

INTRODUCTION

Thank you for your purchase of Z3/Z3 CRP
Series Hematology Analyzer
manufactured by Zybio Inc.
(Hereinafter referred to as "Zybio")

Before using the product,
please carefully read the Operation Manual
so as to use the product correctly.
Please retain this operation manual after reading,
so that you can consult it as needed.

<u>Product name</u>	Hematology Analyzer
<u>Product models</u>	Z3 CRP, Z3, Z31
<u>Product features and composition</u>	It consists of a main unit and accessories, including an automatic sampling system and a data calculation and processing system.
<u>Intended use</u>	<p>The product works in combination with the matched reagents produced by Zybio for quantitative detection of the analytes in human blood samples in clinical settings through the electric impedance, colorimetric and <u>scattering turbidimetry</u> methods.</p> <p>The 23 test items include white blood cell count (WBC #), lymphocyte count (Lym #), intermediate cell count (Mid #), neutrophil count (Gran #), lymphocyte percentage (Lym %), intermediate cell percentage (Mid %), neutrophil percentage (Gran %), red blood cell count (RBC #), hemoglobin (HGB), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red blood cell distribution width-coefficient of variation (RDW-CV), red blood cell distribution width-standard deviation (RDW-SD), hematocrit (HCT), platelet count (PLT #), mean platelet volume (MPV), platelet distribution width (PDW), plateletcrit (PCT), platelet-large cell ratio (P-LCR), platelet-large cell count (P-LCC), C-reactive protein (CRP), and hypersensitive C-reactive protein (Hs-CRP). Models z3 and z31 do not test C-reactive protein (CRP) or hypersensitive C-reactive protein (hs-CRP).</p> <p>Number of product technical requirements / Registration certificate number: YXZZ 20182400068</p> <p>Production license number: YSYJXSCX 20150016</p>
<u>Manufacturer</u>	Zybio Inc.
<u>Domicile of registrant</u>	Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082
<u>Production address</u>	Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082
<u>Date of production</u>	See the nameplate of the main unit
<u>Service life</u>	7 years. This service life is determined according to the lifespan test performed on the instrument. In the course of use, the user shall carry out maintenance and repair of the product according to the Operation Manual. After maintenance and repair, a product that has been confirmed to maintain its basic safety and effectiveness can be used normally.
<u>Release date</u>	2017-10-12

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- The assembly, extensions, readjustments, modifications, and repairs are performed by professionals authorized by Zybio.
- All replacement parts used in the repairs and all accessories and consumables used are products of or approved by Zybio.
- Relevant electrical equipment conforms to national standards and the requirements of this manual.
- The operation of the product shall be carried out in accordance with this manual.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OF FITNESS FOR ANY PARTICULAR PURPOSE.

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Zybio's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Zybio or repairs by people other than Zybio authorized personnel.

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 - Malfunction or damage caused by force majeure such as fire and earthquake.
 - Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
 - Malfunction of the instrument or part whose serial number is not legible enough.
 - Others not caused by instrument or part itself.

After-sales service

Contact: Zybio Inc.
Address: Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China, 400082
Te l: +86 (0)23-6865 5509 **Website:** www.zybio.com
Fax: +86 (0)23-6869 9779 **24-hour service hotline:** 400-056-7879

EC- Representative: Shanghai International Holding Corp. GmbH(Europe)
Address: Eiffestraße 80, 20537 Hamburg, Germany
Te l: 0049-40-2513175 **Fax:** 0049-40-255726

Warning

- This system can only be operated by laboratory professionals, doctors, or laboratory technicians who have been trained by Zybio or by the agents of Zybio.
- If the hospitals or institutions responsible for using this instrument fail to implement a satisfactory maintenance/repair plan, it may cause abnormal instrument failure and may endanger personal health.
- Ensure that the analyzer is used under the conditions specified in the MANUAL. If the usage conditions are not met, the analyzer may not operate normally, its measurement results will not be reliable, or its components may be damaged and personal safety may be endangered.

Precautions

- This equipment must be used by skilled/trained clinical professionals.

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CHAPTER 1

USING THIS MANUAL

Introduction

This chapter explains how to use your Z3/Z3 CRP Series’ operation manual, which is shipped with your Z3/Z3 CRP Series HEMATOLOGY ANALYZER and contains reference information about the analyzer and procedures for operating, troubleshooting and maintaining the analyzer. Read this manual carefully before operating your Z3/Z3 CRP Series analyzer and operate your Z3/Z3 CRP Series analyzer strictly as instructed in this manual.

Who Should Read This Manual

This manual is intended to be read by clinical laboratory professionals. This equipment must only be operated by skilled/trained clinical professionals. This information contains information for clinical laboratory professionals to:

- Learn about the hardware and software of Z3/Z3 CRP Series Hematology Analyzer;
- Customize system parameters;
- Perform daily operations;
- Perform system maintenance and troubleshooting.

How to Find Information

This operation manual comprises 11 chapters and 4 appendices. Refer to the table below to find the information you need.

CHAPTER	INTRO DUTION
Using This Manual	Introduces how to use this manual of Z3/Z3 CRP Series Hematology Analyzer.
Understanding Your Analyzer	Introduces the composition, software interface, and software operation of Z3/Z3 CRP Series Hematology Analyzer.
Working Principles	Introduces the measuring principles and workflow of the Z3/Z3 CRP Series Hematology Analyzer.
Installing Your Analyzer	Introduces the installation requirements and installation methods for Z3/Z3 CRP Series Hematology Analyzer.
Operating Your Analyzer	Introduces daily operations such as the methods of sample collection and preparation, the process of sample analysis, and turning the system on/off.
Reviewing Sample Results	Introduces the process for reviewing of the results of the sample analysis.

Conventions used in This Manual

This manual uses different fonts and formats to distinguish content with special meanings in the text.

FORMAT	DESCRIPTION
[xx]	xx stands for a button in an external keyboard or panel
“xx”	xx stands for the information displayed in the interface
xx	xx stands for the quoted chapter

All illustrations provided in this manual should be used only for reference. The graphs, settings, or data in the illustrations may not exactly match the actual display you see on Z3/Z3 CRP Series Hematology Analyzer.





CHAPTER	INTRODUCTIONW
Using the QC Programs	Introduces the basic requirements for QC and the QC methods provided by Z3/Z3 CRP Series Hematology Analyzer.
Using the Calibration Programs	Introduces the basic requirements for calibration and the calibration methods provided by Z3/Z3 CRP Series Hematology Analyzer.
Customizing the Analyzer Software	Introduces the configuration of system parameters, such as software date format and parameter units.
Maintaining Your Analyzer	Introduces the maintenance and testing processes of Z3/Z3 CRP Series Hematology Analyzer.
Troubleshooting Your Analyzer	Introduces the troubleshooting processes of Z3/Z3 CRP Series Hematology Analyzer.
Appendix A Specifications	Introduces the specifications of Z3/Z3 CRP Series Hematology Analyzer.
Appendix B Key Parts	Introduces the key parts of Z3/Z3 CRP Series Hematology Analyzer.
Appendix C List of Spare Parts	Lists the spare parts for Z3/Z3 CRP Series Hematology Analyzer.
Appendix D Names and Contents of Toxic and Hazardous Substances or Elements	Introduces the toxic and harmful substances or elements in the Z3/Z3 CRP Series Hematology Analyzer and their contents.

Common Operations















ACTION	OPERATION PERFORMED
Click	Tap the xx key or button with your finger or click on xx using the left mouse button.
Enter	Click the “xx” edit box to move the cursor to the appropriate field and use the keyboard or on-screen keyboard to complete the data entry
Delete	Click the left mouse button, or tap directly on the touch screen, or use the [←][→][Home][End] keys on the external keyboard to move the cursor to the point where you want to delete, and then use the [Del] key to delete the character following the cursor or use the [BackSpace] key (the [←] key in the upper right corner of the on-screen keyboard) to delete the character before the cursor.
Select from the drop-down list xx (only for a drop-down list)	Click on the down arrow button in the “xx” box to bring up the drop-down list, (drag the scroll bar to) browse through the current list, and then click on the field in the current list to select; or use the [↑][↓] [PageUp][PageDown] keys to browse the current list and press [Enter] to select the field where the arrow is located.

Safety Information

Symbols used in the MANUAL:

WHEN YOU SEE...	MEANING
	read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
	read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
	read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
	read the statement below the symbol. The statement is alerting you to information that requires your attention.

The analyzer system may contain the following symbols:

WHEN YOU SEE...	MEANING
	Biological risk
	Caution, Consult accompanying Documents
	Exercise caution when working Around to avoid pricking
	Protective earth (ground)
	Alternating current
	For in vitro diagnostic use
	Batch code
	Use by
	Serial number
	Date of manufacture
	Manufacturer
	Consult the operation manual
	Temperature limitation
	The device is fully conformance With the council directive Concerning in vitro diagnostic Medical devices 98/79/ec.

CHAPTER 2

UNDERSTANDING YOUR ANALYZER

Introduction

Z3/Z3 CRP SERIES HEMATOLOGY ANALYZER works in combination with the diagnostic reagents produced by Zybio for quantitative detection of the analytes in human blood samples in clinical settings through electric the resistance method, colorimetric method and scattering turbidimetry method.

Product Models

This product has three models: Z3 CRP, Z3, and Z31. The working principles, main functions, electrical structure and key components of the various models are basically the same. The only difference is their functional configuration (see Table 1 below for details). Therefore, the full-featured Z3 CRP model can cover the Z3 and Z31 models during the registration check.

MODEL	FUNCTIONAL CONFIGURATION
Z3 CRP	Contains the full functionality of all models, with a testing throughput of 70 samples per hour
Z3	Compared with the Z3 CRP model, this model does not include the function of measuring the results of CRP-related parameters, and the testing throughput is 70 samples per hour.
Z31	Compared with the Z3 CRP model, this model does not include the function of measuring the results of CRP-related parameters or the function of providing the results of PLCC/PLCR parameters, and the testing throughput is 60 samples per hour.

Table 2-1 Model Differences

Product Description

Z3/Z3 CRP Series Hematology Analyzer comprises of a main unit and accessories, including an automatic sampling system and a data calculation and processing system.

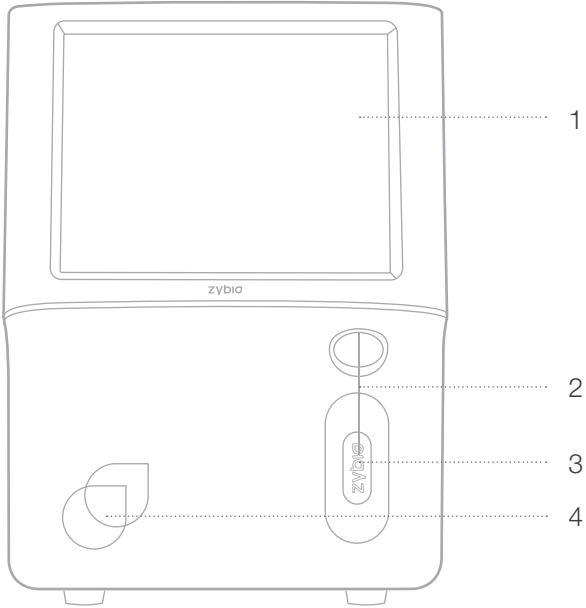


Figure 2-1 Front of the Main Unit

- 1-Touch screen
- 2-Sample probe
- 3-Aspirate key
- 4-Indicator light

This manual uses different fonts and formats to distinguish content with special meanings in the text.

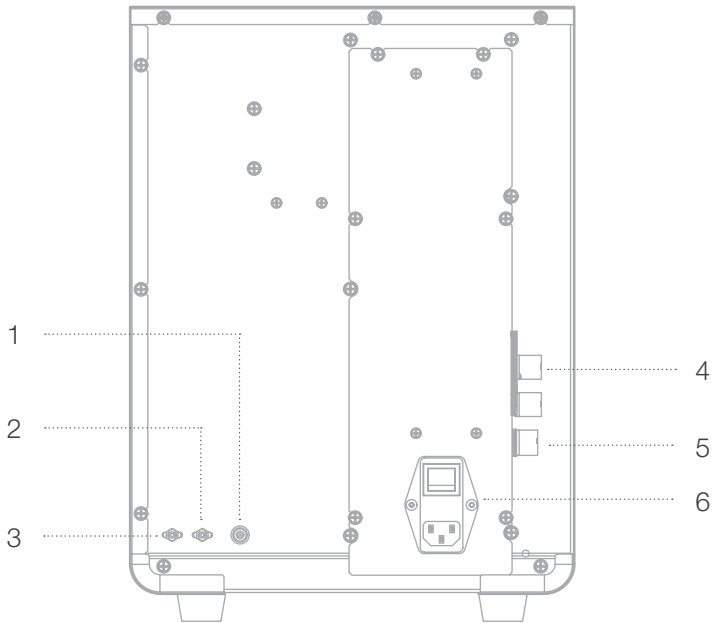


Figure 2-2 Back of the Main Unit

- 1-Waste sensor
- 2-Waste tube connector
- 3-Diluent tube connector
- 4-USB port
- 5-Network port
- 6-Power component

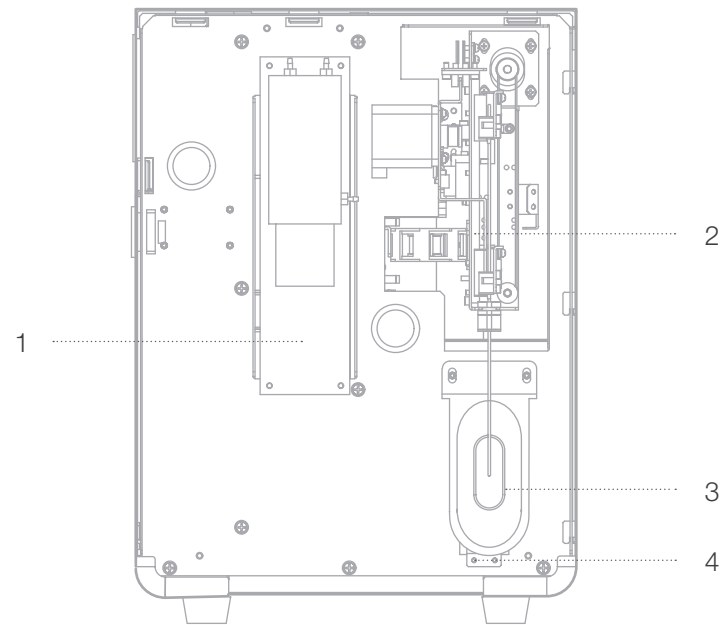


Figure 2-3 View with the Front Panels Removed

- | | |
|----------------------|---------------------|
| 1-Syringe component | 3-Aspirate key |
| 2-Sampling component | 4-Aspirating switch |

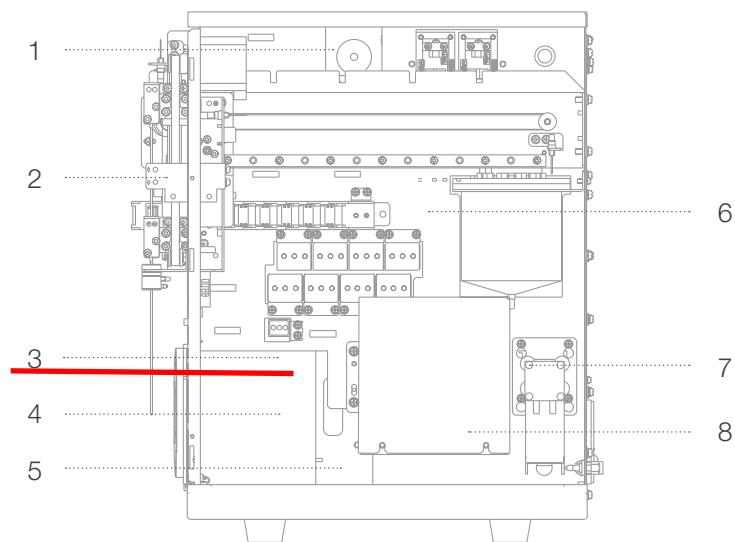


Figure 2-4 Right of the main unit (the right door opened)

- | | |
|---------------------------|------------------------------|
| 1-Air pump | 5-R2 kit |
| 2-Sampling component | 6-Vacuum chamber |
| <u>3-Valve</u> | 7-Liquid pump |
| 4-CRP measuring component | 8-Counting chamber component |

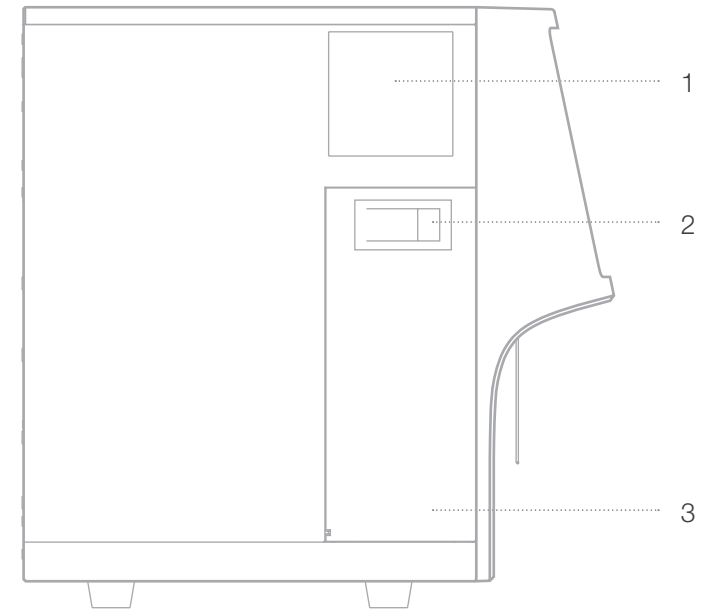


Figure 2-5 Left of the main unit

- | | |
|------------------|-------------|
| 1-Recorder | 3-Side door |
| 2-Side door lock | |

Touch Screen

The touch screen is located on the front of the analyzer and is used to perform interface operations.

Aspirate Key

The aspirating key is located behind the sample probe and is used to start the counting operation, add the diluent or draw the maintenance reagents.

Indicator Light

The indicator light is located on the front side and is used to indicate the current status of the system, providing red, yellow and blue status indicators.

USB port

The analyzer has 4 USB ports for connecting the external mouse, keyboard and USB flash disk during debugging, maintenance and upgrading.

Network Port

The analyzer has a network port on the back, which is used for connecting to an external computer to transmit data.

Operating Interface

Screen Display

After the startup completed, the "Sample Analysis" interface is displayed, as shown in the following figure.



Figure 2-6 "Analysis" Interface

Menu Functions

Press the "Management" button to open the system menu as shown in the following figure.

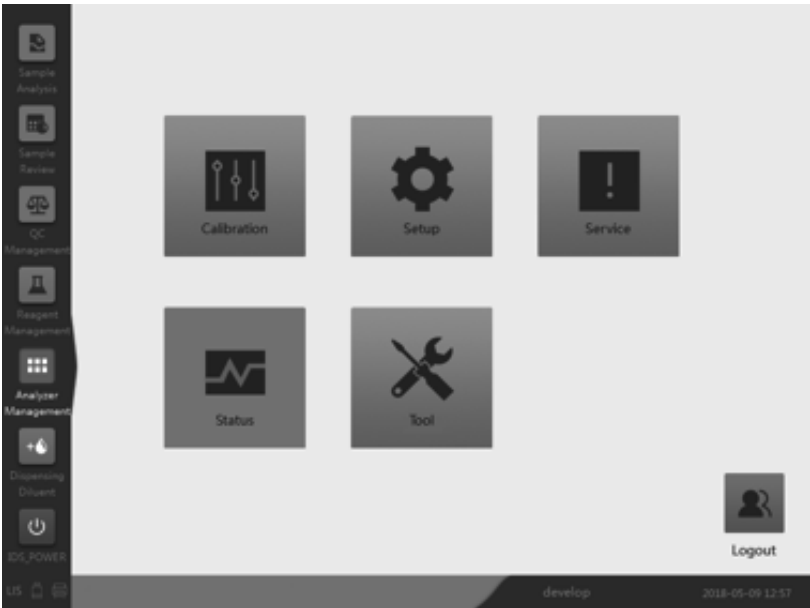


Figure 2-7 "Management" Interface

The management menu includes 4 options, and the operator accesses the corresponding interface through the system menu options to perform various functions of the analyzer.

