Auto Hematology Analyzer

Operator’s Manual

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Table of Contents

1 Using This Manual

1.1 Introduction

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

NOTE

- **Be sure to operate the 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 hardware and software of the analyzer;
- set up system parameters;
- perform daily operating tasks;
- perform system maintenance and troubleshooting.

1.3 How to Find Information

This operator's manual comprises 11 chapters and 5 appendices. Refer to the table below to find the information you need.

If you want to …	See …
learn about the intended use and parameters of the analyzer	**Chapter 2 Understanding Your Analyzer**
learn about the hardware and software of the analyzer	**Chapter 2 Understanding Your Analyzer**
learn about how the analyzer works	**Chapter 3 Understanding the System Principles**
learn about the installation requirements of the analyzer	**Chapter 4 Installing Your Analyzer**
learn about how to define/adjust system settings	**Chapter 9 Customizing the Analyzer Software**
learn about how to collect, prepare and analyze the samples	**Chapter 5 Operating Your Analyzer**
learn about how to use the analyzer perform your daily operating tasks	**Chapter 5 Operating Your Analyzer**
learn about how to review the saved analysis results	**Chapter 6 Reviewing Sample Results**
learn about how to use the quality control programs of the analyzer	**Chapter 7 Using the QC Programs**
learn about how to calibrate the analyzer	**Chapter 8 Using the Calibration Programs**
learn about how to maintain/service the analyzer	**Chapter 10 Maintaining Your Analyzer**
learn about how to solve the problems of the analyzer	**Chapter 11 Troubleshooting Your Analyzer**
learn about the technical specifications of the analyzer	**Appendix B Specifications**
learn about the communication protocol of the analyzer	**Appendix C Communication**
learn about the references of this manual	**Appendix D References**

1.4 Conventions Used in This Manual

This manual uses certain typographical conventions to clarify meaning in the text:

Form	Meaning
[××]	all capital letters enclosed in [ ] indicate a key name
“××”	bold letters included in " " indicate text you can find on the screen of the analyzer
××	italic 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.

1.5 Terms Used in Software Operation

Name	It means…
Click	to press the desired item ×× lightly with your finger; or to left click ×× with the mouse.
Enter	to click the desired edit box "××" and use the external keyboard or the pop-up keyboard to enter the desired characters or digits.
Delete	to left click with the mouse, or directly tap the touch screen, or use the [←][→][Home] [End] key on the external keyboard to move the cursor to the desired position, and then delete the character after the cursor by pressing [Del], or delete the character before the cursor by pressing [Backspace] ([←] on the upper right part of the soft keyboard).
SELECT from ×× pull-down list (for pull-down list)	to click the down arrow button of the desired box "××" to display the pull-down list, and drag scroll bar to browse and then click the desired item; or to press the keys ([↑][↓][Page Up][Page Down]) to browse the current list then press [Enter] to select the desired item.

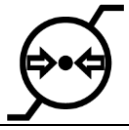
1.6 Symbols

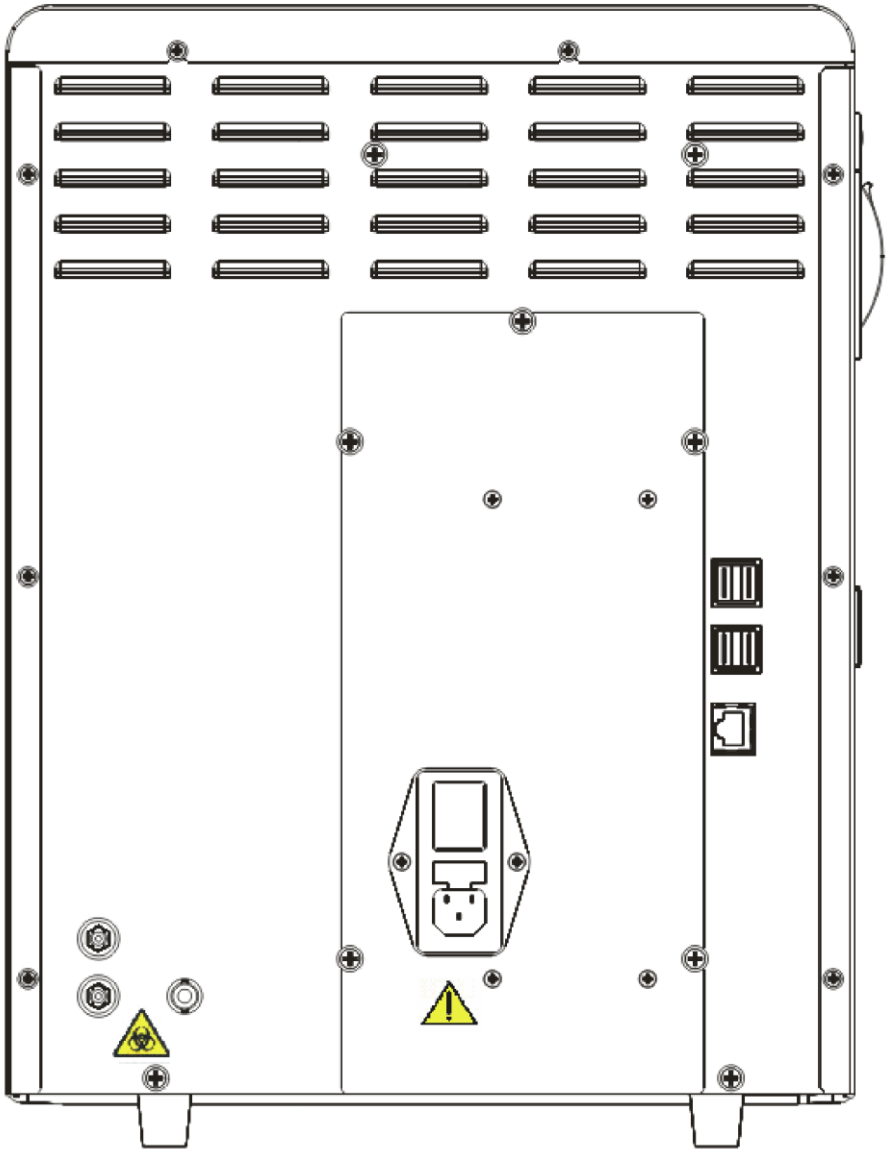
Symbols used in this manual:

When you see...	It means...
	read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
⚠WARNING	read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
⚠CAUTION	read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
NOTE	read the statement below the symbol. The statement is alerting you to information that requires your attention.

You may find the following symbols on package or the body of the instrument:

When you see...	It means...
	Caution Note: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Biological risks
	The sample probe is sharp and potentially biohazardous. Exercise caution when working around it!
	(Off) Power
	(On) Power
	PROTECTIVE CONDUCTOR TERMINAL

When you see...	It means...
	Alternating current
	*In vitro* diagnostic medical device
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limit
	Serial number
	Date of manufacture
	Manufacturer
	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.

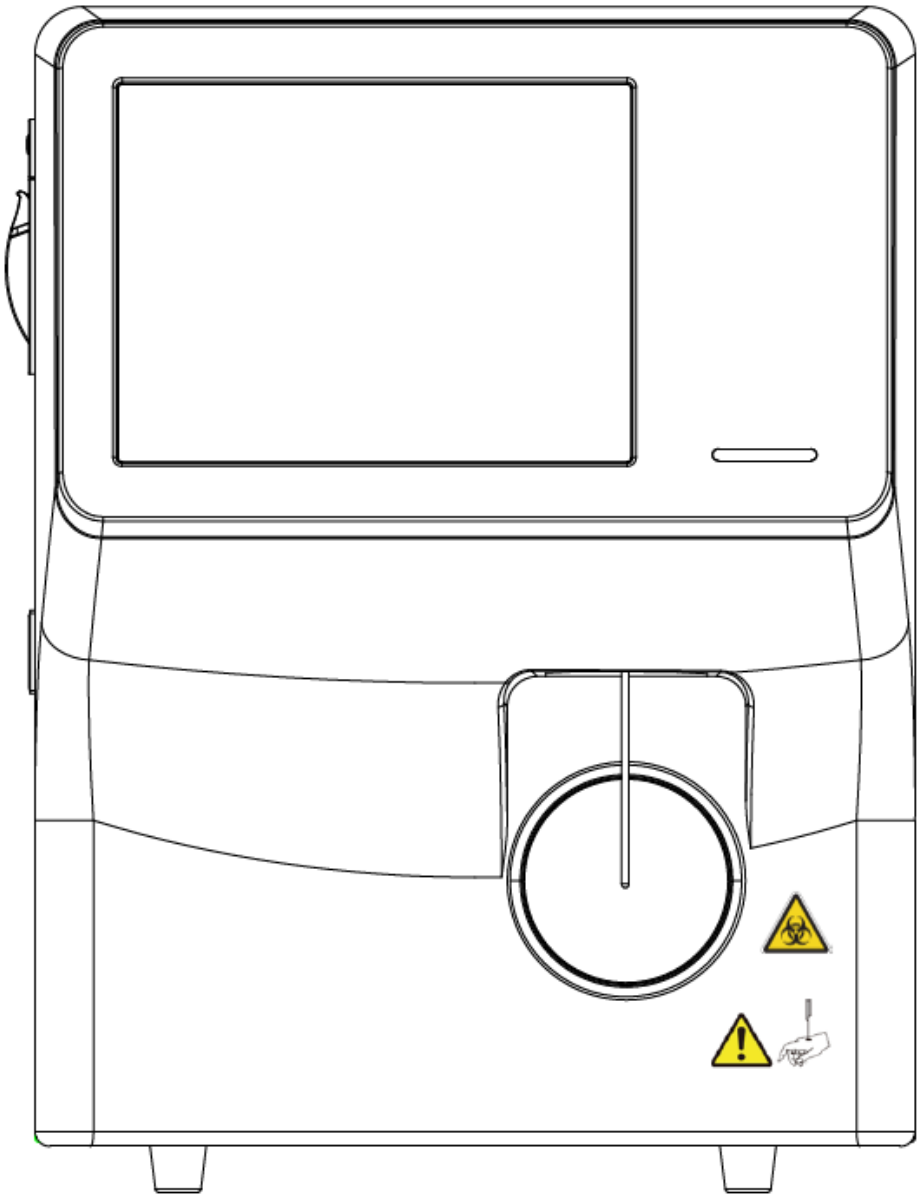


(1) 

- Biological risk.

(2) 

- Connect only to a properly earth grounded outlet.
- To avoid electrical shock, disconnect power prior to maintenance.
- To prevent fire, only use the fuse of specified type and rating.

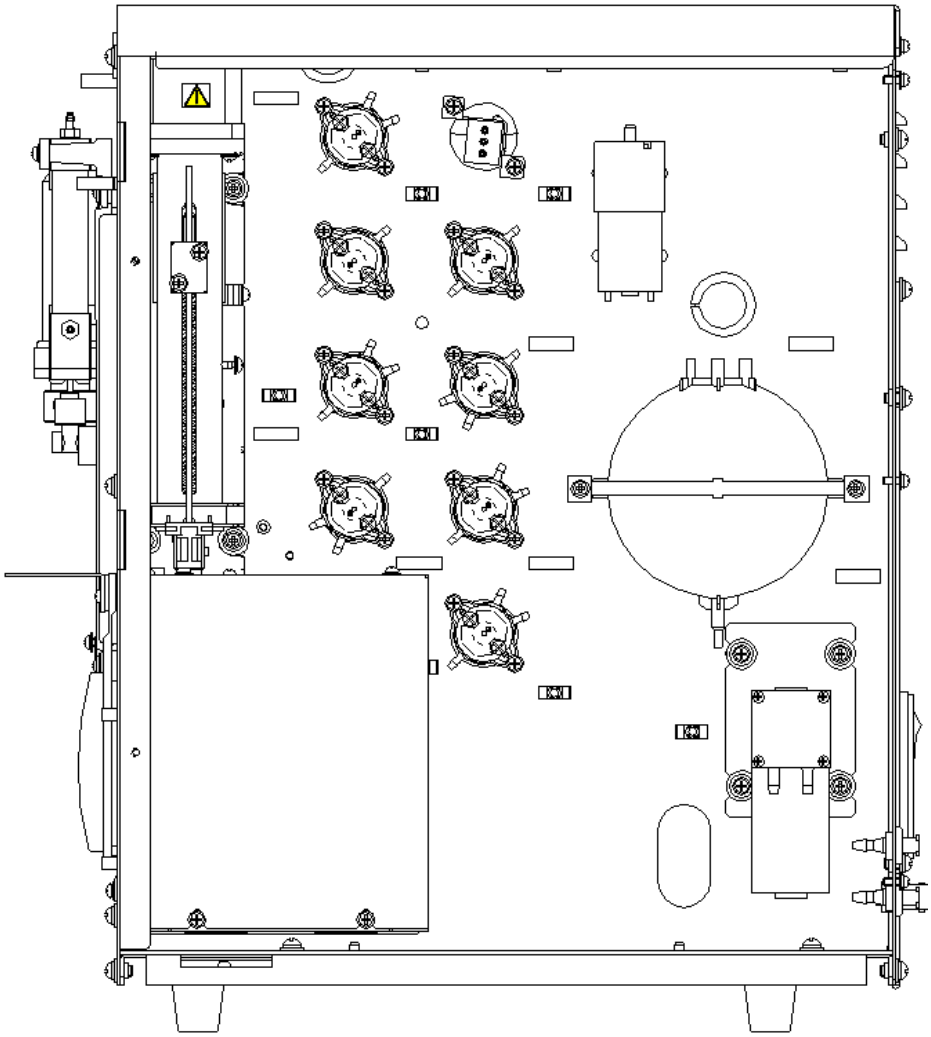


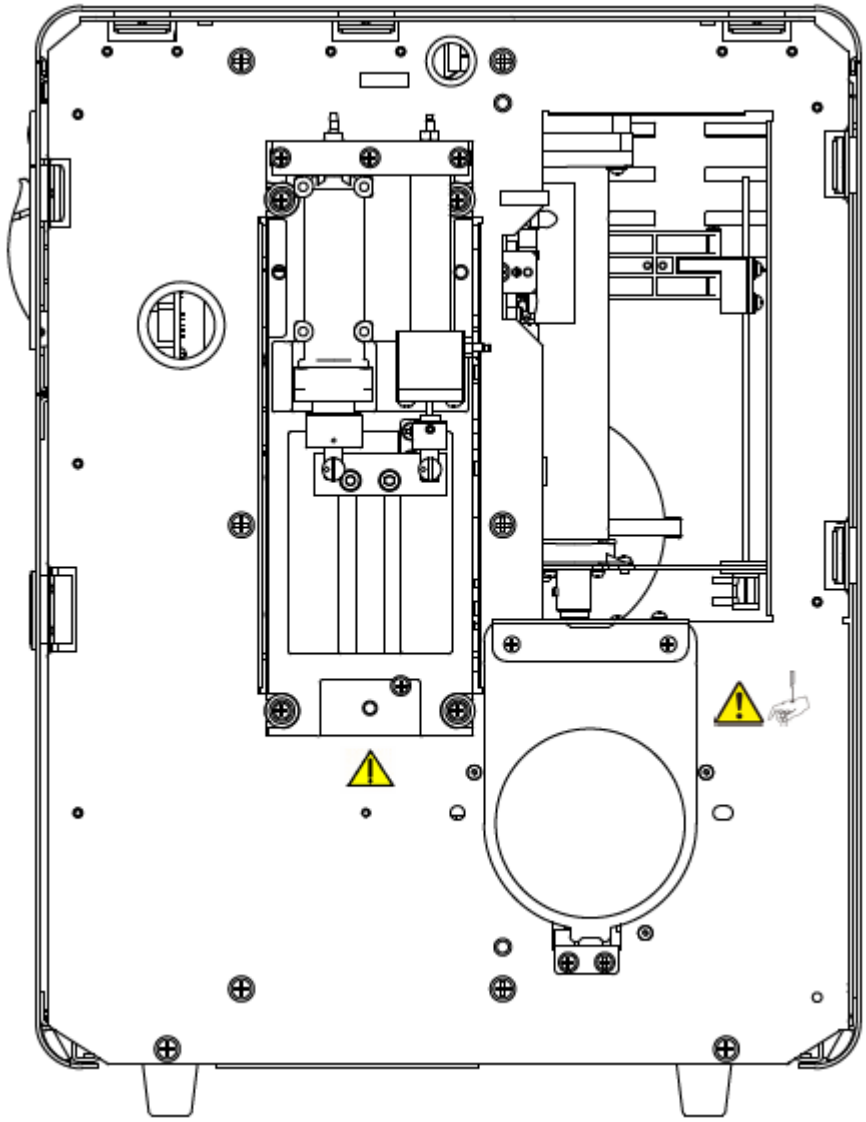
(1) 

- Warning: the sample probe is sharp and potentially biohazardous. Exercise caution when working around it!

(2) 

- Biological risk.





(1) 

- Warning: make sure that the protective cover is closed before operating the analyzer.

(2) 

Warning

- To avoid injury, do not place your hands anywhere near the the aspiration module when the analyzer is working.
- The sample probe is sharp and potentially biohazardous. Exercise caution when working around it!

2 Understanding Your Analyzer

2.1 Introduction

The analyzer is a hematology analyzer and 3-part counter for In Vitro Diagnostic Use in clinical laboratories.

⚠CAUTION

- **Installing other software on the analysis system computer, using mobile storage devices or using the computer for other purposes (e.g. playing games, logging on the internet, etc.) may lead to virus infection, system damage and/or data error. Therefore, please make sure the computer is used for analysis system only.**
- **The installation, authorization, upgrade and modification of the system software must be performed by personnel authorized by us.**
- **The safety of any system incorporating the equipment is the responsibility of the assembler of the system.**

2.2 Product Description

2.2.1 Intended Use

The Auto Hematology Analyzer is a quantitative, automated hematology analyzer and 3-part differential counter for in Vitro Diagnostic Use in clinical laboratories.

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.

2.2.2 Product Composition

Auto Hematology Analyzer (hereinafter called “the analyzer”) system consists of the main unit (analyzer), reagents, controls and calibrators, manuals, and accessories. Performance of the system depends on the combined integrity of all components.

2.2.3 Accessories

The analyzer has the following configured or optional accessories.

Table 2-1 Accessories

	Configured	Optional
Reagent container cap assemblies	√	
Waste tube assembly	√	
Power cord	√	

NOTE

- **For any questions about the configured/optional accessories, consult your sales representative.**
- **Your product accessories may vary based on your product configuration.**

⚠CAUTION

- **Only use the accessories and consumables manufactured or recommended by us to achieve the promised system performance and safety. For more information, contact our Customer Service Department or your local distributor.**
- **Please use the original power cord shipped with the analyzer, which matches the analyzer power supply. Using other power cord may damage the analyzer or lead to unreliable analysis results.**

2.3 Parameter

NOTE

- **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 analyzer is used for the quantitative determination of the following 21 report parameters and provides 3 histograms.

White Blood Cell Count	WBC
Lymphocyte number	Lymph#
Mid-sized Cell number	Mid#
Granulocyte number	Gran#
Lymphocyte percentage	Lymph%
Mid-sized Cell percentage	Mid%
Granulocyte percentage	Gran%
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 Cells Distribution Width - Standard Deviation	RDW-SD
Hematocrit	HCT
Platelet count	PLT
Mean Platelet Volume	MPV
Platelet Distribution Width	PDW
Plateletcrit	PCT
Platelet-Large Cell Ratio	*P-LCR
Platelet-Large Cell Count	*P-LCC
White Blood Cell Histogram	WBC Histogram
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram

Note: The two parameters P-LCR and P-LCC with mark "*" are configurable parameters, which can be configured according to the specific market requirement.

The analyzer may output the following two RUO (research use only) parameters.

Neutrophil-to-lymphocyte ratio	NLR
Platelet-to-lymphocyte ratio	PLR

NOTE

- **The RUO parameters are for research use only, and cannot be use for diagnosis purpose.**

2.4 Main Structure

The Auto Hematology Analyzer consists of the main unit (analyzer) and accessories.

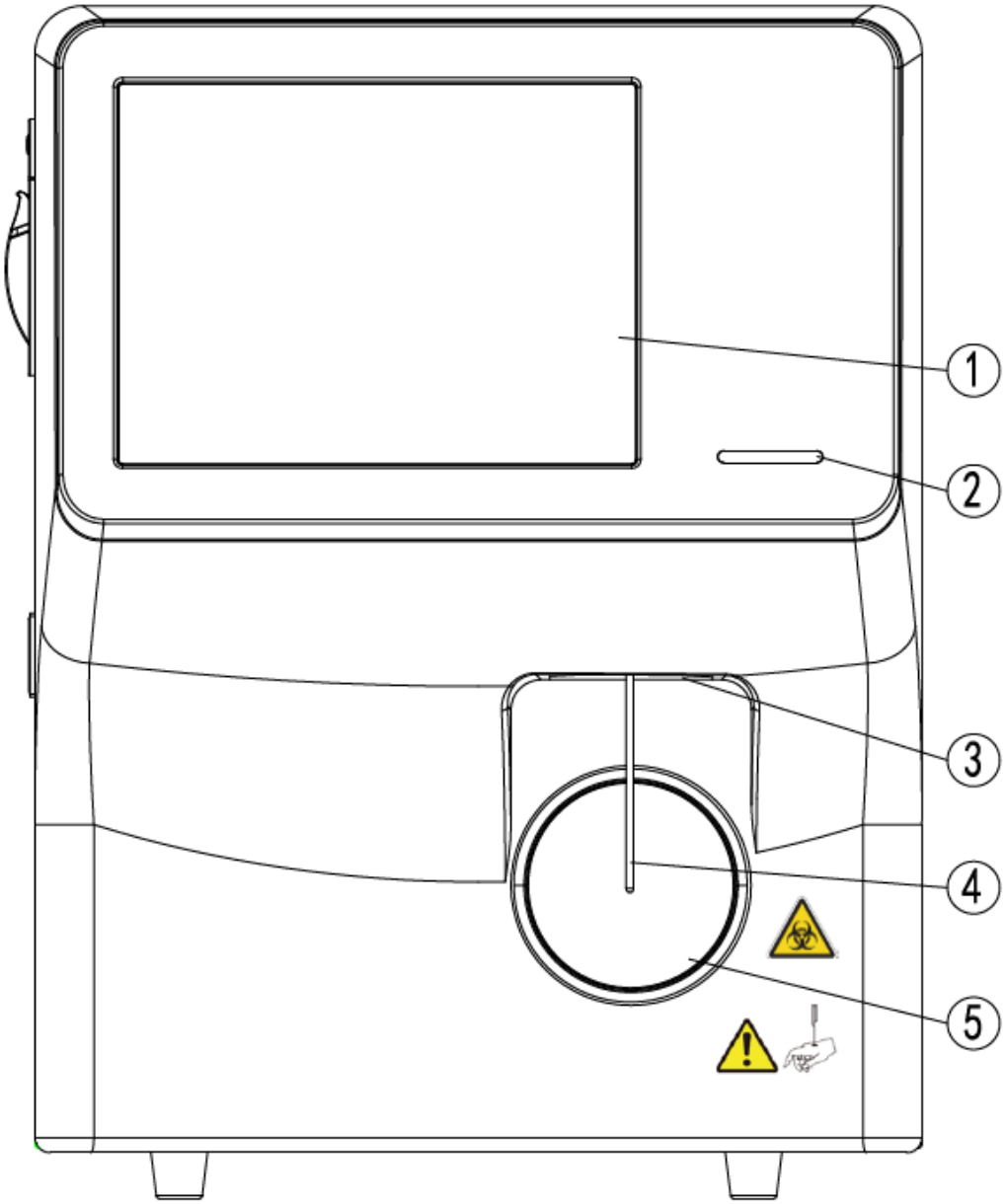


Figure 2-1 Front of the analyzer

1 ---- Touch screen
2 ---- Indicator
3 ---- Probe wipe block
4 ---- Sample probe
5 ---- [Aspirate] key

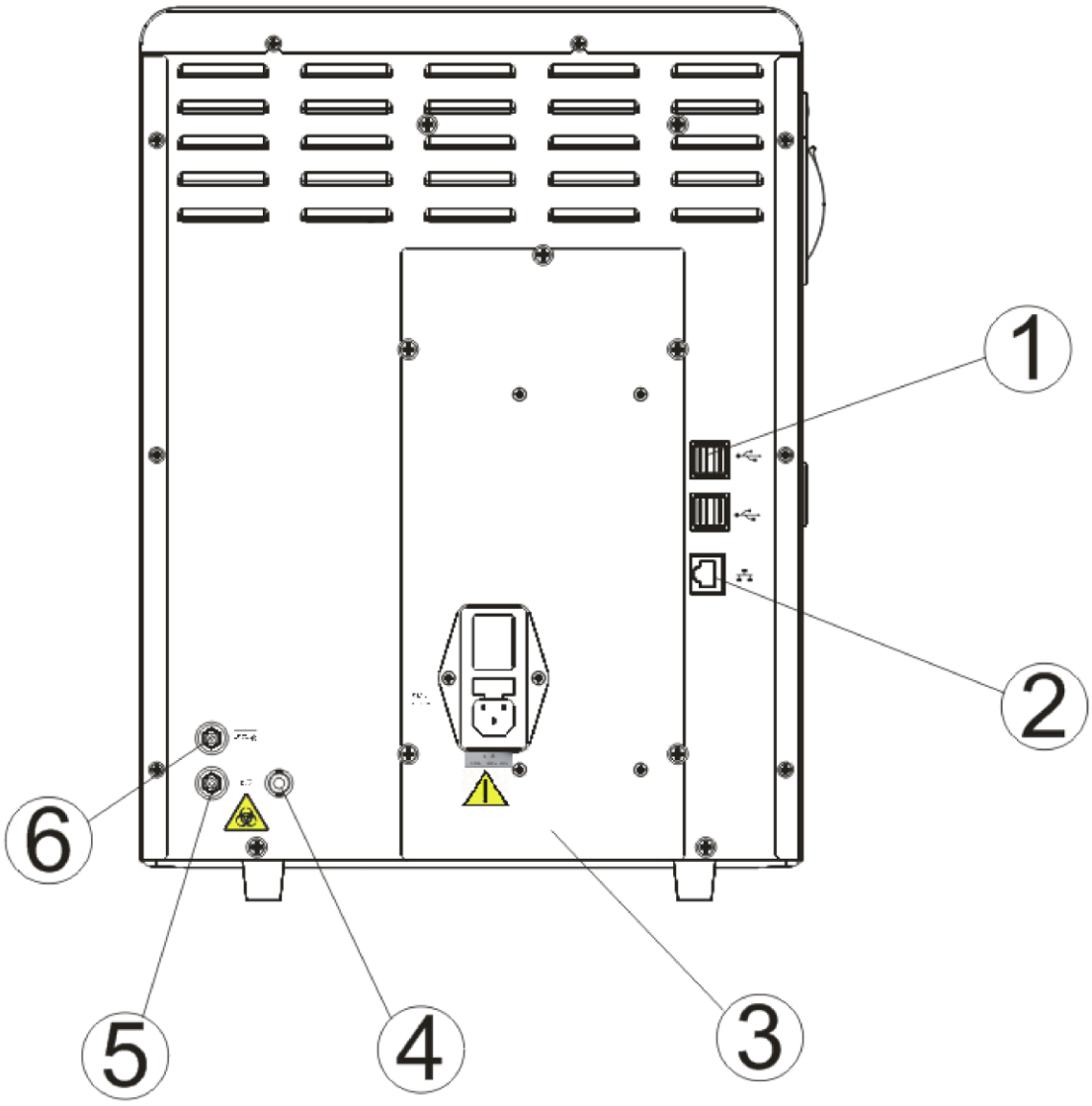


Figure 2-2 Back of the main unit

1 ---- USB port
2 --- Network interface
3 --- Power assembly
4 --- Waste sensor connector
5 --- Waste outlet
6 --- Diluent inlet

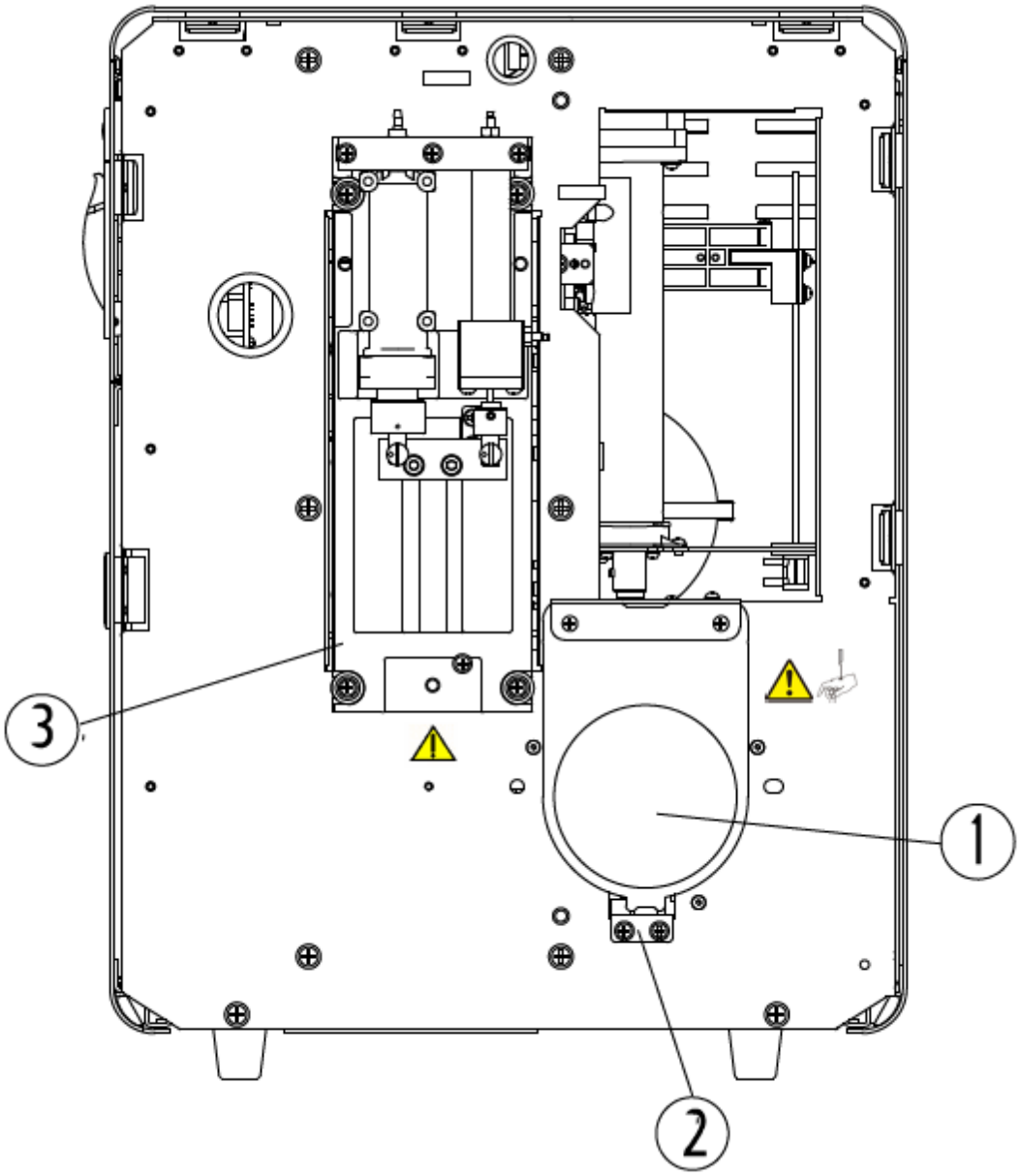


Figure 2-3 Inside of the analyzer (front cover removed)

