# Z3 AUTO HEMATOLOGY ANALYZER

# **SERVICE MANUAL**

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- 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.



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

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# 1 Using This Manual

#### 1.1 Overview

This chapter describes how to use the service manual. In this manual, the repair methods of Z3 are described in detail. Before servicing Z3, 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 Z3 Operator's manual. It does not contain information and procedures already covered in the Operator's manual of Z3.

#### **Notes**

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
[xx]	all capital letters enclosed in [] indicate a key name (either on the pop-up keyboard or the external keyboard)
"××"	letters included in " " indicate text you can find on the screen of Z3
××	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 your analyzer setup or data displayed.

# 1.4 Safety Information

You will find the following symbols in this manual.

Symbols	Meaning
<b>▲ &amp;</b>	Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
WARNING	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
▲ CAUTION	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
NOTE	Read the statement below the symbol. The statement is alerting you to information that requires your attention.



- 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.

#### **AWARNING**

- 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 during normal 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 when handling 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 off
  with plenty of water and immediately go see a doctor.

## **A** 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.

#### Notes

- 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...

Symbols used in this service manual:

Symbol	Meaning
€	The operator is required to follow the instructions below this symbol. Failure to do so may place the operator at a potential risk of biohazard.

WARNING	The operator is required to follow the instructions below this symbol. Failure to do so may cause personal injury.
CAUTION	The operator is required to follow the instructions below this symbol. Failure to do so may cause malfunction or damage of the product or affect the test results.
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.

The analyzer system may contain the following symbols:

## **A**CAUTION

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

When you see	It means
	CAUTION, CONSULT ACCOMPANYING
<u>^</u>	DOCUMENTS.
<u> </u>	Note: It is recommended that the reader
	refers to the accompanying documents
	for important safety information.
	BIOLOGICAL RISK
	WARNING, LASER BEAM
	PROTECTIVE EARTH (GROUND)
•—	USB port
- T-	Network interface
$\sim$	ALTERNATING CURRENT
IVD	FOR IN VITRO DIAGNOSTIC USE

LOT	Batch code
	USE BY (YYYY-MM-DD)
SN	Serial number
	DATE OF MANUFACTURE
<u>A</u>	Pricking danger
	Manufacturer
	TEMPERATURE LIMITATION
[]i	CONSULT INSTRUCTIONS FOR USE
( €	The device fully complies with requirements of EU IVD Directive 98/79/EC

# **2** Product Specifications

# 2.1 Product Name

Name: Auto Hematology Analyzer

Model: Z3

Appearance:



# 2.2 Physical Specifications

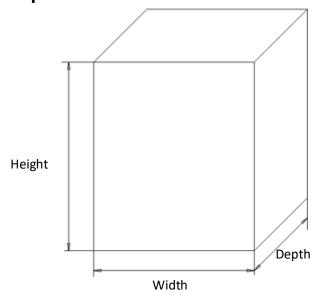


Table 2-1 Dimensions and weight

Z3	Whole device
	Length: 300 mm
Z3	Height: 400 mm (rubber feet included)
	Depth: 410 mm
Weight	≤ 20Kg

# 2.3 Electrical Specifications

Table 2-2 Main unit power supply

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



• Only fuses of specified specification shall be used.

Fuse Specification: 250 V T6.3 AH

# 2.4 Environment Requirements

Operating environment, storage environment and running environment:

**Table 2-3 Overall environment requirements** 

	Operating Environment	Storage Environment	Running Environment
	Requirements	Requirements	Requirements
Ambient			10°C 10°C
Temperature	<b>15℃~35℃</b>	-10°C ∼40°C	10℃~40℃
Relative			400/ 000/
Humidity	20%~85%	10%~90%	10%~90%
Atmospheric			701.5 4061.5
Pressure	70kPa $\sim$ 106kPa	50kPa∼106kPa	70kPa $\sim$ 106kPa

# 2.5 Product Specifications

#### 2.5.1 Sample mode

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

#### 2.5.2 Throughput

The throughput of Z3 WB/PD is 70 samples/hour.

# 2.6 Testing Parameters

The analyzer provides quantified results for 21 report parameters (WBC, RBC, PLT, HGB, etc.) and 3 histograms (WBC, RBC, and PLT). See the table below for details.