Reagents
Controls and Calibrators

The analyzer, reagents, controls and calibrators together constitute a system, which must be used as a whole to ensure proper performance. The operator must use the reagents produced by Zybio. Otherwise, the analyzer may be damaged and cannot meet the performance specifications described in the MANUAL. Unspecified reagents cannot guarantee reliable analysis results. "Reagents" in the MANUAL refer to the reagents used in combination with this analyzer. Before each reagent is used, the package must be checked. Damage to the package may affect the quality of the reagent. Check the package for signs of moisture or leakage. If such signs are noted, do not use the reagent.

NOTE

- Please refer to the MANUAL of each reagent to use or store it.
- The operator should carry out background tests after replacing the diluent, hemolytic agent (hereinafter referred to as "lyse") or cleanser to ensure that the background value is within the normal range, so as to prepare for sample analysis.
- Ensure that the reagent is used before the expired date indicated on the reagent's labels.
- The reagents should stand motionless for a period of time until they become stable.

Reagents

- Diluent

This is an isotonic liquid with a specific electric conductivity. It is used to dilute blood samples and provides a stable environment for blood cell counting.
- Lyse

This is used for dissolving RBCs and generating hemoglobin complex. It is used for human WBC counting, WBC grouping and hemoglobin determination.
- R1 Reagent

This is a CRP reaction buffer used with R2 reagent to determine the content of CRP in human serum.
- R2 Reagent

This is a CRP antibody used with R1 reagent to determine the content of CRP in human serum.
- Probe Cleanser

This is used for regular maintenance and cleaning of the analyzer.

Controls and Calibrators

The controls and calibrators are used for QC and calibration of the analyzer.

The controls are mainly composed of leucocyte-like cells, human erythrocytes, platelet-like cells, preservatives and antiseptics. They are used for daily testing WBC, RBC, HGB, MCV/HCT, PLT, and other parameters of Zybio's analyzer, so as to monitor or evaluate the precision of the results of the analyzer. There are three levels of controls: low, normal and high. Daily QC runs can monitor the operation of the analyzer to ensure the reliability of the results.

The calibrators are mainly composed of leucocyte-like cells, human erythrocytes, platelet-like cells, preservatives and antiseptics, and they are used for calibrating WBC, RBC, HGB, MCV / HCT, PLT and other parameters of Zybio's Automated Hematology Analyzer, thus establishing the metrological traceability of the results of the analyzer.

Refer to the MANUALs of the controls and calibrators for their use and storage.

CRP Calibrators and CRP QC

CRP calibrators and CRP controls are used for the calibration and QC of the analyzer.

CRP calibrators are an industrially-produced serum-like product used for the calibration of this analyzer, thus establishing the metrological traceability of CRP results of the analyzer. There are six calibrator levels: a, b, c, d, e, and f. CRP controls are an industrially-produced serum-like product, which are used to monitor and evaluate the precision of CRP results of the analyzer. There are two levels of controls: I and II. Running the two levels of QC daily can monitor the operation of the analyzer and ensure the reliability of the results. Refer to the MANUAL of CRP controls and calibrators for their use and storage.

The "C-reactive protein (CRP) controls" and "C-reactive protein (CRP) calibrators" mentioned in the MANUAL refer to the special controls and calibrators designated by Zybio, and users must purchase them from Zybio or its agents.

CHAPTER 3

UNDERSTANDING THE
SYSTEM PRINCIPLES**Introduction**

The analyzer uses electrical impedance method to detect the number and volume distribution of WBCs, RBCs and platelets; it uses colorimetry to measure the hemoglobin concentration, and uses immunoturbidimetry to measure the CRP content. Then, the analyzer calculates the results of other parameters.

Aspiration

In the whole blood (hereinafter referred to as WB) mode, the operator can send the WB sample directly to the analyzer for sampling. In this case, the analyzer will aspirate a quantified volume of WB sample.

In the pre-dilution (hereinafter referred to as PD) mode, the operator should first mix 20 μL of capillary blood sample and 0.58 mL of diluent outside the machine to form a diluted sample with a dilution ratio of 1: 30, and then send the diluted sample to the analyzer for sampling. In this case, the analyzer will aspirate a quantified volume of the diluted sample.

Dilution

Various cells usually overlap each other in the samples submitted for testing. In this case, the analyzer cannot accurately count blood cells or determine the volume distribution of blood cells.

Therefore, the samples need to be diluted before the analyzer counts blood cells or determines their volume distribution. The diluted sample allows single blood cells to pass through the detecting aperture individually, and at the same time, it provides a conducive environment for counting so as to facilitate cell counting and determination of cell volume. Usually, RBCs are 1,000 times more than WBCs.

Therefore, the interference of RBCs must first be eliminated before measuring WBCs. RBCs usually have no nucleus, and the lyse can dissolve the erythrocyte membrane so as to eliminate the RBCs in the WBC dilution.

Therefore, the lyse should be added to the diluted WBC samples to eliminate RBCs before counting. The analyzer provides two different working modes - the WB mode and the PD mode for different types of samples.

The analyzer also provides three measurement modes - CBC, CBC + CRP, and CRP.

CBC WB mode

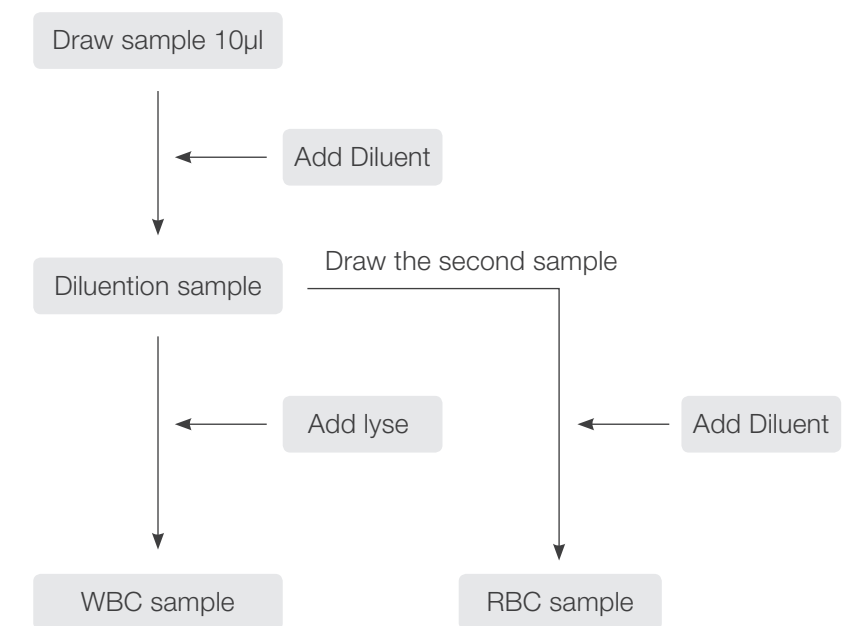


Figure 3-1 The dilution process for WB mode

As shown in Figure 3-1, when the aspirated sample volume is 10 μL in the WB mode, the analyzer aspirates a 10 μL WB sample which is then mixed with the diluent to form a diluted sample. This diluted sample will be used in two parts: One part is mixed with the diluent to form a secondary diluted sample, which is used for counting RBCs and platelets and generating a corresponding distribution histogram. The other part is mixed with the lyse to form another sample, which is used to measure the hemoglobin concentration and count WBCs, and generate a histogram of WBC distribution.

CBC + CRP WB Mode

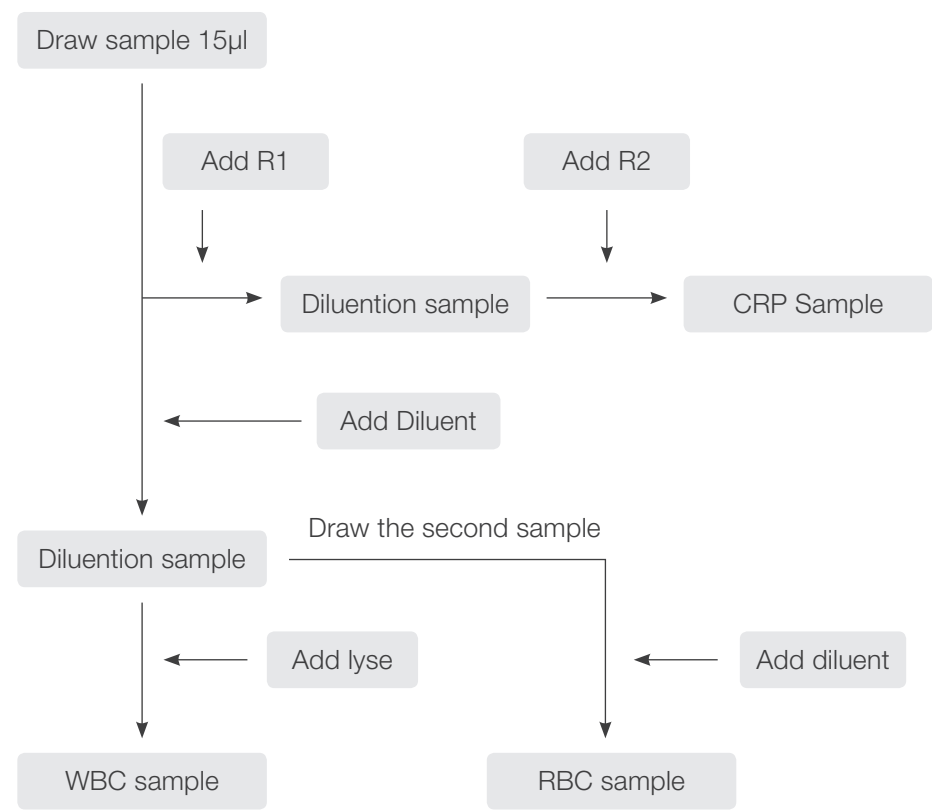


Figure 3-2 The dilution process for CBC + CRP WB mode

As shown in Figure 3-2, when the aspirated sample volume is 15 μL in the CBC+CRP WB mode, the analyzer aspirates a 15 μL WB sample and 4 μL of the sample is mixed with R1 to form a CRP diluted sample, and then R2 is added. The resulting sample is used for CRP measurement.

The remaining sample is mixed with the diluent to form a diluted CBC sample. This diluted sample will be used in two parts: A part is mixed with the diluent to form a secondary diluted sample, which is used for counting RBCs and platelets and generating a corresponding distribution histogram. The remaining sample is mixed with the lyse to form another sample, which is used to measure the hemoglobin concentration and count WBCs, and generate a histogram of WBC distribution.

CRP WB Mode

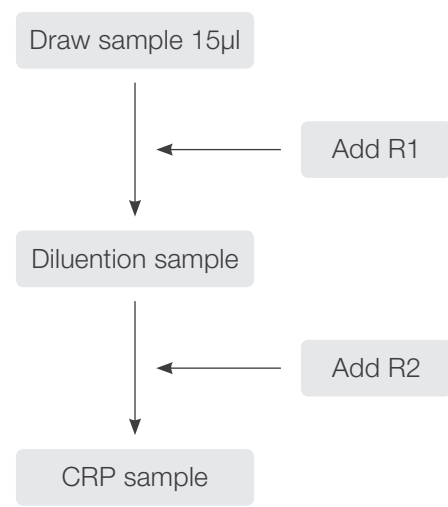


Figure 3-3 The dilution process for CRP WB mode

As shown in the figure above, when the aspirated sample volume is 15 μL in the CRP WB mode, the analyzer aspirates a 15 μL WB sample and 4 μL of the sample is mixed with R1 to form a CRP diluted sample, and then R2 is added. One part is used for CRP measurement. The other part is tested for the HCT value, which is used to correct the CRP results.

CBC PD Mode

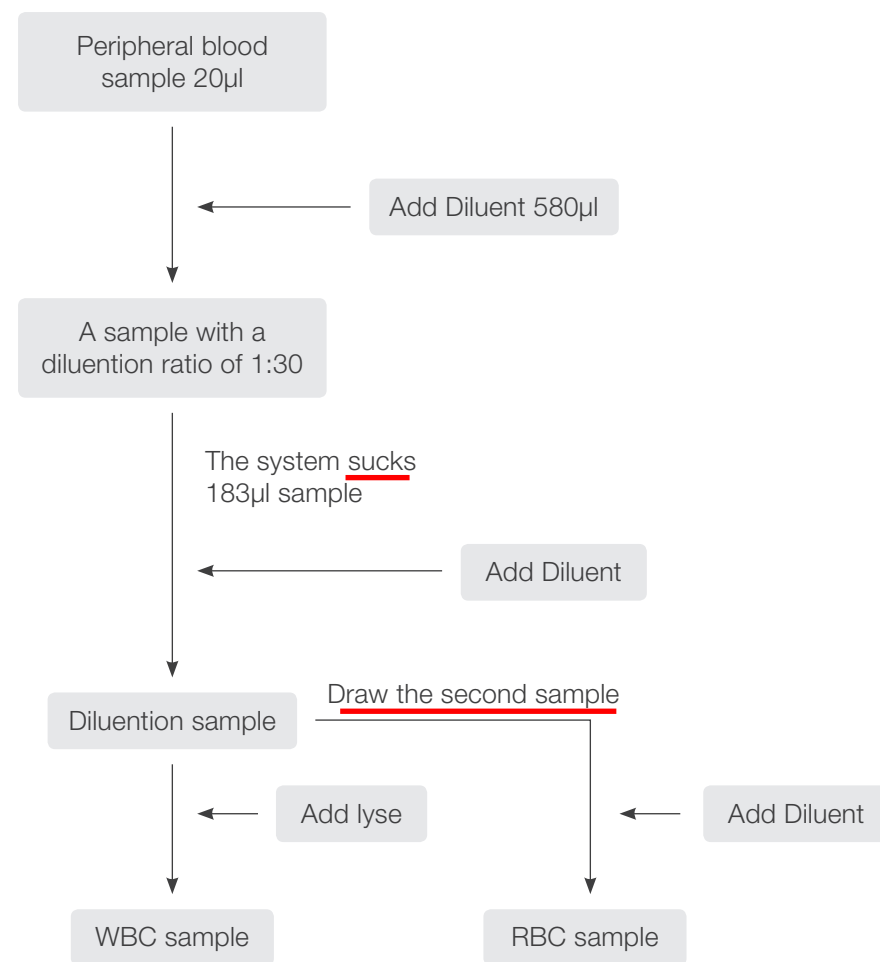


Figure 3-4 The dilution process for PD mode

As shown in the figure above, in the PD mode, 20 μL of capillary blood is mixed with the diluent (Out of Machine dilution) to form a diluted sample. The analyzer aspirates 183 μL of the diluted sample and then it is added with the diluent to form a secondary diluted sample. This diluted sample will be used in two parts: One part is mixed with the diluent to form a secondary diluted sample, which is used for counting RBCs and platelets and generating a corresponding distribution histogram. The other part is mixed with the lyse to form another sample, which is used to measure the hemoglobin concentration and count WBCs, and generate a histogram of WBC distribution.

CBC + CRP PD Mode

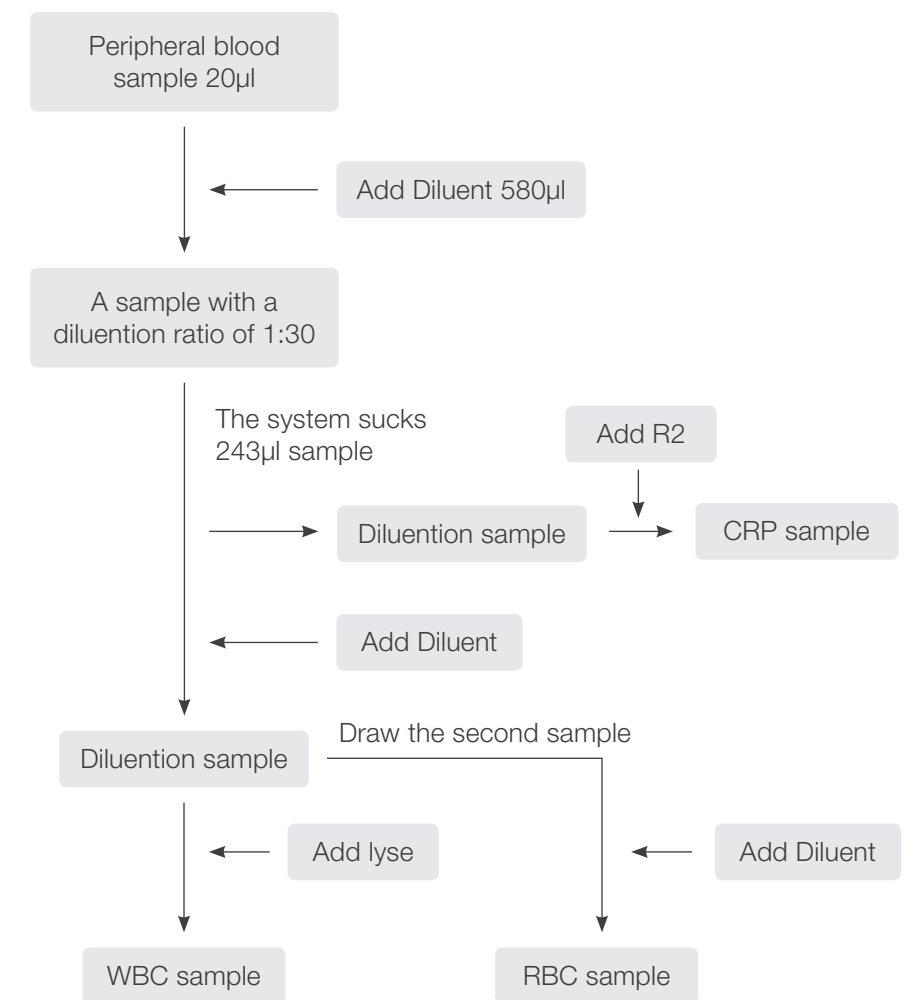


Figure 3-5 The dilution process for PD mode

As shown in the figure above, in the PD mode, 20 μL of capillary blood is mixed with the diluent (Out of Machine dilution) to form a diluted sample. The analyzer aspirates 243 μL of the diluted sample and adds 60 μL to the CRP chamber, and then R2 is added after mixing to form a CRP sample.

The remaining 183 μL is added with the diluent to form a secondary diluted sample. This diluted sample will be used in two parts: One part is mixed with the diluent to form a secondary diluted sample, which is used for counting RBCs and platelets and generating a corresponding distribution histogram. The other part is mixed with the lyse to form another sample, which is used to measure the hemoglobin concentration and count WBCs, and generate a histogram of WBC distribution.

CRP PD Mode

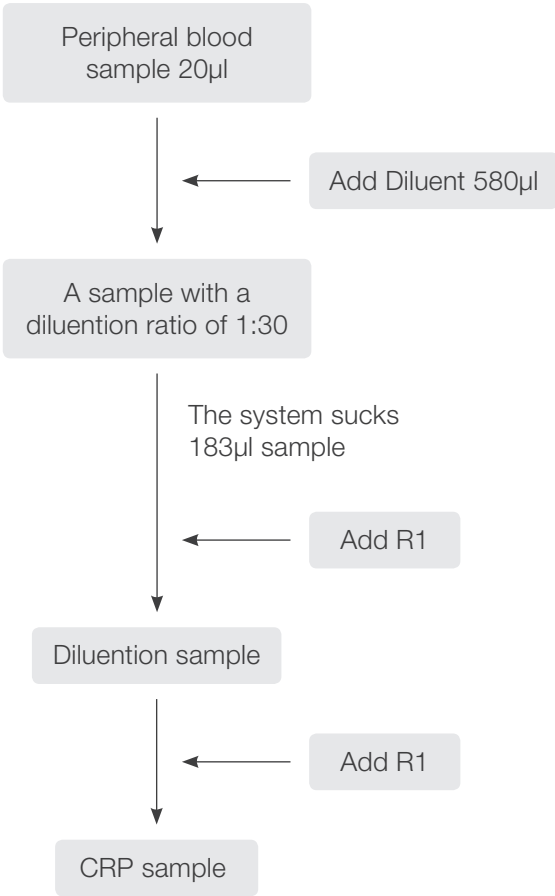


Figure 3-6 The dilution process for CRP PD mode

As shown in the figure above, in the PD mode, 20 μL of capillary blood is mixed with the diluent (Out of Machine dilution) to form a diluted sample. The analyzer aspirates 243 μL of the diluted sample and adds 60 μL to the CRP chamber, and then R2 is added after mixing to form a CRP sample. The remaining sample is tested for the HCT value to correct the CRP results.

WBC/HGB
Measurement

Measuring Principles

- WBC counting principle
- WBCs are counted and sized by the Coulter method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated signals the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle. Each pulse is amplified and compared to the internal reference voltage channels, which only accepts the pulses of certain amplitude. If the pulse generated is above the WBC threshold, it is counted as a WBC.