1 --- [Aspirate] key

2 --- Start assembly

3 ---Syringe module

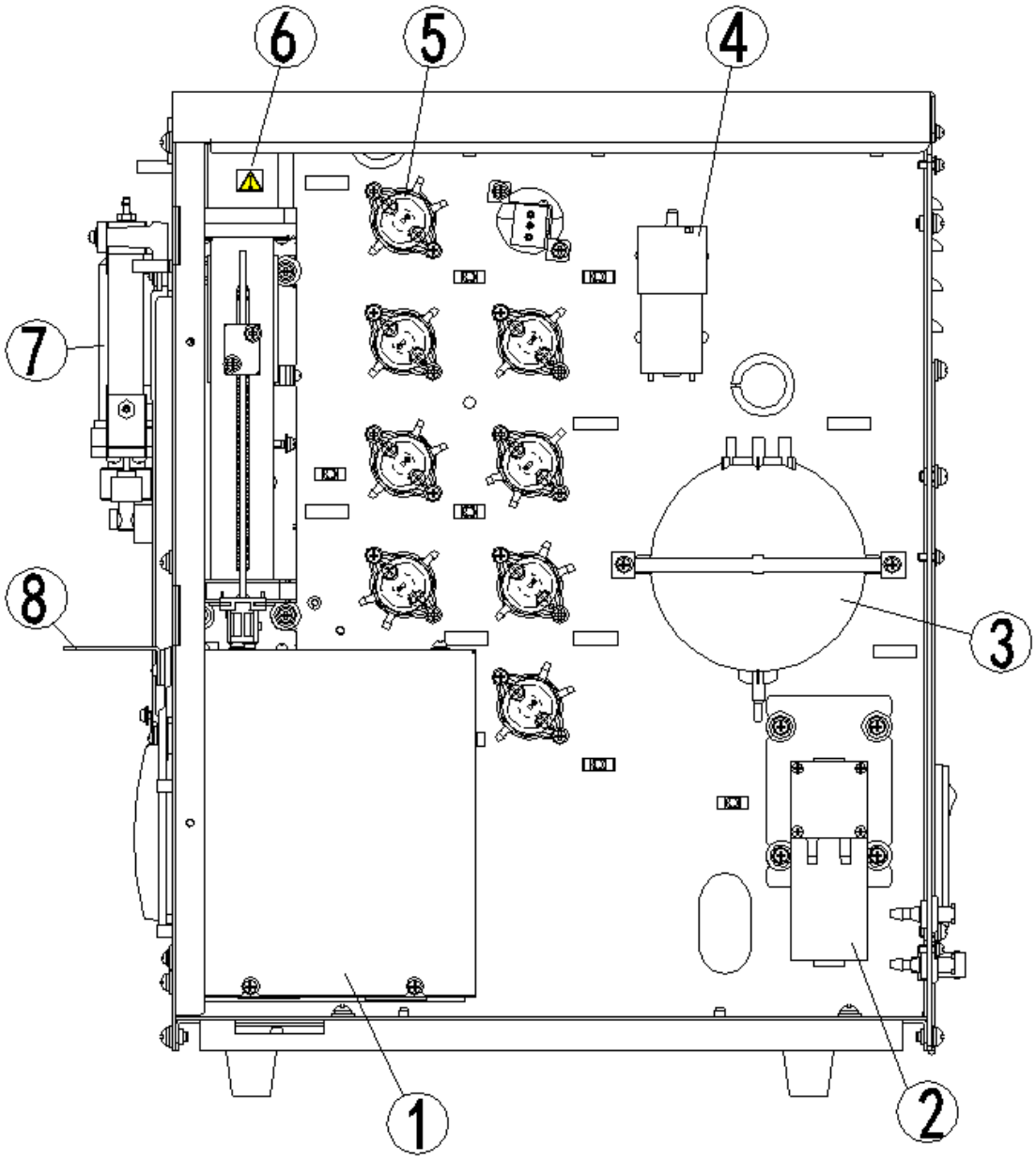


Figure 2-4 Right side of the analyzer (right door open)

1 --- Baths
2 --- Waste pump
3 --- Vacuum chamber
4 --- Air pump
5 --- Valves
6 --- Aspiration module
7 --- Syringe module
8 --- Probe wipe block

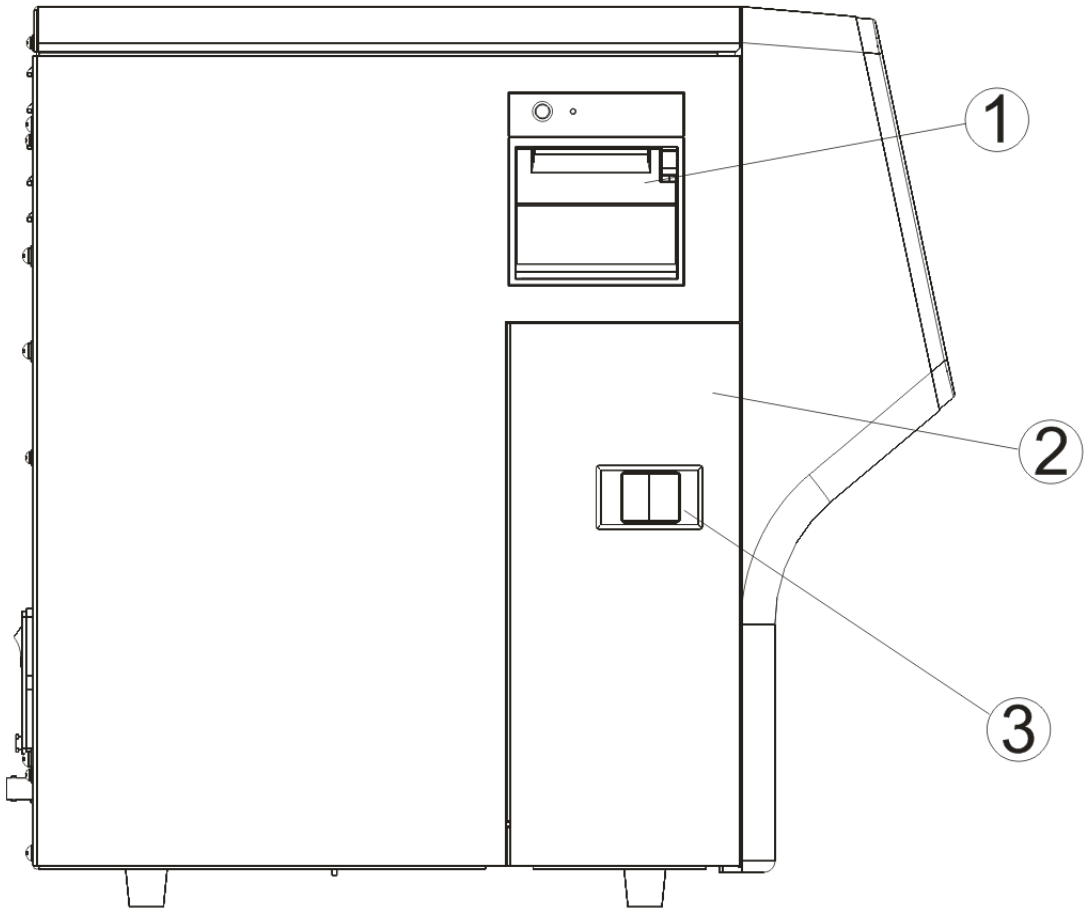


Figure 2-5 Left side of the analyzer

1 --- Recorder 2 --- Left door

3 --- Lock latch of the side door

2.4.1 Touch screen

The touch screen locates on the front of the main unit, which can be used to operate the instrument and display information.

2.4.2 [Aspirate] key

The [Aspirate] key is located behind the sample probe. You can press the key to start the analysis, dispense diluent or perform reagent maintenance.

2.4.3 Indicator

The indicator may light in red, yellow and green to indicate current status of the system. When the indicator stays in green, the analyzer is "Ready"; when it flickers in green, the analyzer is running; when it stays in red, the analyzer encounters error and has stopped running; when it flickers in red, the analyzer encounters error but is still running; and when it stays in yellow, the analyzer is sleeping.

2.4.4 USB Ports

The analyzer has 4 USB ports to connect the keyboard, printer, barcode scanner, recorder, WiFi wireless network card, etc.. The analyzer supports software upgrade through USB.

2.4.5 Network Interface

A PC can be connected to the network interface located on the back of the analyzer for automatic data transmission.

2.4.6 Peripherals

- Keyboard (Optional)

A Keyboard can be connected to a USB port on the analyzer. You can use it to operate your analyzer.

- Mouse (Optional)

A mouse can be connected to a USB port on the back of the analyzer. You can use it to operate your analyzer.

- USB Printer (Optional)

A USB printer can be connected to a USB port on the back of the analyzer. You can use it to print out reports or other interested information displayed on the screen.
Supported printers: EPSON LQ-590K, HP Laser Jet P1505n, HP OfficeJet Pro K5300, HP LaserJet P1606dn, HP Laserjet 1020 plus, EPSON LQ-310, HP319, HP310, HP deskjet1115, and HP LaserJet P2035.

- Barcode scanner (Optional)

A barcode scanner can be connected to a USB port on the back of the analyzer. You can use it to scan the barcode information into the analyzer.

- WiFi wireless network card (Optional)

Supported WiFi wireless network card: NETGEAR® WNA3100M.

NOTE

- **When you purchase a wireless WiFi module by yourself, make sure you comply the relevant local laws and regulations.**

2.5 User Interface

2.5.1 Screen

After the starting procedure, you will enter the "**Sample Analysis**" screen as shown in below figure.

Figure 2-6 Sample Analysis screen

NOTE

- **The two parameters P-LCR and P-LCC are configurable parameters, which can be configured according to the specific market requirement.**

Menus

Tap the "**Menu**" button to display the system menu.

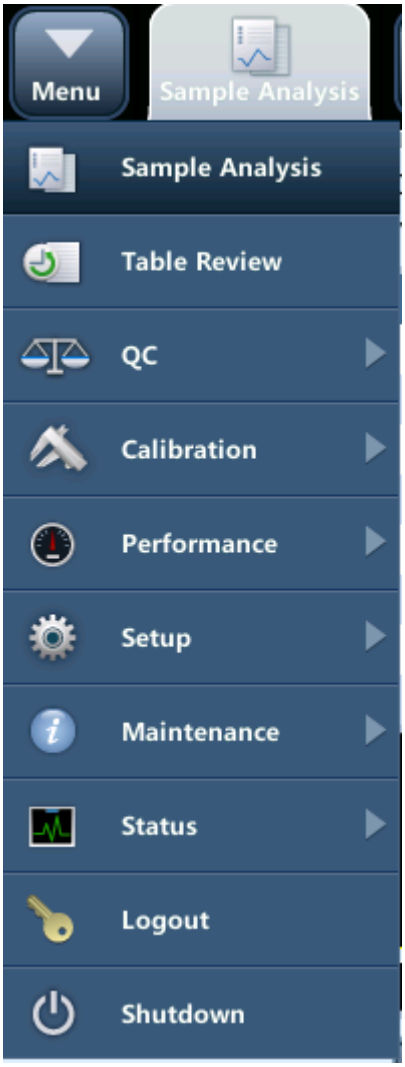


Figure 2-7 System menu

Tap one of the 10 options on the system menu to enter corresponding screen.

2.6 Reagents, Controls and Calibrators

As the analyzer, reagents, controls and calibrators are components of a system, performance of the system depends on the combined integrity of all components. You must only use the specified reagents (see *Appendix B Specifications*) 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. Product integrity may be compromised in packages that have been damaged. Inspect the package for signs of leakage or moisture. If there is evidence of leakage or improper handling, do not use the reagent.

⚠WARNING

- **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 instrument (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water, and seek medical attention immediately.**

NOTE

- **Store and use the reagents as instructed by instructions for use of the reagents.**
- **When you have changed the diluent, lyse, 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.**
- **Please adopt proper measurements to prevent the reagents from being polluted.**

The analyzer supports the following reagents.

NOTE

- **For any questions about the reagents configuration, please consult your sales representative.**

2.6.1 Reagents

- M-30D Diluent

As an isotonic reagent and with specified conductivity, M-30D diluent provides stable environment for hematology analysis.

- M-30CFL Lyse

M-30CFL lyse is formulated to lyse red blood cells and transform the hemoglobin released from red blood cell into hemoglobin complex. It is used for WBC count, WBC 3-part differential and HGB determination.

- M-3CFL Lyse

For use as a cyanide-free lytic reagent for quantitatively determining hemoglobin and for counting and sizing leukocytes.

- Probe Cleanser

Probe Cleanser is used for the regular cleaning of the analyzer.

2.6.2 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.

All references related to controls in this manual refer to the "controls" and "calibrators" specifically formulated for this analyzer. You must buy those controls and calibrators from us or our authorized distributors.

3 Understanding the System Principles

3.1 Introduction

The analyzer uses the electrical impedance method to determine the count and size distribution of RBC, WBC and PLT; and uses the colorimetric method to determine HGB. Based on the above data, the analyzer calculates other parameters.

3.2 Aspiration

If you are to analyze a whole blood sample, present the sample to the analyzer directly, and the analyzer will aspirate 9 μL of the whole blood sample.

If you are to analyze a capillary blood sample under the pre-dilute mode, you should first manually dilute the sample (20 μL capillary sample needs to be diluted by 0.7 mL of diluent to form a 1:36 dilution), and then present the pre-diluted sample to the analyzer, which will aspirate 198uL of the sample.

3.3 Dilution

Usually in blood samples, the cells are too close to each other to be identified or counted. For this reason, the diluent is used to separate the cells so that they draw through the aperture one at a time as well as to create a conductive environment for cell counting. Moreover, red blood cells usually outnumber white blood cells by 1,000 times. For this reason, lyse need to be added to the sample to eliminate the red blood cells before the WBC counting. Because red blood cells usually have no nucleus, they are eliminated when the lyse breaks down their cell walls. The analyzer provides whole blood mode and predilute mode for the analysis of different sample types.

3.3.1 Whole Blood Mode

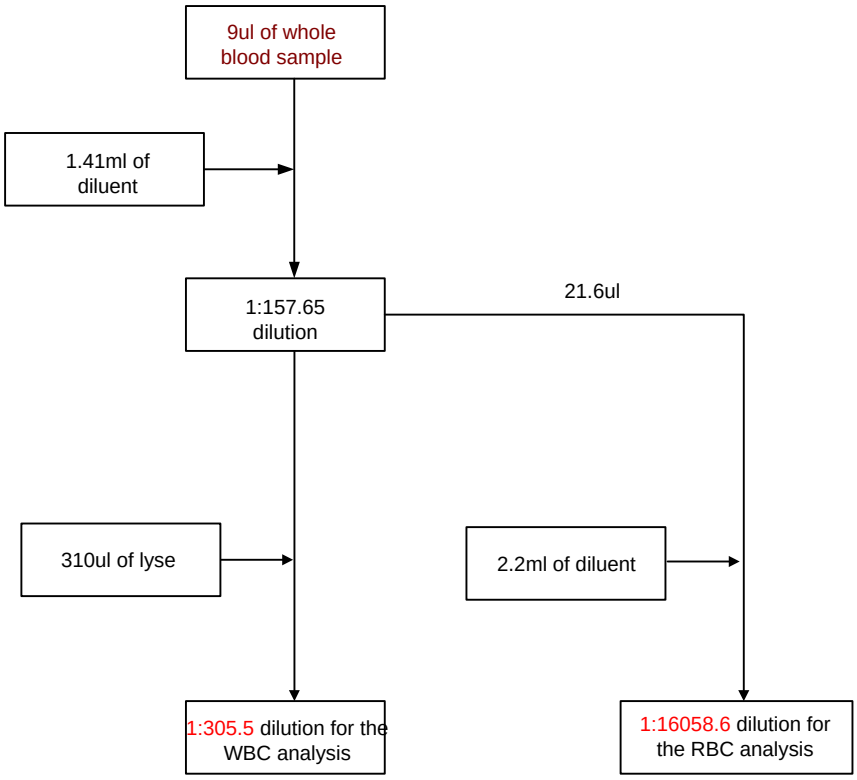


Figure 3-1 Whole blood mode dilution flow chart

As shown on **Figure 3-1**, under the whole blood mode, 9 μL of whole blood sample is aspirated and diluted by 1.41mL of diluent, forming a 1:157.65 dilution. The dilution is then divided into 2 parts: the first 21.6 μL is aspirated and diluted by about 2.2 mL of diluent to form a 1:16058.6 dilution. This sample is used for RBC/PLT count and histogram output. The remaining sample will be mixed with 0.31 mL of lyse to make a 1:305.5 diluted sample for HGB, WBC count and the output of WBC histograms.

3.3.2 Predilute Mode

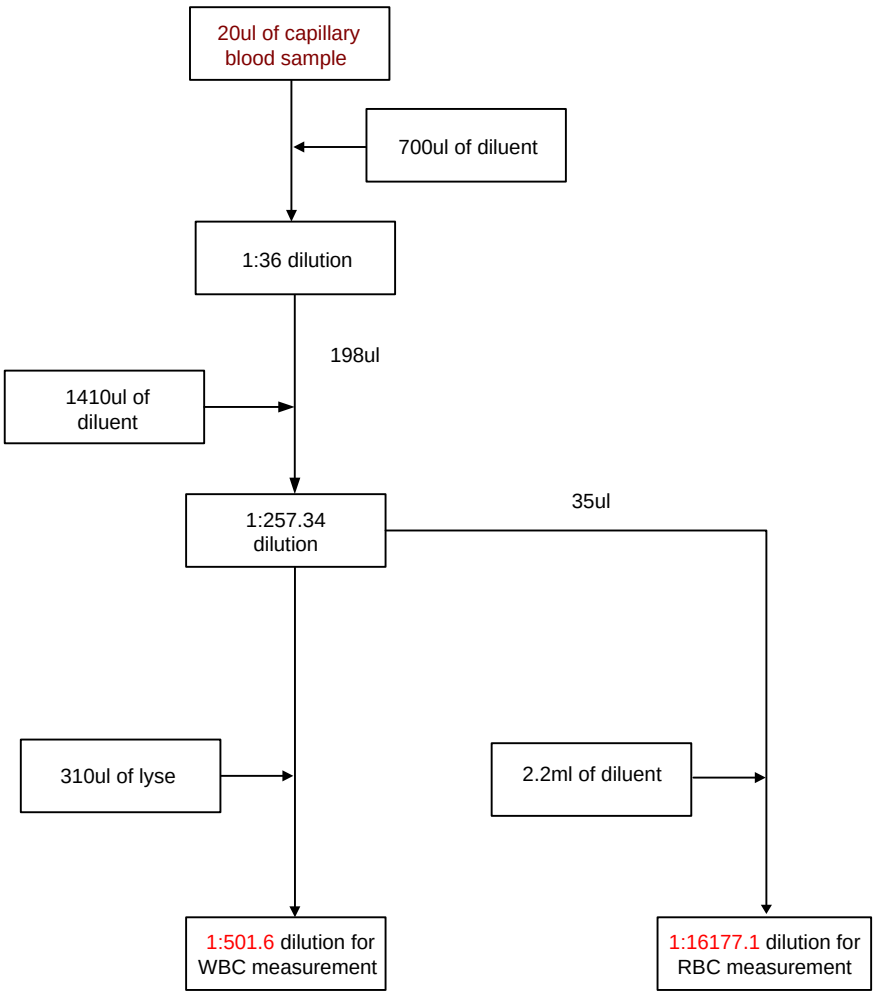


Figure 3-2 Predilute mode dilution flow chart

As shown on the figure above, under the predilute mode, you must first manually mix 20 µL of capillary blood with 0.7 mL of diluent to make a dilution of about 1:36. Then present the dilution to the analyzer. The analyzer will aspirate 198uL of the dilution and add in 1.41 mL of diluent to form a 1:257.34 dilution. The dilution is then divided into 2 parts: the first 35 µL is aspirated and diluted by about 2.2 mL of diluent to form a 1:16177.1 dilution. This sample is used for RBC/PLT count and histogram output. The remaining sample will be mixed with 0.31 mL of lyse to make a 1:501.6 diluted sample for HGB, WBC count and the output of WBC histograms.

3.4 WBC/HGB Measurement

3.4.1 Measurement Principle:

- WBC measurement principle

The WBCs are counted by the impedance method. The analyzer aspirates certain volume of sample, dilutes it with certain volume of conductive solution, and delivers the dilution to the metering unit. The metering unit has a little opening which is called "aperture". A pair of electrodes is positioned on both sides of the aperture to create a constant-current supply. As cells are poor conductors, when each particle in the diluted sample passes through the aperture under the constant negative pressure, a transitory change in the direct-current resistance between the electrodes is produced. The change in turn produces a measurable electrical pulse which is proportional to the particle size. And when the particles pass the aperture in succession, a series of pulses are produced between the electrodes. The number of pulses generated indicates the number of particles passed through the aperture; and the amplitude of each pulse is proportional to the volume of each particle.

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. All the collected pulses are thus classified based on the reference voltage ranges of different channels, and the number of the pluses in the WBC channel indicates the number of the WBC particles. The cell size distribution width is represented by the number of particles falling in each channel.

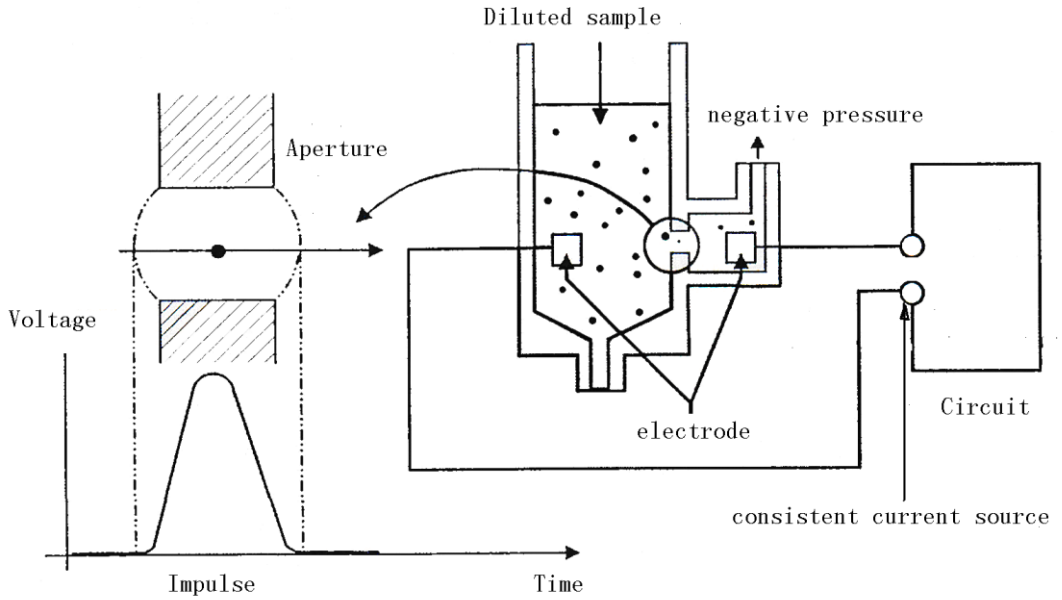


Figure 3-3 Metering diagram

3.4.2 WBC-Related Parameters

- White Blood Cell count

WBC# (10^9/L) is the number of erythrocytes, measured directly by counting the leukocytes passing through the aperture.

Sometimes there are nucleated red blood cells (NRBC) presenting in the sample. While the lyse will not be able to break their nuclear membrane, these NRBCs will also be counted as WBCs. Therefore, when NRBCs are found during microscopic exam, follow below formula to modify the WBC count:

$$WBC' = WBC \times \frac{100}{100 + NRBC}$$

In the formula, WBC′ is corrected WBC count result; WBC is the WBC count provided by the analyzer; and NRBC indicates the number of NRBCs found when every 100 WBCs are counted.

- 3-DIFF of WBC

Lyses and diluents change the sizes of each type of WBCs in various ways and at different time. The WBCs are thus separated into 3 parts (from the largest size to the smallest): lymphocytes, mid-sized cells (including monocytes, eosinophils, and basophils) and granulocytes.

The analyzer then calculates the lymphocyte percentage (Lymph%), mid-sized cell percentage (Mid%) and granulocyte percentage (Gran%) (all presented in %) based on the WBC histograms and in accordance with below formulae:

$$Lymph\% = \frac{PL}{PL + PM + PG} \times 100$$

$$Mid\% = \frac{PM}{PL + PM + PG} \times 100$$

$$Gran\% = \frac{PG}{PL + PM + PG} \times 100$$

In the formulae: PL indicates the number of cells falling in the lymphocyte region, PM the number of cells falling in the mid-sized cell region, and PG the number of cells falling in the granulocyte region. All three parameters are presented in 10^9/L.

When the three percentages are obtained, the analyzer automatically proceeds to calculate the lymphocyte number (Lymph#), mid-sized cell number (Mid#) and granulocyte number (Gran#) with below formulae, all parameters expressed in 10^9/L.

$$Lymph\# = \frac{Lym\% \times WBC}{100}$$

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

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

Lymph%, Mid% and Gran% are expressed in %, while WBC is in 10^9/L.

- White blood cell histogram

Besides the count results, the analyzer also provides a WBC histogram which shows the WBC size distribution, with the x-aixs representing the cell size (in fL) and the Y-axis representing relative cell number (in 10^9/L). After each analysis cycle, you can either check the WBC histogram in the analysis result area on the "**Sample Analysis**" screen or review the histogram on the "**Review**" screen.

$$\text{WBC} = \text{n} \times 10^9 / \text{L}$$

3.4.3 HGB Measurement

The HGB is determined by the colorimetric method. The diluted sample is delivered to the WBC count bath where it is bubble mixed with a certain amount of lyse, which breaks red blood cells, and converts hemoglobin to a hemoglobin complex. An LED is mounted on one side of the bath and emits a beam of monochromatic light with 530~535nm central wavelength. The light is received by an optical sensor mounted on the opposite side, where the light signal is first converted to current signal and then to voltage signal. The voltage signal is then amplified and measured and compared to the blank reference reading (reading taken when there is only diluent in the bath), and the HGB (g/L) is measured and calculated automatically. The whole measurement and calculation process is completed automatically. You can review the results in the analysis result area on the "**Sample Analysis**" screen.
HGB is expressed in g/L.

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

3.5 RBC/PLT Measurement

3.5.1 Impedance Method

RBCs/PLTs are counted by the electrical impedance method. The analyzer aspirates certain volume of sample, dilutes it with certain volume of conductive solution, and delivers the dilution to the metering unit. The metering unit has a little opening which is called "aperture". A pair of electrodes is positioned on both sides of the aperture to creates a constant-current supply. As cells are poor conductors, when each particle in the diluted sample passes through the aperture under the constant negative pressure, a transitory change in the direct-current resistance between the electrodes is produced. The change in turn produces a measurable electrical pulse which is proportional to the particle size. And when the particles pass the aperture in succession, a series of pulses are produced between the electrodes. The number of pulses generated indicates the number of particles passed through the aperture; and the amplitude of each pulse is proportional to the volume of each particle.

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. All the collected pulses are thus classified based on the reference voltage thresholds of different channels, and the number of the pluses in the RBC/PLT channel indicates the number of the RBC/PLT particles. The cell size distribution width is represented by the number of particles falling in each channel.

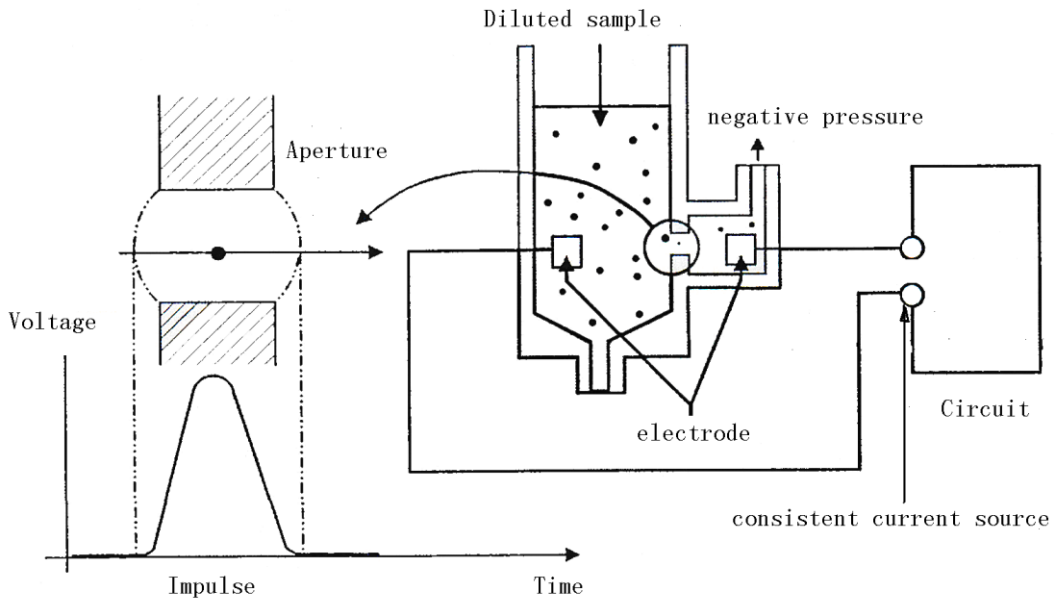


Figure 3-4 Metering diagram

3.5.2 RBC-Related Parameters

- Red Blood Cell count

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

$$RBC = n \times 10^{12} / L$$

- Mean Corpuscular Volume

The analyzer calculates the mean cell volume (MCV, in fL) based on the RBC histogram.

- HCT, MCH and MCHC

The hematocrit (HCT, %), mean corpuscular hemoglobin (MCH, pg) and mean corpuscular hemoglobin concentration (MCHC, g/L) are calculated as follows:

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

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

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

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

- RDW-CV

Red Blood Cell Distribution Width - Coefficient of Variation (RDW-CV) is derived based on RBC histogram. It is expressed in %, and indicates the variation level of RBC size distribution.

- RDW-SD

Red Blood Cells Distribution Width - Standard Deviation (RDW-SD, in fL) measures the width of the 20% level (with the peak taken as 100%) on the RBC histogram, as shown in Figure 3-5..

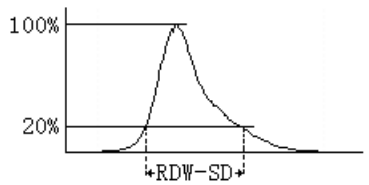


Figure 3-5

- Red blood Cell Histogram

Besides the count results, the analyzer also provides a RBC histogram which shows the RBC size distribution, with the x-aixs representing the cell size (in fL) and the Y-axis representing relative cell number (10^{12}/L). After each analysis cycle, you can either check the RBC histogram in the analysis result area on the "**Sample Analysis**" screen or review the histogram on the "**Review**" screen.

3.5.3 PLT-Related Parameters

- Platelet count

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

$$PLT = n \times 10^9 / L$$

- Mean Platelet Volume

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

- PDW

Platelet distribution width (PDW) is derived from the platelet histogram, and is reported as 10 geometric standard deviations (10 GSD).

- PCT

The analyzer calculates the PCT (%) as follows:
where the PLT is expressed in 10^9/L and the MPV in fL.

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

- Platelet Histogram

Besides the count results, the analyzer also provides a PLT histogram which shows the PLT size distribution, with the x-aixs representing the cell size (in fL) and the Y-axis representing relative cell number (in 10^9/L). After each analysis cycle, you can either check the PLT histogram in the analysis result area on the "**Sample Analysis**" screen or review the histogram on the "**Review**" screen.

3.6 Wash

After each analysis cycle, each element of the analyzer is washed:

- The sample probe is washed internally and externally with diluent;
- The baths are washed with diluent;
- Other elements of the fluidic system are also washed with diluent.

4 Installing Your Analyzer

4.1 Introduction

This chapter introduces how to install the Auto Hematology Analyzer. To ensure all system components function correctly and to verify system performance, authorized representatives will handle the installation and initial software setup.

