OPERATING MANUAL

HEMATOLOGY ANALYZER

BDL-6701

CE ISO9001 CERTIFIED

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INDEX

1. Using This Manual

1.1 Introduction

This chapter explains how to use your BDL-6701 operator's manual, which is shipped with your BDL-6701 Auto 5-part Hematology Analyzer and contains reference information about the BDL-6701 and procedures for operating, troubleshooting and maintaining the analyzer. Read this manual carefully before operating your analyzer and operate your analyzer strictly as instructed in this manual.

1.2 Who Should Read This Manual

This manual contains information written for clinical laboratory professionals to :
Learn about the BDL-6701 hardware and software.
Customize system settings.
Perform daily operating tasks.
Perform system maintenance and troubleshooting.

1.3 Conventions Used in This Manual

This manual uses certain typographical conventions to clarify meaning in the text:
All capital letters enclosed in [ ] indicate a key name on the external keyboard, such as [ENTER].
Bold letters included in " " indicate text you can find on the screen, such as "Clean".
Bold letters indicate chapter titles, such as Chapter 1 Using This Manual.
All illustrations in this manual are provided as examples only. They may not necessarily reflect your analyzer setup or data displayed.

1.4 Safety Information

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

When you see…	Then…
	Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
	Read the statement below the symbol. The statement is alerting you to information that requires your attention.

Table 1

All the samples, controls, calibrators, reagents, waste and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
If leaking happens to the analyzer, the leak is potentially biohazardous.
Please check the firmness of all the doors, covers and boards before running the analyzer.
Make sure all the safety measurements are adopted. Do not disable any safety device or sensor.
Please take action to any alarm and error message immediately.
Do not touch the moving parts.
Contact Manufacturer or Manufacturer-authorized distributors immediately if any damaged part is found.
Be careful when opening/closing and removing/installing the doors, covers and boards of the analyzer.
Discard the analyzer according to government regulations.
Please operate your analyzer strictly as instructed in this manual.
Please adopt proper measurements to prevent the reagents from being polluted.

1.5 Symbols

You will find the following symbols in this manual :

When you see…	Then…
	Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
	Read the statement below the symbol. The statement is alerting you to information that requires your attention.

Table 2

You may find the following symbols of the analyzer system :

When you see…	It means…
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS.
	The sample probe is sharp and potentially biohazardous, please be careful when operating.
	BIOLOGICAL RISK

	HIGH VOLTAGE
	WARNING, LASER BEAM
	CC
	FOR IN VITRO DIAGNOSTIC USE
	BATCH CODE
	SERIAL NUMBER
	CATALOG NUMBER (FOR CONTROLS)
	DATE OF MANUFACTURE
	MANUFACTURER
	CONSULT INSTRUCTIONS FOR USE
	THE FOLLOWING DEFINITION OF THE WEEE LABEL APPLIES TO EU MEMBER STATES ONLY: THE USE OF THIS SYMBOL INDICATES THAT THIS PRODUCT SHOULD NOT BE TREATED AS HOUSEHOLD WASTE. BY ENSURING THAT THIS PRODUCT IS DISPOSED OF CORRECTLY, YOU WILL HELP PREVENT BRINGING POTENTIAL NEGATIVE CONSEQUENCES TO THE ENVIRONMENT AND HUMAN HEALTH. FOR MORE DETAILED INFORMATION WITH REGARD TO RETURNING AND RECYCLING THIS PRODUCT, PLEASE CONSULT THE DISTRIBUTOR FROM WHOM YOU PURCHASED THE PRODUCT.
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Indicates this device is in compliance with Europe Directive

Table 3

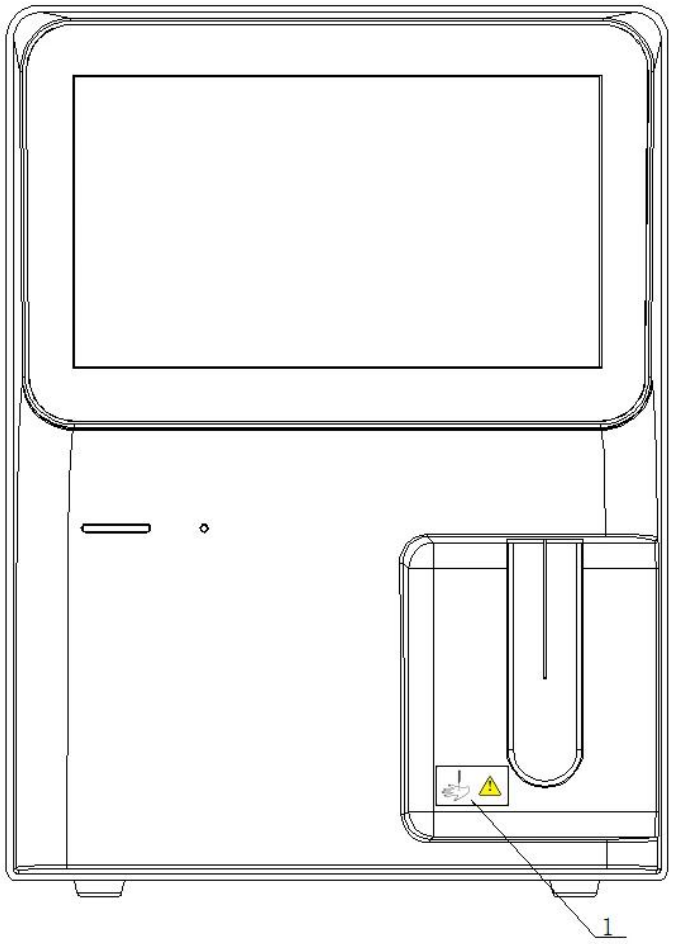

Figure 1 (Front of the analyzer)

The sample probe is sharp and potentially biohazardous, please be careful when operating.

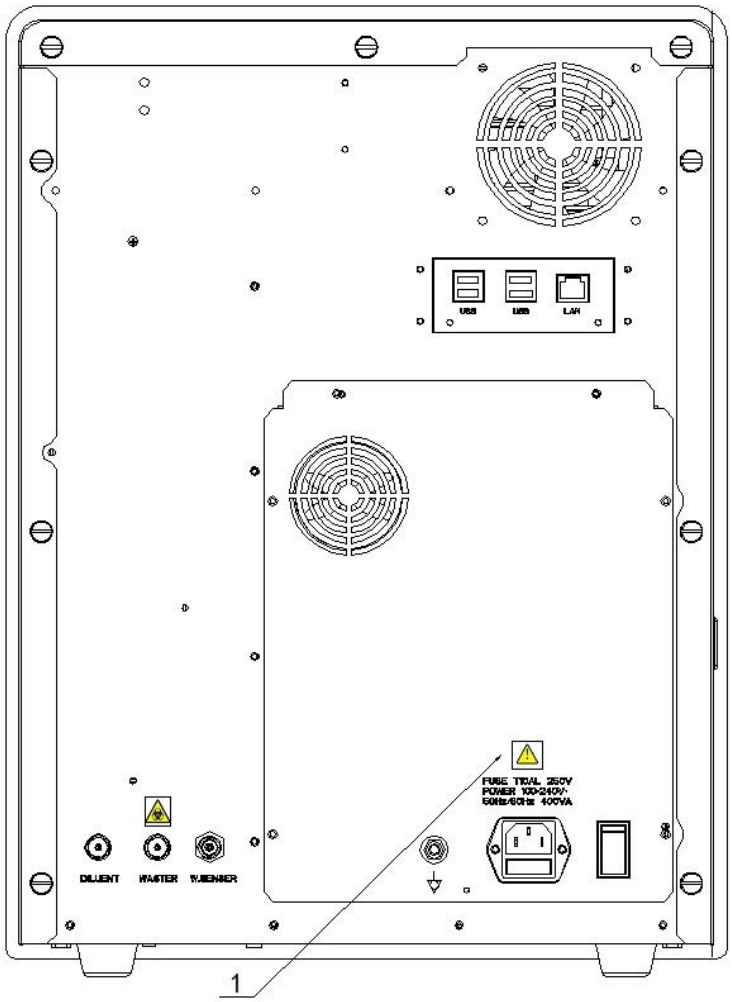

Figure 2 (Back of the Analyzer)

Connect only to a properly earth grounded outlet.
To avoid electric shock, disconnect the power cord prior to removing or replacing fuse.
Replace fuse only with the type and rating specified.

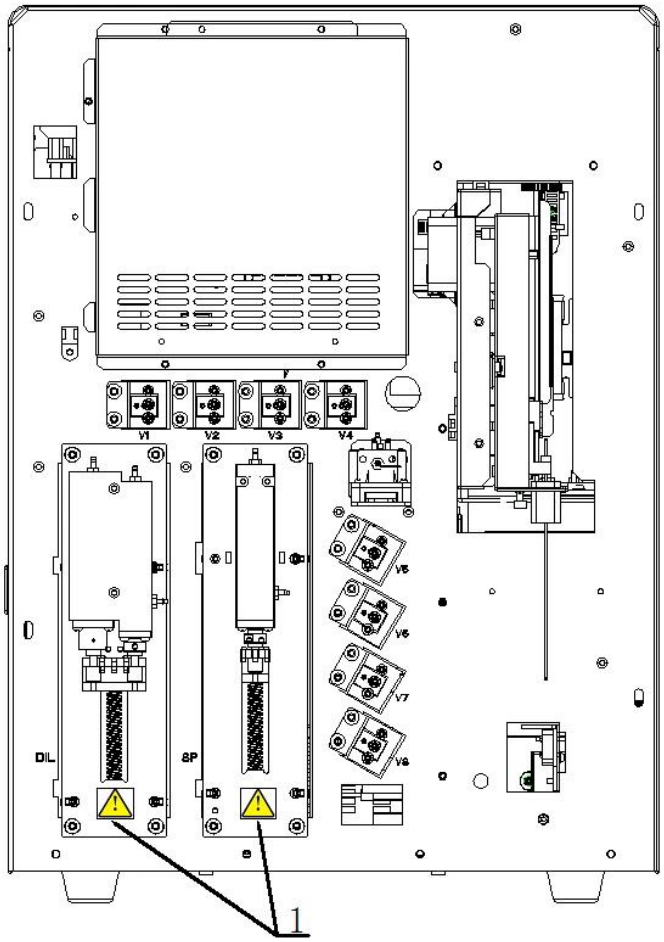

Figure 3 (Front of the analyzer (Front Cover Open))

To avoid injury, do not put your hands around the guide channel of the syringe board.

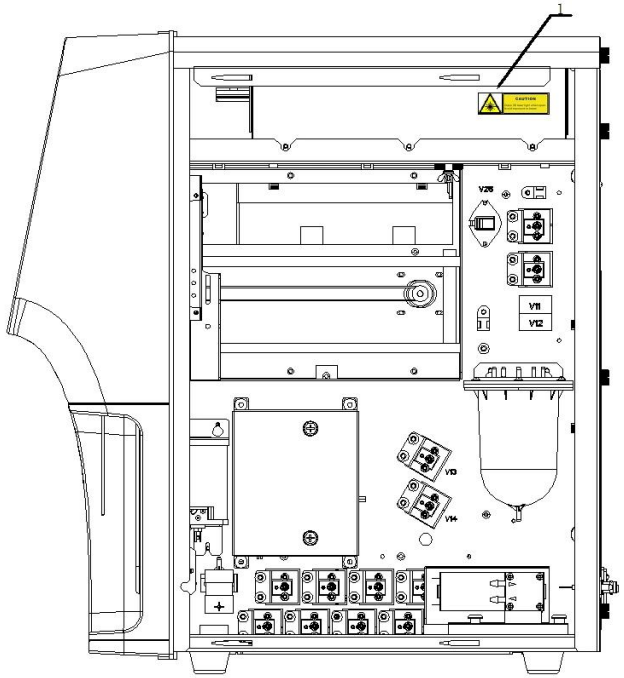

Figure 4 (Right Side of the Analyzer)

 Laser radiation when opening, avoid direct eye exposure.

2. Understanding your analyser

2.1 Introduction

The BDL-6701 Auto 5-part Hematology Analyzer is a quantitative, automated Auto 5-part Hematology analyzer and 5-part differential counter for in Vitro Diagnostic Use in clinical laboratories.

2.2 Intended Use

The purpose of this analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

The BDL-6701 is a quantitative, automated hematology analyzer and 5-part differential counter used in clinical laboratories. It provides the following 25 basic parameters, 4 parameters for research use, 3 histograms and 1 scattergram of blood samples. It supports 2 measurement modes: CBC and CBC+DIFF.

Parameter Name	Abbr.	CBC	CBC+DIFF
White Blood Cell count	WBC	*	*
Neutrophils percentage	Neu%	/	*
Lymphocytes percentage	Lym%	/	*
Monocytes percentage	Mon%	/	*
Eosinophils percentage	Eos%	/	*
Basophils percentage	Bas%	/	*
Neutrophils number	Neu#	/	*
Lymphocytes number	Lym#	/	*
Monocytes number	Mon#	/	*
Eosinophils number	Eos#	/	*
Basophils number	Bas#	/	*
Abnormal Lymphocytes percentage	ALY% (RUO)	/	*
Large Immature Cells percentage	LIC% (RUO)	/	*
Abnormal Lymphocytes number	ALY# (RUO)	/	*
Large Immature Cells number	LIC# (RUO)	/	*

RBC	RBC	*	*
Hemoglobin Concentration	HGB	*	*
Mean Corpuscular Volume	MCV	*	*
Mean Corpuscular Hemoglobin	MCH	*	*
Mean Corpuscular Hemoglobin	MCHC	*	*
Concentration			
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV	*	*
Red Blood Cell Distribution Width Standard Deviation	RDW-SD	*	*
Hematocrit	HCT	*	*
Platelet count	PLT	*	*
Mean Platelet Volume	MPV	*	*
Platelet Distribution Width	PDW	*	*
Plateletcrit	PCT	*	*
Large Platelet count	P-LCC	*	*
Large Platelet percentage	P-LCR	*	
White Blood Cell Histogram	WBC Histogram	*	/
Red Blood Cell Histogram	RBC Histogram	*	*
Platelet Histogram	PLT Histogram	*	*
Differential Scattergram	Diff Scattergram	/	*

Table 4

"*" 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, not for diagnostic use.

2.3 Main Structure

The BDL-6701 Auto 5-part Hematology Analyzer consists of the main u n i t (analyzer) and accessories.
Please check the firmness of all the doors, covers and boards before running the analyzer.
The analyzer is heavy, to move it by one person may cause injury. It is advisable for two people to move it together when transport is needed, and make sure you follow the instructions and use the proper tools.

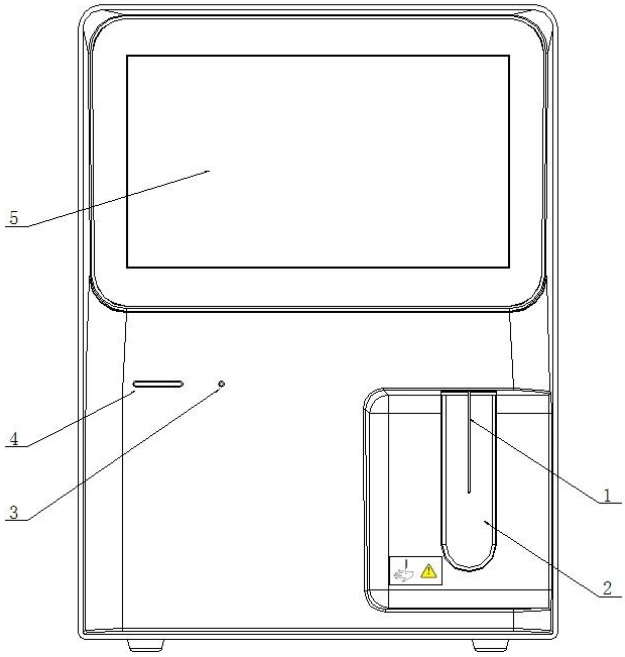

Figure 5 (Front of the Analyzer)

1. Sample probe 2. Aspirate key

3. Laser indicator 4. Power/Status indicator 5. Screen

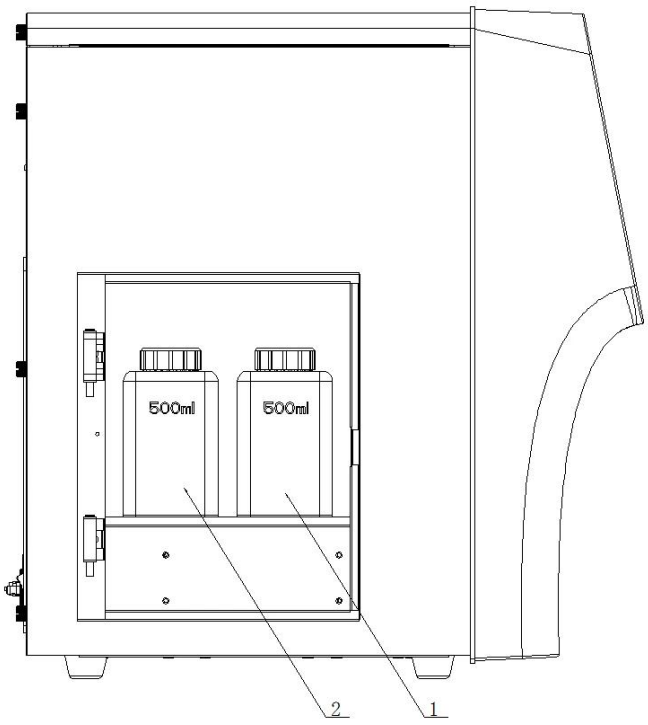

Figure 6 (Left side of the Analyzer)

1. W-61LH Lyse inlet
2. W-61LD Lyse inlet

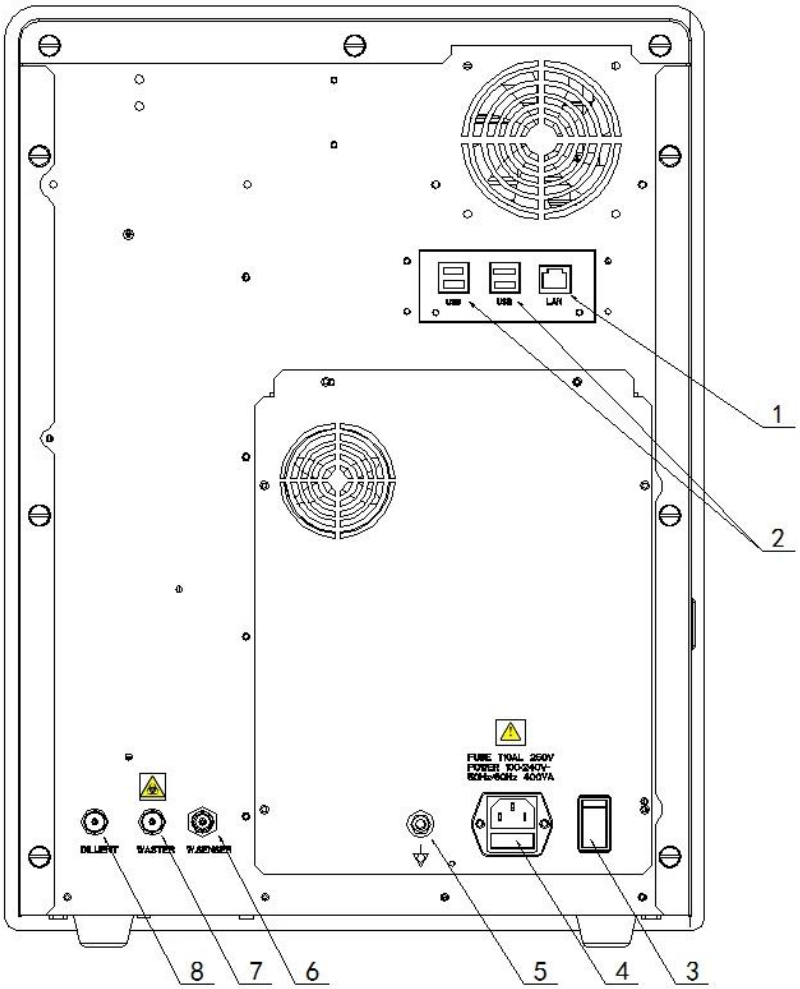

Figure 7 (Back of the Analyzer)

1. Network interface 2. USB interface

3. Power Switch 4. AC input

5. CC 6. Waste sensor

7. Waste outlet 8. W-61D diluent inlet

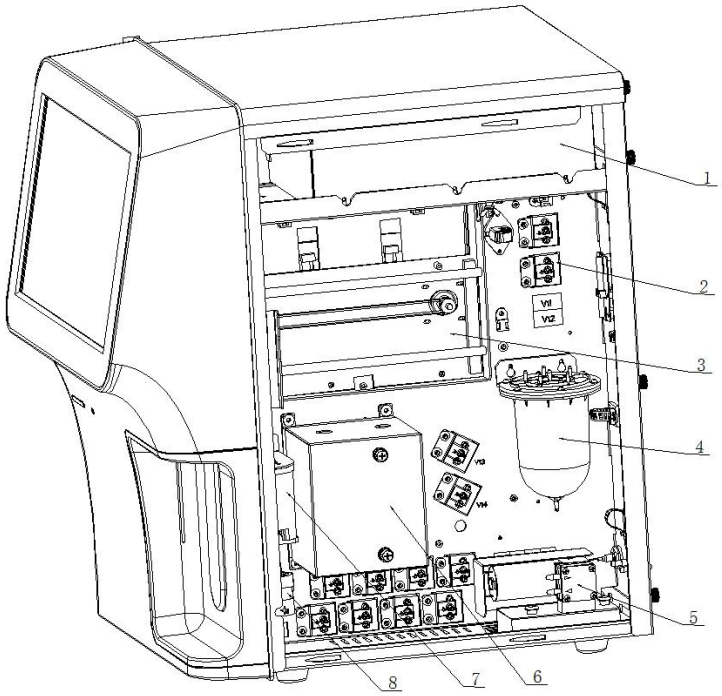

Figure 8 (Right Side of the Analyzer (Right Door Open))

1. Optical system 2. Fluidic valves

3. Sampling module 4. Vacuum chamber

5. Pumps 6. Bath

7. DIFF bath 8. Buffer chamber

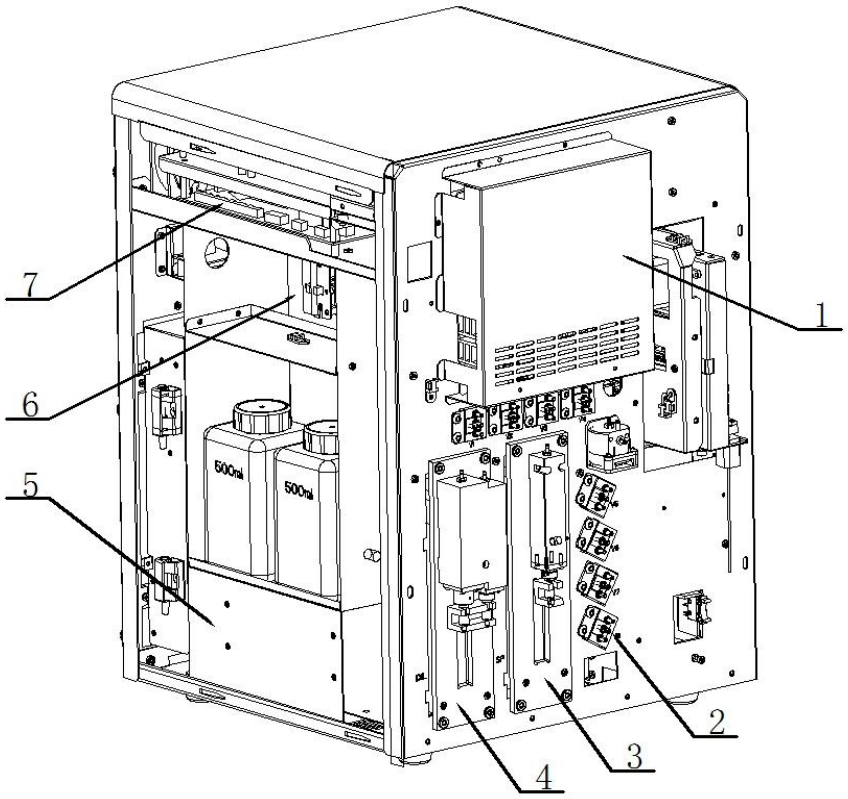

Figure 9 (Left Side of the Analyzer (Left Door Open and Front Cover Removed)

1. IPC cover
2. Fluidic valves
3. Syringes
4. Syringes
5. Reagent chamber
6. Liquid level detection unit
7. PCBA

Main Unit (Analyzer)
The main unit (analyzer) is the principal part of the product. It performs the sample analysis and the data process.

Power/Status Indicator
The Power/Status indicator is located in the middle of the left side of the analyzer (front side). It tells you about the status of the analyzer including ready(green), running(yellow) and error(red).

Power Switch
A power switch is on the back of the analyzer. It starts up or closes down the analyzer.

⚠ CAUTION To avoid damage, do not turn on/off the power of the analyzer continually in a short time.

Aspirate Key
The aspirate key is located behind the sample probe. You can press the key to start the selected analysis cycle, dispense diluent and wake up the analyzer from sleep.

Network Interface
A network interface is located on the back of the analyzer. It connects to the external computer.

2.4 User Interface

After the starting procedure, you will enter the user interface.

Figure 10
The interface can be divided into several areas as follows according to their functions:
1. Information area of the user logged on
This area displays the name and access level of the current user.

2. Information area
It displays the information about the sample ID, analysis mode (whole blood/predilute blood) and measurement mode (CBC/CBC+DIFF) of the next sample. Or other information about the status of the analyzer such as error messages.

3. Reagent Status area
There are status for the remaining of three reagents.

4. LIS/HIS status
Gray icon: disconnected Colorful icon: connected

5. System time
It displays the time of the operation system.

6. Help

You can click the  button to display help information.

7. Menu button

You can click the  button on the left top corner to open the system menu. Click a menu option, a relevant screen or message box will appear if the option is not followed by the symbol ▶ " "; whereas a submenu will appear if the option is followed by the symbol ▶ " ". Click the submenu, a relevant screen or message box will appear.

8. Shortcut button area
The top of the screen is the shortcut button area. When clicking a certain button, you can enter the relevant screen or a message box will pop up.

2.5 Reagents, Controls and Calibrators

Because the analyzer, reagents (diluent, lyses and probe cleanser), controls, and calibrators are components of a system, performance of the system depends on the combined integrity of all components. You should only use the Manufacturer-specified reagents, which are formulated specifically for the fluidic system of your analyzer in order to provide optimal system performance. Do not use the analyzer with reagents from multiple suppliers. In such use, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.
Each reagent package must 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.

Store and use the reagents as instructed by instructions for use of the reagents.
When you have changed the diluent or lyses, run a background 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 a while before use

2.5.1 Reagents

W-61D Diluent
It applies to our Auto 5-part Hematology Analyzer.

W-61LD Lyse
It applies to our Auto 5-part Hematology Analyzer. It rapidly breaks down red blood cell walls. It 5-differentiates WBCs.

W-61LH Lyse

It applies to our Auto 5-part Hematology Analyzer. It rapidly breaks down red blood cell walls to determine the HGB.

W-5P Probe Cleanser
It applies to our Auto 5-part Hematology Analyzer. It is an alkaline cleaning solution formulated to clean the sampler.

2.5.2 Controls and Calibrators
The controls and calibrators are used to verify accurate operation of and calibrate the analyzer.
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 operation of the analyzer and ensures reliable results are obtained. The calibrators are commercially prepared whole-blood products used to calibrate the analyzer. Read and follow the instructions for use to use the controls and calibrators.

3. Understanding the system principles

3.1 Introduction

The measurement methods used in this analyzer are: the Electrical Impedance method for determining the WBC,RBC and PLT data;the colorimetric method for determining the HGB;flow cytometry by laser for determining the WBC 5-part differentiation. During each analysis cycle, the sample is aspirated, diluted and mixed before the determination for each parameter is performed.

3.2 Aspiration

The analyzer supports three types of blood samples - whole blood samples, predilute blood samples and capillary blood samples.
If you are to analyze a whole blood sample, the analyzer will aspirate 19.8μL
(CBC+DIFF mode) or 9.8μL (CBC mode) of the sample.
If you are to analyze a capillary blood sample , you should first manually dilute the sample (20μL of capillary sample needs to be diluted by 400μL of diluent) and then present the pre-diluted sample to the analyzer, which will aspirate 180μL(CBC+DIFF) or 90μL(CBC)of the sample.

3.3 Dilution

The sample will be divided into 2 portions and be diluted and processed by different reagents. After this, they are ready for analysis.
This analyzer can process two types of blood samples - whole blood samples and predilute blood samples.

3.3.1 Dilution Ratio of Each Channel in Whole Blood Mode
WBC test /HGB measurement channel: 1:375 RBC/PLT measurement channel: 1:17000 WBC differentiation channel: 1:80

3.3.2 Dilution Ratio of Each Channel in Predilute Mode
WBC test /HGB measurement channel: 1:536 RBC/PLT measurement channel: 1:20000 WBC differentiation channel: 1:230

3.4 WBC Measurement

3.4.1 Flow Cytometry by Laser

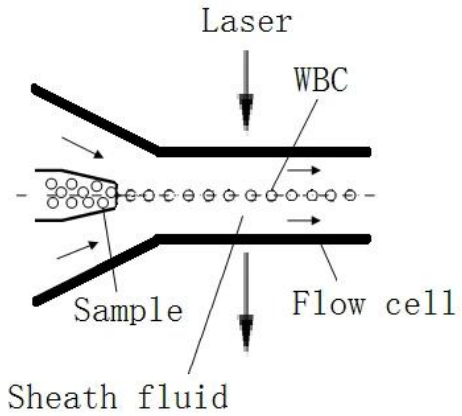

Figure 11 (WBC Measurement)

After a predetermined volume of blood is aspirated and diluted by a certain amount of reagent, it is injected into the flow cell. Surrounded with sheath fluid (diluent), the blood cells pass through the center of the flow cell in a single column at a faster speed. When the blood cells suspended in the diluent pass through the flow cell, they are exposed to a laser beam. The intensity of scatter light reflects the blood cell size, complexity of cell nucleus, and granularity respectively. The low-angle scattered light reflects cell size, and the high-angle scattered light reflects complexity of the cell nucleus, and the side-angle scattered light reflects granularity respectively. The optical detector receives this scatter light and converts it into electrical pulses. Pulse data collected can be used to draw two 2-dimensional distributions (scattergrams). As shown in Figure 3-2 , X-axis represents the intracellular density and Y-axis the blood cell size. Various types of analysis data can then be obtained from the scattergrams.

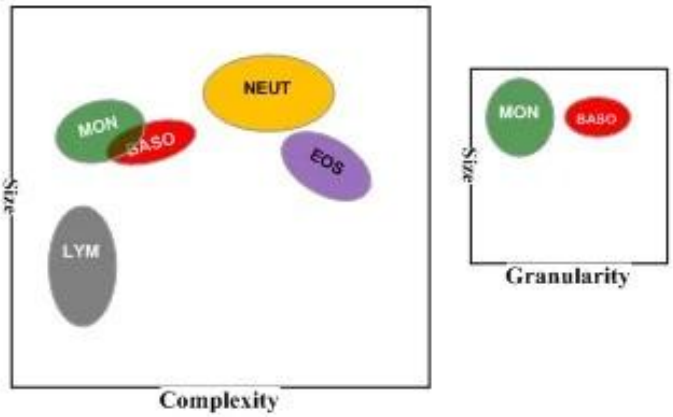

Figure 12 (DIFF channel scattergram)

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

3.4.2 Electrical Impedance Method

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 generated signals the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

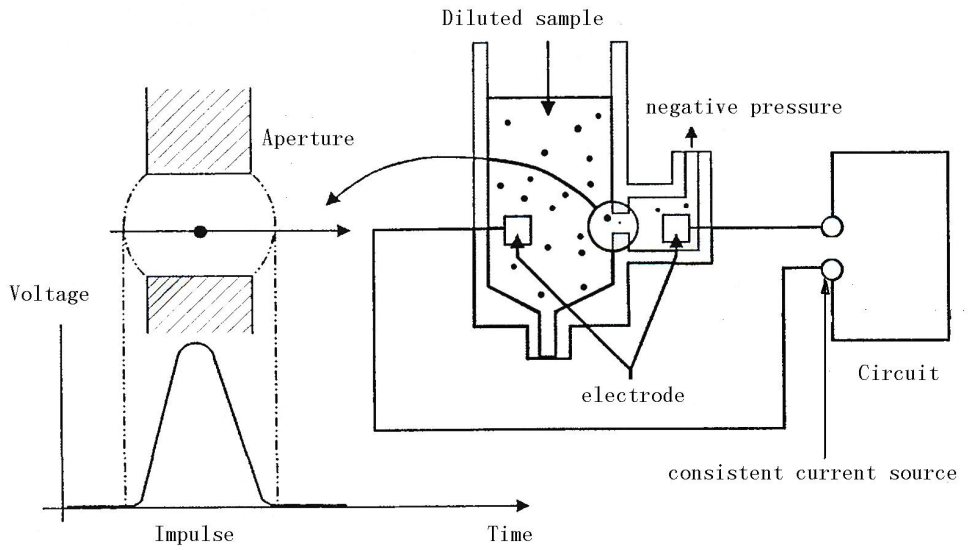

Figure 13 (Electrical Impedance method)

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 lower threshold, it is counted as a WBC. The analyzer presents the WBC histogram, whose x-coordinate represents the cell volume(fL)and y-coordinate represents the number of the cells.

