H9

Hemoglobin Analyzer

User Manual



Lifotronic

STATEMENT

Thank you for buying H9 Hemoglobin Analyzer.

Before use the product, please read carefully the contents of this user manual.

After reading, please keep this manual properly to consult at any time when needed.

Product name: Hemoglobin Analyzer

Product model: H9

Production date: see details in machine label

Shelf life: 5 years

User manual issuing date: 2018-05

Version number: A3

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- The machine is used according to operation instructions;
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- The product has reached its lifetime limit;
- Parts have been disassembled, stretched or readjusted;
- The machine is not used properly according to User Manual.

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Lifotronic will provide fee-based service if the product is not within the range of Lifotronic's warranty provisions;

Within warranty period, fee-based service will be provided if the product defect is caused by:

Misuse;

Man-made damage

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Repair of the machine by personnel not authorized by Lifotronic;

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Uncontrollable natural disasters.

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(2) Freight expense: Freight (including customs fees) of products returned to Lifotronic for service shall be borne by the customer.

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WARNING

The system is operated and used by Lifotronic or designated agents trained professionals, doctor or lab assistant;

If hospitals or institutions can not achieve a satisfactory repair / maintenance plan, it may cause abnormal instrument failure, and may endanger human health.

Ensure to run the instrument under the conditions that are written in this manual. If not, it may fail to run, result in inaccurate results, or even damage the components and injure humans.

NOTE

This manual is for the following clinical laboratory professionals:

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

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Chapter-1 Manual Brief Description

1.1BREIF INTRODUCTION

The chapter introduces how to use the H9 user manual. The user manual is attached with mainframe and describes intend use, function and operation ofH9 Hemoglobin Analyzer in detail. Before use, read the user manual carefully, to ensure rightful use and safety.

NOTE

● Please strictly follow the instructions in the manual when operating

1.2 SCOPE OF THE MANUAL

This guide is intended for medical laboratory professionals, trained doctor, nurse or lab assistant. Applicable for:

- To learn the software and hardware about H9;
- Daily operation;
- System parameter settings;
- System maintenance and troubleshooting.

1.3 CONTENT OF THE MANUAL

The manual includes 11 chapters and 4 appendixes. The brief information of every chapter shows below.

Chapter	Description
Chapter 1 Manual Brief Description	Brief description and framework of the manual
Chapter 2 General Description	Intend use, basic parameters, structures and operation interface of H9
Chapter 3 Working Principle	Measuring principle and operation flow of H9
Chapter 4 Installation	Installation requirements and steps of H9
Chapter 5 Parameter Settings	Set system parameters like date, printer etc
Chapter 6 Daily Operation	Operation steps of H9
Chapter 7 Data Query	Sample result data query
Chapter 8 Quality Control	QC Requirements and method of H9
Chapter 9 Calibration	Calibration requirements and method of H9

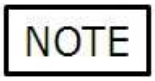
Chapter 10 Service	Maintenance and test method of H9
Chapter 11 Troubleshooting	Failure cause and troubleshooting of H9
Appendix A Specification	Specification , performance index and input/output devices of H9
Appendix B Security Information	Security information
Appendix C Communication Protocol	Communication Protocol
Appendix D Electromagnetic compatibility	Electromagnetic compatibility

1.4 DECLARATION

All the charts and pictures in the manual are only for demonstration. Do not use it for other purpose. And the chart, data might not be entirely consistent with real status.

1.5 SYMBOLS AND LABELS

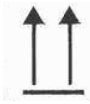
Symbols and labels in this manual

	Meanings
	Remind operator to follow the steps under this symbols, otherwise it will result in personal injury
	Remind operator to follow the steps under this symbols, otherwise it will result in product failure, damage and inaccurate results.
	Remind operator to follow the steps under this symbols, emphasize important/critical information or steps in the manual
	Remind operator to follow the steps under this symbols, otherwise it has bio-infectious risk.

Symbols and labels on the Analyzer, reagent, calibrators and QC materials

	Meanings
	Attention! Please refer to the manual!
	the international symbol for biohazardous material
	In vitro diagnostic medical device
	Batch code

SN	Serial number
	Manufacture date
	Manufacturer
	Temperature limitation
	Consult instrutions for use
Computer Interface	Computer interface
A	A Eluent
B	B Eluent
C	C Eluent
L	Hemolytic agent
Waste Liquid	Waste liquid
DC+24V	Input voltage
ON/OFF	Switch
	Compliance with WEEE Standard

	Keep dry
	Fragile,handle with care
	This way up
	Grounding
	Sticking limit by number

CHAPTER 2 GENERAL DESCRIPTION

2.1 TEST PARAMETERS

NOTE

● H9 Analyzer is a diagnosis device that is used for disease screening. When diagnosing disease, clinicians should take clinical examination results or other test result into consideration.

H9 hemoglobin analyzer is a fully automated system composed of Ion-exchange chromatography testing system and sampling system. It could be connected to LIS/HIS to transfer data.

H9 Analyzer adopts High Performance Liquid Chromatography (HPLC) to measuring the content of HbA1c in human blood.

Installation accessories list:

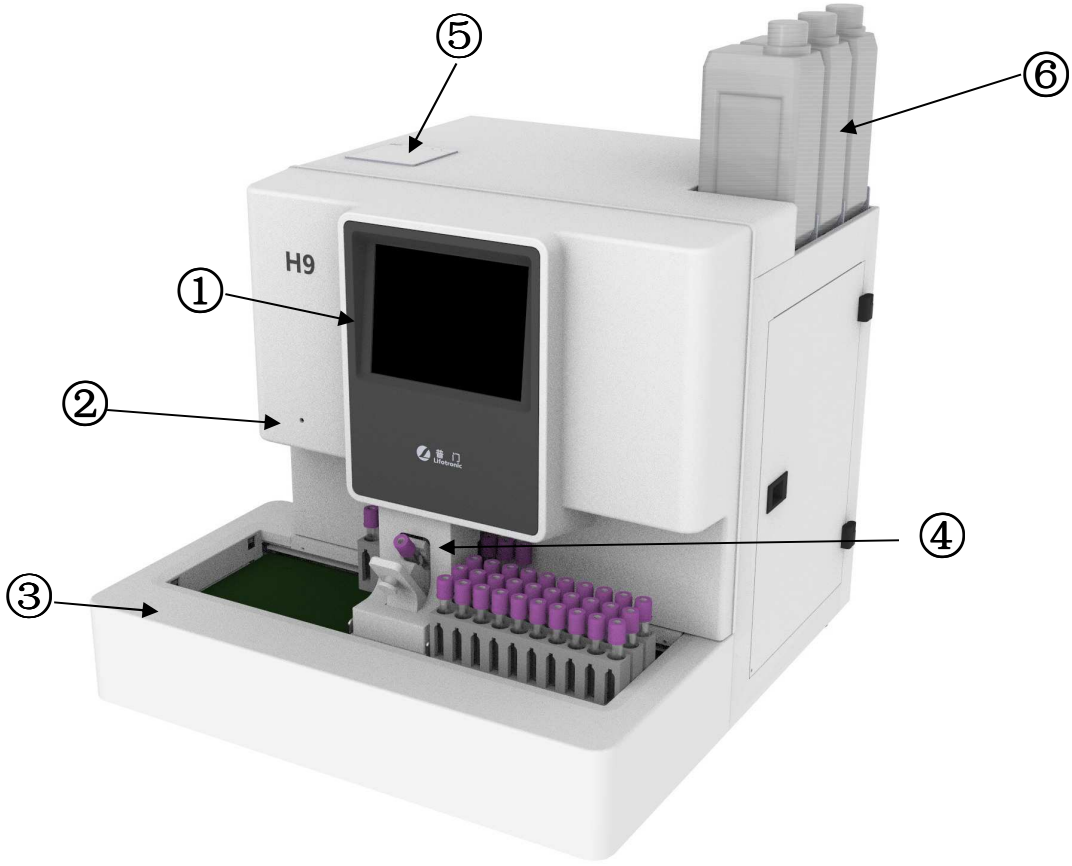
No.	Name	Amount	Unit
1	Waste bottle	1	pcs
2	Power adapter	1	pcs
3	Sample rack	3	pcs
4	Connection tube for waste liquid	1	pcs
5	Connection tube	4	pcs
6	EP tube stand	10	pcs

Accessories list:

No.	Name	Amount	Unit
1	Chromatography Column	1	pcs
2	Filter	5	pcs

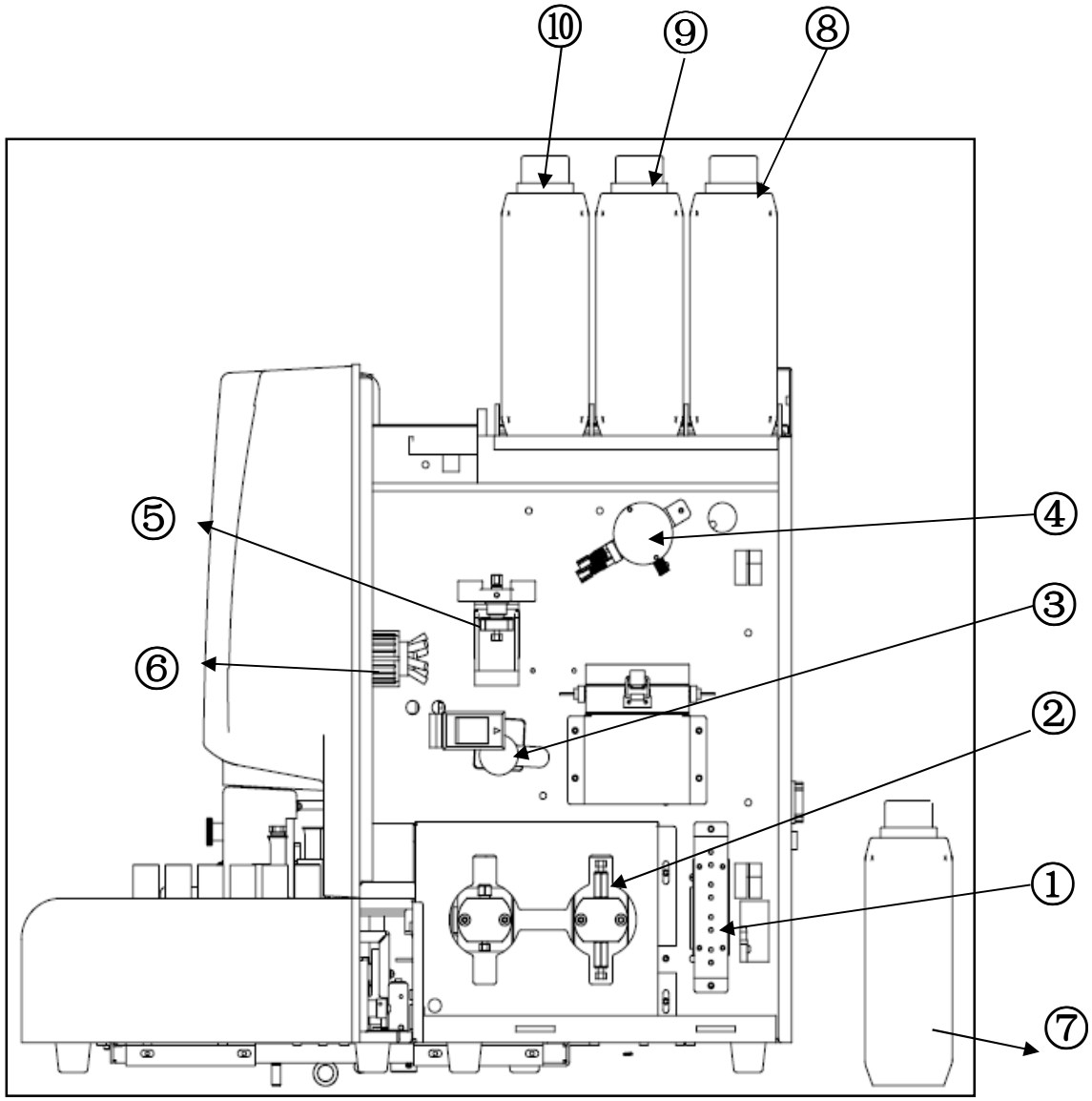
2.2 PRODUCT DESCRIPTION

H9 is composed of the machine, sampling system, chromatography column, filter, power adapter and analyzer system.



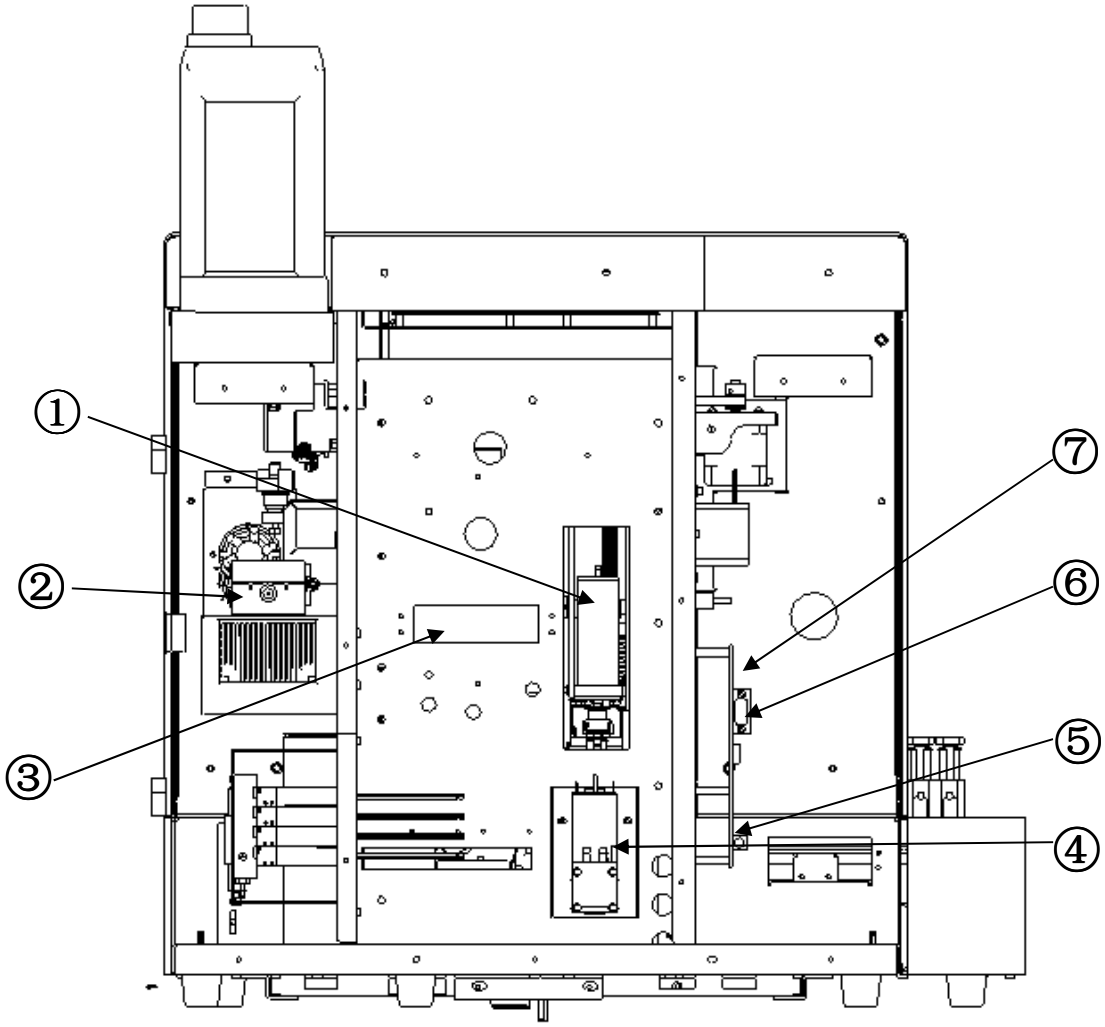
Picture 2-1 Front View

① ---- Display Screen
② ---- Power Light
③ ---- Sampling Stand
④ ---- STAT sample position
⑤ ---- Printer
⑥ ---- Reagent



Picture 2-2 Right Side View

① ---- Switch Valve
② ---- High Pressure Pump
③ ---- Pressure Sensor
④ ---- Colorimetric Module
⑤ ---- Filter
⑥ ---- 6 Way Valve
⑦ ---- Hemolytic Agents
⑧ ---- C Eluent
⑨ ---- B Eluent
⑩ ---- A Eluent



Picture 2-3 Rear View

① ---- Slowing Motor
② ----Peltier Module
③ ---- 3 Valves in Parallel
④ ---- Waste Liquid Diaphragm Pump
⑤ ---- DC Power Input Port
⑥ ---- RS-232 Interface
⑦ ---- Main Board

2.2.1 LCD TOUCH SCREEN

LCD touch screen is on the front side of H9 Analyzer; see in picture 2-1, used for information input and most operations.

2.2.2 THERMAL PRINTER

Thermal Printer is on the front side of H9 Analyzer; see in picture 2-1, used for print results and other information.

2.2.3 COMPUTER INTERFACE

RS-232 interface, for communicating with outer computers.

2.2.4 PRINTER INDICATOR AND PF BUTTON

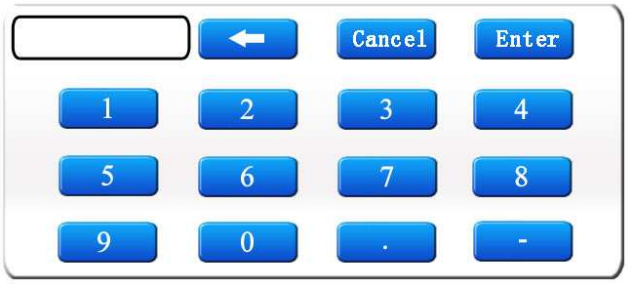
Printer indicator light shows the status of paper consumption .Steady light indicates sufficient paper. Flash light indicates insufficient paper. Meanwhile, the light also function as the PF button; Press the button, and the printer will skip paper outside.

