User Manual

(rev: 1.0)

Note

Thanks for using Automatic 5-Part Hematology Analyzer,

Please read this instruction carefully before using, in order to make sure that use it properly. Please keep the instruction properly after use.

Product Name : Automatic 5-Part Hematology Analyzer

Trade Name: Automatic 5-Part Hematology Analyzer

Model Number : C C 2 3 0 5 1 2 0 1

Manufacturer : China Care Medical Equipment Co.,Ltd

Information of user manual

P/N:

Ver.:1.0

Prepared date:

Copyright

Statement

CHINA CARE MEDICAL has the right of final interpretation of this statement :

- Only when all the following requirements are met can the company consider itself responsible for the safety, reliability and performance of the product.
- Assembly operations, expansion, adjustment, improvement and repairing should be appointed by SINGUWAY and distributors.
- All spare parts, accessories and consumables are supplied by SINGUWAY or any alternatives are approved by the CHINACARE.
- Relevant electrical equipment should meet the national standards and the requirements of this instruction.
- All operations should follow the instruction .

Maintenance and Service

The products purchased are guaranteed free of charge for one year from the date of installation. However, the damage caused by the following circumstances is not included in the free maintenance :

- The use environment does not meet the specifications ;
- Damage caused by failure of use specified power supply or abnormal power supply ;
- Man-made damage ;
- Damage caused by maintenance by unauthorized personnel of manufacturer ;
- Damage caused by other irresistible natural factors, such as earthquakes, fires, wars, etc.

If users have any questions, please contact the distributor or manufacturer at any time according to the following contact information . After the expiration of the warranty period, the company can continue to provide paid maintenance services .

After-sales service company

Email: i n f o @ c h i n a c a r e m e d i c a l . c o m

Website : https://www.chinacaremedical.com

WARNING

- This instrument is only allowed to operate by Singuway staff or the one who is appointed by distributor.
- Please use the analyzer under the condition that the instruction required. If the operation conditions violate the instruction, the analyzer may not work properly, the measurement results are unreliable, the analyzer components may be damaged and personal safety may be harmed.

Catalog

Chapter 1 Manual Overview

1.1 Overview

This chapter describes how to use the Automatic 5-Part Hematology Analyzer instruction manual. This manual comes with the instrument and provides detailed instructions on the use, functions and operational use of the instrument. Before using the analyzer, please read and understand its contents carefully to ensure that you can use the instrument properly, perform at its best, and ensure the safety of the operator.

1.2 Scope of application of the manual

This instruction manual is intended for medical laboratory professionals or trained physicians, nurses or laboratory technicians to read. For use by:

- Knowledge of the hardware and software of the Cellcount-60 Automatic 5-Part Hematology Analyzer.
- Setting system parameters.
- Performing daily operations.
- Perform system maintenance and troubleshooting.

1.3 Introduction to the manual

This manual contains 12 main chapters and one appendix. The operator looks for the appropriate chapter according to the information required.

When you need...	**Reference...**
Understand the purpose of the analyzer and the parameters to be measured	Chapter 2 System Overview
Understand the instrument composition and operating interface of the analyzer	Chapter2System Overview
Understanding the measurement principles and processes of analyzer applications	Chapter3Working Principle
Understanding the installation requirements of the analyzer	Chapter 4 Installation
Understanding the daily operation of the analyzer	Chapter5Daily Operations
Review of sample analysis results	Chapter6Reviewof Results
Understand the basic requirements of quality control and the quality control methods provided by the analyzer	Chapter 7 Quality Control
Understand the basic requirements for calibration and the calibration methods provided by the analyzer	Chapter 8 Calibration
Set date and time, parameter units and other system parameters	Chapter 9 Setting

Understand how to maintain and test the analyzer	Chapter 10 Services
Know the current usage status of the analyzer	Chapter 11 Status
Understand the causes of analyzer failures and how to deal with them	Chapter12 Troubleshooting
Understand the specifications of the analyzer	Appendix A Specifications

1.4 Manual conventions

All illustrations provided in this manual are for illustration purposes only and should not be used for other purposes. The graphics, settings or data in the illustrations may not exactly match the actual display you see on the Cellcount-60.

1.5 Security Information

The following symbols are used in this manual to indicate hazards or information that requires special attention.

Symbols	Meaning
	The operator is prompted to follow the instructions under the symbol, otherwise personal injury may result.
	The operator is prompted to follow the instructions under the symbol, as failure to do so may result in product failure, damage, or affect test results.
	Prompts the operator to follow the instructions under the symbol, emphasizing important information in the operation steps or content that requires the operator's special attention.
	The operator is prompted to follow the instructions under the symbol, otherwise there is a risk of potential biological contagion.

- All items (samples, reagents, controls, calibrators, waste liquids, etc.) and areas in contact with these substances are potentially bio-contagious. Operators should follow laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with relevant items and areas in the laboratory.
- In the event of a leak from the host, the leaking liquid is a bio-contagious hazard.

Warning

- Please be sure to respond and handle all alarms and trouble messages in a timely manner.
- Do not touch moving parts.
- If you find any damaged parts, please make sure to notify Singuway or your distributor in time.
- Please be careful when opening and closing and removing doors, covers and panels.
- Equipment scrapping must be handled in accordance with local regulations.
- Do not touch the patient's blood specimen directly.
- Operators are obliged to comply with the relevant regulations of their regions and countries regarding the discharge and disposal of expired reagents, waste liquids, discarded samples, consumables, etc.
- Reagents can irritate the eyes, skin and mucous membranes. Operators should observe laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with reagent-related items in the laboratory.
- In case of contact with skin, rinse immediately with plenty of water and receive medical attention if necessary; in case of contact with eyes, rinse immediately with plenty of water and receive medical attention.
- Clothes, hair, hands, etc. must be kept at a certain distance from the moving parts to prevent being caught by the moving parts.
- Avoid contact with the sampling needle, which has a sharp tip and may carry blood samples, controls and calibrators that are potentially biologically infectious.
- In the event of equipment failure requiring maintenance, the instrument surface and sampling needles and other biological risk components need to be disinfected and cleaned (75% alcohol wipe is recommended) to avoid biological contamination and other hazards during handling or maintenance.
- The protection provided by the equipment may be compromised if the equipment is not used in accordance with the manufacturer's prescribed methods.

Caution

- Be sure to use this equipment in strict accordance with the instructions in the user's manual.
- Please take appropriate measures to prevent contamination of reagents.

Attention

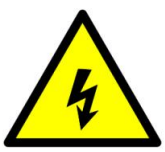
- The operator should use the reagents specified by the company and store and use them in strict accordance with the instructions for their use.
- Before using the analyzer, check to ensure that the reagents are properly connected.

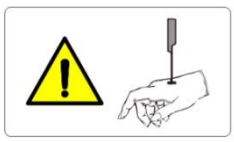
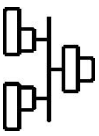
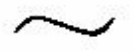
1.6 Symbols

- Symbols used in the instruction manual

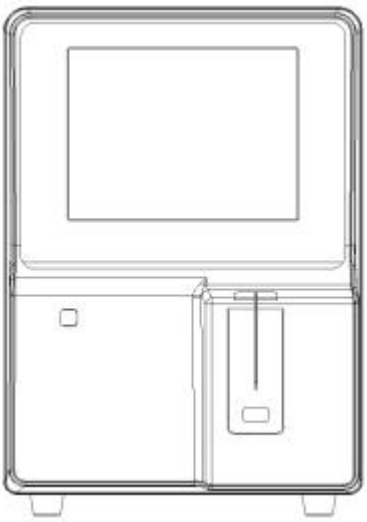
Symbols	Meaning
	The operator is prompted to follow the instructions under the symbol, otherwise personal injury may result.
	The operator is prompted to follow the instructions under the symbol, as failure to do so may result in product failure, damage, or affect test results.
	Prompts the operator to follow the instructions under the symbol, emphasizing important information in the operation steps or content that requires the operator's special attention.
	The operator is prompted to follow the instructions under the symbol, otherwise there is a risk of potential biological contagion.

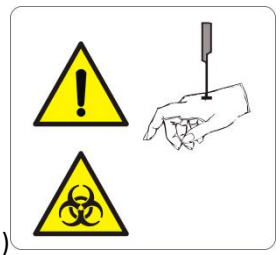
- The following symbols may be seen on analyzers, reagents, quality controls or calibrators

Symbols	Meaning
	Please consult the accompanying documents
	Biohazard symbols
	High voltage warning symbol

	Laser Warning
	Prevent sticking
	Network Interface
	USB interface
	AC Symbols
	In vitro diagnostic medical device
	Batch code
	Use-by date
	Serial number
	Date of manufacturer
	Manufacturer

	Temperature limit
	Consult instruction for use

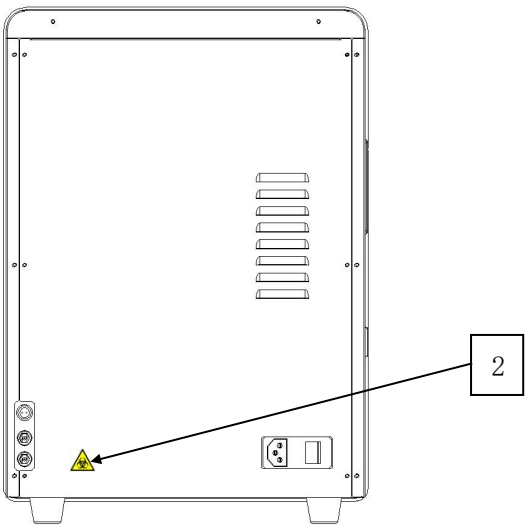




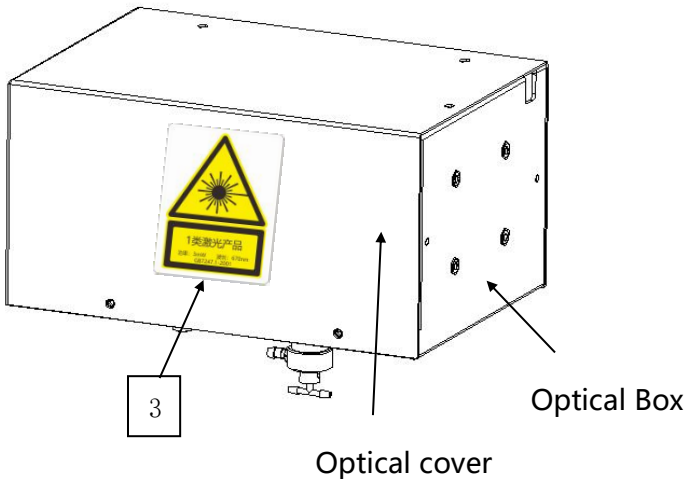
(1)

Pay attention to the sampling needle to prevent sticking.

There is a potential risk of biological contamination, so pay attention to good protective measures when operating.



There is a potential risk of biological contamination.



(3)

As shown in the figure above, the laser is installed in a confined space inside the optical box and optical cover, and the laser is in a confined space during operation.The laser will not cause harm to the user during normal operation.

If you need maintenance or repair, please contact Singuway or your local distributor.

Chapter 2 System Overview

2.1 Overview

This chapter describes the test parameters, main components, operation interface, shortcut buttons and menu items, software operation, operation help information, and supporting reagents of the Automatic 5-Part Hematology Analyzer.

2.2 Test parameters

- outputs a total of 25 reported parameters, 4 study parameters, 2 histograms and 4 scatter plots, which are detailed in the following table corresponding to the parameters in measurement mode.

Table 2-1 Parameter description table

Parameters	Name	Abbreviations	CD	CD+CRP	CD+SAA	CD+CRP+SAA
White blood cell lines (11 items), including 4 study parameters	White blood cell count	WBC	√	√	√	√
	Basophil count	Bas#	√	√	√	√
	Basophil percentage	Bas%	√	√	√	√
	Neutrophil count	Neu#	√	√	√	√
	Neutrophil percentage	Neu%	√	√	√	√
	Eosinophil count	Eos#	√	√	√	√
	Eosinophil percentage	Eos%	√	√	√	√
	Number of lymphocytes	Lym#	√	√	√	√
	Percentage of lymphocytes	Lym%	√	√	√	√
	Number of monocytes	Mon#	√	√	√	√
	Percentage of monocytes	Mon%	√	√	√	√
Red blood cell lineage (8 items)	Number of red blood cells	RBC	√	√	√	√
	Hemoglobin concentration	HGB	√	√	√	√

	Mean red blood cell volume	MCV	√	√	√	√
	The level of mean corpsular hemoglobin	MCH	√	√	√	√
	Mean corpuscular hemoglobin concentration	MCHC	√	√	√	√
	Red blood cell distribution width variation number	RDW-CV	√	√	√	√
	Standard deviation of red blood cell distribution width	RDW-SD	√	√	√	√
	Hematocrit	HCT	√	√	√	√
Platelet lineage (6 items)	Platelet count	PLT	√	√	√	√
	Mean Platelet Volume	MPV	√	√	√	√
	Platelet distribution width	PDW	√	√	√	√
	Plateletcrit	PCT	√	√	√	√
	Platelet-larger cell ratio	P-LCR	√	√	√	√
	Platelet-large platelet count	P-LCC	√	√	√	√

- Histogram

Table 2-2 Histogram description table

Name	Abbreviations	CD	CD+CRP	CD+SAA	CD+CRP+SAA
Histogram of red blood cell distribution	RBC Histogram	√	√	√	√
Platelet distribution histogram	PLT Histogram	√	√	√	√

- Scatter Chart

Table 2-3 Scatter diagram description table

Name	Abbreviations	CD	CD+CRP	CD+SAA	CD+CRP+SAA

High and low angle differentiation scatter plot	HL Diff Scattergram	√	√	√	√
Low and medium angle differentiation scatter plot	ML Diff Scattergram	√	√	√	√
High and medium angle differentiation scatter diagram	HM Diff Scattergram	√	√	√	√
WBC Scatter Plot	WBC Scattergram	√	√	√	√

Attention

- "√" indicates that it is provided in this measurement mode, "/" indicates that it is not provided in this measurement mode.

2.3 Reagents, quality controls and calibrators

The analyzer, reagents, QCs and calibrators together form a system and must be used as a whole to ensure system performance. The operator must use the reagents specified by Singuway (see Appendix A for specifications). Failure to do so may result in damage to the analyzer and failure to meet the performance specifications described in the instructions for use. Non-specified reagents do not guarantee reliable analytical data. The term "reagents" as used in these instructions refers to the compatible reagents used with this analyzer.

Each reagent must be checked for packaging before use; damage to the packaging may affect the quality of the reagent. Confirm that the packaging shows no signs of moisture or leakage. If such conditions occur, do not use the reagent.

Attention

- For the use and storage of the reagents, please refer to the instructions for use of the reagents.
- The operator should perform background testing after changing diluent, lyse solution or cleanser to ensure that the background values are within normal limits and ready for sample analysis.
- Ensure that the reagents are used within the expiration dates indicated on the reagent instructions.

1 Reagents

- Diluent

  Used for blood sample dilution to achieve blood cell count and volume measurement as well as hemoglobin determination.

- Lyse solution

  Used to lyse red blood cells for white blood cell counting and sorting as well as hemoglobin determination.

- Probe cleanser

  This product is used for instrument care and maintenance.

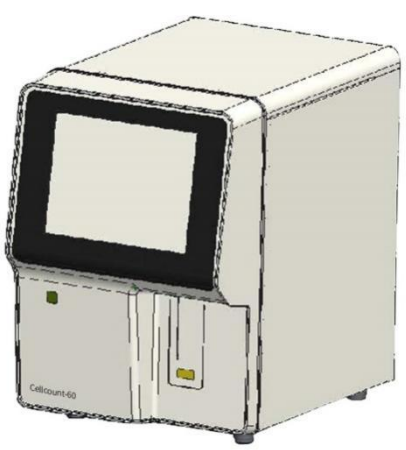
2.3.2 QCs and calibrators

Quality controls and calibrators are used to perform calibration and quality control of the analyzer.

The "quality control substances" and "calibration substances" mentioned in this instruction manual refer to the special quality control substances and calibration substances specified by Singuway, which should be purchased from Singuway's designated agent or Singuway.

2.4 Product structure and composition

Automatic 5-Part Hematology Analyzer mainly consists of host and accessories, where the host includes display, aspiration button, liquid system, optical system, hardware circuit, printer, power supply interface, reagent interface, USB port and network port. The product appearance diagram is as follows.



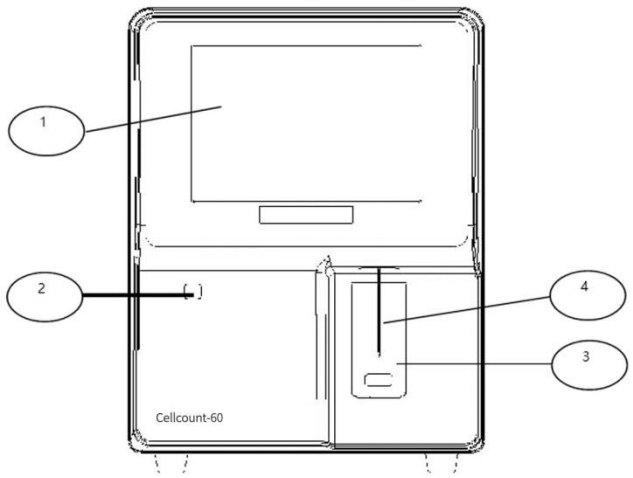


Figure 2-1 Front view of the host

1 ------ Touch Screen/Display 2 ------ Power/Status Indicator
3 ------ aspiration button 4 ------ Sampling needle

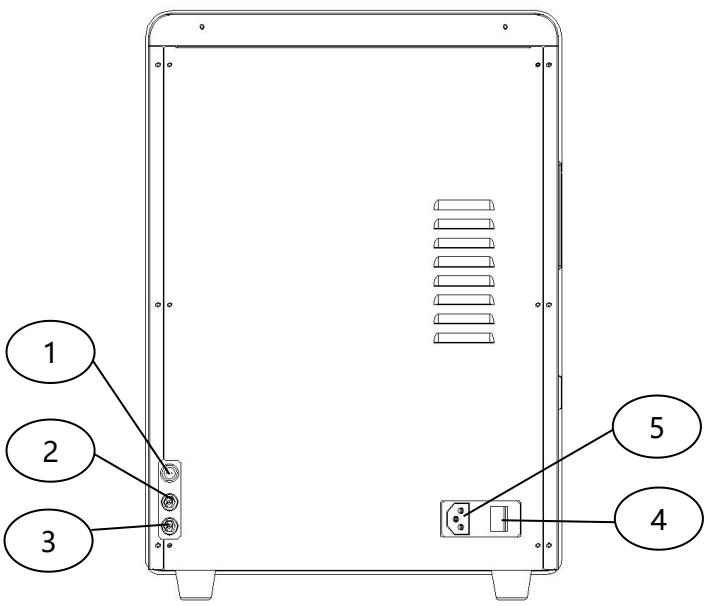


Figure 2-2 Back view of the host

1 ------ Waste liquid detection sensor 2 ------ Dilution liquid line connector
3 ------ Waste liquid line connector 4 ------ Main power switch
5 ------ Power input socket

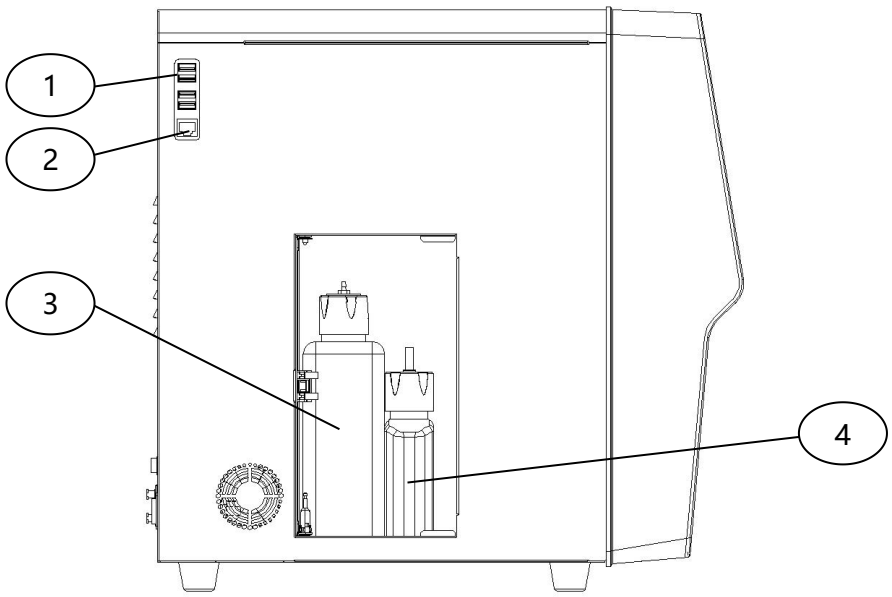


Figure 2-3 Diagram of the left side of the host (open the small door)

1 ------ USB port (4 pcs) 2 ------ Network port (1 pcs)

3 ------ DIFF reagent (consumable) 4 ------ LH reagent (consumable)

2.4.1 Status Indicators

The status indicator is located on the front of the analyzer, at the lower left of the display, and is used to indicate various states such as ready, running, fault, sleep and shutdown of the host computer.

The current status of the system is indicated by the tri-color indicators on the faceplate; all blinks are:

one blink cycle per 2S; the indicators change with the status of the instrument, as shown in the following table.

Table 2-4 Host status indicator prompts

Instrument Status	Indicator light	Remarks
Ready status	Long green light	Allows execution of sequential actions
Operation Status	Green Blink	Sequential action being executed
Operating condition with fault	Red flashing	Faulted and in operation
Non-operating status with fault	Long red light	Fault, but not running
Entering/Exiting Sleep Sequential operation	Yellow flashing	Entering/Exiting Sleep Sequential operation

2.4.2 Buzzer

When a fault occurs, the instrument buzzer gives an alarm tone; when the touch screen is clicked or the fault is eliminated, the alarm tone is automatically cleared; when all the faults are eliminated, the buzzer alarm tone disappears simultaneously; the instrument prompts the user through the buzzer about the operations that can be performed.

Table 2-5 Host buzzer prompts

Tip timing	Tip method	Remarks
Boot process completed	1 short beep	The complete power-up process means that the instrument enters the ready state after the entire power-up process is completed
Failure	Intermittent long tones	Click on the touch screen buzzer to stop

2.4.3 Sampling Needle

The sampling needle is located on the right side of the front of the analyzer and is used for accurate quantitative aspiration of blood samples.

2.4.4 Absorption bond

The aspiration button is located behind the sampling needle and is used to initiate counting

 operations,

add diluent or cancel sleep.

2.4.5 Touch screen / display

The touch screen is located in the middle, upper position on the front of the analyzer and is used to perform interface operations and complete the display of information.

2.4.6 Instrument interface

- Power connector

  Used to plug in the power cord connected to the net power supply.

- Reagent interface

  Connects to various supporting reagents and waste tanks via liquid tubing.

- Data Interface

  HL7

- User Access Control

  User access to the instrument is controlled by user name and password, User type (normal user, administrator, etc.), the above user types can use the instrument by entering the correct user name and password, and the instrument cannot be used except for the above user types.

2.4.7 Power switch

The power switch is located on the back of the host and is used to turn the instrument main power on or off.

- Do not turn the power on/off repeatedly within a short period of time to avoid damage to the host.

Chapter 3 Working Principle

3.1 Overview

This analyzer uses the Coulter principle to detect the number of red blood cells (RBC) and platelets (PLT) as well as their volume distribution; the colorimetric method to measure hemoglobin (HGB) concentration; and the semiconductor laser flow cytometry technique to obtain a statistical count of white blood cells (WBC) in five differentiation (5Diff); the above usually becomes CBC+Diff, abbreviated as " CD". On top of this, the analyzer calculates the results of the remaining parameters.

3.2 Aspiration samples

In whole blood working mode, the analyzer will aspirate 20 μL of whole blood sample.

3.3 Dilution of samples

The sample to be tested is aspirated to the host and then subjected to different reagents in a dilution process to form the test sample for blood routine test (red blood cell/platelet measurement, white blood cell count/hemoglobin measurement, white blood cell sorting measurement).

3.4white blood cell measurements

3.4.1 Laser Flow Cytometry

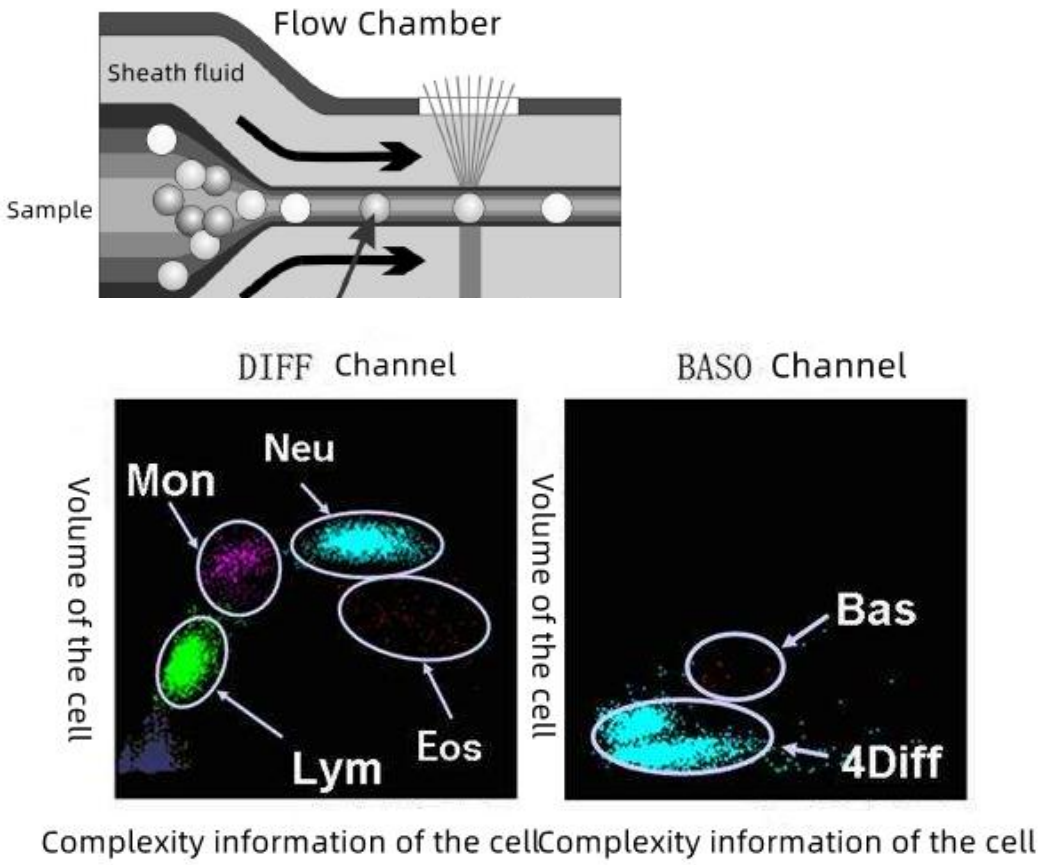


Figure 3-1 white blood cell measurement

After the lyse solution is mixed with the blood sample, the red blood cells are lysed and the white blood cells are stained. The stained white blood cells and red blood cell fragments are injected through a sample needle into a flow chamber filled with diluent. Under the sheath formed by the diluent, the cells are accelerated twice and arranged in rows across the laser detection area. The scattered light generated by the exposure of the cells to the laser beam correlates with the cell size, the refractive index of the cell membrane and the internal cell structure. The photodiode receives these scattered light signals and converts them into electrical pulses. Based on the collected data of these electrical pulses, a two-dimensional distribution of blood cell size and internal cell information, called a scatter plot, can be obtained, as shown in Figure 3-2. The horizontal coordinate reflects the internal complexity information of the cell, and the vertical coordinate reflects the volume of the cell.

Figure 3-2 White blood cell scatter plot

3.4.2 white blood cell parameters

The analyzer obtained the lymphocyte percentage (Lym%), neutrophil percentage (Neu%), monocyte percentage (Mon%), and eosinophil percentage (Eos%) by analyzing the DIFF channel scatter plot and the Lym region, Neu region, Mon region, and Eos region therein. The number of lymphocytes (Lym#),

neutrophils (Neu#), monocytes (Mon#), and eosinophils (Eos#) were then calculated in combination with the number of white blood cells obtained from the BASO channel. Basophil count (Bas#) can be obtained directly from the BASO channel. Cell counts are all in units of 10^9 /L.

A) White blood cell count

The analyzer obtains the white blood cell count (WBC) by directly measuring the number of pulses corresponding to white blood cells in the BASO channel.

B) Basophil count

The analyzer obtains the white blood cell count (Bas#) by directly measuring the number of pulses corresponding to basophils in the BASO channel.

C) Basophil percentage

Bas% = Bas# / WBC * 100%

D) Percentage of lymphocytes

Lym% = the number of particles in the DIFF channel that fall in the Lym region / the sum of the counts of all particles in the DIFF channel except for the blood shadow region * 100%

E) Neutrophil percentage

Neu% = number of particles in the DIFF channel that fall in the Neu region / sum of the counts of all particles in the DIFF channel except for the blood shadow region * 100%

F) Percentage of monocytes

Mon% = number of particles in the DIFF channel that fall in the Mon region / sum of the counts of all particles in the DIFF channel except for the blood shadow region * 100%

G) Eosinophil percentage

Eos% = number of particles in the DIFF channel that fall in the Eos region / sum of the counts of all particles in the DIFF channel except for the blood shadow region * 100%

H) Number of lymphocytes

Lym# = WBC * Lym%

I) Neutrophil count

Neu# = WBC * Neu%

J) Number of monocytes

Mon# = WBC * Mon%

K) Eosinophil count

Eos# = WBC * Eos%

3.5 Hemoglobin concentration measurement

3.5.1 Colorimetric method

When the diluted sample is added to the lyse solution, the red blood cells lyse and release

hemoglobin, which binds to the lyse solution and forms a hemoglobin complex. According to Lambert's law, the transmitted light intensity of the hemoglobin complex solution and the background case can be measured under monochromatic light irradiation of LED with a central wavelength of 530 nm, and the hemoglobin concentration can be obtained by calculation.

3.5.2 Hemoglobin concentration parameters

The hemoglobin concentration (HGB) is calculated in g/L by the following formula.

HGB = Constant * Ln (background transmitted light intensity / sample transmitted light intensity)

3.6 Red blood cell/platelet measurement

3.6.1 Principle of impedance method

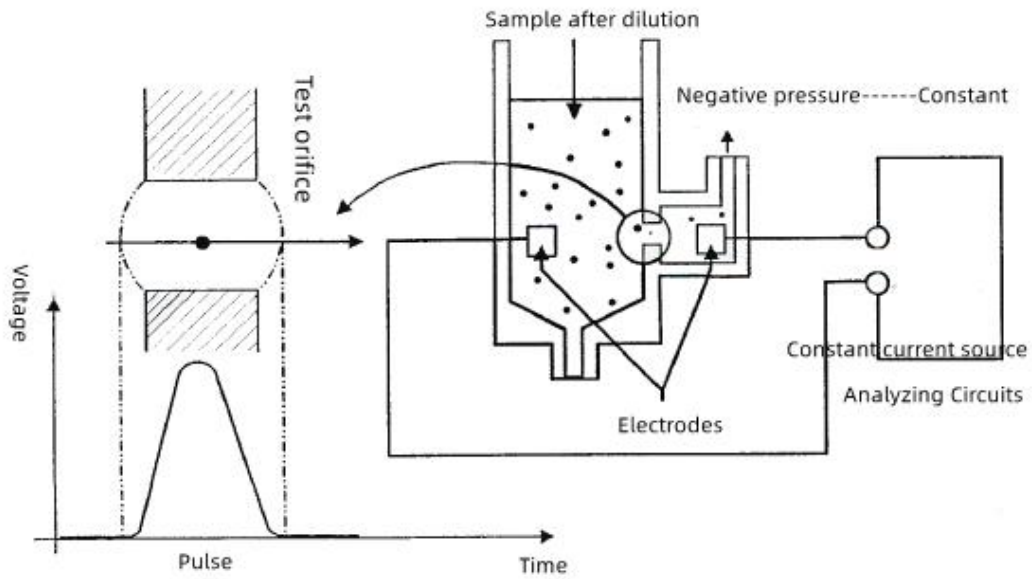


Figure 3-3 Counting schematic

The analyzer uses the principle of impedance method to achieve red blood cell/platelet count. The RBC counting cell has a small opening called the test orifice. There are a pair of positive and negative electrodes on both sides of the small hole, which are connected to a constant current power supply. Since cells are poor conductors of electricity, the resistance between the electrodes changes when cells in a diluted sample pass through the test orifice under constant negative pressure, resulting in a pulse signal at both ends of the electrodes proportional to the size of the cell volume. The number of pulses is equal to the number of cells passing through the pore, and the amplitude of the pulse is proportional to the volume of the cells.

The number of electrical pulses whose amplitude falls within the red blood cell/platelet channel is calculated by comparing the amplification of the acquired electrical pulses with the channel voltage threshold corresponding to the normal red blood cell/Platelet Volume range. Thus, all collected electrical pulses are classified according to different channel voltage thresholds, and the number of electrical pulses

falling in the red blood cell/platelet channel is the number of red blood cells/platelets. The number of cells in each channel range based on pulse voltage amplitude determines the volume distribution of cells. The histogram reflecting the distribution of the cell population is a two-dimensional plot with horizontal coordinates indicating the cell volume and vertical coordinates indicating the relative number of cells.

3.6.2 Red blood cell parameters

(A) Number of red blood cells

The analyzer obtains the red blood cell count (RBC) in units of 10^{12} /L by directly measuring the number of electrical pulses corresponding to the red blood cells.

(B) Mean red blood cell volume

From the histogram of red blood cell distribution, the mean red blood cell volume (MCV) was calculated in fL.

(C) Hematocrit, mean red blood cell hemoglobin content, and mean red blood cell hemoglobin concentration

The Hematocrit (HCT) in %; mean red blood cell hemoglobin content (MCH) in pg; mean red blood cell hemoglobin concentration (MCHC) in g/L.

HCT = RBC * MCV / 10

MCH = HGB /RBC

MCHC = HGB/HCT * 100

(D) Coefficient of variation of red blood cell distribution width

The coefficient of variation of red blood cell distribution width (RDW-CV) was obtained from the histogram of red blood cell distribution in %.

(E) Standard deviation of red blood cell distribution width

The standard deviation of red blood cell distribution width (RDW-SD) was obtained by calculating the standard deviation of the red blood cell volume distribution in fL.

3.6.3 Platelet parameters

A) Platelet count

The analyzer obtains the platelet count (PLT) in units of 10^{9} /L by directly measuring the number of electrical pulses corresponding to platelets.

(B) Mean Platelet Volume

The mean Platelet Volume (MPV) in fL was calculated from the histogram of platelet distribution.

(C) Platelet distribution width

Platelet distribution width (PDW) was obtained from platelet histograms as the geometric

standard deviation of Platelet Volume distribution (10 GSD).

D) Plateletcrit

The analyzer calculates the Plateletcrit (PCT) in % by the following formula

PCT = PLT * MPV / 10000

E) Number of large platelets

The analyzer obtains the number of large platelets (P-LCC) in 10^9 /L by directly measuring the number of electrical pulses corresponding to large platelets.

(F) Platelet-larger cell ratio

P-LCR = P-LCC / PLT * 100%

Chapter 4 Installation

4.1 Overview

- Opening the box or performing the installation process by personnel not authorized or trained by Singuway may result in personal injury or damage to the host computer. Do not open the box or install the host without the presence of authorized personnel from Singuway.
- The installation, verification, upgrade and modification of the analyzer supporting software must be performed by authorized personnel of Singuway.

  This analyzer has been rigorously tested before leaving the factory. To avoid impact during delivery, the analyzer is carefully packed before shipment. When the analyzer arrives, please check the analyzer packaging carefully for physical damage first, and if there is any damage, please notify the after-sales service department of Singuwayor your regional agent immediately.

4.2 Installation requirements

Prior to installation, the operator must ensure that the following space, environmental, and power requirements are met.

4.2.1 Space requirements

To ensure the space needed for repair and maintenance, taking into account the heat dissipation of the instrument and the liquid pipeline behind the host not to be squeezed thus affecting the normal flow of reagents, the host installation needs to meet:

Suitable host placement height.

Retention space between the left and right side doors of the host and the wall ≥100cm.

Retention space between the rear panel of the host and the wall ≥20cm.

- Ensure that there is enough space on the operating table and underneath the host for the diluent and the waste container.
- The diluent is placed under the host and the height relative to the host is required to be within 1.0 m. The lyse solution is placed inside the machine. The mounting table (or floor) should be able to support at least 30Kg of weight.
- Do not place the instrument in a position where it is difficult to operate the disconnected power switch, in case there is an unexpected situation or malfunction, the instrument can be stopped in

time.

