

**Z50/Z52**  
**Hematology Analyzer**

**Operation Manual**



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The CE marking only applies to electrical equipment which has been placed on the market as per the EU Directive mentioned above.

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The Hematology Analyzer is for in vitro diagnostic use.

Second edition (September, 2022)

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## Revision history

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# 1 General

The Hematology Analyzer is developed and manufactured by Zybio Inc. (hereinafter referred to as Zybio) with the state-of-the-art technologies. It is a quantitative automated instrument for in vitro diagnostic use in clinical laboratories. It shall be used in the standardly managed medical laboratory and is not portable.

The Operation Manual (hereinafter referred to as Manual) is intended to help the users to understand the structures, operation principles, functions, performance, operation, sample analysis, maintenance and care, troubleshooting and technical support of the Analyzer.

To ensure correct operation of the Analyzer and the operator safety, please carefully read and understand the Manual prior to operating this Analyzer. The Manual is delivered together with the Analyzer. Please keep it properly for future reference after reading.

## Note

For customer training, please contact the local distributor of Zybio.

## 1.1 Basic information

Refer to the table below for the basics of the instrument. For the specifications and configuration of the instrument, refer to Section 3.3, "Specifications of the analyzer."

## Note

- Only whole blood, capillary blood, and prediluted blood of human should be run;
- Any use other than the intended is regarded as non-specified;
- The test results produced by the Analyzer are only for reference. Confirmation of clinical diagnosis shall be made based on the test results, the clinical symptoms, and other examination results.

**Table 1- 1 Basic analyzer information**

Item	Details
Instrument name	Hematology Analyzer
Model & REF No.	Z50: <b>REF</b> 3030102 Z52: <b>REF</b> 3030104
Intended purpose	The product is used for quantitative analysis of analytes in human blood samples by electrical impedance method, colorimetric method and laser flow cytometry, which are used in conjunction with Zybio matched reagents.

## General

Item	Details
Intended users	Medical laboratory professionals or technicians, and trained medical doctors or nurses.
Overvoltage category	II
Degree of ingress protection (IEC 60529)	IPX0
Means of protection	Class I
Classification of the Analyzer (IEC 60825-1)	Class 1 laser product
	Zybio Inc. Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
	Refer to the product nameplate
	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Service life	7 years <sup>1</sup>

Note 1:

The service life of the Analyzer is determined based on the lifespan test performed on the device. In the process of use, the user shall maintain or repair the Analyzer according to the Manual. The instrument with basic safety and performance after maintenance or repair can be used normally.

## 1.2 Models

This instrument has two models, i.e. Z50 and Z52. The operation principles, main functions, electrical structures, and key components of the two models are basically the same. The difference among them is their functional configuration (see Table 1- 2 below for details).

Table 1- 2 Differences among the models

Models	Functional configuration
Z50	The throughput of Z50 is 65 tests per hour. It has an external RFID reader.
Z52	The throughput of Z52 is 40 samples per hour. Its RFID reader is built-in.

## 1.3 About this manual

The Manual consists of ten chapters and two appendixes. Users can refer to the relevant chapter for the information needed.

Table 1- 3 Manual guide

Chapter	Content
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Chapter	Content
1. General	Introduces the basic information and types of the Analyzer as well as the information symbols in the Manual.
2. Installation	Introduces installation requirements, system connection, installation of printer paper and precautions on use.
3. Analyzer introduction	Introduces the structure, parameters and performance, specification and configuration of the Analyzer, and the software interface.
4. Operation principles	Introduces the testing principle and work flow of the Analyzer.
5. Daily operation	Introduces the methods for sample collection and preparation, the process of sample analysis, and startup and shutdown of the Analyzer, etc.
6. Result review	Introduces the frequently used operations for result review.
7. Quality control	Introduces the setting, analysis, and result review for the quality control part of the Analyzer.
8. Reagent management	Introduces the operations of user interface and reagent replacement.
9. Analyzer management	Introduces calibration, setup, service, status and so on.
10. Troubleshooting	Introduces the fault and disposal, fuse, and maintenance.
Appendix A Related information	Information about the Analyzer.
Appendix B Literature	List of references

## 1.4 Symbols

This chapter describes the symbols used on the Analyzer or in the Manual.

Symbols used in the Manual are as follows:

Table 1- 4 Symbols used in the Manual

Symbols	Explanation
	Indicates a reference to substances that may be hazardous to men, animals, plants, or the environment based on biological activity.
<b>Warning</b>	Indicates that non-compliance with instructions or procedures could lead to physical injury.
<b>Caution</b>	Indicates that non-compliance with instructions or procedures could cause damage to the instrument or

## General

	adverse effect on the test result.
<b>Note</b>	Indicates the important information or content that requires the attention of the user.

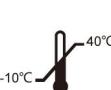
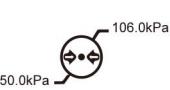
The symbols which may be used on the Analyzer and package are as follows:

**Table 1- 5 Symbols on the analyzer and package**

Symbols	Explanation
	Indicates that there are potential biological risks associated with the medical device. Note: this symbol is used when it comes to a sample probe, a waste drainage, and a waste container, users or service personnel shall be warned with biological risk.
	Indicates the need of taking care regarding the hazard specified by the supplementary sign; the user needs to consult the instructions for use (yellow background).
	Indicates the need for the user to consult the instructions for use for important cautionary information (white background). Note: this label is printed on system label, used for indicating users or service personnel shall consult the instruction for use for further information.
	Indicates the need of taking care to avoid injury from sharp elements. Note: using this symbol when contacting with a sample probe.
	Indicates the presence of the CLASS 3B laser radiation when open to avoid exposure to the beam.
<b>UDI</b>	Indicates a carrier that contains unique device identifier information.
<b>CE</b>	Indicates CE marking of conformity.
<b>IVD</b>	Indicates the instrument that is intended to be used as an in vitro diagnostic medical device.
<b>LOT</b>	Indicates the manufacturer's batch code so that the batch or lot can be identified.

Symbols	Explanation
<b>REF</b>	Indicates the manufacturer's catalogue number so that the medical device can be identified.
<b>EC REP</b>	Indicates the authorized representative in the European Community.
<b>SN</b>	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates the date when the medical device was manufactured.
	Indicates the medical device manufacturer.
	Indicates the need for the user to consult the instructions for use.
	Indicates the date after which the medical device is not to be used.
	Indicates connection to the mains.
	Indicates disconnection from the mains.
	Indicates the protective earth (ground).
	Indicates the function earth (ground).
	Indicates that the device is suitable for alternating current only.
	Indicates LD lyse.
	Indicates LB lyse.
	Indicates that contents of the distribution package are fragile therefore it shall be handled with care.
	Indicates the correct upright position of the distribution package for transport and/or storage.

## General

Symbols	Explanation
	Indicates that distribution packages shall not be rolled or turned over.
	Indicates that distribution packages shall be kept away from rain and be kept in dry conditions.
	Indicates the maximum number of identical transport packages or items which may be stacked on the bottom package.
	Indicates that distribution packages shall be stored, transported, and handled within temperature limits.
	Indicates the atmospheric pressure limits. Indicates that distribution packages shall be stored, transported, and handled within atmospheric pressure limitation.
	Indicates that distribution packages shall be stored, transported, and handled within humidity limits.
	Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.
	Indicates the connecting terminals of the computer network.
	Indicates the USB interface.
	Indicates the position to be pressed to open the door.

## 1.5 Safety precautions

To use your Analyzer safely and effectively, observe the following precautions. If the Analyzer is not used in a manner specified by the manufacturer, the protection provided may be impaired.

### Biological risk



- The liquid wastes and the waste containers are very dangerous. The spare parts of the Analyzer, the reagents and reagent bottles, and the surface of the Analyzer may be polluted by pathogens, please wear a pair of latex gloves

before touching them to prevent cross infection.

- If you accidentally touch the polluted spare parts or Analyzer surface, immediately rinse the affected part with plenty of clean water and disinfect yourself according to the requirements of your lab or hospital.
- Wear a pair of latex gloves and other necessary protective equipment before handling the samples to prevent cross infection. If the sample comes into your eyes or wounds, please immediately rinse the affected part with plenty of clean water and consult a physician.
- Dispose of the reagents, liquid waste, waste samples, consumables, exhaust of hazardous substances, etc. according to the local regulations.
- The controls and calibrators, etc. may be potentially infective. Wear a pair of latex gloves and other necessary protective equipment before handling them to prevent cross infection. If the control or calibrator, etc. comes into your eyes or wounds, immediately rinse the affected part with plenty of clean water and consult a physician.
- Exercise great care when handling the liquid wastes. If the liquid waste spills onto your body or clothes, please disinfect yourself and the clothes strictly.
- Dispose of the used consumables properly to prevent micro-organism breeding and cross infection.
- Do not use broken containers to prevent cross infection.
- Wear a pair of latex gloves and other necessary protective equipment before handling the reagent tray, the reagents, and the reagent bottles.
- Disinfect yourself according to the requirements of your lab or hospital after using the Analyzer to prevent cross infection.

#### General safety information

##### Warning

- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- Dispose of the discarded Analyzer according to the local regulations.
- Only trained professionals can operate the Analyzer.
- Repeated standard tests required by IEC 61010-1 may damage the Analyzer or undermine its protection.
- Use the Analyzer in the required environment.
- Use the Analyzer following the Manual; otherwise, personal injury and/or device failure may be caused, or unreliable test results may be produced.
- Do not use expired consumables or reagents.
- Do not reuse the disposables.
- The Manual describes the risks foreseen by Zybio Inc. (hereinafter referred to as Zybio); however, other risks may also require your attention.
- Device failures shall be handled by the persons specified in this Manual and/or by the professionals appointed by Zybio.
- If the Analyzer produces an unpleasant odor or smoke, or has other abnormal conditions during working, please immediately power off the Analyzer, unplug the power cord, and then contact the maintenance staff for maintenance; otherwise, fire, electric shock, or personal injury may be caused.

## General

- If water or reagent spills into the Analyzer, please power off the Analyzer to prevent electric shock or fire, and contact the Zybio or its local distributor for advice.
- Power off the Analyzer before connecting it to other equipment to prevent electric shock or device failure.
- Do not touch the internal circuits of the Analyzer to prevent electric shock.
- Do not modify the Analyzer without the authorization of Zybio. Zybio shall not be responsible for the device failure caused by unauthorized modification of the Analyzer.
- The USB drive shall be antivirus scanned before being inserted into the USB interface.
- Do not use internet via a router when using LIS.

### Caution

- Use only the reagents and solutions mentioned in this Manual.
- Do not pull or drag the power cord of the Analyzer during its operation to avoid interruption of operation and/or damage of test data.
- In case of fire, please immediately power off the Analyzer and unplug the power cord.
- Do not power off the Analyzer during its operation to avoid device failure.
- Do not click the touch screen with sharp objects (e.g., pen tip) to avoid damage of the screen.
- Be away from fire when using ethanol for disinfection.
- Keep the Analyzer stable and reduce vibration during the test process.

## Laser

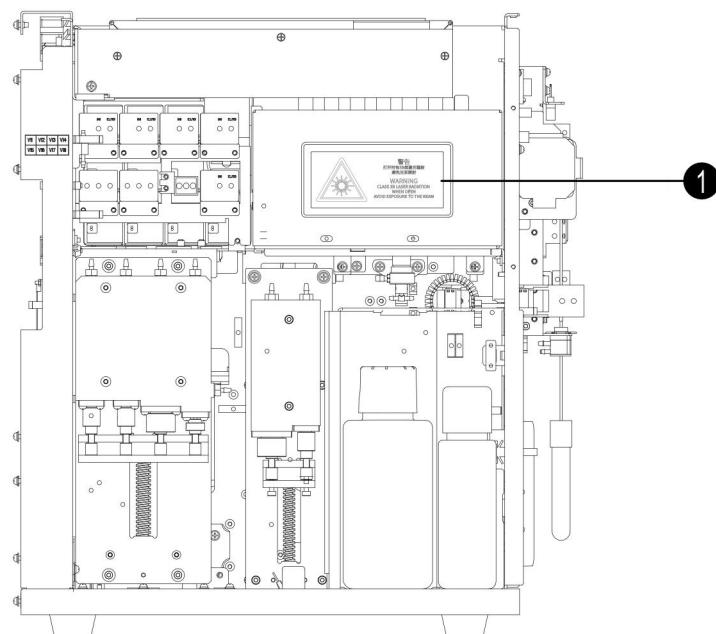


Figure 1- 1 Laser label

No.	Parts
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1	Laser label
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**Warning**

- Inside the Analyzer there is a laser (Class 3B, according to IEC 60825-1:2014). Only professional technicians from Zybio or the local distributor can assemble and dismantle the Analyzer.
- There may be Class 3B laser radiation when the interlocking fails or the Analyzer's cover is opened. Service professionals shall take protective measures and avoid direct exposure to the laser when providing maintenance service.
- The Analyzer is categorized as Class I laser product according to IEC 60825-1:2014. Users shall not open the device cover where the laser label is adhered to.
- Maximum output of laser: 4.5 mW, 670 nm wavelength, continuous, visible light.

**Electromagnetic compatibility****Warning**

- This Analyzer is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- The electromagnetic environment should be evaluated prior to operation of the Analyzer.
- Do not use this Analyzer in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

## 1.6 Electromagnetic emissions and immunity

The Analyzer complies with the emission and immunity requirements described in IEC 61326-2-6 and IEC 61326-1. It is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Users shall ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the Analyzer will perform as intended.

The calculation formula to determine the separation distance between the Analyzer and a mobile phone is given by  $d = 6/E \cdot \sqrt{P}$ , where  $d$  is the minimum separation distance in metres,  $P$  is the maximum power in watts, and  $E$  is the immunity test level in V/m.

Table 1- 6 Emission of the analyzer

Emissions test	EMC basic standard	Test limit	Compliance
Conducted emission	CISPR 11	Group 1, Class A	P
Radiated emission	CISPR 11	Group 1, Class A	P
Harmonic current emissions	IEC 61000-3-2	Class A	N. A.

## General

Voltage changes, Voltage fluctuations and Flicker	IEC 61000-3-3	--	N. A.
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Table 1- 7 Immunity of the analyzer

Port	Phenomenon	EMC basic standard	Test value	Performance criteria
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	2 kV and 4 kV contact discharge; 2 kV, 4 kV and 8 kV air discharge	B
	Electromagnetic field		3 V/m (80 MHz to 1 GHz); 3 V/m (1,4 GHz to 2 GHz); 1 V/m (2,0 GHz to 2,7 GHz)	A
	Power frequency magnetic field		3 A/m, (50 Hz, 60 Hz)	A
AC power (protective grounding included)	Voltage dip	IEC 61000-4-11	0 % during 1 cycle	B
			40 % during 5/6 cycles	B
			70 % during 25/30 cycles	C
	Short interruptions	IEC 61000-4-11	Less than 5 % during 250/300 cycles	C
	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	1 kV (Line to line) / 2 kV (Line to earth (ground))	B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A

## 1.7 Residual risk

The Analyzer is a dedicated medical device, and its functionality requires correct operation of hardware and software components, as well as appropriate operating conditions.

A safe and effective operation of the Analyzer requires that the users have undergone necessary training, especially on the intended purpose of the Analyzer, the safety precautions on the usage, and the cyber security.

The risk mitigation measures are implemented to minimize various hazards (including but not limited to biological hazard and mechanical hazard from aspiration needle) as far as possible; however electromagnetic compatibility hazard cannot be completely excluded.

The Analyzer is used together with the specified calibrators, controls and reagents as a detection system, to provide relevant results of blood counting to aid clinical diagnosis. The test results produced by the Analyzer are for reference only, confirmation of clinical diagnosis shall be made based on the test results, the clinical symptoms, and other examination results.



## 2 Installation

The Analyzer has been carefully tested and well packed before delivery. Check the package upon your acceptance of the Analyzer. If there is any damage in the package, immediately contact Zybio or its local distributor.

Zybio and its local distributor provide field installation service, and only Zybio and its local distributor can assemble, install, and debug the Analyzer. Zybio shall not be liable for instrument failure or personal injury caused by unauthorized installation of the Analyzer.

### **Caution**

Unauthorized or untrained personnel may be injured or damage the Analyzer when unpacking or installing the Analyzer. Do not unpack or install the Analyzer in absence of the representative of Zybio or the local distributor.

### 2.1 Installation requirements

Before installation, the user shall ensure that the installation site, the power supply, and the fuses, etc. are ready.

#### 2.1.1 Space requirements

Leave a sufficient space between the Analyzer and the walls for maintenance and repair of the Analyzer. For good heat dissipation of the instrument and to ensure that the external fluid pipelines are not kinked, the installation site should meet the requirements below:

- The spaces between the wall and the side-doors of the Analyzer respectively should be at least 30 cm;
- The space between the wall and the rear panel of the Analyzer should be at least 20 cm;
- The platform where the Analyzer is placed can bear a weight of at least 100 kg;
- There is enough space on and below the platform to place and/or store reagents and waste liquids.

#### 2.1.2 Power requirements

The power supply connected to the Analyzer shall meet the requirements below:

Main Unit	Power Voltage	Power Frequency	Input Power	Fuse	Mains supply voltage fluctuation
	100V – 240V <sup>~</sup>	50/60 Hz	≤ 200 VA	T6.3AH250V	±10%

**Warning**

- The Analyzer must be used with a well-grounded connection.
- The operator must use a fuse with specified specifications.
- Verify that the input voltage meets the Analyzer requirements.

**Note**

- Additional electrical interference and incorrect analysis results may be caused by using plug board. Please place the Analyzer near the power socket to avoid the use of plug board.
- Use the power cord equipped with the Analyzer. Damage to the Analyzer or incorrect analysis results may be caused by using other power cord.
- The plug is used as a disconnect device to the main supply.
- To avoid the risk of electric shock, this Analyzer must only be connected to the supply with protective earthing.

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### **2.1.3 Environmental requirements**

The environments where the Analyzer is installed, transported, and stored shall meet the requirements below:

- Pollution degree: 2
- Do not place this Analyzer in proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.
- Do not use the Analyzer in flammable and/or explosive environment.
- If room temperature for the Analyzer exceeds the normal operating temperature, the analysis result will be unreliable.
- Do not place the Analyzer near brush-type motors, flashing fluorescent lights, and electrical contact devices that are frequently switched on/off.
- Do not position the Analyzer so that it is difficult to operate the disconnection device.
- Avoid direct sunlight or heat and wind sources.
- The environment should be free from dust, mechanical vibration, major noise sources, and power interference.
- The Analyzer should be installed on non-flammable surface.
- The electromagnetic environment should be evaluated prior to operation of the Analyzer.
- Use a dedicated power outlet. Do not use the same power outlet with device, such as air-conditioners, refrigerators, ultrasound systems, etc., that are likely to emit interference signals.
- Position the Analyzer as close to the wall outlet as possible, taking care to ensure sufficient room for ventilation.
- Place the Analyzer on a flat, stable, and vibration-free surface.
- Well - ventilated;
- Well - grounded connection;
- Indoor use only.

**Warning**

Do not use the Analyzer in presence of flammable substance and/or explosives, otherwise, it may result in fire, explosion, and personal injury, etc.

**Caution**

When the room temperature exceeds the required operating temperature limits, the Analyzer temperature may exceed its limit, and the test results may be unreliable.

Environmental Requirements	Working	Storage	Shipping
Ambient Temperature	10°C – 30°C	-10°C – 40°C	-10°C – 40°C
Relative Humidity	20% – 85% (No condensation)	10% – 90% (No condensation)	10% – 90% (No condensation)
Atmospheric Pressure	80 kPa – 106 kPa	50 kPa – 106 kPa	50 kPa – 106 kPa
Altitude	$\leq 2000\text{ m}$		

## 2.1.4 Handling requirements

The Analyzer's net weight is 29 kg, and its gross weight is about 35 kg, which can be lifted by an adult. Only Zybio or its local distributor can pack and unpack, and relocate the instrument, otherwise the effectiveness and safety of the Analyzer cannot be guaranteed.

**Warning**

- If the Analyzer is unpacked or installed by the personnel not authorized or trained by Zybio, personal injury or main unit damage may occur. Do not unpack or install the main unit in absence of the authorized personnel of Zybio or the local distributor.
- Always disconnect the power supply at first before removal of the Analyzer from use, and contact Zybio or its local distributor for service.

**Caution**

To avoid the damage to sample components during transportation, the movable components are fixed with clamps or cable ties in delivery. Therefore, remove the clamp/cable tie before using the Analyzer.

**Note**

Retain the shipping container and packaging materials in case that the Analyzer

## Installation

needs to be returned to Zybio for service.

### 2.2 System connection

Before running the Analyzer, check that the electrical and fluidic connections are in place and secure.

#### 2.2.1 Power supply connection

The instrument power supply cord uses a 3-prong plug. When the power supply socket is provided with grounding, simply plug it to the socket.

Use a dedicated power outlet. Do not share the power outlet with air-conditioners, refrigerators, ultrasound systems, etc., which may emit electromagnetic signals.

Follow the steps below to connect power supply:

- (1) Place the Analyzer on the designated surface;
- (2) Connect the power port of the Analyzer to the power supply;
- (3) Connect the power supply to a properly grounded mains outlet;
- (4) Press and release the power button to power on the Analyzer.

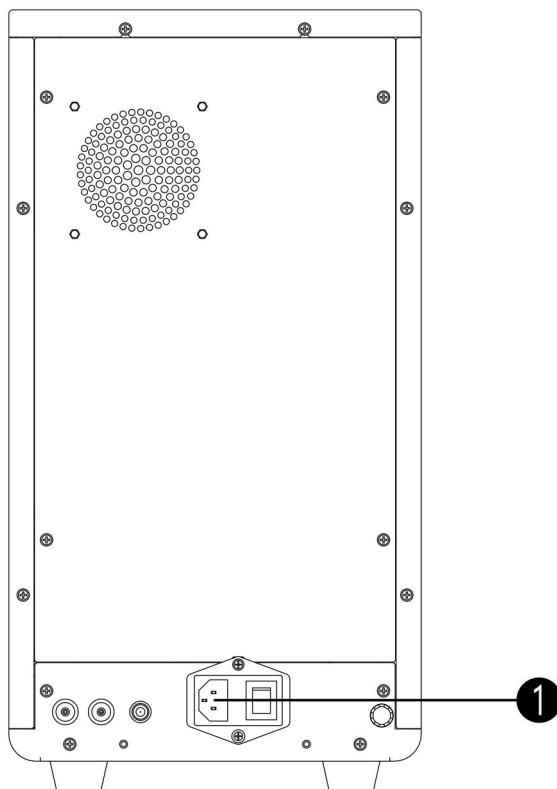


Figure 2- 1 Electrical connection – power supply

No.	Part name	Operation description
1	Power interface	<ol style="list-style-type: none"><li>1) Insert the connector of a power cord into the power interface;</li><li>2) Plug the plug of the power cord into the wall socket.</li></ol>

**Warning**

- The Analyzer must be well grounded.
- Use the specified fuse.
- Verify that the input voltage meets the requirements.
- Connect the Analyzer to the grounded mains supply to prevent electric shock.

**Caution**

- Use of a power strip may pose additional electrical interference and result in erroneous analysis. Place the Analyzer near the power outlet to avoid using a power strip.
- Use the power cords provided by the manufacturer. Using power cords with inadequate rating may damage the Analyzer or cause erroneous analysis.