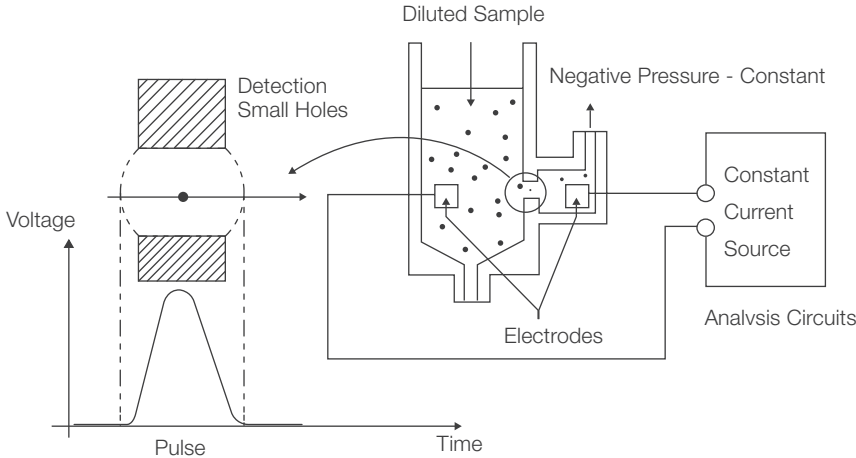


Figure 3-7 Schematic of counting process

- Principle of hemoglobin measurement

The hemoglobin concentration is measured by colorimetry. In the WBC counting chamber, after lyse is added to the diluted sample, the erythrocyte membrane is dissolved to release hemoglobin, and the latter forms a hemoglobin complex after being combined with the lyse. On one side of the WBC counting chamber, the hemoglobin complex solution is illuminated with an LED monochromatic luminous tube with a center wavelength of 525 nm. On the other side, a photocell receives the transmitted light. The light intensity signal is first converted into a current signal, then into a voltage signal and amplified. The hemoglobin concentration (HGB) of the sample (g/L) is determined by comparing with the voltage generated by the background intensity of transmitted light measured before the sample is introduced to the WBC counting chamber (i.e., there is only the diluent in the counting chamber). This measurement and calculation process is automatically conducted by the analyzer, and the results will be displayed in the Results area of the “Count” interface.

WBC Parameters

- WBC count

The analyzer obtains the WBC count (WBC #) (10⁹/L) by directly counting electric pulses corresponding to WBCs.

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

- WBC grouping

WBCs involve many types of cells that can be divided according to their volume. The volume of each type of cell varies depending on the diluent and lyse added, and the hemolysis time. WBCs can be divided into three groups by using certain reagents. They are: lymphocytes, middle size cells (including monocytes, eosinophils, and basophils), and neutrophils.

The analyzer calculates the percentage of lymphocytes (Lym%), the percentage of intermediate cells (Mid%), and the percentage of neutrophils (Gran%) according to the histogram of WBC distribution using the following formulae.

Lym%=

PL

PL + PM + PG

x 100

Mid%=

PM

PL + PM + PG

x 100

Gran%=

PG

PL + PM + PG

x 100

Where, PL is the number of cells in the lymphocyte region, PM is the number of cells in the intermediate cell region, and PG is the number of cells in the neutrophilic region. The unit of these three parameters is 10⁹/L.

Based on the percentage of cells in each subpopulation calculated according to the above formulae, the analyzer automatically calculates the count of lymphocytes (Lym#), the count of middle size cells (Mid#) and the count of neutrophils (Gran#) according to the following formulae. The unit of these three parameters is 10⁹/L.

Lym#=

Lym%×WBC

100

Mid#=

Mid%×WBC

100

Gran#=

Gran%×WBC

100

Where, the unit of Lym%, Mid%, and Gran% is %, and the unit of WBC is 10⁹/L.

- WBC distribution histogram

The analyzer provides WBC volume distribution graphs while providing WBC count results. The abscissa of the histogram is the volume of WBCs (unit: fL) and the ordinate is the relative number of WBCs (unit: 10⁹/L). After each count, the WBC distribution histogram can be viewed in the Result area of the “Analysis” interface. It can also be viewed in the “Review” interface in a retrospective manner.

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

HGB Measurement

The analyzer compares the measured voltage with the voltage of the background transmitted light to calculate the hemoglobin concentration (HGB) in g/L.

HGB=

Constant×Log₁₀

Blank Photocurrent

Sample Photocurrent

RBC/PLT Measurement

Electrical Impedance Method

RBCs/PLTs are counted and sized by the Electrical Impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. A pair of electrodes is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated represents the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

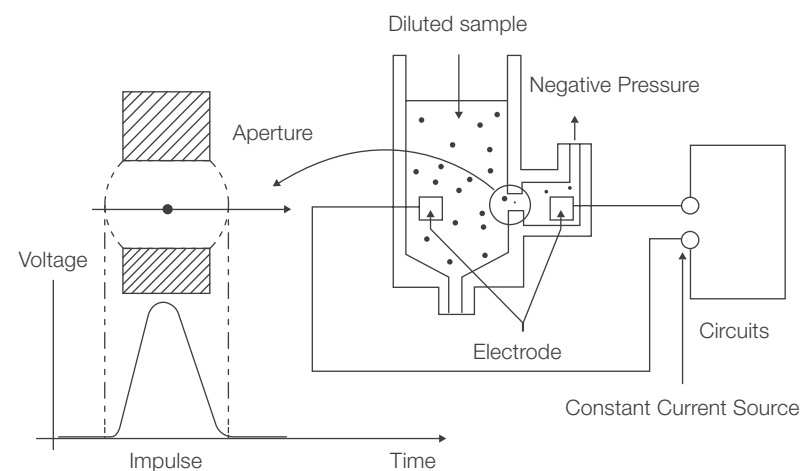


Figure 3-8 Electrical Impedance Method

Derivation of RBC-Related Parameters

- RBC

The analyzer counts RBCs (RBC #) in $10^{12}/L$ by directly counting electrical pulses corresponding to RBCs.

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

- Mean corpuscular volume (MCV)

Based on the RBC distribution histogram, the MCV can be calculated in fL.

- Hematocrit (HCT), mean corpuscular hemoglobin content (MCH), mean corpuscular hemoglobin concentration (MCHC)

HCT in %, MCH in pg, and MCHC in g/L can be calculated using the following formulae.

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

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

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

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

- RBC distribution width - coefficient of variation (RDW-CV)

RDW-CV is derived from the distribution histogram of RBCs. It is the coefficient of variation of the volume distribution expressed as a percentage.

- RBC distribution width - standard deviation (RDW-SD)

RDW-SD is the width of the histogram at the 20% peak of the histogram of the distribution of RBCs in fL, as shown in Figure 3-5.

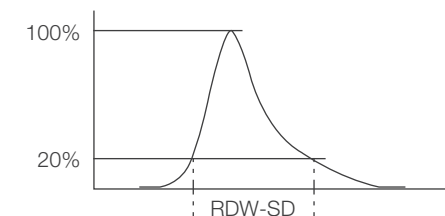


Figure 3-9 Schematic Diagram

- Histogram of RBC distribution

The analyzer provides the RBC volume distribution graph while giving the RBC count results. The graph that can represent the distribution of the cell population is called the RBC distribution histogram. The abscissa of the histogram is the RBC volume (unit: fL) and the ordinate is the relative number of RBCs (unit: $10^{12}/L$). After each count, you can view the RBC distribution histogram in the "Results" area of the "Analysis" interface, or you can enter the "Review" interface to view the RBC distribution histogram in a retrospective manner.

Derivation of PLT-Related Parameters

- PLT

The analyzer counts platelets (PLT) in 10⁹/L by directly counting electrical pulses corresponding to platelets.

$$PLT= \text{ n}\times10^9/L$$

- Mean platelet volume (MPV)

Based on the histogram of platelet distribution, MPV is calculated in fL.

- Platelet distribution width(PDW)

Assuming that the peak height is 100%, the distribution width at the 20% frequency level is PDW in fL.

- Plateletcrit (PCT)

The analyzer calculates PCT in % using the following formula. Where, PLT is in 10⁹/L and MPV in fL.

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

- Platelet-large cell ratio (P-LCR)

According to the histogram of platelet distribution, P-LCR is calculated in %.

- Platelet-large cell count (P-LCC)

Based on P-LCR and the platelet count, P-LCC is calculated in 10⁹/L.

$$P-LCC= PLT \times P - LCR$$

- Histogram of platelet distribution

The analyzer provides the platelet volume distribution graph while giving the platelet count results. This graph that shows the distribution of this cell subpopulation is called the platelet distribution histogram. The abscissa of the histogram is the platelet volume (unit: fl) and the ordinate is the relative number of platelets (unit: 109/ L). After each count, you can view the platelet distribution histogram in the "Results" area of the "Analysis" interface, or you can enter the "Review" interface to view the platelet distribution histogram in a retrospective manner.

CRP Measurement

The analyzer measures the concentration of CRP by immunoturbidimetry. The HCT correction technique is used to obtain the CRP concentration with higher accuracy.

Immunodiffusion Turbidimetry Method

The analyzer emits monochromatic light at a certain wavelength into the CRP chamber, and the light scatters when encountering the antigen (CRP)-antibody complexes. The analyzer receives the scattered light through a photocell and then amplifies the light intensity signal and converts it into a voltage signal. The analyzer obtains the CRP concentration of the sample by comparing the measured voltage signal with the voltage generated by the background light intensity measured before adding the sample to the CRP chamber. The intensity of the scattered light is directly proportional to the content of the complexes, that is, the more antigen (CRP) in the sample, the more complexes form and the stronger the scattered light.

HCT Corrected CRP Results

The analyzer uses the HCT correction technique to calculate the CRP concentration in serum, thus improving the accuracy of the results.

C-reactive Protein Parameters

C-reactive protein (CRP): First, a standard curve is obtained by measuring the antigen calibrators, and then the blood samples are measured. Second, the CRP value before HCT correction is obtained from the standard curve, and then the concentration value of CRP in mg/L is calculated according to the following formula.

$$CRP= \frac{CRP \text{ value on the standard curve}}{1 - HCT}$$

Hypersensitive C-reactive protein (Hs-CRP): Concentration value of Hs-CRP. Unit: mg/L.

Rinse

During each counting process, the analyzer automatically flushes the components through which the sample flows, ensuring that there is no sample residue in the fluidic components.

CHAPTER 4

INSTALLING
YOUR ANALYZER

Introduction

NOTE

Personnel who are not authorized or trained by Zybion may cause personal injury or analyzer damage when unpacking or carrying out the installation process. Do not unpack or install the analyzer in the absence of the personnel authorized by Zybion.

The analyzer has been strictly tested before shipment. To avoid collision during transportation, the analyzer has been carefully packed before transportation. When the analyzer arrives, please carefully check the carton to see if there is any physical damage. If there is any damage, please immediately notify the after-sales service department of Zybion or the local agent.

Installation
Requirements

Before installation, the operator must ensure that the following requirements for the space, power supply, environment and fuses are met.

Space Requirements

Ensure there is sufficient space for maintenance and repair. Considering the heat dissipation of the instrument and the non-extrusion of the fluidic components behind the analyzer (for the normal flow of reagents), the following requirements shall be met:

- a space of ≥ 30 cm left between the left and right doors of the analyzer and the walls;
- a space of ≥ 10 cm left between the rear panel of the analyzer and the wall;
- The installing table (or floor) can bear a weight of at least 40 Kg.
- Make sure there is enough room on the work table surface and below the analyzer to place the reagents, such as diluents, and waste buckets.

Power Requirements

MAIN UNIT	POWER VOLTAGE	POWER FREQUENCY	INPUT POWER	FUSE
	100V - 240 V	(50/60 Hz)± 1Hz	≤200 VA	250 V T6.3 AH

▲WARNING

- The analyzer must be used under good grounding conditions.
- The operator must use a fuse of the specified specifications.
- Verify that the input voltage meets the instrument requirements.

NOTE

- The use of a power strip may introduce additional electrical interference and result in erroneous analysis results. Please place the analyzer near the power outlet to avoid using a power strip.
- Please use the supplied power cord. Using other power cords can damage the analyzer or cause erroneous analysis results.

Environmental Requirements

ENVIRONMENTAL REQUIREMENTS	STORAGE	OPERATION
Ambient temperature	-10°C-40°C	15°C-35°C
Relative humidity	10%-90%	20%-85%
Atmospheric pressure	50kPa-106kPa	70kPa-106kPa

- The environment should be free from dust, mechanical vibration, major noise sources and power interference.
- It is recommended that the electromagnetic environment of the laboratory be evaluated before running the equipment.
- Please use a dedicated power outlet. Do not use the same power outlet as air-conditioners, refrigerators, ultrasound systems, etc. that are likely to emit interference signals.
- Do not place the device near strong electromagnetic interference sources so as not to affect the normal operation of the device.
- Do not place the device near brush-type motors, flashing fluorescent lights, and electrical contact devices that are frequently switched on/off.
- Avoid direct sunlight or heat and wind sources.
- Choose a well-ventilated location.
- Maintain a good grounding environment.
- Indoor use only.

▲WARNING

- The analyzer may not be used in presence of flammable substance and/or explosives

▲CAUTION

- If the room temperature exceeds the normal operating temperature range of the analyzer, the instrument temperature may exceed the limit and the analytical results obtained will be unreliable.

Handling

▲WARNING

- Personnel who are not authorized or trained by Zybio may cause personal injury or damage to the main unit when unpacking or carrying out the installation process. Do not unpack or install the main unit in absence of the authorized personnel of Zybio.

▲CAUTION

- During transportation, in order to avoid damage to the sampling component, the moving components are immobilized with clips/tying tapes when the instrument leaves the factory. The clips/tying tapes must be removed before using the instrument.

The analyzer shall be transported and installed by the personnel authorized by Zybio. Do not move or install the analyzer without contacting the after-sales service department of Zybio or the local agent.

**Connecting the
Analyzer System**

Make electrical and reagent connections as shown in the figure below. The operator must verify that the connections are in place and secure.

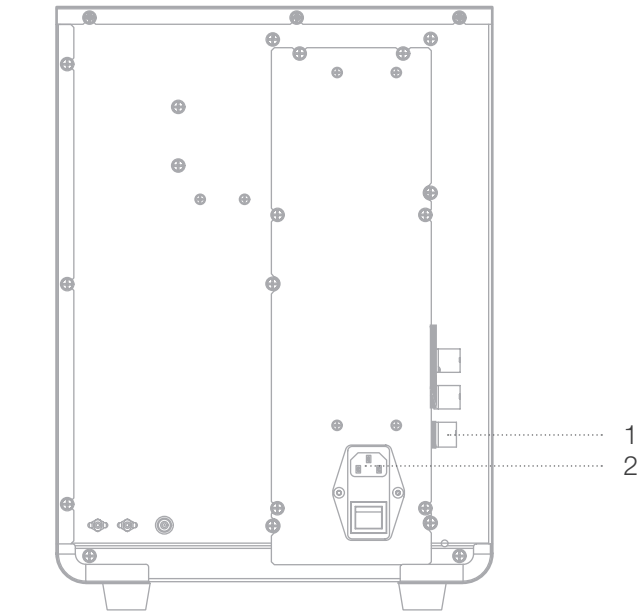


Figure 4-1 Electrical connection diagram

1-Network port

2-Power component

▲WARNING

- The operator is obliged to comply with the relevant national and regional regulations regarding the discharge and processing of expired reagents, waste liquids, waste samples, consumables, etc.
- Reagents may irritate the eyes, skin and mucous membranes. When the operator handles reagent-related articles in the laboratory, he/she shall comply with the laboratory safety practices and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc.).
- Once the reagent contacts the skin, rinse with plenty of water immediately. If necessary, please seek medical treatment. Once the reagent contacts the eyes, immediately rinse with plenty of water and seek medical treatment.

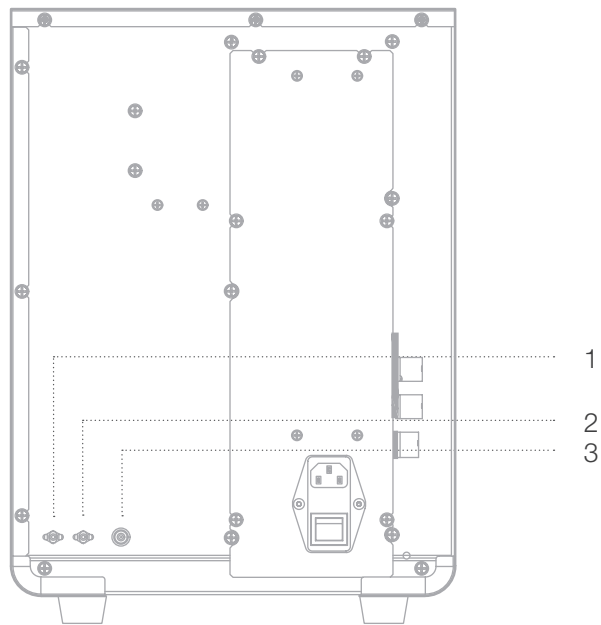


Figure 4-2 Diagram of external reagent connections

1-Connection to diluent 2/3-Connection to a waste bucket

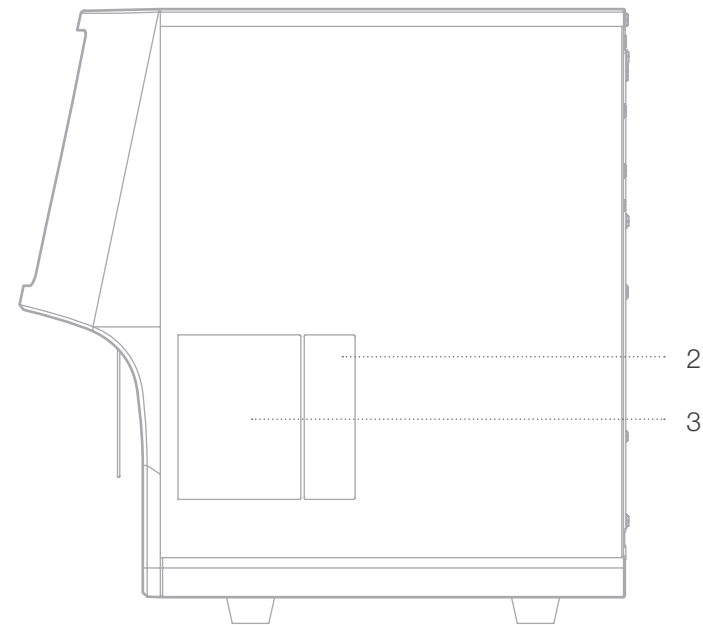
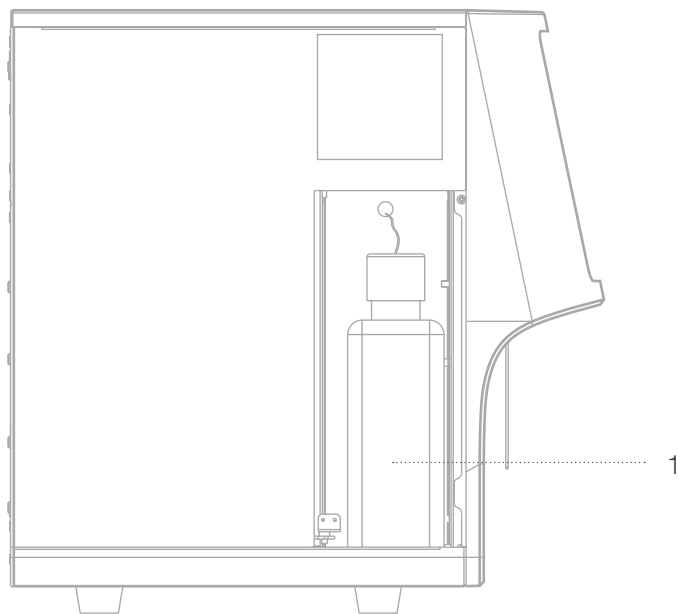


Figure 4-3 Diagram of internal reagent connections

1-Lyse 3-CRP measuring cup
2-R2 kit

▲CAUTION

- Please ensure that the length of the diluent and waste conduits does not exceed 1500mm.
- The top height of the waste and diluent buckets should be lower than the table top on which the instrument is placed.

Installing the thermal paper**▲CAUTION**

- Remove the protective paper from the recorder before installing the thermal paper for the first time.

The thermal paper is installed as follows:

1. Open the recorder door outward.
2. Load the thermal paper into the paper chamber in the direction shown below, with the paper's heading end outside the paper outlet.
3. Close the recorder door.
4. Check the position of the thermal paper to ensure that the thermal paper is aligned with the paper outlet.