- Sampling needle and other moving parts, please do not reach into the instrument or its working rotation range when working, to avoid being touched or scratched.

4.2.2 Power requirements

- The main machine must be used under good grounding conditions.
- Please make sure the input voltage meets the instrument requirements before turning on the host.

- Using a plug-in board may introduce additional electrical interference and lead to incorrect analysis results. Please choose to place thehost close to a power outlet to avoid the use of a plug-in board.
- Please use the supplied three-prong power cord. Using other power cords may damage the host or cause incorrect analysis results.

Power supply

	Voltage	Input power	Frequency
Complete appliance	00V-240VAC	≤180 VA	50Hz/60Hz

4.2.3 Environmental Requirements

Operating temperature range: 10 ℃ ~ 30 ℃

Relative humidity: ≤70%

Working atmospheric pressure range: 70 kPa～106 kPa

- The environment should be as dust-free, free of mechanical vibration, pollution, large noise sources and power interference as possible.
- It is recommended that the electromagnetic environment of the laboratory be assessed prior to operating the equipment.
- Keep away from strong electromagnetic interference sources to avoid affecting the normal operation of the equipment.
- Do not approach brush-type motors, flickering fluorescent lamps and electrical contact equipment that is frequently switched on and off.
- Avoid direct sunlight or placed in front of heat and wind sources.
- Choose a well-ventilated location.
- Do not place the host on an inclined surface.
- Have a good grounding environment.

- Indoor use.

4.2.4 Handling and installation methods

Warning

- Opening the box or performing the installation process by personnel not authorized or trained by Singuway may result in personal injury or damage to the host. Do not open the box or install the host without the presence of authorized personnel from Singuway.
- In order to avoid damage to the sampling components during transportation, the sampling components are fixed with cable ties when the instrument is shipped from the factory.
  The cable ties must be removed before the device.
- This analyzer is to be handled and installed by authorized personnel of Singuway. Please do not handle or install the analyzer without contacting Singuway's service department or your regional distributor.
- When handling, changing the operating location, giving, lending, or repairing instruments, the surface of the instruments should be thoroughly disinfected to minimize biohazards.
- For clients requiring secondary long distance shipping, please contact Singuway's after-sales service department or local agent for technical support or guidance.

4.3 System connection

Make the electrical and reagent connections as shown in the diagram below. The operator needs to make sure that the connections are in place and secure.

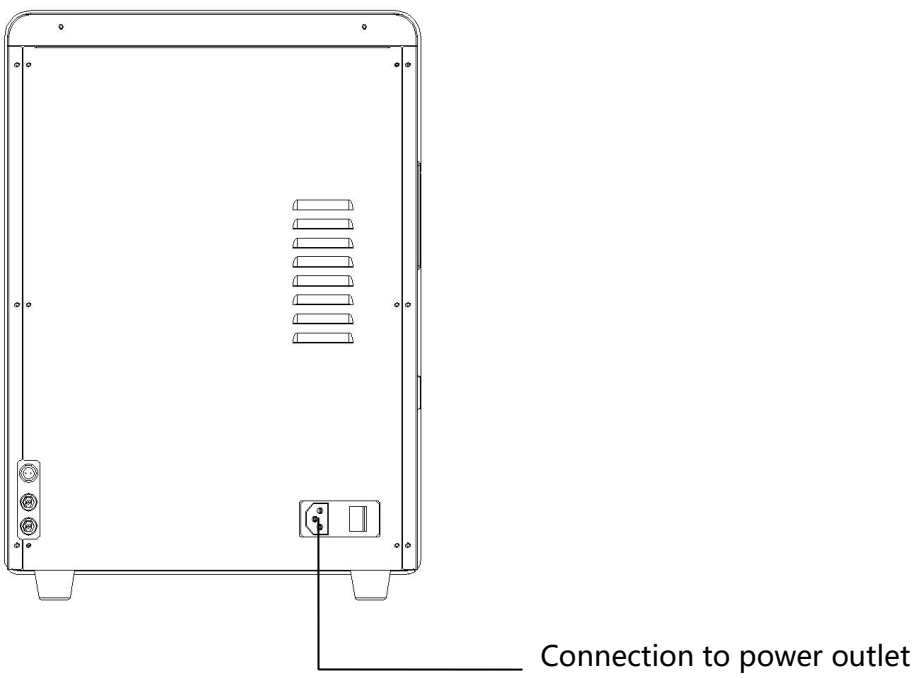


Figure 4-1 Electrical connection diagram

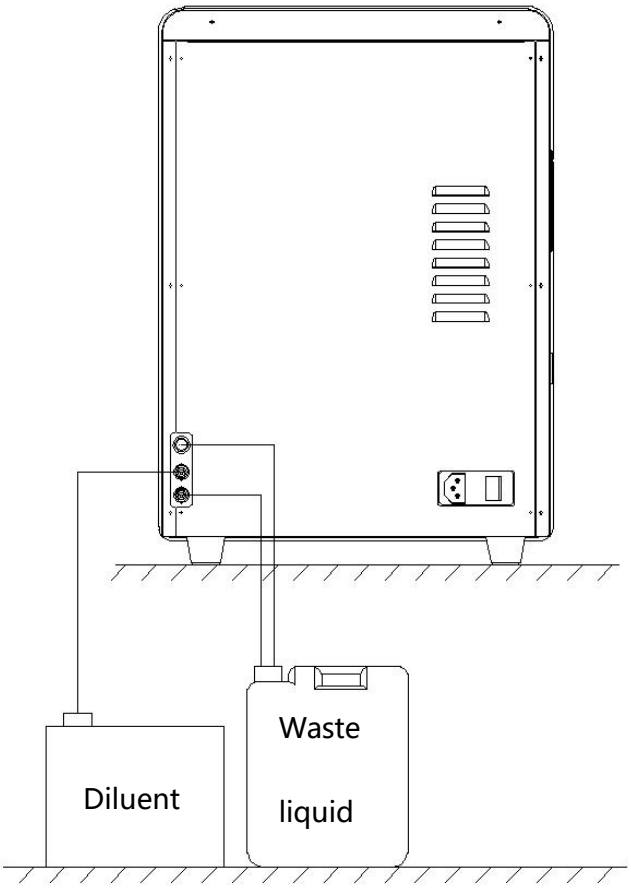


Figure 4-2 External reagent connection diagram

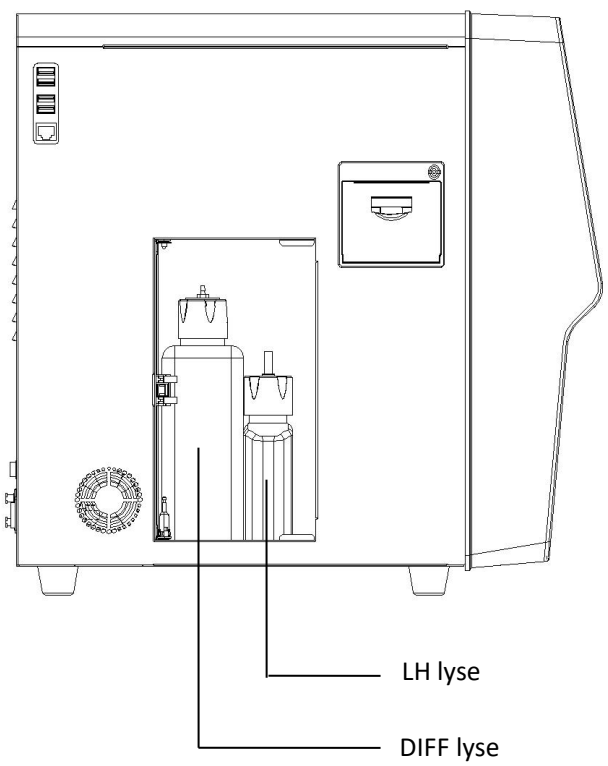


Figure 4-3 Built-in lyse solution connection diagram

- Please make sure that the length of the catheter for the used diluent and waste solution does not exceed 1500mm.
- The height of the top of the diluent and waste liquid containers should be lower than the table where the instrument is placed.

4.4 Precautions for use

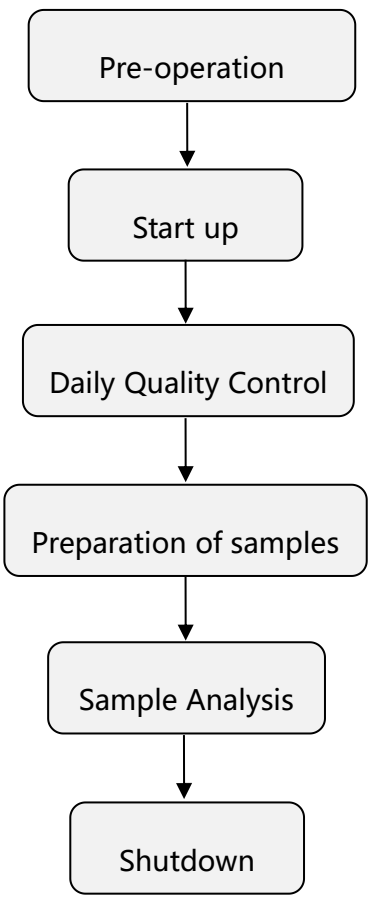
- Instruments in a dusty environment for a long time, which may cause instrument performance degradation.
- Periodic cleaning and disinfection of the external surfaces of the instruments, with the recommended use of alcohol (75%) wipes.
- Instrument swab baffles should be wiped periodically with alcohol (75%).
- Blood collection and sample preparation should be performed in a prescribed manner, which may lead to hazards if abnormal blood collection procedures are used.
- If any hose or parts containing liquid are aged or worn out during use, please stop using them immediately and contact the user service personnel for inspection or replacement in time.
- During the use of the instrument, take care that the connecting tubes of reagents (including diluent, lyse solution and waste solution) are not pressed by heavy objects or bent.
- Should use the supporting reagents specified by Singuway, otherwise it will lead to unreliable test results and may cause damage to the instrument.
- The expiration date of the supporting reagents should be noted and no expired reagents should be used; overdue use of reagents can lead to unreliable test results.

Chapter 5 Daily Operations

5.1 Overview

This chapter describes the entire daily operation process from the analyzer's turn-on to turn-off, focusing on the detailed description of the sample analysis operation process for different operating modes.

The process of daily operation is as follows.



- All items (samples, controls, calibrators, reagents, waste liquids, etc.), and areas in contact with these substances are potentially biologically contagious. Operators should follow laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with relevant items and areas in the laboratory.

- Do not touch the patient's blood specimen directly.

- Operators are obliged to comply with the relevant regulations of their regions and countries regarding the discharge and disposal of expired reagents, waste liquids, discarded samples, consumables, etc.
- Reagents can irritate the eyes, skin and mucous membranes. Operators should observe laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with reagent-related items in the laboratory.
- In case of contact with skin, rinse immediately with plenty of water and receive medical attention if necessary; in case of contact with eyes, rinse immediately with plenty of water and receive medical attention.
- Clothes, hair, hands, etc. must be kept at a certain distance from the moving parts to prevent being caught by the moving parts.
- Avoid contact with the sampling needle, which has a sharp tip and may carry blood samples, controls and calibrators that are potentially biologically infectious.

- Do not reuse disposables.

- The operator should use the reagents specified by the company and store and use them in strict accordance with the instructions for their use.
- Before using the analyzer, check to ensure that the reagents are properly connected.
- Operators should use clean EDTAK2 or EDTAK3 anticoagulated vacuum blood collection tubes, silicone glass/plastic tubes, centrifuge tubes and silicone borated glass capillaries.
- Please use a vacuum blood collection tube that conforms to the recommended size in the appendix.
- Disposable items such as vacuum blood collection tubes, centrifuge tubes, and capillaries used for blood collection must be of the specifications specified by the manufacturer.

5.2 Pre-operation preparation

Before turning on the power to the host, the operator shall check to ensure that the system is ready according to the following requirements.

- Inspection of waste liquid containers

Check whether the waste liquid container is full of liquid, and the waste liquid should be emptied in time.

- Checking reagents

Check whether the reagents are out of shelf life and frozen, and need to rest for 24H after long distance handling.

- Check fluid lines and power supply

  Check the piping of reagents and waste liquids for bends and reliable connections.

  Check that the power plug of the host is safely plugged into the power outlet.

5.3 Boot and user login

- Start host.

  1. Set the "O/I" main power switch on the back of the host to "I".

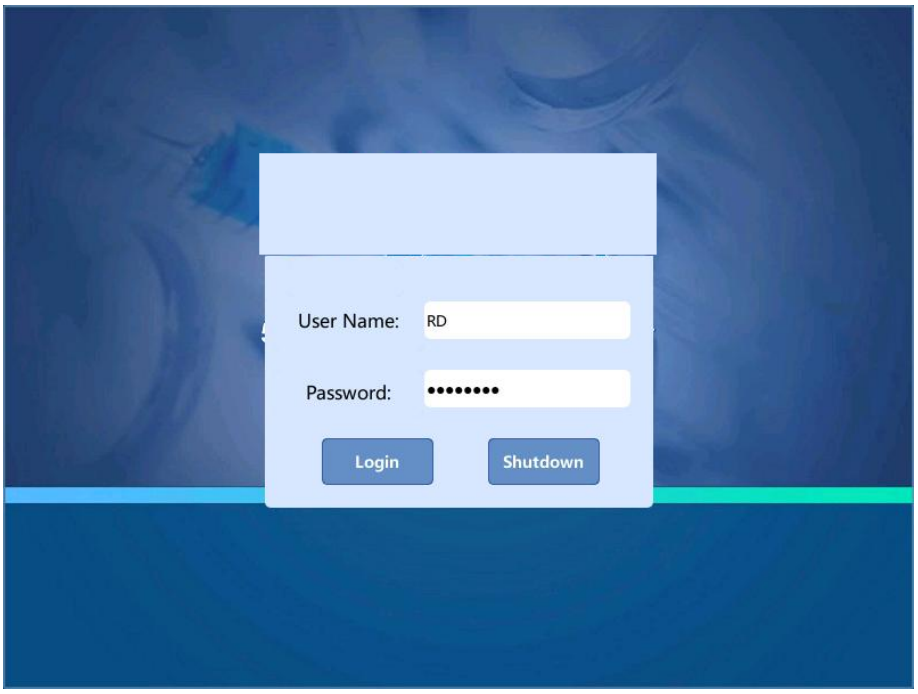
  2. Make sure the indicator light on the host is on.

  3, the system in turn for self-test and boot initialization.

  Attention

  - The time required for the analyzer to initialize the liquid path varies depending on the previous shutdown.
  - Background detection, i.e. the measurement of particle interference and electrical interference by the analyzer.
  - If the first background result obtained during the initialization of the liquid circuit is outside the background range, the analyzer will automatically perform another background check.
  - The sample number corresponding to the background test result is "background".
  - When the result does not meet the background requirements, a "background abnormality" fault will be reported.

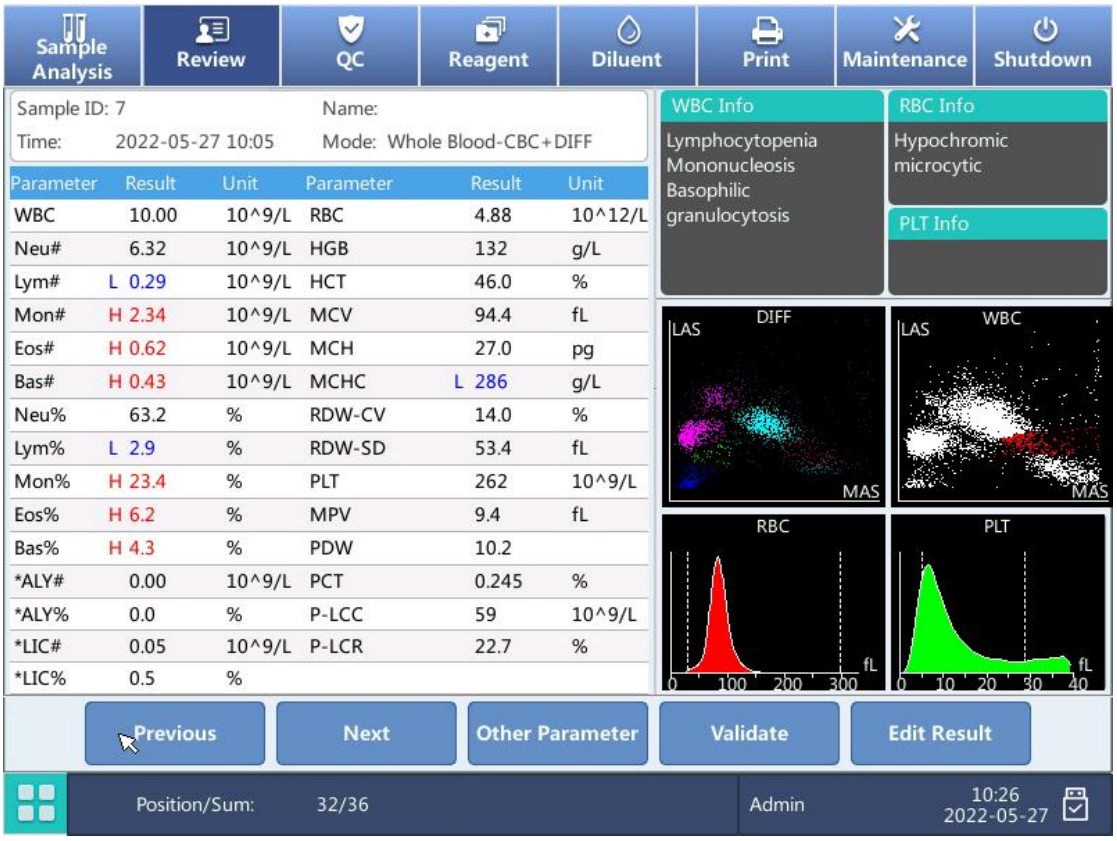
  4、Enter the correct username and password in the login dialog box.



Attention

- If you run the software several times in a row without success, please contact our after-sales service department, or our agent.
- After the power on is completed, please make sure the date/time of the device matches the actual one.
- The initial administrator username defaults to Admin and the password defaults to 123456.
- User name and password are entered in the range of 1-12 digits, Chinese is not allowed to be entered, and the password is not allowed to be empty.

5、Click the "Login" button to enter the software interface.



Attention

- If a fault occurs during the initialization process (e.g., the background detection result is outside the background range), the analyzer will make an alarm indication, see Chapter 12 Troubleshooting for handling.
- See Appendix A specifications for the background range of each parameter.
- The system determines the operator's authority as administrator or normal user according to the user name and password used for login, and opens different functions in all sectors according to the user's authority.
- If you want to switch users, you can click "Logout" in the menu, enter your user name and password in the login dialog, and then click "Login" to log in as a new user.
- Counting in the presence of a "background abnormality" fault will give unreliable detection results.

5.4 Daily Quality Control

Daily QC analysis of the analyzer is required to ensure reliable analytical results. See Chapter 7, Quality Control, for specific QC analysis procedures.

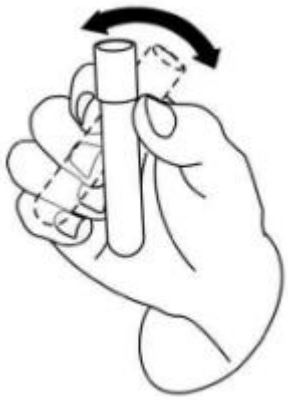
5.5 Preparation of the sample

The sample objects measured by the instrument are divided into: whole blood samples and

peripheral whole blood samples.

Caution

- Samples should be prepared according to the procedures recommended by the test tube manufacturer.
- Samples need to be shaken as shown below to thoroughly mix the sample.



5.5.1 Whole blood samples

1. Collect venous blood samples using EDTAK2 or EDTAK3 anticoagulation vacuum tubes.
2. Immediately mix the venous blood in the tube with the anticoagulant thoroughly.

To ensure the accuracy of the analysis results, ensure that the sample volume of whole blood is at least 0.5mL.

5.5.2 Peripheral whole blood samples

1. Use the sampling tube to collect the peripheral whole blood sample.

To ensure the accuracy of the analysis, ensure that the sample volume of whole blood is at least 120 μL.

Attention

- Please complete the test within 3 minutes to 2 hours after collection of the peripheral whole bloodsample.

5.6 Sample Analysis

Click the "Sample Analysis" button to enter the "Sample Analysis" interface.

5.6.1 Entering sample information

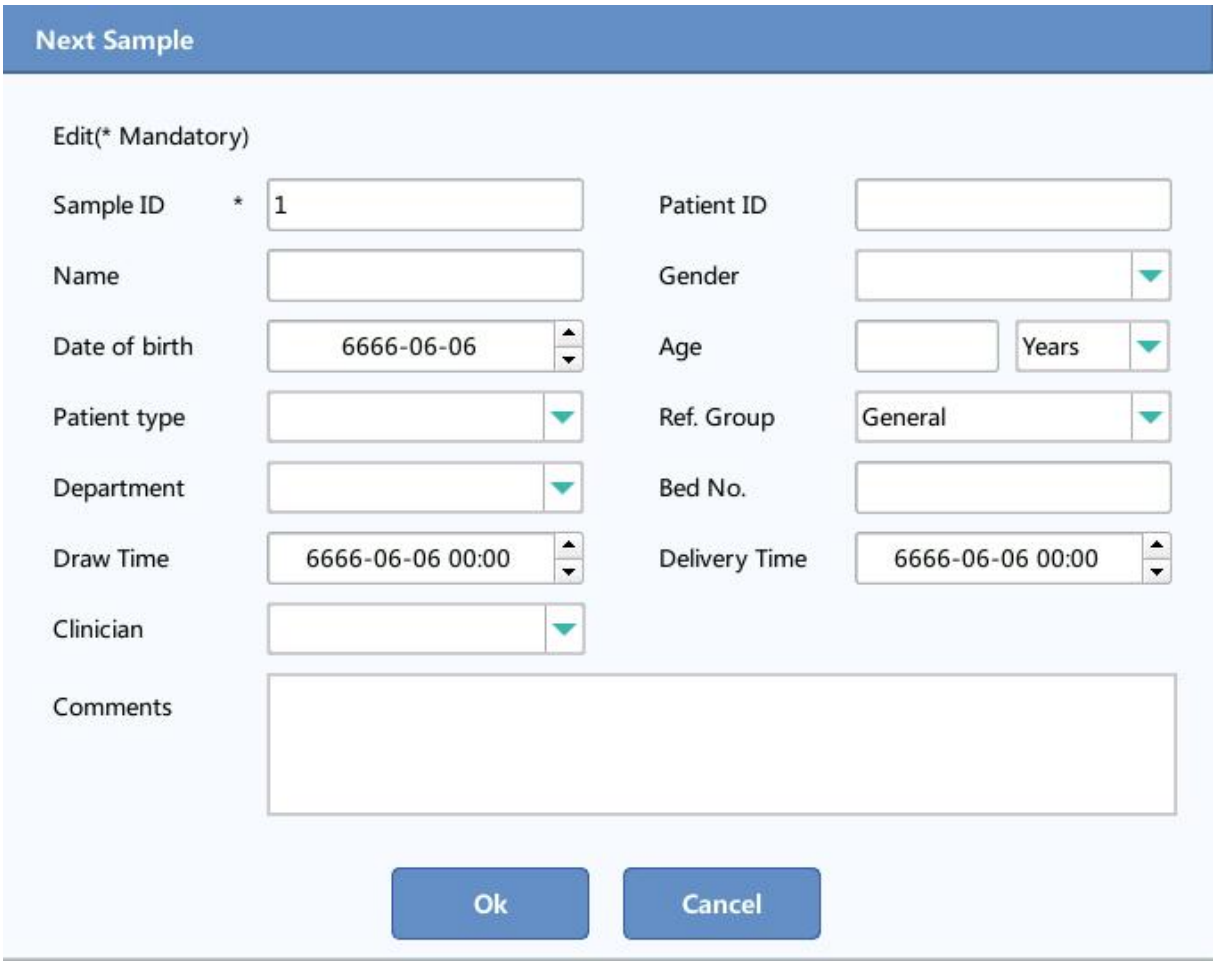
The analyzer can provide two types of sample information entry for the samples to be analyzed: sample number entry and all information entry.

If the operator wishes to enter sample information after the analysis, he/she can skip the introduction of this section and enter the corresponding sample information according to the sample number and result saving time when reviewing the sample results, as described in Chapter 6, Results Review.

After setting the input method of sample information on the “Settings→System Settings→Auxiliary Settings” interface according to the method described in Chapter 9, you can enter the sample information on the “Sample Analysis” interface.

- All information entry

When the next sample entry method is set to "All Information", click "Next Sample" in the "Sample Analysis" screen, and the "All Information" dialog box will pop up, as shown in the figure below. The operator can enter the complete sample information of the next sample in the dialog box. The "Reference Group" item is automatically matched by the system, no need to be set manually by the user.



a) Enter the sample number

Enter the sample number in the "Number" box.

Attention

- The sample number allows the entry of letters, numbers and all characters supported on the keyboard (including special characters).
- The sample number is allowed to be entered in the length range [1,20] and cannot be empty.

b) Enter the medical record number

Enter the patient's medical record number in the "Medical Record Number" box.

c) Enter patient name

Enter the patient's name in the "Name" box.

d) Select patient gender

Select the patient's gender from the "Gender" drop-down list, with two options for "Male" and "Female".

e) Enter the date of birth

Enter the patient's date of birth in the "Date of Birth" box in the same format as the system date format.

f) Enter the patient's age

The analyzer provides four age input methods for patients of different age groups: input by "year", input by "month", input by "day" and input by "hour". Applicable to: people over one year old, people under the one month but less than two years old, people under the one month and people under 48 hours. The operator can choose the input method of the patient's age according to the age of the patient.

Attention

- After entering the date of birth, the age field will be automatically calculated based on the difference between the "Current System Date" and the "Date of Birth", and the newly calculated age value and units will be displayed in the Age Value edit box and Units combo box. At this point, the age edit box will be grayed out, and the age edit box will be reactivated after clearing the "Date of Birth".
- If the date of birth entered is after the current system date, the date of birth is considered invalid.

g) Enter the patient type

Select the type of patient in the "Patient Type" drop-down list.

h) Enter the name of the department

Enter a department name in the "Department" box or select a department name in the "Department" drop-down list (when there is a record in the drop-down list). This field automatically records the contents saved in the Quick Dictionary settings in the drop-down list.

i) Enter the bed number

Enter the patient bed number in the Bed Number box.

j) Input sampling time

Enter the sample time in the "Sample Time" box.

k) Enter the delivery time

In the "Delivery time" box, enter the delivery time.

l) Enter the sender

Enter the corresponding name in the "Sender" box, or select the corresponding name in the "Sender" drop-down list (when there is a record in the drop-down list). This field can be automatically saved in the quick dictionary settings after the content recorded in the drop-down list.

m) Enter the content of the note

Enter some information that needs to be stated in the "Notes" box.

n) Confirm

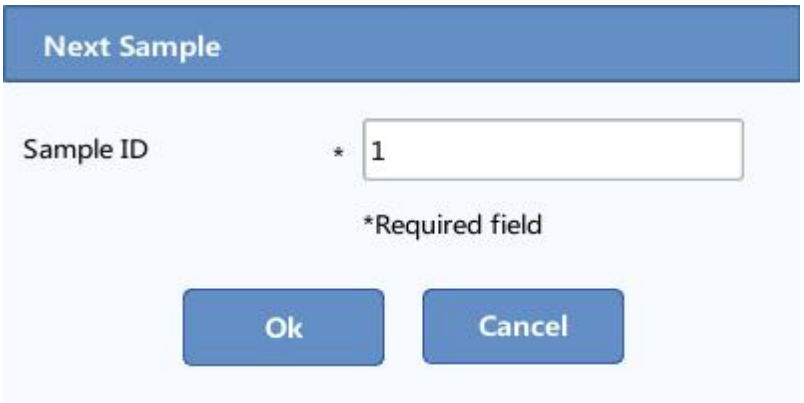
When you have finished entering the sample information, click Confirm to save the input and return to the "Sample Analysis" screen.

o) Cancel

When you have finished entering the sample information, click Cancel to return to the "Sample Analysis" screen and discard the entered sample information.

- Sample number entry

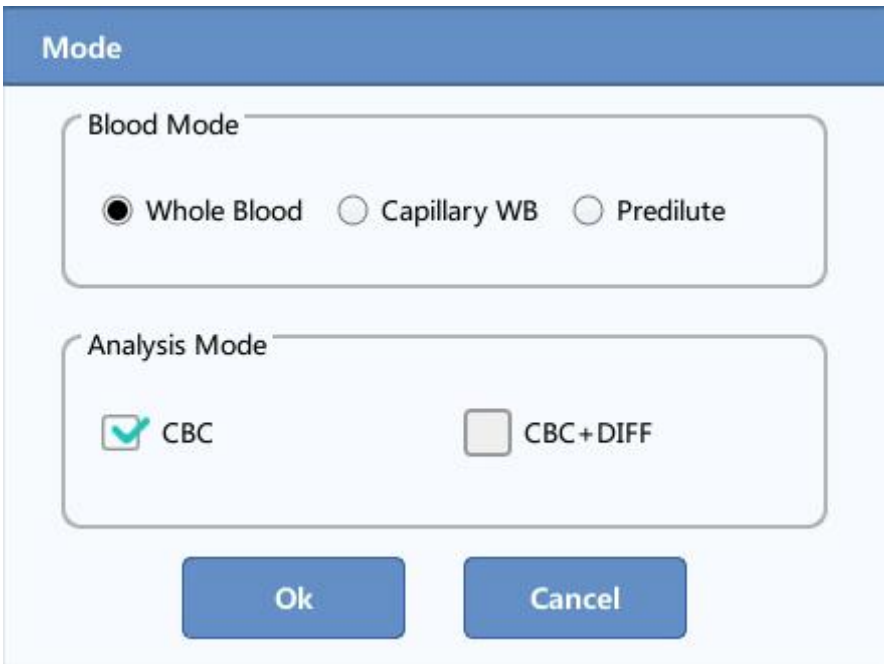
When the next sample entry method is set to enter only the sample number, click "Next Sample" in the "Sample Analysis" interface, and the number entry dialog box will pop up, as shown in the figure below.



Enter a number in the "Sample Number" box. Press "Confirm" to save the entered number and close the dialog box, the number is displayed on the screen as the sample number of the next sample to be analyzed.

5.6.2 Sample analysis steps

1. Click the "Mode" button in the "Sample Analysis" interface, and the dialog box shown below will pop up.



2. Select the blood sample mode type, click "OK" button to save the selection and return to the "Sample Analysis" interface.

3. Put the prepared sample under the sampling needle, so that the sampling needle can inhale the mixed sample.

4.Press the aspirate button, the sampling needle will automatically sample, and it will be automatically removed after the sampling is completed. At this time, the operator can remove the sample, and the sampling needle will add the aspirated sample into the counting cell.

5. The analyzer automatically performs sample analysis and displays the test results in the interface.

Attention

During the analysis, if there is a fault such as blocked hole or bubble, the analyzer will automatically set the relevant measurement parameter value to invalid and prompt an alarm message in the fault message area, see Chapter 12 Troubleshooting for handling.

5.6.3 Analysis results processing

1）Saving of results

The analyzer can automatically save the analysis results. When the number of sample results reaches

the storage limit (50,000 sample records), the newly obtained sample analysis results will automatically overwrite the oldest sample analysis results.

2) Print or upload LIS

If Auto Print is set to On, the analyzer will automatically print analysis reports as set; if Auto Communication is set to On, the analyzer will automatically upload sample analysis results and sample and patient information that meet the communication conditions to the LIS system.

3）Parameter alarm

Parameter alarms include the following.

The display of "H" or "L" to the right of the parameter name indicates that the analysis result obtained exceeds the pre-set parameter reference range (see 9.2.3 Parameter Settings - Reference Range Settings for details).

The display of "R" to the right of the parameter name indicates that the analysis results obtained are suspicious.

If the analysis result is "*****", it means the data is invalid; if the analysis result is "+++++", it means the data exceeds the display range.

4）Alarm prompt message

The alarm messages and meanings of the analyzer are shown in the following table

Flag area	**Alarm information**	**Meaning**	**Judgment Criteria**
WBC Flag	white blood cell abnormalities	There may be PLT aggregation, NRBC interference, and other conditions that affect the white blood cell count or differentiation	Abnormal ratio between Diff and Baso channels affects white blood cell count
	Immature cells?	Various types of naive or primitive cells may be present	More scatter exists in the immature region of the scatter plot
	Heterozygous/abnormal lymphocytes?	Heterozygous or abnormal lymphocytes may be present	More scatter in the region of heterozygous/abnormal lymphocytes in the scatter plot
	Leukopenia	Significantly low white blood cell count	WBC < 2.50×10^9/L
	Leukocytosis	Significantly high white blood cell count	WBC > 18.00×10^9/L
	Neutropenia	Significantly low neutrophil count	NEUT# < 1.00×10^9/L
	Neutrophilia	Significantly high	NEUT# > 11.00×10^9/L

		neutrophil count	
	Lymphocytopenia	Significantly low lymphocytes	LYMPH# < 0.80×10^9/L
	Lymphocytosis	Significantly high lymphocytes	LYMPH# > 4.00×10^9/L
	Mononucleosis	Significantly high monocyte count	NOMO# > 1.50×10^9/L
	Eosinophilia	Significantly high eosinophil count	EO# > 0.70×10^9/L
	Basophilia	Significantly high basophil count	BASO# > 0.20×10^9/L
	Tri-series reduction	Decreased white blood cells, red blood cells and platelets	WBC < 4.0×10^9/L and RBC < 3.5×10^12/L and PLT < 100×10^9/L
RBC Flag	Abnormal blood cell histogram	Abnormalities such as small red blood cells, large red blood cells, uneven red blood cell size, red blood cell agglutination, and double peaks in the histogram may be present	Abnormal red blood cell histogram distribution
	Hemoglobin abnormalities/interference?	May be hemoglobin abnormalities, red blood cell agglutination, or the presence of interfering factors (e.g. high values of wbc, etc.)	MCHC > 380g/L or HGB interference parameters outside a certain range
	Small cell red blood cells	Small red blood cell volume	MCV < 70fL
	Macrocytic red blood cells	Large red blood cell volume	MCV > 110fL
	Anemia	Anemia	HGB < 90g/L
	Erythrocytosis	Significant increase in red blood cells	RBC > 6.5×10^12/L
PLT Flag	Platelet histogram	Abnormalities such as small red blood cells, red blood cell fragments, giant platelets, and platelet aggregation may be present	PLT histogram PLT/RBC demarcation is unclear up to a certain level
	Thrombocytopenia	Significant reduction in	PLT < 60×10^9/L

		platelets	
	Thrombocytosis	Significant increase in platelets	PLT > 600×10^9/L

5.7 Sleep

When the host has been operated without liquid circuit for a total of 15 minutes (default value, can be set, see Chapter *9* Settings), it will prompt "The instrument is going to sleep ......".

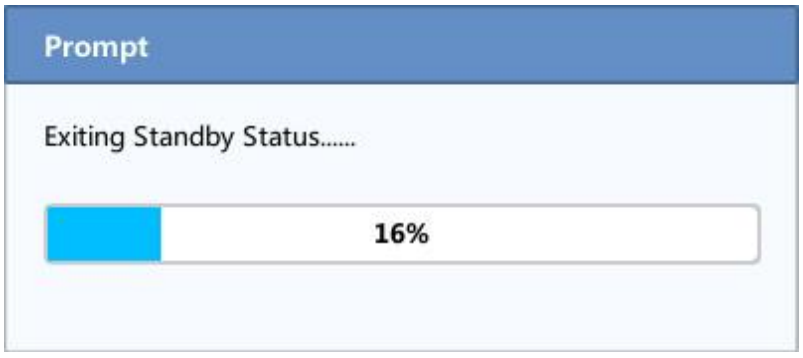
After the host goes into hibernation, the interface shows "Click on the screen to enter the operation interface".

Attention

- In the status screen, it will not go into hibernation.
- When the scheduled hibernation time is up, if the host computer is in a fault state, it will wait until the fault is removed and then determine whether to enter hibernation according to the conditions.
- Timed hibernation does not affect host-independent operations such as communication and printing.
- To modify the wait time for automatic hibernation, refer to Section 9.2.4 Maintenance Settings.
- After going into hibernation, printing and communication continue if there are still print and communication jobs.

- aspiration button / touch screen

You can cancel the hibernation directly by pressing the aspiration button on the instrument or clicking the touch screen, a dialog box will pop up to indicate that "Hibernation is being exited ......".



After canceling the hibernation is completed, the progress bar dialog box above closes automatically and the instrument exits the hibernation state.

