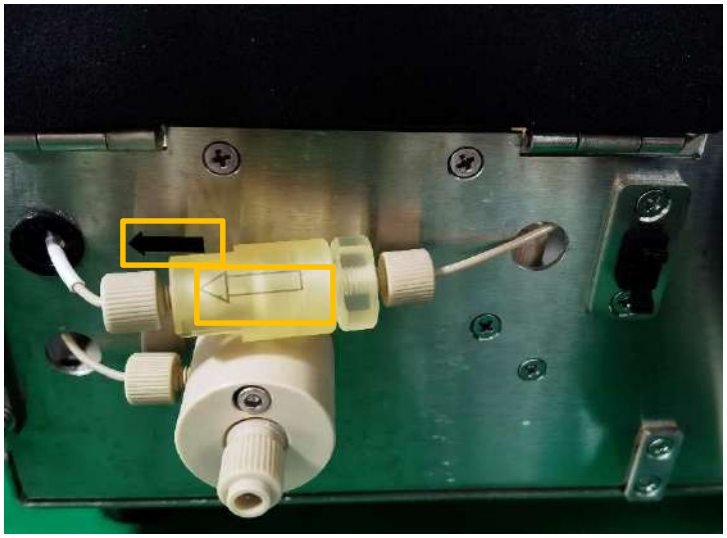
Precautions:

- The chromatography column shall be used exclusively in this analyzer and may not be used in other instruments.
- When not in use for a long time (more than one week), the column should be removed from the instrument, and the accompanying plug should be installed to prevent the interior from drying out. The column should be stored refrigerated.
- The chromatography column should not be subjected to shock or vibration.
- During the test, in case of significant increases in pressure (approximately 3 Mpa higher than the pressure at initial use), the filter should be replaced first. Should the pressure remain high after replacement, replace with a new chromatography column.
- The replacement of the column is necessary to replace the column with a matching RF card

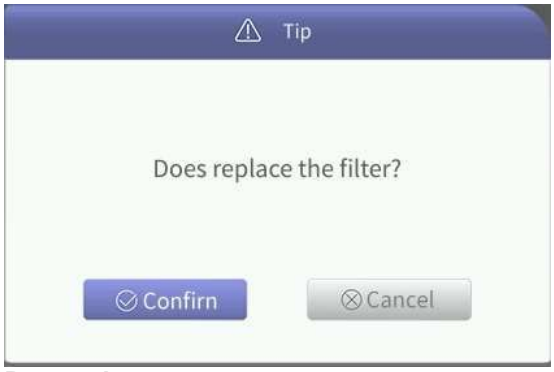


Filter

Open the left door of the instrument. Loosen the pipes at both ends of the filter. Replace the filter used with the instrument. Re-tighten the pipe connectors at both ends.



The filter icon at the bottom of the instrument interface. After installing the filter, click on the phase filter icon.The system will pop up the corresponding dialog box and click [Confirn]



Precautions:

- A new filter must be installed if the instrument is freshly installed or when prompted by the analyzer.
- Only the filter provided by the manufacturer can be used, otherwise the column may be damaged.

Thermal paper (optional)

After opening the thermal paper box on the top of the analyzer, place the thermalthermal paper in the box, pull out approximately 30 mm, and then close the box. Precautions: Do not replace paper while printing.

3.5 Perfusion

Perfusion is required when the reagent is installed for the first time or when no reagent in the reagent tube needs to be replaced.

Perfusion A: Rotate the exhaust valve counterclockwise (open the left door) to 180 degrees. Tap the "Perfusion A" button on the "Service" interface. Insert the 20 mL syringe tip in the accessory box into the exhaust connector, and slowly draw the reagent. When the liquid in the syringe is more than 10 mL, tighten the exhaust valve clockwise, and close the left door. Then perform perfusion for reagent s B, C, and D.

3.6 Wash

After installing the reagent for perfusion, tap the "Wash" button on the "Service" interface to stabilize the "ADC" value between 13,000 and 16,000. If the "ADC" value is not stabilized, it indicates that air has entered the pipe during the replacement of the reagent . In this case, perform the perfusion operation as described in Section 3.5 before tapping the "Wash" button to check whether "ADC" is stabilized within the required range.

4. User Interface

4.1 Login Interface

Boot Interface

Turn on the power switch on the left side of the analyzer to display the boot interface. After a few seconds, the instrument will enter the login interface as shown above. Enter or select the user name in the user name field, enter the user's password in the password field, and tap "Login" to enter the power-on self-test interface. If no user has been set, tap "Login" to directly enter the self-test interface.

4.2 Self-Test Interface

After the instrument enters the self-test program, the system will automatically check the corresponding components. For those components that have passed the self-test, the system will automatically check the corresponding box. For those components that have failed the self-test, the corresponding box will be crossed out to prompt further examination and troubleshooting. After all self-test items have passed the test, the instrument will automatically enter the standby interface.

4.3 Analysis Interface

The lower part of the instrument's analysis Interface mainly displays the pressure, temperature, ADC, and other status of the instrument, as well as the remaining amount of reagent ,chromatography column, and filter. The upper part mainly displays the current status of the instrument, DTU connection status, and LIS connection status.

Description of the buttons on the left of the interface:

No.	Description	Function
1	"Analysis"	Tap to enter the analysis interface: sample test setting, start, and result display interface
2	"Query"	Tap to enter the query interface: Check sample test results, quality control data, and calibration data
3	"QC"	Tap to enter the quality control interface: quality control substance information setting, quality control chart viewing, and quality control start interface
4	"Calibration"	Tap to enter the calibration interface: calibration substance information setting and calibration test interface
5	"Service"	Tap to enter the service interface: Set common parameters and perform daily maintenance
6	"LOG"	Tap to enter the log interface: Display current errors, historical errors, etc.

Description of the contents of the analysis list

No.	Description	Function
1	SN	Display sample serial number
2	ID	Display sample ID
3	HbA1c	Display HbA1c results
4	Type	Display sample type (whole blood, quality control, or diluted sample)
5	Status	Display a symbol to prompt normal or abnormal test results

Description of the buttons on the right of the interface

No.	Description	Function
1	"SN"	Set sample serial number
2	"ID"	Set sample ID
3	"1st ID"	Set initial sample ID
4	"Repeat"	Set the number of repeated measurements of the sample
5	"Loop"	Set the number of cycle measurements of the sample tray
6	Selection box for sample type	Set sample type: WB, DL, QC1, or QC2
7	"Confirm"	Save settings
8	"Run"	Start the instrument for sample testing

During sample testing, the analysis interface of the instrument is as follows:

Description of contents displayed and buttons

No.	Description	Function
1	Real time atlas	Display the chromatogram thumbnail of the current sample. Tap to zoom in the real-time chromatogram
2	^	Scroll up button. Tap to view the test results of previous assay
3	ˇ	Scroll down button. Tap to view the test results of next assay
4	Stop	Tap and the instrument will stop the analysis upon completion of the current sample assay
5	E-Stop	Tap and the instrument will emergency stop
6	Analysis list	Display the test results, sample type, and status of the current batch of samples

Interface for real-time chromatogram during the test

Description of contents displayed on the right part

No.	Description	Function
1	NowID	Display current sample ID
2	Begintime	Display start time of the current sample testing
3	Previous	Display previous sample ID
4	Next	Display next sample ID
5	Test results	Display the peak time and Ratio of each test

Description of the buttons in the middle of the interface

No.	Description	Function
1	"Release"	Tap to confirm to publish and upload the results of samples with questionable status
2	"Refuse"	Tap to decline to publish and upload the results of samples with questionable status
3	[へ] [へ]	Scroll up and down to view the sample chromatograms
4	"Back"	Return to the analysis interface

4.4 Query Interface

Tap "Query" to enter the query interface. Query the sample, calibration, and quality control results through the buttons.

Description of the buttons on the right of the interface

No.	Description	Function
1	"Test Type"	Tap "Sample", "Calibration", or "QC" to query the corresponding test
2	"Sta" for query by date	Select the start date of sample query
3	"End" for query by date	Select the end date of sample query
4	"Sta" for query by serial number	Select the start serial number of sample query
5	"End" for query by serial number	Select the end serial number of sample query
6	" ID"	Tap to input the ID number to query the test results
7	"Type"	Filter the test results by selecting all, whole blood, diluted sample, or abnormal
8	"Status"	Tap to filter and query the test results
9	"Output"	Select printer or LIS
10	"Print"	Print the selected results
11	"Graph"	Tap to view the sample chromatograms
12	"Confirm"	Save operations
13	[⌃] [⌄]	Scroll up and down buttons

Tap "Calibration" to enter the calibration query interface. Filter the calibration results using the buttons in the right part. The calibration results are displayed on the upper part of the screen, mainly including the serial number, batch number, low value, high value, calculation formula, and date.

Description of buttons

No.	Description	Function
1	"Sta Date" for query by date	Set the start date to query the calibration results
2	"End Date" for query by date	Set the end date to query the calibration results
3	"Lot"	Select the Lot of the calibration substance through the drop-down triangle to query the calibration results of the Lot
4	"Output "	Select printer or LIS
5	"Print"	Print the selected results
6	"Confirm"	Confirm relevant selections and start query

Tap "Quality Control" to enter the quality control result query interface. Filter the quality control results using the buttons in the right part. The quality control results are displayed on the upper part of the screen, mainly including serial number, sample ID, HbA1C, type, status, and date.

Description of buttons

No.	Description	Function
1	"Sta Date" for query by date	Set the start date to query the calibration results
2	"End Date" for query by date	Set the end date to query the calibration results
3	"Lot"	Select the Lot of the quality control substance through the drop-down triangle to query the quality control results of the Lot
4	"Level"	Check QC1 or QC2 through the small boxes to query the quality control results
5	"Output Device"	Select printer or LIS
6	"Print"	Print the selected results
7	"Confirm"	Confirm relevant selections and start query

4.5 Quality Control Interface

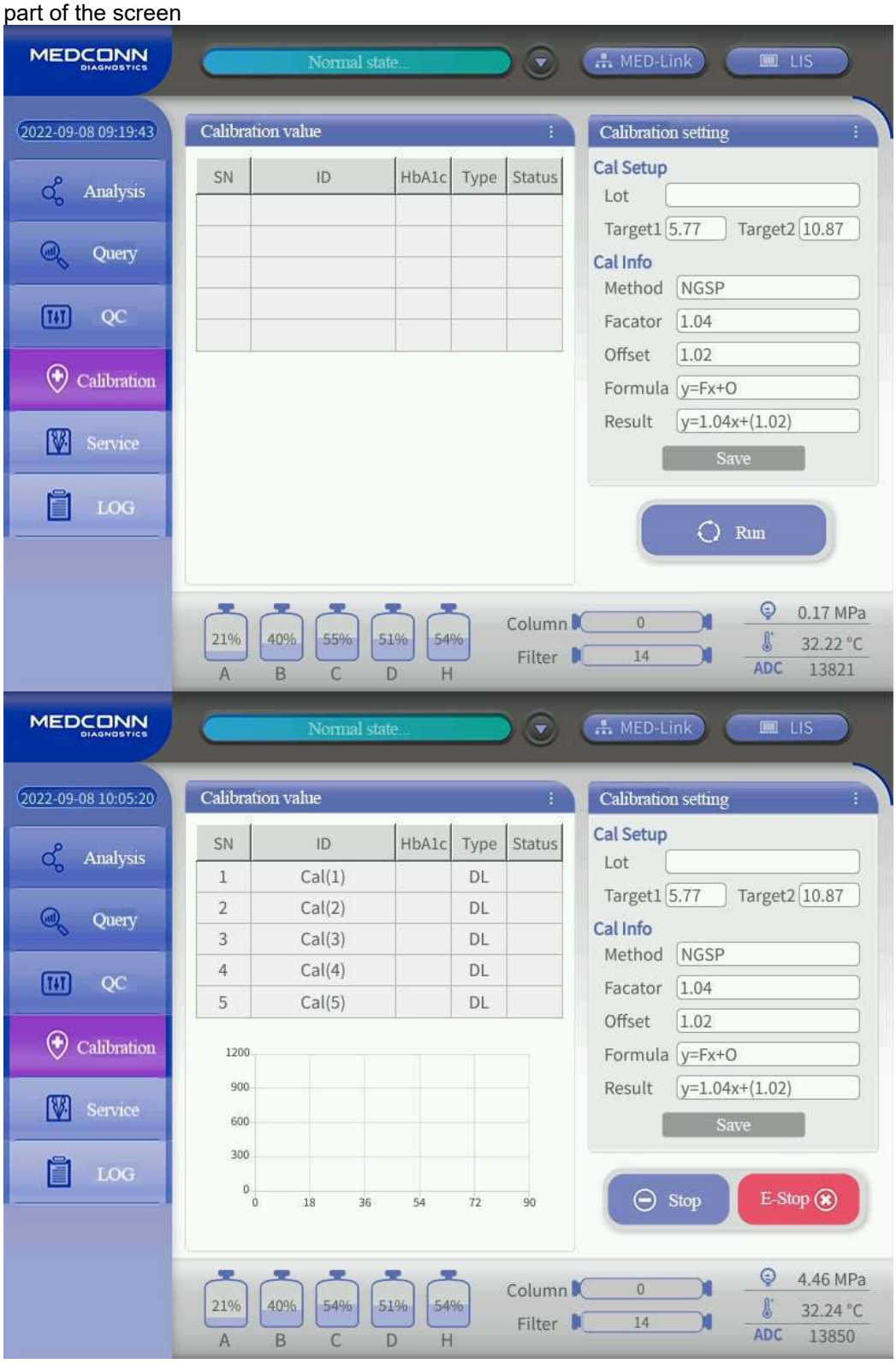
Tap "QC" to enter the quality control interface. Select QC1 or QC2 using the buttons to set the quality control substance information. The quality control charts L–J are displayed on the upper part of the screen