### 2.2.2 Network connection

Only IT equipment, which has been approved according to the insulation requirements of IEC 60950-1 or IEC 62368-1, is permitted to connect with this Analyzer via the USB interface or RJ45 port.

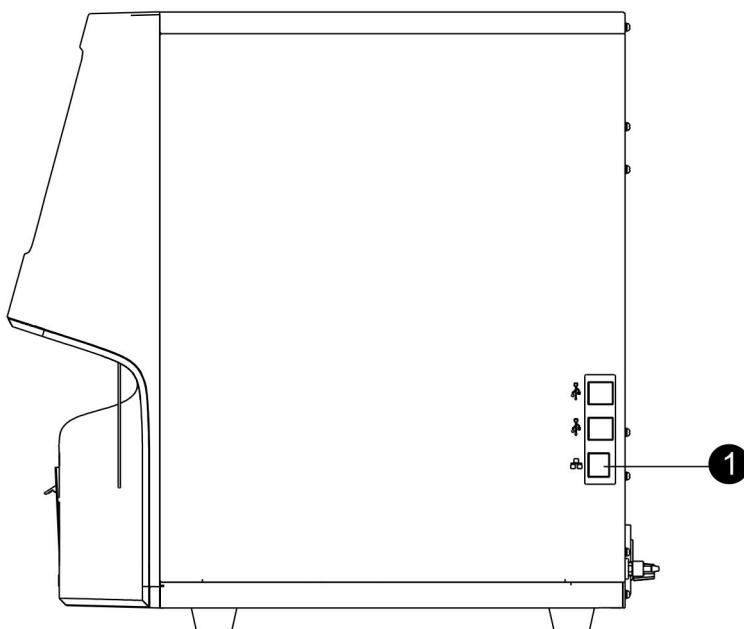
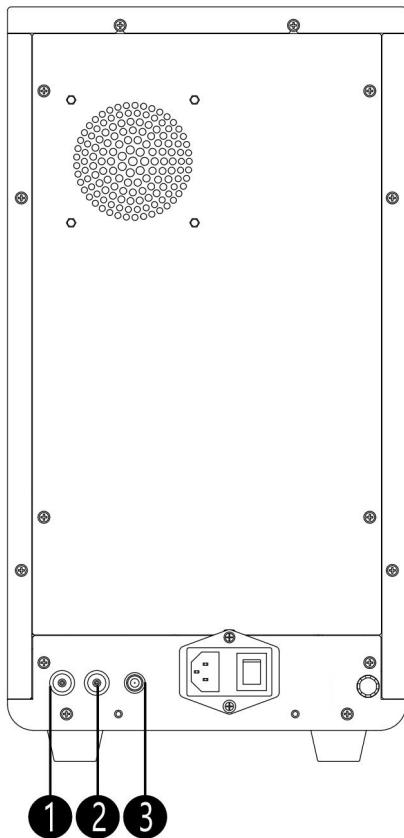


Figure 2- 2 Electrical connection - network

No.	Part name	Operation description
1	Network interface	Use a standard Ethernet data cable not longer than 3 meters and connect to the local network.

### 2.2.3 External fluidic pipeline connection

Follow the steps below to connect the external fluidic pipelines.

**Figure 2-3 External liquid path connection**

No.	Part name	Operation description
1	Diluent tube port	1) Insert the connector of a diluent tube into the diluent tube port; 2) Put the other end of the diluent tube into the diluent container.
2	Liquid waste sensor port	1) Insert the connector of a liquid waste sensor wire into the liquid waste sensor port; 2) Put the other end of the liquid waste sensor wire into the liquid waste container.
3	Waste tube port	1) Insert the connector of a liquid waste tube into the waste tube port; 2) Put the other end of the liquid waste tube into the liquid waste container, or connect to the drainage system of laboratory.

**Caution**

- The operator is obliged to comply with the relevant national and regional regulations regarding the discharge and processing of expired reagents, liquid waste, waste samples, consumables, etc.
- Leave a sufficient space below the table or the instrument to put the liquid

waste container and the diluent container;

- The user shall comply with the relevant national and regional regulations regarding the discharge and processing of expired reagents, liquid wastes, waste samples, consumables, etc.

## 2.2.4 Lyse bottle installation

Install the lyse bottles according to the steps described in Section 8.1, "Replacement of reagent bottle."

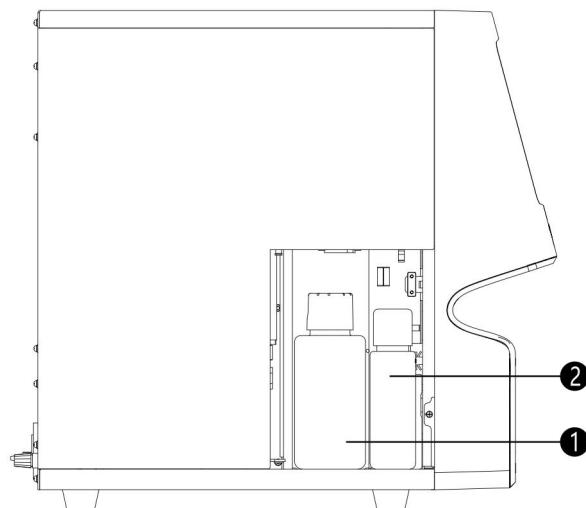


Figure 2-4 Z50 Internal connection of lyse

No.	Name
1	Z5 LD Lyse
2	Z5 LB Lyse

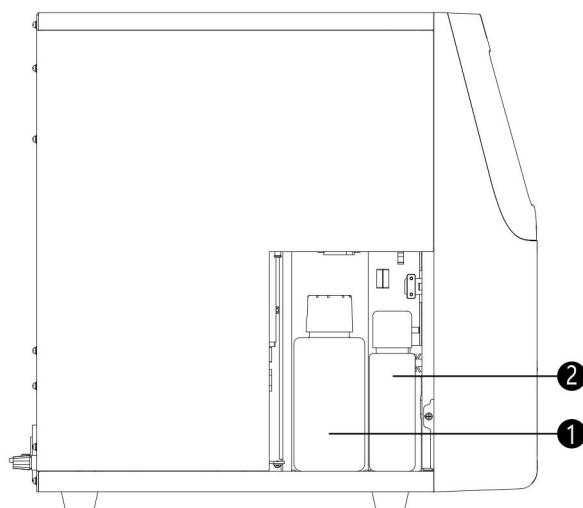


Figure 2-5 Z52 Internal connection of lyse

No.	Name
1	Z5 LD Lyse
2	Z5 LB Lyse

**Caution**

- Reagents may irritate the eyes, skin and mucous membranes. When the user 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 suit, latex gloves, masks, etc.).
- Once the reagent contacts the skin, rinse with plenty of water immediately. If necessary, seek medical treatment. Once the reagent contacts your eyes, immediately rinse with plenty of water and seek medical treatment.

## 2.3 Printer paper installation and external printer connection

The Analyzer has a built-in thermal printer and also can be connected to an external printer. Please use appropriate printer paper and/or an external printer.

The printer paper for the built-in thermal printer shall be as follows.

Paper type	Specification
Thermal paper	57 * 50 (mm) (mm)

Install the printer paper following the steps below:

- (1) Open the door of paper chamber;



**Figure 2- 6 Opening the paper chamber door**

- (2) Load the printer paper into the paper chamber in the direction shown below, with the paper end outside the paper outlet;



Figure 2- 7 Installing the thermal paper into the paper chamber

(3) Close the paper chamber door.



Figure 2- 8 Closing the thermal printer door

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**Note**

- Remove the protective paper from the thermal printer before installing the printer paper for the first time.
  - During printing, do not pull the printer paper with force; otherwise, the thermal printer may be damaged.
  - Keep the thermal printer door open unless you are changing the paper or troubleshooting the recorder.
  - Printer paper installation errors may cause paper jams or printing failure.
- 

The Analyzer can be connected to the external printers including but not limited to:

- HP LaserJet P1008;
- HP LaserJet M12a;
- HP DeskJet 1112.

Please connect the external printer according to the instructions for use of the printer.

## **2.4 Function checks for proper installation**

At the time of installation, the installer from Zybio or the local distributor shall perform diligent checks to ensure that the Analyzer runs normally, and train the user to correctly operate the Analyzer.

## 3 Analyzer introduction

The Analyzer consists of a control center system, a signal and data processing system, a drive and execution system, a terminal interaction system, and the mechanical structure. The control center system serves to perform algorithm processing on data uploaded by signal and data processing system. The signal and data processing system collects and preprocesses the signals from RBC/PLT channel, WBC/HGB channel and optical system. The drive and execution system controls the motor stepper, valves as well as pumps in the Analyzer, and also monitors the position sensor, the vacuum pressure, the ambient temperature and the power supply. The terminal interaction system provides man-machine interaction functions, such as sample information input, result display, review, export, communication, print, upgrade, ect. The mechanical structure serves as a base for installation of all parts and as a partition between the external and internal of the Analyzer.

This chapter introduces the Analyzer structure, the parameters and performance, the Analyzer specification and configuration, the software interface, and the reagents compatible with the Analyzer.

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**Note**

The illustrations below may be inconsistent with the Analyzer you obtained due to the differences in product variants, software versions, etc.

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### 3.1 Structure

This section briefly introduces the front, side and rear views as well as the main parts of the Analyzer through illustrations.

### 3.1.1 Front view

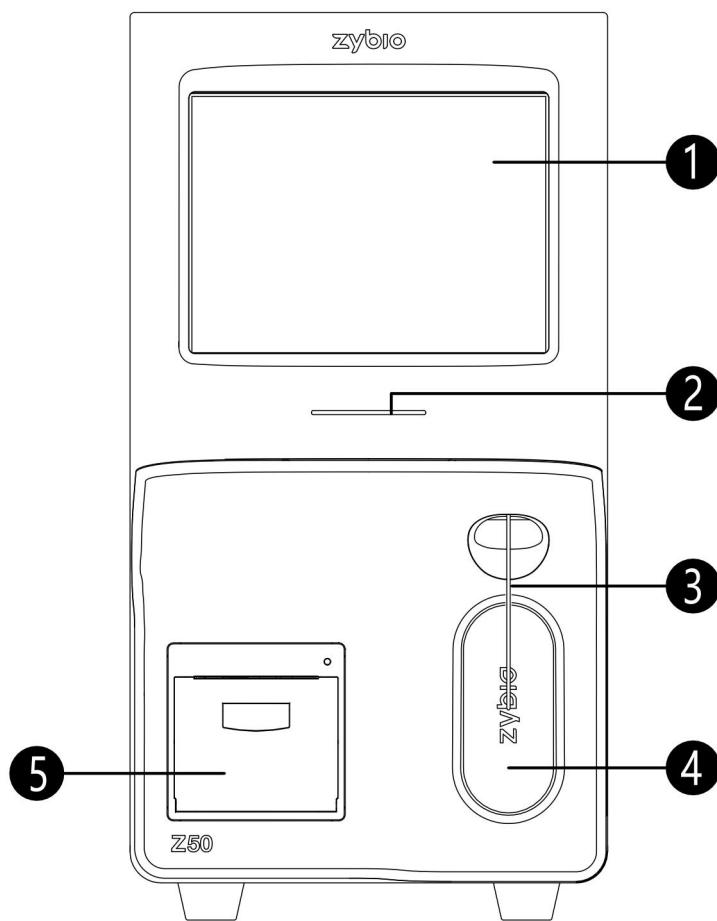


Figure 3- 1 Z50 Front view

No.	Parts	Description
1	Touch screen	An 8.4-inch color TFT touch screen. Used for user interaction and display of information.
2	Indicator light	Indicates the status of the Analyzer with red, yellow, and blue colors. Blue: normal working Yellow: standby Red: fault
3	Sample probe	Aspirates sample.
4	Aspirate key	Used to start blood cell counting, adding diluent, or aspiration of sample. Standby state: press it to exit standby. Working state: press it to start aspiration of sample.
5	Built-in thermal printer	Prints the analysis results on paper.

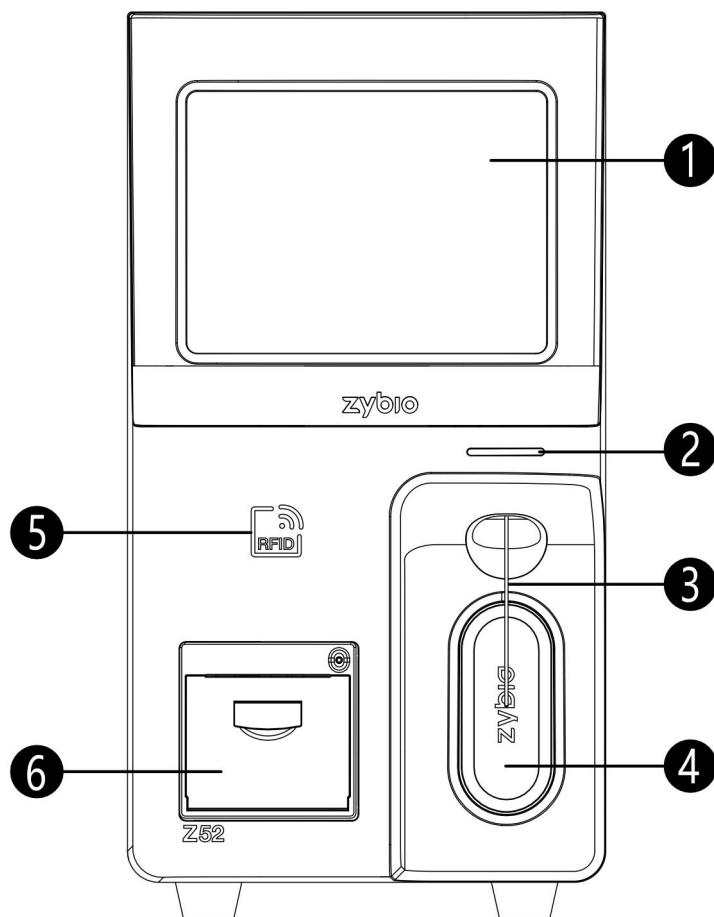


Figure 3- 2 Z52 Front view

No.	Parts	Description
1	Touch screen	An 8.4-inch color TFT touch screen. Used for user interaction and display of information.
2	Indicator light	Indicates the status of the Analyzer with red, yellow, and blue colors. Blue: normal working Yellow: standby Red: fault
3	Sample probe	Aspirates sample.
4	Aspirate key	Used to start blood cell counting, adding diluent, or aspiration of sample. Standby state: press it to exit standby. Working state: press it to start aspiration of sample.
5	RFID reader	RFID reader is designed to read or write the label identifier and stored data by radio communication between radio and RFID electronic labels.
6	Built-in thermal printer	Prints the analysis results on paper.

### 3.1.2 Rear view

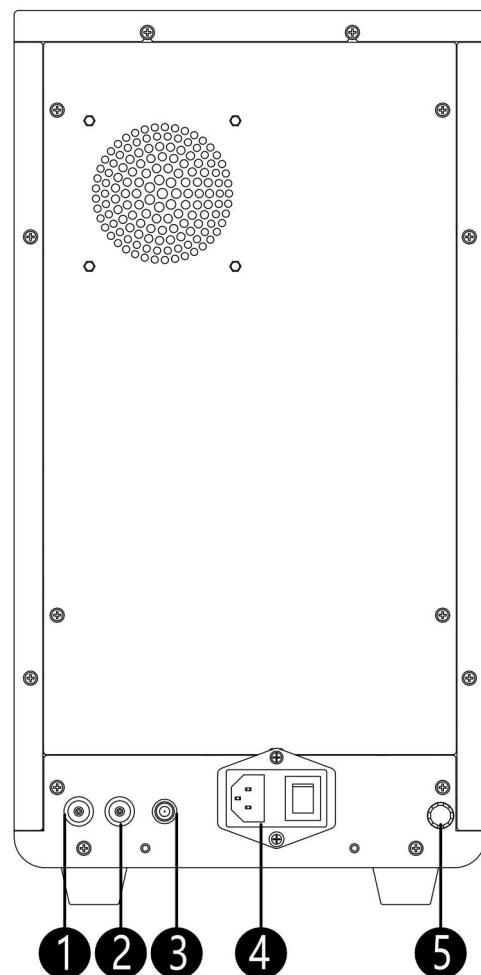


Figure 3- 3 Rear view

No.	Parts	Description
1	Diluent tube port	Connects the diluent tube through which the diluent flows.
2	Waste tube port	Connects the liquid waste tube through which the liquid waste flows.
3	Liquid waste sensor	Monitors the amount of liquid waste.
4	Power source subassembly	Consists of a power cord port and a power switch, etc. for power connection.
5	Protective earthing	For protective grounding.

### 3.1.3 Right view

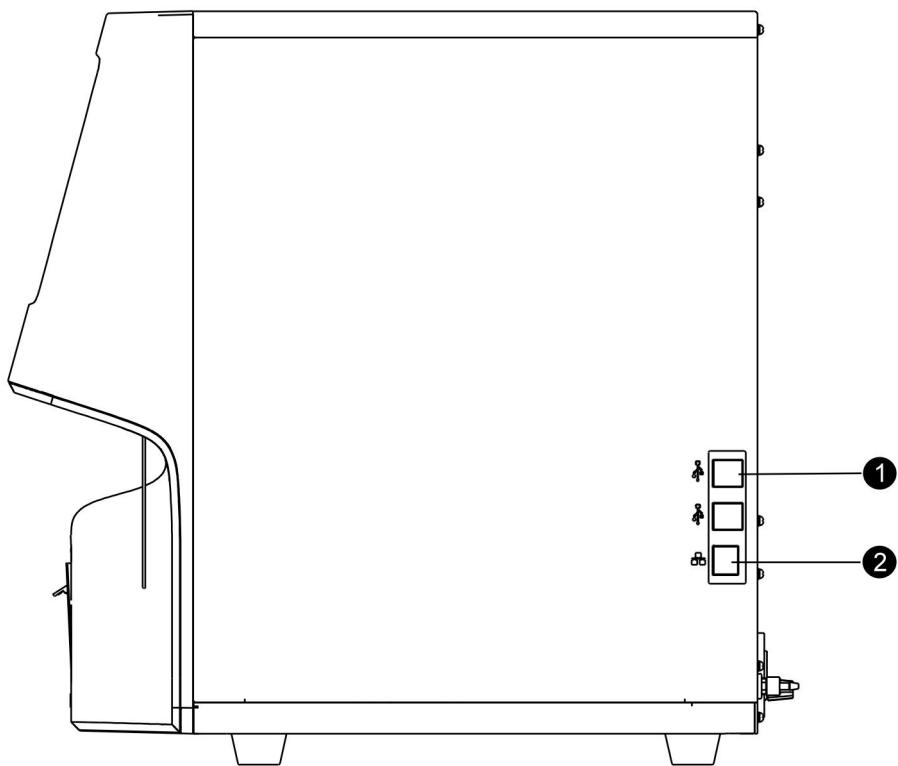


Figure 3- 4 Right view

No.	Parts	Description
1	USB interface	There are 4 USB interfaces for connecting the Analyzer to an external printer, a USB drive, a memory card reader, a keyboard or a mouse during debugging, maintenance and upgrading.
2	Network interface	There is one network interface on the back of Analyzer for connecting the Analyzer with LIS of computer to transmit data.

### 3.1.4 Left view

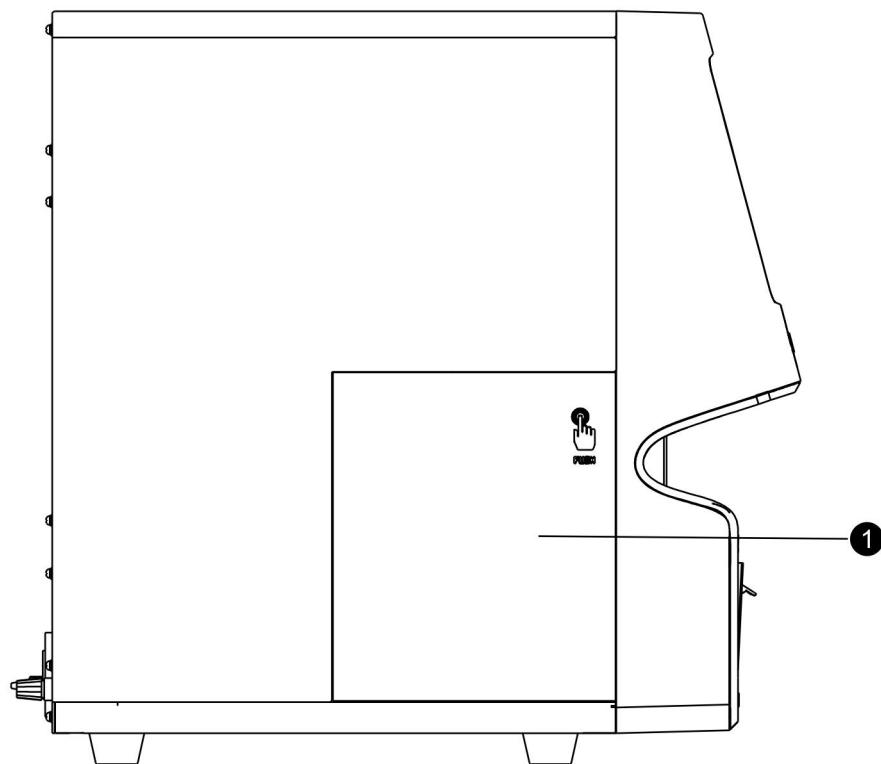


Figure 3- 5 Left view

No.	Parts	Description
1	Reagent chamber	Open the door to put in or take out the reagent bottles.

## 3.2 Parameters and performance

The parameters below defines the performance of the Analyzer.

### 3.2.1 Background count

The background count parameters of the Analyzer meet the requirements below:

Table 3- 1 Background count value requirement

Parameter	Background count requirement
WBC	$\leq 0.2 \times 10^9 / L$
RBC	$\leq 0.02 \times 10^{12} / L$
HGB	$\leq 1 g/L$
HCT	$\leq 0.5 \%$
PLT	$\leq 5 \times 10^9 / L$

### 3.2.2 Carryover rate

The carryover rate of the Analyzer meets the requirements below:

Table 3- 2 Carryover rate of the analyzer

Parameter	Carry over
WBC	$\leq 0.5\%$
RBC	$\leq 0.5\%$
HGB	$\leq 0.5\%$
HCT	$\leq 0.5\%$
PLT	$\leq 1.0\%$

### 3.2.3 Linear parameters

The linear parameters of the Analyzer meet the requirements below:

Table 3- 3 Linear parameter range

Parameter	Linearity range	Linear error (WB mode)	r
WBC	$0.00 \times 10^9/L$ – $100.00 \times 10^9/L$	Within $\pm 0.50 \times 10^9/L$ or $\pm 5\%$	$\geq 0.990$
	$100.01 \times 10^9/L$ – $500.00 \times 10^9/L$	Within $\pm 10\%$	
RBC	$0.00 \times 10^{12}/L$ – $8.00 \times 10^{12}/L$	Within $\pm 0.05 \times 10^{12}/L$ or $\pm 5\%$	$\geq 0.990$
HGB	0 g/L – 250 g/L	Within $\pm 2$ g/L or $\pm 2\%$	$\geq 0.990$
PLT	$0 \times 10^9/L$ – $1000 \times 10^9/L$	Within $\pm 10 \times 10^9/L$ or $\pm 8\%$	$\geq 0.990$
	$1001 \times 10^9/L$ – $5000 \times 10^9/L$	Within $\pm 12\%$	
HCT	0%~67%	Within $\pm 2\%$ (HCT value) or $\pm 3\%$ (error percentage)	$\geq 0.990$

### 3.2.4 Precision and accuracy

The precision of the Analyzer was calculated after the qualified samples were tested for 10 times. Please refer to the tables below for reference.