Attention

- Depending on the length of time in hibernation, the host will automatically perform different levels of maintenance when exiting hibernation, and the maintenance time will vary.
- If a failure occurs during the process of canceling hibernation, see Chapter 12 Troubleshooting for handling.
- After normal exit from hibernation, the host computer will automatically return to the state before entering hibernation. At this time, the indicator on the host computer also shows a long green light.

5.8 Shutdown

Caution

- Please do not turn on the machine immediately after shutdown, you need to wait at least 10 seconds, otherwise the machine may be damaged.

Attention

- To ensure the stability of the analyzer and the accuracy of the analysis results, please perform the shutdown operation as required after the analyzer has worked continuously for 24 hours.

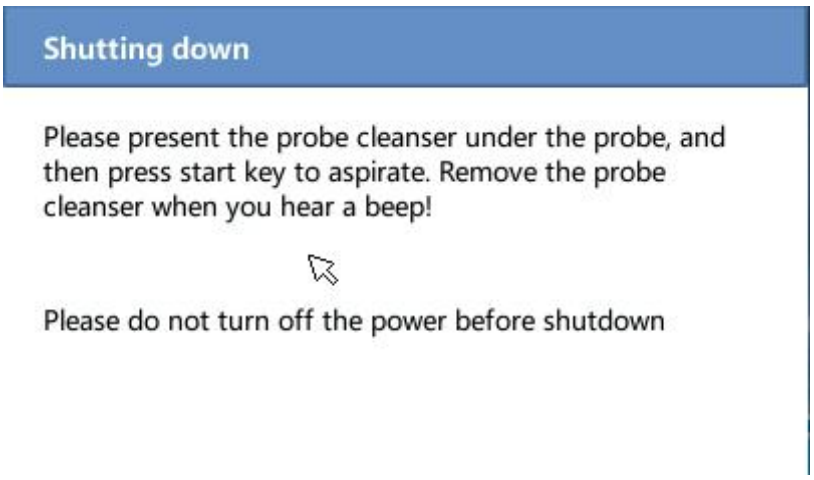
The operator must perform the normal shutdown procedure for shutting down the machine by following these steps.

1. Click the shutdown button under the main menu, the following dialog box will pop up

2. Click the "OK" button to start executing the shutdown sequence.

3. When the interface pops up a prompt box asking to perform the probe liquid maintenance operation, follow the prompts to place the probe liquid under the sampling needle and press the

aspiration button for probe liquid maintenance.



4. When the interface shows "Please turn off the power", put the "O/I" switch behind the host to "O".

5. After shutting down the machine, empty the waste liquid in the waste liquid container and dispose of the waste liquid properly.

Warning

- Operators are obliged to comply with the relevant regulations of their regions and countries regarding the discharge and disposal of expired reagents, waste liquids, discarded samples, consumables, etc.

Attention

- During the shutdown process, please do not force the power off.
- If a fault affecting shutdown occurs during shutdown, the analyzer will return to the state before shutdown was performed and an alarm will be displayed, see Chapter 12 Troubleshooting for instructions.

Chapter 6 Results Review

6.1 Overview

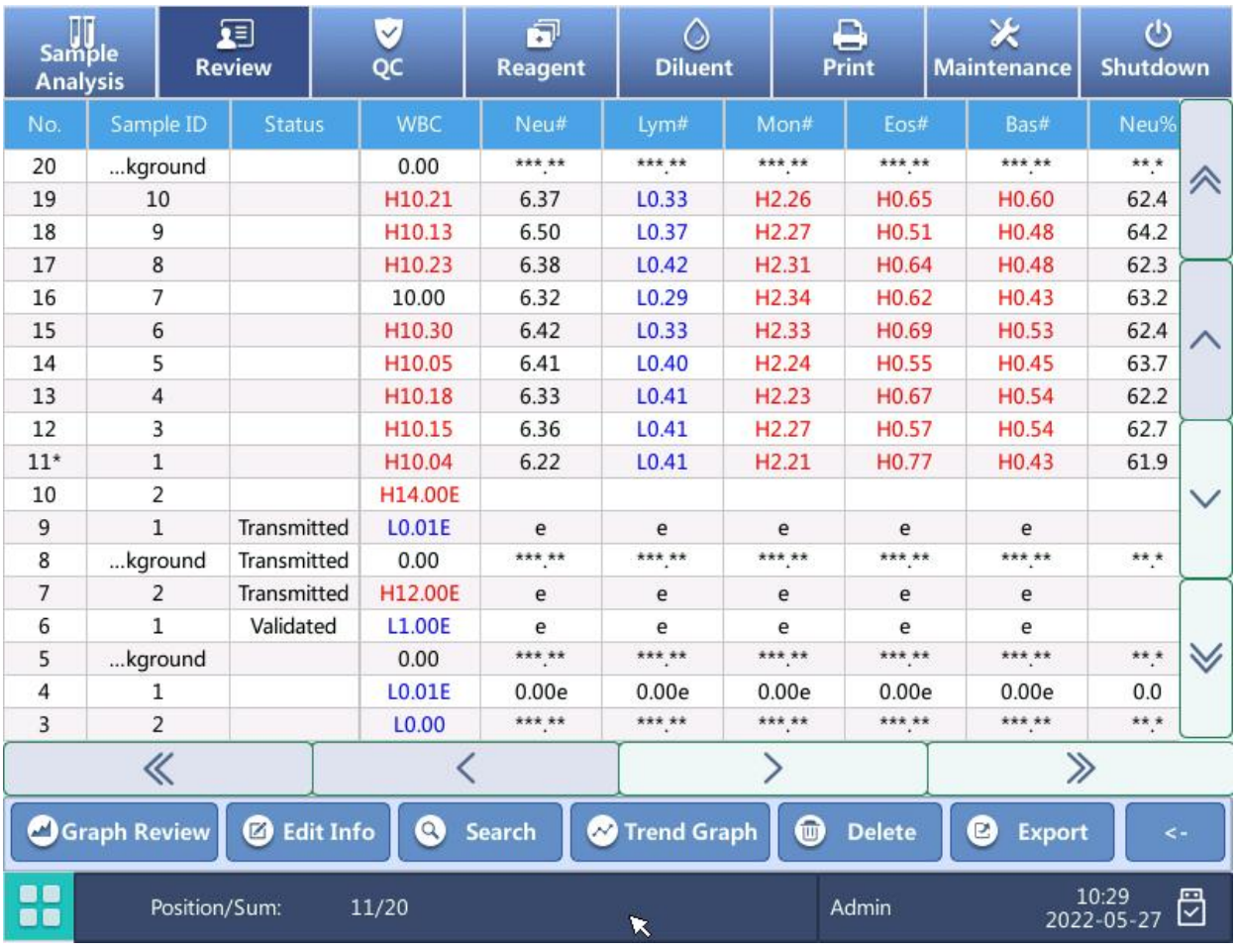
After each sample analysis is performed, the analyzer automatically stores the analysis results in the sample library. The analyzer sample library can store up to 50,000 sample records.

The operator can review all stored sample parameter results and scatter plots and histograms in the sample library in a list or graphical format, and edit and manipulate the result reports.

6.2 List Review

Operators can browse, review, query, edit, and export data from the review screen for past results.

Click "List Review" to enter the "List Review" screen.



6.2.1 List area

The list area shows the list of analyzed samples, which contains the basic information of the samples, such as sample number, sample status, etc.

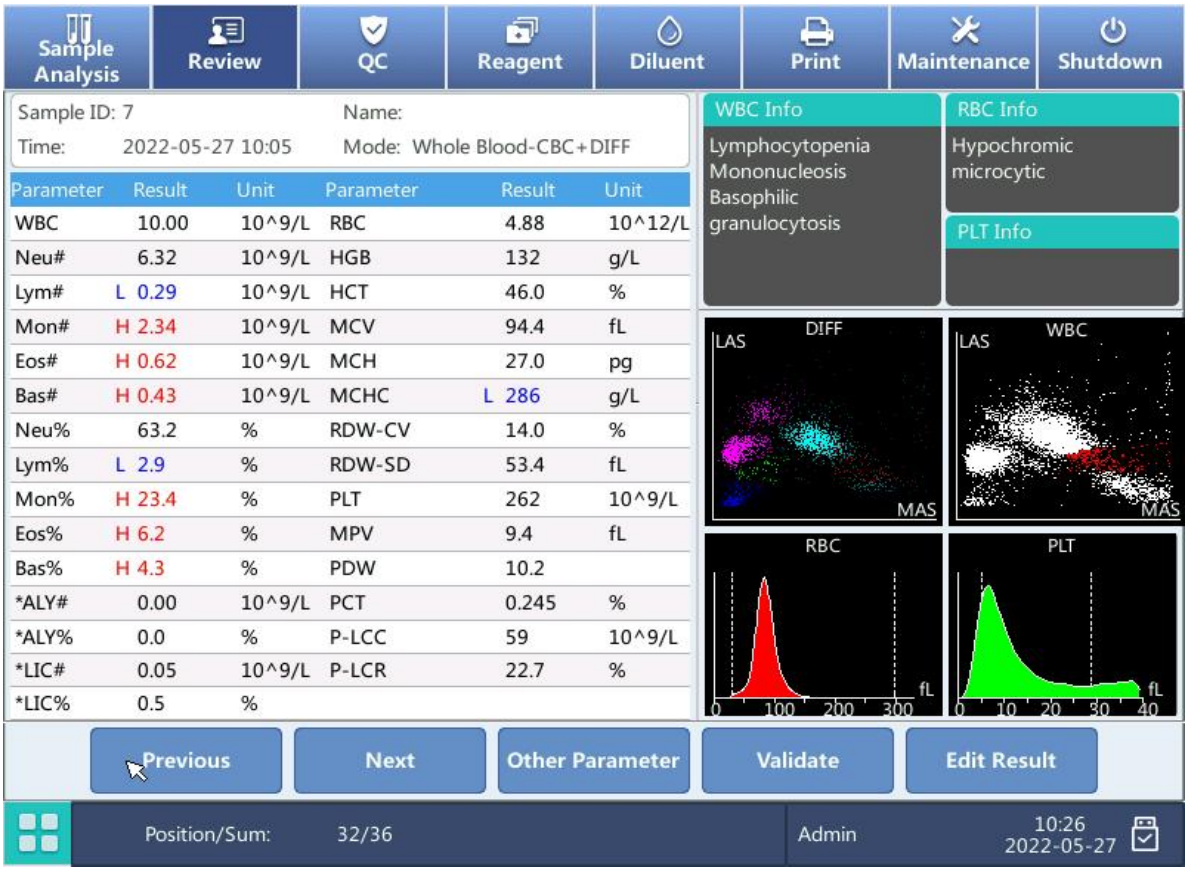
No.	Sample ID	Status	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%
20	...kground		0.00	***.**	***.**	***.**	***.**	***.**	**.*
19	10		H10.21	6.37	L0.33	H2.26	H0.65	H0.60	62.4
18	9		H10.13	6.50	L0.37	H2.27	H0.51	H0.48	64.2
17	8		H10.23	6.38	L0.42	H2.31	H0.64	H0.48	62.3
16	7		10.00	6.32	L0.29	H2.34	H0.62	H0.43	63.2
15	6		H10.30	6.42	L0.33	H2.33	H0.69	H0.53	62.4
14	5		H10.05	6.41	L0.40	H2.24	H0.55	H0.45	63.7
13	4		H10.18	6.33	L0.41	H2.23	H0.67	H0.54	62.2
12	3		H10.15	6.36	L0.41	H2.27	H0.57	H0.54	62.7
11*	1		H10.04	6.22	L0.41	H2.21	H0.77	H0.43	61.9
10	2		H14.00E						
9	1	Transmitted	L0.01E	e	e	e	e	e	
8	...kground	Transmitted	0.00	***.**	***.**	***.**	***.**	***.**	**.*
7	2	Transmitted	H12.00E	e	e	e	e	e	
6	1	Validated	L1.00E	e	e	e	e	e	
5	...kground		0.00	***.**	***.**	***.**	***.**	***.**	**.*
4	1		L0.01E	0.00e	0.00e	0.00e	0.00e	0.00e	0.0
3	2		L0.00	***.**	***.**	***.**	***.**	***.**	**.*

Attention

- The list area displays the latest sample records that have been analyzed by default.

6.2.2 Graphical review

The operator can click the "Graphical Review" button in the "List Review" screen, or click "Previous Record" in the "Sample Analysis" screen to view the detailed analysis results of each sample.



Parameter	Result	Unit	Parameter	Result	Unit
WBC	10.00	10^9/L	RBC	4.88	10^12/L
Neu#	6.32	10^9/L	HGB	132	g/L
Lym#	L 0.29	10^9/L	HCT	46.0	%
Mon#	H 2.34	10^9/L	MCV	94.4	fL
Eos#	H 0.62	10^9/L	MCH	27.0	pg
Bas#	H 0.43	10^9/L	MCHC	L 286	g/L
Neu%	63.2	%	RDW-CV	14.0	%
Lym%	L 2.9	%	RDW-SD	53.4	fL
Mon%	H 23.4	%	PLT	262	10^9/L
Eos%	H 6.2	%	MPV	9.4	fL
Bas%	H 4.3	%	PDW	10.2	
*ALY#	0.00	10^9/L	PCT	0.245	%
*ALY%	0.0	%	P-LCC	59	10^9/L
*LIC#	0.05	10^9/L	P-LCR	22.7	%
*LIC%	0.5	%			

6.2.3 Review/Cancel Review (Administrator level)

- Review sample data

After you select one or more sample records that have not been reviewed in the list review screen, click the "Review" button, and the word "Reviewed" will appear in the sample status area of the sample record.

- Cancel review of sample data

After selecting one or more reviewed sample records in the list review screen, click the "Cancel Review" button, and the "Reviewed" word in the sample status will disappear.

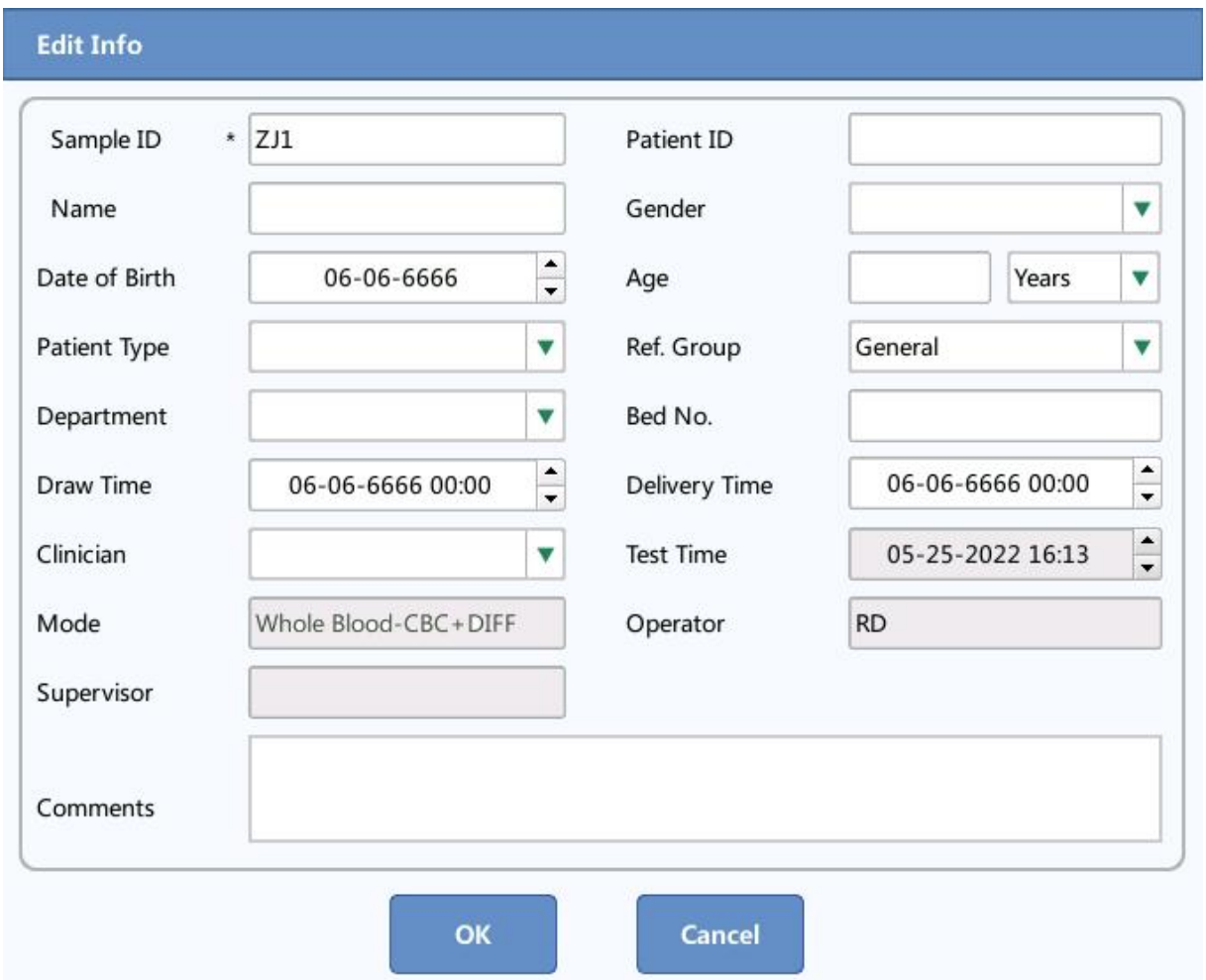
6.2.4 Delete (administrator level)

1. Select the sample records to be deleted in the list area
2. Click the "Delete" button, the following dialog box will pop up

3、Click OK to delete the selected sample records and close the dialog box.

6.2.5 Editing information

In the list review screen, you can select a piece of data and click the "Edit Information" button to bring up the screen shown below.



Click the OK button to save the changes to the sample information and patient information items. After saving, return to the list review screen and the display information will be refreshed.

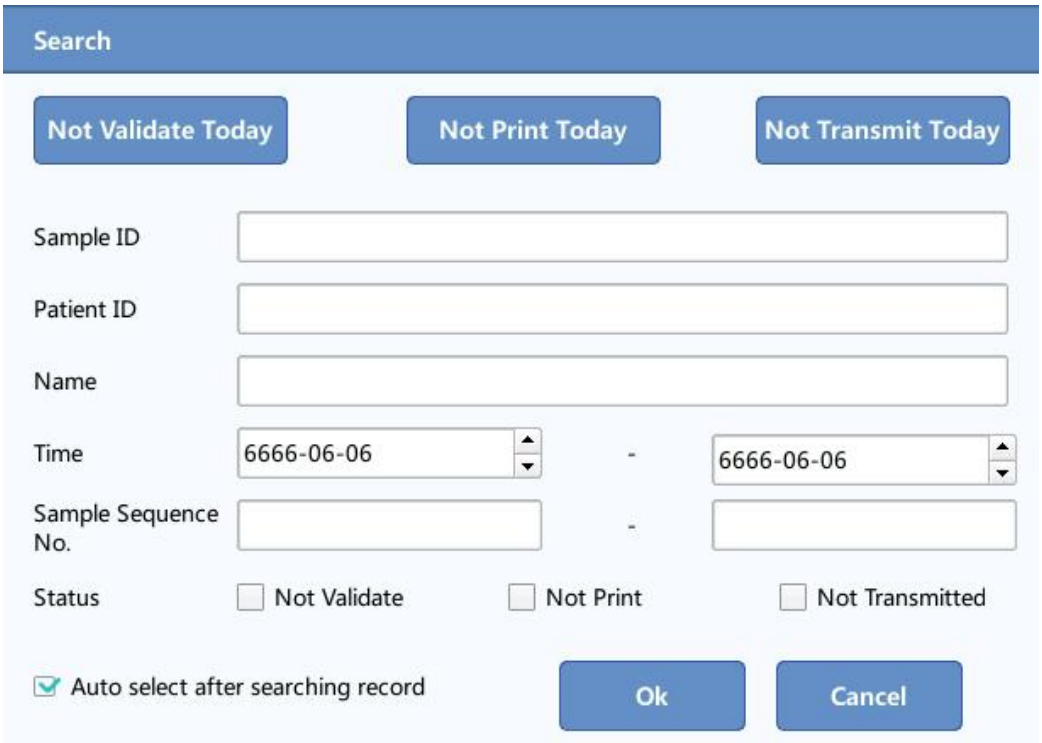
6.2.6 Editing results

You can switch a data in the graphical review screen and click the "Edit Results" button to bring up the screen shown below.

Modify some measurement results of the sample, and click the "OK" button to save the modified content. After saving, return to the graphical review interface. The parameter results on the interface will be automatically recalculated and refreshed according to the modified results.

6.2.7 Queries

1. Click the "Inquiry" button, and the dialog box shown below will pop up.



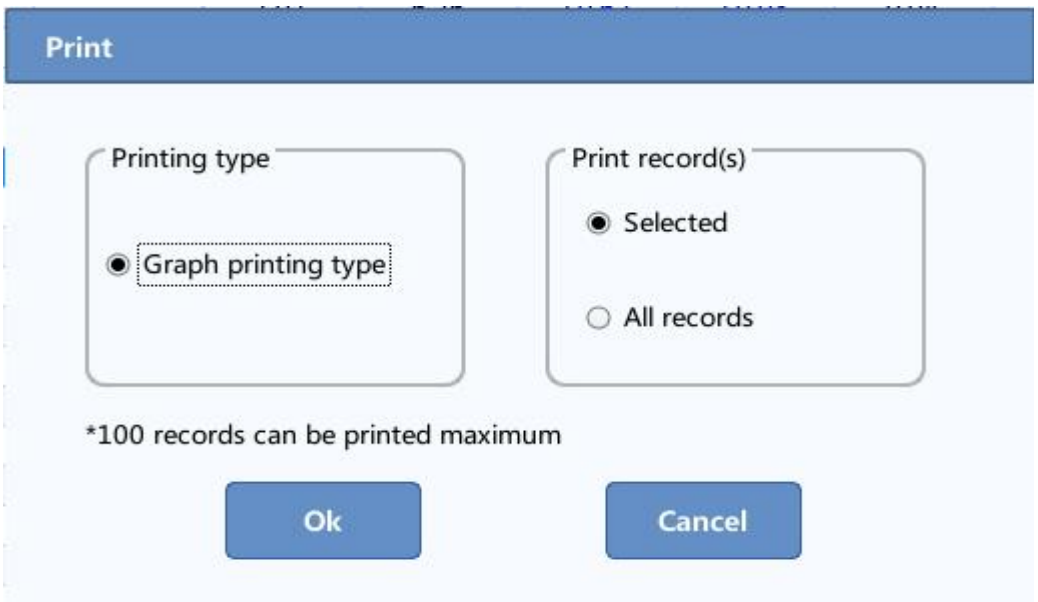
2. Define the query criteria by typing in the corresponding edit box or selecting in the drop-down list.

3. Click "OK" to close the dialog box and start the query, the query results will be displayed in the list area.

6.2.8 Printing

The user can print the sample records as needed.

1. Select the sample records to be printed in the list area, and then click the "Print" button to bring up the dialog box shown below.



2、Select the print method and print record.

3、Click the "OK" button to print.

Printed samples will appear as "Printed" in the status bar of the list review screen.

No.	Sample ID	Status	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%
169	XX1		7.07	6.26	L0.62	L0.08	0.04	H0.07	H88.6
168	ZJ10		9.24	L1.46	2.84	0.52	0.49	H3.93	L15.9
167	ZJ9		9.03	L1.26	2.92	0.49	0.40	H3.96	L14.1
166	ZJ8		9.03	L1.23	2.88	0.51	0.45	H3.96	L13.5
165*	ZJ7	Printed	8.80	L0.90	2.84	0.48	H0.62	H3.96	L10.1
164	ZJ6		9.03	L1.36	2.81	0.46	0.43	H3.97	L15.0
163	ZJ5		8.84	L1.16	2.78	0.48	H0.65	H3.77	L13.3
162	ZJ4		9.04	L1.44	2.82	0.47	0.43	H3.88	L15.9
161	ZJ3		8.86	L1.24	2.70	0.51	H0.55	H3.86	L14.0
160	ZJ2		8.74	L1.29	2.79	0.39	0.40	H3.87	L14.7
159	ZJ1		9.02	L1.40	2.79	0.48	0.43	H3.92	L15.5
158	10		9.13	L1.27	2.84	0.48	H0.58	H3.96	L13.9
157	9		7.30	4.12	2.98	0.10	0.05	0.05	56.4
156	8		5.26	3.37	1.69	L0.06	0.05	H0.09	64.0
155	7		8.01	3.62	H3.89	0.13	0.30	H0.07	45.1
154	6		7.46	H6.44	L0.83	L0.04	0.05	H0.10	H86.2
153	5		9.48	H7.67	1.55	0.15	0.03	H0.08	H80.9
152	4		7.64	5.03	2.37	0.11	0.08	0.05	65.9

Attention

- The priority of the words displayed in the sample status bar: Reviewed > Printed.

6.2.9 Communication

1. Select the sample to be communicated in the list review screen.

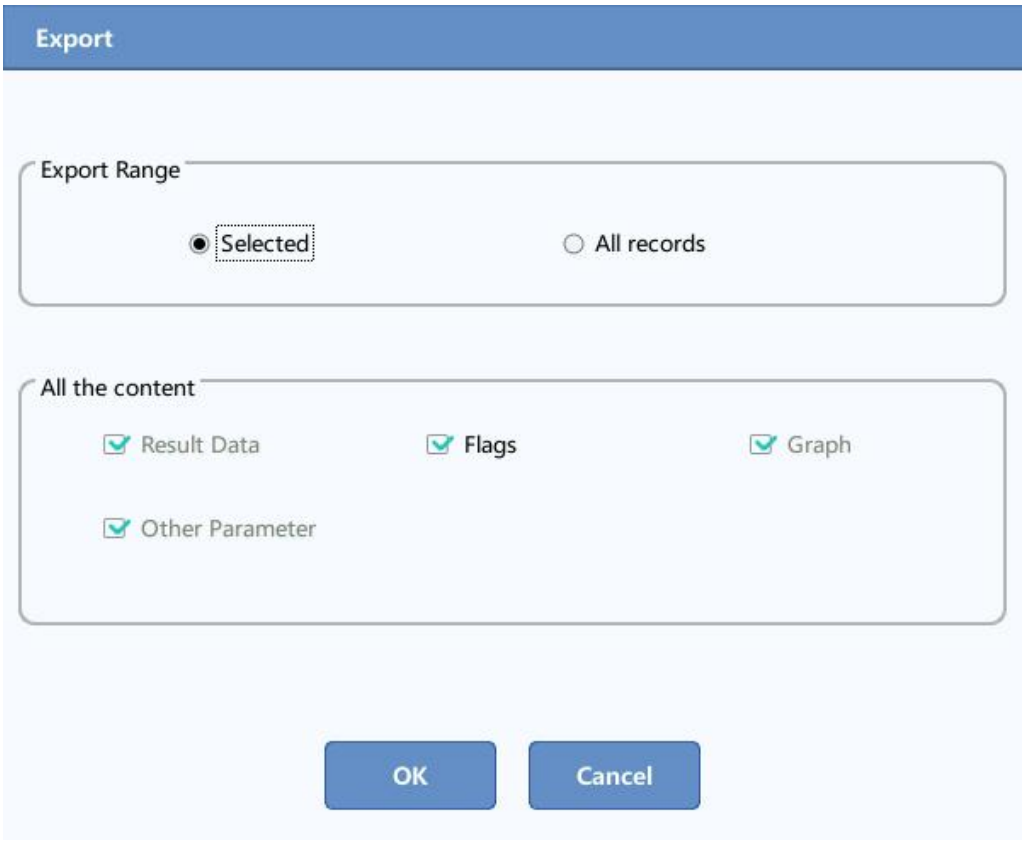
2. Click the "Communication" button, and the "Communication" dialog box will pop up as shown below.

3. Select "Selected Records" or "All Records".

4、Click "OK" to close the dialog box and start communication to communicate the specified results to the data management software side.

6.2.10 Exporting

1. Insert the USB flash drive, click the "Export" button, and the following dialog box will pop up.



2. In the "Export Range" area, select "Selected Records" or "All Records".

3. In the "Export Content" area, check the types of information to be exported as needed (you can check all of them).

Chapter 7 Quality Control

7.1 Overview

Hematology analyzers may produce some degree of error during long-term use. The presence of errors will likely result in incorrect or unreliable analysis results.

QC is the routine monitoring of the performance of the hematology analyzer using QCs to which values have been assigned for various parameters. The operator tests the quality control on the hematology analyzer in the same manner as the blood sample and compares the results with known reference values for the quality control according to specific statistical methods. If the comparison results show large deviations, certain measures are required.

The QC procedure provides an effective method for detecting possible errors, and the operator can effectively exclude the influence of errors on the analytical results only if he or she is familiar with the theory of QC and has mastered the actual operation. To ensure the reliability of the sample results, it is recommended that the operator perform a daily QC of each analyzer with a median QC. When a new batch of QC is used, the new batch should be used in parallel with the existing QC for 5 days and run twice a day, and the results should be within the reference range specified in the instructions for use of the QC. The analyzer provides two QC methods: L-J QC and X-B floating mean method QC.

- All items (samples, controls, calibrators, reagents, waste liquids, etc.), and areas in contact with these substances are potentially biologically contagious. Operators should follow laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with relevant items and areas in the laboratory.

- Clothes, hair, hands, etc. must be kept at a certain distance from the moving parts to prevent being caught by the moving parts.
- Samples may spill out of uncapped blood collection tubes and cause biological contamination. Be careful when handling uncapped tubes.
- Reagents can irritate the eyes, skin and mucous membranes. Operators should observe laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with reagent-related items in the laboratory.
- In case of contact with skin, rinse immediately with plenty of water and receive medical attention if necessary; in case of contact with eyes, rinse immediately with plenty of water and receive medical attention.

Caution

- Running QC with a malfunction may result in incorrect analysis results. If a fault alarm occurs during QC analysis, be sure to run QC analysis after the fault has been cleared.
- Do not reuse disposables.
- Agglutination of samples may lead to inaccurate analysis results. Please check for agglutination of the quality control before analysis, and if so, follow the relevant laboratory procedures.

Attention

- The operator should use the QC substances and reagents specified by the company and store and use them in strict accordance with the instructions for use of the QC substances and reagents. The use of other quality control substances may result in incorrect quality control results.
- Refer to the instructions for the use and storage of the quality control substances.
- QCs that have been left for a period of time need to be re-mixed before they can be analyzed.
- Disposable items such as vacuum blood collection tubes, centrifuge tubes, and capillaries used for blood collection must be of the specifications specified by the manufacturer.

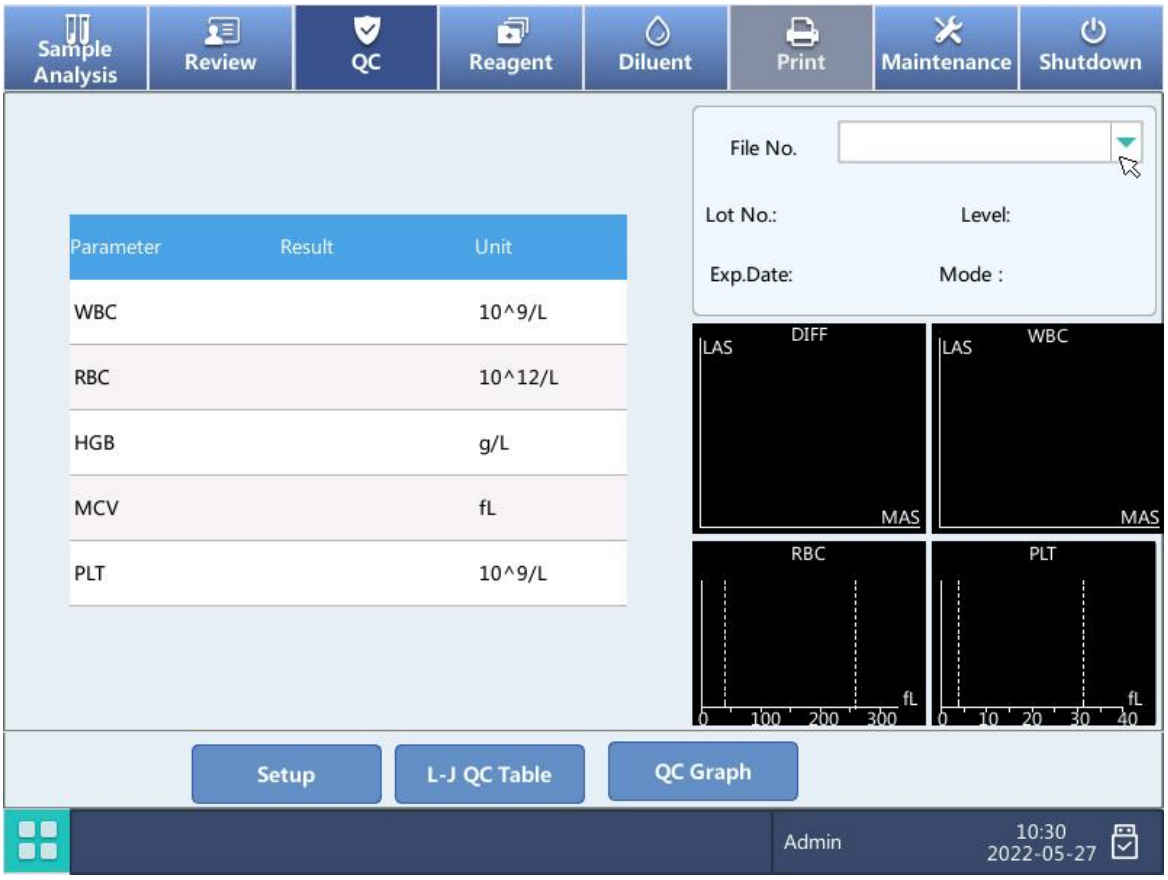
7.2 L-J QC

7.2.1 QC settings (administrator level)

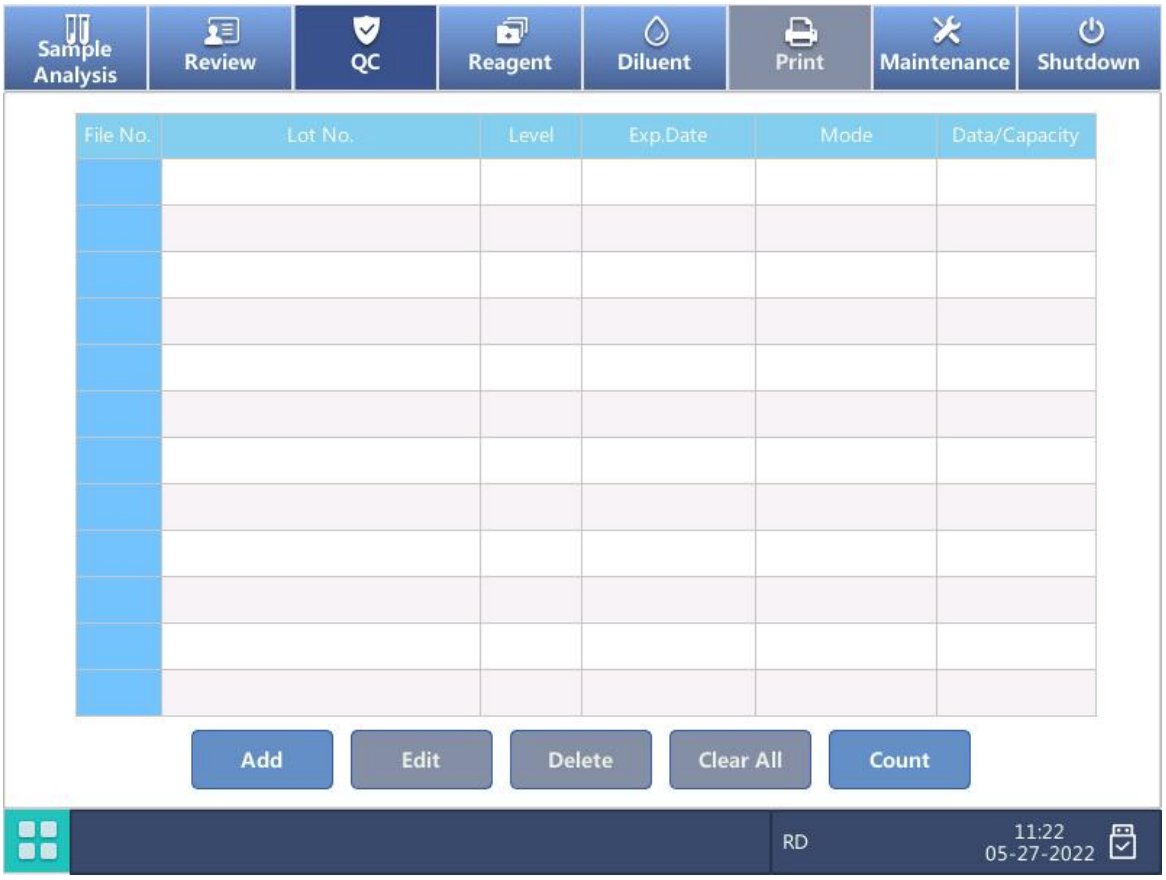
Before performing the analysis of a new batch of QCs, a QC file needs to be set up for each batch of QCs.

