MR 36 Auto Hematology Analyzer

Operator's Manual

Preface

Thank you for purchasing the Auto Hematology Analyzer manufactured by MR.

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:MR36

Product Components: Blood Aspiration Module, Dilution Unit, Cleaning Unit, Analyzing and Measuring Unit and Microprocessor.

Scope of Use: blood cell counting, white blood cell 3-part classification and hemoglobin concentration measurement in clinical examinations.

Copyright

Declaration

This operator’s manual may be modified without notice.

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

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.

MR 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, and repair of the product are performed by the authorized personnel of MR.
- 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.

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Contents

1 Manual Overview

1.1 Introduction

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

Read this manual carefully before operating the analyzer and operate your analyzer in strict accordance with this manual.

1.2 Who Should Read This Manual

This manual contains information written for clinical laboratory professionals to:

- Learn about the hardware and software of the analyzer.
- Customize system settings.
- Perform daily operations.
- Perform system maintenance and troubleshooting.

1.3 How to Find Information

This operator's manual comprises 13 chapters and 3 appendix. Find the information you need by referring to the table below.

See…	You can find…
1 Manual Overview	Instructions for using the auto hematology analyzer.
2 Installation	Installation requirements for the auto hematology analyzer.
3 System Overview	Applications, measurable parameters, instrument configuration, software interface and software operations of the auto hematology analyzer.
4 Working Principle	Measuring principle and procedures of the auto hematology analyzer.
5 Setup	Settings of the system parameters such as the software date format and parameter units.
6 Daily Operations	Daily operations such as sample collection and preparation, the analysis procedures, startup and shutdown of the instrument.
7 Sample Analysis	Sample analysis procedure and handling of the analysis results.

See…	You can find…
8 Result Review	Review of the analysis results.
9 Quality Control	Basic requirements for quality control and the quality control methods provided by the auto hematology analyzer.
10 Calibration	Basic requirements for calibration and the calibration methods provided by the auto hematology analyzer.
11 Reagent Management	Settings and management of the reagents for the auto hematology analyzer.
12 Service	Methods for maintaining and testing the auto hematology analyzer.
13 Troubleshooting	Troubleshooting methods for the auto hematology analyzer.
Appendix A Specifications	Specification indicators of the auto hematology analyzer.
Appendix B Terms and Abbreviations	Terms and abbreviations of the auto hematology analyzer.
Appendix C Packing List	Packing list of the auto hematology analyzer.

1.4 Conventions Used in This Manual

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

Format	Definition
[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 text displayed on the screen, such as **Report**.
XX	*XX* indicates variables and the specific content depends on the actual situation.
XX	Bold and italic characters Indicate chapter titles, such as ***1.1 Introduction***.

1.5 Symbol Conventions

The following symbols are used to indicate danger and alert messages in this manual.

When you see …	Then …
	Follow the instruction below the symbol to avoid potential biocontamination.

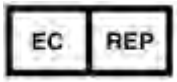
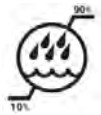
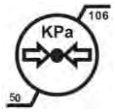
When you see …	Then …
 WARNING	Follow the instruction below the symbol to avoid personnel injury.
 CAUTION	Follow the instruction below the symbol to avoid analyzer damage and failure, or unreliable analysis results.
NOTE	Follow the instruction below the symbol. The symbol highlights the important information in operating procedures that calls for special attention.
	Puncture Warning: The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.

The analyzer or the outer packaging may have the following labels or symbols.

NOTE

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

When you see	It means
	Caution
	Biohazard
	Exercise caution to prevent puncture
	Instruction for Moving
	Network interface
	Protective grounding
	Alternating current (AC)
IVD	For in vitro diagnosis only

When you see	It means
	Lot No.
	Expiry date
	Serial No.
	The device is in full compliance with the council directive concerning in vitro diagnostic medical devices 98/79/EC.
	Authorized Representative in the European Community
	Date of manufacture
	Manufacturer
	Storage temperature
	Humidity level for storage
	Atmospheric pressure level for storage
	Consult the operator’s manual
	Avoid sunlight
	Keep dry
	No rolling
	No Stacking.
	Let this side face upward.

When you see	It means
	Fragile, handle with care
	Recyclable materials
	The analyzer, after being scrapped, should not be disposed with other household garbage, instead, it should be collected and recycled following the disposal instructions for scrapped electronic and electrical equipment.

1.6 Safety Information

- 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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.
- If leak happens to the analyzer, the leak liquid is potentially biohazardous.

WARNING

- Please check the firmness of all the door/ covers/panels before running the analyzer to prevent unexpected opening or loosening when the analyzer is working.
- Make sure all the safety measures are taken. Do not disable any safety device or sensor.
- Please respond to any alarm and error message immediately.
- Do not touch the moving parts.
- Contact MR or MR authorized agents upon the identification of any damaged part.
- Be careful when opening/closing and removing/installing the doors, covers and panels of the analyzer.
- Dispose the analyzer according to government regulations.

CAUTION

- Please use the analyzer in strict accordance with this manual.
- Please take proper measures to prevent the reagents from being polluted.

2 Installation

2.1 Introduction

WARNING

Installation by personnel not authorized or trained by MR International Healthcare Technology Co.,Ltd may cause personal injury or damage to the analyzer. Do not install the analyzer without the presence of MR- authorized personnel.

Your analyzer has passed strict tests before it is shipped from the factory. Internationally-recognized symbols and instructions show the carrier how to properly handle this electronic instrument in transportation. When you receive your analyzer, carefully inspect the packaging. If you see any sign of mishandling or damage, contact MR customer service department or your local agent immediately.

2.2 Installation Personnel

The analyzer should only be installed by MR or its authorized agents. You need to provide the appropriate environment and space. When the analyzer needs to be relocated, please contact MR or your local agents.

When you receive the analyzer, please notify MR or your local agent immediately.

2.3 Installation Requirements

WARNING

- Connect only to a properly grounded outlet.
- Before turning on the analyzer, make sure the input voltage meets the requirements.

CAUTION

- Using a patch board may introduce electrical interference and generate incorrect analysis results. Please place the analyzer near the electrical outlet to avoid using the patch board.
- Please use the original electrical wires shipped with the analyzer. Using other electrical wires may damage the analyzer or generate incorrect analysis results.

Installation requirements for the analyzer are as follows.

Installation Environment	Requirements
Site	• Level ground and stable workbench with load capacity ≥50kg. • Free of dust, mechanical vibration, heat and wind sources, contamination, heavy-noise source or electrical interference. • Avoid direct sunlight and keep good ventilation. • It's recommended to evaluate the electromagnetic environment of the laboratory before operating the analyzer. • Keep the analyzer away from sources of strong electromagnetic interference, otherwise, its proper functioning may be affected.
Space (In addition to the space required for the analyzer itself, set aside)	• At least 50cm from each side, which is the preferred access to perform service procedures. • At least 20cm from the back for cabling and ventilation. • Enough room on and below the countertop to accommodate for the diluent and waste containers. • Place the analyzer near the electrical outlet and avoid being blocked by any objects, so that you can disconnect the power plug easily as required.
Optimal operating temperature	10°C~30°C
Optimal operating humidity	20%~85%
Operating atmospheric pressure	70kPa~106kPa
Ventilation	Keep air exchange to ensure good air circulation. The wind should not blow directly at the analyzer.
Power	AC100V~240V, Input Power ≤200VA, 50/60HZ.
Electromagnetic Wave	Keep the analyzer away from electric-brush motors, flashing fluorescent and electric-contact equipment which is switched on/off frequently.
Waste Disposal	Dispose of the waste as per the requirements of the local environment protection authorities.

2.4 Damage Inspection

Before packing and shipping, MR has applied rigid inspection on all the analyzers. Upon receiving the analyzer, please check carefully before unpacking to see if there are any of the following damages:

- The outer packaging is placed upside down or distorted.
- The outer packaging shows obvious signs of having been exposed to humid conditions.
- The outer packaging shows obvious signs of having been crashed.
- The outer packaging shows signs of having been opened.

Once you find the above damages, please notify your local agent immediately.

If the packaging is intact, please open the packaging in the presence of personnel from MR or its agents and apply the following inspections:

- Check if all the items listed in the packing list are in the packaging.
- Carefully inspect the appearance of all the items to check if they are damaged or distorted.

2.5 Unpacking

Please unpack the analyzer by taking the following steps:

1. Open the outer packing box; take out the accessory pack; take out the analyzer together with the protective and cushioning materials.
2. Remove the foam and the protective PE bag.
3. Open the right door (open the linear-shaped cam lock on the right door with a slotted screwdriver).
4. Remove the binder clips, which are used for fixating two conveyor belts.

   To avoid the possible collision resulting from the slippage caused by shaking and slanting during transportation, the central position of those two belts is fixated with binder clips before they are shipped from the factory. The binder clips must be removed during unpacking.
5. Remove the binder clips, which are used for fixating sampling assembly.

NOTE

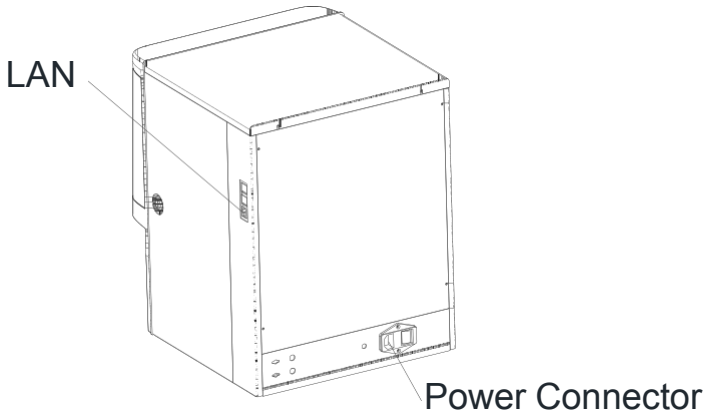
To avoid damage during the transportation, the sampling assembly of the analyzer is fixated with clamps. Do remove the clamps before using the analyzer.

2.6 Connecting the Analyzer System

2.6.1 Electrical Connections

Please refer to Figure 2-1 for the electrical connections of the analyzer.

Figure 2-1 Connecting the electric lines



2.6.2 Reagent Connections

WARNING

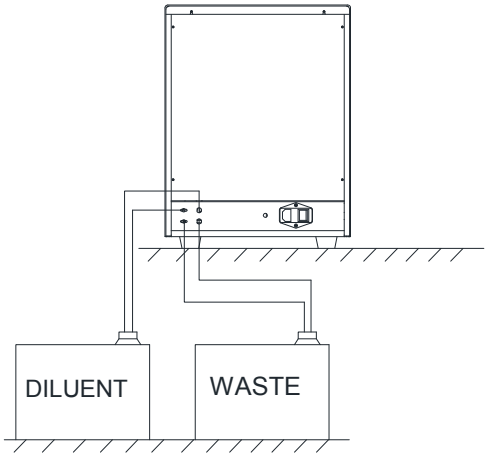
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see a doctor.

CAUTION

- Please make sure the length of the diluent pipe and the waste pipe should be no longer than 1500mm; the length of the lyse pipe and the cleanser pipe should be no longer than 850mm.
- Tighten the panel connector of the fluidic line so that the overall fluidic line is closed to prevent leakage and seepage caused by siphonage, etc.

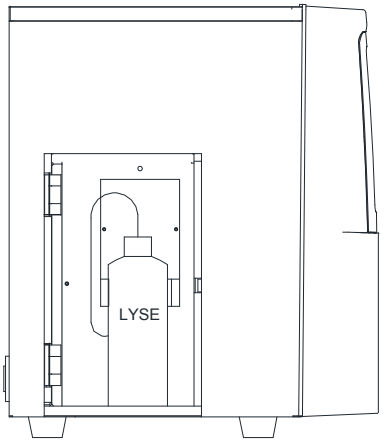
Refer to Figure 2-2 for the connection of the reagents placed outside the analyzer.

Figure 2-2 Connecting reagents placed outside the analyzer



Refer to Figure 2-3 for the connection of the reagent placed inside the analyzer.

Figure 2-3 Connecting reagents placed inside the analyzer (left door opened)



2.6.3 Installing the Diluent Float Sensor and Replacing the Reagents

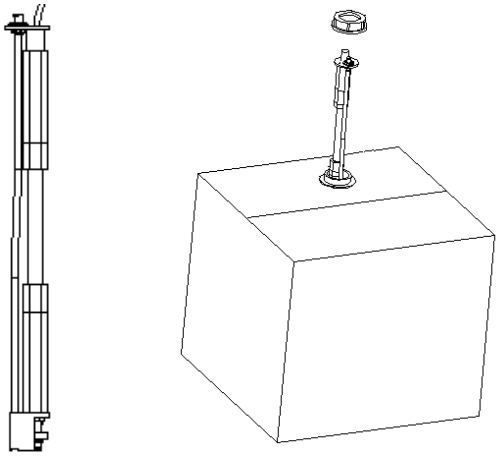
Please install the diluent float sensor and replace the diluent as per the approaches stated in this section.

2.6.3.1 Installing the Diluent Float Sensor

Install the diluent float sensor according to the following steps.

1. Press down and remove the round cardboard with dotted cutting line on the top side of the diluent box so as to reveal a round hole.
2. Pull out the cover of the container so that the cardboard around the round hole can seize the neck under the vial cap to prevent invagination.
3. Turn and open the cap (keep the cap) and prevent any foreign objects from getting into the container.
4. Install the diluent float sensor assembly in the accessory pack as shown in Figure 2-4.The float sensor shall be kept as vertical as possible during installation and the self-contained cap of the sensor shall be tightened.

Figure 2-4 Installing the Diluent Float Sensor



2.6.3.2 Replacing Reagents

Steps for the replacing the diluent are the same as that for installing the sensor. Please keep the empty diluent container and the cap for future use.

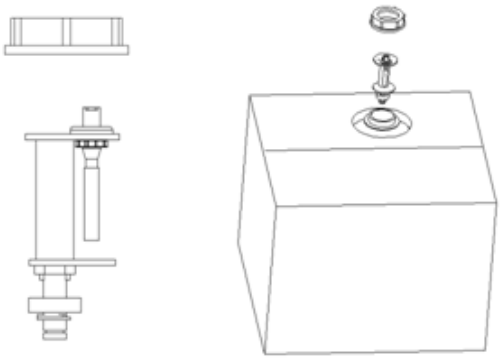
2.6.4 Installing the Waste Float Sensor

NOTE

The float sensors used in the analyzer are only applicable to MR- supplied waste containers or the containers with the same specification and model (such as the vacant diluent container).

1. Take a proper waste container (it can be a vacant diluent container, the opening of which is required to be pulled out of the hole of the box to expose the opening) and open the vial cap.
2. Install the waste float sensor assembly in the accessory pack as shown in Figure 2-5. The float sensor shall be kept as vertical as possible during installation and the self-contained cap of the sensor shall be tightened at the same time to prevent the spilling of the waste.

Figure 2-5 Installing the Waste Float Sensor



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

WARNING

Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

2.7 Installing Thermal Paper

CAUTION

- Use only specified thermal paper. Otherwise, it may cause damage to the thermal printer head, or the printer may be unable to print, or poor print quality may result.
- Never pull the thermal printer paper with force when a recording is in process. Otherwise, it may cause damage to the thermal printer.
- Do not leave the thermal printer door open unless you are installing paper or removing error.
- Improper installation of thermal printer paper may jam the paper and/or result in blank printout.

NOTE

Remove the protective paper between the thermal printer head and the roller inside the thermal printer before installing thermal paper for the first time.

Follow the procedure below to install the thermal paper.

1. Use the latch (as shown in Figure 2-6) at the upper right corner of the thermal printer door to pull the door open.

Figure 2-6 Installing Thermal Paper (1)

2. Insert a new roll into the compartment as shown below.

Figure 2-7 Installing Thermal Paper (2)

3. Close the thermal printer door.

4. Check if paper is installed correctly and the paper end is feeding from the top.

Figure 2-8 Installing Thermal Paper (3)

5. To ensure the normal use of the thermal paper, press the feed key to start paper feeding, and then press the feed button again to stop feeding when a short paper is sent out.

3 System Overview

3.1 Introduction

Auto Hematology Analyzer is a quantitative, automated hematology analyzer and 3-part differential counter used in clinical laboratories.

This section describes in details the intended use, measurement parameters, structure, user interface and compatible reagents of the analyzer.

3.2 Intended Use

It's intended for blood cell counting, 3-part classification of white blood cell and hemoglobin concentration measurement in clinical examinations.

NOTE

The analyzer is intended for screening in the clinical examination. When making clinical judgment based on the analysis results, the doctors should also take into consideration the clinical examination results or other test results.

3.3 Measurement Parameters

As shown below, the analyzer provides quantitative analysis results for 21 hematology parameters and three histograms.

Type	Parameter Name	Abbreviation
WBC (7 items)	White Blood Cell count	WBC
	Percentage of Granulocytes	Gran%
	Percentage of Lymphocytes	Lym%
	Percentage of Mid-sized Cells	Mid%
	Number of Granulocytes	Gran#
	Number of Lymphocytes	Lym#
	Number of Mid-sized Cells	Mid#
RBC (8 items)	Red Blood Cell count	RBC
	Hemoglobin Concentration	HGB

Type	Parameter Name	Abbreviation
	Mean Corpuscular Volume	MCV
	Mean Corpuscular Hemoglobin	MCH
	Mean Corpuscular Hemoglobin Concentration	MCHC
	Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV
	Red Blood Cell Distribution Width - Standard Deviation	RDW-SD
	Hematocrit	HCT
PLT (6 items)	Platelet count	PLT
	Mean Platelet Volume	MPV
	Platelet Distribution Width	PDW
	Plateletcrit	PCT
	Platelet-large cell ratio	P-LCR
	Platelet-large cell count	P-LCC
Histogram	White Blood Cell Histogram	WBC Histogram
	Red Blood Cell Histogram	RBC Histogram
	Platelet Histogram	PLT Histogram

3.4 Structure of the Analyzer

WARNING

- Please check the firmness of all the doors, covers and boards before running the analyzer.
- The analyzer is heavy, so moving by one person alone may cause injury. It is advisable for two people to move it together when the transportation is necessary, and make sure you follow the instructions and use the proper tools.
- Connect only to a properly grounded outlet.
- To avoid electrical shocks, disconnect the power supply before opening the cover.
- To prevent fire, use the fuses with specified model number and working current.

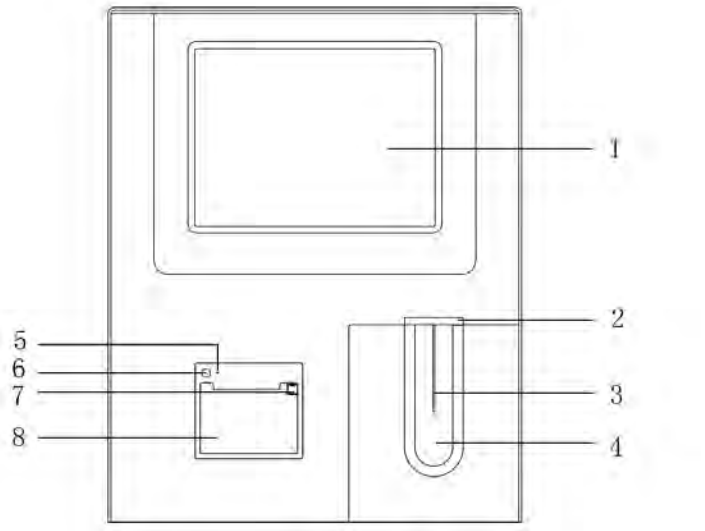
The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.

3.4.1 Host

The Auto Hematology Analyzer consists of the main unit (analyzer) and accessories. The main unit is the main part for analysis and data processing.

- Front of the analyzer

Figure 3-1 Front of the analyzer



1: Touch screen 2: Power/Status indicator

3: Sample probe 4: Aspirate key

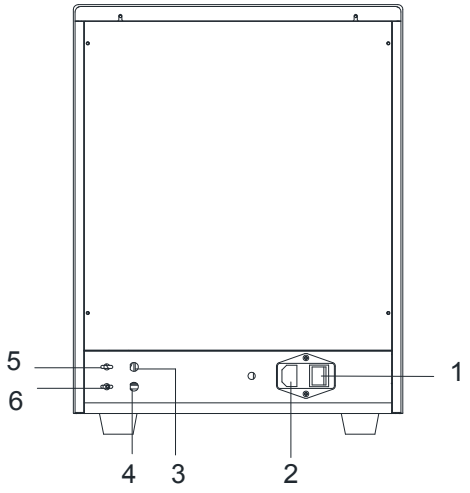
5: Printer status indicator 6: Paper feed key

7: Key for opening the paper compartment of the thermal printer

8: Paper compartment of the thermal printer

- Back of the analyzer

Figure 3-2 Back of the analyzer



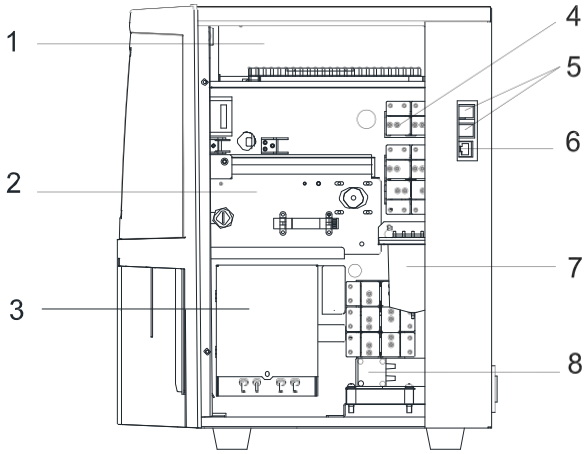
1: Power switch 2: AC input

3: Diluent presence detection connector 4: Waste level detection connector

5: DIL-E diluent inlet 6: Waste outlet

- Right side of the analyzer (right door opened)

Figure 3-3 Right side of the analyzer



1: Power Supply 2: Sampling assembly

3. Count bath assembly 4: Valve assembly

5: USB interface 6: Network interface

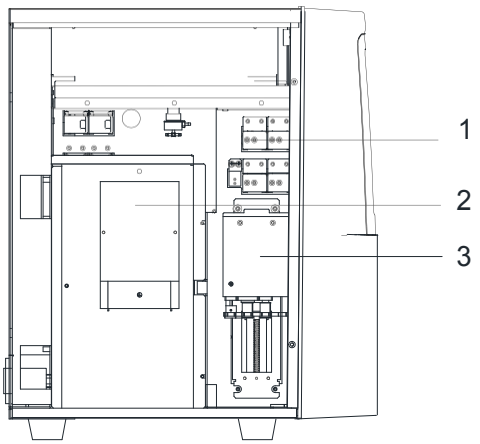
7: Pressure chamber 8: Pump

- Left side of the analyzer (left door opened)

WARNING

To prevent injuries, do not place your hands near the bottom guide tracks of the syringes when the analyzer is running.

Figure 3-4 Left side of the analyzer



1: Valve assembly 2: Liquid level detection unit

3: Syringe

3.4.2 Touch Screen

The touch screen is located on the front side of the analyzer for performing interface operations and displaying the information.

3.4.3 Aspirate key

The aspirate key is located in the middle of the front side (behind the sample probe) to start the sample analysis, to add diluent, or to cancel sleep.

3.4.4 Power/Status indicator

The status indicator is located in the middle section of the right part of the analyzer (front side). It shows the status of the analyzer including ready, running, error, sleep and on/off, etc.

The indicators change with the status of the main unit. Details are shown in Table 3-1.

Table 3-1 Main Unit Status Indicators

Instrument Status	Indicator Status	Remarks
Shutdown	Off	The main unit has been shut down.
Stopped running with error conditions	Red light on	Stopped running with the occurrence of errors
Running with error conditions	Red light flickering	Running with the occurrence of errors
Time sequence deactivated	Yellow light on	Initialization or sleep status irrelevant to running
Running	Green light flickering	Execution of the sequence actions is in process.
Ready	Green light on	Execution of the sequence actions is allowed.

NOTE

While the analyzer is running, if the indicator turns dim or off, please contact MR or MR's agent for maintenance.

3.4.5 Paper Feed Key

The paper feed key is located below the touch screen. After you press it, the built-in thermal printer will send out the paper with records.

3.4.6 Thermal Printer

The thermal printer is located below the touch screen. It will send out the paper with records after you press the paper feed key.

3.4.7 Power Switch

CAUTION

To avoid damage, do not power on/off the analyzer repetitively within a short time.

A power switch is located in the bottom back of the analyzer. It turns on or shuts down the analyzer.

3.4.8 USB interface

The USB interface is located on the right side of the main unit. There are 4 interfaces in total for external equipment (printer, barcode scanner, mouse or keyboard, and so on) connection or data transmission.

3.4.9 Network interface

The network interface is located on the right side of the main unit. There is 1 network interface in total for connecting with the Ethernet.

3.4.10 External Equipment (Optional)

The analyzer can be connected with the following external equipment:

- Keyboard

  The keyboard is connected with the USB interface on the right side of the analyzer for controlling the analyzer.

- Mouse

  The mouse is connected with the USB interface on the right side of the analyzer for operations on the analyzer.

- Printer

  The printer is connected with the USB interface on the right side of the analyzer for printing reports and other information displayed on the screen.

- Barcode Scanner

  The barcode scanner is connected with the USB interface on the right side of the analyzer for entering barcode information in an easy and fast way.

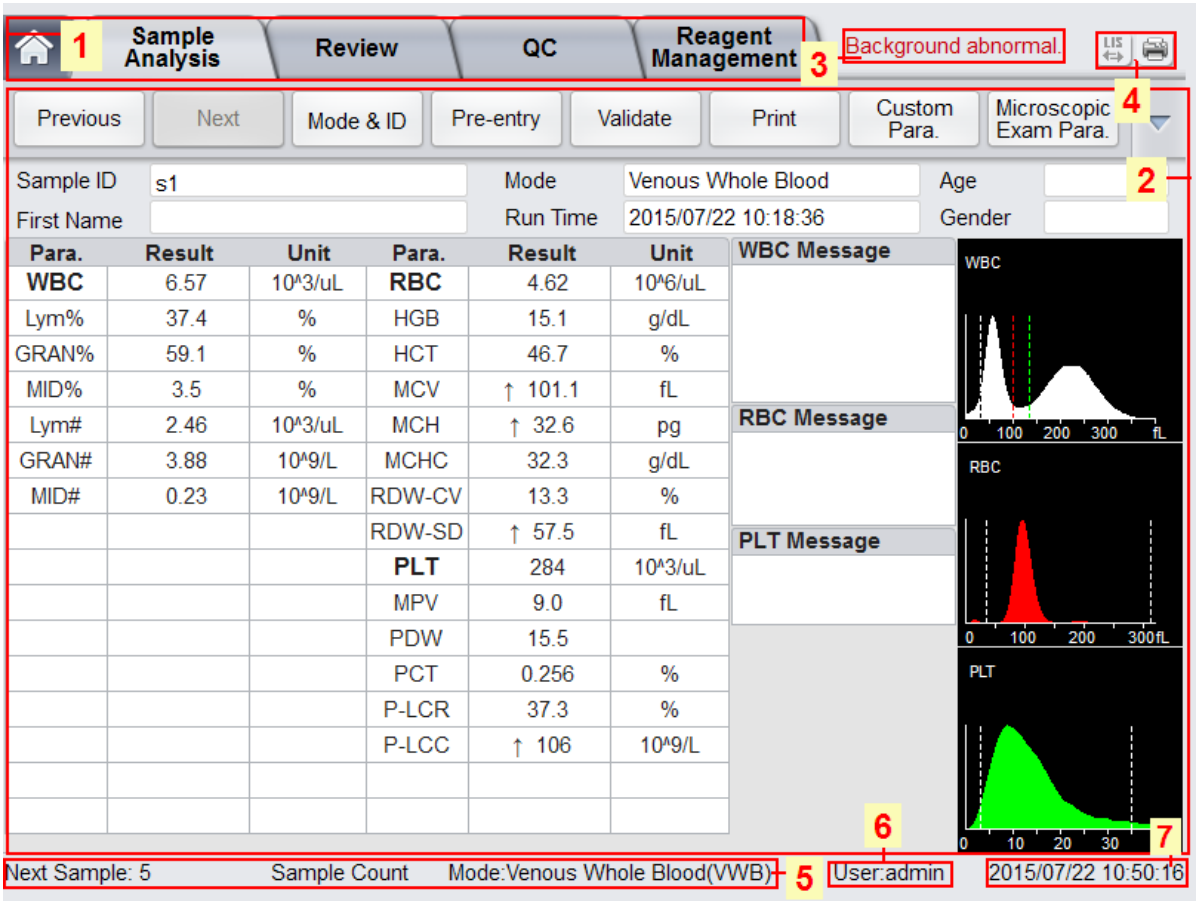
- USB flash disk

  The USB flash disk is connected with the USB interface on the right side of the analyzer for exporting sample data.

3.5 User Interface

After the startup procedure, you will enter the user interface (**Sample Analysis** as default). See Figure 3-5.

Figure 3-5 User Interface



The interface can be divided into several areas as follows according to their functions:

- 1 - Menu navigation area

  On the top of the screen is the menu navigation area. Once a menu button is pressed, the system goes immediately to the corresponding screen.

- 2 - Menu content display area

  It displays the selected screen and the corresponding function buttons.

- 3 - Error message area

  Upon the occurrence of a system failure, the corresponding error message will appear in this area. When there is more than one failure, the error message for the latest failure will appear in this area.

  Click in this area, you can deal with the failures in the popup dialog box of troubleshooting help. For more information, see ***13 Troubleshooting***.

- 4 - Status display area

  On the top right of the screen is the status display area where the connection status between the computer and the LIS system and printer status are displayed from left to right. The icons change with the status of the main unit, as shown in Table 3-2.

Table 3-2 Status Icon Description

Status	Icon	Remarks
LIS/HIS status	Gray icon 	The computer is not connected to the LIS/HIS.

Status	Icon	Remarks
	Black icon 	The computer is connected to the LIS/HIS.
Print status	Gray icon 	The printer is not connected to the analyzer yet.
	Color icon 	The printer is connected to the analyzer.

- 5 - Information area of the next sample

  This area displays the information about the sample ID, sample position and blood mode of the next sample.
- 6 - Username of the current user
- 7 - Current date and time of the analyzer.

3.6 Reagents, Controls and Calibrators

Because the analyzer, reagents, controls, and calibrators are components of the system, system performance depends on the combined integrity of all the components. You should only use the MRspeeified reagents (see ***A.2 Reagents***), which are formulated specifically for the fluidic system of your analyzer in order to achieve optimal system performance. Do not operate the analyzer using reagents from multiple suppliers. Under such circumstances, the analyzer may not achieve the performance specified in this manual and may generate unreliable results. All references to “reagents” in this manual refer to the reagents specifically formulated for this analyzer.

Each reagent package should be examined before use. Inspect the package for signs of leakage or moisture. Product integrity may be compromised in packages that have been damaged. If there is evidence of leakage or improper handling, do not use the reagent.

NOTE

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- Store and use the reagents by following the instructions for use of the reagents.
- When you have changed the diluents or lyses, run a background check to see if the results meet the requirement.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.

3.6.1 Reagents

The following reagents are intended to be used with the analyzer for 3-part diff counting, daily cleaning and other operations.

- DIL-E Diluent

  This product is intended for sample dilution and preparation of cell suspension before running the samples.
- LYE-1 LYSE

This product is intended for lysing the red blood cells, determining the hemoglobin, white blood cell classification and counting the total number of white blood cells.

- CLE-P Cleanser

  This product is intended for cleaning the fluidic system of the analyzer and regular instrument cleaning.

3.6.2 Controls and Calibrators

The controls and calibrators are used for quality control and analyzer calibration.

The controls are commercially prepared whole-blood products used to verify that the analyzer is functioning properly. They are available in low, normal, and high levels. Daily use of all levels verifies the normal operation of the analyzer and ensures the acquisition of reliable results. The calibrators are commercially prepared whole-blood products used to calibrate the analyzer.

Read and follow the instructions to use the controls and calibrators.

The "calibrators" and "controls" mentioned in this manual refer to MR‑specified calibrators and controls and need to be purchased from MR or its specified agent.

4 Working Principle

4.1 Introduction

The measurement methods used in this analyzer are: the Electrical Impedance method for determining the WBC, RBC and PLT and their volume distribution; the colorimetric method for determining the HGB. During each analysis cycle, the sample is aspirated, diluted and mixed before the determination for each parameter is performed.

4.2 Aspiration

The analyzer supports Whole Blood mode (including Venous Whole Blood and Capillary Whole Blood) and Predilute mode.

In Whole Blood mode, the analyzer will aspirate quantitative whole blood sample.

In Predilute mode, the analyzer will aspirate the prediluted sample (with the dilution ratio of 1:10) which is a mixture of 20μL of whole blood/capillary blood sample and 180μL of diluent the diluted sample thus prepared is then delivered to the analyzer for sampling and aspiration.

4.3 Dilution

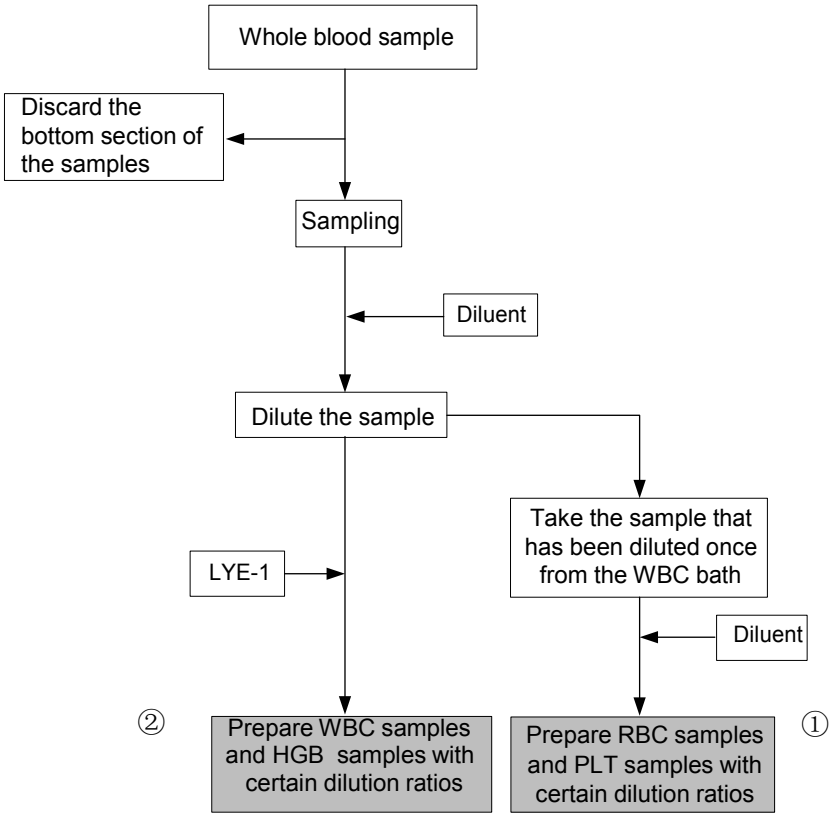
After being aspirated into the analyzer, the sample is divided into two parts. After the reaction with reagents in parallel dilution procedures, each part forms the sample for red blood cell/platelet, white blood cell count/hemoglobin measurement.

To meet different needs, the analyzer offers two working modes –Whole Blood and Predilute. The dilution procedures for whole blood samples and prediluted samples will be presented on the following pages.

4.3.1 Dilution Procedures in Whole-Blood Mode

Dilution Procedures in Whole-Blood Mode are shown in Figure 4-1.

Figure 4-1 Dilution Procedures in Whole-Blood Mode

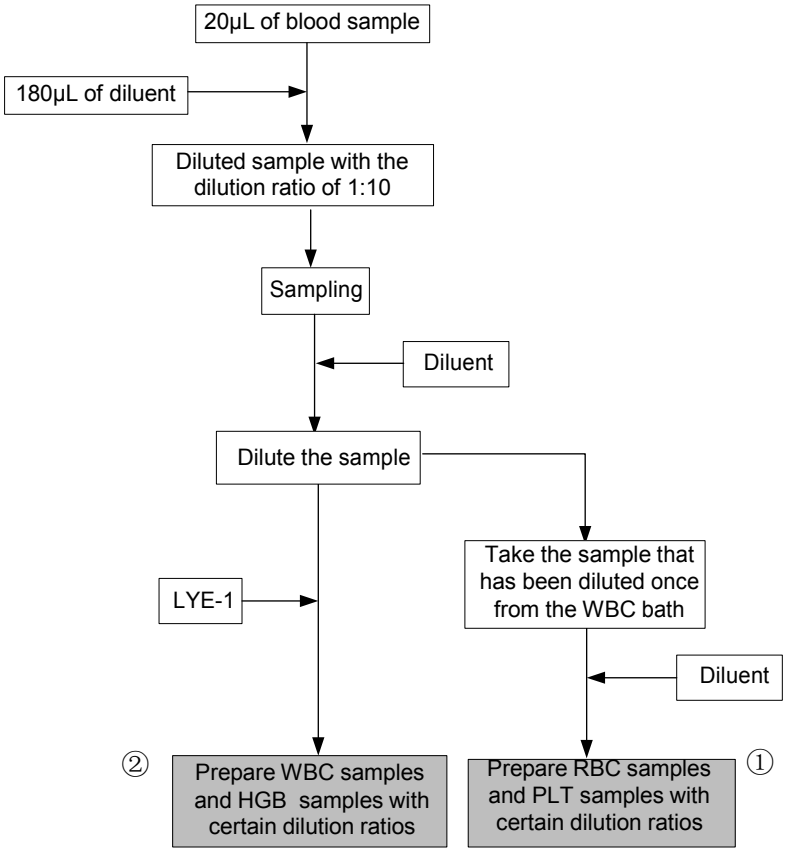


① is the dilution procedure for red blood cell and platelet; ② is the dilution procedure for white blood cell count/hemoglobin; namely CBC.

4.3.2 Dilution Procedures in Predilute Mode

The dilution procedure for the prediluted sample is shown in Figure 4-2.

Figure 4-2 Dilution Procedures in Predilute Mode



① is the dilution procedure for red blood cell and platelet; ② is the dilution procedure for white blood cell count/hemoglobin; namely CBC.

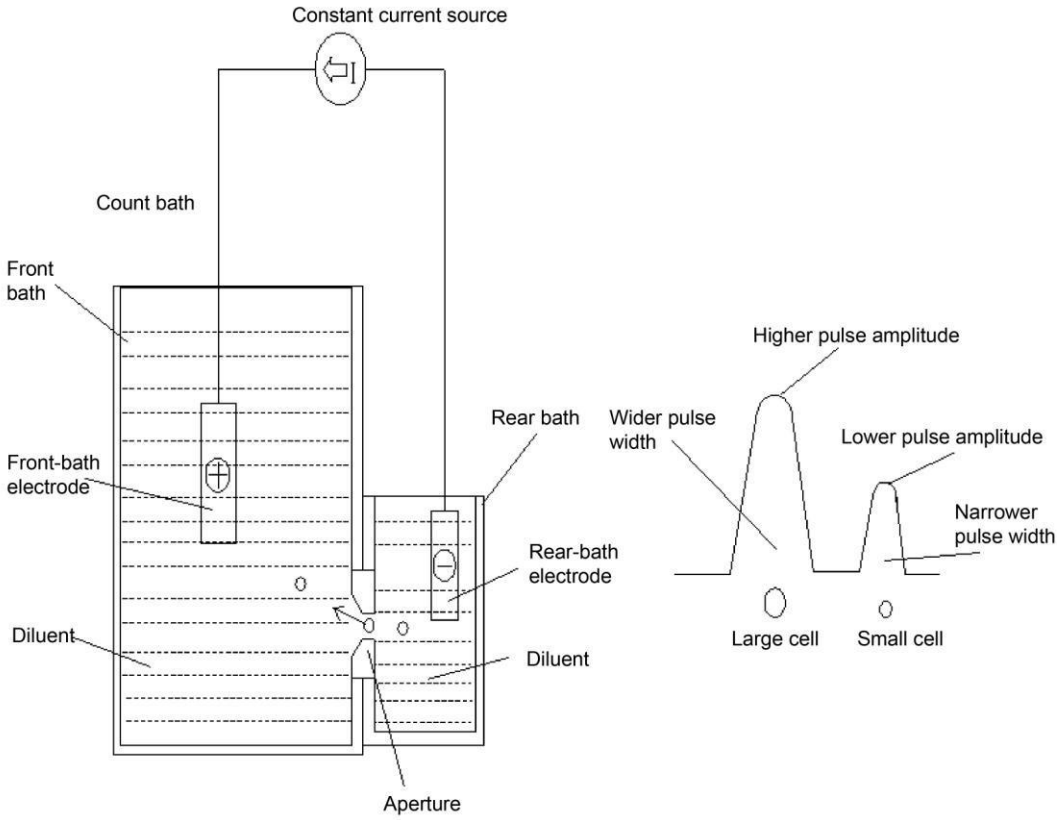
4.4 WBC/RBC/PLT Measurement

The analyzer detects the white blood cell count, red blood cell count and platelet count and their volume distribution by impedance method and eventually obtains the results of related parameters.

4.4.1 Electrical Impedance Method

WBCs/RBCs/PLTs are counted and sized by the Electrical Impedance method. 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 a 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.

The analyzer presents the WBC/RBC/PLT histogram, where the x-coordinate represents the cell volume (fL) and the y-coordinate represents the number of the cells.

4.4.2 Derivation of WBC-Related Parameters

White blood cells have a variety of types and can be categorized according to their volume. The volume of each type of cells varies with the added diluent, lyse and the lysing time. With the action of reagents, white blood cells can be classified into three groups, in the order from small volume to large volume: Lymphocytes, Mid-sized Cells (including Monocytes, Eosinophils and Basophils) and Granulocyte.

Based on the white blood cell histogram and the analysis for the Lym zone, Mid zone and Gran zone, the analyzer can get the percentage of lymphocytes (Lym%), the percentage of mid-sized cells (Mid%) and the percentage of granulocytes (Gran%), and then get the number of lymphocytes (Lym#), the number of mid-sized cells (Mid#) and the number of granulocytes (Gran#) based on the calculation with the white blood cell count obtained with the electrical impedance method. The unit of the number of cells is 10^9/L.

- White Blood Cell count

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

- Percentage of Lymphocytes (Lym%)

$$\text{Lym\%} = \frac{\text{Particle count in the } \textit{Lym} \text{ zone}}{\text{Sum of particle count in the } \textit{Lym} \text{ zone, } \textit{Mid} \text{ zone and } \textit{Gran} \text{ zone}} \times 100\%$$

- Percentage of Mid-sized Cells

$$\text{Mid\%} = \frac{\text{Particle count in the } \textit{Mid} \text{ zone}}{\text{Sum of particle count in the } \textit{Lym} \text{ zone, } \textit{Mid} \text{ zone and } \textit{Gran} \text{ zone}} \times 100\%$$

- Percentage of Granulocytes (Gran%)

$$\text{Gran\%} = \frac{\text{Particle count in the } \textit{Gran} \text{ zone}}{\text{Sum of particle count in the } \textit{Lym} \text{ zone, } \textit{Mid} \text{ zone and } \textit{Gran} \text{ zone}} \times 100\%$$

- Number of lymphocytes (Lym#)

$$\text{Lym\#} = \text{WBC} \times \text{Lym\%}$$

- Number of Mid-sized Cells

$$\text{Mid\#} = \text{WBC} \times \text{Mid\%}$$

- Number of Granulocytes (Gran#)

$$\text{Gran\#} = \text{WBC} \times \text{Gran\%}$$

4.4.3 RBC

- Red Blood Cell count

  RBC (12^{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) as follows, where the RBC is expressed in 10^{12}/L, MCV in fL and HGB in g/L.

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

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

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

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

  Based on the RBC histogram, this 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.

4.4.4 PLT

- Platelet count (PLT count, 10^9/L)

  PLT is measured directly by counting the platelets passing through the aperture.

- Mean Platelet Volume (MPV, fL)

  Based on the PLT histogram, this analyzer calculates the MPV.

- Platelet Distribution Width (PDW)

  PDW is the geometric standard deviation (GSD) of the platelet size distribution. Each PDW result is derived from the platelet histogram data and is reported as 10(GSD).

- Plateletcrit (PCT)

  This analyzer calculates the PCT as follows and expresses it in %, where the PLT is expressed in 10^9/L and the MPV in fL.

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

- Platelet-Large Cell Count (P-LCC, 10^9/L)

  P-LCC is measured directly by counting the large platelets passing through the aperture.

- Platelet-Large Cell Ratio (P-LCR)

  $$P-LCR = \frac{P\text{-}LCC}{PLT} \times 100\%$$

4.5 HGB Measurement

HGB is determined by the colorimetric method.

4.5.1 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).

4.5.2 HGB

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

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

4.6 Flushing

After each analysis cycle, each component of the analyzer is flushed.

5 Setup

5.1 Introduction

The analyzer has been initialized before delivery. The interfaces upon the initial startup of the analyzer are system settings by default. Some parameters of the analyzer can be reset to meet various demands in practical applications.

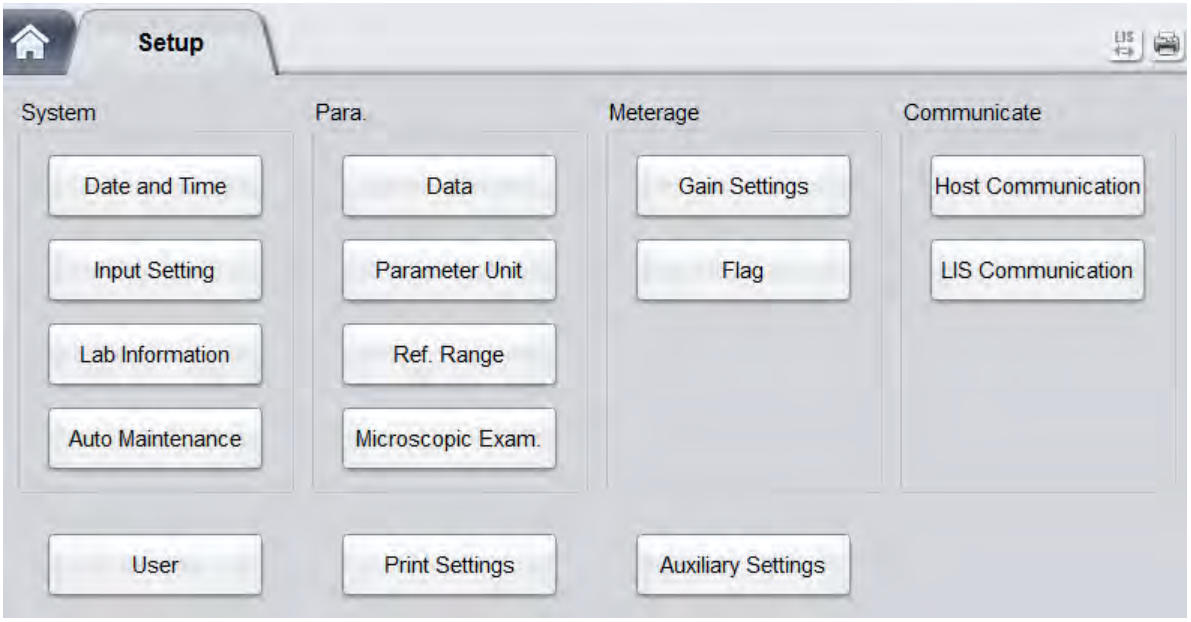
The analyzer divides the operators into two access levels, common user and administrator. Note that an administrator can access all the functions accessible to a common user. This chapter introduces how to customize your analyzer as an administrator.

5.2 Interface Introduction

After logging in the software system (see ***6.3 Startup***), click  , and choose Setup to access the Setup interface.

See Figure 5-1.

Figure 5-1 Setup



The administrator is allowed to set the following functions in the **Setup** interface:

- System settings
- Parameter settings
- LIS communication

- Meterage settings
- User management
- Print settings
- Auxiliary settings

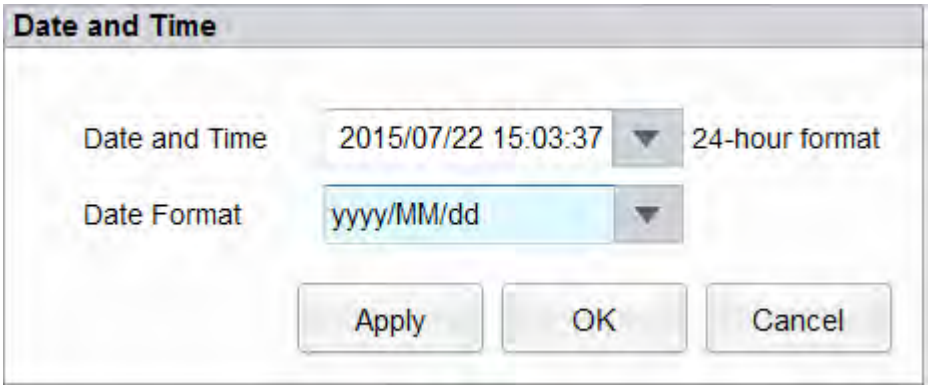
5.3 System Settings

5.3.1 Date and Time

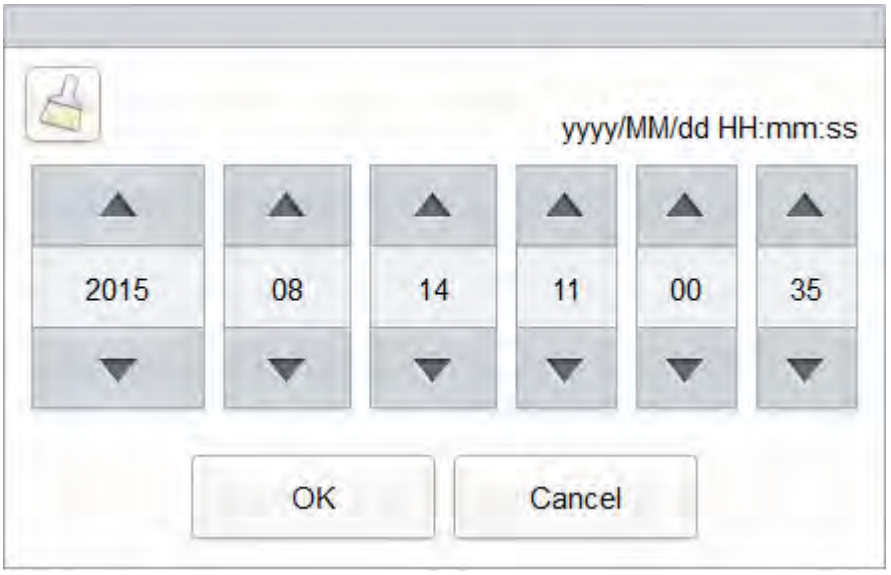
You can set the current date and time, as well as the date display format in the analyzer system. Specific steps are shown below:

1. Click **Date and Time** in the **System** area.

   The date and time format setting interface pops up.



2. Click the **Date and Time** dropdown list and set the current date and time of the system in the popup dialog box.



Related descriptions:

➢ The input sequence of the controls is the same with the date fomat on the top right corner of

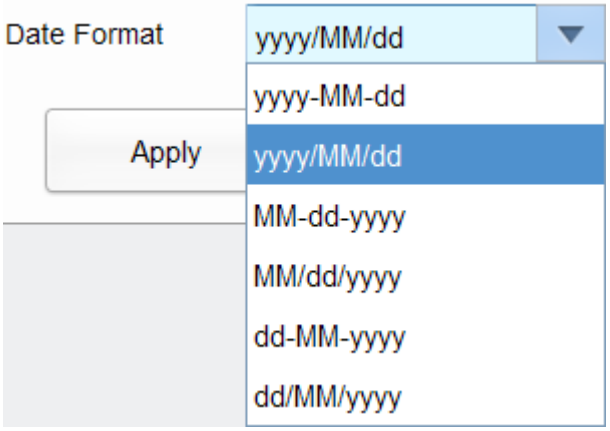
the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm:ss**, you should input the data in the sepuence of year, month, date, hour, minute, and second.

- Click  or  to select the date and time or click the textbox to enter them directly.
- Click  to clear the data and input again.

3. Click **OK** to save and close the message box.
4. Select the format setting from the dropdown list of the **Date Format**.

   See Figure 5-2.

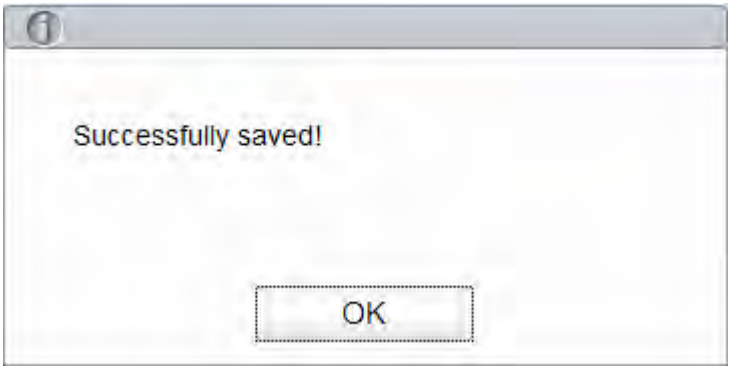
Figure 5-2 Setting the Date Format



5. Click **Apply**.

   The system message will pop up, indicating the successful setting. See Figure 5-3.

Figure 5-3 Successful Setting of the Date Format



The date and time at the bottom right corner will be displayed in the newly set format as shown in 06/26/2015 15:11:44.

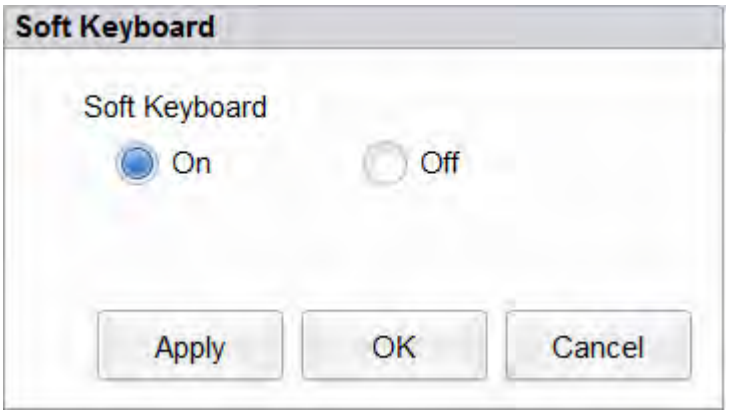
6. Click **OK** to close the message box.
7. Click **OK** to exit.

5.3.2 Input Settings

Click **Input setting** in the **System** area, and then you can set the soft keyboard for screen input.

As shown in Figure 5-4, You can set to turn the soft keyboard on or off.

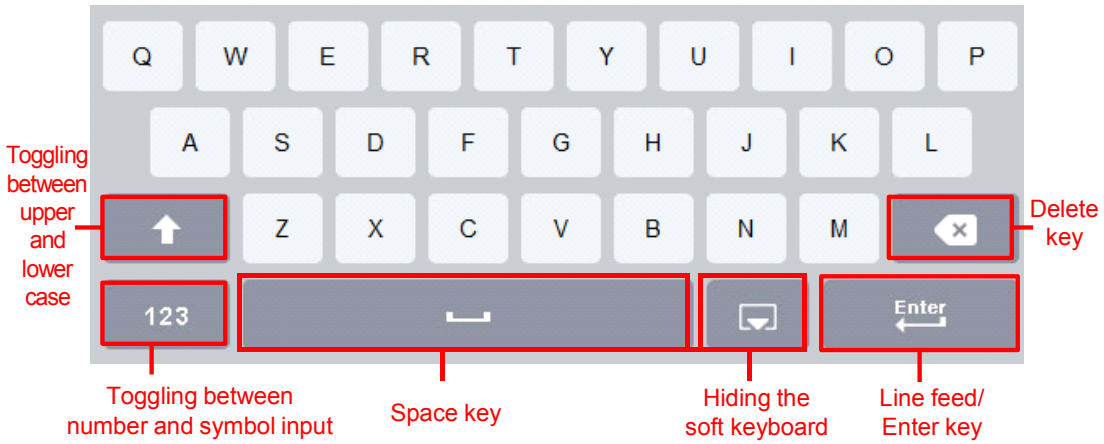
Figure 5-4 Input Settings



- Soft Keyboard
  - ➢ Open (default)

    You can enter content using the soft keyboard popped up on the screen. Functions and applications for the keys are shown in Figure 5-5.

Figure 5-5 Soft Keyboard



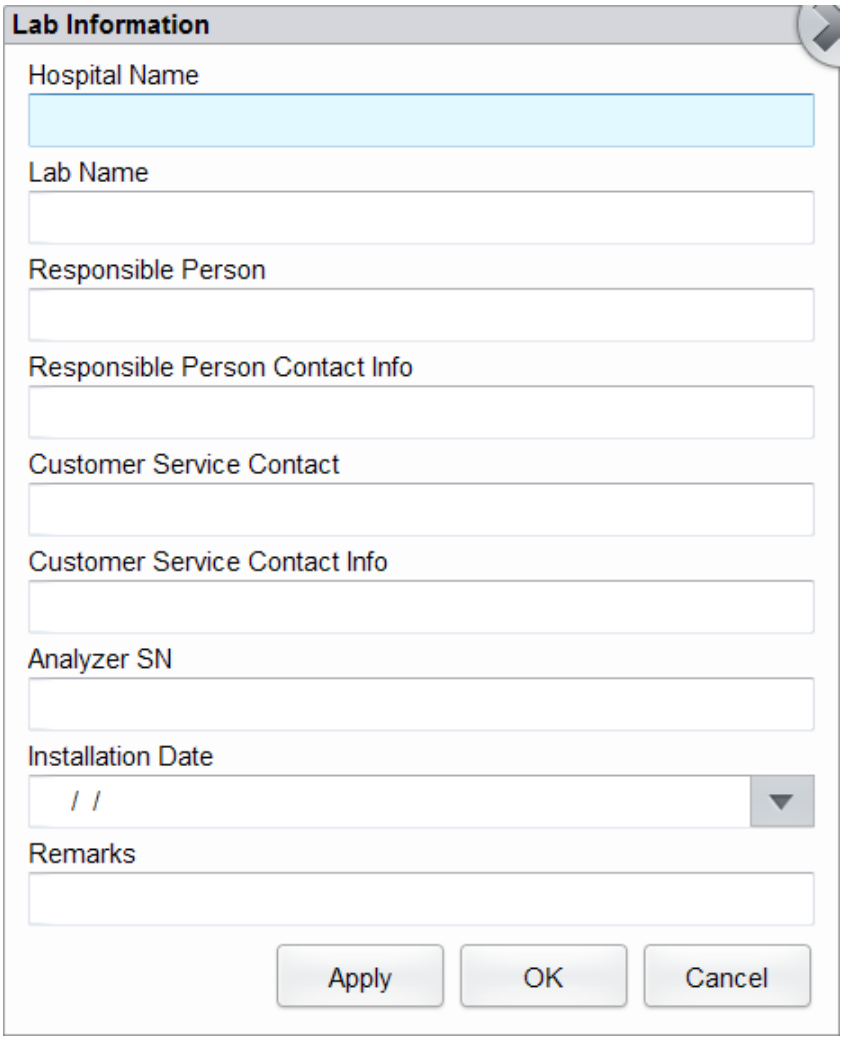
  - ➢ Close

    You need to use an externally connected USB keyboard for entering content.