Description of buttons

No.	Description	Function
1	"Filter Criteria"	Filter by start and end date, level, Lot, etc., to display charts L–J
2	Level	Check box for the level of quality control to set level QC1 or QC2 of quality control
3	"Low"	Enter the low value of the quality control substance
4	"Mean"	Enter the mean value of the quality control substance
5	"High"	Enter the high value of the quality control substance
6	"Lot"	Enter the Lot
7	"ID"	Set the sample ID corresponding to the quality control test
8	"Modify QC Info"	Save relevant settings
9	"Confirm"	Tap the "Confirm" button to save the current settings
10	"L–J Print"	Tap the button to print charts L–J

4.6 Calibration Interface

Tap "Calibration" to enter the calibration interface. Set the calibration substance information using the buttons. The calibration test results are displayed on the upper part of the screen



Description of buttons and contents displayed

No.	Description	Function
1	" Method"	Display calibration method NGSP

2	"Factor"	Display current factor
3	"Offset"	Display current Offset
4	"Formula"	Display the calculation formula
5	"Result"	Display the current calculation formula
6	"Lot"	Set the Lot of calibration substance
7	"Target1"	Set the low value of the calibration substance
8	"Target2"	Set the high value of the calibration substance
9	"Save"	Save relevant settings
10	"Run"	Start calibration
11	"Stop"	Tap and the instrument will stop the calibration upon completion of the current sample assay
12	"E-Stop"	Tap and the instrument will emergency stop

4.7 Service Interface"

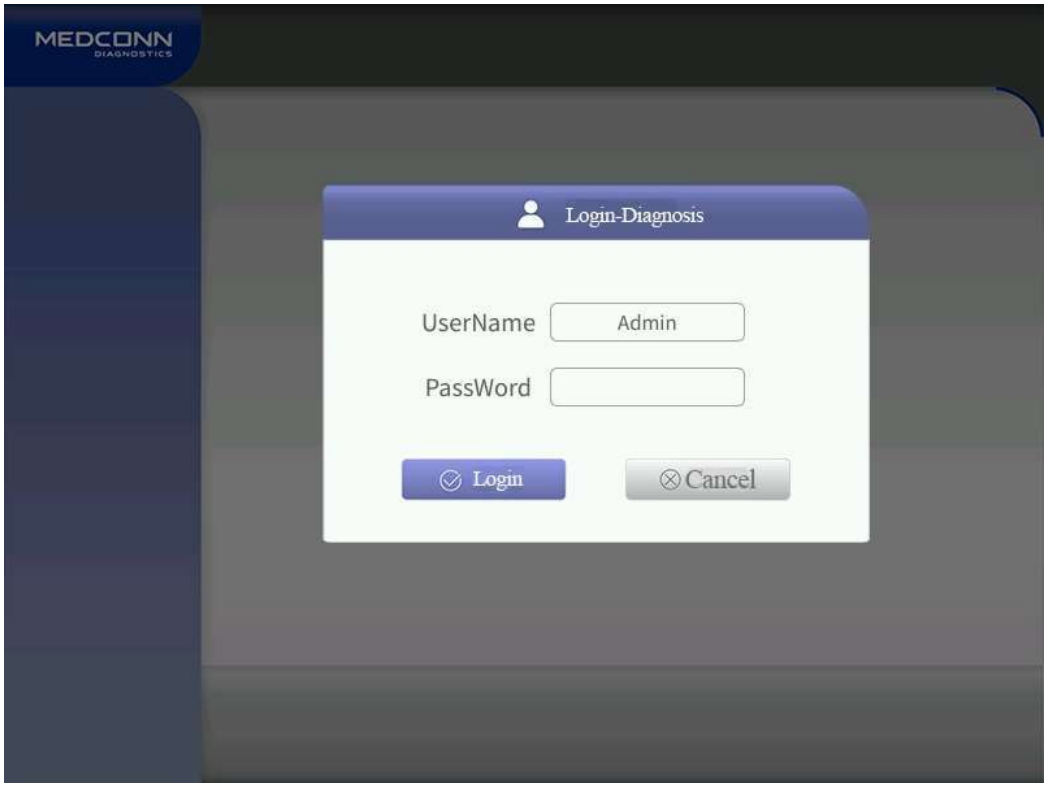
Tap "Service" to enter the service interface to perform common settings and simple operations for routine use. Reagent-related information is displayed, including the batch number, validity period, and bottle opening date.

Description of the buttons in the interface

No.	Description	Function
1	"Prime A"	Start the Prime program with reagent A
2	"Prime B"	Start the Prime program with reagent B
3	"Prime C"	Start the Prime program with reagent C
4	"Prime D"	Start the Prime program with reagent D
5	"Prime H"	Start the Prime program with haemolyser H
6	"Rinse"	Perform the Rinse program
7	"Printer"	Test the printer
8	"Function Setting"	Check the box to turn on the printer, LIS, or barcode scanner
9	"Print Format"	Select report printing format
10	"Mode Set"	The default setting is standard mode
11	"Time Set"	Set the date and time
12	"RS232 Setting"	Set RS32 baud rate, data bit, parity check, stop bit, and flow control
13	"Save"	Save relevant settings
14	"Diagnosis"	Enter the diagnosis interface (for engineers)
15	"Reset"	Instrument reset button. Tap and the moving parts will return to the origin

4.8 Diagnosis Interface

Tap the "Diagnosis" button in the "Service" interface and a dialog box will pop up. Enter the password to enter the diagnosis interface.



The diagnosis interface can only be used by service engineers to inspect and repair the instrument. It should not be used by other personnel. The basic functions are as follows:

No.	Description	Function
1	Sensor display	Display the status of each sensor on the instrument
2	Motion test	Select various motion tests to determine whether the instrument is working normally based on the display status of the sensor
3	Parameter	Adjust various parameters of the instrument

4.9 Log Interface

Tap the "Log" button to enter the main log interface. Select current errors, abnormal samples of the day, historical errors, error statistics, or log records to display correspondingly. The instrument number, software release version, full version, and total test count are displayed in the middle of the interface.