3.5 RBC/PLT Measurement

3.5.1 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 generated signals the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

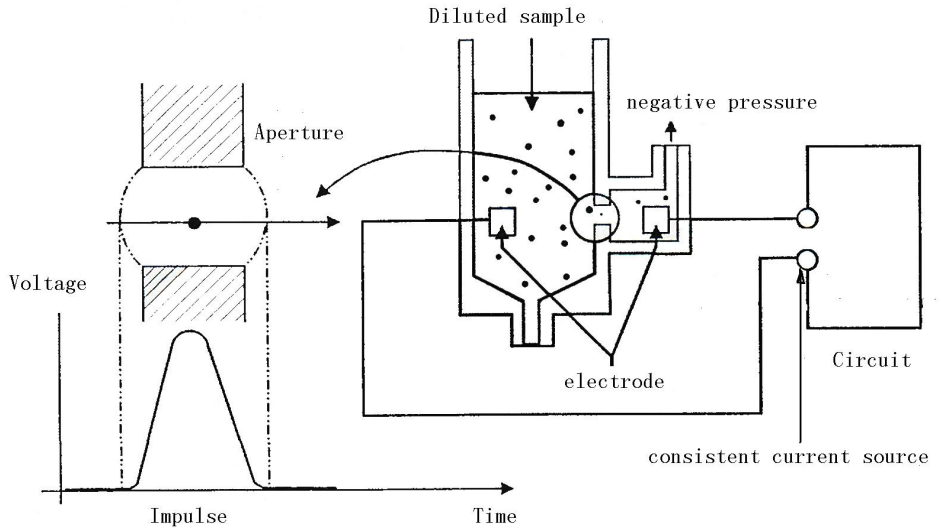

Figure 14 (Electrical Impedance method)

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

3.5.2 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%. Having achieved the WBC, 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 expresses them in 109/L.

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

Basophils percentage
Bas% = Particles in Base region of Diff channel / Sum of all particles in Diff channel except those in Ghost region * 100%

Lymphocytes percentage
Lym% = Particles in Lym region of Diff channel / Sum of all particles in Diff channel except those in Ghost region * 100%
Neutrophils percentage
Neu% = Particles in Neu region of Diff channel / Sum of all particles in Diff channel except those in Ghost region * 100%
Monocytes percentage
Mon% = Particles in Mon region of Diff channel / Sum of all particles in Diff channel except those in Ghost region * 100%

Eosinophils percentage
Eos% = Particles in Eos region of Diff channel / Sum of all particles in Diff channel except those in Ghost

region * 100%

Basophils number
Bas# = WBC * Bas%

Lymphocytes number
Lym# = WBC * Lym%

Neutrophils number

Monocytes number

Neu# = WBC * Neu

Mon# = %WBC * Mon%

Eosinophils number
Eos# = WBC * Eos%

3.6 HGB Measurement

3.6.1 Colorimetric Method
HGB is determined by the colorimetric method. The WBC/HGB dilution is delivered to the HGB bath where it is bubble mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 535 nm. An LED is mounted on one side of the bath and emits a beam of monochromatic light, whose central wavelength is 535nm. The light passes through the sample and is then measured by an optical sensor that is mounted on the opposite side. The signal is then amplified and the voltage is measured and compared to the blank reference reading (readings taken when there is only diluent in the bath), and the HGB is measured and calculated in the analyzer automatically.

3.6.2 HGB
The HGB is calculated per the following equation and expressed in g/L.
HGB(g/L) = Constant * Blank Photocurrent / Ln

4. Installing your analyser

4.1 Introduction

Installation by personnel not authorized or trained by the Manufacturer may cause injury or damage to your analyzer. Do not install your analyzer without the presence of Manufacturer-authorized personnel. Your analyzer is tested before it is shipped from the factory. International symbols and special handling instructions tell the carrier how to treat this electronic instrument. When you receive your analyzer, carefully inspect the carton. If you see any signs of mishandling or damage, contact the Manufacturer customer service department or your local distributor immediately.

4.2 Installation Requirements

4.2.1 Installation Requirements

Check the site for proper space allocation. In addition to the space required for the analyzer itself, arrange for

• at least 100 cm on each side, which is the preferred access to perform service procedures.
• at least 50 cm behind the back side for cabling and ventilation.
• enough room on and below the countertop to accommodate the diluent and waste containers.

4.2.2 Power Requirements

• Make sure the analyzer is properly grounded.
• Before turning on the analyzer, make sure the input voltage meets the requirements.
• Using a plug-board may bring electrical interference and the analysis results may be unreliable. Please place the analyzer near the electrical outlet to avoid using the plug-board.
• Please use the original electrical wire shipped with the analyzer. Using other electrical wire may damage the analyzer or cause unreliable analysis results.

	Voltage	Input power	Frequency
Analyzer	A.C. 100V-240V	300 VA	50/60 Hz

Table 5

4.2.3 General Environment

• Operating temperature:15°C - 30°C, Optimal operating temperature: 15°C - 30 °C
• Optimal operating humidity: ≤ 85 %
• Operating atmospheric pressure: 70 kPa - 106 kPa.
• The environment should be as free as possible from dust, mechanical vibrations, loud noises, pollution and electrical interference.
• It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
• Do not use this analyzer in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.
• Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close.
• Do not place the analyzer in direct sunlight or in front of a source of heat or drafts.
• The environment should be good ventilation.

• Do not place the analyzer on a slope.
• The analyzer is not waterproof.

4.2.4 Transport and Installation
• Transport or installation by personnel not authorized or trained by the Manufacturer may cause injury or damage to your analyzer. Do not install your analyzer without the presence of Manufacturer-authorized personnel.

• To avoid damage during the transportation, the sampling assembly of the analyzer is fixed with a plastic cable tie and a clamp. Do remove them before using the analyzer.

The transport and installation shall be conducted by Manufacturer-authorized personnel. Do not transport or install the analyzer without contacting our customer service department or your local distributor.

5. Start-up

5.1 Introduction

The BDL-6701 is a flexible laboratory instrument that can be tailed to your work environment. You can use the " Setup" program to customize the software options as introduced in this chapter.
The analyzer divides the operators into two levels, common user and administrator. Note that an administrator can access all the functions open to a common user. This chapter introduces how to start and customize your analyzer respectively as a common user level and as an administrator.

5.2 Precautions before Power-on

Before you power on the analyzer each time, pay attention to the following to ensure the system is ready:
Reagents
You should use the reagents designated by the Manufacturer and store and use them strictly according to the instructions of the reagents.
Before using the analyzer, check that the reagents are connected correctly.
Before use, ensure the reagent bottles or containers have adequate reagents.

Waste Liquid Container
Check whether the waste liquid container is full. It is suggested to empty the waste liquid container before powering the machine.

Liquid Tube
Check whether the reagent and waste liquid tubes are bent and whether the connection is reliable.

Power Supply
Check whether the power plug of the analyzer has been fully inserted into the power socket.

5.3 Logging on System

1. Turn on the power of the analyzer.
2. Check that the indicator on the analyzer is lit up.

After the software is started, the login dialogue box will be popped up, as shown in the figure below:

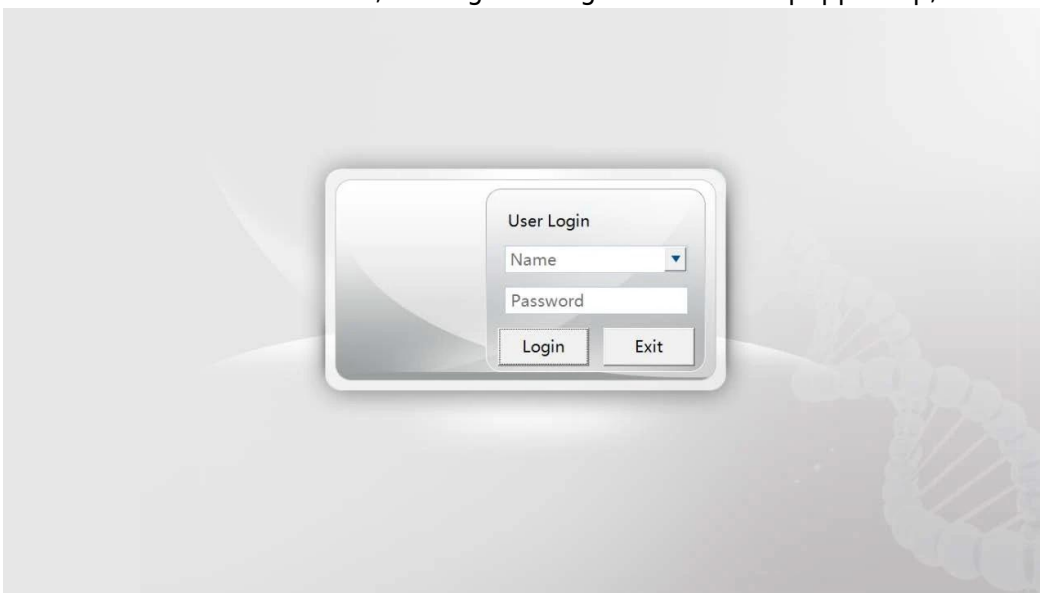

Figure 15

The initial administrator username and password are "admin".

1. Input the correct username and password and click the "Login" button, and the analyzer will execute the startup initialization operation, as shown in the figure below:

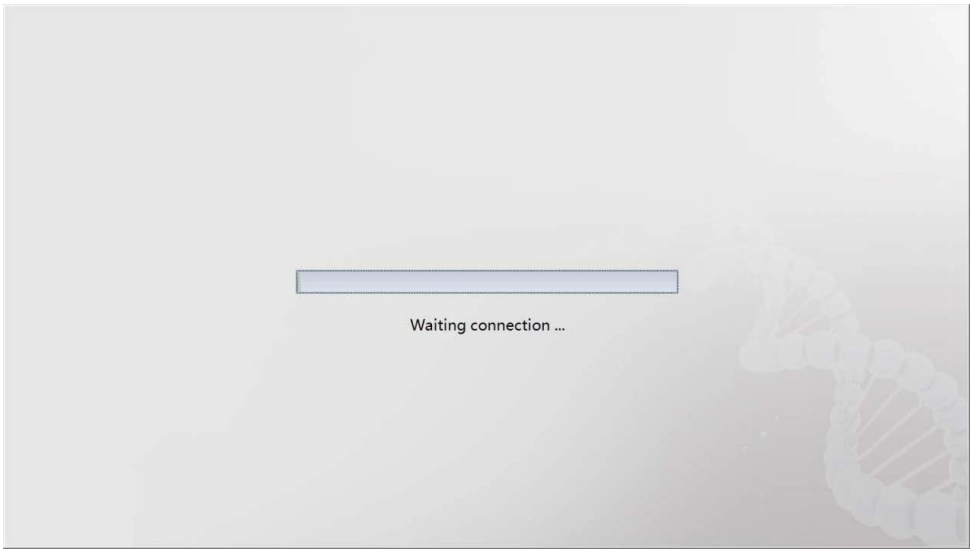

Figure 16

2. During the initialization, the cleaning and blank test will be performed. When the blank test is ended, the system will enter the sample analysis interface and display the result of the blank test, as shown in the figure below:

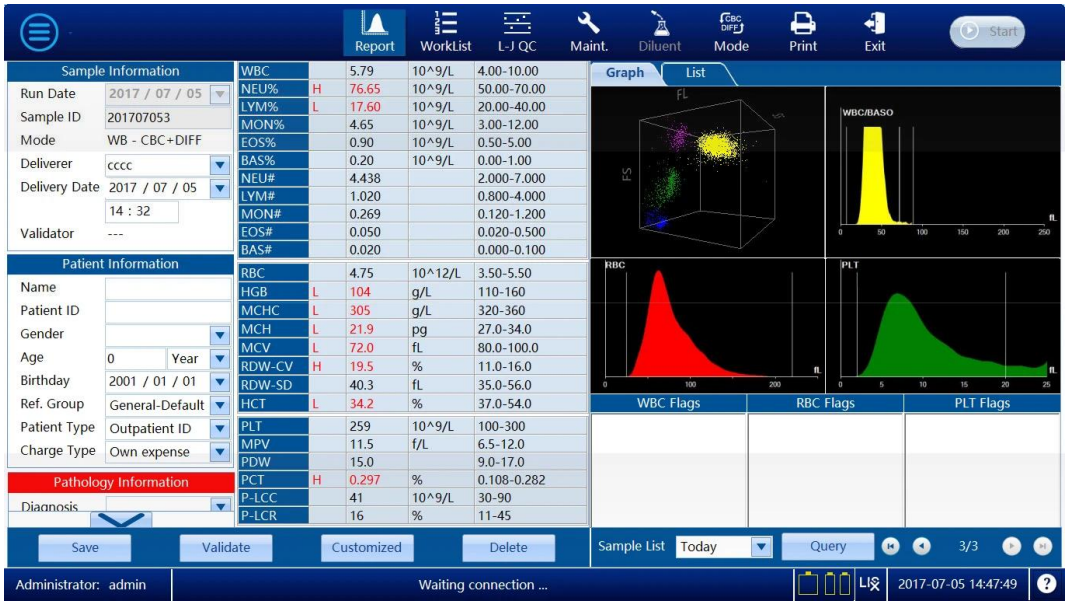

Figure 17

For the blank test, only the test values of WBC, RBC, HGB, HCT, and PLT are displayed. The acceptable range is as follows:

Parameter	Limits
WBC	≤ 0.2 x 109 / L
RBC	≤ 0.02 x 1012/ L
HGB	≤ 1g / L
HCT	≤ 0.5%
PLT	≤ 10 x 109 / L

Table 6 (Acceptable Limits of Blank)

5.4 System Setup

The analyzer has been initialized before leaving the factory. You can set some parameters to meet the different needs, in order to ensure the safety of setup and data, the analyzer divides the operators into administrators and common users and opens different setup functions for different user authorities. Administrators have higher authority than common users and can set more items.

5.4.1 Ref. Range

Click the button on the screen, and then select "Setup""Ref.Range" on the pop-up menu to enter the interface.

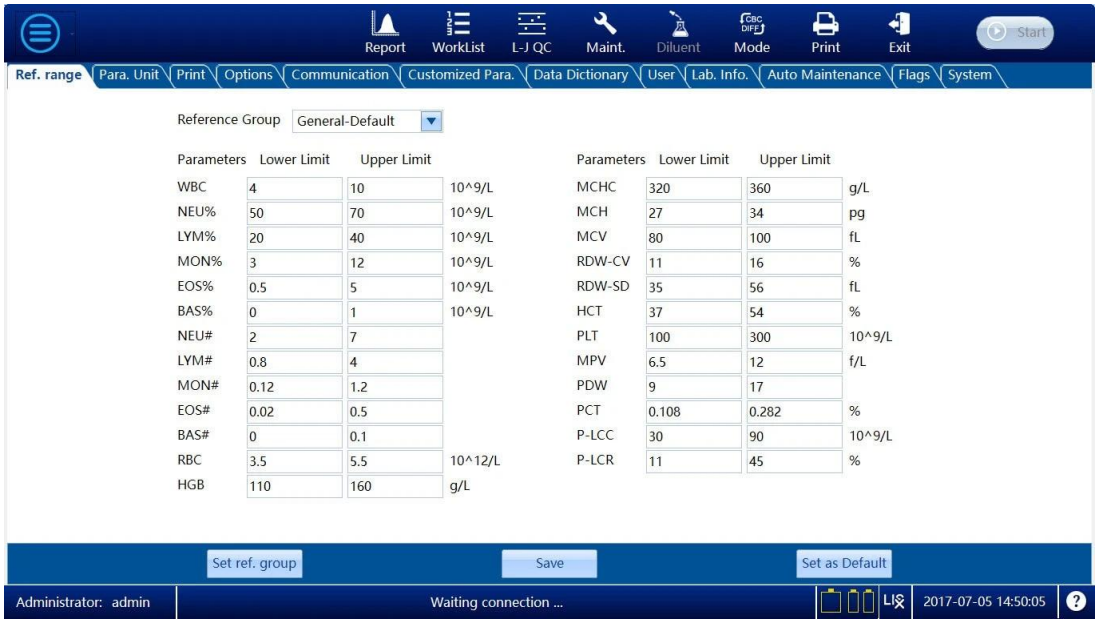

Figure 18

The range of normal values is the range of reference values based on different normal groups. If the analysis result is out of the range of normal values, this will be deemed clinical abnormality. On the interface and the printed report, "H" indicates the analysis result is higher than the upper limit of the range of normal values; "L" indicates lower than the lower limit.

The analyzer has general default, man, woman, child, infant, neonate, and 10 customized reference ranges. The default setting is "General default,". You should select appropriate reference groups according to the actual situation of the samples and set appropriate range of reference values.
From the Population Classification dropdown box, select the class to be set, and the software will automatically read the corresponding setting. The default upper and lower limits of customized reference ranges are 0. In the edit box, input the corresponding values and click the "Save" button to save the current settings.
To check the information on the range of reference values or modify the name, age range and gender of a user-defined reference group, click the "Set Reference Group" button to open the Reference Group Setup dialogue box, as shown in the figure below:

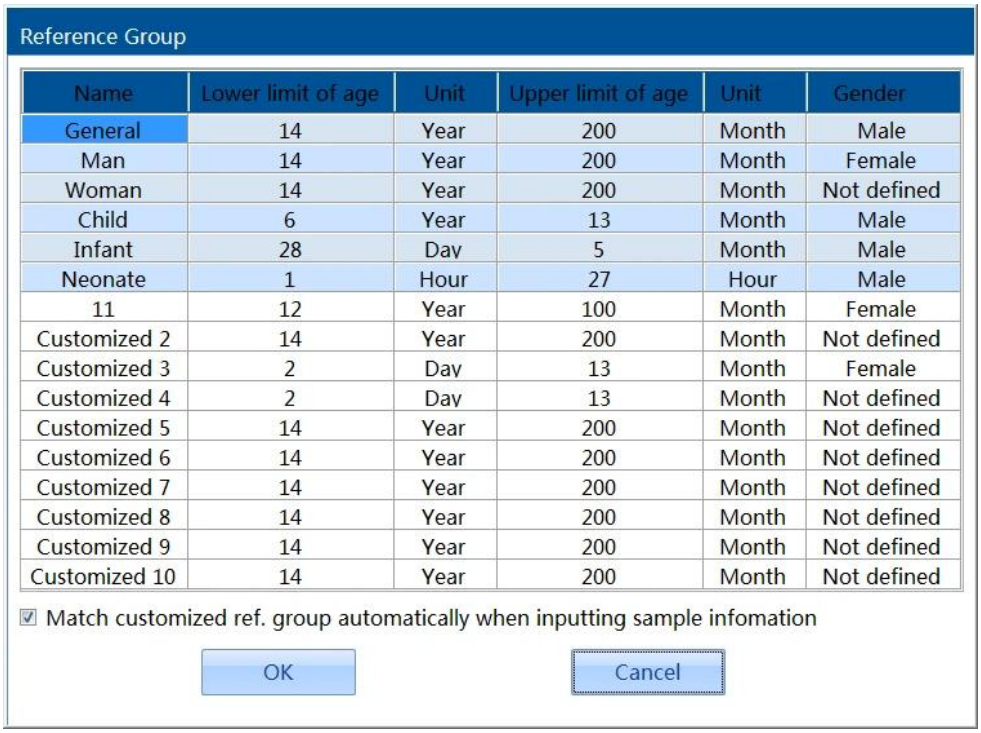

Figure 19

The reference group name and other information of the 6 fixed reference groups in the list of reference groups can't be modified. You can modify the name, age range, and gender of the 10 customized reference groups as needed.

(1) The reference group name must not be empty.
(2) The name of a customized reference group must not be the same as that of any fixed reference group, and the names of the customized reference groups must be different from each other.

If "Automatically match customized reference groups according to the gender and age" is not selected, when the sample information is inputted, the system will automatically select one of the fixed reference groups according to the gender and age. Otherwise, the system will select a matched group from the fixed reference groups and customized reference groups, and you do not need to input the information manually.

5.4.2 Units

Click the button on the screen, and then select "Setup" "Para. Unit" on the pop-up menu enter to the interface.

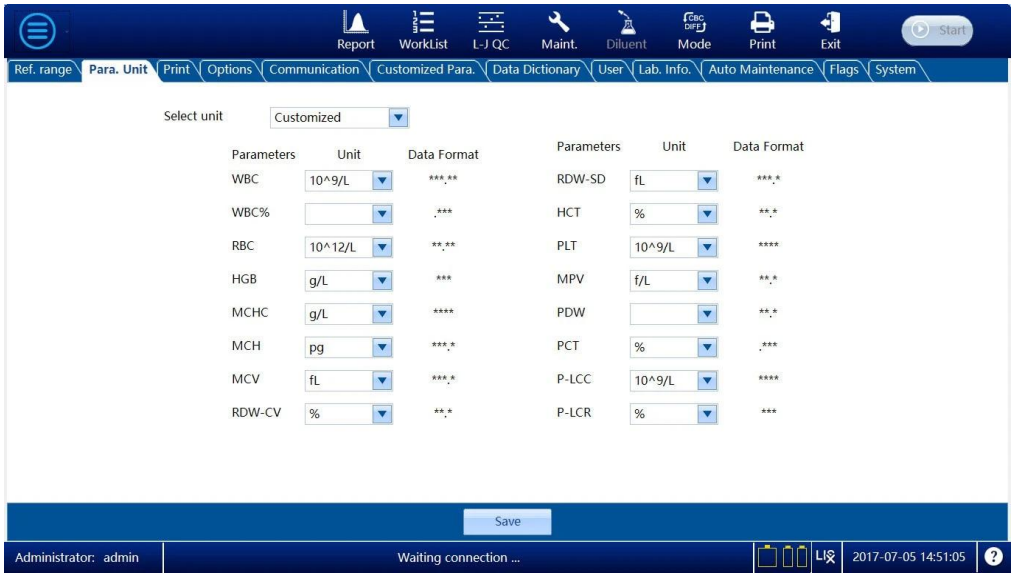

Figure 20

This analyzer provides 3 fixed units and 1 customized unit. You can directly select fixed units or define the units of the parameters according to the actual needs. The units of all modules of the system are set here.
For other options except "Customized", the units of the parameters can be viewed only and can't be modified. If "Customized" is selected, the units of the parameters can be modified. Click the "Save" button to save the user-defined unit settings.

5.4.3 Print

Click the button on the screen, and then select "Setup""Print" on the pop-up menu to enter the interface.

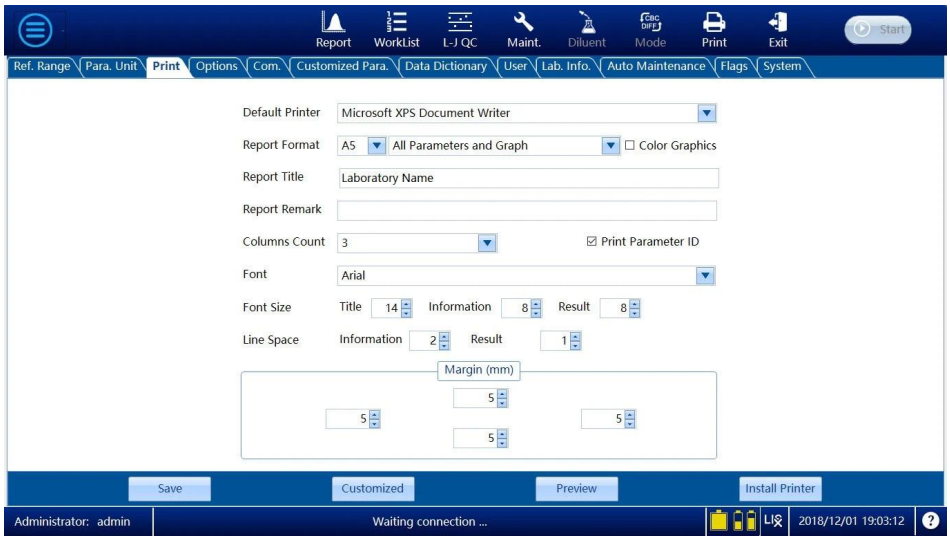

Figure 21

Default Printer
The default printer will be used for the printing for all modules. If you have modified the default printer in the operation system, the printer name in this combo box will change. At the same time, if the printer is modified here, the default printer in the Windows OS will also change.

Format of Report
For report printing, A4 and A5 are supported. The formats include
1. A4 all parameters with graphs; 2. A4 all parameters without graphs; 3. A5 all parameters with graphs; 4. A5 all parameters without graphs. "All parameters" means all parameters measured by the analyzer are printed. "With graphs" means histograms and scattergrams are printed. "Color Graphic" means the graphics in report are colorful.

Reporting Title
The name of the unit printed on the report heading.

Remarks of Report
Printed in the bottom left corner of the report to explain the report.

Font Size
"Title F" is used to set the font size of the heading of the report to be printed; "Parameter" is used to set the font size of the sample parameters name fields and inspection information fields; "Item" is used to set the font size of the test parameters and results.

Line space
The space height between lines of report.

Customized
Click the "Customized" button to open the following dialogue box :
On the Sample Information tab, the fields and sequence of printing of the
report can be set. The items added to the right list are the printing items, and the printing sequence is from top to bottom. On the Result tab, the number and sequence of printing parameters can be set. The number of parameters of each template and their sequence on the report are adjustable.

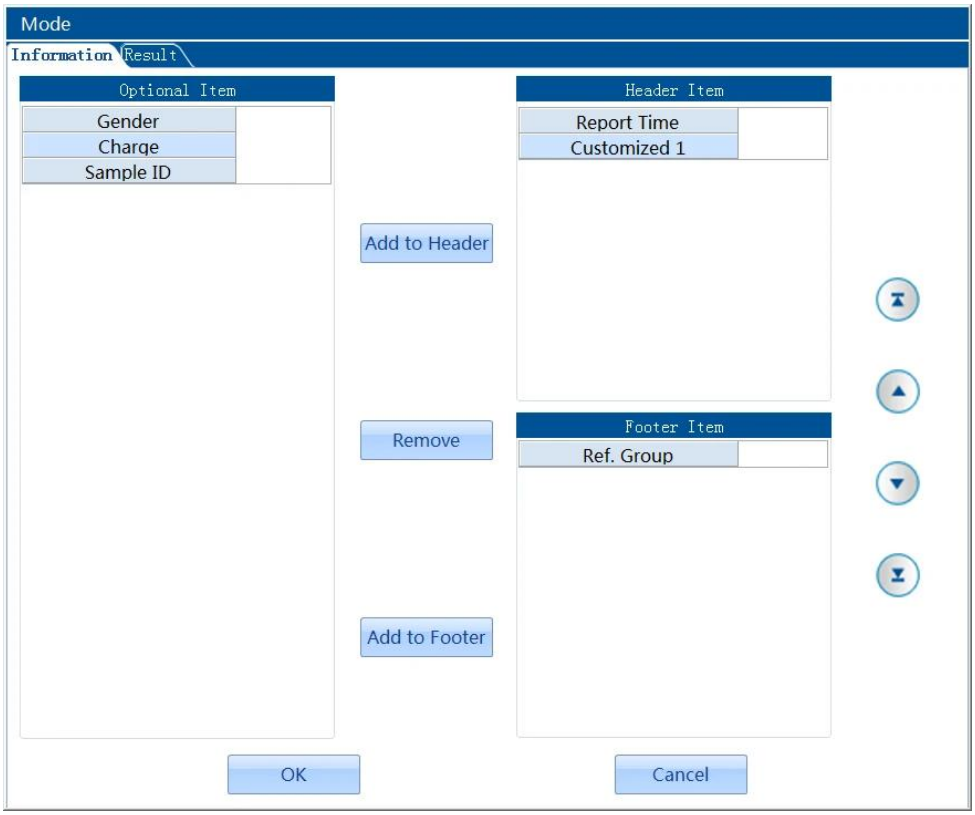

Figure 22

On the Sample Information tab, the fields and sequence of printing of the report can be set. The items added to the right list are the printing items, and the printing sequence is from top to bottom. On the Result tab, the number and sequence of printing parameters can be set. The number of parameters of each template and their sequence on the report are adjustable.

5.4.4 Options

Click the button on the screen, and then select "Setup""Options" on the pop-up menu to enter the interface.

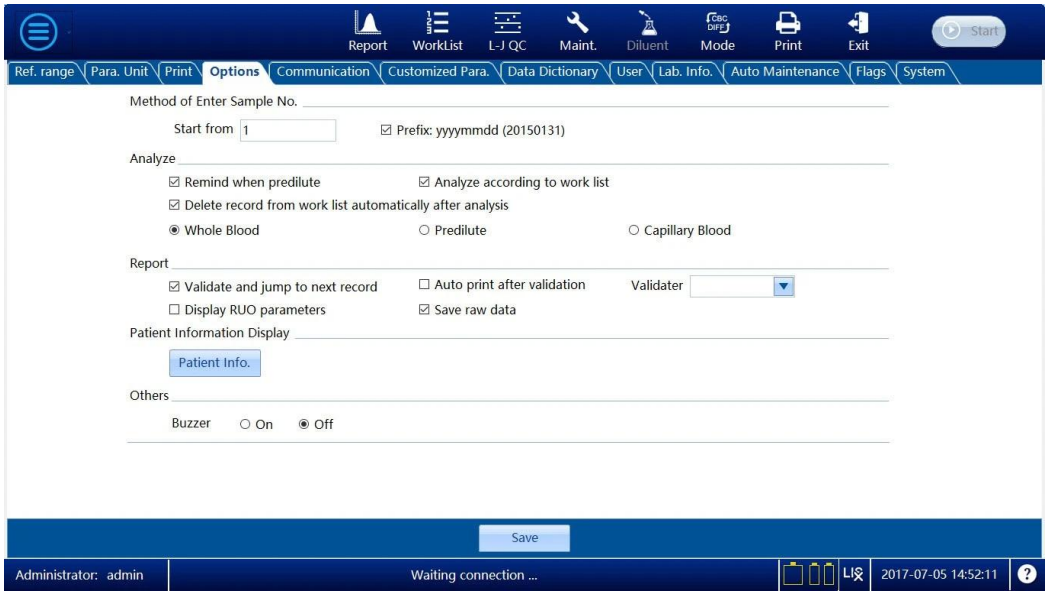

Figure 23

• Method of Entry Sample No.
The start sample number of each day can be set, with the default of 1. The sample number for the day is the last sample number plus 1. To use a date prefix, tick the Use Prefix option. An example of the sample number format is "20150131". By default, this option is not ticked.
• Remained when Pre-diluted
In the sample analysis, if the blood sample mode is Pre-diluted, when the analysis is going to begin, the system will prompt whether to analyse in the Pre-diluted mode. If you select "Yes", the analysis in the Pre-diluted mode will begin; if you select "No", no operation will be executed.
• Analyze according to Worklist
If this option is selected, the analysis will be performed according to the sample information input in the worklist. Each sample newly analyzed matches the entry "To be Run" in the worklist.
• Delete record from work list automatically after analyzation
If "Analysis according to Worklist" is selected, when the sample analysis is ended, the corresponding sample entry in the worklist will be deleted automatically.
• Default Sample Type
Set the initial sample type when the analyzer is powered on and enters the Sample Analysis interface.
• Validate and jump to next record
If this option is selected, after the sample is verified on the Details
Review interface, the system will automatically display the next sample not verified.
• Verifier
When you enter the interface for the first time after installing the software, if you have the verification authority, the field will display your username by default; otherwise, it will display the username of the first operator with verification authority in the User Management list by default.
The dropdown list displays all usernames with verification authority set on the User Management interface. After the settings are saved, if you have the verification authority, when the verification operation is executed successfully, the Verifier field will display your name set here; otherwise, the username in the login dialogue box popped up will be displayed.
• Display research use parameters
If this option is selected, when the sample analysis is ended, you can click the "RUO" button to open the Research Use Parameters interface to view the result of the research use parameters.
• Patient Information
Select patient information you wanted display and edit.
• Buzzer
After the Alarm Buzzer is started, the buzzer in the analyzer will give
alarm sound in case of alarm; if the Alarm Buzzer is turned off, the buzzer will not give alarm sound.

Figure 24

5.4.5 Communication

Click the button on the interface, and then select "Setup" "Communication" on the pop-up menu to enter the interface.

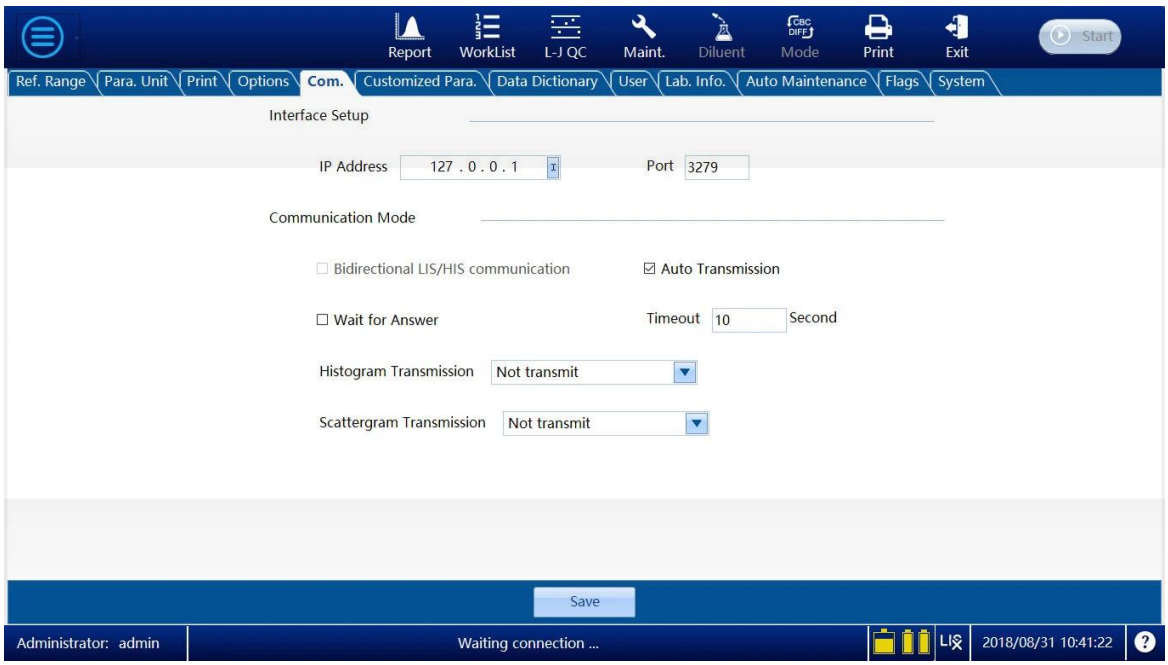

Figure 25

• Interface Setup

The "IP Address"and "Port" are the IP and port of LIS server. The setting should correspond to the server's setting.