- **Quality control settings**

  1. Select "Quality Control" in the pull-up menu and enter the interface shown below.

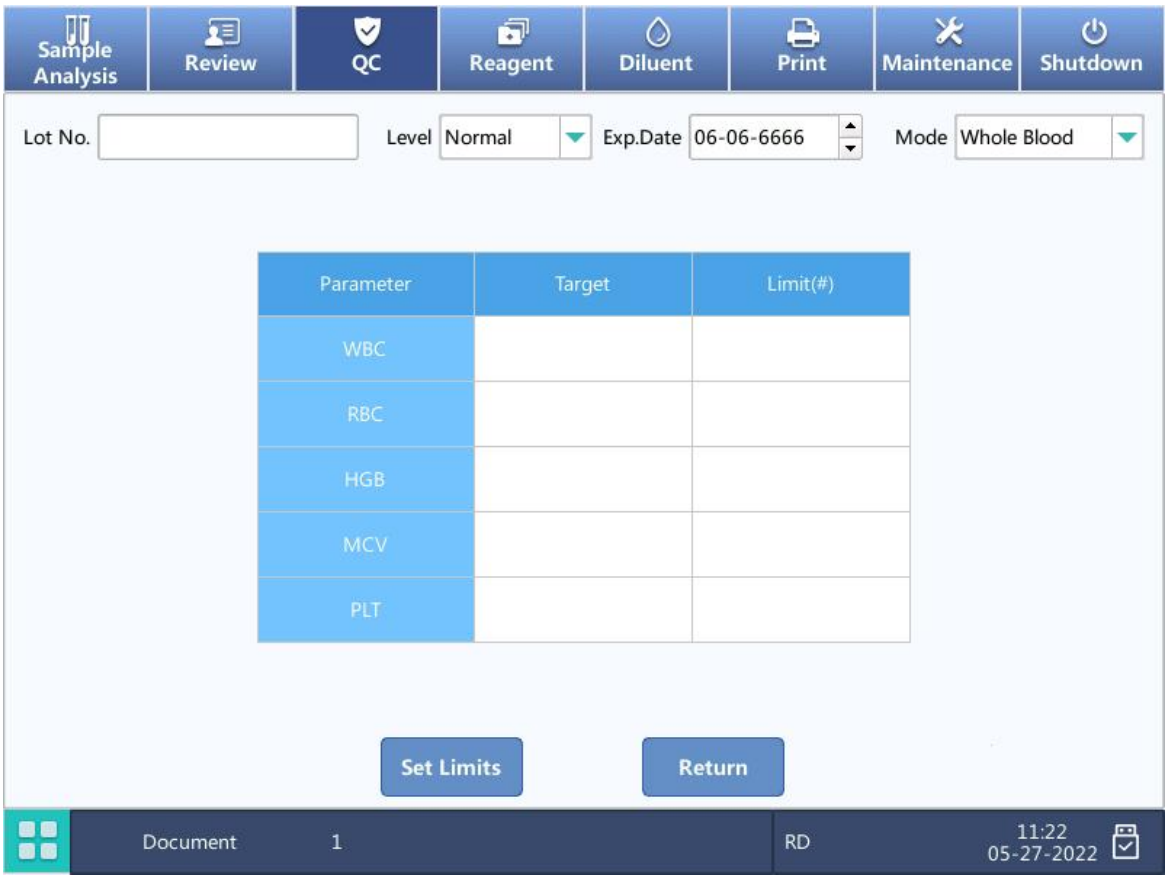


2. Click the "Setup" button to enter the dialog box shown below.



3. click the "Add" button; or select a QC file without QC count results, click the "Edit" button, the

dialog box shown below will pop up.



4. by manually entering the batch number of the quality control in the edit box.

Attention

- Batch number is not allowed to be empty, the entry range is 1-16 bits, characters, numbers, letters and special characters are allowed to be entered, but Chinese is not supported.

5. Select the level of quality control substances.

6. Enter the batch expiration date of the quality control substance.

7. Select the QC mode for analyzing QCs.

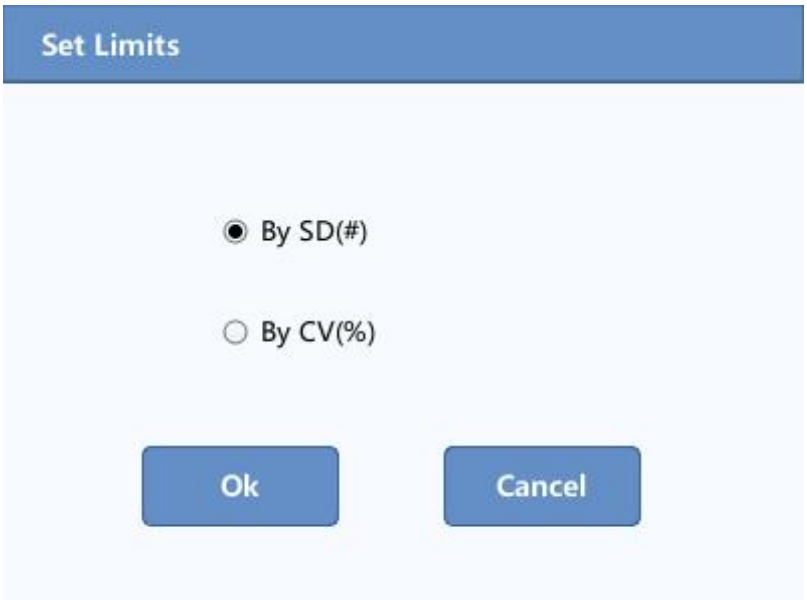
8. According to the target value table of the corresponding batch number, enter its reference value and deviation limit in the edit box after the parameter you want to control.

9. Switch interface to save the entered QC information.

- **Set deviation limit**

If you wish to adjust the display form of the deviation limits, you can do so as follows.

1. Click the "Set deviation limit" button.



2. Click "Calculate by absolute value" if you want the deviation limit to be displayed as absolute value; click "Calculate by percentage" if you want the deviation limit to be displayed as percentage.

3. Click the "OK" button to save the deviation limit settings.

7.2.2 Quality control analysis

Caution

- Running QC with a malfunction may give incorrect analysis results. If a fault alarm occurs during QC analysis, be sure to run QC analysis after the fault has been cleared.
- Agglutination of samples may lead to inaccurate analysis results. Please check for agglutination of the quality control before analysis, and if so, follow the relevant laboratory procedures.
- **Quality Control Analysis**

  1. Select "Quality Control" in the pull-up menu to enter the quality control counting interface.

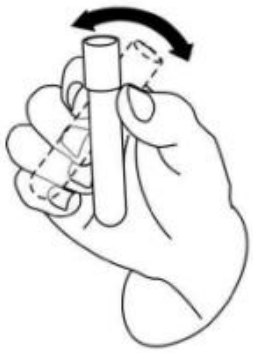
  Attention

  - It is necessary to confirm that the level of the QC to be analyzed is consistent with that shown in the selected QC file, and that the QC to be analyzed has not expired.
  - The expiration date field for expired QCs is highlighted in red underline.

  2. Prepare the quality control according to the instructions for the use of quality control substances.

  3. Perform QC analysis.

  1) Shake thequality controlas shown below to thoroughly mix the sample.



2) Place the QC under the sampling needle of the instrument and click the aspiration button on the instrument to start counting.

3) After the aspiration sample is finished, the operator can safely take away the quality control.

4. After the analysis, the obtained QC results are automatically saved to its QC file and the latest obtained QC results are displayed in the current interface.

Attention

- Up to 100 QC results can be stored per QC file.

5、Continue QC analysis as above if needed

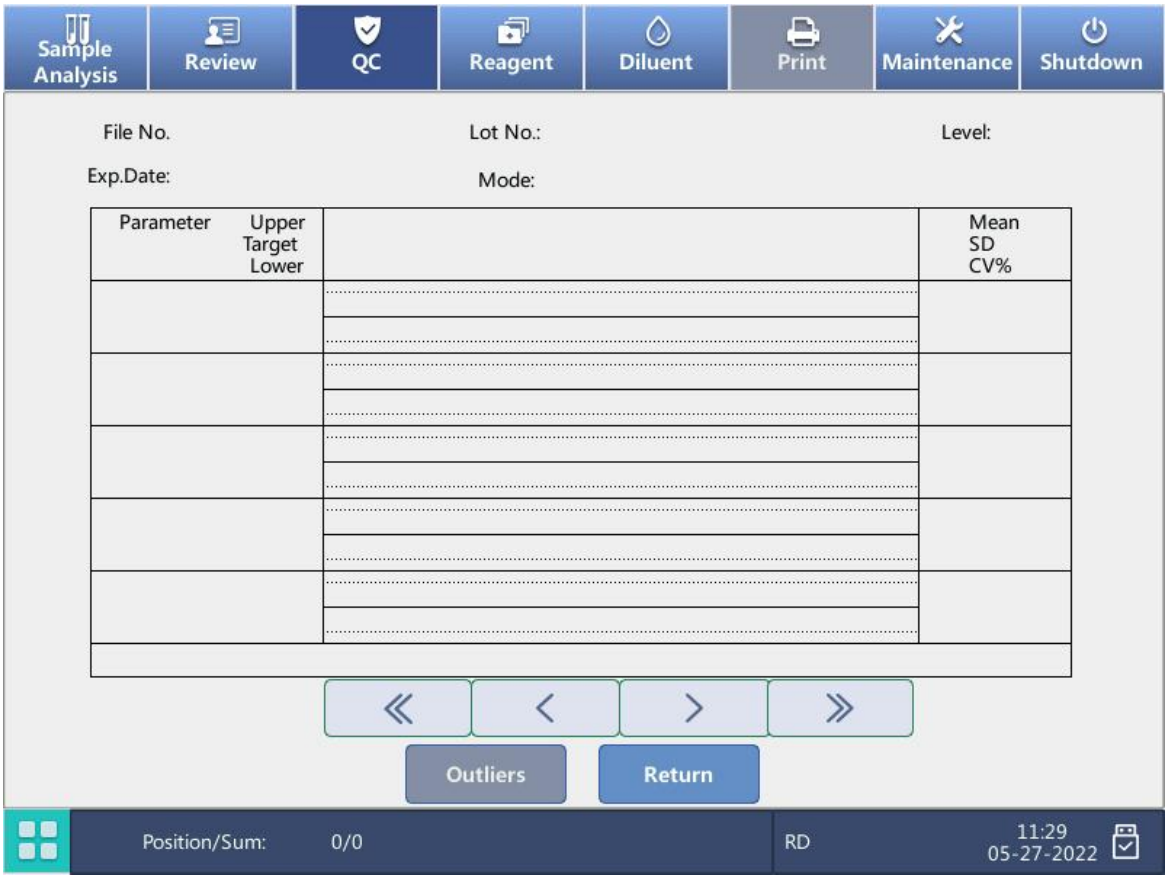
7.2.3 Review of quality control results

After completing the QC analysis, the user can review the QC results in two ways.

- Quality Control Chart
- Quality Control List

- **Quality Control Chart Review**

1. In the "quality control" count interface, click the "quality control chart" button to enter the quality control chart interface corresponding to the quality control file.



2. Click the page flip button on the right side of the QC chart to browse the QC chart of the parameter you wish to review. Click the page button below the QC chart to browse all QC results.

Attention

- For QC files with QC results, if changes in parameter reference values or deviation limits are made and saved, resulting in changes in some parameter reference values and deviation limits, the changed data will be highlighted in yellow.

- Print

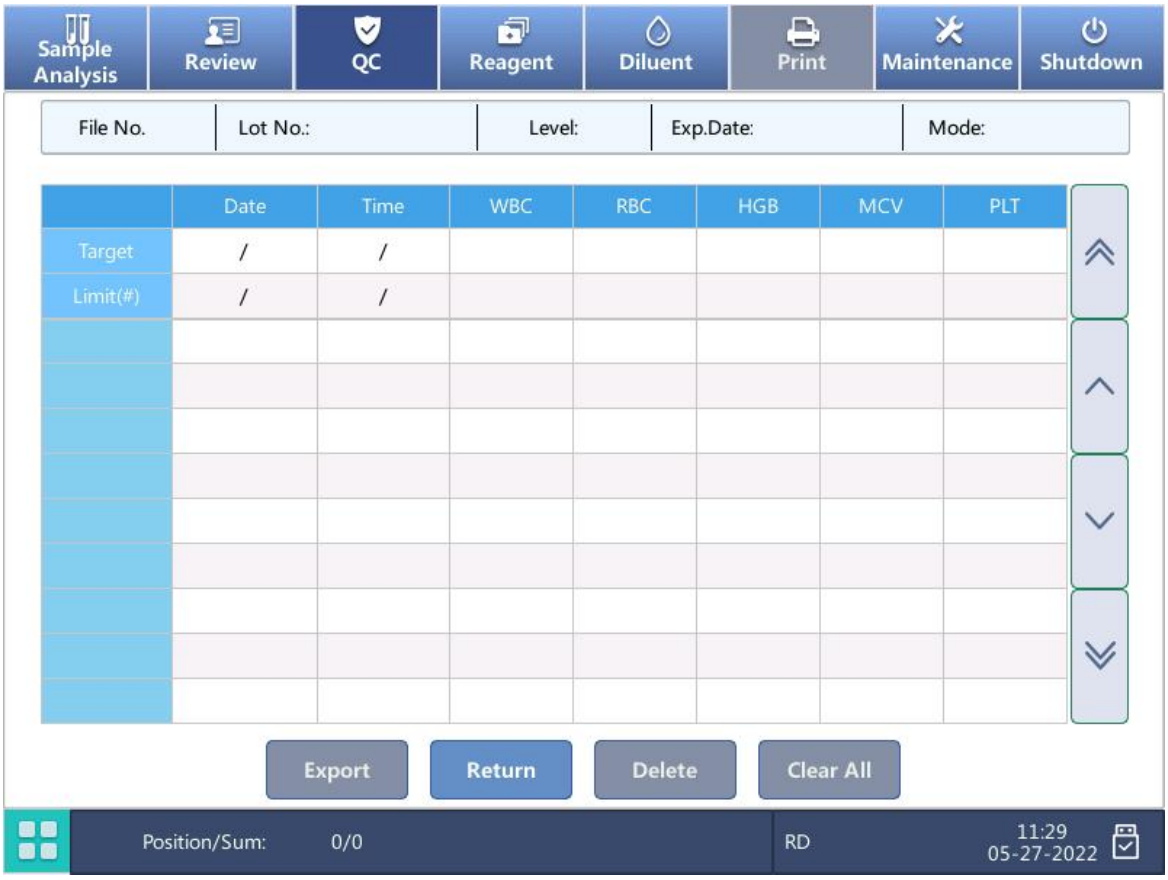
Click the "Print" icon in the top status bar to print the file information of the current QC file and the QC chart of all QC parameters.

Attention

- Does not print the green vertical line in the QC chart, and the value of the QC point corresponding to it.

- **Quality Control List Review**

1.In the "quality control" count interface click the "quality control list" button, enter the quality control file corresponding to the quality control list interface.



2. Click the page button to the right of the QC list to browse all QC records. Click the page button below the QC list to browse all parameter results.

Attention

- For QC files with QC results, if changes in parameter reference values or deviation limits are made and saved, resulting in changes in some parameter reference values and deviation limits, the changed data will be highlighted in yellow.

- Delete (admin level)

1. Click the "Delete Selected Records" button, and the following dialog box pops up.

2、Click "Yes" to delete the selected data.

Attention

- The delete operation is recorded in the log.

- Print

If you wish to print the QC list, click the "Print" icon in the top status bar to print.

- Export

If you wish to export the QC information and QC results for the current QC file, you can do the following.

1. Insert the USB flash drive and click the "Export" button.

2. The system will automatically detect the USB flash drive, and then export the data.

3. Prompt "Export completed".

7.3 X-B QC

7.3.1 Principles of quality control

X-B floating mean method, through the monitoring of the stability of red blood cell parameters such as MCV, MCH, MCHC, etc., to achieve the monitoring of analyzer performance. It belongs to the quality control without quality control substances, and the quality control substance control is the same analyzer performance monitoring means, can reflect the analyzer's analytical performance from different sides, can not replace each other.

X-B QC is recommended when the daily sample size of the analyzer is greater than 100. This QC method requires the use of random samples and is therefore not applicable to samples after differentiation by disease type. It consists of a reference range with a given reference value and upper and lower limits.

Observe the trend of QC results on the reference range.

This analyzer performs X-B QC on three parameters, MCV, MCH, and MCHC. The number of samples per group for X-B numerical analysis can be set from 20 to 200, and the samples are derived from the results of normal analyzer counts without distinguishing between modes.

The analyzer can save up to 500 X-B QC results. When more than the maximum number of QC results are saved, the new QC results will overwrite the oldest results.

7.3.2 QC settings (administrator level)

1. Select "Quality Control">"X-B Quality Control">"Settings" in the pull-up menu, and enter the interface shown below.

In the X-B QC setting screen, you can edit the "X-B QC" information and "Reference Value/Deviation Limit", and set the "Sample Validity".

- **Quality control information setting**

1. Specify the sample size required for X-B QC calculation in the "Number of samples/group" box in the X-B QC setting interface (range 20-200, default is 20).

2. Select "On" or "Off" for X-B QC. If on, samples that meet the sample validity settings will be included in the X-B QC calculation.

- Reference value / deviation limit setting

Before performing QC analysis, you need to complete the setting of reference values/deviation limits by manual entry.

Attention

- The unit of each parameter reference value/deviation limit is the same as the "Parameter unit" setting interface.

1. In the "Reference Value/Deviation Limit" area of X-B QC interface, manually enter the reference value and deviation limit of the QC parameters.

Attention

- Reference values and deviation limits for all QC parameters must be entered and are not allowed to be empty.
- When used for the first time, the initial values of the reference and deviation limits of the relevant QC parameters are provided by default.

2. Switch the interface to save the entered data.

- Sample validity setting

In X-B QC, a sample is considered invalid and not included in the QC calculation if it meets any of the following conditions.

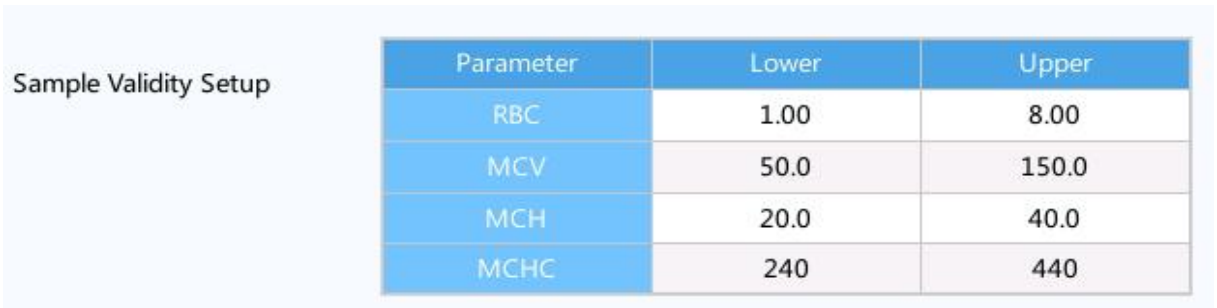
- Samples with results outside the linear range of the instrument.
- Start-up background.
- Sample results that do not meet the "sample validity setting".
- QC data for QC modes other than X-B QC (e.g., L-J, X-mean, and X-mean-R).
- Calibration data.
- The calculated sample result in the event of an instrument malfunction that affects the sample count (e.g. insufficient aspiration or blocked wells).

The "sample validity setting" is to set the validity range of the four parameters RBC, MCV, MCH and MCHC. The sample results must meet the validity range of these four parameters at the same time, otherwise the sample will not be included in the X-B QC calculation. The setting method is as follows.

1. "X-B" quality control select "open"

Set the upper and lower limits of the validity range for the four parameters in the "Sample validity setting" area.

The default initial range of validity for each parameter is shown below.



2. Click the "Save" button when exiting to save the set validity range.

Attention

- In the sample validity setting, the upper limit of the parameter should be no less than the lower limit, otherwise a pop-up will be displayed with an invalid setting.
- The valid range of values allowed to be entered for the RBC parameters is their linear range, and the valid range of values allowed to be entered for each of the remaining parameters is the range of these parameters displayed on the software interface.
- The upper and lower limits of each parameter can only be numeric and can only include one decimal point. The length of the entered value cannot exceed the length of the edit box.
- When the valid range of the parameter is changed, the number of valid samples will be

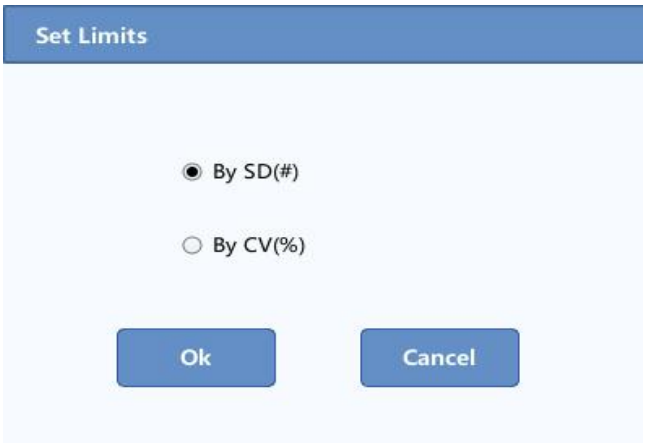
recalculated. For example, if you set the number of valid samples required to derive each set of X-B QC data to 20, and the number of valid samples is 10, when the valid range of the parameter is changed, the previous 10 samples will be discarded and the number of valid samples will be recalculated from 0.

- The units of the upper and lower limits of each parameter are the same as those in the "Parameter Units" setting interface. See 9.2.3 Parameter Setting - Parameter Unit Setting for the setting method.

- Set deviation limit

If you wish to adjust the display format of the deviation limits, you can do the following

1. Click the "Set deviation limit" button.



2. Click "Calculate by absolute value" if you want the deviation limit to be displayed as absolute value; click "Calculate by percentage" if you want the deviation limit to be displayed as percentage.

3. Click the "OK" button to save the deviation limit settings.

- Restore default values

When editing the QC, if you want to restore the parameter reference values and deviation limits to the default initial values, you can click the "Restore default values" button to read the default initial values saved by the system into the X-B QC setting interface.

The default initial values of the reference values/deviation limits for each parameter are

Parameters	Reference value	Deviation limit **(#)**
MCV	89.5	2.7
MCH	30.5	0.9
MCHC	340	10

7.3.3 Quality Control Analysis

Once the QC editing is completed, the system will automatically start accumulating X-B QC counts.

For every 20 to 200 (determined by settings) valid sample results obtained, the system automatically performs an X-B QC calculation, and the obtained QC results can be reviewed in the X-B QC chart or X-B QC list.

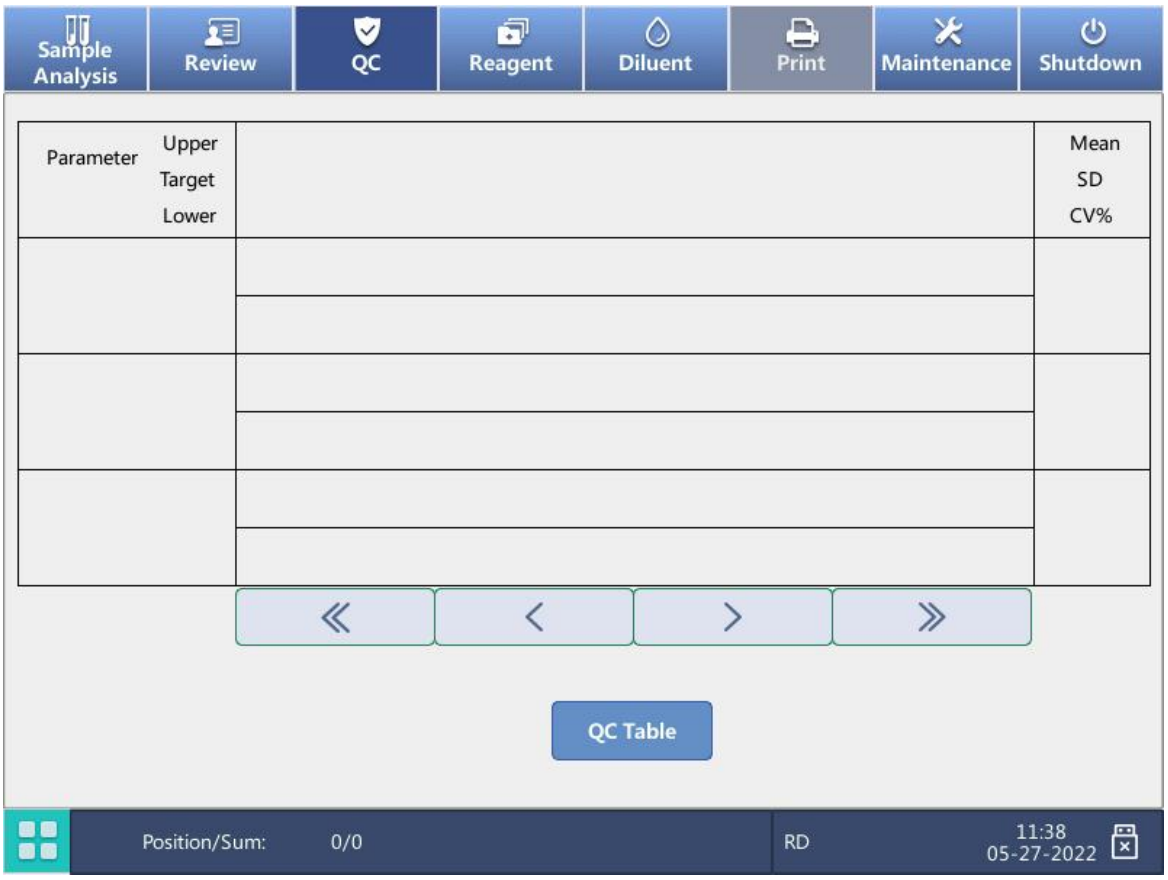
7.3.4 QC results review

After completing the QC analysis, the user can review the QC results in two ways.

- Quality Control Chart
- Quality Control List

- **Quality Control Chart Review**

1.Select "Quality Control">"X-B Quality Control">"Figure" in the pull-up menu to enter the screen shown below.



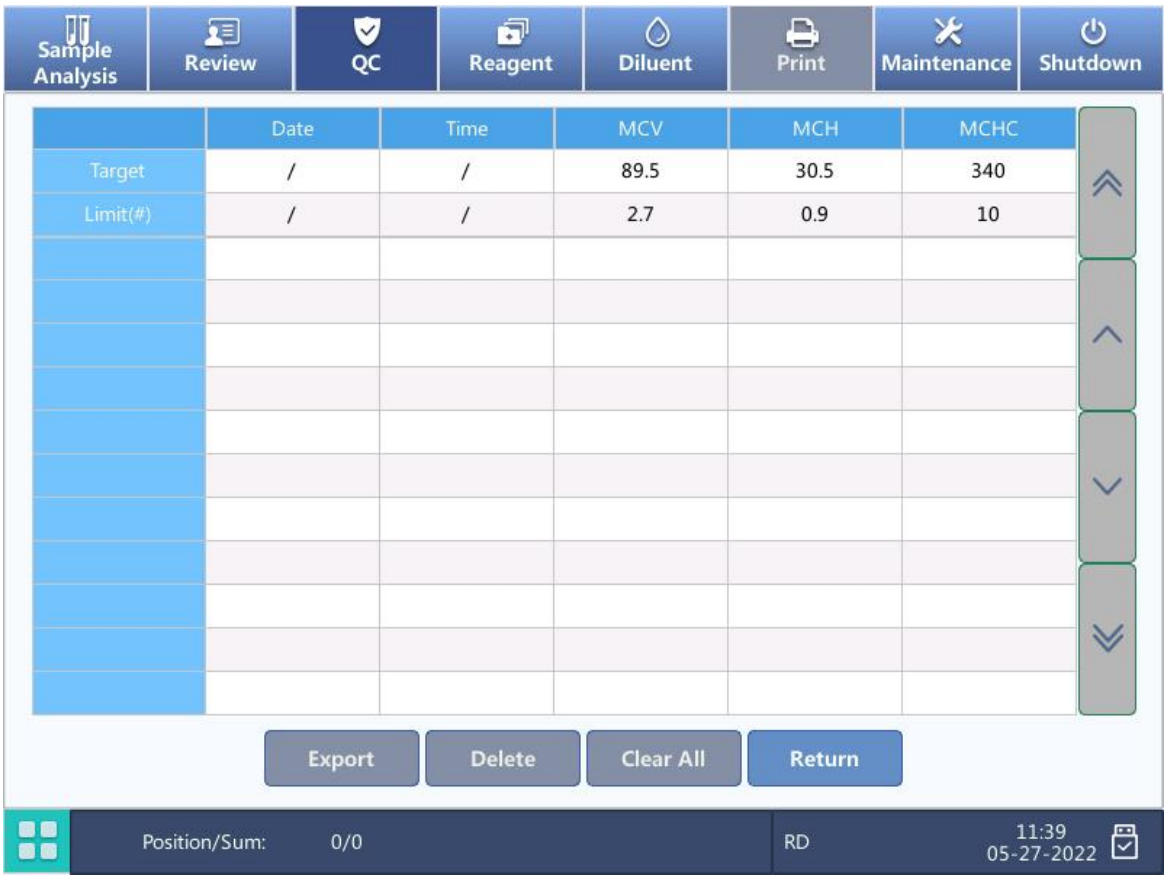
2. Select the file number of the QC file you wish to review, the interface displays the corresponding file information and QC chart.

3. Click the page turn button below the QC chart to browse all the QC results.

- **Quality Control List Review**

1. "In X-B quality control chart" interface.

2. click the "Quality Control List" button to enter the quality control file corresponding to the quality control list interface.



3. Click the page button on the right side of the QC list to browse all the QC records.

Similarly, the QC list interface also provides "delete selected records", "print" and "export" functions, and the operation steps are the same as those of the L-J QC list review.

Chapter 8 Calibration

8.1 Overview

Calibration is the determination of the bias correction factor for blood sample analysis under specified conditions in order to obtain accurate measurement results. To obtain accurate blood sample analysis results, the analyzer should be calibrated when needed according to the procedures given in this chapter.

The analyzer offers three types of calibration: manual calibration , calibrator calibration, and fresh blood calibration.

All or some of the parameters in WBC, RBC, HGB, MCV, PLT can be calibrated.

- All items (samples, controls, calibrators, reagents, waste liquids, etc.), and areas in contact with these substances are potentially biologically contagious. Operators should follow laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with relevant items and areas in the laboratory.

- Reagents can irritate the eyes, skin and mucous membranes. Operators should observe laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with reagent-related items in the laboratory.
- In case of contact with skin, rinse immediately with plenty of water and receive medical attention if necessary; in case of contact with eyes, rinse immediately with plenty of water and receive medical attention.
- Clothes, hair, hands, etc. must be kept at a certain distance from the moving parts to prevent being caught by the moving parts.
- Operators are obliged to comply with the relevant regulations of their regions and countries regarding the discharge and disposal of expired reagents, waste liquids, discarded samples, consumables, etc.

- Do not reuse disposables.

- Disposable products such as vacuum blood collection tubes, centrifuge tubes, capillaries, etc., which are used for blood collection specified by the manufacturer, must be used.
- Only operators with administrator privileges can perform calibration operations.
- The operator should use the calibrators and reagents specified by the company and store and use them in strict accordance with the instructions for use of the calibrators and reagents.
- Only calibrator counts performed in the calibration interface are recognized by the analyzer as calibration operations.
- Calculation of repeatability should also be included in the calibration step.

8.2 Calibration frequency

This analyzer has been calibrated before leaving the factory. Since the analyzer itself is stable in performance, it does not need to be calibrated frequently. The operator still needs to calibrate the analyzer in the following four cases.

- Before first use.
- After the replacement of major components.
- When the host is not used for a longer period of time and resumes use.
- Daily review of the day's QC data for significant deviations.
- When the use environment (e.g., temperature) changes significantly.

Attention

- The analyzer must be calibrated before the measured data can be used as valid data.

8.3 Calibration method

8.3.1 Preparation

Before calibration, check the following steps to confirm that the background range, repeatability and carry-over contamination rate of the analyzer are within the range specified in the manual before calibration. Otherwise, find the cause and wait until the problem is solved before judging whether calibration is needed. If the problem cannot be solved, please contact Singuway after-sales service department.

1. Check the host computer and reagents to ensure that the amount of reagents is sufficient to complete the entire calibration process. If the reagents are used up during the calibration process, it is necessary to perform the calibration again.

2. Perform background test (for calibration directly after power on) or blank count result, if "Background abnormal" is indicated at the bottom of the screen, refer to Chapter 12 Troubleshooting to ensure that the background test result meets the requirements (see Appendix A for local range).

3. Count 11 consecutive times in whole blood-CBC+DIFF mode with the median quality control, and ensure that the reproducibility of the count results in the "List Review" interface is within the range specified in the table below.

Parameters	**Scope**	**Whole blood sample reproducibility (CV)**
WBC	4.00×10^9 /L ~ 15.00×10^9 /L	≤ 2.0%
RBC	3.50×10^{12} /L ~ 6.00×10^{12} /L	≤ 1.5%
HGB	110g/L~ 180 g/L	≤ 1.5%
MCV	70 fL ~ 120 fL	≤ 1.0%
PLT	100×10^9 /L~ 149×10^9 /L	≤ 6.0%
	150~500×10^9 / L	≤4.0%

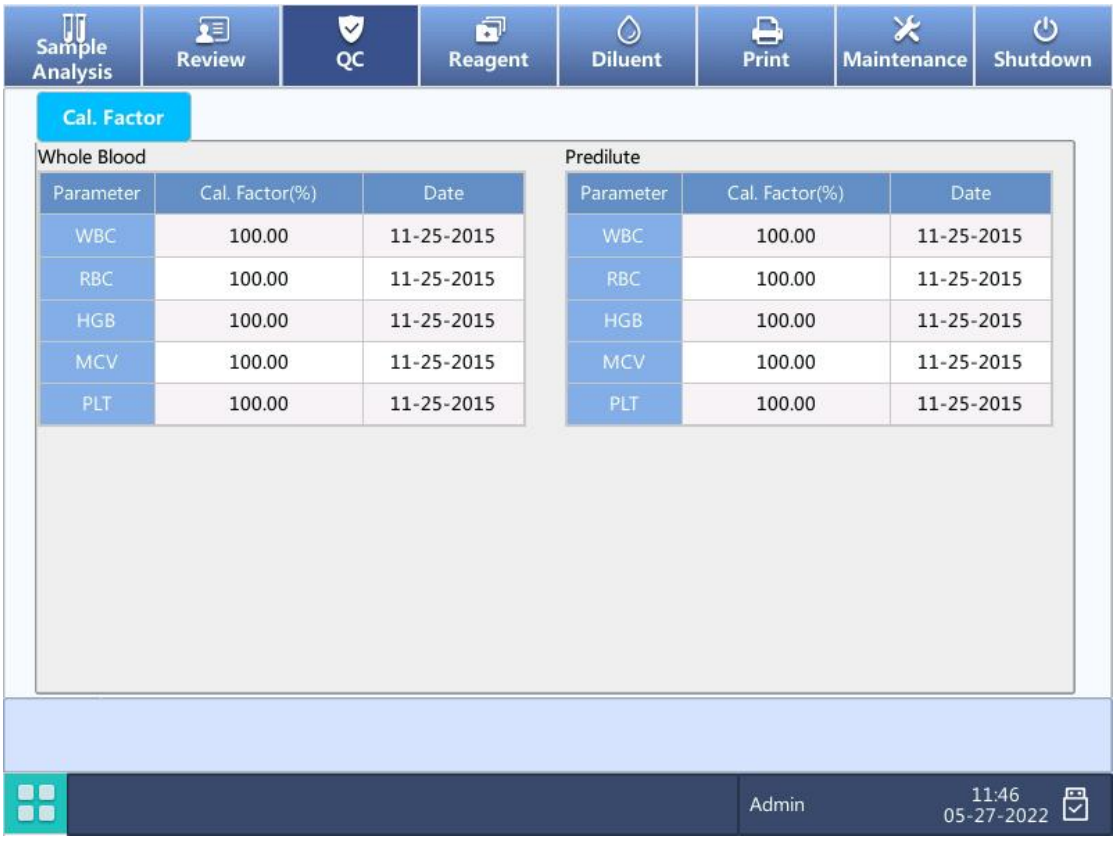
4. It is recommended that the operator create a record file and make a record sheet and then file it. The content of the record sheet is recommended to contain the following entries: date, source of calibrator, lot number and its reference value, and background test value.

