Z50 SERIES

AUTO HEMATOLOGY ANALYZER

SERVICE MANUAL

CE

Second edition(November 2022)

Intellectual Property

Trade mark

Responsibility on the Manufacturer Party

Contents of this manual are subject to changes without prior notice.

All information contained in this manual is believed to be correct. Zybio shall not be liable for errors contained herein nor for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Zybio is responsible for the effects on safety, reliability, and performance of this product, only if:

All installation operations, expansions, changes, modifications, and repairs of this product are conducted by Zybio authorized personnel.

The electrical installation of the relevant room complies with the applicable national and local requirements.

The product is used in accordance with the instructions for use.

Warning

- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
- Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.

Note

This equipment must be operated by skilled/trained clinical professionals.

Warranty

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

Exemptions

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

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Customer Service Department

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Revision history

Edition	Release date	Contents revised
01	2019	First release
02	November 15, 2022	1. Update the analyzer’s model type and specifications. 2. Update the analyzer’s diagrams.

Contents

1 Using this manual

1.1 Overview

This chapter describes how to use the service manual. In this manual, the repair methods of Z50 series are described in detail. Before servicing Z50 series, please carefully read and understand the content in order to properly carry out maintenance procedures and ensure the safety of service personnel.

This manual must be used in conjunction with the Z50 series Operator's manual. It does not contain information and procedures already covered in the Operator's manual of Z50 series.

Note

Be sure to operate and service the analyzer strictly as instructed in this manual and the operator's manual.

1.2 Who should read this manual

This manual is intended to be read by service professionals who:

- Have comprehensive knowledge of circuitry and fluidics.
- Have comprehensive knowledge of reagents.
- Have comprehensive knowledge of quality control.
- Have comprehensive knowledge of troubleshooting.
- Are familiar with the operations of the system.
- Are able to use basic mechanical tools and understand the terminology.
- Are skilled users of the digital voltmeter and oscillograph.
- Are able to analyze the circuit diagrams and fluidic charts.

1.3 Conventions used in this manual

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

Format	Meaning
[××]	all capital letters enclosed in [ ] indicate a key name (either onthe pop-up keyboard or the external keyboard)
"××"	letters included in " " indicate text you can find on the screen of Z50 series
××	italic letters indicate titles of the chapters that are referred to

All illustrations in this manual are provided as examples only. They may not necessarily reflect youranalyzer setup or data displayed.

1.4 Safety information

You will find the following symbols in this manual.

Symbol	Meaning
	Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
Warning	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
Caution	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
Note	Read the statement below the symbol. The statement is alerting youto information that requires your attention.

- All the samples, controls, calibrators, reagents, wastes, and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
- If the main unit of the instrument leaks, the leaked liquid is potentially biohazardous.

Warning

- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
- Never use combustible gas (e.g. anesthetic) or combustible liquid (e.g. ethanol) around the analyzer. Otherwise, the risk of explosion may exist.
- Contacting exposed electronic components while the equipment is attached to power can cause personal injury from electric shock or damage to electronic components. Power down before removing covers to access electronic components.
- Connect the analyzer to a socket having sole fuse and protective switch. Do not use the same fuse and protective switch with other equipment (e.g. life supporting equipment). Otherwise, the equipment failure, over current or impulse current that occurs at the startup moment may lead to tripping.
- To prevent personal injury during the maintenance, keep your clothes, hairs, and hands from the moving parts, such as the sample probe.
- Possible mechanical movement of the warned position may lead to personal injury duringnormal operation, removal, maintenance, and verification.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- The reagents are irritating to eyes, skin, and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures whenhandling them in the laboratory.
- If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them offwith plenty of water and immediately go see a doctor.

Caution

- Improper maintenance may damage the analyzer. Maintain the analyzer strictly as instructed by the service manual and inspect the analyzer carefully after the maintenance.
- For problems not mentioned in the service manual, contact Zybio customer service department for maintenance advice.
- To prevent personal injury or damage to equipment components, remove metal jewelry before maintaining or servicing electronic components of the equipment.
- Electrostatic discharge may damage electronic components. If there is a possibility of ESD damage with a procedure, then do that procedure at an ESD workstation, or wear an antistatic wrist strap.

Note

- The operator is required to follow the instructions below this symbol.
- The instructions will emphasize important information or information that requires particular attention of the operator.

1.5 When you see...

The analyzer system may contain the following symbols:

Caution

Ensure the labels are in good condition and not damaged while servicing the analyzer.

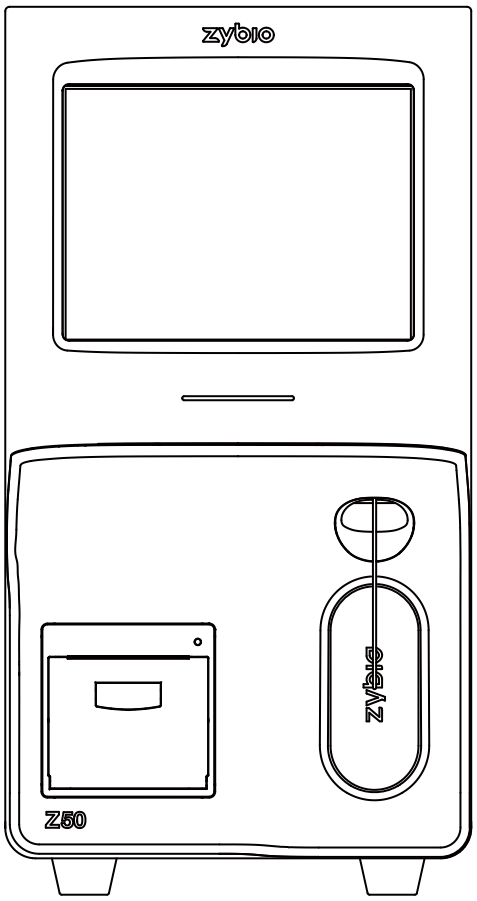
When you see…	It means…
	Indicates the need of taking care regarding the hazard specified by the supplementary sign; the user needs to consult the instructions for use (yellow background).
	Indicates that there are potential biological risks associated with the medical device, necessary to consult instructions for use for details.
	Indicates the presence of the CLASS 3B laser radiation when open. Avoid exposure to the beam.
	Indicates the protective earth (ground) terminal.
	Indicates the USB interface.
	Indicates the connecting terminals of the computer network.
	Indicates that the device is suitable for alternating current only.

When you see…	It means…
IVD	Indicates the instrument that is intended to be used as an in vitro diagnostic medical device.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date after which the medical device is not to be used.
SN	Serial number
	Indicates the date when the medical device was manufactured.
	Indicates the need of taking care to avoid injury from sharp elements.
	Indicates the medical device manufacturer.
	Indicates that distribution packages shall be stored, transported, and handled within temperature limits.
	Indicates the need for the user to consult the instructions for use.
CE	Indicates the CE marking of conformity.
	This electronic product contains certain toxic substances, and has an Environmental Protection Use Period (EPUP) of 20 years. It canbe used safely during the EPUP, but shall be recycled after the EPUP.

2 Product specifications

2.1 Product name

- **Name:** Auto Hematology Analyzer
- **Model:** Z50 series
- Appearance:



2.2 Models

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

Table 2-2 Differences among the models

Models	Functional configuration	Software		
		Name	Model	Release version
Z50	The throughput of Z50 is 60 tests per hour. It has an external RFID reader.	5-part Differential Hematology	Z50	V02

Models	Functional configuration	Software		
		Name	Model	Release version
Z52	The throughput of Z52 is 40 samples per hour. Its RFID reader is built-in.	Analyzer Operating Software	Z52	V02

2.3 Physical specifications

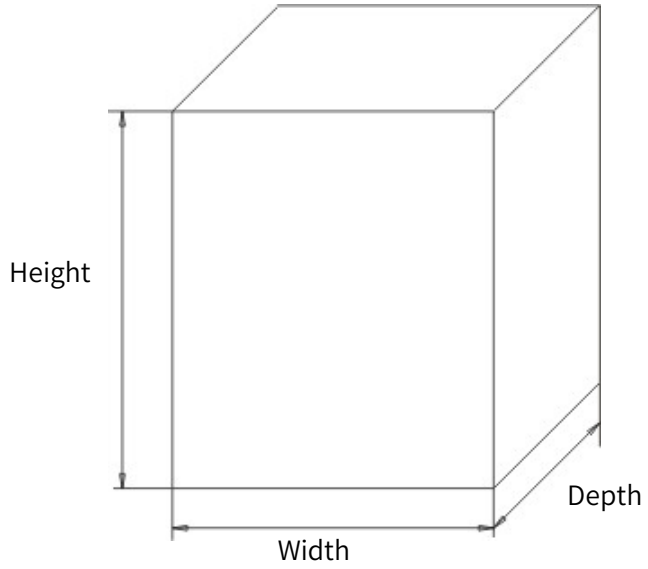


Table 2-1 Dimensions and weight

Z50 series	Whole device
Dimensions	Depth: 455 mm Width : 230 mm Height : 435 mm (rubber feet included)
Weight	⩽ 35Kg

2.3.1 Electrical specifications

Table 2-2 Main unit power supply

Parameter	Value
Voltage	(100V-240V~) ±10%
Input Power	⩽200VA
Frequency	50/60±1Hz

Warning

Only fuses of specified specification shall be used.

Fuse Specification: 250 V T6.3 AH.

2.3.2 Environment requirements

Operating environment, storage environment and running environment:

Table 2-3 Overall environment requirements

Environmental Requirements	Operating	Storage	Running
Ambient Temperature	10°C～30°C	-10°C～40°C	10°C～40°C
Relative Humidity	20%～85%	10%～90%	10%～90%
Atmospheric Pressure	70kPa～106kPa	50kPa～106kPa	70kPa～106kPa

2.3.3 Product specifications

- Measurement mode

Two measurement modes are provided: CBC and CBC+DIFF.

- Sample mode

Two sample modes are provided: WB (whole blood) mode and PD (pre-diluted) mode.

- Throughput

The throughput of Z50 is 60 tests per hour. The throughput of Z52 is 40 samples per hour.

2.4 Testing parameters

The analyzer provides quantified results for 25 report parameters and 4 research parameters, one 3-D DIFF scatter gram, one 2-D BASO scatter gram, RBC & PLT histograms. See the table below for details.

Table 2-4 Parameters

Name	Abbreviation	UNIT	CBC	CBC + DIFF
White Blood Cell count	WBC	10^9 /L	√	√
Basophils number	Bas#	10^9 /L	/	√
Basophils percentage	Bas%	%	/	√
Neutrophils number	Neu#	10^9 /L	/	√
Neutrophils percentage	Neu%	%	/	√
Eosinophils number	Eos#	10^9 /L	/	√
Eosinophils percentage	Eos%	%	/	√
Lymphocytes number	Lym#	10^9 /L	/	√
Lymphocytes percentage	Lym%	%	/	√
Monocytes number	Mon#	10^9 /L	/	√
Monocytes percentage	Mon%	%	/	√
Percentage of Abnormal Lymphocytes	ALY%(Research parameters)	10^9 /L	/	√
Percentage of Large Immature Cells	LIC%(Research parameters)	%	/	√

Name	Abbreviation	UNIT	CBC	CBC + DIFF
Number of Abnormal Lymphocytes	ALY#(Research parameters)	10^9 /L	/	√
Number of Large Immature Cells	LIC#(Research parameters)	%	/	√
Red Blood Cell count	RBC	10^{12} /L	√	√
Hemoglobin Concentration	HGB	g/L	√	√
Mean Corpuscular Volume	MCV	fL	√	√
Mean Corpuscular Hemoglobin	MCH	pg	√	√
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L	√	√
Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV	%	√	√
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	%	√	√
Platelet-Large Cell Count	P-LCC	10^9 /L	√	√

Table 2-5 Histograms

Name	Abbreviation	CBC	CBC + DIFF
Red Blood Cell Histogram	RBC Histogram	√	√
Platelet Histogram	PLT Histogram	√	√

Table 2-6 Scatter grams

Name	Abbreviation	CBC	CBC + DIFF
3D Differential Scatter gram	3D Diff Scatter gram	/	√
2D Differential Scatter gram	2D Diff Scatter gram	/	√
WBC/BASO Scatter gram	WBC/BASO Scatter gram	/	√
WBC Scatter gram	WBC Scatter gram	/	√

2.5 Performance requirements

2.5.1 Background/blank count

Background refers to the background count performed automatically by the analyzer during thestartup process; its result shall meet the requirements in the following table.