• Communication Mode

If "Auto Transmission" is checked, the results will be sent automatically when analyses of samples are finished.

If "Wait for Answer" is checked , a response is supposed when a message is sent to LIS server. "Timeout"is the maximum time to wait for the response.

If "Transmit as a bitmap file"is selected, the histograms picture of analyses will be sent to LIS server.

• Save

Click "Save"button to save the setting .

5.4.6 Customized Para.

Click the button on the interface, and then select "Setup""Customized Para." on the pop-up menu to enter the interface.

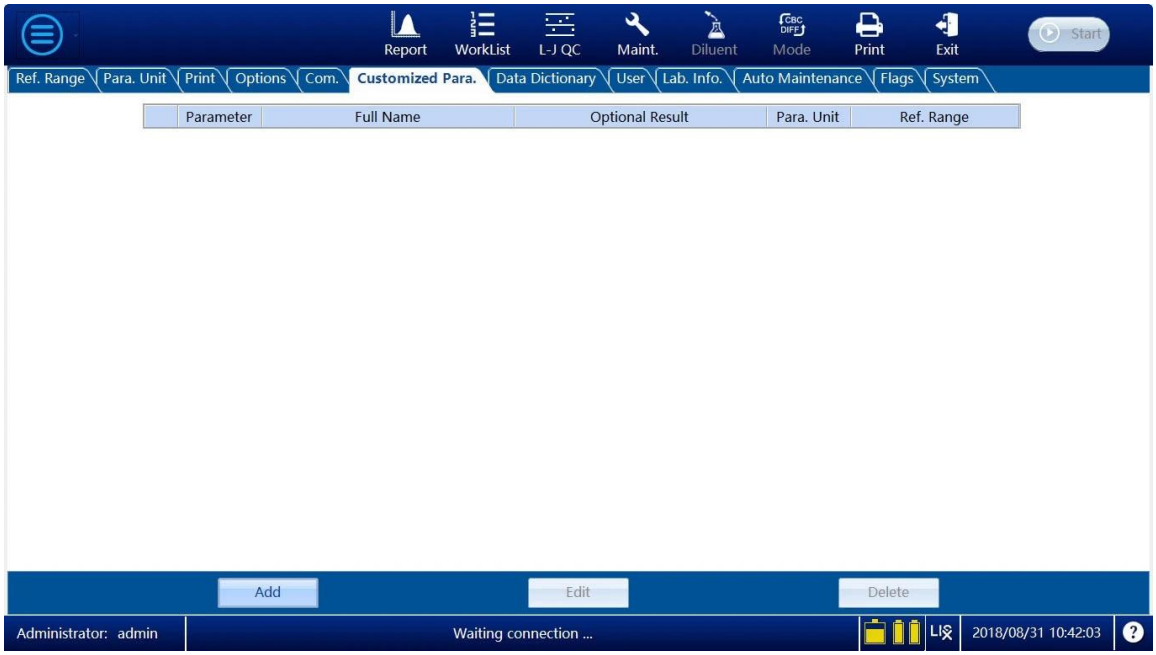

Figure 26

Customized Parameters are the items that can be analyzed through other methods . They can be inputted into the system and printed in the same report with the results generated by the Auto 5-part Hematology Analyzer.

Click "Add"button ,the editing interface will be displayed.

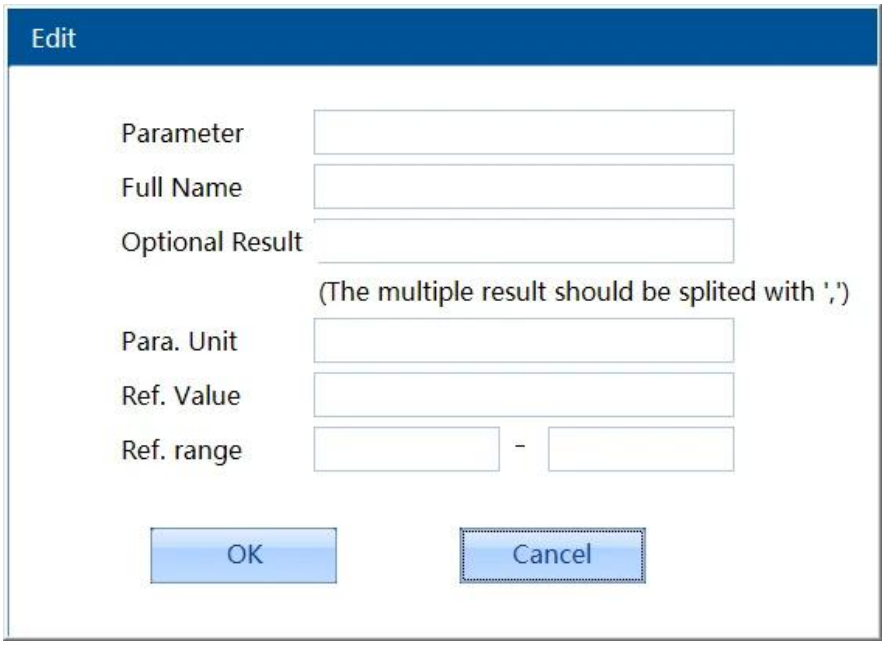

Figure 27

"Optional Result"is a series of results which are divided by comma. In the Input interface of Customized parameters , the optional results will be listed in a combo box. Operator can select a result instead of inputting manually.
"Ref. Value" and "Ref. range" are alternatives. For a quantitative parameter, a "Ref. range" is proper . On the contrary, for a qualitative parameter, a "Ref. Value" will be more reasonable.

Edit
Click the record you want to edit, then click the "Edit" button. The editing interface will be displayed. After the information has been modified, click the "OK" button to save the modification.

Delete
Click the record you want to delete, then click the "Delete" button. The record will be deleted.

5.4.7 Data Dictionary

Click the button on the screen, and then select "Setup"" Data Dictionary" on the pop-up menu to enter the interface.

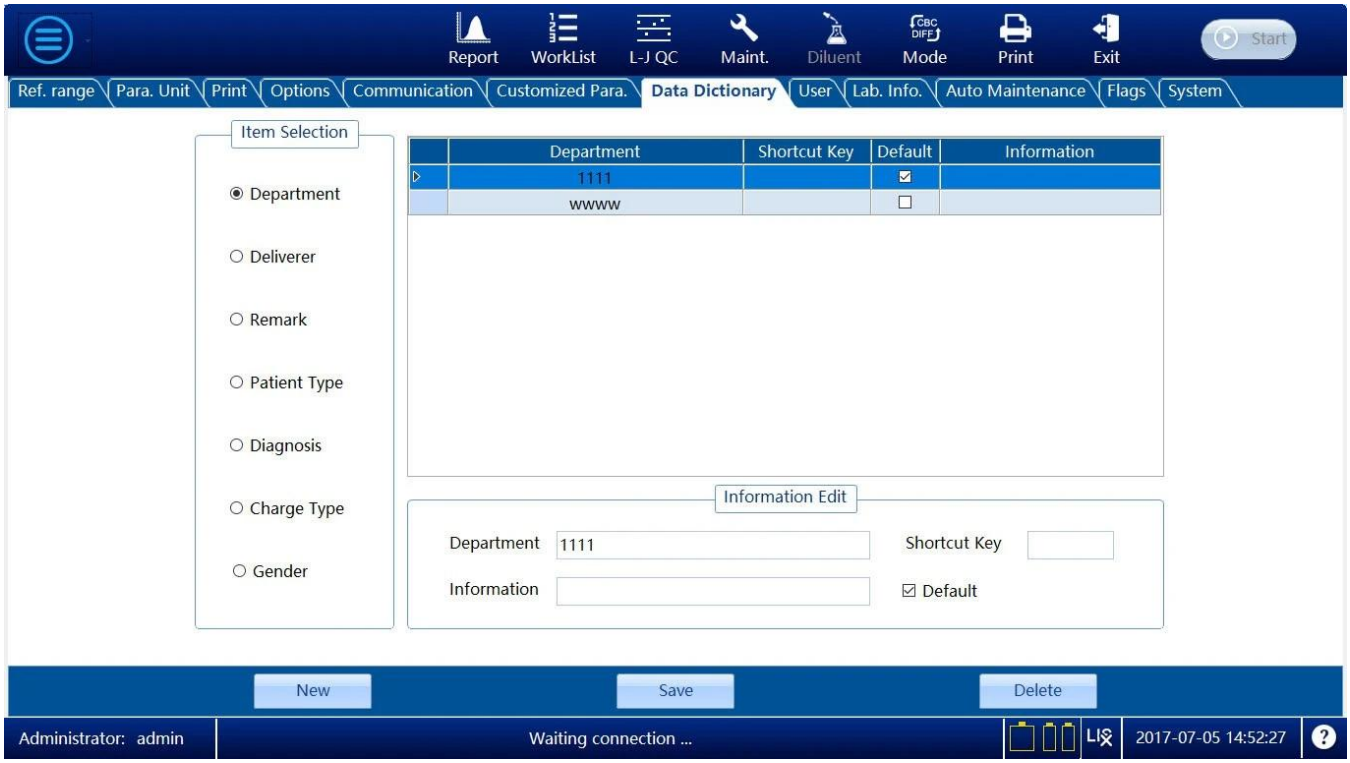

Figure 28

Click "New "button then input the field name, shortcut code, and note in the fields of "Edit Information". If "Default" is selected, before the sample information is input, the default set will be displayed in the corresponding field. It is suggested to use numbers and letters or their combination to form a shortcut key. The remarks information can be empty.

Save

When an item is selected, the information on this item can be modified. Click "Save"button to save the edited item .

Delete

When an item is selected, this item can be deleted, and the sample information fields input for this item will also be deleted.

5.4.8 User Management

Click the button on the screen, and then select "Setup""User" on the pop-up menu to enter the interface.

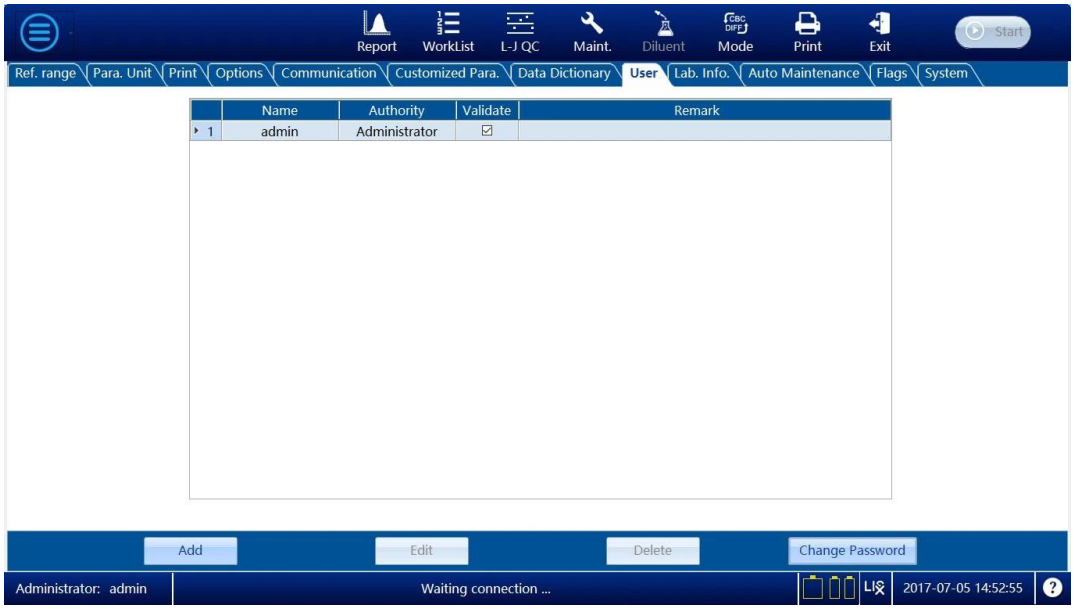

Figure 29

The "Add" function is used to add users. Click the "Add" button to open the following Add User dialogue box :

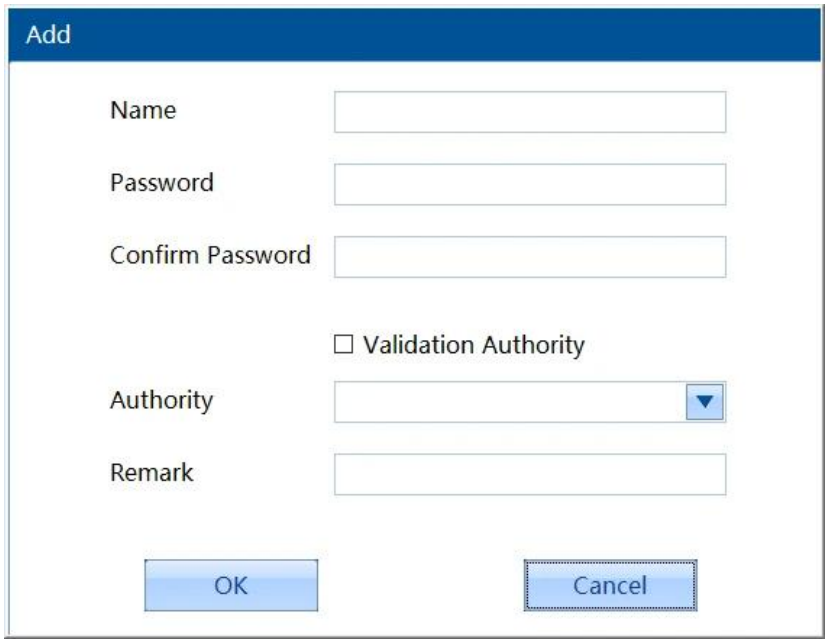

Figure 30

Input the contents in the edit box, click the "Authority" combo box, and set the authority of the new user to "Common User" and "Administrator". Click "OK" to save the settings or "Cancel" to directly exit.

Edit

In the user list, click the user cell to be modified. Click the "Edit" button to pop up the following dialogue box :

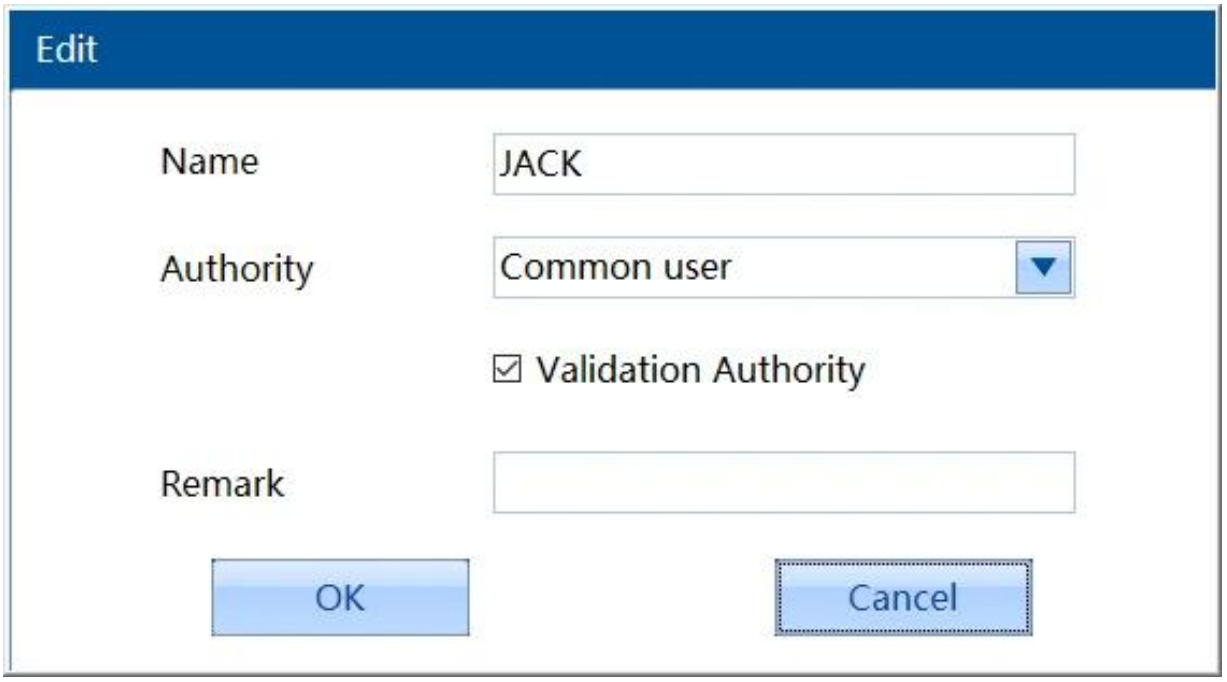

Figure 31

You can modify your username and authority as needed. Click the "OK" button to save the user information modified.

Delete

In the user list, select a user line and click the "Delete" button to pop up the confirmation dialogue box. After you click "OK", the current user will be deleted.

Change Password

Figure 32

"Change Password" is used to change the password of the current user. Input the old password of the user correctly, input the new password, click "OK", and the system will prompt "The password has been changed".

5.4.9 Lab Information

Click the button on the screen, and then select "Setup""Lab Info." on the pop-up menu to enter the interface.

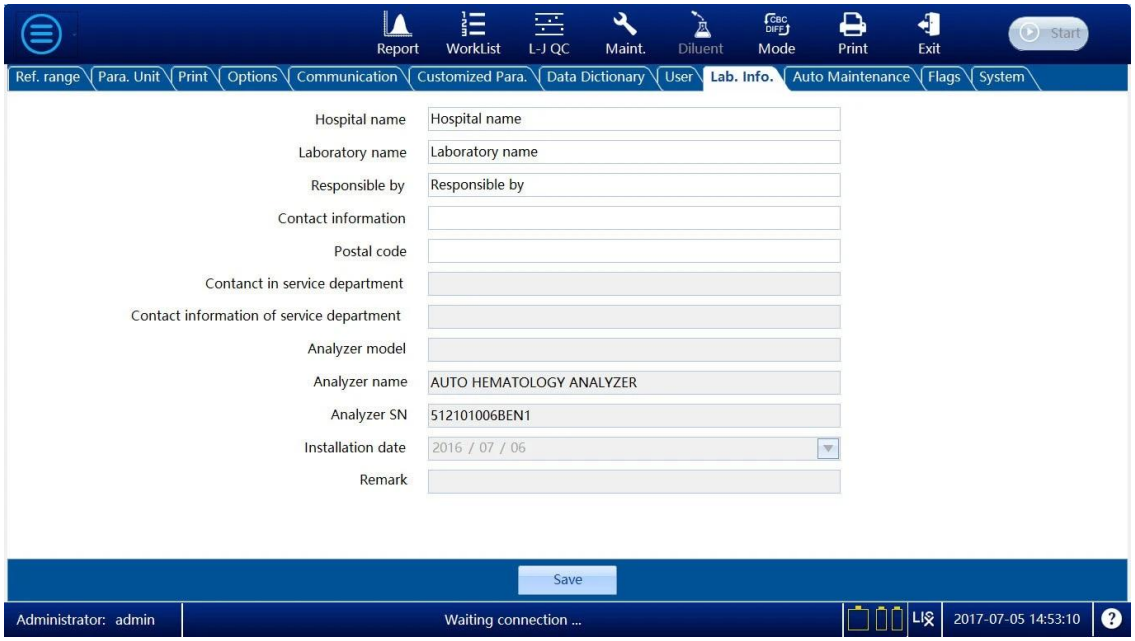

Figure 33

Save
Click the "Save" button to save the information.

5.4.10 Auto Maintenance

Click the button on the screen, and then select "Setup"" Auto Maintenance" on the pop-up menu to enter the interface.

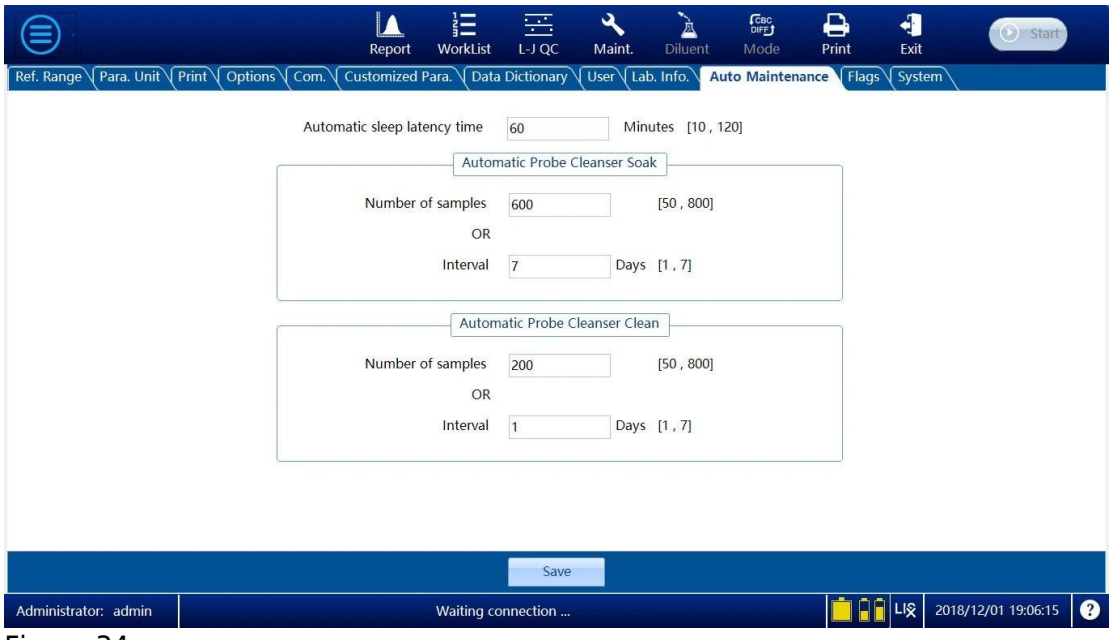

Figure 34

Automatic sleep latency time
When there is no action of the fluidics, the analyzer will enter the sleep mode according to this set time, with the range of 10 to 60 minutes and the default of 30 minutes.

Automatic Probe Cleanser Soak
Used for setting how many tests can be performed or how long time keep working before the "Soak with Probe Cleanser" operation starts automatically, with the range of 50 to 800 samples and the default of 500 samples or the range of 1 to 7 days and the default of 7 days.

Automatic Probe Cleanser Clean
Used for setting how many tests can be performed or how long time keeps working before the "Clean with Probe Cleanser" operation start automatically, with the range of 50 to 800 samples and the default of 500 samples or the range of 1 to 7 days and the default of 7 days.

Save
Click the "Save" button to save the setting.

5.4.11 Flags

Click the button on the screen, and then select "Setup""Flags" on the pop-up menu to enter the interface.

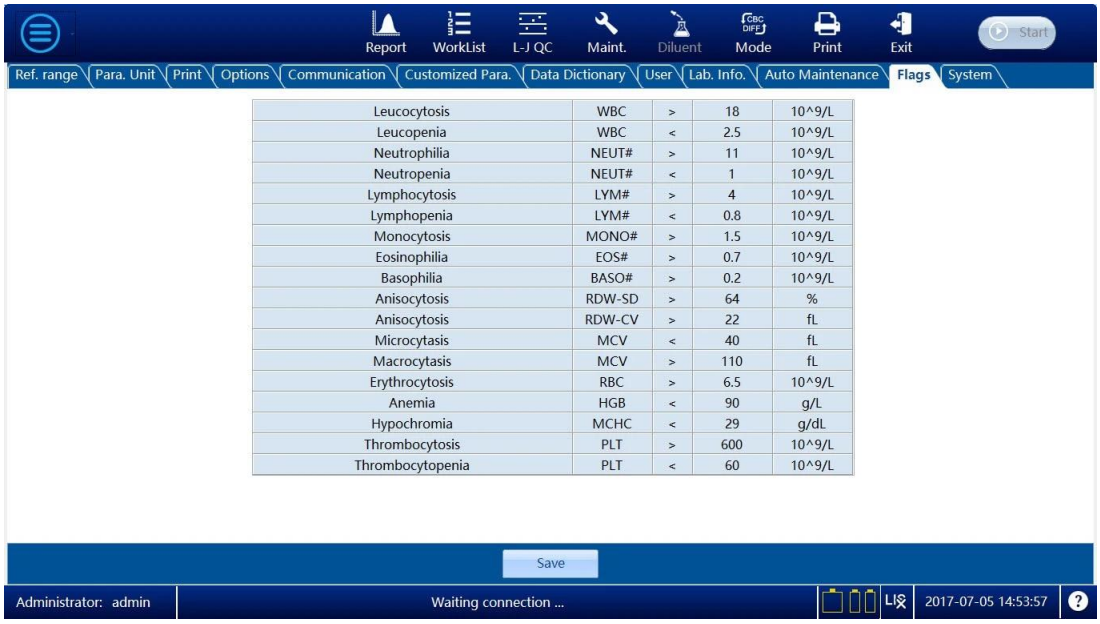

Figure 35

You can set some flags of the analyzer on this interface. If the result of analysis exceeds the flags limit set, the analyzer will give the corresponding flags text.

Save
Click the "Save" button to save the information.

5.4.12 System

Click the button on the screen, and then select "Setup""System" on the pop-up menu to enter the interface.

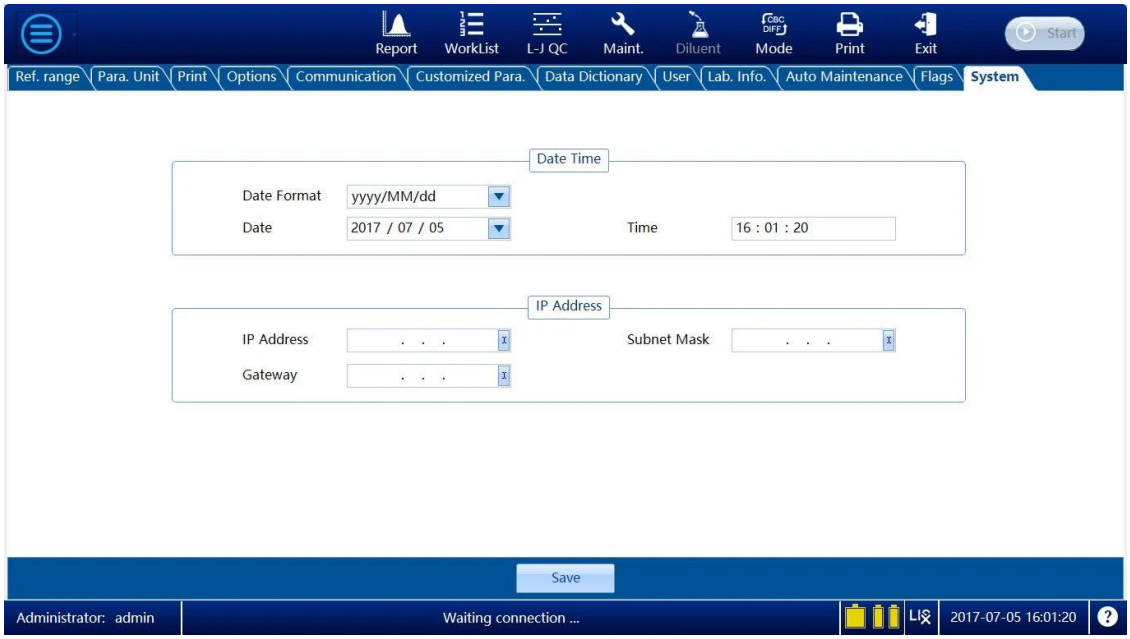

Figure 36

It is used to set the date and time, date formats and IP address of the analyzer.

Save

Click the "Save" button to save the information.

6. Operating your analyzer

6.1 Introduction

This chapter provides step-by-step procedures for operating your analyzer on a daily basis. A flow chart indicating the common daily operating process is presented below

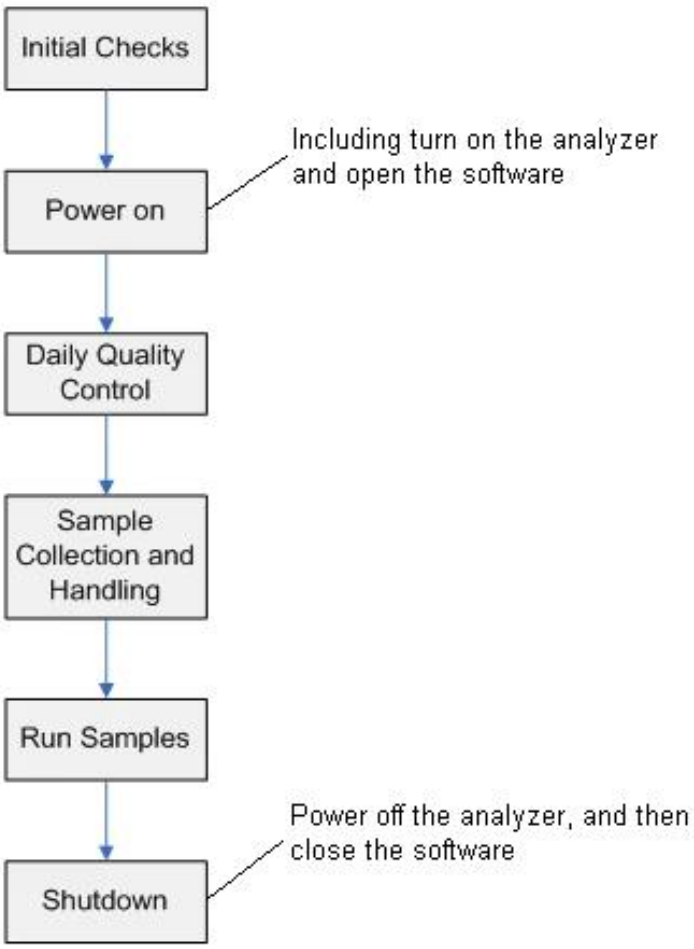

Figure 37 (Daily Operating Process)

6.2 Initial Checks

Perform the following checks before turning on the analyzer.

■ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
■ Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
■ The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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 to 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, hair and hands away from the moving parts to avoid injury.
• You should only use the Manufacturer-specified reagents. Store and use the reagents as instructed by instructions for use of the reagents.
• Check if the reagents are connected correctly before using the analyzer.
After installing a new container of reagent, keep it still for a while before use.
• Checking the waste container
Check and make sure the waste container is empty.

• Checking 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.
• Checking the printer (optional)
Check and make sure enough printer paper is installed. Check and make sure the power cord of the printer is properly plugged into the power outlet. Check and make sure the printer is properly connected to the external computer.

6.3 Startup and Login

Starting the analyzer:
1. Turn on the power switch of the analyzer. The power indicator light will be on.
2. After starting the software, the screen will show.

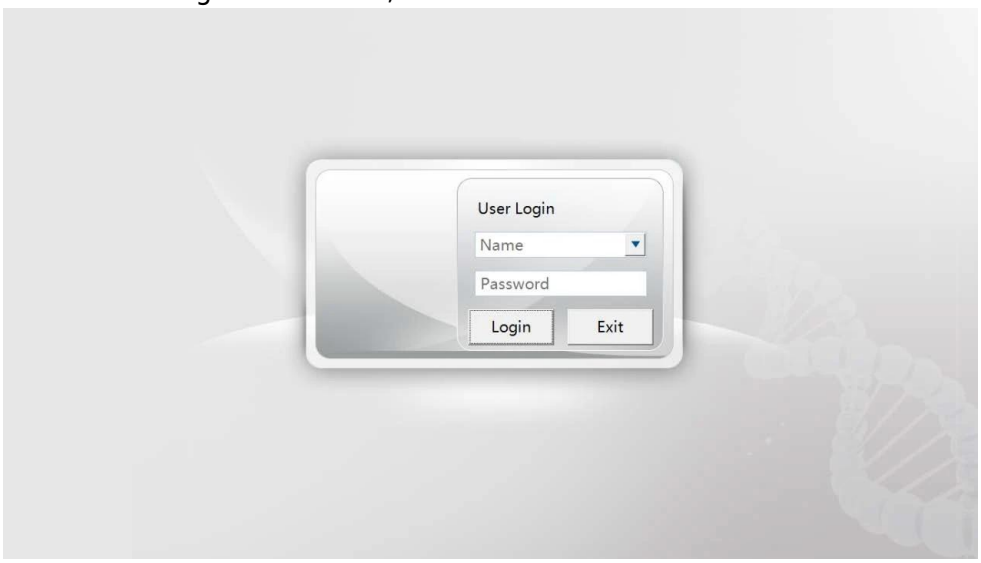

Figure 38
Input the correct user name and password in the "Login" screen. Click the "OK" button to initialize the system.

