MQ-8000/MQ-8000PT
Glycated Hemoglobin Analyzer
Instruction Manual

Shanghai Medconn Medical Technology Co., Ltd.

Dear user,

Thank you for choosing our product!

This instruction manual will guide you through the safe and proper use of the MQ-8000/MQ-8000PTGlycated hemoglobin analyzer. Please read this instruction 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!

Table of Contents

Foreword

This instruction manual that comes with the MQ-8000/MQ-8000PTGlycated 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-8000/MQ-8000PT;
- Perform daily operations and maintenance;
- Perform system maintenance and troubleshooting.

Common Symbols

<table>
<tr><td colspan="2">  Caution: Be careful! Risk of electric shock.Check the instruction manual when seeing this symbol.</td></tr>
<tr><td colspan="2">  Caution: Be careful! Danger. Check the instruction manual when seeing this symbol.</td></tr>
<tr><td colspan="2">  Caution: Biohazard. This warning alerts you to a potentially dangerous condition of biological infection.</td></tr>
<tr><td colspan="2">  Caution: Mechanical Injury. This warning alerts you to a potentially dangerous condition of mechanical injury.</td></tr>
<tr><td>
AC symbol</td><td> 
Grounding symbol</td></tr>
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In vitro diagnostic product</td><td> 
Refer to the instruction manual</td></tr>
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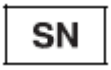
Manufacturer</td><td> 
Instrument SN</td></tr>
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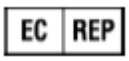
Date of Manufacture</td><td> 
Authorized Representative in the Eurporean Commiunity</td></tr>
<tr><td> 
CE Mark</td><td> 
Caution</td></tr>
<tr><td> 
Separate collection</td><td> 
Expiration Date</td></tr>
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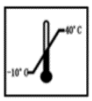
Meaning of symbols on packaging boxes

 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.
- The MQ-8000/MQ-8000PTGlycated 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, GB 7247.1/ IEC/EN 60825-1, YY 0648/IEC/EN 61010-2-101. Follow this instruction 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-8000/MQ-8000PTGlycated 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, GB 7247.1/IEC/EN 60825-1, 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, IEC/EN 60825-1, 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 in the roller of the thermal printer to prevent finger injury.
- Do not place your fingers between the test tube rack 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, QC 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.
- When the instrument needs to be repaired, handled, stopped, or transported, the instrument must be cleaned before the above actions can be carried out.

Chemical Safety Precautions

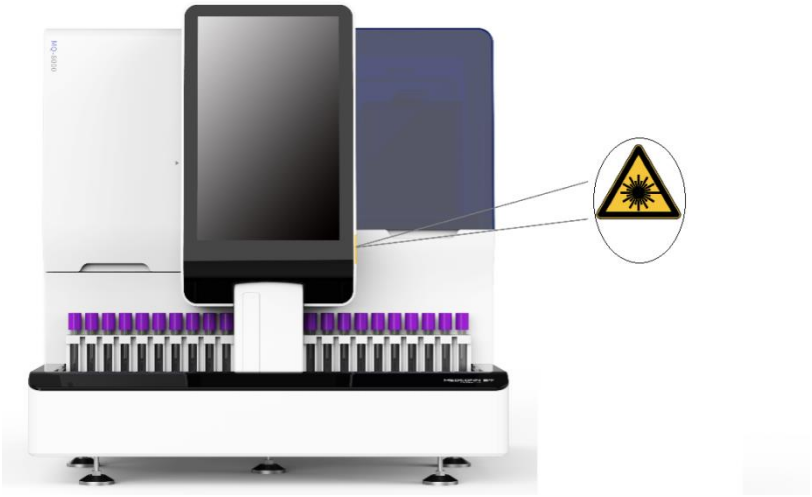
The reagent used with this instrument contains 0.02% sodium azide, and skin or eye contact with or ingestion of the reagent should be prevented.

- 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.

Laser Safety Precautions

Please read the following laser safety precautions carefully to avoid personal injury:

- The barcode scanner in this instrument is a Class 1 laser product, which will generate laser radiation during barcode scanning. Therefore, DO NOT look directly at the laser beam.
- The maximum output power of the laser: 0.013 mW; emission wavelength: 650 nm.
- Avoid intrabeam viewing in the laser product.
- The positions of the laser signs are as follows:



- Note: Harmful radiation exposure may be caused by using, controlling, or adjusting the instrument or performing various steps without following this regulation.
- Customers or users are not allowed to open the housing of the instrument for inspection and repair.
- The instrument can be replaced or repaired only by the technical service department and maintenance organization authorized by the company using the barcode scanner and other accessories provided by the company according to the original installation and wiring methods.

1. Overview

1.1 Product Introduction

In a 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) is receiving 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-8000/MQ-8000PT analyzer is an automated instrument for measuring the content of Glycated hemoglobin in the blood. It has the characteristics of small sample size and fast analysis speed. It can be used to monitor the level of HbA1c 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 Glycated hemoglobin;
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;
IFCCInternational 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

GHb refers to the hemoglobin (Hb) bound to any form of carbohydrate. Human Hb mainly includes HbA (95%–97%), HbA2 (< 3%), and HbF (< 1%). In HbA, the one that is not bound to carbohydrate is HbA0 (90%), and the one bound to carbohydrate is HbA1 (5%–7%), i.e., GHb. Among them, HbA1 includes HbA1al bound to fructose-1, 6-diphosphate glucose, HbA1a2 bound to glucose-6-phosphate, HbA1b bound to unknown carbohydrates, and HbA1c bound to glucose. HbA1c accounts for 70%–90% of GHb. HbA1c is formed by an irreversible and non-enzymatic reaction in the tissue between the free aldehyde group of glucose and the amino group of the N-terminal valine on the ß chain of HbA. This process is called glycosylation. The formation of GHb mainly depends on blood glucose concentration and the contact time between blood glucose and Hb. GHb can reflect the average blood glucose level in the last 2 to 3 months. In 2002, the American Diabetes Association clearly stipulated that HbA1c should be tested regularly and used as a gold standard for monitoring glycemic control in diabetes.

