MR56 Auto Hematology Analyzer

Operator’s Manual

CE

Preface

Thank you for purchasing the MR56 Auto Hematology Analyzermanufactured by MR group

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

Product name: MR56 Auto Hematology Analyzer

Model: MR56

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

Scope of Use: blood cell counting, white blood cell 5-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 operators manual.
- The electrical appliances in the relevant working room complies with applicable national and local requirements.

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 2 appendices. 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 Daily Operations	Daily operations such as sample collection and preparation, the analysis procedures, startup and shutdown of the instrument.
6 Setup	Settings of the system parameters such as the software date format and parameter units.
7 Report	How to process the sample results upon the completion of the

See…	You can find…
	analysis.
8 Worklist	How to input the sample information and patient information using the worklist.
9 Result Review	Review of the analysis results.
10 Quality Control	Basic requirements for quality control and the quality control methods provided by the auto hematology analyzer.
11 Calibration	Basic requirements for calibration and the calibration methods provided by the auto hematology analyzer.
12 Maintenance	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 Packing List	List of items in the product packaging 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.

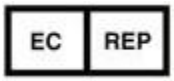
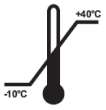
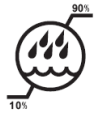
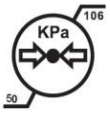
When you see …	Then …
	Follow the instruction below the symbol to avoid potential biocontamination.
 WARNING	Follow the instruction below the symbol to avoid personnel injury.
 CAUTION	Follow the instruction below the symbol to avoid analyzer damage and failure, or unreliable analysis results.
NOTE	Follow 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.
	Laser Warning: This sign serves as a reminder of laser radiation. Avoid staring into the laser beam or viewing through an optical instrument.

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

When you see	It means
	Warning for laser beam
	Instruction for Moving
	Network interface
	Protective grounding
	Alternating current (AC)
	For in vitro diagnosis only
	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

When you see	It means
	Avoid sunlight
	Keep dry
	No rolling
	No Stacking.
	Let this side face upward.
	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 subject to potential biohazard. 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.
- Make sure to install only Dymind-authorized software on the computer.
- Please install the original software edition to prevent the computer from being infected by virus.
- Please take proper measures to prevent the reagents from being polluted.
- It is recommended that the anti-virus software should be installed on the computer and run regularly.
- When running the software for the first time or click the combo boxes for selecting the desired option, the antivirus software may prompt you to stop running the software. In this case, please choose to allow the software to run, otherwise, the software may have problems in running.

2 Installation

2.1 Introduction

WARNING

Installation by personnel not authorized or trained by Dymind may cause personal injury or damage to the analyzer. Do not install the analyzer without the presence of Dymind-authorized personnel.

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.

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 Dymind customer service department or your local agent immediately.

2.2 Installation Personnel

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

When you receive the analyzer, please notify Dymind 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

- Do not install the software and database in the system disk. The default installation path for the software and database is **C:\Program Files\Dymind\MR56**. You can change it.
- 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 ≥100kg. • 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 100 cm from each side, which is the preferred access to perform service procedures. • At least 50 cm 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	15°C~30°C
Optimal operating humidity	30%~85%
Operating atmospheric pressure	70kPa~110kPa

Installation Environment	Requirements
Ventilation	Keep air exchange to ensure good air circulation. The wind should not blow directly at the analyzer.
Power	AC100V~240V, Input Power ≤250VA, 50/60HZ.
Peripheral Computer	• Compliant with related safety requirements • CPU: >1.4G • RAM: >2G • Hard disk space available: >20G • Graphics Card: OpenGL 2.0 or above • Operating system: preinstalled 32-bit Windows XP/Windows 7 • Display aspect ratio: 10: 6 • Resolution: 1280*768
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, Dymind 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 Dymind 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.

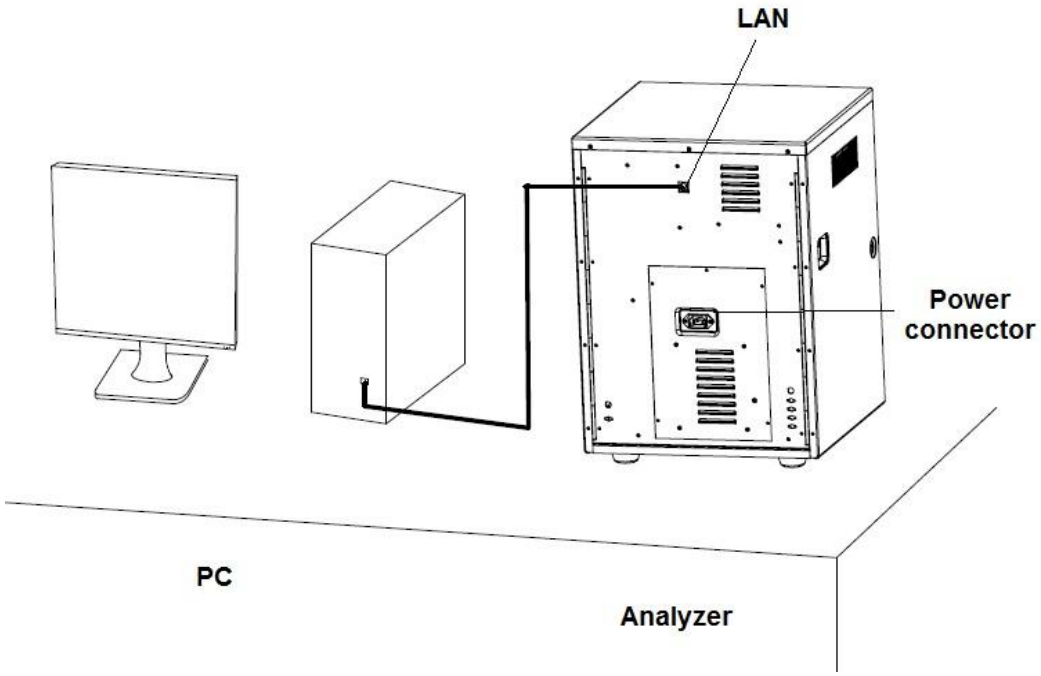
   To avoid the possible collision resulting from the slippage caused by shaking and slanting during transportation, the central position of those two belts is fixated with binder clips before they are shipped from the factory. The binder clips must be removed during unpacking.

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

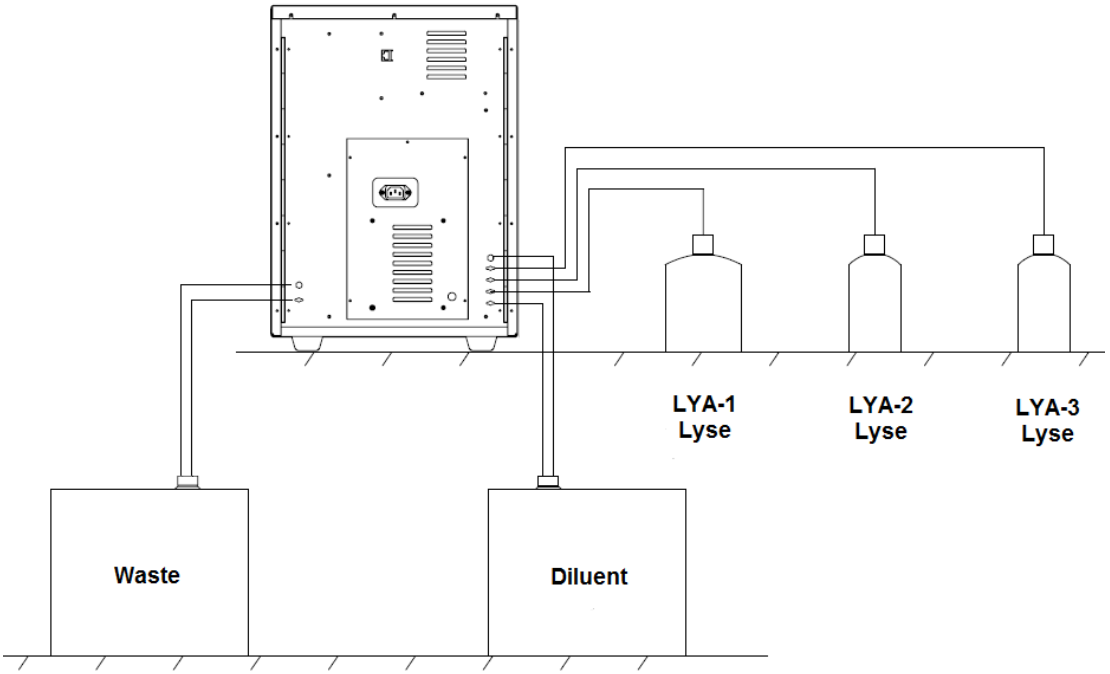
- Be sure to dispose reagents, waste, samples, consumables, etc. according to you local legislations and regulations.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling 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.

Please refer to Figure 2-2 for the connection of the fluidic lines of the analyzer.

Figure 2-2 Connecting the Fluidic Lines



2.6.3 Installing the Diluent Float Sensor and Replacing the Reagents

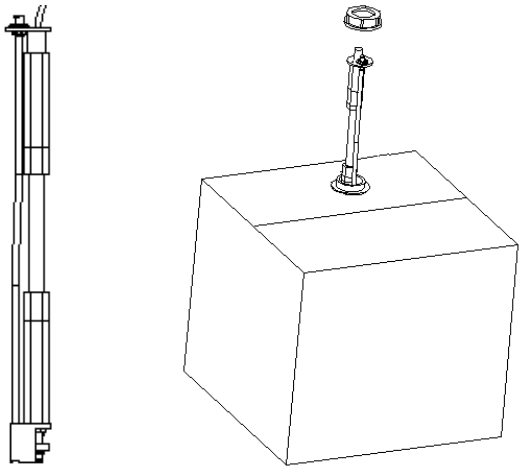
Please install the diluent float sensor and replace the diluent as per the approaches stated in this section.

2.6.3.1 Installing the 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 2-3. The float sensor shall be kept as vertical as possible during installation and the self-contained cap of the sensor shall be tightened.

Figure 2-3 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.

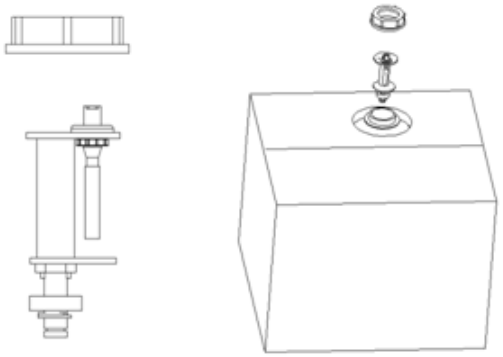
2.6.4 Installing the Waste Float Sensor

NOTE

The float sensors used in the analyzer are only applicable to Dymind-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 2-4. 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 2-4 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 reagents, waste, samples, consumables, etc. according to government regulations.

3 System Overview

3.1 Introduction

MR56 Auto Hematology Analyzeris a quantitative, automated hematology analyzer and 5-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, 5-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 25 hematology parameters and four research parameters, three histograms, one three-dimensional scattergram, three two-dimensional scattergrams and two measurement modes, namely CBC and CBC+DIFF.

Parameter Name	Abbr.	CBC	CBC+DIFF
White Blood Cell count	WBC count	*	*
Percentage of Neutrophils	Neu%	/	*
Percentage of Lymphocytes	Lym%	/	*
Percentage of Monocytes	Mon%	/	*
Percentage of Eosinophils	Eos%	/	*
Percentage of Basophils	Bas%	/	*
Number of Neutrophils	Neu#	/	*
Number of Lymphocytes	Lym#	/	*
Number of Monocytes	Mon#	/	*

Parameter Name	Abbr.	CBC	CBC+DIFF
Number of Eosinophils	Eos#	/	*
Number of Basophils	Bas#	/	*
Percentage of Abnormal Lymphocytes	ALY% (RUO)	/	*
Percentage of Large Immature Cells	LIC% (RUO)	/	*
Number of Abnormal Lyphocytes	ALY# (RUO)	/	*
Number of Large Immature Cells	LIC# (RUO)	/	*
Red Blood Cell count	RBC count	*	*
Hemoglobin Concentration	HGB concentration	*	*
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	*	*
Platelet count	PLT count	*	*
Mean Platelet Volume	MPV	*	*
Platelet Distribution Width	PDW	*	*
Plateletcrit	PCT	*	*
Platelet-Large Cell Ratio	P-LCR	*	*
Platelet-Large Cell Count	P-LCC	*	*
White Blood Cell/ Basophils Histogram	WBC/BASO Histogram	/	*
White Blood Cell Histogram	WBC Histogram	*	/
Red Blood Cell Histogram	RBC Histogram	*	*
Platelet Histogram	PLT Histogram	*	*
3D Differential Scattergram	3D DIFF Scattergram	/	*
2D Differential Scattergram	2D DIFF Scattergram	/	*

NOTE

- “*” means the parameter is provided in the mode. “/” means the parameter is not provided.
- ALY%, LIC%, ALY# and LIC# are parameters for research use only (RUO), not for diagnostic use.

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.

CAUTION

Installing other software on the analysis system computer, using mobile storage devices or using the computer for other purposes (e.g. playing games, browsing the internet, etc.) may lead to virus infection, system damage and/or data error. Therefore, please make sure the computer is used for the analysis system only.

The sampling probe is sharp and may contain biohazardous materials. Care must be taken when working with it.

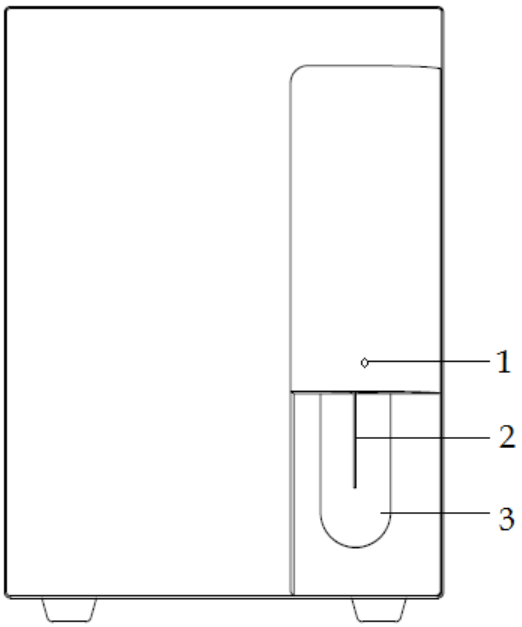
This sign warns of laser radiation. Do not look directly at the laser beams or see through the optical instrument.

3.4.1 Main Unit

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

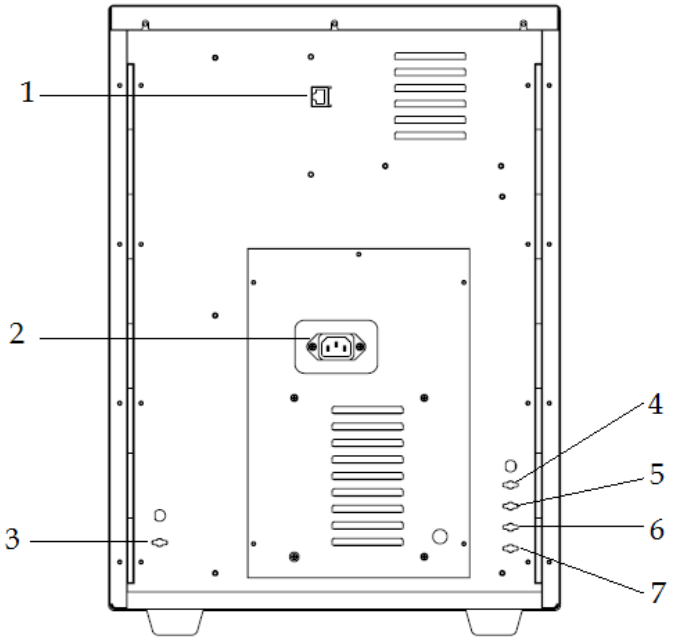


1: Power/Status indicator 2: Sample probe

3: Aspirate key

- Back of the analyzer

Figure 3-2 Back of the analyzer



1: Network interface 2: AC input

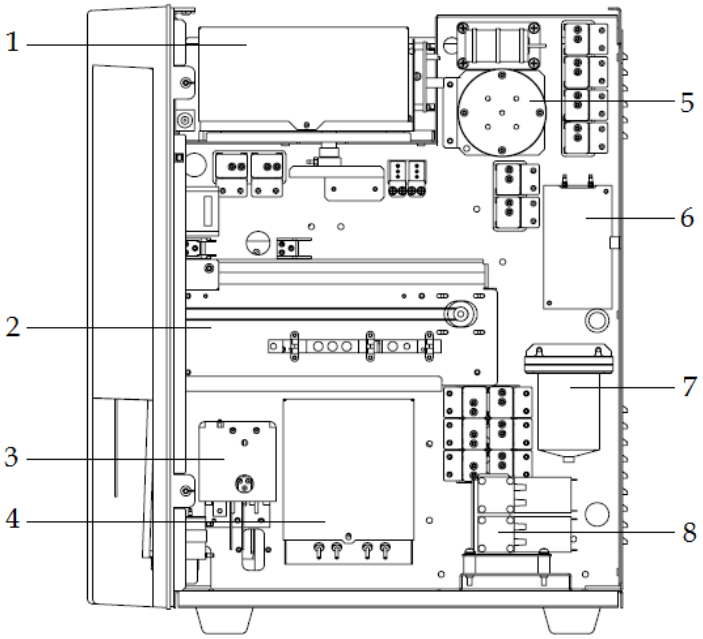
3: Waste outlet 4: LYA-3 Lyse inlet

5: LYA-2 Lyse inlet 6: LYA-1 Lyse inlet

7: DIL-A diluent inlet

- Right side of the analyzer (right door opened)

Figure 3-3 Right side of the analyzer (right door opened)



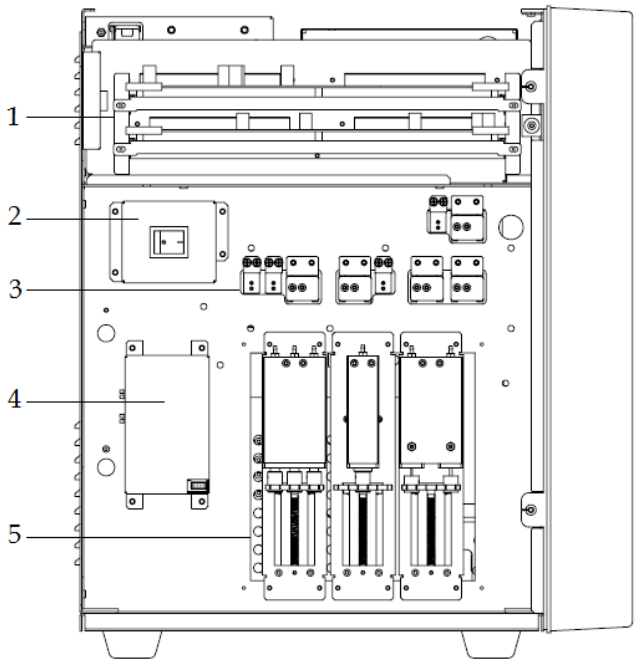
1: Optical system
2: Sampling assembly
3: DIFF bath
4: Counting bath
5: Positive pressure chamber
6: Metric unit
7: Negative pressure chamber
8: Pump

- 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 (left door open)



1: Circuit boards
2: Power switch
3: Fluidic valves
4: Liquid level detection unit
5: Syringes

3.4.2 Power/Status Indicator

The Power/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 Dymind or Dymind's agent for maintenance.

3.4.3 Power Switch

CAUTION

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

A power switch is on the left side of the analyzer. It turns on or shuts down the analyzer.

3.4.4 Aspirate key

It's located behind the sample probe for starting the counting operations or for adding diluent.

3.4.5 Network Interface

A network interface is located on the back of the analyzer. It connects the peripheral computer.

3.5 User Interface

After the startup procedure, you will enter the user interface, as shown in Figure 3-5.

Figure 3-5 User Interface

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

- 1 - Status area

On the top of the screen is the menu navigation area. Click on a menu tab to access the corresponding interface or dialog box.

- 2 - Status display area

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

Table 3-2 Status Icon Description

Status	Icon	Remarks
Current Counting Status (displayed in the same way as the power/status indicator on the main unit)	Green icon 	The main unit allows the execution of the sequential actions.
	Flickering green icon	The main unit is executing the sequential actions.
	Red icon 	The main unit has a problem and is not running.
	Flickering red icon	The main unit has a problem and is running.
	Yellow icon 	The main unit is in a condition with no errors but not allowing the execution of the counting (such as: sleep status)
Connection status between the analyzer and the computer	Gray icon 	The computer is not connected to the analyzer yet.
	Color icon 	The computer is connected to the analyzer.
LIS/HIS status	Gray icon 	The computer is not connected to the LIS/HIS.
	Color 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.

- 3 - Function screen area

  It displays the selected screen and the corresponding function buttons.

- 4 - Operation/status information area

  The area displays the information about the current operation of the analyzer/computer, or the current status of the analyzer/computer. For example, in the startup process, **Fluidics cleaning…** appears in this area.

- 5 - Information area of the next sample

  This area displays the information about the sample ID, sample position, blood mode (whole blood/predilute) and measurement mode (CBC/CBC+DIFF) of the next sample.

- 6, 7 - Function Button Area

The Function Button Area is divided into two parts: the upper area and the lower area

- The upper area contains the Minimize button, the Logoff button and the Shutdown button.

   : You can click the button to minimize the interface to the taskbar of the operation system.

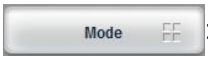
  NOTE

  Click the interface icon displayed on the taskbar, you can restore the display of the interface after minimizing it

   : Clicking this button will log off the current account. Entering another account's username and password in the pop-up dialog box will switch to another user's interface.

   : Clicking this button will activate the shutdown operation.

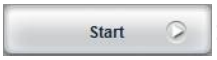
- The lower area is where you can set the measurement modes, add diluent, start the counting and perform other operations.

  : Click this button to set the blood sample mode, measurement mode and sample ID.

  : Click this button to add diluent.

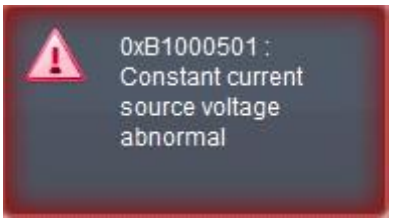
  

  : Click this button to start the counting.

- 8 - Error message area

  Upon the occurrence of a system failure, the corresponding error message will appear in this area (See Figure 3-6). When there is more than one failure, the error message for the latest failure will appear in this area.

Figure 3-6 Error Message Area



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

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 Dymind-specified 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

- 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.
- After installing a new container of reagent, keep it still for at least one day before use.

3.6.1 Reagents

The following reagents are intended to be used with the analyzer for 5-part diff counting, daily cleaning and other operations.

- DIL-A diluent

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

- LYA-3 Lyse

  This product is intended for lysing the red blood cells and it works with LYA-2 Lyse for white blood cell classification.

- LYA-2 Lyse

  This product is intended for lysing the red blood cells and it works with LYA-3 Lyse for the white blood cell classification and eosinophils coloration.

- LYA-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.

- 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.

NOTE

The "calibrators" and "controls" mentioned in this manual refer to Dymind-specified calibrators and controls and need to be purchased from SHENZHEN DYMIND BIOTECHNOLOGY CO., LTD. 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/BAS, RBC and PLT data; the colorimetric method for determining the HGB; laser-based flow cytometry for determining the WBC data. 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 20μL of 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 and white blood cell differential measurement.

To meet different needs, the analyzer offers two working modes –Whole Blood and Predilute, and two measurement modes- CBC and CBC+DIFF.

Taking CBC+DIFF mode as an example, this section introduces the dilution procedures of the test sample in Whole Blood mode and Predilute mode separately. (The dilution procedure in CBC mode is not introduced here since it's the same as that in CBC+DIFF mode.)

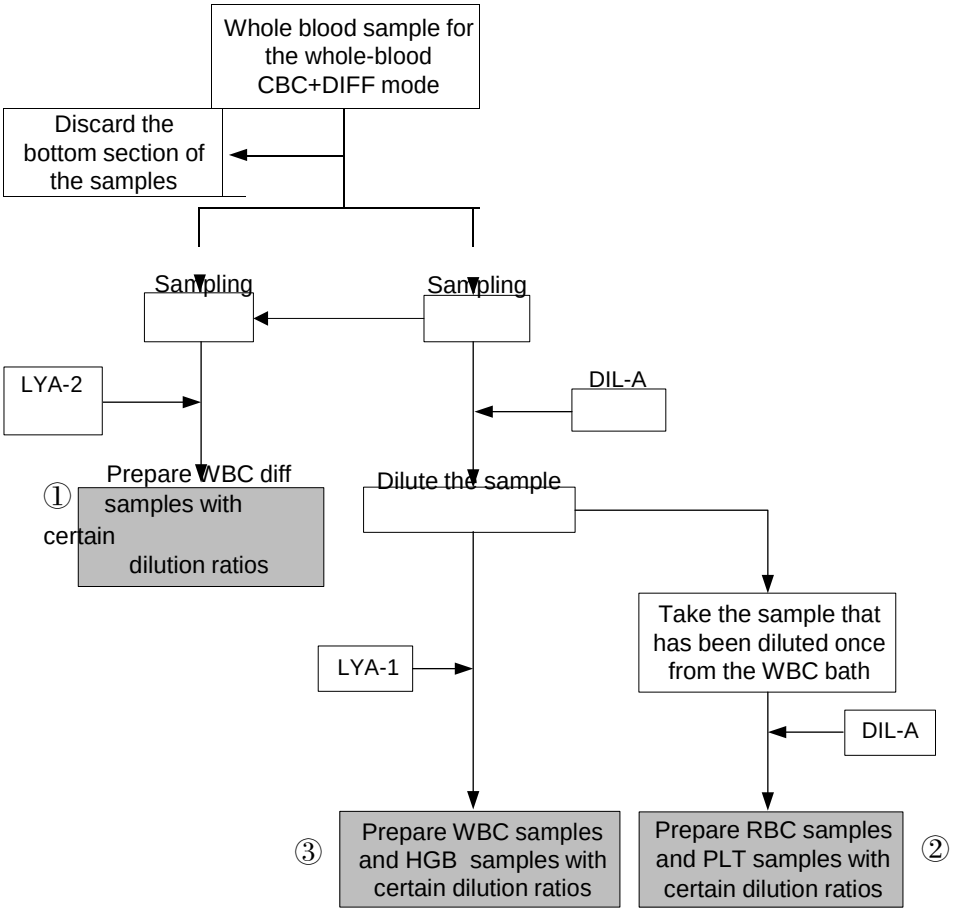
NOTE

CBC mode, namely complete blood cell count, is intended for counting only, not for white blood cell classification. CBC+DIFF mode is intended for both counting and white blood cell classification.

4.3.1 Dilution Procedures in Whole-Blood CBC+DIFF Mode

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

Figure 4-1 Dilution Procedures in Whole-Blood CBC+DIFF Mode



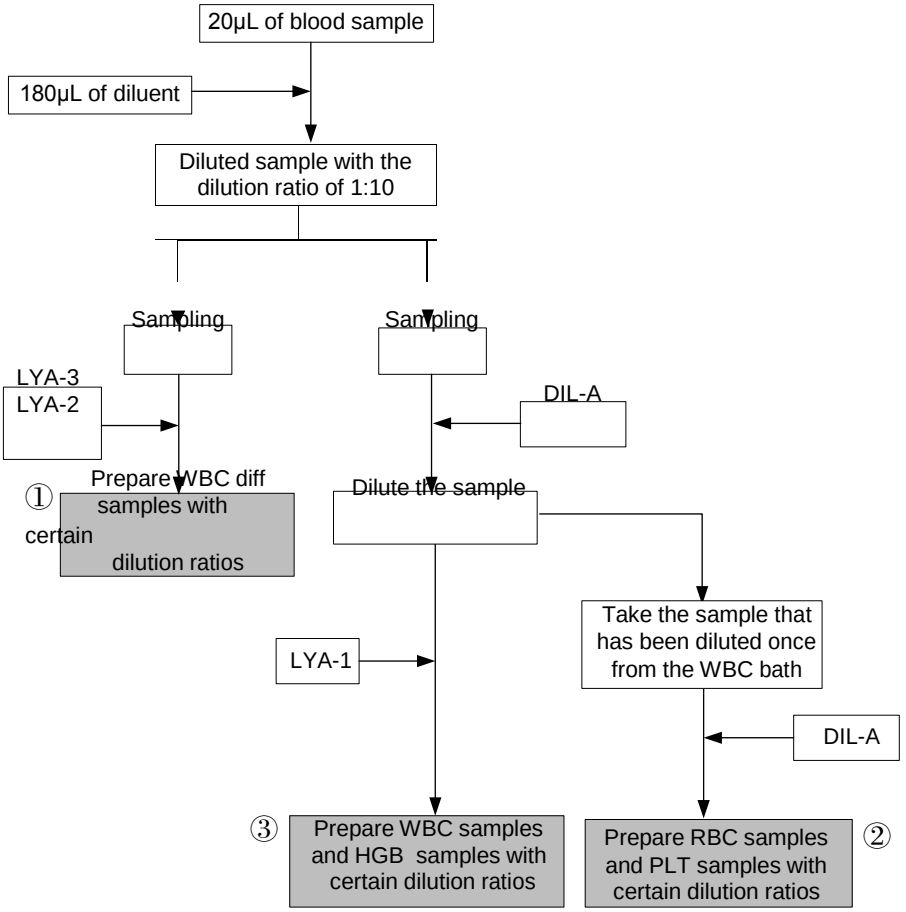
Where,

- ① is the dilution procedure for white blood cell diff, namely DIFF;
- ② is the dilution procedure for red blood cell and platelet, ③ is the dilution procedure for white blood cell count/hemoglobin; namely CBC.

4.3.2 Dilution Procedure in Predilute CBC+DIFF Mode

In CBC+DIFF mode, the dilution procedure for the prediluted sample is shown in Figure 4-2.

Figure 4-2 Dilution Procedure in Predilute CBC+DIFF Mode



Where,

- ① is the dilution procedure for white blood cell diff, namely DIFF;
- ② is the dilution procedure for red blood cell and platelet; ③ is the dilution procedure for white blood cell count/hemoglobin; namely CBC.

4.4 WBC Measurement

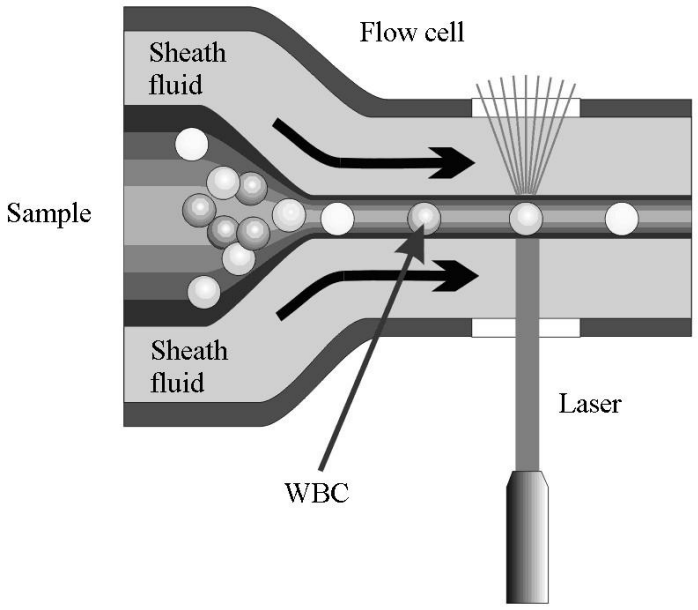
The analyzer obtains the white blood cell differential count using a semiconductor-laser-based flow cytometry, obtains the white blood cell count/basophils count using the principle of impedance method (also known as Coulter principle) and eventually calculates the parameters relevant to white blood cells.

4.4.1 Working Principle of Laser-based Flow Cytometry

The analyzer obtains the white blood cell differential count using semiconductor-laser-based flow Cytometry.

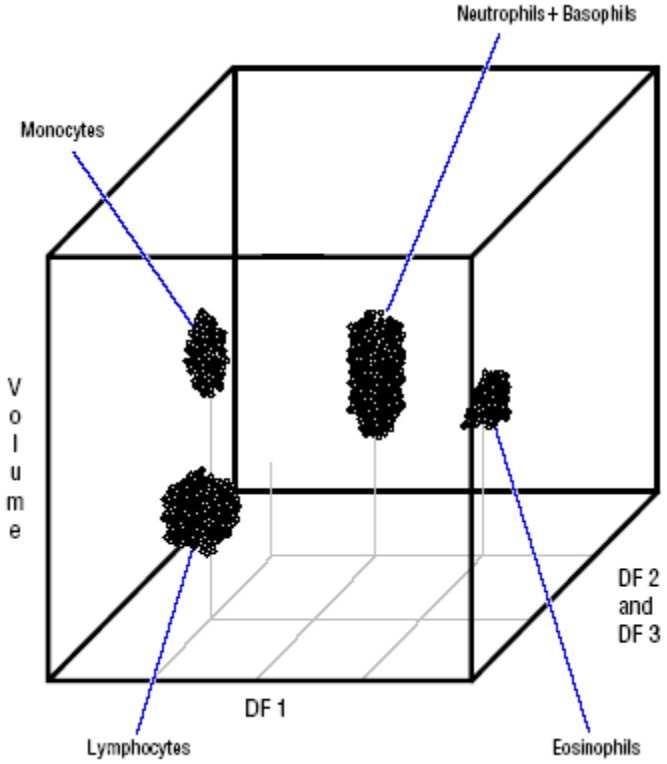
The principle of laser-based flow cytometry is illustrated by Figure 4-3.

Figure 4-3 WBC Measurement



After a predetermined volume of blood is aspirated and diluted by a certain amount of reagent, it is injected into the flow chamber. Surrounded with sheath fluid (diluent), the blood cells pass through the center of the flow chamber in a single column at a faster speed. When the blood cells suspended in the diluent pass through the flow chamber, they are exposed to a laser beam. The intensity of scattered light reflects the blood cell size and intracellular density. The low-angle scattered light reflects cell size, while the high-angle scattered light reflects intracellular density (nucleus size and density). The optical detector receives this scattered light and converts it into electrical pulses. Pulse data thus collected can be used to draw a 2-dimensional distribution (scattergram) as shown in Figure 4-4.

Figure 4-4 DIFF channel scattergram



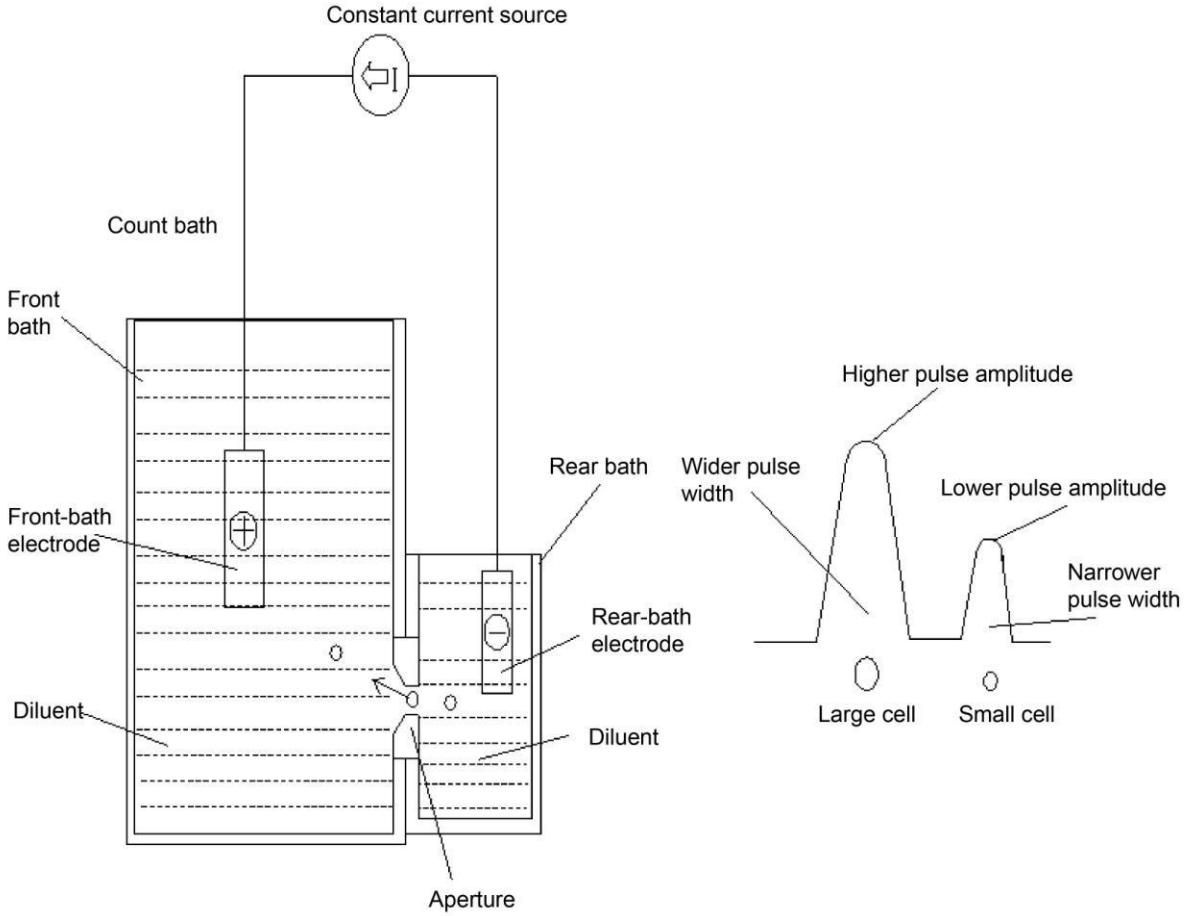
By analyzing the DIFF channel scattergram, the analyzer presents the Lym%, Mon%, Eos% and Neu%.

4.4.2 Electrical Impedance Method

BASs/WBCs 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 have passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

Figure 4-5 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/BAS lower threshold value, it is counted as a WBC/BAS. The analyzer presents the WBC/BAS histogram, where the x-coordinate represents the cell volume (fL) and the y-coordinate represents the number of the cells.

4.4.3 Derivation of WBC-Related Parameters

Based on the analysis of the DIFF channel scattergram and the Lym region, Neu region, Mon region and Eos region, the analyzer calculates the Lym%, Mon%, Eos% and Neu%. After WBC measurement, the analyzer proceeds to calculate Lym#, Neu#, Mon# and Eos# per the following equations while Bas# is obtained directly by the Electrical Impedance method and expressed in 10^9/L.

- White Blood Cell count

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

- Number of Basophils (Bas#)

  Bas# is the number of Basophils measured directly by counting the Basophils passing through the aperture.

- Percentage of Basophils (BAS%)

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

- Percentage of Lymphocytes (Lym%)

$$Lym\% = \frac{\text{Particles in Lym region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100\%$$

- Percentage of Neutrophils (Neu%)

$$Neu\% = \frac{\text{Particles in Neu region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100\%$$

- Percentage of Monocytes (Mon%)

$$Mon\% = \frac{\text{Particles in Mon region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100\%$$

- Percentage of Eosinophils (EOS%)

$$Eos\% = \frac{\text{Particles in Eos region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100\%$$

- Number of lymphocytes (Lym#)

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

- Number of Neutrophils (Neu#)

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

- Number of Monocytes (Mon#)

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

- Number of Eosinophils (EOS#)

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

4.5 HGB Measurement

HGB is determined by the colorimetric method.

4.5.1 Colorimetric Method

HGB is determined by the 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.

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

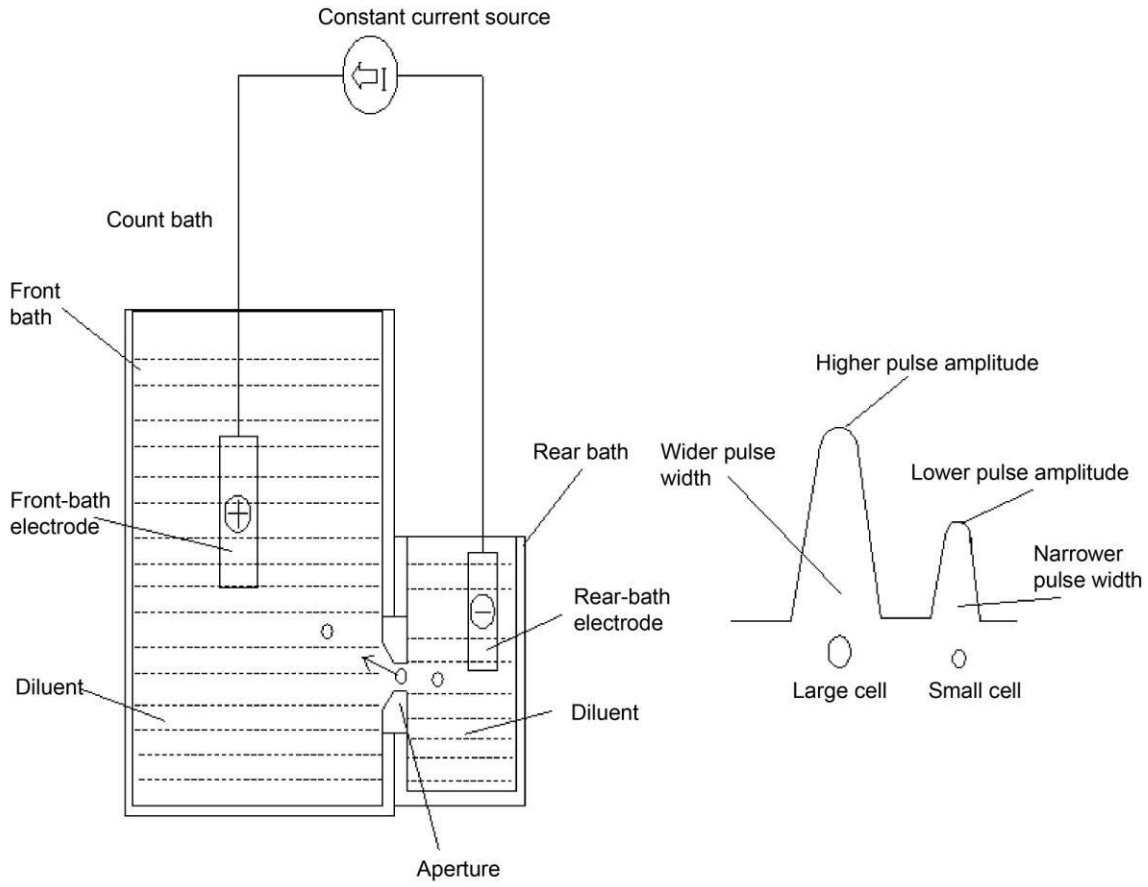
4.6 RBC/PLT Measurement

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

4.6.1 Electrical Impedance Method

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 4-6 Counting Principle



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 RBC/PLT lower

threshold value, it is counted as a RBC/PLT. The analyzer presents the RBC/PLT histogram, where the x-coordinate represents the cell volume (fL) and the y-coordinate represents the number of the cells.

4.6.2 RBC

- Red Blood Cell count

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

- Mean Corpuscular Volume

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

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

  This analyzer calculates the HCT (%), MCH (pg) and MCHC (g/L) as follows, where the RBC is expressed in 10^{12}/L, MCV in fL and HGB in g/L.

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

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

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

- 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.

4.6.3 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)

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

4.7 Flushing

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

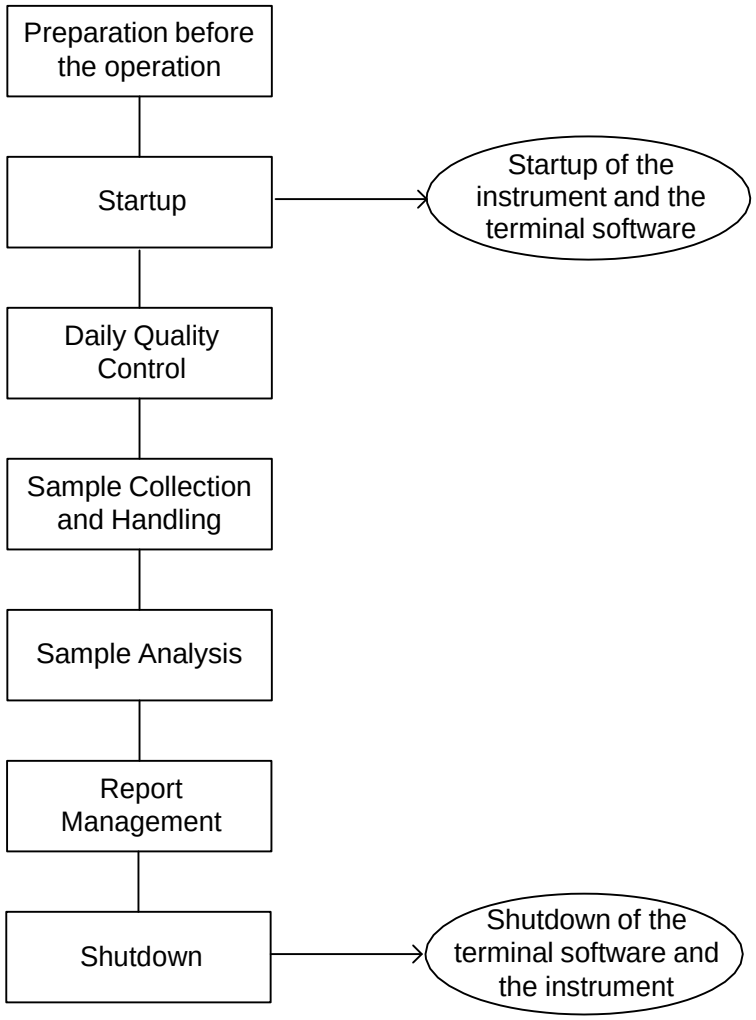
5 Daily Operations

5.1 Introduction

This chapter introduces the daily operations from the startup to the shutdown of the analyzer with a focus on the detailed operation procedures for running samples in different working modes.

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

Figure 5-1 Daily Operations Procedure



5.2 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 them and the relevant areas in the laboratory.

WARNING

- Be sure to dispose reagents, waste, samples, consumables, etc. according to you 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 clothing, 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 Dymind-specified reagents. Store and use the reagents 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 should 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 Dymind-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 printer paper is installed, the power cord of the printer is properly plugged into power outlet, and the printer is properly connected to the peripheral computer.

- Keyboard, mouse and peripheral computer

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

  Check and make sure the keyboard and the mouse are well connected to the peripheral computer.

5.3 Startup

This section introduces the operations related to the startup of the analyzer, including turning on the instrument and launching the terminal software.

5.3.1 Start the analyzer

1. Place the power switch at the left side 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.

5.3.2 Log in Terminal Software

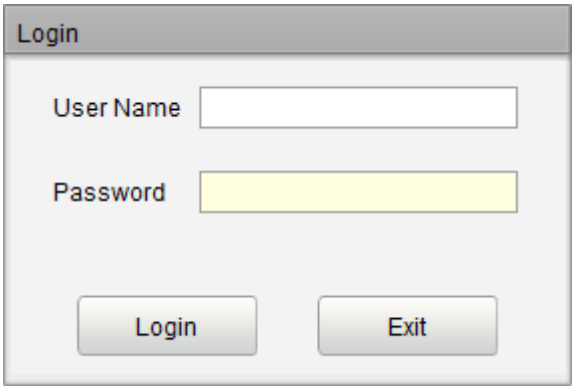
NOTE

- Before running the software, make sure the network cable of the peripheral computer is properly connected to the analyzer. The analyzer starts to initialize only when the connection are detected.
- If you failed to run the software continuously, please contact Dymind customer service department or your local agent immediately.
- After startup, please make sure the data/time of the computer is correct.
- You can either start up the main unit first or run the software first.

1. Start the peripheral computer.
2. Turn on the display.
3. After entering the operation system, double click the  icon to run the software.

   After starting the software, the message box as shown in Figure 5-2 will pop up.

Figure 5-2 Login



4. Enter the correct user name and password in the **Login** message box.

   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.

5. Click **Login**.

   The system starts to execute the initialization operations.

   The whole process lasts for 4 to 12 minutes. The time needed for initializing the system depends on how the analyzer was shut down previously.

   For the background Ref. Range of each parameter, please see ***A.5.2 Normal Background***.

NOTE

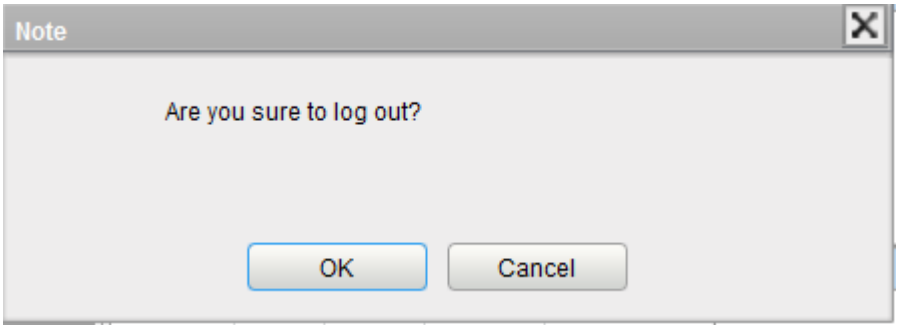
- The background test is designed for detecting particle interference and electrical interference.
- The sample ID for the background test is **background**.
- If the background results exceed the Ref. Range for the first time during fluidics initialization, then the analyzer will run the background 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.

5.3.3 Log off/Switch User

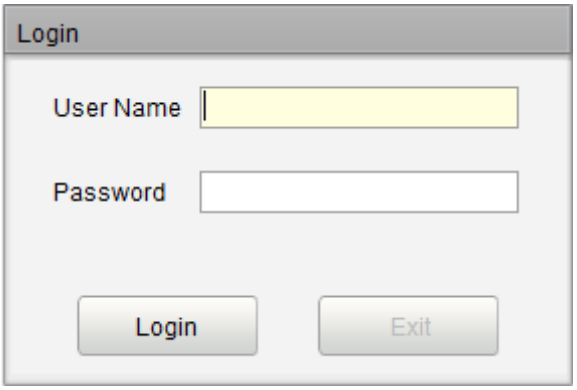
You can refer to the following steps to log off or switch users.

1. Click  on the top right corner of the screen.

   The following dialog box will pop up.



2. Click **OK** and enter the username and password in the dialog box.



3. Click **Login** to log in the interface as a different user.

5.4 Daily Quality Control

To ensure reliable analysis results, conduct daily QC analysis on the analyzer before running samples. See ***10 Quality Control***.

5.5 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 them and the relevant areas in the laboratory.

WARNING

Do not touch the patients' blood sample directly.

CAUTION

- Do not re-use such disposable product 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 Dymind-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.

5.5.1 Venous Whole Blood Samples

The procedure for preparing whole blood samples 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. Shake the sample well according to your laboratory's protocol.

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.

5.5.2 Capillary Whole Blood Samples

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

1. User clean centrifugal tube with anticoagulant to collect capillary whole blood samples.
2. Mix the sample according to your laboratory's protocol.

CAUTION

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

NOTE

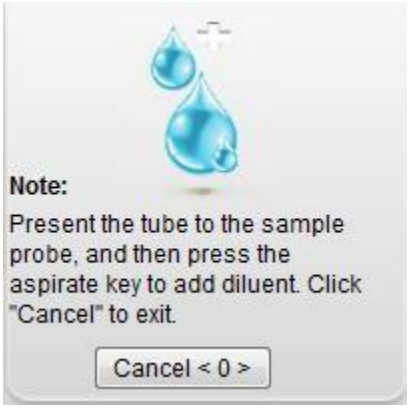
Run the capillary whole blood sample within 3 minutes to 2 hours after its collection.

5.5.3 Prediluted Samples

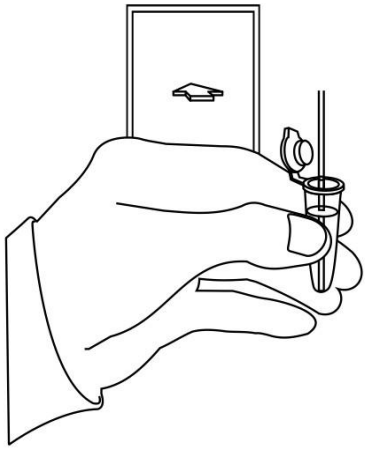
The procedure for preparing prediluted sample is as follows:

1. Click the **Add Diluent** button in the function button area.

   The system will prompt you with a message to add the diluent.



2. Take a clean centrifugal tube, uncap and set it under the sample probe as shown in the following picture so that 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.



3. 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.
4. Add 20μL of capillary blood to the diluent, close the tube cap and shake the tube to mix the sample.
5. After the prediluted sample is prepared, click **Cancel** to exit dispensing the diluent.
6. If more portions of diluent are needed, repeat steps 3~4.

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.

5.6 Sample Analysis

5.6.1 Entering Worklist Information

You can enter the worklist information of the samples to be tested before the analysis. For detailed procedures of adding a new worklist, you can refer to ***8 Worklist.***

NOTE

- If the analyzer is shut down abnormally, you will lose the unsaved worklist information of the samples.
- If you want to complete the worklist information after the analysis, see 7 Report for details.

5.6.2 Running the 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 them and the relevant 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 product as collection tubes, test tubes, capillary tubes, etc.
- Make sure that the entered sample ID and configuration exactly match those of the test samples to be run.

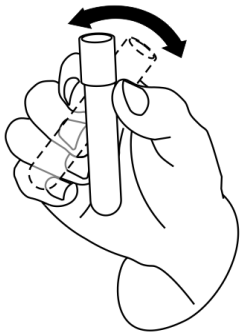
NOTE

- 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 Counting Mode is **Venous Blood-CBC+DIFF**.
- If the counting mode is set to Run as per the worklist (See *6.3.1 Auxiliary Settings*), the sample analysis will be conducted according to the worklist upon start-up. If the worklist is empty, the sample analysis will be conducted in the counting mode of the last run.

5.6.2.1 Running the Venous Blood Samples

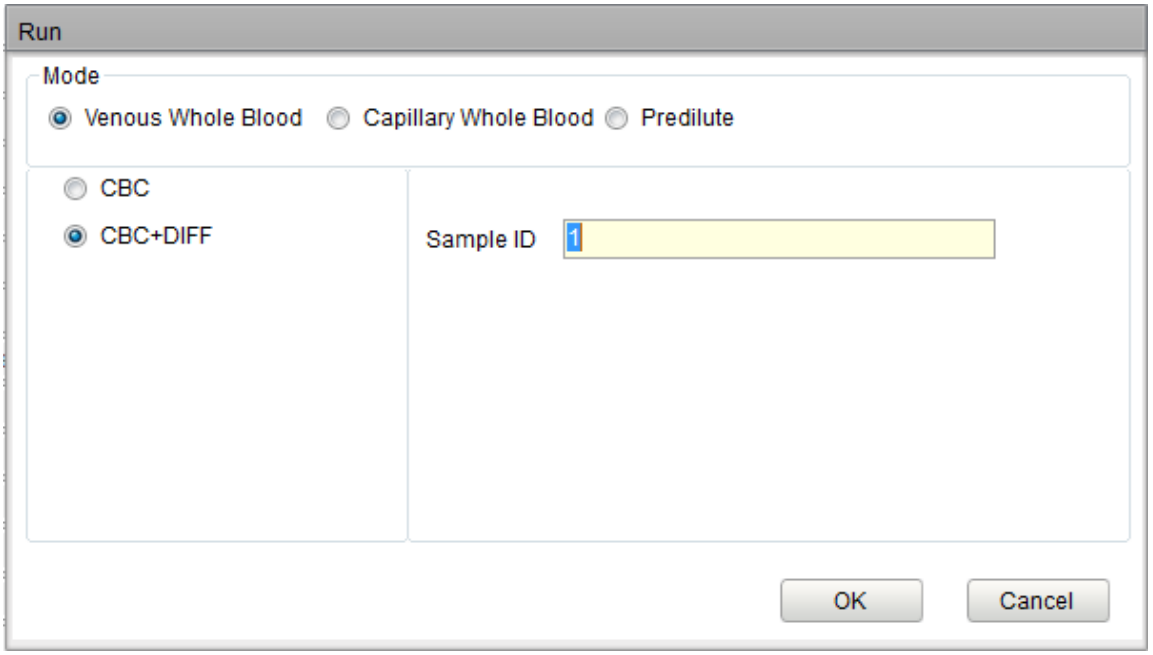
Procedures for running the venous whole blood samples are as follows:

1. Shake the venous whole blood sample in a manner as shown below for a homogeneous specimen.



2. When the green indicator light is steady-on, click Mode in the Function screen area to enter the Counting interface.
3. Select **Venous Whole Blood** in the Mode selection screen.

Figure 5-3 Running the Venous Whole Blood Samples



4. Select the measurement mode **CBC** or **CBC+DIFF** according to the actual test case, and enter the Sample ID.

   Please refer to ***5.6.2.4 Parameter Description*** for the related parameter descriptions.
5. Click **OK**.
6. Place the whole blood sample under the probe so that the probe can aspirate the well-mixed sample.
7. Click **Start** or press the aspirate key 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; the information area of the **Next Sample** will be refreshed.

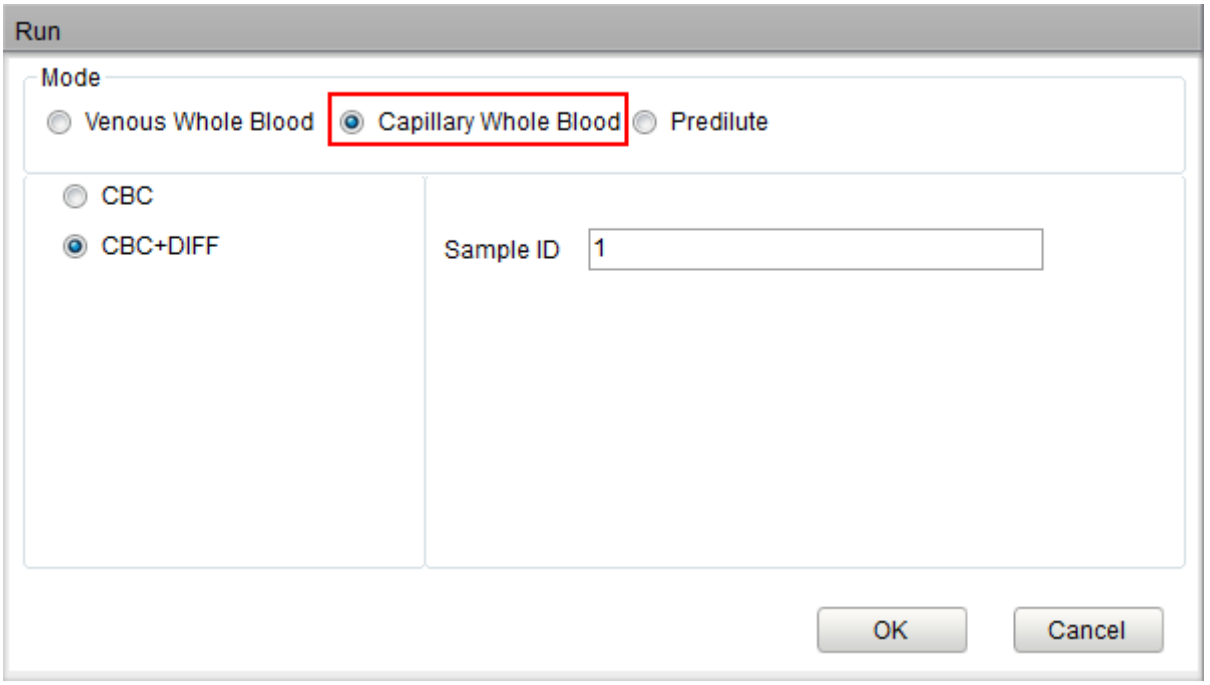
   When the analysis is complete, the analysis status icon and analyzer indicator return to constantly-on green.
9. Repeat steps 1~88 to run the remaining whole blood samples.

5.6.2.2 Running the Capillary Whole Blood Samples

Procedures for running the capillary whole blood samples are as follows:

1. Shake the capillary whole blood sample for a homogeneous specimen.
2. When the green indicator light is steady-on, click **Mode** in the Function screen area to enter the Counting interface.
3. Select **Capillary Whole Blood** in the Mode Selection screen.

Figure 5-4 Running the Capillary Whole Blood Sample



4. Select the measurement mode **CBC** or **CBC+DIFF** according to the actual test case, and enter the Sample ID.

   Please refer to ***5.6.2.4 Parameter Description*** for the related parameter descriptions.
5. Click **OK**.
6. Place the whole blood sample under the probe so that the probe can aspirate the well-mixed sample.
7. Click **Start** or press the aspirate key 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; the information area of the **Next Sample** will be refreshed.

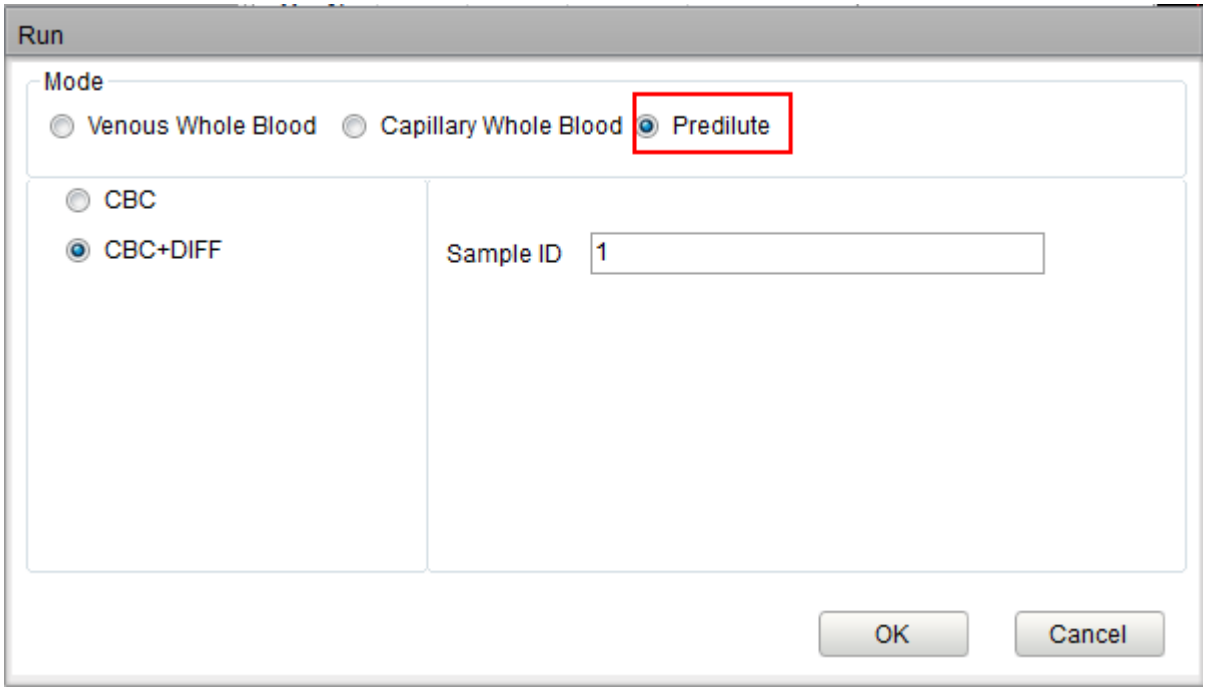
   When the analysis is complete, the analysis status icon and analyzer indicator return to constantly-on green.
9. Repeat steps 1~8 to run the remaining whole blood samples.

5.6.2.3 Running the Predilute Samples

Procedures for running the prediluted samples are as follows:

1. When the green indicator light is steady-on, click **Mode** in the Function screen area to enter the Counting interface.
2. Select **Predilute** in the Mode selection screen.

Figure 5-5 Running the Predilute Samples



3. Select the measurement mode **CBC** or **CBC+DIFF** according to the actual test case, and enter the Sample ID.

   Please refer to ***5.6.2.4 Parameter Description*** for the related parameter descriptions.
4. Shake the capped tube of prediluted sample for a homogeneous specimen.
5. Remove the tube cap carefully and place the prediluted sample under the probe so that the probe can aspirate the well-mixed sample.
6. Click **Start** or press the aspirate key to start running the sample.

NOTE

When the predilute counting begins, the system will prompt a dialog box. To disable such reminders, please refer to ***6.3.1 Auxiliary Settings***.