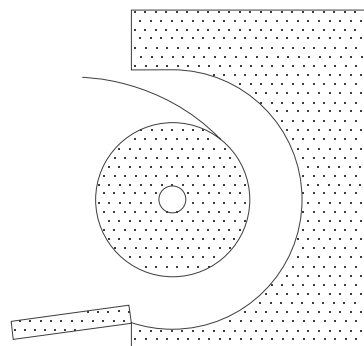


Figure 4-4 Installing the thermal paper

- Select qualified 50mm thermal paper.
- During the printing process of the recorder, the thermal paper cannot be pulled outwards by force; otherwise the recorder may be damaged.
- Do not leave the recorder door open unless you are changing the paper or troubleshooting the recorder.
- Thermal paper installation errors may cause paper jams or printing failure.

Notes

- The reagents designated by Zybio should be used, otherwise the test results will be unreliable and operation may cause damage to the instrument.
- Attention should be paid to the expiry date of the reagents. Expired reagents may not be used. The use of expired reagents will lead to unreliable test results.
- After the reagent is connected with the analyzer, the reagent bottle cap must be replaced to prevent the reagent from being polluted.
- The analyzer performance may be undermined if it has been placed in environment of high dustiness.
- The surface of the analyzer shall be cleaned and sterilized regularly with alcohol (75%).
- The probe wipe block of the analyzer (see Figure 4-5 Front of the analyzer) shall be wiped with alcohol (75%) regularly.
- Blood collection and sample preparation shall be carried out in accordance with the specified methods. Inappropriate blood collection procedures may cause harm.
- If any hoses or parts filled with liquid are aged or worn during use, please stop using them immediately and contact the user's service personnel for inspection or replacement in a timely manner.
- During the use of the instrument, care should be taken not to compress with heavy objects or bend the connection tubing of the reagents (including the diluent, lyse and waste liquid).

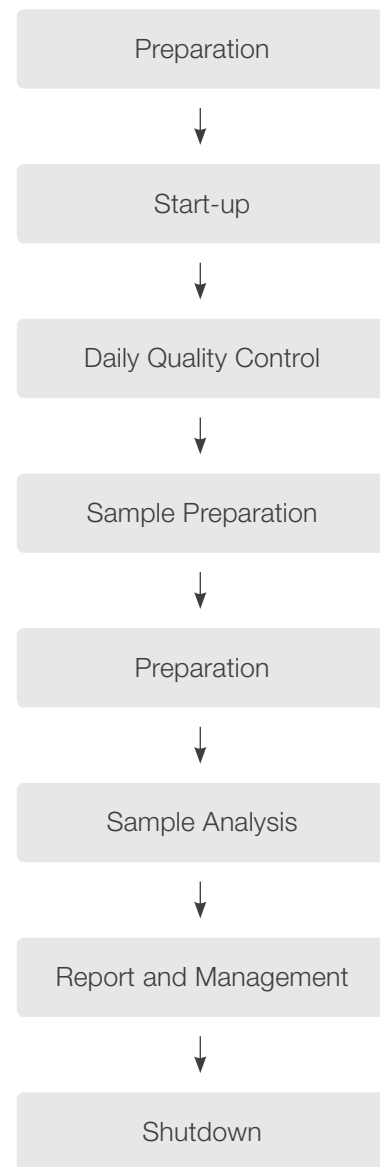
CHAPTER 5

OPERATING YOUR ANALYZER

Introduction

This chapter introduces the routine operation process from the start-up to the shut-down of the analyzer, detailing the sample analysis process in different working modes.

The routine operation process is as follows:



Initial Checks

Before powering on the main unit, the operator must check the following to ensure that the system is ready.



All articles (samples, controls, calibrators, reagents, waste liquid, etc.) and the areas that come into contact with these substances pose potential biological risks. When the operator comes into contact with such articles and areas in the laboratory, you shall comply with the laboratory safety practices and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc.).

▲WARNING

- The operator is obligated to comply with the relevant national and regional regulations regarding the discharge and processing of reagents, waste liquid, waste samples, consumables, etc.
- Reagents may irritate the eyes, skin and mucous membranes. When the operator handles reagent-related articles in the laboratory, he/she shall comply with the laboratory safety practices and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc.).
- Once the reagent contacts the skin, rinse with plenty of water immediately. If necessary, please seek medical treatment.
- Keep your clothing, hair, and hands at a certain distance from the moving parts

▲CAUTION

- The operator shall use the reagents specified by Zybio and store and use them in strict accordance with their MANUAL.
- Before using the analyzer, verify that the reagents are properly connected.
- The reagents should be allowed to stand motionless for a period of time until they become stable.

NOTE

- Check the waste bucket
The operator must put a waste bucket in place and ensure that it is empty before starting the machine each day.
- Check the fluidic components and power supply
Check the reagent and waste tubing for bending or insecure connections.
Check that the power plug of the main unit is firmly inserted into the power socket.
- Check the recorder and printer (optional)
Check the recorder and printer for insufficient paper or inappropriate installation.

Startup and Login

- **Start up the main unit:**
 1. Switch the power I/O switch on the back of the analyzer to position "I" and the power indicator will illuminate.
 2. Verify that the indicator on the main unit is On.
 3. In the login dialog box, enter the current user's username and password in the "User name" and "Password" boxes.¹



Figure 5-1 Login dialog box

4. The analyzer performs self-check and power-on initialization in sequence. The time required for the analyzer to initialize the fluidic components varies according to the previous shutdown conditions.

NOTE

- If analysis is performed when the analyzer reports "Background Abnormal", the analyzer will yield unreliable results. Please handle this error according to Chapter 11 Troubleshooting Your Analyzer.
- The system judges the operator's privileges as Administrator or Common User according to the user name and password used for login, and then enables different functions in each interface according to the user's privilege.
- To switch users, click "Logout" in the menu, enter the user name and password in the login dialog box, and click "Login" to log into the software interface as a new user.
 1. The initial username and password of the Administrator default to Admin.
 2. If the software fails to run after several consecutive attempts, please contact the after-sales service department of Zybion or your local agent.
 3. Please verify that the date/time of the device is valid after startup.

Daily Quality
Control

Before carrying out sample analysis, QC analysis shall be carried out on the analyzer daily to ensure that the analyzer obtains reliable analysis results. Refer to Chapter 7 Quality control for specific QC analysis methods.

Sample
Preparation

The samples measured by the instrument are: whole blood samples, and pre-diluted samples

▲CAUTION

- Samples should be prepared according to the procedures recommended by the reagent manufacturer.
- All kinds of samples must be thoroughly mixed.



All articles (samples, controls, calibrators, reagents, waste liquid, etc.) and the areas that come into contact with these substances pose potential biological risks. When the operator comes into contact with such articles and areas in the laboratory, he/she shall comply with the laboratory safety practices and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

▲WARNING

- Do not directly come into contact with the patient's blood samples.

▲CAUTION

- Do not reuse disposable supplies.

NOTE

- The operator should use clean EDTAK₂ anticoaguled vacuum blood collection tubes, silicified glass/plastic test tubes, centrifuge tubes and borosilicate glass capillary tubes.
- Disposable supplies such as vacuum blood collection tubes, centrifuge tubes and capillary tubes used in blood collection must be in accordance with the specifications specified by the manufacturer.

Whole Blood Samples

1. Venous blood samples are collected using EDTAK₂anticoagulated vacuum tubes.
1. Quickly mix venous blood in the tube with the anticoagulant thoroughly.

▲CAUTION

- To ensure the accuracy of the results, the sample volume of capillary WB should not be less than 120 µL.

NOTE

- Samples for WBC differential counting or platelet counting should be stored at room temperature and analyzed within 8 hours.
- If the sample is kept in a refrigerator at 2°C- 8°C, it can be analyzed within 24 hours. Refrigerated samples should be left at room temperature for at least 30 minutes before analysis.
- Samples placed for a certain period of time need to be remixed before analysis.
- Please complete the analysis 5 minutes to 2 hours after sample collection.

Sample Analysis

Pre-diluted Samples

1. Click on the mode switch icon to change the analysis mode from “WB” to "PD".
2. Click the "Diluent" icon to display the diluent dispensing prompt dialog box.

Place a clean centrmanualge tube under the sample probe and press the Aspirate Key to start adding the diluent (580 µL). While adding the diluent, the prompt box displays “Adding diluent ...” and a progress bar appears.

Collect 20 µL venous or capillary blood and quickly inject it into a centrmanualge tube filled with the diluent. Replace the cap and mix thoroughly. After the PD sample is prepared, click the “Cancel” button to exit diluent dispensing.

NOTE

- The operator can also use a pipette to draw 580 µL of diluent.
- The prepared diluent should be kept away from dust and volatilization prevented, otherwise analysis errors will occur.
- After the capillary blood reacts fully with the diluent, it needs to be left for 3 minutes and remixed before analysis.
- It is recommended that the analysis be completed within 30 minutes of sample dilution.
- Samples unused for a certain period of time need to be remixed before analysis.
- Each laboratory shall evaluate the stability of the sample analysis results in the PD mode according to its own sample number, sample collection method and technical level.

Click the "Analysis" button to enter the "Analysis" interface. Click the “Mode switch" button in this interface to select the "WB" or “PD" mode.

Enter the sample information

The analyzer provides two methods to enter the sample information: Sample ID entry and all information entry.

If the operator wishes to enter the sample information after analysis, he/she can skip the introduction in this section and enter the sample information according to the Sample ID and the result saving time when reviewing the sample results. See Chapter 6 Review of results for the method.

Once the sample information entry method has been set in the "Setup → Auxiliary" interface according to Chapter 9 Setup, the sample information can be entered in the "Analysis" interface.

Entering all information

When the entry method of the next sample is set to "All Information", click "Analysis" and "Next Sample" to open the all information entry dialog box, as shown in the following figure. The operator can enter the complete sample information for the next sample in the dialog box.

WB

PD

CBC

CRP

CBC+CRP

Sample ID

1

Med Rec. No.

Name

Patient Type

Last Name

Dept.

Gender

Ref. Group

General

Age

Year(s)

Bed No.

Birthday

YYYY-MM-DD

Deliverer

Draw Time

YYYY-MM-DD HH:MM

Delivery Time

YYYY-MM-DD HH:MM

Remarks

OK

Figure 5-2 All information entry dialog box

- Sample mode selection
Click "WB"/"PD" to select the sample mode.
- Measurement mode
Click "CBC"/"CRP"/"CBC + CRP" mode to select the measurement mode.
- Enter Sample ID
Enter the Sample ID in the "ID" box.
- Enter patient name
Enter the patient's name in the "Name" box.
- Select patient gender
Select the gender of the patient from the "Gender" drop-down list. There are three options: "Male", "Female" and "Unknown". The default option is "Unknown".

- Enter patient age
The analyzer provides five time units for various age groups: by "Years", by "Months", by "Weeks", and by "Days" and by "Hours". They are applicable, respectively, to: people aged over one year, people aged a full month but under two years, people aged a full week but under ten weeks, people aged under a full month and people aged under 48 hours. The operator can select the time unit of the patient's age accordingly.

In the "Age" drop-down list, select the time unit of the age in "Years" , "Months" , "Weeks" , "Days" or "Hours" and enter the patient's age in the entry box in front of the time unit.

NOTE

- Enter patient age
The analyzer provides five time units for various age groups: by "Years", by "Months", by "Weeks", and by "Days" and by "Hours". They are applicable, respectively, to: people aged over one year, people aged a full month but under two years, people aged a full week but under ten weeks, people aged under a full month and people aged under 48 hours. The operator can select the time unit of the patient's age accordingly.
- In the "Age" drop-down list, select the time unit of the age in "Years" , "Months" , "Weeks" , "Days" or "Hours" and enter the patient's age in the entry box in front of the time unit.

- Enter the birth date
Enter the patient's birth date in the "Birth date" box. The date format is consistent with the system date format.
- Enter the deliverer
Enter the name in the "Deliverer" box or select the name in the "Deliverer" drop-down list (when there is a record in the drop-down list).
- Enter the delivery time
Enter the draw time in the "Delivery Time" box.
- Enter the patient ID
Enter the patient ID in the "Patient ID" box.
- Select the patient type
Select the patient's type from the "Patient Type" drop-down list. There are four options: Outpatient, Inpatient, Checkup, and Emergency.
- Enter the department name
Enter the department name in the "Dept." box, or select the department name in the "Dept." drop-down list (when there is a record in the drop-down list).
- Enter the bed number
Enter the patient's bed number in the "Bed No." box.
- Enter the draw time
Enter the draw time in the "Draw Time" box.
- Enter remarks
Enter necessary remarks in the "Remarks" box.
- OK
After entering the sample information, click OK to save the entry and return to the "Analysis" interface.
- Cancel
After entering the sample information, click "Cancel" to return to the "Analysis" interface and discard the entry.
- Enter Sample ID
When the entry method of the next sample is set to Sample ID only, click "Next Sample" in the "Analysis" interface to open the ID entry dialog box.

Edit current sample information

Click on the sample information area in the "Analysis" interface and the “Graph Review” interface to open the sample information editing dialog box to edit the information of the current sample. Sample information for background and validated samples cannot be edited.

The image shows a 'Sample Information' dialog box with a close button (X) in the top right corner. The dialog box contains the following fields and controls:

- Sample ID: Text box with '1' entered.
- Patient ID: Text box.
- First Name: Text box.
- Patient Type: Drop-down menu.
- Last Name: Text box.
- Dept.: Drop-down menu.
- Gender: Drop-down menu.
- Ref. Group: Drop-down menu with 'General' selected.
- Age: Text box and 'Year(s)' drop-down menu.
- Bed No.: Text box.
- Birthday: Text box with format 'YYYY-MM-DD'.
- Deliverer: Text box.
- Draw Time: Text box with format 'YYYY-MM-DD HH:MM'.
- Delivery Time: Text box with format 'YYYY-MM-DD HH:MM'.
- Remarks: Large text area.
- OK and Cancel buttons at the bottom right.

Sample Analysis Steps



All articles (samples, controls, calibrators, reagents, waste liquid, etc.) and the areas that come into contact with these substances pose potential biological risks. When the operator comes into contact with relevant articles and areas in the laboratory, he/she shall comply with the laboratory safety practices and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

▲WARNING

- The sample probe is sharp, and it may carry blood samples, controls and calibrators that are potentially biologically hazardous. Therefore, the operator shall not touch the sample probe.

▲CAUTION

- Do not reuse disposable supplies.

NOTE

- When the sample probe is aspirating, it needs to be fully immersed in the sample and its tip should be kept at a certain distance from the bottom of the container, otherwise the sample volume aspirated may be insufficient and inaccurate.
- The operator should avoid blood splashing caused by the contact between the test tube wall and the sample probe.

Sample analysis

WB samples are analyzed according to the following steps:

1. Verify that the Analysis status in the system status area is ready and the working mode is “WB” or “PD”.
2. Place the prepared WB sample under the sample probe so that the sample probe can aspirate the mixed sample.
3. Press the Aspirate Key to start the sample analysis process. At this point, the blue flashing status of the analyzer indicator indicates that the sample analysis is in progress.
4. The sample probe automatically sucks in the sample and then lifts itself up, while buzzing. After the sample probe is lifted, the operator can remove the sample. Then, the sample probe adds the aspirated sample to the counting chamber. The analyzer automatically performs sample analysis.
5. After the analysis is finished, the sample probe is reset and ready for the next sample analysis. The results will be displayed in the results area of the interface. Simultaneously, the number of the next sample is automatically increased by one.
6. If automatic printing is set to On, the analyzer will automatically print the analysis report as configured. If auto communication is set to On, the analyzer will automatically upload the sample analysis results and sample and patient information that meet the communication conditions to the LIS system.
7. The remaining samples are analyzed by following the same procedure.

Report Management

- Save the analysis results
The analyzer automatically saves the results. When the number of sample results reaches its upper limit, the newly obtained results will automatically overwrite the oldest results.

Text alarms

Flags	Alarm information	Description
WBC Flag	<u>Leucopenia</u>	WBC count significantly low
	Leucocytosis	WBC count significantly high
	Granulopenia	Granulocyte count significantly low
	Granulocytosis	Granulocyte count significantly high
	WBC Abnormal	There may be nucleated RBC, abnormal lymphocytes, immature cells, primitive cells or other abnormalities
	Lymphopenia	Lymphocyte count significantly low
	Lymphocytosis	Lymphocyte count significantly high
	Increased Intermediate Cells	Intermediate cell count significantly high
RBC/HGB Flag	RBC Abnormal	There may be small RBCs, large RBCs, anisocytosis, RBC agglutination, double peaks on the histogram and other abnormalities
	Hemoglobin Abnormal/Interference?	There may be abnormal hemoglobin, RBC agglutination, etc.
	Microcytosis	RBC volume is low
	Macrocytosis	RBC volume is high
	Anemia	Anemia
	Erythrocytosis	RBC count significantly high
PLT Flag	Platelets Abnormal	There may be small RBCs, RBC fragments, giant platelets, platelet aggregation and other abnormalities
	Thrombopenia	Platelet count significantly low
	Thrombocytosis	Platelet count significantly high

Validate

Validate the results of the current sample.

Sleep

Once the fluidic-related operations have stopped for a time period sufficient to trigger the sleep mode as set by the operator in the setting interface, the analyzer enters the sleep state.

After the main unit enters sleep mode, the lower-left corner of the interface shows “The analyzer is sleeping, please click Aspirate Key to wake up”.

Shutdown

Perform the shutdown procedure before powering off the analyzer each day, which includes the following steps:



All articles (samples, controls, calibrators, reagents, waste liquid, etc.) and the areas that come into contact with these substances pose potential biological risks. When the operator comes into contact with relevant articles and areas in the laboratory, he/she shall comply with the laboratory safety practices and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

▲WARNING

- The sample probe is sharp, and it may carry blood samples, controls and calibrators that are potentially biologically hazardous. Therefore, the operator shall not touch the sample probe.

NOTE

- To ensure the stability of the analyzer and the accuracy of the results, please shut down the analyzer as required after 24 hours of continuous operation.
- The operator must implement the required shutdown procedure to shut down the machine according to the following steps.
- Please do not forcibly turn off the power supply during shutdown.
- If there is a failure that affects shutdown, the analyzer will return to the state before shutdown and give an alarm. See Chapter 11 Troubleshooting for the workaround.

1. Click the “Shutdown” button at the bottom-left of the interface;
2. Select “Yes”, place the probe cleanser under the sample probe, and press the Aspirate Key. The analyzer automatically performs probe soaking.
3. After the analyzer automatically performs the shutdown process, it prompts “Please turn off the power!”. Then, turn off the analyzer’s power switch.
4. Empty the waste bucket and dispose of the waste properly.

▲WARNING

- The operator is obliged to comply with the relevant national and regional regulations regarding the discharge and processing of expired reagents, waste liquids, waste samples, consumables, etc.

CHAPTER 6

REVIEWING SAMPLE RESULTS

Introduction

After each sample analysis, the analyzer automatically stores the results in the sample library. The sample library can store up to 40,000 results including parameter results and histograms.

The operator can review all of the sample parameter results and histograms stored in the sample library and search library by listing or by single samples with histograms.

NOTE

- Effective backups should be performed to prevent data loss in the event of hardware or software failure.

Sample review

Click “Review” in the menu to review the analyzed record. The serial number, Sample ID, sample status, and analysis parameters are displayed in sequence in the sample results area as a list.

Sample Analysis

Sample Review

QC Management

Reagent Management

Analyzer Management

Dispensing Diluent

ID% POWER

Sequence

☐ 103☐ 104☒ 105☐ 106☐ 107☐ 108

Sample ID	46001	46002	46003	431061001	431061002	431061003
Status			Validated			
WBC	9.24	9.18	9.02	6.59	6.43	6.61
Lym%	28.7	28.2	28.1	45.2	46.3	46.6
Mid%	7.2	7.2	7.4	14.0	14.0	13.7
Gran%	64.1	64.6	64.5	40.8	39.7 ↓	39.7 ↓
RBC	4.50	4.54	4.55	4.19	4.20	4.15
HCT	39.6	40.0	40.0	39.9	40.0	39.3
MCV	87.9	88.1	87.9	95.3	95.2	94.9
HGB	140	138	138	131	131	130
MCHC	352	346	346	327	328	332
PLT	331	331	329	339	327	344
Lym#	2.65	2.59	2.53	2.98	2.98	3.08

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▶▶

Query

Graph Review

Trend Graph

Validate

Cancel validate

Print

▶

Postion/Sum

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Search

Click the "Search" button to open the dialog box shown below.

Search

Search By

Not Validated TodayNot Printed TodayNot Transferred Today

Search By Conditions

Sample ID

Patient ID

First Name

Last Name

Test Date2018 - 06 - 11 - 2018 - 07 - 11

Print Status

Validation Status

Comm. Status

☒ Select all search results

OKCancel

Define the search criteria by entering content in the corresponding edit boxes or selecting from the drop-down list.