The blank count requirements apply to both whole blood and pre-dilute modes.

Blank count test method: run diluent on the analyzer consecutively for 3 times, the highest value among the 3 results shall meet the requirements in the following table.

Table 2-6 Background/blank count requirements

Parameter	Background/blank count requirements
WBC	⩽ 0.20×10^{9} / L
RBC	⩽ 0.02×10^{12}/ L
HGB	⩽1 g/L
HCT	⩽ 0.5 %
PLT	⩽ 5×10^{9} / L

2.5.2 Carryover

Carryover refers to the transfer of blood cells from high concentration sample to low concentration sample.

Verification method:

Prepare a high concentration sample (centrifuged high value control or special high value linearity control) which is within the range specified in Table 2-6, mix and then test it consecutively for 3 times, and the test results are i1, i2, and i3; prepare a low concentration sample (diluted low value control, dilution ratio: 1:10) which is within the range specified in Table 2-8, test it consecutively for 3 times, and the test results are j1, j2, and j3. Calculate the carryover according to the following equation, and the result shall meet the requirements in Table 2-7.

$$carryover = \frac{(j1 - \mathrm{j3})}{(\mathrm{i3} - j3)} \times 100\%$$

Table 2-7 Carryover Requirements

Parameter	Carryover
WBC	⩽0.5%
RBC	⩽0.5%
HGB	⩽0.5%
HCT	⩽0.5%
PLT	⩽1.0%

2.5.3 Repeatability

Test a sample which meets repeatability requirement on the analyzer consecutively for 10 times, calculate the CV(%) and absolute deviation (*d*) of each parameter, and the results shall meet the requirements in the following table.

$$CV = s/\overline{x} \times 100\%$$

$$d = x_i - \overline{x}$$

In the equation:

s— standard deviation of sample test results.

$\overline{x}$— mean value of sample test results.

x_i—actual test result of the sample.

d— absolute deviation of the sample test results.

Table 2-8 Whole Blood Repeatability Requirements

Parameter	Condition	Whole Blood Repeatability (CV/absolute deviation d)	Pre-dilute Repeatability (CV/absolute deviation d)
WBC	3.5×10^9/L～6.9×10^9 / L	⩽2.5%	⩽4.0%
	7.00×10^9/L～15.00×10^9 / L	⩽2.0%	⩽4.0%
Neu%	50.0%～70.0%	±4.0(d)	±8.0(d)
Lym%	20.0%～40.0%	±3.0(d)	±6.0(d)
Mon%	5.0%～10.0%	±2.0(d)	±4.0(d)
Eos%	2.0%～5.0%	±1.5(d)	±2.5(d)
Bas%	0.5%～1.5%	±0.8(d)	±1.2(d)
RBC	3.50×10^{12} / L ~ 6.00×10^{12} / L	⩽1.5%	⩽3.0%
HGB	110 g/L ~ 180 g/L	⩽1.5%	⩽3.0%
MCV	70 fL～120 fL	⩽0.5%	⩽2.0%
PLT	100×10^9 / L ~ 149 $\times10^9$ / L	⩽6.0%	⩽10.0%
	150×10^9 / L ~ 500×10^9 / L	⩽4.0%	⩽8.0%
MPV	/	⩽4.0%	⩽8.0%

2.6 Linearity

Linearity was determined by running diluted samples. Samples of different concentrations were tested in both whole blood and pre-dilute modes; the slope and intercept were calculated per the linear regression equation, and then the deviation between the theoretical value and test result was obtained, which shall meet the requirements in the following table.

Table 2-9 Linearity Requirements

Parameter	Linearity Range	Deviation Range (Whole Blood)	Correlation Index
WBC	0.0～100.0×10^9/L	±0.50×10^9/L or 5%	⩾0.990

Parameter	Linearity Range	Deviation Range (Whole Blood)	Correlation Index
	100.1 ～ 500.0×10^9/L	±10%	
RBC	0.0～8.00×10^{12}/L	±0.05 ×10^{12}/Lor ±5%	⩾0.990
HGB	0～250 g/L	±2g/L or ±2%	⩾0.990
PLT	0～1000×10^9/L	±10×10^9/L or ±8%	⩾0.990
	1001 ~ 5000×10^9/L	±12%	
HCT	0~67%	±2% (HCT value) or ±3% (deviationpercent)	⩾0.990

Note: The linearity ranges above are expressed in both absolute deviation and deviation percent, meetingeither of the ranges are OK.

2.7 Product description

Z50 series Auto Hematology Analyzer is mainly composed of the analysis module, information management module, result output module and accessories.

Warning

The analyzer is heavy. Do not try to carry it by oneself, or serious injury may be caused. It requires at least two persons to transport the analyzer. Use necessarytools if possible.

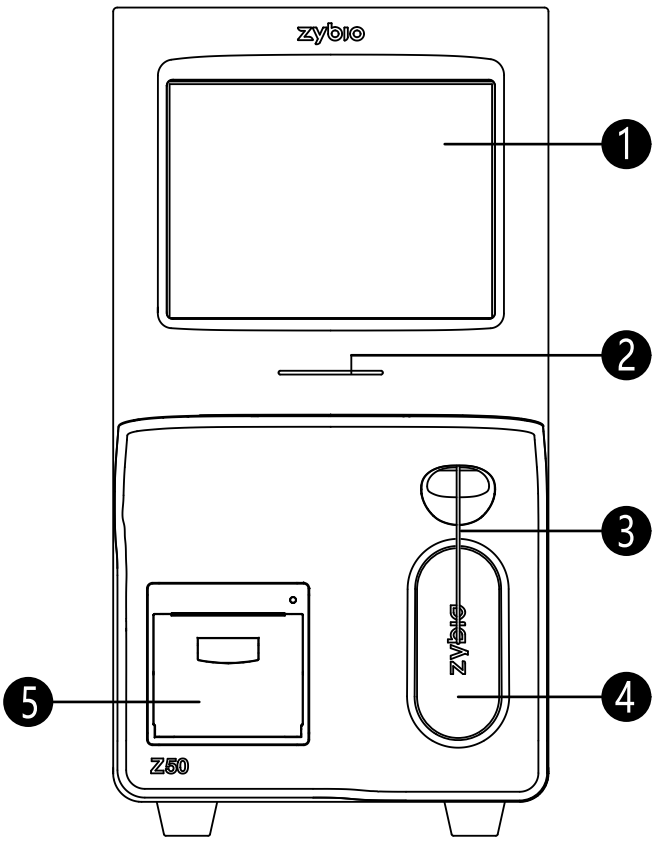


Figure 2-1 Z50 Front view

No.	Parts	No.	Parts
1	Touch screen	2	Indicator light
3	Sample probe	4	Aspirate key
5	Built-in thermal printer		

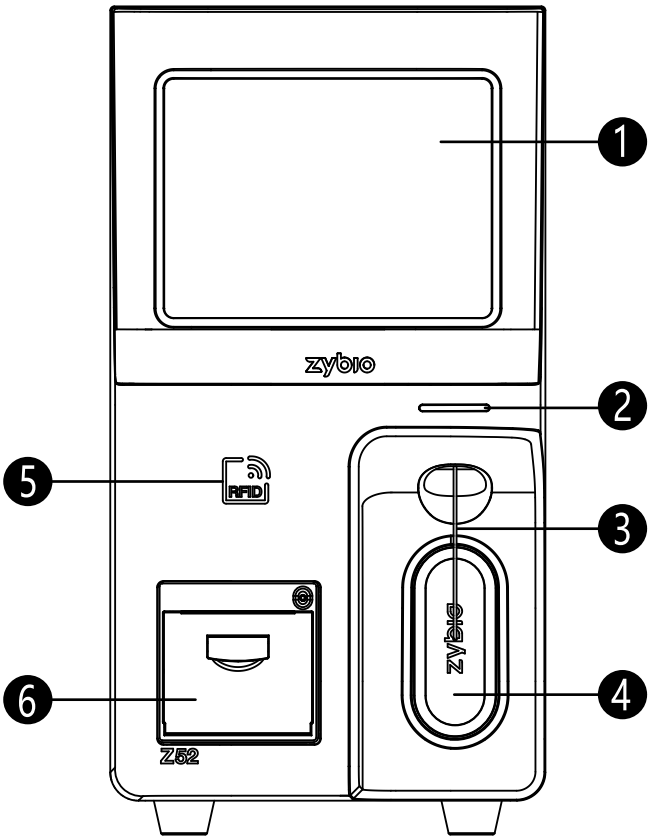


Figure 2-1 Z52 Front view

No.	Parts	No.	Parts
1	Touch screen	2	Indicator light
3	Sample probe	4	Aspirate key
5	RFID Reader	6	Built-in thermal printer

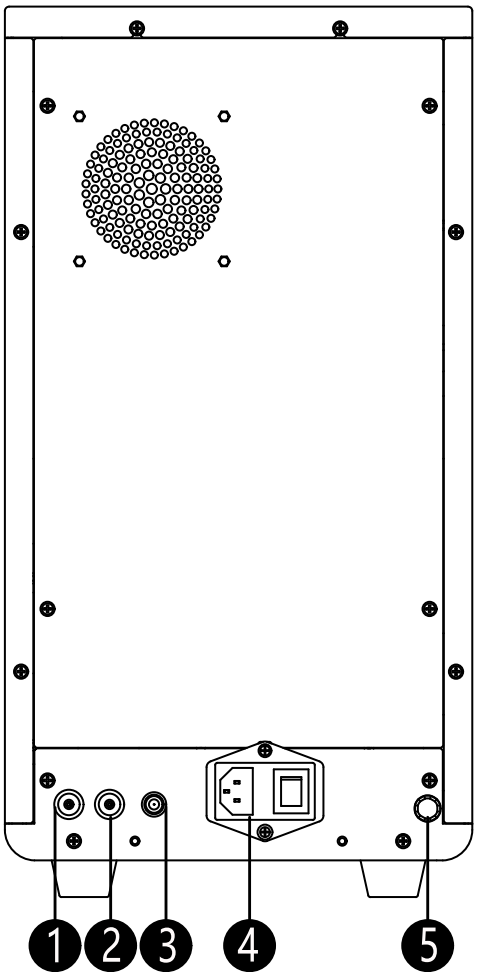


Figure 2-2 Back of the analyzer

No.	Parts	No.	Parts
1	Diluent tube port	2	Waste tube port
3	Liquid waste sensor	4	Power source subassembly
5	Protective earthing		

