DYMIND

Auto Hematology Analyzer

Operator's Manual

Preface

Thank you for purchasing the Auto Hematology Analyzer manufactured by Dymind Biotech.

Read and understand the entire operator's manual before operating this device. Store this operator's manual properly for future reference.

Product name: Auto Hematology Analyzer

Model: DH-600, DH-602, DH-605, DH-610, DH-612, DH-615

Product components: aspiration module, dilution module, cleaning module, analyzing and measuring module, pneumatic unit, microprocessor, main unit software, PC software and accessories.

Scope of use: the Auto Hematology Analyzer is a quantitative, automated hematology analyzer for in vitro diagnostic use in clinical laboratories. It classifies and enumerates the following parameters for whole blood specimens (collected in K_2EDTA anticoagulant and obtained by venipuncture or fingerstick) and body fluid samples: WBC, RBC, HGB, MCV, MCH, MCHC, RDW-CV, RDW-SD, HCT, PLT, MPV, PDW, PCT, IPF, P-LCR, P-LCC, Neu%, Lym%, Mon%, Eos%, Bas%, Neu#, Lym#, Mon#, Eos#, Bas#, IG#, IG%, RET, RET%, LFR, MFR, HFR, IRF, RHE, WBC-BF, RBC-BF, TC-BF#, MN%, MN#, PMN%, PMN#, Eos-BF#, Eos-BF%, Neu-BF#, Neu-BF%, LY-BF#, LY-BF%, MO-BF#, MO-BF%, HF-BF#, HF-BF%, RBC-BF(R). The purpose of the Auto Hematology Analyzer is to identify the normal human patient, with normal system-generated parameters, from patients whose results require additional studies. The device is used for aided diagnosis of adult and pediatric populations, and mainly used as a non-specific inflammatory marker.

NOTE

The tests of pre-dilution sample and body fluid sample are for DH-610 and DH-612 only.

Contact Info for After-sales Services

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Declaration

The version of this manual is AF, and the release date is 2025-01-03. This operator’s manual may be modified without notice.

Dymind Biotech reserves the right of final interpretation of this operator’s manual.

All information in this manual does not constitute a warranty of any kind, express or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Every effort has been made in the preparation of this manual to ensure accuracy of the contents. However, Dymind Biotech assumes no liability or responsibility for any errors or omissions in the contents of this document. Dymind Biotech reserves the right to improve any products to enhance product reliability, functionality, or design.

The reader of this manual is the user who is authorized to use this guide as part of Dymind’s instrument they purchased. Unauthorized persons are not allowed to use this manual.

Operator’s manual is intended to help you operate the analyzer properly, but will not explain for software and hardware configuration. Please refer to the contract of the analyzer (if any), packing list or consult Dymind or local agents for detailed configurations.

The pictures in this operator’s manual are for reference only. If there is inconsistency between the pictures and the actual product, the actual product shall prevail. Do not use the pictures for other than intended use.

Dymind Biotech shall be responsible for the safety, security, and performance of the product only when all of the following conditions are met:

- The assembly, re-commissioning, extension, modification, repair and system upgrade of the product are performed by the authorized personnel of Dymind Biotech.
- The product is operated based on this operator's manual.
- The electrical appliances in the relevant working room comply with applicable national and local requirements.

Contents

1 Manual Overview

This chapter explains how to use this operator's manual, which is shipped with the Auto Hematology Analyzer and contains reference information about the analyzer and procedures for operating, troubleshooting and maintaining the analyzer.

Before operating the Auto Hematology Analyzer, please read this manual carefully to ensure correct operation, best performance and user's safety.

1.1 Who Should Read This Manual

This manual is written for clinical laboratory professionals, trained doctors, nurses or laboratory technicians to:

- Learn about the hardware and software of the Auto Hematology Analyzer;
- Set up system parameter;
- Perform daily operations;
- Perform system maintenance and troubleshooting.

1.2 How to Find Information

This operator's manual comprises 16 chapters and 3 appendixes. Refer to the table below to find the information you need.

See...	You can find...
1 Manual Overview	Instructions for using the operator's manual of the Auto Hematology Analyzer, and to the safety information before using the analyzer.
2 Installation and Connection	The introduction to installation requirements and methods of the Auto Hematology Analyzer.
3 System Overview	The introduction to the usage and system components of the Auto Hematology Analyzer.
4 Working Principles	The introduction to the measurement principles of the Auto Hematology Analyzer.

See...	You can find...
5 Daily Operations	The introduction to the sample preparation, the analysis procedure, startup and shutdown of the analyzer, and other daily operations.
6 Sample Analysis	The introduction to the procedure of sample analysis.
7 Review and Statistics	The introduction to the processing of the sample results.
8 Reagent Management	The introduction to the methods of replacing reagents, extending the service life of the reagent and viewing reagents replacing history.
9 Quality Control	The introduction to the methods of the quality control of the Auto Hematology Analyzer.
10 Calibration	The introduction to the basic requirements of calibration and the calibration methods provided by the Auto Hematology Analyzer.
11 Settings	The introduction to the parameter settings of the Auto Hematology Analyzer.
12 Service	The introduction to the maintenance functions and the relevant reference information of the Auto Hematology Analyzer, and to the sample tracking function, of how to view version information, and to the functions of other menus of DMS software.
13 Performance	The introduction of how to view various performance specifications of the Auto Hematology Analyzer.
14 Log Management	The introduction to the log functions of the Auto Hematology Analyzer.
15 Routine Maintenance	The introduction to the daily maintenance of the Auto Hematology Analyzer.
16 Troubleshooting	The introduction to the troubleshooting and commonly-used error information reference of the Auto Hematology Analyzer.
Appendix A Specifications	The introduction to the specification indicators of the Auto Hematology Analyzer.
Appendix B List of Accessories	The introduction to accessories, optional accessories and packing list of the Auto Hematology Analyzer.
Appendix C Terms and Abbreviations	The introduction to the terms and abbreviations of the Auto Hematology Analyzer.

1.3 Conventions Used in this Manual

The texts with special meaning in the manual are highlighted by different fonts and formats.

Format	Meaning
[XX]	All uppercase characters enclosed in [ ] indicate the name of a key on the analyzer or the peripheral keyboard, such as [ENTER].
XX	Bold characters indicate the text displayed on the screen.
XX	Italic characters indicate variables and the specific content depending on the actual situation.
XX	Bold and italic characters indicate chapter titles, such as ***1.1 Introduction***.

1.4 Symbols

The symbols that may be found in this document are defined as follows.

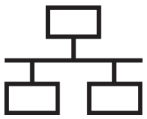
Symbol	Meaning
	Follow the instructions below the symbol to avoid potential biohazard.
	Follow the instructions below the symbol to avoid personnel injury.
	Follow the instructions below the symbol to avoid analyzer damage and failure, or unreliable analysis results.
	Follow the instructions below the symbol, which highlights the important information of operating procedures that call for special attention.
	Puncture Warning: The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.
	Laser Warning: It serves as a reminder of the laser radiation. Do not stare into beam or view directly with optical instruments.

The analyzer or the outer packaging may include labels or symbols as shown in Table 1-1.

NOTE

- If the labels are damaged or lost, please contact Dymind or Dymind's agents for replacement.
- All illustrations in this manual are provided as references only. They may not necessarily reflect the actual configuration or display in the Auto Hematology Analyzer.

Table 1-1 Labels or Symbols

Symbol	Meaning
	Warning
	Biological hazard
	Exercise caution to prevent puncture
	Warning; Crushing of hands
	Laser radiation warning: It is a Class 3B laser product with 8.0 mW of maximum power output at 638 nm. Avoid direct eye exposure to the laser beam.
	Class 1 Laser Product
	Do not rotate the knob without authorization.
	Instruction for moving: it reminds users that put the hands under this label and move upwards when moving.
	Computer network

Symbol	Meaning
	Universal Serial Bus (USB), port/plug
	Protective earth; protective ground
	Alternating current
	In Vitro diagnostic medical device
	Batch code
	Use-by date
	Serial number
	CE MARKING OF CONFORMITY
	Authorized representative in the European Community/European Union
	Date of manufacture
	Manufacturer
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Consult instructions for use or consult electronic instructions for use
	Keep away from sunlight
	Keep dry

Symbol	Meaning
	Distribution packages shall not be rolled or turned over.
	Stacking of the distribution packages is not allowed and no load shall be placed on the distribution packages.
	This is the correct upright position of the distribution packages for transport and/or storage.
	Contents of the distribution packages are fragile therefore it shall be handled with care.
	General symbol for recovery/recyclable
	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC(WEEE)

1.5 Safety Information

This section explains the safety information and notes when using the Auto Hematology Analyzer.

1.5.1 General Information

Warning

- Please check the tightness of all the doors/ covers/boards before running the analyzer to prevent unexpected opening or loosening when the device is working.
- Make sure all the safety measures provided by the device are taken. Do not disable any safety unit or sensor.
- Please respond to any alarm and error information immediately.
- Do not touch the moving parts.
- Contact Dymind or the agent upon the identification of any damaged part.
- Be careful when opening/closing and removing/installing the doors/covers/boards of the analyzer.
- Dispose of the analyzer according to local regulations.
- Keep your clothes, hair and hands away from the moving parts to avoid being caught or crushed.
- If any soft tubes or components with liquids leak or corrode due to aging or wear during the use of this analyzer, please stop using the analyzer immediately, and contact Dymind or the local agent.
- The main unit is equipped with the thermal protector, and the heating component can only be heated up to 60°C. When it reaches 60°C, the thermal protector is automatically disconnected.
- If the analyzer alarms when there is no error during the use of the analyzer, the analyzer is still in normal operation. If it alarms because of an error, please refer to *16 Troubleshooting* to deal with the error.

The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.

Caution

- Please use the analyzer in strict accordance with this manual. Otherwise, the protection provided by the device may be damaged.
- Please take proper measures to prevent the reagents from being polluted.
- Do not reuse the disposable product.

NOTE

- Use only the calibration, quality control product and reagent specified by Dymind, and store and use them in strict accordance with the corresponding instructions.
- Use only the vacuum blood collection tube, centrifugal tube, capillary tube and other disposable tube specified by the manufacturer.

1.5.2 Biological Harm

- All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.
- If the main unit leaks, the leaked liquid is dangerous for biological infection.

Warning

- You are obligated to discharge and dispose of the reagents, wastes, samples, consumables according to local legislations and regulations.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while contacting them and the relevant areas in the laboratory.
- Once the reagent accidentally comes in contact with your skin, rinse with plenty of water immediately and receive medical treatment if necessary. If you accidentally get any of the reagent into your eyes, rinse with plenty of water immediately, and receive medical treatment.
- The sample may spill from the uncapped tube and result in bio-contamination. Be careful when operating an uncapped tube with sample.
- The tip of the sampling probe is sharp and may contain substance with bio-contamination. Be careful when operating the main unit. Do not contact the sample probe.

1.5.3 Cleaning and Disinfection

Warning

- Please shut down the analyzer and pull out the power cord before disinfection to avoid the risk of electric shock. Always wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) when cleaning the surface of the analyzer.
- After disinfection, please wash your hands with hand cleanser or soapy water, and then rinse off with water.
- Do not open the device for internal disinfection.
- If dangerous substances leak on the surface of the device or enter the inside of the device, proper disinfection should be taken. For details, please refer to Table 1-2.
- Please use the reagents listed in Table 1-2 for disinfection or cleaning. Do not use cleaning agents or disinfectants that are dangerous due to chemical reactions with device parts or materials contained in the device.

NOTE

If you have any questions about the compatibility of disinfectants/cleaning agents with the device parts/materials contained in the device, please consult Dymind or the local agent.

To avoid the bio-contamination when using the device, please refer to Table 1-2 to disinfect the device according to different situations.

Table 1-2 Disinfection

Situation	Disinfection Steps
Accidents such as liquid (samples, controls, calibrators, reagents, waste, etc.) spillage on the surface of the analyzer.	Wipe the surface of the device 2 times with 75% alcohol solution and wait for 3 minutes. Then clean it with water to remove residual alcohol. Finally, dry with disposable cloth.

Situation	Disinfection Steps
When the analyzer will not be used for a long time, before moving or before long-distance transportation	• Clean the surface of the device. Wipe the surface of the device 2 times with 75% alcohol solution and wait for 3 minutes. Then clean it with water to remove residual alcohol. Finally, dry with disposable cloth. • Clean the sampling probe. Clean the surface of the sampling probe with disposable cloth or tissue paper soaked in 75% alcohol solution and wait for 3 minutes. Then dry with disposable cloth. • Clean the reagent probe. Clean the surface of the sample probe with disposable cloth or tissue paper soaked in 75% alcohol solution and wait for 3 minutes. Then dry with disposable cloth.

1.5.4 Software

Caution

- Make sure that the external computer is installed only the software authorized by Dymind.
- Be sure to install only the original software to prevent computer viruses.
- It is recommended that you install anti-virus software on the external computer and check for viruses regularly.
- When you run the PC software for the first time or click the combo box to select content, the PC end antivirus software may pop up a dialog box, prompting you to prevent the software from running. Please allow the running of the software, otherwise the software may fail to run.
- Before using USB or other mobile devices, make sure to check if they contain virus.

1.5.5 Laser

- There is a class 3B laser radiation in the optical system of the analyzer. To avoid laser damage, only Dymind-authorized technician can open the analyzer. Operators must wear proper laser-light protective goggles (optical density ≥3).
- If you disassemble the device without permission, the laser may leak and result in personal injury.
- Do not use the analyzer around the flammable anesthetic or oxygen gas (such as N_2O) or O_2 to avoid the fire.

The specifications of the laser inside the optical component are as follows:

- Wavelength: 638 nm
- Maximum output power: 8.0 mW
- Laser level: 3B

1.5.6 EMC Description

Warning

- This equipment is not intended for use in residential environments and may not provide adequate protection for radio reception in such environments.
- This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- Do not use this equipment in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.
- The electromagnetic environment should be evaluated prior to operation of the equipment.

The Auto Hematology Analyzer complies with the emission and immunity requirements of the IEC 61326-1:2012, EN 61326-1:2013, IEC 61326-2-6:2012, EN 61326-2-6:2013, EN IEC 61326-1:2021, and EN IEC 61326-2-6:2021. See Table 1-3 and Table 1-4.

Table 1-3 Emission requirements

Test Item/Basic Standard	Test Requirement
CISPR 11:2009+A1; CISPER 11:2015+A1+A2 Conducted Emission	Group 1-Class A

Test Item/Basic Standard	Test Requirement
CISPR 11:2009+A1 Radiated Emission	
IEC 61000-3-2: 2019 Harmonic Currents Emission	n.a.
IEC 61000-3-3:2013+A12019 Voltage Fluctuations/Flicker	n.a.

Table 1-4 EMC Immunity

Test Item	Basic Standard	Test Requirement	Performance Criteria
ESD	IEC 61000-4-2: 2008	Contact discharge: ±2kV, ±4kV Air discharge: ±2kV, ±4kV, ±8kV	B
Radiated,radio-frequency elec-tromag-netic field im-munity	IEC 61000-4-3: 2006+A1+A2	3V/m, 80MHz~6.0GHz	A
EFT	IEC 61000-4-4: 2012	AC Mains:±1kV(5kHz) Signal Port:±0.5kV(5kHz)	B
Surge	IEC 61000-4-5: 2005 IEC 61000-4-5: 2014+A1	AC Mains: L-PE, N-PE:±2kV L-N:±1kV Signal Port: Line-PE:±1kV	B
Radio-Frequency Continuous Conducted	IEC 61000-4-6: 2013	AC Mains:3V(150kH to 80MHz) Signal Port:3V(150kH to 80MHz)	A
Power Frequency magnetic field	IEC 61000-4-8:2009	3A/m, 50/60Hz	A

Test Item	Basic Standard	Test Requirement	Performance Criteria
Voltage Dips and interruptions	IEC 61000-4-11: 2004 IEC 61000-4-11: 2020	0.5 cycle, 0%; 1 cycle, 0%; 5/6 cycles, 40%; 25/30 cycles, 70%; 250/300 cycle, 5%	B B C C C
Definition: A. The performance is normal in the limit during test. B. The performance or function declines or loses but it can automatically recover during test. C. The performance or function declines or loses that operator needs to intervene or reset the system during test.			

2 Installation and Connection

The analyzer has passed strict tests before shipping. To avoid being crushed during transportation, the analyzer is packed carefully before transportation. When receiving the analyzer, carefully inspect the packaging to see if there are physical damages. If yes, contact Dymind customer service department or your local agent immediately.

This chapter introduces notes and environmental requirements of the installation, and contents of system connection. For detailed installation steps, please refer to ***Auto Hematology Analyzer Installation Guide***.

2.1 Installation Personnel

- The analyzer should only be installed by Dymind or the authorized agents.
- You need to provide the appropriate environment and space.
- When you receive the analyzer, please notify Dymind or your local agent immediately.
- When the analyzer needs to be relocated, please contact Dymind or your local agent. Do not move at will, otherwise it may damage the analyzer or cause personal hazards.

NOTE

The analyzer is heavy. Move the analyzer by one person may cause personal injury. If needed, it is suggested that 2-4 persons move the analyzer together. Comply with the corresponding safety regulations and use appropriate tools when moving.

2.2 Installation Requirements

Before installation, make sure that the installation environment meets the requirements listed in Table 2-1.

Table 2-1 Installation Requirements

Installation environment	Requirements
Site	● Indoor use. ● Place on a stable countertop with load capacity larger than 130 kg and locating on level ground. ● Free of dust, mechanical vibration, heat and wind sources, contamination, heavy-noise source or electrical interference. ● Avoid direct sunlight and keep good ventilation.
Space	● The reserved space between the left and right side doors of the main unit and walls should be ≥100 cm. ● The reserved space between the rear board of the main unit and the wall should be ≥50 cm. ● Ensure that there is enough space on and below the countertop to accommodate the diluent and waste containers. ● Ensure that the air inlet and outlet of the pneumatic unit are not obstructed by any objects, and therefore heat can be dissipated smoothly. Do not put the pneumatic unit in a closed space like in a box or a closet. ● Do not place the device to the position that is difficult to operate the disconnecting unit. Place the analyzer near the electrical outlet and avoid being blocked by any objects, so that you can disconnect the power plug easily when needed.
Temperature	15°C~32°C
Relative humidity	30%~85%
Atmospheric pressure	70 kPa~106 kPa
Altitude	<3,000 m
Ventilation	Keep air exchange to ensure good air circulation. The wind should not blow directly at the analyzer.

Installation environment	Requirements
Power supply	● Main unit: AC 100 V~240 V, input power 660 VA, 50/60 Hz; fuse specifications T6.3AL 250 V. ● Sampler unit: AC 100 V~240 V, input power 150 VA, 50/60 Hz; fuse specifications T6.3AL 250 V. ● Pneumatic unit: AC 220 V~240 V / AC 115 V, input power 600 VA, 50/60 Hz; fuse specifications T6.3AL 250 V. **Note** ● The analyzer must be properly grounded. ● Please use the original power cord enclosed with the device. Using other power cord may damage the analyzer or generate incorrect analysis results. ● Power supply voltage fluctuation: not more than ±10% of the nominal voltage.
External computer	The minimum configuration of the external computer should meet the following requirements: ● Meet the corresponding safety requirements ● CPU: 3.5GHz or above ● RAM: ≥4 GB ● Hard disk: ≥500 GB ● Network interface: >2 ● USB interface: >4 ● Operating system: Microsoft Windows 7, Microsoft Windows 10 or the compatible versions ● Displayer configuration: ≥22 inches ● Resolution: support 1920*1080 (recommended) and 1600*900 ● External computer should be equipped with optical drive ● Network conditions: Network architecture: CS architecture Network type: LAN Network bandwidth: 100Mbps **Note** Do not install the PC software in the system disk. You can change the default installation path when installing.

Installation environment	Requirements
Electromagnetic environment	● For the normal operation of the device, it's recommended that you evaluate the electromagnetic environment of the laboratory before operating. ● Keep the device away from sources of strong electromagnetic interference; otherwise, its proper functioning may be affected. ● Keep the device away from electric-brush motors, flashing LED light and electric-contact equipment which is switched on/off frequently. ● Operate the device in dry environment, especially with artificial materials (synthetic fabric, carpet, etc.) may lead to a damaged electromagnetic discharging, and therefore resulting in incorrect analysis results.
Waste disposal	Dispose of waste as per the requirements of the local environmental protection authorities.

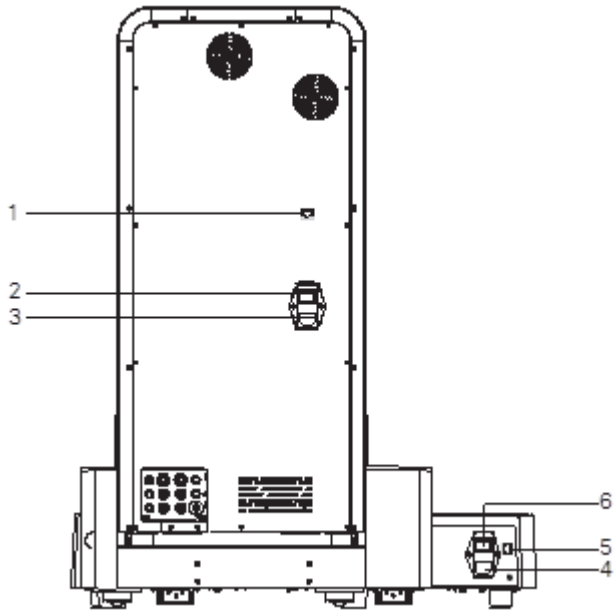
2.3 System Connection

This section introduces the electrical connection, reagents connection, the connection between the main unit, sampler unit, DMS software and CMS software, and the communication connection between LIS and DMS software.

2.3.1 Electrical Connection

Complete the electrical connection of the main unit and the autosampler by referring to Figure 2-1.

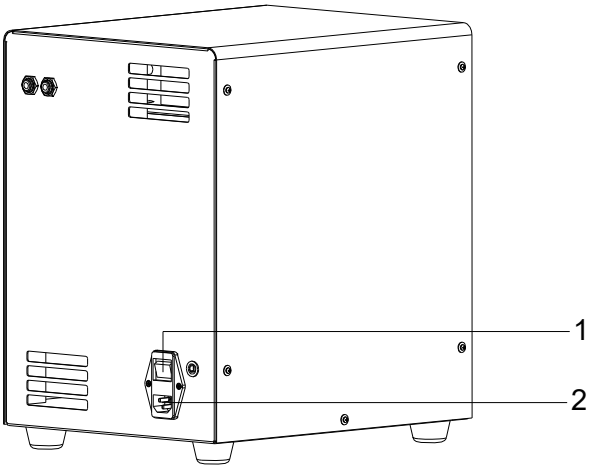
Figure 2-1 Electrical Connection of the Main Unit and the Autosampler



No.	Name	Description
1	LAN port of the main unit	To connect the main unit with the interchanger.
2	Power switch of the main unit	To turn on/off the power supply of the main unit.
3	Power input socket of the main unit	AC power input port. Use the power cord enclosed with the device to power the main unit.
4	Power input socket of the autosampler	AC power input port. Use the power cord enclosed with the device to power the autosampler.
5	LAN port of the autosampler	To connect the autosampler with the interchanger.
6	Power switch of the autosampler	To turn on/off the power supply of the autosampler.

See Figure 2-2 to power on the pneumatic unit (external air supply).

Figure 2-2 Power Connection of the Pneumatic Unit



No.	Name	Description
1	Power switch of the pneumatic unit	To turn on/off the power supply of the pneumatic unit.
2	Power input socket of the pneumatic unit	AC power input port. Use the power cord enclosed with the device to power on the pneumatic unit.

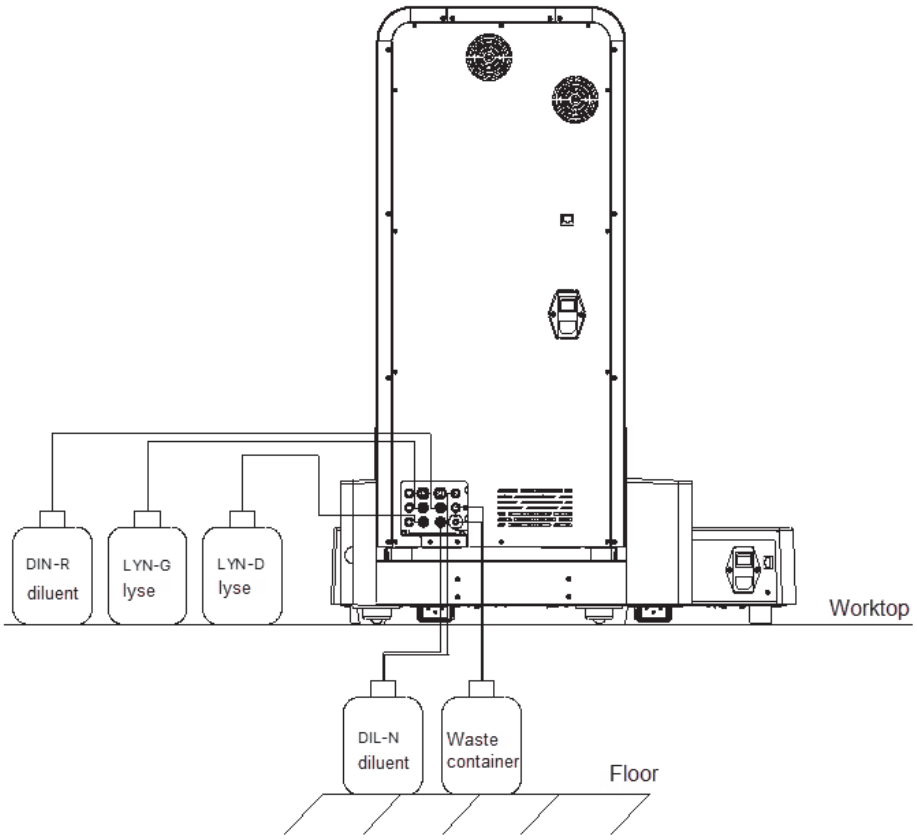
2.3.2 Reagent Connection

Perform reagent connection of the main unit by referring to this section.

2.3.2.1 Connecting Lyse/Diluent/Waste Container

Refer to Figure 2-3 to connect lyse, diluent and waste container to the main unit.

Figure 2-3 External Reagent Connection

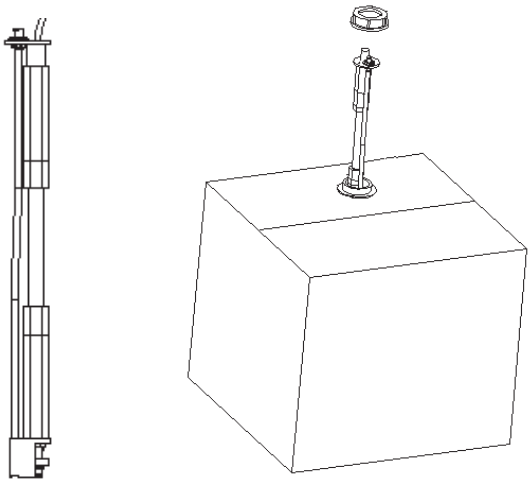


Installing the DIL-N diluent float sensor

Follow below steps to install the DIL-N diluent float sensor.

1. Press down and open the circular cardboard with the dotted cutting line on the upper side of the diluent box to expose the hole.
2. Pull up the bucket cap so that the cardboard around the hole can stick the bottleneck under the cap to prevent it from sinking in.
3. Rotate to open the cap (keep the cap) and prevent any foreign matter from entering the bucket.
4. Install the DIL-N diluent float sensor components in the accessory box as shown in Figure 2-4. Keep the float sensor vertical during installation, and tighten its own cap.

Figure 2-4 Installing the DIL-N diluent Sensor



The DIL-N diluent can be replaced according to the steps mentioned above. After the replacement of the DIL-N diluent, keep the vacant diluent bucket and the cap for future use.

Installing the waste float sensor

Warning

You are obligated to discharge and dispose of the reagents, wastes, samples, consumables according to local legislations and regulations.

NOTE

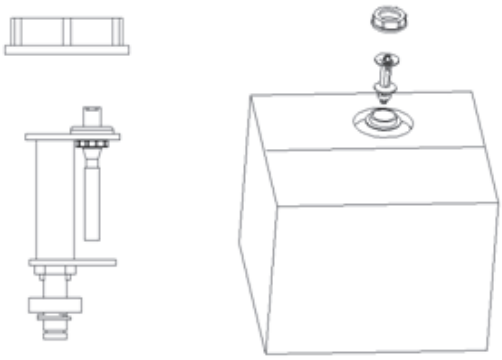
The float sensors of the main unit are only applicable to Dymind-supplied waste containers or the containers with the same specification and model (such as the vacant diluent bucket).

The main unit provides two ways to discharge the waste: waste container or the medical waste discharge system required by local hospitals. For the setting method of waste discharge method, please refer to ***11.1.2 Auxiliary Settings***.

If using the waste container to collect the waste, you need to follow below steps to install the waste float sensor when installing or replacing the waste container.

1. Take a proper waste container (it can be a vacant diluent bucket, in which case the opening of the bucket should be pulled out from the box hole, and be stuck by the diluent bucket holder) and open the cap.
2. Install the waste float sensor components in the accessory box as shown in Figure 2-5. Keep the float sensor vertical during installation, and tighten its own cap to prevent spillage.

Figure 2-5 Installing the Waste Float Sensor

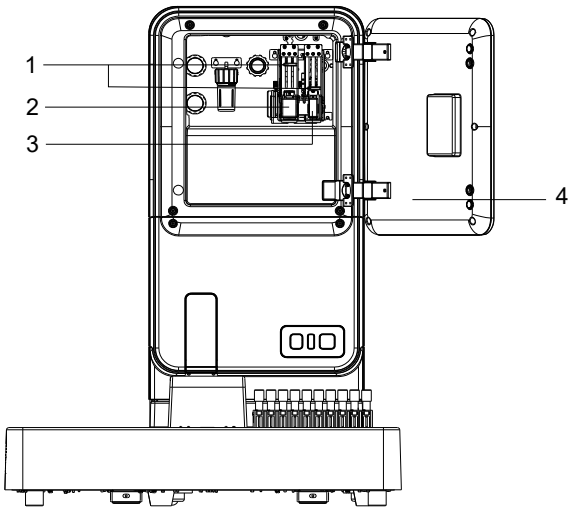


The waste container can be replaced according to the steps mentioned above. After the replacement of the waste container, the replaced waste shall be properly disposed of to avoid contamination.

2.3.2.2 Connecting the Dye

See Figure 2-6 to connect the dye with the main unit (you need to open the front door of the main unit first).

Figure 2-6 External Reagent Connection



1	Slider	2	FDN-D dye
3	FDN-R dye	4	Front door of the main unit

Detailed steps of installing the dye are as follows.

1. Open the front door of the main unit.
2. Lift the slider.
3. Place FDN-D dye or FDN-R dye into the corresponding position.
4. Put down the slider.
5. Close the front door of the main unit.

2.3.3 Connection of Main Unit, Sampler Unit, and DMS with CMS

The main unit needs to connect with CMS software to control the autosampler through CMS software, and therefore to deliver the sample. Then by connecting DMS software with CMS software, the main unit can transmit data with DMS software.

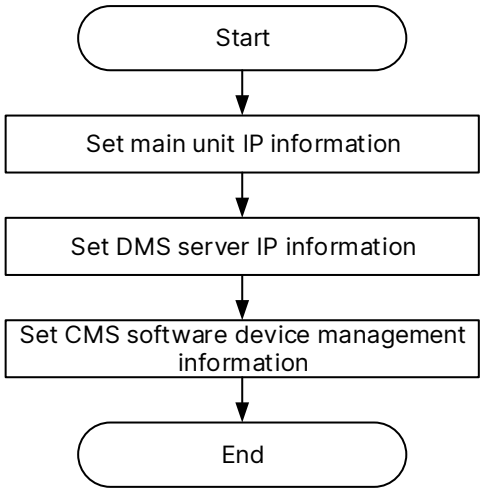
CMS software can connect up to 2 main units, 1 autosampler, and 1 DMS software server in the same network segment to form a workstation.

NOTE

- The IP addresses of the main unit, autosampler, and DMS software must be on the same network segment.
- The IP address of the autosampler is 10.0.0.102, which is not allowed to be modified. If you need to modify, please contact Dymind customer service department or the agent.

The flow for connecting the main unit, sampler unit, DMS with CMS is shown in Figure 2-7.

Figure 2-7 Communication Connection Flow



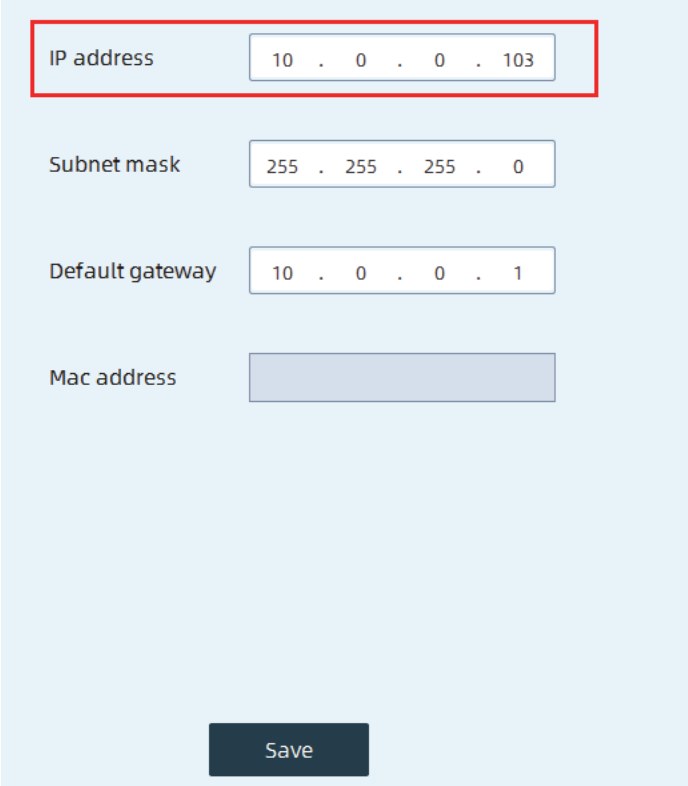
Setting the IP information of the main unit

The administrator can set the IP information of current main unit, but the ordinary user can only browse.

The steps for setting the IP information of the main unit are as follows.

1. Click  > **Settings** > **Communication Settings** on HOST software to enter the communication setting interface.
2. Set the main unit IP information on the communication setting interface, including IP address, subnet mask and default gateway. See Figure 2-8.

Figure 2-8 Setting the IP Information of the Main Unit



3. Click **Save**.

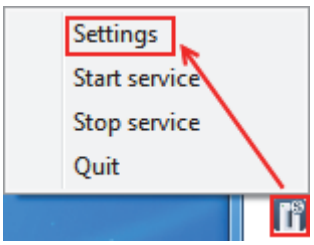
If you need to connect two main units, please follow the above steps to set the IP information of the other main unit.

Service DMS Server IP Information

The steps for setting the IP information of the DMS server are as follows.

1. Right click the DMS server icon "" in the task bar, and then click **Settings**. See Figure 2-9.

   Figure 2-9 DMS Server Menu

2. Click **Stop service** in the pop-up interface as shown in Figure 2-10.

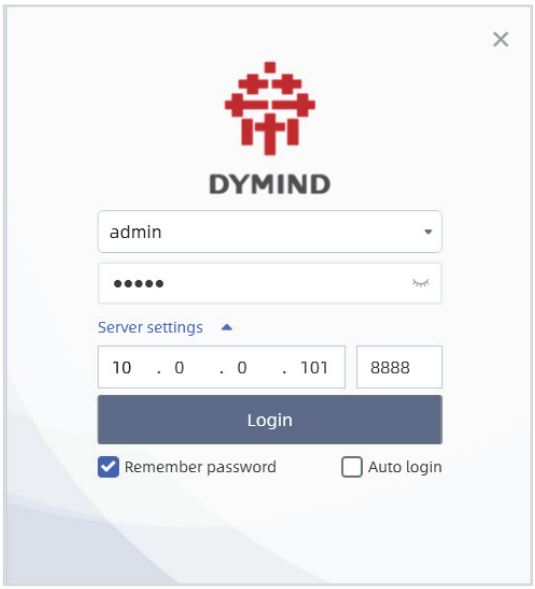
Figure 2-10 DMS Server Interface

3. Click the drop-down list to select the IP address according to actual needs.
4. Re-input the port number in the port number edit box. The input range is an integer between 1 and 65535.
5. Click **Start service**.

After setting the DMS server IP information, you need to input the IP address and port number of the DMS server on DMS software login interface according to the following steps (that is, DMS software obtains data from the DMS server and displays the data).

1. Double click the DMS software icon "" to start DMS software and enter DMS software login interface.
2. Click the icon "" on the right side of the server settings on DMS software login interface, and input the DMS server IP address and port number in the pop-up server settings window as shown in Figure 2-11.

Figure 2-11 DMS Server Settings

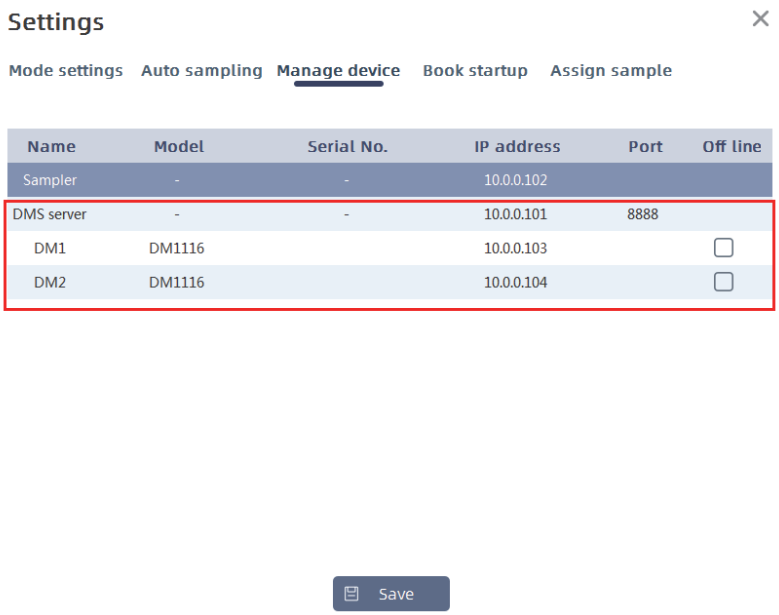


Setting CMS Software Device Management Information

After setting the main unit IP information and the DMS server IP information, set the relevant information on the Manage device interface of the CMS software as follows to complete the connection of main unit, sampler unit, DMS with CMS.

1. Click > **Settings** > **Manage device** to enter the interface. See Figure 2-12.

Figure 2-12 Device Management Settings



2. Input the main unit IP address set above into the **IP address** cell.
3. Input the main unit IP address set above into the IP address cell.
4. Click **Save**.
5. Click **Yes** on the pop-up dialog box. Then restart CMS software.

2.3.4 Connection of LIS and DMS Software

If DMS software needs to communicate with laboratory information system (LIS), you can complete the connection between LIS and DMS software by the steps listed in this section.

2.3.4.1 Installing LIS Workstation

1. Install LIS workstation and set the type and model of the device.
2. Enter the network setting interface of LIS workstation after installation, and set the IP address and port number of LIS.

NOTE

Refer to ***Description of LIS Communication Protocol*** for the device from Dymind customer service engineer to complete the support of the LIS workstation to the LIS communication protocol of the device.

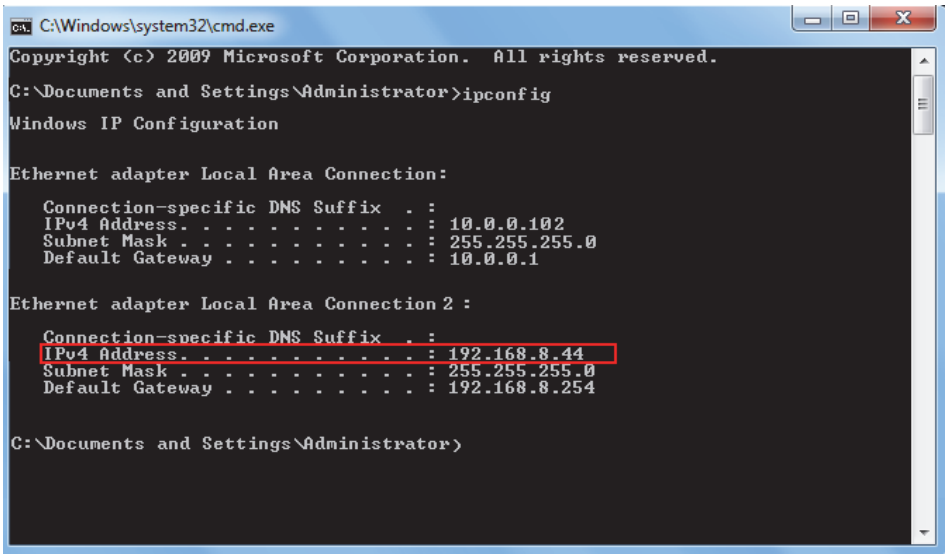
2.3.4.2 Connecting DMS Software with LIS

1. Prepare a network cable and connect the computer where DMS software locates to the LAN where LIS locates through another network card.
2. Log in to DMS software.
3. Click **Settings** > **LIS comm. settings** on DMS software to enter the LIS communication setting interface.
4. Input the IP address and port number of LIS Workstation in the **Network settings** area.

   You can obtain the IP address and port number of LIS on the network setting interface of the LIS workstation. If you cannot obtain the IP address, you can obtain the information through the following steps:

   a. Enter the operating system of the LIS workstation.
   b. Press combination key [WINDOWS+R] to open the **Run** window.
   c. Input **cmd**, and then click **OK**.
   d. Input the **ipconfig** command into the cmd.exe window popping out.

      The interface displays the similar content as follows:



The IPv4 address in the red box is the IP address of the LIS workstation.

NOTE

- The IP address “192.168.8.44” of LIS workstation shown above is used as an example, the actual IP address should be in the same network segment with LIS server.
- Please refer to ***11.3.8 LIS Communication Settings*** for detailed steps.

3 System Overview

This chapter introduces the scope of application, measurement parameters, the structure, external equipment, reagents, and software operation interface of Auto Hematology Analyzer.

3.1 Scope of Application

The Auto Hematology Analyzer is a quantitative, automated hematology analyzer for in vitro diagnostic use in clinical laboratories. It classifies and enumerates the following parameters for whole blood specimens (collected in K_2EDTA anticoagulant and obtained by venipuncture or fingerstick) and body fluid samples: WBC, RBC, HGB, MCV, MCH, MCHC, RDW-CV, RDW-SD, HCT, PLT, MPV, PDW, PCT, IPF, P-LCR, P-LCC, Neu%, Lym%, Mon%, Eos%, Bas%, Neu#, Lym#, Mon#, Eos#, Bas#, IG#, IG%, RET, RET%, LFR, MFR, HFR, IRF, RHE, WBC-BF, RBC-BF, TC-BF#, MN%, MN#, PMN%, PMN#, Eos-BF#, Eos-BF%, Neu-BF#, Neu-BF%, LY-BF#, LY-BF%, MO-BF#, MO-BF%, HF-BF#, HF-BF%, RBC-BF(R). The purpose of the Auto Hematology Analyzer is to identify the normal human patient, with normal system-generated parameters, from patients whose results require additional studies. The device is used for aided diagnosis of adult and pediatric populations, and mainly used as a non-specific inflammatory marker.

NOTE

- The analyzer should be used in a medical laboratory environment with normal management level and should not be used as a portable device.
- The analyzer must be operated by trained medical testing professionals, doctors, nurses, or laboratory technicians.
- The analyzer is a clinical examination equipment for screening. When doctors make the clinical judgment based on the results of the analysis, they should also consider the results of clinical examinations or other test results.
- The analyzer can be used for laboratory research.
- The tests of pre-dilution sample and body fluid sample are for DH-610 and DH-612 only.

3.2 Analysis Modes and Measurement Parameters

This section introduces the measurement modes and parameters of Auto Hematology Analyzer.

3.2.1 Analysis Mode Supported by Samples

The analyzer supports 8 analysis modes: CBC, RET, CBC+DIFF, CBC+RET, CBC+DIFF+RET, CBC+DIFF (LW), CBC+RET (LP) and CBC+DIFF+RET (LW+LP). Different analysis modes support different samples. See Table 3-1.

Table 3-1 Analysis Mode Supported by Samples

Analysis Mode	Venous whole blood	Capillary whole blood	Pre-dilution	Body fluid
CBC	√	√	√	×
RET	√	√	×	×
CBC+DIFF	√	√	√	√
CBC+RET	√	√	√	×
CBC+DIFF+RET	√	√	√	×
CBC+DIFF (LW)	√	√	×	×
CBC+RET (LP)	√	√	×	×
CBC+DIFF+RET (LW+LP)	√	√	×	×

NOTE

"√" means the sample is supported the mode, "×" means the sample is not supported.

3.2.2 Analysis Modes

The analyzer supports 8 analysis modes: CBC, RET, CBC+DIFF, CBC+RET, CBC+DIFF+RET, CBC+DIFF (LW), CBC+RET (LP) and CBC+DIFF+RET (LW+LP).

The analyzer outputs different results in different modes. See Table 3-2.

Table 3-2 Parameters of Analysis Modes

Analysis Mode	Mode Description	Parameter Result
CBC	Blood cells count	The analyzer provides the quantitative analysis results of 22 parameters (16 report parameters and 6 research parameters) and 3 histograms.

Analysis Mode	Mode Description	Parameter Result
RET	Reticulocyte count	The analyzer provides the quantitative analysis results of 16 parameters (7 report parameters and 9 research parameters), 1 RET 3D scattergram, 3 RET 2D scattergrams, 1 PLT-O scattergram, and 1 RET-EXT scattergram.
CBC+DIFF	Blood cells count+WBC 5-part classification	Blood: The analyzer provides the quantitative analysis results of 48 parameters (28 report parameters and 20 research parameters), 3 histograms, 1 DIFF 3D scattergram and 3 DIFF 2D scattergrams.
		Body fluid: The analyzer provides the quantitative analysis results of 18 parameters (7 report parameters and 11 research parameters), 1 RBC distribution histograms, 1 DIFF 3D scattergram and 3 DIFF 2D scattergrams.
CBC+RET	Blood cells count+Reticulocyte count	The analyzer provides the quantitative analysis results of 38 parameters (23 report parameters and 15 research parameters), 3 histograms, 1 RET 3D scattergram, 3 RET 2D scattergrams, 1 PLT-O scattergram, and 1 RET-EXT scattergram.
CBC+DIFF+RET	Blood count+WBC 5-part classification+Reticulocyte count	The analyzer provides the quantitative analysis results of 64 parameters (35 report parameters and 29 research parameters), 3 histograms, 1 DIFF 3D scattergram, 3 DIFF 2D scattergrams, 1 RET 3D scattergram, 3 RET 2D scattergrams, 1 PLT-O scattergram, and 1 RET-EXT scattergram.

Analysis Mode	Mode Description	Parameter Result
CBC+DIFF (LW)	Blood cells count+WBC 5-part classification (Low WBC)	The analyzer provides the quantitative analysis results of 48 parameters (28 report parameters and 20 research parameters), 3 historgrams, 1 DIFF 3D scattergram and 3 DIFF 2D scattergrams.
CBC+RET (LP)	Blood cells count+Reticulocyte count (Low PLT)	The analyzer provides the quantitative analysis results of 38 parameters (23 report parameters and 15 research parameters), 3 histograms, 1 RET 3D scattergram, 3 RET 2D scattergrams, 1 PLT-O scattergram, and 1 RET- EXT scattergram.
CBC+DIFF+RET (LW+LP)	Blood count+WBC 5-part classification+Reticulocyte count (Low WBC+Low PLT)	The analyzer provides the quantitative analysis results of 64 parameters (35 report parameters and 29 research parameters), 3 histograms, 1 DIFF 3D scattergram, 3 DIFF 2D scattergrams, 1 RET 3D scattergram, 3 RET 2D scattergrams, 1 PLT-O scatter-gram, and 1 RET- EXT scatter-gram.

3.2.3 Measurement Parameters

Measurement parameters of Auto Hematology Analyzer include blood report parameters (Table 3-3), blood research parameters (Table 3-4), body fluid report parameters (Table 3-5) and body fluid research parameters (Table 3-6).

Table 3-3 Blood Report Parameters

Type	Parameter Name	Abbreviation	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
WBC (13 parameters)	White Blood Cell count	WBC	√	×	√	√	√
	Neutrophils percentage	Neu%	×	×	√	×	√
	Lymphocytes percentage	Lym%	×	×	√	×	√

Type	Parameter Name	Abbreviation	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
	Monocytes percentage	Mon%	×	×	√	×	√
	Eosinophils percentage	Eos%	×	×	√	×	√
	Basophils percentage	Bas%	×	×	√	×	√
	Neutrophils number	Neu#	×	×	√	×	√
	Lymphocytes number	Lym#	×	×	√	×	√
	Monocytes number	Mon#	×	×	√	×	√
	Eosinophils percentage	Eos#	×	×	√	×	√
	Basophils number	Bas#	×	×	√	×	√
	Immature Granulocyte number	IG#	×	×	√	×	√
	Immature Granulocyte number	IG%	×	×	√	×	√
RBC (8 parameters)	Red Blood Cell count	RBC	√	×	√	√	√
	Hemoglobin Concentration	HGB	√	×	√	√	√
	Mean Corpuscular Volume	MCV	√	×	√	√	√
	Mean Corpuscular Hemoglobin	MCH	√	×	√	√	√
	Mean Corpuscular Hemoglobin Concentration	MCHC	√	×	√	√	√

Type	Parameter Name	Abbreviation	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
	Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV	√	×	√	√	√
	Red Blood Cell Distribution Width Standard Deviation	RDW-SD	√	×	√	√	√
	Hematocrit	HCT	√	×	√	√	√
PLT (7 parameters)	Platelet count	PLT	√	×	√	√	√
	Mean Platelet Volume	MPV	√	×	√	√	√
	Platelet Distribution width	PDW	√	×	√	√	√
	Plateletcrit	PCT	√	×	√	√	√
	Immature Platelet fraction	IPF	√	×	√	√	√
	Platelet-large cell ratio	P-LCR	√	×	√	√	√
	Platelet-large cell count	P-LCC	√	×	√	√	√
Reticulocyte (7 parameters)	Reticulocyte number	RET	×	√	×	√	√
	Reticulocyte percentage	RET%	×	√	×	√	√
	Low fluorescent ratio	LFR	×	√	×	√	√
	Middle fluorescent ratio	MFR	×	√	×	√	√
	High fluorescent ratio	HFR	×	√	×	√	√

Type	Parameter Name	Abbreviation	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
	Immature reticulocyte fraction	IRF	×	√	×	√	√
	Reticulocyte Hemoglobin Expression	RHE	×	√	×	√	√
Histogram	White Blood Cell/Basophils Histogram	WBC/BASO Histogram	√	×	√	√	√
	Red Blood Cell Histogram	RBC Histogram	√	×	√	√	√
	Platelet Histogram	PLT Histogram	√	×	√	√	√
Scattergram	3D Differential Scattergram	3D DIFF Scattergram	×	×	√	×	√
	2D Differential Scattergram	3D DIFF Scattergram	×	×	√	×	√
	3D Reticulocyte Scattergram	3D RET Scattergram	×	√	×	√	√
	2D Reticulocyte Scattergram	2D RET Scattergram	×	√	×	√	√
	PLT-O Scattergram	PLT-O Scattergram	×	√	×	√	√
	RET-EXT Scattergram	RET-EXT Scattergram	×	√	×	√	√

NOTE

- "√" means the parameter is provided in the mode, "×" means the parameter is not provided.
- Research parameters are for research use only (RUO), and cannot be deemed as basis for clinical diagnosis.

Table 3-4 Blood Research Parameters

Type	Parameter Name	Abbreviation	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
WBC (10 parameters)	White blood cell count-DIFF	WBC-D	×	×	√	×	√
	Total nucleated cell counts-DIFF	TNC-D	×	×	√	×	√
	Immature eosinophil percentage	IME%	×	×	√	×	√
	Immature eosinophil number	IME#	×	×	√	×	√
	Neutrophil-to-lymphocyte ratio	NLR	×	×	√	×	√
	Lymphocyte-to-monocyte ratio	LMR	×	×	√	×	√
	Platelet-to-lymphocyte ratio	PLR	×	×	√	×	√
	Derived neutrophil-to-lymphocyte ratio	d-NLR	×	×	√	×	√
	High fluorescent Cell number	HFC#	×	×	√	×	√
	High fluorescent Cell percentage	HFC%	×	×	√	×	√
RBC (8 parameters)	Nucleated red blood cell number	NRBC#	×	×	√	×	√
	Nucleated red blood cell percentage	NRBC%	×	×	√	×	√
	Microcyte percentage	Micro%	√	×	√	√	√

Type	Parameter Name	Abbreviation	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
	Microcyte count	Micro#	√	×	√	√	√
	Macrocyte percentage	Macro%	√	×	√	√	√
	Macrocyte count	Macro#	√	×	√	√	√
	High forward scatter NRBC ratio	H-NR%	×	×	√	×	√
	Low forward scatter NRBC ratio	L-NR%	×	×	√	×	√
PLT (2 parameters)	Platelet Distribution Width Coefficient of Variation	PDW-CV	√	×	√	√	√
	Platelet count-Impedance	PLT-I	√	×	√	√	√
Reticulocyte (9 parameters)	Optical Red Blood Cell count	RBC-O	×	√	×	√	√
	Optical Platelet count	PLT-O	×	√	×	√	√
	Optical white blood cell count	WBC-O	×	√	×	√	√
	Mean Reticulocyte Volume	MRV	×	√	×	√	√
	Reticulocyte Production Index	RPI	×	√	×	√	√
	Immature Platelet Count	IPF#	×	√	×	√	√
	High Fluorescent Immature Platelet fraction	H-IPF	×	√	×	√	√

Type	Parameter Name	Abbreviation	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
	RBC Fragment count	FRC#	×	√	×	√	√
	RBC Fragment percentage	FRC%	×	√	×	√	√

Table 3-5 Body Fluid Report Parameters

Type	Parameter Name	Abbreviation	CBC	RET	CBC+ DIFF	CBC+ RET	CBC+ DIFF+ RET
WBC (6 parameters)	White Blood Cell count – Body fluid	WBC-BF	×	×	√	×	×
	Total Nucleated Cell count – Body fluid	TC-BF#	×	×	√	×	×
	Mononuclear Cell count	MN#	×	×	√	×	×
	Mononuclear Cell percentage	MN%	×	×	√	×	×
	Polymorphonuclear Cell count	PMN#	×	×	√	×	×
	Polymorphonuclear Cell percentage	PMN%	×	×	√	×	×
RBC (1 parameter)	Red Blood Cell count – Body fluid	RBC-BF	×	×	√	×	×

Table 3-6 Body Fluid Research Parameters

Type	Parameter Name	Abbreviation	CBC	RET	CBC+ DIFF	CBC+ RET	CBC+ DIFF+ RET
WBC (10	White Blood Cell count – Body fluid	Eos-BF#	×	×	√	×	×
	Eosinophils percentage- body fluid	Eos-BF%	×	×	√	×	×

Type	Parameter Name	Abbreviation	CBC	RET	CBC+ DIFF	CBC+ RET	CBC+ DIFF+ RET
pa-rame-ters)	Neutrophils num-ber- body fluid	Neu-BF#	×	×	√	×	×
	Neutrophils per-centage- body fluid	Neu-BF%	×	×	√	×	×
	Lymphocytes num-ber- body fluid	LY-BF#	×	×	√	×	×
	Lymphocytes per-centage- body fluid	LY-BF%	×	×	√	×	×
	Monocytes num-ber- body fluid	MO-BF#	×	×	√	×	×
	Monocytes per-centage- body fluid	MO-BF%	×	×	√	×	×
	High fluorescent cell number- body fluid	HF-BF#	×	×	√	×	×
	High fluorescent cell percentage-body fluid	HF-BF%	×	×	√	×	×
RBC (1 pa-rame-ter)	Red blood cell count-body fluid	RBC-BF(R)	×	×	√	×	×

NOTE

- "√" means the parameter is provided in the mode, "×" means the parameter is not provided.
- Research parameters are for research use only (RUO), and cannot be deemed as basis for clinical diagnosis.

3.3 System Structure

The system structure consists of the main unit (includes HOST software), pneumatic unit, and PC software (CMS software and DMS software).

3.3.1 Main Unit of the Analyzer

The main unit includes the internal parts and external structure.

3.3.1.1 Internal Parts

The main unit of the analyzer consists of aspiration module, dilution module, cleaning module, analyzing and measuring module, microprocessor, and HOST software.

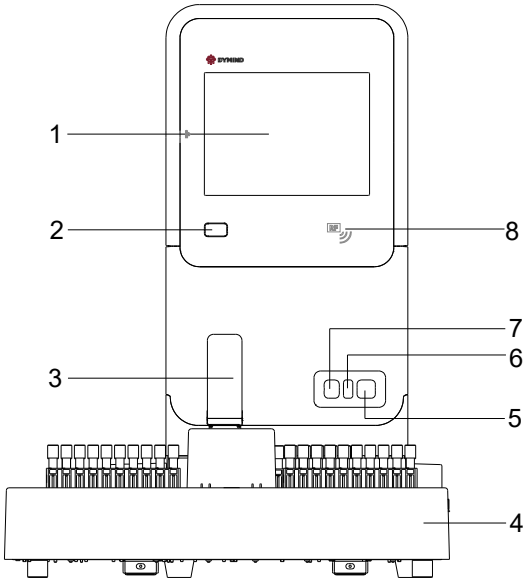
HOST software is used to control the test process of the sample in the analyzer, receive test order from CMS software, and return the test results back to CMS software.

3.3.1.2 External Structure

This section introduces the external structure of the main unit from four parts: front view, left view, right view, and back view.

Front View

Figure 3-1 Front View of the Main Unit (Including the Autosampler)



No.	Name	Description
1	Touch screen	To perform HOST software interface operation and display information. The size of the touchscreen is 12.1 inch.
2	[ON] key	To start the main unit and run HOST software when the main unit powered on. **Note:** Only when the power switch of the main unit is set to [I], the [ON] key can take effect.
3	Manual (emergency) sampling door	Sampling door for manually (EMER) loading the sample.