Table 3- 4 Precision of the analyzer

Parameter	Measuring Range	WB	PD
		(CV/ Absolute d)	(CV/ Absolute d)
WBC	$3.5 \times 10^9/L$ – $6.9 \times 10^9/L$	$\leq 2.5\%$	$\leq 4.0\%$
	$7.00 \times 10^9/L$ – $15.00 \times 10^9/L$	$\leq 2.0\%$	$\leq 4.0\%$
Neu%	50.0% – 70.0%	$\pm 4.0(d)$	$\pm 8.0(d)$
Lym%	20.0% – 40.0%	$\pm 3.0(d)$	$\pm 6.0(d)$
Mon%	5.0% – 10.0%	$\pm 2.0(d)$	$\pm 4.0(d)$

## Analyzer introduction

Parameter	Measuring Range	WB	PD
		(CV/ Absolute d)	(CV/ Absolute d)
Eos%	2.0% - 5.0%	±1.5 (d)	±2.5 (d)
Bas%	0.5% -1.5%	±0.8 (d)	±1.2 (d)
RBC	$3.50 \times 10^{12}/L$ - $6.00 \times 10^{12}/L$	≤1.5%	≤3.0%
HGB	110 g/L - 180 g/L	≤1.5%	≤3.0%
MCV	70 fL - 120 fL	≤0.5%	≤2.0%
PLT	$100 \times 10^9/L$ - $149 \times 10^9/L$	≤6.0%	≤10.0%
	$150 \times 10^9/L$ - $500 \times 10^9/L$	≤4.0%	≤8.0%
MPV	/	≤4.0%	≤8.0%

The accuracy of the Analyzer is as below:

Table 3- 5 Accuracy of the analyzer

Parameter	Measuring range	Comparability deviation /%
WBC	$3.5 \times 10^9/L$ - $9.5 \times 10^9/L$	Within ±15%
RBC	$3.8 \times 10^{12}/L$ - $5.8 \times 10^{12}/L$	Within ±6%
HGB	115 g/L - 175 g/L	Within ±6%
HCT/MCV	35% - 50% (HCT) or 82fL - 100 fL (MCV)	Within ± 9.0% (HCT) or ±7.0% (MCV)
PLT	$125 \times 10^9/L$ - $350 \times 10^9/L$	Within ± 20%

### 3.3 Specifications of the analyzer

Refer to the table below for the specifications and configuration of the product.

Table 3- 6 Product specification and configuration

Item	Description		Remarks
Dimensions	Width: 230 mm Height: 435 mm (rubber feet included) Depth: 455 mm		/
Net weight	29 kg		/
Throughput (CBC/CBC+DIFF mode)	Z50	WB mode: ≤ 65 tests per hour PD mode: ≤ 65 tests per hour	/
	Z52	WB mode: ≤ 40 tests per hour	

Item	Description	Remarks
	PD mode: ≤40 tests per hour	
Output/input devices	Touch screen Indicator light Built-in thermal printer Buzzer RFID reader	/
Output/input ports	RJ45 port (LAN port): compatible with TCP/IP protocol, used for connecting the Analyzer to the Laboratory Information System (LIS) for one-way data transmission. 4 USB ports: type A, female, USB 2.0; working output voltage: DC 5V.	All external attachments connected shall comply with the electrical insulation requirement according to IEC 60950 or IEC 62368-1.
Power supply	Voltage: 100 V - 240 V ~ Input power: 200 VA Frequency: 50/60 Hz	/
Fuse	T6.3AH250V	/
Noise level	Standby mode sound pressure level ≤ 60 dB Operation mode sound level ≤ 65 dB	No hazardous sound emission.
Hardware configuration	Processor: ARM A8 (the lowest) Memory: 256M RAM (the lowest)	/
Operating software	5-part Differential Hematology Analyzer Operating Software	/
Software operating environment	Linux 3.0.35 or above, embedded in the Analyzer	/
Data transmission protocol	TCP/IP	/
Network requirements	Network architecture: CS Network type: LAN Bandwidth: no requirement Connecting to external internet is forbidden, otherwise the cybersecurity cannot be guaranteed.	/
Security software	None	/
User access control	The software authenticates the user identity (system administrator, ordinary user, or maintenance personnel) and initiates the	/

Item	Description	Remarks
	corresponding access control mechanism through the user's name and login password.	
Requirements for updating software environment and security software:	None.	/

### 3.4 Software interface

After the Analyzer starts up, it shows the interface of "Analysis" as below:

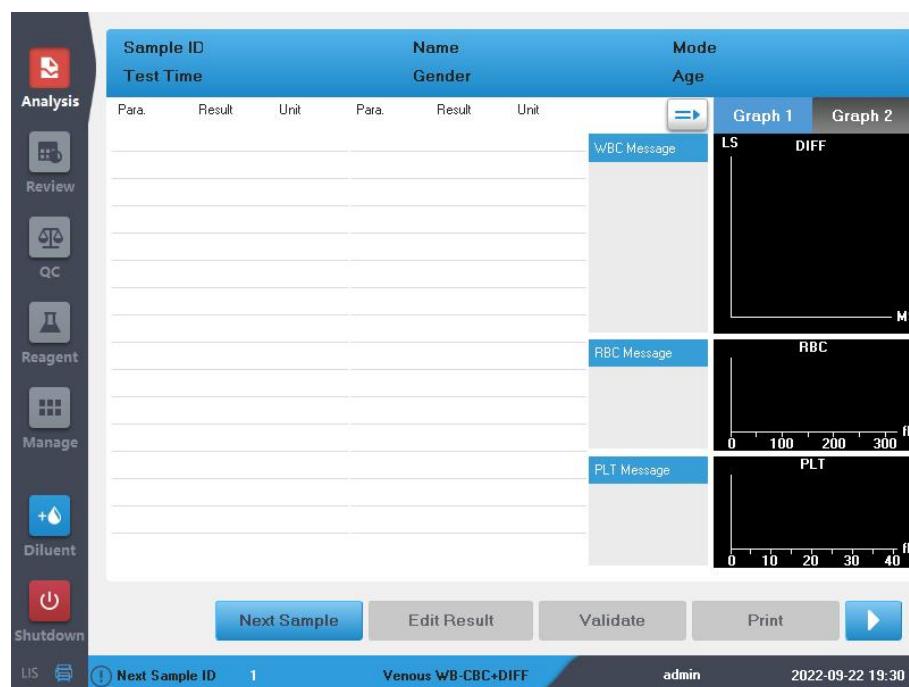


Figure 3- 6 Interface after startup

As shown in Figure 3- 6, on the right side of the interface there are 7 major functional modules, including "Analysis", "Review", "QC", "Reagent", "Manage", "Diluent", and "Shutdown", through which users can implement corresponding functions.

- Refer to Section 5.5, "Sample analysis," for the operation in the module of "Analysis";
- Refer to Chapter 6, "Result review," for the operation in the module of "Review";
- Refer to Chapter 7, "Quality control," for the operation in the module of "QC";
- Refer to Chapter 8, "Reagent management," for the operation in the module of "Reagent";
- Refer to Chapter 9, "Analyzer management," for the operation in the module of "Manage";

- Click “Diluent” icon to add diluent for pre-dilution;
- Click “Shutdown” icon to shut down the system.

The bottom of the interface is the information bar consisting of a blue area and a gray area. The blue area displays the information of the current functional module, while the gray area displays the user name, the system time, and the error information (hidden when there is no error).

### 3.5 Reagents, controls, and calibrators

Reagents, controls, and calibrators are an indispensable part of the Analyzer. The Analyzer can only use the reagents produced by Zybio Inc. Use of reagents produced by other manufacturers may damage the Analyzer or cannot achieve the desirable performance. “Reagents” in the Manual include diluent, LB lyse, LD lyse, and probe cleanser.

Check the reagent package before using the reagent to see if there is any damage, leakage, or damp. If there is, do not use it.

**Note**

For ordering of reagents, controls, and calibrators, please contact the local distributor.

#### 3.5.1 Reagents

The following reagents are to be used together with the Analyzer.

Table 3- 7 Reagents used with the analyzer

Name	Model	REF	Package specification s	Intended use	Manufacturer
Diluent	Z5 DN	3010702	20 L×1	This is an isotonic liquid with a specific electric conductivity. It is used to dilute specimens and prepare cell suspension before blood cell analysis.	Zybio Inc.
Lyse	Z5 LD	3010601	500 mL×1	It is used to break down red blood cells and protect white blood cells to maintain their natural physiological form. The instrument classifies 4-part white blood cells differentiation via distinguishing the morphological differences among cellular granularity cell volume and cellular complexity.	Zybio Inc.
		3010602	500 mL×4	Zybio Inc.	

Name	Model	REF	Package specification s	Intended use	Manufacturer
Lyse	Z5 LB	3010501	100 mL×1	It's used to break down red blood cell membrane to release hemoglobin before blood cell analysis. It also could shrink other WBC cells except basophils while keeps the original volume of basophils. The instrument detects hemoglobin concentration, and classifies basophile and count total white blood cell via distinguishing the morphological differences among cell volume and cellular complexity.	Zybio Inc.
		3010502	100 mL×4		Zybio Inc.
Probe cleanser	/	3010202	50 mL×2	It is used for cleaning the system detection pool and pipeline.	Zybio Inc.

### Note

- Use the reagents produced by Zybio.
- Do not use the expired reagents.
- Refer to the instructions for use of reagents for use and storage.
- Place the reagents still for some time until they become stable before using them.
- After replacing the diluent, the lyse, or the probe cleanser, conduct background tests and make sure that the background values are normal before starting sample test.

### 3.5.2 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 Inc.'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.

### 3.6 Cybersecurity

This section mainly describes information on cybersecurity.

Restrictions on use

- The instrument is not allowed to be connected to Internet during operation, otherwise the cybersecurity cannot be guaranteed.
- Only authorized users can access the instrument.
- The software of this Analyzer shall only be installed and updated by personnel authorized by Zybio.
- For the USB flash drive plugged into the Analyzer, it shall be scanned and cleaned for the virus regularly.
- For LIS, it only needs to be connected to the LAN provided by the corresponding medical institutions when operating, and shall not be connected to the WAN for security concerns.
- The Analyzer shall be operated in a protected wired LAN environment.
- Users are recommended to edit the patient information on the PC side when the communication is executed through LIS.
- No security software or anti-virus or malware software is needed.
- For off-the-shelf software, Linux 3.0.35 is already embedded in the analyzer, no further 3rd party software is needed for operators.
- Users can set the IP address, subnet mask and default gateway through communication setup function.
- Data backup and restore
- The backup of system configuration parameters will be executed automatically when the Analyzer sleeps or is shutdown.
- If the calibration parameters cannot be saved properly, users can contact Zybio or its agents to restore the default setup.



# 4 Operation principles

The Analyzer counts the red blood cells and the platelets and detects the distribution of them by means of impedance technology, and detects the concentration of hemoglobin by means of colorimetry, and counts and classifies the white blood cells by means of flow cytometry. Based on these detections, the Analyzer calculates the results of other parameters.

## 4.1 Sampling

The user places the blood sample into the Analyzer for sampling, then the Analyzer aspirates 20  $\mu\text{L}$  of sample for following process and analysis.

## 4.2 Dilution

As a blood sample has various cells overlapped, therefore it should be diluted before it is detected. The Analyzer provides two sample modes for different types of samples, i.e. whole blood mode (hereinafter referred to as WB mode) and pre-dilution mode (hereinafter referred to as PD mode). In different sample modes, the sample is diluted in different ways.

### 4.2.1 WB mode

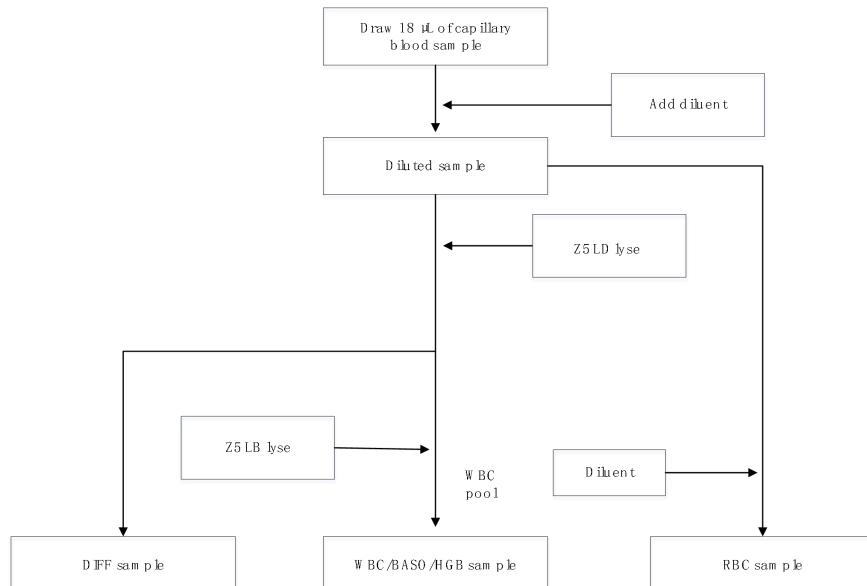
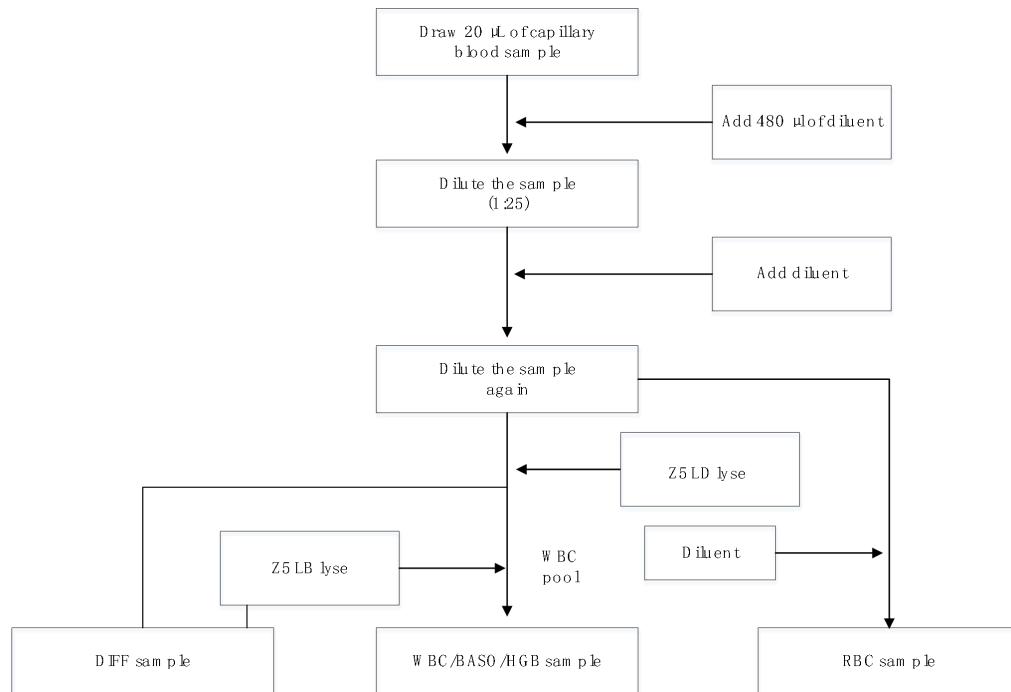


Figure 4- 1 The process of WB Mode

In WB mode, dilution of sample is completed by the Analyzer. As shown in Figure 4 1 , the Analyzer aspirates 18  $\mu\text{L}$  of whole blood sample and mix it with 680  $\mu\text{L}$  of diluent to obtain a diluted sample. The diluted sample is then divided into two portions, with one portion of the sample diluted again for counting red blood cells and platelets to obtain the corresponding distribution histogram. The other portion of sample is mixed with Z5 LD Lyse to obtain a mixed sample .The mixed sample is divided in two portions, with one portion used for white blood cell count and obtaining a white blood cell scatter plot, and the other mixed with Z5 LB lyse and used for detection of the hemoglobin concentration and white blood cell counting.

#### **4. 2. 2PD mode**



**Figure 4- 2 The process of PD mode**

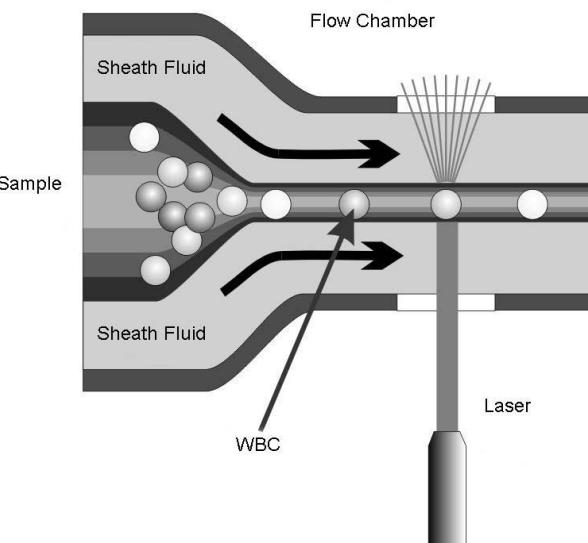
In PD mode, the sample is pre-diluted by the user. As shown in Figure 4-2, the user draws 20 μL of blood sample and mixes it with 480 μL of diluent in proportion of 1 : 25 outside the Analyzer to obtain a diluted sample, and then draws 210 μL of the diluted sample and places it into the Analyzer. The Analyzer divides the diluted sample into two portions, with one portion mixed with 378 μL of diluent to obtain a secondary-diluted sample for counting red blood cells and platelets and obtaining corresponding distribution histograms. The other portion is mixed with the Z5 LB lyse for white blood cell counting and hemoglobin concentration measurement.

#### **4. 3 WBC measurement**

The Analyzer provides two modes for measuring white blood cells, i.e. CBC mode and CBC+DIFF mode. CBC mode only counts but not differentiates the white blood cells, while CBC+DIFF mode counts and differentiates the white blood cells.

Counting and differentiation of white blood cells are realized by flow cytometry technology.

Principle of flow cytometry



**Figure 4- 3 Count principle**

After sufficient reaction of Z5 LD lyse and sample, the red blood cells are dissolved, while the white blood cells are stained. The stained white blood cells and the red blood cell debris are injected by the sample probe into the diluent-filled flow chamber. Wrapped by the sheath fluid of diluent, the cells are accelerated for the second time and arrayed in a line, passing through the laser detection area. The light scattered from the laser light on the cells is related to the cell size and the refractive index of the cell membrane structure and internal cell structure. A photodiode receives the scattered light signals and transforms the signals into electric pulses. Based on the electric pulses acquired, a 3-D distribution plot or scatter plot is obtained, which shows the blood cell size and the information about the internal cell structure. The results of five-part differential and counting of white blood cells are obtained through the scatter plot.

#### 4.4 HGB measurement

The hemoglobin concentration is measured by colorimetry.

##### Principle of colorimetry

In the white blood cell counting chamber, the diluted sample is mixed with Z5 LB lyse, which dissolves the red blood cell membrane to release the hemoglobin. The hemoglobin combines with the lyse to generate hemoglobin compound. At one side of the white blood cell counting chamber, there is an LED monochromatic luminescent tube which emits lights of 530 nm central wavelength. The light beams pass through the hemoglobin compound solution and are received by the photoelectric tube at the other side of the chamber. The light intensity signals are transformed into current signals and then voltage signals. The magnified voltage signals are compared with the detected voltage of background light intensity thus to obtain the HGB concentration measured in g/L. The Analyzer automatically completes sample detection and calculation displays the results in the "Counting" interface.

##### Hemoglobin concentration

The Analyzer compares the measured voltage with the voltage of the background transmitted light and calculates the hemoglobin concentration (HGB) in g/L.

$$\text{HGB} = \text{Constant} \times \log_{10} \left( \frac{\text{Blank photocurrent}}{\text{Sample photocurrent}} \right)$$

## 4.5 RBC/PLT measurement

The Analyzer counts the red blood cells or platelets by means of impedance technology.

### 4.5.1 Principle of impedance technology

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.

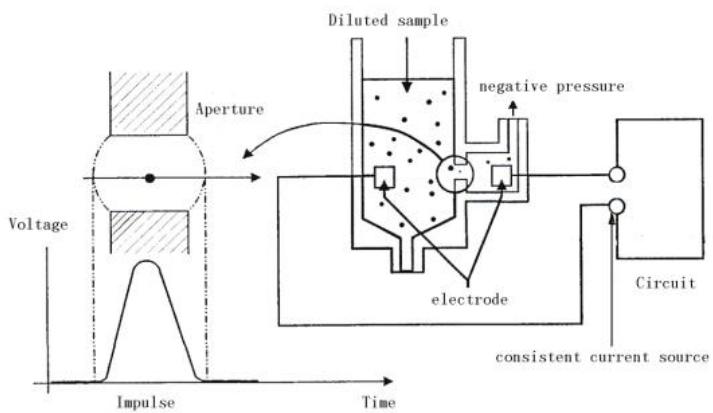


Figure 4- 4 Electrical impedance method

### 4.5.2 RBC-related parameters

#### Red blood cell count (RBC)

The Analyzer counts red blood cells (RBCs) in  $10^{12}/L$  by means of counting the electrical pulses in relation to RBCs.

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

#### Mean corpuscular volume (MCV)

The Analyzer calculates the MCV in fL based on the red blood cell distribution.

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

HCT in %, MCH in pg, and MCHC in g/L reobtained through the following formula.

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

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

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

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

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

RDW-CV derives 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.

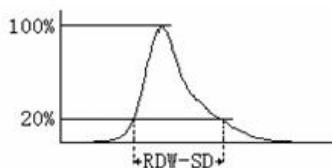


Figure 4- 5 Schematic diagram

#### 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.

### 4. 5. 3 PLT-related parameters

#### PLT

The Analyzer counts platelets (PLT) in  $10^9/L$  by means of counting the electrical pulses in relation to platelets.

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

#### Mean platelet volume (MPV)

The Analyzer obtains the MPV in fL based on the histogram of platelet distribution.

#### Platelet distribution width (PDW)

Provided that the peak height is 100%, the distribution width at the horizontal level at the 20% peak value is PDW, measured in fL .

#### Plateletcrit (PCT)

The Analyzer obtains PCT in % through the following formula, where PLT is in  $10^9/L$  and MPV in fL.

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

#### Platelet-large cell ratio (P-LCR)

The Analyzer obtains P-LCR in % based on the histogram of platelet distribution.

#### Platelet-large cell count (P-LCC)

The Analyzer obtains P-LCC in  $10^9/L$  based on the P-LCR and the platelet count.

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

#### 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:  $10^9/\text{L}$ ). 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.

## 4.6 Rinsing

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.