• If you failed to run the software continuously, please contact Manufacturer customer service department or your local distributor immediately.
• After startup, please make sure the date/time of the computer is correct.
• Up to 12 digits can be input for user name and password.

During the Initialization, the startup information will be displayed on the screen. The whole process lasts 4 to 12 minutes. Time needed for initializing the system depends on how the analyzer was previously shut down.
After the initialization process, you can enter the "Report" screen to check the background result.

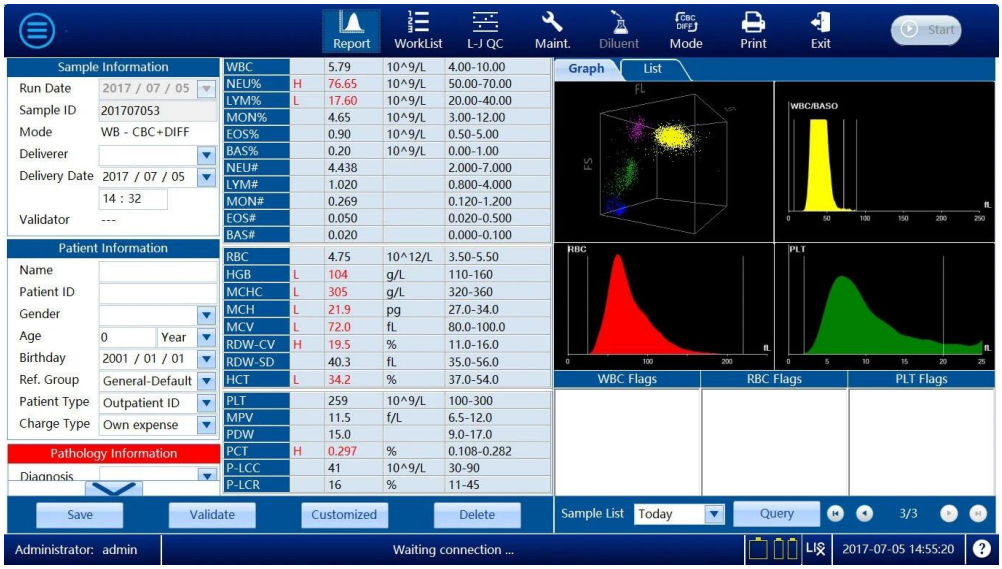

Figure 39

After initialization, if the unfinished sample records in the Worklist are detected,
a message box will pop up to confirm the set first unfinished in the worklist as the next sample to be run.
Click "Yes" to set the first record in the worklist as the next sample to be run.
Click "No" to hide all the records in the worklist.

• The background test is to detect the particle interference and electrical interference.
• 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.
The sample ID for background test is "0".
• If error happens during initialization (e.g. the background results exceed the Ref. Range), the analyzer will alarm. See Troubleshooting Your Analyzer for solutions.
• The system opens different functions for the users according to their authority levels. The user's authority level depends on the user name and the password when the user logs in the system.
• You can click the "Exit" button to switch to another user. Input the new user name and password in the Login message box, and then click "OK" to re-login as a new user.
• Running a test when there is an "Abnormal background", you would get an unreliable testing result.

6.4 Daily Quality Control

Before running any samples, run the controls. See Quality Control for details.

6.5 Sample Collection and Handling

■ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contracted areas in the laboratory.
■ Do not contact the patients' sample blood directly.
■ Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.
■ Be sure to use clean K2EDTA anticoagulant collection tubes, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.

• Whole blood samples
1. Use clean K2EDTA(1.5 - 2.2mg/mL) anticoagulant collection tubes to collect venous blood samples.
2. Mix the sample according to your laboratory's protocol.

◦ When using the Φ12X75 (without the cap) evacuated collection tube, be sure the volume of the whole blood sample is not less than 0.5mL.
◦ For the whole blood samples to be used for WBC differential or PLT count, you should 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
refrigerated samples at room temperature for at least 30 minutes before running them.
◦ Be sure to mix any sample that has been prepared for a while before running it.

• Pre-dilute samples
1. At the shortcut button area, click the "Diluent" button, then a message box will pop up.
2. After the preparation is done, the following message box will pop up.
3. Present a clean centrifugal tube to the sample probe and make sure the probe reaches the bottom of the tube and then keep the tube vertical, as the figure shows, to avoid spills, hangings and bubbles.

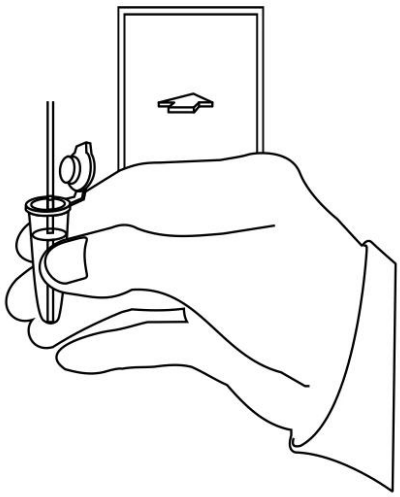

Figure 40

4. Press the aspirate key to start dispensing the diluent. During the procedure, a
progress bar will display.
5. The buzzer sounds when the dispensing is finished, then you can remove the centrifugal tube. Then, the following message box will display.
6. Add 20μL of capillary blood to the diluent, close the tube cap and shake the tube to mix the sample.
7. After the pre-dilute sample is prepared, click the "Cancel" button to exit
dispensing the diluent.
8. After exiting, the above message box will close automatically.
9. If more portions of diluent are needed, repeat the procedure 3-5.

◦ You can also dispense 400μL of diluent by pipette into the tube.

◦ Be sure to keep dust from the prepared diluent.
◦ After mixing the capillary sample with the diluent, be sure to wait 3 minutes before running the sample.
◦ Be sure to run the pre-dilute 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 pre-dilute stability based on your laboratory's sample population and sample collection techniques or methods.

6.6 Sample Analysis

6.6.1 Input Work List Information
You can input the work list information for the next sample before running it.

• If the analyzer is shut down abnormally, you will lose the worklist information of the samples that have not been saved yet.
Click the "Worklist" button on the shortcut area to enter the "Worklist" screen.

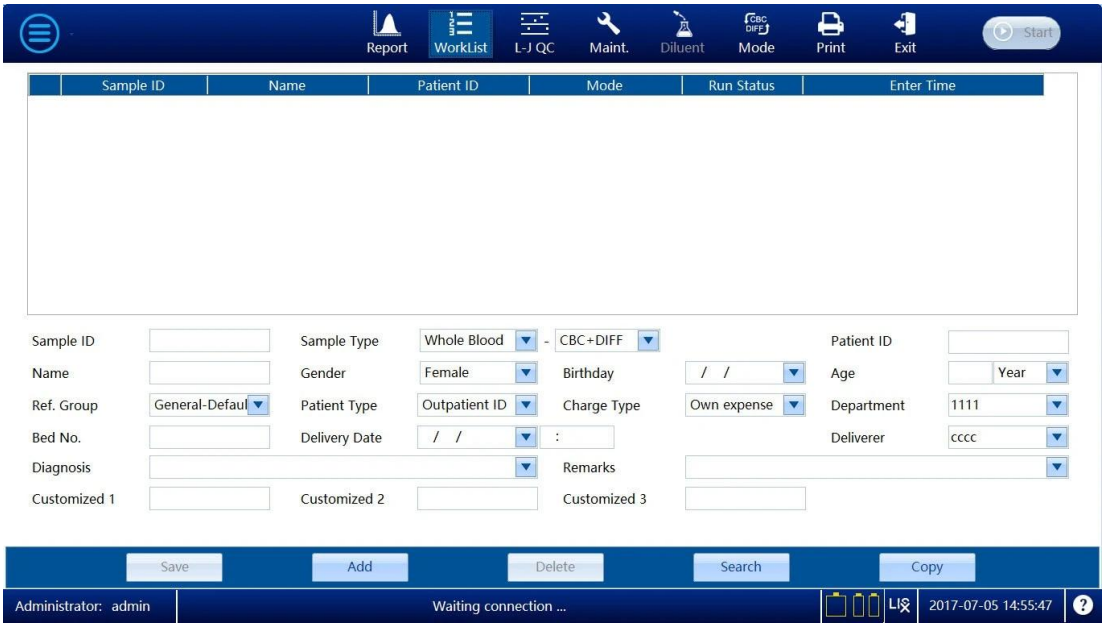

Figure 41

• The Run Status of a new record is "To Be Run".
• You can switch between options in the Sample Info./Patients Info area by the [Tab] key. You can also use the [Enter] key to switch after setting
• Input the Sample ID
Input the Sample ID in the "Sample ID".
◦ The sample ID could be letters, numbers and all the keyboard-supported characters (including special characters).
◦ The sample ID must be input and its acceptable length is [1, 20].
◦ The sample ID must be alphanumeric ended with a numeric. Sample ID being all "0" will be considered invalid.

• Selecting Analysis Mode
Select the blood mode ("Whole Blood", "Predilute" or "Whole Capillary

Blood") and select the measurement mode ("CBC" or "CBC+DIFF") from the two pull-down lists respectively.

◦ In the "CBC" measurement mode, the analyzer only counts the blood cells without further differentiating the white blood cells. In the "CBC+DIFF" mode, the analyzer counts the blood cells and further differentiates the white blood cells into 5 sub-populations.

• Selecting ref. group
Select the reference group for the sample from the "Ref. Group" pull-down list. The analyzer will judge the test results according to the reference range of the Ref. group. When the results exceed the reference range, the analyzer will flag.

◦ If you have selected the gender and age of the patient, then the system will provide a matching Ref. Group automatically.
◦ If the auto-matching Ref. The group is different from the one that you selected before (excluding the 5 customized Ref. Groups), then the system will adopt the auto-matching Ref. Group.

• Input the delivery time
Select the delivery date from the date control and then input the delivery time into the time edit box.

• Input the patient ID
Input the patient ID into the "Patient ID" box.

• Input the patient name
Input the patient name into the "Name" boxes.

• Input the patient gender
Input the gender of the patient into the "Gender" box or select it from the "Gender" pull-down list.

• Input the patient age
The analyzer provides four ways for you to input the patient age - in years, in months, in days and in hours. The first way is designed for the adult or pediatric patients older than one year; the second for the infant patients one month to one year; the third for the neonatal patients no older than one month and the fourth for the neonatal no older than 24 hours. You can choose only one of the four ways to input the patient age.
The "Age" pull-down list provides four ways for you to input the patient age- in years, in months, in days and in hours, and you can input the patient age into the box followed by the age unit.

• Input the birthday
Select the patient's birthday from the date control.

◦ After input the birthday, the age field will calculate automatically according to the difference between the current system date and the "Birthday", and then a new result of age and its unit will be displayed in the age edit box and the unit combo box respectively. Then, the age box will be unavailable to edit unless the "Birthday" is cleared.
If the input birthday is later than the current system, it is considered invalid.

• Input the name of the department

Input the name of the department, from which the sample came, into the "Department" box or select it from the "Department" pull-down list.

• Input the Bed No.
Input the bed No. of the patient into the "Bed No." box.

• Input the name of the deliverer
Input the name of the deliverer into the "Deliverer" box or select it from the "Deliverer" pull-down list (if there are previously saved deliverers' names in the list).

• Input the content of clinical diagnosis
Input the suspicions information of diagnosis into the "Diagnosis" box.

• Input the remarks
Input the remarks into the "Remark" box.

• Saving
When you finish input the work list information, you can click the "Save" button to save all the information.
◦ The "Sample ID" of the current record can not be the same as the unfinished records of the following status: "To Be Run", "Running" and "Error".

6.6.2 Running the samples
• All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
• The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
• Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.
• The sample probe should be kept away from the tube bottom when the probe is aspirating sample. Otherwise, the aspirated volume may be imprecise.
• The probe tip should not contact the sample tube. Otherwise, the blood may spill.
• Proper reference range shall be selected at the "Setup" screen before analysis. Otherwise, the results may be flagged erroneously.
• When running as per the worklist, then the next sample ID will always be the first unhide (or error) sample to be run in the worklist till there is no unhide sample left or the worklist is empty. If you set the method of entry for the sample ID as "Auto Increase", the ID of the latter sample will increase by 1 automatically.
• If you directly run the sample with an empty worklist, the default analysis mode is the same as the previous sample. The default initial analysis mode is "WB-CBC+DIFF".

• Running whole blood samples
1. At the main screen, be sure that the sample mode "WB" is displayed in the "Next Sample" information area.
2. Shake the whole blood sample as shown below to well mix it.

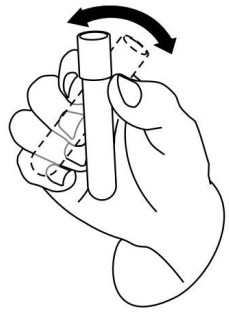

Figure 42

3. When it is ready to run a sample (i.e. the analysis status icon and analyzer indicator is green), present the whole blood sample to the sample probe.
4. Press the aspirate key to start the analysis.
5. The sample probe will automatically aspirate the sample. When you hear the beep, remove the sample tube. The analyzer will automatically run the sample. The analysis status led will change to yellow.
6. When the analysis is finished, the analysis status returns to green.
7. Run the rest samples as instructed above.

• Running predilute samples

1. At the main screen, be sure that the sample mode "PD" is displayed in the "Next Sample" information area.
2. Shake the capped predilute sample to well mix it.

When it is ready to run a sample (i.e. the analysis status led is green), carefully open the tube cap and present the predilute sample to the sample probe.
Press the aspirate key to start running.

◦ You can disable the message box before the predilute run. See Setup section for details.

3. The sample probe will automatically aspirate the sample. When you hear the beep, remove the sample tube. The analyzer will automatically run the sample and the analysis status led change to yellow.
4. When the analysis is finished, the sample and the analysis status led return to green.
5. Run the rest samples as instructed above.

◦ 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 Graph/Table review screen to perform operations including data browsing, validating, sample information editing and printing, etc., and you can also switch to other screens.
◦ When the analyzer is running, all the functions related to the fluidics sequence are not available.
◦ If you switch to the Graph review screen from other screens, the latest record information together with its result and graph will be refreshed and then displayed.

6.6.3 Dealing with the analysis results

• Automatic saving of analysis results

This analyzer automatically saves sample results. When the maximum number has been reached, the latest result will overwrite the oldest (already backed up). The maximum number of automatic saving

results is 100,000.

• Parameter flags
• If the parameter follows an "H" or "L", it means the analysis result has exceeded the upper or lower limit of the reference range but still within the display range.
• If the parameter follows a "?", it means the analysis result is suspect.
• If you see *** as opposed to the result, it means the result is either invalid or out of the display range.

◦ For the background test, the flags of parameter or flags of abnormal blood cell differential or morphology are not available.

• Flags of Abnormal Blood Cell Differential or Morphology
The analyzer will flag abnormal or suspect WBC, RBC and PLT according to the scattergrams and histograms. The flag information is defined in the following table:

Parameter	Flag Type	Flag Information
WBC	Abnormal	Abnormal WBC scattergram
	Abnormal	Abnormal WBC histogram
	Abnormal	WBC abnormal
	Abnormal	Leucocytosis
	Abnormal	Leucopenia
	Abnormal	Neutrophilia
	Abnormal	Neutropenia
	Abnormal	Lymphocytosis
	Abnormal	Lymphopenia
	Abnormal	Monocytosis
	Abnormal	Eosinophilia
	Abnormal	Basophilia
	Suspect	Left Shift?
	Suspect	Immature Granulocyte (IG)?
	Suspect	Abnormal/Atypical Lymphocyte?
	Suspect	RBC Lyse Resist?
RBC/HGB	Abnormal	Erythrocytosis
	Abnormal	RBC abnormal distribution
	Abnormal	Anisocytosis
	Abnormal	Macrocytosis
	Abnormal	Microcytosis
	Abnormal	Dimorphologic
	Abnormal	Anemia

	Abnormal	Hypochromia
	Suspect	HGB Abn/Interfere?
PLT	Abnormal	PLT Abnormal Distribution
	Abnormal	Thrombocytosis
	Abnormal	Thrombopenia
	Suspect	PLT Clump?

Table 7

The analyzer will flag abnormal or suspect WBC, RBC and PLT according to the scattergrams and histograms. The following table shows how the flags affect parameter results:

Type	Flag	Whole Blood - CBC	Whole Blood - CBC + 5DIFF	Predilute - CBC	Predilute - CBC + 5DIFF
WBC	WBC abnormal?	x	√	x	x
	RBC Lyse Resist?	x	√	x	x
	Abnormal WBC scattergram	x	√	√	√
	Abnormal WBC histogram	x	√	√	√
	Left Shift?	x	√	x	x
	Immature Granulocyte (IG)?	x	√	x	x
	Abnormal/Atypical Lymphocyte?	x	√	x	x
	Leucocytosis	√	√	√	√
	Leucopenia	√	√	√	√
	Neutrophilia	x	√	x	x
	Neutropenia	x	√	x	x
	Lymphocytosis	x	√	x	x
	Lymphopenia	x	√	x	x
	Monocytosis	x	√	x	x
	Eosinophilia	x	√	x	x
	Basophilia	x	√	x	x
RBC/HGB	Dimorphologic	√	√	x	x
	HGB Abn/Interfere?	√	√	x	x
	Anisocytosis	√	√	x	x
	Microcytosis	√	√	√	√
	Macrocytosis	√	√	√	√
	Erythrocytosis	√	√	√	√
	Anemia	√	√	√	√

	Hypochromia	√	√	√	√
	RBC abnormal distribution	√	√	x	x
PLT	PLT Clump?	√	√	x	x
	Thrombocytosis	√	√	√	√
	Thrombopenia	√	√	√	√
	PLT Abnormal Distribution	√	√	x	x

Table 8

◦ When the PLT value is less than 100 109 / L, a manual count by the microscope is recommended.

6.7 Worklist

Click the "Worklist" button on the shortcut area to enter the "Worklist" interface.

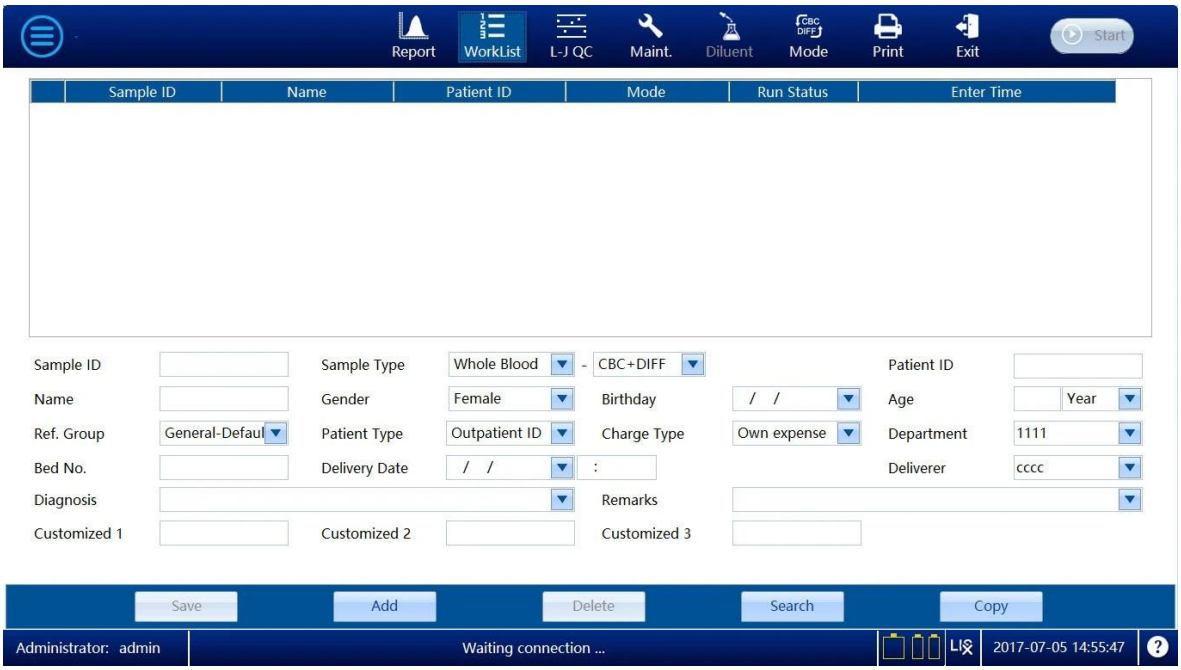

Figure 43

The upside of the screen is the worklist; the downside is information entry area including Sample Info. and Patient Info. The bottom of the screen is the function button area.

■ The worklist can save a maximum of 1000 records.

■ All the information fields in the worklist are input through the information entry area except the "No.", "Run Status" and "Entry Time".

■ If the worklist is empty, all the information fields in the information entry area are blank and displayed in gray.

■ If a record in the worklist is being operated (highlighted), the corresponding information of the record will display in the information entry area.

In the "Worklist" screen, you can perform the following operations to the worklist.

• Adjusting the width of each column
Click and hold the boundary line between the two columns, then drag the line to adjust the width of each column.

If you click a record in the worklist to highlight it, the corresponding information of the record will display in the information entry area. You can edit each information field in the information entry area.
◦ For records whose "Run Status" are "Running", you can not edit their "Sample ID" and "Mode".

• Add
You can click the "Add" button to add a new sample record, see Input Work List Information section of this chapter for details

• Save
After performing the "Add"operation, you can click the "Save" button to save all the information.

◦ The "Sample ID" of the current record can not be the same as the records of the following status: "To Be Run", "Running" and "Error".

• Delete
1. Click the" Delete" button, then the "Delete" message box will pop up.

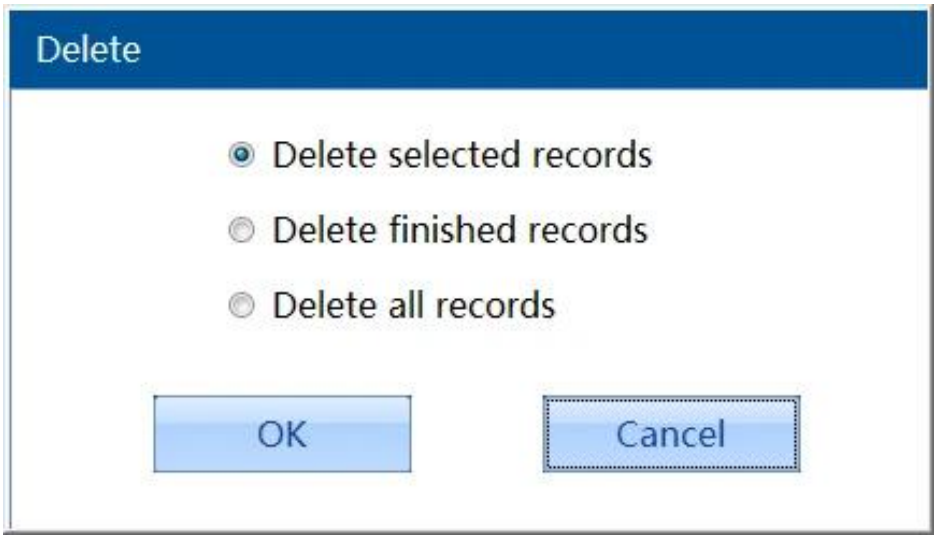

Figure 44

2. Click the radio button "Selected Samples", "All finished records" or "All records" to select the records you want to delete." Selected Samples" are those selected with "√" marks in the worklist.
3. Click the "OK" button to delete the record and refresh the worklist

◦ The records whose "Run Status" are "Running" can not be deleted.
• Search
Click the" Search" button, then the "Search" message box will pop up.

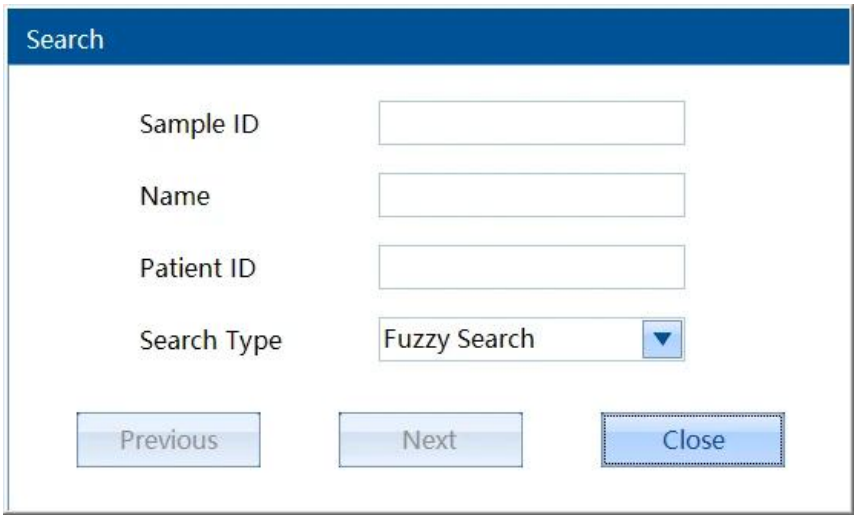

Figure 45

1. Click one or more check boxes to define the desired search condition(s).
2. Input the search content in the edit box of the desired search condition.
3. If you wish to perform the exact search, you can select the "Exact search" check box to select it; if you wish to perform the fuzzy search (means to search the related records which contain the content that you input), you should select the "Fuzzy search".
4. Click the "Previous"/"Next" button to start searching upwards/downwards from the highlighted record. The matching record found will be highlighted. Then you can click the "Previous"/"Next" button to continue searching.
◦ If the first/last record is reached, then the searching cycle will start again from the last/first record upwards/downwards.
5. A searching cycle will be completed when backing to the initial record. If
there is no matching record found, the prompt message box" No record found!" will pop up at the screen; otherwise, the prompt message box" Search finished!" will pop up. Click the "OK" button to close the message box.
6. You can repeat procedure 2 to 6 to search for other content; or click the "Close" button to finish searching and close the message box.
• Copy
1. Click the desired record in the worklist to highlight it.
2. Click the "Copy" button to add a new record in the worklist and highlight it. The sample ID of this new added record is empty or will automatically increase by 1 based on the last sample ID in the worklist; the other information remains the same as the record be copied from.

• Print
1. Select the check box of the desired record in the worklist.
2. Click the "Print" button to start printing.

6.8 Shutdown

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

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

■ 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 strictly as instructed below.

The shutdown procedure includes closing the analyzer and exiting the software. The following content will introduce the two procedures respectively.
Turning off the analyzer
1. Click the shortcut button "Exit", or select "Exit""Shutdown" option, the confirm message box will pop up.
2. Click the "OK" button to shut down the analyzer.
3. During the shutdown procedure, the shutdown information will be displayed in the information indicating area at the bottom of the screen.
4. After the shutdown is finished, a message box will pop up.
5. Place the power switch at the left side of the analyzer in the OFF position (O). The message box will be closed automatically.
6. Empty the waste container and dispose of the waste properly.

◦ Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
◦ When the analyzer is running or performing other fluidics sequence, do not shutdown the analyzer forcibly.
◦ If error happens during shutdown procedure, the analyzer will return to the status before the shutdown procedure is performed, and then alarm. See Troubleshooting Your Analyzer for details to remove the error.
◦ You will not exit the software after the shutdown of the analyzer, and you can still perform operations that are available without the cooperation of the analyzer.

7. Reviewing sample results

7.1 Introduction

The analyzer automatically saves analysis results. Totally 100,000 results can be saved, including sample information, parameters, flags, scattergrams and histograms.
You can browse sample results either in the table or graph mode.

7.2 Result Review

Click the shortcut button "Report" to enter the screen :

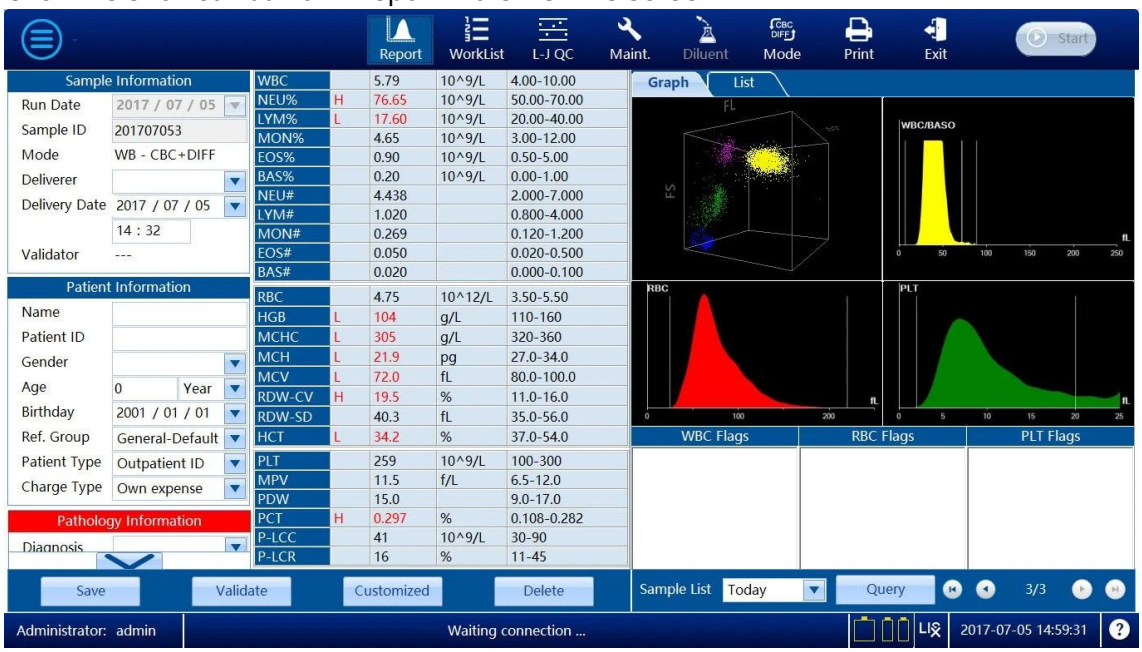

Figure 46

7.2.1 Sample/patient information
You can use the record switch column in the down right of the screen to browse the sample records one by one.

You can see the Sample/Patient Info on the upside of the screen. You can edit
all the patient information except the "Operator" and the "Verifier". For details of editing information, see Editing work list information in Chapter 6 Operating Your Analyzer.

• You can enable users of common level to edit the sample ID by setting in the "Setup" screen.
• You can edit all the information of the sample except the Mode and Run Time.

7.2.2 Sample Result
You can view and edit sample results in the result list.

• 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/suspect flags will also be refreshed.

• Only the result of the measurement parameters (WBC, RBC, HGB, MCV and PLT) can be modified.
• No matter if the sample result is validated or not, as long as it is edited, the result of the parameter that you modified manually will be flagged with an "E". If any parameter result is then changed due to the one that you modified manually, it will be flagged with an "e". ("E" or "e" will be displayed between the parameter result and its unit.)
You can not edit the results of the background.

7.2.3 List
Click tab "List", the sample list will display in the screen, you can browse each sample record and its Sample/Patient information in the "List" screen.

Figure 47

• For the error sample result, the content of each information field is displayed in red.
• For the validated sample, its cell in the "Validate" column displays "√".
• For the printed sample, its cell in the "Print" column displays "√".
• For the transmitted sample, its cell in the "Transmission" column displays "√".
you can perform the following operation:
• Selecting the sample table
Click the "Sample List" combo box, then you can select "Today" (default), "All" and "Query".

The List will display different records according to the different options:

Record option	Records displayed
Today	Display only the sample records within today
All S	Display all the saved sample records.
Query	Display all the sample records met the search requirements.

Figure 46

• Switching
Double click a record in the list; the tab will switch to the graph review screen of the record automatically.

7.2.4 Function of the Buttons
• Save
Click the "Save" button to save the modified information on all tabs of the current result.

• Print
Click the "Print" button to print the information, results, histograms and scattergrams of the current sample.

◦ You can set the amount of copies for the printed report in the "Setup" screen.
◦ At the "Setup" screen, you can select whether to print the Flag information in the report.

• Delete
Click the "Delete" button, and then a message box will pop up
Click "OK" to delete the current displayed sample record in the "Graph" screen.
◦ The "Delete" button and the corresponding deleting operation are not available to users of common-level.

• Validate
Click the "Validate" button to perform the validating operation.

◦ You can enable the users of common level to validate by setting in the "Setup" screen. Otherwise, the user name and the password of administrator level are required.
◦ After validating, you can not edit the Sample/Patient Info. and result.
◦ You can not validate the background record.

• Cancel (validate)
Click the "Cancel" button to cancel the validating operation.

◦ If the current sample result is validated, the "Validate" button will be replaced by the "Cancel" button.
◦ The users of common level is enabled the authority of "Cancel" together with "Validate" when you setting in the "Setup" screen. Otherwise, the user name and the password of administrator level are required.
◦ After canceling, you can edit the Sample/Patient Info. and result.

• Query
You can search for the specified sample record from all records in the current list as default.
Click the " Query" button, and then a " Query" message box will pop up.

