

Z50 VET Z52 VET
Hematology Analyzer

Operation Manual



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Fourth edition (November, 2022)

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02	December, 2021	<ol style="list-style-type: none">1. Update the accessory list.2. Update the screenshots of software.3. Update information about online update.4. Delete software type.
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1 General

The Hematology Analyzer (hereinafter referred to as the Analyzer), using impedance technology, colorimetry, and flow cytometry, is designed for hematological analysis of the samples collected from animals. It is featured in precision and easy operation and can be used in pet clinics, zoos, and large livestock farms.

The Operation Manual (hereinafter referred to as the 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 this Manual prior to operating this Analyzer. The Manual is delivered together with the Analyzer, and please keep it properly for future reference after reading. The Analyzer is for veterinary use only and Zytopia shall not assume any responsibility for the consequences if the Analyzer is used for other purposes.

This chapter mainly introduces the basic information and model of the Analyzer, use of the manual, Analyzer symbols, laser warning, electromagnetic compatibility, and safety information.

1.1 Basic information

This chapter introduces the basic information of the Analyzer.

Table 1-1 Basic information

Category	Details
Product name	Hematology Analyzer
Product model	Z50 VET, Z52 VET
Animal category	Feline, canine, cattle, sheep, rabbit, hamster, guinea pig, mink, pig, alpaca, horse, and camel.
Product structure and compositions	The Analyzer is composed of a sampling system, a reaction system, an optical system, a data processing system, and an operating software.
Intended use	The hematology analyzer is a quantitative automated instrument for veterinary diagnostic use in laboratories. It uses impedance technology, colorimetry, and flow cytometry. It is used together with the reagents provided by Zytopia for clinical quantitative detection of the blood samples collected from animals. Test items involve the five-part analysis of blood cell count, hemoglobin (HGB), and white blood cell (WBC).
Contraindication	None
Manufacturer	Zytopia Ltd.

General

Category	Details
Address	Building 38, No. 8 Taikang Road, C Zone, Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082
Manufacturing date	Refer to the product nameplate.

1.2 Models

The instrument has two models, i.e., Z50 VET and Z52 VET. The descriptions in this Manual are based on Z50 VET.

Please refer to the table below for the differences between the two models.

Table 1-2 Model differences

Model	Throughput	RFID reader	Thermal printer
Z50 VET	Greater than or equal to 60 samples per hour	Built-in	NA
Z52 VET	50 samples per hour	External	Built-in

1.3 About this manual

The Manual consists of ten chapters and one appendix. Readers may refer to the corresponding chapter for the information needed.

Table 1-3 Manual guide

Chapter	Content
1. Introduction	This chapter mainly introduces the basic information and model of the Analyzer, use operation manual, Analyzer symbols, laser warning, electromagnetic compatibility, and safety information.
2. Installation	This chapter introduces the installation requirements, system connection, printer paper installation and use precautions.
3. Analyzer introduction	This chapter introduces the appearance, parameters and performance, specification and configuration of the Analyzer, the software interface, reagents, controls and calibrators.
4. Operation principles	This chapter mainly introduces the detection flow and detection principles of the Analyzer.
5. Daily operation	This chapter mainly introduces pre-operation preparation, startup and shutdown of the Analyzer, quality control procedure, sample collection, sample preparation, sample analysis, and standby.
6. Result review	This chapter mainly introduces the software interface and daily operations.
7. Quality control	This chapter mainly introduces settings, analysis, and result review of quality control.
8. Reagent management	This chapter mainly introduces interface operation and reagent replacement.




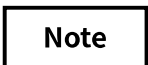
Chapter	Content
9. Analyzer management	This chapter mainly introduces calibration, setting, status, and performance.
10. Troubleshooting	This chapter mainly introduces information about troubleshooting, fuse and maintenance.
Appendix A Analyzer information	It introduces the information related to the Analyzer including parameter interpretation and accessory list.

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.
	Indicates a situation that, if not avoid, could result in hazards or other serious adverse consequences from the use of a medical device.
	Indicates a potentially hazardous situation which, if not avoid, could result in minor or moderate injury, or damage of the medical device or incorrect results.
	Indicates the important information or content that requires the attention of the operator.










Symbols used on the instrument are as follows:

Table 1-5 Symbols on the instrument

Symbols	Explanation
	Indicates that there are potential biological risks associated with the medical device, necessary to consult the Manual for details when operation.
	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).
	Indicates the need of taking care to avoid injury to hands when in the vicinity of equipment with closing mechanical parts.
	Indicates the protective earth (ground) terminal.

General

Symbols	Explanation
	Indicates the function earth(ground).
	Indicates that the device is suitable for alternating current only.
CE	Indicates that the product complies with the applicable directives/regulations of the European Union.
For veterinary use only	It indicated that the hematology analyzer are for veterinary diagnostic use only.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date after which the device is not to be used.
	Indicates the manufacturer's serial number so that a specific device can be identified.
	Indicates the date when the device was manufactured.
	Indicates the device manufacturer.
	Indicates the need for the user to consult the instructions for use.
	Indicates the presence of the CLASS 3B laser radiation when open. Avoid exposure to the beam.
T6.3AH250V	Indicates the fuse specification.
	Indicates the connecting terminals of the computer network.
	Indicates the USB interface.
	Indicates connection to the mains.
○	Indicates disconnection from the mains.
	Indicates the position to be pressed to open the door.
	Indicates V - LD lyse
	Indicates V - LB lyse

Symbols	Explanation
	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 maximum number of identical transport packages/items which may be stacked on the bottom package is 1.
	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 correct upright position of the distribution package for transport and/or storage.
	Indicates that contents of the distribution package are fragile therefore it shall be handled with care.
	Indicates that distribution packages shall be stored, transported, and handled within temperature limits.
	Indicates that distribution packages shall be stored, transported, and handled within humidity limits.
	Indicates that distribution packages shall be stored, transported, and handled within atmospheric pressure limitation.

1.5 Laser warning

- Laser is installed inside the Analyzer. In order to avoid personal injury caused by laser, only professional personnel designated by Zytopia can assemble and maintain the Analyzer.
- There may be Class 3B laser radiation (according to IEC 60825-1:2014, 15 May, 2014) when opening the Analyzer or interlocking fails.
- Avoid direct exposure to strong light.
- Maximum output power: 4.5 mW, continuous output, wavelength 670 nm, visible light.

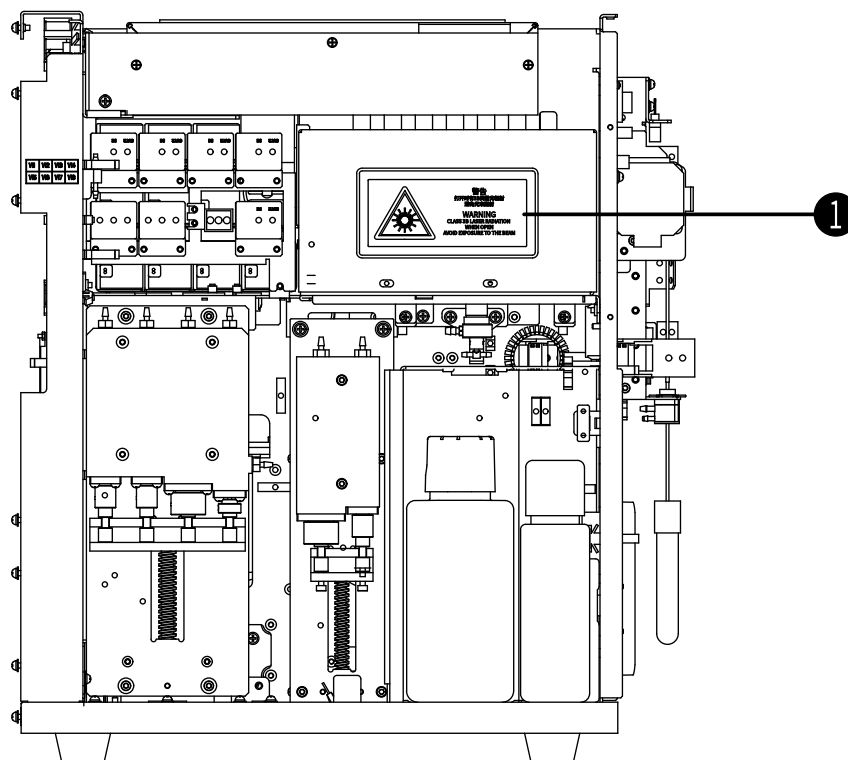


Figure 1-1 Laser label position

No.	Parts
①	Laser label

1.6 Electromagnetic compatibility warning

This Analyzer complies with the electromagnetic emission and immunity requirements specified in IEC 61326-2-6. Pay attention to the followings:

- 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.
- The Analyzer is designed and tested to comply with Group 1, Class A medical device, pursuant to CISPR 11. In the household environment, the Analyzer may pose radio interference on household appliances, therefore protective measures are required.
- The electromagnetic environment should be evaluated prior to operation of the Analyzer. The user should ensure that compatible electromagnetic environment below can be maintained so that the Analyzer will be used as intended.
- The Analyzer cannot be used in the household environment, in this case where radio reception cannot be sufficiently protected.

1.7 Safety precautions

This section mainly describes safety information.



- All items (samples, controls, calibrators, liquid wastes, etc.), as well as areas in contact with these items, have a risk of biological infection. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, masks, etc.) when contacting reagent related items in the laboratory.

-
-
- Do not touch the sample probe. The sample probe is sharp, and the blood samples, controls, and calibrators probably on the sample probe have a risk of biological infection.
 - The operator is obliged to comply with the national and regional regulations on the discharge and disposal of reagents, liquid wastes, waste samples, consumables, etc. They shall be disposed before discharging.
 - Do not directly contact the blood samples.
 - The sample probe is sharp, and the blood samples, controls, and calibrators probably on the sample probe have a risk of biological infection. Therefore, please do not touch the sample probe during it is running down, or it may cause personal injury.
 - The sample probe shall not touch the wall of the test tube in operation to avoid blood splash.

Warning

- All hospitals or institutes that employ this instrument shall prepare a comprehensive maintenance/repair plan, otherwise system failure or personnel injury may arise.
- The reagents can cause irritation to eyes, skin and mucous membranes. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, masks, etc.) when contacting reagent related items in the laboratory.
- Once the reagent touches the skin or eyes, rinse immediately with plenty of water. If necessary, please contact physicians for medical treatment.
- The Analyzer shall be used with a sound ground connection.
- The operator shall use the fuse with specified specifications.
- The input voltage shall meet the Analyzer requirements.
- Do not use the Analyzer in flammable and explosive environment.
- All the parts other than the fuse shall be replaced by manufacturer or the authorized distributor. Otherwise, the user shall assume all the responsibilities.
- The Analyzer complies with the IEC 61010-1; hence repeat any tests described in this standard may damage the Analyzer and undermine the protection already obtained by the Analyzer.

Caution

- The Analyzer damage may occur due to improper maintenance. The operator shall maintain the Analyzer as instructed by the Manual.
- If any problem not mentioned in this Manual is encountered, please contact the After-sales Department of Zytopia for maintenance advices.
- Additional electrical interference and incorrect analysis results may be caused by the use of power strip. Place the Analyzer near the power socket to avoid the use of power strip.
- Use the power cable delivered with the Analyzer. Analyzer damage or incorrect analysis results may be caused by the use of other power cable.
- Please operate the Analyzer under the situation specified in this manual. If the Analyzer is not operated as directed by the Manual, improper operation of the Analyzer, unreliable analysis results, the Analyzer damage, and personal injury may occur.
- Keep your clothes, hair, and hands a certain distance from the movable parts to avoid personal injury.

General

- For the Analyzer' s performance and safety, all maintenance spare parts in the above form shall be purchased from the manufacturer or authorized distributor. Use the parts provided or specified by Zytopia. If any questions, please contact the After-sales Department of Zytopia.

2 Installation

This chapter mainly describes the information related to Analyzer installation, including installation requirements, system connection, print paper installation, and precautions on use.

Please note that the Analyzer has gone through a strict test before delivery. To avoid collision, the Analyzer has been carefully packed before transportation. When in delivery, check the Analyzer package carefully, and confirm whether there is damage. If so, please inform After-sales Department or local distributor of Zytopia immediately.

Note

If the Analyzer is unpacked or installed by the personnel not authorized or trained by Zytopia, personal injury or the Analyzer damage may occur. Do not unpack or install the Analyzer when the authorized personnel of Zytopia are not on site.

2.1 Installation requirements

Only when requirements on installation space, power supply, environment and fuse are met can the installation be performed by the operator.

2.1.1 Installation space requirements

To provide enough space for service and maintenance, heat dissipation of the analyzer, and the liquid tubing not kinked, the installation requirements shall conform to the followings:

- The reserved space between the left & right doors and the wall is no less than 30 cm.
- The reserved space between the rear plate and the wall is no less than 20 cm.
- The surface (or ground) can bear at least 50 Kg.
- Ensure that there is enough space for the operation surface and the lower part of the Analyzer to place diluent, other reagents, and waste container.
- Do not place the device in a position where it is difficult to disconnect the device.

2.1.2 Power supply requirements

This section mainly describes the power supply requirements.

Table 2-1 Power supply requirements

Item	Power supply voltage	Power frequency	Input power	Fuse	Mains power voltage fluctuation
Value	100V-240V~	50/60 Hz	200 VA	T6.3AH250V	10%

Warning

- The Analyzer shall be used with a sound ground connection.
- The operator shall use the fuse with specified specifications.
- The input voltage shall meet the Analyzer requirements.

Caution

- Additional electrical interference and incorrect analysis results may occur due to use of a power strip. Please place the Analyzer near the power socket to avoid use of a plug strip.
 - Use the power cable delivered with the Analyzer. Analyzer damage or incorrect analysis results may occur due to use of other power cables.
-

2.1.3 Environment requirements

This section mainly describes the environment requirements for installation, including:

- The environment shall be with minimum dust, and free from vibration, sources of strong noise, and power interference.
- The electromagnetic environment should be evaluated prior to operation of this Analyzer.
- Use a separate power socket. Do not share a power socket with an air conditioner, refrigerator, and ultrasonic instrument, as they may easily interfere signals.
- Do not place the Analyzer close to sources of strong electromagnetic interference, as these may interfere normal operation of the Analyzer.
- Do not place the Analyzer close to the brush motor, flashing fluorescent lamp, and electrical contact device with frequent switch.
- Avoid exposure to direct sunlight or heat or wind source.
- Well-ventilated.
- Well-grounded connection.
- Indoor use only.

2.1.4 Transportation method

The Analyzer shall be transported and installed by the authorized person of Zytopia. To avoid the sample components damage during transportation, the movable components are fixed with clamp or cable tie in delivery. Therefore, remove the clamp/cable tie before using the Analyzer. Do not transport or install the Analyzer without contacting After-sales Department or local distributor of Zytopia.

Note

If the Analyzer is unpacked or installed by Zytopia or its distributor, personal injury or host damage may occur. Do not unpack or install the host when the authorized personnel of Zytopia are not on site.

2.2 System connection

This section mainly describes the system connection. Ensure the system connection is proper and suitable, and the diluent pipeline and waste liquid pipeline are no more than 1500 mm. Place the waste container and diluent container lower than the Analyzer. Electrical connection and reagent connection are shown as below.



The operator is obliged to comply with the national and regional regulations on the discharge and disposal of reagents, liquid wastes, waste samples, consumables, etc. They shall be disposed of before discharging.

Warning

- The reagents can irritate eyes, skin and mucous membranes. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, masks, etc.) when contacting reagent related items in the laboratory.
 - Once the reagent comes in contact with skin or eyes, rinse immediately with plenty of water. If necessary, please contact a physician for medical treatment.
-

2.2.1 Power supply

This section mainly describes the power supply connection and precautions.

Warning

- The fuse with specified specifications shall be used.
- The Analyzer shall be well grounded.
- The input voltage shall meet the Analyzer requirements.
- The power socket shall be grounded.

Note

- Do not use a power strip. The Analyzer shall be connected to the power socket. As a power strip may result in electronic interference which may cause incorrect analysis results.
 - The power cable shall be provided by the manufacturer. The Analyzer damage and/or incorrect analysis results may occur due to the inadequate rating value of power cable.
-

Follow the steps below to make a power connection:

- (1) Place the Analyzer on a required surface.
 - (2) Connect two ends of the power cable to a power interface (shown as the number ① in the figure below) and a well-grounded power socket. Do not share the power socket with other devices.
 - (3) Start up by pushing the power button.
-

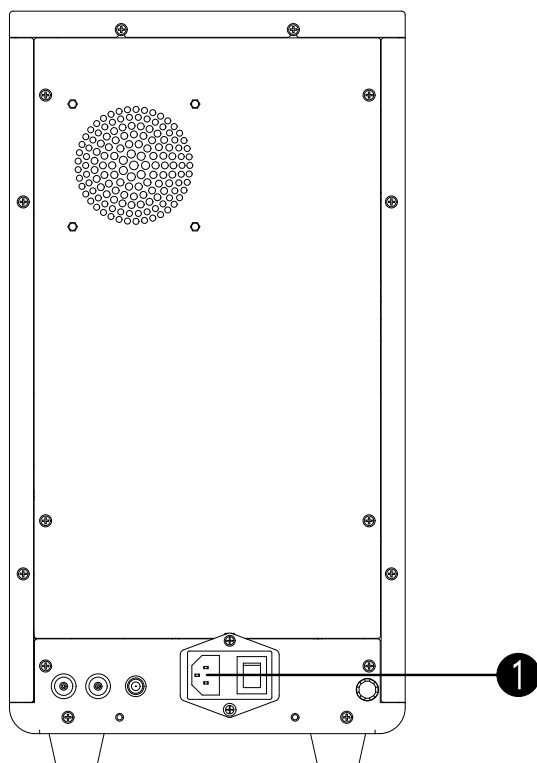


Figure 2-1 Electrical connection

NO.	Parts	Description
①	Power supply socket interface	Used to connect the power supply socket.