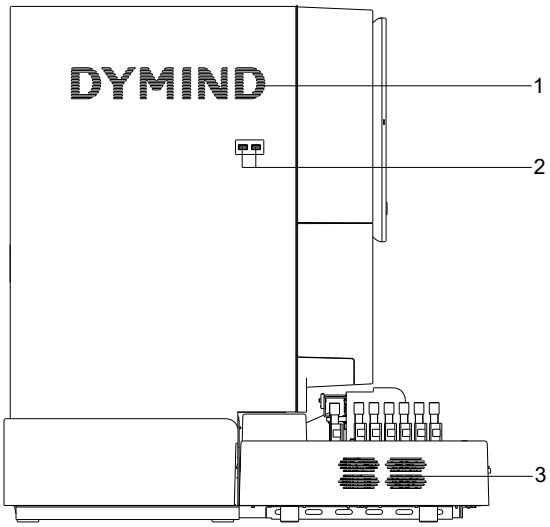
No.	Name	Description
4	Autosampler	To deliver the sample.
5	[RUN] key	To start the sample analysis of manual sampling.
6	Status indicator	To indicate the current status of the main unit. ● Off: the main unit is turned off. ● Green light stays lit: the main unit is ready for performing operations. ● Green light flashes: the main unit is running normally. ● Yellow light stays lit: the main unit is in the initialization status or in sleep mode. ● Yellow light flashes: the main unit is entering or exiting from sleep mode. ● Red light stays lit: the main unit has errors but is not running. ● Red light flashes: the main unit has errors and is running.
7	[MODE] key	To select the sampling method: auto sampling and manual sampling.
8	Card-reading position	The card-reading position for reagent card, which is for verifying the reagent information before replacing the reagent.

NOTE

During the running of the main unit, if the indicator becomes dim or goes off, please contact Dymind or the agent for maintenance.

Left View

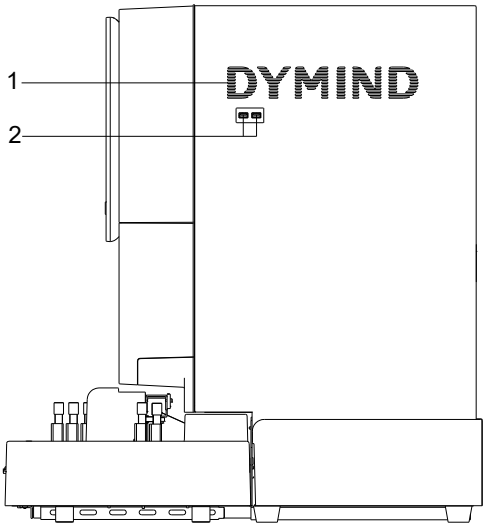
Figure 3-2 Left View of the Main Unit (Including the Autosampler)



No.	Name	Description
1	Left air inlet	The air inlet of the heat dissipation channel of the main unit.
2	USB interface	To connect with external devices.
3	Air outlet of the autosampler	To dissipate the heat of the autosampler.

Right View

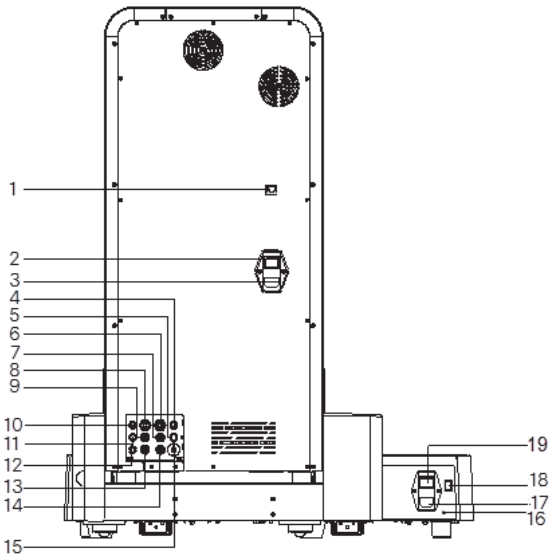
Figure 3-3 Right View of the Main Unit (Including the Autosampler)



No.	Name	Description
1	Right air inlet	The air inlet of the heat dissipation channel of the main unit.
2	USB interface	To connect with external devices.

Back View

Figure 3-4 Back View of the Main Unit (Including the Autosampler)



No.	Name	Description
1	LAN port of the main unit	To connect the main unit with the interchanger.
2	Analyzer power switch	To turn on/off the power supply of the main unit.
3	Power input socket of the main unit	AC power input port. Use the power cord enclosed with the device to power the main unit.
4	DIL-N diluent sensor connector	To connect with DIL-N diluent sensor.
5	Waste sensor connector of the main unit	To connect with the waste sensor.
6	Negative pressure connector of external air supply	To connect with negative pressure of the pneumatic unit.
7	DIN-R diluent connector	To connect with DIN-R diluent container.
8	Positive pressure connector of external air supply	To connect with positive pressure of the pneumatic unit.

No.	Name	Description
9	LYN-G lyse connector	To connect with LYN-G lyse container.
10	Control connector of external air supply	To connect with the control wire of external air supply.
11	Sample delivery connector	To connect with the control wire of assembly line.
12	Ground stud of the main unit	To connect with the ground wire.
13	LYN-D lyse connector	To connect with LYN-D lyse container.
14	DIL-N lyse connector	To connect with DIL-N diluent bucket.
15	Waste container connector of the main unit	To connect with the waste container.
16	Control connector of external air supply	To connect with the control wire of external air supply.
17	Power input socket of the autosampler	AC power input port. Use the power cord enclosed with the device to power the autosampler.
18	LAN port of the autosampler	To connect the autosampler with the interchanger.
19	Power switch of the autosampler	To turn on/off the power supply of the autosampler.

3.3.2 (Optional Accessory) Sampler Unit

The sampler unit (autosampler) is an optional accessory, which is used to deliver samples, and deliver the tube rack with belt. Two types of samplers can be configured currently: single sampler and dual sampler. This manual introduces the single sampler. The single sampler can load 60 samples at a time.

3.3.3 Pneumatic Unit

Warning

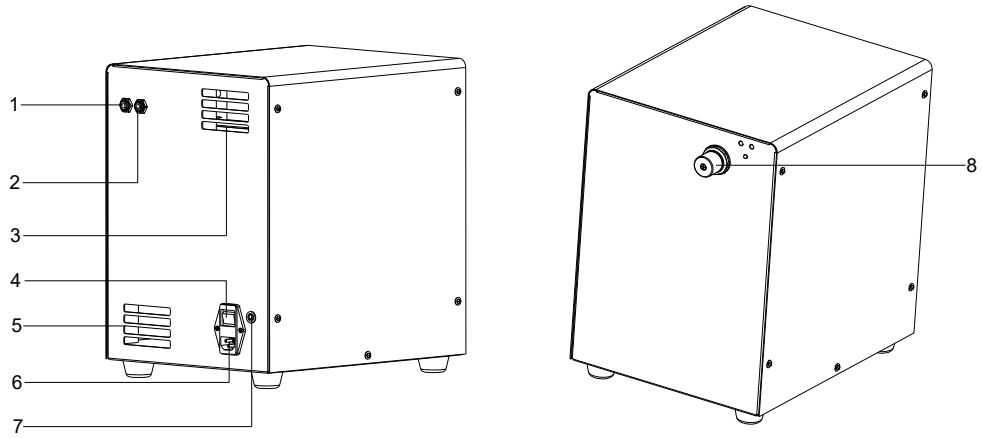
Do not rotate the knob without authorization; otherwise it may damage the analyzer or cause personal hazards.

The pneumatic unit (external air supply) provides greater power supply for the analyzer.

The pneumatic unit outputs a positive pressure (230 Kpa) and a negative pressure (-85% of local atmospheric pressure).

The external structure of the pneumatic unit is as shown in Figure 3-5.

Figure 3-5 External Structure of the Pneumatic Unit



No.	Name	Description
1	Negative pressure output side of the pneumatic unit	Connect with the negative pressure connector of external air supply.
2	Positive pressure output side of the pneumatic unit	Connect with the positive pressure connector of external air supply.
3	Air inlet of the pneumatic unit	The air inlet of the heat dissipation channel of the pneumatic unit.
4	Power switch of the pneumatic unit	To turn on/off the power supply of the pneumatic unit.
5	Air outlet of the pneumatic unit	For the heat dissipation of the pneumatic unit
6	Power input socket of the pneumatic unit	AC power input port. Use the power cord enclosed with the device to power on the pneumatic unit.
7	Control connector of the pneumatic unit	Connect with the external air supply control connector of the autosampler through the control line
8	Pressure regulation valve of the pneumatic unit	To regulate the pressure. **Note** If you need to rotate the knob of the value, please contact Dymind or your local agent.

3.3.4 PC Software

The main unit needs to be used together with 2 PC software, namely CMS software and DMS software.

CMS Software (PC)

CMS software is used to control the autosampler to delivery samples, and act as a bridge between DMS software and HOST software to transmit test commands and results.

CMS software can connect up to 2 main units of the same network segment, 1 autosampler, and 1 DMS server to form a workstation.

DMS Software (PC)

DMS software is used to input test orders before sample test, analyze the results after sample test, and validate and issue the test report.

3.4 External Equipment

The external computer can connect with the following equipment:

- Keyboard

  The keyboard is connected to the USB interface of the external computer to control the external computer.

- Mouse

  The mouse is connected to the USB interface of the external computer to operate the external computer.

- Printer

  The printer is connected to the USB interface of the external computer to print reports and other screen display information.

- Barcode Scanner

  The barcode scanner is connected to the USB interface of the external computer for easy and quick input of barcode information.

- USB Flash Disk

  The USB flash disk is connected to the USB interface of the external computer to export sample records.

The main unit can be connected with the following equipment:

- Printer

  The printer can be connected to the USB interface of the main unit.

- Barcode scanner

  The barcode scanner can be connected to the USB interface of the main unit.

- Interchanger

  The interchanger can be connected to the main unit by the network cable.

3.5 Reagents, Controls and Calibrators

Warning

If the tubing breaks, a small amount of liquid may spill out. If that happens, please contact Dymind or the local agent.

NOTE

- The analyzer, reagents, controls, and calibrators should be used together to ensure reliable results. Otherwise, the analyzer may be damaged, fail to perform normally as described in the manual.
- All reagents mentioned in this manual refer to the reagents specifically formulated for the analyzer by Dymind. Make sure that you are using the reagent specified by Dymind, and use and store the reagent according to the instructions.
- For information about the specific uses and specifications of the reagent, please refer to the instructions of the reagent.

The analyzer uses DIL-N diluent, DIN-R diluent, LYN-G lyse, LYN-D lyse, FDN-D dye, DFN-R dye, controls, calibrators, and cleansers specified by Dymind for sample analysis and daily operations.

Table 3-7 Reagents, Controls and Calibrators

Reagent name	Usage
DIL-N diluent	It is used for sample dilution and preparation of cell suspension before sample analysis.
DIN-R diluent	It is used for sample dilution and preparation of cell suspension before sample analysis.
LYN-G lyse	It is used to destroy red blood cells, lyse out hemoglobin, and maintain the shape of the cells to be tested before blood cell analysis, thereby facilitating cell differential count or quantitative determination of hemoglobin.
LYN-D lyse	It is used to destroy red blood cells, lyse out hemoglobin, and maintain the shape of the cells to be tested before blood cell analysis, thereby facilitating cell differential count or quantitative determination of hemoglobin.

Reagent name	Usage
FDN-D dye	It is used to stain blood cells to observe their morphology and structure, so that the hematology analyzer can perform blood cell differential count.
FDN-R dye	It is used to stain blood cells to observe their morphology and structure, so that the hematology analyzer can perform blood cell differential count.
Cleanser	It is used to clean the device regularly.
DM-6D control	It is used for the quality control of WBC, RBC, HGB, MCV, PLT, 5DIFF, and IG.
DM-RET control	It is used for the quality control of RET.
DM-CAL-5E calibrator	It is used for the calibration of WBC, RBC, HGB, MCV, and PLT.

3.6 Introduction to the Software Operation Interface

This section introduces the operation interface of the main unit software (HOST software) and PC software (CMS and DMS software).

3.6.1 HOST Software Operation Interface (Analyzer Side)

Log in to HOST software, and it enters the count interface by default. See Figure 3-6.

Figure 3-6 HOST Software Operation Interface

The related descriptions of HOST software operation interface are as shown in Table 3-8.

Table 3-8 Descriptions of Host Software Operation Interface

No.	Name	Description
1	Menu navigation area	The upper left area of the interface is the menu navigation area. Click a menu to enter the corresponding interface. In addition to the count, review, QC and reagent menus, you can also click the "" button in the upper left corner to view other menus of HOST software, including calibration, settings, log, maintenance, etc.
2	Menu content display area	According to the menu selected in the menu navigation area, the content of the currently selected menu is displayed.

No.	Name	Description
3	Prompt information area	The upper right area of the interface is the prompt information area, including the current login user and system time, error information area and CMS connection status icon. ● The current login user and system time area It displays the user name currently logged in to HOST software and current system time. ● Error information area It displays the corresponding error information when the analyzer has any error. When there is more than one error, it displays the latest error information. Click this area to deal with the error in the popup troubleshooting dialog box. For more information, see ***16 Troubleshooting***. ● CMS connection status icon It displays the connection status of the main unit with CMS software. Please refer to ***2.3.3 Connection of Main Unit, Sampler Unit, and DMS with CMS*** for the method of connecting the main unit and CMS software. ➢ Dimmed: the main unit is not connected with CMS software or CMS software is not logged in. ➢ Lighted: the main unit is connected with CMS software successfully.

3.6.2 CMS Software Operation Interface (PC Side)

The operation interface of CMS software is as shown in Figure 3-7.

Figure 3-7 CMS Software Operation Interface

The related descriptions of CMS software operation interface are as shown in Table 3-9.

Table 3-9 Descriptions of CMS Software Operation Interface

No.	Name	Description
1	Main unit information area	There are two main unit information areas on CMS software. Each area displays the relevant information of the main unit successfully connected with CMS software, including the main unit connection status icon, device name, sample No., retest icon, test mode, error information, sample location and reagent status icon. See Figure 3-8.
2	Sampler unit connection status icon	It displays the connection status of the sampler unit with CMS software. Please refer to ***11.2.3 Device Management Settings*** for the method of connecting the sampler unit and CMS software. ● Dimmed: the sampler unit is not connected with CMS software or the sampler unit is not started. ● Green light stays lit: the sampler unit is successfully connected with CMS software, and is ready for performing operations. ● Green light flashes: the sampler unit is running normally and is performing an operation. ● Red light stays lit: the sampler unit has errors but is not running. ● Red light flashes: the sampler unit has errors and is running.
3	Error information area of the sampler unit	It displays the current error information of the sampler unit. When there are several errors, they will be displayed in rotation. The interval is 2 seconds, and the error with the highest level will be displayed first.
4	Menu button	Click the menu button ( ) of CMS software to view the related menus of CMS software, including exit, version, log and sample tracking, etc.
5	Minimize button	Click the minimize button to minimize CMS software interface.

No.	Name	Description
6	DMS connection status icon	It displays the connection status of DMS software with CMS software. Please refer to ***2.3.3 Connection of Main Unit, Sampler Unit, and DMS with CMS*** for the method of connecting DMS software and CMS software. • Dimmed: DMS software is not connected with CMS software or DMS software is not logged in. • Lighted: DMS software is connected with CMS software successfully.
7	Settings button	Click the settings button to enter the setting interface for related settings, including mode settings and auto sampling settings, etc.
8	Start/Suspend button	To start/suspend the sample analysis of auto sampling. After starting the sample analysis of auto sampling, the **Start** button changes to the **Suspend** button. If clicking the **Suspend** button, the **Suspend** button changes back to the **Start** button.
9	Stop button	To stop the sample analysis of auto sampling.

The following is a detailed introduction to the main unit information area on CMS software. The operation interface is as shown in Figure 3-8 and the corresponding description is as shown in Table 3-10.

Figure 3-8 Main Unit Information Area

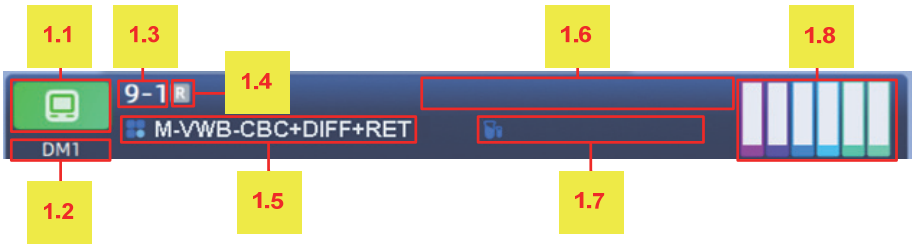


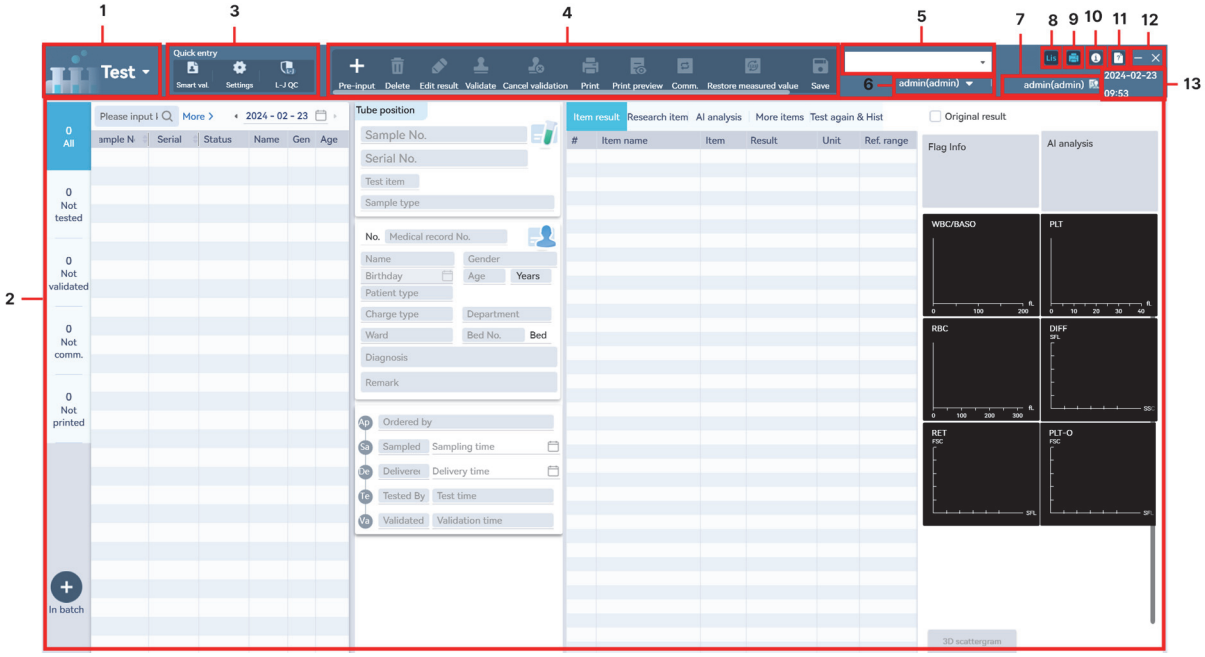
Table 3-10 Descriptions of Main Unit Information Area

No.	Name	Description
1.1	Main unit connection status icon	It displays the connection status of the main unit with CMS software. Please refer to ***2.3.3 Connection of Main Unit, Sampler Unit, and DMS with CMS*** for the method of connecting the main unit and CMS software. ● Dimmed: the main unit is not connected with CMS software or the main unit is not started. ● Green light stays lit: the main unit is successfully connected with CMS software, and is ready for performing operations. ● Green light flashes: the main unit is running normally and is performing an operation. ● Yellow light stays lit: the main unit is in sleep mode. ● Yellow light flashes: the main unit is entering or exiting from sleep mode. ● Red light stays lit: the main unit has errors but is not running. ● Red light flashes: the main unit has errors and is running.
1.2	Device name area	It displays the name of the main unit. The name of the device is consistent with the setting in ***11.2.3 Device Management Settings***.
1.3	Sample No. area	It display the sample No. of the current sample of the main unit.
1.4	Retest icon	The retest icon is visible when the test results of the current sample triggers the retest rule; otherwise, the retest icon is not visible.
1.5	Measurement mode area	It displays the measurement mode of the current sample of the main unit, which is displayed by the combination of “sampling way-sample type-analysis mode".
1.6	Error information area	It displays the current error information of the main unit. When there are several errors, they will be displayed in rotation. The interval is 2 seconds, and the error with the highest level will be displayed first.
1.7	Sample position area	It displays the tube position of the current sample during auto sampling. The sample position will not be displayed during manual sampling.
1.8	Reagent status icon	Click the reagent status icon to view the reagent information of each reagent, including reagent name, batch code, expiry date, and residual amount.

3.6.3 DMS Software Operation Interface (PC Side)

The operation interface of DMS software is as shown in Figure 3-9.

Figure 3-9 DMS Software Operation Interface



The related descriptions of DMS software operation interface are as shown in Table 3-11.

Table 3-11 Descriptions of DMS Software Operation Interface

No.	Name	Description
1	Menu drop-down list	The upper left corner of the interface is the DMS menu drop-down list. Click a menu to enter the corresponding interface.
2	Menu content display area	According to the menu selected in the menu drop-down list, the content of the currently selected menu is displayed.
3	Quick entry area	It displays the name of the menus that the user has recently entered, 3 names at most. Click this area to enter the corresponding menu interface directly.
4	Function button area	According to the menu selected in the menu drop-down list, the function button of the currently selected menu is displayed.

No.	Name	Description
5	Device drop-down list	It displays the name of the device that connected successfully at present. The name of the device is consistent with the setting in ***11.2.3 Device Management Settings***. Select the device name to display the corresponding results. You can select the name of a main unit, or you can select **All**.
6	Information area of current user	It displays the user name (name) that logs in to DMS software currently. You can also click the icon on the right side of the user name to log out or change the password.
7	Validator information area	It displays the information of the validator. You can select the Validator Login section to log into or log out the validator account.
8	LIS system connection status icon	It displays the connection status of DMS software with LIS. Please refer to ***2.3.4 Connection of LIS and DMS Software*** for the method of connecting DMS software and LIS. ● Dimmed: DMS software is not connected with LIS software. ● Lighted: DMS software is connected with LIS software successfully.
9	Printer connection status icon	It displays the connection status of the printer. You can print only when the external computer is properly connected with the printer. ● Dimmed: The external computer is not connected with the printer. ● Lighted: The external computer is connected with the printer successfully.
10	Software version button	Click the button to view the current version of DMS software.
11	Help button	Click the button to view the instructions for use of DMS software.
12	Minimize and close button	● Click the minimize button to minimize DMS software interface. ● Click the close button to close DMS software.
13	Current system time area	It displays current system time. The date format is the same as that set in ***11.3.4 Date Format Settings.***

4 Working Principles

Auto Hematology Analyzer adopts the electrical impedance method (also known as Coulter principle), fluorescent staining method and semiconductor laser-based flow cytometry for blood cells classification and count; adopts colorimetric method for the measurement of hemoglobin concentration.

4.1 Sample Aspiration

The analyzer supports two ways of sampling: auto sampling and manual sampling.

- In the auto sampling mode, place the prepared venous whole blood sample or capillary whole blood sample to the loading platform of the autosampler. The analyzer aspirates quantitative venous whole blood sample or capillary whole blood sample.
- In the manual sampling mode, place the prepared sample on the assigned position of sample delivery component according to the sample types.
  - If the sample is venous whole blood or capillary whole blood, place the tube to the venous whole blood sampling position or capillary whole blood sampling position of the sample delivery component. The analyzer aspirates quantitative venous whole blood sample or capillary whole blood sample.
  - If the sample is pre-dilution, mix the pre-dilution sample in the tube with 20μL of capillary blood (with the dilution ratio of 1:6), place the tube to the capillary whole blood sampling position of the sample delivery component. The analyzer aspirates quantitative pre-dilution sample.
  - If it is body fluid, place the tube to the venous whole blood sampling position of the sample delivery component. The analyzer aspirates quantitative body fluid sample.

NOTE

- Only the manual sampling mode supports the test of pre-dilution sample and body fluid.
- The pre-dilution sample only supports capillary whole blood for test.
- The tests of pre-dilution sample and body fluid sample are for DH-610 and DH-612 only.

4.2 Sample Dilution

To meet different needs, the analyzer supports 8 analysis modes: CBC, RET, CBC+DIFF, CBC+RET, CBC+DIFF+RET, CBC+DIFF (LW), CBC+RET (LP) and CBC+DIFF+RET (LW+LP). Among them:

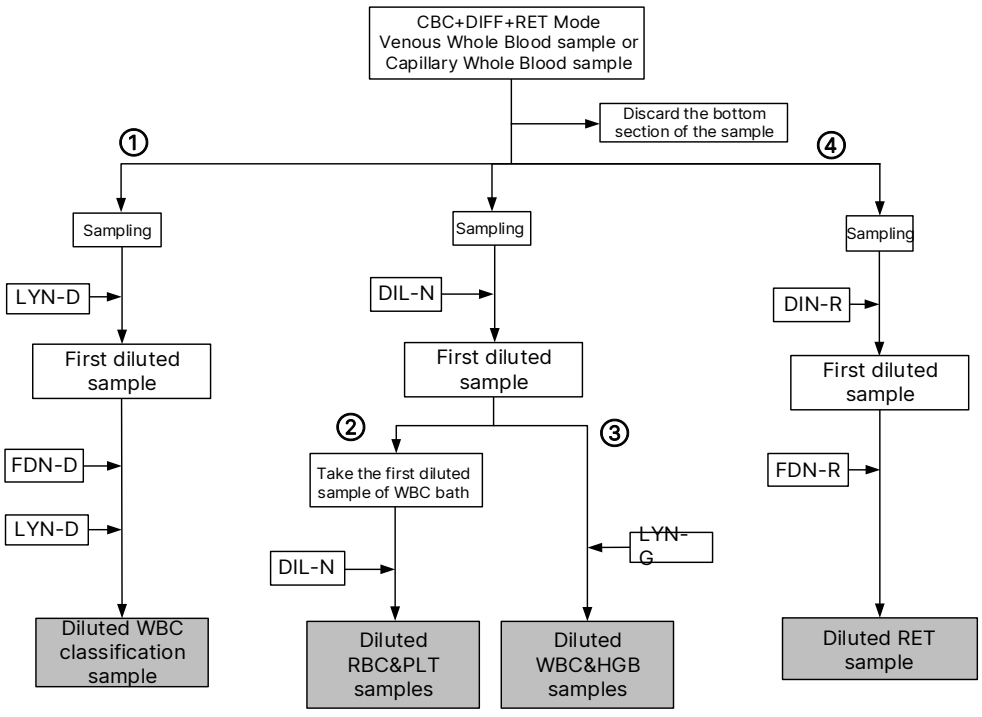
- The dilution processes of venous whole blood and that of capillary whole blood are the same.
- CBC mode means whole blood count, in which case the analyzer only counts and does not classify white blood cells.
- CBC+DIFF mode means that the analyzer counts and classifies white blood cells.
- RET mode means that the analyzer counts the reticulocyte.

Taking CBC+DIFF+RET mode as an example, this section introduces the dilution procedures of the whole blood sample and pre-dilution sample separately. Since the measurement mode of the analyzer consists of CBC, CBC+DIFF, and RET, and the dilution process is processed in parallel, this section will not go through all the details.

4.2.1 Dilution Procedures in Whole Blood CBC+DIFF+RET Mode

In Whole Blood CBC+DIFF+RET mode, the sample will be aspirated into the main unit, and then enters into a parallel dilution process. After reacting with reagents in parallel dilution procedures, the sample will be prepared separately for WBC classification, RBC/PLT measurement, WBC count/HGB measurement, and RET measurement. See Figure 4-1.

Figure 4-1 Dilution Process of CBC+DIFF+RET Mode



① : the sample dilution process of DIFF channel. The diluted sample is for WBC classification.

② : the sample dilution process of RBC/PLT channel. The diluted sample is for RBC and PLT measurement.

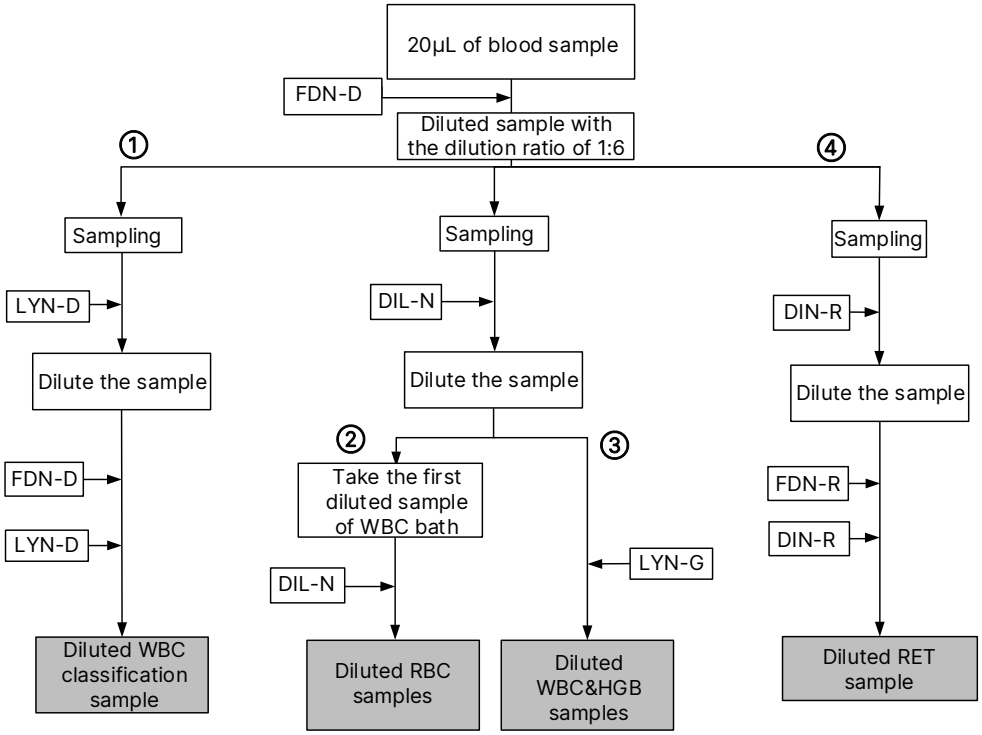
③ : the sample dilution process of WBC/HGB channel. The diluted sample is for WBC and HGB measurement.

④ : the sample dilution process of RET channel. The diluted sample is for RET measurement.

4.2.2 Dilution Procedures in Pre-dilution CBC+DIFF+RET Mode

In pre-dilution CBC+DIFF+RET mode, the sample will be aspirated into the main unit, and then enters into a parallel dilution process. After reacting with reagents in parallel dilution procedures, the sample will be prepared separately for WBC classification, RBC measurement, WBC count/HGB measurement, and RET measurement. See Figure 4-2.

Figure 4-2 Dilution Process of Pre-dilution CBC+DIFF+RET Mode



Among them:

① : the sample dilution process of DIFF channel. The diluted sample is for WBC classification.

② : the sample dilution process of RBC channel. The diluted sample is for RBC measurement.

③ : the sample dilution process of WBC/HGB channel. The diluted sample is for WBC and HGB measurement.

④ : The sample dilution process of RET channel. The diluted sample is for RET measurement.

4.3 Measurement Principles

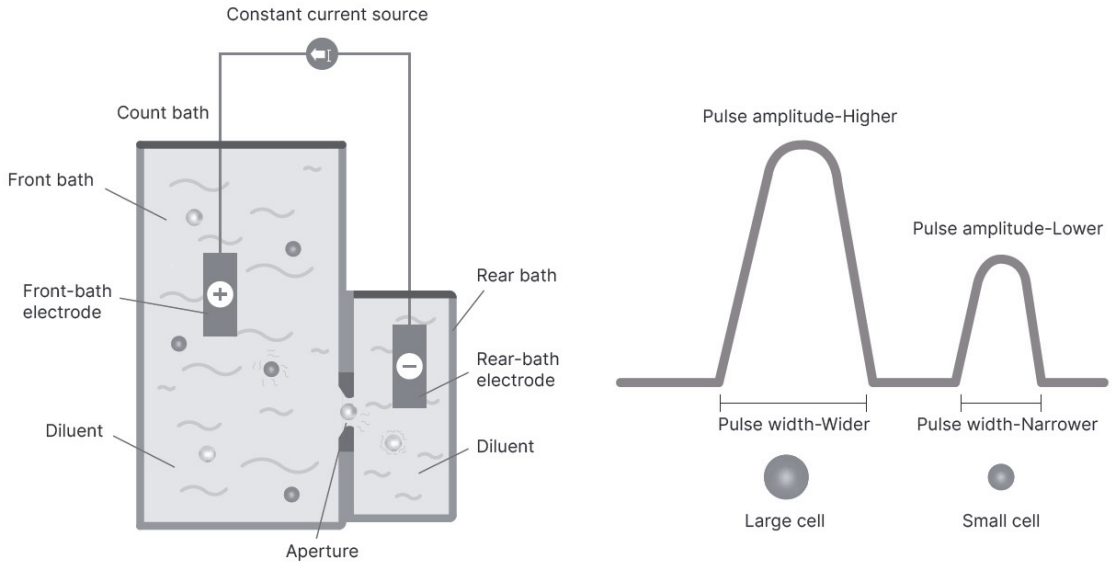
This section introduces the measurement principles.

4.3.1 Electrical Impedance Method

The analyzer adopts the electrical impedance method to count WBC/BAS (or RBC/PLT).

The sample enters WBC test unit after being diluted (or RBC/PLT test unit). This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses thus generated is equal to the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

Figure 4-3 Electrical Impedance Method



Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of certain amplitude. If the pulse generated is above the WBC/RBC/PLT lower threshold value, it is counted as a WBC/RBC/PLT. The cell volume distribution is determined by the cell count within each channel classified by the pulse amplitude, where the x-coordinate represents the cell volume and the y-coordinate represents the number of the cells. The 2D graph drawn with this is a histogram reflecting the distribution of the cell population.

4.3.2 Fluorescent Staining Method

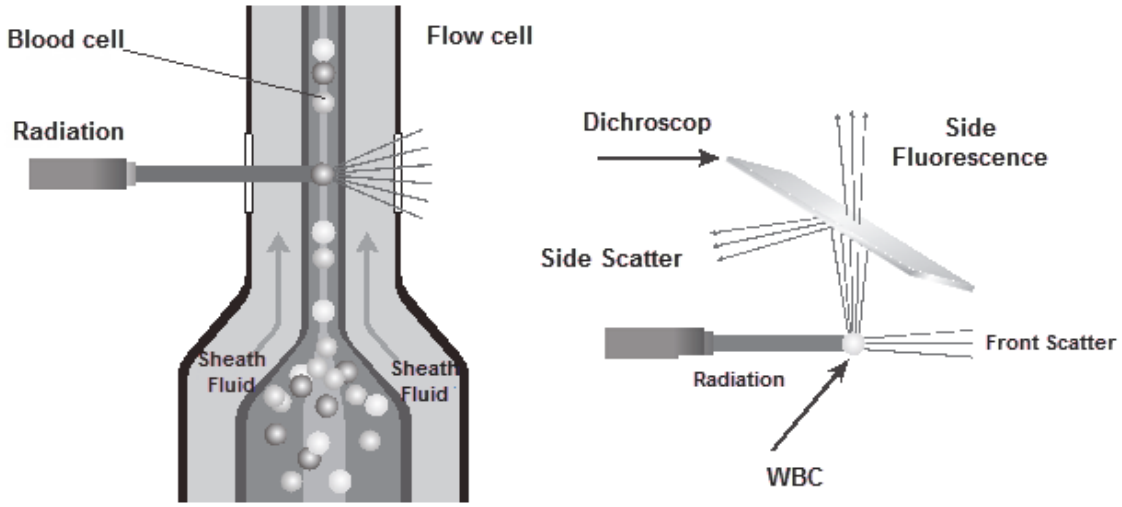
During the dilution process, the analyzer stains and labels the nucleic acids in the cells with the dye. The nucleic acid purity of cells in different species, different stages or abnormal develop-

ment states are different, and therefore the volume of the fluorescent dye volume will be different. When the light shines on fluorescent materials such as blood cells that have been fluorescence-stained, the light that has a longer wavelength than the incident light will be produced. With the increase of stain concentration, the fluorescence intensity also increases. By measuring fluorescence intensity, the information about the staining degree of blood cells can be obtained.

4.3.3 Semiconductor Laser-based Flow Cytometry

A certain amount of blood cells are injected into a conical flow chamber filled with diluent after fluorescent staining. The blood cells pass through the center of the flow chamber in a single column at a faster speed, and they are exposed to a laser beam. In this case, the light is scattered at different angles. See Figure 4-4.

Figure 4-4 Blood Cell Measurement Principle



The optical detector receives front scatter, side fluorescence and side scatter, and converts them into electrical pulses. These electrical pulses can be used to draw a 3D distribution (also known as scattergram) of blood cell size, information inside the cell, and fluorescence intensity.

Among them, front scatter (FSC) reflects the differences of blood cells sizes, side scatter (SSC) reflects the different complexity of particles inside blood cells, and side fluorescence reflects the staining degree of blood cells.

4.3.4 Colorimetric Method

The WBC/HGB diluent is delivered to the HGB bath where it is mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 525 nm. An LED is mounted on one side of the bath and emits a beam of monochromatic light with a central wavelength of 525nm. The light passes through the sample and is then measured by an optical sensor mounted on the opposite side. The signal is then amplified and the voltage is measured and compared with the blank reference reading (readings taken when there is only diluent in the bath).

4.4 Test Items

The measurement principles of different test items are different. Details will be explained below.

4.4.1 WBC Parameters

WBC channel of the analyzer adopts electrical impedance method (Coulter principle) for WBC/BAS count, and then calculates the related WBC parameters. DIFF channel adopts fluorescent staining method and semiconductor laser-based flow cytometry to identify and detect immature granulocytes precisely after WBC 5-part classification.

Based on the analysis of the WBC classification scattergram and the Lym region, Neu region, Mon region and Eos region, the analyzer calculates the Lym%, Neu%, Mon%, Eos% and IG%. After WBC measurement, the analyzer proceeds to calculate Lym#, Neu#, Mon#, Eos# and IG#. What's more, the analyzer calculates Bas% through WBC# and Bas# obtained from WBC test channel. The unit of the number of cells is 10^9/L.

The calculation formula of each parameter is shown below.

- White Blood Cell count

  WBC count is the number of leukocytes measured directly by counting the leukocytes passing through the aperture.

- Basophils count

  Bas count is the number of leukocytes measured directly by counting the leukocytes passing through the aperture.

- Percentage of Basophils (Bas%)

  $$\text{Bas\%} = \frac{\text{Bas\#}}{\text{WBC}} \times 100\%$$

- Percentage of Lymphocytes (Lym%)

  $$\text{Lym\%} = \frac{\text{Cell count in Lym area of DIFF channel}}{\text{All cell count in DIFF channel (excluded blood shadow)}} \times 100\ \%$$

- Percentage of Neutrophils (Neu%)

  $$\text{Neu\%} = \frac{\text{Cell count in Neu area of DIFF channel}}{\text{All cell count in DIFF channel (excluded blood shadow)}} \times 100\ \%$$

- Percentage of Monocytes (Mon%)

  $$\text{Mon\%} = \frac{\text{Cell count in Mon area of DIFF channel}}{\text{All cell count in DIFF channel (excluded blood shadow)}} \times 100\ \%$$

- Percentage of Eosinophils (Eos%)

  $$\text{Eos\%} = \frac{\text{Cell count in Eos area of DIFF channel}}{\text{All cell count in DIFF channel (excluded blood shadow)}} \times 100\ \%$$

- Number of Lymphocytes (Lym#)

$$Lym\# = WBC \times Lym\%$$

- Number of Neutrophils (Neu#)

  $$Neu\# = WBC \times Neu\%$$

- Number of Monocytes (Mon#)

  $$Mon\# = WBC \times Mon\%$$

- Number of Eosinophils (EOS#)

  $$Eos\# = WBC \times Eos\%$$

- Percentage of Immature Granulocyte (IG%)

  $$IG\% = \frac{Cell\ \ count\ \ in\ IG\ area\ \ of\ DIFF\ \ channel}{All\ cell\ \ count\ \ in\ DIFF\ \ channel\ \ (excluded\ \ \ blood\ \ \ shadow)} \times 100\ \%$$

- Number of Immature Granulocyte (IG#)

  $$IG\# = WBC \times IG\%$$

4.4.2 RBC Parameters

RBC/PLT channel adopts the electrical impedance method for RBC measurement.

- Red Blood Cell count

  RBC (10^{12}/L) is the number of erythrocytes measured directly by counting the erythrocytes passing through the aperture.

- Mean Corpuscular Volume

  Based on the RBC histogram, this analyzer calculates the mean corpuscular volume (MCV) and expresses the result in fL.

- Hematocrit (HCT), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC)

  This analyzer calculates the HCT (%), MCH (pg) and MCHC (g/L) according to the following formulas:

  $$HCT = \frac{RBC \times MCV}{10}$$

  $$MCH = \frac{HGB}{RBC}$$

  $$MCHC = \frac{HGB}{HCT} \times 100$$

  RBC is expressed in 10^{12}/L, MCV in fL and HGB in g/L.

- Red Blood Cell Distribution Width Coefficient of Variation (RDW-CV)

  Based on the RBC histogram, the analyzer calculates the CV (Coefficient of Variation, %) of the erythrocyte distribution width.

- Red Blood Cell Distribution Width Standard Deviation (RDW-SD)

RDW-SD (RBC Distribution Width – Standard Deviation, fL) is obtained by calculating the standard deviation of the red blood cell size distribution.

4.4.3 PLT Parameters

RBC/PLT channel adopts the electrical impedance method for PLT measurement.

- Platelet Count

  PLT (10^9/L) is measured directly by counting the platelets passing through the aperture.

- Mean Platelet Volume

  Based on the PLT histogram, this analyzer calculates the MPV (fL).

- Platelet Distribution Width

  PDW (fL) is obtained by PLT distribution hisrtorgram.

- Plateletcrit

  The analyzer calculates the PCT according to the following formula, and expresses it in %.

  $$PCT = \frac{PLT \times MPV}{10000}$$

  PLT is expressed in 10^9/L, and the MPV in fL.

- Immature Platelet Fraction

  The analyzer calculates the immature platelet fraction (IPF) according to the following formula, and expresses it in %.

  $$IPF = \frac{\text{Cell count in IPF area of RET channel}}{\text{All cell count of PLT - O}} \times 100\ \%$$

- Platelet-Large Cell Ratio (P-LCR)

  P-LCR is obtained by PLT distribution histogram. It is the ratio of the number of platelets with volume exceeding 12fL to the total number of platelets. It is expressed in %.

- Platelet-Large Cell Count (P-LCC)

  The analyzer calculates the P-LCC count according to the following formula, and expresses it in 10^9/L.

  $$P\text{-}LCC = PLT \times P\text{-}LCR$$

4.4.4 HGB Concentration Parameter

HGB channel adopts colorimetric method for HGB concentration measurement.

The HGB is calculated by using the following formula and is expressed in g/L.

$$HGB(g/L) = Constant \times Ln\left(\frac{\text{Blank Photocurrent}}{\text{Sample Photocurrent}}\right)$$

4.4.5 RET Parameters

RET channel adopts fluorescent staining method and semiconductor laser-based flow cytometry for RET measurement.

- Percentage of Reticulocyte (%)

$$RET\% = \frac{\text{Cell count in RET area}}{(\text{Cell count in mature RBC area} + \text{Cell count in RET area})} \times 100\%$$

- Number of Reticulocyte (10^{12}/L)

$$RET\# = RBC \times RET\%$$

- High Fluorescent Ratio (%)

$$HFR = \frac{\text{Cell count in HFR area}}{\text{Cell count in RET area}} \times 100\%$$

- Middle Fluorescent Ratio (%)

$$MFR = \frac{\text{Cell count in MFR area}}{\text{Cell count in RET area}} \times 100\%$$

- Low Fluorescent Ratio (%)

$$LFR = 100 - HFR - MFR$$

- Immature Reticulocyte Ratio (%)

$$IRF = HFR + MFR$$

- Reticulocyte Hemoglobin Expression (pg)

  RHE is calculated through the information of RET scatter.

4.4.6 Body Fluid Parameters

- White Blood Cell count – Body fluid

  WBC-BF=All cell count in DIFF channel (excluded ghost and high fluorescent)

- Total Nucleated Cell count – Body fluid

  TC-BF#= All cell count in DIFF channel (excluded ghost)

- Mononuclear Cell percentage (%)

$$MN\% = \frac{\text{Cell count in MN area of DIFF channel}}{\text{WBC - BF}}$$

- Polymorphonuclear Cell count (%)

$$PMN\% = \frac{\text{Cell count in PMN area of DIFF channel}}{\text{WBC - BF}} \times 100\%$$

- Mononuclear Cell count (#)

  $MN\# = WBC\text{-}BF \times MN\%$

- Polymorphonuclear Cell count (#)

  PMN#=WBC-BF$_{\times}$PMN%

- Red Blood Cell count – Body fluid

  The analyzer directly measures the number of pulses corresponding to RBC and obtains the RBC count in body fluids.

4.5 Flushing

The analyzer automatically flushes every participant of the analysis cycle to make sure that there is no residual in fluidics.

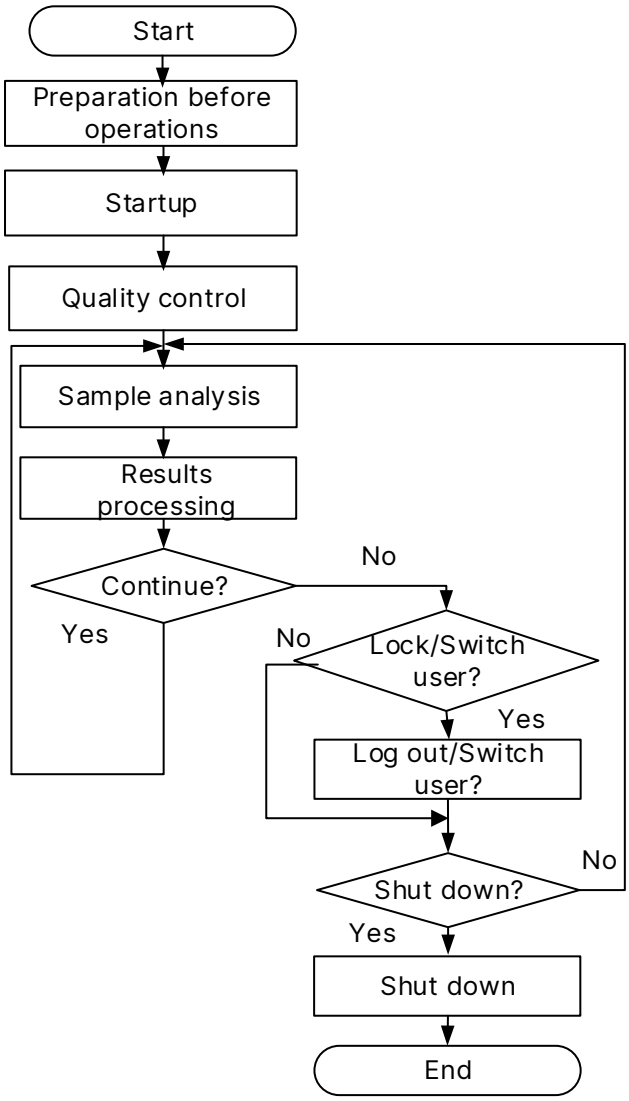
5 Daily Operations

This chapter introduces the daily operation process of the system. You should, on the basis of understanding the overall operation process, refer to the contents of relevant chapters in the manual to carry out each operation.

5.1 Overall Operation Process

See Figure 5-1 for overall operation process.

Figure 5-1 Daily Operation Process



5.2 Preparation before Operation

5.2.1 Equipment Inspection

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

Warning

- Keep your clothes, hair and hands away from the moving parts to avoid being caught or crushed.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
- The reagent probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
- Do not touch the sample directly.

NOTE

- Use only the calibration, quality control product and reagent designated by Dymind, and store and use them in strict accordance with the corresponding instructions.
- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- Be sure to use clean K_2EDTA vacuum blood collection tubes with anticoagulant, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Use only the vacuum blood collection tube, centrifugal tube and other disposable materials specified by the manufacturer.

Check the following items before turning on the main unit of the analyzer to ensure that the system gets ready.

- Waste container

  If using the waste container to collect the waste, you should prepare the waste container, and make sure that it is emptied before starting every day.

- Fluidics tubing and power supply

  ➢ Check and make sure that the reagents and waste tubing are not bent and are properly connected.

  ➢ Check and make sure that the power cords of the main unit, sampler unit, pneumatic unit, interchanger and external computer are properly plugged into the power socket.

- (Optional) Printer

- Check and make sure that the printer paper is sufficient and the installation is in place.
- Check and make sure that the power cord of the printer is properly plugged into power socket, and the printer is properly connected with the external computer.

- Keyboard, mouse, and network cable
  - Check and make sure that the network cables of the external computer, main unit and sampler unit are properly connected with the interchanger.
  - Check and make sure that cables of the keyboard and mouse are connected with the external computer.
- Pressure tubing, control line
  - Check and make sure that the pressure tubing (positive/negative pressure) of the pneumatic unit is connected with the main unit.
  - Check and make sure that the control line of the pneumatic unit is connected with the sampler unit.

5.2.2 Preparation of Test Tube and Barcode

Before performing sample analysis, you shall prepare the test tube and its barcode with the specification specified by Dymind.

Tube Rack

- Each analyzer is equipped with 6 tube racks.
- Each tube rack has a digital number and a barcode.
- The coding system of the tube rack is CODE128 coding system, and the barcode has 22 digits.

Specifications of Test Tube

- Venous Whole Blood Sample

  Please use one of the following vacutainer blood collection tubes to collect whole blood sample.
  - 13*75 mm (without cap) vacutainer blood collection tube
  - 12*75 mm (without cap) vacutainer blood collection tube

  NOTE

  The height of vacutainer blood collection tube (with cap) should be no more than 83mm.

- Capillary Whole Blood Sample

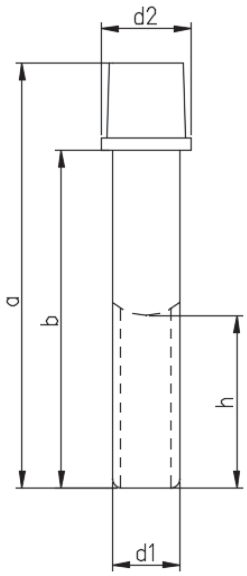
  Use different disposable capillary blood collection tubes with different specifications for different sampling ways. Please select the capillary blood collection tubes of corresponding specifications according to the actual sampling ways to collect capillary whole blood sample.

The specifications of capillary blood collection tubes for different sapling ways are introduced below.

➢ Auto sampling

Specifications of capillary blood collection tube supported by auto sampling are as shown in Table 5-1.

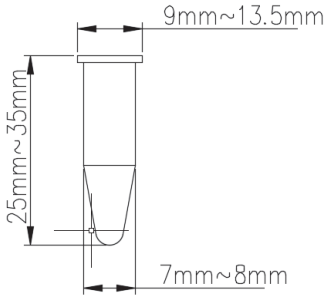
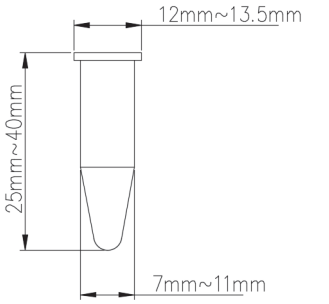
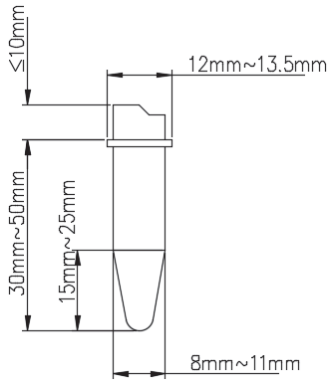
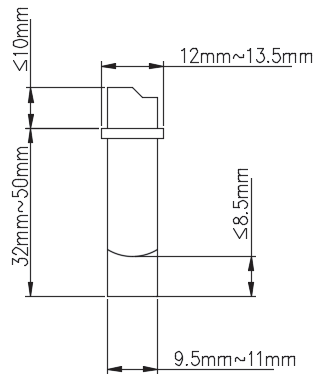
Table 5-1 Specifications of Capillary Blood Collection tube Supported by Auto Sampling

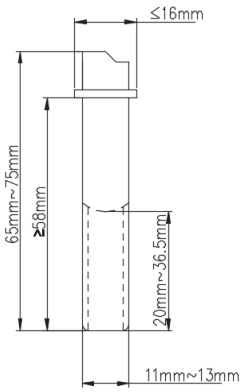
Specification Diagram	Specifications	Recommended Manufacturer (Model)	Recommended Blood Volume
	● Total length of test tube with cap (a): 60 mm≤a≤85 mm ● The length below the convex edge (b): b≥58 mm ● The diameter of the tube body (d1): 11.6 mm≤d1≤12.6 mm ● The diameter of the convex edge (d2): (d1+1 mm)≤d2≤18 mm ● The height from the bottom of the vessel to the bottom of the tube (h): 20 mm≤h≤36.5 mm	XINLE MEDICAL (Type D2 K_2EDTA 0.25mL)	≥100 μL
		GONGDONG MEDICAL (EDTA-K_2 GD005EK_2S 0.5mL)	≥80 μL
		Improve (EDTA-K_2 normal type 0.5mL)	≥100 μL
		KANGJIAN MEDICAL (KJ001-1 0.5mL EDTA-K_2)	≥80 μL

➢ Manual sampling

Specifications of capillary blood collection tube supported by manual sampling are as shown in Table 5-2.

Table 5-2 Specifications of capillary blood collection tube supported by manual sampling

Test Tube Type	Specifications	Recommended Manufacturer (Model)	Recommended Blood Volume
A		KANGJIAN MEDICAL, KJ201 (EDTA.K_2), 0.5mL	≥60μL
B		KANGJIAN MEDICAL, KJ202 (EDTA.K_2), 1.5mL	≥80μL
C		KANGJIAN MEDICAL, KJ003 (EDTA.K_2~A3), 0.5mL	≥80μL
D		KANGJIAN MEDICAL, KJ001 (EDTA.K_2), 0.5mL	≥100μL

Test Tube Type	Specifications	Recommended Manufacturer (Model)	Recommended Blood Volume
E		BD (Unit States) (Microtainer MAP)	≥100μL

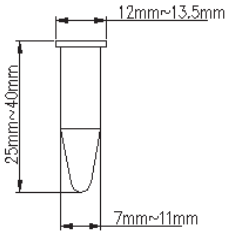
NOTE

The capillary blood collection tube of manual sampling needs to be used with corresponding adepter. The adapter is marked with the test tube type (A, B, C, D, E), please use the adapter corresponding to the test tube type.

- Pre-dilution sample:

  Specification supported by pre-dilution sample is as shown in Figure 5-3.

Table 5-3 Specification Supported by Pre-dilution Sample

Test tube type	Specification Diagram	Recommended Manufacturer (Model)	Recommended Blood Volume
B		KANGJIAN MEDICAL, KJ202 (EDTA.K_2), 1.5mL	≥80μL

- Body fluid sample

  Specification supported by body fluid sample is as shown in Figure 5-4.

Table 5-4 Specification Supported by Body Fluid Sample Tube

Test tube type	Recommended Blood Volume
12*75mm body fluid collection tube	≥2mL

Format of Test Tube Barcode

Please use any of the following formats to make test tube barcode.

- CODE39

  The length is variable and ranges from 1 to 20.

- CODE93

  The length is variable and ranges from 1 to 20.

- CODE128

  The length is variable and ranges from 1 to 20.

- CODABAR

  The length is variable and ranges from 1 to 20.

- ITF

  The length is variable and ranges from 1 to 20.

Barcode Specifications

Detailed requirements are as follows:

- Barcode height: D ≥ 10 mm
- Barcode label width: A ≤ 45 mm
- Blank space on both sides of the barcode: B ≥ 5 mm, C ≥ 5mm
- Width ratio of wide and narrow units: from 2.5:1 to 3:1
- Barcode quality: not less than grade C according to ANSI MH10.8M

NOTE

Barcode quality is generally divided into A, B, C, D, F five grades. Ranges of each grade (G): A (3.5≤G≤4.0), B (2.5≤G<3.5), C (1.5≤G<2.5), D (0.5≤G<1.5), F (G<0.5).

5.2.3 Reagent Inspection and Preparation

Before performing sample analysis, you shall make sure that there are enough reagents for the sample analysis of the day. Please prepare a little more reagent than you need for the day.

For details about reagent replacement, please refer to ***8 Reagent Management***.

5.2.4 Reagent Preparation

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

Warning

Do not touch the sample directly.

Caution

- Do not reuse the disposable product.
- Prepare samples according to the procedure recommended by the sample manufacturer.

NOTE

- Be sure to use clean K_2EDTA vacuum blood collection tubes with anticoagulant, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Use only the vacuum blood collection tube, centrifugal tube, capillary tube and other disposable tube specified by the manufacturer.
- Samples for WBC classification or PLT count should be kept at room temperature and analyzed within 8 hours after collection.
- If PLT, MCV or WBC classification analysis results are not required, the sample can be stored in a refrigerator at 2°C and 8°C for 24 hours. Refrigerated samples should be kept at room temperature for at least 30 minutes before the test.
- Samples placed for a period of time need to be remixed before the test.

5.2.4.1 Venous Whole Blood Sample

The preparation steps of venous whole blood sample are as follows:

1. Use K_2EDTA (with the blood volume of 1.5 mg/mL ~ 2.2 mg/mL) anticoagulant vacuum tube to collect venous blood samples.
2. Mix well the venous whole blood with the anticoagulant in the tube immediately.

Caution

For vacuum blood collection tube (Φ12×75, cap excluded), please make sure the volume of the whole blood sample is not less than 1 mL.

5.2.4.2 Capillary Whole Blood Sample

The preparation steps of capillary whole blood sample are as follows.

1. Please use disposable capillary blood collection tube with anticoagulant to collect capillary whole blood sample.
2. Mix the sample well according to the laboratory regulations.

Caution

For the accuracy of the analysis, make sure the volume of the capillary whole blood sample is not less than 80 μL.

NOTE

- Please analyze the capillary whole blood sample within 3 minutes to 2 hours after collection.
- The tube shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube may be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.

5.2.4.3 Pre-dilution Sample

Caution

Do not use anticoagulant in the pre-dilution sample; otherwise, the analysis result will be affected.

NOTE

Each laboratory should evaluate the stability of the sample analysis results of the pre-dilution sample according to their respective sample number, sample collection method and technical level.

The preparation steps of pre-dilution sample are as follows.

1. Click the **Add diluent** button in the function button area. The system pops up a dialogue box prompting that **Prepare to add diluent...**.

   The sample delivery component automatically moves to the manual sampling position.
2. When the pop-up dialogue box prompts you to add diluent, take a clean centrifugal tube, and place the tube to the capillary whole blood sampling position of the sample delivery component.
3. Press the [RUN] key of the main unit, the sample delivery component automatically moves under the sampling probe to add diluent.

4. After completing, click the **Cancel** button on the dialogue box, the sample delivery component automatically moves to the manual sampling position, then remove the centrifuge tube with diluent.

NOTE

- You can also dispense 100μL of diluent by pipette into the tube.
- Be sure to keep dust from the prepared diluent.

5. Add 20μL of capillary blood to the diluent, close the tube cap and shake the tube to mix the sample.
6. If more portions of diluent are needed, repeat steps 3~4.