Description of buttons and contents displayed

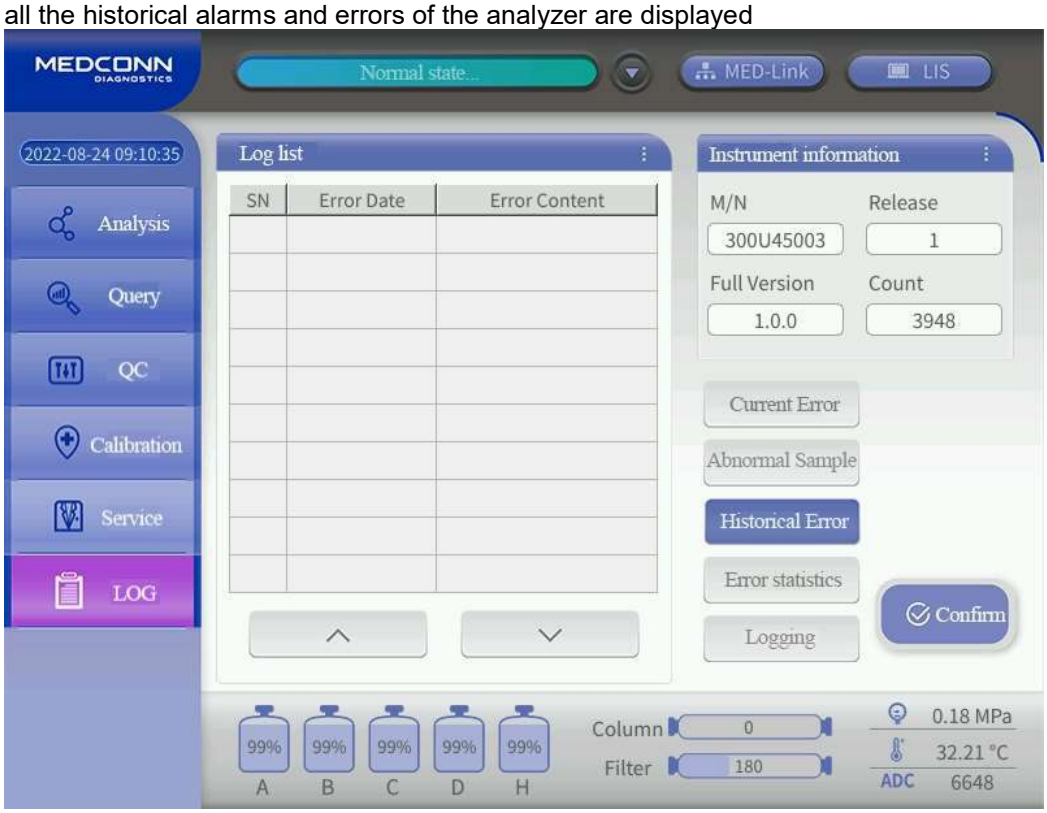
No.	Description	Function
1	Error content	Display current instrument error content
2	Solvable solution	Display possible solutions
3	Instrument information	Display M/N, Release version, Full version, and total test count
4	"Confirm"	Confirm button for errors

Tap "Abnormal Sample" to enter the interface for the summary of abnormal samples of the day, where all the test results with abnormal prompts of the day are displayed.

Description of buttons and contents displayed

No.	Description	Function
1	Sample information	Display the SN, sample ID, HbA1c, type, status, and date of the abnormal tests of the day
2	[∧] [∨]	Scroll up and down buttons
3	"Confirm"	Review button for abnormal results

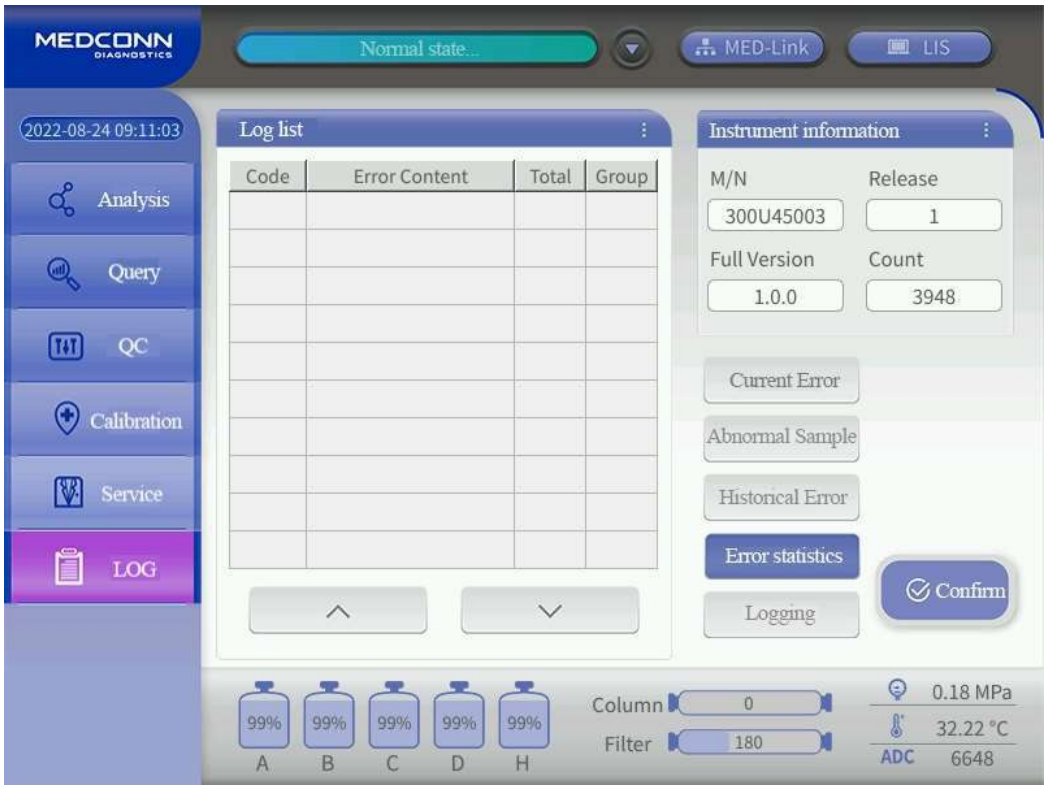
Tap "Historical Errors" to enter the interface for the summary of historical errors, where all the historical alarms and errors of the analyzer are displayed



Description of buttons and contents displayed

No.	Description	Function
1	Error information	Display SN, Error Date , and Error Content
2	"Confirm"	Confirm button for error information

Tap "Error Statistics" to enter the error statistics interface, where the error code, error content, total count, and group are displayed.



Tap "Logging" to enter the log record interface, where the latest 50 relevant log contents of the analyzer are displayed, including log SN, log date, and log Content.

5. Instrument Operations

5.1 Preparation

Sample tube

The instrument can directly use the sample drawn by the vacuum blood collection tube, and the test tube can be placed directly on the sample tray.

Sample cup

Diluted samples, quality control substances, and calibration substances should be placed in sample cups.