The MQ-8000/MQ-8000PT analyzer detects Glycated hemoglobin 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 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 and 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-8000/MQ-8000PT analyzer automatically recognizes the various peaks of hemoglobin. After calculation, the test results are displayed on the screen and printed automatically. Reported range of Glycated hemoglobin concentration: 3%–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 to 30 °C;
- Relative humidity: ≤ 80%;
- Altitude: ≤ 2000 m;
- Power supply voltage: 100-240 V;
- Power frequency: 50/60 Hz;
- Rated power: 180 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 ± 3.0%;
- Repeatability: CV ≤ 1.0 %;
- Range of linearity: The linear range of HbA1c is 3.0% to 20.1%, and the correlation coefficient r is ≥ 0.9900;
- Rate of carry-over: ≤ 2.0%;
- 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:
  a) Data interface: network port (RJ45), USB, RS232
  Transfer protocol: UDP, USB2.0, RS232.
  The network port (RJ45) outputs the sample analysis results using the UDP protocol.
  USB performs database backup, database import, software upgrade, and factory setting backup using the USB2.0 protocol.
  RS232 outputs the sample analysis results using the RS232 protocol.
  b) Storage format: db file.
- User access control:
  User access is limited by password: Ordinary users do not need a password. System

admins need to enter the system admin password.
Different user types and permissions are described as follows:

a) Ordinary users: Analysis, query, QC, calibration, service (maintenance), service (function setting), and log operations.
b) System admins: Service (diagnosis) operations in addition to all the permissions of ordinary users.

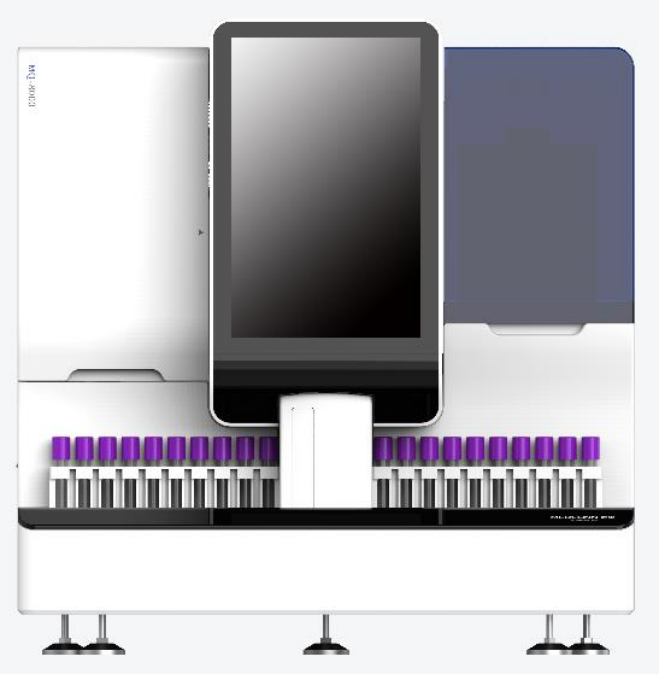
- Minimum hardware configuration:
  Cortex-A9 quad-core processor: 1 GHz.
  RAM: 2 GB.
  Display: A touchable display device with a resolution of 800 × 1280.
- Software configuration: operating system arm-Linux 2.0 and its compatible versions.

2. Instrument Overview

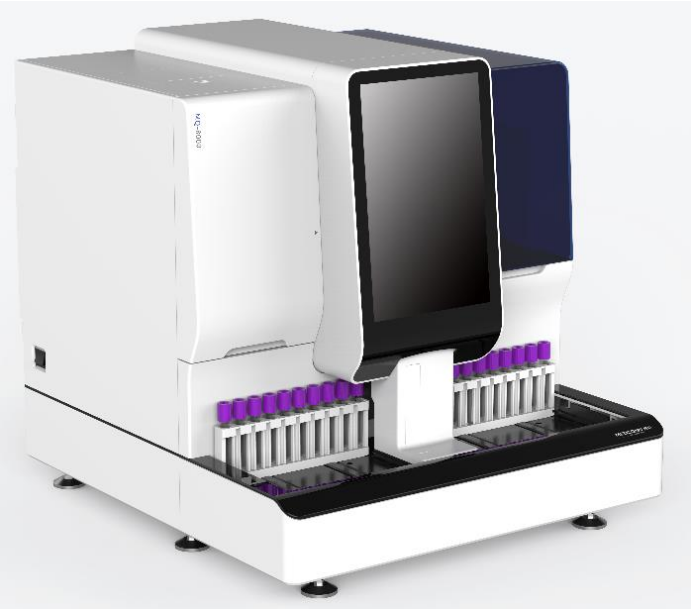
2.1 Scope of Application

The MQ-8000/MQ-8000PTGlycated hemoglobin analyzer ("MQ-8000/MQ-8000PT analyzer") is used in conjunction with the approved hemoglobin A1c 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

2.3 Main Components of the Instrument

This instrument is mainly composed of a micro-control unit including the MQ-8000/MQ-8000PT Glycated hemoglobin analyzer system software (release version 1), a barcode scanner, a sample loading system, a high-pressure pump, a detector, a column oven, an operation panel, a thermal printer, and a power supply switch:

- **Micro-control unit:** The main control unit of the instrument uses an embedded computing module. The entire instrument acts as required under the control of the MQ-8000/MQ-8000PT 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.