   The sample will be automatically aspirated by the sample probe.
7. 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; the information area of the **Next Sample** will be refreshed.

   When the analysis is complete, the analysis status icon and analyzer indicator return to constantly-on green.
8. Repeat steps 1~7 to run the remaining prediluted samples.

NOTE

- When the analyzer is running, you can perform any operation (including new, edit and cancel, etc.) to other **To Be Run** or **Error** samples in the work list.
- When the analyzer is running, you can switch to **Review** interface to perform operations including data browsing, validating, sample information editing and printing, etc., and you can also switch to other interfaces.
- When the analyzer is running, all the functions related to the fluidics sequence are not available.

5.6.2.4 Parameter Description

When running the samples, the operator can refer to the settings for relevant parameters as described in Table 5-1.

Table 5-1 Sample Analysis Parameter Descriptions

Parameter	Meaning	Operation
CBC	Complete Blood Count with no differential count for white blood cells. The counting results comprise 15 parameters and the histograms for WBC, RBC and PLT.	Selected from the radio box.
CBC+DIFF	Complete Blood Count plus differential count for white blood cells. In addition to a total of 25 parameters, differential scattergrams and the histograms for WBC/BASO, RBC and PLT, the counting results also include 4 research parameters.	Selected from the radio box.
Sample ID	Identification number for the samples to be run.	Directly entered into the textbox. **NOTE** • Sample ID can consist of English letters, numbers and all the other characters on the keyboard (including special characters) and disallows Chinese characters or any other language (such as Japanese and Korean). • 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.

5.6.3 Dealing with the Analysis Results

5.6.3.1 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 300,000.

5.6.3.2 Parameter Flags

- If parameter is followed by a "↑" or "↓", 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.

5.6.3.3 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 5-2 Flags of abnormal blood cell differential or morphology

Flag Type		Flag information
WBC	Abnormal	Leucocytosis
		Leucopenia
		Neutrophilia
		Neutropenia
		Lymphocytosis
		Lymphopenia
		Monocytosis
		Eosinophilia
		Basophilia
	Suspicious	Abn.WBC scattergram
		Abn. WBC histogram
		Left Shift?
		Immature Cell?
		RBC Lyse Resistant?

Flag Type		Flag information
		Abn./Atypical Lym?
RBC/HGB	Abnormal	Erythrocytosis
		Anisocytosis
		Macrocytosis
		Microcytosis
		Anemia
		Hypochromia
	Suspicious	RBC Distribution Abn.
		Dimorphologic
		Iron Deficiency?
		HGB Abn./Interfere?
		RBC Clump?
PLT	Abnormal	Thrombocytosis
		Thrombopenia
	Suspicious	Abnor. PLT Distr.
		PLT Clump?

The system shows flags for abnormal or suspicious items in different samples and measurement modes in accordance with the impact of the abnormal or suspicious WBC, RBC or PLT items on the results of the parameters. The correlation is shown in the following table.

Table 5-3 Flags for abnormal or suspicious itemsin different samples and measurement modes

Type	Flag	Whole Blood		Predilute	
		CBC	CBC+DIFF	CBC	CBC+DIFF
WBC	WBC abnormal?	√	√	√	√
	RBC Lyse Resistant?	×	√	×	√
	Abnormal WBC scattergram	×	√	×	√
	Abnormal WBC histogram	√	√	√	√
	Left Shift?	×	√	×	√
	Immature Granulocyte (IG)?	×	√	×	√
	Abnormal/Atypical Lymphocyte?	×	√	×	√
	Leucocytosis	√	√	√	√

Type	Flag	Whole Blood		Predilute	
		CBC	CBC+DIFF	CBC	CBC+DIFF
	Leucopenia	√	√	√	√
	Neutrophilia	×	√	×	√
	Neutropenia	×	√	×	√
	Lymphocytosis	×	√	×	√
	Lymphopenia	×	√	×	√
	Monocytosis	×	√	×	√
	Eosinophilia	×	√	×	√
	Basophilia	×	√	×	√
RBC/HGB	Dimorphologic	√	√	√	√
	HGB Abn/Interfere?	√	√	√	√
	Anisocytosis	√	√	√	√
	Microcytosis	√	√	√	√
	Macrocytosis	√	√	√	√
	Erythrocytosis	√	√	√	√
	Anemia	√	√	√	√
	Hypochromia	√	√	√	√
	Abn. RBC distr,	√	√	√	√
	Iron Deficiency?	√	√	√	√
	RBC Clump?	√	√	√	√
PLT	PLT Clump?	√	√	√	√
	Thrombocytosis	√	√	√	√
	Thrombopenia	√	√	√	√
	Abnor. PLT distr.	√	√	√	√

NOTE

- "√" indicates that flags will be displayed in the mode. "×" indicates that flags will not be displayed in the mode.
- When the PLT value is less than 100×10^9/L, a manual count by the microscope is recommended.

5.7 Report Management

Upon the completion of sample analysis, you can process the results in the **Report** interface and print the report.

For more details on the report, please refer to *7* ***Report***.

5.8 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 them and the relevant areas in the laboratory.

The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.

CAUTION

Do not turn on the analyzer immediately after its shutdown. 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.
- Be sure to shut down the analyzer in strict accordance with the instruction below.

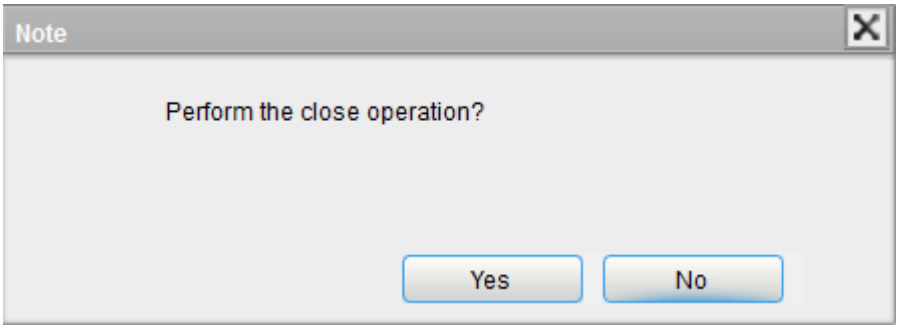
Shutdown here refers to the shutdown of the analyzer and the peripheral computer. The following sections will introduce both procedures.

5.8.1 Shutting down the analyzer

Procedures for shutting down the analyzer are as follows:

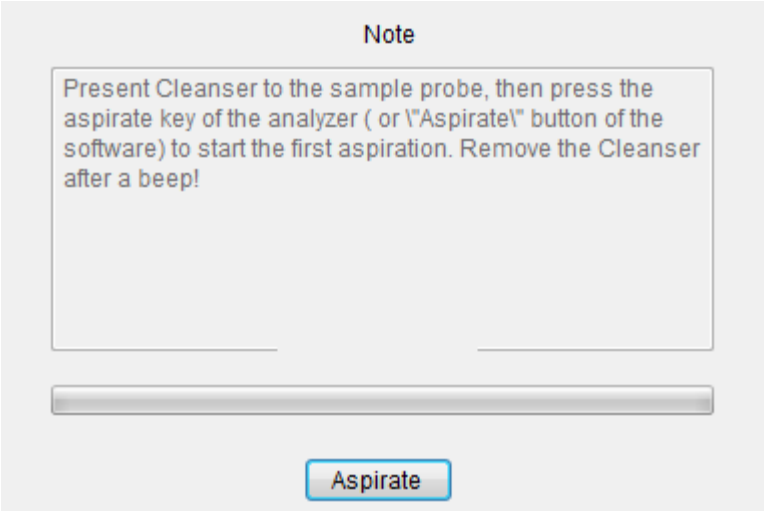
1. Click  on the top right corner of the screen.

   The following message box will pop up.



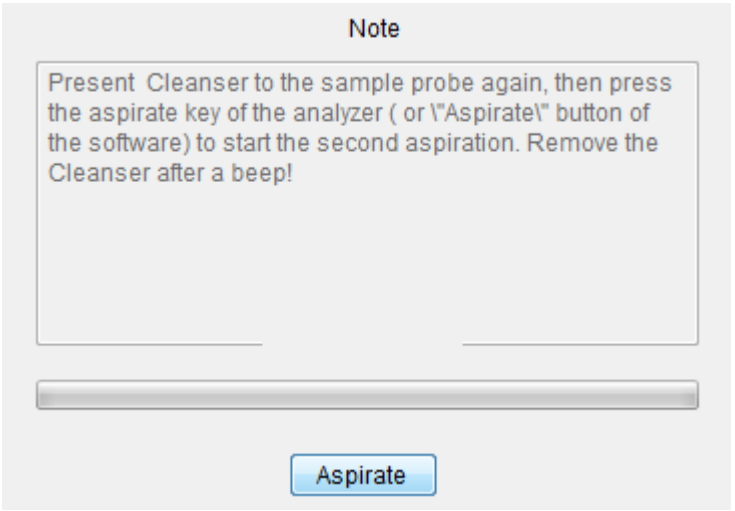
2. Click **Yes**.

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



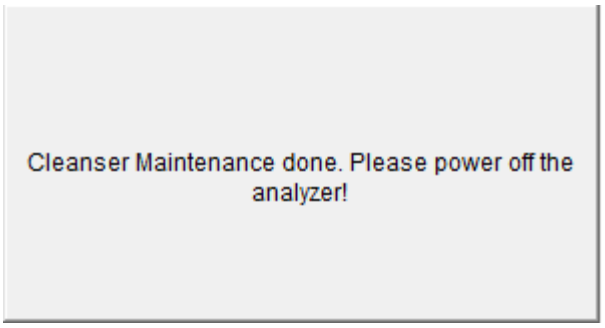
3. Follow the instructions and set the cleanser under the sample probe, and press the aspirate key on the analyzer or click **Aspirate** to run the first cleanser sample aspiration.

   Upon the completion of the first sample aspiration, a message box will pop up as below.



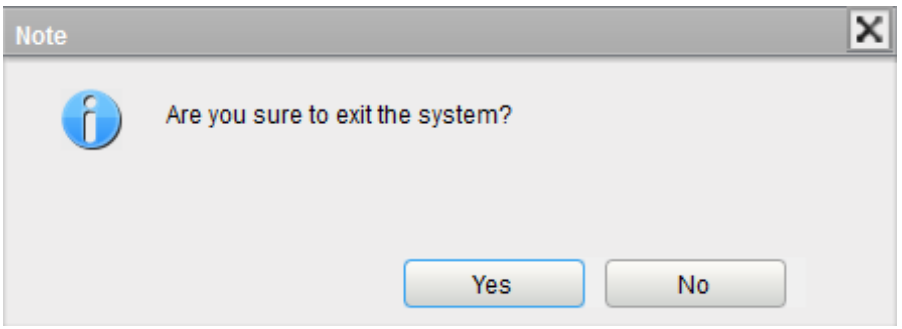
4. Follow the instruction and set the cleanser under the sample probe again, press the aspirate key on the analyzer or click **Aspirate** to run the second cleanser sample aspiration.

   Upon the completion of cleanser maintenance, a dialog box will pop up as below.



5. Turn to [O] the [O/I] switch located on the left side of the analyzer.

   Once the analyzer is powered off, the following dialog box will pop up.



6. Click **Yes** and the software program will automatically shut down.

   If you click **No**, the software program will not exit and you are still able to perform any operation independent from the analyzer.

7. After the shut-down, vacate the waste containers and handle the waste properly.

WARNING

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

NOTE

- When the analyzer is not connected to the computer, shutdowns will not be executed.
- 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.

5.8.2 Turning off the peripheral computer

NOTE

You should exit the terminal software first and then turn off the peripheral computer according to standard procedures. Otherwise, the database of the terminal software might be lost!

1. Turn off the peripheral computer according to the shutdown procedures of the operation system.
2. Turn off the display.

6 Setup

6.1 Introduction

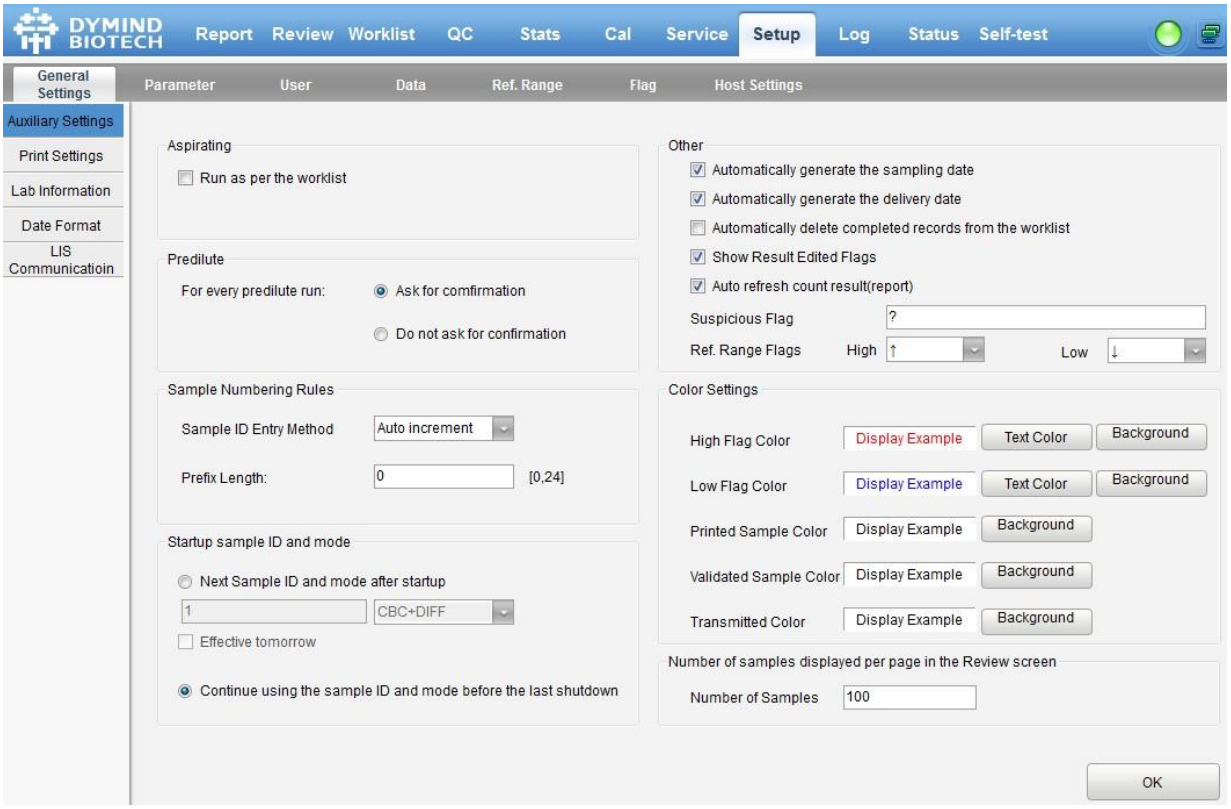
The analyzer has been initialized before delivery. The interfaces the user sees upon the initial startup of the analyzer are system settings by default. Some parameters of the analyzer can be reset to meet various demands in practical applications.

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.

6.2 Interface Introduction

Click **Setup** to access the **Setup** interface as shown in Figure 6-1.

Figure 6-1 Setup



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

- General Settings
- Parameter
- User Management

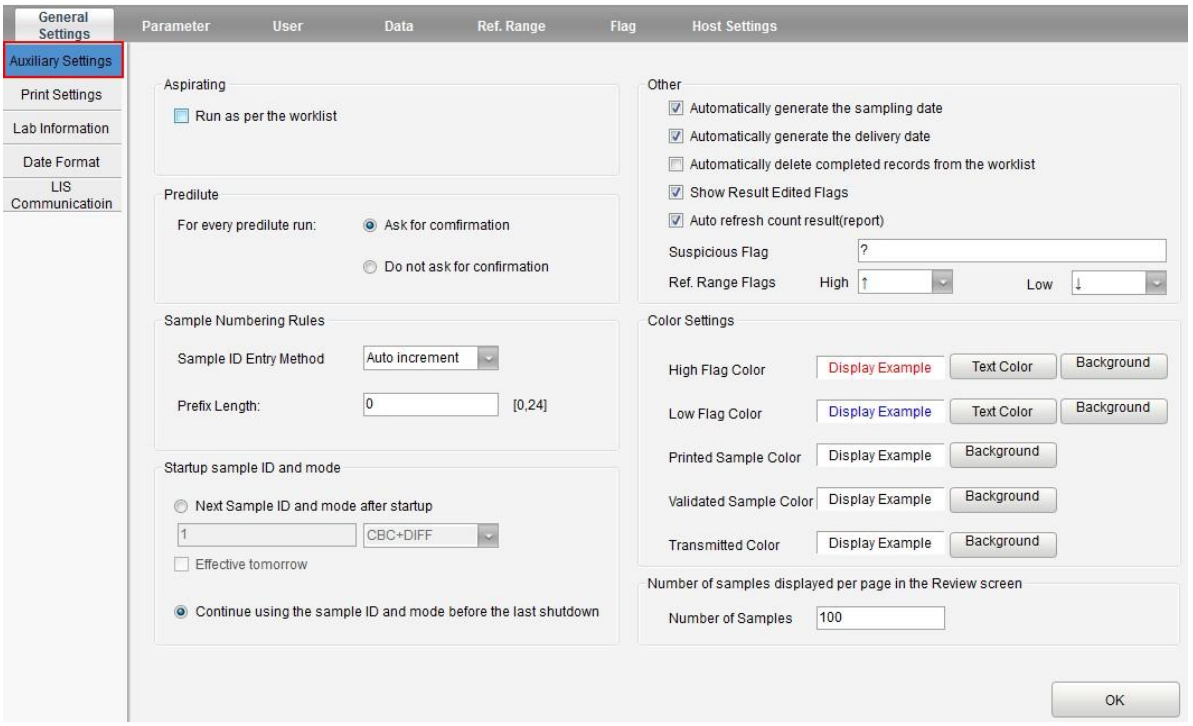
- Data Dictionary
- Ref. Range
- Flag
- Host Settings

6.3 General Settings

6.3.1 Auxiliary Settings

Clicking **Setup** > **General Settings** to access the **Auxiliary Settings** interface by default. See Figure 6-2.

Figure 6-2 Auxiliary Settings



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

- Aspirating
- Predilute
- Sample numbering rules
- Startup sample IP and mode
- Color Settings
- Number of samples displayed per page in the Review interface
- Other

6.3.1.1 Aspirating

Set if you want the system to the run the samples as per the worklist upon aspiration.

- Run as per the worklist

  When you start the counting, the system automatically obtains the sample list in the worklist and executes the counting operations in sequence.

6.3.1.2 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.

6.3.1.3 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.

6.3.1.4 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 and mode set by the user will be used by the system after the next startup when the specified sample ID is entered into the textbox and the measurement mode (CBC or CBC+DIFF) is selected from the dropdown list.

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.

6.3.1.5 Color Settings

Set the text color and background color of the high/low flag as well as the background color of the **Printed**, **Validated** and **Transmitted** items displayed on the screen.

- High/Low Flag Color

  Click the corresponding **Text Color** button of the **High Flag Color** (or **Low Flag Color**) to select the text color of the flag items.

  Click the corresponding **Background** button of the **High Flag Color** (or **Low Flag Color**) to select the background color of the flag items.

  After setting, you can view the effect in the **Display Example** box.

- Printed Sample Color

  Click the corresponding **Background** button of the **Printed Sample Color** to select the background color of the printed items.

  After setting, you can view the effect in the **Display Example** box.

- Validated Sample Color

  Click the corresponding **Background** button of the **Validated Sample Color** to select the background color of the validated items.

  After setting, you can view the effect in the **Display Example** box.

- Transmitted Sample Color

  Click the corresponding **Background** button of the **Transmitted Color** to select the background color of the transmitted items.

  After setting, you can view the effect in the **Display Example** box.

6.3.1.6 Number of samples displayed per page in the Review interface

Set the number (100 by default) of sample results displayed per page in the result list in the **Review** interface. An Integer between 100 and 2000 can be entered.

6.3.1.7 Other

- Automatically generate the sampling/delivery date

  Checked: the current date will be displayed in the date textbox in **Sampling Time/Delivery Time** by default when a new sample record is added in the Worklist interface.

  Unchecked (default setting): the **Sampling Time/Delivery Time** shall be manually entered by the user when a new sample record is added in the Worklist interface.

- Automatically delete completed records from the worklist

  It's unchecked by default. If it is checked, the corresponding sample record in the worklist will be automatically deleted by the software system upon the completion of sample analysis.

- 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

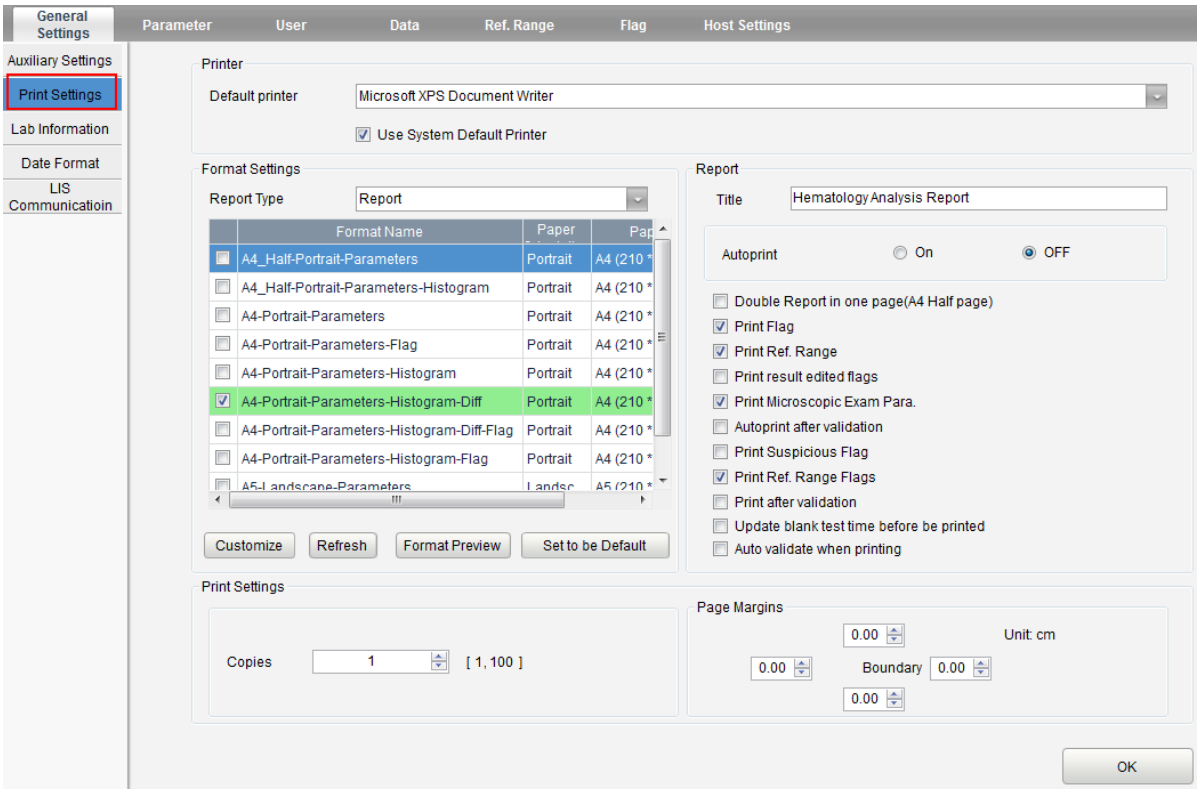
A single character (an English letter only) can be re-entered in the textbox as a suspicious flag. The default value is **?.**

- Ref. Range Flags

  You can select the Ref. Range Flags from the dropdown list. The default high flag is ↑ and the default low flag is ↓.

6.3.2 Print Settings

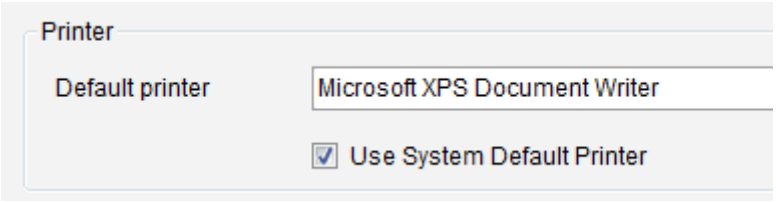
Click **Print Settings** in the **Setup** > **General Settings** interface for relevant print settings, including the default printer, template, report, copies and margins, etc.



6.3.2.1 Default Printer Settings

The analyzer uses the system default printer (see Figure 6-3).

Figure 6-3 Default Printer Settings



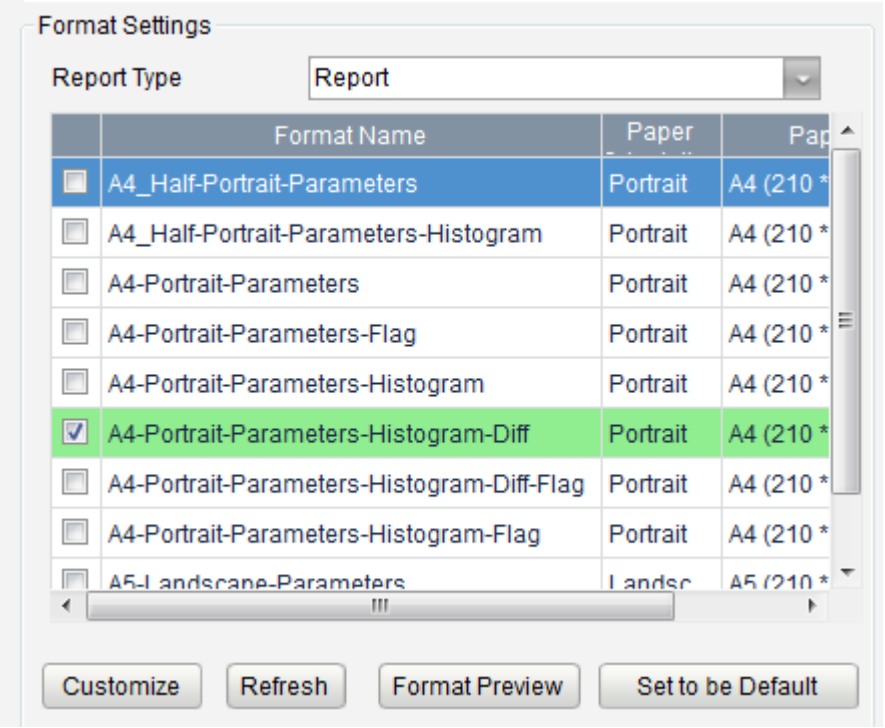
To set your desired default printer, uncheck **Use System Default Printer** and select a printer from the dropdown list of the **Default printer**, then click **OK** to save the modification. Thereafter, all the printing tasks issued by the analyzer will be assigned to this printer by default.

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.

6.3.2.2 Format Settings

The **Type**, **Customize**, **Format Preview** and **Set to be Default**, etc. can be set in the **Format Settings** combo box. See Figure 6-4.

Figure 6-4 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**.

- Customization

  The administrator can customize the format as per the actual demand (common user does not have such access). Click the **Customize** button to access the Template Designer interface.

- Refresh

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

- Format Preview

  Click the **Format Preview** button to check the printing effect of the current report.

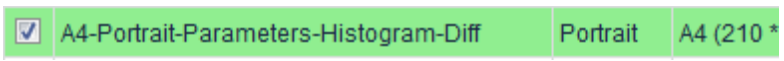
NOTE

After the print setting is completed, the operator should preview the printing effect of the current report, then print the report after the confirmation of its correctness.

- Setting the Default Template

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

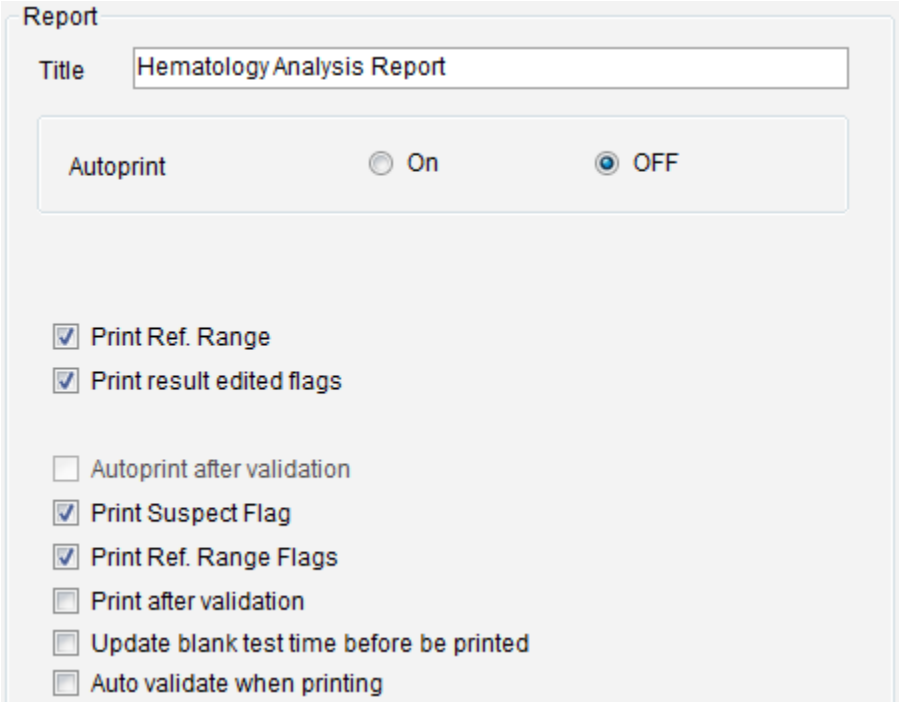
  The template with bright green background is the default setting. See the figure below.



6.3.2.3 Report Settings

The user is allowed to set relevant parameters of the report in the **Report** combo box. See Figure 6-5.

Figure 6-5 Report Print Setting



- Title

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

- Autoprint

  The default setting is **OFF**. If it is set to be **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.

- 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 result edited flags

  It's checked by default, which means the mark (**M** or **m**) for the edited results will be shown in the printed report if the parameters have been modified by the user.

  If it's unchecked, the mark for the edited results will not be shown in the printed report.

- Autoprint 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 be **On**.

- Print Suspicious Flag "?"

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

- Print Ref. Range Flags

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

- 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.

- 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.

- 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.

6.3.2.4 Print Setting

The user can set the number of copies and page margins for each report in the **Print Setting** combo box.

- Copies

  The user can enter the number of copies to be printed for a report in the **Copies** textbox according to the actual demand. Range of the copies is between 1 and 100 and the default value is **1**.

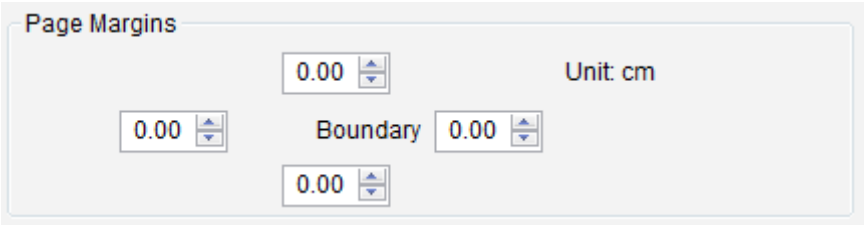
Figure 6-6 Copies

- Page Margins

  The user can adjust the page margins according to the actual needs.

  The upper, lower, left and right textboxes are designed for adjusting the margins on the top, bottom, left and right. The default value is 0.00 and the default unit is cm. See Figure 6-7.

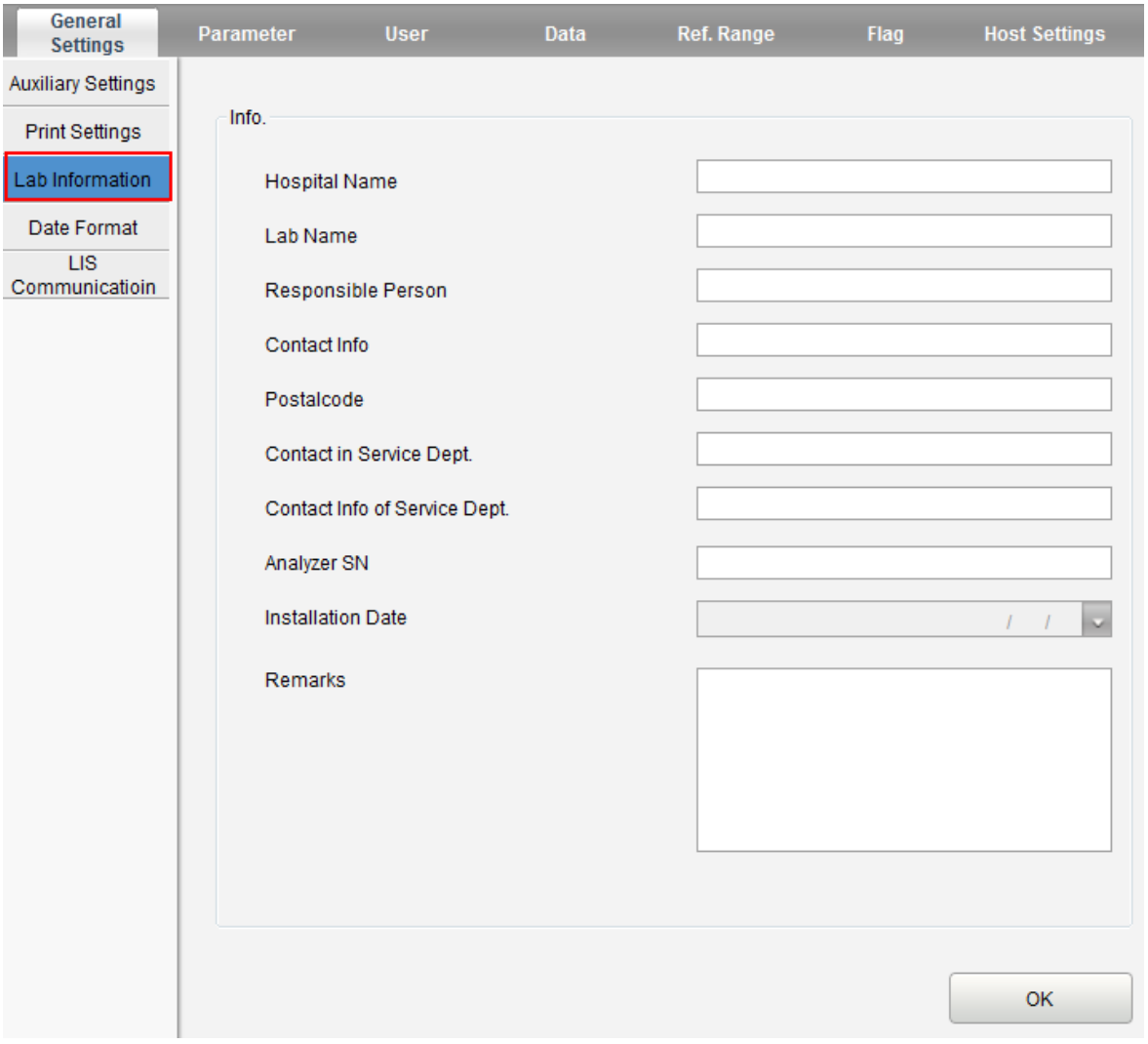
Figure 6-7 Adjusting Page Margins



6.3.3 Lab Information

Click **Lab Information** in the **Setup** > **General Settings** interface, then you can set the lab information. See Figure 6-8.

Figure 6-8 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 6-1 Setting Lab Information

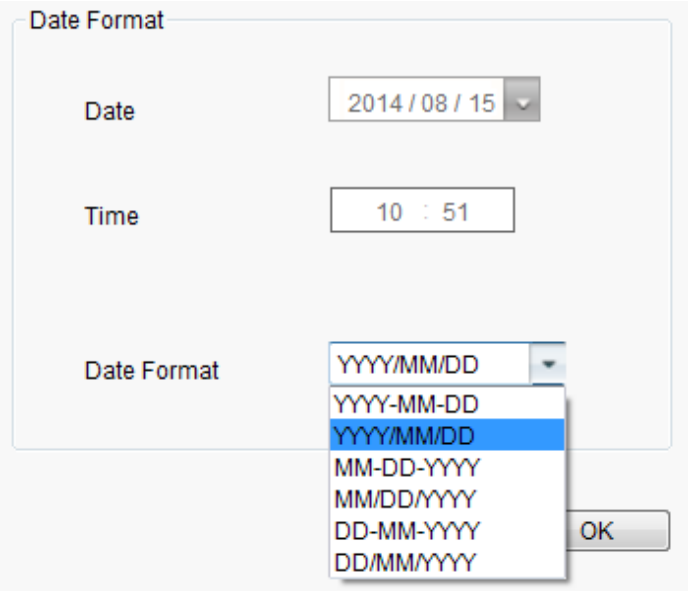
Parameter	Setting instructions
Hospital Name	Enter the name of the hospital where the lab is located.
Lab Name	Enter the lab name.
Responsible Person	Enter the responsible person of the lab.
Contact Information	Enter the contact information (telephone number or E-Mail) of the lab.
Postal code	Enter the postal code of the hospital.
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.
Analyzer SN	Display the serial number of the analyzer. It cannot be edited.
Installation Date	Display the installation date of the analyzer. It cannot be edited.
Remarks	Enter the remarks regarding the lab.

6.3.4 Date Format

Click **Date Format** in the **Setup** > **General Settings** interface to enter the date format setting interface. You can set the date format of the system.

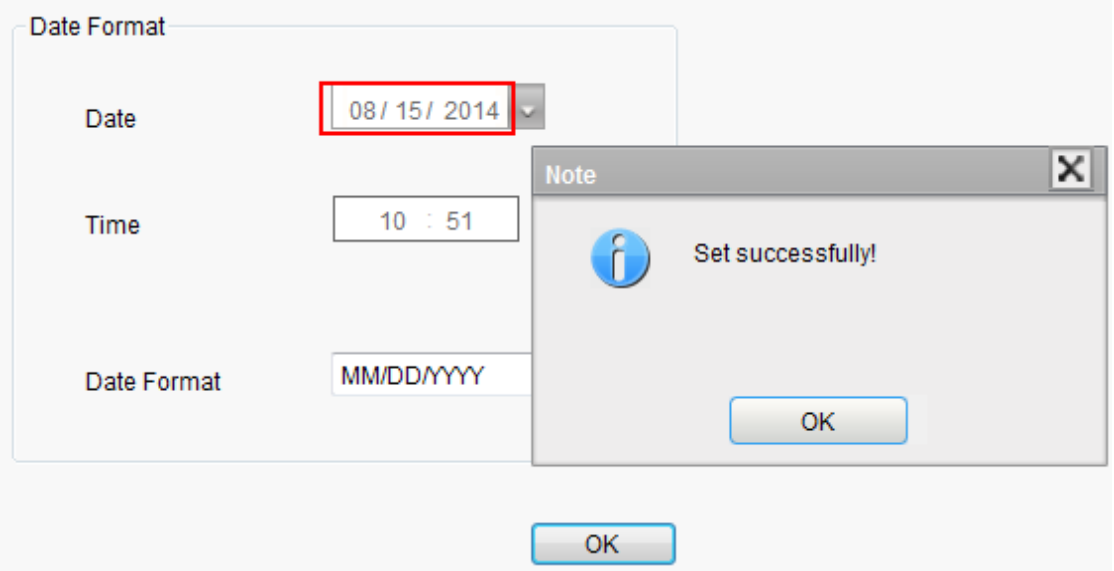
Select the format setting from the dropdown list of the **Date Format** and click **OK** as shown in Figure 6-9.

Figure 6-9 Setting the Date Format



You'll be prompted that the date format is set successfully and you'll see the updated date format. See Figure 6-10.

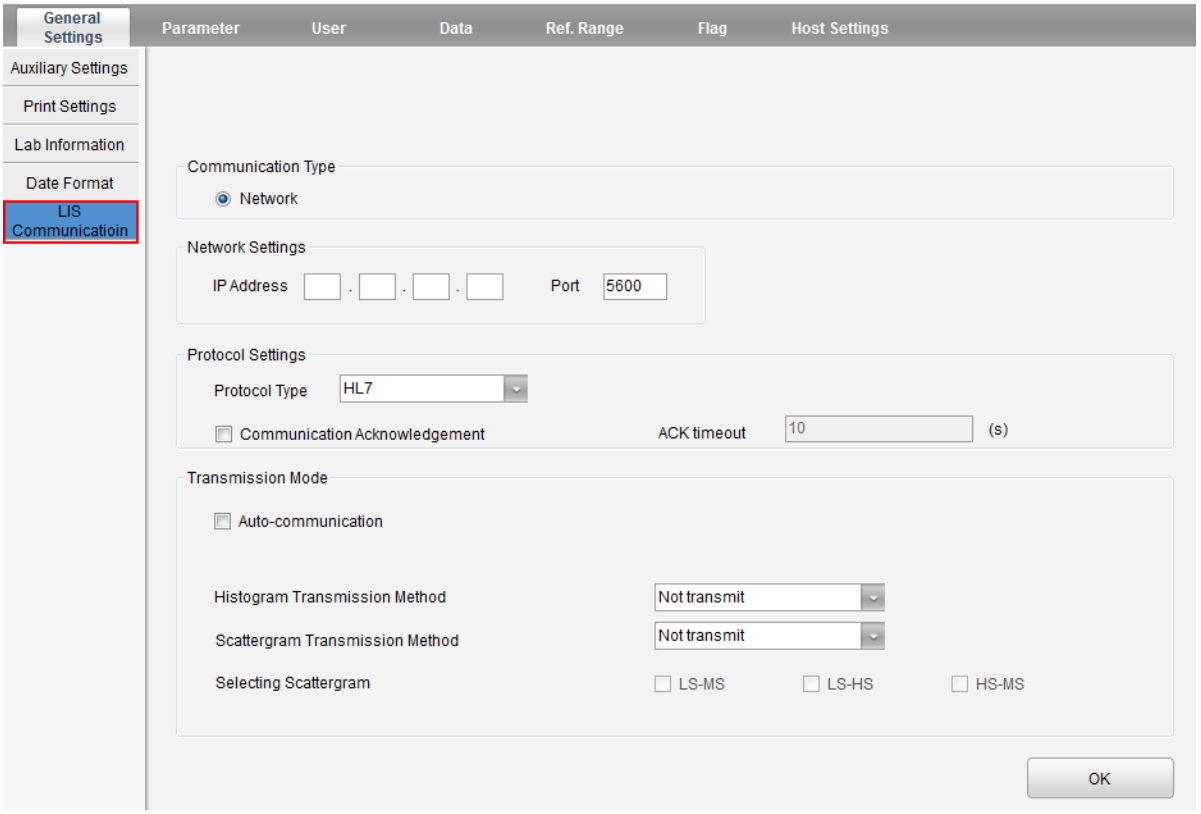
Figure 6-10 Successful Setting of the Date Format



6.3.5 LIS Communication

Click **LIS Communication** in the **Setup** > **General Settings** interface to enter the laboratory information system (LIS) communication setting interface. You can set the communication between the system and the LIS. See Figure 6-11.

Figure 6-11 Setting LIS Communication



Refer to Table 6-2 for the description of relevant parameters

Table 6-2 Description of LIS Communication Setting Parameters

Parameter		Meaning	Operation
Communication Type		Type of the communication between the system and the LIS. The current version of software support communication with the LIS via network.	N/A
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.
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
	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 enter in the textbox. Input range: an integer between 0 and 100. Unit: second. **NOTE** The parameter is valid only when the **Communication Acknowledgement** is checked.

Parameter		Meaning	Operation
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.	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.
	Scattergram Transmission Method	The methods for transmitting the scattergram to the LIS when the result is transmitted by the system, including: • Not transmit Do not transmit the scattergram to the LIS. • Bitmap Transmit the scattergram to the LIS in the format of screen display. • Transmitting bitmap for printing The scattergram is transmitted by the system to the LIS in the format of a printed report.	Please choose according to the actual situation.
	Selecting Scattergram	You can set the system to transmit one or several specified scattergrams to the LIS, including LS-MS, LS-HS and HS-MS.	Please choose according to the actual situation. **NOTE** The parameter is invalid when **Not transmit** is set as the **Scattergram Transmission Method**.

6.4 Parameter Settings

6.4.1 Research Use Only (RUO) Parameters

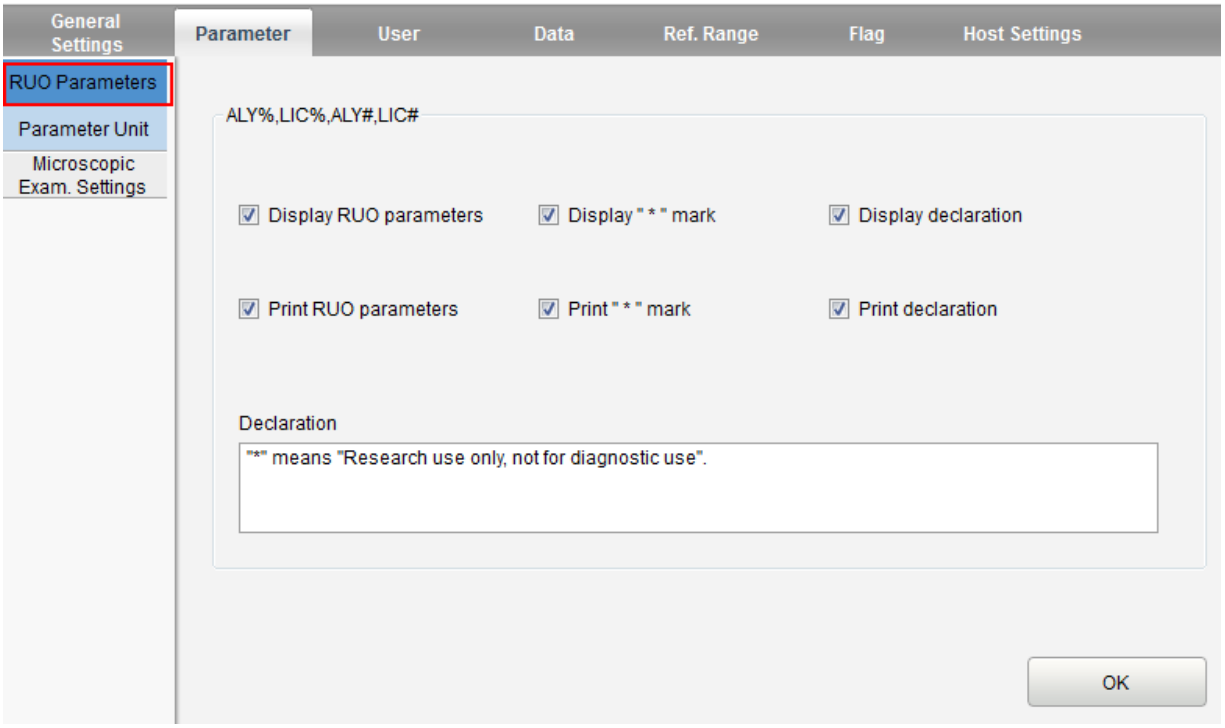
The RUOs include ALY%, LIC%, ALY# and LIC#.

NOTE

The RUO parameters are for research use only, not for diagnostic use.

Click **RUO Parameters** in the **Setup** > **Parameter** interface to enter the **RUO Parameters** setting interface. See Figure 6-12.

Figure 6-12 Setting RUO Parameters



- Display RUO Parameters
  - It's checked by default, which means the information regarding the RUO parameters will be displayed in the counting results. If it's unchecked, the RUO parameters, the "*" mark and the declaration will not be displayed in the counting results.
  - **Display "*" mark**: It's checked by default, which means the "*" mark will be displayed in the counting results; If it's unchecked, the "*" mark and the declaration will not be displayed.
  - **Display declaration**: It's checked by default, which means the declaration will be displayed in the counting results; if it's unchecked, the declaration will not be displayed.
- Print RUO parameters
  - It's checked by default, which means the RUO parameters will be printed in the report. If it's unchecked, the RUO parameters, the "*" mark and the declaration will not be printed

in the report.

- **Print “*” mark:** It’s checked by default, which means the “*” mark will be printed in the report. If it’s unchecked, the “*” mark and the declaration will not be printed in the report.
- **Print declaration**: It’s checked by default, which means the declaration will be printed in the report. If it’s unchecked, the declaration will not be printed in the report.

- Editing Declaration

  The default declaration is: "*" means "research use only, not for diagnostic use". You can modify the declaration in the textbox as per the actual demand.

NOTE

Any change made to the display settings or printing of the RUO parameters, the “*” mark and the declaration will be applied to all the RUO parameters (before and after the change).

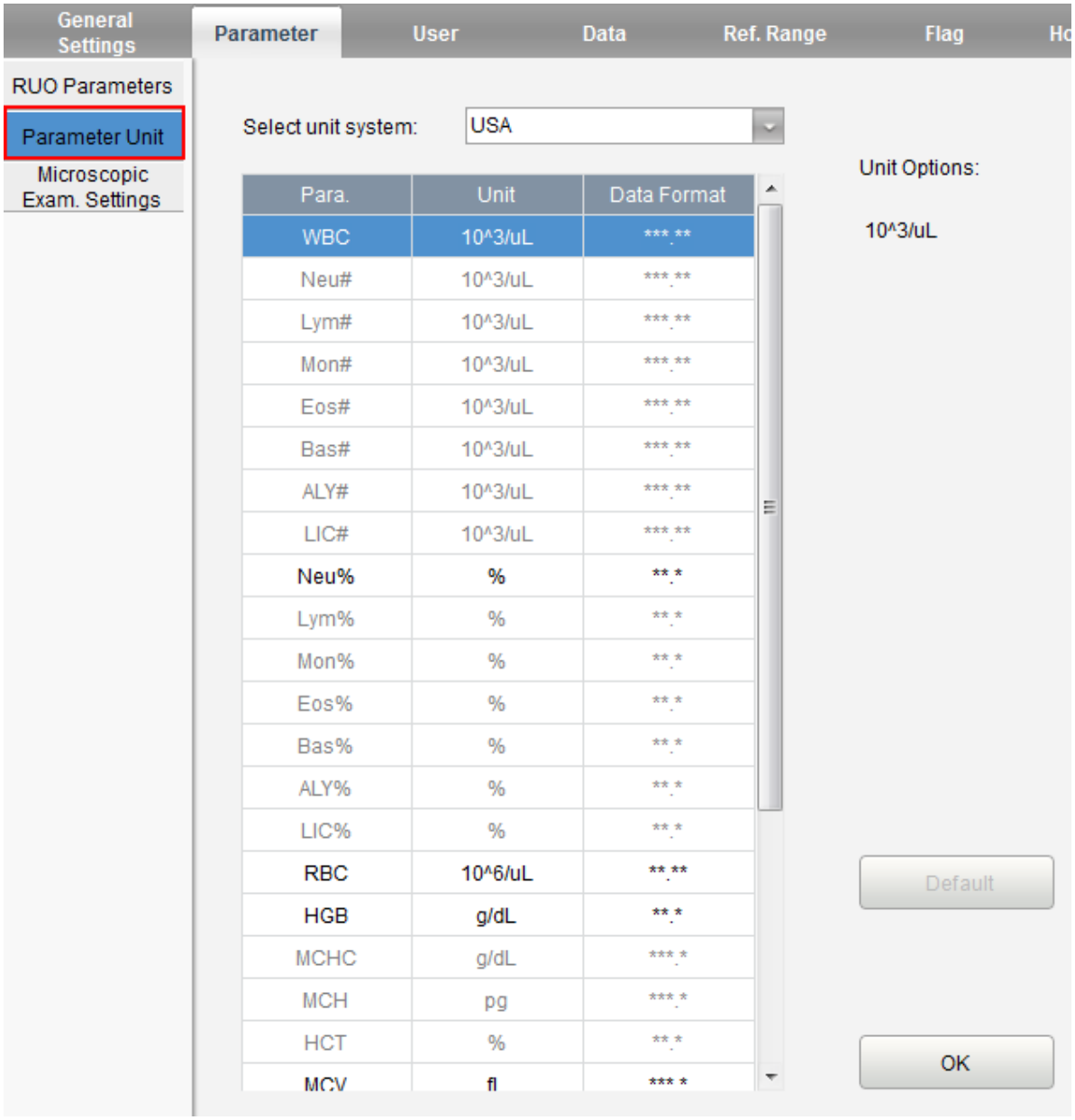
6.4.2 Parameter Unit

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

6.4.2.1 Accessing the interface

Click **Parameter Unit** in the **Setup** > **Parameter** interface to access the Parameter Unit setting interface. See Figure 6-13.

Figure 6-13 Setting Parameter Unit



6.4.2.2 Selecting Unit System

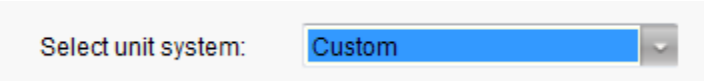
Click the **Select unit system** dropdown list and select a unit system for the parameters among the 7 unit systems (Custom, China, International, Britain, Canada, USA and Netherlands). The default unit system is **USA**.

NOTE

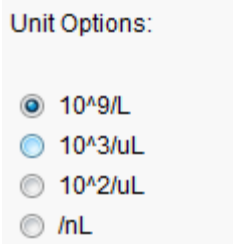
- When selecting different unit standards, the corresponding unit list and unit option will be displayed differently.
- If another option is selected except the **Custom**, then the unit of each parameter can only be browsed.

6.4.2.3 Customizing Parameter Unit

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



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



- Click **OK** to save the configuration.

NOTE

- For parameters in a same group, if the unit of any parameter changes, the units of the rest 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.)
- For parameters in the same group, if the unit of any parameter changes, the units of the other parameters change accordingly. The unit of MCH changes according to MCHC and HGB, the operator can not modify it.
- If the parameters units change, the display format of the list data will change accordingly.

6.4.2.4 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.

6.4.3 Microscopic Exam. Settings

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

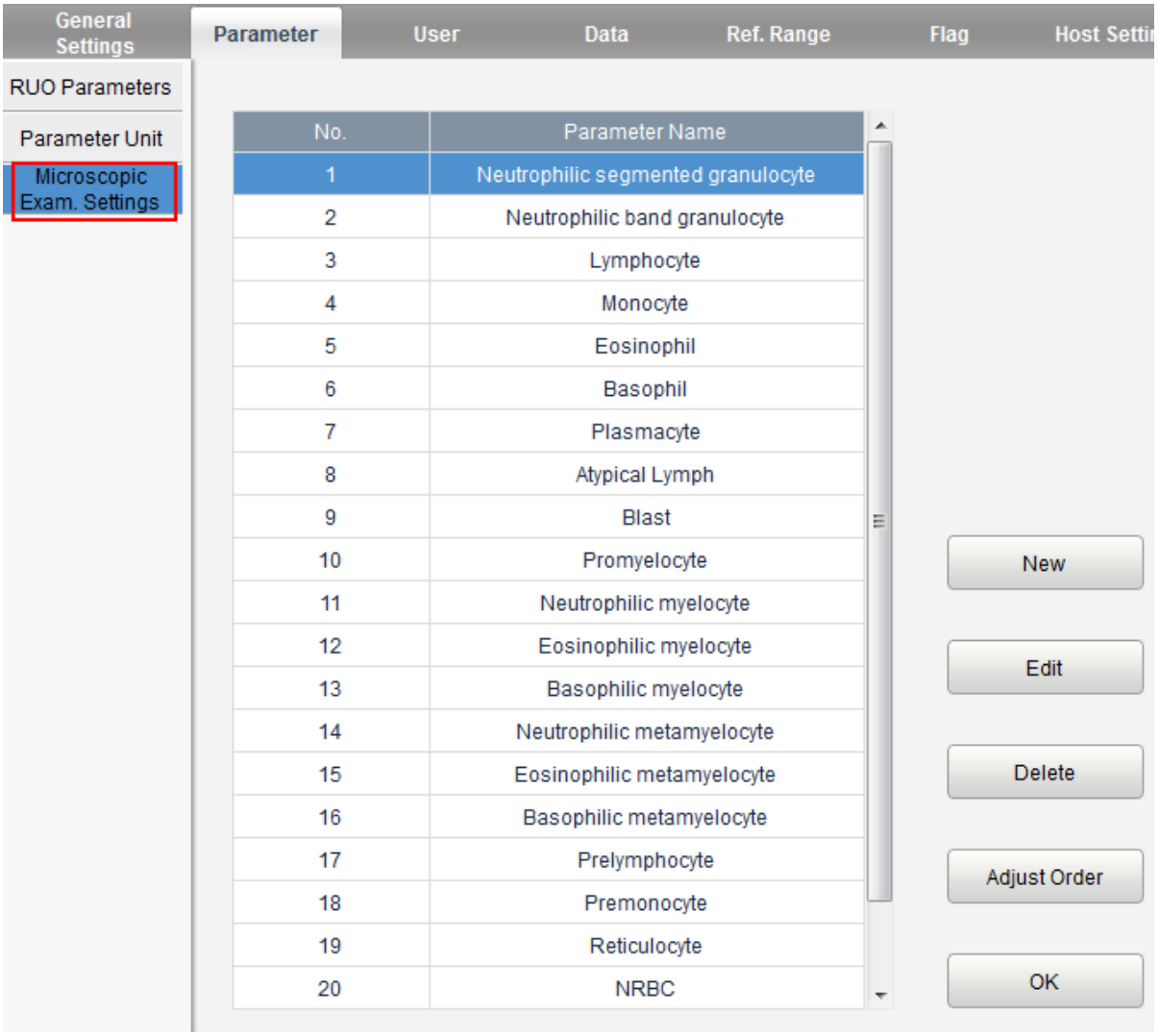
NOTE

The operations of adding, editing, deleting and adjusting the list order 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.

6.4.3.1 Accessing the interface

Click **Microscopic Exam. Settings** in the **Setup** > **Parameter** interface to access the **Microscopic Exam. Settings** interface. See Figure 6-14.

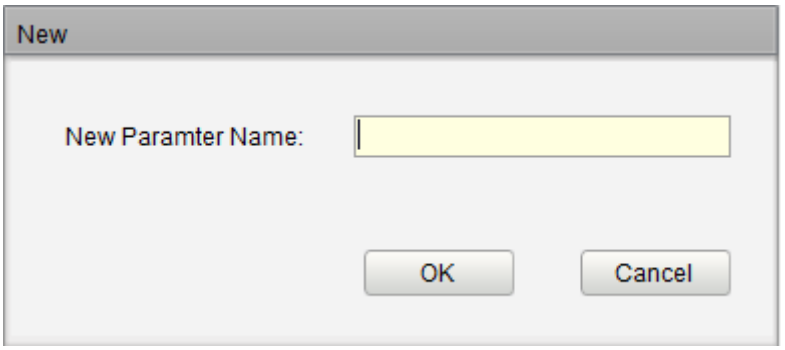
Figure 6-14 Microscopic Exam. Settings



6.4.3.2 Adding a New Microscopic Exam. Parameter

Click **New** and enter the name of the new parameter in the popup dialog box, then click **OK**.

Figure 6-15 Adding a New Microscopic Exam. Parameter



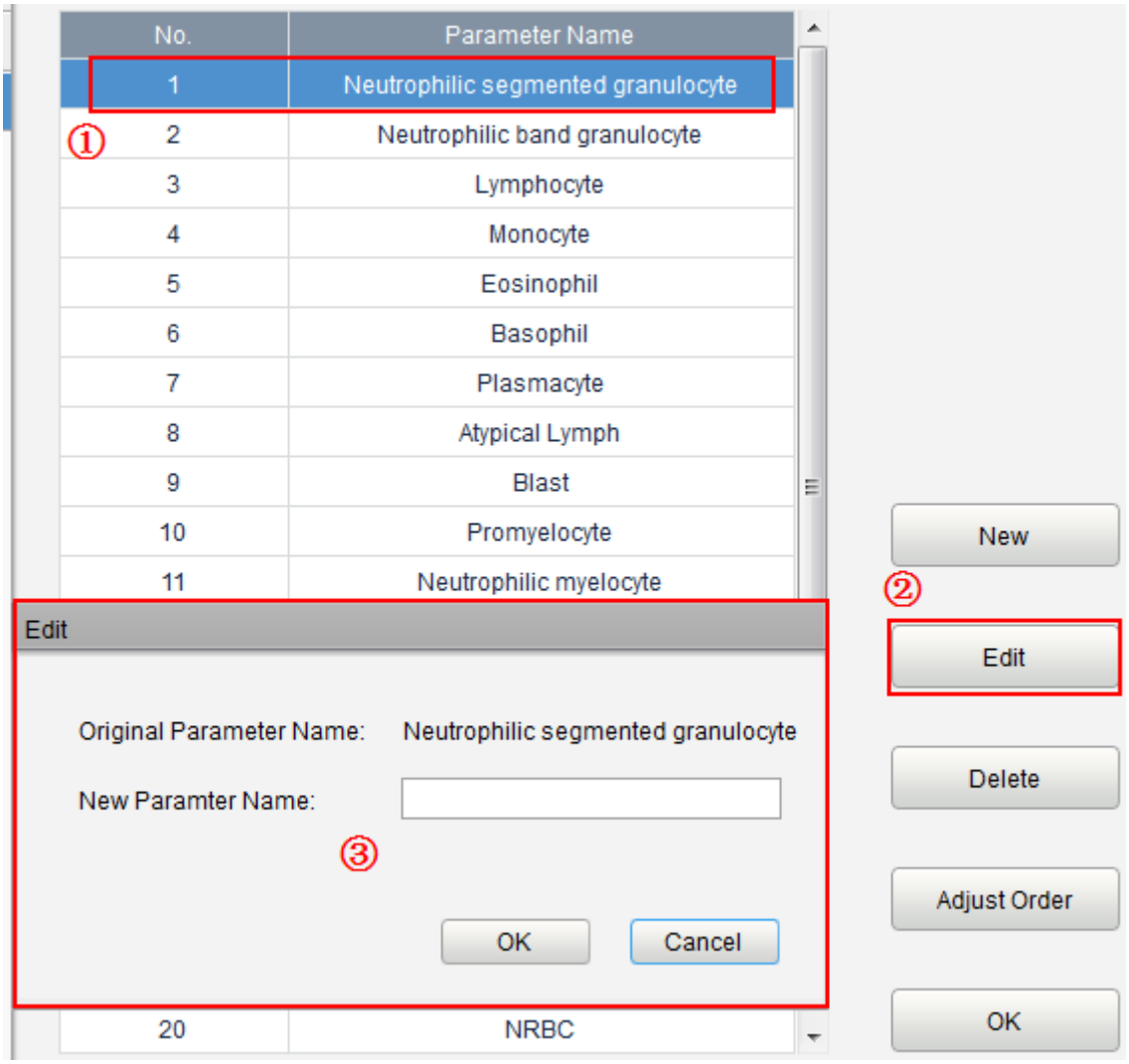
The name of the new parameter will be displayed in the microscopic exam. parameter list.

Up to 40 microscopic exam. parameters can be added.

6.4.3.3 Editing a Microscopic Exam. Parameter

Select a parameter name from the list and click **Edit** to modify it. See Figure 6-16.

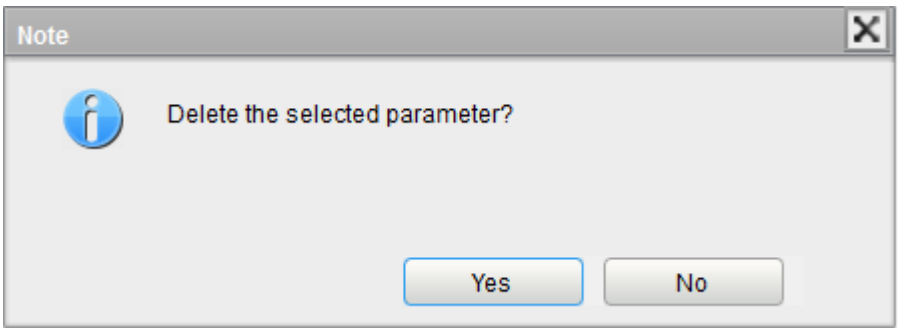
Figure 6-16 Editing a Microscopic Exam. Parameter



6.4.3.4 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.