NOTE

- The pre-dilution sample prepared after single blood collection can be counted twice.
- Be sure to run the pre-dilution samples within 30 minutes after the mixing.
- Samples placed for a period of time need to be remixed before the test.
- The tube shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube may be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.

5.2.4.4 Body Fluid Sample

Caution

- It is recommended to add anticoagulants to the hydrothorax sample and ascites sample to ensure long-term stability of the samples.
- Do not add anticoagulants to the cerebrospinal fluid sample.

The preparation steps of body fluid sample are as follows.

1. Use the disposable tube to collect body fluid sample.
2. Mix the sample well according to the laboratory regulations.

NOTE

- The body fluid test only supports cerebrospinal fluid sample, hydrothorax sample and ascites sample currently.
- Make sure to complete the sample analysis soon as possible after sample collection, otherwise the obtained analysis results are not reliable.

5.3 Startup

Startup operations include starting the device (including the pneumatic unit, the sampler unit and the main unit), and starting PC side software.

Start the device first, and then start PC side software.

5.3.1 Starting the Device

The device includes the pneumatic unit, the sampler unit and the main unit.

The device startup is divided into manual startup and appointed startup.

5.3.1.1 Manual Startup

Start the pneumatic unit and sampler unit before starting the main unit.

Starting the Pneumatic Unit and the Sampler Unit

Set the power switch of the pneumatic unit and the sampler unit to [I], and start the pneumatic unit and the sampler unit respectively.

Starting the Main Unit

Warning

- Please check the tightness of all the doors/covers/boards before running the main unit to prevent unexpected opening or loosening during use.
- Keep your clothes, hair and hands away from the moving parts to avoid being caught or crushed.

The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.

Caution

Do not turn on/off the power supply repeatedly for a short period of time to avoid damage to the device.

NOTE

Before starting the main unit, make sure the auto sampling area is emptied and without test tube rack or other items.

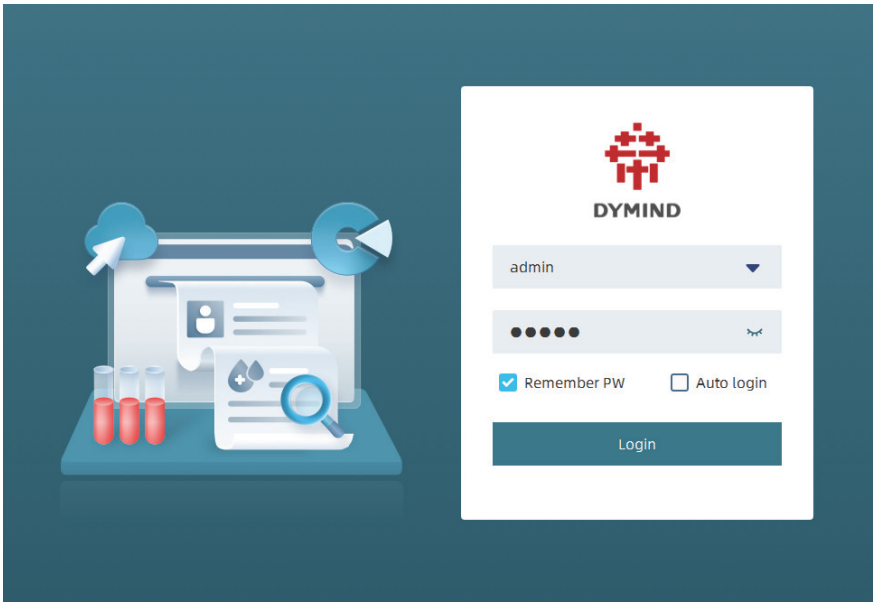
Start the main unit according to the steps below.

1. Check the device, and prepare the test tube, reagent and sample according to ***5.2 Preparation before Operation***.
2. Place the power switch of the main unit to [I].

   At this time, the power switch indicator light is on, indicating that the main unit has been powered on and the device is running as a whole.
3. Press the [ON] key of the main unit.

   Start HOST software.
4. Input the correct user name and password in the Login dialog box. See Figure 5-2.

   Figure 5-2 Logging in to HOST Software



   - The user name and password of the factory default preset user are both “admin”.
   - If **Remember PW** and **Auto login** are checked, the login dialog box will no longer pop up when restarting, and the startup process will be performed directly.
5. Click **Login**.

   The main unit automatically performs the startup process, including hardware self-test, configuration file loading, component clearance and self-test, fluidics initialization, startup cleaning and maintenance, background count, etc.

   The startup process lasts about 4-12 minutes (the specific time varies according to the previous shutdown).

   After the main unit is started successfully, it enters the count interface by default.

NOTE

- If the first background results obtained during the startup process exceed the background range, the main unit will automatically perform another background count. If the background results are still abnormal for the second time, enter the background count interface, and the error information area will prompt the abnormal background count.
- Running a test when there is an abnormal background error, you would obtain unreliable test results. Handle the error by referring to ***16 Troubleshooting***, and then perform other operations.
- If there is an error during the initialization process, the main unit will give an alarm. Please refer to 16 Troubleshooting to handle the error.
- If you need to log out or switch users, click  > **Shut down** > **Log out**, and click **OK** in the pop-up dialog box. The software will return to the login dialog box. Enter correct user name and password, click **Login**, then you can log in again or log in to HOST software with another user identity.

5.3.1.2 Startup Appointment

NOTE

- The prerequisite for the startup appointment to take effect is that the power switches of the main unit, the pneumatic unit, and the sampler unit are not turned off.
- Please refer to ***11.2.4 Startup Appointment Settings*** or the setting of startup appointment.

If the startup appointment is set on CMS software, HOST software, the sampler unit, and the pneumatic unit will automatically start at the set time.

Startup appointment includes the following two situations.

- If **Remember PW** and **Auto login** are checked before the last login, when the appointed startup time is reached, HOST software will automatically start and log in, and the startup process will be performed directly.
- If **Remember PW** and **Auto login** are not checked before the last login, when the appointed startup time is reached, the login dialog box of HOST software will pop up. You need to input correct user name and password, click **Login**, and then the startup process will be performed.

5.3.2 Starting PC Side Software

NOTE

- Before starting up PC side software, make sure the pneumatic unit, the sampler unit and the main unit have been started successfully.
- If you fail to start the software continuously, please contact Dymind customer service department or the agent.

The main unit needs to be used together with 2 PC side software.

- CMS software: to control the autosampler to deliver the sample. CMS can connect with up to 2 main units to form a workstation.
- DMS software: to input test orders before sample test, to analyze the results after sample test, and to validate and issue the test report.

CMS software and DMS software support one-key startup, that is, start one software and the other software is started automatically. For example, if you start CMS software, DMS software is automatically started, and a login box pops up.

The steps of one-key startup will not be repeated, the following introduces the steps of starting one software alone.

5.3.2.1 Starting External Computer

Start the external computer according to the startup process of the operating system.

5.3.2.2 Starting CMS Software

Double click CMS software icon ( ) on the external computer, and CMS software will be logged in with admin access level by default without inputting user name and password.

5.3.2.3 Starting DMS Software

Starting DMS software includes starting DMS server and logging into DMS software.

Starting DMS Server

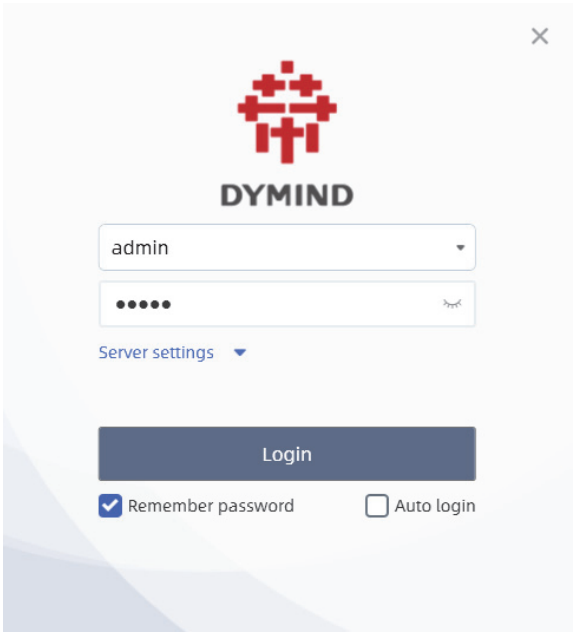
Double click the DMS server icon ( ) on the external computer to start the DMS server.

Logging in to DMS Software

Log in to DMS software according to following steps.

1. Double click DMS software icon ( ) on the external computer to start DMS software.
   A login interface pops up after DMS software is started. See Figure 5-3.

Figure 5-3 Logging in to DMS Software

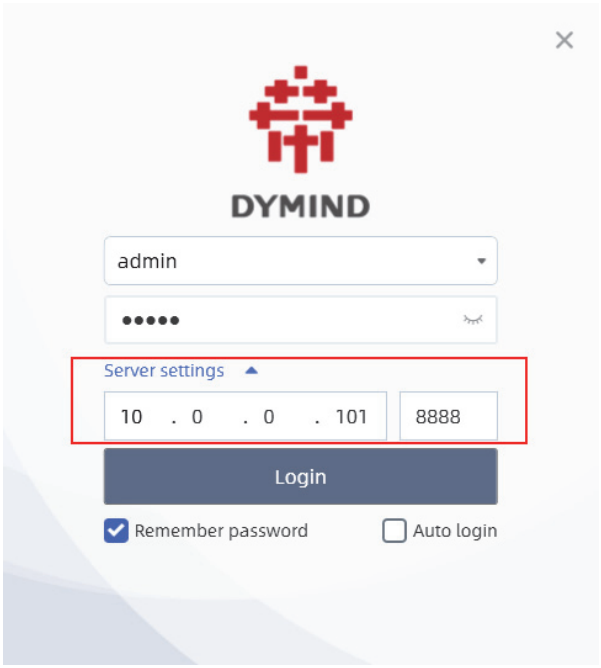


Remember password and **Auto Login** are not checked by default for the first login. You can set them according to your actual need. If **Remember password** and **Auto Login** are checked, the login dialog box will no longer pop up when restarting, and it enters the test interface directly.

2. Input correct user name and password.
3. Set DMS server IP address and port number.

   When you use DMS software for the first time or need to modify DMS server configuration, you can click the " " button on the right side of the server settings on the login interface, and input the DMS server IP address and port number in the server settings window shown in Figure 5-4.

Figure 5-4 Logging in to DMS Server



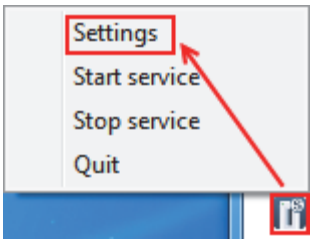
4. Click **Login**.

   The system enters into the test interface by default after logging in successfully.

   If IP address or the port number of the server settings is wrong, it prompts **Failed to connect, please check the network or local firewall**. Follow below steps to handle the problem.

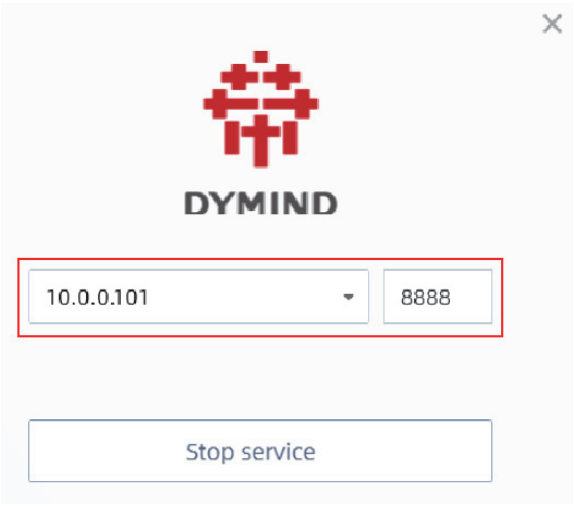
   a. Right click the DMS server icon "" in the task bar, and click **Settings**. See Figure 5-5.

   Figure 5-5 DMS Server Menu

   b. Check the IP address and port number of the DMS server in the pop-up interface as shown in Figure 5-6.

Figure 5-6 DMS Server Interface



c. Check whether the IP address and port number on the login interface of DMS software are correct or not. If not, input the IP address and port number on the login interface of DMS software again.

d. Click **Login**.

   If the problem still exists, contact Dymind customer service department or the local agent.

5.4 Daily Quality Control

Before sample analysis, you should perform QC analysis to the analyzer every day to ensure reliable analysis results. For detailed QC methods, please refer to ***9 Quality Control***.

5.5 Performing Sample Analysis

After preparing the sample, you can start the sample analysis.

For detailed introduction to sample analysis, please refer to ***6 Sample Analysis***.

5.6 Logging out/Switching User

It includes logging out/switching HOST software user and logging out/switching DMS software user.

Logging out/Switching HOST Software User

If you need to log out or switch the user of HOST software, follow the steps below.

1. Click  > **Shut down** > **Log out** on HOST software.

   It prompts Are you sure to log out?

2. Click **OK**.

   The current user will log out and the software returns to the login interface.

3. Input correct user name and password.

4. Click **Login**.

   The new user logs in to HOST software.

Logging out/Switching DMS Software User

If you need to log out or switch the user of DMS software, follow the steps below.

1. On the DMS software, click the "" icon in the information area of the currently logged-in user in the upper right corner of the interface.

   It prompts **Log out of the current account?**.

2. Click **Yes**.

   The current user will log out and the software returns to the login interface.

3. Input correct user name and password.

4. Click **Login**.

   The new user logs in to DMS software.

5.7 Shutting down

NOTE

Please follow the normal shutdown procedure to shut down the device, otherwise the device may be damaged or cannot operate properly.

The shutdown operation includes shutting down the main unit, the sampler unit, the pneumatic unit, the PC side software and the external computer.

5.7.1 Shutting down the Main Unit

Warning

You are obligated to discharge and dispose of the reagents, wastes, samples, consumables according to local legislations and regulations.

Caution

- Please follow the normal shutdown procedure to shut down the device, otherwise the device may be damaged or cannot operate properly.
- Do not start the analyzer immediately after shutdown. Wait for at least 10 seconds, otherwise the main unit may be damaged.

NOTE

- Do not shut down the main unit forcibly while the system is performing tests or other operations related to the main unit.
- Do not turn off the power before the shutdown is completed.

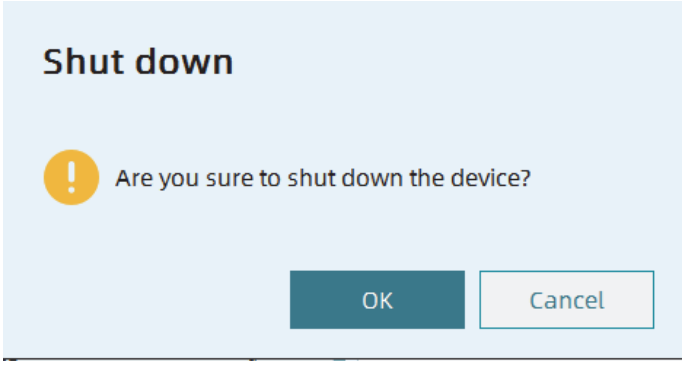
You can shut down the main unit on HOST software.

Follow below steps to shut down the main unit.

1. Click  > **Shut down** > **Shut down**.

   A prompt box as shown in Figure 5-7 pops up.

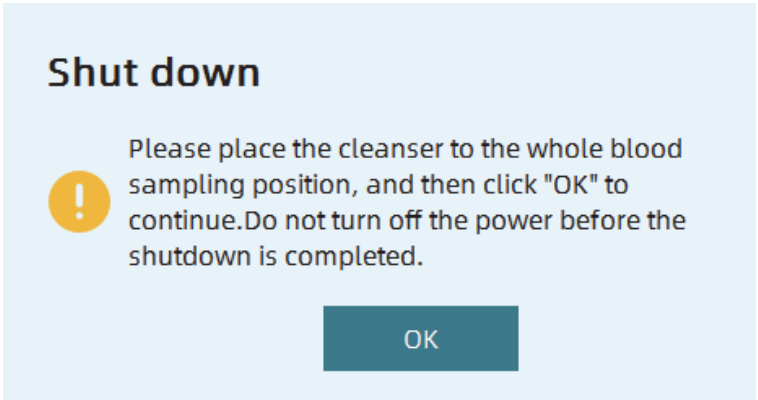
   Figure 5-7 Shut Down

2. Click **OK**.

   A prompt box as shown in Figure 5-8 pops up. The sample delivery component moves to the manual sampling position.

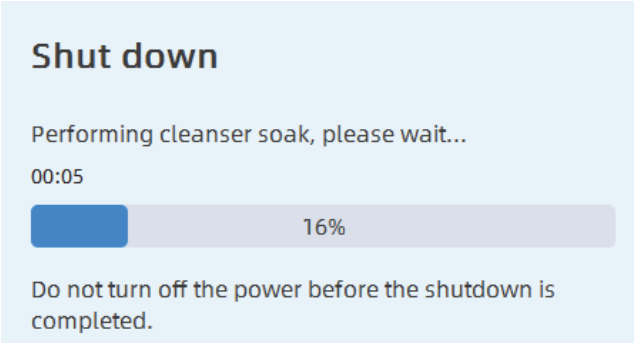
   Figure 5-8 Shutdown Process Prompt 1

3. Please place the cleanser to the whole blood sampling position of the sample delivery component, and then click **OK**.

   The main unit starts the shutdown operation, and indicates that it is shutting down. See Figure 5-9.

   Figure 5-9 Shutdown Process Prompt 2

   When the shutdown operation is completed, it prompts **The screen display will be automatically cut off after 1 min. Do not power off the device if book startup is enabled!**.

4. Turn off the power switch on the back of the main unit.

   If the startup appointment is set on CMS software, do not turn off the power switch of the main unit. Otherwise, the startup appointment will not take effect.

5. After shutdown, empty the waste in the waste container, and dispose of it properly.

   If the direct discharge method is used to discharge the waste to the medical waste discharge system of the hospital, there is no need to perform the last step.

5.7.2 Shutting down the Sampler Unit and Pneumatic Unit

Shut down the sampler unit and pneumatic unit respectively.

If the startup appointment is set on CMS software, do not turn off the sampler unit and pneumatic unit. Otherwise, the startup appointment will not take effect.

5.7.3 Shutting down PC Side Software

There is no required order for the shutdown of CMS and DMS software. You can shut down PC side software according to the actual situation.

5.7.3.1 Closing CMS Software

Click  > **Exit** on CMS software, and follow the instructions on the interface to close CMS software.

5.7.3.2 Closing DMS Software

Click **Close** in the upper right corner of the interface on DMS software, and follow the instructions on the interface to close DMS software.

5.7.4 Shutting down External Computer

NOTE

Before shutting down the external computer, please exit PC side software first, and then shut down the external computer according to the shutdown process of the operating system.

After shutting down the PC Software, shut down the external computer as follows.

1. Shut down the external computer according to the shutdown process of the operating system.
2. Shut down the displayer.

6 Sample Analysis

Sample analysis is the most important function of Auto Hematology Analyzer. This chapter introduces the procedure of sample analysis and the usage of related functions.

6.1 Interface Introduction

The count interface of HOST software and test interface of DMS software will be introduced in the following contents.

6.1.1 Count (HOST Software)

Click **Count** on HOST software to enter the count interface. See Figure 6-1.

Figure 6-1 Count (HOST Software)

Explanations:

- 1 - Sample information area

  It displays the sample information of the current sample, including sample number, measurement mode (*sample type-analysis mode*) and test time.

- 2 - Graphs and results area

They display the analysis results of the current sample, including report parameter results, flag information, graphs (histogram and scattergram), and research parameter results.

- 3 - Information area of the next sample

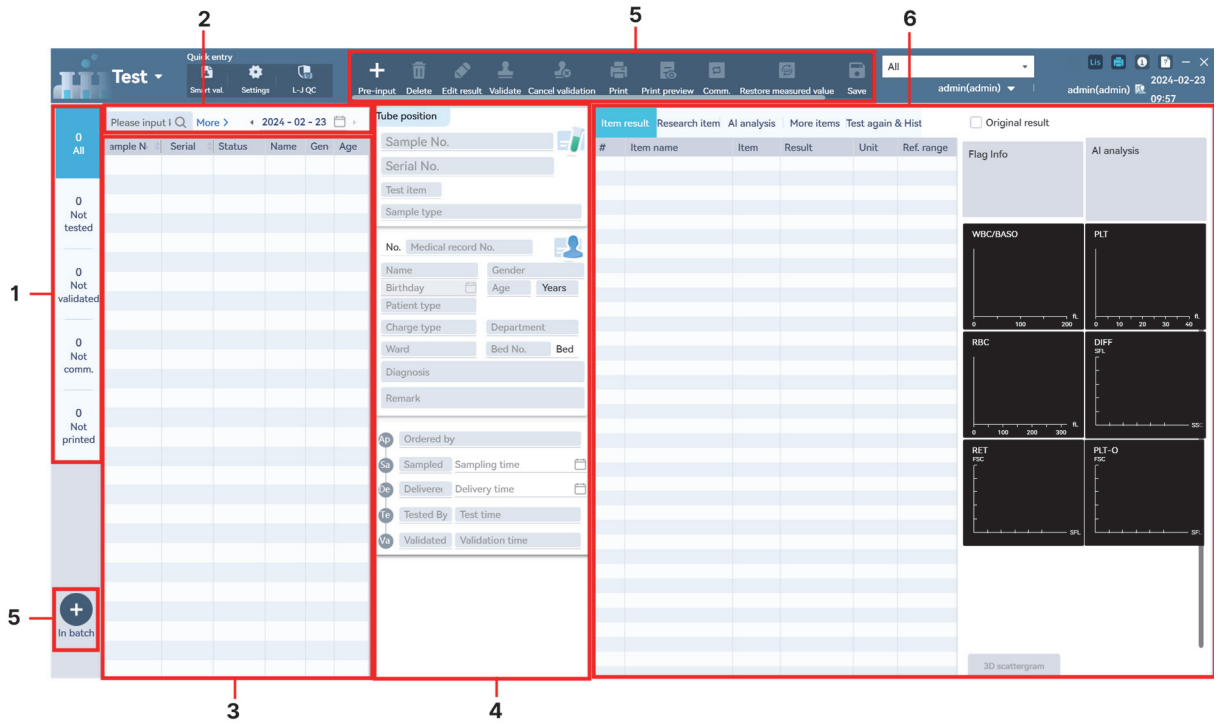
  It displays the sample ID and measurement mode (*sample type-analysis mode*) of the next sample. It is blank if there is no next sample information.

  Only when the main unit is switched to manual sampling, the **Mode** button is lighted.

6.1.2 Test (DMS Software)

Click **Test** on DMS software to enter the test interface. See Figure 6-2.

Figure 6-2 Test (DMS Software)



Explanations:

- 1 - Sample status tab

  You can click the different status tabs to view the corresponding sample records. The **All** tab is selected by default.

  - All: the sample record that has been input and has result data.
  - Not tested: the sampler record that has been input but to be analyzed.
  - Not validated: to the sample record that has result data but has not been validated. The sample record that has been canceled validation is also displayed on this tab.
  - Not comm.: the sample record that has result data but has not been communicated to LIS system.
  - Not printed: the sample record that has result data but has not been printed.

- 2 - Search condition area

  You can input the specified condition to search the corresponding sample record.

- 3 - Sample list area

  It displays the sample record that meets the specified condition.

  If the analysis result of the sample triggers the retest rule, the retest indicator is displayed at the sample number.

- 4 - Sample information area

  It displays the sample information (including patient information) of the selected sample record.

- 5 - Function button area

  You can click **Pre-input** or **In batch** to input the sample information, and you can also validate/cancel the validation, edit the results, restore the results, delete, export, and print the sample records of the existing result data.

- 6 - Sample results area

  It displays the result data of the selected sample record, including item results, research item, AI Analysis, more items and retest & history.

6.2 Preparation before Analysis

1. Check if there is any left tube rack on the autosampler; if there is, please remove the rack.
2. Check devices, prepare test tubes and barcode, check and prepare reagents, and prepare samples according to ***5.2 Preparation before Operation***.
3. Check if the autosampler and external air supply has been started.
4. Check if the main unit, sampler unit, CMS software and DMS software are connected to each other.

6.3 Inputting Sample Information (DMS Software)

Before performing sample analysis, you need to input the sample information first.

It includes the following two ways.

- DMS automatically obtains the sample information of LIS system.
- Manually input the sample information on DMS software.

6.3.1 Automatically Obtaining LIS Sample Information

You can automatically obtain the sample information of the same sample number in LIS system by pre-inputting the sample number on DMS software.

The steps to automatically obtain LIS sample information are as follows.

1. Refer to ***2.3.4 Connection of LIS and DMS Software*** to connect DMS and LIS software.

   The lighted LIS system connection status icon in the upper right corner of DMS software means that the DMS and LIS software are successfully connected.

2. Click **Settings** > **LIS comm. settings** on DMS software, and select **Bidirectional LIS/HIS communication**.
3. Click **Pre-input** on the test interface.
4. Input the sample number of the LIS side in the sample number edit box.
5. Press the [ENTER] key on the keyboard.

   DMS software automatically obtains the sample information of LIS system, and displays the information in the sample information area of the test interface.

6.3.2 Manual Input

Manual input of sample information on DMS software includes input individually and input in batch.

Input Individually

Steps of individual input are as follows.

1. Click **Test** to enter the test interface.
2. Click **Pre-input**.

   A blank line is added in the sample list area, which means to input a sample record.

3. Refer to Table 6-1 to set the sample information in sample information area.

Table 6-1 Pre-input Sample Parameter Explanation

Parameter	Meaning	Operation
Sample No.	The number of the sample.	Input in the edit box directly, required field. **Note** • The sample No. cannot be empty. • The end character of the sample No. must be a number. • If the sample No. is the same as the sample No. of the day, it will prompt **The sample No. of the day cannot be repeated!** when you save the number, please input a valid sample No. again. • If the sample No. is the same as the QC sample No., it will prompt **It is not allowed to add the sample No. that is the same with QC sample No.!** when you click **Save**, please input a valid sample No. again. • For sample No., you can input letters, digits and other characters except ”/\”, ”:”, “*”, “?”, “<”, “>”, “|”.

Parameter	Meaning	Operation
Analysis Mode	The analysis mode of the sample, which includes: ● CBC ● RET ● CBC+DIFF ● CBC+RET ● CBC+DIFF+RET ● CBC+DIFF (LW) ● CBC+RET (LP) ● CBC+DIFF+RET (LW+LP)	Select from the drop-down list or input directly, required field. The default value is CBC+DIFF. **Note** If you select **Display test parameters when pre-inputting** in ***11.3.3 Auxiliary Settings***, after you select the analysis mode, the tabs of item results, research item, and more items will display the corresponding item information in this mode (including item name, item unit and reference range).
Sample position	The rack No. and test tube No. of the auto sampling sample. For example, “1-2” means the rack No. of the sample is 1, and the tube No. is 2.	Read only. After the analysis of the auto sampling sample is completed, it is transmitted to DMS software through CMS software.
Sample type	The type of the sample, including: ● Venous whole blood ● Capillary whole blood	Read only. When performing sample analysis, the type of sample is judged by identifying the type of test tube rack, and transmitted to DMS software through CMS software.
Name	The name of the patient.	Input in the edit box directly.
Gender	The gender of the patient. It includes: ● (blank) ● Male ● Female	Select from the drop-down list or input directly.

Parameter	Meaning	Operation
Birthday	The patient's date of birth.	Select from the date control. The input sequence of each control is consistent with the date format displayed on the upper right corner of DMS interface. For example, if the date format is "yyyy/MM/dd", then the input sequence is year, month, and day.
Age	The age of the patient.	Select the unit of age from the drop-down list (Year, Month, Day or Hour) and input the age of the patient in the textbox before the age unit. **Note** The age is displayed automatically if **Birthday** is set.
Medical record No.	The medical record No. of the patient.	Input in the edit box directly.
Patient type	The type of the patient.	Select from the drop-down box, or manually input. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in *11.3.10 Dictionary Settings*.
Phone	The patient's contact number.	Input in the edit box directly.
Charge type	Charge type of an item.	Select from the drop-down box, or manually input. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in *11.3.10 Dictionary Settings*.
Department	The department to which the patient belongs.	Select from the drop-down box, or manually input. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in *11.3.10 Dictionary Settings*.
Ward	The ward to which the patient belongs.	Select from the drop-down box, or manually input. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in *11.3.10 Dictionary Settings*.

Parameter	Meaning	Operation
Bed No.	The bed No. of inpatient patient.	Input in the edit box directly. **Note** Only when the **Patient Type** is **Inpatient**, the bed No. is required.
Diagnosis	Suspected diagnosis information.	Select from the drop-down list or input directly. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in ***11.3.10 Dictionary Settings***.
Remark	The information or comments that need to be declared.	Select from the drop-down list or input directly. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in ***11.3.10 Dictionary Settings***.
Ordered by	The person who inputs the sample.	Select from the drop-down box, or manually input. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in ***11.3.10 Dictionary Settings.***
Sampled by	The person who collects the sample.	Select from the drop-down box, or manually input. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in ***11.3.10 Dictionary Settings***.
Sampling time	The collecting date and time of the sample.	Click the date control to set. The input sequence of each control is consistent with the date format displayed on the upper right corner of DMS interface. For example, if the date format is “yyyy/MM/dd”, then the input sequence is year, month, and day. **Note** • The system automatically takes the current time as the sampling time if **Auto input sampling time is checked** in ***11.3.3 Auxiliary Settings***. • The sampling time cannot be later than the system time.
Delivered by	The person who delivers the sample.	Select from the drop-down box, or manually input. **Note** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in ***11.3.10 Dictionary Settings***.

Parameter	Meaning	Operation
Delivery time	The delivery date and time of the sample.	Click the date control to set. The input sequence of each control is consistent with the date format displayed on the upper right corner of DMS interface. For example, if the date format is “yyyy/MM/dd”, then the input sequence is year, month, and day. **Note** • The system automatically takes the current time as the delivery time if **Auto input delivery time** is checked in ***11.3.3 Auxiliary Settings***. • The delivery time cannot be earlier than the sampling time and cannot be later than the system time.
Tested by	The person responsible for the sample analysis.	Read only. It is displayed automatically after the sample analysis is completed and there are count results.
Test time	The analysis time of the sample.	Read only. It is displayed automatically after the sample analysis is completed and there are count results.
Validated by	The person responsible for sample validation.	Read only. It is displayed automatically after the sample is validated.
Validation time	The validation time of the sample.	Read only. It is displayed automatically after the sample is validated.

4. Click **Save** to save the settings.
5. If you need to edit the sample information again, follow the steps below.
   a. Select the sample to be edited in the sample list area.
   b. Refer to Table 6-1 to set the sample information in sample information area.
   c. Click **Save**.

Input in Batch

Steps of input in batch are as follows.

1. Click **Test** to enter the test interface.
2. Click **In batch** to enter the interface.
   A blank line is added by default, which means to input a batch of sample record.
   You can input one or more batches of sample records in batch, that is, add or delete lines through the **Insert** and **Delete** buttons.

3. Refer to Table 6-2 to input the sample record in batch.

Table 6-2 Parameter Description of Input in Batch

Parameter	Meaning	Operation
Start sample No.	The starting sample number of the batch of samples.	Input in the edit box directly, required field. **Note** ● The start sample No. cannot be empty. ● The end character of the sample No. must be a number. ● If the sample No. is repeated with the sample No. of the day (existing in the database) or the current interface, it will prompt **The sample No. of the day cannot be repeated!** when you save the number, please input a valid sample No. again. ● If the sample No. is the same as the QC sample No., it will prompt **It is not allowed to add the sample No. that is the same with QC sample No.!** when you click **Save**, please input a valid sample No. again. ● If the sample No. is repeated with the preset increased No. of the current interface, the first newly added data shall prevail, and please input a valid sample No. again.
Increased number	The total increased number of samples in this batch, including: ● 10 ● 20 ● 30 ● 40 ● 50 ● 60	Select from the drop-down list, required field.

Parameter	Meaning	Operation
Analysis mode	The analysis mode of samples in this batch, including: ● CBC ● RET ● CBC+DIFF ● CBC+RET ● CBC+DIFF+RET ● CBC+DIFF (LW) ● CBC+RET (LP) ● CBC+DIFF+RET (LW+LP)	Select from the drop-down list, required field.
The text wraps around after scanning or pressing [Enter], and the sample No. increases	● Checked (default): after scanning or pressing [ENTER], a new row is automatically added, and the sample No. is increased. ● Unchecked: after scanning or pressing [ENTER], a new row is not automatically added.	Select according to the actual situation.

Parameter	Meaning	Operation
Automatically input the increased number and analysis mode of previous line after wrapping	• Checked (default): automatically input the increased number and analysis mode of previous line after pressing [ENTER] to wrap. • Unchecked: not input the information automatically after pressing [ENTER] to wrap.	Select according to the actual situation.

4. Click **Save**.

   The new sample record will be saved to the sample list area.

5. After inputting the sample records in batch, the patient information of this batch is blank.

   If you need to input the patient information, follow the steps below.

   Click the sample record that needs to be input patient information in the sample list area.

   Refer to Table 6-1 to set the information in sample information area.

6.4 Performing Sample Analysis

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

Warning

The left blood, QC materials, and calibrators on the sampling probe may pose a potential risk of bio-contamination, so please avoid contact with the sampling probe.

Caution

- Do not reuse the disposable product.
- You should make sure that the input sample number and analysis mode are the same with that of the sample to be analyzed.

NOTE

- The test tube (centrifugal tube) shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube may be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.
- Before performing sample analysis, you should select appropriate reference ranges on **Ref. range settings** interface of DMS software; otherwise incorrect alarms may be given after sample analysis.
- If abnormal samples are found in the test, the analyzer automatically goes back for retest.

After completing the preparation and input of sample information before analysis, you can perform sample analysis. Sample analysis consists of sample analysis of manual sampling and that of auto sampling.

6.4.1 Sample Analysis of Manual Sampling

NOTE

Only when the main unit is switched to manual sampling, the sample analysis of manual sampling can be performed, and the **Mode** button in the next sample information area is valid.

Follow below steps to start the sample analysis of manual sampling in the main unit.

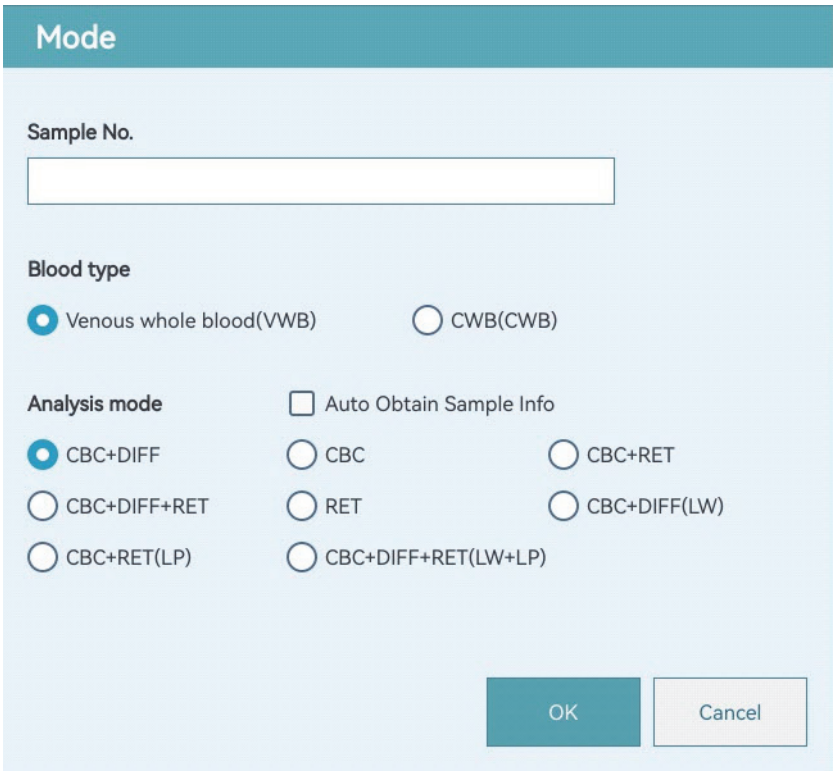
1. Press the [MODE] key of the main unit to switch to manual sampling mode.

   The **Mode** button in next sample area is lighted.

   If the main unit is manual sampling mode already, you can directly perform step 2.

2. Click the **Mode** button in next sample area. See figure 6-3.

Figure 6-3 Inputting Next Sample Information



3. Set the sample No..

   Input the sample No. of the next sample in the edit box. The sample No. cannot be empty and must end with a number.

4. Set blood type.

   The blood types include venous whole blood, capillary whole blood, pre-diluted blood. Some models only support venous whole blood, subject to the actual interface display.

5. Set the analysis mode.

   - If Auto Obtain Sample Info is selected.

     The analyzer automatically obtains the analysis modes of the input sample No. from the DMS.

   - If Auto Obtain Sample Info is deselected, you will need to manually set the analysis mode.

     The analysis modes of the sample include CBC, RET, CBC+DIFF, CBC+RET and CBC+DIFF+RET, CBC+DIFF (LW), CBC+RET (LP) and CBC+DIFF+RET (LW+LP).If the main unit disables the RET channel, the analysis modes are CBC, CBC+DIFF and CBC+DIFF(LW). If you need to disable the RET channel, contact Dymind customer service department or the local agent.

6. Click **OK** to save the settings.

   The sample No., blood type and analysis mode are displayed in the next sample area.

7. Mix the capped sample thoroughly.

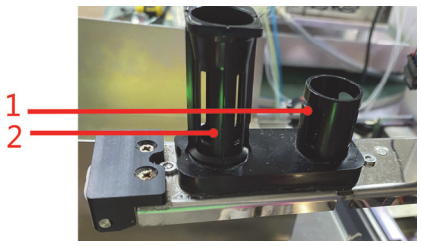
8. Uncap the sample carefully, and place the sample to the sample delivery component. See Figure 6-4.

NOTE

When the sample is venous whole blood, the operation can be performed with cover opened or closed.

- If it is venous whole blood or body fluid, place the tube to the venous whole blood sampling position of the sample delivery component.
- If it is capillary whole blood or pre-dilution, place the tube to the capillary whole blood sampling position of the sample delivery component.

Figure 6-4 Sampling Position of Sample Delivery Component



1	Capillary whole blood sampling position	2	Venous whole blood sampling position

9. Press the [RUN] key of the main unit to start the sample analysis of manual sampling.

   The sample delivery component automatically moves under the sampling probe to complete the blood collecting.

10. Then the sample delivery component moves to the manual sampling position. Please take away the sample tube.

    When the analysis is completed, the sample results are displayed on the count interface of HOST software, and are transmitted to test interface of DMS software.

    - If there is a sample record with the same sample number on DMS software, the analysis result will be overwritten to the sample record.
    - If the sample number is not pre-input on DMS software, a new sample record will be added to the sample list area.

6.4.2 Sample Analysis of Auto Sampling

NOTE

- Only when the main unit is switched to auto sampling, the sample analysis of auto sampling can be performed.
- For the auto sampling setting and mode setting of CMS software, please refer to ***11.2.2 Auto Sampling Settings*** and ***11.2.1 Mode Settings***.
- Capillary whole blood and venous whole blood can be tested in batch on the device simultaneously.
- Only the Auto Hematology Analyzer with the model of DH-610, DH-612, or DH-615 supports capillary whole blood test in the auto mode.

The sample number and analysis mode of the sample of auto sampling vary according to the user's settings. There are the following 3 situations.

- If both **Obtain DMS sample info** and **Automatically scan sample No.** on the auto sampling settings interface of CMS software are not checked, the sample number and analysis mode of the sample analysis of auto sampling will follow the mode settings interface of CMS software.

  After the analysis is completed, the sample number and analysis mode are transmitted to DMS software.

  - If there is a sample record with the same sample number on DMS software, the analysis mode and result will be overwritten to the sample record.
  - If the sample number is not pre-input on DMS software, a new sample record will be added to the sample list area.
- If **Obtain DMS sample info** is checked, but **Automatically scan sample No.** is not checked, the sample number and analysis mode of the sample analysis of auto sampling will follow the pre-input information on DMS software.

  After the analysis is completed, the analysis results are transmitted to the corresponding sample records on DMS software.
- If both **Obtain DMS sample info** and **Automatically scan sample No.** are checked, the sample number of the sample analysis of auto sampling should be that of the scanned barcode, and the analysis mode should follow the mode settings interface of CMS software.

  After the analysis is completed, the sample number and analysis mode are transmitted to DMS software.

  - If there is a sample record with the same sample number on DMS software, the analysis mode and result will be overwritten to the sample record.
  - If the sample number is not pre-input on DMS software, a new sample record will be added to the sample list area.

The sample type of auto sampling depends on the tube rack used when performing sample analysis. When performing sample analysis, the type of sample is judged by identifying the type of tube rack, and is transmitted to DMS software through CMS software.

- If it is identified as a venous whole blood tube rack, the sample type is venous whole blood.
- If it is identified as a capillary whole blood tube rack, the sample type is capillary whole blood.

During the sample analysis of auto sampling, you can stop or suspend the analysis.

6.4.2.1 Starting Sample Analysis

Complete ***6.2 Preparation before Analysis*** and ***6.3 Inputting Sample Information (DMS Software)***, and then start the sample analysis of auto sampling according to this section.

The starting of the sample analysis of auto sampling is divided into manual start and auto start.

- The steps for manual start are as follows.
  a. Press the [MODE] key in the main unit to switch to auto sampling mode.
     If the main unit is auto sampling mode already, you can directly perform step b.
  b. Place the tube rack loading with sample on the loading platform of the autosampler.
  c. Click **Start** button on CMS software.
  d. When the analysis is completed, you can view the analysis results on DMS software.
- The steps for auto start are as follows.
  a. Press the [MODE] key in the main unit to switch to auto sampling mode.
     If the main unit is auto sampling mode already, you can directly perform step b.
  b. Check **Automatically start auto sampling** on auto sampling settings interface of CMS software.
  c. Place the tube rack loading with sample on the loading platform of the autosampler.
     When the system detects that the loading platform has a tube rack, it will automatically start the auto sampling analysis.
  d. When the analysis is completed, you can view the analysis results on DMS software.

6.4.2.2 Suspending Sample Analysis

During the sample analysis of auto sampling, the **Start** button changes to the **Suspend** button. If you click the **Suspend** button, the sample that is being distributed or to be distributed is suspended but the current tube rack is not unloaded, but the sample being analyzed continues the analysis.

If you click the **Start** button again, the system enters the test tube distribution process to redistribute the currently undistributed samples.

6.4.2.3 Stopping Sample Analysis

During the sample analysis process, if you click the **Stop** button, the CMS sends a stop command, and the sampler unloads the current track after receiving the stop command and returns to the initial position.

6.5 Dealing with Analysis Results

You can deal with the sample results on HOST software or DMS software.

6.5.1 Saving Analysis Results

When the analysis is completed, HOST software will save the current analysis results automatically. And you can view all the information, result data and graphs of the samples that have been analyzed on the review interface.

When the number of sample results reaches the storage limit, the newly obtained sample analysis results will automatically overwrite the oldest, backed up sample analysis results.

If the connection between the main unit, CMS software, and DMS software is normal, each time a sample is analyzed, the sample result is automatically transmitted to the test interface of DMS software.

6.5.2 Parameter Flag

- "↑" ("H") or "↓" ("L") displayed on the left side of the parameter result indicates that the obtained analysis result is beyond the parameter reference range set previously, but still within the display range.
- "R" or "r" displayed on the left side of the parameter result indicates that the obtained analysis result is suspicious.
- "&" displayed on the left side of the parameter result indicates that the obtained analysis result is the modified result of the algorithm.
- "@" displayed on the left side of the parameter result indicates that the obtained analysis result is beyond the linearity range.
- If the parameter result displays as "++++", it indicates that the obtained analysis result is beyond the display range.
- If the parameter result displays as "****", it indicates that the obtained analysis result is unreliable, so it will not display the result. But you can check the original data by checking the **Original result** check box on the test interface of DMS software.
- The edited parameter result is marked with a "E" on the left side. The parameter result changed with the manually modified parameter results will be marked with a "e" on the left side.

NOTE

The main unit will not give parameter flag and abnormal classification or morphology flag to the background test result.

6.5.3 Alarm of Abnormal Classification or Morphology

According to the scattergram and histogram, the analyzer reports abnormal or suspicious alarm of WBC, RBC, PLT and RET lines. The definition of the prompt information is as shown in Table 6-3.

Table 6-3 Alarm of Abnormal Classification or Morphology

Information Type		Flag Information
WBC line (21 items)	Abnormal (10 items)	Leucopenia
		Leucocytosis
		Neutropenia
		Neutrophilia
		Lymphopenia
		Lymphocytosis
		Monocytosis
		Eosinophilia
		Basophilia
		Pancytopenia
	Suspicious (11 items)	DIFF Scattergram Abn.
		WBC Histogram Abn.
		Blasts?
		Abn Lympho/ Blasts?
		Immature Gran?
		Left Shift?
		Reactive Lymphocytes?
		RBC Lyse Resistant?
		NRBC?
		Lipid Particles?
		WBC Fragments?
RBC line (12 items)	Abnormal (6 items)	Anisocytosis
		Microcytosis
		Macrocytosis

Information Type		Flag Information
		Hypochromia
		Anemia
		Erythrocytosis
	Suspicious (7 items)	RBC Histogram Abn.
		Dimorphic Population
		RBC Agglutination?
		Turbid/HGB Interf?
		Iron Deficiency?
		Thalassemia?
		Fragments?
PLT line (5 items)	Abnormal (2 items)	Thrombopenia
		Thrombocytosis
	Suspicious (7 items)	PLT Scattergram Abn.
		PLT Histogram Abn.
		PLT Clumps?
RET line (3 items)	Abnormal (1 items)	Reticulocytosis
	Suspicious (2 items)	RET Scattergram Abn.
		Infected RBC?

6.5.4 Searching (DMS Software)

The test interface of DMS software displays the sample records of the day by default. You can set relevant conditions in the search condition area to search sample records according to actual needs.

It includes fuzzy search and more search.

- Fuzzy search
  a. Select the date to be searched in the date control.
  b. Input the field to be searched in the keyword input edit box.

     The types of search fields that can be input include sample No., medical record No., name, clinical diagnosis, and remark.

c. Click  .

- ✧ If there exists any data, the sample list area is refreshed.
- ✧ If there exists no data, it prompts **Search for no data!**.

d. After the search is completed, delete the search field and click  .

It returns to display all sample records of the day.

- More search

a. Click **More** to enter the interface.

b. Set the conditions.

Includes device name, test date, sample No., item conditions, etc.

c. Click **OK**.

- ✧ If there exists data, the sample list area is refreshed.
- ✧ If there exists no data, it prompts **Search for no data!**.

d. After the search is completed, click **Exit search**.

It returns to display all sample records of the day.

6.5.5 Editing Results (DMS Software)

NOTE

- The validated sample is not allowed to be edited.
- The edited parameter result is marked with a “E”. If any parameter result is then changed with the one that you modified manually, it is marked with a “e”. The mark “E” or “e” is displayed on the left side of the result by default.

You can follow below steps to edit the report parameter results (the parameter results in the item result tab) of the selected sample.

1. Click **Test** on DMS software to enter the test interface.
2. Select the sample record to be edited in the sample list area.
3. Click **Edit Result**.
4. Modify the test result of the sample parameter.
5. Click **Save** to save the results.

   If the sum of the percentages of the modified classification items (Neu%, Lym%, Mon%, Eos%, Bas%) is not equal to 100% or the WBC value is invalid, the system will pop up a message box prompting that the input is invalid. Please confirm and input again.

   After modifying the results, the results and alarm information of the related parameters also change accordingly.

6.5.6 Restoring Results (DMS Software)

You can follow below steps to restore the report parameter results of the selected sample.

1. Click **Test** on DMS software to enter the test interface.
2. Select the sample record that has been edited in the sample list area.
3. Click **Restore result**.

   The report parameter results will be restored to the original results (that is, when transmitted from CMS software).

6.5.7 Validating Sample (DMS Software)

NOTE

After validating the sample successfully, the sample analysis results are not allowed to be modified or deleted.

Follow below steps to validate the sample.

1. Click **Test** on DMS software to enter the test interface.
2. Select the sample record to be validated in the sample list area.
3. Click **Validate**.

6.5.8 Canceling Validating Sample (DMS Software)

NOTE

The admin can modify the patient information and analysis results after canceling the validation.

Follow below steps to cancel the validation.

1. Click **Test** on DMS software to enter the test interface.
2. Select the validated sample record in the sample list area.
3. Click **Cancel Validation**.

6.5.9 Exporting (DMS Software)

You can export the sample records on DMS software to back up. There are two ways to export the sample record: export the selected records or export the records of the specified date ranges.

- Export the selected records
  a. Select the sample record to be exported in the sample list area of test interface.

b. Click **Export**.

A dialog box will pop out. The default option is **Selected records**.

c. You can choose the exported contents according to your actual needs.

You can export: sample result, patient information, graph, flag alarm and retest data. All options are selected by default. The sample results cannot be unchecked, and other contents can be checked or unchecked according to actual needs.

d. Click **OK**.

e. In the pop-up dialog box, select the exported path, and input the backup file name.

You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

- ✧ The exported path defaults to the external computer desktop, or the path selected last time.
- ✧ If the exported contents are sample result, patient information, graph, flag alarm and retest data, there are two naming formats for the exported file.

  The default exported file name of the file with flag is "Sample_yyyyMMdd_hhmmss.csv", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting. Please refer to ***6.5.2 Parameter Flag*** for the specific meaning of each flag.

  The default exported file name of the file without flag is "Sample_yyyyMMdd_hhmmss_noflag.csv", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
- ✧ If the exported contents are graphs, the exported file format is .png.

f. Click **Save**.

After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

- Export the records of the specified date ranges.

a. Click **Export**.

b. Select **Select time**, and set the test date range of the samples in the two date edit boxes.

c. You can choose the exported contents according to your actual needs.

You can export: sample result, patient information, graph, flag alarm and retest data. All options are selected by default. The sample results cannot be unchecked, and other contents can be checked or unchecked according to actual needs.

d. Click **OK**.

e. In the pop-up dialog box, select the exported path, and input the backup file name.

You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

- ✧ The exported path defaults to the external computer desktop, or the path selected last time.
- ✧ If the exported contents are sample result, patient information, graph, flag alarm and retest data, there are two naming formats for the exported file.

  The default exported file name of the file with flag is “Sample_yyyyMMdd_hhmmss.csv”, in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting. Please refer to ***6.5.2 Parameter Flag*** for the specific meaning of each flag.

  The default exported file name of the file without flag is “Sample_yyyyMMdd_hhmmss_noflag.csv”, in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
- ✧ If the exported contents are graphs, the exported file format is .png.

f. Click **Save**.

After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

6.5.10 Communication (DMS Software)

NOTE

- If **Auto comm.** is checked on LIS communication settings interface, after DMS software receives the analysis results of the normal sample No. transmitted by the main unit, it will automatically transmit the results to LIS without validation. Please refer to ***11.3.8 LIS Communication Settings*** for details.
- If **Auto comm. after validation** is checked on LIS communication settings interface, the system will transmit the sample record to LIS automatically after the sample is validated. Please refer to ***11.3.8 LIS Communication Settings*** for details.
- If **Auto comm. after modifying the result** is checked on LIS communication settings interface, the system will transmit the sample record to LIS automatically after the sample result is modified. Please refer to ***11.3.8 LIS Communication Settings*** for details.
- Only when DMS and LIS are connected normally, the **Comm.** button will be lighted. The lighted LIS system connection status icon in the upper right corner of DMS software means that the DMS and LIS software are connected normally.

Follow below steps to transmit the current sample records to LIS on the test interface of DMS software.

1. Click to select one or more sample records.
2. Click **Comm.** to transmit the sample records to LIS.
   - ➢ If all are communicated successfully, the interface prompts ***X*** **pcs are communicated successfully!**.
   - ➢ If some fails, the interface prompts **The communication is completed! Succeed: *X* pcs, fail: *Y* pcs. Reason for failure: *XXXX*!**.

- If all fail, the interface prompts **The communication is completed! Fail: *X* pcs. Reason for failure: *XXXX*!**.

6.5.11 Printing Preview Report Sheet (DMS Software)

Before printing the report, you can first click **Print preview** to browse the result to be printed. And click **Print** to print the report after confirming.

6.5.12 Printing Report Sheet (DMS Software)

NOTE

You can print only when the external computer is properly connected with the printer.

If you want to print the sample results report, you can follow the steps below.

1. Click **Test** on DMS software to enter the test interface.
2. Click to select the sample.
3. Click **Print**.

   The report is printed.

6.5.13 Deleting Sample (DMS Software)

NOTE

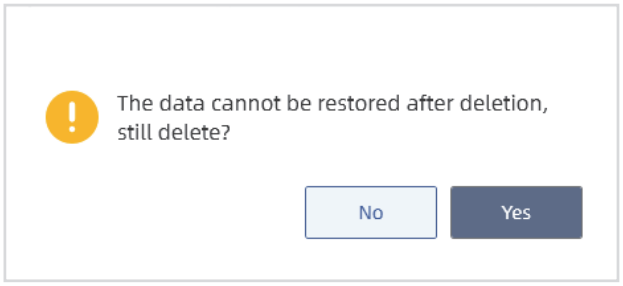
- You cannot delete validated samples.
- The ordinary user has no permission to delete the sample records.
- The data cannot be restored after deletion.

Follow below steps to delete the sample.

1. Click to select one or more sample records.
2. Click **Delete**.

   A dialog box will pop up as shown in Figure 6-5.

Figure 6-5 Deleting Sample



3. Click **Yes**.

   The selected sample record and the results are all deleted.

7 Review and Statistics

After each sample analysis, the analyzer will automatically store the sample information, result data and result marks to the retrospective database. On the review interface of HOST software, you can view the stored sample information, result data and result marks, and search, communicate and export historical samples.

You can also view the statistics results under the statistics menu on DMS software.

This chapter introduces the menu function after logging in to the software as admin.

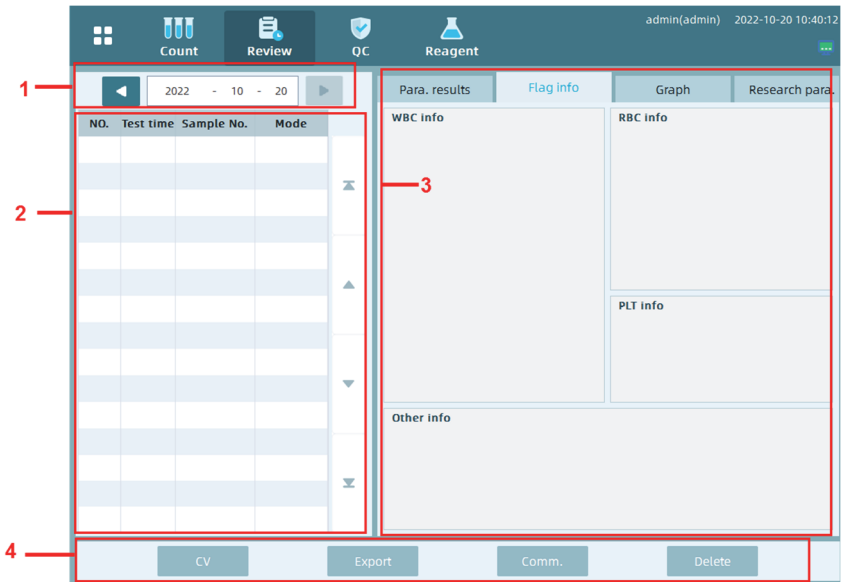
7.1 Review (HOST Software)

On the review interface of HOST software, you can view the stored sample information, result data and result marks, and search, communicate and export historical samples.

7.1.1 Interface Introduction

Click **Review** on HOST software to enter the interface. See Figure 7-1.

Figure 7-1 Review



Explanations:

- 1 - Test date

  Input the test date to be searched, and you can view all tested sample records of that day.

You can only select one day for searching.

You can also click  and  to view the sample records of the day before and the day after the current test date.

- 2 - Sample list area

  It displays all sample records whose sample analyses are completed on the test date.

- 3 - Graphs and results area

  The result area of selected sample record, including flag information, parameter results, graphs (histogram and scattergram) and research parameter results.

- 4 - Function button area

  You can communicate export, delete the sample results, and calculate CV of the sample results, etc.

7.1.2 Searching

You can view the sample records of the specified date by inputting the test date.

You can also click  and  to view the sample records of the day before and the day after the current test date.

7.1.3 Exporting

You can export the sample record to back up the sample record. There are two ways to export the sample record: export the selected records or export the records of the specified date ranges.

- Export the selected records

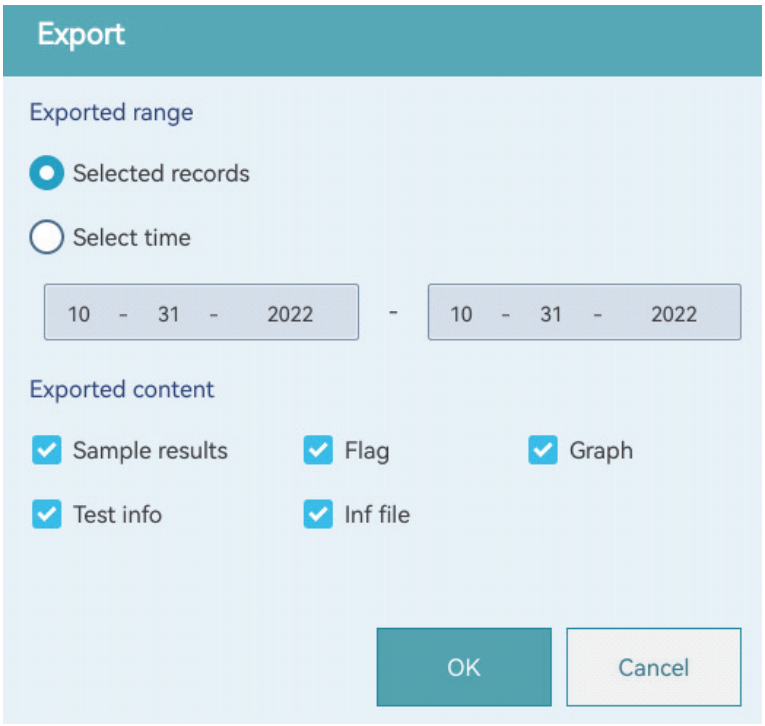
  a. Insert the USB flash disk into the USB interface of the main unit.

  b. Select the sample record to be exported in the sample list area of the review interface.

  c. Click **Export**.

     A dialog box will pop up. The default export range is **Selected records**. See Figure 7-2.

Figure 7-2 Export Selected Records



d. You can choose the exported contents according to your actual needs.

   You can export: sample results, flag alarms and graphs. All options are selected by default. The sample results and flag alarms cannot be unchecked, and graphs can be checked or unchecked according to actual needs.

e. Click **OK**.

f. In the pop-up dialog box, select the exported path, and input the backup file name.

   The system automatically creates a folder named with the device serial No. in the root directory of the USB flash disk, and all the exported contents of the main unit with the same device serial No. are exported to this folder.

   ✧ If the exported contents are sample results and flag alarms, there are two naming formats for the exported file.