2.2.5 POWER INPUT SOCKET

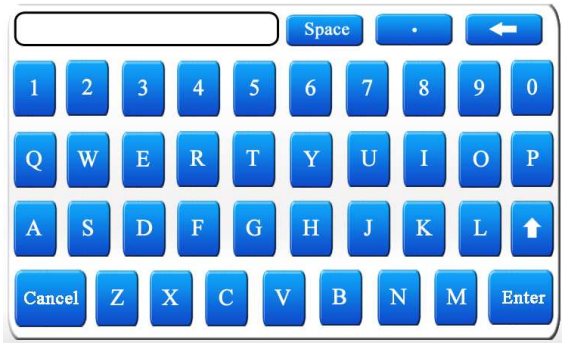
Input voltage is DC+24v. Input power is 150VA

2.2.6 KEYPAD

There are two kinds of touch key pad for information input – numeric keypad and comprehensive keypad, see in the below.



Picture 2-4 Numeric Keypad

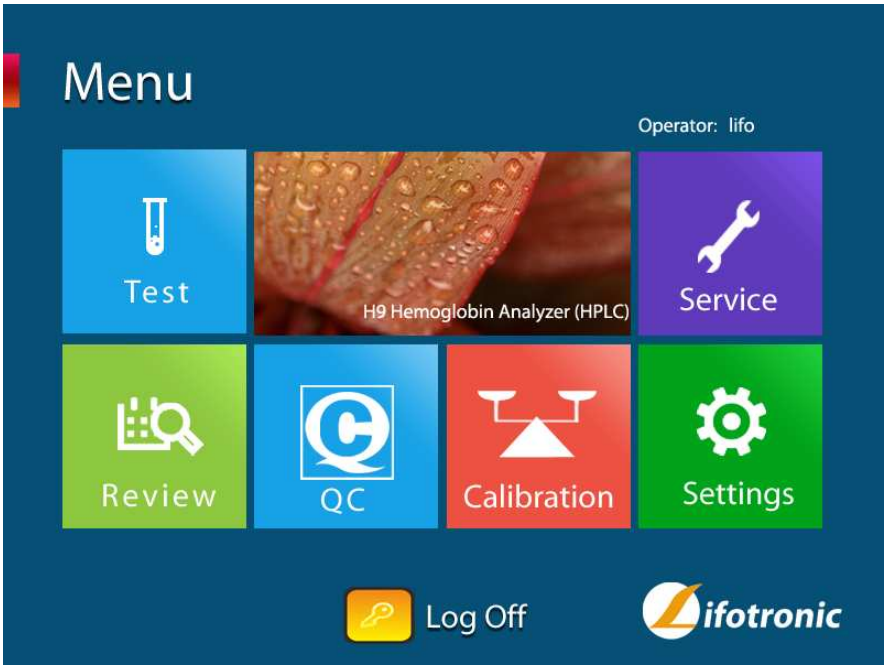


Picture 2-5 Comprehensive Keypad

2.3 OPERATION INTERFACE

2.3.1 MENU

After start-up process, it's menu interface, see in picture 2-6. Press the functional areas to enter corresponding interface.



Picture 2-6 Menu Interface

2.3.2 FUNCTION BRIEF INTRODUCTION

Table 2-1 Function Correspondence Table

Key	Function
Test	Load sample information, set sample loader starting and ending positions and start testing
Query	Query sample results, delete and print the results
QC	Set the parameters of QC materials and start QC
Calibration	Set calibrator parameters and start calibration
Settings	Set time and printer
Service	Check and confirm the system setting, execute related service operations

2.4 REAGENT, CHROMATOGRAPHY COLUMN, FILTER, QC MATERIAL AND CALIBRATOR

Analyzer, reagent, chromatography column, filter, QC material and calibrator form a complete system, which should be used as a whole to ensure the performance of the system. Operators should use reagent kits designated by Lifotronic (See specification in Appendix A). Otherwise, H9 Analyzer may not be able to reach the performance level described in this manual. Use of non-specified reagent kits will not guarantee reliable results. All the "reagent" in the manual means the reagents designated by Lifotronic. Check reagent package before use – the damage of package may affect the quality of reagents. If there are damages, DO NOT use the reagent!

NOTE

● Refer to the user manual of reagent to see how to use and store reagent.

● After replace eluent, chromatography column, filter or hemolytic agent, the operator should rinse the system to ensure ADC value in normal range.

● Ensure use reagents, column and filter before expiration date.

● Allow the eluent and hemolytic agent to reach room temperature (15–30 °C) before performing the assay. Mix each bottle by gently inverting prior to installation.

● Do not use any reagents which were frozen.

● Do not use any reagents which have any indications of discoloration, cloudiness or precipitation.

● Do not use any reagents that show any signs of leakage.

● Do not use the calibrator or QC if the pellet is brown or the vial is broken. If the lyophilized material contains insoluble matter, discard the material and reconstitute a new vial.

2.4.1REAGENT

■ A Eluent

Used to elute HbA1a 、HbA1b and HbF those are less positively charged

■ B Eluent

Used to elute LA1c and HbA1c those are well positively charged

■ C Eluent

Used to elute HbA0 that is most positively charged

■ L-Hemolytic Agent

Used to lyse erythrocytes and release glycosylated hemoglobin

2.4.2 CHROMATOGRAPHY COLUMN

Chromatography column contains cation exchange resin to adsorb glycosylated hemoglobin. With increase of eluent concentration, HbA1a,HbA1b, HbF, HbA1c, HbA0 will be eluted respectively.

2.4.3 FILTER

There is an inside filter board used to filtrate the impurities and granule in blood; Avoid blocking the column and protect the stability and reliability of system,

2.4.4 QC MATERIAL AND CALIBRATOR

QC material and calibrator are used for QC and calibration of H9. QC material is a type of whole blood product, applied to test elution function of H9, including high level QC material and low level QC material. Running QC program every day can detect the status of H9 and ensure testing results reliable.

Calibrator is also a type of whole blood product. Refer to the user manuals of QC material and calibrator for the usage and storage method.

All the "QC material" and "calibrator" mentioned in this manual means the specific QC material and calibrator designated by Lifotronic. Users needs to purchase from Lifotronic or authorized distributors.

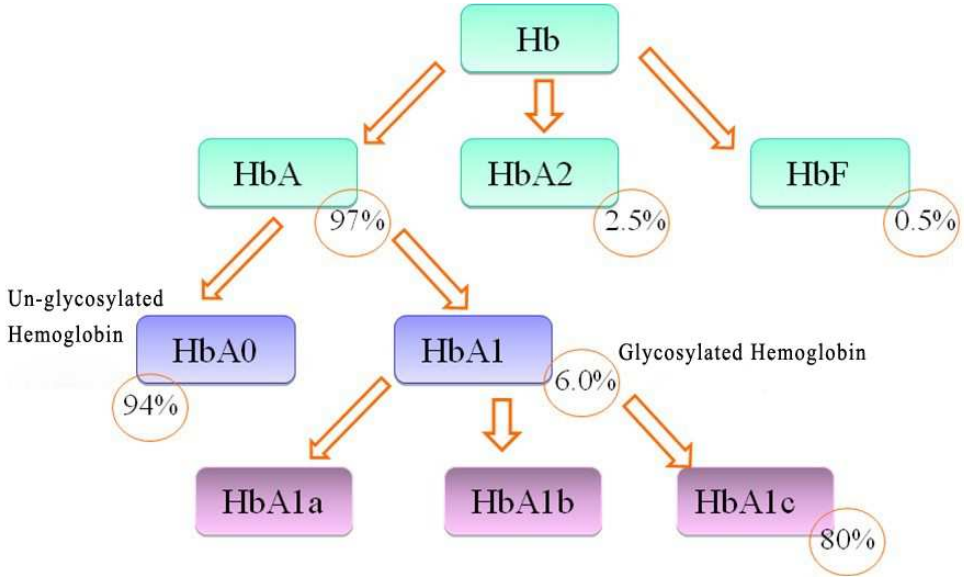
CHAPTER 3 WORKING PRINCIPLE

In human blood, there are three kinds of hemoglobin (Hb): hemoglobin A (HbA), hemoglobin A2 (HbA2) and hemoglobin F (HbF).

For adult, the level of HbA consists 97% of total hemoglobin, and HbA includes 2 subfractions: glycosylated hemoglobin (HbA1)(6%), un-glycosylated hemoglobin (HbA0)(94%).

Glycosylated hemoglobin is a compound that is formed in the non-enzymatic reaction between hemoglobin and carbohydrate. Glycosylated hemoglobin is called HbA1c and un-glycosylated hemoglobin is called HbA0.On the basis of combination with different carbohydrate compound, glycosylated hemoglobin is divided into HbA1a1、HbA1a2、HbA1b and HbA1c. Among of which, HbA1c is about 80% of HbA1, a stable addition compound formed by one or two strips of β-chain amino terminal and glucose carbonyl.

See constituent of hemoglobin below.



Picture 3-1 Constituent of Hemoglobin

Synthesis process of HbA1c is slow and irreversible. And it accumulates in the 120 days lifetime of erythrocytes. The synthesis rate is proportional to the concentration of blood glucose and its structure is stable. Therefore, the level of HbA1c reflects the average level of blood glucose in the past 2-3 months. As the average amount of blood glucose increases, the fraction of glycated hemoglobin increases in a predictable way, which is not related to blood drawing time, whether it is fast or not and whether use insulin or not. It's a reliable marker to indicate the control of blood glucose levels.

H9 Analyzer adopts High Performance Liquid Chromatography (HPLC) method to measure the level of HbA1ab, HbA1c and HbA0. And the Analyzer calculates the rest items.

3.1 ASPIRATE SAMPLE

There are two methods to load sample – venous whole blood sample loading method and diluted blood sample loading method.

Aspirate 10 μL whole blood sample when using venous whole blood sample loading method.

When using diluted blood sample loading method:

1)Aspirate 1500uL Hemolytic agent(L) into vial

2)Add 10uL venous whole blood or peripheral blood. Cover then shake it gently

3)Place the vial on the sample rack to test.

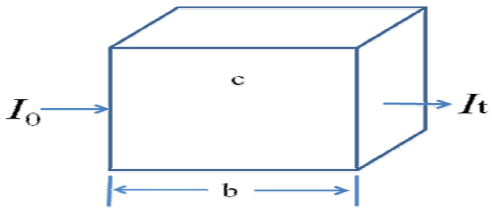
3.2 MEASUREMENT

3.2.1 ION EXCHANGE THEORY

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

3.2.2 COLORIMETRIC ANALYSIS PRINCIPLE

According to Lambert-Beer law, when a collimated monochromatic light transit a even solution medium, part of this light will be absorbed and the other part will be reflected by container. Define the incident light intensity as I0, the transmission light intensity as It, the solution concentration as c, and the thickness of liquid as b. See the absorbing schematic diagram below.



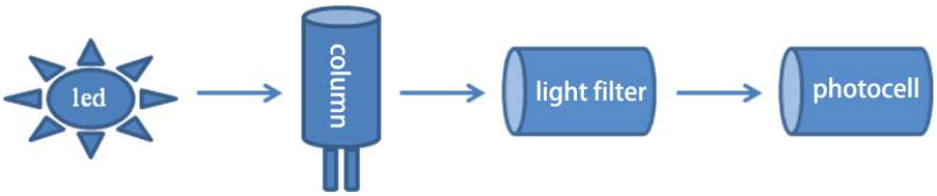
Picture 3-2 Absorbing Schematic Diagram

Written as：

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

In the equation above, A means absorbance; K is absorption coefficient. The equation means that the absorbance of solution is in direct proportion to the product of solution concentration and liquid thickness.

The absorption peak wavelength of glycosylated hemoglobin is 415nm. So when 415 nm LED light transmit a cuvette, it will be absorbed by photocell after passing through a 415nm band pass filter. Light intensity is proportion to the converted potential. See the schematic diagram below.



Picture 3-3 Colorimetric Analysis Principle

Therefore, absorbance could be also written as:

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

In the equation above，E0 means incident light potential; Et means transmission light potential. Through amplifying and acquiring photocell signal by computer, measure real-time absorbance of the eluates continuously.

3.3 RESIN BALANCE AND SYSTEM RINSE

During the elution process of the former sample, the system rinses sample probe and mixing cup automatically. And then, the system will complete the whole process of the latter sample, loading, hemolysis, mixing and sample probe rinse. After a complete rinse cycle, the system will balance the column to prepare for next sample.

CHAPTER 4 INSTALLATION

The chapter introduces installation procedure and considerations.

To make sure the Analyzer function normally, installation at the time of delivery and initial setting ought to be conducted by authorized personnel.

CAUTION

● It might damage the device to unpack and install without authorized or trained personnel. So do not unpack or install the device without present of one authorized or trained personnel.

4.1 INSTALLATION REQUIREMENTS

The operator must ensure to meet the following environment, space and power requirements before installation.

4.1.1 ENVIRONMENT CONDITIONS

- Temperature: 10 °C～35 °C
- Humidity: ≦80%(no dewing)
- Air Pressure：75 kPa～106 kPa
- Dust-free, no mechanical vibration, no noisy source and power interference
- Evaluate the magnetic environment of laboratory before running the device
- DO NOT let the device close to strong electromagnetic interference source, in case of malfunction or the inaccuracy of data
- DO NOT get close to brush-type motors, fluorescent flashing lights and frequent switch electrical contact device
- Avoid direct sunlight or putting in front of heat source or wild source
- Maintain good ventilation

WARNING

● DO NOT operate in flammable and explosive environment

NOTE

● If room temperature exceeds normal operating temperature range, the obtained results will be inaccurate

4.1.2 SPACE

To keep enough space for maintenance, troubleshooting, heat dissipation and liquid line flowing normally, the installation space should be:

Distance of left/right side from the wall ≥ 50 cm

Distance of rear side from the wall ≥ 50 cm

4.1.3 POWER SUPPLY

Voltage：a.c.100～240V；

Frequency：50/60 Hz；

Input Power：120VA

WARNING

- The Analyzer must be used in a good grounding condition
- Make sure input voltage meet the requirements.
- Make sure the switch is off ("OFF") before connecting power cord of adapter

4.2 OPEN PACKAGE

4.2.1 OPENING STEPS

In order to avoid striking while transportation, the Analyzer has been strictly inspected before dispatched from factory, and been packaged cautiously. Therefore, check the package carefully for damage before opening. If it appears, please inform service department of Lifotronic or local distributor of that.

Follow the steps below to remove the package if there is not any damage.

- Put the box uprightly and make sure the arrow on the box is upward.
- Remove the packing taper and check all the accessories referring to packing list. If anything is missing, please inform service department of Lifotronic or local distributor of that.
- Take out the foam cover, pull out the device and place it on a table.

4.2.2 MOVE THE ANALYZER

- The reagent kits on the top of the device ought to be removed before moving and transporting, in case of falling down
- Drain the liquid line of the Analyzer before moving
- Protect the LCD screen and sample probe from external force when moving

- Keep the device upright, avoid shake. DN NOT tilt it or put it on its side. Inspect and debug before operation after moving it.

NOTE

- The Analyzer must be placed on a sturdy and horizontal table, not placed on a slope.
- Please keep the packing box, in order to pack the Analyzer when moving a long distance.

4.3 INSTALLATION PROCEDURE

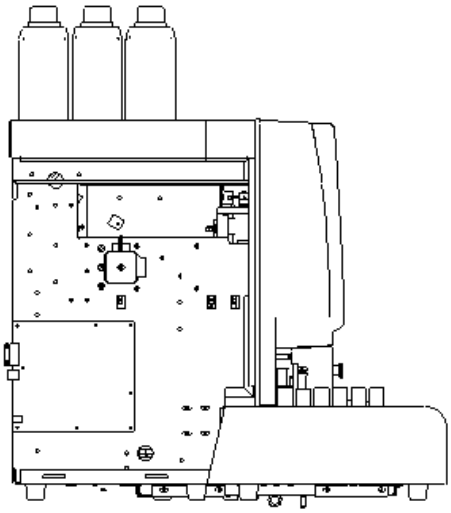
WARNING

- Operator should wear on gloves and avoid direct contact with sample probe. Because sample probe is sharp, sample loader, sample probe, Chromatography Column and filter may carry with blood and QC material and calibrator is bio-hazard
- The cloths, hair and hands should keep a certain distance from moving parts like sample probe and sample loader, in case of crushing or stabbing

4.3.1 REMOVE 2 SCREWS

The 2D arm is tied to metal plate with 2 screws to avoid damage. Remove that 2 screws before use. See detailed steps below.

1) Follow the direction of the arrows to open left and rear doors, remove that 2 screws as shown in picture 4-1:



Picture 4-1 Open the left and rear doors

2) Push 2D arm slightly to recover to free status, the sensor lights of the two arms will turn on.

4.3.2 REAGENT CONNECTION

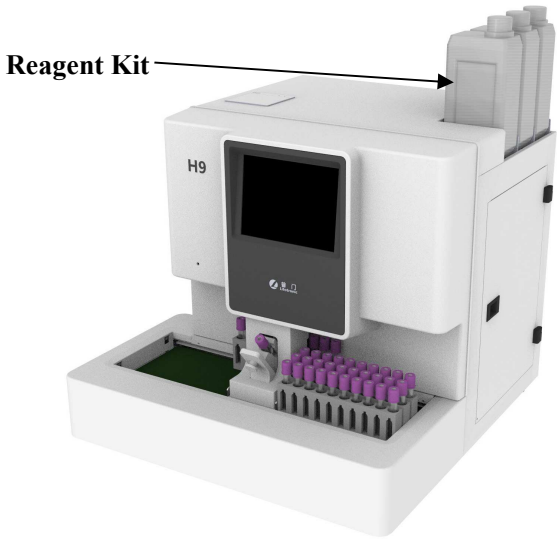
WARNING

- Operators are in duty to bound to local laws and regulations about disposing overdue reagents, waste liquid, waste samples and consumables.
- Reagents may irritate eyes, skin and mucous membranes. Operators ought to comply with safety regulations and wear on personal protective equipments (like protective clothing, gloves).
- Once the reagent contact with skin, wash immediately with plenty of water, if necessary, please seek medical treatment; Once the reagent contact with eyes, rinse immediately with plenty of water and seek medical treatment.