⚠CAUTION

- **Installation by personnel not authorized or trained may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of an authorized personnel.**
- **The installation, test, update, and modification of the software associated with the analyzer shall only be performed by authorized personnel.**
- **If there is any damaged component, please notify us or the distributor.**
- **Keep your clothes, hair and hands away from the moving parts to avoid injury.**
- **Please wear rubber gloves and use specified tools and accessories to maintain, check and service the analyzer. After the operation, wash your hands with sanitizer.**

NOTE

- **If the analyzer stops operating because of the error, the operator can remove the error per the instruction of the operator's manual, contact our customer service of the errors which are not specified in the operator's manual.**
- **The safety of any system incorporating the equipment is the responsibility of the assembler of the system.**
- **Please operate the instrument strictly per the instruction of the Operator's manual.**

The analyzer is tested and packed with care before it is shipped from the factory. When you receive your analyzer, carefully inspect the carton. If you see any signs of mishandling or damage, contact our Customer Service department or your local distributor immediately. After you open the package, check the integrity of the product according to the packing list. If you find any part missing, contact our Customer Service Department or your local distributor immediately.

4.2 Installation Requirements

Before installation, you should ensure that the following space, power, environmental and fuse protection requirements are met.

4.2.1 Space Requirements

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

- at least 30 cm to both left and right sides;
- at least 10 cm behind the analyzer;
- enough room on or below the countertop to accommodate the reagent (for example diluent) and waste containers.
- the table (or the floor) where the analyzer is placed shall be able to withstand at least 40kg of weight.

4.2.2 Power Requirements

	Voltage	Input power	Frequency
Analyzer	(100V-240V～) ±10%	≤180VA	(50/60Hz)±1Hz

Fuse: 250V T3.15AH

⚠WARNING

- **Make sure the analyzer is properly grounded.**
- **Before turning on the analyzer, make sure the input voltage meets the requirements.**
- **Before connecting the power cord, make sure the power switch of the analyzer is at the off position.**
- **When installing the instrument, ensure that the power switch is in close proximity to the equipment and within easy reach of you.**

⚠CAUTION

- **Using pinboard may bring electrical interference and the analysis results may be unreliable. Place the analyzer near the electrical outlet to avoid using the pinboard.**
- **Please use the original power cable shipped with the analyzer. Using other electrical wire may damage the analyzer or lead to unreliable analysis results.**
- **Before powering on the equipment, check and ensure that the power cable is not bent.**
- **Be sure to use the fuse of specified model and specifications to avoid fire hazard.**

4.2.3 Environment Requirements

	Storage and Transportation Environment	Normal-Operation Environment	Working Environment
Ambient Temperature	-10℃～40℃	15℃～30℃	10℃～40℃
Relative Humidity	10%～90%	20%～85%	10%～90%
Atmospheric Pressure	50kPa～106kPa	70.0kPa～106.0kPa Note1	70kPa～106kPa

Note1: The altitude requirement for instrument normal – operation is -400m ~ 3000m.

The environment shall be as free as possible from dust, mechanical vibrations, loud noises, and electrical interference. Do not place the analyzer in direct sunlight or in front of a source of heat or drafts. Please use a separate power socket; do not use the same socket with devices like air conditioning, refrigerator and ultrasonic system, as they may interfere with the proper operation of the analyzer. It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer. Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close. The environment shall be well ventilated. Do not place the analyzer in direct sunlight. Connect only to a properly earth grounded outlet. Only use this analyzer indoors.

⚠WARNING

- **Do not place the analyzer in a flammable or explosive environment.**

NOTE

- **If the ambient temperature is out of the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. When temperature errors are reported in the error information area after analysis, see Chapter 11 Troubleshooting Your Analyzer for solutions.**

4.2.4 Moving and Installing the Analyzer

⚠WARNING

- **Installation by personnel not authorized or trained may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of an authorized personnel.**
- **To prevent personal injury during the operation, keep your clothes, hairs and hands from the moving parts like sample probe.**
- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**

NOTE

- **To protect it from being damaged during transportation, the aspiration module is fixed by cables ties and clamps before the analyzer is shipped out of factory. Remove the cable ties and clamps before using the analyzer.**

Moving and installation of the analyzer shall be conducted by authorized personnel. Do not move or install your analyzer without the presence of authorized personnel.

4.2.5 Fuse requirement

⚠WARNING

- **Only install fuses of specified specification on the analyzer.**

Fuse specification: 250V T3.15AH

4.3 Connecting the System

Connect the power and the reagents as shown below. Make sure the connections are correct and firm.

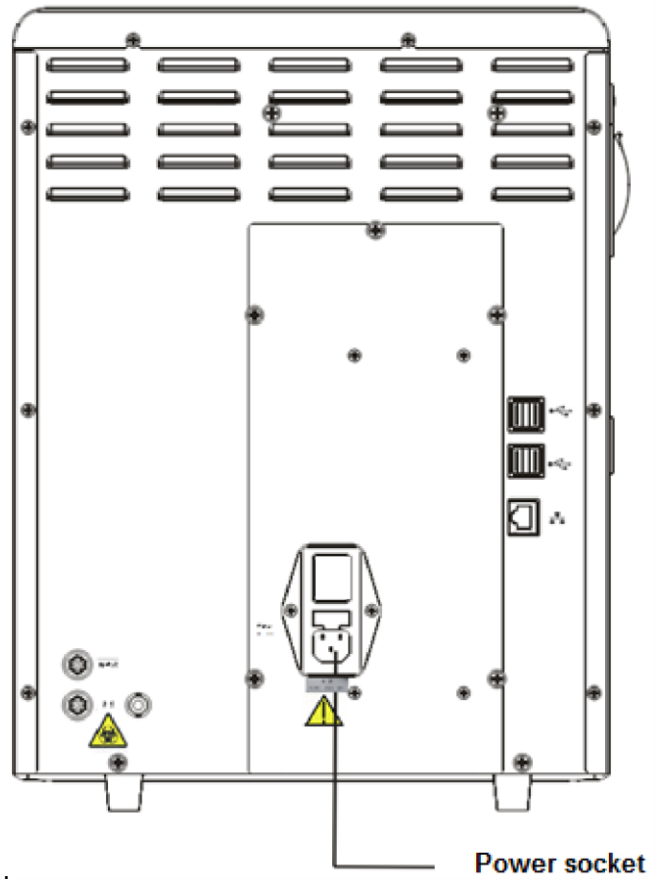


Figure 4-1 Connecting the analyzer to a power socket

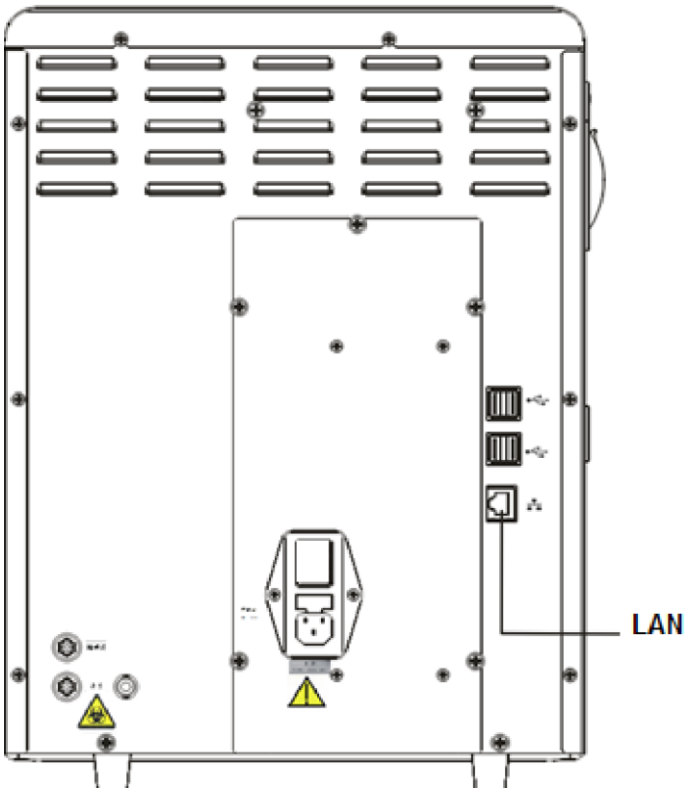


Figure 4-2 Connecting the network port on the analyzer

⚠WARNING

- **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 and the contacted areas in the laboratory.**
- **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**

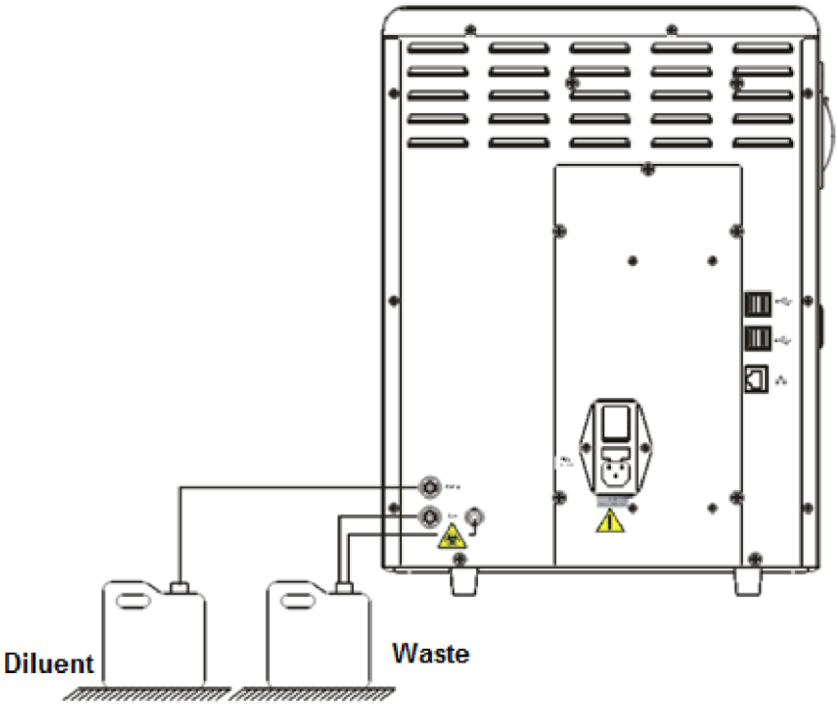


Figure 4-3 Connecting reagents placed outside the analyzer

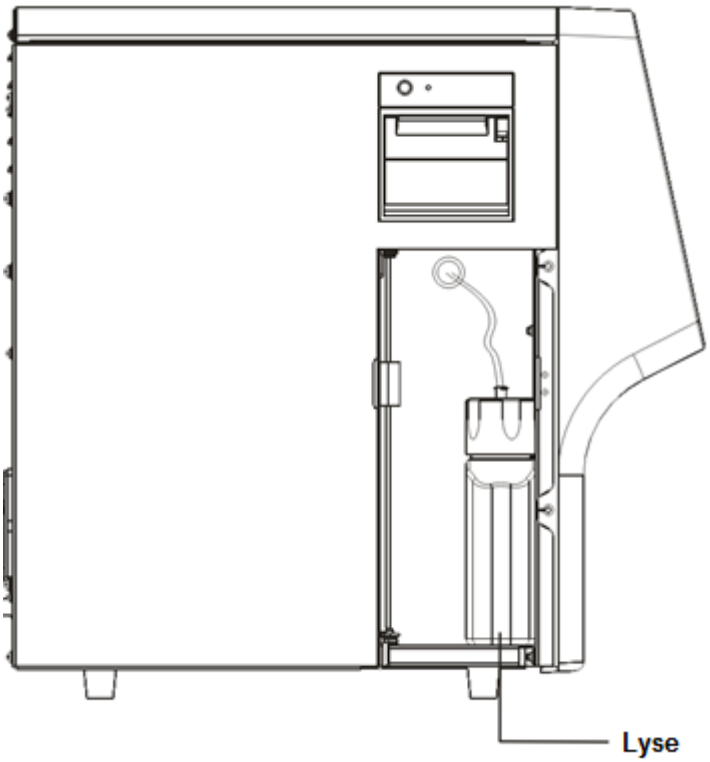


Figure 4-4 Connecting reagents placed inside the analyzer

⚠ CAUTION

- **Liquid ingression may damage the analyzer. Do not place any bottles on the analyzer.**
- **Make sure the diluent pipe and waste pipe are no longer than 1500mm.**
- **The top of the waste container and the diluent container should be lower than the countertop where the analyzer is placed.**
- **When you are using a waste container to dispose waste, make sure the pickup tube is smooth, not bend, and is above the cap assembly of the waste container.**
- **If the waste is discharged directly, make sure the waste pump is at a lower position than the waste outlet on the analyzer.**

NOTE

- **Use the manufacturer-specified reagents.**
- **Let the reagents stand for a while before using them.**
- **Never use expired reagents.**
- **To prevent contamination, tighten the container caps when the installation is finished.**

4.4 Installing the Recorder Paper

NOTE

- **Remove the protective paper in the recorder before installing recorder paper.**

Follow the procedure below to install the record paper.

1. Use the latch at the upper right corner of the recorder door to pull the door open.
2. Insert a new roll into the compartment with the paper end out of the recorder exit, as shown below.
3. Close the recorder door.
4. Check whether the paper is installed correctly and the paper end is feeding from the top.

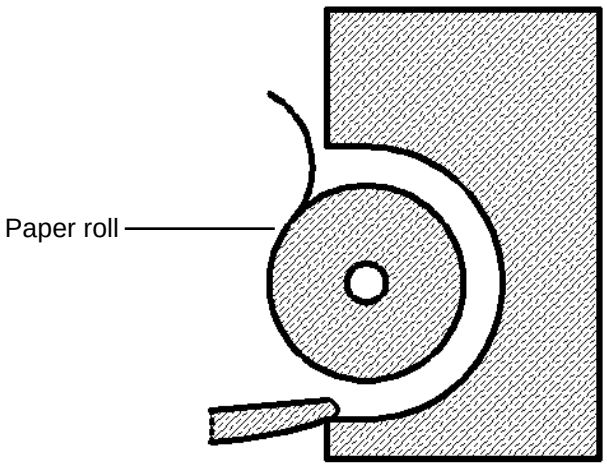


Figure 4-5 Installing recorder paper

⚠CAUTION

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

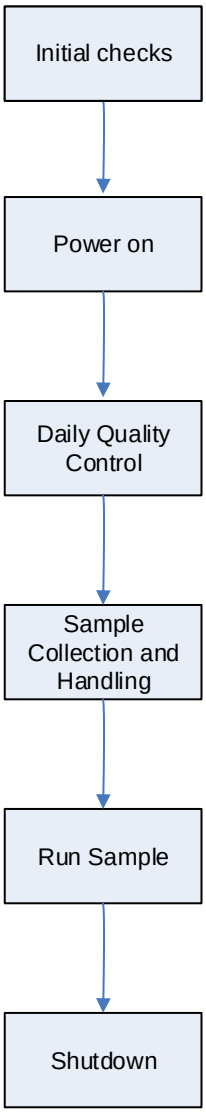
4.5 Precautions

- If the analyzer is kept in an environment with heavy dust for a long time, its performance may be reduced.
- It is recommended to clean and sterilize the outer surface the analyzer with 75% ethanol.
- The probe wipe block of the analyzer (see Figure 2-1 Front of the analyzer) shall be wiped with 75% alcohol regularly.
- Collect and prepare samples in accordance with the standard procedure of your laboratory; otherwise it may result in inaccurate analysis results or damage to the analyzer.
- If any of the pipes or fluidic components are worn out, stop using the analyzer and contact our Customer Service Department immediately for inspection or replacement.
- Make sure the tubings of the reagents (including diluent, lyse and waste) are not pressed by heavy objects or bent over.
- Use only specified reagents; otherwise it may result in inaccurate results or damage to the analyzer.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents. Otherwise it may result in inaccurate results.

5 Operating Your Analyzer

5.1 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.



5.2 Initial Checks

Perform the following checks before turning on the analyzer.

- **All the samples, controls, calibrators, reagents, wastes and areas contacted 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.**

⚠WARNING

- **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 and the contacted areas in the laboratory.**
- **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**
- **To prevent personal injury during the operation, keep your clothes, hairs and hands from the moving parts like sample probe.**
- **Use the analyzer strictly as instructed by this manual to avoid unexpected product damage or personal injury.**

NOTE

- **Use the reagents specified by the manufacturer only. Store and use the reagents as instructed by instructions for use of the reagents.**
- **Check if the reagent tubings are properly connected 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 (not supplied) is empty.

- Checking tubing and power connections

Check and make sure the reagent, waste and pneumatic unit tubes are properly connected and not bent.
Check and make sure the power cord of the analyzer is properly plugged into the power outlet.

- Checking recorder (optional) and printer (optional)

Check and make sure the printer and recorder are properly installed, and have enough paper.

5.3 Startup and Login

Power on the analyzer:

1. Place the power switch at the back of the analyzer in the "I" position. The switch will light on.
2. Make sure that the power indicator on the analyzer lights on.
3. Enter your user ID and password in the login dialog box.

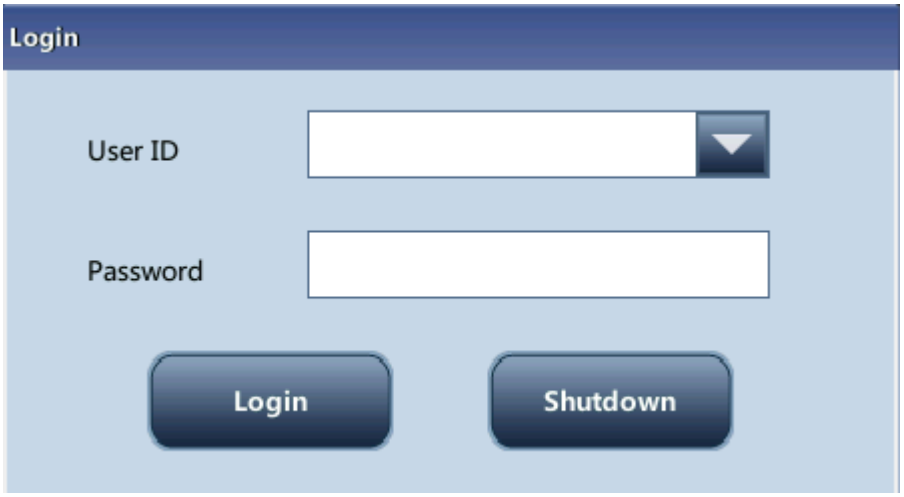


Figure 5-1 Login dialog box

4. The analyzer will sequentially do the self-test and initialize the system.

NOTE

- **When "Background abnormal" is reported during the startup process, follow the corresponding troubleshooting instruction for the error in Chapter 11 Troubleshooting to remove the error.**
- **The system opens different function for the user according to the user level. The user level depends on the user ID and the password when the user logs in.**
- **To switch to another user, tap the "Logout" button first. Enter the desired user ID and password in the displayed login dialog box, and then tap "OK" to log in.**
- **If you failed to run the software continuously, please contact our Customer Service Department or your local distributor.**
- **After startup, please make sure the date/time of the computer is correct.**
- **The default user ID and password for administrator are both "Admin".**
- **1-12 characters are allowed for user ID and password; Chinese characters are not allowed.**

5.4 Daily Quality Control

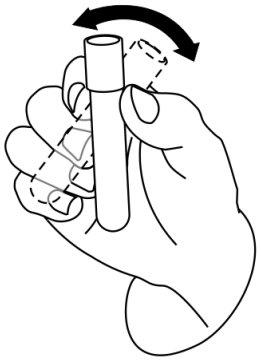
Before running any samples, run the controls to finish auto setup and ensure reliable results of the analyzer. See *Chapter 7*Using the QC Programs *for details.*

5.5 Sample Preparation

The analyzer supports two sample types: whole blood sample (including capillary whole blood sample) and prediluted sample.

⚠CAUTION

- **Prepare samples following the recommend procedure of the manufacturer.**
- **Always shake the samples as shown below to well mix it**



- **Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.**

- **All the samples, controls, calibrators, reagents, wastes and areas contacted 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.**

⚠WARNING

- **Do not contact the patients' sample blood directly.**

NOTE

- **Be sure to use clean EDTAK2 anticoagulant collection tubes, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.**
- **Be sure to use the specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes etc.**

5.5.1 Whole Blood Samples (Including Capillary Whole Blood Samples)

Use clean EDTAK2 anticoagulant collection tubes to collect venous blood samples.
Mix the sample immediately according to your laboratory's protocol.

⚠CAUTION

- **To attain accurate analysis results, make sure the sample volume is no less than 120uL.**

NOTE

- **For the whole blood samples to be used for WBC differential, you shall store them at the room temperature and run them within 8 hours after collection.**
- **Samples stored in a refrigerator at the temperature of 2℃—8℃ must be analyzed within 24 hours after collection. The refrigerated samples must be kept at room temperature for at least 30 minutes before analysis.**
- **Be sure to mix any sample that has been prepared for a while before running it.**
- **After the sample is prepared, be sure to wait for at least 5 minutes before running it; and you must complete the analysis within 2 hours after its collection.**

5.5.2 Prediluted Sample

1. Tap the mode switching icon to switch the working mode from whole blood to "**PD**".
2. Tap the "**Diluent**" button on the top status bar, a message box will pop up.

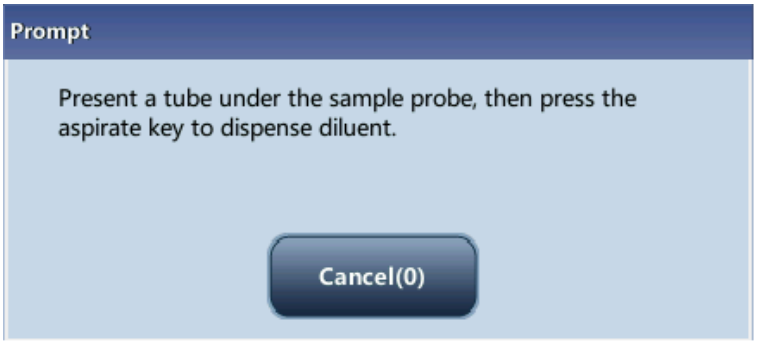


Figure 5-2 "Diluent" dialog box

3. Present a tube to the analyzer, and tap the [Aspirate] key on the analyzer to dispense diluent (700μL). During dispensing the diluent, a progress bar will display.
4. If more portions of diluent are needed, repeat the procedure.
5. Add 20μL of capillary blood to the centrifugal tube of diluent, close the tube cap and shake the tube to mix the sample.
6. After the prediluted sample is prepared, tap the “Cancel” button to exit dispensing the diluent.

NOTE

- **You can also dispense 700μL of diluent by pipette into the tube.**
- **Take methods to prevent the diluent from dust and volatilization; otherwise the results may be unreliable.**
- **After mixing the capillary sample with the diluent, be sure to wait at least for 3 minutes, and mix the sample again before running the sample.**
- **Complete the analysis within 30 minutes after diluting the sample. It is recommended to complete the analysis as soon as possible.**
- **Be sure to mix any sample that has been prepared for a while before running it. Do not use a vortex mixer for mixing, for the shaking be too violent and cause hemolysis.**
- **Be sure to evaluate predilute stability based on your laboratory’s sample population and sample collection techniques or methods.**

5.6 Sample Analysis

Tap "**Sample Analysis**" to enter the sample analysis screen. Tap the "**Mode**" switching button on the sample analysis screen to select from "**WB**" and "**PD**" modes.

⚠CAUTION

- **Before running samples, make sure the analyzer background results are in acceptable range.**
- **Before using the analyzer, check and ensure that the analyzer is in normal operation status, that is, the indicator on the analyzer is in steady green, and no temperature alarm, liquid level alarm, or any other alarm is reported.**
- **The purpose of this analyzer is to identify the normal patient with normal system-generated parameter, and to flag or identify patient results that require additional studies.**

5.6.1 Enter Sample Information

You can either enter the ID or the full information of samples.

You can skip the sample information entering procedure at this stage, but enter the information based on sample ID or sample result saving time after analysis. For details, check *Chapter 6**Reviewing Sample Results**.*

Before entering sample information on the "**Sample Analysis**" screen, set up your desired way for entering sample information on the "**Setup → Auxiliary Setup**" screen (see *Chapter 9 **Customizing the Analyzer Software***).

5.6.1.1 Enter All Information

When you have set "**Entry of next sample info**" to "**Enter all information**", tap "**Next sample**" on the "**Sample Analysis**" screen, and a dialog box pops up as follows. You can enter full sample information for the next sample except for "**Ref. group**", for the system will assign a matched group automatically.

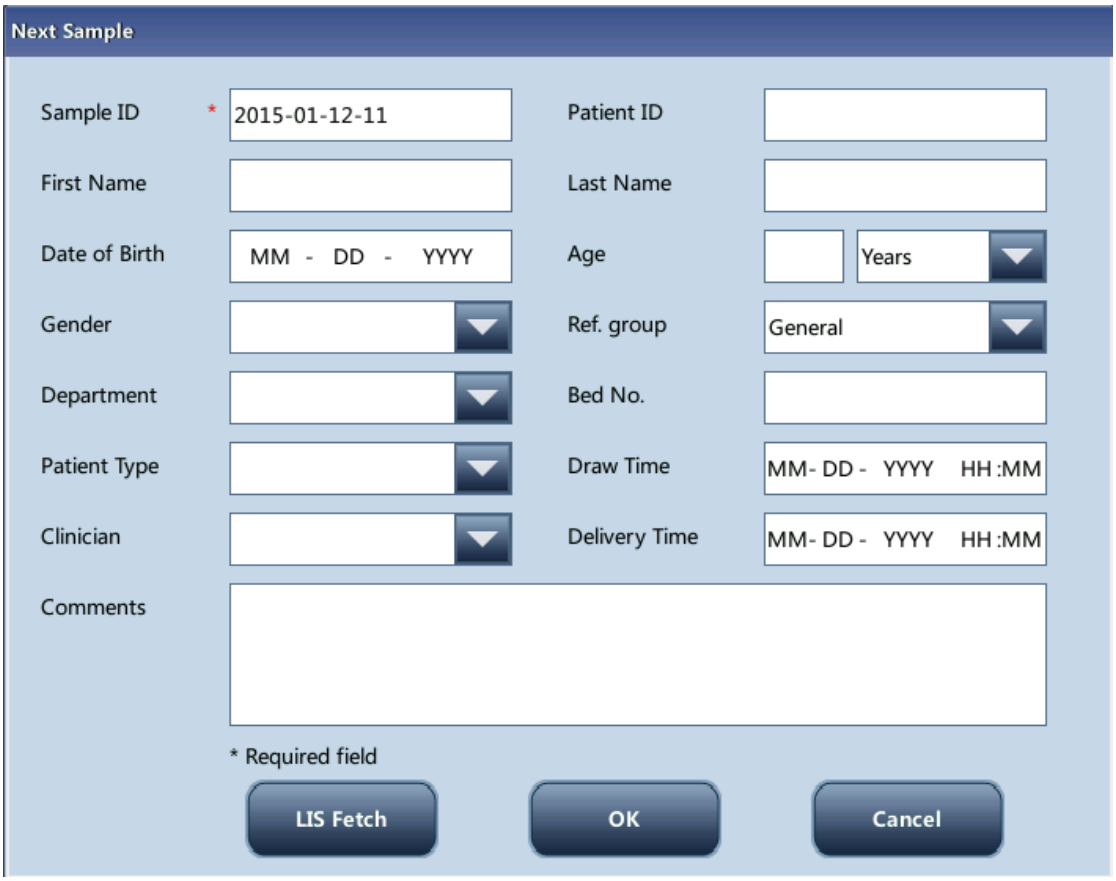


Figure 5-3 Enter all information

■ Entering the sample ID

Enter the ID in the "**Sample ID**" box.

NOTE

- **You can enter letters, digits and all other characters on the keyboard for sample ID, only for [a-z][A-Z][0-9][-_].**
- **1 to 20 characters are allowed. It cannot be left empty.**
- **The sample ID must end with a digit; and it cannot only consist of "0".**

■ Entering the patient ID

Enter the patient ID to the "**Patient ID**" box.

■ Entering the patient name

Enter the patient name in the "**Patient**" box.

■ Entering the patient gender

Select the desired item (“**Male**”, “**Female**”, or null) from the "**Gender**" pull-down list. The

default option is "**Unknown**".

■ Entering the date of birth

Enter the birth date of the patient into the "**Date of Birth**" box, the birth date format being the same of the system date.

■ Entering the patient age

The analyzer provides 5 ways for you to enter patient age – in years, in months, in days and in hours. The first way is designed for the patients no younger than one year; the second for the infant patients of one month to two year; the third for the neonatal of one week to ten weeks; the fourth for the neonatal no older than one month, and the fifth for the neonatal no older than 48 hours. You may choose one of the four ways to enter the patient age.
Select the desired item from the "**Age**"pull-down list ("**Years**", "**Month(s)**", "**Weeks**","**Days**" and "**Hours**"), and you may enter the patient age in the box followed by the age unit.

NOTE

- **When you enter the patient birth date, the system will automatically calculate the patient age using the entered "Birth of Date" and current "System Date" and display the result in the "Age" box and the age "Unit" combo box, The "Age" box will then be greyed, and will become editable again when the "Date of Birth" is cleared.**
- **The patient birth date should be no later than current system date.**

■ Entering the patient type

Select "**Outpatient**", "**Inpatient**", "**Medical Examination**" or "**STAT**" from the "Patient Type" pull-down list.

■ Entering the department name

You can either enter the department name in the "**Department**" box, or select the desired department from the "Department" pull-down list (if there are previous entries saved in the list).

■ Entering the bed number

Enter the bed number of the patient to the "**Bed No.**" box.

■ Entering the draw time

Enter the time when the sample is collected into the "**Draw Time**" box.

- Entering the delivery time

Enter the time when the sample is sent into the "**Delivery Time**" box.

- Entering the clinician name

You can either enter the clinician name into the "**Clinician**" box, or select the desired clinician from its pull-down list (if there are previous saved entries in the list).

- Entering the comments

Enter necessary information to the "**Comments**" box.

- OK

When you have finished entering the sample information, tap "**OK**" to save the information and return to the "**Sample Analysis**" screen.

- Cancel

If you do not want to save the entered sample information, tap "**Cancle**" to return the "**Sample Analysis**" screen without saving the changes.

5.6.1.2 Enter Sample ID

When you have set "**Entry of next sample info**" to "**Enter sample ID only**", tap "**Next sample**" on the "**Sample Analysis**" screen, and a dialog box pop up as follows.

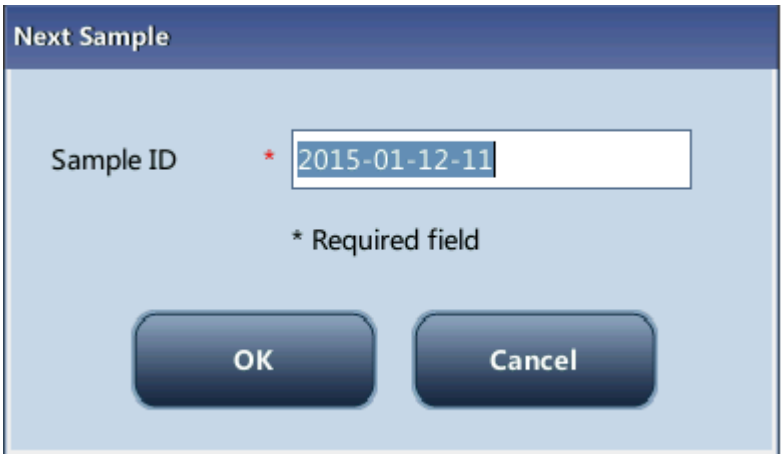


Figure 5-4 Enter sample ID

Enter the ID in the "**Sample ID**" box. Tap the "**OK**" button to save the sample ID and close the dialog box. The ID will be displayed in the "**Next Sample**" information area on the bottom of the screen.

5.6.1.3 Edit Current Sample Information

Tap the sample information area of the sample analysis screen or graph review screen, the "**Edit Info**" dialog box will pop up. In this dialog box, you can edit the information of the sample whose analysis is just completed. This function does not apply to background analysis and validated samples.