# 5 Daily operation

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:

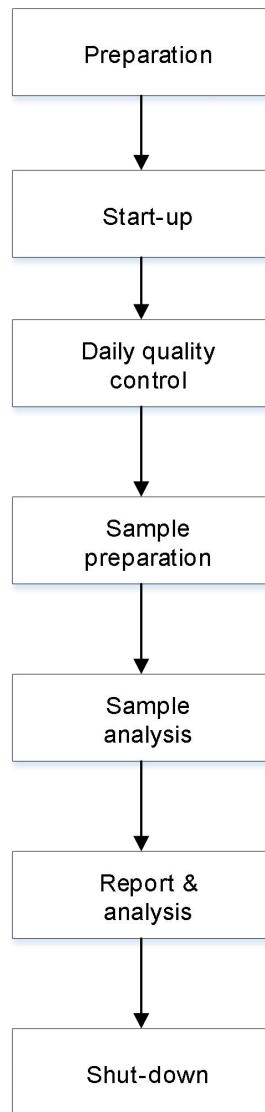


Figure 5– 1 Daily operation

## 5.1 Preparation

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

- Check the waste container: the user must put a waste container in place and ensure that it is empty before starting the instrument each day;

## Daily operation

---

- Check the fluidic components and power supply according to Section 2.1.2, "Power requirements" ;
  - 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 sufficient paper or appropriate installation.
- 



- Samples, controls, calibrators, liquid wastes, etc. pose biological risks. Please follow the laboratory safety practices and wear protective equipment (such as protective suit and latex gloves, facial masks, etc.) before touching the relevant parts.
- Reagents may irritate the eyes, skin and mucous membranes. Follow the safety practices of your lab and/or hospital and wear necessary protective equipment (e.g. protective suit, latex gloves, masks, etc.) when handling reagent-related objects.

### Warning

- Keep your clothes, hair, and hands away from the moving parts of the Analyzer;
- Access to the disconnection device (power cord) shall be available.

### Caution

- Use the reagents specified by Zybio, and store and use them according to the instructions for use.
  - Before using the Analyzer, ensure that the reagents are properly connected.
  - Place the reagents still for some time until they become stable before using them.
- 

## 5.2 Startup

Start up the main unit:

- (1) Turn the power switch on the back of the Analyzer to "I" state;
- (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.

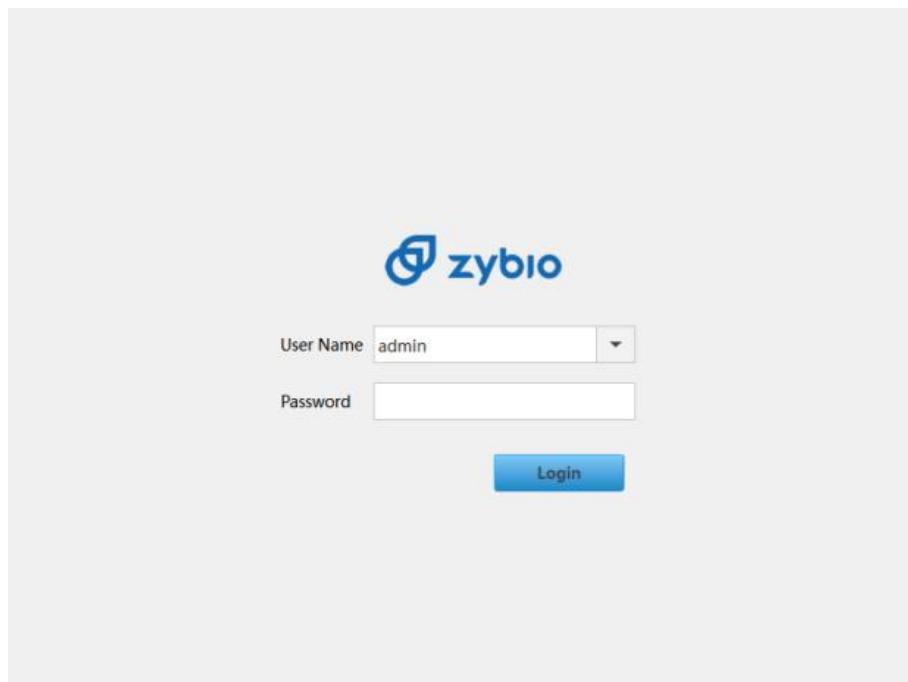


Figure 5- 2 “Login” interface

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 Section 10.1, “Error information and handling.”
- The system judges the user'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.
- The initial username and password of the Administrator default to Admin.
- If the software fails to run after several consecutive attempts, contact Zybio or its local distributor.
- Check that the date/time of the device is valid after startup.
- The administrator can manage all common users through the user setup function.

## 5.3 Daily quality control

Before carrying out sample analysis, carry out quality control analysis everyday to ensure the test results are reliable. Please refer to Chapter 7 “Quality control,” for operation.

## 5.4 Sample preparation

The Analyzer is designed to test whole blood samples and pre-diluted blood samples. To ensure the accuracy of the analysis results, the volume of capillary whole blood sample should be no less than 100 µL.

Samples to be tested by the Analyzer should be collected and preserved properly.

---



- Samples, controls, calibrators, liquid wastes, etc. may pose biological risks. Please follow the laboratory safety practices and wear protective equipment (such as protective suit and latex gloves, facial masks, etc.) before touching the relevant parts.
- Do not directly touch the patient's blood samples.

### Caution

- Collect, prepare, and preserve blood samples following the instructions of reagent manufacturer. Neglect of the instructions may make the test result unreliable.
  - All kinds of samples must be thoroughly mixed.
  - Vacuum blood collection tubes, centrifuge tubes, and capillary tubes used for blood collection must meet the requirements specified by the manufacturer.
  - The user should use clean K<sub>2</sub>EDTA or K<sub>3</sub>EDTA anticoagulated vacuum blood collection tubes, specified glass/plastic test tubes, centrifuge tubes and borosilicate glass capillary tubes.
  - Do not reuse disposables.
- 

### 5.4.1 Whole blood samples

Prepare whole blood samples following the procedure below:

Collect the venous blood samples with K<sub>2</sub>EDTA or K<sub>3</sub>EDTA anticoagulated vacuum tubes.

Quickly mix the venous blood in the tube with the anticoagulant thoroughly.

---

### Note

- Samples for WBC differential counting or platelet counting should be stored at room temperature and analyzed within 8 hours after being collected.
  - If the sample is stored 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.
  - Remix the samples placed for a certain period of time before analysis.
  - Capillary blood samples shall be analyzed in 3 minutes to 2 hours after they are collected.
- 

### 5.4.2 Pre-diluted samples

Prepare pre-diluted samples following the steps below:

---

- (1) Click “PD” and then “OK” to switch to PD mode;
- (2) Click the “Diluent” icon on the left side of the interface of “Analysis”, a prompt dialog box shows.
- (3) Place a clean centrifuge tube under the sample probe and press the [Aspirate] key to add 480  $\mu\text{L}$  of diluent into the tube. While adding the diluent, the prompt box displays “Adding diluent” and a progress bar shows.
- (4) Draw 20  $\mu\text{L}$  of venous or capillary blood and quickly inject it into a centrifuge tube filled with the diluent. Cap the tube and mix thoroughly. After the pre-diluted sample is ready, click “Cancel” to exit diluent dispensing.

### Note

- The user can also use a pipette to draw 480  $\mu\text{L}$  of diluent.
- Keep the prepared diluent away from dust and volatilization, otherwise analysis errors will occur.
- After the capillary blood reacts fully with the diluent, leave it sit for 3 minutes and then remix it before analysis.
- It is recommended to analyze the sample within 30 minutes after it is diluted.
- Samples sit for a while need to be remixed before being analyzed.
- Each laboratory shall evaluate the stability of the sample analysis results in the PD mode according to the sample quantity, sample collection method, and their technical level.

## 5.5 Sample analysis

Perform sample analysis following the steps below:

- (1) Click the “Analysis” icon to enter the “Analysis” interface. Click the “Next Sample” to enter the interface below.

Next Sample		Analysis	
		Capillary WB	PD
		CBC+DIFF	
Venous WB	Capillary WB	PD	
CBC	CBC+DIFF		X
Sample ID 1	Patient ID		
First Name	Patient Type		
Last Name	Dept.		
Gender	Ref. Group		
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

Figure 5- 3 “Venous WB” mode, Capillary WB” mode, or “PD” mode

(2) Click “Venous WB” , “Capillary WB” , or “PD” , and then “OK” to switch to the corresponding sample mode.

### 5.5.1 Enter the sample information

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

If the user wants 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, Result review, for the method.

Once the sample information entry method has been set in the “Auxiliary” , 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” , the all information entry dialog box shows as in the following figure. The user can enter the complete sample information for the next sample in the dialog box.

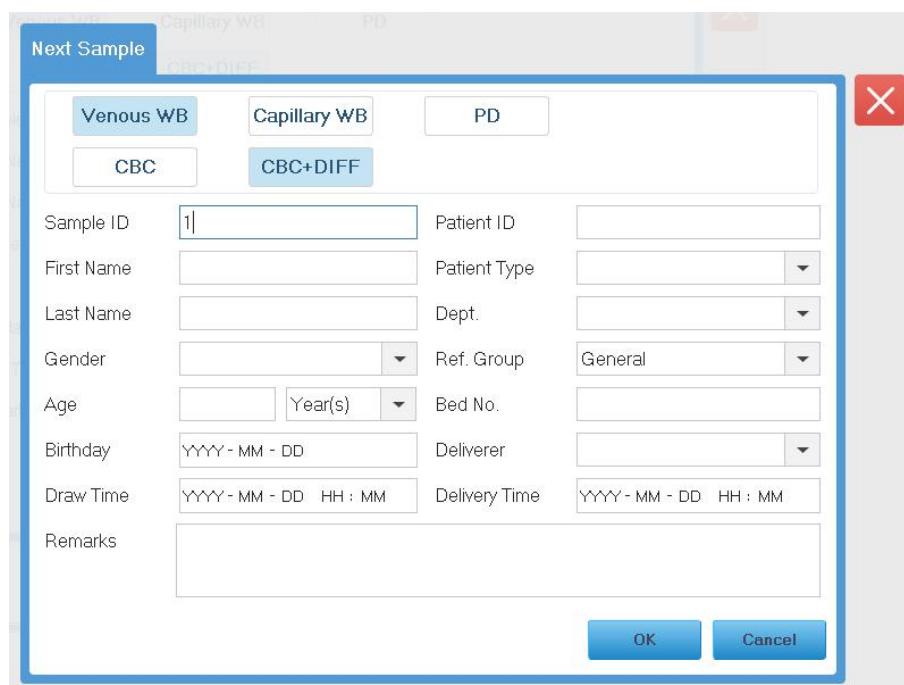


Figure 5- 4 Interface of “All Information”

#### Sample mode selection

Click “Venous WB” , “Peripheral WB” , or “PD” to select the sample mode.

#### Measurement mode

Click “CBC” or “CBC+DIFF” 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” boxes.

#### Select patient gender

Select the gender of the patient from the “Gender” drop-down list. There are three options: “Male”, “Female” and “Empty”. The default option is “Empty”.

#### 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 user 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

- After entering the birth date, the age field will be automatically propagated based on the difference between the “Current system date” and the “Birth date”, and the newly calculated age value and time unit will be displayed in the age value edit box and time unit box. At this point, the age edit box will be grayed out. When “Birth date” is cleared, the age edit box will be reactivated.
  - If the birth date entered is later than the current system date, the birth date is considered invalid.
- 

#### Enter the birth day

Enter the patient's birth day in the “Birthday” 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.

## Daily operation

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### 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.

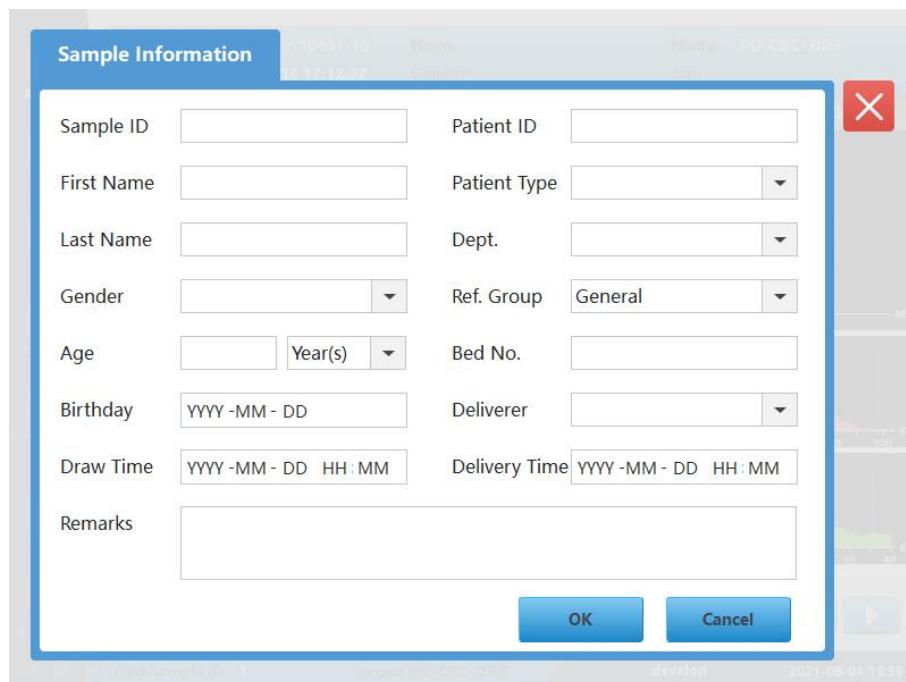


Figure 5- 5 Interface of “Sample Information”

## 5. 5. 2 Sample analysis steps

### Sample analysis

Analyze the WB samples by following the steps below:

- (1) Check that the analysis status in the system status area is ready and the working mode is “Venous WB” or “Capillary WB” or “PD” ;
- (2) Place the prepared WB sample under the sample probe so that the sample probe can aspirate the mixed sample solution;
- (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 user 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.



Samples, controls, calibrators, liquid wastes, etc. pose biological risks. Please follow the laboratory safety practices and wear protective equipment (such as protective suit and latex gloves, facial masks, etc.) before touching the relevant parts.

### **Warning**

Do not touch the sample probe. It is sharp and may carry blood samples, controls, and calibrators which are considered biologically hazardous.

### **Caution**

Do not reuse the disposables.

### **Note**

Avoid blood splashing caused by the contact between the test tube wall and the sample probe.

## **5.5.3 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.

**Table 5- 1 Text alarms**

<b>Flag</b>	<b>Alarm Information</b>	<b>Description</b>
<b>WBC Flag</b>	Leucopenia	WBC count significantly low
	Leucocytosis	WBC count significantly high
	Granulopenia	Granulocyte count significantly low
	Granulocytosis	Granulocyte count significantly high

Flag	Alarm Information	Description
WBC Flag	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 counts significantly high
	Eosinophilia	Eosinophil count is significantly higher
	Basophilic	Basophil count is significantly higher
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

## 5.5.4 Validate

Validate the results of the current sample.

## 5.6 Standby

When fluid-related operations stop for a preset period of time, the Analyzer enters the standby mode and shows a prompt "Standby. Press the [Aspirate] key to exit." at the lower-left corner of the interface.

## 5.7 Shutdown

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



Samples, controls, calibrators, liquid wastes, etc. pose biological risks. Please follow the laboratory safety practices and wear protective equipment (such as

protective suit and latex gloves, facial masks, etc.) before touching the relevant parts.

**Warning**

- The sample probe is sharp, and it may carry blood samples, controls and calibrators that are potentially biologically hazardous. Therefore, the user shall not touch the sample probe.
- Comply with the relevant national and regional regulations regarding the discharge and processing of expired reagents, liquid wastes, waste samples, consumables, etc.

**Note**

- When the Analyzer is not used, turn off the power or place the Analyzer in the standby mode.
- 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 user must implement the required shutdown procedure to shut down the machine according to the following steps.
- Do not disconnect 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.

- 
- (1) Click the “Shutdown” at the bottom-left of the interface;
  - (2) Click “Yes”, place the probe cleanser under the sample probe, and press the [Aspirate] key. The Analyzer automatically performs probe soaking;
  - (3) After the Analyzer executes the shutdown process, it prompts “Please turn off the power!”. Then, turn off the Analyzer’s power switch;
  - (4) Empty the waste container and dispose of the waste properly.



# 6 Result review

After each sample analysis, the Analyzer automatically saves the results in the sample library. The sample library can save up to 50,000 results including parameter results and histograms.

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

## Note

Backup the data effectively to prevent data loss due to the hardware or software failure.

### 6.1 Sample review

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

The screenshot shows the 'Review' interface of the Analyzer. On the left is a vertical toolbar with icons for Analysis, Review (selected), QC, Reagent, Manage, Diluent, and Shutdown. The main area displays a grid of sample results. The columns are labeled Seq, 5416, 5417, 5418, 5419 (highlighted with a green circle), 5420, and 5421. The rows represent various parameters: Sample ID, Status, WBC, Neu%, Lym%, Mon%, Eos%, Bas%, RBC, HGB, MCV, HCT, and MCHC. Each cell contains numerical values and small icons indicating trends (up, down, stable). To the right of the grid are vertical scroll bars and a set of navigation arrows (left, right, up, down). At the bottom are buttons for Search, Graph Review, Trend Graph, Validate, Cancel Validate, Print, and a status bar showing Position/Sum, admin, and the date/time 2022-09-23 11:14.

Seq	5416	5417	5418	5419	5420	5421
Sample ID	ICAT-XG-KB6	ICAT-XG-KB7	ICAT-XG-KB8	ICAT-XG-2-01	ICAT-XG-2-02	ICAT-XG-2-03
Status	●	●	●	●	●	●
WBC	0.01 ↓	0.02 ↓	0.00 ↓	6.33	0.05 ↓	0.01 ↓
Neu%	***	***	***	53.5	***	***
Lym%	***	***	***	36.7	***	***
Mon%	***	***	***	7.5	***	***
Eos%	***	***	***	1.5	***	***
Bas%	***	***	***	0.8	***	***
RBC	0.00 ↓	0.00 ↓	0.00 ↓	6.29	0.01 ↓	0.00 ↓
HGB	0 ↓	0 ↓	0 ↓	178 ↑	0 ↓	0 ↓
MCV	***	***	***	93.8 ↑	***	***
HCT	0.0 ↓	0.0 ↓	0.0 ↓	59.0 ↑	0.1 ↓	0.0 ↓
MCHC	***	***	***	302	***	***

Figure 6- 1 Interface of “Review”

#### Search

Click “Search” to open the dialog box as shown below:

## Result review

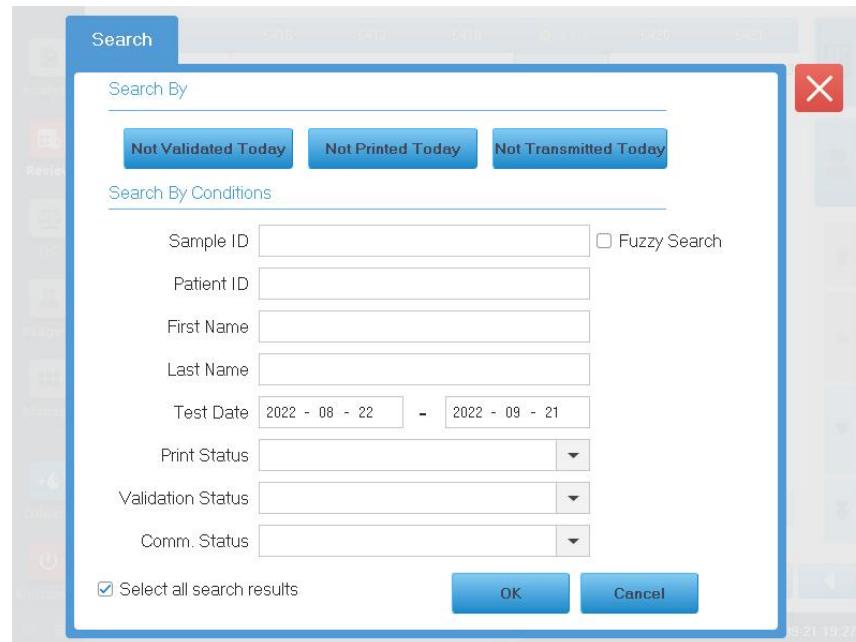


Figure 6- 2 Interface of “Search”

- (1) Define the search criteria by entering content in the corresponding edit boxes or selecting from the drop-down list;
- (2) Click “OK” to close the dialog box and start the search. The search results will be displayed in the list area.

## Graph

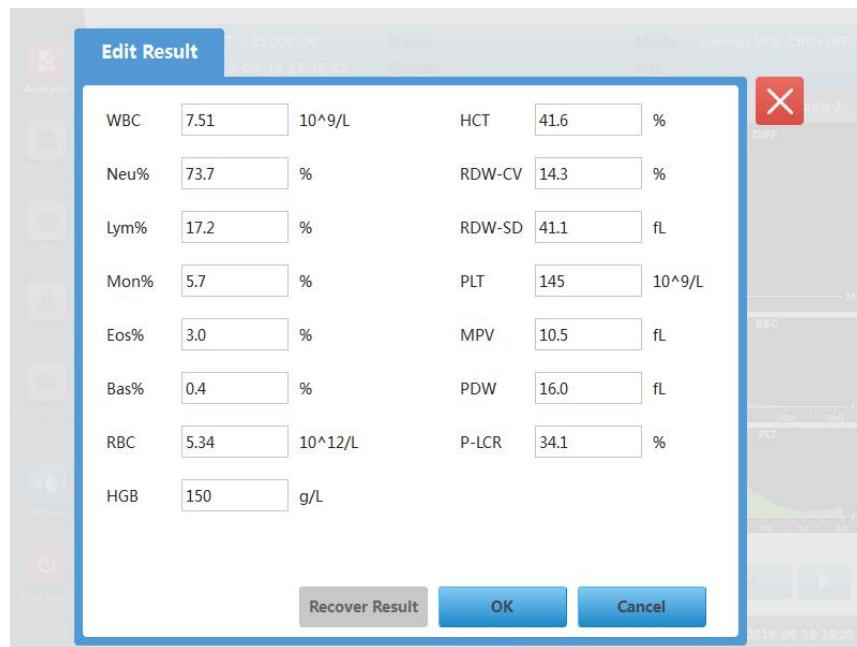
Click the “Graph Review” in the “Sample review” interface to browse the detailed analysis results of each sample.