   The default file naming format of the file with flag is “Review_flag__*device serial No.*_year_month_day_hour_minute_second.csv”.

   Please refer to ***6.5.2 Parameter Flag*** for the specific meaning of each flag.

   The default file naming format of the file without flag is “Review_*device serial No.*_year_month_day_hour_minute_second.csv”.

   ✧ If the exported contents are graphs, the exported file format is .png.

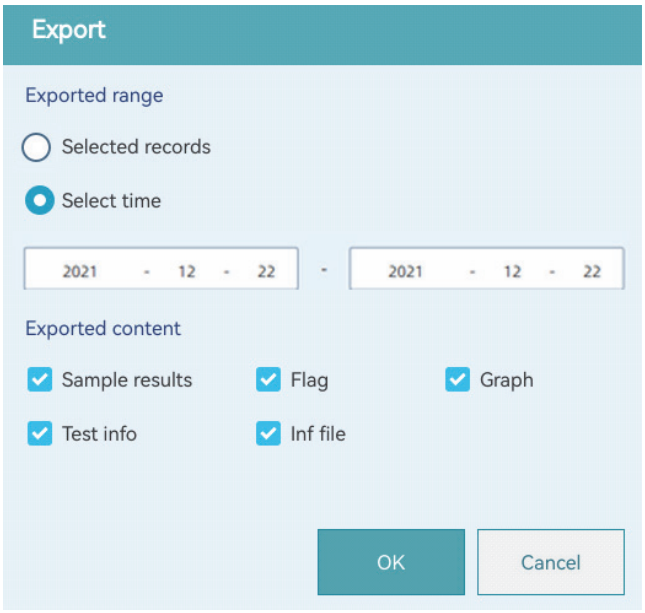
g. Click **Save**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

h. Click **OK** to close the prompt box.

- Export the records of the specified date ranges.
  a. Insert the USB flash disk into the USB port of the analyzer.
  b. Click **Export**.
  c. Select **Select time**, and set the test date range of the samples in the two date edit boxes. See Figure 7-3.

Figure 7-3 Export Records of the Specified Dates



  d. You can choose the exported contents according to your actual needs.

     You can export: sample results, flag alarms and graphs. All options are selected by default. The sample results and flag alarms cannot be unchecked, and graphs can be checked or unchecked according to actual needs.
  e. Click **OK**.
  f. In the pop-up dialog box, select the exported path, and input the backup file name.

     The system automatically creates a folder named with the device serial No. in the root directory of the USB flash disk, and all the exported contents of the main unit with the same device serial No. are exported to this folder.

     ✧ If the exported contents are sample results and flag alarms, there are two naming formats for the exported file.

     The default file naming format of the file with flag is “Review_flag__*device serial No.*_year_month_day_hour_minute_second.csv”.

     Please refer to ***6.5.2 Parameter Flag*** for the specific meaning of each flag.

     The default file naming format of the file without flag is “Review_*device serial No.*_year_month_day_hour_minute_second.csv”.

     ✧ If the exported contents are graphs, the exported file format is .png.
  g. Click **Save**.

After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

h. Click **OK** to close the prompt box.

7.1.4 Communication

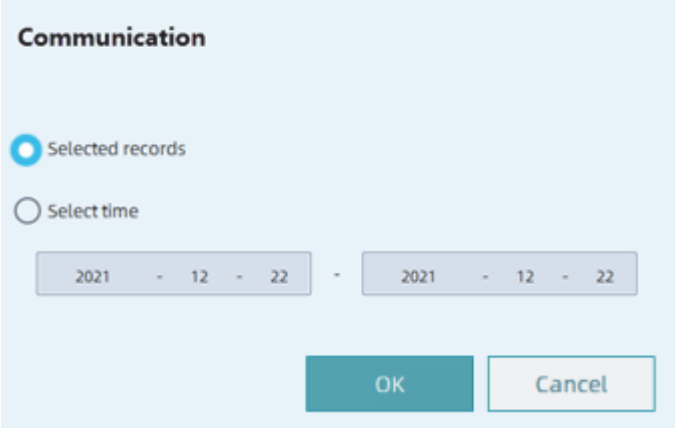
NOTE

Only when HOST and CMS/DMS are connected normally, the **Comm.** button will be lighted. Please refer to ***2.3.3 Connection of Main Unit, Sampler Unit, and DMS with CMS*** for the connection method.

In **Review** interface, you can transmit the selected sample record or the sample record within a specified date range to DMS software.

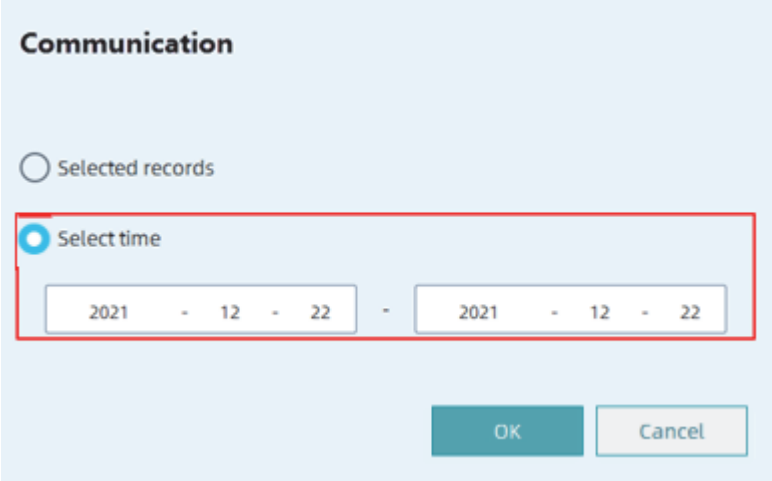
- Communicate the selected sample record
  a. Select the sample records to be deleted in the sample list area of the review interface.
  b. Click **Comm.**.
     A dialog box will pop up as shown in Figure 7-4. **Selected records** is selected by default.

Figure 7-4 Communicate the selected sample record



  c. Click **OK**.
     When the data is transmitted to DMS software, the interface prompts **Communication completed!**.
  d. Click **OK** to close the prompt box.
- Communicate the sample records within the specified date range
  a. Click **Comm.**.
  b. Select **Select time**, and set the test date range of the sample in the two date edit boxes. See Figure 7-5.

Figure 7-5 Communicate the Sample Records Within the Specified Date Range



c. Click **OK**.

When the data is transmitted to DMS software, the interface prompts **Communication completed!**.

d. Click **OK** to close the prompt box.

7.1.5 CV

You can view the repeatability index values of each parameter of the selected sample results.

NOTE

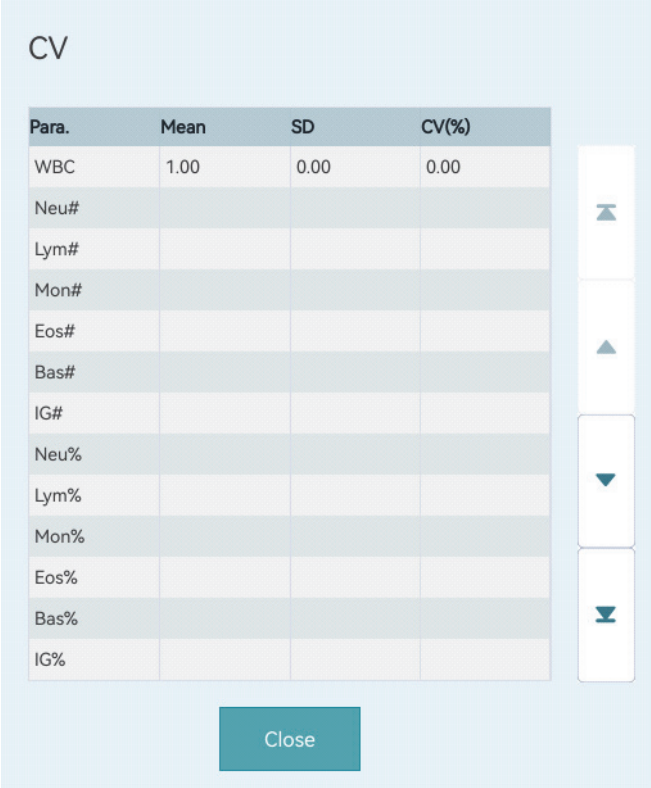
- You should select at least 3 sample records to calculate CV.
- CV calculation does not limit the type of sample records, and you can choose all records in the review list for CV calculation.

Detailed steps are shown below:

1. Click to select the sample records that participate in the calculation of the repeatability index.
2. Click **CV** button.

   The system will automatically calculate the repeatability value, and the calculation results dialog box will pop out. See Figure 7-6.

Figure 7-6 CV Calculation Results



3. Click **Close** to exit CV calculation interface.

7.1.6 Deleting

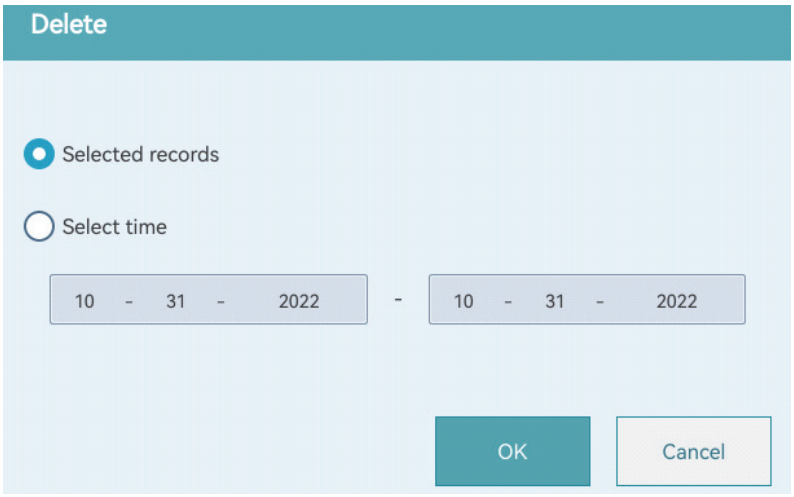
NOTE

Only the admin has the permission to delete the sampler record. The ordinary user does not have this permission.

In **Review** interface, the admin can delete the selected sample records or the sample records within a specified date range.

- Delete the selected sample records
  a. Select the sample records to be deleted in the sample list area of the review interface.
  b. Click **Delete**.
     A dialog box will pop up as shown in Figure 7-7. **Selected records** is selected by default.

Figure 7-7 Delete the selected sample records



c. Click **OK**.

The interface prompts **Deleting, please wait....**

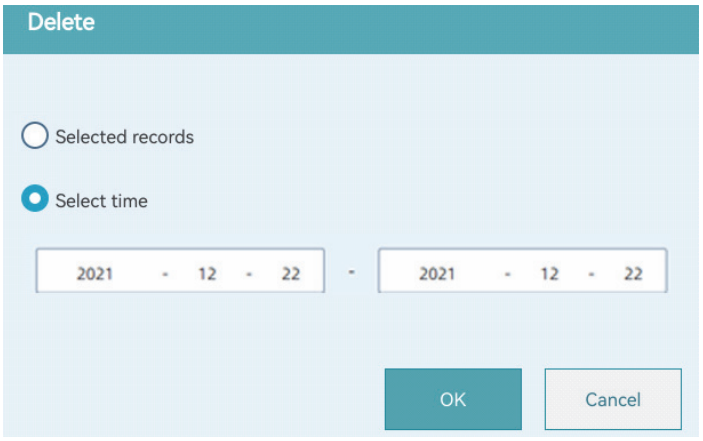
When the deletion is completed, the interface prompts **The deletion is completed!**.

- Delete the sample records within the specified date range

a. Click **Delete**.

b. Select **Select time**, and set the test date range of the sample in the two date edit boxes. See Figure 7-8.

Figure 7-8 Delete the Sample Records Within the Specified Date Range



c. Click **OK**.

The interface prompts **Deleting, please wait....**

When the deletion is completed, the interface prompts **The deletion is completed!**.

7.2 Statistics (DMS Software)

The statistics menu of DMS software provides sample statistics function.

Click **Statistics** to enter workload statistics interface. You can set search conditions and view the

workload's statistics results of specified conditions; you can also print preview, print, or export the searched results.

7.2.1 Searching

You can search the workload statistics results under corresponding conditions within the specified date range. Detailed steps are as follows.

1. Set the date range.

   Set the date range in the two date edit boxes.

2. Set other search conditions.

   a. You can check one or more condition categories according to actual needs.

      The conditions include test item, patient type, department, ward, charge type, sample type, ordering personnel, testing personnel, and validating personnel.

      Check at least one category. Each time a condition category is checked, the corresponding column will be added to the statistics result list on the right side of the interface.

   b. Select the needed option from the drop-down list on the right of the checked condition category or manually input the needed option.

3. Click **Search**.

   The statistics result list on the right side of the interface displays the results that meet the conditions.

7.2.2 Print Preview

Before printing the statistics results, you can first click **Print preview** to browse the results to be printed. And click **Print** after confirming.

7.2.3 Printing

NOTE

You can print only when the external computer is properly connected with the printer.

If you need to print the workload statistics results, you can follow the steps below.

1. Follow the method of ***7.2.1 Searching*** to search the workload statistics results of the required conditions.
2. Click **Print**.

7.2.4 Exporting

If you need to export the workload statistics results, you can follow the steps below.

1. Follow the method of ***7.2.1 Searching*** to search the workload statistics results of the required conditions.
2. Click **Export**.
3. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default exported file name is “Workload Statistics_yyyyMMdd_hhmmss.csv”, in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
4. Click **Save**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

7.2.5 Retest Rate Statistics

Click **Statistics** > **Retest Rate Statistics** to enter the retest rate statistics interface. You can set by Day or by Month. Set a specific date and click **Search**, and the retest statistics graph under specified conditions will be displayed.

8 Reagent Management

This chapter introduces the methods of replacing reagents, testing reagent card, extending the service life of the reagent and viewing reagent replacing history.

Warning

- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while contacting them and the relevant areas in the laboratory.
- Once the reagent accidentally comes in contact with your skin, rinse with plenty of water immediately and receive medical treatment if necessary. If you accidentally get any of the reagent into your eyes, rinse with plenty of water immediately, and receive medical treatment.

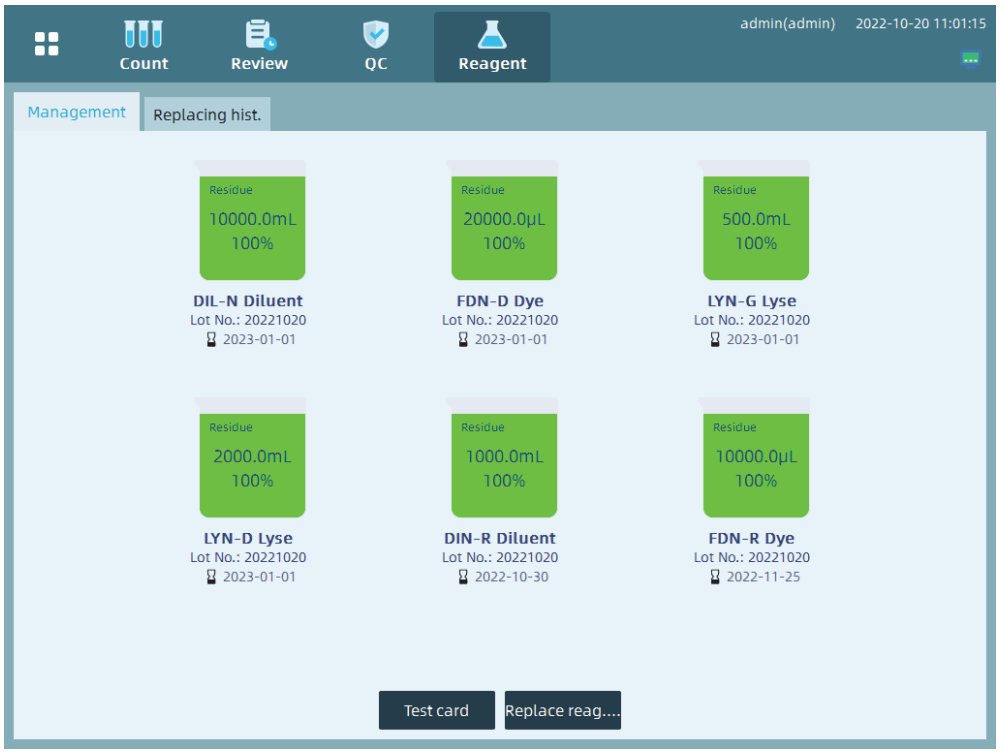
NOTE

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- You should perform background test after replacing the reagent to ensure the background values are within the normal ranges, and to make preparation for the sample analysis.
- When replacing reagents, avoid spilling liquid on the external computer, mouse, keyboard, external barcode scanner, or the printer.

8.1 Interface Introduction (HOST software)

Click **Reagent**, and it enters the reagent management interface by default. See Figure 8-1.

Figure 8-1 Reagent Management



Explanations:

- You can view the reagent name, lot No., expiry date and remaining amount of each reagent.
- The unit of diluent and lyse is displayed in mL, and the unit of dye is displayed in μL, both rounding to 1 decimal place.
- If the main unit disables the RET channel, the reagent management interface displays the information of diluent and lyse only. If you need to disable the RET channel, contact Dymind customer service department or the local agent.

8.2 Replacing Reagents

If you need to replace reagent, you should set the reagent information on reagent management interface, including expiry date and the remaining amount. Replace the reagent after completing the reagent setting.

Different reagents are replaced in different methods. The replacement methods of open and closed reagents are introduced as follows.

8.2.1 Open System

The open reagent of the analyzer is DIL-N diluent.

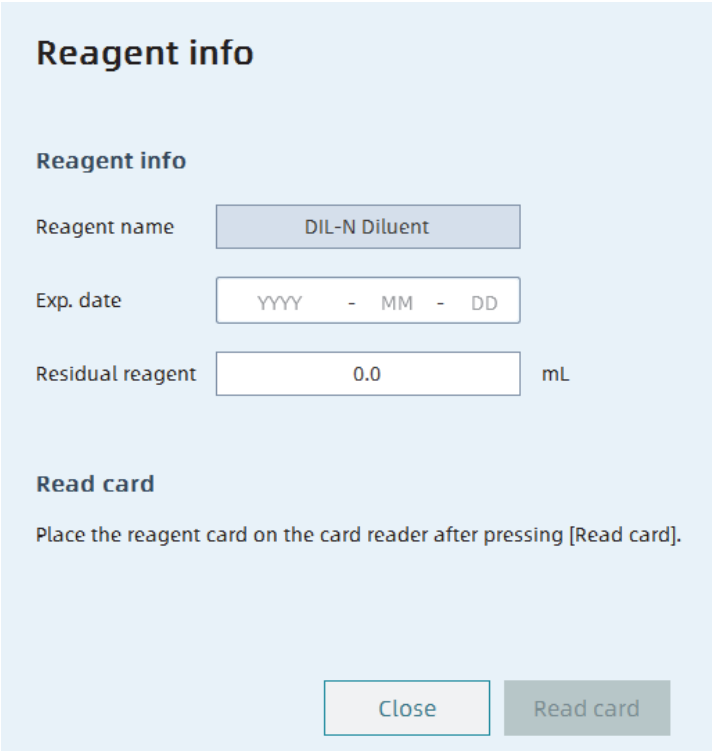
If you need to change the DIL-N diluent, take the following steps.

1. Refer to Figure 2-3 of ***2.3.2 Reagent Connection*** for DIL-N diluent connection.

2. Click **DIL-N diluent** to be replaced on the reagent management interface.

   It enters the reagent information setting interface. See Figure 8-2.

Figure 8-2 Reagent Information



3. Refer to Table 8-1 to set relevant information of DIL-N diluent.

Table 8-1 Parameter Description of Reagent Information

Parameter	Meaning	Operation
Reagent name	The name of the reagent.	It will be displayed automatically. Read only.
Exp. date	The expiry date of the reagent after first opening.	Click the date control to set. The input sequence of each control is consistent with the date format displayed on the upper right corner of HOST interface. For example, if the date format is “yyyy/MM/dd”, then the input sequence is year, month, and day. **Note** The expiry date of the reagent can be no later than the expiry date indicated on the packaging and cannot be earlier than the current system date.

Parameter	Meaning	Operation
Residual reagent	The current residual volume of the reagent.	Input in the textbox. **Note** The unit of diluent and lyse is displayed in mL, and the unit of dye is displayed in μL, both rounding to 1 decimal place.

4. Click **Close**.

   Save the reagent information and exit the reagent information setting interface.

5. Click  > **Maintenance** > **Replace & perfuse reagent** to enter the interface.

6. Click "**Replace DIL-N Diluent**".

   The interface prompts **Performing "Replace DIL-N Diluent", please wait...**.

   When the replacing is completed, the interface prompts **"Replace DIL-N Diluent" is completed!**.

7. Click **OK** to close the prompt box.

8.2.2 Closed Reagent

The closed reagents of the analyzer include DIN-R diluent, LYN-D lyse, LYN-G lyse, FDN-D dye, and FDN-R dye. You can replace the reagents according to this section.

Replacing DIN-R diluent, LYN-D lyse, and LYN-G lyse

The reagent card and bucket of DIN-R diluent, LYN-D lyse, and LYN-G lyse are separate to each other.

The following takes the replacement of DIN-R diluent as an example to introduce the replacement methods of these three types of closed reagents.

1. Refer to Figure 2-3 of ***2.3.2 Reagent Connection*** for reagent connection.
2. Click the icon of DIN-R diluent on the reagent management interface.

   It enters the reagent information setting interface.

   The card reading area displays **Place the reagent card on the card reader after pressing [Reading]**.

3. Click Read card.
4. Place the RF card of the DIN-R diluent on the card reading position of the main unit.

   The reagent information is being read.

   The expiry date and residual volume in the reagent information area will be refreshed after reading successfully. The card reading area displays **DIN-R diluent needs to be replaced after loading. Please make sure that the new reagent is connected, and click "OK" to perform the replacement immediately. DIL-R diluent card reading successfully**.

NOTE

If the card reading fails, please use the correct card to re-read the card according to the prompt information on the software interface.

5. Click **OK**, and the replacement will be operated automatically.

Replace FDN-D dye and FDN-R dye

The reagent cards of FDN-D dye and FDN-R dye are directly attached to the reagent bucket, which can identify reagent information automatically.

The following takes the replacement of FDN-D dye as an example to introduce the replacement methods of these two types of closed reagents.

1. Refer to Figure 2-6 of ***2.3.2.2 Connecting the Dye*** to correctly place the new FDN-D dye.
2. Click the icon of FDN-D dye on the reagent management interface.

   It enters the reagent information setting interface.

   The card reading area displays **Please put the dye reagent bottle into the reagent tank in the correct direction!**.
3. Click Read card.

   The reagent information is being read.

   The expiry date and residual volume in the reagent information area will be refreshed after reading successfully. The card reading area displays **FDN-D dye needs to be replaced after loading. Please make sure that the new reagent is connected, and click "OK" to perform the replacement immediately. FDN-D dye card reading successfully**.

NOTE

If the card reading fails, please use the correct card to re-read the card according to the prompt information on the software interface.

4. Click **OK**, and the replacement will be operated automatically.

8.3 Card Testing

You can check the reagent information stored in the reagent card through the card testing function, including the reagent name, expiry date, specifications, cipher text of agent information and the availability.

- Reagent name: the name of the reagent stored in the reagent card.
- Exp. date: the expiry date of the reagent stored in the reagent card.
- Specifications: the specifications of the reagent stored in the reagent card. The unit is mL.

- Agent info ciphertext: the ciphertext of the corresponding agent information in the reagent card. When it is empty, it means it is standard reagent.
- Available or not: the status of the reagent card, including used, available, and not available.
  - Used: the reagent currently used by the main unit is displayed as **Used**.
  - Available: the reagent that can be used by the current main unit but have not been used before is displayed as **Available**.
  - Not available: the reagent that cannot be used by the current main unit is displayed as **Not available**.

Take the following steps to perform card testing operation.

1. Click **Test card** on the reagent management interface.
2. Click Read card.
3. Place the reagent card on the card reading position of the main unit.

   The reagent information is being read, and is refreshed.
4. Click **Close**.

   Exit the card testing interface.

8.4 Extending Reagent Service Life

NOTE

- The **Extend life** button is visible only when the main unit is the closed system.
- The **Extend life** button is lighted only when the main unit reports that a certain reagent is insufficient.

When you have no valid reagent card, in order to ensure the normal sample analysis of the main unit, you can apply to extend the service life of the reagent. You can extend the service life of the reagent for 10 times on each main unit, and the extended time is 72 hours (three natural days).

Take the following steps to perform service life extending operation.

1. Click **Extend life** on the reagent management interface.
2. On the pop-up interface, select the reagent whose service life needs to be extended.
3. Click **Extend**.

8.5 Reagent Replacing History

Click **Reagent** > **Replacing Hist.** to enter the reagent replacing history interface. You can view the history information of the closed reagent replacement of the closed system.

9 Quality Control

Auto Hematology Analyzer may produce a certain degree of error during long-term use. The existence of error may result in wrong or unreliable analysis results.

Quality control (QC) refers to the daily monitoring of the performance of the device by using controls whose parameters have been assigned with values already.

In order to ensure the reliability of sample analysis results, it is recommended that you use different levels of controls to perform QC on each test item every day. When using a new lot of controls, you should use the new controls and old controls together for 5 days, and perform QC twice a day. The results should be within the reference range of the instructions for the controls.

There are 3 kinds of QC methods: L-J QC, multirule QC and X-B moving average QC. The chapter introduces the content of L-J QC and X-B QC. Multirule QC is similar to L-J QC, which will not be repeated here.

9.1 L-J QC

On L-J QC, you can perform quality control to the test parameters. You can select the QC mode according to the actual need, and make QC setting to the corresponding parameters. After completing QC setting, you can perform quality control to the corresponding parameters according to the set QC mode. Each QC file can set one lot No., corresponding to high, normal or low quality control.

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

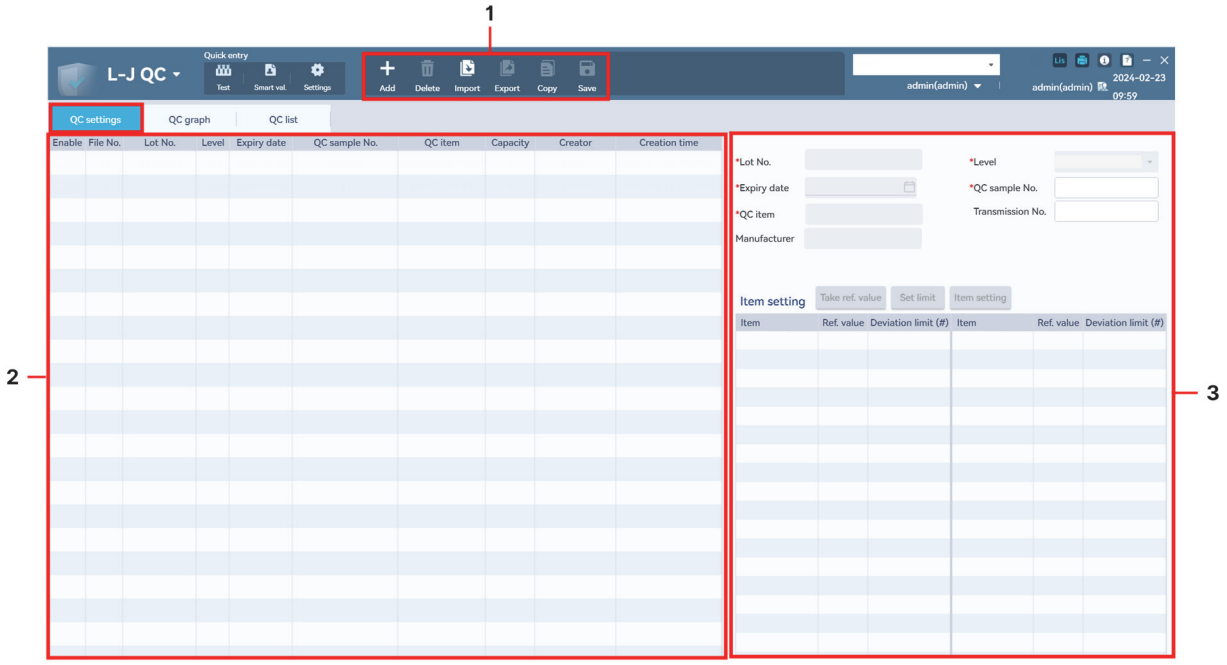
NOTE

- You should use the Dymind-specified controls and reagents only. Store and use the controls and reagents by following the instructions for the controls and reagents.
- Controls beyond their expiry date shall not be used. Controls (similar to standard blood samples) must be returned to the room temperature and well mixed before use.

9.1.1 Control Setting (DMS Software)

Click **QC** > **L-J QC** > **QC settings** to enter the interface. See Figure 9-1.

Figure 9-1 Control Setting



Explanations:

- 1 - Function button area

  It includes add, delete, import, export, copy and save.

- 2 - QC file list area

  It displays the current QC files.

  - ➢ You can place the mouse between the two column headers, long press and drag the mouse left and right to adjust the column width.
  - ➢ Double click any line of data in the list, it will automatically jump to the QC graph interface, and display the QC graph of the QC file.

- 3 - QC file detailed information area

  It displays the detailed information of the selected QC file.

9.1.1.1 Inputting QC Information

Before analyzing the new batch of controls, you should set a QC file for each batch of controls.

When the connections between the main unit, CMS, and DMS are normal, after you input the QC file information on DMS software and enable the file, DMS software will automatically synchronize the enabled QC file to HOST software.

You can input the QC information by the following three ways.

- Manual input

- Import by file
- Import by QR code

Inputting QC Information Manually

You can input the QC information on the L-J control settings interface on DMS software directly. Follow below steps to input the information.

1. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Add**.

   A blank line is added in the QC file list area.
4. Refer to Table 9-1 to set the relevant information of the control in the QC file detailed information area.

Table 9-1 QC File Information

Parameter	Parameter Explanation	Operation Explanation
File No.	QC file No.. The system provides 999 QC files for user settings.	Read only. It is generated automatically.
Lot No.	The lot No. of the control.	Input in the edit box, required field. **Note** You cannot leave it blank. The input length is 1-25 digits. And it supports characters, numbers, letters and special characters, but not Chinese.
Level	The level of the control, including ● High ● Normal ● Low	Select from the drop-down list, required field.
Expiry date	The expiry date of the control.	Select from the date control, required field. The input sequence of each control is consistent with the date format displayed on the upper right corner of DMS interface. For example, if the date format is “yyyy/MM/dd”, then the input sequence is year, month, and day.

Parameter	Parameter Explanation	Operation Explanation
QC sample No.	The number of the QC sample.	Input in the edit box, required field. **Note** • You cannot leave it blank. The input length is 1-25 digits. • The end character of the QC sample No. must be a number. • If the QC sample No. is the same as the enabled QC sample No., it will prompt **The enabled QC sample No. cannot be repeated!** when you save the number, please input a valid QC sample No. again. • If the QC sample No. is the same as the enabled QC sample No. on the multirule QC interface, it will prompt **The enabled QC sample No. cannot be the same with the multirule QC file No.!** when you save the number, please input a valid QC sample No. again.
Transmission No.	The transmission No. of the QC file.	Input in the edit box. This field is left blank by default. **Note** The input length is 0 to 25 digits. It supports characters, numbers, letters and special characters, but not Chinese.
QC item	QC mode of the control, including: • Whole Blood-CBC+DIFF • Whole Blood-RET • Whole Blood-CBC+DIFF+RET	Select from the drop-down list, required field. Whole Blood-CBC+DIFF is selected by default.
Enable	Set whether to enable the QC file. • Checked (default): the QC sample No. of the QC file is in use, that is, the file information function is enabled. • Unchecked: Not to enable the QC file.	Select according to the actual situation. **Note** • If there are QC files with the same QC sample No., only one of them can be enabled. • When the connections between the main unit, CMS, and DMS are normal, after checking **Enable**, DMS will automatically synchronize the enabled QC files to HOST software.

Parameter	Parameter Explanation	Operation Explanation
Manufacturer	The manufacturer information of the control.	Fill in the textbox as necessary. This field is optional and is left blank by default. Support input of any characters with an input length of 0 to 10 digits
Reference value	The reference values of QC parameters.	According to the control target value table of the corresponding lot No., input the reference value in the **Ref. value** cell corresponding to the item in the item list.
Deviation limit	The deviation limit of QC parameters.	According to the control target value table of the corresponding lot No., input the deviation limit in the **Deviation limit** cell corresponding to the item in the item list. **Note** Click **Set deviation limit** to adjust the display form of the deviation limit or the calculation method of the deviation limit in the preset value. • Select **2SD** or **3SD** in **By SD**, then the deviation limit is calculated as 2 times or 3 times SD. • Select **2CV** or **3CV** in **By CV**, then the deviation limit is calculated as 2 times or 3 times CV.
Capacity	The total number of QC data that already exists in the current QC file.	Read only.
Creator	It displays the user name who logs in to DMS software when setting the current QC file.	Read only.
Creation time	It displays the system time when setting the current QC file.	Read only.
Item setting	It displays the parameters to be monitored.	Select the **Item setting**, and set the item as necessary.

5. Click **Save** to save the input QC information.

Importing QC Information by File

You can input the QC information by importing QC files in .qcs format.

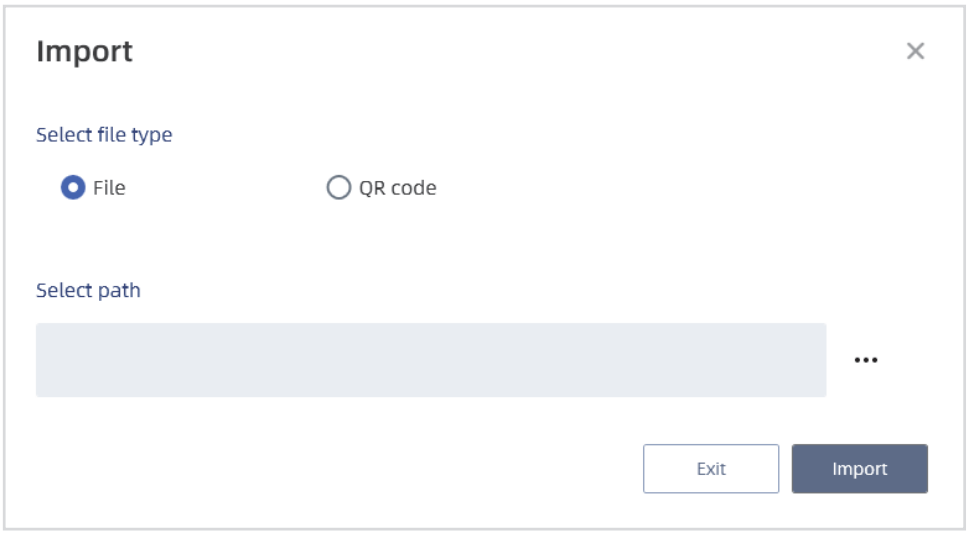
NOTE

If you need to input the QC information, please consult the customer service engineer for QC files in .qcs format.

1. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Add**.

   A blank line is added in the QC file list area.
4. Click **Import**, and select imported type as **File**. See Figure 9-2.

   Figure 9-2 Import



5. Click " ••• ".
6. Select the .qcs QC file to be imported.
7. Click **Open**.
8. Click **Import**.

   The interface displays the QC information of the file after importing successfully.
9. Check if the QC information is correct, and then click **Save.** The import of the QC information is completed.

   You can edit the QC information on the interface directly.

   For detailed information of the parameters on the interface, please refer to Figure 9-1.

Importing QC Information by QR Code

You can input the QC information by scanning the QR code with the QC information.

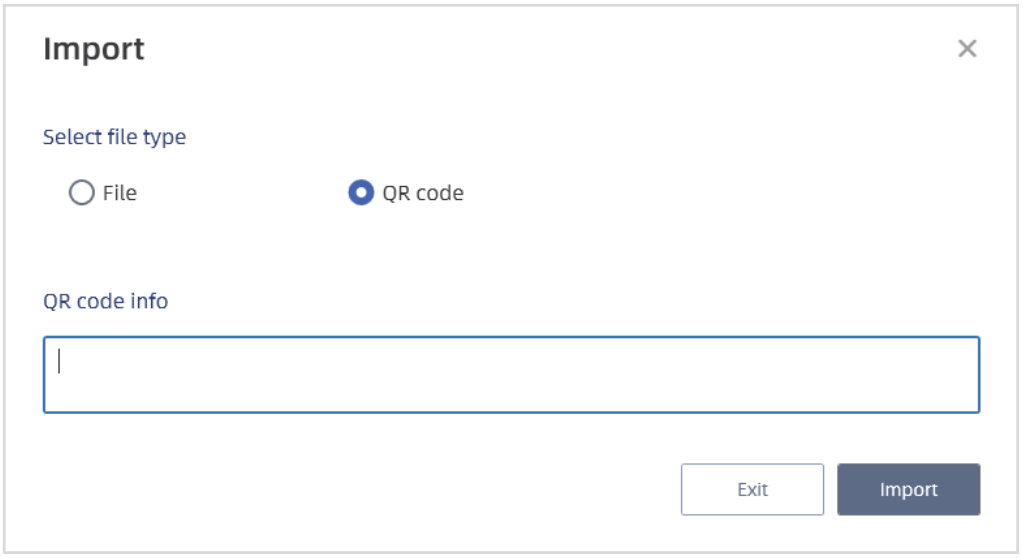
NOTE

- When the barcode scanner is turned on, there is a laser. Do not look directly at the beam.
- Please consult the customer service engineer for the QC target value table with QC code.
- Please purchase the barcode scanner provided or specified by Dymind separately.

1. Before importing the QC information, you need to connect the QR code scanner to the USB interface of the external computer first.
2. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
3. Select the main unit from the device drop-down list.
4. Click **Add**.

   A blank line is added in the QC file list area.
5. Click **Import**, and select imported type as **QR Code**. See Figure 9-3.

   Figure 9-3 Import



6. Hold the scanner to scan the QR code.

   After hearing a beep, which means that the scanning succeeds, the interface displays the QR code information.
7. Click **Import**.

   The interface displays the QC information of the QR code after importing successfully.
8. Check if the QC information is correct, and then click **Save.** The import of the QC information is completed.

   You can edit the QC information on the interface directly.

   For detailed information of the parameters on the interface, please refer to Figure 9-1.

9.1.1.2 Reading Saved Reference Value

If DMS software has saved the reference value (reference value and deviation limit) of the current level, you can save them to the current QC file.

1. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Add**.

   A blank line is added in the QC file list area.
4. Refer to Figure 9-1 to set the parameter information of the QC file, including lot No., level, expiry date, QC sample No. and QC item.
5. Click **Take ref. value** to read the parameter reference value and deviation limit corresponding to the current level saved in the **Calc. ref. value** in the QC graph into the current QC file.

   NOTE

   If the reference values are not provided for some items, you need to manually input the reference values and deviation limits; if you do not want to perform quality control on some items with reference values, you can manually delete the reference values and deviation limits after taking the reference values.
6. Click **Save** to save the QC information.

9.1.1.3 Exporting QC Information

You can export the QC information by the following two ways on DMS software.

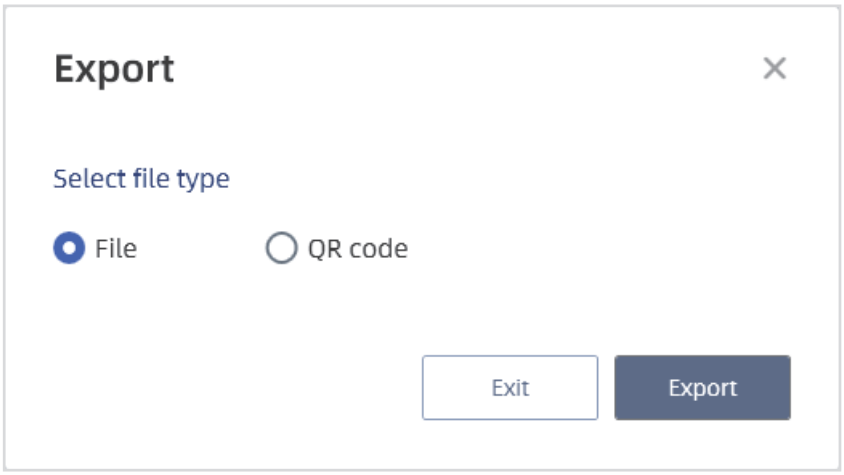
- Export by file
- Export by QR code

Exporting QC Information by File

You can export the QC file in .qcs format.

1. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select the sample to be exported on the sample list area.
4. Click **Export**, and select exported type as **File**. See Figure 9-4.

Figure 9-4 Export



5. Click **Export**.
6. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default export file name is "QCFile_*file No._lot No._level*_yyyyMMdd_hhmmss.qcs", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
7. Click **Export**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

Exporting QC Information by QR Code

You can export the QC files in .bmp format.

1. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Export**, and select exported type as **QR Code**.
4. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default export file name is "QCFile_*file No._lot No._level*_yyyyMMdd_hhmmss.bmp", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.

5. Click **Export**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

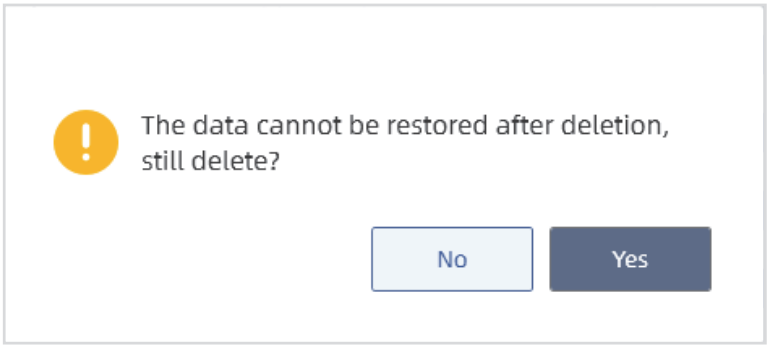
9.1.1.4 Deleting QC File

If you want to delete the QC file that is no longer in use, you can follow the steps below on DMS software.

1. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select the QC file to be deleted in the QC file list area.
4. Click **Delete**.

   A dialog box will pop up as shown in Figure 9-5.

   Figure 9-5 Deleting QC File



5. Click **Yes**.

   The selected QC file and its QC results are deleted.

9.1.1.5 Copy QC Files

NOTE

Only QC files with data can be copied.

If you want to copy a QC file, you can follow the steps below on the DMS software.

1. Click **QC** > **L-J QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select the QC file that you want to copy.
4. Click **Copy**.

   A new line with the copied content is added in the QC file list area.

5. Click **Save** to save the copied QC information.

9.1.2 QC Analysis (HOST Software)

When the QC setting is completed, you can perform QC analysis on HOST software by one of the following ways.

- Perform QC analysis on the **QC** interface
- Perform QC analysis on the **Count** interface

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

Warning

- The tip of the sampling probe is sharp and may contain substance with bio-contamination hazards. Be careful when operating the main unit. Do not contact the sampling probe.
- The sample may spill from the uncapped tube and result in bio-contamination. Be careful when operating an uncapped tube with sample.
- A ruptured blood collection tube may cause personal injury and/or biological hazards. When loading the blood collection tube into the blood collection tube holder or removing the blood collection tube from the blood collection tube holder, be careful not to damage the blood collection tube.
- Keep your clothes, hair and hands away from the moving parts to avoid being caught or crushed.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while contacting them and the relevant areas in the laboratory.
- Once the reagent accidentally comes in contact with your skin, rinse with plenty of water immediately and receive medical treatment if necessary. If you accidentally get any of the reagent into your eyes, rinse with plenty of water immediately, and receive medical treatment.

Caution

- Running quality controls in presence of errors may result in incorrect analysis results. If there is an error reported during the QC analysis, please remove the error before continuing the QC analysis.
- Sample agglutination may result in incorrect analysis results. Check if the control agglutinates before the QC analysis; if it does, deal with it according to the related laboratory operation requirements.

NOTE

- Use the control designated by Dymind only, and store and use the control in strict accordance with the instructions for use. Using other controls may result in incorrect QC results.
- Controls beyond their expiry date shall not be used. Controls must be returned to the room temperature and well mixed before use.

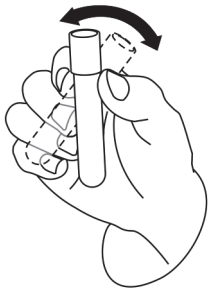
9.1.2.1 Performing QC analysis on the QC interface

Perform QC analysis on the QC interface of HOST software after completing QC setting.

Performing QC analysis on the QC interface supports manual sampling only. The detailed steps are as follow.

1. Click **QC** on HOST software to enter the interface.
2. Select the QC file No. to perform the QC analysis.
3. Check if the lot No. and level of the control to be analyzed are the same with the QC file, and if the control is within the expiry date.
4. Check if the QC mode is correct, and if the indicator of the main unit is green light staying lit.
5. Prepare the control in according to the set QC mode and the instructions for use of the control.
6. Mix the prepared control well according to the method shown in Figure 9-6.

   Figure 9-6 Mixing the Control

7. Press the [MODE] key of the main unit to switch to manual sampling mode.

   Then the sample delivery component moves to the manual sampling position.

   If the main unit is manual sampling mode already, you can directly perform step 8.

8. Place the control to the venous whole blood collecting position of the sample delivery component.
9. Press the [RUN] key of the main unit to start the QC count.

   The sample delivery component automatically moves under the sampling probe to complete the blood collecting.

   Then the sample delivery component moves to the manual sampling position. Please take away the control.

9.1.2.2 Performing QC analysis on the Count interface

After completing the QC settings, you can place the control with the daily sample, and perform auto QC on the **Count** interface of HOST software. When the analysis is completed, the system will store the results to the QC file corresponding to the QC sample No.

NOTE

Do not place the control and the daily sample on the same row of tube rack. The control should be placed on an independent row of tube rack.

The QC analysis performed on the **Count** interface only supports auto sampling. Take the steps as follows.

1. Input QC information on the DMS software. Make sure to set the QC sample No.
2. Click  > **Auto sampling** on the CMS software, and then check **Obtain DMS sample info** and **Automatically scan sample No.**
3. Prepare the control according to the set QC mode and the instructions of the control, and place the control in the daily samples
4. Click to enter the **Count** interface of HOST software.
5. Click the Start button () on CMS software.

   When the system recognizes that the sample number is the QC sample number, it will perform a QC analysis on the main unit. After the analysis is over, the QC results are automatically transferred to the DMS software.

9.1.3 QC Result Review (DMS Software)

NOTE

The QC interface of HOST software only displays the last QC result of each QC file. You can view the other records on DMS software.

When the QC analysis is completed, you can view the QC graph and QC list on the L-J QC interface of DMS software, and search, print, deal with outliers and set outlier rules to the QC results.

9.1.3.1 QC Graph

Click **QC** > **L-J QC** > **QC graph** to enter the interface. You can view, delete and print the QC graph.

Searching

Select the main unit, file No., and set the start and end dates in the search condition area, and the QC graph that meets the conditions will be automatically filtered out.

New Vial

If the QC results are obtained by analyzing a new vial of control from the same batch, you should mark the QC points of the new vial to distinguish the QC results from the old one. The steps for marking new vial QC points are as follows:

1. Click the last QC point of the old vial on the QC graph (the previous QC point of the new vial).
2. Click **New Vial**.

   A new vial edit vertical line appears between the selected QC point and the QC point of the new vial. All the QC results after this mark are the analysis results of the new vial control.
3. After opening the new vial of the same batch control again and saving its QC analysis results, click the **Cancel new vial** button to cancel the original mark, and then follow steps 1 to 2 to mark the QC point of the current new vial.

Deleting

NOTE

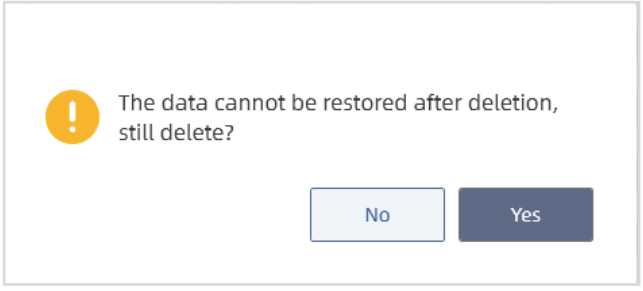
The QC data cannot be restored after deletion.

Follow below steps to delete.

1. Click **QC** > **L-J QC** > **QC graph** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select the QC data to be deleted in the QC graph.
4. Click **Delete**.

   A dialog box will pop up as shown in Figure 9-7.

Figure 9-7 Deleting QC Graph Data



5. Click **Yes**.
   All the selected QC data are deleted.

Printing

NOTE

You can print only when the external computer is properly connected with the printer.

Follow below steps to print.

1. Click **QC** > **L-J QC** > **QC graph** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Print**.
4. Select the item to be printed.
   All items are selected by default.
5. Click **OK** to enter the print preview interface.
6. Click **Print**.
   The QC graph is printed.

Outlier Handling

When performing QC analysis, you should record the reason of outliers if there appears any outlier. The detailed steps are as follows.

1. Select the outlier data that has not been handled.
2. Click Outlier handling.
3. Select the outlier reason.
   If there is no suitable option, select **Others**, and input the reason manually in the edit box.
4. Click **OK** to save the setting, and exit the interface.

Calculating Reference Value

The user can perform the operation of calculating the reference value to obtain the reference value, which can be used to directly take the reference value when setting the control later, without manually inputting the reference value and deviation limit of the item.

The steps for calculating the reference value are as follows.

1. Click **Calc. ref. value**.
   It enters the reference value calculating interface. It displays all the QC results of current QC graph.
2. Set the date range.

Set the date range in the two date edit boxes.

The QC results within the specified date range are displayed in the list, and the Mean, SD, CV (%) of each item are automatically calculated.

- If the data involved in the calculation is less than 20 groups, the number font color of Mean, SD, CV (%) is light gray.
- If the data involved in the calculation is greater than or equal to 20 groups, the number font color of Mean, SD, CV (%) is normal.

3. Click **OK**.

   The reference value is saved and the system exits the reference value calculating interface.

9.1.3.2 QC List

Click **QC** > **L-J QC** > **QC list** to enter the interface.

You can view the QC list, delete, edit the results, restore the results, print, communicate and export on this interface.

Searching

Select the main unit, file No., and set the start and end dates in the search condition area, and the QC graph that meets the conditions will be automatically filtered out.

Deleting

NOTE

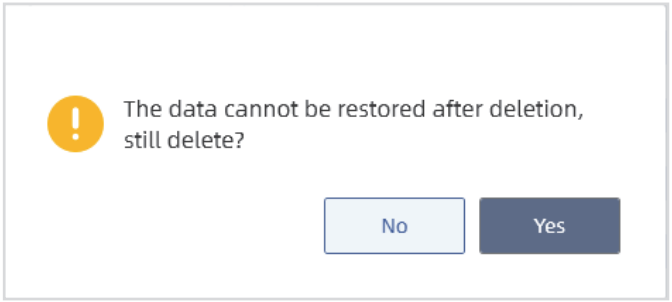
The QC data cannot be restored after deletion.

Follow below steps to delete.

1. Click **QC** > **L-J QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select one or more QC data to be deleted in the QC list.
4. Click **Delete**.

   A dialog box will pop up as shown in Figure 9-8.

Figure 9-8 Deleting QC List Data



5. Click **Yes**.

   All the selected QC data are deleted.

Editing Results

Click **Edit result** or double click a cell in the QC list to edit the selected QC data.

The edited data will be marked with a **E**.

Restoring Results

Select the edited data and click **Restore result** to cancel the editing to the QC result. The E mark in front of the restored data will disappear.

Printing

NOTE

You can print only when the external computer is properly connected with the printer.

Follow below steps to print.

1. Click **QC** > **L-J QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Print**.
4. Select the item to be printed.

   All items are selected by default.
5. Click **OK** to enter the print preview interface.
6. Click **Print**.

   The QC list is printed.

Communication

NOTE

If **Auto comm. QC data** is checked on LIS communication settings interface, after DMS software receives the QC analysis results transmitted by the main unit, it will automatically transmit the results to LIS. Please refer to ***11.3.8 LIS Communication Settings*** for details.

Follow below steps to transmit the QC list data to LIS on the QC list interface.

1. Click **QC** > **L-J QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select one or more QC data.
4. Click **Comm.** to transmit the QC data to LIS.

- If all are communicated successfully, the interface prompts ***X* pcs are communicated successfully!**.
- If some fails, the interface prompts **The communication is completed! Succeed: *X* pcs, fail: *Y* pcs. Reason for failure: *XXXX*!**.
- If all fail, the interface prompts **The communication is completed! Fail: *X* pcs. Reason for failure: *XXXX*!**.

Exporting

1. Click **QC** > **L-J QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Export**.
4. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

   - The exported path defaults to the external computer desktop, or the path selected last time.
   - There are two naming formats for the exported file.
     - The default exported file name of the file with flag is "QC_L-J_Data_*lot No.*_yyyyMMdd_hhmmss.csv", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting. Please refer to ***6.5.2 Parameter Flag*** for the specific meaning of each flag.
     - The default exported file name of the file without flag is "QC_L-J_Data_*lot No.*_yyyyMMdd_hhmmss_noflag.csv", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
5. Click **Save**.

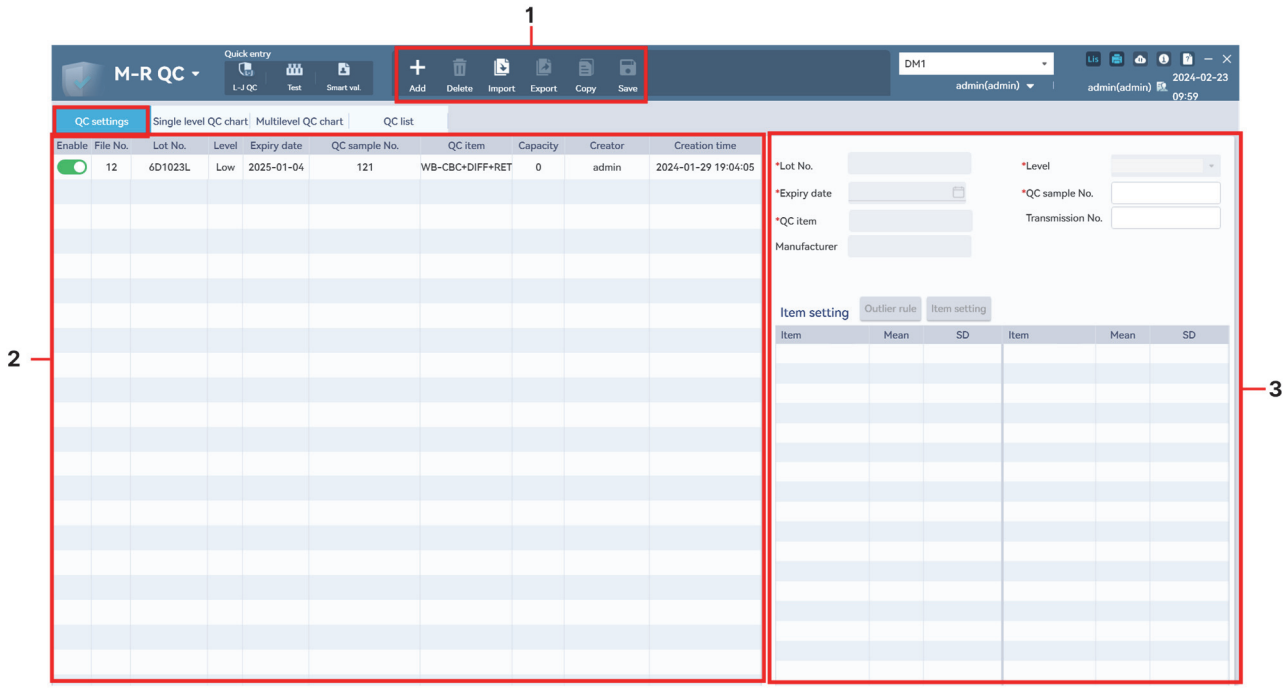
   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

9.2 Multi-rule QC

9.2.1 QC Settings (DMS Software)

Click **QC** > **M-R QC** > **QC settings** to enter the interface. See Figure 9-9.

Figure 9-9 Multi-rule QC



Explanations:

- 1—Function button area

  It includes add, delete, import, export, copy and save.

- 2—QC file list area

  It displays the current QC files.

- 3—QC file detailed information area

  It displays the detailed information of the selected QC file.

9.2.1.1 Inputting QC Information

Before analyzing the new batch of controls, you should set a QC file for each batch of controls.

When the connections between the main unit, CMS, and DMS are normal, after you input the QC file information on DMS software and enable the file, DMS software will automatically synchronize the enabled QC file to HOST software.

You can input the QC information by the following three ways.

- Manual input
- Import by file
- Import by QR code

Inputting QC Information Manually

You can input the QC information on the M-R QC settings interface on DMS software directly. Follow below steps to input the information.

1. Click **QC** > **M-R QC** > **QC settings** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Click **Add**.

   A blank line is added in the QC file list area.
4. Refer to Table 9-2 to set the relevant information of the control in the QC file detailed information area.

Table 9-2 QC File Information

Parameter	Parameter Explanation	Operation Explanation
Lot No.	The lot No. of the control.	Input in the edit box, required field. **Note** You cannot leave it blank. The input length is 1-25 digits. And it supports characters, numbers, letters and special characters, but not Chinese.
Level	The level of the control, including ● High ● Normal ● Low	Select from the drop-down list, required field.
Expiry date	The expiry date of the control.	Select from the date control, required field. The input sequence of each control is consistent with the date format displayed on the upper right corner of DMS interface. For example, if the date format is “yyyy/MM/dd”, then the input sequence is year, month, and day.

Parameter	Parameter Explanation	Operation Explanation
QC sample No.	The number of the QC sample.	Input in the edit box, required field. **Note** • You cannot leave it blank. The input length is 1-25 digits. • The end character of the QC sample No. must be a number. • If the QC sample No. is the same as the enabled QC sample No., it will prompt **The enabled QC sample No. cannot be repeated!** when you save the number, please input a valid QC sample No. again. • If the QC sample No. is the same as the enabled QC sample No. on the multirule QC interface, it will prompt **The enabled QC sample No. cannot be the same with the multirule QC file No.!** when you save the number, please input a valid QC sample No. again.
Transmission No.	The transmission No. of the QC file.	Input in the edit box. This field is left blank be default. **Note** The input length is 0 to 25 digits. It supports characters, numbers, letters and special characters, but not Chinese
QC item	QC mode of the control, including: • Whole Blood - CBC+DIFF • Whole Blood- CBC++DIFF+RET • Whole Blood -RET	Select from the drop-down list, required field.
Enable	Set whether to enable the QC file. • Checked (default): the QC sample No. of the QC file is in use, that is, the file information function is enabled. • Unchecked: Not to enable the QC file.	Select according to the actual situation. **Note** • If there are QC files with the same QC sample No., only one of them can be enabled. • When the connections between the main unit, CMS, and DMS are normal, after checking **Enable**, DMS will automatically synchronize the enabled QC files to HOST software.