5.3.3 Lab Information

Click **Lab Information** in the **System** selection, then you can set the lab information. See Figure 5-6.

Figure 5-6 Setting Lab Information



NOTE

Only the administrator has the access for setting the lab information. General users are only allowed to browse such information.

Refer to the table below for the detailed instructions of parameter setting.

Table 5-1 Setting Lab Information

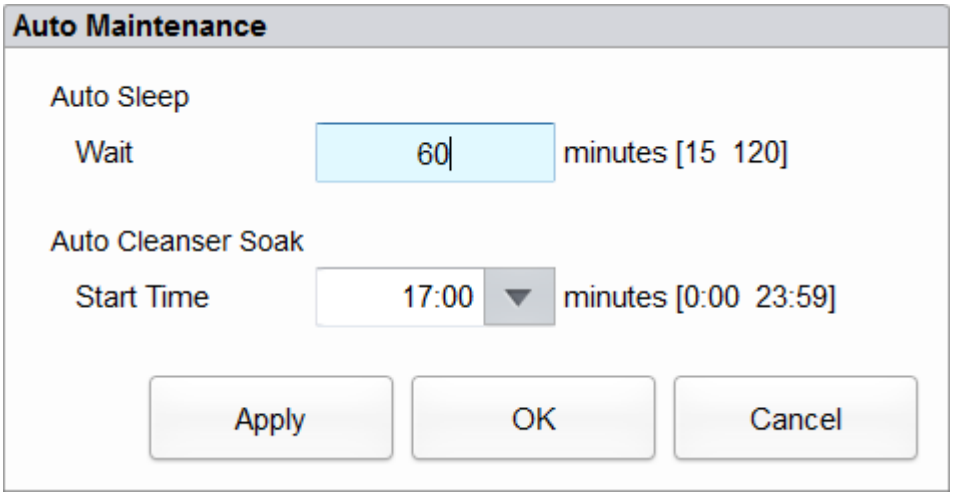
Parameter	Setting Description
Hospital Name	Enter the name of the hospital where the lab is located.
Lab Name	Enter the lab name.
Responsible Person	Enter the responsible person of the lab.
Contact Information	Enter the contact information (telephone number or E-Mail) of the lab.
Contact in Service Department	Enter the name of the contact person in Service Department.
Contact Information of Service Department	Enter the contact information of the contact person in the Service Department.

Parameter	Setting Description
Analyzer SN	Display the serial number of the analyzer. Read only.
Installation Date	Display the installation date of the analyzer. Read only.
Remarks	Enter the remarks regarding the lab.

5.3.4 Auto Maintenance

Click **Auto Maintenance** in the **System** selection to access the **Auto Maintenance** setting interface. The system auto sleep waiting time and cleanser maintenance time can be set in the **Auto Maintenance** interface.

Figure 5-7 Auto Maintenance



Auto Sleep

In the **Wait** textbox, the administrator is allowed to set the waiting time for entering the sleep state after the main unit is halted. The range is between 15 and 120 minutes and the default value is 60 minutes.

Auto Cleanser Soak

The administrator is allowed to set the start time of the cleanser soak in the **Start Time** textbox. The acceptable value ranges from 0:00 to 23:59 and the default value is 17:00

5.4 Parameter Settings

5.4.1 Data Dictionary

You can set shortcut codes for the relevant items of the patient information.

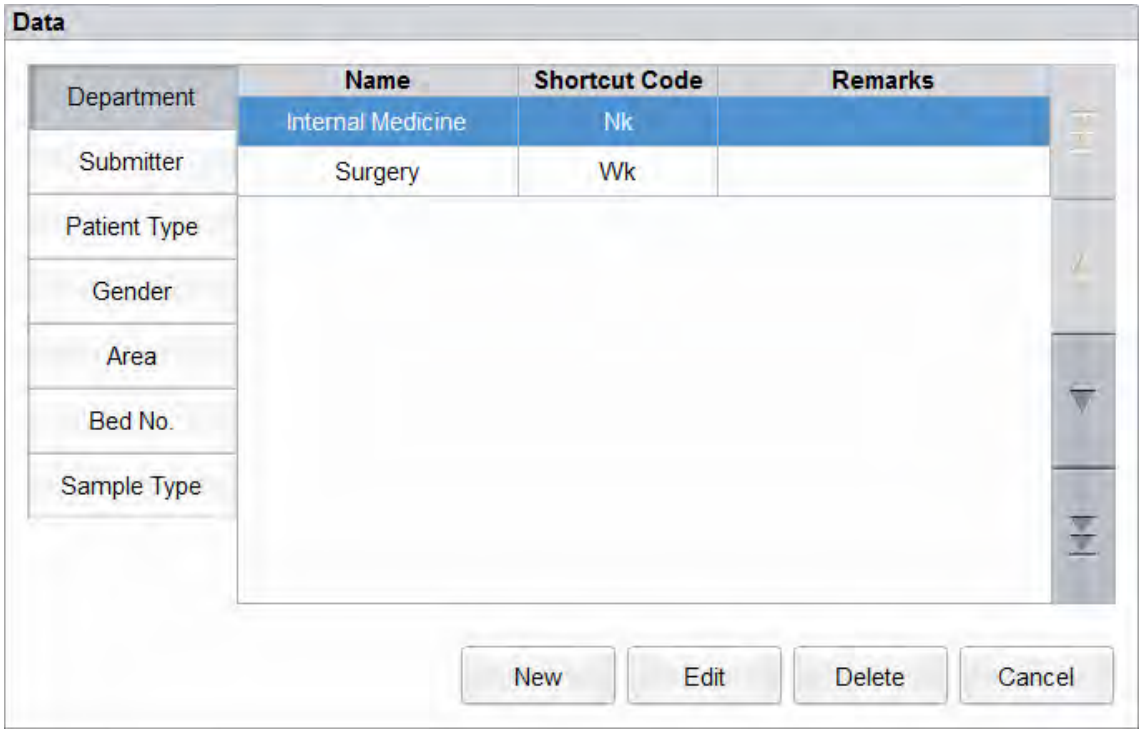
If a shortcut code is set, the shortcut code corresponding to the above mentioned item can be entered directly when the information is input or numbered, then the complete information can be displayed without entering (or selecting) complete information.

It is a shortcut operation. Different items can share one shortcut code.

5.4.1.1 Accessing the Interface

Click **Data** in the **Para.** selection to access the data dictionary setting interface. See Figure 5-8. You can set the shortcut code for the relevant items of the patient information in this interface.

Figure 5-8 Shortcut Code



You can set the shortcut code for the following items: **Department**, **Submitter**, **Patient Type**, **Gender**, **Area**, **Bed No**. and **Sample Type**.

5.4.1.2 Adding a New Item

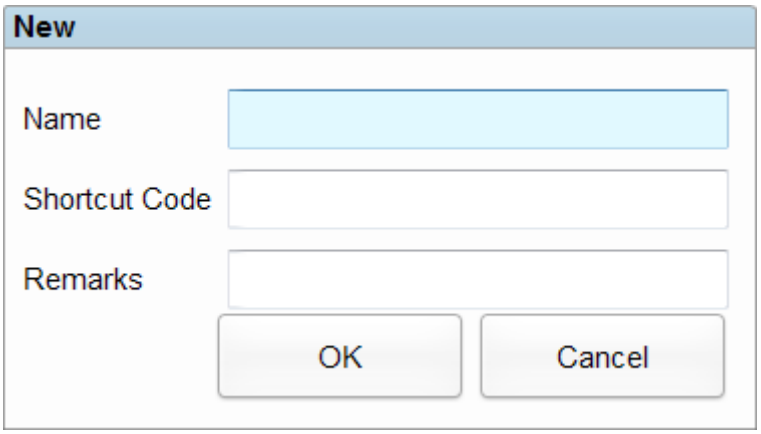
This section takes the adding of a new department as an example to introduce the method for adding a new item and its shortcut code. The method for adding other new items is similar and is not introduced in details herein.

Steps for adding a new department are shown as follows:

1. Click **New** in the **Department** interface.

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

Figure 5-9 Adding a New Item



2. Enter a new department name, shortcut code and remarks.

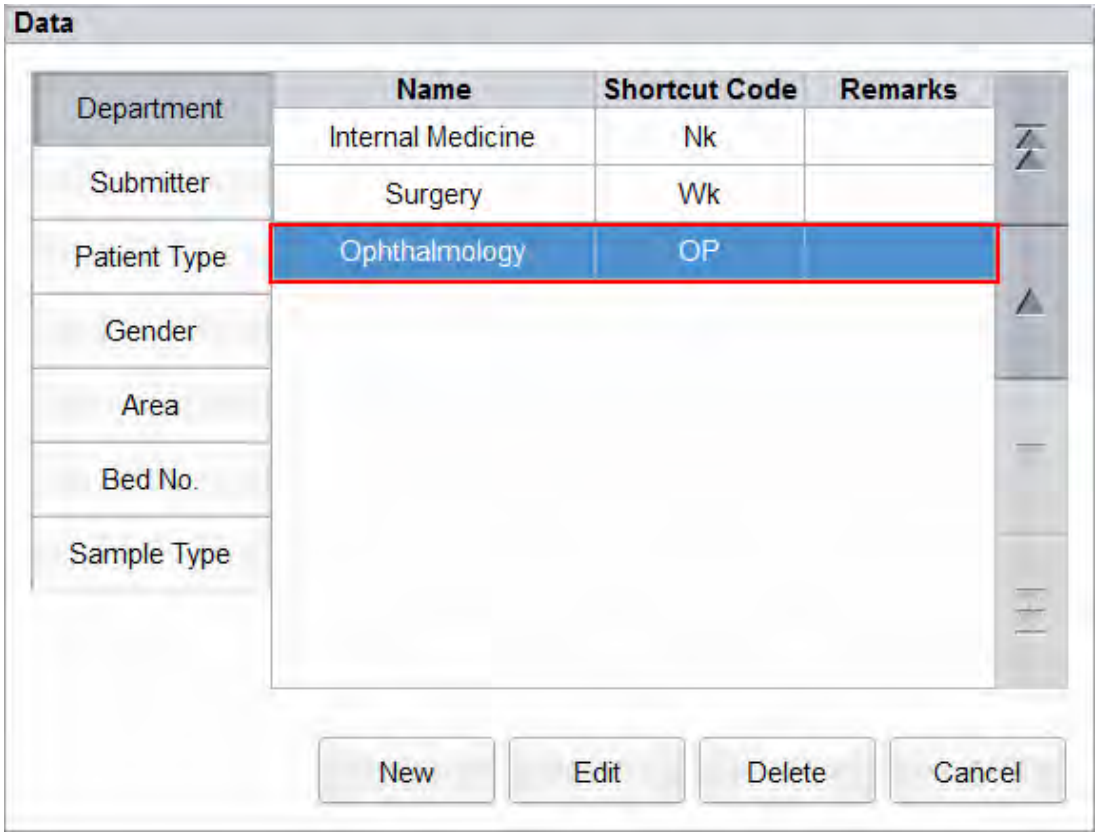
NOTE

- Newly added department name must be entered and it can not be the same as existing ones.
- The shortcut code is not necessary to be entered, but once set, every code must be unique.

3. Click **OK** to save the information about the new department.

   Information about the newly added department will be displayed in the department interface. See Figure 5-10.

Figure 5-10 Information of the Newly Added Department



5.4.1.3 Editing Items/Shortcut Code

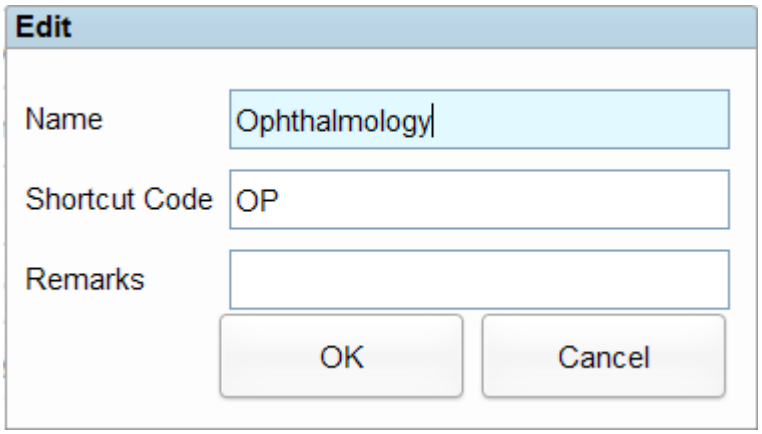
This section takes the editing of a department as an example to introduce the method for editing items and its shortcut code. The method for editing other new items is similar and is not introduced in details herein.

Steps for editing a department are shown as follows:

1. Select the department to be modified in the **Department** interface (for example the Internal Medicine), then click **Edit**.

   A dialog box will pop up as shown in Figure 5-11.

Figure 5-11 Editing Item/Shortcut Code



2. Modify the **Name**, **Shortcut Code** and **Remarks** in each textbox according to the actual demand.

NOTE

- Newly added department name must be entered and it can not be the same as existing ones.
- The shortcut code is not necessary to be entered, but once set, every code must be unique.

3. Click OK to save the information.

5.4.1.4 Deleting a Shortcut Code

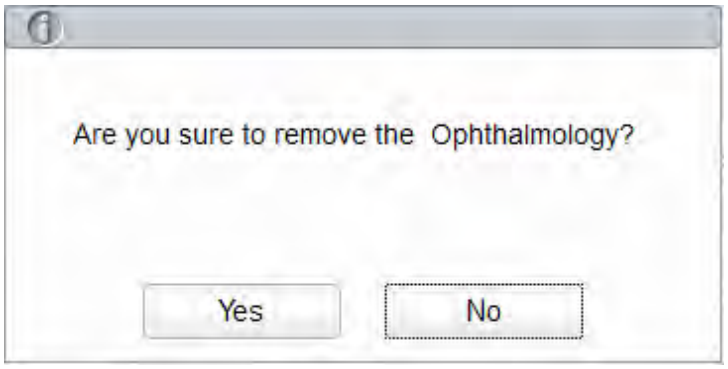
This section takes the deleting of a department as an example to introduce the method for deleting items and this shortcut code. The method for deleting other new items is similar and is not introduced in details herein.

Steps for deleting a department are shown as follows:

1. Select the department to be deleted in the **Department** interface, and then click **Delete**.

   A dialog box will pop up as shown below.

Figure 5-12 Deleting a Department



2. Click **Yes** to delete the department.

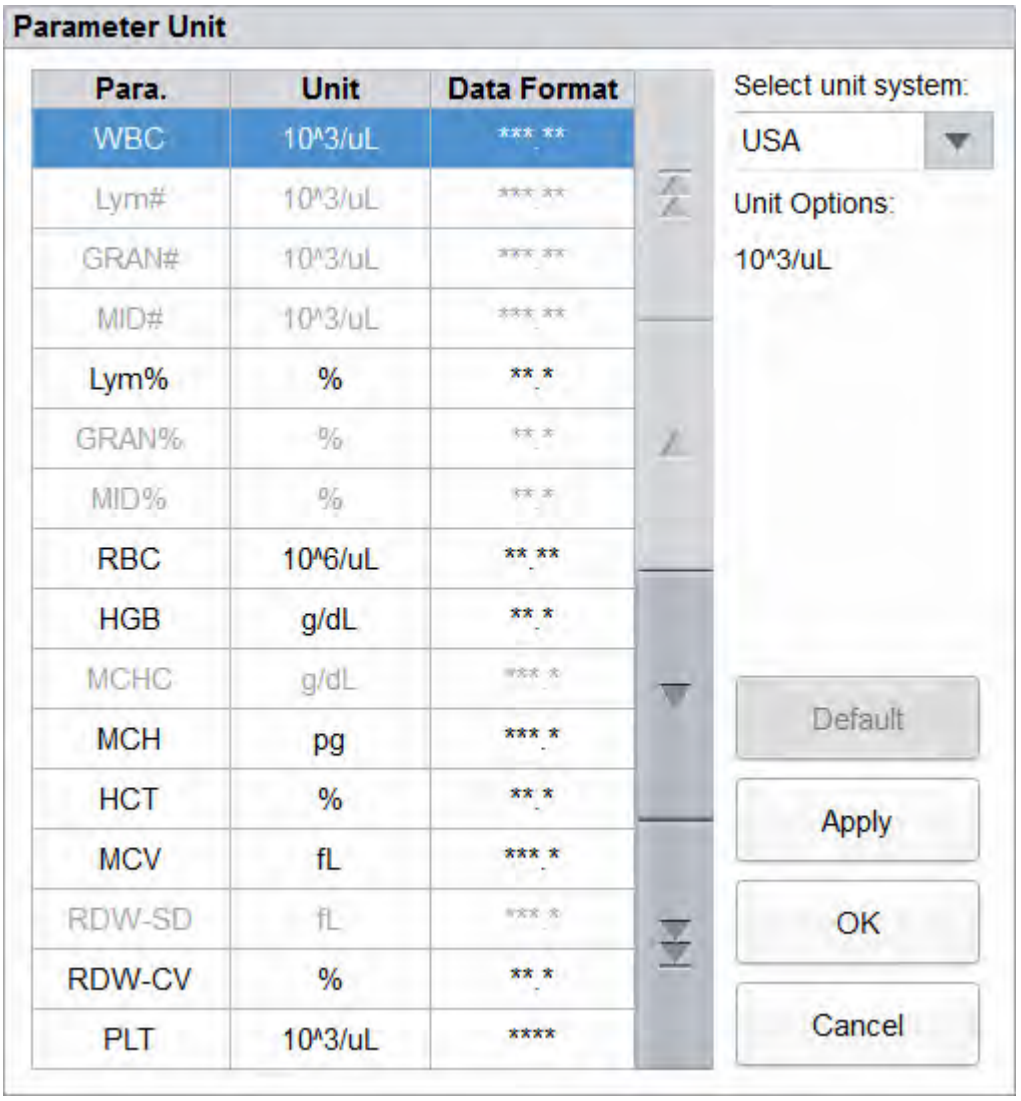
5.4.2 Parameter Unit

Some of the parameters of the analyzer can use different units which can be chosen as per user demand.

5.4.2.1 Accessing the Interface

Click **Parameter Unit** in the **Para.** selection to access the **Parameter Unit** setting interface. See Figure 5-13.

Figure 5-13 Setting Parameter Unit



5.4.2.2 Selecting Unit System

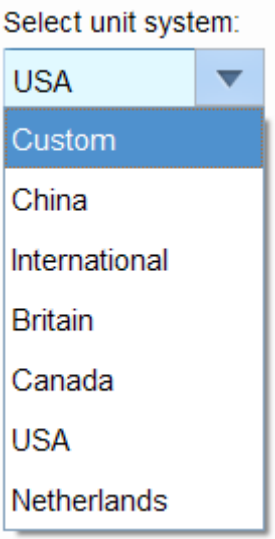
Click the **Select unit system** dropdown list and select a unit system for the parameters among the 7 unit systems (Custom, China, International, Britain, Canada, USA and Netherlands).

NOTE

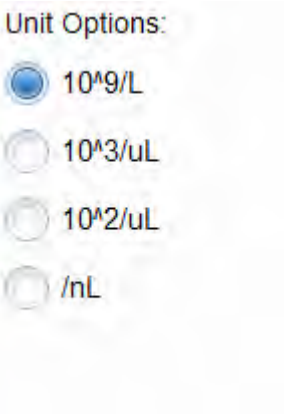
- When selecting different unit standards, the corresponding unit list and unit option will be displayed differently.
- If another option is selected except the **Custom**, then the unit of each parameter can only be browsed.

5.4.2.3 Customizing Parameter Unit

1. Select **Custom** from the dropdown list of **Select unit system**.



2. Click the parameter, of which the unit is to be set, from the parameter list (such as **WBC**).
3. Select a new parameter unit from the Unit Options list.



4. Click **Apply** or **OK** to save the configuration.

NOTE

- For parameters in the same group, if the unit of any parameter changes, the units of the other parameters change accordingly. (In the list, parameters will be sorted by group; the first parameter will be displayed in black and the other parameters in the same group will be displayed in grey.)
- If the parameters units change, the display format of the list data will change accordingly.

5.4.2.4 Retrieving Defaults

When setting the **Custom** unit system, if you click **Default**, the unit of the parameters can be restored to the initial default values.

5.4.3 Ref. Range

The reference range based on various normal groups can be set for the analyzer in the actual practice. If the analysis result of a sample is beyond the reference range, it will be regarded as

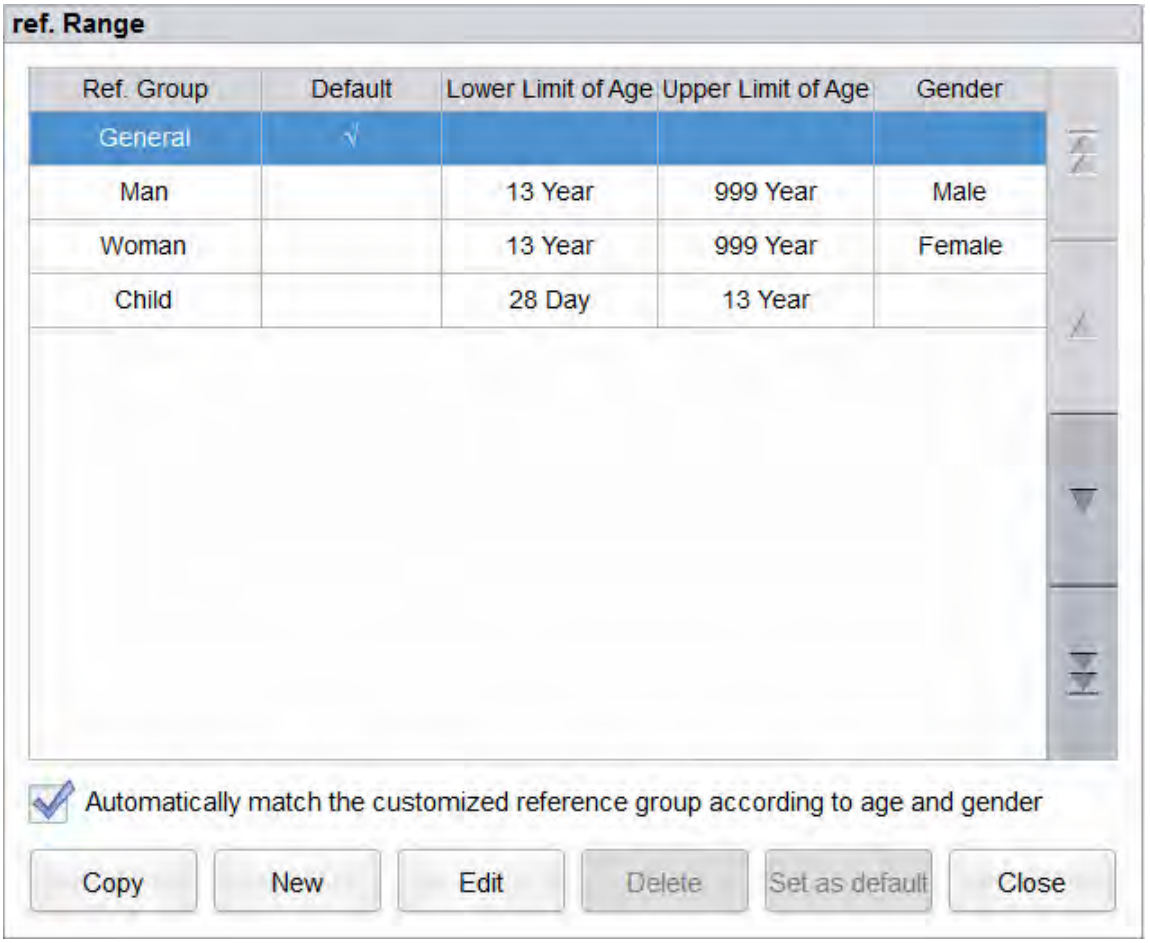
clinically abnormal. The Ref. Range interface is where you view and set the high and low limits for your patients. The analyzer flags any parameter value above (↑ or **H**) or below (↓ or **L**) these limits.

This analyzer divides the patients into 4 demographic groups: **General**, **Man**, **Woman** and **Child**. You can also customize other groups. The recommended limits are for reference only. To avoid misleading parameter flags, be sure to set the patient limits according to the characteristics of local population.

5.4.3.1 Accessing the Interface

Click **Ref. Group** in the **Para.** selection to access the reference group settings interface. See Figure 5-14.

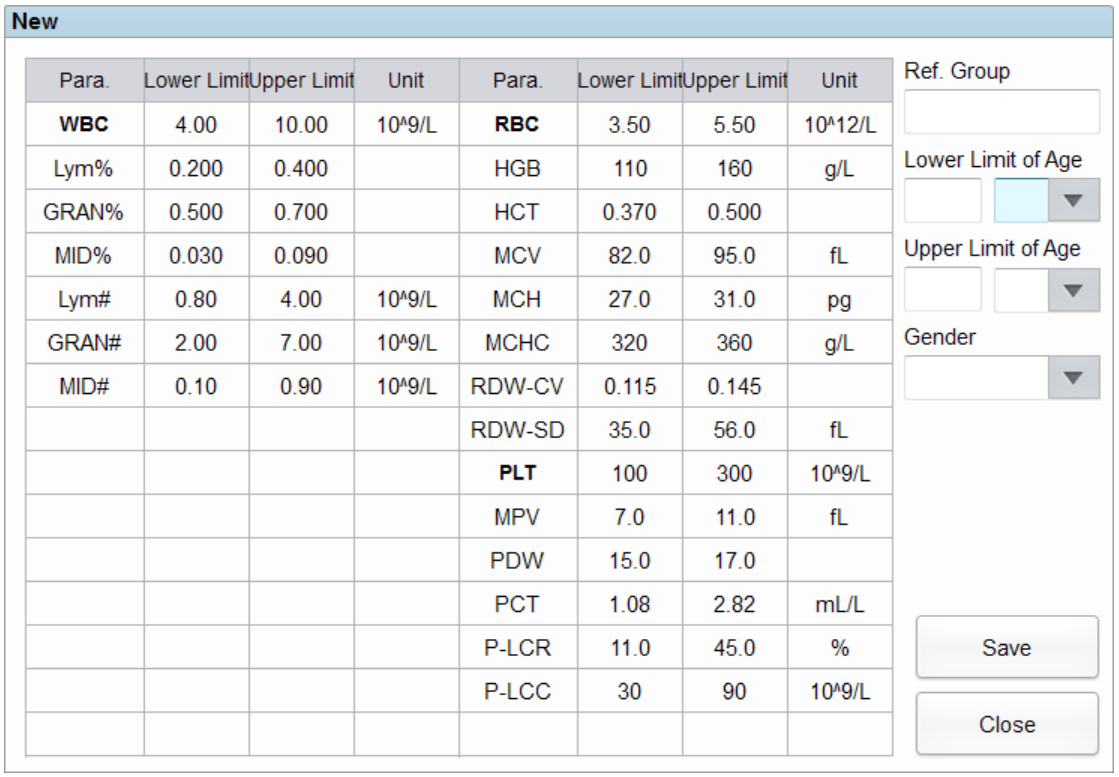
Figure 5-14 Ref. Range



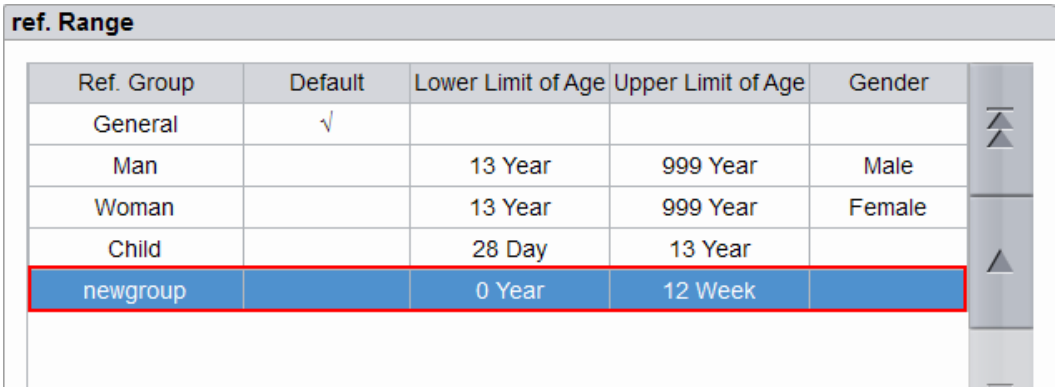
5.4.3.2 Copying a Ref. Group

Select a reference group and click **Copy**, and a new reference group with everything the same except the name of the reference group will be added to the system and a screen as shown in Figure 5-15 will pop up.

Figure 5-15 Copying a Ref. Group



You can edit the new reference group. Save and close the screen, and then the copied reference group will be shown in the reference group list.



NOTE

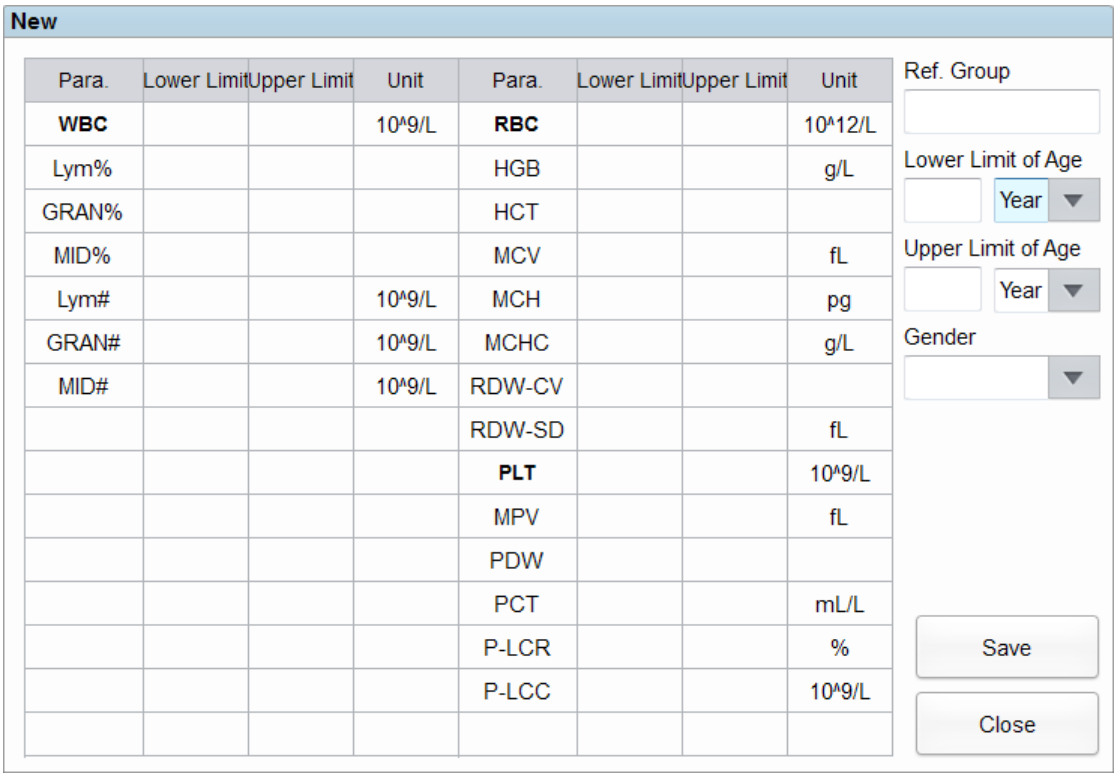
The reference group name entered is not allowed to be empty nor the same as the existing ones.

5.4.3.3 Adding a New Ref. Group

If the built-in reference groups cannot meet the actual demand, you can add new ones and manually enter the information such as reference ranges for each parameter, names and genders. The procedures are shown as below:

1. Click **New**, and a screen for adding a new reference group will pop up. See Figure 5-16.

Figure 5-16 Adding a New Ref. Group



2. Complete the entries for each parameter with reference to the parameter description in Table 5-2.

Table 5-2 Description of Ref. Group parameters

Parameter	Meaning	Operation
Ref. Group	Name of the new reference group.	Click the edit box and enter the information using the soft keyboard. English characters and numbers are allowed to be entered, while special characters are not. **NOTE** The reference group name entered is not allowed to be empty nor the same as the existing ones.
Lower Limit of Age	Lower limit of age of the reference group.	Enter an integer value in the textbox and select the age unit from the drop list on the right. (**Year**, **Month**, **Week**, **Day** or **Hour**) **NOTE** The Lower Limit of Age must be smaller than the Upper Limit of Age.
Upper Limit of Age	Upper limit of age of the reference group.	Enter an integer value in the edit box and select the age unit from the drop list on the right: **Year**, **Month**, **Week**, **Day** or **Hour.** **NOTE** The Upper Limit of Age must be greater than the Lower Limit of Age.

Parameter	Meaning	Operation
Gender	Gender of the reference group.	Select **Man**, **Woman**, **Not defined** from the dropdown list. The default setting is empty.
Lower Limit (of parameter)	Lower limit of parameters of the reference group. If the test result is lower than this value, it would be regarded as clinically abnormal.	Click the **Lower Limit** cell which corresponds to the parameter and enter a new value. **NOTE** The **Lower Limit** must be smaller than the **Upper Limit.**
Upper Limit (of parameter)	Upper limit of parameters of the reference group If the test result is higher than this value, it would be regarded as clinically abnormal.	Click the **Lower Limit** cell which corresponds to the parameter and enter a new value. **NOTE** The **Upper Limit** must be greater than the **Lower Limit**.

3. Click **Save** to save the settings.
4. Click **Close** to exit the interface.

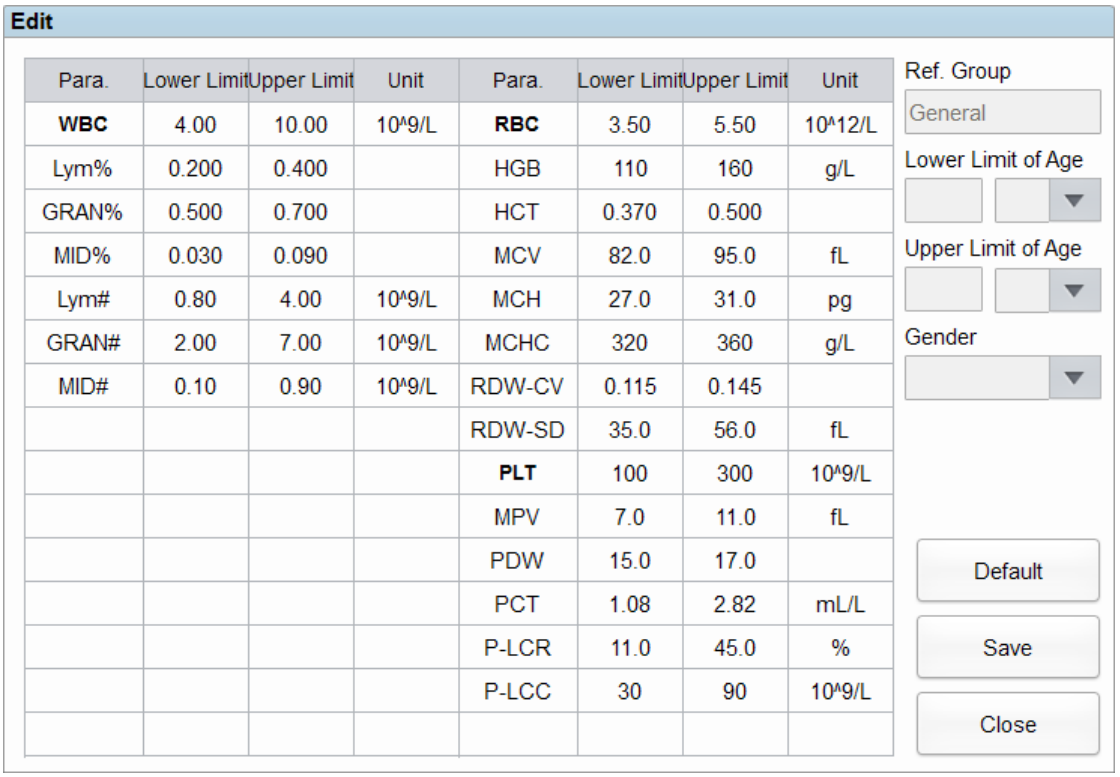
5.4.3.4 Editing a Ref. Group

You can modify the reference range of the parameters according to actual needs and set suitable reference intervals (age range, gender, etc.).

The procedures are shown as below:

1. Select the Ref. group to be set, and click **Edit** to enter the interface as shown in Figure 5-17.

Figure 5-17 Editing a Ref. Group



2. Refer to Table 5-2 for the description of the parameters to finish the editing.

NOTE

- For the built-in reference group, you can modify the upper limit and lower limit of the parameters, but not its name, the upper limit and lower limit of age as well as gender.
- Click Set as default to restore the setting of the selected reference group to the default value.
- Non-built-in reference group (which is added by user) cannot restore defaults.

3. Click **Save** to save the modification.
4. Click **Close** to exit.

5.4.3.5 Deleting a Ref. Group

Click **Delete**, and select **Yes** in the pop-up dialog box to delete the selected customized reference group.

NOTE

Built-in reference group can not be deleted.

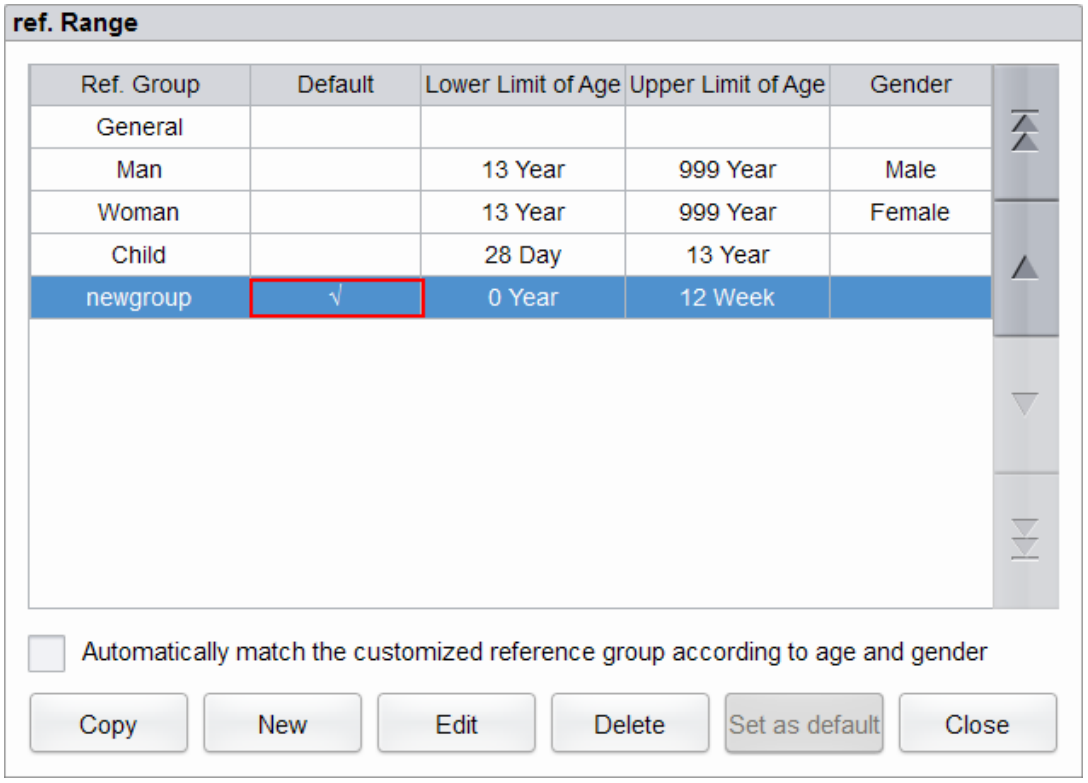
5.4.3.6 Setting Default Ref. Group

When you pre-enter patient information in the **Sample Analysis** interface, the **Ref. Group** displayed by default is the default reference group.

The default setting is **General**. You can change it as required. Select a reference group and click **Set as default** to set the selected reference group as the default group.

As shown in Figure 5-18, the reference group with a check mark in its **Default** column is a default reference group.

Figure 5-18 Setting Default Ref. Group



5.4.3.7 Automatically match the customized reference group according to age and gender

If **Automatically match the customized reference group according to age and gender** is checked, the customized reference group will be automatically assigned patients by the system according to their age and gender when the patient information is entered. If it fails to find a matching customized reference group for a patient, the patient will be assigned to the built-in reference group.

When the system automatically matches the reference group according to age and gender, the rules listed in Table 5-3 shall be followed.

Table 5-3 Rules for Matching the Reference Group

Automatically match the customized reference group according to age and gender	Customized reference group	Match the reference group
Unchecked	N/A	Built-in reference group
Checked	Does not exist	Built-in reference group
Checked	Created	Preferentially match the customized reference group

NOTE

When the customized ref. groups are used to match the reference group, the matching will be performed from top down according to the customized ref. groups displayed in the screen.

5.4.4 Microscopic Exam. Settings

You can perform the microscopic exam. settings, including adding, editing and deleting as per the actual demand.

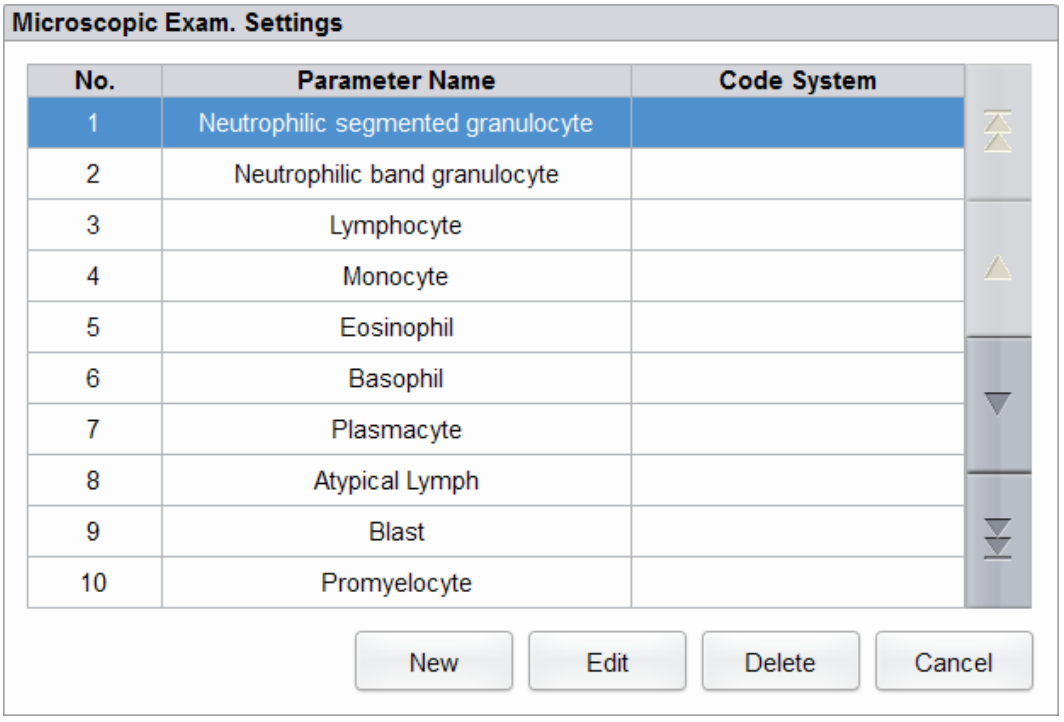
NOTE

The operations of adding, editing and deleting do not affect the sample record in which the microscopic examination results have been entered and saved. Such operations are only valid for the record in which the microscopic examination results have not been saved, and the samples analyzed after the setting operations.

5.4.4.1 Accessing the Interface

Click **Microscopic Exam.** in the **Para.** selection to access the microscopic examination setting interface. See Figure 5-19.

Figure 5-19 Microscopic Exam.Settings



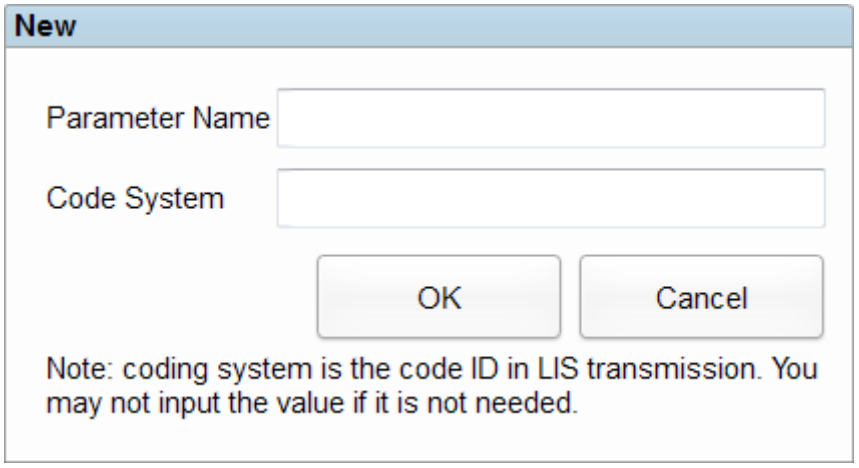
5.4.4.2 Adding a New Microscopic Exam. Parameter

Do as follows to add a new microscopic exam. parameter.

1. Click **New** in the **Microscopic Exam. Settings** interface.

A dialog box will pop up as shown in Figure 5-20.

Figure 5-20 Adding a New Microscopic Exam. Parameter



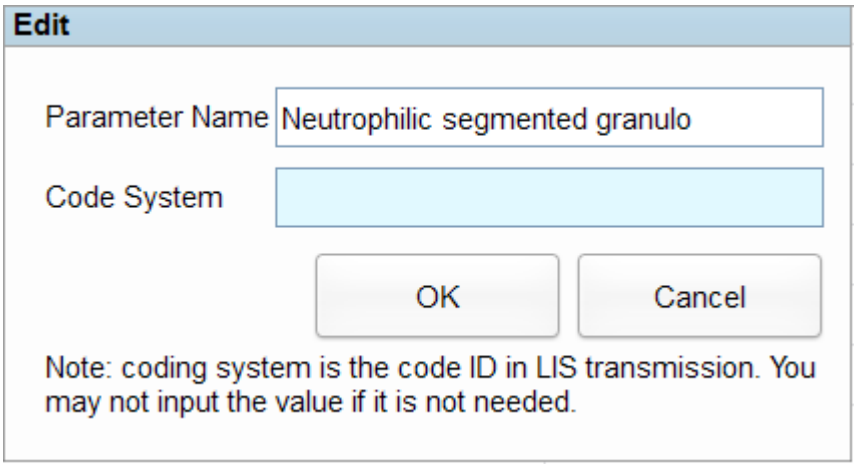
2. Input the parameter name and its coding system in the corresponding textboxes.
   - The **Parameter Name** can not be empty.
   - The **Code System** is the code ID of the parameter. It is for LIS transmission only when the parameter is transmitted to the LIS. You may not input the value if it is not needed.
3. Click **OK**.

   The name of the new parameter will be displayed in the microscopic exam. parameter list.

5.4.4.3 Editing a Microscopic Exam.Parameter

Select a parameter name from the list and click **Edit** to modify it. See Figure 5-21.

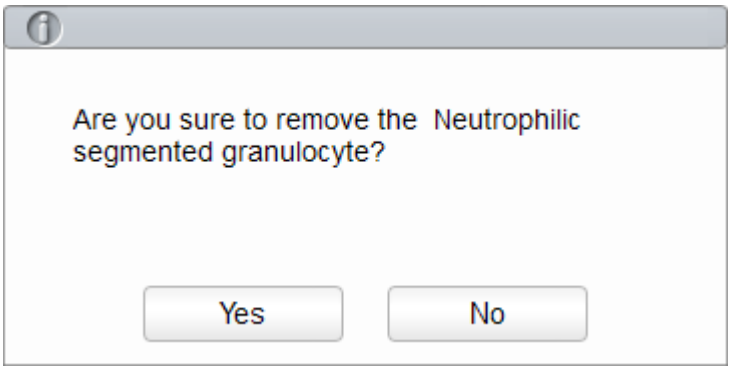
Figure 5-21 Editing a Microscopic Exam. Parameter



5.4.4.4 Deleting a Microscopic Exam.Parameter

Select a parameter name from the list, click the **Delete** button and then click **Yes** in the popup dialog box to delete this parameter.

Figure 5-22 Deleting a Microscopic Exam.Parameter



5.4.5 Customized Parameters

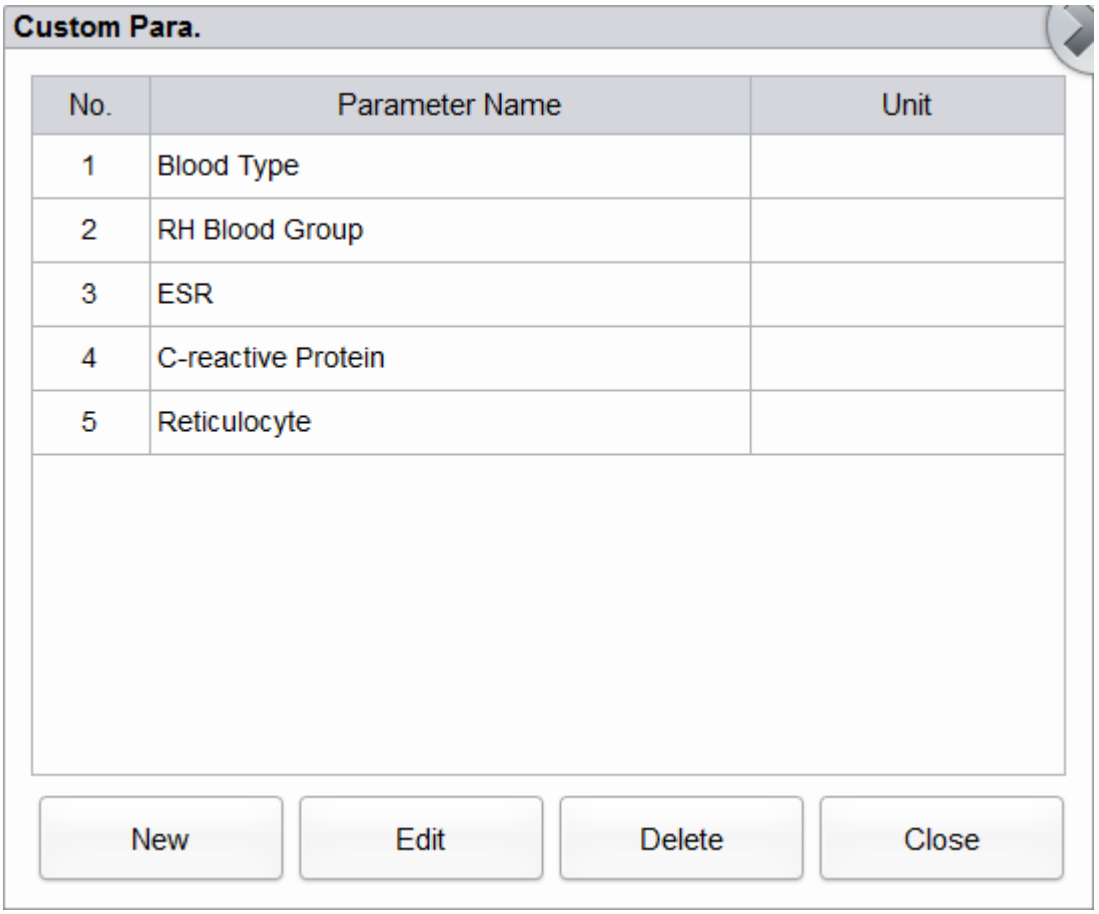
Except for this analyzer's analysis parameters, parameters collected from other testing instruments or via manual testing by the user are customized parameters. You can set customized parameters so they can be printed together with this analyzer's analysis parameter details on the **Hematology Analysis Report**.

This analyzer's default customized parameters include: Blood Type, RH Blood Group, ESR, C-reactive Protein and Reticulocyte. You can set the unit and reference range of default customized parameters as well as add and set customized parameters.

5.4.5.1 Accessing the interface

Click **Custom Para.** in the **Para.** selection to access the customized parameters setting interface. See Figure 5-1.

Figure 5-1 Customized Parameter Settings

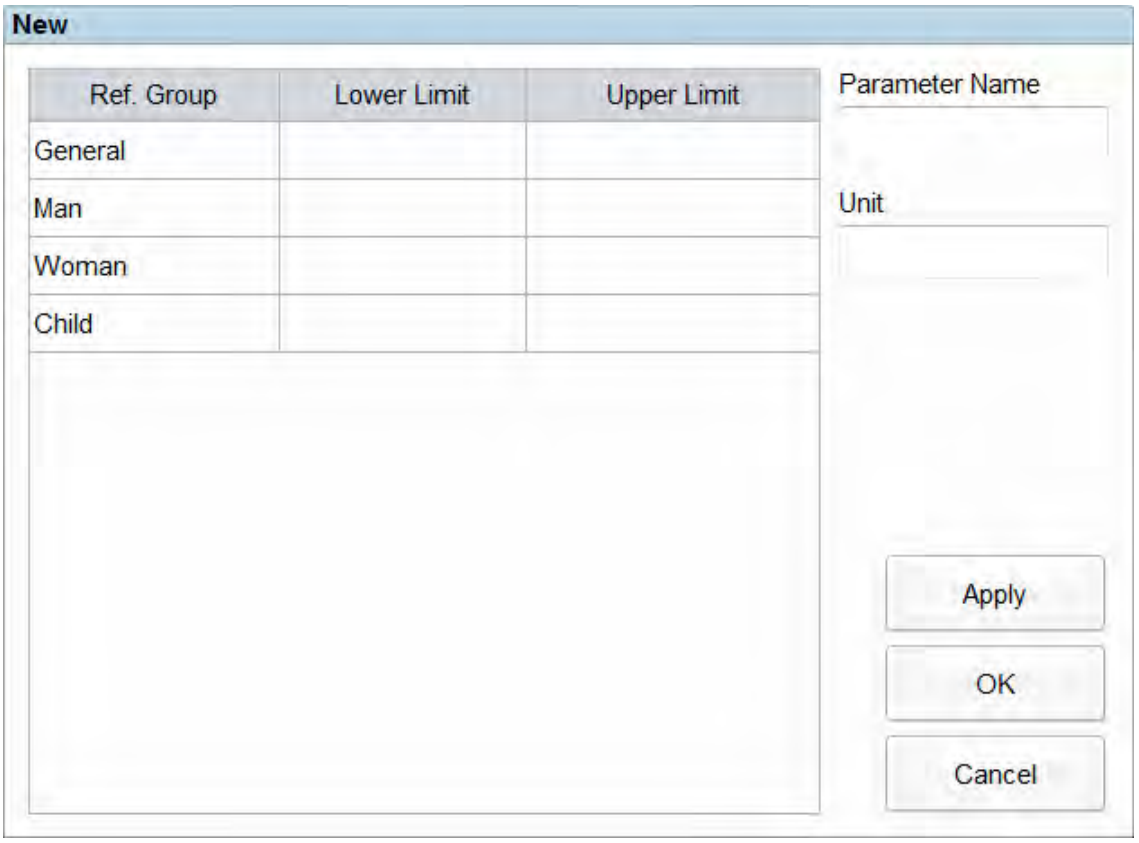


5.4.5.2 Adding a Customized Parameter

1. Click **New**,

   A dialog box will pop up as shown in Figure 5-2.

Figure 5-2 Adding a Customized Parameter



2. Click the textboxes of **Parameter Name** and **Unit** respectively, and enter the name and unit of the customized parameter.
3. Click corresponding cells of the **Upper Limit** and **Lower Limit** of the reference group, and input values.

   You can also customize the reference group according to the actual situation. For details, see ***5.4.3 Ref***. Range***.***
4. Click **OK**.

   The added parameter will be displayed in the customized parameter list.

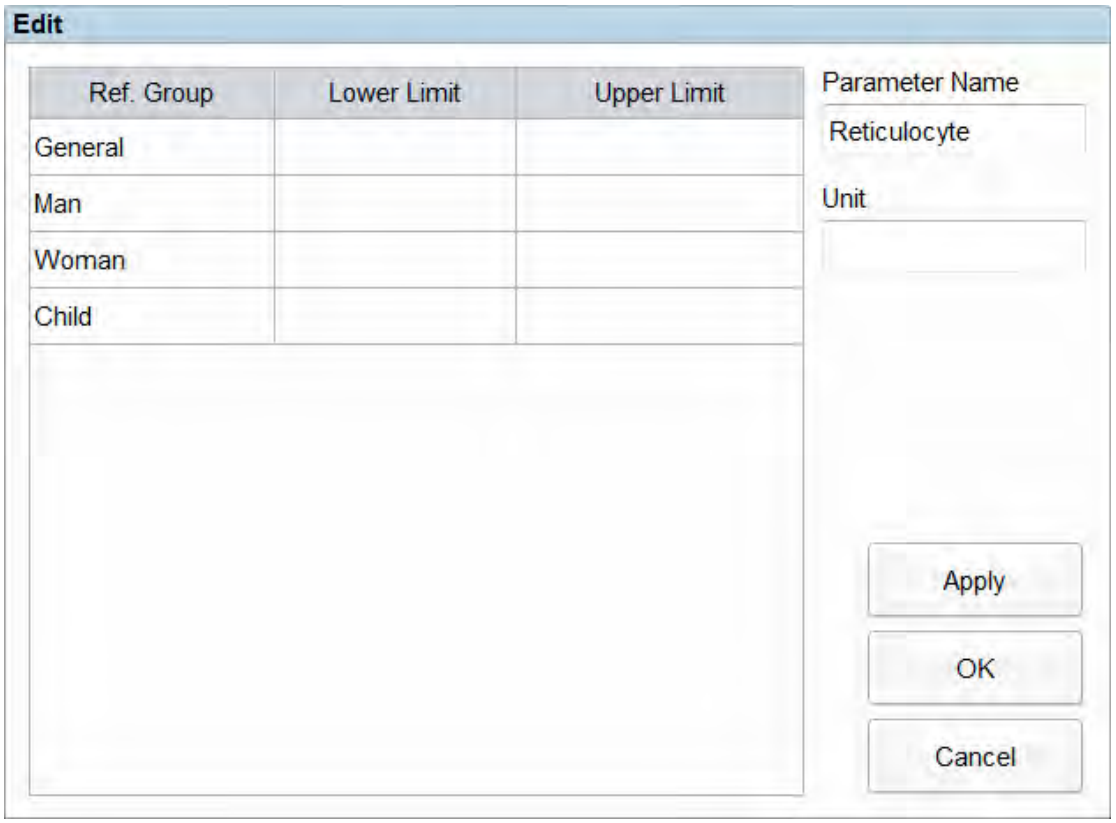
5.4.5.3 Editing a Customized Parameter

You can set the unit and reference range of customized parameters. Detailed steps are as follows:

1. Select the customized parameter to be edited, and click **Edit**.

   A dialog box will pop up as shown in Figure 5-23.