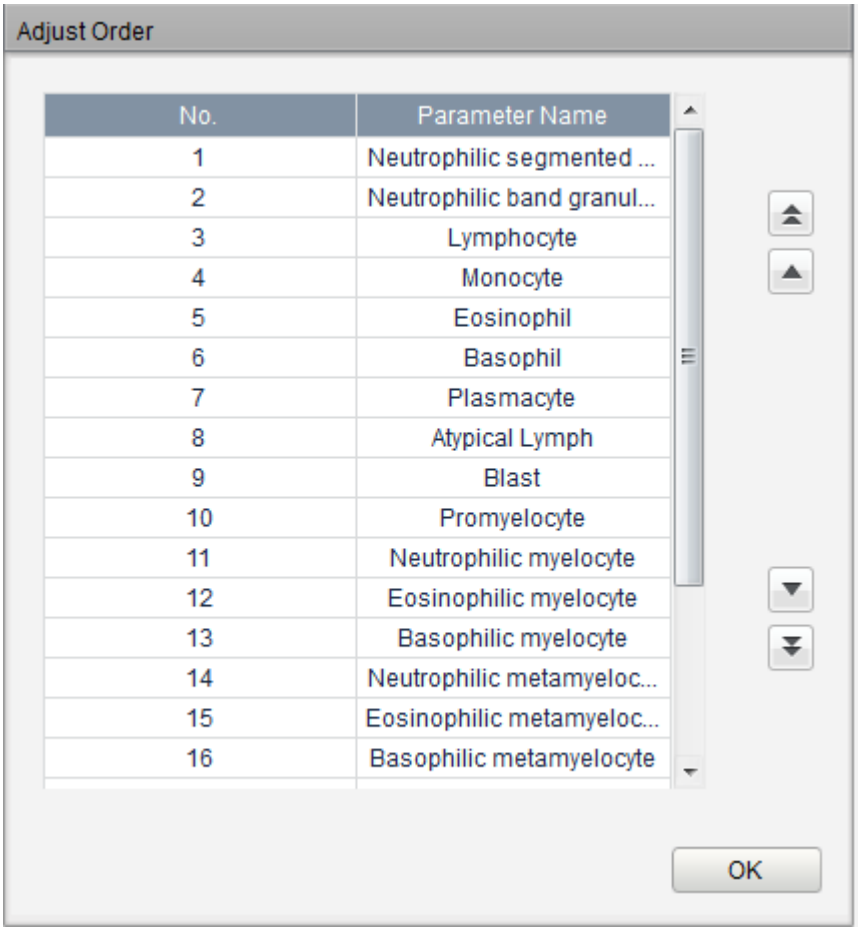
Figure 6-17 Deleting a Microscopic Exam. Parameter



6.4.3.5 Adjusting Order

Click **Adjust Order** to move the selected parameter to the top ( ) or bottom ( ) or move it upwards ( ) and downwards ( ) on the popup screen.

Figure 6-18 Adjusting the Order of the Microscopic Exam. Parameters



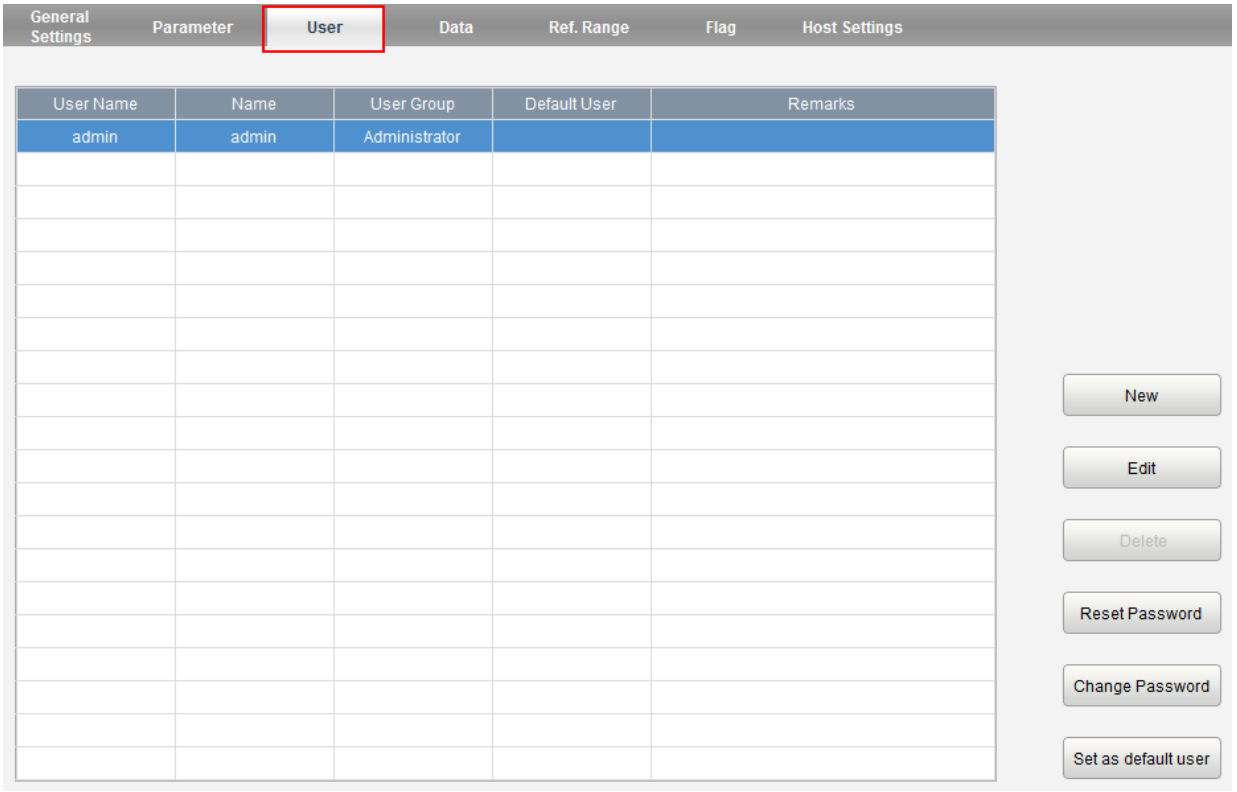
6.5 User Management

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.

6.5.1 Accessing the Interface

Click **Setup** > **User** to access the **User management** interface. See Figure 6-19.

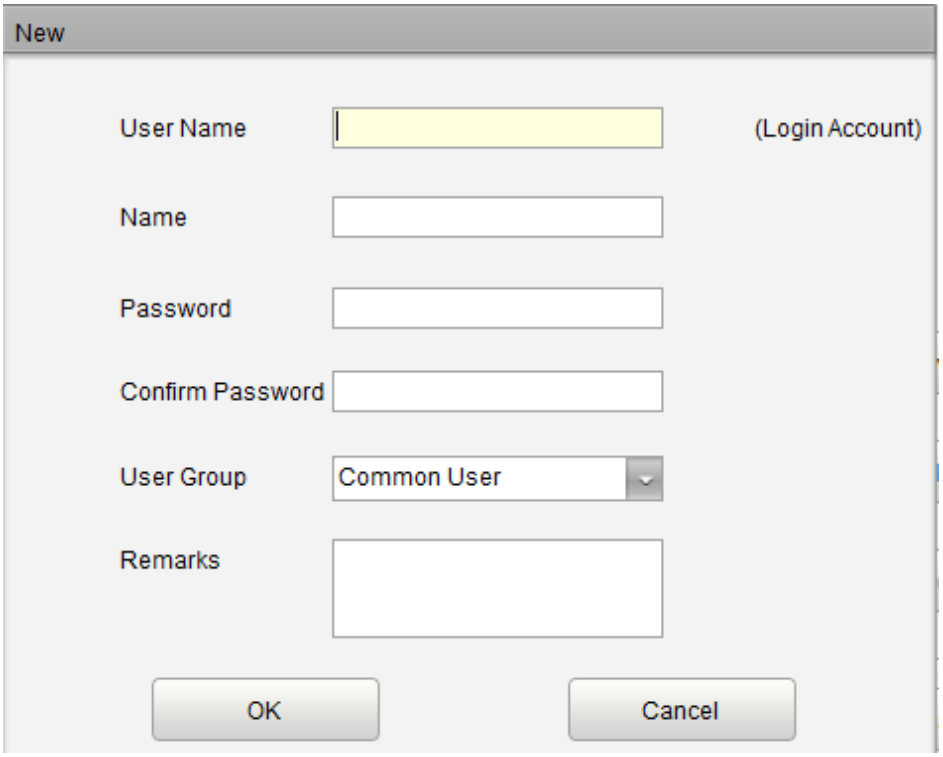
Figure 6-19 User management



6.5.2 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 6-20.

Figure 6-20 Creating a user



NOTE

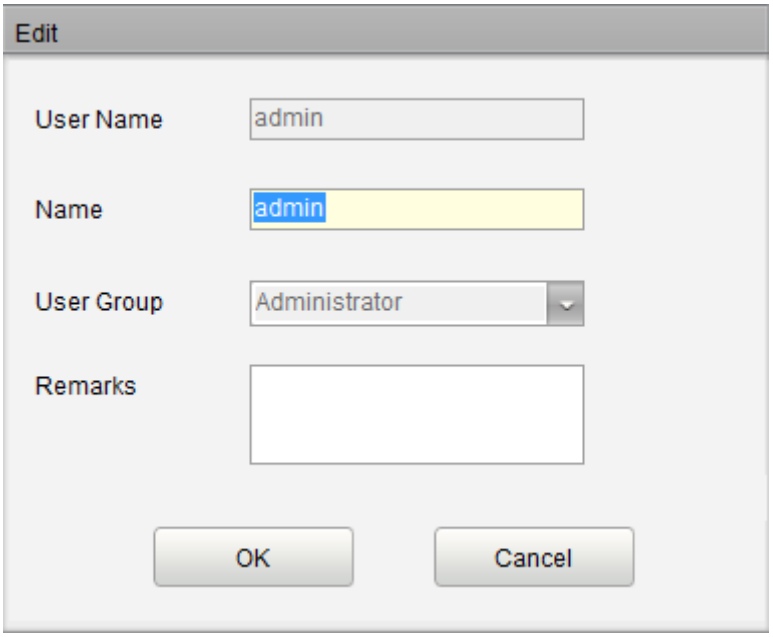
User Group includes **Common User** and **Administrator**. Users are assigned different access levels according to the user group they belong to.

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

6.5.3 Editing a User

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

Figure 6-21 Editing a User



6.5.4 Deleting a User

Select the user to be deleted and click **Delete** to delete the selected user.

NOTE

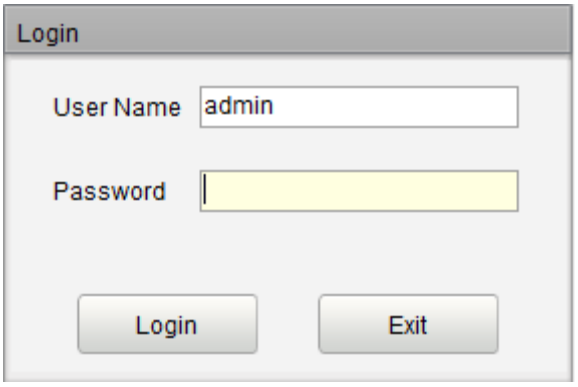
The administrator cannot delete his/her own information.

6.5.5 Setting the Default User

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

After it is set successfully, the default user name will be displayed in the login box next time and the user only needs to enter the corresponding password. See Figure 6-22.

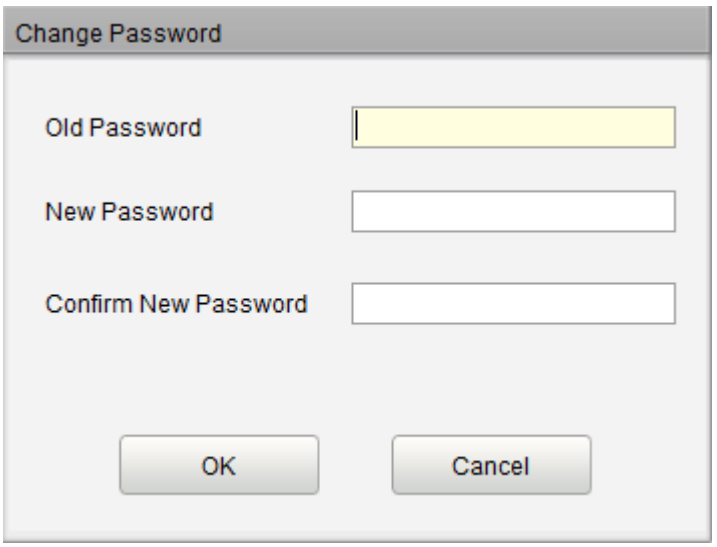
Figure 6-22 Login after Setting the Default User



6.5.6 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 6-23 Changing Password



NOTE

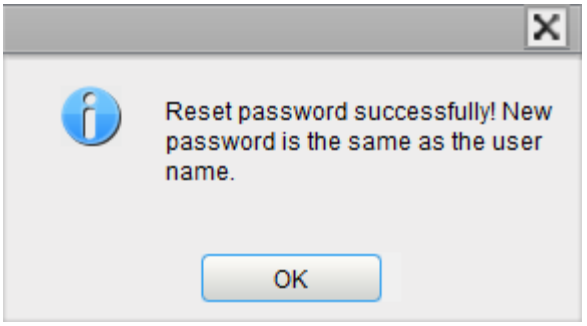
The user can only change his/her own password and cannot change the password of other users.

6.5.7 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 6-24 shows that the password is successfully reset.

Figure 6-24 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.

6.6 Data Dictionary

Users 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 by the user, then the complete information can be displayed by pressing the [Enter] key without entering (or selecting) complete information. It is a shortcut operation.

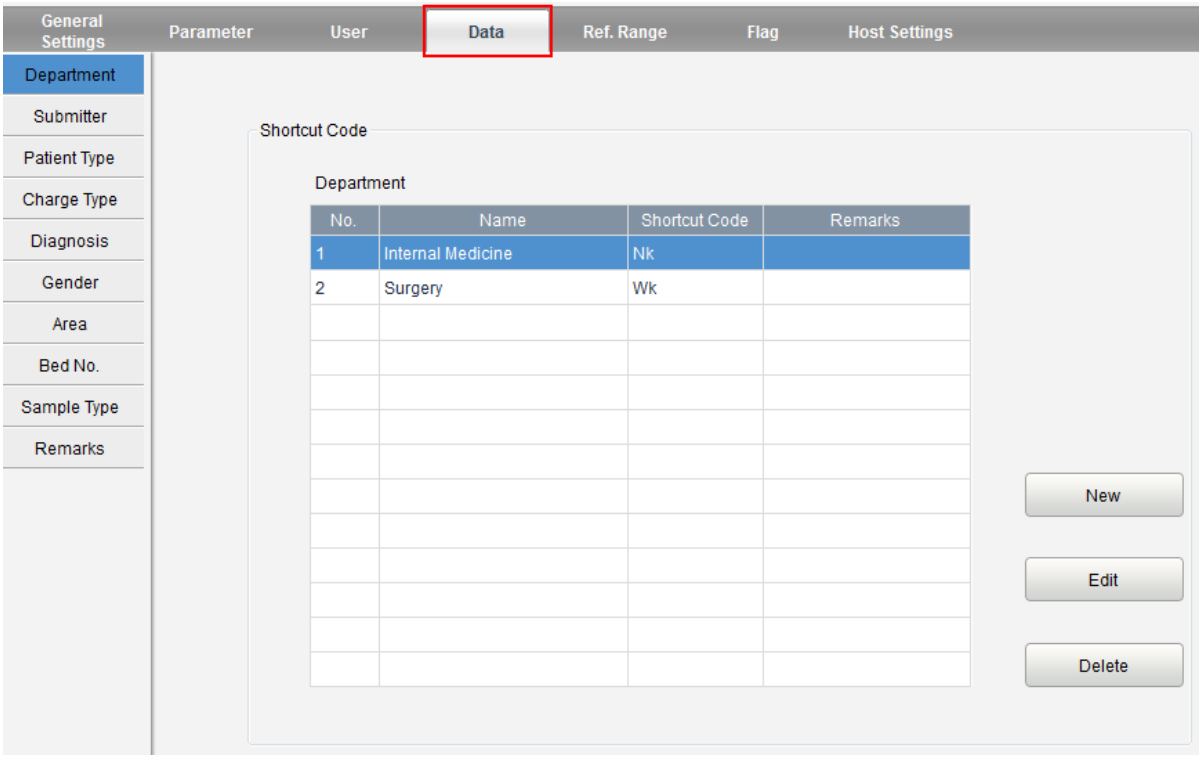
Different items can share one shortcut code.

6.6.1 Accessing the Interface

Click **Setup** > **Data** to access the data dictionary setting interface. The user can set the shortcut code for the relevant items of the patient information in this interface.

You can set the shortcut code for the following items: **Department**, **Submitter**, **Patient Type**, **Charge**, **Diagnosis**, **Gender**, **Area**, **Bed No.**, **Sample Type** and **Remarks**. See Figure 6-25.

Figure 6-25 Shortcut Code



6.6.2 Adding a New Item

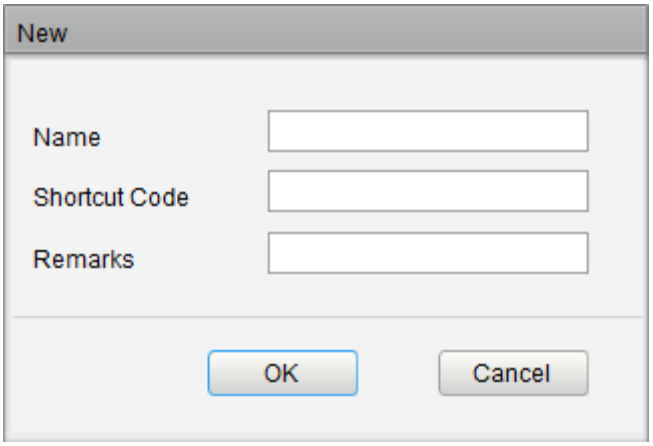
This section takes the adding of a new department as an example to introduce the method for adding a new item and its shortcut code. The method for adding other new items is similar and is not introduced in details herein.

Steps for adding a new department are shown as follows:

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

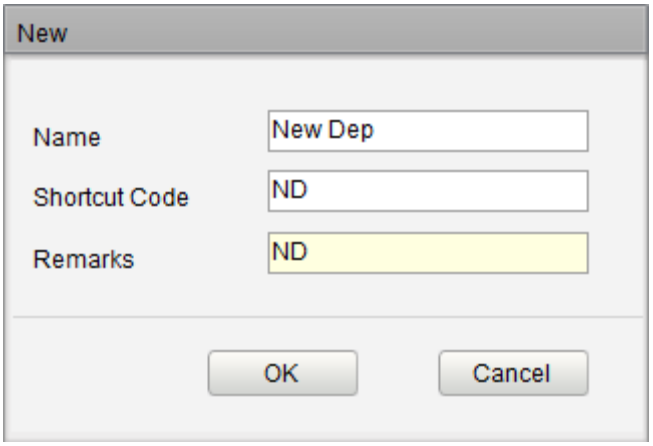
   A dialog box will pop up as shown in Figure 6-26.

Figure 6-26 Adding a New Item



2. Enter a new department name, shortcut code and remarks. See Figure 6-27.

Figure 6-27 Entering the Department Name and Shortcut Code



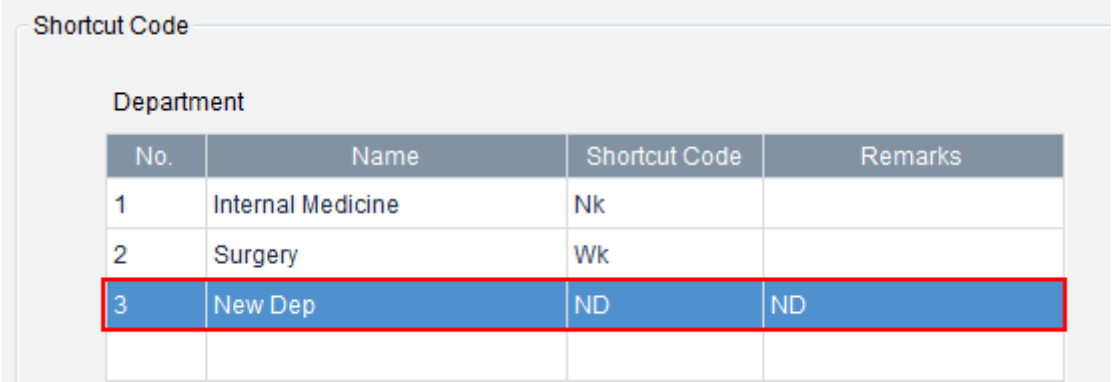
NOTE

- 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 6-28.

Figure 6-28 Information of the Newly Added Department



6.6.3 Editing Items/Shortcut Code

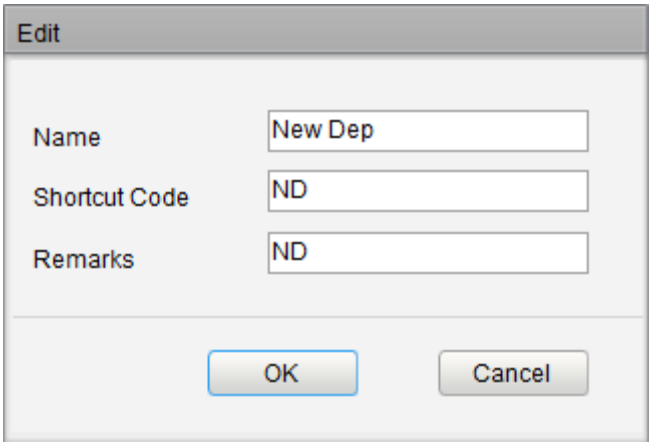
This section takes the editing of a department as an example to introduce the method for editing items and its shortcut code. The method for editing other new items is similar and is not introduced in details herein.

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 6-29.

Figure 6-29 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.

6.6.4 Deleting a Shortcut Code

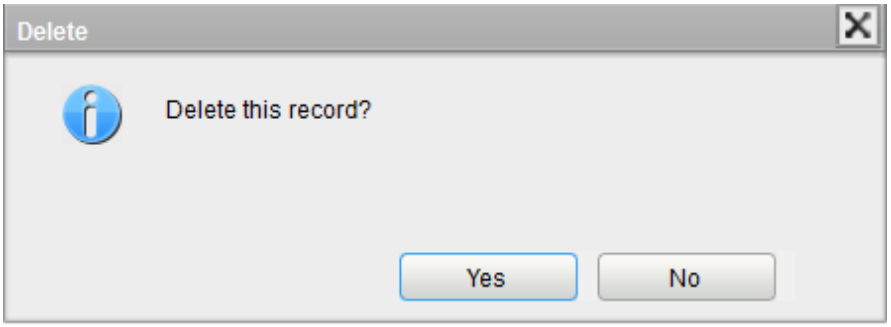
This section takes the deleting of a department as an example to introduce the method for deleting items and this shortcut code. The method for deleting other new items is similar and is not introduced in details herein.

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 6-30 Deleting a Department



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

6.7 Reference 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.

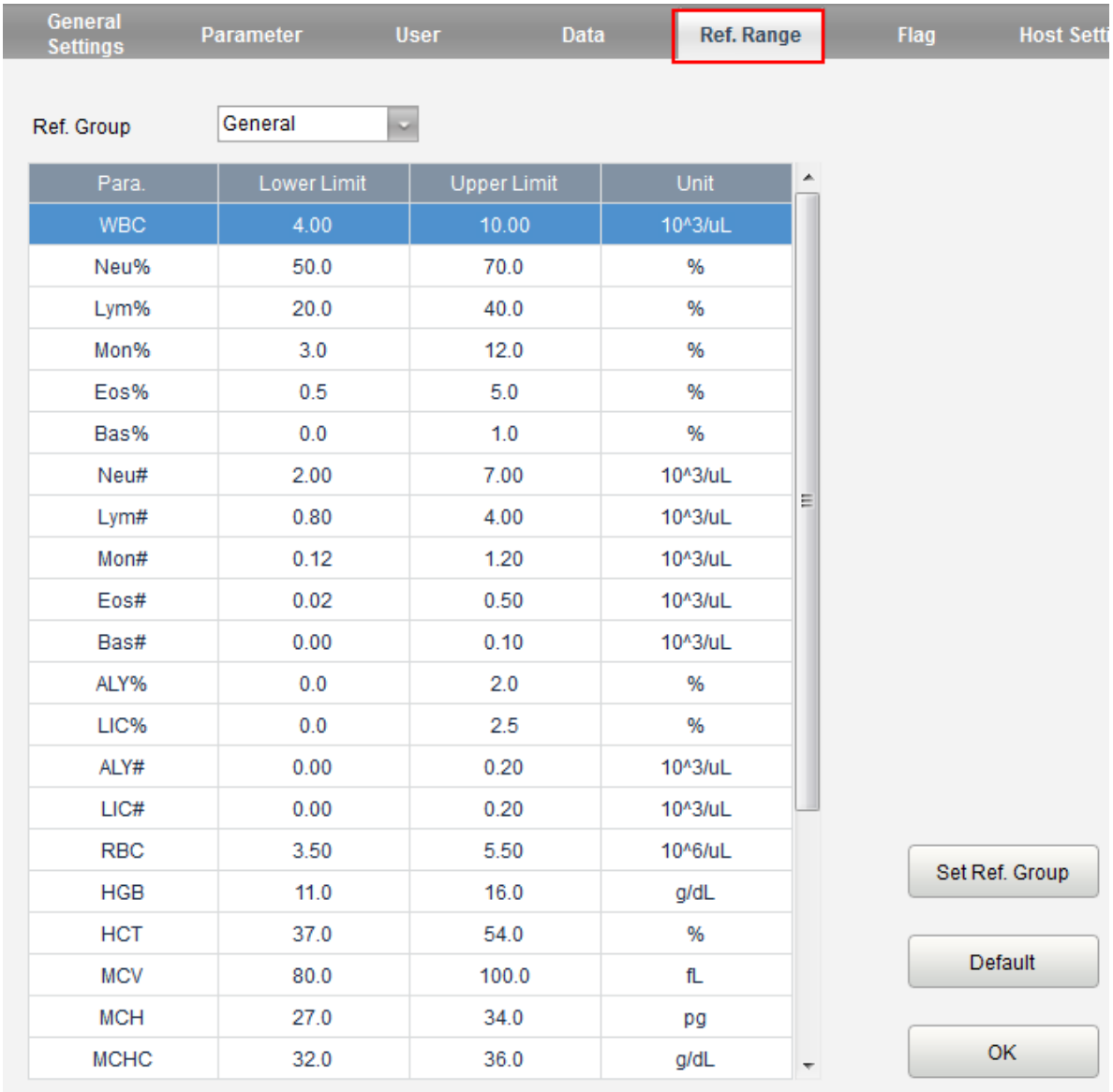
The **Ref. Range** interface is where you view and set the high and low limits for your patients. The analyzer flags any parameter value above (↑) or below (↓) these limits.

This analyzer divides the patients into 5 demographic groups: General, Man, Woman, Child and Neonate. You can also customize another 10 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.

6.7.1 Accessing the Interface

Click **Setup** > **Ref. Range** to access the **Ref. Range** setting interface. See Figure 6-31.

Figure 6-31 Ref. Range



Para.	Lower Limit	Upper Limit	Unit
WBC	4.00	10.00	10^3/uL
Neu%	50.0	70.0	%
Lym%	20.0	40.0	%
Mon%	3.0	12.0	%
Eos%	0.5	5.0	%
Bas%	0.0	1.0	%
Neu#	2.00	7.00	10^3/uL
Lym#	0.80	4.00	10^3/uL
Mon#	0.12	1.20	10^3/uL
Eos#	0.02	0.50	10^3/uL
Bas#	0.00	0.10	10^3/uL
ALY%	0.0	2.0	%
LIC%	0.0	2.5	%
ALY#	0.00	0.20	10^3/uL
LIC#	0.00	0.20	10^3/uL
RBC	3.50	5.50	10^6/uL
HGB	11.0	16.0	g/dL
HCT	37.0	54.0	%
MCV	80.0	100.0	fL
MCH	27.0	34.0	pg
MCHC	32.0	36.0	g/dL

6.7.2 Setting Reference Group

You can set the name, age range and gender of the customized reference group in the **Set Ref. Group** interface. In addition, you can also set the selected reference group as the default reference group.

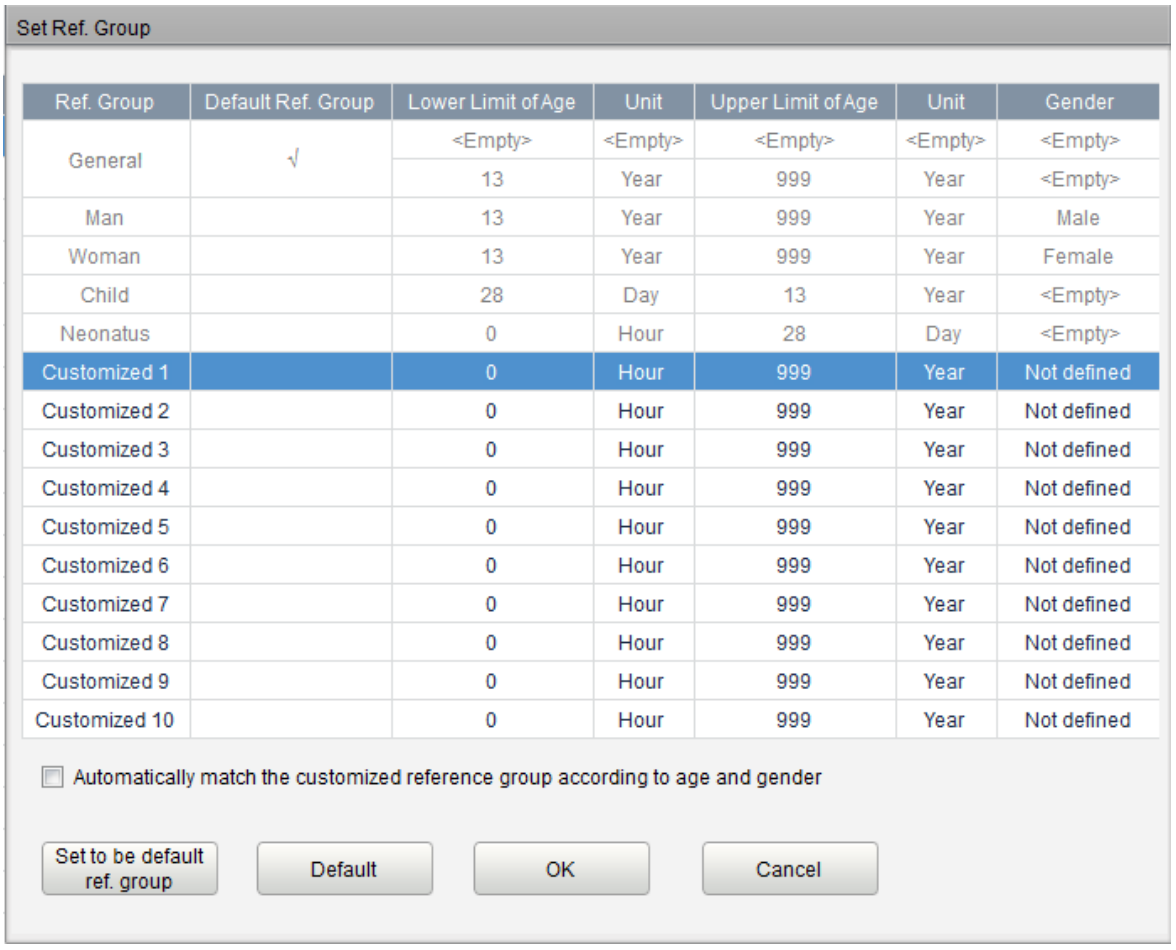
6.7.2.1 Setting Customized Reference Group

If the fixed reference group does not meet the actual requirements, you can customize a proper reference group by taking the following steps:

1. Click **Set Ref. Group**.

   A screen will pop up as shown in Figure 6-32.

Figure 6-32 Customized Ref. Group



2. Double click the cell of the customized group (e.g. Customized 1) and directly enter the name of the new reference group.
3. Double click the cell to set the **Upper Limit of Age** and **Lower Limit of Age** of the reference group. Set the age **Unit** and **Gender**, etc. of the reference group from the dropdown list.

NOTE

- The reference group name entered is not allowed to be empty nor the same as the existing ones.
- You can not modify the names and corresponding information of the five fixed reference groups in the list.

4. Click **OK** to complete the setting of the customized reference group.

6.7.2.2 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 fixed reference group.

When the system automatically matches the reference group according to age and gender, the rules listed in Table 6-3 shall be followed.

Table 6-3 Rules for Matching the Reference Group

Automatically match the customized reference group according to age and gender	Information of the default customized reference group	Match the reference group
Unchecked (default setting)	N/A	Built-in reference group
Checked	No change	Built-in reference group
Checked	With change	Preferentially match the customized reference group

6.7.2.3 Setting Default Ref. Group

The default setting is **General**.

Select a reference group and click **Set to be default ref. group** to set the selected reference group as the default group.

6.7.2.4 Restoring Defaults

Select a customized reference group and click the **Default** button under the reference group list to restore the setting of the selected reference group to the default value.

6.7.3 Changing the Ref. Range of the Ref. Group

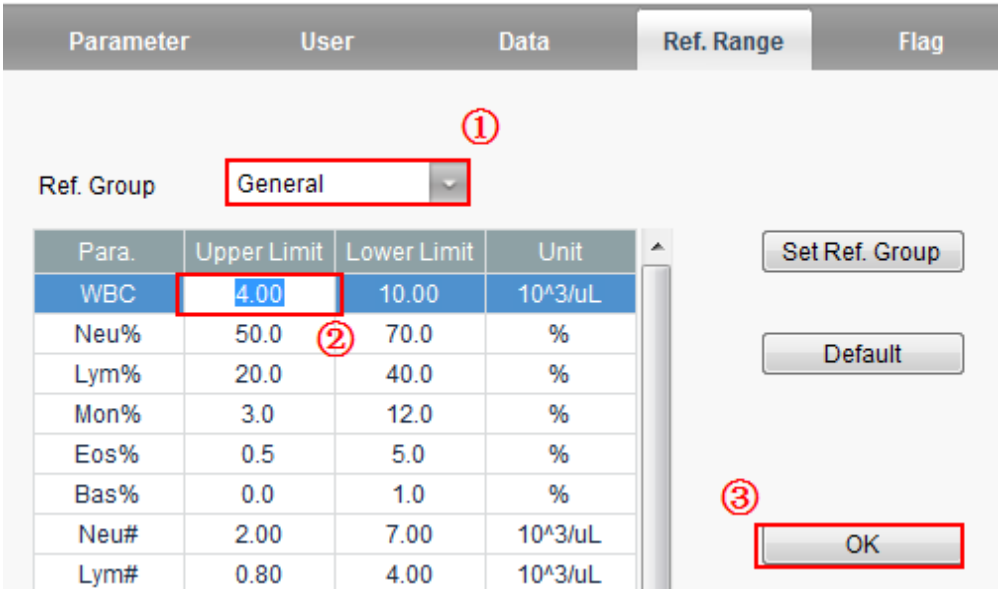
You can modify the reference range of the specified parameter in the **Ref. Range** setting interface.

1. Select the reference group, of which the range is intended to be modified, from the **Ref. Group** dropdown list (e.g. **General**).

2. Double click the **Upper Limit** (or **Lower Limit**) cell in the row, where the parameter to be modified is located, and enter the **Upper Limit** (or **Lower Limit**) of the parameter value.

   See Figure 6-33.

Figure 6-33 Setting the Ref. Range of the Ref. Group



3. Click **OK** to save the modification.

6.7.4 Restoring Defaults

Click **Default** to restore the upper/lower limit of the selected reference group to the default value.

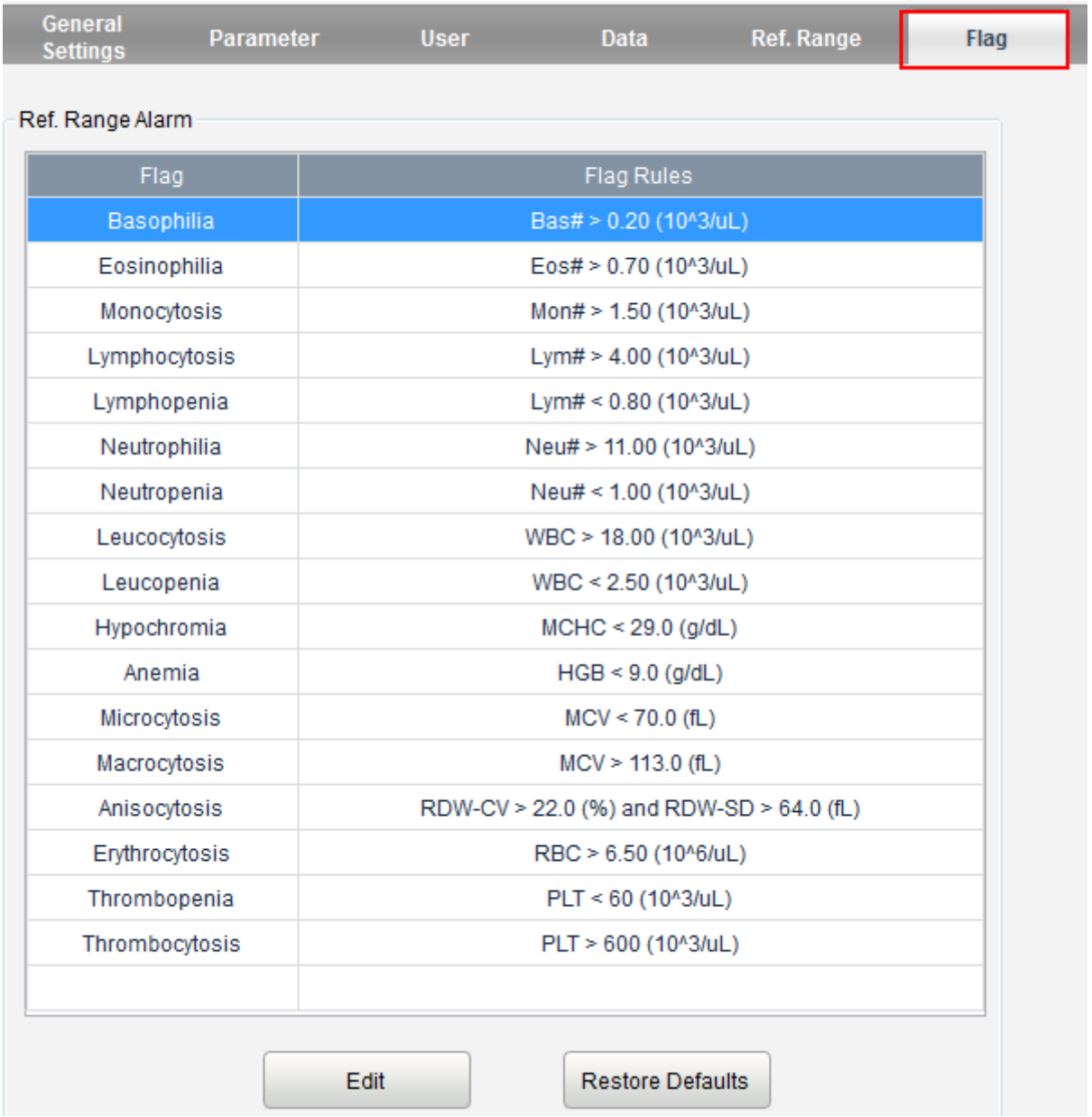
6.8 Flag

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

6.8.1 Accessing the Interface

Click **Setup** > **Flag** to access the Flag rules setting interface. See Figure 6-34.

Figure 6-34 Flag

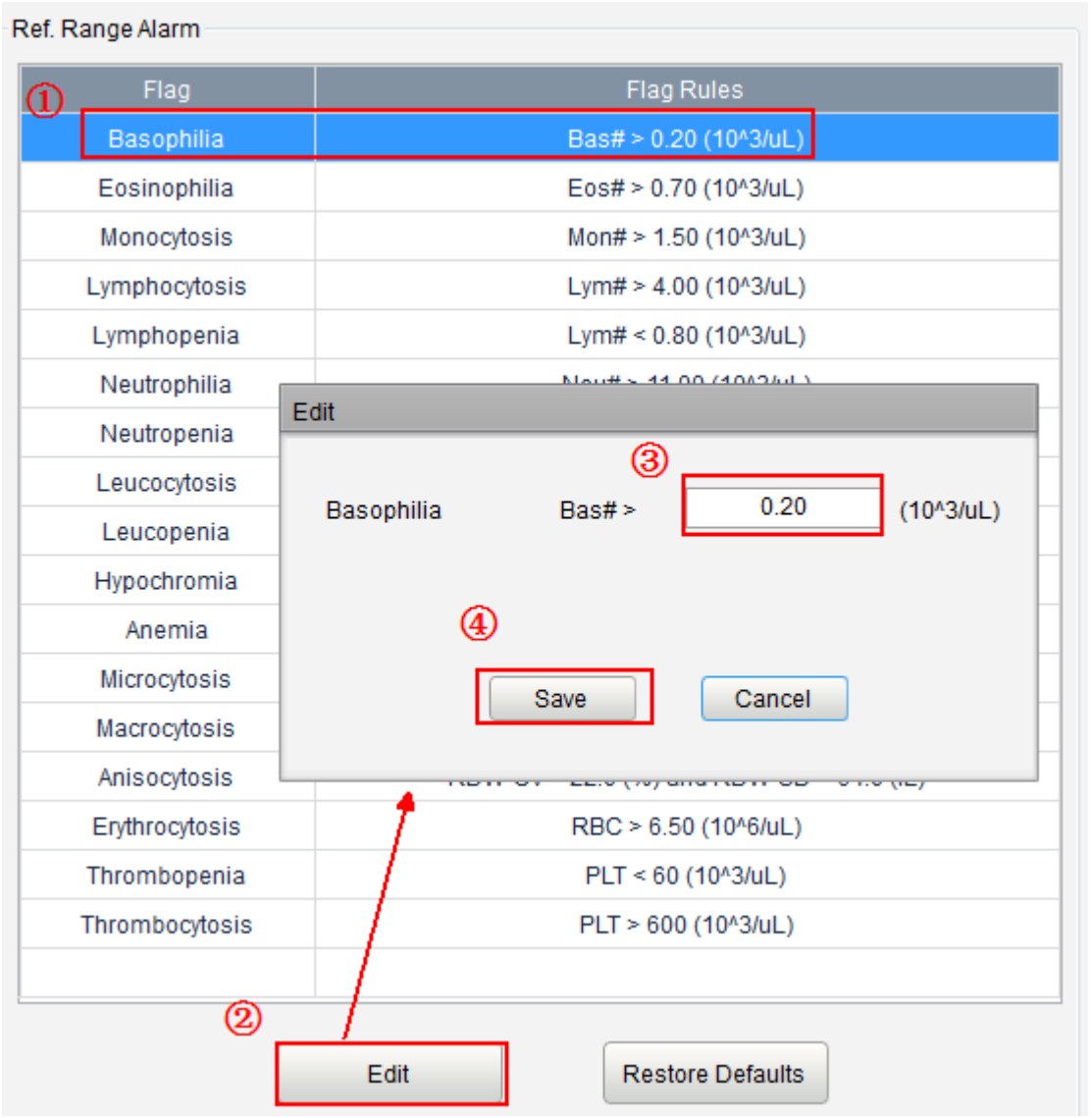


6.8.2 Setting Flag Rules

The user can select the name of the Flag in the **Flag** interface, then click **Edit** to modify the rules in the popup dialog box.

For example, if the Flag rules of the leucopenia are required to be modified, the user can refer to Figure 6-35 for operations.

Figure 6-35 Setting Flag Rules



Click **Restore** to restore the parameter to the default value.

6.9 Host Settings

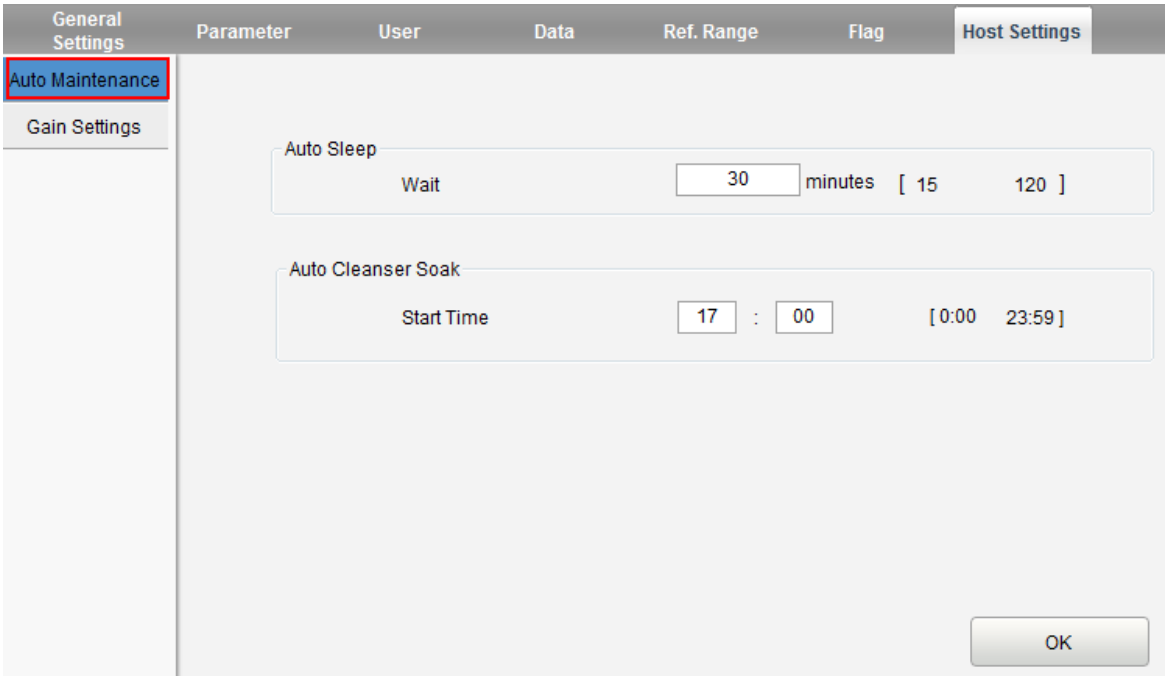
6.9.1 Auto Maintenance

The system auto sleep waiting time and cleanser maintenance time can be set in the auto maintenance interface.

6.9.1.1 Accessing the Interface

Click **Auto Maintenance** in the **Setup** > **Host Settings** interface to access the **Auto Maintenance** setting interface. See Figure 6-36.

Figure 6-36 Auto Maintenance



6.9.1.2 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.

6.9.1.3 Auto Cleanser Soak

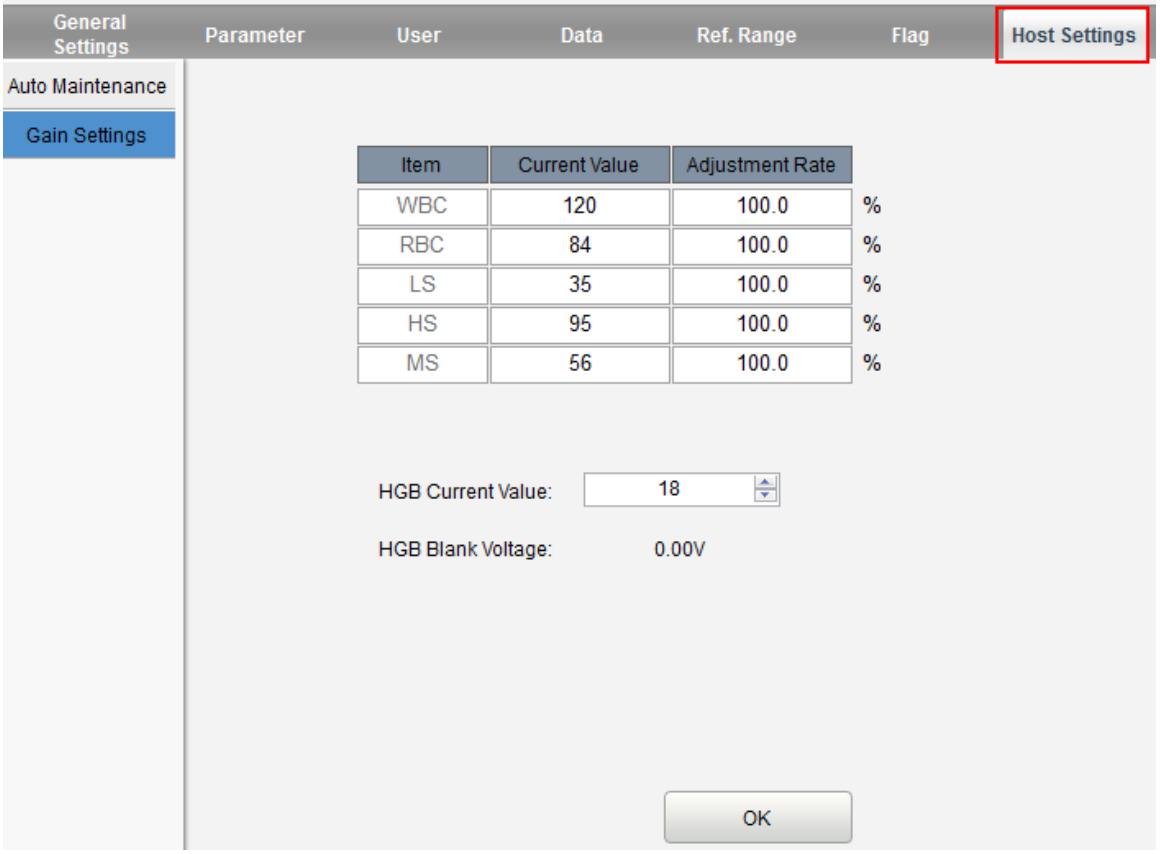
The administrator is allowed to set the start time of the cleanser soak in the **Start Time** textbox and the default value is 17:00. The acceptable value ranges from 0:00 to 23:59.

6.9.2 Gain Settings

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

At the **Setup** > **Host Settings** interface, click the **Gain Settings** button to enter the **Gain Settings** interface. See Figure 6-37.

Figure 6-37 Gain Settings



NOTE

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

- Setting the WBC gain

  The WBC gain here is under the 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 RBC 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**.

- Setting the LS/HS/MS gain

  Optical channel gain.

  Setting method I: Click the current value of the LS (HS, or MS) and enter the new value.

  Setting method II: Click the **Adjustment Rate** cell of the LS (HS, or MS) and enter the adjustment rate of the new value relative to the current value.

7 Report

7.1 Introduction

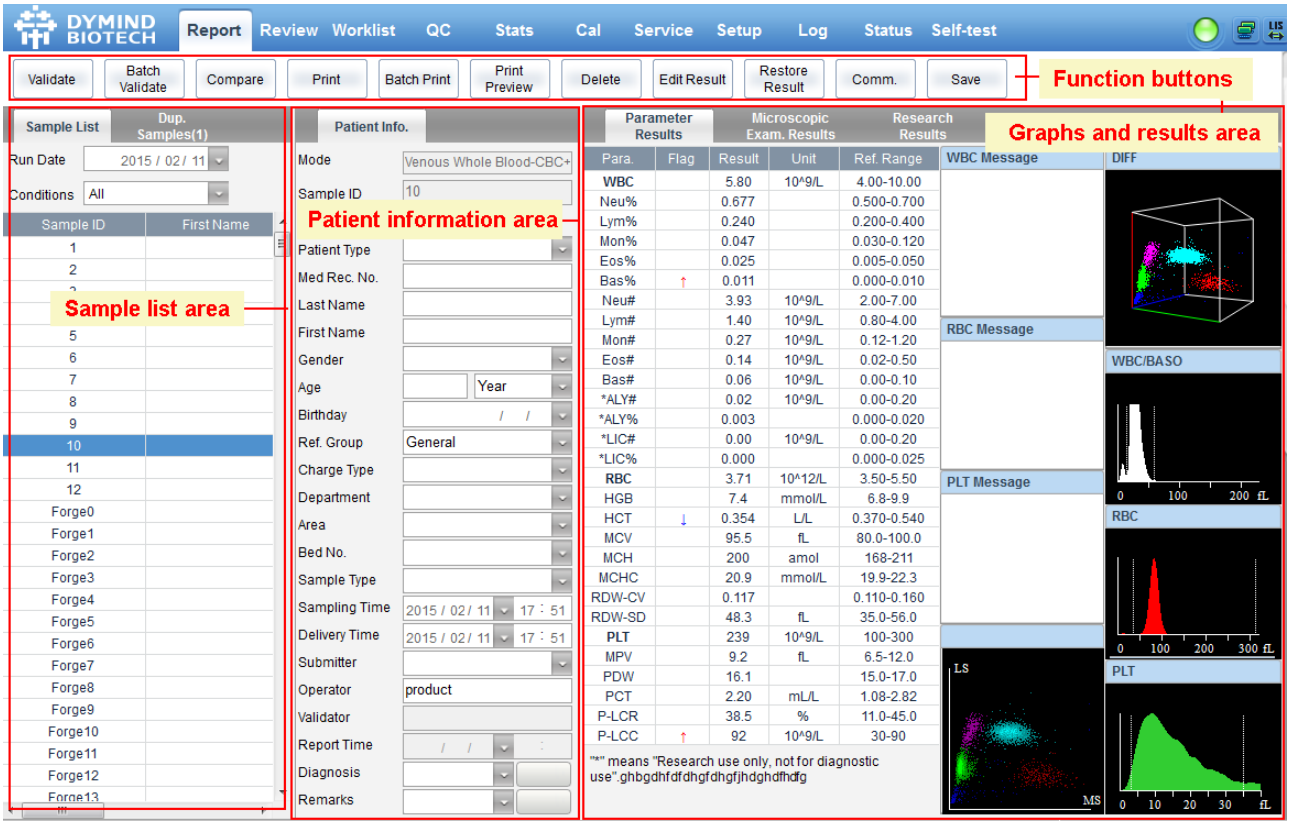
The report interface is the main interface of the analyzer. It is used for assisting the user to perform various operations after the sample analysis is completed and before the report is printed.

Before the report is printed, the user can carry out operations, such as validation, comparison and editing of the test results in **Report** interface.

7.2 Interface Introduction

Click **Report** to enter **Report** interface. See Figure 7-1.

Figure 7-1 Report



The report interface can be divided into the following four areas:

- Sample list area

  It displays the result list with specified date and conditions. It displays all the samples of the current day by default. The user can browse various sample records and the main sample/patient information in this area.

- Patient information area

  The user can manually enter the relevant information of the patient corresponding to the selected sample.

- Graphs and results area

  The user can check/edit various parameter results, enter the microscopic exam. parameters and browse the research results in this area.

- Function buttons

  The user can perform operations such as validation, batch validation, result comparison, editing and restoration, export and printing, etc. for the sample selected from the result list by clicking the function buttons.

7.3 Sample List Area

7.3.1 Sample List

The result list displays all the sample results of the current day by default.

The user can carry out the following operations in sample list area:

- Browse the sample list with specified conditions.
- Modify the sample ID

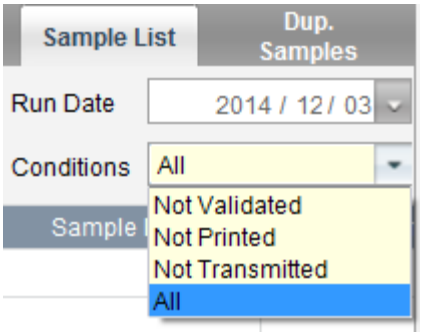
In addition to the aforementioned operations, the user can also carry out other operations such as editing/restoring result, validation/cancelling validation, printing/batch printing and deletion, etc. by clicking the function buttons. For details, see ***7.6 Functions of the Buttons***.

7.3.1.1 Browsing the Sample List with Specified Conditions

1. Click the **Run Date** control and select the run date of the sample.
2. Click the **Conditions** dropdown box and select the sample with specified conditions.

   The system will display the qualified sample results, including sample information, name, run date and sample status (whether it is validated, printed or transmitted). See Figure 7-2.

Figure 7-2 Report Result List



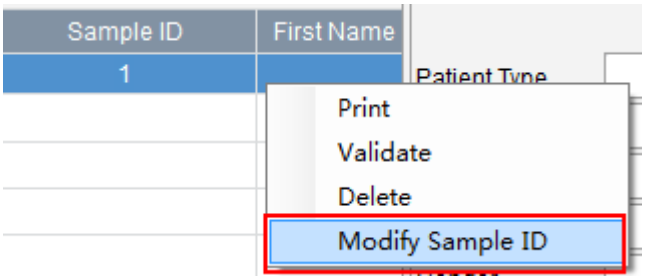
With different options selected, the records displayed in the list will vary. Refer to the table below for the correlation.

Options	Records displayed in the list
All (default setting)	Display all the sample records of specified dates.
Not Validated	Display the unverified sample records of specified dates.
Not Printed	Display the unprinted sample records of specified dates.
Not Transmitted	Display the sample records, which are not transmitted to the LIS, of specified dates.

7.3.1.2 Modifying Sample ID

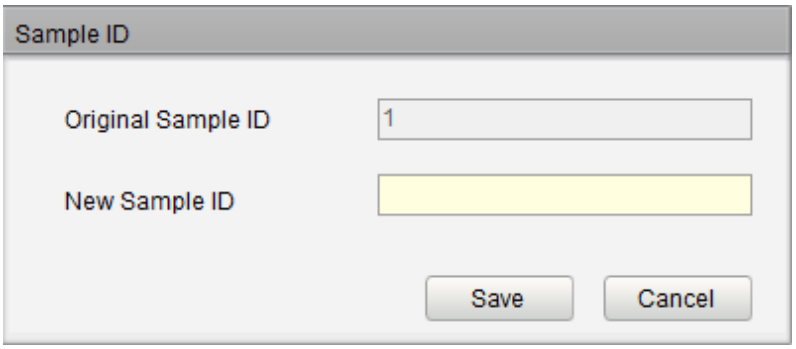
1. Select and right click a row of record from the list and select **Modify Sample ID** in the popup shortcut menu. See Figure 7-3.

Figure 7-3 Modifying Sample ID (1)



2. Enter a new sample ID and click **Save** to finish the modification as shown in Figure 7-4.

Figure 7-4 Modifying Sample ID (2)



NOTE

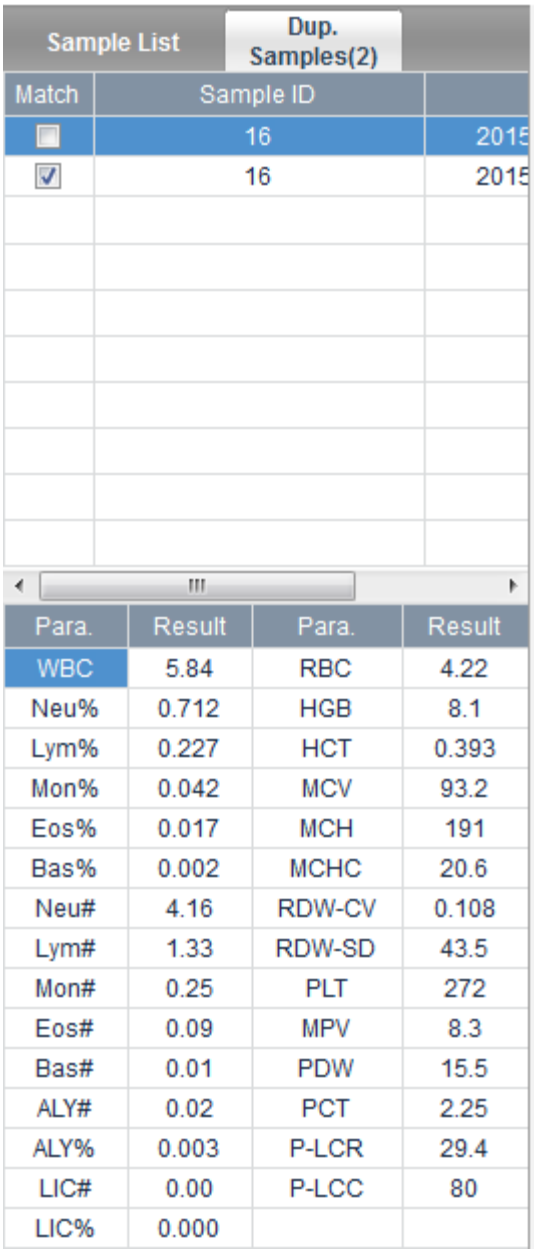
The operator only has the access to modify the ID of the samples which are not validated.

7.3.2 Dup. Samples

The **Dup. Samples** interface displays the sample results with the same sample ID received by the system within the same day.

Select a sample from the top of dup. samples list and browse the corresponding parameter result of this sample at the lower part of the screen. See Figure 7-5.

Figure 7-5 Dup. Results



Tick off one of the samples to match the patient information with this sample to generate a report for this sample.

NOTE

The matching operation is not allowed to be executed over validated samples.

7.4 Patient Information Area

The user can enter the patient information corresponding to the sample before or after the test result is obtained. Click the **Save** button after information input to save the entered information.

Please refer to Table 7-1 Parameter Description for the description and entry methods of each parameter.

Table 7-1 Parameter Description

Parameter	Meaning	Operation
Run Date	Run date of the sample	You do not need to enter it and it will be displayed by the system automatically
Sample	ID of the sample under analysis	You do not need to enter it and it will be displayed by the system automatically.
Patient Type	Patient type, including: • Inpatient • Physical Examination • STAT • Outpatient	Select from the dropdown list.
Med Rec. No.	Med Rec. No. of a patient.	Directly enter in the textbox.
First Name	First name of a patient	Directly enter in the textbox.
Last Name	Last name of a patient	Directly enter in the textbox.
Gender	Patient gender, including: • Not defined • Male • Female	Select from the dropdown list.
Age	Age of a patient	Select the age unit from the dropdown list (**Year**, **Month**, **Day** or **Hour**) and enter a number into the box next to the age unit.
Birthday	Birthday of a patient	Select from the date control.

Parameter	Meaning	Operation
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 by the user or not). • Refer to ***6.7 Reference Range*** for the setting of the reference group and range.
Charge Type	Charge type of an item, including: • Public expense • Military expense • Medicare • Self-pay	Select from the dropdown list.
Department	Department, to which a patient is admitted.	Select from the dropdown list or directly enter.
Area	The ward area where a patient is admitted.	Select from the dropdown list or directly enter.
Bed No.	The bed number of a patient	Directly enter in the textbox. **NOTE** The bed No. is required to be filled only for inpatients.
Sample Type	Type of the sample under analysis • Venous blood • Capillary blood • Cord blood • Blood	Select from the dropdown list.
Sampling Time	Sampling date and time	Select the sampling date from the date control and enter the time in the time textbox. **NOTE** • If the **Automatically generate the sampling date** is set, the system will automatically get the operating system date and take it as the sampling date. Please refer to 6.3.1 ***Auxiliary Settings*** for the setting of this parameter. • The sampling time can be no later than the current system time.