2.2.2 Network

Normally, there' s no need to make the network connection. When the instrument needs to be connected to the data system of the hospital, use a standard Ethernet data cable not longer than 3 meters. The IT equipment connected to the network interface shall comply with the IEC 60950-1 or IEC 62368-1.

Connect two ends of the Ethernet cable to the network interface (shown as number ① in the figure below) and external interface or switch.

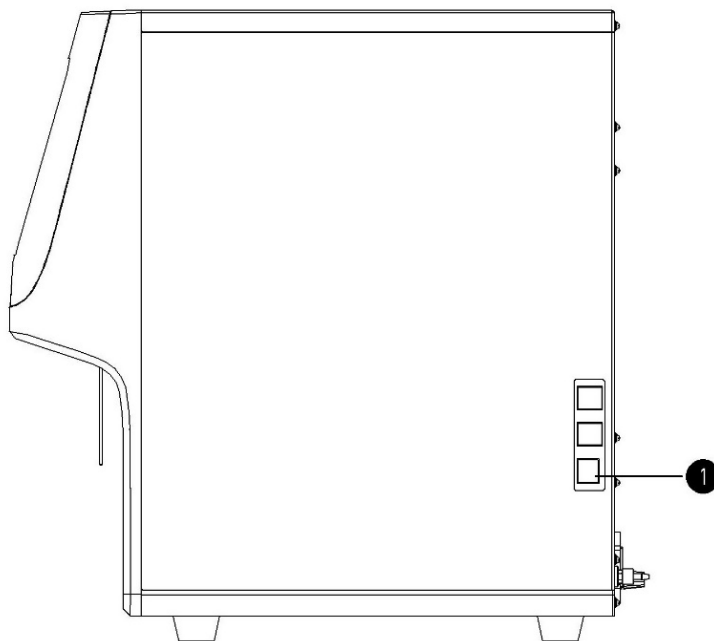


Figure 2-2 Network connection

NO.	Parts	Description
①	Network interface	Used to connect the network.

2.2.3 Data management system

The Data Management System is supporting software used on computers, which can enable users execute sample information input, printing, and other operations on computers. This section mainly describes the procedures to connect the Analyzer and the Data Management System. Note that this system is not a necessity, and users can also operate the Analyzer through the touch screen.

To achieve the data transmission between the Analyzer and the computer where the Data Management System is installed, the following steps should be followed:

(1) Connect the USB interface on the Analyzer and the network interface on the computer by using a standard Ethernet network cable.

(2) Configure the Analyzer as per the following steps:

1) Click “Manage” > “Setup” > “General” > “Communication” , and then set the “Wired IP” .

Note that the IP address in the “Wired IP” of the Analyzer and that of the computer should be in the same network segment. The IP address will only be effective after the Analyzer restarts.

2) Click “Manage” > “Setup” > “General” > “LIS” , and then set the “LIS IP Address” and the “LIS Port” . The wired IP address of the computer should be typed in the “LIS IP Address” box, and the listener port of the Data Management System should be typed in the “LIS Port” .

(3) Configure the Data Management System on the computer as per the following descriptions:

Click “Data Management System” > “Analyzer Setup” , set the IP address as the wired IP address of the analyzer, and then save the change.

Now, the connection between the analyzer and the computer is completed successfully.

2.2.4 External waste liquid pipeline

This section mainly describes the external liquid pipeline connection and precautions.

The steps for external liquid pipeline connection are as follows:

Waste liquid pipeline:

Carefully connect the waste liquid pipeline to the waste liquid outlet (shown as number ② in the figure below) and the liquid waste container, and connect the sensor line to the sensor interface (shown as number ③ in the figure below) and the liquid waste container. The pipeline should be shorter than 1.5 m.

Diluent pipeline:

Carefully connect the diluent pipeline to the diluent outlet and the diluent container. The pipeline should be shorter than 1.5 m.

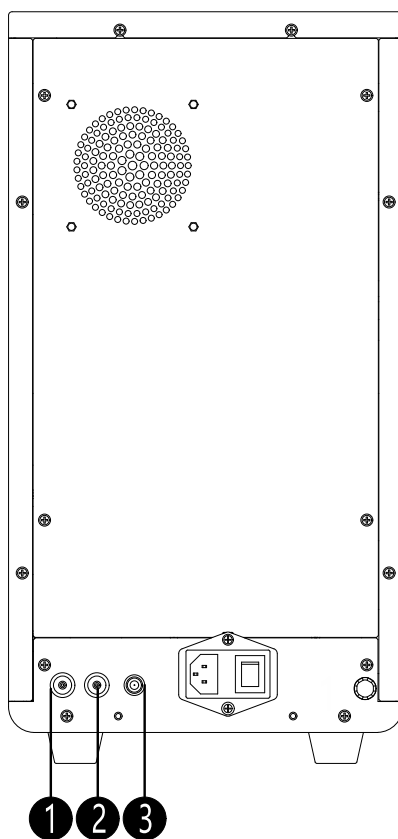


Figure 2-3 External reagent connection

NO.	Parts	Description
①	Diluent entry	Used to input the diluent.
②	Liquid waste port	Used to discharge the liquid waste.
③	Sensor port	Used to connect the signal cable of liquid waste sensor.

2.2.5 Internal liquid pipeline

This section mainly describes the internal liquid pipeline connection and precautions.

Precautions are as below:

- Wear latex gloves when contacting device and reagent bottles.
- Use the stipulated reagents:

- After long-distance transportation, keep the diluent still for more than one day before using it.
- Perform a blank count test after adding reagents, and make a sample analysis when the blank count value is normal.
- Do not shake or vibrate the diluent container, otherwise an incorrect alarm may occur.

Steps for internal liquid pipeline connection are as follows:

- (1) Open the reagent door, take out the reagent (shown as number ① and number ② in figure below).
- (2) Open the reagent bottle, insert the reagent pipeline into the new reagent bottle, then place into the reagent cabin.

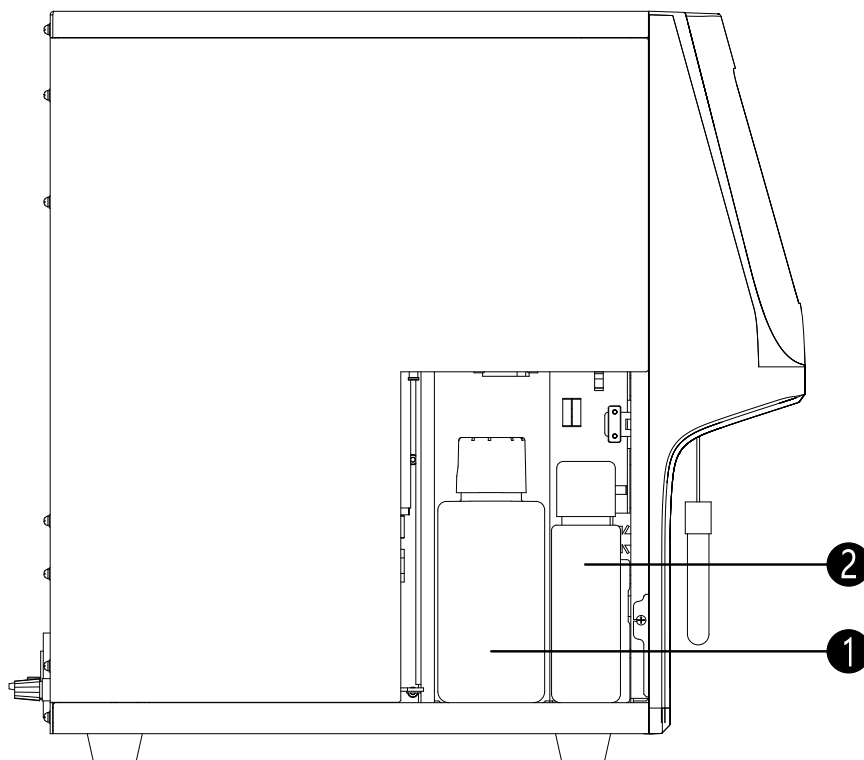


Figure 2-4 Internal reagent connection

NO.	Parts	Description
①	V - LD lyse	Used to dissolve the red blood cells and classify the white blood cells.
②	V - LB lyse	Used to dissolve the red blood cells, count and classify the white blood cells, and measure the hemoglobin.

2.3 Printer paper installation

This section mainly describes the information related to printer paper installation (only applicable to Z52 VET).

Precautions are as below:

- Before installing the printer paper for the first time, please remove the protection paper in the thermal printer.
- The printer paper shall be a good-quality 57 x 50 thermal paper, otherwise printing failure, poor printing quality or printing head damage may occur.

Installation

- Do not pull the printer paper by force during its operation, or thermal printer may be damaged.
- Do not open the thermal printer, except for paper change or troubleshooting.
- Incorrect installation of printer paper may cause paper jam or no printing result.

Printer paper installation shall observe the following steps:

- (1) Open thermal printer door outwards.
- (2) Place the printer paper into the paper cavity with the paper head outside the paper outlet in the direction shown as the figure below.
- (3) Close thermal printer door.
- (4) Check the printer paper location, and ensure printer paper is aligned with the paper outlet.

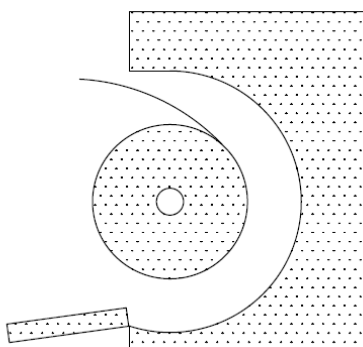


Figure 2-5 Printer paper installation

2.4 Precautions on use

This section mainly describes the precautions on use of the Analyzer, see details as below:

- Use the specified reagent by Zytobia. Otherwise, unreliable test result and the Analyzer damage may occur.
- Do not use the expired reagent. Unreliable test results may occur due to use of the expired reagent.
- To avoid reagent contamination, cap the reagent bottle after the reagent has been connected to the Analyzer.
- If the Analyzer is placed in a dusty environment for a long time, the performance decrease may occur.
- Wipe the Analyzer surface with a cloth soaked in 75% ethanol or water, or clean its surface in accordance with Technical Specification for Disinfection of Medical Institutions WS/T 367-2012.
- Collect blood and prepare sample in a specified manner, otherwise safety risk or unreliable results may occur.
- If any aging or wearing is found in any tube or parts during use, please stop using the Analyzer and immediately contact the After-sales Department for maintenance or replacement.
- Please note that the connecting pipeline of reagent (including diluent, hemolysis reagent and liquid waste) shall not be pressed or kinked by heavy objects during use.

3 Analyzer introduction

This chapter introduces the structure, parameters and performance, specification and configuration of the Analyzer, the software interface, and the reagents equipped with the Analyzer. Please note that as there may be differences among different types of product and different versions of software, the illustrations may be inconsistent with what you see on the actual product.

3.1 Structure

This section describes the front, side and back views and the main parts of the analyzer through illustrations and tables.

3.1.1 Front view

This section introduces the structures and relevant important parts of the front of the Analyzer. Shown as below:

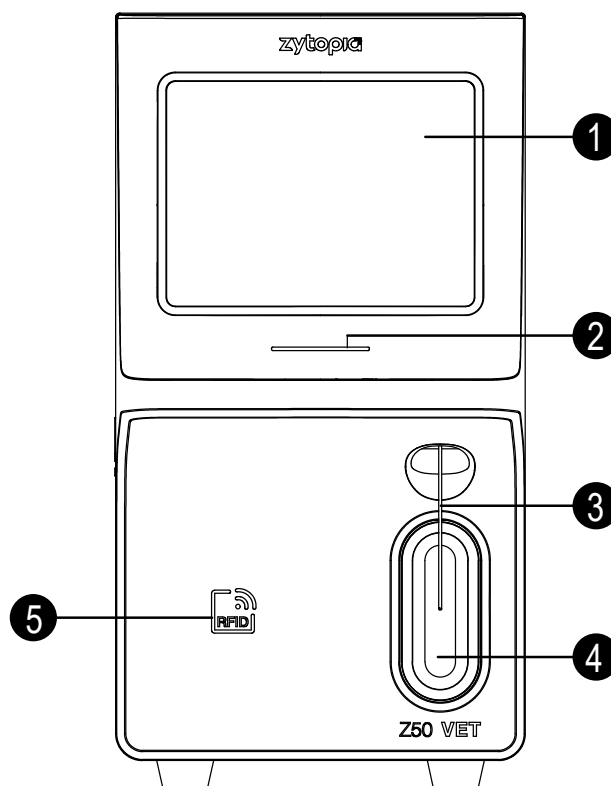


Figure 3-1 Z50 VET Front view

No.	Parts	Description
①	Touch screen	8.4-Inch color TFT touch screen, located in the front of the Analyzer, used for interface operations
②	Indicator	Indicates the current status of the analyzer, providing red, yellow, and green indications

Analyzer introduction

No.	Parts	Description
		<ul style="list-style-type: none"> • Green: normal running • Yellow: standby • Red: fault
③	Sample probe	Used to aspirate samples
④	Aspirate key	Located behind the sample probe, used to start counting, add diluent, or aspirate the maintenance reagent <ul style="list-style-type: none"> • Sleep state: quit sleep • Working state: the sample probe aspirates the sample after the key is pressed
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

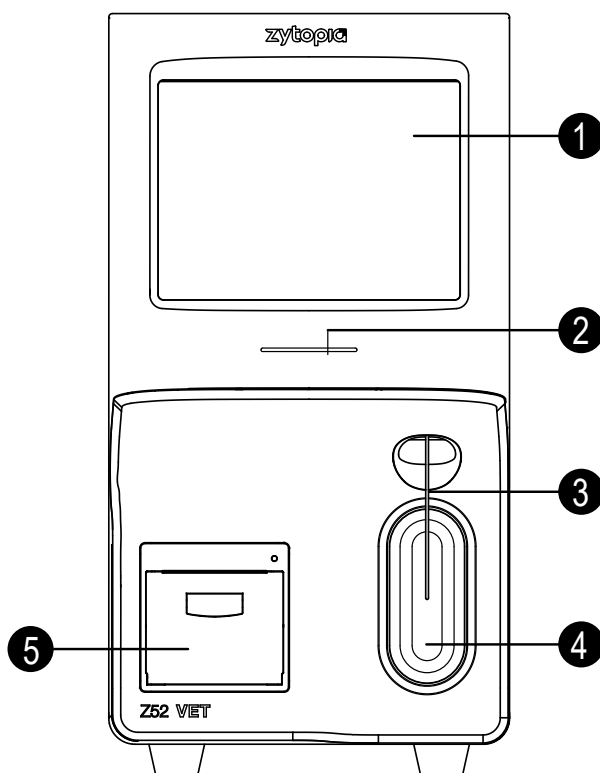


Figure 3-2 Z52 VET Front view

No.	Parts	Description
①	Touch screen	8.4-Inch color TFT touch screen, located in the front of the Analyzer, used for interface operations
②	Indicator	Indicates the current status of the analyzer, providing red, yellow, and green indications <ul style="list-style-type: none"> • Green: normal running • Yellow: standby • Red: fault
③	Sample probe	Used to aspirate samples

No.	Parts	Description
④	Aspirate key	Located behind the sample probe, used to start counting, add diluent, or aspirate the maintenance reagent <ul style="list-style-type: none"> • Sleep state: quit sleep • Working state: the sample probe aspirates the sample after the key is pressed
⑤	Built-in thermal printer	Prints the analysis results on paper.