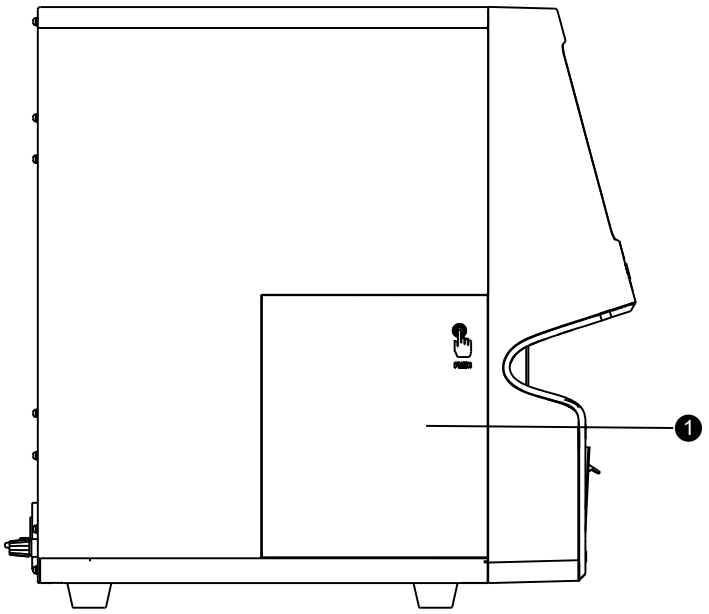


Figure 2-3 Left side of the analyzer

No.	Parts
1	Reagent chamber door

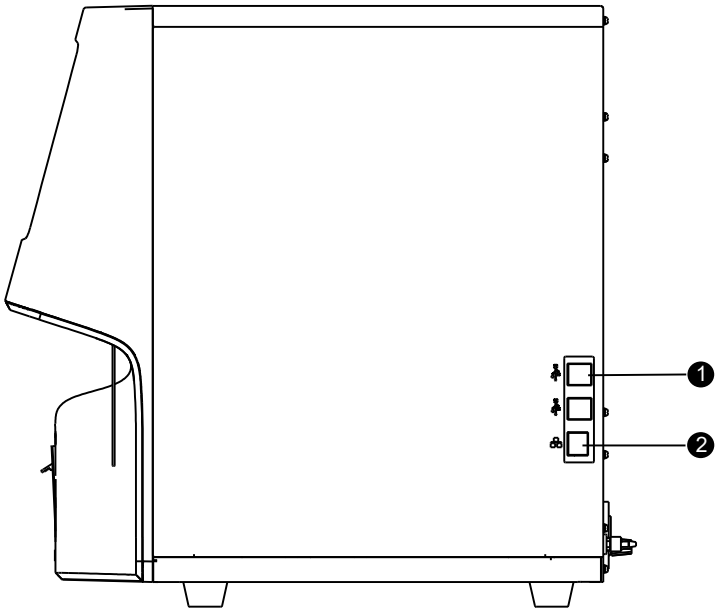


Figure 2-4 Right side of the analyzer

No.	Parts
1	USB interface
2	Network interface

2.7.1 Main unit

The main unit performs sample analysis and data processing. It is the main part of the instrument.

2.7.2 Power/status indicator

The power/status indicator tells you about the status of the analyzer including ready, running,error, standby and on/off, etc.

2.7.3 Power input socket

The power input socket is at the back of the main unit. It is used to turn on or off the analyzer.

Caution

Once you turn on/off the analyzer, do not operate the power switch again in 10 seconds, or it may cause damage to the analyzer.

2.7.4 [Aspiration] key

The [Aspiration] key is used to start the analysis, dispense diluent, or exit the standby mode.

2.7.5 USB ports

The analyzer has 4 USB ports on the back panel of the main unit to connect peripherals andtransmit data.

2.8 Product configuration

By standard configuration, the instrument includes the main unit, standard accessories, and the reagents. We also provide external barcode scanner and printer as optional accessories.

Connect the printer through the USB ports. Printer supports PCL 6 series driver.

2.9 Reagents, controls, and calibrators

As the analyzer, reagents, controls, and calibrators are components of a system, performance of the system depends on the combined integrity of all components which are formulated specifically for the fluidic system of your analyzer in order to provide optimal system performance. Do not use the analyzer with reagents from multiple suppliers. In such use, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.

Each reagent package must be examined before use. Product integrity may be compromised in packages that have been damaged. Inspect the package for signs of leakage or moisture. If anysign of leakage or moisture is found, do not use the reagent.

Note

- Store and use the reagents as instructed by instructions for use of the reagents.
- When you have changed the diluent, lyses, run a background to see if the results meet the requirement.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.
- After installing a new container of reagent, keep it still for a while before use.

2.9.1 Reagents

- Diluent

  Diluent is formulated to dilute the blood samples. It is used to determine the count and size distribution of blood cells.

- DIFF LYSE

  Used for lysing red blood cells to categorize quartile groups of white blood cells.

- LB LYSE

  Used for lysing red blood cells to achieve functions such as white blood cell counting, classification ofbasophils and hemoglobin measurement.

- Probe Cleanser

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

2.9.2 Controls and calibrators

The controls and calibrators are used for the analysis quality control and calibration of the analyzer.

The controls are suspension of stimulated human blood, specifically manufactured to monitor and evaluate the analysis precision of the analyzer. The controls are prepared with three levels, namely low, normal, and high. The calibrators are also suspension of stimulated human blood, specifically manufactured for the calibration of the analyzer, so as to build the metrological traceability of analysis results. For the use and storage of controls and calibrators,please refer to the Instruction for Use of each product.

All references related to the controls and calibrators in this manual refer to the “controls” and “calibrators” Zybio specifically formulated for Z50 series by Zybio.

2.10 Information storage capacity

Table 2-10 Data storage requirements

Data storage capacity	Z50 series: 50,000 samples
Information	The information stored should at least include the following: result information, scatter grams, histograms, patient information, flags as well as any special information of the analyzer.

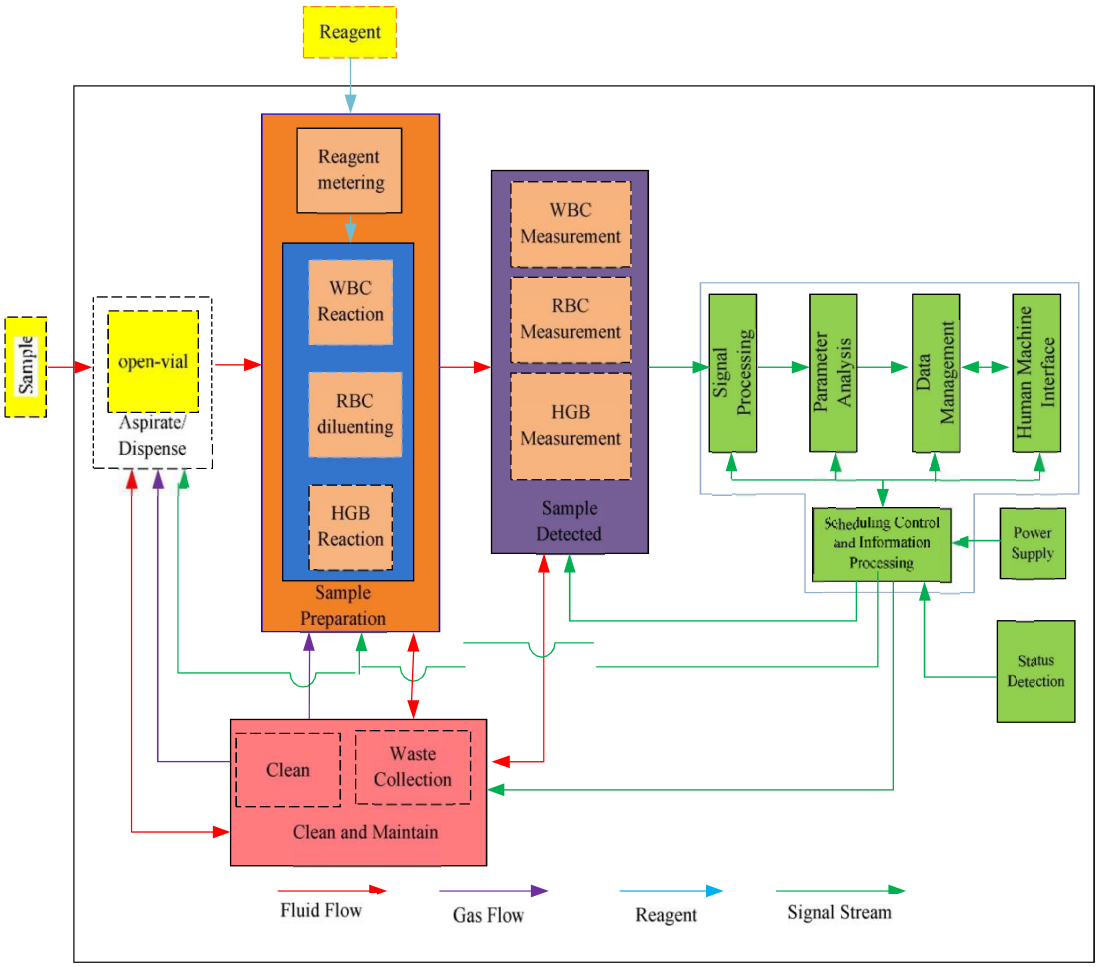
3 System principles

3.1 Introduction

This analyzer employs Coulter principle to test RBC and PLT amount, colorimetric method to measure the hemoglobin concentration, and semiconductor laser flow cytometry to obtain differential statistics of white blood cells. The analyzer will calculate the other parameters based on these results.

3.2 Analyzer workflow

We have defined the whole operation workflow of the analyzer by its major functions: reagent system, sample aspirate and distribution, sample preparation, sample measurement, signal processing, parameter analysis, status monitoring, scheduling control and information processing, human machine interface, power supply as well as cleaning and maintenance. The relationships between the functions are illustrated as below:



The scheduling control and information processing module coordinates and regulates other functional modules to work by defined process and requirements, so as to ensure the completing of sample measurement, the ultimate task of the analyzer.

3.3 Aspiration

If you want to analyze a whole blood sample, present the sample to the analyzer directly, and the analyzer will aspirate 18μL of the whole blood sample.

If you want to analyze a capillary blood sample under the pre-dilute mode, you should first manually dilute the sample (20μL capillary sample needs to be diluted by 480ul of diluent to form a 1:25 dilution), and then present the pre-diluted sample to the analyzer for testing.

3.4 Dilution

Usually in blood samples, the cells are too close to each other to be identified or counted. For this reason, the diluent is used to separate the cells so that they draw through the aperture one at a time as well as to create a conductive environment for cell counting. Moreover, red blood cells usually outnumber white blood cells by 500-1000 times. Because red blood cells usually have no nucleus, they are eliminated when the lyse breaks down their cell walls. For this reason, lyse need to be added to the sample to eliminate the red cells before the WBC counting. The analyzer provides whole blood mode and pre-dilute mode for the analysis of different sample types.

3.5 Wbc measurement

Laser flow cytometry

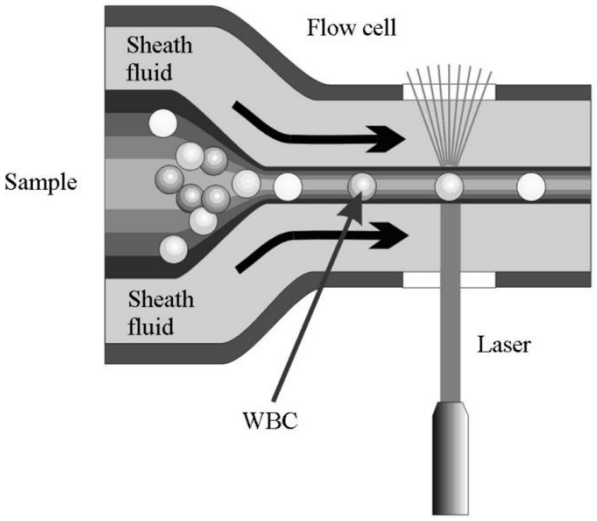


Figure 3-1 Metering diagram

After the blood sample is mixed with the lyse, the red blood cells will be dissolved, and the white blood cells will be dyed. Through the sample probe, the dyed white blood cell and fragments of red blood cell are injected into the flow cell, which is filled with the diluent. Wrapped in the sheath fluid formed by the diluent, the cells go through the laser detection area in rows after a secondary acceleration. When the cells are exposed to laser beam, the scattered light is related to the cell size and the refractive index of both the cell membrane and the internal structure. These scattered light signals are received and converted into electrical pulses by the photodiode. From these electrical pulses, a two-dimensional distribution map of the cell size and internal information and be obtained, which is called a scatter gram. From the WBC scatter gram and histogram, the white blood cell differential and count can be obtained.