5.2 Boot

Toggle the rocker switch on the left side of the instrument to "|" (the "|" position means that the input and output of the rocker switch are turned on) to turn on the input power of the instrument. The analyzer starts and enters the self-test interface. After the self-test is completed, the instrument will automatically enter the standby interface. Tap "Analysis" to enter the analysis interface and wait for the test sample.

5.3 Calibration

Calibration should be performed using a calibration substance after installing a new column.

First place 5 samples on the sample tray and tap "Analysis" - "Run" to activate the column.

Prepare the calibrator according to the instructions of the calibrator and draw no less than 2.0 mL of the prepared calibrator into the sample cup. Place two sample cups containing low- and high-value calibrators, respectively, into the first and second positions of the sample tray. Place the sample tray on the sample tray of the instrument. In the "Calibration" interface, enter the batch number (batch number of calibrator), parameter 1 (target value of low value calibrator), and parameter 2 (target value of high value calibrator). Tap the "Save Settings" button and then tap the "Run" button to start the calibration procedure.

After the calibration is completed, the system will automatically update the slope and intercept. If the calibration fails, use the slope and intercept obtained from the last calibration or re-calibrate in the calibration interface.

5.4 QC

In order to ensure the normal condition of the instrument, the laboratory should arrange quality control cycles as needed to test the quality control substance.

Prepare diluted samples at two levels for testing according to the instructions of the quality control substance.

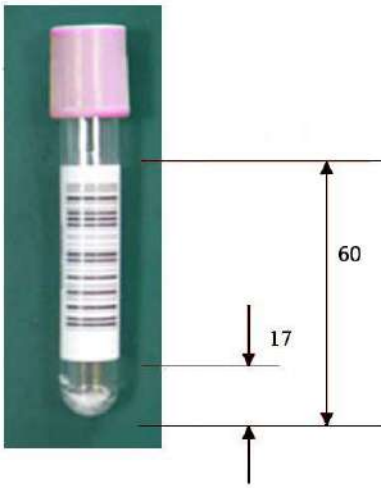
Before testing the quality control samples of a new batch, set the quality control substance parameters in the "Quality Control" interface. After confirming to save the information, check QC1 or QC2 in the "Analysis" interface to perform the test.

5.5 Sample Requirement

The precise volume and proper storage of samples ensure the accuracy of the test results of the MQ-3000 analyzer. The sample requirements are as follows:

- Blood samples must be collected correctly by a dedicated medical professional.
- Blood samples are collected using a vacuum blood collection tube containing anticoagulant EDTA-K_2 (the use of blood collection tubes with other anticoagulants may shorten the life of the column), and the blood samples should not be stored for more than 5 days at 2–8 °C.
- The amount of anti-coagulated whole blood sample in the test tube must be larger than 1 mL. If it is less than 1 mL, the instrument may not be able to draw a sufficient sample amount.
- If the sample volume of the whole blood in the test tube is less than 1 mL, the blood in the test tube should be mixed well before 10 μL of the blood sample is manually drawn and diluted 250 times with the haemolyser. Then, the diluted sample is tested.
- The diluted sample should be placed in the sample cup and the sample volume should not be less than 1 mL, which is placed on the sample tray.

5.6 Barcode Requirement (optional)



The MQ-3000 analyzer comes with an optional barcode scanner to facilitate sample analysis during LIS transmission. To ensure the success rate of barcode scanning, the samples with the test tube cap should be placed on the sample tray, and make sure that the barcode is facing the notch of the test tube position of the sample tray. The barcode should be affixed between 17 mm and 60 mm from the bottom of the test tube, as shown in the figure.

The instrument is compatible with φ 12 × 75 mm and φ 12 × 100 mm vacuum blood collection tubes.

Types of barcode

The instrument automatically recognizes the following barcodes:

- Interleaved 2-5 barcode: The first 2 digits are 25, and there is a string below the barcode.
- Code 39 (Extended) barcode: The first 2 digits are 39, and there is a string below the barcode.
- Code 128 barcode: The first 3 digits are 128, and there is a string below the barcode.
- Codabar barcode: The first 3 digits are 123, and there is a string below the barcode.

Barcode dimension

- Width of barcode: 26 to 30 mm; the width is related to barcode type and the number of bits in the strings.
- The height of barcode (without strings) should be ≥ 13 mm, as shown in the attached figure.

interleaved 2-5	code 39 (Extended)	code 128	codabar
			

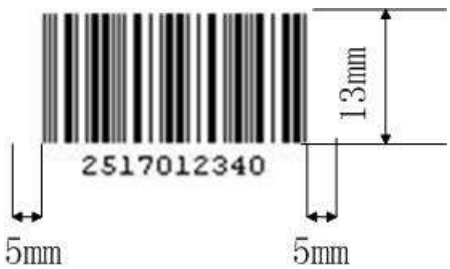


Diagram of barcode dimension. There should be a blank space of 5 mm or more at the edge of the label along the length direction of the barcode.

5.7 Sample Placement

The instrument can hold 18 samples at a time. Place the samples to be tested in the sample tray, then tap the "Run" button in the "Analysis" interface. The instrument will automatically perform the test and analysis. After the analysis of each sample is completed, the results are displayed on the analysis interface while the analysis report is automatically printed. Alternatively, the results are output to the LIS system.
Note: Do not place your hand between the sample tray and the right side of the instrument during testing to avoid mechanical injury.

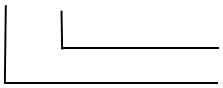
5.8 Input of Sample Information

On the left side of the analysis interface, input the information of the sample, or the serial number, the number of repeated measurements, and the sample ID.
Methods for sample ID input:

- Input single sample ID number: Enter the sample number in the "Sample ID" field.
- Input multiple sample ID numbers: Enter the number of the first sample in the "Initial ID" field and the numbers of subsequent samples will be automatically incremented.
- Automatically obtain sample ID number: When a barcode is attached to the sample tube, the instrument will automatically recognize the sample number.

For example, if there are 20 samples of "In-Patient Internal Medicine", you can use Method 2 and enter "zynk001" in the "Initial ID" field:

zynk001 represents sample 001 of In-Patient Internal Medicine



Then, the sample numbers will be set to zynk001 to zynk020.

5.9 Sample Test

After the above steps are completed, directly tap the "Run" button in the "Analysis" interface to perform the sample test. Each sample test can be completed in as fast as 90 s. If the test needs to be stopped during the test, tap the "Stop" button and the instrument will continue to test the current sample before entering the standby state. If the test needs to be stopped immediately during the test, tap the "Emergency Stop" button and the instrument will stop the operation immediately and enter the standby state. If there is no subsequent sample test, shut down the instrument.