Parameter	Parameter Explanation	Operation Explanation
Manufacturer	Manufacturer information of controls.	Input according to the actual situation. Text box, required field, blank by default. It supports the input of any characters, and the input length is 0~10.
Mean	The reference values of QC parameters.	According to the control target value table of the corresponding lot No., input the reference value in the Mean cell corresponding to the item in the item list.
SD	Standard deviation of QC parameters.	According to the control target value table of the corresponding lot No., input the standard deviation in the SD cell corresponding to the item in the item list.
Capacity	The total number of QC data that already exists in the current QC file.	Read only.
Creator	It displays the user name who logs in to DMS software when setting the current QC file.	Read only.
Creation time	It displays the system time when setting the current QC file.	Read only.
Item setting	It displays the parameters to be monitored.	Select according to the actual situation.

5. Click **Save** to save the input QC information.

Importing QC Information by File

You can input the QC information by importing QC files in .qcs format.

NOTE

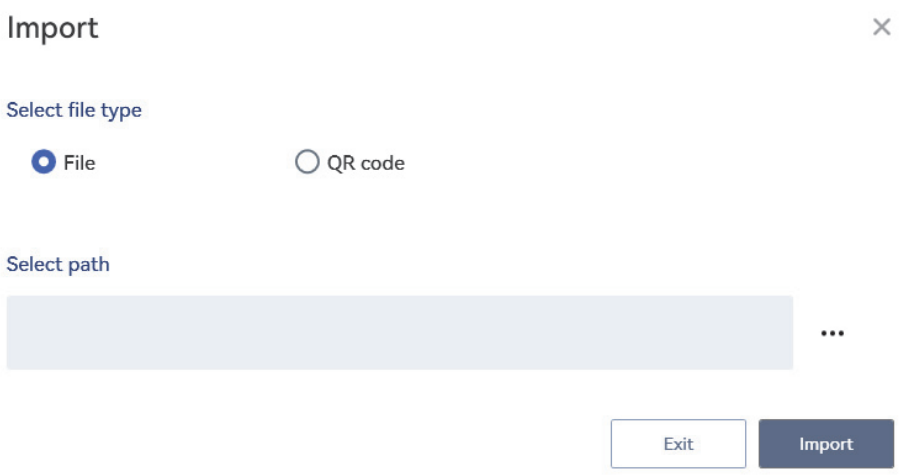
If you need to input the QC information, please consult the customer service engineer for QC files in .qcs format.

1. Click **QC** > **M-R QC** > **QC settings** to enter the interface.

2. Select the main unit series from the device drop-down list.
3. Click **Add**.

   A blank line is added in the QC file list area.
4. Click **Import**, and select imported type as **File**. See Figure 9-10.

   Figure 9-10 Import



5. Click “Browse”.
6. Select the .qcs QC file to be imported.
7. Click **Open**.
8. Click **Import**.

   The interface displays the QC information of the file after importing successfully.
9. Check if the QC information is correct, and then click **Save.** The import of the QC information is completed.

   You can edit the QC information on the interface directly.

   For detailed information of the parameters on the interface, please refer to Table 9-2.

Importing QC Information by QR Code

You can input the QC information by scanning the QR code with the QC information.

NOTE

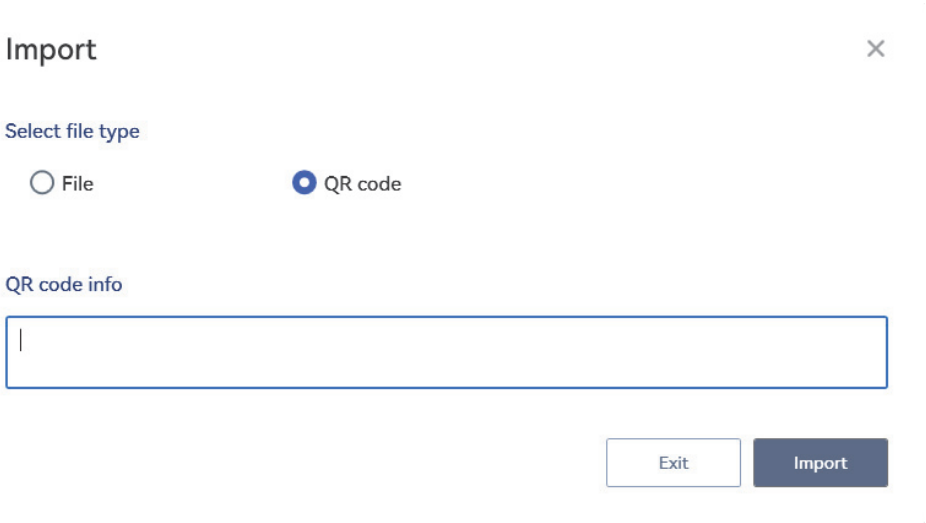
- When the barcode scanner is turned on, there is a laser. Do not look directly at the beam.
- Please consult the customer service engineer for the QC target value table with QC code.
- Please purchase the barcode scanner provided or specified by Dymind separately.

1. Before importing the QC information, you need to connect the QR code scanner to the USB interface of the external computer first.
2. Click **QC** > **M-R QC** > **QC settings** to enter the interface.

3. Select the main unit series from the device drop-down list.
4. Click **Add**.

   A blank line is added in the QC file list area.
5. Click **Import**, and select imported type as **QR Code**. See Figure 9-11.

   Figure 9-11 Import



6. Hold the scanner to scan the QR code.

   After hearing a beep, which means that the scanning succeeds, the interface displays the QR code information.
7. Click **Import**.

   The interface displays the QC information of the QR code after importing successfully.
8. Check if the QC information is correct, and then click **Save.** The import of the QC information is completed.

   You can edit the QC information on the interface directly.

   For detailed information of the parameters on the interface, please refer to Table 9-2.

9.2.1.2 Exporting QC Information

You can export the QC information by the following two ways on DMS software.

- Export by file
- Export by QR code

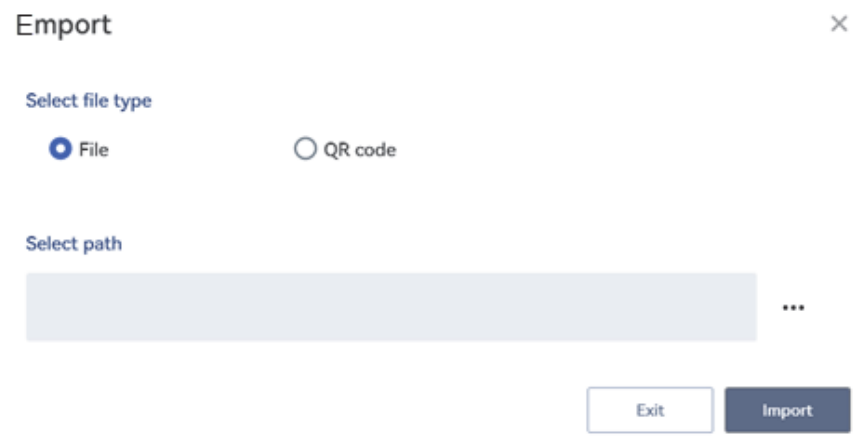
Exporting QC Information by File

You can export the QC file in .qcs format.

1. Click **QC** > **M-R QC** > **QC settings** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Click and select the QC file to be exported in the QC file list area.

4. Click **Export**, and select exported type as **File**. See Figure 9-12.

   Figure 9-12 Export



5. Click **Export**.
6. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.
7. Click **Export**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

Exporting QC Information by QR Code

You can export the QC files in .bmp format.

1. Click **QC** > **M-R QC** > **QC settings** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Click **Export**, and select exported type as **QR Code**.
4. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.
5. Click **Export**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

9.2.1.3 Deleting QC File

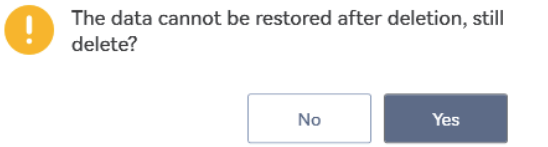
If you want to delete the QC file that is no longer in use, you can follow the steps below on DMS software.

1. Click **QC** > **M-R QC** > **QC settings** to enter the interface.
2. Select the main unit series from the device drop-down list.

3. Select the QC file to be deleted in the QC file list area.
4. Click **Delete**.

   A dialog box will pop up as shown in Figure 9-13.

   Figure 9-13 Deleting QC File



5. Click **Yes**.

   The selected QC file and its QC results are deleted.

9.2.1.4 Setting Outlier Rule

You can set the outlier rule according to the actual situation.

1. Click **Outlier rule** on the **M-R QC** interface.
2. Check the rule that needs to be set in the list of outlier rule.
3. Click **OK** to complete the settings.

9.2.1.5 Copy QC Files

NOTE

Only QC files with data can be copied.

If you want to copy a QC file, you can follow the steps below on the DMS software.

1. Click **QC** > **M-R QC** > **QC settings** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select the QC file that needs to be copied.
4. Click **Copy**

   A new line with the copied content is added in the QC file list area.
5. Click **Save** to save the copied QC information.

9.2.2 QC Analysis (HOST Software)

The QC analysis of multi-rule QC is similar to that of L-J QC. See ***9.1.2 QC Analysis (HOST Software)***.

9.2.3 Multi-Rule QC Result Review

When the QC analysis is completed, you can view the single-level QC graph, multi-level QC graph, and QC list on the M-R QC interface of DMS software, and search, print, deal with outliers and delete outlier rules to the QC results.

9.2.3.1 Single-Level QC Graph

Click **QC** > **M-R QC** > **Single-Level QC Graph** to enter the interface. You can view, delete and print the single-level QC graph.

Searching

Select the main unit, file No., and set the start and end dates in the search condition area, and the QC graph that meets the conditions will be automatically filtered out.

New Vial

If the QC results are obtained by analyzing a new vial of control from the same batch, you should mark the QC points of the new vial to distinguish the QC results from the old one. The steps for marking new vial QC points are as follows:

1. Click the last QC point of the old vial on the QC graph (the previous QC point of the new vial).
2. Click **New Vial**.

   A new vial edit vertical line appears between the selected QC point and the QC point of the new vial. All the QC results after this mark are the analysis results of the new vial control.
3. After opening the new vial of the same batch control again and saving its QC analysis results, follow steps 1 to 2 to mark the QC point of the current new vial.

Deleting

NOTE

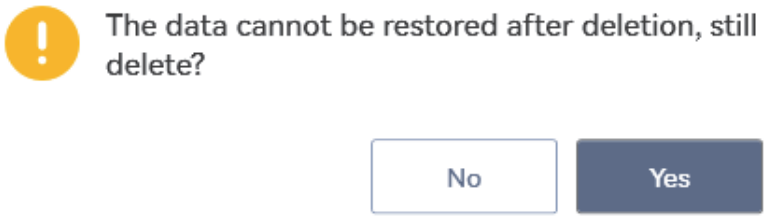
The QC data cannot be restored after deletion.

Follow below steps to delete.

1. Click **QC** > **M-R QC** > **Single Level QC Graph** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Select the QC data to be deleted in the QC graph.
4. Click **Delete**.

   A dialog box will pop up as shown in Figure 9-14.

Figure 9-14 Deleting QC Graph Data



5. Click **Yes**.
   All the selected QC data are deleted.

Printing

NOTE

You can print only when the external computer is properly connected with the printer.

Follow below steps to print.

1. Click **QC** > **M-R QC** > **Single Level QC Graph** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Click **Print**.
4. Select the item to be printed.
   All items are selected by default.
5. Click **OK** to enter the print preview interface.
6. Click **Print**.
   The QC graph is printed.

Outlier Handling

When performing QC analysis, you should record the reason of outliers if there appears any outlier. The detailed steps are as follows.

1. Select the outlier data that has not been handled.
2. Click Outlier handling.
3. Select the outlier reason.
   If there is no suitable option, select **Others**, and input the reason manually in the edit box.
4. Click **OK** to save the setting, and exit the interface.

Calculating SD

The user can perform the operation of calculating the reference value to obtain the reference value, which can be used to directly take the reference value when setting the control later, without manually inputting the Mean and SD of the item.

The steps for calculating the reference value are as follows.

1. Click **Calc. SD**.

   It enters the SD calculating interface. It displays all the QC results of current QC graph.

2. Set the date range.

   Set the date range in the two date edit boxes.

   The QC results within the specified date range are displayed in the list, and the Mean, SD, CV (%) of each item are automatically calculated.

   - If the data involved in the calculation is less than 20 groups, the number font color of Mean, SD, CV (%) is light gray.
   - If the data involved in the calculation is greater than or equal to 20 groups, the number font color of Mean, SD, CV (%) is normal.

3. Click **Yes**.

   The system saves the reference value and assigns the calculated value to the Mean and SD set in the QC file.

9.2.3.2 Multi-Level QC Graph

Click **QC** > **M-R QC** > **Multi-Level QC Graph** to enter the interface. You can view and print the multi-level QC graph.

NOTE

When you select 1 QC file or 3 QC files, use the single concentration point to determine whether there is outlier; when you select 2 QC files, use the single concentration point and 2 concentration points to determine whether there is outlier.

Searching

Select the main unit, batch, low, normal and high QC files of the corresponding batch., and set the start and end dates as well as QC points in the search condition area, and the QC graph that meets the conditions will be automatically filtered out.

Printing

NOTE

You can print only when the external computer is properly connected with the printer.

Follow below steps to print.

1. Click **QC** > **M-R QC** > **Multi-Level QC Graph** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Click **Print**.
4. Select the item to be printed.
   All items are selected by default.
5. Click **OK** to enter the print preview interface.
6. Click **Print**.
   The QC list is printed.

9.2.3.3 QC List

Click **QC** > **M-R QC** > **QC List** to enter the interface.

You can view the QC list, delete, edit the results, restore the results, print, communicate and export on this interface.

Searching

Select the main unit, file No., and set the start and end dates in the search condition area, and the QC graph that meets the conditions will be automatically filtered out.

Deleting

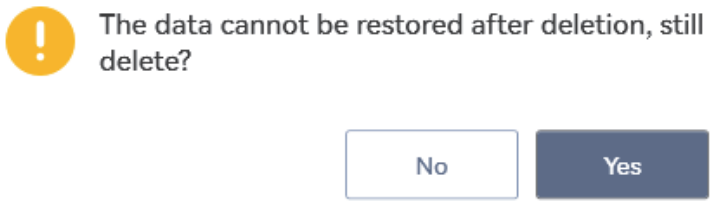
NOTE

The QC data cannot be restored after deletion.

Follow below steps to delete.

1. Click **QC** > **M-R QC** > **QC list** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Select one or more QC data to be deleted in the QC list.
4. Click **Delete**.
   A dialog box will pop up as shown in Figure 9-15.

Figure 9-15 Deleting QC List Data



5. Click **Yes**.
   All the selected QC data are deleted.

Editing Results

Click **Edit result** or double click a cell in the QC list to edit the selected QC data.

Whether the edited data is marked with an **E** is associated with the auxiliary settings. The font color is consistent with that of QC results.

Printing

NOTE

You can print only when the external computer is properly connected with the printer.

Follow below steps to print.

1. Click **QC** > **M-R QC** > **QC list** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Click **Print**.
4. Select the item to be printed.
   All items are selected by default.
5. Click **OK** to enter the print preview interface.
6. Click **Print**.
   The QC list is printed.

Communication

NOTE

If **Auto comm. QC data** is checked on LIS communication settings interface, after DMS software receives the QC analysis results transmitted by the main unit, it will automatically transmit the results to LIS. Please refer to 11.3.8 LIS Communication Settings for details.

Follow below steps to transmit the QC list data to LIS on the QC list interface.

1. Click **QC** > **M-R QC** > **QC list** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Select one or more QC data.
4. Click **Comm.** to transmit the QC data to LIS.

Restoring Results

Select the edited data and click “Restore result” to cancel the editing to the QC result. The system will recover the test data. No matter how many times the user edits, it restores the CMS transmission results.

Exporting

1. Click **QC** > **M-R QC** > **QC list** to enter the interface.
2. Select the main unit series from the device drop-down list.
3. Click **Export**.
4. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.
5. Click **Save**.

After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

9.3 X-B QC

X-B moving average method monitors the performance of the analyzer by monitoring the stability of MCV, MCH, MCHC, and other RBC parameters. It belongs to the quality control without using controls, and is also the performance monitoring method of the analyzer. Compared with the quality control with controls, it can reflect the analysis performance of the analyzer from a different side, and they cannot replace each other.

When the daily sample number of the analyzer is greater than 100, X-B QC is recommended. This quality control method requires the use of random samples, so it is not suitable for samples classified by disease type. Its reference range consists of a given reference value and the upper and lower limits. You can observe the changing trend of QC results in the reference range.

The analyzer performs X-B QC on MCV, MCH and MCHC. The number of samples for X-B QC in each group can be set from 20 to 200. The samples results are the normal test results of the analyzer despite of venous whole blood mode and capillary whole blood mode. The system can save up to 1000 X-B QC results; when the saved QC results exceed the maximum number, the

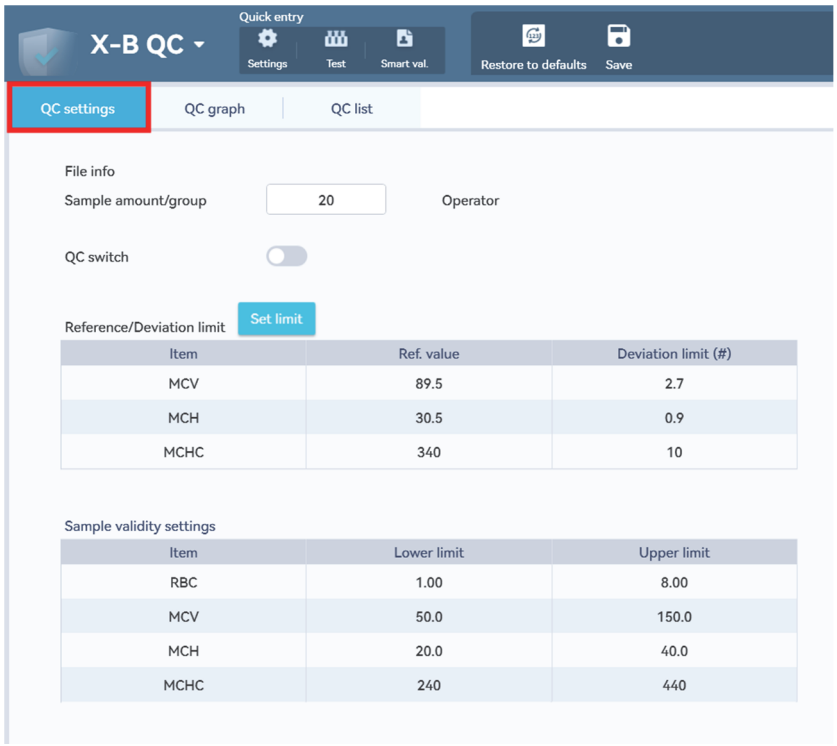
new quality control results will overwrite the oldest results.

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

9.3.1 QC Settings (DMS Software)

Click **QC** > **X-B QC** > **QC settings** on DMS software to enter the interface. You can input X-B QC information, set deviation limit and reset to the default values. See Figure 9-16.

Figure 9-16 X-B QC



9.3.1.1 Inputting QC Information

Before QC analysis, you need to set the QC file on DMS software first. The detailed steps are as follows.

1. Click **QC** > **X-B QC** > **QC settings** to enter the interface.
2. Choose the target main unit from the device drop-down list.
3. In the **Sample amount/group** edit box, input the number of sample results selected for each X-B QC point calculation.

The selection range is 20 ~ 200, and the recommended number is 20.

NOTE

When the value of **Sample amount/group** changes, the effective sample number will be recalculated. For example, the number of effective samples required for each group of XB QC points is originally set to 20; when the number of effective samples is 10, but the value of **Sample amount/group** is modified to 30, then the previous 10 samples will be cleared, and the number of valid samples will be recalculated from 0.

4. Click to open **QC switch**.

   After that, the effective result obtained by sample count on the main unit will be used as the sample result required for X-B QC analysis.

5. In the **Reference/Deviation limit** area, set the reference value and deviation limit of the QC parameters.

NOTE

- You cannot leave any reference value or deviation limit of the QC parameters blank.
- When used for the first time, the system defaults to provide the initial reference value or deviation limit of MCV, MCH and MCHC.
- If there are QC data in the QC file, the reference value or deviation limit are not allowed to be modified.

6. In the **Sample validity settings** area, set the upper and lower limits of the validity of the QC parameters.

   The sample validity setting is to set the validity range of RBC, MCV, MCH and MCHC. The sample results must meet the validity range of these four parameters at the same time before they can be included in the X-B QC calculation.

NOTE

When the validity range changes, the number of effective samples will be recalculated. For example, the number of effective samples required for each group of X-B QC points is originally set to 20; when the number of effective samples is 10, but the value of **Sample validity settings** is modified to 30, then the previous 10 samples will be cleared, and the number of valid samples will be recalculated from 0.

7. Click **Save** to save the settings.

   If the input value exceeds the acceptable range or the upper limit is lower than the lower limit, a reminder box will pop up. Please input the correct data and save it again.

9.3.1.2 Setting Deviation Limit

The system defaults to calculate the QC deviation limit by 2SD of the absolute value. If you want to change the display way or the calculation way of the deviation limit in the preset value, follow

below steps.

1. In the Set deviation limit area, select By SD or By CV.
   - If you want the deviation limit to be displayed as the absolute value form, click **By SD**.
     That is, the deviation limit is calculated as 2 times SD.
   - If you want the deviation limit to be displayed as the percentage form, click **By CV**.
     That is, the deviation limit is calculated as 2 times CV.
2. Click **Save** to save the settings.

9.3.1.3 Restoring to Defaults

You can click **Restore defaults** to restore reference values, deviation limit, and sample validity range to default values.

The default values of the reference values, deviation limit and sample validity range of different parameters are as shown in Table 9-3.

Table 9-3 Default Values of QC Parameters

Parameter	Unit	Reference value	Deviation limit (#)	Sample validity settings	
				Lower limit	Upper limit
MCV	fL	89.5	2.7	50.0	150.0
MCH	pg	30.5	0.9	20.0	40.0
MCHC	g/L	340	10	240	440
RBC	10^{12}/L	N/A	N/A	1.00	8.00

NOTE

- If there are QC data in the QC file, then it is not allowed to restore to defaults.
- By clicking **Restore defaults**, only the reference values, deviation limit, and sample validity range can be restore to defaults. The X-B QC switch (Open or Close), and **Sample amount/group** will not be restored.

9.3.2 QC Analysis (HOST Software)

When the setting of X-B QC is completed, the system automatically starts to perform X-B QC count.

The system automatically performs an X-B QC calculation when every 20~200 (according to the setting) valid sample results are obtained. You can view the QC results on X-B QC analysis interface on DMS software.

The following sample results are not valid sample results for X-B QC, and therefore will not be included in the calculation.

- The result that is out of the linearity range of the device
- The result of background sample
- The result that is out of the range of **Sample validity settings**
- The QC data of other QC mode (such as, L-J QC)
- The calibration data
- The result that is obtained when the device has an error that affects the sample analysis (such as insufficient sample aspiration or clog)

9.3.3 QC Result Review (DMS Software)

When the X-B QC analysis is completed, you can view the QC graph and QC list on the X-B QC interface of DMS software, and print, export, delete the QC results.

9.3.3.1 QC Graph

Click **QC** > **X-B QC** > **QC graph** to enter the interface. You can view, delete and print the QC graph.

Deleting

NOTE

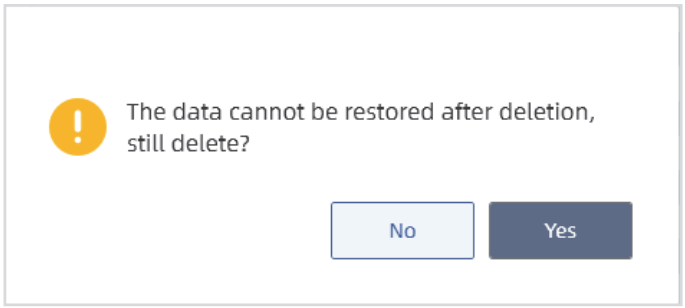
The QC data cannot be restored after deletion.

Follow below steps to delete.

1. Click **QC** > **X-B QC** > **QC graph** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select the QC data to be deleted in the QC graph.
4. Click **Delete**.

   A dialog box will pop up as shown in Figure 9-17.

   Figure 9-17 Deleting QC Graph Data



5. Click **Yes**.

   All the selected QC data are deleted.

Printing

NOTE

You can print only when the external computer is properly connected with the printer.

Follow below steps to print.

1. Click **QC** > **X-B QC** > **QC graph** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Print** to enter the print preview interface.
4. Click **Print**.
   The QC graph is printed.

9.3.3.2 QC List

Click **QC** > **X-B QC** > **QC list** to enter the interface.

You can view the QC list, delete, print, communicate and export on this interface.

Deleting

NOTE

The QC data cannot be restored after deletion.

Follow below steps to delete.

1. Click **QC** > **X-B QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select one or more QC data to be deleted in the QC list.
4. Click **Delete**.
   A dialog box will pop up.
5. Click **OK**.
   All the selected QC data are deleted.

Printing

NOTE

You can print only when the external computer is properly connected with the printer.

Follow below steps to print.

1. Click **QC** > **X-B QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Print** to enter the print preview interface.
4. Click **Print**.

   The QC list is printed.

Communication

NOTE

If **Auto comm. QC data** is checked on LIS communication settings interface, after DMS software receives the QC analysis results transmitted by the main unit, it will automatically transmit the results to LIS. Please refer to ***11.3.8 LIS Communication Settings*** for details.

Follow below steps to transmit the QC list data to LIS on the QC list interface.

1. Click **QC** > **X-B QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Select one or more QC data.
4. Click **Comm.** to transmit the QC data to LIS.
   - If all are communicated successfully, the interface prompts ***X*** **pcs are communicated successfully!**.
   - If some fails, the interface prompts **The communication is completed! Succeed:** ***X*** **pcs, fail:** ***Y*** **pcs. Reason for failure:** ***XXXX*****!**.
   - If all fail, the interface prompts **The communication is completed! Fail:** ***X*** **pcs. Reason for failure:** ***XXXX*****!**.

Exporting

1. Click **QC** > **X-B QC** > **QC list** to enter the interface.
2. Select the main unit from the device drop-down list.
3. Click **Export**.
4. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.
   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default export file name is "QC_X-B_Data_yyyyMMdd_hhmmss.xls", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.

5. Click **Save**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

10 Calibration

Calibration is to obtain accurate measurement results, determine the deviation calibration coefficient of sample analysis under specified conditions. Auto Hematology Analyzer must be calibrated before the measured results can be used as valid data.

This chapter introduces the calibration information of Auto Hematology Analyzer. Please calibrate the analyzer according to the steps specified in this chapter when needed.

NOTE

- Only users with admin permission can perform calibration operations; ordinary users can only browse manual calibration coefficients.
- Use the calibration and reagent specified by Dymind only, and store and use them in strict accordance with the corresponding instructions for use.
- Only the calibrator count performed under the calibration interface is a calibration operation.
- The calibration supports the manual sampling only.

10.1 When to Calibrate

The analyzer has been calibrated before leaving the factory. The performance of the analyzer is stable and it does not require constant calibration. However, you still need to perform calibration to the analyzer on HOST software in following situations:

- Before the first time use (this is usually done by the Dymind-authorized representative when installing the device).
- When the main components are replaced.
- When quality control results indicate there exists systematic error (deviation) or when the data exceeds a predefined limit.
- When the working environment (e.g. temperature) changes obviously.
- When internal quality control is out of control and cannot be corrected.
- Normally, calibrate the analyzer once a year.

10.2 Calibration Preparation

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

Warning

- The left blood, QC materials, and calibrators on the sampling probe may pose a potential risk of bio-contamination, so please avoid contact with the sampling probe.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while contacting them and the relevant areas in the laboratory.
- Once the reagent accidentally comes in contact with your skin, rinse with plenty of water immediately and receive medical treatment if necessary. If you accidentally get any of the reagent into your eyes, rinse with plenty of water immediately, and receive medical treatment.
- Keep your clothes, hair and hands away from the moving parts to avoid being caught or crushed.
- You are obligated to discharge and dispose of the reagents, wastes, samples, consumables according to local legislations and regulations.

Caution

Do not reuse the disposable product.

NOTE

- Use the calibration and reagent specified by Dymind only, and store and use them in strict accordance with the corresponding instructions for use.
- Use only the vacuum blood collection tube, centrifugal tube, capillary tube and other disposable tube specified by the manufacturer.

Check according to the steps below before calibration. You can carry out the calibration only when the background range, repeatability and carryover are within the specified limits given in the manual. Otherwise, the problems must be identified and solved before you determine if calibration is needed. If you cannot solve the problems, please contact Dymind customer service department.

1. Check the main unit and the reagent, and make sure that the reagents are enough for the calibration. You need to start over the calibration if the reagents run out during the process.
2. Perform background count.

If **Abnormal background** is displayed in the error area, you should refer to ***16 Troubleshooting*** to solve the problem, and then perform background count by referring to ***13.2 Performing Background Count*** to make sure that background results meet the requirements (refer to ***A.2.2 Blank Count (Background Range)*** for background ranges).

3. Perform repeatability test.

   Take the sample that meets the requirements and test it 10 times continuously. Then calculate the repeatability results. Make sure that the repeatability results are within the range of ***A.2.5 Repeatability***.

4. Perform carryover test.

   a. When the device runs under stable conditions, test the high-level value sample 3 times, and then immediately test the low-level value sample 3 times.

   b. Calculate the carryover according to the formula below.

$$\text{Carryover (\%)} = \frac{\text{First low - level sample result - Third low - level sample result}}{\text{Third high - level sample result - Third low - level sample result}} \times 100\%$$

   The calculated carryover shall meet the requirement of ***A.2.4 Carryover***.

5. It is recommended that you create a record file and make a record sheet before archiving. The suggested items for the record sheet are: calibration date, source of the calibrator, lot No., reference values, and background count values.

10.3 Calibration Method

The analyzer supports 3 calibration methods: manual calibration, calibrator calibration and fresh blood calibration.

You can calibrate all or part of the parameters of WBC, RBC, HGB, MCV, and PLT.

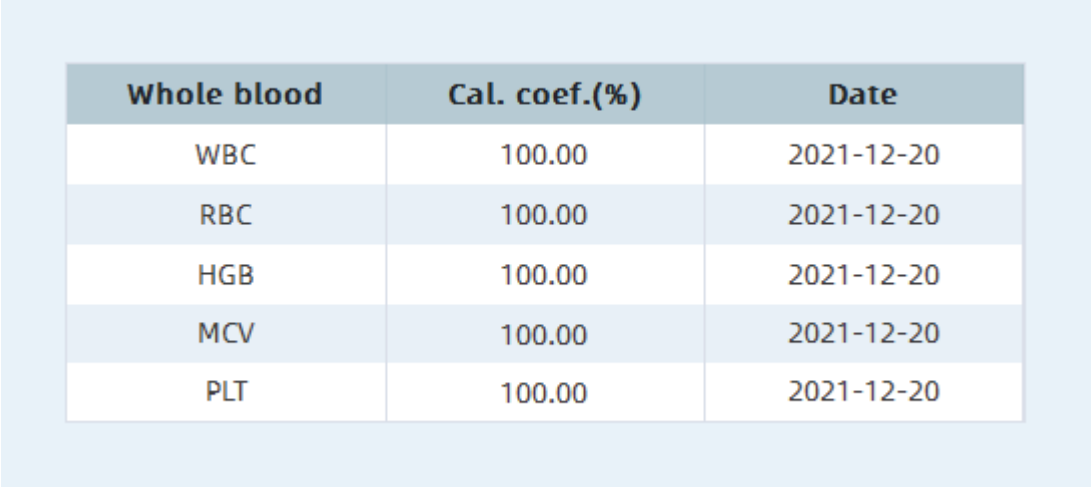
10.3.1 Manual Calibration

Manual calibration is to calculate the calibration coefficients manually through indirect methods, and directly modify the calibration coefficients manually on the input interface of HOST software.

Complete the manual calibration according to the steps below:

1. Click  > **Calibration** > **Manual calibration** to enter manual calibration interface. See Figure 10-1.

Figure 10-1 Manual Calibration



Whole blood	Cal. coef.(%)	Date
WBC	100.00	2021-12-20
RBC	100.00	2021-12-20
HGB	100.00	2021-12-20
MCV	100.00	2021-12-20
PLT	100.00	2021-12-20

NOTE

You can only view the calibration coefficient of the current page if you log in as ordinary user, and cannot perform calibration. If you need to perform the calibration, please log out and then log in as the admin.

2. View the calibration coefficients of each parameters, and calculate the new coefficients using the below formula.

$$\text{New calibration factor} = \frac{\text{Current calibration factor} \times \text{Reference value}}{\text{Mean}}$$

For example, the WBC reference value of a calibrator is 8.3, and the current calibration coefficient of the whole blood mode is 99.00%.

Test the calibrator in whole blood mode 10 times consecutively, and the results are: 8.4, 8.2, 8.2, 8.3, 8.3, 8.1, 8.2, 8.1, 8.2, 8.2. The obtained CV is 1.1% and the mean value is 8.22. The results meet the requirements, and the mean value is valid.

Therefore, the new calibration coefficient can be calculated:

$$\text{New calibration factor} = \frac{99.00\% \times 8.3}{8.22} = 99.96\%$$

If the calculated calibration coefficient of some parameter is beyond the effective range (75.00%~125.00%), the coefficient is invalid. In this case, you should identify the reason (it may because the sample is not mixed thoroughly, incorrect operations, etc.), and remove the problem before you calibrate again. Then calculate the calibration coefficient.

3. Input the new calibration coefficient into the factor cell of the parameter that needs calibration.

NOTE

The input calibration coefficients shall be between 75.0%~125.0%, and only two decimal places can be retained.

- If the new calibration coefficient is valid and different from the old one, the system prompts **Save new calibration coefficient?** when you switch the interface.
  - Click **Yes**, and the calibration coefficient on the interface is refreshed to be the new one and the calibration date is refreshed to be the current system date. The interface is switched to the one you selected.
  - Click **No**, the old calibration coefficients are retained, and the interface is switched to the one you selected.
- If the new calibration coefficient is invalid, the system prompts **Invalid coefficient. It will not be saved if you exit. Exit?** when you switch the interface.
  - Click **Yes**, the old calibration coefficients are retained, and the interface is switched to the one you selected.
  - Click **No** to close the prompt box and return to the manual calibration interface to input a valid new calibration coefficient.

10.3.2 Calibrator Calibration

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

NOTE

- You should use Dymind-specified calibrators only. Dymind will not be responsible for any incorrect result caused by using other calibrators.
- See the instructions for use for the lot No., expiry date and the target of the calibrators.
- Only the admin has the permission to calibrator calibration.

The admin can perform the calibrator calibration on the calibrator calibration interface, and can export calibration data (including calibration count results and new calibration coefficients).

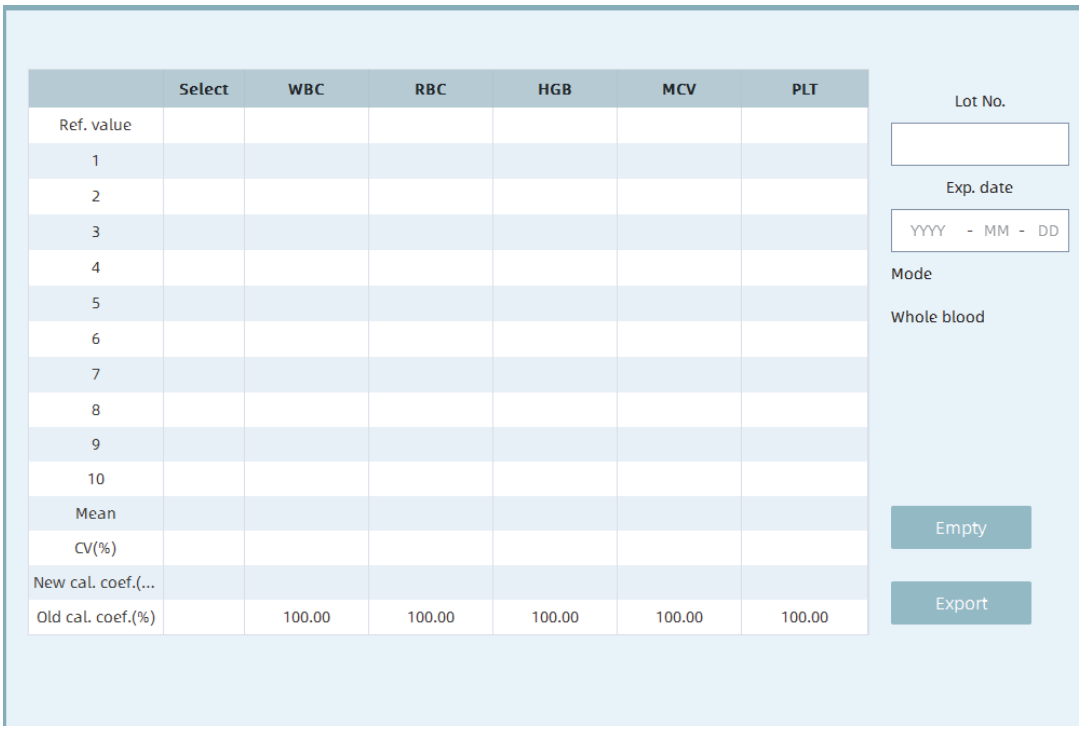
Performing Calibrator Calibration

Calibrator calibration refers to the process in which the system calculates and compares the target values of the calibrator with the actual measurement results after counting and analyzing the calibrator dedicated to the analyzer under specified conditions to obtain the deviation calibration coefficient of the sample analysis.

The calibrator calibration only supports manual sampling. Follow below steps to perform the calibrator calibration.

1. Click  > **Calibration** > **Calibrator calibration** to enter the interface. See Figure 10-2.

Figure 10-2 Calibrator Calibration



2. Input the lot No. of the calibrator into the **Lot No.** box.

NOTE

Once the valid calibration count results are generated, the lot No. is not allowed to be edited and the lot No. edit box turns gray.

3. Set the expiry date of the calibrator.

NOTE

- The expiry date cannot be earlier than the current system date.
- The expiry date input by the admin should be either the expiry date after first opening or the expiry date written on the instructions for use, whichever is earlier. The expiry date after first opening is calculated as follows: the date when the container is opened + the stability days after first opening.
- Once the valid calibration count results are generated, the expiry date is not allowed to be edited and the expiry date edit box turns gray.

4. Input the target value of each parameter in the corresponding **Target** table cell.
5. Press the [MODE] key of the main unit to switch to manual sampling mode.

   Then the sample delivery component moves to the manual sampling position.

   If the main unit is manual sampling mode already, you can directly perform step 6.
6. Prepare the calibrator according to the instructions for use and place the calibrator under the sample delivery component.

7. Press the [RUN] key to start the calibration.

   The sample delivery component automatically moves under the sampling probe to complete the blood collecting.

   Then the sample delivery component moves to the manual sampling position. Please take away the calibrator.

   - The valid calibration results within the linearity range will be displayed directly.
   - If the calibration data of any parameter exceeds the display range or linearity range of the parameter in the current calibration count, a message box will pop up to prompt **The calibration data of this time are invalid.**.

     Click **OK** to close the dialog box, and the calibration data displayed in the list will be deleted automatically.

NOTE

- After the valid calibration result is obtained, the parameter whose check box is checked with "√" will be included in the calculation of the calibration coefficients by default.
- If you switch to other interface before the new calibration coefficients are obtained, the system will discard the current calibration data and keep the original calibration coefficients.

8. Repeat steps 6~7 for 10 times to obtain 10 valid count results.

   The analyzer will, by default, calculate the mean value, CV% and the new calibration coefficients based on all checked calibration data according to the formula.

9. Select at least 5 groups of data to calculate the calibration coefficients.

   When there are 10 valid calibration data on the list, the system will prompt you **Current calibrator calibration is completed.**. Click **OK** to close the prompt box.

   If the system prompts you that the calibration coefficients are invalid, please click **Yes** to close the dialog box, and then click **Empty** to empty current data. Then calibrate again.

NOTE

The out-of-range CV% does not affect the display of the calibration coefficients.

10. After the calibration coefficient calculation is completed, the switch of the interface can be divided into the following two situations.

    - If the calculated calibration coefficients of all parameters are within the range of 75%~125% (>=75% and <=125%), and the CV% of all parameters are also within the repeatability range, then a message box will prompt **Save new calibration coefficient?**.
      - ✧ Click **Yes**, the new calibration coefficients are saved, and the interface is switched to the one you selected.
      - ✧ Click **No**, the old calibration coefficients are retained, and the interface is switched to the one you selected.

- If the calculated calibration coefficients of any parameter is out of the range of 75%~125% (<75% or >125%), or the CV% of any parameter is out of the repeatability range, then a message box will prompt **Invalid new calibration coefficient. It will not be saved if you exit. Exit?**.
  - Click **Yes**, the old calibration coefficients are retained, and the interface is switched to the one you selected.
  - Click **No** to close the prompt box and return to the manual calibration interface. You can perform the calibrator calibration again.

Exporting Calibration Data

NOTE

Only after the calculation of the new calibration coefficients is completed, the admin can export the calibration data.

The detailed steps are as follow.

1. Insert the USB flash disk into the USB interface of the main unit.
2. Click **Export** when the new calibration coefficients are calculated.
   - If the new calibration coefficients are valid and are not saved yet, the system prompts **Save new calibration coefficient?**.
     - Click **Yes** to save the new calibration coefficients, and export the calibration data (include calibration count results and new calibration coefficients) to the USB flash disk.
     - Click **No** to save the old calibration coefficients, and return to the calibrator calibration interface without exporting.
   - If the new calibration coefficients are valid and saved, the system directly exports the data.
   - If the new calibration coefficients are invalid, the system prompts **Invalid new calibration coefficient.**.

     Click **OK** to save the old calibration coefficients, and return to the calibrator calibration interface without exporting.

10.3.3 Flesh Blood Calibration

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while in contact with them and the relevant areas in the laboratory.

NOTE

Only the admin has the permission to fresh blood calibration.

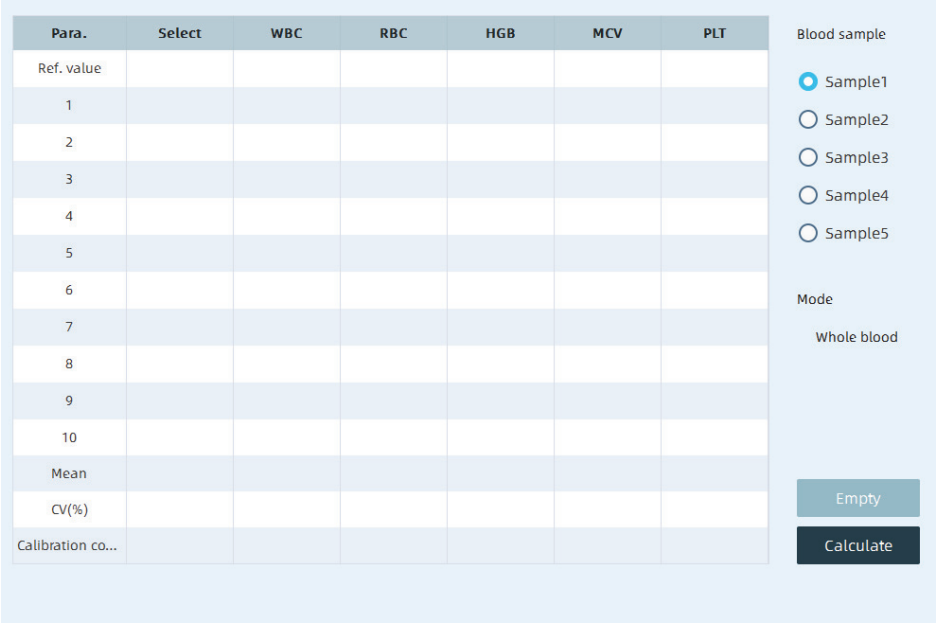
The admin can perform the fresh blood calibration on the fresh blood calibration interface, and can export calibration data (including calibration count results and mean calibration coefficient).

Performing Flesh Blood Calibration

Flesh blood calibration only supports manual sampling. Follow below steps to perform flesh blood calibration.

1. Click > **Calibration** > **Flesh Blood Calibration** to enter the interface. See Figure 10-3.

   Figure 10-3 Flesh Blood Calibration



2. Refer to the sample preparation method in ***5.2.4 Reagent Preparation***, and prepare 3~5 pieces of normal flesh blood samples.
3. Test each of the prepared samples on the reference device at least three times separately, and calculate the mean value, which should be taken as the reference value.

   NOTE

   The reference device must be a standard analyzer running normally so as to ensure the accuracy of the reference value.

4. Input the reference value for the parameter to be calibrated in the corresponding **Target** textbox.
5. Press the [MODE] key of the main unit to switch to manual sampling mode.

   Then the sample delivery component moves to the manual sampling position.

If the main unit is manual sampling mode already, you can directly perform step 6.

6. Place blood sample 1 on the sample delivery component, and press the [RUN] key to start the calibration.

   The system will calculate WBC, RBC, HGB, MCV and PLT values of blood sample 1.

7. Repeat step 6 for 10 times, and calculate the 10 count results of blood sample 1.

   The system will calculate the Mean, CV and calibration coefficient of each parameter of the blood sample.

   If the calculated calibration coefficient of any parameter is out of the valid range, or the CV% of any parameter is out of the repeatability range, then a message box pops out indicating that the new calibration coefficients are invalid. Click **Empty** to empty the calibration data of this blood sample. And recalibrate, or replace with another blood sample that meets the requirements.

8. Refer to steps 6~7 to test the other 4 blood samples.

   The system will calculate the Mean, CV and calibration coefficient of each parameter of the 4 blood samples.

9. Click Calculate.

   The system will calculate the average calibration coefficient of the five blood samples, that is, the mean calibration coefficient (%), as the new calibration coefficient

   You can also select at least three groups of calibration coefficient to calculate the mean calibration coefficient (%).

10. After the mean calibration coefficient calculation is completed, the switch of the interface can be divided into the following two situations.

    - If the calculated mean calibration coefficients are all within the range of 75%~125% (>=75% and <=125%), then a message box will prompt **Save mean calibration coefficient?**.
      - Click **Yes**, the mean calibration coefficient is saved, and the interface is switched to the one you selected.
      - Click **No**, the old calibration coefficients are retained, and the interface is switched to the one you selected.
    - If the calculated mean calibration coefficients are not within the range of 75%~125% (<75% or >125%), then a message box will prompt **Invalid mean calibration coefficient. It will not be saved if you exit. Exit?** when you leave the flesh blood calibration interface.
      - Click **Yes**, the old calibration coefficients are retained, and the interface is switched to the one you selected.
      - Click **No** to close the prompt box and return to the flesh blood calibration interface. You can perform the flesh blood calibration again.

NOTE

The out-of-range CV% does not affect the display of the calibration coefficients.

Exporting Calibration Data

NOTE

Only after the calculation of the mean calibration coefficient is completed, the admin can export the calibration data.

The detailed steps are as follow.

1. Insert the USB flash disk into the USB interface of the main unit.
2. Click **Export** when the mean calibration coefficient is calculated.
   - If the mean calibration coefficient is valid and is not saved yet, the system prompts **Save mean calibration coefficient?**.
     - Click **Yes** to save the mean calibration coefficient, and export the calibration data (include calibration count results and mean calibration coefficient) to the USB flash disk.
     - Click **No** to save the old calibration coefficient, and return to the calculation interface without exporting
   - If the mean calibration coefficient is valid and saved, the system directly exports the data.
   - If the mean calibration coefficient is invalid, the system prompts **Invalid mean calibration coefficient.**.

     Click **OK** to save the old calibration coefficient, and return to the calculation interface without exporting.

10.4 Calibration History

Click  > **Log** > **Calibration history** to browse the calibration history.

NOTE

The admin can browse the calibration history records of admin and that of all ordinary users, and ordinary users can only view their own calibration history records.

11 Settings

This chapter introduces the main unit settings (HOST software), CMS software settings and DMS software settings.

11.1 Main Unit Settings (HOST Software)

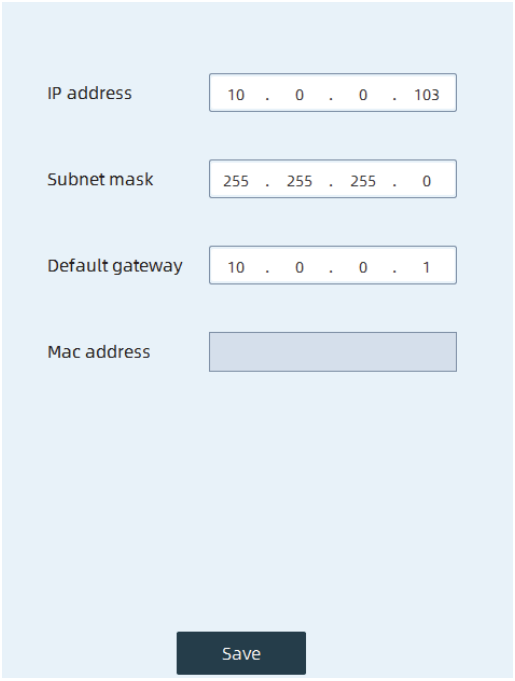
The main unit has been initialized before delivery. The interface upon the initial starting is the default interface. Some parameters of the main unit can be reset on HOST software to meet different needs in practical applications, including communication settings, auxiliary settings, auto maintain settings, ref. range flag setting, Suspicious flag sensitivity settings, lab info settings and gain settings.

In order to ensure the safety of product settings and data, the main unit divides users into the ordinary user and the admin (the admin has all the permissions of the ordinary user). This chapter introduces the setting functions after logging in to the software as the admin.

11.1.1 Communication Settings

Click  > **Settings** > **Communication settings** to enter the interface. See Figure 11-1.

Figure 11-1 Communication Settings



The admin can set the IP address, default gateway, subnet mask, etc. of the current main unit, but the ordinary user can only browse.

- IP address

  The default is 10.0.0.103, and the admin can directly input it in the edit box according to the actual situation. The IP address cannot be empty.

- Default gateway

  The default is 10.0.0.1, and the admin can directly input it in the edit box according to the actual situation. The default gateway cannot be empty.

- Subnet mask

  The default is 255.255.255.0, and the admin can directly input it in the edit box according to the actual situation. The subnet mask cannot be empty.

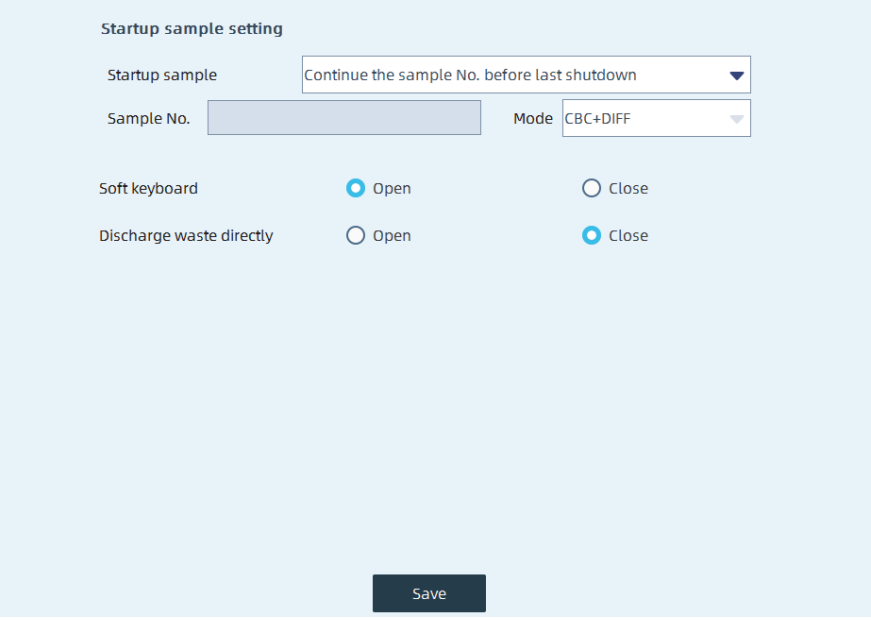
- Mac address

  The system will read the address automatically. You are not allowed to input.

11.1.2 Auxiliary Settings

Click > **Settings** > **Auxiliary settings** to enter the interface. See Figure 11-2.

Figure 11-2 Auxiliary Settings



Auxiliary settings include startup sample setting, enabling soft keyboard, enabling direct discharge of waste, and off-line settings.

Startup Sample Setting

Click the drop-down box of **Startup sample** to select the rule for the first sample after startup. **Continue the sample No. before last shutdown** is selected by default.

- If you select **Continue the sample No. before last shutdown**, then the first sample No. after startup will default to be the number that is added one on the last analyzed sample No. before shutdown.
- If you select **Customize**, then you need to input the specified sample No. in the **Sample No.** edit box, and click the drop-down list of **Mode** to select the analysis mode (CBC, RET, CBC+DIFF, CBC+RET, CBC+DIFF+RET, CBC+DIFF (LW), CBC+RET (LP), or CBC+DIFF+RET (LW+LP)). Set the sample No. and analysis mode of the first sample after startup.

  When starting the device next time, the system will use the sample No. and analysis mode you set.

Soft Keyboard

- Open (default): you can input the content on the soft keyboard that pops up on the interface.
- Close: you need to use an external USB keyboard to input the content.

Discharge Waste Directly

Only the admin has the permission to set the switch for direct discharge of waste, and the ordinary user can only browse.

- Open: discharge waste directly to the medical waste discharge system of local hospitals.
- Close (default): use the waste container to collect the waste. The status of the waste container is reported through the waste float sensor. If the waste container is full, the waste full error is reported.

Off-line Settings (Auto sampling clogged for 3 times consecutively)

Only the admin has the permission to off-line setting, and the ordinary user can only browse.

- Checked: when auto sampling clogged for 3 times consecutively, the analyzer will automatically stop the auto sampling count.
- Unchecked (default): when the clogged error occurs during the process of auto sampling, the analyzer will not stop the auto sampling count.

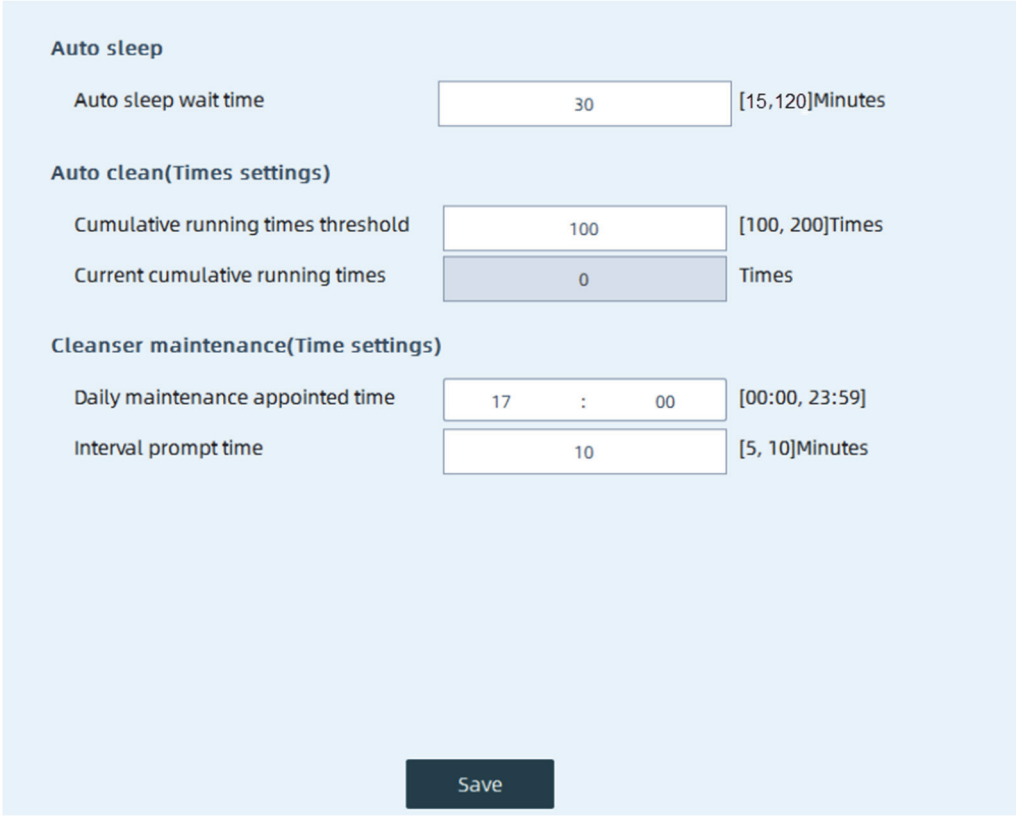
11.1.3 Auto Maintain Settings

NOTE

Only the admin has the permission to edit the settings of auto maintenance, and the ordinary user can only browse.

Click  > **Settings** > **Auto maintain settings** to enter the interface. The admin can set the auto sleep wait time, auto clean times and cleanser soak time. See Figure 11-3.

Figure 11-3 Auto Maintain Settings



Auto Sleep

If the main unit does not have any fluidics operation for a period of time, it will enter the sleep mode and perform the corresponding sleep sequence. In the **Auto sleep wait time** edit box, the admin can set the waiting time before entering the sleep mode. The time ranges are between 15 min and 120 min, and the default setting is 30 min.

Auto Clean (Times Setting)

After the main unit performs a certain sample analysis count and reaches the set threshold value of times, it will perform auto clean operation.

- Cumulative running times threshold

  In the **Cumulative running times threshold** edit box, the admin can set the threshold value of cumulative times of sample analysis. The times range is between 100 and 200, and the default setting is 100.

- Current cumulative running times

  Each time the main unit performs a sample analysis count, the current cumulative running times will be automatically added 1, and it is not editable.

  Each time the main unit performs an auto clean, the current cumulative running times will be automatically reset and re-accumulated.

Cleanser Maintenance (Time Setting)

To ensure the performance of the analyzer, you need to perform cleanser soak operation to the main unit every day. The admin can set the daily maintenance appointed time and interval prompt time for cleanser soak maintenance.

- Daily maintenance appointment time

  In the **Daily maintenance appointment time** edit box, the admin can set the start time of cleanser soak maintenance. The time range is between 0:00 and 23:59, and the default setting is 17:00.

- Interval prompt time

  In the **Interval prompt time** edit box, the admin can set the interval prompt time for cleanser soak maintenance. When the main unit reminds you to perform the cleanser soak maintenance, if you cancel the operation, the timer will start. After the set wait time is reached, it will remind you again. The time range is between 5 min and 10 min, and the default setting is 10 min.