NOTE

- Must use specified reagent kits
- Stand the reagents before use, to make it stable
- Ensure use reagents and columns before expiration date
- Cover the bottles after reagents and the Analyzer connected, in case of contamination

Place reagent kits on the top of the device, and the sequence of A elunet, B eluent, C eluent and hemolytic agent(L).Connect the end of reagent tube with Luer taper to the Luer taper on the Analyzer. Fix the other end to regent bottle cover after passing through the holes on reagent kit.



Picture 4-2 Reagent Connection

4.3.3 WASTE BOTTLE

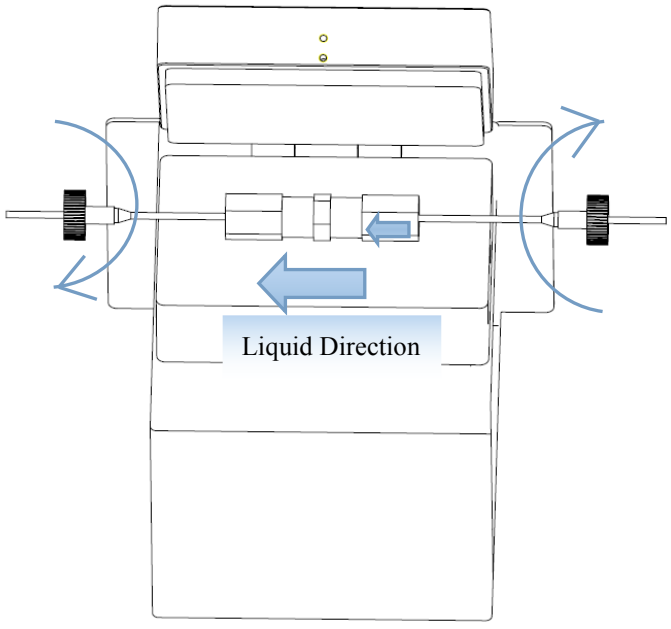
Take out the waste liquid tube with Luer taper. Place the waste bottle on the back side of the Analyzer. Connect one end of waste tube to the waste connection on the rear side and the other end to the waste bottle.

4.3.4 FILTER AND CHROMATOGRAPHY COLUMN INSTALLATION

NOTE

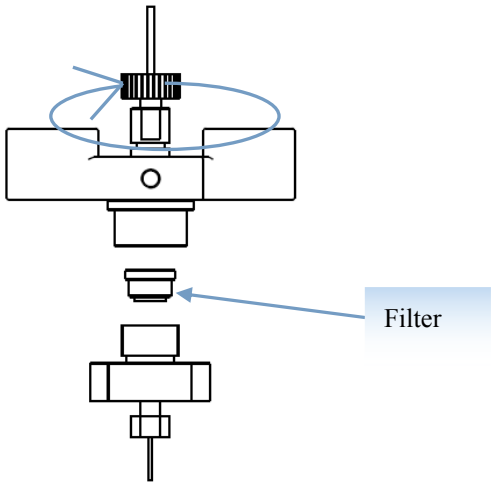
- Operator should wear on gloves for safety operation due to the biohazard of filter and Chromatography Column.
- There might be reagents that soaked filter and Chromatography Column dropping on the device and operating desk. So please prepare tissue for cleaning.

Take out filter and Chromatography Column from reagent kit, clean up with a tissue. Connect them according to the direction of the thread.



Picture 4-3 Chromatography Column Installation

Screw the peek connection tightly according to Picture 4-3, and then Prime A Eluent. Please observe carefully both sides of chromaotography column. If there is no leakage from both sides of the column, close and lock the column cover for next step.



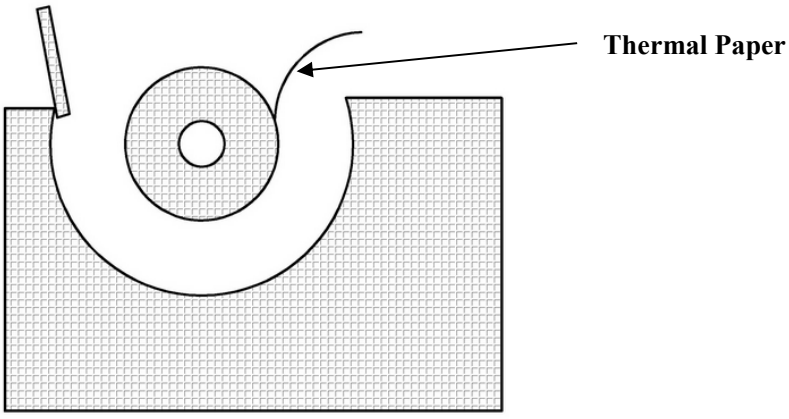
Picture 4-4 Filter Installation

Unscrew the filter switch, put the smaller side of filter towards the filter holder, and screw the switch tightly as Picture 4-4.

Prime A Eluent, and then observe whether there is leakage. If there is leakage from the filter, please screw the filter switch more tightly. If not, please go to the next step.

4.3.5 THERMAL PAPER INSTALLATION

Pull the holder on top right corner of printer, and open printer door. Load thermal paper according to the direction in Picture 4-5, and leave a segment of paper outside the exit. Close the door, and inspect thermal paper position, to ensure thermal paper aligning at the exit.



Picture 4-5 Thermal Paper Installation

4.3.6 POWER ADAPTER CONNECTION

Take out power adapter with three-core cord. Plug one end of power cord into power adapter and the other end into socket. Then plug the output end of power adapter into the port on the rear side of Analyzer.

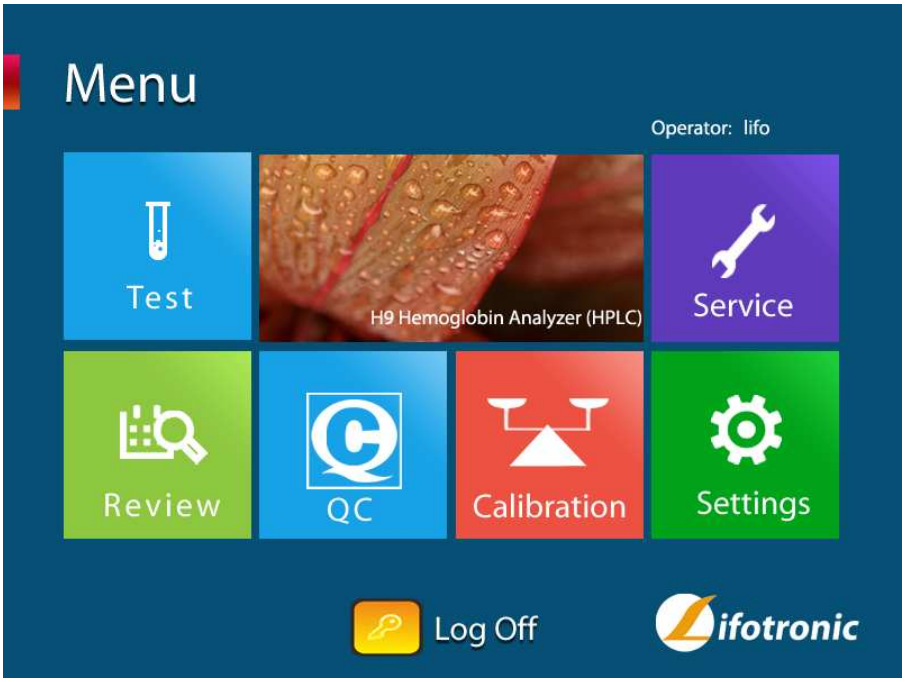
4.4 START-UP FOR THE FIRST TIME

Turn one the switch on the rear side.The system will run self test and system cleaning program.



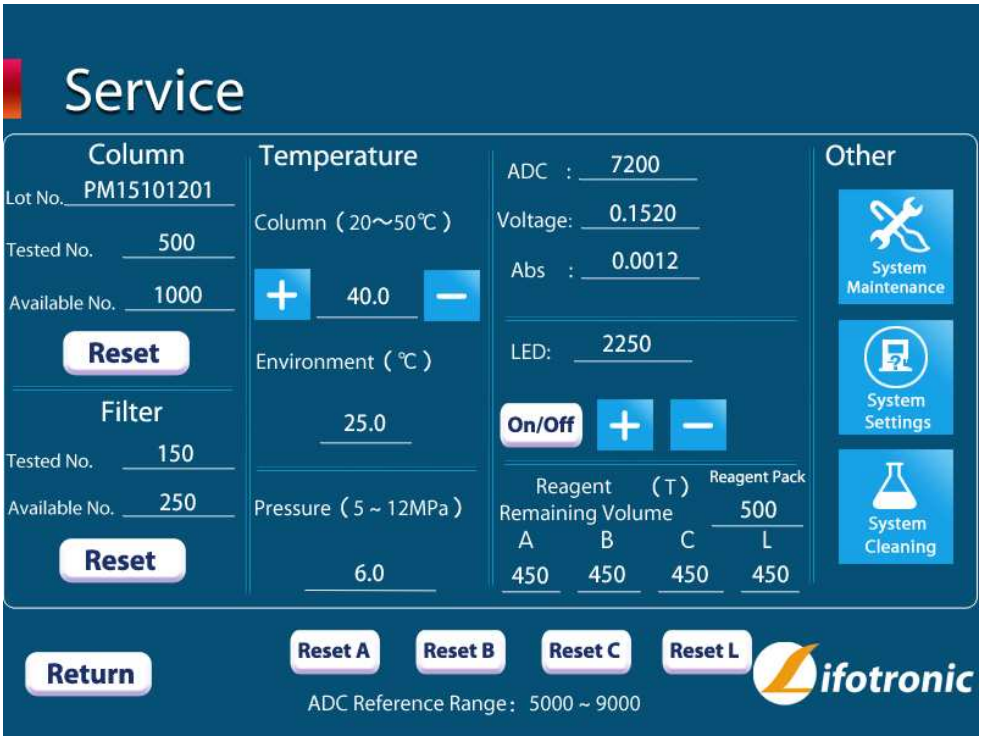
Picture 4-6 Power on Self Test and System Cleaning

Click "Yes", the system will enter menu interface in about 10 minutes.



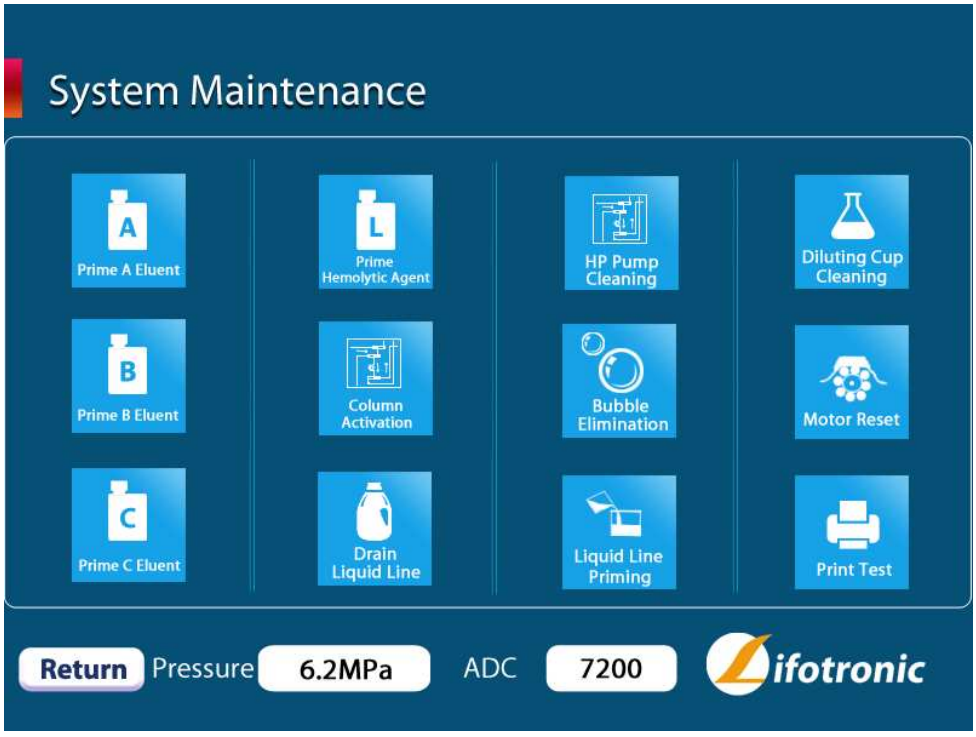
Picture 4-7 Menu

Click "Service", enter into service interface:



Picture 4-8 Service

Press "System Maintenance":



Picture 4-9 System Maintenance

Prime the liquid line. Then press "Column Activation" to keep ADC value between 5,000~9,000.

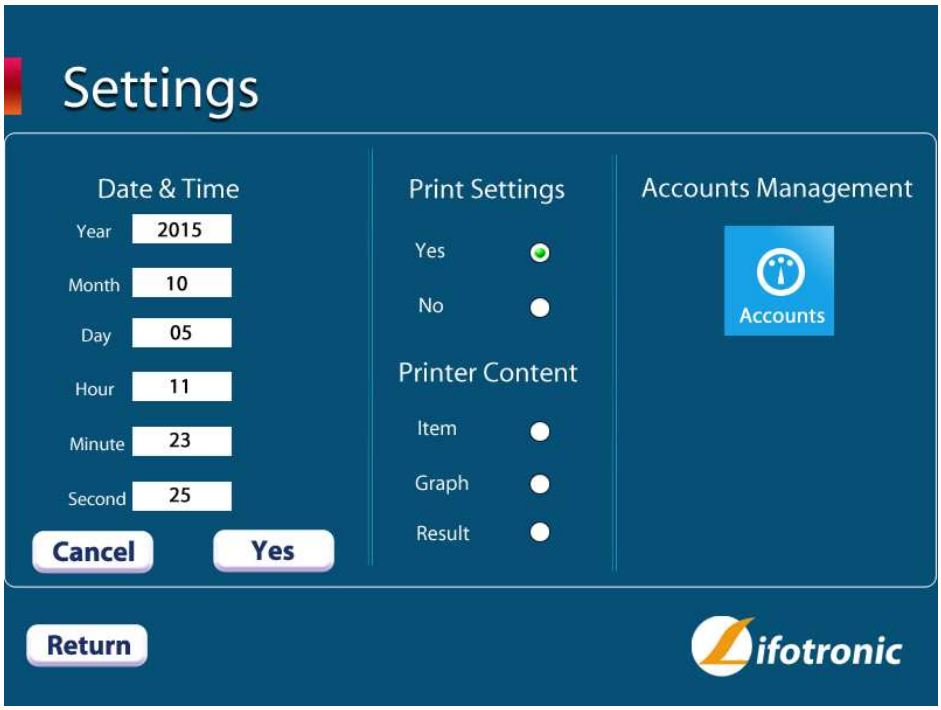
If encounter other malfunctions during operation above, refer to Chapter 11.

CHAPTER 5 PARAMETER SETTINGS

Parameters of H9 Analyzer had been initialized setting before dispatched from the factory. All the parameters are defaulted by the system for the first start-up. To meet the actual needs of those laboratories, user could reset those parameters.

5.1 PRINTER SETTINGS

Press "Settings" to enter the mode on Menu interface,



Picture 5-1 Settings

Select Yes or no to set whether to print out the results automatically after test.

The operator can choose to print 6 different test items, chromatogram between 4 output formats.

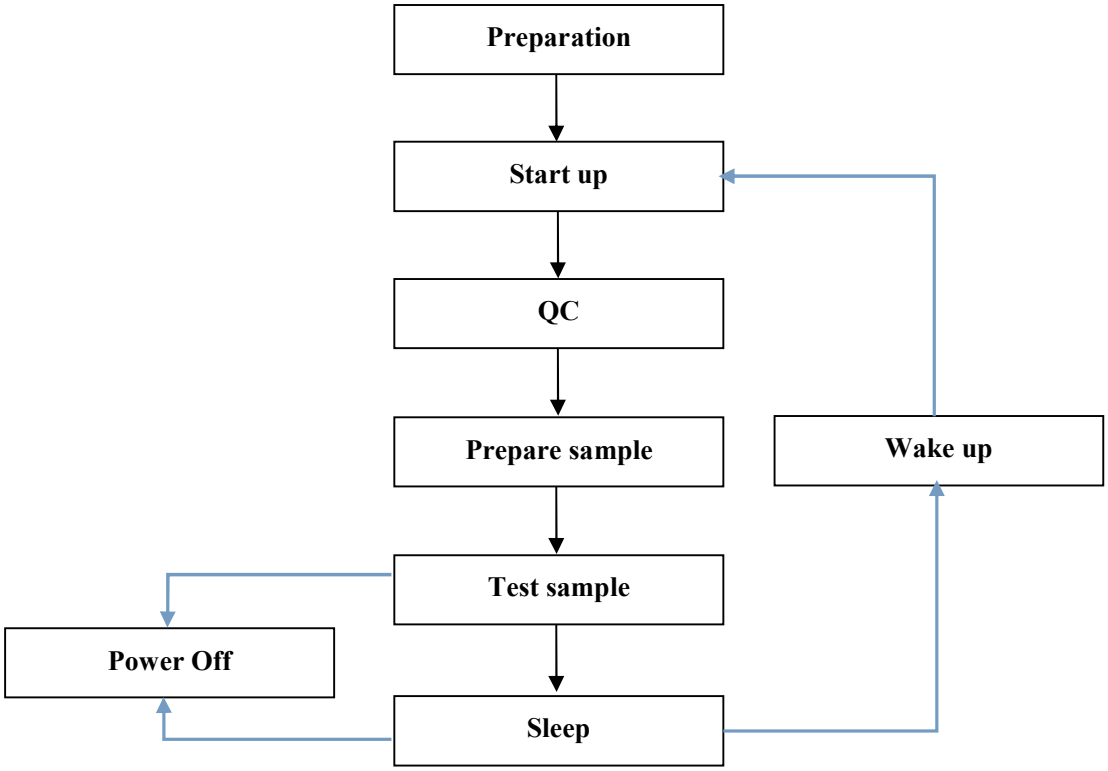
5.2 DATE AND TIME

Press the areas to enter Year, Month, Day, Hour, Minutes, Second to update system time. Press "Ok" when complete inputs.