Figure 5-23 Editing a Customized Parameter



2. Click the textboxes of **Parameter Name** and **Unit** respectively, and modify the name and unit of the customized parameter.
3. Click corresponding cells of the **Upper Limit** and **Lower Limit** of the reference group, and input values.

   You can also customize the reference group according to the actual situation. For details, see ***5.4.3 Ref***. Range***.***
4. Click **Apply** or **OK**.

5.4.5.4 Deleting a Customized Parameter

Select a customized parameter, and click on **Delete**. Then, the parameter and its corresponding reference group can be deleted.

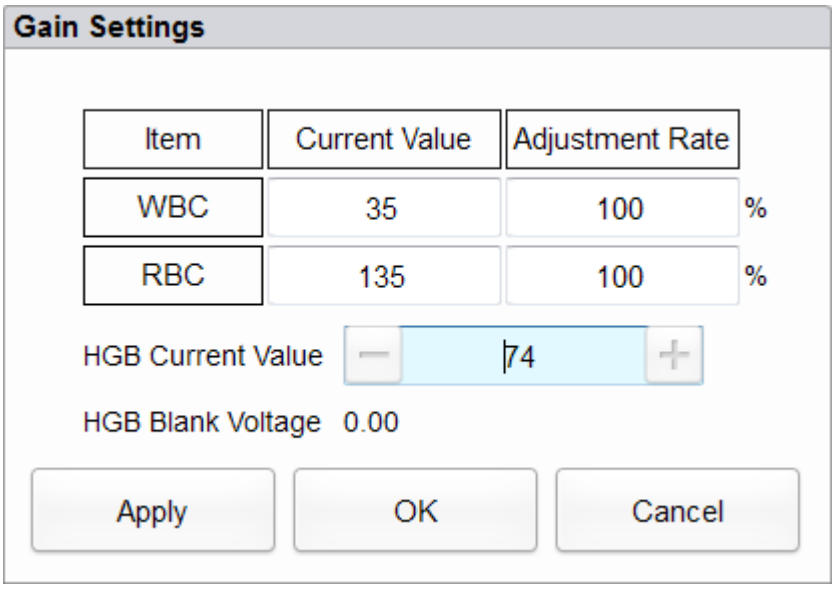
5.5 Meterage Settings

5.5.1 Gain Settings

You can adjust each digital pot at the **Gain Settings** interface. It is not recommended to adjust gains frequently.

Click **Gain Settings** in the **Meterage** selection to access the gain setting interface. See Figure 5-24.

Figure 5-24 Gain Settings



NOTE

New value of the gain adjustment = Current Value × Adjustment Rate.

- Setting the WBC gain

  The WBC gain here is in Whole Blood Mode.

  Setting method I: click the **current value** of the WBC and enter the new value.

  Setting method II: click the **Adjustment Rate** cell of the WBC and enter the adjustment rate of the new value relative to the current value.

- Setting the WBC gain

  RBC channel gain.

  Setting method I: click the **current value** of the RBC and enter the new value.

  Setting method II: click the **Adjustment Rate** cell of the RBC and enter the adjustment rate of the new value relative to the current value.

- Setting the HGB gain

  Current digital circuit gain. The purpose for adjusting the HGB channel gain is to change the HGB background voltage.

  You can enter the value directly in the **HGB Current Value** textbox or click the adjusting button to adjust the HGB gain.

- Setting the HGB Blank Voltage

  The background voltage derived from HGB gain cannot be modified. **HGB Background Voltage** can be adjusted within the specified range (4.2~4.8V) by modifying **HGB Current Value**.

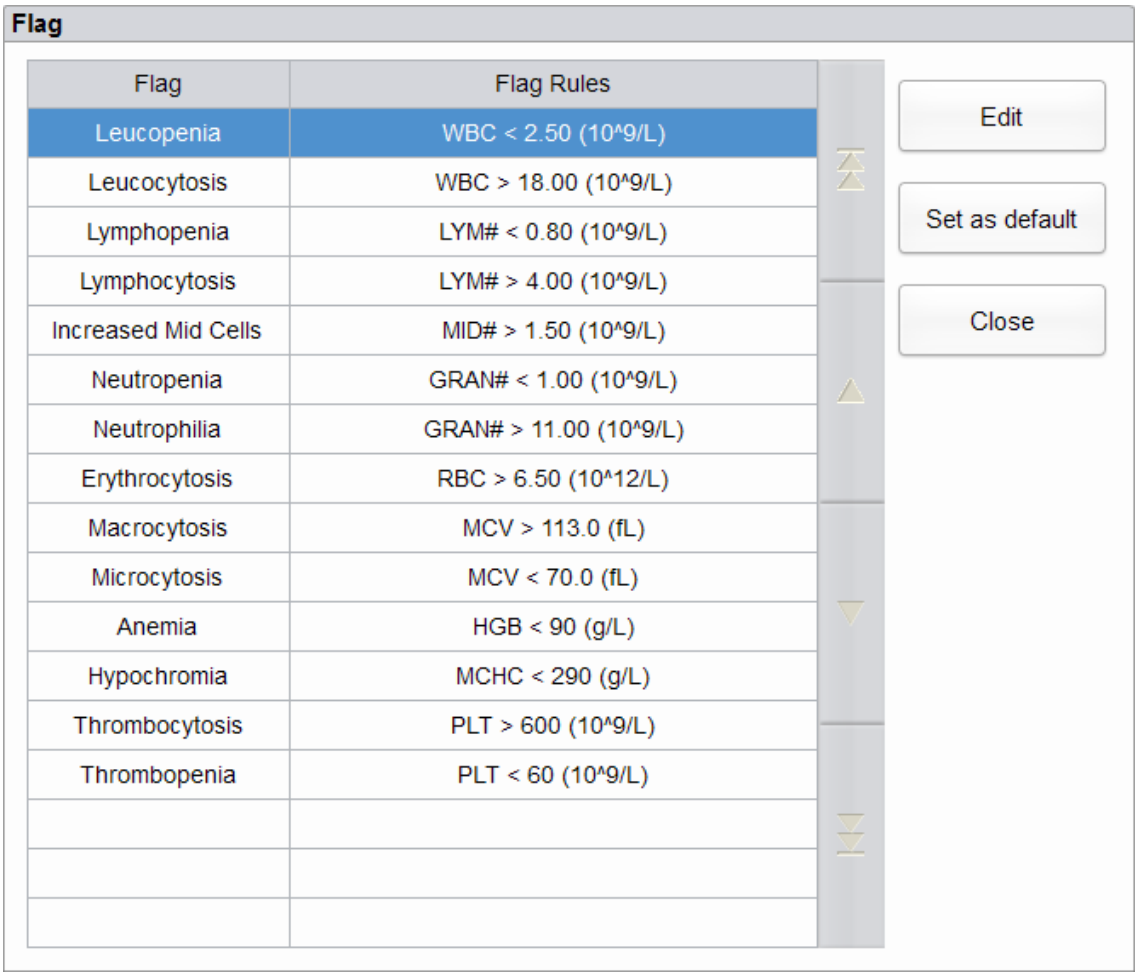
5.5.2 Flag

When the test result meets the requirement of the Flag rules, the corresponding Flag will be displayed on the screen. You can edit the Flag rules as per the actual demand and relevant lab procedures.

Accessing the Interface

Click **Flag** in the **Meterage** selection to access the Flag rules setting interface. See Figure 5-25.

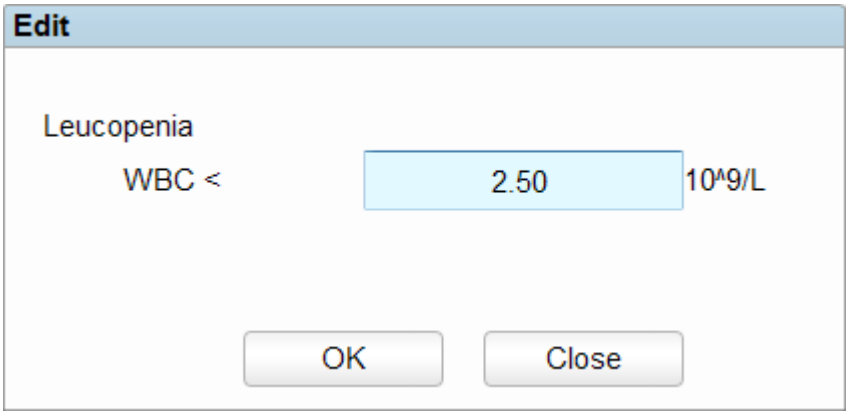
Figure 5-25 Flag



Setting Flag Rules

You can select the name of the **Flag** in the Flag interface, then click **Edit** to modify the rules in the popup dialog box. See Figure 5-26.

Figure 5-26 Setting Flag Rules



Restoring Defaults

Click **Set as default** to restore the parameter to the default value.

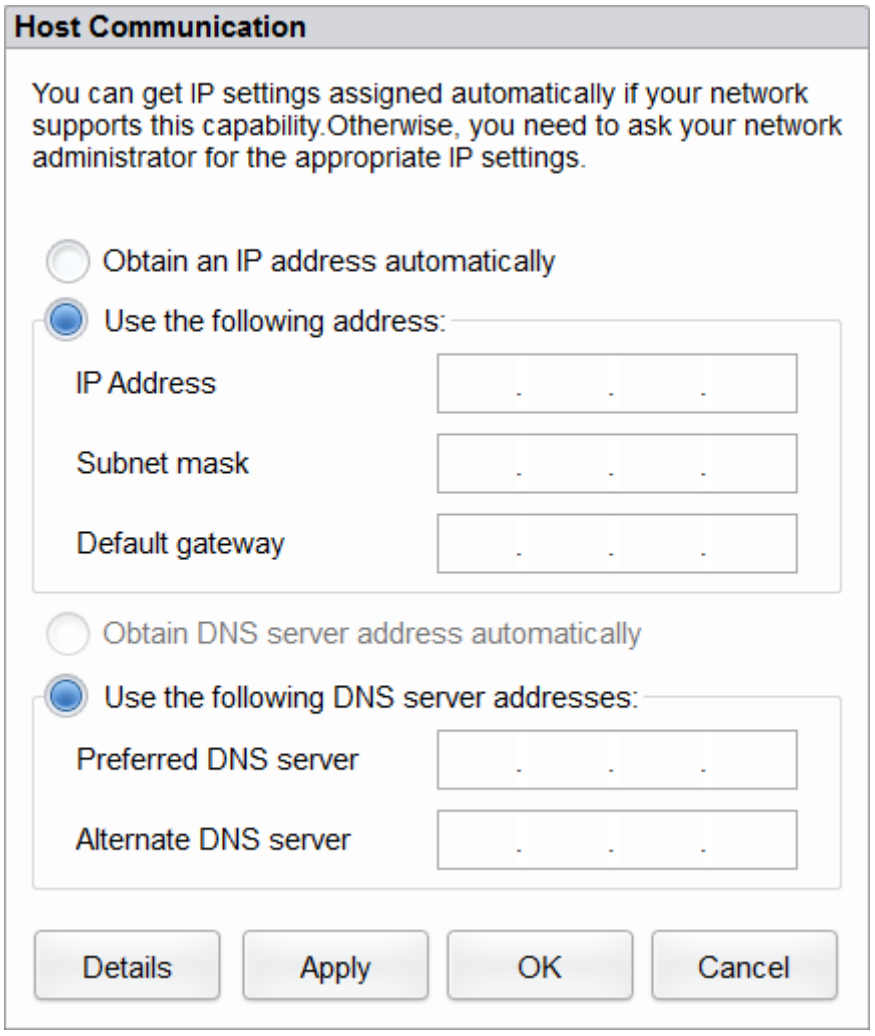
5.6 Communication

5.6.1 Host Network Settings

On the host communication screen, you can set the network information of the analyzer to enable its network connection.

Click **Host Communication** in the **Communicate** selection to access the host network setting interface. See Figure 5-27.

Figure 5-27 Host Network Settings



Refer to Table 5-4 for the description of relevant parameters.

Table 5-4 Description of Host Communication Setting Parameters

Parameter	Meaning	Operation
Obtain an IP address automatically	The host gets the IP address dynamically from a DHCP server or a PPP dial-up network access server. This option is not applicable for the dial-up connection of SLIP server.	Please choose according to the actual situation.

Parameter	Meaning	Operation
Use the following address:	Specify the host to use the manually set IP address. If this option is selected, you need to set: ● IP address The IP address obtained from the network administrator or Internet service provider. ● Subnet mask The subnet mask obtained from the network administrator or Internet service provider. ● Default gateway The IP address of the default gateway; the router's IP address for connecting the independent IP network segment.	Obtain the IP address, subnet mask and default gateway of the host from the network administrator or Internet service provider.
Obtain DNS server address automatically	Automatically obtain the IP address of the Domain Name Server.	Please choose according to the actual situation.
Use the following DNS server addresses:	Specify the IP address of the DNS server of the host. ● Preferred DNS server The IP address of preferred or primary DNS servers. ● Alternate DNS server (Optional) The IP address of alternative or secondary DNS servers of the host. This server will be used if the specified IP address of the **Preferred DNS server** is not available or if the DNS name cannot be resolved as the IP address of the DNS server which the host has inquired.	Obtain the IP address of DNS server from the network administrator or Internet service provider.

NOTE

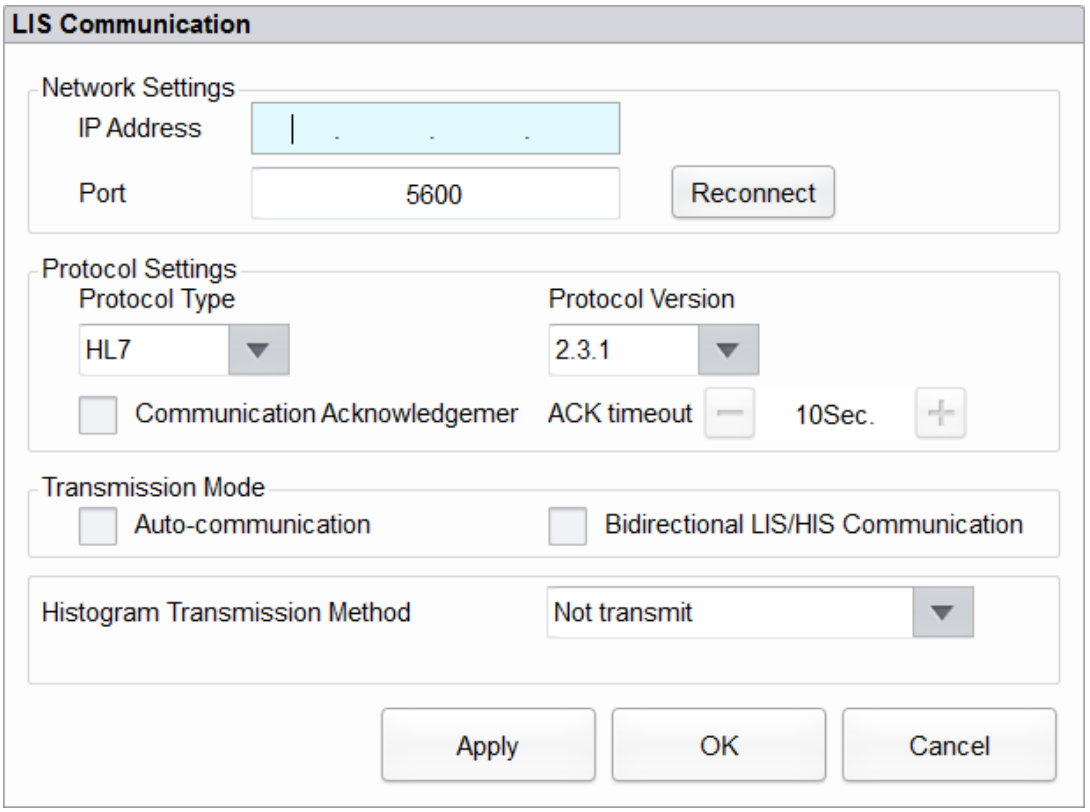
You can click **Details** to check the network information of the analyzer, including physical address, IP address, subnet mask, default gateway, DNS server, etc.

5.6.2 LIS Communication

In the **LIS Communication** interface, You can set the communication between the system and the LIS, including network settings, protocol settings and transmission mode.

Click **LIS Communication** in the **Communication** selection to access the Laboratory Information System (LIS) communication setting interface. See Figure 5-28.

Figure 5-28 Setting LIS Communication



Refer to Table 5-5 for the description of relevant parameters.

Table 5-5 Description of LIS Communication Setting Parameters

Parameter		Meaning	Operation
Network Settings	IP address	The IP Address of the LIS.	Please set it according to the actual situation.
	Port	The port of the LIS. The default value is **5600**.	Please set it according to the actual situation. An integer between 1025 and 65535 can be entered. **NOTE** If the analyzer is disconnected with the LIS , click the **Reconnect** button to connect the LIS again.
Protocol Settings	Protocol Type	Type of the protocol used for the communication between the system and the LIS. The default value is **HL7**.	N/A
	Protocol Version	Version of the protocol used for the communication between the system and the LIS. The default value is **2.3.1**.	N/A

Parameter		Meaning	Operation
	Communication Acknowledgement	If checked, the communication between the system and the LIS is successful when the ACK response from the LIS is received within the duration of **ACK timeout**; no response received indicates communication failure. If unchecked, the communication between the system and the LIS shall be considered successful no matter the ACK response from the LIS is received or not. **NOTE** The system will send the next message continuously no matter the communication is successful or not.	Please choose according to the actual situation.
	ACK timeout	Timeout duration of the ACK response. The default value is 10 seconds, that is, the communication will be considered failed if the system receives no ACK response within 10 seconds.	Click  or  or directly input in the textbox. An integer between 1 and 120 can be entered. Unit: Second (sec.) **NOTE** The parameter is valid only when the **Communication Acknowledgement** is checked.
Transmission Mode	Auto-communication	If checked, the system will automatically upload the result to the LIS upon the completion of the analysis. If unchecked, the result of analysis will not be automatically uploaded. **NOTE** If the **Bidiectional LIS/HIS Communication** is checked, this parameter will be checked automatically.	Please choose according to the actual situation.

Parameter		Meaning	Operation
	Bidiectional LIS/HIS Communication	If checked, the system will automatically obtain the sample/patient information from LIS/HIS after the Sample ID is inputted or scanned, and automatically upload the result to the LIS upon the completion of the analysis. If unchecked, the software system will not execute any operations.	Please choose according to the actual situation.
Histogram Transmission Method		The methods for transmitting the histogram to the LIS when the result is transmitted by the system, including: ● Not transmit Do not transmit the histogram to the LIS. ● Bitmap Transmit the histogram to the LIS in the format of screen display. ● Transmitting bitmap for printing The histogram is transmitted by the system to the LIS in the format of a printed report.	Please choose according to the actual situation.

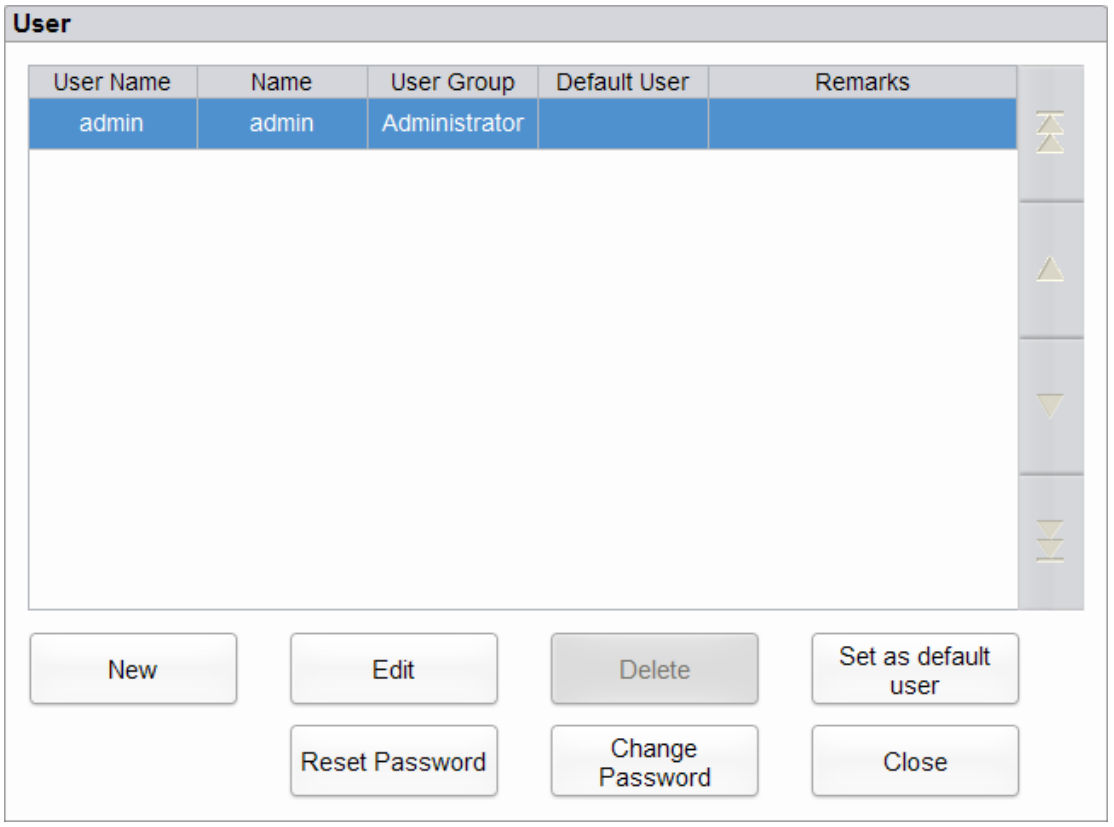
5.7 User Management

After logging in the system, the administrator has the access to set the account information of general users and other administrators; common users can only browse the user list and change their own passwords.

5.7.1 Accessing the Interface

Click **User** in the **Setup** interface to access the user management interface as shown in Figure 5-29.

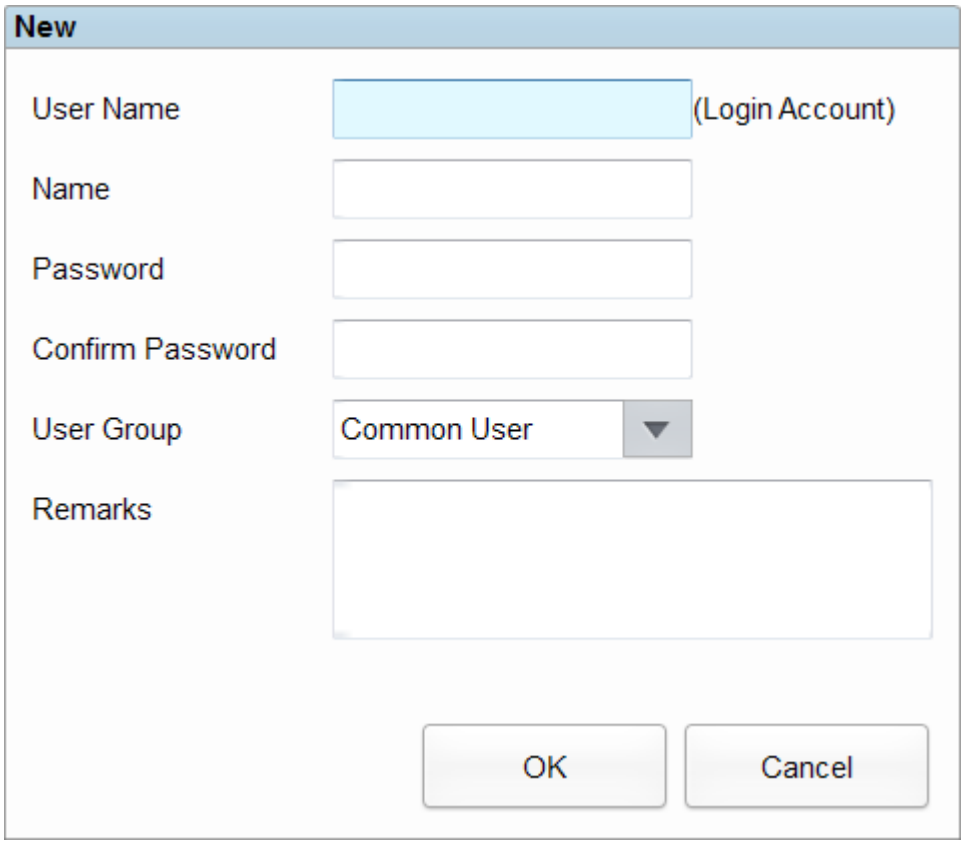
Figure 5-29 User management



5.7.2 Creating a User

Click **New** to set the account information of a new user in the popup interface, including username, first and last name, password, user group and remarks, etc. See Figure 5-30.

Figure 5-30 Creating a user



NOTE

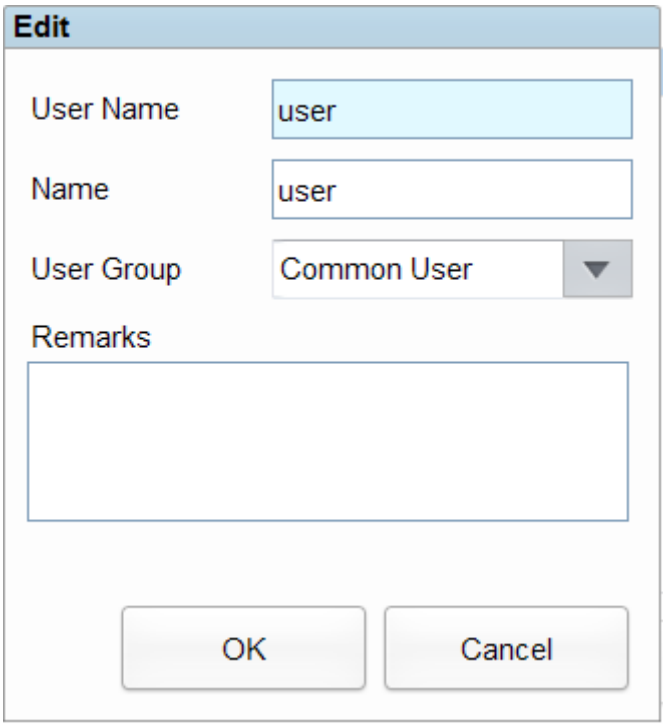
User Group includes **Common User** and **Administrator**. Users are assigned different access levels according to the user group they belong to.

Click **OK** after the setting is complete. The information of the new user will be shown in the user list.

5.7.3 Editing a User

Select the user to be edited and click **Edit** to modify the name and user group.

Figure 5-31 Editing a User



5.7.4 Deleting a User

Select the user to be deleted and click **Delete**, and then select **OK** in the pop-up dialog box to delete the user.

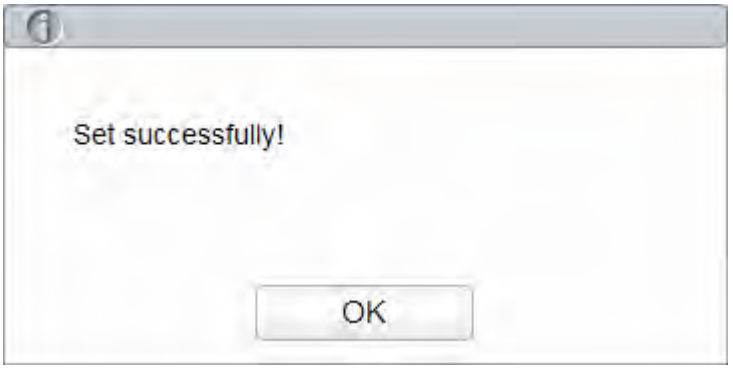
NOTE

The administrator cannot delete his/her own information.

5.7.5 Setting the Default User

Select a user and click **Set as default user** to set this user as the default user.

After the cleaning is completed, the following message box will pop up.



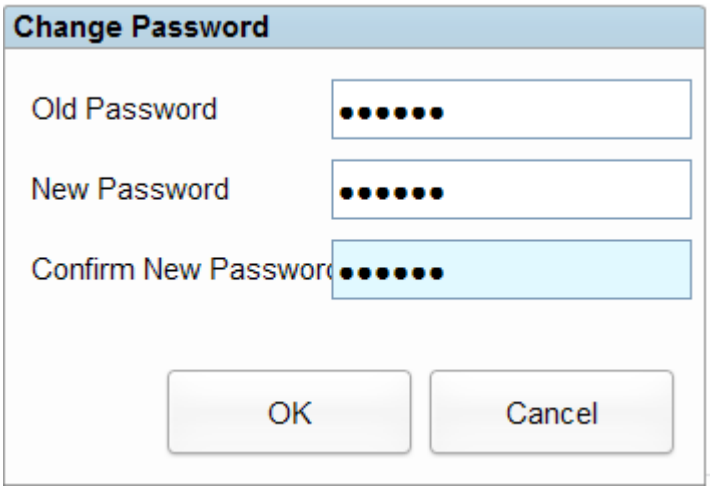
After it is set successfully, the default user name will be displayed in the login box next time and you only needs to enter the corresponding password. See Figure 5-32.

Figure 5-32 Login after Setting the Default User

5.7.6 Changing Password

Click **Change Password**, enter the old password and new password of the user and confirm the new password in the popup dialog box, then click **OK**.

Figure 5-33 Changing Password



NOTE

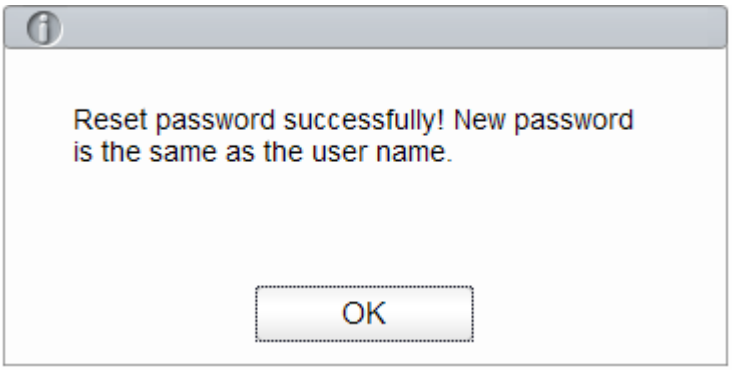
You can only change his/her own password and cannot change the password of other users.

5.7.7 Resetting Password

If the user forgets the password or the password is required to be reset due to other reasons, please click **Reset Password** to reset the password of the selected user to the initial password. The reset password is the same as the user name.

Figure 5-34 shows that the password is successfully reset.

Figure 5-34 Resetting Password



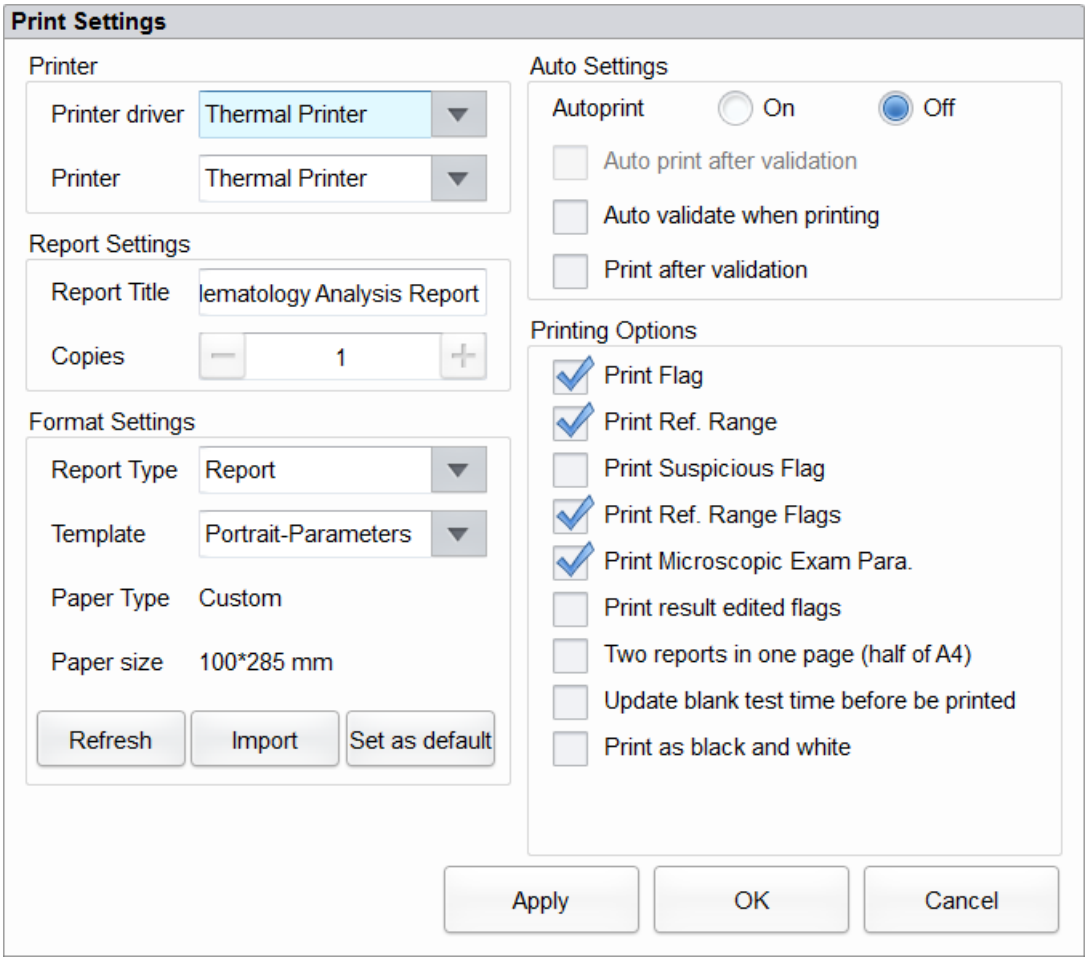
NOTE

The administrator is allowed to reset the password of all administrators and general users; general users do not have the access to reset the password.

5.8 Print Settings

Click **Print Settings** in the **Setup** interface for relevant print settings, including the default printer, template, report, copies and margins, etc.

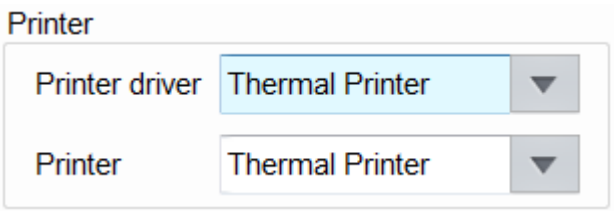
Figure 5-35 Print Settings



Printer Settings

You can set the printer and driver of the system in the **Printer** combo box. See Figure 5-36.

Figure 5-36 Printer Settings



- Printer Driver

  The analyzer uses the built-in thermal printer by default. If the **Check automatically** is selected, you can select a different printer in the **Printer** list.

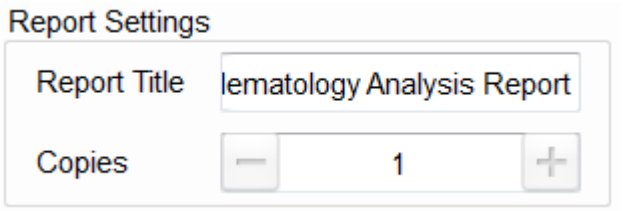
- Printer

  The analyzer uses the built-in thermal printer by default. Select a printer to be used from the dropdown list as required. If the dropdown list is blank, it indicates that no printer has been installed for the operating system. In this case, install a printer, and then perform the relevant settings and printing operations.

Report Settings

You can set relevant parameters of the report in the **Report Settings** combo box. See Figure 5-37.

Figure 5-37 Report Print Setting



- Report Title

  Enter the title of the report in the **Report Title** textbox. The default setting is **Hematology Analysis Report**.

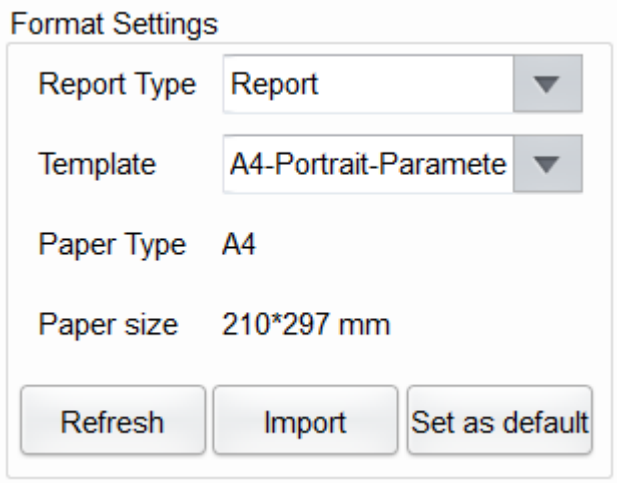
- Copies

  You can enter the number of copies to be printed for a report in the **Copies** textbox according to the actual demand. Click  to increase the number of copies and click  to decrease the number of copies or enter the number of copies in the edit box directly. Range of the copies is between 1 and 100 and the default value is **1**.

Format Settings

Report type and template of prints can be set in the Format Settings combo box. See Figure 5-38.

Figure 5-38 Format Settings



- Selecting Report Type

Select the format type to be set from the dropdown list of the **Report Type**. The default setting is **Report**.

- Selecting Template

  Select the template to be set from the dropdown list of the **Template**. The default value is **A4-Portrait-Parameters-Microscopic Exam.**.

  After the selection is completed, paper type and size of the template will be shown at the bottom of the list.

- Refresh

  Click **Refresh** to refresh the format list after the customization by the administrator.

- Importing template

  Click **Import** to import the report template from the USB flash disk.

- Setting the Default Template

  Select the report template according to the actual demand and click **Set as Default** to set the current template as the default template.

Auto Settings

- Autoprint

  The default setting is **Off**, which means the report should be printed manually after the results are obtained.

  If it is set to **On**, the system will automatically print the report of the sample as per the current report template once the counting results are obtained.

NOTE

- If **Print after validation** is checked, the autoprint function becomes invalid.
- Auto print is not applicable for the background results.

- Auto print after validation

  It's unchecked by default, which means the system can print the report automatically without validation.

  If it's checked, the report will be printed automatically after it's been validated instead of being printed right after the results are obtained each time.

NOTE

The parameter is valid only when the **Autoprint** is set to **On**.

- Auto validate when printing

  It's unchecked by default, which means the report will not be automatically validated by the system at the time of printing.

  If it's checked, the report will be automatically validated and printed by the system at the time of printing.

- Print after validation

  It's unchecked by default, which means the report can be printed without validation.

  If it's checked, the report can be printed only after validation and autoprint is unexecutable.

Printing Options

- Print Flag

  It's checked by default, which means the flag information will be printed in the report. If it's not checked, it will not be printed.

- Print Ref. Range

  It's checked by default, which means the reference range of the parameter will be shown in the printed report; If it's unchecked, the results alone, rather than reference range, will be shown in the printed report and the reference range will not.

- Print Suspicious Flag

  It's unchecked by default, which means the suspicious flag "?" will not be shown in the printed report; if it's checked, such flag can be shown.

- Print Ref. Range Flags

  It's checked by default, which means the printed report can show the ref. range flag (such as ↑ or ↓); if it's unchecked, such a flag will not be shown.

- Print Microscopic Exam. Para.

  It's checked by default, which means the result of Microscopic Exam. Parameters will be printed in the report. If it's not checked, it will not be printed.

- Print result edited flags

  It's unchecked by default, which means the mark for the edited results will not be shown in the printed report.

  If checked, the mark (**M** or **m**) for the edited results will be shown in the printed report if the parameters have been modified.

- Two reports in one page (half of A4)

  It's unchecked by default. If this is checked, the default template size in **Format Settings** is half an A4 page (e.g., **A4_Half-Portrait-Parameters**), so two reports can be printed in one piece of A4 paper.

NOTE

When **Autoprint** is **On**, a page remains to be printed with one report.

- Update blank test time before be printed

  It's unchecked by default, which means the blank test time will not be processed by the system.

  If it's checked, the **Delivery Time** will be automatically updated as the **Run Time** by the system at the time of printing.

- Print as black and white

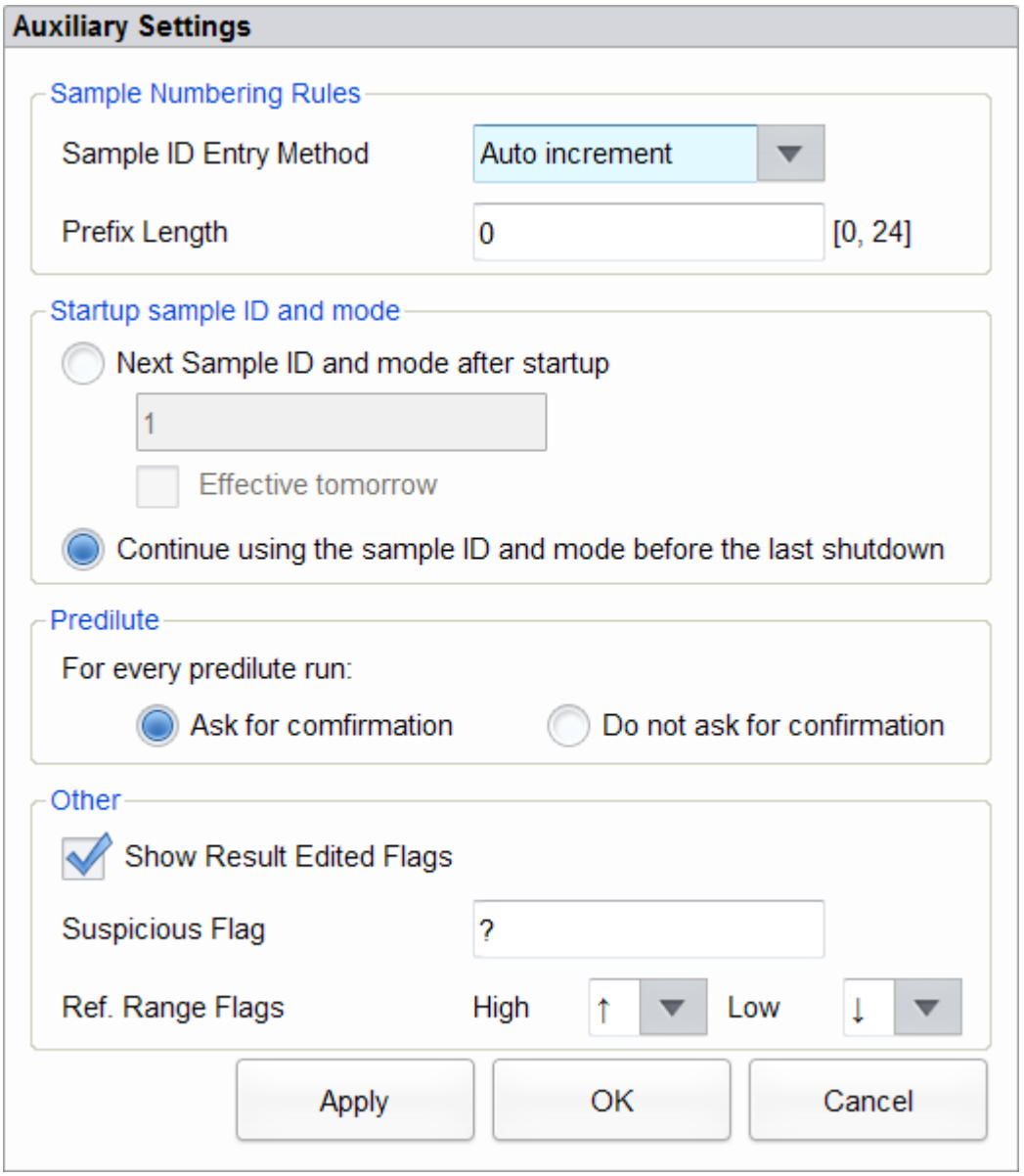
  It's unchecked by default, whick means the report will be printed according to the default settings of the printer.

  If it's checked, the resport will be printed as black and white.

5.9 Auxiliary Settings

Click **Auxiliary Settings** in the **Setup** interface to access the **Auxiliary Settings** interface. See Figure 5-39.

Figure 5-39 Auxiliary Settings



The administrator is allowed to set the following functions in the Auxiliary Settings interface:

- Sample numbering rules
- Startup sample IP and mode
- Predilute
- Other

Sample Numbering Rules

Set the sample ID entry rules.

- Sample ID Entry Method

  Click the dropdown list of the **Sample ID Entry Method** and select the entry method of the sample ID from the following options.

  - Auto increment (default setting)
  - Manual entry

- Prefix Length

  When **Auto Increment** is selected as the **Sample ID entry method**, you can add a prefix to a certain batch of samples for identification.

  Enter the prefix length ranging from 0 to 24 (e.g. 2) of the sample ID in the **Prefix Length** textbox. The prefix length will applied to all sample IDs after the setting is saved.

Startup sample IP and mode

Set the sample ID and measurement mode for the next sample after startup.

- Next Sample ID and mode after startup

  The sample ID set by the user will be used after the next startup when the specified sample ID is entered into the textbox.

NOTE

If the **Effective tomorrow** is checked, the modification of the next sample ID and mode after startup will become effective on the next day.

- Continue using the sample ID and mode before the last shutdown

  If checked, the system will by default add 1 to the last sample ID analyzed before shutdown as the next sample ID after startup.

Predilute

Set if you wish to see a popup dialog box when you perform the Predilute counting.

- Ask for confirmation (default setting): in the **Predilute** mode, when you press the aspirate key to start the analysis, a dialog box will pop up to remind you that the ongoing analysis is for Predilute counting.
- Do not ask for confirmation: the dialog box for confirming the Predilute counting will not pop up.

Other

- Show Result Edited Flags

  It's unchecked by default, which means the edited results are marked with an **M** at the end, while the corresponding results with manual modifications are marked with an **m** at the end. **M** or **m** is displayed between the result data and the parameter unit by default.

  If unchecked, the edited result will not be marked with an **M** or **m**.

- Suspicious Flag

  A single character (an English letter only) can be re-entered in the textbox as a suspicious flag. The default value is **?.**

- Ref. Range Flags

  You can select the Ref. Range Flags from the dropdown list. The default high flag is ↑(or **H**) and the default low flag is ↓(or **L**).

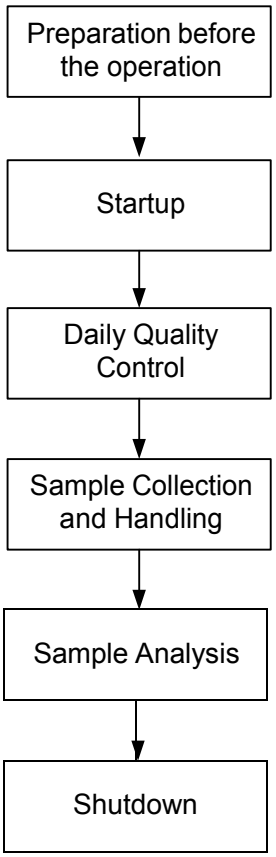
6 Daily Operations

6.1 Introduction

This chapter introduces the daily operations from the startup to the shutdown of the analyzer.

A flow chart indicating the common daily operation process is presented below.

Figure 6-1 Daily Operations Procedure



6.2 Pre-operation 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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

WARNING

- Be sure to dispose of reagents, waste, samples, consumables, etc. 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, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see a doctor.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

NOTE

- You should only use the MR-specified reagents. Store and use thereagents as specified in instructions for use of the reagents.
- Check if the reagents are connected correctly before using the analyzer.
- 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 vacutainer blood collection tubes with anticoagulant, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Be sure to use the MR- specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.

Perform the following checks before turning on the analyzer.

- Waste container

  Check and make sure the waste container is empty.

- Fluidic tubing and power connections

  - Check and make sure the reagents and waste tubing are properly connected and not bent.
  - Check and make sure the power cord of the analyzer is properly plugged into the power outlet.

- Printer (Optional)

  Check and make sure enough paper is installed.

- Network Cable (Optional)

  Check and make sure the network cable is properly connected to the analyzer.

6.3 Startup

This section introduces the operations related to the startup of the analyzer.

NOTE

- If you failed to start the analyzer continuously, please contact MR customer service department or your local agent immediately.
- After startup, please make sure the data/time displayed on the screen is correct.

1. Place the power switch at the back of the analyzer in the [**I**] position.

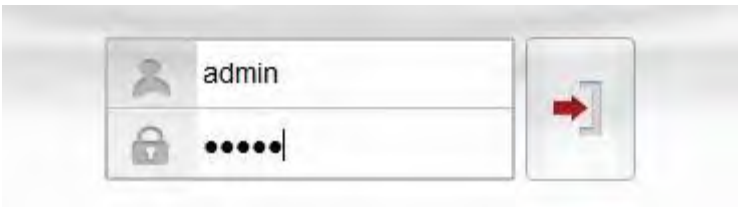
   The power indicator light will be on.

2. Check the indicator light on the analyzer.

   If the indicator light is on, it indicates the analyzer has been started up. The analyzer will perform self-test and initialization in sequence. The whole process will last for 4 to 10 minutes. (Time needed for initializing the fluidic systems depends on how the analyzer was previously shut down.)

3. Enter the correct user name and password in the **Login** message box. See Figure 6-2.

Figure 6-2 Login



   The initial user name and password of administrator are **admin**, which was set by service engineer.

   1 to 12 digits of numeric characters can be entered for the user name and the password. No Chinese character is allowed.

4. Click  to enter the user interface.

   The system will display the **Sample Analysis** screen by default and display the test result of the background when the analyzer is started.

NOTE

- The **Sample Analysis** interface will be displayed by default. And the background checked will be displayed on the screen. The background test is designed for detecting particle interference and electrical interference.
- For the background Ref. Range of each parameter, please see ***A.4.2 Normal Background***.
- The sample ID for the background test is **background**.
- If the background results exceed the Ref. Range for the first time during fluidics initialization, then the analyzer will run the background test one more time.
- Running a test when there is a **Background abnormal**, you would obtain an unreliable testing result.
- If any error is detected during initialization (e.g. the background results exceed the Ref. Range), the analyzer will activate the alarm. For details, see ***13 Troubleshooting***.
- To lock or switch a user, click  on the menu screen and click **Yes** on the pop-up dialog box.

  The system will return to the login dialog box. Enter the user name and password, click  , then you can log in again or log in the software interface with another user identity.

6.4 Daily Quality Control

To ensure reliable analysis results, conduct daily QC analysis on the analyzer before running samples. For details, see ***9 Quality Control***.

6.5 Sample Collection and Handling

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

WARNING

Do not touch the patients' blood sample directly.

CAUTION

- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
- Prepare the samples as per the procedures recommended by the reagent manufacturer.

NOTE

- Be sure to use clean K_2EDTA vacutainer blood collection tubes with anticoagulant, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Be sure to use the MR-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- For the whole blood samples to be used for WBC classification or PLT count, store them at room temperature and run them within 8 hours after collection.
- If you do not need the PLT, MCV and WBC differential results, you can store the samples in a refrigerator (2°C - 8°C) for 24 hours. You need to warm the keep samples at room temperature for at least 30 minutes before running them.
- Be sure to shake any sample that has been prepared for a while before running it.

6.5.1 Running the Venous Whole Blood Samples

The procedure for preparing capillary whole blood sample is as follows:

1. Use clean K_2EDTA (1.5~2.2mg/mL) vacutainer blood collection tubes with anticoagulant to collect venous blood samples.
2. Mix the venous blood with the anticoagulant well in the tube immediately.

CAUTION

For vacutainer blood collection tube (Φ12X75, cap excluded), please make sure the volume of the whole blood sample is not less than 0.5mL.

6.5.2 Capillary Whole Blood Samples

Collect the capillary whole blood sample with a vacuum blood collection tube specified by the manufacturer.

CAUTION

To ensure the accuracy of the analysis, make sure the volume of the capillary whole blood sample is not less than 100μL.

NOTE

Run the capillary whole blood sample within 3 minutes to 2 hours after its collection.

6.5.3 Prediluted Samples

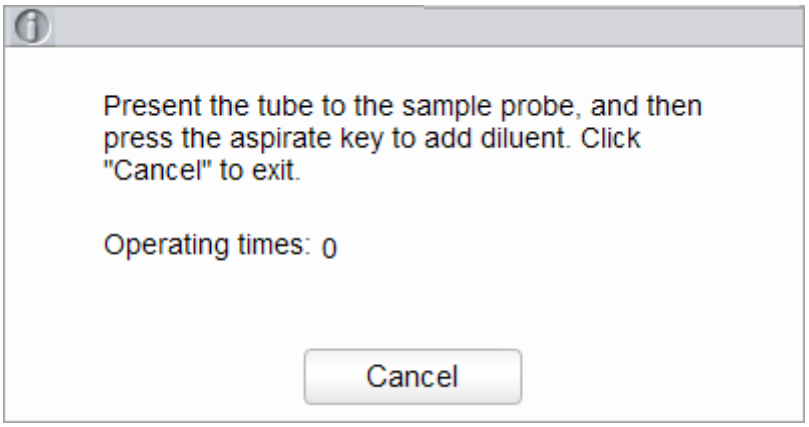
The procedure for preparing prediluted sample is as follows:

1. Click the  on the top left corner and enter the menu screen as shown in Figure 6-3

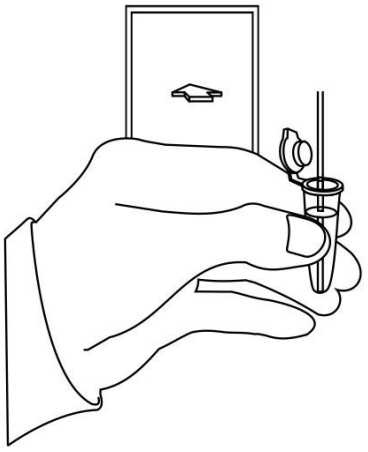
Figure 6-3 Menu Screen

2. Click the **Add Diluent** icon.

   A prompt box will pop up on the screen as shown below.



3. Take a clean centrifugal tube, uncap it and present it to the sample probe in a manner as shown in the following picture in which the probe tip is vertically in contact with the bottom of the tube so as to avoid bubbles, liquid attached to the inner wall or spatter.



4. Press the aspirate key and add the diluent (180μL at a time).

   After the diluent is added and you hear a beep, you can remove the centrifugal tube.
5. If more portions of diluent are needed, repeat steps 3~4.
6. Add 20μL of blood to the diluent, close the tube cap and shake the tube to mix the sample.
7. After the prediluted sample is prepared, click **Cancel** to exit dispensing the diluent.

NOTE

- You can also dispense 180μL of diluent by pipette into the tube.
- Be sure to keep dust from the prepared diluent.
- Be sure to run the prediluted samples within 30 minutes after the mixing.
- Be sure to mix any sample that has been prepared for a while before running it.
- Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

6.6 Sample Analysis

After the sample is prepared, you can perform the operations for sample analysis.

For details, see ***6.6 Sample Analysis***.

6.7 Shutdown

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

WARNING

The sample probe is sharp and potentially biohazardous. Do not turn on the analyzer immediately after its shutdown.

CAUTION

Wait at least 10 seconds before power-on to avoid damage to the machine.

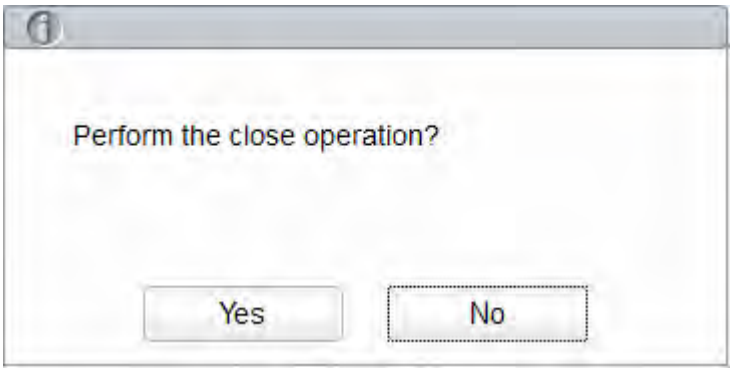
NOTE

- To ensure stable analyzer performance and accurate analysis results, be sure to perform the Shutdown procedure to shut down the analyzer after it has been running continuously for 24 hours.
- When the analyzer is running or performing other fluidics sequence, do not force shutdown the analyzer.
- If any error is detected during shutdown procedure, the analyzer will return to the status before the shutdown procedure is performed, and then activate the alarm. See ***13 Troubleshooting*** for details of removing the error.
- Be sure to shut down the analyzer in strict accordance with the instruction below.

Procedures for shutting down the analyzer are as follows:

1. Click the  button on the menu screen.

   A dialog box will pop up as shown below.

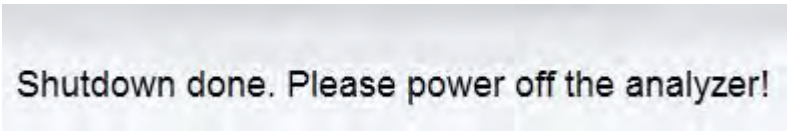


2. Click **Yes**.

   The system starts to execute the shutdown sequence and a message box pops up showing the procedures for cleanser maintenance.

3. Follow the instructions and set the cleanser under the sample probe, and press the aspirate key on the analyzer or click **Aspirate** to run the cleanser aspiration.

   Upon the completion of cleanser maintenance, a message displayed on the screen indicates the cleanser maintenance is completed.



4. Place the [O/I] switch at the back of the main unit in the [**O**] position.
5. After shutdown, empty the waste in the waste container, and dispose of it.

WARNING

Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

7 Sample Analysis

7.1 Introduction

Sample analysis is the most important function of the auto hematology analyzer. You can get the blood cell count, HGB concentration and the 3-part classification counting results of the white blood cells by performing the sample analysis.