5.6.2 Running the Samples

- **All the samples, controls, calibrators, reagents, wastes and areas contacted 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.**

⚠WARNING

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

⚠CAUTION

- **Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.**

NOTE

- **Make sure that the sample probe is fully immersed into the sample and not in contact with the tube bottom; otherwise the aspiration volume may be insufficient, or the aspirated volume may not be accurate.**
- **Make sure the sample probe tip does not touch the tube wall, otherwise the blood sample may spill.**

5.6.2.1 Sample Analysis

Do as follows to run samples:

1. Make sure the analyzer indicator shows that the analyzer is ready for sample analysis, and the analysis mode is "**WB**" or "**PD**".
2. Present a well mixed sample to the sample probe for aspiration.
3. Press the [Aspirate] key to start sample analysis. When the analyzer indicator flickers in green, the analyzer is running.
4. The sample probe will automatically aspirate certain volume of the WB or PD samples. When you hear the beeps, remove the sample tube. The probe will ascend and add the aspirated sample to the count baths. The analyzer will automatically run the sample.
5. When the analysis is finished, the result will be displayed in the analysis result area on the screen. The sample probe returns to the original position and gets ready for the next analysis.
6. When "**Auto print after sample analysis**" is set to "**On**", the analyzer will automatically print the analysis result report in the preset format; when "**Auto Communicate**" is set to "**On**", the analyzer will automatically upload the eligible sample results as well as sample and patient information to the LIS system.
7. Repeat above steps to run other samples.

NOTE

- **If the analyzer detects clogging or bubbles during the analysis, the corresponding error message will be displayed in the error message area and the results of all related parameters will be invalidated. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- **If the ambient temperature is out of the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis**

results may be unreliable. When temperature errors are reported in the error information area after analysis, see *Chapter 11 Troubleshooting Your Analyzer* for solutions.

5.6.3 Processing Analysis Results

5.6.3.1 Saving of analysis results

The analyzer automatically saves sample results. When the maximum number has been reached, the newest result will overwrite the oldest.

5.6.3.2 Histogram flags

The system will flag abnormal histograms. Both WBC histogram and PLT histogram are flagged for abnormal results.

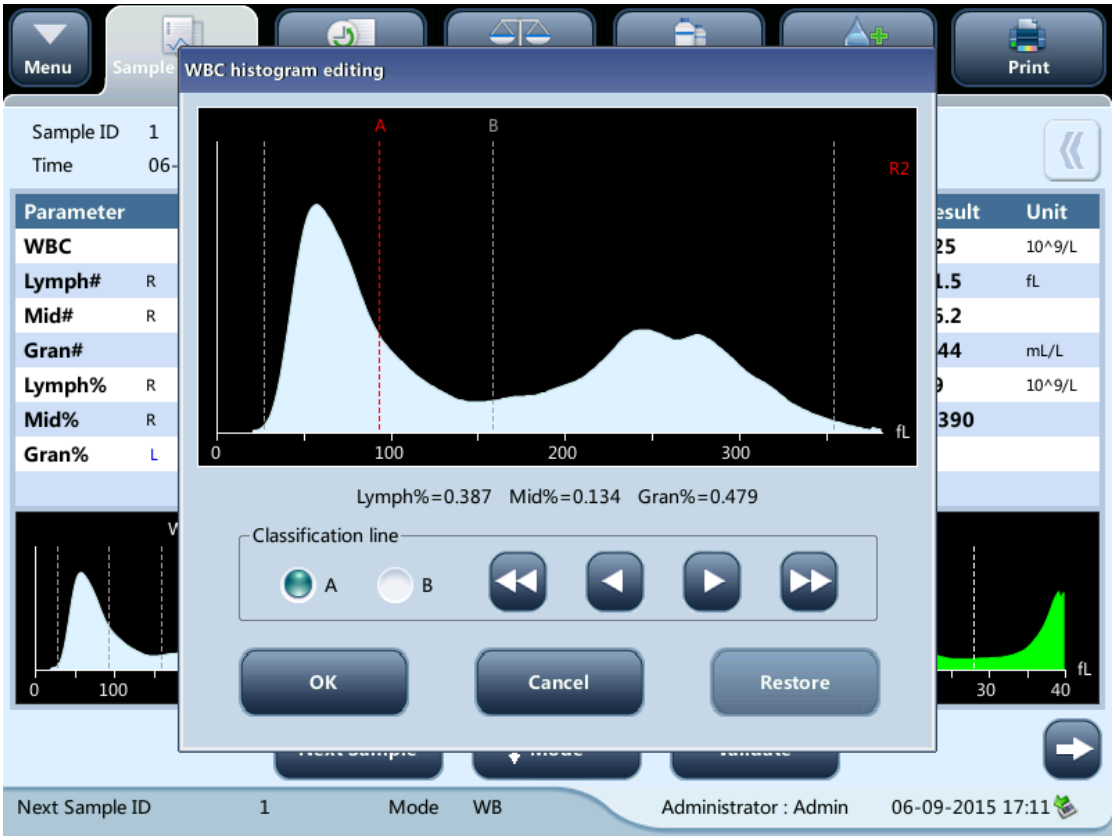
WBC histogram flags

Abnormal WBC histograms will be flagged by one of the markings: R1, R2, R3, R4 and Rm. The indications of the markings are as follows:

- R1 indicates abnormality on the left side of the lymphocyte hump and possible presence of platelet clump, giant platelet, nucleated red cell, lyse resistant RBC, high molecular weight protein and lipoid debris in sample, or electrical noise.
- R2: indicates abnormality between the lymphocyte hump and the mid-sized cell area, possible presence of atypical/immature lymphocyte, plasma cell, blast cell in the sample, eosinophilia or basophilia.
- R3: indicates abnormality between the mid-sized cell area and the granulocyte hump, possible presence of immature granulocyte, blast cell, left shift, immature monocyte or eosinophilia.
- R4: indicates abnormality on the right side of the granulocytes hump, possible presence of immature granulocyte, blast cell, agglutinated white cell, or netrophilia.
- Rm: indicates at least two R flags.

5.6.3.3 Editing the histogram (for administrators only)

Tap the WBC histogram to activate the editing function, and then you can edit the position of the discriminator A or B. After the histogram is edited, the system will automatically re-calculate the differential results.



PLT histogram flags

Abnormal PLT histograms will be flagged by the marking Pm, PS, PL.
The indication of the marking is as follows:

- Pm: indicates blur demarcation between the platelet area and red blood cell area and possible presence of large platelet, platelet clump, small red blood cell, cell debris or high molecular weight protein.
- PS：small platelet possibly high notice.
- PL：giant platelet possibly high notice.

5.6.3.4 Parameter flags

Table 5-1 Flags of abnormal blood cell differential or morphology

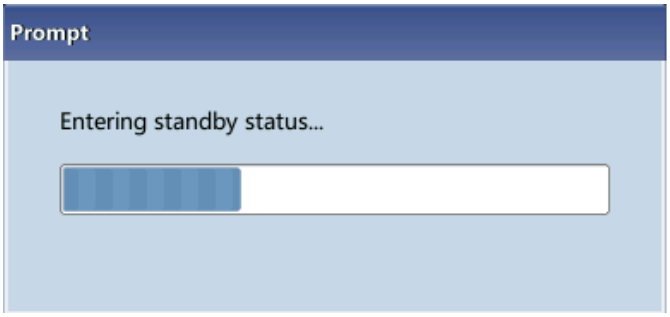
Flag type	Information	Meaning
WBC Flag	Leucopenia	Low WBC count
	Leucocytosis	High WBC count
	Granulocyte decreased	Low granulocyte number
	Granulocyte increased	High granulocyte number
	WBC abnormal	NRBCs, abnormal/atypical lymphocytes, immature or blast cells may present
	Lymphocyte decreased	Low lymphocyte number
	Lymphocyte increased	High lymphocyte number
	Mid-size cell increased	High mid-sized cell number
	Pancytopenia	Low WBC, RBC and PLT count
RBC Flag	RBC Distribution Abnormal	Possible presence of microcytosis, macrocytosis, anisocytosis, RBC agglutination and diamorphologic histogram.
	HGB Abn./Interfere?	HGB results may be abnormal or interference may exist (for example, high WBC count)
	Microcytosis	Small MCV
	Macrocytosis	Large MCV
	Anemia	Anemia
	Erythrocytosis	High RBC count
PLT Flag	PLT Distribution Abnormal	Possible presence of microcytosis, RBC debris, large platelet and platelet coagulation.
	Thrombopenia	Low PLT count
	Thrombocytosis	High PLT count

NOTE

- **Abnormal parameter or histogram results of background check will not be flagged. When the background results do not meet requirements, the analyzer will alarm for abnormal background.**

5.7 Standby

When the fluidics system stops working for 15 minutes (default, which can be set at the setup screen. See *Chapter 9* ***Customizing the Analyzer Software*** for details), then the analyzer will enter the standby status automatically.



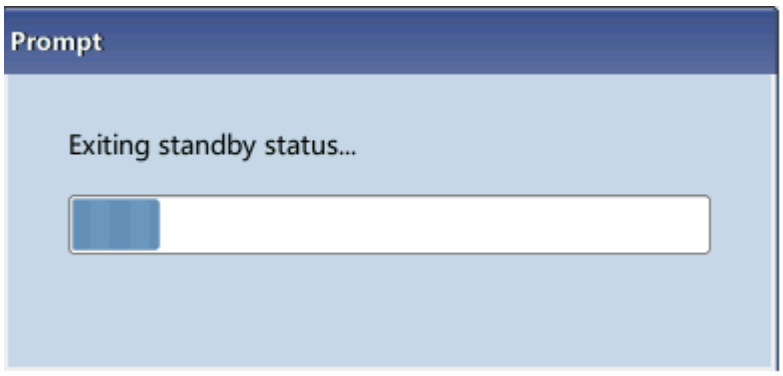
After entering the sleep mode, the bottom right of the screen displays "**Standby. Press the [Aspirate] key to exit.** "

NOTE

- **On the "Status" screen, the analyzer cannot enter the standby status.**
- **If it is the time for standby but the analyzer has an error, then only after the error is removed will the auto-standby starts accordingly.**
- **You can perform the operations not involving the analyzer when it is on standby, such as communication and print etc.**
- **Refer to *Section 9.2.5 Maintenance Setup* for how to edit waiting time before entering standby mode.**
- **Under stand-by mode, if there are unfinished printing or communication tasks, the analyzer will go on processing them.**

[Aspirate] key

Press the [Aspirate] key on the analyzer to exit the standby mode.



After canceling the standby mode, the progress bar will be closed automatically, the analyzer will exit the standby mode.

NOTE

- **Different maintenances will be performed by the analyzer automatically when exiting the standby status, and the exiting time depends on how long the analyzer was in the standby status.**
- **If any error happens during the process of exiting the standby status, see *Chapter 11 Troubleshooting Your Analyzer* for details to remove the error.**
- **After exiting standby mode, the analyzer will return to the status before standby. The analysis status icon on at the screen displays in green. The indicator on the analyzer displays in green at the same time.**

5.8 Shutdown

Perform the "**Shutdown**" procedure to shut down the analyzer every day.

- **All the samples, controls, calibrators, reagents, wastes and areas contacted 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.**

⚠WARNING

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

NOTE

- **To ensure stable analyzer performance and accurate analysis results, be sure to perform the "Shutdown" procedure to shut down the analyzer after it has been running continuously for 24 hours.**
- **Be sure to shut down the analyzer strictly as instructed below.**
- **Do not force power off the analyzer during the "Shutdown" procedure.**
- **If error that will affect shutdown occurs during the showdown process, the analyzer will resume to its original status and report the error. See C*hapter 11 Troubleshooting Your Analyzer* for solutions.**

1. Tap the "**Shutdown**" button on the main menu, the shutdown dialog box shown as below will display:

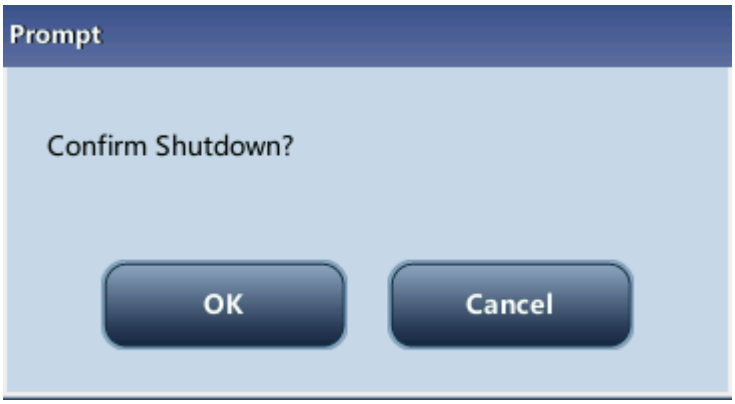


Figure 5-5 Shutdown

2. Tap "**OK**", and follow the instruction to present probe cleanser to the sample probe, then press the [Aspirate] key.

   The sample probe automatically aspirates the probe cleanser; then the probe cleanser maintenance starts. A progress bar will be displayed on the screen to indicate the probe cleanser maintenance progress.

3. When the shutdown procedure is finished, the screen will display "**Please power off the analyzer**". Turn off the analyzer.

4. Empty the waste container and dispose of the waste properly.

⚠WARNING

- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**

6 Reviewing Sample Results

6.1 Introduction

After every analysis cycle, the analyzer automatically saves the analysis results into the sample database. Totally 200,000 records (including parameter results and histograms) can be saved.

You can either choose the "**Table Review**" mode to review the parameter results of all samples saved in the sample and search databases; or the "**Graph Review**" mode to review both the parameter results and the histograms of each sample.

NOTE

- **The sample result data must have proper backup in case of data lost caused by hardware or software error.**

6.2 Table Review

You can browse, review, search, edit and export previous saved data on the "**Table Review**" screen. Tap "**Table Review**" to enter the "**Table Review**" screen.

	26	27	28*	29	30	31
Sample ID	1	2	3	4	c-123	c-124
Sample State					Printed	Printed
WBC	5.5	6.1	5.3	6.7	4.2	7.9
Lymph%	↓ 0.157 R	0.204 R	0.296	↓ 0.101 R	0.271	0.265
Mid%	↑ 0.250 R	0.126 R	0.110	↑ 0.191 R	0.110	0.075
Gran%	0.593 R	0.670	0.594	↑ 0.708	0.619	0.660
RBC	4.71	4.46	3.80	4.38	4.77	4.27
HCT	↓ 0.345	↓ 0.338	↓ 0.267	↓ 0.343	↓ 0.337	↓ 0.327
MCV	↓ 73.4	↓ 75.8	↓ 70.2	↓ 78.2	↓ 70.7	↓ 76.6
HGB	↑ 167 R	↑ 163 R	126 R	↑ 163 R	↑ 169 R	156 R
MCHC	↑ 482 R	↑ 483 R	↑ 471 R	↑ 476 R	↑ 499 R	↑ 478 R
PLT	222	234	162	109	146	186

6.2.1 Table area

The table area displays the list of the analyzed samples with basic information like sample ID and sample state.

	26	27	28*	29	30	31
Sample ID	1	2	3	4	c-123	c-124
Sample State					Printed	Printed
WBC	5.5	6.1	5.3	6.7	4.2	7.9
Lymph%	↓ 0.157 R	0.204 R	0.296	↓ 0.101 R	0.271	0.265
Mid%	↑ 0.250 R	0.126 R	0.110	↑ 0.191 R	0.110	0.075
Gran%	0.593 R	0.670	0.594	↑ 0.708	0.619	0.660
RBC	4.71	4.46	3.80	4.38	4.77	4.27
HCT	↓ 0.345	↓ 0.338	↓ 0.267	↓ 0.343	↓ 0.337	↓ 0.327
MCV	↓ 73.4	↓ 75.8	↓ 70.2	↓ 78.2	↓ 70.7	↓ 76.6
HGB	↑ 167 R	↑ 163 R	126 R	↑ 163 R	↑ 169 R	156 R
MCHC	↑ 482 R	↑ 483 R	↑ 471 R	↑ 476 R	↑ 499 R	↑ 478 R
PLT	222	234	162	109	146	186

NOTE

- **The latest sample record is on the utmost top of the table.**

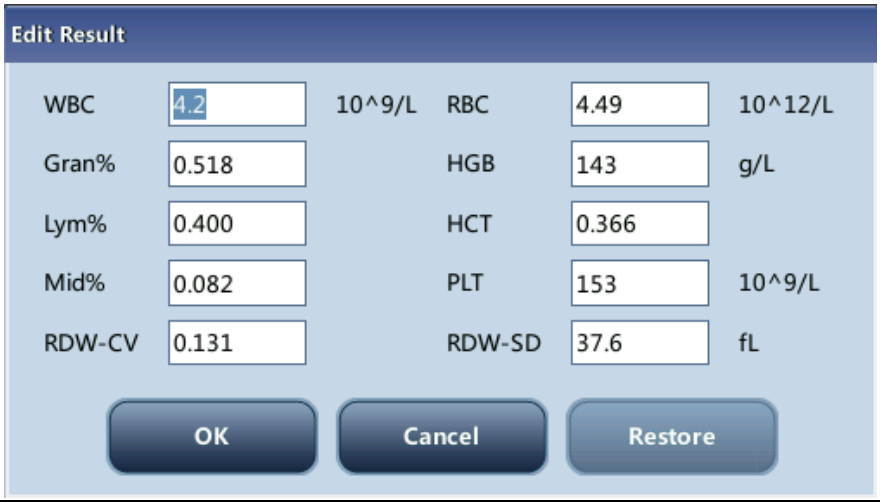
6.2.2 Graph review

You can either tap the "**Graph Review**" button on the "**Table Review**" screen or tap "**Previous**" on the "**Sample Analysis**" screen to review the detailed results of each sample.

Tap the  button to switch between the "**Count**" screen and the "**Graph Review**" screen.

6.2.3 Edit results

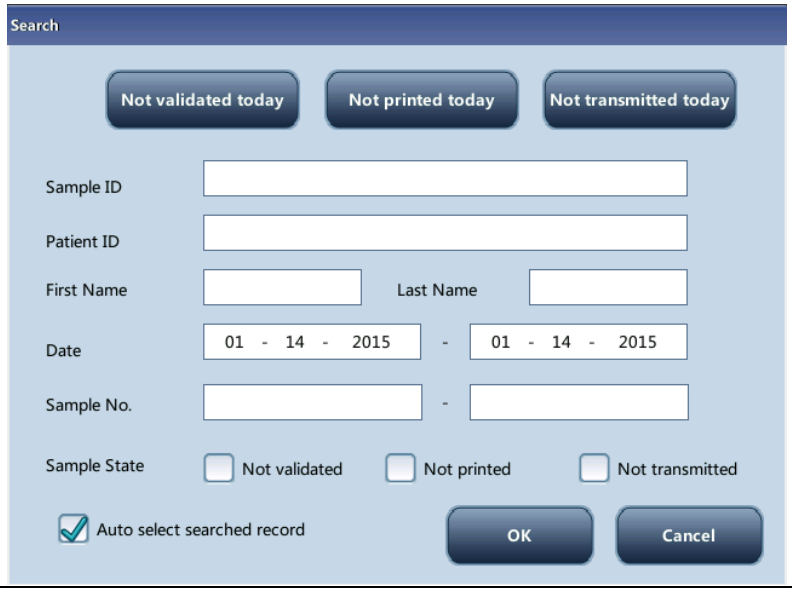
1. Tap the desired sample result and it will be highlighted. Tap the "**Edit Result**" button and the following dialog box will display.



2. Modify the results and tap "**OK**" to save the changes. The information on the graph review screen will be refreshed.

6.2.4 Searching for sample

1. Tap "**Search**", the following dialog box will display.

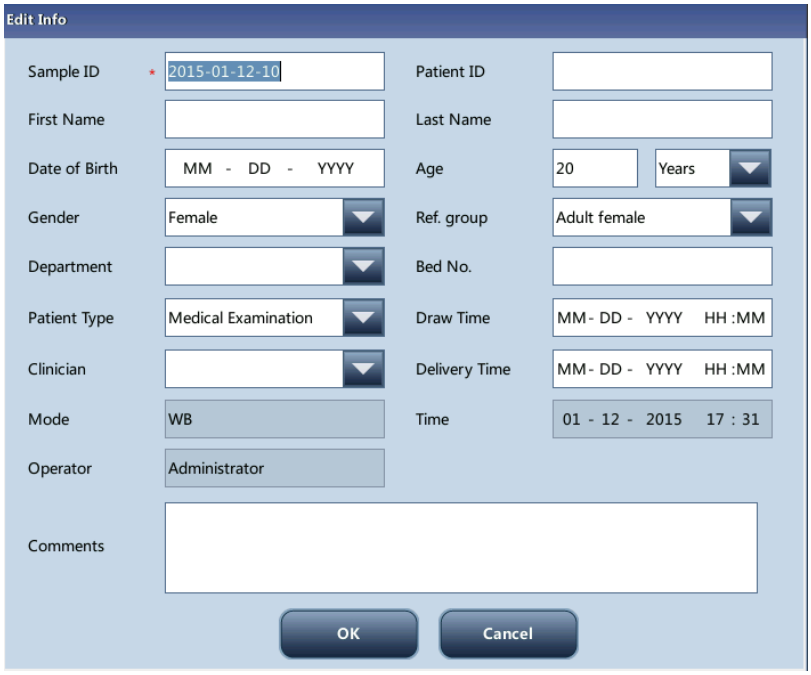


2. Enter searching conditions into the edit boxes or select them from the pull-down lists.

3. Tap "**OK**" to start search, the results will displayed in the table.

6.2.5 Edit information

1. Tap the desired sample result on the "**Table Review**" screen and it will be highlighted. Tap the "**Edit Info**" button and the following dialog box will display.



2. Modify the sample and patient information as necessary, and tap "**OK**" to save the

changes. The information on the table review screen will be refreshed.

6.2.6 Validate/Cancel Validate (for administrators only)

■ Validate sample data

Select the sample record(s) to be validated on the “**Table Review**” screen, and then tap the "**Validate**" button to validate. The "**Sample State**" of the record(s) will become "Validated".

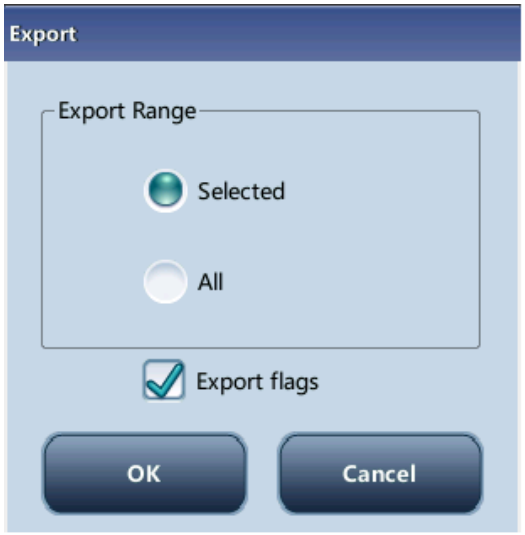
	26	27	28*	29	30	31
Sample ID	1	2	3	4	c-123	c-124
Sample State		Validated	Validated		Printed	Validated
WBC	5.5	6.1	5.3	6.7	4.2	7.9
Lymph%	↓ 0.157 R	0.204 R	0.296	↓ 0.101 R	0.271	0.265
Mid%	↑ 0.250 R	0.126 R	0.110	↑ 0.191 R	0.110	0.075
Gran%	0.593 R	0.670	0.594	↑ 0.708	0.619	0.660
RBC	4.71	4.46	3.80	4.38	4.77	4.27
HCT	↓ 0.345	↓ 0.338	↓ 0.267	↓ 0.343	↓ 0.337	↓ 0.327
MCV	↓ 73.4	↓ 75.8	↓ 70.2	↓ 78.2	↓ 70.7	↓ 76.6
HGB	↑ 167 R	↑ 163 R	126 R	↑ 163 R	↑ 169 R	156 R
MCHC	↑ 482 R	↑ 483 R	↑ 471 R	↑ 476 R	↑ 499 R	↑ 478 R
PLT	222	234	162	109	146	186

■ Cancel validate

Select the validated sample record(s) on the "**Table Review**" screen, and then tap the "**Cancel validate**" button. The text of "**Validated**" will disappear from the "**Sample State**".

6.2.7 Export

1. Tap "**Export**", the following dialog box will display.

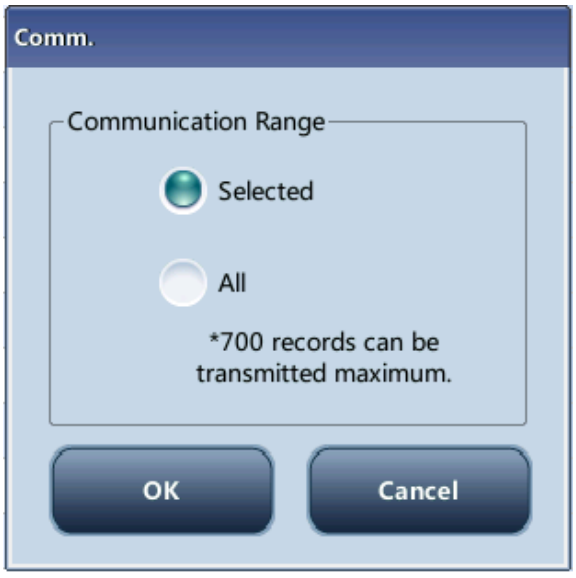


2. Select "**Selected**" or "**All**" in the "**Export Range**" area.

6.2.8 Communication

■ Transmit selected data

1. Select sample(s) to be transmitted on the "**Table Review**" screen.
2. Tap "**Comm.**", the following dialog box will display.



3. Tap the "**Selected**" radio button.
4. Tap "**OK**" to start transmitting specified results to the data management software.

■ Transmit all data

1. Tap "**Comm.**", the following dialog box will display.

2. Tap the "**All**" radio button.
3. Tap "**OK**" to start transmitting all results to the data management software.

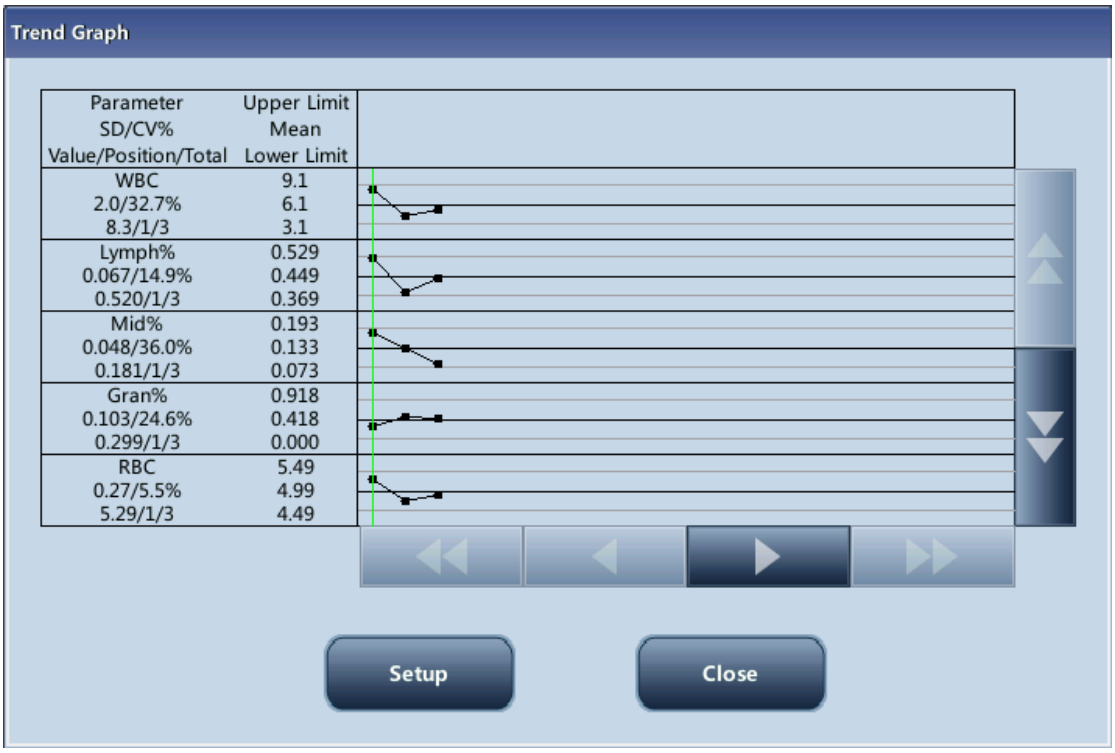
6.2.9 Delete (for administrators only)

1. Select the sample record to be deleted.
2. Tap the "**Delete**" button, the following dialog box will display.

3. Tap "**OK**" to delete the record, and the dialog box will be closed.

6.2.10 Trend Graph

Tap the "**Trend Graph**" button to see the trend graph of sample results.



6.2.11 Print

■ Print reports as per the default report template

Select sample records to be printed, and then tap "**Print**" to print them. On the "**Graph Review**" screen, the "**Sample State**" of the printed sample will become "**Printed**".

	30	31*	32	33	34	35
Sample ID	c-123	c-124	c-125	c-126	c-127	c-128
Sample State	Printed	Printed				
WBC	4.2	7.9	8.0	8.0	8.0	8.1
Lymph%	0.271	0.265	0.251	0.265	0.274	0.274
Mid%	0.110	0.075	0.086	0.088	0.078	0.076
Gran%	0.619	0.660	0.663	0.647	0.648	0.650
RBC	4.77	4.27	4.32	4.29	4.28	4.28
HCT	↓ 0.337	↓ 0.327	↓ 0.331	↓ 0.329	↓ 0.329	↓ 0.328
MCV	↓ 70.7	↓ 76.6	↓ 76.8	↓ 76.8	↓ 76.8	↓ 76.7
HGB	↑ 169 R	156 R	160 R	156 R	156 R	159 R
MCHC	↑ 499 R	↑ 478 R	↑ 483 R	↑ 475 R	↑ 475 R	↑ 485 R
PLT	146	186	202	189	188	193

NOTE

- **When a sample has been validated and printed, its "Sample State" will display "Validated".**

6.2.12 Review the Results of RUO Parameters

NOTE

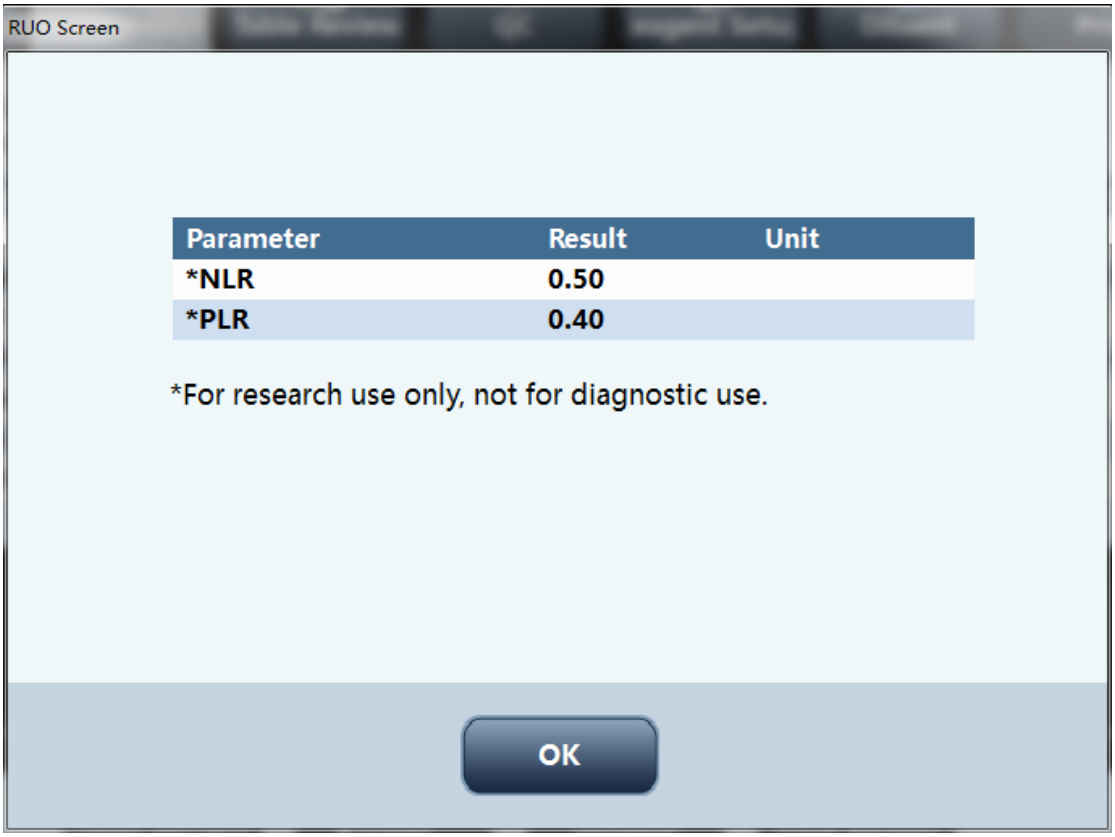
- **The RUO parameters are for research use only; and cannot be used for diagnosis purpose.**
- **The RUO parameter results are only available when you have enabled the "RUO parameters" function. For the instruction to enable the function, see 9.2.4.3 RUO Para. Setup.**

When the RUO parameters are enabled, you can review the RUO parameter results in the following two ways:

■ On a sample's "Graph Review" screen, tap the "Other Para." Button.