CHAPTER 6 DAILY OPERATION

This chapter introduces daily operation method of H9, and makes a detailed thorough introduction about whole blood sample mode and prediluted sample mode.

See the daily operation flowchart below:



6.1 CHECK BEFORE OPERATION

Before switching on the power, operator ought to check the system according to the following requirements.



● Sample, QC material, calibrator, column,filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipment (Safe clothing, gloves) when contacting lab articles.



● Operator is obliged to comply with local and national regulations about discharging reagents, waste, waste samples, and consumables.

● Reagents may irritate eyes, skin and mucous membranes. Operator should comply with laboratory safe regulations and wear on personnel protective equipments (Safe clothing, gloves) when contacting lab articles.

1. Check Rest Reagent Volume

Check whether the rest volume of A eluent, B eluent, C eluent and Hemolytic agent are enough or not.

2. Waste Container

Check the waste container to ensure it's empty before operating every day.

3. Liquid Line and Power Supply

Check whether reagent and waste liquid lines are kink or not, connections are reliable or not.

Check whether there is any leakage or not

Check whether the power plug into the socket or not.

4. Thermal Printer

Check whether there are adequate papers or not and the settings are ready or not.

5. Bar Code Scanner

Check the connection between bar code scanner and the analyzer.

6.2 PREPARATION BEFORE OPERATION

Switch on the power on the rear side, the screen will be on. About 2 seconds later the screen will show available test numbers of chromatography column and filter and the screen will turn to system POST(Power-On-Self-Test) and self-cleaning confirmation interface.

Press "Yes", the system will run POST and Self-cleaning program. The process will last 5 minutes. Once completed, the system will enter Menu interface.

Press "No" to skip POST and Self-cleaning process and enter Menu interface directly.

If failure or malfunction occurs in initialization, the corresponding information will show on the screen and sound "De-De-De" alarm continuously. Operator should troubleshoot and then conduct next step. Refer to Chapter 11 for the methods of troubleshooting.

NOTE

● Operator should run POST and Self-cleaning program every day. Otherwise it may lead to malfunctions that cannot be found or wrong results.

6.3 DAILY QC

Before assaying the sample, operator ought to conduct QC procedure to ensure the analyzer could get reliable results. See details steps of QC in Chapter 8.

Since the ion balance status of chromatography column will affect the next sample test result, each day's first sample test result(<1%) will be influenced by the column ion balance status and storage

condition. To reduce that influence, Lifotronic recommend to ignore each day's first sample test result, and H9 has "Previous Samples" and "Initial Running No." parameters. "Previous Samples" is the samples(will ignore the test results) and QC samples placed ahead of normal samples. "Initial Running No." is the first sample of the day to test and defaulted to be starting from 1 every day. Thus Lifotronic recommend to place the samples on first sample rack as below:

1. A blood sample will be ignored its test result
2. A blood sample will be ignored its test result
3. Low level QC
4. A blood sample will be ignored its test result
5. High level QC
6.
7.
8.
9.
10.

6.4 PREPARATION FOR SAMPLE



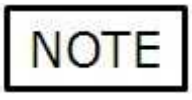
- Sample, QC material, calibrator, chromatography column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipments (Safe clothing, gloves) when contacting lab articles.



- DO NOT contact blood sample directly.



- DO NOT reuse disposable supplies



- Operator should use clean K2EDTA anticoagulant vacutainer, siliconized glass/ plastic tubes, EP tubes and 20uL Borosilicate glass capillary.

6.4.1 WHOLE BLOOD SAMPLE

See preparation method of whole blood sample below:

1. Use clean K2EDTA anticoagulant vacutainer（1.5～2.2mg/mL）to collect venous blood.
2. Quickly thoroughly mix venous blood with anticoagulant in the tube.
3. Blend the sample tube from upside to down 3 times and then place the tube on sample rack to test. (Lab dancer is recommended)

6.4.2 PREDILUTED SAMPLE

See preparation method of prediluted sample below:

1) Aspirate 1500uL deionized water into EP tube.
2) Add 10uL venous whole blood or peripheral blood. Cover then shake it gently.
3) Place the EP tube on the sample rack to test.

Normal total hemoglobin concentration corresponds to a total area of approximately 10.000 volt•second.Low, medium, and high whole blood patient samples were diluted to achieve total areas from 6.000 to 20.000 volt•second. More reliable range is from 8.000 to 12.000 volt•second.If the sample total area is still outside of the expected range, the sample should be rediluted to within the 8.000 to 12.000 volt•second total area count range and rerun.

NOTE

- It's recommended that operator uses oscillator to shake t blood collection tube or prediluted EP tube. Otherwise it may influence testing result.
- If there are bubbles or flock in the blood of blood collection tube, sample probe cannot aspirate blood sample. It might result in 0% result. Once it appears, shake the tubes thoroughly and test it again.

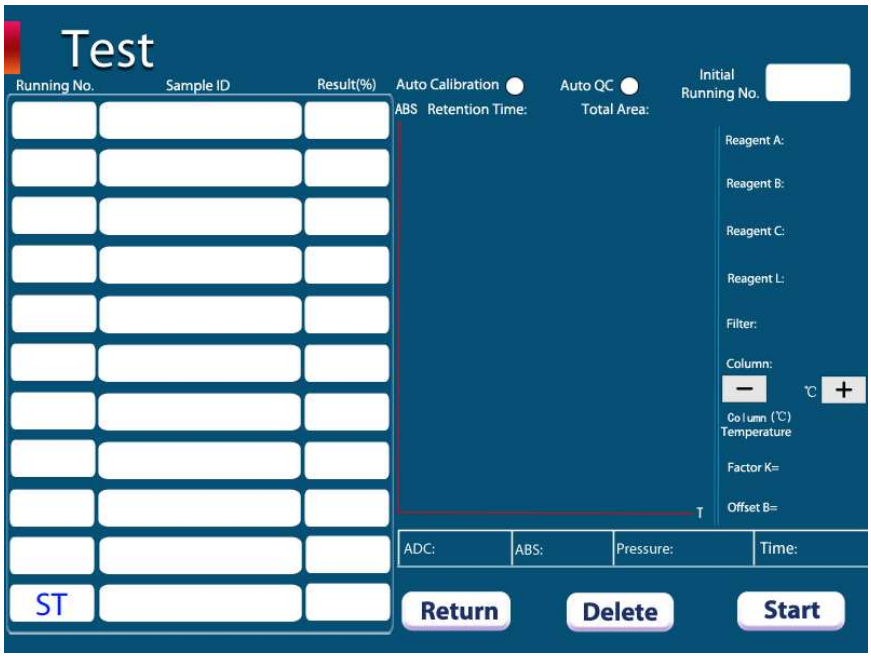
6.4.3 CHECK BEFORE TEST

1) At service page, record the chromatography column Lot No., Tested No., and Available No.. If Filter's Tested No.≧400, please change new filter;
2) Check whether there are enough eluent and hemolytic agent remaining;
3) Check whether there is leakage from liquid line;
4) Check whether there is bubbles in cleaning tank of high pressure pump. (If there are bubbles, execute "HP Pump Cleaning".)
5) Check whether waste bottle is full.

6.5 ASSAY WHOLE BLOOD SAMPLE

6.5.1 LOAD SAMPLE INFORMATION

Press "Test" on Menu to enter Loading Sample Information interface, see the picture below.



Picture 6-1 Venous Whole Blood Sample

Put the sample on the sample rack, then put the sample rack on the auto sampler, click start.

The 1st sample of daily test must be a whole blood sample, the instrument will test it 3 times and use the 3rd test result.

Put an empty sample rack behind normal sample rack to abort sample test status. After testing all the samples on the auto sampler, the system will automatically execute Prime C Eluent, Prime B Eluent, Prime A Eluent and then High Pressure Pump Cleaning. And then enter standby mode.

Once the system is in standby mode for 90 minutes, it will go to sleep mode.

H9 can automatically rotate the sample tube for barcode scanning. It will display “Running No.”, “Sample ID” and HbA1c “Result%” in scroll for the last 10 samples.

The operator can edit “Running No.” and “Sample ID” by click to review a specific sample result.

NOTE

- The maximum length of the sample ID number 15, if it exceeds 15, the analyzer will default before 15 as the current ID number
- Pressure range should be 5-12 MPa, recommended pressure range is 6-8 MPa

6.5.2 STAT SAMPLE LOADING

If it needs to load sample emergently, put the sample on the STAT sample position, and click “ST” button on test screen, it will turn to red and do the STAT sample test after current test.

●Sample, QC material, calibrator, chromatography column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipments (Safe clothing, gloves) when contacting lab articles.

WARNING

- Avoid direct contact with blood sample.
- The cloths, hair and hands should keep a certain distance from moving parts like sample probe and sample loader, in case of crushing or stabbing
- DO NOT place sample or touch sample loader when sample loader turning or sample probe aspirating, in case of failure or malfunction.

CAUTION

● If room temperature exceeds the normal working temperature range of the Analyzer, the testing results will be unreliable

6.6 POWER OFF

1. After each test, the system will automatically execute Liquid Line Priming and Cleaning. Therefore, the operator doesn't need to run Power off program. Once the system enter Standby mode or Sleep mode, the operator could power off the system by tuning off power switch on rear.And then empty the waste bottle and discharge waste liquid properly.

WARNING

- Operator is obliged to comply with local and national regulations about discharging reagents, waste, waste samples, and consumables.
- Power off the system during test is prohibited;
- Power off the system is recommended for below situation:
  - Need to change parts;
  - Need to move the analyzer to new position;
  - AC power will be off.

Only when the system enter standby mode or sleep mode, the operator can turn off the analyzer by switch off the power on the rear side. The system can work continuously for over 24 hours.

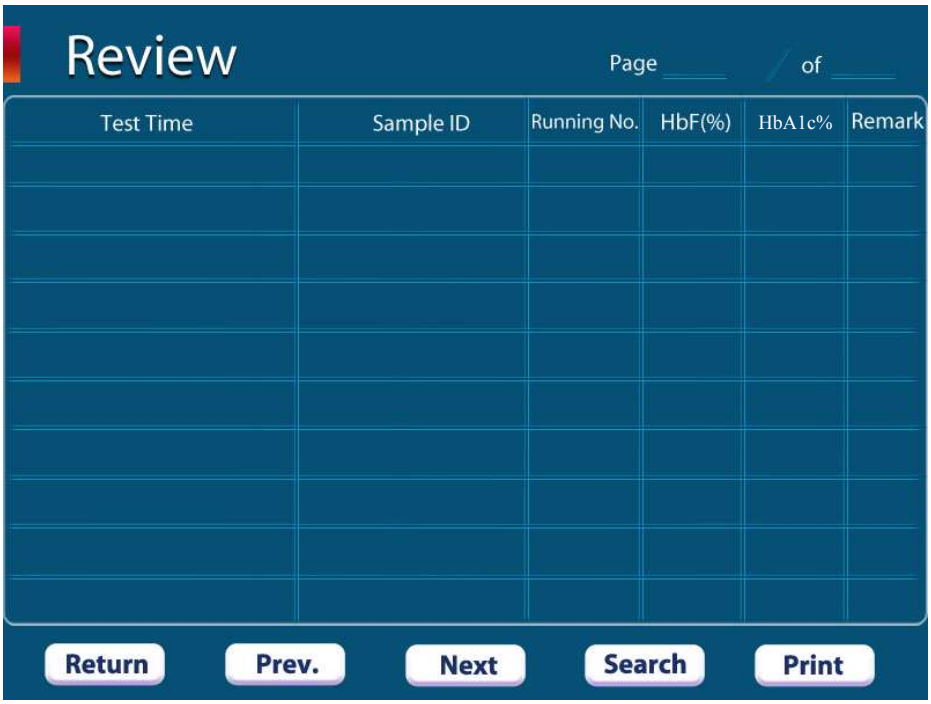
If Auto Power Off selected, the system will automatically power off at setup time. Since the system execute cleaning program automatically, the operator doesn't need to do extra cleaning procedure before power off.
If Auto Power On selected, the system will automatically power on at setup time and then execute Self Test and Cleaning program.

CHAPTER 7 DATA REVIEW

H9 will store testing results to database automatically after every single test. The maximum storage is 4,000 testing result. Operator could review and query all the stored parameters and chromatograms by pressing "Prev" or "Next".

7.1 DATA EXPLORATION

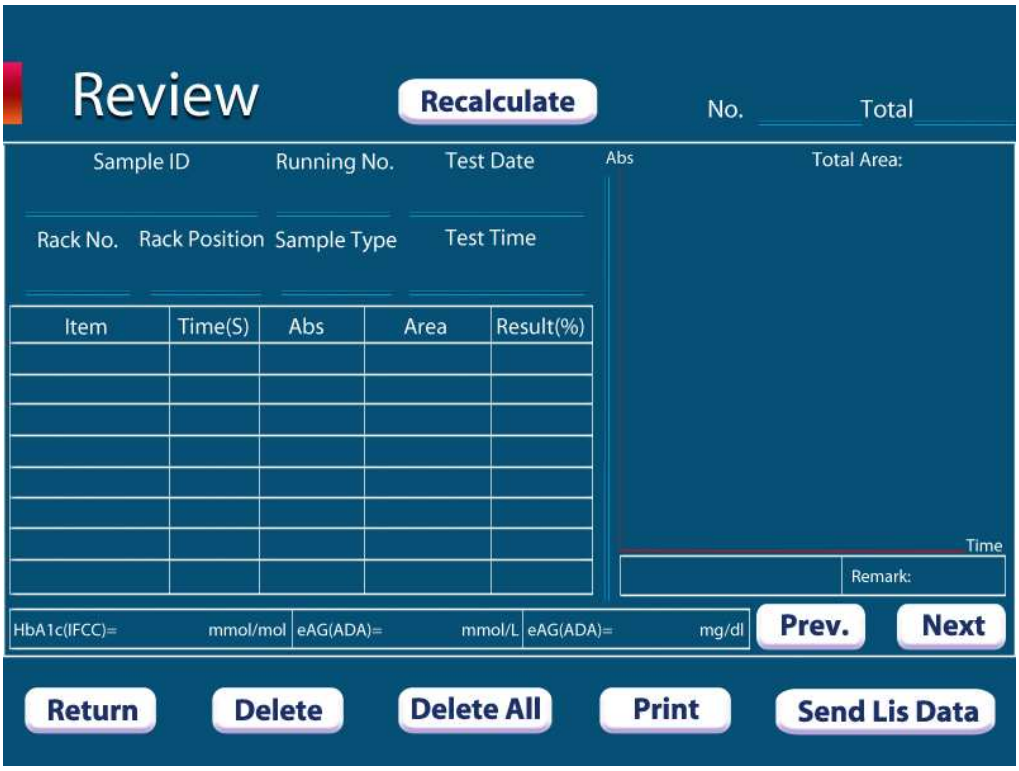
The Analyzer provides "Prev" and "Next" browsing method to explore the results. Press "Review" to enter review mode on Menu interface:



Picture 7-1 Review

Operator could view the results one by one by pressing "Prev" and "Next". Press any sample, it will enter to the single sample interface with detailed information including Test Time, Sample ID, Running No., HbF(%), HbA1c(%) and remarks for different warning. Click a specific sample result to enter single sample result review page, and the system will send complete sample result to Lab's LIS/HIS system.

7.2 SINGLE SAMPLE DATA EXPLORATION



Picture 7-2 Single Sample Data Review

Operator could browse sample results. View the results one by one by pressing "Prev" and "Next". There are total quantities of database, current Sample ID, Running No., Test Date, Rack No., Rack Position, Sample Type, Test Time and Chromatogram shown on Data Review interface. Press “Print” to print the complete sample result.

7.2.1DATABASE STORAGE

Maximized storage of sample results are 4,000 tests(including chromatograms). Once the stored sample results reached 4,000, the system database will display 4,000 test and automatically replace the oldest sample results with latest results. Lifotronic recommend to backup sample results before storage full.

7.2.2DATABASE BACKUP

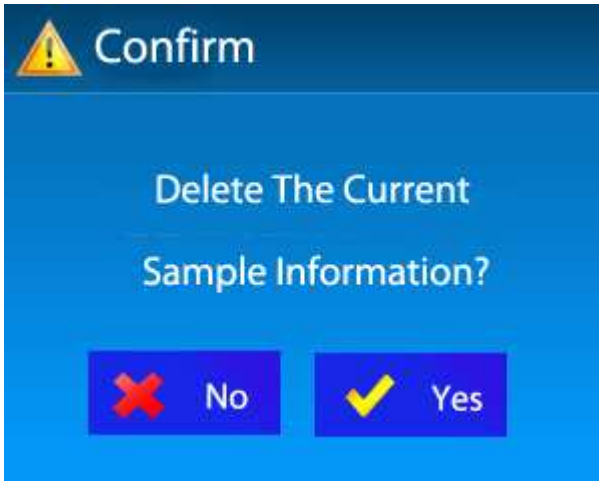
Backup the sample results to a PC. Use RS-232 cable to connect the analyzer with a PC installed Lifotronic backup software(supplied by Lifotronic or Lifotronic distributor).

Click Service--> System Maintenance--->Input Password---->Hardware----->Data Transmission. The system will transfer all the sample results to the PC. Excel back up file format is supported.

7.3 DELETE DATA

7.3.1DELETE CURRENT SAMPLE DATA

Operator could delete testing results of current sample. Press "Delete", popping up Popup Window:



Picture 7-3 Popup Window of Deleting Current Sample Data

Press "Yes" to proceed.