3.6 Hgb measurement

The HGB is determined by the colorimetric method. The diluted sample is delivered to the WBC count bath where it is bubble mixed with a certain amount of lyse, which breaks red blood cells, and converts hemoglobin to a hemoglobin complex. An LED is mounted on one side of the bath and emits a beam of monochromatic light with central wavelength of

530~535nm. The light is received by an optical sensor mounted on the opposite side, where the light signal is first converted to current signal and then to voltage signal. The voltage signal is then amplified and measured and compared to the blank reference reading (reading taken when there is only diluent in the bath), and the HGB (g/L) is measured and calculated automatically. The whole measurement and calculation process is completed automatically.

You can review the results in the analysis result area on the "Sample Analysis" screen. HGB is expressed in g/L.

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

3.7 Rbc/plt measurement

3.7.1 Impedance method

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

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

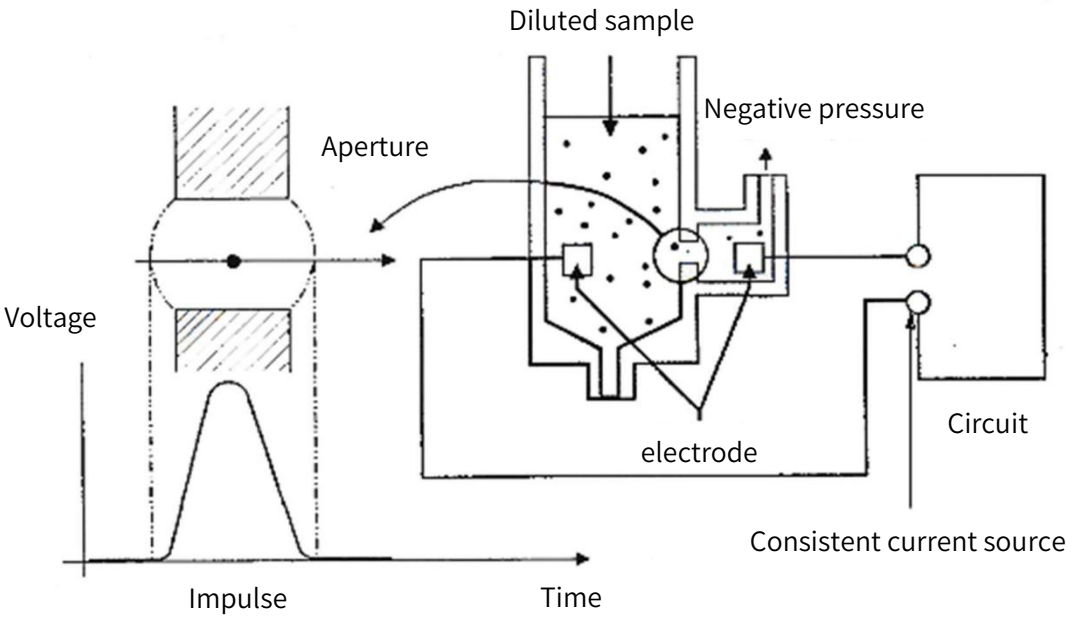


Figure 3-2 Metering diagram

3.7.2 Rbc-related parameters

- Red Blood Cell count

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

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

- Mean Corpuscular Volume

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

- HCT, MCH and MCHC

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

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

$$\mathrm{MCT}=\frac{\mathrm{HGB}}{\mathrm{RBC}}$$

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

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

- RDW-CV

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

- RDW-SD

  Red blood cells distribution width - standard deviation (RDW-SD, in fL) measures the width of the 20% level (with the peak taken as 100%) on the RBC histogram, as shown in Figure 3-3.

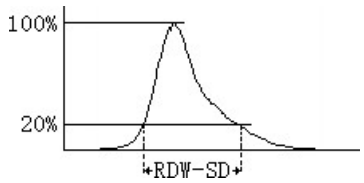


Figure 3-3

- Red blood Cell Histogram

  Besides the count results, the analyzer also provides a RBC histogram which shows the RBC size distribution, with the x-axis representing the cell size (in fL) and the Y-axis representing relative cell number (in 10^{12}/L) (as shown below). With a normal blood samples, the RBCs mostly fall in the region of 70~120fl.

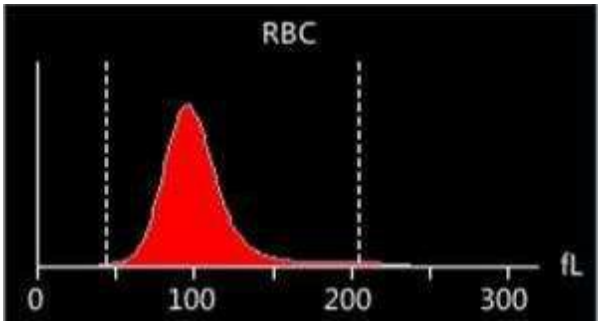


Figure 3-4

After each analysis cycle, you can either check the RBC histogram in the analysis result area on the "Sample Analysis" screen or review the histogram on the "Review" screen.

3.7.3 Plt-related parameters

- Platelet count

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

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

- Mean Platelet Volume

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

- PDW

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

- PCT

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

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

- Platelet-Large Cell Ratio

  The analyzer calculates the number of platelets larger than 12fl in size based on the platelethistogram and then derives the large platelet ratio (%).

- Platelet Histogram

  Besides the count results, the analyzer also provides a PLT histogram which shows the PLT size distribution. As shown in below, most PLTs of a normal blood sample should fall into the 0~20fl region, with the x-axis representing the cell size (in fL) and the Y-axis representing relative cell number (in 10^9/L).

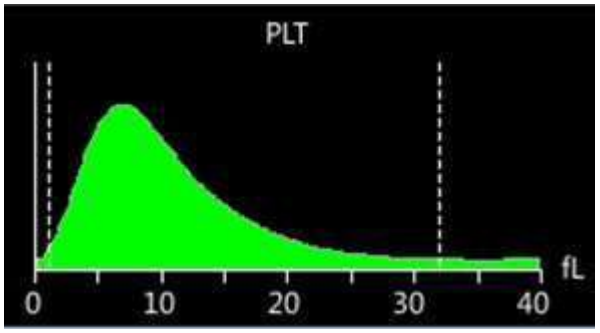


Figure 3-5

After each analysis cycle, you can either check the PLT histogram in the analysis result area on the "Sample Analysis" screen or review the histogram on the "Review" screen.

3.8 Wash

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

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

4 Software and interface

4.1 Calibration

4.1.1 Calibration factors and transfer factor

Calibration is performed to ensure the analyzer may deliver accurate sample analysis results. During the calibration process, a calibrator factor will be calculated. This factor will be used to multiply with the analysis results to output the final results. When running a calibrator, the analysis results after being adjusted by the factor should be as close to its assigned targets. Thus the calibrator factoris derived by below formula:

$$\text{Calibration factor} = \frac{\text{the target result}}{\text{the analysis result}}$$

There are two different analysis modes, CBC+DIFF and CBC. The two analysis modes respectively correspond to two fluidics sequence. Therefore, the analysis results of the same sample in different modes are different. However, this difference is relatively fixed. During calibration, it is only required to obtain the calibration factor of one mode. The calibration factor of the other mode can be calculated by multiplying this fixed difference coefficient, which is called the transfer factor.

The calculation equation of the transfer factor is:

$$\text{Transfer factor} = \frac{\text{CBC analysis result}}{\text{CBC+DIFF analysis result}}$$

There are two different sample modes, whole blood mode and prediluted mode, which also correspond to different fluidics sequence. Therefore, different sample modes need to be calibrated separately.

The calibration factors can be classified as factory calibration factor and user calibration factor. For the CBC+DIFF mode, the analysis result will be calculated by the following equation: Analysis result=measurement value * factory calibration factor * user calibration factor

For the CBC mode, the analysis result will be calculated by the following equation:

Analysis result = measurement value × factory calibration factor × transfer factor

- user calibration factor

The calibration will only generate calibration factors and transfer factors of five traceable parameters:WBC, RBC, HGB, MCV and PLT.

Caution

When you perform calibration at the service access level, the calibration factors of manufacturer will be modified, and the calibration factors of user will change to 100.00%.

4.1.2 Calibration with calibrator

Figure 4-1 Calibration at Service Access Level

When performing calibration with calibrator at service access level, the analyzer calculates all factory calibration factors automatically. **You need to run calibrator at least 5 times to calculate and save calibration factors. When 10 calibrations are done, a dialog box will be displayed prompting that calibration has been completed; and you will be prompted to save the new calibration factors whenexiting the screen.**

Before calibration, make sure to set up the lot numbers, expiration dates, analysis modes and the target values for the calibrators.

The calibration factors should fall into the range of [75%, 125%].

Caution

Never use expired calibrators.

Note

If the calibrated factors or CVs are out of allowable range, they will be displayed in red, andthe values cannot be saved.

4.2 Gain setup

You can set up the gain for HGB on the “Gain Setup” screen. Gains for other parameters areobtained by gain calibration and cannot be edited.

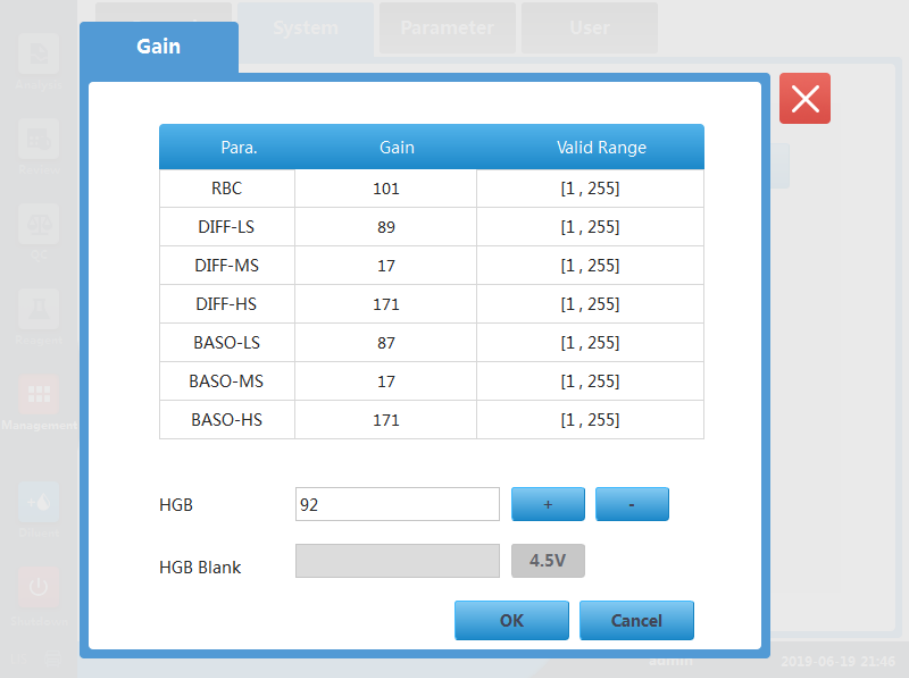


Figure 4-2 Gain Setup

Adjust the HGB gain by clicking + or – button to change HGB gain value to get HGB blank value around4.5±0.1V, then save HGB gain.