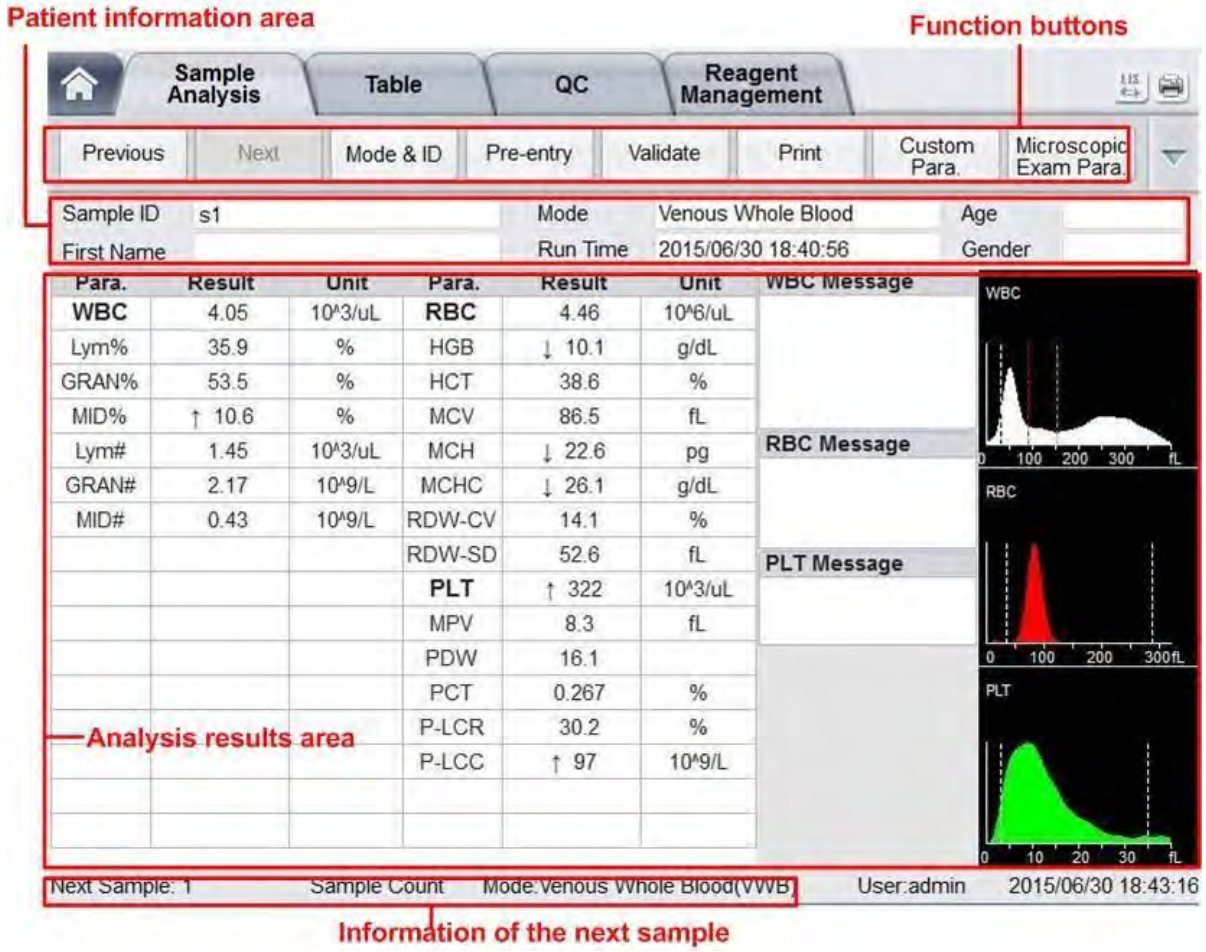
The summary of sample analysis procedures is as follows:

1. Entering the sample information.
2. Running the samples.
3. Processing the analysis results.

7.2 Interface Introduction

The **Sample Analysis** interface is the main interface of the analyzer (Figure 7-1). You can complete the operations such as entering the sample information, performing sample analysis, reviewing/printing analysis results in the **Sample Analysis** interface.

Figure 7-1 Sample analysis interface



Related descriptions:

- Function buttons

  You can perform operations such as setting the mode for the samples, pre-entering information, reviewing previous/next records and printing. Click and view all function buttons. See section ***7.6 Functions of the Buttons***.

- Patient information area

  It displays the patient information corresponding to the current sample.

- Analysis results area

  It displays the analysis results of the sample, including the parameter results, Flags and histograms. They system displays the analysis results of the most recent run by default.

  - Parameter Results

    This list displays the analysis results of all the parameters of the samples.

    You can compare the values in the Result column with the corresponding Ref. Range. If the values are within the reference range, it means that they are normal. If not, it indicates that the sample may be abnormal and the corresponding symbols will be displayed in the Flag column.

  - WBC Message

    Displays the alert message regarding the WBC.

  - RBC Message

Displays the alert message regarding the RBC.

- PLT Message

  Displays the alert message regarding the platelet.

- WBC

  RBC distribution histogram

- RBC

  RBC distribution histogram

- PLT

  Platelet distribution histogram.

- Information of the next sample

  It displays the sample ID and analysis mode of the next sample.

7.3 Entering Sample Information

You can enter the worklist information of the samples to be tested before the analysis.

NOTE

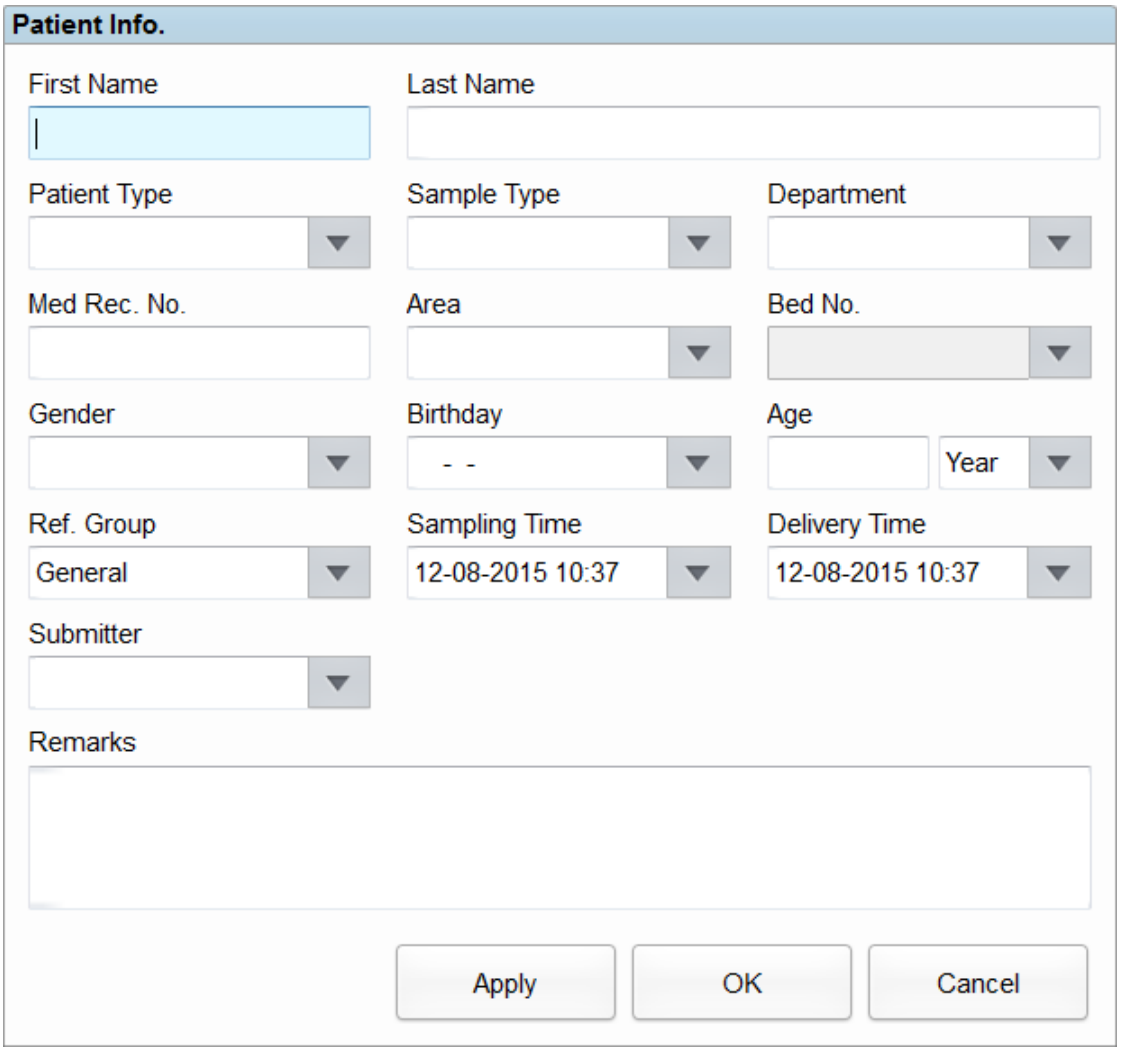
You can also enter sample/patient information after the sample analysis is completed. For details, please refer to ***8 Result Review***.

Specific steps are shown below:

1. Click the **Pre-entry** button in the function button area.

   The interface as shown in Figure 7-2 will pop up on the screen.

Figure 7-2 Pre-entering Patient Information



2. Enter patient information with reference to the parameter description in Table 7-1.

Table 7-1 Parameter Description

Parameter	Meaning	Operation
First Name	First name of patient.	Enter in the textbox directly.
Last Name	Last name of patient.	Enter in the textbox directly.
Patient Type	Type of patient. Values: • Inpatient • Physical Examination • STAT • Outpatient	Select from the dropdown list.

Parameter	Meaning	Operation
Sample Type	Type of sample for microscopic examination. Values: • Venous blood • Capillary • Cord blood • Blood	Click the **Sample Type** dropdown list box and select the type of sample for microscopic examination.
Med Rec. No.	Med Rec. No. of patient.	Enter in the textbox directly.
Gender	Gender of patient. Values: • Male • Female • Not defined	Select from the dropdown list.
Birthday	Birthday of a patient.	Select from the date control. • The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sepuence of year, month, and date. • Click  or  select the date or click the textbox to input them directly. • Click  to clear the data and input again.
Age	Age of a patient.	Select the unit of age from the dropdown list (**Year**, **Month**, **Day** or **Hour**) and enter the age of the patient in the textbox before the age unit. **NOTE** If the **Birthday** is set, the age will be displayed automatically.
Ref. Group	Reference group of the sample under analysis. The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.	Select from the dropdown list. **NOTE** • If the **Automatically match the customized reference group according to age and gender** is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). • Refer to ***5.4.3 Ref. Range*** for the setting of the reference group and range.
Department	Department receiving the patient.	Select from the dropdown list.
Area	Ward area of patient.	Select from the dropdown list or input directly.

Parameter	Meaning	Operation
Bed No.	Bed No. of inpatient.	Select from the dropdown list or input directly. **NOTE** The bed No. is required to be filled only for **inpatients**.
Sampling Time	Date and time when the sample is collected.	Click the date control for the settings. ● The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sepuence of year, month, date, hour, and minute. ● Click  or  to select the date or click the textbox to enter them directly. ● Click  to delete the current data and re-enter information. **NOTE** ● The system automatically displays the current time as sampling time. ● The sampling time can be no later than the current system time.
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.
Delivery Time	Date and time when the sample is delivered.	Click the date control for the settings. ● The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sepuence of year, month, date, hour, and minute. ● Click  or  to select the date or click the textbox to enter them directly. ● Click  to delete the current data and re-enter information. **NOTE** ● The system automatically displays the current time as sample delivery time. ● The delivery time can be no later than the current system time.
Remarks	Clarifications or notes.	Input in the textbox directly.

3. Click **Apply** or **OK** to save the configuration.

7.4 Running Samples

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

WARNING

The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

CAUTION

- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
- Make sure that the entered sample ID and mode exactly match those of the samples to be run.

NOTE

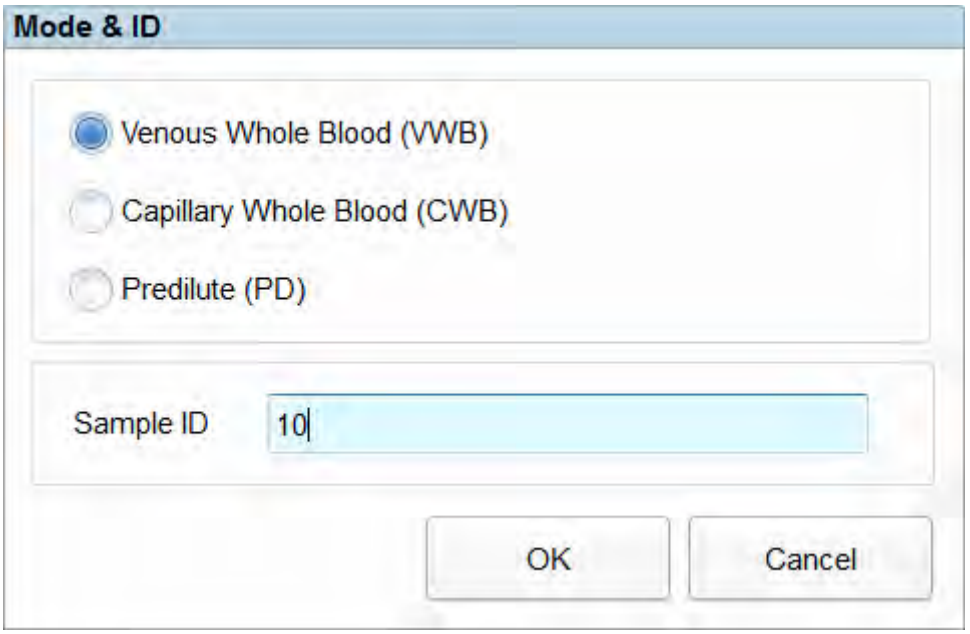
- During aspiration, the tip of the probe should be kept at a certain distance from the bottom of the sample container, otherwise the accuracy of aspiration volume will be affected.
- Keep the tip of the probe from contacting with the wall of the test tube to avoid blood splashing.
- Proper reference range shall be selected on the **Setup** interface before analysis. Otherwise, the results may be flagged erroneously.
- The default system setting for **Mode & ID** is **Venous Whole Blood (VWB).**
- When the analyzer is running the samples, you can switch to **Review** interface to perform operations including browsing and exporting, etc., and you can also switch to other interfaces.
- When the analyzer is running the samples, all the functions related to the fluidics sequence are not available.

Take the following steps to perform sample analysis.

1. Prepare samples as instructed by ***6.5 Sample Collection and Handling***.
   - For details about the preparation of venous whole blood samples, see ***6.5.1 Running the Venous Whole Blood Samples.***
   - For details about the preparation of capillary whole blood samples, see ***6.5.2 Capillary Whole Blood Samples***.
   - For details about the preparation of prediluted samples, see ***6.5.3 Prediluted Samples***.
2. Shake the capped tube of sample for a homogeneous specimen.
3. When the green indicator light is steady-on, click **Mode & ID** in **Sample Analysis** interface.

   A dialog box will pop up as shown below.

Figure 7-3 Mode & ID Settings



4. Select the blood sample mode **Venous Whole Blood** (VWB), **Capillary Whole Blood** (CWB) or **Predilute** (PD) of the sample, and input the **Sample ID**.
   - Letters, numbers and all characters that can be entered through the keyboard (including special characters) are allowed for the Sample ID. Chinese and other languages (such as Japanese, Korean, etc) are not supported.
   - The length of the entries ranges from 1 to 25 and the entries shall not be empty.
   - The last character of a sample ID must be numeric, but a string of "0" only is not an acceptable sample ID.
5. Click **OK**.
6. Remove the tube cap carefully and place the sample under the probe so that the probe can aspirate the well-mixed sample.
7. Press the aspirate key on the analyzer to start running the sample.

   The sample will be automatically aspirated by the sample probe.
8. When you hear a beep, remove the sample tube.

   The analyzer will automatically run the sample and the analysis status icon and analyzer indicator is flickering in green. When the analysis is complete, the analyzer indicator returns to constantly-on green.
9. Repeat steps 1~8 to run the remaining samples.

7.5 Dealing with the Analysis Results

7.5.1 Automatic saving of analysis results

This analyzer automatically saves sample results. When the maximum number has been reached, the newest result will overwrite the oldest (already backed up). The maximum number of the automatically saved results is 50,000.

7.5.2 Parameter Flags

- If parameter is followed by a "↑" (**H**) or "↓"(**L**), it means the analysis result has exceeded the upper or lower limit of the reference range but still within the display range.
- If the parameter is followed by a "**?**", it means the analysis result is suspicious.
- If you see "***" instead of a result, it means the result is either invalid or beyond the display range.

NOTE

For the background test, the flags for parameters or abnormal blood cell differential and morphology are not available.

7.5.3 Flags of Abnormal Blood Cell Differential or Morphology

The analyzer will flag abnormal or suspicious WBC, RBC and PLT according to the scattergrams and histograms. The flag information is defined in the table below.

Table 7-2 Flags of abnormal blood cell differential or morphology

Flag Type		Flag information
WBC	Abnormal	Leucocytosis
		Leucopenia
		Granulocytosis
		Granulopenia
		Lymphocytosis
		Lymphopenia
		MID Increase
	Suspicious	Background/Aspiration Abn.
		WBC abnormal?
		Abnormal WBC histogram
		Abnormal WBC Channel
RBC/HGB	Abnormal	Erythrocytosis
		Anisocytosis
		Macrocytosis
		Microcytosis
		Anemia
		Hypochromia
	Suspicious	Abnor. RBC Distr.
		Dimorphologic

Flag Type		Flag information
		Iron Deficiency?
		HGB Abn/Interfere?
		RBC Clump?
		Abnormal RBC Channel
		Abnormal HGB Channel
PLT	Abnormal	Thrombocytosis
		Thrombopenia
	Suspicious	Abnor. PLT Distr.
		PLT Clump?

7.6 Functions of the Buttons

7.6.1 Previous/Next

Click **Previous**, and the screen will display the sample analysis results prior to the current one.

Click **Next**, and the screen will display the sample analysis results after the current one.

7.6.2 Mode & ID

Click this button to set the sample mode and measurement mode during the sample analysis. See section ***7.4 Running Samples.***

7.6.3 Pre-entry

Click this button, and you can pre-enter the information of the sample to be tested before performing the sample analysis. See section ***7.3 Entering*** Sample Information.

7.6.4 Validate/Cancel Validation

After running sample, you can click **Validate** to validate the sample. After validating, the button will replaced by **Cancel Validation**. After validating, you can not edit the sample/patient information and the result.

If the current sample has been validated, the sample validation can be canceled by clicking **Cancel Validation**. After canceling the validation, you can edit the sample/patient information and the result.

7.6.5 Print

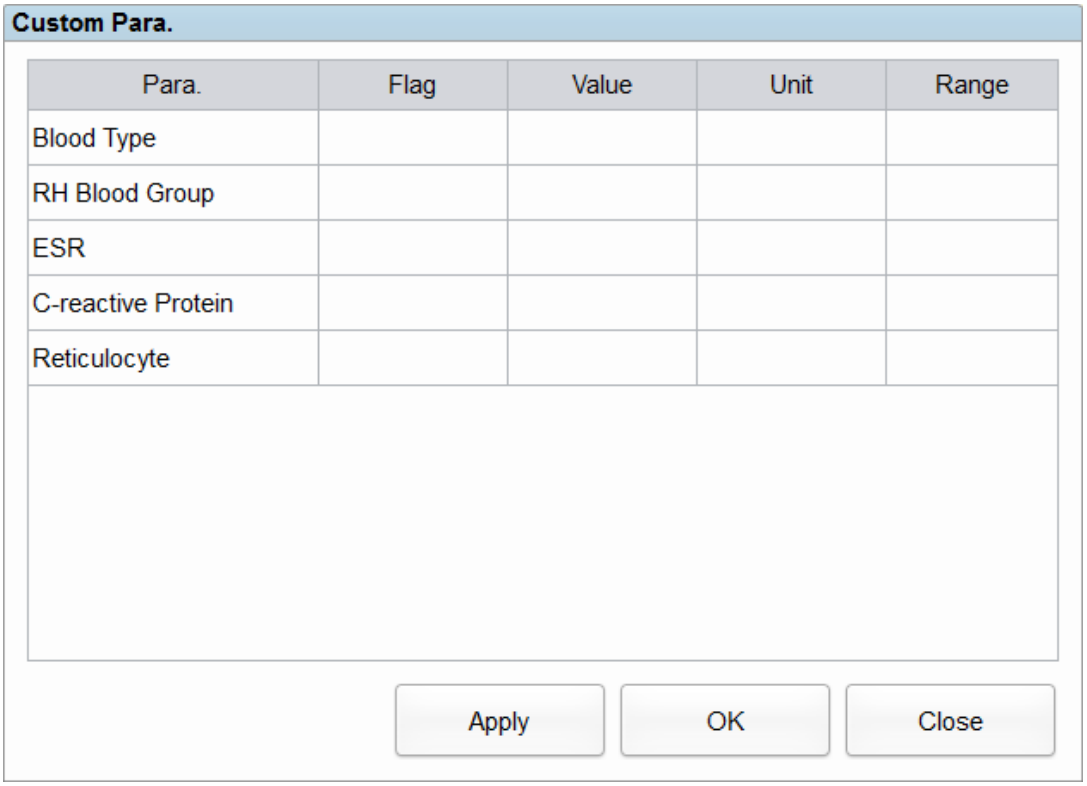
You can click Print to print the report of the sample result.

7.6.6 Customized Parameters

You can browse and edit the customized parameters results of the selected sample in the **Sample Analysis** interface. The operation procedures are as shown below:

1. Click **Custom Para.** to enter the customized parameters setting interface as shown in Figure 7-4.

Figure 7-4 Customized Parameters



2. Click the cell corresponding to its **Value** column of the parameter, and enter the value.

   If the unit and reference range of parameters have been set in the **Setup** > **Parameter** > **Custom Para.** interface, the corresponding unit and range (lower limit~upper limit) will be displayed in this tab. When both the value and range of parameters are numbers, and the number is out of the reference range, the relevant mark ↑ or ↓ will be displayed in the Flag column.

   Please refer to ***5.4.5 Customized Parameter*** for customized parameters settings.

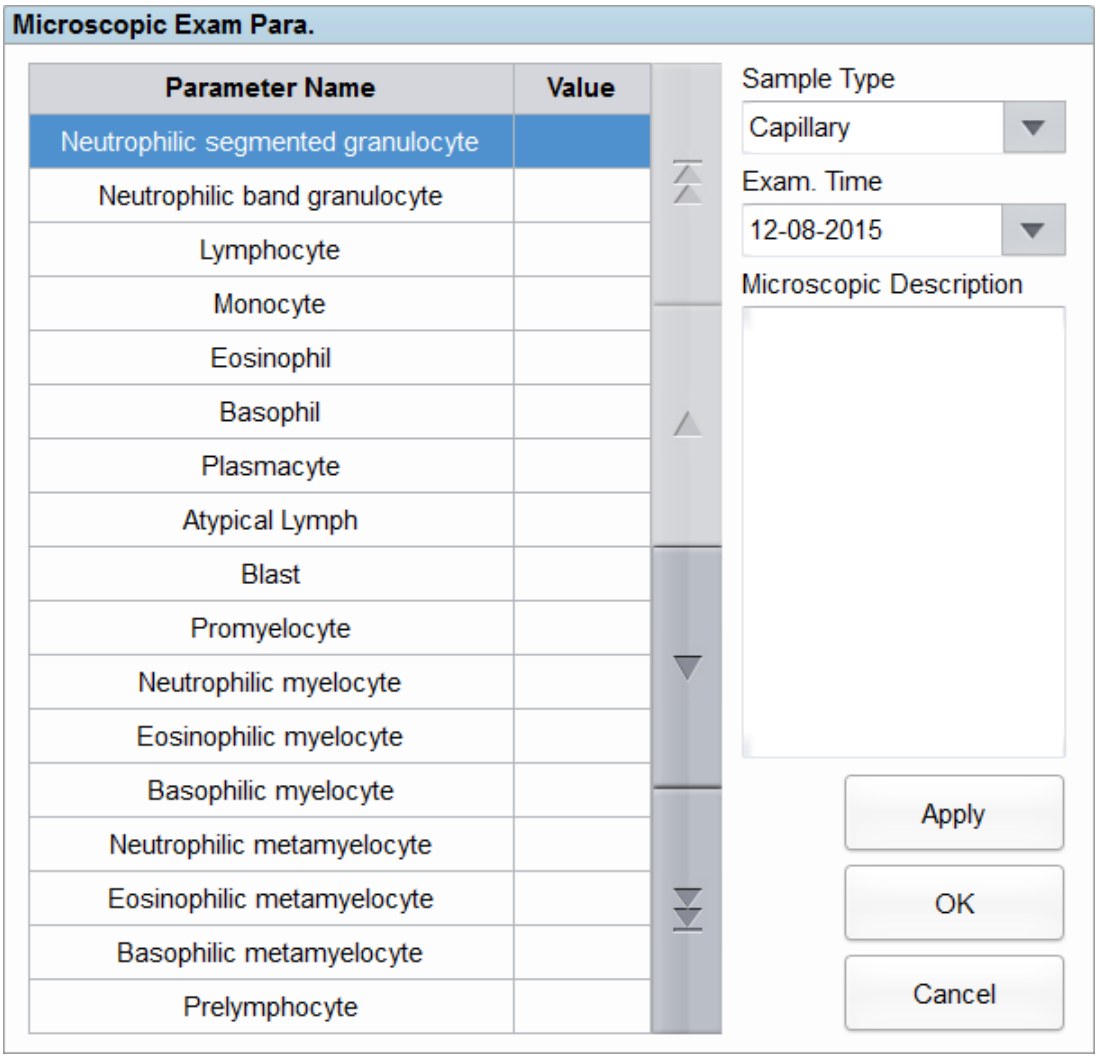
7.6.7 Microscopic Exam. Parameters

You can perform the microscopic examination settings as per the following steps.

1. Click **Microscopic Exam. Para**.

   The microscopic examination parameters interface as shown in Figure 7-5 will pop up on the screen.

Figure 7-5 Adding a New Microscopic Exam. Parameter



2. Set the microscopic examination parameters by referring to Table 7-3.

Table 7-3 Microscopic Exam. Parameters

Parameter	Meaning	Operation
Sample Type	Type of sample for microscopic examination. ● Venous blood ● Capillary ● Cord blood ● Blood	Click the **Sample Type** dropdown list box and select the type of sample for microscopic examination.
Blood Type	Blood type of a patient.	Select the blood type of the patient in the **Blood Type/ESR** column. Click the first combo box next to the blood type, you can select from **Blank**, **A**, **B**, **O** and **AB**; click the second combo box, you can select from **Blank**, **RH+** and **RH-**.

Parameter	Meaning	Operation
Exam. Time	Time of microscopic examination.	Click the date control for the settings. • The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sepuence of year, month, date, hour, and minute. • Click  or  to select the date or click the textbox to enter them directly. • Click  to delete the current data and re-enter information. **NOTE** The Microscopic exam. time can be no later than the current system time.
Microscopic Description	Description of cells morphology.	Enter the morphology information for cells into the multi-line textbox.

7.6.8 Communication

You can transmit the current sample data (except the background sample) to the LIS/HIS system in the **Sample Analysis** interface. The operation procedures are as shown below:

1. Click  to unfold all function buttons.
2. Click **Comm.**.

7.6.9 Edit Result

NOTE

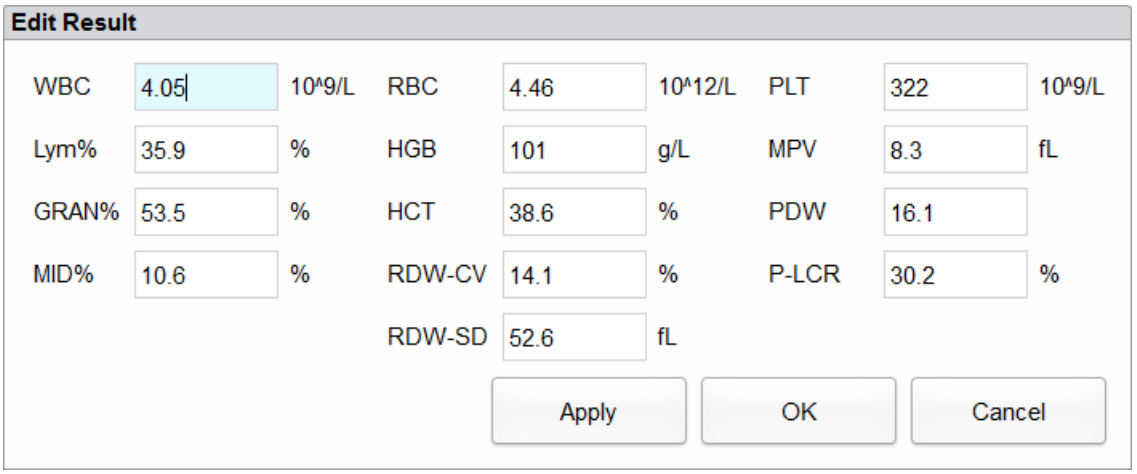
- You can not edit the results of validated samples.
- You can not edit the results of the background.

You can edit the parameter result of the selected sample as per the following steps.

1. Click  to unfold all function buttons.
2. Click **Edit Result**.

   The **Edit Result** dialog box will pop up on the screen as shown in Figure 7-6.

Figure 7-6 Editing Parameter Result



3. Modify the counting results of the corresponding sample parameters.
4. Click **Apply** or **OK** to save the changes.

   If the sum of the percentage of the diff parameters is not equal to 100.00% or the WBC value is invalid after modification, the system will prompt in a message box that the entered value is invalid. Please re-enter after confirmation.

   If the result of one parameter is modified, then the result of other related parameter(s) will be changed accordingly and the high or low/suspicious flags will also be updated.

NOTE

The result of the parameter that you modified manually will be flagged with an **M**. If any parameter result is then changed due to the one that you modified manually, it will be flagged with an **m**.

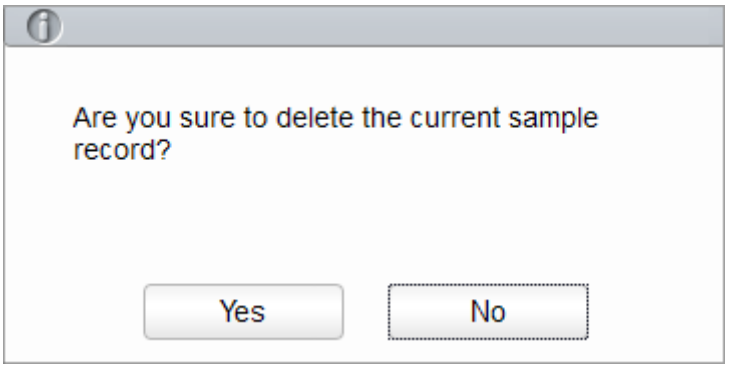
7.6.10 Delete

NOTE

- Validated samples are not allowed to be deleted.
- The common user has no access to delete the sample records.

1. Click  to unfold all function buttons.
2. Click **Delete**, and then click **Yes** in the pop-up dialog box to delete the sample.

Figure 7-7 Delete Sample Records



8 Result Review

8.1 Introduction

Upon the completion of each sample analysis, the analyzer will automatically save the sample information, result data, flag messages, histograms and scattergrams to the Review Database. The sample pool of the analyzer can save up to 50,000 sample records.

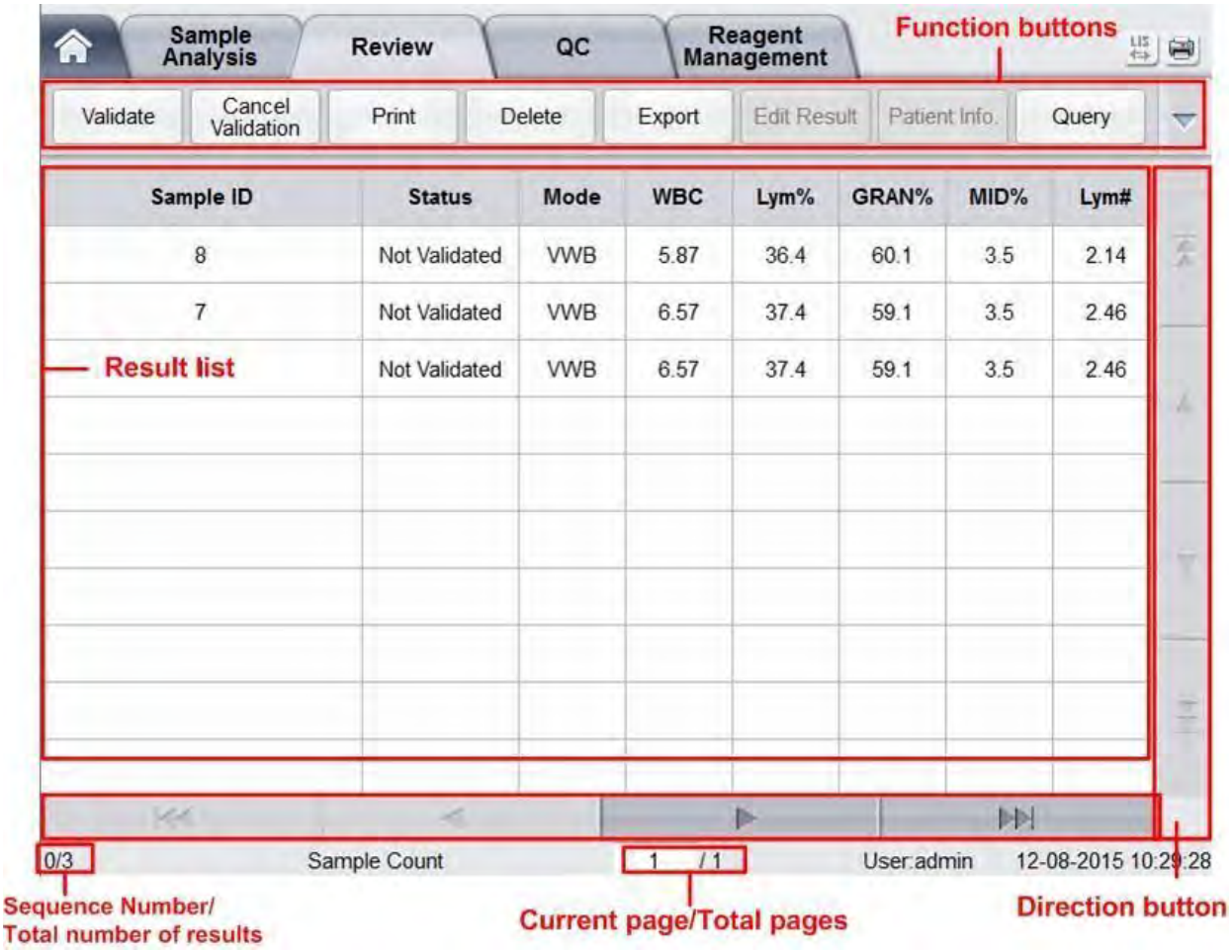
In the **Review** Interface, you can browse the saved sample information, result data, flag messages, histograms and scattergrams, and can search, compare or export the saved sample information.

8.2 Interface Introduction

You can browse, search, compare, print, and export the existing results in the Review interface.

Click **Review** to enter the sample review interface. See Figure 8-1.

Figure 8-1 Review



Interface Description:

- Result list: you can see browse detailed sample records.
- Function buttons: you can perform the operations such as comparing or searching the sample results, deleting and viewing the Run Charts, exporting and printing reports.
- Direction button: If you click different direction buttons, the list will move toward the corresponding directions.
  - From left to right, it indicates in sequence: the first column, moving to the left page, moving to the right page, and the last column.
  - From top to bottom, it indicates in sequence: the first page, the previous page, the next page, and the last page.

8.3 Sample List

The review interface shows a list of the analyzed samples, which contains the sample ID, mode, status and results of various parameters and other information.

Click a sample or multiple samples in the list area, then you perform operations such as exporting in batch for the selected samples. To cancel the selection, click the selected samples again.

8.4 Functions of the Buttons

8.4.1 Validate

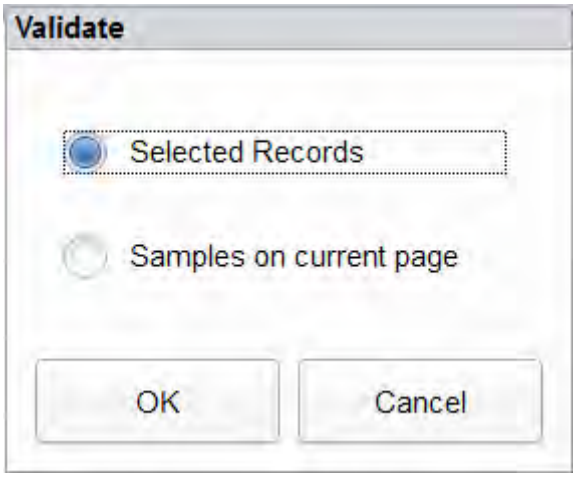
NOTE

After validating, you can not edit the sample/patient information and the result.

After running samples, you can validate the samples as per the following steps.

1. Click **Validate**.

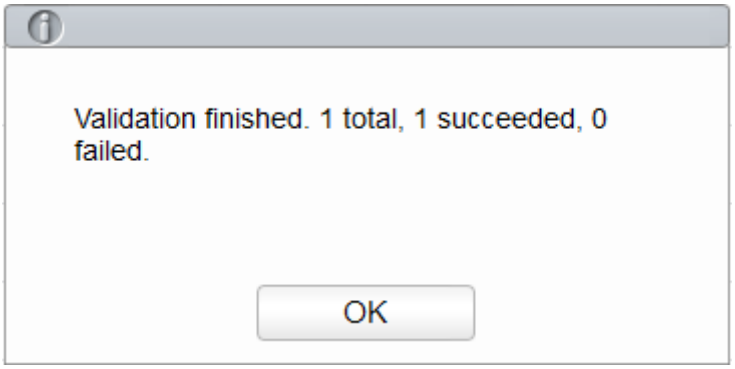
   A dialog box will pop up as shown below.



2. Select the sample which needs to be validated.
   - **Selected Records**: The sample results shown on the highlighted page.
   - **Samples on current page**: Results of all the samples shown on the current page.
3. Click **OK**.

   The system will prompt the validation results as shown in Figure 8-2.

Figure 8-2 Validation Results



4. Click **OK** to close the message box.

8.4.2 Cancel Validation

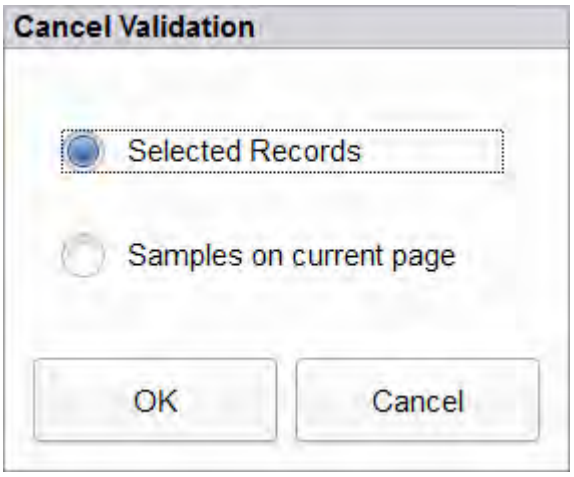
NOTE

After canceling the validation, you can edit the sample/patient information and the result.

You can cancel the validation of validated samples. Specific steps are shown below:

1. Click **Cancel Validation**.

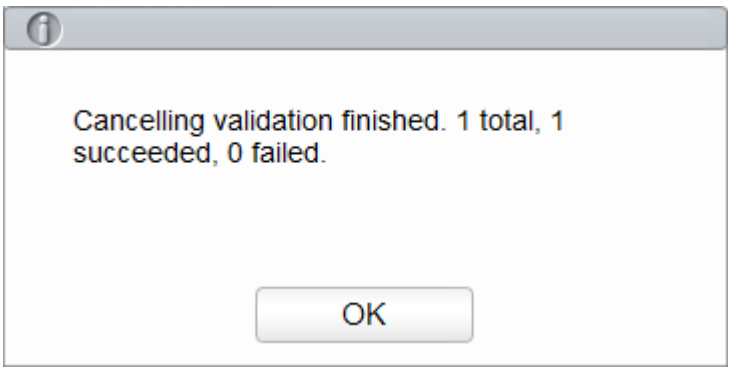
   A dialog box will pop up as shown below.



2. Select one or more samples to be validated.
   - Select **Selected Records**, and the system will cancel the validation for the current highlighted sample results.
   - Select **Samples on current page**, and the system will cancel the validation for all the samples on the current page.
3. Click **OK**.

   The system will prompt the operation results as shown in Figure 8-3.

Figure 8-3 Validation Results



4. Click **OK** to close the message box.

8.4.3 Print

Click **Print** to print the result report of the selected sample.

8.4.4 Delete

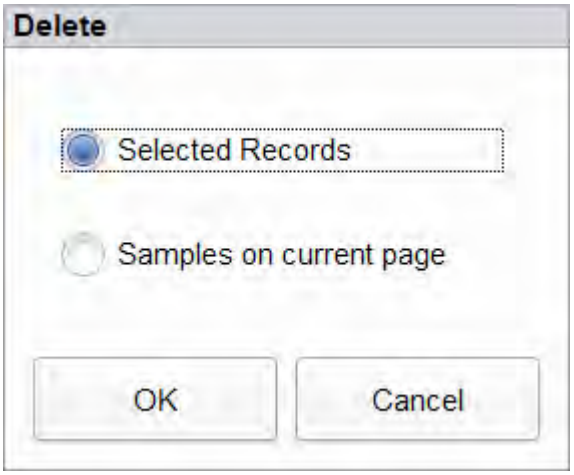
NOTE

- Validated samples are not allowed to be deleted.
- The common user has no access to delete the sample records.

1. Select one or several sample records to be deleted.
2. Click **Delete**.

   A prompt box will pop up on the screen as shown below.

Figure 8-4 Delete Sample Records



3. Select one or several sample records to be deleted according to the actual situation.
   - **Selected Records:** The sample results shown on the highlighted page.
   - **Samples on current page:** Results of all the samples shown on the current page.
4. Click **OK** to delete the selected record(s).

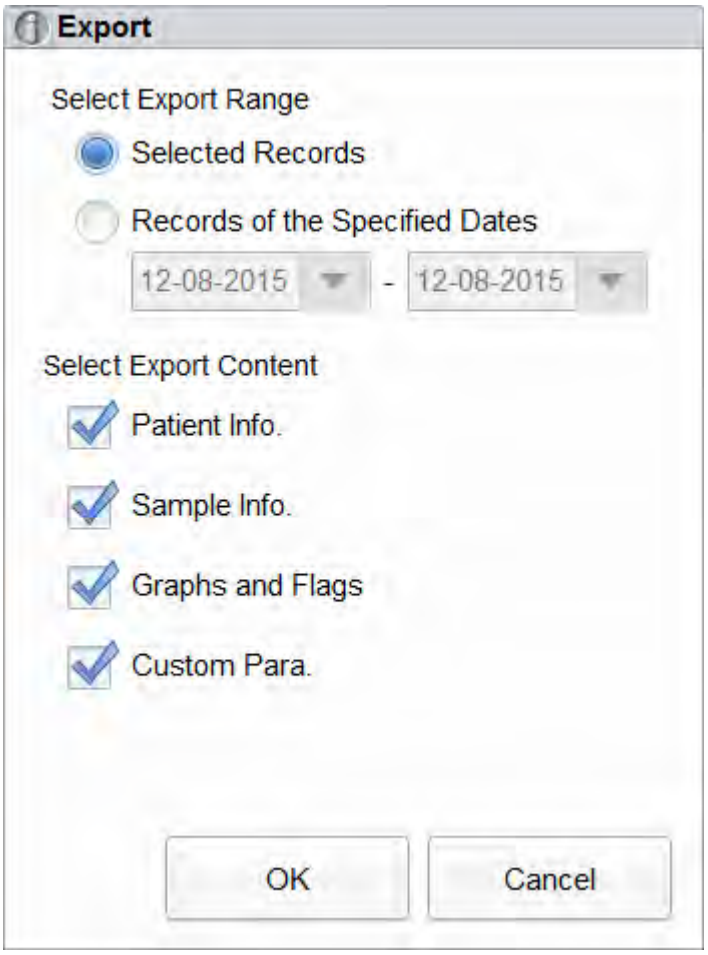
8.4.5 Export

The operator can export the sample data to the USB flash disk for backup. There are two ways of exporting the sample data: exporting selected records and exporting records of specified dates.

- Export Selected Records
  a. Insert a USB flash disk in the USB interface on the analyzer.
  b. Select records to be backed up, and click **Export**.

     As shown in the following figure, the export range of the system is **Selected Records** by default.

Figure 8-5 Export Selected Records



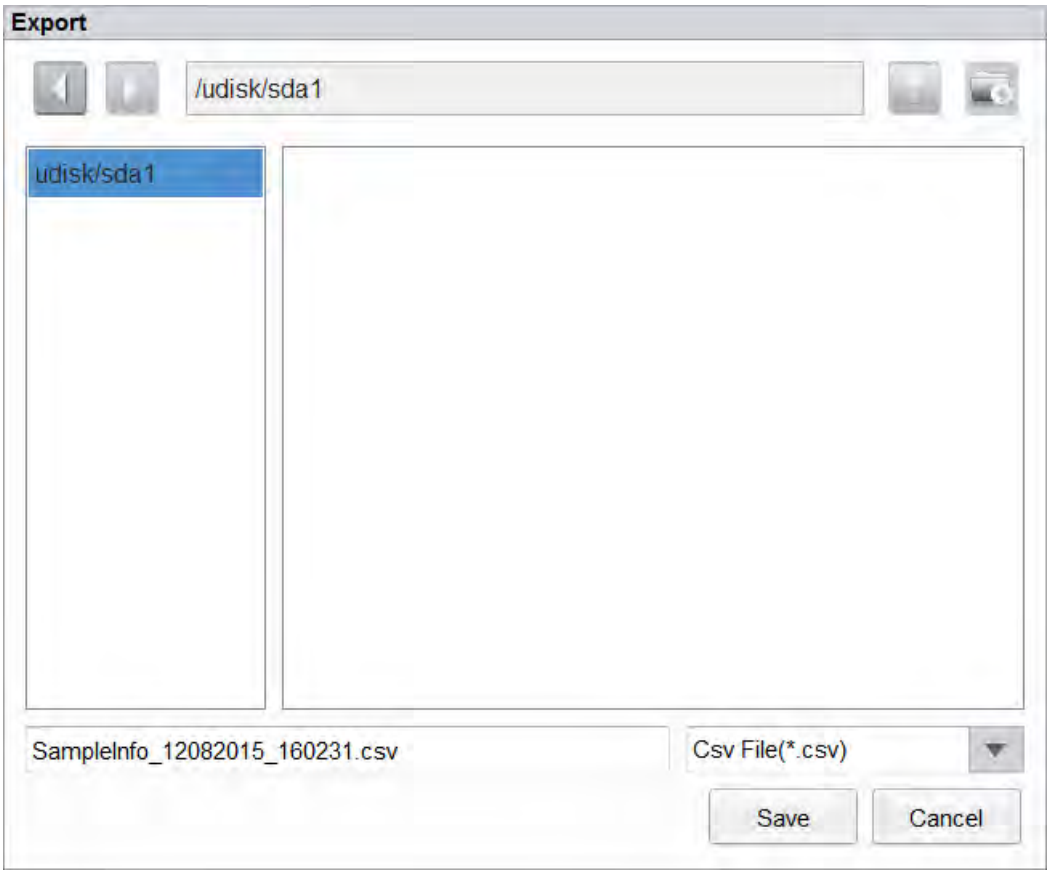
c. Select the content to be exported according to the actual demand.

   Content available for export includes: **Patient Info.**, **Sample Info.**, **Graphs and Flags**, and **Custom Para.**.

d. Click **OK**.

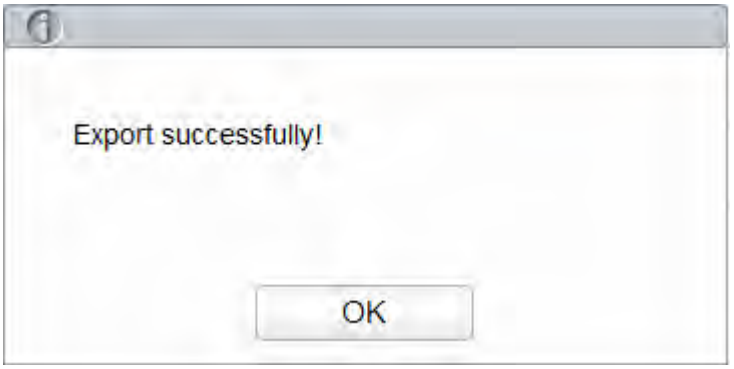
e. Select the data export path in the popup dialog box, enter the backup file name, and click **Save**.

   The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.csv. Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.



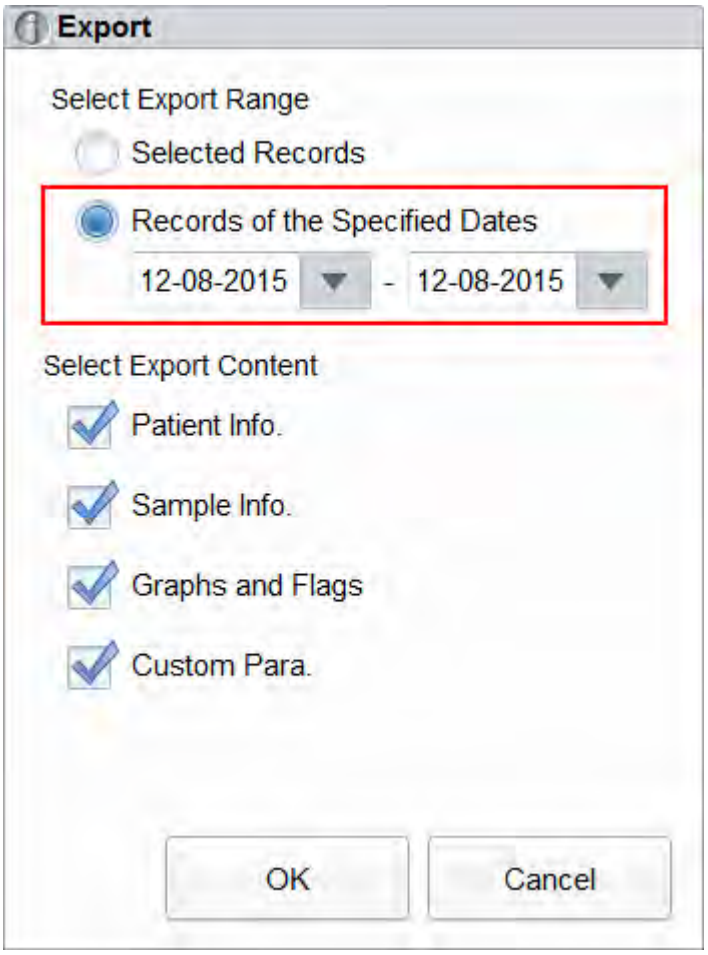
f. Click Save.

The system pops up a dialog box as shown below to indicate that the data export is successful.



- Export Records of the Specified Dates
  a. Insert a USB flash disk into the USB interface on the analyzer.
  b. Click **Export**.
  c. Select **Records of the Specified Dates** and set the run date range of sample in the two date textboxes. See Figure 8-6.

Figure 8-6 Export Records of the Specified Dates



d. Select the content to be exported according to the actual demand.

   Content available for export includes: **Patient Info.**, **Sample Info.**, **Graphs and Flags**, and **Custom Para.**.

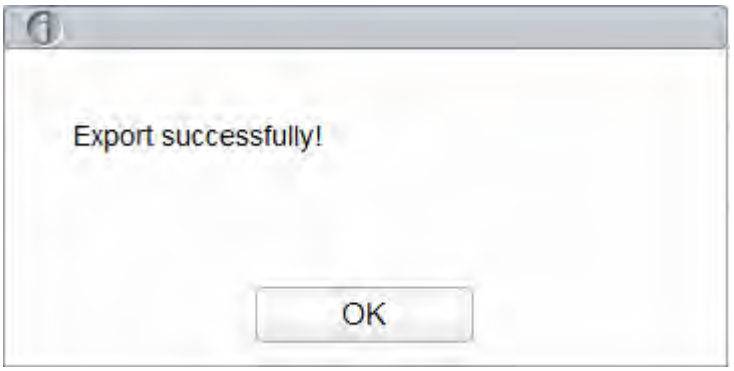
g. Click **OK**.

h. Select the data export path in the popup dialog box, enter the backup file name, and click Save.

   The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.csv. Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.

i. Click **Export**.

   The system pops up a dialog box as shown below to indicate that the data export is successful.



8.4.6 Edit Result

NOTE

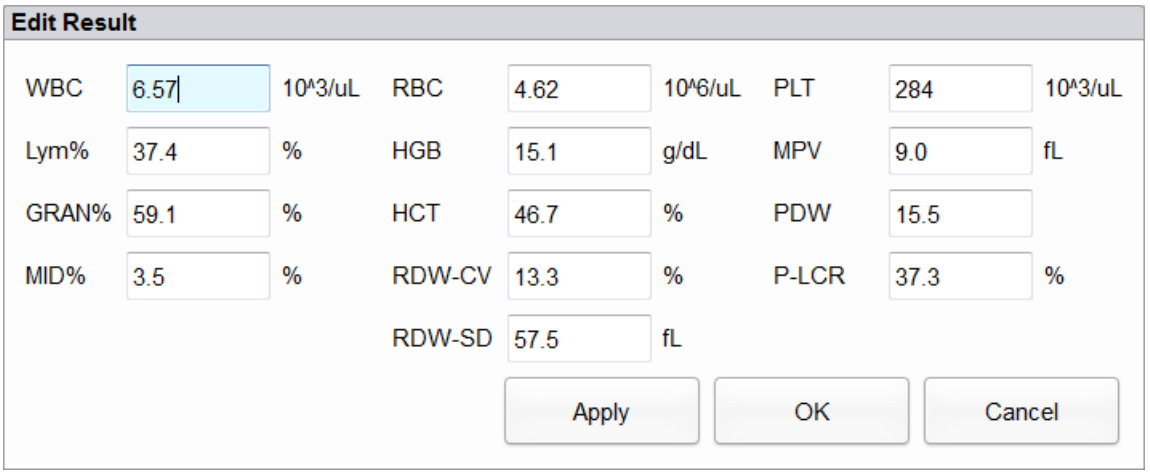
- You can not edit the results of validated samples.
- You can not edit the results of the background.

You can edit the parameter result of the selected sample as per the following steps.

1. Select a row of record from the result list and click the **Edit Result** button.

   The **Edit Result** dialog box will pop up on the screen as shown in Figure 8-7.

Figure 8-7 Editing Parameter Result



2. Modify the counting results of the corresponding sample parameters.
3. Click **Apply** or **OK** to save the changes.

   If the sum of the percentage of the diff parameters is not equal to 100.00% or the WBC value is invalid after modification, the system will prompt in a message box that the entered value is invalid. Please re-enter after confirmation.

   If the result of one parameter is modified, then the result of other related parameter(s) will be changed accordingly and the high or low/suspicious flags will also be updated.

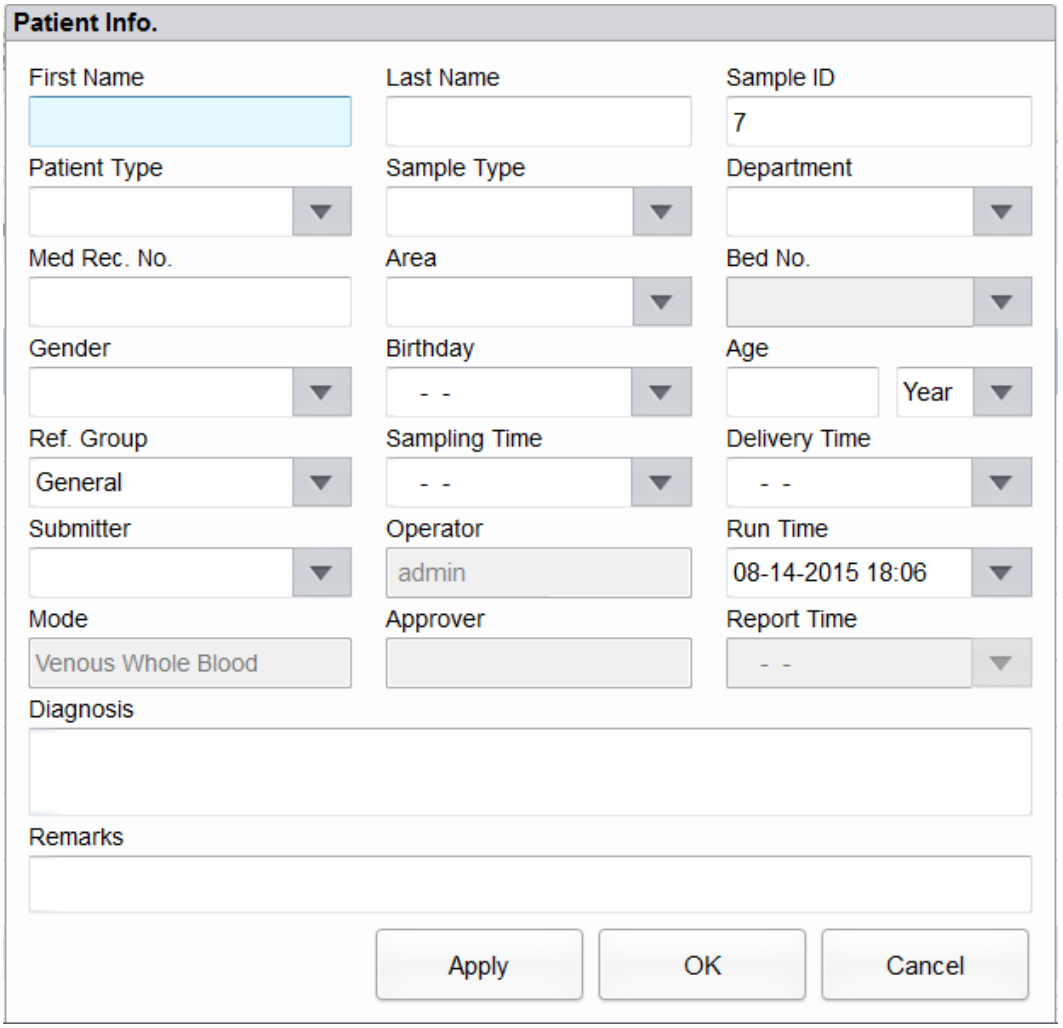
8.4.7 Patient Info.

You can browse and edit sample/patient information after the sample analysis is completed. Specific steps are shown below:

1. Click **Patient Info.**.

   The patient information page will pop up as shown in Figure 8-8.

Figure 8-8 Patient Info.



2. Enter patient information with reference to the parameter description in Table 8-1.

Table 8-1 Parameter Description

Parameter	Meaning	Operation
Sample ID	Number of the selected sample.	It will be displayed automatically, and you can modify it manually.
First Name	First name of patient.	Input in the textbox directly.
Last Name	Last name of patient.	Input in the textbox directly.
Patient Type	Type of patient. Values: ● Inpatient ● Physical Examination ● STAT ● Outpatient	Select from the dropdown list.

Parameter	Meaning	Operation
Sample Type	Type of selected sample. • Venous blood • Capillary • Cord blood • Blood	Select from the dropdown list.
Med Rec. No.	Medical record number of patient.	Input in the textbox directly.
Gender	Gender of patient. Values: • Male • Female • Undefined	Select from the dropdown list.
Birthday	Birthday of a patient.	Select from the date control. • The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sepuence of year, month, and date. • Click  or  select the date or click the textbox to input them directly. • Click  to clear the data and input again.
Age	Age of a patient.	Select the unit of age from the dropdown list (**Year**, **Month**, **Day** or **Hour**) and enter the age of the patient in the textbox before the age unit.
Ref. Group	Reference group of the sample under analysis. The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.	Select from the dropdown list. **NOTE** • If the **Automatically match the customized reference group according to age and gender** is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). • Refer to ***5.4.3 Ref. Range*** for the setting of the reference group and range.
Department	Department receiving the patient.	Select from the dropdown list.
Area	Ward area of patient.	Select from the dropdown list or input directly.
Bed No.	Bed No. of inpatient.	Select from the dropdown list or input directly. **NOTE** The bed No. is required to be filled only for **inpatients.**

Parameter	Meaning	Operation
Sampling Time	Date and time when the sample is collected.	Click the date control for the settings. • The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sepuence of year, month, date, hour, and minute. • Click  or  to select the date or click the textbox to enter them directly. • Click  to delete the current data and re-enter information. **NOTE** The sampling time can be no later than the current system time.
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.
Mode	Counting mode of the selected sample.	You do not need to enter it and it will be displayed automatically.
Delivery Time	Date and time when the sample is delivered.	Click the date control for the settings. • The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sepuence of year, month, date, hour, and minute. • Click  or  to select the date or click the textbox to enter them directly. • Click  to delete the current data and re-enter information. **NOTE** The delivery time can be no later than the current system time and cannot be earlier than the sampling time.
Checker	Personnel running the sample.	You do not need to enter it and it will be displayed automatically.
Run Time	Time when the sample is run.	You do not need to enter it and it will be displayed automatically.
Approver	Personnel validating the sample.	This parameter will be automatically displayed after the sample is validated.
Report Time	The date and time when the report is printed for the last time.	This parameter will be automatically displayed after the report is printed.