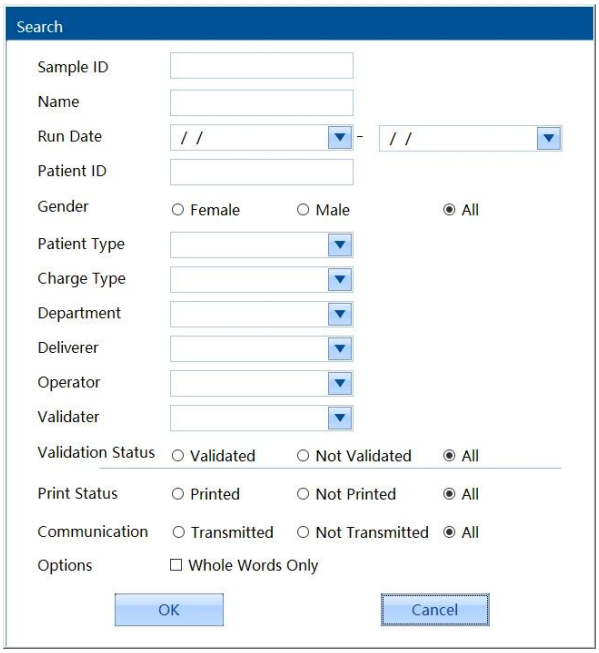

Figure 47

You can define the desired searching conditions.
• Input the sample ID
Select the check box of "Sample ID", and then Input the desired sample ID into the "Sample ID" edit box.

• Input the patient name
Select the check boxes of "Last Name" and "First Name", and then Input the desired patient name into the boxes.

• Selecting the "Run Date"
Select the check box of "Run Date", and then select the limits of the run date.

• Selecting the patient gender
Select the check box of "Gender", and then click the radio button "Male", "Female" or "Empty" to select the patient gender.

• Input the patient ID
Select the check box of "Patient No.", and then input the desired patient No. into the "Patient No." edit box.

• Input the department name
Select the check box of "Department", and then Input the desired department name in the "Department" edit box.

• Input the Bed No.
Select the check box of "Bed No.", and then Input the desired bed No. into the "Bed No." edit box.

• Input the Deliverer
Select the check box of "Deliverer", and then Input the desired deliverer into the "Name" edit box.

• Selecting the Validate Status
Select the check box of the "Validate Status", and then click the radio button "Validated" or "Not Validated" to select the validate status.

• Selecting the print status
Select the check box of "Print Status", and then click the radio button "Printed" or "Not Printed" to select the print status.

• Selecting the Communicate Status
Select the check box of the "Communication Status", and then click the radio button "Transmitted" or "Not Transmitted" to select the communication status.

• Selecting the matching type
Select the check box of "Whole Words Only", and then the precise search will be performed; otherwise, the fuzzy search (means to search the related records which contain the content that you input) will be performed.

Click "OK" to perform the search and switch to the "Samples found" list of the "Table" screen, and the searching results will display.

◦ The desired record is searched from all the sample records as default.

8. Quality Control

8.1 L-J Quality Control

■ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
■ Only users of administrator-level can edit the L-J settings.
■ For the QC files with saved QC results, if any change is made to the target or the limits, the changed data will be highlighted in yellow, and the change will be recorded into the system log.

8.1.1 L-J Setting

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

You can Click the shortcut button "LJ-QC" or Click the  button on the screen, and then select "QC""L-J QC" on the pop-up menu to enter the interface.
Click the "QC Settings" tab to enter the L-J setup screen.

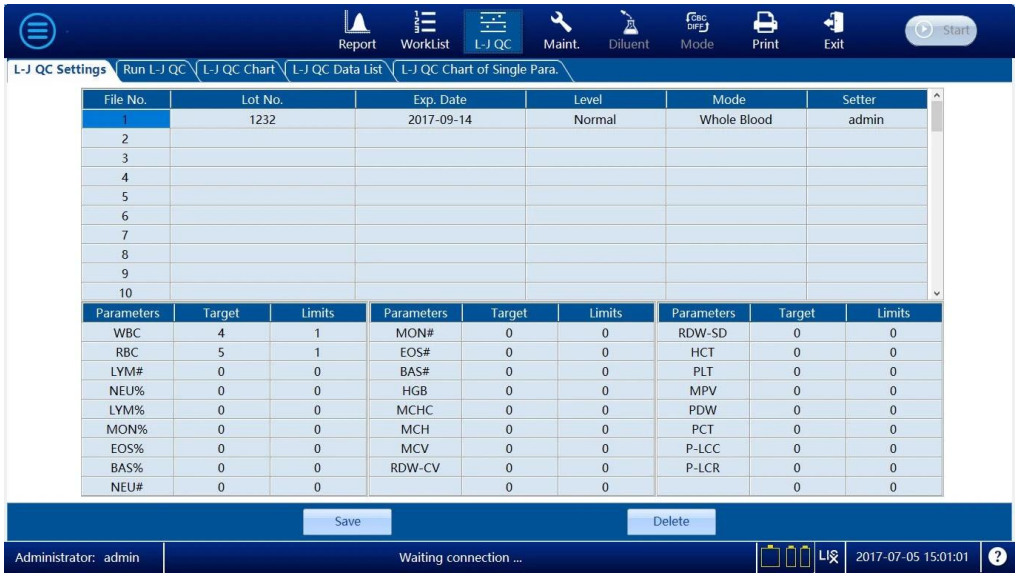

Figure 48

Select a QC File No. with empty QC information.
• You can select the file No. within the range [1, 60].

Input the lot No. of the control.
• The lot No. can not be empty and up to 16 digits can be input. You can input characters, numbers, letters and special characters, but no Chinese characters are allowed.
• Different QC files can not have the same lot No.

Input the batch expiration date of the controls.
• You must input the expiration date, and the entry range is [current system date, 2099-12-31].

Select the QC mode.
• Different QC files can not have the same lot No. and QC mode.

Select the control level.
According to the target list of the corresponding lot No., input the target and limits into the edit boxes of the parameters to be included in the QC run.
Click the "Save" button to save all the settings of the QC.

8.1.2 Running controls
After editing the QC information, you can start one of the following QC analyses according to the selected QC mode.
• Whole Blood
• Predilute
• Running controls (whole blood)

◦ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contracted areas in the laboratory.
◦ The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.

◦ The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
◦ Collection tubes broken may cause personal injury and/or biohazard. Exercise caution when loading the collection tubes to the rack or getting the collection tubes from the rack, be sure not to break the tubes.
◦ Keep your clothes, hair and hands away from the moving parts to avoid injury.
◦ The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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.
◦ Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.

You can enter the run qc menu by one of the following ways:
• Click the shortcut button "L-J QC"
• Click the button on the screen, and then select "QC""L-J QC" on the pop-up menu.

Figure 49

Select the QC file No. to be run; the screen displays the corresponding file information.
Be sure that the level of the control to be run corresponds with the current QC file
Be sure that the control to be run is not expired.
Prepare the control as instructed by instructions of the controls. Run the controls:
1) Make sure the QC mode is "whole blood" and the analysis led is green.
2) Shake the prepared control as shown below to well mix it.

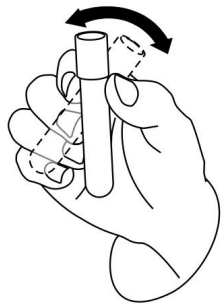

Figure 50

3) Present the control to the sample probe.
4) Press the aspirate key to start QC run.
5) When you hear the beep, remove the control.
When finished running, the QC results will be displayed in the current screen and be saved in the QC file automatically.
◦ Up to 300 QC results can be saved for each QC file.
Do the above procedures to continue running the controls if necessary.

• Running controls(Predilute)
◦ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contracted areas in the laboratory.
◦ The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.
◦ The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
◦ Collection tubes broken may cause personal injury and/or biohazard. Exercise caution when loading the collection tubes to the rack or getting the collection tubes from the rack, be sure not to break the tubes.
◦ Keep your clothes, hair and hands away from the moving parts to avoid injury.
◦ The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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.
◦ Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.

1. You can enter the run qc menu by one of the following ways:
• Click the shortcut button "L-JQC".
• Click the button on the screen, and then select "QC""L-J QC" on the pop-up menu.

Figure 51

Select the QC file No. to be run; the screen displays the corresponding file information.
Be sure that the level of the control to be run corresponds with the current QC file.
Be sure that the control to be run is not expired.
Prepare the control as instructed by instructions for use of the controls. Run the controls:
1) Make sure the QC mode is "Predilute" and the analysis status led is green.
2) Click the shortcut button "Diluent", and then a message box will pop up.
3) After the preparation is done, the following message box will pop up.
4) Present a clean centrifugal tube to the sample probe and make sure the probe reaches the bottom of the tube and keep the tube vertical, as the figure shows, to avoid spills, hangings and bubbles.

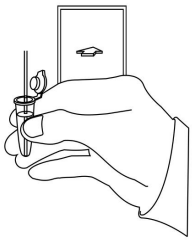
Figure 51
5) Press the aspirate key to start dispensing the diluent.
6) The buzzer sounds when diluent is finished, then you can remove the centrifugal tube.
7) Add 20μL of control to the diluent, close the tube cap and shake the tube to mix the sample.
8) Click the "Cancel" button to exit the "Diluent" message box.
9) After the cleaning is finished, close the prompt.
10) Present the prepared control to the sample probe.
11) Press the aspirate key to start QC run.
12) When you hear the beep, remove the control.
When finished running, the QC results will be displayed in the current screen and be saved in the QC file automatically.

◦ You can also dispense 400µL of diluent by pipette into the tube.
◦ Be sure to keep dust from the prepared diluent.
◦ After mixing the control with the diluent, be sure to wait 3 minutes before running.
◦ Be sure to run the predilute 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 QC stability based on your laboratory's sample population and sample collection techniques or methods.
◦ Up to 300 QC results can be saved for each QC file.

Do the above procedures to continue running the controls if necessary.
• Print
Click the "Print" button to print the results of the current QC Run screen.

8.1.3 L-J Chart

Click the  button on the screen, and then select "QC""L-J QC" on the pop-up menu. And click the "L-J QC Chart" tab.
Select the QC file No. you want to review, and then the screen will display the corresponding information and the graph.

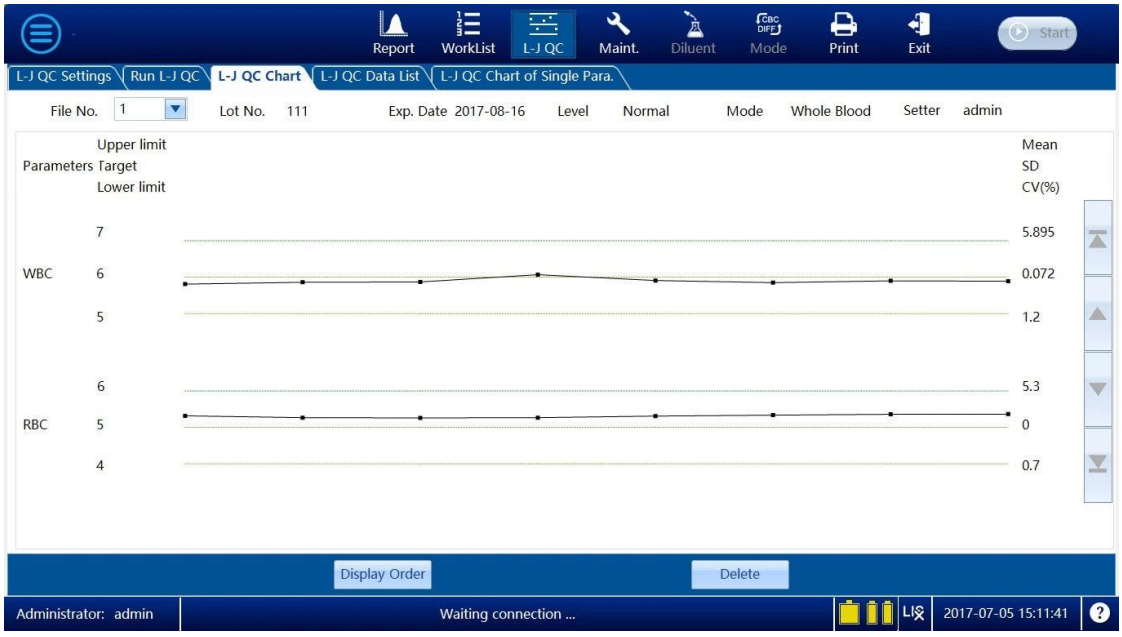

Figure 52

1- The Mean, SD and CV% of all the QC results of each parameter in the current graph.
2- 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.
3- When you clicking a QC point in the graph, the QC points of other parameters that saved together with this one will be marked by a red line.

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

• Delete

The administrator can delete the QC results by the following steps:
If you wish to delete a single QC result, move the red line to the desired QC result; if you wish to delete all the data, perform step 2 directly.
Click the "Delete" button to select "Selected Data" or "All Data".

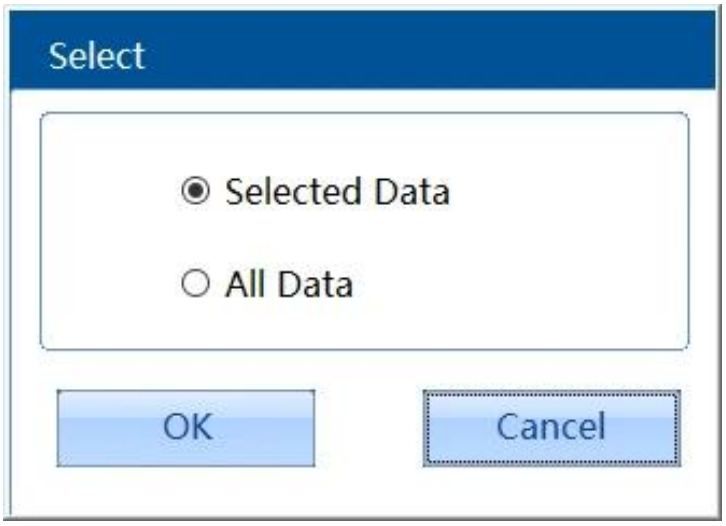

Figure 53

Click the data you want to delete.
Click the "OK" button and then confirm to delete the selected data.

◦ The deleting operation will be recorded in the log.
• Print
Click the "Print" button to print all the file information and graphs of the parameters of the current QC file.

• Display Order
You can take the following steps to adjust the display order of different parameters. Click the "Display Order" button to check the current display order of the parameters.

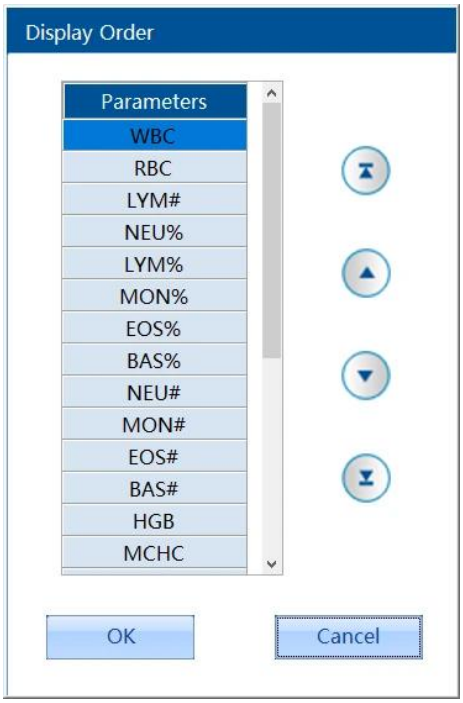

Figure 54

Click the parameter that you want to adjust.
You can click the button or button to move the parameter upward or downward; you can click the button or button to move the parameter to the first or the last position.
Click the "OK" button to refresh the display order of the parameters.

8.1.4 L-J Data List
Click the button on the screen, and then select "QC""L-J QC" on the pop-up menu. And click "L-J Qc Data List" tab.
Select the QC file No. you want to review, and then the screen will display the corresponding information and the graph.

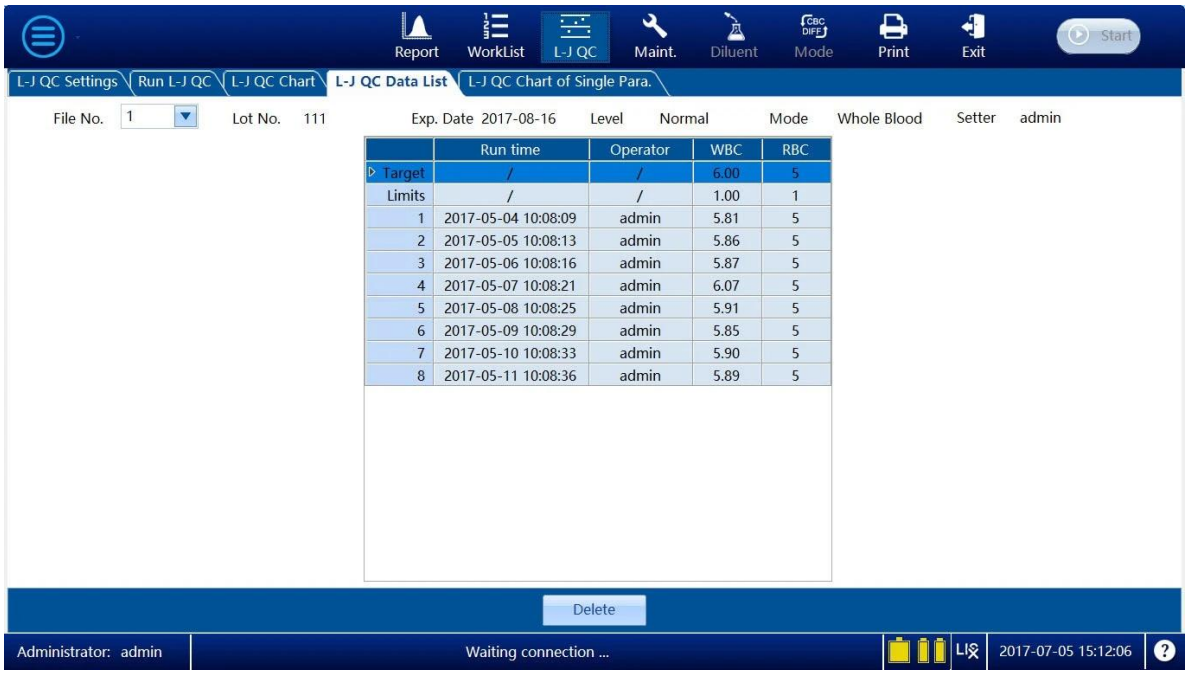

Figure 55

• Delete
The administrator can delete the QC results by the following steps:
If you wish to delete Selected QC result, select record to the desired QC result; if you wish to delete all the data, perform step 2 directly.
If you wish to delete span QC results, select date range.
Click the "Delete" button to select "Selected Data" , "Date Range" or "All Data".

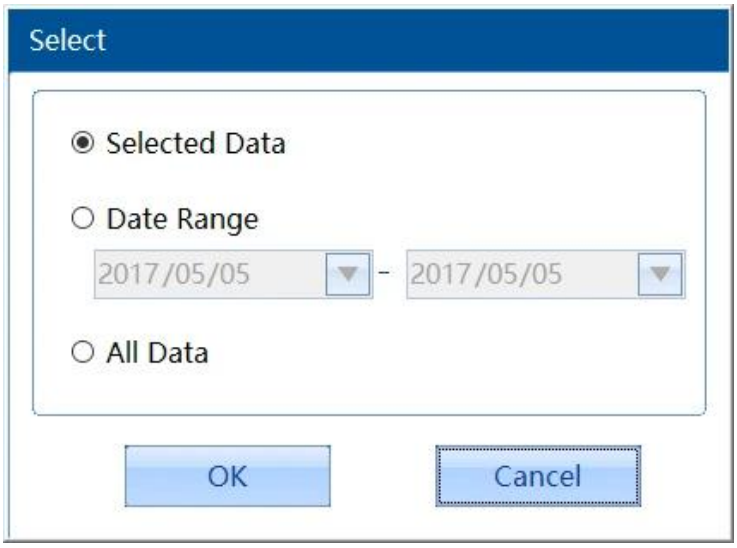

Figure 56

Click the data you want to delete.
Click the "OK" button and then confirm to delete the selected data.

◦ The deleting operation will be recorded in the log.

• Print
Click the "Print" button to print all the result list of the parameters of the current QC file.

8.1.5 L-J Chart of One Para.
Click the button on the screen, and then select "QC""L-J QC" on the pop-up menu. And click "QC Chart of One Para." tab.
Select the QC file No. you want to review, and then the screen will display the corresponding information and the graph.

Figure 57

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

• Calculate
You can use some QC results of a date range to calculate "mean","SD "and "CV".

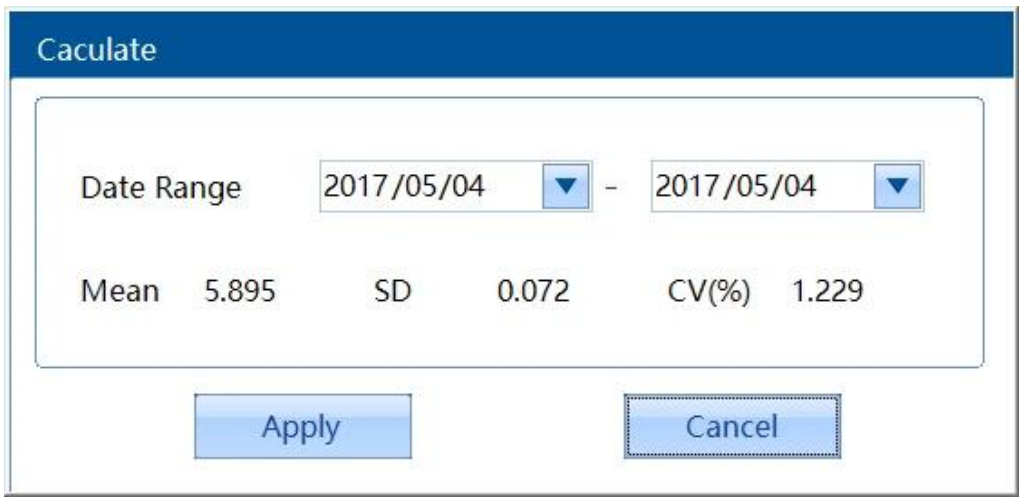

Figure 58

Select the date range you wanted. Click the "Apply" button.

• Save
Save calculate data as setting.
• Print
Click the "Print" button to print all the file information and graphs of the parameter of the current QC file.
• Rule
You can take the following steps to set the current QC rule.

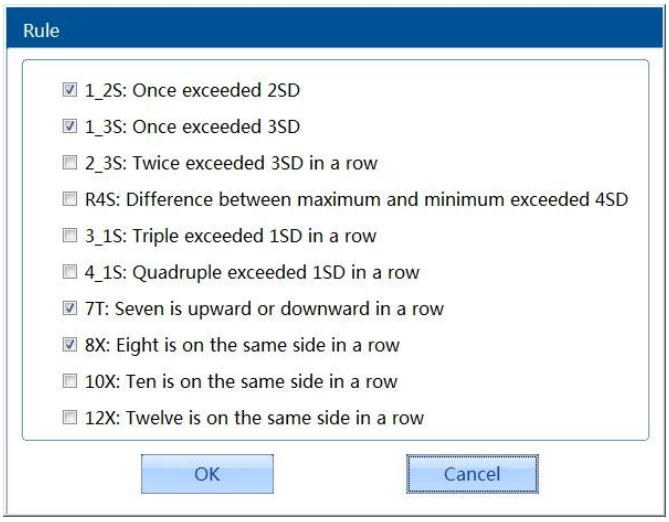

Figure 59
Check the rule that you want to use.

Click the "OK" button to save the setting.

8.2 X-B QC Program

8.2.1 X-B QC Principles
The X-B analysis is a weighted moving average analysis that uses values obtained from patient samples. It uses the 3 red cell indices, MCV, MCH and MCHC to indicate the hematology instrument performance. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices.

It is recommended the X-B analysis be activated when the sample volume of your laboratory is greater than 100 samples per day. The analyzer can save maximum 500 X-BQC results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest.

8.2.2 X-B Settings
• Only administrators can edit the X-B settings.

Before the X-B analysis, you should finish editing the QC information You can enter the graph screen by one of the following ways:
Click the shortcut button "QC".
Click the button on the screen, and then select "QC""X-B QC" on the pop-up menu.

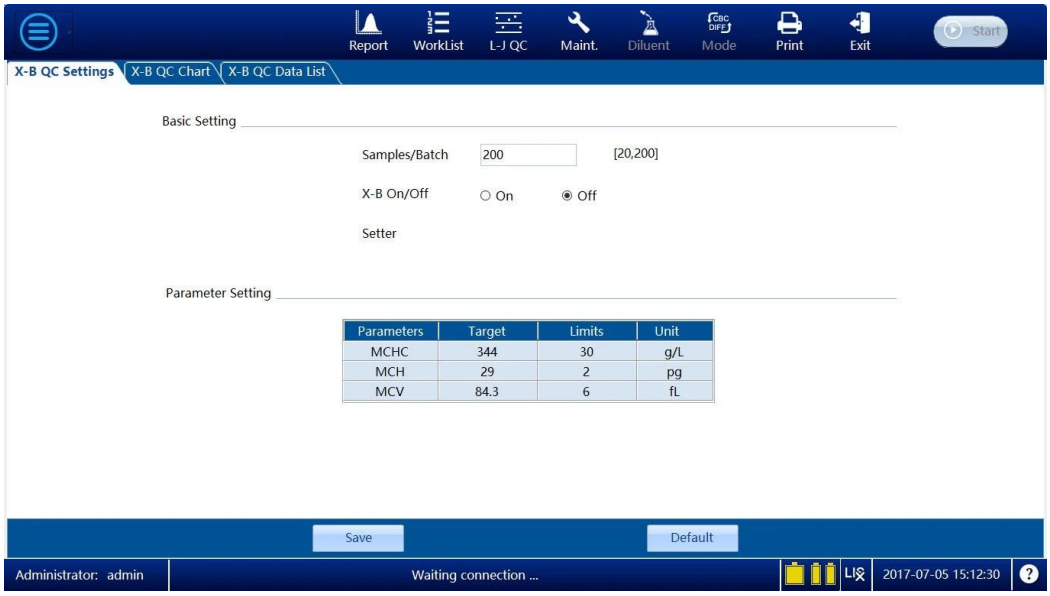

Figure 60

In the "Samples/Batch" edit box, you can input the amount of samples
[within the range 20(recommended) to 200] to be included in calculating for an X-B QC point.
Click the "On" button of "X-B One/Off" to open the X-B QC, and from the time on, all the valid sample results will be included to calculate the X-B.
Input the target and Limits for the QC parameters.

• All the targets and limits for the QC parameters shall be input without empty.
• When first use, the default setting will provide the Initial values for the targets and limits of the three QC parameters.
• If the QC data have existed in the QC file, you are not allowed to edit the target and limits.

• Save
Click the "Save" button to save all the settings of the QC.

• Default
When editing the QC settings, if you wish to restore the target and limits to the defaults, you can click the "Default" button to read-in the defaults to the X-B QC file.
• The default target for each parameter:
MCV :89.5fL
MCH :30.5pg
MCHC:340g/L
• The default limits for each parameter:
MCV:2.7 fL
MCH:0.9 pg
MCHC:10 g/L

◦ If the QC data have existed in the QC file, you are not allowed to restore defaults.
8.2.3 X-B Chart

You can enter the chart screen, click the button on the screen then select "QC""X-B QC" on the pop-up menu and click the"QC Chart"tab.

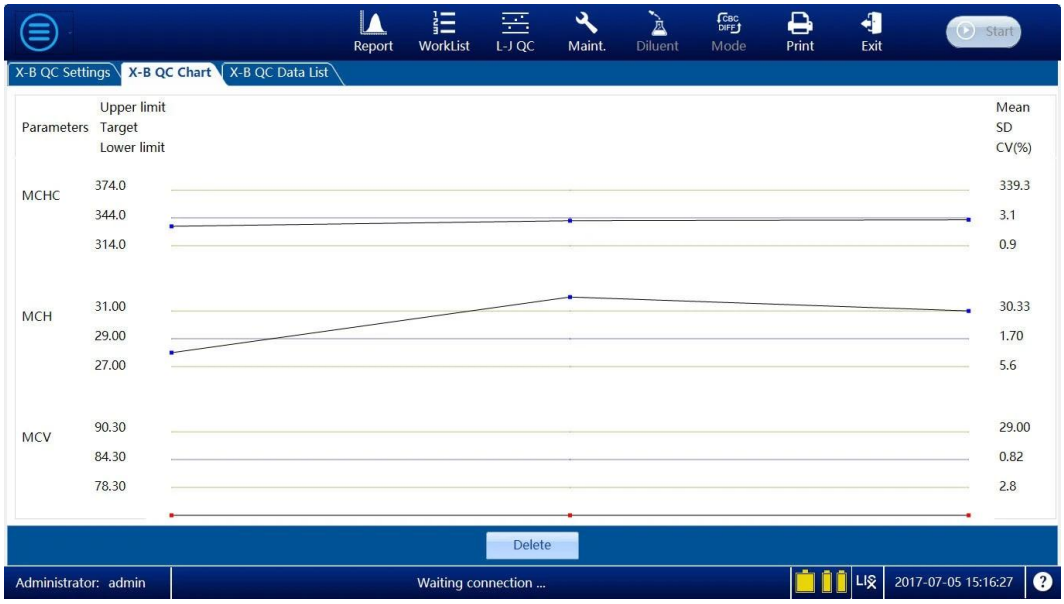

Figure 61

1. The Mean, SD and CV% of all the QC results of each parameter in the current graph.
2. 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.
3. When you click a QC point in the graph, the QC points of other parameters that are saved together with this one will be marked by a red line.
◦ The outliers are excluded from the calculation of Mean, SD and CV%.

• Delete
The administrator can delete the QC results by the following steps:
If you wish to delete a single QC result, move the red line to the desired QC result; if you wish to delete all the data, perform step 2 directly.
Click the "Delete" button to select "Selected Data" or "All Data".

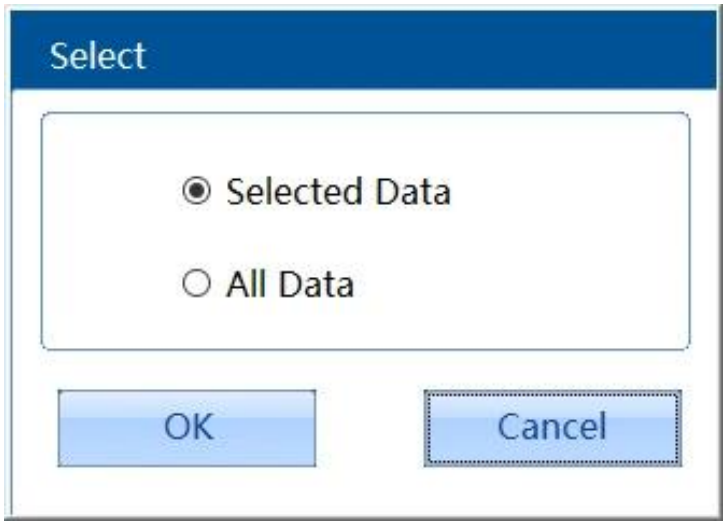

Figure 62

Click the data you want to delete.
Click the "OK" button and then confirm to delete the selected data.
◦ The deleting operation will be recorded in the log.

• Print
Click the "Print" button to print all the file information and graphs of the parameters of the current QC file.

8.2.4 X-B Data List

Click the button on the screen, and then select "QC""X-B QC" on the pop-up menu. And click the "QC Data List" tab.

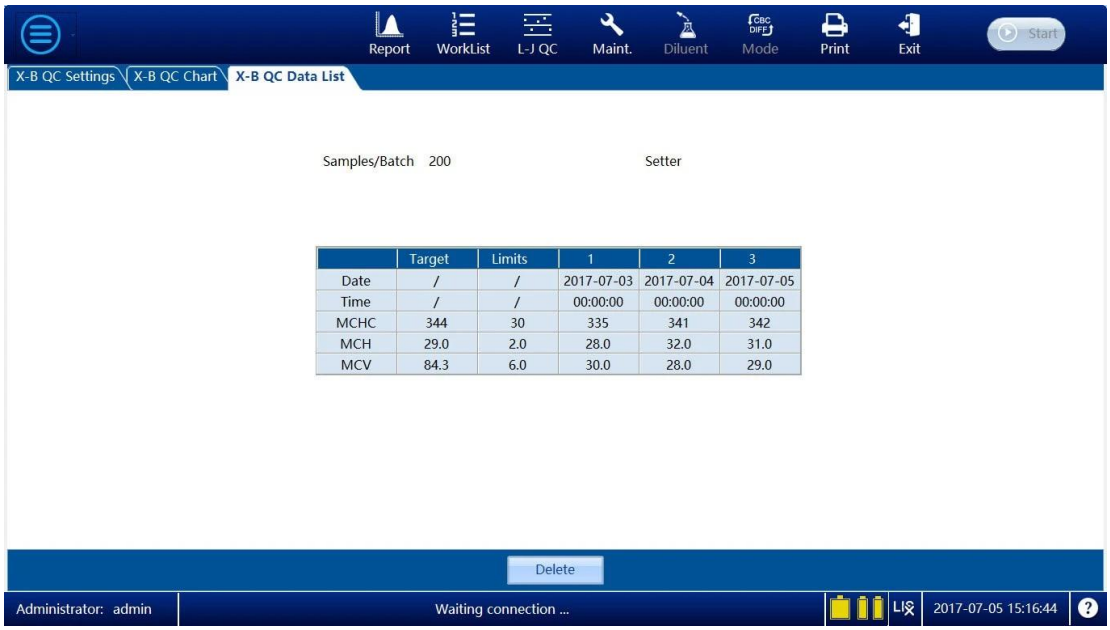

Figure 63

• Delete
The administrator can delete the QC results by the following steps:
If you wish to delete Selected QC result, select record to the desired QC result; if you wish to delete all the data, perform step 2 directly.
Click the "Delete" button to select "Selected Data" or "All Data".