3.1.2 Left view

This section introduces the structures and relevant important parts at the left side of the analyzer. Shown as below:

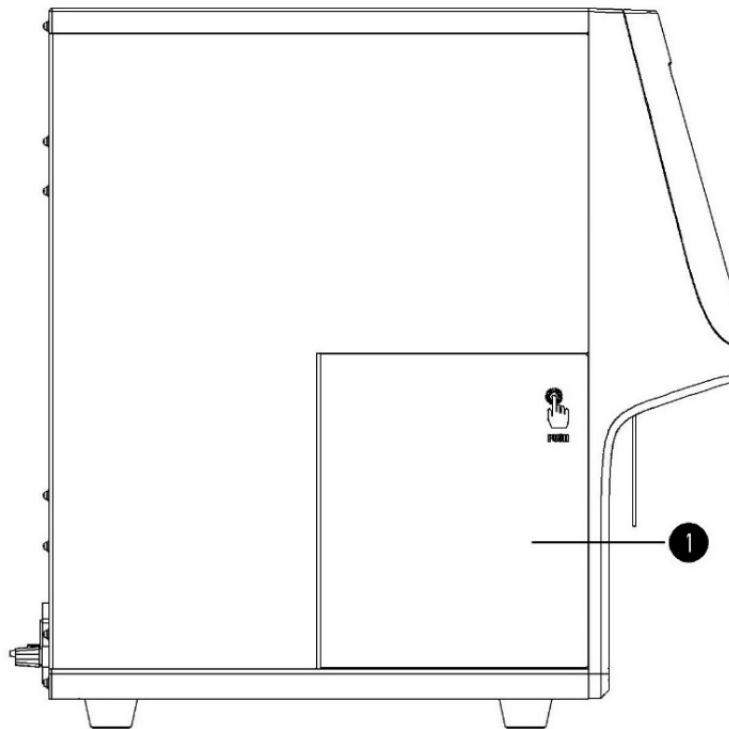


Figure 3-3 Left view

No.	Parts	Description
①	Reagent door	Open the door to place or take out the reagent

3.1.3 Right view

This section introduces the structures and relevant important parts at the right side of the analyzer. Shown as below:

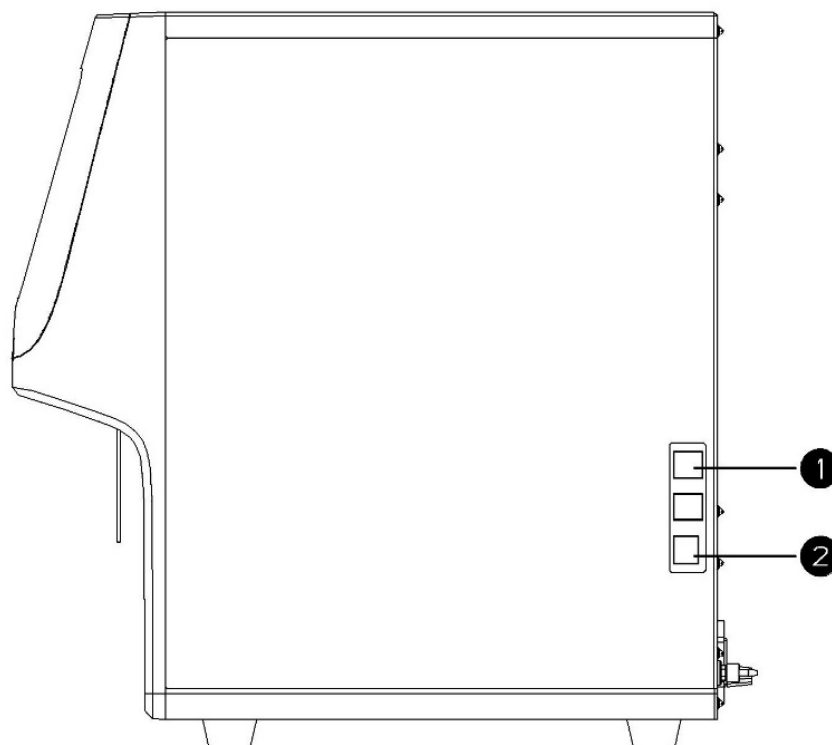


Figure 3-4 Right view

No.	Parts	Description
①	USB port	<ul style="list-style-type: none">4 USB ports Connected with the mouse, the keyboard, and the USB drive in case of debugging, maintenance and upgrading of system
②	Network interface	<ul style="list-style-type: none">1 network port Connected with a computer for data transmission

3.1.4 Back view

This section introduces the structures and important parts at the back of the analyzer.

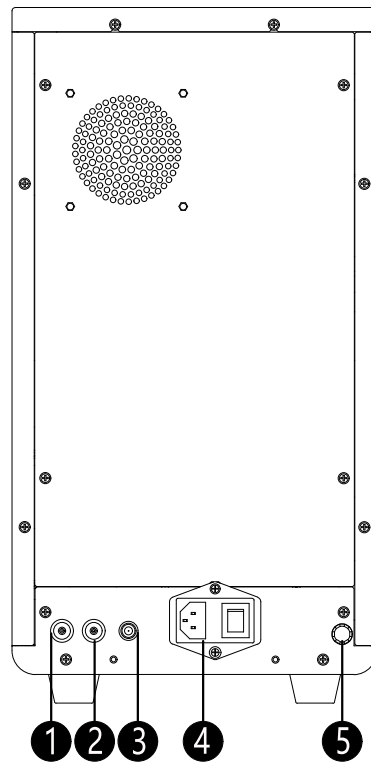


Figure 3-5 Back view

No.	Parts	Description
①	Diluent port	Diluent flows in through the port
②	Liquid waste port	Liquid waste flows out through the port
③	Liquid waste sensor	Monitors the liquid waste
④	Power source assembly	Power supply port and anti-shock device, etc.
⑤	Grounding pole	Used for grounding

3.2 Parameters and performance

This section introduces the testing parameters including blank count, carryover rate, test result deviation, linear parameters, precision, and accuracy.

3.2.1 Blank count

This section introduces the requirements for blank count. Please refer to the table below reference.

Table 3-1 Blank count requirements

Parameters	Requirements	Parameters	Requirements
WBC	$\leq 0.2 \times 10^9/L$	HCT	$\leq 0.5\%$
RBC	$\leq 0.02 \times 10^{12}/L$	PLT	$\leq 5 \times 10^9/L$
HGB	$\leq 1 \text{ g/L}$		

3.2.2 Carryover rate

This section introduces the carryover rate of the Analyzer. Please refer to the table below for reference.

Table 3-2 Carryover rate

Parameters	Carryover rate	Parameters	Carryover rate
WBC	≤ 0.5%	HCT	≤ 0.5%
RBC	≤ 0.5%	PLT	≤ 1.0%
HGB	≤ 0.5%		

3.2.3 Test result deviation

This section introduces the test result deviation of the Analyzer. Please refer to the table below for reference.

Table 3-3 Test result deviation

Parameters	Test result deviation	Parameters	Test result deviation
WBC	±10%	HGB	±7%
RBC	±6%	PLT	±15%

3.2.4 Linear parameters

This section mainly introduces the linear parameters of the Analyzer. Please refer to the table below for reference.

Table 3-4 Linear parameters

Parameters	Linearity range	Linearity deviation	Correlation coefficient
WBC	$0.00 \times 10^9/L - 100.00 \times 10^9/L$	$\leq \pm 0.50 \times 10^9/L$ or $\pm 5\%$	≥ 0.990
	$100.01 \times 10^9/L - 500.00 \times 10^9/L$	$\leq \pm 10\%$	
RBC	$0.00 \times 10^{12}/L - 17.00 \times 10^{12}/L$	$\leq \pm 0.05 \times 10^{12}/L$ or $\pm 5\%$	≥ 0.990
HGB	0 g/L - 250g/L	$\leq \pm 2g/L$ or $\pm 2\%$	≥ 0.990
PLT	$0 \times 10^9/L - 1000 \times 10^9/L$	$\leq \pm 10 \times 10^9/L$ or $\pm 8\%$	≥ 0.990
	$1001 \times 10^9/L - 5000 \times 10^9/L$	No more than $\pm 12\%$	
HCT	0% - 67%	$\leq \pm 2\%$ (HCT) or $\pm 3\%$ (deviation ratio)	≥ 0.990

3.2.5 Precision

This section mainly describes the precision of the Analyzer. The precision is obtained by measuring the required blood samples 10 times successively on the Analyzer. Please refer to the table below for reference.

Table 3-5 Precision

Parameters	Test scope	(CV/absolute deviation, d)
WBC	$3.5 \times 10^9/L - 15.0 \times 10^9/L$	$\leq 3.0\%$
Neu%	50.0% - 70.0%	± 4.0 (d)
Lym%	20.0% - 40.0%	± 3.0 (d)
Mon%	5.0% - 10.0%	± 2.0 (d)
Eos%	2.0% - 5.0%	± 1.5 (d)
Bas%	0.5% - 1.5%	± 0.8 (d)
RBC	$3.50 \times 10^{12}/L - 6.00 \times 10^{12}/L$	$\leq 2.0\%$
HGB	110 g/L - 180 g/L	$\leq 2.0\%$
MCV	70 fL - 120 fL	$\leq 1.0\%$
PLT	$100 \times 10^9/L - 500 \times 10^9/L$	$\leq 6.0\%$
MPV	/	$\leq 4.0\%$

3.2.6 Accuracy

This section mainly introduces the accuracy of the Analyzer. Please refer to the table below:

Table 3-6 Accuracy

Parameters	Test scope	Permissible relative deviation range / %
WBC	$3.5 \times 10^9/L - 9.5 \times 10^9/L$	$\leq \pm 15\%$
RBC	$3.8 \times 10^{12}/L - 5.8 \times 10^{12}/L$	No more than $\pm 6\%$
HGB	115 g/L - 175 g/L	No more than $\pm 6\%$
HCT or MCV	35% - 50% (HCT) or 82fL - 100 fL (MCV)	$\leq \pm 9.0\%$ (HCT) or $\pm 7.0\%$ (MCV)
PLT	$125 \times 10^9/L - 350 \times 10^9/L$	No more than $\pm 20\%$

3.3 Specifications and configuration

This section introduces the specification and configuration of the environmental requirements for and the electromagnetic compatibility of the Analyzer.

Specification and configuration

Please refer to the table below for reference.

Table 3-7 Specification and configuration

Item	Description	Remarks
Dimensions	<ul style="list-style-type: none"> • Width: 230 mm • Height: 435 mm (mat included) • Depth: 455 mm 	

Analyzer introduction

Item	Description	Remarks
Weight	≤ 29 kg	
Output / input device	<ul style="list-style-type: none"> • Touch screen • Indicator light • Buzzer • Thermal printer (only for Z52 VET) • RFID reader 	The buzzer alerts analyzer faults. The buzzer alert stops automatically after a click on the screen or the fault is eliminated.
Host ports	<ul style="list-style-type: none"> • LAN port: 1 port, built-in network adapter, networking, compatible with TCP/IP protocol • USB port: 4 ports 	
Power supply	<ul style="list-style-type: none"> • Voltage: 100V-240V~ • Input power: 200 VA • Frequency: 50/60 Hz 	
Fuse	T6.3AH250V	
Sound pressure	<ul style="list-style-type: none"> • Standby: no more than 60 dB • Operating: no more than 65 dB 	
Classification of laser product	Class I	According to IEC 60825-1:2014
Overvoltage category	Class II	
Pollution degree	2	
Hardware configuration	<ul style="list-style-type: none"> • Processor: ARM A8 (the lowest) • Memory: 256M RAM (the lowest) 	
Software operating environment:	Linux 3.0.35	
Network requirements	<ul style="list-style-type: none"> • Network architecture: CS • Network type: LAN • Bandwidth: no requirement 	
Security software	No	
Data and device (system) port	<ul style="list-style-type: none"> • Connect to the LIS through the network port to transmit the data in one-way communication. • Transmission protocol: TCP/IP 	
User access control	The software authenticates the user identity (system administrator, ordinary user, or maintenance personnel) and initiates the corresponding access control mechanism through the user name and login password.	

Item	Description	Remarks
Requirements for updating software environment and security software:	None.	

Environmental specifications

For environmental specifications, refer to the table below:

Table 3-8 Environmental requirements

Item	Ambient temperature	Relative humidity (no condensation)	Atmospheric pressure	Altitude
Working environment ¹	10°C - 30°C	20% - 85%	70 kPa - 106 kPa	≤ 3000 m
Operating environment ²	10°C - 40°C	10% - 90%	70 kPa - 106 kPa	≤ 3000 m
Storage environment	-10°C - 40°C	10% - 90%	50 kPa - 106 kPa	/
Transportation environment	-10°C - 40°C	10% - 90%	50 kPa - 106 kPa	/

Note:

- Working environment refers to the environment which ensures normal working of the Analyzer and normal result output.
- Operating environment refers to the environment which ensures normal working of the Analyzer but cannot ensure the accuracy of the test result.

Store and operate the Analyzer in the environment specified. If the room temperature exceeds the normal operating temperature of the Analyzer, an incorrect analysis result may occur.

Warning

Do not use the Analyzer in flammable and explosive environment.

3.4 Software interface

This section mainly describes the software interface.

As shown in the picture below, the software interface mainly consists of the following 4 parts:

- Function area, including “Sample analysis”, “Sample review”, “QC”, “Reagent”, and “Manage”.
- Frequently used function buttons, including “Add diluent” and the shutdown button.
- In status area there is a printing button.
- The green area at the bottom of the interface is the display area of service functions, and the black area includes the fault information bar (hidden when there is no fault) and the system status area.



Figure 3-6 Software interface

3.5 Reagents, controls and calibrators

Reagents, controls, and calibrators are an indispensable part of the Analyzer. Only when these reagents, controls and calibrators are correctly used can the Analyzer work normally and the test results be accurate. This section introduces the details of reagents, controls, and calibrators.

3.5.1 Reagent

This section introduces the reagents used by the Analyzer.

Table 3-9 Reagents

Reagent name	Package specifications	Description
Diluent for analysis of animal blood Cells	V-5DN 10 L×1	The diluent, isotonic with a specific electrical conductivity, dilutes the blood sample and provides a stable environment for blood cell counts.
A lyse for blood cell analysis	V - LD 280 ml × 1, 280 ml × 4 480 ml × 1, 480 ml × 4	Used to dissolve the red blood cells and classify the white blood cells.
	V-LB 60 ml × 1, 60 ml × 4 100 ml × 1, 100 ml × 4	Used to dissolve the red blood cells, count and classify the white blood cells, and measure the hemoglobin.
Probe cleanser for animal blood analysis	25 ml × 2, 50 ml × 2	Used for periodic cleaning of the Analyzer.

Precautions on use are as follows:

- Examine the package of reagents and make sure that there is no signs of damp or leakage before using the reagents.
- Damage to packaging may affect the quality of the reagent. If the package is broken, do not use the reagent.
- For use and storage of the reagent, please refer to the instructions for use for the reagent.
- Use the reagent that is within its shelf life.
- After replacing the diluent and the lyse, the operator should conduct background test and ensure that the blank test value is within the normal range ready for sample analysis.
- Before using the reagent, place it for a period to make it stable.

Note

The operator must use the reagents produced by Zytobia, otherwise the Analyzer may be damaged and cannot achieve the desired performance described in this IFU. Zytobia shall not assume any responsibility for the neglect of this by operators.

3.5.2 Controls and calibrators

Controls and calibrators are used to control the test quality and calibrate the test results respectively.

The controls serve to control the parameters of WBC, RBC, HGB, MCV/HCT, and PLT, etc. and thus control and evaluate the precision of the test results. There are low, medium, and high values of quality control materials. Running the quality control procedure everyday can monitor the operating status of the Analyzer to ensure the reliability of the analysis results.

The calibrator serves to calibrate the parameters of WBC, RBC, HGB, MCV/HCT, etc. and thus to set up the metrological traceability of the test results.

For details about controls and calibrators, refer to the table below:

Table 3-10 Controls and calibrators

Item	Controls		Calibrators
Product name	Controls for Hematology Analyzer		Calibrators for Hematology Analyzer
Model	V-5D		V-CAL
Package specifications	High value, medium value, low value	3 mL×1 3 mL×6	3 mL×1; 3 mL×2; 3 mL×3; 3 mL×4; 3 mL×5; 3 mL×6
	High, medium, and low kits	3 level ×1 pcs ×3 mL 3 level ×2 pcs ×3 mL	
Use and storage	Refer to the Instructions for Use for controls.		Refer to the Instructions for Use for calibrators.

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. This chapter explains the operation principles of the Analyzer.

4.1 Sampling

The operator directly places the whole blood sample into the Analyzer for sampling, then the Analyzer absorbs a certain amount of whole blood sample.

4.2 Sample dilution

Various cells can be overlapped in the samples to be tested generally. The Analyzer cannot accurately count the blood cells or detects the cell distribution. Therefore, before Analyzer counting or detecting the cell distribution, the sample should be diluted.

WB is employed to count and classify the white blood cells.