7.3.2DELETE ALL SAMPLE DATA

Operator could delete testing results of all samples. Press "Delete All", popping up Popup Window:



Picture 7-4 Popup Window of Deleting All Samples Data

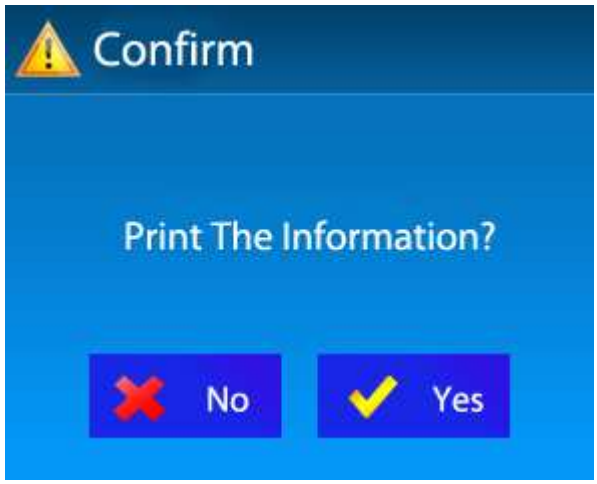
Press "Yes" to proceed.

NOTE

- Once data has been deleted, they can't be recovered. It's recommended to print or keep data backup by connecting to computer with RS232 serial port line. Contact the manufacturer and authorized distributors for backup software.

7.3 PRINT RESULT

Operator could print out current sample date. Press "Print", popping up the following Popup Window.



Picture 7-5 Popup Window of Printing Current Sample Data

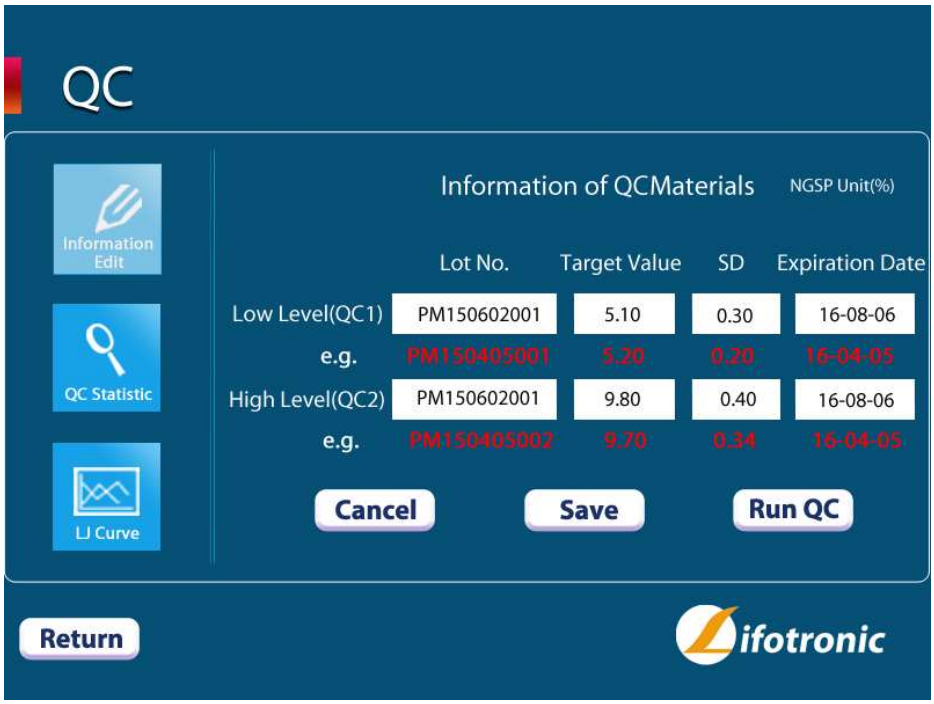
Press "Yes" to proceed with printing. The name of operator will also be printed in the print report. See "Appendix A Specification" about related description of printer format.

CHAPTER 8 QUALITY CONTROL

H9 Hemoglobin Analyzer may have a certain degree of error in the process of long-term use. The existence of error could lead to mistakes or unreliable test results. QC (Quality Control) program provides a effective method to detect possible error. Only be familiar with quality control theory and master operation method, can operator eliminate the error influence on the test results effectively.
In order to guarantee the reliability of the sample test results, operator should conduct QC procedure with low level and high level QC materials every day.

8.1QC MATERIAL INFORMATION INPUT

Press "QC" on Menu to enter QC interface.



Picture 8-1 QC Information

If need to revise the information it can be input manually.
Press effective display area of Lot No., target value and SD value of low/high level QC materials, to enter QC information.
Press "Cancel" to cancel information input
After finishing input, press "Save".

NOTE

- The length of lot Nos. is 15. If exceeding, the system will default the first 15 numbers as current lot No..

- Once lot Nos. being changed, all the original QC data will be overwritten. It's recommended to print or keep data backup by connecting to computer with RS232 serial port line. Contact the manufacturer and authorized distributors for backup software.

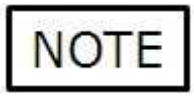
8.2 START QC



Sample, QC material, calibrator, chromatography column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipments (Safe clothing, gloves) when contacting lab articles.



- Operator should wear on gloves and avoid direct contact with sample probe. Because sample probe is sharp, sample loader, sample probe, chromatography column, filter may carry with blood and QC material and calibrator is bio-hazard
- The cloths, hair and hands should keep a certain distance from moving parts like sample probe and sample loader, in case of crushing or stabbing
- DO NOT place sample or touch sample loader when sample loader turning or sample probe aspirating, in case of failure or malfunction.



- Operator should use specific QC material designated by Lifotronic. Lifotronic takes no responsibility for inaccurate QC result by using any other QC materials
- Refer to QC material user manual for its usage and storage methods

See test steps of QC material below:

1．Prepare 1 piece low level QC material, 1 piece high level material, add 100 µl deionized water respectively, dissolve them and then keep them steady for 10 minutes

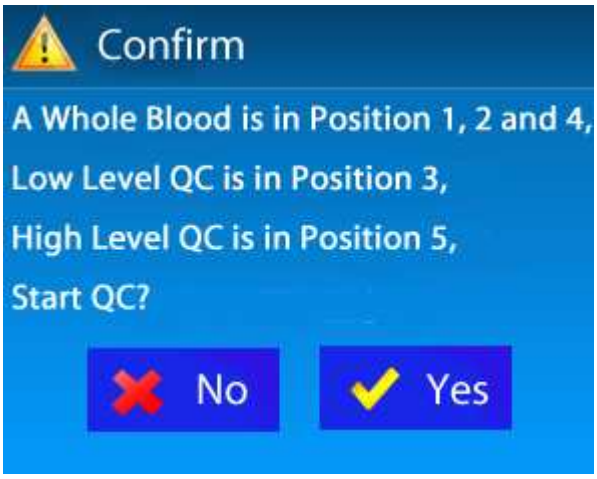
2．Load them to centrifugal tube(1.5 mL) and aspirate 10µl to each centrifugal tube and label on them. The sealed re-dissolving materials should be stored at -20℃. (-60 ℃ is best if you have the facility)

3．When using, take out high/low level QC material, recover to room temperature, add 1500 µl deionized water to dilute.

4. Place a blood sample on position 1,2 and 4, low level EP tube on the position 3 of sample rack, high level EP tube on the position 5 of sample rack. Then start test.

1) A blood sample will be ignored its test result
2) A blood sample will be ignored its test result
3) Low level QC
4) A blood sample will be ignored its test result
5) High level QC
6)
7)
8)
9)
10)

Press "Start QC", popping up the Popup Window below.



Picture 8-2 Start QC

Press "Yes" to start QC.

Select Auto QC in Test interface and place QC material to rack correctly according to indicator of system.

NOTE

- If bubbles form during QC test, the system will set related parameter to no avail and alarm. See Chapter 11 for how to solve this problem.
- If room temperature exceeds normal working temperature range, obtained results may be unreliable.

8.3 QC STATISTICS

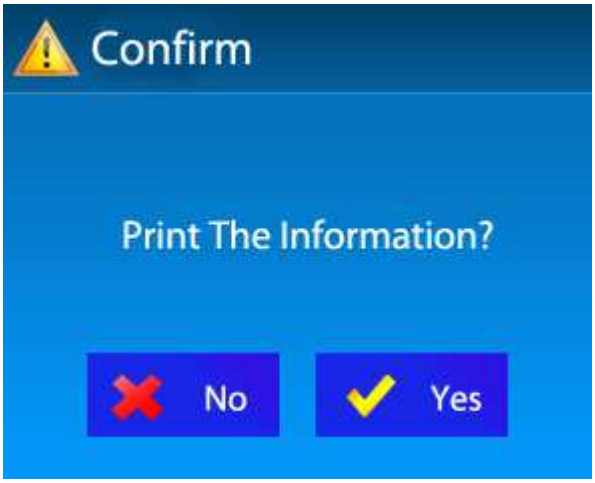
Once QC repeats 5 times, the system will start QC statistics.

Press "QC Statistic" to enter the interface.



Picture 8-3 QC Statistic

The QC statistic items include MEAN, SD and CV of low/high level QC material. Press "Print" to print these data, popping up the Popup Window:



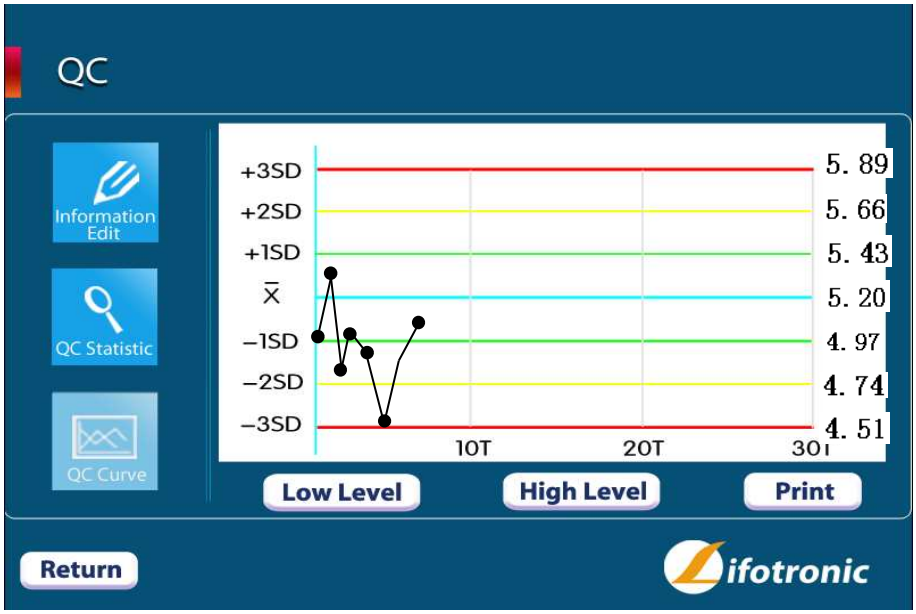
Picture 8-4 Print QC Statistic Record

Press "Yes" to confirm.

If QC repeats less than 5 times, on the top of the screen will show: Warm Prompt: QC Test Time <5! N=0".

8.4 QC CURVE

Press "QC Curve" to view the low level (default) QC curve.



Picture 8-5 Low Level QC Curve

The QC curves of the last 30 times can be reviewed in the Analyzer.

Press "High Level" to view high level QC curve if need.

If want to print out these QC curves, please press "Print", popping up the following Popup Window.



Picture 8-6 Print QC Curve Popup Window

Press "Yes" to confirm.

CHAPTER 9 CALIBRATION

Calibrating the Analyzer is to ensure the accuracy of the test results. In order to obtain reliable results, operators should calibrate the system according to the procedures written in this chapter.

The quality of calibration depends on the quality of used chromatography column, filter,calibrator and reagents. Users ought to use specified chromatography column, filter, calibrator and reagents and follow the instructions and guide to use and store.

9.1 CALIBRATION FREQUENCY

The Analyzer has been calibrated before dispatched from the factory. Only in the three circumstances, can the operator calibrate the Analyzer.

- First installation
- After replace column or filter
- Long periods of inactivity, and to recover
- Obvious deviation appears when running QC program

NOTE

Only after the Analyzer calibrated, can the measured data be used as valid data

9.2 CALIBRATION METHOD

There are two kinds of calibration methods: auto calibration and manual calibration. During auto calibration or manual calibration, all the mathematical calculation related are been executed by the Analyzer. Calibrated calibration factor will be stored automatically. The system can auto store this and last calibration factor.

Preparation before Calibration

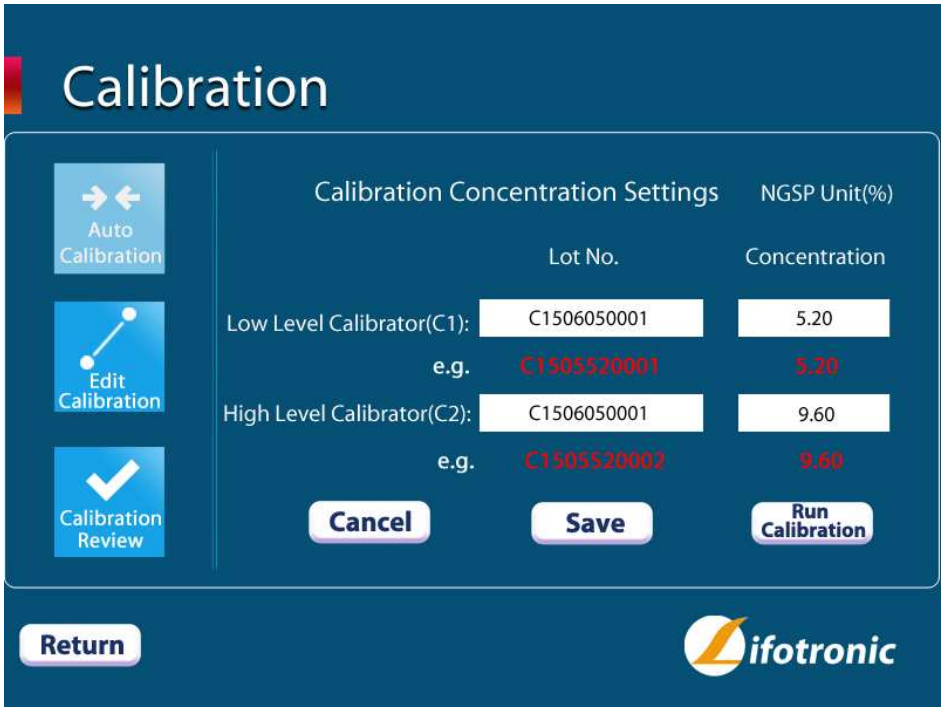
Follow the bellowing steps to prepare. If problems were found, DO NOT calibrate. Operator should find out the causes. Solve the problems and then determine whether it needs calibration. If can't solve, contact the service department of Lifotronic.

1. Check analyzer and reagent and ensure the reagent volume is adequate for the whole calibration process. If the reagents run out during calibration, it needs to be calibrated another time.
2. Check available test numbers of column and filter when starting up. If the available number is zero, please handle according to Chapter 11.Make sure the available numbers of column and filter meet requirements.
3. Check whether ADC value is within 5000-9000. If not, run "Liquid Line Priming" program. If the problems still exist, increase/decrease the LED value.

4. Suggest test one whole blood sample 4 to 5 times before calibration till the results is stable, then calibrate.

9.3 CALIBRATOR INFORMATION INPUT

Press "Calibration" on Menu to enter calibrator information interface.



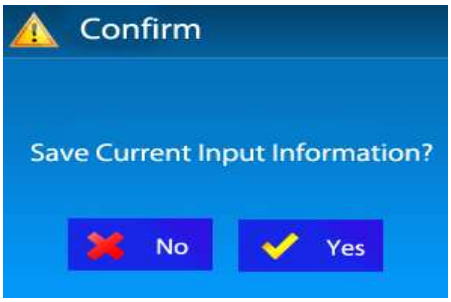
Picture 9-1 Calibrator Information

If need to revise the information it can be input manually.

Press effective display area of Lot No.and concentration of low/high level calibrators, to enter calibration information.

Press "Cancel" to cancel information input.

After finishing input, press "Save". The Popup Window below pops up:



Picture 9-2 Save Calibrator Information Input

Press "Yes" to confirm.

Select Auto Calibration in Test interface and place calibrator to rack correctly according to indicator of system.

9.4 START CALIBRATION



Sample, QC material, calibrator, chromatography column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipments (Safe clothing, gloves) when contacting lab articles.

WARNING

- Operator should wear on gloves and avoid direct contact with sample probe. Because sample probe is sharp, sample loader, sample probe, column and filter may carry with blood and QC material and calibrator is bio-hazard
- The cloths, hair and hands should keep a certain distance from moving parts like sample probe and sample loader, in case of crushing or stabbing
- DO NOT place sample or touch sample loader when sample loader turning or sample probe aspirating, in case of failure or malfunction.

NOTE

- Refer to calibrator user manual for its usage and storage method
- Operator should use specific calibrator designated by Lifotronic. Lifotronic takes no responsibility for inaccurate calibration result by using any other calibrator
- After calibration, the operator has to click save to confirm the saving, otherwise the system won't store the calibrator factors automatically

See test steps of calibrator below:

1. Prepare 1 piece low level calibrator, 1 piece high level calibrator, add 100 µl deionized water respectively, dissolve them and then keep them steady for 10 minutes.
2. Load them to centrifugal tube(1.5 mL) and aspirate 10µl to each centrifugal tube and label on them. The sealed re-dissolving materials should be stored at -20℃. (-60 ℃ is best if you have the facility).
3. When using, take out high/low level calibrator, recover to room temperature, add 1500 µl deionized water to dilute.
4. Place a blood sample on position 1,2 and 4, low level EP tube on the position 3 of sample rack, high level EP tube on position 5 of sample rack. Then start test.