- **Barcode scanner:** It reads the barcode label affixed to the blood collection tube as the sample ID during testing.
- **Sample loading system:** It automatically identifies the sample type and draws the sample. It automatically dilutes whole blood samples and sends them to the test pipeline of the analyzer. After assay, the sample loading system starts to transport the test tube racks, and retrieves and identifies samples until an empty test tube rack is detected. This analyzer can accommodate a maximum of 10 test tube racks, with each rack holding 10 samples. Therefore, a total of 100 samples can be loaded.
- **High-pressure pump:** A plunger pump for transporting the reagent necessary for analysis and assay. During the sample assay process, when the high-pressure pump is working, reagents with different salt concentrations are switched and transported through the solenoid valve within the elution cycle to form a gradient. The various components of hemoglobin are separated by chromatography column.
- **Detector:** A unit component that converts the dynamic concentration of the eluted sample in the column to an electrical signal, which is recorded and calculated by the data processing system after conversion.

  The requirements for interference filters used in the detector are as follows:

  Peak transmittance: The nominal center wavelength is 415 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 415/525 nm, and the deviation between the center wavelength and the nominal center wavelength should not exceed ± 2 nm.
- **Column oven:** It adjusts and measures the temperature of the column inside to maintain an environment of constant temperature. To prevent the change in room temperature from affecting the assay results of the analyzer, the chromatography column usually needs a column oven to maintain a certain temperature. The column oven will maintain a constant temperature as long as the main power switch (the rocker switch on the side of the analyzer) is kept on.
- **Operation panel:** A color display with a touch panel, which displays the system operation interface to control the operation of the analyzer by touch input.
- **Thermal printer:** Thermal roll-paper printer, which prints out test results, instrument parameters, and prompt information.
- **Power switch:** Used to control the power input of the entire analyzer and located behind the left side of the instrument.

2.4 Instrument Interface

- **Reagent port:** Connecting reagents A, B, and C 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, software upgrade, and factory setting backup.
- **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 outlet:** Used to plug in the power cord and connect the instrument to a power source.

3. Instrument Installation

3.1 Installation Environment

The MQ-8000/MQ-8000PT analyzer requires the following environment for installation:

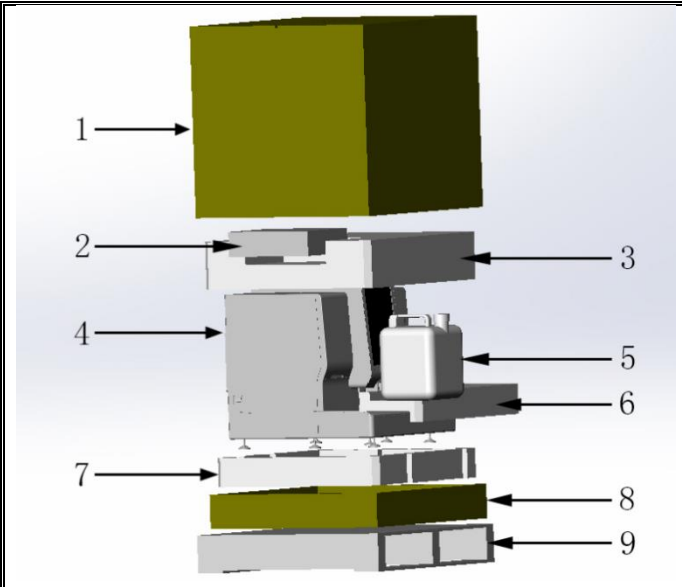
- Do not install the instrument at the following places: places with high fluctuations of voltage and temperature, places close to air outlets, places with a high amount of dust and dirt, places with vibration, places with high humidity, places close to flames, places with poor ventilation, and places 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 70 kg.
- Keep a space of 400 mm on both sides of the instrument and keep a space of 100 mm behind the instrument for air convection by the fan.
- Make sure the power cord is 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

SN	Name	Unit	Quantity
1	Test tube rack assembly	N/A	10
2	Injector	N/A	1
3	Thermal printing paper	Roll	2
4	COM serial port cable with 9 pins	N/A	1
5	FEP tube	N/A	3
6	Sample cup	N/A	10
7	Fuse 2 A/250 V	N/A	2
8	Power cord 3GTJ1/3GTJA	N/A	1
9	Two-way PEEK connector	N/A	2
10	Instruction manual	N/A	1
11	Liquid waste bottle	N/A	1

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

3.3 Unpacking



1	Outer package
2	Accessory box
3	Upper bearer
4	Analyzer
5	Liquid waste bottle
6	Front bearer
7	Lower bearer
8	Lower inner box
9	Wooden box

After unpacking the package box, 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

Liquid waste tube

Insert the waste liquid tube firmly into the liquid waste discharge port on the back of the analyzer. The liquid waste tube should be fixed firmly so that it cannot be easily pulled out. Insert the other end of the liquid waste tube 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 liquid waste tube.
- After the analyzer is relocated, the liquid waste tube should be checked for signs of loosening or breakage, so as not to clog the discharge of liquid waste.