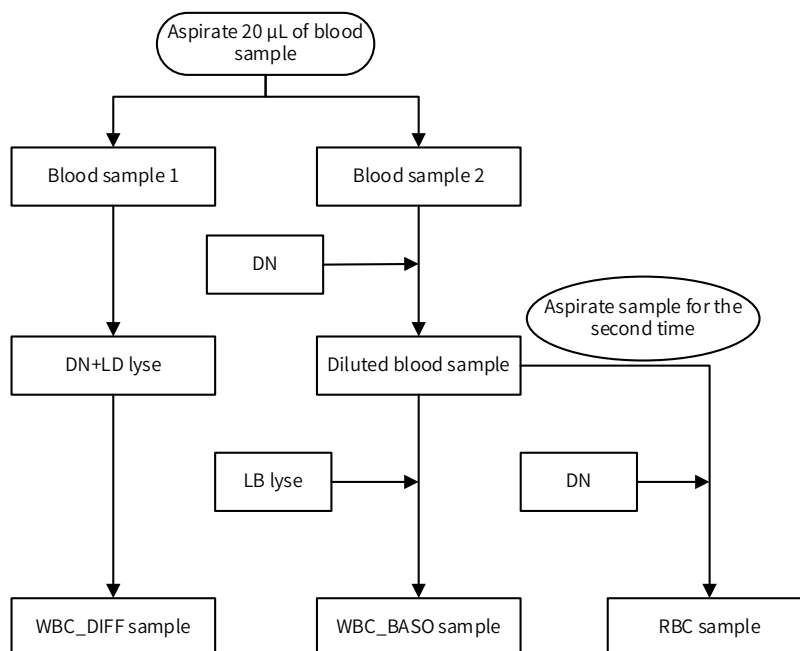


Figure 4-1 CBC+DIFF whole blood mode dilution process

As shown in Figure 4-1, the 20 µL of CBC+DIFF blood sample will be divided into two portions, with one portion of the sample mixed with DN diluent and LD lyse together to obtain a DIFF sample and start the testing. While WBC_DIFF sample testing process is operating, the WBC chamber will be cleaned. The other portion of the blood sample will be mixed with DN diluent to prepare a diluted blood sample. The diluted sample will then be divided into two portions, with one portion of it mixed again with LB lyse to prepare BASO/HGB sample, and the other portion mixed again with DN diluent to prepare RBC sample. The BASO/HGB counting and RBC/PLT counting will be done at the same time.

4.3 Detection of white blood cells

This section explains the principle of detecting white blood cells and related parameters.

4.3.1 Detection principle

Counting and white blood cells differential are realized by means of laser flow cytometry.

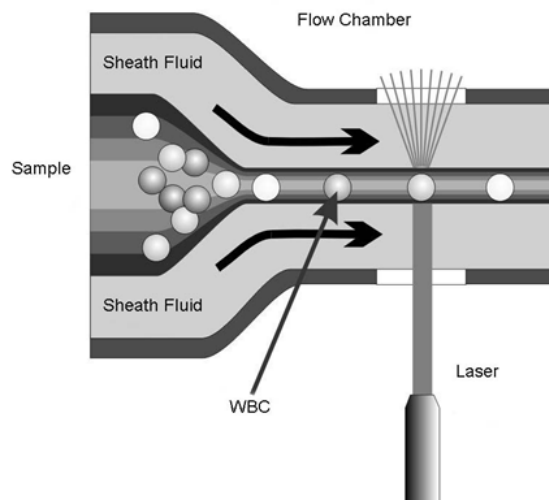


Figure 4-2 Counting principle

After the blood sample is mixed with a lyse, the red blood cells will be lysed while the white blood cells be 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 structure. The results of five-part WBC differential and counting are obtained through WBC scatter plots and histogram.

4.3.2 WBC parameters

WBC parameters are calculated by the formula below (measured in $10^9/L$).

- WBC count

$$\text{WBC} = \text{total particles except the blood shadow region in the BASO channel}$$

- Lymphocyte percentage

$$\text{Lym}\% = \text{LymNum}/\text{AllNum} \times 100\%$$

Where Lym represents Lymphocyte, LymNum represents the total number of particles in the Lymphatic region of the Diff channel, and AllNum represents the total number of all particles except the blood shadow region in the Diff channel.

- Monocyte percentage

$$\text{Mon}\% = \text{MonNum}/\text{AllNum} \times 100\%$$

Where Mon represents monocyte, MonNum represents the total number of particles in the monocyte region of the Diff channel, and AllNum represents the total number of all particles except the blood shadow region in the Diff channel.

- Neutrophil percentage

$$\text{Neu\%} = \text{NeuNum}/\text{AllNum} \times 100\%$$

Where Neu represents Neutrophil, NeuNum represents the total number of particles in the Neutrophil region of the Diff channel, and AllNum represents the total number of all particles except the blood shadow region in the Diff channel.

- Eosinophilia percentage

$$\text{Eos\%} = \text{EosNum}/\text{AllNum} \times 100\%$$

Where Eos represents Eosinophils, EosNum represents the total number of particles in the Eosinophilia region of the Diff channel, and AllNum represents the total number of all particles except the blood shadow region in the Diff channel.

- Basophil percentage

$$\text{Bas\%} = \text{Bas\#}/\text{WBC} \times 100\%$$

- Number of basophils

Bas# = the number of particles in the Bas region of the BASO channel

- Lymphocyte count

$$\text{Lym\#} = \text{WBC} \times \text{Lym\%}$$

- Monocyte count

$$\text{Mon\#} = \text{WBC} \times \text{Mon\%}$$

- Neutrophil count

$$\text{Neu\#} = \text{WBC} \times \text{Neu\%}$$

- Eosinophils count

$$\text{Eos\#} = \text{WBC} \times \text{Eos\%}$$

4.4 Detection of HGB concentration

This section introduces the principle of detecting HGB concentration and related parameters.

4.4.1 Detection principle

The Analyzer detects the HGB concentration by means of colorimetry. In the WBC counting chamber, the diluted sample is mixed with lyse, which dissolves the red blood cell membrane to release the hemoglobin. The hemoglobin is combined with the lyse to generate hemoglobin compound. At one side of the WBC 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 white blood cell counting pool. 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 detection and calculation shall be completed by the Analyzer, and the results shall be displayed on the analysis result area of the "Counting" interface.

4.4.2 HGB concentration parameters

The magnified voltage signals are compared with the detected voltage of background light intensity thus to obtain the HGB concentration measured in g/L.

$$\text{HGB} = \text{constant} \times \text{Log}_{10} \left(\frac{\text{background light intensity}}{\text{sample light intensity}} \right)$$

4.5 Detection of red blood cells / platelets

This section explains the principle of detecting red blood cells or platelets.

4.5.1 Detection principle

The Analyzer counts the red blood cells or platelets by means of impedance technology. The quantitative sample diluted by the quantitative conductive solution is transferred to the detection unit of the Analyzer. The detection unit has an aperture, called detection aperture. The aperture has a pair of positive and negative electrodes connected to a constant current power supply. As the cells are poorly conductive, the direct current impedance between the poles will change and result in the pulse change at the two poles in proportion to the cell size when the cells pass through the aperture under a constant negative pressure. As cells successively pass through the aperture, a series of electric pulses will be generated at the two poles. The number of pulses is the same with the number cells passing through the aperture, and the amplitude of the pulses is in proportion to the cell size.

The electric pulses are magnified and then compared with the threshold voltage of the channel corresponding to the normal red blood cell / platelet size range to obtain the number of pulses corresponding to the electric amplitude in the channel. All the electric pulses acquired are classified according to different channel voltage thresholds, and the number of pulses fall in the red blood cell / platelet channel are the number of red blood cells / platelets. The number of cells in the channel divided according to the pulse voltage range determines the cell volume distribution.

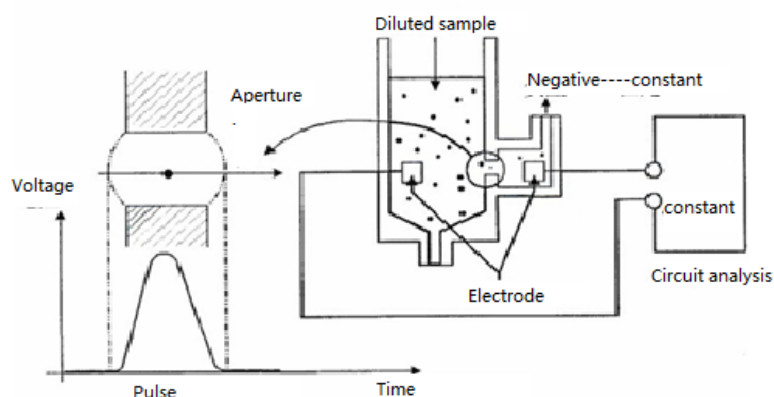


Figure 4-3 Principle of blood cell counting

4.5.2 Red blood cell parameters

This section introduces the parameters related with the red blood cells, including the red blood cell count, the mean red blood cell volume, the hematocrit (HCT), the mean HGB content of red blood cells (MCH), the mean HGB concentration of red blood cells (MCHC), the variation coefficient of red blood cell distribution width (RDW-CV), the standard deviation of red blood cell distribution width (RDW-SD), and the red blood cell distribution histogram.

- **Red blood cell count**

The Analyzer detects directly the number of electric pulses corresponding to the red blood cells and obtains the red blood cell count measured in $10^{12}/L$.

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

- **Mean red blood cell volume**

According to the red blood cell distribution histogram, the Analyzer calculates the mean red blood cell volume (MCV) measured in fL.

- **HCT, MCH, and MCHC**

The HCT measured in %, MCH measured in pg, and MCHC measured in g/L are calculated through the following equations respectively.

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

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

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

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

- **RDW-CV**

RDW-CV is obtained from the red blood cell distribution histogram. The percentage denotes the volume distribution variation coefficient.

- **RDW-SD**

RDW-SD measured in fL refers to the width of the histogram at the peak value of 20% of the red blood cell distribution histogram, as shown in “Figure 4-4 Illustration “.

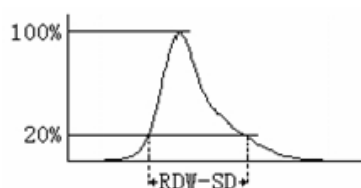


Figure 4-4 Illustration

- **Red blood cell distribution histogram**

The Analyzer provides both the red blood cell count and a red blood cell volume distribution plot, which indicates the distribution of red blood cells. The abscissa denotes the red blood cell volume (measured in fL), and the ordinate denotes the relative red blood cell count (measured in $10^{12}/\text{L}$). Every time after counting, the red blood cell distribution histogram can be reviewed in the analysis result area of the “Sample analysis” interface or in the “Result review” interface.

4.5.3 Platelet parameters

This section introduces the parameters related to the platelet, including the platelet count (PLT), the mean platelet volume (MPV), the platelet distribution width (PDW), the thrombocytocrit (PCT), the platelet-large cell ratio (P-LCR), the platelet-large cell count (P-LCC), and the platelet distribution histogram.

- **PLT**

The Analyzer detects directly the number of electric pulses corresponding to the platelets and obtains the platelet count measured in $10^9/\text{L}$.

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

- **MPV**

According to the platelet distribution histogram, the Analyzer calculates the mean platelet volume measured in fL.

- **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.

- **PCT**

Operation principles

The Analyzer calculates the plateletcrit (PCT) measured in % through the following equation. PLT measured in $10^9/L$, MPV measured in fL.

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

- **P-LCR**

According to the platelet distribution histogram, the Analyzer calculates the P-LCR measured in %.

- **P-LCC**

According to the P-LCR and the PLT, the Analyzer calculates the P-LCC measured in $10^9/L$.

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

- **Platelet distribution histogram**

The Analyzer provides both the platelet count and platelet volume distribution plot, which indicates the distribution of platelets. The abscissa denotes the platelet volume (measured in fL), and the ordinate denotes the relative platelet count (measured in $10^9/L$). Every time after counting, the platelet distribution histogram can be reviewed in the analysis result area of the “Sample analysis” interface or in the “Result review” interface.

4.6 Rinsing

The Analyzer shall automatically rinse the parts which the sample passes through to ensure that there is no residual sample in the fluid path.

5 Daily operation

This chapter introduces the entire daily operation process from the Analyzer startup to shutdown, and explains the operation process of sample analysis in details.

Warning

All hospitals or institutes that employ this instrument shall prepare a comprehensive maintenance/repair plan, otherwise system failure or personnel injury may arise.

Caution

Please operate the Analyzer under the conditions specified in this Manual. If the Analyzer is not operated in the specified conditions, it may not work properly, the analysis results may be unreliable, and damage to Analyzer components and personal injury may be caused.

Note

This Analyzer shall only be used by clinical laboratory professionals, medical doctors, and laboratory technicians trained by Zytobia or its distributors.

Daily operation process is as below:

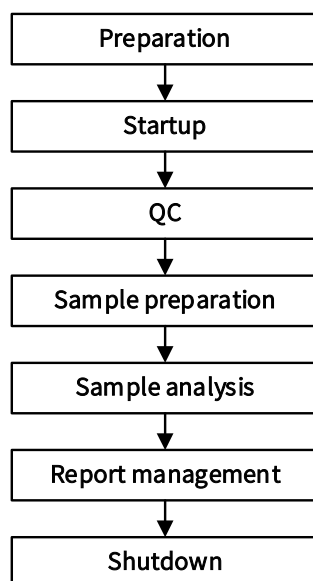


Figure 5-1 Daily operation process

5.1 Preparations before operation

The operator shall perform inspection according to the following requirements before

Daily operation

powering on the main unit.



- All items (samples, controls, calibrators, reagents, liquid wastes, etc.), as well as areas in contact with these items, have a risk of biological infection. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, etc.) when contacting relevant items and areas in the laboratory.
- The operator is obliged to comply with the national and regional regulations on the discharge and disposal of reagents, liquid wastes, waste samples, consumables, etc. They shall be disposed of before discharging.

Warning

- The reagents can irritate eyes, skin and mucous membranes. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, etc.) when contacting reagents or relevant items in the laboratory.
- Once the reagent contacts your skin or eyes, rinse immediately with plenty of water. If necessary, please contact a physician for medical treatment.

Caution

Please keep your clothes, hair, and hands away from the moving parts to avoid personal injury.

Note

- The operator shall use the reagents designated by Zytopia, and store and use them strictly following the instructions for use of the reagents.
- Please make sure the reagents are properly connected before operating the Analyzer.
- Keep the reagents rest for a period to be stable before using them.

The inspection is performed as following steps:

- Check the waste tank
The waste container is prepared by the operator, and it shall be emptied every time before starting up the Analyzer.
- Check the fluid path and the power supply
Check the connections of the reagent and fluid path to see whether they are straight or reliable.
- Check the power plug of the main unit to make sure it is safely connected.
- Check the thermal printer (for Z52 VET) and external printer.
Check the thermal printer or external printer to make sure the printing paper is sufficient and properly placed.

5.2 Start up and login

This section mainly describes the startup and login process of the Analyzer.

Start up:

- (1) Set the power switch on the back of the Analyzer to “I” state, and the power indicator is on.
- (2) Check if the main unit indicator is on.
- (3) Enter the user name and password of the current user in the login box.

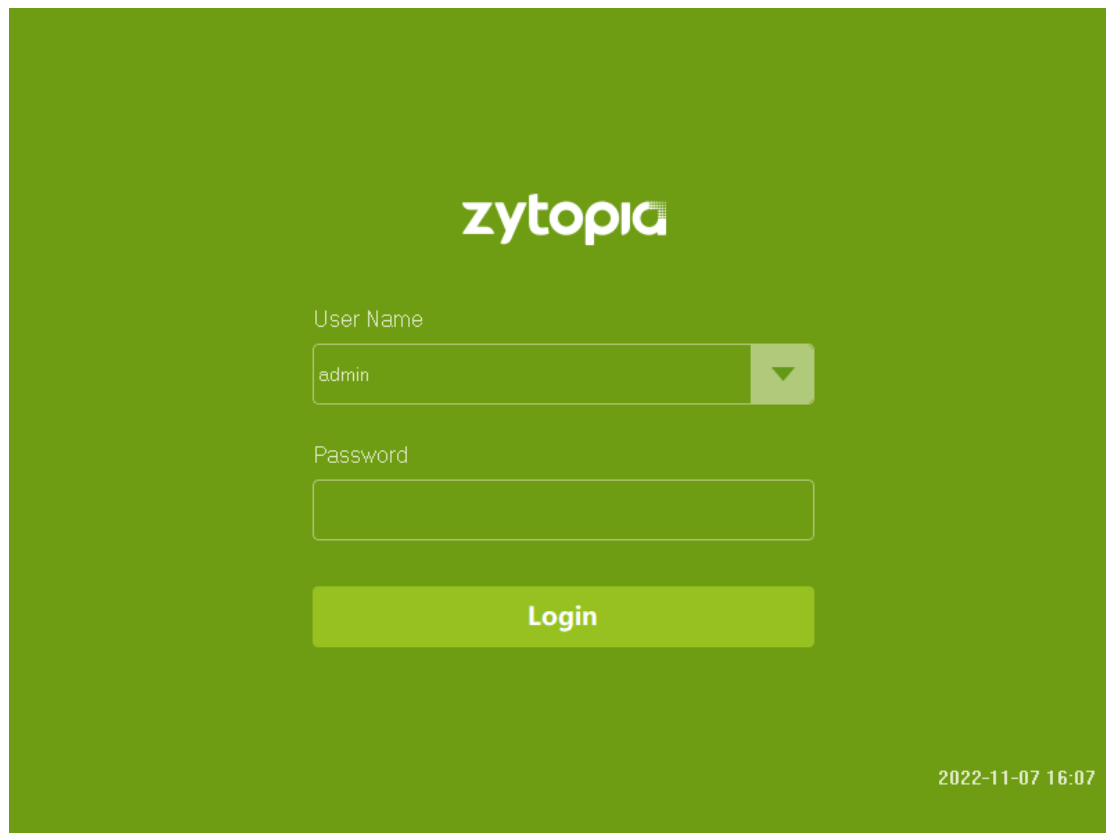


Figure 5-2 Login

- (4) The Analyzer executes self-check and initialization in sequence. The time required for fluidics initialization varies according to the previous shutdown process.
- (5) After the Analyzer starts up, it will automatically enter the “Analysis” interface, as shown in the figure below.