Parameter	Meaning	Operation
Diagnosis	Suspected diagnosis information.	Input in the textbox directly.
Remarks	Clarifications or notes.	Input in the textbox directly.

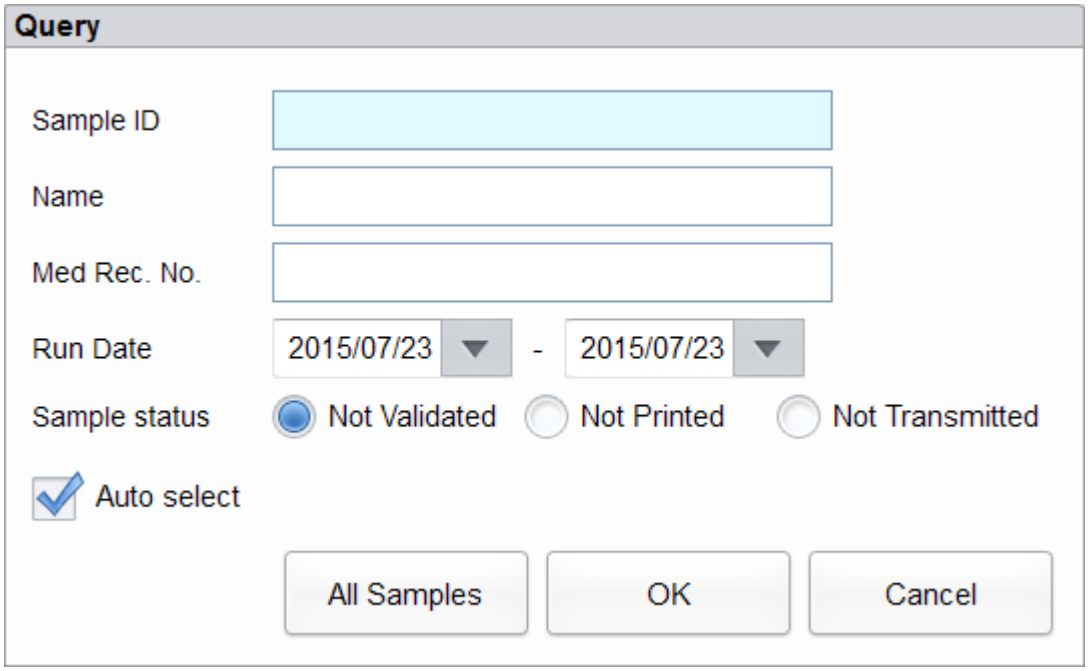
3. Click **Apply** or **OK** to save the changes.

8.4.8 Query

You can view the test results of a patient within a certain test date range by entering the query conditions. The procedures are shown as below:

1. Click the **Query** button to enter the multi-conditional query dialog box as shown below.

Figure 8-9 Query Conditions



2. Determine the query conditions as needed.

   For the specific parameter description, see Table 8-2.

Table 8-2 Parameter Description of Query Conditions

Parameter	Meaning	Operation Description
Sample ID	Sample ID to be queried.	Input in the textbox.
Name	Name of patient.	Input in the textbox.
Med Rec. No.	Med Rec. No. of patient.	Input in the textbox.
Run Date	Test date range of sample.	Select the starting and ending dates of the sample test in the two data controls successively.

Parameter	Meaning	Operation Description
Sample status	Status of validation, printing or communication of the sample. Values: • Not Validated • Not Printed • Not Transmitted	Please choose according to the actual situation. The default value is **Not Validated**.

NOTE

- **Auto select** checked by default indicates that the query result is being selected (with a blue background color). If it's unchecked, the query result will remain on a white background color.
- Click **All Samples** to close the current window, display all the samples again and restore all the filter conditions to the default values.

3. Click **Query**.

   The system will display all the query results which meet the conditions.

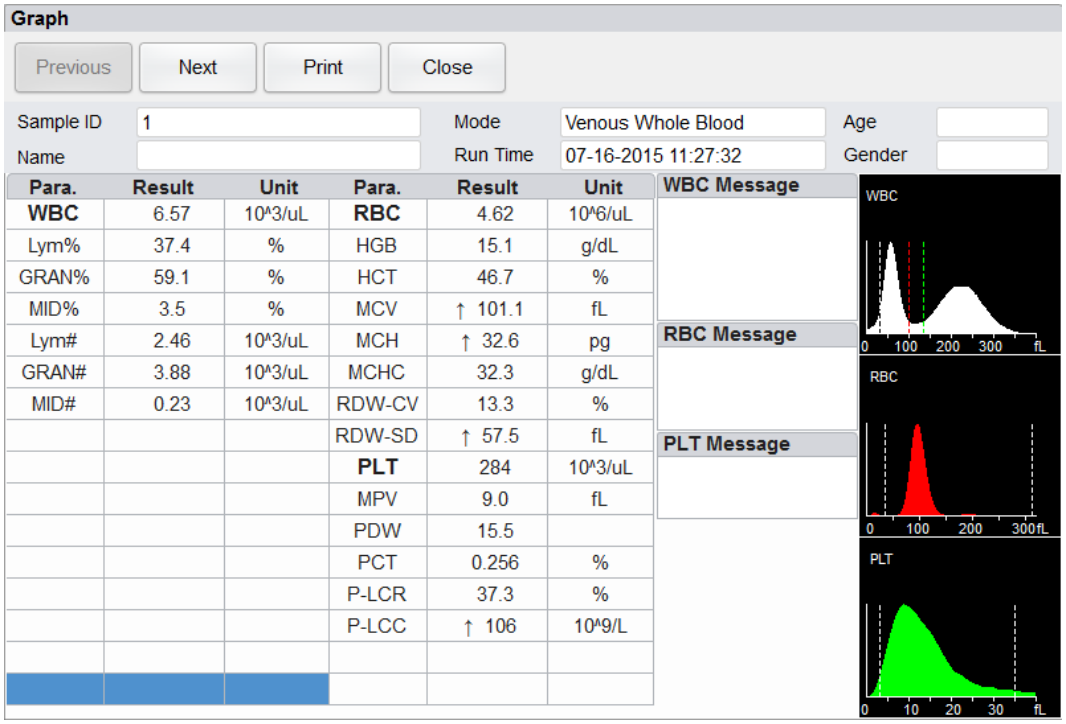
8.4.9 Graph

In the **Review** interface, you can click **Graph** to browse the selected sample graph results, parameter results and flag messages. The procedures are shown as below:

1. Select a result to review in graph interface.
2. Click  to unfold all function buttons.
3. Click **Graph** to enter the graph interface.

   In the **Graph** interface, you can view sample information such as parameter results, graph results and flag messages. In addition, you can also print the analysis report as. See Figure 8-10.

Figure 8-10 Graphs Review



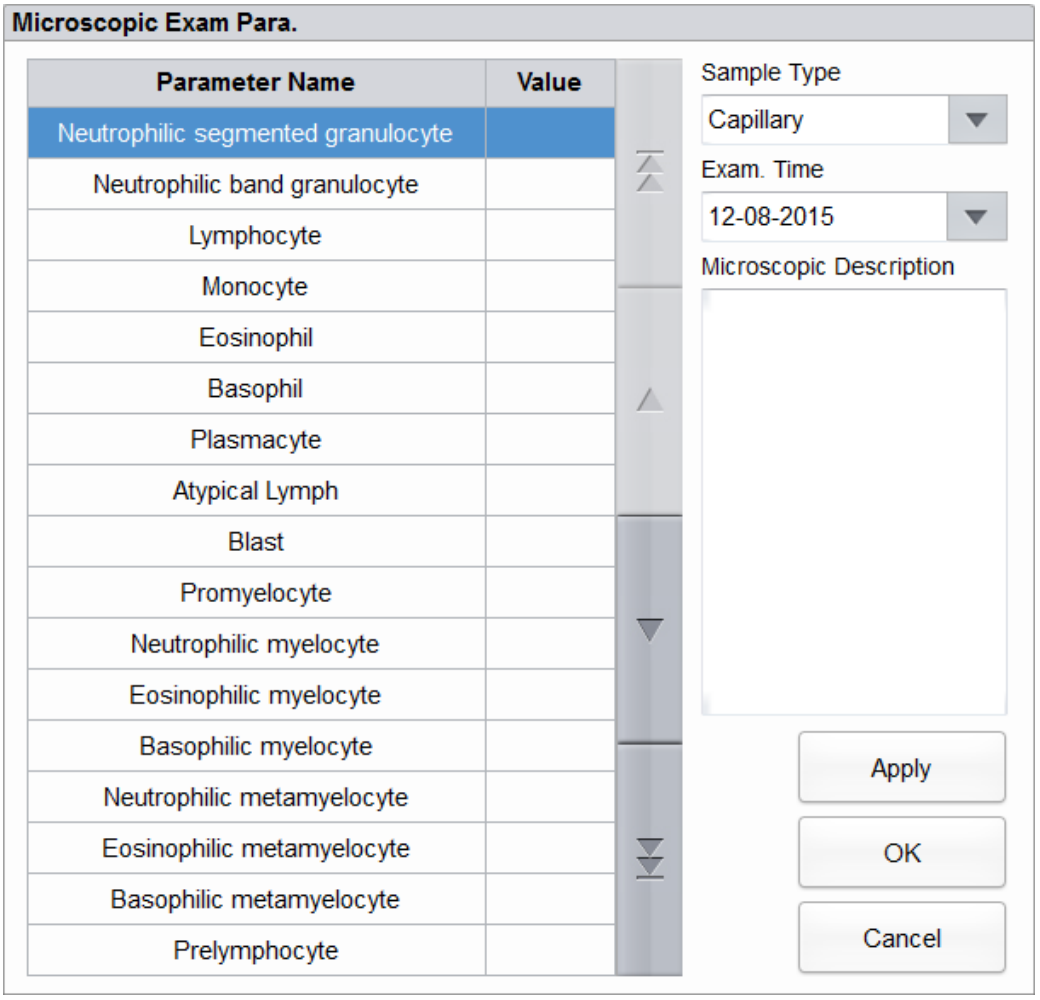
8.4.10 Microscopic Exam Para.

You can perform the microscopic examination parameter settings as per the following steps.

1. Click Microscopic Exam Para..

   The microscopic examination parameters interface as shown in Figure 8-11 will pop up on the screen.

Figure 8-11 Microscopic Exam Para.



2. Set the microscopic examination parameters by referring to Figure 8-3.

Table 8-3 Microscopic Exam. Parameters

Parameter	Meaning	Operation
Sample Type	Type of sample for microscopic examination. ● Venous blood ● Capillary ● Cord blood ● Blood	Click the **Sample Type** dropdown list box and select the type of sample for microscopic examination.

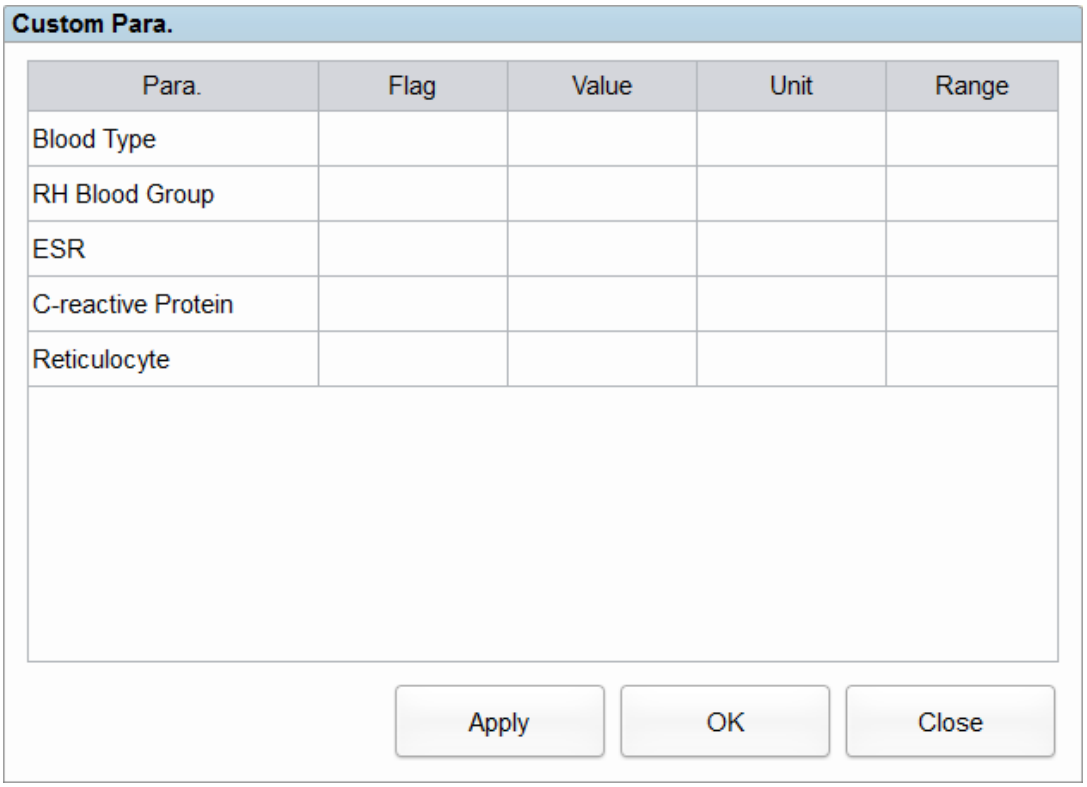
Parameter	Meaning	Operation
Blood Type	Blood type of a patient.	Select the blood type of the patient in the **Blood Type/ESR** column. Click the first combo box next to the blood type, you can select from **Blank**, **A**, **B**, **O** and **AB**; click the second combo box, you can select from **Blank**, **RH+** and **RH-**.
Exam. Time	Time of microscopic examination.	Click the date control for the settings. ● The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sepuence of year, month, date, hour, and minute. ● Click  or  to select the date or click the textbox to enter them directly. ● Click  to delete the current data and re-enter information. **NOTE** The Microscopic exam. time can be no later than the current system time.
Microscopic Description	Description of cells morphology.	Enter the morphology information for cells into the multi-line textbox.

8.4.11 Customized Parameters

You can browse and edit the customized parameters results of the selected sample in the **Review** interface. The operation procedures are as shown below:

1. Click **Custom Para.** to enter the customized parameters setting interface as shown in Figure 8-12.

Figure 8-12 Customized Parameters



2. Click the cell corresponding to its **Value** column of the parameter, and enter the value.

   If the unit and reference range of parameters have been set in the **Setup** > **Parameter** > **Custom Para.** interface, the corresponding unit and range (lower limit~upper limit) will be displayed in this tab. When both the value and range of parameters are numbers, and the number is out of the reference range, the relevant mark ↑ or ↓ will be displayed in the Flag column.

   Please refer to ***5.4.5 Customized Parameter*** for customized parameters settings.

8.4.12 Run Chart

Operators can check and review run charts of sample parameter results in the database. There are three view modes: selected samples, samples on current page and samples on specified run dates.

- View the run chart of the selected sample (default)

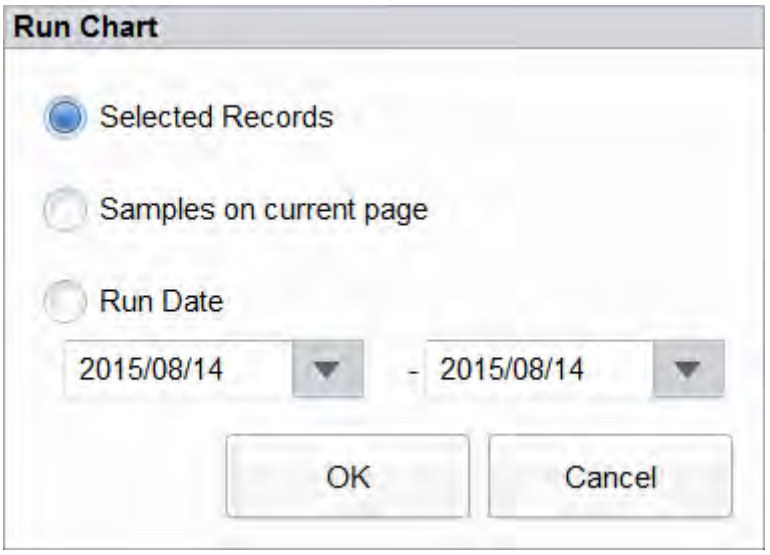
  a. Check no fewer than three sample records.

  a. Click  to unfold all function buttons.

  b. Click **Run Chart**.

     The system pops up a dialog box as shown below.

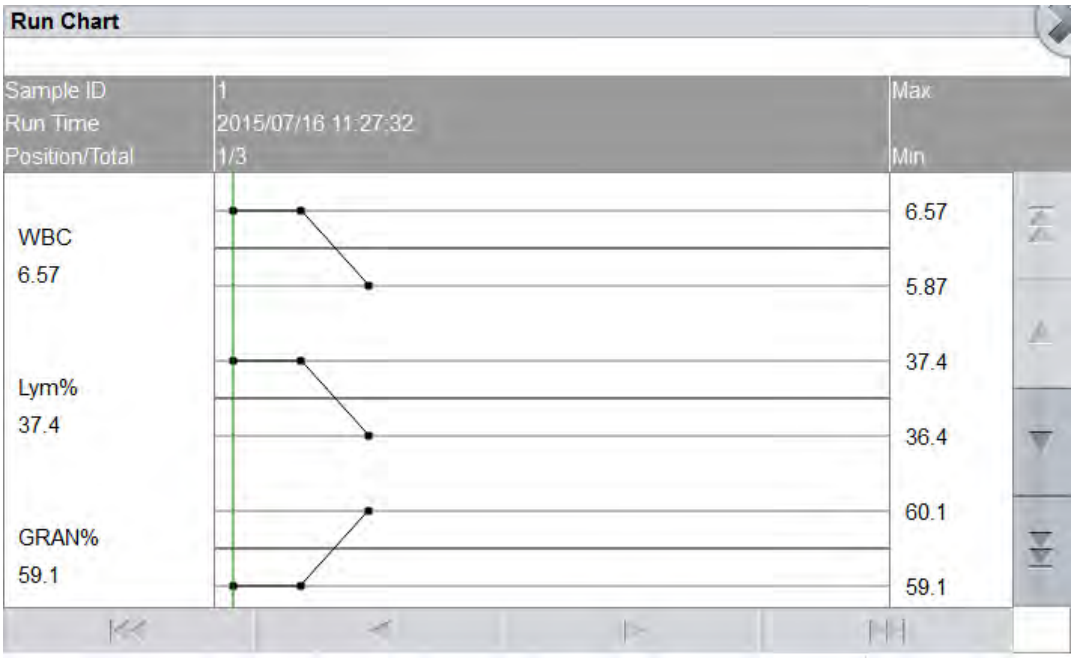
Firgure 8-13 Viewing the Run Chart of the Selected Sample



c. Click **OK**.

The screen will show the parameter result run chart of the selected sample. See Figure 8-14.

Figure 8-14 Run Chart

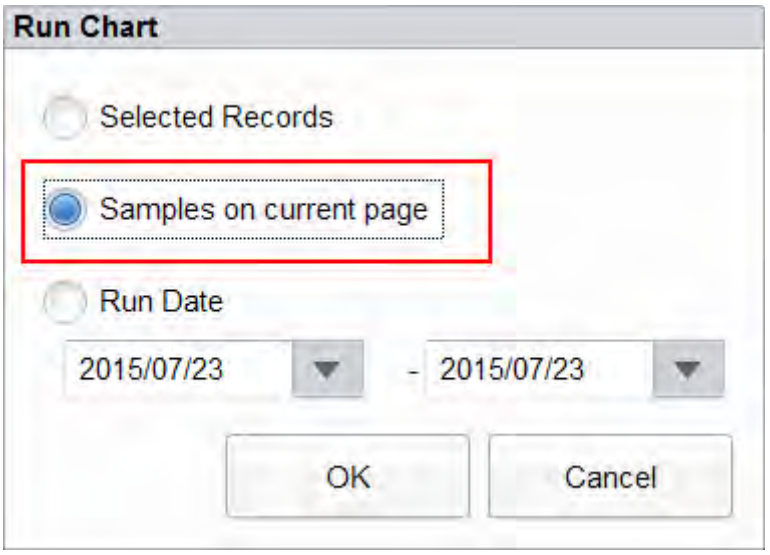


- View the run chart of samples on current page

a. Click  on the current page to unfold all function buttons.

b. Click the **Run Chart** button and select samples on current page in the pop-up dialog box. See Figure 8-15.

Figure 8-15 Viewing the Run Chart of Samples on the Current Page



c. Click **OK**.

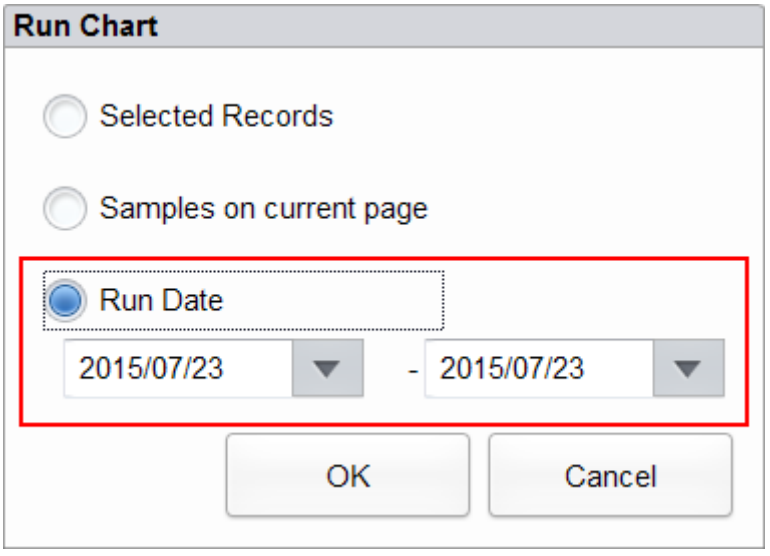
The screen will show the parameter result run chart of the selected sample.

- View the run chart of samples on specified run dates

a. Click  to unfold all function buttons.

b. Click the **Run Chart** button, and select **Run Date** in the pop-up dialog box. See Figure 8-16.

Figure 8-16 Viewing the Run Chart of Samples on Specified Run Dates



c. Click the date edit box, set a date range in the pop-up dialog box, then click **OK**.

- The input sequence of the controls is the same with the date fomat on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sepuence of year, month, and date.
- Click  or  to select a date and time or enter the information in the textbox directly.
- Click  to clear the current data and re-enter the information.

d. Click **OK**.

The screen will show the parameter result run chart of the selected sample.

9 Quality Control

9.1 Introduction

Quality Control (QC) consists of strategies and procedures that measure the precision and stability of the analyzer. The results imply the reliability of the sample results. QC involves measuring materials with known, stable characteristics at frequent intervals.

Analysis of the results with statistical methods allows the inference that sample results are reliable. MR recommends running the QC program on a daily basis with low, normal and high level controls. A new lot of controls should be analyzed in parallel with the current lot prior to their Exp. dates. This may be accomplished by running the new lot of controls twice a day for five days using any empty QC file. The QC files calculate the mean, standard deviation and coefficient of variation for each selected parameter. The instrument-calculated results should be within the expected ranges published by the manufacturer.

NOTE

- You should only use the MR-specified controls and reagents. Store and use the controls and reagents by following the instructions for use of the controls and reagents. Controls beyond their Exp. date shall not be used. Controls (similar to standard blood samples) must be well mixed before use.
- General users only have the access for browsing and executing the QC analysis other than editing.

9.2 L-J Quality Control

9.2.1 QC Principle

In the L-J quality control, quality control can be applied to 21 parameters. You can set the QC information by setting the QC file before performing the QC analysis. Each QC file can be assigned 1 batch number for high, normal and low level controls. Each QC file can store up to 500 QC results. When there are more than 500 QC results, the new QC results will overwrite the oldest results in sequence.

9.2.2 QC Settings

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

NOTE

Only users with administrator-level access can edit the L-J settings.

Before running a new batch of controls, you need to assign a QC file to each batch of controls. You can complete the QC settings by setting QC information in the QC files.

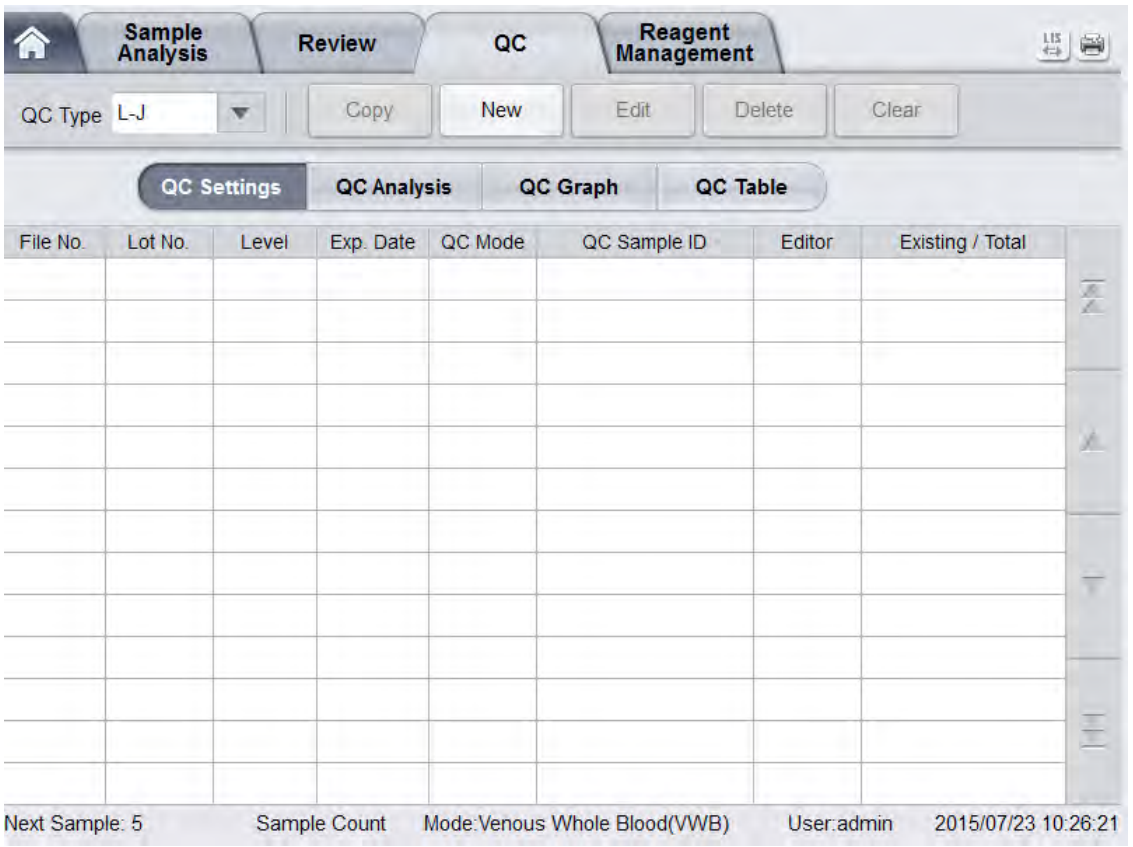
9.2.2.1 Entering QC Information

The administrator can set the QC files by operations such as Copy, New, and Edit. Specific steps are shown below:

1. Click **QC** to access the QC interface.
2. Click **QC Settings** to enter the **QC Settings** interface.

   See Figure 9-1.

Figure 9-1 L-J Quality Control

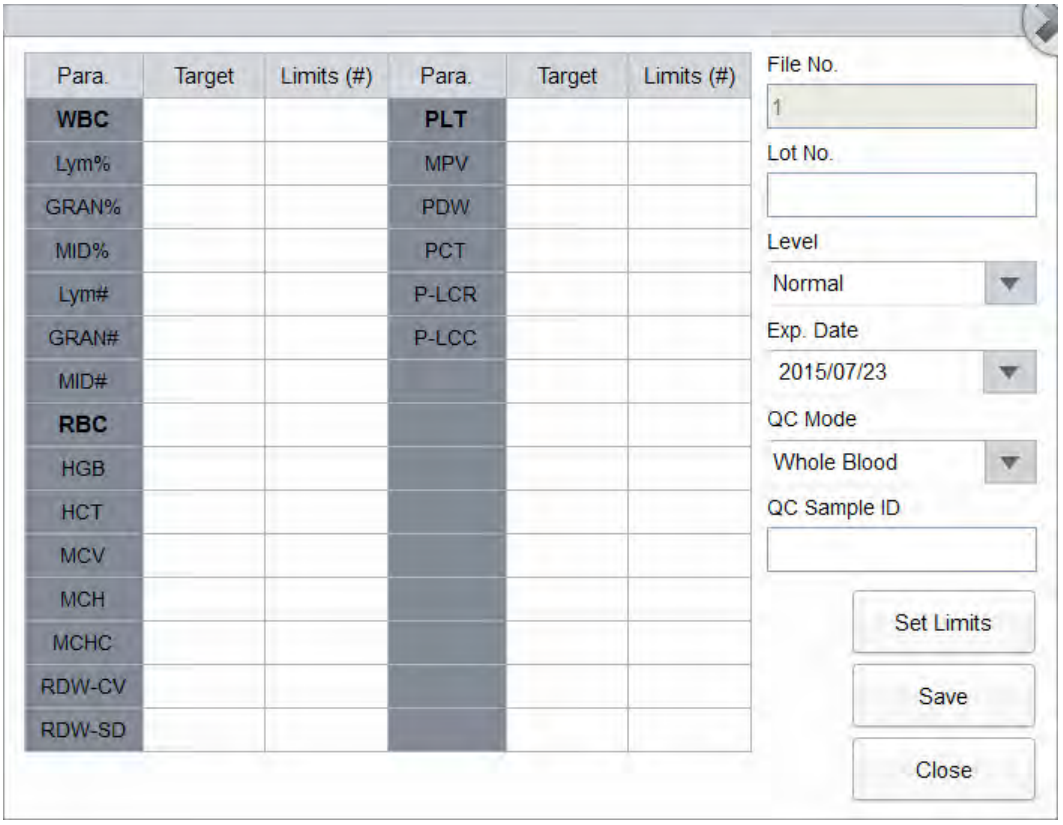


3. Click the **New** button or select a QC file (Existing/Total is 0/500) without QC counting results and

click the **Edit** button.

The interface as shown in Figure 9-2 will pop up on the screen.

Figure 9-2 Entering QC Information



You can also select the QC file of which data has been set and then click **Copy**, and edit the content based on the original data.

4. Set related information of the controls with reference to Table 9-1.

Table 9-1 QC File Information

Parameter	Parameter Description	Operation Description
File No.	QC file No.. Each QC file can store up to 500 QC results.	Read only.
Lot No.	Lot number of controls.	Enter into the textbox directly. **NOTE** The lot No. can not be empty and up to 16 digits can be entered. You can enter characters, numbers, letters and special characters, but no Chinese characters are allowed.
Level	Level of the controls, including 3 levels, i.e. High, Normal and Low	Select from the dropdown list.
Exp.Date	Exp. date of the controls.	The default Exp.Date is the current system date and needs to be changed to the actual Exp. date of the controls.

Parameter	Parameter Description	Operation Description
QC Mode	QC mode of the controls, including Whole Blood and Predilute.	Select from the dropdown list.
QC Sample ID	Number of the QC sample ● Users need to set the number of the controls here if he/she is used to performing the analysis with the controls placed among the daily samples. See section ***9.2.3.2 Completing QC Analysis in the Sample Analysis Interface.*** ● If the user performs the analysis in the **QC Analysis** interface, the ID cannot be entered.	Enter into the textbox directly. **NOTE** ● Letters, numbers and all characters that can be entered through the keyboard (including special characters) are allowed for the QC ID, but the number must end with a nonzero number. Chinese and other languages (such as Japanese, Korean, etc) are not supported. ● The length of the entries ranges from 1 to 25 and the entries shall not be empty. ● The last character of a sample ID must be numeric, but a string of "0" only is not an acceptable sample ID.
Target	Target of the QC parameter.	Enter the targets in the cell corresponding to the expected QC parameter according to the control target list with the corresponding lot No.
Limits (#)	Limits (#) of the QC parameter.	Enter the limits in the cell corresponding to the expected QC parameter according to the control target list with the corresponding lot No.

5. According to the target list of the corresponding lot No., enter the target and limits into the textboxes of the parameters to be included in the QC run.

   You can set the display form of the limits or the calculation method of the limits among the preset values. Please refer to ***9.2.2.2 Setting Limits*** for the setting methods.

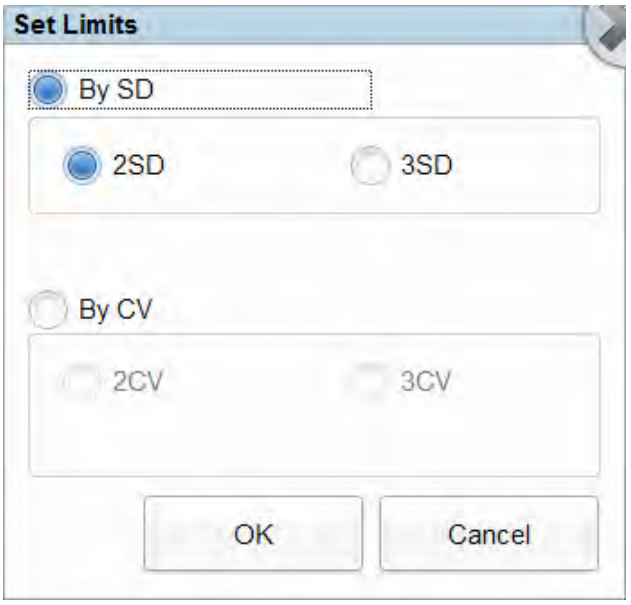
6. Click the **Save** button to save all the settings of the QC.

9.2.2.2 Setting Limits

You can take the following steps to adjust the display format of the limits and the calculation method of the preset limits.

1. Click **QC** to access the QC interface.
2. Click **QC Settings** to enter the **QC Settings** interface.
3. Click **Set Limits**.

   A dialog box will pop up as shown below.

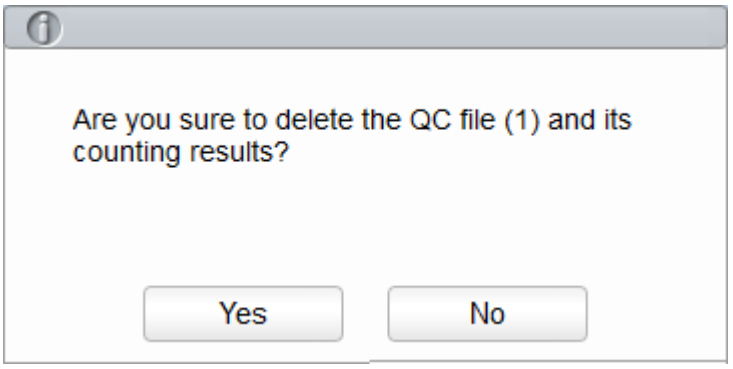


4. Select **By SD** or **By CV** according to the actual needs.
   - If **By SD** is selected, the limits will be displayed in form of absolute value.
     Click **2SD** or **3SD** to select either double or triple standard deviation to be the limits.
   - If **By CV** is selected, the limits will be displayed in form of percentage.
     Click the **2CV** or **3CV** to select either double or triple coefficient of variation to be the limits.
5. Click **OK** to save all the settings for the limits.

9.2.2.3 Deleting QC File

If you want to delete the QC files which will not be used any more, please take the following steps:

1. Click **QC** to access the QC interface.
2. Click **QC Settings** to enter the **QC Settings** interface.
3. Select the QC file to be deleted, and click **Delete**.
   A dialog box will pop up as shown below.



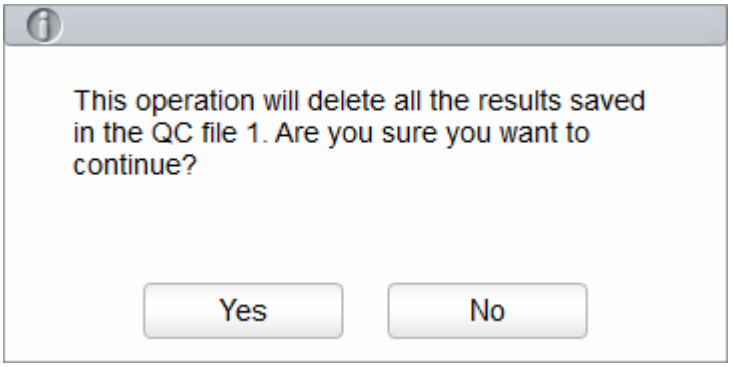
4. Click **Yes**.
   All selected QC files together with their QC results will be completely deleted.

9.2.2.4 Clearing QC results

If you want to delete QC results of a specified file, please take the following steps:

1. Click **QC** to access the QC interface.
2. Click **QC Settings** to enter the **QC Settings** interface.
3. Select the QC file in which the QC results are expected to be deleted, and click **Clear**.

   A dialog box will pop up as shown below.



4. Click **Yes**.

   QC results in the selected QC file will be deleted. As shown below. The value in the **Existing/Total** column will be restored to the initial value.

File No.	Lot No.	Level	Exp. Date	QC Mode	QC Sample ID	Editor	Existing / Total
1	L001	Normal	2015/12/30	Whole ...	QC001	admin	0/500
2	L002	Normal	2015/12/30	Whole ...	QC002	admin	0/500

9.2.3 Quality Control Analysis

After completing the QC settings, you can choose one of the following two modes according to the selected QC mode to run the quality control samples:

- Completing QC analysis in the **QC Analysis** interface
- Completing QC analysis in the **Sample Analysis** interface

9.2.3.1 Completing QC Analysis in the QC Analysis 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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

WARNING

- The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
- Collection tubes broken may cause personal injury and/or biohazard. Be sure to place the collection tubes in the right adapter before running, otherwise, the collection tubes may be broken and cause biohazard.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see a doctor.

CAUTION

- Running quality controls in presence of errors may lead to incorrect analysis results. If you see the error alarms when running the quality controls, please stop and resume the analysis until the errors are removed.
- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
- Sample clump may lead to incorrect analysis results. Check if clump exists before running the controls; if it does, handle it as per the related laboratory procedures.

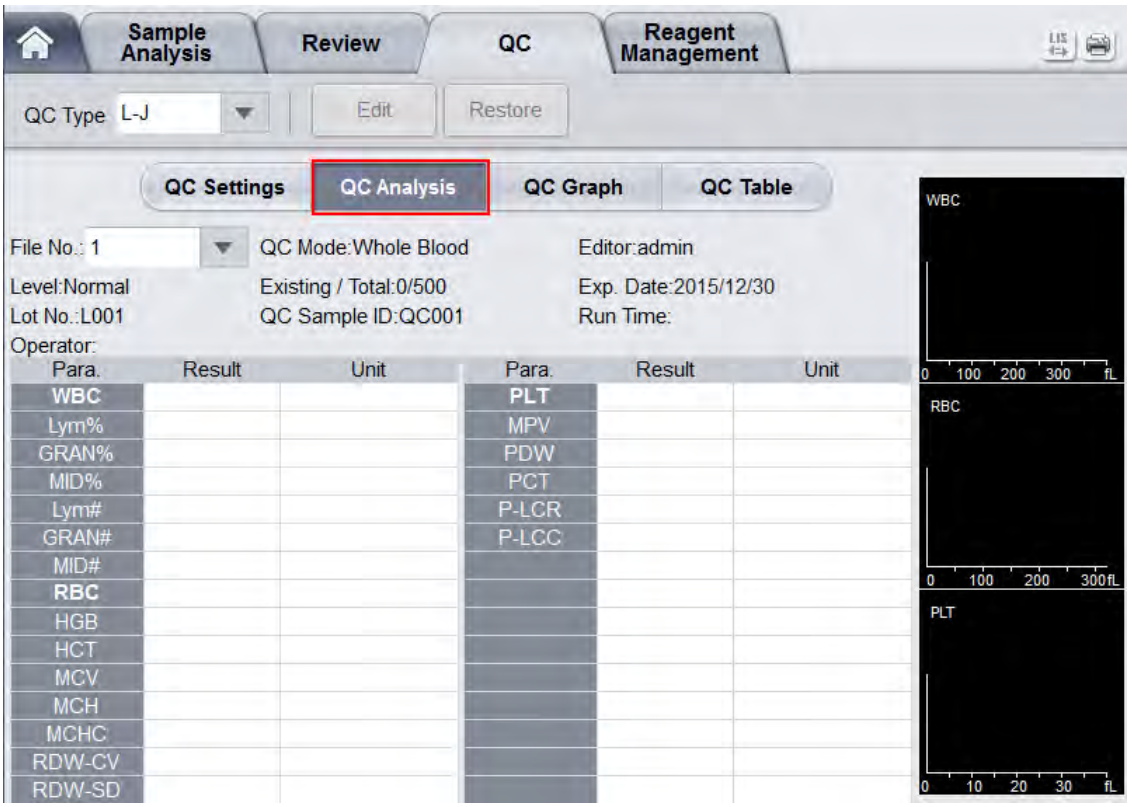
NOTE

- You should only use the MR‑specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents. Using other controls may lead to incorrect QC results.
- Before being used for analysis shake well the controls that have been settled for a while.
- Be sure to use the MR‑specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.

After completing the QC settings, users can perform the QC analysis in the **QC Analysis** interface Specific steps are shown below:

1. Click **QC** to access the QC interface.
2. Click **QC Analysis** and enter the QC analysis interface as shown in Figure 9-3.

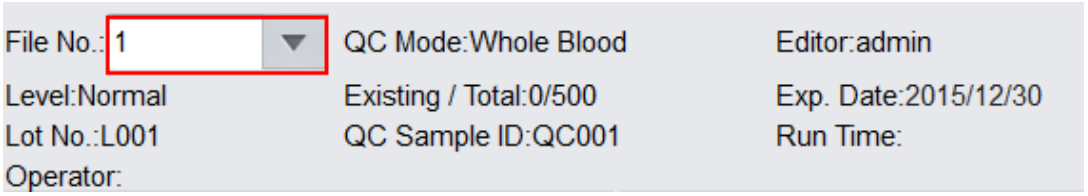
Figure 9-3 QC Analysis



3. Select the QC file No. to be run.

   The screen displays the corresponding file information, as shown in Figure 9-4.

Figure 9-4 QC File Information



4. Be sure that the level of the control to be run is the same with the current QC file, and the control to be run is not expired.
5. Prepare the controls according to the set control mode and control instructions.

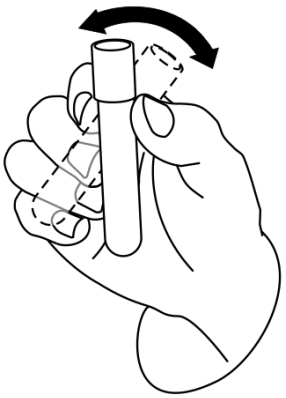
   Predilute the controls with reference to ***6.5 Sample Collection and Handling*** and get diluted QC samples if the QC mode is **Predilute**.

NOTE

Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

6. Shake the prepared control as shown below to mix it well.

Figure 9-5 Mixing the Controls



7. In the ready for counting state (namely, the indicator light of the main unit is green), place the controls under the sample probe where the probe can aspirate the well mixed sample.
8. Press the aspirate key and start running the controls.
9. Upon the completion of the aspiration, you'll hear a beep and you can remove the controls.

   When the running of QC analysis is complete, the QC results will be displayed in the current screen (as shown in Figure 9-6) and saved in the QC file automatically.

Figure 9-6 QC Analysis Results

10. Perform the above procedures to continue running the controls if necessary.

NOTE

- If the QC file is outdated, its valid period will be displayed in red.
- "↑" or "↓" alarm symbol will be displayed next to the results with deviations exceeding the set limits.

9.2.3.2 Completing QC Analysis in the Sample Analysis 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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

WARNING

- The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
- Collection tubes broken may cause personal injury and/or biohazard. Be sure to place the collection tubes in the right adapter before running, otherwise, the collection tubes may be broken and cause biohazard.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see a doctor.

CAUTION

- Running quality controls in presence of errors may lead to incorrect analysis results. If you see the error alarms when running the quality controls, please stop and resume the analysis until the errors are removed.
- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
- Sample clumps may lead to incorrect analysis results. Check if clump exists before running the controls; if it does, handle it as per the related laboratory procedures.

NOTE

- You should only use the MR-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents. Using other controls may lead to incorrect QC results.
- Before being used for analysis shake well the controls that have been settled for a while.
- Be sure to use the MR-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- If the blood-sample mode is **Predilute**, then a reminder of predilute counting will pop up if the user presses the aspirate key to perform the counting. To close the prompt, please refer to ***5.9 Auxiliary Settings.***

After completing the QC settings, you can place the controls among the daily samples and perform analysis together in the **Sample Analysis** interface. After the analysis is completed, the system will

store the results to the QC file with the corresponding ID.

Specific steps for performing QC analysis in the **Sample Analysis** interface are as follows:

1. Preparing the controls as per the set QC mode and instructions for the controls.

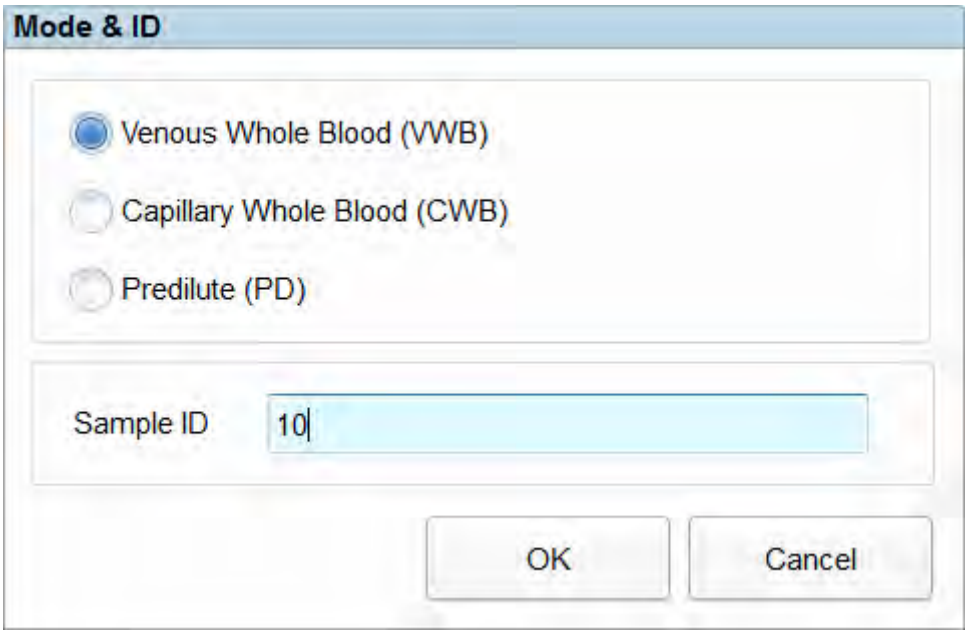
   Prediluting the controls with reference to ***6.5 Sample Collection and Handling*** to get diluted QC samples if the QC mode is **Predilute**.

NOTE

Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

2. Click **Mode & ID** in the **Sample Analysis** screen.

   A dialog box will pop up as shown below.



3. Enter the set **QC Sample ID** in the **Sample ID** edit box (other options can be ignored).

   Refer to ***9.2.2.1 Entering QC Information*** for the setting of the **QC Sample ID**.

4. Well mix the prepared controls.
5. In the ready for counting state (namely, the indicator light of the main unit is green), place the controls under the sample probe where the probe can aspirate the well-mixed controls.
6. Press the aspirate key and start running the controls.
7. Upon the completion of the aspiration, you'll hear a beep and you can remove the controls.

   When the running of the controls is complete, the QC results will be saved in the QC file automatically.

8. Perform the above procedures to continue running the controls if necessary.

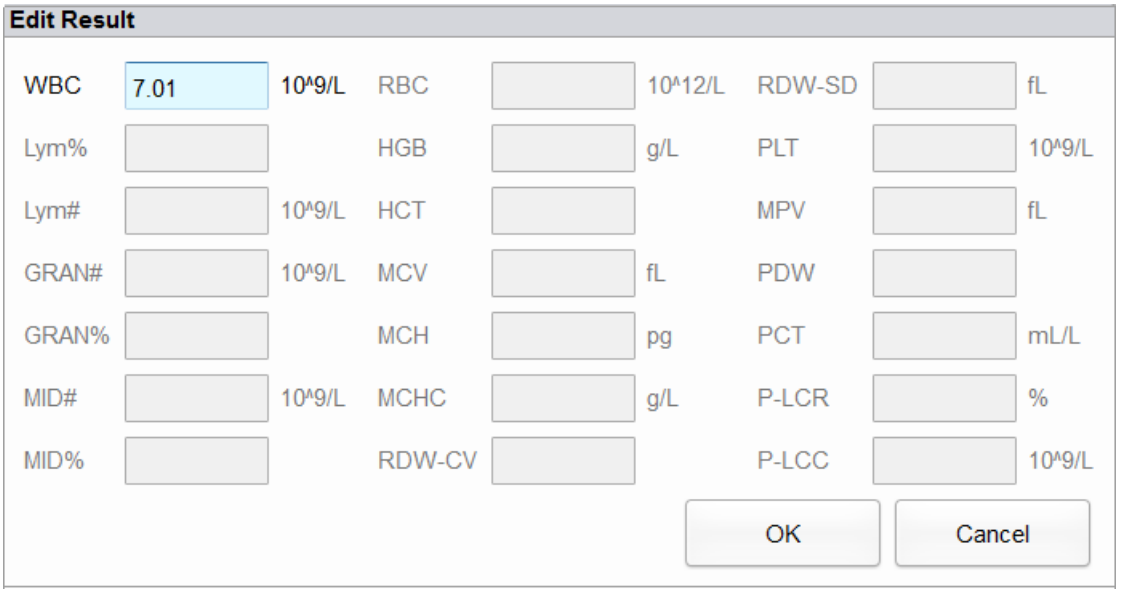
NOTE

- If the QC file is outdated, its valid period will be displayed in red.
- "↑" or "↓" alarm symbol will be displayed next to the results with deviations exceeding the set limits.

9.2.3.3 Edit Result

Clicking **Edit** will allow you to edit the QC analysis result after the QC analysis is performed. See Figure 9-7.

Figure 9-7 Editing QC Results



The edited data will be marked with an **E**. As shown below.

Para.	Result	Unit
WBC	E 7.01	10^3/uL

9.2.3.4 Restore Result

Clicking **Restore** will allow the QC analysis results to be restored to the original results. After the data is restored, the **E** mark will disappear.

9.2.4 QC Result Review

After running controls, you can review the QC results in the following two forms:

- QC Graph
- QC Table

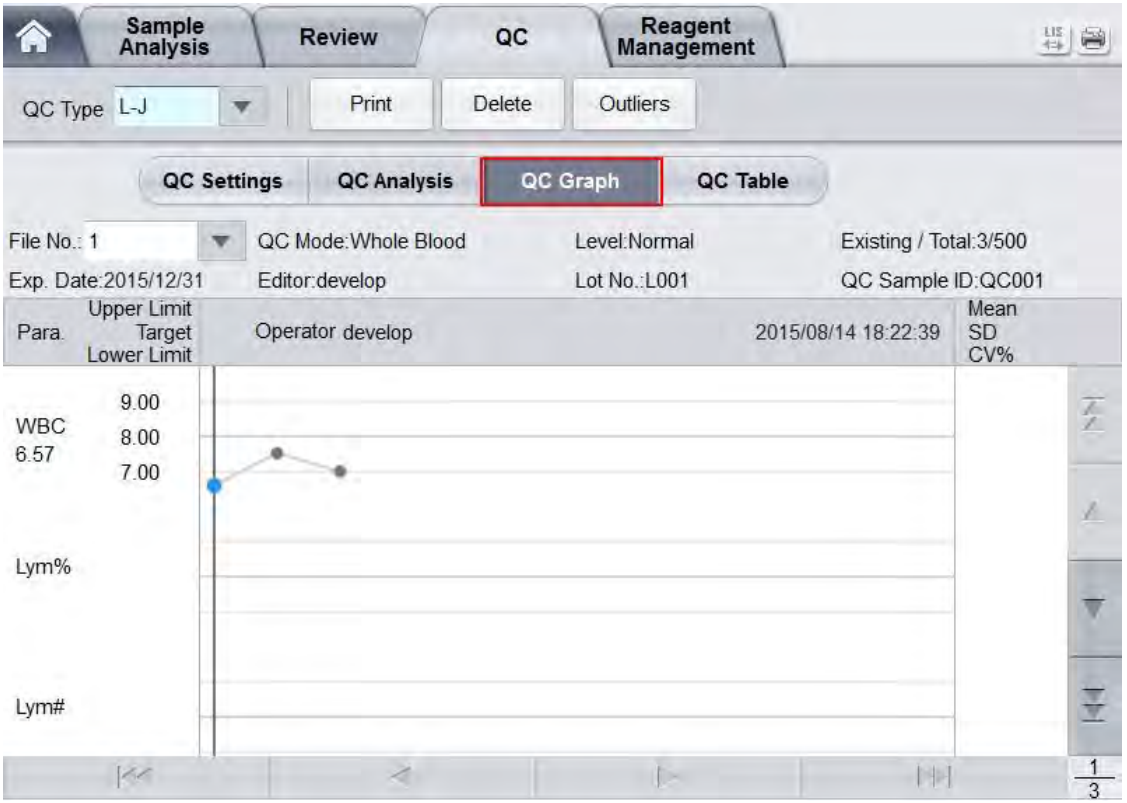
9.2.4.1 Graph

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

You can review the result of L-J QC graph as per the following steps.

1. Click **QC** to access the QC interface.
2. Click **Graph** and enter the interface as shown in Figure 9-8.

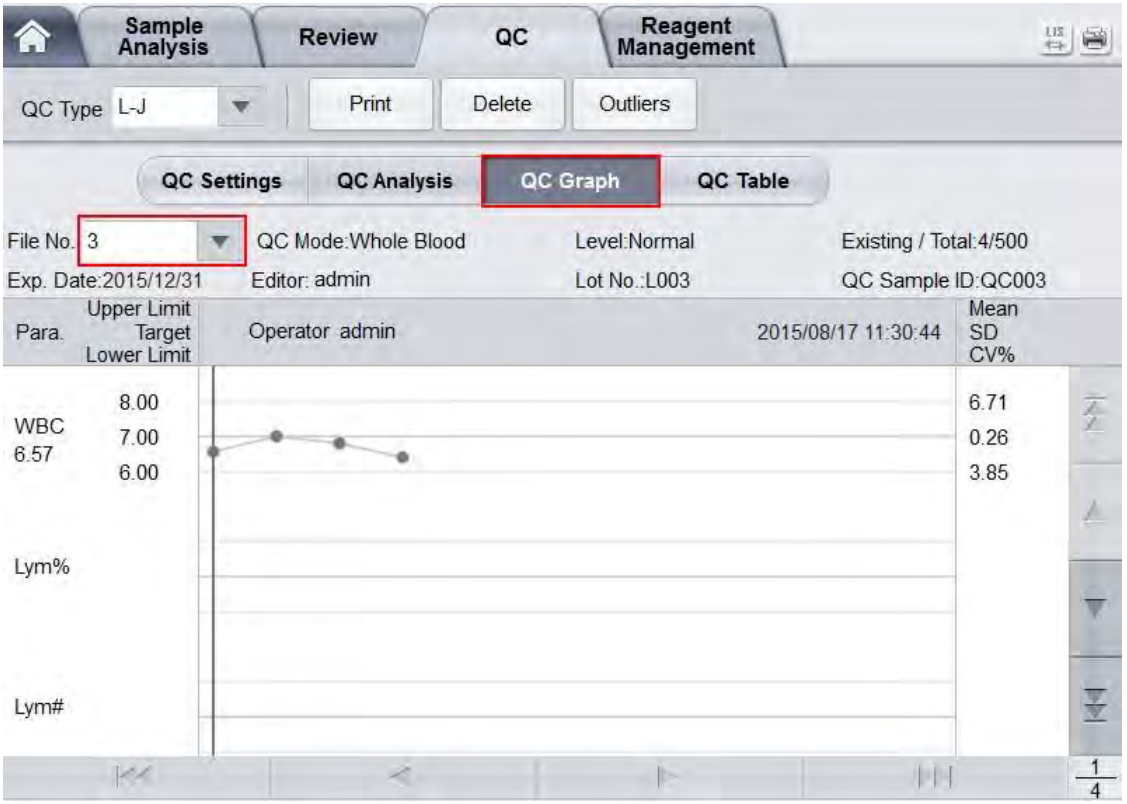
Figure 9-8 L-J QC Graph Interface



3. Select the QC file No. you want to review.

   The screen will display the corresponding information and the graph. See Figure 9-9.

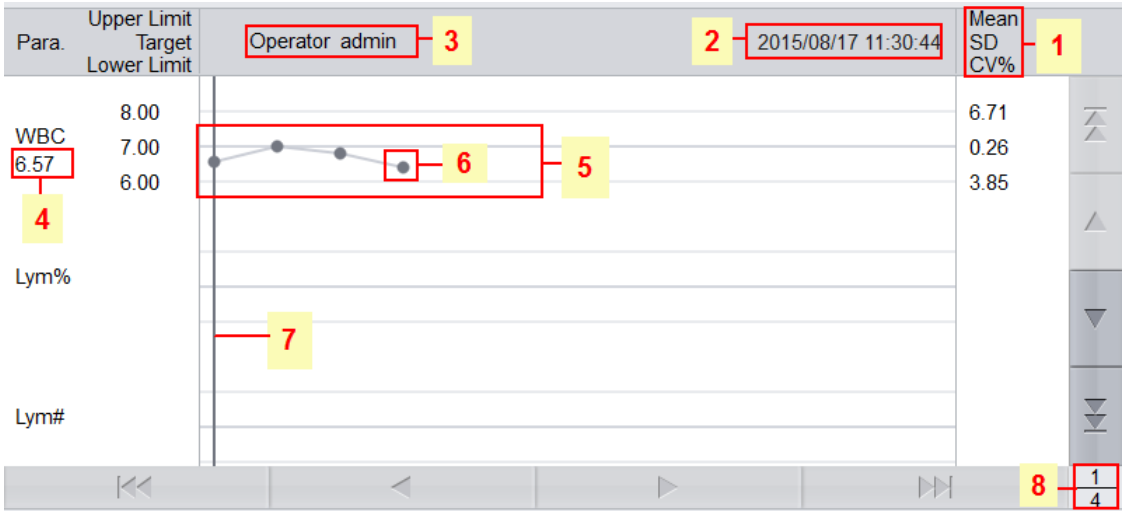
Figure 9-9 QC Graph



4. Click the buttons at the right side of the QC graph, then you can browse QC graphs of different parameters; click the buttons at the bottom of the QC graph, then you can browse all QC results.