Reagent tube

Verify the markings A, B, C, and H on the reagent tubes. Pass the Teflon tube through the corresponding bottle cap. Fix the reagent tube to the stainless steel pendant with the M6 connector (in the accessory box). Attach the corresponding tube to the stainless steel pendant. Insert the reagent tube into the reagent bottle and tighten the bottle cap.

Power cord

The power cord 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. Push the snap ring on the column oven upwards to open the oven lid.

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.

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.

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.

Printing Paper

After opening the printing paper box on the top of the analyzer, place the thermal printing paper in the box, pull out approximately 30 mm, and then close the box.

Precautions: Do not replace paper while printing.

3.5 Exhaust

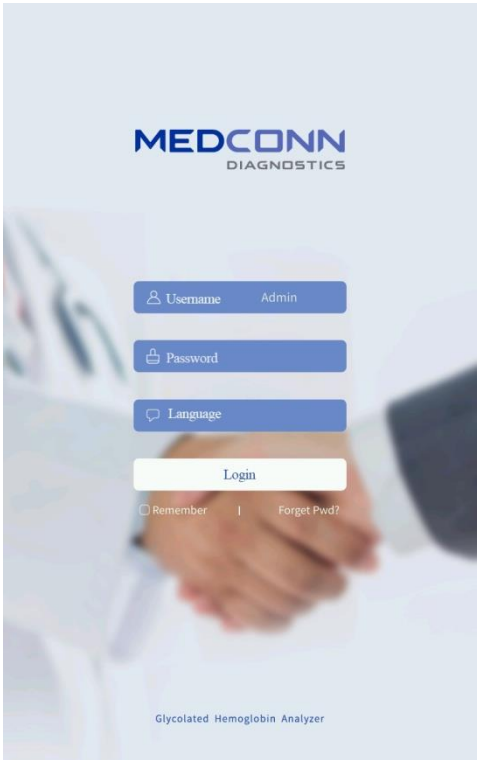
Exhaust operation is needed after the reagent is installed for the first time. Rotate the exhaust valve counterclockwise (open the left door) to 90 degrees. Tap the "Exhaust" button on the "Service" interface so that the instrument automatically starts the exhaust program to exhaust the air from the high pressure pump and the line before the high pressure pump; after the exhaust operation is completed, tighten the exhaust valve in the clockwise direction. Close the left door.

3.6 Prime

After installing or replacing the reagent, tap the "PrimeX" button corresponding to the reagent on the "Service" interface to stabilize the "ADC" value between 200,000 and 400,000. If the "ADC" value is not stabilized after the "Perfusion" button is tapped for three times, it indicates that air has entered the pipe during the replacement of the reagent. In this case, perform the exhaust operation as described in Section 3.5. Then, continue the Primeuntil the "ADC" value becomes stable. Tap the "Wash" button to complete the replacement of the reagent.

4. User Interface

4.1 Login Interface



Turn on the power switch on the left side of the analyzer. 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

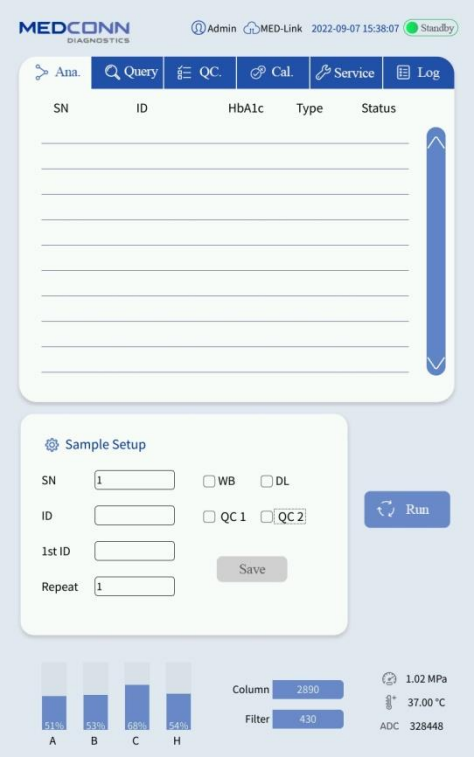
After the instrument enters the self-test program, the system will automatically check the

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 Standby Interface

The lower part of the instrument's standby 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 user, DTU connection status, time, and instrument operating status. The middle part displays the current sample assay progress and the position of the test tube rack where the sample is located. Tap "Ana." to enter the analysis interface.