Note

As the gain settings affect the validity of analysis results, be careful when you adjust them.

4.3 Performance

4.3.1 Background count

Press the [Aspirate] key to start background count. You do not need to run actual samples. The background is acceptable only when all the result boxes display "pass" on the background count screen.

4.3.2 Reproducibility

Test a sample which meets reproducibility requirement on the analyzer for 10 times, and calculate the CV (%) and absolute deviation (d) of each parameter, and the results shall meet the reproducibilityrequirements.

Note

End users usually use normal controls to calculate the reproducibility.

4.3.3 Carryover

Make sure the analyzer is working properly and steadily. Run a high value sample consecutively for 3 times and then run a low value sample consecutively for 3 times. Calculate the carryover per below formula:

$$Carryover(\%) = \frac{First\ low - level\ sample\ result - Tird\ low - level\ sample\ result}{Third\ high - level\ sample\ result - Third\ low - level\ sample\ result} \times 100\%$$

4.4 Advanced toolbox

4.4.1 Export

You can use this function to export instrument information, software debug information, reproducibility test results, accuracy test results, factory calibration results, background test results, carryover results, aging data, as well as gain calibration results, system self-test results, version information, configuration information, inf. files, and user operation logs.

4.5 Software update

Note

- The USB should have been formatted to FAT32 before you copy and paste the “update” directory to it.
- Recommended USB models: Kingston 8/16G, SanDisk 8/16G and Maxell 4/8G.
- Make sure there is enough free space (at least 4G) on the USB.

- Prepare the USB for update

  Unzip the file named “update.tar.gz”, and then copy the “update” directory in the unzipped file tothe root directory of the formatted USB.

Note

The USB should have been formatted to FAT32 before you copy and paste the “update” directory to it.

- Update

  Insert the USB to one of the USB ports on the analyzer, and perform update.

Caution

Do not pull the USB or disconnect power during the update; otherwise, the analyzer may not start.

Note

The update usually takes some minutes, but depends on the number of modules to be updated. Do not leave the analyzer as the process requires user operation.

- When update fails

  If the update fails, try again.

4.6 Status indicator

The indicator on the front panel of the analyzer may light in 3 colors. When it flickers, it flickers at the frequency of 2 seconds. The relationships between the indicator status and the analyzer status are listed below:

Table 4-1 Status indicator

Analyzer status	Indicator	Remarks
Ready	Static green	Waiting for actions
Running	Flickering green	Performing actions
Running with error	Flickering red	Running, but there is/are error(s)
Error and not running	Static red	There is/are error(s), and the analyzer is not running
No error, but fluidic actions are not allowed	Static yellow	Startup initialization or standby, not involving fluidic actions
Enter/exit standby	Flickering yellow	Enter/exit standby

4.7 Buzzer

When there is any error, the buzzer gives out an alarm sound. Tap the touch screen to silent the buzzer; or when the errors are removed the alarm sound will stop automatically. The buzzer also sounds in other ways indicating different system status.

Table 4-1 Buzzer sounds

When...	The buzzer sounds	Remarks
Startup process completed	a short beep	Startup process is completed when the analyzer is started and ready foranalysis
Sample presentation/aspiration under open-vial mode is completed	2 short beeps	
On the analysis related screens (e.g. screens of sample analysis, QC, reproducibility, carryover, background, aging or gain calibration), press the [Aspiration] key to start analysis	A long beep	When there are dialog boxes popped out prompting further action, the buzzer may not sound.
Error	Long beeps at intervals	Tap the “Remove error” button tosilent the buzzer
Analyzer ready	1 short beeps	Analyzer gets ready from other status
The analyzer screen becomes black, and prompts “Please turn off the power of the analyzer!”	Silent	When there is/are error(s) during shut down process, the buzzer stops when the analyzer screen becomes black.
Analyzer ready	1 short beeps	Analyzer gets ready from other status

When...	The buzzer sounds	Remarks
The analyzer screen becomes black, and prompts “Please turn off the power of the analyzer!”	Silent	When there is/are error(s) during shut down process, the buzzer stops when the analyzer screen becomes black.

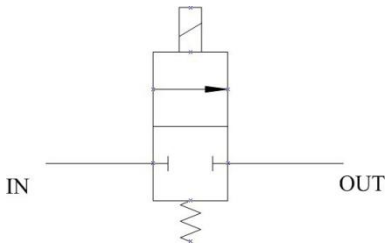
5 Fluidics

5.1 Introduction to fluidic parts

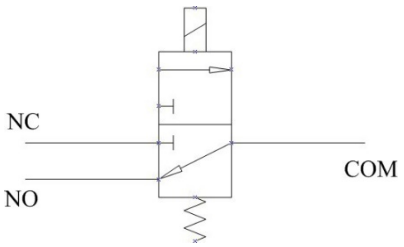
5.1.1 Valves

- Symbol:

2-way valve



3-way valve



- Appearance:

2-way valve

3-way valve

- Function:

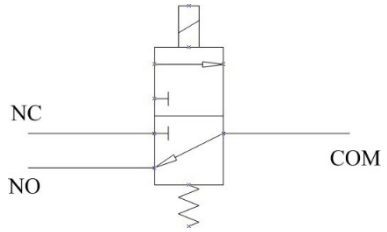
  (1) 2-way valve: to build up or cut off a passage. When power off, the passage from the inlet of the valveto outlet is cut off; when power on, the passage is built up.

  (2) 3-way valve: to switch among passages. When power off, the public end (COM) and the NO (normally open) end are connected; when power on, the public end and the NC (normally closed)end are connected.

Note: the operating voltage of valves is 12V, and maximal bearable pressure is 200KPa. The internal movement of the valves is driven by electromagnet and the restoration is driven by the spring, so it is recommended not put the valves power-on for too long. When the electromagnet valve is working, the spring pole will lower down, and it will rise to the initial position when power off. You can touch the valve body and feel to determine whether it is in action.

5.1.2 Lvm fluidic valve

- Symbol:



- Appearance:

3-way LVM fluidic valve

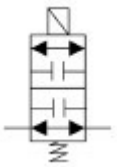
- Function:

  3-way valve: to switch among passages. When power off, the public end (COM) and the NO (normally open) end are connected; when power on, the public end and the NC (normally closed) end are connected. Compared with the 2-way valve, this valve bears higher pressure and has a pump with smaller action volume; so it may adapts to more strict flow control and greater temperature and pressure changes in.

  Note: the maximal bearable pressure of the LVM fluidic valve is 200KPa, and the CV of the flow isabout 0.03. The SV02 in the fluidic charts is LVM fluidic valve.

5.1.3 Pinch valve

- Symbol:



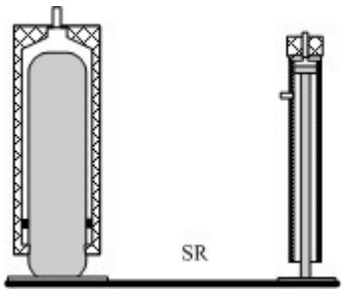
- Appearance:

- Function:

  A clamp-on type valve switched by electromagnetic force. Used for switching the fluid flow.

5.1.4 Linkage syringe device

- Symbol: SR



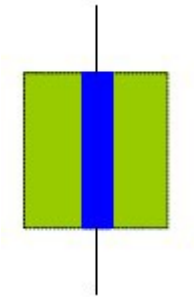
- Function: the linkage syringe device, driven by a motor and a unit of driving assembly, consists of two syringes: one with a high dispensing volume, the other with a low dispensing volume.

Table 5-1 Syringe specifications and functions

Name	Specification	Function
Low volume syringe	Full range is 250ul	Aspirate and dispense blood sample of precise volume, and perform second aspiration.
High volume syringe	Full range is 10ml	Dispense fixed volume of diluent to the WBC and RBC bathes, dispense liquid to the probe wipes, and supports the cleaning of the interior and exterior of sample probe as well as the baths.

5.1.5 Preheat bath

- Symbol

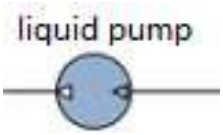


- Appearance:Preheat Bath

- Function: Used for heating DIFF reagents to ensure the temperature of DIFF reaction.

5.1.6 Vacuum pump

- Symbol:



- Appearance:

- Function: to empty probe wipes, WBC bath and RBC bath; empty the vacuum chamber and buildvacuum pressure in the chamber

5.1.7 Air pump

- Symbol:

- Appearance:

- Function: to provide pressure and generate bubbles for WBC and RBC chamber mixing.

5.1.8 Sample probe

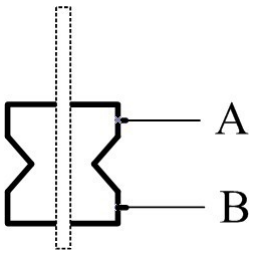
- Symbol:

- Appearance:

- Function: provides a rigid, blood corrosion-resistant cavity for aspiration and dispensing of sample andprobe cleanser.

5.1.9 Probe wipes

- Symbol:



- Appearance:

- Function: provide a cavity where the interior and exterior walls of open-vial probe or piercing probe can be cleaned by liquid flow; and the waste thus produced is also collected here.

5.1.10 Baths

- WBC bath: Used for providing a place for WBC sample reactions and supplying well reacted DIFF and BASO samples, and for HGB measurement.
- RBC bath: Consists of front bath, back bath, and an aperture. It is where the RBC sample is mixed for analysis; supports the measurement of RBC/PLT.
- Vacuum chamber: where a stable vacuum is built and stored to support RBC count (impedance method); and the front and back baths as well as the sample probe wipe are cleaned.
- Preheat bath: Used for heating DIFF reagents to ensure the temperature of DIFF reaction.
- WBC isolation chamber: Provides an air space to isolate exterior interference.
- RBC isolation chamber: Provides an air space to isolate exterior interference.

6 Hardware system

The hardware system not only consists of power board, main control board, indicator board, touch screen control board and liquid detection board, but also the electrified drives and components (e.g., motors, valves, pumps, sensors, screens, and power filters), as well as the cables connecting different boards or connecting boards and components.

6.1 System problem

Hardware system errors mainly include board errors, cable errors and component errors. The subsequent sections should have provided troubleshooting methods for most of such errors; but when the power supply to the hardware system is abnormal (for example, the analyzer cannot be powered on, or would start self-protect mechanism immediately after being powered on), you need to start troubleshooting from the system level. Figure 6-1 demonstrates the troubleshooting procedure for power supply errors. Figure 6-2 displays a power filter locating at the lower part at the rear of the analyzer. The power filter controls the power supply and frequency filtering of the analyzer. Figure 6-3 shows the troubleshooting flowchart for power-on protection.