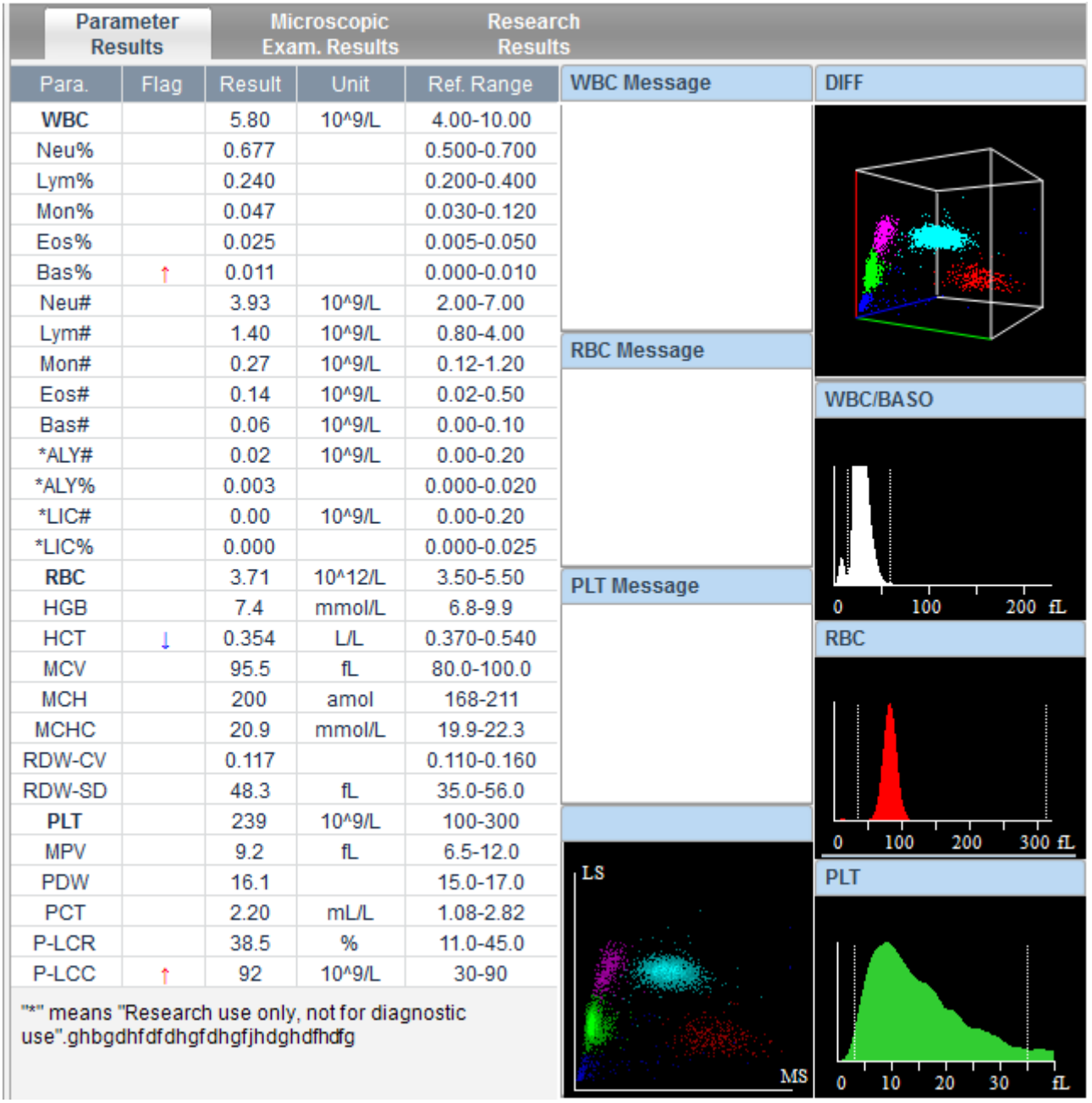
Parameter	Meaning	Operation
Delivery Time	Delivery time and date	Select the delivery date from the date control and enter the time in the time textbox. **NOTE** • If the **Automatically generate the sampling date** is set, the system will automatically get the operating system date and take it as the delivery date. Please refer to 6.3.1 ***Auxiliary Settings*** for the setting of this parameter. • The delivery time can be no later than the current system time.
Submitter	Personnel submitting the sample.	Select from the dropdown list or directly enter.
Operator	Personnel testing the sample.	The default operator is the user name who is carrying out the current analysis. It can be modified according to the actual situation.
Validator	The person who validates 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 first time.	This parameter will be automatically displayed after the report is printed.
Diagnosis	Suspected diagnosis information	Select from the dropdown list or enter in the textbox. **NOTE** The administrator can set the shortcut code for the options of this parameter list in the **Setup** > **Data** interface and the corresponding name will be displayed in the dropdown list. Please refer to ***6.6 Data Dictionary*** for the setting methods.
Remarks	Clarifications or notes.	Select from the dropdown list or enter in the textbox. **NOTE** The administrator can set the shortcut code for the options of this parameter list at the **Setup** > **Data** interface and the corresponding name will be displayed in the dropdown list. Please refer to ***6.6 Data Dictionary*** for the setting methods.

7.5 Graphs and Results Area

7.5.1 Parameter Results

After selecting a sample from the sample list area, the user can browse the parameter results, scattergram (DIFF), histogram and alarm information, etc. of this sample under the **Parameter Results** tab and can edit the results. See Figure 7-6.

Figure 7-6 Parameter Results



Double click the DIFF diagram or the histogram to check the enlarged image. Furthermore, the DIFF diagram can be dragged around to browse the 3D histogram of the WBC diff.

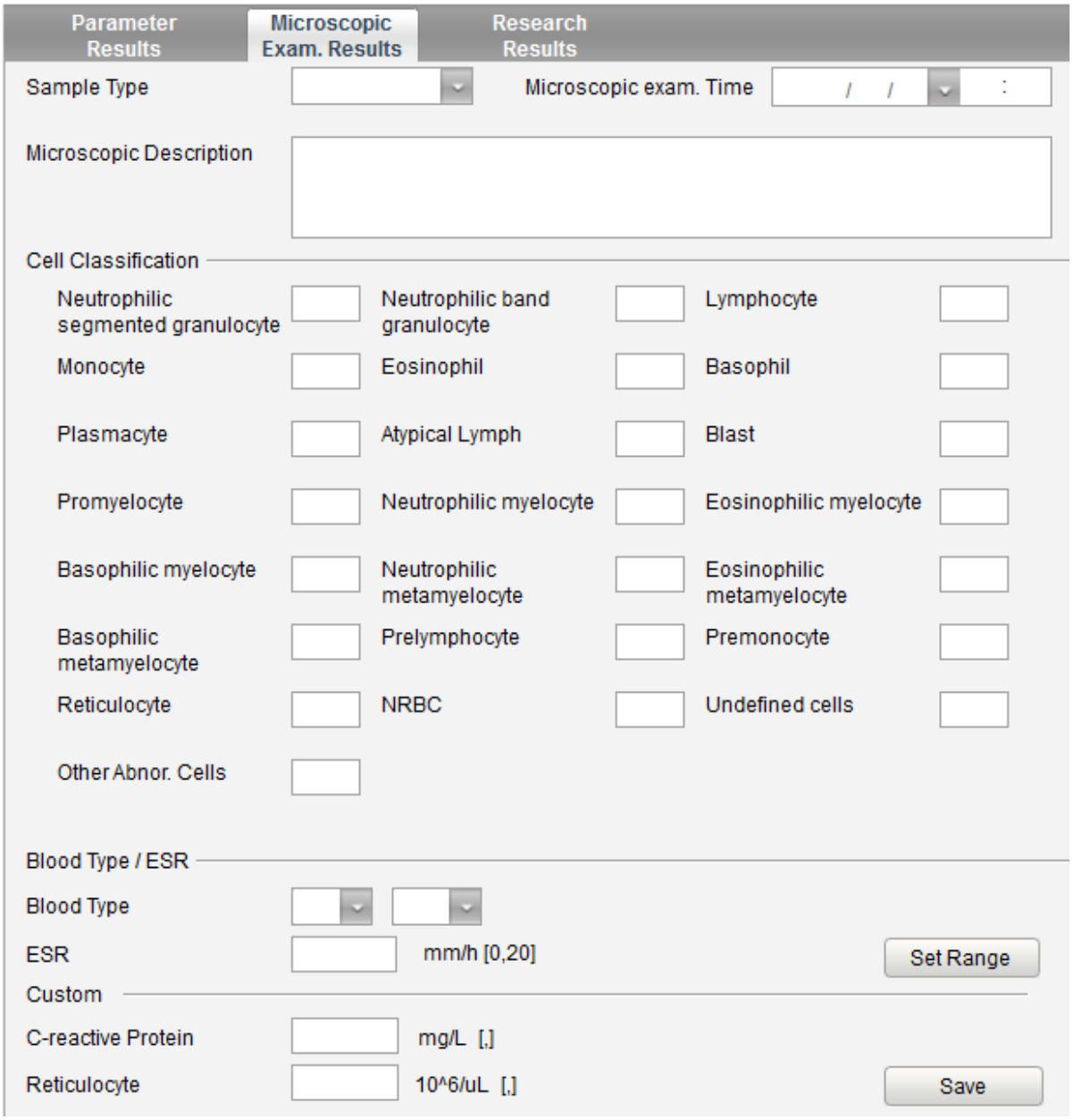
NOTE

- The user can set whether or not to display the four RUO parameters, “*” mark and declaration ("*" means "Research user only, not for diagnostic use".) in the setting interface. For details, see ***Chapter 5 Setup***.
- Please refer to 7.6.5 Edit Result and 0
- Restore Result for the detailed operations concerning the editing and restoring of the result data.

7.5.2 Microscopic Exam. Results

After selecting a sample from the sample list area, the user can enter the microscopic exam. results of this sample under the **Microscopic Exam. Results** tab, including the **Microscopic Exam. Time, Microscopic Description** and **Cell Classification**, etc. See Figure 7-7.

Figure 7-7 Microscopic Exam. Results



Please refer to Table 7-2 for the description and operating methods of the parameters relevant to the microscopic exam. results.

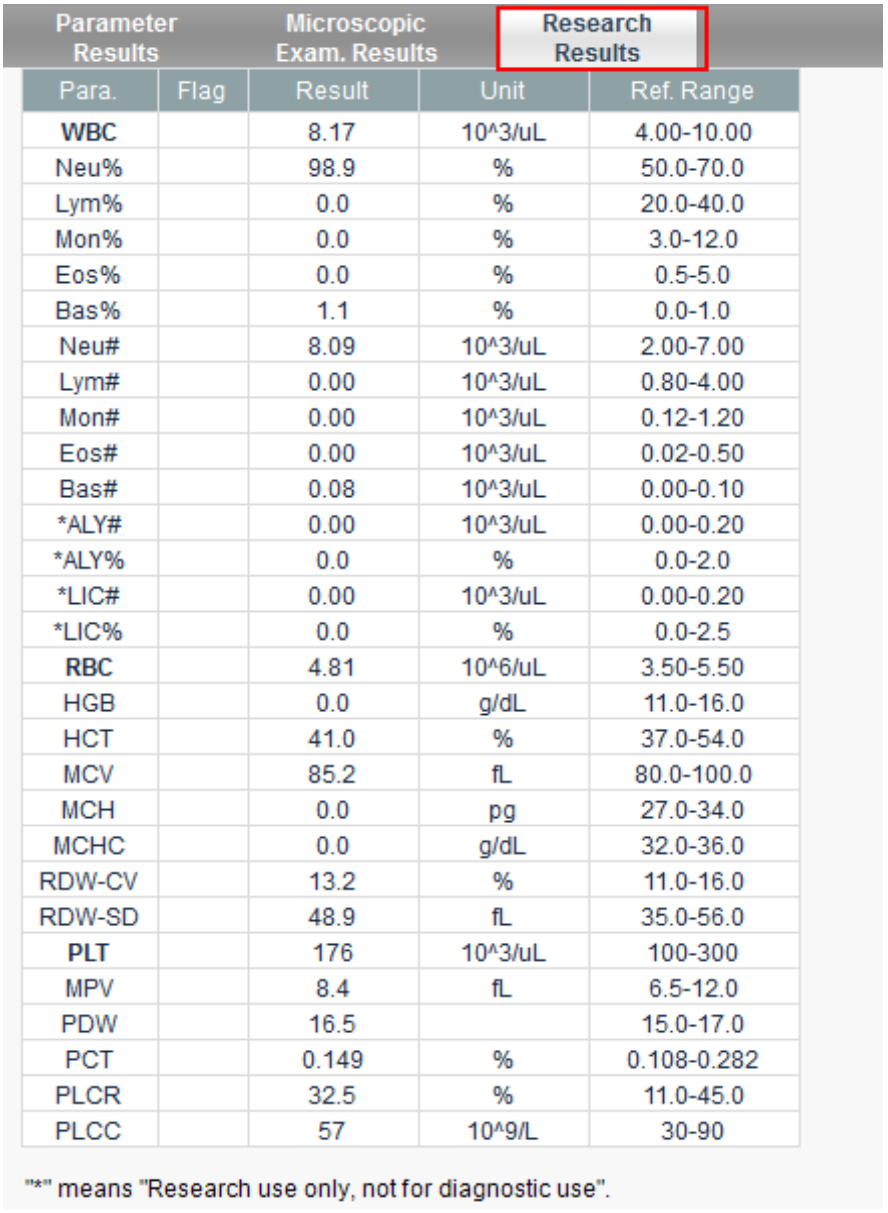
Table 7-2 Microscopic Exam. Parameter

Parameter	Meanings	Operation
Sample Type	Type of the microscopic exam. sample • Venous blood • Capillary blood • Cord blood • Blood	Click the **Sample Type** dropdown list box and select the type of the microscopic exam. sample. The default sample type is **Venous Blood**.
Microscopic exam. Time	Time of the microscopic exam.	Click the **Microscopic exam. Time** combo box and select the date and time of the microscopic exam. **NOTE** The Microscopic exam. time can be no later than the current system time.
Microscopic Description	Description of WBC, RBC and PLT morphology.	Enter the morphology information for WBC, RBC and PLT respectively into the multi-line textbox.
Cell Classification	Percentage of each cell classification in total cell count	Enter the percentage or other form of differential result of each cell classification into the textbox next to the cell class name respectively. You can enter a value within the range [0.0-100.0] and the unit is **%**.
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-**.
ESR	Erythrocyte sedimentation rate (ESR) measurement. If the measurement value is beyond the reference range, the system will show a "↑" mark to indicate it's beyond the higher limit and a "↓" mark to indicate it's below the lower limit.	1. Click **Set Range**. 2. Enter the lower limit and upper limit of the ESR, C-reactive Protein and Reticulocyte in **Lower Limit** and **Upper Limit** textboxes respectively. 3. Click **OK** to save all the settings and refresh the information.
Custom	Percentage of the C-reactive protein and the reticulocyte in total cell count	Enter their percentage in total cell count in the textboxes next to the C-reactive protein and the reticulocyte respectively.

7.5.3 Research Results

After selecting a sample from the sample list area, the user can check the detailed results of each parameter under the **Research Results** tab. See Figure 7-8.

Figure 7-8 Research Results



Para.	Flag	Result	Unit	Ref. Range
WBC		8.17	10^3/uL	4.00-10.00
Neu%		98.9	%	50.0-70.0
Lym%		0.0	%	20.0-40.0
Mon%		0.0	%	3.0-12.0
Eos%		0.0	%	0.5-5.0
Bas%		1.1	%	0.0-1.0
Neu#		8.09	10^3/uL	2.00-7.00
Lym#		0.00	10^3/uL	0.80-4.00
Mon#		0.00	10^3/uL	0.12-1.20
Eos#		0.00	10^3/uL	0.02-0.50
Bas#		0.08	10^3/uL	0.00-0.10
*ALY#		0.00	10^3/uL	0.00-0.20
*ALY%		0.0	%	0.0-2.0
*LIC#		0.00	10^3/uL	0.00-0.20
*LIC%		0.0	%	0.0-2.5
RBC		4.81	10^6/uL	3.50-5.50
HGB		0.0	g/dL	11.0-16.0
HCT		41.0	%	37.0-54.0
MCV		85.2	fL	80.0-100.0
MCH		0.0	pg	27.0-34.0
MCHC		0.0	g/dL	32.0-36.0
RDW-CV		13.2	%	11.0-16.0
RDW-SD		48.9	fL	35.0-56.0
PLT		176	10^3/uL	100-300
MPV		8.4	fL	6.5-12.0
PDW		16.5		15.0-17.0
PCT		0.149	%	0.108-0.282
PLCR		32.5	%	11.0-45.0
PLCC		57	10^9/L	30-90

"*" means "Research use only, not for diagnostic use".

NOTE

- The specific values of the parameter results that are beyond the display range or without data collected cannot be provided.
- The editing of the parameter results will not affect the display of parameters in the **Research Results** tab.
- The content of this tab can only be viewed and used for research; it cannot be edited or printed.

7.6 Functions of the Buttons

7.6.1 Validate

The user can select one or several samples from the result list for validation.

1. Select one or several (point at and click on the target while pressing the [Ctrl] key on the keyboard) samples.
2. Click **Validate** or right click and select **Validate** from the shortcut menu popped up.

   The system will perform validation operations for the selected sample(s).

   If the selected records contain samples with no test results, after validating the samples with test results, the system will prompt you that the samples with no test results cannot pass the validation.

NOTE

- After validating, you can not edit the sample/patient information and the result.
- For the validated samples, "√" will be displayed in the cell corresponding to its **Validate** column and the button icon will turn into **Cancel Validation**; for the samples which are not validated, the cell corresponding to its **Validate** column will not be checked.

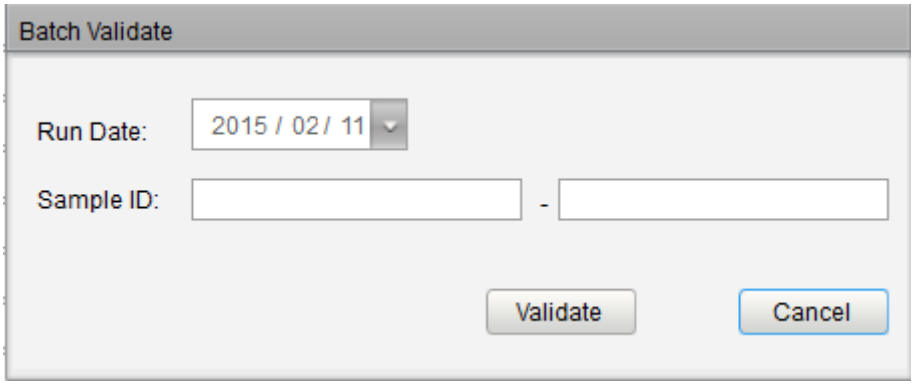
7.6.2 Batch Validate

If the number of samples required to be validated is large, the function of batch validate can be used for the samples within the specified ID range. Steps for such an operation are shown as below:

1. Click **Batch Validate**.

   The **Batch Validate** dialog box will pop up on the screen as shown in Figure 7-9.

Figure 7-9 Batch Validate

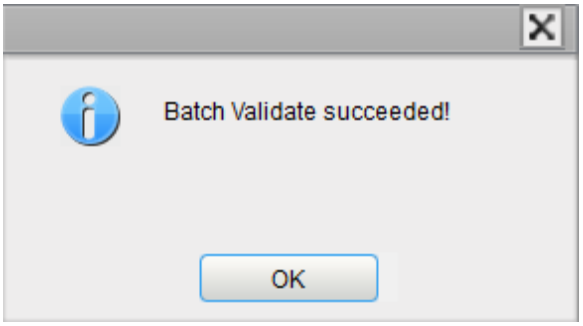


2. Select the run date of the sample according to the actual situation, e.g. **08/21/2014**.
3. Enter the ID range of the sample to be validated.

   If the sample IDs **000001** and **000100** are entered, it means that the system will validate the samples between 000001 and 000100 in batches.
4. Click **Validate**.

   Upon the successful validation, a dialog box will pop up as shown in Figure 7-10.

Figure 7-10 Batch Validate Succeeded



NOTE

- After validating, you can not edit the sample/patient information and the result.
- For the validated samples, "√" will be displayed in the cell corresponding to its **Validate** column and the button icon will turn into **Cancel Validation**; for the samples which are not validated, the cell corresponding to its **Validate** column will not be checked.

7.6.3 Cancel Validation

The user can cancel the validation of one or several validated samples from the result list.

1. Select one or several (point at and click on the target while pressing the [Ctrl] key on the keyboard) validated samples.
2. Click **Cancel Validation** or right click and select **Cancel Validation** from the popup shortcut menu.

   The system will cancel the validation of the selected sample(s).

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

NOTE

For the sample of which the validation is cancelled, the cell corresponding to its **Validate** column will be unchecked and the button icon will turn into **Validate**.

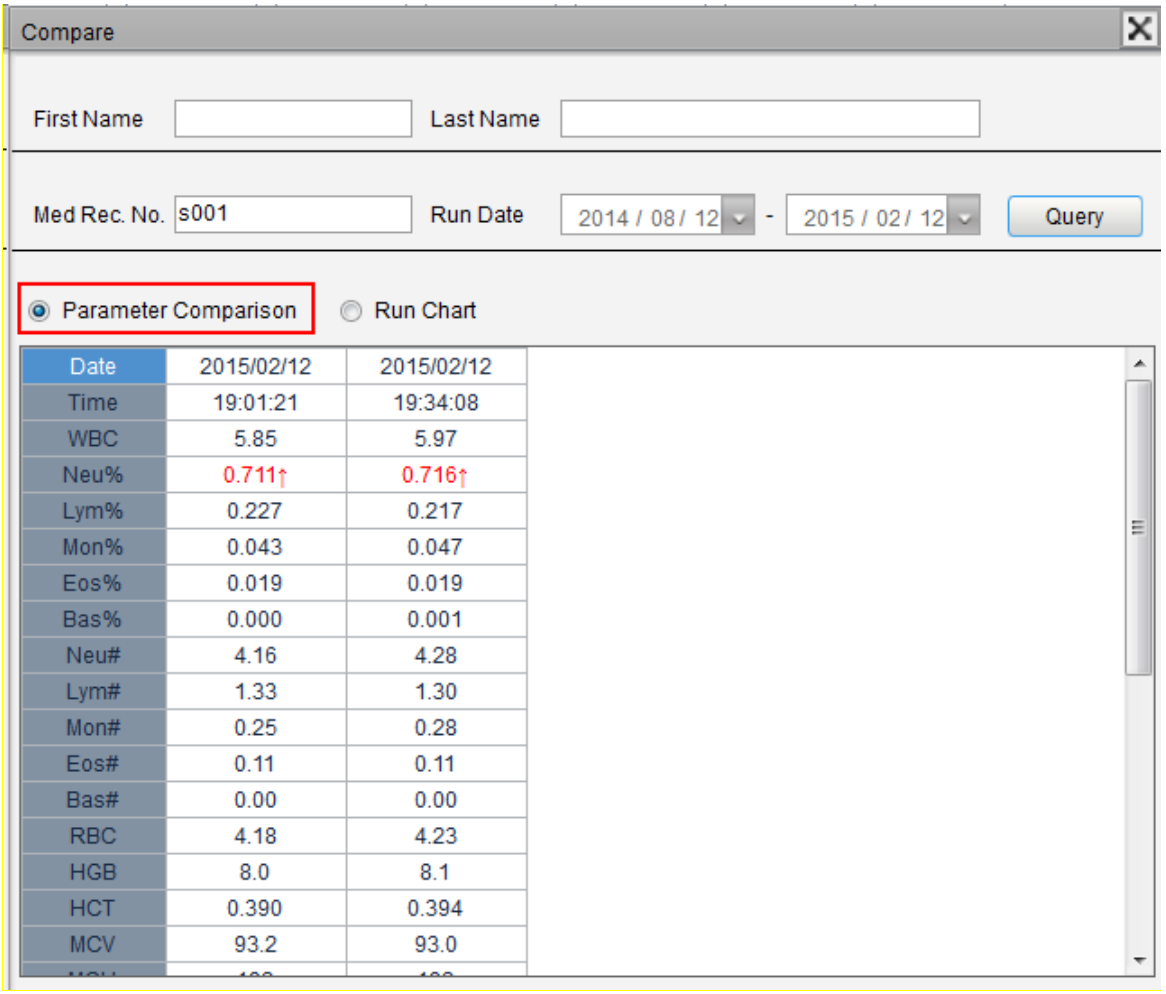
7.6.4 Compare

The user can compare the sample results of one patient obtained from several runs.

- Parameter Comparison
  - Click **Compare**, enter the **First Name**, **Last Name**, **Med Rec. No.** and **Run Date** of the patient and click **Query**.
  - Select the record to be compared from the sample list (including the name and Med Rec. No.), click **Compare**, then click **Query**.

  The **Compare** interface will pop up as shown in Figure 7-11.

Figure 7-11 Results Comparison (1)

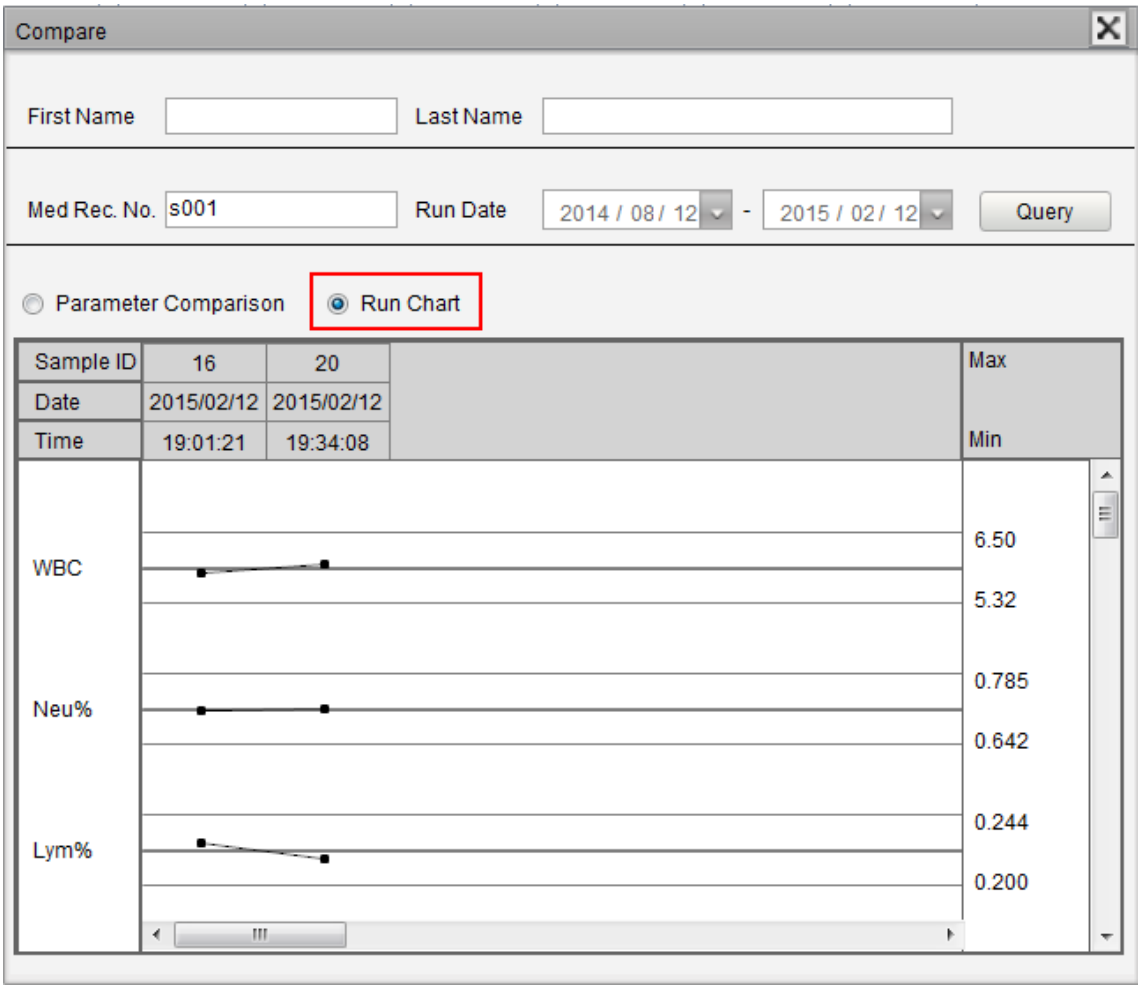


Date	2015/02/12	2015/02/12
Time	19:01:21	19:34:08
WBC	5.85	5.97
Neu%	0.711↑	0.716↑
Lym%	0.227	0.217
Mon%	0.043	0.047
Eos%	0.019	0.019
Bas%	0.000	0.001
Neu#	4.16	4.28
Lym#	1.33	1.30
Mon#	0.25	0.28
Eos#	0.11	0.11
Bas#	0.00	0.00
RBC	4.18	4.23
HGB	8.0	8.1
HCT	0.390	0.394
MCV	93.2	93.0

- Run Chart

  Click **Run Chart** in the **Compare** interface to view the Run Chart of the results of a qualified patient obtained from several runs. See Figure 7-12.

Figure 7-12 Run Chart



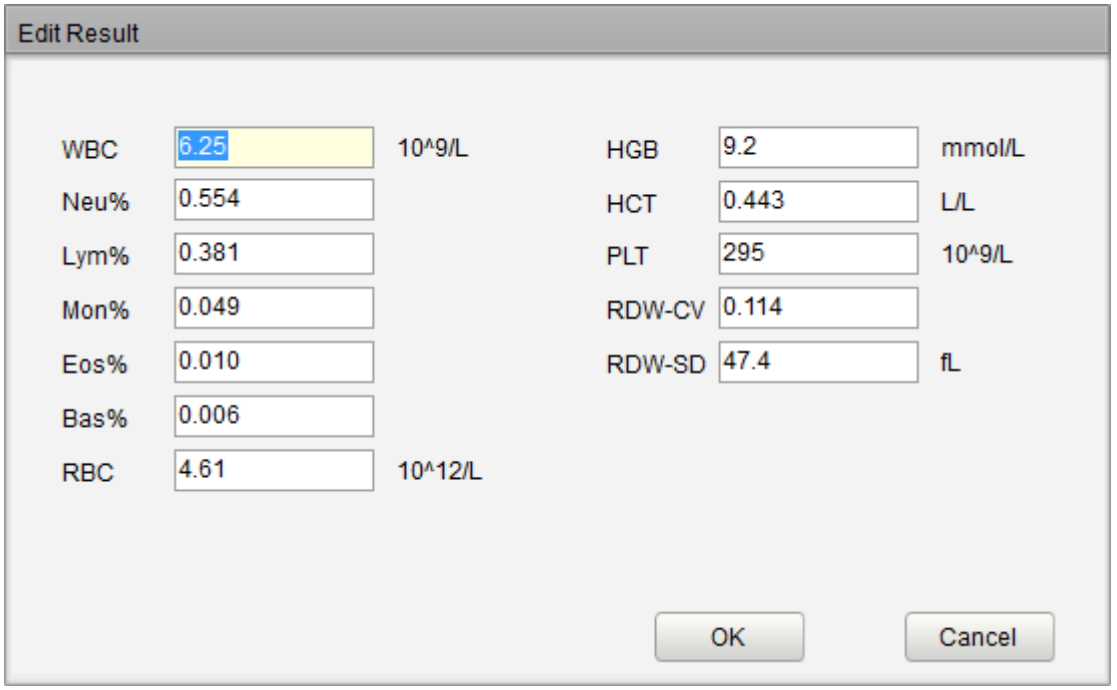
7.6.5 Edit Result

The user 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 7-13.

Figure 7-13 Editing Parameter Result



2. Edit the result of each parameter and WBC DIFF results in the popup textbox.
3. Click **OK** to save the changes and exit.

   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

- You can not edit the results of validated samples.
- You can not edit the results of the background.
- In the CBC mode, only the results of the test parameters are available, the results concerning the percentage of the WBC diff parameters are not available.
- Only the results concerning the percentage of the measurement parameters (WBC, RBC, HGB, HCT and PLT) and WBC diff parameters are allowed to be modified.
- 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**. **M** or **m** will be displayed in the Flag column by default. To cancel the display, please refer to ***6.3.1.7 Other*** for modifying the settings in the **Setup** interface.

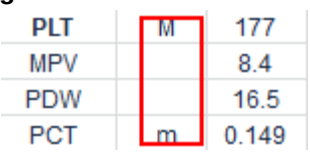
7.6.6 Restore Result

The user can restore the modified results to the initial measurement results as per the following steps.

1. Select the modified result record from the result list.

In the **Parameter Results** interface in the Graphs and Results area, the edited parameter is flagged with an **M** (or **m**) as shown in Figure 7-14.

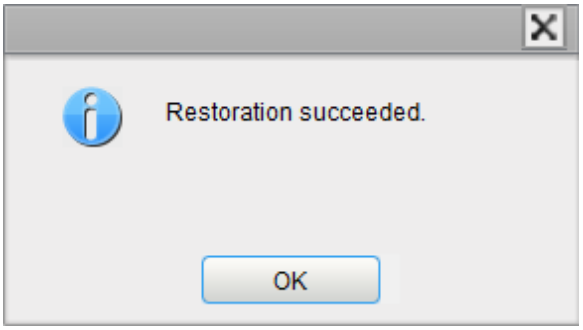
Figure 7-14 Edited Results



2. Click **Restore Result**.

   A message box indicating the successful restoration will pop up on the screen as shown in Figure 7-15.

Figure 7-15 Restoring Result



After the restoration is successful, the flag (M or m) generated after the **Restore Result** operation will be removed.

7.6.7 Print Preview

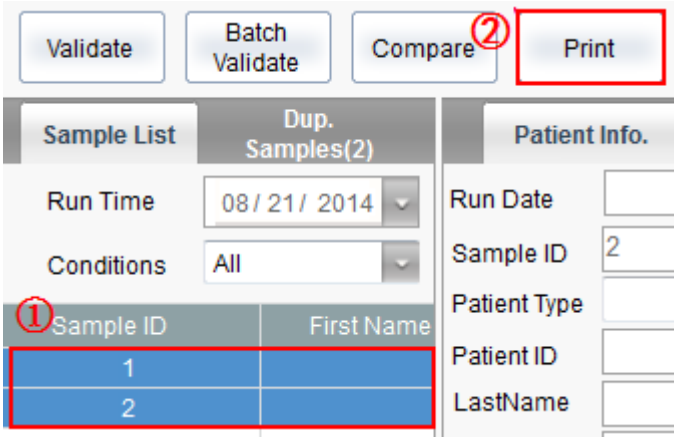
Before printing the result of comparison, the user can first click **Print Preview** to browse the result to be printed. Click  to print the result after the confirmation of its correctness.

7.6.8 Print

The user can click **Print** in the result list to print the report of one or several selected samples.

1. Select the samples to be printed.
   - Select one sample: click to select the sample.
   - Select several discontinuous samples: click to select each sample while pressing the [Ctrl] key on the keyboard.
   - Select several continuous samples: click the first sample and press the [Shift] key on the keyboard, and then click to select the last sample.

Figure 7-16 Printing the Report



In case of printing several continuous samples, the user can also use the **Batch Print** function to print the samples within the specified ID range. Please refer to ***7.6.9 Batch Print*** for detailed operations.

2. Click **Print**.

NOTE

For the printed sample, "√" will be displayed in the cell corresponding to its **Print** column; for the sample which is not printed, the cell corresponding to its **Print** column will be unchecked.

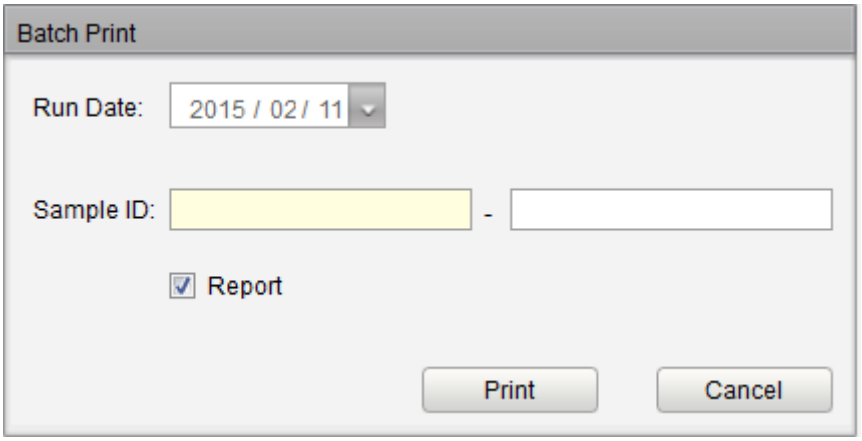
7.6.9 Batch Print

If you want to print a large number of samples within a specified ID range, you can choose Batch Print and the system will print the report in sequence.

1. Click **Batch Print**.

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

Figure 7-17 Batch Print



2. Select the run date, e.g. **2014/05/22**.
3. Enter the ID range of the samples to be printed.

If you enter **1137** in the first textbox and **1140** in the second textbox, the system will print the report between ID 1137 and 1140 in sequence.

4. Click **Print**.

   The system will print the selected records in a batch.

NOTE

For the printed sample, "√" will be displayed in the cell corresponding to its **Print** column; for the sample which is not printed, the cell corresponding to its **Print** column will be unchecked.

7.6.10 Delete

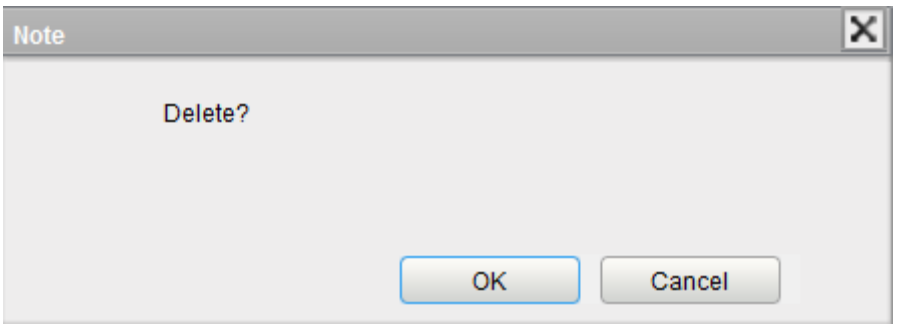
NOTE

- Validated samples are not allowed to be deleted.
- General users do have the access to delete the sample record.

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 7-18 Deleting Record



3. Click **OK** to delete the record selected from the list.

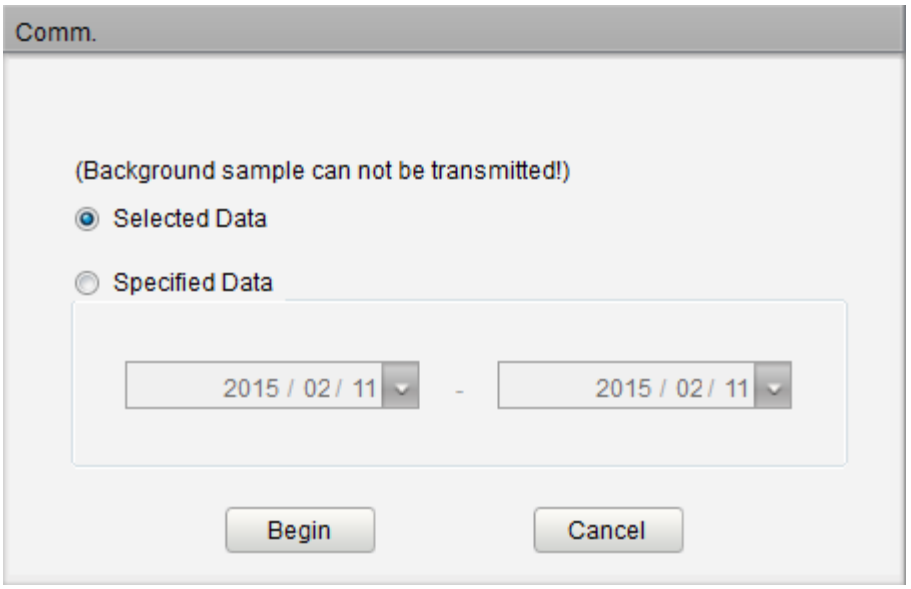
7.6.11 Comm.

The user can transmit the selected sample data or the sample data within the specified date range (excluding the blank sample) to the LIS/HIS system.

- Transmitting the selected data
  1. Select one or several samples from the result list for data transmission.
  2. Click **Comm.**.

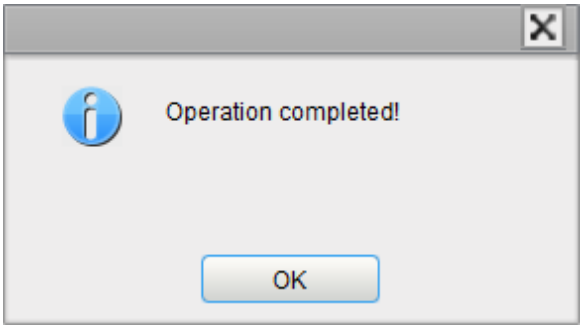
     A prompt box will pop up on the screen as shown below.

Figure 7-19 Transmitting the Selected Data



3. Select **Selected Data**.
4. Click **Begin** to start transmitting.

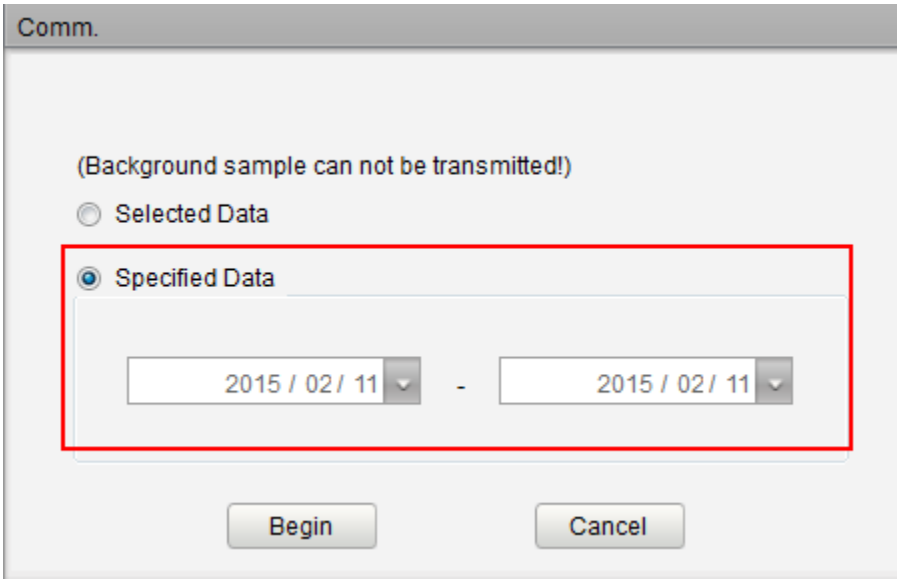
   A prompt box will pop up on the screen as shown below after the data is transmitted to the LIS/HIS.



- Communication for the data within the specified date range.
  1. Click **Comm.**.
  2. Select **Specified Data** and set the starting and ending dates for the data to be communicated.

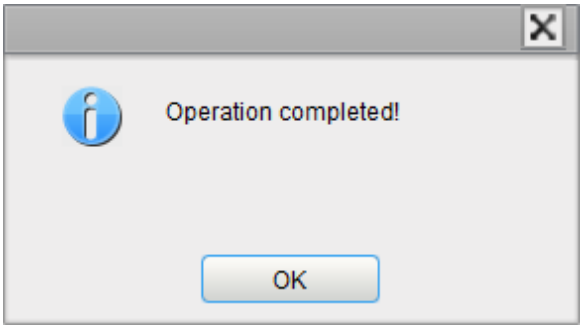
     See Figure 7-20.

Figure 7-20 Communication for the data within the specified date range



3. Click **Begin** to start transmitting.

   A prompt box will pop up on the screen as shown below after the data is transmitted to the LIS/HIS.



NOTE

After the communication starts, the interface will show the comm. progress and the **Stop** button. If you click the **Stop** button, the transmission will be stopped after the current sample record is transmitted.

7.6.12 Save

The operator can click **Save** after modifying the patient information to save the entered information.

8 Worklist

8.1 Introduction

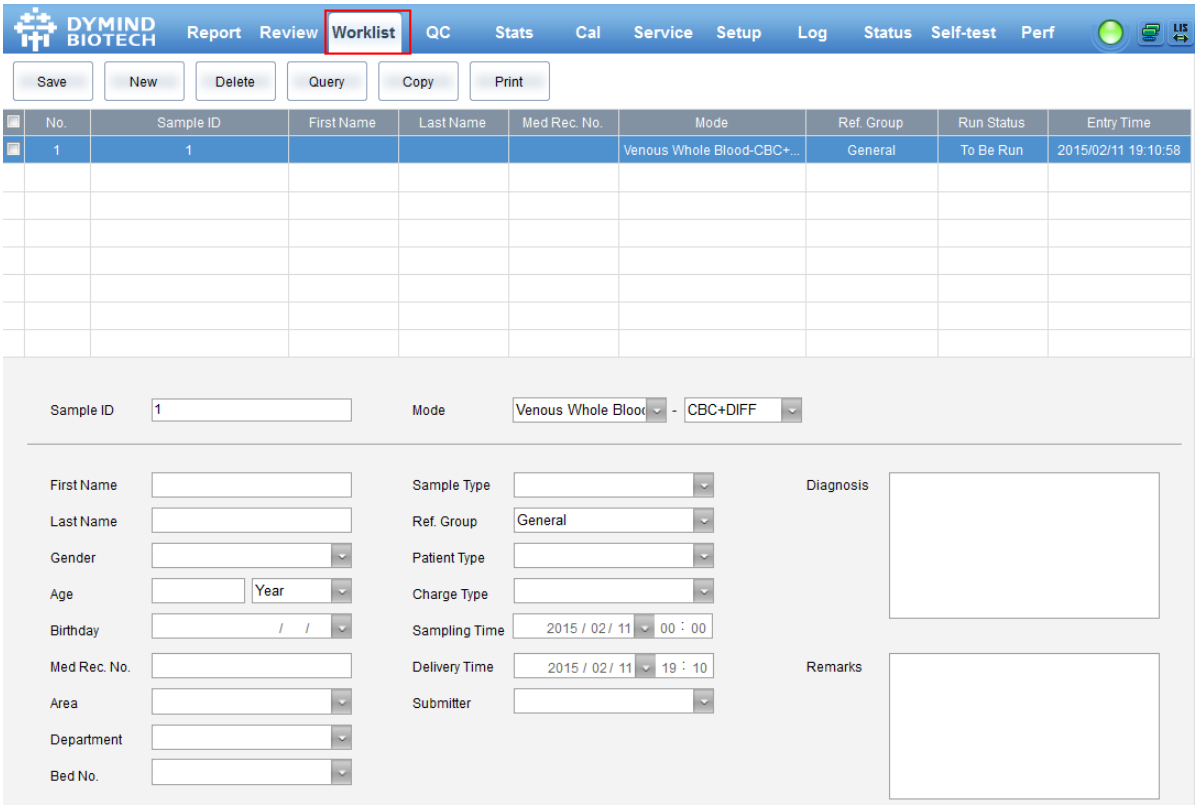
If a large number of samples are to be entered in batches or in advance, the worklist function provided in this system can be used. Once the counting of the samples in the worklist is completed, the corresponding patient information can be viewed in the **Review** Interface.

The worklist can save a maximum of 5000 records.

8.2 Interface Introduction

Click **Worklist** to access the Worklist Interface. See Figure 8-1.

Figure 8-1 Worklist



In the interface, the upper part consists of the function buttons and the worklist list and the lower part contains the worklist contents, including the sample information and the patient information. The operation results of the function buttons and the worklist content will be displayed in the worklist list; and when a record in the list is selected, the worklist content will be shown below the record.

8.3 Basic Operations

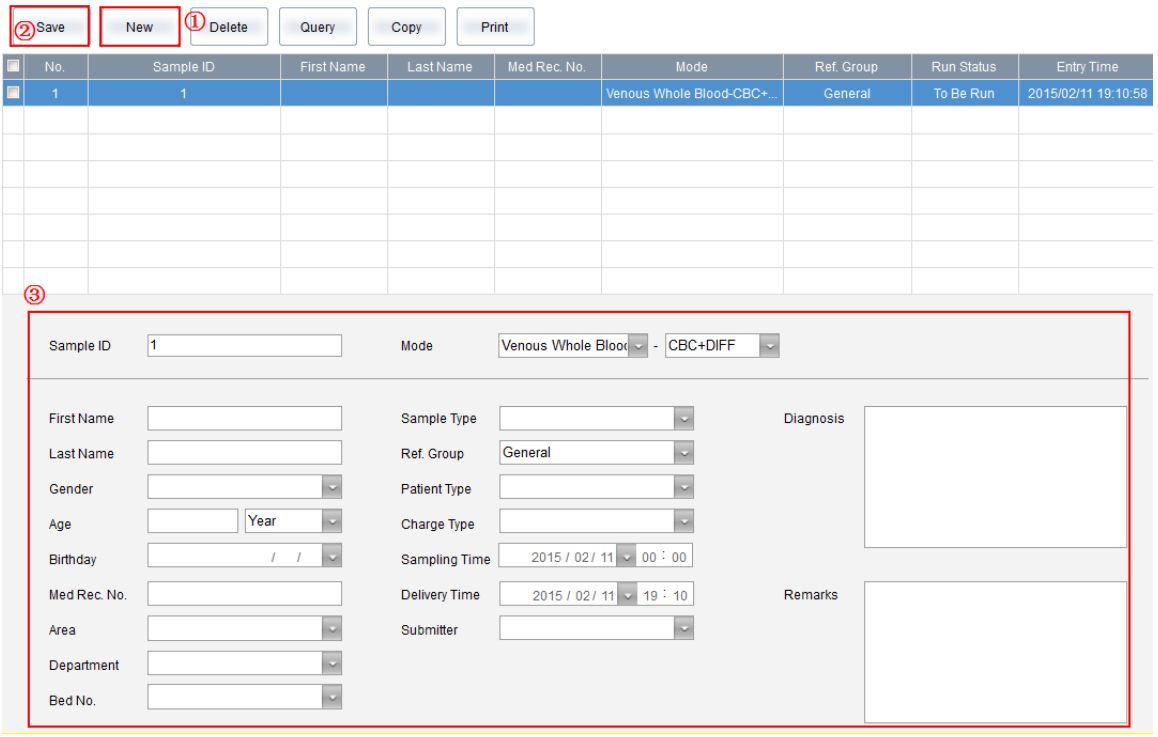
8.3.1 Adding a Worklist

The operation procedures for adding a worklist and executing the counting are as shown below:

1. Click the **New** button to add one record at the bottom of the worklist list.
2. Enter the sample/patient information in the worklist content area.

   See Figure 8-2.

Figure 8-2 Adding a Worklist



   For relevant parameter description, please refer to ***8.4 Parameter Description***.

3. Click **Save** to save all the worklist information.

   The added record will be displayed in the worklist list. The analysis status of the record is **To Be Run**.

   Click the **Start** button or press the aspirate key on the analyzer to start the sample analysis.

8.3.2 Editing a Worklist

When a worklist in the worklist list area is selected, its content can be edited in the worklist content area.

- For the worklist with the analysis status of **To Be Run** or **Error**, all information is editable.
- For the worklist with the analysis status of **Running**, the Sample ID and Mode are non-editable and the other parameters are editable.
- For the worklist with the analysis status of **Finished**, all information is non-editable.

For the meaning and entering method of parameters in the worklist, please refer to ***8.4 Parameter Description***.

8.3.3 Saving the Worklist

After performing the **Edit**, or **New** operation, you can click the **Save** button to save all the information.

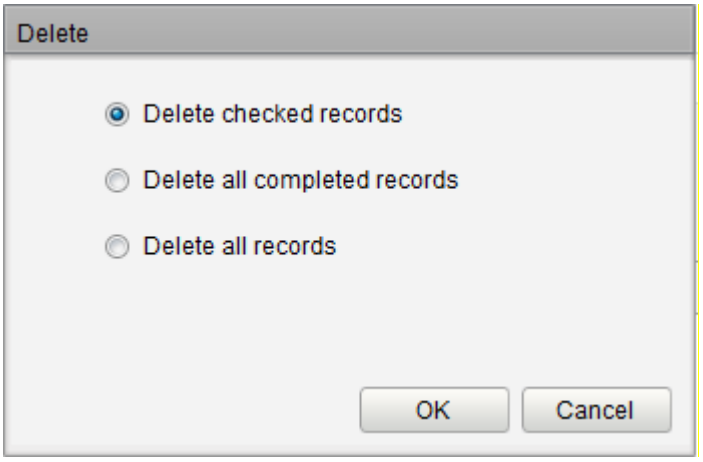
8.3.4 Deleting a Worklist

The operation procedures for deleting a worklist are as shown below:

1. Check the worklist you want to delete and then click **Delete,** or directly click **Delete**.

   The pop-up dialog box appears as shown in Figure 8-3.

Figure 8-3 Deleting a Worklist



2. Select the records you want to delete.
   - Delete checked records: Delete the checked records in the worklist list.
   - Delete all completed records: Delete all the records whose **Run Status** are **Finished** in the worklist list.
   - Delete all records: Delete all the records in the worklist except those whose **Run Status** are **Running**..

NOTE

The records whose **Run Status** are **Running** can not be deleted.

3. Click **OK**.

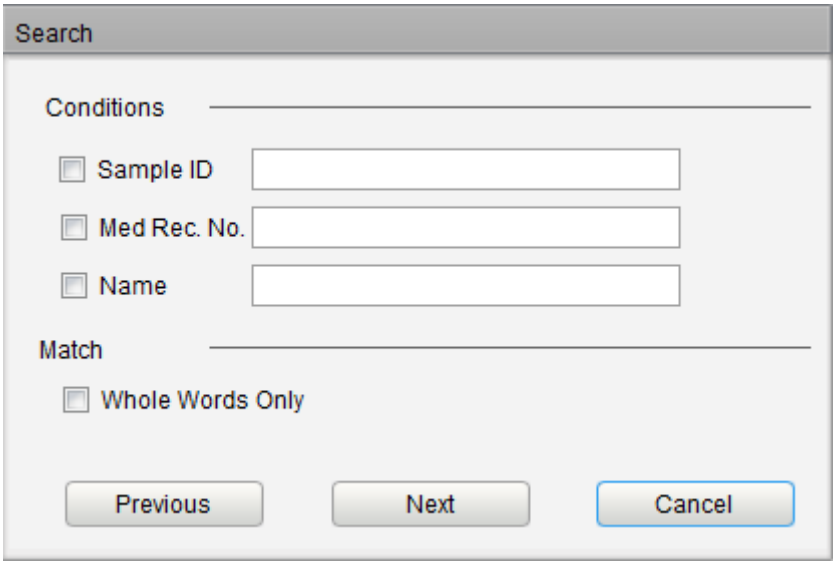
   The system will delete all the records selected by the user and refresh the worklist list.

8.3.5 Quering a Worklist

1. Click **Query**.

   The pop-up dialog box appears as shown in Figure 8-4.

Figure 8-4 Searching for a Worklist



2. Enter the Sample ID, Med Rec. No. or First Name of the patient record to be search for.
3. Click **Previous** or **Next**.

   system will start searching upward or downward from the currently highlighted record, and the eligible records will be highlighted.
4. Click **Cancel** to close the Search dialog box.

8.3.6 Copying a Worklist

Select one worklist from the worklist list and click the **Copy** button to add one record at the bottom of the list. The Sample ID of this record is 1 plus the Sample ID of the last record entered into the worklist, and the other information is the same as the copied worklist.

8.4 Parameter Description

Table 8-1 introduces the meaning and operation methods on sample information and patient information in the worklist.

Table 8-1 Parameter Description

Parameter	Meaning	Operation
Sample ID	Identification number of the sample to be analyzed	Enter in the textbox directly. **NOTE** • 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.

Parameter	Meaning	Operation
Mode	Blood Sample modes and Measurement modes. Among which, Blood Sample modes include: • Venous whole blood • Capillary whole blood • Predilute Measurement modes include: • CBC Complete Blood Count without DIFF. The counting results include 15 parameters, WBC histogram, RBC histogram and PLT histogram. • CBC+DIFF Complete Blood Count plus DIFF. The counting results include 25 parameters, DIFF scattergram, WBC/BASO histogram, RBC histogram, PLT histogram and 4 RUO parameters.	Separately select the Blood Sample mode and Measurement mode from two dropdown lists.
Ref. Group	Reference group of the samples to be analyzed. The system evaluates the counting results based on the reference range of the reference group and flags the results beyond the normal range.	Select from the dropdown list. **NOTE** • If you have set **Automatically match the customized reference group according to age and gender,** when you enter the gender and age of a patient, the system will automatically match the patient with the corresponding reference group (no matter whether user has selected a reference group or not.) • Refer to ***6.7 Reference Range*** for the settings of the reference group and reference range.
Sampling Time	Date and time when the sample is collected.	Select the sampling date in the calendar control and enter the sampling time in the Time textbox. **NOTE** • If you have set **Automatically generate the sampling date,** the system wil automatically capture the system date as the sampling date. Please refer to 6.3.1 ***Auxiliary Settings*** for the settings. • The sampling time can be no later than the current system time.

Parameter	Meaning	Operation
Delivery Time	Date and time when the sample is delivered.	Select the delivery date in the Calendar control and enter the delivery time in the Time textbox. **NOTE** • If you have set **Automatically generate the delivery date,** the system wil automatically capture the system date as the delivery date. Please refer to 6. 3. 1 ***Auxiliary Settings*** for the settings. • The delivery date can be no later than the current system time.
Med Rec. No.	Med Rec. No. of a patient.	Enter in the textbox directly.
First Name	First name of a patient	Enter in the textbox directly.
Last Name	Last name of a patient.	Enter in the textbox directly.
Gender	Gender of a patient. You can choose from the following: • Not defined • Male • Female	Select from the dropdown list.
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.
Birthday	Birthday of a patient.	Select in the data control.
Patient Type	You can choose from the following: • Inpatient • Physical Examination • STAT • Outpatient	Select from the dropdown list.
Charge Type	Type of the charge. You can choose among the following: • Public expense • Military expense • Medicare • Self-pay	Select from the dropdown list.
Area	The ward area in which the patient is admitted	Select from the dropdown list or enter directly.
Department	The department in which the patient is admitted	Select from the dropdown list or enter directly.
Bed No.	The bed number of the patient in the hospital.	Enter in the textbox directly. **NOTE** The **Bed No.** is required to be filled only when the **Patient Type** is **Inpatient**.

Parameter	Meaning	Operation
Submitter	Personnel submitting the sample.	Select from the dropdown list or enter directly.
Diagnosis	Suspicious diagnosis.	Enter in the textbox directly.
Remarks	Clarification, notes or explanation.	Enter in the textbox directly.

9 Result Review

9.1 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 300,000 sample records.

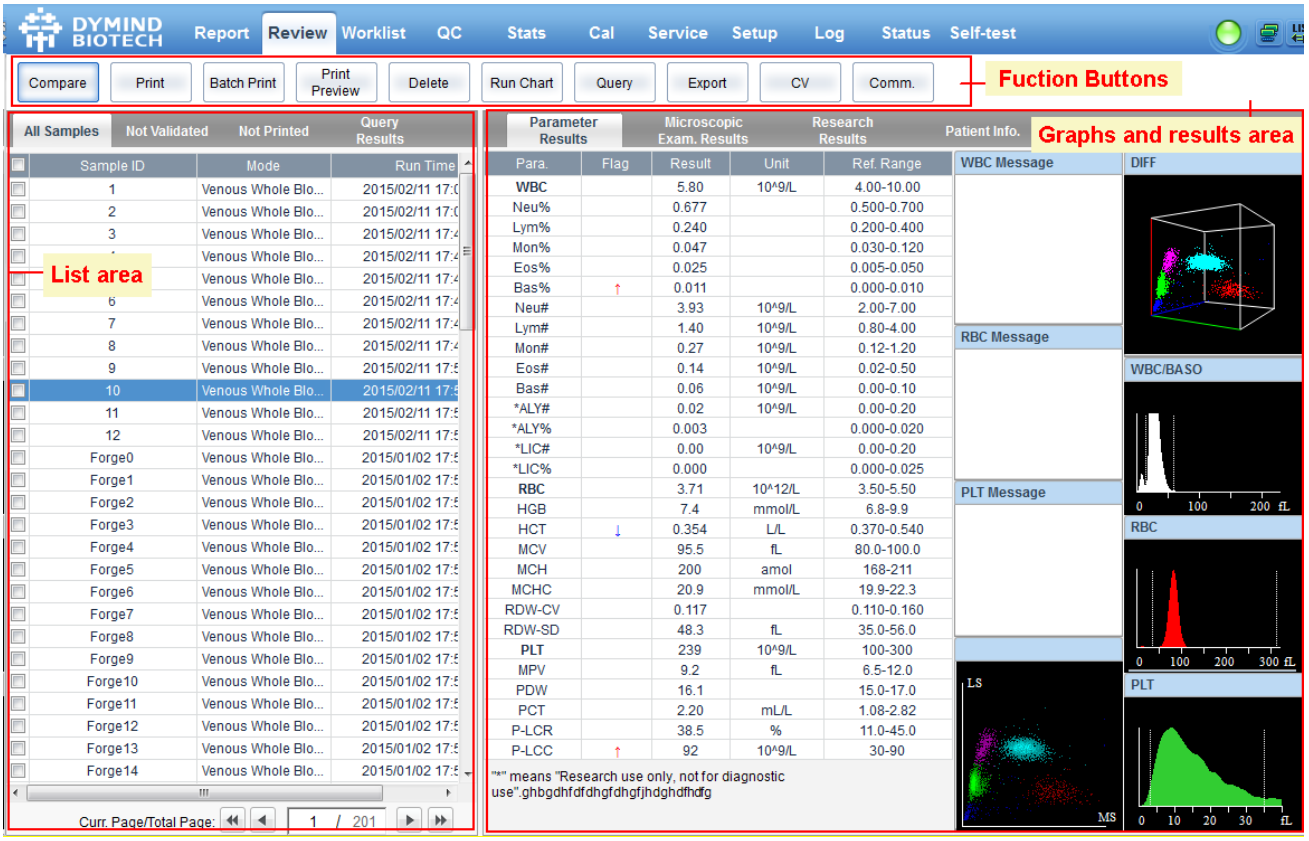
In the **Review** Interface, the user can browse the saved sample information, result data, flag messages, histograms and scattergrams, and can search, compare or export the saved sample information.

9.2 Interface Introduction

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

Click **Review** to access the **Review** Interface. See Figure 9-1.

Figure 9-1 Review



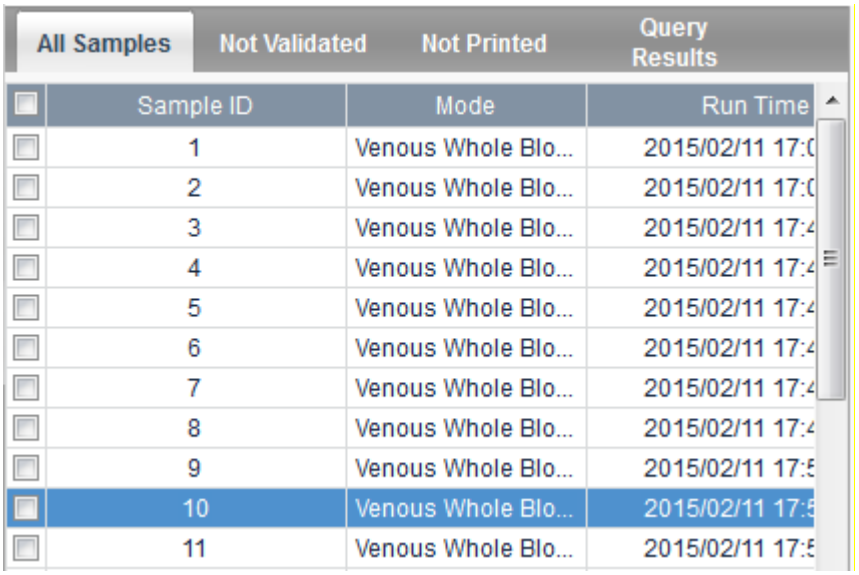
The Review interface can be divided into three areas, namely the List Area, the Graph Area and the Function Buttons Area.

- List area: Sample records and their main sample/patient information can be browsed here.
- Graphs and results area: Test Parameter Results (Main Window), Microscopic Examination Results, RUO Results, Patient Information, etc. can be viewed here.
- 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.

9.3 List Area

The List Area is in the left of Review interface and displays the list of analyzed samples, including the basic information of samples, such as the **Sample ID**, **Mode**, **Run Time**, etc. See Figure 9-2.

Figure 9-2 List Review



Click a sample in the List Area to view the detailed parameter information of this sample in the Graph Area.

NOTE

The List Area displays all the analyzed records by default.