■ On the "Sample Analysis" screen, tap "RUO Screen".

The RUO parameter results display.



NOTE

- **The RUO parameters are for research use only; and cannot be used for diagnosis purpose.**
- **The RUO parameter results are only available when you have enabled the "RUO parameters" function. For the instruction to enable the function, see 9.2.4.3 RUO Para. Setup.**

7 Using the QC Programs

7.1 Introduction

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

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

This analyzer provides two QC programs: L-J QC and X-B QC.

NOTE

- **Use the controls and reagents specified by the manufacturer only. Store and use the controls and reagents as instructed by their instructions for use.**

7.2 L-J QC

7.2.1 Editing L-J Settings (for Administrators Only)

Before running a new lot of controls, you must set up a QC file for each lot of controls.

1 Tap the menu option "**QC**" > **"L-J QC**" > "**Setup**".

2. Enter the L-J QC setup screen.

You may set up QC information by any of the following two ways.

- Reading the information provided by the manufacturer
- Manual Entry

7.2.1.1 Reading the information provided by the manufacturer

1. Enter the L-J QC setup screen.
2. Tap "**New**", or select a QC file without QC results, and then tap "**Edit**".
3. Tap "Import File".

4. Select the QC file to be imported.
5. Tap "**OK**" to close the dialog box and return to the L-J QC setup screen.
6. Tap "**OK**" to read the selected QC information to the current QC file.

NOTE

- **The "Import target/limits" check box is selected by default. If it is deselected, the operator must enter the target and limits of QC parameters manually.**

7. Select the "**Control type**" from the pull-down list.
8. Select the QC mode.
9. Set QC sample ID: if you are used to analyzing control together with blood samples, you can set a unique ID for the control. The analyzer will recognize the sample as control when it reads the unique ID. After the analysis completes, the results will be saved into the QC file of the QC sample ID.
10. Tap other icons to switch screen and save the QC information.

7.2.1.2 Manual Entry

1. Enter the L-J QC setup screen.
2. Tap "**New**", or select a QC file without QC results, and then tap "**Edit**".
3. Enter the lot No. of the controls in the edit box manually.

NOTE

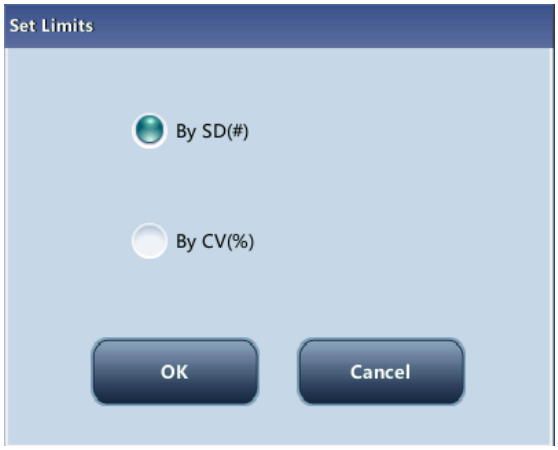
- **The lot No. shall not be empty and up to 16 digits can be entered. You can enter characters, numbers, letters.**

4.	Select the control level.
5.	Enter the expiration date of the lot.
6.	Select the "**Control type**" from the pull-down list.
7.	Select the QC mode.
8.	Set QC sample ID: if you are used to analyzing control together with blood samples, you can set a unique ID for the control. The analyzer will recognize the sample as control when it reads the unique ID. After the analysis completes, the results will be saved into the QC file of the QC sample ID.
9.	Enter the target and limits in the edit boxes according to the package insert of the lot of controls.
10.	Tap other icons to switch screen and save the QC information.

7.2.1.3 Setting Limits

You can adjust the format of limits as per the following procedure:

1. Tap "Set Limits".



2. Tap “**By SD**” to display the limits in the form of absolute value;
   or tap “**By CV**” to display the limits in the form of percentage.
3. Tap the “**OK**” button to save the settings.

7.2.2 Running Controls

You can select one of the two ways below to run controls:

- Run controls under the "**QC**" screen.
- Put controls together with normal samples, and run the controls under the sample analysis screen.

7.2.2.1 Running Controls Under the "QC" Screen

After editing the QC information, you can start QC analysis by one of the following ways according to the selected QC mode.

- Whole blood
- Predilute

⚠CAUTION

- **Running QC sample with error present will lead to unreliable results. If errors are reported during QC analysis, remove the errors first and then continue with the analysis.**
- **Sample agglutination may result in inaccurate analysis results. Check the control samples to see if there is any agglutination, if yes, process the samples according to your laboratory's protocols.**

NOTE

- **When switching mode from "PD" to "WB", a progress bar will be displayed while the analyzer runs mode switching sequence.**

1. Tap "**QC**" > "**L-J QC**" > "**Count**" to enter the QC count screen.

NOTE

- **Be sure that the level of the control to be run is the same with the current QC file, and the control is not expired.**

The expiration date of expired controls is displayed in red.

2. Prepare the control as instructed by instructions for use of the controls.

3. Run QC analysis:

   1) Make sure the analysis mode is "**WB**" or "**PD**" and the indicator of the analyzer is green.

   2) Shake the vial of sample as instructed by instructions for use of the control to mix the sample thoroughly.

   3) Present the control sample to the sample probe. Press the [Aspirate] key to start QC run.

4) When you hear the beep, remove the control.

4. When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE

- **Up to 100 QC results can be saved in each QC file.**

5. Do the above procedures to continue running QC analysis if necessary.

7.2.2.2 Putting controls together with normal samples, and running the controls under the sample analysis screen

After setting special "**QC Sample ID**" for a control under the QC setup screen, you can put the control together with normal samples, and run it under the "**Sample Analysis**" screen.

When editing worklist or entering next sample information in the "**Next Sample**" dialog box before daily analysis, enter the special "**QC Sample ID**" as "**Sample ID**".

Based on the QC mode selected, you can choose to run QC analysis from one of the following ways:

- Whole blood
- Predilute

1. Prepare the control as instructed by instructions for use of the controls.
2. Refer to section 5.5 Sample Preparation for sample preparation under whole blood and predilute modes.
3. When it is ready to run a sample (i.e. the status icon and the analyzer indicator is green), present the sample to the sample probe.
4. When you hear the beep, remove the control.
5. When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE

- **Up to 100 QC results can be saved in each QC file.**

6. Do the above procedures to continue running QC analysis if necessary.

NOTE

- **When switching blood mode from "PD" to "WB", a progress bar will be displayed while the analyzer runs mode switching sequence.**

7.2.2.3 Editing and saving results (for administrators only)

Tap "**Edit Result**" on the QC screen to edit results and tap "**OK**" to save the edited results. The edited results will be marked with an "**E**".

7.2.2.4 Restoring results (for administrators only)

Operators of administrator access level can restore the edited results to the original measurement results.

1. Tap "**Restore**" on the "**Edit Result**" screen.
2. Tap "**OK**" to restore the measurement values.
3. Tap "**OK**" to close the dialog box and start to restore results.

7.2.3 Reviewing L-J Results

After QC analysis, you can review the QC results in the following ways:

- QC Graph
- QC Table

7.2.3.1 L-J QC graph review

1. Tap "**Graph**" button on the "**L-J QC Run**" screen to enter the L-J QC graph screen.

2. You can tap the arrow buttons on the right of the graph to browse graphs of the parameters. You can tap the arrow buttons under the graph horizontally to browse all the QC results.

NOTE

- **If a parameter target/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters changes accordingly, those changed data will be highlighted in yellow.**

Print

Tap the "**Print**" icon in the status bar to print information of the current QC file and the QC graph of all parameters.

NOTE

- **The green vertical line and values of the corresponding QC points will not be printed.**

7.2.3.2 L-J QC table review

1. Tap the "**QC Table**" button on the **"L-J QC Run**" screen to enter the L-J QC table

screen.

2. You can tap the arrow buttons on the right of the QC table to browse all QC records. You can tap the arrow buttons under the QC table to browse all the parameter results.

NOTE

- **If a parameter target/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters changes accordingly, those changed data will be highlighted in yellow.**

■ Delete (for administrators only)

1. Tap "**Delete**", the following dialog box will display.

2. Tap "**Yes**" to delete the selected records.

NOTE

- **The operation will be recorded in the system log.**

■ Print

You can tap the "**Print**" icon in the status bar to print the QC table.

■ Transmission

To transmit QC data to external data management software or HIS/LIS/HIS, tap the "**Comm.**" button to transmit specified results to the data management software.

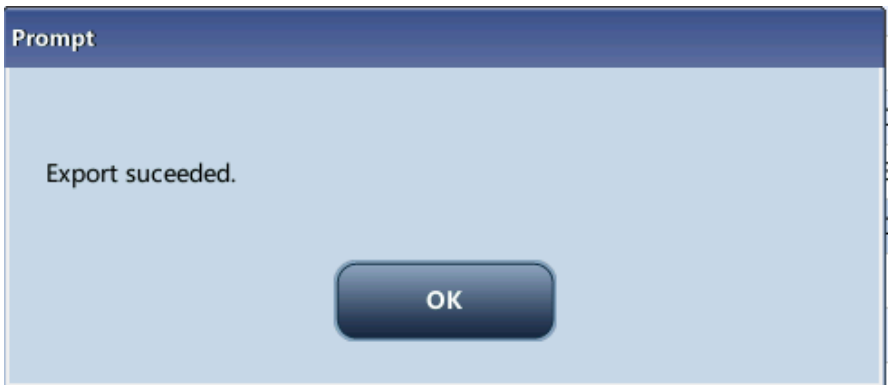
NOTE

- **If auto-communication is enabled and a sample is run during the transmission of the QC data, then only when the QC data transmission finished will the auto-communication of the sample result start.**
- **The QC data saved in the process of transmission will not be transmitted.**

■ Export

To export QC information and results of the current QC file, do as follows:

1. Insert a USB and then tap "**Export**".
2. The system will detect the USB and export data automatically.
3. The prompt "**Export succeeded.**" will display.



7.3 X-B QC Program

7.3.1 Introduction

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.

It is recommended the X-B QC be activated when the sample volume of your laboratory is greater than 100 samples per day. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices. It observes the trend of QC results in the reference range formed by the specified target and limits.

The analyzer implement X-B QC on the 3 parameters: MCV, MCH and MCHC, each group of samples for X-B analysis consists of 20-200 sample results obtained from normal analysis of both WB and PD modes. The analyzer can save up to 1,000 X-B QC results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest.

7.3.2 Editing X-B Settings (for Administrators Only)

1. Tap the menu option "**QC**">"**X-B QC**">"**Setup**", the following screen will display.

2. On the X-B QC setup screen, you may activate/deactivate X-B QC, set target/limits, and configure the sample validity setup.

7.3.2.1 Editing X-B settings

1. In the “**Sample number/group.**” edit box, you may enter the amount of samples [within the range 20(default) to 200] to be included in calculating for an X-B QC point.
2. Set X-B QC "**On**" or "**Off**". If X-B QC is activated, the samples meeting validity requirements will be included in X-B QC.

7.3.2.2 Setting target/limits

Before the X-B QC analysis, you shall set up the target and limit for each parameter at the X-B QC setup screen.

NOTE

- **The units of target/limits of all parameters are the same as those in the parameter unit setup screen.**

1. In the “**Target/Limit**” area of the X-B QC setup screen, specify the targets and limits in the “Target/Limit” table by entering manually.

   NOTE

   - **Do not leave any of the targets and limits for the QC parameters blank.**
   - **When first use, the default setting will provide the initial values for the targets and limits of all QC parameters.**

2. Tap other icons to switch screen and save the settings.

7.3.2.3 Setting sample validity

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

- Sample results exceeding the linearity range;
- Background results;
- Sample results not conforming to the "Sample Validity Setup";
- QC data for QC programs other than X-B;
- Calibration data;
- Results generated while there are errors which could affect the accuracy of the results (insufficient aspiration volume or clogging for example).

"**Sample Validity Setup**" is to set up the ranges of valid RBC, MCV, MCH and MCHC results. Only when the results of all these four parameters are within the specified ranges, the sample results can be used for X-B QC calculation. Do as follows to set the sample validity:

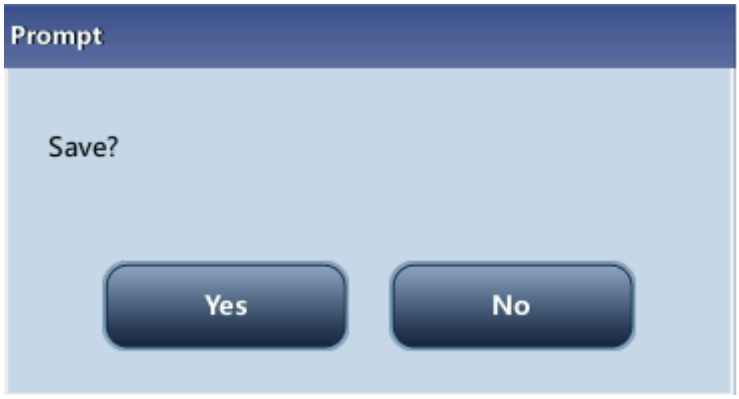
1. Select "**On**" to activate X-B QC.

   In the "**Sample Validity Setup**" of the X-B QC setup screen, set the upper and lower limits of the 4 parameters in the sample validity setup area.

   The default validity range of each parameter is shown in the following figure.

Sample Validity Setup	Parameter	Lower Limit	Upper Limit
	RBC	1.00	8.00
	MCV	50.0	150.0
	MCH	20.0	40.0
	MCHC	240	440

2. Tap "**Save**" to save the setup.



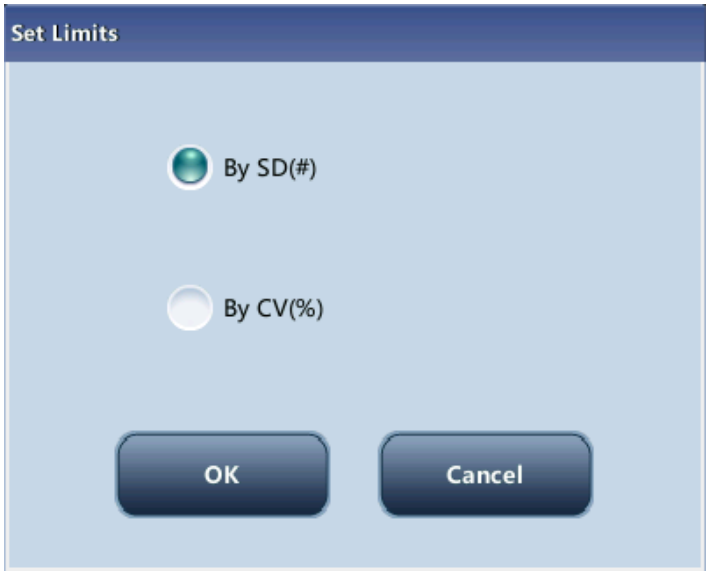
NOTE

- **In the sample validity setup, the upper limit shall be no smaller than the lower limit. Otherwise, there will be prompted message asking you to revise.**
- **The valid ranges of the RBC parameters are their linearity ranges; the valid ranges of other parameters are their display ranges.**
- **All the entries shall be numbers with only one decimal point. The length of the number entered cannot be longer than the length of the text box.**
- **Once the validity range is changed, the previous results will not be used in the QC calculation as valid results. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the validity range after 10 groups of valid sample results have been acquired, these 10 groups of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.**
- **The units of lower and upper limits of all parameters are the same as those in the " Reference Unit Setup " screen. See section *9.2.4 Setting Parameters-Parameter unit setup.***

7.3.2.4 Setting limits

You can adjust the format of limits as per the following procedure:

1. Tap "**Set Limits**".



2.	Tap “**By SD**” to display the limits in the form of absolute value;
3.	Tap “**By CV**” to display the limits in the form of percentage.
4.	Tap the “**OK**” button to save the settings.

7.3.2.5 Restoring defaults

If you want to restore the default targets and limits of the parameter, tap "**Restore Defaults**". The default values of the target and limits of each parameter are as follows:

Parameter	Target	Limits (#)
MCV	89.5	2.7
MCH	30.5	0.9
MCHC	340	10

7.3.3 QC Analysis

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

7.3.4 Reviewing X-B Results

After QC analysis, you can review the QC results in the following ways:

- QC Graph
- QC Table

7.3.4.1 X-B QC graph review

1. Tap the menu option "**QC**" > "**X-B QC**" > "**Graph**", the following screen will display.

2. Select QC file No., the information of the file and the QC graph will be displayed on the screen.

3. You can tap the arrow buttons under the graph horizontally to browse all the QC results.

7.3.4.2 X-B QC table review

1. Enter the "**X-B QC Graph**" screen.

2. Tap the "**Table**" button to enter the X-B QC table screen.

3. You can tap the arrow buttons on the right of the QC table to browse all QC records.

The delete, print and export operations can all be performed same as stated in the L-J QC table review section.

8 Calibrating Your Analyzer

8.1 Introduction

Calibration is a procedure to standardize the analyzer by determining its deviation under certain specified conditions. In order to get accurate sample analysis results, you should calibrate the analyzer per the procedure below when necessary.

The analyzer supports 3 calibration programs, namely manual calibration, auto calibration using calibrators and auto calibration using fresh blood samples; and two calibration modes, namely "WB" and "PD".

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

NOTE

- **Calibration procedures can only be performed by users of the administrator-level.**
- **Use the calibrators and reagents specified by the manufacturer only. Store and use the calibrators and reagents as instructed by their instructions for use.**
- **Calculation of reproducibility is included in the calibration procedure.**

8.2 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:

- an analytical component has been changed.
- you are going to re-use the analyzer after a long-term storage.
- the quality control results indicate there may be a problem.

NOTE

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

8.3 How to Calibrate

8.3.1 Preparing Your Analyzer

Before calibration, follow the CLSI standards or your laboratory protocol to do tests, and make sure the analyzer's background (blank count) results, repeatability results and carryover results are all within the specified ranges.

If any of the above items is not in the range, check if the analyzer is in error. Remove the errors (if there are) and check again. If the problem cannot be solved, contact our Customer Service Department.

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.

NOTE

- **Be sure to use the evacuated collection tubes recommended in the Appendix.**
- **If fresh blood samples are used for reproducibility test, make sure the sample volume is enough to support the test.**

8.3.2 Manual Calibration

Tap "**Calibration**" > "**Manual**" in the menu to enter the following screen.

NOTE

- **If you log in at the operator access level, you can only view the calibration factors. To perform calibration, please log out and then log in at the administrator access level.**

Do as follows to calibrate the analyzer.

On the manual calibration screen, check the calibration factors and calculate the new factors per the following equation:

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

For example: Suppose the WBC reference value of a calibrator is 8.4, and the current calibration factor of the whole blood mode is 98.90%.

Run the calibrator under the whole blood mode for 10 consecutive times and take the WBC results 8.1, 8.0, 8.1, 8.1, 8.3, 8.3, 8.2, 8.0, 8.1, 8.3 to calculate. The obtained CV is 1.5% and Mean is 8.16, which meet the requirements.

The new calibration factor is obtained:

$$\text{New calibration factor} = \frac{98.90\% \times 8.4}{8.16} = 101.81\%$$

The calculated calibration factors shall be between 75.00%～125.00%. In case of an invalid calibration factor, try to find out the reason (e.g. calibration material not thoroughly mixed,

misoperation, etc.). Then recalibrate the analyzer and recalculate the calibration factors. Enter the new calibration factors into the factor cell of the parameter that require calibration. When you switch screen after entering the new calibration factor, a prompt will display.

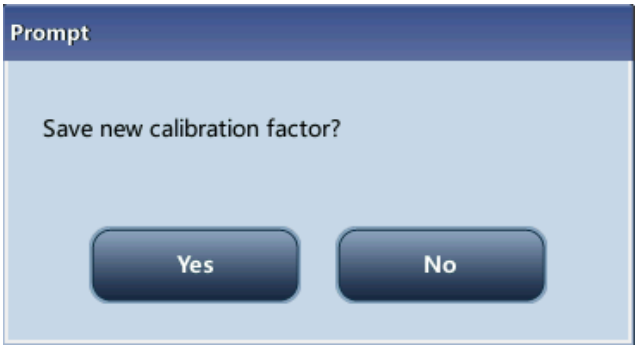
- If the entered calibration factors are valid, a dialog box will pop up asking you to save the new factor when you are exiting the screen. And the calibration date of the corresponding parameter changes to current system date.
- If the entered calibration factors are invalid, a dialog box will pop up prompting "**Invalid entry**" when you are switching to another screen. The new calibration factor will not be saved, and the calibration date will not be refreshed.

8.3.2.1 Other Operations

Print

Tap "**Print**" to print the current calibration factor.

- If the calibration factor does not change, the current calibration factor is printed.
- If the calibration factors are invalid, you will not be able to print them and the dialog box "**New calibration factor is invalid.**" will display.
- If the calibration factors are valid but not saved, a dialog box will display asking you to save the factors.



Tap "**Yes**" to save and print the factors. Or Tap "**No**" to cancel the operation without saving or printing them.

8.3.3 Calibration with Calibrator

Tap "**Calibration**" > "**Calibrator**" in the menu to enter the following screen.

NOTE

- **The calibrator calibration can only be performed under whole blood mode.**
- **Only specified calibrators shall be used. We will not be responsible for any erroneous result caused by using other calibrators.**
- **See the instruction for use of the calibrators for the lot No., expiration date and the target.**
- **The out-of-range CV% does not influence the display of calibration factors.**

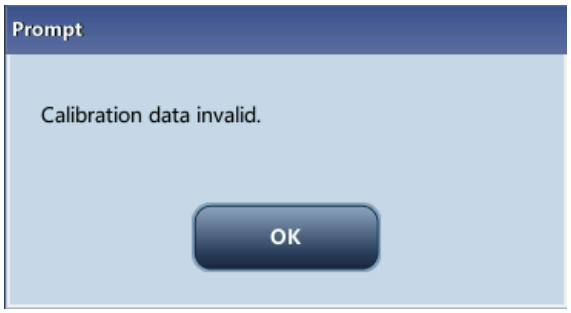
Do as follows to calibrate the analyzer with calibrators.

1. Check the mode on the analyzer screen.
2. Enter the lot No. of the calibrator into the "**Lot No.**" box.
3. Enter the "**Exp. Date**". The expiration date defaults to the current system date. When you need to modify it, tap the "**Exp. Date**" edit box, and reset the date. The expiration date shall not be earlier than the current system date.

   The entered expiration date should be either the expiration date printed on the instructions for use 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.
4. Enter the targets into the "**Target**" cells.
5. Prepare the calibrator as instructed by instructions for use of the calibrators.
6. Press the [Aspirate] key to start calibration.

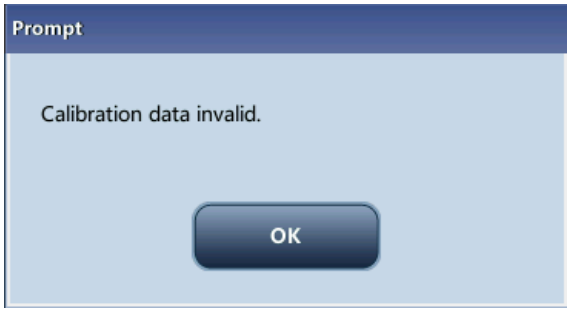
7. When the current calibration is done, the progress bar will close. The analyzer will have different responses to different analysis results:

   If there is a parameter whose calibration data is out of its linearity range but still within the display range, then the calibration data will be displayed in the list and a message box will also pop up.



   Tap “**OK**” to close the message box, and the data will be deleted from the table without saving automatically.

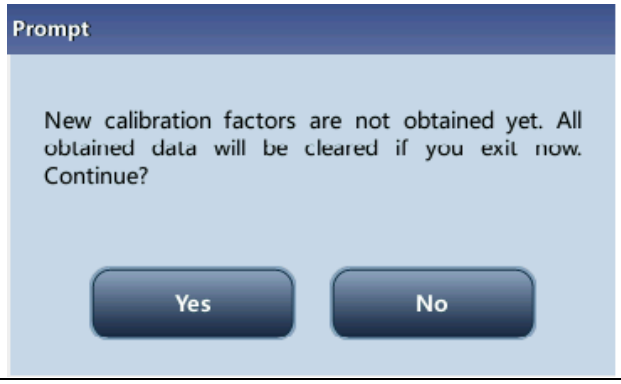
   If there is a parameter whose calibration data is out of the display range, then the non-numeric parameter values "***" will be displayed in the list and a message box will pop up.



   Tap “**OK**” to close the message box, and the data will be deleted from the table without saving automatically.

   If the calibration data is within the linearity range, its will be displayed directly. Valid calibration results will be marked with "√", and will be taken to calculate calibration factors.

   If the calibration factors have not been calculated but you switch to another screen, then a message box will pop up.



Tap "**Yes**" to switch to another screen while discarding the calibration data and closing the message box. The original calibration factors remain.

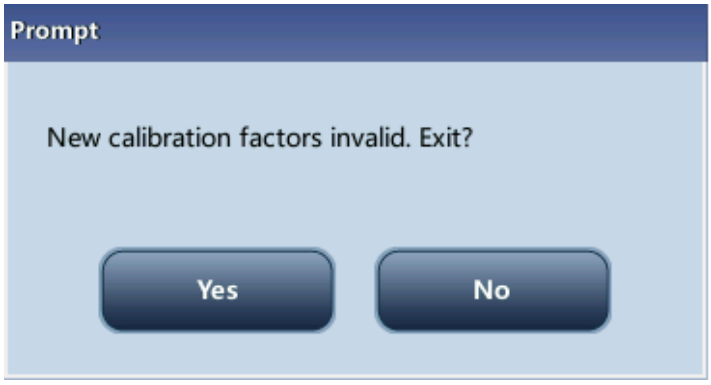
8. When calibration count has been performed to a sample for n times (n≥5), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with "√" (calibration data of the first run is not marked with "√", so it is not included in the calculation).

   You can select several data to calculate the calibration factors, but only after at least 5 groups of the data are marked with "√" can you get the calibration factors. The calibration factors will be refreshed whenever you select "√" or deselect "√".

   When the amount of valid calibration data in the list reaches 10, a message box "**Calibration is completed!**" will pop up. Then, if you press the [Aspirate] key again, the analyzer will beep without starting analysis.

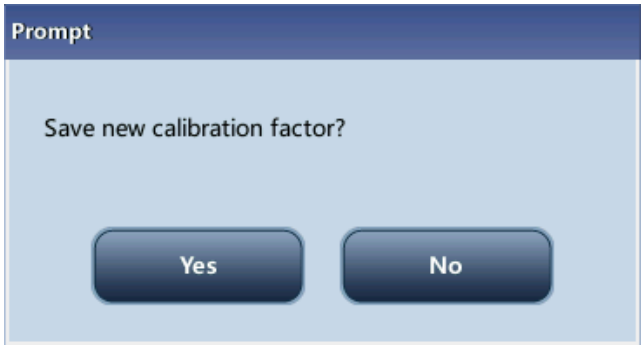
9. There may be two cases when you are switching to another screen:

   If the calibration factors of any parameter is out of the range [75%-125%] or the CV% of any parameter exceeds the reproducibility range, then the calculated calibration factors of all parameters will not be saved and a message box will also pop up.



   Tap "**Yes**" to close the dialog box and switch to another screen. The calibration factors and dates of all parameters will not be changed.

   If the calculated calibration factors of all parameter are within the range [75%-125%] and the CV% of all parameter are also within the reproducibility range, then a message box will pop up.

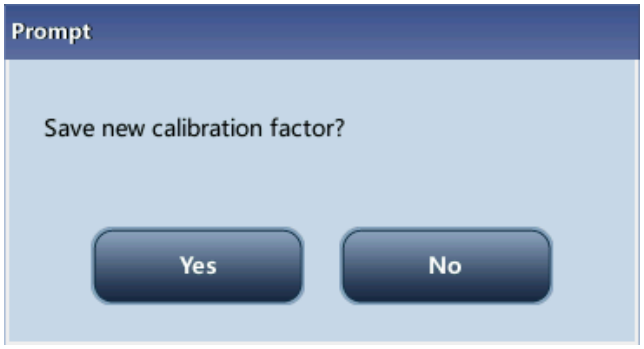


Tap "**Yes**" to save the new calibration factors while closing the message box and switching to another screen.

8.3.3.1 Other Operations

Print

If the calibration factors are invalid, tap "**Print**", the dialog box "**New calibration factor is invalid.**" will display.
If the calibration factors are valid, tap "**Print**", a dialog box will display.



Tap "**Yes**" to close the dialog box, save and print the calibration results. Or tap "**No**" to cancel the operation without saving or printing them.

8.3.4 Calibration with Fresh Blood

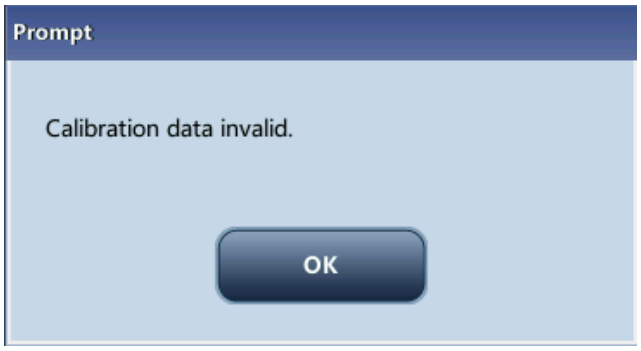
Tap "**Calibration**" > "**Fresh Blood**" in the menu to enter the following screen.

Do as follows to calibrate the analyzer with fresh blood.

1.	Prepare three to five normal fresh blood samples as instructed in Chapter 5 ***Operating Your Analyzer***..
2.	Run each of the prepared samples on the reference instrument (or by the reference method) five times at least. Calculate the mean values and use them as the targets. Or perform measurement and calculation as per the reference method and take the calculated data as the targets.
3.	Tap the “**Mode**” button, and select the radio button “**WB**” or “**PD**” as the desired mode.
4.	Select the ID of current sample from the pull-down box "**Current Sample ID**".
5.	Select the parameter to be calibrated from the check box on the first line of the list.
6.	Enter the targets into the "**Target**" cells.
7.	Prepare fresh blood sample.
8.	Press the [Aspirate] key to start calibration.

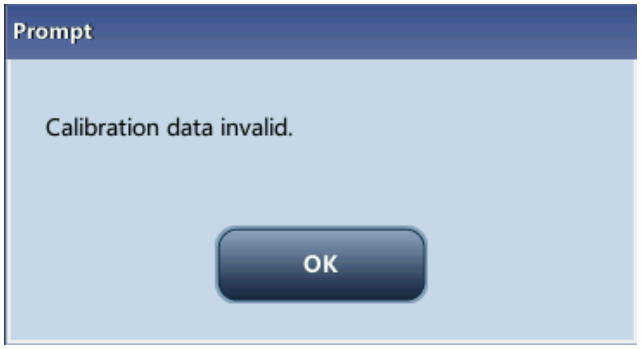
9. After the analysis, the progress bar will close. The analyzer will have different responses to different analysis results.