4.4 Analysis Interface



Description of the buttons on the top of the interface:

No.	Description	Function
1	"Ana."	Tap to enter the analysis interface: sample analysis setting, startup, and result display interface
2	"Query"	Tap to enter the query interface: Check sample test results, QC data, and calibration data
3	"QC."	Tap to enter the QC interface: QC substance information setting, QC chart viewing, and QC start interface
4	"Cal."	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 contents displayed on the upper part

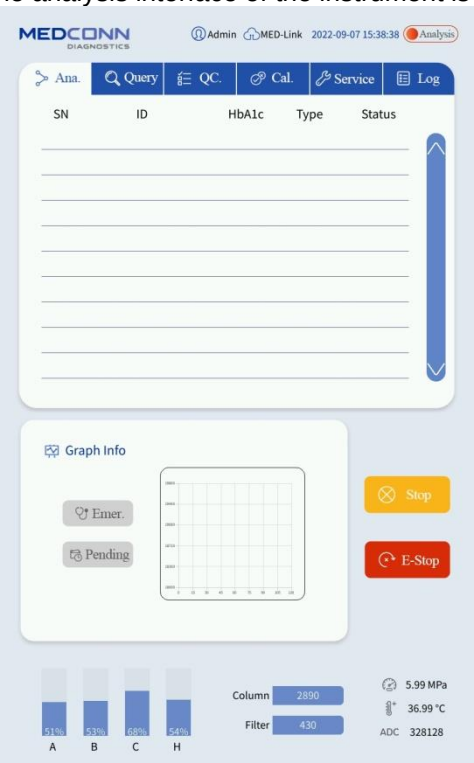
No.	Description	Function
1	SN	Display sample SN
2	ID	Display sample ID
3	HbA1c	HbA1c value
4	Type	Display sample type (WB, QC, or DL)
5	Status	Display a symbol to prompt normal or abnormal test results

Description of the buttons in the middle of the interface

No.	Description	Function

1	"SN"	Set sample SN
2	" ID"	Set sample ID
3	"1st ID"	Set initial sample ID
4	"Repeat"	Set the number of sample assays (≤ 10)
5	Selection box for sample type	Set sample type: WB(whole blood), DL(diluted sample), QC1, or QC2
6	"Save"	Save settings
7	"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	Graph Info.	Display the chromatogram thumbnail of the current sample. Tap to zoom in the real-time chromatogram
2	Emer.	Tap and the instrument will prioritize emergency sample assay
3	Pending	Tap to display sample assay results with questionable status
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	Test results	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 middle part

No.	Description	Function
1	NowID	Display current sample ID
2	Begin time	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 percentage of each test component

Description of the buttons on the right 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	"Up""Down"	Scroll up and down to view the sample chromatograms
4	"Back"	Return to the analysis interface
5	Stop	Tap and the instrument will stop the analysis upon completion of the current sample assay.
6	E- Stop	Tap and the instrument will emergency stop.

4.5 Query Interface

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

Description of buttons

No.	Description	Function
1	"Test Type"	Tap "Sample", "Calibration", or "QC" to query the corresponding test
2	"Sta. Date"	Select the start date of sample query
3	"End Date"	Select the end date of sample query
4	"Sta. SN"	Select the start SN of sample query
5	"End SN"	Select the end SN 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	"Output "	Select printer or LIS
9	"Start Query"	Query according to settings and checkmarks.
10	"Print"	Print the selected results
11	"Graphic"	Tap to view the sample chromatograms

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

Description of buttons

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

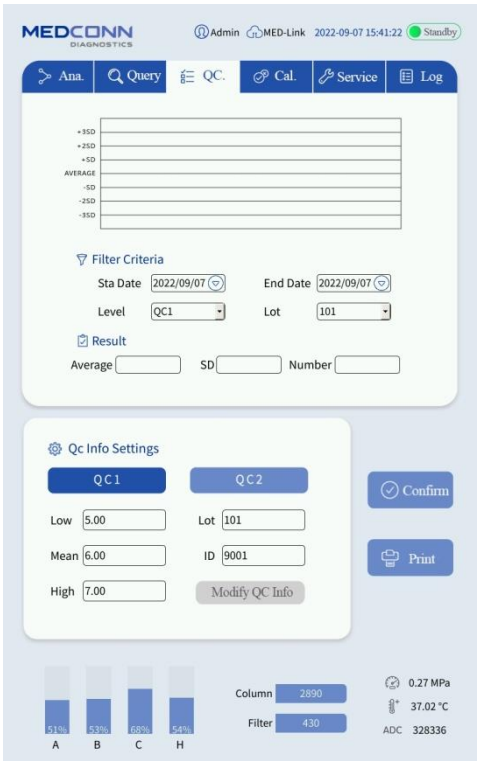
Tap "QC" to enter the QC result query interface. Filter the QC results using the buttons in the middle part. The QC results are displayed on the upper part of the screen, mainly including SN, ID, HbA1C, type, and date.

Description of buttons

No.	Description	Function
1	"Sta. Date"	The start date can be set to query the QC results.
2	"End Date"	The end date can be set to query the QC results.
3	" Level"	The results of QC1 and QC2 can be queried by checking the boxes
4	"Lot"	Select the Lot of the QC substance through the drop-down triangle to query the QC results of corresponding batch
5	"Output"	Select printer or LIS
6	"Start Query"	Confirm relevant selections and start query
7	"Print"	Print the selected results