11.1.4 Reference Range Flag Settings

NOTE

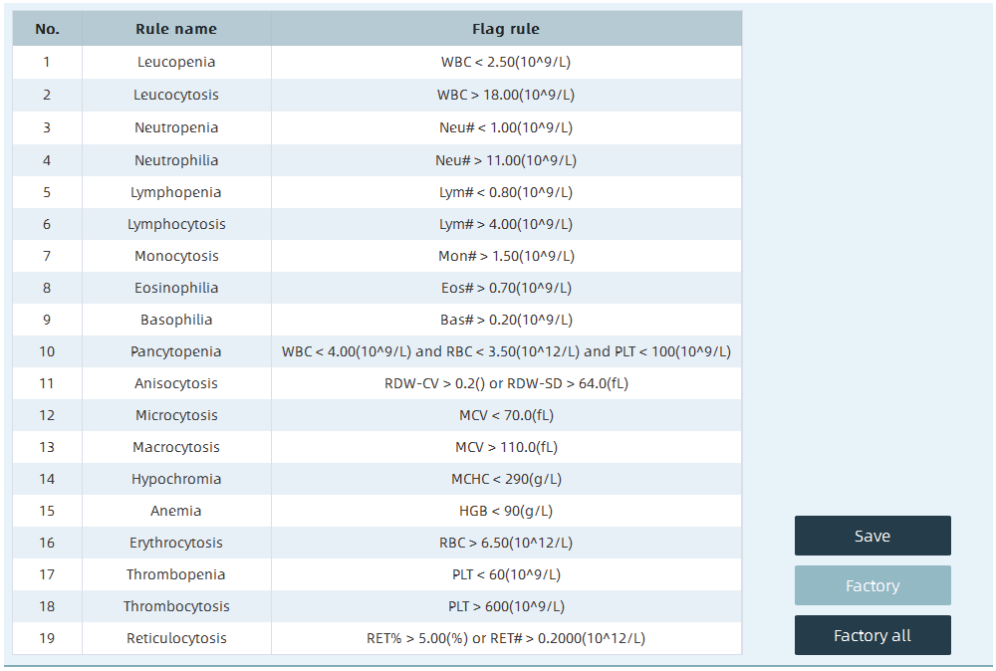
Only the admin has the permission to reference range flag settings.

When the measurement results meet the requirements of flag rules, the interface of HOS software will display the corresponding flag information. The admin can modify the flag rules according to actual situations and the related procedure of the laboratory.

Entering the Interface

Click  > **Settings** > **Ref. range alarm settings** to enter the interface. See Figure 11-4.

Figure 11-4 Ref. Range Alarm Settings



No.	Rule name	Flag rule
1	Leucopenia	WBC < 2.50(10^9/L)
2	Leucocytosis	WBC > 18.00(10^9/L)
3	Neutropenia	Neu# < 1.00(10^9/L)
4	Neutrophilia	Neu# > 11.00(10^9/L)
5	Lymphopenia	Lym# < 0.80(10^9/L)
6	Lymphocytosis	Lym# > 4.00(10^9/L)
7	Monocytosis	Mon# > 1.50(10^9/L)
8	Eosinophilia	Eos# > 0.70(10^9/L)
9	Basophilia	Bas# > 0.20(10^9/L)
10	Pancytopenia	WBC < 4.00(10^9/L) and RBC < 3.50(10^12/L) and PLT < 100(10^9/L)
11	Anisocytosis	RDW-CV > 0.2() or RDW-SD > 64.0(fL)
12	Microcytosis	MCV < 70.0(fL)
13	Macrocytosis	MCV > 110.0(fL)
14	Hypochromia	MCHC < 290(g/L)
15	Anemia	HGB < 90(g/L)
16	Erythrocytosis	RBC > 6.50(10^12/L)
17	Thrombopenia	PLT < 60(10^9/L)
18	Thrombocytosis	PLT > 600(10^9/L)
19	Reticulocytosis	RET% > 5.00(%) or RET# > 0.2000(10^12/L)

Saving

The admin can modify the flag rule according to actual situations.

1. Select the ref. range flag whose rule needs to be modified.
2. Modify the value in the parameter edit box to the right of the flag rule.
   The number of decimal places should be the same as that of the corresponding parameter.
3. Click **Save** to save the settings.

Restoring to Factory Defaults

The admin can select the desired ref. range flag, and then click **Factory** to restore the rule to the default.

Restoring all to Factory Defaults

The admin can click **Factory all** to restore all rules to the defaults.

11.1.5 Suspicious Flag Sensitivity Settings

NOTE

Only the admin has the permission to suspicious flag sensitivity settings.

The admin can modify the sensitivity of each suspicious flag according to actual situations.

Entering the Interface

Click  > **Settings** > **Suspicious flag sensitivity settings** to enter the interface. See Figure 11-5.

Figure 11-5 Suspicious Flag Sensitivity Settings

No.	Suspicious flag name	Value[0, 100]	No.	Suspicious flag name	Value[0, 100]
1	Abnormal DIFF scattergram	40	13	Dimorphic Population	40
2	WBC Histogram Abn.	40	14	RBC agglutination?	40
3	Blasts?	40	15	Turbid/HGB Interf?	40
4	Abn Lympho/ Blasts?	40	16	Iron Deficiency?	40
5	Immature gran?	40	17	Thalassemia?	40
6	Left shift?	40	18	Fragments?	40
7	Atypical Lympho?	40	19	Infected RBC?	40
8	RBC lyse resistant?	40	20	PLT Scattergram Abn.	40
9	NRBC?	40	21	PLT Histogram Abn.	40
10	Lipid particles?	40	22	PLT Clumps?	40
11	WBC fragments?	40	23	RET Scattergram Abn.	40
12	RBC Histogram Abn.	40			

Save Factory all

Saving

The admin can click the **Value** cell corresponding to the suspicious flag, input the new value, and click **Save** to complete the settings. The input range is between 0 and 100, and the default setting is 40.

Restoring all to Factory Defaults

The admin can click **Factory all** to restore the sensitivity of all suspicious flags to the defaults.

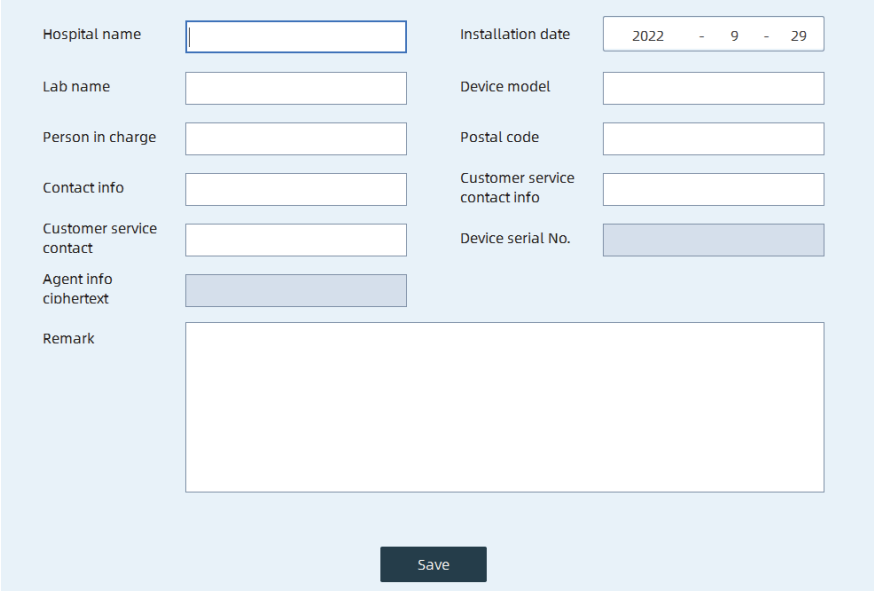
11.1.6 Laboratory Information Settings

NOTE

Only the admin has the permission to edit the laboratory information, and the ordinary user can only browse.

Click  > **Settings** > **Lab Info Settings** to set the related information of the laboratory. See Figure 11-6.

Figure 11-6 Lab Info Settings



Detailed descriptions to parameter settings are as shown in Table 11-1.

Table 11-1 Lab Info Settings

Parameter	Description	
Hospital name	Input the name of the hospital where the lab locates.	**Note** • It is blank by default. • You can input up to 100 characters. • All characters, numbers, letters and other special characters on the keyboard are allowed to be input.
Lab name	Input the lab name.	
Person in charge	Input the name of the person in charge of the laboratory.	**Note** • It is blank by default. • You can input up to 50 characters. • All characters, numbers, letters and other special characters on the keyboard are allowed to be input.
Contact info	Input the contact information of the laboratory (Tel or e-mail).	
Customer service contact	Input the name of the customer service contact person.	
Customer service contact info	Input the contact information of the customer service contact person.	
Installation date	It displays the installation date of HOST software by default.	**Note** • You can edit the installation date, but cannot leave it blank. • The installation date cannot be later than the current system date.

Parameter	Description	
Device model	Input the model of the analyzer.	**Note** • It is blank by default. • You can input up to 20 characters. • All characters, numbers, letters and other special characters on the keyboard are allowed to be input.
Postal code	Input the postal code of the area where the laboratory is located.	**Note** • It is blank by default. • You can input up to 20 characters. • You can input number only.
Device serial No.	It displays the serial No. of the device. Read only.	
Agent info ciphertext	It displays the cipher text of the agent information. Read only.	
Remark	Input the remark of the laboratory.	**Note** • It is blank by default. • You can input up to 2,000 characters. • All characters, numbers, letters and other special characters on the keyboard are allowed to be input.

11.1.7 Gain Settings

NOTE

Only the admin has the permission to gain settings.

The admin can view the FSC, SSC, SFL, PMT, laser gain value and laser current value of the DIFF channel and RET channel on the gain settings interface; and set the gain value of WBC, RBC, HGB and adjust the HGB background voltage value.

Entering the Interface

Click  > **Settings** > **Gain settings** to enter the interface. See Figure 11-7.

Figure 11-7 Gain Settings

Viewing Current Values

After entering the gain settings interface, the admin can view the gain value, current and voltage values of each parameter.

Setting WBC, RBC, and HGB Gain Values

The admin can follow steps below to set WBC, RBC, and HGB gain values.

1. Click the **Set value** cell.
2. Input the value.

   The input range is 0 to 250.
3. Click **Save**.

Adjusting Background Voltage

The admin can adjust the HGB background voltage value by setting the HGB parameter gain, or adjust the HGB background voltage value through the **Auto adjust** button. The range of HGB background voltage is 4.20 V ~ 4.80 V.

Please refer to the contents above for the steps of setting the HGB parameter gain.

The method to adjust through the **Auto adjust** button is: Click , the system automatically adjusts to the range of about 4.50V, and automatically stops the adjustment when the optimal value is reached. During the adjustment process, the HGB setting value also automatically changes; and the setting value also stops changing after the adjustment is stopped.

11.1.8 Settings of Sampling Probe Aspirate Position

Click > **Settings** > **Sampling Probe Aspirate Pos. Settings** to enter the interface. You can select **Auto Capillary WB Tube** or **Manual Capillary WB Tube** according to the actual needs. After modifying the tube type, click **Save** to complete the settings.

11.2 CMS Software Settings

You can perform auto sampling settings, device management settings, startup appointment settings, mode setting and sample assignment settings on CMS software.

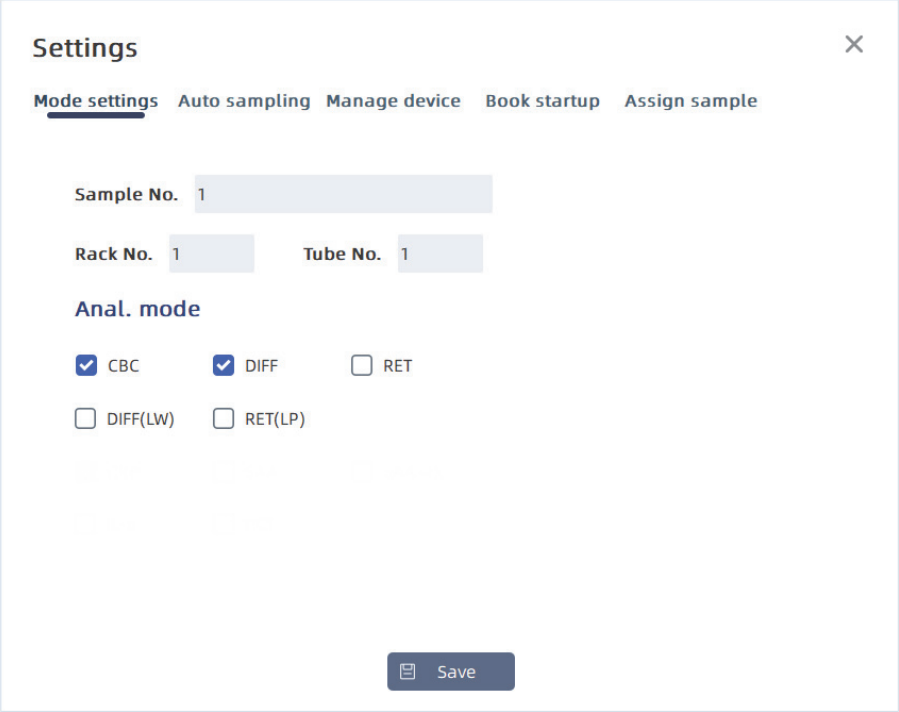
11.2.1 Mode Settings

You can set the sample No. and analysis mode for the sample analysis of auto sampling on CMS software.

Detailed steps are as follows:

1. Click > **Settings** > **Mode settings** to enter the interface. See Figure 11-8.

   Figure 11-8 Mode Settings



2. Set the sample No.
   - The sample No. cannot be empty.
   - If **Automatically scan sample No.** is checked as described in ***11.2.2 Auto Sampling Settings***, the sample No. edit box on the mode settings interface is gray and cannot be edited.
3. Set the rack No. and tube No.

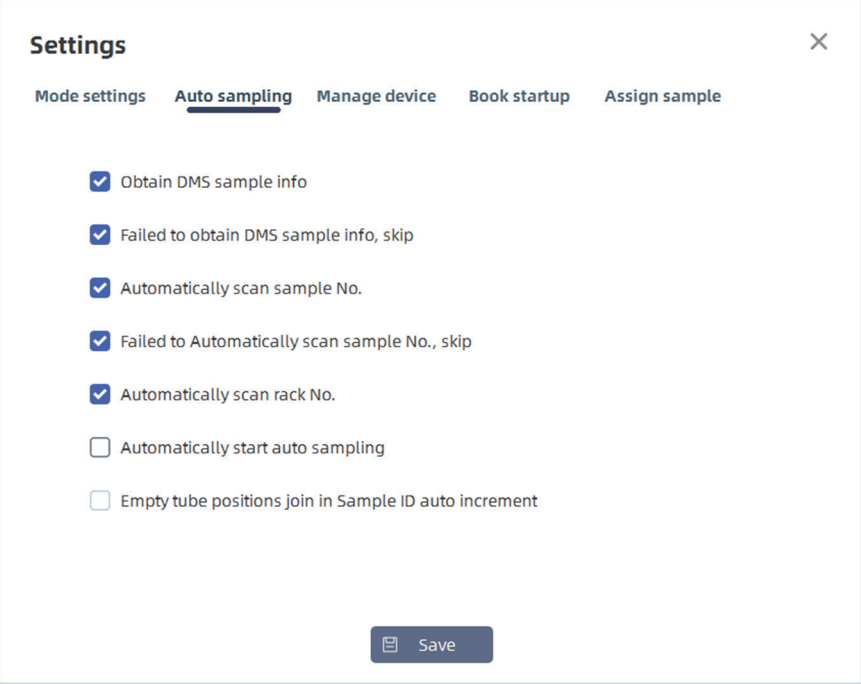
- The rack No. and tube No. cannot be empty.
- If **Automatically scan sample No.** is checked as described in *11.2.2 Auto Sampling Settings*, the sample No. edit box on the mode settings interface is gray and cannot be edited.

4. Set the analysis mode.
   - CBC and DIFF are checked by default, and you can recheck them according to actual needs.
   - You need to check at least one mode. If you do not check any mode, **Check at least one item!** will be prompted when switching tabs.
   - If DIFF mode is selected, CBC mode will be selected automatically.
5. Click **Save** to save the settings.

11.2.2 Auto Sampling Settings

Click > **Settings** > **Auto Sampling** to enter the interface. See Figure 11-9.

Figure 11-9 Auto Sampling



- Obtain DMS sample info
  - Checked (default): during the sample analysis, it will match with the sample information on DMS software (including worklist, LIS side) according to the sample No.
  - Unchecked: it will use the sample No. on the **Settings** > **Mode settings** interface of CMS software.
- Failed to obtain DMS sample info, skip

  This option is only valid when **Obtain DMS sample info** is checked and will be automatically checked.

- Checked: during the sample analysis, it will skip the sample if it failed to obtain the sample information from DMS software according to the sample No.
- Unchecked: it will use the sample No. on the **Settings** > **Mode settings** interface of CMS software.

- Automatically scan sample No.
  - Checked (default): it will scan the sample No. automatically, and then obtain the sample information from DMS software.
  - Unchecked: it will use the sample No. set on the **Settings** > **settings** interface of CMS software, and test the sample incrementally.
- Failed to scan sample No. automatically, skip

  This option is only valid when **Automatically scan sample No.** is checked and will be automatically checked.
  - Checked: during the sample analysis, if it fails to scan the sample No., it will skip this sample.
  - Unchecked: if it fails to scan the sample No., it will automatically assign a number INVALID* (* is an incremented number starting from 1, and is restarted from 1 at 00:00 of the next day) to the sample, and continue to test this sample.
- Automatically scan rack No.
  - Checked (default): it will scan the rack No. automatically, and the rack position is identified automatically with a range from 1 to 10.
  - Unchecked: the default start No. is * (* is an incremented number starting from 1 with a range from 1 to 1,000. It will restart from 1 when reaching the upper limit); the rack position is identified automatically with a range from 1 to 10.
- Automatically start auto sampling
  - Checked: when you place the rack in the loading area, it will automatically start the detecting and scanning procedures. You do not need to perform any operation.
  - Unchecked (default): when you place the rack in the loading area, it will not automatically start the detecting and scanning procedures. You need to press the **Start** key on CMS software to start the detecting and scanning procedures.
- Empty tube positions join in Sample ID auto increment

  This item is valid when **Automatically scan sample No.** is unchecked.
  - Checked: when there are empty tube positions on the rack, sample ID sequentially increases according to the test tube position.
  - Unchecked (default): when there are empty tube positions on the rack, sample ID does not sequentially increase.

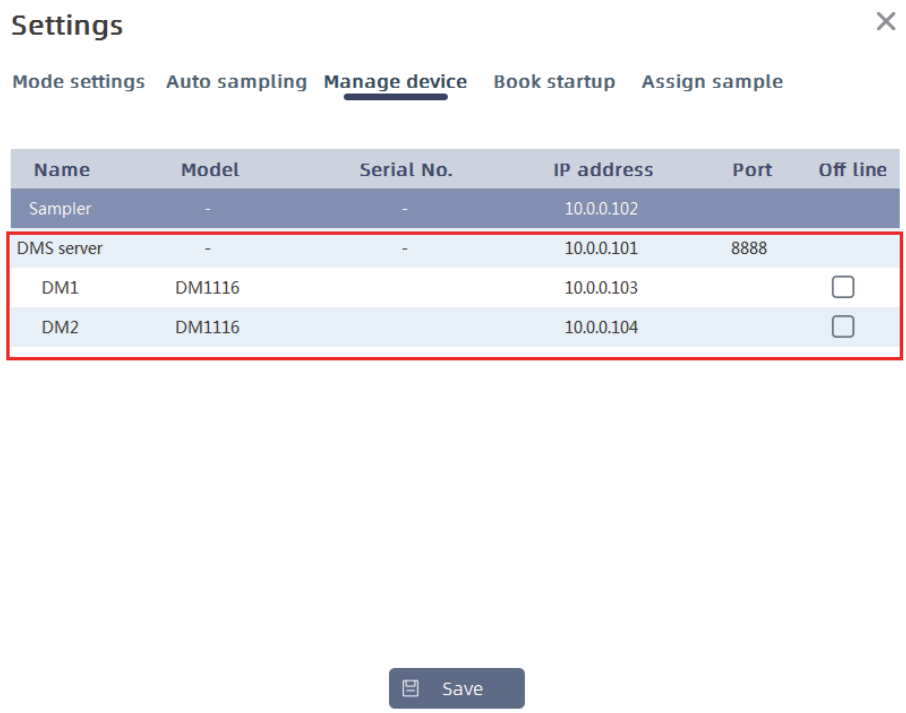
11.2.3 Device Management Settings

CMS software can connect up to 2 main units in the same network segment, 1 autosampler, and 1 DMS software server to form a workstation. You can set the related information on CMS software to complete the connections between HOST, CMS, DMS and autosampler.

Steps to set the device information are as follows.

1. Click > **Settings** > **Manage device** to enter the interface. See Figure 11-10.

Figure 11-10 Manage Device



2. You can set the related parameters according to actual situations.

   See Table 11-2 for related parameters.

Table 11-2 Parameter Description of Device Management

Parameter	Meaning	Operation
Name	The name of the main unit, autosampler, and DMS software server.	It is a required field, and you can input directly. **Note** • The default values are DM1, DM2, autosampler, DMS server. • The name cannot be empty, the input range is 1-10 digits. It is allowed to input any characters.

Parameter	Meaning	Operation
Model	The model of the main unit.	It is obtained by inputting the IP address of the main unit. **Note** • If is obtained successfully, the model of the main unit will be displayed directly, and you are not allowed to modify. • If fails, the model will be empty. • The autosampler and DMS server do not have model information.
Serial No.	The serial number of the main unit.	It is obtained by inputting the IP address of the main unit. **Note** • If obtains successfully, the serial number of the main unit will be displayed directly, and you are not allowed to modify it. • If fails, the serial number will be empty. • The autosampler and DMS server do not have the serial number.
IP address	The IP address of the main unit, autosampler, or DMS software server.	• The IP address of the autosampler is 10.0.0.102, which is not allowed to be modified. If you need to modify, please contact Dymind customer service department or the agent. • The IP address of the main unit, Input, or DMS software can be input directly, and can be left blank. **Note** • The IP addresses of the main unit, autosampler, and DMS software must be on the same network segment. • The IP addresses of the main unit and DMS software are allowed to be modified, but the modified IP address is not allowed to be the same as the IP address of other devices. • If the modified IP address does not comply with IP rules, it will prompt you when you click **Save** to submit the modification.
Port	The port number of DMS server, and the default value is 8888.	It is a required field, and you can input directly. **Note** • The port number of DMS server cannot be empty. Input range: an integer between 1 and 65535. • The main unit and the autosampler do not have port number.

Parameter	Meaning	Operation
Off line	Select whether the main unit is off line.	The check box is not checked by default. You can select it as required. • If the check box is checked, the main unit does not perform sample assignment of auto sampling, but can still perform other operations unrelated to the main unit. • If the check box is not checked, the main unit will perform sample assignment of auto sampling normally. **NOTE** Only the main unit supports off line function.

3. Click **Save**.
   - If the IP address or port is modified, click **OK** on the pop-up dialog box. Then restart CMS software.
   - If the name is modified, the interface prompts **Saved successfully!**, which takes effect immediately without restarting CMS software.

11.2.4 Startup Appointment Settings

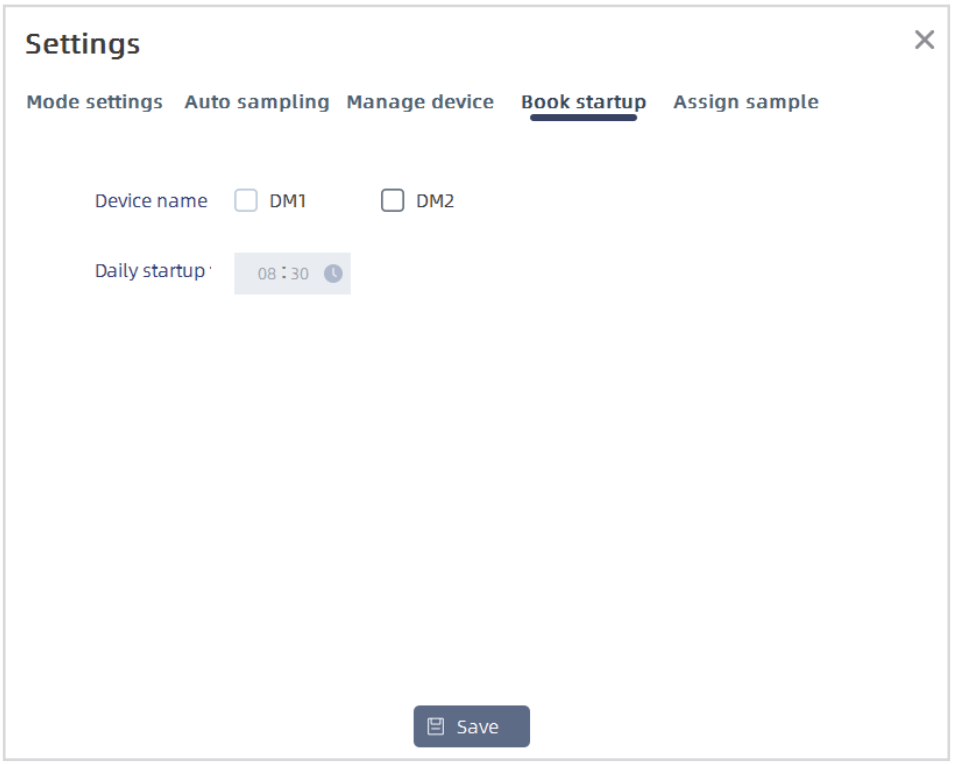
You can set the startup appointment on CMS software.

The analyzer will activate the startup procedure at the setting time, provided that the power switches of the main unit, pneumatic unit, and sampler unit are not turned off.

Detailed steps are as follows:

1. Click  > **Settings** > **Book startup** to enter the interface. See Figure 11-11.

Figure 11-11 Book Startup



2. Select the name of the main unit that you want to book the startup.

   Device name: it displays the corresponding device name through the IP address of the main unit set on the manage device interface.

   If one IP address of the main unit is set, one device name will be displayed here; if two IP addresses of the main units are set, two device names will be displayed, and the information is updated simultaneously.

   - The check box is not checked by default, and you can check or uncheck it according to actual needs.
   - Only when the analyzer is successfully connected with CMS software, the check box can be checked.

3. Set the daily startup time

   The time when the analyzer enables the startup procedure. The set range is between 00:00 and 23:59, and the default setting is 08:30.

   Only when the name of the device that needs to be scheduled to start is checked, the appointed startup time can be set.

4. Click **Save** to save the settings.

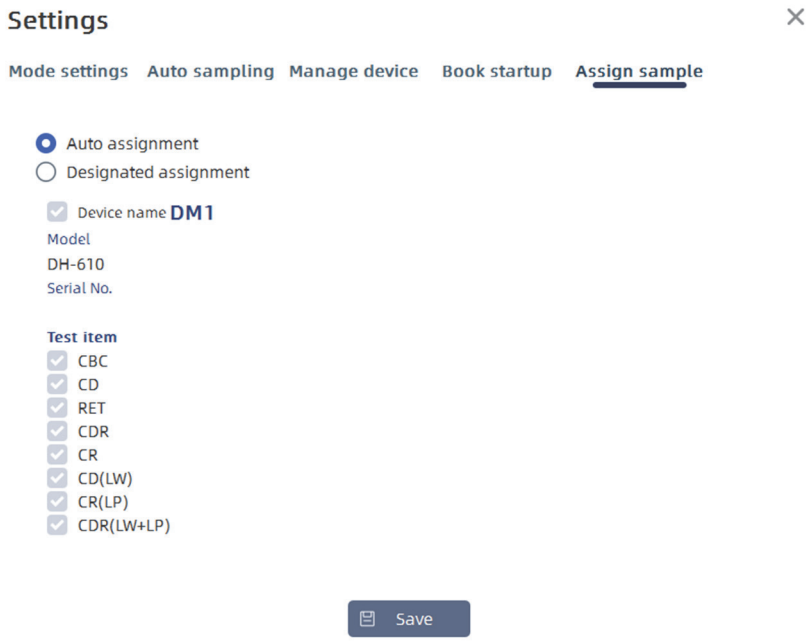
11.2.5 Sample Assignment Settings

You can set the sample assignment way of auto sampling on CMS software when CMS connects with 2 main units.

Entering the Interface

Click > **Settings** > **Assign sample** to enter the interface. See Figure 11-12.

Figure 11-12 Assign Sample



Auto Assignment

Auto assignment is checked by default.

When CMS software is connected to 1~2 main units, and when the main units are in the normal count status, the samples will be evenly distributed to the main units according to the idle time of the connected main units (in the count status), the count mode the main units support, and the principle of proximity.

Designated Assignment

If it is checked, you can select the connected main unit for custom assignment of samples, including device customization and test item customization.

- Device customization

  You can check the connected device for custom settings according to actual needs. Check at least one device. For example: if CMS is connected with 2 main units, you can decide to assign the samples to 1 or 2 main units for analysis.

- Test Item Customization

  Set the test items that the current analyzer supports. Check at least one test item.

11.3 DMS Software Settings

You can perform customized item settings, user management, auxiliary settings, date and format

settings, print settings, item order settings, reference range settings, LIS communication settings, item unit settings and dictionary settings on DMS software.

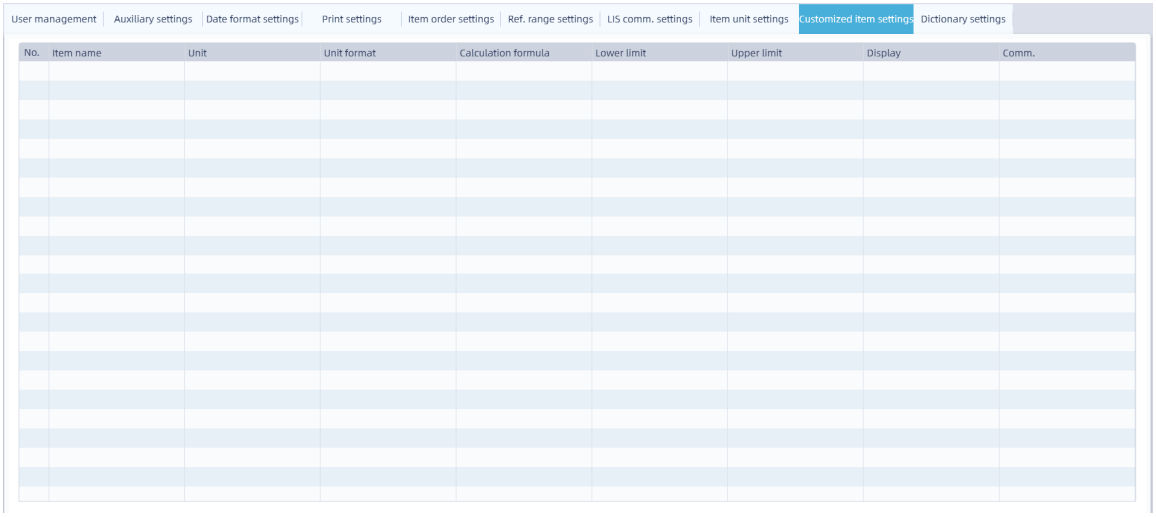
11.3.1 Customized Item Settings

You can add, edit, and delete on the customized item settings interface.

11.3.1.1 Entering the Interface

Click **Settings** > **Customized item settings** to enter the interface. See Figure 11-13.

Figure 11-13 Customized Item Settings



11.3.1.2 Adding Customized Item

The steps for adding a customized item include adding a customized item, setting the reference range and status of the customized item.

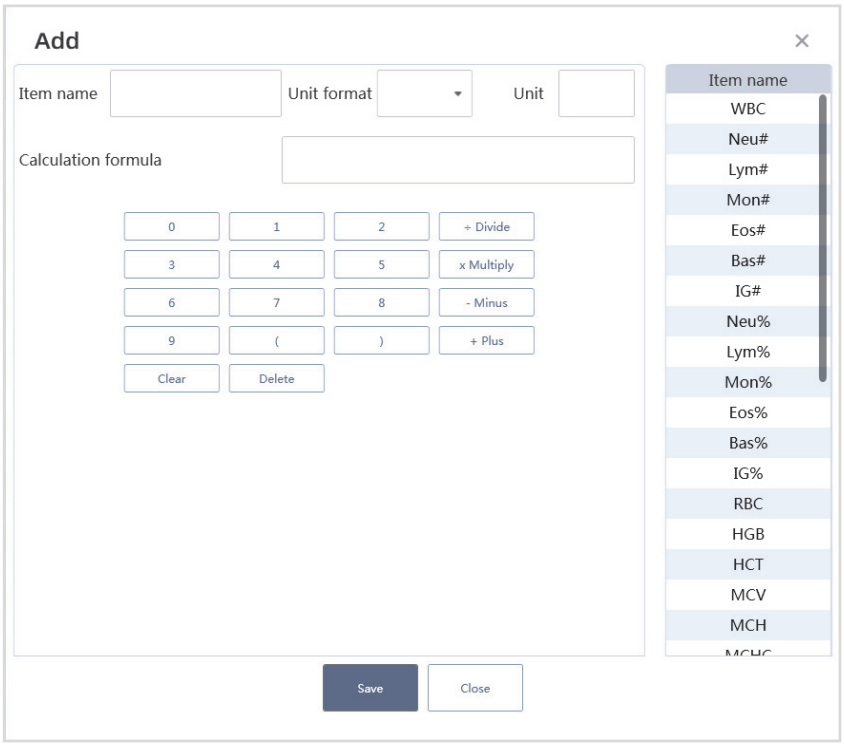
Adding A Customized Item

You need to add the needed customized item in the customized item list first, and the steps are as follows.

1. Click **Add** on the customized item settings interface.

   The adding interface will pop up as shown in Figure 11-14.

Figure 11-14 Adding A Customized Item



2. Refer to Table 11-3 to set the basic information.

Table 11-3 Parameter Description of Customized Item Information

Parameter	Meaning	Operation
Item name	The name of the customized item.	Input in the edit box directly. **Note** The item name cannot be empty, the input range is 1-20 digits. It is allowed to input any characters.

Parameter	Meaning	Operation
Data format	The displayed data format of the customized item. It includes: ● (blank) ● *.* ● *.** ● *.*** ● **.* ● **.** ● **.*** ● ***.* ● ***.** ● ***.*** ● * ● ** ● *** ● ****	It is blank by default. Select from the drop-down list.
Unit	The unit of the customized item.	Input in the edit box directly. **Note** The unit cannot be empty, the input range is 1-10 digits. It is allowed to input Chinese.
Calculation formula	The calculation formula of the customized item.	Click to select an item in the item list on the right, and select the calculation symbol below the calculation formula text box. **Note** ● The calculation formula can be empty. ● Items must be connected by calculation symbols, numbers or (). ● Items or numbers or () must be connected between calculation symbols.

3. Click **Save**.

   The newly added customized item will be displayed in the customized item list.

Setting Reference Range of Customized Item

NOTE

- The upper and lower limits are allowed to be empty at the same time; however, one item is not allowed to be a valid value while the other item is empty.
- The lower limit cannot be greater than the upper limit.

Follow below steps to set the reference range of customized item.

1. Select the customized item in the customized item list.
2. Click the cells of lower limit and upper limit to set the reference range of the customized item.
3. Click **Save** to complete the settings.

Setting Customized Item Status

You can set the status of the customized item, including **Display**, **Print**, and **Comm.**

- Display
  - Checked (default): the customized item and its result are displayed on the **More items** tab of the test interface.
  - Unchecked: the customized item and its result are not displayed on all interfaces.
- Print
  - Checked (default): the customized item is printed when printing the report.
  - Unchecked: the customized item is not printed when printing the report.
- Comm.
  - Checked (default): The customized item can be communicated to LIS.
  - Unchecked: The customized item cannot be communicated to LIS.

The steps to set the customized item status are as follows.

1. Select the customized item in the customized item list.
2. Check or uncheck the **Display**, **Print**, and **Comm.** check boxes according to actual needs.
3. Click **Save** to complete the settings.

11.3.1.3 Editing Customized Item

The steps to edit the customized item are as follows.

1. Select the customized item in the customized item list.
2. Click the cells corresponding to the **lower limit** and **upper limit** to re-edit the reference range according to actual needs.

3. Check or uncheck the **Display**, **Print**, and **Comm.** check boxes according to actual needs.
4. Click **Save**.

11.3.1.4 Deleting Customized Item

The steps to delete the customized item are as follows.

1. Select the customized item in the customized item list.
2. Click **Delete**.
3. Click **Yes** on the pop-up dialog box, and the selected customized item is deleted.

11.3.2 User Management Settings

NOTE

- Only the admin has the permission to user management settings.
- The user name and password of the factory default preset user are both “admin”.
- After the password of the preset user is changed, the new password will be synchronized to the main unit.

The system divides users into two access levels: the ordinary user and the admin. The interfaces display differently to users with different access levels.

- When logging in to the system, the admin can set the account information of ordinary users on the user management interface; the admin can set the role information on the role management interface to configure permissions for different roles.
- When the ordinary user logs in to the system, there is no **User management** menu in the settings menu.

Generally, for each medical institution, you add only one admin who usually is the director of the department; you can add several ordinary users with the authority to manage users, who are usually the deputy directors of the department or the group leaders.

This section introduces the setting functions of user management and role management after logging in to the software as the admin.

11.3.2.1 User Management

Click **Settings** > **User management** to enter the interface. You can add, edit, delete the user or reset the password on this interface.

Adding User

NOTE

When the number of users in the system reaches 100, it will prompt **The user number has reached 100!** when adding user, and the operation will not be performed.

Follow below steps to add new user.

1. Click **Settings** > **User management** to enter the interface.
2. Click **Add**.

   A blank line is added in the user list area.
3. Click the cell in the blank line, and input the user information (user name, name, password, remark).

   NOTE

   - The user name cannot be empty and repeated.
   - The name can be empty but cannot be repeated.
   - The password cannot be empty, and Chinese characters are not supported.
   - The remark can be empty.
   - The input range is 1-20 characters.

4. Click the **Role** drop-down list and select the user's role.

   NOTE

   - The role cannot be empty.
   - The options in the **Role** drop-down list are the same as those on the role interface. If you need to add a new role, please refer to *11.3.2.2 Role Management*.

5. Click **Save** to complete the settings.

Editing User

Follow below steps to edit the user.

1. Click **Settings** > **User management** to enter the interface.
2. Select the user to be edited in the user list area.
3. Click the cell or the drop-down list, and edit the user information (user name, name, password, role, remark).

NOTE

- The admin cannot be edited again.
- The user name cannot be empty and repeated.
- The name can be empty but cannot be repeated.
- The password cannot be empty, and Chinese characters are not supported.
- The role cannot be empty.
- The remark can be empty.
- The input range is 1-20 characters.

4. Click **Save** to complete the settings.

Deleting User

NOTE

- Only the admin has the permission to delete users.
- The admin cannot delete his/her own information.
- The preset role cannot be deleted.
- The currently logged-in user cannot be deleted.

Follow below steps to delete the user.

1. Click **Settings** > **User management** to enter the interface.
2. Select the user to be deleted in the user list area.
3. Click **Delete**.
4. Click **Yes** on the pop-up dialog box to delete the user.

Resetting Password

NOTE

Only the admin has the permission to reset the password.

If the user forgets the password or needs to reset the password for other reasons, the admin can reset the password. The reset password is the same as the user name.

Follow below steps to reset the password.

1. Click **Settings** > **User management** to enter the interface.
2. Select the user that needs to reset the password in the user list area.
3. Click Reset Password.
4. Click **Yes** on the pop-up dialog box to reset the password.

11.3.2.2 Role Management

NOTE

Only the admin has the permission to role management.

The admin needs to assign different permissions to different ordinary users during use. In order to avoid setting each user individually, the admin can set different roles with different permissions on the role management interface, and directly assign the appropriate role to the new user when adding a new user.

The admin can add, edit, or delete the role on the role management interface.

Adding Role

NOTE

When the number of roles in the system reaches 10, it will prompt **The role number has reached 10!** when adding role, and the operation will not be performed.

Follow below steps to add new role.

1. Click **Settings** > **User management** > **Role** to enter the interface.
2. Click **Add**.

   A blank line is added in the role list area on the left of the interface.
3. Click the cell in the blank line, and input the role information (role name, remark).

   NOTE

   - The role name cannot be empty and repeated.
   - The remark can be empty.
   - The input range is 1-20 characters.

4. Check or uncheck the permission of the role in the permission detail area on the right side of the interface.

   NOTE

   All permissions are checked by default, and the admin can check or uncheck according to actual needs.

5. Click **Save** to complete the settings.

Editing Role

Follow below steps to edit the role.

1. Click **Settings** > **User management** > **Role** to enter the interface.
2. Select the role to be edited in the role list area on the left of the interface.
3. Click the cell, and edit the role information (role name, remark).

NOTE

- The role name cannot be empty and repeated.
- The remark can be empty.
- The input range is 1-20 characters.

4. Check or uncheck the permission of the role again in the permission detail area on the right side of the interface.

NOTE

The permission details of the admin role can only be viewed, but cannot be checked or unchecked.

5. Click **Save** to complete the settings.

Deleting Role

NOTE

The preset role cannot be deleted.

Follow below steps to delete the role.

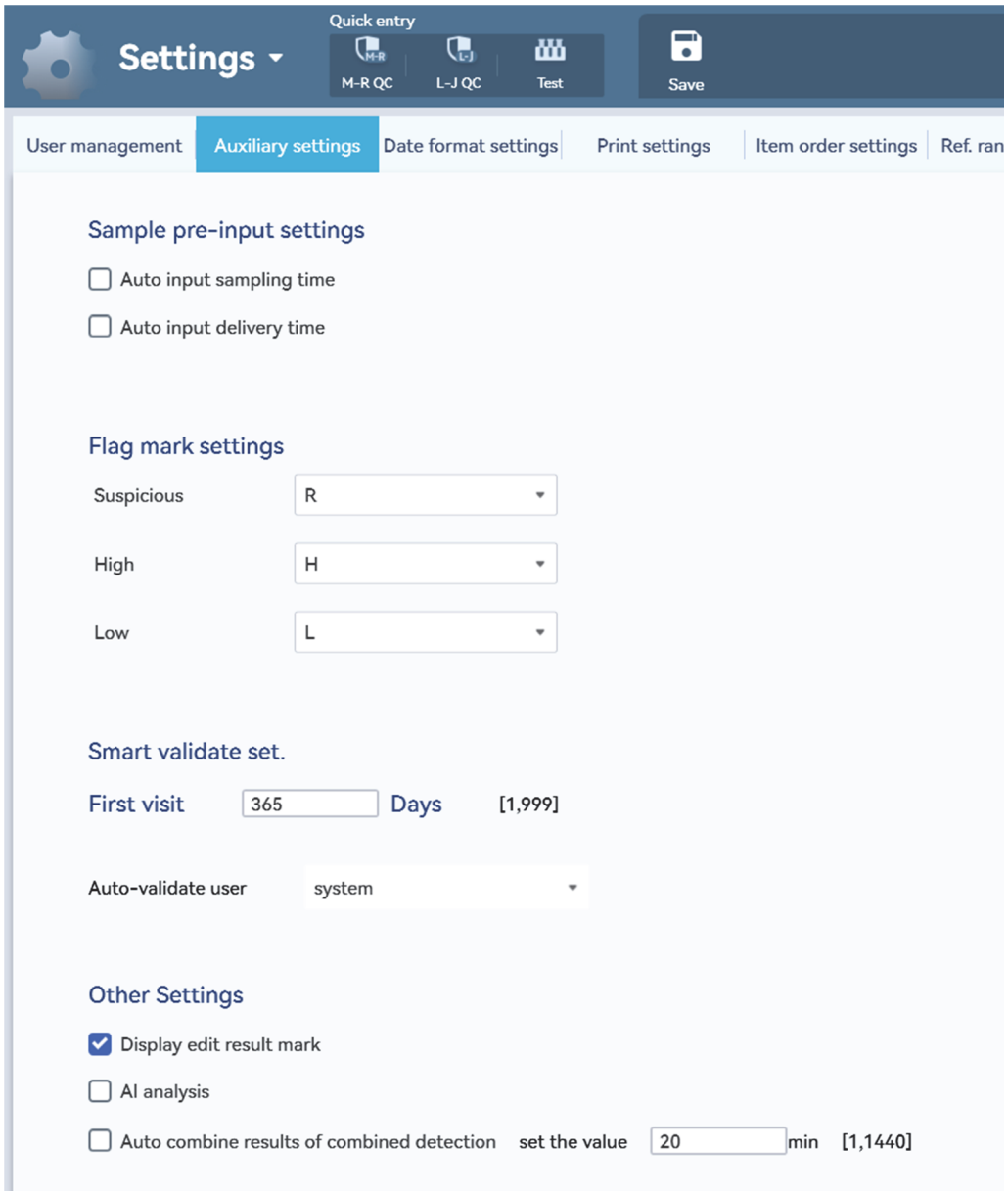
1. Click **Settings** > **User management** > **Role** to enter the interface.
2. Select the role to be deleted in the role list area on the left of the interface.
3. Click **Delete**.
   - ➢ If the role has not been used, a dialog box pops up with **Still delete?**.
     - ✧ Click **Yes** to delete the role.
     - ✧ Click **No** to cancel the operation.
   - ➢ If the role has been used, a dialog box pops up with **The role is in use, still delete?**.
     - ✧ Click **Yes** to delete the role. Then the role cell of the user who uses this role displays as blank.
     - ✧ Click **No** to cancel the operation.

11.3.3 Auxiliary Settings

Click **Settings** > **Auxiliary settings** to enter the interface. See Figure 11-15. You can perform sample pre-input settings and flag mark settings.

If DMS software connects successfully with HOST software and CMS software, the flag mark settings will be synchronized to the main unit and CMS.

Figure 11-15 Auxiliary Settings



Sample Pre-input Settings

- Auto input sampling time
  - ➢ Unchecked (default): when the sample information is pre-input on the test interface, the sampling time of the sample is empty by default.

- Checked: when the sample information is pre-input on the test interface, the sampling time of the sample is filled with the system time by default.

- Auto input delivery time
  - Unchecked (default): when the sample information is pre-input on the test interface, the delivery time of the sample is empty by default.
  - Checked: when the sample information is pre-input on the test interface, the delivery time of the sample is filled with the system time by default.

Flag Mark Settings

- Suspicious

  You can click the drop-down list to select the suspicious flag mark (R, r, ?), and R is selected by default.

- High

  You can click the drop-down list to select the high flag mark (H, h, ↑), and H is selected by default.

- Low

  You can click the drop-down list to select the low flag mark (L, l, ↑), and L is selected by default.

Smart Validate Settings

- First visit time

  You can input the first visit time in the First visit text box.

NOTE

- The input range is [1, 999].
- If the patient is examined within the time range of first visit, it will be defined as the return visit; if it is beyond the time range, it will be defined as the first visit.

- Auto-validate User

  You can set the validator for auto sample validation in the **Auto-validate User**.

Other Settings

- Display of edited result marks
  - Unchecked (by default): On the **Test** and **QC** interfaces, for edited parameters, the edited result (E/e) mark is not displayed.
  - Checked: On the **Test** and **QC** interfaces, for edited parameters, the edited result (E/e) mark is displayed.

- AI Analysis

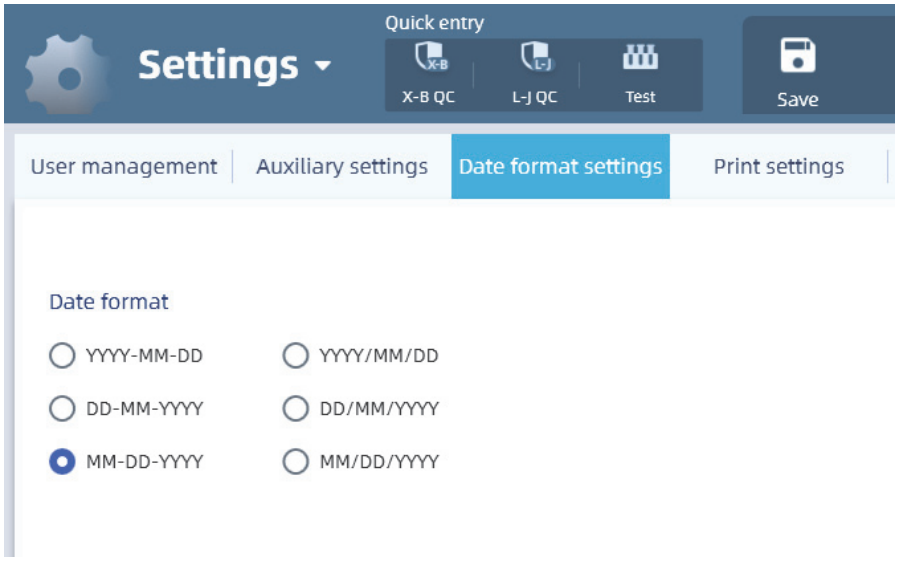
- Unchecked (by default): AI analysis tab and the small window are not displayed. If printing templates related to AI analysis is selected, the system will not print AI analysis contents.
- Checked: AI analysis tab and the small window are displayed. If printing templates related to AI analysis is selected, the system will print AI analysis contents.

11.3.4 Date Format Settings

Click **Settings** > **Date format settings** to enter the interface. See Figure 11-16. You can set the date format on this interface. MM-DD-YYYY is selected by default.

If DMS software connects successfully with the main unit and CMS software, the date format will be synchronized to the main unit and CMS.

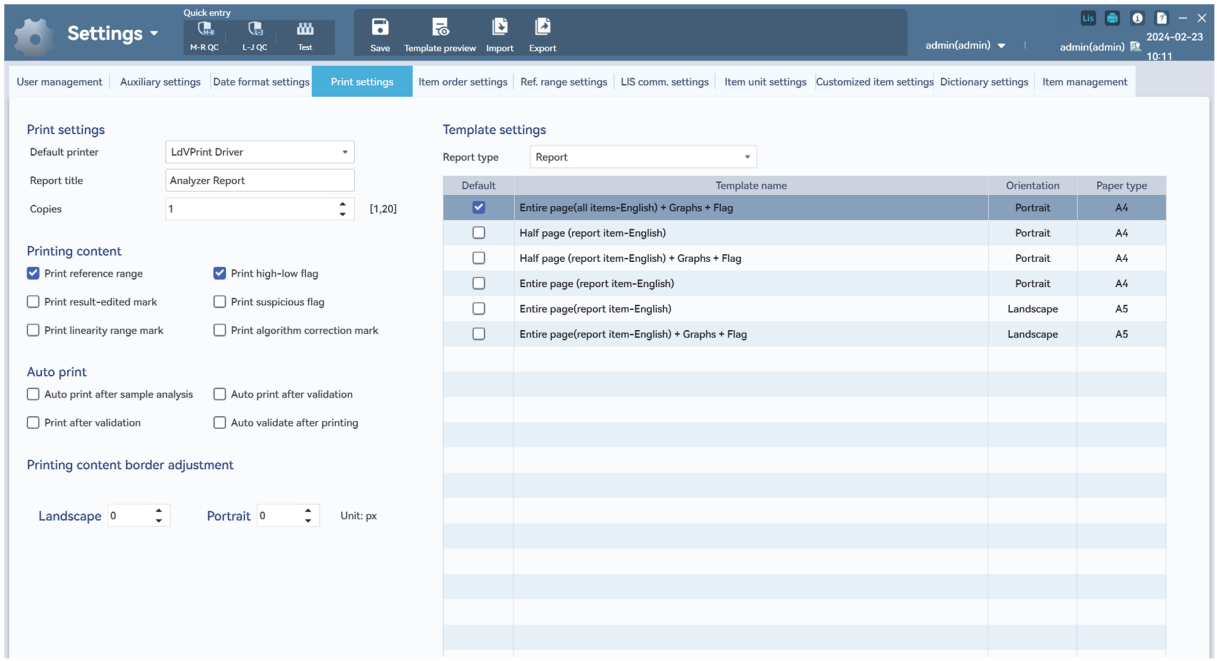
Figure 11-16 Date Format Settings



11.3.5 Print Settings

Click **Settings** > **Print settings** to enter the interface. See Figure 11-17. You can make print-related settings, including print settings, auto print settings, and template settings.

Figure 11-17 Print Settings



NOTE

You can edit the print template by print template editor. Please refer to the **Print Template Editor Operation Guide** to operate.

Print Settings

- Default printer

  Select the default printer from the drop-down list.

  If the list is empty, it means that the external computer does not install the printer. Please install the printer before proceeding with related settings and printing operations.

- Report title

  Input the report title in the edit box. The default is **Test Report**. The report title can be empty, and the character range is within 60 characters.

- Copies

  Input the number of copies of the same report to be printed in the edit box. The input range is 1~20, and the default value is 1.

Printing content

- Print flag

  Checked (default): the flag is printed when printing the report.

  Unchecked: the flag is not printed when printing the report.

- Print reference range

  Checked (default): the reference range is printed when printing the report.

Unchecked: the reference range is not printed when printing the report.

- Print high-low flag

  Checked (default): the high-low flag is printed when printing the report.

  Unchecked: the high-low flag is not printed when printing the report.

- Print result-edited mark

  Checked: the result-edited mark is printed when printing the report.

  Unchecked (default): the result-edited mark is not printed when printing the report.

- Print suspicious flag

  Checked: the suspicious flag is printed when printing the report.

  Unchecked (default): the suspicious flag is not printed when printing the report.

- Print linearity range mark

  Checked: the linearity range mark is printed when printing the report.

  Unchecked (default): the linearity range mark is not printed when printing the report.

- Print algorithm correction mark

  Checked: the algorithm correction mark is printed when printing the report.

  Unchecked (default): the algorithm correction mark is not printed when printing the report.

Auto print

When one of them is checked, the other 3 items are automatically unchecked.

- Auto print after sample analysis
  - Checked: after DMS software receives the sample information transmitted by the main unit, it automatically prints the sample report.
  - Unchecked: after DMS software receives the sample information transmitted by the main unit, it does not print the sample report.
- Auto print after validation
  - Checked: after validating the sample on DMS software, it automatically prints the sample report.
  - Unchecked: after validating the sample on DMS software, it does not print the sample report.
- Print after validation
  - Checked: after validating the sample on DMS software, it is allowed to click **Print** to print the sample report.
  - Unchecked: it is allowed to click **Print** to print the sample report even without validation.
- Auto validate after printing
  - Checked: the system automatically validate the sample after you print the sample report, and the status of the sample changes to **Validated**.

- Unchecked: the system does not validate the sample automatically after you print the sample report.

Template Settings

In the Template settings combo box, you can set the report type, preview the template and set default template.

- Select report type

  Select the report type (report, others) from the drop-down list of the **Report type**. The report is selected by default.

- Template preview

  The steps for template preview are as follows.

  Select the report type from the drop-down list of the **Report type**.

  Click any template in the template list.

  Click Template preview.

  You can preview the report printing effect of the current template.

  NOTE

  After completing the print settings, it is suggested that you preview the set report sheet before printing the report.

- Set default template

  The steps to set default template are as follows.

  a. Select **Report** for the report type.

  Check the radio button of the **Default** column in the template list.

  Click **Save** to complete the settings.

  The checked template is set as default template.

  NOTE

  Only the template whose report type is **Report** can be set as the default template.

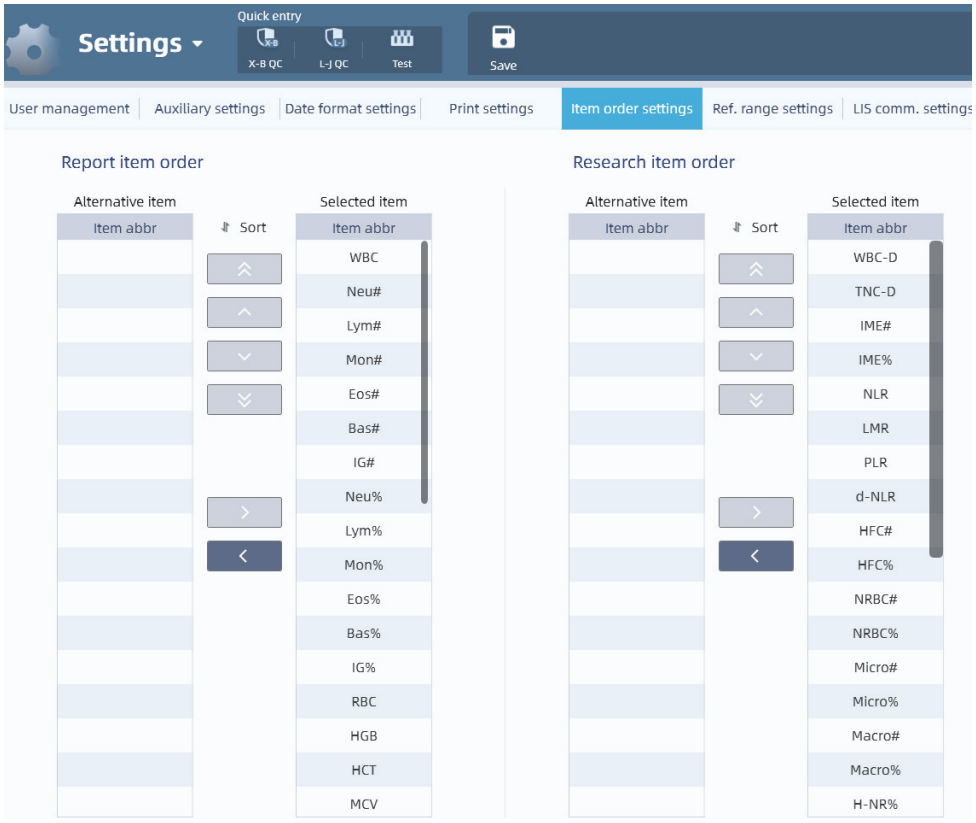
Printing content border adjustment

Since different printers have different printing areas, it is possible that some printers may not print completely. By adjusting position, the software can zoom the print content to display the print content completely. Landscape or portrait position; the default setting is 0px and the inputting range is 0~100. After adjusting the border, you need to click **Save** before the adjustments take effect.

11.3.6 Item Order Settings

Click **Settings** > **Item order settings** to enter the interface. See Figure 11-18. You can adjust the display order of the report item or research item on the test interface of DMS software through the adjusting button. Only the display order on the test interface of DMS software is adjusted, and that of the main unit remains the same.

Figure 11-18 Item Order Settings



Follow below steps to adjust the order.

1. Click **Settings** > **Item order settings** to enter the interface.
2. Adjust the display items by moving left and right buttons. Click to select an item in the alternative item list.

   : move the selected item from the alternative item list to the selected item list.

   : move the selected item from the selected item list to the alternative item list.
3. In the selected item list, click to select the item that need to be adjusted.
4. Use the adjusting button to adjust the order of the items in the selected item list.

   : move to the top.

   : move up for one position.

   : move down for one position.

   : move to the end.