Figure 5-3 Analysis

Note

Do not carry out the analysis process if there is a “Background Abnormal” failure, or the results will be unreliable. Please see “10.1 Error information and error handling” for details.

The administrator and the normal user have different user names and passwords. The system will identify the user type according to the user name and password used at the time of login, and enable different functions in each interface.

To switch users, click “Logout” in “Manage”, enter the user name and password of the new user in the login interface, and click “Login” to log in as a new user.

The initial administrator user name and password default to “admin”.

Please make sure the Analyzer displays the current date and time after it starts up.

If you fail to run the software after several attempts, please contact our after-sales service department or the agent.

5.3 Daily quality control

Before analyzing the samples, please perform daily quality control analysis to ensure the analysis results are reliable. Please see “7 Quality control” for details.

5.4 Sample preparation

The sample shall be whole blood sample. The sample volume required for each analysis of this Analyzer is less than or equal to 20 μ L.



- All items (samples, controls, calibrators, reagents, liquid wastes, etc.), as well as areas in contact with these items, have a risk of biological infection. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, etc.) when contacting relevant items and areas in the laboratory.
- Do not directly contact the blood samples.

Note

- All the samples shall be mixed thoroughly.
 - Do not reuse the disposable products.
 - The samples shall be prepared in accordance with the procedures recommended by the reagent manufacturer.
 - Samples that require analysis of leukocyte differential count or platelet count shall be stored at room temperature, and analyzed within 8 hours after collection.
 - If the sample is stored in a refrigerator at the temperature of 2 °C to 8°C, it can be analyzed within 24 hours after collection. The samples stored in the refrigerator shall be placed at room temperature for at least 30 minutes before being analyzed.
 - The samples after being placed for a period need to be mixed thoroughly again before being analyzed.
 - Please analyze the blood sample in 3 minutes to 2 hours after it is collected.
 - The EDTA anticoagulation vacutainer, K₂ siliconized glass / plastic test tubes, centrifuge tubes, and borosilicate glass capillary tubes used for blood collection shall be clean.
 - Use the vacutainers, centrifuge tubes, capillary tubes, and other disposable items specified by the manufacturer to collect blood sample.
-

The preparation process of whole blood samples is as follows:

- (1) Collect venous blood samples using EDTAK₂ anticoagulation vacutainer.
- (2) Quickly mix the venous blood in the tube with the anticoagulant thoroughly.

5.5 Sample analysis

This section mainly describes the sample analysis related information including sample information, sample analysis process and report management. Click “Analysis” to enter the analysis interface.

5.5.1 Input the sample information

This Analyzer offers two ways to input the sample information, including sample ID input and all information input.

If the operator inputs the sample information after sample analysis, you may skip this section. When reviewing the sample results, input the sample information according to the sample number and result save time. See “6 Result review” for reference.

Click “Manage” > “Setup” > “General” > “Auxiliary” to set the sample information

Daily operation

input mode as “All information” , then input all the sample information in the interface of “Analysis” .

(1) All information input

When the next sample input mode is “All Information” , click “Next Sample” in “Analysis” , the all information input interface displays, as shown below. The sample information to be input in the dialog box includes animal type, sample ID, patient ID, animal name, etc.

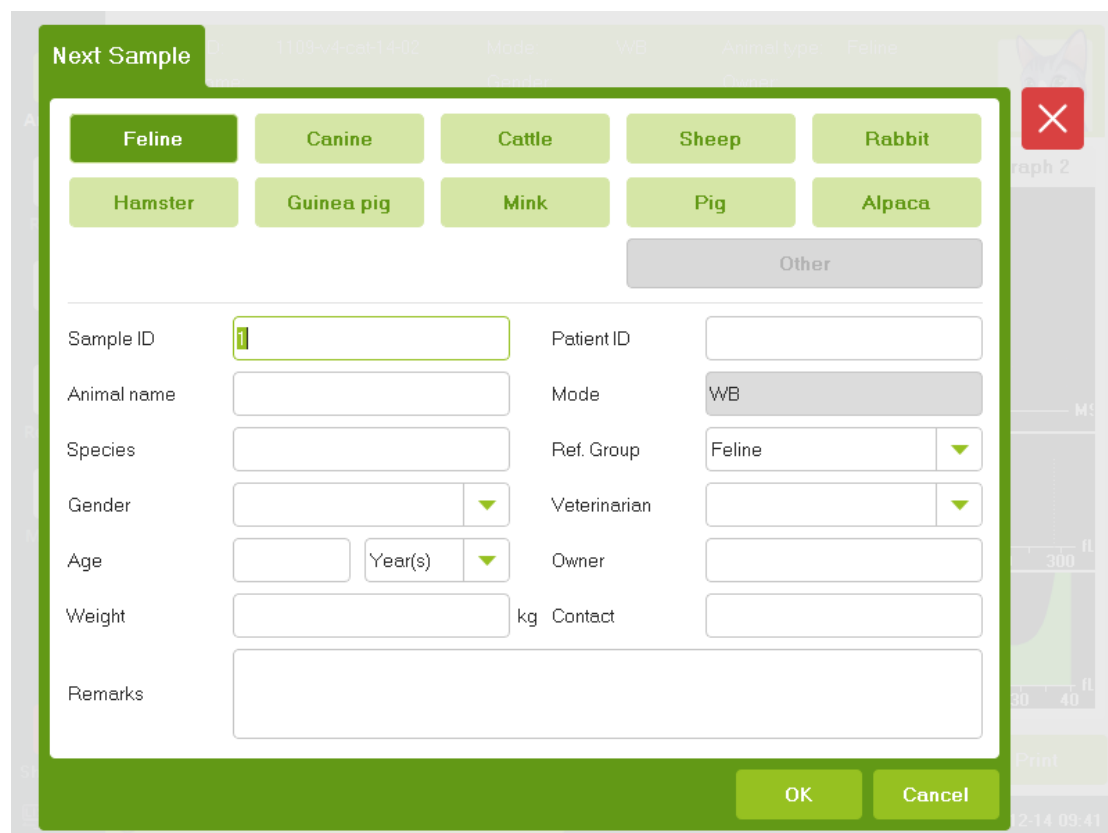


Figure 5-4 All information input interface

(2) Edit the current sample information

Click the sample information area in the “Analysis” interface or “Graph Review” interface, the sample information can be edited in the pop-up dialog box. The background sample information cannot be edited.

5.5.2 Sample analysis process

This section mainly describes the sample analysis process.

The operator shall be a specially trained professional. Analyze the whole blood sample according to the steps described below:



- All items (samples, controls, calibrators, reagents, liquid wastes, etc.), as well as areas in contact with these items, have a risk of biological infection. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, etc.) when contacting relevant items and areas in the laboratory.
- The sample probe is sharp, and it may carry the blood samples, controls, and

calibrators that are potentially biological infectious. Therefore, do not touch the sample probe when it is running down, or it may cause personal injury.

- The sample probe shall not touch the wall of the test tube in operation to avoid blood splash.

Caution

Do not reuse the disposable products.

Note

When aspirating the sample, the sample probe shall be fully immersed in the sample and keep a certain distance away from the bottom of the container, otherwise the aspirated volume may be insufficient.

- (1) Make sure the sample analysis is ready, and the working mode is “WB” ;
- (2) Place the prepared whole blood sample under the sample probe and make sure the thoroughly mixed sample can be aspirated by the probe.
- (3) Press “Aspirate” key to start the analysis process. The indicator of the Analyzer will flash in green, indicating that sample analysis is running.
- (4) The sample probe aspirates the sample automatically and lifts up, and the buzzer sounds at the same time. The sample can be removed after the sample probe lifts. The sample probe adds the aspirated sample in the counting chamber, then the Analyzer performs sample analysis automatically.
- (5) After the analysis is completed, the sample probe is reset and ready for the next analysis. The analysis result will display in the result analysis area. Meanwhile, the next sample number will be automatically added by 1.
- (6) If the “Auto Print” function is enabled, the Analyzer will automatically print the analysis report according to the previous settings; if the “Auto Communication” function is enabled, the Analyzer will automatically upload the analysis results, the information of samples and patients that meet the communication conditions to the LIS.
- (7) The other samples are analyzed in this process.

5.5.3 Report management

This section mainly describes the report management, including the analysis results save and abnormal text alarms.

- (1) The Analyzer can save the analysis results automatically. The new sample analysis results will automatically overwrite the oldest analysis results when the number of sample results reaches the upper limit.
- (2) This Analyzer also has the text abnormal alarm function, see the table below for details:

Table 5-1 Text abnormal alarm

Flag	Alarm information	Explanation
WBC Flag	Leucopenia	The white blood cell count is significantly low.
	Leucocytosis	The white blood cell count is significantly high.
	Neutropenia	The neutrophil count significantly low.
	Neutrophilia	The neutrophil count is significantly high.
	WBC Abnormal	There may be abnormalities in nucleated red blood cells, atypical / abnormal lymphocytes, juvenile cells, and protocell, etc.
	Lymphopenia	The lymphocyte count is significantly low.
	Lymphocytosis	The lymphocyte count is significantly high.
	Monocytosis	The monocyte count is significantly high.
	Eosinophilia	The eosinophil count is significantly high.
	Basophilia	The basophil count is significantly high.
RBC/HGB Flag	Abnor. RBC Distr.	There may be abnormalities in microcytes, macrocytes, anisocytosis, agglutination of red blood cell, double peaks in histograms, etc.
	HGB Abnor. /Interfere	There may be abnormal hemoglobin, agglutination of red blood cell, etc.
	Microcytosis	Red blood cell volume is small.
	Macrocytosis	Red blood cell volume is large.
	Anemia	Anemia
	Erythrocytosis	The red blood cell increases significantly.
PLT Flag	Abnor. PLT Distr.	There may be abnormalities in microcytes, red blood cell fragments, giant platelet, platelet clump, etc.
	Thrombopenia	The platelet decreases significantly.
	Thrombocytosis	The platelet increases significantly.

5.6 Standby

If fluidics related operation stops for the set time period, the Analyzer will enter standby mode, and 3 minutes later, enter screen locking status.

When the Analyzer is standby, the lower left corner of the interface will display “On Standby. Press the [Aspirate] key to exit.”

5.7 Shutdown

This section mainly describes the shutdown process.

The shutdown process shall be executed first before powering off the Analyzer. Steps are as below:



- All items (samples, controls, calibrators, reagents, liquid wastes, etc.), as well as areas in contact with these items, have a risk of biological infection. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, etc.) when contacting relevant items and areas in the laboratory.
- Do not touch the sample probe. The sample probe is sharp, and it may carry the blood samples, controls, and calibrators that are potentially biological infectious.
- The operator is obliged to comply with the national and regional regulations on the discharge and disposal of reagents, liquid wastes, waste samples, consumables, etc. They shall be treated before discharging.

Note

- To ensure the stability of the Analyzer and the accuracy of the analysis results, please shut down the Analyzer after it has kept working for 24 hours.
- The operator shall shut down the Analyzer following the steps below:
- Do not forcibly power off in the shutdown process.
- If a fault that affects the shutdown occurs during the shutdown process, the Analyzer will return to the status before shutdown, and an alarm will display. Please see “10 Troubleshooting” for details.

-
- (1) Click “Shutdown” at the lower left of the interface.
 - (2) Click “Yes” , place the probe cleanser under the sample probe, and press the “Aspirate” key; The Analyzer will execute probe cleaning automatically.
 - (3) After the shutdown process is completed, the operator powers off the Analyzer when “Please turn off the power!” displays.
 - (4) Empty the waste liquid in the waste container and dispose of waste liquid properly.

6 Result review

The Analyzer will automatically save the analysis results in the sample library after each analysis is completed. The sample library of this Analyzer can save up to 50 000 analysis results with sample parameters, scatter plots and histograms. The operator can review the sample parameters, scatter plots, and histograms saved in the sample library and query library in the form of a list or a single sample with the histogram. Back up the analysis results to avoid data loss in case of hardware or software failure.

This chapter mainly describes the information and related common operations in “Review” interface.

6.1 Main software interface

This section mainly describes the information in “Review” interface.

Click “Review” to enter the main interface of list review. There are two types of information, i.e., parameter information and animal information.

Parameter information: the sequence number, the patient ID, the sample ID, the animal name, and the parameters will display in sequence in the sample result area as shown in the figure below.



Figure 6-1 Review – parameter information

Animal information: the sequence number, the patient ID, the sample ID, the animal name,

Result review

and the parameters will display in sequence in the sample result area as shown in the figure below.

Seq	180	181	182	183	184	185
Patient ID						
Sample ID	1109-v4-cat-11	1109-v4-cat-11	1109-v4-cat-11	1109-v4-cat-11	1109-v4-cat-11	1109-v4-cat-11
Animal name						
Species						
Animal type	Feline	Feline	Feline	Feline	Feline	Feline
Gender						
Age						
Weight						
Status						
Mode	WB	WB	WB	WB	WB	WB
Test Date	2021-11-09	2021-11-09	2021-11-09	2021-11-09	2021-11-09	2021-11-09
Test Time	15:03:27	15:05:09	15:06:40	15:07:55	15:09:41	15:10:45
Ref. Group	Feline	Feline	Feline	Feline	Feline	Feline
Owner						

Figure 6-2 Review – animal information

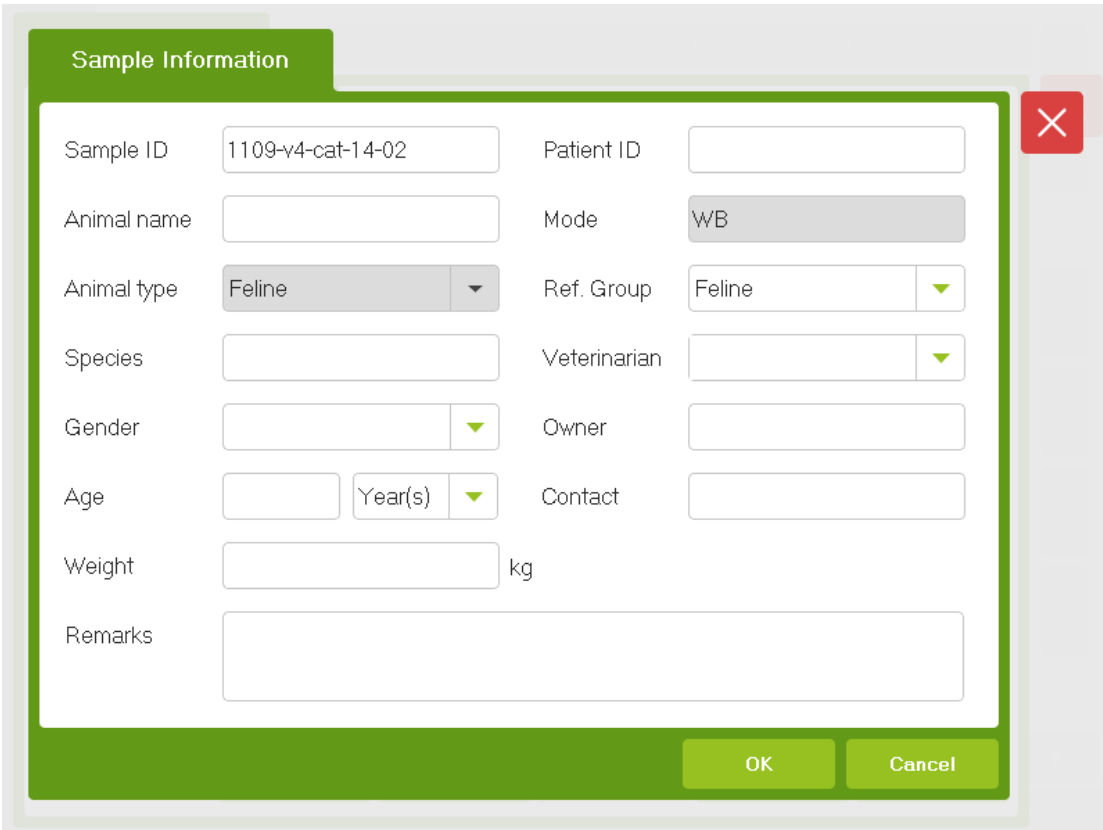
The main functions in the “Review” interface are explained in the list below.

Table 6-1 “Review” interface description

Heading	Secondary heading	Description
Search	Search By	Search by “Not Printed Today” and “Not Transmitted Today” .
	Search By Conditions	Enter the search conditions in the corresponding edit box or select the conditions in the drop-down list.
Graph review	Special Info.	View the detailed analysis results of each sample in “Graph Review” main interface. View DN diluent, Pre-heat pool, etc. in “Special Info.” interface.
Trend graph	\	View the run chart of the sample analysis result. View the CV value of the sample in “Chart” interface.
Export	\	Export the data.
Comm.	\	Communicate with LIS.
Delete	\	Delete the result.
Print	\	Print the result.