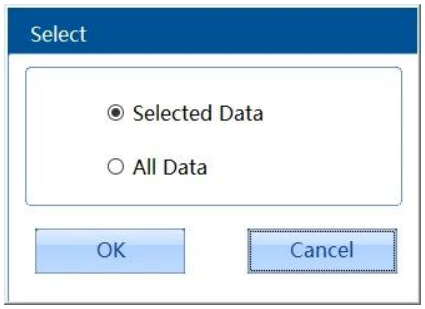

Figure 64

Click the data you want to delete.
Click the "OK" button and then confirm to delete the selected data.
◦ The deleting operation will be recorded in the log.

• Print
Click the "Print" button to print all the result list of the parameters of the current QC file.

8.3 X-AVG Quality Control

■ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
■ Only users of administrator-level can edit the L-J settings.
■ For the QC files with saved QC results, if any change is made to the target or the limits, the changed data will be highlighted in yellow, and the change will be recorded into the system log.

8.3.1 X-AVG Setting

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

You can Click the button on the screen, and then select "QC""X-AVG QC" on the pop-up menu to enter the interface
Click the "X-AVG Settings" tab to enter the X-AVG setup screen.

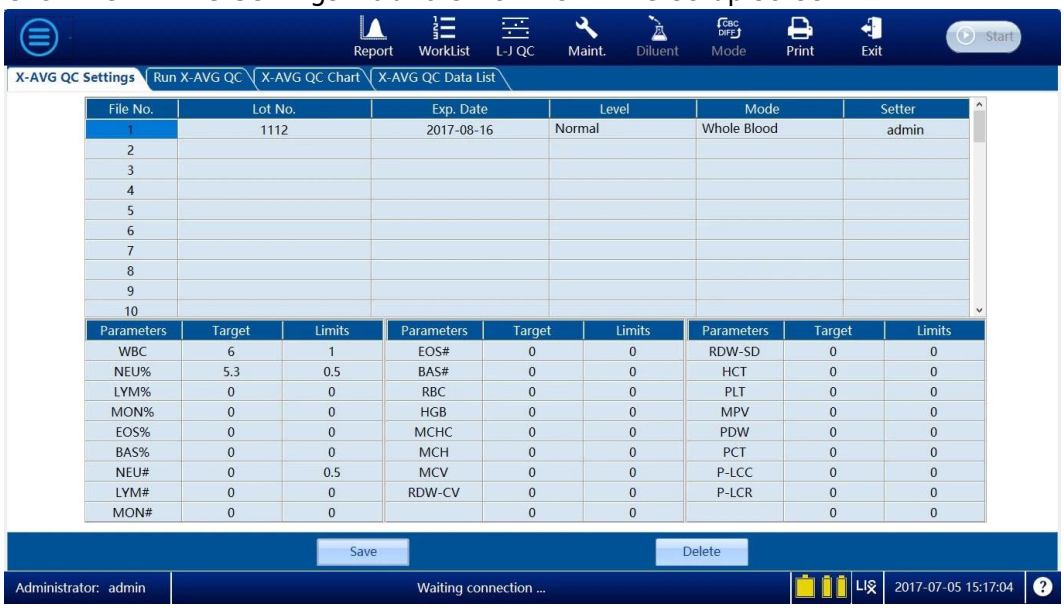

Figure 65

Select a QC File No. with empty QC information.

You can select the file No. within the range [1, 60].

Input the lot No. of the control.
• The lot No. can not be empty and up to 16 digits can be input. You can input characters, numbers, letters and special characters, but no Chinese characters are allowed.
• Different QC files can not have the same lot No.
Input the batch expiration date of the controls.

• You must input the expiration date, and the entry range is [current system date, 2099-12-31].

Select the QC mode.
• Different QC files can not have the same lot No. and QC mode.

Select the control level.
According to the target list of the corresponding lot No., input the target and limits into the edit boxes of the parameters to be included in the QC run.
Click the "Save" button to save all the settings of the QC.

8.3.2 Running controls
After editing the QC information, you can start one of the following QC analyses according to the selected QC mode.
• Whole Blood
• Predilute
• Running controls (whole blood)

◦ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
◦ The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.
◦ The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
◦ Collection tubes broken may cause personal injury and/or biohazard. Exercise caution when loading the collection tubes to the rack or getting the collection tubes from the rack, be sure not to break the tubes.
◦ Keep your clothes, hair and hands away from the moving parts to avoid injury.
◦ The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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.
◦ Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.

You can Click the button on the screen, and then select "QC""X-AVG QC" on the pop-up menu, and Click "Run X-AVG" tab.

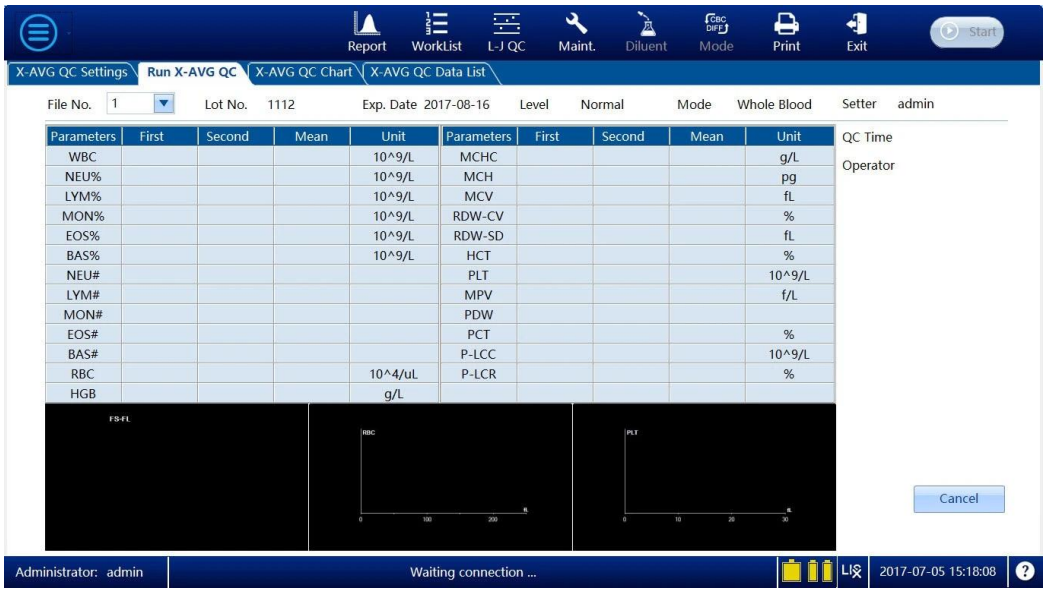

Figure 66

Select the QC file No. to be run; the screen displays the corresponding file information.
Be sure that the level of the control to be run corresponds with the current QC file.
Be sure that the control to be run is not expired.
Prepare the control as instructed by instructions of the controls. Run the controls:
1) Make sure the QC mode is "whole blood" and the analysis led is green.
2) Shake the prepared control as shown below to well mix it.

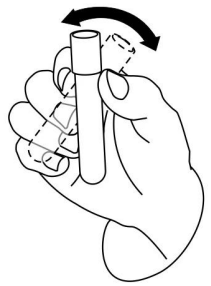

Figure 67

3) Present the control to the sample probe.
4) Press the aspirate key to start QC run.
5) When you hear the beep, remove the control.
6) Mix the control well again, to run the control for the second time according to the prompt.

◦ You can do not do the second run and the results obtained in the first run will not be saved as well. When finish running, the QC results (values of the two QC runs and the mean X) will be displayed in the current screen and be saved in the QC file automatically.
◦ When the QC result of the second QC run is obtained, the screen will refresh the displayed histograms and scattergrams according to the second QC run.
◦ Up to 300 QC results (mean X) can be saved for each QC file.
Do the above procedures to continue running the controls if necessary.

• Running controls (Predilute)
◦ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
◦ The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.
◦ The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
◦ Collection tubes broken may cause personal injury and/or biohazard. Exercise caution when loading the collection tubes to the rack or getting the collection tubes from the rack, be sure not to break the tubes.
◦ Keep your clothes, hair and hands away from the moving parts to avoid injury.
◦ The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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.

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

1.You can Click the button on the screen, and then select "QC""X-AVG QC" on the pop-up menu, and Click "Run X-AVG" tab.

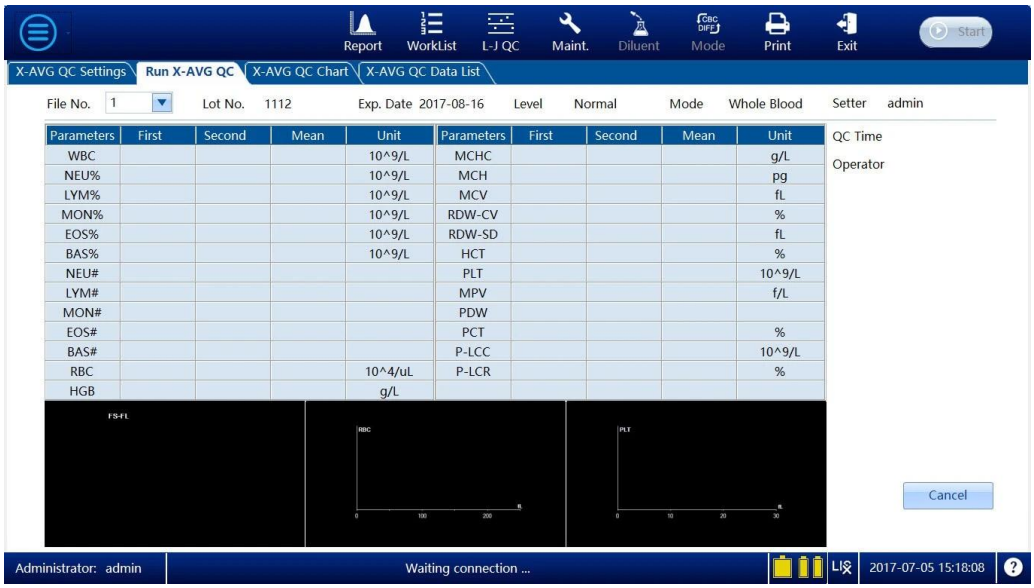

Figure 67

Select the QC file No. to be run; the screen displays the corresponding file information.
Be sure that the level of the control to be run corresponds with the current QC file.
Be sure that the control to be run is not expired.
Prepare the control as instructed by instructions for use of the controls. Run the controls:
1) Make sure the QC mode is "Predilute" and the analysis status led is green.
2) Click the shortcut button "Diluent", and then a message box will pop up.
3) After the preparation is done, the following message box will pop up.
4) Present a clean centrifugal tube to the sample probe and make sure the probe reaches the bottom of the tube and keep the tube vertical, as the figure shows, to avoid spills, hangings and bubbles.

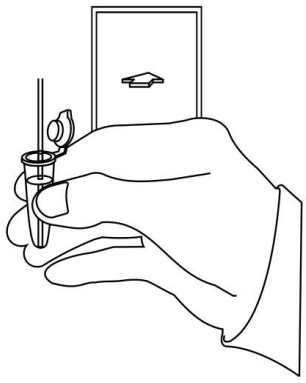

Figure 68
5) Press the aspirate key to start dispensing the diluent.
6) The buzzer sounds when diluent is finished, then you can remove the centrifugal tube.
7) Add 20μL of control to the diluent, close the tube cap and shake the tube to mix the sample.

8) Click the "Cancel" button to exit the "Diluent" message box.
9) After the cleaning is finished, close the prompt.
10) Present the prepared control to the sample probe.
11) Press the aspirate key to start QC run.
12) When you hear the beep, remove the control.
13) Mix the control well again, to run the control for the second time according to the prompt.

When finished running, the QC results will be displayed in the current screen and be saved in the QC file automatically.

◦ You can also dispense 400μL of diluent by pipette into the tube.
◦ Be sure to keep dust from the prepared diluent.
◦ After mixing the control with the diluent, be sure to wait 3 minutes before running.
◦ Be sure to run the predilute 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 QC stability based on your laboratory's sample population and sample collection techniques or methods.
◦ Up to 300 QC results can be saved for each QC file.

Do the above procedures to continue running the controls if necessary.
• Print
Click the "Print" button to print the results of the current QC Run screen.

8.3.3 X-AVG Chart

Click the  button on the screen, and then select "QC""X-AVG QC" on the pop-up menu. And click "X-AVG Chart" tab.
Select the QC file No. you want to review, and then the screen will display the corresponding information and the graph.

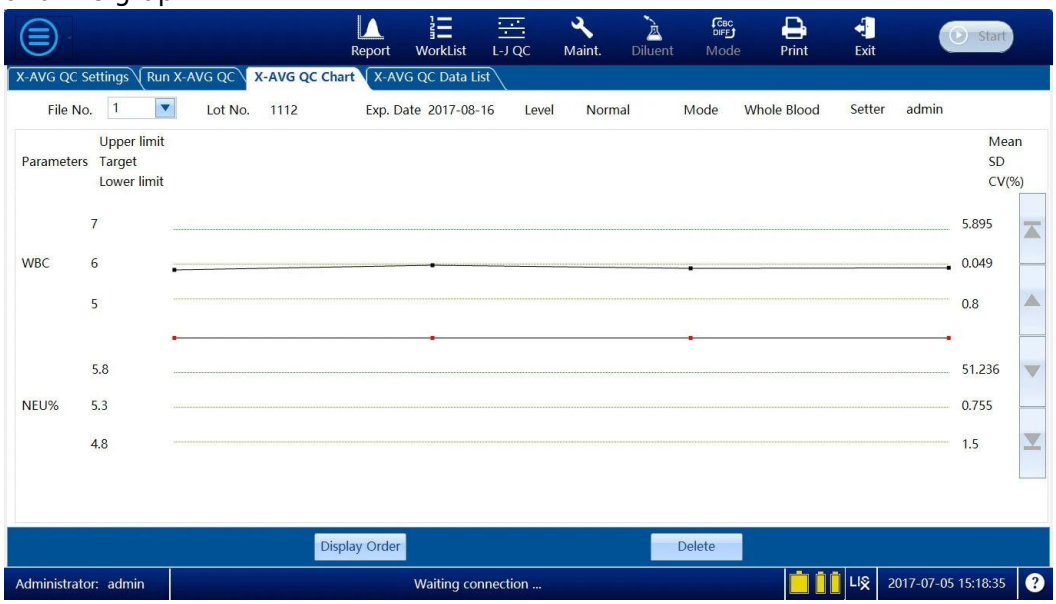

Figure 69

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

graph.
2. 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.
3. When you clicking a QC point in the graph, the QC points of other parameters that saved together with this one will be marked by a red line.
◦ The outliers are excluded from the calculation of Mean, SD and CV%.

• Delete
The administrator can delete the QC results by the following steps:
If you wish to delete a single QC result, move the red line to the desired QC result; if you wish to delete all the data, perform step 2 directly.
Click the "Delete" button to select "Selected Data" or "All Data".

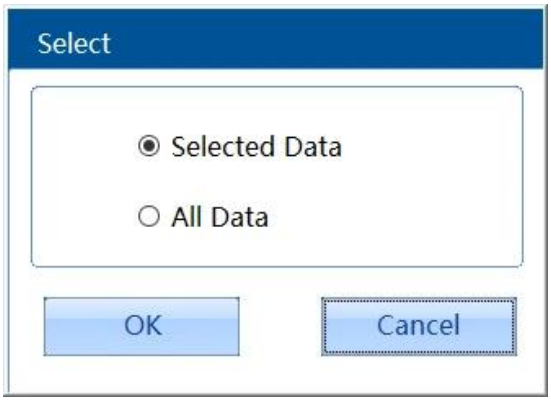

Figure 70

Click the data you want to delete.
Click the "OK" button and then confirm to delete the selected data.
◦ The deleting operation will be recorded in the log.

• Print
Click the "Print" button to print all the file information and graphs of the parameters of the current QC file.

• Display Order
You can take the following steps to adjust the display order of different parameters. Click the "Display Order" button to check the current display order of the parameters.

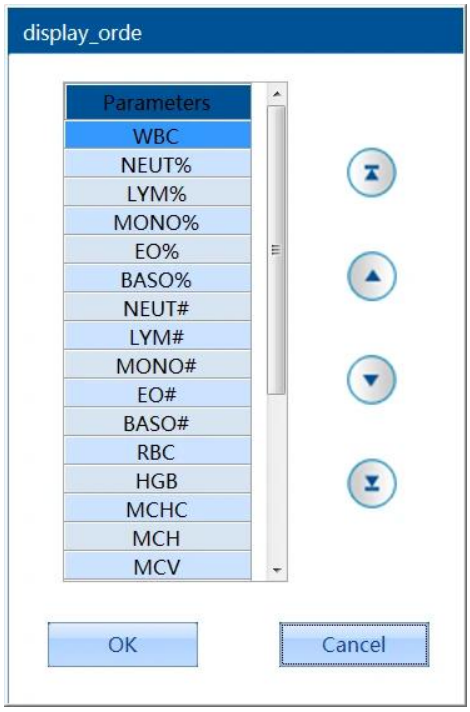

Figure 71

Click the parameter that you want to adjust.
You can click the button or button to move the parameter upward or downward; you can click the button or button to move the parameter to the first or the last position.
Click the "OK" button to refresh the display order of the parameters.

8.3.4 X-AVG Data List

Click the button on the screen, and then select "QC""X-AVG QC" on the pop-up menu. And click the "X-AVG Data List" tab.
Select the QC file No. you want to review, and then the screen will display the corresponding information and the graph.

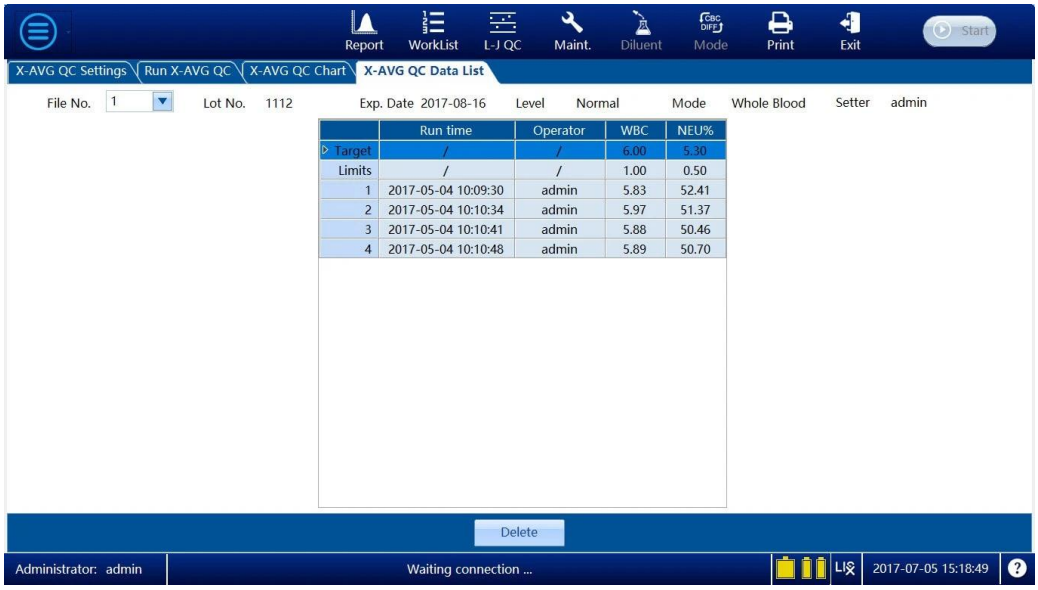

Figure 72

• Delete
The administrator can delete the QC results by the following steps:
If you wish to delete Selected QC result, select record to the desired QC result; if you wish to delete all the data, perform step 2 directly.
If you wish to delete span QC results, select date range.
Click the "Delete" button to select "Selected Data" , "Date Range" or "All Data".

Figure 73

Click the data you want to delete.
Click the "OK" button and then confirm to delete the selected data.

◦ The deleting operation will be recorded in the log.

• Print
Click the "Print" button to print all the result list of the parameters of the current QC file.

8.4 X-AVG R Quality Control

■ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contracted areas in the laboratory.
■ Only users of administrator-level can edit the L-J settings.
■ For the QC files with saved QC results, if any change is made to the target or the limits, the changed data will be highlighted in yellow, and the change will be recorded into the system log.

8.4.1 X-AVG R Setting

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

You can click the button on the screen, and then select "QC""X-AVG R QC" on the pop-up menu to enter the interface.

Click the "X-AVG R Settings" tab to enter the X-AVG R setup screen.

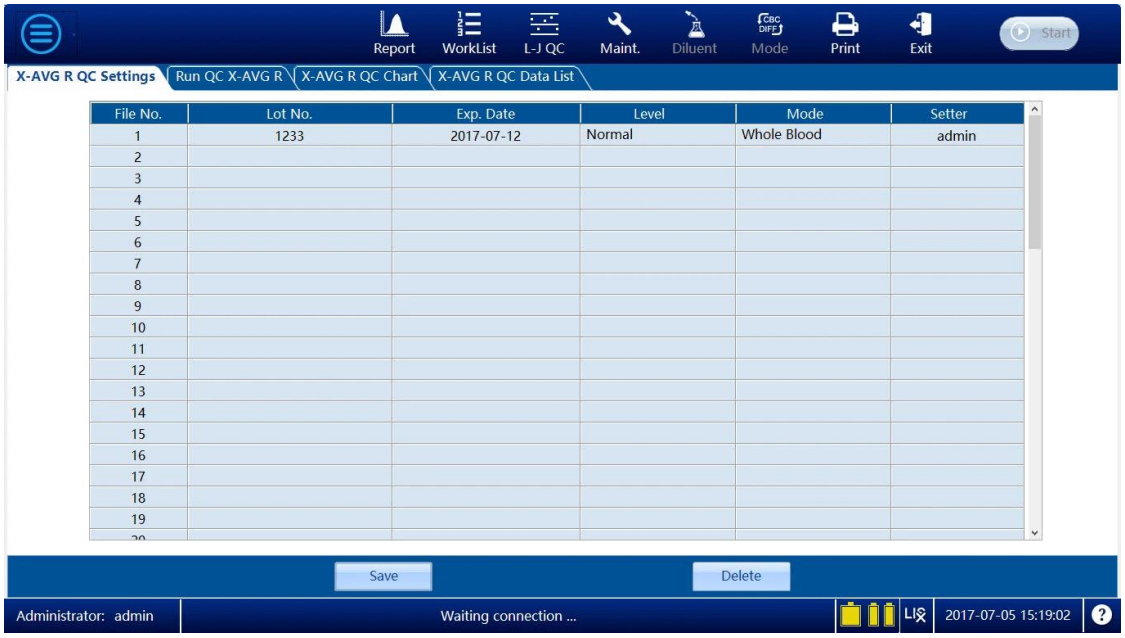

Figure 74

Select a QC File No. with empty QC information.
• You can select the file No. within the range [1, 60].
Input the lot No. of the control.

• The lot No. can not be empty and up to 16 digits can be input. You can input characters, numbers, letters and special characters, but no Chinese characters are allowed.
• Different QC files can not have the same lot No.

Input the batch expiration date of the controls.
• You must input the expiration date, and the entry range is [current system date, 2099-12-31].
Select the QC mode.

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

Select the control level.
Click the "Save" button to save all the settings of the QC.

8.4.2 Running controls
After editing the QC information, you can start one of the following QC analyses according to the selected QC mode.
• Whole Blood
• Predilute
• Running controls (whole blood)

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

◦ The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.
◦ The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
◦ Collection tubes broken may cause personal injury and/or biohazard. Exercise caution when loading the collection tubes to the rack or getting the collection tubes from the rack, be sure not to break the tubes.
◦ Keep your clothes, hair and hands away from the moving parts to avoid injury.
◦ The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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.
◦ Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.

You can Click the button on the screen, and then select "QC""X-AVG R QC" on the pop-up menu, and Click "Run X-AVG R" tab.

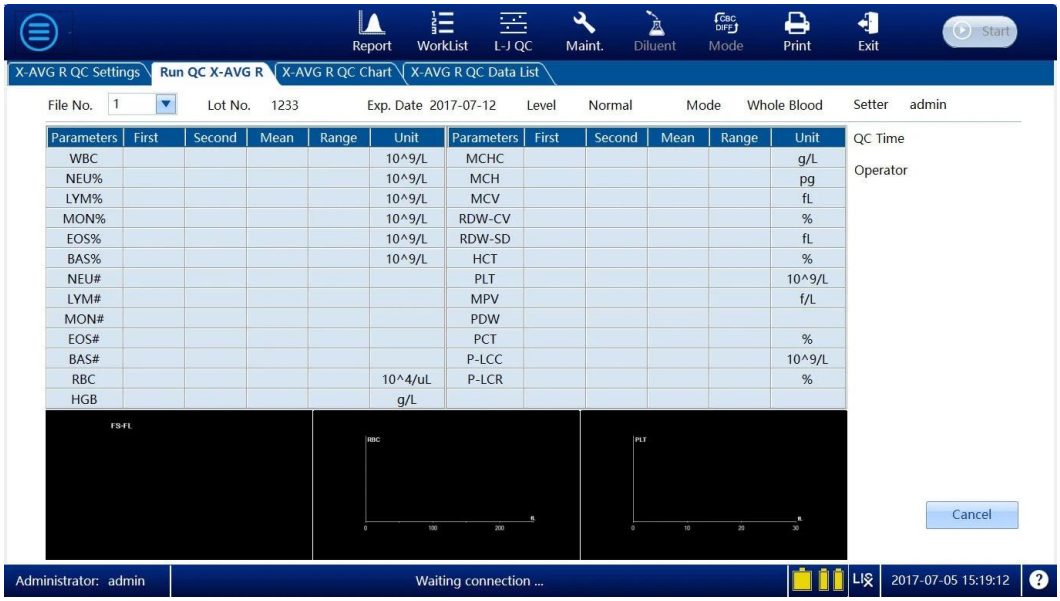

Figure 75

Select the QC file No. to be run; the screen displays the corresponding file information.
Be sure that the level of the control to be run corresponds with the current QC file.
Be sure that the control to be run is not expired.
Prepare the control as instructed by instructions of the controls. Run the controls:
1) Make sure the QC mode is "whole blood" and the analysis led is green.
2) Shake the prepared control as shown below to well mix it.

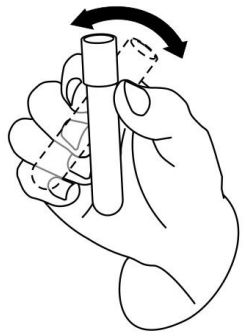

Figure 76

3) Present the control to the sample probe.
4) Press the aspirate key to start QC run.
5) When you hear the beep, remove the control.
6) Mix the control well again, to run the control for the second time according to the prompt.
◦ You can do not do the second run and the results obtained in the first run will not be saved as well.

When finish running, the QC results (values of the two QC runs , the mean X
and the range) will be displayed in the current screen and be saved in the QC file automatically.

◦ When the QC result of the second QC run is obtained, the screen will refresh the displayed histograms and scattergrams according to the second QC run.
◦ Up to 300 QC results (mean X) can be save for each QC file.

Do the above procedures to continue running the controls if necessary.

• Running controls (Predilute)

◦ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
◦ The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.
◦ The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
◦ Collection tubes broken may cause personal injury and/or biohazard. Exercise caution when loading the collection tubes to the rack or getting the collection tubes from the rack, be sure not to break the tubes.
◦ Keep your clothes, hair and hands away from the moving parts to avoid injury.
◦ The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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.
◦ Do not re-use such disposable product as collection tubes, test tubes, capillary tubes, etc.

You can Click the button on the screen, and then select "QC""X-AVG R QC" on the pop-up menu, and Click "Run X-AVG R" tab.

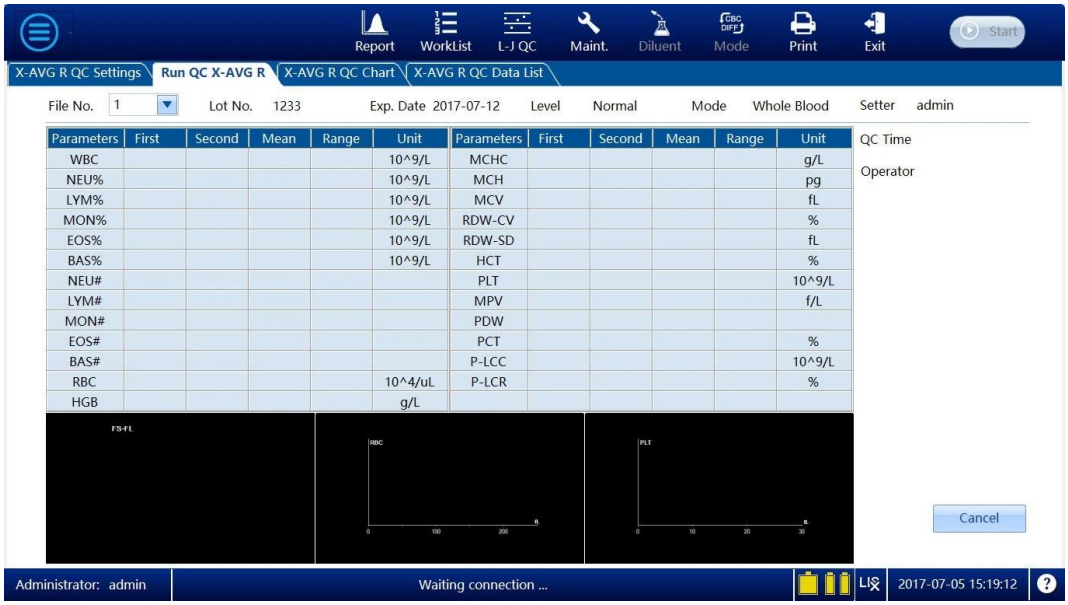

Figure 77

Select the QC file No. to be run; the screen displays the corresponding file information.
Be sure that the level of the control to be run corresponds with the current QC file.
Be sure that the control to be run is not expired.
Prepare the control as instructed by instructions for use of the controls. Run the controls:
1) Make sure the QC mode is "Predilute" and the analysis status led is green.
2) Click the shortcut button "Diluent", and then a message box will pop up.
3) After the preparation is done, the following message box will pop up.
4) Present a clean centrifugal tube to the sample probe and make sure the probe reaches the bottom of the tube and keep the tube vertical, as the figure shows, to avoid spills, hangings and bubbles.

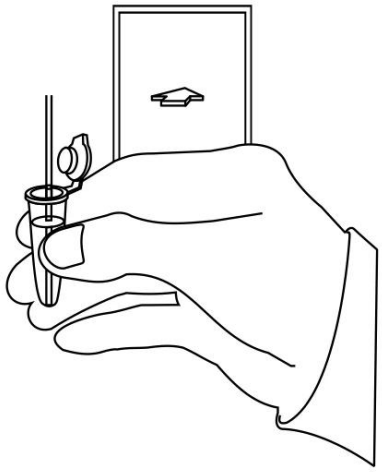

Figure 78

5) Press the aspirate key to start dispensing the diluent.
6) The buzzer sounds when diluent is finished, then you can remove the centrifugal tube.
7) Add 20μL of control to the diluent, close the tube cap and shake the tube to mix the sample.
8) Click the "Cancel" button to exit the "Diluent" message box.
9) After the cleaning is finished, close the prompt.
10) Present the prepared control to the sample probe.
11) Press the aspirate key to start QC run.
12) When you hear the beep, remove the control.
13) Mix the control well again, to run the control for the second time according to the prompt.

When finished running, the QC results will be displayed in the current screen and be saved in the QC file automatically.

◦ You can also dispense 400μL of diluent by pipette into the tube.
◦ Be sure to keep dust from the prepared diluent.
◦ After mixing the control with the diluent, be sure to wait 3 minutes before running.
◦ Be sure to run the predilute 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 QC stability based on your laboratory's sample population and sample collection techniques or methods.
◦ Up to 300 QC results can be saved for each QC file.

Do the above procedures to continue running the controls if necessary.

• Print
Click the "Print" button to print the results of the current QC Run screen.

8.4.3 X-AVG R Chart
Click the button on the screen, and then select "QC""X-AVG R QC" on the pop-up menu. And click the "X-AVG R Chart" tab.
Select the QC file No. you want to review, and then the screen will display the corresponding information and the graph.

Figure 79

1. The Mean and Range of all the QC results of each parameter in the current graph.
2. 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.
3. When you clicking a QC point in the graph, the QC points of other parameters that saved together with this one will be marked by a red line.

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

• Delete
The administrator can delete the QC results by the following steps:
If you wish to delete a single QC result, move the red line to the desired QC result; if you wish to delete all the data, perform step 2 directly.
Click the "Delete" button to select "Selected Data" or "All Data".

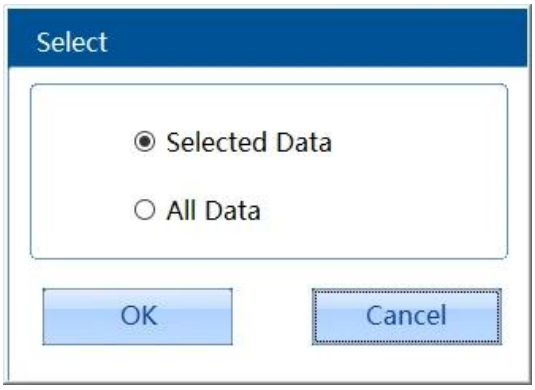

Figure 80
Click the data you want to delete.
Click the "OK" button and then confirm to delete the selected data.
◦ The deleting operation will be recorded in the log.