11.3.7 Setting Reference Range

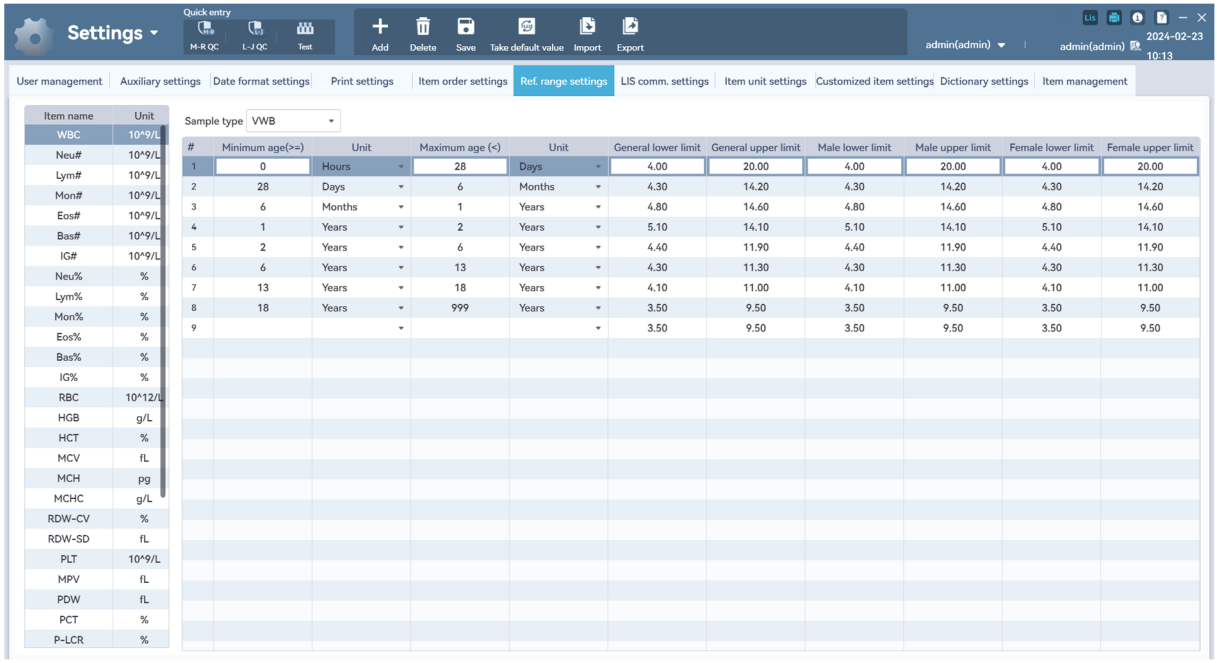
Each laboratory should select a suitable reference range according to the actual sample situation, and set a suitable reference range. The reference range varies with population, gender, age, and geographic location.

In actual use, you can set the reference ranges based on different age groups. If the analysis result of a sample exceeds the reference range, it will be considered as abnormal clinically. There will be "↑" or "↓" on the left side of the result displayed on the interface and the test result printed by the printer, where "↑" means the test result is higher than the upper limit, and "↓" means the test result is lower than the lower limit.

11.3.7.1 Entering the Interface

Click **Settings** > **Ref. range settings** to enter the interface. See Figure 11-19.

Figure 11-19 Ref. Range Settings



11.3.7.2 Adding Reference Group

If the preset reference groups cannot meet the actual need, you can add new reference group.

This section takes the adding of WBC reference group as an example to introduce the method of adding a new reference group. The method for adding the reference group of other item is similar and will not be repeated.

Follow below steps to add a new reference group.

1. Select the sample type from the **Sample type** drop-down list.
2. Click to select **WBC** in the item list on the left side of the interface.
3. Click **Add**.

   A blank line is added in the reference group list area on the right side of the interface.

4. Refer to Table 11-4 to set the information of the reference group.

Table 11-4 Parameter Description of Reference Group

Parameter	Meaning	Operation
Minimum age (>=)	The minimum age limit for the reference group.	Input an integer value in the edit box, and the input range is 0~999; and select the age unit from the **Unit** drop-down list on the right. **Note** The minimum age must be less than the maximum age.
Maximum age (<)	The maximum age limit for the reference group.	Input an integer value in the edit box, and the input range is 0~999; and select the age unit from the **Unit** drop-down list on the right. **Note** The maximum age must be greater than the minimum age.
Unit	The unit of the age. ● Hours ● Days ● Month ● Year	It is blank by default. Select from the drop-down list.
General lower limit	The lower limit of the general reference group of the parameter.	Click the **General lower limit** cell and input a new value. **Note** The general lower limit must be smaller than the general upper limit.
General upper limit	The upper limit of the general reference group of the parameter.	Click the **General upper limit** cell and input a new value. **Note** The general upper limit must be greater than the general lower limit.
Male lower limit	The lower limit of the male reference group of the parameter.	Click the **Male lower limit** cell and input a new value. **Note** The male lower limit must be smaller than the male upper limit.
Male upper limit	The upper limit of the male reference group of the parameter.	Click the **Male upper limit** cell and input a new value. **Note** The male upper limit must be greater than the male lower limit.

Parameter	Meaning	Operation
Female lower limit	The lower limit of the female reference group of the parameter.	Click the **Female lower limit** cell and input a new value. **Note** The female lower limit must be smaller than the female upper limit.
Female upper limit	The upper limit of the female reference group of the parameter.	Click the **Female upper limit** cell and input a new value. **Note** The female upper limit must be greater than the female lower limit.

NOTE

- The input ranges of the upper and lower limits of the reference group are the display ranges of the parameter. For the display range of main parameters, please refer to ***A.2.1 Display Range of Main Parameters***.
- The upper and lower limits are allowed to be empty at the same time; however, one item is not allowed to be a valid value while the other item is empty.
- When inputting the sample information, if the patient's gender is not set, the general reference group corresponding to the age group is used; if the patient's gender is set, the reference group corresponding to the gender of the corresponding age group is used.
- If the test result is lower than the lower limit or higher than the upper limit, it would be regarded as clinically abnormal.
- Customized reference group is supported. The system provides 9 reference groups by default. You can customize and add 21 reference groups at a time.

5. Click **Save** to complete the settings.

11.3.7.3 Editing Reference Group

You can modify the reference group of the parameters according to the actual need.

This section takes the editing of WBC reference group as an example to introduce the method of editing the reference group. The method for editing the reference group of other item is similar and will not be repeated.

Follow below steps to edit the reference group.

1. Select the sample type from the **Sample type** drop-down list.
2. Click to select **WBC** in the item list on the left side of the interface.
3. Select **the referen**ce group to be edited in the refe**ren**ce group list area on the right side of the interface.
4. Refer to Table 11-4 to edit the information of the reference group (age range and reference range).

5. Click **Save**.

11.3.7.4 Deleting Reference Group

This section takes the deleting of WBC reference group as an example to introduce the method of deleting the reference group. The method for deleting the reference group of other item is similar and will not be repeated.

Follow below steps to delete the reference group.

1. Select the sample type from the **Sample type** drop-down list.
2. Click to select **WBC** in the item list on the left side of the interface.
3. Select one or more reference groups to be edited in the reference group list area on the right side of the interface.
4. Click **Delete**.

   The selected reference groups are deleted.

11.3.7.5 Taking Default Value

You can restore the reference ranges of all items under the current sample type to the default values.

Follow below steps to restore to the default values.

1. Select the sample type from the **Sample type** drop-down list.
2. Click Take default value.
3. Click **Yes** on the pop-up dialog box.

   The interface prompts **Restored to defaults successfully!**, indicating that the default values are restored successfully.

11.3.7.6 Import

You can import the reference ranges of all items under the current sample type.

Detailed steps are as follows.

1. Select the sample type from the **Sample type** drop-down list.
2. Click **Import**.
3. Click **Yes** on the pop-up dialog box.
4. In the pop-up dialog box, select the imported file.
5. Click **Open**.

   The interface prompts **Imported successfully!**, indicating that the reference ranges are imported successfully.

11.3.7.7 Exporting

You can export the reference ranges of all items under the current sample type.

Detailed steps are as follows.

1. Select the sample type from the **Sample type** drop-down list.
2. Click **Export**.
3. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

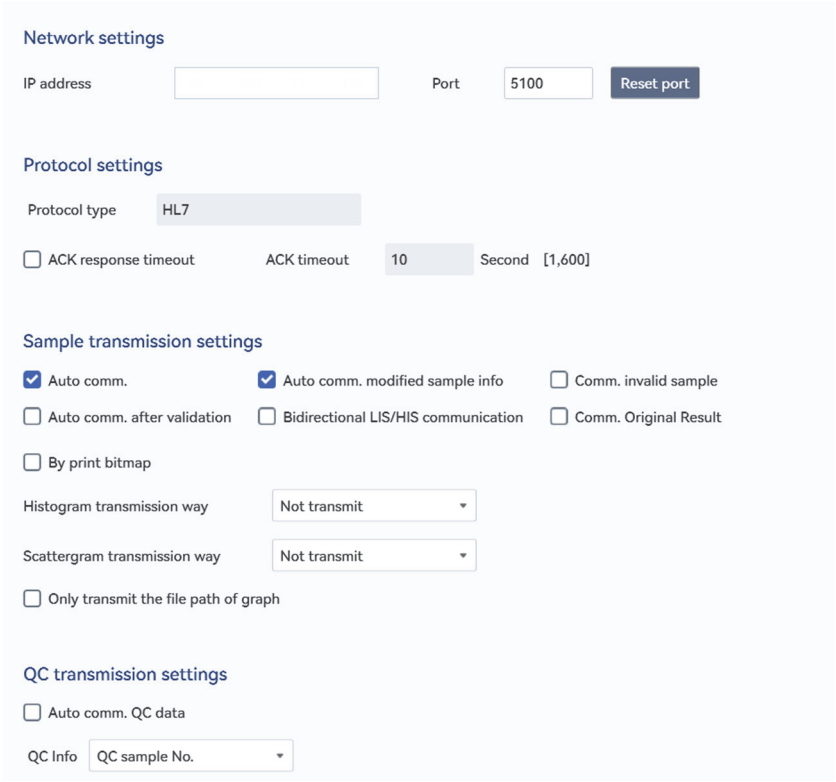
   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default export file name is "ReferenceRange_yyyyMMdd_hhmmss.csv", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
4. Click **Save**.

   The interface prompts **Exported successfully!**, indicating that the reference ranges are exported successfully.

11.3.8 LIS Communication Settings

Click **Settings** > **LIS comm. settings** to enter the interface. See Figure 11-20. You can set the communication between DMS software and LIS.

Figure 11-20 LIS Comm. Settings



Refer to Table 11-5 for the descriptions of related parameters.

Table 11-5 Parameter Descriptions of LIS Communication Settings

Parameter		Meaning	Operation
Network settings	IP address	The IP address of LIS workstation. If the LIS workstation and DMS software are installed on the same computer, the IP address can be set to the IP address of the computer, or "127.0.0.1".	Please set according to the actual situation. **Note** If DMS software is disconnected from LIS, please click **Reset port** to reconnect with LIS.
	Port	The port No. of the LIS workstation, and the default value is 5000.	Please set according to the actual situation. Input range: an integer between 1 and 65535.
Protocol settings	The type of the protocol.	It displays the current protocol type, the default type is HL7.	Read only.
	ACK response timeout	Set whether to turn on ACK response timeout. ● Checked: when DMS software communicates with LIS, if the ACK response from LIS is received within the set **ACK timeout** time, it means the communication succeeds; otherwise, the communication fails. ● Unchecked (default): when DMS software communicates with LIS, it always deems that the communication succeeds no matter whether it receives the ACK response from LIS. **Note** Regardless of whether the communication succeeds or not, DMS software will continue to send the next message.	Select according to the actual situation.

Parameter		Meaning	Operation
	ACK timeout	The timeout time of ACK response. The default time is 10s, that is, if DMS software does not receive the ACK response within 10s, it is considered that the communication fails. **Note** This parameter is valid only when **ACK response timeout** is checked.	Input in the edit box directly. Input range: an integer between 1 and 600. Unit: second (s).
Sample transmission settings	Auto comm.	Set whether DMS software automatically transmits the analysis results of the normal sample No. and the invalidated sample to LIS. ● Checked: after DMS software receives the analysis results of the normal sample No. transmitted by the main unit, it will automatically transmit the results to LIS without validation. ● Unchecked (default): it does not transmit the sample results to LIS automatically.	Select according to the actual situation.
	Auto comm. after modifying the result	Set whether DMS software automatically transmits the analysis results without validation to LIS/HIS after you modify the results. ● Checked: DMS software automatically transmits the analysis results to LIS/HIS without validation after you modify the results. ● Unchecked (default): DMS software does not transmit the analysis results after you modify the results. **Note** The Auto comm. after modifying the result is displayed only when Auto comm. is checked.	Select according to the actual situation.

Parameter		Meaning	Operation
	Comm. invalid sample	Set whether DMS software automatically transmits the analysis results of the sample whose number is Invalid to LIS. ● Checked: after DMS software receives the analysis results of the sample whose number is Invalid transmitted by the main unit, it will automatically transmit the results to LIS. ● Unchecked (default): it does not transmit the sample whose number is Invalid to LIS automatically. **Note** The **Comm. invalid sample** is displayed only when **Auto comm.** is checked.	Select according to the actual situation.
	Auto comm. after validation	Set whether DMS software automatically transmits the analysis results to LIS after you validate the results on DMS software. ● Checked: DMS software transmits the analysis results to LIS automatically after you validate the results on DMS software. ● Unchecked (default): DMS software does not perform any operation after you validate the results on DMS software.	Select according to the actual situation.

Parameter		Meaning	Operation
	Bidirectional LIS/HIS communication	Set whether DMS software communicates with LIS in both directions. ● Checked: after pre-inputting the sample or auto sampling, DMS software automatically obtains the corresponding mode and patient information from LIS according to the sample No.; and after the sample analysis is completed, it automatically transmits the analysis results to LIS. ● Unchecked (default): DMS software does not automatically obtain the sample information; after the sample analysis is completed, the setting of the **Auto Comm.** determines whether to transmit the sample results to LIS.	Select according to the actual situation.
	Comm. Original Results	Set whether the DMS transmit the original results to the LIS. ● Checked: transmit only the original results to the LIS. ● Unchecked (default): only the results processed by the DMS will be transmitted to the LIS.	Set as necessary.
	By print bitmap	Set whether to transmit sample data to LIS by print bitmap. ● Checked: transmit sample data to LIS by print bitmap. ● Unchecked (default): do not transmit sample data to LIS by print bitmap.	Select according to the actual situation.

Parameter		Meaning	Operation
	Histogram transmission way	The transmission way of histogram when DMS software communicates the sample results to LIS. It includes: ● Not transmit (default) Do not transmit the histogram to the LIS. ● By BMP bitmap Transmit the histogram to LIS by BMP bitmap. ● By PNG bitmap Transmit the histogram to LIS by PNG bitmap. ● By data Transmit the histogram data to LIS.	Select according to the actual situation.
	Scattergram transmission way	The transmission way of scattergram when DMS software communicates the sample results to LIS. It includes: ● Not transmit (default) Do not transmit the scattergram to LIS. ● By BMP bitmap Transmit the scattergram to LIS by BMP bitmap. ● By PNG bitmap Transmit the scattergram to LIS by PNG bitmap. ● By data Transmit the scattergram data to LIS.	Select according to the actual situation.

Parameter		Meaning	Operation
	Only transmit the file path of the graph	• Checked: if the graph or scattergram transmission is set and **only transmit the file path of the graph** is checked, it will only transmit graph storage path to LIS. • Unchecked (default): if the graph or scattergram transmission is set but **only transmit the file path of the graph** is unchecked, it will not transmit graph storage path to LIS.	Select according to actual situation.
QC transmission settings	Auto comm. QC data	• Checked: after DMS software receives the QC analysis results transmitted by the main unit, it automatically transmits the results to LIS. • Unchecked (default): after DMS software receives the QC analysis results transmitted by the analyzer, it does not transmit the results to LIS.	Select according to the actual situation.
	QC Info	The QC information transmitted to the LIS when DMS software is performing QC analysis result communication, including: • QC sample No. The QC sample ID is transmitted to the LIS during QC communication. • File No. The File No. is transmitted to the LIS during QC communication.	Select according to the actual situation.

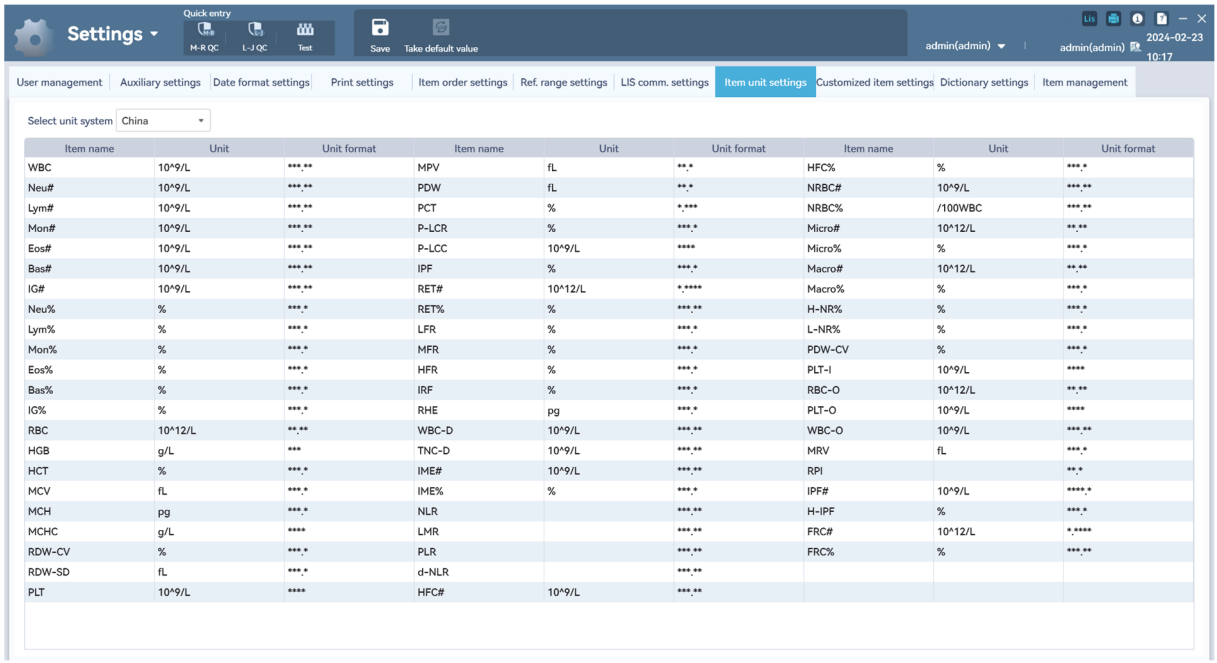
11.3.9 Item Unit Settings

Some of the parameters of the analyzer can use different units. You can choose according to actual needs.

11.3.9.1 Entering the Interface

Click **Settings** > **Item unit settings** to enter the interface. See Figure 11-21.

Figure 11-21 Item Unit Settings



Item name	Unit	Unit format	Item name	Unit	Unit format	Item name	Unit	Unit format
WBC	10^9/L	***.**	MPV	fL	**.*	HFC%	%	***.*
Neu#	10^9/L	***.**	PDW	fL	**.*	NRBC#	10^9/L	***.**
Lym#	10^9/L	***.**	PCT	%	*.***	NRBC%	/100WBC	***.**
Mon#	10^9/L	***.**	P-LCR	%	***.*	Micro#	10^12/L	**.**
Eos#	10^9/L	***.**	P-LCC	10^9/L	****	Micro%	%	***.*
Bas#	10^9/L	***.**	IPF	%	***.*	Macro#	10^12/L	**.**
IG#	10^9/L	***.**	RET#	10^12/L	*.****	Macro%	%	***.*
Neu%	%	***.*	RET%	%	***.**	H-NR%	%	***.*
Lym%	%	***.*	LFR	%	***.*	L-NR%	%	***.*
Mon%	%	***.*	MFR	%	***.*	PDW-CV	%	***.*
Eos%	%	***.*	HFR	%	***.*	PLT-I	10^9/L	****
Bas%	%	***.*	IRF	%	***.*	RBC-O	10^12/L	**.**
IG%	%	***.*	RHE	pg	***.*	PLT-O	10^9/L	****
RBC	10^12/L	**.**	WBC-D	10^9/L	***.**	WBC-O	10^9/L	***.**
HGB	g/L	***	TNC-D	10^9/L	***.**	MRV	fL	***.*
HCT	%	***.*	IME#	10^9/L	***.**	RPI		**.*
MCV	fL	***.*	IME%	%	***.*	IPF#	10^9/L	****.*
MCH	pg	***.*	NLR		***.**	H-IPF	%	***.*
MCHC	g/L	****	LMR		***.**	FRC#	10^12/L	*.****
RDW-CV	%	***.*	PLR		***.**	FRC%	%	***.**
RDW-SD	fL	***.*	d-NLR		***.**			
PLT	10^9/L	****	HFC#	10^9/L	***.**			

11.3.9.2 Selecting Unit System

Click the **Select unit system** drop-down list and select a unit system for the parameters among the 7 unit systems (China, International, Britain, USA, Canada, Netherlands, and customize). The default unit system is **International**.

NOTE

- The unit of each parameter is displayed differently when selecting different unit systems.
- The unit of each parameter of the **Customize** unit system can be modified; the parameters of other options can only be viewed but not modified.

11.3.9.3 Modifying the Unit of Customized Item

You can modify the unit of each item in the customized unit system.

Detailed steps are as follows.

1. Select **Customize** in the **Select unit system** drop-down list.
2. Click the **Unit** drop-down list corresponding to the item whose unit needs to be modified, and select a new unit.

NOTE

- When the unit of an item is modified, the units of other items related to it also change.
- After selecting different units, the corresponding item format will be changed accordingly.

3. Click **Save** to complete the settings.

11.3.9.4 Taking Default Value

When setting the **Customize** unit system, if you click **Take default value**, the units of the parameters can be restored to the initial default values.

11.3.10 Dictionary Settings

You can set the shortcut code for the patient information. The types of the patient information that can set a shortcut code include: patient type, department, sample type, charge type, ward, physician, diagnosis and remark.

The shortcut codes of different types can be the same.

If a shortcut code is set, you can directly input the shortcut code corresponding to the item when inputting or editing the patient information, and then press the [ENTER] key to display the complete information. You do not need to input the complete information.

11.3.10.1 Entering the Interface

Click **Settings** > **Dictionary settings** to enter the interface. Patient type, and charge type already have some preset data. See Table 11-6.

Table 11-6 System Preset Data

Type	Preset Data	
	Dictionary Name	Shortcut Code
Patient type	Outpatient	mz
	Inpatient	zy
	Emergency	jz
	Physical examination	tj
Charge type	Self-pay	zf
	Public	gf
	Medicare insurance	yb

11.3.10.2 Adding Data Dictionary

In addition to the data dictionary preset in the system, you can also add new data dictionary according to actual needs.

This section takes the adding of a new patient type as an example to introduce the method of adding a new data dictionary. The method of adding other type of data dictionary is similar, and will not be repeated.

Follow below steps to add a new data dictionary of patient type:

1. Click Patient type.
2. Click **Add**.

   A blank line is added in the data dictionary list area on the right of the interface.
3. Click the cell in the blank line, and input the information of the data dictionary (name, shortcut code, and remark).

   NOTE

   - The name of the data dictionary cannot be empty, and the name of the same type cannot be the same.
   - The shortcut code of the data dictionary can be empty, but the shortcut code of the same type cannot be the same.
4. Click **Save** to complete the settings.

11.3.10.3 Editing Data Dictionary

NOTE

The name of the data dictionary preset in the system is not allowed to be edited, but you can edit its shortcut code and remark; you can edit the data dictionary you add.

This section takes the editing of the patient type as an example to introduce the method of editing the data dictionary. The method of editing other type of data dictionary is similar, and will not be repeated.

Follow below steps to edit the data dictionary of patient type:

1. Click **Patient type**.
2. Select the data dictionary to be edited in the data dictionary list area on the right of the interface.
3. Double click, and edit the information of the data dictionary (name, shortcut code, and remark).

NOTE

- The name of the data dictionary cannot be empty, and the name of the same type cannot be the same.
- The shortcut code of the data dictionary can be empty, but the shortcut code of the same type cannot be the same.

4. Click **Save** to finish editing.

11.3.10.4 Deleting Data Dictionary

NOTE

The data dictionary preset in the system cannot be deleted, but you can delete the data dictionary you add.

This section takes the deleting of the patient type as an example to introduce the method of deleting the data dictionary. The method of deleting other type of data dictionary is similar, and will not be repeated.

Follow below steps to delete the data dictionary of patient type:

1. Click **Patient type**.
2. Select the data dictionary to be deleted in the data dictionary list area on the right of the interface.
3. Click **Delete**.

   The selected data dictionary is deleted.

12 Service

In order to ensure the accurate and effective operation of the main unit, you shall carry out daily maintenance to the main unit according to the requirements of this chapter.

This chapter introduces the maintenance functions of the main unit on HOST software and the maintenance-related reference information. It also introduces the sample tracking function of CMS software and how to browse version information, as well as other menu functions of DMS software.

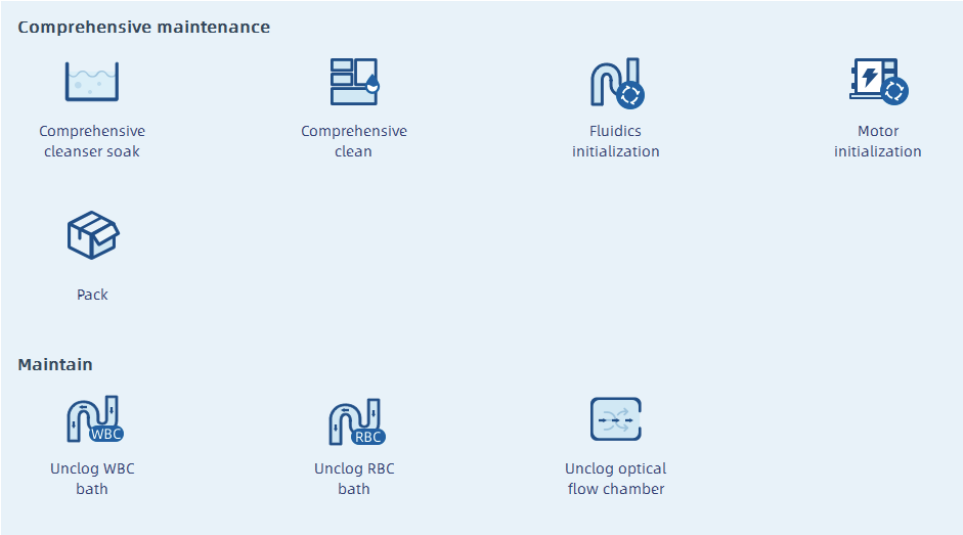
12.1 Maintenance (HOST Software)

A number of maintenance functions are provided on HOST software to facilitate you to complete daily maintenance work. They include comprehensive maintenance, cleaning, reagent replacing and prefusing.

12.1.1 Comprehensive Maintenance

Click > **Maintenance** > **Device maintenance** to enter the interface. The interface consists of two parts: comprehensive maintenance and maintain. See Figure 12-1.

Figure 12-1 Device Maintenance



12.1.1.1 Comprehensive Maintenance

Comprehensive maintenance function consists of comprehensive cleanser soak, comprehensive

clean, fluidics initialization, motor initialization and pack.

Comprehensive Cleanser Soak

When the following situations occur, please perform comprehensive cleanser soak.

- When the background result is out of the background range, the QC is abnormal, the scattergram classification effect is reduced, etc., you should perform comprehensive cleanser soak. The reason for these situations may be that the analyzer has not been used for a long time or is restarted after an abnormal power failure.
- When other maintenance operations have been performed after the analyzer is clogged, but the clogging is not improved, you should perform comprehensive cleanser soak.

Follow below steps to perform comprehensive cleanser soak.

1. In the comprehensive maintenance area, click **Comprehensive cleanser soak**.

   The interface prompts **This operation will take a long time. Do you want to continue?**.

2. Click **Yes**.

   - If the sample delivery component is already in the manual sampling position, the interface prompts **Please place the cleanser to the whole blood sampling position**. Now you can perform step 3.
   - If the sample delivery component is not in the manual sampling position, click **Yes** again in the pop-up dialog box. The interface prompts **Please place the cleanser to the whole blood sampling position.**, and the sample delivery component moves to the manual sampling position. Now you can perform step 3.

3. Please place the cleanser to the venous whole blood sampling position, and then click **OK** to continue.

   The interface prompts **Cleanser maintaining, please wait...**.

   When the maintenance is completed, the interface prompts **"Comprehensive cleanser soak" is completed!**.

   Whenever the comprehensive cleanser soak succeeds, the **Current cumulative running times** in *11.1.3 Auto Maintain Settings* will be automatically cleared.

4. Click **OK** to close the prompt box.

Comprehensive Cleaning

You should perform comprehensive cleaning when the background results of various parameters exceed the ranges.

Follow below steps to perform comprehensive cleaning.

1. In the comprehensive maintenance area, click **Comprehensive clean**.

   The interface prompts **Performing "Comprehensive clean", please wait...**.

   When the maintenance is completed, the interface prompts **"Comprehensive clean" is completed!**.

2. Click **OK** to close the prompt box.

NOTE

When performing the compressive cleaning, the aperture can be cleaned by positive and negative pressure and burned by high pressure to reduce the clogging rate in the process of using the analyzer.

Fluidics Initialization

If the main components are replaced or the analyzer fluidics system is repaired, you should perform fluidics initialization.

Detailed steps are as follows.

1. In the comprehensive maintenance area, click **Fluidics initialization**.

   The interface prompts **Performing "Fluidics initialization", please wait...**.

   When the fluidics initialization is completed, the interface prompts **"Fluidics initialization" is completed!**.

2. Click **OK** to close the prompt box.

Motor Initialization

If necessary, perform the motor initialization according to the following steps.

1. In the comprehensive maintenance area, click **Motor initialization**.

   The interface prompts **Performing "Motor initialization", please wait...**.

   When the motor initialization is completed, the interface prompts **"Motor initialization" is completed!**.

2. Click **OK** to close the prompt box.

Packing

If the analyzer is not used for a long time or transported over long distances, you should perform packing maintenance.

Detailed steps are as follows.

1. In the comprehensive maintenance area, click **Pack**.

   The interface prompts **Pack?**.

2. Click **Yes**.

   The interface prompts **Take out the pipes in all reagent barrels except the waste barrel, and click "OK" to continue.**.

3. Take out the pipes in all reagent barrels except the waste barrel, and click **OK**.

   The main unit starts to empty the fluidics, and the interface prompts **Emptying fluidics, please wait...**.

When the fluidics is emptied, the interface prompts **Place the pipes in all reagent barrels except the waste barrel into distilled water, and click "OK" to continue.**.

4. Place the pipes in all reagent barrels except the waste barrel into the beaker with distilled water, and click **OK**.

NOTE

- In order to ensure the normal use of the device, please be sure to use distilled water for perfusing, and the beaker containing the distilled water must be thoroughly cleaned.
- Place the diluent pipe and the lyse pipe into separate beakers.
- About 1,000ml of distilled water is required for the entire perfusing process.

The main unit starts to perfuse, and the interface prompts **Perfusing distilled water, please wait....**

When the perfusing is completed, the interface prompts T**ake out all pipes in distilled water, and click "OK" to continue.**.

5. Take out all pipes in distilled water, and click **OK**.

   The main unit starts to empty the fluidics, and the interface prompts **Emptying fluidics, please wait....**

   When the fluidics is emptied, the interface prompts **Please power off the device!**.

6. Turn off the power switch of the main unit. Empty the waste in the waste container, and dispose of the waste properly.

Warning

You are obligated to discharge and dispose of the reagents, wastes, samples, consumables according to local legislations and regulations.

12.1.1.2 Maintain

It includes WBC bath unclogging, RBC bath unclogging and optical flow chamber unclogging.

The following takes the WBC bath unclogging as an example to introduce the unclogging steps. The other two types of unclogging are similar, and will not be repeated.

1. In the maintain area, click **Unclog WBC bath**.

   The interface prompts **Performing "Unclog WBC bath", please wait....**

2. When the unclogging is completed, the interface prompts **"Unclog WBC bath" is completed!**.
3. Click **OK** to close the prompt box.

NOTE

When performing the compressive cleaning, the aperture can be cleaned by positive and negative pressure and burned by high pressure to reduce the plugging rate in the process of using the analyzer.

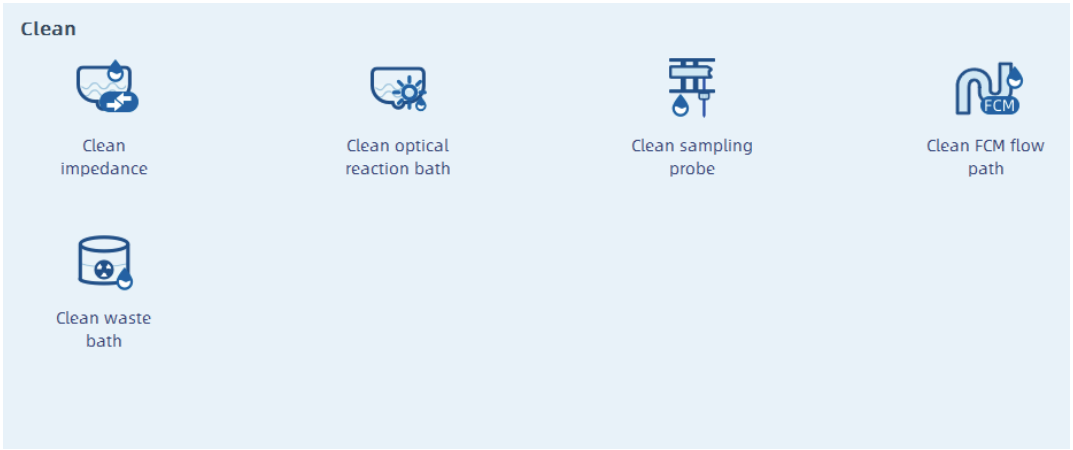
12.1.2 Cleaning

It includes impedance bath cleaning, optical reaction bath cleaning, sampling probe cleaning, FCM flow path cleaning and waste bath cleaning.

The following takes the cleaning of impedance bath as an example to introduce the cleaning steps. The steps of cleaning other two components are similar, and will not be repeated.

1. Click  > **Maintenance** > **Clean** to enter the interface. See Figure 12-2.

   Figure 12-2 Clean



2. Click **Clean impedance bath**.
3. The interface prompts **Performing "Clean impedance bath", please wait....**

   When the cleaning is completed, the interface prompts **"Clean impedance bath" is completed!**.
4. Click **OK** to close the prompt box.

12.1.3 Replacing and Perfusing Reagents

Warning

- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, mask, etc.) and comply with laboratory safety procedures while contacting them and the relevant areas in the laboratory.
- Once the reagent accidentally comes in contact with your skin, rinse with plenty of water immediately and receive medical treatment if necessary. If you accidentally get any of the reagent into your eyes, rinse with plenty of water immediately, and receive medical treatment.

NOTE

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- You should perform background test after replacing the reagent to ensure the background values are within the normal ranges, and to make preparation for the sample analysis.

You can replace and perfuse reagents in the replace & perfuse reagent interface

Reagent replacement

- The systems prompts that the reagent is used up.
- It is suspected that the reagent in the tubing is contaminated
- The reagent is contaminated or expired.
- It is suspected that there exist bubbles in the tubing.

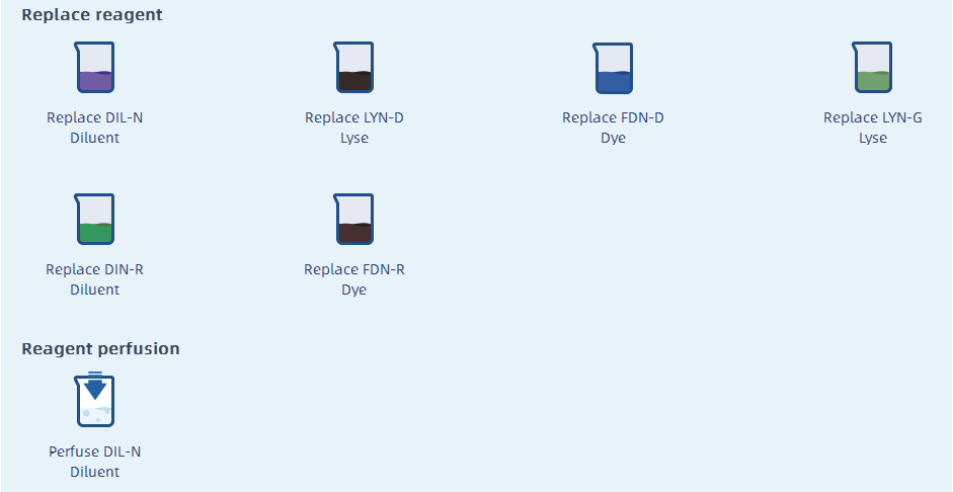
You can replace the following reagents:

- DIL-N diluent
- DIN-R diluent
- LYN-D lyse
- LYN-G lyse
- FDN-D dye
- FDN-R dye

The steps of replacing the reagent are as follows.

1. Perform reagent connection by referring to Figure 2-3 and Figure 2-6 of ***2.3.2 Reagent Connection***.
2. Click  > **Maintenance** > **Replace & perfuse reagent** to enter the replace & perfuse reagent interface. See Figure 12-3.

Figure 12-3 Replace & perfuse Reagent



If the main unit disables the RET channel, the reagent replacement interface only displays the icons of diluent and lyse. If you need to disable the RET channel, contact Dymind customer service department or the local agent.

3. Click the reagent that needs to be replaced, for example, **Replace DIL-N Diluent**.

   The interface prompts **Performing "Replace DIL-N Diluent", please wait....**

   When the replacing is completed, the interface prompts **"Replace DIL-N Diluent" is completed!**.

4. Click **OK** to close the prompt box.

Refer to the above steps to replace other reagents if needed.

Reagent perfusion

The steps of DIL-N diluent perfusion are as follows:

1. Click > **Maintenance** > **Replace & perfuse reagent** to enter the replace & perfuse reagent interface.
2. Click **Perfuse DIL-N Diluent**.

   The interface prompts **Performing "perfuse DIL-N Diluent", please wait...**

   When the replacing is completed, the interface prompts **"Perfuse DIL-N Diluent" is completed!**.

3. Click **OK** to close the prompt box.

12.2 Self-test (HOST Software)

HOST software supports the service of touch screen calibration self-test.

NOTE

- After entering the touch screen calibration interface, if it is the set auto sleep time, the main unit is not allowed to enter the sleep mode at this time. After exiting the touch screen calibration interface, the main unit enters the auto sleep mode immediately.
- After entering the touch screen calibration interface, if it is the set cleanser maintenance time, the main unit is not allowed to enter the cleanser maintenance process at this time. After exiting the touch screen calibration interface, the analyzer performs the cleanser maintenance process immediately.
- After exiting the touch screen calibration interface, when you click the error information area in the upper right corner of the interface, the interface prompts **Error removing operation cannot be performed on this interface. Please exit this interface before viewing the detailed error information.**

Detailed steps are as follows.

1. Click  > **Self-test** > **Touch screen calibration** to enter the interface.
2. Click Touch screen calibration.

   The main unit enters the full-screen mode of touch screen calibration.

   The touch screen is calibrated through five points including the four corners and the center position of the screen, and the calibration position is marked with the symbol "+".
3. Perform calibration from the upper left corner, upper right corner, lower right corner, lower left corner, center position of the screen in a clockwise order.

   When completing the calibration of one point, the calibration position marker will automatically jump to the next calibration point.

   When calibrating, the input that is not within the calibration range cannot facilitate it to jump to the next calibration point.
4. After the calibration is completed, the analyzer automatically exits the full-screen mode, the interface prompts **The calibration is completed!**.
5. Click **OK** to close the prompt box.

12.3 Status (HOST Software)

You can check the current status information of the main unit on the status interface of HOST software, including sensor status, temperature status, pressure status, voltage and current status and version information.

12.3.1 Sensor Status

NOTE

- After entering the sensor status interface, if it is the set auto sleep time, the main unit is not allowed to enter the sleep mode at this time. After exiting the sensor status interface, the main unit enters the auto sleep mode immediately.
- After entering the sensor status interface, if it is the set cleanser maintenance time, the main unit is not allowed to enter the cleanser maintenance process at this time. After exiting the sensor status interface, the main unit performs the cleanser maintenance process immediately.
- After exiting the sensor status interface, when you click the error information area in the upper right corner of the interface, the interface prompts **Error removing operation cannot be performed on this interface. Please exit this interface before viewing the detailed error information.**.
- There is no capillary blood mixing motor on the sensor status interface of some models, and the actual interface display shall prevail.

Click > **Status** > **Temperature status** to enter the interface. You can view the trend chart of various temperatures, including ambient temperature, FCM reaction bath temperature, FCM preheating bath temperature, and laser diode temperature. You can also export and empty on this interface.

12.3.2 Temperature Status

NOTE

- After entering the temperature status interface, if it is the set auto sleep time, the main unit is not allowed to enter the sleep mode at this time. After exiting the temperature status interface, the main unit enters the auto sleep mode immediately.
- After entering the temperature status interface, if it is the set cleanser maintenance time, the main unit is not allowed to enter the cleanser maintenance process at this time. After exiting the temperature status interface, the main unit performs the cleanser maintenance process immediately.
- After exiting the temperature status interface, when you click the error information area in the upper right corner of the interface, the interface prompts **Error removing operation cannot be performed on this interface. Please exit this interface before viewing the detailed error information.**.

Click > **Status** > **Temperature status** to enter the interface. You can view the trend chart of various temperatures, including ambient temperature, FMC reaction bath temperature, FMC preheating bath temperature, laser diode temperature, MPPC chip temperature, MPPC board temperature, MPPC sheet metal temperature, and impedance diluent temperature. You can also export and empty on this interface.

12.3.3 Pressure Status

NOTE

- After entering the pressure status interface, if it is the set auto sleep time, the main unit is not allowed to enter the sleep mode at this time. After exiting the pressure status interface, the main unit enters the auto sleep mode immediately.
- After entering the pressure status interface, if it is the set cleanser maintenance time, the main unit is not allowed to enter the cleanser maintenance process at this time. After exiting the pressure status interface, the main unit performs the cleanser maintenance process immediately.
- After exiting the pressure status interface, when you click the error information area in the upper right corner of the interface, the interface prompts **Error removing operation cannot be performed on this interface. Please exit this interface before viewing the detailed error information.**.

Click > **Status** > **Pressure status** to enter the interface. You can view the pressure status of the main unit. If the pressure detection value exceeds the normal range, it will be highlighted with a red background color.

12.3.4 Voltage and Current Status

NOTE

- After entering the voltage and current status interface, if it is the set auto sleep time, the main unit is not allowed to enter the sleep mode at this time. After exiting the voltage and current status interface, the main unit enters the auto sleep mode immediately.
- After entering the voltage and current status interface, if it is the set cleanser maintenance time, the main unit is not allowed to enter the cleanser maintenance process at this time. After exiting the voltage and current status interface, the main unit performs the cleanser maintenance process immediately.
- After exiting the voltage and current status interface, when you click the error information area in the upper right corner of the interface, the interface prompts **Error removing operation cannot be performed on this interface. Please exit this interface before viewing the detailed error information.**.

Click > **Status** > **Voltage&Current status** to enter the interface. You can view the voltage and current information of the analyzer. If the voltage or current detection value exceeds the normal range, it will be highlighted with a red background color.

12.3.5 Version Information

Click > **Status** > **Version info** to enter the interface. You can view the version information of HOST software and hardware component of current main unit. See Figure 12-4.

Figure 12-4 HOST Software Version Information

Name	Version No.
Software release version	1
Software full version	1.2.11.8600
Technical file version	A2.11
MLO	0.11.9.1388
Boot software	0.11.9.1388
Algorithm	1.3.18160.23745P
Sequence	1116.1.10.01
App software	1.2.11.8600
Driver board MCU	1.0.0.20049
Driver board FPGA	0.40.0.20
Main control board FPGA	0.37.0.40
Reader board MCU	1.0.0.16425
Temp. control board MCU	1.0.0.20171
Optical adapter board MCU	1.0.0.20374

12.3.6 Device Statistics

Click  > Status > Device Statistics to enter the interface. You can view the times of sample analysis, quality control, calibration, and background sample analysis of the device.

12.4 Sleep (HOST Software)

The main unit will automatically enter the sleep mode when the accumulated time of the main unit without fluidics operation reaches the wait time set by the system (the default is 30 minutes).

When the main unit enters the sleep mode, the screen prompts that the device is in the sleep mode. Click the screen, or press the aspiration button on the device and click **Exit sleep** to exit from the sleep mode.

NOTE

- Please refer to ***11.1.3 Auto Maintain Settings*** to modify the auto sleep wait time if needed.
- If it is the time to auto sleep but the main unit is in error status, then only after the error is removed will the auto sleep be started accordingly.
- According to the length of sleep time, the main unit will automatically perform different levels of maintenance when exiting from sleep mode, and the maintenance time will be different.
- If any error appears during the process of exiting from sleep mode, please refer to ***16 Troubleshooting*** to solve the problem.

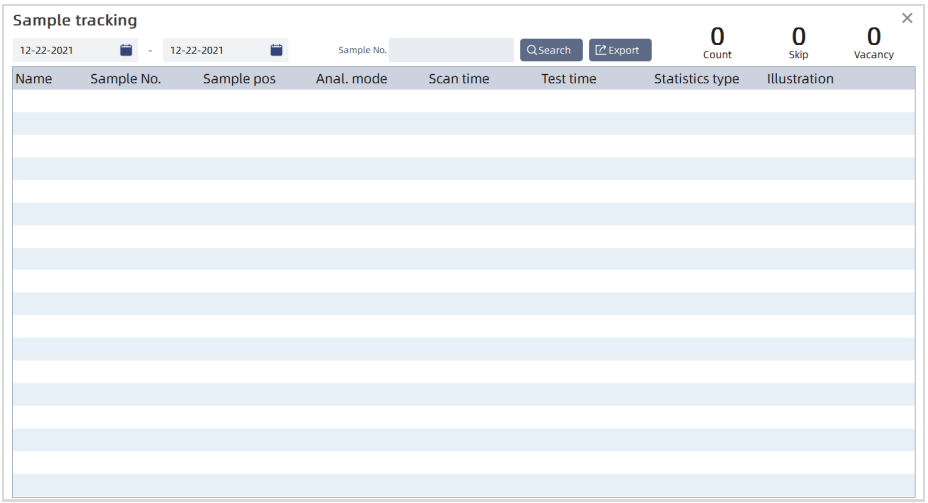
12.5 Sample Tracking (CMS Software)

On the sample tracking interface of CMS software, you can search the tracking record of auto sampling sample under specified conditions, and can also export the record.

12.5.1 Entering the Interface

Click > **Sample tracking** to enter the interface. See Figure 12-5.

Figure 12-5 Sample Tracking



The statistics type includes count, skip, and vacancy.

- Count: the sample that is counted under auto sampling.
- Skip: the sample that is skipped under auto sampling.
- Vacancy: the sample position without test tube under auto sampling.

12.5.2 Searching Sample Tracking Record

You can search the sample tracking record within the specified date range; you can also search

the sample tracking record of the specified sample No. within the specified date range in combination with the sample No.

- Searching the record within the specified date range

  Set the date range.

  Set the date range in the two date edit boxes.

  Click **Search**.

  The records that meet the date range are displayed in the sample tracking list, and the data of each statistics type in the upper right corner of the interface is refreshed.

- Searching the record of the specified sample No. within the specified date range

  a. Set the date range.

  Set the date range in the two date edit boxes.

  Set the sample No.

  Input the sample No. in the sample number edit box.

  Click **Search**.

  The records with specified sample No. that meet the date range are displayed in the sample tracking list, and the data of each statistics type in the upper right corner of the interface is refreshed.

12.5.3 Exporting Sample Tracking Record

You can export the qualified records after searching.

1. Click **Export**.
2. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default export file name is “SampleTracking__yyyyMMdd_hhmmss.csv", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.

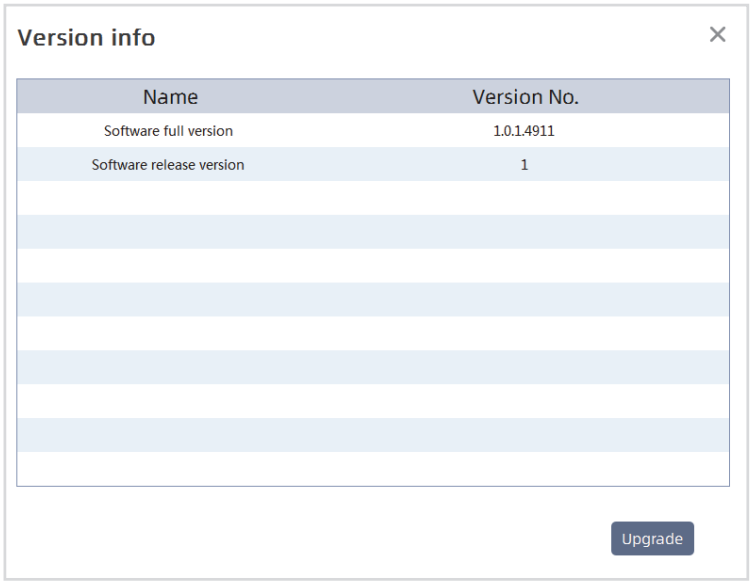
3. Click **Save**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

12.6 Version Information (CMS Software)

Click > **Version** on CMS software to view the version information of CMS software. See Figure 12-6.

Figure 12-6 CMS Software Version Information



12.7 Others (DMS Software)

The main functions of the others menu on DMS software include backing up DMS software data and restoring DMS software data.

12.7.1 Entering the Interface

Click **Others** to enter the interface. You can perform operations such as data backup and data restoring.

12.7.2 Backing up DMS Software Data

The content of the data backup includes sample data, L-J QC data, X-B QC data, and setting data.

Data backup is divided into auto backup and manual backup.

- Auto backup

  The software automatically backs up data after reaching the set conditions according to the set backup period and the time of starting the backup. After the auto backup is completed, the interface displays the information of the last successful backup.

- Manual Backup

You can back up the data within the specified date range by clicking **Start backup** to start manual backup.

Auto backup

The detailed steps are as follow.

1. Click **Others** to enter the interface.
2. Set the auto backup cycle.

   Check the **Auto** radio box, and select the auto backup cycle (1 day, 3 days, 7 days, 30 days) according to actual needs. The default is 7 days.
3. Set the time of starting the auto backup.

   Set the start time of auto backup in the **Start backup** edit box. The time range is between 0:00 and 23:59, and the default is 00:00.
4. Select backup path.

   You can use the system default backup path, or reselect the path according to actual needs.

   - Default path: the backup path defaults to the “Dymind DMS data” folder of the local disk (exclude local disk C) with the smallest free space of the external computer; or the path selected last time.
   - Reselect the path: click **Browse**, and reselect the path in the pop-up dialog box.
   - The default backup file name is “DMS data_ *Backup start time _ Backup end time*.sql”.

Manual backup

The detailed steps are as follow.

1. Click **Others** to enter the interface.
2. Set the manual backup cycle.

   Check the **Manual** radio box, and set the date range in the two date edit boxes.
3. Select backup path.

   You can use the system default backup path, or reselect the path according to actual needs.

   - Default path: the backup path defaults to the “Dymind DMS data” folder of the local disk (exclude local disk C) with the smallest free space of the external computer; or the path selected last time.
   - Reselect the path: click **Browse**, and reselect the path in the pop-up dialog box.
   - The default backup file name is “DMS data_ *Backup start time _ Backup end time*.sql”.
4. Click **Start backup** to start back up the data.

   After the backup is complete, click **OK** in the prompt box to close the prompt box.

12.7.3 Restoring DMS Software Data

NOTE

- The import process cannot be interrupted, please make sure the file is correct.
- During the import process, the software cannot perform other operations, please be patient.

It supports the recovery of a single file data at a time, and also supports the recovery of all file data at one time.

The detailed steps are as follow.

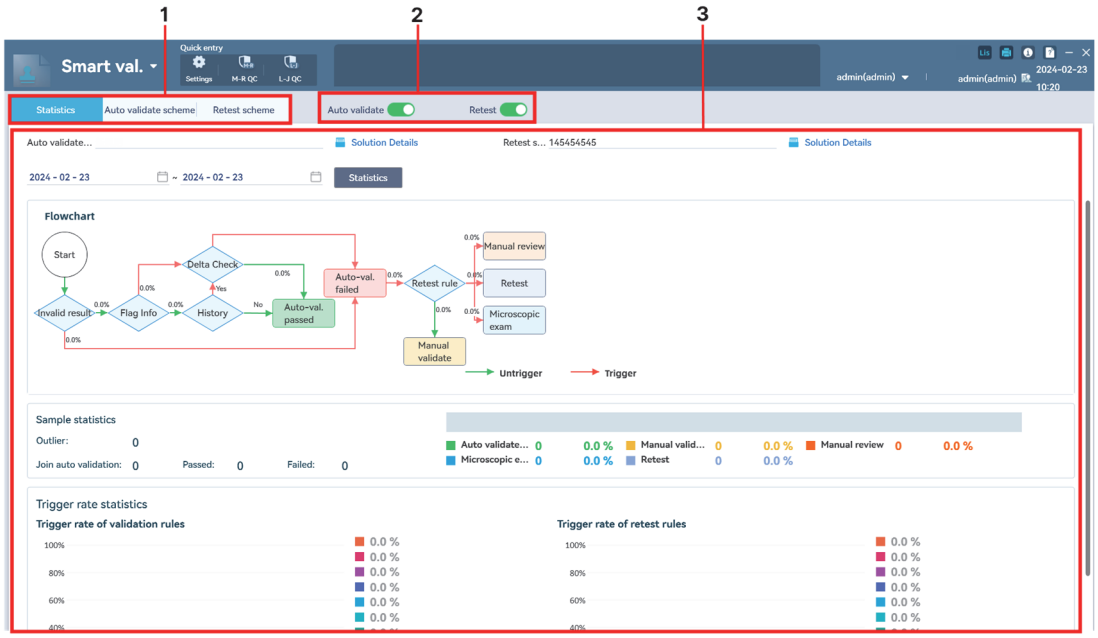
1. Click **Others** to enter the interface.
2. Click **Browse**, and select the imported file in the pop-up dialog box.
3. Click **Start restore** to start restore the data.

12.8 Smart Validation

Smart validation realizes the customization of validation rules and retest rules, which enables users to customize solutions of sample validation and retest.

12.8.1 Entering the Interface

Click **Smart Validate** to enter the interface. You can set validation rules and retest rules on the interface.



Explanations:

- 1—Tabs

Including statistics tabs, auto validate scheme tabs and retest scheme tabs.

- 2—Auto validate and retest switch
  - Open: the system automatically validates or retests the sample results.
  - Close: the operator validates or retests the sample results.
- 3—Detailed info area

  The detailed interface of the selected tab is displayed.

12.8.2 Retest

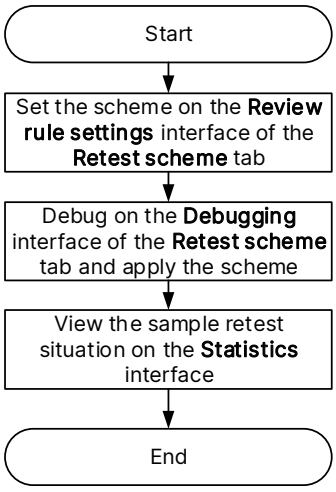
Retest refers to the secondary test conducted on the sample results that trigger the retest rule according to the set rule during the test. The Auto Hematology Analyzer provides the auto retest function, which enables users to set the retest rule on DMS software according to actual needs. After retest settings are completed, the analyzer will automatically return and retest the samples that trigger the retest rule.

NOTE

- Please prudently set the auto retest rule in strict accordance with the laboratory operation requirements.
- The auto retest function is only available for auto sampling. Manual sampling is not supported, and it only triggers the retest scheme rules, the system will not start the retest.
- If you need to use the retest function, you need to open the **Retest** button on the **Smart Validate** interface.
- When multiple retest rules are triggered concurrently, the retest priority is manual validation > microscopic exam > retest.

The process of using auto retest rule is as shown in Figure 12-7.

Figure 12-7 Auto Retest Flowchart



12.8.2.1 Setting Scheme

You can set and enable retest rule in the **Review rule settings** according to actual needs.

Click **Auto Validate** > **Retest scheme** > **Review rule settings** to enter the interface.

Add Retest Rule

Add a new retest rule by taking the following steps.

1. Click **New**.
2. Add a line in the retest rule list.
3. Set the retest rule in the **Rule details setting**. Specific parameter settings are as shown in Table 12-1, Table 12-2, Table 12-3 and Table 12-4.

Table 12-1 Parameter Description of Rule Details Setting

Parameter	Meaning	Operation Description
Rule name	Name of the rule	Input in the edit box

Parameter	Meaning	Operation Description
Solution	Measures applied by the rule, including: ● Manual review ● Test again ● Extra test ● Blood smearexam. Among them, test again can analyze the sample in the specified measurement mode during retest, including: ● Test again under the same mode ● C ● CD ● CDR ● CR ● R ● CD (LW) ● CDR (LW+LP) ● CR (LP) New-item test can add specified items based on the original measurement, including: ● +C ● +CD ● +CDR ● +CR ● +R ● +CD (LW) ● +CDR (LW+LP) ● +CR (LP)	Select in the drop-down list. **Notes** The analyzer supports the retest of low-level WBC and low-level PLT. You can set the measure to CD (LW), CR (LP) or CDR (LW+LP) according to actual situations for low-level value retest.

Parameter	Meaning	Operation Description
Rule type	Type of the rule, including: ● Clinical feature ● Item range ● Flag information ● Item range Delta Check ● Flag Delta Check	Select the rule you want to edit and click "+" to expand the table for editing.
Rule details	Details of the rule	Click "Update" for the selected content in the table, and the setting content will be displayed in the rule details simultaneously.
Rule relation	Relations between rules, including: ● OR ● AND	Select in the drop-down list.
Clinical feature	Set the clinical feature.	Refer to Table 12-2 for specific explanation and operation.
Item range	Select the parameter range for the applicable rule.	Refer to Table 12-3 for specific explanation and operation.
Flag information	Select Flag information.	Select and refresh in the drop-down list.
Item range Delta Check	Set item range Delta Check.	Refer to Table 12-4 for specific explanation and operation.
Flag Delta Check	Set Flag Delta Check information.	Click “+” to add a new column. Select Flag name in the drop-down list, input number of days and relations and save.

Table 12-2 Parameter Description of Clinical Feature Setting

Parameter	Meaning	Operation Description
First visit/return visit	Select the sample as first visit or return visit, including: ● First visit ● Return visit	Select and refresh in the drop-down list.
Ward	Select the ward for the sample.	Select and refresh in the drop-down list. **Notes** The data in the drop-down list is obtained from the data dictionary. The data set in ***11.3.10 Dictionary Settings*** prevails.
Patient type	Select patient type.	Select and refresh in the drop-down list. **Notes** The data in the drop-down list is obtained from the data dictionary. The data set in ***11.3.10 Dictionary Settings*** prevails.
Test item	Select the items for testing, including: ● Conforming conditions After checking conditions in this tab, items conforming to conditions trigger the retest rule. ● Exceptional conditions After checking conditions in this tab, other test items trigger the retest rule except the checked test items.	Select and refresh in the drop-down list.