Click “OK” to close the dialog box and start the search. The search results will be displayed in the list area.

Graph

The operator can click the "Graph Review" button in the “Sample review” interface to browse the detailed analysis results of each sample.

Graph Review

Sample ID1

Name

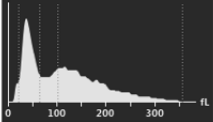
ModeWB-CBC

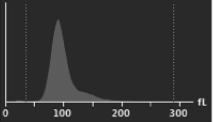
Test Time2018-07-11 11:14:08

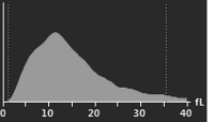
Gender

Age

Para.	Result	Unit	Para.	Result	Unit	Para.	Result	Unit
WBC	5.46	10 ⁹ /L	RBC	4.28	10 ¹² /L	PLT	184	10 ⁹ /L
Lym#	1.92	10 ⁹ /L	HGB	135	g/L	MPV	11.9	fL
Mid#	0.62	10 ⁹ /L	HCT	42.4	%	PDW	16.4	fL
Gran#	2.92	10 ⁹ /L	MCV	99.0	fL	PCT	0.219	%
Lym%	35.1	%	MCH	31.5	pg	P-LCC	79	10 ⁹ /L
Mid%	11.4	%	MCHC	318	g/L	P-LCR	42.8	%
Gran%	53.5	%	RDW-CV	13.2	%			
			RDW-SD	47.1	fL			







Previous

Next

Validate

Edit Result

Back

11 11:17

Edit result

The operator can click on a result entry in the "Graph" interface and click the "Edit Result" button to open the interface shown in the following figure:

Edit Result

WBC

0.01

10^9/L

RDW-SD

fL

Lym%

%

PLT

0

10^9/L

Mid%

%

MPV

fL

Gran%

%

PDW

fL

RBC

0.00

10^12/L

P-LCR

%

HGB

0

g/L

HCT

0.0

%

RDW-CV

%

Recover Result

OK

Cancel

Modify some of the results of this sample, and click the "OK" button to save. Then, return to the "Graph Review" interface. The parameter results on the interface will be automatically recalculated and refreshed based on the modified results.

Edit information

In the "Review" interface, select an entry, click the "Graphic review" button, and then click the sample information area to open the interface shown in the following figure:

Next Sample

WB

PD

CBC

Sample ID

1

Patient ID

First Name

Patient Type

Last Name

Dept.

Gender

Ref. Group

General

Age

Year(s)

Bed No.

Birthday

YYYY-MM-DD

Deliverer

Draw Time

YYYY-MM-DD HH:MM

Delivery Time

YYYY-MM-DD HH:MM

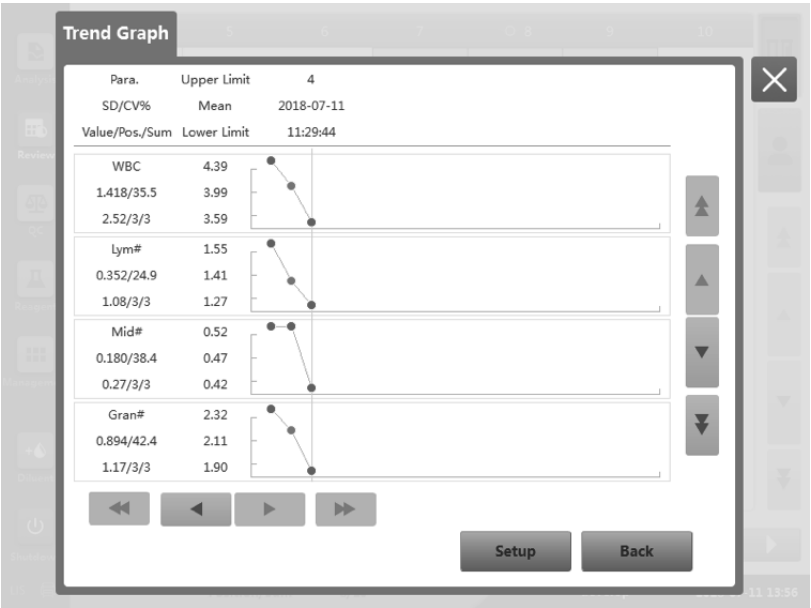
Remarks

OK

Cancel

Trend graph

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



From the trend graph, you can view the sample CV value over a period of time.

Validate/Cancel Validation (for administrators only)

- Validate sample data
After selecting one or more unvalidated sample records in the "Review" interface, click the "Validate" button, and the word "Validated" will appear in the sample status bar of the sample records.

Sequence	5	6	7	8	9	10
Sample ID	2	1	2	3	4	5
Status	Transmitted	Transmitted	Validated	Validated	Validated	
CRP						
Hs-CRP						
WBC	0.00 ↓	5.46	5.35	4.10	2.52 ↓	2.90 ↓
Lym%	***	35.1	33.3	33.3	42.8	40.7
Mid%	***	11.4	11.5	12.8	10.8	12.7
Gran%	***	53.5	55.2	53.9	46.4	46.6
RBC	0.00 ↓	4.28	4.40	5.50	6.57 ↑	6.64 ↑
HCT	0.0 ↓	42.4	43.6	55.1 ↑	66.0 ↑	67.2 ⊕
MCV	***	99.0	99.2	100.0	100.5 ↑	101.3 ↑
HGB	0 ↓	135	138	172	202 ↑	205 ↑
MCHC	***	318	317	312 ↓	307 ↓	305 ↓

Search

Graph Review

Trend Graph

Validate

Cancel Validate

Print

Position/Sum

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- Cancel validation

After selecting one or more validated sample records in the "Review" interface, click the "Cancel" button, and the word "Validated" in the sample status disappears.

Print

Select the sample records to be printed in the list area, and then click the "Print" button to print. For the samples already printed, the word "Printed" will appear in the sample status bar of the "Review" interface.

LIS

1. Click the "LIS " button in the "Review" interface.
2. Select the "Check Record" radio button.
3. Click "OK" to close the dialog box and start communicating. The selected results can be pushed to the data management software.

Export

1. Insert a USB flash disk into the USB port on the back of the instrument.
2. Click the "Export" button to bring up a dialog box.
3. In the "Export Range" area, select "Selected Records" or "All Records".

Delete

1. Select the sample records to be deleted in the list area.
2. Click the "Delete" button.
3. Click "OK" to delete the selected sample records and close the dialog box.

CHAPTER 7

USING THE
QC PROGRAMS

Introduction

Hematology analyzers may produce somewhat erroneous results after a long period of use. The presence of errors can lead to wrong or unreliable analysis results. The QC program provides an effective method for detecting possible errors. The operator can only effectively eliminate the influence of errors on the results if he/she is familiar with the theory of QC and masters the practical operation methods.

To ensure the reliability of the sample analysis results, it is recommended that the operator conduct QC on the analyzer with low, medium, and high levels of controls each day. When a new lot of controls is to be used, the new lot of controls and the existing controls are used in parallel for 5 days, two runs a day. The results should fall in the reference range specified in the MANUAL of the controls.

The analyzer provides two QC methods. Click on the “QC” menu and select “L-J QC” or “X-B QC”.

NOTE

- The operator should use the specified controls and reagents, and store and use them strictly in accordance with their MANUALs.

L-J QC

QC Settings

Before the analysis of a new lot of controls, a QC file needs to be set up for each lot of controls.

1. Click "Quality Management" > "L-J QC" > "Setting".
2. Enter the QC setting interface shown below.



Enter QC Information

1. Enter the L-J QC setting interface.
2. Click the "Setting" > "New" buttons, or select a QC file with no QC count results and click the “Modify” button.
3. Manually enter the Lot.

NOTE

- The Lot cannot be blank. The entry should be 1-16 characters, and special characters, numbers and letters are allowed, but Chinese characters are not supported.

Para.	Target	Limits(#)	Unit
WBC			10 ⁹ /L
Lym#			10 ⁹ /L
Mid#			10 ⁹ /L
Gran#			10 ⁹ /L
Lym%			%
Mid%			%
Gran%			%
RBC			10 ¹² /L
HGB			g/L
HCT			%
MCV			fL

Para.	Target	Limits(#)	Unit
MCH			pg
MCHC			g/L
RDW-CV			%
RDW-SD			fL
PLT			10 ⁹ /L
MPV			fL
PDW			fL
PCT			%
P-LCC			10 ⁹ /L
P-LCR			%
W_MCV			fL

4. Select the level of the controls.

5. Enter the expiry date of the control lot.

6. Select the appropriate "QC Type" from the drop-down list.

7. Select the QC mode for analyzing the controls.

8. Select the measurement mode for analyzing the controls.

9. Setting QC ID: If the operator is accustomed to placing the controls into daily samples for analysis, a special number can be set here for the controls. If the instrument recognizes this special number during the analysis of daily samples, it will automatically recognize it as a control. After the analysis, the test results will be stored in the QC file corresponding to this number.

10. According to the target value table of the corresponding lot, enter the reference value and limits respectively in the edit boxes after the parameter subject to QC.

11. Click "Save" to save the entered QC information.

Set Limits

If you want to adjust the display of the limits, you can follow the following steps:

1. Click the "Set Limits" button.

2. If you want the limits to be displayed as an absolute value, click "By SD (#)"; if you want the limits to be displayed as a percentage, click "By CV (%)".

3. Click the "OK" button to save the settings.

QC Count

The operator can choose one of the following two methods for QC analysis according to his/her preference:

- Use controls to perform QC analysis in the QC counting interface
- Place controls in daily samples and perform QC analysis in the sample counting interface

Use controls to perform QC analysis in the QC counting interface

After QC editing, you can select one of the following methods for QC analysis according to the selected QC mode:

- WB
- PD

NOTE

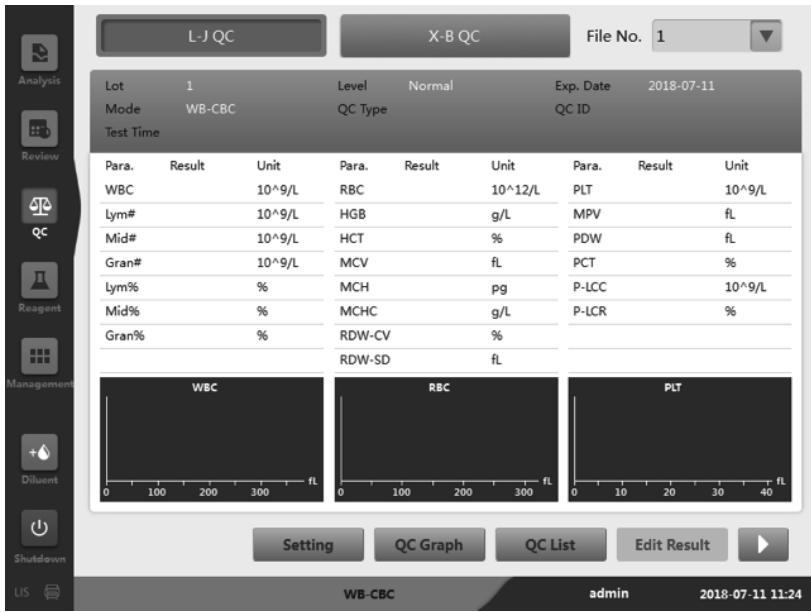
• Running a QC in the event of a error may result in incorrect analysis results. If a error alarm occurs during QC analysis, be sure to perform QC analysis after troubleshooting.

• Sample agglutination may result in inaccurate analysis results. Before the analysis, please check the controls for agglutination. If there is sample agglutination, please handle according to the relevant operating requirements of the laboratory.

1. Click "QC" > "L-J QC" to enter the QC counting interface.

NOTE

- Verify that the level of the control to be analyzed is as shown in the selected empty file and that the control to be analyzed has not expired.
- The expiry date field of expired controls is indicated in red.



2. Prepare controls in accordance with the MANUAL of the controls.
3. Perform QC analysis:
- 1) Verify that the QC mode is "WB" or "PD" and the main unit indicator is blue.
 - 2) Mix and manipulate the controls according to their MANUAL and thoroughly mix the samples.
 - 3) Place the control object under the sample probe and click on the Aspirate Key to start counting.
 - 4) After the aspiration, the operator can safely remove the control.

4. After the analysis, the QC results are automatically saved to the QC file, and the newest QC results are displayed in the current interface.

NOTE

- Each QC file stores up to 200 QC results.

5. If necessary, repeat the above steps to continue the QC analysis.

Place controls in daily samples and perform QC analysis in the sample counting interface

After setting a special "QC ID" for the control in the QC interface, the operator can place the controls in the daily samples and complete the QC analysis in the sample counting interface.

Before daily sample counting, when the operator edits the work order or enters information in the "Next Sample" dialog box, the special "QC ID" that has been set is entered as the "Sample ID".

According to the selected QC mode, select one of the following methods for QC analysis:

- WB
- PD

1. Prepare controls in accordance with their MANUAL.
2. Sample preparation in WB mode and PD mode is carried out as described in Section 5.5.1 Sample preparation.
3. When the counting operation is ready (i.e. the status icon and the indicator light of the instrument are solid blue), the prepared sample is placed under the sample probe and the QC analysis starts by clicking on the Aspirate Key.
4. After the aspiration, the operator can safely remove the control.
5. After the analysis, the QC results are automatically saved to its empty file, and the newest QC results are displayed in the current interface.
6. If necessary, repeat the above steps to continue the QC analysis.

Edit and save results (Administrator level)

Click the "Edit Result" button in the QC interface to edit the results. After finishing the edit, press the "OK" button to save it. The edited result is automatically marked with "E".

Restore results (Administrator level)

With Administrator privileges, the edited result can be restored to the initial measurement value.

1. In the edit result interface, click the "Recover Result" button.
2. Select OK to restore the result.
3. Click "OK" to close the dialog and perform data recovery.

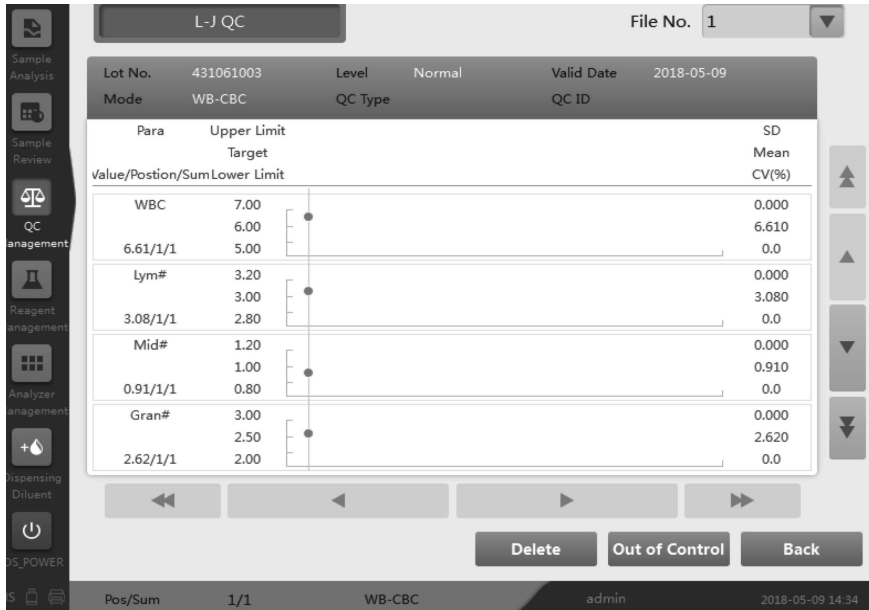
QC Results Review

After completing the QC analysis, the user can review the QC results in the following two ways:

- QC Graph
- QC List

QC graph review

1. Click the "QC Graph" button in the "L-J QC Count" interface to enter the QC graph interface corresponding to the QC file.



2. Click the page up/page down buttons on the right of the QC graph to browse the parameter QC results you wish to review. Click the page left/page right buttons at the bottom of the QC graph to browse all the QC results.

QC list review

1. Click the "QC List" button in the "L-J QC Count" interface to enter the QC graph interface shown below.

Sequence	Date	Time	WBC	Lym#	Mid#	Gran#	Lym%	Mid%
Target	/	/	5.00					
Limits(#)	/	/	2.00					

2. Click the page up/page down buttons on the right of the QC list to browse all QC records. Click the page left/page right buttons at the bottom of the QC list to browse all parameter results.

Delete (Administrator level)

1. Click the “Delete selected records” button to open the following dialog box.



2. Click "Yes" to delete the selected records.

NOTE

- Delete operations are recorded in the log.

Print

To print the QC list, click the "Print" icon.

Export

To export the QC information and QC results of the current QC file, use the following procedure:

1. Insert a USB flash drive and click the "Export" button.
2. The system will automatically detect the USB drive and export the data.
3. The system prompts the "Export Succeed" message.

X-B QC

QC Principles

The X-B floating average method monitors the performance of the analyzer by monitoring the stability of RBC parameters, such as MCV, MCH, and MCHC. It is a QC method without controls. It, along with QC with controls, is the performance monitoring method of the analyzer. They can reflect the analytical performance of the analyzer from different aspects, and cannot replace each other.

The X-B method requires the use of random samples and therefore does not apply to samples classified by disease. It involves a reference range consisting of a given reference value and the upper and lower limits. The trend of the QC results in the reference range is observed. This method is recommended when the analyzer's daily throughput is more than 100 samples.

The analyzer performs X-B QC on the three parameters of MCV, MCH, and MCHC. The samples are the analyzer's normal count results, without distinguishing between WB and PD modes. The number of samples for each X-B numerical analysis set can be 20 - 200, and the analyzer can store up to 1000 X-B QC results. When the number of the QC result saved exceeds the limit, the newest QC results will overwrite the oldest.

QC Settings

Click "Menu" > “QC” > "X-B QC" > "Setting" to enter the following X-B QC setting interface.



In the X-B QC Setting interface, you can edit the "X-B QC" information and the “Ref. Value/Deviation setting” and perform "Sample validity setting".

QC Analysis

After QC editing is completed, the system will automatically start performing X-B QC counting.

Once 20 to 200 (according to the setting) valid sample results are obtained, the system automatically executes an X-B QC calculation. The resulting QC results can be reviewed in the X-B QC graph or the X-B QC list.

QC Results Review

After completing the QC analysis, the user can review the QC results in the following two ways:

- QC Graph
- QC Lis

QC graph review

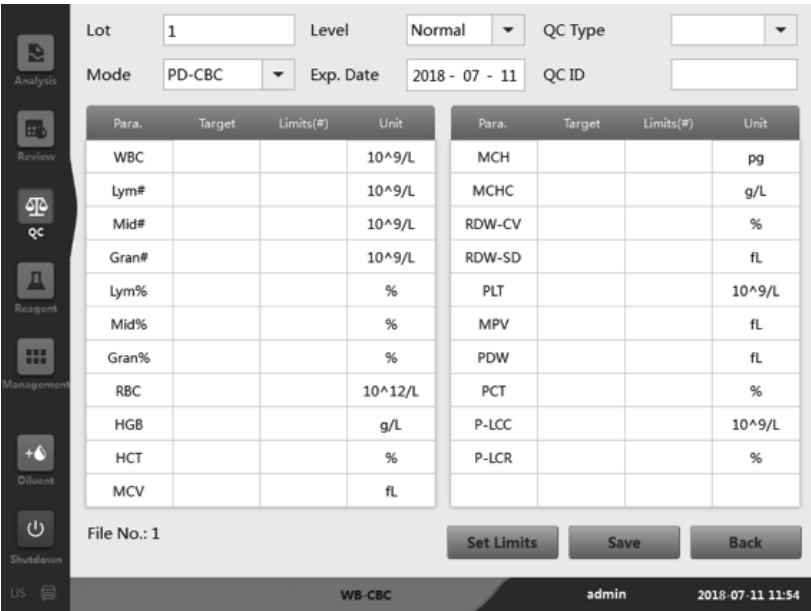
1. Click “Menu” > “QC” > “X-B QC” > “QC Graph” to enter the X-B QC graph interface:



2. Select the file number of the QC file you want to review, and the interface displays the file information and QC graph for the selected file.
3. Click the page left/page right buttons at the bottom of the QC graph to browse all the QC results.

QC list review

1. In the “X-B QC Graph” interface:
2. Click the "QC List" button to enter the QC list interface corresponding to the QC file.



3. Click the page left/page right buttons at the bottom of the QC list to browse all the QC records.
- Similarly, the QC list also provides functions such as “Delete selected records” and “Export”.