In the Sample Results List Area, the user can switch between the tabs above the list to view the following types of sample lists:

- All Samples

  Display all the sample records saved in the Sample Pool.
- Not Validated

  Display non-validated sample records in the Sample Pool.
- Not Printed

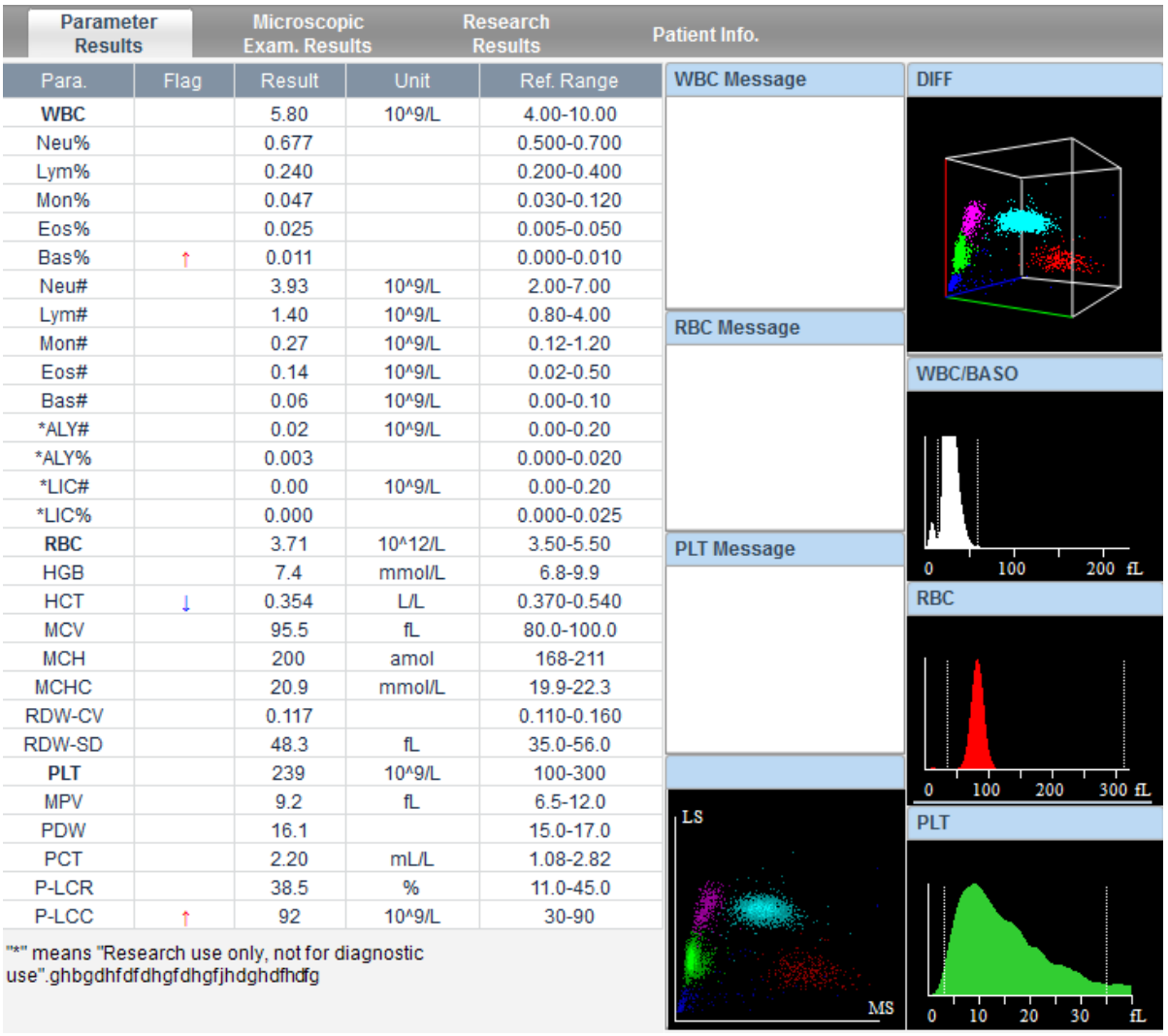
  Display non-printed sample records in the Sample Pool.
- Query Results

  Display all the sample records that satisfy the query conditions.

9.4 Graphs and Results

The user can switch between the tabs on top of the Graphs and Results area to view the main window, microscopic examination information, RUO information and patient information.

Figure 9-3 Graphs Review

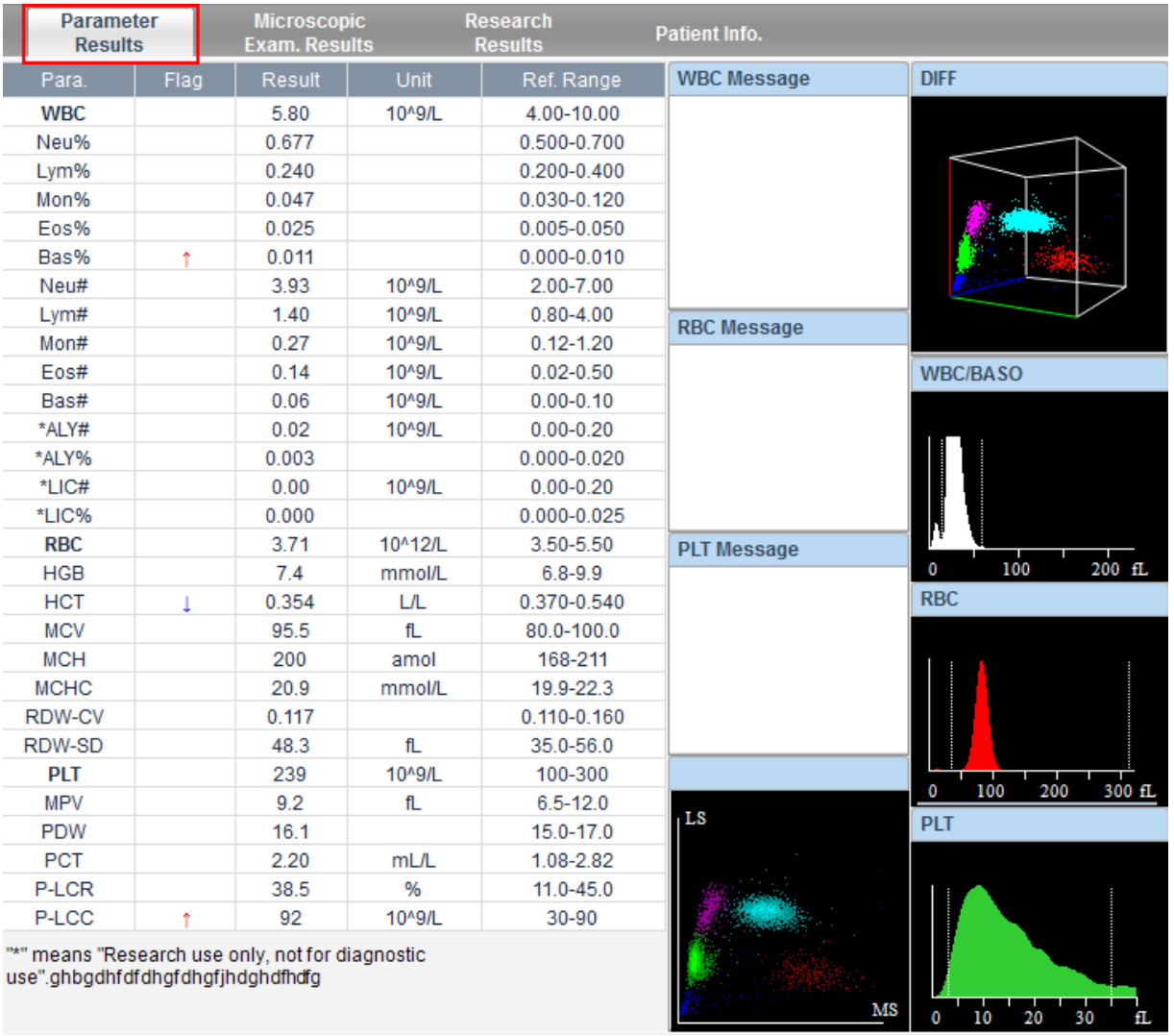


Double-clicking the scattergram or histogram will launch an enlarged view. Click  to exit.

9.4.1 Parameter Results

The main window displays by default all the report parameter results, RUO parameter results, flags, one 3D scattergram (DIFF), three histograms (including WBC/BASO, RBC and PLT) and three 2D scattergrams (DIFF).

Figure 9-4 Parameter Results



NOTE

The user can set whether or not to display the four RUO parameters, “*” mark and declaration ("*" means "Research use only, not for diagnostic use".) in the Setting interface. For details, see ***Chapter 5 Setup***.

- Parameter Results

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

  The user 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.
- DIFF

  WBC 3D scattergram (DIFF) in the CBB+DIF mode.
- WBC/BASO

  WBC distribution histogram in CBC mode. BASO distribution histogram in CBC+DIFF mode.
- RBC

  RBC distribution histogram
- PLT

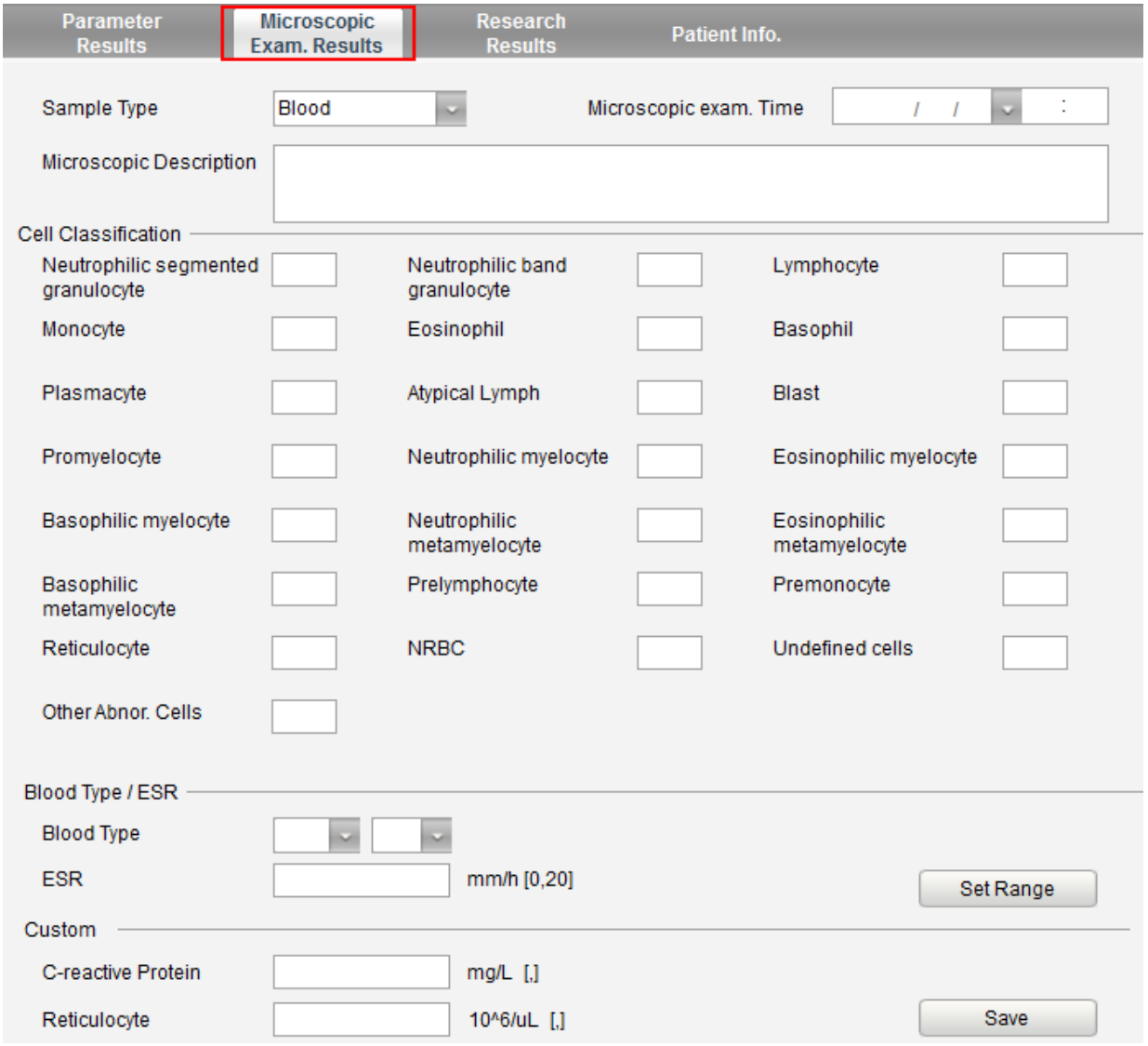
  Platelet distribution histogram.
- HS/MS/LS

  Three 2D scattergrams for WBC (DIFF) in CBB+DIFF mode, namely HS/MS, MS/LS and HS/LS.

9.4.2 Microscopic Exam. Results

After selecting a sample in the sample list area, the user can enter the microscopic exam. results including the microscopic exam. date and time, description and cell classification under the **Microscopic Exam.** tab. See Figure 9-5.

Figure 9-5 Microscopic Exam.



Refer to Table 9-1 for parameter description and operation methods regarding the microscopic examination.

Table 9-1 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. The default sample type is **Venous Blood.**

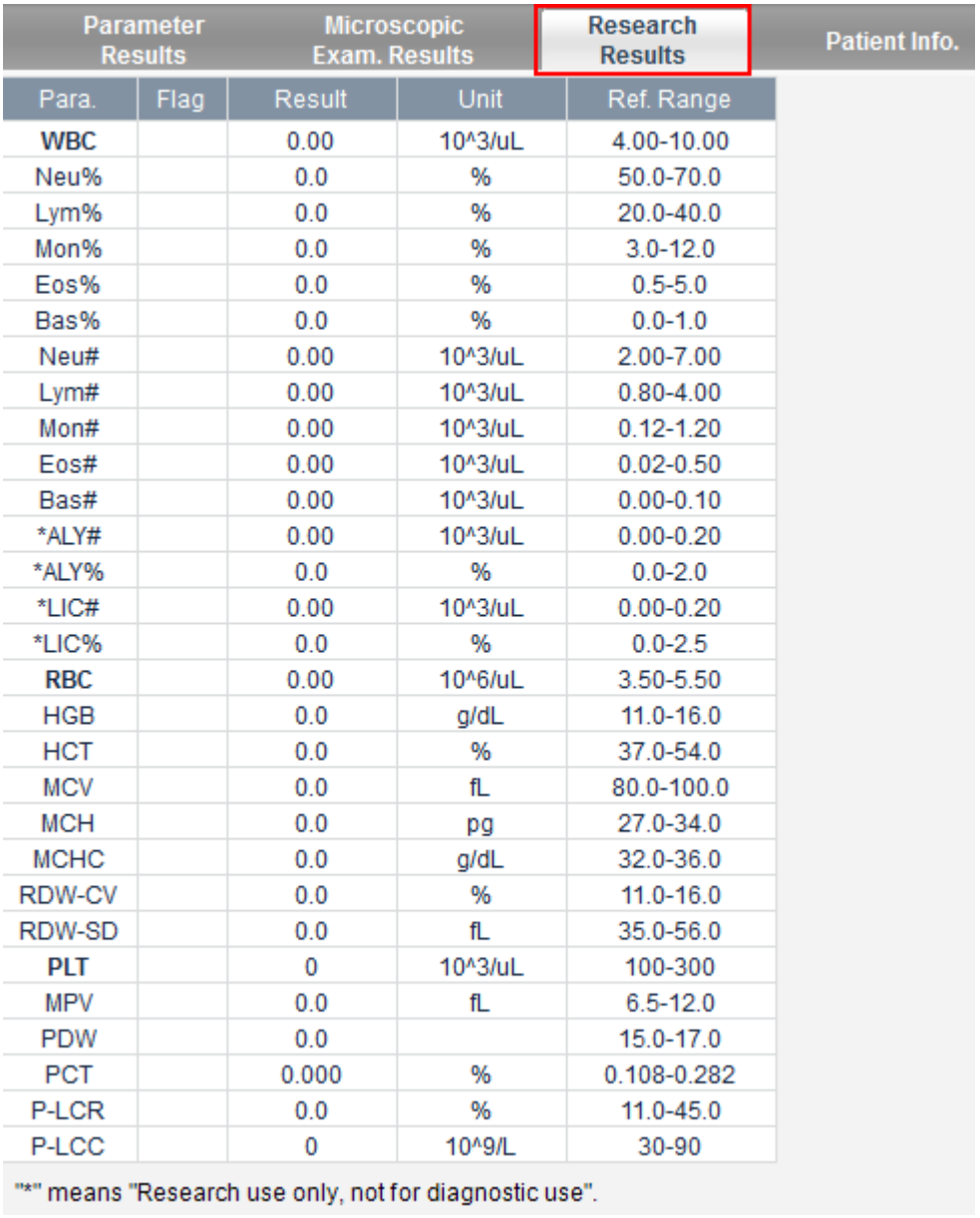
Parameter	Meaning	Operation
Microscopic exam. Time	Time of microscopic examination	Click the **Microscopic exam. Time** combo box and select the time and date for the microscopic examination. **NOTE** The Microscopic exam. time can be no later than the current system time.
Microscopic Description	Description of WBC, RBC and PLT morphology.	Enter the morphology information for WBC, RBC and PLT respectively into the multi-line textbox.
Cell Differential	Percentage of each cell classification in total cell count	Enter the percentage or other form of differential result of each cell classification into the textbox next to the cell classification name respectively. You can enter a value within the range [0.0-100.0] and the unit is **%**.
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-**.
ESR	Erythrocyte sedimentation rate (ESR) measurement. If the measurement value is out of the reference range, the system will show a "↑" mark to indicate it's beyond the higher limit and a "↓" mark to indicate it's below the lower limit.	1. Click **Set Range**. 2. Enter the lower limit and upper limit of ESR, C-reactive Protein and Reticulocyte in **Lower Limit** and **Upper Limit** textboxes respectively. 3. Click **OK** to save all the settings and refresh the information.
Custom	Percentage of the C-reactive protein and the reticulocyte in total cell count	Enter their percentages in total cell count in the textboxes next to the C-reactive protein and the reticulocyte respectively.

9.4.3 Research Results

After selecting a sample from the sample list area, the user can browse the detailed results of each parameter under the **Research Results** tab.

Clicking the **Research Results** tab in the **Review** interface to access the **Research Results** interface as shown in Figure 9-6.

Figure 9-6 Research



Parameter Results | Microscopic Exam. Results | Research Results | Patient Info.

Para.	Flag	Result	Unit	Ref. Range
WBC		0.00	10^3/uL	4.00-10.00
Neu%		0.0	%	50.0-70.0
Lym%		0.0	%	20.0-40.0
Mon%		0.0	%	3.0-12.0
Eos%		0.0	%	0.5-5.0
Bas%		0.0	%	0.0-1.0
Neu#		0.00	10^3/uL	2.00-7.00
Lym#		0.00	10^3/uL	0.80-4.00
Mon#		0.00	10^3/uL	0.12-1.20
Eos#		0.00	10^3/uL	0.02-0.50
Bas#		0.00	10^3/uL	0.00-0.10
*ALY#		0.00	10^3/uL	0.00-0.20
*ALY%		0.0	%	0.0-2.0
*LIC#		0.00	10^3/uL	0.00-0.20
*LIC%		0.0	%	0.0-2.5
RBC		0.00	10^6/uL	3.50-5.50
HGB		0.0	g/dL	11.0-16.0
HCT		0.0	%	37.0-54.0
MCV		0.0	fL	80.0-100.0
MCH		0.0	pg	27.0-34.0
MCHC		0.0	g/dL	32.0-36.0
RDW-CV		0.0	%	11.0-16.0
RDW-SD		0.0	fL	35.0-56.0
PLT		0	10^3/uL	100-300
MPV		0.0	fL	6.5-12.0
PDW		0.0		15.0-17.0
PCT		0.000	%	0.108-0.282
P-LCR		0.0	%	11.0-45.0
P-LCC		0	10^9/L	30-90

"*" means "Research use only, not for diagnostic use".

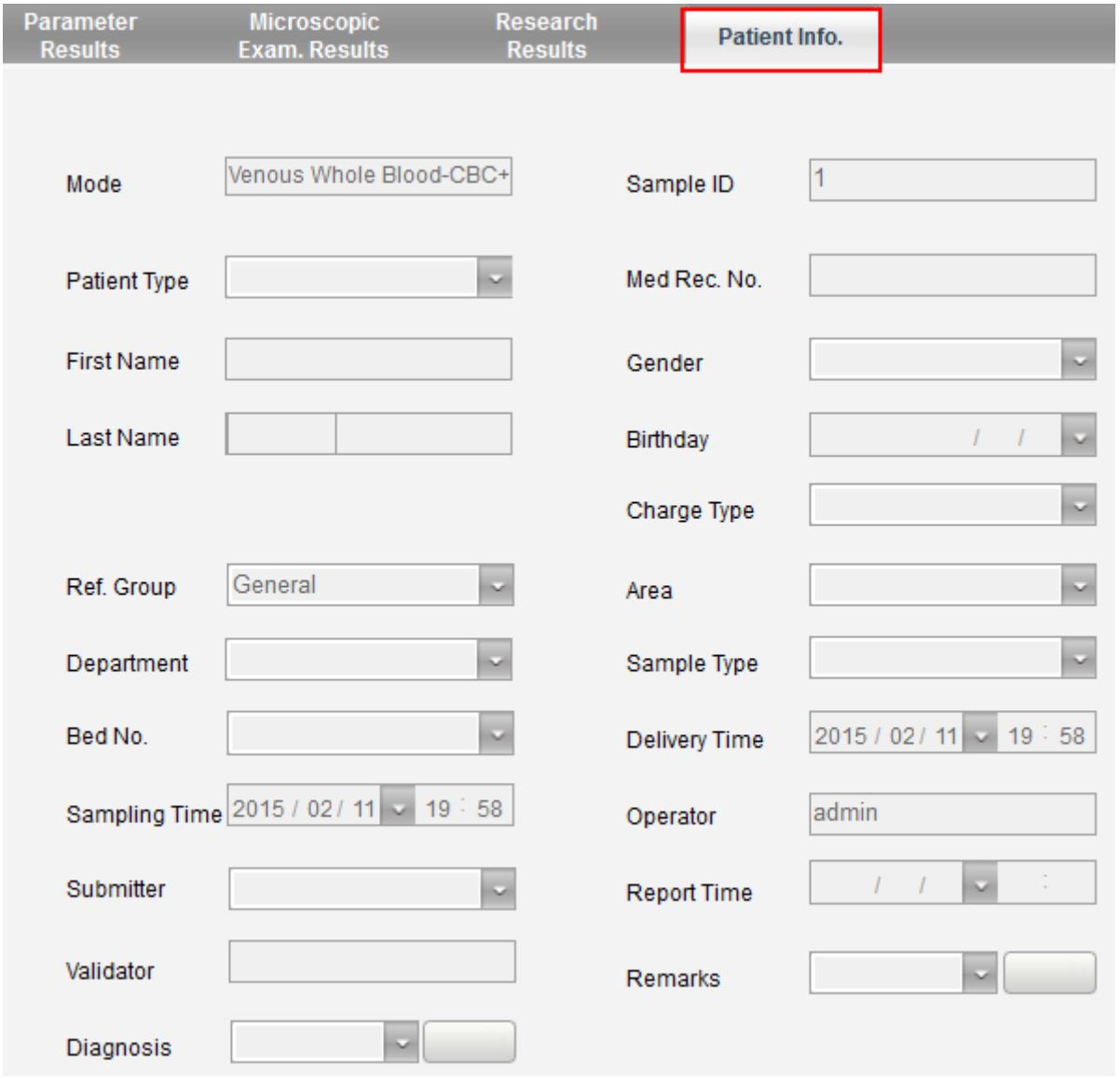
NOTE

- The specific values of the parameter results that are beyond the display range or without data collected cannot be provided.
- The editing of the parameter results will not affect the display of parameters in the **Research** tab.
- The content under this tab can only be viewed and used for research; it cannot be edited or printed.

9.4.4 Patient Info.

Click the **Patient Info.** tab in the **Review** interface and view the sample information and patient information corresponding to the currently selected records in the sample list. See Figure 9-7.

Figure 9-7 Patient Info.



NOTE

The content under this tab can only be viewed and used for research; it cannot be edited or printed.

You can refer to ***8.4 Parameter Description*** for parameter description of the patient information.

9.5 Functions of the Buttons

9.5.1 Compare

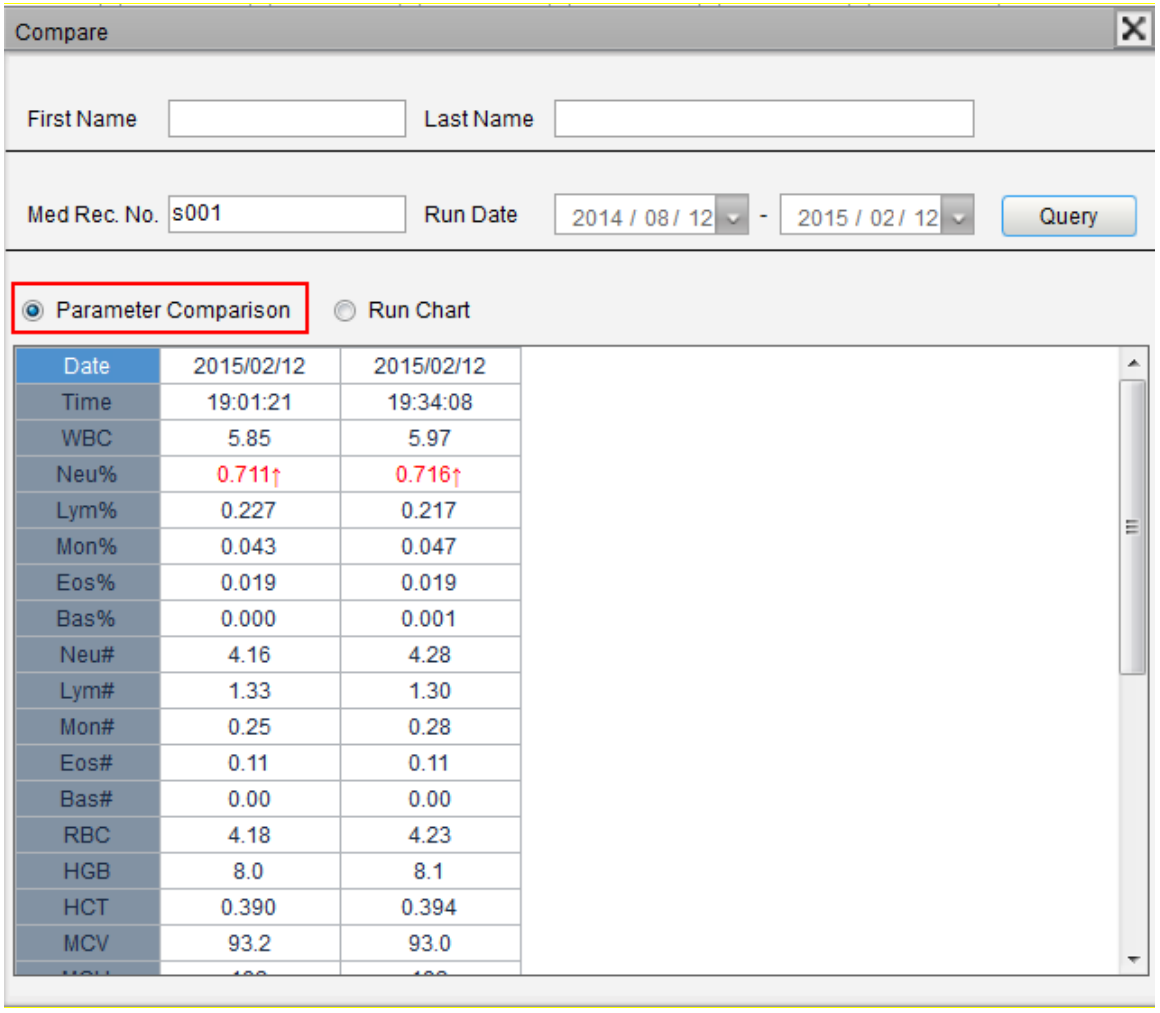
The user can compare the test results of several samples taken from the same patient.

- Parameter Comparison

  Click **Compare**, enter the **First Name**, **Last Name**, **Med Rec. No.**, **Run Date** and other information of the patient, and click **Query**.

  The system will launch the Parameter Result Comparison interface as shown in Figure 9-8.

Figure 9-8 Parameter Result Comparison

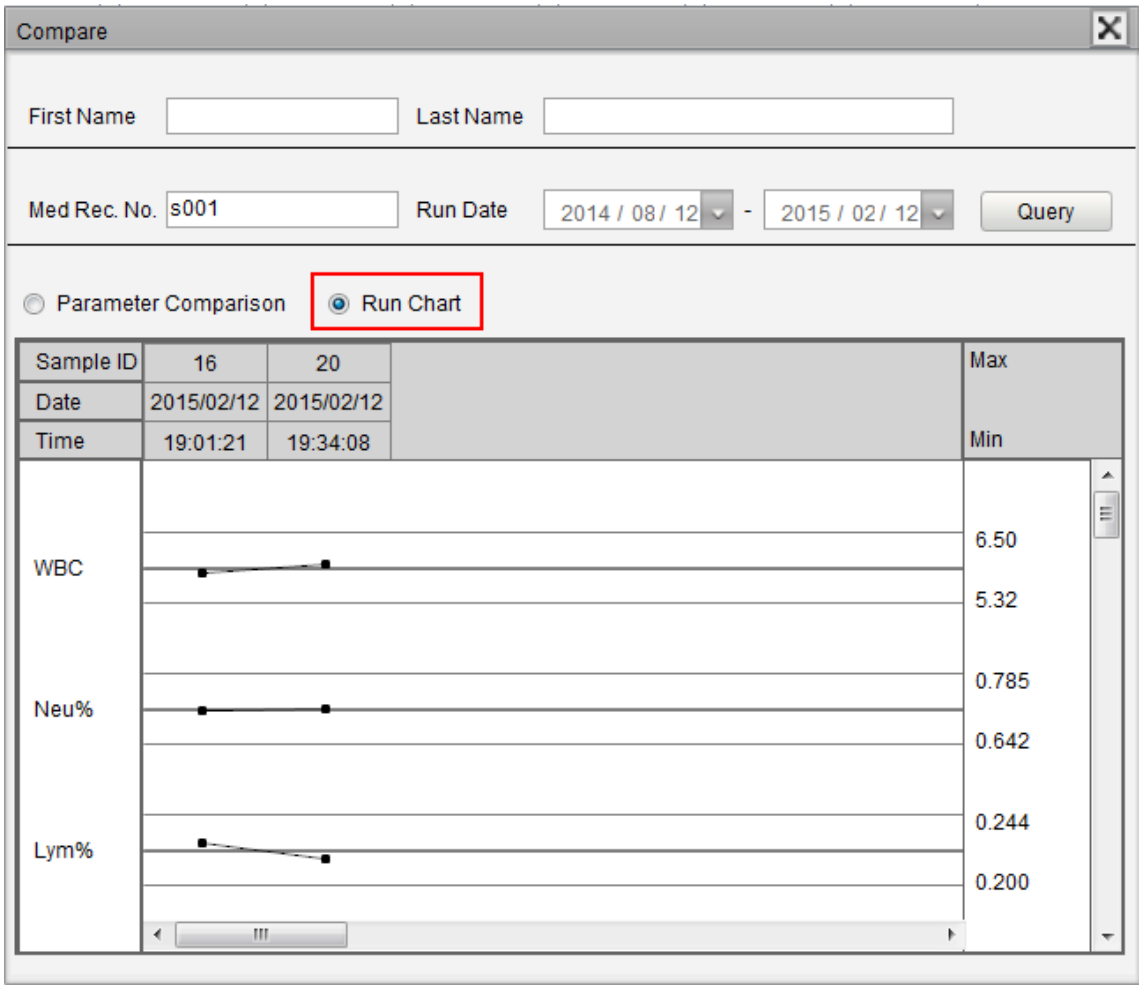


Date	2015/02/12	2015/02/12
Time	19:01:21	19:34:08
WBC	5.85	5.97
Neu%	0.711↑	0.716↑
Lym%	0.227	0.217
Mon%	0.043	0.047
Eos%	0.019	0.019
Bas%	0.000	0.001
Neu#	4.16	4.28
Lym#	1.33	1.30
Mon#	0.25	0.28
Eos#	0.11	0.11
Bas#	0.00	0.00
RBC	4.18	4.23
HGB	8.0	8.1
HCT	0.390	0.394
MCV	93.2	93.0

- Run Chart

  Click **Run Chart** in the **Compare** interface to view the Run Chart for several test results of an eligible patient. See Figure 9-9.

Figure 9-9 Run Chart



9.5.2 Print Preview

Before printing the comparison result, the operator can preview the printing effect by clicking **Print Preview**, and then clicking  for printing after confirmation.

9.5.3 Print

In the sample list, the user can click the **Print** button to print the test report of selected samples.

1. Check the samples to be printed in the list.

   If several samples are to be printed in a row, the user can use the **Batch Print** function to print samples within the specified ID range. See ***9.5.4 Batch Print*** for the detailed operations.

2. Click **Print**.

NOTE

The user can view the non-printed samples in the **Not Printed** tab.

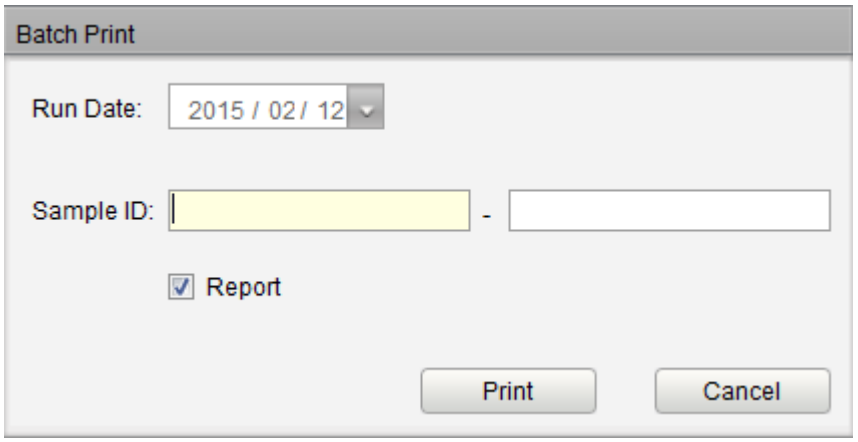
9.5.4 Batch Print

If you want to print a large number of samples within the specified ID range, select the Batch Print and the system will print the test report in sequence.

1. Click **Batch Print**.

   The interface pops up a dialog box as shown below.

Figure 9-10 Batch Print



2. Select the Sample Date, e.g. **2015/02/12**.
3. Enter the Sample ID range to be printed.

   If **1137** is entered in the first textbox and **1140** is entered in the second textbox, the system will print the test report of samples numbered from 1137 to 1140 in sequence.
4. Click **Print**.

   The system will perform the Batch Print for all selected records.

NOTE

The user can view the non-printed samples in the **Not Printed** tab.

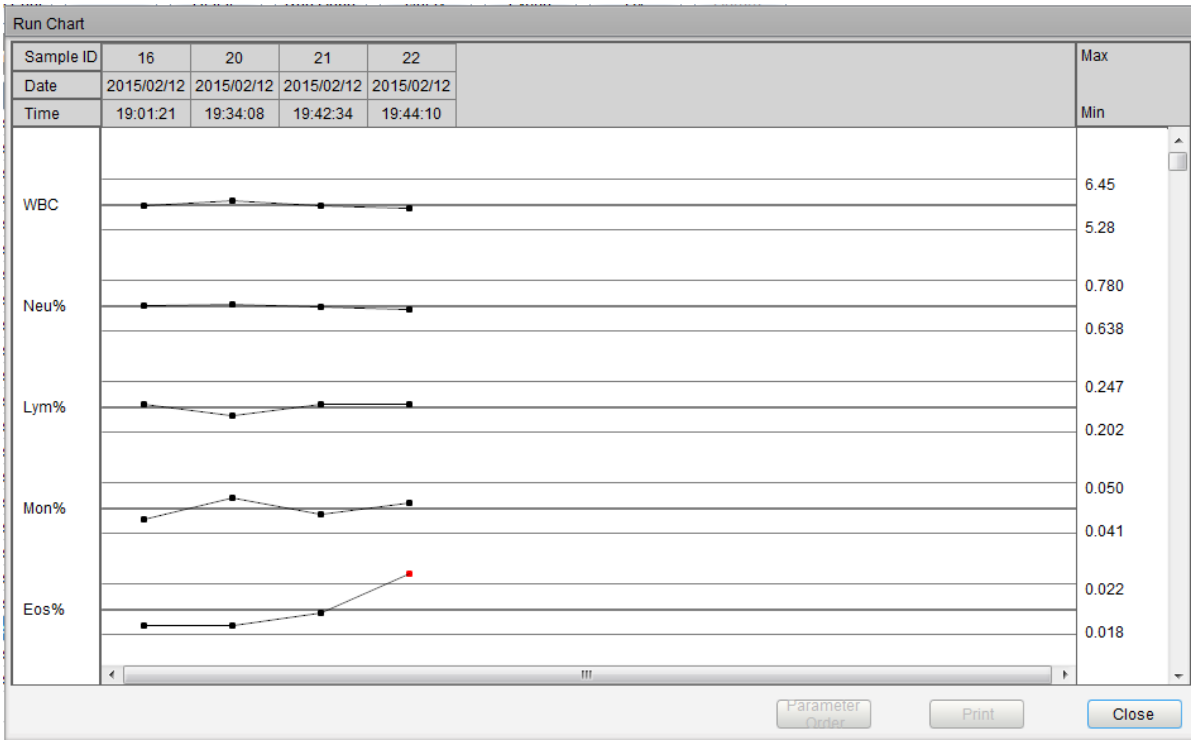
9.5.5 Run Chart

The operator can view the Parameter Result Run Chart of all samples in the Review Database. The operation procedures are shown below:

1. Check no fewer than three sample records.
2. Click **Run Chart**.

   The system pops up a dialog box as shown below to display the parameter result Run Chart of selected samples.

Figure 9-11 Run Chart



3. Click **Close** to exit.

NOTE

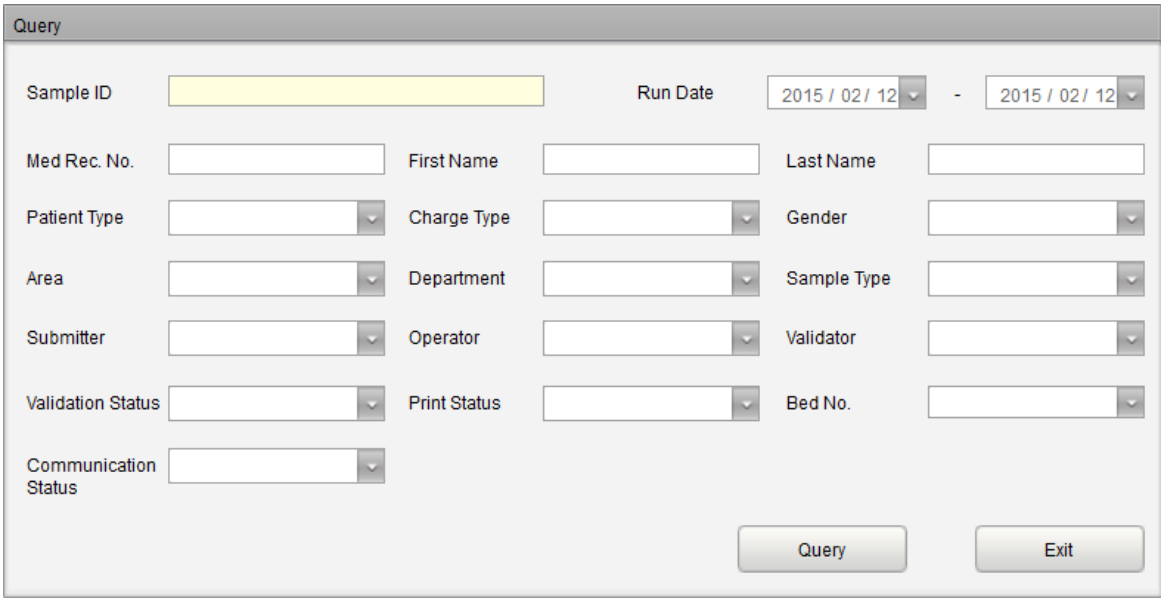
- The upper limit of number of selected records is the number of all the records in the review list.
- There is no restriction when selecting the sample records as long as they are in the review list.

9.5.6 Query

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

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

Figure 9-12 Query Conditions



2. Determine the query conditions as needed.

   For the specific parameter description, see Table 9-2.

Table 9-2 Parameter Description of Query Conditions

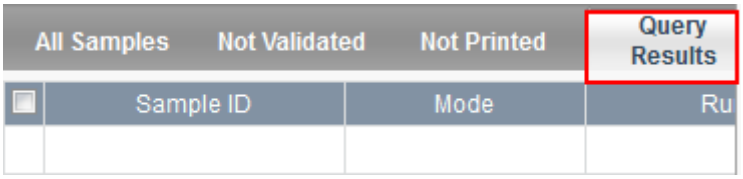
Parameter	Meaning	Operation Description
Sample ID	Sample ID to be queried.	Enter into the textbox directly.
Med Rec. No.	Med Rec. No. of patient.	Enter into the textbox directly.
First Name	First name of patient.	Enter into the textbox directly.
Run Time	Test date range of sample.	Select the starting and ending dates of the sample test in the two data controls successively.
Gender	Gender of patient. Including: • Not defined • Male • Female	Select from the dropdown list.
Patient Type	Type of patient. Including: • Inpatient • Physical Examination • STAT • Outpatient	Select from the dropdown list.

Parameter	Meaning	Operation Description
Charge Type	Charge type of an item. Including: • Public expense • Military expense • Medicare • Self-pay	Select from the dropdown list.
Sample Type	Type of analyzed sample. • Venous blood • Capillary • Cord blood • Blood	Select from the dropdown list.
Area	Ward area of patient.	Select from the dropdown list or entered directly.
Department	Department receiving the patient.	Select from the dropdown list or entered directly.
Bed No.	Bed No. of inpatient.	Enter into the textbox directly. **NOTE** The **Bed No.** is required to be filled only when the **Patient Type** is **Inpatient**.
Submitter	Personnel submitting the sample.	Select from the dropdown list or enter directly.
Operator	Personnel testing the sample.	Select from the dropdown list or enter directly.
Validator	Personnel validating the sample.	Select from the dropdown list or entered directly.
Validation Status	Validation status of sample. Including: • Validated • Not Validated	Select from the dropdown list.
Print Status	Print status of sample. • Printed • Not Printed	Select from the dropdown list.
Communication Status	Communication status of sample. • Transmitted • Not Transmitted	Select from the dropdown list.

3. Click **Query**.

   The system performs the query operation as per the query conditions, automatically switches to the **Query Results** list, and displays all query records. See Figure 9-13.

Figure 9-13 Query Results



9.5.7 Export

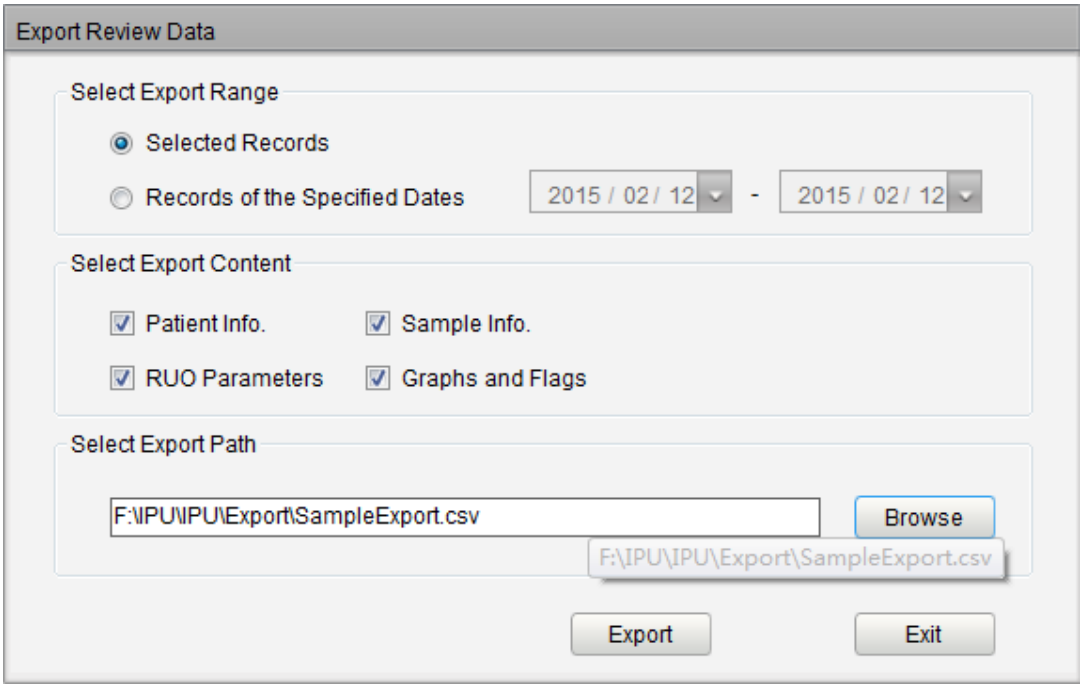
The operator can export the sample data to the peripheral computer for backup. There are two ways of exporting the sample data: exporting selected records and exporting records of specified dates.

- Export selected records in the list

1. Check records to be backed up in the Review List Area, and click **Export.**.

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

Figure 9-14 Export Selected Records



2. Select the Export Content according to the actual demand.

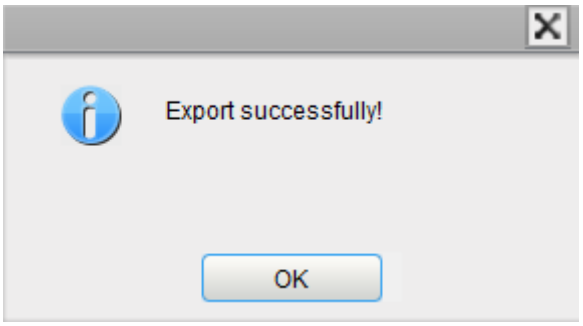
   Content available for export includes: Patient Info., Sample Info., RUO Parameters, Graphs and Flags.

3. Click **Browse**.
4. Select the data Export Path in the popup dialog box, enter the backup file name, and click **Save**.

   Files are exported to the system installation path and are named as **SampleExport.csv** by default.

5. Click **Export**.

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

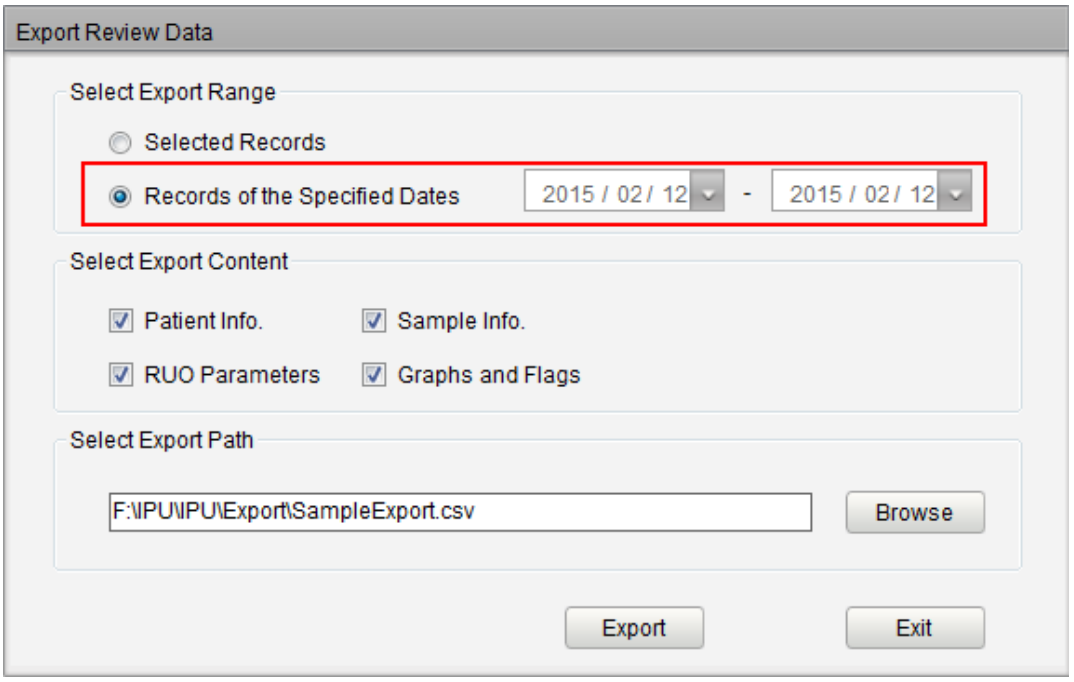


- Export record of the specified test dates

1. Click **Export**.

   The system pops up a dialog box as shown below.

Figure 9-15 Export Records of the Specified Dates



2. Select **Records of the Specified Dates** in the Export Range and set the test date range of sample in the two date textboxes.

   For example, 

.

3. Select the export content according to the actual demand.

   Content available for export includes: Patient Info., Sample Info., RUO Parameters, Graphs and Flags.

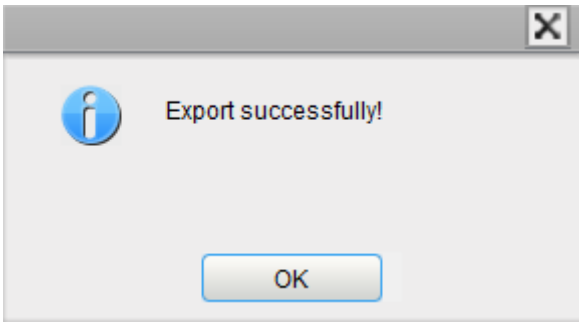
4. Click **Browse**.

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

   Files are exported to the system installation path and are named as **SampleExport.csv** by default.

6. Click **Export**.

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



9.5.8 CV

You can check the repeatability of the selected sample record. Specific steps are shown below:

1. Select the sample record used for calculating the repeatability.

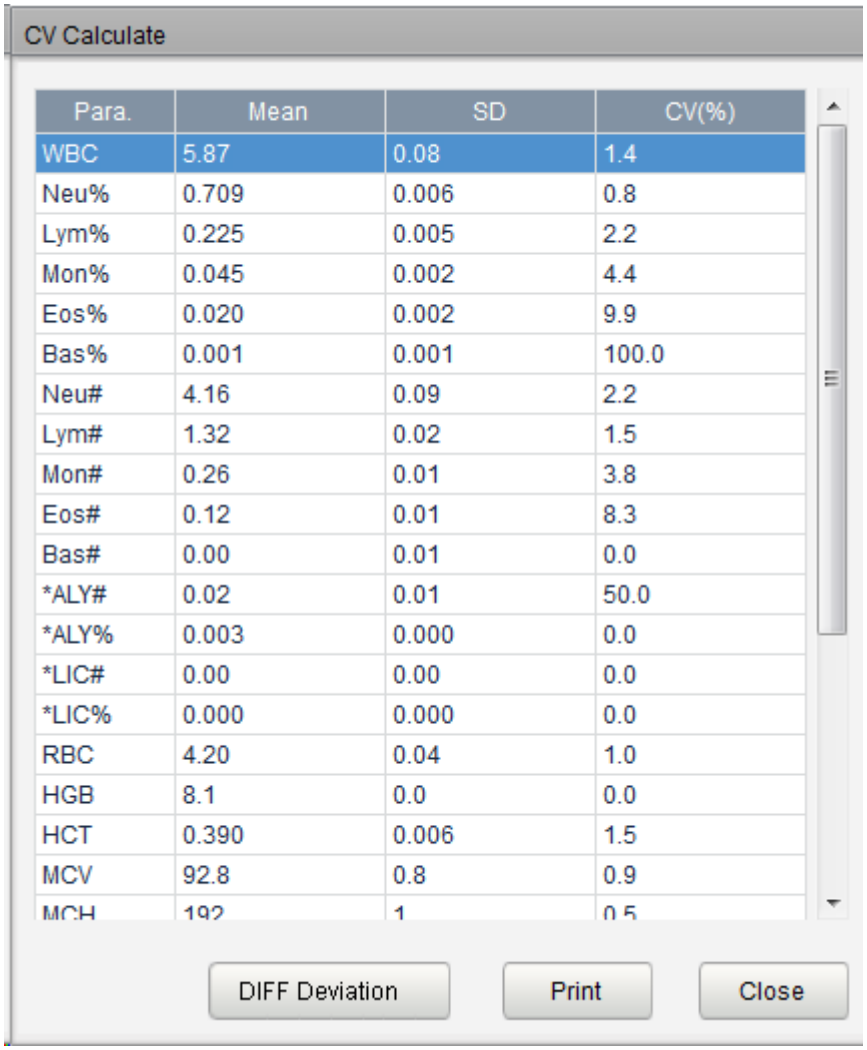
NOTE

- At least 3 records should be selected to calculate the repeatability.
- There is no restriction to the sample records selected to calculate the repeatability as long as they are in the review list.
- If the selected sample records contain records in CBC Mode, only the repeatability of CBC parameters will be calculated and the repeatability of WBC DIFF parameters and the DIFF absolute deviation will not be calculated.

2. Click **CV** to start calculating the repeatability.

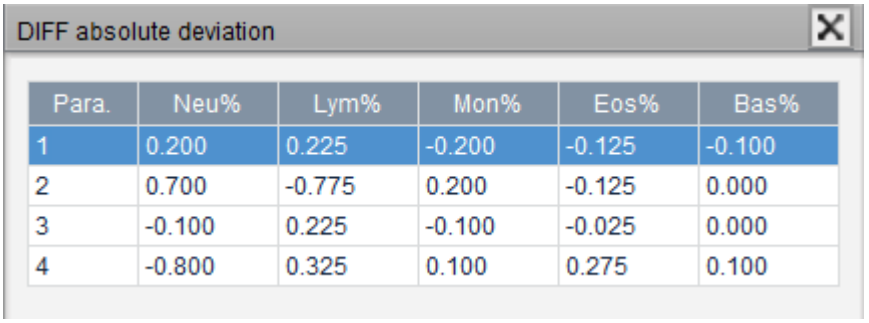
   The result message box as shown in Figure 9-16 will pop up.

Figure 9-16 Calculation Results



3. Click **DIFF Deviation**.

   You can check the absolute deviation of the 5 WBC-related parameters of percent-style.



4. After browsing, click  to return to the CV Calculation Results dialog box.
5. Click **Print** to print the CV Calculation Results, or Click **Close** to exit.

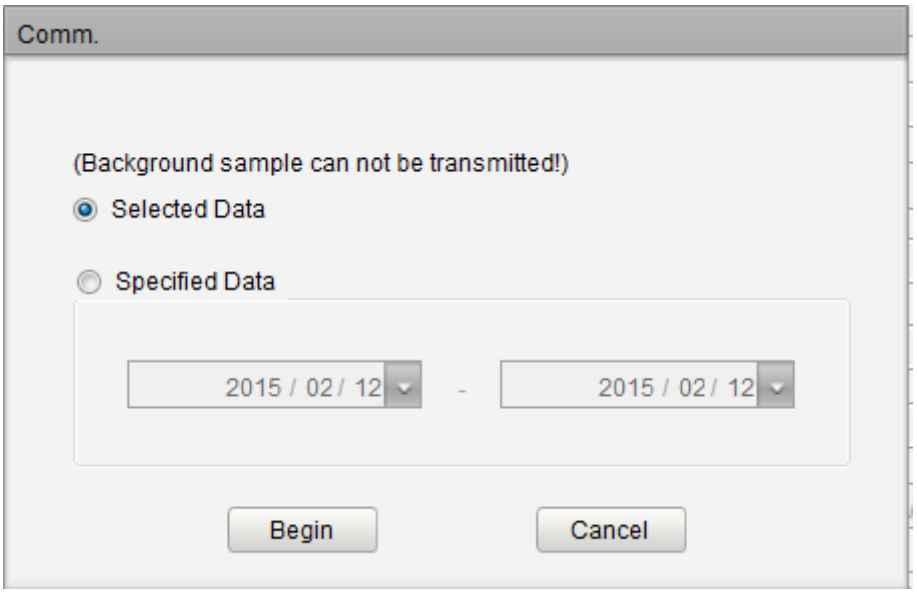
9.5.9 Comm.

The user can transmit the selected or specified sample data (except the background sample) to the LIS/HIS system.

- Communication for selected data
  1. Select one or several sample data to be communicated in the result list.
  2. Click **Comm.**.

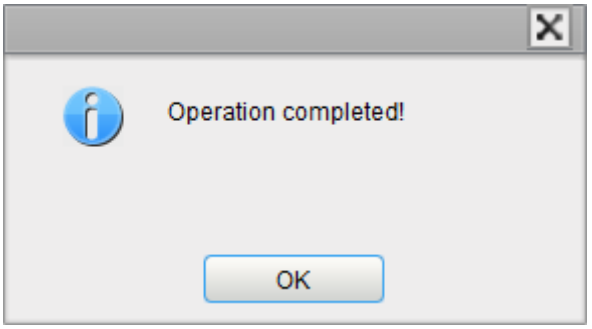
     The interface pops up a dialog box as shown in Figure 9-17.

Figure 9-17 Communication for Selected Data



  3. Select **Selected Data**.
  4. Click **Begin** to start transmitting.

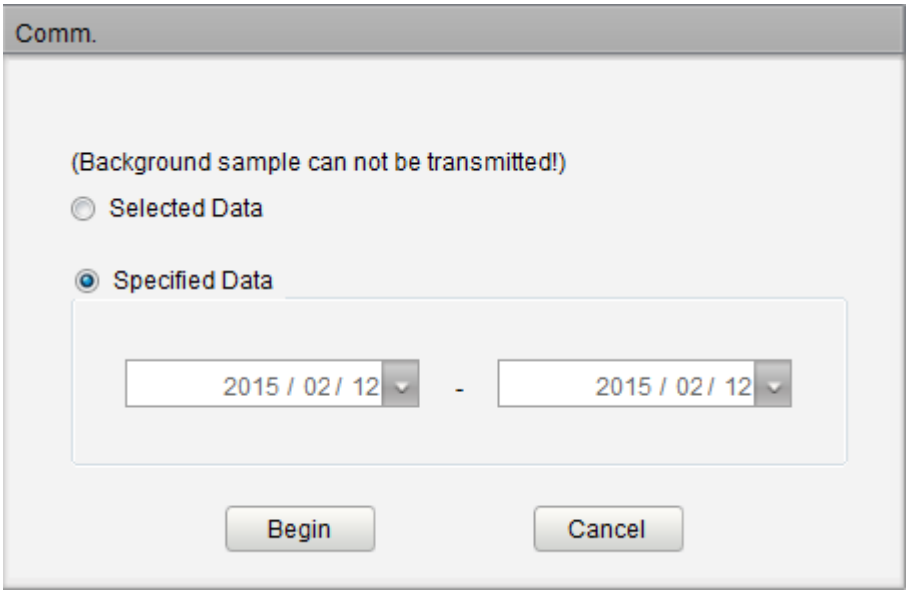
     After the data are transmitted to LIS/HIS, the interface will pop up a dialog box as shown below.



- Communication for the data within specified date range
  1. Click **Comm.**.
  2. Select **Specified Data**, and set the starting and ending dates of data to be communicated.

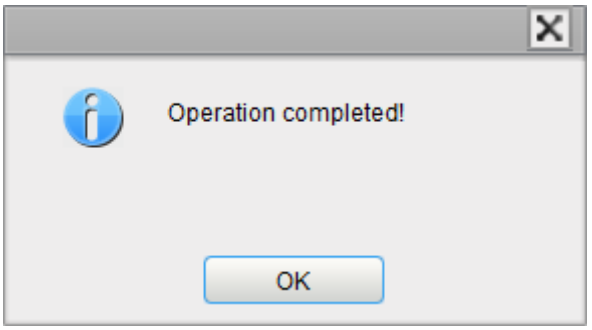
     See Figure 9-18.

Figure 9-18 Communication for data on specified dates



3. Click **Begin** to start transmitting.

   After the data are transmitted to LIS/HIS, the interface will pop up a dialog box as shown below.



NOTE

After the communication starts, the interface will show the comm. progress and the **Stop** button. If you click the **Stop** button, the transmission will be stopped after the current sample record is transmitted.

9.5.10 Delete

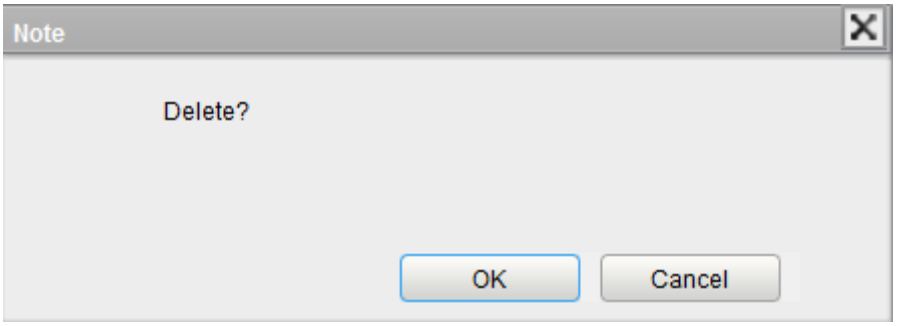
NOTE

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

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

   The interface pops up a dialog box as shown below.

Figure 9-19 Delete Sample Records



3. Click **OK** to delete the selected records in the list.

10 Quality Control

10.1 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. Dymind 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 Dymind-specified controls and reagents. Store and use the controls and reagents as instructed by 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.

10.2 L-J Quality Control

10.2.1 QC Principle

In the L-J quality control, quality control can be applied to 25 parameters. Considering operators' different needs, the system allows operators to apply quality control to a few parameters. The analyzer provides 60 QC files for storing the QC parameters and results. Each QC file can be assigned1 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.

10.2.2 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 them and the relevant 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 any of the following means in the QC files.

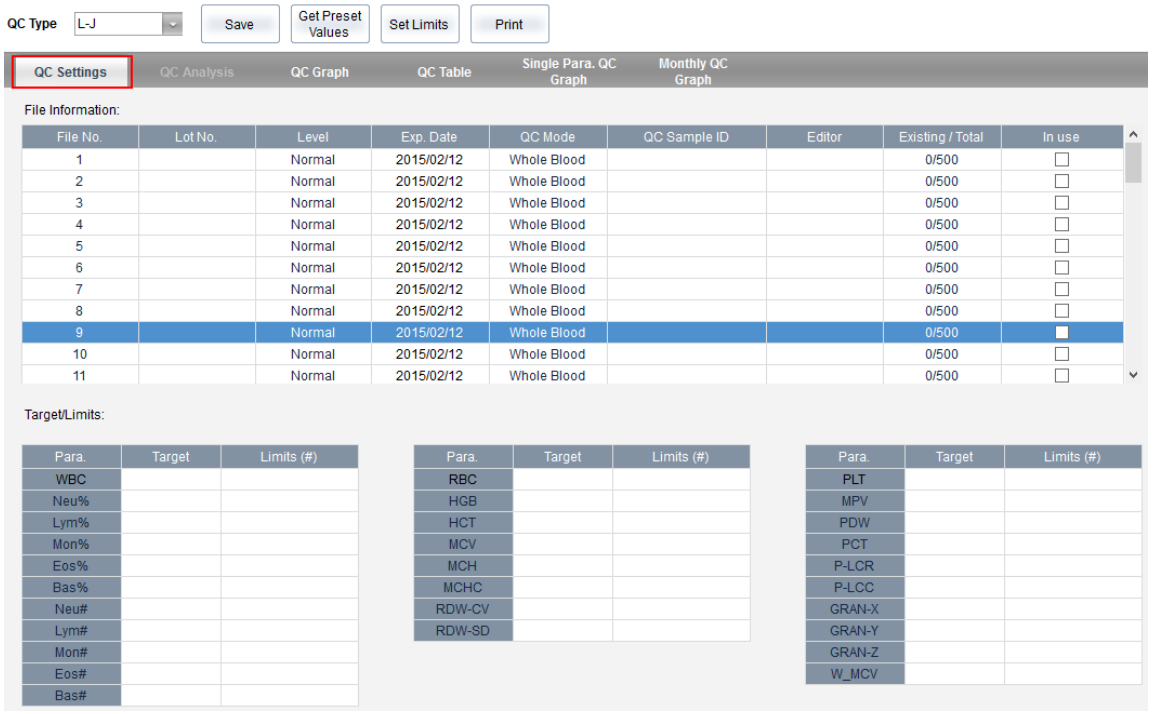
- Manual entry
- Reading the saved preset values

10.2.2.1 Manual entry

1. Click **QC** > **QC Settings** to enter the QC Settings interface.

   See Figure 10-1.

Figure 10-1 L-J Quality Control



2. Select a QC File No. with empty QC information (the selection range is 1~60), refer to Table 10-1 for setting the parameters in the QC files, including lot number, level, Exp. date of the controls, QC mode and sample ID.

NOTE

Different QC files can not have the same lot No. or QC mode.

Table 10-1 QC File Information

Parameter	Parameter Description	Operation description
File No.	QC file No.. The system provides 60 QC files in total for users to set the parameters.	Read only.
Lot No.	Lot number of controls.	Manual entry. **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.
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	It can be empty. But you are not allowed to enter any sample ID other than the finished ones. **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.
Editor	The one who is setting the QC files, namely the user who is currently logged in the system.	Read only.
Existing/Total	The existing data and total QC results in the current QC file. Up to 500 QC results can be saved for each QC file.	Read only.