• Print
Click the "Print" button to print all the file information and graphs of the parameters of the current QC file.

• Display Order
You can take the following steps to adjust the display order of different parameters. Click the "Display Order" button to check the current display order of the parameters.

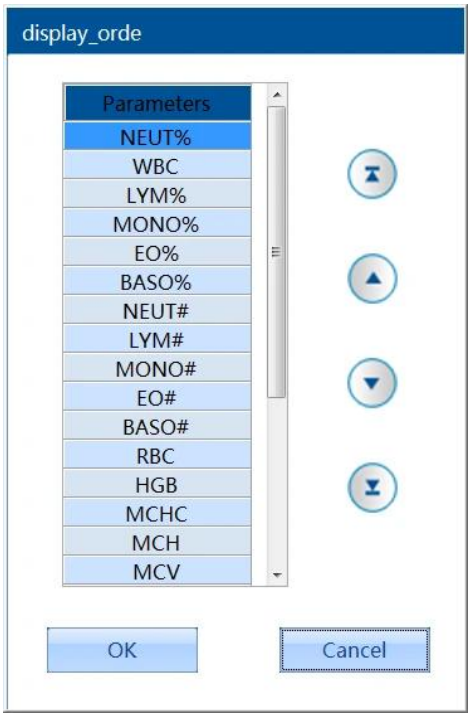

Figure 81

Click the parameter that you want to adjust.

You can click the button or button to move parameter upward or downward; you can click the button or button to move the parameter to the first or the last position. Click the "OK" button to refresh the display order of the parameters.

8.4.4 X-AVGR Data List

Click the button on the screen, and then select "QC""X-AVG R QC" on the pop-up menu. And click the "X-AVG R Data List" tab.
Select the QC file No. you want to review, and then the screen will display the corresponding information and the graph.

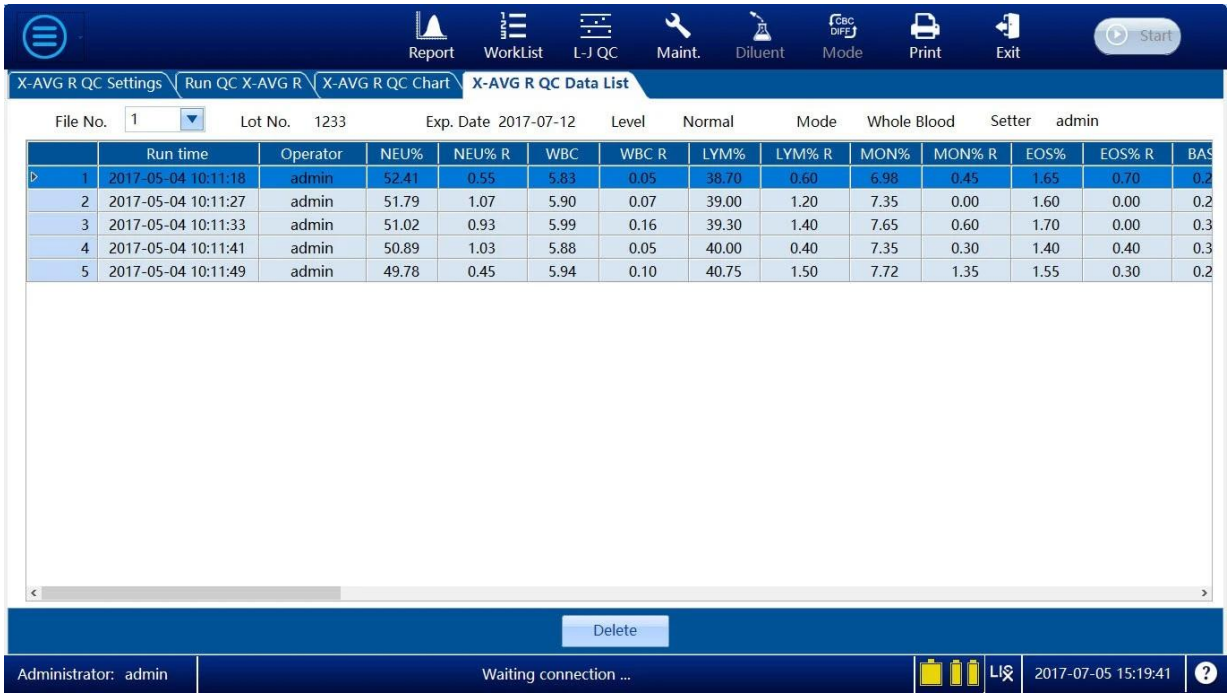

Figure 82

• Delete
The administrator can delete the QC results by the following steps:
If you wish to delete Selected QC result, select record to the desired QC result; if you wish to delete all the data, perform step 2 directly.
If you wish to delete span QC result, select date range.
Click the "Delete" button to select "Selected Data", Date Range" or "All Data".

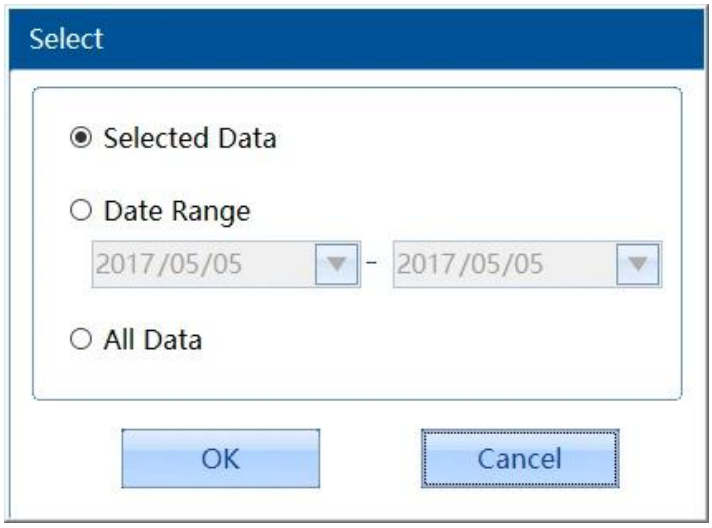

Figure 83

Click the data you want to delete.

Click the "OK" button and then confirm to delete the selected data.
◦ The deleting operation will be recorded in the log.

• Print

Click the "Print" button to print all the result list of the parameters of the current QC file.

9. Using the calibration programs

9.1 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.
There are three calibration programs available on this analyzer: manual calibration, auto calibration using calibrator and auto calibration using fresh blood samples.
All the parameters or part of the parameters of WBC, RBC, HGB, MCV and PLT
can be calibrated by the calibration procedure.

◦ Calibration procedures can only be performed by users of the administrator-level.
◦ You should only use the Manufacturer-specified calibrators and reagents. Store and use the calibrators and reagents as instructed by instructions for use of the calibrators and reagents.
◦ The analyzer identifies a sample as a calibration sample only if the analysis is started from the "Calibration" screen.
The calculation of reproducibility is included in the calibration procedure.

9.2 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 Manufacturer-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 there may be a problem.

◦ All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.

9.3 How to Calibrate

9.3.1 Preparing your analyzer
Do the following pre-calibration procedures before calibration. If problems are detected during these checks, do not attempt to calibrate the analyzer. If necessary, call Manufacturer customer service department or your local distributor for assistance.
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.
Do the background check. If the analyzer alarms for abnormal background results, see Troubleshooting Your Analyzer for solutions.
Run a vial of normal control in the WB-CBC+DIFF mode for 11 consecutive times. Enter the "Table"

screen to check the reproducibility of the second to eleventh runs and make sure they meet the following requirements.

Parameter Condition		Whole Blood Reproducibility (CV%)	Predilute Reproducibility (CV%)
WBC	(4.0-15.0) x 10^9/L	≤ 2.0%	≤ 4.0%
RBC	(3.50-6.00) x 10^{12}/L	≤ 1.5%	≤ 3.0%
HGB	(110-180) g/L	≤ 1.5%	≤ 3.0%
MCV	(70-120) fL	≤ 1.0%	≤ 2.0%
PLT	(150-500) x 10^9/L	≤ 4.0%	≤ 8.0%

Table 9

Run a vial of high control three consecutive times and then immediately run the diluent three consecutive times. Calculate the carryover per the following equation.

Carryover (%) = First low - level sample result -Third low - level sample result / Third high - level sample result-Third low - level sample result * 100%

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

Parameter	Carryover
RBC	≤0.5%
HGB	≤0.6%
HCT	≤0.5%
PLT	≤1.0%

Table 10

It is recommended that you create a log table for your analyzer. This log table should contain all necessary information that is pertinent to your analyzer. 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.

• All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
• 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 diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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, hair and hands away from the moving parts to avoid injury.
• Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.

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

9.3.2 Manual calibration
Do as follows to calibrate the analyzer:

Click the button; select "Calibration" "Calibration Factors" to enter the "Calibration Factors" screen. The calibration factors of whole blood mode and predilute mode are displayed at the "Calibration Factors" screen.

The login users of common-level can not perform the calibration procedures but only browse the calibration factors at the current screen. To perform the calibration, please logout and then re-login as users of administrator-level.

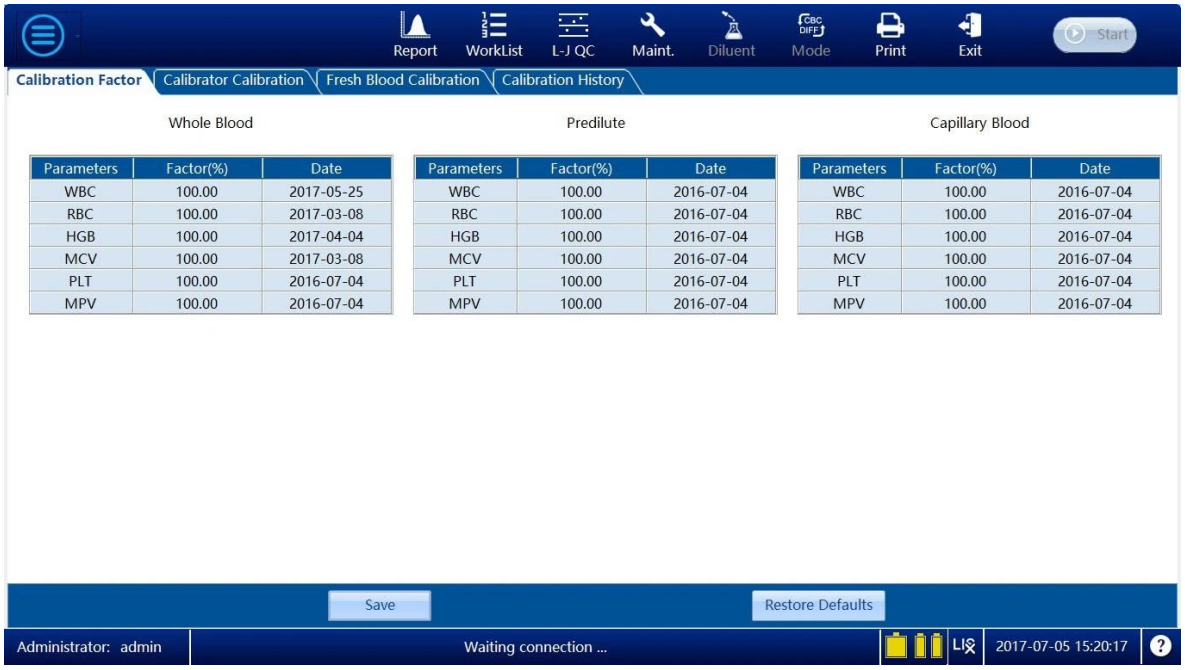

Figure 84

Enter the "Calibration Factors" screen to check the calibration factors and calculate the new factors per the following equation.
New calibration factor= Current calibration factor * Reference value / Mean

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

◦ The input calibration factors shall be between 75.0% - 125.0% (calculate to two decimal places).
Input the new calibration factors into the factor cell of the parameter that
requires calibration.
After the entry, click the "Save" button at the bottom of the screen. If the new calibration factors are valid and different from the originals, a message box shown below will pop up.
Click "Yes" to save the news calibration factors and the calibration date of the corresponding parameter changes to the current system date. Then, close the message box and return to the "Calibration Factors" screen without any cell being highlighted.
If the new calibration factors are invalid, the message box will pop up.

Click "OK" to close the message box and the cell of the first invalid calibration factors is highlighted with the data displayed.

• Other operations
• Restore Defaults
Click the "Restore Defaults" button to restore the calibration factors to the values displayed when you entering the "Calibration Factors" screen.

• Print
If the calibration factors have not been changed, click the "Print" button to print the current calibration factors.

9.4 Auto calibration using calibrators

Do as follows to calibrate the analyzer with calibrators. Click the button, and then select "Calibration" "Calibrator" to enter the "Calibrator" screen.

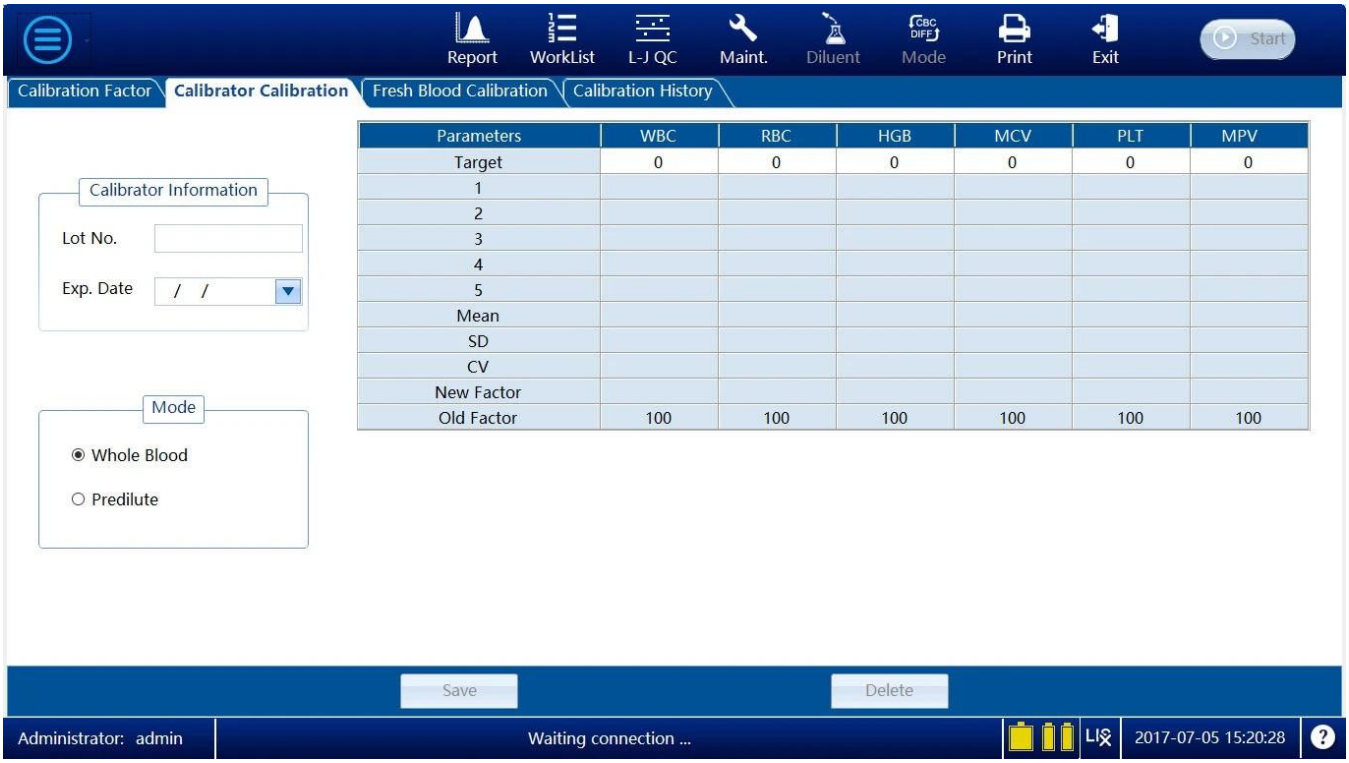

Figure 85

Only in the whole blood mode" can the calibration using calibrators be performed.
◦ The default "Exp. Date" is the current system date.

Input the lot No. of the calibrator into the "Lot No." box.
Input the expiration date. The default "Exp. Date" is the current system date. You can click the "Exp. Date" box, and then edit the date.
Set target of the parameter to be calibrated on the first line of the list.

◦ All the samples, controls, calibrators, reagents, wastes and areas contacted with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe

laboratory procedures when handling them and the contacted areas in the laboratory.
◦ Only Manufacturer-specified calibrators shall be used. Manufacturer will not be responsible for any error result caused by using other calibrators.
◦ See the instructions for use of the calibrators for the lot No., expiration date and the target.
◦ The lot No. must be input.
◦ The expiration date can not be earlier than the current system date.
◦ The input expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.

Prepare the calibrator as instructed by instructions for use of the calibrators. Present the calibrator to the sample probe. Then press the aspirate key to start calibration. When you hear the beep, remove the calibrator.

• When the current running is done, if there is a parameter whose calibration data is out of its linear range, then the calibration data will be displayed in the list and a message box will also pop up.

Click "OK" to close the message box and delete the data from the table without saving.
• The valid results within the linear range will be displayed directly.

◦ When the valid result is obtained, it will be selected to be included in the calculation for the calibration factors.

When the amount of the valid calibration reaches N (N ≥3), the analyzer will automatically calculate the mean, CV% and new calibration factors with all the selected data (the first data is excluded).
You can also select the desired data (5 at least) to calculate the calibration factors. Every time when you select or de-select data by clicking the check box, the calibration factors will be refreshed immediately.
◦ The out-of-range CV% does not influence the display of the calibration factors.
• Other operations
• Save
Save the contents of the current calibration.

• Delete
Delete the current record from list.

• Print
Print the contents of the current calibration screen.

9.4.1 Auto calibration using fresh blood samples
Do as follows to calibrate the analyzer with fresh blood samples.
Click the  button, and then select "Calibration" "Fresh Blood" to enter the "Fresh Blood" screen.

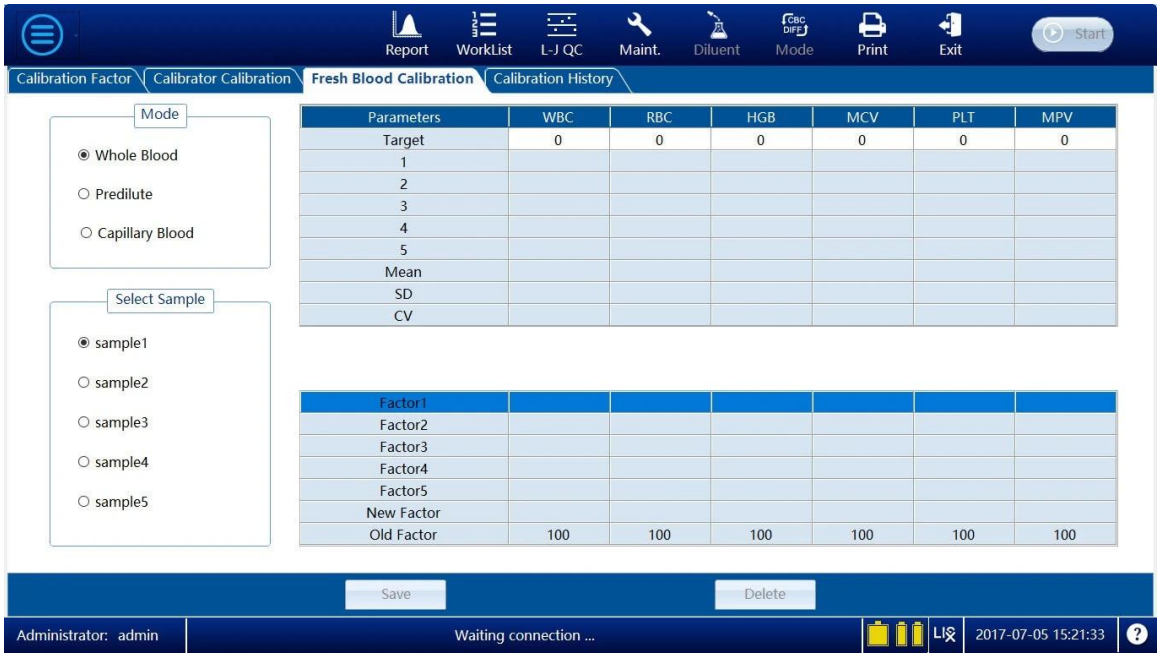

Figure 86

Prepare 3 to 5 normal fresh blood samples as instructed in Operating Your Analyzer.
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
Click the radio button "Whole Blood" or "Predilute" on the screen to select the desired calibration mode.

Select the sample ID of the current sample from the "Current sample ID" pull-down list.
Select the parameter to be calibrated from the check box on the first line of the list.
Input the target into the "Target" cells.
Prepare the whole blood or predilute fresh blood sample ready for calibration. Present the sample to the sample probe. Then press the aspirate key to start calibration. When you hear the beep, remove the sample.

• If the results are out of the linear range but still within the display range, the message box will pop up at the same time the results are displayed in the table.
Click "OK" to close the message box and delete the results from the table without saving.
• If the results are out of the display range, the non-numeric parameter values "***" are obtained and the message box will pop up.

Click "OK" to close the message box and delete the results from the table without saving.
• The valid results within the linear range will be displayed directly.

◦ When the valid result is obtained, it is selected to be included in the calculation for the calibration factors.

When the amount of the valid calibration reaches N (N ≥6), the analyzer will calculate the Mean, CV% and Calibration Factors of the data selected with "√" automatically (the first data is excluded).

You can select several data to calculate the calibration factors, but only after 5 groups of the data are selected can you get the calibration factors. Every time when you select or cancel a data by selecting its check box, the calibration factors will be refreshed and displayed immediately.

◦ The out-of-range CV% does not influence the display of the calibration factors.
Select other calibration samples from the "Current sample ID" pull-down list,
run the samples as instructed in steps 8 to 12 to obtain the calibration factors of each sample.
• Other operations
• Print
If the mean calibration factors are invalid, then a message box will pop up when you clicking the "Print" button.
Click "OK", then the cell of the first invalid calibration factor will be
highlighted and the data in the cell will not be cleared.

If the mean calibration factors are valid, click the "Print" button to print the following data in the form of list, namely, the calibration factors of the sample in the "Calculated Result" table, the results included in calculating the calibration factors, the CV% of the calibration factors and the mean calibration factors.

9.4.2 Verifying calibration factors
It is recommended that you take the following steps to verify the calibration factors:
Run the calibrator at least three times and check whether the means of the obtained results are within the expected ranges.
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.
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.

10. Maintaining your analyzer

10.1 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.
■ 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 Manufacturer customer service department or your local distributor for assistance.
■ Only Manufacturer-supplied parts can be used for maintenance. For any questions, contact Manufacturer customer service department or your local distributor.
■ Exercise caution to avoid contact with the sharp sample probe when performing maintenance.

10.2 Maintenance

10.2.1 Replacing Reagent

• The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory 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.
• After installing a new container of reagent, keep it still for a while before use.
• When you have changed the diluent or lyses, run a background to see if the results meet the requirement.

You should change the reagents when:
• A new container of reagent is installed.
• The reagent is contaminated
• WBC/RBC bubbles are reported

Click the button on the screen, and then select "Service""Maintenance" on the pop-up menu.

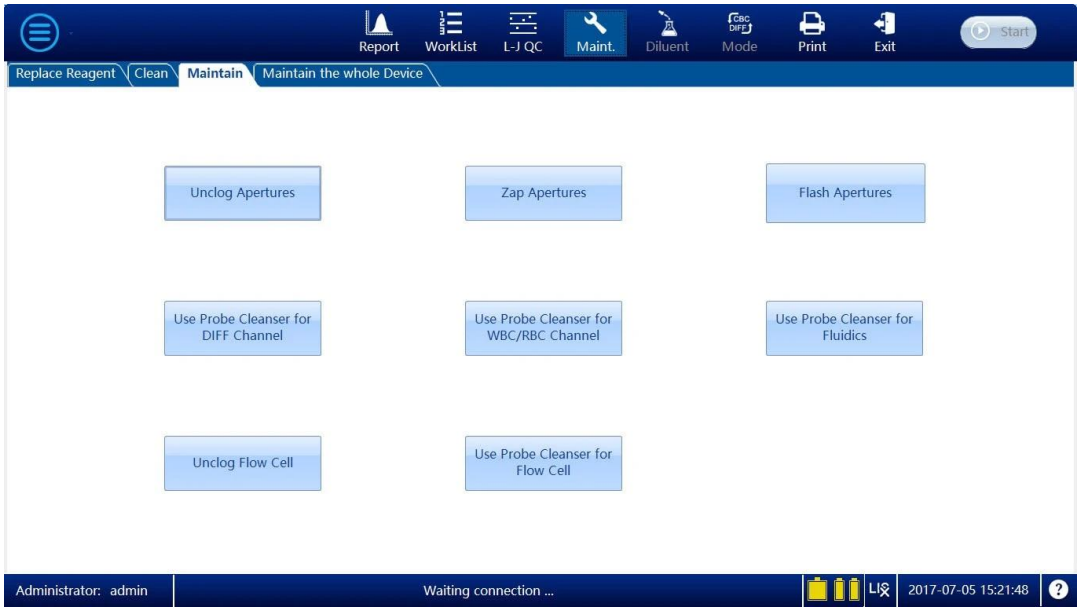

Figure 87

Click the "Replace Reagent" tab to enter the "Replace Reagent" screen.

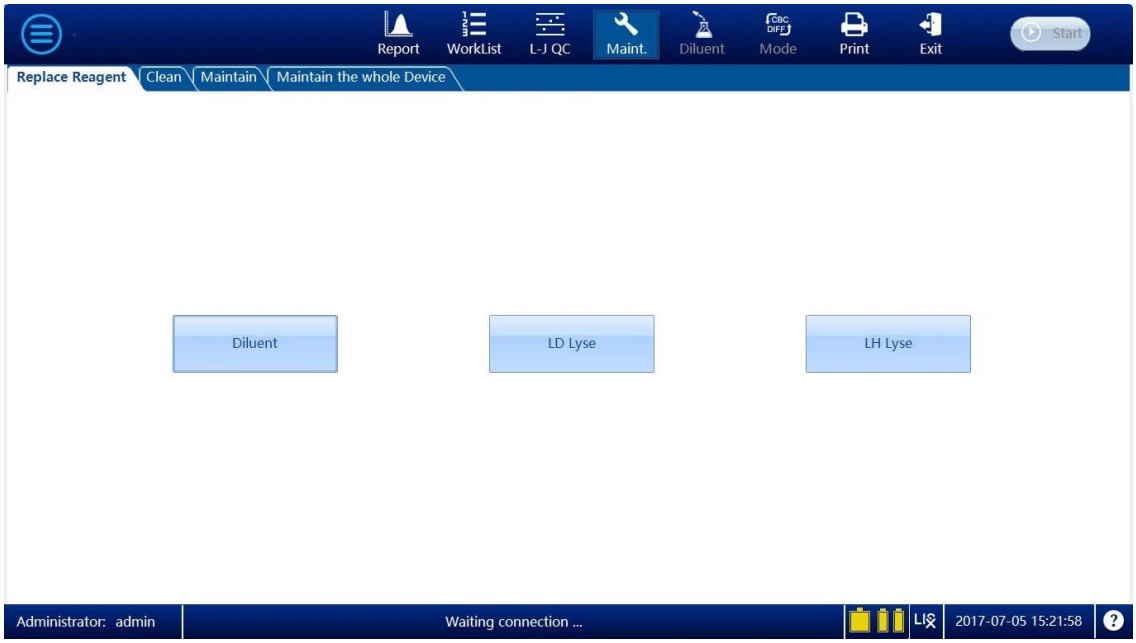

Figure 88

You can replace any of the following reagents:
• Diluent
• W-61LD Lyse
• W-61LH Lyse

Do as follows to replace the reagents:
Double click the icon of the desired reagent, and then click the "replace".

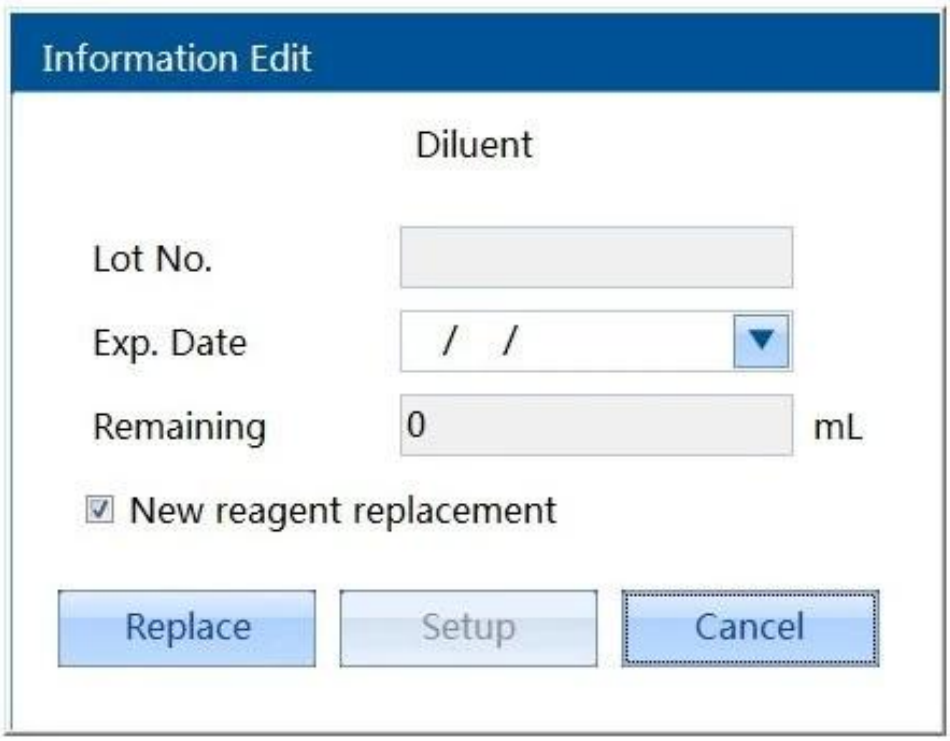

Figure 89

The following interface will pop up on the screen:

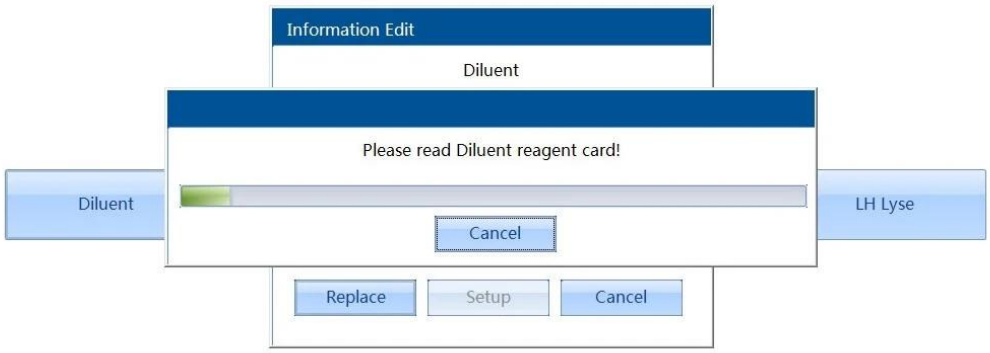

Figure 90
Then put the corresponding reagent card into the mark as shown below on the surface shell.

Figure 91

The analyzer will automatically read the information in the reagent card and automatically change the reagent.
Do the above procedures to replace other reagents if necessary.
The reagent card is single use. It will be invalid after swiping. Please discard as soon as possible, to prevent confusing the new card.

10.2.2 Cleaning
You should clean the corresponding components under the following circumstances:
• When the background of WBC and (or) HGB relative parameters exceeds the Ref. Range, you should clean the WBC bath.
• When the background of RBC and (or) PLT relative parameters exceeds the Ref. Range, you should clean the RBC bath.
• When the background of the scattergram has abnormal excessive cells, you should clean the DIFF Bath.
• When the background of the scattergram has abnormal excessive cells, or bad differential of WBC, you should clean the flow cell.
• When the sample probe is dirty, you should clean the sample probe.

Click the button on the screen, and then select "Service""Maintenance" on the pop-up menu. Then, click the "Clean" tab to enter the "Clean" screen.