CHAPTER 8

CALIBRATING YOUR ANALYZER

Introduction

The aim of calibration is to determine the deviation correction factor of blood sample analysis under the specified conditions in order to obtain accurate measurement results. To obtain accurate analysis results, the analyzer should be calibrated according to the steps described in this chapter when necessary.

The analyzer provides three calibration methods: Manual calibration, calibration with calibrators, calibration with fresh blood. The calibration modes include "WB" and "PD".

All or part of the parameters of WBC, RBC, HGB, MCV, PLT, CRP can be calibrated.

NOTE

- Only operators with Administrator privileges can perform calibration.
- The operator shall use the calibrators and reagents specified by Zybio and store and use them in strict accordance with their MANUAL.
- The calculation of reproducibility should also be included in the calibration step.

When to Calibrate

The analyzer has been calibrated before shipment. Since the analyzer itself is stable in performance, there is no need for frequent calibrations. The operator still needs to calibrate the analyzer in the following four situations:

- Before the first installation (usually by manufacture or an authorized representative);
- After replacing main components;
- When there is obvious deviation in the QC data or the data exceeds the predefined limit;
- When the main unit is not in use for a long time period and is put to use again;
- When the operating environment (such as temperature) has changed substantially.

NOTE

- The analyzer must be calibrated, or the measured data cannot be used as valid data.

How to Calibrate

Preparing Your Analyzer

Before calibration, check the analyzer according to the following steps to verify that the background range, reproducibility and carry-over rate of the analyzer are within the ranges specified in the MANUAL. Otherwise, you must find the reasons and judge whether calibration is needed after the problem is solved. If the problem cannot be solved, please contact the after-sales service department.

1. Check the main unit and reagents to ensure that the reagents are sufficient to complete the entire calibration process. If the reagents are used up during the calibration process, the calibration needs to be carried out again.
2. Perform background tests: Ensure that the background test results meet the specified requirements (see Appendix A "Specifications" for the background range).
3. Perform reproducibility tests: In the "Sample count" interface, count 10 consecutive times with a normal control or a blood sample equivalent to the normal control range. In the "Review" interface, check the reproducibility of the 10 count results to ensure that they are within the specified range (see Appendix A "Specifications" for the reproducibility indexes).
4. Detection of carry-over rate: Count 3 times with high value samples/controls, and then immediately count 3 times with the compatible diluent/low value samples. Then, the carry-over rate is calculated according to the following formula.

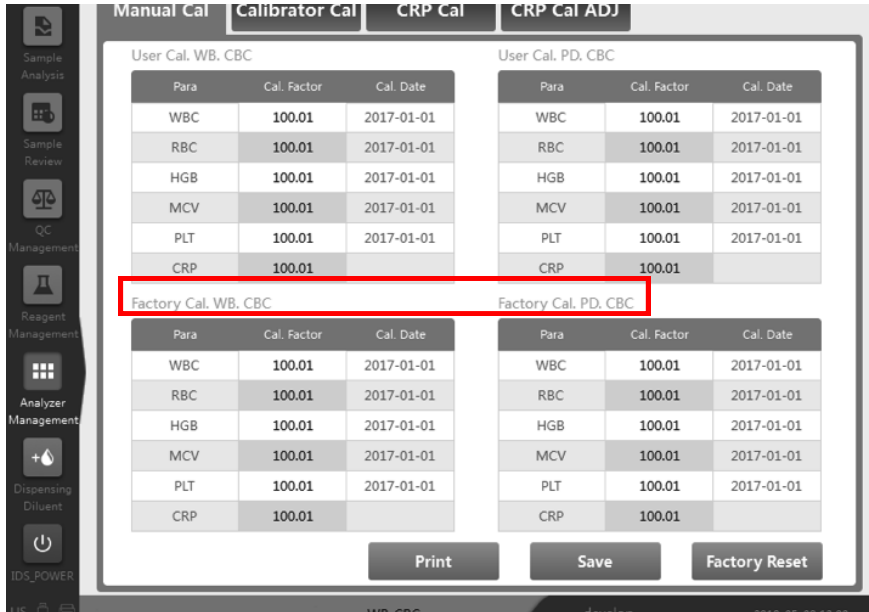
$$\text{Carry-over Rate} = \frac{(j1-j3)/(i3-j3)}{1} \times 100\%$$

It is suggested that the operator establish a record file and make a record form for archiving. The record form should include: date, source of calibrators, lot, reference value and background value.

Manual Calibration

After the operator logs into the system with Administrator privileges, he/she can click on the calibration factor of each parameter under the “Manual Cal.” interface and enter and edit the new calibration factor.

Click “Management” > “Calibration” > “Manual Cal.” to enter the “Manual Cal.” main interface as shown below. The calibration factor corresponding to each parameter in the "WB" or "PD" mode and the operation time of the factor are displayed in the interface. The operator selects and displays the current calibration factor corresponding to the mode selected for manual calibration.



NOTE

• The operator who logs in as a normal user can only view the calibration factor in the current interface and cannot perform calibration. If he/she need to calibrate the analyzer, he/she should first log out of the current user and log in as an Administrator.

Use the following procedure to complete manual calibration. The operator enters the “Manual Cal.” interface to view the calibration factor and uses the following formula to calculate the new calibration factor for each parameter:

New Cal.Factor= $\frac{\text{Current Cal.Factor} \times \text{Reference value}}{\text{Mean measured value}}$

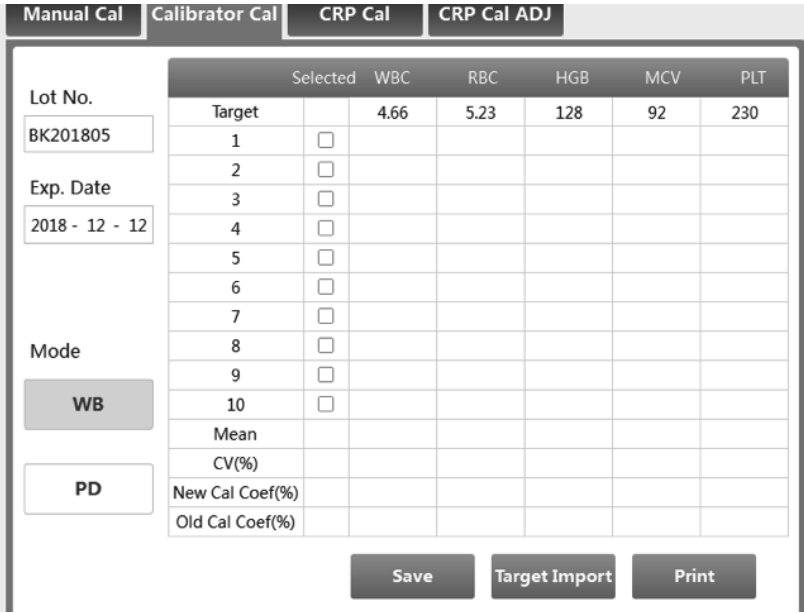
If the calculated calibration factor of a parameter falls out of the effective range of the calibration factor (the calibration range is 75% - 125%), then the calibration factor is invalid. In this case, the operator must find the reason, troubleshoot, recalibrate it, and calculate the calibration factor again. If the problem cannot be solved, please contact the after-sales service or the authorized agent of Zybio .

After obtaining the new calibration factor, enter it in the calibration factor cell where the parameter calibration is needed.

When the new calibration factor is entered, click “Save”.

Calibration with Calibrator

Click “Management” > “Calibration” > “Calibrator Cal.” to enter the interface shown below.



NOTE

- Calibration of calibrators can only be performed in the WB mode.
- The lot, expiry date and parameter reference value of the calibrator are shown in the MANUAL of the calibrator.
- The operator must use the calibrators designated by Zybio for this analyzer. Zybio will not be responsible for any error results caused by the use of other calibrators.

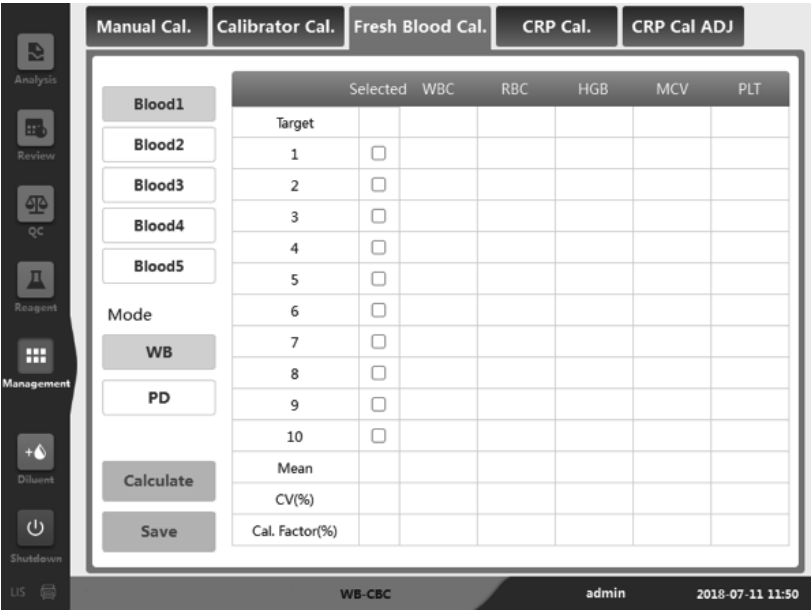
Complete the calibration of the calibrator as follows:

1. Verify the mode on the instrument control panel.
2. Enter the lot of the current calibrator in the “Lot” edit box.
3. Set the expiry date. The default expiry date of the calibrator in the analyzer is the current date. If you need to modify it, click the "Exp. Date" edit box to set the expiry date. The expiry date of the calibrator cannot be earlier than the current system date.
4. Enter the “Exp.date”. The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.
5. Enter the target value in the “Target” edit box corresponding to the parameter to be calibrated.
6. Prepare the calibrator according to its MANUAL.
7. Press the Aspirate Key on the analyzer to start the calibration count.
8. When the total times of calibration counts reach n (n is greater than or equal to 5), the analyzer will calculate the mean value, CV% and the new calibration factor.
9. Save the calibration factor.

If the calculated calibration factor of any parameter to be calibrated is not within the range of 75% - 125% (i.e. < 75% or > 125%), or the CV% value of any calibration parameter exceeds the reproducibility index of the analyzer, the calibration factor value will not be saved.

Calibration with Fresh Blood

Click “Management”, “Calibration” and “Fresh Blood Calibration” to enter the main “Fresh Blood Calibration” interface shown below.



Perform fresh blood calibration as follows:

1. Prepare 3 - 5 normal fresh blood samples according to the sample preparation method introduced in Chapter 5 Routine operation.
2. Take the 3 - 5 samples of the prepared normal fresh blood, measure at least 5 times on a reference instrument, and calculate the mean value, which is used as the reference value. Or, measure and calculate according to the reference method, and the obtained data is used as the reference value.
3. Click the “Mode” button to select the fresh blood calibration mode and then the WB or PD mode.
4. Select the number of the current calibration blood sample in the “Current Blood Sample ID” drop-down list.
5. Select the parameter to calibrate from the check boxes in the first row of the list.
6. Enter the reference value of the parameter to be calibrated in the edit box corresponding to “Reference value”.
7. Prepare WB or PD fresh blood samples.

8. Place the blood sample under the sample probe and press the “Aspirate Key” on the instrument to start the calibration counting sequence.

9. Once the calibration count is completed, the calibration count progress bar dialog box closes automatically, and the analyzer will perform different processing depending on the calibration count results.

- If the calibration count result is not within the linear range, but within the display range, the calibration count result is displayed in the list and the calibration result is not saved.
- If the calibration count result is not within the display range, the calibration count result in the list will show * * * (* * * displayed according to the data format of each parameter), and the calibration result will not be saved.
- If the calibration count result is in the linear range, it is valid and is displayed.

After obtaining valid calibration and count results, the check box in front of them changes to "√", and they are used in the calculation of the blood sample calibration factor by default.

10. For each blood sample, when 5 or more successive valid count results are available, the CV% and calibration factor are calculated for each parameter.

11. Press the "Blood Sample 2" to "Blood Sample 5" buttons to enter the "Fresh Blood Calibration" interface for Blood Samples 2-5. Follow the calibration procedure for sample 1 and complete the calibration counts for at least three more fresh blood samples to get their respective calibration factors.

12. After obtaining the calibration factors of more than 3 fresh blood samples, press the "Calculate" button to enter the fresh blood calibration result “Calculation” interface shown in the following figure.

Selected	WBC	RBC	HGB	MCV	PLT
Cal. Factor1(%) <input checked="" type="checkbox"/>	99.75	99.56	99.53	100.77	99.71
Cal. Factor2(%) <input checked="" type="checkbox"/>	99.30	98.25	100.73	102.27	100.27
Cal. Factor3(%) <input checked="" type="checkbox"/>	98.77	94.66	101.93	103.78	99.14
Cal. Factor4(%) <input type="checkbox"/>					
Cal. Factor5(%) <input type="checkbox"/>					
Mean Calibration Factor(%)	99.27	97.49	100.73	102.27	99.71

• Click the check box in front of each blood sample's calibration factor to select or cancel the calibration factors to be used in the calculation of the mean calibration factor.

• When the “√” ticked calibration factors are no less than 3 sets, the CV% value of the calibration factors will be automatically recalculated accordingly.

13. If you have not calculated the mean calibration factor, switch to the fresh blood calibration interface, or while switching the calibration mode, there will be a reminder” if the mean calibration factor has not been calculated, exit and abandon all intermediate data. Continue or no?”

14. If the calculated mean calibration factor is within the valid range, the fresh blood calibration interface is switched on.

CRP Calibration

On the menu bar, select "Management" > "Calibration" > "CRP Cal." to enter the interface shown below.

Selected	CRP
Target	
Count1(Response) <input type="checkbox"/>	
Count2(Response) <input type="checkbox"/>	
Count3(Response) <input type="checkbox"/>	
Count4(Response) <input type="checkbox"/>	
Count5(Response) <input type="checkbox"/>	
SD	
CV(%)	
Mean	

Follow these steps to complete CRP calibration:

1. Select "Method" as Logit-Log4p.
2. Enter the target of the calibrator in the target value field.
3. Three tests are performed using the calibrators of corresponding solubility and the analyzer calculates the SD, CV, and mean values of the calibrator response.

NOTE

- The tests of the calibrator are from the low to the high concentrations, and the order cannot be reversed.
 - If the CV value of the calibration exceeds the set value of the system, the user needs to recalibrate.
4. After testing the three concentrations of the calibrator, click "Calculate". The analyzer will determine the correspondence between the CRP concentration and the response according to the target and the calculated results of the response.
 5. (Optional) Click "Graphics View" to view the calibration curve; click "Close" to close the window.
 6. Click "Save" to save the current calibration result; or click "Empty" and click "Yes" in the pop-up dialog box to clear the current calibration result and re-run the calibration.

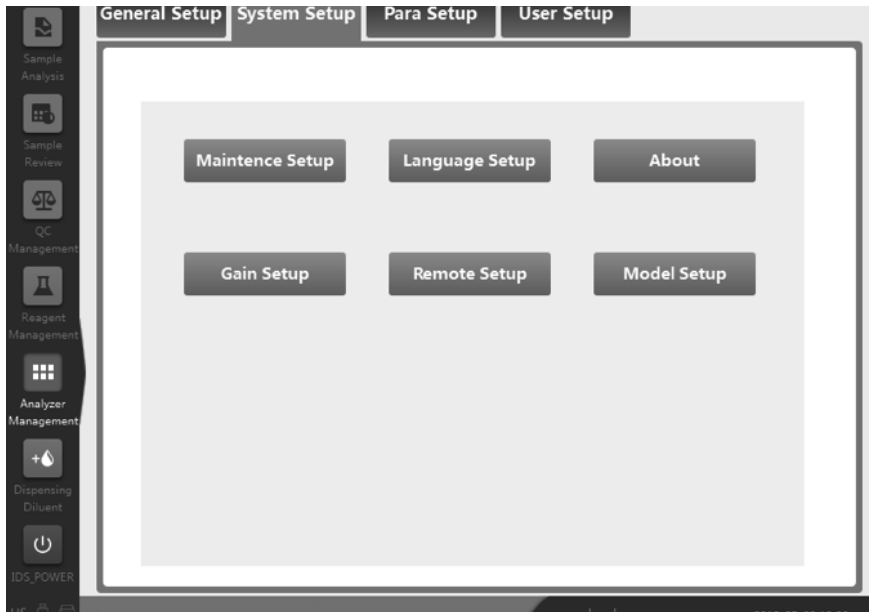
CHAPTER 9

CUSTOMIZING THE ANALYZER SOFTWARE

Introduction

Initialization setting of the analyzer has been conducted before shipment. The interface the user sees after the initial power-on is the system default. To meet the different needs of actual applications, you can use the “Setup” program to customize the software options as introduced in this chapter.

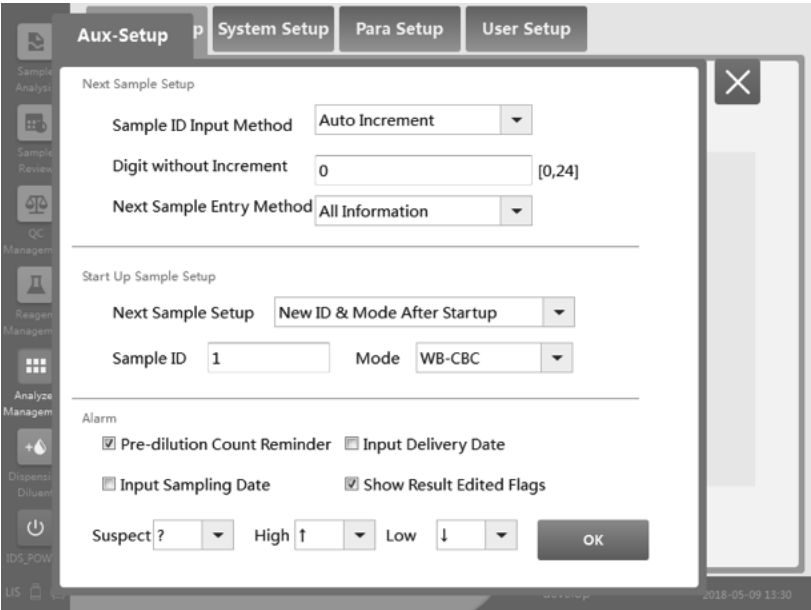
Click "Management" > "Settings" to enter the setting interface, as shown below:



General Settings

Auxiliary Settings

In the menu, select "Management" > "Settings" > "General" > "Auxiliary" to enter the interface shown below.



- Next Sample Setup

Select sample ID entry method

Click the drop-down list and select the sample ID entry method from the following options:

- Auto Increment
- Manual Entry

Locked prefixion digits

The user can set the number of digits in Sample ID that do not adopt auto-increment.

This edit box is activated when the Sample ID entry mode is "Auto Increment".

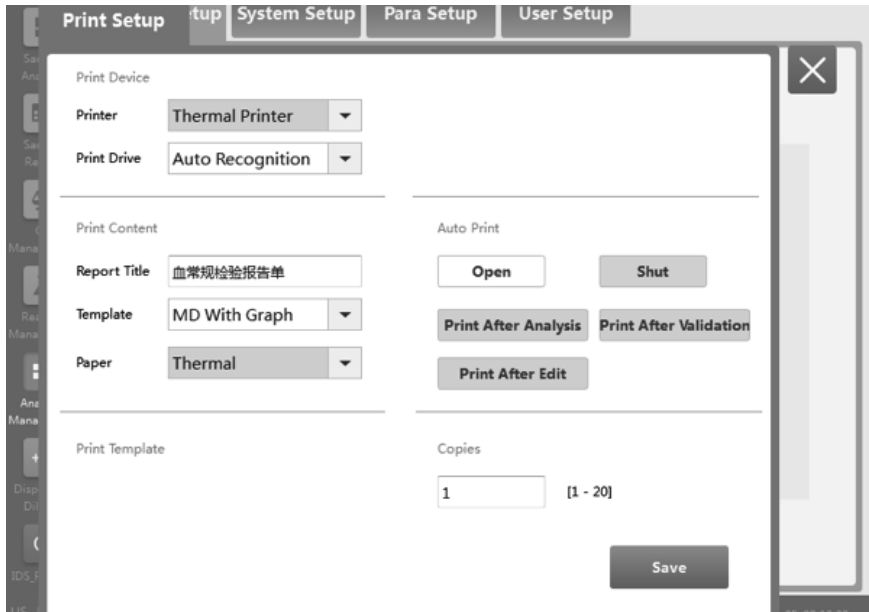
In the "Locked prefixion digits" edit box, enter the desired number n. The first n characters of all Sample IDs do not adopt the increment.