4.6 QC Interface

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

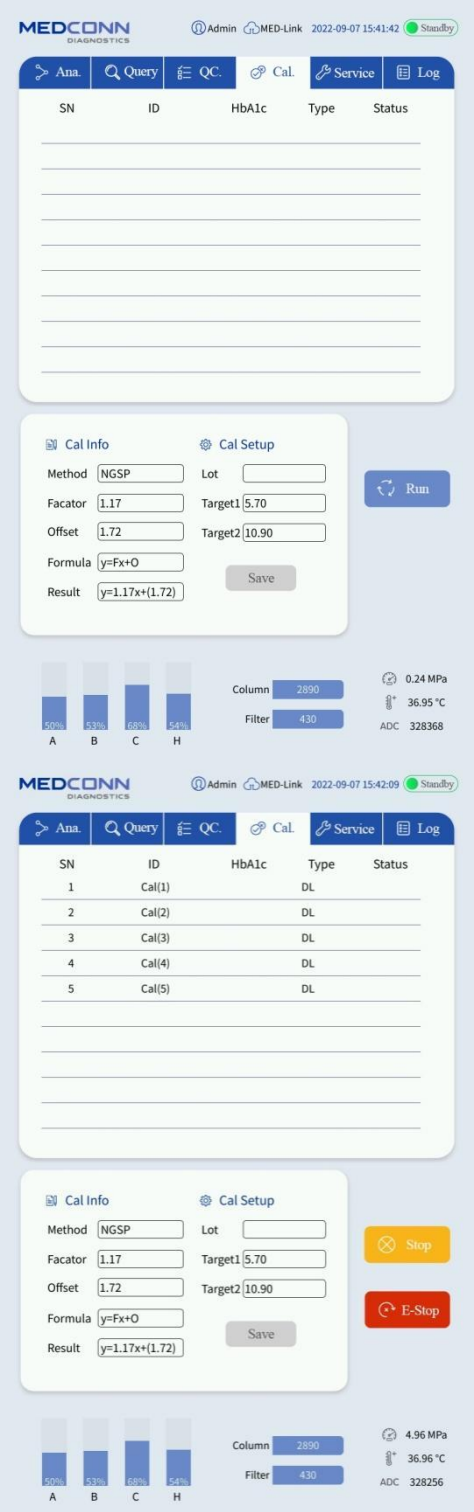


Description of buttons

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

4.7 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"	Calibration method
2	"Factor"	Display current slope used for calibration
3	"Offset"	Display current intercept used for calibration
4	"Formula"	Display the currently used calculation formula

5	" Result"	Display the current calculation result
6	"Lot"	Set the Lot of calibration substance
7	"Target 1"	Set the low value of the calibration substance
8	"Target 2"	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

4.8 Service Interface

Tap "Service" to enter the service interface to perform common settings and simple operations for routine use. Reagent-related information is displayed in the middle of the interface, including the Lot, validity period, bottle opening date, and remaining column volume for testing.

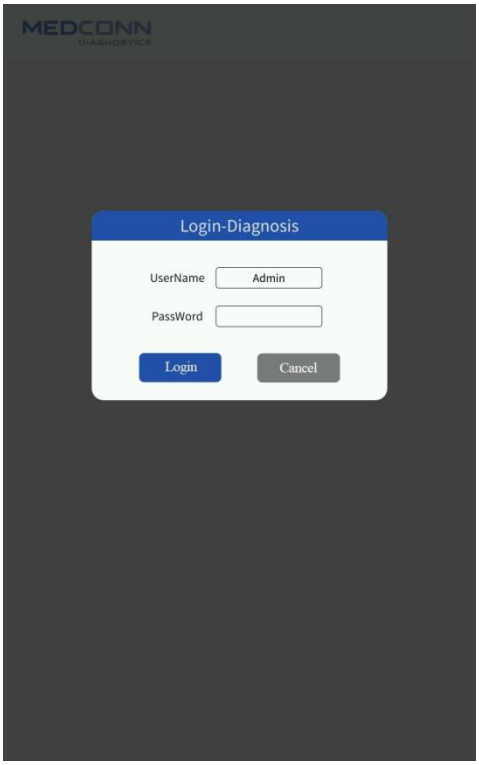
Description of the buttons in the interface

No.	Description	Function
1	"PrimeA"	Perfuse reagent A.
2	"PrimeB"	Perfuse reagent B.
3	"PrimeC"	Perfuse reagent C.
4	"PrimeH"	Perfuse haemolyser H.
5	"Prime ALL"	Perfuse reagents A, B, and C and haemolyser H twice each.
6	"Exhaust"	Remove air from the pipe.
7	"Rinse"	Perform the wash program once
8	"Printer"	Test the printer
9	"Reset All"	Reset the instrument.

10	"Function Setup"	Check the box to open the printer, LIS transmission, or barcode scanner
11	"Printer Format"	Select report printing format
12	"ModeSet"	The default setting is standard mode
13	"DateTimeSet"	Set the date and time
14	"Save"	Save relevant settings
15	"Diagnosis"	Enter the diagnosis interface (for engineers)

4.9 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

4.10 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	Solution	Display possible solutions
3	"Confirm"	Confirm button for errors

Tap "Abnormal Samples " 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

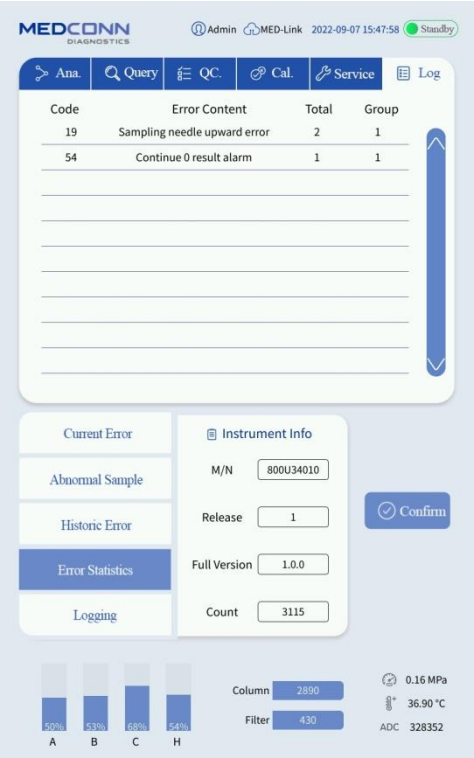
No.	Description	Function
1	Sample information	Display the SN, ID, HbA1c, sample type, and status
2	Drop down list	Display the summary in the drop down list.
3	"Confirm"	Review button for abnormal results