Figure 6- 3 Interface of “Graph Review”

## Edit result

The user can click on a result entry in the “Graph” interface and click “Edit Result” to open the interface as shown in the figure below:



The screenshot shows the 'Edit Result' dialog box overlaid on a background of a blood test interface. The dialog box contains a table of results:

WBC	7.51	10 <sup>9</sup> /L	HCT	41.6	%
Neu%	73.7	%	RDW-CV	14.3	%
Lym%	17.2	%	RDW-SD	41.1	fL
Mon%	5.7	%	PLT	145	10 <sup>9</sup> /L
Eos%	3.0	%	MPV	10.5	fL
Bas%	0.4	%	PDW	16.0	fL
RBC	5.34	10 <sup>12</sup> /L	P-LCR	34.1	%
HGB	150	g/L			

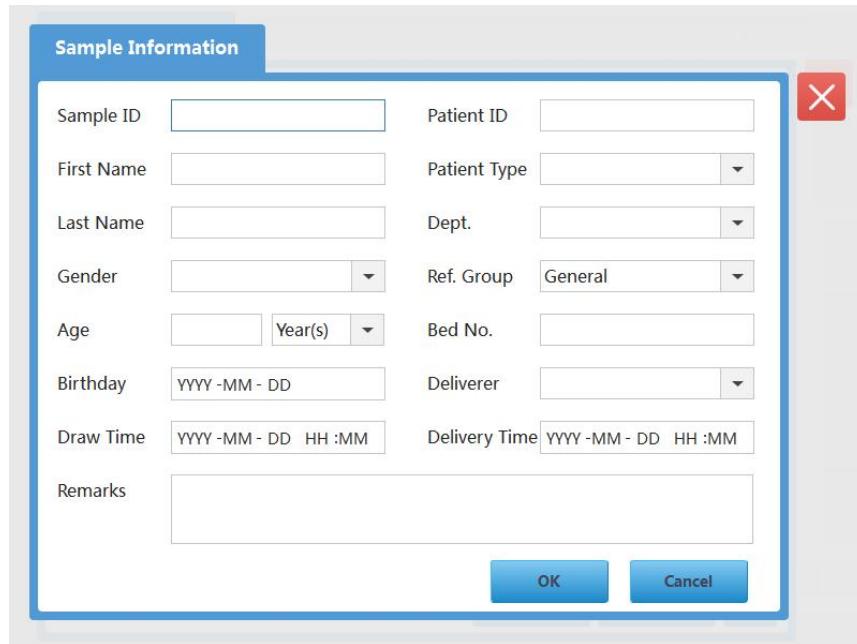
At the bottom of the dialog box are three buttons: 'Recover Result' (grey), 'OK' (blue), and 'Cancel' (grey).

**Figure 6- 4 Interface of “Edit Result”**

Modify some of the results of this sample, and click “OK” to save. Then, return to “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 “Graphic review”, and then click the sample information area to open the interface shown in the picture below:



The screenshot shows the 'Sample Information' dialog box. It contains the following fields:

Sample ID	<input type="text"/>		Patient ID	<input type="text"/>	
First Name	<input type="text"/>		Patient Type	<input type="button" value="▼"/>	
Last Name	<input type="text"/>		Dept.	<input type="button" value="▼"/>	
Gender	<input type="button" value="▼"/>		Ref. Group	<input type="button" value="▼"/>	
Age	<input type="text"/>	<input type="button" value="Year(s) ▼"/>	Bed No.	<input type="text"/>	
Birthday	<input type="text"/> YYYY -MM - DD		Deliverer	<input type="button" value="▼"/>	
Draw Time	<input type="text"/> YYYY -MM - DD HH :MM		Delivery Time	<input type="text"/> YYYY -MM - DD HH :MM	
Remarks	<input type="text"/>				

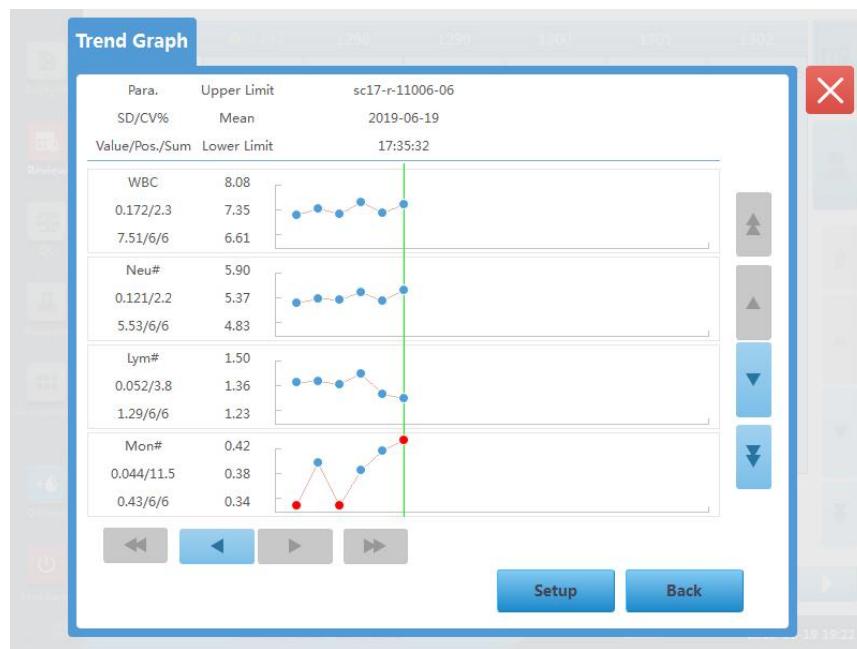
At the bottom of the dialog box are two buttons: 'OK' (blue) and 'Cancel' (grey).

**Figure 6- 5 Interface of “Sample Information”**

## Trend graph

## Result review

Click “Trend Graph” to see the trend graph of sample results.



**Figure 6- 6 Interface of “Trend Graph”**

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

### Validate sample data (for administrator user only)

After selecting one or more invalidated sample records in the “Review” interface, click “Validate”, and the word “Validated” will show in the sample status bar of the sample records.

The screenshot shows the 'Validate' interface. On the left is a vertical toolbar with icons for Analysis, Review, QC, Reagent, Management, Diluent, and Shutdown. The main area is a table with columns for Sequence (1300, 1301, 1302, 1303, 1304, 1305) and rows for various parameters (Sample ID, Status, WBC, Neu#, Lym#, Mon#, Eos#, Bas#, Neu%, Lym%, Mon%, Eos%, Bas%). The '1305' column header is highlighted with a green dot. The 'Status' row shows blue icons for users. The 'Lym%' row for sequence 1305 shows a red downward arrow and the value '18.9 ↓'. The bottom navigation bar includes buttons for Search, Graph Review, Trend Graph, Validate, Cancel Validate, Print, and a LIS icon. The status bar at the bottom shows Position/Sum 1305/1305, admin, and 2019-06-21 09:50.

**Figure 6- 7 Validate the sample data**

**Cancel validation (for administrator user only)**

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

**Print**

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

**LIS**

- (1) Click “LIS” in the “Review” interface;
- (2) Click “Check Record” radio button;
- (3) Click “OK” to close the dialog box and start communicating. The selected results can be transferred to the data management software.

**Export**

- (1) Insert a USB flash disk into the USB interface on the back of the instrument;
- (2) Click “Export” to bring up a dialog box;
- (3) In the “Export Range” area, select “Selected Records” or “Date Range” .

**Delete**

- (1) Select the sample records to be deleted in the list area;
- (2) Click “Delete” ;
- (3) Click “OK” to delete the selected sample records and close the dialog box.



## 7 Quality control

As a result of lengthy use, the Analyzer may have a certain degree of error that may lead to incorrect or unreliable analysis results. The quality control (hereinafter referred to as QC) procedure provides an effective method for detecting possible errors. Only when the user is familiar with the quality control theory and masters the operation method, can the impact of the error on the analysis result be effectively eliminated.

To ensure the reliability of the sample analysis results, it is recommended that the user conduct daily quality control on the Analyzer with low, medium, and high levels of controls. When a new lot of controls are 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 instructions for use of the controls.

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

---

### Note

Use the specified controls and reagents, and store and use them strictly in accordance with their instructions for use.

---

### 7.1 L-J QC

L-J quality control (L-J QC) is one of the most common tools used to track laboratory quality control samples. An L-J chart and the Westgard Rules are frequently used to verify trends, biases, or errors in quality controls.

#### 7.1.1 QC settings

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

Click “Quality Management” > “L-J QC” > “Setting” to enter the QC setting interface below:

## Quality control

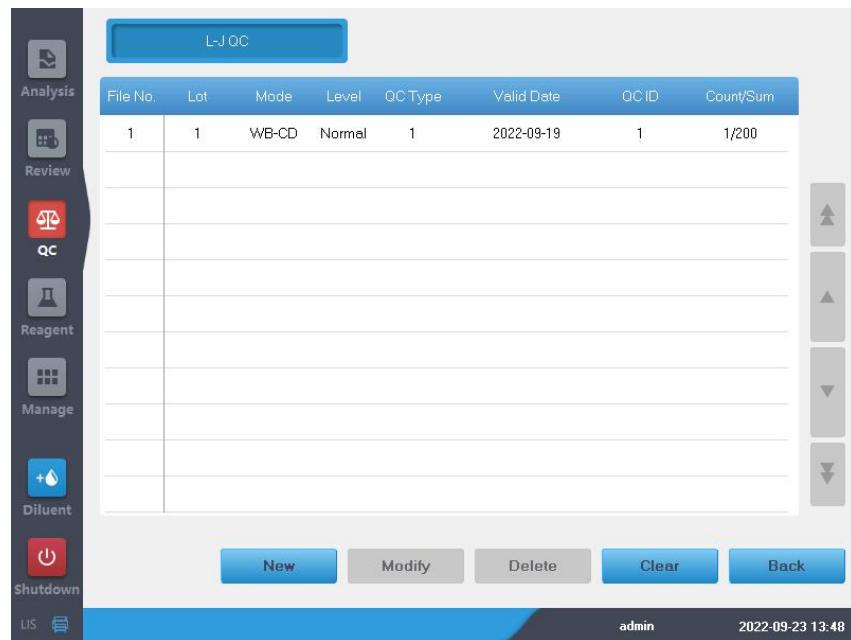


Figure 7- 1 Interface for setting quality control

### Enter QC information

- (1) Enter the L-J QC setting interface;
- (2) Click “Setting” > “New”, or select a QC file without QC count results and click “Modify” ;
- (3) Type in the lot number.

#### Note

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

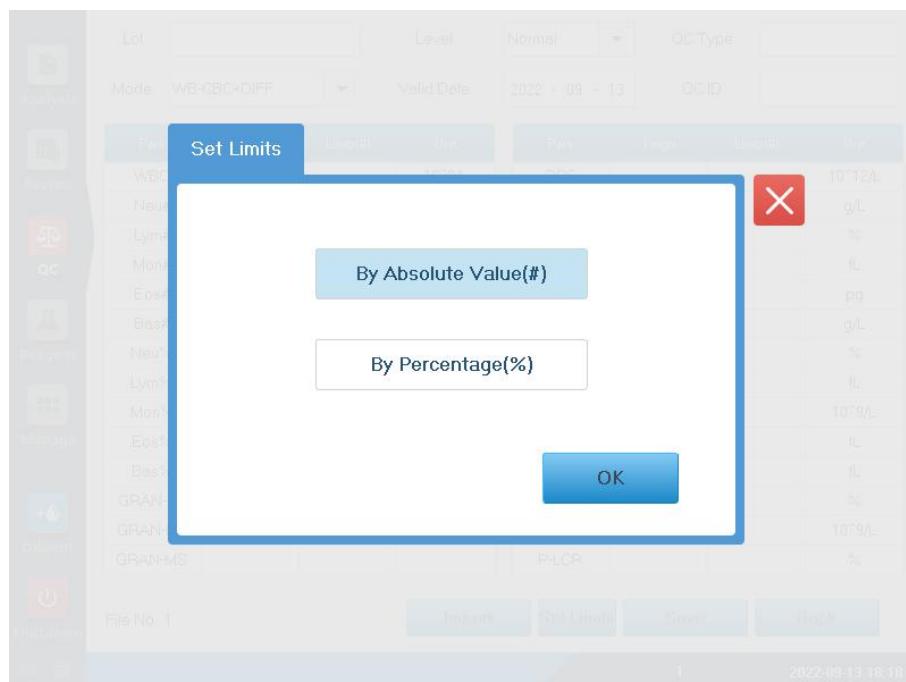
Figure 7- 2 QC interface

- (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) Setting QC ID: If the user 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;
- (9) According to the target value table of the corresponding lot, type in the reference value and limits respectively in the edit boxes after the parameter subject to QC;
- (10) 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 “Set Limits” ;



**Figure 7- 3 Interface of “Set Limits”**

- (2) If you want the limits to be displayed as an absolute value, click “By Absolute Value(#)” ; if you want the limits to be displayed as a percentage, click “By Percentage(%)” ;
- (3) Click “OK” to save the settings.

### 7.1.2 QC counting

The user can choose one of the following two methods for QC analysis according to actual needs.

- Use controls and perform QC analysis in the interface of “QC” .
- Add controls in the samples and perform QC analysis in the interface of “Analysis” .

### Note

- Running a QC in the event of an error may result in incorrect analysis results. If an 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.

### Perform QC analysis in the interface of “QC”

- (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 yellow.

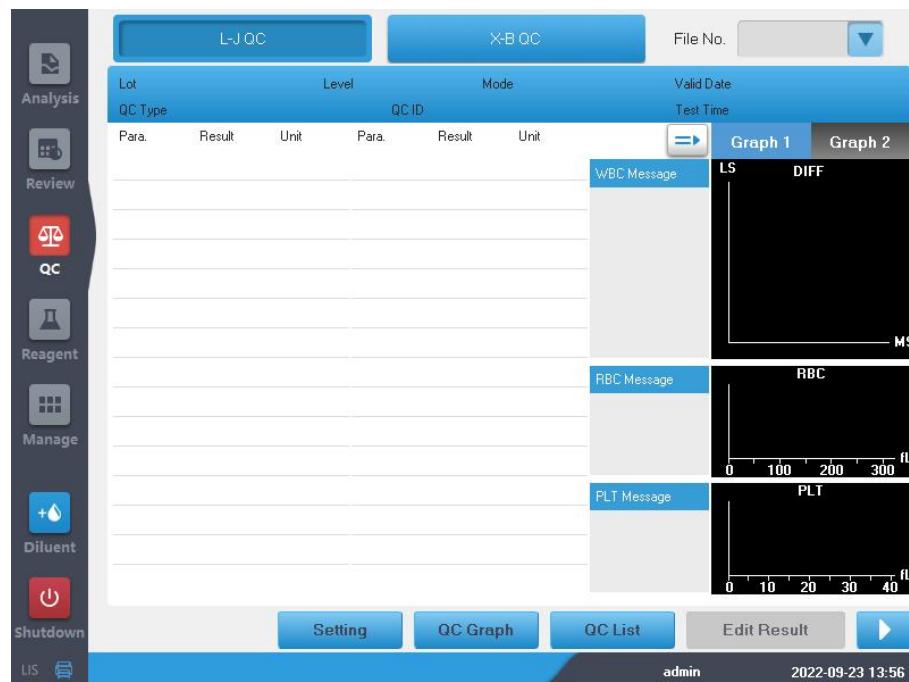


Figure 7- 4 Quality control counting interface

- (2) Prepare controls in accordance with the instructions for use 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 instructions for use 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 user can safely remove the control.
  - 5) 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.

---

After the analysis is over, the quality control results are automatically saved in the quality control file, and the latest results are displayed in the current interface. If necessary, continue the quality control analysis following the steps above.

**Perform QC analysis in the interface of “Analysis”**

If the user performs quality control analysis with daily sample analysis together, a special “QC ID” for quality control material can be set in the QC interface. Place the quality control material in the daily sample, and complete the quality control analysis in the sample test interface.

Before daily sample counting, when the user edits the work sheet or inputs the information of next sample in the “Next Sample” dialog box, enter the special “QC ID” as the “Sample ID” .

**Select either “WB” or “PD” for QC analysis and follow the steps below:**

- (1) Prepare controls in accordance with their instructions for use;
- (2) Prepare samples in WB mode and PD mode as described in Section 5.4, “Sample preparation” ;
- (3) When the counting operation is ready (i.e. the status icon and the indicator light of the instrument are solid blue), place the prepared sample below the sample probe, press [Aspirate] key to start sample aspiration;
- (4) After the aspiration, the user 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.

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

**Edit and save results (for administrator user)**

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

**Restore results (for administrator user)**

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

- (1) In the edit result interface, click “Recover Result” ;
- (2) Click “OK” to restore the result and close the dialog.

### 7.1.3 QC results review

After completing the QC analysis, the user can review the QC results through either “QC Graph” or “QC List” .

**QC graph review**

## Quality control

- (1) Click “QC Graph” in the “L-J QC Count” interface to enter the QC graph interface corresponding to the QC file.

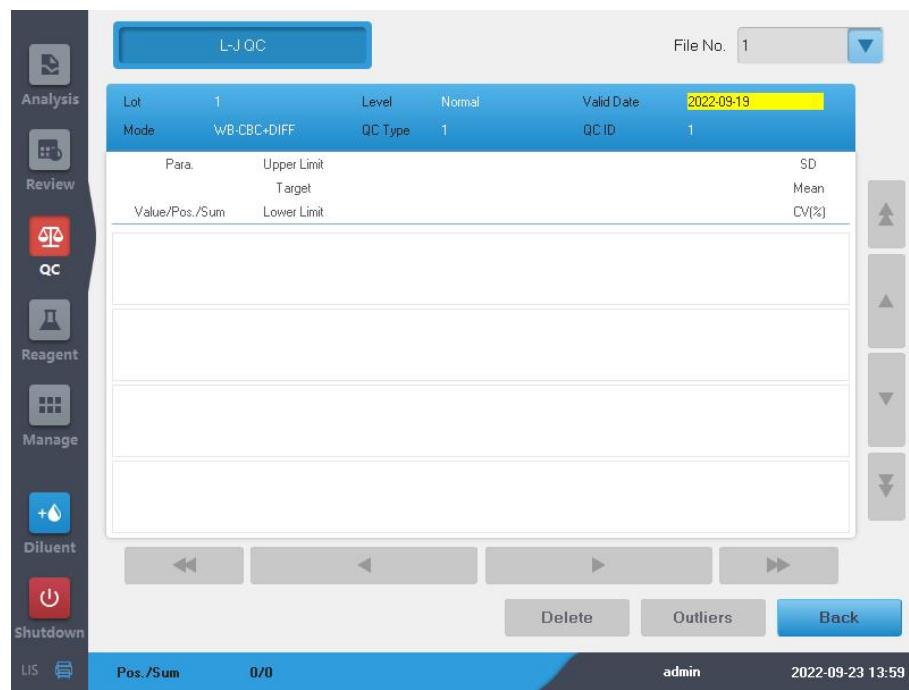


Figure 7- 5 Interface of “QC Graph”

- (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 “QC List” in the “L-J QC Count” interface to enter the QC graph interface below:

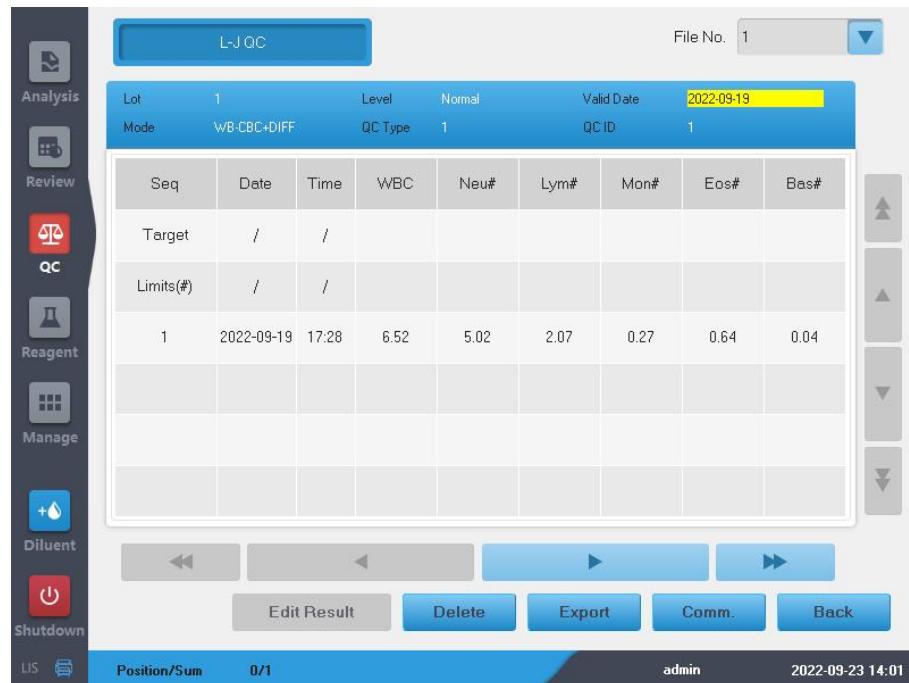
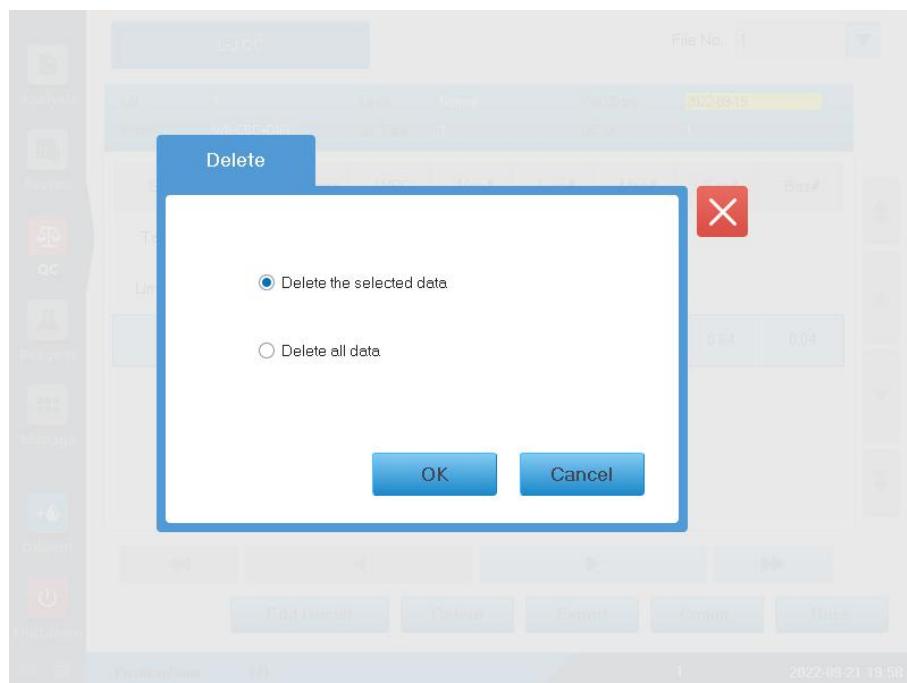


Figure 7- 6 Interface of “QC List”

- (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 (for administrator user)

- (1) Click “Delete selected records” to open the following dialog box;



**Figure 7- 7 Confirmation or cancelation of file delete**

- (2) Click “OK” to delete the selected records.

#### Note

Delete operations are recorded in the log.

#### Export

Export the QC information and QC results of the current QC file following the steps below:

- (1) Insert a USB flash drive and click “Export” ;
- (2) The system will automatically detect the USB drive and export the data;
- (3) The system prompts the message of “Export Succeed.”

## 7.2 X-B QC

The X-B floating average method monitors the performance of the Analyzer by monitoring the stability of RBC series related parameters, such as MCV, MCH, and MCHC. It is a QC method without controls. It monitors the Analyzer’s performance with controls. 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.