1) A blood sample will be ignored its test result
2) A blood sample will be ignored its test result

3) Low level Calibrator

4) A blood sample will be ignored its test result

5) High level Calibrator

6)

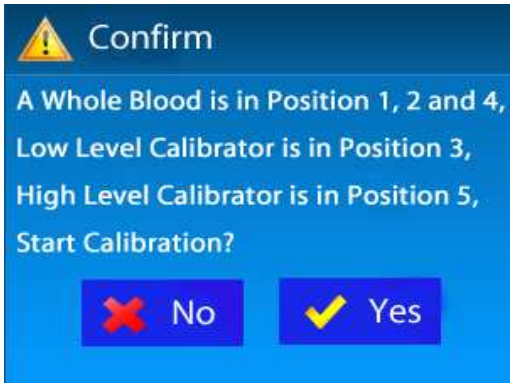
7)

8)

9)

10)

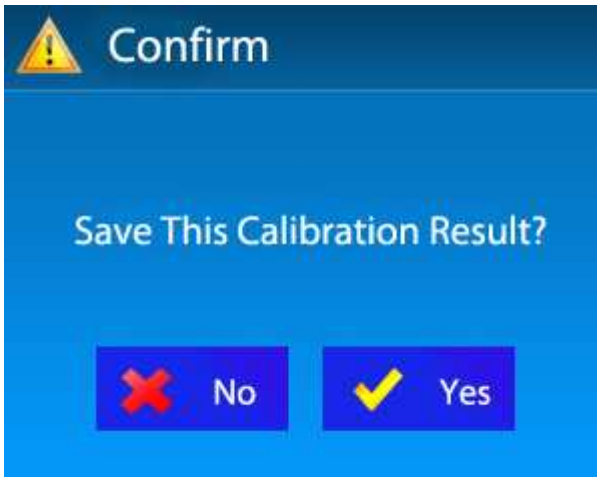
Press "Start Calibration", popping up the Popup Window below.



Picture 9-3 Start Calibration

Press "Yes" to start calibration test. It will jump to calibration query interface automatically after calibration (Picture 9-3).

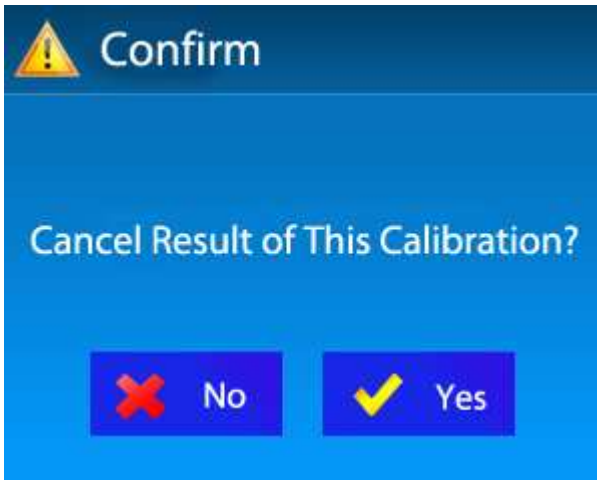
To save this calibration result, operator should press "Save", popping up the following Popup Window:



Picture 9-4 Save Calibration Result

Press "Yes" to cancel the calibration factor.

To cancel this calibration result, operator should press "No", popping up the following Popup Window:



Picture 9-5 Cancel Save Calibration Result

Press "Yes" to saving the calibration result.

The system will automatically test the low/high level calibrator twice to calculate with the mean value.

NOTE

- The system may alarm for calibration failure under below situation:
  - No blood sample in position 1 of sample rack;
  - No calibrator on position 2/3 of sample rack;
  - High level calibrator put on position 2 or low calibrator put on position 3;
  - The difference of 2 tests>0.5% for either calibrator;
  - Extra sample rack put behind the testing rack will cause to calibration failed.
- If bubbles form during calibration test, the system will set related parameter to no avail and alarm. See Chapter 11 for how to solve this problem.
- If room temperature exceeds normal working temperature range, obtained results may be unreliable.

9.5 MANUAL CALIBRATION

The Analyzer allows operator enter calibration factor manually. Press "Manual Calibration" to start.



Picture 9-6 Manual Calibration

Operator press Factor/Offset area to input corresponding factors. Press "Yes" to save the manual calibration result.

NOTE

- The factor range is 0.0001～9.9999，and offset range is -9.9999～9.9999. Default as 1 integer place and 4 decimal places. The Analyzer will indicates an error if beyond the ranges.

9.6 CALIBRATION QUERY

Press "Calibration Query" to view the calibration records:



Picture 9-7 Calibration Query

To print out calibration information, press "Print". The following Popup Window pops up.



Picture 9-8 Print out Calibration Information

Press "Yes" to confirm.

CHAPTER 10 SERVICE

To keep the Analyzer workings accurately and effectively, operator should perform routine maintenance according to the procedures in this chapter. The Analyzer provides various maintenance functions, to facilitate the operator to complete maintenance work.

This chapter describes the various maintenance functions of H9 Hemoglobin Analyzer and some measures when encountering failure and alarm.



- Surface of all the assembly units of H9 are bio-hazard, please take safety and protective measures when operating and maintaining.
- Sample loader, sample probe, chromatography column, filter might be contaminate by blood. QC material and calibrator are bio-hazardous! Operator should wear on gloves while operating and avoid direct contact with sample probe.



- Improper maintenance may damage the Analyzer. Operator must follow the guidance manual for maintenance.
- If you encounter problems that there is no clear instructions, please contact Service Department of Lifotronic. Designated professionals will offer maintenance advises.
- Must use components and parts that provided by Lifotronic for maintenance. Any questions, please contact Service Department of Lifotronic.

10.1 MAINTENANCE GUIDE

Inspection before Test

Appearance: No dust and scratches externally, liquid lines well connected, thermal printer no lack of paper, no leakage and no physical damage.

Safety: Well grounding and connection. The indicator light is on.

Chromatography Column: Available number is more than 0.

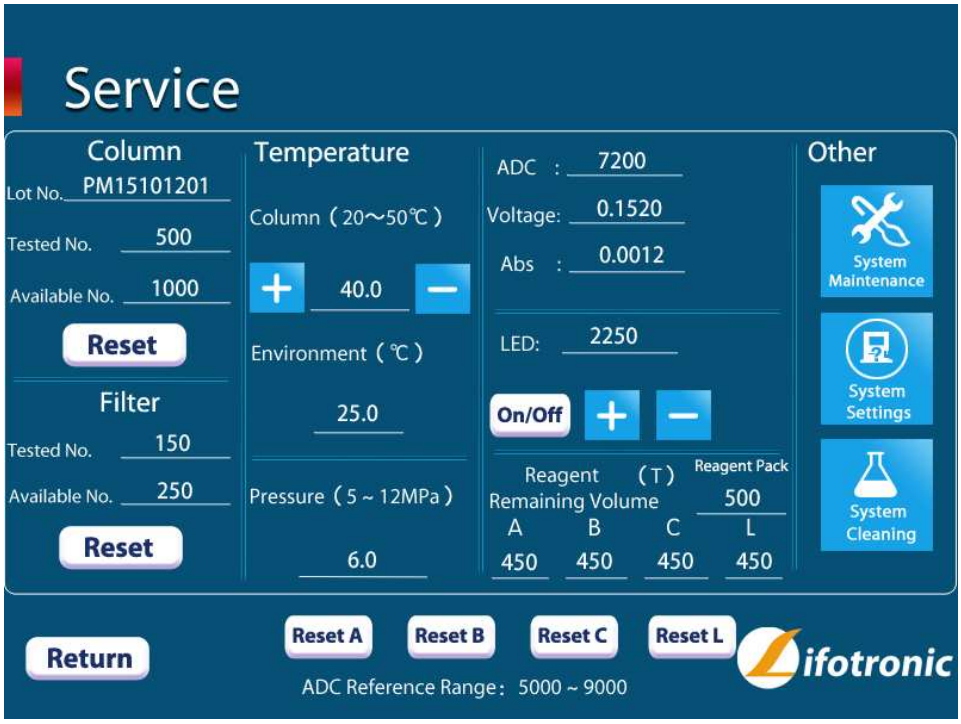
Filter: Available number is more than 0.

Reagent: Use designated reagent, adequate hemolytic agent, adequate A/B/C eluent and waste bottle has been emptied.

Operation: Correct date and time, LCD screen performs well. A long time beep after start-up, available numbers of column and filter shown on the screen, swipe-card program is normal.

10.2 DAILY SERVICE

Press "Service" to enter the interface:



Picture 10-1 Service

The interface shows information about chromatography column, filter, temperatures of column and environment, ADC value and LED value of sample aspiration system.

NOTE

- Operator must use designated and specific Chromatography Column, filter. Lifotronic takes no responsibility for inaccurate test results by using any other columns or filters.
- Before unsealing the columns and filters unsealed, operator should check whether the packaging is damaged. If damage results in column and filter unusable, please contact Service Department of Lifotronic immediately.

10.2.1 FILTER INFORMATION

The information of filter will be input to the system when swiping the card, It is consumable and initial available time is 1500 T (not including calibration,QC and previous sample for balance test). Tested number of filter means tested sample quantity by the filter. Test 1 time, the system automatically counts 1. If the available number is 0, operator should change new filter. Refer to Chapter10.4.5 How To Replace Column.

10.2.2 FILTER INFORMATION

The filter is consumable and initial available time is 400 T (ot including calibration,QC and previous sample for balance test). Tested number of filter means tested sample quantity by the filter. Test 1 time, the system automatically counts 1. If the available number is 0, operator should change new filter.

10.2.3 ENVIRONMENT TEMPERATURE

Normal working temperature of the Analyzer is 10～35℃, suggest 20～25℃. Exceeding the range may affect test results, please adjust the environment temperature according to real temperature.

10.2.4 LED VALUE

The Analyzer uses high-performance high-brightness LED lamp as its light source, and allows 24 hours standby. LED value reflects the brightness of LED light source, normal range is 1800～3000. The greater the value is, the brighter the light is. Press "+"or "-" to adjust LED value. And press "On/Off" to switch on/off the LED light. Check optical system of the Analyzer in this way.

10.2.5 POTENTIAL DETECTION

The Analyzer adopts high-precision optical sampling system. In normal state, ADC ranges from 5,000 to 9,000. Voltage is kind of photoelectric converting analog input voltage. Absorbance could be calculated as:

$$\mathbf{ABS} = \lg\frac{9000}{ADC}$$

If the ADC value is not normal, run bubbles elimination and the liquid line cleaning program. If LED value it still out of this range after this step, fine adjust LED value by pressing "+" or "-". Every time pressing "+" or "-" needs to wait 1 seconds before the 2nd hit.

10.2.6 REAGENT REPLACEMENT

Before using the eluent and hemolytic agent, recover them to room temperature. Ensure the liquid temperature and room temperature difference is less than 4°C to avoid bubbles.

1. When the instrument reminds for reagent replacement, please ensure the system is in standby mode, and then loosen the reagent bottle cap and take out the tube vertically;
2. Take away the empty bottle, remove the new reagent bottle cap, and then lock that cap with empty reagent bottle;
3. Put the new reagent bottle on reagent holder, put the liquid tube into new reagent bottle and then lock it tightly;
4. Execute “System Cleaning” at service page;

NOTE

- To avoid cross contamination and unstable test results, Adding reagent directly by pouring without change bottle is strictly prohibited;
- Every time to replace specific reagent, the operator need to select the proper reagent pack and reset it accordingly;
- After chromatography column replacement or accident power off during test or emergency stop, please ensure to execute “System Cleaning” after instrument power on again.

10.2.7 CHROMATOGRAPHY COLUMN REPLACEMENT

For every 1500 sample tests, the system need to replace a new chromatography column.

1. Open the right door of the analyzer, find the chromatography column module, unlock the holder and open the cover.
2. Take out the column, unscrew it anticlockwise;
3. Remove the brown blocker of new column, put the column as the liquid direction horizontally;
4. Put the new column on the holder, place the both liquid lines into slots. Close the cover and lock the column holder;
5. Enter service page, input the column Lot No.;
6. Press “Reset” to reset the column, the “Test No.” will change to 0 and “Available No.” will change to 1500.

10.2.8 FILTER REPLACEMENT

For every 400 sample tests, the system need to replace a new filter.

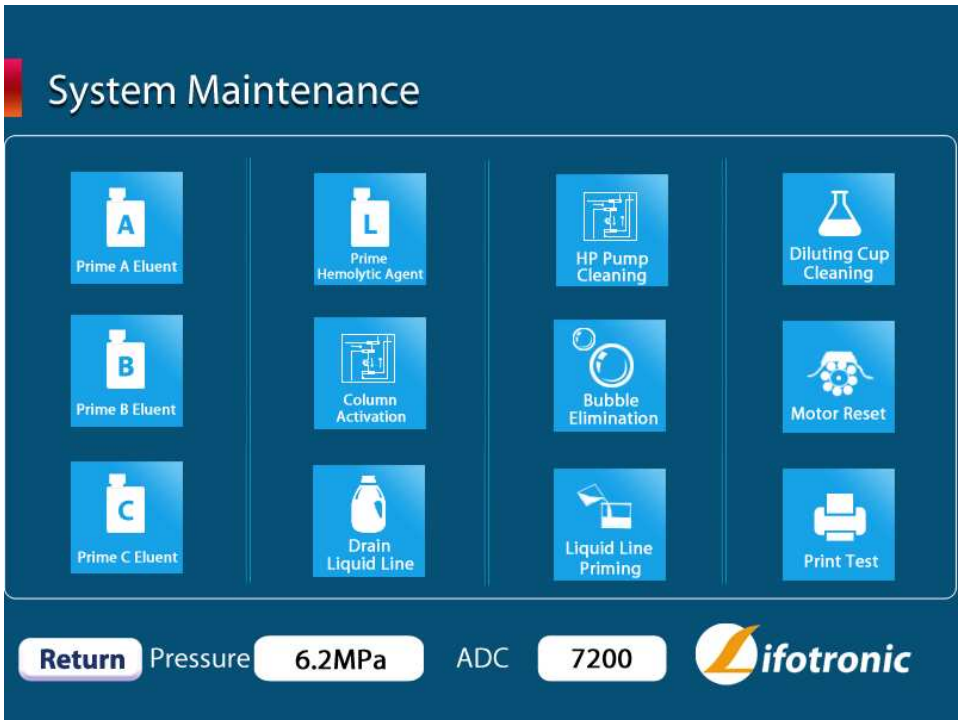
1) Open the right door of the analyzer, find the filter module on the top left;
2) Unscrew the cross type switch anticlockwise;
3) Remove the used filter to replace a new one;
4) Screw the cross type switch tightly clockwise;
5) Execute Prime A Eluent, observe whether there is leaking from the filter switch. If there is leaking, please screw the switch more tightly;
6) Press “Reset” to reset the filter, the “Test No.” will change to 0 and “Available No.” will change to 400.

10.2.9 RESET REAGENT

Enter service page, choose appropriate reagent pack, and then press “Reset A/B/C/L” to reset them accordingly.

10.3 SYSTEM MAINTENANCE

Press "System Maintenance" to enter the interface below:



Picture 10-2 System Maintenance

10.3.1 PRIME A ELUENT

Press "Prime A Eluent" to prime liquid line 1 minute by A eluent.

10.3.2 PRIME B ELUENT

Press "Prime B Eluent" to prime liquid line 1 minute by B eluent.

10.3.3 PRIME C ELUENT

Press "Prime C Eluent" to prime liquid line 1 minute by C eluent.

10.3.4 PRIME HEMOLYTIC AGENT

Press "Prime Hemolytic Agent" to dispose 5mL hemolytic agent by the plunger pump.

10.3.5 COLUMN ACTIVATION

After each column replacement, “Column Activation” should be done before test.

Please a whole blood sample without cap into STAT position, enter “Service” page and choose “System”, click “Column Activation” and wait till it finished.

10.3.6 DRAIN LIQUID LINE

If it needs to drain the inner fluid, please disconnect the lines that connect with A/B/C eluent and hemolytic agent, then press "Drain Liquid Line". The system will run drain program that will last about 8 minutes.

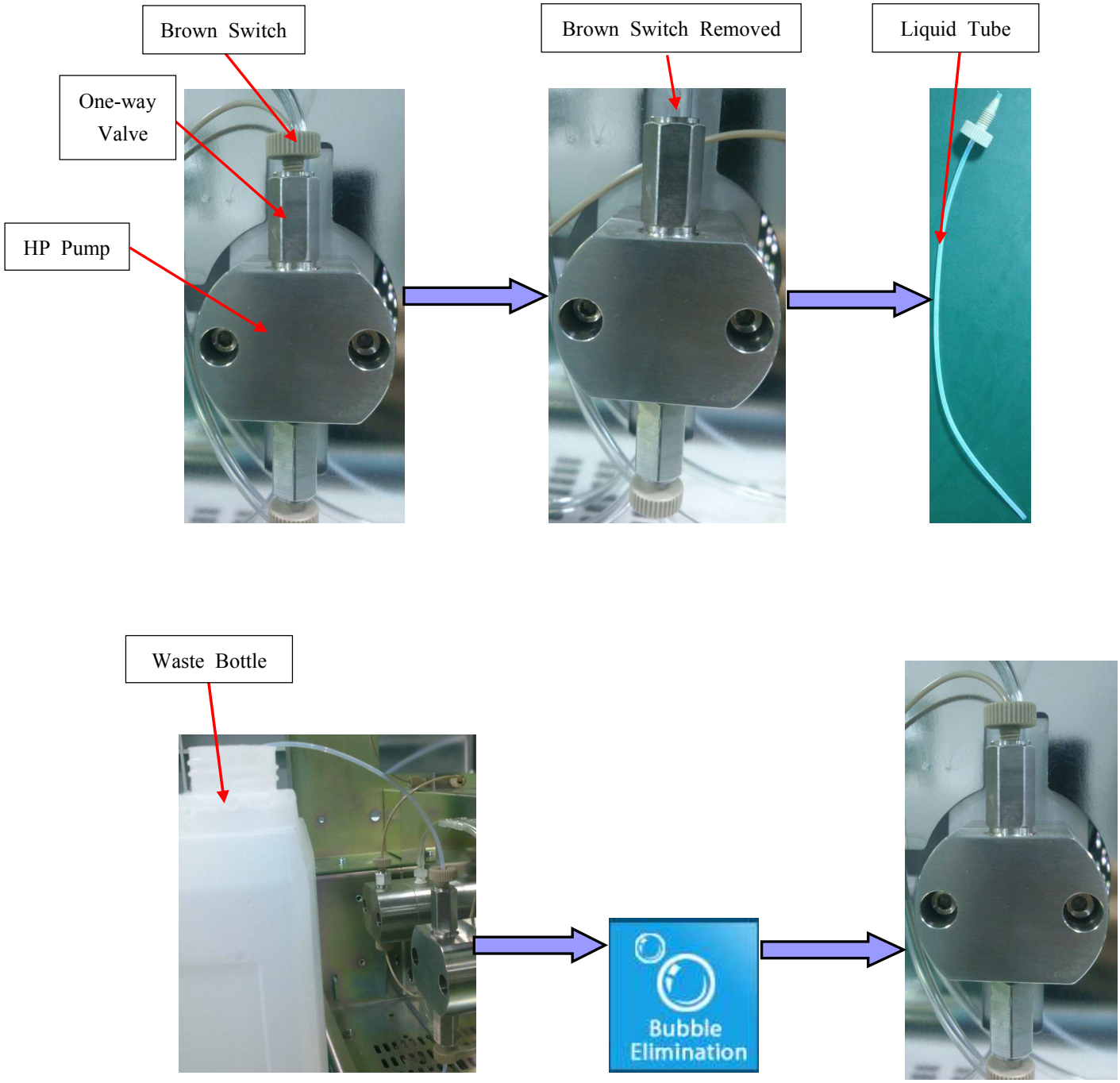
10.3.7 HIGH PRESSURE PUMP CLEANING

Press "HP Pump Cleaning", system will clean the high pressure pump with hemolytic agent. It will last 1 minute.