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

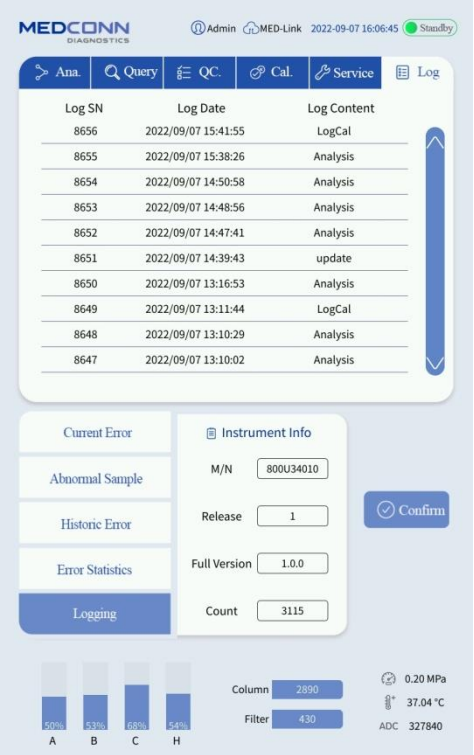
Description of buttons and contents displayed

No.	Description	Function
1	Error information	Display the SN, date of occurrence, and detailed records of the error information.
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 level-related information of all the error information of the analyzer 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 test tube rack.

Sample cup
Diluted samples, QC substances, and calibration substances should be placed in sample cups.

Test tube rack

The instrument uses a test tube rack to test samples. The analysis will end automatically when all the samples in the rack are tested. Alternatively, an empty rack can be placed at the end, and the analysis will also end automatically when the instrument detects no test tubes on the rack.

5.2 Boot

Turn on the power switch on the left of the instrument (toggle to "|"). 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 whole blood samples on the test tube rack 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 test tube rack. Place the test tube rack on the test tube rack tray of the instrument.
In the "Calibration" interface, enter the Lot (Lot 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.
Precautions:
The positions for low- and high-value samples of the calibrators must not be reversed; otherwise, calibration will fail.

5.4 QC

In order to ensure the normal condition of the instrument, the laboratory should arrange QC cycles as needed to test the QC substance.
Prepare diluted samples at two levels for testing according to the instructions of the QC substance.
Before testing the QC samples of a new batch, set the QC substance parameters in the "QC" interface. After confirming to save the information, check QC1 or QC2 in the "Analysis" interface to perform the test.

5.5 Sample Requirement

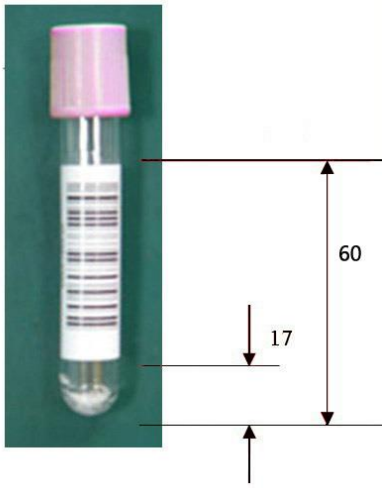
The precise volume and proper storage of samples ensure the accuracy of the test results of the MQ-8000/MQ-8000PT analyzer. The sample requirements are as follows:

- 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 1.5 mL. If it is less than 1.5 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 1.5 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 2.0 mL, which is placed on the test tube rack.

5.6 Barcode Requirement



The MQ-8000/MQ-8000PT analyzer comes with a 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 test tube rack. The barcode should be affixed between 17 mm and 60 mm from the bottom of the test tube, as shown in the figure.

The default size of the test tube tailored for the instrument is φ 12 × 75 mm (the test tube rack has a collar by default), and it is compatible with φ 15 × 75 mm and φ 15 × 100 mm vacuum blood collection tubes (the collar inside the test tube rack should be removed). If the collar inside the test tube rack is removed, while the default φ 12 × 75 mm test tube is still used, the test tube may tilt during sampling and the sampling needle may be inserted into an incorrect position or even be bent or broken. When testing with a 100 mm test tube, remove the tube stopper.

Precautions:
Match the stopper and test tube correctly for the test tube rack while testing; otherwise, a rack jam may occur.

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

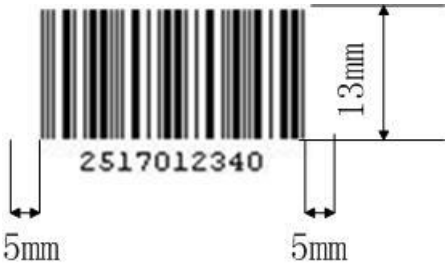


Diagram of barcode dimension. There should be a blank space of 5 mm or more at the edge of the label along the length direction of the barcode.

5.7 Sample Placement

The instrument can hold 100 samples at a time. The cycle function can also be turned off (after which the test tube rack to be tested can be placed only on the right side of the instrument). Place the samples to be tested into the test tube racks and place 5 test tube racks on each of the left and right sides of the test tube rack tray of the instrument. The test tube racks should be in close contact with the outer frame. An empty test tube rack should be placed in the last row. When the instrument completes sample testing, the analysis will end automatically.