### 7.2.1 QC settings

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

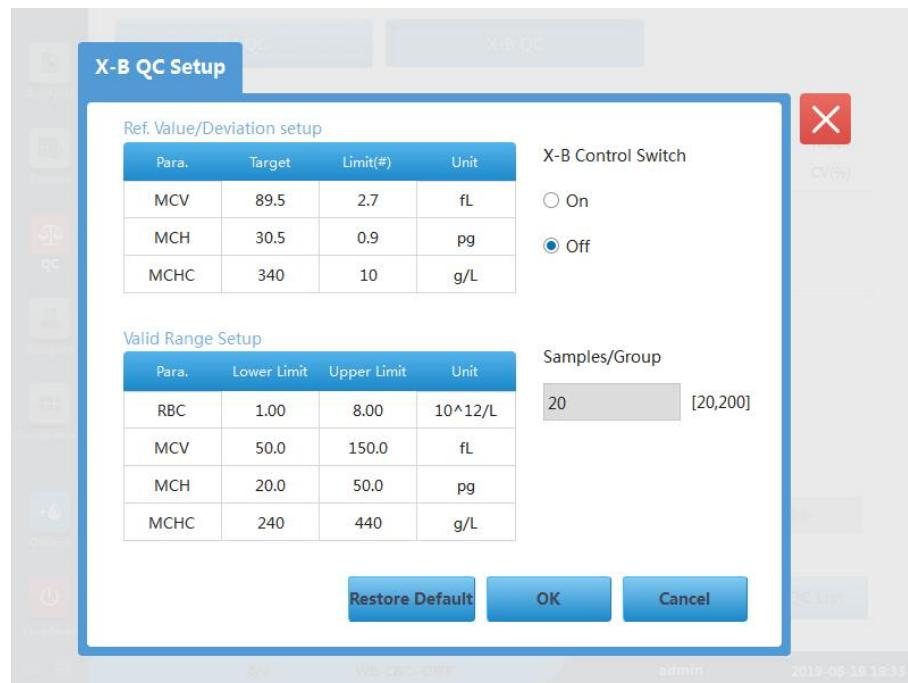


Figure 7- 8 Interface of “X-B QC”

In the X-B QC Setting interface, you can edit the information about the “X-B QC” and the “Ref. Value/Deviation setup” and perform “Valid Range Setup” .

### 7.2.2 QC analysis

After QC editing is completed, the system will automatically start 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.

### 7.2.3 QC results review

After completing the QC analysis, the user can review the QC results through either “QC Graph” or “QC List” .

#### QC Graph Review

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

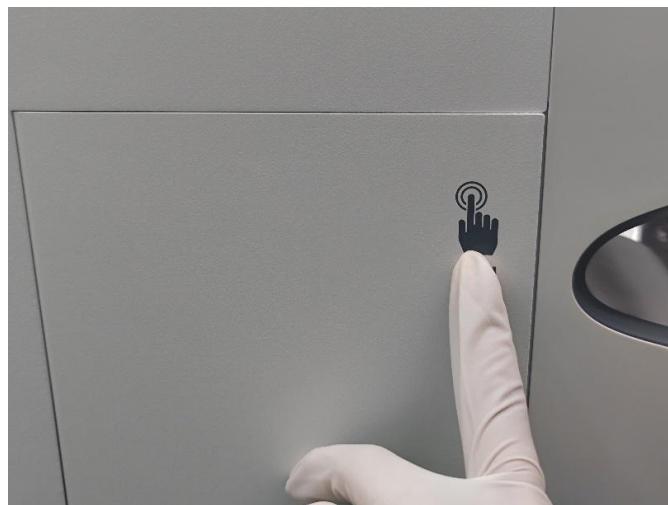
# 8 Reagent management

Reagent management involves replacement of the reagent bottle and replacement of the reagent in the pipelines.

## 8.1 Replacement of reagent bottle

When the reagent runs out, the user replaces a new bottle of reagent in the reagent cabin following the steps below:

- (1) Open the reagent cabin door and take out the reagent bottle;



**Figure 8- 1 Pressing to open the reagent cabin door**

- (2) Open a new bottle of reagent (ensure that the correct reagent is used) and take out the old reagent bottle;
- (3) Put the reagent tube into the new reagent bottle and tighten it;



**Figure 8- 2 Putting the reagent tube into the reagent bottle**

- (4) Place the new reagent bottle into the reagent cabin and close the cabin door.



Figure 8- 3 Placing the new reagent bottle into the reagent cabin door

---

**Note**

- Wear a pair of latex gloves before touching the device and reagent bottles.
  - Use the specified reagents, and do not use contaminated reagents.
  - Set the diluent still for more than one day after long-distance transportation.
  - Carry out a background test after replacing the reagents (such as the diluent or the lyse) to ensure that the background value is normal and ready for sample analysis.
  - Do not get the diluent container vibrated or collided, otherwise the alarm may be unreliable.
- 

## 8.2 Replacement of the reagent in the pipelines

Replace the reagent in the pipelines when:

- A new bottle of reagent is used;
- The reagents in the pipeline may be contaminated;
- There may be bubbles in the pipelines.

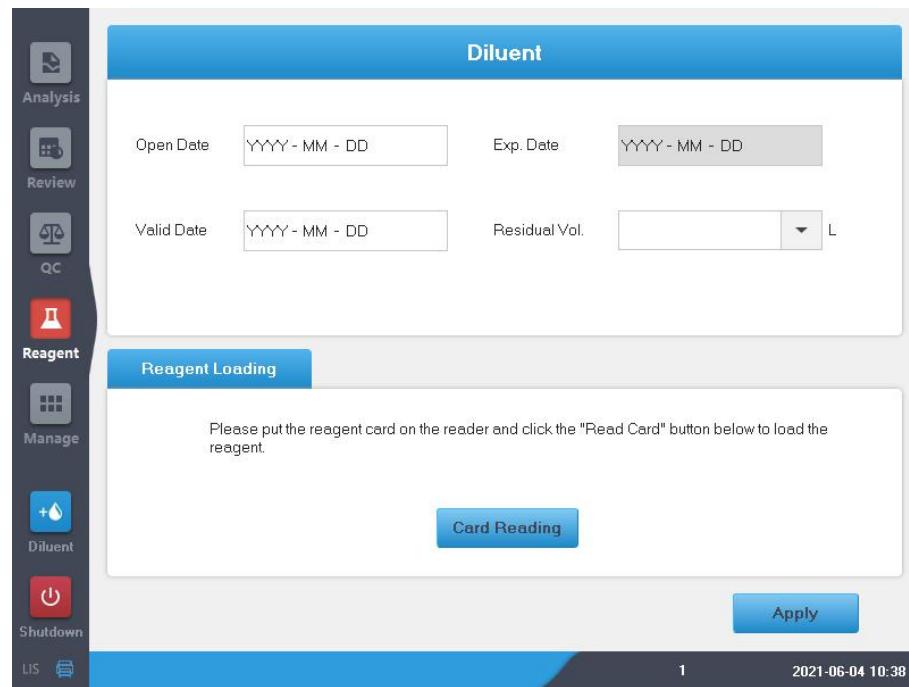
Steps to replace the reagent in the pipelines:

- (1) Click the “Reagent” enter the interface as below. The color of the bottle icon indicates the residual volume of the reagent. Blue indicates that there is sufficient reagent, while red indicates that the reagent is running out;



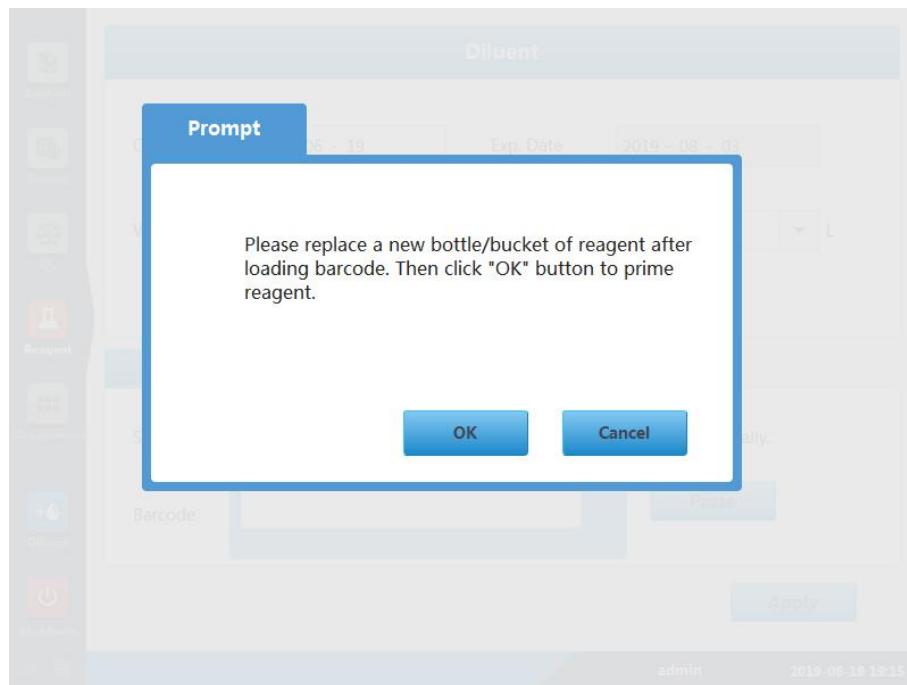
**Figure 8- 4 Interface of “Reagent”**

- (2) Click the “Replace Reagent” below the corresponding reagent icon. For instance, if you need to replace the diluent in the pipelines, click the “Replace Reagent” below the diluent icon to enter the next interface as below:



**Figure 8- 5 Interface for reagent replacement**

- (3) Put the reagent card on the card reader and click “Card Reading”. The open date, expiry date, valid date, and residual volume of the diluent will be displayed in the interface;
- (4) Click “Apply”. If the diluent is qualified, a prompt dialogue shows as below;



**Figure 8- 6 Confirmation or cancelation of reagent replacement**

- (5) Click “OK”, the system implements the reagent replacement process and saves the diluent information; click “Cancel” to give up diluent replacement.

Follow the above steps to replace the LB lyse or LD lyse if necessary.

## 9 Analyzer management

In the interface of “Manage”, there are five options for administrator users and four options for common users.

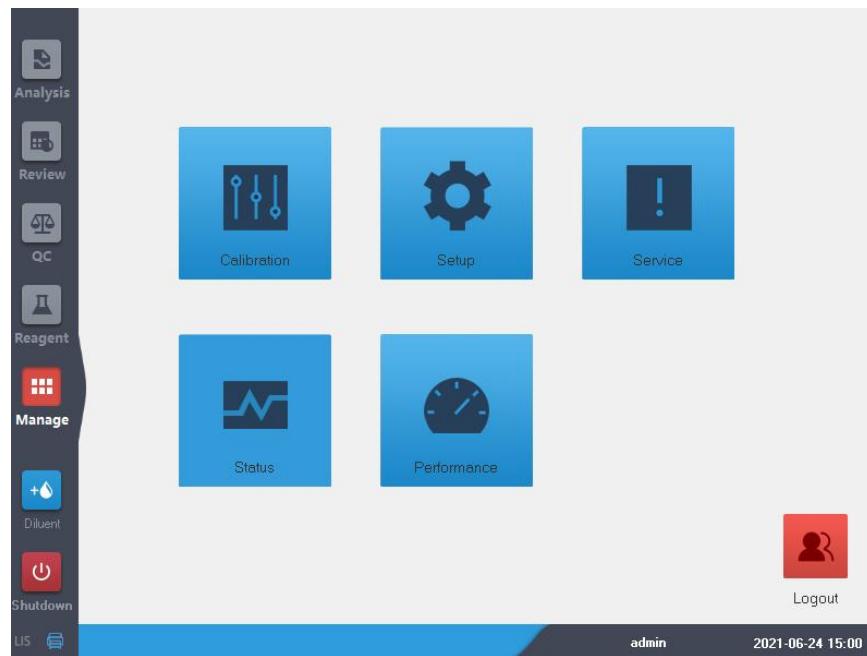


Figure 9- 1 Interface of “Manage” for administrator user

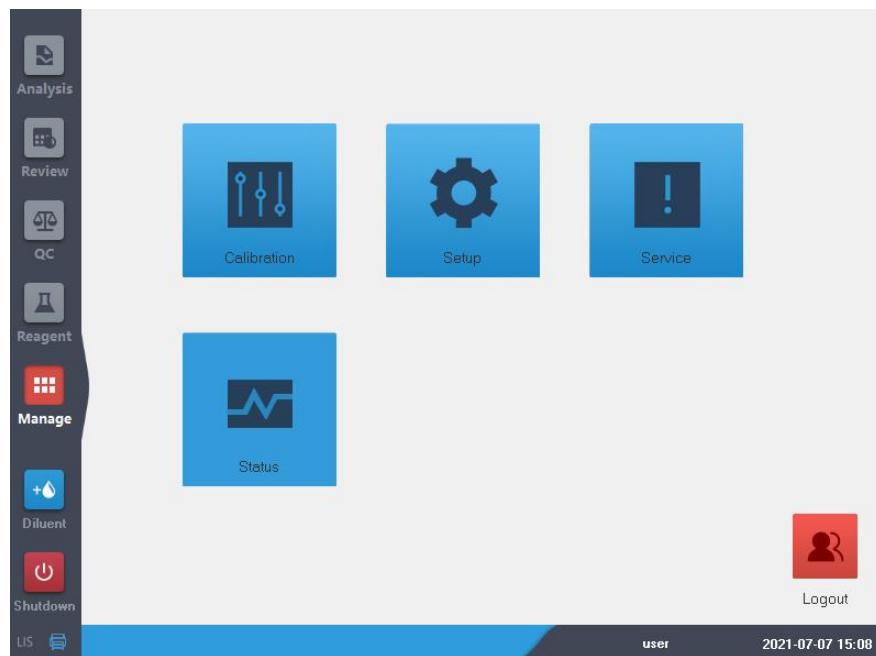


Figure 9- 2 Interface of “Manage” for common user

Click “Logout” at the lower right corner of the interface to log out the current user.

## 9.1 Calibration (for administrator user only)

Calibration is intended to ensure accurate test results. Calibrate the sample analysis when necessary following the steps described herein.

The Analyzer provides three calibration methods, i.e. manual calibration, calibration with calibrators, and calibration with fresh blood. Each of the calibration methods involves both "WB" mode and "PD" mode.

Users can calibrate the results of WBC, RBC, HGB, MCV, PLT.

---

### Note

- Only Administrator user can perform calibration.
  - Use the calibrators and reagents specified by Zybio, and store and use them according to the instructions for use.
  - Calculation involves reproducibility calibration.
- 

### 9.1.1 Frequency of the calibration

Since this Analyzer has been calibrated before delivery, and the Analyzer itself has stable performance, it does not need to be calibrated frequently. The user still may calibrate the Analyzer in the following conditions.

- Calibrate the Analyzer after installation of the Analyzer; (Conducted by the technician or the authorized representative of Zybio);
  - Calibrate the Analyzer after replacing the main components;
  - Calibrate the Analyzer when there is obvious deviation in the quality control data, or the data are out of the preset range;
  - Calibrate the Analyzer when it is restarted after being put aside unused for a long time;
  - Calibrate the Analyzer when the operating environment (such as temperature) changes substantially.
- 

### Note

In the situations mentioned above, calibration of the Analyzer is a must, otherwise the test results may be unreliable.

---

### 9.1.2 Calibration methods

#### Preparation

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 normal. 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 Zybio or its local distributor.

- (1) Check the main unit and reagents to ensure that the reagents are sufficient to complete the entire calibration process. If the reagents run out 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 Section 3.2.1, "Background count");
-

- (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;
- (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.

$$\text{Carry-over Rate} = (j_1 - j_3) / (i_3 - j_3) \times 100\%$$

It is suggested that the user 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 user 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 “Manage” > “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 user selects and displays the current calibration factor corresponding to the mode selected for manual calibration.

User Cal-WB			User Cal-PD		
Para.	Cal. Factor	Cal. Date	Para.	Cal. Factor	Cal. Date
WBC	100.00		WBC	100.00	
RBC	100.00		RBC	100.00	
HGB	100.00		HGB	100.00	
MCV	100.00		MCV	100.00	
PLT	100.00		PLT	100.00	

Print Save

admin 2019-06-19 20:34

Figure 9- 3 Interface of “Manual Calibration”

#### Note

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

Follow the procedure to complete manual calibration.

## Analyzer management

The user enters the “Manual Cal.” interface to view the calibration factor and uses the following formula to calculate the new calibration factor for each parameter:

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

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 user 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 “Manage” > “Calibration” > “Calibrator Cal.” to enter the interface below.

Target	Selected	WBC	RBC	HGB	MCV	PLT
1	<input type="checkbox"/>					
2	<input type="checkbox"/>					
3	<input type="checkbox"/>					
4	<input type="checkbox"/>					
5	<input type="checkbox"/>					
6	<input type="checkbox"/>					
7	<input type="checkbox"/>					
8	<input type="checkbox"/>					
9	<input type="checkbox"/>					
10	<input type="checkbox"/>					

Figure 9- 4 Interface of “Calibrator Calibration”

### Note

- Calibration with calibrators can be performed only in the WB mode.
- The lot, expiry date and parameter reference value of the calibrator are shown in the instructions for use of the calibrator.
- The user must use the calibrators designated by Zybio for this Analyzer. Zybio will not be responsible for any erroneous results due to the use of other calibrators.

Complete the calibration with 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 instructions for use.
- (7) Press the [Aspirate] key on the Analyzer to start the calibration count.
- (8) When the total times of calibration 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 “Manage” > “Calibration” > “Fresh Blood Calibration” to enter the main “Fresh Blood Calibration” interface below.

	Selected	WBC	RBC	HGB	MCV	PLT
Target						
1	<input type="checkbox"/>					
2	<input type="checkbox"/>					
3	<input type="checkbox"/>					
4	<input type="checkbox"/>					
5	<input type="checkbox"/>					
6	<input type="checkbox"/>					
7	<input type="checkbox"/>					
8	<input type="checkbox"/>					
9	<input type="checkbox"/>					
10	<input type="checkbox"/>					
Mean						
CV(%)						
Cal. Factor(%)						

WB-CBC+DIFF      admin      2019-06-19 20:36

Figure 9– 5 Interface of “Fresh Blood Calibration”

Perform fresh blood calibration as follows:

- (1) Prepare 3 to 5 normal fresh blood samples according to the sample preparation method introduced in Chapter 5, “Daily operation” ;

- (2) Take the 3 to 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” 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 closes automatically, and the Analyzer will perform different processing depending on the calibration count results.

If the calibration count result is not within the linearity range, but within the display range, the calibration count result is displayed in the list but not saved.

If the calibration count result is not within the display range, it will be displayed as “\* \* \*” according to the data format of each parameter and will not be saved.

If the calibration count result is in the linearity range, it is valid and will be 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. For each blood sample, when five or more successive valid count results are available, the CV% and calibration factors are calculated for each parameter.

- (1) Press the “Blood Sample 2” to “Blood Sample 5” buttons to enter the “Fresh Blood Calibration” interface for Blood Samples 2 to 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;
- (2) After obtaining the calibration factors of more than three fresh blood samples, press “Calculate” to enter the fresh blood calibration result “Calculation” interface as shown in the picture below:

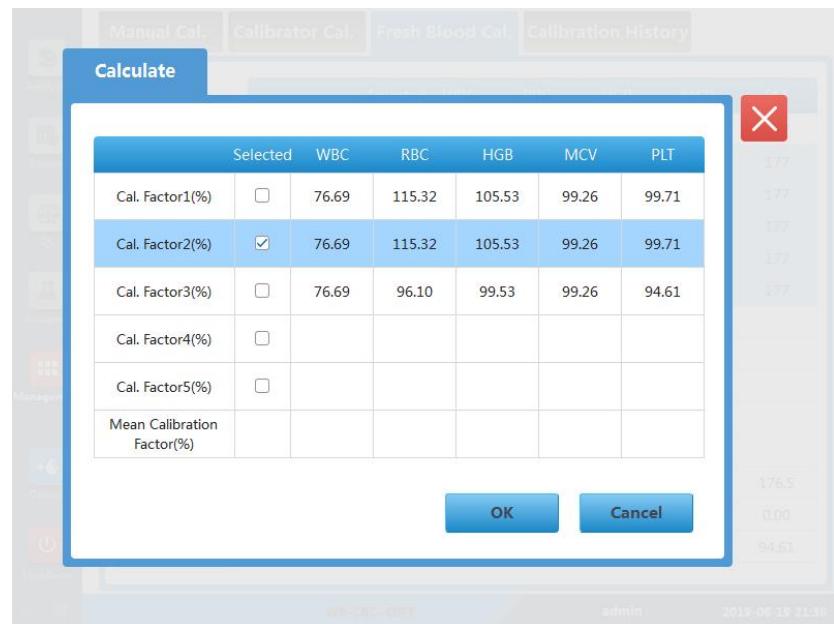


Figure 9-6 Interface fresh blood calibration result

- (3) 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;
- (4) 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 not?”

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

### 9.1.3 Calibration history

Follow the steps below to check the calibration history:

- (1) Click “Manage” > “Calibration” > “Calibration History” to view the calibration history;
- (2) Click “Export” in the interface of “Calibration History” to export the calibration history.

## 9.2 Setup

The Analyzer has undergone initialization before delivery. The interface is defaulted, when the Analyzer is powered on for the first time. Users can customize the software options through “Setup” .

### 9.2.1 General settings

In the interface of “General”, there are nine setting options for administrator user and six options for common user.

Click “Manage” > “Setup” to enter the interface of “General” .