Parameter	Parameter Description	Operation description
In-use	Set if you want to specify the QC sample ID in the selected file so that you can run the QC sample in the interface other than the QC interface. If it's checked, you can run the sample with the corresponding sample ID in any interface and the system will run the QC analysis for this sample. If it's not checked, you can only run the QC sample in the QC interface.	It is not checked by default. Select according to the actual situation.

3. 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.
4. Click the **Save** button to save all the settings of the QC.

10.2.2.2 Reading the Saved Preset Values

If the current level of preset values (**Target** and **Limits**) is saved in the system, they can be read into the current QC file.

NOTE

Refer to ***10.2.4 QC Result Review*** *for* calculation and saving methods for the preset values.

1. Click **QC** > **QC Settings** to enter the QC Settings interface.
2. Select a QC File No. with empty QC information (the selection range is 1~60), refer to Table 10-1 for setting the parameters in the QC files, including lot number, level, Exp. date of the controls, QC mode and sample ID.
3. Click the **Get Preset Values** button read the saved preset target and limits (corresponding to the current level) into the current QC file.

NOTE

If some of the expected QC parameters are not provided with preset values, you need to manually enter their reference values and deviation limits. If you do not wish to carry out quality control on some parameters with preset values, you can manually delete their reference values and deviation limits.

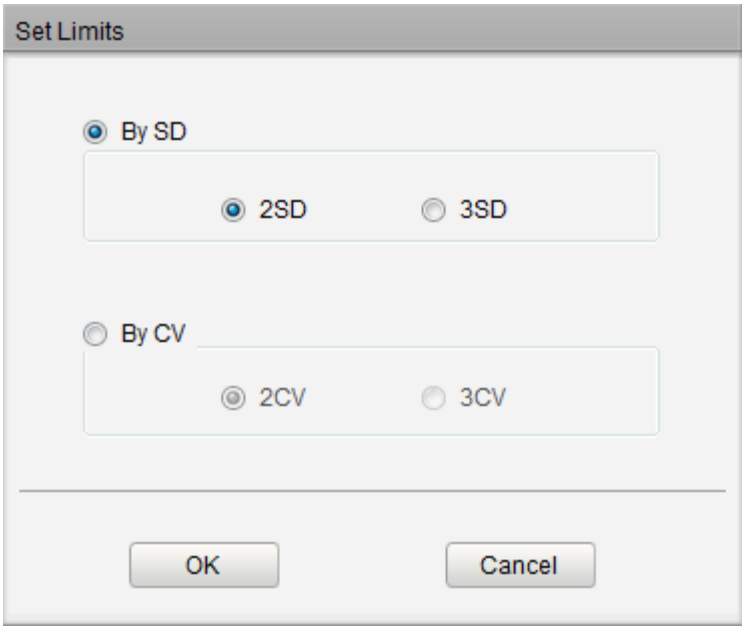
4. Click the **Save** button to save all the settings of the QC.

10.2.2.3 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** > **QC Settings** to enter the QC Settings interface.
2. Click the **Set Limits** button, and then the following message box will pop up.

Figure 10-2 Set Limits



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

10.2.3 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:

- Whole Blood
- Predilute

10.2.3.1 Quality Control Analysis (Whole Blood)

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 them and the relevant 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.
- Be sure to avoid reversing the collection tube when loading, otherwise, the collection tube may be broken and cause 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 your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your 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

- Be sure to use the Dymind-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- Before being used for analysis shake well the controls that have been settled for a while.
- Be sure to use the Dymind-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- When you switch the mode from Predilute to Whole Blood, the system will prompt you with a dialog box for mode switch. To close the prompt, please refer to ***6.3.1 Auxiliary Settings***.

Procedure for quality control analysis in Whole Blood mode is as follows:

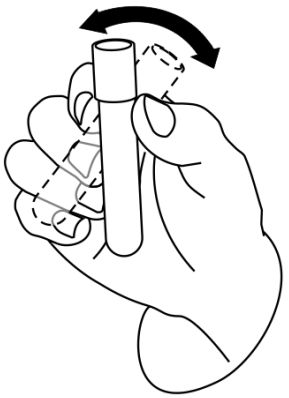
1. Click **QC** > **QC Settings** to access the QC Settings interface.
2. Click **QC Analysis**.
3. Select the QC file No. to be run.

   The screen displays the corresponding file information, as shown in Figure 10-3.

Figure 10-3 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 control as instructed by the instructions for use of the controls.
6. Make sure the QC mode is **Whole Blood** and the analysis status icon and analyzer indicator are both green.
7. Shake the prepared control as shown below to mix it well.

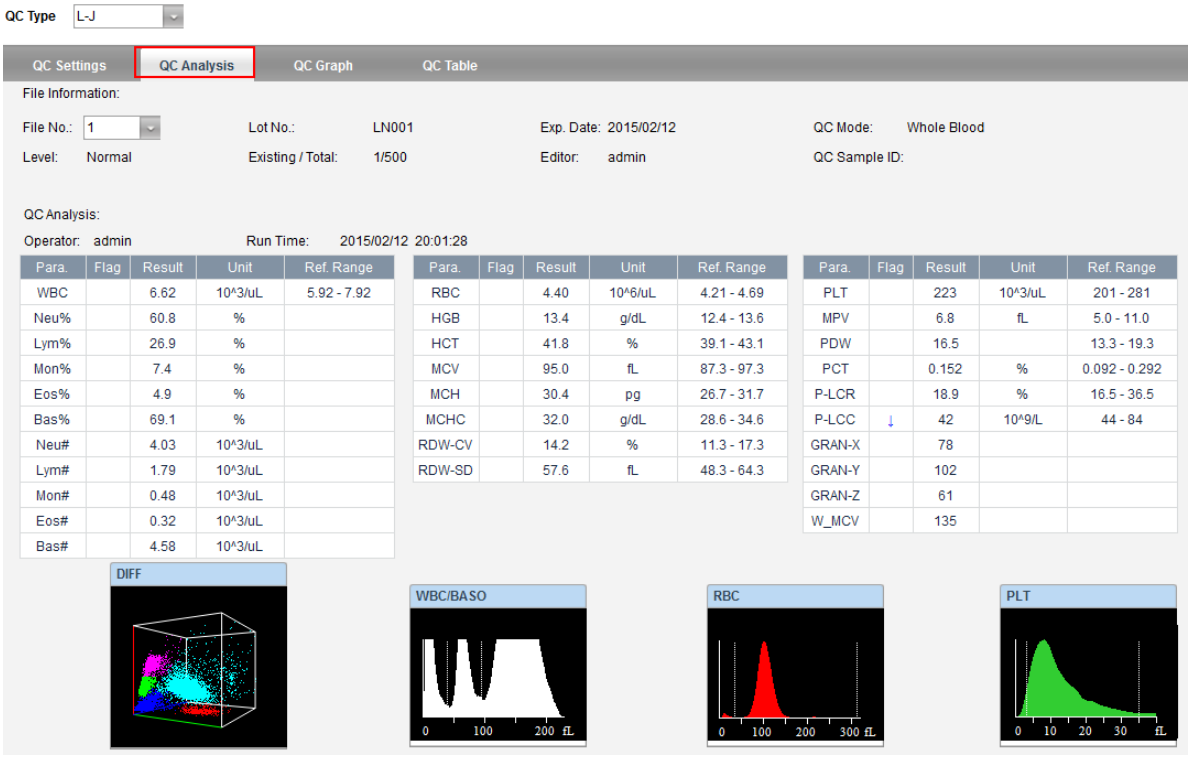
Figure 10-4 Mixing the Controls



8. Place the controls under the sample probe where the probe can aspirate the well mixed sample.
9. Press the aspirate key and start running the controls.
10. 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 10-5) and saved in the QC file automatically.

Figure 10-5 QC Analysis Results



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

10.2.3.2 QC Analysis (Predilute)

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 them and the relevant 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.
- Be sure to avoid reversing the collection tube when loading, otherwise, the collection tube may be broken and cause 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 your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your 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 product as collection tubes, test tubes, capillary tubes, etc.
- Sample clumps may lead to incorrect analysis results. Check if clumps exist before running the controls; if it does, handle it as per the related laboratory procedures.

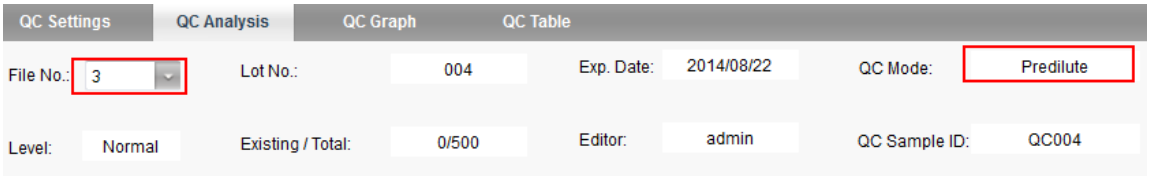
NOTE

- You should only use the Dymind-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.
- Be sure to use the Dymind-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- 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.

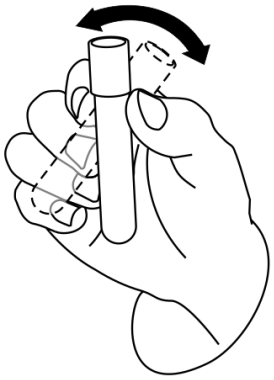
1. Click **QC** > **QC Settings** to access the QC Settings interface.
2. Click **QC Analysis**.
3. Select the QC file No. to be run.

   The screen displays the corresponding file information, as shown in Figure 10-6.

Figure 10-6 QC File Information (Predilute Mode)



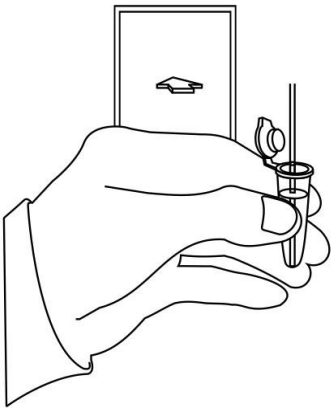
4. Be sure that the level of the control to be run is the same with the current QC file, and the control to be run is not expired.
5. Prepare the control as instructed by instructions for use of the controls.
6. Make sure the QC mode is **Predilute** and the analysis status icon and analyzer indicator are green.
7. Shake the prepared control as shown below to mix it well.



8. Click the **Add Diluent** button in the shortcut button area.

   You'll be prompted with a message shown in the Operation/Status information area.

9. 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.



10. Press the aspirate key and start adding diluent. Upon the completion, you'll hear a beep and you can remove the centrifugal tube.
11. Add 20μL of control to the diluent, seal the tube with the cap and shake the tube to mix the sample.
12. Click **Cancel** to exit dispensing the diluent.
13. Place the centrifugal tube under the aspiration key and press the aspirate key. Upon the completion, you can remove the centrifugal tube.

    When the running of the controls is complete, the QC results will be displayed in the current screen and be saved in the QC file automatically.
14. 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.

10.2.4 QC Result Review

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

- Graph
- Table

10.2.4.1 QC 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 them and the relevant areas in the laboratory.

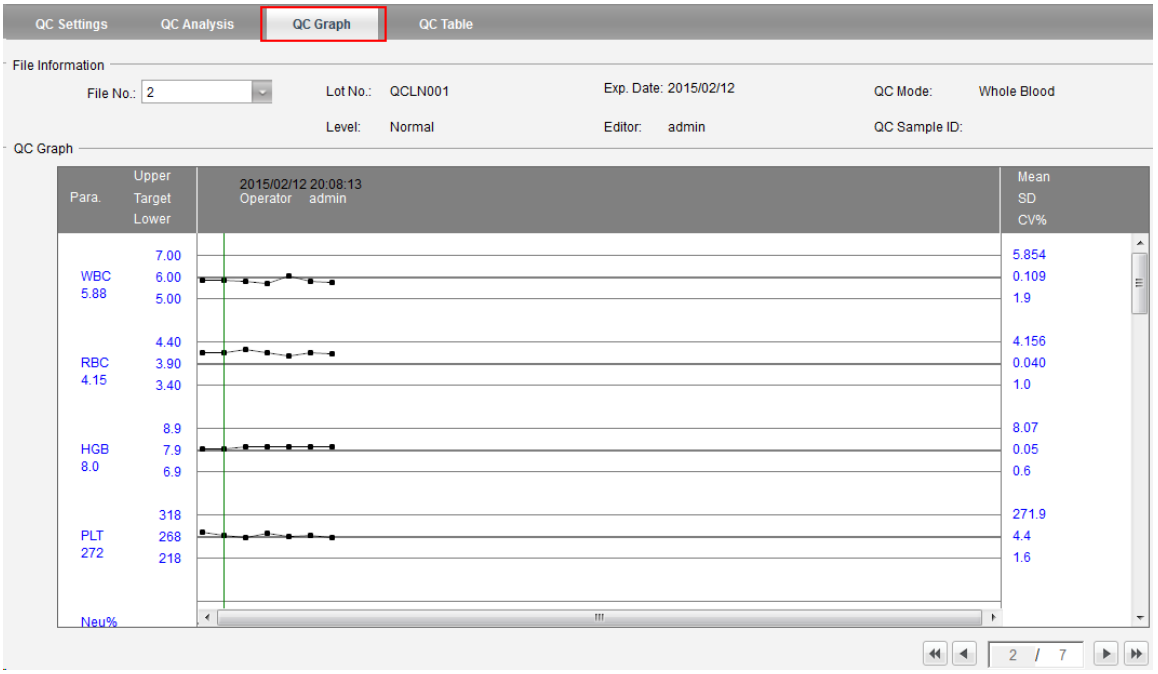
Access the L-J QC Graph interface by taking the following steps:

1. Click **QC** > **QC Settings** to access the QC Settings interface.
2. Click **QC Graph**.

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

   The screen will display the corresponding information and the graph. See Figure 10-7.

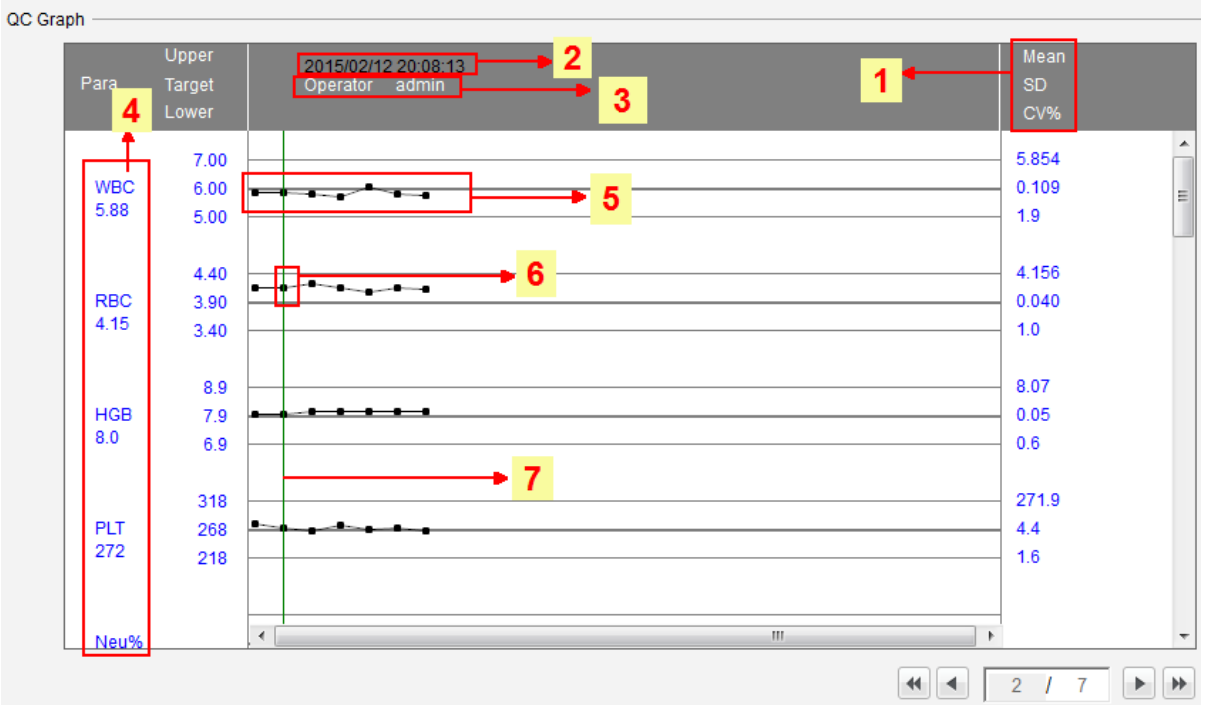
Figure 10-7 QC Graph



4. You can drag the scroll bar on the right of the graph to browse the desired graph of the parameter. You can also drag the scroll bar down to the graph horizontally to browse all the QC results.

Introduction to the Graph Interface

Figure 10-8 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 green line.

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

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.

NOTE

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

New Vial

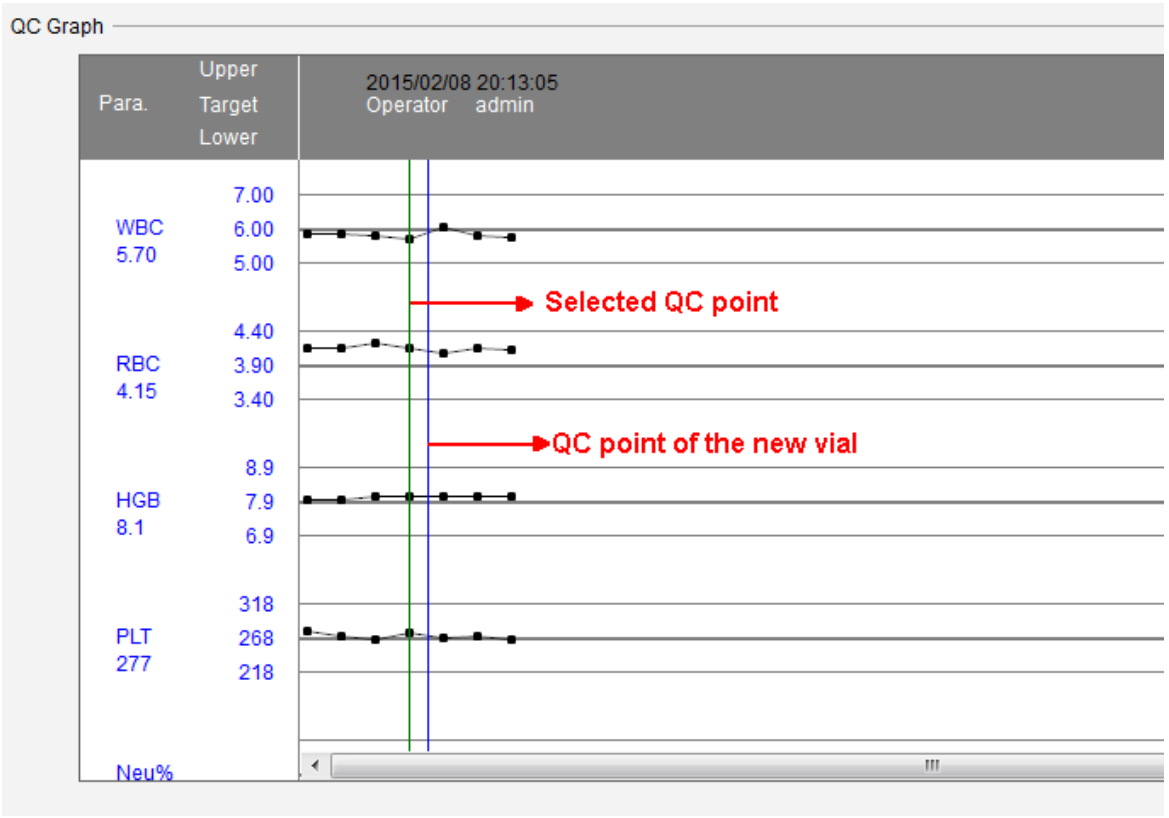
If the reviewed QC results are obtained by analyzing a new vial of control from the same batch, you should mark the QC points of the new vial to distinguish the QC results from the old one.

The procedure for marking new vial QC points is as follows:

1. Move the green line to the first QC point of the new vial.
2. Click **New Vial**.

   A blue line appears at the QC point of the new vial. See Figure 10-9.

Figure 10-9 QC Point of the New Vial



3. Reopen the same lot of controls and save its QC analysis results, click the **Cancel "New Vial"** button. After the original mark is cancelled, follow steps 1~2 and mark the current QC point of the new vial.

Calculate Preset Values/Save Preset Values

If the existing QC parameter has 3 or more QC results within the limits, take the followings steps to calculate and save the preset values of the QC parameters.

1. Click **Calc Preset Values**.

   The screen will display two lines for you to select the range for calculating the preset values.
2. Click and drag the two lines respectively to place them at the beginning and the ending of the range for calculating the preset values.

   The Mean, SD and CV% (on the right of the graph) will change into the new results obtained by calculating the selected range.
3. Click **Save Preset Values** to save the current Mean, SD and CV% as the preset values for the corresponding level (high/normal/low).

   Then, the two selecting lines will disappear and the Mean, SD and CV% will return to the calculated results of all QC results.

NOTE

- If the QC results are less than 3, the preset value cannot be obtained.
- When calculating the preset values, the results of all parameters should be within their limits.

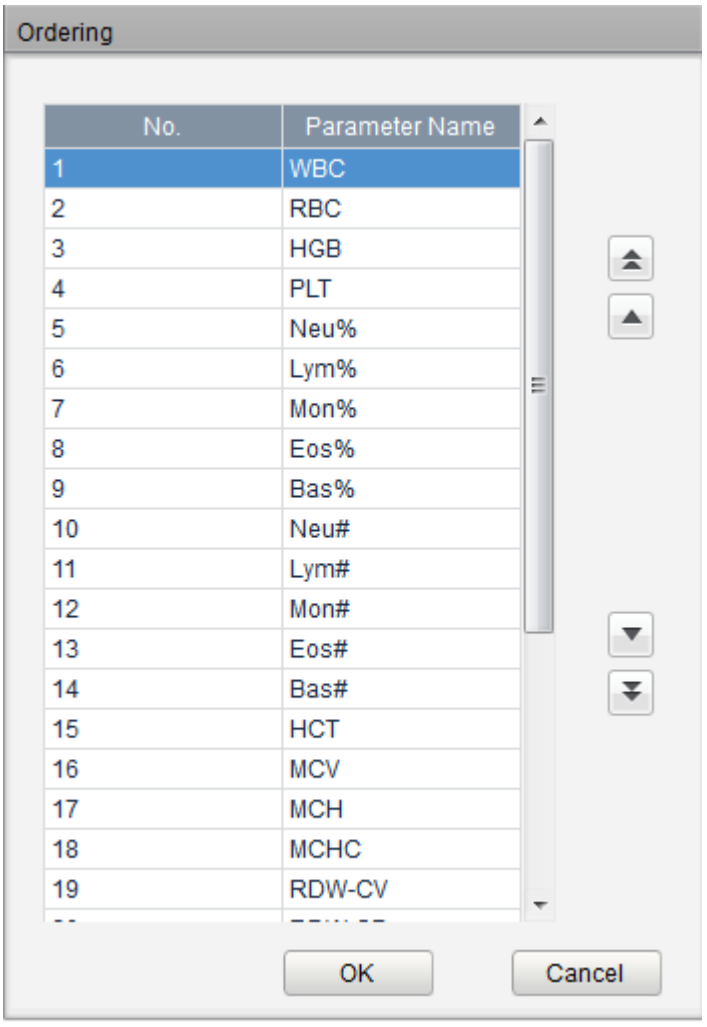
Ordering

Do as follows to adjust the display order of different graphs.

1. Click **Ordering**.

   A window as shown in Figure 10-10 will pop up.

Figure 10-10 QC Graph Parameter Sorting



2. Select the parameter that you want to adjust the order (such as WBC), and sort the parameters by clicking  (top),  (moving upwards),  (moving downwards) or  (bottom).
3. Click **OK**.

Entering the Reasons for the Outliers

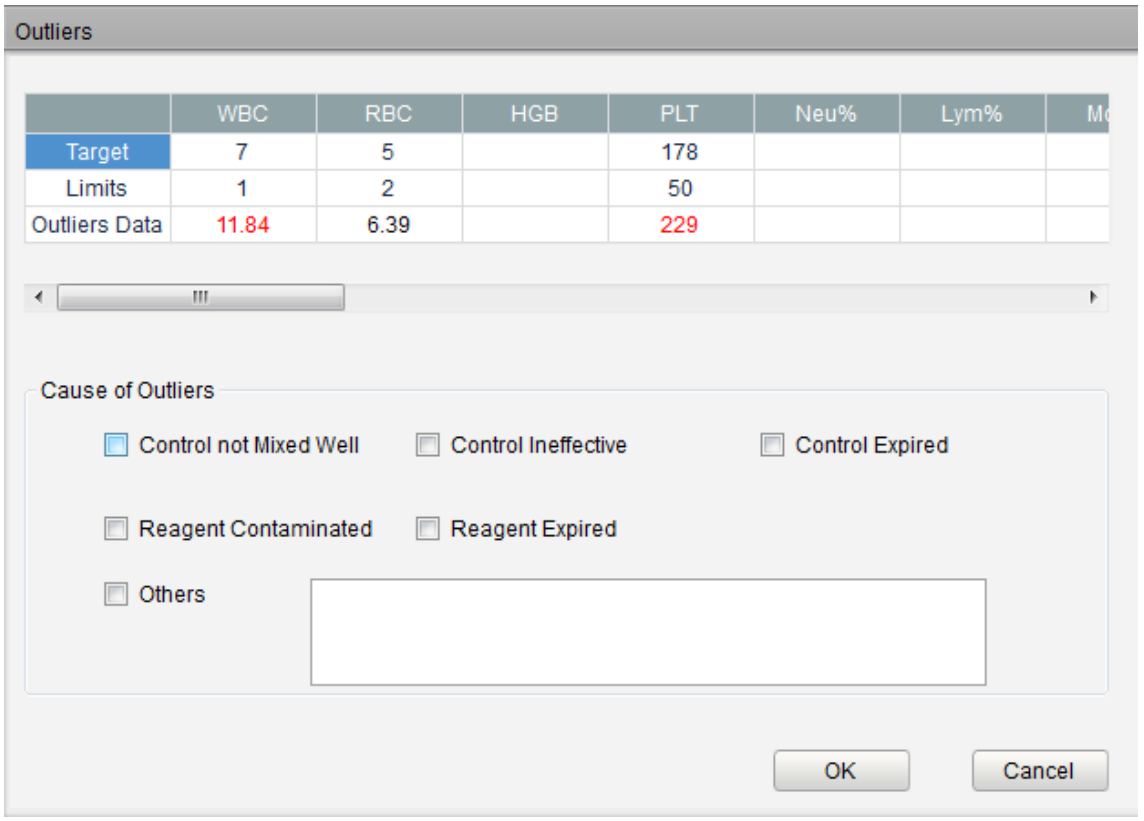
Do as follows to enter the reasons for the outliers:

1. Move the green 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 green line as shown in Figure 10-11.

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

Figure 10-11 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.

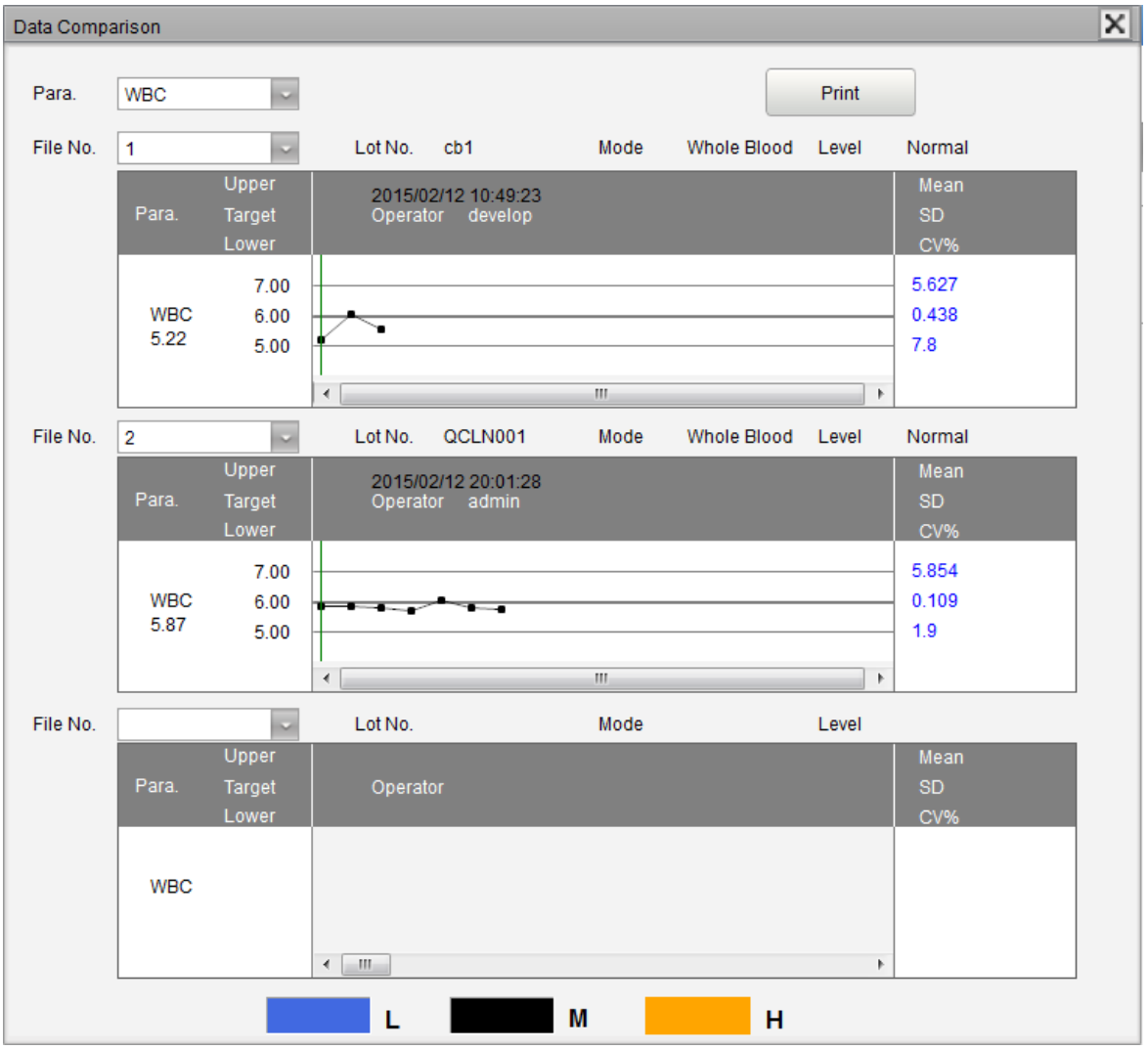
Data Comparison

As per the following steps, you can compare the QC graph of the same parameters for controls from different lots.

1. Click **Compare**.

   The system pops up the Data Comparison window as shown in Figure 10-12.

Figure 10-12 QC Data Comparison



2. Select from the dropdown list the **parameters** you wish to compare, such as **WBC**.
3. Select the desired QC file No. from the **File No.** box (3 files can be selected at most).

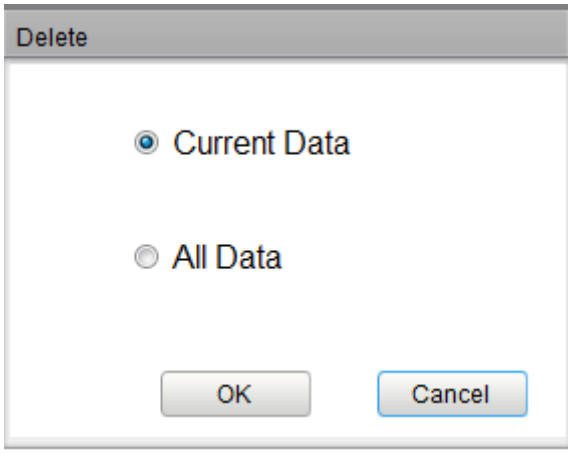
   The graph of the selected QC file will be displayed below together with its lot No., QC mode and level.

Delete

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

- Delete a single QC result
  1. Move the green line to the desired QC result, and click **Delete**.
  2. Select **Current Data** in the pop-up dialog box as shown in Figure 10-13.

Figure 10-13 Deleting Current QC Data (QC Graph)

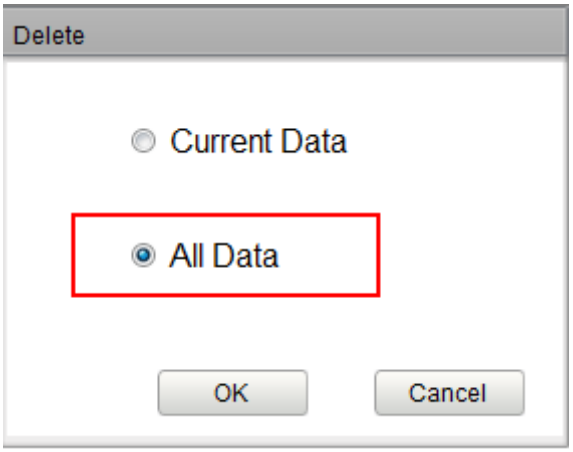


3. Click **OK**.

- 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 10-14.

Figure 10-14 Deleting all QC Data (QC Graph)



Print

1. Click **Print**.

   The system launches the screen where you can preview the QC graph before printing.

2. After confirmation, you can click  and the system will execute the printing operations.

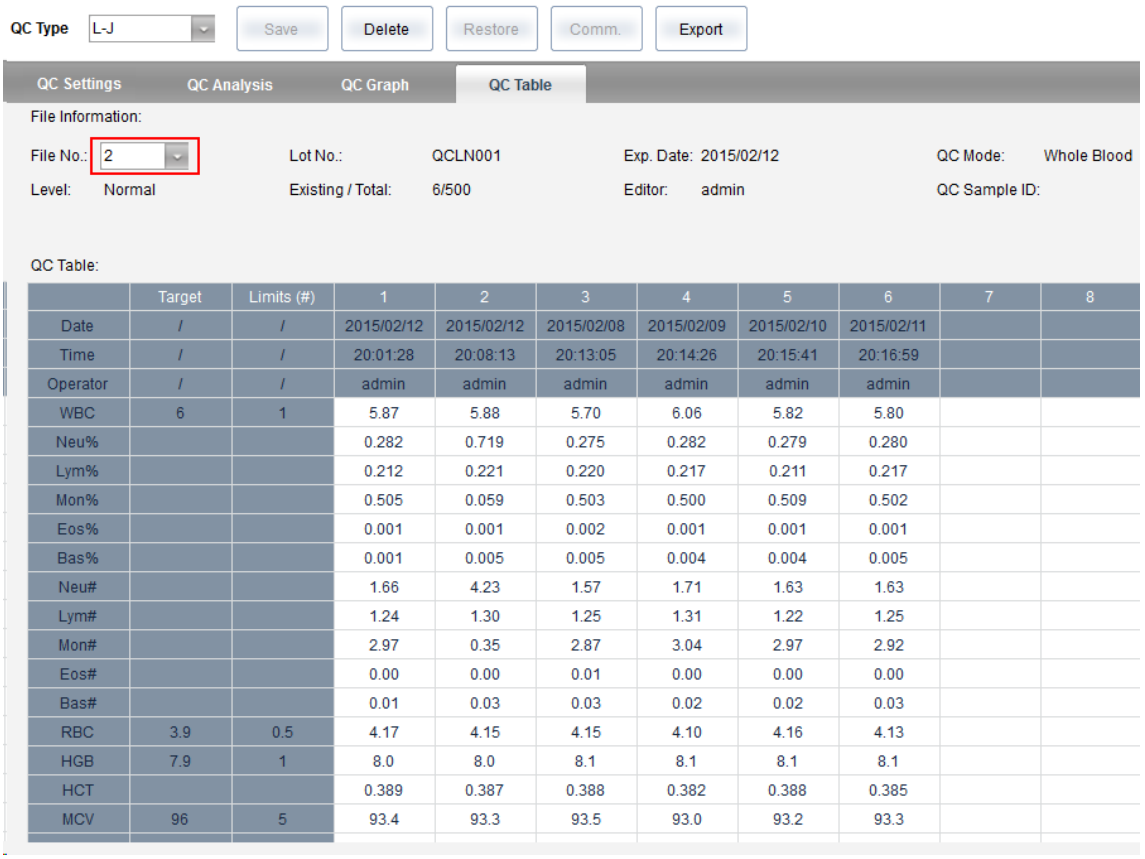
10.2.4.2 QC Table

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 them and the relevant areas in the laboratory.

1. Click **QC** > **QC Settings** to access the QC Setting interface.
2. Click QC Table.
3. Select the QC file No. you want to review, such as **2**.

The corresponding file information and QC table are displayed on the screen as shown in Figure 10-15.

Figure 10-15 QC Table



	Target	Limits (#)	1	2	3	4	5	6	7	8
Date	/	/	2015/02/12	2015/02/12	2015/02/08	2015/02/09	2015/02/10	2015/02/11		
Time	/	/	20:01:28	20:08:13	20:13:05	20:14:26	20:15:41	20:16:59		
Operator	/	/	admin	admin	admin	admin	admin	admin		
WBC	6	1	5.87	5.88	5.70	6.06	5.82	5.80		
Neu%			0.282	0.719	0.275	0.282	0.279	0.280		
Lym%			0.212	0.221	0.220	0.217	0.211	0.217		
Mon%			0.505	0.059	0.503	0.500	0.509	0.502		
Eos%			0.001	0.001	0.002	0.001	0.001	0.001		
Bas%			0.001	0.005	0.005	0.004	0.004	0.005		
Neu#			1.66	4.23	1.57	1.71	1.63	1.63		
Lym#			1.24	1.30	1.25	1.31	1.22	1.25		
Mon#			2.97	0.35	2.87	3.04	2.97	2.92		
Eos#			0.00	0.00	0.01	0.00	0.00	0.00		
Bas#			0.01	0.03	0.03	0.02	0.02	0.03		
RBC	3.9	0.5	4.17	4.15	4.15	4.10	4.16	4.13		
HGB	7.9	1	8.0	8.0	8.1	8.1	8.1	8.1		
HCT			0.389	0.387	0.388	0.382	0.388	0.385		
MCV	96	5	93.4	93.3	93.5	93.0	93.2	93.3		

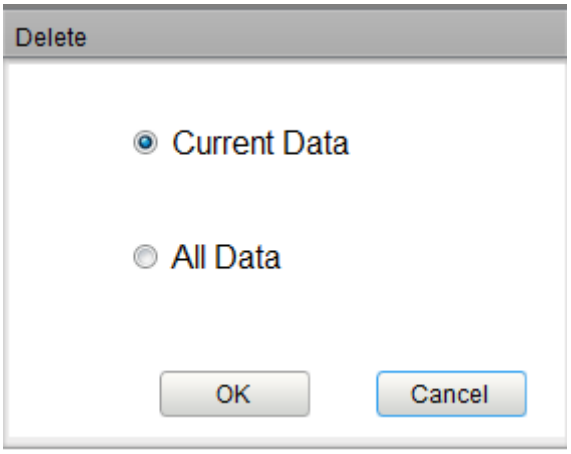
4. You can drag the scroll bar on the right of the table vertically to browse the desired table of the parameter. You can also drag the scroll bar down to the table horizontally to browse all the QC results.

Delete

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

- Delete a single QC result
  1. Click the column containing the desired QC result, and then click **Delete**.
  2. Select **Current Data** in the popup dialog box as shown in Figure 10-16.

Figure 10-16 Deleting current QC data (QC Table)

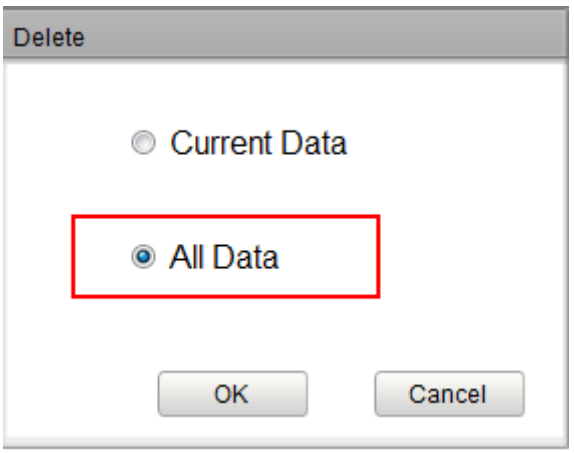


3. Click **OK**.

- Deleting all the QC results in the current QC file

  Click **Delete,** select **All Data** in the popup dialog box, then click **OK.** See Figure 10-17.

Figure 10-17 Deleting all QC Data (QC Table)

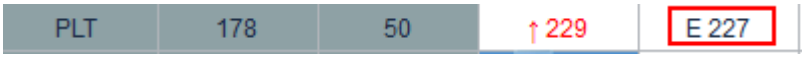


Editing

Double click the cells in the QC table, then you can edit the selected QC data.

The edited data will be marked with an “E”. See Figure 10-18.

Figure 10-18 Editing QC Results



Restoring

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

Saving

Click **Save** to save the editing operations for the QC results.

Communication

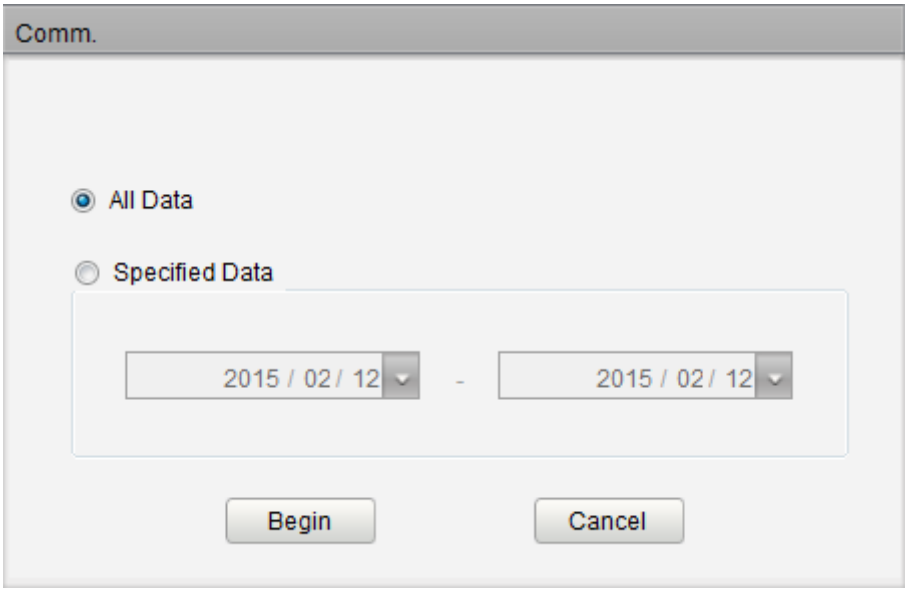
All the QC data or the data within the specified date range can be transmitted to LIS/HIS.

- Communication for all data

1. Click **Comm.**.

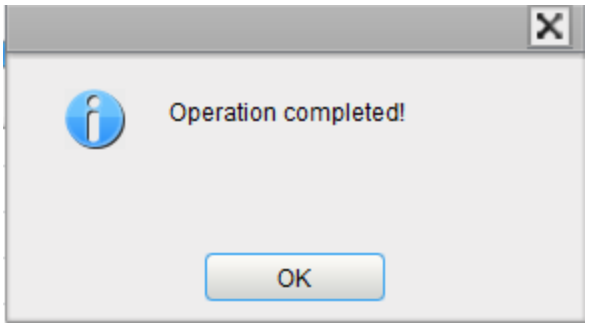
   A message box as shown below will pop up.

Figure 10-19 Communication for all data



2. Select **All Data**.
3. Click **Begin** and start the communication.

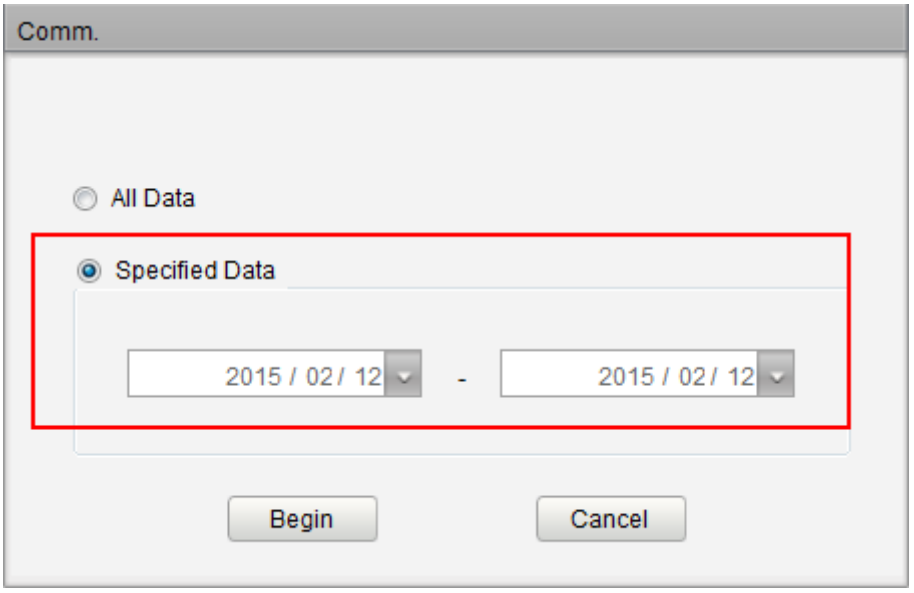
   After the data is transmitted to LIS/HIS, a message box as shown below will pop up.



- Communication for the data within the specified date range.
  1. Click **Comm.**.
  2. Select **Specified Data,** and set the starting and ending dates for the data to be communicated.

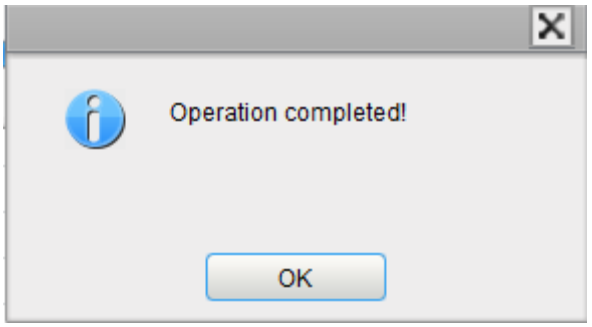
     See Figure 10-20.

Figure 10-20 Communication for the Data within the Specified Date Range



3. Click **Begin** and start the communication.

   After the data is transmitted to LIS/HIS, A message box as shown below will pop up.



NOTE

After the communication is started, the communication progress and the **Stop** button will appear on the screen. If you click **Stop**, the system will stop the communication after the current QC data is completely transmitted.

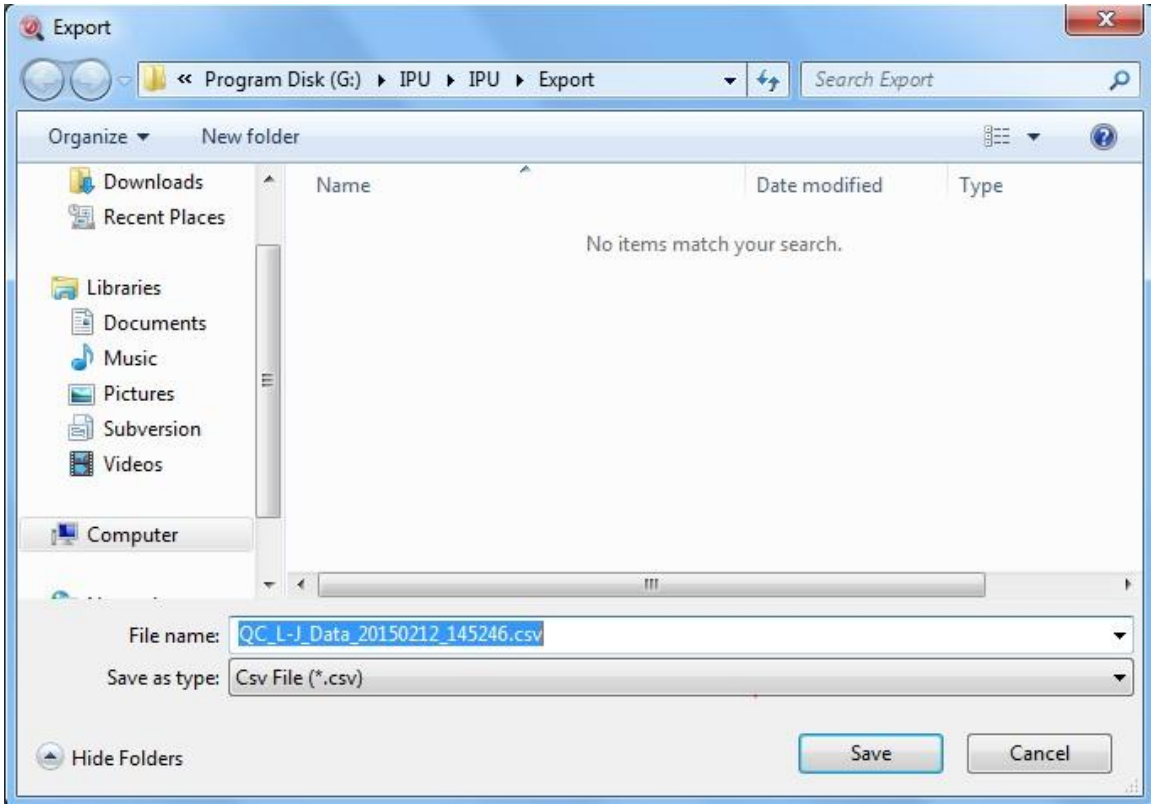
Export

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

1. Click **Export**.
2. Select the export directory.
3. Enter the name for the export data.

   The default file name is [QC_L-J_Data_saving date_saving time]. The file format is .csv. See Figure 10-21.

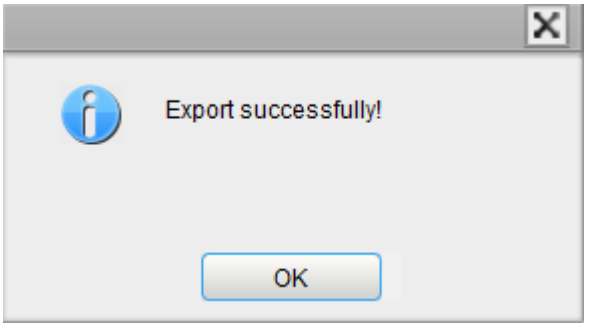
Figure 10-21 Export QC Data



4. Click **Save** to start exporting.

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

Figure 10-22 Export successfully



5. Click **OK** to exit.

11 Calibration

11.1 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 regular calibration of the analyzer following the procedures given in this chapter.

NOTE

- Calibration procedures can only be performed by users with the administrator-level access.
- You should only use the Dymind-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.

11.2 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 only need to recalibrate this analyzer if:

- it is the first time this analyzer has been used (usually done by a Dymind-authorized representative when installing the analyzer).
- an analytical component has been changed.
- you are going to re-use the analyzer after long-term storage.
- the quality control results indicate that there may be a problem.

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.

11.3 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.

11.3.1 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 them and the relevant 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 your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your 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 Dymind-specified controls and reagents. Store and use the controls and reagents by following the instructions for use of the controls and reagents.
- Be sure to use the Dymind-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 Dymind Service Department.

Before the launch of a calibration, do as follows to make sure that the analyzer is ready for use.

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 to ***A.5.2 Normal Background*** for background range.)
3. Run the median controls in Whole Blood CBC+DIFF 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 the table below.

Parameter	Condition	Whole Blood Repeatability (CV)
WBC	(4.0~15.0)×10^9/L	≤2.0%
RBC	(3.50~6.00)×10^{12}/L	≤1.5%
HGB	(110~180)g/L	≤1.5%
MCV	(70~120)fL	≤1.0%
PLT	(150~500)×10^9/L	≤4.0%

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:

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

   The calculated carryovers shall meet the requirements in the following table.

Parameter	Carryover
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.5%
HCT	≤0.5%
PLT	≤1.0%

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.

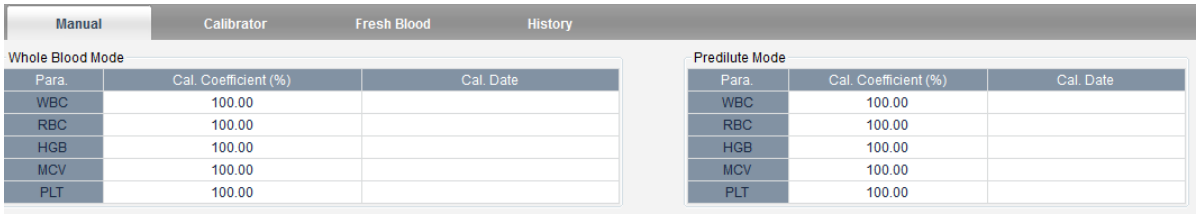
11.3.2 Manual Calibration

Complete the manual calibration as per the following procedure:

1. Click **Cal** to access the **Manual** interface.

   See Figure 11-1. The calibration coefficients of whole blood mode and predilute mode are displayed on the **Manual** interface.

Figure 11-1 Manual Calibration



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.

2. 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.

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

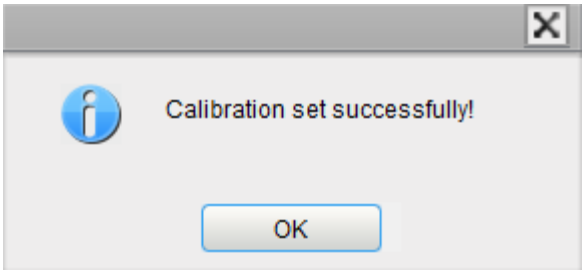
NOTE

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

4. Click **Save**.

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

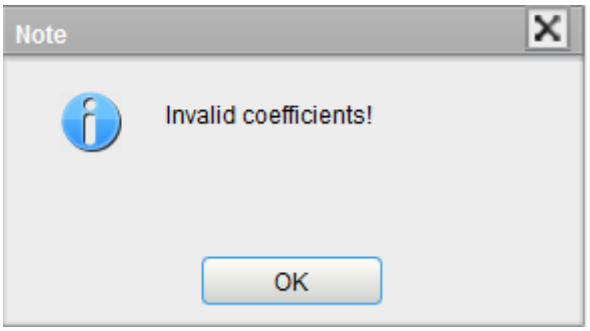
Figure 11-2 Calibration set successfully



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.

Figure 11-3 Invalid Coefficients



Click **OK** to close the message box and enter a valid factor.

11.3.3 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 them and the relevant areas in the laboratory.

NOTE

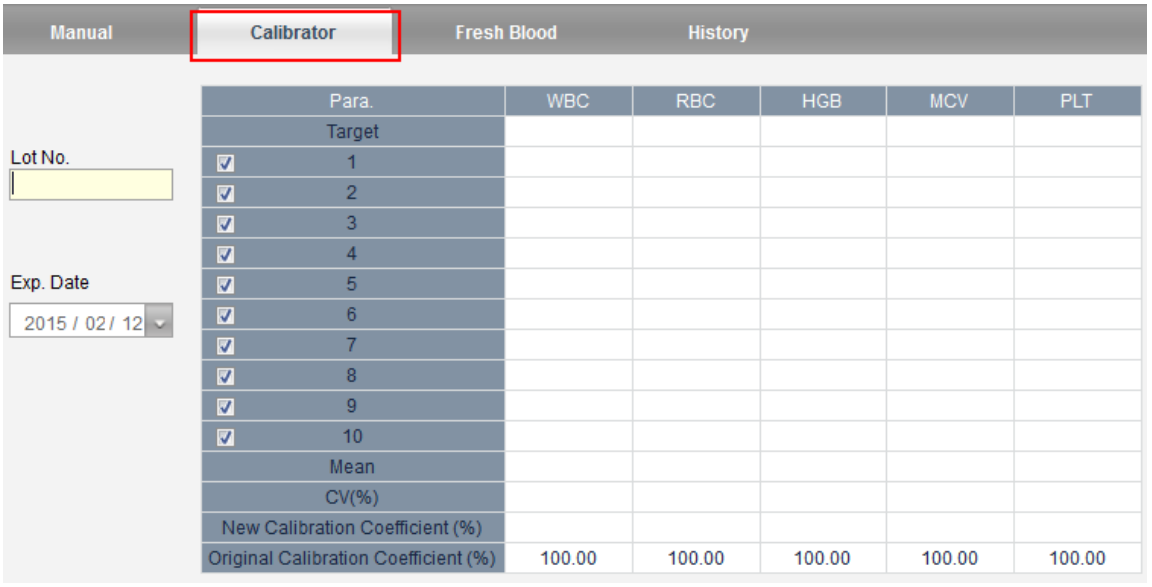
- Only Dymind-specified calibrators shall be used. Dymind will not be responsible for any erroneous result caused by using other calibrators.
- See the instructions for use of the calibrators for the lot No., Exp. date and the target.
- Calibration with calibrators can only be carried out in Whole Blood CBC+DIFF mode.

Complete the calibration with calibrators as per the following procedure:

1. Click **Cal** > **Calibrator**.

   Access the **Calibration Using Calibrators** interface as shown in Figure 11-4.

Figure 11-4 Auto Calibration Using Calibrators



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

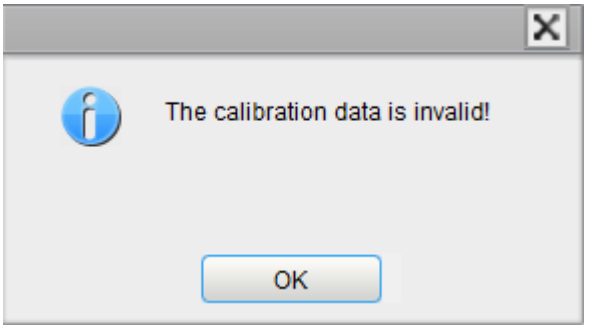
NOTE

- 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.

4. Enter the target values of the parameters in the corresponding **Target** textboxes.
5. Prepare the calibrators following their instructions for use and place the calibrators under the sampling probe.
6. To start the calibration counting sequence, click the **Start** button or press the aspiration key on the analyzer.C

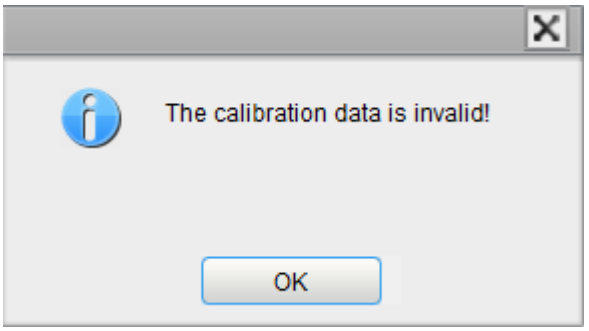
   After every calibration run, the progress bar will close automatically and the analyzer will have different responses according to different analysis results.

   - The valid results within the linearity range will be displayed directly.
   - When the current running is complete, if there is a parameter whose calibration data is beyond its linearity range but still within the display range, then the calibration data will be displayed in the list and a message box as below will also pops up.



   Click **OK** to close the message box and delete the data from the table without saving.

➢ When the running is complete, if there is a parameter whose calibration data is beyond the display rage, then the non-numeric parameter values "***" will be displayed in the list and a message box as below will pop up.



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 the user switches to other interfaces before the new calibration coefficients are obtained, the system will discard the current calibration data and keep the original calibration coefficients.

7. To get 10 valid counting results, repeat steps 5~6 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.

8. 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.

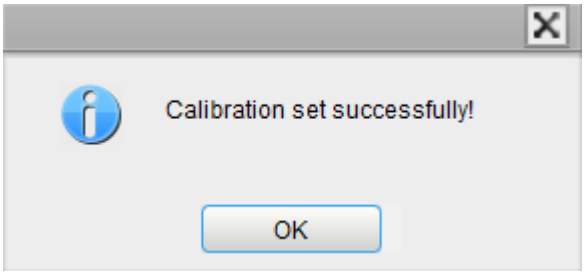
NOTE

- The out-of-range CV% does not influence the display of the calibration coefficients.
- When the amount of the valid calibration data in the list reaches 11, a message box of **Calibrator calibration done!** will pop up. Then, if you press the aspirate key again, the analyzer will beep and does not respond.

9. Click **Save**.

➢ If the calculated calibration coefficients of all parameter are within the range of 75%~125% and the CV% of all parameter are also within the repeatability, then a message box will pop up.

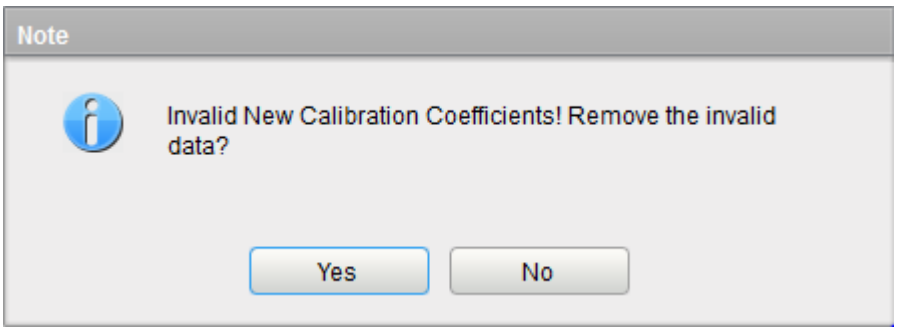
Figure 11-5 Save New Calibration Coefficients



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.

Figure 11-6 Invalid New Calibration Coefficients



Clicking **Yes** will clear the data of the current calibration operation; clicking **No** will return to the original screen.

11.3.4 Auto Calibration Using Fresh Blood Samples

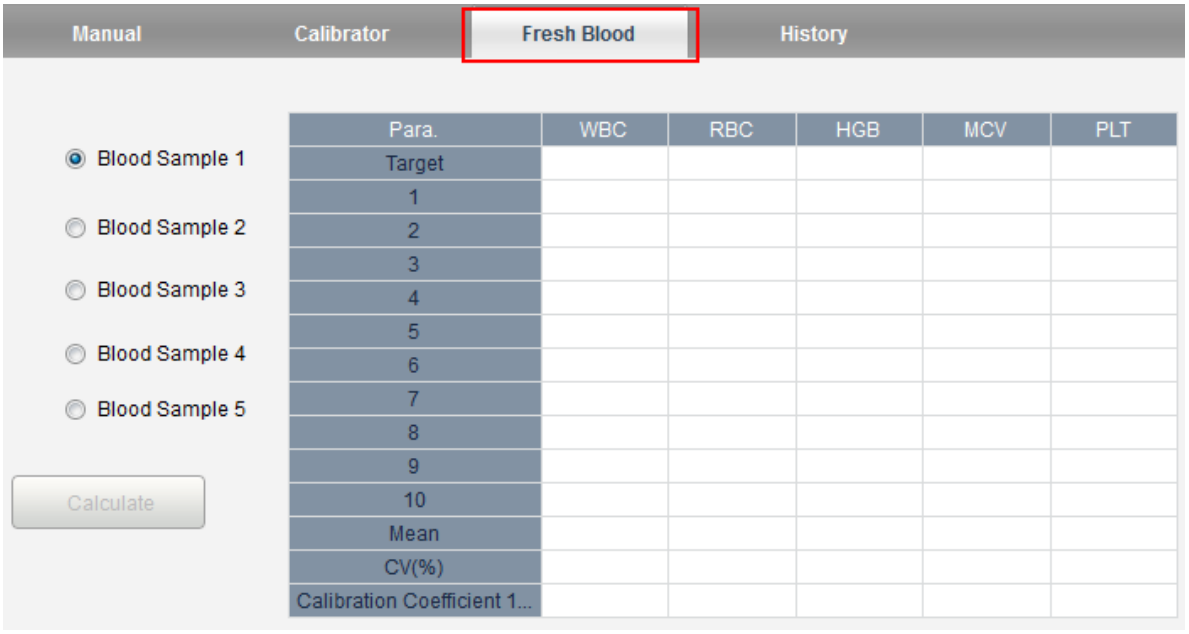
All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them and the relevant areas in the laboratory.