Attention

- Please use a vacuum blood collection tube that conforms to the recommended size in the appendix.
- If fresh blood is being used for a repeatable assay, ensure that the sample size is sufficient to support the test.

8.3.2 Manual calibration

Select "Calibration">"Manual Calibration" in the pull-up menu to enter the screen shown below.



Attention

- The operator who logs in as a normal user can only view the calibration coefficients in the current interface and cannot perform calibration operations. If you need to calibrate the analyzer, you should first log out the current user and then log in as an administrator.

Follow the steps below to complete the manual calibration operation.

1 . The operator enters the "Manual Calibration" screen to view the calibration coefficients and calculates the new calibration coefficients for each calibration parameter using the following formula.

New calibration factor = (current calibration factor x reference value)/measurement average

For example, suppose the WBC reference value for a calibrator is 8.4 and the current calibration factor for the whole blood mode is 98.90%. The WBC parameter of this calibrator is measured 10 times in the whole blood mode and the results are taken 10 times (n=10) and the results are 8.1, 8.0, 8.1, 8.1, 8.3, 8.3, 8.2, 8.0, 8.1, 8.3. The reproducibility index CV=1.5% and Mean=8.16. The requirements are met and the measurement mean is valid.

Calculate the new calibration factor.

New calibration factor = (98.90% x 8.4)/8.16 = 101.81%

If the calculated calibration factor for a parameter is outside the valid range (75.00% to 125.00%), the calibration factor is invalid. In this case, the operator should look for the reason (sample not sufficiently mixed or incorrect operation, etc.). Re-calibrate and calculate the calibration coefficient.

2. Once the new calibration coefficients are obtained, enter the new calibration coefficients in the

cells of the calibration coefficients where the calibration parameters need to be performed.

3. When the new calibration coefficient is entered, a prompt will be given when the screen is switched.

If the entered calibration coefficients are valid, the new coefficients are automatically saved when the "Save" button is clicked. At the same time, the calibration date of the corresponding calibration parameter is also refreshed to the current system date.

If the entered calibration coefficients are invalid, clicking "Save" will display "Calibration coefficients entered are invalid!". The modified calibration coefficients and corresponding calibration dates are not saved.

- **Other operations**
  - Print

    If the calibration coefficients are not changed, click the "Print" button to print the current calibration coefficients directly.

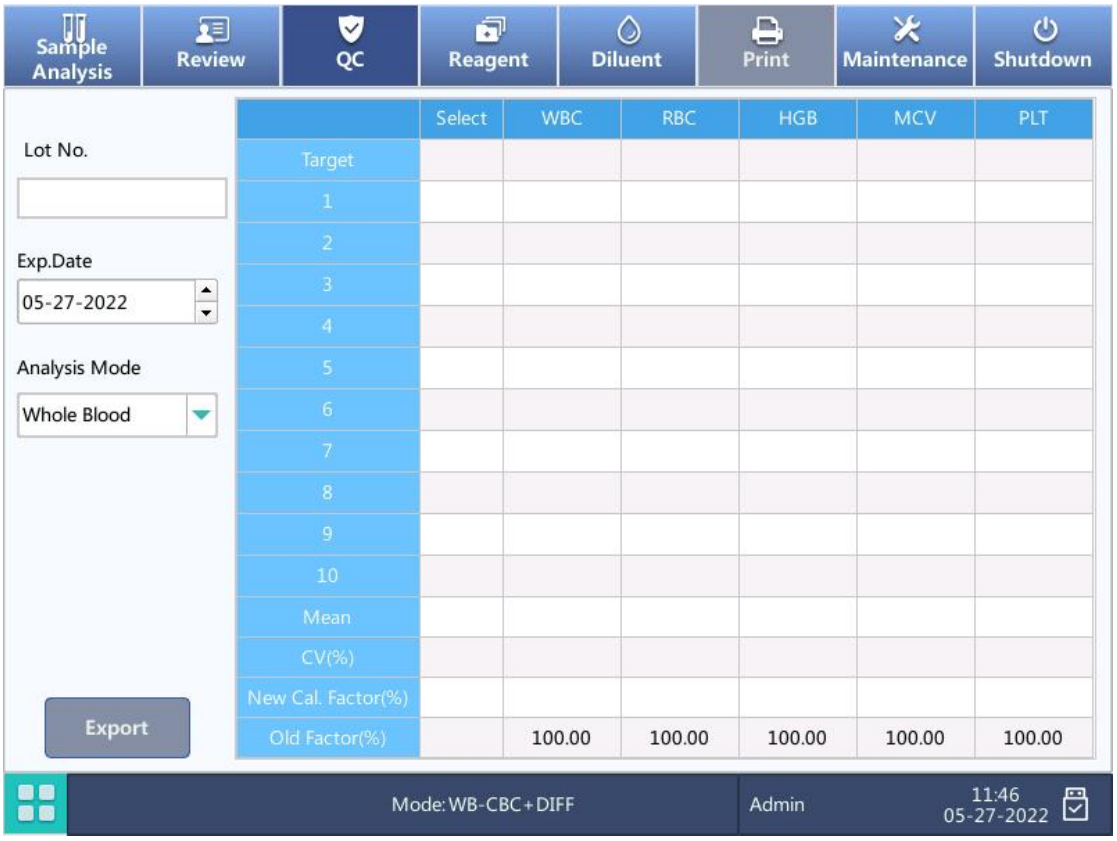
    If the changed calibration factor is invalid, click the "Print" button and a pop-up will appear saying "New calibration factor is invalid! .

    If the changed calibration coefficients are valid but not yet saved, clicking the "Print" button brings up a prompt dialog asking "Do you want to save the average calibration coefficients?" .

    Click "Yes" to close the prompt dialog box, save the new calibration coefficients and the corresponding calibration date, and then print the new calibration coefficients; click "No" to close the prompt dialog box, do not save the new calibration coefficients and the corresponding calibration date, and then print the saved calibration coefficients before editing.

8.3.3 Calibration of calibrators

Select "Calibration">"Calibrator Calibration" in the pull-up menu to enter the screen shown below.



Attention

- Calibrator calibration can be performed in whole blood-CBC+DIFF, pre-diluted-CBC+DIFF mode.
- The operator must use the calibrator specified by the company exclusively for this analyzer, and the company will not be responsible for the use of other calibrators that result in inaccurate analytical results.
- See the instructions for use of the calibrator for the lot number, expiration date and parameter target values.
- CV% value exceeded does not affect the display of calibration coefficients.

Complete the calibrator calibration operation by following the steps below.

1. Confirm the mode on the instrument control panel.

2. Enter the current calibrator lot number in the "Lot Number" edit box (required).

3. Set the expiration date. The default expiration date of the analyzer is the current date. If you want to modify the expiration date, click the "Expiration Date" edit box to reset the expiration date. The expiration date of the calibrator cannot be less than the current system date.

The expiration date (date) value entered by the operator should be the date the calibrator was opened + the expiration date after the calibrator was opened or the expiration date stated in the instructions for use

of the calibrator, if the two are not equal, whichever is smaller will ensure that the calibrator is always within the expiration date during use.

4. In the corresponding edit box of "Target value", enter the target value of the parameter to be calibrated.

5. Prepare the calibrator according to the instructions for use of the calibrator.

6. Press the aspiration button on the analyzer to start the calibration counting sequence.

7. Each time the calibration count is completed, the calibration count progress bar dialog box will be closed automatically, and the analyzer will process differently according to the calibration count results:

- If there is a parameter in the current count for which the calibration count data exceeds the linear range of that parameter but is within the display range, the calibration data is displayed in the list and, at the same time, a prompt dialog box pops up.

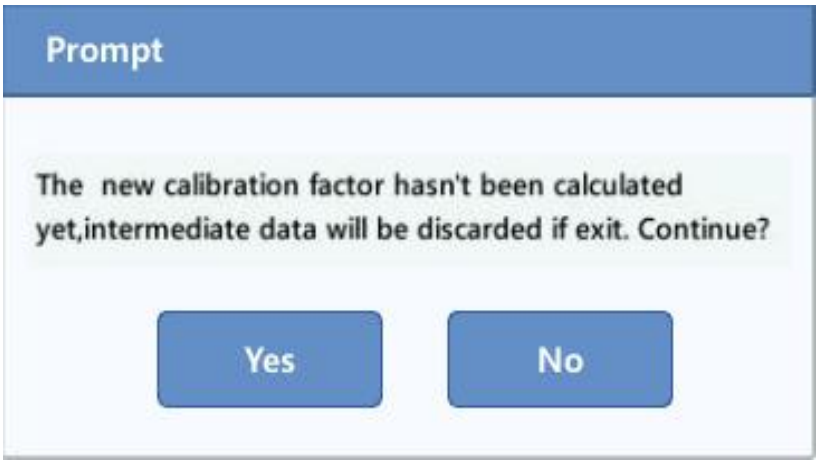
After clicking "OK", the dialog box will be closed and the calibration data shown in the list will be deleted automatically and the calibration data will not be saved.

If the calibration count data of one parameter in the current count exceeds the display range of that parameter, *** will be displayed in the list (*** will be displayed according to the data format of each parameter), and at the same time, a prompt dialog box will pop up.

- If the calibration count result is within the linear range then the result is considered valid and is

displayed directly. After a valid calibration count result is obtained, the checkbox in front of it changes to the "√" selected state and the technique of calibration coefficients is engaged by default.

8. When the new calibration coefficient has not been calculated, if the operator switches the interface, a prompt dialog box will pop up.



Click "Yes" to discard the existing calibration data, close the prompt dialog, and switch to another screen without changing the original calibration coefficients.

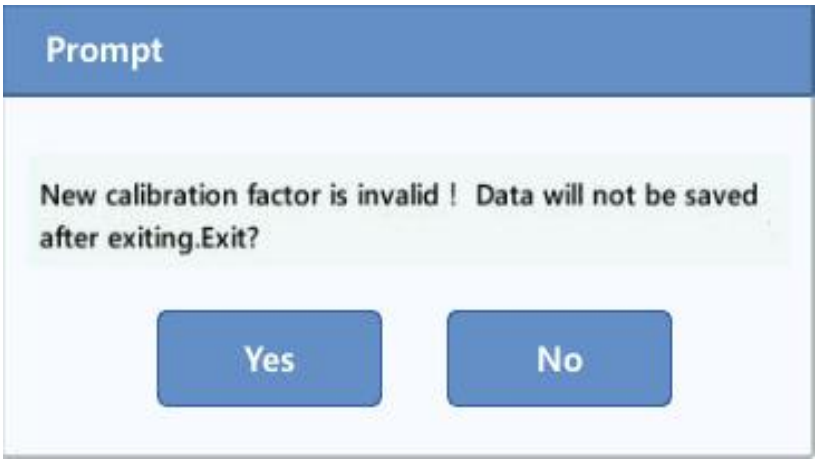
9. When the total number of valid calibration counts reaches n (n is greater than or equal to 5), the analyzer will automatically calculate the average Mean, CV% and new calibration coefficients for all calibration data selected by "√" according to the formula by default (the calibration data of the 1st count does not have "√ " selected, so it is not involved in the calculation either).

The operator can select certain groups of data to calculate the calibration coefficients, but the calibration coefficients can be calculated only after at least 5 groups of data are selected by "√". The calibration coefficients are refreshed every time the operator clicks the checkbox "√" to select or uncheck the data.

When the valid calibration data in the list reaches 10, a pop-up dialog box will appear immediately, "The calibration of this calibrator has been completed!". If you press the aspiration button on the analyzer again, an alarm tone of "drop" will sound, which will not affect the counting.

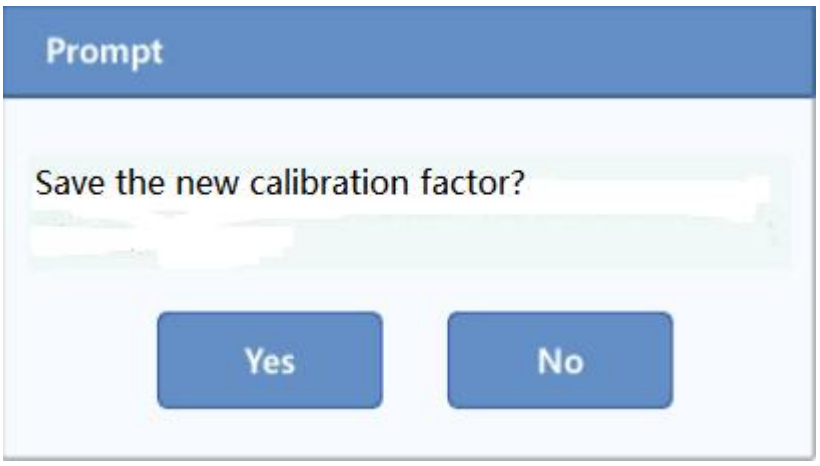
10. After obtaining the new calibration coefficients, the operator switches the interface to distinguish between the following.

- If the calculated calibration coefficient of any parameter to be calibrated is not in the range of 75% to 125%, i.e. <75% or >125%, or the CV% value of any calibration parameter exceeds the repeatability index of the analyzer, the coefficient values of all parameters to be calibrated are not saved and a prompt dialog box will pop up.



Click "Yes" to close the prompt dialog and switch to other screens. At the same time, the calibration coefficient and calibration date of each calibration parameter are not modified.

- If the calculated calibration coefficients are all within the range of 75% to 125% (i.e. ≥ 75% and ≤ 125%) and the CV% values of all calibration parameters do not exceed the repeatability index of the analyzer, a prompt dialog box pops up.

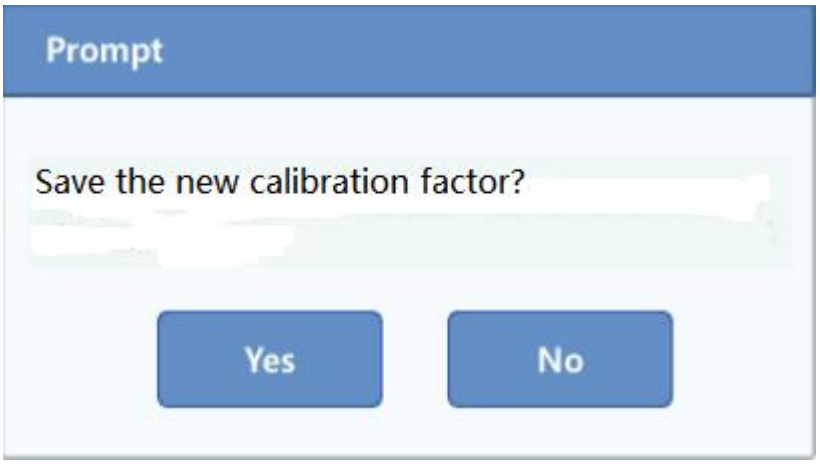


Click "Yes" to save the calibration coefficients, close the prompt dialog box, exit the current calibration interface, and switch to other interfaces.

- **Other operations**
  - Print

    If the calibration coefficients are invalid, clicking the "Print" button will bring up a pop-up message that the calibration coefficients are invalid.

    If the calibration coefficients are valid, click the "Print" button to bring up the prompt dialog.



Click "Yes" to close the prompt dialog box, save the calibration result and the corresponding calibration date, and then print the content of the current calibration interface; click "No" to close the prompt dialog box, and do not save the calibration result and the corresponding calibration date.

8.3.4 Fresh blood calibration

Select "Calibration">"Fresh Blood Calibration" in the pull-up menu to enter the screen shown below.

Complete the fresh blood calibration operation as follows.

1. Prepare 3 to 5 normal fresh blood samples by referring to the sample preparation method described in Chapter 5, Daily Operations.

2. Take 3~5 prepared normal fresh blood, make at least 5 measurements on the reference instrument respectively, calculate the average value, and use the average value of the resulting data as the reference value; or make measurements and calculations according to the reference method, and use the resulting data as the reference value.

3. Click the "Analysis Mode" drop-down menu to select the calibration mode for fresh blood calibration, which can be whole blood-CBC+DIFF or pre-diluted-CBC+DIFF mode.

4. Select the current calibration blood sample number in the "Current Blood Sample Number" drop-down list box.

5. Select the parameter to be calibrated in the checkbox in the first row of the list.

6. Enter the reference value of the parameter to be calibrated in the corresponding edit box of "Reference Value".

7. Prepare a fresh blood sample.

8. Press the aspiration button on the instrument to start the calibration counting sequence.

9. Each time the calibration count is completed, the calibration count progress bar dialog box will be closed automatically, and the analyzer will be processed differently according to the calibration count results.

- If the calibration count result is not within the linear range, but is within the display range, a prompt dialog box pops up while the calibration count result is displayed in the list.

After clicking "OK", the dialog box closes and the calibration results shown in the list are automatically deleted, and the calibration results are not saved.

- If the calibration count result is not in the displayed range, the calibration count result in the list is displayed *** (*** is displayed according to the data format of each parameter), and at the same time, the prompt dialog pops up.

After clicking "OK", the dialog box closes and the calibration results shown in the list are automatically deleted, and the calibration results are not saved.

- If the calibration count result is within the linear range then the result is considered valid and is displayed directly.

After a valid calibration count result is obtained, the checkbox in front of it becomes ticked and the blood sample calibration factor is calculated by default.

10. For each blood sample, when the total number of valid calibration counts reaches n (n is greater than or equal to 5), the analyzer will automatically calculate the mean Mean, CV% and blood sample calibration coefficient according to the formula, by default, for all calibration data selected by "√".

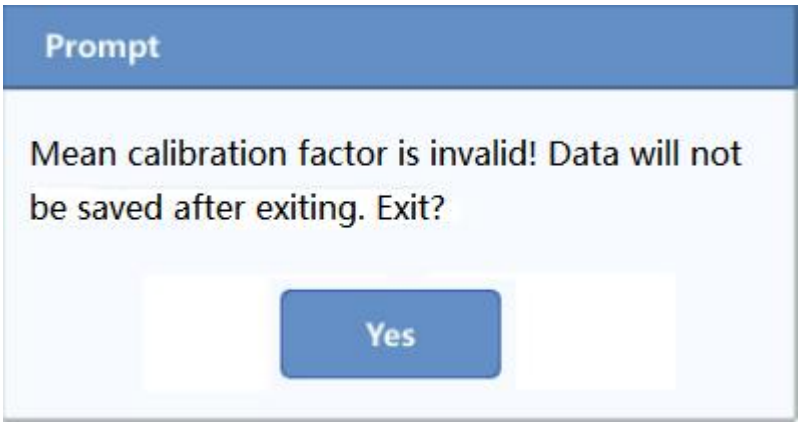
The operator can select certain groups of data to calculate the blood sample calibration coefficient, but the data selected by "√" is at least 5 groups before the blood sample calibration coefficient can be calculated. The calibration coefficients are refreshed each time the operator clicks the checkbox "√" to select or uncheck the data.

When the list of valid calibration data reaches 10, starting the calibration count again will bring up the dialog box "Current blood sample calibration is complete."

11. Select other calibration blood samples in the "Current blood sample number" drop-down list box, and complete the counting of other calibration blood samples with reference to steps 8 to 10 above, and get the calibration coefficients of each blood sample.

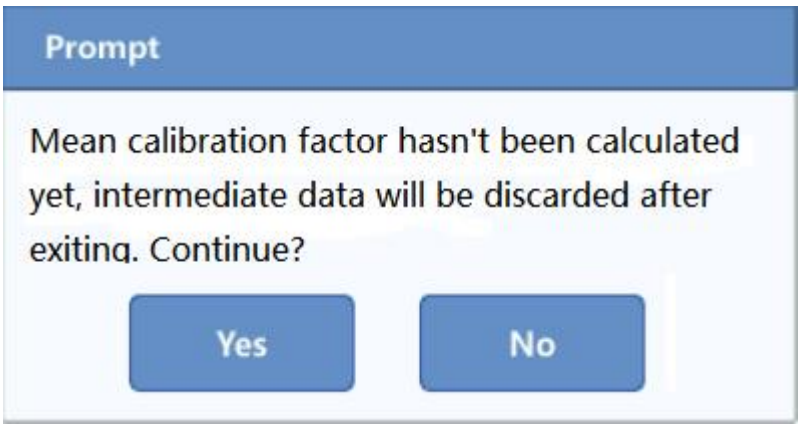
12. Switch blood samples to distinguish between the following.

- If the calculated calibration coefficient for a blood sample is not within the valid range, or if the CV% value of any of the calibration parameters exceeds the analyzer's repeatability index, a prompt dialog box pops up when another blood sample is selected.



Click "Yes" to clear the reference values entered for the current blood sample, all existing calibration data, and all calculated values, including calibration coefficients, then close the prompt and switch to another blood sample.

- If a new calibration factor has not yet been calculated for this blood sample, a prompt dialog box will pop up.



Click "Yes" to clear the entered reference values and all existing calibration data, close the prompt dialog, and switch directly to other blood samples.

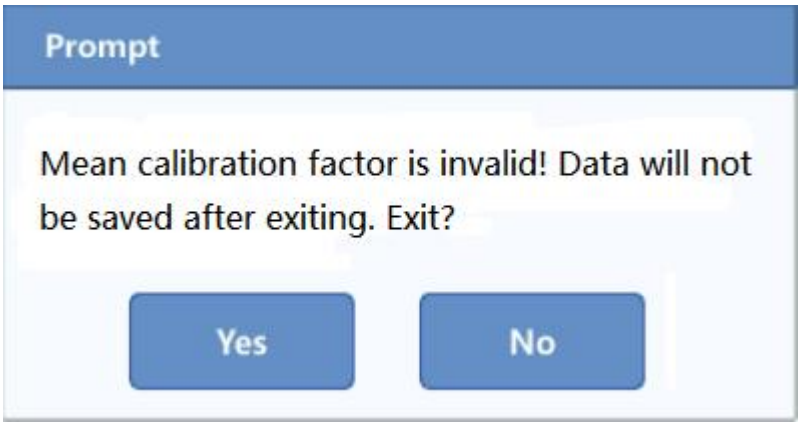
- If the calibration coefficients for this blood sample are within the valid range and the CV% values for all calibration parameters do not exceed the repeatability index of the analyzer, then direct switching is allowed without any prompt.

13. After getting the calibration coefficients of more than 3 fresh blood samples, click the "Calculate" button on the interface to enter the fresh blood calibration calculation interface.

Click the check box in front of each blood sample calibration coefficient to select or cancel the participation of the calibration coefficient of a blood sample in the calculation of the average calibration coefficient.

When the calibration coefficients selected by "√" are greater than or equal to 3 groups, the CV% value between calibration coefficients will be automatically recalculated according to the calibration coefficients currently selected by "√".

When the calibration coefficients selected by "√" are greater than or equal to 3 groups, the average calibration coefficients will be automatically recalculated according to the calibration coefficients currently selected by "√". If the absolute value deviation between the calibration coefficients involved in the average calculation and the original calibration coefficients is greater than or equal to 5%, the average calibration coefficient is judged to be invalid, and the following dialog box will pop up when exiting the fresh blood calibration interface of the current calibration mode.

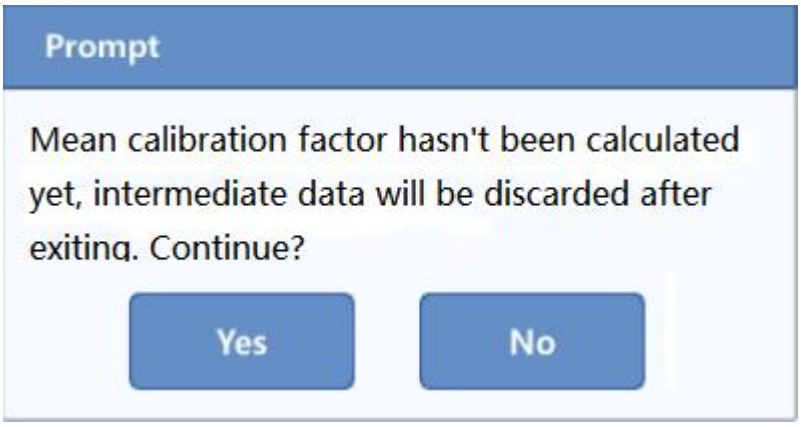


Click "Yes" to close the prompt dialog, exit and clear the current calibration data, and switch to the

corresponding interface.

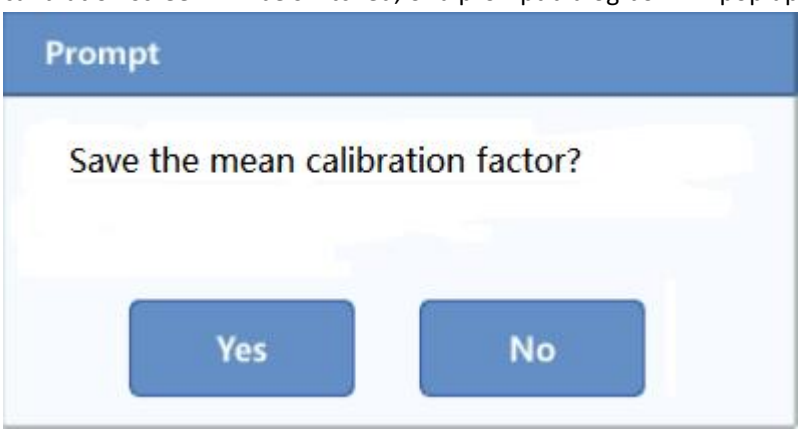
Click "No" to return to the current screen. Invalid average calibration coefficients are accompanied by a "?" and are marked in red.

14. If the average calibration coefficient has not been calculated, the new blood calibration interface will be switched, or a dialog box will pop up when the calibration mode is switched.



Click "Yes" to discard the existing calibration data, close the prompt dialog, and switch to another screen or another calibration mode without changing the original calibration coefficients and dates.

15、 If the calculated average calibration coefficient is within the valid range, the fresh blood calibration screen will be switched, or a prompt dialog box will pop up when switching calibration modes.



Click "Yes" to save the current average calibration coefficients. Then, switch to other interface or other calibration mode; click "No" to not save the average calibration coefficients and all calibration data, close the prompt dialog box directly, and switch to other interface or other calibration mode.

- **Other operations**
  - Print

    If the average calibration factor is invalid, clicking the "Print" button will bring up a pop-up message that the calibration factor is invalid.

    If the average calibration coefficient is valid, click on the "Print" button to print the calibration coefficients for one (or more) groups of blood samples in the "Calculated Results" table in order (with

or without "√ "), as well as the intermediate calibration count results and average calibration coefficients for each calibration factor.

Chapter 9 Setting

9.1 Overview

The analyzer has been initialized and set up at the factory, and the interface that users see after the initial power-on is the system default. To meet the different needs of the actual application, some parameters of the analyzer can be reset.

To ensure the security of product settings and data, the analyzer divides the operators into two permission levels: normal user and administrator (the administrator has all the permissions of a normal user). The settings menu bar is shown below.

9.2 Instrument Setting

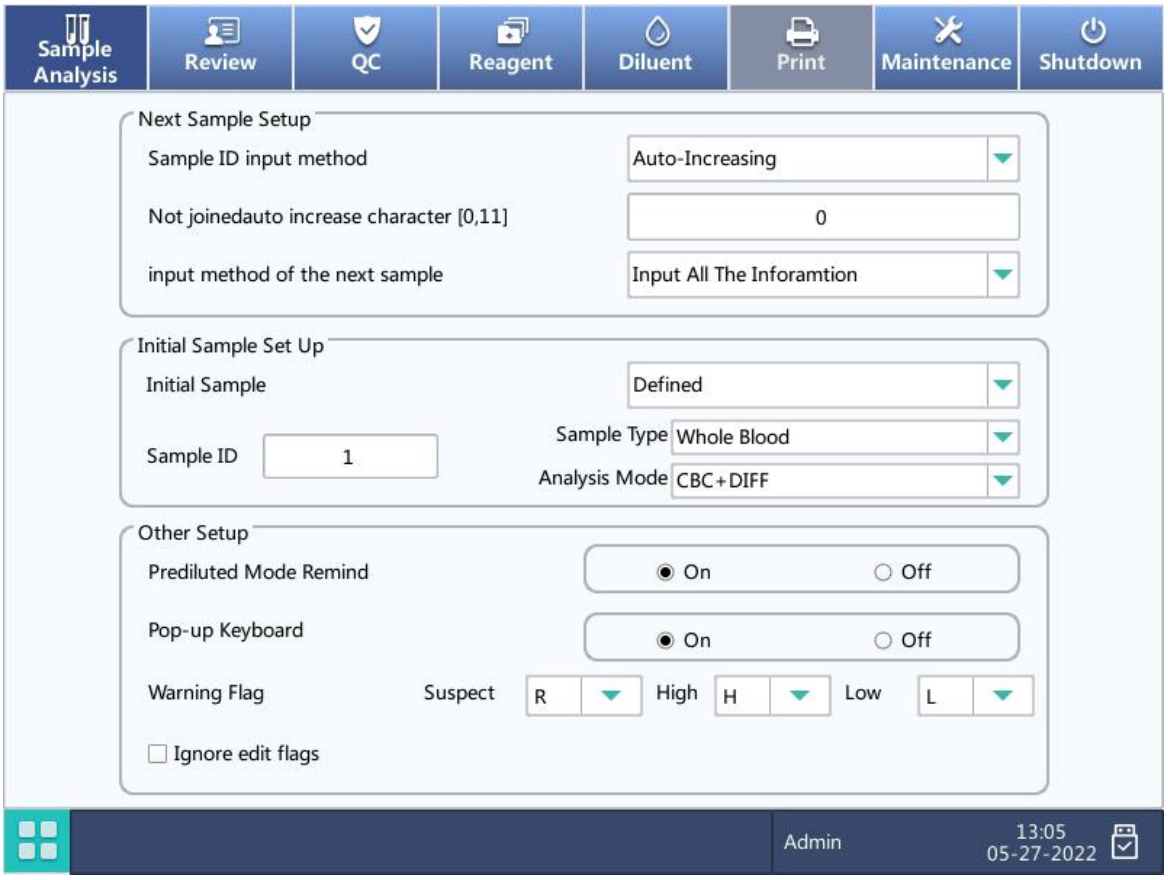
9.2.1 System Settings

- **Auxiliary settings**

In the pull-up menu, select "Settings">"System Settings">"Auxiliary Settings" to enter the screen shown below. The operator can complete the following settings.

- Next sample setting
- Boot start sample setting

- Other settings



- Next sample setting

Select the sample number entry method

Click on the drop-down list and select the entry method for the sample number from the following options.

- Auto Increment
- Manual entry

Does not participate in automatic incremental digit

The user can set the number of bits in the sample number that do not participate in auto-increment.

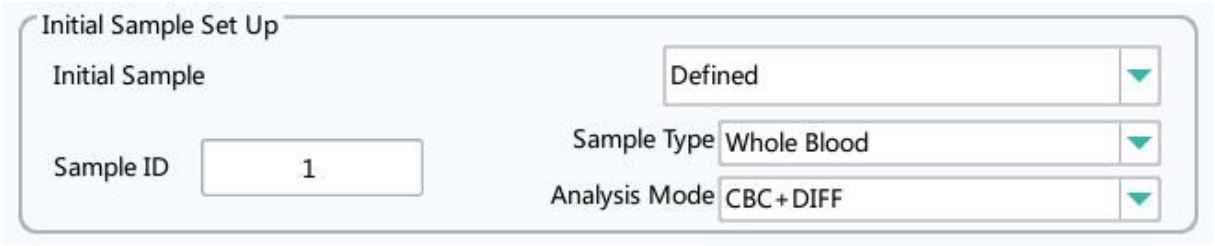
This edit box is activated when the sample number entry method is selected as "Auto Increment".

In the "Do not participate in auto-increment digits" edit box, enter the desired number n. Then the first n characters of all sample numbers do not participate in auto-increment.

- Boot start sample setting

Operators can.

Select to set the sample number to the specified value after power on, and enter this value in the edit box. Or select "Continue with sample number before shutdown".



- Other settings

Radio box selection settings

Select the "On" radio box to activate the corresponding function (select the "Off" radio box to disable the corresponding function).

Alarm markers

Set suspicious alarm mark: The operator can re-enter a single character in the edit box as a suspicious alarm mark (default is "R").

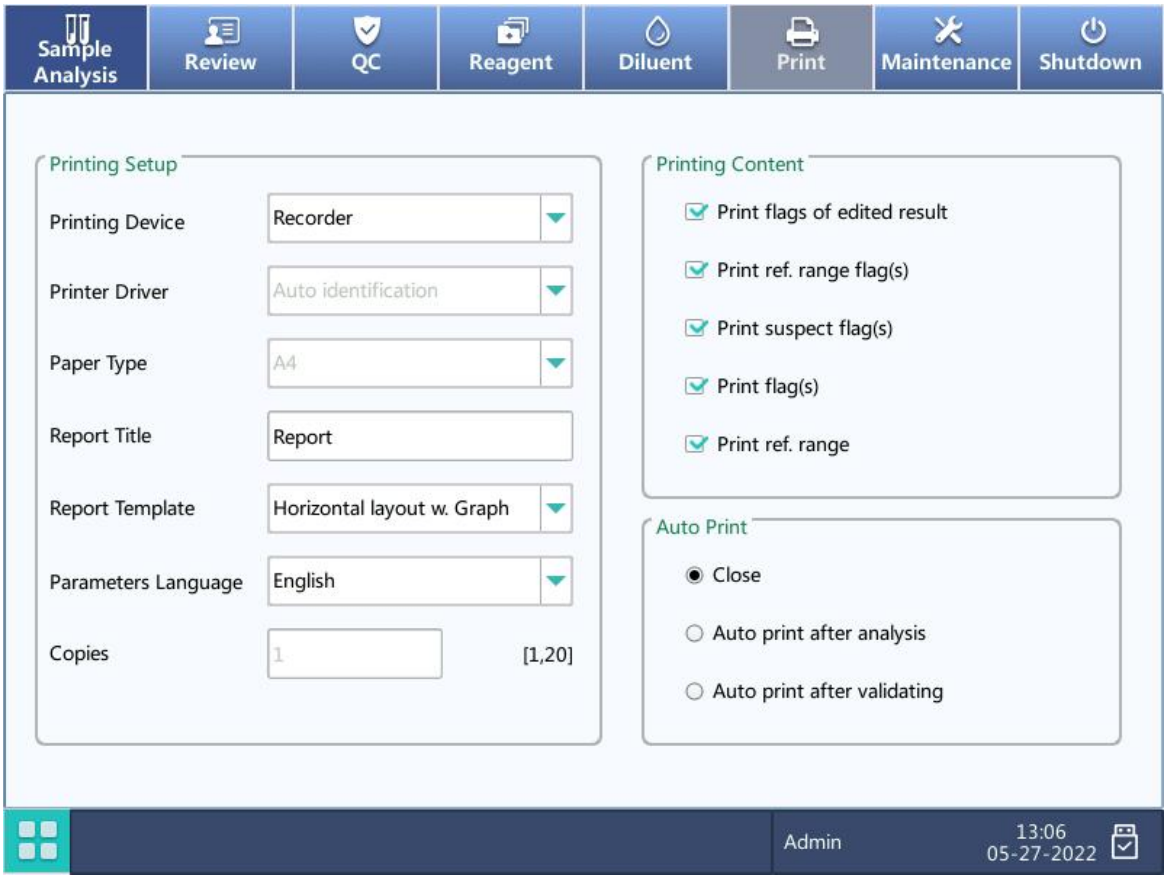
Set high and low alarm markers: The operator can enter a single character in each of the two edit boxes or select from the drop-down list as the high and low alarm markers (the default high alarm marker is "H" and the low alarm marker is "L").

- **Print Settings**

Select "Settings">"System Settings">"Print Settings" in the pull-up menu to enter the screen shown below. The operator can complete the following settings.

- Print Settings

- Print content
- Automatic printing



- Print Settings

Printing Equipment

Click on the drop-down list to select the printing device used by the instrument.

Printer Drivers

Click on the drop-down list and select the printer driver used by the instrument.