## Analyzer management

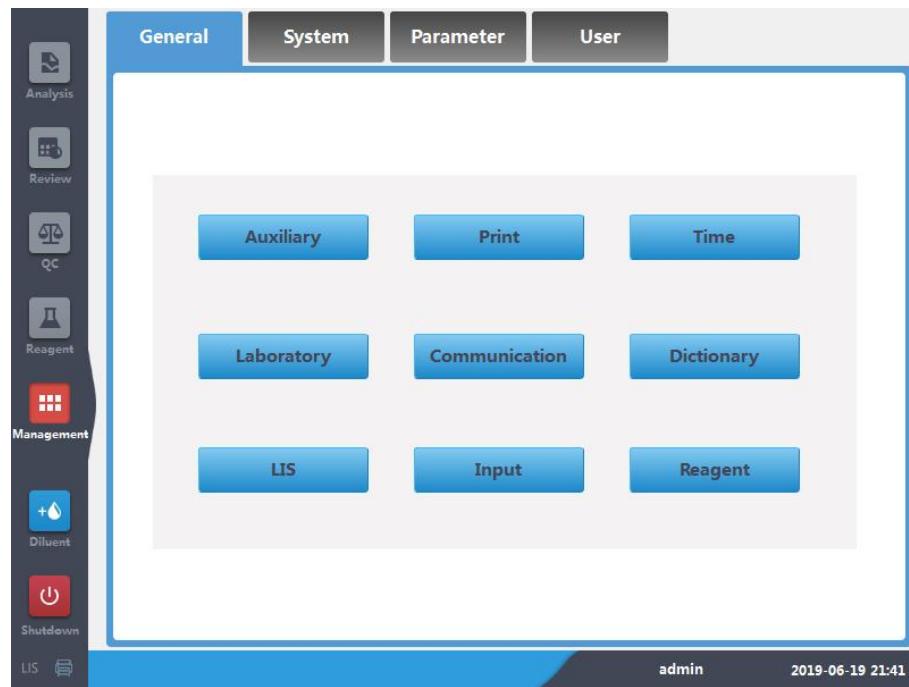


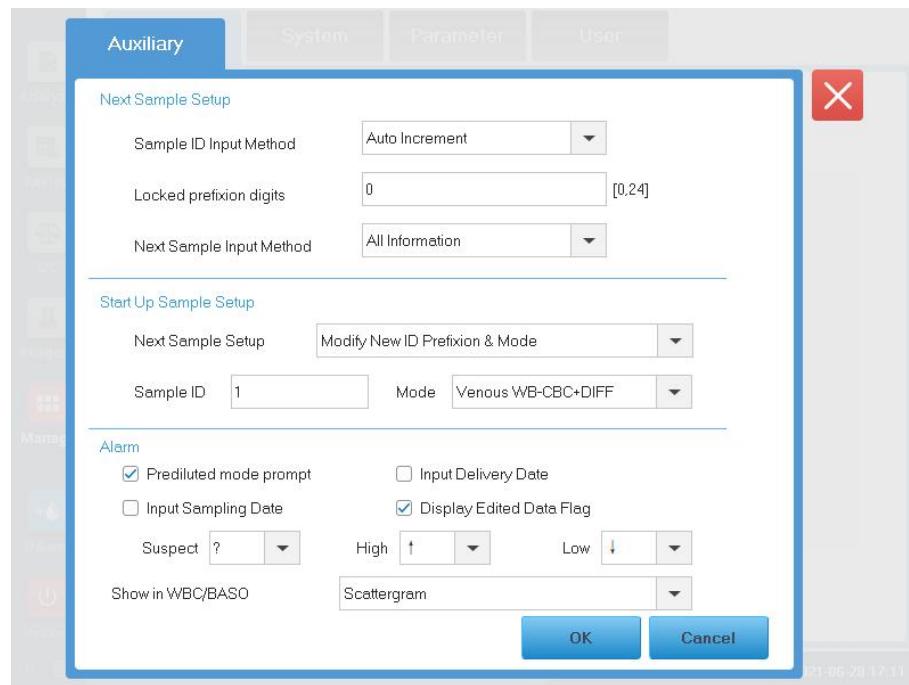
Figure 9- 7 General settings for administrator user



Figure 9- 8 General settings for common user

### Auxiliary

In the menu, select "Manage" > "Setup" > "General" > "Auxiliary" to enter the interface below:



**Figure 9– 9 Interface of “Auxiliary Setting”**

#### Next Sample Setup

Click the drop-down list of “Sample ID Input Method” and select either “Auto Increment” or “Manual Input” as the sample ID input method.

#### 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 input method is “Auto Increment” .

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

#### Startup Sample Setup

The user may customize the first sample ID after startup by entering it into the edit box. Or the user can select “Continue with Sample ID before last shutdown” .

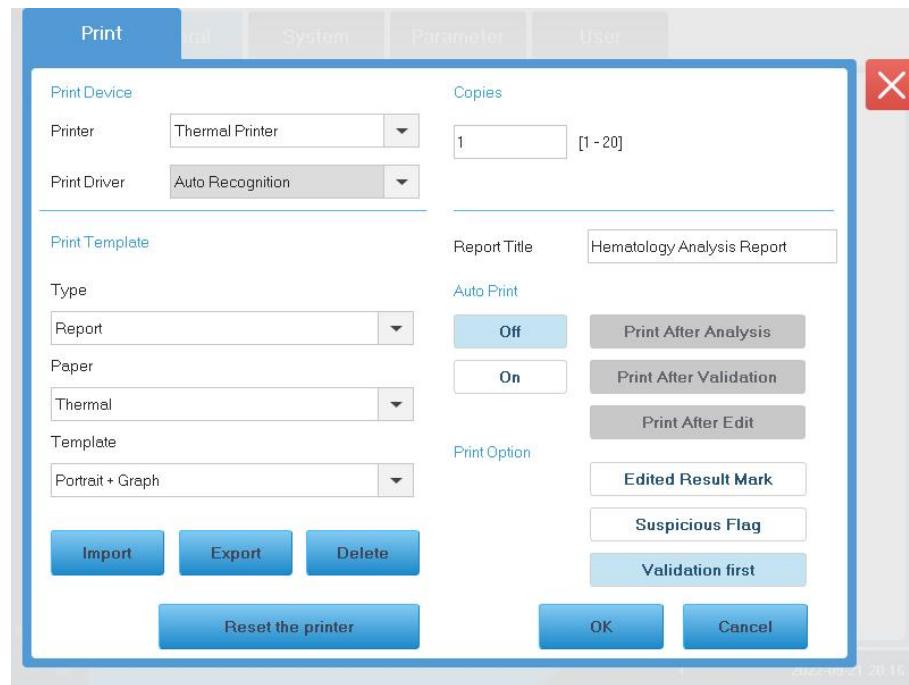
#### Alarm

Set up warning flags: The user can select the suspect warning flags in the drop-down list. The default is “?” .

Set high and low warning flags: The user 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

In the menu, select “Manage” > “Setup” > “General” > “Print” to enter the interface below:

**Figure 9– 10 Interface of “Print Setting”**

Follow the steps below to set printing:

- (1) Select the printer in the “Printer” drop-down box. There are two types of printers, i.e., thermal printer and external printer;
- (2) Select the type, such as report;
- (3) Set the paper. The default paper setting is thermal;
- (4) Select the template;
- (5) Type in the report title;
- (6) Set the number of copies;
- (7) Enable automated printing.

#### **System time**

From the menu, select “Manage” > “Setup” > “General” > “Time” to enter the interface below. The date, time and date format of the Analyzer can be set in this interface.

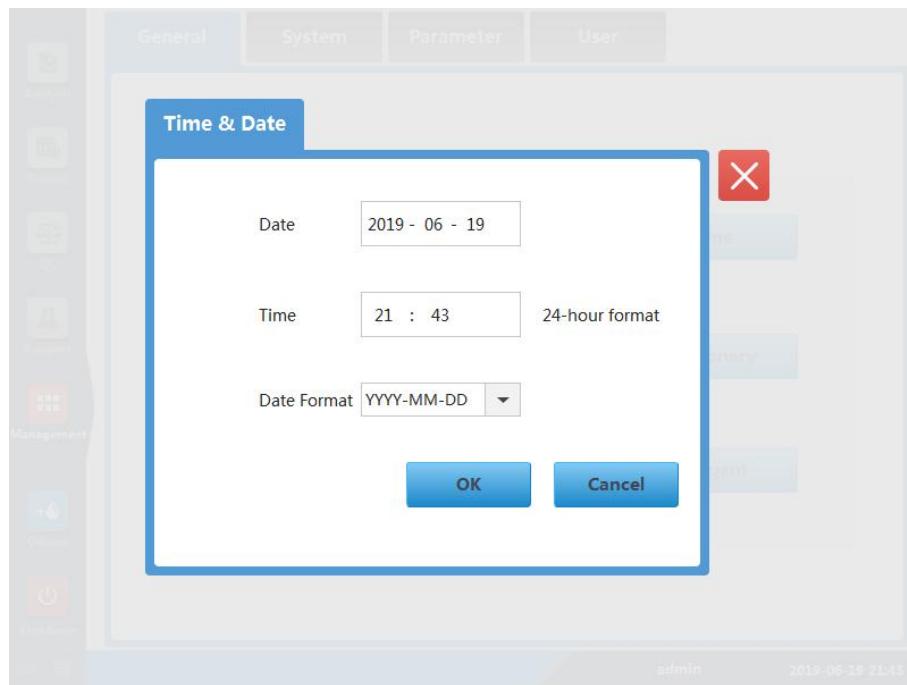


Figure 9- 11 Interface of "System Time Setting"

#### Laboratory information

Click "Manage" > "Setup" > "General" > "Laboratory" in the menu. Enter the interface below. The user can enter, save and view laboratory information. The user can click on the corresponding edit box and enter relevant laboratory information as needed.

The screenshot shows a dialog box titled 'Laboratory'. It contains fields for Lab Name, Principal, Contact, Postalcode, Fax, Analyzer Model (set to Z50), Analyzer SN, Installation Date (set to YYYY - MM - DD), Service Person, Service Tel./Email, and Remarks. There are 'OK' and 'Cancel' buttons at the bottom. The background shows a menu bar with tabs like General, System, Parameter, and User.

Figure 9- 12 Interface of "Laboratory"

#### Dictionary

To add the information of department and deliverer.

#### LIS (for administrator user)

To set the LIS.

**Input (for administrator user)**

To enable or disable the on-screen keyboard.

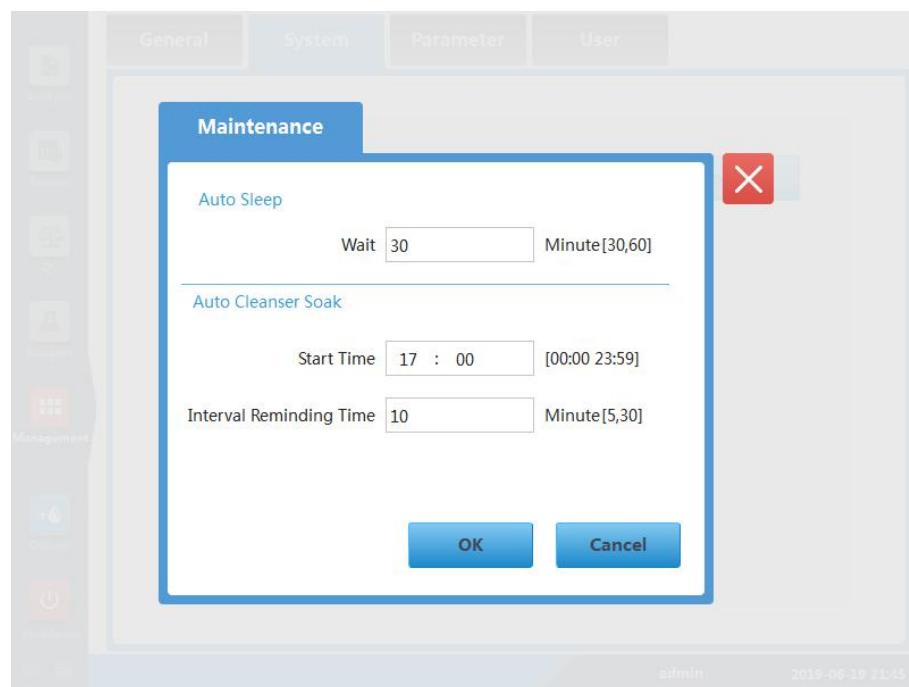
**Reagent (for administrator user only)**

To enable the reminder for reagent expiry and residual volume of reagent.

## **9.2.2 System settings**

### **Automatic maintenance settings**

Click “Manage” > “Setup” > “System” > “Maintenance” to enter the interface below:



**Figure 9- 13 Interface for setting automatic maintenance**

#### **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 administrator user only)**

Click “Manage” > “Setup” > “System” > “Gain” in the menu. Enter the interface below:

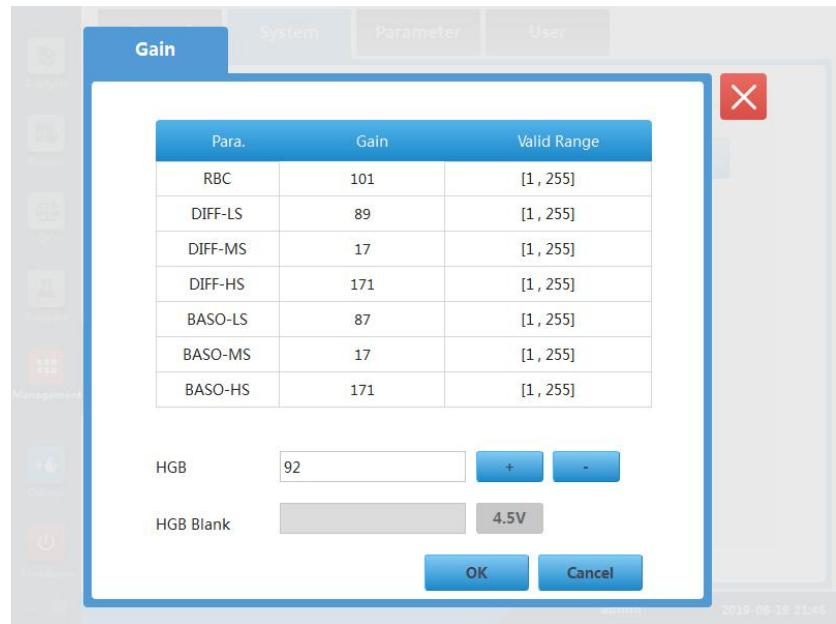


Figure 9- 14 Interface for setting gain

**HGB Gain**

Adjust the HGB Blank to  $4.5V \pm 0.1V$ .

**Software version**

Click “Manage” > “Setup” > “System” > “About” to check the software version of the system.

**Brightness control**

Click “Manage” > “Setup” > “System” > “Brightness control” to adjust screen brightness as needed as shown below:

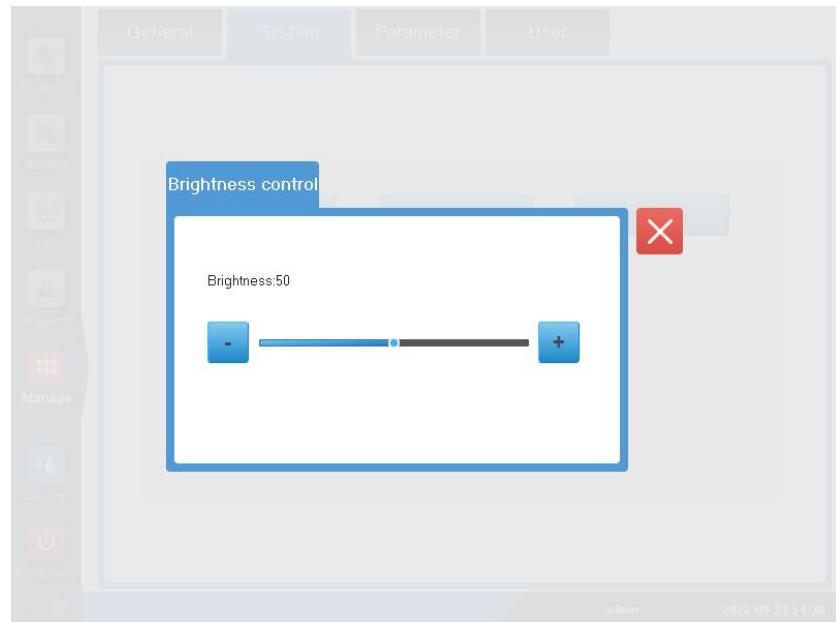


Figure 9- 15 Interface for setting gain

**9.2.3 Parameter settings****Parameter Unit**

## Analyzer management

Click “Manage” > “Setup” > “Parameter” > “Para. Unit” to enter the interface below:

Para.	Unit	Format
WBC	10 <sup>9</sup> /L	***.**
Neu#	10 <sup>9</sup> /L	***.**
Lym#	10 <sup>9</sup> /L	***.**
Mon#	10 <sup>9</sup> /L	***.**
Eos#	10 <sup>9</sup> /L	***.**
Bas#	10 <sup>9</sup> /L	***.**
Neu%	%	**.*
Lym%	%	**.*
Mon%	%	**.*
Eos%	%	**.*
Bas%	%	**.*
Aly#	10 <sup>9</sup> /L	***.**
Lic#	10 <sup>9</sup> /L	***.**
Aly%	%	**.*
Lic%	%	**.*

Para.	Unit	Format
RBC	10 <sup>12</sup> /L	**.**
HGB	g/L	***
HCT	%	**.*
MCV	fL	***.**
MCH	pg	***.**
MCHC	g/L	****
RDW-CV	%	***.**
RDW-SD	fL	***.**
PLT	10 <sup>9</sup> /L	****
MPV	fL	**.*
PDW	fL	**.*
PCT	%	*.***
P-LCC	10 <sup>9</sup> /L	****
P-LCR	%	***.*

Select Unit  
China  
 %  
 mL/L

Restore Default  
Save  
Cancel

Figure 9- 16 Interface for setting parameter unit

### Select Unit

- (1) Click the “Select Unit” drop-down list and select the required unit;
- (2) Customized Unit Settings: Under each unit system, the user can click on the “Unit” cell to customize the unit for any parameter. Click the “Restore Default” to restore the default settings for each unit.

### Reference Range

Click “Manage” > “Setup” > “Parameter” > “Ref. Range” to enter the interface below:

Ref. Group Name	Default	Lower Age Limit	Upper Age Limit	Gender
General	<input checked="" type="radio"/>	0	0	
Man	<input type="radio"/>	0	0	
Woman	<input type="radio"/>	0	0	
Child	<input type="radio"/>	0	0	
Neonates	<input type="radio"/>	0	0	
仓鼠	<input type="radio"/>	0	0	
豚鼠	<input type="radio"/>	0	0	
貂	<input type="radio"/>	0	0	
猪	<input type="radio"/>	0	0	

Match Customized Group First

Set Default New Edit Delete Close

Figure 9- 17 Interface for setting reference range

The interface provides 9 internal reference groups and 10 customized reference groups for the user 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” to enter the reference group setting interface and set information such as the name, age range, and parameter range of the reference group.

#### 9.2.4 User settings

Click “Manage” > “Setup” > “User” in the menu to enter the interface below:

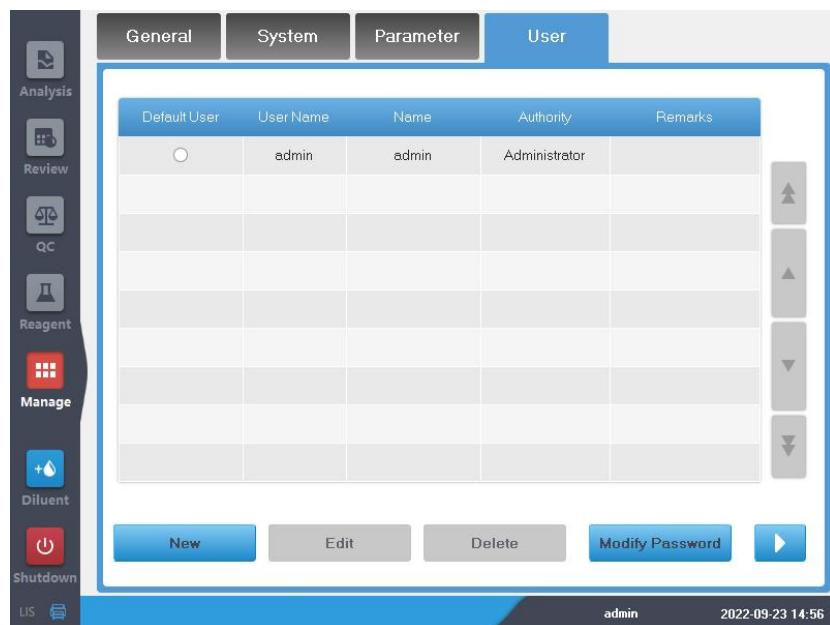


Figure 9- 18 Interface of “User” setting for administrator user

The administrator user can add new users, edit and delete the user, and modify the password. The common users can only modify their passwords.

##### New (for administrator user only)

(1) Click “New” to enter the dialog box below:

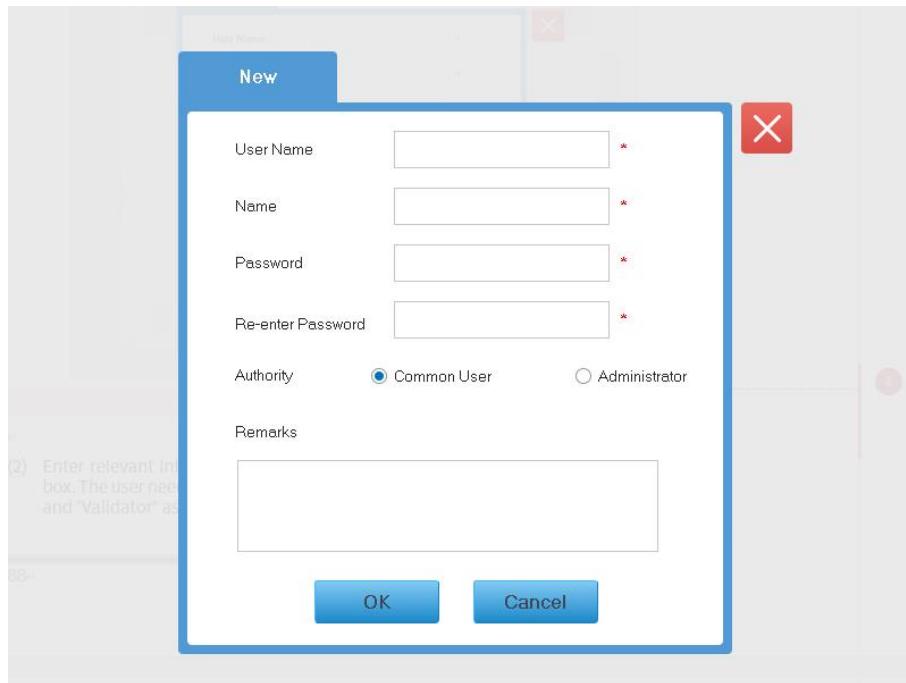


Figure 9- 19 Interface for adding a new user

- (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 (for administrator user)

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

### 9.3 Service

This chapter introduces maintenance and care of the Analyzer. The Analyzer has been designed to require minimal routine maintenance. However, to ensure the accurate and effective performance and prolong the service life of the Analyzer, the user shall carry out necessary maintenance and care according to the requirements in this chapter.

Users and service personals (individuals responsible for maintenance in the medical institutions) can operate the Analyzer or conduct limited maintenance only after completing the training provided by Zybio or its local distributors.

Only Zybio or its local distributors can assemble and dismantle the Analyzer. If the user dismantles and assemblies the Analyzer without Zybio's prior

permission, Zybio shall assume no responsibility for the consequent accidents and the Analyzer failure.

The following tools and materials may be needed for service personnel.

**Table 9- 1 Maintenance tools and materials**

No.	Tool
1	Slotted screwdriver (for replacing fuse)
2	Medical gloves
3	75% ethanol

For quality control, please refer to Chapter 7, “Quality control”; for installation, refer to Chapter 2, “Installation”; for calibration, refer to Section 9.1, “Calibration (for administrator user only).”

#### Routine cleaning

- Clean the environment where the Analyzer is placed everyday;
- If the Analyzer surface is dirty, wipe it with a piece of lint-free cloth damped by 75% ethanol;
- Conduct scheduled maintenance through “Service” function provided by the Analyzer itself.

If hazardous substance spills into the equipment, please consult the local distributor for professional cleaning advice.

The waste liquid is connected to a waste container which shall be labeled as biological waste.

If the waste container or diluent container have breakage, immediately turn off the Analyzer and deal with the situation according to lab management regulations. Please pay special attention to biological risk.



The samples, reagents, calibrators, controls, and the surface of all parts of the Analyzer may pose biological risks. Please wear protective suit and a pair of latex gloves when performing service or maintenance.

#### Warning

- Power off the Analyzer and unplug its power cord before cleaning the Analyzer surface to avoid electric shock.
- Decontamination shall be carried out if hazardous material is spilled onto or into the equipment.
- Those decontamination or cleaning agents (such as strong alkali or acid detergents) shall not be used, which will cause a hazard as a result of a reaction with parts of the equipment or with material contained in it.
- If there is any doubt about the compatibility of decontamination or cleaning agents with parts with the equipment or with material contained in it, Zybio or its local distributor shall be consulted.