6.2 Edit sample information

This section mainly describes how to edit the information in the “Review” interface. Select a line of data in the “Review” interface, click “Graph Review”, then click the sample information area, the interface below will display.



The screenshot shows a dialog box titled "Sample Information" with a green header and a red close button in the top right corner. The dialog contains the following fields:

Sample ID	<input type="text" value="1109-v4-cat-14-02"/>	Patient ID	<input type="text"/>
Animal name	<input type="text"/>	Mode	<input type="text" value="WB"/>
Animal type	<input type="text" value="Feline"/>	Ref. Group	<input type="text" value="Feline"/>
Species	<input type="text"/>	Veterinarian	<input type="text"/>
Gender	<input type="text"/>	Owner	<input type="text"/>
Age	<input type="text"/> <input type="text" value="Year(s)"/>	Contact	<input type="text"/>
Weight	<input type="text"/> kg		
Remarks	<input type="text"/>		

At the bottom of the dialog, there are two buttons: "OK" and "Cancel".

Figure 6-3 Modify sample information

The user can set the sample ID, patient ID, animal name, etc.

7 Quality control

This chapter mainly describes the L-J quality control information of the Analyzer, including quality control setting, quality control test, and quality control result review.

The Analyzer may have certain errors if it has been used for a long time. The error may lead to incorrect or unreliable analysis results. The quality control procedure provides an effective method for detecting possible errors. Only when the operator is familiar with the quality control theory and masters the operation method can the effect of the error on the analysis result be effectively eliminated.

To ensure the reliability of the sample analysis results, it is recommended that the operator carry out quality control procedures on the Analyzer every day using the low, medium and high levels of controls respectively. If it is necessary to use a new batch of controls, the new batch of controls shall be used in parallel with the existing one for five days and twice a day, and the results shall be within the reference range specified in the instructions for use of the controls.

This Analyzer adopts L-J quality control method. Click "QC" to enter "L-J QC" interface as shown below.



Figure 7-1 L-J quality control

Note

The operator shall use the controls and reagents specified by Zytopia, and store and use them strictly following the instructions for use.

7.1 QC setting

This section mainly describes the quality control setting of L-J quality control.

Before analyzing a new lot of control, it is necessary to set up a QC file for each lot of control.

To enter quality control setting interface, click “QC” > “L-J QC” > “Setting” .

7.1.1 Input QC information

This section mainly describes the steps to input QC information.

The lot number is required. The lot number shall be within 1 to 16 digits, including characters, numbers, and letters, but Chinese characters are not supported.

Steps to input QC information

- (1) Enter “L-J QC” interface.
- (2) Click “Setting” > “New” ; or select a QC file without QC test results, and click “Modify” .
- (3) Manually input the lot number of the control in the edit box.
- (4) Select the level of the control.
- (5) Input the expiration date of the control.
- (6) Select the “QC Type” in the drop-down list.
- (7) Select the QC mode of the control.
- (8) Set QC ID: if the operator tends to perform quality control analysis with daily samples analysis, a special ID for the control can be set here. If the Analyzer recognizes this special ID in the process of analyzing daily samples, it will automatically identify the sample to be analyzed as the control. After analysis, the test result will be saved in the QC file corresponding to this ID.
- (9) According to the target table of the corresponding lot number, enter the target and limits in the edit box of the parameter that needs to be controlled.
- (10) Click “Save” to save the input quality control information.

7.1.2 Set limits

This section mainly describes the process to set limits.

To adjust the display form of the limits, please follow the steps below:

- (1) Click “Setting” .
- (2) Click “Add” .
- (3) Click “Set Limits” .
- (4) Click “By Absolute Value (#)” , the limits will be displayed in absolute value, and click “BY Percentage (%)” , the limits will be displayed in percentage.
- (5) Click “OK” to save the limits setting.

7.2 Quality control analysis

This section mainly describes the information related to quality control analysis.

7.2.1 Quality control analysis method

This section mainly describes the quality control analysis method.

There are two quality control analysis methods, and the operator can choose either of the following methods:

- Perform quality control analysis in “QC” interface.
- Perform quality control analysis in the “Analysis” interface through sample analysis.

7.2.2 Quality control analysis steps

This section mainly describes the sample analysis steps.

When performing quality control analysis, pay attention to the followings:

- Performing quality control in the event of a failure may result in incorrect analysis results.
- If an error alarm occurs during quality control analysis, ensure quality control is performed after troubleshooting.
- Sample agglutination may result in inaccurate analysis results. Please check if the control has agglutinated before analysis. If it has, please handle it according to the relevant laboratory requirements.
- Check if the control to be analyzed expires, and if its level is the same with that in the selected QC file. The expiration date of the expired control is marked in yellow background.
- Each QC file can save up to 200 quality control results. if there are more than 200 results, it will remind the user that the count capacity is full.

Quality control analysis steps are shown as below:

- (1) Click “QC” > “L-J QC” to enter the QC count interface.
- (2) prepare the controls as instructed by the instructions for use.
- (3) Quality control analysis:
 - 1) Mix the control thoroughly and operate the control as instructed by the instructions for use.
 - 2) Place the control under the sample probe, and press “Aspirate” key to start aspiration.
 - 3) After aspiration, remove the control safely.

After the analysis, 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.

To perform quality control analysis through sample analysis, set a special “QC ID” for the control in the QC interface. Place the control in the daily sample, and complete the quality control analysis in the sample analysis interface.

Before daily sample counting, when the operator 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” .

Quality control analysis steps are shown as below:

- (1) Prepare the control according to the instructions.

- (2) See “5.4 Sample preparation” for sample preparation.
- (3) When the Analyzer is ready for counting, that is, the status icon and the Analyzer indicator light is green and always on, place the prepared sample under the sample probe, and press the “Aspirate” key to aspirate the control.
- (4) After aspiration, remove the control safely.
- (5) After analysis, the quality control results are automatically saved in the QC file, and the latest results are displayed in the current interface.
- (6) If necessary, continue the quality control analysis following the steps above.

7.3 Quality control result review

This section mainly describes the information related to quality control result review. The operator can review the quality control result in the following two ways after the quality control analysis is over.

- QC Graph
- QC List

7.3.1 QC Graph

The QC graph review steps are as follows:

- (1) Click “QC Graph” in the “L-J QC” interface to enter the corresponding QC graph interface.
- (2) Click the page turn button at the right side of the QC graph to browse the quality control graph. Click the page turn button at the bottom of the QC graph to browse all the quality control results.

7.3.2 QC list review

This section mainly describes quality control list review steps. The details are as follows:

- (1) Click “QC list” in the “L-J QC” interface to enter the corresponding QC list interface.
- (2) Click the page turn button at the right side of the QC list to browse all the quality control records; Click the page turn button at the bottom of the QC list to browse all the parameter results.

7.3.3 Delete (Administrator)

The QC result deleting steps are as follows:

- (1) Select the QC result record to be deleted, click “Delete” , and a dialog box will display.
- (2) Click “Yes” to delete the selected result.
- (3) The deletion operation will be recorded in the log.

7.3.4 Export

The QC information and QC result export steps are as follows:

- (1) Insert the USB flash drive, and click “Export” .
- (2) The system will recognize the USB flash drive and export the data.
- (3) “Export Successfully” will display if the data export is completed.

8 Reagent management

This chapter mainly describes the operation of “Reagent” interface and information about reagent replacement.

8.1 Software interface operation

This section mainly describes the operation of “Reagent” interface, as shown below:

(1) Click “Reagent” to enter the interface below.



Figure 8-1 Reagent

The following information is displayed in the interface:

- If the residual volume is in green, it indicates that the reagent is sufficient.
- If the residual volume is in red, it indicates that the reagent replacement is required.
- If the residual volume is in yellow, it indicates that the reagent expires.
- After replacing with new bottle of reagent, or when it is necessary, this function can be used to replace the reagents in the fluid path.

(2) Click the icon of the reagent that needs to be replaced to enter the corresponding reagent setting interface.

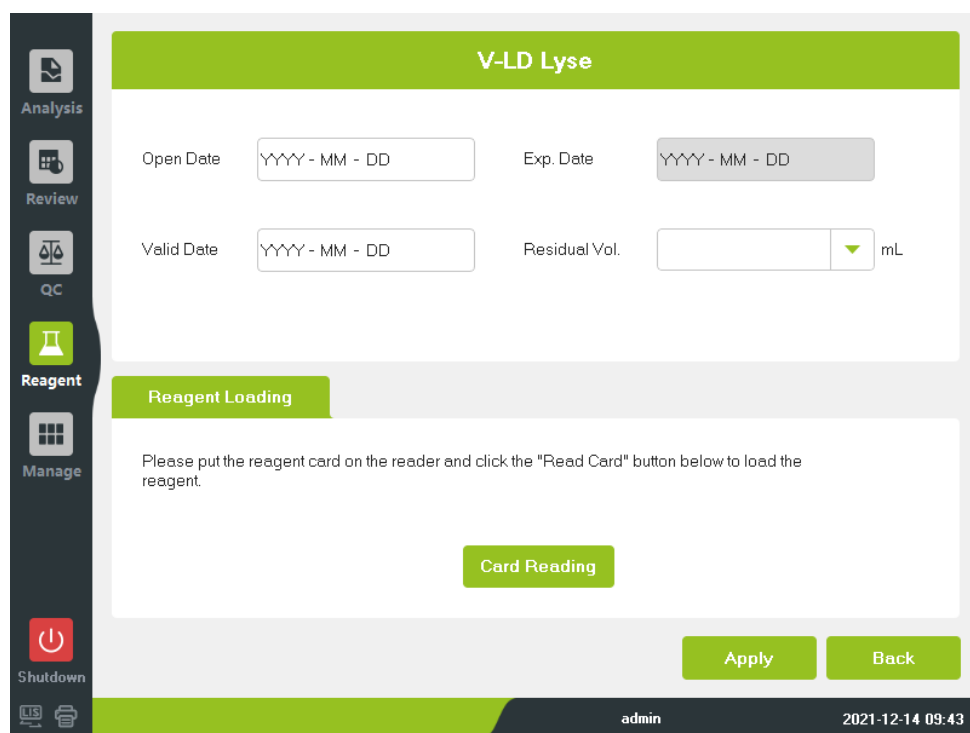


Figure 8-2 Reagent setting

- (3) Put the reagent card on the card reader, click “Card Reading” to load the reagent.
- (4) Click “Apply” , if the input information meets the requirement, it will prompt to replace the reagent.

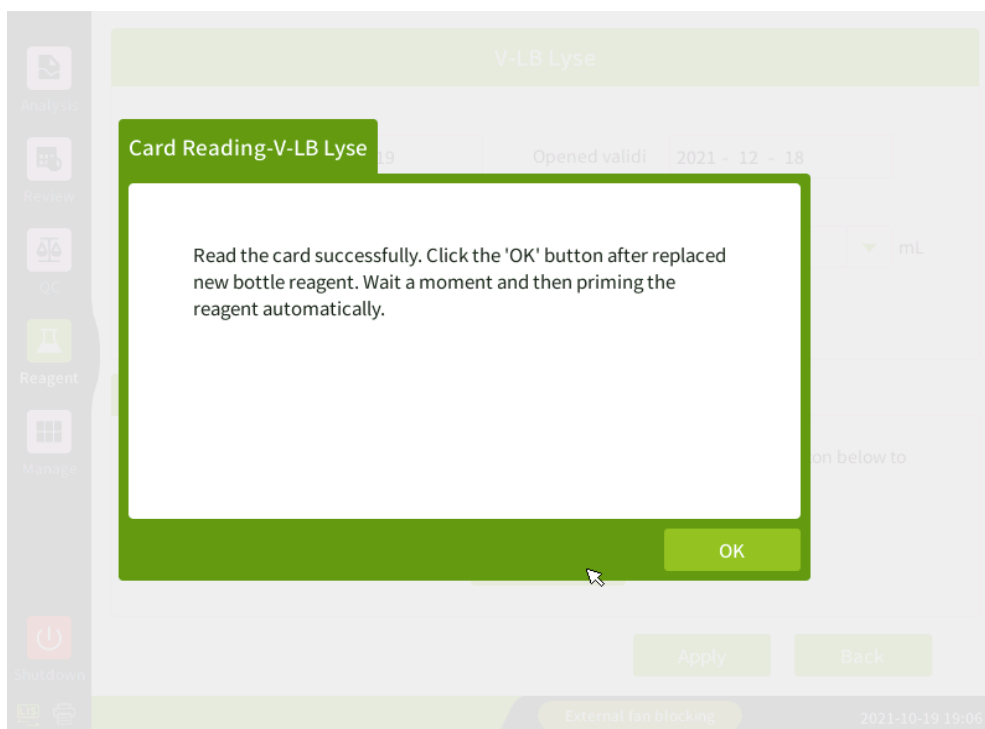


Figure 8-3 Replace reagent prompt

- (5) Click “OK” to perform the timing of replacing the reagent and save the reagent information.

If necessary, continue to replace other reagents according to the steps above.

8.2 Reagent replacement information

This section mainly describes the relevant information of reagent replacement, including the conditions that reagents need to be replaced, the types of reagents to be replaced, and the operation steps to replace the diluent bucket.

- (1) The operator should replace the reagent, provided that
 - The whole bucket/bottle of new reagent is used.
 - The reagent contamination is suspected in the pipeline.
 - The air bubbles are suspected in the pipeline.
- (2) The operator can replace the reagents below:
 - Diluent
 - V - LD lyse
 - V - LB lyse
- (3) When replacing the diluent bucket, please follow the steps below:
 - 1) Hold the opening of the diluent bucket with the support plate of the bucket.
 - 2) Insert the diluent bottle cap assembly vertically into the diluent bucket, and tighten the cap. Otherwise, the alarm may be unreliable.

Pay attention to the followings:

- Do not vibrate the diluent barrel violently or collide with other objects, otherwise the alarm may be unreliable.
- After long-distance transportation, please keep the diluent rest for more than one day before using it.
- After replacing the reagent, such as the diluent or the lyse, the operator should conduct background test and ensure that the background value is within the normal range ready for sample analysis.

9 Analyzer management

This chapter mainly describes the information about the “Manage” interface, including “Calibration”, “Service”, “Setting”, “Status”, and “Performance”. “Manage” interface is shown as below:

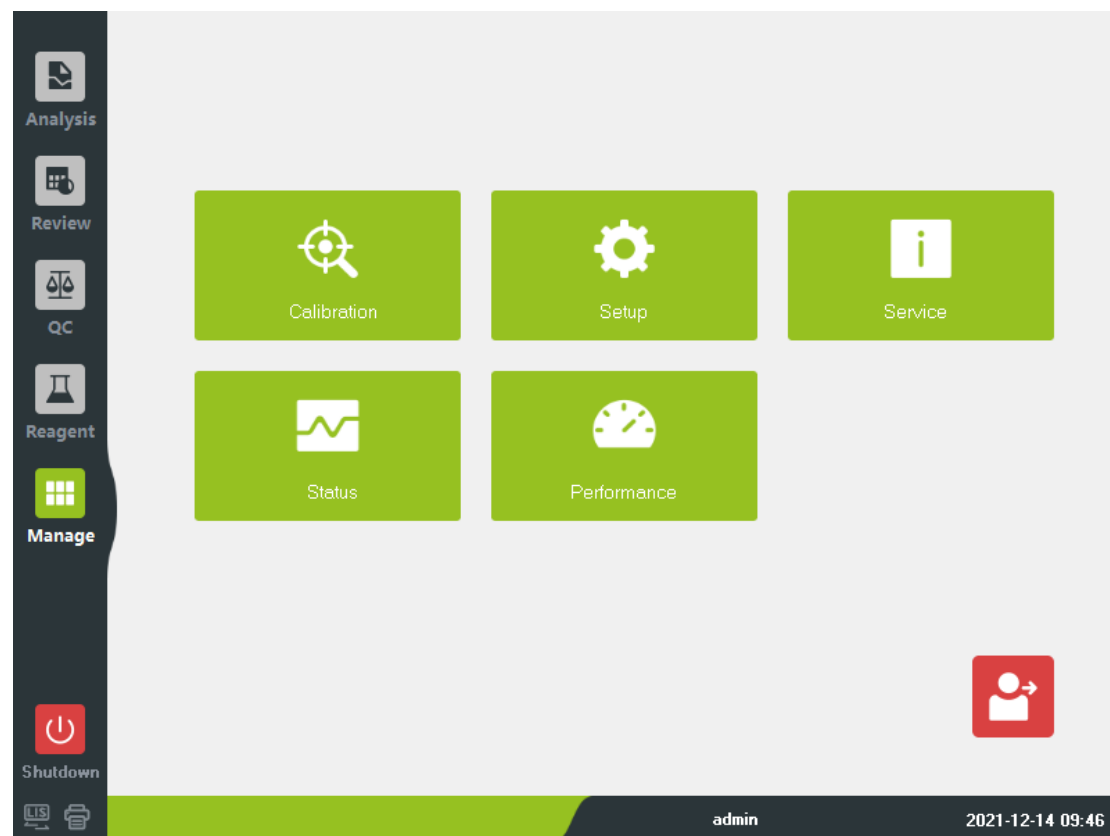


Figure 9-1 Manage

Click “Logout” in the lower right corner to log out.