Parameter	Meaning	Operation Description
Sample type	Select the sample type, including: ● Conforming conditions After checking conditions in this tab, sample types conforming to conditions trigger the retest rule. ● Exceptional conditions ● After checking conditions in this tab, other sample types trigger the retest rule except the selected sample types.	Select and refresh in the drop-down list.
Age	Set the sample age.	Input a number in the text box. Select year, month, day, or hour (“year” by default) from the drop-down list and update.
Clinical diagnosis	Select clinical diagnosis.	Select and refresh in the drop-down list. **Notes** The data in the drop-down list is obtained from the data dictionary. The data set in ***11.3.10 Dictionary Settings*** prevails.
Gender	Select gender, including: ● Null (by default) ● Male ● Female	Select and refresh in the drop-down list (optional).

Parameter	Meaning	Operation Description
Remarks	● Set the information or annotations to be declared, including: ● Conforming conditions After checking conditions in this tab, remarks conforming to conditions trigger the retest rule. ● Exceptional conditions After checking conditions in this tab, other remarks trigger the retest rule except the selected remarks.	Select or input directly in the drop-down list. **Notes** The data in the drop-down list is obtained from the data dictionary. The data set in ***11.3.10 Dictionary Settings*** prevails.
Department	Select the department to which the sample belongs, including: ● Conforming conditions After checking conditions in this tab, samples conforming to the selected department trigger the retest rule. ● Exceptional conditions After checking conditions in this tab, other departments trigger the retest rule except the selected departments.	Select or input directly in the drop-down list. **Notes** The data in the drop-down list is obtained from the data dictionary. The data set in ***11.3.10 Dictionary Settings*** prevails.
Refresh	Function button.	Click **Refresh** and save the settings.

Table 12-3 Parameter Description of Item Range Setting

Parameter	Meaning	Operation Description
Item name	Select the report parameter(s) for the sample.	Select in the drop-down list.
Condition	Conditions between parameter(s), including: ● > ● < ● = ● >= ● <=	Select in the drop-down list.

Parameter	Meaning	Operation Description
Value	Value of parameter(s)	Input directly in the edit box.
Relation	Relations between rules, including: ● Null ● OR ● AND	Select in the drop-down list.
Refresh	Function button. Click to save the settings.	/
“+” button	Function button. Click to add a column.	/
“-” button	Function button. Click to delete the selected column.	/

Table 12-4 Parameter Description of Item Range Delta Check

Parameter	Meaning	Operation Description
Item name	Select the report parameter(s) for the sample.	Select in the drop-down list.
Days	Set range of days for the sample.	Input directly in the edit box.
Change	Change of parameter(s), including: ● Add ● Decrease ● Change	Select in the drop-down list.
Diff (#)	Set the absolute number of the difference between two test results.	Input directly in the edit box.
Diff (%)	Set the relative number of the difference between two test results.	Input directly in the edit box.
Relation	Relations between rules, including: ● Null ● OR ● AND	Select in the drop-down list.

Parameter	Meaning	Operation Description
Refresh	Function button. Click to save the settings.	/
“+” button	Function button. Click to add a column.	/
“-” button	Function button. Click to delete the selected column.	/

4. After settings are completed, click **Save**.
5. Select to check checkbox in the retest rule listsor not according to actual conditions.
   - If checked, the analyzer will perform auto retest according to corresponding measures or prompts after it completes sample analysis and meets the auto retest requirements.
   - If not checked, the analyzer will not perform auto retest after it completes sample analysis.
6. After completion, save or save as new scheme.

Delete Retest Rule

Delete a retest rule by taking the following steps.

1. Enter the **Review rule settings** interface.
2. Select the rule to be deleted.
3. Click **Delete**.
4. Click **Yes**.

Import Retest Scheme

If you have a conforming import file, you can import the file in .rule format to record the retest scheme .

1. Enter the **Review rule settings** interface.
2. Click **Import**.
3. Select the file to be imported.
4. Click **Open** to import the file.
5. After confirming the correctness of retest scheme, click **Save** to complete the scheme entry.

NOTE

- The corresponding auto retest rule must be imported on the **Review rule settings** interface of auto retest. The corresponding auto validate scheme must be imported on the **Review rule settings** interface of auto validate.
- After adding, editing or modifying the scheme, you need to click **Save** or **Save as new scheme**.
- After saving the scheme, you need to click **Debugging** > **Apply** before the scheme takes effect.

Export Retest Scheme

You can export the retest rule in .rule format.

1. Enter the **Review rule settings** interface.
2. Select the scheme to be exported.
3. Click **Export**.
4. Select an export path and input the exported file name.
5. Click **Save** to export the file.

Restore Default Retest Scheme

You can restore the default value of the default scheme.

1. Enter the **Review rule settings** interface.
2. Select the default scheme.
3. Click **Restore to defaults**.
4. Click **Yes**.

NOTE

Only default scheme can restore default value.

Delete Retest Scheme

You can delete retest scheme according to the steps below.

1. Enter the **Review rule settings** interface.
2. Click **Delete Scheme**.
3. Select the scheme to be deleted.
4. Click **Yes**. Debug Scheme

After setting the retest rule, you can check whether the rule meets the requirements on the **Debugging** interface.

12.8.2.2 Debugging Retest Scheme

1. Click **Auto Validate** > **Retest scheme**> > **Debugging** to enter the interface.
2. Set the time in “Time range” and select the sample for debugging.
3. Click **Start Debug**.
4. If debugging conforms to the requirements, click **Apply** and this retest scheme is applied to the test procedures.

   After the debugging is completed, you can view relevant data in **Debugging sample statistics** and **Trigger rate of retest rules**.

Comparison between Manual Operation and Auto Retest

After completing the retest rule debugging, you can view or calculate the retest accuracy rate in **Manual operation and retest** area.

Calculate retest accuracy rate by taking the following steps.

1. In the “Gold standard” area of “Retest result”, input the number of samples for “True positive A”, “False positive B”, “False negative C” and “True negative D” respectively.

   The parameter description of the gold standard is as shown in Table 12-5.

   Table 12-5 Parameter Description of Gold Standard

Parameter	Meaning
True positive A	Sample(s) for which both the gold standard and the device trigger the retest rule.
False positive B	Sample(s) for which the device triggers the retest rule but the gold standard does not.
False negative C	Sample(s) for which the gold standard triggers the retest rule but the device does not.
True negative D	Sample(s) for which neither the gold standard nor the device triggers the retest rule.
A+C	Sample(s) for which the gold standard triggers the retest rule.
B+D	Sample(s) for which the gold standard does not trigger the retest rule.
A+B	Sample(s) triggering the retest rule.
C+D	Sample(s) not triggering the retest rule.
T	Total sample involved in retest rule judgment or gold standard.

2. Click **Calculate**.

   If you input the wrong content or want to re-input, click **Reset** to reset.

   Confirm the validate accuracy according to “sensitivity”, “specificity”, “false negative rate”, “false positive rate”, “positive prediction rate”, and “negative prediction rate”. The detailed parameter meaning is as shown in the table below.

Parameter	Meaning
Sensitivity	People who are sick are diagnosed as positive.
Specificity	People who are not sick are diagnosed as negative.
False negative rate	Proportion (rate of missed diagnosis) of sick people mistakenly diagnosed as anosis.
False positive rate	Proportion (rate of misdiagnosis) of healthy people mistakenly diagnosed as sick.
Positive prediction rate	Proportion of sick cases in positive test results.
Negative prediction rate	Proportion of healthy cases in negative test results.

12.8.2.3 Statistics Data

NOTE

- If the scheme is modified, the system will perform statistics again.
- If **Retest** switch and **Auto Validate** switch are opened at the same time, you can view the statistics information of retest and auto validate on the **Statistics** interface.
- You can view only the retest statistics information on the Statistics interface when only the Retest switch is on.

After setting, debugging and applying the auto retest rule, the analyzer uses the selected scheme to determine whether the sample passes retest. After the retest, you can click **Auto Validate** > **Statistics** to enter the interface to view the sample statistics and trigger rate statistics.

12.8.3 Auto Validate

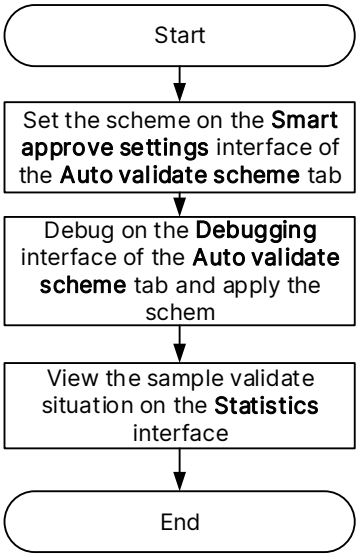
The Auto Hematology Analyzer offers the auto validate function, which enables users to set the auto validate rule on DMS software according to actual needs, so as to improve validation efficiency.

NOTE

- Please prudently set the auto validate rule in strict accordance with the laboratory operation requirements.
- If you need to use the auto validate function, you need to open **Auto Validate** Button on the **Smart Validate** interface

The process of auto validate is as shown in Figure 12-8.

Figure 12-8 Auto Validate Flowchart



12.8.3.1 Setting Scheme

You can set and enable auto validate rule according to actual needs in the **Smart approve settings** interface.

Click **Smart Validate** > **Auto Validate Scheme** > **Smart approve settings** to enter the **Smart approve settings** interface.

Modify Auto Validate Scheme

The analyzer offers the default scheme for use. You can modify it in case of any other demands.

Modify the auto validate scheme by taking the following steps.

1. Select the scheme to be modified.
2. Check the rule to be used in the “Rule” column.

   If you check a rule, it will be highlighted in the flowchart and displayed in the flowchart under the **Statistics** interface; if you do not check a rule, it will turn grey in the flowchart and will not be displayed in the flowchart under the **Statistics** interface.

Set the rule in the corresponding rule scheme list. The specific description is as shown in Table 12-6, Table 12-7, Table 12-8, Table 12-9, Table 12-10, Table 12-11, Table 12-12 and

3. Table 12-13.

Table 12-6 Rule Scheme Description

Parameter	Meaning	Operation Description
QC rule	Set whether to enable QC rule.	Check checkbox according to actual situations.
Logic rule	Set the logical rule for flow judgment.	Refer to Table 12-7 for specific explanation and operation.
Critical val.	Set the critical val. rule for flow judgment.	Refer to Table 12-8 for specific explanation and operation.
Flag information	Set the Flag for flow judgment.	Check the Flag to be used according to actual situations.
Delta Check	Set whether there are history judgment and Delta Check judgment in flow judgment, including, including: ● Item range Delta Check ● Flag Delta Check	Refer to Table 12-9 for specific explanation and operation of item range Delta Check. Refer to Table 12-10 for specific explanation and operation of Flag Delta Check.
Manage limit	Set the limit management for flow judgment.	The specific explanation and operation are similar as critical val. settings, as shown in Table 12-11.
Item relate	Set the item relation for flow judgment.	The specific explanation and operation are similar as logic rule settings, as shown in Table 12-12.
Exception	Set the exception for flow judgment, including: ● Exception 1 ● Exception 2	Refer to Table 12-13 for specific explanation and operation. **Notes** The settings of clinical feature and exception 2 are consistent with those of clinical feature and exception 1.

Table 12-7 Description of Logic Rule Settings

Parameter	Meaning	Operation Description
Logic rule list	The content set in logic rule is displayed in this list in sync.	/

Parameter	Meaning	Operation Description
Rule name	The name of the rule.	Input directly in the edit box.
Rule details	Set the rule details.	Input with reference to the example in the interface.
Add	Function button. Click to add a new column.	/
Delete	Function button. Click to delete the selected column.	/
Save	Function button. Click to save the settings.	/

Table 12-8 Description of Critical Value Rule Settings

Parameter	Meaning	Operation Description
Critical val. list	The critical value condition settings are displayed in the list in sync.	/
Rule name	Set the name of the rule.	Select in the drop-down list.
Rule details	After setting in the condition setting area below, the area updates in sync.	Not editable.
Min. critical val. (<)	Set the minimum critical value.	Input directly in the edit box.
Max. critical val. (>)	Set the maximum critical value.	Input directly in the edit box.
Gender	Select gender.	Select in the drop-down list.
Min. age (>=)	Set the minimum age.	Input directly in the edit box.
Unit	Set the unit of age, including: ● Null ● Hour ● Day ● Month ● Year	Select in the drop-down list.
Max. age	Set the maximum age.	Input directly in the edit box.

Parameter	Meaning	Operation Description
Unit	Set the unit of age, including: ● Null ● Hour ● Day ● Month ● Year	Select in the drop-down list.
Department	Select the department to which the sample belongs.	Select or input directly in the drop-down list. **Notes** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in ***11.3.10 Dictionary Settings***.
+	Function button. Click to add a column in the critical value condition setting area.	/
-	Function button. Click to delete the selected column in the critical value condition setting area.	
Refresh	Function button. Click to refresh settings.	/
Save	Function button. Click to save the settings.	/
Add	Function button. Click to add a column.	/
Delete	Function button. Click to delete the selected column.	/

Table 12-9 Description of Item Range Delta Check Rule Settings

Parameter	Meaning	Operation Description
Item range Delta Check list	The condition settings of item range Delta Check are displayed in the list in sync.	/
Rule name	Set the name of the rule.	Input directly in the edit box.

Parameter	Meaning	Operation Description
Rule details	After setting in the condition setting area below, the area updates in sync.	Not editable.
Item name	Select the item parameter	Select in the drop-down list.
Days	Set the days range of the sample(s)	Input directly in the edit box.
Change	The change of parameters, including: ● Add ● Decrease ● Change	Select in the drop-down list.
Diff (#)	Set the absolute number of the difference between two test results.	Input directly in the edit box.
Diff (%)	Set the relative number of the difference between two test results.	Input directly in the edit box.
Relation	The relations between rules, including: ● Null ● OR ● AND	Select in the drop-down list.
+	Function button. Click to add a column in the critical value condition setting area.	/
-	Function button. Click to delete the selected column in the critical value condition setting area.	
Refresh	Function button. Click to refresh settings.	/
Save	Function button. Click to save settings.	/
Add	Function button. Click to add a column.	/
Delete	Function button. Click to delete the selected column.	/

Table 12-10 Description of Flag Information Delta Check Rule Settings

Parameter	Meaning	Operation Description
Flag Delta Check list	Flag Delta Check condition settings are displayed in the list in sync.	/
Flag name	Select Flag information.	Check the check box.
Days	Set the days range of Flag.	After checking the corresponding flag name, input directly in the edit box.
Save	Function button. Click to save the settings.	/

Table 12-11 Description of Manage Limit Rule Settings

Parameter	Meaning	Operation Description
Manage limit list	The limit settings are displayed in the list in sync.	/
Rule name	Set the name of the rule.	Select in the drop-down list.
Rule details	After setting in the condition setting area below, the area updates in sync.	Not editable.
Min. limit (<)	Set the minimum limit.	Input directly in the edit box.
Max. limit(>)	Set the maximum limit.	Input directly in the edit box.
Gender	Select gender.	Select in the drop-down list.
Min. age (>=)	Set the minimum age.	Input directly in the edit box.
Unit	Set the unit of age, including: ● Null ● Hour ● Day ● Month ● Year	Select in the drop-down list.
Max. age (<)	Set the maximum age.	Input directly in the edit box.

Parameter	Meaning	Operation Description
Unit	Set the unit of age, including: ● Null ● Hour ● Day ● Month ● Year	Select in the drop-down list.
Department	Select the department to which the sample belongs.	Select or input directly in the drop-down list. **Notes** The data of the drop-down list comes from the data dictionary, which is subject to the settings set in 11.3.10 Dictionary Settings.
+	Function button. Click to add a new column in limit settings area.	/
-	Function button. Click to delete the selected column in limit setting area.	
Refresh	Function button. Click to refresh the settings.	/
Save	Function button. Click to save the settings.	/
Add	Function button. Click to add a column.	/
Delete	Function button. Click to delete the selected column.	/

Table 12-12 Description of Item Relate Rule Settings

Parameter	Meaning	Operation Description
Item relate rule list	The item relate settings are displayed in the list in sync.	/
Rule name	The name of the rule.	Input directly in the edit box.
Rule details	Set the rule details.	Input with reference to the example in the interface.

Parameter	Meaning	Operation Description
Save	Function button. Click to save the settings.	/
Add	Function button. Click to add a column.	/
Delete	Function button. Click to delete the selected column.	/

Table 12-13 Description of Exception Rule Settings

Parameter	Meaning	Operation Description
Rule list	The rule list settings are displayed in the list in sync.	/
Rule name	The name of the rule.	Input directly in the edit box.
Rule type	The types of rule(s), including: ● Clinical feature ● Item range ● Flag	Select the rules you want to edit and click "**+**" to expand the table for editing.
Rule details	Details of rule(s).	For selected contents in the list, click **Refresh** and the settings will be displayed in the rule details in sync.
Rule relation	Relations between rules, including: ● Null ● OR ● AND	Select in the drop-down list.
Clinical feature	Set the clinical feature.	The specific explanation and operation are similar as auto retest settings, as shown in Table 12-2.
Item range	Select the parameter range for the applicable rule.	The specific explanation and operation are similar as auto retest settings, as shown in Table 12-3.
Flag information	Select Flag information.	Select and refresh in the drop-down list.

Parameter	Meaning	Operation Description
Save	Function button. Click to save the settings.	/
Add	Function button. Click to add a column.	/
Delete	Function button. Click to delete the selected column.	/

4. After the settings are completed, click **Save** or **Save as New Scheme**.
5. Select to check checkboxor not according to actual conditions.
   - If checked, the analyzer will automatically validate after it completes the test .
   - If not checked, the analyzer will not determine the rule type after it completes the test.
6. After completion, save or save as new scheme.

Import the Auto Validate Scheme

If you have a conforming import file, you can import the file in .rule format to record the auto validate scheme.

1. Enter the **Smart approve settings** interface.
2. Click **Import**.
3. Select the file to be imported.
4. Click **Open** to import the file.
5. After confirming the correctness of auto validate scheme, click **Save** to complete the scheme entry.

NOTE

- The corresponding auto retest rule must be imported on the **Smart approve settings** interface of auto retest. The corresponding auto validate scheme must be imported on the **Smart approve settings** interface of auto validate.
- After adding, editing or modifying the scheme, you need to click **Save** or **Save as New Scheme**.

After saving the scheme, you need to click **Debugging** > **Apply** before the scheme takes effect.

Export Auto Validate Scheme

You can export the auto validate rule in .rule format.

1. Enter the **Smart approve settings** interface.
2. Select the scheme to be exported.

3. Click **Export**.
4. Select an export path and input the exported file name.
5. Click **Save** to export the file.

Restore to Default Value

You can restore the default value in default scheme.

1. Enter the **Smart approve settings** interface.
2. Select the default scheme.
3. Click **Restore to Defaults**.
4. Click **Yes**.

NOTE

Only the default scheme can restore to defaults.

12.8.3.2 Debugging Scheme

After setting the auto validate rule, you can check if the test scheme meets requirements on the **Debugging** interface.

Debugging Validate Rule

1. Click **Smart Validate** > **Auto validate scheme** > **Debugging** to enter the interface.
2. Select a scheme in the **Scheme Name**.
3. Click **Debugging** to enter the interface.

   Set the range of time and validation in "Time Range".
4. Click the **Start Debugging** button.

After the debugging is completed, you can view relevant data in the **Debugging sample statistics** and **Trigger rate of validation rules** areas.

Comparison between Manual Operation and Auto Validate

After the auto validate rule debugging is completed, you can calculate the accuracy rate of validation in the **Manual operation and auto validate** area.

Calculate the accuracy rate of auto validate by taking the following steps.

1. Input the number of samples for “True positive A”, “False positive B”, “False positive C” and “True negative D” respectively in the “Gold standard” area of “Auto validate result”.

   The description of gold standard parameters is as shown in Table 12-14.

Table 12-14 Description of Gold Standard Parameters

Parameter	Meaning
True positive A	Sample(s) that fail both the gold standard validation and the analyzer validation.
False positive B	Sample(s) that pass the gold standard validation but fail the analyzer validation.
False negative C	Sample(s) that fail the gold standard validation but pass the analyzer validation.
True negative D	Sample(s) that pass both the gold standard validation and the analyzer validation.
A+C	Sample(s) that fail the gold standard validation.
B+D	Sample(s) that pass the gold standard validation.
A+B	Sample(s) that fail the analyzer validation.
C+D	Sample(s) that pass the analyzer validation.
T	Total sample involved in validation or gold standard.

2. Click **Calculate**.

   If you input the wrong content, or want to re-input, click **Reset** to reset.

3. Confirm the validate accuracy according to “sensitivity”, “specificity”, “false negative rate”, “false positive rate”, “positive prediction rate”, and “negative prediction rate”. The detailed parameter meaning is as shown in the table below.

Parameter	Meaning
Sensitivity	People who are sick are diagnosed as positive.
Specificity	People who are not sick are diagnosed as negative.
False negative rate	Proportion (rate of missed diagnosis) of sick people mistakenly diagnosed as anosis.
False positive rate	Proportion (rate of misdiagnosis) of healthy people mistakenly diagnosed as sick.
Positive prediction rate	Proportion of sick cases in positive test results.

Parameter	Meaning
Negative prediction rate	Proportion of healthy cases in negative test results.

12.8.3.3 Statistics Data

NOTE

- If the scheme is modified, the system will perform statistics again.
- If the **Auto Retest** switch and **Validate** switch are opened at the same time, you can view the stats. informstion of auto retest and validate on the **Statistics** interface.
- You can view only the statistics information of auto validation on the Statistics interface when only the Auto Validate switch is on.

After setting , debugging and applying the auto retest rule, the analyzer uses the set rule to determine whether the sample passes validation.

After the sample analysis, you can click **Auto Validate** > **Statistics** to enter the interface to view the sample statistics and trigger rate statistics.

13 Performance

Background count is the measurement of particle interference and electrical interference. The results obtained from the background count can determine whether the factors affecting the measurement results such as the fluidics, hardware and external interference are normal or not.

You can perform background count on the background count interface of HOST software, and export the history records of the background count.

13.1 Entering the Interface

Click > **Performance** > **Background count** to enter the interface. See Figure 13-1.

Figure 13-1 Background Count

Explanations:

- The background count records of the “Whole Blood-CBC+DIFF+RET” mode are displayed by default.

  If the main unit disables the RET channel, the background count records of the “Whole Blood-CBC+DIFF” mode are displayed by default. If you need to disable the RET channel, contact Dymind customer service department or the local agent.

  In different modes, the supported measurement parameters are different. See Table 13-1.

Table 13-1 Parameters of Background Count

Parameter \ Mode	CBC	RET	CBC+DIFF	CBC+RET	CBC+DIFF+RET
WBC	√	×	√	√	√
RBC	√	×	√	√	√
HGB	√	×	√	√	√
PLT	√	×	√	√	√
HCT	√	×	√	√	√

NOTE

"√" means the parameter is provided in the mode, "×" means the parameter is not provided.

- The top of the interface is the background count result list, which displays the background count history of the current mode, including the date and time, the operator and the count results of the background parameters supported by the current mode.
- The bottom of the interface is the result judgment list, which displays the blank count (background range) limits of the parameters supported for measurement in this mode, and the judgment results of the background test record selected in the upper list.
  - If the actual measured value of a parameter in the selected background count record is less than or equal to its corresponding limit, the judgment result of the parameter is "Pass", and is displayed in the result column.
  - If the actual measured value of a parameter in the selected background count record is greater than its corresponding limit or the result value of a parameter is invalid, the judgment result of the parameter is "Fail", and is displayed in red font in the result column.
- Statistics number is the number of selected background count records. If no record is selected, the statistics number is displayed as 0.

13.2 Performing Background Count

NOTE

- Only the count performed under the background interface is the background count.
- Each mode can record up to 30 background count records, and the oldest record will be automatically overwritten when the number exceeds 30.

The main unit needs to meet the following conditions before you can perform background count.

- There exists no error that affects the count.
- There is no other fluidics sequence running.
- There is no prompt box or setting dialog box popping up.
- The sample delivery component already is in the manual sampling position.

The steps of background count are as follows.

1. Click > **Performance** > **Background** to enter the interface.
2. Click **Mode**, select the sample type and analysis mode for background count in the pop-up dialog box (analysis modes include CBC, RET, CBC+DIFF, CBC+RET and CBC+DIFF+RET), and then click **OK**.
3. Press the [MODE] key of the main unit to switch to manual sampling mode.

   Then the sample delivery component moves to the manual sampling position.
4. Press the [RUN] key of the main unit to start the background count.

   After the background count is completed, the background result of each parameter is displayed in the background count result list. The system selects the background **test** record of this time by default, and then the judgment result of the specific parameters of the record (Pass or Fail) is displayed in the result judgment list.

13.3 Exporting Background Count Record

The steps of exporting background count record are as follows.

1. Insert the USB flash disk into the USB interface of the main unit.
2. Click > **Performance** > **Background** to enter the interface.
3. Click **Mode**, select the sample type and analysis mode for background count in the pop-up dialog box (analysis modes include CBC, RET, CBC+DIFF, CBC+RET and CBC+DIFF+RET), and then click OK.
4. Click **Export**.
   - The system automatically creates a folder named with the device serial No. in the root directory of the USB flash disk, and all the exported contents of the main unit with the same device serial No. are exported to this folder.
   - The default file naming format is “Background_*device serial No._year_month_day hour_minute_second*.csv”.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.
5. Click **OK** to close the prompt box.

14 Log Management

The log records the important user operations and important software settings. You can view various log information, search qualified log records, and export log records on HOST software, CMS software and DMS software.

14.1 Main Unit Log (HOST Software)

On HOST software, click > **Log** to enter the interface. You can view all logs, other logs, parameter modification, error information, maintenance records and calibration history of the main unit. You can also export logs on all log tabs.

The following takes **All logs** as an example to introduce how to view, search, and export.

Viewing Log Information

You can click > **Log** > **All logs** to enter the interface and view the log information (including date and time, overview, details, and the operator.)

Searching Log Record

You can follow steps below to search qualified log records according to the actual needs.

1. Click > **Log** > **All**.
2. Set the date range.
   Set the date range in the two date edit boxes.
3. Click **Search**.
   The interface displays all qualified log records.

Exporting Log Record

Only the records on all log tab can be exported, and other tabs have no export function.

You can follow steps below to export the qualified log records after searching the log record on all log tab.

1. Insert the USB flash disk into the USB interface of the main unit.
2. Click **Export**.
3. Set the exported range.

Set the exported range of log records in the pop-up dialog box.

The input range is 1~n (n represents the total number of log records on all log tab after searching).

You can set the start value and end value of the exported range, or directly check **Maximum range** to export all records.

- Starting point: to start exporting from this serial No. record.
- End point: end the exporting after exporting this serial No. record.
- Maximum range: check **Maximum range** to export all records.

NOTE

- When the starting value or end value is empty, after clicking **OK**, the interface prompts **You should input both the starting and end ranges**.
- The starting point value cannot be greater than the end point value.

4. Click **OK**.

   The interface prompts **Exporting, please wait....**

   - The system automatically creates a folder named as the device serial No. in the root directory of the USB flash disk, and then creates a folder named "log_*device serial No.*" in this folder. All the exported logs of the main unit with the same device serial No. are exported to this folder.
   - The default file naming format is “Background_*device serial No._year_month_day hour_minute_second*.csv”.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

5. Click **OK** to close the prompt box.

14.2 Log (CMS Software)

On CMS software, click > **Log** to enter the interface. You can view all logs, parameter setting, error logs and other logs. You can also export the log records.

The following takes **All logs** as an example to introduce how to view, search, and export.

Viewing Log Information

You can click > **Log** > **All** to enter the interface and view the log information (including date and time, overview, details, and the operator.)

Searching Log Record

You can follow steps below to search qualified log records according to the actual needs.

1. Click  > **Log** > **All logs**.
2. Set the date range.

   Set the date range in the two date edit boxes.
3. Click **Search**.

   The interface displays all qualified log records.

Exporting Log Record

You can follow steps below to export the qualified log records after searching the log record.

1. Click **Export**.
2. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default export file name is “Log_yyyyMMdd_hhmmss.csv", in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
3. Click **Save**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

14.3 Log (DMS Software)

On the log interface of DMS software, you can view all logs of DMS software, report modification log, item modification log and other log. You can also export the log records.

The following takes **All** as an example to introduce how to view, search, and export.

Viewing Log Information

Click **Log** to enter the interface, and check **All** radio box to view all log information (including date and time, overview, details, and the operator).

Searching Log Record

You can follow steps below to search qualified log records according to the actual needs.

1. Check **All** radio box on the log interface.
2. Set the date range.

   Set the date range in the two date edit boxes.
3. Click **Search**.

The interface displays all qualified log records.

Exporting Log Record

You can follow steps below to export the qualified log records after searching the log record.

1. Click **Export**.
2. Select the exported path and input the exported file name.

   You can use the system default exported path and default file name, or reselect the path and rename it according to actual needs.

   - The exported path defaults to the external computer desktop, or the path selected last time.
   - The default export file name is “Log_yyyyMMdd_hhmmss.xls”, in which, yyyyMMdd_hhmmss refers to the year, month, day, hour, minute and second when exporting.
3. Click **Save**.

   After the export is completed, the interface prompts **Exported Successfully!**, indicating that the data is exported successfully.

15 Routine Maintenance

In order to make the analyzer in the best working condition, you need to perform maintenance to the analyzer.

This chapter introduces the requirements and steps for routine maintenance of the analyzer, including regular maintenance and irregular maintenance.

15.1 Regular Maintenance

You should regularly clean and maintain the sample probe, reagent rack, sample rack and other parts of the device.

15.1.1 Daily Maintenance

Check Sample Probe

After completing the test, please clean the sample probe in time; make sure that there is no residual liquid.

Check Waste Container

After completing the test, please clean the waste container in time.

Check Printer

Make sure that the printing paper is sufficient for the entire test process. If it is out of paper, please refill the printing paper.

If the printer is running out of paper during the operation, it will cause communication failure to the device.

15.1.2 Weekly Maintenance

Clean the Tubing

Clean the internal tubing, and perfuse and empty the fluidics of the device.

Clean the Device

Wipe clean the surface of the device with a gauze soaked with alcohol.

15.1.3 Monthly Maintenance

Clean the Air Inlet Dust Net

Check the air inlet dust net of the analyzer. If the air inlet dust net is dirty, you must take it out and clean it. Detailed steps are as follows.

1. Pull the handle on the outside of the fan filter and pull out the fan filter.
2. Rinse the filter under the tap and gently pat it to remove all dust.
3. Air dry the fan filter.
4. Insert the dry fan filter back to the analyzer.

Check the LED

Check the LED inside the analyzer and calibrate it.

Clean Test Hole and Incubation Hole

Clean the powder or debris of the test hole and incubation hole.

15.1.4 Semi-annual Maintenance

Mechanical Guide Rail Maintenance

Clean the dirt and dust on the mechanical guide rail, and spray special grease.

Mechanical Position Calibration

Calibrate the mechanical position of the analyzer.

15.2 Custom Maintenance

- Packing maintenance

  If the device will not be used for more than 1 week or before long distance transportation (the transportation time is more than 2 hours), you should perform packing maintenance to the device.

- Valve/Pump connector check

  It is recommended that every 3 months or so, let the customer service person perform valve/pump connector check.

  a. Remove the back board of the device.

  b. Check if any valve/pump connector leaks or becomes loosened.

16 Troubleshooting

This chapter introduces the possible error information of the device and provides the corresponding solution.

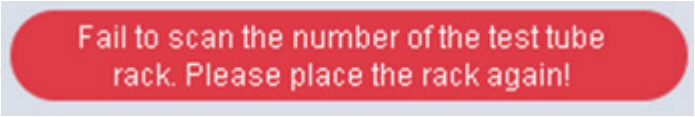
NOTE

This manual is not a service manual. It only provides the measures that you should take when the analyzer fails. For specific maintenance steps, please refer to the service manual.

16.1 Dealing with Error Information

In the use of the analyzer, if the software detects an abnormal condition, the error information area of the software interface will display the error information. See Figure 16-1. What's more, the main unit will sound an alarm.

Figure 16-1 Error Information



You can refer to the following steps to deal with the error information.

1. Click the error message area.

   A dialog box pops up. The dialog box displays the error code, description and its troubleshooting information. If there are more than one errors, the error information will be displayed in the order of the occurrence of errors.

2. Click **Remove error**.

   Normally, the system will automatically remove the error.

   For errors that cannot be removed automatically, you can resolve them by following the error help information.

16.2 Error Information Reference

Possible errors and the corresponding help information are as shown in Table 16-1.

Table 16-1 Error Information Reference

Error name	Error help information
-12V power supply abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, please contact our customer service.
12V power supply abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, please contact our customer service.
24V power supply abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, please contact our customer service.
Optical component cover open.	1. Please close the cover of optical component. 2. Click Remove Error button to remove the error automatically. 3. If the error still exists, please contact our customer service.
The CC source voltage abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, please contact our customer service.
The laser current abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, please contact our customer service.
Fails to execute startup process.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Not execute startup initialization.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Right side door open.	1. Please close the right side door. 2. Click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.
Left side door open.	1. Please close the left side door. 2. Click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.
+12V power abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, please contact our customer service.
The DIFF bath temperature setting exceeds the limit.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
HOST data transmission error.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.

Error name	Error help information
The air filter of the volume tube clogged.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
RBC aperture voltage abnormal.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
WBC aperture voltage abnormal.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Abnormal background.	1. Please check if the diluent is contaminated. 2. If it is not, click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.
Sample syringe action timeout.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Sample syringe busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Sampling component busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The vertical motor busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Reading DIFF bath temperature error.	1. Please make sure that the installation of temperature sensor is correct. 2. Click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.
Reading optical system temperature error.	1. Please make sure that the installation of temperature sensor is correct. 2. Click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.
Reading ambient temperature error.	1. Please make sure that the installation of temperature sensor is correct. 2. Click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.

Error name	Error help information
Waste is full.	1. Empty the waste container, or replace with a new one. 2. Click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.
The optical system temperature setting exceeds the limit.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Optical system temperature is out of the working range.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Flow chamber clogged.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The horizontal motor busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Diluent syringe action timeout.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The diluent syringe busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The pressure of the positive-pressure chamber exceeds the working range.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The pressure of the positive-pressure chamber abnormal (lower).	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The pressure of the positive-pressure chamber abnormal (higher).	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The sample probe clogged.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.

Error name	Error help information
The pressure of the negative-pressure chamber exceeds the working range.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The pressure of the negative-pressure chamber abnormal (lower).	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The pressure of the negative-pressure chamber abnormal (higher).	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
SOCKET initialization fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The network connection is disconnected abnormally.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The loading motor busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Loading motor action timeout.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Fails to start mixing.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Fails to mix.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Mixing component busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Feeding component busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Fails to start feeding.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Fails to feed.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.

Error name	Error help information
Feeding action timeout.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Autosampler busy.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Unloading platform full.	1. Remove all test tube racks on the unloading platform manually. 2. Click **Remove error** button to remove the error automatically. 3. If the error still exists, please contact our customer service.
The counter is triggered by mistake.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
The counter is triggered abnormally.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Driver board communication fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Autosampler board communication fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
RF reader board communication fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Main control board FPGA communication fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Card reader reset fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
RF card reading fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Reagent refrigerating board communication fails.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.

Error name	Error help information
Reagent is not enough.	1. Please check the *reagent* bottle/barrel; if there is no reagent, please replace with new *reagent*. 2. Click the **Remove error** button, and the **Reagent** interface will pops out. 3. Refer to 8 Reagent Management to replace the reagent. 4. If the error still exists, please contact our customer service.
Reagent is expired.	1. Please check if the reagent is expired; if it is, please replace with the new reagent. 2. Click the **Remove error** button to automatically remove the error. 3. If the error still exists, please contact our customer service.
Reagent is not replaced.	1. Click **Remove error** button to remove the error automatically. 2. If the error still exists, please contact our customer service.
Reagent is running out or there are air bubbles in tubing.	1. Check if there are air bubbles in inlet tubing of the reagent or if the reagent is running out. If there are air bubbles, please perform next step; if the reagent is running out, please replace with the new reagent. 2. Click **Remove error** button to remove the error automatically. 3. If the reagent is enough, or the error still exists after replacing with the new reagent, please contact our customer service.

NOTE

Reagent: the code name of the reagent that is matched with the analyzer; please refer to the actual situation as to which reagent error is reported.

Appendix A Specifications

A.1 General Information

A.1.1 Sampling Way

Auto sampling and manual sampling.

NOTE

Only DH-610 and DH-612 provide pre-dilution and body fluid parameters.

A.1.2 Measurement Speed

Analysis Mode	Venous Whole Blood Measurement Speed (Sample/Hour)	Capillary Whole Blood Measurement Speed (Sample/Hour)
CBC	100	90
RET	66	55
CBC+DIFF	90	70
CBC+RET	66	55
CBC+DIFF+RET	66	55

A.1.3 Minimum and Single Test Sample Volume

Blood Sample Type	Mode	Minimum Sample Volume	Single Test Sample Volume
Venous Whole Blood	CBC	1mL	≤20μL
	RET		≤35μL
	CBC+DIFF		≤30μL
	CBC+RET		≤35μL
	CBC+DIFF+RET		≤35μL
	CBC		≤20μL

Blood Sample Type	Mode	Minimum Sample Volume	Single Test Sample Volume
Capillary Whole Blood	RET	80μL	≤26μL
	CBC+DIFF		≤21μL
	CBC+RET		≤26μL
	CBC+DIFF+RET		≤26μL

A.1.4 Sample Storage Capacity

The PC software has a sample storage capacity of at least 500,000 samples, subject to the specific PC's storage space.

A.2 Performance Specifications

A.2.1 Display Range of Main Parameters

Table A- 1 Display Range of Main Parameters of Blood

Parameter	Linearity Range	Display Range
WBC	(0.00~500.00)×10^9/L	(0.00~999.99)×10^9/L
Neu%	/	(0.0~100.0)%
Lym%	/	(0.0~100.0)%
Mon%	/	(0.0~100.0)%
Eos%	/	(0.0~100.0)%
Bas%	/	(0.0~100.0)%
RBC	(0.00~8.60)×10^{12}/L	(0.00~99.99)×10^{12}/L
HGB	(0~260) g/L	(0~300) g/L
HCT	(0.0~75.0)%	(0.0~100.0)%
MCV	/	(0.0~250.0)fL
PLT	(0~5000)×10^9/L	(0~9999)×10^9/L
RET#	(0.0000~0.8000)×10^{12}/L	(0.0000~9.9999)×10^{12}/L
RET%	(0.00~30.00)%	(0.00~100.00)%

Table A- 2 Display Range of Main Parameters of Body Fluid

Parameter	Linearity Range	Display Range
WBC-BF	(0.000~10.000)×10^9/L	(0.000~999.99)×10^9/L
RBC-BF	(0.000~5.000)×10^{12}/L	(0.000~99.999)×10^{12}/L
TC-BF#	(0.000~10.000)×10^9/L	(0.000~999.99)×10^9/L
MN%	/	(0.0~100.00)%
MN#	/	(0.000~999.99)×10^9/L
PMN%	/	(0.0~100.00)%
PMN#	/	(0.000~999.99)×10^9/L

A.2.2 Blank Count (Background Range)

Table A- 3 Blank Count of Blood

Parameter	Requirement
WBC	≤0.10×10^9/L
RBC	≤0.02×10^{12}/L
HGB	≤1g/L
PLT	≤5×10^9/L
HCT	≤0.5%

Table A- 4 Blank Count of Body Fluid

Parameter	Requirement
WBC-BF	≤0.001×10^9/L
RBC-BF	≤0.003×10^{12}/L
TC-BF#	≤0.001×10^9/L

A.2.3 Linearity

Table A- 5 Blood Linearity

Parameter	Linearity Range	Acceptable Deviation Range (Whole Blood)	Acceptable Deviation Range (Predilution)	Linearity Correlation Coefficient
WBC	(0.00~10.00)×10^9/L	≤±0.50×10^9/L	≤±0.50×10^9/L	≥0.990
	(10.01~100.00)×10^9/L	≤±5%	≤±5%	
	(100.01~350.00)×10^9/L	≤±6%	≤±6%	
	(350.01~500.00)×10^9/L	≤±10%	≤±10%	
RBC	(0.00~1.00)×10^{12}/L	≤±0.05×10^{12}/L	≤±0.05×10^{12}/L	≥0.990
	(1.01~8.60)×10^{12}/L	≤±5%	≤±5%	
HGB	(0~70) g/L	≤±2 g/L	≤±2 g/L	≥0.990
	(71~260) g/L	≤±2%	≤±3%	
PLT	(0~100)×10^9/L	≤±10×10^9/L	≤±10×10^9/L	≥0.990
	(101~1000)×10^9/L	≤±8%	≤±10%	
	(1001~5000)×10^9/L	≤±10%	≤±10%	
HCT	(0.0~75.0)%	≤±1.0% (HCT value) or ≤±3%(percentage error)	≤±2.0% (HCT value) or ≤±4%(percentage error)	/
RET#	(0.0000~0.0750)×10^{12}/L	≤±0.015×10^{12}/L	/	/
	(0.0751~0.8000)×10^{12}/L	≤±20%	/	
RET%	(0.00~1.50)%	≤±0.3% (RET value)	/	/
	(1.51~30.00)%	≤±20%	/	

Table A- 6 Body Fluid Linearity

Parameter	Linearity Range	Acceptable Deviation Range
WBC-BF	(0.000~0.050)×10^9/L	≤±0.010×10^9/L
	(0.051~1.000)×10^9/L	≤±20%
	(1.001~10.000)×10^9/L	≤±20%

Parameter	Linearity Range	Acceptable Deviation Range
RBC-BF	(0.000~0.100)×10^{12}/L	≤±0.010 or ≤±5%
	(0.101~5.000)×10^{12}/L	≤±0.030 or ≤±2%
TC-BF#	(0.000~0.050)×10^{9}/L	≤±0.010×10^{9}/L
	(0.051~1.000)×10^{9}/L	≤±20%
	(1.001~10.000)×10^{9}/L	≤±20%

A.2.4 Carryover

Table A- 7 Blood Carryover

Parameter	Carryover
WBC	≤1.0%
RBC	≤1.0%
HGB	≤1.0%
HCT	≤1.0%
PLT	≤1.0%

Table A- 8 Body Fluid Carryover

Parameter	Carryover
WBC-BF	≤0.3% or ≤0.001×10^{9}/L
RBC-BF	≤0.3% or≤0.003×10^{12}/L
TC-BF#	≤0.3% or≤0.001×10^{9}/L

A.2.5 Repeatability

Table A- 9 Blood Repeatability

Parameter	Test Range	Repeatability (Whole Blood) (CV/absolute deviation d*)	Repeatability (Pre-dilution) (CV/absolute deviation d*)
WBC	(3.50~3.99)×10^{9}/L	≤3.0%	≤4.0%
	(4.00~15.00)×10^{9}/L	≤2.5%	≤3.5%

Parameter	Test Range	Repeatability (Whole Blood) (CV/absolute deviation d*)	Repeatability (Pre-dilution) (CV/absolute deviation d*)
Neu%	Neu%≥30.0% WBC≥3.50×10^9/L	≤6.0%	≤12.0%
Lym%	Lym%≥15.0% WBC≥3.50×10^9/L	≤6.0%	≤12.0%
Mon%	Mon%≥5.0% WBC≥3.50×10^9/L	≤16.0%	≤32.0%
Eos%	WBC≥3.50×10^9/L	≤20.0% or ≤±1.5% (d)	≤40.0% or ≤±3.0% (d)
Bas%	WBC≥3.50×10^9/L	≤30.0% or ≤±1.0% (d)	≤60.0% or ≤±2.0% (d)
IG%	WBC≥3.50×10^9/L IG%≥2.0%	≤25.0% or≤ ±1.5%(d)	/
Neu#	Neu#≥1.20×10^9/L	≤6.0%	≤12.0%
Lym#	Lym#≥0.60×10^9/L	≤6.0%	≤12.0%
Mon#	Mon#≥0.20×10^9/L	≤16.0%	≤32.0%
Eos#	WBC≥3.50×10^9/L	≤20.0% or ≤±0.12×10^9/L(d)	≤40.0% or≤±0.24×10^9/L(d)
Bas#	WBC≥3.50×10^9/L	≤30.0% or ≤±0.06×10^9/L(d)	≤60.0% or≤±0.12×10^9/L(d)
IG#	WBC≥3.50×10^9/L IG#≥0.10×10^9/L	≤25.0% or≤±0.12×10^9/L(d)	/
RBC	(3.50~6.00)×10^{12}/L	≤1.5%	≤2.0%
HGB	(110~180)g/L	≤1.0%	≤2.0%
MCV	(70.0~120.0)fL	≤1.0%	≤2.0%
PLT	(100~500)×10^9/L	≤4.0%	≤8.0%
HCT	(30.0~50.0)%	≤1.5%	≤3.0%
MCH	/	≤1.5%	/
MCHC	/	≤1.5%	/
RDW-SD	/	≤2.0%	/

Parameter	Test Range	Repeatability (Whole Blood) (CV/absolute deviation d*)	Repeatability (Pre-dilution) (CV/absolute deviation d*)
RDW-CV	/	≤2.0%	/
MPV	/	≤3.0%	/
PDW	/	≤10.0%	/
PCT	/	≤5.0%	/
P-LCR	/	≤15.0%	/
P-LCC	/	≤15.0%	/
IPF	PLT≥50×10^9/L IPF≥3%	≤25.0%	/
RET#	RBC≥3.00×10^{12}/L RET%(1.00~4.00)%	≤15.0%	≤30.0%
RET%	RBC≥3.00×10^{12}/L RET%(1.00~4.00)%	≤15.0%	≤30.0%
LFR	RBC≥3.00×10^{12}/L LFR≥20.0% RET%(1.00~4.00)%	≤30.0%	/
MFR	RBC≥3.00×10^{12}/L MFR≥20.0% RET%(1.00~4.00)%	≤50.0%	/
HFR	RBC≥3.00×10^{12}/L RET%(1.00~4.00)%	≤100.0% or≤±2.0%(d)	/
IRF	RBC≥3.00×10^{12}/L IRF≥20.0% RET%(1.00~4.00)%	≤30.0%	/
RHE	RET#≥0.0200×10^{12}/L	≤5.0%	/

Table A- 10 Body Fluid Repeatability

Parameter	Test Range	Repeatability
WBC-BF	(0.015~0.10)×10^9/L	≤30.0%

Parameter	Test Range	Repeatability
RBC-BF	(0.003~0.05)×10^{12}/L	≤40.0% or ≤0.007×10^{12}/L(d)
TC-BF#	(0.015~0.10)×10^{9}/L	≤30.0%

*: Absolute deviation (d) = Measured value - Mean measured value

A.2.6 Trueness

Parameter	Test Range	Acceptable Relative Deviation Range
WBC	(3.50~9.50)×10^{9}/L	≤±15%
RBC	(3.80~5.80)×10^{12}/L	≤±6.0%
HGB	(115~175)g/L	≤±6.0%
HCT or MCV	(35.0~50.0)% (HCT) or (82.0~100.0)fL (MCV)	≤±9.0% (HCT) or ≤±7.0% (MCV)
PLT	(125~350)×10^{9}/L	≤±20.0%

A.2.7 WBC Classification Accuracy

The test results of Neu, Lym, Mon, Eos, and Bas should be within the acceptable range (99% credibility interval).

When the test result of the reference method is 0 and the test result of the analyzer is ≤1.0%, the test conclusion is qualified.

A.2.8 Index of Between-mode Comparability

Parameter	Test Range	Acceptable Relative Deviation Range (Whole blood)	Acceptable Relative Deviation Range (Pre-dilution)
WBC	(3.50~9.50)×10^{9}/L	≤±7.5%	≤±10.0%
RBC	(3.80~5.80)×10^{12}/L	≤±3.5%	≤±4.0%
HGB	(115~175)g/L	≤±3.5%	≤±4.0%
MCV	(82.0~100.0)fL	≤±3.0%	≤±6.0%
HCT	(35.0~50.0)%	≤±3.0%	≤±6.0%
PLT	(125~350)×10^{9}/L	≤±10.0%	≤±14.0%

A.2.9 Correlation

Table A- 11 Blood Correlation

Parameter	Compare with Reference Device
WBC	≥0.99
RBC	≥0.99
HGB	≥0.98
MCV	≥0.98
PLT	≥0.95
RET#	≥0.90
IPF	≥0.80

Table A- 12 Body Fluid correlation

Parameter	Correlation
WBC-BF	≥0.90 and slope is 0.7-1.3
RBC-BF	≥0.80 and slope is 0.7-1.3
TC-BF#	≥0.90 and slope is 0.7-1.3
MN%	≥0.70
MN#	≥0.90
PMN%	≥0.70

A.3 Sample Interference

Parameter	Analysis Result	Interference Source
WBC	WBC count is low.	WBC aggregation

Parameter	Analysis Result	Interference Source
	WBC count is high.	● PLT aggregation may occur. ● Coldinsoluble protein ● Cryoglobulin ● Fibrous protein ● Too many large PLT (PLT >1,000×10^9/L) ● NRBC present
RBC	WBC count is low.	● RBC aggregation (cold agglutinin) ● Microcytosis ● Divided RBCs may exist.
	RBC count is high.	● WBC increases (>100×10^9/L) ● Too many large PLT (PLT >1,000×10^9/L)
HGB	HGB count is high.	● WBC increases (>100×10^9/L) ● Chylemia ● Jaundice blood ● Paraprotein
HCT	HCT count is low.	● RBC aggregation (cold agglutinin) ● Microcytosis ● Divided RBCs may exist.
	HCT count is high.	● WBC increases (>100×10^9/L) ● Severe diabetes ● Uremia ● Spherocyte
PLT	PLT count is low.	● PLT aggregation may occur. ● PTCP ● Large PLT

Parameter	Analysis Result	Interference Source
	PLT count is high.	• Microcytosis • Divided RBCs may exist. • WBC debris • Coldinsoluble protein • Cryoglobulin
RET	RET count is high.	• RBC aggregation (cold agglutinin) • Large PLT • PLT aggregation may occur. • WBC debris • Malaria • Howell-jolly body

A.4 Input/Output Equipments

Warning

- Accessory equipment connected to the analogue and digital interfaces must comply with the relevant Safety and EMC standards (e.g., IEC 60950 Safety of Information Technology Equipment Standard and CISPR 22 EMC of Information Technology Equipment Standard (CLASS A)). Anyone who connects additional equipment to the signal input or output ports and configures an IVD system is responsible for ensuring that the system works properly and complies with the safety and EMC requirements. If you have any problem, consult the technical service department of the local agent.
- Be sure to use specified fuse only.

- Main unit
  - ➢ Network interface (1)
  - ➢ USB interface (4)
  - ➢ HOST software operating environment
    - ✧ Hardware configuration: CPU is ARM3358, with 512M or larger memory
    - ✧ Software environment: the operating system is Linux 3.2.0 and the compatible versions
- External computer

  The configuration of the external computer should meet the following requirements:

- CPU: 3.5GHz or above
- RAM: ≥4 GB
- Hard disk: ≥500 GB
- Network interface: >2
- USB interface: >4
- Operating system: Microsoft Windows 7, Microsoft Windows 10 or the compatible versions
- Displayer configuration: ≥22 inches
- Resolution: support 1920*1080 (recommended) and 1600*900
- External computer should be equipped with optical drive
- Network conditions:
  - Network architecture: CS architecture
  - Network type: LAN
  - Network bandwidth: 100Mbps

- Power strip

  Requirements for the power strip are:
  - Outlet number: 6 or above, and should come with at least one two-prong outlet to connect with the interchanger
  - Power: 1,600W or above
- Interchanger

  Requirements for the interchanger are:
  - Protocol standard: IEEE 802.3, IEEE 802.3u, IEEE 802.3x
  - Interface: eight 10/100m Adaptive RJ45 ports (Auto MDI/MDIX)
  - Network media:
    - 10Base-T: grade 3 UTP or above
    - 100Base-TX: grade 5 UTP
  - Power specifications: 5VDC/0.4A
- (Optional) Keyboard

  Standard 101 keyboard
- (Optional) Mouse
- (Optional) External barcode scanner
- (Optional) Printer
- Power supply requirements

Equipment	Voltage (Frequency)	Power	Fuse
Main unit	AC 100 V~240 V (50/60 Hz)	660 VA	T6.3 AL 250 V
Sampler unit	AC 100 V~240 V (50/60 Hz)	150 VA	
Pneumatic unit	AC 220 V~240 V (50/60 Hz)	600 VA	
	AC 115V~240V 60Hz	600 VA	

A.5 Cybersecurity Requirements

Data Interface

- Interface: USB interface, LAN interface
- Transmit data to LIS through HL7 protocol
- The storage format is CSV

User Access Control

- User identity authentication method: use user name and password to log in.
- User type and permission: the user type includes the ordinary user and the admin user. Among them, the ordinary user has general user permission, and the admin user has advanced user permission.

A.6 Environmental Conditions

NOTE

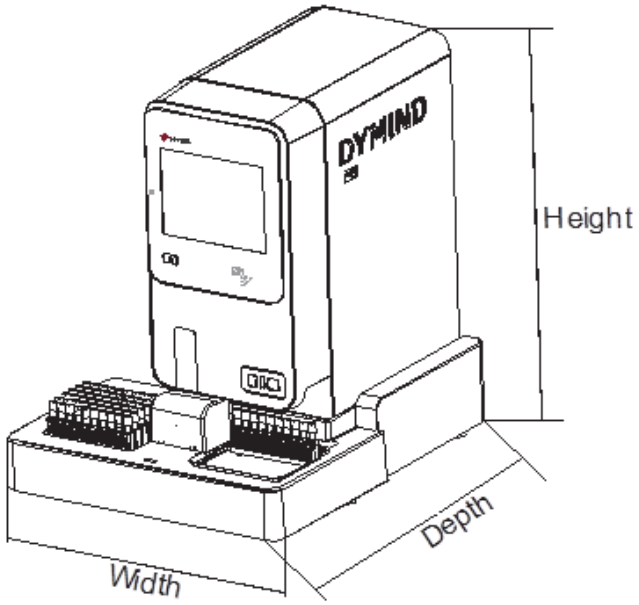
Store and use the analyzer in the specified environments.

Environment	Working environment	Storage environment	Running environment
Ambient temperature	15°C~32°C	-10°C~40°C	5°C~40°C
Relative humidity	30%~85%	10%~90%	10%~90%
Atmospheric pressure	70 kPa~106 kPa	50 kPa~106 kPa	70kPa~106kPa

A.7 Dimensions and Weight

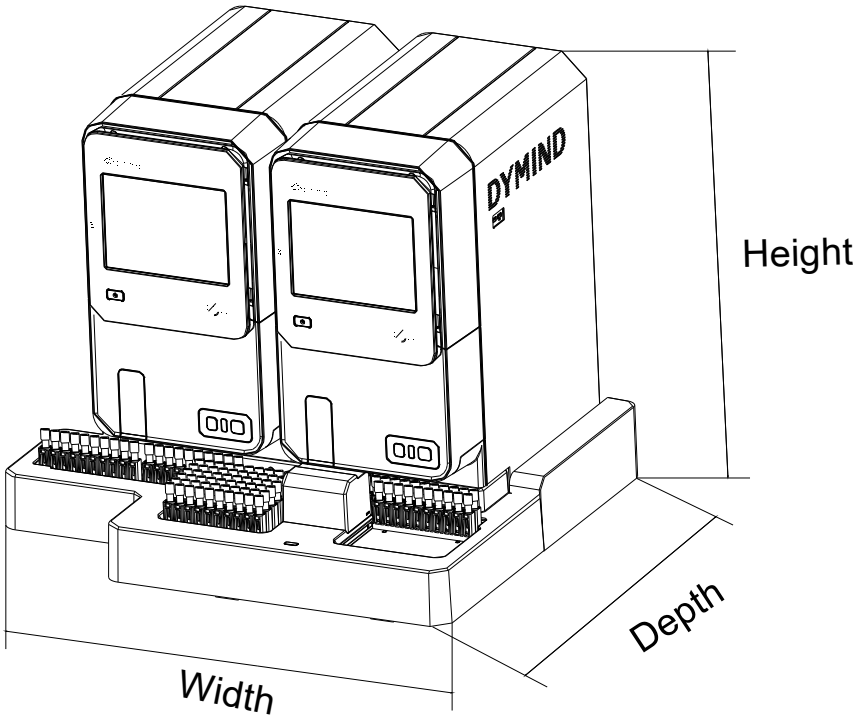
A.7.1 Dimensions and Weight of the Whole Device

Main Unit + Single Sampler



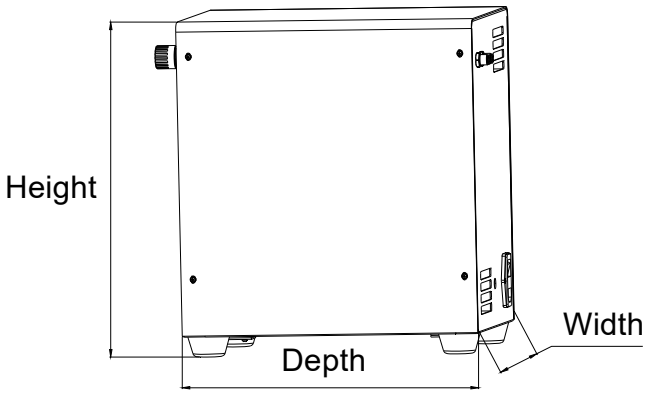
Whole Device (including single sampler)	Dimensions and Weight
Width (mm)	≤665
Height (mm)	≤870
Depth (mm)	≤820
Weight (kg)	≤100

Main Unit + Dual Samplers



Whole Analyzer (including dual samplers)	Dimensions and Weight
Width (mm)	≤1000
Height (mm)	≤870
Depth (mm)	≤820
Weight (kg)	≤180

A.7.2 Dimensions and Weight of Pneumatic Unit



Pneumatic unit	Dimensions and Weight
Width (mm)	≤282
Height (mm)	≤407
Depth (mm)	≤395
Weight (kg)	≤20

A.8 Expected Service Life

8 years

NOTE

Stop using the device when it reaches the expected service life.

A.9 Noise Level

Sound pressure ≤65 dB

NOTE

The sound pressure level measured and calculated at a distance of 1 meter from the device housing when running the device normally.

A.10 Over-voltage Category and Pollution Grade

- Over-voltage category: category II
- Pollution grade: grade 2

A.11 Thermal Protector

- AC 125 V/10 A: in the case of a voltage of 125 V, the current cannot exceed 10 A.
- AC 250 V/7A: in the case of a voltage of 250 V, the current cannot exceed 7 A.

Appendix B List of Accessories

B.1 Accessories

- Tube rack
- Reagent tubing component
- Waste container
- Power cord
- Network cable
- Ground wire
- Diluent bucket mouth holder

B.2 Optional Accessories

- Blood collector (applicable to Model DH610, DH612, and DH615)
- Sampler unit
- Base unit

B.3 Packing List

Please refer to the packing list enclosed with the device.

Appendix C Terms and Abbreviations

A-CWB	Auto-vial-Capillary Whole Blood
A-VWB	Auto-Venous Whole Blood
CWB	Open-vial- Capillary Whole Blood
RF	Radio Frequency
RUO	Research use only
VWB	Open-vial-Venous Whole Blood

CE

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