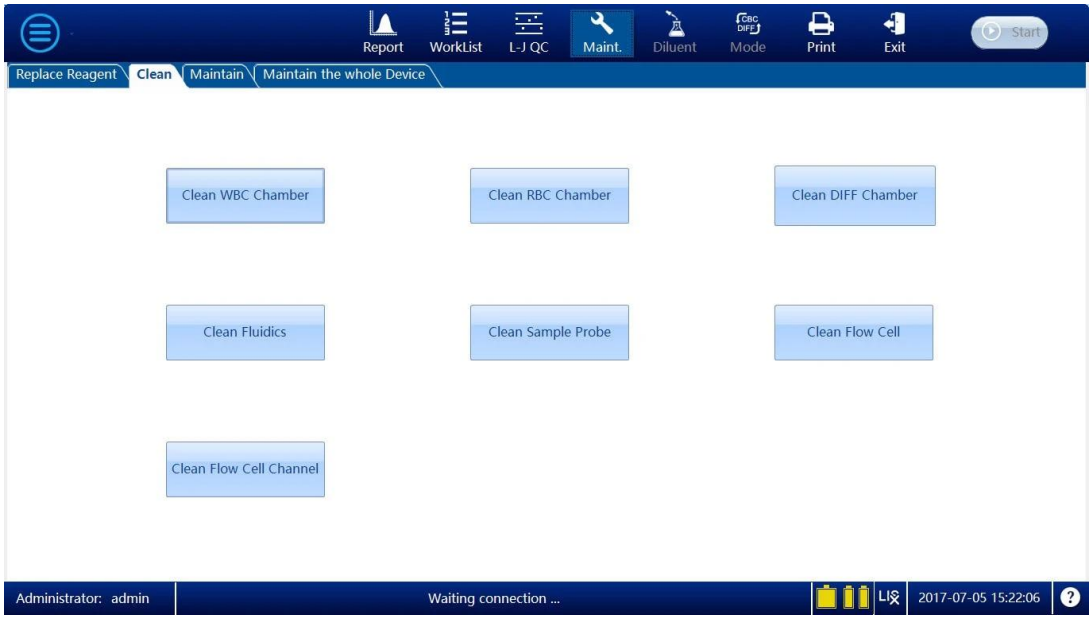

Figure 92

You can clean any of the following components:
• WBC bath
• RBC bath
• DIFF bath
• Flow cell
• Sample probe
• Flow Cell Channel
• Fluidics

Do as follows to clean:
Click the icon of the desired component to start cleaning.
Do the above procedures to clean other components if necessary.

10.2.3 Maintain
You should keep the analyzer in good repair in the following cases :

• When Apertures clogging happens or there are inaccurate results obtained
owing to a suspect clogging, Zap Apertures, and Flush Apertures can be executed.
• When the blank test values of the analyzer are out of the Ref. range, the differentiation effect of WBC scattergram is not good or the aperture is blocked after other maintenance have been adopted. The fluidics cleanser can be executed.
• If abnormal measurement values are caused in the DIFF channel, which is not improved after other maintenance have been adopted, the DIFF Channel clean or flow cell clean in Probe Cleanser maintenance function can be executed.
The steps of DIFF Channel Clean in Concentrated Cleanser are as follows:
1,Click the "DIFF Channel Probe Cleanser Clean" button to pop up a dialogue box prompting you to confirm cleaning.
2,Click the "OK" button to pop up the dialogue box prompting you to put the test tube containing concentrated cleanser under the sampling probe. 3,Press the Aspirate Key to pop up a prompt box and begin clean preparation. 4,When the preparation is finished, a countdown dialog box shown below will be

popped up, and the soaking process will begin.
5 , The soaking time is 5 minutes, during which, the soaking can't be terminated.
6,When the soaking is finished, cleaning will be performed.
7,When the cleaning is finished, the finished dialogue box will pop up. 8,Click the "OK" button to close the dialogue box.

• If abnormal measurement values are caused by the blockage of the aperture, which is not improved after other maintenance have been adopted, the WBC and RBC Bath clean in probe Cleanser maintenance function can be executed.
The steps of WBC/RBC Probe Cleanser Clean are the same as DIFF Channel Probe Cleanser Clean.
• The analyzer in use should be cleaned in a probe cleanser every week by clicking "Fluidics Probe Cleanser Clean".
The steps of Fluidics Probe Cleanser Clean are the same as DIFF Channel Probe Cleanser Clean.
• When flow cell clogging happens, unclog flow cells should be executed.

Click the "Maint." Key on the interface, then, click the "Maintain" tab to enter the following interface. And you can execute all the maintenance operations on the interface.

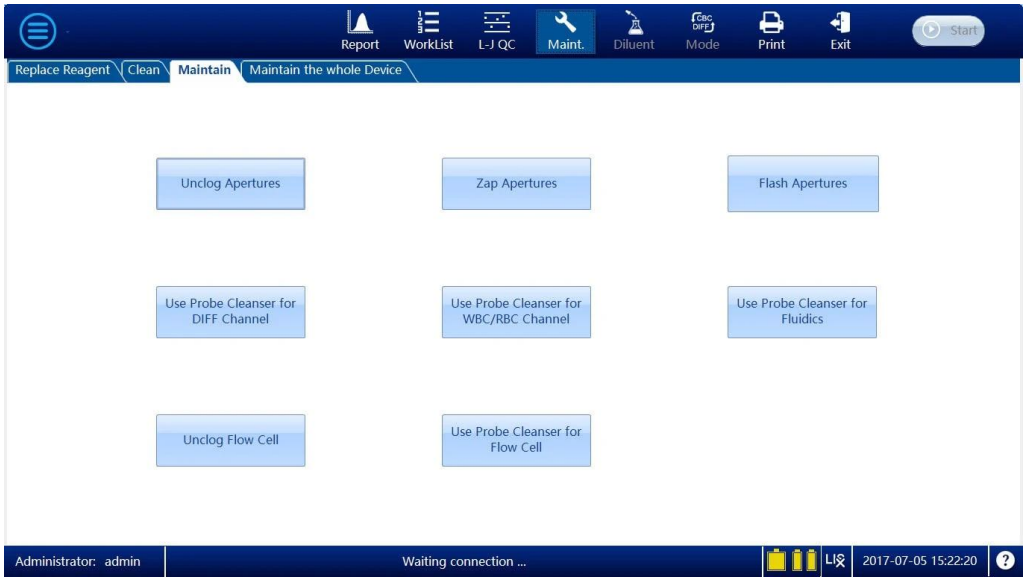

Figure 93

10.2.4 Maintain the whole Device
Click the "Maint." Key on the interface, then, click the "Maintain the whole Device" tab to enter the following interface. And all the maintenance operations on the interface can be executed when needed.

Figure 94

◦ When replacing the components of WBC channel, execute the Empty WBC bath function first.
◦ When replacing the components of RBC channel, execute the Empty RBC bath function first.
◦ When replacing the components of DIFF bath, execute the Empty DIFF bath function first.
◦ Before short-distance transport of the analyzer, the Empty Fluidics function should be executed.
◦ When replacing the components of Flow Cell, execute the Empty Flow Cell function first.
◦ When replacing the components of Pressure Chamber, execute the Empty Pressure Chamber function first.
◦ The analyzer needs preparing to ship before it is let sit out of service for a period of time (more than 1 week) or before long-distance transport.

The steps of preparing to ship are as follows:
Click the "Prepare to Ship" button to pop up a prompt dialogue box.
After taking out all the tubes from the reagent container according to the prompt. Click the "OK" button to begin the Drain function, and the following prompt will be popped up.
When the drain is finished, a prompt dialogue box will be popped up.
Put the tube into the distilled water container according to the prompt. Click the "OK" button to begin the distilled water perfusion, and the following dialogue box will be popped up.
When the distilled water perfusion is finished, the following prompt dialogue box will be popped up.
When cleaning is finished, the following prompt dialogue box will be popped up.
Take the tube out of the distilled water container according to the prompt. Click the "OK" button to execute the Drain function again, and a prompt will be popped up.
When the drain is finished, the following dialogue box will be popped up to prompt that the packing has been finished.
Click the "OK" button to turn off the analysis software. Power off the analyzer.
■ When replacing all reagents at a time, the Prime Fluidics function can be executed.
■ You should execute Fluidics initialization in the following cases:

1. Any main component is replaced, or the fluidics system is repaired.
2. Any error occurs. There is a prompt for device run-time error.

10.2.5 Auto Probe Cleaner Soak

When the sample count times reach or over 200(default) or it is the time for Probe Cleaner Soak, the analyzer will ask you for confirmation to perform the probe cleanser soak.

Click "Yes", and then the progress bar shown below will pop up and the analyzer is preparing.
When the preparation is done, a message box will pop up.

After aspirating the probe cleanser for the first time as instructed, the following progress bar will pop up and the analyzer starts the first-time priming automatically.
After the first-time priming is done, the progress bar closes and a message box will pop up.
After aspirating the probe cleanser for the second time as instructed, the following progress bar will pop up and the analyzer starts the second-time priming automatically.
When the second-time priming is complete, the progress bar closes and a count-down box will pop up. The soaking process starts.
The soaking process will last about 20 minutes. You may click the "OK"
button in the dialog box to stop it after five minutes. The cleaning process starts after the soaking progress is done.
After the cleaning is complete, a dialog box will pop up. Then, click the "OK" button to close the box.

• If it is the time to perform the auto prompt for probe cleanser soak but the analyzer is running or error happens; only after the running is completed or the error is removed will the auto prompt starts.
• If you cancel the procedure of probe cleanser soaking when it is auto-prompted, the confirmation prompt will pop up again every time when you finish running the samples.
• After the probe cleanser soaking is complete, the sample count times will reset to zero automatically.

10.2.6 Auto Probe Cleanser Clean

When the sample count times reach or over 200(default) or it is the time for probe cleanser cleaning, the analyzer will ask for confirmation to perform the procedure.
After you confirm, the soaking preparation starts.
After the preparation is finished, the progress bar will be closed automatically and a count-down box will pop up. The soaking process starts.
The soaking process will last about 20 minutes. You may click the "OK"
button in the message box to stop it after five minutes. The cleaning process starts automatically after the soaking progress is done
After the cleaning is complete, a message box will pop up. Click the "OK"
button to close the message box.

• Only when the connecting time of the analyzer and the computer reaches or over 24hours will the preset probe cleanser cleaning be prompted.
• If it is the time to prompt for probe cleanser cleaning but the analyzer is in running or error status, then only after the running is complete or the error is removed will the prompt starts accordingly.
• If you cancel the procedure of cleanser soaking when it is prompted, then the analyzer will perform the probe cleanser cleaning automatically when the preset time is reached.

10.2.7 Auto Sleep

When the fluidics system stops working for 15 minutes (default), then the analyzer will enter sleeping status automatically.
When the analyzer is in sleeping status, a prompt will display on the screen.

• You can set the waiting time for auto-sleeping.
• If it is the time to auto-sleep but the analyzer is error status, then only after the error is removed will the auto-sleeping starts accordingly.
• You can perform the operations without the cooperation of the analyzer when it is sleeping, namely, communication and print etc.

10.3 System Status

■ If the results of the status testing exceed the normal range, they will be highlighted by the red background.

Click the "Menu" button on the screen, and then select "Service""Status" on the pop-up menu.

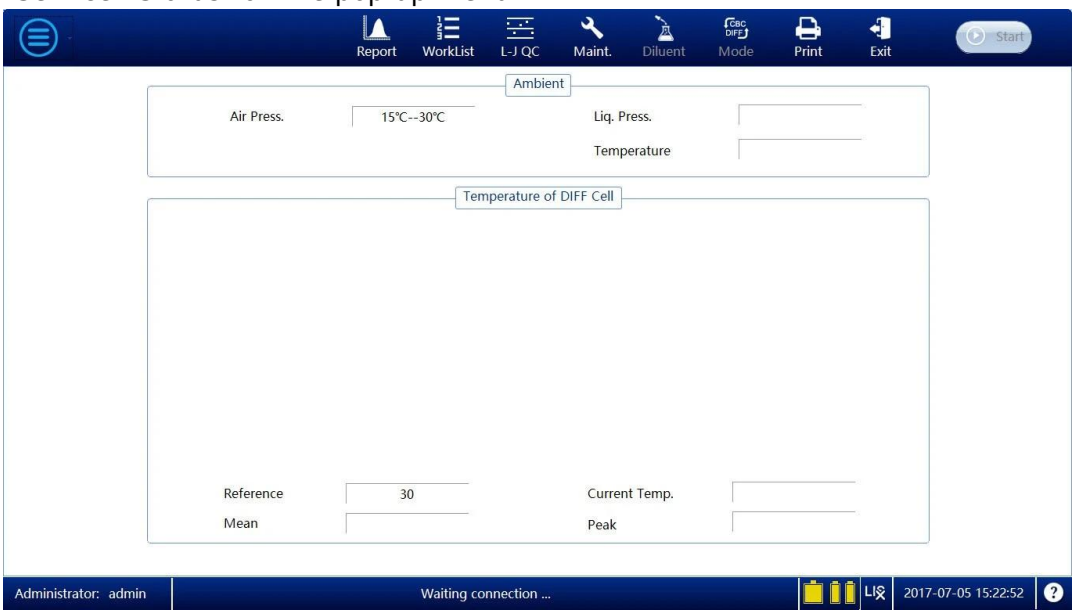

Figure 95

You can check the information about the temperature and pressure, and also export or print the information.

10.4 Self-test

Click the "Menu" button on the screen, and then select "Service""Self-test" on the pop-up menu.

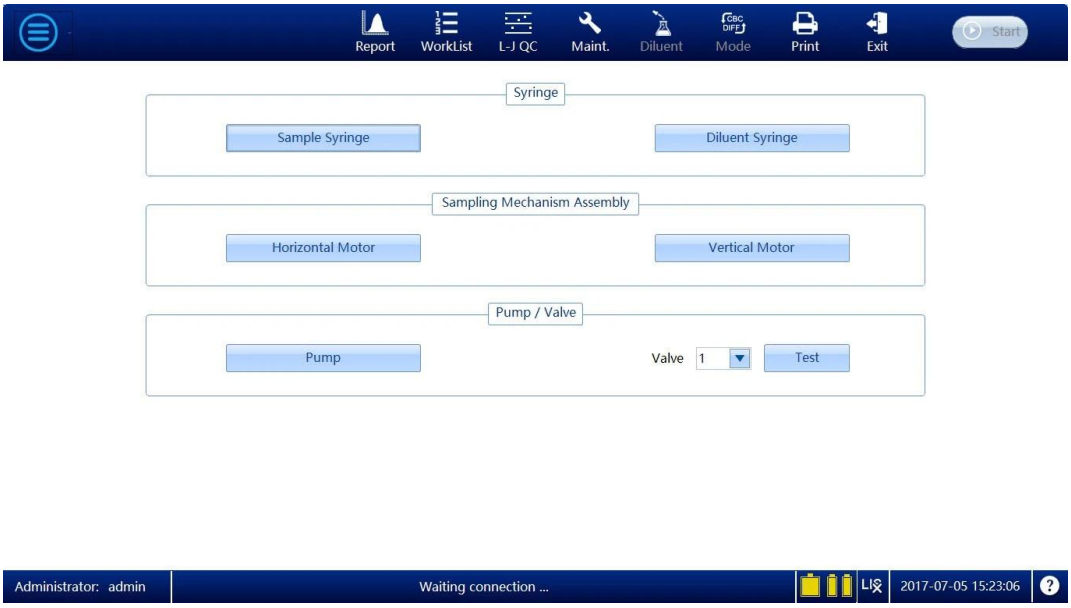

Figure 96

You can check the status of all items
• Syringe and Motor
Click the desired button, then identify whether it works well by judging its sound.
• Pump
Click the "Pump" button, then identify whether it works well by judging its sound when opening and closing
• Single valve
Click the desired Valve No. (e.g. "1"), then identify whether it works well by judging its sound when opening and closing.
• All valves
After clicking the "All Valves" button, all valves will be tested according to their No. one by one. A progress bar will pop up at the same time.

10.5 Counter

Click the "Menu" button on the screen, and then select "Service""Counter" on the pop-up menu.

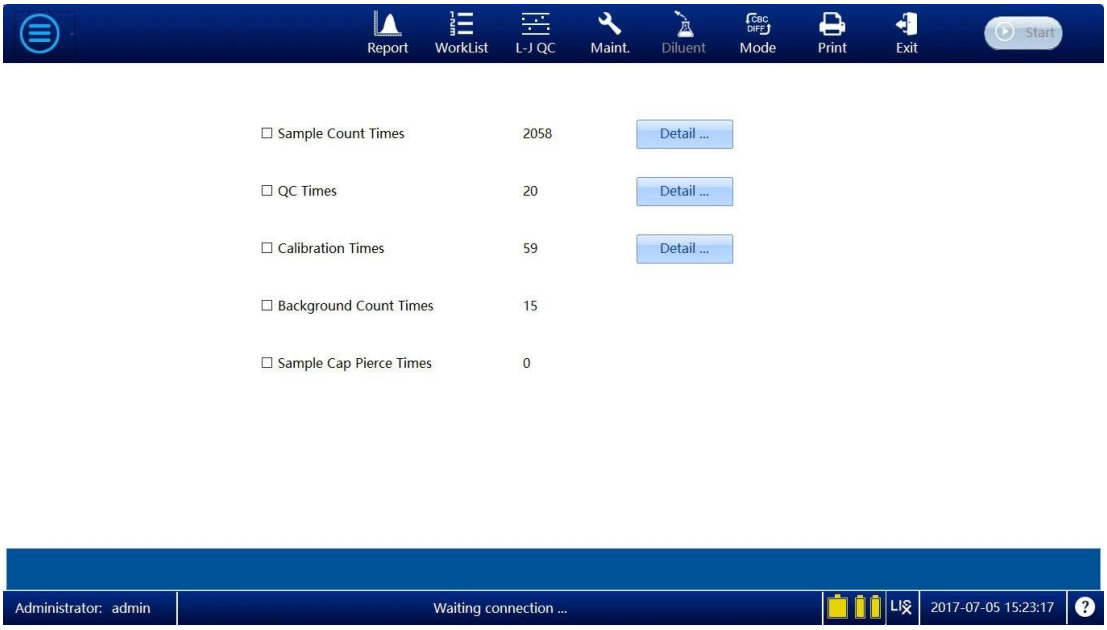

Figure 97

You can check the statistic information of all the above items and the detail statistical information of some items.

• Checking the detail information

You can check the detailed information for the sample count times, QC times and calibration times. You can click the "Detail..." button next to the "Sample Count Times" to display the detail statistical information about the sample count times.

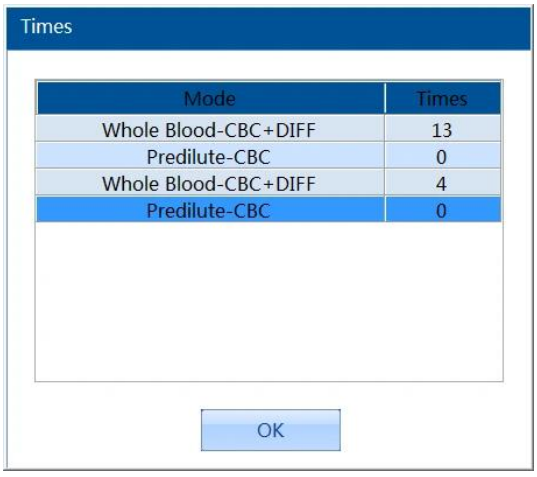

Figure 98

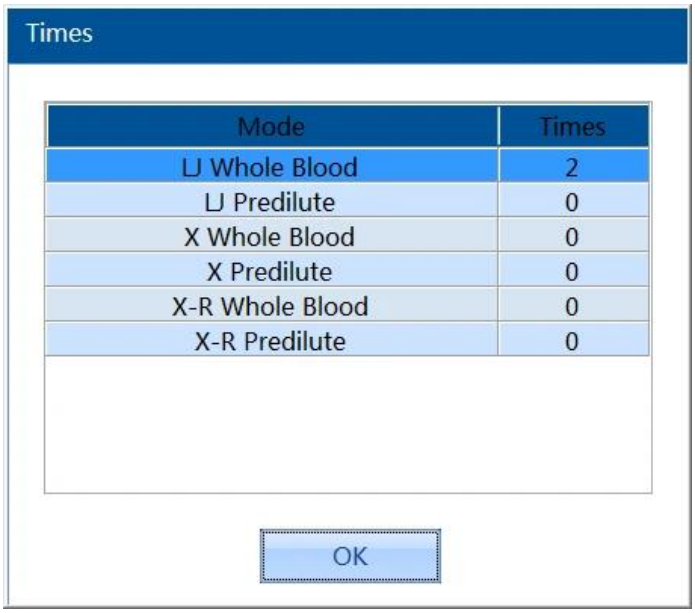

Figure 99

You can click the "Detail..." button next to the "Calibration Times" to display the detailed statistical information about the calibration times.

Figure 100

10.6 Log

■ If you add a new record when the log is full, the newest record will overwrite the oldest automatically.
■ Up to records of one year can be saved in the log.
■ Up to 50 characters can be input for remarks.

Click the "Menu" button on the screen, and then select "Service""Log" on the pop-up menu.

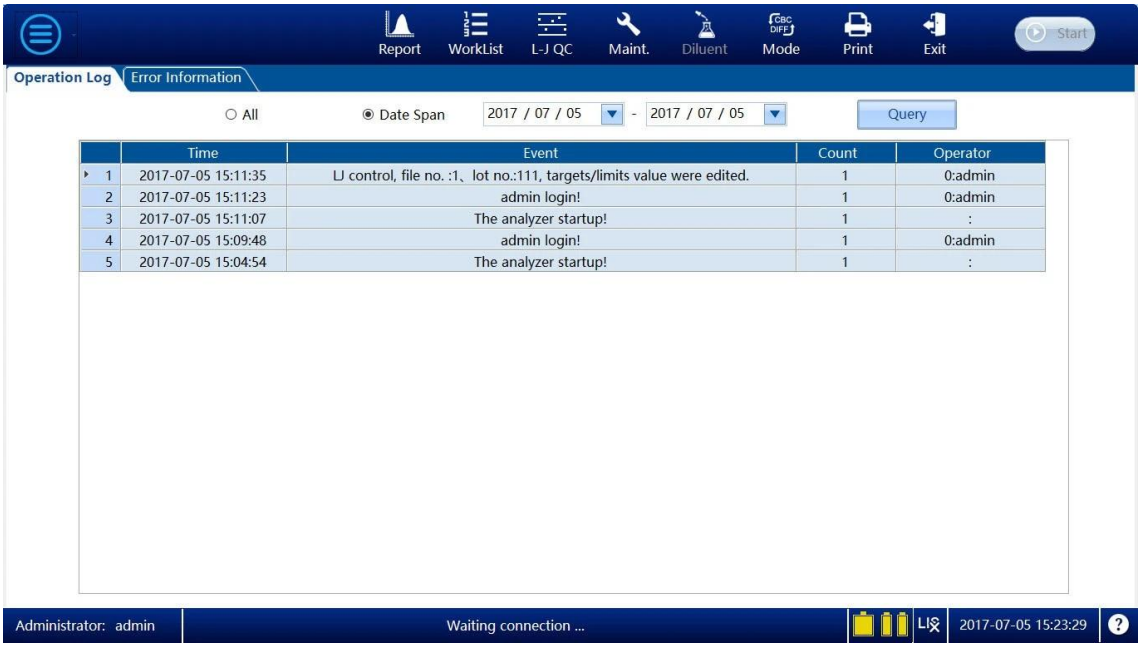

Figure 101

You can check the log information.

11. Troubleshooting

11.1 Introduction

This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analyzer.
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 the customer service department or your local distributor.

11.2 Errors indicated by error messages

During the operation, if errors are detected, the analyzer will beep and display the corresponding error message on the status bar of the interface, and the background color of the status bar will change. The background color for general errors is yellow; for severe errors, red. If the buzzer is not set to Off in System Setup, the buzzer will also give out an alarm sound. Click the zone of the status bar to open the following dialogue box, where you can view and clear the error.

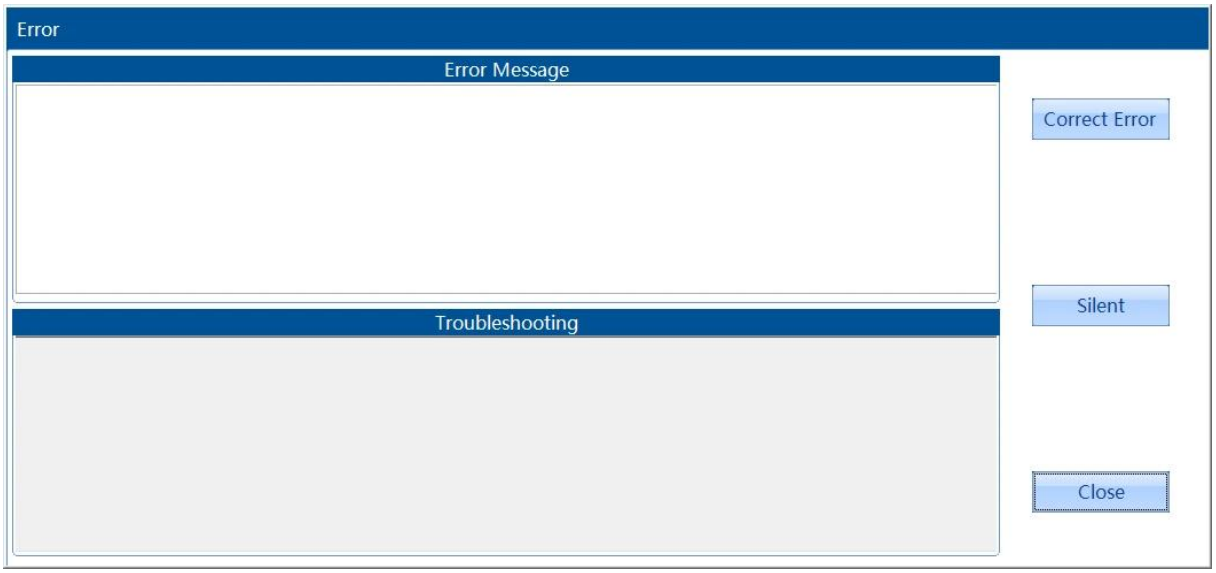

Figure 102

You can see the error names and the corresponding troubleshooting information in the pop-up message box. The error names are displayed in order.

You can click the error name in the message box to select it and check the corresponding troubleshooting information in the "Troubleshooting" list under the message box. The troubleshooting information of the first error will display. Follow the instructions in the message box to remove the errors.
The following functions are provided in the current message box. Correct Error
Click the "Remove error" button, then the system will remove the error automatically if possible. If the errors still exist, you should follow the instructions of the troubleshooting to remove the errors.

Silent
Click the "Silent" button to disable the alarm.

Close the "Error" message box
Click the "Cancel" button to close the "Error" message box, but the corresponding error message will display in the error message area. If you click the error message again, the "Error" message box will be re-opened.

The possible errors and the corresponding troubleshooting information are listed below:

Error Name	Troubleshooting Information

Syringe action error (Diluent syringe and Sample syringe)	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
Sampling needle action error	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
Pressure establishment exceeds the high limit	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
Pressure establishment is less than the low limit	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
Pressure of sheath fluid exceeds the limit	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
Pressure exceeds the high limit	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
Pressure is less than the low limit	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
DIFF pipeline blocked	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
DIFF pipeline leaks	Contact our customer service department.
Back bath pipeline leaks	Contact our customer service department.
Liquid drain pipeline leaks	Contact our customer service department.
Flow cell clog	1. Click the "Remove error" button to remove this error.2. If the error still exists, contact our customer service department.
DIFF bath temp. error	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, 32].2. Analysis results may be incorrect if the ambient temperature is out of the normal range.3. If the ambient temperature is within the normal range, the error will be removed automatically.4. If the error still exists, contact our customer service department.
LH Lyse expired	1. Check if the LH Lyse is expired. If so, change a new container of lyse, and setting to modify the reagent expiration date.2. If the lyse is not expired, enter "Replace Reagent" → "LH Lyse" settings to modify the reagent expiration date.
LD Lyse expired	1. Check if the LD Lyse is expired. If so, change a new container of lyse, and setting to modify the reagent expiration date.2. If the lyse is not expired, enter "Replace Reagent" → "LD Lyse" settings to modify the reagent expiration date.
Diluent expired	1. Check if the diluent is expired. If so, change a new container of diluent, and setting to modify the reagent expiration date.2. If the diluent is not expired, enter "Replace Reagent" → "Diluent" settings to modify the reagent expiration date.

No Diluent	1. Check whether the diluent container is empty.2. If there is no diluent, install a new container of diluent. Then click the "Remove error" button to prime the analyzer with the diluent.3. Enter "Replace Reagent" → "Diluent" settings to modify the reagent expiration date.4. If there is still plenty of diluent, or if the error still exists after a new container of diluent is installed, contact our customer service department.
No LH Lyse	1. Check whether the LH Lyse container is empty.2. If there is no lyse, install a new container of LH Lyse. Then click the "Remove error" button to prime the analyzer with the LH Lyse.3. Enter "Replace Reagent" → "LH Lyse" settings to modify the reagent expiration date.4. If there is still plenty of lyse, or if the error still exists after a new container of lyse is installed, contact our customer service department.
No LD Lyse	1. Check whether the LD Lyse container is empty.2. If there is no lyse, install a new container of LD Lyse. Then click the "Remove error" button to prime the analyzer with the LD Lyse.3. Enter "Replace Reagent" → "LD Lyse" settings to modify the reagent expiration date.4. If there is still plenty of lyse, or if the error still exists after a new container of lyse is installed, contact our customer service department.
Waste is full	1. Empty the waste container or install a new waste container.2. If the error still exists, contact our customer service department.
Laser assembly cover open	1. Close the laser assembly cover.2. If the error still exists, contact our customer service department.
Background abnormal	1. Check whether the diluent is contaminated.2. If it is not contaminated, click the "Remove error" button to remove the error.3. If the error still exists, contact our customer service department.
WBC clog	1. Click the "Remove error" button to remove this error.2. If the error reports frequently, see Chapter 10 Maintenance to clean the WBC channel with the probe cleanser.3. If the error still exists, contact our customer service department.
RBC clog	1. Click the "Remove error" button to remove this error.2. If the error reports frequently, see Chapter 10 Maintenance to clean the RBC channel with the probe cleanser.3. If the error still exists, contact our customer service department.
Network communication error	1. Check if the communication cable is well connected.2. If it is well connected, check whether the communication cable is damaged.3. If the cable is not damaged, click the "Remove error" button to remove the error.4. If the error still exists, contact our customer service department.

Table 11

Specifications

The BDL-6701 is a quantitative, automated hematology analyzer and 5- part differential counter used in clinical laboratories. It provides t he following 25 basic parameters, 4 parameters for research use, 3 histograms and 1 scattergram of blood samples. It supports 2 measurement modes: CBC and CBC+DIFF.

Parameter Name	Abbr.	CBC	CBC + DIFF
White Blood Cell count	WBC	*	*

Neutrophils percentage	Neu%	/	*
Lymphocytes percentage	Lym%	/	*
Monocytes percentage	Mon%	/	*
Eosinophils percentage	Eos%	/	*
Basophils percentage	Bas%	/	*
Neutrophils number	Neu#	/	*
Lymphocytes number	Lym#	/	*
Monocytes number	Mon#	/	*
Eosinophils number	Eos#	/	*
Basophils number	Bas#	/	*
Abnormal Lymphocytes percentage	ALY% (RUO)	/	*
Large Immature Cells percentage	LIC% (RUO)	/	*
Abnormal Lymphocytes number	ALY# (RUO)	/	*
Large Immature Cells number	LIC# (RUO)	/	*
Red Blood Cell count	RBC	*	*
Hemoglobin Concentration	HGB	*	*
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	*	*
Mean Platelet Volume	MPV	*	*
Platelet Distribution Width	PDW	*	*
Plateletcrit	PCT	*	*
Large Platelet count	P-LCC	*	*
Large Platelet percentage	P-LCR	*	*
White Blood Cell Histogram	WBC Histogram	*	*
Red Blood Cell Histogram	RBC Histogram	*	*
Platelet Histogram	PLT Histogram	*	*
Differential Scattergram	Diff Scattergram	/	*

Table 12

Performance
Blank Requirements

Parameter	Limits
WBC	≤0.2 x 109 /L
RBC	≤0.02 x 1012 /L
HGB	≤1g/L
PLT	≤10 x 109 /L
HCT	≤0.5%

Table 13

Carry-over

Parameter	Carry-over, %
WBC	0.5
RBC	0.5
HGB	0.5
PLT	1

Table 14

Repeatability

Parameter	Whole Blood Mode CV(%) or Absolute Deviation	Reference Range
WBC	≤2%	(4-15) x 10^9/L
RBC	≤1.5%	(3.5-6) x 10^{12}/L
HGB	≤1.5%	(110-180) g/L
HCT/MCV	≤1%	35%-50% / (70-120) fL
PLT	≤4%	(100-500) x 10^9/L
NEU%	±4 (Absolute Deviation)	(50%-60%) and WBC ≥ 4 x 10^9/L
LYM%	±3 (Absolute Deviation)	(25%-35%) and WBC ≥ 4 x 10^9/L
MON%	±2 (Absolute Deviation)	(5%-10%) and WBC ≥ 4 x 10^9/L
EOS%	±1.5 (Absolute Deviation)	(2%-5%) and WBC ≥ 4 x 10^9/L
BAS%	±0.8 (Absolute Deviation)	(0.5%-1.5%) and WBC ≥ 4 x 10^9/L

Table 15

Linearity

Parameter	Whole Blood Mode (%)	Measurement Range
WBC	Within ±0.5 x 109 /L	(1.0~10.0) x 109 /L
	Within ±5%	(10.01~99.9) x 109 /L
RBC	Within ±0.05 x 1012 /L	(0.30~1.00) x 1012 /L
	Within ±5%	(1.01~7.00) x 1012 /L

HGB	Within ±2g/L	(20~70)g/L
	Within ±2%	(71~240)g/L
PLT	Within ±10 x 109 /L	(20~100) x 109 /L
	Within ±8%	(101~999) x 109 /L
HCT	±3% or ±2HCT%	0-67%

Table 16

Comparability

Technical Parameters

Testing Principle:	WBC/RBC/PLT: Electrical impedance; HGB: Colorimetry; WBC 5-part differentiation: Laser scattering method
Measuring Speed:	≤60s/test
Work Environment:	15C~30C; RH≤85%; Air Pressure 70kpa-106kpa
Storage Environment:	0C~55C; RH ≤93%
Mains Input:	a.c.100V-240V, 50Hz/60Hz
Input Power:	300VA

Table 17

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