10.3.8 BUBBLE ELIMINATION

The existence of bubbles in cuvette will seriously affect the stability and reliability, and pressure can't be between 5-12MPa while the hemolytic agent stop moving. The instrument will alarm for "Pressure too low". Under this situation, bubbles must be eliminated.

1) Unscrew the brown connection switch (Anticlockwise) of high pressure pump;
2) Use the waste liquid tube to connect from one-way valve to waste bottle;
3) Execute "Bubble Elimination";
4) After "Bubble Elimination", remove the liquid tube, screw the brow connection switch clockwise, and then "Prime A Eluent";
5) The pressure will return to 5-12MPa in about 1 minute.



Picture 10-3 Bubble Elimination Procedure

10.3.9 LIQUID LINE PRIMING

When the Analyzer was installed firstly or reuse after draining the liquid line, Press "Liquid Line Priming" to prime the whole liquid line. About 8 minutes later, on the top of the screen will show "Complete Priming, Please Observe ADC Value! ". Operator should observe the ADC value carefully. If bubbles still exist, please execute “Prime A Eluent” 4-5 times.

10.3.10 DILUTING CUP CLEANING

Lifotronic recommend to clean the diluting cup once a month.Aspirate 1.5ml Sodium hypochlorite solution into EP tube, put the EP tube into STAT position, press "Diluting Cup Cleaning". The instrument will aspirate the solution to clean the diluting cup automatically.

10.3.11 MOTOR RESET

Press "Motor Reset", to reset motor (pack up sample probe to the inner of the Analyzer).

10.3.12 PRINTER TEST

After installing printer paper, press "Printer Test". System will print out the content below: "********Lifotronic*********".

10.4 SERVICE MAINTENANCE

10.4.1 DAILY MAINTENANCE

Check each bottle’s remaining reagent and waste bottle, replace reagent and empty waste bottle in time;

Execute QC daily after Power On Self Test and System Cleaning(automatically).

Clean sample rack and sample loader;

10.4.2 MONTHLY MAINTENANCE

1. Surface Cleaning:

Clean the instrument surface with a wet cloth or sponge.

Do not use corrosive detergent, if necessary, use diluted soap solution to clean the surface. And then clean with a wet cloth or sponge.

2. Interior Cleaning:

Use soft tissue or cloth to clean the liquid on interior from bottom to top, tighten all the connector may be leaking;

3. Clean Sampler Belt:

Use wet soft cloth or sponge to clean the sampler belt;

4. Clean Diluting Cup:

Clean diluting cup once a month. Inject 1.5mL 5‰ sodium hypochlorite solution an EP tube, and put the EP tube with holder into STAT position, enter System Maintenance page, press “Diluting Cup Cleaning” to clean;

5. Sample Probe Cleaning:

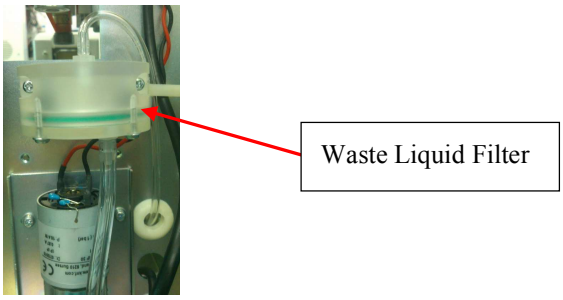
Clean the sample probe once a month. Open the front cover, use soft cloth or sponge with 5‰ sodium hypochlorite solution to clean it.

10.4.3 OTHER MAINTENANCE

1. Waste Liquid Filter Maintenance:

Open the rear cover, execute “Prime Hemolytic Agent”; When diaphragm pump working, there is

blocking happened, the waste liquid filter needs to be replaced. Lifotronic recommend to replace it every 6 months.

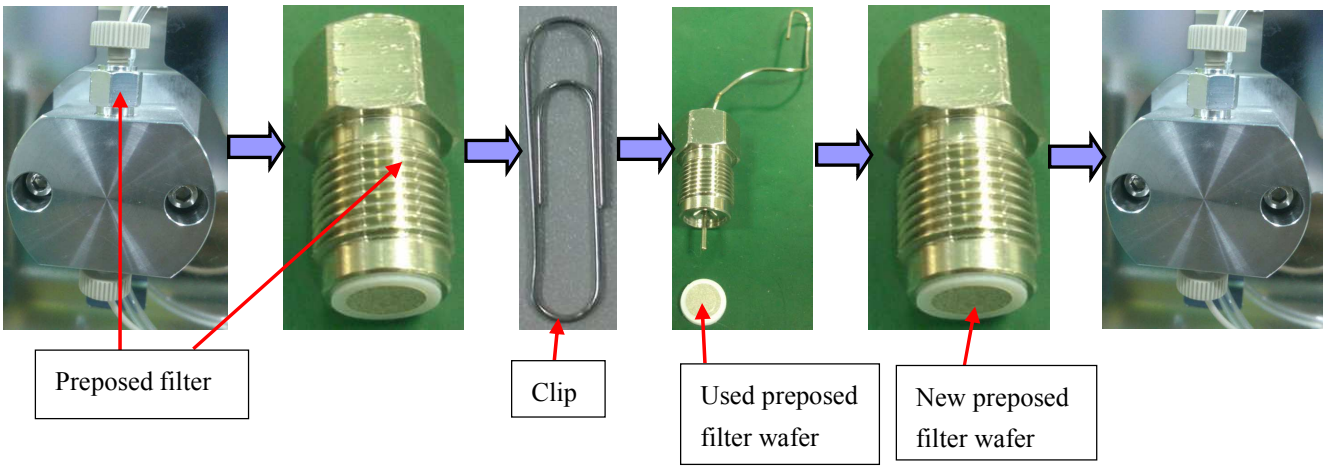


Picture 10-4 Waste Liquid Filter

2. Preposed Filter Maintenance:

Open right door, execute “Prime A Eluent”, if there are large noise from high pressure pump, the preposed filter disc needs to be replaced. Lifotronic recommend to replace it every 6 months.

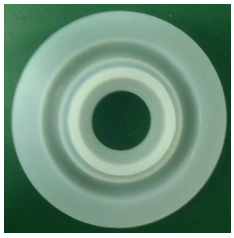
1) Unscrew brown switch (anticlockwise) of the preposed filter;
2) Use twisted clip to push out the preposed filter wafer;
3) Press a new preposed filter wafer into the filter;
4) Screw the preposed filter tightly and brown switch (Clockwise).



Picture 10-5 Replace Preposed Fitler Wafer Procedure

3. HP Pump Cleaning Tank Gasket Maintenance:

Open right door, and check whether there are bubbles in liquid line connected to high pressure pump cleaning tank. If yes, the white teflon cleaning tank gasket needs to be replaced. Lifotronic recommend to replace it every 12 months.



Picture 10-6 High Pressure Pump Cleaning Tank Gasket

4. Z Axis Belt Maintenance:

Open the front cover, check the attrition rate of Z Axis belt and ponders under the belt. Clean the ponders with wet cloth. If Z Axis belt damaged too much, please replace it. Lifotronic recommend to replace it every 2 years.

CHAPTER 11 TROUBLESHOOTING

In this chapter we introduce possible failures and malfunctions and provide trouble shootings methods.

WARNING

When repairing and fixing, shut down the power! It may damage electrical components with Analyzer on!

CAUTION

- In case of inaccurate test results, be sure to analyze samples after troubleshooting when faulty alarms appear.

NOTE

- This manual can't be considered as repair manual. Only can be use for basic troubleshooting when faulty alarm appears.



- Sample, QC material, calibrator, chromatography column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipments (Safe clothing, gloves) when contacting lab articles.

11.1 FAULTS AND TROUBLESHOOTING

If there is a fault phenomena listed in the table below before or during use, please refer to the relevant troubleshooting steps to removal. if the fault persists, please contact Service Department of Lifotronic.

Faults	Cause	Troubleshooting Steps
Analyzer fails to run after switch on the power	1. Linkage fault 2. Adapter broken 3. AC outlet no power	1. Examine power cord connection 2. Check whether adapter indicator lights 3. Confirm electric power supply
Fluid leakage	1. High-pressure pump is broken 2. Luer tapper is broken 3. Luer tapper aren't screwed tightly	1. Replace another high-pressure pump 2. Replace another Luer tapper 3. Tighten Luer tapper 4. Replace another filter

	4. Filter is blocked 5. Connection between chromatography column, filter becomes loose	5. Screw down filter and column
Printer fails to work	1. Out of paper 2. Paper jam 3. Electrical circuit is broken	1. Prepare papers 2. Removal the jammed paper 3. Enter system maintenance, press "Printer Test". If test fails, replace for another PCB or thermal printer
Sample loader fails to rotate or rotated position is not in place	1. Poor contact of the positioning sensor signal line or motor 2. Positioning sensor broken 3. Motor failure	1. Pull out/in connecting line again 2. Change for another sensor 3. Change for another motor
Touch screen input abnormal	1. Touch screen was installed tightly 2. Touch screen broken	1. Loosen the screws 2. Change for another screen
High-pressure pump does not rotate	1. Poor contact of motor signal line 2. Motor failure 3. Mainboard broken	1. Pull out/in connecting line again 2. Change for another motor 3. Change for another mainboard
Test result is 0%	1. There are bubbles, or flocs in blood 2. Software process error	1. Shake the blood collection tube and then put it to test again 2. Contact Service Department to update software

11.2 SYSTEM CHECKOUT INFORMATION AND TROUBLESHOOTING

In the process of operation, if system detects abnormal conditions, it will indicate corresponding prompt message and sound continued "De-de-de". Operator should solve these problems according to the troubleshooting methods in this section. If problems persist, please contact Service Department of Lifotronic for solutions.

Faults	**Cause**	**Troubleshooting Steps**
Real-time clock fault	1. LCD screen battery had be pulled out 2. Poor contact of battery, or invalid battery	1. Press "Settings"→"Time & Date", reset the time 2. Change for another battery
Plunger pump fault	1. Poor contact of the positioning sensor signal line or motor	1. Pull out/in connecting line again 2. Change for another sensor

	2. Positioning sensor broken 3. Motor broken 4. Pump core get stuck	3. Change for another motor 4. Open the rear side door to check whether the pump core reaches to top. If so, press "Service" –"System Maintenance", and run "Prime Hemolytic Agent" program
2D arm	1. Sample probe get stuck 2. Poor contact of the positioning sensor signal line or motor 3. Positioning sensor broken 4. Motor broken 5. Result is 0 6. 2D arm gets stuck and errors	1. Open the right side door and check whether sample probe has been stuck 2. Pull out/in connecting line again 3. Change for another sensor 4. Change for another motor 5. Sample probe don't absorb blood, it needs to adjust Z axle 6. 2D arm is outside and cannot reset, it just need push it to the normal range

11.3 OPTICAL SYSTEM FAULTS AND TROUBLESHOOTING

If test ADC value abnormal during operation, operator should troubleshoot according to the steps below. If the problem persists, please contact Service Department of Lifotronic for solutions.

Faults	Cause	Troubleshooting Steps
ADC value is 0	1. Bad contact of ADC detection board or LED board signal lines 2. ADC detection board broken 3. LED board broken	1. Pull out/in connecting line again 2. Change for another ADC detection board 3. Change for another LED board
ADC value keeps above 9,000	1. LED value is set too high 2. ADC detection board broken 3. Bubbles in the colorimetric cell	1. Lower LED value manually 2. Change for another ADC detection board 3. Execute "Prime A Eluent" 4-5 times, take out the colorimetric cell and flip it with finger to eliminate the bubbles.
ADC value cannot be stable at 5,000 to 9,000	Bubbles in the colorimetric cell	Execute "Prime A Eluent" 4-5 times, take out the colorimetric cell and flip it with finger to eliminate the bubbles.

11.4 OUTER CONNECTION FAULT AND TROUBLESHOOTING

In the process of testing, if outer component connections are abnormal, operator should troubleshoot according to the steps below. If the problems persist, please contact Service Department of Lifotronic for solutions.

Faults	Cause	Troubleshooting Steps

Communication fault	1. Communication connection becomes loose 2. Analyzer communication parameter isn't compatible with received end	1. Check whether the connections are correct 2. Modify software of received end referring to Appendix C Communication
Bar code scanner communication failure	1. Bar code scanner isn't connected properly 2. Connecting line between serial port board and mainboard becomes loose	1. Check whether bar code scanner has been connected correctly 2. Check whether connection between serial port board and mainboard is correct
Invalid bar code	1. Bar code scanner couldn't match 2. Invalid bar code data 3. Baud rate of bar code scanner is wrong	Please contact Service Department of Lifotronic

11.5 FAULTS OF REAGENTS, COLUMN OR FILTER AND TROUBLESHOOTING

In the process of testing, if faults of reagents, column and filter result in system malfunction, operator should troubleshoot according to the steps below. If the problems persist, please contact Service Department of Lifotronic for solutions.

Faults	Cause	Troubleshooting Steps
No hemolytic agent	1. Connecting tube of hemolytic agent has not reach into fluid 2. Hemolytic agent runs out	1. Check the connection 2. Check whether hemolytic agent has ran out
No A eluent	1. Connecting tube of A eluent has not reach into fluid 2. A eluent runs out	1. Check the connection 2. Check whether A eluent has ran out
No B eluent	1. Connecting tube of B eluent has not reach into fluid 2. B eluent runs out	1. Check the connection 2. Check whether B eluent has ran out
No C eluent	1. Connecting tube of C eluent has not reach into fluid 2. C eluent runs out	1. Check the connection 2. Check whether C eluent has ran out
Bubble appears	A/B/C eluent has been ran out or the tubes doesn't reach into the fluid	Check connection and the volume of reagents

Abnormal chromatogram	1. Liquid line blocked 2. filter or column becomes valid 3. Reagents become valid 4. Environment temperature is higher than 35℃ or lower than 10℃ 5. Bubbles form	1. Replace column and then rinse the system 2. Replace column or filter 3. Replace reagents 4. Adjust environment temperature to 10℃-35℃ 5. Eliminate bubbles
Test range exceeds 3%-18%	1. Liquid line blocked 2. filter or column becomes valid 3. Reagents become valid 4. Environment temperature is higher than 35℃ or lower tha 10℃ 5. Bubbles form 6. Use K3EDTA vacuum blood tube	1. Replace column and then rinse the system 2. Replace column or filter 3. Replace reagents 4. Adjust environment temperature to 10℃-35℃ 5. Eliminate bubbles 6. Change to K2EDTA vacuum blood tube
Error e1	1. Sampling too less or sampling nothing 2. No sample on the position	1. Retest after shaking up. Or use diluted blood to test 2. Put the sample to the right position and retest
Error e2	1. Sampling too much 2. Bubbles form	1. Retest after shaking up. Or use diluted blood to test 2. Retest after eliminating bubbles

11.6 FAULTS TABLE AND TROUBLESHOOTING

SN	Faults	Appearance	Possible Reason	Actions
1	Z Axis Sensor Error	Z Axis can not return to default position	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
2	X Axis Sensor Error	X Axis can not return to default position	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
3	100ul Plunger Pump Error/5ml Plunger Pump Error	1．Plunger pump block; 2．Plunger pump can’t return up to default position.	1．Motor connection cable loosen; 2．Motor broken; 3．Sensor connection cable loosen;	1．Check whether motor cable properly connected, and reconnect it; 2．Replace the motor; 3．Check whether sensor cable properly connected, and reconnect it;

			4．Sensor broken	4．Replace the sensor.
4	Autosampler Left Front Sensor Error	1．Front motor can’t move to left; 2．Front motor keeps moving to left.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
5	Autosampler Right Front Sensor Error	1．Front motor can’t move to right; 2．Front motor keeps moving to right.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
6	Autosampler Front Motor Error	1．Front motor can’t move; 2．Front motor move to reverse direction	1．Motor connection cable loosen; 2．Motor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the motor.
7	Autosampler Left Back Sensor Error	1．Back motor can’t move to left; 2．Back motor keeps moving to left.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
8	Autosampler Right Back Sensor Error	1．Back motor can’t move to right; 2．Back motor keeps moving to right.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
9	Autosampler Back Motor Error	1．Back motor can’t move; 2．Front motor move to reverse direction.	1．Motor connection cable loosen; 2．Motor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the motor.
10	Autosampler Left Front Sensor Error	1．Front motor can’t move to right; 2．Front motor can’t move to left.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
11	Autosampler Left Back Sensor Error	Back motor can’t move to left for sample aspiration.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.