After the samples are placed, tap the "Run" button in the "Analysis" interface, and 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 test tube rack 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 SN, 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

Sample 001
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 45 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.

6. Precautions and Tips for Potential Risks

6.1 Precautions for Operation

- The MQ-8000/MQ-8000PT analyzer uses a 220 V ± 22 V, 50 Hz ± 1 Hz AC power supply.
- Equipment connected to the external ports of the MQ-8000/MQ-8000PT 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 instruction manual or by a designated customer service representative.

7. Service and Maintenance

7.1 Service

The following operations shall be performed for daily maintenance:

- Check for leaks in the liquid lines and fittings and replace them if necessary.
- 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 of reagent C	
	Replacement of haemolyser	
	Replacement of thermal printing paper	After a red line appears on the edge of the paper
★	Puncture needle cleaning	Weekly
★	Automatic cleaning of the flow path	Weekly
★	Cleaning of instrument outer surface	Monthly
★	Cleaning of instrument inner surface	Monthly
★	Maintenance of the puncture needle cleaning block	Monthly
★	Clean the test tube rack	Monthly
★	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-8000/MQ-8000PT 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.

Perform the "Perfusion" program once and then place all external connections of reagent containers into the deionized water bottle before running the "Perfusion" program twice. Remove all reagent tubes from the reagent bottles and perform the "Exhaust" program. The instrument will automatically start the exhaust procedure and sequentially discharge the air in the lines of reagent A, reagent B, and reagent C. Run the "Perfusion" program again until there is no liquid waste emission from the liquid waste tube for one minute. Turn off the power switch and unplug the power cord.

Cleaningand disinfection

Wipe clean the surface of the instrument with a cloth dampened with a neutral cleaning solution and wring dried.

When the surface is heavily contaminated, wipe it with a cloth dampened with ethanol.

If hazardous substances such as reagents, samples, or test waste leak on the surface of the instrument or enter the inside of the instrument, wipe the instrument with a cloth dampened with ethanol for disinfection.

Do not use any cleaning agents or disinfectants that can chemically react with the instrument parts or materials in the instrument to cause danger.

In case of any doubt about the compatibility of disinfectants or cleaning agents with instrument parts or materials in the instrument, please consult the manufacturer or agent.

8. Troubleshooting

8.1 Failure Analysis

If the result of the MQ-8000/MQ-8000PT 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-8000/MQ-8000PT 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 injector 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 1.5 mL.	Mix the blood in the test tube well before 10 μL of the blood sample is manually drawn and diluted 250 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 range; peak is not detected	Data input error.	Check whether the parameters entered for the calibrator are 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 200,000–400,000. Perform the "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 test tube rack is stuck in the sample loading slot.	The test tube rack is not placed correctly.	The test tube rack should be placed in parallel to the front side of the instrument.
	The speed of the rack entry is too fast.	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 < 3 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 > 15 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^2sec; 5 × 20 mm time-delay glass tube fuse T2AL250V) can be used.

The power fuse of the MQ-8000/MQ-8000PT analyzer is installed in the power outlet. If the fuse blows, please follow the steps below for fuse replacement.

- Disconnect the power cord plug 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, printing 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

SN	Name
1	Hemoglobin A1c assay kit (HPLC)
2	HbA1c haemolyser
3	HbA1c column kit (HPLC)
4	Sample cup, thermal printing paper, and filter
5	Calibrator of Glycated hemoglobin $A1_C$
6	QC substance for Glycated hemoglobin

10. Package, Transportation, and Storage

10.1 Package

The instrument has a net weight of 65 kg and a gross weight of 70 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: 720 mm × 700 mm × 700 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-8000/MQ-8000PT 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-8000/MQ-8000PT 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 SN
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 QC 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-8000/MQ-8000PT analyzer to the computer via the serial port:
<SEND>
<M>MQ8000 | Q8000JCA006</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-8000/MQ-8000PT analyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user of the MQ-8000/MQ-8000PT 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-8000/MQ-8000PT 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-8000/MQ-8000PT 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-8000/MQ-8000PT analyzer is expected to be used in the electromagnetic environment specified below, and the purchaser or user of the MQ-8000/MQ-8000PT 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-8000/MQ-8000PT analyzer is higher than the above level for RF compliance, the operation of the MQ-8000/MQ-8000PT 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-8000/MQ-8000PT 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-8000/MQ-8000PT 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.

[DateofApprovalandRevisionofInstructionManual]

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 ShanghaiMedconnMedicalTechnologyCo., Ltd.

Address：Rm 1001- 1003, 1F, EastofBuilding4 & 2F, EastofBuilding4, No. 1018 WeichangRoad,

ShanyangTown, JinshanDistrict, Shanghai, China

Postcode: 201508

Tel.: +86-21-31653268

Fax: +86-21-50316450

Website: http://www.medconn.com

GlobalSalesAgent： ShanghaiMedconnDiagnosticsTechnologyCo., Ltd.

EC REP

LotusNLB.V.

Address: KoninginJulianaplein 10, 1eVerd, 2595AA, TheHague, Netherlands.

Email : peter@lotusnl.com.

FCC ID：2BHV21501

FCC Caution ： This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

The equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment, this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. The equipment should be installed and operated with minimum distance 20cm between the radiator and your body.