- First sample ID setup after startup
The operator may customize the first sample ID after startup by entering it into the edit box. Or the operator can select "Continue with Sample ID before last shutdown".
- Warning Flags
Set up warning flags: The operator can select the suspect warning flags in the drop-down list. The default is “?”.

Set high and low warning flags: The operator can enter single characters in the two edit boxes or select high and low warning flags in the drop-down list (the default high warning character is “↑” and the default low warning character is “↓”).

Print Settings

In the menu, select "Management" > "Settings" > "General" > "Print" to enter the interface shown below.



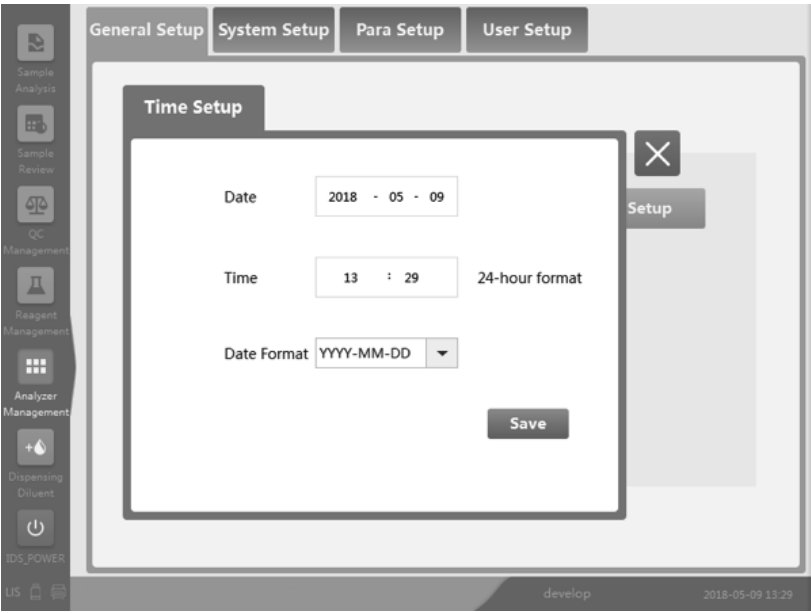
Print setting steps are as follow:

1. Select the print device in the "Print device" drop-down box. There are two types of print devices: “Recorder” and “Printer”.
2. Set paper type
Select the paper type in the "Paper type" drop-down box. The available paper sizes are A4, A5, Z4, continuous paper, letter paper, and thermal paper

3. Set print title
Enter the report title in the "Report Title" box.
4. Set a report template
Select the type of print template in the "Template" drop-down box.
5. Set number of copies
In the “Number of copies” box, enter the number of copies to be printed for each report.
6. Automatic print settings
The operator can choose automatic print as needed.

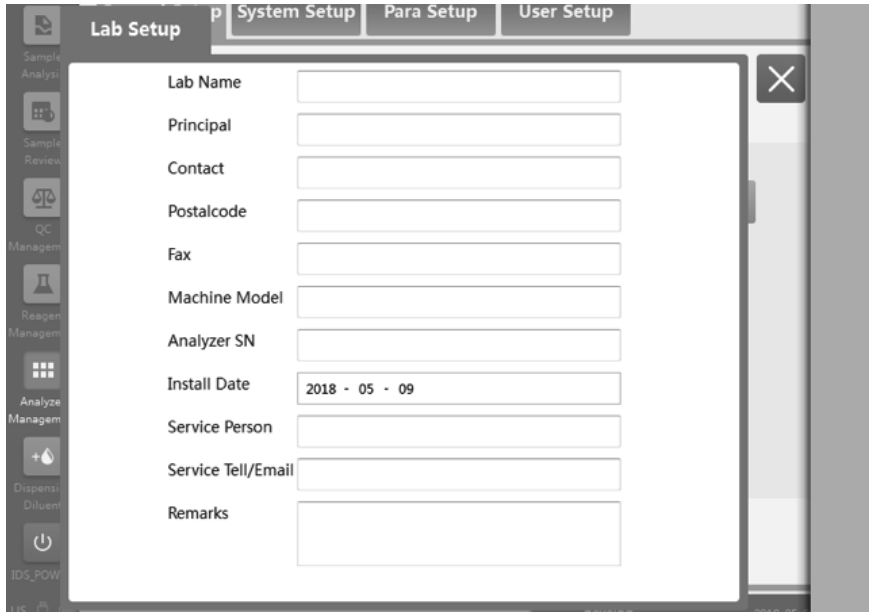
System Time Setting

From the menu, select "Management" > "Settings" > "General" > "Time" to enter the interface shown below. The date, time and date format of the analyzer can be set in this interface.



Laboratory Information Settings

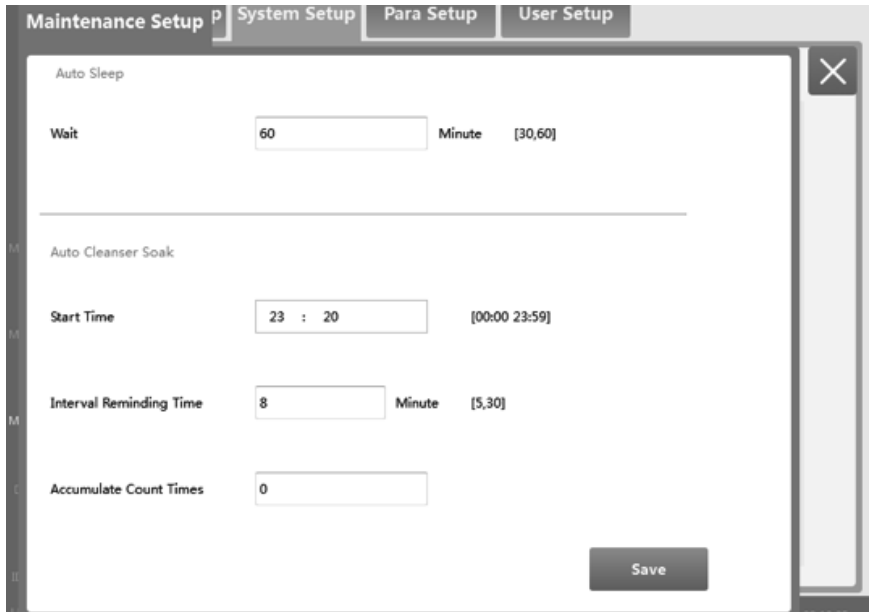
Select "Management" > "Settings" > "General" > "Lab Information Settings" in the menu. Enter the interface shown below. The operator can enter, save and view laboratory information. The operator can click on the corresponding edit box and enter relevant laboratory information as needed.



System Settings

Automatic Maintenance Settings

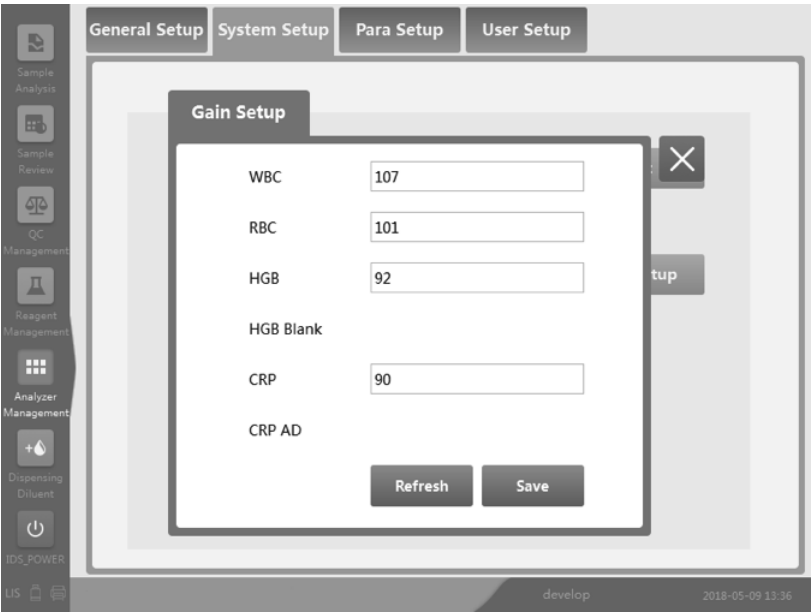
Select "Management" > "Settings" > "System" > "Maintenance" in the menu. Enter the interface shown below.



- Auto Sleep
If you need to set the time required to start auto sleep after the operations of the fluidic components stop, it can be entered in the "Wait" edit box. The range is 30 - 60 minutes.
- Auto Cleanser Soak
Select the start time of the probe cleanser maintenance. If you need to set the probe cleanser maintenance time, enter it in the interval reminding time edit box.

Gain Settings (for administrators only)

Select "Management" > "Settings" > "System" > "Gain" in the menu. Enter the interface shown below.



- HGB gain
Adjust the HGB Blank to 4.5V ± 0.1V.

Parameter Settings

Parameter Unit Settings

Select "Management" > "Setup" > "Parameter" > "Para. Unit" in the menu. Enter the following interface.

Para	Unit	Format	Para	Unit	Format
WBC	10^9/L	***.##	MCHC	g/L	****
Lym#	10^9/L	***.##	RDW-CV	%	***.##
Mid#	10^9/L	***.##	RDW-SD	fL	***.##
Gran#	10^9/L	***.##	PLT	10^9/L	****
Lym%	%	**.##	MPV	fL	**.##
Mid%	%	**.##	PDW	fL	**.##
Gran%	%	**.##	PCT	%	*.***
RBC	10^12/L	**.##	P-LCC	10^9/L	****
HGB	g/L	***	P-LCR	%	***.##
HCT	%	**.##	CRP	mg/L	***.##
MCV	fL	***.##	Hs-CRP	mg/L	***.##
MCH	pg	***.##			

- Select Unit
Click the "Select Unit" drop-down list and select the required unit.
- Customized unit settings
Under each unit system, the operator can click on the "Unit" cell to customize the unit for any parameter. Click the "Restore Default" button to restore the default settings for each unit.

Reference Range Settings

Select "Management" > "Setup" > "Parameter" > "Ref. Range" in the menu. Enter the interface shown below.

Ref. Group Name	Default	Lower Age Limit	Upper Age Limit	Gender
General	<input checked="" type="radio"/>	13Year(s)	999Year(s)	
Man	<input type="radio"/>	13Year(s)	999Year(s)	Male
Woman	<input type="radio"/>	13Year(s)	999Year(s)	Female
Child	<input type="radio"/>	28Day(s)	13Year(s)	
Neonates	<input type="radio"/>	0Hour(s)	28Day(s)	

The interface provides 5 internal reference groups and 10 customized reference groups for the operator to select and set up. Each laboratory shall select appropriate reference ranges according to their actual samples and set up appropriate reference intervals. The reference interval varies according to race, gender, age, and geographical location.

- Customized Group
In the reference group list, select the target reference group row and click the "New" button to enter the reference group setting interface and set information such as the name, age range, and parameter range of the reference group.

User Settings

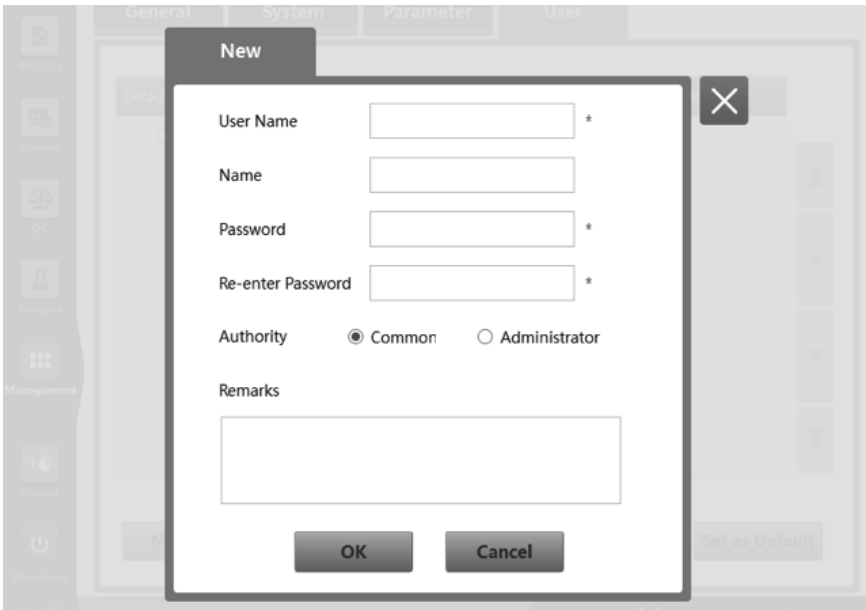
Select "Management" > "Settings" > "User" in the menu. Enter the interface shown below.

Default User	User Name	Name	Authority	Remarks
<input type="checkbox"/>	admin		Administrator	

- Reset PWD
The currently logged in user can modify the password of the current login account. Enter up to 12 characters.

- New

1) Click the “New” button to bring up the following dialog box.



2) Enter relevant information such as “Username”, “Name” and “Password” in each edit box. The user needs to enter the “Username” to log in. The name is that of the "Inspector" and “Validator" as seen in the Review and printed report.

3) Select user authority.

4) Click “OK” to save and close the dialog box.

NOTE

- The username cannot be blank. A maximum of 12 characters are allowed.
- The password cannot be blank. A maximum of 12 characters are allowed.
- The name cannot be blank. A maximum of 20 characters are allowed.

- Delete a user

Click on the list to select a user and click on the “Delete” button to delete it.

CHAPTER 10

SERVICING
YOUR ANALYZER

Introduction

To ensure the accurate and effective performance of the analyzer, the operator shall carry out routine maintenance according to the requirements of this chapter. The analyzer provides multiple maintenance functions to help the operator to complete the maintenance.

This chapter introduces various maintenance functions of the analyzer as well as some measures in case of errors and alarms.



The surface of all parts of the analyzer pose potential biological hazards. Therefore, safety precautions should be taken during operations and maintenance.

CAUTION

- Improper maintenance may damage the analyzer. The operator must carry out maintenance according to the MANUAL.
- If there is any issue not clearly mentioned in the MANUAL, please contact the after-sales service department of Zybio and the professional personnel designated by Zybio for maintenance suggestions.
- The analyzer must be maintained with the spare parts provided by Zybio. If you have any questions, please contact the after-sales service department of Zybio.
- When carrying out maintenance, avoid touching the sharp tip of the sample probe.

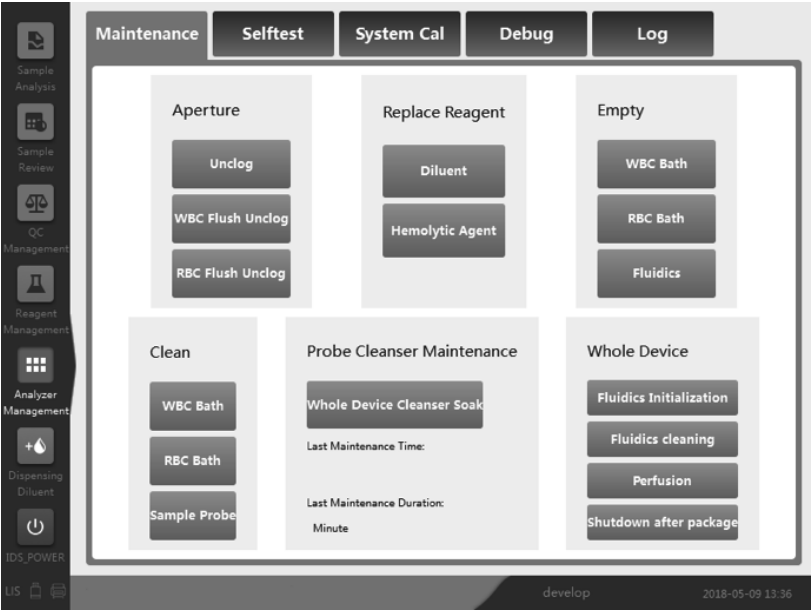
The following is a list of tools that may be required in maintenance.

SERIAL#	TOOL
1.	Phillips screwdriver
2.	Slotted screwdriver
3.	Allen wrench
4.	Medical gloves
5.	Alcohol

Maintenance

Maintenance includes: Routine maintenance, cleaning and whole machine maintenance.

On the menu bar, choose "Management" > "Service" > "Maintenance" and enter the interface shown below.



- Unclogging
 - Unclogging includes burning and back flushing. In the event of clogging, the unclogging operation can be performed. The operations are as follow:
 - 1) Click the "Unclog" button to start unclogging.
 - 2) After the unclogging is completed, the system prompts "Maintenance completed".
 - 3) If necessary, a single channel operation of "WBC Flush Unclog" and "RBC Flush Unclog" can be performed.
- Replace Reagent
 - The reagents for the corresponding channels can be refilled.
- Empty
 - Empty the liquid from the corresponding channel.

• Cleaning

The user needs to clean the parts in the following situations:

- 1) If the WBC and/or HGB background results exceed the background ranges, the WBC chamber can be cleaned.
- 2) If RBC and/or PLT results exceed the background ranges, the RBC chamber can be cleaned.
- 3) If the sample probe is dirty, perform sample probe cleaning.

• Probe Cleanser Maintenance

The user should perform Probe Cleanser Deeply Soak under the following conditions:

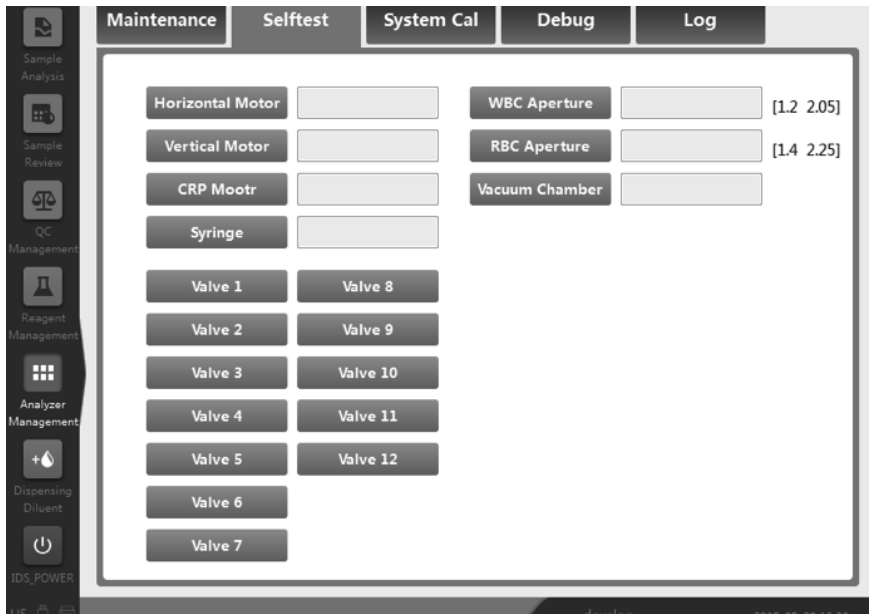
- 1) If the background is out of range and the QC result is abnormal because the analyzer has not been in use for a long period, or if unclogging fails despite other maintenance operations.
- 2) If the instrument shuts down due to abnormal power failure.

• Whole device

- 1) Whole device initialization: Restore all moving parts and sensors of the instrument to their initial state.
- 2) Whole device cleaning: Clean all the fluidic components of the instrument.
- 3) Prime: Fill the instrument's fluidic components with reagent.
- 4) Drain All: When the instrument has not been used for more than one week, perform "Drain All" by emptying the instrument and washing the instrument with distilled water according to the interface prompts.

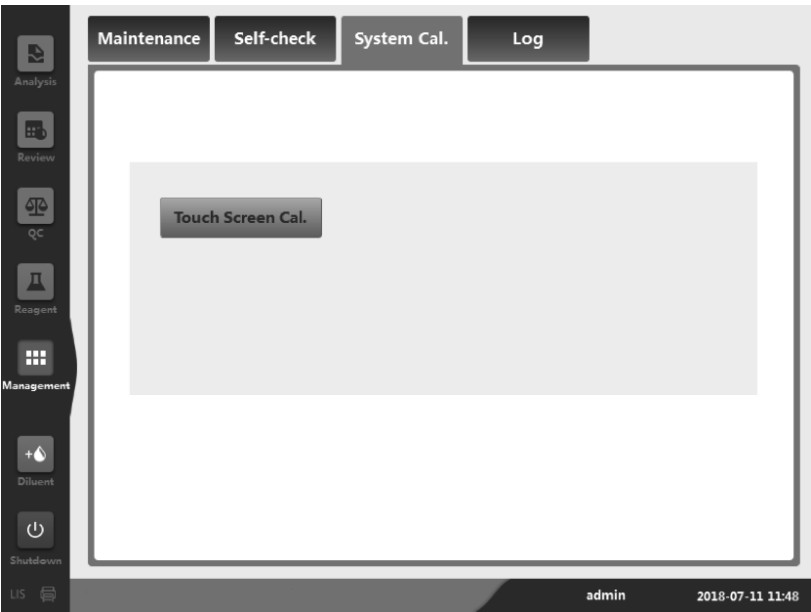
Self-check

Select "Management" > "Service" > "Self-check" to enter the following interface to perform system and valve self-checks.