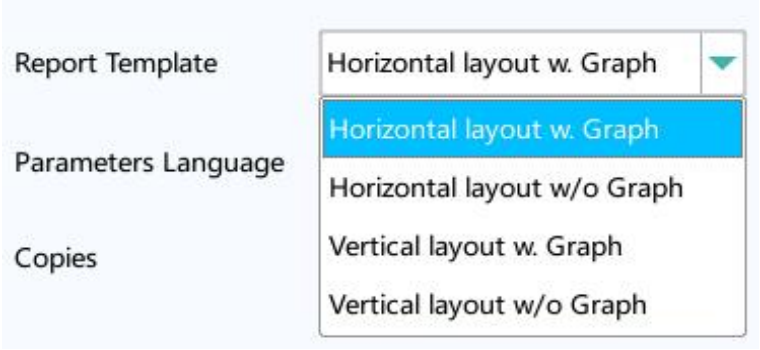
Paper type selection

Click the drop-down list to set the type of paper used for report sheet printing.

Report Card Title

Report form template

Click on the drop-down list to set the template to be used for report sheet printing.



Parametric Language

Click the drop-down box to select the language type of the parameter display on the report form.

Number of copies printed

Enter the number of copies of the report to be printed each time in the "Number of copies to print" edit box.

- Print content

The operator can activate the relevant print settings by clicking to check the desired option in the following check boxes, as required.

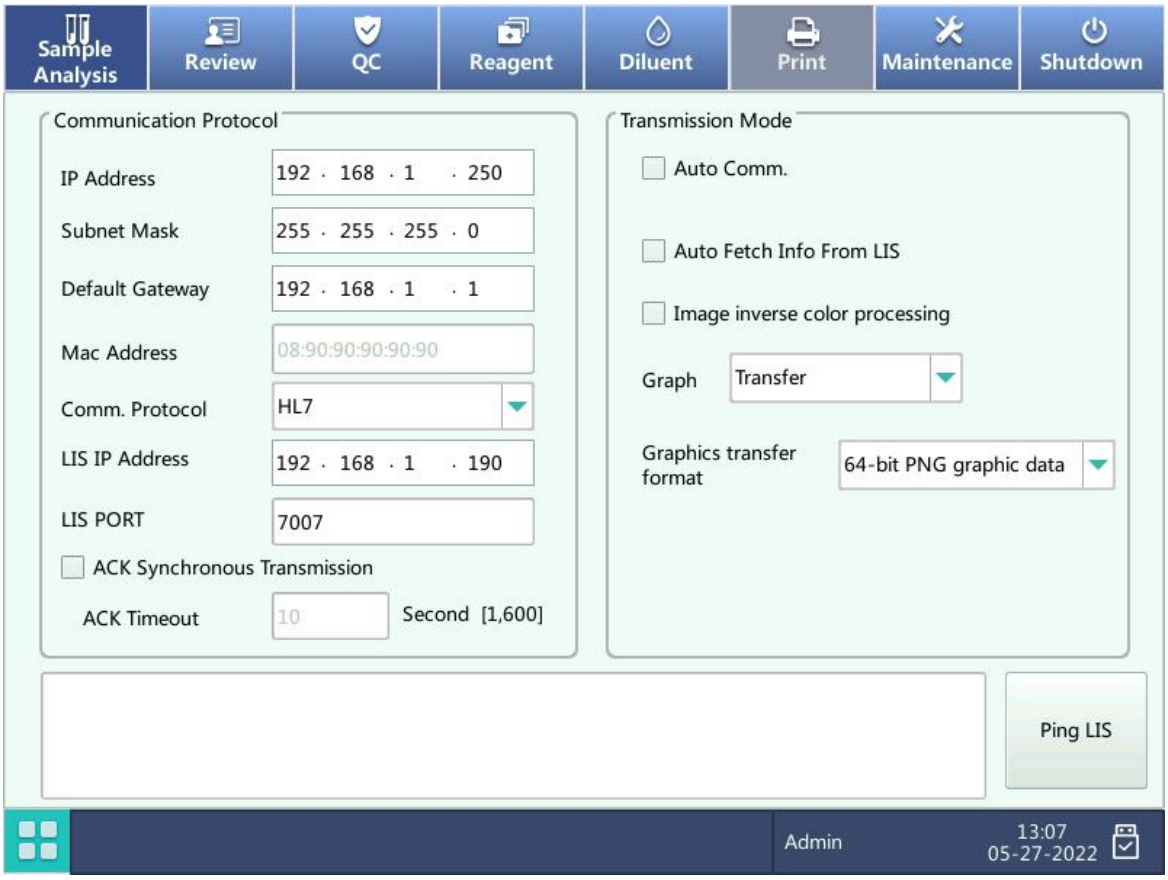
- Automatic printing

  The timing of automatic printing can be selected or turned off.

- **Communication settings**

Select "Settings">"System Settings">"Communication Settings" in the pull-up menu to enter the screen shown below. The operator can complete the following settings.

- Protocol Settings
- Transfer Mode



- Protocol Settings

Click the "IP Address", "Subnet Mask" and "Default Gateway" edit boxes and enter the correct IP address, subnet mask and default gateway.

Communication protocols

Select the protocol type, click on the drop-down list, and select the appropriate communication protocol type from the options.

ACK synchronous communication

Click to check the "ACK synchronous communication" checkbox to activate this function.

When this function is active, the default number of ACK timeout seconds is "10" seconds, which can be re-entered by the operator in the edit box.

- Transfer Mode

The operator can activate the relevant communication settings by clicking to check the desired option in the following check boxes, as required.

- Automatic communication
- Automatic acquisition of sample information
- Image inversion processing

Click on the drop-down list and select the graphical transfer method.

- Transmission
- No transmission

Click on the drop-down list and select the graphic transfer format.

- 64-bit PNG graphic data
- 64-bit JPG graphic data

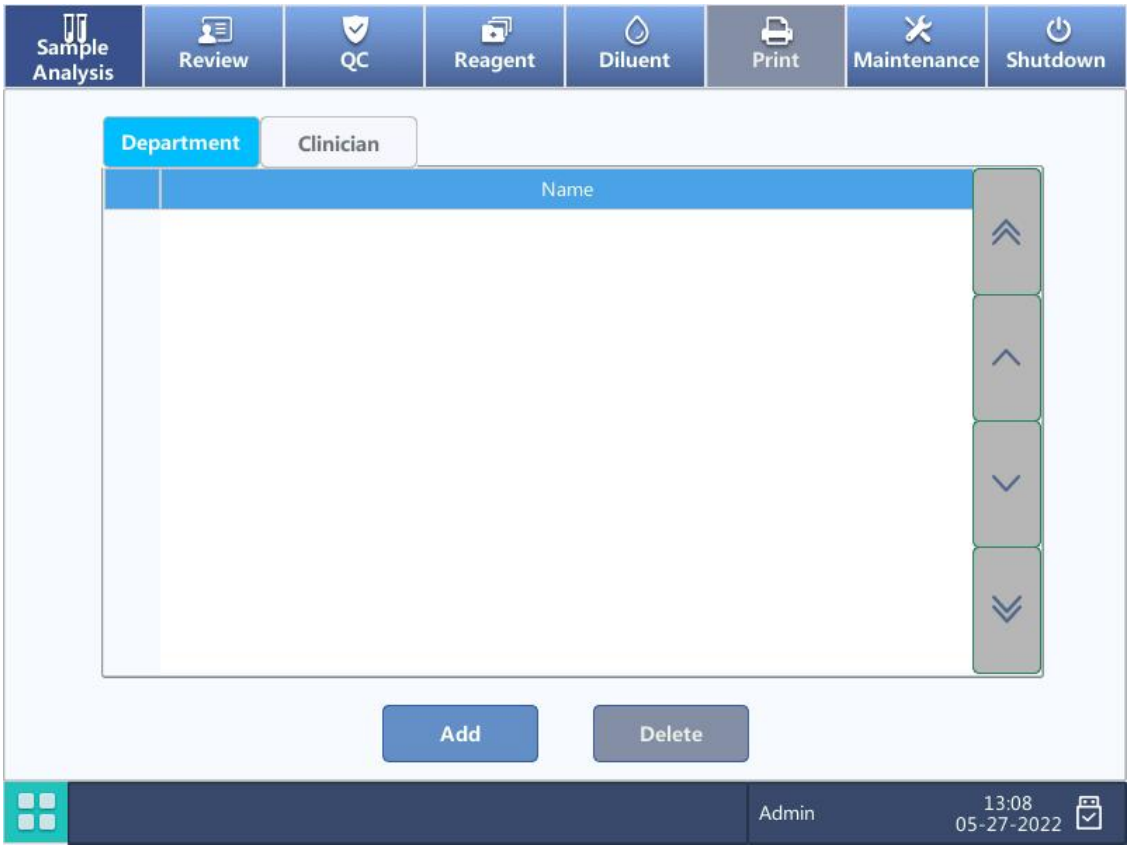
- **Flag alarm sensitivity**

Select "Settings">"System Settings">"Flag Alarm Sensitivity" in the pull-up menu to enter the interface shown below. The sensitivity setting of the corresponding alarm can be set according to the actual needs.

The Flag page displays the values that may cause an alarm. The administrator can modify the reference value of Flag. The reference value of Flag alarm shows the possibility of generating an alarm. The lower the value, the more likely it is to cause an alarm.

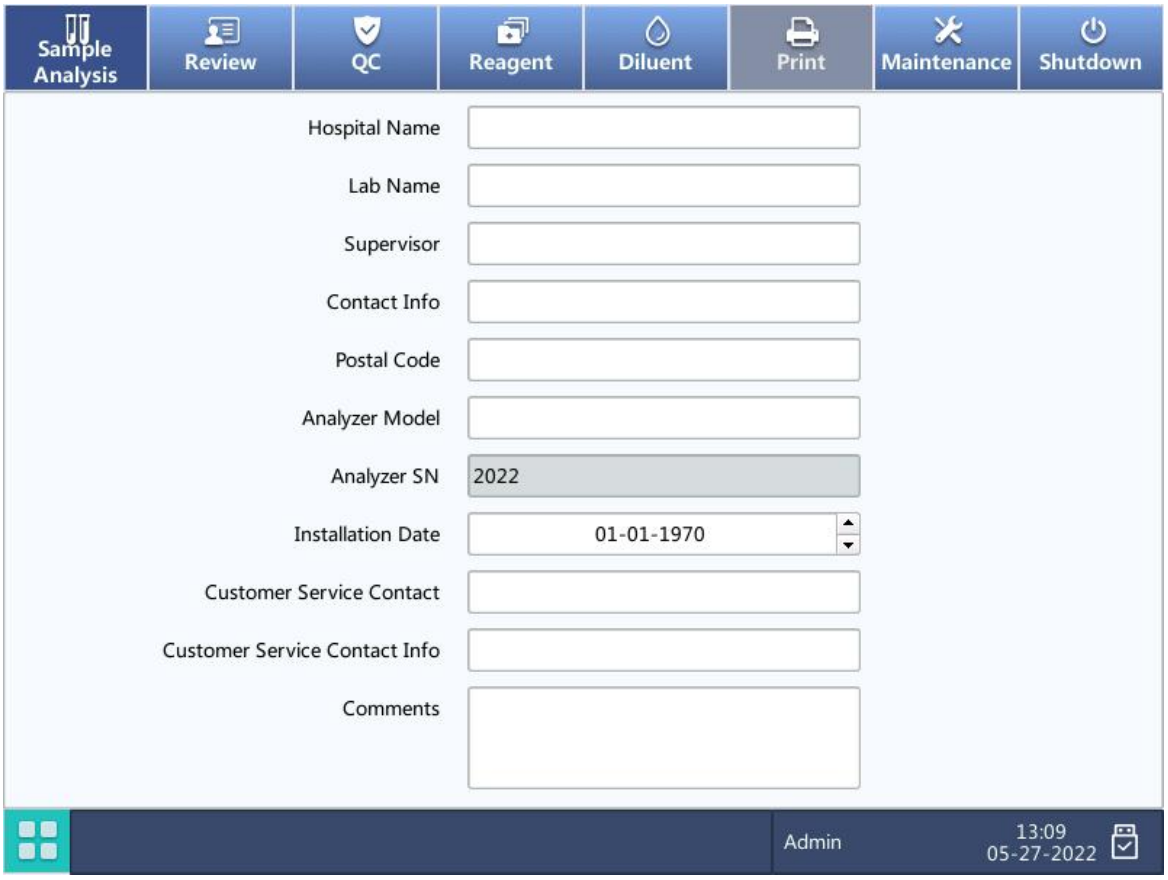
- **Department / Sender Settings**

In the pull-up menu, select "Settings">"System Settings">"Department/Sender Settings" to enter the interface shown below. Users can add new departments or senders information as needed



- **Lab Information Setting**

Select "Settings">"System Settings">"Lab Information Settings" in the pull-up menu to enter the interface shown below. The operator can enter, save and view the lab information. The operator can click the corresponding edit box to enter relevant lab information as needed.

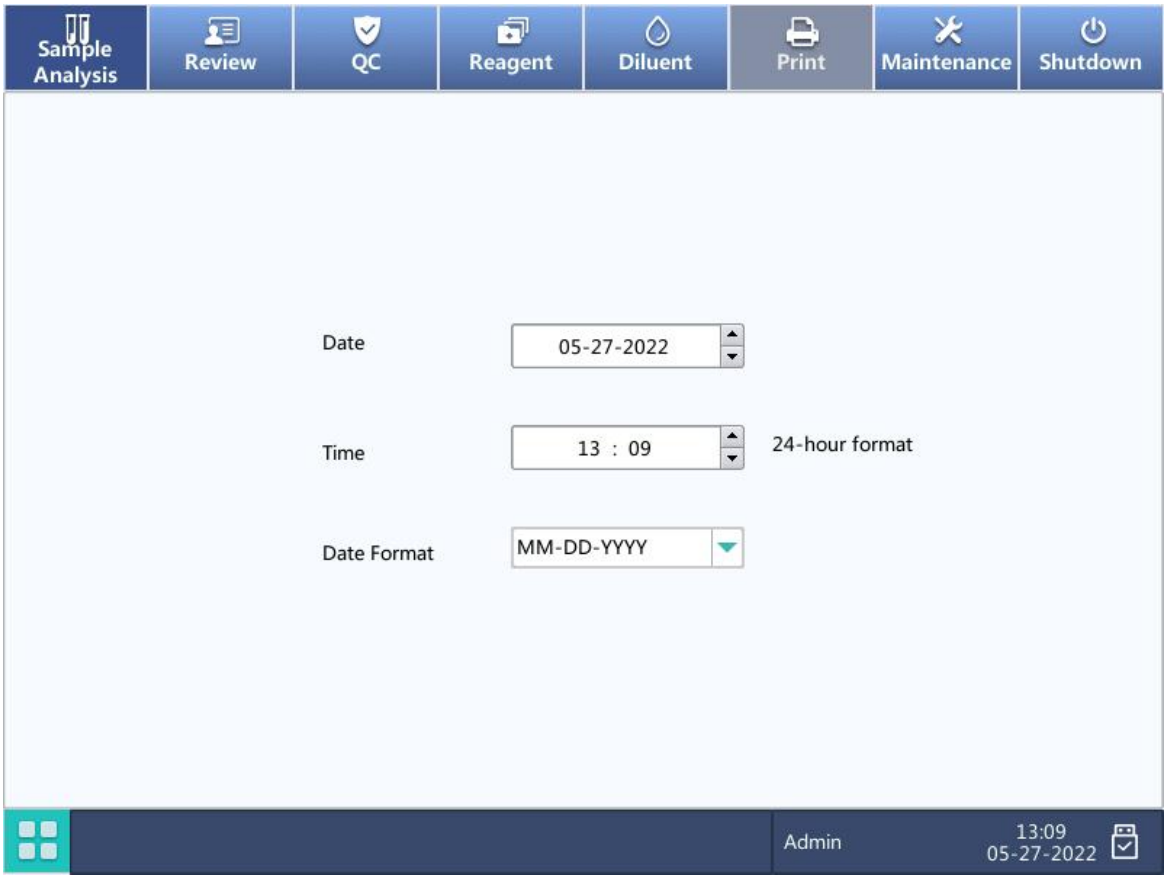


Attention

- The instrument serial number is not editable and defaults to the factory serial number set by the instrument.
- The installation date defaults to the instrument's installation date, which can be edited by the operator and whose value cannot be greater than the current system date.

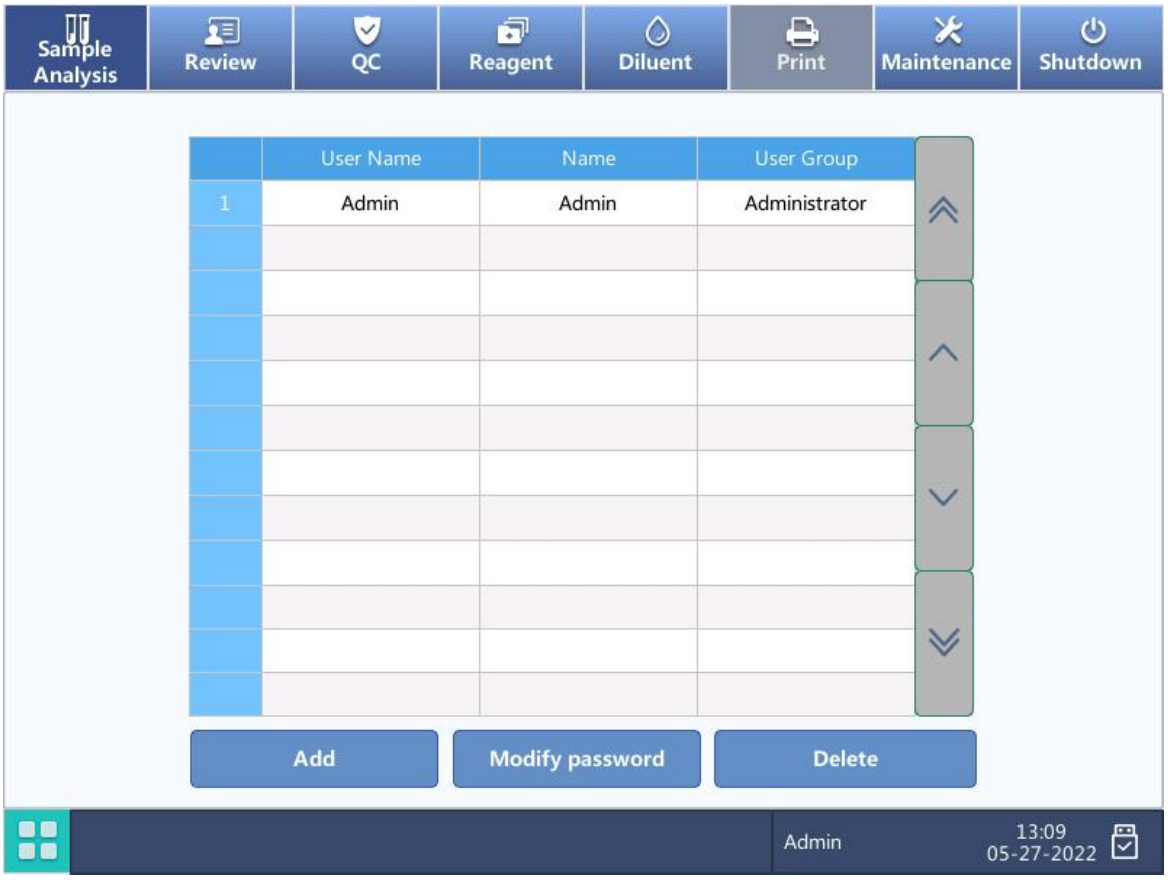
- **Date/time setting**

Select "Settings">"System Settings">"Date/Time Settings" in the pull-up menu to enter the screen shown below. You can set the date, time, and date format of the analyzer in this screen.



2 User management

Select "Settings">"User Management" in the pull-up menu to enter the screen shown below.



- **Change password**

Current login user, you can change the password of the current login account.

1. Click the list to select the current login account, and then click "Change Password", the following dialog box will pop up.

2. Enter the old and new passwords and other related information in each edit box in turn.

3. Click "OK" to save and close the dialog box.

Attention

- The password is not allowed to be empty, and up to 12 characters can be entered.

- **New User**

1. Click the "New" button, and the following dialog box pops up in the interface.

2. Enter "User Name", "Name", "Password" and other relevant information in each edit box in turn.

3. Click on the "User Groups" drop-down list and select user permissions from the following options.

- Administrators
- General users

4. Click "OK" to save and close the dialog box.

Attention

- The user name is not allowed to be empty, and up to 12 characters can be entered.
- The password is not allowed to be empty, and up to 12 characters can be entered.
- The name is not allowed to be empty, and up to 20 characters can be entered.

- **Delete User**

Click on the list to select a user and click the "Delete" button to remove them.

Attention

- The currently logged-in user cannot be deleted.

9.2.3 Parameter setting

- **Parameter unit setting**

Select "Settings">"Parameter Settings">"Parameter Unit Settings" in the pull-up menu to enter the interface shown below. In the "Parameter Unit Setting" window, the operator can make settings related

to the parameter unit.

Parameter	Unit	Format	Parameter	Unit	Format
WBC	10^9/L	***.**	RBC	10^12/L	**.**
Neu#	10^9/L	***.**	HGB	g/L	***
Lym#	10^9/L	***.**	HCT	%	**.*
Mon#	10^9/L	***.**	MCV	fL	***.*
Eos#	10^9/L	***.**	MCH	pg	***.*
Bas#	10^9/L	***.**	MCHC	g/L	****
Neu%	%	**.*	RDW-CV	%	**.*
Lym%	%	**.*	RDW-SD	fL	***.*
Mon%	%	**.*	PLT	10^9/L	****
Eos%	%	**.*	MPV	fL	**.*
Bas%	%	**.*	PDW		**.*
*ALY#	10^9/L	***.**	PCT	%	*.***
*ALY%	%	**.*	P-LCC	10^9/L	****
*LIC#	10^9/L	***.**	P-LCR	%	**.*
*LIC%	%	**.*			

- Unit system selection

Click on the "Unit system selection" drop-down list and select the desired unit system.

- Customized unit system settings

Under each unit system, the operator can click on the "Units" cell to customize the units for any parameter.

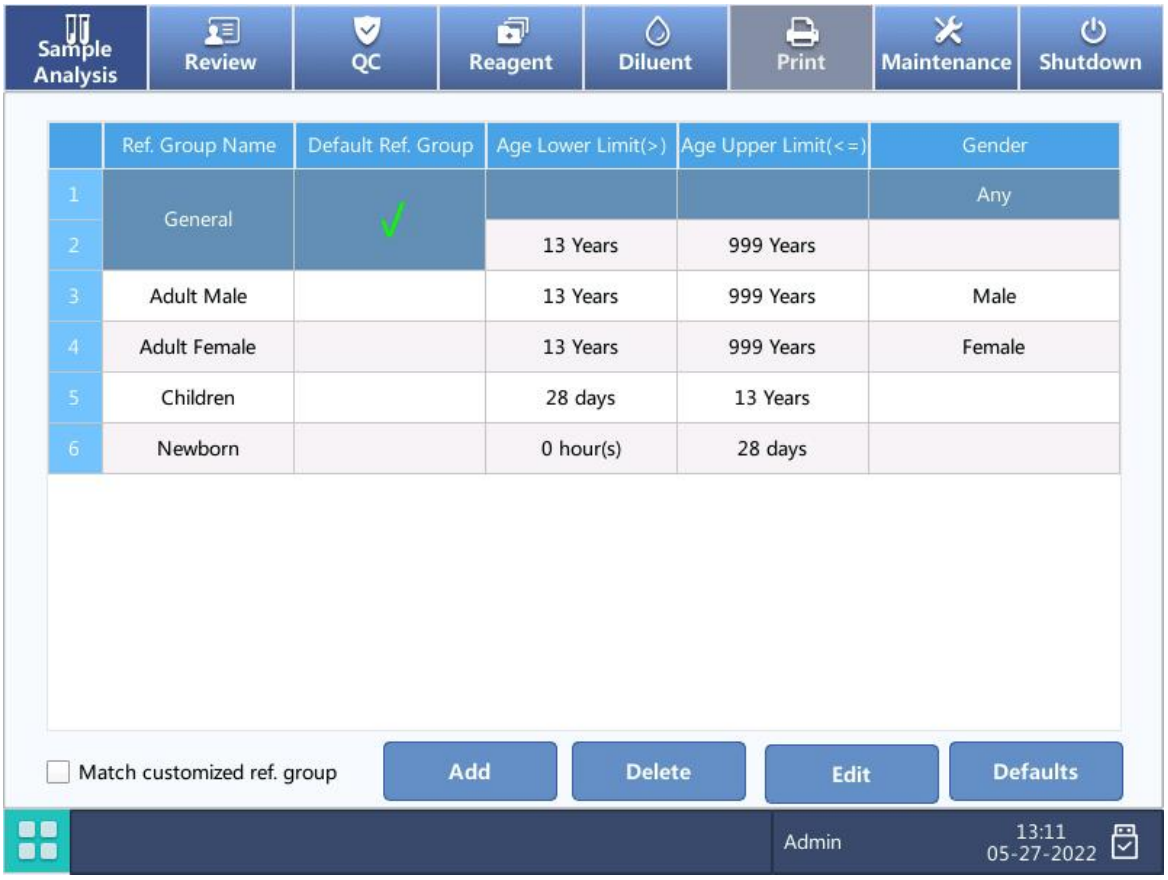
Click the "Take Defaults" button to restore the default settings for each unit system.

Attention

- Select a different unit system and its corresponding unit list will be displayed differently.

- **Reference range settings**

Select "Settings">"Parameter Settings">"Reference Range Settings" in the pull-up menu to enter the interface shown below. The "Reference range setting" interface provides 5 built-in reference groups and 10 custom reference groups for the operator to select and set. Each laboratory should select the appropriate reference range and set the appropriate reference interval according to the actual sample situation. The reference range varies by ethnicity, gender, age, and geographic location.



- Custom Reference Groups

In the reference group list, select the target reference group row and click "New" or "Edit" button to enter the reference group setting interface and set the reference group name, age range, each parameter range and other information.

For the built-in reference group, if you click the "Take Default" button on the right side of the reference range list in the reference group setting interface, you can restore the parameter range of the selected reference group to the system default value.

Attention

- The entered reference group name is not allowed to be empty.
- The name of the reference group entered cannot be duplicated with the five names "General, Adult Male, Adult Female, Child, Newborn", and the names between the respective defined reference groups are not allowed to be duplicated.

- Setting the default reference group

Click the list to select a reference group, and then click "Set as default reference group" to set the selected reference group as the default reference group.

Attention

- The name, age range, gender, and other items of the built-in reference group are not allowed to be changed.
- The input range for age is [0,999].

- Modify reference range

In the reference group setting screen, edit the reference range list by entering it directly to set the

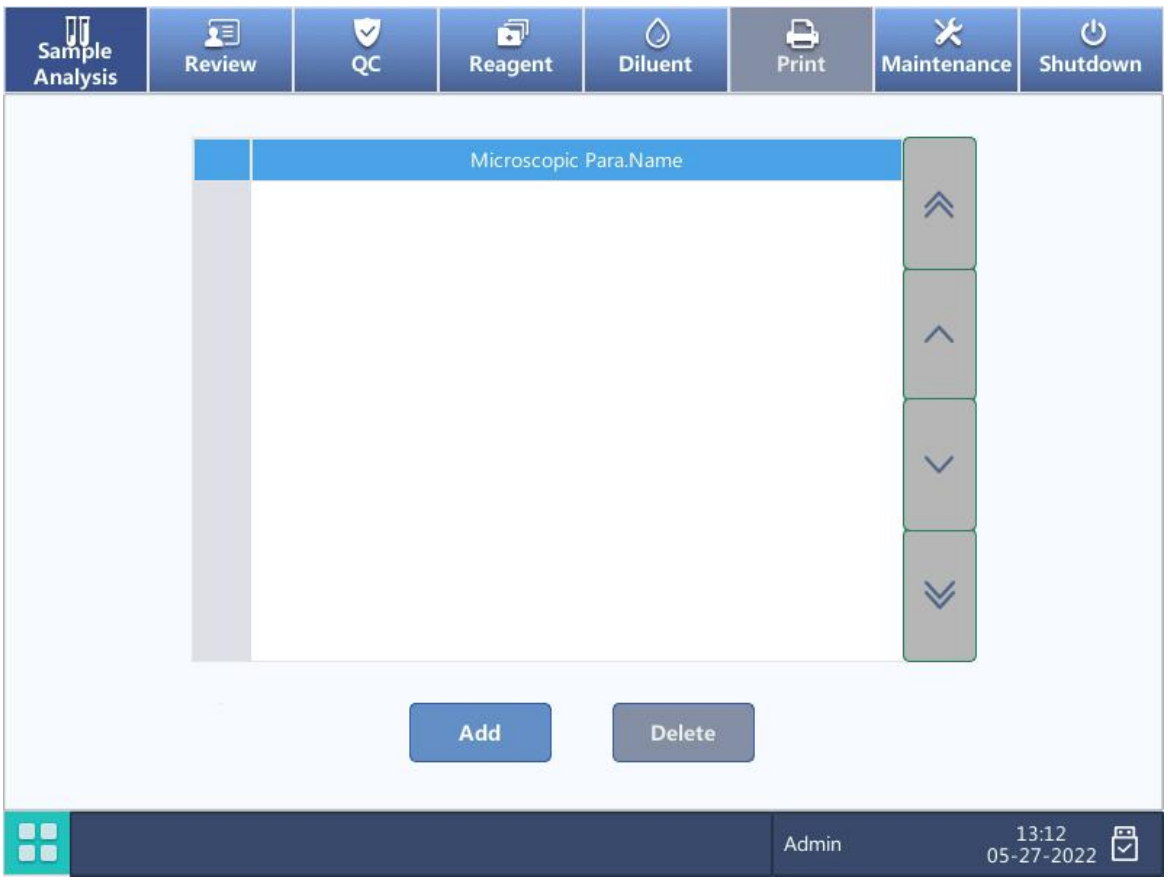
upper and lower limits of each parameter reference range.

Click the "Take Default" button above the reference range list to restore the upper and lower limit settings of the selected reference range.

The operator can choose to check the "Match custom reference group first" checkbox, if the age range of the custom reference group conflicts with the age range of the default reference group, the appropriate custom reference group will be matched first when matching reference groups according to age and gender in the sample analysis and review interface.

- **Microscopy parameter setting**

In the drop-down menu, select "Settings">"Parameter Settings">"Microscopy Parameter Settings" to enter the interface shown below. The operator can make settings related to microscopy parameters.



- New microscopy parameters

Click the "Add" button at the bottom of the interface to add a new row to the list, and then enter the parameter name in the "Microscopy Parameters" column.

- Delete microscopy parameters

Click the name of a parameter in the selected list and click the "Delete" button at the bottom of the interface to delete the parameter.

- Editor

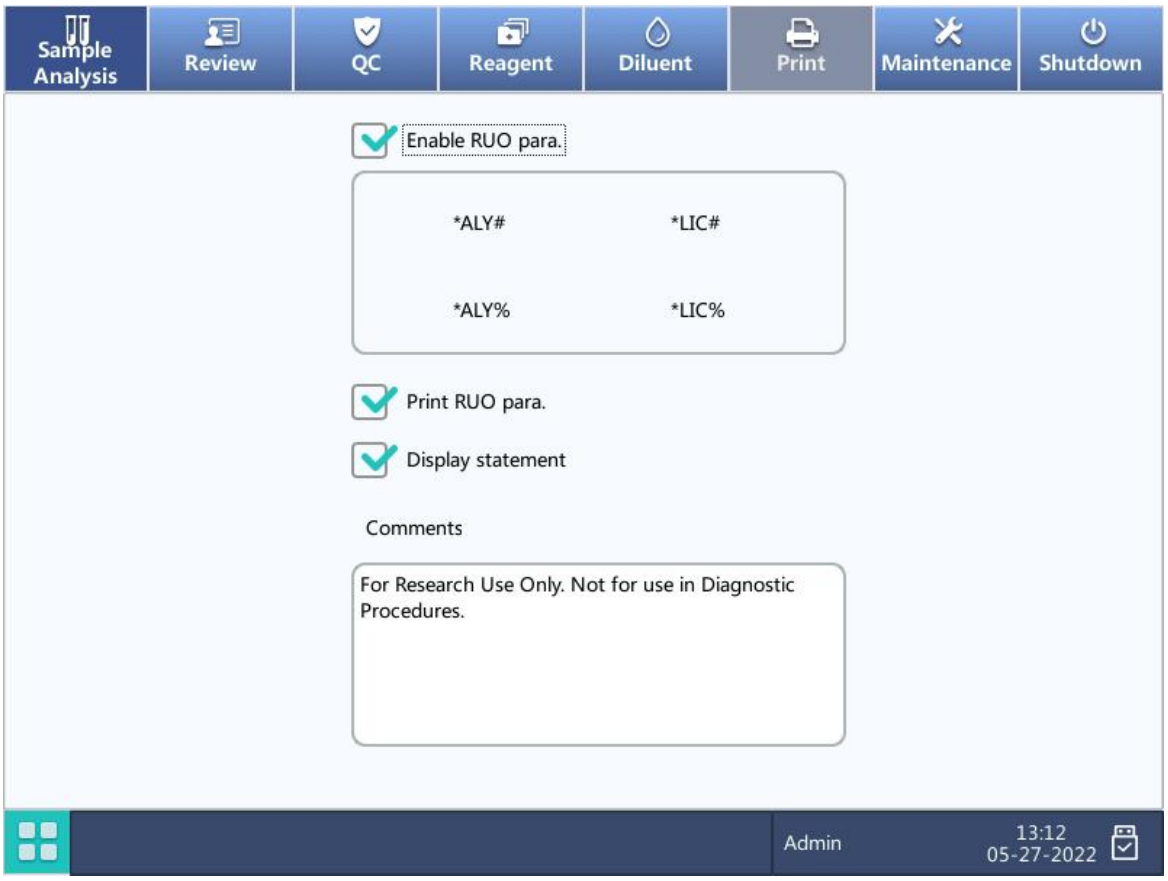
Select a parameter column in the list to edit the name of that parameter.

Attention

- Supports up to 40 new microscopy parameters.
- After executing the add, edit and delete operations, it is invalid for the sample records where the microscopy results have been entered and saved, and only valid for the sample records where the microscopy results have not yet been saved and for the samples where the counting is executed after setting.

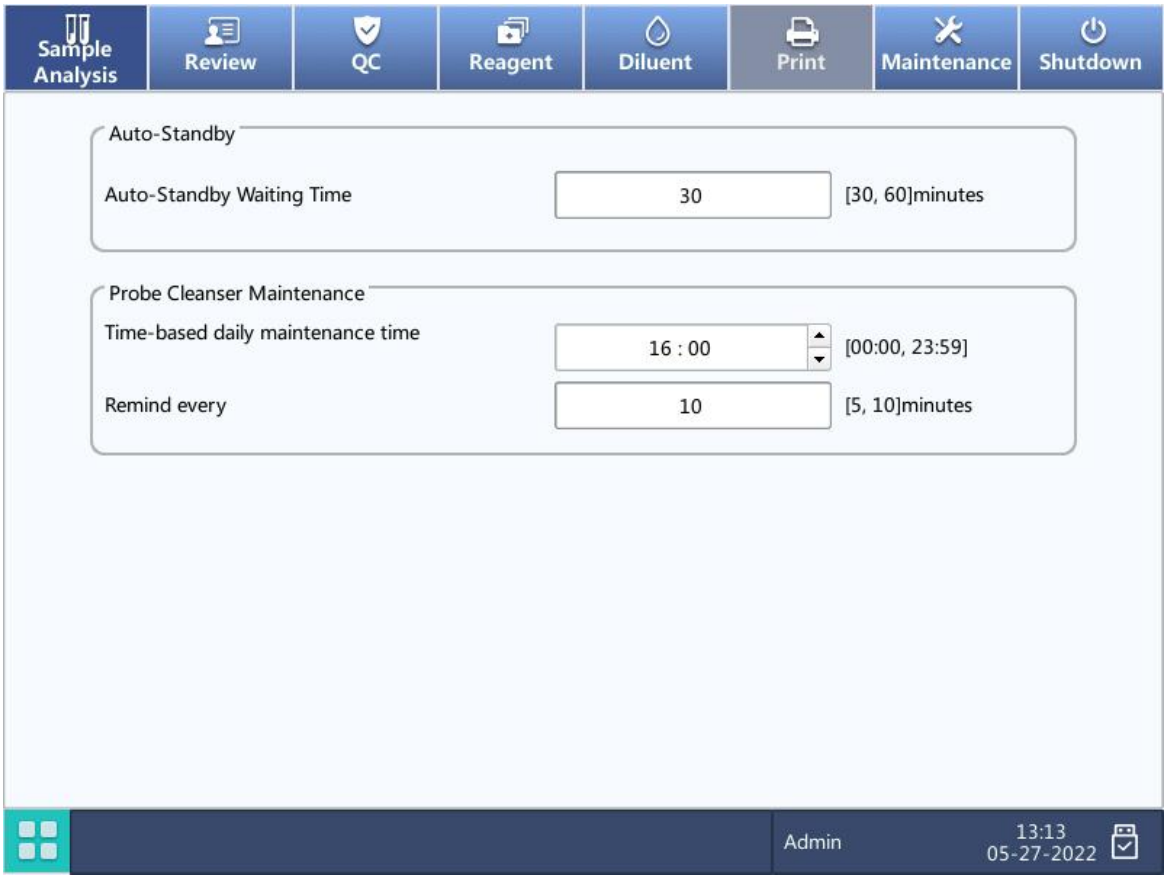
- **Study parameter settings**

Select "Settings">"Parameter Settings">"Study Parameter Settings" in the drop-down menu to enter the screen shown below. The operator can make settings related to the study parameters.