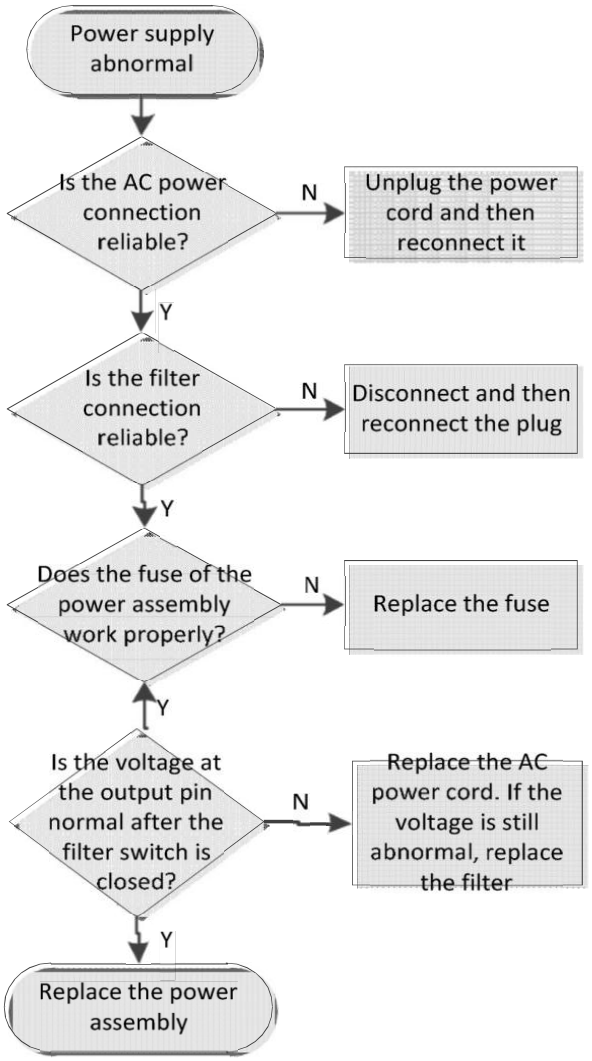


Figure 6-1 Troubleshooting for power supply problem

Figure 6-2 Power Filter

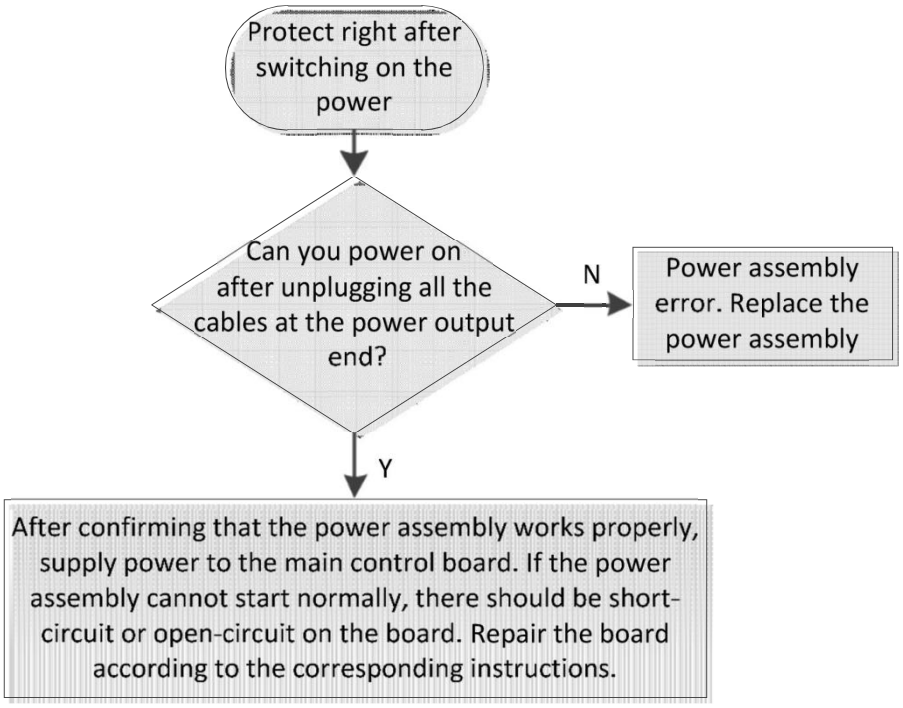


Figure 6-3 Troubleshooting for power-on protection problem

6.2 Main control board

6.2.1 Introduction

The main control board consists of analog module, digital module, and power drive module; among which, the analog module conditions and amplifies the signals from the impedance channel and HGB channel as well as other analog signals like monitoring voltages, and converts them into digital signals through the A/D converter. The digital module is responsible for the drive and control of mechanical parts as well as the processing, outputting, and communication of data. The power drive follows the instruction of CPU to drive the motors, valves, pumps, and heaters.

6.2.2 Components

The structure of the main control board is illustrated in figure 6-4. It mainly consists of digital circuits

and several ADC circuits for A/D conversion. The digital circuit module is responsible for processing data, saving, and outputting results. Furthermore, as the core of the main control board and even the whole hardware system, it takes the management and communication job. ADC circuits uses A/D converters to convert analog value monitoring signals (like WBC, RBC, PLT counts etc.) to digital signals. The control function of the main

control board is realized with a "CPU+FPGA" structure. The main control board mainly provides the following functions:

- A/D conversion
- Data processing
- Peripheral interface enabling
- Control interface extending

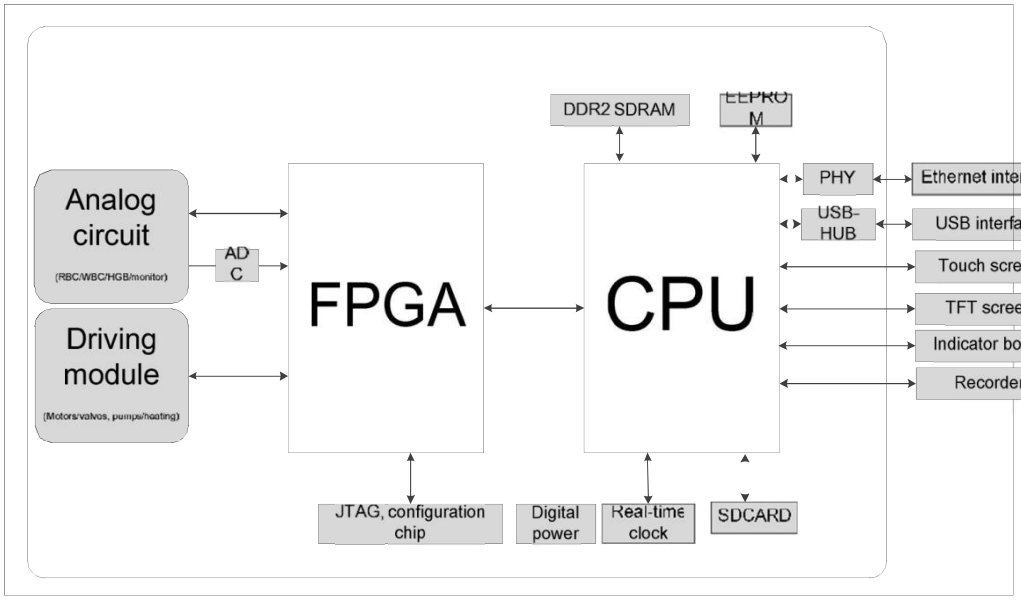


Figure 6-4 Main control board structure

Introduction

- Drive module

  Consists of motor drive and power component drive.

- A/D conversion

  Converts analog signals to digital signals which can be processed by FPGA or CPU.

- Data processing

  FPGA filters the digital signals collected during A/D sampling and saves the particular parameters. It then transmits the data to CPU by various means (like interrupt control) for further processing. The processed data will be displayed on the LCD screen.

- Peripheral interface enabling

  CPU module acts as the platform for software operation. It also enables the peripheral interfaces like indicator board interface, LCD display interface, Ethernet interface, USB printer interface, and the ports to barcode scanner, keyboard, and USB. Besides, it provides a JTAG interface for FPGA online programing, and a CPU debugging interface.

- Control interface extending

  Provide control logic and interfaces to the LCD screen, SD card, touch screen and recorder.

6.2.3 Troubleshooting for main control board

Table 6-1 lists the errors commonly found on the main control board as well as their solutions. However, the list only includes hardware errors and sometimes software errors may cause similarproblem. Also, many errors need to be detected by software.

Check the following items before troubleshooting the main control board:

- Check whether the cables connecting to the main control board get loose or insecure.
- Check whether the position No. marked on the cable correspond to the sockets there are connected to; and whether the cables are broken or damaged;
- Check whether the input power of sockets on the board are normal (measure the voltages with a multimeter).
- Check whether the indicators on the main control board work properly.

When you have confirmed all the cables are properly connected, all the input power andindicators work normally, follow the instruction in Table 6-1 for troubleshooting.

Table 6-1 Troubleshooting for main control board

No.	Error	Troubleshooting	Solution
1	LCD screen becomes black.	1. Check whether the cable connecting the main control board and the backlight socket, and the cable connecting the main control board and the LCD screen is properly connected. Unplug and then reconnect such cables. Power on the analyzer again and see whether the error is removed. If not, proceed to next step.	Unplug and reconnect the cable connecting the main control Board and the backlight and the cable connecting the main control board and the LCD screen.
		2. Replace the cable connecting the main control board and the backlight and the cable connecting the main control board and the LCD screen. If the error still exists, proceed to next step.	Replace the cable connecting the main control board and the backlight and the cable connecting the main control board and the LCD screen.
		3. Replace the LCD screen. If the error remains,proceed to next step.	Replace the LCD screen
2	LCD display flickers	1. Reconnect the cable connecting the main control board and the backlight socket, and the cable connecting the main control board and the LCD screen. Power on the analyzer again and see whether the error is removed. If not, proceed to next step.	Control board and the backlight and the cable connecting the main control board and the LCD screen.
		2. Replace the cable connecting the main control board and the backlight and the cable connecting the main control board and the LCD screen. If the error still exists, proceed to next step.	Replace the cable connecting the main control board and the backlight and the cable connecting the main control board and the LCD screen.
		3. Replace the main control board. If the error is removed, then the problem is caused by main control board. If not, proceed to next step.	Replace the main control board.

No.	Error	Troubleshooting	Solution
		4. Replace the LCD screen (screen assembly). If the error is removed, then the problem was caused by LCD assembly failure.	Replace the screen assembly
3	LCD displays strange patterns	1. Reconnect the cable connecting the main control board and the LCD screen. Power on the analyzer again and see whether the error is removed. If not, proceed to next step.	Reconnect the cable connecting the main control board and the LCD screen.
		2. Replace the cable connecting the main control board and the LCD screen. If the error still exists, proceed to next step.	Replace the cable connecting the main control board and the LCD screen.
		3. Replace the main control board. If the errorremains, proceed to next step.	Replace the main controlboard
		4. Replace the LCD screen (screen assembly). If the error is removed, then the problem was caused by LCD assembly failure.	Replace the screen assembly
4	Bad network connection	1. Check whether the IP of the PC falls in the same network segment of the main control board IP (192.168.0.X). When it is not, reset the IP of the PC to 192.168.0.1, and see whether the network connection is OK. If the network connection still fails, proceed to next step.	Set the IP of the PC to 192.168.0.1.
		2. When the analyzer is powered on and connected to PC, but network port LEDs do not light on, then the network connection is bad or the network cable is damaged. If can't solve problem, proceed to next step.	Reconnect or replace the network cable.
		3. Network port LEDs do not light on, but networkconnection is OK.	Replace the main controlboard
5	Clock time resets every time after startup	1. Power off the analyzer, and use a multimeter to measure the voltage between the two ends of the button cell. When the measured voltage is <1.8V, then the cell is with low power. If can't solve problem, proceed to next step.	Replace the buttoncell.

No.	Error	Troubleshooting	Solution
6	Analyzer gives no respond when the [Aspirate] key is pressed	1. Check whether the cable connecting to the [Aspirate] key gets loose or broken. If yes, reconnect the cable or replace it. 2. If the error remains after step 1, Disassemble the connecting board to the [Aspirate] key switch, and see whether there is liquid split on the switch. If yes, clean the liquid and re-install the board.	

6.3 Motor drive board

6.3.1 Introduction

The motor drive board consists of power drive module which is controlled by ARM to drive motorsvalves and pumps.