5.10 Shutdown

Toggle the rocker switch on the left side of the instrument to "○" to turn off the power input (the "○" position means that the input and output of the rocker switch are disconnected), and the instrument is shut down.

6. Precautions and Tips for Potential Risks

6.1 Precautions for Operation

- The MQ-3000 analyzer uses a 220 V ± 22 V,50 Hz ± 1 Hz AC power supply.
- Equipment connected to the external ports of the MQ-3000 analyzer must be safety certified and should carry a safety certification sign.
- The safe DC voltage for the output of external RS232 port is 5 V.
- Do not use expired assay kits and columns.
- The filter and column should not be used for more than the specified number of tests, otherwise the pressure inside the system will exceed the limit and the test data will be biased.
- When replacing the column, follow the steps on the screen.
- When the liquid waste is almost full, it should be emptied in time. The liquid waste shall not be discharged directly into the drainage system. Please dispose of liquid waste according to the local "Measures for the Management of Medical Waste at Medical and Health Institutions" (the user does not need to set up a special drainage system).
- When the instrument is in normal use, various reagents and liquid waste will not leak into the instrument. If a leakage is found, it should be checked and repaired in time. In addition, the leaked liquid should be wiped off. Wear protective medical gloves when wiping off the leaked liquid to prevent biological infection.

6.2 Tips for Biological Risks

- All samples should be treated with caution to prevent biological infections.
- Wear protective clothing (glasses, gloves, masks, etc.) when handling samples and waste.
- The reagents contain 0.02% sodium azide, and skin or eye contact with or ingestion of the reagent should be prevented.
- In case of inadvertent skin or eye contact, wash the site of contact thoroughly with water.
- In case of inadvertent ingestion, wash the mouth thoroughly with water and drink plenty of water.
- The remaining samples, waste after analysis, expired reagents and scrapped accessories shall be disposed of in accordance with the provisions in the local "Management Measures for Medical Wastes of Medical and Health Institutions" to avoid damage to health and environment.

6.3 Tips for Data Risks

- Only authorized external equipment is permitted to be connected to the analyzer.
- Make sure that all external equipment is protected by appropriate security software.
- Do not connect other storage devices through the USB port unless instructed to do so by the official user manualor by a designated customer service representative.

7. Service and Maintenance

7.1 Service

In the use of the analyzer, the user should be in accordance with the requirements of maintenance and maintenance, after maintenance, confirmed that the basic safety and effectiveness of products can be maintained, normal use for 8 years.
The following operations shall be performed for daily maintenance:

- Check for leaks in the liquid lines and fittings and replace them if necessary.
- If the instrument is equipped with an optional printer, check if there is enough paper. If the paper appears red on one side, it means that the paper is running out. Please prepare to replace the paper.
- Check if there are enough reagents.
- Empty the waste container every day.

7.2 Maintenance

Refer to the table below and perform maintenance on a regular basis.


Items with ★ in the table below mean that protective gloves should be worn to prevent infection of pathogenic microorganisms.
The liquid waste discharged from the analyzer, used parts, and cleaning tools, etc., shall be disposed of in accordance with the local "Management Measures for Medical Wastes of Medical and Health Institutions".

	Maintenance item	Time of maintenance
★	Check for leaks in the liquid lines and fittings and replace them if necessary.	Daily
★	Liquid waste treatment	Daily, when replacing the reagents, when prompted by the software
	Replacement of reagent A	Replace the reagent when the text box prompting reagent replacement appears
	Replacement of reagent B	
	Replacement o freagent C	
	Replacement of reagent D	
	Replacement of haemolyser H	
	Replacement of thermalthermal paper (optional)	After a red line appears on the edge of the paper
★	Automatic cleaning of the flow path	Weekly
★	Replacement of column	When the text box prompting replacement appears
	Check whether the temperature control system is functioning effectively	Before analysis

Long-Term Deactivation of the Instrument
When the MQ-3000 analyzer is not used for a long time, the column should be removed, and a two-way valve should be installed in the position of the column. The both ends of the removed column should be sealed with sealing plugs and the column should be placed in an environment of 2 °C to 8 °C away from light.
Remove all reagent pipe from the reagent bottles and perform the "Perfusion" program with reference to Section 3.5. The instrument sequentially discharges the air in the lines of reagent A, reagent B, reagent C, and reagent D. Turn off the power switch and

unplug the Power cableuntil there is no liquid waste emission from the waste pipe for one minute.

8. Troubleshooting

8.1 Failure Analysis

If the result of the MQ-3000 analyzer is abnormal, you need to check the instrument according to the following process:

- Failure analysis of chemical analysis system (i.e., column or reagent)
- Failure analysis of chromatographic peaks
- Failure analysis of instrument software and hardware (i.e., one part of the MQ-3000 analyzer is damaged or loses its functionality)

8.2 Chemical Analysis System

In case of changes in the shape and peak time of chromatographic peaks detected by this instrument, the accuracy of the analysis will be reduced. If the above situation occurs, check the expiration date of the reagent and column first, and replace expired parts immediately. If they are still within the validity period, please contact your local engineer for repair.

8.3 Failure Analysis of Chromatographic Peaks

In cases of the problems shown in the table (Troubleshooting of chromatographic peaks) below, please troubleshoot the problems according to the method recommended in the table first.

Problem	Possible reason	Recommended solution
There are no peaks on the chromatogram; there are multiple vertical lines; no data is displayed on the report	The reagents are used up.	Replace the reagents.
	There is air in the reagent line and sample syringe line.	Exhaust the air in the line and run the "Perfusion" program 1–2 times.
There are no peaks on the chromatogram; there are no vertical lines; no data is displayed on the report	The sample condenses into blocks.	Perform the "Wash" program once and prepare the sample again for testing.
	The sample size is less than 1 mL.	Mix the blood in the test tube well before 10 μL of the blood sample is manually drawn and diluted 200 times with the haemolyser. Then, the diluted sample is placed in the sample cup for testing.
	Pipeline leakage.	Tighten the leaking connector.
	The sampling needle is bent or blocked and the metering valve is not switched to the correct position.	Please contact your local engineer.
	The LED or the photoelectric receiving tube of the analysis head is damaged.	Turn off or turn on the LED light after entering the diagnosis interface to see if the ADC value changes. If there is no change, it means that the LED or the photoelectric receiving tube is damaged. Please contact your local engineer.
Abnormal peak shape	Expired or contaminated reagents.	Replace the reagents.
	Expired or damaged column.	Replace the column.
	Expired or damaged filter.	Replace the filter.
Failed calibration; peak exceeds the	Data input error.	Check whether the parameters entered for the calibrator are

range; peak is not detected		correct.
	Use the wrong calibrator.	Check whether incorrect or expired calibrators are used. Use qualified calibrators.
	The volume of calibrator is insufficient.	Check to make sure that the calibrator volume in the sample cup is greater than 2.0 mL.
	There are bubbles in the detector and/or the pump system.	Check whether the ADC value is stable in the range of 13,000–16,000. Perform "Wash" program 1–2 times.
	Expired or contaminated reagents.	Replace the reagents.
	Expired or damaged column.	Replace the column.