9.2. 4 Maintenance settings (administrator level)

Select "Settings">"Maintenance Settings" in the pull-up menu to enter the screen shown below. The operator can complete the following settings.



- Auto-sleep

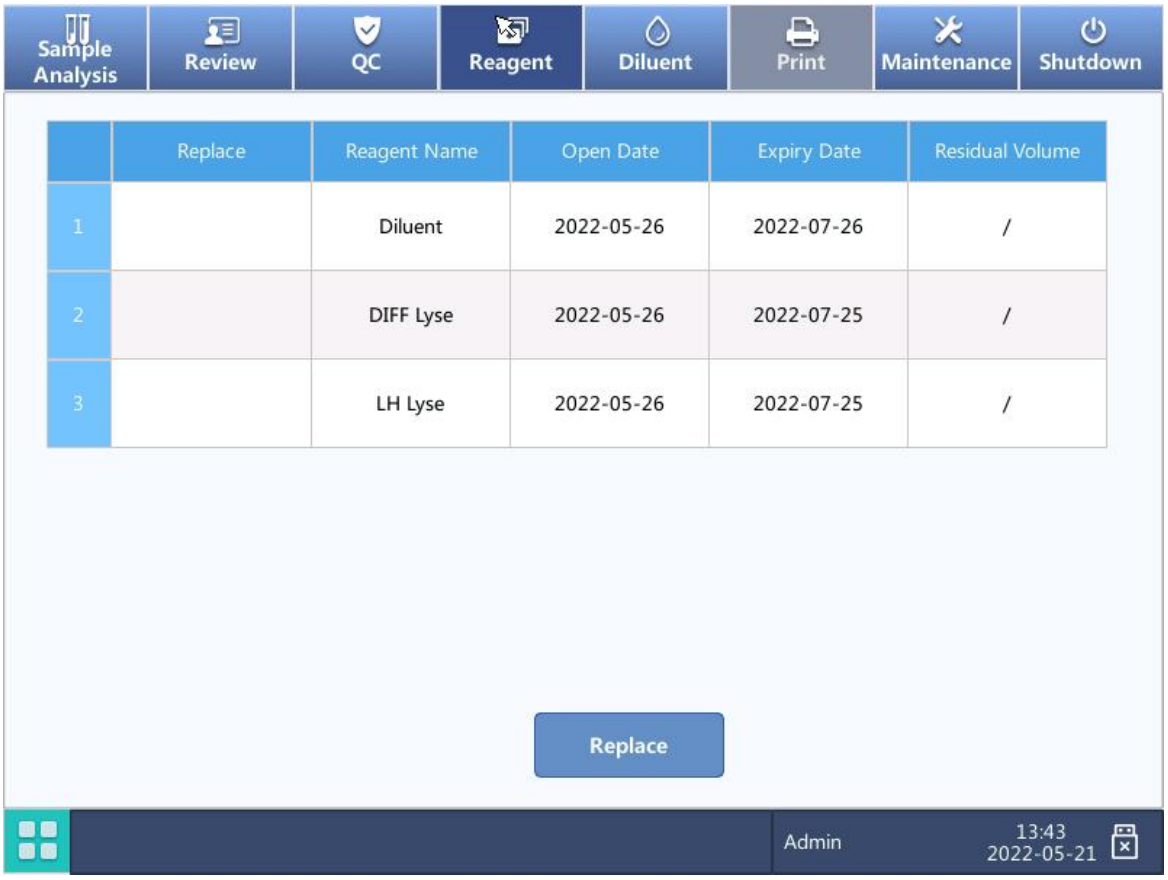
If you want to set the time to wait for the auto-sleep to start after the liquid circuit related operation is stopped, you can enter it in the "Auto-sleep waiting time" edit box. The range is from 30 minutes to 60 minutes, and the default is 30 minutes.

- Probe fluid maintenance

Select the start time of probe liquid maintenance, if you want to set the probe liquid maintenance time, you can enter it in the edit box.

9.2.5 Reagent management

Select "Settings">"Reagent Management" in the pull-up menu to enter the screen shown below.



The operator can use this function to change the reagents in the line after replacing a new container/bottle of reagents or other times when needed.

Attention

- The diluent needs to rest for more than one day before use after a long transport.
- The operator should perform background testing after changing reagents such as diluent or lyse solution to ensure that the background values are within normal limits and ready for sample analysis.

Users need to change reagents when.

- Replaced whole containers/bottles with new reagents.
- The reagents in the line are suspected to be contaminated.
- Air bubbles are suspected to be present in the line.

The user can replace the following reagents.

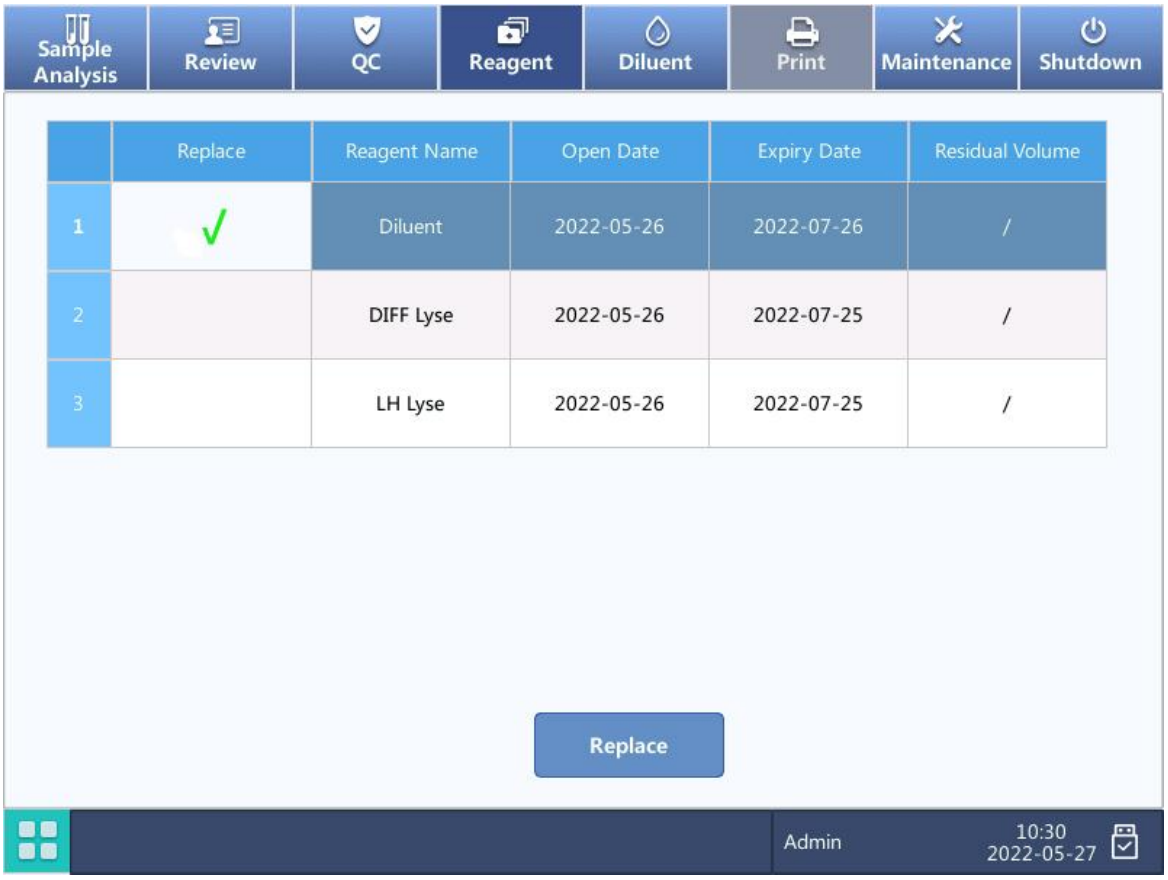
- Diluent
- DIFF lyse solution
- LH lyse solution

The steps for replacing diluent and lyse solution are as follows.

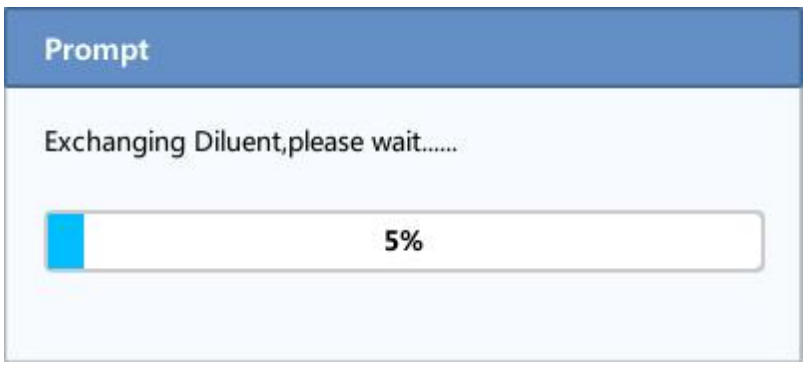
1. Take the whole barrel/bottle of new reagent that needs to be replaced and connect it in the

corresponding pipeline.

2. Select the reagent that needs to be replaced in the reagent management interface, as shown in the figure below.



3. click the "Replace" button to start the implementation of the reagent replacement, the progress bar prompts the progress.



4. After completion, the progress bar disappears and the reagent replacement is finished.

5. If necessary, you can continue to replace other reagents according to the above steps.

Attention

- Do not shake the diluent container violently or collide with other objects, as this may cause

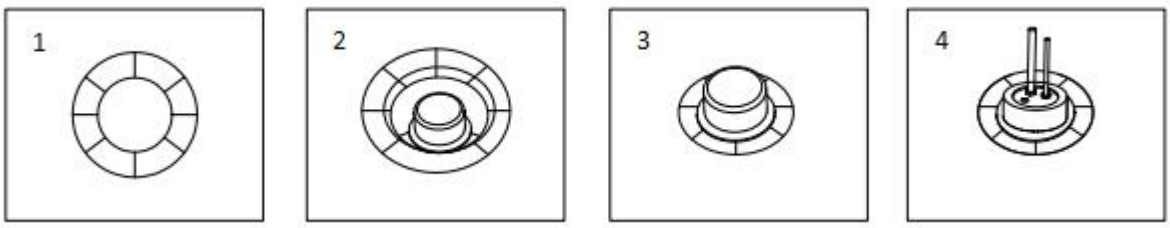
unreliable alarms.

- When replacing the diluent container, follow these steps.

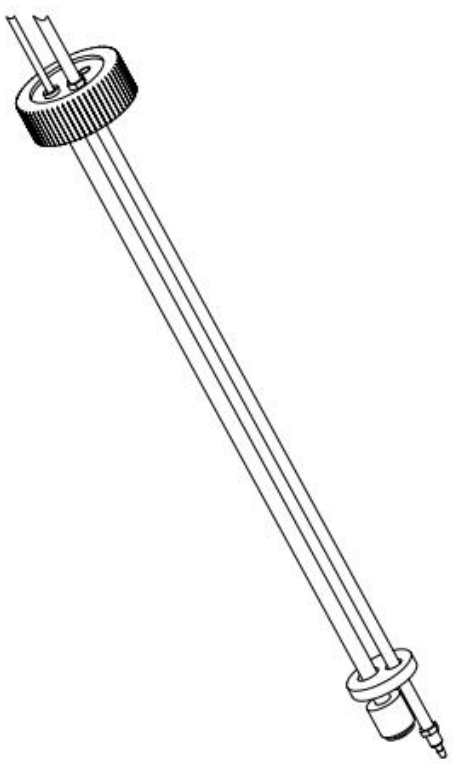
1) Take a new container of reagent and open a gap at the easy-tear line of the paper packing box as shown in the figure below.

2) Pull the lid of the barrel out of the box inside the box as shown in the picture below.

3) Use the paper in the gap of the packing box to jam the mouth of the barrel, as shown in the figure below.



4) Open the container lid and insert the diluent container lid assembly (shown below) vertically into the diluent container and tighten the lid (as shown above), otherwise the alarm may not be reliable.



6 Gain settings (administrator level)

Select "Setting">"Gain Settings" in the pull-up menu to enter the screen shown below. The gain setting is used to adjust each digital potentiometer, and it is not recommended that the operator make adjustments frequently.

- **RBC Gain**

  Click the "RBC" current value cell, enter the RBC channel gain adjustment new value.

- **HGB Gain**

  The purpose of adjusting the HGB channel gain is to change the HGB background voltage.

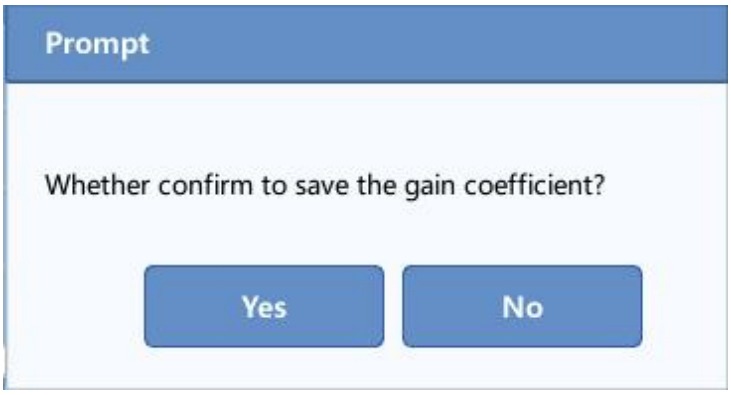
  The operator enters the value directly into the "HGB Setpoint" edit box to modify the HGB gain.

  Attention

  - The gain of LAS, MAS and WAS cannot be modified.

9.3 Save Setting

Enter each setting item by clicking the menu, and after modifying the settings in each setting interface, if you want to save the settings, you can choose to switch the interface, and the following saving prompt will pop up.



Click "Yes" to save the settings, close the prompt box and switch to the target screen. Click "No" to not save the settings, close the prompt box and switch to the target screen.

Chapter 10 Services

10.1 Overview

To ensure accurate and efficient operation of the analyzer, the operator performs routine maintenance on the analyzer as required by this chapter. This analyzer provides several maintenance functions to facilitate the operator to complete the maintenance work.

This chapter describes the various maintenance functions of the analyzer.

- All surfaces of the analyzer's components are potentially infectious and safety precautions should be taken during operation and maintenance.

- Reagents can irritate the eyes, skin and mucous membranes. Operators should observe laboratory safety practices and wear personal protective equipment (e.g., laboratory gowns, gloves, etc.) when in contact with reagent-related items in the laboratory.
- In case of contact with skin, rinse immediately with plenty of water and receive medical attention if necessary; in case of contact with eyes, rinse immediately with plenty of water and receive medical attention.
- If samples or reagents leak on the surface of the equipment or get inside the equipment, wipe and disinfect the instrument with 75% alcohol or pasteurized solution in a timely manner.
- Cleaning agents or disinfectants that cause a chemical reaction with equipment parts or materials contained in the equipment and cause a hazard cannot be used.
- If in doubt about the compatibility of a cleaner or disinfectant with equipment components or materials contained within the equipment, please consult with Singuwayor your local distributor.

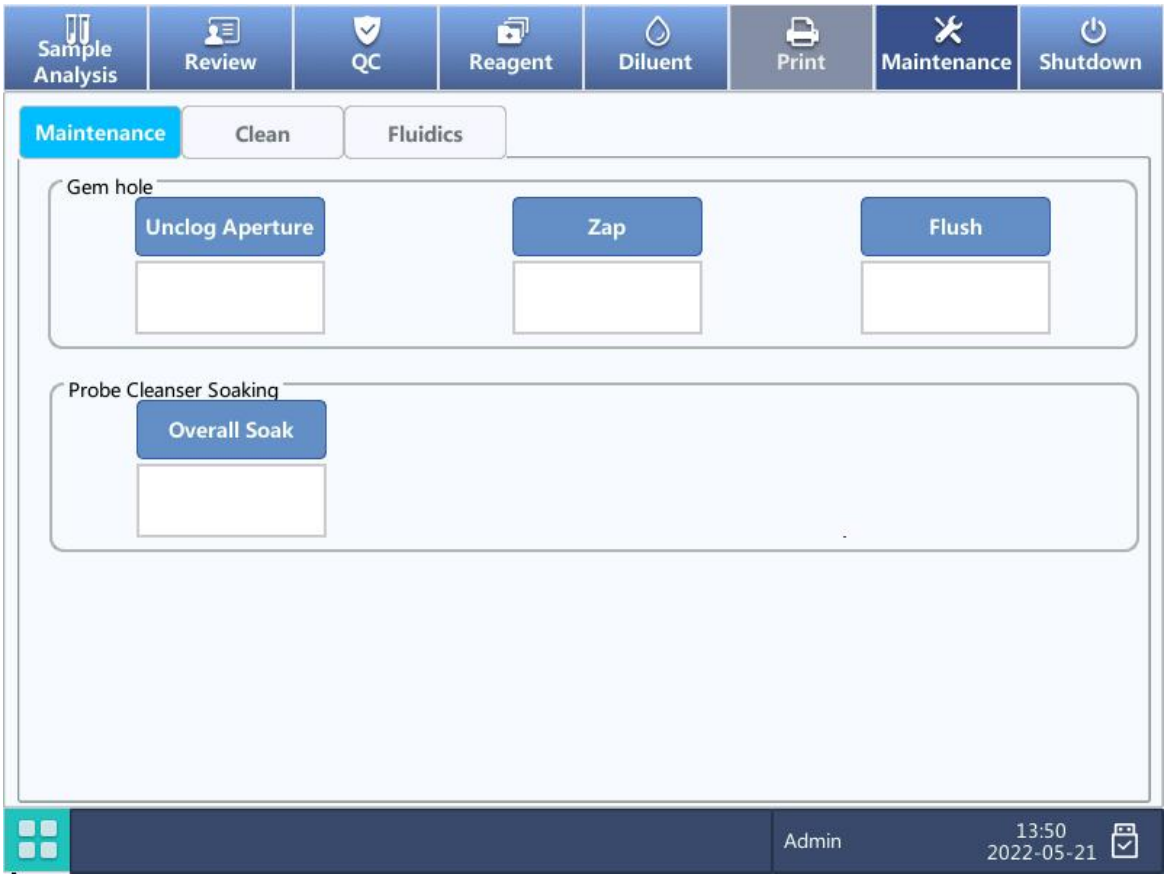
- Improper maintenance may damage the analyzer. The operator must follow the instructions in the operating instructions for maintenance.
- If you encounter a problem that is not clearly defined in the manual, please contact the service department of Singuway for maintenance advice from Singuway's designated professional staff.
- The analyzer must be maintained with the parts provided by Singuway. If you have any questions, please contact the Singuway Service Department.
- When performing maintenance, avoid touching the tip of the sampling needle.

10.2 Maintenance

Maintenance includes: maintenance, cleaning and complete machine maintenance.

10.2.1 Maintenance

In the pull-up menu, select Service > Maintenance > Maintenance tab to enter the screen shown below.

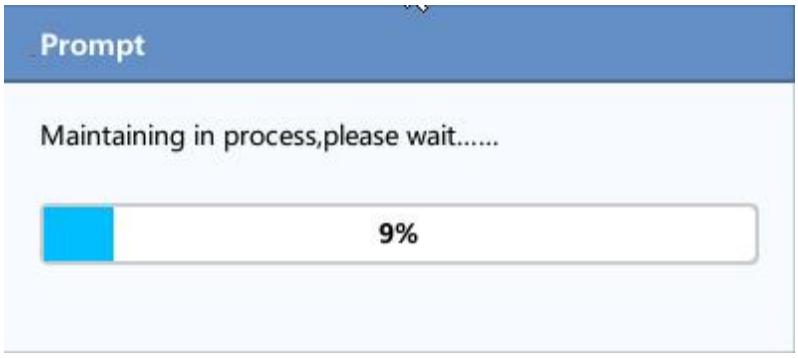


- **Jewel Hole**

If there is a failure of blocked holes, perform maintenance operations on the jewel hole by de-blocking, cauterizing and backflushing them.

The steps for de-clogging are as follows.

1.Click on the "Drain" button to start draining, and a pop-up box will show "Maintenance in progress, please wait .....".



2.After the blocking is completed, the window message area displays "Maintenance operation complete".

3. If necessary, you can continue the blocking, scorching and backflushing operation according to the above steps. If the problem cannot be solved after several operations, the probe liquid immersion operation can be executed.

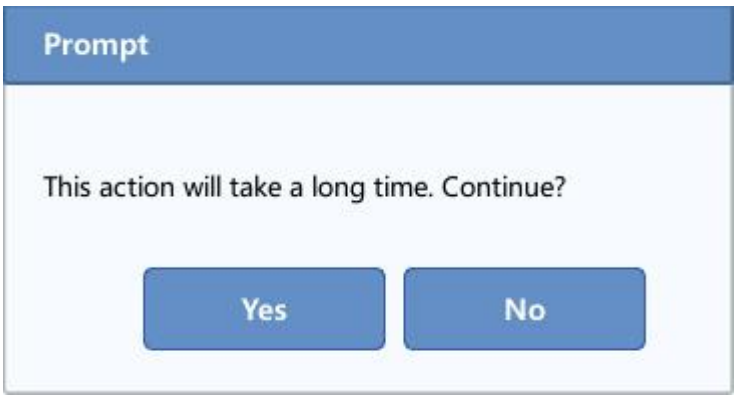
- **Probe fluid immersion**

The user performs probe cleanser immersion under the following conditions.

- If the situation does not improve after performing other maintenance operations when the instrument has not been used for a long period of time, resulting in an out-of-range background, abnormal quality control, reduced scatter plot differentiation, or a plugged hole.
- If the instrument is turned off due to an abnormal power failure, a probe cleanser soak is required after the power is turned on.

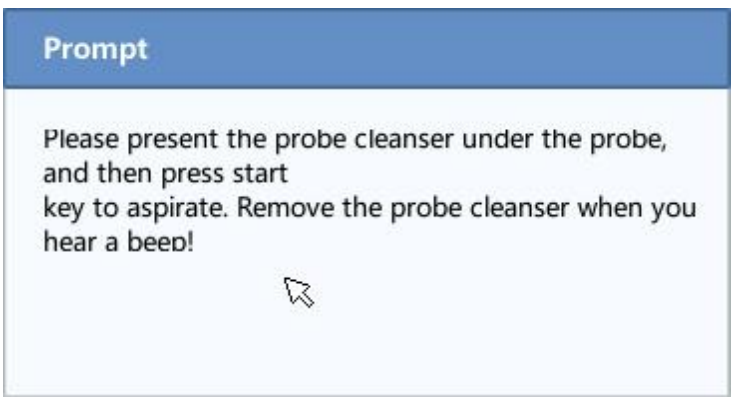
Probe cleanser soaking steps are as follows.

1. Click the "Soak the complete machine" button, the following dialog box will pop up.

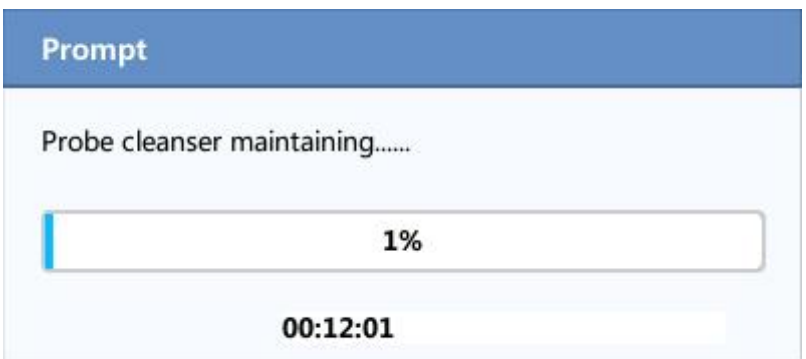


2. Click the "Yes" button to start the soaking preparation.

3. After the preparation, a prompt dialog box pops up.



4. After following the prompts for fluid washing, a progress bar dialog box will appear and the automatic execution of probe fluid maintenance will begin.



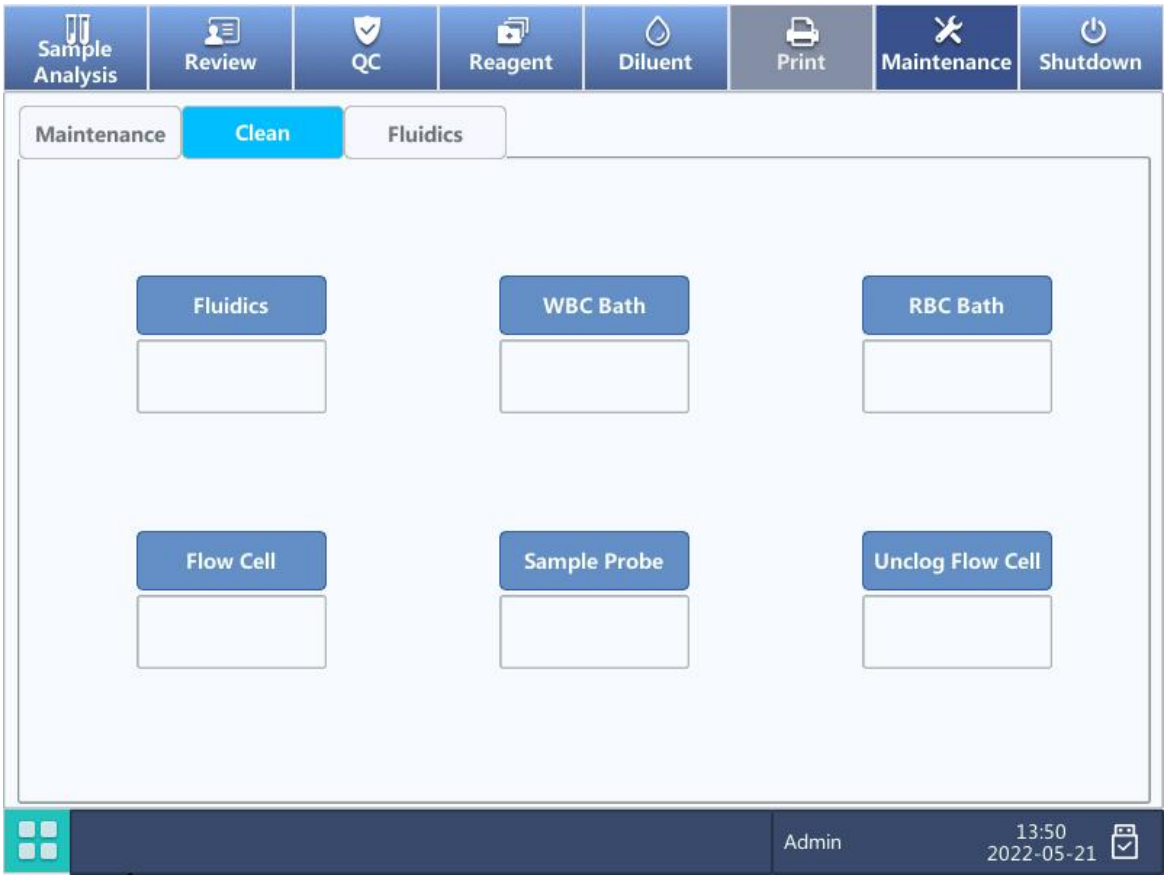
5. When finished, the progress bar dialog box will automatically close and prompt a pop-up dialog box to complete the probe fluid immersion.

10.2.2 Cleaning

The user needs to clean the corresponding parts in the following cases.

- If the WBC and/or HGB background results are outside the background range, perform a WBC pool cleaning. If this is not effective, perform a WBC probe soak.
- If the RBC and/or PLT results are out of background, perform an RBC pool cleaning. If the results are not good, perform an RBC probe soak.
- If there are more particles in the scatter plot of the background results, perform a WBC cell cleaning. If the results are not good, perform a WBC probe liquid immersion operation.
- If the sampling needle is dirty, perform a cleaning of the sampling needle.

Select "Service">"Maintenance">"Cleaning" tab in the pull-up menu to enter the screen shown below.



Users can clean the following components.

- Complete appliance
- WBC Pool
- RBC Pool
- Flow Chamber
- Sampling Needle
- Flow chamber de-clogging

The steps for cleaning are as follows.

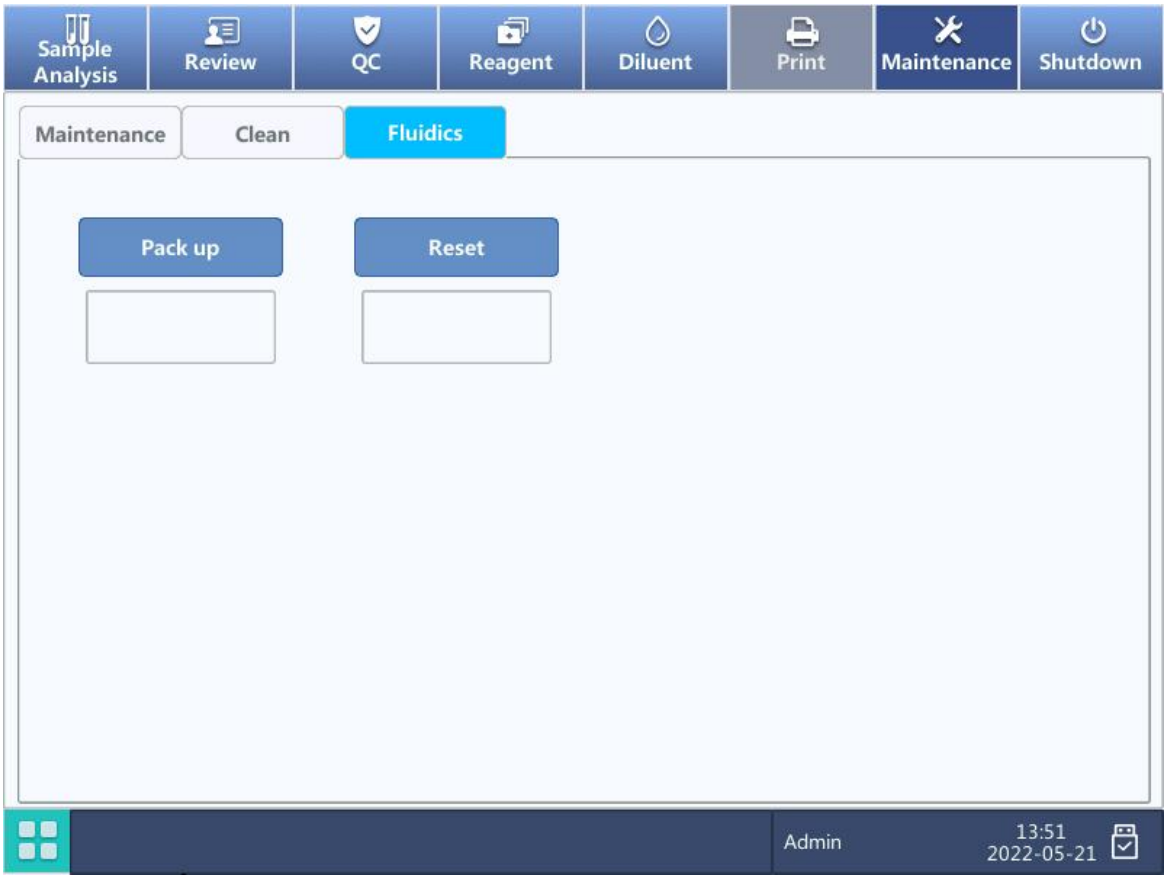
1. Click the button of the part you want to clean, and start cleaning the part. The window message area will display "Cleaning is in progress, please wait .....".

2. After the cleaning is completed, the window information area shows "Cleaning operation completed".

3. If necessary, you can continue to clean the other parts according to the above steps.

10.2.3 Complete appliance maintenance

In the pull-up menu, select Services > Maintenance > Machine Maintenance tab to enter the screen shown below.



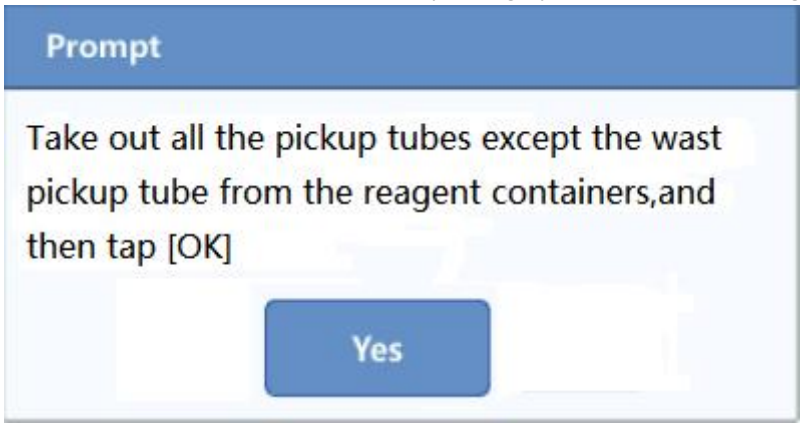
- **Wrapping**

When the machine is not used for more than two weeks, this function can be executed to complete the operation of emptying the instrument and cleaning it with distilled water (no alcohol can be used).

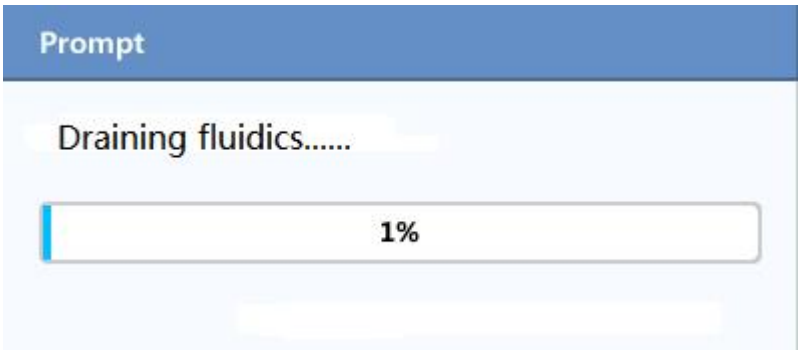
The steps for packing are as follows.

1、Click the "Package" button and a dialog box will pop up asking whether to perform the package operation.

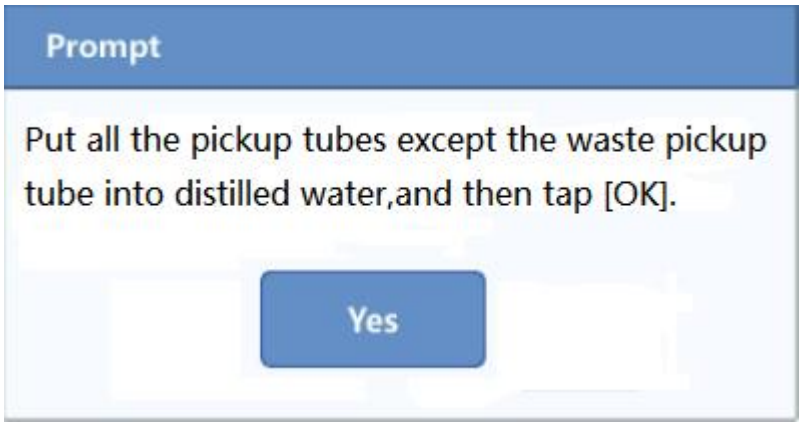
2、Click the "Yes" button to start the packing operation. The following dialog box is also displayed.



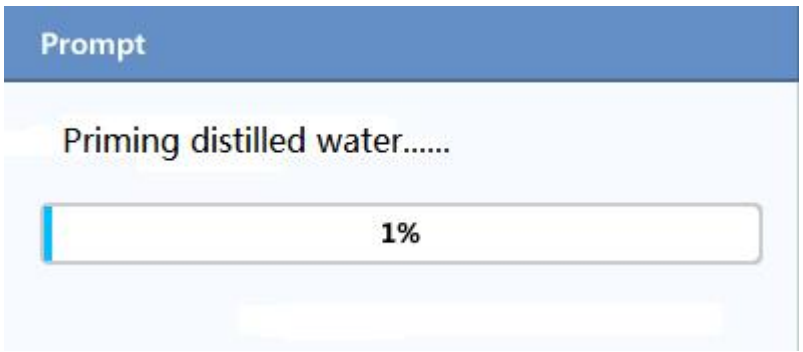
3、After removing the reagent catheter as prompted, click the "OK" button to perform the emptying.