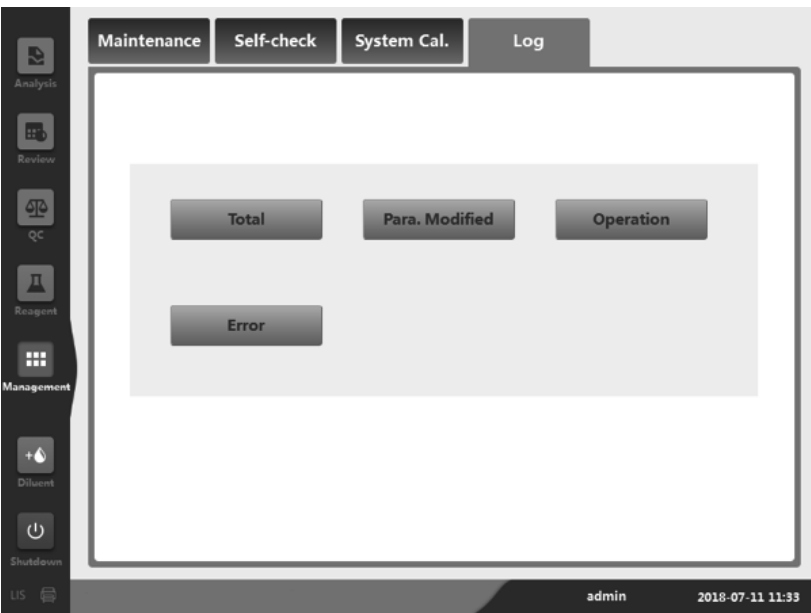
System Calibration

Choose "Management" > "Service" > "System Cal." to enter the following interface to perform touch screen calibration.



Log

Choose "Management" > "Service" > "Log" to enter the following interface.



The error, parameter modification, and daily operation logs can be viewed in this interface.

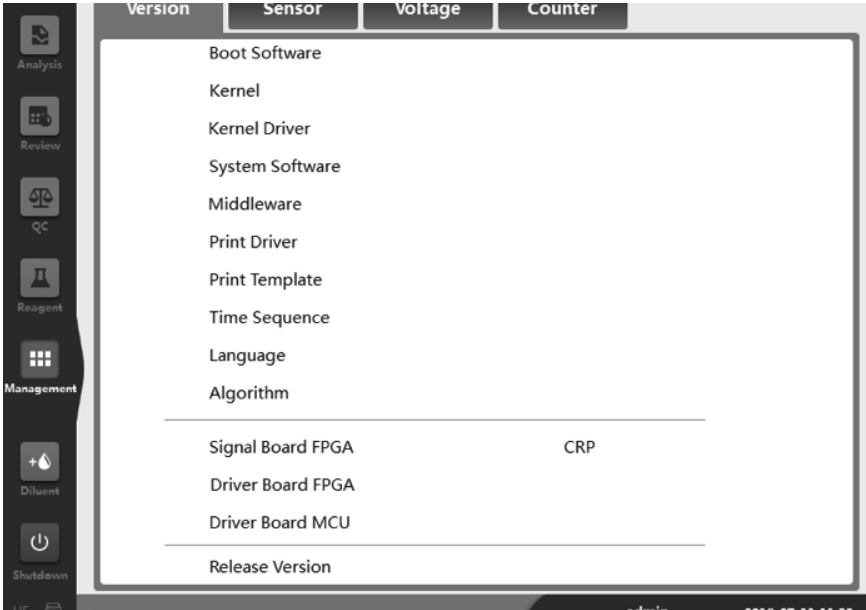
The logs can be used to record the use of the analyzer, and are important for the operator to search the use history and for the service personnel to troubleshoot problems.

- Log export
 - 1) Insert a "USB flash drive".
 - 2) Click "Export" and the following dialog box will pop up.
 - 3) Select the log records to export.
 - 4) The interface prompts "Export succeeded".

Status

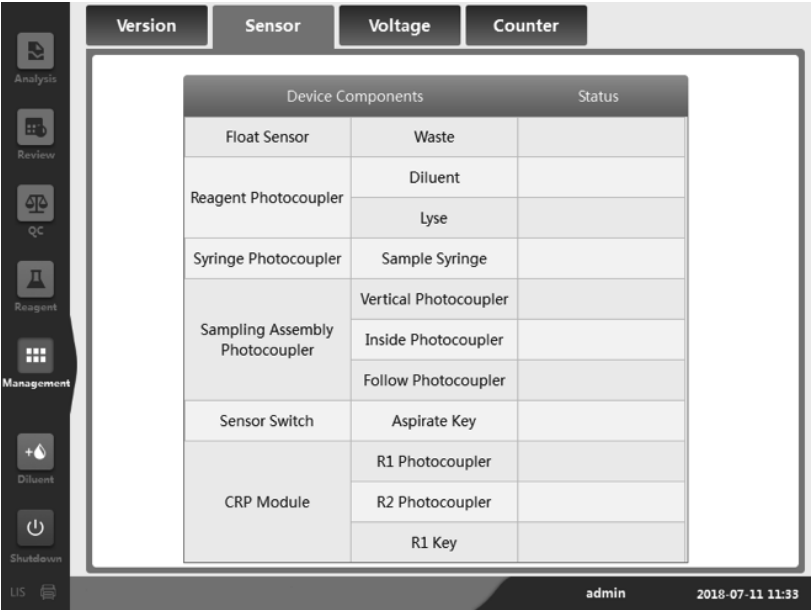
Version

Select "Management" > "Status" > "Version" to view the instrument's software version.



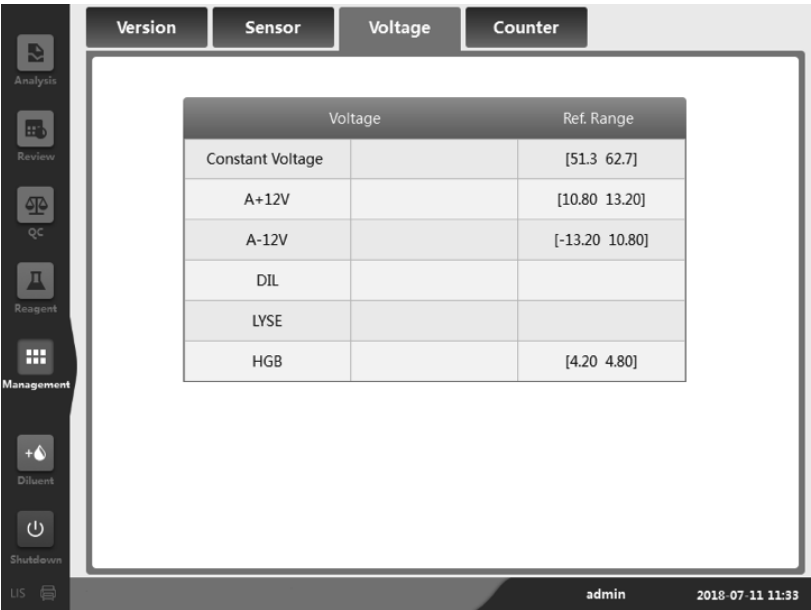
Sensor

Select "Management" > "Status" > "Sensor" to view the instrument's sensor status.



Voltage

Select "Management" > "Status" > "Voltage" to view the instrument's voltage status.



CHAPTER 11

TROUBLESHOOTING
YOUR ANALYZER

Introduction

This chapter describes the possible errors of the analyzer and provides the corresponding corrective actions.



Samples, controls, calibrators, waste liquid, etc. pose potential biological hazards. When the operator comes into contact with related articles in the laboratory, he/she shall comply with the laboratory safety practices and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

NOTE

This MANUAL does not serve as the maintenance manual and it only provides the measures that the operator should take when the analyzer gives a error alarm.

Error Information
and Handling

During the use of the analyzer, if an abnormal condition is detected, the corresponding error prompt message will be displayed at the bottom of the analyzer’s display interface, and the main unit will also sound an alarm.

Click on the error alarm area to open the error dialog box. The error dialog box provides the error messages and help information. The error messages will be displayed in the chronological order in which the errors occur.

The operator can select the error message in the dialog box by clicking on it. The help information of the selected error can be viewed in the “Error help” list box at the bottom of the dialog box. The help information of the first error is displayed by default. The operator shall deal with the errors in sequence according to the contents of the error help.

To help the operator look up errors, error messages that the analyzer may display are listed in the MANUAL, in which the possible causes and corrective actions are also provided. Thus, the operator is able to troubleshoot and clear the error messages accordingly. If the problem still exists, please contact the after-sales service department.

ERROR NAME	ACTIONS
Communication Abn	1. Click “Clear”, and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
Voltage Abnormal	1. Please turn off the power directly and contact our after-sales service department.
System Clock Abnormal	1. Please turn off the power directly and contact our after-sales service department.
No Reagent R2	1. Click “Clear” and enter the barcode of the new reagent in the popup message. 2. Change the reagent bottle and click the "Apply" button to prime the reagent. 3. If the error still exists, please contact our after-sales service department.
Diluent Expired	1. Click “Clear” and enter the barcode of the new reagent in the popup message. 2. Change the reagent bottle and click the "Apply" button to prime the reagent. 3. If the error still exists, please contact our after-sales service department.
Lyse Expired	1. Click “Clear” and enter the barcode of the new reagent in the popup message. 2. Change the reagent bottle and click the "Apply" button to prime the reagent. 3. If the error still exists, please contact our after-sales service department.
Waste Full	1. Empty the waste bucket or change to a new one. 2. Click the “Clear” button and this error will automatically clear. 3. If the error still exists, please contact our after-sales service department.
Diluent Empty	1. Click “Clear” and enter the barcode of the new reagent in the popup message. 2. Change the reagent bottle and click the "Apply" button to prime the reagent. 3. If the error still exists, please contact our after-sales service department.
Lyse Empty	1. Click “Clear” and enter the barcode of the new reagent in the popup message. 2. Change the reagent bottle and click the "Apply" button to prime the reagent. 3. If the error still exists, please contact our after-sales service department.
Voltage Abnormal	1. Please turn off the power directly and contact our after-sales service department.
Syringe Component Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.

ERROR NAME	ACTIONS
Sampling Component Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
Background Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
HGB Blank Voltage Abnormal	1. <u>Please check id the diluent empty or not.</u> If there is no reagent, please replace it with a new one. 2. Click the “Clear” button and this error will automatically clear. 3. If the error still exists, please contact our after-sales service department.
Vacuum Pressure Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
WBC Clog	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
WBC Aperture Voltage Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
WBC Impedance Signal Interference	1. Please remove the source of interference. 2. Click the “Clear” button and this error will automatically clear.
RBC Clog	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
RBC Aperture Voltage Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact our after-sales service department.
RBC Impedance Signal Interference	1. Please remove the source of interference. 2. Click “Clear” and this error will automatically clear.
Detection Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please restart the analyzer. 3. If the error still exists, please contact the after-sales service department.

Repair

The instrument may fail during use. If the user cannot repair it by himself/herself, he/she need to contact a service technician to check the failure on site. It may be necessary to replace the accessories. See Appendix C for a list of accessories.

APPENDIX A

SPECIFICATIONS

Classification

According to the CE classification, Z3/Z3 CRP Series belongs to In vitro diagnostic medical devices other than those covered by Annex II and devices for performance evaluation.

Reagents

Please use the reagents produced by Zybio.

Applicable Tubes

According to the CE classification, Z3/Z3 CRP Series belongs to In vitro diagnostic medical devices other than those covered by Annex II and devices for performance evaluation.

TYPE	SPECIFICATIONS AND DIMENSIONS	APPLICABLE MODE
Vacuum blood collection tube	Ø 12-15×75mm(without tube cap)	WB mode
Small anticoagulant tube	Ø 10.7×42mm(size without cap), 0.5ml, it can be tested for cap opening. Recommended: 0.5ml closed anticoagulant tube (REF. 365974) produced by BD Inc.	Capillary WB mode
Centrmanualge tube (bullet)	Ø 11×40mm 0.5ml and 1.5ml centrmanualge tubes	PD and capillary WB modes

Parameters

PARAMETER	ABBREVIATION	DEFAULT UNIT
WBC count	WBC	10 ⁹ /L
Lymphocyte count	Lym#	10 ⁹ /L
Intermediate cell count	Mid#	10 ⁹ /L
Neutrophil count	Gran#	10 ⁹ /L
Percentage of lymphocytes	Lym%	%
Percentage of intermediate cells	Mid%	%
Percentage of neutrophils	Gran%	%
RBC count	RBC	10 ¹² /L
Hemoglobin	HGB	g/L
Mean corpuscular volume	MCV	fL
Mean corpuscular hemoglobin content	MCH	pg
Mean corpuscular hemoglobin concentration	MCHC	g/L
RBC distribution width - coefficient of variation (RDW-CV)	RDW-CV	%
RBC distribution width - standard deviation (RDW-SD)	RDW-SD	fL
Hematocrit	HCT	%
Platelet count	PLT	10 ⁹ /L
Mean platelet volume	MPV	fL
Platelet distribution width	PDW	/
Plateletcrit	PCT	%
Platelet-large cell ratio	P-LCR	%
Platelet-large cell count	P-LCC	10 ⁹ /L
C-reactive protein	CRP	mg/L
Hypersensitive C-reactive protein	Hs-CRP	mg/L

Sampling Features

Sample Volume Required for Each Analysis

WB mode	≤ 15μl
PD mode	≤ 20μl

Throughput

CBC MODE	WB mode	Throughput no less than 70 samples/hour
	PD mode	Throughput no less than 70 samples/hour
WITH CRP MODE	WB mode	Throughput no less than 60 samples/hour
	PD mode	Throughput no less than 60 samples/hour

Performance Specifications

- Background/Blank Test

PARAMETER	BACKGROUND /BLANK COUNT REQUIREMENTS
WBC	≤0.2 × 10 ⁹ /L
RBC	≤0.02 × 10 ¹² /L
HGB	≤1g/L
HCT	≤0.5%
PLT	≤5 × 10 ⁹ /L
CRP	≤0.2mg/L

- Linearity Ranges

PARAMETER	LINEARITY RANGE	LINEAR ERROR (WB MODE)
WBC	(0 - 100.00)×109/L	≤±0.30×10 ⁹ /L or ≤±5%
	(100.01 ~ 300.00)×109/L	≤±9%
RBC	(0 - 8.00)×1012/L	≤±0.05×10 ¹² /L or ≤±5%
HGB	(0 - 250)g/L	≤±2g/L or ≤±2%
PLT	(0 - 1000)×109/L	≤±10×10 ⁹ /L or ≤±10%
	(1001 - 4000)×109/L	≤±12%
HCT	0% - 67%	≤± 2% (HCT) or ≤± 3% (error percentage)
CRP	0.2 mg/L - 10.0 mg/L	≤±1.0mg/L
	10.1 mg/L - 100.0mg/L	≤±15%
	100.1 mg/L - 320.0 mg/L	≤±20%

Input and
Output Devices

- Reproducibility

PARAMETER	DETECTION RANGE	WB (CV)	PD (CV)
WBC	(7.00 - 15.0)×109/L	≤ 2.0%	≤ 4.0%
	(4.00 - 6.9)×109/L	≤ 2.5%	
RBC	(3.50 - 6.50)×1012/L	≤ 1.5%	≤ 3.0%
HGB	110 g/L - 180 g/L	≤ 1.5%	≤ 3.0%
MCV	70fL - 110fL	≤ 0.5%	≤ 2.0%
PLT	(100 - 149)×109/L	≤ 5.0%	≤ 10.0%
	(150 - 500)×109/L	≤ 4.0%	≤ 8.0%
CRP	(0 - 10) mg/L	≤ 10%	≤ 15%
	(10.1 - 320) mg/L	≤ 5.0%	≤ 10%

- Carryover

PARAMETER	CARRYOVER
WBC	≤ 0.5%
RBC	≤ 0.5%
HGB	≤ 0.5%
PLT	≤ 1.0%
CRP	≤ 0.5%

- Comparability

ITEM	COMPARABILITY DEVIATION
WBC	≤± 5%
RBC	≤± 2.5%
HGB	≤± 2.5%
PLT	≤± 8%
MCV	≤± 3%

Touch Screen

10.4-inch TFT color touch screen, up to 24-bit color, resolution: 800 ×600.

Indicator Light

Used to indicate the analyzer's status: Power On/Off, Running, or Sleep.

Recorder

Built-in thermal recorder.

Buzzer

Used to indicate that the instrument is malfunctioning. The buzzer's alarm sound can be cleared automatically by tapping the touch screen or “Clear”.

Main Unit Interfaces

Main Unit Interfaces

- One network port, one built-in network card with networking function, compatible with TCP/IP protocol
- Four USB ports

Power Supply

	VOLTAGE	INPUT POWER	FREQUENCY
MAIN UNIT	100V - 240V	≤200VA	50Hz

Fuse

Analyzer fuse specifications: T 6.3AH 250V

▲WARNING

- Always use a fuse meeting the specified specifications.

The fuse can be replaced by the user. To replace the fuse, disconnect the power cord and pull the fuse out of the fuse slot in the filter:



Fuse
Fuse slot

Electromagnetic
Compatibility

1. Do not use this product near strong radiation sources (such as unshielded RF sources). Doing so may interfere with the normal operation of the product.
2. This product meets the emission and immunity requirements as specified in GB/T 18268.1 and GB/T 18268.26.
3. This product is designed and tested in accordance with GB 4824 Class A equipment.
4. Before using this product, users need to evaluate the electromagnetic environment.

Sound Pressure

Sound Pressure

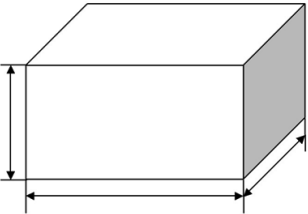
Operating
Environment

ENVIRONMENTAL REQUIREMENTS	STORAGE	OPERATION
Ambient temperature	-10°C-40°C	15°C-35°C
Relative humidity	10%-90%	20%-85%
Atmospheric pressure	50kPa-106kPa	70kPa-106kPa

NOTE

- Be sure to store and use the analyzer under the specified environmental conditions.

Dimensions
and Weights



MAIN UNIT	
Width (mm)	≤300
Height (mm)	≤410 (with support pads)
Depth (mm)	≤400
Weight (Kg)	≤20kg

Contraindications

None

Safety Classification

Level of transient overvoltage: Category II
Rated pollution degree: Level 2

APPENDIX B

KEY PARTS

SERIAL#	NAME
1	Switch power supply
2	Power cord
3	Filter
4	Fuse
5	Stepper motor

APPENDIX C

LIST OF SPARE PARTS

SERIAL#	PART
1	Switch power supply
2	Power cord
3	Filte
4	Fuse
5	Stepper motor
6	Three-way solenoid valve
7	Two-way solenoid valve
8	WBC counting chamber
9	RBC counting chamber
10	Liquid pump
11	Air pump
12	Main control board PCBA
13	Driver board PCBA
14	CRP measuring component
15	Open sample probe
16	Swab
17	Touch screen
18	Display

APPENDIX D

TOXIC AND HAZARDOUS
SUBSTANCES OR
ELEMENTS

PART	TOXIC AND HAZARDOUS SUBSTANCES OR ELEMENTS					
	LEAD (PB)	MERCURY (HG)	CADMIUM (CD)	HEXAVALENT CHROMIUM (CR(VI))	POLYBRO-MINATED BIPHENYLS (PBB)	POLYBRO-MINATED DIPHENYL ETHER (PBDE)
Built-in circuit board	×	○	○	○	○	○
Enclosure	×	○	○	×	○	○
Display	×	○	○	○	○	○
Optoelec-tronic com-ponents	×	○	○	○	○	○
Internal electronic wires	×	○	○	○	○	○
Accessories	×	○	○	○	○	○
<p>○: Indicates that the contents of the toxic and hazardous substances in all homogeneous materi als of the part is below the limit specified in SJ/T 11363-2006.</p> <p>×: Indicates that the contents of the toxic and hazardous substances in at least one homogeneous material of the part exceeds the limit specified in SJ/T 11363-2006.</p>						

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