9.1 Calibration

This section mainly describes the information in “Calibration” interface. The purpose of calibration is to obtain accurate test results and determine the deviation correction coefficient of blood sample analysis under specified conditions. To obtain accurate blood sample analysis result, please calibrate the Analyzer according to the steps given in this chapter when necessary.

“Calibration” interface is shown as below:

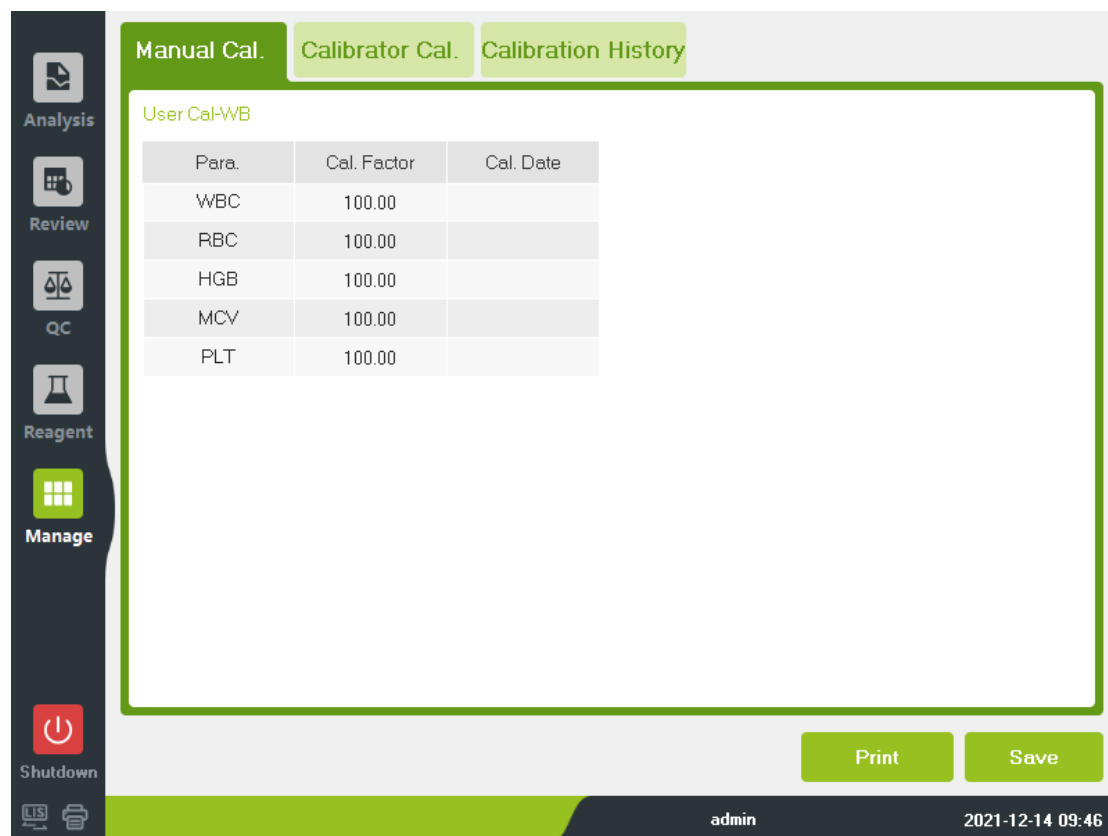


Figure 9-2 Calibration

There are two calibration methods: manual calibration and calibrator calibration. Part or all the parameters in WBC, RBC, HGB, MCV, PLT can be calibrated.

Pay attention to the followings:

- Only the operator with administrator authority can perform calibration operation.
- The operator shall use the calibrators and reagents designated by Zytopia, and store and use them strictly following the instructions for use of the calibrators and reagents.
- The calculation precision shall also be included in the calibration step.

9.1.1 Frequency calibration

This section mainly describes the frequency calibration of the Analyzer. Since this Analyzer has been calibrated before delivery, and the Analyzer itself has stable performance, it does not need to be calibrated frequently. The Analyzer shall be calibrated before the data are used as valid data. The operator still needs to calibrate the Analyzer in the following conditions:

- Before the first use (usually performed by Zytopia or its local distributor when installing the Analyzer).
- After replacing the main components.
- The quality control data has obvious deviation, or the data exceeds the predefined limit.
- Reuse the Analyzer after a long-term idle.
- The working environment (such as temperature) changes significantly.

9.1.2 Calibration method

There are two calibration methods: manual calibration and calibrator calculation.

9.1.2.1 Preparation

This section mainly describes the calibration preparation. Before calibration, the user shall make sure that the background range, accuracy and precision, and carryover are within the range specified in the manual. If they are not, eliminate the problems before calibration. If the problem cannot be solved, please contact the After-sales Department of Zytopia.

Calibration steps are as follows:

- (1) Check the host and reagent to ensure sufficient reagent for the whole calibration; If the reagent runs out during calibration, recalibrate the Analyzer.
- (2) Carry out blank test: ensure that the blank test results meet the requirements (See “3.2.1 Blank count” for background value range).
- (3) Carry out accuracy and precision test: perform 10 consecutive tests on the medium-level control or the blood samples equivalent to the medium-level control in the “Sample Count” interface. Check the count results in the “Review” interface, ensuring that they are in the specified range (See “3.2 Parameters and performance” for precision index).
- (4) Carry out carryover test: carry out 3 consecutive tests on the high-level samples or controls, followed by 3 consecutive tests on diluent or low-level samples. Then calculate the carryover rate according to the formula below:

$$\text{Carryover rate(\%)} = \frac{H1-L3}{H3-L3} \times 100$$

It is suggested to document the results and archive the files. The record table may include date, source of calibrator, lot number of calibrator, reference range, blank test results.

9.1.2.2 Manual calibration

This section mainly describes the information related to manual calibration. Login the administrator account, click “Manage” > “Calibration” to enter the “Manual Calibration” interface as shown in the figure below, then edit the calibration factors.

The calibration factor of each parameter and saving time of the factor are displayed in this interface.

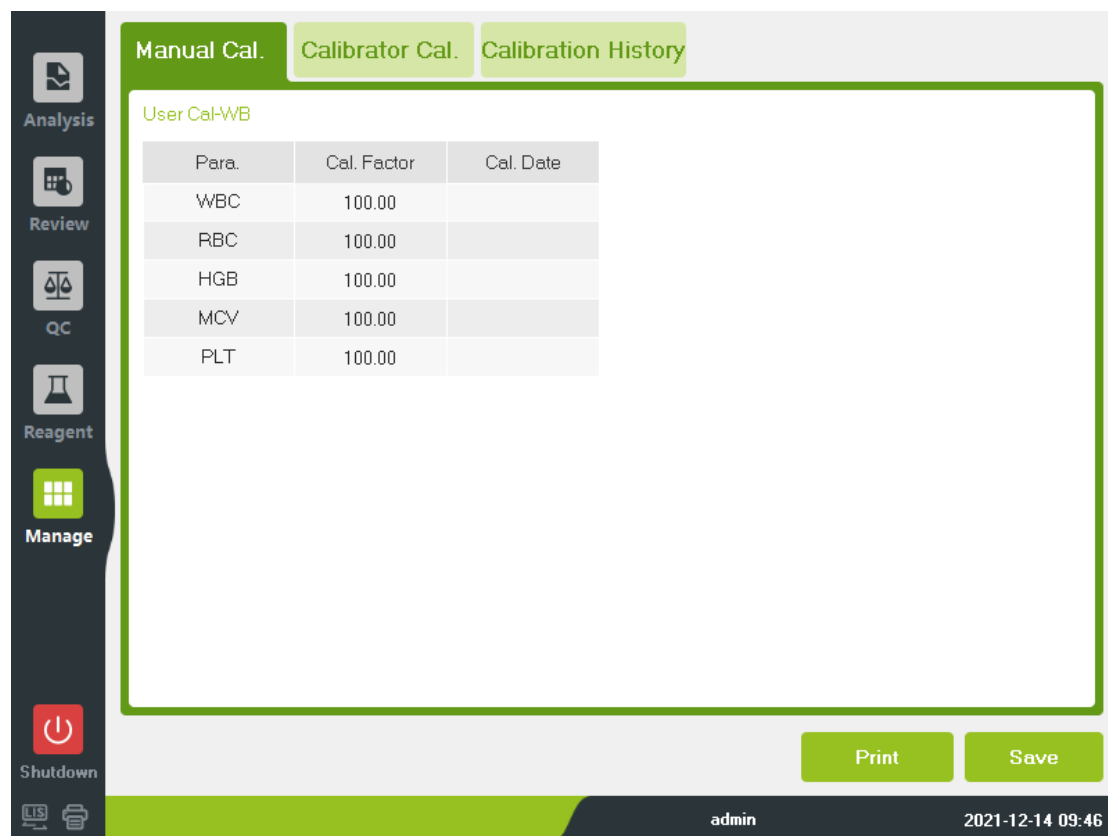


Figure 9-3 Manual calibration

Common user can only review the calibration factors in the current interface but cannot perform calibration. If to calibrate the Analyzer, log out the common user account, and log in the administrator account.

Manual calibration requires use of Zytopia specified calibrator or customized fresh blood samples.

If use customized fresh blood samples, the samples shall meet the following requirements:

- The morphology of red blood cells, white blood cell, and platelets is normal.
- The test results are within the reference range.
- The sample volume is sufficient for the whole calibration process.

Steps

The manual calibration is performed as following steps:

- (1) Repeat n times ($n \geq 3$) of test on the calibrator or customized fresh blood samples.
- (2) Calculate the coefficient value and the mean value the test results; Review the coefficient value and mean value in the “Review” interface.
- (3) Check if the coefficient value of test results is within the specified range.
If not, check if the Analyzer fails. If the Analyzer fails, eliminate the problem and perform tests again. If the problem cannot be solved, please contact the After-sales Department of Zytopia.
- (4) Click “Manage” > “Calibration” to enter “Manual Cal.” Interface.
- (5) Calculate the new calibration factors according to the formula below, keeping the number with two decimal places.

$$\text{New calibration factor} = \frac{\text{current calibration factor} \times \text{ref value}}{\text{Mean value}}$$

- (6) Check if the new calibration factors are within the range of 75.00% to 125.00%.
If not, the calibration factors are invalid. In this case, figure out the cause and eliminate the problems, then perform calibration again and calculate new calibration factors. If the problem cannot be solved, please contact the After-sales Department of Zytopia.
- (7) Input the new calibration factor in the calibration factor editing box.
- (8) After this entry, click “Save” .

9.1.2.3 Calibrator calculation

This section mainly describes the information related to calibrator calculation.

To enter “Calibrator Cal.” interface, please click “Manage” > “Calibration” > “Calibrator Cal” .

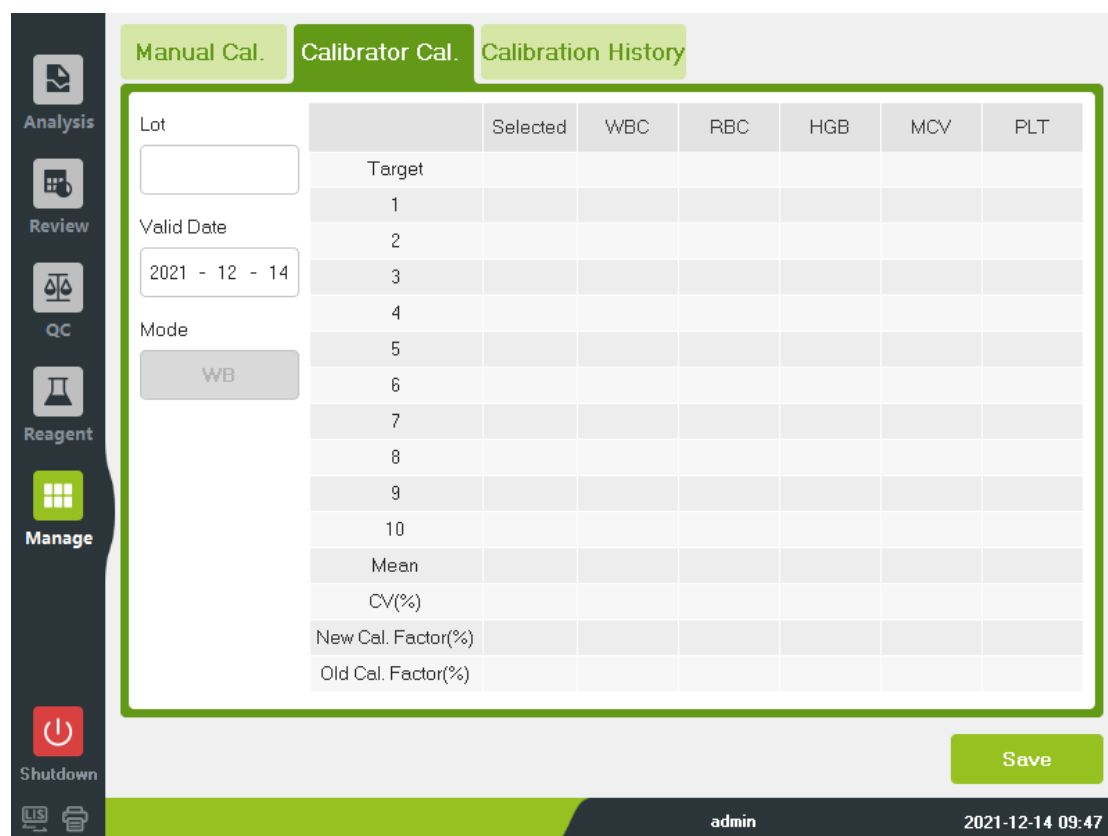


Figure 9-4 Calibrator calculation

Note

The operator shall use the Zytopia specified calibrator. Zytopia shall not assume any responsibility for the inaccurate analysis results due to use of non-specified calibrators.

Refer to the instructions for use of the calibrator for the calibrator lot number, expiration date, and parameter reference ranges.

Calibrator calibration steps are as follows:

- (1) Input the lot number of current calibrator in the “Lot” box.
- (2) Set expiration date. The default valid date of calibrator is the current date. If modification is required, click the “Valid Date” box to reset the valid date; The validity period of the calibrator shall be no less than current date in the system.

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- (3) The valid date shall be the open day plus the calibrator service life after open, or the use-by date noted in the instructions for use of calibrator. If the two dates are not the same, take the shorter period as the final to ensure the validity.
- (4) Input the target value of the parameter to be calibrated in the edit box of “Target Value” .
- (5) Prepare the calibrator following the instructions for use of calibrator.
- (6) Press the [Aspirate] key in the Analyzer to start calibration count.
- (7) When the calibration test times amount to n times ($n \geq 5$), the Analyzer will calculate the mean value, CV%, and the new calibration factor.
- (8) Save the calibration factor.

If the calibration factor of any calculated parameter which needs to be calibrated is out of the range 75% to 125%, or the CV% of any calibration parameter exceeds the precision index of the Analyzer, the calibration factor value will not be saved.

9.2 Setup

This section mainly introduces “Setup” in “Manage” . To satisfy different requirements in actual application, user can reset some parameters of the Analyzer.

Click “Manage” > “Setup” to enter the setup interface. “Setup” interface includes “General” , “System” , “Parameter” , and “User” .