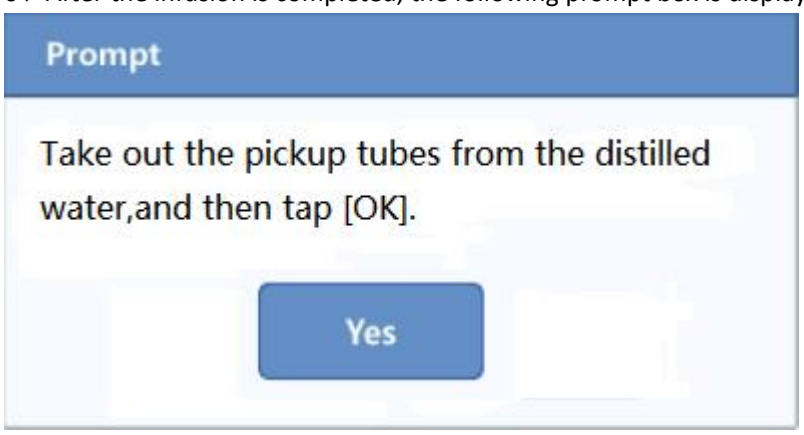
4、After the emptying is completed, the interface continues to pop up with the following dialog box.



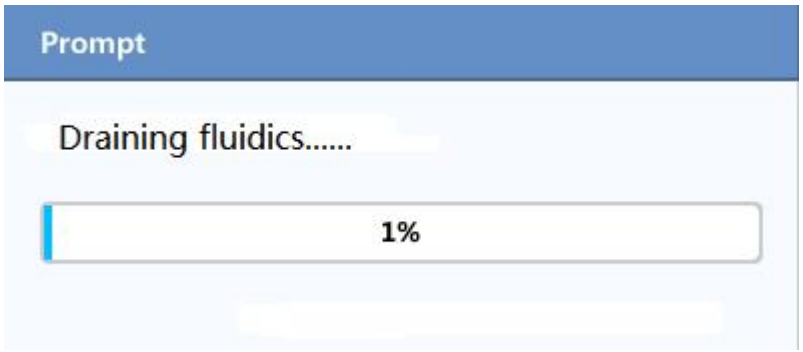
5、After placing the reagent catheter in distilled water as prompted, click the "OK" button to perform the perfusion.



6、After the infusion is completed, the following prompt box is displayed again.



7、After removing the reagent catheter as prompted, click the "OK" button to perform the evacuation again.



8、After the emptying is completed, a pop-up box will show "Packing is complete!".

9、The user follows the prompts on the interface to turn off the power to the host.

- **Reset**

If major components have been replaced or repairs have been made to the analyzer's liquid circuit system, a liquid circuit reset should be performed. The steps are as follows.

1、Click the "Reset" button and a dialog box will pop up asking if you are sure to perform the operation.

2、Click the "OK" button to start the initialization, the window message area will display "Liquid circuit is being reset, please wait .....".

3、When the reset is complete, the window message area will display "Liquid circuit reset complete!".

4、If necessary, you can continue the operation of resetting by following the above steps.

10.3 Daily maintenance items

10.3.1 Clean the exterior of the instrument

The outer surface of the analyzer is prone to dripping with reagents and serum and should be removed promptly. After daily shutdown, please follow the following steps to clean it.

- Cleaning: Wipe the outer surface of the analyzer with a damp towel moistened with distilled water until all stains are wiped away, recommended once a day.
- Disinfection: Use a wet towel with 75% alcohol or pasteurization solution to wipe and disinfect the surface of the instrument's shell. After a quarter of an hour, wring out the clean wet towel and wipe the outer surface of the analyzer to remove the remaining disinfection water, which is recommended once a week.

- The outer surface of the instrument should be considered infectious and protective gloves should be worn when operating.

Attention

- It is forbidden to use corrosive acids, alkalis and strong volatile organic solvents such as acetone to clean the surface of the instrument, only neutral detergents can be used, and it is forbidden to clean the inside of the instrument.

10.3.2 Checking waste liquid containers/tubes

Check the waste tubes in the following order.

1) Check for leaks at the joints where the waste tube is connected to the analyzer.
2) If the liquid leaks, use gauze to dry the liquid on the connector and then unscrew the connector counterclockwise to check if the waste liquid tube is blocked, clear the blockage and then re-tighten the connector.
3) Check whether the waste liquid tube is bent or not, and straighten it out if there is a bend.

Warning

- All waste liquids should be considered infectious and protective gloves should be worn when handling.
- The waste liquid discharge should meet the requirements of local environmental protection department.

10.4 Quarterly maintenance items

10.4.1 Waste liquid container cleaning

Warning

- Operators are obliged to comply with the relevant regulations of their region and country regarding the discharge and disposal of waste liquids.
- All waste liquids should be considered infectious and protective gloves should be worn when handling.

Please clean the waste liquid containers in the following order.

1) Open the lid of the containerand remove the waste tube.

(2) Pouring waste liquid into the waste pond.

3) Pour in water to 1/4 and add the appropriate amount (3 to 5 caps) of pasteurizer and gently shake

the waste container.

(4) Swing the waste container so that the liquid in the container touches every place possible.

(5) Allow to stand for 10 minutes and pour off the liquid in the barrel.

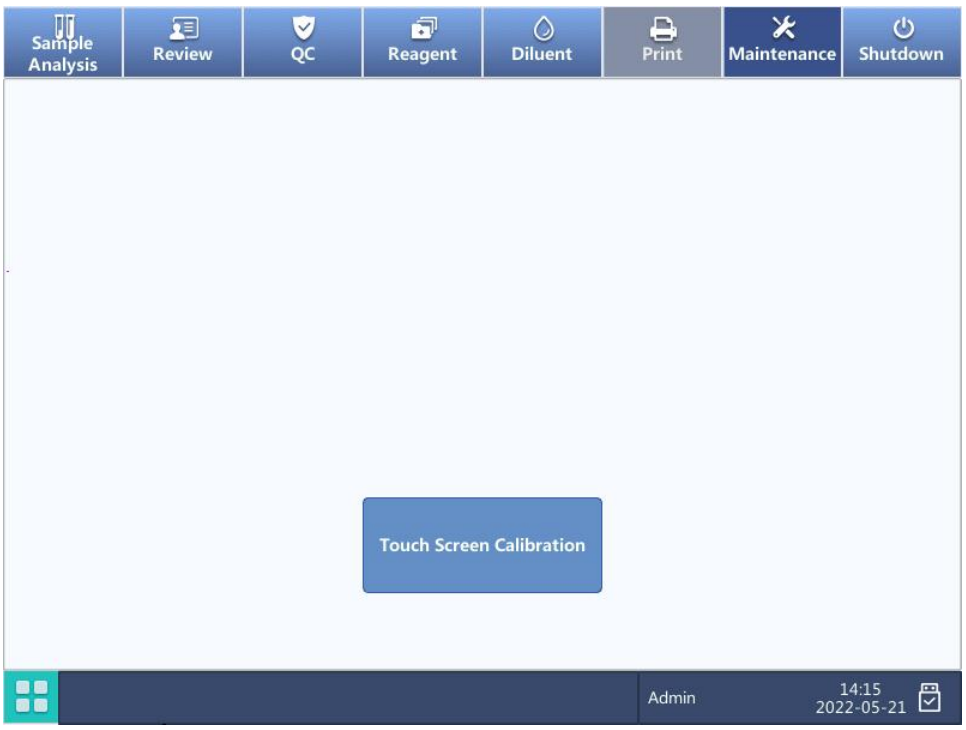
6) Rinse the container with clean water and wash the outer surface of the container at the same time.

Warning

- The pasteurizer is very corrosive, please wear protective gloves when operating and avoid contact between the liquid and the skin, if accidentally contacted, please wash immediately and repeatedly with water.

10.5 Touch Screen Calibration

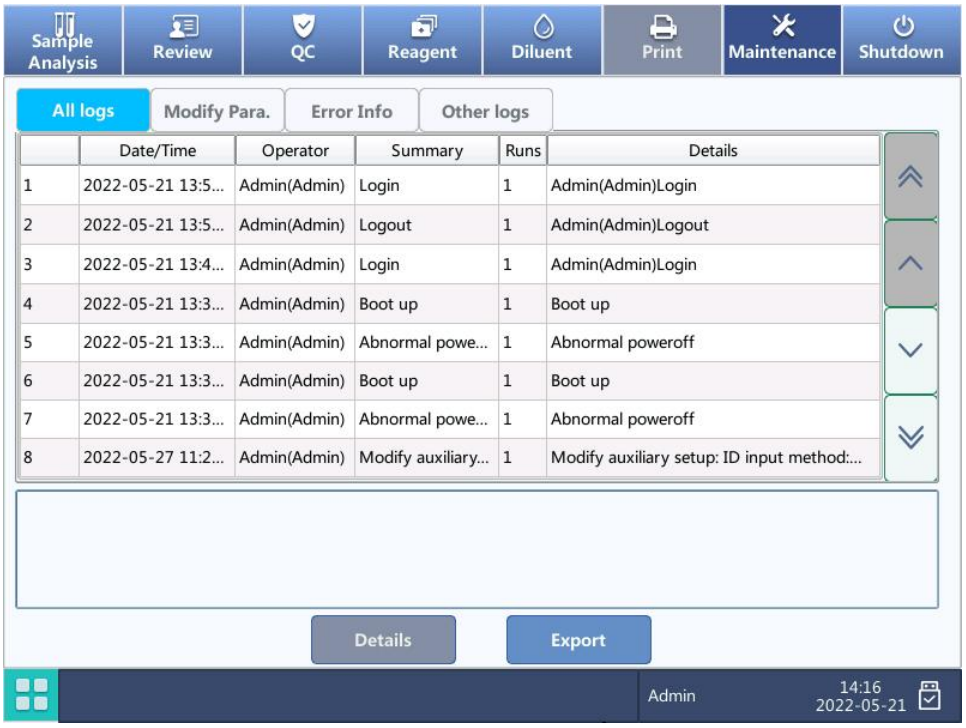
Select "Service">"Touch Screen Calibration" in the pull-up menu to enter the screen shown below.



Click the "Touch Screen Calibration" button to enter the touch screen calibration interface, click the cross-arrow position to calibrate the touch screen after entering the interface (a total of 5 times to click the touch screen, respectively, the upper left corner, upper right corner, lower right corner, lower left corner and the middle position).

10.6 Logs

Select "Services">"Logs" in the pull-up menu to enter the screen shown below.



You can view fault information, parameter modification information, and records of daily operations in the log.

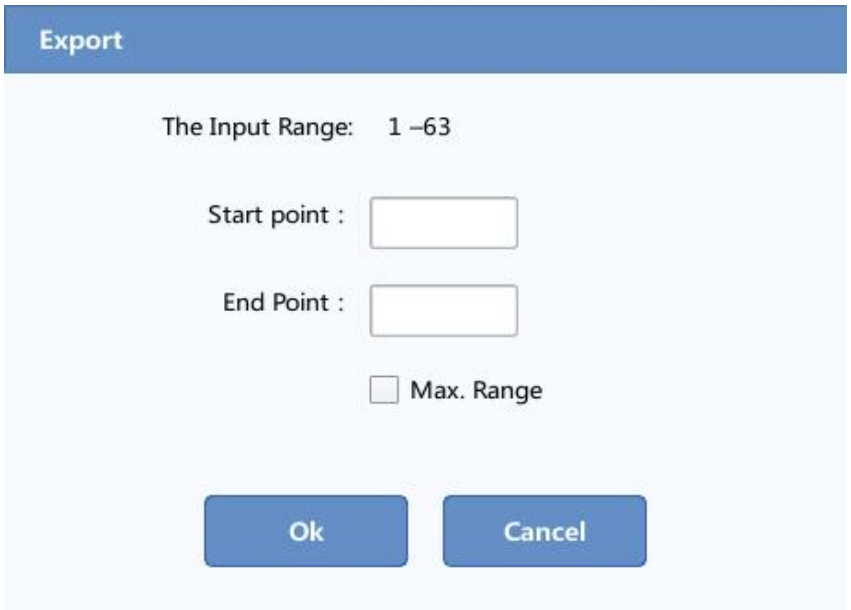
Logs are used to record analyzer usage and are important for operators to check usage history and for maintenance personnel to troubleshoot problems.

Attention

- If the log is full when adding a new record, the system will automatically overwrite the oldest record.
- Up to two years of logs can be stored.

- **Log Export**

1. Click the "Export" button, and the following dialog box will pop up.



2. Select to export the log records within the specified serial number range.

3. Click "OK" to close the dialog box and execute the log export operation.

10.7 Coin cell battery replacement instructions

The main board comes with replaceable coin cell battery, the main role of the coin cell battery is used to record the system time, that is, to maintain the accuracy of the system clock, such as a lack of power will lead to every time the system time is wrong when the power is turned on, then you need to replace the new coin cell battery.

Warning

- If you need to replace the coin cell battery, please contact Singuway'safter-sales service department or your regional agent.
- Please replace the coin cell battery specified by Singuway, otherwise the host may be damaged.

Caution

- Button cell model: BATTERY, CR2032, 3.0V, Φ20

10.8 Eliminate or reduce the instructions for stopping use

Blood, reagents or other kinds of liquid are considered infectious, such as a small amount of spilled on the surface of the instrument, please use a cotton ball with "75% alcohol" to wipe clean, otherwise touch the surface of the instrument may lead to infection and other biological risks; if a large amount of liquid spilled and penetrated into the instrument, please stop using, pull out the power from the socket, and contact with Singuwayor contact your local agent.

For handling, changing operation location, giving away, lending or repairing the instrument, the surface of the instrument needs to be thoroughly disinfected to minimize biohazards. If the instrument is collided or dropped, regardless of whether there is obvious damage on the surface of the instrument shell or inside, it should be stopped and contacted with Singuwayor contacted with the local agent.

If the instrument is faulty after the warranty period, it should be repaired by a Singuway maintenance engineer, a hospital instrumentation department maintenance engineer or another engineer with maintenance qualifications, otherwise it may lead to electric shock and other hazards. It is advisable to get in touch with Singuway before carrying out repairs.

When the instrument reaches the end-of-life period, it is recommended to stop using it or to use it again after a complete overhaul and maintenance by Singuway.

Use is limited to personnel who have been trained and authorized by Singuwayor its agents, as failure to do so may damage the protection provided by the equipment or will have a significant impact on test results.

Chapter 11 Status

11.1 Overview

This analyzer provides a number of status information to facilitate the user to understand the current usage status of the instrument.

Attention

- If the status detection value is outside the normal range, it is highlighted with a red background color.

11.2 Counters

Select "Status">"Counters" in the pull-up menu to enter the screen shown below. Users can view the statistics of each item, detailed statistics of some items such as the number of sample counts, the number of valid sample counts, and other information.

- **View Details**

Users can click the "Details" button after "Number of Sample Counts", "Number of Quality Control" or "Number of Calibration" to view the details of the number of sample counts, quality control counts and calibration counts.

- **Print**

  Click on the "Print" icon to print all statistics for the current screen.

11.3 Temperature and Pressure

Select "Status">"Temperature and Pressure" in the pull-up menu to enter the screen shown below. Users can check the current temperature and pressure information in this screen.

11.4 Voltage and Current

Select "Status">"Voltage and Current" in the drop-down menu to enter the interface shown below. Users can query the current voltage and current information of the instrument in this interface.

11.5 Version Information

Select "Status">"Version Information" in the drop-down menu to enter the interface shown below. Users can query the current version information of the instrument in this interface.

11.6 About

Select "Status">"About" in the drop-down menu to enter the screen shown below. Users can check the current version information of the instrument in this interface.

Chapter 12 Troubleshooting

12.1 Overview

This chapter presents information about possible analyzer faults and provides the corresponding treatment.

Attention

- This instruction manual is not a maintenance manual, but only provides the measures to be taken by the operator in the event of a fault alarm in the analyzer.

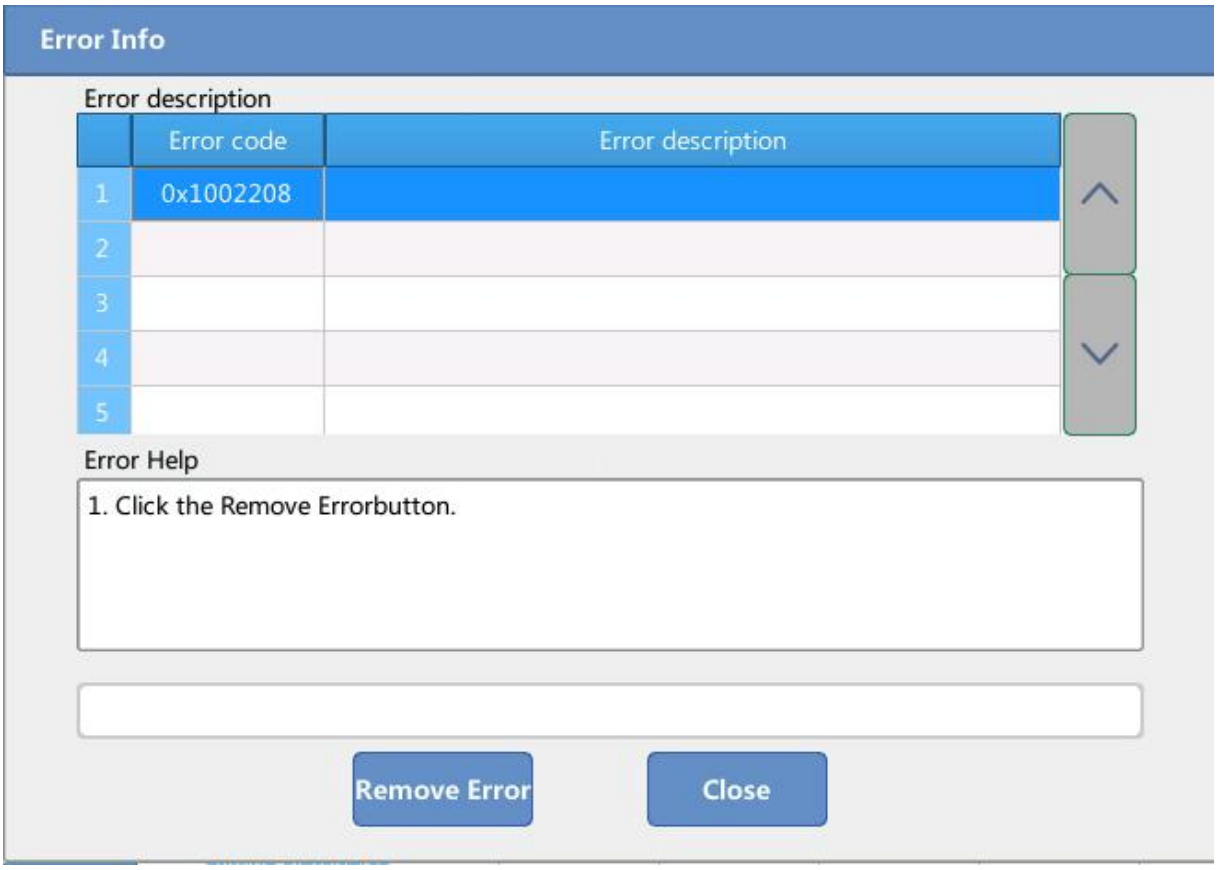
12.2 Fault information and handling

During the use of the analyzer, if a fault is recognized in the instrument, the fault information area in the lower right corner of the software interface will display summary information about the fault, and at the same time, the indicator will turn red and the host will sound an alarm.

The background colors used in the fault information area are red, yellow and green in descending order according to the fault level.

- Red: Indicates a fatal level fault. When such a fault occurs, the host terminates the current action immediately and any operation on it is prohibited.
- Yellow: indicates a no-action level fault. When such a fault occurs, the host immediately terminates the current action.
- Green: indicates a prompt-level fault. After such a fault occurs, the host can still continue to perform the current operation and does not restrict any other operation.

Clicking on the fault Information area in the lower right corner will bring up the dialog box shown below.



The fault dialog box provides the name of the fault that appears and its fault help information. The fault names are displayed in the order in which they appear.

The operator can click the fault name in the dialog box to make it selected (blue background display), and then view the help information of the selected fault in the "Fault Help" list box at the bottom of the dialog box, and the default display is the help information of the first fault. The operator can handle the fault according to the content of the fault help.

The following functions are available in the current dialog box.

- Troubleshooting

  By clicking the "Remove Fault" button, the software will automatically remove the faults that can be removed. For the faults that cannot be eliminated automatically, the operator can follow the fault help information to handle the faults accordingly.

- Close the Fault dialog box

  Clicking on the "Close" button will close the fault dialog, but the fault information area on the interface will display the corresponding fault information. If you click on the fault information area again, you can open the fault dialog box again.

The possible faults of the analyzer and the corresponding help information are shown in the following

table.

Fault name	Troubleshooting help information
Driver board communication abnormality	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Valve control abnormalities	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Pump control abnormalities	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Abnormal vacuum pressure	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Fluid pressure abnormalities	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
LH lyse solution used up	1. Please replace the LH lyse solution. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent, please contact our after-sales service department.
DIFF lyse solution used up	1. Please replace the DIFF lyse solution. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent, please contact our after-sales service department.
Diluent used up	1. Please replace the diluent. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent, please contact our after-sales service department.
Waste liquid container full	1. Please empty the waste liquid container or replace the empty waste liquid container. 2. Click the "Remove Fault" button. 3. If the fault still exists, please contact our after-sales service department.
Input parameters out of range	1. Re-enter the data as required. 2. Click the "Remove Fault" button.
Failure of the horizontal motor to stop rotating	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.

The state recorded by the software is different from the expected state of the action (component is busy)	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Instruction execution time length is greater than the time length given by the timing sequence (timeout)	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The horizontal motor reset action has not reached the initial position after the number of steps	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The horizontal motor reset action has not left the initial position after walking the number of steps	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The horizontal motor has not reached the RBC position after taking the number of steps	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The horizontal motor has not reached the WBC position after walking the number of steps	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The current position is wrong when the horizontal motor reaches the specified position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Vertical motor down fails in reaction position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The lift motor reset action has not reached the starting position after walking the number of steps	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Lift motor reset action after walking the number of steps did not leave the starting position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
HGB background voltage abnormality	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Plugging the hole	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Failure to exit hibernation	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Boot not completed	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Expired diluent	1. Please replace the diluent within the expiration date. 2. Click the "Remove Fault" button and enter the

	barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent within the validity period, please contact our after-sales service department.
DIFF lyse solution expiration	1. Please replace the DIFF lyse solution within the expiration date. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent within the validity period, please contact our after-sales service department.
LH lyse solution expired	1. Please replace the LH lyse solution within the expiration date. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent within the validity period, please contact our after-sales service department.
Insufficient diluent remaining	1. Please replace the diluent. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent within the validity period, please contact our after-sales service department.
Insufficient DIFF lyse solution remaining	1. Please replace the DIFF lyse solution. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent within the validity period, please contact our after-sales service department.
Insufficient LH lyse solution remaining	1. Please replace the LH lyse solution. 2. Click the "Remove Fault" button and enter the barcode of the new reagent to be replaced in the pop-up reagent setting dialog box. 3. If the fault still exists after replacing the reagent within the validity period, please contact our after-sales service department.
Positive 12V analog voltage abnormal	1. Click the "Remove Fault" button. 2. If the fault still exists, please try to restart the instrument.

	3. If the fault still exists after restart, please contact our after-sales service department.
Negative 12V analog voltage abnormal	1. Click the "Remove Fault" button. 2. If the fault still exists, please try to restart the instrument. 3. If the fault still exists after restart, please contact our after-sales service department.
24V power voltage abnormal	1. Click the "Remove Fault" button. 2. If the fault still exists, please try to restart the instrument. 3. If the fault still exists after restart, please contact our after-sales service department.
12V power voltage abnormal	1. Click the "Remove Fault" button. 2. If the fault still exists, please try to restart the instrument. 3. If the fault still exists after restart, please contact our after-sales service department.
5V power voltage abnormal	1. Click the "Remove Fault" button. 2. If the fault still exists, please try to restart the instrument. 3. If the fault still exists after restart, please contact our after-sales service department.
Background anomalies	1、It is recommended to perform background measurements several times and pass them before performing sample measurements. 2、If the background measurement still fails several times, it is recommended to perform the background measurement again after performing the whole probe fluid maintenance. 3. If the fault still exists, please contact our after-sales service department.
Printer failure	1. Please solve the printer failure first. 2. Click the "Remove Fault" button. 3. If the fault still exists, please contact our after-sales service department.
Logger out of paper	1. Loading of printing paper. 2. Click the "Remove Fault" button. 3. If the fault still exists, please contact our after-sales service department.
Logger overheating	1. waiting for the recorder to cool down, which takes about 5 minutes. 2. Click the "Remove Fault" button. 3. If the fault still exists, please contact our after-sales service department.
Wrong machine model	1. Click the "Remove Fault" button.

	2. If the fault still exists, please contact our after-sales service department.
Instruction length error	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The host is busy and cannot respond to the current command	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Action timeout or no result response	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
The lower computer failed to execute the action	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Timing execution timeout	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle no result response	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle without this command	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle level X motor is busy, not accepting commands	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle level Y motor is busy, not accepting commands	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle syringe motor is busy and not accepting commands	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle level X reset failed to reach the reset position after walking the number of steps	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle horizontal Y reset failed, after walking the number of steps did not reach the reset position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle syringe reset failed to reach the reset position after walking the number of steps	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle level X reset failed, did not come out of reset sensor	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle level Y reset failed, did not come out of	1. Click the "Remove Fault" button.

reset sensor	2. If the fault still exists, please contact our after-sales service department.
Sample needle syringe reset failed to come out of reset sensor	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample Pin Timing Execution Timeout	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle positioning failure, wrong position, no action allowed	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle cleaning failed, not in initial position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle cleaning failed, sample syringe not in initial position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle aspiration failure, not in sample position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle aspiration failure, rise failure	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle drainage failure, not in response position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle configuration parameter error	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle drainage failed, sample needle did not aspirate	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle drainage failure and rise failure	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle drainage failure, drop failure	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Blood routine timing execution error	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle positioning failed, sample being shaken or sample shaking not in reset position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle aspiration failure, fixed motor drop	1. Click the "Remove Fault" button.

failure	2. If the fault still exists, please contact our after-sales service department.
Sample needle aspiration failure, fixed motor rise failure	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle action failed, valve status error	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle positioning failure	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle aspiration failure, no aspiration from syringe	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle positioning failure, vertical motor not in initial position	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Sample needle aspiration failure, drop failure	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
Waste liquid tank is full	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
No diluent	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.
No results to answer	1. Click the "Remove Fault" button. 2. If the fault still exists, please contact our after-sales service department.

Appendix A Specifications

A. 1 Product Companion Reagent

Diluent	Diluent
Lyse solution	Lyse solution
	lyse solution
Maintenance reagents	Probe cleanser

A. 2 Vacuum Blood Collection Tube Models

The following sizes of test tubes can be used.

Φ12 ～ 15×75mm size (excluding tube cap size) vacuum blood collection tube, suitable for whole blood mode.

Φ11x40mm size (1.5ml centrifuge tube) and 0.5ml centrifuge tube for pre-dilution and peripheral whole blood mode.

Φ10.7x42mm (without cap size) closed small anticoagulation tube, 0.5ml, open cap testable, suitable for peripheral whole blood mode. Recommended tube: 0.5ml closed anticoagulation tube of BD company product number 365974.

A. 3 Parameter Description

Parameter system	Name	Abbreviations	Unit
White blood cell lines (11 items), including 4 study parameters	White blood cell count	WBC	10^9 /L
	Basophil count	Bas#	10^9 /L
	Basophil percentage	Bas%	%
	Neutrophil count	Neu#	10^9 /L

	Neutrophil percentage	Neu%	%
	Eosinophil count	Eos#	10^9 /L
	Eosinophil percentage	Eos%	%
	Number of lymphocytes	Lym#	10^9 /L
	Percentage of lymphocytes	Lym%	%
	Number of monocytes	Mon#	10^9 /L
	Percentage of monocytes	Mon%	%
Red blood cell lineage (8 items)	Number of red blood cells	RBC	10^{12} /L
	Hemoglobin concentration	HGB	g/L
	Mean red blood cell volume	MCV	fL
	Mean red blood cell hemoglobin content	MCH	pg
	Mean red blood cell hemoglobin concentration	MCHC	g/L
	Coefficient of variation of red blood cell distribution width	RDW-CV	%
	Standard deviation of red blood cell distribution width	RDW-SD	fL

	Hematocrit	HCT	%
Platelet lineage (6 items)	Platelet count	PLT	10^9 /L
	Mean Platelet Volume	MPV	fL
	Platelet distribution width	PDW	None
	Plateletcrit	PCT	%
	Platelet-larger cell ratio	P-LCR	%
	Platelet-large platelet count	P-LCC	10^9 /L
Histogram	Histogram of red blood cell distribution	RBC Histogram	None
	Platelet distribution histogram	PLT Histogram	None
Scatter Chart	High and low angle differentiation scatter plot	HL Diff Scattergram	None
	Low and medium angle differentiation scatter plot	HL Diff Scattergram	None
	High and medium angle differentiation scatter diagram	HL Diff Scattergram	None
	WBC Scatter Plot	WBC Scattergram	None

A. 4 Performance indicators

A. 4.1 Blank Count

Parameters	Blank Counting Requirements
WBC	≤ 0.20×10^9 /L
RBC	≤ 0.02×10^{12} /L
HGB	≤ 1g/L
PLT	≤ 10×10^9 /L

A.4.2 Linearity

Parameters	Linear Range	Linearity error (whole blood mode)	Linear correlation coefficient r
WBC	0.00×10^9 /L～10.00×10^9 /L	No more than ±0.30×10^9 /L	≥0.990
	10.1×10^9 /L～100.0×10^9 /L	No more than ±5%	
RBC	0.00×10^{12} /L～1.00×10^{12} /L	No more than ±0.05×10^{12} /L	≥0.990
	1.01×10^{12} /L～8.00×10^{12} /L	No more than ±5%	
HGB	0 g/L～70g/L	No more than ±2g/L	≥0.990
	71 g/L～250g/L	No more than ±2%	
PLT	0×10^9 /L～100×10^9 /L	No more than ±10×10^9 /L	≥0.990
	101×10^9 /L～1000×10^9 /L	No more than ±8%	

A.4.3 Accuracy

Projects	Testing Scope	Allowable relative deviation range
WBC	3.5×10^9 /L～9.5×10^9 /L	No more than ±10%
RBC	3.8×10^{12} /L～5.8×10^{12} /L	No more than ±4%
HGB	115 g/L～175 g/L	No more than ±4%
PLT	125×10^9 /L～350×10^9 /L	No more than ±15%
MCV	82 fL to 100 fL	No more than ±5%

A.4.4 Accuracy

Parameters	Testing Scope	Accuracy
WBC	3.5×10^9 /L～15.0×10^9 /L	≤2.0%
RBC	3.50×10^{12} /L ~ 6.00×10^{12} /L	≤1.5%
HGB	110 g/L ~ 180 g/L	≤1.5%
MCV	70 fL～120 fL	≤1.0%
PLT	100×10^9 /L ~ 149×10^9 /L	≤6.0%
	150×10^9 /L ~ 500×10^9 /L	≤4.0%

A.4.5 Carrying contamination rate

Parameters	Carrying contamination rate
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6 %
PLT	≤1.0 %

A. 5 Cybersecurity

a) Operating environment

Hardware configuration: processor is ARM Cortex-A8 600MHz or more, memory is 256M RAM or more configuration, hard disk space 2G or more.

Software environment: Linux 3.0.0 or above operating system.

Network conditions: network architecture is CS, network type is personal domain network, bandwidth is not required.

b) Security software: none

c) Data and device interface

Data interface USB: export test data in csv format.

Data interface network port: Use wired network to connect LIS system with analyzer for data transmission.

d) User access control

User use of this analyzer is controlled by user name and password, user type (normal user, administrator), and the above user types can use this analyzer by entering the correct user name and

password.

e) Software updates

Software updates are performed by the manufacturer's after-sales engineers or by trained and qualified dealer engineers via USB flash drive, without user operation.

A. 6 Power Supply

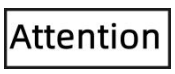
	Voltage	Input power	Frequency
Host	100V-240VAC	≤180 VA	50Hz/60Hz

A. 7 Fuses

Fuses of specified size must be used

Analyzer fuse specification: F6.3AL250V

A. 8 Electromagnetic compatibility



- The Cellcount-60 Automatic 5-Part Hematology Analyzer meets the emission and immunity requirements specified in this part of GB/T 18268.26, as shown in the table below.
- It is the user's responsibility to ensure the EMC environment of the equipment so that the equipment can work properly.
- It is recommended that the electromagnetic environment be evaluated prior to the use of the equipment.

- The Cellcount-60 Automatic 5-PartHematology Analyzer is designed and tested as a Class A device in accordance with GB 4824. In a home environment, this device may cause radio interference and requires protective measures.
- It is prohibited to use this equipment next to strong radiation sources (e.g., non-shielded RF sources), as this may interfere with the normal operation of the equipment.

Table I:

Electromagnetic emission	
Launch test	**Conformity**

GB 4824 Conductive emission	Group 1 Class A
GB 4824 Radiation emission	
GB 17625.1 Harmonic emission	Not applicable
GB 17625.2 Voltage fluctuation / flicker emission	Not applicable

Table 2.

Electromagnetic Immunity			
Immunity test items	**Basic Standards**	**Test value**	**Compliance with performance criteria**
Electrostatic Discharge (ESD)	GB/T 17626.2	Contact discharge: ±2kV, ±4kV Air discharge: ±2kV, ±4kV, ±8kV	B
Radio Frequency Electromagnetic Field	GB/T 17626.3	3V/m, 80MHz~2.0GHz, 80% AM	A
Pulse group	GB/T 17626.4	Power line: ±1kV (5/50ns,5kHz)	B
Surge	GB/T 17626.5	Line-to-ground: ±2kV Line-to-line: ±1kV	B
Radio Frequency Conduction	GB/T 17626.6	Power line: 3V/m, 150kHz to 80MHz, 80% AM	A
Industrial frequency magnetic field	GB/T 17626.8	3A/m, 50/60Hz	A

Voltage transients, interruptions	GB/T 17626.11	0% for 1 cycle. 40% for 5/6 cycles. 70% of 25/30 cycles. 250/300 cycles 5%	B C C C
Performance discrimination. A. The performance is normal within the specification limits during the test. B. The function or performance is temporarily reduced or lost during the test, but can recover on its own. C. The function or performance is temporarily reduced or lost during the test, but requires operator intervention or system reset.			

Attention

- Be sure to store and use the analyzer under the specified environmental conditions.

A. 9 Work Environment

Ambient temperature range: 10℃ ~ 30℃

Ambient humidity range: ≤70%

Atmospheric pressure range: 70 kPa to 106 kPa

A. 10 Storage Environment

Ambient temperature range: -10 ℃ ~ 55 ℃

Relative humidity range: 10 % to 93 %

Atmospheric pressure range: 50 kPa to 106 kPa

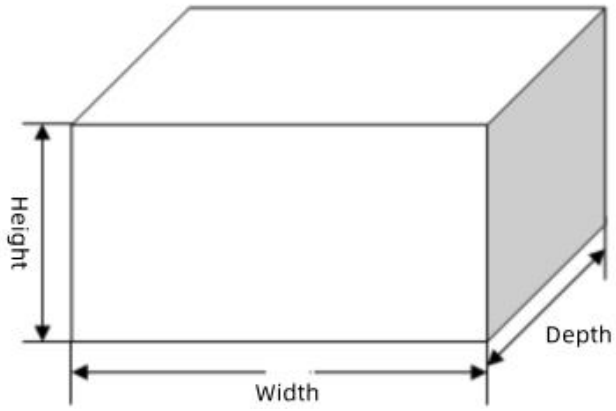
A. 11 Operating Environment

Ambient temperature range: 10 ℃ ~ 30 ℃

Relative humidity range: ≤70%

Atmospheric pressure range: 70 kPa to 106 kPa

A. 12 Dimensions and weight



Cellcount-60	Complete appliance
Size	Width ≤ 325mm Height ≤ 465mm (including footing) Depth ≤ 470 mm
Weight	≤30Kg(bare weight)

A. 13 Laser Description

Laser Type	Wave length	Power	Maximum output power	Horizontal launch angle	Vertical launch angle
Class 1 Laser	670nm	3.0mW	10mW	8°	45°

You will likely see the following laser warning sticker on the outside or inside of the instrument, please follow the instructions to operate and beware of laser hazards!

This sticker is placed on the laser shield box of the optical components inside the machine

A. 14 Contraindications

None

A. 15 Accessories List

For the accessories list and accessories replacement precautions, please refer to the accompanying accessories list.