   If the results are out of the linearity range but still within the display range, a dialog box will pop up when the results are displayed in the table.



   Tap “**OK**” to close the message box, and the data will be deleted from the table without saving automatically.

   If the results are out of the display range, the non-numeric parameter values "***" are obtained and a dialog box will pop up.



   Tap “**OK**” to close the message box, and the data will be deleted from the table without saving automatically.

   If the results are within the linearity range and they are valid, they will be displayed directly.

   Valid calibration results will be marked with "√” per the default setting, and will be taken to calculate calibration factors.

10. When valid calibration count has been performed to a sample for n times (n≥5), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with "√" automatically.

    You can select several data to calculate the calibration factors, but only after at least 5 groups of the data are marked with "√" can you get the calibration factors. The calibration factors will be refreshed whenever you select “√” or deselect “√”.

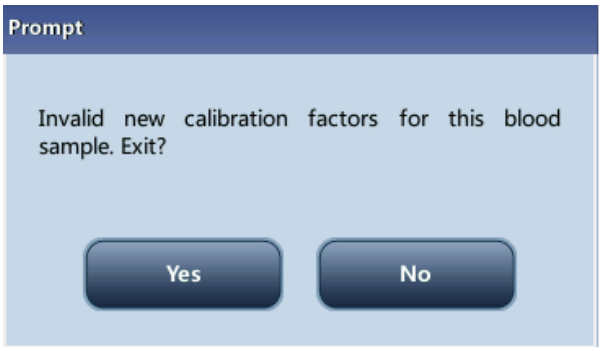
    When the amount of valid calibration data in the list reaches 10, a message box

"**Calibration with the current blood sample is completed.**" will pop up when you start calibration again.

11. Select other calibration sample ID from the "**Current Sample ID**" pull-down box, analyze other samples according to Step 8～10 above to obtain the calibration factors of all samples.

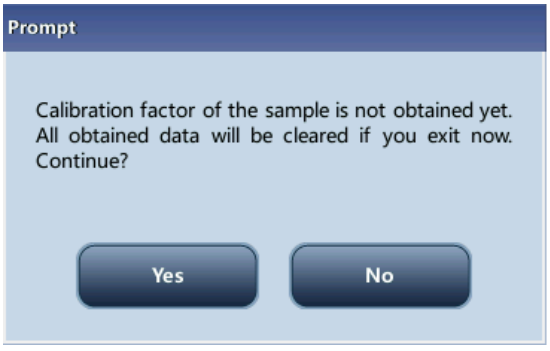
12. There may be several cases when switching to another blood sample:

    If the calibration factors of the blood sample are invalid or the CV% of any parameter exceeds the reproducibility range, a dialog box will pop up when switching to another blood sample.



    Tap "**Yes**" to empty the entered target of the current sample, all the calibration data obtained and each calculated value including calibration factors, then close the dialog box and switch to another blood sample.

    If the calibration factors have not been calculated, a dialog box will pop up.



    Tap "**Yes**" to empty the entered target of the current sample and all the calibration data obtained, then close the dialog box and switch to another blood sample.

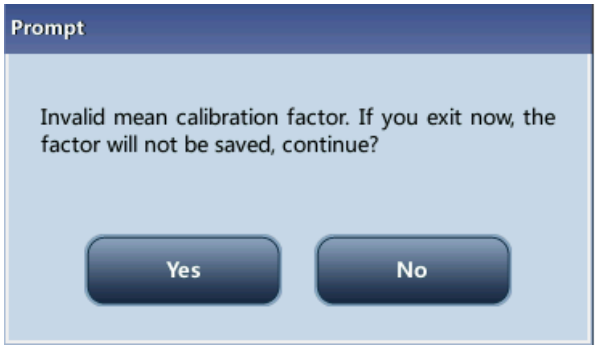
    If the calibration factors of the sample are valid and the CV% of all the parameters do not exceed the reproducibility range, you can switch to another blood sample directly.

13. After calibration factors of at least three fresh blood samples are obtained, tap the "**Calculate**" button to enter the screen of calibration calculation.

Select or deselect the calibration factors of a blood sample for the calculation of the Mean calibration factors by tapping the check boxes before the calibration factors.

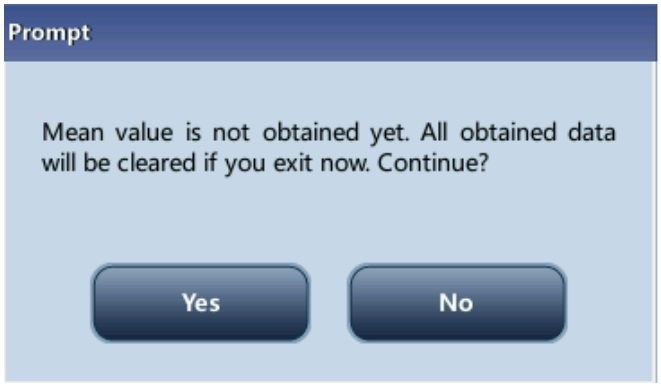
When three or more groups of calibration factors are checked, CV% will be re-calculated automatically base on the checked calibration factors.

When three or more groups of calibration factors are checked, the mean calibration factor will be re-calculated automatically base on the checked calibration factors. The mean calibration factors are regarded as invalid if the deviation of absolute value between the calibration factors included in calculating the mean and the original calibration factors reaches or exceeds 5%; a dialog box will pop up when you exit the current fresh blood calibration screen.



Tap "**Yes**" to close the dialog box and exit with the current calibration data emptied, and switch to another screen.

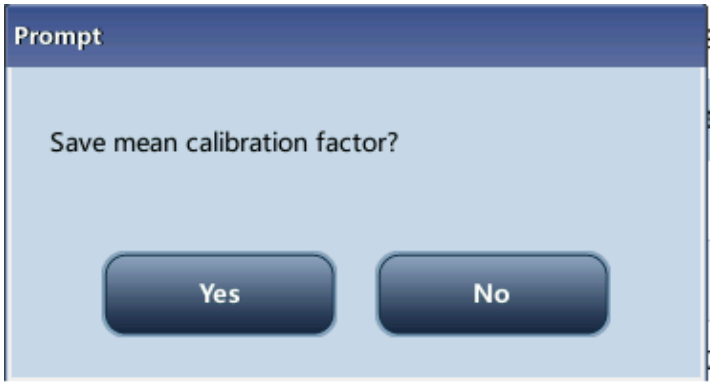
14. If the mean calibration factors have not been calculated, when you exit the fresh blood screen or switch to another calibration mode, a dialog box will pop up.



Tap "Yes" to discard the calibration data, close the dialog box, and switch to another screen or calibration mode. The original calibration factors and date remain the same.

Tap "No" to return to the current screen. Invalid mean calibration factors are followed w "?". and displayed in red.

If the calculated mean calibration factors are valid, when exiting the fresh blood calibration screen or switching to another calibration mode, a dialog box will pop up.



15. Tap "**Yes**" to save the current mean calibration factors. Then, you can switch to another screen or calibration mode. Tap "**No**" to close the dialog box and switch to another screen or calibration mode without saving the mean calibration factors and all the calibration data.

8.3.4.1 Other operations

Print

If the mean calibration factors are invalid, tap "**Print**", the dialog box "**Calibration factor is invalid.**" will display.

If the mean calibration factors are valid, you can tap "**Print**" to print the calibration factors of a group (or more) of blood samples in table form, no matter whether they are selected ("√") or not. The results obtained in the calibration process and the mean calibration factors can also be printed.

9 Customizing the Analyzer Software

9.1 Introduction

The analyzer 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.

Menu functions are introduced as below.

See the following figure for the setup menu.

9.2 System Setup

9.2.1 System Setup

9.2.1.1 Date/Time Setup

Tap the menu option "**Setup**" > "**System Setup**" > "**Date/Time Setup**" to enter the "**Date/Time Setup**" screen as shown below. You can set up the date, time and date format of the analyzer at the screen.

9.2.1.2 Print Setup

Tap the menu option "**Setup**" > "**System Setup**" > " **Print Setup**" to enter the "**Print setup**" screen as shown below. You can set up the following contents:

- Print Setup
- Printing content
- Auto print after sample analysis

■ Print Setup

- **Print Device**

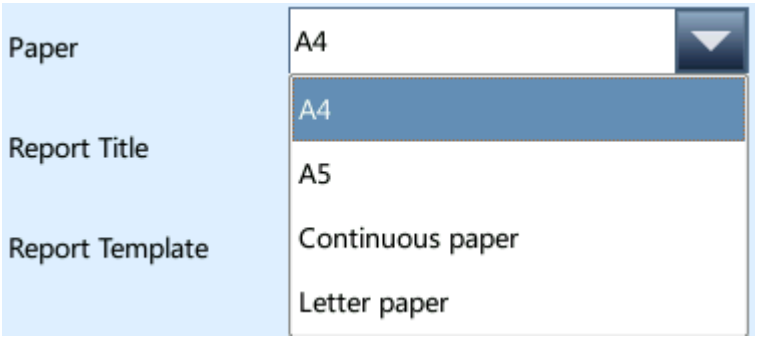
You can select "**Printer**" or "**Recorder**" from the "**Print Device**" pull-down list.

- **Print Drive**

Tap the pull-down list to select print drive of the analyzer.

- **Paper**

Tap the pull-down list to select the paper type of the reports to be printed.



- **Para. language**

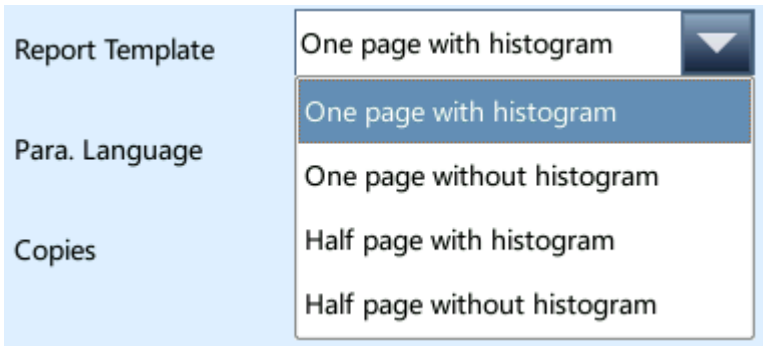
Tap the pull-down list to select the parameter language of the reports.

- **Copies**

Enter the number of copies to be printed for each report into the edit box "**Copies**".

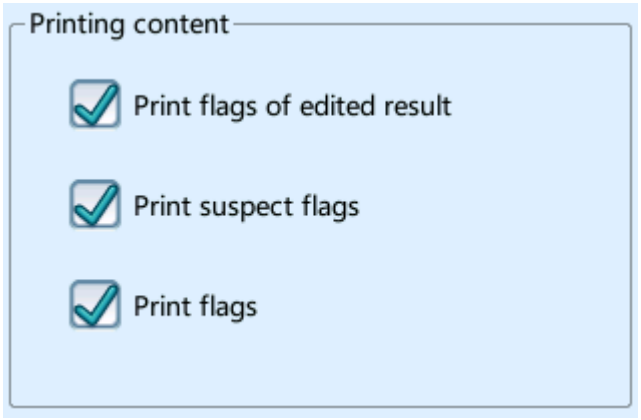
- **Report title**

- **Report template**



■ Printing content

You can choose to select the functions based on your needs by tapping on the check boxes.



■ Auto print after sample analysis

You can choose to disable auto print or set up printing conditions.

9.2.1.3 Communication Setup

Tap the menu option "**Setup**" > "**System Setup**" > "**Communication"** to enter the communication setup screen as shown below. You can set up the following contents:

■ Communication

■ Network Device

■ Protocol Setup

■ Transmission Mode

■ Communication

You can select "Network port comm." or "Serial port comm.".

■ Network Device

You can select "**Wireless**" or "**Wired**" from the "**Network Type**" pull-down list.

If you select "**Wireless**", tap the wireless network setup icon  , and choose a WiFi hot spot from the popped out dialog box to establish connection.

■ Protocol Setup

Tap the "**IP Address**", "**Subnet Mask**" and "**Default Gateway**" edit boxes to enter the contents.

Communication Protocol

Tap the "**Comm. Protocol**" pull-down list to select the communication protocol.

■ Transmission Mode

You can select the functions based on your needs by tapping on the check boxes.

- **Auto retransmit**
- **Auto comm.**
- **Auto Fetch Info From LIS**

- **Transmit as Print Bitmap Data**
- **ACK synchronous transmission**

ACK synchronous transmission

Tap on the "**ACK Synchronous Transmission**" check box to activate the function.
When the function is activated, ACK overtime is 10 seconds by default. You can re-enter the ACK overtime is the edit box.

Transmission mode of histogram

Tap the pull-down lists to select the transmission modes of histogram.

- **Not to be transmitted**
- **Bitmap**
- **Data**

9.2.1.4 Shortcut Code Setup

Tap the menu option "**Setup**" > "**System Setup**" > "**Shortcut Code Setup**" to enter the screen as shown below. This function allows you to set up shortcut codes for the contents on the "**Next Sample**" screen and the "**Edit Info**" screen of "**Grap Review**".

■ Add shortcut codes

1. Select "**Dpt.**" or "**Ordered by**" tab.
2. Tap "**Add**", a line will be added in the table.

3. Enter the "**Name**", "**Shortcut Code**" and "**Digital Code**" based on your needs.

■ Edit shortcut codes

1. Select "**Dpt.**" or "**Ordered by**" tab.

Select the line of the shortcut code to be edited.

Modify it directly in the table.

■ Delete shortcut codes

1. Tap the shortcut code to be deleted.

Select the line of the shortcut code to be deleted.

Tap "**Delete**" to delete it.

9.2.1.5 Lab info. setup

Tap the menu option "**Setup**" > "**System Setup**" > "**Lab Info. Setup**" to enter the screen as shown below. Operators may enter, save and view lab information. Tap on the edit boxes to enter the information.

NOTE

- **The analyzer SN cannot be edited.**
- **The date of installation is the date the analyzer is installed by default. It can be edited, but cannot be later than the current system date.**

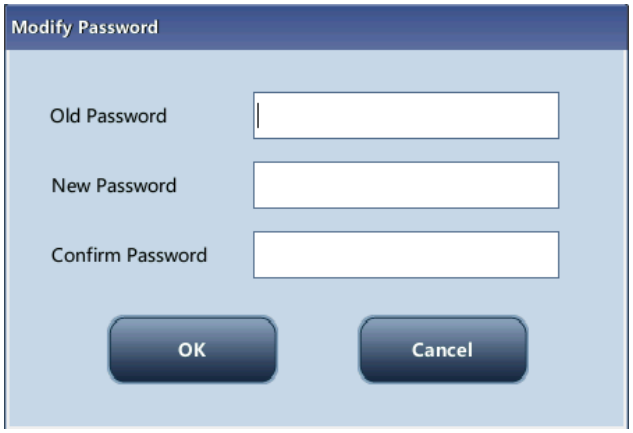
9.2.2 User Management

Tap "**Setup**" > "**Access Setup**" in the menu to enter the following screen.

9.2.2.1 Modifying password

You can modify your own password.

1. Select the current user, and then tap "**Modify Password**", the following dialog box will display.



2. Enter the required information in the text boxes.
3. Tap "**OK**" to save the change and close the dialog box.

NOTE

- **Up to 12 characters can be entered.**

9.2.2.2 Adding a new user

1. Tap "**New**", the following dialog box displays.

2. Enter the "**User ID**", "**Name**" and "**Password**" information. The "**User ID**" refers to your login account; and the "**Name**" will be displayed in the "**Operator**" or "**Validated By**" fields on the "**Table Review**" screen and on the printed reports.

3. Select access level of the user:
   - Administrator
   - Operator
4. Tap "**OK**" to save the change and close the dialog box.

NOTE

- **The user ID cannot be null and up to 12 characters can be entered.**
- **The password cannot be null and up to 12 characters can be entered.**
- **The name cannot be null and up to 20 characters can be entered.**

9.2.2.3 Deleting a User

Select a user and then tap "**Delete**" to delete it.

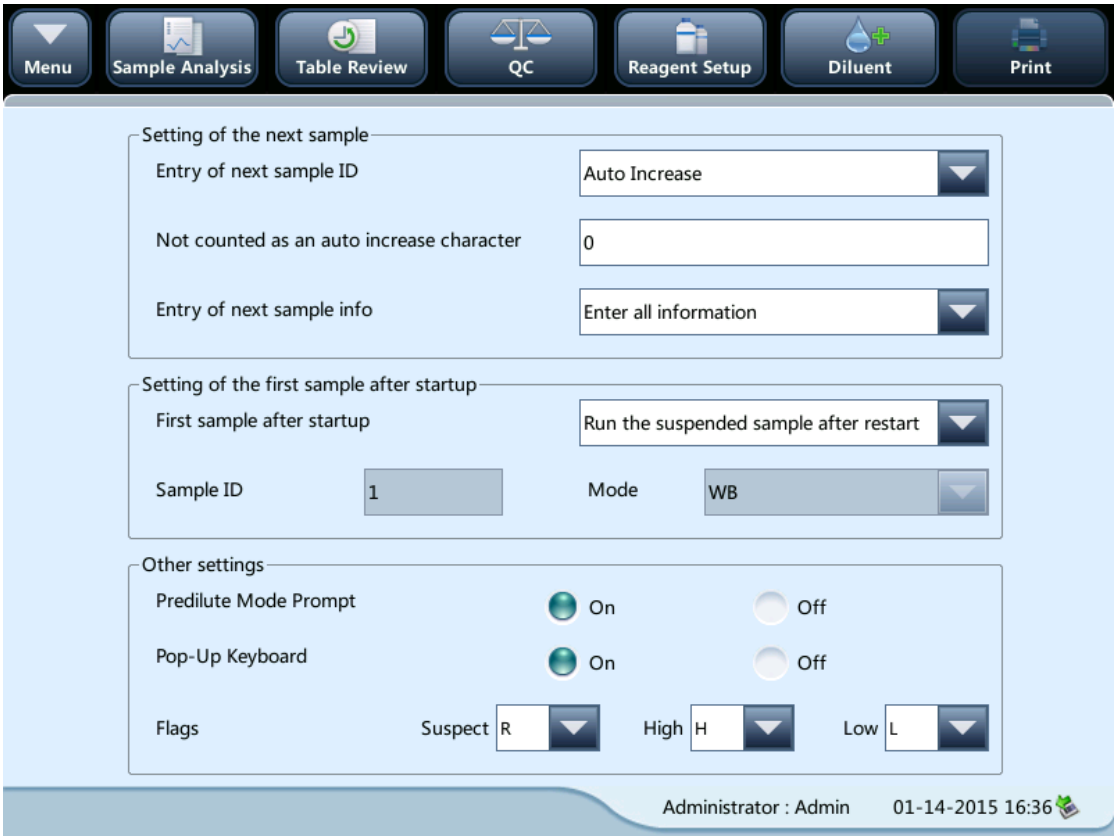
NOTE

- **The current login user cannot be deleted.**

9.2.3 Auxiliary Setup

Tap "**Setup**" > "**Auxiliary Setup**" in the menu to enter the following screen. You can set up the following contents:

- Setting of the next sample
- Setting of the first sample after startup
- Other settings



9.2.3.1 Setting of the next sample

- Entry of the next sample ID

Tap the pull-down list to select the way to enter the next sample ID.

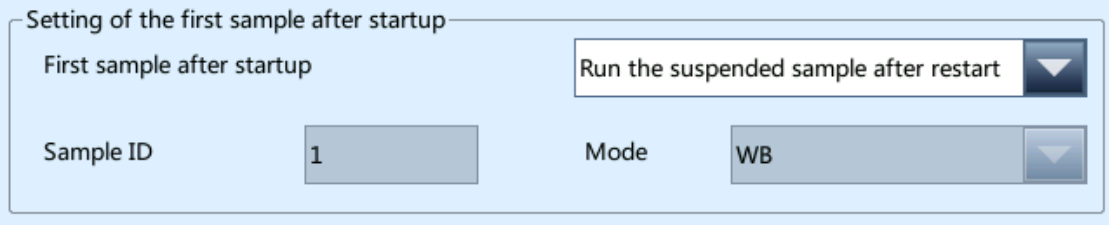
- **Auto Increase**
- **Manual Entry**

- Not counted as an auto increase character

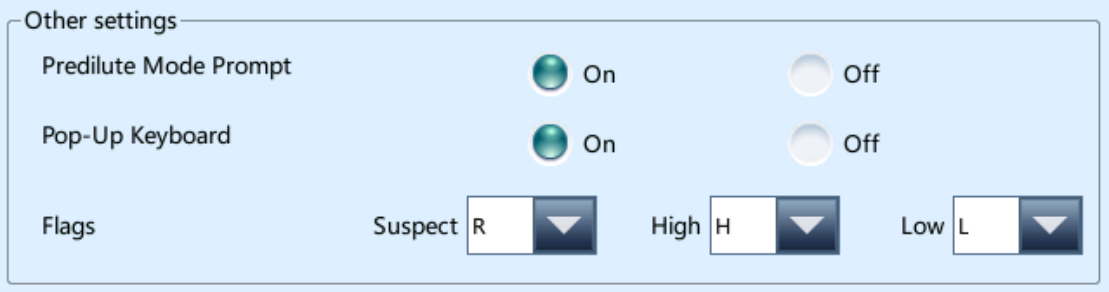
You can set up the number of characters in the sample ID that will not be auto increased.
When "**Auto Increase**" is selected as the way to enter the next sample ID, this edit box will be activated.
Enter a number (n) into the edit box of "**Not counted as an auto increase character**". The first n characters in the sample ID will not be auto increased.

9.2.3.2 Setting of the first sample after startup

You may customize the first sample ID after startup by entering it into the edit box; or select to continue with the sample ID before last shutdown.



9.2.3.3 Other settings



- On/Off radio buttons

Select "**On**" or **"Off**" to activate or deactivate the functions.

- Flags

You may set up the "**Suspect"** flag by entering a character into the edit box, or selecting a letter from the pull-down list (the default character is "**R**").

You may set up the "**High**" or "**Low**" flag by entering characters in the edit boxes, or selecting letters from the pull-down lists (the default character of high flag is "**H**", and that of low flag is "**L**").

9.2.4 Setting Parameters

9.2.4.1 Parameter unit setup

Tap the menu option "**Setup**" > "**Parameter Setup**" > "**Reference Unit Setup**" to enter the screen as shown below. You can set up parameter units on this screen.

■ Selecting unit system

Tap the "**Unit System**" pull-down list to select unit system.

■ Customizing parameter units

Under each unit system, you can tap the "**Unit**" cell to customize the parameter unit.
Tap the "**Default**" button to restore the default units.

NOTE

- **The units displayed will be different when different unit system is selected.**

9.2.4.2 Reference range setup

Tap the menu option "**Setup**" > "**Parameter Setup**" > "**Reference Range Setup**" to enter the screen as shown below.
Five factory reference groups and 10 customized reference groups are provided for your choice. Each laboratory shall select a proper reference range of its own based on its patient demographics. The reference range differs among races, genders, ages and geographic locations.

■ Customizing reference groups

Tap "**New**", or select a reference group and tap "**Edit**" to enter the reference group setup screen. You can set up the name, lower and upper limits of age, gender, and parameter reference range.

NOTE

- **When you have enabled the RUO parameters function, you can also set parameter result ranges for the RUO parameters. For the instruction of enabling RUO parameter function, refer to 9.2.4.3 RUO Para. Setup.**
- **The name of the reference group cannot be null.**
- **The names of the customized reference groups shall not repeat the names of the five default groups (General, Adult male, Adult female, Child, and Neonate) and they shall not repeat each other either.**

For factory reference groups, you can tap the "**Default**" button to restore the default parameter settings.

NOTE

- **The name, lower and upper limits of age and gender of the factory reference groups cannot be modified.**
- **The input range of age is [0,999].**

■ Setting as default reference group

Select a reference group and then tap "**Set to Default**" to set it as default reference group.

NOTE

- **The name, lower and upper limits of age and gender of the factory reference groups cannot be modified.**
- **The input range of age is [0,999].**

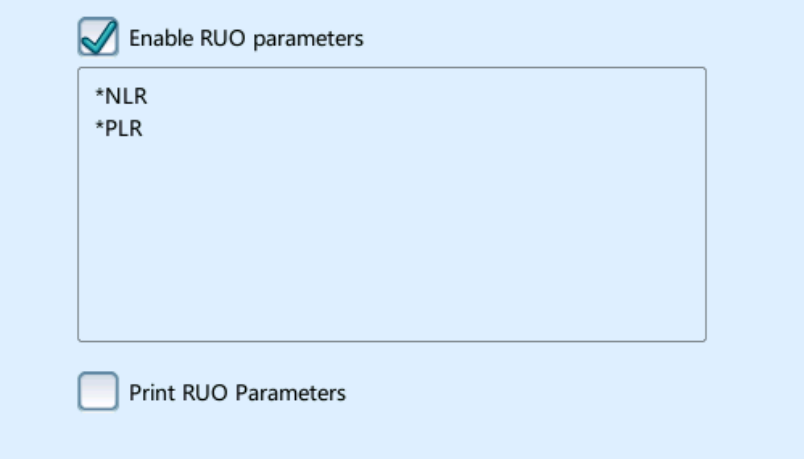
■ Modifying reference range(s)

To modify the reference range of a reference group, select the group from the reference group list on the left, and then:

- **Tap the cells of upper and lower limits in the table and re-enter the values.**
- **For a factory reference group, you can tap the “Default” button on right of the screen to restore the reference ranges to defaults.**
- **Select "Match customized ref. group first", when the age ranges of the customized reference group and the default reference group contradicts with each other, the customized reference group will be matched first on the sample analysis and review screens.**

9.2.4.3 RUO parameters setup

Tap the menu option "Setup" > "Parameter Setup" > "RUO Para. Setup" to enter the screen as shown below.
You may modify RUO parameter related settings.

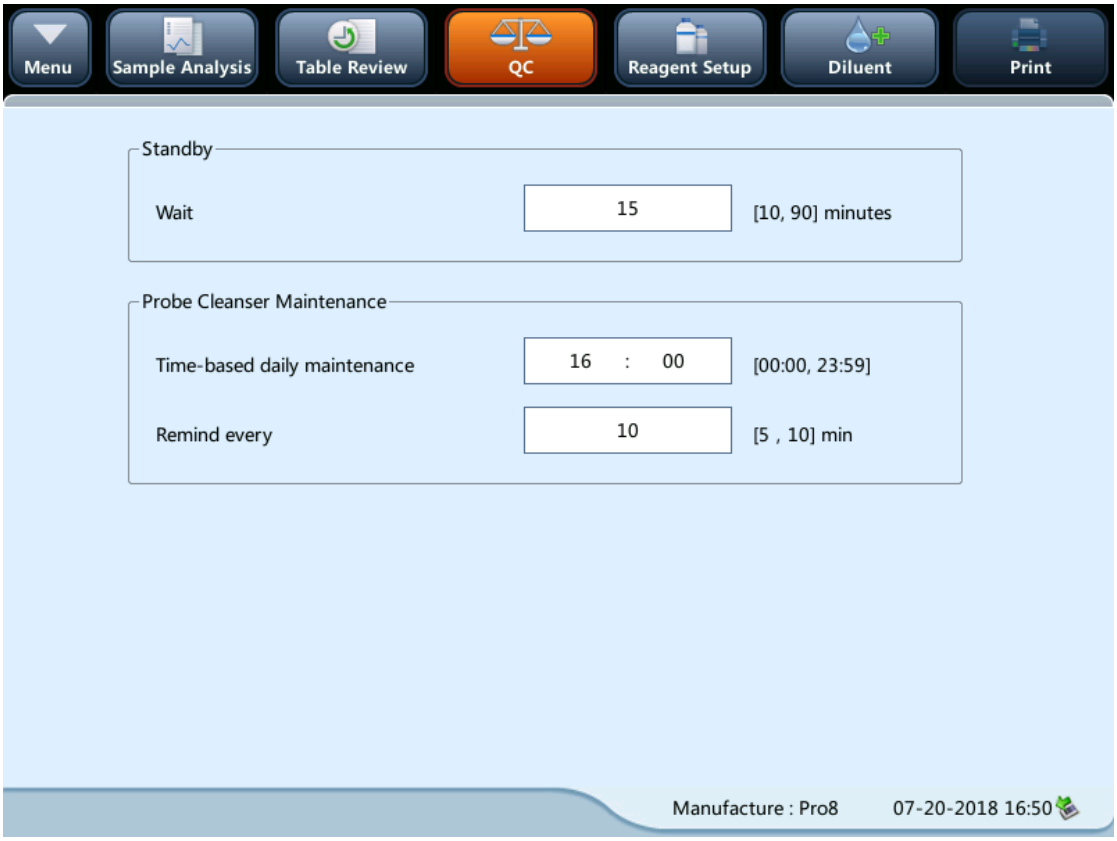


Select "Enable RUO parameters". The RUO parameter results will be given for the samples analyzed thereafter.

- **To print RUO parameters on the result reports, select "Print RUO Parameters" When “Print RUO Parameters” are selected, the RUO parameter results will be printed on the result, with a statement that the RUO parameters are “for research use only, not for diagnostic use”.**

9.2.5 Maintenance Setup (for Administrators Only)

Tap "**Setup**" > "**Maintenance**" in the menu to enter the following screen. You can set up the following contents:



9.2.5.1 Standby

Tap the text box "**Wait**" and enter the waiting time before entering the standby status. The range allowed is 10 -90 minutes, and the default setting is 15 minutes.

9.2.5.2 Probe cleanser maintenance

Tap the "**Time-based daily maintenance**" text box in the "**Probe Cleanser Maintenance**" area to enter the time to start time-based probe cleanser maintenance. Enter a time to the "**Remind every**" text box. Then when the operator cancels the time-based maintenance, a reminder dialog box will pop up after the defined minutes.

9.2.6 Reagent Management

9.2.6.1 Reagent Management for Indian Clients

Tap "**Setup**" > "**Reagent Setup**" in the menu to enter the following screen.

This function may also be used to refill reagent inside the fluidic system when a new container of reagent is loaded.

NOTE

- **The diluent must be kept still for at least a day after long-term transportation.**
- **When you have changed the diluent, lyse or rinse, run a background to see if the results meet the requirement.**

You should replace reagents when:

- the reagent ran out and a new container of reagent is installed.
- the reagent in the tubing is contaminated.
- there are bubbles in the tubing.