## Analyzer management

- Please wear a pair of latex gloves when handling the cleaning reagents.

Through “Service” function of the Analyzer, users can perform device maintenance, device self-check, system calibration, and log query.

### 9.3.1 Maintenance

Though the Analyzer requires minimal maintenance, users are still suggested to perform scheduled maintenance to retain the best performance of the Analyzer.

#### Note

If the Analyzer has run for a long time, the disk may become full, restart the Analyzer to clear the temporary memory.

#### Daily maintenance

- Shutdown;
- Probe cleanser soak: click “Whole Device” below “Probe Cleanser Soak” .

#### Periodical maintenance

Depending on the service contract or sales contract, Zybio or its local distributor will provide periodical maintenance service.

#### As-needed maintenance

The Analyzer has been designed to provide as-needed maintenance. Click “Manage” > “Service” > “Maintenance” to enter the interface below:

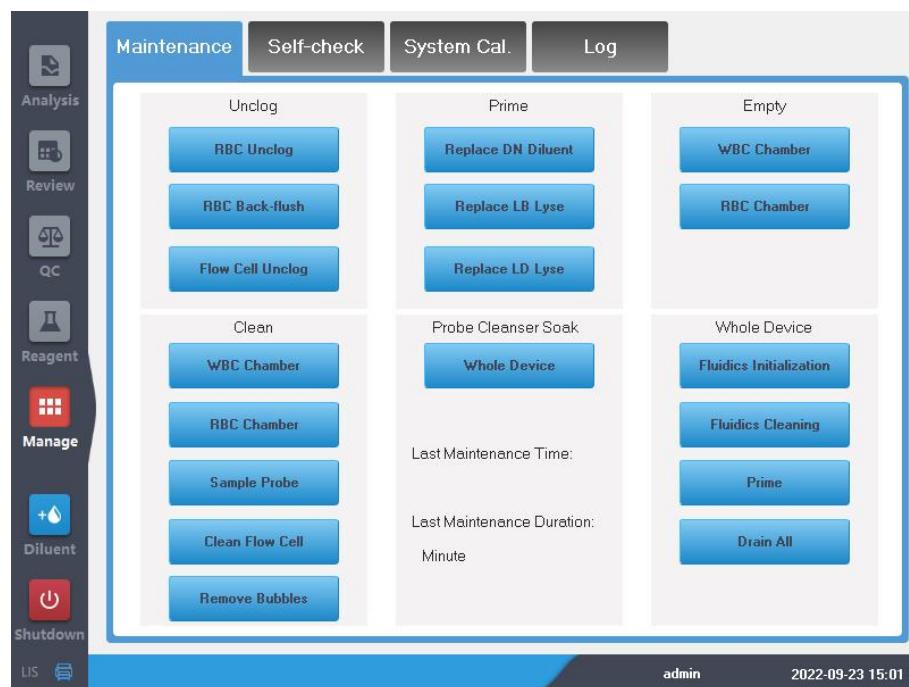


Figure 9- 20 Maintenance for common user

#### Unclog

Unclogging involves burning and back flushing. When the RBC channel is blocked, carry out the operations below:

- 
- (1) Click “RBC Unclog” to start unclogging;
  - (2) After unclogging is completed, the system prompts “Maintenance completed” ;
  - (3) If necessary, click “RBC Back-flush” or “Flow Cell Unclog” .

#### **Prime**

Click the buttons below “Prime” to refill the chamber with necessary reagent.

#### **Empty**

Click the buttons below “Empty” to empty the liquid from the corresponding chambers.

#### **Clean**

Click the buttons below “Clean” to clean the concerned parts.

- (1) Click “WBC Chamber” to clean the WBC chamber when the background values of WBC and/or HGB exceed the expected ranges;
- (2) Click “RBC Chamber” to clean the RBC chamber when the background values of RBC and/or PLT exceed the expected ranges;
- (3) Click “Sample Probe” to clean the sample probe when the sample probe is dirty;
- (4) Click “Clean Flow Cell” when the flow cell is dirty;
- (5) Click “Remove Bubbles” when there are bubbles in the pipelines.

#### **Probe cleanser soak**

Click “Whole Device” below “Probe Cleanser Soak” to get the whole system soaked with probe cleanser when:

- The background values and quality control results are abnormal and the aperture is blocked, because the Analyzer has been left unused for a long time, and maintenance operations fail to improve the situation;
- The Analyzer shuts down due to abnormal power failure.

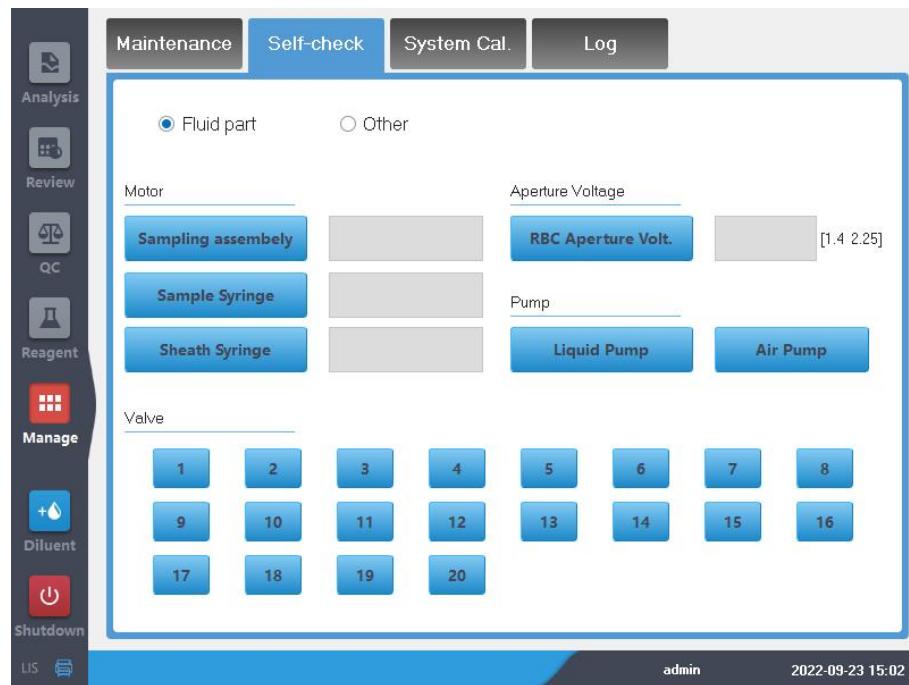
#### **Whole device**

- Click “Fluidics Initialization” to restore all the moving parts and sensors to their initial state;
- Click “Fluidics Cleaning” to clean all the components of the fluidic path;
- Click “Prime” below “Whole Device” to fill the pipelines full with reagents;
- Click “Drain All” and then follow the instructions on the screen to empty the Analyzer and clean it with distilled water, when the Analyzer has been left unused for more than one week;

### **9.3.2 Self-check**

The Analyzer runs self-check upon startup, users are suggested check the Analyzer through “Self-check” once per week to detect any defects.

Click “Manage” > “Service” > “Self-check” to check the motors, the aperture voltage, the laser, the fans, the valves, the pumps, etc.

**Figure 9- 21 Self-check**

### 9.3.3 Safety check

This section mainly introduces the safety check. For the safety of users and the Analyzer, the user should check:

- If the power cord is well connected;
- If there is any damage to the Analyzer appearance;
- If there is any damage to the sample probe;
- If there is any odor in the Analyzer;
- If there is any leakage in the tubing and inside the Analyzer;
- If there is any overtemperature inside the Analyzer.

### 9.3.4 System calibration

By clicking “Manage” > “Service” > “System Cal.” , users can calibrate the touch screen, as shown below:

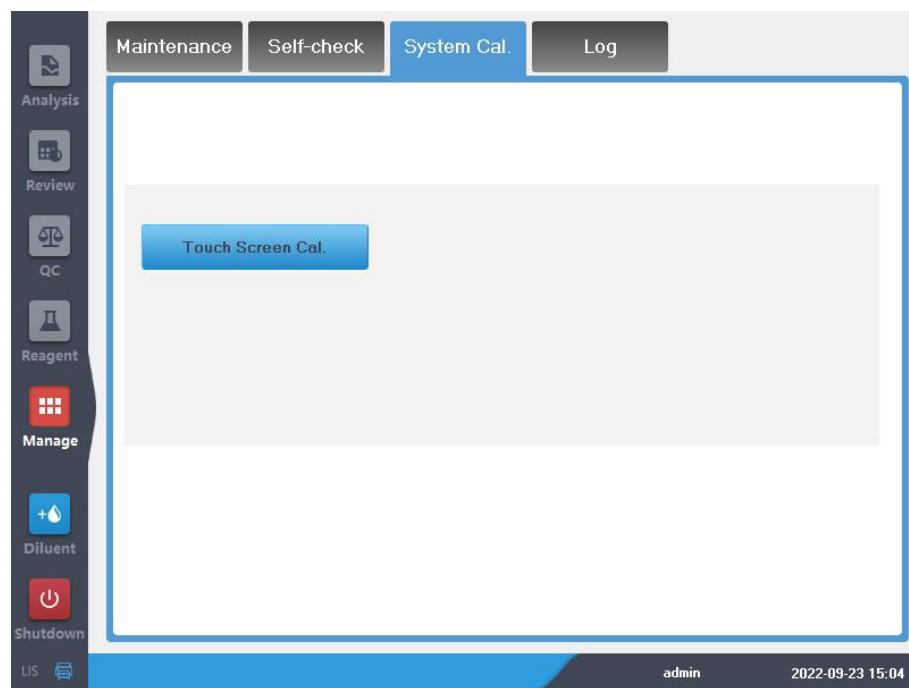


Figure 9- 22 System calibration

### 9.3.5 Log

Through “Log” , users can view and export the logs.

By clicking “Manage” > “Service” > “Log” , users can view and export the logs of parameter modifications, operations, and errors.

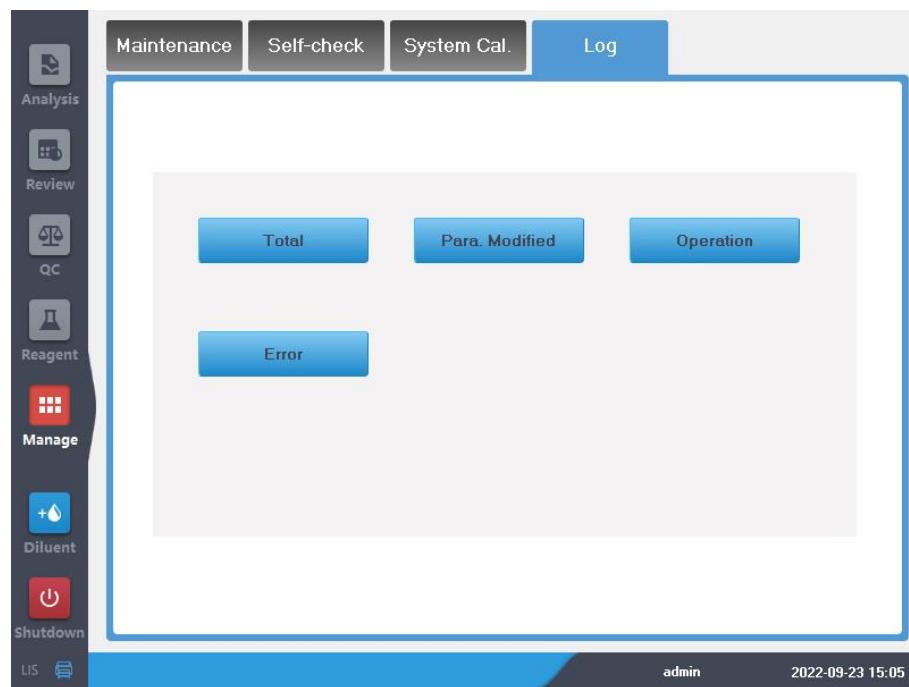


Figure 9- 23 Logs

The logs record the use history of the Analyzer, and are important for the maintenance personnel to troubleshoot problems.

#### Log export

- Insert a “USB flash drive” onto the Analyzer;

- Click “Export” ;
- Select the logs for export;
- After export is done, the interface prompts a reminder of “Export succeeded” .

## 9.4 Status

Through “Status”, users can check the device information or version, the temperature and pressure of different parts, the sensor status of different device parts, the device voltage and current, the disk information, and the counter.

### 9.4.1 Version

To view the Analyzer’s software version, click “Management” > “System” > “About” .

The software version is V02.

### 9.4.2 Sensor

Click “Manage” > “Status” > “Sensor” to view the instrument’s sensor status.

Device Components		Status
Float Sensor	Waste	
Syringe Optocoupler	Sample Syringe	
	Sheath flow syringe	
Sampling Assembly Optocoupler	Vertical Optocoupler	
	Inside Optocoupler	
	Follow Optocoupler	
Sensor Switch	Aspirate Key	
	Optical Module Lid	
Fan	Inner fan	
	Outer fan	

admin      2022-09-23 15:07

Figure 9- 24 Sensor status

### 9.4.3 Voltage/current

Click “Manage” > “Status” > “Volt./Current” to view the instrument’s voltage status.

The screenshot shows the 'Disk Info.' tab selected in the top navigation bar. The main content area is a table with columns 'Items', 'Result', and 'Ref. Range'. The table data is as follows:

Items	Result	Ref. Range
A+12V(V)		[10.50, 13.50]
A-12V(V)		[-13.50, -10.50]
HGB(V)		[4.20, 4.80]
DIL(V)		
LB(V)		
LD(V)		
Constant Current(V)		[51.00, 61.00]
Optical Background(V)		[1.70, 2.70]
Laser Current(mA)		[20.00, 60.00]
AD Reference(V)		[2.40, 2.60]

Figure 9- 25 Status of voltage and current

#### 9.4.4 Disk information

Click “Manage” > “Status” > “Disk info.” to view the disk information.

#### 9.4.5 Counter

Click “Manage” > “Status” > “Counter” to view the counter status.

### 9.5 Performance (for administrator user only)

Through “Performance”, the administrator user can check the background values, repeatability, and carryover of the Analyzer.



# 10 Troubleshooting

This chapter describes the errors the Analyzer may have and the method for replacing the fuse.



Samples, controls, calibrators, liquid wastes, etc. pose biological risks. Please follow the laboratory safety practices and wear protective equipment (such as protective suit and latex gloves, facial masks, etc.) before touching the relevant parts.

## Note

- For maintenance and repair of the Analyzer, please refer to the Service Manual.
- If liquid leakage occurs inside the Analyzer which results in pressure change, an alarm will be triggered.

## 10.1 Error information and handling

During 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 user 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 user shall deal with the errors in sequence according to the contents of the error help.

To help the user 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 user is able to troubleshoot and clear the error messages accordingly. If the problem still exists, please contact the after-sales service department of Zybio.

The possible errors of the Analyzer and the corresponding help information are as below:

**Table 10- 1 Error and handling**

Error Name	Actions
Communication Abnormal	1. Click "Clear", and this error will automatically clear. 2. If the error still exists, please contact the after-sales service department of Zybio.

## Troubleshooting

---

Error Name	Actions
Voltage Abnormal	Please turn off the power directly and contact Zybio.
System Clock Abnormal	Please turn off the power directly and contact Zybio.
Diluent Expired	1. Click “Clear” and read the reagent card of the new reagent in the popup message. 2. Change the reagent bottle and click the “Apply” to prime the reagent. 3. If the error still exists, please contact the after-sales service department of Zybio.
Lyse Expired	1. Click “Clear” and read the reagent card of the new reagent in the popup message. 2. Change the reagent bottle and click the “Apply” to prime the reagent. 3. If the error still exists, please contact the after-sales service department of Zybio.
Waste Full	1. Empty the waste bucket or change another bucket. 2. Click “Clear” button to remove the error. 3. If the error still exists, please contact the after-sales service department of Zybio.
Diluent Empty	1. Please check if the diluent runs out. If there is no reagent, please replace a new one. 2. Click “Clear” button to remove the error. 3. If the error still exists, please contact the after-sales service department of Zybio.
LD/LB Lyse Empty	1. Please check if the lyse runs out. If there is no reagent, please replace a new one. 2. Click “Clear” button to remove the error. 3. If the error still exists, please contact the after-sales service department of Zybio.
Syringe Component Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact the after-sales service department of Zybio.
Sampling Component Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact the after-sales service department of Zybio.
Background Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact the after-sales service department of Zybio.
HGB Blank Voltage Abnormal	1. Please check id the diluent empty or not. If there is no reagent, please replace it with a new one. 2. Click the “Clear” and this error will automatically clear.

---

Error Name	Actions
	3. If the error still exists, please contact the after-sales service department of Zybio.
Vacuum Pressure Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact the after-sales service department of Zybio.
WBC Clog	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact the after-sales service department of Zybio.
WBC Aperture Voltage Abnormal	1. Click “Clear” and this error will automatically clear. 2. If the error still exists, please contact the after-sales service department of Zybio.

## 10. 2Repair

When the Analyzer breaks down, please contact Zybio or its local distributor for checking and repair. For the spare parts that may be replaced, please refer to A.2 of Appendix A.

Removal of the Analyzer from use for repair or disposal shall be conducted by shall be conducted by the Zybio or its local distributor. If the Analyzer needs professional maintenance or repair, contact Zybio or its local distributor for support.

When a malfunction occurs, users or service personnel shall consult the Manual immediately for correct handling. The personnel from Zybio or its local distributor may provide remote instructions or field maintenance if necessary.

### Note

- Always power off the Analyzer and disconnect the power cord first before moving the Analyzer.
- Only professional personnel from Zybio or its local distributor can assemble and dismantle the Analyzer.
- Use the spare parts provided by Zybio for replacement. If you have any questions, please contact Zybio.

### 10. 2. 1 Replacement of fuse

Users can independently replace the fuse on the back of the Analyzer following the steps below:

- (1) Power off the Analyzer and disconnect the power cord;
- (2) Pull out the fuse holder in the filter;



**Figure 10– 1 Pulling out the fuse holder**

- (3) Take out the blown fuse and insert a new fuse into the fuse holder. There are a pair of fuses in the fuse holder;



**Figure 10– 2 Taking out the blown fuse**

- (4) Mount the fuse holder back onto the back of the Analyzer.



Figure 10- 3 Mounting the fuse holder back

### Note

- Please use the specified fuse (T6.3AH250V).
  - Caution on electric shock.
-

# Appendix A Related information

## A.1 Parameters

There are 29 parameters (including four research parameters), two histograms, one 3-D scatter plot, three 2-D scatter plots, and the CBC and CBC+DIFF test mode results are as follows:

Table A-1 Analyzer parameters

Parameter	Abbreviation	Unit	CBC	CBC + DIFF
White blood cell count	WBC	$10^9 /L$	✓	✓
Basophils number	Bas#	$10^9 /L$	/	✓
Basophils percentage	Bas%	%	/	✓
Neutrophils number	Neu#	$10^9 /L$	/	✓
Neutrophils percentage	Neu%	%	/	✓
Eosinophils number	Eos#	$10^9 /L$	/	✓
Eosinophils percentage	Eos%	%	/	✓
Lymphocytes number	Lym#	$10^9 /L$	/	✓
Lymphocytes percentage	Lym%	%	/	✓
Monocytes number	Mon#	$10^9 /L$	/	✓
Monocytes percentage	Mon%	%	/	✓
Percentage of abnormal lymphocytes	ALY% (Research parameters)	$10^9 /L$	/	✓
Percentage of large immature cells	LIC% (Research parameters)	%	/	✓
Number of abnormal lymphocytes	ALY# (Research parameters)	$10^9 /L$	/	✓
Number of large immature cells	LIC# (Research parameters)	%	/	✓
Red blood cell count	RBC	$10^{12} /L$	✓	✓
Hemoglobin concentration	HGB	g/L	✓	✓
Mean corpuscular volume	MCV	fL	✓	✓
Mean corpuscular hemoglobin	MCH	pg	✓	✓
Mean corpuscular hemoglobin concentration	MCHC	g /L	✓	✓
Red blood cell distribution width-coefficient of variation	RDW-CV	%	✓	✓

## Related information

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Parameter	Abbreviation	Unit	CBC	CBC + DIFF
Red blood cell Distribution width-standard deviation	RDW-SD	fL	✓	✓
Hematocrit	HCT	%	✓	✓
Platelet count	PLT	10 <sup>9</sup> /L	✓	✓
Mean platelet volume	MPV	fL	✓	✓
Platelet distribution width	PDW	fL	✓	✓
Platelet	PCT	%	✓	✓
Platelet-large cell ratio	P-LCR	%	✓	✓
Platelet-large cell count	P-LCC	10 <sup>9</sup> /L	✓	✓

Table A- 2 Histogram

Parameter	Abbreviation	CBC	CBC + DIFF
Red blood cell histogram	RBC Histogram	✓	✓
Platelet histogram	PLT Histogram	✓	✓

Table A- 3 Scatter plot

Parameter	Abbreviation	CBC	CBC + DIFF
3-D Differential scatter plot	3-D Diff scatter plot	/	✓
2-D Differential scatter plot	2-D Diff scatter plot	/	✓
WBC/BASO scatter plot	WBC/BASO scatter plot	/	✓
WBC scatter plot	WBC scatter plot	✓	/

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### Note

- “✓” means available “/” means unavailable
  - ALY%, LIC%, ALY#, LIC# are research parameter, only used for research, not for clinical diagnosis.
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## A.2 List of materials

Table A-4 Accessory list

No.	Part
1	Diluent adapter tube
2	Waste float adapter tube
3	Stylus pen
4	RFID reader
5	Power cable
6	Ground wire
7	Fuse

Table A-5 Spare parts

No.	Part
1	Switched-mode power supply
2	Power cord
3	Filter
4	Stepper motor
5	Three-way solenoid valve
6	Two-way solenoid valve
7	WBC counting chamber
8	RBC counting chamber
9	Liquid pump
10	Air pump
11	Main control board PCBA
12	Driver board PCBA
13	Open sample probe
14	Swab
15	Touch screen
16	Display

**Related information****Table A- 6 List of miscellaneous materials**

No.	Material name
1	Protective suit
2	Latex gloves
3	Surgical mask
4	Medical alcohol
5	Vacuum blood collection tube
6	Centrifugal tube
7	Capillary tube
8	Slotted screwdriver
Note: Users shall prepare the materials above, and the list may not be exhaustive.	

**Table A- 7 Applicable tubes**

Type	Specifications and dimensions	Applicable mode
Vacuum blood collection tube	Ø12 – 15 × 75mm (without cap)	WB mode
Small anticoagulant tube	Ø10.7 × 42mm (without cap), 0.5 mL, it can be tested for cap opening. Recommended: 0.5-mL closed anticoagulant tube (REF. 365974) produced by BD Inc.	Capillary WB mode
Centrifuge tube (bullet)	Ø11 × 40mm , 0.5-mL and 1.5-mL centrifuge tubes	PD and capillary WB modes

## Apendix B Literature

- (1) ISO 20916:2019 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice.
- (2) Clinical and Laboratory Standard Institute. Reference Leukocyte(WBC) Differential Count (Proportional) and evaluation of Instrumental methods : Approved Standard - Second edition. CLSI document H20-A2 (ISBN 1-56238-628-X). Clinical and laboratory Standards institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.