Introduction to the Graph Interface

Figure 9-10 L-J QC Graph Interface



Interface Description:

1 - The Mean, SD and CV% of all the QC results of each parameter in the current graph.

2 - The saving date and time of the QC points located on the gray line

3- The operator who run the QC analysis and obtained the QC points located on the gray line.

4 - The QC results of the parameters that correspond to the QC points located on the gray line.

5 - The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest. The QC points are connected by a line to illustrate the distribution trend.

6 - The QC point corresponds to each QC result. Only the selected QC point displays its value under the parameter. The black QC point indicates the value is within the limit; the red QC point indicates the value is out of the limit.

7 - When you clicking a QC point in the graph, the QC points of other parameters saved together with this one will be marked by a gray line.

8 - The relative position of the QC point located on the gray line and the total QC points saved currently.

NOTE

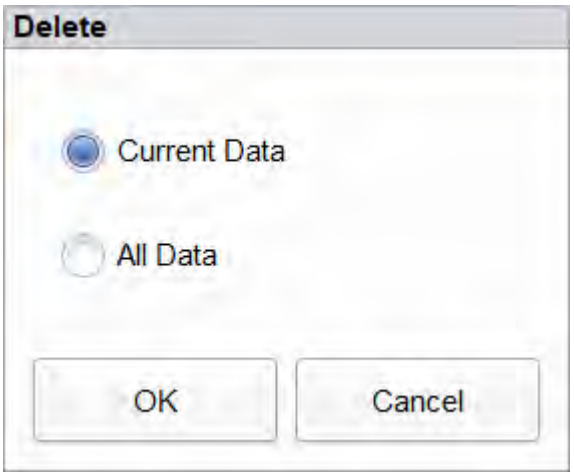
The outliers are excluded from the calculation of **Mean**, **SD** and **CV%**.

Delete

The administrator can delete the QC results by the following steps:

- Delete a single QC result
  a. Move the grayline to the desired QC result, and click **Delete**.
  b. Select **Current Data** in the pop-up dialog box as shown in Figure 9-11.

Figure 9-11 Deleting Current QC Data (QC Graph)

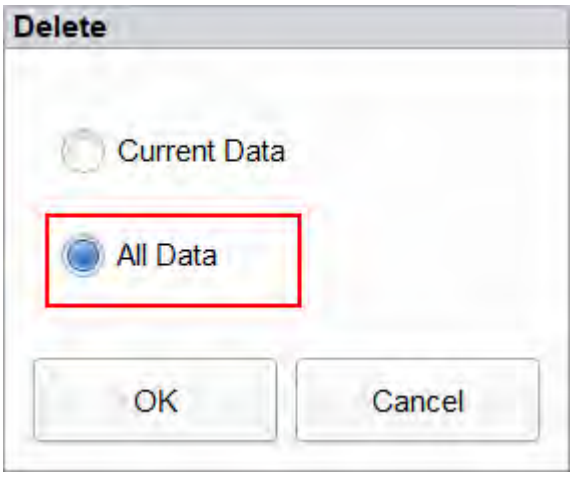


c. Click **OK**.

- Deleting all the QC results in the current QC file

  Click Delete, select **All Data** in the pop-up dialog box, then click **OK**. See Figure 9-12.

Figure 9-12 Deleting all QC Data (QC Graph)



Entering the Reasons for the Outliers

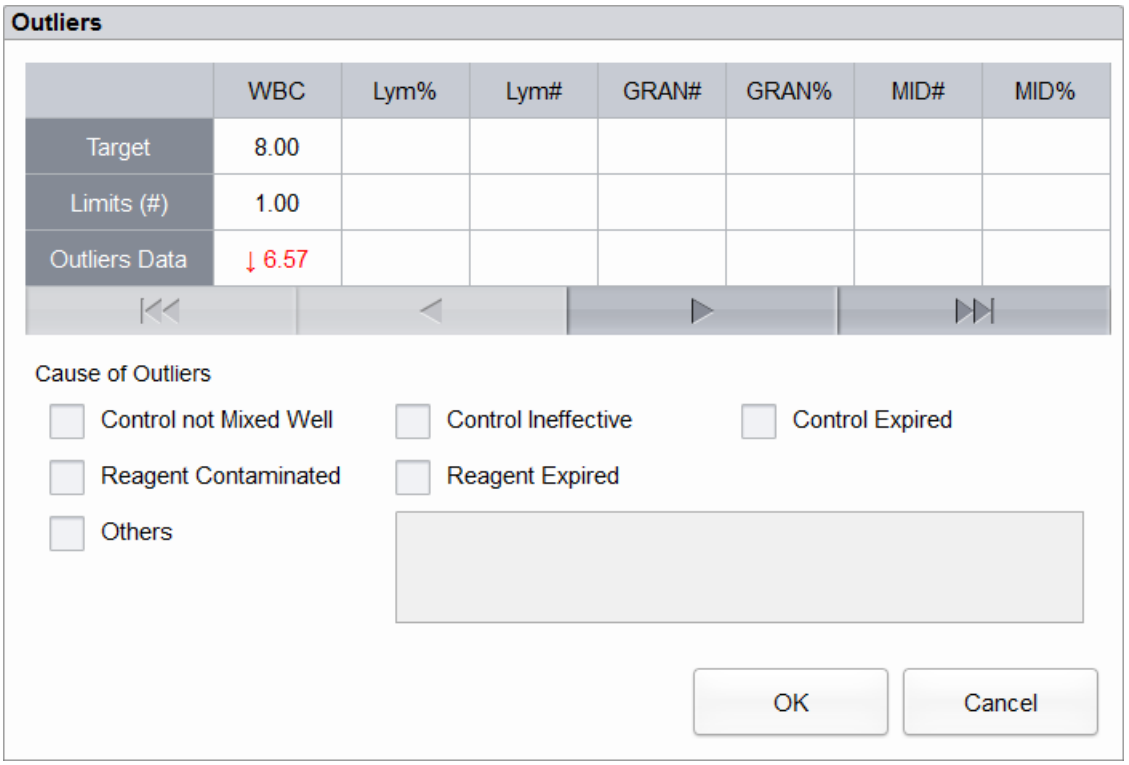
Do as follows to enter the reasons for the outliers:

1. Move the gray line to the desired QC point, and then click **Outliers**.

   The pop-up window displays the QC results, reference values and deviation limits of all parameters corresponding to the gray line as shown in Figure 9-13.

   The QC results exceeding the limit will be displayed in red.

Figure 9-13 Enter Cause of Outliers



2. You can select the reason from the given ones or manually enter the reasons (up to 200 characters) into the textbox after selecting Others.
3. Click **OK** to save the reasons for the outliers and exit.

NOTE

If you enter the reason for the group of QC points whose results are actually within the limits, then their corresponding QC data both in the QC Graph and QC Table will be displayed in red. And the data will return in black if you cancel the reason and then save the changes.

Print

You can have the QC data of the current page or all QC data in the QC file printed by clicking the **Print** button.

NOTE

The printed QC graph will not show any parameters which are not involved in the quality control.

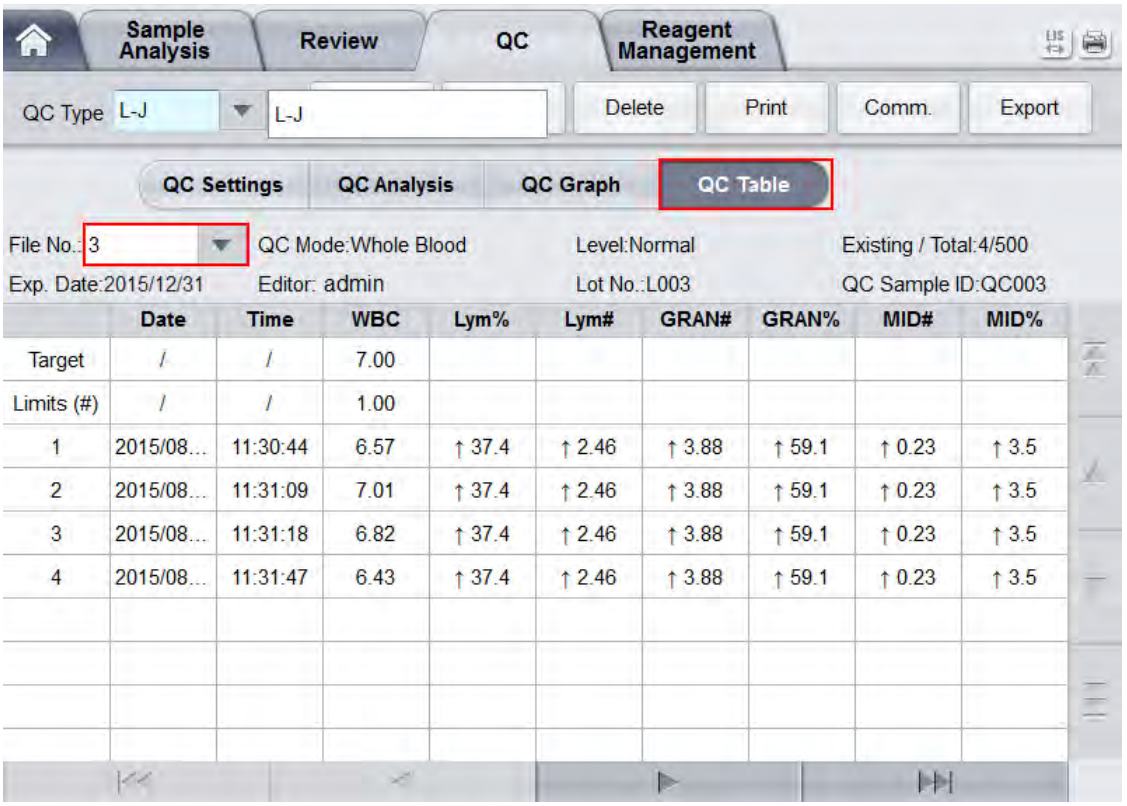
9.2.4.2 Table

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

1. Click **QC** to access the QC interface.

2. Click **QC Table** to access the interface as shown in Figure 9-14.

Figure 9-14 L-J QC Graph Interface



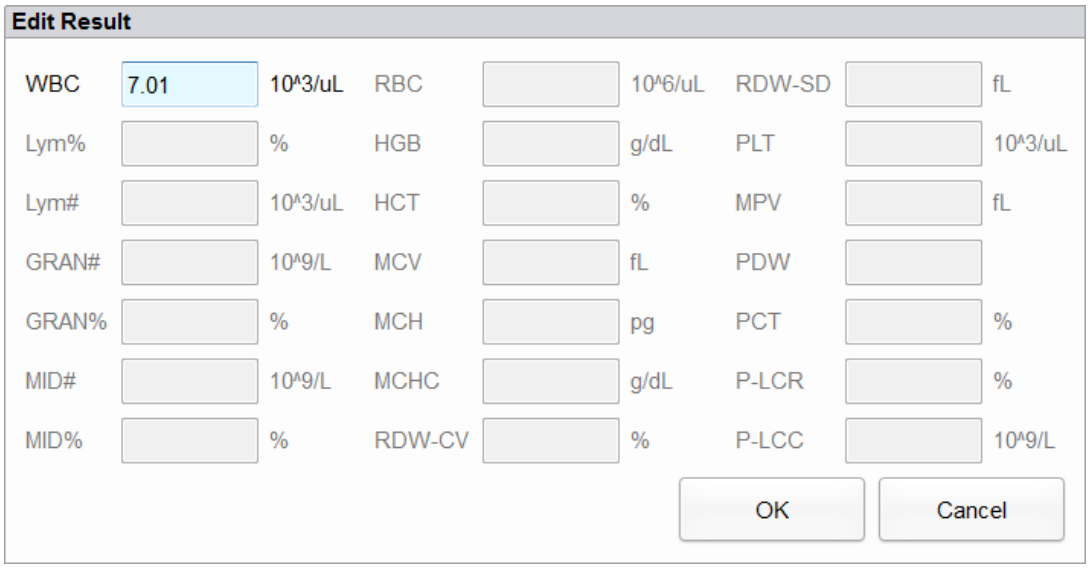
3. Select the QC file No. you want to review.

   The screen will display the corresponding information and the graph.

4. Click the buttons at the bottom of the table to browse the QC data of desired parameters; Click the buttons on the right of the table to browse the QC results.

Editing

Choose a row in the QC table and click **Edit**, then you can edit the selected QC data.



The edited data will be marked with an **E**. See Figure 9-15.

Figure 9-15 Editing QC Results

	Date	Time	WBC
Target	/	/	7.00
Limits (#)	/	/	1.00
1	2015/08...	11:30:44	6.57
2	2015/08...	11:31:09	E 7.01

Restoring

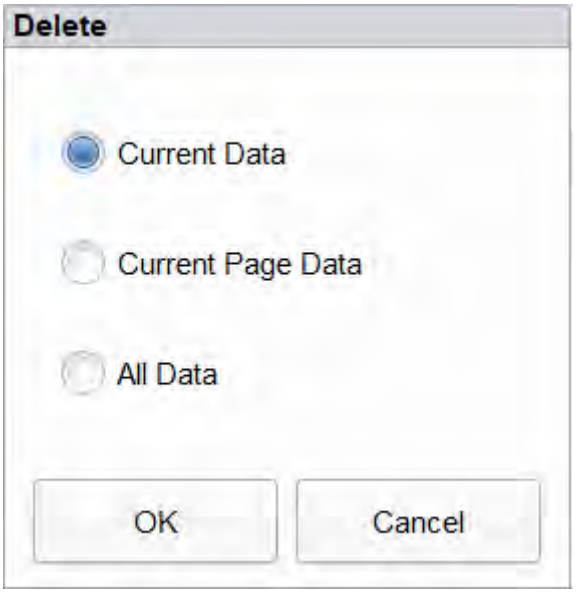
Click **Restore** to cancel the editing of the QC results. After the data is restored, the **E** mark will disappear.

Delete

With the administrator-level access, users can delete the selected QC data, QC data on the current page and all QC data.

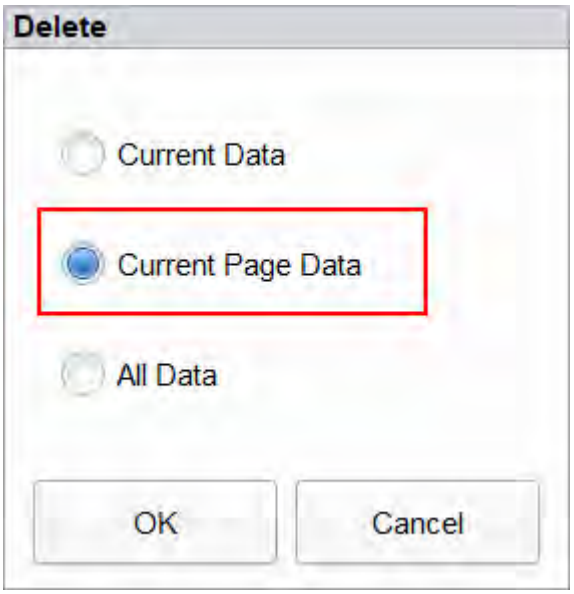
- Delete a selected QC result
  a. Click the column containing the desired QC result, and then click **Delete**.
  b. Select **Current Data** in the pop-up dialog box as shown in Figure 9-16.

Figure 9-16 Deleting Current QC Data (QC Graph)



  c. Click **OK**.
- Delete QC data on the current page
  a. Click **Delete** on the page which contains the QC results expected to be deleted.
  b. Select **Current Data** in the pop-up dialog box as shown in Figure 9-17.

Figure 9-17 Deleting all QC Data (QC Graph)



c. Click **OK**.

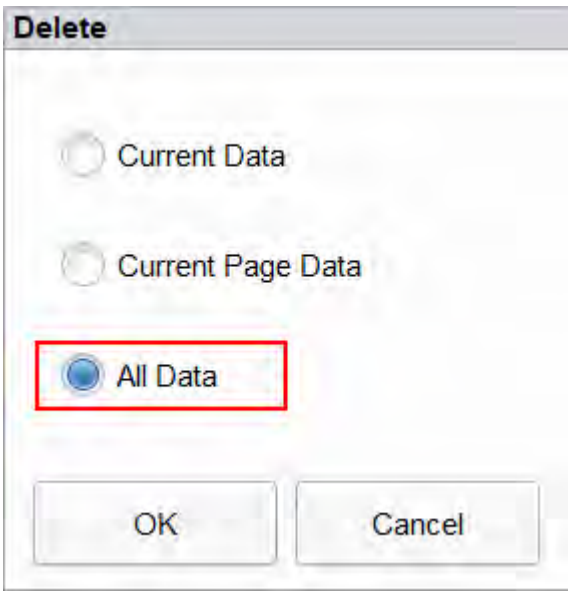
- Delete all QC results

NOTE

Please note that this operation will delete all QC results of the selected QC file and cannot be reverted!

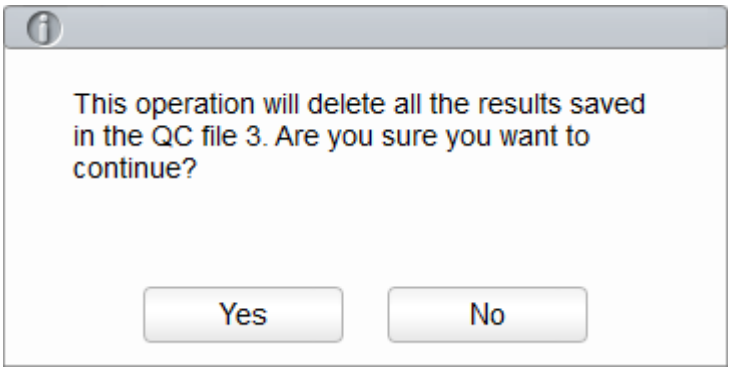
a. Click **Delete**.

b. Select **All Data** in the pop-up dialog box.



c. Click **OK**.

A dialog box will pop up as shown below.



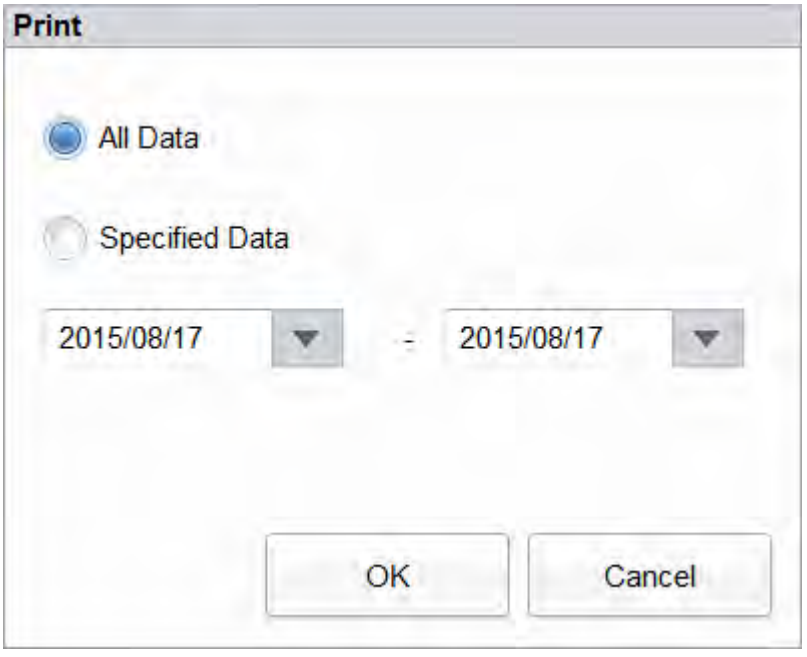
d. Click **Yes** to delete all the QC results in the current QC file.

Print

All the QC data or the data within the specified date range can be transmitted to LIS/HIS. Specific steps are shown below:

1. Select a QC file No. to be printed.
2. Click **Print**.

   A dialog box will pop up as shown below.



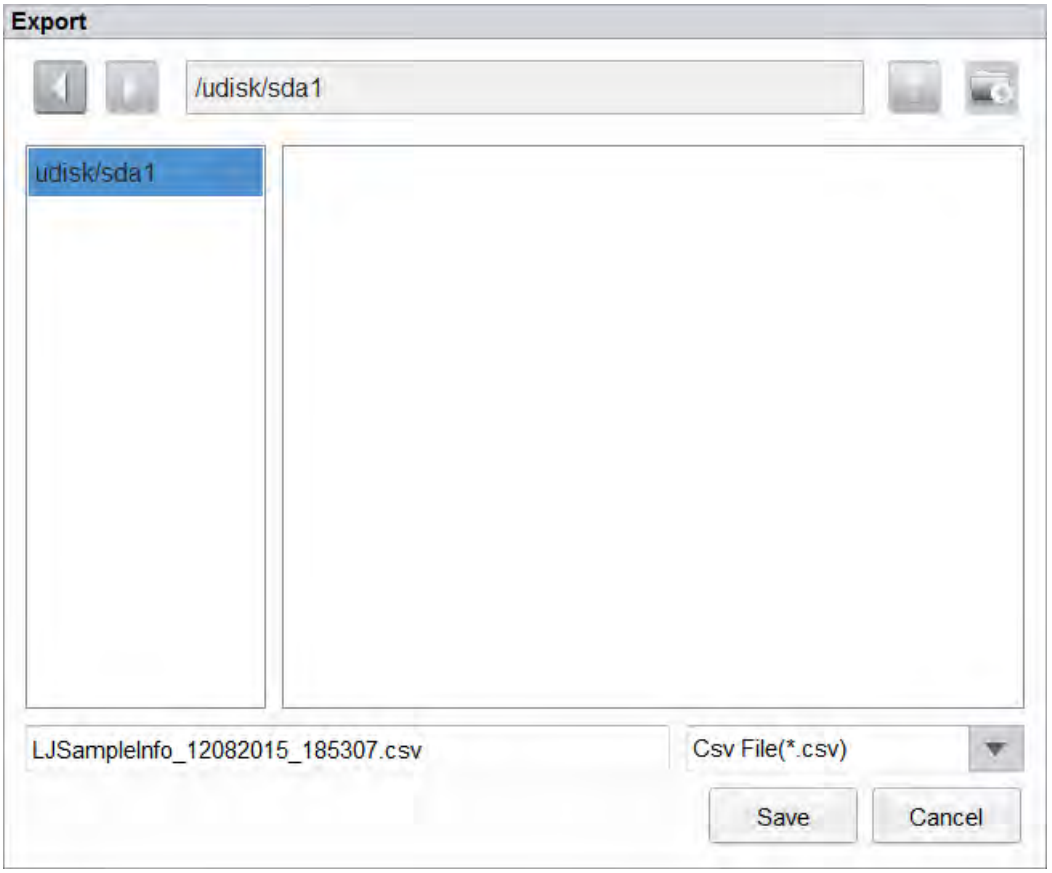
3. Select the QC data to be printed: all data or specified data.
   - Choose **All Date** to print all the QC date of the table.
   - Select **Specified Data** and set the date range in the date edit box, and QC data within the specified date range will be printed.
4. Click **OK** to print the data.

Export

If you wish to export the information and the result of the current QC file, do as follows:

1. Inset a USB flash disk in the USB interface on the machine.
2. Click **Export**.

A message box shown below will pop up.



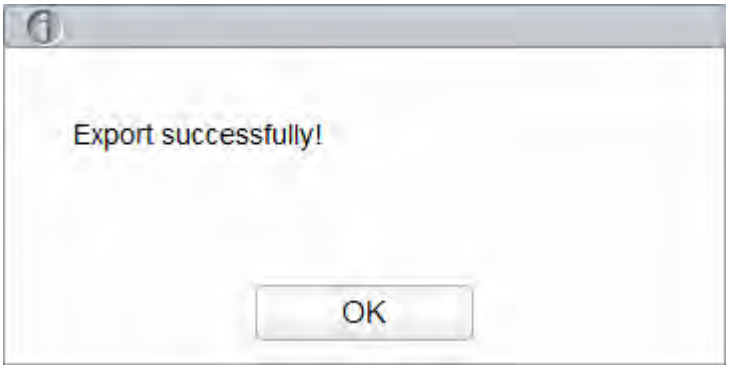
3. Select the export path, and then enter the file name.

   The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.**csv**. Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.

4. Click **Save**.

   When the export is finished, a message box as shown below will pop up.

Figure 9-18 Export successfully



5. Click **OK** to close the message box.

9.3 X-B Quality Control

9.3.1 QC Principle

The X-B analysis is a weighted moving average analysis that uses values obtained from patient samples. It uses the 3 red cell indices, MCV, MCH and MCHC to indicate the hematology instrument performance. This is QC with no controls, which is a method of performance control like QC with controls. Both methods reflect the analysis performance of the analyzer from different perspective. Thus, one method should not be replaced with the other.

It is recommended the X-B analysis be activated when the sample volume of your laboratory is greater then 100 samples per day. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices. A reference range is established by the given reference values as well as lower and upper limits for the purpose of observing the variation of QC results within the reference range.

The analyzer performs X-B QC for three parameters, MCV, MCH, and MCHC. Twenty to two hundred samples can be grouped together for X-B numerical analysis. The samples are derived from the results of normal analyzer counting, with no distinction of whole-blood or predilute mode. The analyzer can save maximum 1000 X-B QC results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest.

9.3.2 QC Settings

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

NOTE

Only users with administrator-level access can edit the L-J settings.

Perform the QC Settings before running the controls. You can complete the QC settings by entering the QC information.

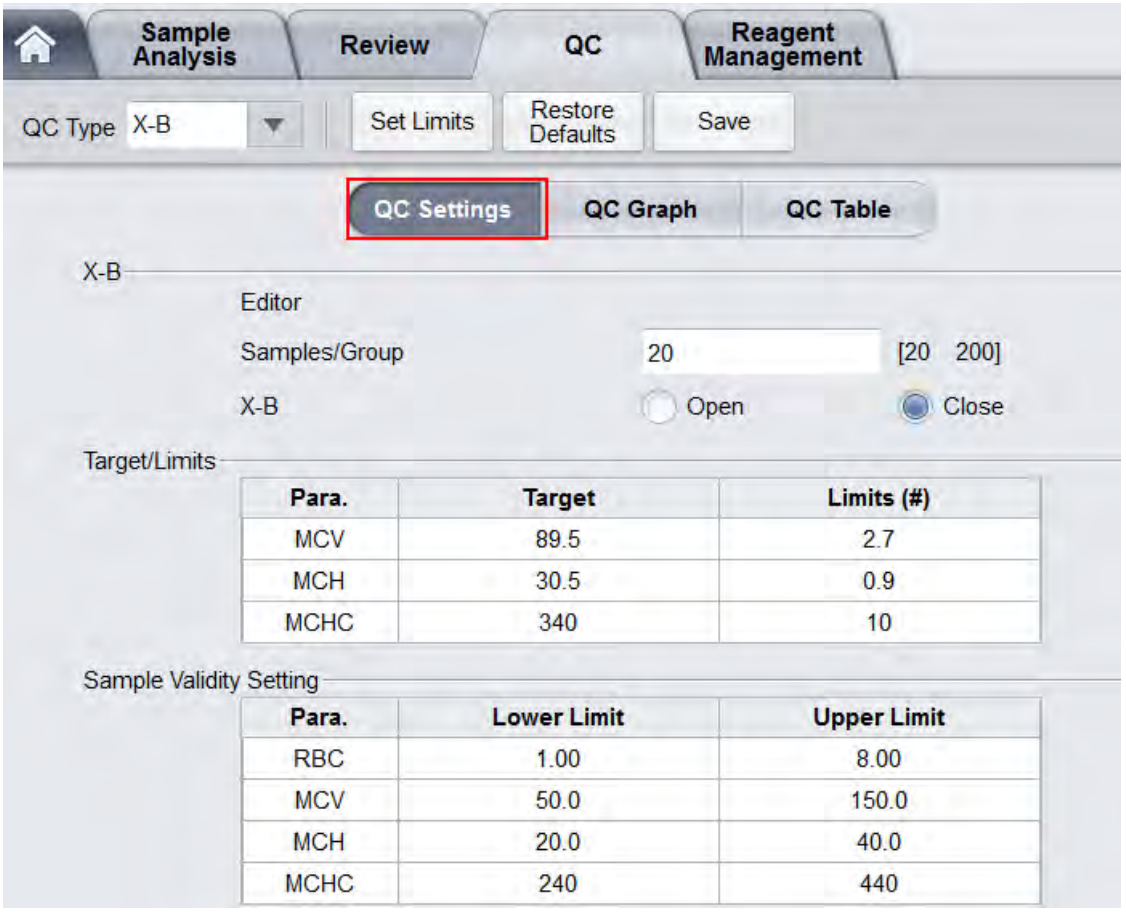
9.3.2.1 Entering QC Information

You can complete the X-B QC settings as per the following steps:

1. Click **QC** to access the QC interface.
2. Select **X-B** from the dropdown list of the **QC Type**.
3. Click **QC Settings**.

   You'll enter the QC Settings interface as shown in Figure 9-19.

Figure 9-19 X-B QC Setting



4. In the **Samples/Batch** edit box, enter the amount of samples to be included in calculating for an X-B QC point.

   The range is between 20 and 200 and the recommended value is 20.

NOTE

Once the **Samples/Batch** is changed, the number of valid sample results will be recalculated. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the value of Samples/Batch after 10 group of valid sample results have been acquired, these 10 group of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.

5. Click the **Open** button of **X-B** to open the X-B quality control.

   The samples results will be included to calculate the X-B.

6. Enter the targets and limits for the QC parameters.

NOTE

- All the targets and limits for the QC parameters must be entered.
- When first use, the default setting will provide the Initial values for the targets and limits of the three QC parameters.
- If the QC data have existed in the QC file, you are not allowed to edit the target and limits.

You can set the display form of the limits or the calculation method of the limits among the preset values. See section ***9.3.2.2 Setting Limits.***

7. Set the valid upper and lower limits for the QC parameter in **Sample Validity Setting** field.

   Setting sample validity is to set the valid range of four QC parameters, RBC, MCV, MCH and MCHC. To be incorporated into X-B QC calculation, the sample results should satisfy the validity ranges of all these four parameters.

NOTE

Once the **Samples/Batch** is changed, the number of valid sample results will be recalculated. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the value of Samples/Batch after 10 group of valid sample results have been acquired, these 10 group of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.

8. Click the **Save** button to save all the settings of the QC.

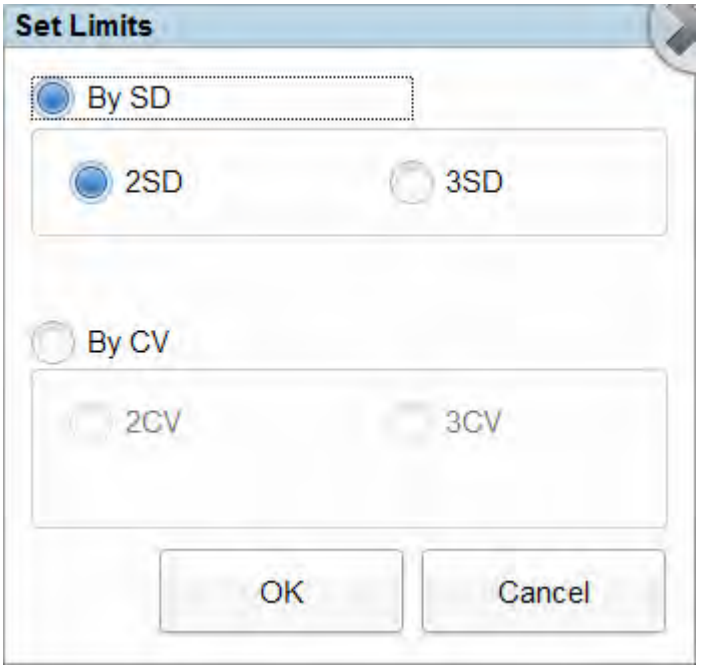
   If the entered value exceeds the acceptable range or the upper limit is lower than the lower limit, a reminder message will pop up and you will be prompted to re-enter the correct data and save the entry again.

9.3.2.2 Setting Limits

You can take the following steps to adjust the display format of the limits and the calculation method of the preset limits.

1. Click **Set Limits**.

   A dialog box will pop up as shown below.



2. Select **By SD** or **By CV** according to the actual needs.
   - If **By SD** is selected, the limits will be displayed in form of absolute value.
     Click 2**SD** or **3SD** to select either double or triple standard deviation to be the limits.
   - If **By CV** is selected, the limits will be displayed in form of percentage.
     Click the **2CV** or **3CV** to select either double or triple coefficient of variation to be the limits.

3. Click **OK** to save all the settings for the limits.

9.3.2.3 Restoring Defaults

In QC setting, click **Restores Defaults** button to restore the parameter reference values, limits and sample validity to the default settings.

NOTE

- If the QC data have existed in the QC file, you are not allowed to restore the parameters.
- Clicking **Restores Defaults** can only store the default settings of **Target**, **Limits** and **Sample Validity Setting**, while **Samples/Group**, X-B QC switch and limit settings cannot be restored.

9.3.3 Quality Control 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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

After the QC settings, the analyzer will automatically start the X-B QC analysis.

After every 20~200 results (determined by the setting) are obtained, the system will perform the X-B calculation once automatically. You can review the result in X-B graph or X-B table.

In X-B QC, sample results conforming to any of the following conditions will be considered as invalid and can not be used in the QC calculation.

- Sample results exceeding the linearity range
- Background results
- Sample results not conforming to the **Sample Validity Setting**
- QC data for other QC programs (such as L-J QC)
- Calibration data
- Results generated while there are errors which could affect the accuracy of the results (insufficient aspiration volume or clogging for example).

9.3.4 QC Result Review

After running controls, you can review the QC results in the following two forms:

- QC Graph
- QC Table

9.3.4.1 Graph

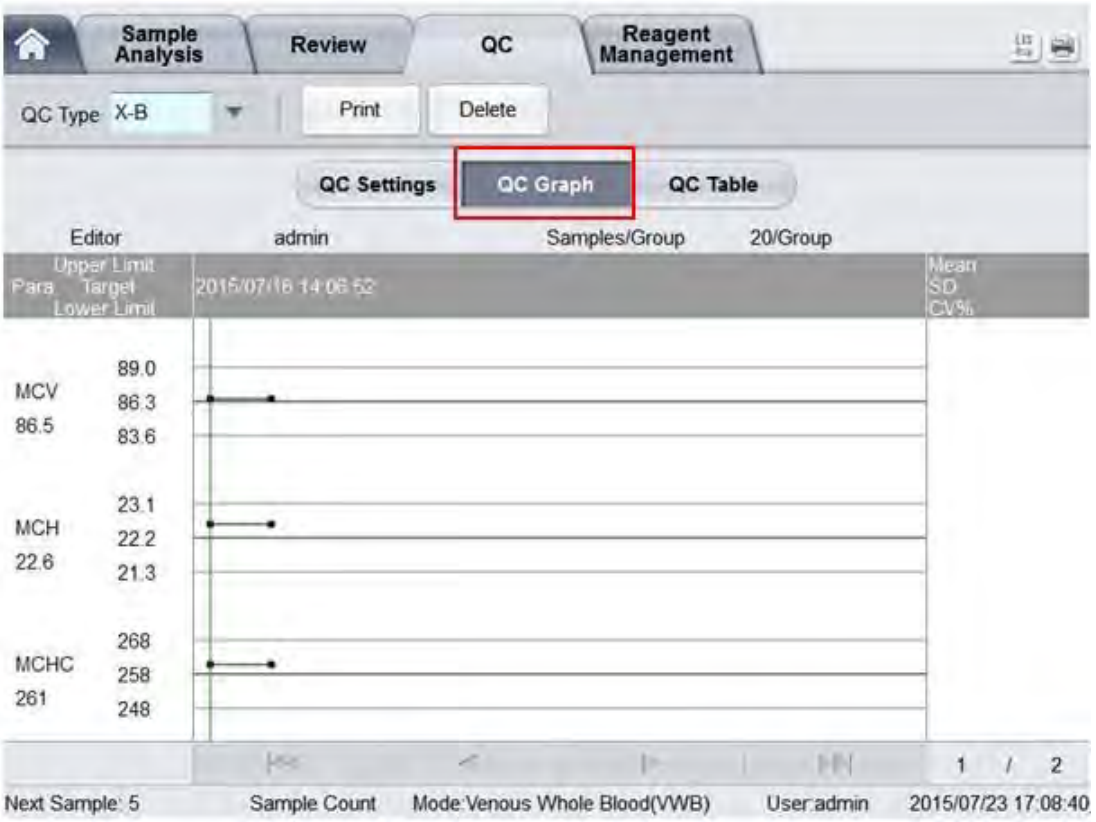
All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

Access the X-B QC Graph interface by taking the following steps:

1. Click **QC** to access the QC interface.
2. Select X-B from the dropdown list of the **QC Type**.
3. Click **Graph**.

   The X-B QC Graph interface will be displayed. See Figure 9-20.

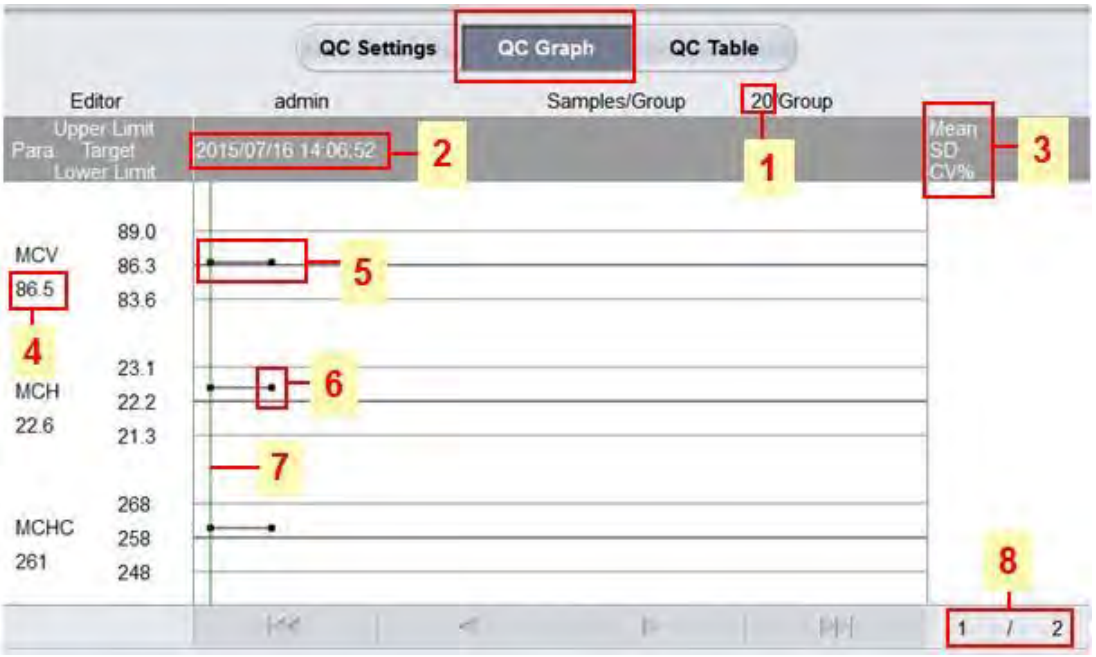
Figure 9-20 QC Graph



4. You can also drag the scroll bar down to the graph horizontally to browse all the QC results.

Introduction to the Graph Interface

Figure 9-21 X-B QC Graph



1 - The amount of samples included in calculating for each QC point.

2 - The saving date and time of the QC points located on the green line

3 - The Mean, SD and CV% of all the QC results of each parameter in the current graph.

4 - The QC results of the parameters that correspond to the QC points located on the green line.

5 - The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest. The QC points are connected by a line to illustrate the distribution trend.

6 - The QC point corresponds to each QC result. Only the selected QC point displays its value under the parameter. The black QC point indicates the value is within the limit; the red QC point indicates the value is out of the limit.

7 - When you clicking a QC point in the graph, the QC points of other parameters saved together with this one will be marked by a green line.

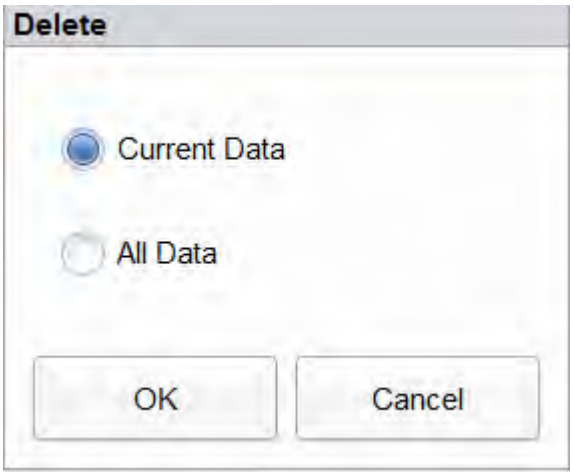
8 - The relative position of the QC point located on the green line and the total QC points saved currently.

Delete

The administrator can delete the QC results by the following steps:

- Delete a single QC result
  a. Move the green line to the desired QC result, and click **Delete**.
  b. Select **Current Data** in the pop-up dialog box as shown in Figure 9-22.

Figure 9-22 Deleting Current QC Data (QC Graph)

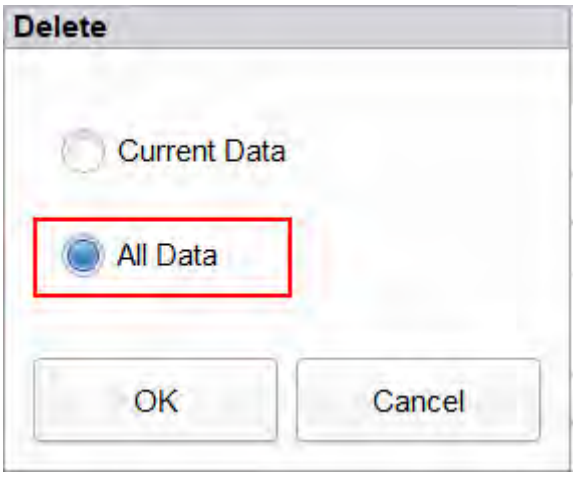


c. Click **OK**.

- Deleting all the QC results in the current QC file

  Click **Delete**, select **All Data** in the pop-up dialog box, and then click **OK**. See Figure 9-23.

Figure 9-23 Deleting all QC Data (QC Graph)



Print

Click the **Print** button to print the QC table.

9.3.4.2 Table

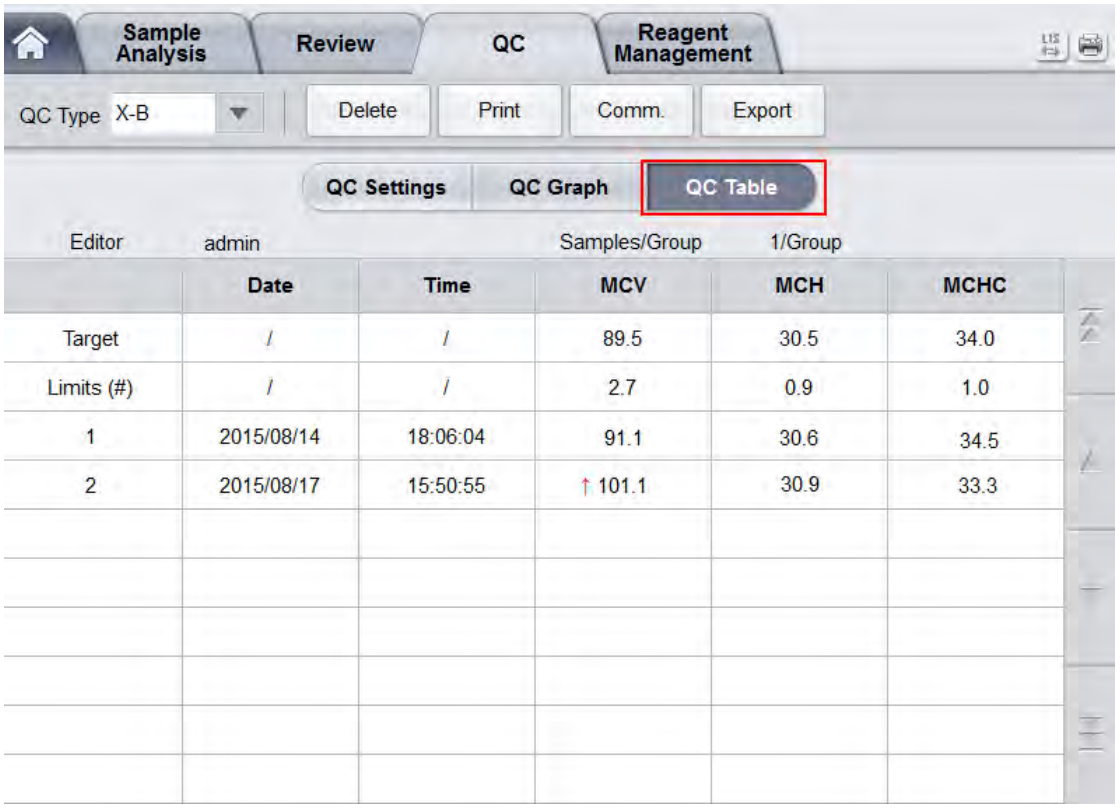
All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

Access the X-B QC Graph interface by taking the following steps:

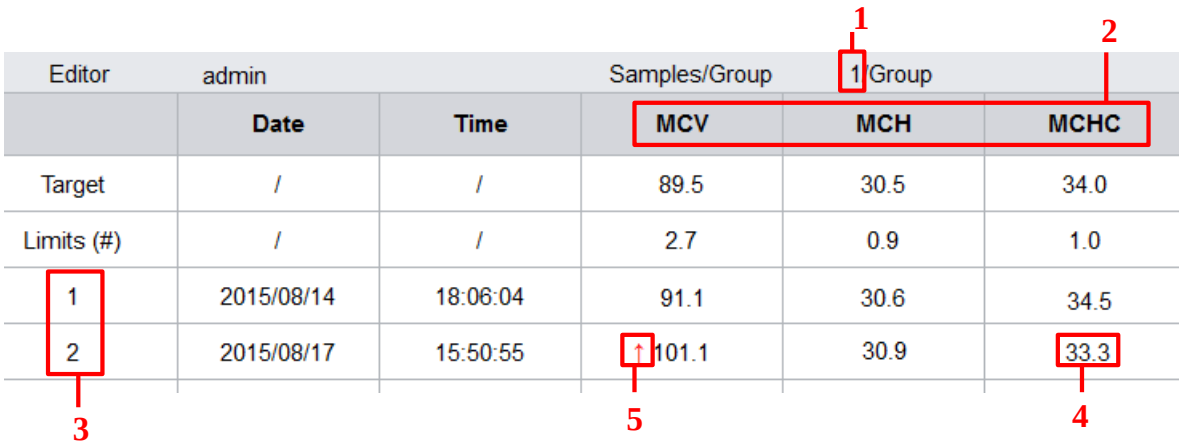
1. Click **QC** to access the QC interface.
2. Select X-B from the dropdown list of the **QC Type**.
3. Click **QC Table**.

The X-B QC table interface will be displayed. See Figure 9-24.

Figure 9-24 QC Table



Introduction to the QC Table Interface



1 - The amount of samples included in calculating for each QC point.

2 - QC parameters (displayed in the same order as the **Graph** screen)

3 - The No. of the QC result saved in the QC file (arranged from left to right in the order that from the earliest to the latest)

4 - QC Result. The value of the QC result is the X-B result of each batch of samples.

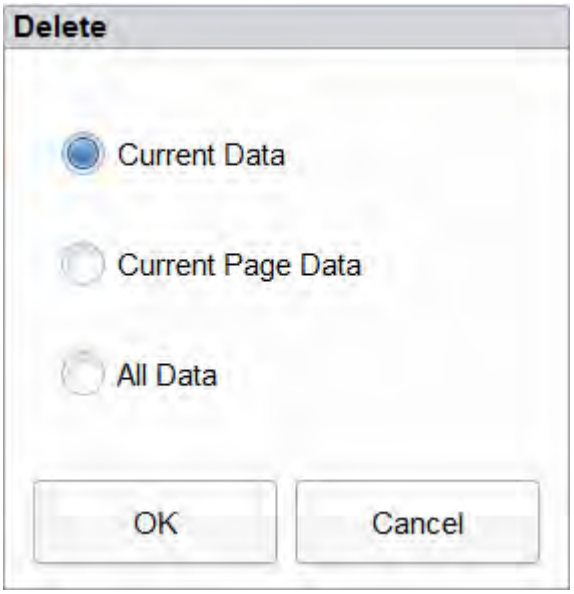
5 - QC flag: The flag ↑ or ↓ will be used to prompt the result that out of the limits

Delete

With the administrator-level access, users can delete the selected QC data, QC data on the current page and all QC data.

- Delete the selected QC data
  a. Choose the desired QC result, and then click **Delete**.
  b. Select **Current Data** in the pop-up dialog box as shown in Figure 9-25.

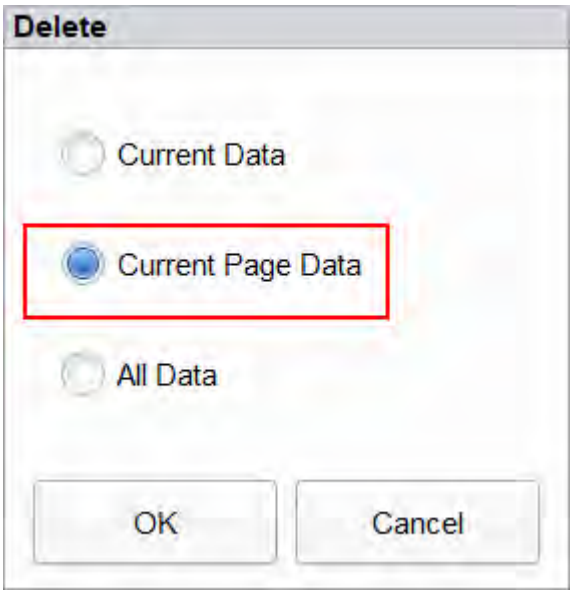
Figure 9-25 Deleting Current QC Data (QC Graph)



  c. Click **OK**.

- Delete current page QC data
  a. Click **Delete** on the page which contains the QC results expected to be deleted.
  b. Select **Current Page Data** in the pop-up dialog box as shown in Figure 9-26.

Figure 9-26 Deleting all QC Data (QC Graph)



  c. Click **OK**.

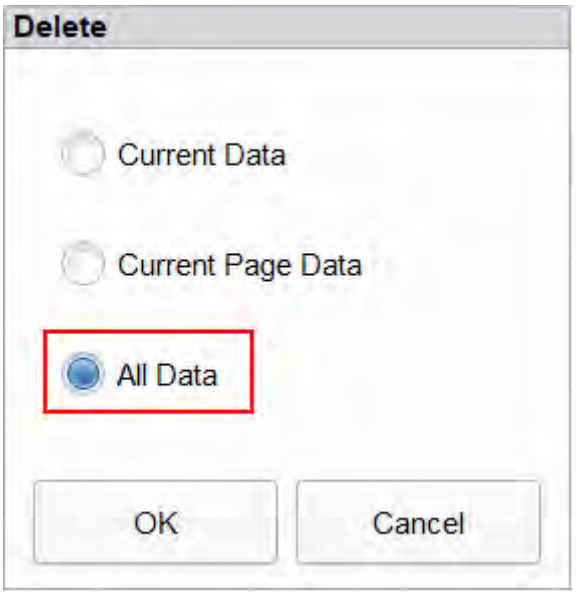
- Delete all QC data

NOTE

Please be careful to perform this operation as it will delete all QC data of the selected QC file.

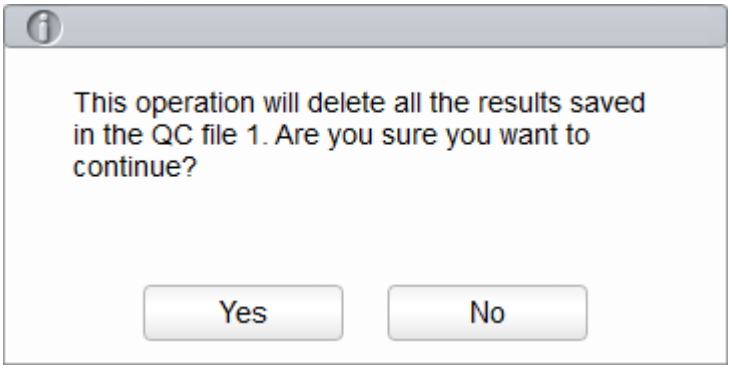
a. Click **Delete**.

b. Select **All Data** in the pop-up dialog box.



c. Click **OK**.

A dialog box will pop up as shown below.



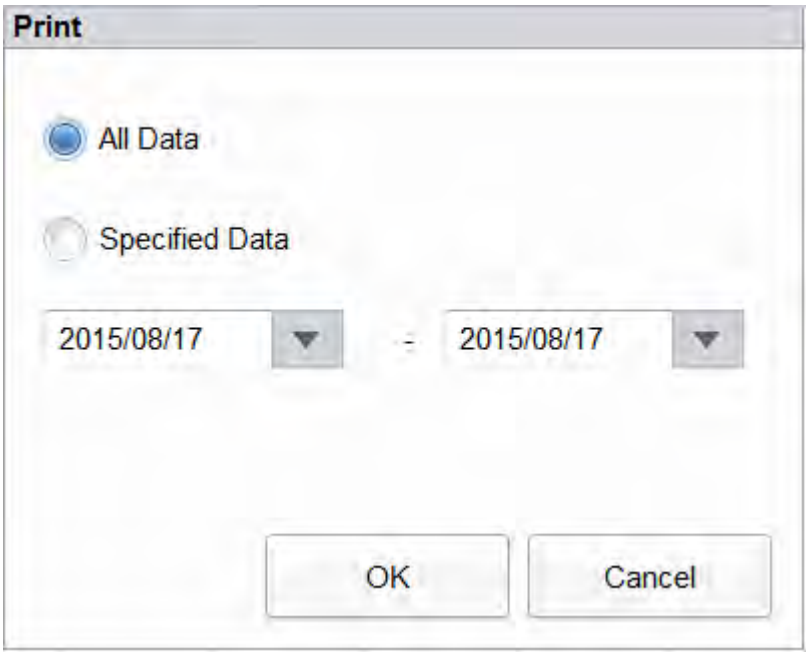
d. Click **Yes** to delete all data of the current QC file.

Print

You can print all the QC data or the data within the specified date range of the selected QC file. Specific steps are shown below:

1. Select a QC File No. to be printed.
2. Click **Print**.

   A dialog box will pop up as shown below.



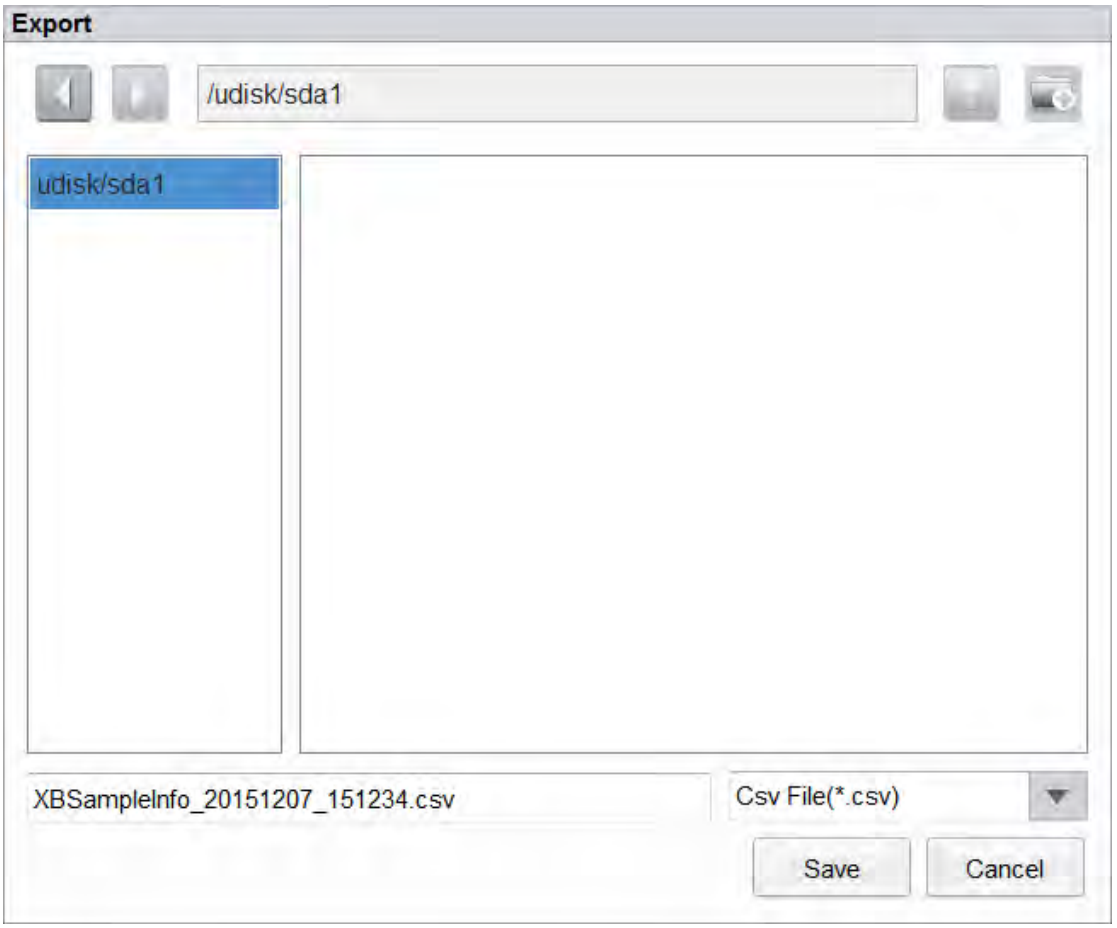
3. Select the QC data to be printed: all data or specified data.
   - Select **All Data** to print the data in the whole QC list.
   - Select **Specified Data**, set the date range in the date edit box, and QC data within the specified date range will be printed.
4. Click **OK** to print.

Export

If you wish to export the information and the result of the current QC file, do as follows:

1. Insert a USB flash disk in the USB interface on the analyzer.
2. Click **Export**.

   A message box shown below will pop up.