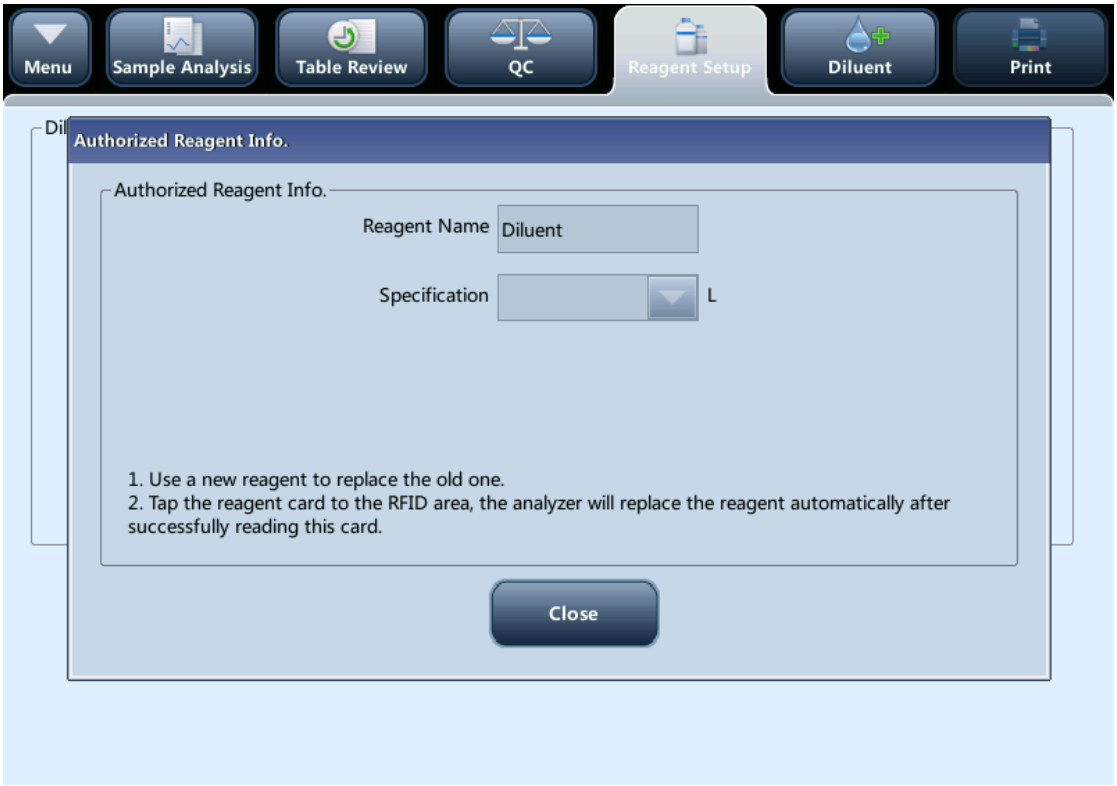
You can replace the following reagents in the fluidics:

- Diluent
- Lyse

There are respectively two methods for replacing lyse and diluent. You can replace them according to your analyzer setup.

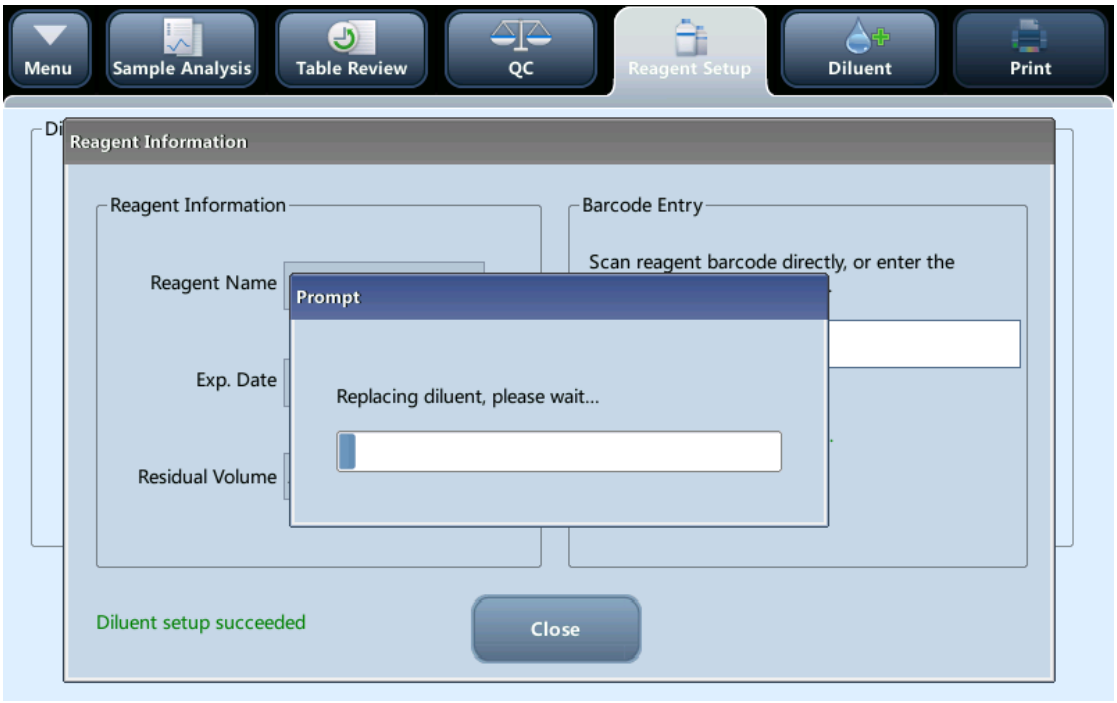
Do as follows to replace diluent:
Method one:

1. Tap “Replace” button on the screen, the following window will pop out:



2. Use a new reagent to replace the old one and then tap the reagent card to the RFID area, the following window will pop out:

3. Scan the reagent barcode with the external barcode scanner, or enter the numbers under the reagent barcode. If the reagent is valid, the system will prompt “Diluent Setup succeeded” and the progress bar will be displayed.

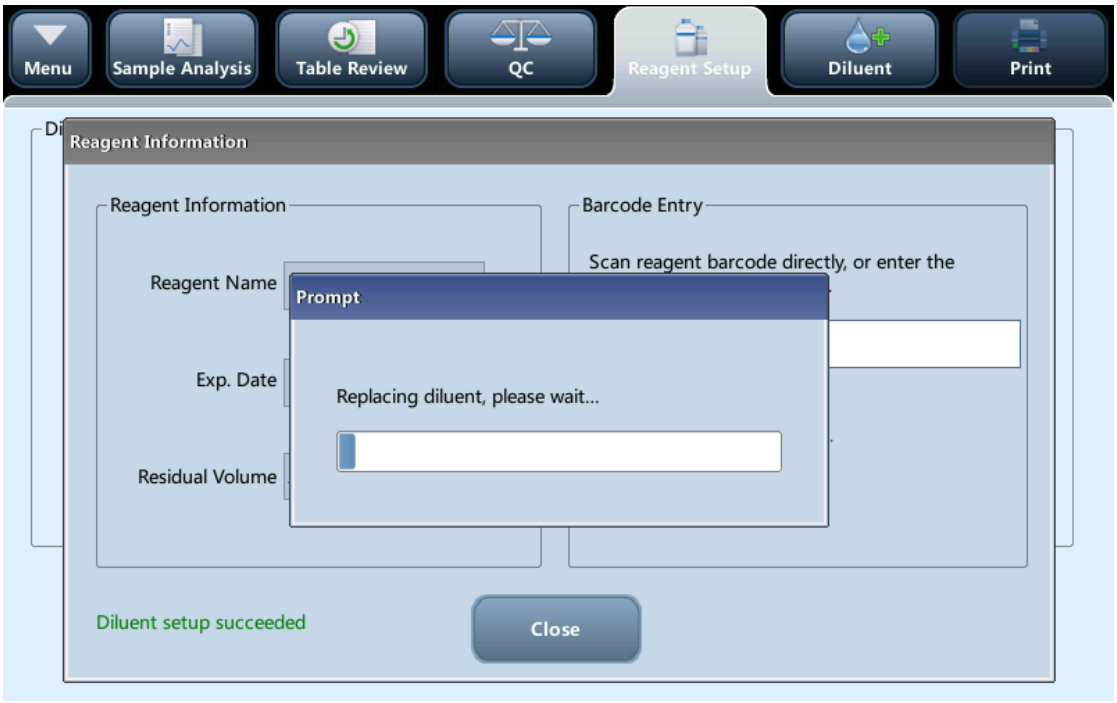


4. When the diluent is replaced successfully, the system will automatically return to the “Reagent Setup” screen.

Method two:

1. Tap “Replace” button on the screen, the following window will pop out:

2. Scan the reagent barcode with the external barcode scanner, or enter the numbers under the reagent barcode. If the reagent is valid, the system will prompt “Diluent Setup succeeded” and the progress bar will be displayed.

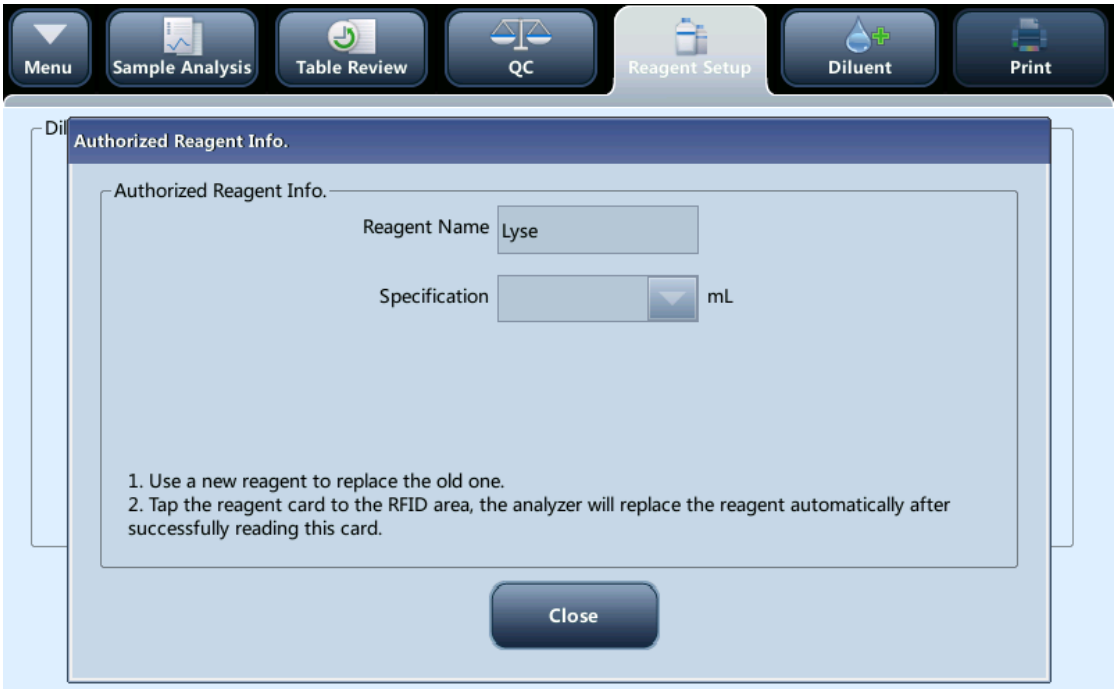


3. When the diluent is replaced successfully, the system will automatically return to the “Reagent Setup” screen.

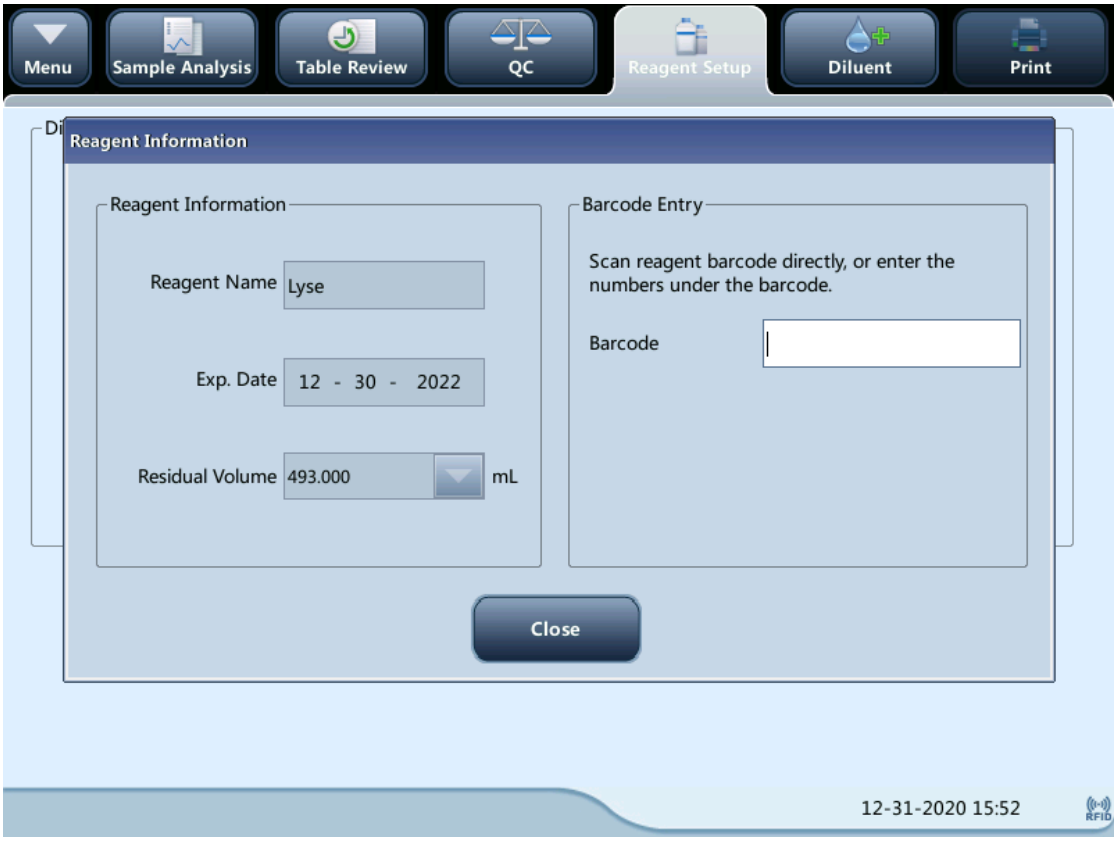
Do as follows to replace lyse:

Method one:

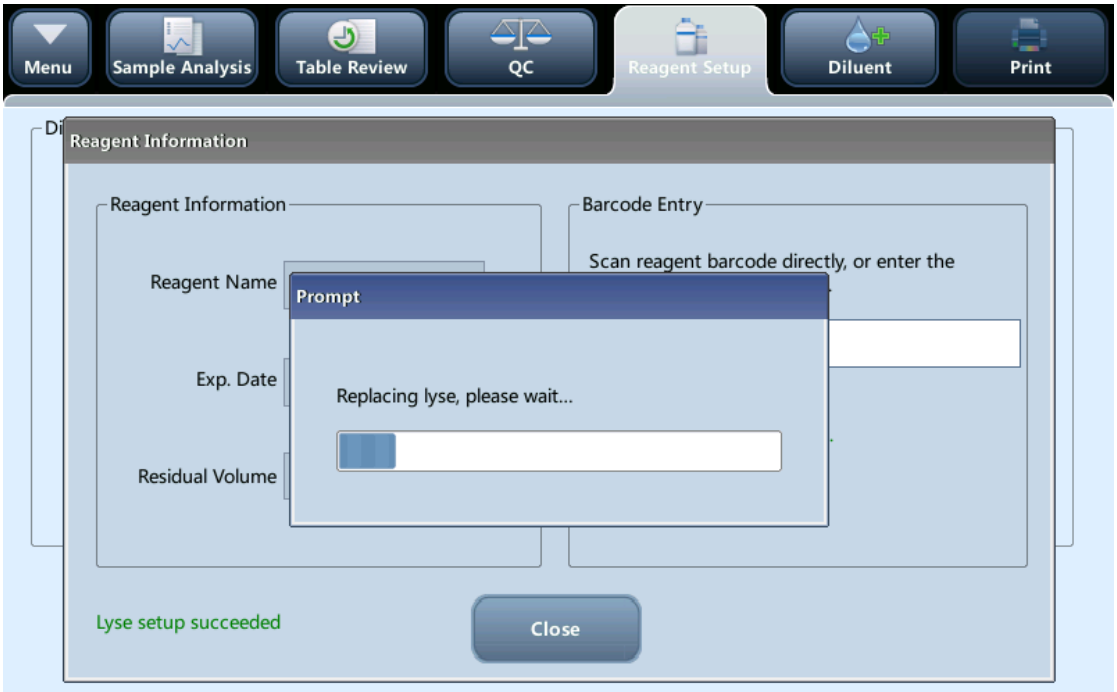
1. Tap “Replace” button on the screen, the following window will pop out:



2. Use a new reagent to replace the old one and then tap the reagent card to the RFID area, the following window will pop out:



3. Scan the reagent barcode with the external barcode scanner, or enter the numbers under the reagent barcode. If the reagent is valid, the system will prompt “Lyse Setup succeeded” and the progress bar will be displayed.



4. When the lyse is replaced successfully, the system will automatically return to the “Reagent Setup” screen.

Method two:

1. Tap “Replace” button on the screen, the following window will pop out:

2. Use a new reagent to replace the old one and then tap the reagent card to the RFID area, the system will prompt “Lyse Setup succeeded” and the progress bar will be displayed

3. When the lyse is replaced successfully, the system will automatically return to the “Reagent Setup” screen.

NOTE

- **The reagent replacement procedures only apply to Indian clients.**

9.2.6.2 Reagent Management for non-Indian Clients

Tap "**Setup**" > "**Reagent Setup**" in the menu to enter the following screen.

This function may also be used to refill reagent inside the fluidic system when a new container of reagent is loaded.

NOTE

- **The diluent must be kept still for at least a day after long-term transportation.**
- **When you have changed the diluent, lyse or rinse, run a background to see if the results meet the requirement.**

You should replace reagents when:

- the reagent ran out and a new container of reagent is installed.
- the reagent in the tubing is contaminated.
- there are bubbles in the tubing.

You can replace the following reagents in the fluidics:

- Diluent
- Lyse

Do as follows to replace the reagents.

1.	Enter reagent information at the screen.
2.	Or enter the barcode by scanning. If the barcode is valid, the corresponding reagent information will automatically display.
3.	Tap "**Apply**" to save the exp. date and start to replace the reagent. A progress bar will be displayed in the process.
4.	Replace other reagents as per the above procedures if needed.

9.2.7 Gain Setup (for Administrators Only)

Tap "**Setup**" > "**Gain Setup**" in the menu to enter the following screen. Gain setup function allows you to adjust the digital potentiometers. The operation shall not be performed frequently.

9.2.7.1 Setup

9.2.7.2 HGB gain

Tap the "**Auto Cal HGB.B.V**" button, the HGB blank voltage will be set automatically.

9.3 Saving the settings

To save the modified settings, you may switch to another screen, the following dialog box will display.

Tap "**Yes**" to save the settings and switch to the corresponding screen. Tap "**No**" to switch to the corresponding screen without saving the settings.

10 Servicing 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, so take proper protective measures for operation and maintenance.**
- **We do not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**
- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
- **Discard the system according to government regulations.**

⚠WARNING

- **Do not use any decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it.**
- **Exercise caution to avoid contact with the sharp sample probe when performing maintenance.**
- **If you accidently spill hazardous material (for example, reagents and samples) on the instrument, clean and sterilize the instrument with specified disinfectant. 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.**
- **Stop using the instrument when you find any fluid tubing or part filled with fluid is aging or wearing, and contact the service engineer or your local distributor to replace.**
- **When the instrument operation is stopped for maintenance, transportation or service, clean and sterilize the instrument cover as well as the parts and components with biological risks (such as the sample probe). Remind the persons who handle the instrument of the related risks.**
- **Check the equipment state after repair. Make sure the equipment is safe before offering it to users.**

⚠CAUTION

- **Improper maintenance may damage the analyzer. Operators must follow the instruction of this Operator's Manual to perform maintenance operations.**
- **For any questions, contact our customer service department.**
- **Only the parts supplied by our company can be used for maintenance. For any questions, contact our customer service department.**
- **Do not use any decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it.**
- **If any of the pipes or fluidic components are worn out, stop using the analyzer and contact our customer service department immediately for inspection or replacement.**

The following table lists the tools that may be used in maintenance.

No.	Tools
1.	Cross-headed screwdriver
2.	Slotted head screwdriver
3.	Medical gloves
4.	Alcohol

10.2 Maintaining Your Analyzer

Maintenance options of the analyzer includes: maintenance, cleaning and fluidics maintenance.

10.2.1 Maintenance

Programs	Timing	Purpose
Overall Soak	■ Background results are outside the specified range, or QC results are abnormal due to long term idleness of the analyzer ■ The analyzer is started up after shutdown due to abnormal power break-off	Clean the whole system
Clear Apecture	When clogging error is reported	Clear the clogging
Drain Fluidics	Before moving an analyzer	Drain the fluidics of the whole system to avoid the occurrence of liquid leakage when moving the analyzer
Drain Preheat Bath	Before replacing or repairing the preheater bath when the preheat bath is faulty	Drain the preheat bath
WBC bath flushing and zapping	When the clogging error of baths is frequently reported	Clear the WBC bath clogging
RBC bath flushing and zapping		Clear the RBC bath clogging
Drain WBC Bath	Before repairing or maintaining a bath-related part	Drain the WBC bath
Drain RBC Bath		Drain the RBC bath

Tap "**Maintenance**" > "**Maintenance**", and select the "**Maintenance**" tab to enter the following screen.

10.2.1.1 Unclogging

Unclogging includes zapping and flushing the aperture. When a clog error is reported, you should unclog the aperture.

The unclogging procedures are:

1.	Tap the "**Clear Apecture**" button to start unclogging.
2.	When the progress ends, a message will display indicating "**Maintaining finished!**".
3.	Do the above procedures to continue unclogging if necessary. If the error persists, perform probe cleanser maintenance for the related channels.

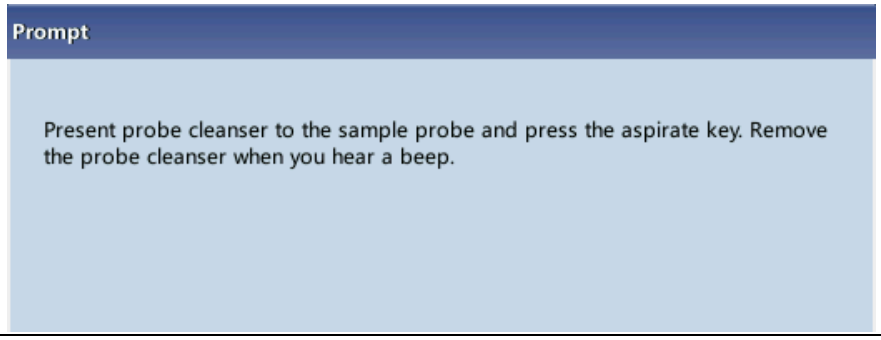
10.2.1.2 Overall Soak

You should perform the overall soaking procedure with the probe cleanser when:

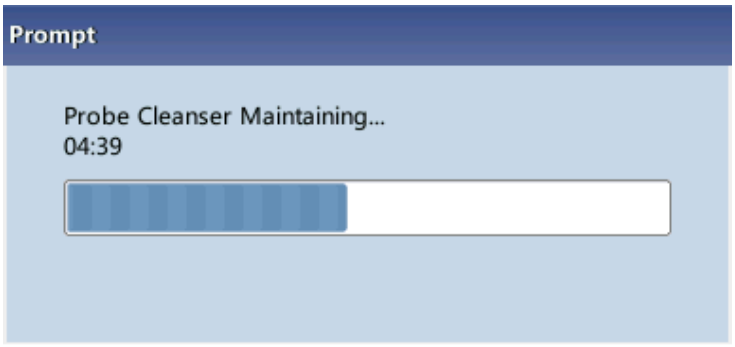
- Background results are outside the specified range, QC results abnormal due to long term idleness of the analyzer; or when other maintenance operations fail to solve the clog error.
- The analyzer shuts down due to abnormal power break-off; probe cleanser maintenance must be performed after it is started up again.

The overall soak maintenance procedures with the probe cleanser are as follows:

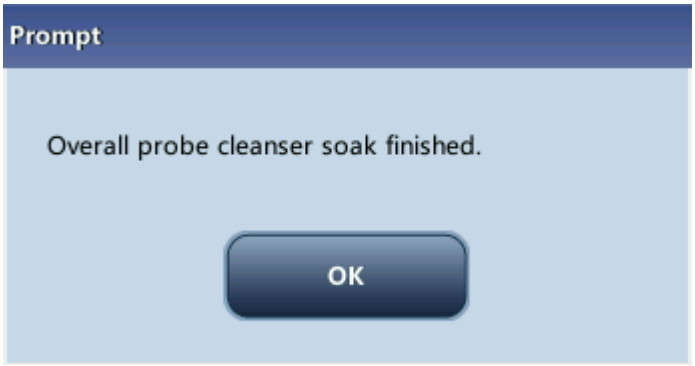
1. Tap the "**Overall Soak**" button, the following dialog box will display.
2. Tap "**Yes**", the analyzer starts to prepare for the maintenance.
3. When the preparation is done, the following dialog box will display.



4. After aspirating probe cleanser, the analyzer performs probe cleanser soak automatically, and a progress bar will display indicating the progress.



5. When the progress ends, the following dialog box will display, tap “**OK**” to close the dialog box.



10.2.2 Cleaning

You should perform cleaning when:

- WBC and (or) HGB background results exceed their limits, perform WBC bath cleaning. If WBC bath cleaning does not solve the problem, perform WBC probe cleanser maintenance.
- RBC and (or) PLT background results exceed their limits, perform RBC bath cleaning. If RBC bath cleaning does not solve the problem, perform RBC probe cleanser

maintenance.

- sample probe gets dirty, perform sample probe cleaning.

Tap "**Maintenance**" > "**Maintenance**", and select the "**Cleaning**" tab to enter the following screen.

You may perform cleaning operation to the following components:

- Analyzer
- Sample probe
- WBC bath
- RBC bath

The cleaning procedures are:

1. Tap the button of the component you want to clean. The message "**Cleaning in process. Please wait...**" will display.
2. When the progress ends, a message will display indicating "**Cleaning finished!**".
3. Clean other components as per the above procedures if needed.

10.2.3 Overall Maintenance

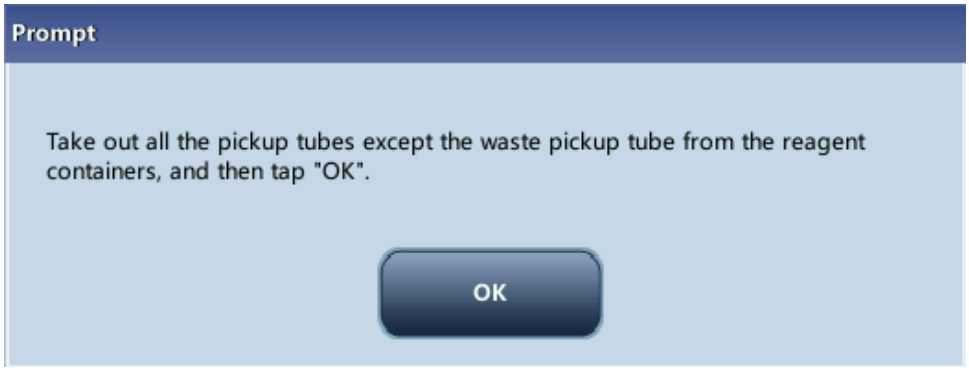
Tap "**Maintenance**" > "**Maintenance**", and select the "**Fluidics**" tab to enter the following screen.

10.2.3.1 Packing Up

You should perform the pack-up procedure when the analyzer is not to be used for over two weeks.

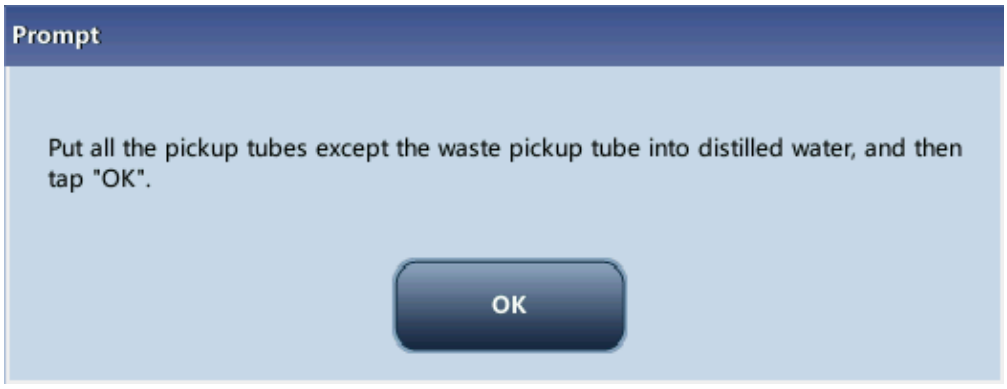
The pack-up procedure is as follows:

1. Tap "**Pack-up**", the dialog box "**Start pack-up?**" will pop up.
2. Tap "**Yes**" to perform the pack-up procedure. The following dialog box will be displayed.

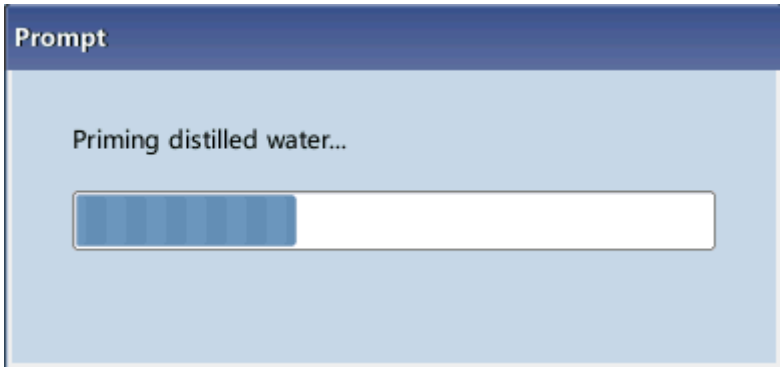


3. Remove all reagent pickup tube assemblies according to the prompt, and then Tap the "**OK**" button to start emptying the fluidic system.

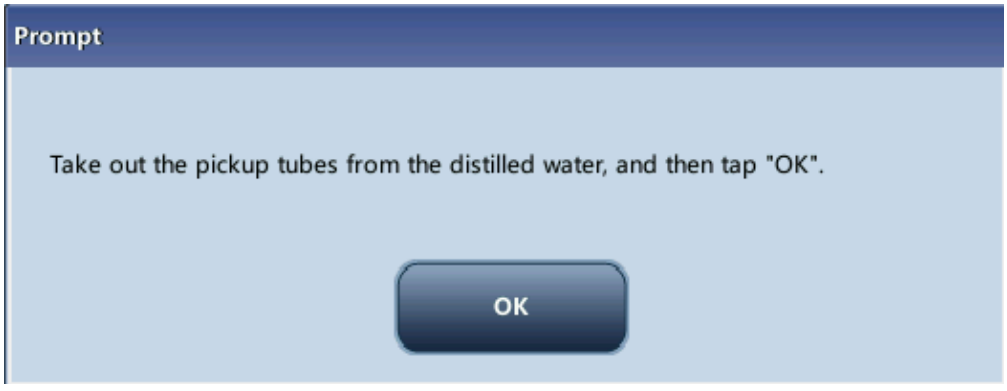
4. After the emptying is complete, a message box will pop up.



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

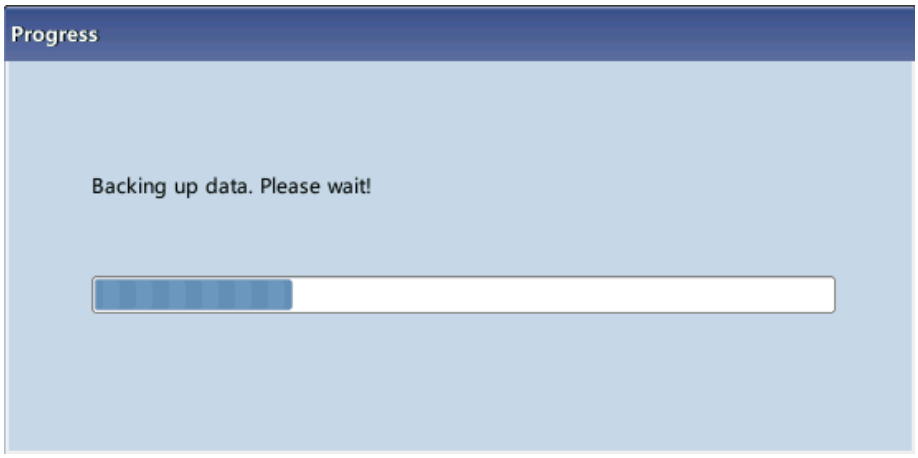


6. After the cleaning is done, a message box will display.



7. Remove all reagent pickup tube assemblies according to the prompt, and then tap the “**OK**” button to start emptying the fluidic system for the second time.