12	Autosampler Right Front Sensor Error	Front motor can't move to right	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
13	Autosampler Right Back Sensor Error	1．Back motor can't move to left; 2．Back motor move to left without rack.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
14	Autosampler Rack Locating Sample Sensor Error	Back motor load first sample rack can't match default position	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
15	Autosampler Rack Regular Sample Sensor Error	1．The instrument can't detect sample tube; 2．The instrument aspirate from empty tube.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
16	Autosampler Rack Hall Sensor Error	1．The instrument can't detect diluted sample tube; 2．The instrument aspirate diluted sample method from regular sample position.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
17	Autosampler STAT Position Sensor Error	1．The instrument can't detect sample tube; 2．The instrument aspirate from empty tube.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
18	Autosampler STAT Position Hall Sensor Error	1．The instrument can't detect diluted sample tube from STAT position; 2．The instrument aspirate diluted sample method from STAT position as regular sample tube.	1．Sensor connection cable loosen; 2．Sensor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the Sensor.
19	Autosampler Left Motor Error	1．Left motor fail to move; 2．Left motor move to wrong direction.	1．Motor connection cable loosen; 2．Motor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the motor.

22	Autosampler Right Motor Error	1．Right motor fail to move; 2．Right motor move to wrong direction.	1．Motor connection cable loosen; 2．Motor broken.	1．Check whether cable properly connected, and reconnect it; 2．Replace the motor.

11.6.1 E1 ERROR(ASPIRATION TOO LOW)

Chromatogram total area ideally should be 5-20, trustful total area would be 5.5-12. If total area <5, usually it's anemia patient's sample whose red blood cell density is low. Lifotronic suggest to use dilution ratio>300 to retest.

11.6.2 E2 ERROR(ASPIRATION TOO MUCH)

Chromatogram total area ideally should be 5-20, trustful total area would be 5.5-12. If total area >15, usually it's a precipitated sample whose red blood cell density is high. Lifotronic suggest to reduce dilution ratio or shake the blood well to retest.

11.6.3 PEAK TIME EXPLANATION

HbA1c peak time ideally should be 25-42 seconds, trustful peak time would be 30-35 seconds. Flow speed of HP pump, temperature , tested no. of chromatography column , and ion balance status of column will affect the peak time.

The flow speed be faster, the peak time will be shorter ; The flow speed be slower, the peak time will be longer. The system allow the lowest flow speed is 1.5ml/min, default setting is 1.6ml/min.

The column temperature be higher, the peak time will be shorter; The column temperature be lower, the peak time will be longer. Every 2℃ difference, peak time will be 1 sec difference, default setting is 35±1℃.

The tested no. be more, the peak time be shorter; The tested no. be less,the peak time be longer;

The column's Na Ion density be higher, the peak will be shorter; The column's Na Ion density be lower, the peak will be longer;

The peak time be shorter, original value will be larger; The peak time be longer, original value will be smaller;

Chromatography column default peak time will be 30-35 seconds within 1,500 tests. If there are obvious peak time deviation, it will need to reset the column temperature and calibrate the system. Please contact Lifotronic or Lifotronic distributor for assistance.

11.6.4 TEST RESULT FAILED TO MATCH CLINICAL EVIDENCE

Hemolytic anemia, hemorrhagic anemia, cirrhosis, splenomegaly, chronic renal failure, and chronic persistent hypoglycemia patients' blood sample may have low test results;

Chronic renal failure patients use of glucose dialysate for hemodialysis, kidney disease, chronic alcoholism, thalassemia, leukemia, and postsplenectomy patients' blood sample may have high test results.

Please contact Lifotronic or Lifotronic distributor for more assistance.

Appendix A Specification

A.1 PRODUCT CLASSIFICATION

H9 could be classified by the standard below:

China Medical Equipment Management Classification:

Belong to clinical analytical instrument hematology system, Class Ⅱ

A.2 REAGENT KIT

A eluent, B eluent, C eluent and hemolytic agent

A.3 CHROMATOGRAPHY COLUMN, FILTER

Designated Chromatography Column, filter

A.4 QC MATERIAL

Designated QC material

A.5 CALIBRATOR

Designated calibrator

A.6 POWER INPUT

- Voltage：a.c.100V—240V
- Frequency：50/60Hz
- Input Power：120VA

A.7 WORKING ENVIRONMENT

- Environment Temperature：10℃～35℃
- Humidity：≤80%（no condensation)
- Air Pressure：75kPa～106kPa
- No frost, condensation, water seepage, wet and sun

A.8 STORAGE TEMPERATURE

- Environment Temperature：0℃~55℃；
- Humidity：≤93%；
- Air Pressure：75kPa～106kPa
- Storage Place：Instrument should be stored in well-ventilated, and does not allow acidic, alkaline, and other harmful gases indoor.
- Storage Lift：No more than 1 year

A.9 DIMENSIONS

- Length：44cm

- Width：34cm
- Height：45cm

A.10 WEIGHT

45kg

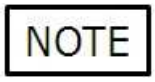
A.11 LIFE SPAN

Life span is 5 years. More than 5 year service life of the machine shall be processed in accordance with relevant laws and regulations, please contact the manufacturer or dealer for more information.

Appendix B Safety Information

B.1 BRIEF DESCRIPTION

In this manual we use the symbols below for the information that needs attention or is hazardous

Symbol	Meaning
	Remind operator to follow the steps under this symbols, otherwise it will result in personal injury
	Remind operator to follow the steps under this symbols, otherwise it will result in product failure, damage and inaccurate results.
	Remind operator to follow the steps under this symbols, emphasize important/critical information or steps in the manual
	Remind operator to follow the steps under this symbols, otherwise it has bio-infectious risk.

B.2 WARNING



- DO NOT operate in flammable and explosive environment
- The Analyzer must be used in a good grounding condition
- Make sure input voltage meet the requirements.
- Make sure the switch is off ("○") before connecting power cord of adapter
- Operator should wear on gloves and avoid direct contact with sample probe. Because sample probe is sharp, sample loader, sample probe, Chromatography Column, filter may carry with blood and QC material and calibrator is bio-hazard.
- The cloths, hair and hands should keep a certain distance from moving parts like sample probe and sample loader, in case of crushing or stabbing
- Operators are in duty to bound to local laws and regulations about disposing overdue reagents, waste liquid, waste samples and consumables
- Reagents may irritate eyes, skin and mucous membranes. Operators ought to comply with safety regulations and wear on personal protective equipments (like protective clothing, gloves).
- Once the reagent contact with skin, wash immediately with plenty of water, if necessary, please seek medical treatment; Once the reagent contact with eyes, rinse immediately with plenty of water and seek medical treatment.
- DO NOT contact blood sample directly.
- DO NOT place sample or touch sample loader when sample loader turning or sample probe aspirating, in case of failure or malfunction.

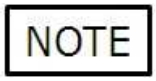
- When repairing and fixing, shut down the power! It may damage electrical components with Analyzer on!
- Operation of the instrument should be conducted by the personnel that received formal training, or master safe operation skills. For clinical trials, the instrument should be used in charge of personnel management or clinical management personnel.
- To prevent electrical shock and / or equipment damage, operator should not open three covers of the instrument. Only maintenance staff can be allowed to complete instrument maintenance or repair.
- If the instrument's door open, DO NOT repair with the instrument power on. Powered touch internal circuit will cause injury.
- Instrument installation must be equipped with reliable power outlet to ensure electrical safety.
- Anomalies appear in the power-on or during operation, the operator should immediately turn off the power, and check by a qualified professional service personnel before re-power operation.

B.3 CAUTION



- It might damage the device to unpack and install without authorized or trained personnel. So do not unpack or install the device without present of one authorized or trained personnel.
- DO NOT reuse disposable supplies
- If room temperature exceeds the normal working temperature range of the Analyzer, the testing results will be unreliable
- Improper maintenance may damage the Analyzer. Operator must follow the guidance manual for maintenance.
- If you encounter problems that there is no clear instructions, please contact Service Department of Lifotronic. Designated professionals will offer maintenance advises.
- Must use components and parts that provided by Lifotronic for maintenance. Any questions, please contact Service Department of Lifotronic.

B.4 NOTE



- This manual is for and only for:

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

- H9 Analyzer is a diagnosis device that is used for disease screening. When diagnosing disease, clinicians should take clinical examination results or other test result into consideration.
- Refer to the user manual of reagent to see how to use and store reagent

- After replace eluent, Chromatography Column, filter or hemolytic agent, the operator should rinse the system to ensure ADC value in normal range
- Ensure use reagents, Chromatography Column, filter before expiration date
- Stand the reagents before use, to make it stable
- If room temperature exceeds normal operating temperature range, the obtained results will be inaccurate
- The Analyzer must be placed on a sturdy and horizontal table, not placed on a slope.
- Please keep the packing box, in order to pack the Analyzer when moving a long distance.
- Must use specified reagent kits
- Cover the bottles after reagents and the Analyzer connected, in case of contamination
- Operator should run POST and Self-cleaning program every day. Otherwise it may lead to malfunctions that can't be found or wrong results.
- Operator should wear on gloves for safety operation due to the biohazard of column and filter.
- There might be reagents that soaked cChromatography Column, filter dropping on the device and operating desk. So please prepare tissue for cleaning.
- Operator should use clean K2EDTA anticoagulant vacutainer, siliconized glass/ plastic tubes, EP tubes and 20uL Borosilicate glass capillary.
- It's recommended that operator uses oscillator to shake t blood collection tube or prediluted EP tube. Otherwise it may influence testing result.
- If there are bubbles or flock in the blood of blood collection tube, sample probe can not aspirate blood sample. It might result in 0% result. Once it appears, shake the tubes thoroughly and test it again.
- The maximum length of the sample ID number 15, if it exceeds 15, the Analyzer will default before 15 as the current ID number
- Samples should be placed consecutively (one by one). DO NOT leave space between Start and End position. Otherwise, the result of blank position will be shown as 0%.
- Once data has been deleted, they can't be recovered. It's recommended to print or keep data backup by connecting to computer with RS232 serial port line. Contact the manufacturer and authorized distributors for backup software.
- The length of lot Nos. is 15. If exceeding, the system will default the first 15 numbers as current lot No..
- Once lot Nos. being changed, all the original QC data will be overwritten. It's recommended to print or keep data backup by connecting to computer with RS232 serial port line. Contact the manufacturer and authorized distributors for backup software
- Operator should use specific QC material designated by Lifotronic. Lifotronic takes no responsibility for inaccurate QC result by using any other QC materials
- Refer to QC material user manual for its usage and storage methods
- If bubbles form during QC test, the system will set related parameter to no avail and alarm. See Chapter 11 for how to solve this problem.

- If room temperature exceeds normal working temperature range, obtained results may be unreliable.
- Only after the Analyzer calibrated, can the measured data be used as valid data
- Operator should use specific calibrator designated by Lifotronic. Lifotronic takes no responsibility for inaccurate calibration result by using any other calibrators
- Refer to calibrator user manual for its usage and storage method
- The factor range is 0.0001～9.9999，and offset range is -9.9999～9.9999. Default as 1 integer place and 4 decimal places. The Analyzer will indicates an error if beyond the ranges.
- Operator must use designated and specific Chromatography Column, filter. Lifotronic takes no responsibility for inaccurate test results by using any other Chromatography Column, filter.
- Before unsealing the Chromatography Column, filter unsealed, operator should check whether the packaging is damaged. If damage results in Chromatography Column, filter unusable, please contact Service Department of Lifotronic immediately.
- Do not allow the sample to remain in the pipeline for a long time, especially in chromatography columns. Liquid Line Priming after every test. DO NOT shut down the system during test. If abnormalities appear, clean the system before test! when not in use lines and chromatography must be filled with reagents.
- When the instrument is operating, DO NOT touch sensitive components such as optical systems and other devices, otherwise it will cause measurement error results

B.5 BIO-HAZARD



- Sample, QC material, calibrator, Chromatography Column, filter and waste liquid are bio-hazardous! Operator should comply with laboratory safe regulations and wear on personnel protective equipments (Safe clothing, gloves) when contacting lab articles.
- Surface of all the assembly units of H9 are bio-hazard, please take safety and protective measures when operating and maintaining.
- Sample loader, sample probe, Chromatography Column, filter might be contaminate by blood. QC material and calibrator are bio-hazardous! Operator should wear on gloves while operating and avoid direct contact with sample probe.

Appendix C Communication

C.1 RS232 COMMUNICATION PARAMETERS

- Baud Rate：115200
- Stop Bit：1
- Data Bit：8
- Odd-even Check：No
- Hardware Flow：No
- Software Flow：No
- Connection way of serial line：Direct connection

C.2 COMMUNICATIONS INSTRUCTIONS

Code

【STX】 0x02

【ETX】 0x03

"S" 0x53

"Q" 0x51

"C" 0x43

"#" 0x30-0x39

"*" 0x2A

"-" 0x2D

"+" 0x2B

"." 0x2E

Blood type codes have the following meanings:

Code	Meaning
0x30	Venous Blood
0x31	Diluted Blood
0x32	QC Material
0x33	Calibrator

Error codes have the following meanings:

Code	Meaning
0x30	No error
0x31	E1 error code, sampling too less
0x32	E2 error code, sampling too much

C.3 SAMPLE DATA FORMAT

Data start flag 【STX】

Data block specifier	"S" stands for normal sample, "Q" stands for QC material, "C" stands for calibrator
Version No.	##
Number of parameters	##
Parameter description format number	##
Code length	##
Sample ID.	###############
Sample rack No.	####
Sample rack position	## or "ST"
Running No.	####
Blood type	#
Year	##
Month	##
Day	##
Hour	##
Minute	##
Second	##
HbA1a appearance time	##
HbA1b appearance time	##
HbF appearance time	##
LA1c appearance time	##
HbA1c appearance time	##
HbA0 appearance time	##
HbA1a absorbance	#.####
HbA1b absorbance	#.####
HbF absorbance	#.####
LA1c absorbance	#.####
HbA1c absorbance	#.####
HbA0 absorbance	#.####
HbA1a peak area	##.###
HbA1b peak area	##.###
HbF peak area	##.###
LA1c peak area	##.###
HbA1c peak area	##.###
HbA0 peak area	##.###
HbA1a peak area ratio	##.##
HbA1b peak area ratio	##.##
HbF peak area ratio	##.##
LA1c peak area ratio	##.##

HbA1c peak area ratio	##.##
HbA0 peak area ratio	##.##
HbA1c content in IFCC	###.#
Average blood glucose concentration in ADAG(mmol/L)	##.#
Average blood glucose concentration in ADAG(mg/dl)	###.#
Sent chromatographic curve number	###
Sent chromatographic curve values	#.####
Test error code	#
Data end flag	【ETX】

C.4 QC DATA FORMAT

Data start flag	【STX】
Data block specifier	"Q"
Lot No. length of low level QC material	##
Lot No. of low level QC material	###############
Lot No. length of high level QC material	##
Lot No. of high level QC material	###############
Low level QC target value	##.#
High level QC target value	##.#
Low level SD value	#.##
High level SD value	#.##
Low level QC material expiration date Year	##
Low level QC material expiration date Month	##
Low level QC material expiration date Day	##
High level QC material expiration date Year	##
High level QC material expiration date Month	##
High level QC material expiration date Day	##
Tested number of QC material	##
Low level QC material test value	##.##
High level QC material test value	##.##
Low level QC material average value	##.##
High level QC material average value	##.##
Low level QC material SD value	#.####
High level Qc material SD value	#.####
Low level QC material CV	##.##
High level QC material CV	##.##
Data end flag	【ETX】

C.5 CALIBRATION DATE FORMAT

Data start flag	【STX】
Data block specifier	"C"
Lot No. length of low level calibrator	##
Lot No. of low level calibrator	###############
Lot No. length of high level calibrator	##
Lot No. of high level calibrator	###############
Low level calibrator concentration	##.#
High level calibrator concentration	##.#
Current calibration factor K	#.####
Current calibration offset b	+#.#### or -#.####
Current calibration date Year	##
Current calibration date Month	##
Current calibration date Day	##
Data end flag	【ETX】

Electromagnetic compatibility

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below,The customer or the user of the device should ensure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function.Therefore,its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The device is suitable for use in all establishments,including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Group A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below.The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic Discharge(ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood,concrete or ceramic tile.If floors are covered with synthetic material,the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power Supply lines ±1 kV for input/output lines	±2kVfor power Supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or a hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or a hospital environment.

Voltage dips,short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95%dip in U_T) FOR 0,5cycles 40% U_T (60% dip in U_T) for 5 cycles <5% U_T (>95%dip in U_T) for 5 sec	<5% U_T (>95%dip in U_T) FOR 0,5cycles 40% UT (60% dip in U_T) for 5 cycles <5% U_T (>95%dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or a hospital environment.If the user of the device requires continued operation during power mains interruptions,it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below.The customer or the user of the device should ensure that it is used in such an environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vms 150kHz to 80 MHz 3Vms 80MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device ,including cables,than the recommended separation distance calculate from the equation applicable to frequency of the transmitter. **Recommended separation distance** **$d=1.2\sqrt{P}$** **$d=1.2\sqrt{p}$ 80MHz to 800MHz** **$d=2.3\sqrt{p}$ 800MHz to 2.5 GHz** where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter distance in metres(m). Field strengths from fixed RF transmitters,as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol

NOTE 1 At 80 MHz and 800 MHz,the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations.Electromagnetic propagation is affected by absorption and reflection from structures,objects and people.

[a] Field strengths from fixed transmitters,such as base stations for radio(cellular/cordless)telephones and land mobile radios,amateur radio,AM and FM radio broadcast and TV broadcast cannot be predicated theoretically survey should be considered.If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above,the Medical device should be observed to verify normal operation.If abnormal performance is observed,additional measures may be necessary,such as reorienting or relocating the device .

[b] Over the frequency range 150 kHz to 80 MHz,field strengths should be less than [V_1] V/m.

Recommended separation distances between

Portable and mobile RF communications equipment and the Medical device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.The customer or the user of the Medical device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment(transmitters)and the device as recommended below,according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150kHz to 80 MHz $d = [\frac{3.5}{V1}]\sqrt{P}$	80MHz to 800MHZ $d = [\frac{3.5}{E1}]\sqrt{P}$	800MHz to 2.5 GHz $d = [\frac{7}{E1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.37
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above,the recommended separation distance *d in* meters(m) can estimated using the equation applicable to the frequency of the transmitter,where *p* is the maximum output power rating of the transmitter in watts(W)according to the transmitter manufacturer.

NOTE 1 AT 80 MHz,the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations.Electromagnetic propagation is affected by absorption an reflection from structures,objects and people.

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