By default, click “Manage” > “Setup” to directly enter the “General” interface as shown below:

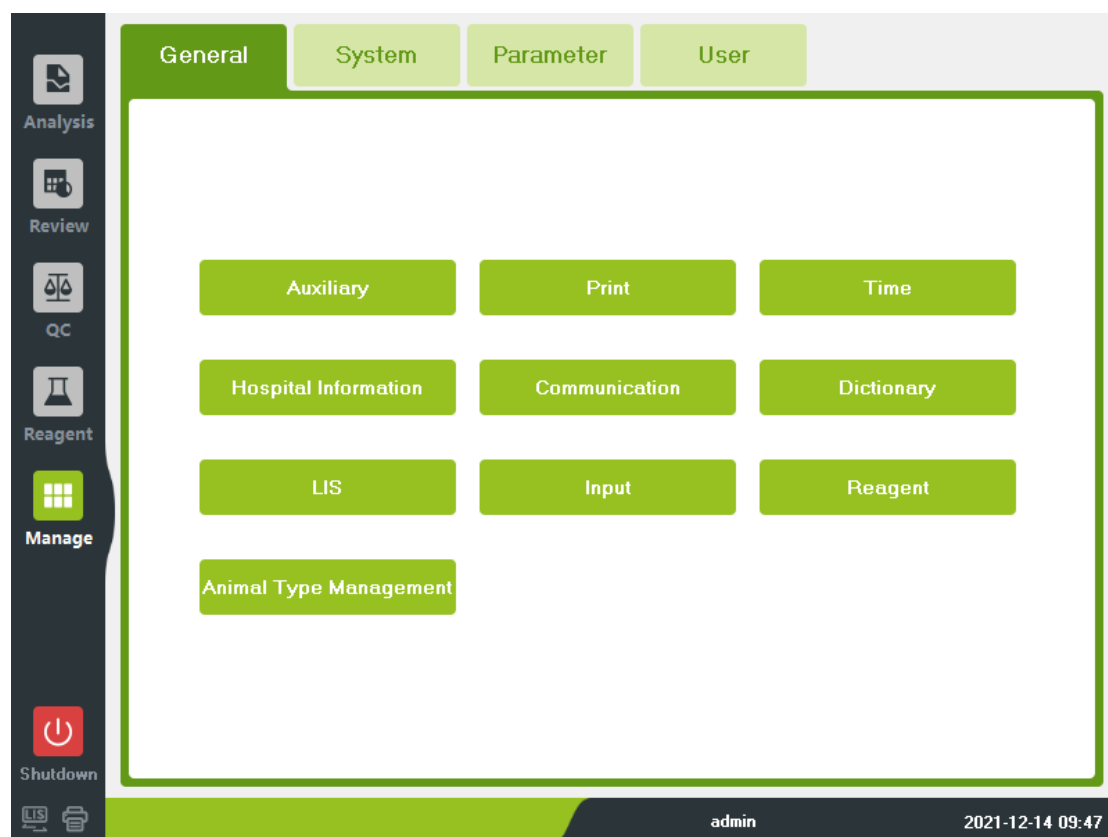


Figure 9-5 Setup interface

9.2.1 General setup

This section mainly describes the information related to “General” interface. Click

“Manage” > “Setup” to enter the “General” interface. “General” interface includes “Auxiliary” , “Print” , “Time” and so on. Refer to the table below:

Table 9-1 “General” interface introduction

Name	Description
Auxiliary setup	To set the next sample, start up sample, and alarm.
Print setup	To set the printing device, copies, printing template, auto printing, printing options, and to import, export, and delete printing template.
System time setup	To set the system time.
Hospital information	To set the information such as hospital name, and contacts.
Communication setup	To select network equipment type to set the protocol.
Dictionary setup	To set the veterinary and related shortcut code.
LIS setup	To set the IP address of LIS, the LIS terminal, the communication protocol, etc.
Input setup	To enable or disable the virtual keyboard.
Reagent setup	To set reminding of expiration of reagent.
Animal type management setup	To set the animal type.

9.2.2 System setup

This section mainly describes the information related to “System” interface. Click “Manage” > “Setup” > “System” to enter the “System” interface. The “System” interface includes “Maintenance” , “Gain” , “About” , and “Brightness control” . See the table below for details.

Table 9-2 “System” interface introduction

Name	Description
Auto maintenance setup	To set the wait time to enter auto sleep and set the start time of probe cleanser soak. <ul style="list-style-type: none"> The user can input the wait time (15 minutes to 90 minutes) in the edit box below “Auto Sleep” . Beside the start time of probe cleanser soak, the user can also set the interval reminding time.
Gain setup	To set the parameter gain and HGB gain.
About	To provide information related to software version and mode type.
Screen brightness	Adjust the screen brightness as needed.

9.2.3 Parameter setup

This section mainly describes the information related to “Parameter” interface. Click “Manage” > “Setup” > “Parameter” to enter the “Parameter” interface. This interface includes “Para. Unit” and “Ref. Range” . See the table below for details.

Table 9-3 “Parameter” interface introduction

Name	Description
Parameter unit	To set the unit, such as Chinese units, British units, or international units.
Reference range	Set the reference range related to animal type.

9.2.4 User setup

This section mainly describes the information related to “User” interface. Click “Manage” > “Setup” > “User” to enter the interface of user setting. User can modify the password and set the default user in this interface. Administrator can add new user.

- Modify password
Current user can modify the password of current user account. The password contains 12 digits at most.
- Add new user
Follow the steps below to add new user:
 - (1) Click “New” .
 - (2) Enter the “User Name” , “Name” , “Password” in related edit box by order. The “User Name” refers to the account name to be input for login; the “Name” refers to the name of “Tester” displayed in the list review and print report.
 - (3) Choose the user permissions.
 - (4) Click “OK” to save and close the dialog box.

Pay attention to the followings:

- The user name cannot be empty, and it contains 12 digits at most.
- The password cannot be empty, and it contains 12 digits at most.
- The name cannot be empty, and it contains 20 digits at most.

9.3 Service

This section mainly describes the information related to “Service” interface. For correct and effective operation of this Analyzer, the operator shall make regular maintenance as instructed in this section.

Click “Manage” > “Service” to enter “Service” interface. The interface includes “Maintenance” , “Self check” , “System Cal.” , and “Log” .



All the components of the Analyzer may be potentially infectious, take safety measures when operating and repairing the Analyzer.

Warning

During maintenance, please avoid contact with the sharp tip of sample probe.

Caution

- Improper maintenance may impair the Analyzer. The operator shall observe the Manual to perform maintenance.
- If the contents are not mentioned in the Manual, please contact the After-sales Department of Zytopia for maintenance advice.
- Use the spare parts provided by Zytopia to repair the Analyzer. If any questions, please contact the After-sales Department of Zytopia.

The tool for maintenance is listed as followings:

Table 9-4 Tool list

No.	Tools	No.	Tools
1	Phillips screwdriver	4	Medical gloves
2	Straight screwdriver	5	Medical alcohol
3	Hexagon key		

9.3.1 Maintenance

This section mainly describes the information related to “Maintenance” interface. Click “Manage” > “Service” > “Maintenance” to enter the “Maintenance” interface.

In this interface, the user can carry out operations of “unclog” , “prime” , “empty” , “clean” , “probe cleanser soak” , and “whole device” .

- **Unclog**
 Unclog involves burning and back-flush. If there is any clogging, implement this operation. Operating steps are as follows:
 - (1) Click “Unclog” to unclog.
 - (2) After unclog finishes, the Analyzer will prompt “Maintenance finishes.”
 - (3) If necessary, perform “WBC Flush Unclog” and “Flush Unclog” of a single channel respectively.
- **Reagent prime**
 To prime the reagent of the corresponding channel again.
- **Empty**
 To empty the corresponding channel.
- **Clean**
 The user shall clean the corresponding components, if:
 - Clean the WBC chamber when the background values of WBC and/or HGB are out of range.
 - Clean the RBC chamber when results of RBC and/or PLT are out of range.
 - If the sample probe is stained, clean the sample probe.
- **Probe cleanser soak**
 The user shall carry out probe cleanser soak of whole device, provided that:
 - The background out of range, abnormal quality control or clogging occur due to a long time of not using the Analyzer, which cannot be solved after maintenance.
 - A shutdown is caused by an abnormal power failure.
- **Whole device**

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- Fluidics initialization: to restore all the movable parts and sensors to their startup state.
- Fluidics cleaning: to clean all the fluidics components.
- Prime: to perfuse the tubing with fluid.
- Drain All: to empty the Analyzer and clean the Analyzer internal with distilled water, if the Analyzer has not been used for at least one week.

9.3.2 Self-check

This section mainly describes the information related to “Self-check” interface. Click “Manage” > “Service” > “Self-check” to enter “Self-check” interface. In this interface, the user can set the motor, aperture voltage, fan, valve, pump, and other parts.

9.3.3 System calibration

This section mainly describes the information related to “System Cal.” interface. Click “Manage” > “Service” > “System Cal.” to enter the interface of system calibration, where the user can carry out touch-screen calibration, position adjustment, gain calibration, temperature calibration, optical calibration, and optical debugging.

9.3.4 Log

This section mainly describes the information related to “Log” interface. Click “Manage” > “Service” > “Log” to enter log interface. This interface includes “All Logs” , “Para. Modified Logs” , “Operation Logs” , and “Error Logs.”

The user can check the error information, parameter modification information, and daily operation information. The log also records the use history of the Analyzer, which is important for the operator to view the use history and for the service personnel to eliminate errors.

9.4 Status

This section mainly describes the information related to “Status” interface. This interface contains “Version” , “Temperature and Pressure” , “Sensor” , “Voltage and Current” , “Disk Information” , and “Counter.”

Table 9-5 “Status” interface introduction

Name	Description
Version	Provide information related to software, kernel, kernel driver, system software, middleware and signal board FPGA.
Temperature and pressure	Provide temperature and pressure information related to diluent, pre-heat pool, optical system temperature, and hydraulic level.
Sensor	Provide information related to float sensor, and sampling assembly optocoupler.
Voltage/current	Provide voltage/Current information related to constant current and optical background.
Disk information	Provide the information related to RAM, core board and processor.
Counter	Provide counter information related to sample test times and QC test times.

9.5 Performance

This section mainly describes the information related to “Performance” interface. This interface contains “Background” , “Repeatability” , and “Carryover.”

Table 9-6 “Performance” interface introduction

Name	Description
Background	To detect and record the background performance.
Repeatability	To detect and record the repeatability and review the graphs.
Carryover	To detect and record the carryover rate.

10 Troubleshooting

This chapter introduces the information about the possible errors and provides corresponding troubleshooting methods. The manual cannot be used as the Service Manual; therefore, it provides the troubleshooting methods for the error alarms.



All items (samples, controls, calibrators, reagents, liquid wastes, etc.), as well as areas in contact with these items, have a risk of biological infection. The operator shall strictly abide by the laboratory safety regulations and wear personal protective equipment (laboratory protective suit, gloves, etc.) when contacting relevant items in the laboratory.

10.1 Error information and error handling

The Analyzer will display an alarm at the bottom of the screen and sounds an alert if any abnormality is detected during use.

Click the alarm area, the error dialog box displays, giving the error name and help information. The error names display in order of occurrence.

Click the error name to select the error, view the help information in the list of “Help” . The help information about the first error displays by default. The operator shall handle the error in order of the help information.

For the convenience of operator, this section provides the information about all possible errors, the possible causes, and corresponding troubleshooting methods. The operator shall perform troubleshooting according to the methods provided here.

If the error still exists, please contact the after-sales department of Zytopia.

The possible errors and help information are as follows:

Table 10-1 Error and help information

No.	Fault name	Help information
1	Abnormal communication	Click “Clear” , the error will be eliminated.
2	The diluent expires.	Click “Clear” and read the reagent card of the new reagent in the popup message. Change the reagent bottle and click the “Apply” to prime the reagent.
3	Lyse expires.	Click “Clear” and read the reagent card of the new reagent in the popup message. Change the reagent bottle and click the “Apply” to prime the reagent.

Troubleshooting

No.	Fault name	Help information
4	Liquid waste full	Empty the liquid waste container or replace the liquid waste container; Click “Clear” , the error will be eliminated.
5	No diluent	Please check if the diluent runs out. If there is no reagent, please replace a new one. Click “Clear” button to remove the error.
6	No LB/LD lyse	Please check if the lyse runs out. If there is no reagent, please replace a new one. Click “Clear” button to remove the error.
7	Sample syringe component abnormal	Click “Clear” , the error will be eliminated.
8	Sampling assembly abnormal	Click “Clear” , the error will be eliminated.
9	Abnormal background	Click “Clear” , the error will be eliminated.
10	HGB Background abnormal	Check if there is reagent in the diluent container. If not, replace a new bottle of reagent; Click “Clear” , the error will be eliminated.
11	Vacuum pressure abnormal	Click “Clear” , the error will be eliminated.
12	RBC clogged	Click “Clear” , the error will be eliminated.
13	RBC aperture voltage abnormal	Click “Clear” , the error will be eliminated.
14	Abnormal voltage	Power off the Analyzer, and contact the After-sales Department of Zytopia.
15	Abnormal system clock	Power off the Analyzer, and contact the After-sales Department of Zytopia.
16	Sheath flow syringe assembly abnormal	Click “Clear” , the error will be eliminated.

10.2 Fuse

This section introduces the methods for replacing the fuse. Replace the fuse when it is broken. The user can replace the fuse independently.

Warning

- Use the specified fuse.
- Caution on electric shock.

Before replacing the fuse, disconnect the power cable of the Analyzer, and take out the fuse holder.

The fuse is illustrated as follows:

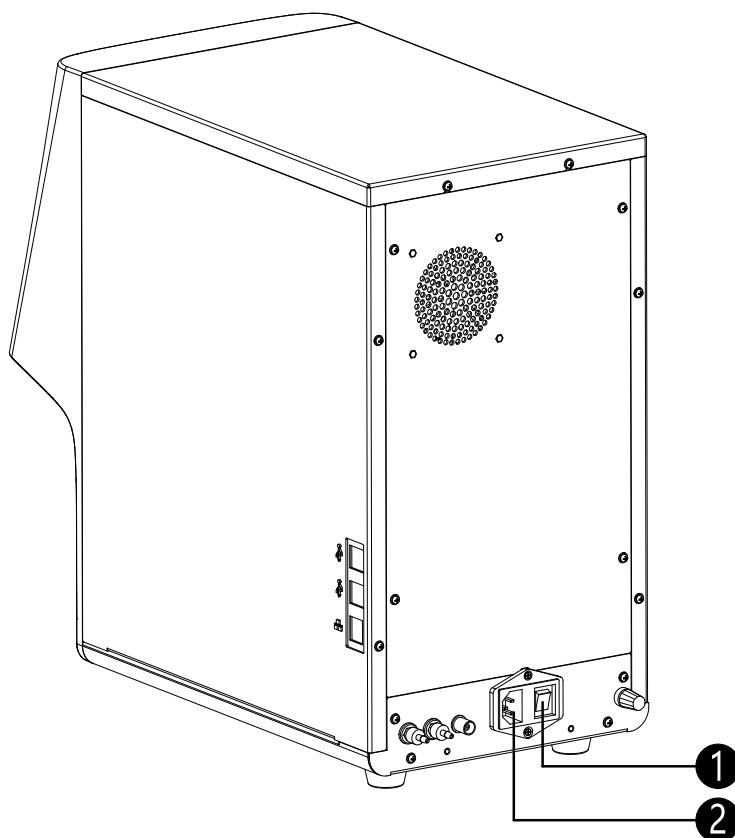


Figure 10-1 Fuse structure

No.	Parts	Description
①	Fuse	Have a fusing function.
②	Fuse holder	To hold the fuse.

10.3 Maintenance

If an error which cannot be resolved by the operator occurs during use, please contact the local distributor. For the performance and safety of the Analyzer, the spare parts in the list shall be purchased from the manufacturer or its local distributor. Only the engineers designated by the manufacturer can check and replace the hoses (fluidic tubing) of the Analyzer.

These spare parts require examination and replacement by the manufacturer or its local distributor are as follows:

Table 10-2 Spare parts

No.	Name	No.	Name
1	Switched-mode power supply	9	Liquid pump
2	Power cable	10	Air pump
3	Filter	11	Master control board (PCBA)
4	Stepper motor	12	Driver board (PCBA)
5	Three-way solenoid valve	13	Unlimited sample probe
6	Two-way solenoid valve	14	Wiper

Troubleshooting

No.	Name	No.	Name
7	WBC chamber	15	Touch screen
8	RBC chamber	16	Display

Warning

All the parts other than the fuse shall be replaced by manufacturer or the authorized distributor. Otherwise, the user shall assume all the responsibilities.

Appendix A Analyzer Information

A.1 Parameter explanation

The Analyzer yields 25 parameters, two histograms, one three-dimension scatter plot, and four two-dimension scatter plots. See the table below for the detailed explanation.

Table A-1 Parameter description

Full name	Abbr.	Unit
WBC	WBC	10 ⁹ /L
Basophils number		10 ⁹ /L
Basophils percentage	Bas%	%
Neutrophils number		10 ⁹ /L
Neutrophils percentage	Neu%	%
Eosinophils number	Eos#	10 ⁹ /L
Eosinophils percentage	Eos%	%
Lymphocytes number		10 ⁹ /L
Lymphocytes percentage	Lym%	%
Monocytes number	Mon%	10 ⁹ /L
Monocytes percentage	Mon%	%
Red Blood Cell count	RBC	10 ¹² /L
Hemoglobin Concentration	HGB	L
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	L
Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV	%
Red Blood Cell Distribution Width - Standard Deviation	RDW-SD	fL
Hematocrit	HCT	%
Platelet count	PLT	10 ⁹ /L
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	fL
Plateletcrit	PCT	%
Platelet-Large Cell Ratio	P-LCR	%

Full name	Abbr.	Unit
Platelet-Large Cell Count	P-LCC	10 ⁹ /L

Table A-2 Histogram description

Full name	Abbr.
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram

Table A-3 Scatter plot description

Full name	Abbr.
3D Differential Scattergram	3D Diff Scattergram
2D Differential Scattergram	2D Diff Scattergram
WBC/BASO Scattergram	WBC/BASO Scattergram

A.2 Accessory list

The accessory list is as follows:

Table A-4 Accessories

No.	Name	No.	Name
1	Power cable	6	External ground wires
2	Fuse	7	Repair parts package
3	Liquid waste container	8	Capacitive stylus pen
4	Diluent connection assembly	9	Thermal printer paper (only for Z52 VET)
5	Waste connection assembly	10	RFID reader (only for Z52 VET)