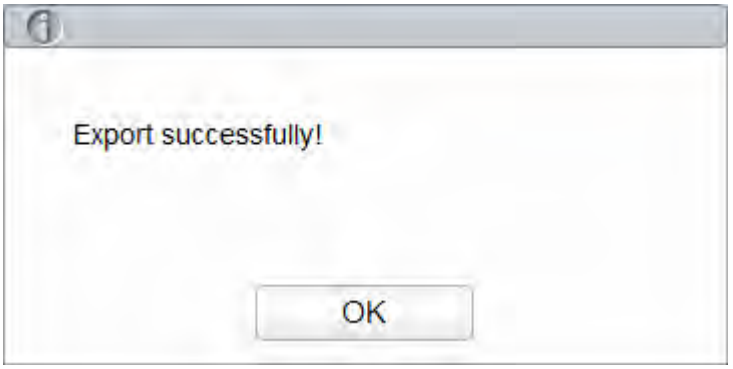
3. Select an export path for the data and enter the file name.

   The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.**csv.** Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.

4. Click **Save**.

   When the export is finished, a message box as shown below will pop up.

Figure 9-27 Export successfully



5. Click **OK** to close the message box.

10 Calibration

10.1 Introduction

Calibration is a procedure to standardize the analyzer by determining its deviation, if any, from calibration references and to apply any necessary correction factors. To get accurate blood analysis results, perform calibration of the analyzer following the procedures given in this chapter when it's needed.

NOTE

- Calibration procedures can only be performed by users with the administrator-level access. The login users with the access level of general users can not perform the calibration procedures but only browse the calibration coefficients.
- You should only use the MR- specified calibrators and reagents. Store and use the calibrator and reagents following the instructions for use of the calibrations and reagents.
- The analyzer identifies a sample as a calibration sample only if the analysis is started from the Cal interface.
- The calculation of repeatability is included in the calibration procedure.

10.2 When to Calibrate

This analyzer is calibrated at the factory just before shipment. It is electronically stable and does not require frequent recalibration if you operate and maintain it as instructed by this manual. You need to recalibrate this analyzer if:

- it is the first time this analyzer has been used (usually done by a MR- authorized representative when installing the analyzer).
- an analytical component has been changed.
- the quality control results indicate that there may be a problem.
- the operating environment (such as the temperature) has changed significantly.

NOTE

- All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.
- For laboratories conducting routine tests, the calibration should be applied at least once every six months.

10.3 How to Calibrate

There are three calibration programs available on this analyzer: manual calibration, auto calibration

using calibrators and auto calibration using fresh blood samples.

All or part of the parameters of WBC, RBC, HGB, MCV and PLT can be calibrated by the calibration procedure.

10.3.1 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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

WARNING

- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see a doctor.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

CAUTION

Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.

NOTE

- You should only use the MR- specified controls and reagents. Store and use the controls and reagents as instructed by the instructions for use of the controls and reagents.
- Be sure to use the MR-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.

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 MR Service Department.

1. Check and make sure enough reagents have been prepared for the calibration. You need to start over the calibration if the reagents run out during the process.
2. Do the background check.

   If the analyzer alarms are activated for **abnormal background** results, see ***13 Troubleshooting*** for solutions. (Refer ***A.4.2 Normal Background*** to for background range.)
3. Run the median controls in Whole Blood mode consecutively for 11 times, take and view repeatability of the counting results from the 2nd run through the 11th run in the **Review** interface

and make sure they are within the range specified in ***A.4.4 Repeatability***.

4. Run the corresponding diluent for 3 times immediately after running the high-level controls for 3 times and calculate the carryover by the following formulae:

$$\text{Carryover (\%)} = \frac{\text{First low-value sample result} - \text{Third low-level sample result}}{\text{Third high-value sample result} - \text{Third low-level sample result}} \leq 100\%$$

The calculated carryovers shall meet the requirements in ***A.4.5 Carryover***.

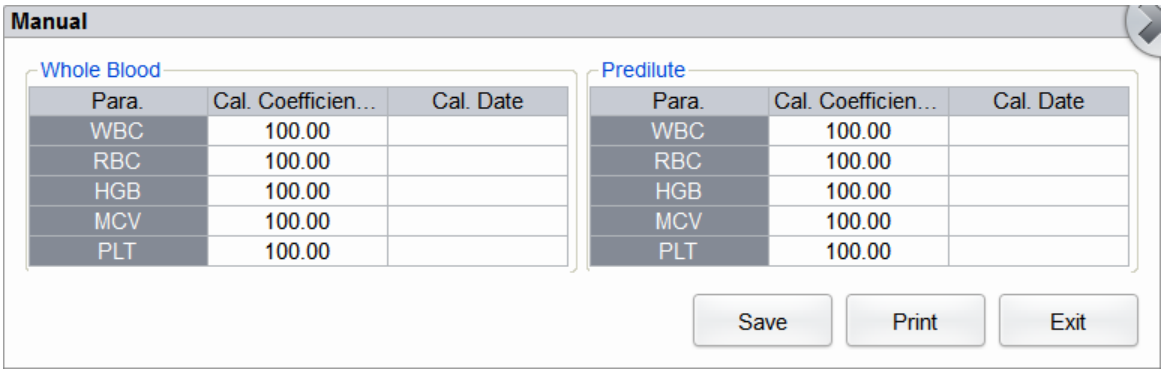
5. It is recommended that you create a log table for your analyzer. This log table should contain all the necessary information pertinent to your analyzer. The suggested items that you may want to include in the log table are: calibration date, supplier of calibrator, lot number, expected results and limits, and result of background check.

10.3.2 Manual Calibration

Complete the manual calibration as per the following procedure:

1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Manual** to access the manual calibration interface. See Figure 10-1.

Figure 10-1 Manual Calibration



The calibration coefficients of whole blood mode and predilute mode are displayed on the **Manual** interface.

NOTE

The login users with the access level of general users can not perform the calibration procedures but only browse the calibration coefficients on the current screen. To perform the calibration, please log out and then log in as users with administrator-level access.

3. Check the calibration coefficient and calculate the new coefficient using the following equation.

$$\text{New calibration factor} = \frac{\text{Current calibration factor} \times \text{Reference value}}{\text{Mean}}$$

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%.

Run the calibrator in whole blood mode for 11 consecutive times and calculate the WBC results of the 2nd to 11th runs (n=10): 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 is 8.22, which meet the requirements.

The new calibration coefficient is obtained:

$$\text{New calibration factor} = \frac{99.00\% \times 8.3}{8.22} = 99.96\%$$

The calculated calibration coefficients shall be between 75%~125%. In case of an invalid calibration coefficient, try to find out the reason (e.g. calibration material not thoroughly mixed, incorrect operation, etc.).Then recalibrate the analyzer and recalculate the calibration coefficients.

4. Enter the new calibration coefficients into the factor cell of the parameter that requires calibration.

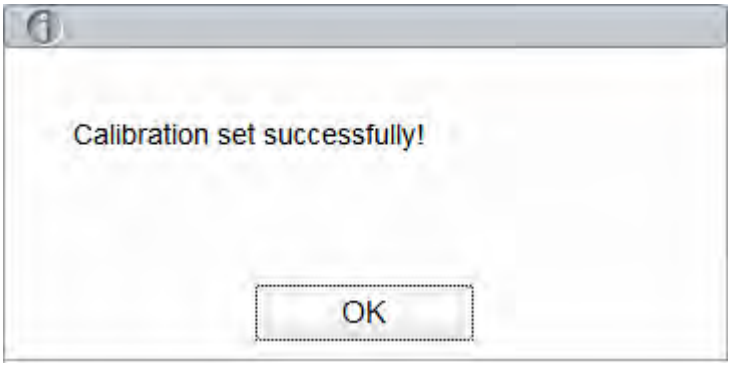
NOTE

The entered calibration coefficients shall be between 75.0%~125.0% (calculation results rounded to two decimal places).

5. Click **Save.**

   - If the new calibration coefficient is valid and different from the original value, the following dialog box will pop up.3

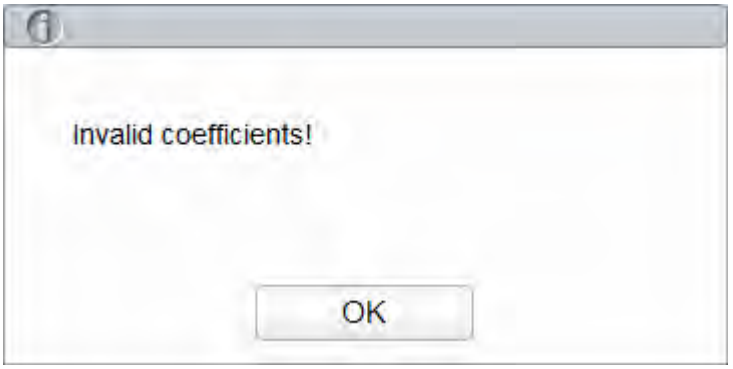
Figure 10-2 Calibration set successfully



On the screen, the calibration coefficient is refreshed to be the new one and the calibration date is refreshed to be the current system date.

   - If the new calibration coefficients are invalid, the message box will pop up. Click **OK** to close the message box and enter a valid factor.

Figure 10-3 Invalid Coefficients



6. (Optional) Click **Print** to print the current calibration coefficient.
7. Click **Exit** to close the **Manual** interface.

10.3.3 Auto Calibration Using Calibrators

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, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

NOTE

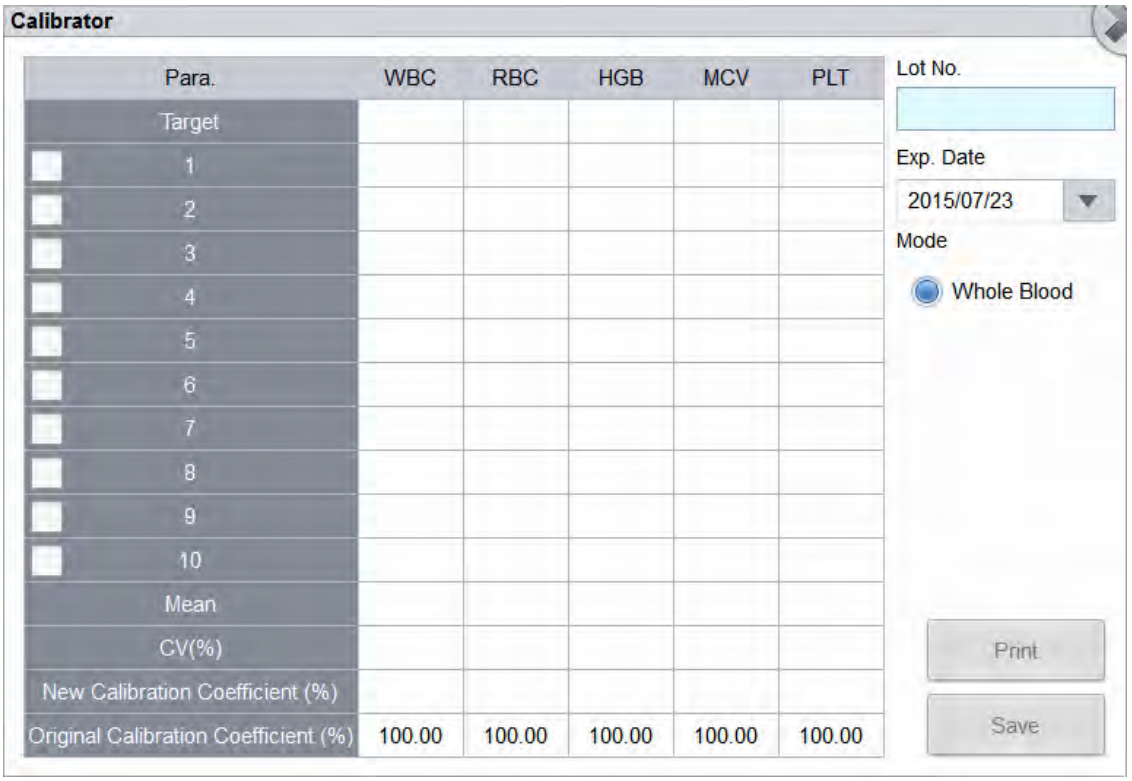
- Only MR-specified calibrators shall be used. MR will not be responsible for any erroneous result caused by using other calibrators.
- See the instructions for use of the calibrators for the lot No., Exp. Date and the target.

Complete the calibration with calibrators as per the following procedure:

1. Click **Cal** in the menu page to access the **calibration** interface.
2. Click **Calibrator**.

   The **Calibrator** interface pops up as shown in Figure 10-4.

Figure 10-4 Auto Calibration Using Calibrators



3. Enter the lot No. of the calibrator into the **Lot No.** box.
4. Click the **Exp. Date** box, and then edit the Exp. Date.

NOTE

- The Exp. Date can be no earlier than the current system date.
- The entered Exp. Date should be either the Exp. Date printed on the labeling or the open-container Exp. Date, whichever is earlier. The open-container Exp. Date is calculated as follows: the date on which the container is opened + the open-container stability days.

5. Input the **target values** of the parameters in the corresponding cell.
6. Prepare the calibrators following their instructions for use and place the calibrators under the sampling probe.
7. Press the aspirate key to start the calibration counting.
   - The valid results within the linearity range will be displayed directly.
   - If the calibration counting data of any parameter in the current counting are out of the display range or linearity range of the parameter, a message box will pop up on the screen prompting that the calibration data is invalid.

     Click **OK** to close the message box and delete the data from the table without saving.
   - If any of the parameter's value in the calibration counting differs from the Target value by more than 50%, the system will prompt you with a message box asking if the calibration counting results should be kept.

     To keep the results, click **Yes**; to remove the results, click **No**.

NOTE

- After the valid calibration result is obtained, the parameters with corresponding checkboxes ticked off will be involved in the calculation of the calibration coefficients by default.
- If you switch to other interfaces before the new calibration coefficients are obtained, the system will discard the current calibration data and keep the original calibration coefficients.

8. To get 10 valid counting results, repeat steps 6~7 ten times.

   The analyzer will, by default, calculate the Mean, CV% and the new calibration coefficients based on all the ticked-off calibration data according to the formulae.
9. You can select a few groups of data for the calculation of the calibration coefficients which can be obtained unless at least 5 groups of ticked-off data are included. Each time when you tick off or uncheck the checkboxes, the calibration coefficients will be refreshed and displayed in time.

   When the amount of the valid calibration data in the list reaches 10, a message box of **Calibrator calibration done!** will pop up. Click **OK** to close the message box.

NOTE

The out-of-range CV% does not influence the display of the calibration coefficients.

10. Click **Save**.
    - If the calculated calibration coefficient is within the range of 75%~125% (i.e.,>=75% and <=125%) and the CV% values of all the calibration parameters are not beyond the repeatability index, a dialog box prompting the successful calibration setting will pop up. Click **OK** to close the message box.
    - If the obtained calibration coefficient of any parameter is not within the range of 75%~125% or the CV% of any calibrated parameter does not meet the repeatability, the calibration coefficient will not be saved and a dialog box will pop up. Click **Yes** to close the dialog box and repeat the calibration operations.
11. (Optional) Click **Print** to print the calibration results.

10.3.4 Auto Calibration Using Fresh Blood Samples

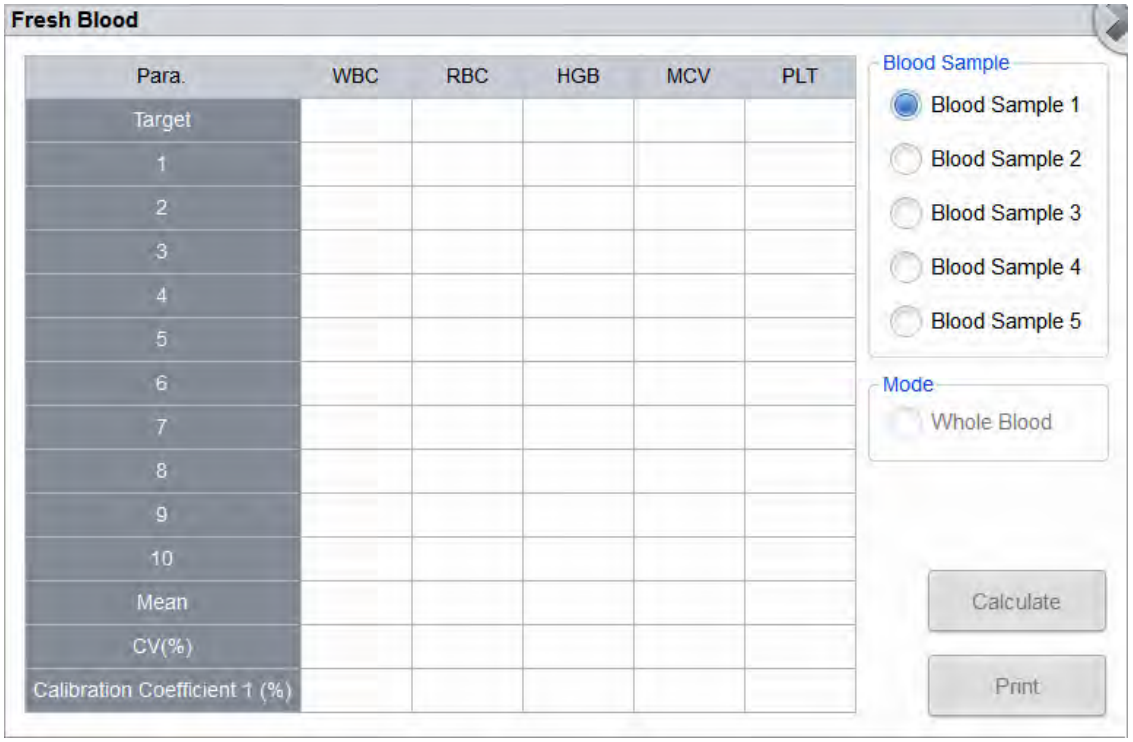
All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

Complete the calibration using fresh blood samples as per the following procedure:

1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Fresh Blood**.

   The fresh blood sample calibration interface pops up, as shown in Figure 10-5.

Figure 10-5 Auto Calibration Using Fresh Blood Samples



3. Prepare 3 to 5 normal fresh blood samples as instructed by ***6.5 Sample Collection and Handling***.
4. Run each of the prepared samples on the reference instrument three times at least. Average the results for your reference values.

NOTE

The reference instrument must be a properly running standard analyzer so as to ensure the accuracy of the reference values.

5. Enter the reference values for the parameters to be calibrated in the corresponding **Target** textbox.
6. Place the blood sample under the sampling probe, press the **aspirate key** on the analyzer to run the samples.

   The system will calculate the values for WBC, RBC, HGB, MCV and PLT of the sample.

7. Repeat step 6 for 10 times and calculate the counting results for sample No. 1 in the 10 runs.

   The system will calculate the Mean, CV and Calibration coefficient for each parameter of the sample.

   If the obtained calibration coefficient for any sample is not within the valid range or CV% or any calibrated parameters does not meet the repeatability, a dialog box indicating invalid new calibration coefficient will pop up when you are selecting other blood samples.

   Click **Yes** to clear the calibration data of the sample. Redo the calibration or redo after running another sample meeting all criteria.

8. Refer to steps 6~7 and perform the counting operations for the remaining four blood samples.

   The system will calculate the Mean, CV and Calibration Coefficient for each parameter of the remaining 4 blood samples.

9. Click **Calculate**.

   The system will calculate the average of the calibration coefficients, namely, the mean calibration coefficient (%), as the new calibration coefficient based on the five blood samples.

   You can also check at least three accurate calibration coefficients and the system will re-calculate the mean calibration coefficient (%).

NOTE

The mean calibration coefficient is invalid if its absolute value of deviation from the original calibration coefficient is greater than or equal to 5%.

10. Click **Save**.

    - If the mean calibration coefficient is within the valid range (the absolute value of deviation from the original calibration coefficient is less than 5%), you'll be prompted that the mean calibration coefficient is saved successfully.
    - If the mean calibration coefficient is not within the valid range (the absolute value of deviation from the original calibration coefficient is greater than or equal to 5%), you'll be prompted that the mean calibration coefficient is invalid.

NOTE

CV% out of standard will not affect the display of calibration coefficient.

11. Click **OK** to close the message box.
12. (Optional) Click **Print** to print the calibration results.

10.4 Verifying Calibration Coefficients

It is recommended that you take the following steps to verify the calibration coefficients:

1. Run the calibrator at least three times and check whether the means of the obtained results are within the expected ranges.
2. Run the low-, normal- and high-level controls each for three times at least, and check whether the means of the obtained results are within the expected ranges.
3. Run at least three fresh blood samples with known reference values, each for six times at least, and check whether the means of the obtained results are within the expected ranges.

11 Reagent Management

Once the new reagent is connected to the analyzer, you should set the reagent configurations, including validity period, residue volume and reagent barcode on the **Reagent Management** interface. Upon the completion of reagent configuration, you can perform the procedures for reagent replacement.

WARNING

- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see a doctor.

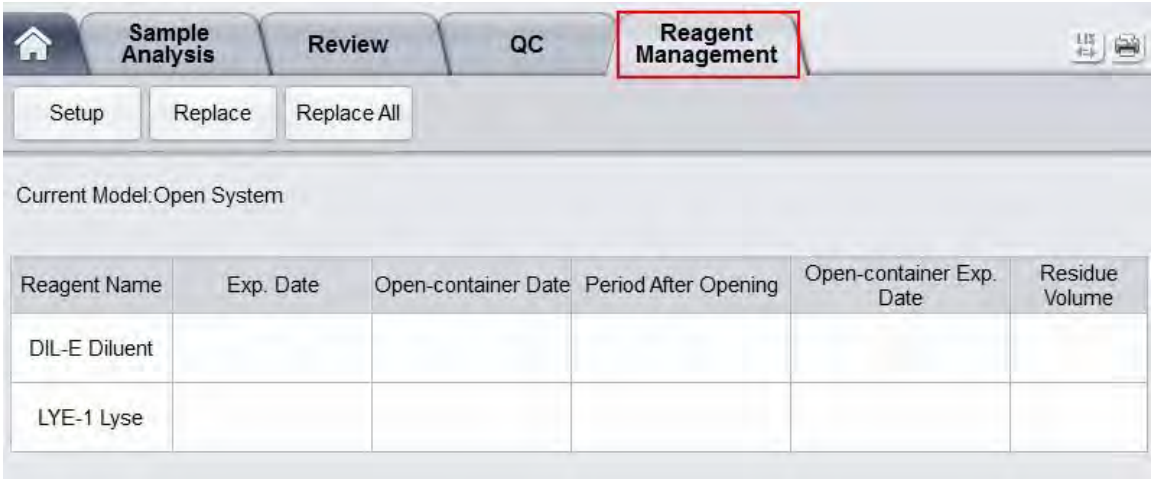
NOTE

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- When you have replaced the diluent, cleansers or lyses, run a background check to see if the results meet the requirement.

11.1 Accessing the Interface

Click **Reagent Management** in the menu navigation area or menu page, to access the reagent management setting interface. See Figure 11-1.

Figure 11-1 Reagent Management



Refer to Table 11-1 for related parameter descriptions.

Table 11-1 Parameter Description for Reagent Management

Parameter	NOTE
Current Model	Current model of the analyzer. ● Open system ● Closed system Reagent setting procedures for different analyzer models vary, please refer to ***11.2 Reagent Information Settings***.
Reagent Name	Name of the reagent.
Exp.Date	Exp. Date of the unopened reagent will be shown upon the completion of the reagent settings. Any reagent, regardless of its container being opened or not, should not be used beyond this date.
Open-container Date	The date on which the reagent container is opened. The default open-container date is the date on which the reagent settings are completed.
Period after opening (PAO)	The validity period (days) after the reagent container is opened. It will be shown upon the completion of the reagent settings.
Open-container Exp. Date	Exp. Date of the opened reagent, and it will be shown upon the completion of the reagent settings.
Residue Volume	The current residue volume of the reagent, and it will be shown in ml upon the completion of the reagent settings. The unit is ml.

11.2 Reagent Information Settings

Once the new reagent is connected to the analyzer, you need to set the reagent configurations, including validity period, residue volume and reagent barcode on the **Reagent Management** interface. Upon the completion of reagent configuration, you can perform the procedures for reagent replacement.

Reagent setting procedures for different analyzer models vary. The reagent setting procedures for both open and closed models will be presented on the following pages.

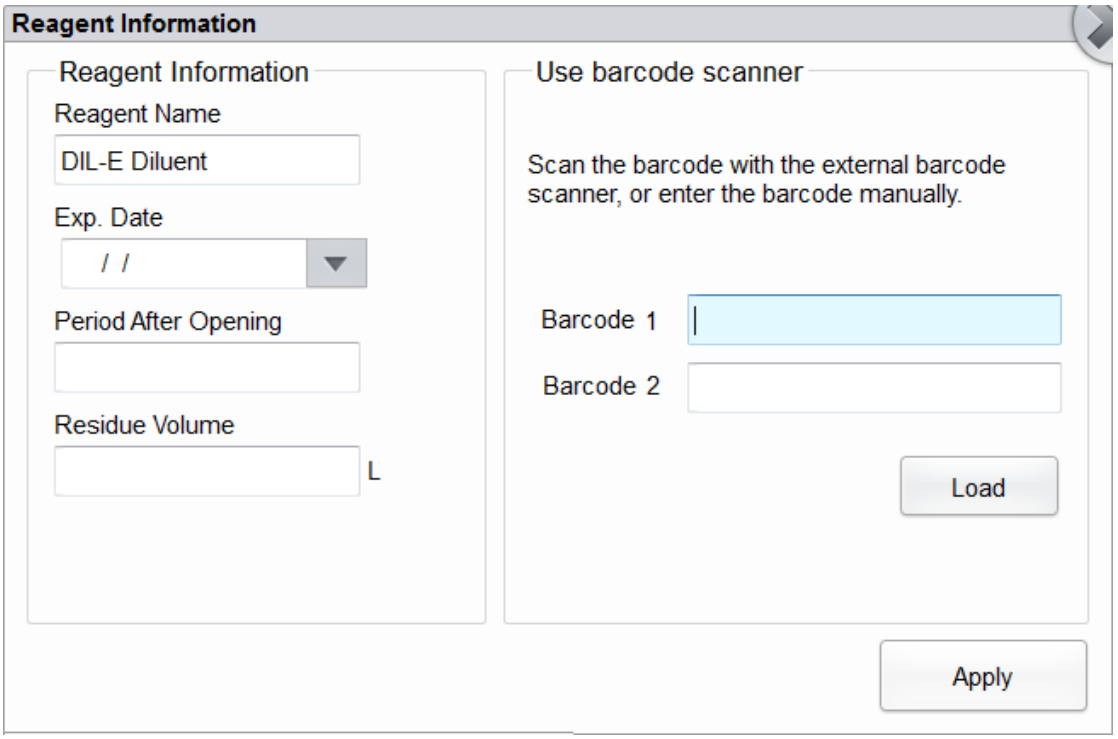
11.2.1 Open system

For open systems, reagent setting procedures are as follows:

1. Select the reagent to be set, and then click **Setup**.

   This launches the **Reagent Information** page as shown in Figure 11-2.

Figure 11-2 Reagent Information



2. To enter the reagent information, use any of the following methods.

➢ Manual Entry

Detailed parameter description is shown in Table 11-2.

Table 11-2 Parameter Description of Reagent Information

Parameter	Meaning	Operation
Reagent Name	Name of the reagent to be set.	Input in the textbox directly.
Exp.Date	The expiration date of the unopened reagent (see the outer packaging of the reagent). Any reagent, regardless of its container being opened or not, should not be used beyond this date.	Click the date control for the settings. ● The input sequence of the controls is: year, month, and date. ● Click ▲ or ▼ to select the date or click the textbox to enter them directly. ● Click to delete the current data and re-enter information. **NOTE** The validity date of the reagent can be no later than the validity date indicated on the packaging and cannot be earlier than the current system date.
Period after opening (PAO)	The validity period (days) of the open-container reagent (see the product packaging).	Input in the textbox directly.

Parameter	Meaning	Operation
Residue Volume	The current residue volume of the reagent (ml).	Input in the textbox directly.

- Manually input the reagent barcode, and click **Load**; or input the barcode via a peripheral barcode scanner.

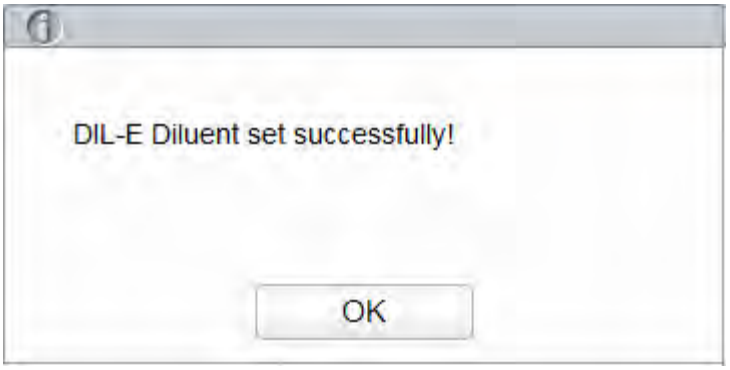
  A correctly entered barcode will prompt a message shown below the barcode box, indicating a successful loading, and the validity date and residue volume will be shown in the corresponding textboxes.

  If the bar code fails to be loaded, check if the reagent has been used or expired and the reagent name is correct. If all the information is correct, but the failure persists, please contact MR After-sales Service Department.

3. Click **Apply.**

   The system message will pop up, indicating the successful reagent settings.

Figure 11-3 Successful Reagent Settings



4. Click **OK**.

5. Continue to perform 1~4 and set the other reagent information; or click  to exist the setting interface.

NOTE

- Once the reagent settings are successfully completed, the system prompt at the top right corner of the screen will show that the reagent has not been replaced. To remove this error, click the error message and then click **Remove Error** in the pop-up dialog box. The analyzer will complete the reagent replacement and remove the error automatically.
- When you have replaced the diluent, cleansers or lyses, run a background check to see if the results meet the requirement.

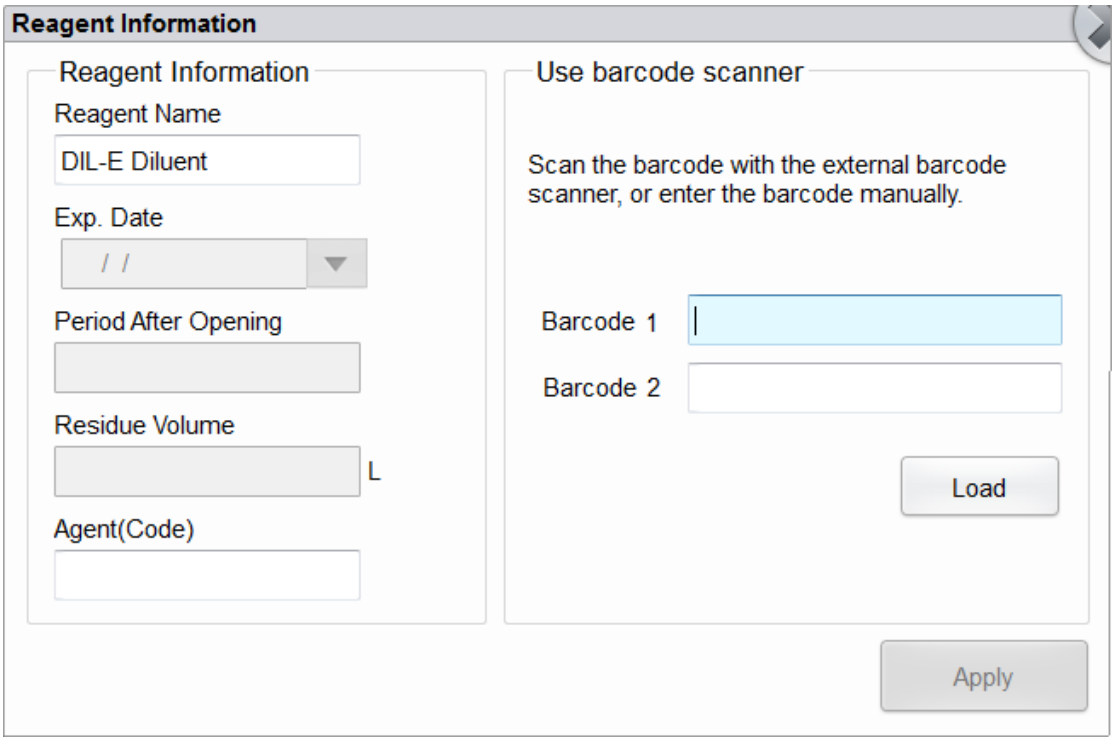
11.2.2 Closed system

For closed systems, reagent setting procedures are as follows:

1. Select the reagent to be set, and then click **Setup**.

   This launches the **Reagent Information** page as shown in Figure 11-4.

Figure 11-4 Reagent Information



2. Input the barcode via a peripheral barcode scanner or manual input, and then click **Load**.

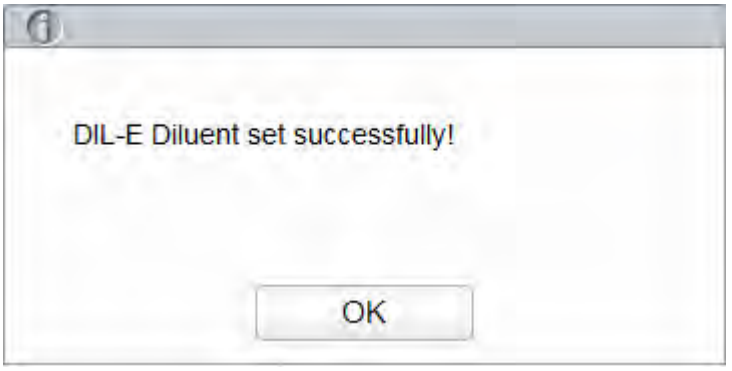
   A correctly entered barcode will prompt a message shown below the barcode box, indicating a successful load, and the validity date and residue volume will be shown in the corresponding textboxes.

   If the barcode fails to be loaded, check if the reagent has been used or expired and the reagent name is correct. If all the information is correct, but the failure persists, please contact MR After-sales Service Department.

3. Click **Apply**.

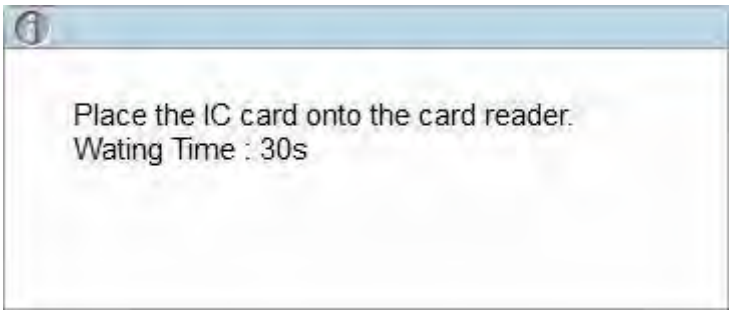
   ➢ For the settings of diluents, a pop-up dialog box as shown in Figure 11-5 indicates the completion of the settings. Please perform steps 5~6.

Figure 11-5 Successful Diluent Settings



   ➢ For the settings of lyses, a dialog box as shown in Figure 11-6 will pop up. Please perform the next step.

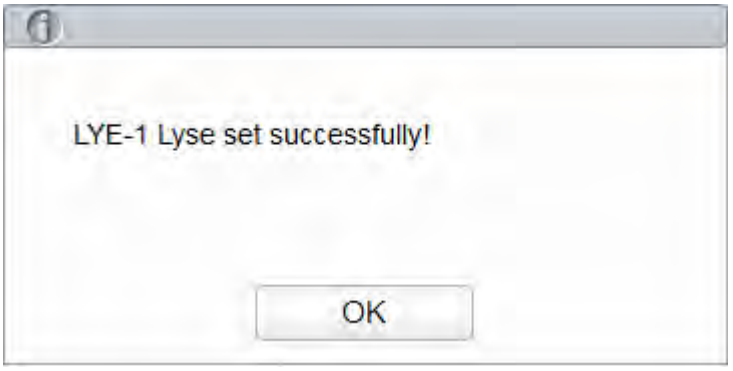
Figure 11-6 IC Card Verification



4. Put the RF card attached to reagent packing on the RF card reader in front of the analyzer.

   The beeping of the card reader and a pop-up dialog box as shown in Figure 11-7 indicate the successful reagent settings.

Figure 11-7 Successful Reagent Settings



NOTE

- The IC card is intended for single use only.
- If IC card verification fails, please follow the system prompts and use a valid IC card for re-reading.

5. Click **OK**.
6. Click **Close** to exit.

NOTE

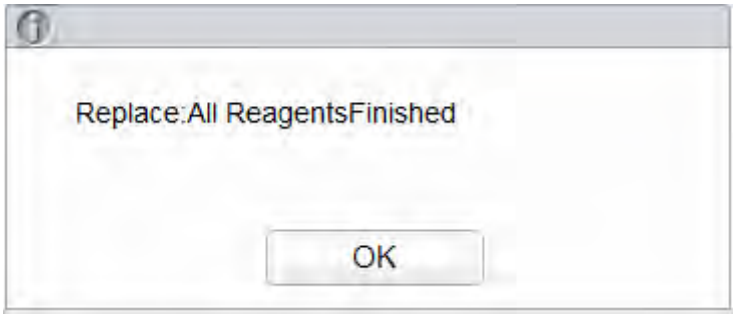
- After the reagent settings are successfully completed, the error message area at the top right of the software interface will prompt that the reagent is not replaced. Please click the error message and click **Remove Error** in the pop-up dialog box. The analyzer will complete the replacement of the reagent and remove the error.
- When you have changed the reagents, run a background check to see if the results meet the requirement.

11.3 Reagent Replacement

After completing the reagent settings, you should perform the reagent replacement operations. You can select to replace one type of reagent at a time or all reagents. The statistical method is applied as follows:

1. Select a type of reagent to be replaced, and click **Replace**; or click **Replace All** to replace all the reagents.

   After the replacement is completed, a message box as shown below will pop up on the screen.



2. Click **OK** to close the message box.

12 Service

12.1 Introduction

This analyzer provides multiple maintenance functions for this purpose. This chapter introduces how to use the provided functions to maintain and troubleshoot your analyzer. Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition.

All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.

CAUTION

- Performing unauthorized maintenance procedures can damage your analyzer. Do not perform any maintenance procedures that are not described in this chapter.
- In case of problems not specified in this manual, contact MR customer service department or your local agent for assistance.
- Only MR-supplied parts can be used for maintenance. For any question, contact MR customer service department or your local agent.
- Exercise caution to avoid contact with the sharp sample probe when performing maintenance.

12.2 Maintenance

The analyzer provides multiple service functions helping users to perform daily maintenance.

12.2.1 Reagent Replacement

WARNING

- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see a doctor.

NOTE

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- When you have replaced the diluent, cleansers or lyses, run a background check to see if the results meet the requirement.

You should replace the reagents when:

- The system indicates that the reagent is used up
- The suspicious flag indicates that the reagent in the pipeline is contaminated
- The reagent is contaminated or expired
- WBC or RBC bubbles are identified.

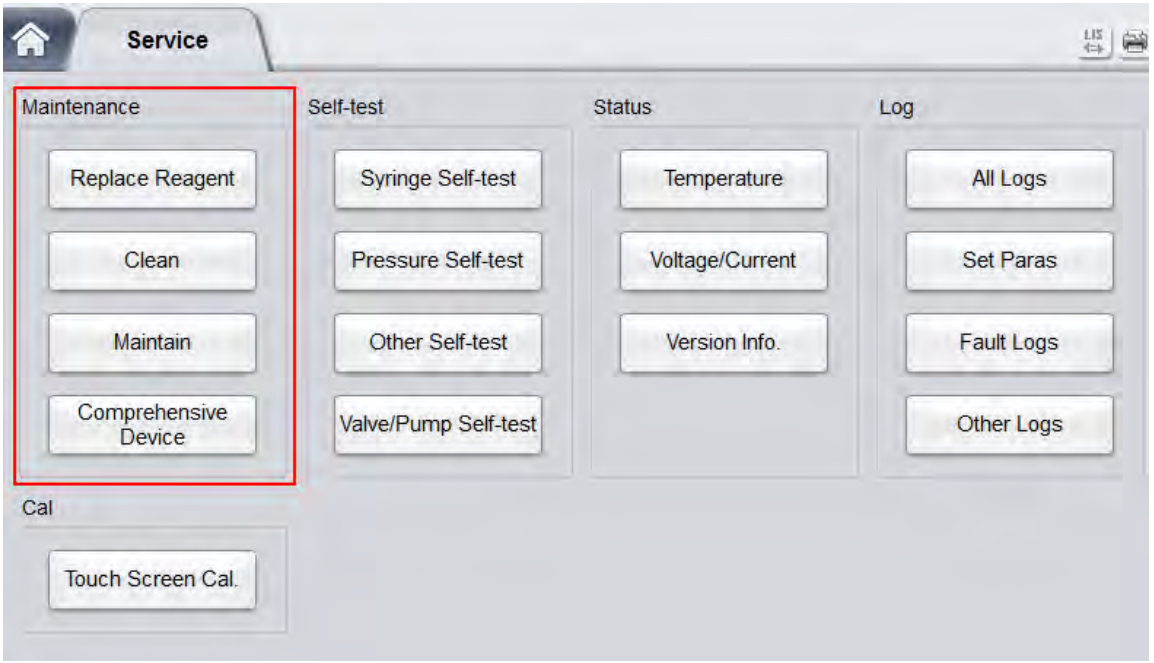
You can replace any of the following reagents:

- DIL-E Diluent
- LYE-1 LYSE

Do as follows to replace the reagents:

1. Refer to Figure 2-2 in ***2.6.1 Electrical Connections*** for reagent connections.
2. Click the **Service** icon in the menu page to access the **Service** interface as shown in Figure 12-1.

Figure 12-1 Service



3. Click **Replace Reagent** in the **Maintenance** selection.

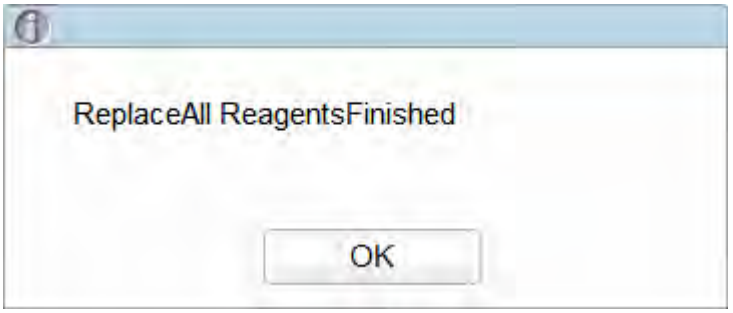
   The interface as shown in Figure 12-2 will pop up on the screen.

Figure 12-2 Reagent Replacement

4. Double click the name of the reagent that needs to be replaced, such as **Replace DIL-E Diluent**.

   After the replacement is completed, the following message box will pop up.

Figure 12-3 Reagent Replaced



5. Click **OK** to close the message box.
6. Perform the above procedures to replace other reagents if necessary.

12.2.2 Cleaning

Clean corresponding parts according to the actual situation:

- WBC bath

  When the background of WBC- and/or HGB-specific parameters exceeds the Ref. Range, you should clean the WBC bath.

- RBC bath

  When the background of RBC- and (or) PLT-specific parameters exceeds the Ref. Range, you should clean the RBC bath.

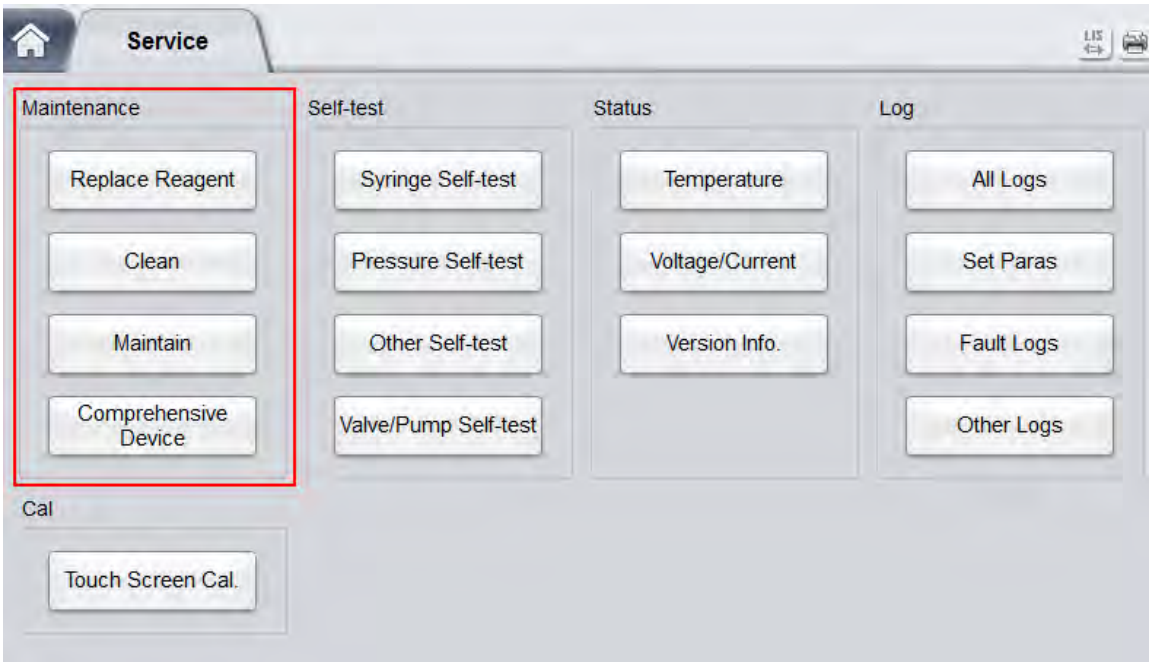
- Sample probe

  When the sample probe is dirty, you should clean the sample probe.

The cleaning procedures are as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.

Figure 12-4 Service



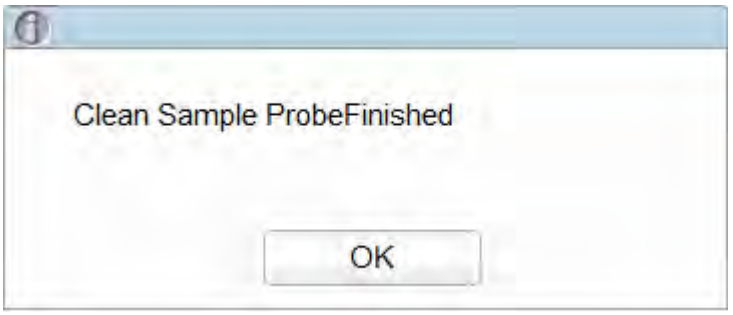
2. Click **Clean** in the **Maintenance** selection, an interface as shown in Figure 12-5 will pop up on the screen

Figure 12-5 Cleaning

3. Double click the icon of the part that needs to be cleaned, such as **Clean Sample Probe.**

When the system cleaning is complete, the message box will pop up to show that the cleaning is done.

Figure 12-6 Cleaning Done



4. Click **OK** to close the message box.
5. Perform the above procedures to clean other components if necessary.

12.2.3 Maintenance

Maintenance of the analyzer includes unclogg and cleanser soak.

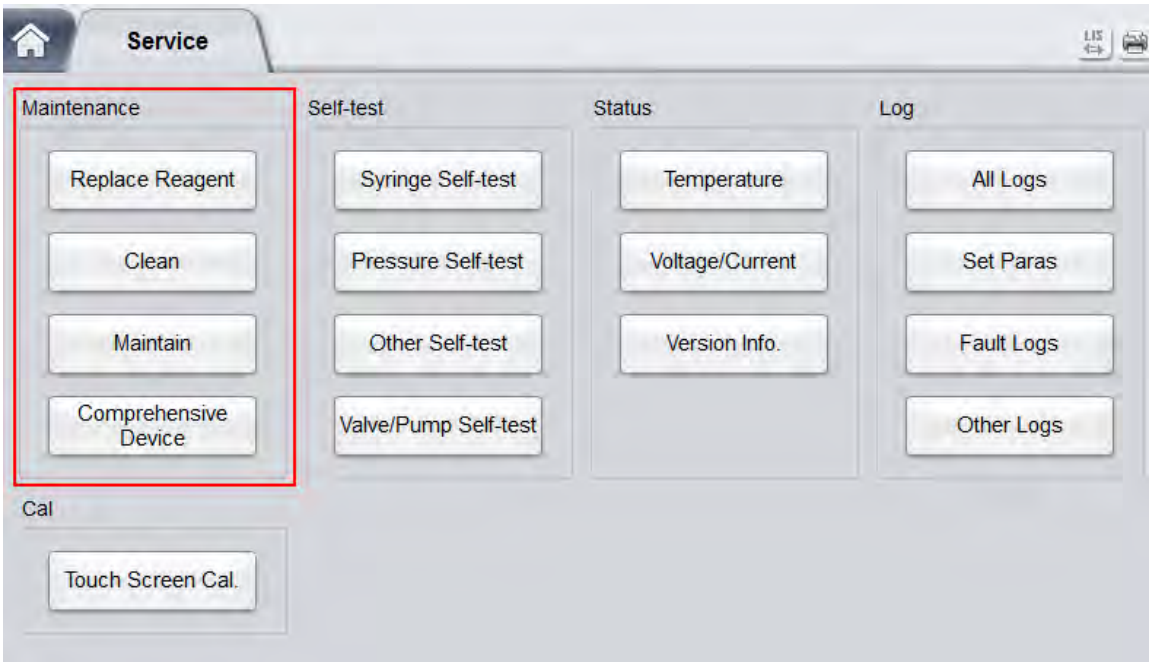
12.2.3.1 Unclogging

If clogging is found, or it is suspected that the counting results are not accurate due to aperture clogging, you can perform the unclogging operations.

The unclogging procedures are shown as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.

Figure 12-7 Service



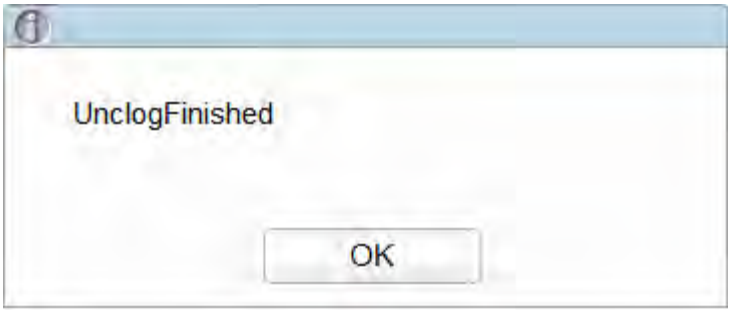
2. Click **Maintain** in the **Maintenance** selection.

   The interface as shown in Figure 12-8 will pop up on the screen.

Figure 12-8 Maintenance

3. Click the **Unclog** icon.

   The system will start clogging, and a message box will pop up. After the unclogging is completed, a message box will pop up to show that the clogging is done.



4. Click **OK** to close the message box.
5. Perform the above procedures to continue unclogging if necessary.

12.2.3.2 Cleanser Soak

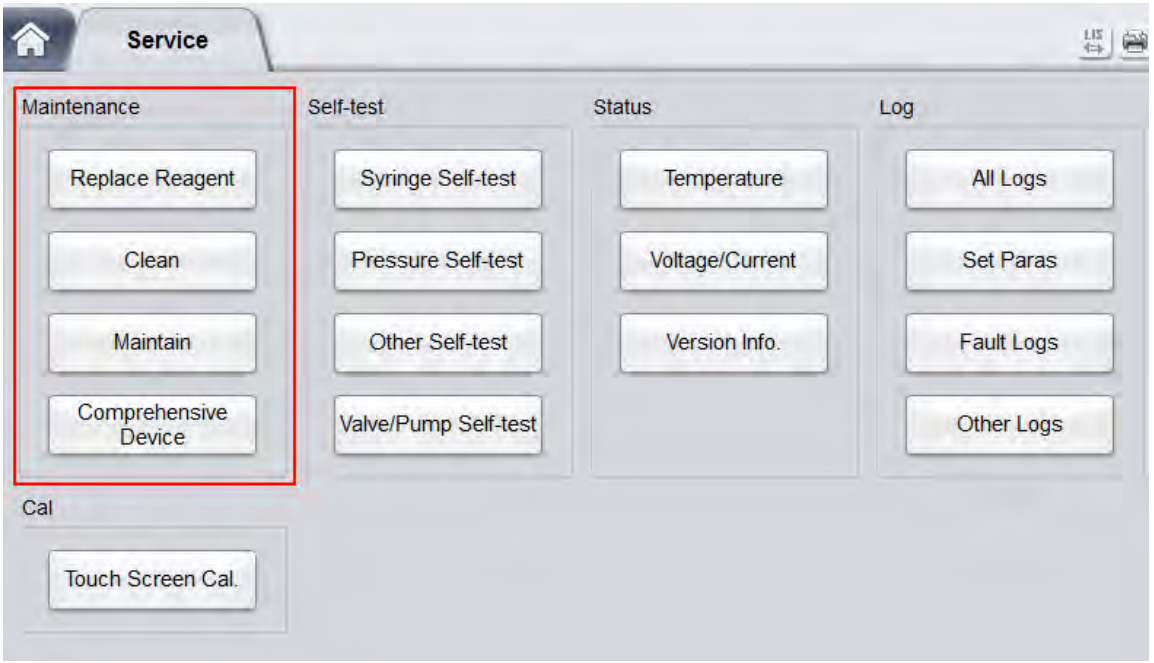
The cleanser soak should be performed under the following circumstances:

- When the problems including the background results exceed the Ref. Range and clogging still exist after other maintenance procedures have been adopted.
- Analyzer has been running for more than 24 hours.

The cleanser soak procedures are shown as follows.

1. Click the **Service** icon in the menu page to access the **Service** interface.

Figure 12-9 Service



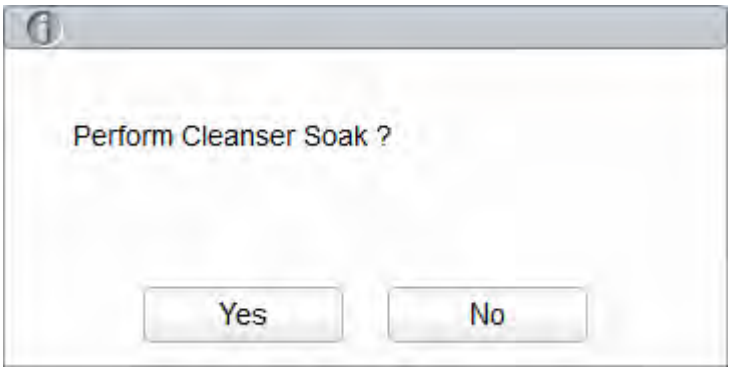
2. Click **Maintain** in the **Maintenance** selection.

   The interface as shown in the following picture will pop up on the screen.

3. Click the icon of **Cleanser Soak**.

   A dialog box as shown below will pop up.

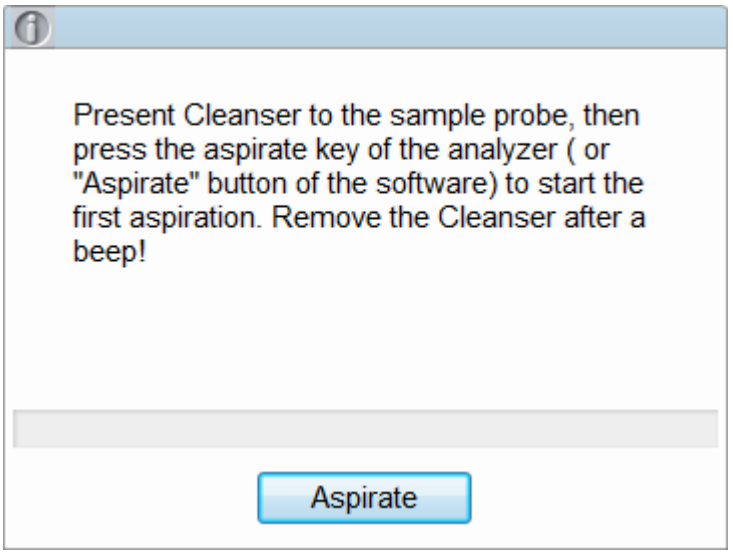
Figure 12-10 Cleanser Soak



4. Click **Yes**.

   A dialog box as shown below will pop up.

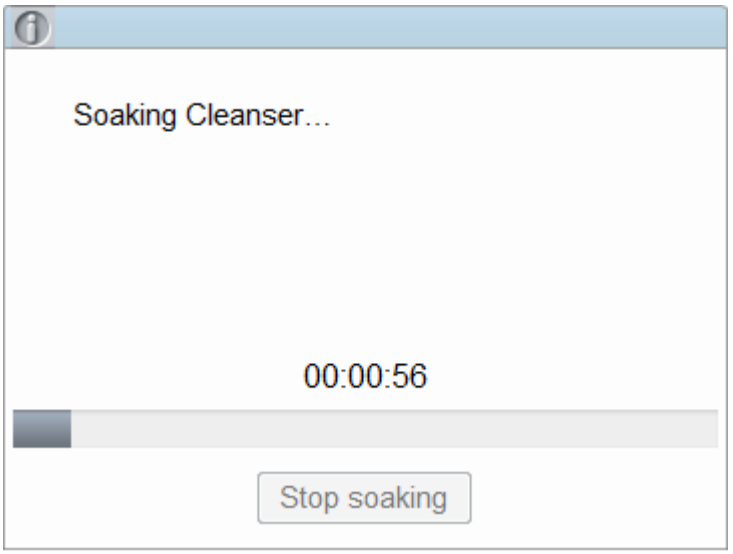
Figure 12-11 Cleanser Soak Prompt



5. Present the cleanser to the sample probe as per the prompt, and press the aspirate key or click the Aspirate button.

   “Cleanser soaking…” and the soaking time will appear as shown below. As shown below.

Figure 12-12 Cleanser Soaking Process Prompt

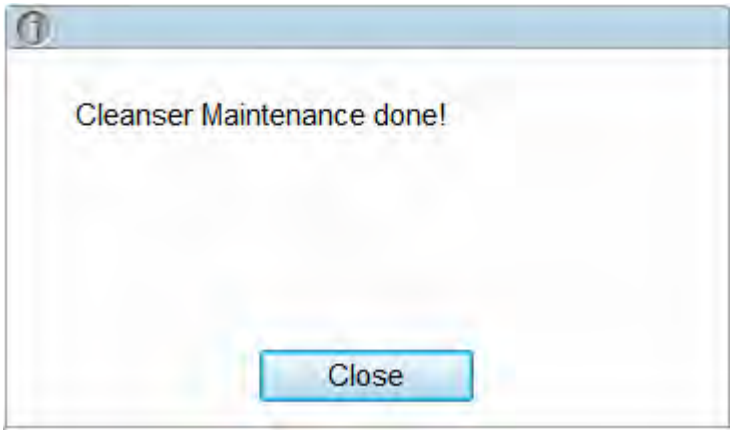


   After one minute of soaking, you can stop it manually.

6. Click the **Stop soaking** button, or wait for 19 minutes until the automatic soaking is completed.

   After the soaking is completed, a prompt “**Cleanser Maintenance done!**” will appear. See Figure 12-13.