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

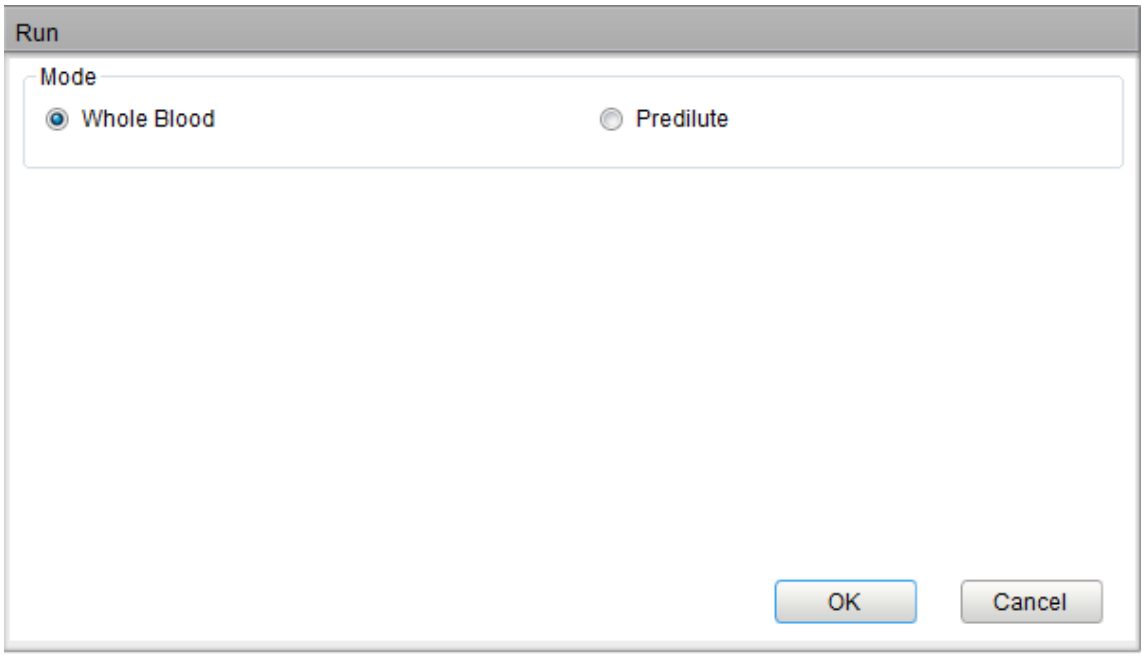
1. Click **Cal** > **Fresh Blood**.

   Enter the **Calibration Using Fresh Blood Samples** interface as shown in Figure 11-7.

Figure 11-7 Auto Calibration Using Fresh Blood Samples



2. Click the **Mode** button in the function button area and select **Whole Blood** or **Predilute** as the calibration mode for fresh blood samples in the pop-up dialog box.



3. Prepare 3 to 5 normal fresh blood samples as instructed by ***5.5 Sample Collection and Handling***.
4. Run each of the prepared samples on the reference instrument (or by the reference method) three times at least. Average the results for your reference values

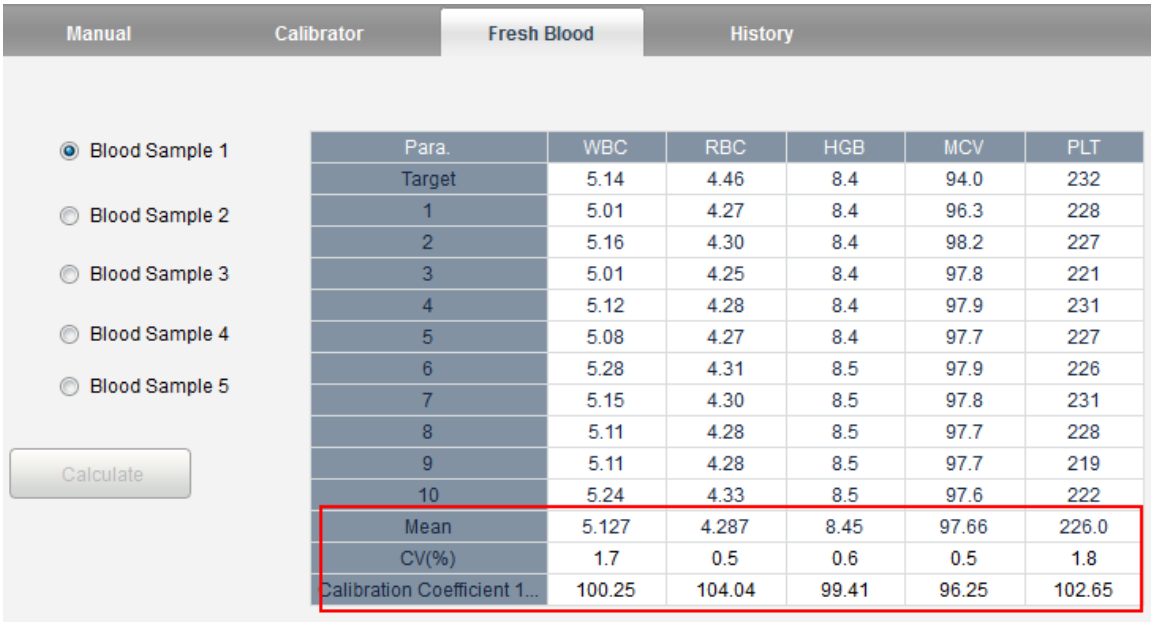
NOTE

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, click the Start button or press the aspirate key on the analyzer to run the samples.
7. Repeat step 6 for 10 times and calculate the counting results for sample No. 1 in the 10 runs.

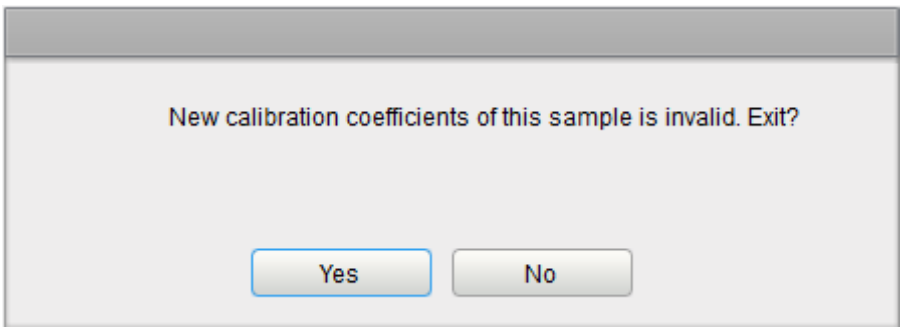
   The system will calculate the Mean, CV and Calibration coefficient for each parameter of the sample. See Figure 11-8.

Figure 11-8 Calibration Results for Fresh Blood Samples



Para.	WBC	RBC	HGB	MCV	PLT
Target	5.14	4.46	8.4	94.0	232
1	5.01	4.27	8.4	96.3	228
2	5.16	4.30	8.4	98.2	227
3	5.01	4.25	8.4	97.8	221
4	5.12	4.28	8.4	97.9	231
5	5.08	4.27	8.4	97.7	227
6	5.28	4.31	8.5	97.9	226
7	5.15	4.30	8.5	97.8	231
8	5.11	4.28	8.5	97.7	228
9	5.11	4.28	8.5	97.7	219
10	5.24	4.33	8.5	97.6	222
Mean	5.127	4.287	8.45	97.66	226.0
CV(%)	1.7	0.5	0.6	0.5	1.8
Calibration Coefficient 1...	100.25	104.04	99.41	96.25	102.65

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 as shown below 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**.

   As shown below, 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.

Figure 11-9 Calculating Mean Calibration Coefficient (%)

Para.	WBC	RBC	HGB	MCV	PLT
☑ Calibration Coefficient 1 (%)	100.25	104.04	99.41	96.25	102.65
☑ Calibration Coefficient 2 (%)	99.41	98.78	101.30	100.35	99.90
☑ Calibration Coefficient 3 (%)	98.04	107.03	101.78	95.25	101.49
☑ Calibration Coefficient 4 (%)	102.80	107.04	104.94	98.20	97.84
☑ Calibration Coefficient 5 (%)	87.17	105.41	102.68	93.35	98.97
Mean Calibration Coefficient (%)	97.53	104.46	102.02	96.68	100.17
Original Calibration Coefficient (%)	101.11	104.23	104.76	96.18	99.49

You can also check at least three accurate calibration coefficients and the system will re-calculate the mean calibration coefficient (%).

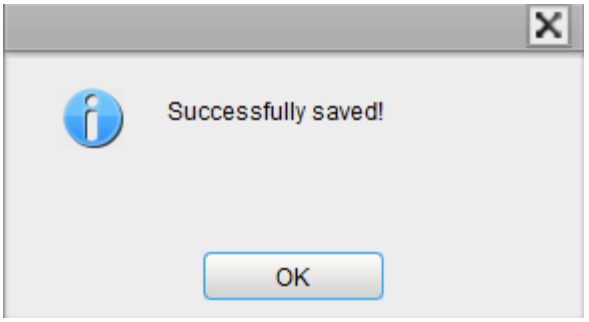
NOTE

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 greater than or equal to 5%), a dialog box will pop up.

Figure 11-10 Saving New Calibration Coefficient



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

- If the mean calibration coefficient is 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

- If the mode is switched from Predilute to Whole Blood, you'll be prompted for the mode switching. To close the prompt, see *6.3.1 Auxiliary Settings*.
- CV% out of standard will not affect the display of calibration coefficient.

11.3.5 Verifying Calibration Coefficients

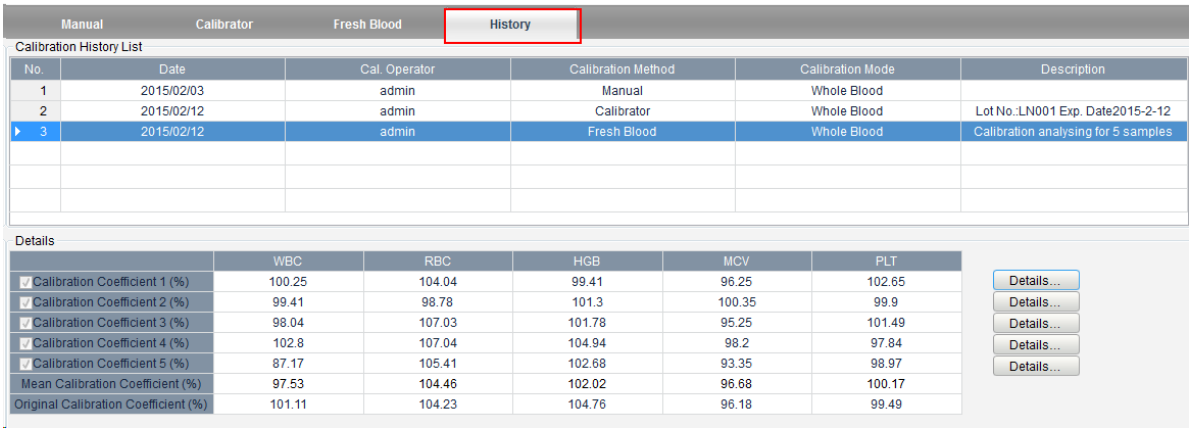
It is recommended that you take the following steps to verify the calibration coefficients:

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.

11.3.6 Calibration History

Click **Cal.** > **History** to enter the calibration history screen. You can view the calibration history list and the detailed calibration data.

Figure 11-11 Calibration History



- Calibration History List

  The list shows the latest 100 calibration history records, including the following items:

  - Date: The operating system date when the calibration coefficient is saved.
  - Cal. Operator: The one who performs the calibration operations, such as the Admin.
  - Calibration Method: Including **Manual, Calibrator** and **Fresh Blood**.
  - Calibration Mode: The mode adopted for the calibration, including **Whole Blood** and **Predilute.**
  - Description: Supplementary description of the calibration information about the corresponding entries.

- Detailed Calibration Data

  Selecting any row of record in the **Calibration History List** will enable you to view the detailed calibration data of that record.

  If the calibration method of the selected record is **Fresh Blood**, you can click **Details…** next to each intermediate calibration record and view the detailed calibration data of each intermediate calibration record.

12 Maintenance

12.1 Introduction

Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition. This analyzer provides multiple maintenance functions for this purpose.

This chapter introduces how to use the provided functions to maintain and troubleshoot your analyzer.

All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.

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 your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.

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 Dymind customer service department or your local agent for assistance.
- Only Dymind-supplied parts can be used for maintenance. For any question, contact Dymind customer service department or your local agent.
- Exercise caution to avoid contact with the sharp sample probe when performing maintenance.

12.2 Service

The analyzer provides multiple service functions helping users to perform daily maintenance.

12.2.1 Replacing Reagents

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 your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your 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.
- When you have changed 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-A Diluent
- LYA-3 Lyse
- LYA-2 Lyse

Do as follows to replace the reagents:

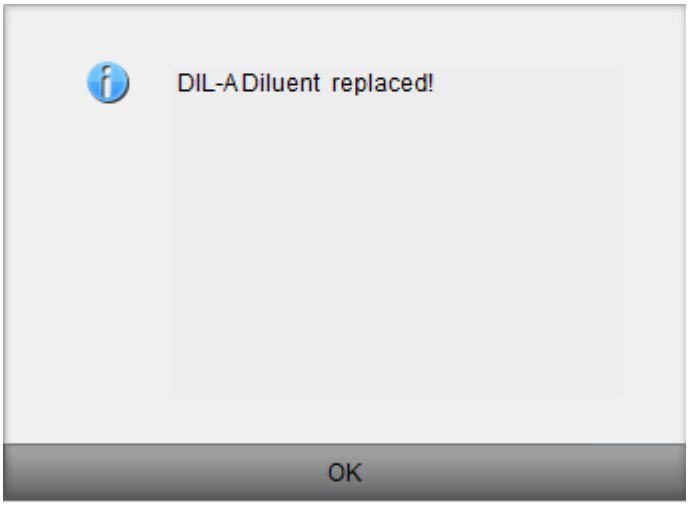
1. Refer to Figure 2-2 in 2.6.2 ***Reagent Connections*** for reagent connections.
2. Click **Service** > **Replace Reagent** to access the interface as shown in Figure 12-1.

Figure 12-1 Replacing Reagents

3. Double click the name of the reagent that needs to be replaced, such as **DIL-A Diluent.**

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

Figure 12-2 Reagent Replaced



4. Click **OK** to close the message box.
5. Perform the above procedures to replace other reagents if necessary.

12.2.2 Cleaning

Clean corresponding parts according to the actual situation:

- DIFF bath

  When the background of the scattergram has abnormal excessive cells, you should clean the DIFF Bath.

- 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.

- Flow chamber

  When the background of the scattergram has abnormal excessive cells, or bad differential of WBC, you should clean the flow chamber.

- Sample probe

  When the sample probe is dirty, you should clean the sample probe.

The cleaning procedures are as follows:

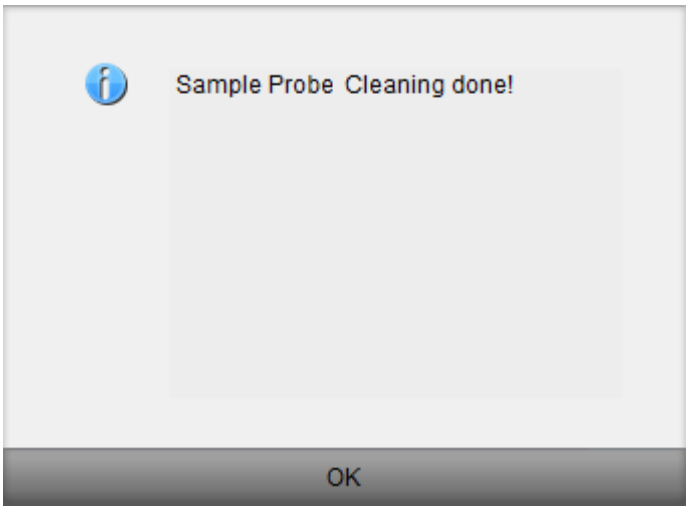
1. Click **Service** > **Clean** to access the interface as shown in Figure 12-3.

Figure 12-3 Cleaning

2. Double click the icon of the part that needs to be cleaned, such as Sample Probe.

   When the system cleaning is complete, the message box will pop up to show that the cleaning is done.

Figure 12-4 Cleaning Done



3. Click **OK** to close the message box.
4. Perform the above procedures to clean other components if necessary.

12.2.3 Maintenance

Instrument maintenance includes: unclogging, cleanser soak, cleanser soak for DIFF channels, cleanser soak for WBC channel, and cleanser soak for RBC channel.

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.

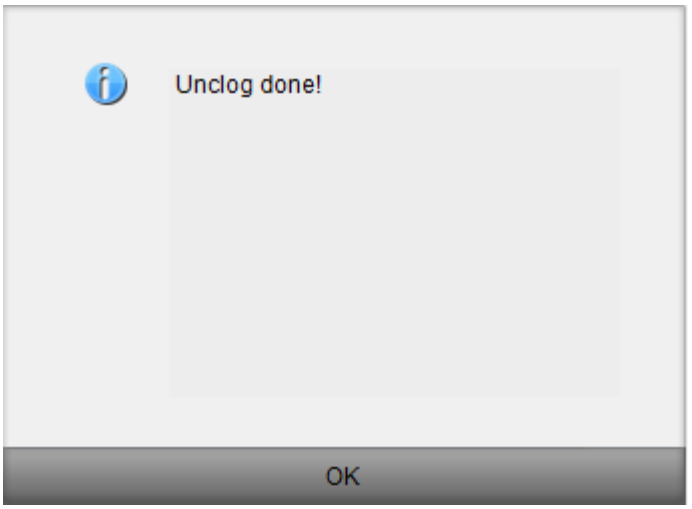
The unclogging procedures are shown as follows:

1. Select **Service** > **Maintain** tab to access the interface as shown in Figure 12-5.

Figure 12-5 Maintenance

2. Double click the **Unclog** icon to start unclogging.

   After the unclogging is completed, a message box will pop up.



3. Click **OK** to close the message box.
4. 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, bad differential of scattergram and clogging still exist after other maintenance procedures have been adopted.
- If the sample size is small (less than 20 samples per day), the user should conduct the cleanser soak upon the shutdown each day, so as to prevent the accumulation of internal contamination (because this may seriously affect the results and the analyzer when the contamination accumulates to a certain extent!), and ensure the accuracy of results.
- Analyzer has been running for more than 24 hours.

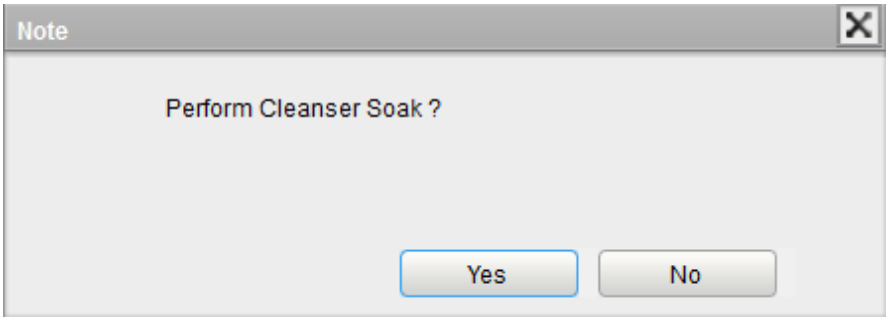
The cleanser soak procedures are shown as follows.

1. Select **Service** > **Maintain** tab to access the **Maintain** interface.

2. Double click the icon of **Cleanser Soak**.

   A dialog box as shown below will pop up.

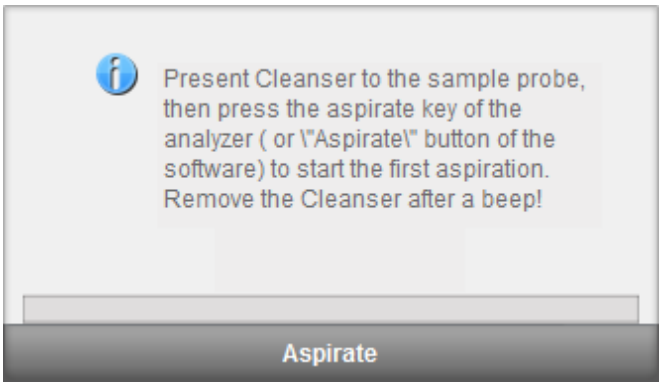
Figure 12-6 Cleanser Soak



3. Click **Yes**.

   A dialog box as shown below will pop up.

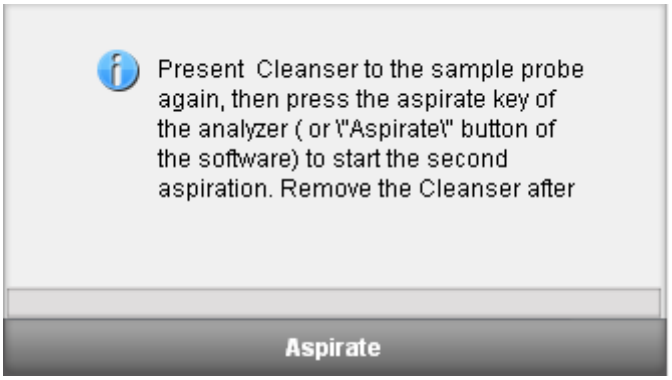
Figure 12-7 Cleanser Soak Prompt



4. Present the cleanser to the sample probe as per the prompt, and press the aspirate key or click the **Aspirate** button.

   30 seconds after the first aspiration of the cleanser soak, the following dialog box will pop up.

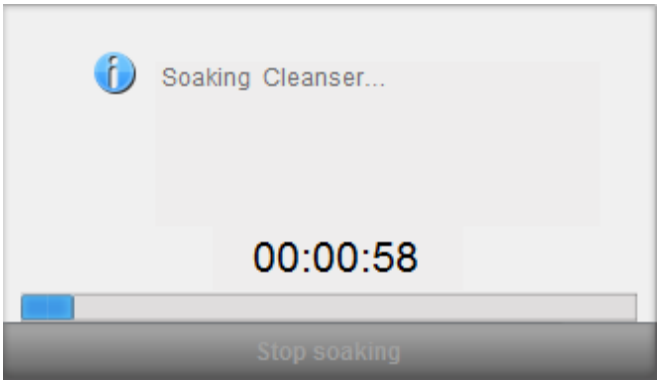
Figure 12-8 Cleanser Soak Prompt Again



5. Present the cleanser to the sample probe again, then press the aspirate key or click the **Aspirate** button.

   Soaking Cleanser… and the soaking time will appear as shown below.

Figure 12-9 Cleanser Soaking Process Prompt

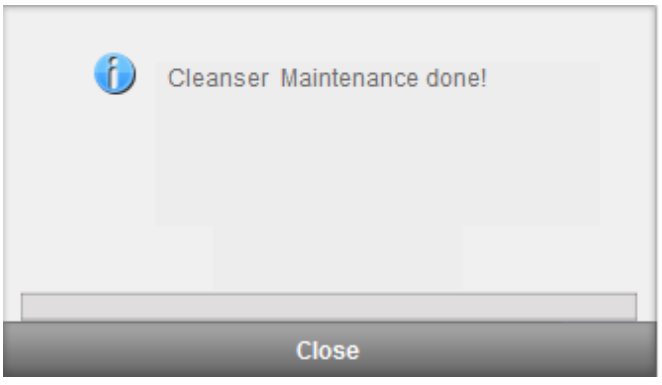


   After one minute of soaking, the user can stop it manually.

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 12-10.

Figure 12-10 Cleanser Maintenance Done



7. Click **Close**.
8. Perform the above procedures to perform the cleanser soak again if necessary.

12.2.3.3 Cleanser Soak for DIFF Channel

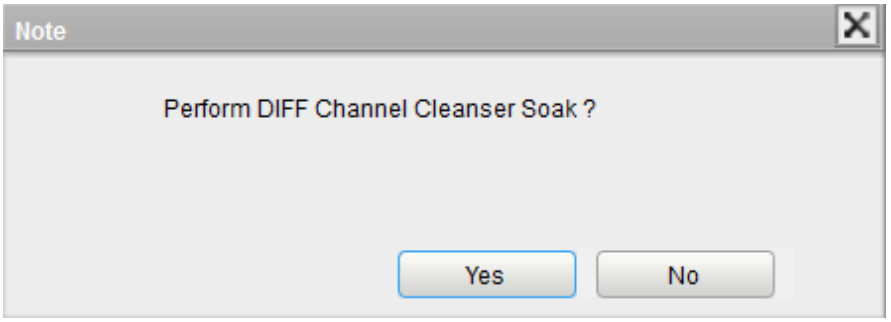
In case the DIFF channel scattergram is abnormal or the clogging is believed to exist in the flow chamber, the Cleanser Soak for DIFF Channel feature can be used as a means for troubleshooting.

Procedures of cleanser soak for DIFF channel are shown as below:

1. Select **Service** > **Maintain** to access the **Maintain** interface.

2. Double click the icon of **DIFF Channel Cleanser Soak**.

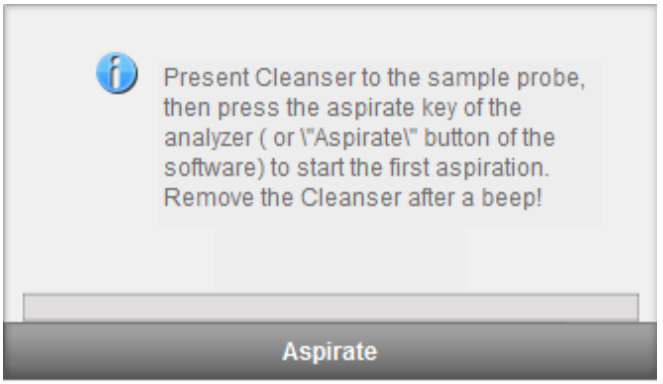
   A dialog box will pop up.



3. Click **Yes**.

   A dialog box will pop up.

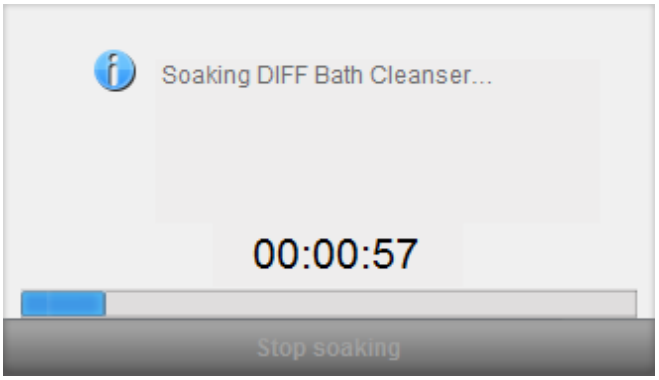
Figure 12-11 DIFF Channel Cleanser Aspiration Prompt



4. 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.

Figure 12-12 DIFF Channel Soaking Process

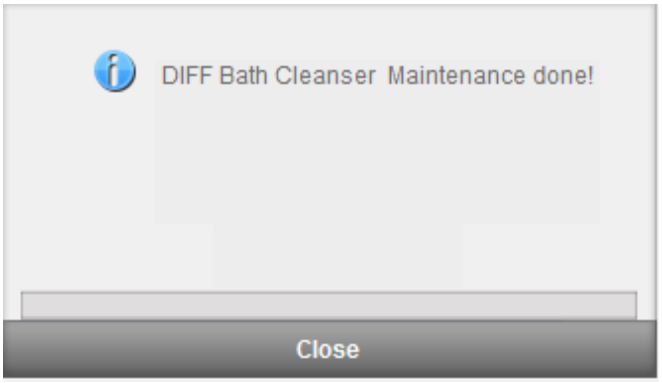


After one minute of soaking, the user can stop it manually.

5. 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.

Figure 12-13 Cleanser Maintenance Done



6. Click **Close**.
7. Perform the above procedures to perform the DIFF channel cleanser soak again if necessary.

12.2.3.4 Cleanser Soak for WBC Channel

Probe cleanser soaking for WBC channel can be used to remove the errors for aperture clogging or abnormal scattergram.

Please refer to ***12.2.3.3 Cleanser Soak for DIFF Channel*** for performing the operations for cleanser soaking for WBC channel.

12.2.3.5 Cleanser Soak for RBC Channel

In case the RBC distribution histogram is abnormal or the clogging is believed to exist in the flow chamber, Cleanser Soak for PBC Channel feature can be used as a means for troubleshooting.

Please refer to ***12.2.3.3 Cleanser Soak for DIFF Channel*** for procedures of Cleanser Soaking for RBC Channel.

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.

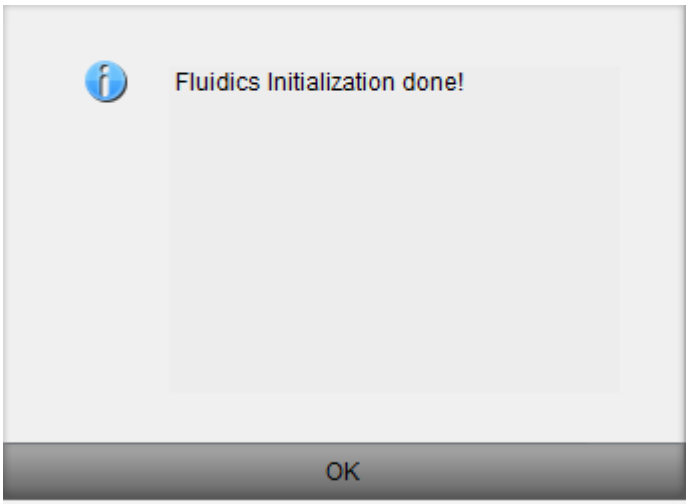
Do as follows to perform the fluidics initialization:

1. Select **Service** > **Comprehensive Device** tab to access the **Comprehensive Device** maintenance interface.

2. Double click the icon of **Fluidics Initialization**.

   A prompt saying "**Performing Fluidics Initialization…**" will appear.

   After the initialization is complete, a message box will pop up.



3. 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.

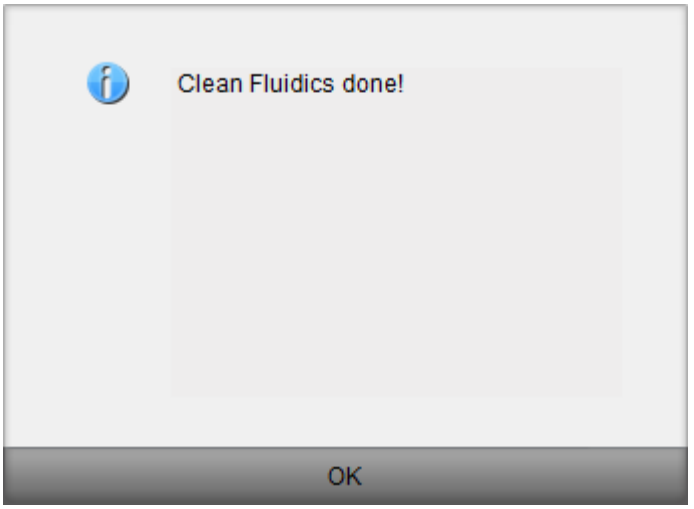
Procedures for comprehensive device cleaning are shown as below:

1. Select **Service** > **Comprehensive Device** tab to access the **Comprehensive Device** maintenance interface.

2. Double click the icon of **Clean Fluidics**.

   A prompt saying "**Performing Clean Fluidics…**" will appear.

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



3. Click **OK**.

12.2.4.3 Empty Fluidics

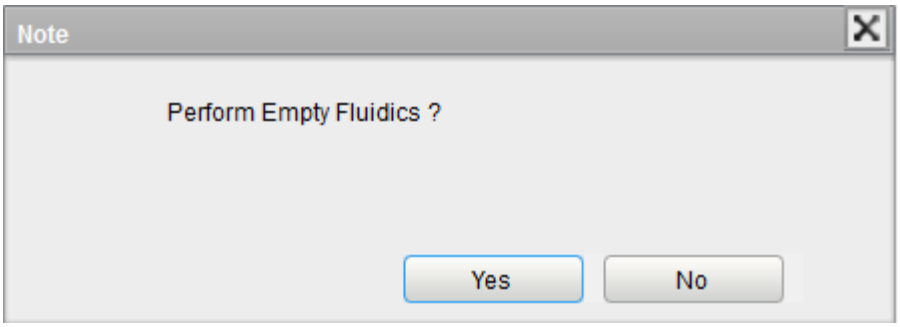
This function enables the device to empty fluidics to prevent crystallization and maintain device performance when the device has not been used for more than one week.

Procedures for emptying fluidics are shown as below:

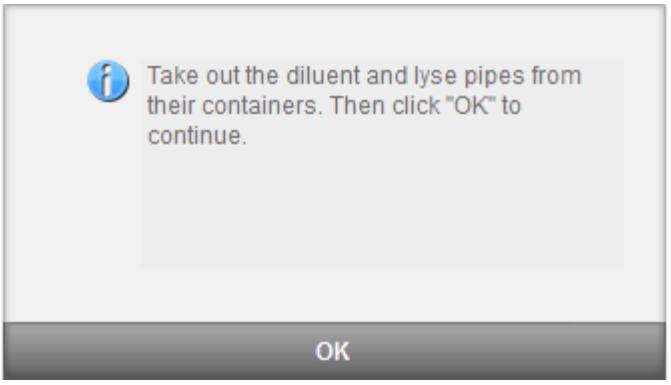
1. Select **Service** > **Comprehensive Device** tab to access the **Comprehensive Device** maintenance interface.

2. Double click the icon of **Empty Fluidics**.

   A message box shown below will pop up.

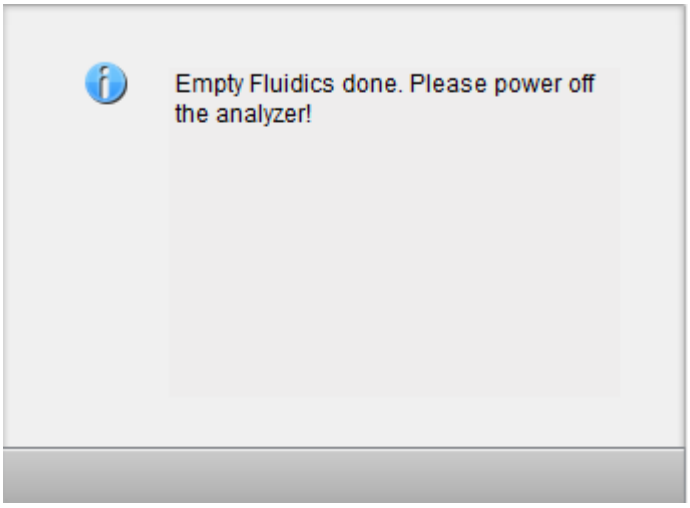


3. Click **Yes** to start the emptying, and a message box shown below will pop up.



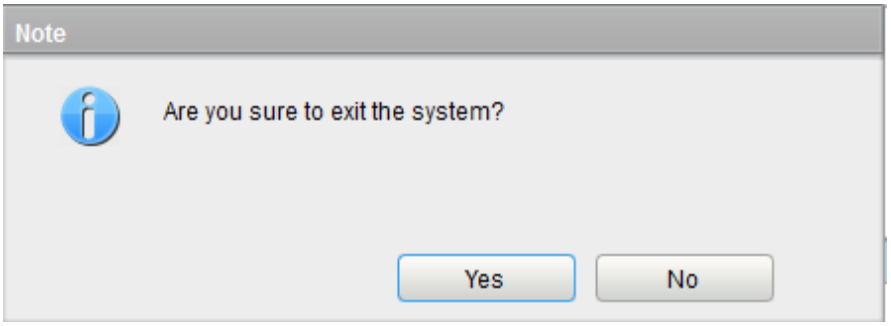
4. Remove all reagent pickup tube assemblies according to the prompt, and then click **OK** to start emptying the fluidic system.

   After the emptying is complete, a message box will pop up.



5. Place the [O/I] switch at the left side of the main unit in the [O] position.

   Once the main unit is powered off, the following dialog box will pop up.



6. Click **Yes**, the software system will close automatically.

   If clicking **No**, the user can still use the software for any operation not related to the main unit.

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

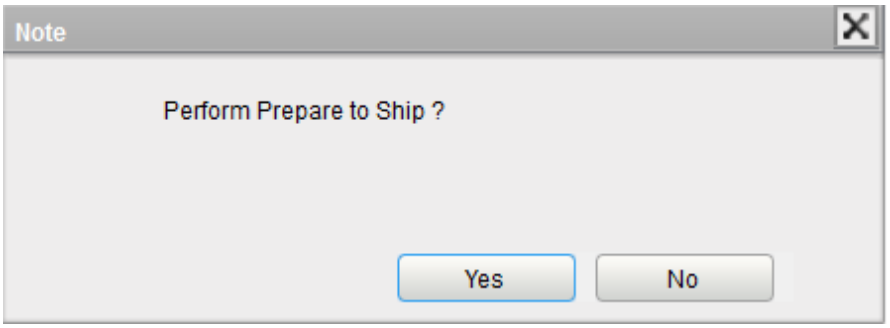
If the analyzer is not to be used for over two week or needs be transported over a long distance (transporting time>2h), you should perform this procedure.

Do as follows to perform the prepare-to-ship procedure:

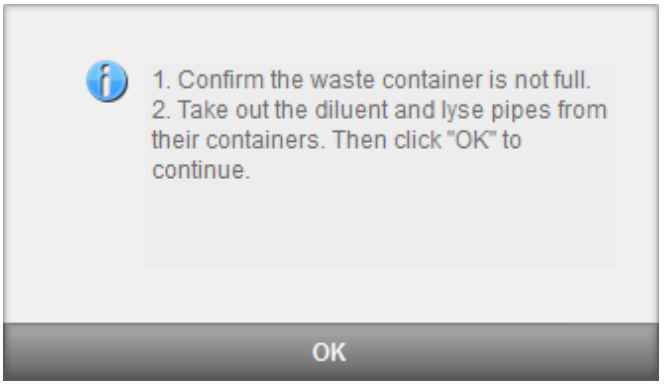
1. Select **Service** > **Comprehensive Device** tab to access the **Comprehensive Device** maintenance interface.

2. Double click the icon of **Prepare to Ship**.

   A message box shown below will pop up.

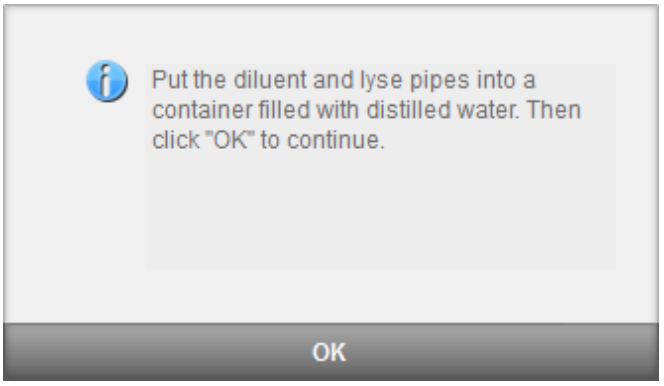


3. Click **Yes** button to perform the packing up and a message box shown below will pop up.



4. 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.

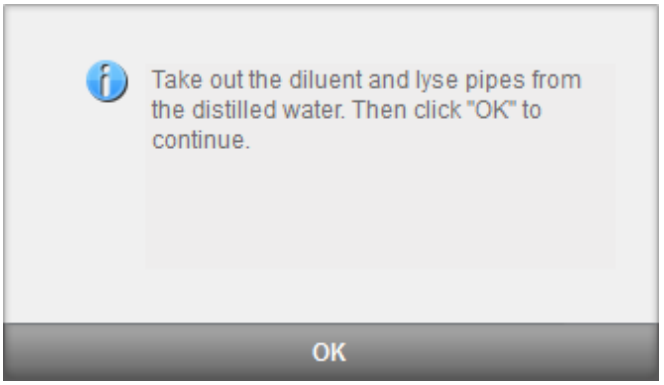


5. Place all reagent pickup tube assemblies into the distilled water, and then click **OK** to start priming.

NOTE

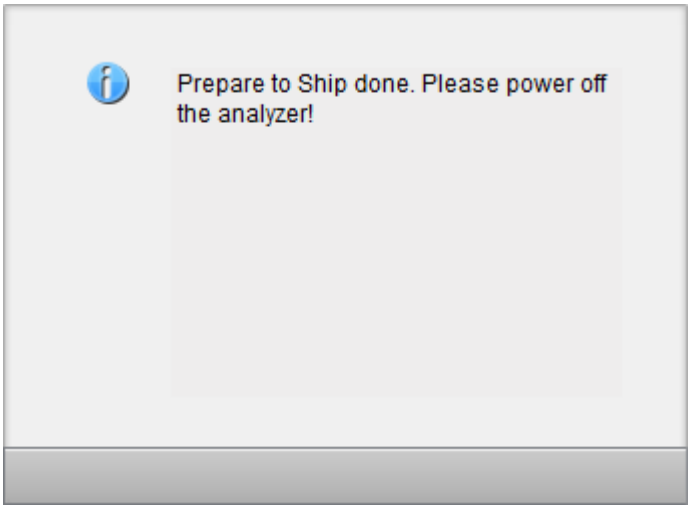
- Be sure to use distilled water in order to ensure the normal use of the device in the future. In addition, the beaker holding the distilled water needs to be cleaned thoroughly.
- The diluent pipe and lyse pipe should be stored separately in two beakers.

System performs the filling operation. After the filling is completed, the following dialog box will pop up.



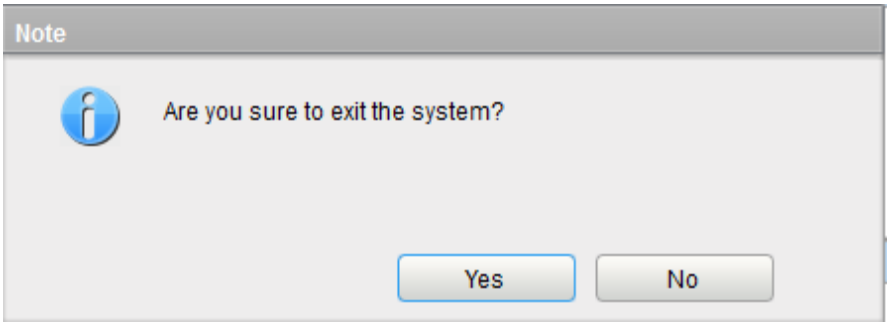
6. Take out the diluent and lyse pipes from the distilled water as per the prompt, then click **OK**.

   A dialog box will pop up to prompt you to power off the device.



7. Place the [O/I] switch at the left side of the main unit in the [O] position.

   Once the main unit is powered off, the following dialog box will pop up.



8. Click **Yes**, the software system will shut down automatically.

   If clicking **No**, the user can still use the software for any operation not related to the main unit.

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 Reagent Management

Once the new reagent is connected to the analyzer, you can 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 your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.

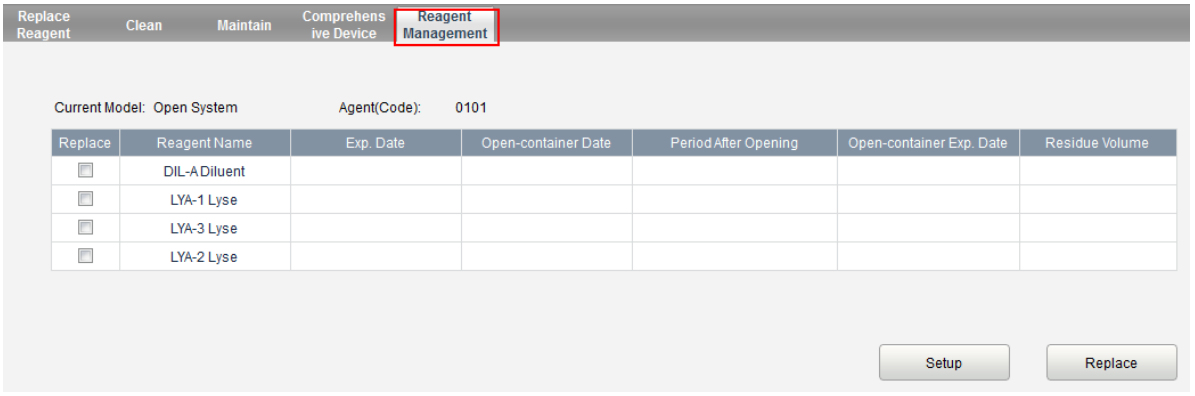
NOTE

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- When you have changed the diluent, cleansers or lyses, run a background check to see if the results meet the requirement.

12.2.5.1 Accessing the interface

Click **Service** > **Reagent Management** to access the **Reagent Management** setting interface. See Figure 12-14.

Figure 12-14 Reagent Management



Refer to Table 12-1 for related parameter descriptions.

Table 12-1 Parameter Description for Reagent Management

Parameter	Description
Current Model	Current model of the analyzer. • Open system • Closed system Reagent setting procedures for different analyzer models vary, please refer to ***12.2.5.2 Reagent Information Settings.***
Agent (code)	Agent Code of the reagent.
Replace	Please tick off the corresponding box in the **Replace** column for the reagent before reagent replacement. You can select multiple reagents and click **Replace** button to replace multiple reagents.
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.

12.2.5.2 Reagent Information Settings

This section will show you how to set the Exp. date, residue volume and other information for the connected reagent.

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.

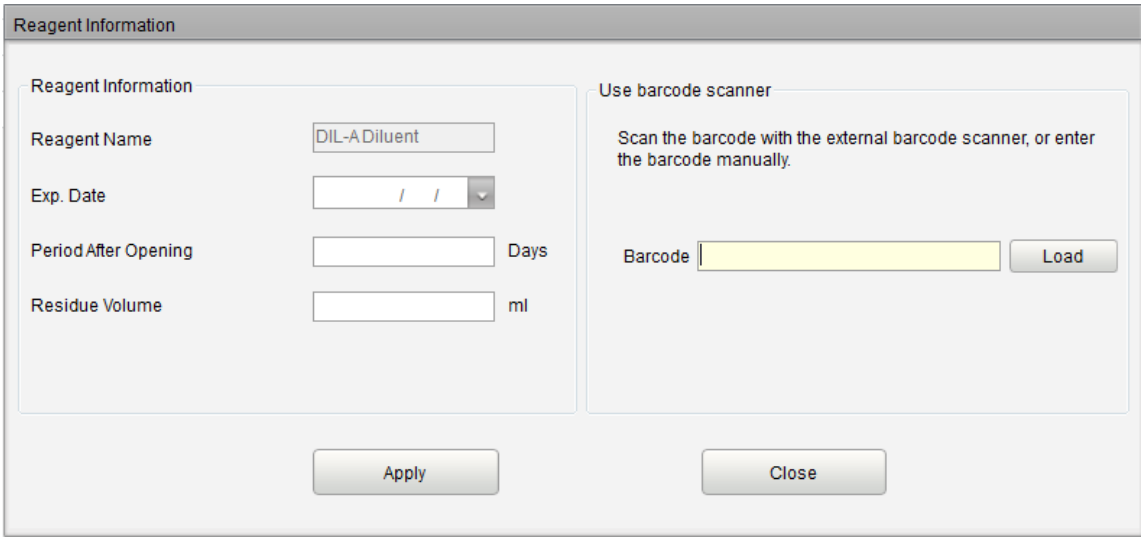
Open system

For open systems, reagent setting procedures are as follows:

1. Select the reagent to be set (such as LYA-1 Lyse), and then click **Setup.**

   This launches the Reagent Information Settings page as shown in Figure 12-15.

Figure 12-15 Reagent Information



2. To enter the reagent information, use any of the following methods.

   ➢ Manual Entry

   Detailed parameter description is shown in Table 12-2.

Table 12-2 Parameter Description of Reagent Information

Parameter	Meaning	Operation
Exp. Date	Exp. date of the unopened reagent (see the outer packaging of the reagent). The reagent, regardless of the container being opened or not, should not be used beyond this date.	Click the date control for the settings **NOTE** The validity date of the reagent should be no later than the current system date or the validity date indicated on the packaging.
Period after opening (PAO)	The validity period (days) of the open-container reagent (see the product packaging).	Enter the information directly into the textbox.
Residue Volume	The current residue volume of the reagent (ml).	Enter the information directly into the textbox.

- Manually enter the reagent barcode, and click **Load.**

  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 Dymind After-sales Service Department.

- Input the barcode via a peripheral barcode scanner

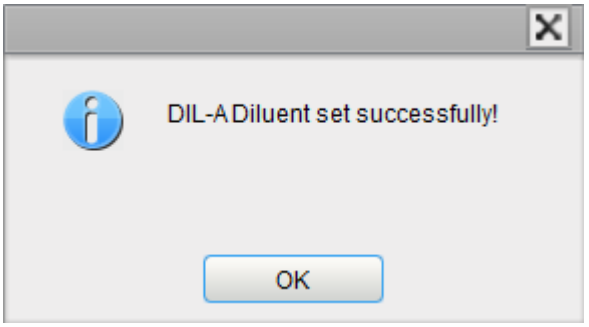
  A correctly entered barcode will prompt a message shown below the barcode box, indicating a successful loading, and the validity date and residue volume will be shown in the corresponding textboxes.

  If the bar code fails to be loaded, check if the reagent has been used or has expired and the reagent name is correct. If all the information is correct, but the failure persists, please contact Dymind After-sales Service Department.

3. Click **Apply**.

   The system message will pop up, indicating the successful reagent settings.

Figure 12-16 Successful Reagent Settings



4. Click **OK**.
5. Click **Close** to exit.

NOTE

- Once the reagent settings are successfully completed, the system prompt at the bottom right corner of the screen will show that the reagent has not been replaced. To complete the reagent replacement, please refer to ***12.2.5.3 Reagent Replacement***.
- When you have changed the diluents, cleansers or lyses, run a background check to see if the results meet the requirement.

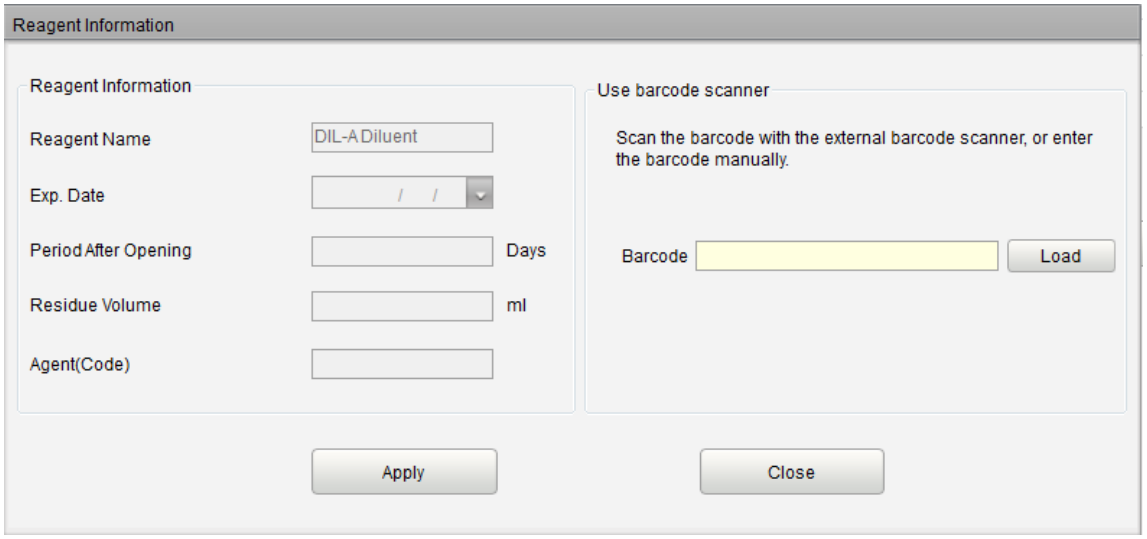
Closed system

For closed systems, reagent setting procedures are as follows:

1. Select the reagent to be set (such as LYA-1 Lyse), then click **Setup**.

   This launches the Reagent Information Settings page as shown in Figure 12-17.

Figure 12-17 Reagent Information



2. Input the barcode via a peripheral barcode scanner or manual input, and then click **Load.**

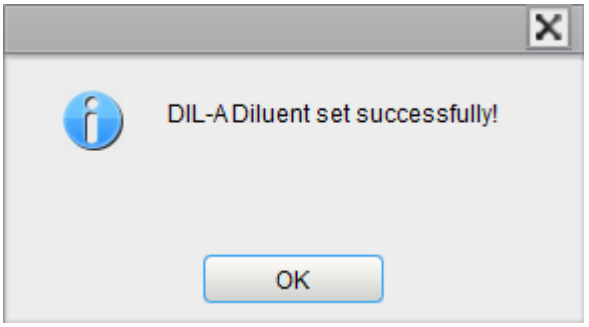
   A correctly entered barcode will prompt a message shown below the barcode box, indicating a successful load, and the validity date and residue volume will be shown in the corresponding textboxes.

   If the 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 Dymind After-sales Service Department.

3. Click **Apply**.

   ➢ For the settings of diluents, a pop-up dialog box as shown in Figure 12-18 indicates the completion of the settings. Please perform steps 6~7.

Figure 12-18 Successful Diluent Settings



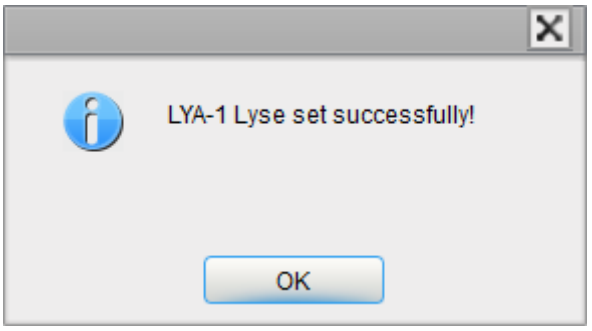
   ➢ For the settings of lyses, a dialog box as shown in Figure 12-19 will pop up. Please perform the next step.

Figure 12-19 IC Card Verification

4. Connect the included IC card reader to the peripheral computer.
5. Insert the IC card included in the reagent package into the card reader, and click **OK.**

   The beeping of the card reader and a pop-up dialog box as shown in Figure 12-20 indicate the successful reagent settings.

Figure 12-20 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.

6. Click **OK**.
7. Click **Close** to exit.

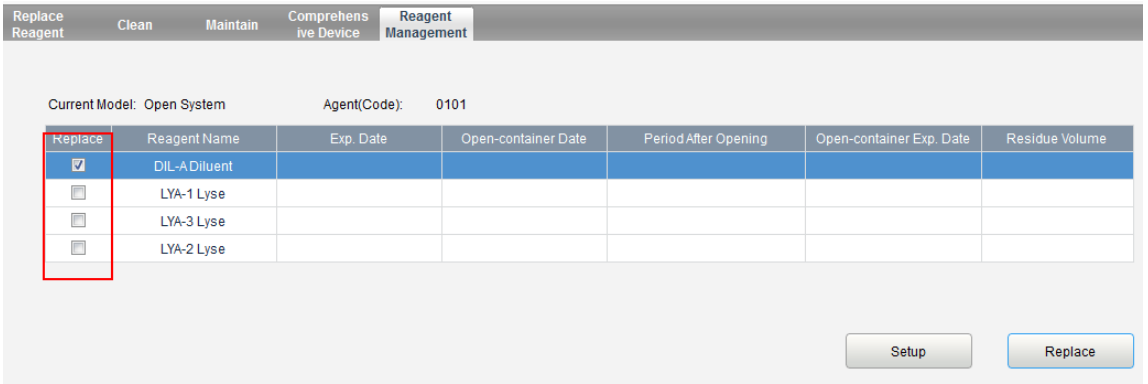
NOTE

- Once the reagent settings are successfully completed successfully, the system prompt at the bottom right corner of the screen will show that the reagent has not been replaced. To complete the reagent replacement, please refer to ***12.2.5.3 Reagent Replacement.***
- When you have replaced the diluent, cleansers or lyses, run a background check to see if the results meet the requirement.

12.2.5.3 Reagent Replacement

1. Tick off one or multiple reagents in the **Service** > **Reagent Management** interface.

Figure 12-21 Reagent Replacement



2. Click **Replace**.

   A message box will pop up indicating reagent replacement is in progress, as is shown below.

Upon the completion of reagent replacement, the message box will be closed automatically.

12.2.6 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.

12.2.7 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

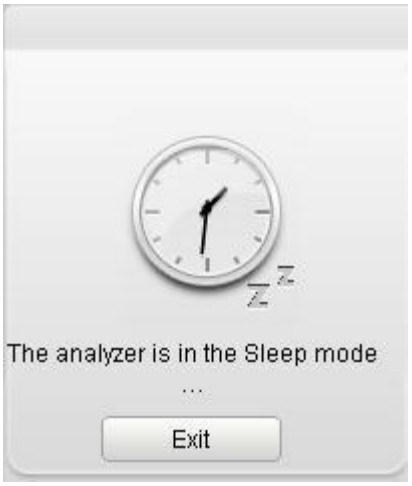
- Administrators can set auto maintenance time for cleanser. See 6.9.1 Auto Maintenance.
- At the **Self-test** or **Status** interface, the analyzer does not ask for confirmation to perform the cleanser soak.
- If the analyzer is running or has problems when the conditions of auto prompt for cleanser 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.

12.2.8 Auto Sleep

When the fluidics system stops working for 30 minutes (default setting), then the analyzer will enter the sleeping status automatically.

When the main unit is in the Sleep state, operation/status message area will show that the device is in the Sleep mode (Figure 12-22). Click **Exit** to exit the Sleep mode.

Figure 12-22 Sleep



NOTE

- You can set the waiting time for auto sleeping, see 6.9.1 Auto Maintenance.
- At the **Self-test** or **Status** interface, the analyzer can not sleep.
- 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.
- You can perform the operations without the cooperation of the analyzer when it is sleeping, namely, communication and print etc.
- 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.

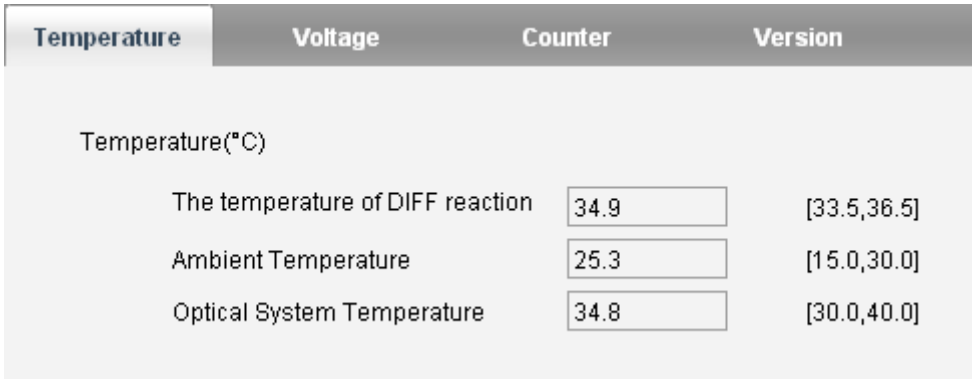
12.3 System Status

User can view the current status information of the analyzer in the Status interface, including temperature, voltage and current, counting statistics and version information.

12.3.1 Temperature

Click **Status** > **Temperature** to access the **Temperature** interface. See Figure 12-23.

Figure 12-23 View Temperature Status

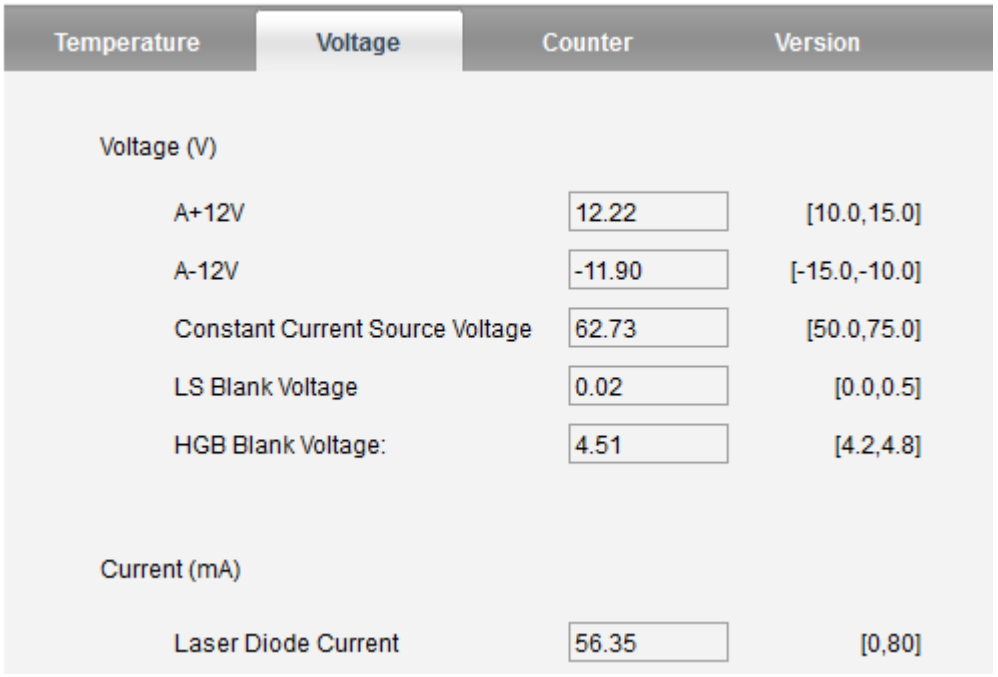


User can view the current temperature information of the analyzer, including the temperature of DIFF reaction bath, ambient temperature and the temperature of the optical system. If the results of the temperature testing exceed the normal range, they will be highlighted by the red background.

12.3.2 Voltage and Current

Click **Status** > **Voltage** to access the **Voltage** interface.

Figure 12-24 Voltage and Current

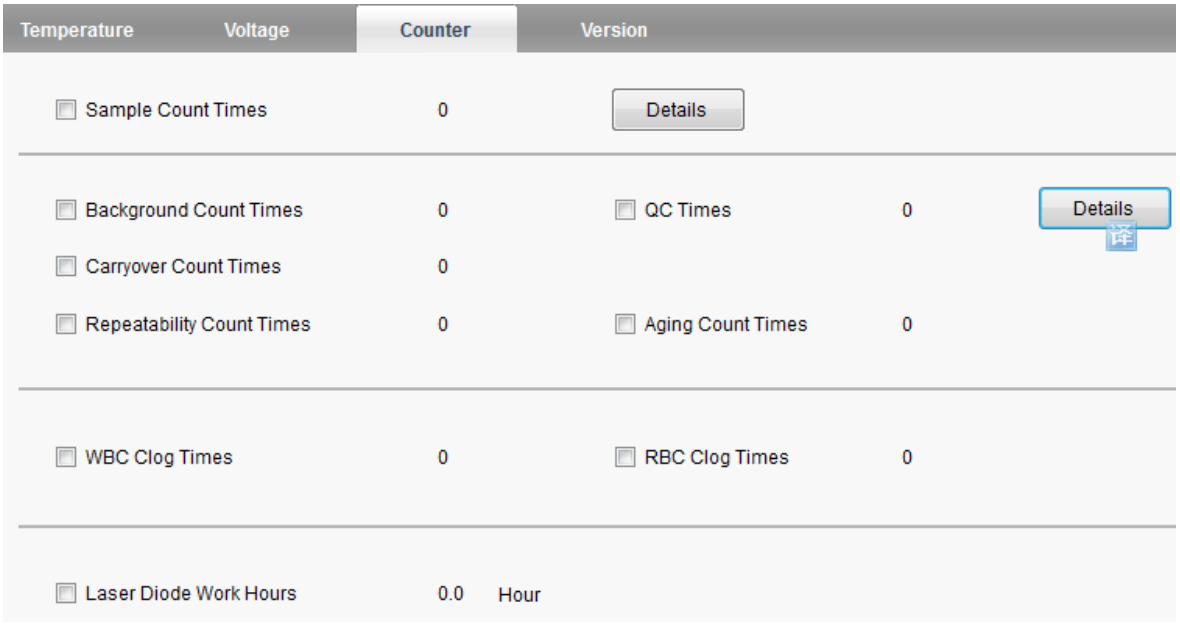


User can view the voltage and current information of the analyzer. The voltage or current value that exceeds the normal range will be displayed in a red background.

12.3.3 Counter

Click **Status** > **Counter** to access the **Counter** interface.