8.4 Failure Analysis of Instrument Software and Hardware

In cases of the problems shown in the table below, please troubleshoot the problems according to the method recommended in the table first.

Problem	Possible reason	Recommended solution
The display screen shows abnormal content and is not operational.	The system fails to start properly.	Turn off the power and turn it on again after 8 seconds. If it does not start normally after 3 times of machine boot, please contact your local engineer.
The instrument is not running and the LCD screen is not lit after the main power switch is turned on.	Power off.	Check if there is power in the power outlet and if the neutral wire is disconnected.
	The fuse for the main power is faulty.	Check the fuse to see if it is blown. If the fuse is blown, replace one group (two) of fuses. If the fuse blows again, contact your local engineer.
	The main power switch is faulty.	Please contact your local engineer.
An error is shown on the screen interface.	Fail to turn on the system or encounter an error during operation.	Turn off the power and turn it on again. If the problem persists, please contact your local engineer.
The cursor cannot be moved or cannot be operated.	1. The system program enters an infinite loop and crashes. 2. The touch screen is damaged.	Turn off the power and turn it on again after 8 seconds. If the problem persists after 3 times of machine boot, please contact your local engineer.
The system displays that the reagents are empty	The reagents are used up	Replace the reagents
The printer delivers the paper but it does not show some lines or the ink is too light.	The paper does not meet the requirements.	Must use the paper supplied by our company.
	The paper is installed along the wrong direction.	Reload the paper.

	The printer is faulty and needs to be replaced.	Please contact your local engineer.
The temperature is out of control.	The temperature control system is damaged.	Shut down the machine and contact your local engineer.
The pressure is < 2 MPa during the analysis.	Air has entered into the pipeline.	Remove air from the pipe.
	The pipe connector leaks.	Tighten the leaking connector.
	A component is damaged or leaking.	Shut down the machine and contact your local engineer.
The pressure is > 10 MPa during the analysis.	The filter or column is damaged or exceeds the specified number of usage.	Replace the filter or column.
	The pipeline is blocked.	Shut down the machine and contact your local engineer.

Replace the Fuse

To ensure safety, only the fuses supplied by our company (rated current: 2 A; rated voltage: 250 V; nominal fusing heat value: 14.45 A^2*sec*; 5 × 20 mm time-delay glass tube fuse T2AL250V) can be used.

The power fuse of the MQ-3000 analyzer is installed in the power outlet. If the fuse blows, please follow the steps below for fuse replacement.

- Disconnect the Power cableplug from the back of the instrument.
- Insert a small screwdriver at the edge of the power outlet and then gently pry open the power outlet and remove the fuse holder.
- Replace the fuse and reset the fuse holder, as shown in the figure below.

If the problem cannot be resolved as described above, please contact your dealer or local engineer.

Note: The operator can replace the reagents, columns,thermal papers and fuses provided with this instrument. However, the operator shall not replace other parts in the instrument. Operators are not allowed to choose substitutes for the parts by themselves.

The repair of this instrument can only be carried out by the technical service department and maintenance organization authorized by the company.

Our company will not be responsible for the damage caused by the operator's own use of substitutes or repairs carried out by unauthorized personnel!

You can check with your dealer regarding the local technical service department. You can also check the website of the Global Technical Service Center for this instrument.

9. Consumables

Consumables required for this analyzer

Serial number	Name
1	Hemoglobin assay kit (HPLC)
2	HbA1c haemolyser
3	HbA1c column kit (HPLC)
4	Sample cup, thermalthermal paper, and filter
5	Calibrator of Glycated hemoglobin $A1_C$
6	Quality control substance for Glycated hemoglobin

10. Package, Transportation, and Storage

10.1 Package

The instrument has a net weight of 22 kg and a gross weight of 47 kg. A wooden pallet is provided with the instrument for easy shipping with tools. The stacking of the pellets must not exceed 2 layers.
The package size of the instrument is: 669 mm ×559 mm × 835 mm.
Schematic of packaging:

10.2 Transportation

The products packaged with the original packaging materials at the factory can be transported by common means of transportation. They must not be stored in open cabins and compartments during transportation. They should not be stored in open storage during transit, and are not allowed to be shipped with flammable, explosive and corrosive products during transportation. The product should not be exposed to rain, snow or liquid substances. The product should be protected against severe collision, impact and mechanical damage during transportation and handling.

10.3 Storage

The packaged product should be stored at −10 °C to 40 °C and relative humidity of not more than 80% in a well ventilated environment free of corrosive gas.

11. Communication Protocol

The MQ-3000 analyzer can automatically/manually upload analysis data to the Laboratory Information System (LIS) via the serial port or the network port.
The analysis results for each sample, including instrument model, sample information, sample data, and a pair of start and stop characters, are transmitted to the LIS system.

Physical Connection and Communication Settings
The MQ-3000 analyzer can be connected to the LIS system through the serial port or the network port. The communication protocol can be set in the network settings interface as needed according to the LIS system.

Content of Transmission
Part 1 (start and stop characters, invisible characters)
The symbols and tags included are: <SEND>, </SEND>,
Each uploaded data starts with a start character and ends with a stop character; the content between tags <SEND> and </SEND> is the main content.

Part 2 (instrument model)
The symbols and tags included are: <M>, |, </M>
This part occupies only 1 row, containing only 1 separator and 2 content segments.
The left side of the separator is the instrument model; the right side of the separator is the instrument number.

Part 3 (sample information)
The symbols and tags included are: <I>, |, </I>
This part occupies only 1 row, containing only 4 separators and 5 content segments.
They are arranged as: content segment 1 | content segment 2 | content segment 3 | content segment 4 | content segment 5

Content segment	Note for the meaning of content
Content segment 1	Sample Fixed English word for the sample
Content segment 2	End time of the analysis, in the time format of YYYY-MM-DD HH:MM
Content segment 3	Sample serial number
Content segment 4	Sample ID (In the #NN#n suffix, NN means the number of rows, and n means the number of position)
Content segment 5	Sample type (0 means a whole blood sample, 1 means a quality control sample, 2 means a calibration sample, and 3 means a diluted sample)

Part 4 (sample data)
The symbols and tags included are: <R>, |, </R>
This part occupies 3 or 4 rows, with each row corresponding to one data item of a sample
The left side of the separator in each line is the content of the data item, while the right side of the separator is the value of the data item. The value should be accurate to one decimal place.
They are: %A1ab, %F, %La1c, %A1c, %A1, and %A0.