6.3.2 Components

The structure of the main control board is illustrated in figure 6-5. It mainly is controlled by power control, and monitors vacuum pressure. Power control consists of motors valves and pumps control. The control function of the motor drive board is realized with an “ARM+FPGA” structure. The m board mainly provides the following functions:

- Valves and pumps control
- Motors control
- Vacuum pressure monitoring

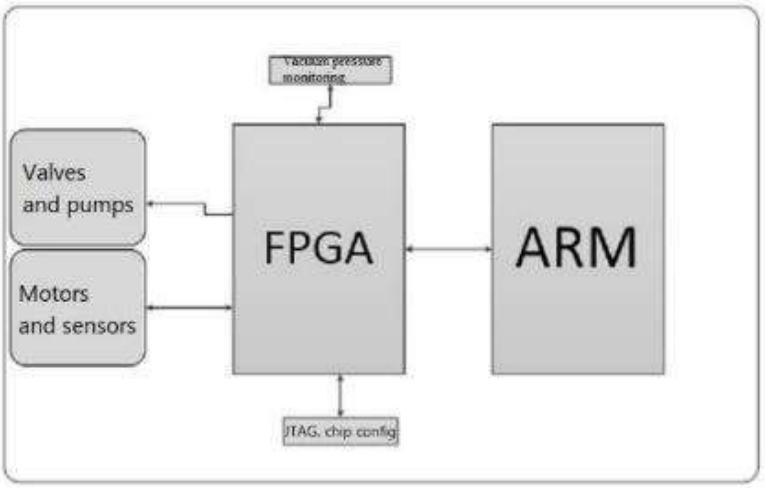


Figure 6-5 Motor drive board structure

Introduction

- Valves and pumps control module

  Drive valves and pumps
- Motors control module

  Drive motors and control motor steps
- Vacuum pressure monitoring

  Monitor Vacuum pressure

6.3.3 Troubleshooting for motor drive board

Table 6-2 lists the errors commonly found on the motor drive board as well as their solutions. However, the list only includes hardware errors and sometimes software errors may cause similarproblem. Also, many errors need to be detected by software.

Check the following items before troubleshooting the main control board:

- Check whether the cables connecting to the motor drive board get loose or insecure.
- Check whether the position No. marked on the cable correspond to the sockets there are connected to; and whether the cables are broken or damaged;
- Check whether the input power of socket on the board is normal (measure the voltages with a multimeter).
- Check whether the indicators on the motor drive board work properly.

When you have confirmed all the cables are properly connected, all the input power and indicators worknormally, follow the instruction in Table 6-2 for troubleshooting.

Table 6-2 Troubleshooting for motor drive board

Error	Troubleshooting	Solution		
Valves, pumps, or motors do notwork	1. Turn off power, check if communication cable of motor drive board and main control board is connected well, then reconnect it. Turn on power to check if problem is solved. If can’t solve problem, proceed to next step.	Reconnect motor drive board and main control board communication cable		
	2. Replace motor drive board to check if problem is solved. If can’t solve problem, proceed to next step.	Replace board	motor	drive
	3. Replace main control board to check if problem is solved.	Replace main control board		

6.4 Power board

6.4.1 Introduction

The power board provides the analyzer with 6 units of reliable power output, including DC 5V, +12V, -12V, DC110V and 24V.

Definition of interfaces

There are 2 interfaces to external systems on the power board.AC-L and AC-N are AC input connecting cables, wiring from the side of the board to the sockets. The interface positions on the power board are illustrated as below:

Figure 6-6 Interface connections on the power board

The functions of the interfaces are listed below:

Table 6-3 AC input connection cable

PIN	Definition
AC-L	Live wire terminal to AC
AC-N	Neutral wire terminal to AC

Table 6-4 Outlet sockets

Name	Description
5V	V3：5V
12V, 24V	V2：12V V1：24V
+12V, -12V	V4:+12V V5:-12V
DC110V	V6

6.4.2 Power board replacing and wiring

The power board plays a very important part in the device, and any error with the board may endanger the operation of the whole. Follow below steps to replace the power board when needed:

Tools: cross-headed screwdriver, multimeter.Disassembly:

- Shut down the analyzer and pull out the AC cables;
- Take out the power assembly from the main unit case;
- Open the power unit, remove the screws on the power board, and take out the board from the power unit.

Warning

- Wear an antistatic wrist strap while removing the board;
- Always shut down the power and pull out the power cable before removing the board. Installation:

Installation:

Install the power board in the reversed order of the disassembly steps:

- Check whether all the screws on the board are properly fixed;
- Connect the power cable, and turn on the AC switch. The analyzer starts its initialization, andall the indicators on the board light on.

Caution

- Ensure the power unit is tightly fixed to the main unit case with screws.
- Before disassemble the power board, ensure the power board and its peripherals havecooled off.

6.4.3 Power board problem

Follow below procedure for power board troubleshooting.

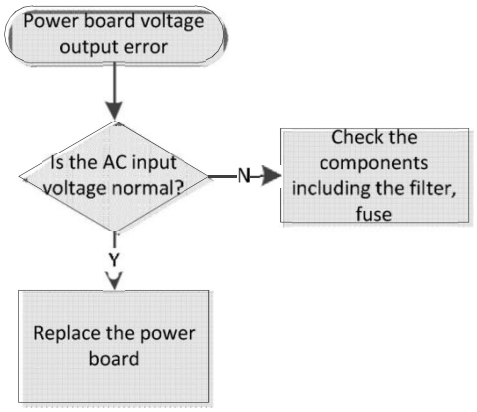


Figure 6-7 Troubleshooting for power board problem

6.5 Motors, photocouplers and micro-switches

6.5.1 Introduction

Motors drive the aspiration module and syringe module etc.; photocouplers detect the motor movements; and micro-switches are used to start analysis process. See below for the illustrations of motors and photocouplers.

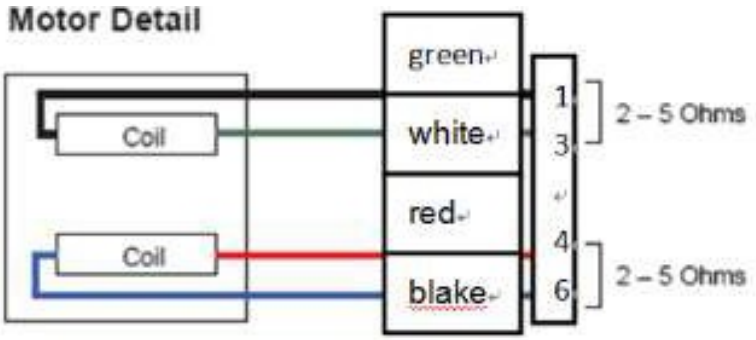


Figure 6-8 Motors illustrations

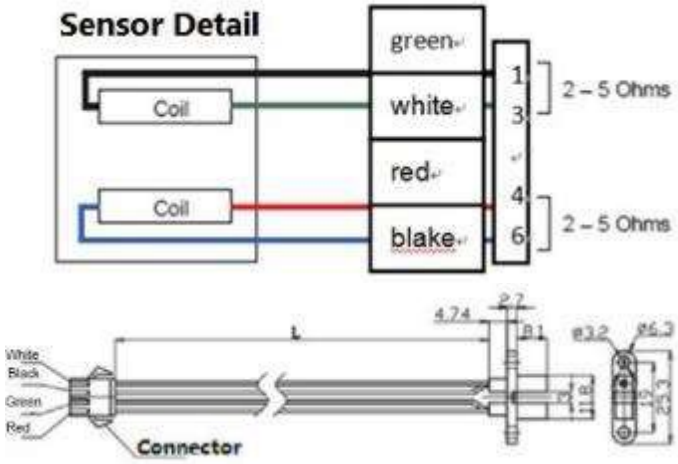


Figure 6-9 Photocouplers illustrations

6.5.2 Motor and photocoupler problem

Table 6-5 Troubleshooting for motors, photocouplers and micro-switches

No.	Problem type	Problem description	Troubleshooting
1	Motors	The motor does not rotate.	1. Check whether the problem is caused by main control board problem (whether LCD may display properly, if there is any power-related alarms); when the main control board is with error, remove the main control board error first; 2. Check whether the cable connecting a motor and the main control board get loose or broken; reconnect and replace the cable if necessary; 3. If cable errors can be excluded, replace the motor.
		Motor won't stop at designated position	

No.	Problem type	Problem description	Troubleshooting
2	Photocoupler	Motor rotates, but won't arrive at the designated position.	1. Check whether the problem is caused by main control board problem (whether LCD may display properly, if there is any power-related alarms); when the main control board is with error, remove the main control board error first; 2. Check whether the cable connecting a photocoupler and the main control board get loose or broken; reconnect and replace the cable if necessary; 3. If cable errors can be excluded, replace the photocoupler.

6.6 Liquid detection board

6.6.1 Introduction

The liquid detection board detects whether there is liquid in the tubes by monitoring the index of refraction.

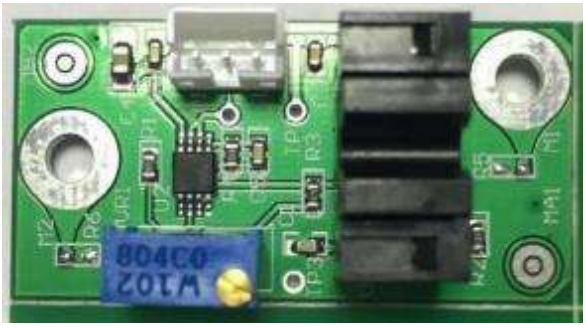


Figure 6-10 Liquid detection board

6.6.2 Components

The most important components of the board are the photocouplers. You can use a piece of paper toblock the photocoupler and check whether the board is working properly.

6.6.3 Liquid detection board problem

When there is reagent, the TP1 on the board should output voltage (about 4.0 V); when there is no reagent, TP4 should output voltage (lower than 2.0 V). When there is a problem, check whether the test point is in accordance with reagent status.

7 Mechanical system

7.1 Introduction to mechanical structure

This section demonstrates the positions of major serviceable components in the analyzer so our service people may find these component quickly to remove or replace them. Figures, pictures, and drawings in this manual are prepared based on Z50 series.