Figure 12-13 Cleanser Maintenance Done



7. Click **Close.**
8. Perform the above procedures to perform the cleanser soak again if necessary.

12.2.4 Comprehensive Device Maintenance

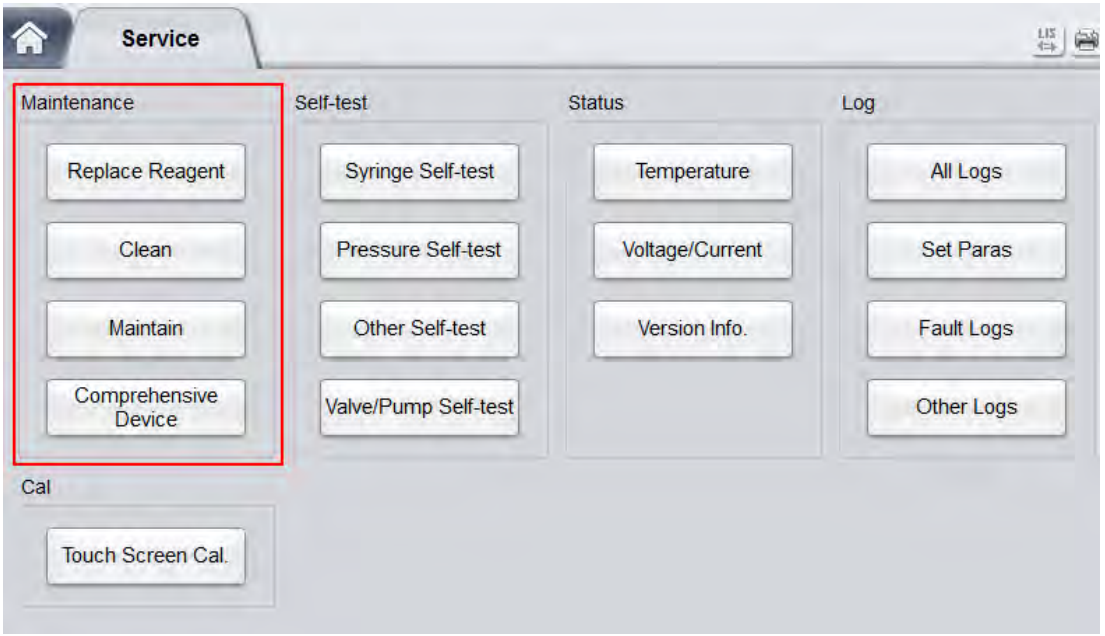
The Comprehensive Device Maintenance feature includes fluidics initialization, comprehensive device cleaning, emptying fluidics and preparing to ship.

12.2.4.1 Fluidics Initialization

After maintaining the fluidic system or replacing a main part of the analyzer, you should perform this procedure to initialize the fluidic system.

Do as follows to perform the fluidics initialization:

1. Click the **Service** icon in the menu page to access the **Service** interface.



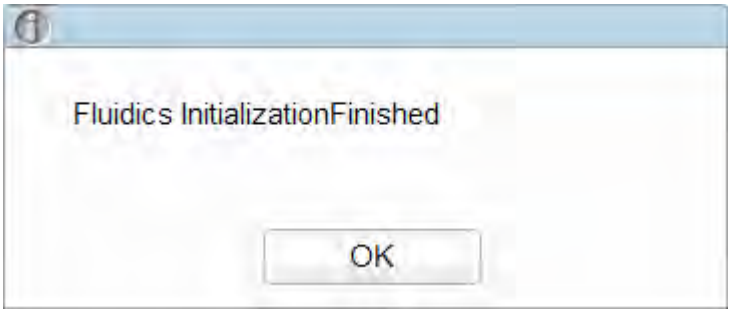
2. Click **Comprehensive Device** in the **Maintenance** selection.

   The interface as shown below will pop up on the screen.

Figure 12-14 Comprehensive Device Maintenance

3. Double click the icon of **Fluidics Initialization**.

   The analyzer starts to perform the fluidics initialization procedure. After the initialization is complete, a message box will pop up.



4. Click **OK**.

12.2.4.2 Clean Fluidics

If the background results of parameters are out of the background range, the comprehensive device cleaning should be cleansed.

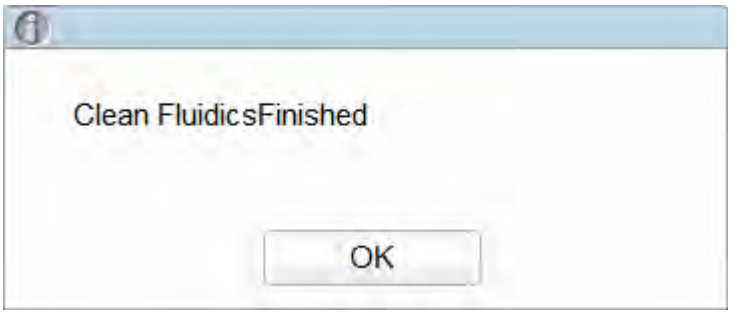
Procedures for comprehensive device cleaning are shown as below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.

   A dialog box will pop up as shown below.

3. Click the icon of **Clean Fluidics**.

   The analyzer starts to perform the fluidics cleaning procedure. After the cleaning is completed, the following message box will pop up.



4. Click **OK**.

12.2.4.3 Empty Fluidics

This function enables the device to empty fluidics to prevent crystallization and maintain device performance when the device has not been used for more than one week.

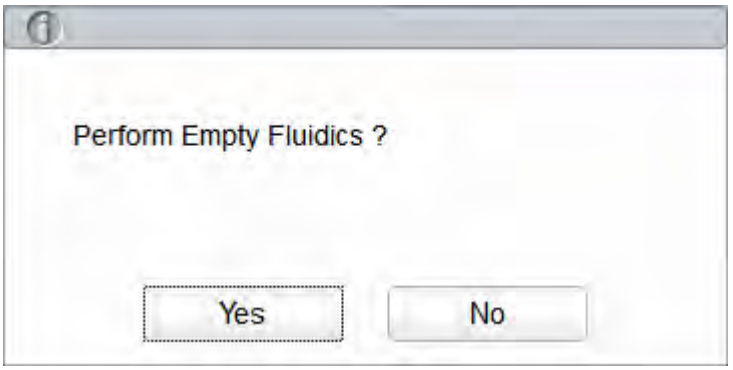
Procedures for emptying fluidics are shown as below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.

   The interface as shown below will pop up on the screen.

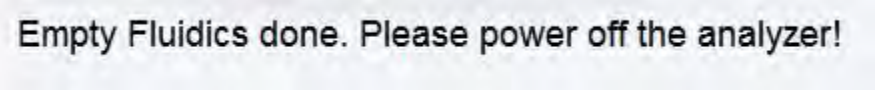
3. Click the icon of **Empty Fluidics**.

   A dialog box will pop up as shown below.



4. Click **Yes**.
5. Remove all reagent pickup tube assemblies according to the prompt, and then click **OK** to start emptying the fluidic system.

   A dialog box will pop up to prompt you to power off the device after the emptying is complete.



6. Turn to [O] the [O/I] switch located on the left side of the analyzer.
7. After shutdown, empty the waste in the waste container, and dispose of it.

WARNING

Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

12.2.4.4 Prepare to Ship

If the analyzer is not to be used for over two weeks or needs be transported over a long distance (transporting time>2h), you should perform this procedure.

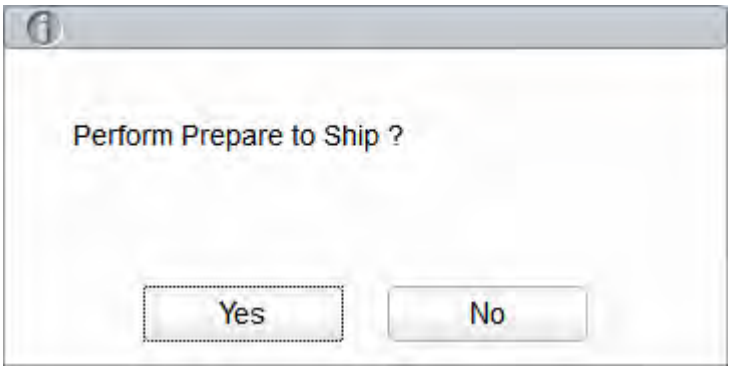
Do as follows to perform the prepare-to-ship procedure:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.

   The interface as shown below will pop up on the screen.

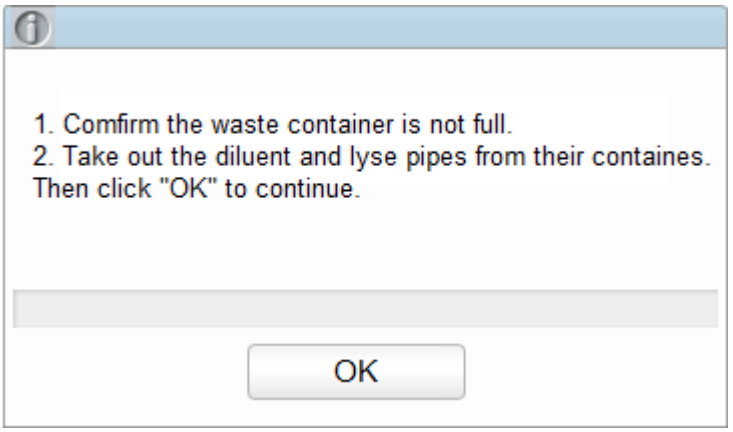
3. Click the icon of **Prepare to Ship**.

   A message box shown below will pop up.



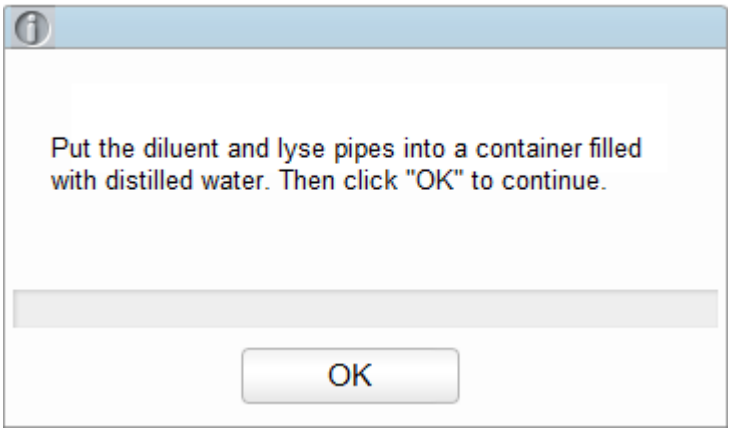
4. Click **Yes**.

   A dialog box will pop up as shown below.



5. Remove all reagent pickup tube assemblies according to the prompt, and then click **OK** to start emptying the fluidic system.

   After the emptying is complete, a message box will pop up.

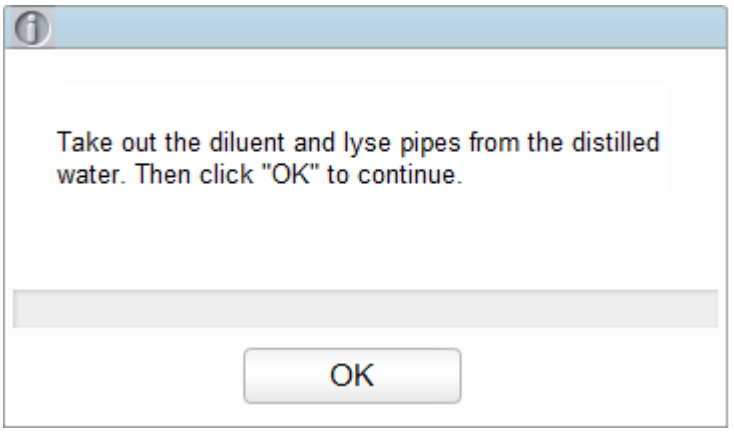


6. Place all reagent pickup tube assemblies into the distilled water, and then click **OK** to start priming.

NOTE

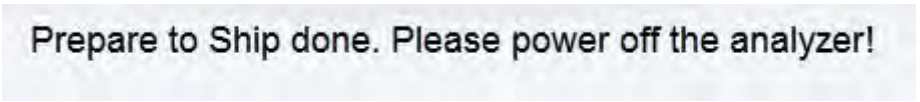
- Be sure to use distilled water in order to ensure the normal use of the device in the future. In addition, the beaker holding the distilled water needs to be cleaned thoroughly.
- The diluent pipe and lyse pipes should be stored separately in two beakers.

System performs the filling operation. After the filling is completed, the following dialog box will pop up.



7. Take out the diluent and lyse pipes from the distilled water as per the prompt, then click **OK**.

   After the operation, dialog box will pop up to prompt you to power off the device.



8. Turn to [O] the [O/I] switch located on the left side of the analyzer.
9. After shutdown, empty the waste in the waste container, and dispose of it.

WARNING

Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

12.2.5 Auto Clean

There will be a certain amount of contamination accumulated after running a certain amount of samples without shutting down the analyzer. When the sample count amounts to over 100, the analyzer will perform the cleaning procedure automatically once, and a prompt will be displayed on the screen.

In addition, the analyzer will perform the auto clean procedures if there has been no fluidics sequential operation for more than one hour.

NOTE

Once the auto clean is performed or the analyzer is shut down, the statistical data of auto clean will be cleared automatically.

12.2.6 Auto Prompt for Cleanser Soak

If the analyzer has been running for more than 24 hours but hasn't performed cleanser maintenance when the auto maintenance time is reached, the system will prompt to perform cleanser soak immediately, so as to prevent the accumulation of contamination.

Click **Yes**, then you can perform the cleanser maintenance as per the prompt and the description in ***12.2.3.2 Cleanser Soak***.

Click **No**, then the system will remind you every 10 minutes until you perform the maintenance.

NOTE

- At the **Self-test** or **Status** interface, the analyzer does not ask for confirmation to perform the cleanser soak.
- If the analyzer is running or has problems when the conditions of auto prompt for cleanser soak is satisfied, the analyzer will prompt again after the current operation is completed or the problems are resolved.
- After cleanser soak is completed, the accumulative count values will be cleared automatically.
- Cleanser soak is an important step in comprehensive device maintenance. It is recommended not to stop soaking halfway.

12.2.7 Auto Sleep

When the fluidics system stops working for 60 minutes (default setting), then the analyzer will enter the sleeping status automatically. You can change the waiting time for auto sleeping as needed, see **5.3.4 Auto Maintenance.**

When the analyzer is in the sleep mode, a prompt will be displayed on the screen. Touch the screen or press the aspirate key on the analyzer to wake it up.

NOTE

- If it is the time to auto sleep but the analyzer is error status, then only after the error is removed will auto sleep start accordingly.
- Different maintenances will be performed by the analyzer automatically when exiting the sleep mode, and the exiting time depends on how long the analyzer was in the sleep mode.
- If errors occur when you are trying to cancel the auto sleep of the analyzer, please refer to***13 Troubleshooting*** for solving the problems.

12.3 Self-inspection

This feature is to test if some important components of the device can function properly or not, including syringe and sampling assembly self-inspection, pressure and vacuum self-inspection, valve self-inspection and other self-inspections.

NOTE

If the testing result is abnormal, you should try again for several times; if the abnormalities persist, please contact MR customer service department or your local agent.

12.3.1 Syringe and Sampling Mechanism

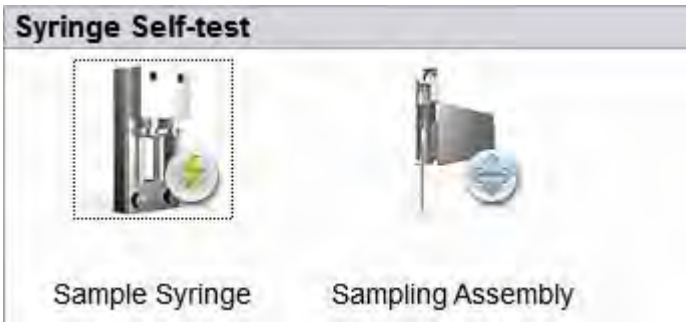
You can test the performance of all syringes and sampling mechanisms.

The self-inspection procedures are shown as below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Syringe Self-test** in the **Self-test** selection.

   The interface as shown in Figure 12-15 will pop up on the screen.

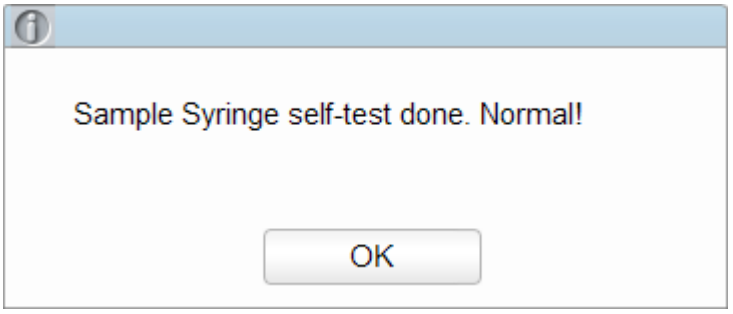
Figure 12-15 Syringe



3. Double click the part that needs to be tested, e.g. **Sample Syringe**, and wait for the self-inspection results.

   After the self-test is completed, a dialog box will pop up to show the self-test results.

Figure 12-16 Syringe Self-test Results



4. Click **OK** to close the message box.

12.3.2 Pressure and Vacuum

This feature is to test the pressure and vacuum inside the device.

Procedures for pressure (or vacuum) self-inspection are shown as below:

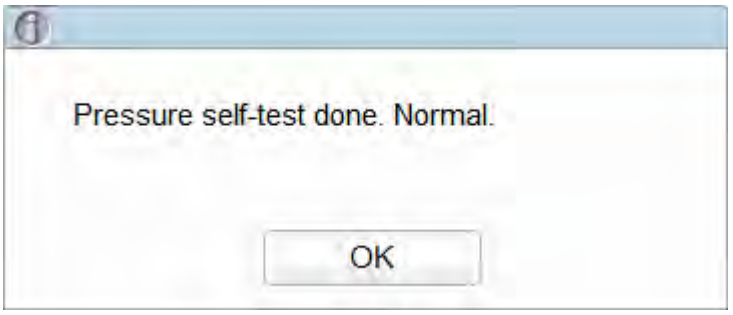
1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Pressure Self-test** in the **Self-test** selection.

   The interface as shown in Figure 12-17 will pop up on the screen.

Figure 12-17 Pressure and Vacuum Self-inspection

3. Click **Pressure** (or **Vacuum**).

   The system will perform the corresponding self-test operations. After the self-test is completed, a dialog box will pop up to show the self-test results.



4. Click **OK** to close the message box.

12.3.3 Valve & Pump

When controlling the switches of different valves (pumps), you can judge if the valves (pumps) are operating properly by the sound of opening, closing or manually touching the corresponding valves (pumps).

The procedures for valve self-inspection are shown as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Valve/Pump Self-test** in the **Self-test** selection.

   The interface as shown in Figure 12-18 will pop up on the screen.

Figure 12-18 Valve/Pump Self-test

3. Click the desired Valve No. (e.g. 1), then confirm whether it works properly by the sound of its opening and closing.

12.3.4 Others

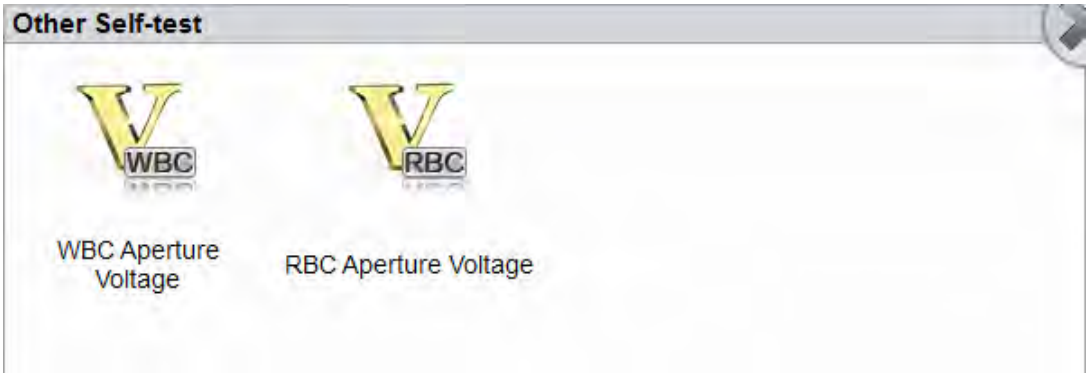
You can perform the self-test for WBC and RBC aperture voltage.

Take the self-test for RBC aperture voltage as an example, its operation steps are as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Other Self-test** in the **Self-test** selection.

The interface as shown in Figure 12-19 will pop up on the screen.

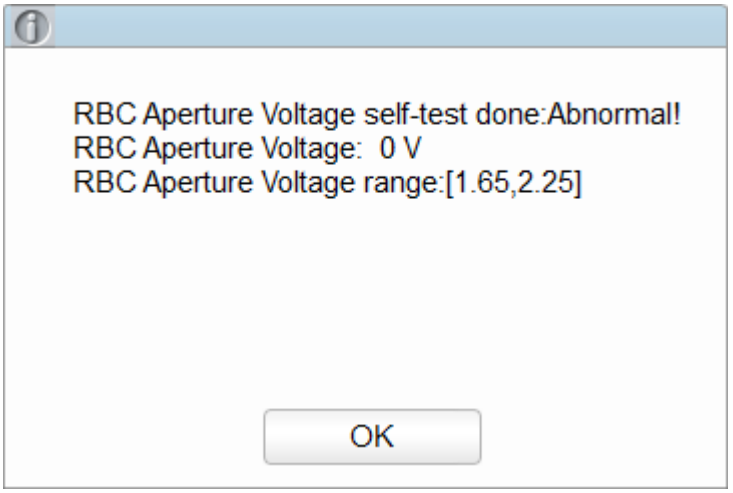
Figure 12-19 Other Self-test



3. Click **RBC Aperture Voltage** to start self-test.

   The system will perform the corresponding self-test operations. After the self-inspection is completed, a dialog box will pop up to show the self-inspection results.

Figure 12-20 RBC Aperture Voltage Self-test Results



12.4 System Status

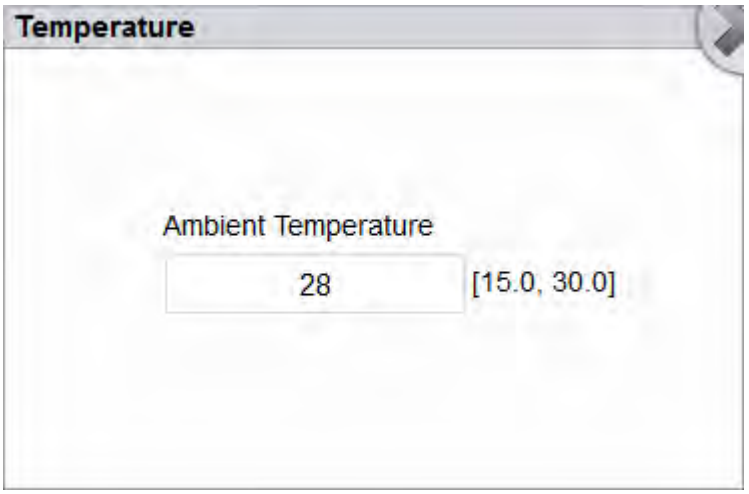
You can view the current status information of the analyzer in the **Status** selection, including temperature, voltage and current, and version information.

12.4.1 Temperature

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Temperature** in the **Status** selection.

   The interface as shown in Figure 12-21 will pop up on the screen.

Figure 12-21 View Temperature Status



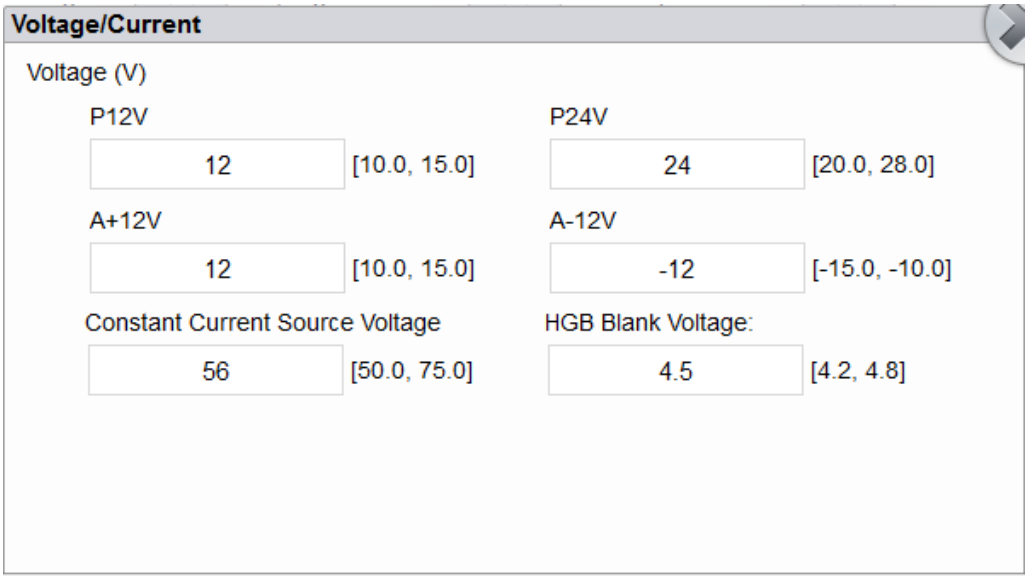
You can view the current ambient temperature of the analyzer. If the results of the temperature testing exceed the normal range, they will be highlighted by the red background.

12.4.2 Voltage and Current

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Voltage/Current**.

   The interface as shown below will pop up on the screen.

Figure 12-22 Voltage and Current



You can view the voltage and current information of the analyzer. The voltage or current value that exceeds the normal range will be displayed in a red background.

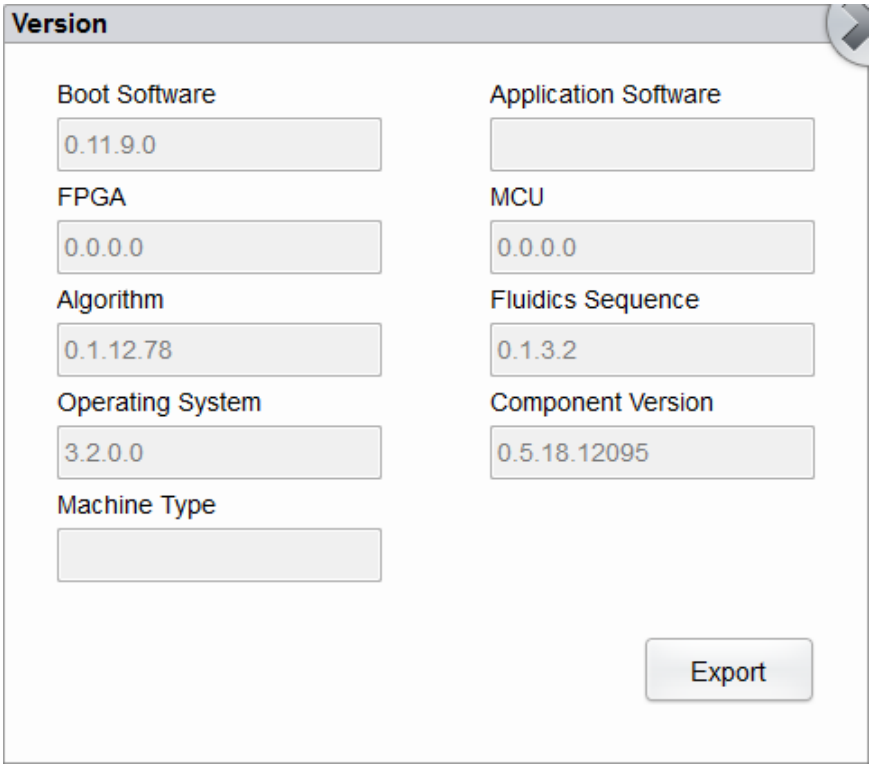
12.4.3 Version Information

You can view the current version information of all parts of the analyzer, and export the version information to a USB flash disk. Specific steps are shown below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Version Info.** In the **Status** selection.

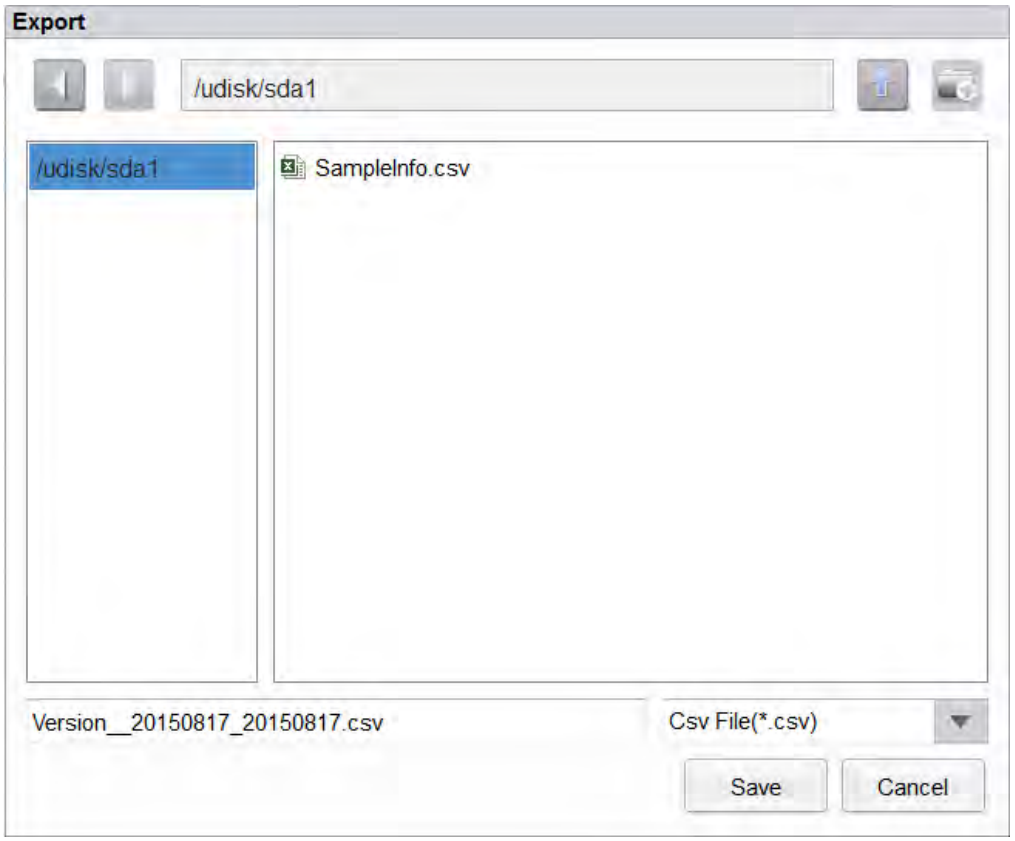
   Version information interface will pop up on the screen. See Figure 12-23.

Figure 12-23 Version Information



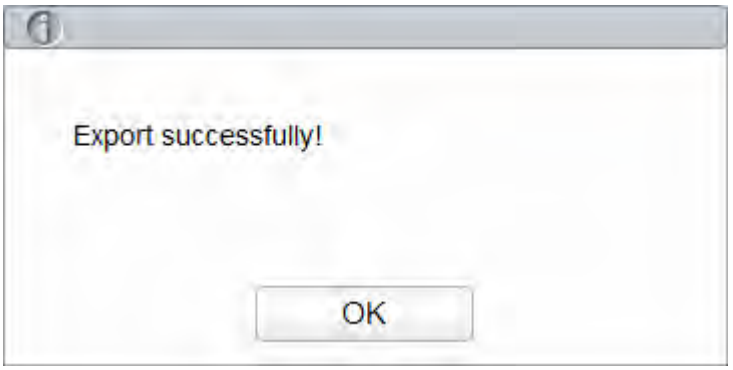
3. Insert a USB flash disk in the USB interface on the analyzer.
4. Click **Export**, and select the export path in the dialog box, and then enter the file name.

   The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) by default as shown below.



5. Click **Save** to start exporting.

   After Export is completed, the message box as shown below will pop up.



6. Click OK to exit.

12.5 Log

In the **Log** selection, you can view the records of **All Logs, Set Paras**, **Fault Logs** and **Other Logs**.

NOTE

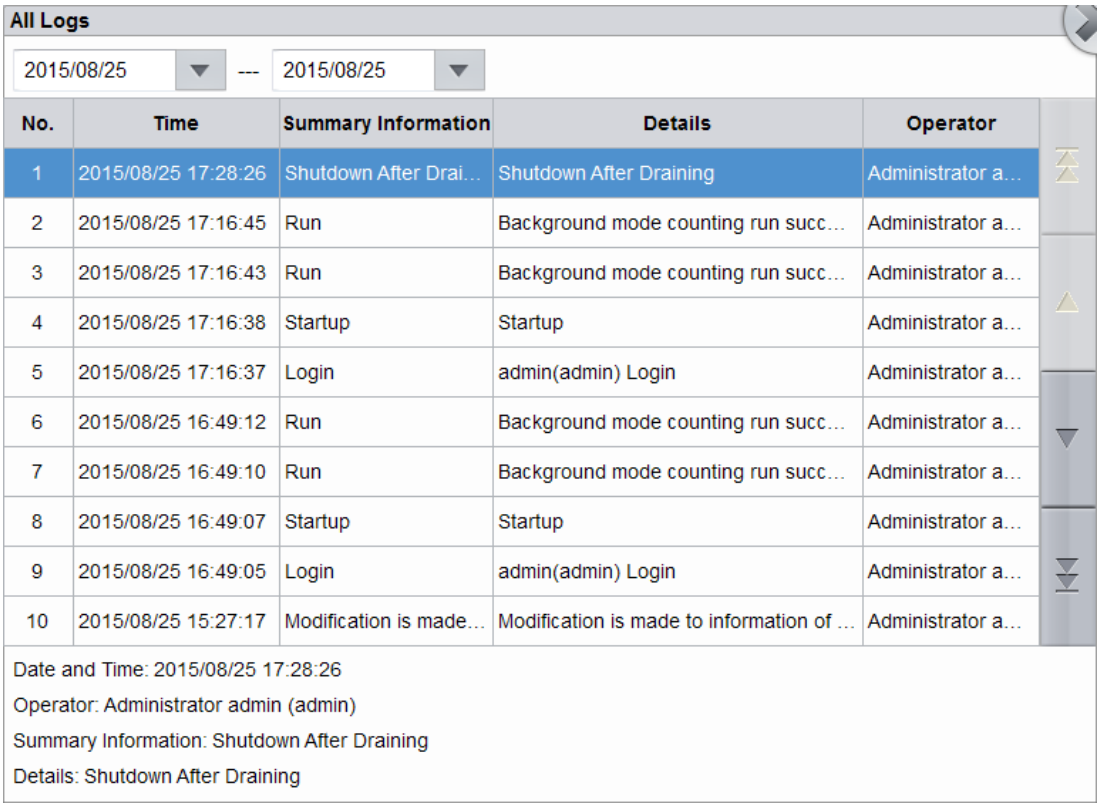
- If a new record is added when the log is full, the newest record will overwrite the oldest one automatically.
- The administrator can view both his/her own operation logs and the general users' operation logs, while the general users can only review their own operation logs.
- The log can keep records of up to 5 years.

12.5.1 All Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **All Logs** in the **Log** selection.

   You can view all logs (visible to the users of the current access level).

Figure 12-24 All Logs



3. Select the dates in the two date textboxes, and then you can view the all logs within the date range, including operation time, log information and the operator.

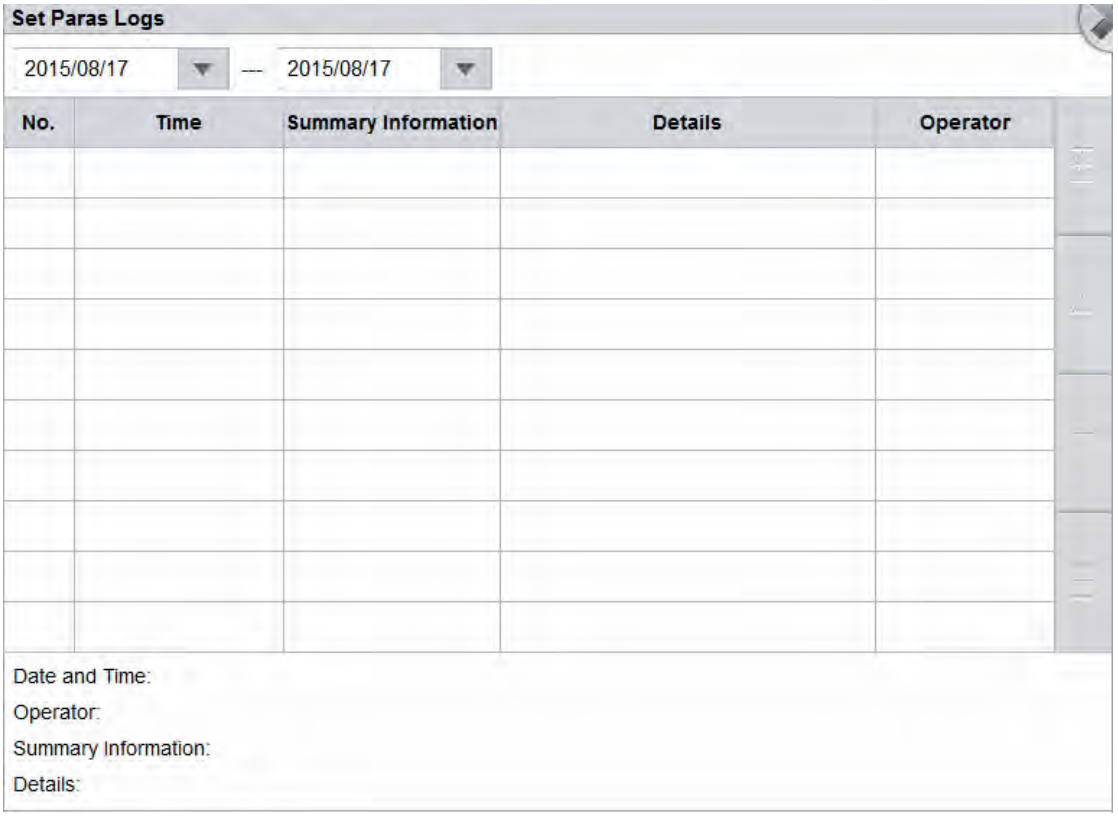
12.5.2 Parameter Revision Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Set Paras** in the **Log** selection.

   You can view the parameter revision logs (which can be viewed by the user with the current level

of access) within a specified date range.

Figure 12-25 Parameter Revision Logs



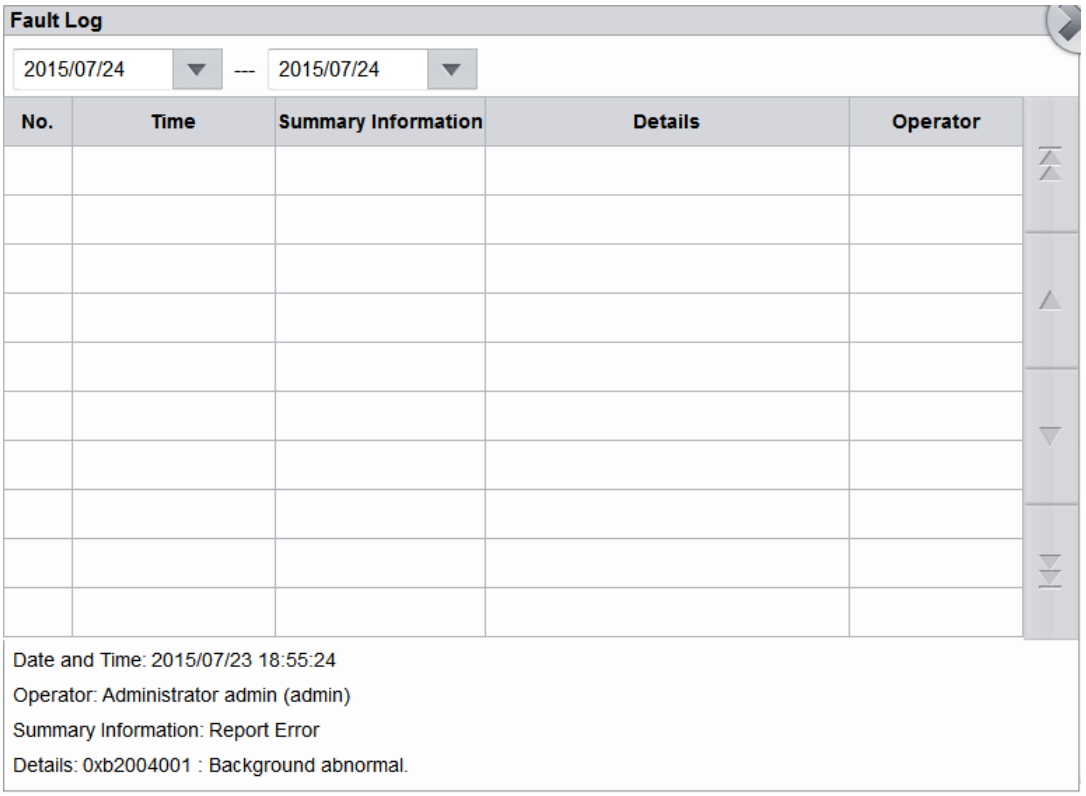
3. Select the dates in the two date textboxes, and then you can view the parameter revision logs within the date range, including the revision date and time, revision summary and the operator.

12.5.3 Fault Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Fault Logs** in the **Log** selection.

   You can view all logs (visible to the users of the current access level).

Figure 12-26 Fault Logs



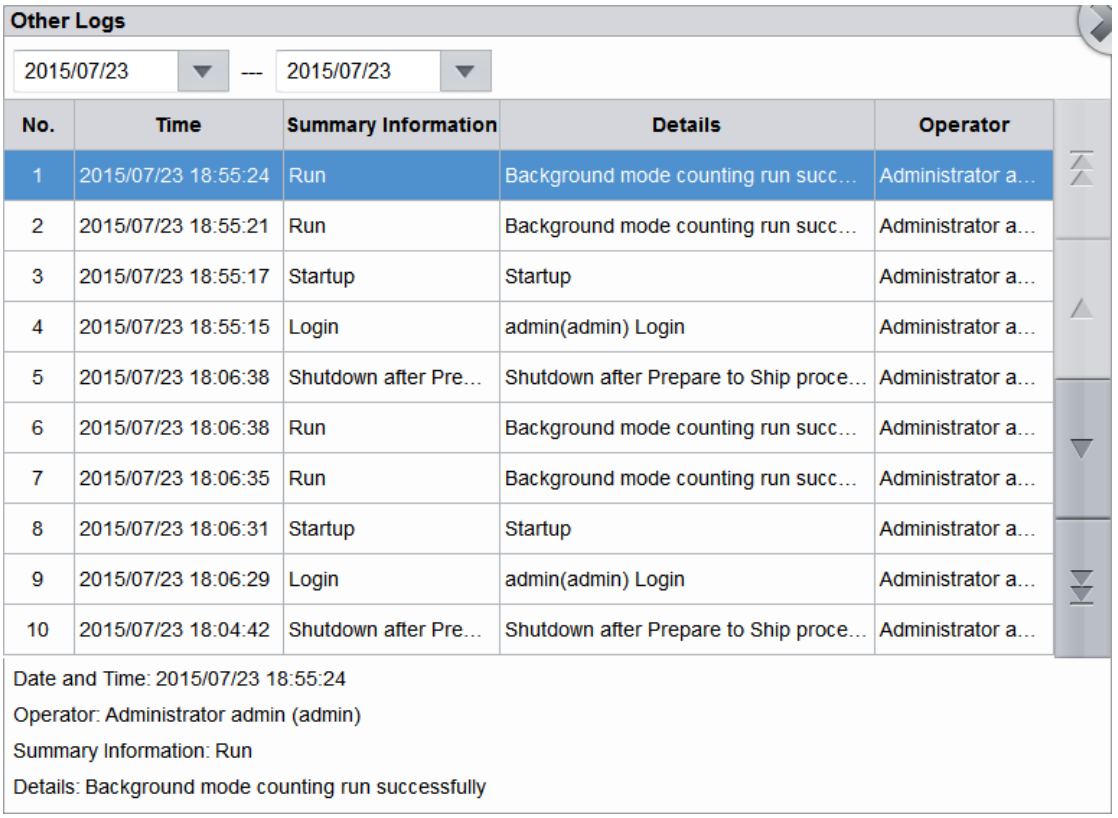
3. Select the dates in the two date textboxes, and then you can view the fault logs within the date range, including date and time when the faults occur, fault description and the operator.

12.5.4 Other Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Other Logs** in the **Log** selection.

   You can view other logs besides parameter revision logs and fault logs.

Figure 12-27 Other Logs



3. Select the dates in the two date textboxes to view the logs within the date range, including operation date and time, operation records and the operator.

12.6 Touch Screen Calibration

When the touch screen has offset, it needs to be recalibrated. Specific steps are shown below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Touch Screen Cal.** in the **Cal** selection.
3. Click the calibration point “+” on the screen in order.

   When the calibration point disappears and the system return to the service screen, it indicates the completion of the calibration.

13 Troubleshooting

13.1 Introduction

This chapter contains information that is helpful in locating and resolving problems that may occur during the operation of your analyzer.

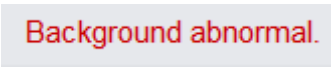
NOTE

This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer. If the recommended solution fails to solve the problem, contact MR customer service department or your local agent.

13.2 Dealing with Error Messages

In the use of the analyzer, when the software detects abnormalities, an error message will be displayed on the upper right of the screen as shown in Figure 13-1 and the main unit will sound an alarm.

Figure 13-1 Error Messages

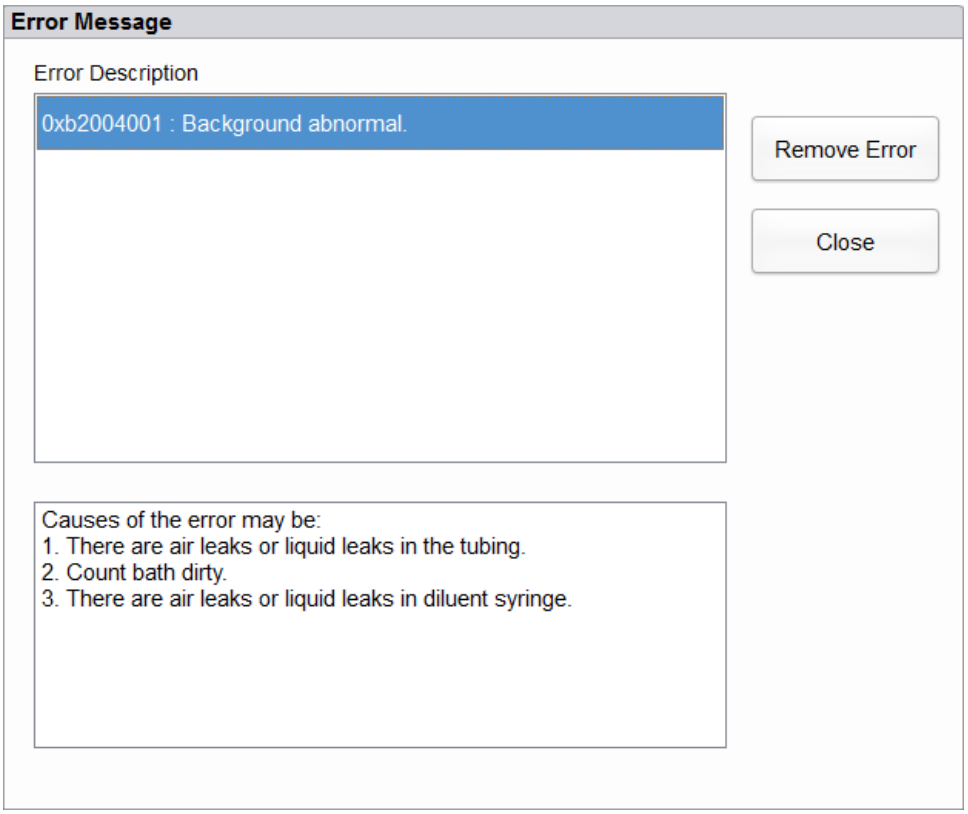


You can refer to the following steps to deal with the error messages.

1. Click the error message area.

   As shown in Figure 13-2, the popup dialog box displays the error description and its help information. The error descriptions are displayed in the order of error occurrence.

Figure 13-2 Error Message Dialog Box



2. Touch the screen to disable the beep.
3. Click **Remove Error**.

   Normally, the system will automatically remove the errors and close the dialog box.

   For errors which cannot be removed automatically, you can take appropriate actions by following the error help information or ***13.3 Error Message Reference***.

13.3 Error Message Reference

Possible errors and the corresponding help information are shown in Table 13-1.

Table 13-1 Error Message Reference

Error description	Troubleshooting Information
Abnormal -12V power.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Abnormal voltage of constant-current voltage abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Startup failure.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Startup initialization is not executed.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.

Error description	Troubleshooting Information
Right side door is open.	1. Close the right side door. 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
Abnormal +12V power.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
DIL-E expiration.	1. Check if the DIL-E diluent expires. If so, replace it with a new container of DIL-E. 2. Click the **Remove Error** button, the **Reagent Management** screen will be displayed. 3. Set the reagent information by referring to ***11 Reagent Management.*** 4. If the error still exists, contact our customer service department.
LYE-1 expiration.	1. Check if the LYE-1 lyse expires. If so, replace it with a new container of LYE-1. 2. Click the **Remove Error** button, the **Reagent Management** screen will be displayed. 3. Set the reagent information by referring to ***11 Reagent Management.*** 4. If the error still exists, contact our customer service department.
Abnormal HGB background voltage	1. Adjust the HGB background voltage within the specified range (4.2V~4.8V), preferably 4.5V. Refer to ***5.5.1 Gain Settings***. 2. If the error still exists, contact our customer service department.
Abnormal RBC aperture voltage.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal WBC aperture voltage	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
RBC clogging	Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, see ***12.2.3.2 Cleanser Soak*** to dip the RBC bath in the cleanser. 3. If the error still exists, contact our customer service department.
WBC clogging.	Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, see ***12.2.3.2 Cleanser Soak*** to dip the RBC bath in the cleanser. 3. If the error still exists, contact our customer service department.
Abnormal background	Check whether the diluent is contaminated. If not, click the **Remove Error** button to remove the error. If the error still exists, contact our customer service department.
Failed to read sample syringe parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.

Error description	Troubleshooting Information
Failed to configure sample syringe parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Sample syringe timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Sample syringe is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Command parameter error of the sampling assembly.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Sampling assembly timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Sampling assembly is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor instruction parameter error.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read vertical motor parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read the remaining steps of vertical motor.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read ambient temperature.	1. Make sure the temperature sensor is correctly installed. 2. If the error still exists, contact our customer service department.
Waste container is full.	1. Empty the waste container or install a new waste container. 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
Failed to read horizontal motor parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to configure Horizontal motor parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Horizontal motor timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal horizontal-motor photocoupler.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.

Error description	Troubleshooting Information
Horizontal motor is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
No DIL-E.	1. Check whether the DIL-E container is empty. If so, perform step 2; or if there is still plenty of DIL-E contact our customer service department. 2. Install a new container of DIL-E. 3. Click the **Remove Error** button to remove this error. If the error still exists after a new container of DIL-E is installed, contact our customer service department.
No LYE-1.	1. Check whether the LYE-1 container is empty. If so, perform step 2; or if there is still plenty of LYE-1, contact our customer service department. 2. Install a new container of LYE-1. 3. Click the **Remove Error** button to remove this error. 4. If the error still exists after a new container of LYE-1 is installed, contact our customer service department.
DIL-E not replaced.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
LYE-1 not replaced.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal 12V driving power supply.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Abnormal 24V driving power supply.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Insufficient LYE-1.	1. Check whether the LYE-1 container is empty. If so, perform step 2; or if there is still plenty of LYE-1, contact our customer service department. 2. Install a new container of LYE-1. 3. Click the **Remove Error** button, the **Reagent Management** screen will be displayed. 4. Set the reagent information by referring to ***11 Reagent Management.*** 5. If the error still exists, contact our customer service department.
Insufficient DIL-E.	1. Check whether the DIL-E container is empty. If so, perform step 2; or if there is still plenty of DIL-E, contact our customer service department. 2. Install a new container of DIL-E. 3. Click the **Remove Error** button, the **Reagent Management** screen will be displayed. 4. Set the reagent information by referring to ***11 Reagent Management.*** 5. If the error still exists, contact our customer service department.

Appendix A Specifications

A.1 Classification

According to the CE classification, the Auto Hematology Analyzer belongs to in vitro diagnostic medical devices, rather than those covered by Annex II and devices for performance evaluation.

A.2 Reagents

Reagent Type	Reagent Name
Diluent	DIL-E Diluent
Lyse	LYE-1 LYSE
Medical cleanser	CLE-P Cleanser

A.3 Parameters

Parameter	Abbreviation	Default Unit
White Blood Cell count	WBC	10^9/L
Number of Granulocytes	Gran#	10^9/L
Number of Lymphocytes	Lym#	10^9/L
Number of Mid-sized Cells	Mid#	10^9/L
Percentage of Granulocytes	Gran%	%
Percentage of Lymphocytes	Lym%	%
Percentage of Mid-sized Cells	Mid%	%
Red Blood Cell count	RBC	10^{12}/L
Hemoglobin Concentration	HGB	g/L
Hematocrit	HCT	%
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L

Parameter	Abbreviation	Default Unit
Red Blood Cell Distribution Width Standard Deviation (RDW-SD)	RDW-SD	fL
Red Blood Cell Distribution Width Coefficient of Variation (RDW-CV)	RDW-CV	%
Platelet count (PLT count, 10^9/L)	PLT	10^9/L
Mean Platelet Volume (MPV, fL)	MPV	fL
Platelet Distribution Width (PDW)	PDW	N/A
Plateletcrit (PCT)	PCT	%
Platelet-large cell ratio	P-LCR	%
Platelet-large cell count	P-LCC	10^9/L
Red Blood Cell Histogram	RBC Histogram	N/A
Platelet Histogram	PLT Histogram	N/A
White Blood Cell Histogram	WBC Histogram	N/A

A.4 Performance Specifications

A.4.1 Display Range

Parameter	Linearity Range	Display Range
WBC	0~300×10^9/L	0~999×10^9/L
RBC	0.00~8.50×10^{12}/L	0~18.00×10^{12}/L
HGB	0~250g/L	0~300g/L
PLT	0~3000×10^9/L	0~5000×10^9/L
HCT	0~67%	0%~80%

A.4.2 Normal Background

Parameter	Normal Background
WBC	≤0.2×10^9/L
RBC	≤0.02×10^{12}/L
HGB	≤1g/L
PLT	≤5×10^9/L
HCT	≤0.5%

A.4.3 Linearity Range

Parameter	Linearity range	Deviation range (Whole blood mode)
WBC	(0.00~100.00)×10^9/L	±0.30×109/L or ±5%
	(100.01~300.00)×10^9/L	±10%
RBC	(0.00~8.50)×10^{12}/L	±0.05×1012/L or ±5%
HGB	(0~250) g/L	±2g/L or ±2%
PLT	(0~1000)×10^9/L (RBC≤7.0)	±1 0×109/L or ±8%
	1001~3000×10^9/L (RBC≤7.0)	±12%
HCT	0~67%	±2% (HCT value) or ±3% (deviation percent)

A.4.4 Repeatability

These repeatability requirements apply only to the situation in which a qualified sample has been run for 11 times and the results of the 2nd to 11th runs are used to calculate the repeatabilities.

Parameter	Condition	Repeatability (CV%/absolute deviation d*)
WBC	(7.0~15.0)×10^9/L	≤2.0%
	(4.0~6.9)×10^9/L	≤3.5%
RBC	(3.5~6.5)×10^{12}/L	≤1.5%
HGB	(100~180)g/L	≤1.5%
MCV	(70~110)fL	≤0.5%
PLT	(150~500)×10^9/L	≤4.0%

Absolute deviation d = analysis result – average of analysis results

A.4.5 Carryover

Parameter	Carryover
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.5%
PLT	≤1.0%
WBC	≤0.5%

A.5 Input/output Device

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 B)).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 services department of your local agent.

- Host
  - Touch screen: 10.4 inches embedded touch screen with a resolution of 800×600
  - Thermal printer
  - One LAN interface
  - 4 USB interfaces
- Power
  - Voltage: A.C 100V~240V
  - Input power: ≤200VA
  - Frequency: 50/60 Hz
- Keyboard (Optional, USB)
- Mouse (Optional, USB)
- External barcode scanner (optional, USB)
- Printer (optional, USB)
- USB flash disk (optional, USB)

A.6 EMC Description

This equipment complies with the emission and immunity requirements of the IEC 61326-1:2012, EN 61326-1:2013, IEC 61326-6-2-6:2012 and EN 61326-2-6:2013.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

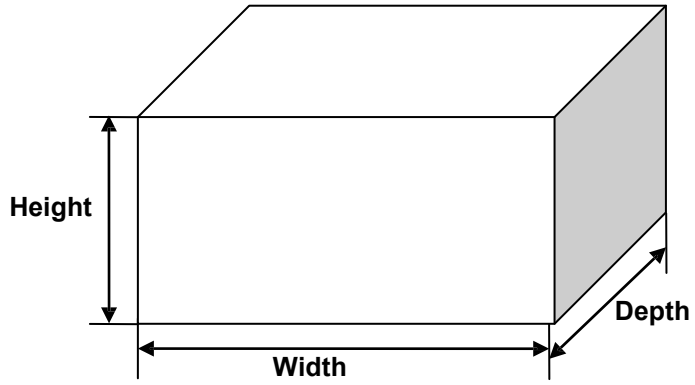
A.7 Environmental conditions

NOTE

Be sure to use and store the analyzer in the specified environment.

Environmental conditions	Operating Environment	Storage Environment	Running Environment
Ambient temperature	10℃~30℃	-10℃~40℃	5℃~40℃
Relative humidity	20%~85%	10%~90%	10%~90%
Atmospheric pressure	70kPa~106kPa	50kPa~106kPa	70kPa~106kPa

A.8 Dimensions and Weight



Analyzer	Dimensions and Weight
Width (mm)	≈360
Height (mm)	≈455
Depth (mm)	≈410
Weight (kg)	≈24

A.9 Expected service life

More than 5 years.

A.10 Contraindications

N/A

Appendix B Terms and Abbreviations

CWB	Capillary Whole Blood
PD	Predilute Blood **RF**
	Radio Frequency
VWB	Venous Whole Blood

Appendix C Packing List

No.	Name	Quantity
1	Auto Hematology Analyzer	1
2	Power cable	1
3	Grounding cable	1
4	Operator's Manual	1
5	Software installation CD-ROM	1
6	Quick Operation Guide Card	1
7	Diluent Adapter Tube	1
8	Waste Float Adapter Tube	1
9	DIL-E Diluent (20L)	1
10	LYE-1 Lyse (200mL)	1
11	Cleanser (50mL)	1
12	Warranty Card	1
13	Waste container	1
14	Auto Hematology Analyzer Inspection Record	1
15	Certificate of Delivery and Acceptance	1
16	Packing list	1
17	Reagent Operation Guide for Closed System (for closed system only)	1