Example of Transmission
The following is an example of data that is transmitted from the MQ-3000 analyzer to

the computer via the serial port:
<SEND>
<M>MQ3000 | Q3000JCA006</M>
<I>
sample | 2020-03-02 15:10|4|--#01#2|0
</I>
<R>
HbA1ab | 0.0
HbF | 0.0
HbLa1c | 0.0
HbA1c | 0.0
HbA1 | 0.0
HbA0 | 0.0
</R>
</SEND

12. Electromagnetic Compatibility Statement

Electromagnetic Emission		
The MQ-3000 analyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user of the MQ-3000 analyzer should ensure that it is used in this electromagnetic environment:		
Emission Test	Compliance	Electromagnetic Environment - Guide
Radio frequency emission GB 4824	1 set	The MQ-3000 analyzer uses RF energy only for its internal functions. Therefore, its RF emission is low and there is little possibility of interference with nearby electronic equipment.
Radio frequency emission GB 4824	Class A	The MQ-3000 analyzer is an instrument not used in household and will not be directly connected to residential low-voltage power supply network facilities.
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation/flashing emission GB 17625.2	Not applicable	

Electromagnetic Immunity			
The MQ-3000 analyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user of the MQ-3000 analyzer should ensure that it is used in this electromagnetic environment:			
Electromagnetic Immunity Test	GB/T18268.26 Testing Electric Level	Electric Level Meeting the Requirements	Electromagnetic Environment - Guide
Electrostatic discharge GB/T 17626.2	Contact discharge: 2kV, 4kV	Contact discharge: 2kV, 4kV	The ground should be made of wood, concrete or ceramic. If the floor is covered with man-made materials, the relative humidity should be at least 30%.
	Air discharge: 2kV,	Air discharge:	

	4kV, 8kV	2kV, 4kV, 8kV	
Radiated electromagnetic field GB/T 17626.3	3V/m, 80MHz to 2.0GHz, 80% AM	3V/m, 80MHz to 2.0GHz, 80% AM	
Power frequency magnetic field GB/T 17626.8	3A/m, 50Hz	3A/m, 50Hz	The power frequency magnetic field should have the characteristics of a power frequency magnetic field representing a typical commercial or hospital environment.
Electrical fast transient burst GB/T 17626.4	1kV (5/50ns, 5kHz)	1kV (5/50ns, 5kHz)	The power supply of power grid should have the quality of the power grid used in a typical commercial or hospital environment.
Surge GB/T 17626.5	Line to ground: 2kV/line to line: 1kV	Line to ground: 2kV/line to line: 1kV	The power supply of power grid should have the quality of the power grid used in a typical commercial or hospital environment.
Transit voltage dip GB/T17626.11	1 cycle 0%; 5 cycles 40%; 25 cycles 70%	1 cycle 0%; 5 cycles 40%; 25 cycles 70%	The power supply of power grid should have the quality of the power grid used in a typical commercial or hospital environment.
Voltage interruption GB/T17626.11	5%, duration: 250 cycles	5%, duration: 250 cycles	The power supply of power grid should have the quality of the power grid used in a typical commercial or hospital environment.
Radio frequency conduction GB/T 17626.6	3V, 150kHz to 80MHz, 80% AM	3V, 150kHz to 80MHz, 80% AM	

The field strength of stationary transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, cannot be accurate predicted in theory. In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic environment should be considered. If the measured field strength of the location of the MQ-3000 analyzer is higher than the above level for RF compliance, the operation of the MQ-3000 analyzer should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as adjusting the orientation or position of the MQ-3000 analyzer.

The field strength should be less than 3V/m over the entire frequency range from 150kHz to 80MHz.

Our company declares:

1. The MQ-3000 analyzer meets the emission and immunity requirements specified in GB/T 18268.1/IEC 61326-1 and GB/T 18268.26/IEC 61326-2-6.

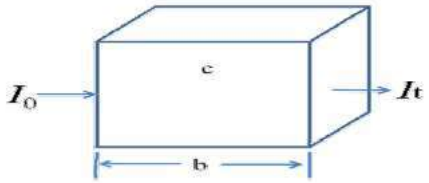
2. This equipment is designed and tested in accordance with Class A equipment in GB 4824/CISPR 11, and should not be used in a household environment.

3. It is recommended to evaluate the electromagnetic environment before using the equipment.

The use of this equipment near strong radiation sources is forbidden, as this may interfere with the normal operation of the equipment.

Appendix A. Principle of Colorimetry

According to the Lambert-Beer light absorption law, when a beam of parallel monochromatic light passes through a uniform solution medium, it can be selectively absorbed, with part of it reflected by the vessel. Assume the intensity of the incident light as Io, the intensity of the transmitted light as It, the concentration of the solution as c, and the thickness of the liquid layer as b. The diagram of light absorption is as follows:

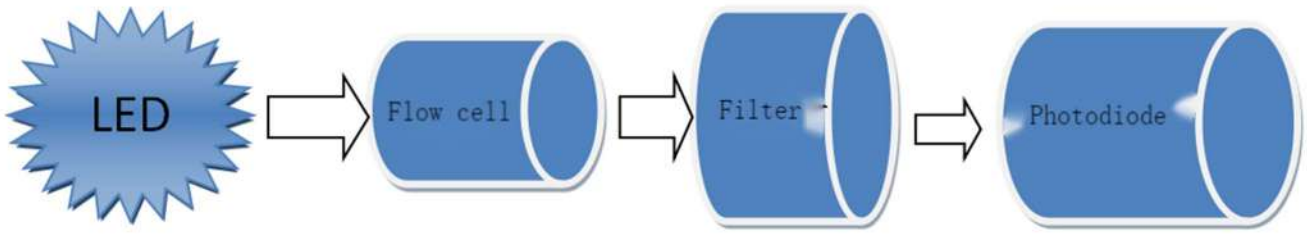


Thus,

$$A = kbc = \lg\frac{Io}{It}$$

Where, A is the absorbance, and K is the absorption coefficient, which means that when a beam of parallel monochromatic light passes through a solution, the absorbance of the solution is proportional to the product of the concentration of the solution and the thickness of the liquid layer.

The wavelength of absorption peak of hemoglobin is 415 nm. When the 415 nm LED purple light passes through the flow cell and is absorbed by the photodiode after passing through the 415 nm bandpass filter, the intensity of the light is proportional to the converted potential. The diagram is as follows:



Therefore, the absorbance can be calculated by the following formula:

$$A = \lg\frac{Io}{It} = \lg\frac{Vo}{Vt}$$

Where, Vo is the potential generated by incident light and Vt is the potential generated by transmitted light. The photodiode signal is amplified and collected by the computer. The absorbance of the eluted substance is continuously measured in real time to obtain the corresponding hemoglobin chromatogram. The integral area and the percentage of area of the absorbance of each component are calculated by integration.