7.1.1 Front of the analyzer

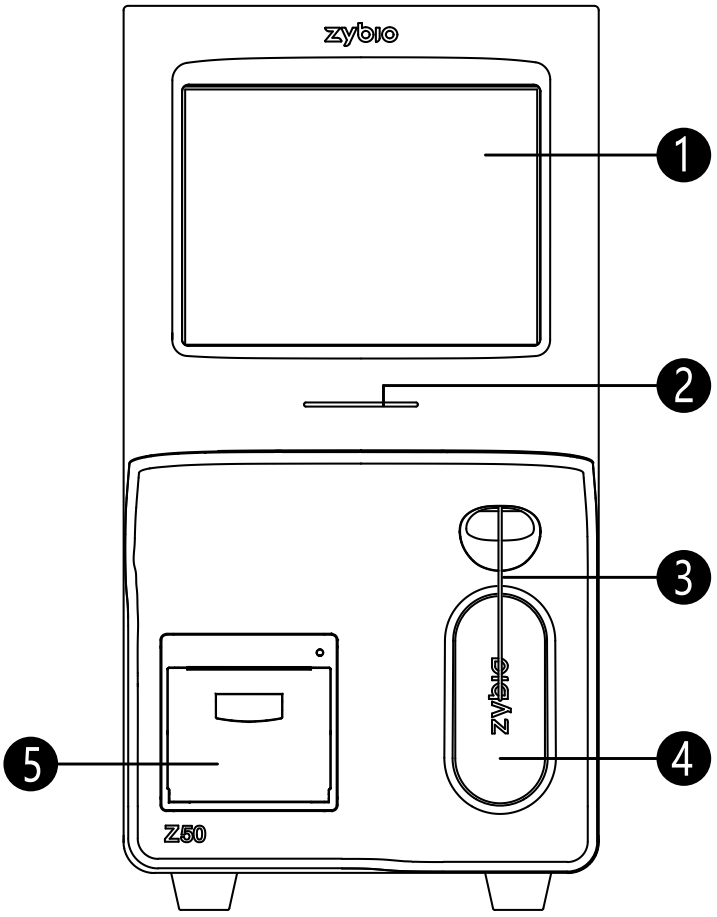


Figure 7-1 Z50 Front view

No.	Parts	No.	Parts
1	Touch screen	2	Indicator light
3	Sample probe	4	Aspirate key
5	Built-in thermal printer		

7.1.1 Front of the analyzer (front cover open)

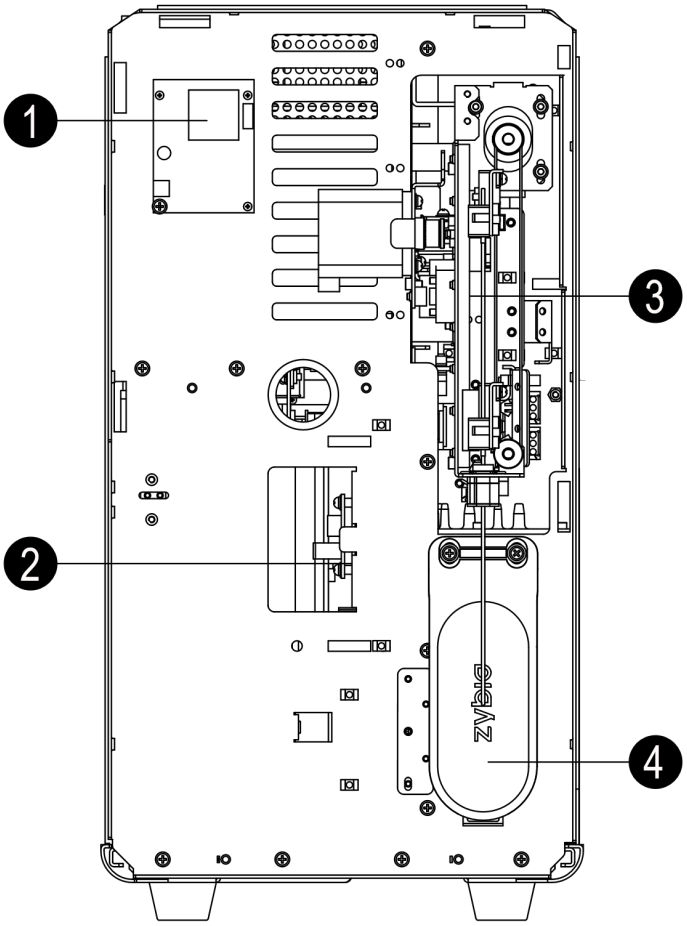


Figure 7-2 Front of the Analyzer (front cover open)

No.	Parts	No.	Parts
1	3G module	2	Reagent presence or absence detection plate
3	Sampling assembly	4	[Aspiration] Key

7.1.2 Back of the analyzer

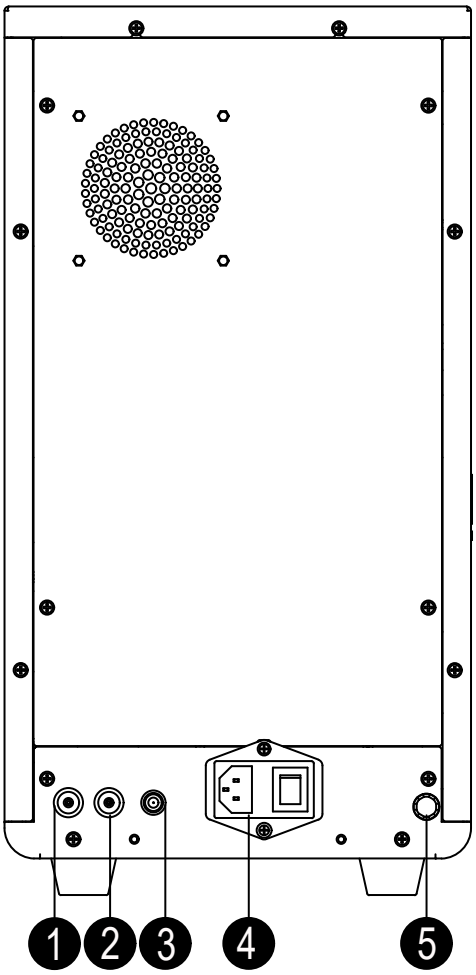


Figure 7-3 Back of the analyzer

No.	Parts	No.	Parts
1	Diluent tube port	2	Waste tube port
3	Liquid waste sensor	4	Power source subassembly
5	Protective earthing		

7.1.3 Right side of the analyzer

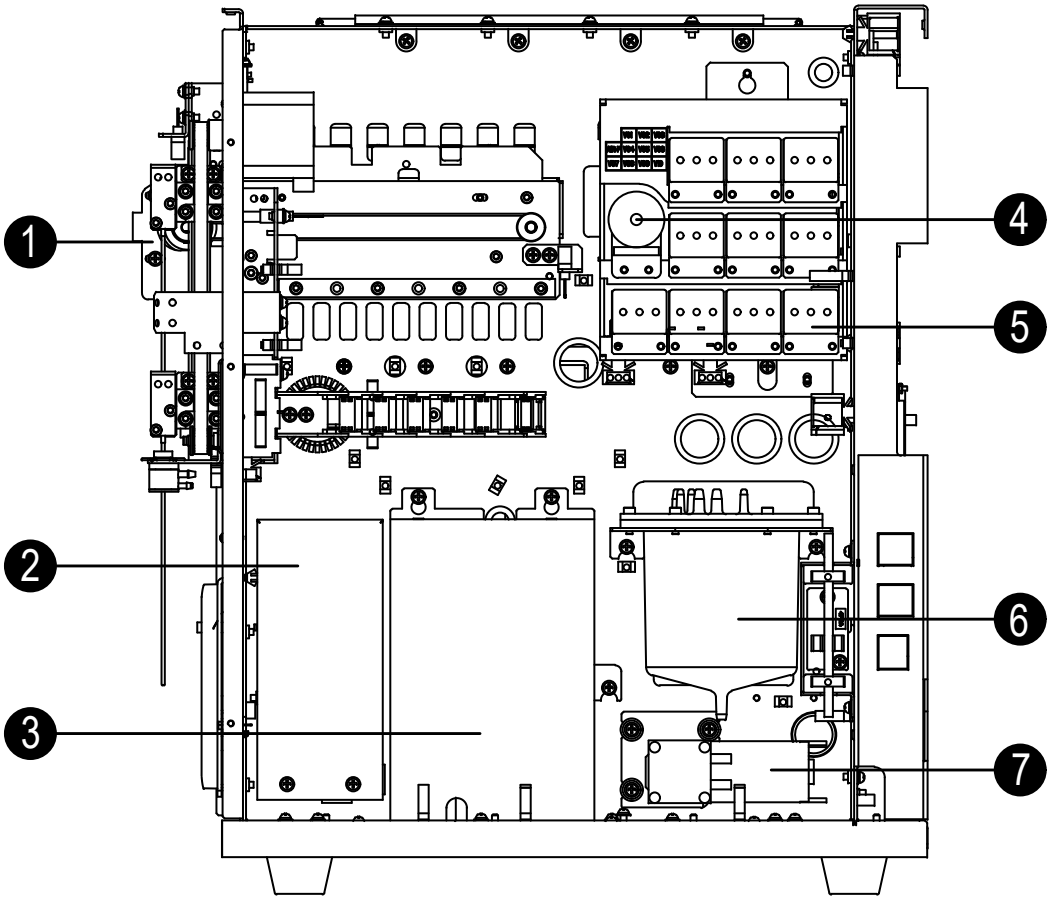


Figure 7-4 Left side of the analyzer

No.	Parts	No.	Parts
1	Sampling assembly	2	RBC chamber
3	WBC chamber	4	Mixing pump
5	Valves	6	Vacuum tank
7	Vacuum pump		

8 Troubleshooting

Error	Code	Troubleshooting	Solution
Abnormal communication	0x01000001	Communication error.	Reconnect communication cable or replace PCBA board.
Voltage Abnormal	0x01000002	AD out of range [2.44-2.55]V	/
System Time Error	0x01000004	The time indicated by the system clock is earlier than 2000-01-01	1. Check whether the button cell of the main control board is installed; 2. Replace with a new button cell, and set up the date and time in the setup screen. Save the settings, shut down the analyzer and then restart; 3. If the error still exists after restarting the analyzer, replace the main control board.
Fail To Exit Sleeping Mode	0x01000010		
Diluent Expired	0x01000107	System time is later than expire time	Check reagent expire time, replace, and prime diluent.
Lyse Expired	0x01000108	System time is later than expire time	Check reagent expire time, replace, and prime Lyse.
Wastes Full	0x01000110	Floater status: 1. Check once in startup, and the status is full; 2. Check for 3 times when the analyzer is idled, and the results all show that the status is full.	Check the floater, connecting cable.
Diluent Empty	0x01000114	The reagent detection reports no diluent	
Diluent Empty	0x01000115	The reagent detection reports no diluent	

Error	Code	Troubleshooting	Solution
Diluent is not replaced	0x01000117		
Lyse is not replaced	0x01000118		
Voltage Abnormal	0x01000201	Digital board 56V out of range [47.0，63.0] V, constant current: 51.5V ~ 61.5V	/
Voltage Abnormal	0x01000202	Digital board +12V out of range [11.0，13.0]V, +12V: 10.5V ~ 13.5V	/
Voltage Abnormal	0x01000203	Digital board -12V out of range [-14.0，-9.0]V, -12V：-13.5V ~ -10.5V	/
Background Abnormal	0x01000702	Blank reading is out of range，WBC≤0.2 *10^9 / L，RBC≤0.02*10^12/ L，HGB≤1 g / L，HCT≤0.5 %，PLT≤5*10^9 / L	Retest or maintenance
HGB Blank Voltage Abnormal	0x01000801	1. HGB voltage out of range [3.85，4.85]V 2. HGB higher than 4.85V	Adjust HGB gain or maintenance WBC chamber.
Vacuum Pressure Abnormal	0x01000804	Vacuum Pressure is not in range	/
Clog	0x01000901	Aperture signal does not stable	Unclog and test blank
Aperture Voltage Abnormal	0x01000902	Aperture voltage is lower than 14V	Maintenance chamber or replace main control board.
Impedance Signal Interference	0x01000903	1. Signal interference. 2. PLT noise signal more than 10%.	/
Clog	0x01000904	Aperture signal does not stable	Unclog and test blank
Aperture Voltage Abnormal	0x01000905	Aperture voltage is lower than 14V	Maintenance chamber or replace main control board.
Impedance Signal Interference	0x01000906	1. Signal interference. 2. PLT noise signal more than 10%	/

Error	Code	Troubleshooting	Solution
Thermal printer is out of paper	0x08000303	Lack of printer paper.	Replace printer paper
Thermal Printer Error	0x08000304	Thermal Printer too hot	Wait for a while and print again.
Thermal printer open	0x08000305	Thermal printer pole is not installed well	Close thermal printer cover
Startup fail	0x09000001		Restart instrument, replace main
Fluidics Has Not Initialized	0x09000002		Restart instrument, replace main control board or motor drive board.
Cell counting Abnormal	0x09000003		Restart instrument, replace main control board or motor drive board.