Figure 12-25 Counter

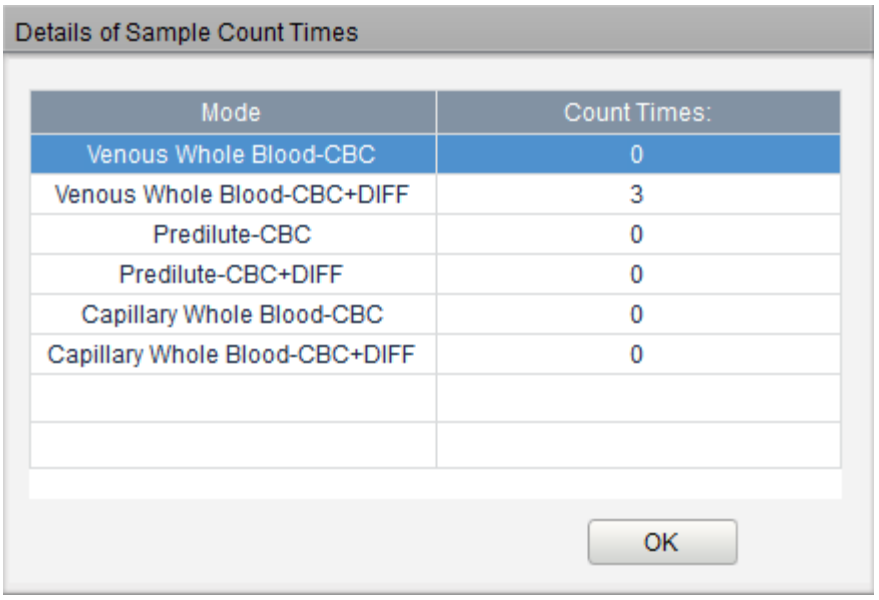


User can view the device related statistics, such as Sample Count, QC Count, Laser Diode Lifetime (hr), and Clogging Count. Besides, user can view the detailed statistics of Sample Count and QC Count.

- View details of Sample Count.

  Click the **Details** button next to **Sample Count**, the detailed statistics of Sample Count will be displayed. See Figure 12-26.

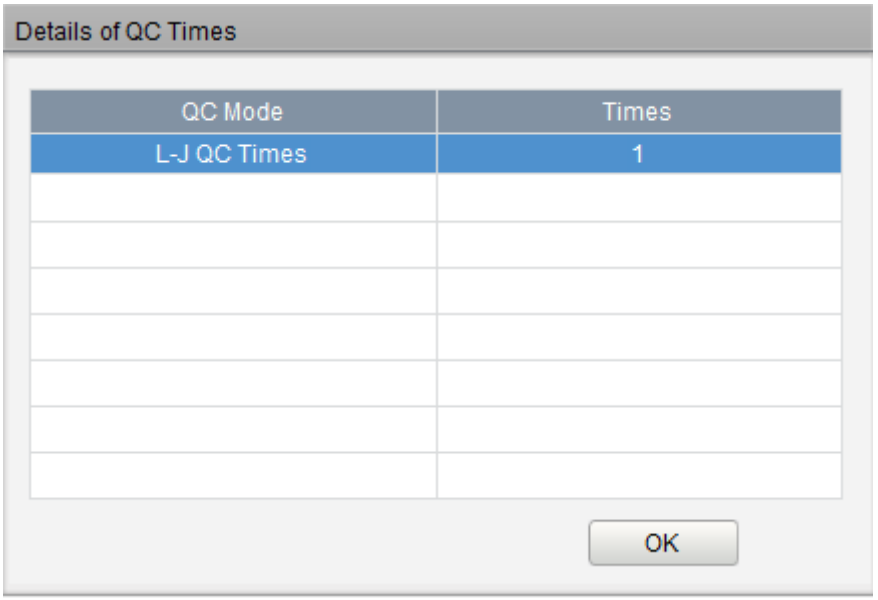
Figure 12-26 Details of Sample Count



- View details of QC Count.

  Click the **Details** button next to **QC Count**, the detailed statistics of QC Count will be displayed. See Figure 12-27.

Figure 12-27 Details of QC Count

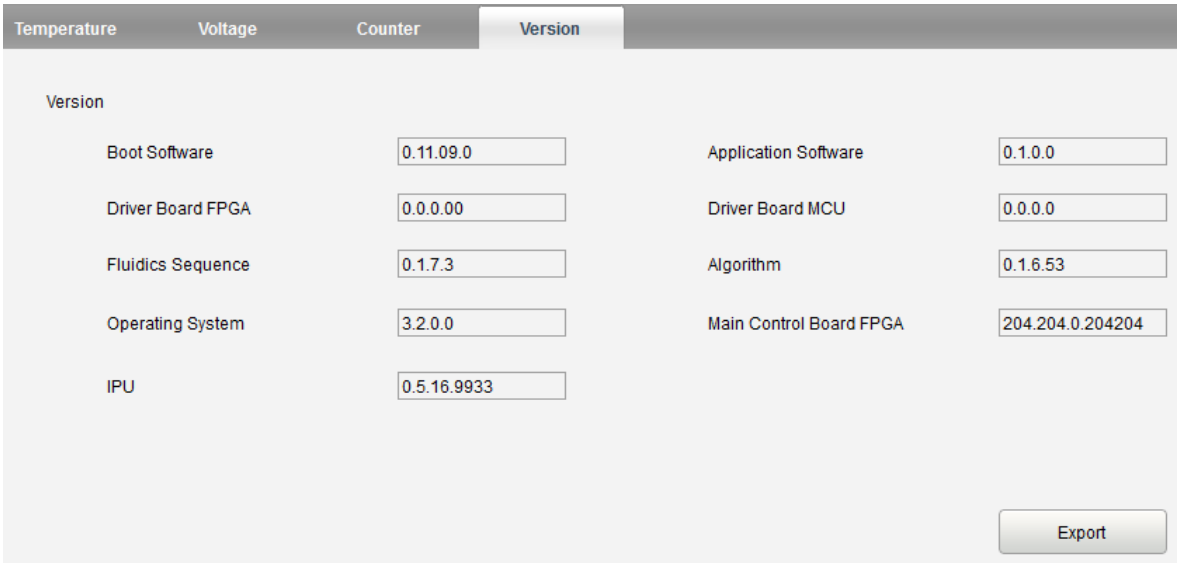


12.3.4 Version Information

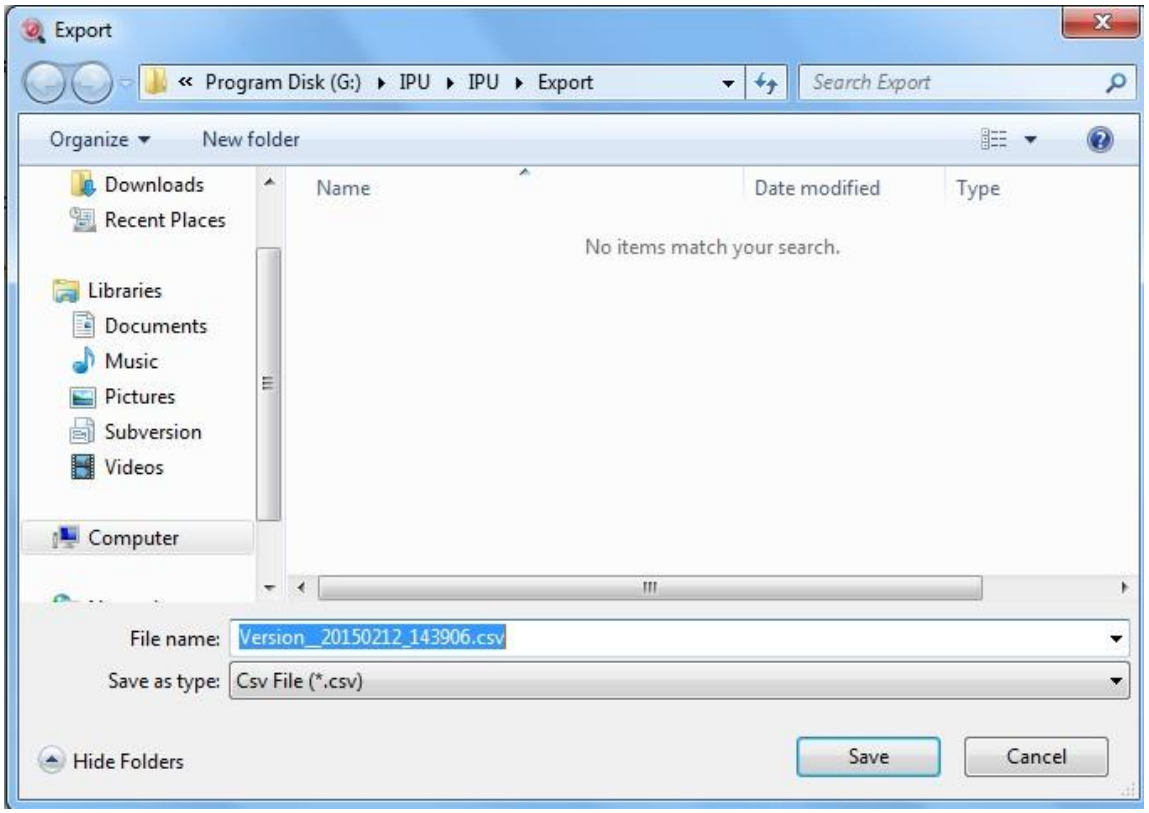
User can view the current version information of all parts of the analyzer, and export the version information to a local disk. Procedures are shown as follows:

1. Click **Status** > **Version** to access the Version Information interface. See Figure 12-28.

Figure 12-28 Version Information

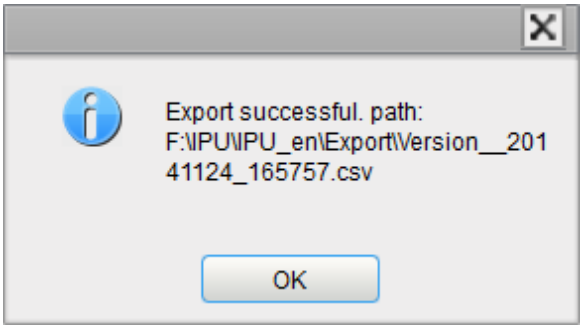


2. Click **Export**, and select the export path in the dialog box, and then enter the file name. As shown below.



3. Click **Save** to start exporting.

   After Export is completed, the message box as shown below will pop up.



4. Click **OK** to exit.

12.4 Self-inspection

This feature is to test if some important components of the device can function properly or not, including syringe 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 Dymind customer service department or your local agent.

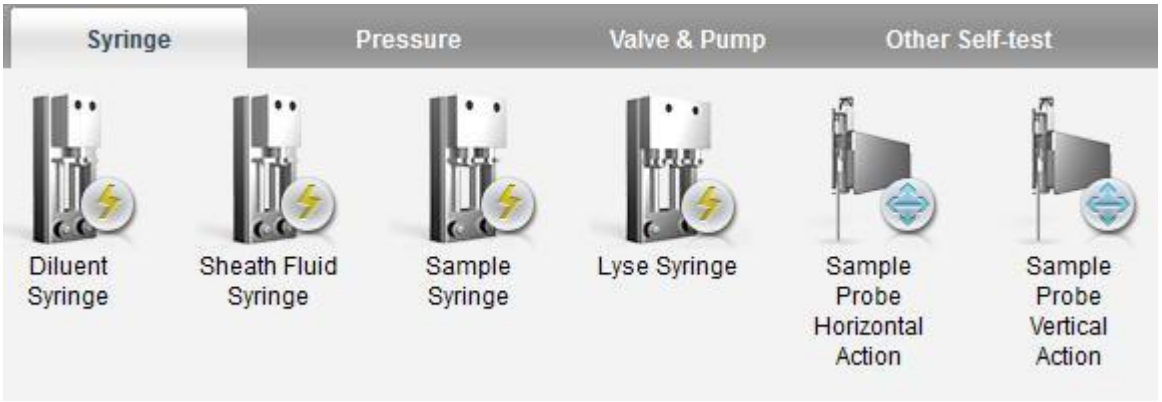
12.4.1 Syringe and Sampling Mechanism

The user can test the performance of all syringes and sampling mechanisms.

The self-inspection procedures are shown as below:

1. Click **Self-test > Syringe** to access the Syringe self-test interface. See Figure 12-29.

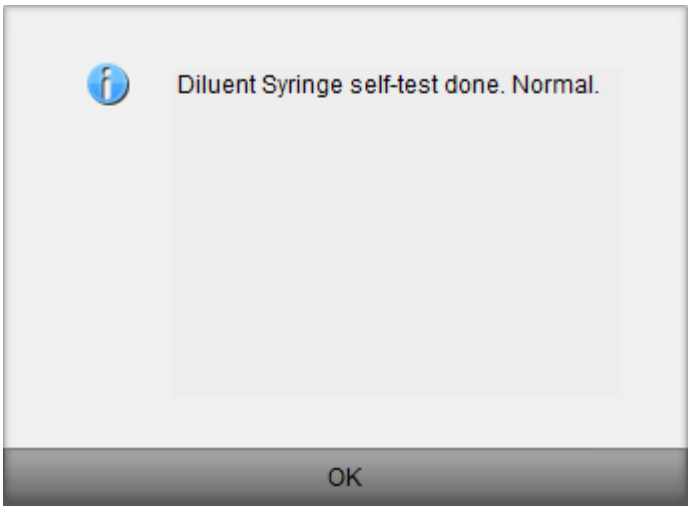
Figure 12-29 Syringe



2. Double click the part that needs to be tested, e.g. **Diluent 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 12-30 Syringe Self-test Results



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

12.4.2 Pressure and Vacuum

This feature is to test the pressure and vacuum inside the device.

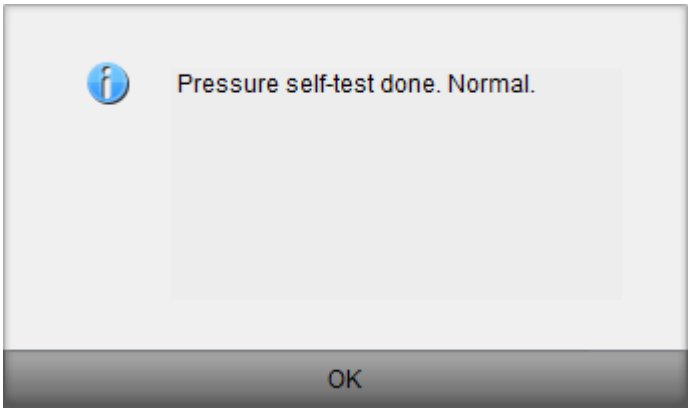
Procedures for pressure (or vacuum) self-inspection are shown as below:

1. Click **Self-test > Pressure** to access the Pressure and Vacuum interface.

Figure 12-31 Pressure and Vacuum Self-inspection

2. Double 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.



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

12.4.3 Valve & Pump

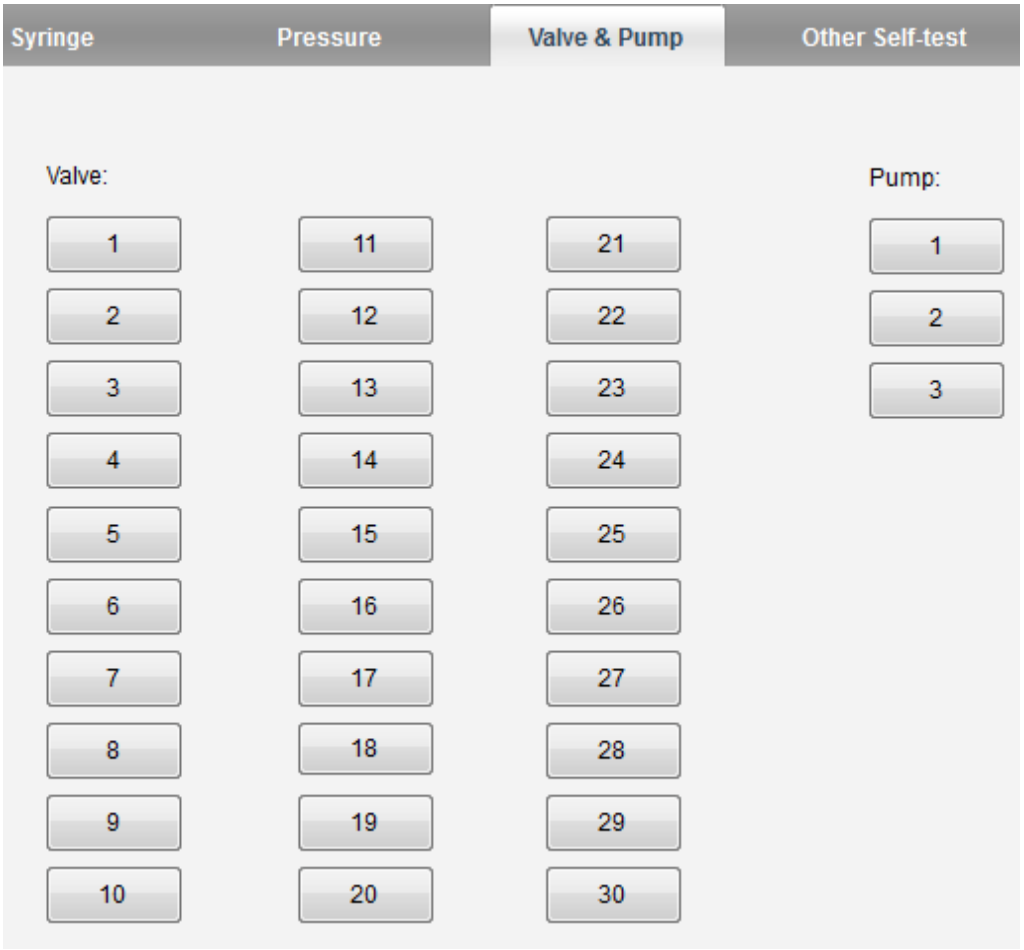
When controlling the switches of different valves (pumps), the user can judge if the valves (pumps) are operating properly by the sound of opening, closing or manually touching the corresponding valves (pumps).

The procedures for valve self-inspection are shown as follows:

1. Select **Self-test > Valve & Pump** tab.

   The **Valve & Pump** self-test interface appears as shown in Figure 12-32.

Figure 12-32 Valve Self-test



2. Click the desired Valve No. (e.g. **1**), then confirm whether it works properly by the sound of its opening and closing.

12.4.4 Others

The user can also perform the following self-inspections:

- WBC aperture voltage
- RBC aperture voltage
- WBC volumetric tube filter
- RBC volumetric tube filter
- Counting time: counting time for WBC and RBC

The procedures are shown as below:

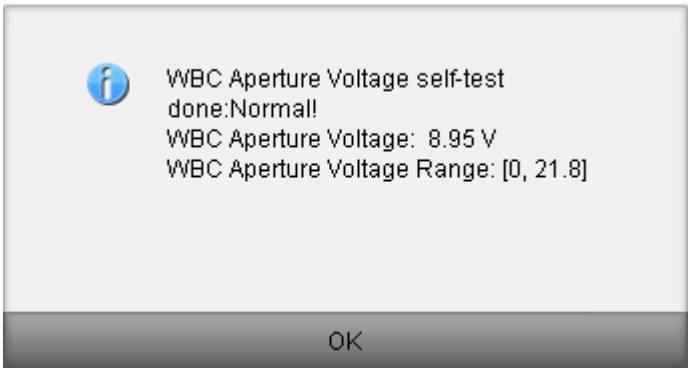
1. Click **Self-test > Other Self-test** to access the interface as shown in Figure 12-33.

Figure 12-33 Other Self-inspections

2. Double click the icon of the desired item, e.g. **WBC Aperture Voltage,** to start self-inspection.

   The system will perform corresponding self-inspection operations. After the self-inspection is completed, a dialog box will pop up to show the self-inspection results.

Figure 12-34 Other Self-inspection Results



12.5 Log

In the **Log** interface, the user can view the records of Set Paras, Other Logs, Fault Logs and All Logs.

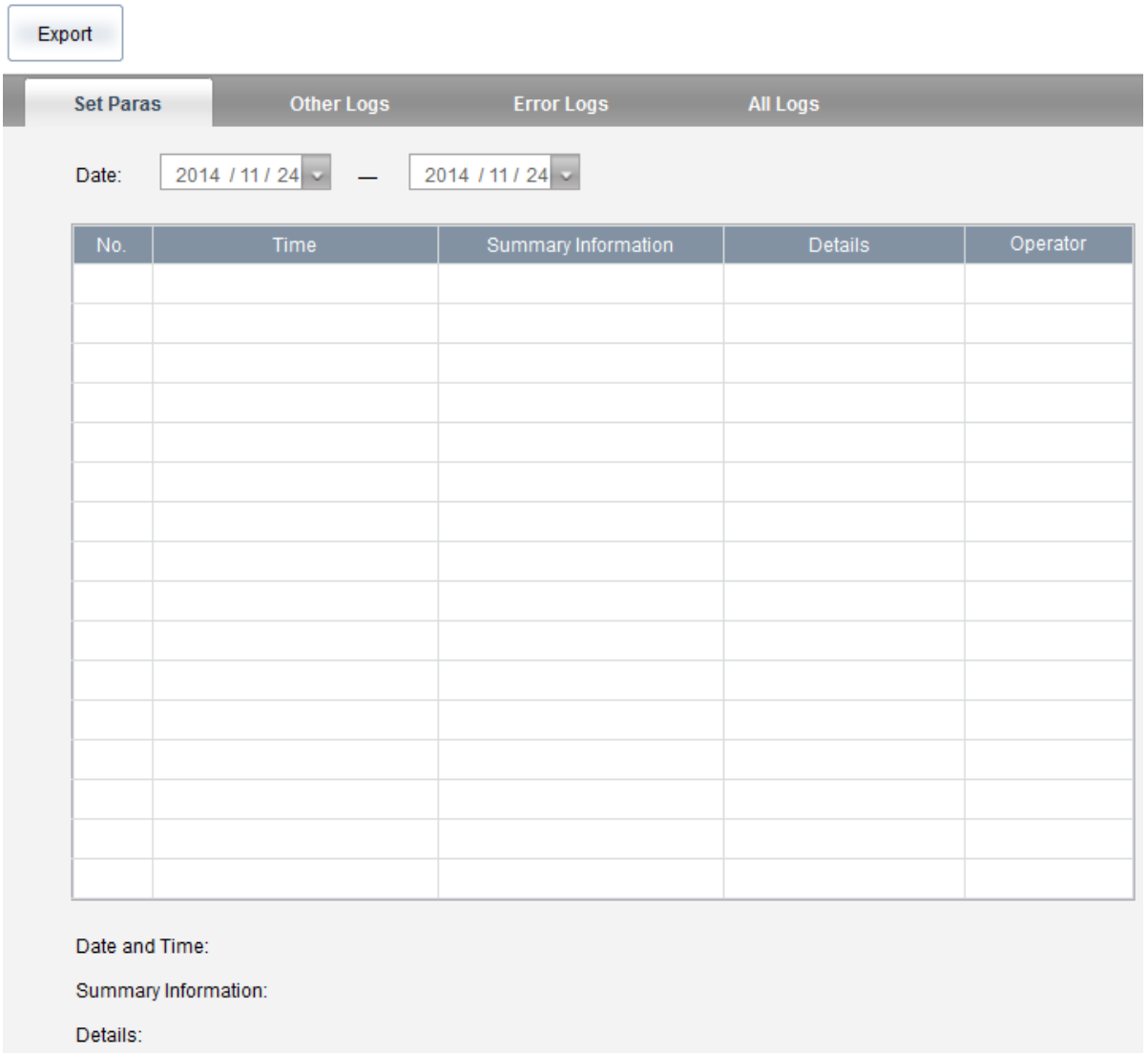
NOTE

- 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 Parameter Revision Logs

Click **Log** > **Set Paras** to access the **Parameter Revision Logs** interface.

Figure 12-35 Parameter Revision Logs



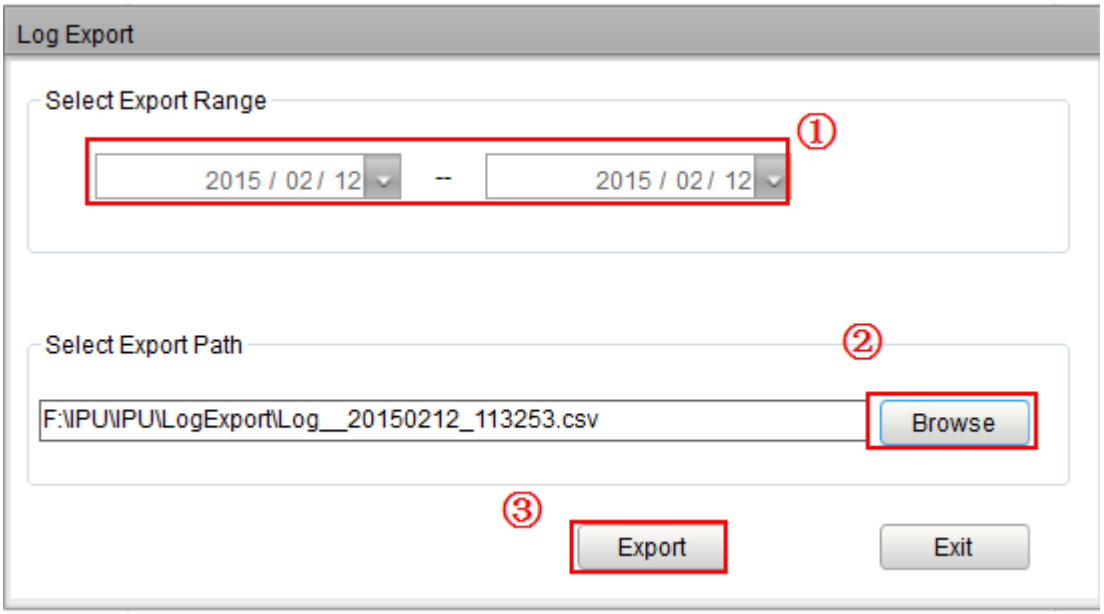
- View the parameter revision logs on specified dates

  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.

- Exporting Logs

  Click **Export**, and select the export range and export path in the dialog box, then you can save the parameter logs of the specified dates to the peripheral computer, as shown below.

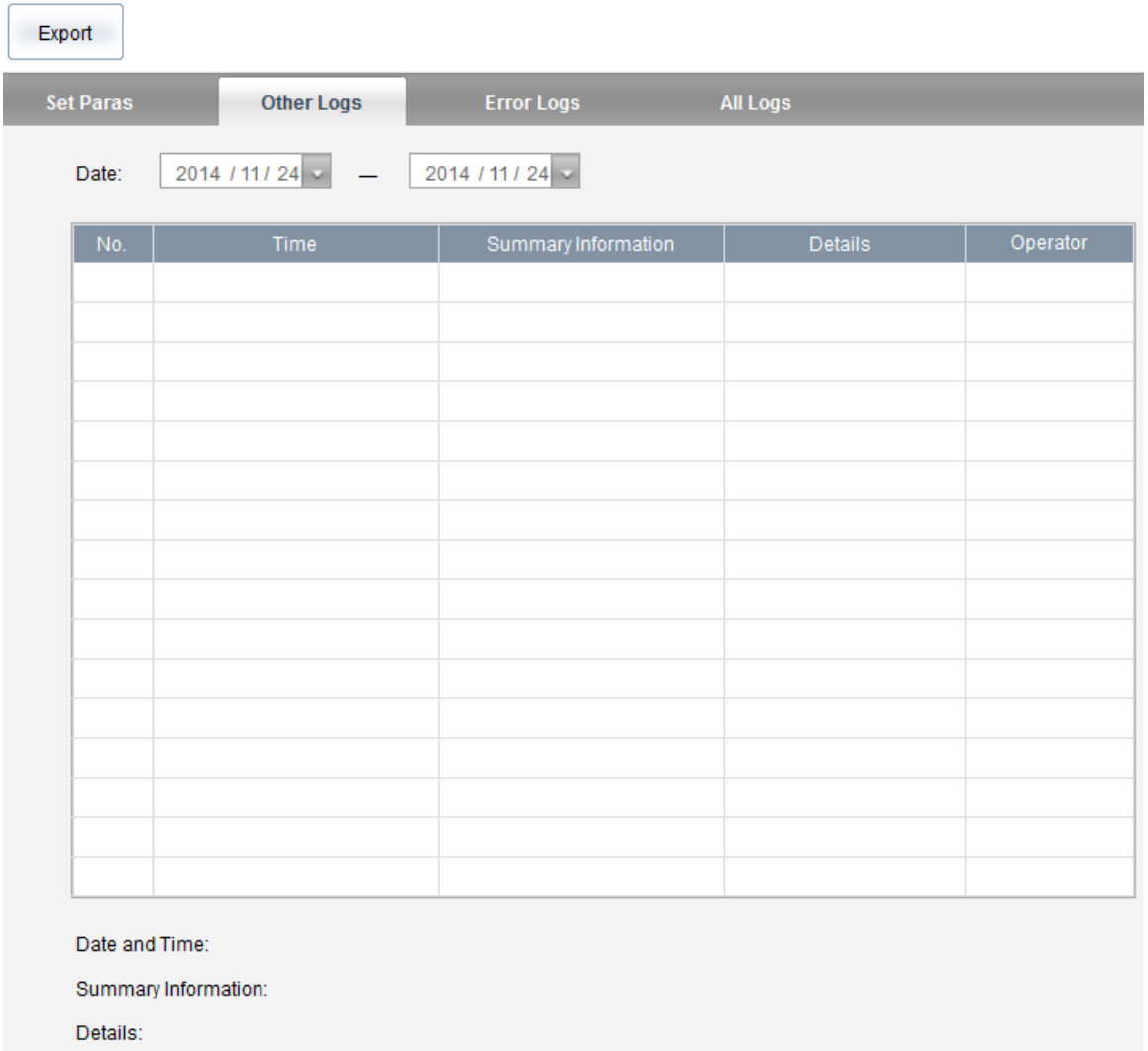
Figure 12-36 Exporting Logs



12.5.2 Other Logs

Click **Log** > **Other Logs** to access the **Other Logs** interface (except for Parameter Revision Logs and Fault Logs).

Figure 12-37 Other Logs



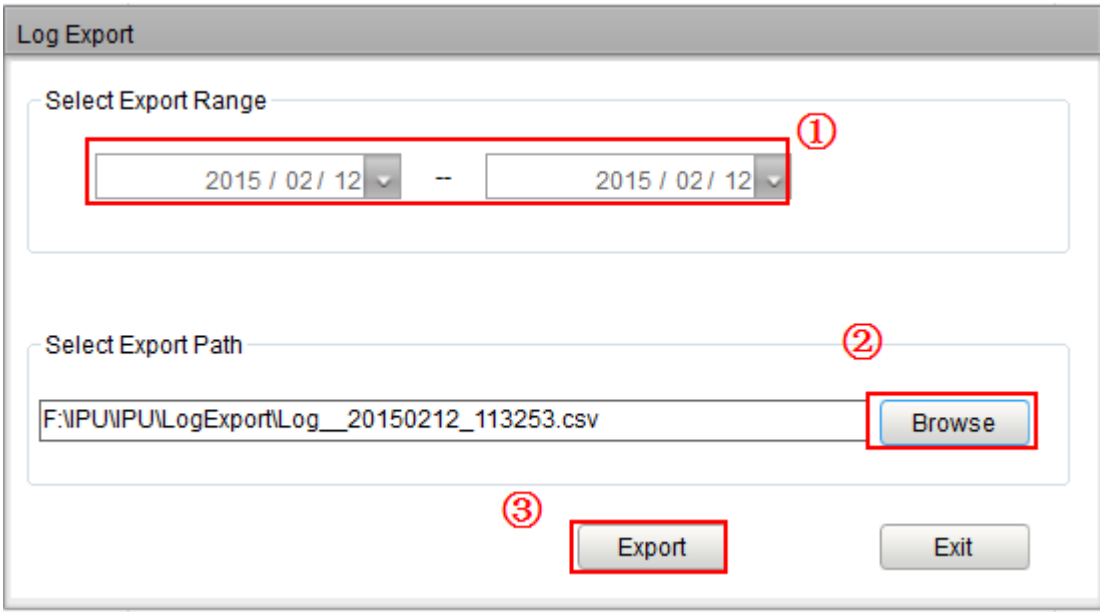
- View the logs of the specified date

  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.

- Exporting Logs

  Click **Export**, and select the export range and export path in the dialog box, then you can save the other logs of the specified dates to the peripheral computer, as shown below.

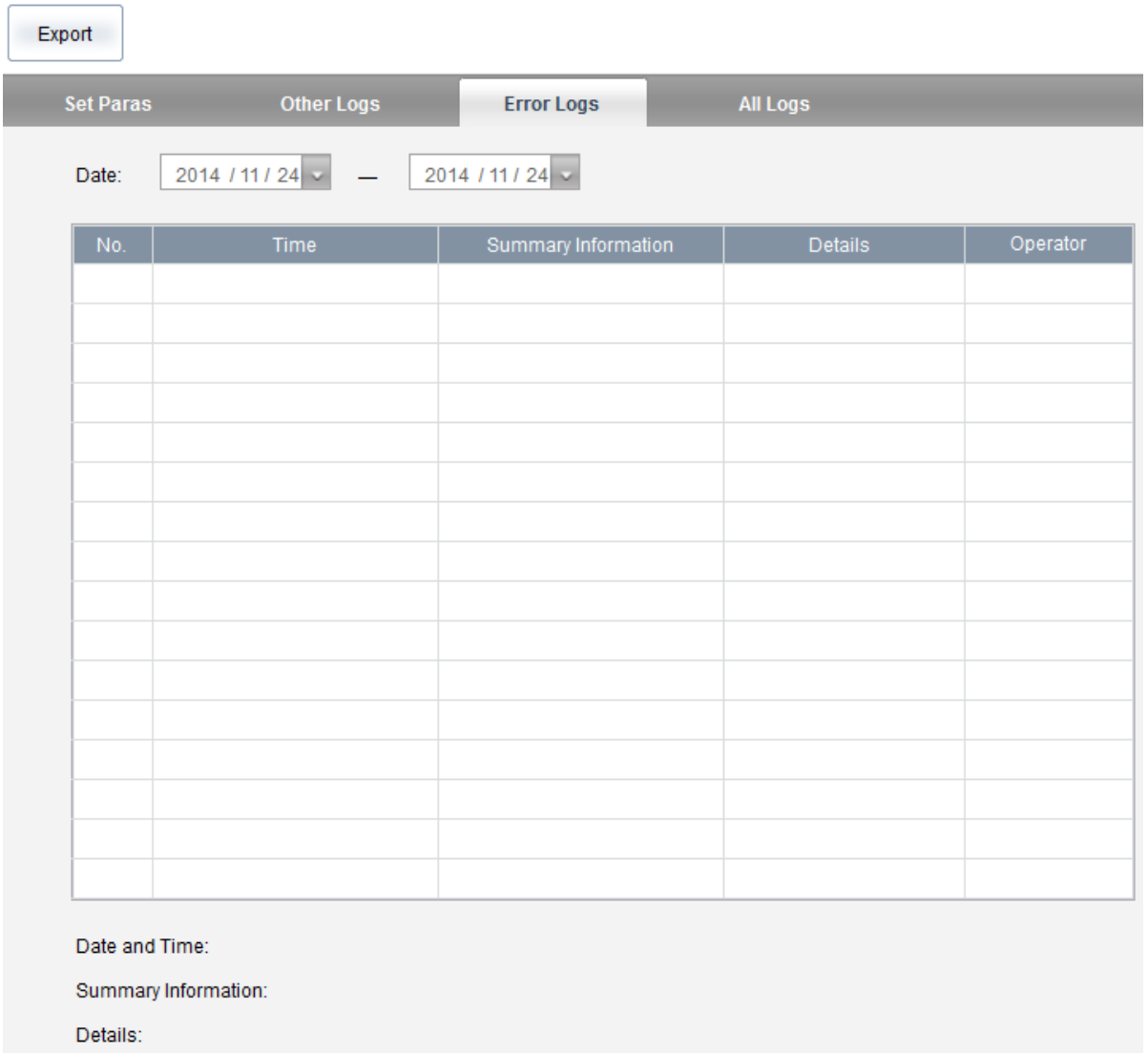
Figure 12-38 Exporting Logs



12.5.3 Fault Logs

Click **Log > Fault Logs** to access the **Fault Logs** interface.

Figure 12-39 Fault Logs



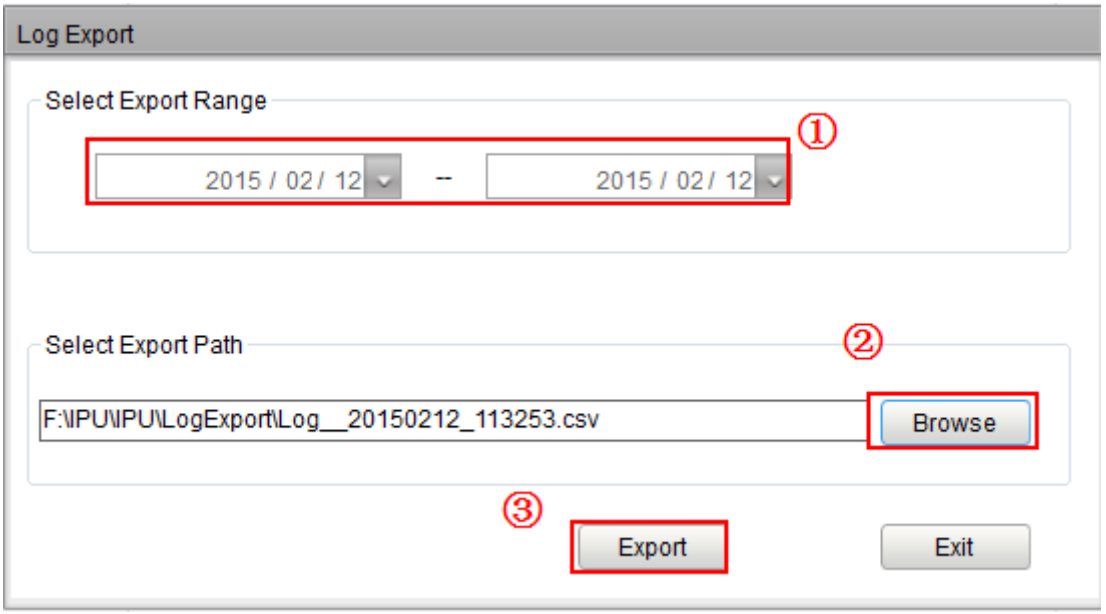
- View the fault logs of the specified dates

  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.

- Exporting Logs

  Click **Export**, and select the export range and export path in the dialog box, then you can save the fault logs of the specified dates to the peripheral computer, as shown below.

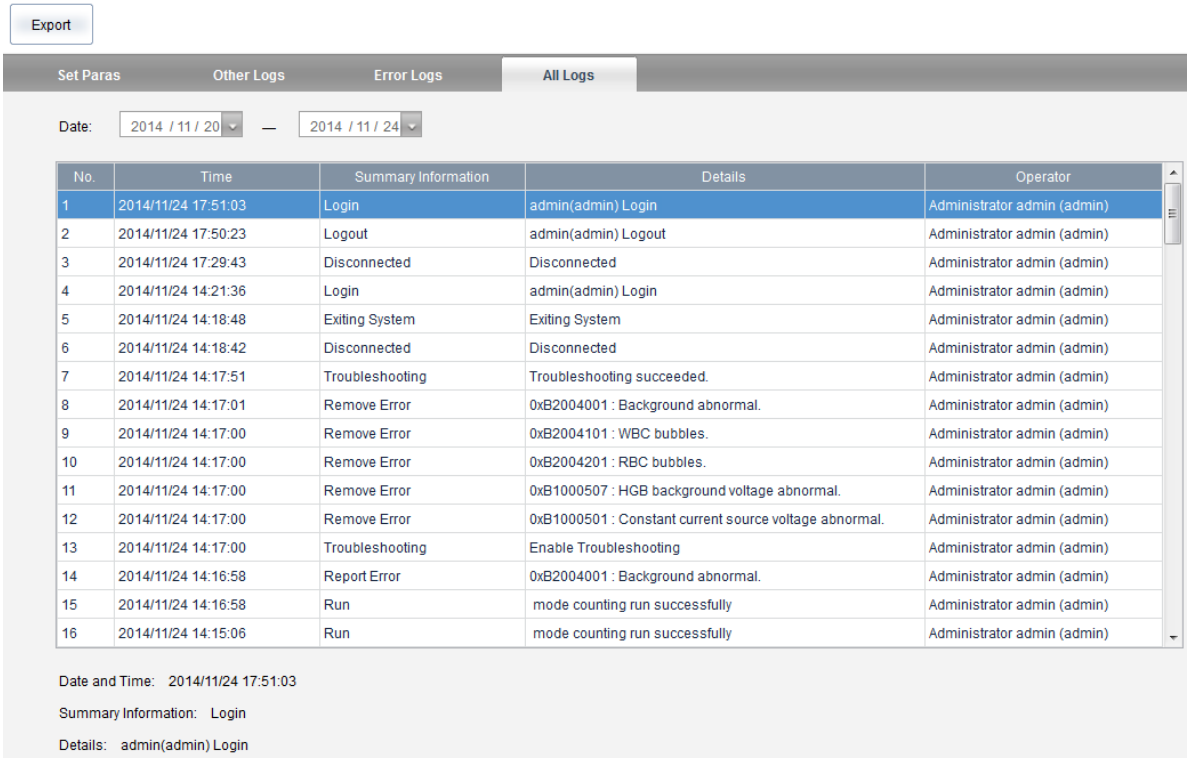
Figure 12-40 Exporting Logs



12.5.4 All Logs

Click **Log** > **All Logs** to access the **All Logs** interface. User can view All Logs (visible to the users of the current access level).

Figure 12-41 All Logs



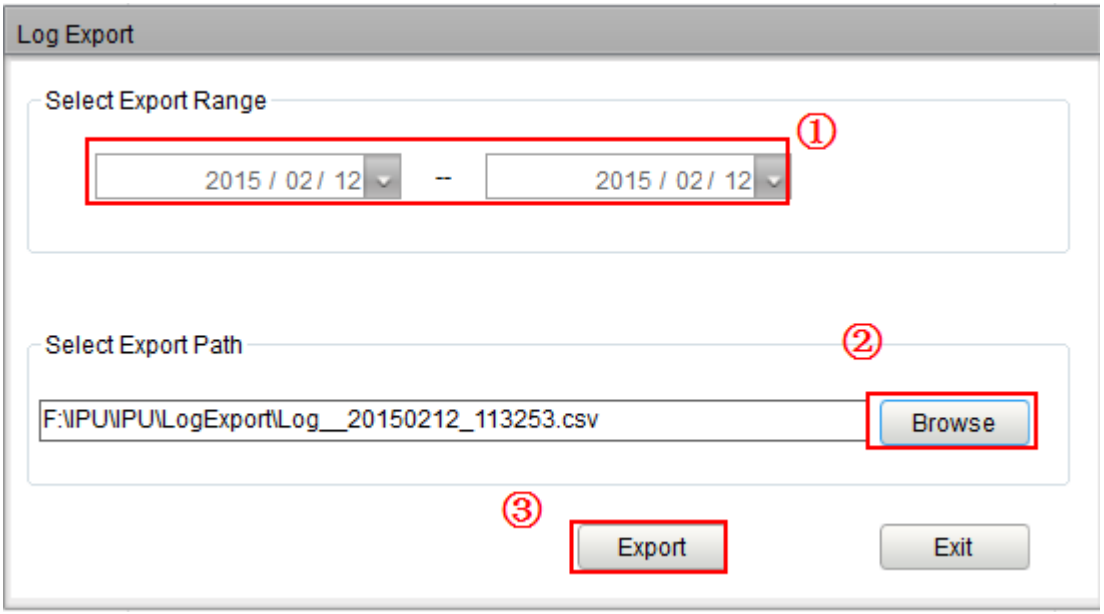
- View all the fault logs of the specified date

Select the dates in the two date textboxes, and then you can view the all logs within the date range, including operation date and time, operation details and the operator.

- Exporting Logs

  Click **Export**, and select the export range and export path in the dialog box, then you can save all logs of the specified dates to the peripheral computer, as shown below.

Figure 12-42 Exporting Logs



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.

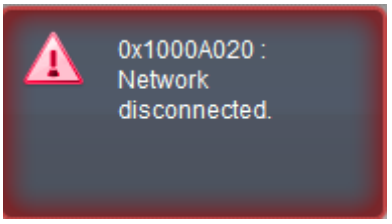
NOTE

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 Dymind 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 bottom right of the screen as shown in Figure 13-1 and the main unit will sound an alarm.

Figure 13-1 Error Messages

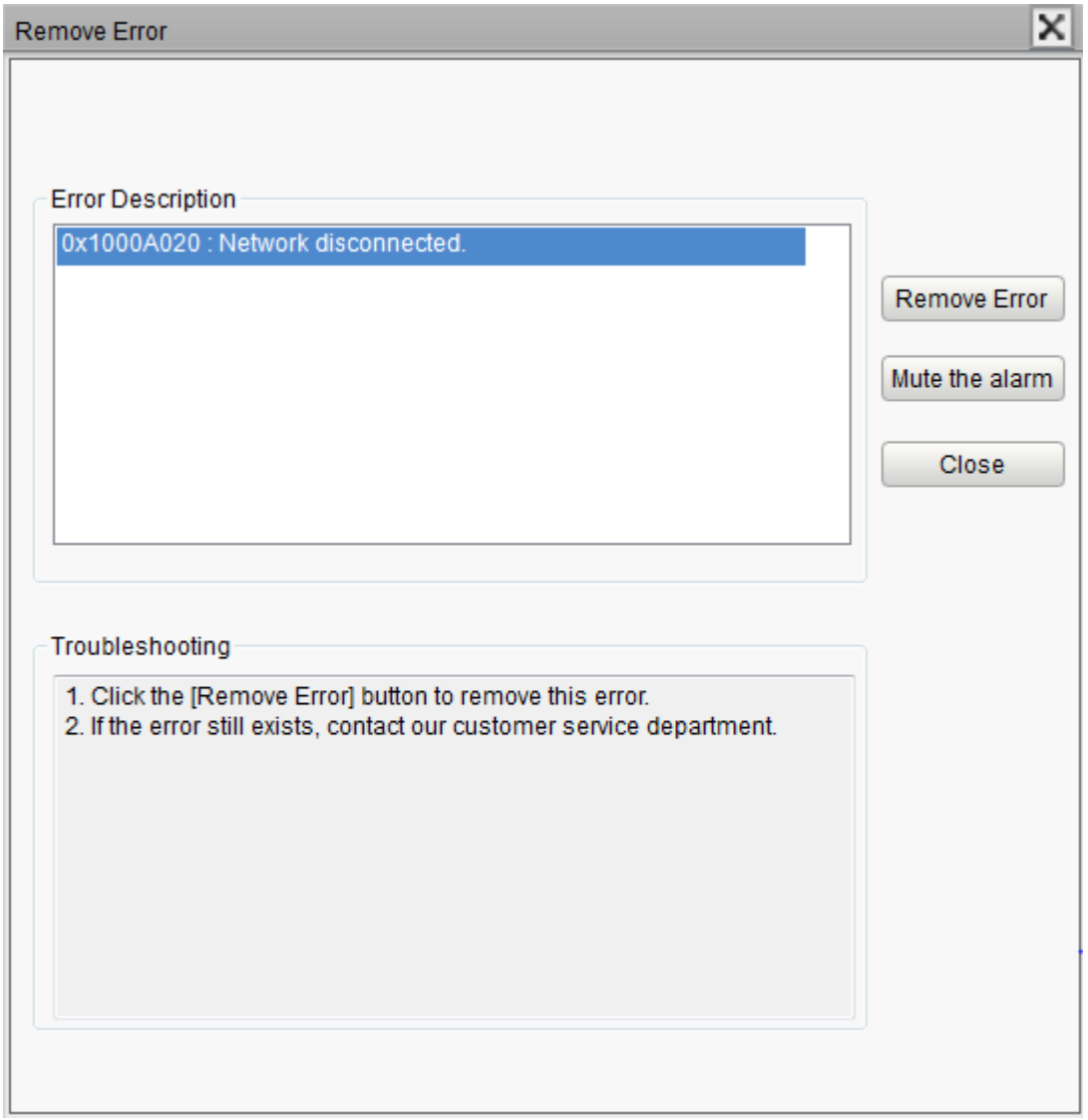


You can refer to the following steps to deal with the error messages.

1. Double 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. Press **Mute the Alarm** to disable the beep.
3. Click **Remove Error**.

   Normally, the system will automatically remove the errors.

   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
CAN initialization failure.	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
SPI initialization failure	1. Click the **Remove Error** button to remove this error. 2. 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.
Optical assembly cover is open.	1. Close the optical assembly cover. 2. Click the **Remove Error** button to remove this error. 3. 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.
Abnormal laser current.	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.
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 turn off the analyzer power directly and restart later. 2. If the error still exists, contact our customer service department.
The temperature setting of DIFF bath exceeds the limit.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal HGB background voltage	1. Adjust the HGB gain by entering the dialog box to set the voltage within [4.2, 4.8] V, preferably 4.5V as instructed in 6.9.2 ***Gain Settings***. 2. If the error still exists, contact our customer service department.
Data transmission failure	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
RBC clogging	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, see ***12.2.3.5 Cleanser Soak for RBC Channel*** to dip the RBC bath in the cleanser. 3. If the error still exists, contact our customer service department.
RBC volumetric tube is dirty.	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, see ***12.2.3.5 Cleanser Soak for RBC Channel*** to dip the RBC bath in the cleanser. 3. If the error still exists, contact our customer service department.

Error description	Troubleshooting Information
RBC end photocoupler is triggered repeatedly.	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, do the **Clean Fluidics** operation. 3. If the error still exists, contact our customer service department.
RBC start photocoupler is triggered repeatedly.	1. Click the **Remove Error** button to remove this error. 2. If the error reports frequently, do the **Clean Fluidics** operation. 3. If the error still exists, contact our customer service department.
RBC bubbles.	1. Check whether the pickup tube connection is loosened. 2. If the connection is not loose, click the **Remove Error** button to remove the error. 3. If the error still exists, contact our customer service department.
Clogging of RBC volumetric tube filter.	1. Click the **Remove Error** button to remove this error. 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.
WBC clogging.	1. Click the **Remove Error** button to remove this error. 2. If the error reports frequently, see ***12.2.3.4 Cleanser Soak for WBC Channel*** to dip the WBC bath in the cleanser. 3. If the error still exists, contact our customer service department.
WBC volumetric tube is dirty.	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, see ***12.2.3.4 Cleanser Soak for WBC Channel*** to dip the WBC bath in the cleanser. 3. If the error still exists, contact our customer service department.
WBC end photocoupler is triggered repeatedly.	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, See ***12.2.4.2 Clean Fluidics*** to do the Clean Fluidics operation. 3. If the error still exists, contact our customer service department.
WBC start photocoupler is triggered repeatedly.	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, See ***12.2.4.2 Clean Fluidics*** to do the Cleanse Fluidics operation. 3. If the error still exists, contact our customer service department.
WBC bubbles.	1. Check whether the pickup tube connection is loosened. 2. If the connection is not loose, click the **Remove Error** button to remove the error. 3. If the error still exists, contact our customer service department.
Clogging of WBC volumetric tube filter	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.

Error description	Troubleshooting Information
Abnormal background	1. Check whether the diluent is contaminated. 2. If not, click the **Remove Error** button to remove the error. 3. If the error still exists, contact our customer service department.
Pump 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 sample syringe 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 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 DIFF bath temperature.	1. Make sure the temperature sensor is correctly installed. 2. If the error still exists, contact our customer service department.
Failed to read optical system temperature.	1. Make sure the temperature sensor is correctly installed. 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.

Error description	Troubleshooting Information
Failed to read pressure AD.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Valve number error.	1. Click the **Remove Error** button to remove this error. 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.
The setting value of optical system temperature exceeds the limit.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Optical system temperature out of working range.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Temperature out of working range.	1. Make sure the ambient temperature is within the normal range [15, 30] °C. Analysis results may be incorrect if the ambient temperature is out of the normal range. 2. Click the **Remove Error** button to remove the error. 3. If the error still exists, contact our customer service department.
Flow chamber clogging.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read SH syringe 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 SH syringe parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
SH syringe timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
SH syringe 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 LYSE syringe 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 LYSE syringe parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
LYSE syringe timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
LYSE syringe busy.	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 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.
Failed to read the remaining steps of Horizontal motor.	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.
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.
DIL-A expiration.	1. Check if the DIL-A diluent expires. If so, replace it with a new container of DIL-A. 2. Set the reagent Exp. date as instructed in ***12.2.5 Reagent Management***. 3. Click the **Remove Error** button to remove this error. 4. If the error still exists after a new container of DIL-A is installed, contact our customer service department.
Insufficient DIL-A.	1. Enter **Reagent Management** to modify the reagent information as instructed in ***12.2.5 Reagent Management***. 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
DIL-A not replaced.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
No DIL-A.	1. Check whether the DIL-A container is empty. If so, perform step 2; or if there is still plenty of DIL-A, contact our customer service department. 2. Install a new container of DIL-A. Then click the **Remove Error** button to prime the analyzer with the DIL-A. 3. Enter Reagent Management to modify the reagent Exp. date as instructed in ***12.2.5 Reagent Management***. 4. If the error still exists after a new container of DIL-A is installed, contact our customer service department.

Error description	Troubleshooting Information
LYA-1 expiration.	1. Check if the LYA-1 lyse expires. If so, replace it with a new container of LYA-1. 2. Set the reagent Exp. date as instructed in ***12.2.5 Reagent Management***. 3. Click the **Remove Error** button to remove this error. 4. If the error still exists after a new container of LYA-1 is installed, contact our customer service department.
InsufficientLYA-1.	1. Enter Reagent Management to modify the reagent information as instructed in ***12.2.5 Reagent Management***. 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
LYA-1 not replaced.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
No LYA-1.	1. Check whether the LYA-1 container is empty. If so, perform step 2; or if there is still plenty of LYA-1, contact our customer service department. 2. Install a new container of LYA-1. Then click the **Remove Error** button to prime the analyzer with the LYA-1. 3. Enter Reagent Management to modify the reagent Exp. date as instructed in ***12.2.5 Reagent Management***. 4. If the error still exists after a new container of LYA-1 is installed, contact our customer service department.
LYA-2 expiration.	1. Check if the LYA-2 lyse expires. If so, replace it with a new container of LYA-2. 2. Set the reagent Exp. date as instructed in ***12.2.5 Reagent Management***. 3. Click the **Remove Error** button to remove this error. 4. If the error still exists after a new container of LYA-2 is installed, contact our customer service department.
Insufficient LYA-2.	1. Enter Reagent Management to modify the reagent information as instructed in ***12.2.5 Reagent Management***. 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
LYA-2 not replaced.	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
No LYA-2.	1. Check whether the LYA-2 container is empty. If so, perform step 2; or if there is still plenty of LYA-2, contact our customer service department. 2. Install a new container of LYA-2. Then click the **Remove Error** button to prime the analyzer with the LYA-2. 3. Enter Reagent Management to modify the reagent Exp. date as instructed in ***12.2.5 Reagent Management***. 4. If the error still exists after a new container of LYA-2 is installed, contact our customer service department.
LYA-3 expiration.	1. Check if the LYA-3 lyse expires. If so, replace it with a new container of LYA-3. 2. Set the reagent Exp. date as instructed in ***12.2.5 Reagent Management***. 3. Click the **Remove Error** button to remove this error. 4. If the error still exists after a new container of LYA-3 is installed, contact our customer service department.
Insufficient LYA-3.	1. Enter Reagent Management to modify the reagent information as instructed in ***12.2.5 Reagent Management***12.2.5 . 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
LYA-3 not replaced.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
No LYA-3.	1. Check whether the LYA-3 container is empty. If so, perform step 2; or if there is still plenty of LYA-3, contact our customer service department. 2. Install a new container of LYA-3. Then click the **Remove Error** button to prime the analyzer with the LYA-3. 3. Enter Reagent Management to modify the reagent Exp. date as instructed in ***12.2.5 Reagent Management***12.2.5 . 4. If the error still exists after a new container of LYA-3 is installed, contact our customer service department.
Failed to read diluent syringe 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 diluent syringe parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Diluent syringe timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Diluent syringe busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Build positive pressure busy.	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 build positive pressure.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
The pressure of the positive-pressure chamber exceeds the normal operation range.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Positive pressure is abnormal (low).	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Positive pressure is abnormal (high).	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
DIFF probe clogging	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Build Vacuum pressure busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to build vacuum pressure.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vacuum pressure out of working range.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vacuum pressure is abnormal (low).	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vacuum pressure is abnormal (high).	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
SOCKET initialization failed.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal network disconnection	1. Click the **Remove Error** button to remove this error. 2. 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-A Diluent
Lyse	LYA-3 Lyse
	LYA-2 Lyse
	LYA-1 Lyse
Medical cleanser	Cleanser

A.3 Parameters

Parameter	Abbreviation	Default Unit
White Blood Cell count	WBC count	10^9/L
Number of Neutrophils	Neu#	10^9/L
Number of Lymphocytes	Lym#	10^9/L
Number of Monocytes	Mon#	10^9/L
Number of Eosinophils	Eos#	10^9/L
Number of Basophils	Bas#	10^9/L
Number of Abnormal Lymphocytes	ALY# (RUO)	10^9/L
Number of Large Immature Cells	LIC# (RUO)	10^9/L
Percentage of Neutrophils	Neu%	%
Percentage of Lymphocytes	Lym%	%
Percentage of Monocytes	Mon%	%
Percentage of Eosinophils	Eos%	%

Parameter	Abbreviation	Default Unit
Percentage of Basophils	Bas%	%
Percentage of Abnormal Lymphocytes	ALY% (RUO)	%
Percentage of Large Immature Cells	LIC% (RUO)	%
Red Blood Cell count	RBC count	10^{12}/L
Hemoglobin Concentration	HGB concentration	g/L
Hematocrit	HCT	%
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L
Red Blood Cell Distribution Width Standard Deviation	RDW-SD	fL
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV	%
Platelet count	PLT count	10^{9}/L
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	NA
Plateletcrit	PCT	%
Platelet-large cell ratio	P-LCR	%
Platelet-large cell count	P-LCC	10^{9}/L
Red Blood Cell Histogram	RBC Histogram	NA
Platelet Histogram	PLT Histogram	NA
White Blood Cell/Basophils Scattergram	WBC/BASO Histogram	NA
White Blood Cell Histogram	WBC Histogram	NA
5 Differential Scattergram	DIFF Scattergram	NA

A.4 Sampling Features

A.4.1 Sample Volume Required for Each Analysis

No more than 20 μL.

A.4.2 Throughput

No less than 60 samples/hour.

A.5 Performance Specifications

A.5.1 Display Range

Parameter	Linearity Range	Display Range
WBC	(0.00~300) $\times10^9$/L	(0.00~999.99) $\times10^9$/L
RBC	(0.00~8.50) $\times10^{12}$/L	(0.00~18.00) $\times10^{12}$/L
HGB	0~250g/L	0~300g/L
PLT	0~3000$\times10^9$/L	0~5000$\times10^9$/L
HCT	0~67%	0%~80%

A.5.2 Normal Background

Parameter	Background Result
WBC	≤0.2$\times10^9$/L
RBC	≤0.02$\times10^{12}$/L
HGB	≤1g/L
PLT	≤10$\times10^9$/L
HCT	≤0.5%

A.5.3 Linearity Range

Parameter	Linearity range	Deviation range (Whole blood mode)	Deviation range (Predilute Mode)
WBC	(0.00~100.00) $\times10^9$/L	±0.50$\times10^9$/L or ±5%	±0.60$\times10^9$/L or ±6%
	(100.01~300.00) $\times10^9$/L	±10%	±12%
RBC	(0.00~8.50) $\times10^{12}$/L	±0.05$\times10^{12}$/L or ±5%	±0.10$\times10^{12}$/L or ±10%
HGB	(0~250) g/L	±2g/L or ±2%	±4g/L or ±4%
PLT	(0~1000) $\times10^9$/L (RBC≤7.0)	±10$\times10^9$/L or ±8%	±20$\times10^9$/L or ±16%
	(1001~3000) $\times10^9$/L (RBC≤7.0)	±12%	±20%
HCT	0~67%	±2% (HCT value) or ±3% (deviation percent)	±4% (HCT value) or ±6% (deviation percent)

A.5.4 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	Whole Blood Repeatability (CV%/absolute deviation d※)	Predilute Repeatability (CV%/absolute deviation d※)
WBC	(4.0~15.0)×10^9/L	≤2.0%	≤4.0%
Neu%	50.0%~60.0%	±4.0 (absolute deviation)	±8.0 (absolute deviation)
Lym%	25.0%~35.0%	±3.0 (absolute deviation)	±6.0 (absolute deviation)
Mon%	5.0%~10.0%	±2.0 (absolute deviation)	±4.0 (absolute deviation)
Eos%	2.0%~5.0%	±1.5 (absolute deviation)	±2.5 (absolute deviation)
Bas%	0.5%~1.5%	±0.8 (absolute deviation)	±1.2 (absolute deviation)
RBC	(3.50~6.00)×10^{12}/L	≤1.5%	≤3.0%
HGB	(110~180) g/L	≤1.5%	≤3.0%
PLT	(150~500)×10^9/L	≤4.0%	≤8.0%
MCV	(70~120) fL	≤1.0%	≤2.0%

※ Absolute deviation d = analysis result – average of analysis results

A.5.5 Carryover

Parameter	Carryover
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.5%
PLT	≤1.0%
HCT	≤0.5%

A.6 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.

NOTE

If LIS communication is required, the peripheral computer must have two network interface cards.

- External Computer (Optional)

  The peripheral computer for the analyzer must meet the following requirements:

  - RAM: ≥2G
  - Hard disk space: ≥20G
  - Operation system: 32-bit Windows XP/Windows 7
  - CPU: ≥1.4G
  - Graphics Card: OpenGL 2.0 or above
  - Display aspect ratio: 10: 6
  - Resolution: 1280*768
- Keyboard (Optional)

  101-Key alpha-numeric keyboard
- Mouse (Optional)
- External barcode scanner (optional)
- IC card reader (for closed systems only)
- Printer (Optional)
- One LAN interface
- Power Supply
  - Voltage: A.C 100V~240V
  - Input power: ≤250VA
  - Frequency: 50/60 Hz

A.7 EMC Description

This equipment complies with the emission and immunity requirements of the IEC 61326-1:2012, EN 61326-1:2013, IEC 61329-6-2-6:2012 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.

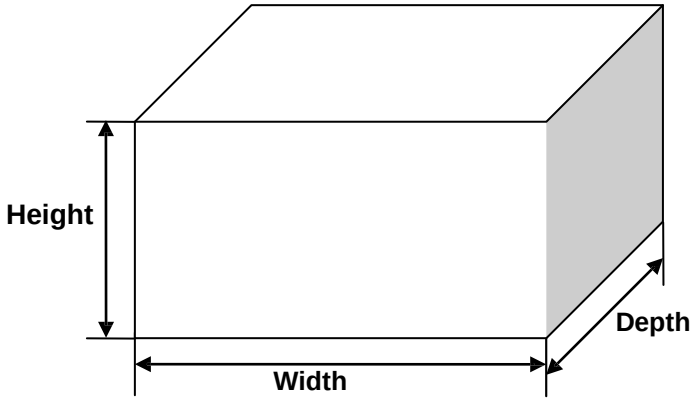
A.8 Environment Conditions

NOTE

Be sure to use and store the analyzer in the specified environment.

Environment Conditions	Operating Environment	Storage Environment	Running Environment
Ambient temperature	15°C~30°C	-10°C~40°C	10°C~40°C
Relative humidity	30%~85%	10%~90%	10%~90%
Atmospheric pressure	70kPa~110kPa	50kPa~110kPa	70kPa~110kPa

A.9 Dimensions and Weight



Analyzer	Dimensions and Weight
Width(mm)	≤380
Height(mm)	≤540
Depth(mm)	≤450
Weight(Kg)	≤42

A.10 Expected service life

5 years.

A.11 Contraindications

None

Appendix B Packing List

No.	Name	Quantity
1	Auto Hematology Analyzer	1
2	Power Cable	1
3	Data Cable (Network Cable)	1
4	Peripheral Grounding Cable	1
5	Operator's Manual	1
6	Software installation CD-ROM	1
7	Quick Operation Guide Card	1
8	LYA-1 Lyse Adapter Tube Assembly	1
9	LYA-2 Lyse Adapter Tube Assembly	1
10	LYA-3 Lyse Adapter Tube Assembly	1
11	Diluent Adapter Tube	1
12	Waste Float Adapter Tube	1
13	DIL-A Diluent	1
14	LYA-1 Lyse	1
15	LYA-2 Lyse	1
16	LYA-3 Lyse	1
17	Cleanser	1
18	Warranty Card	1
19	Air Filter	6
20	Waste container	1
21	Barcode scanner (optional)	1
22	IC Card Reader (for closed systems only)	1