8. After the emptying is complete, a message box will display.



9. Turn off the power switch according to the prompt displayed on the screen.

NOTE

- **This software can still be used after the pack-up.**

10.2.3.2 Resetting the Fluidics

When major components of the analyzer have been replaced, or the fluidic system has been serviced, you must reset the fluidics. Do as follows:

1. Tap "**Reset**", a dialog box will pop up asking you to comfirm the operation.
2. Tap "**OK**" to start initialization, the message "**Resetting fluidics. Please wait...**" will be displayed.
3. When the progress ends, a dialog box will display indicating "**Resetting fluidics finished!**".
4. Do the above procedures to continue resetting fluidics if necessary.

10.3 Self-Test

Select “**Maintenance**”> “**Self-Test**” from the pull-down menu to enter the following screen and perform system and valve self-tests.

10.4 Gain Calibration

Select “**Maintenance**”> “**Gain Calibration**” from the pull-down menu to enter the following screen and calibrate the gains.

10.5 Advanced Toolbox

Select “**Maintenance**”> “**Advanced Toolbox**” from the pull-down menu to enter the following screen, where you can switch the languages and perform one-key export.

10.6 Sample Probe Debug

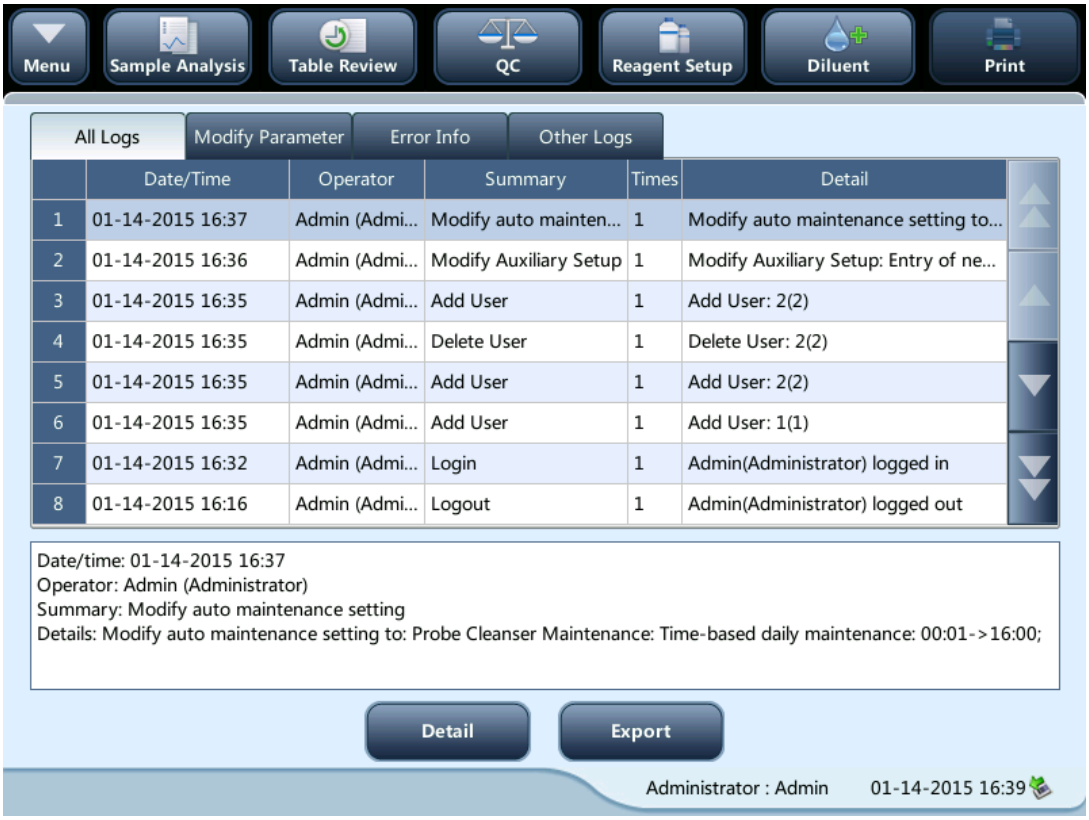
Select "**Maintenance**"> "**Sample Probe Debug**" from the pull-down menu to enter the following screen, where you may initialize the sample probe position and fix the probe height.

10.7 Touch Screen Calibration

Tap "**Maintenance**" > "**Calibrate Touchscreen**" in the menu to enter the following screen.

10.8 Viewing Logs

Tap "**Maintenance**" > "**Log**" in the menu to enter the following screen.



You may view the error info., parameter modification info. and records of daily operation in the log.

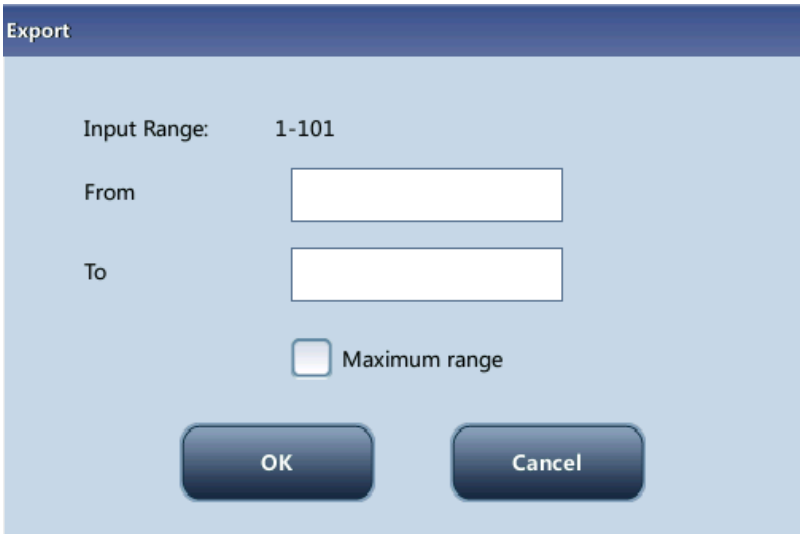
The log screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

NOTE

- **The oldest record will be overwritten automatically when number of log records reaches the utmost.**
- **Records of two years can be stored at most.**

10.8.1 Exporting logs

1. Tap "**Export**", the following dialog box will display.



2. Select the range of the logs that you want to export.
3. Tap "**OK**" to close the dialog box and export the logs.

10.9 Checking the Analyzer Status

NOTE

- **If the status is outside normal range, it will be highlighted with red background.**

10.9.1 Counter

Tap "**Status**" > "**Counter**" in the menu to enter the following screen.

You can check detailed statistics on the screen, for example, running times of the analyzer and the valid sample runs.

10.9.1.1 Viewing details

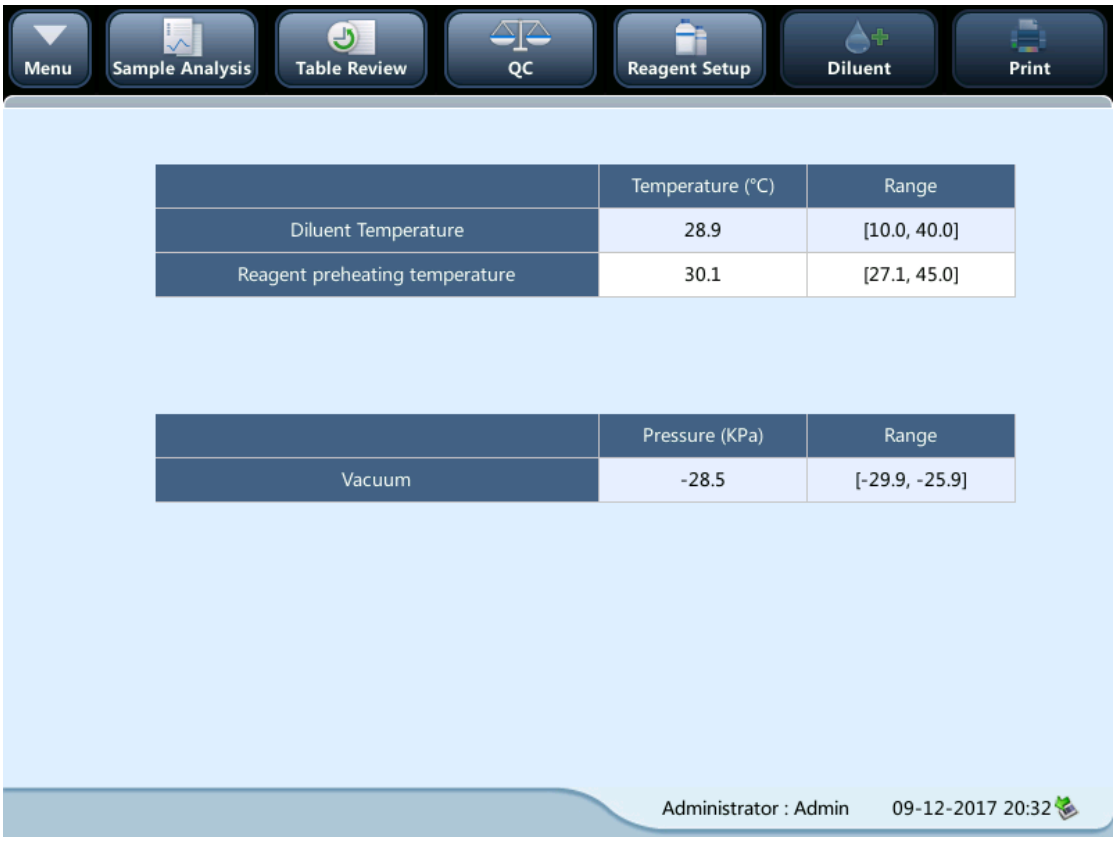
You may tap the "**Detail...**" buttons following "**Sample Runs**", "**QC Runs**" or "**Calibration Runs**" to view the related details.

10.9.1.2 Print

Tap the "**Print**" icon to print all information on the screen.

10.9.2 Temperature and Pressure

Tap "**Status**" > "**Temp.&Pressure**" in the menu to enter the following screen. You may check, export or print the temperature and pressure values of different components of the analyzer.



	Temperature (°C)	Range
Diluent Temperature	28.9	[10.0, 40.0]
Reagent preheating temperature	30.1	[27.1, 45.0]

	Pressure (KPa)	Range
Vacuum	-28.5	[-29.9, -25.9]

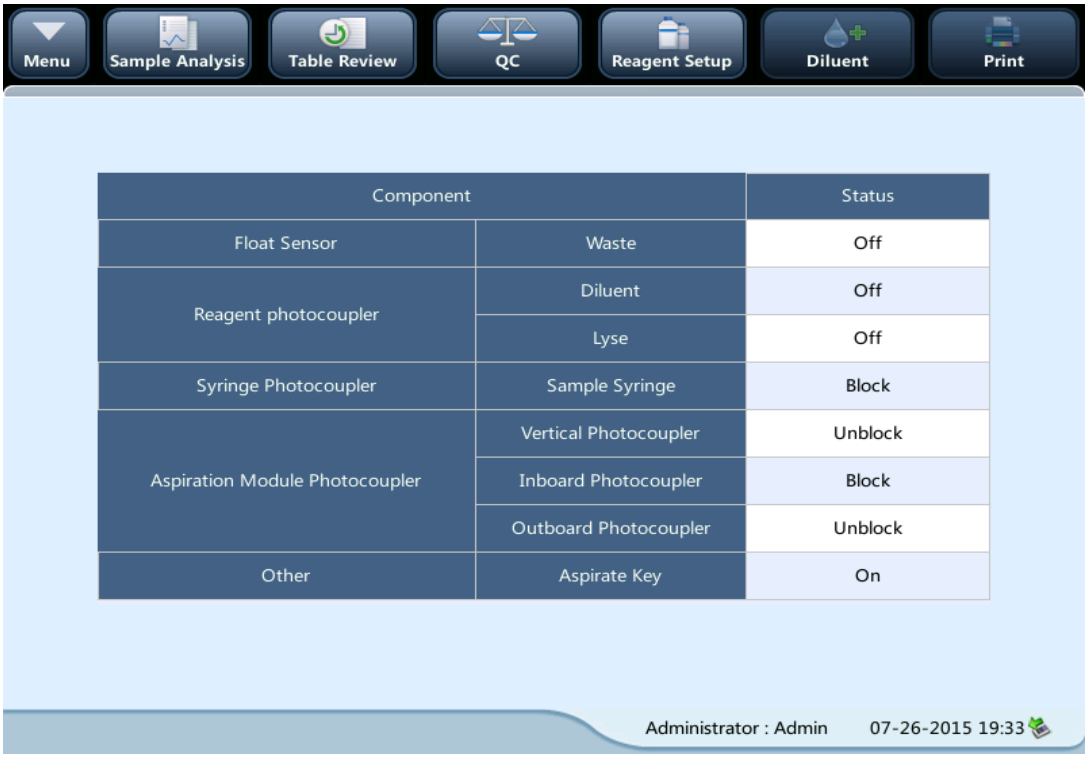
10.9.3 Voltage

Tap "**Status**" > "**Voltage**" in the menu to enter the following screen. You may view the current voltage of the analyzer.

	Volt. (V)	Range
Power +12V	12.1	[11.0, 14.0]
Power +24V	24.6	[20.0, 30.0]
Analog +12V	12.1	[11.0, 13.0]
Analog -12V	-12.2	[-14.0, -9.0]
Digital +56V	55.1	[47.0, 63.0]
HGB Blank Voltage	4.46	[3.85, 4.85]

10.9.4 Sensor

Tap "**Status**" > "**Sensor**" in the menu to enter the following screen. You may view the current sensor information of the analyzer.



10.9.5 Version information

Tap "**Status**" > **"Version Info.**" in the menu. You may view the current version information of the analyzer.

NOTE

- **The version information displayed in the above figure is only for demonstration. Take the queried version information of the analyzer as standard.**

10.10 Cover Sterilization

- **We do not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**

⚠CAUTION

- **Do not use any decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it.**
- **If there is any doubt about the compatibility of the decontamination or cleaning agents with parts of the equipment or with material contained in it, please contact our customer service department or the local distributor.**
- **If you accidently spill hazardous material (for example, reagents and samples) on the instrument, clean and sterilize the instrument with specified disinfectant. Wear proper personal protective equipment (e.g. gloves, lab coat, goggles, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **The user shall perform regular cleaning and sterilization to the cover of the system. Use the specified materials to sterilize the equipment only. For any damage to the instrument or other accidents caused by using materials other than specified, we will not provide any warranty.**
- **We do not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**
- **The sterilization may damage the system to some extent. It is recommended to perform sterilization only when necessary according to your laboratory protocol. Remember to clean the equipment before sterilizing.**

The user shall perform regular cleaning and sterilization to the cover of the system.

Table 10-1 When, Why and Tools Needed

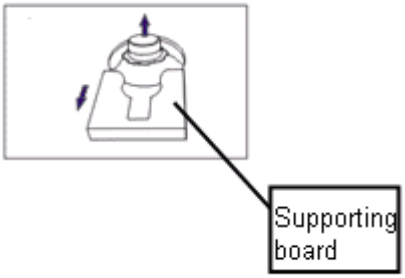
What	When	Why	Tools Needed
Cover Sterilization	As needed.	Remove contaminators on the cover	Recommended disinfectant: 70％ ethanol; 70％ isopropyl alcohol; Cidex 2% Glutaral + Activator. Prohibited disinfectant: 3% hydrogen peroxide; Aerodesin 2000, Cidex OPA .

10.11 Replacing Waste Container

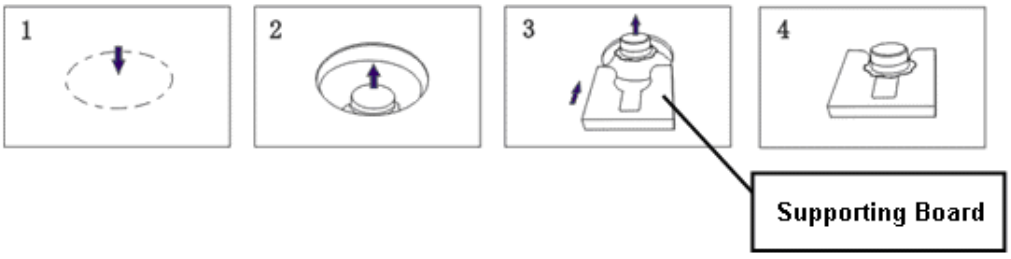
⚠WARNING

- **Be sure to dispose of reagents, wasted waste, samples, consumables, etc. according to the local government's regulations.**
- **To avoid waste overflowing from the container, remove the waste container cap assembly and replace the waste container only when the power indicator is not flickering.**
- **When you are using a waste container to dispose waste, make sure the pickup tube is smooth, not bend, and is above the cap assembly of the waste container.**

1. Remove the cap of a new waste container, and place the container next to the one to be replaced.
2. Remove the supporting board under the old container's cap.



3. Turn the cap counterclockwise and remove the cap assembly from the old container with caution.
4. Insert the old cap assembly into the new container vertically, and secure the cap by turning it clockwise.
5. Install the supporting board under the new container's cap as shown below.



6. Cap the old container with the cap of the new one, and then dispose of the waste properly.

10.12 Replacing Fuse

If the fuse is damaged, please contact our customer service department or your local distributor to replace it.

⚠WARNING

- **Be sure to use the fuse of specified model and specifications to avoid fire hazard.**

11 Troubleshooting Your Analyzer

11.1 Introduction

This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analyzer.

- **Samples, controls, calibrators and waste are potentially infectious. 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.**

NOTE

- **This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer.**

11.2 Error Information and Handling

During the operation, if error(s) is/are detected, the analyzer will beep and display the corresponding error message in the error information area at the bottom right of the screen. Meanwhile, the indicator will turn red.

According to the severity of the errors, the colors of error messages are red, orange, blue.

- Red: fatal error. When this kind of error occurs, the analyzer will stop running immediately, and any further operation is prohibited.
- Orange: error that stops operation. When this kind of error occurs, the analyzer will stop running immediately.
- Blue: error that restricts certain operations. When this kind of error occurs, the analyzer can still continue with the current operation, but any other operations related to the error will be restricted.

The following figure is the error prompt dialog box.

The name and troubleshooting method of the errors are displayed. Names of the errors are displayed by the order of their occurrence.

You may tap to select the error, and view its troubleshooting information in the troubleshooting box. The troubleshooting information of the first error is displayed by default. Follow the instruction in the dialog box to remove error(s).

The following functions are provided:

11.2.1 Clearing the errors

Tap the "**Remove**" button to clear all the errors that can be removed automatically. For the errors that cannot be removed automatically, follow the troubleshooting method to solve them.

11.2.2 Closing the fault prompt dialog box

Tap "**Close**" to close the fault prompt dialog box, but the errors will still be displayed in the error info. area on the screen. Tap the error info. area again, the fault prompt dialog box will be displayed again.

The possible error(s) and the corresponding troubleshooting information are listed below:

Error name	Actions
Main board error	1. Power off the analyzer directly and contact our customer service department.
System clock error	1. Power off the analyzer directly and contact our customer service department.
Diluent ran out	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the diluent container, tap "**Apply**" to prime the diluent. 3. If the problem still persists after replacing the diluent, contact our customer service department.
Diluent ran out	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the diluent container, tap "**Apply**" to prime the diluent. 3. If the problem still persists after replacing the diluent, contact our customer service department.
Lyse ran out	1. Tap "**Remove**", and enter the new barcode of the lyse into the reagent setup dialog box. 2. After replacing the lyse container, tap "**Apply**" to prime the lyse. 3. If the problem still persists after replacing the lyse, contact our customer service department.
Lyse ran out	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the lyse container, tap "**Apply**" to prime the lyse.

Error name	Actions
	3. If the problem still persists after replacing the lyse, contact our customer service department.
Diluent expired	1. Tap "Remove", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the diluent container, tap "**Apply**" to prime the diluent. 3. If the problem still persists after replacing the diluent, contact our customer service department.
Lyse expired	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the lyse container, tap "**Apply**" to prime the lyse. 3. If the problem still persists after replacing the lyse, contact our customer service department.
Waste container full	1. Empty the waste container or use a new waste container. 2. Tap “**Remove**” to see if the error can be removed. 3. If the problem still persists, contact our customer service department.
Power error	1. Power off the analyzer directly and contact our customer service department.
Syringe module error	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Aspiration module lift mechanism error	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Aspiration module rotary mechanism error	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Background abnormal	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
HGB background voltage abnormal	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.

Error name	Actions
Vacuum pressure abnormal	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Diluent temperature goes beyond higher limit	The diluent temperature goes beyond higher limit, contact our customer service department.
Diluent temperature goes beyond lower limit	The diluent temperature goes beyond lower limit, contact our customer service department.
Preheat bath temperature is too high	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Preheat bath temperature is too low	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Clogging (WBC)	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Clogging (RBC)	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Power interfere	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Hemolysis abn.	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Aperture abnormal	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Sys. config abn.	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
Aperture voltage abnormal (WBC)	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.

Error name	Actions
Aperture voltage abnormal (RBC)	1. Tap “**Remove**” to see if the error can be removed. 2. If the problem still persists, contact our customer service department.
No paper or paper jam	1. Please check whether there is no paper or paper jam. 2. Tap "**Remove**" to remove automatically. 3. If the problem persists when you try to print again, contact our customer service department.
Other printer error	1. Tap "**Remove**" to remove automatically. 2. If the problem persists when you try to print again, contact our customer service department.
No paper in the recorder or recorder cover open	1. No paper in recorder. Please install a new roll. 2. Tap "**Remove**" to remove automatically. 3. If the problem persists when you try to print again, contact our customer service department.
Recorder error	1. Tap "**Remove**" to remove automatically. 2. If the problem persists when you try to print again, contact our customer service department.
Communication disconnected	1. Communication disconnected. Please check the network connection. 2. Tap "**Remove**" to remove automatically. 3. If the problem persists when you try to communicate again, contact our customer service department.
Communication error	1. Tap "**Remove**" to remove automatically. 2. If the problem persists when you try to communicate again, contact our customer service department.

12 Appendices

A Index

B Specifications

B.1 Reagents

The analyzer supports the following reagents, controls, and calibrators.

NOTE

- **For any questions about the reagents, controls and calibrators configuration, please consult your sales representative.**

Diluent	M-30D Diluent
Lyse	M-30CFL and M-3CFL Lyse
Probe Cleanser	Probe Cleanser
Controls (Impedance Method)	B30
Controls (Impedance Method)	BC-3D
Calibrators (Impedance Method)	S30
Calibrators (Impedance Method)	SC-CAL PLUS

B.2 Applicable Tubes

Φ12～15×75mm evacuated collection tube (without cap) for whole blood mode

Φ11×40mm (1.5ml centrifugal tube) and 0.5ml centrifugal tube, for predilute and capillary whole blood mode

Φ10.7×42mm small closed anticoagulated tube (without cap), 0.5ml, can be used with cap opened, for capillary whole blood mode. Recommended tube: No. 365974 closed anticoagulated tube (0.5ml) manufactured by BD.

B.3 Parameters

Name	Abbreviation	Default Unit
White Blood Cell count	WBC	10^9/ L
Lymphocyte number	Lymph#	10^9/ L
Mid-sized Cell number	Mid#	10^9 / L
Granulocyte number	Gran#	10^9 / L
Lymphocyte percentage	Lymph%	%
Mid-sized Cell percentage	Mid%	%
Granulocyte percentage	Gran%	%

Name	Abbreviation	Default Unit
Red Blood Cell count	RBC	$\times 10^{12}$/L
Hemoglobin Concentration	HGB	g/L
Hemoglobin Concentration	HGB	g/L
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV	%
Red Blood Cells Distribution Width - Standard Deviation	RDW-SD	fL
Hematocrit	HCT	%
Platelet count	PLT	$\times 10^{9}$/L
Platelet-Large Cell Ratio	*P-LCR	%
Platelet-Large Cell Count	*P-LCC	$\times 10^{9}$/L
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	/
Plateletcrit	PCT	%

Note: The two parameters P-LCR and P-LCC with mark "*" are configurable parameters, which can be configured according to the specific market requirement.

B.4 Sampling Features

B.4.1 Sample Volumes Required for Each Analysis

Whole blood mode	≤ 9μL
Predilute mode	≤ 20μL

B.4.2 Throughput

Whole blood mode	The throughput shall be no less than 40 samples/hour
Predilute mode	The throughput shall be no less than 40 samples/hour

B.5 Performance Specifications

B.5.1 Display Ranges for Major Parameters

Parameter	Display range
WBC	(0.0 ~ 999.9) x 10^9/L
RBC	(0.00 ~ 9.99) x 10^{12}/L
HGB	(0 ~ 300) g/L
MCV	(0.0 ~ 250.0) fL
PLT	(0 ~ 9999) x 10^9/L

B.5.2 Blank Count Parameter Specifications

Parameter	Display range
WBC	≤ 0.2 x 10^9 / L
RBC	≤ 0.02 x 10^{12}/ L
HGB	≤ 1 g / L
HCT	≤ 0.5 %
PLT	≤ 5 x 10^9 / L

B.5.3 Linearity Range

Parameter	Linearity range	Deviation Range (Whole Blood)	Deviation Range (Predilute)
WBC	(0～100.0)×10^9/L	±0.30×10^9/L or ±5％	±0.50×10^9/L or ±5％
RBC	(0～8.00)×10^{12}/L	±0.05×10^{12}/L or ±5％	±0.05×10^{12}/L or ±5％
HGB	(0-280)g/L	±2g/L or ±2％	±2g/L or ±3%
PLT	(0～1000)×10^9/L	±10×10^9/L or ±10%	±10×10^9/L or ±10%
HCT	(0～67)%	±4% (HCT value) or ±6% (percentage error)	/

B.5.4 Reproducibility

Reproducibility range (whole blood)

Parameter	Condition	CV%
WBC	(7.0 ~ 15.0) 10^9 / L	≤ 2.0%
	(4.0 ~ 6.9) 10^9 / L	≤ 3.5%
RBC	(3.50 ~ 6.50) 10^{12} / L	≤ 1.5%
HGB	(100 ~ 180) g/L	≤ 1.5%
MCV	(70.0~ 110.0) fL	≤ 0.5%
PLT	(150 ~ 500) 10^9 / L	≤ 4.0%
	(100~149) 10^9 / L	≤ 5.0%

B.5.5 Carryover

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

B.5.6 Error of Indication

Parameter	Error of indication
WBC	≤±10%
RBC	≤±6%
HGB	≤±7%
PLT	≤±15%

B.6 Input/Output Devices

⚠WARNING

- **Be sure to use the specified devices only.**
- **External equipment connected to the analyzer and digital interfaces must be authorized and complied with relevant safety and EMC standards (e.g. IEC 60950 Safety of Information Technology Equipment Standard and CISPR 22 EMC of Information Technology Equipment Standard (Class B)). Any person who connects additional equipment to the signal input or output ports and configures an IVD system, is responsible for ensuring that the system works normally and complies within the safety and EMC requirements. If you have**

any questions, consult the technical service department of your local representative.

B.6.1 Touch Screen

8 inch TFT color touch screen, supporting 24 bit color at highest, with display resolution of 800×600.

B.6.2 Indicator

The indicator indicates analyzer the status of the analyzer, including on/off, running or sleeping.

B.6.3 Keyboard (Optional)

101-Key alpha-numeric USB keyboard

B.6.4 Mouse(Optional)

USB mouse.

B.6.5 Barcode Scanner (Optional)

External USB barcode scanner

B.6.6 Printer (Optional)

Supports USB printer.

B.6.7 Recorder

A thermal recorder is included.

B.6.8 Buzzer

The buzzer sounds when there is an error. Tap the touch screen or when the error is removed, the buzz alarm will be silent automatically,

B.6.9 USB WiFi Wireless Network Card (Optional)

WiFi wireless network card with chip RTL8192CU

B.7 Interfaces

- One network interface, built-in network card, network access and TCP/IP compatible.
- Four USB ports (USB: DC 5V, 500mA, USB 2.0)

B.8 Power supply

	Voltage	Input power	Frequency
Analyzer	(100V-240V～) ±10%	≤180VA	(50/60Hz)±1Hz

B.9 Fuse

⚠WARNING

- **Only install fuses of specified specification on the system and the pneumatic unit.**

Fuse: 250V T3.15AH

B.10 EMC Description

- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.
- This IVD medical equipment complies with the emission and immunity requirements described in IEC 61326-1:2012 / EN 61326-1:2013 and IEC 61326-2-6:2012 / EN 61326-2-6:2013.
- The intended use environments of this IVD medical equipment includes typical healthcare environments (hospitals, clinics, doctor's offices), this equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- Advise that the electromagnetic environment should be evaluated prior to operation of the device.

NOTE

- **It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.**
- **It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device**

will perform as intended.

B.11 Sound Pressure

Maximal sound pressure: 80 dB

B.12 Normal Operation Environment

- Ambient temperature: 15℃～30℃
- Operating humidity: 20%～85%
- Atmospheric pressure: 70.0kPa～106.0kPa

B.13 Storage and Transportation Environment

- Ambient temperature: -10℃～40℃
- Relative humidity: 10%～90%
- Atmospheric pressure: 50.0kPa～106.0kPa

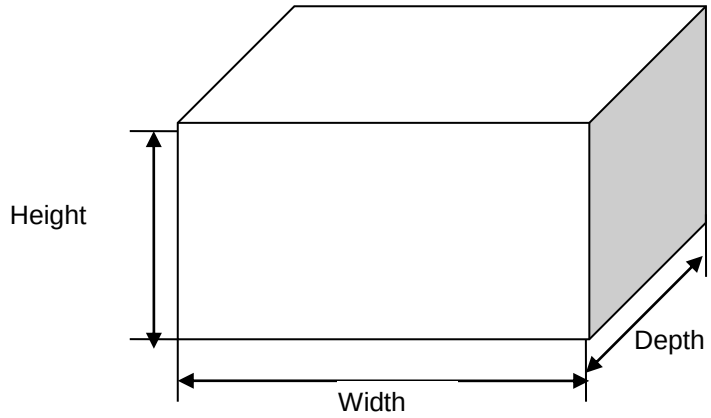
B.14 Running Environment

- Ambient temperature: 10℃～40℃
- Relative humidity: 10%～90%
- Atmospheric pressure: 70.0kPa～106.0kPa

NOTE

- **Be sure to use and store the analyzer in the specified environment.**

B.15 Dimensions and Weight



	Analyzer
Width (mm)	≤300
Height (mm)	≤400 (foot pad included)
Depth (mm)	≤410
Weight (Kg)	≤20

B.16 Contraindication

None

B.17 Safety Classification

Level of transient overvoltage: Category II.

Rated pollution degree: 2.

B.18 Packing List

- Power cord
- Hand-held barcode scanner
- Analyzer
- Waste container cap assembly
- Lyse container cap assembly
- Diluent container cap assembly
- Diluent container supporting board
- Reagent soft bottle
- Operator's Manual (EN)
- Lithium metal battery label

NOTE

- **Your product accessories may vary based on your actual product configuration.**
- **For any questions about the configured/optional accessories, consult your sales representative.**
- **Only use the manufactured or recommended accessories and consumables to achieve the promised system performance and safety. For more information, contact our Customer Service Department or your local distributor.**

B.19 Software Version

Main unit software version: 01

C Communication

The LIS/HIS function of the analyzer enables the communication between the analyzer and the PC in laboratory through Ethernet, including sending analysis results to and receiving worklist from PC.

The LIS/HIS communication protocol involved in communication of the analyzer are 15ID and HL7. For details about the connection control, and the introduction, message definition and examples, please contact our Customer Service Department or your local distributor.

D References

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4. Westgard, J.O., P.L. Barry, and M.R. Hunt (1981). "A Multi-rule Shewhart Chart for Quality Control in Clinical Chemistry,"Clinical Chemistry, vol. 27, pp. 493-501.
5. Westgard, J.O., P.L. Barry (1986). "Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes"AACC Press.7, 8
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E Maintenance Log

NOTE

- **The log table is intended for one month's use. Make enough copies for future use.**
- **Refer to Chapter 10Servicing Your Analyzer for recommended maintenance protocols.**

Manual cleaning:

Days	Instrument cover	Days	Instrument cover
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16			

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