**Table 2-4 Parameters** 

Name	Abbreviation
White Blood Cell count	WBC
Lymphocyte number	Lymph#
Mid-sized Cell number	Mid#
Granulocyte number	Gran#
Lymphocyte percentage	Lymph%
Mid-sized Cell percentage	Mid%
Granulocyte percentage	Gran%
Red Blood Cell count	RBC
Hemoglobin concentration	HGB
Mean Corpuscular Volume	MCV
Mean Corpuscular Hemoglobin	MCH

Mean Corpuscular Hemoglobin Concentration	MCHC
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV
Red Blood Cell Distribution Width Standard Deviation	RDW-SD
Hematocrit	НСТ
Platelet count	PLT
Mean Platelet Volume	MPV
Platelet Distribution Width	PDW
Plateletcrit	PCT
Platelet Larger Cell Ratio*	P-LCR*
Platelet Larger Cell Count*	P-LCC*

**Table 2-5 Histograms** 

White Blood Cell Histogram	WBC Histogram
Red Blood Cell Histogram	RBC Histogram
Platelet Cell Histogram	PLT Histogram

# 2.7 Performance Requirements

## 2.7.1 Background/Blank Count

Background refers to the background count performed automatically by the analyzer during the startup 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 <sup>9</sup> / L	
RBC	≤ 0.02×10 <sup>12</sup> / L	
HGB	≤1 g/L	
НСТ	≤ 0.5 %	
PLT	≤5×10 <sup>9</sup> /L	

#### 2.7.2 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.

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

**Table 2-7 Carryover Requirements** 

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

**Table 2-8 Sample Concentration Range of Carryover Test** 

Parameter	Unit	High concentration range	Low concentration range
WBC	×10 <sup>9</sup> /L	> 90.00	< 3.00
RBC	×10 <sup>12</sup> /L	> 6.20	< 1.50
HGB	g/L	> 220	< 50
PLT	×10 <sup>9</sup> /L	> 900	< 30

#### 2.7.3 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;

*Xi* ----actual test result of the sample;

*d* ----absolute deviation of the sample test results.

**Table 2-9 Whole Blood Repeatability Requirements** 

Parameter	Condition	Whole Blood Repeatability	Pre-dilute Repeatability	
		(CV/absolute deviation d)	(CV/absolute deviation d)	
MADC	$7.0{\sim}15.00{\times}10^9$ / L	≤2.0%	≤4.0%	
WBC	$4.0 \sim 6.9 \times 10^9 / L$	≤ 3.5	24.070	
RBC	$3.50 \sim 6.50 \times 10^{12} / L$	≤1.5%	≤2.0%	
HGB	100 ~ 180 g/L	≤1.5%	≤2.0%	
MCV	70.0 $\sim$ 110.0 fL	≤1.0%	≤1.5%	
DIT	100 ~ 149×10 <sup>9</sup> / L	≤5.0%	≤8.0%	
PLT	150 ~ 500×10 <sup>9</sup> / L	≤4.0%	≥8.0%	
HCT	30~50%	/	≤ 2.5	
MPV	-	≤4.0%	≤5.0%	

## 2.7.4 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 2-10 Linearity Requirements** 

Para	Linearity Range	Deviation Range	Deviation Range
meter		(Whole Blood)	(Pre-dilute)
WBC	0.0~100.0×10 <sup>9</sup> /L	±0.30×10 <sup>9</sup> /L or 5 %	±0.50×10 <sup>9</sup> /L or 5 %
	100.1~200.0×10 <sup>9</sup> /L	±9%	±18%
RBC	0.0∼8.00×10 <sup>12</sup> /L	±0.05 ×10 <sup>12</sup> /L or	±0.05 ×10 <sup>12</sup> /L or
		±5%	±5%
HGB	0∼280 g/L	±2g/L or ±2%	±2g/L or ±3%
PLT	0∼1000×10 <sup>9</sup> /L	±10×109/L or ±10%	±10×109/L or ±10%
	1001 ~ 4000×10 <sup>9</sup> /L	±12%	±20%
HCT	0~67%	±4% (HCT value) or	/
		±6% (deviation	
		percent)	

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

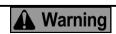
# 2.8 Display Range

Table 2-11 Display Range

Parameter	Display Range
WBC	0.00×10 <sup>9</sup> /L∼999.99×10 <sup>9</sup> /L
RBC	0.00×10 <sup>12</sup> /L~18.00×10 <sup>12</sup> /L
HGB	0 g/L∼300g/L
PLT	0×10 <sup>9</sup> /L~9999×10 <sup>9</sup> /L
HCT	0%~80%

# 2.9 Product Description

Z3 Auto Hematology Analyzer is mainly composed of the analysis module, information management module, result output module and accessories.



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 necessary tools if possible.

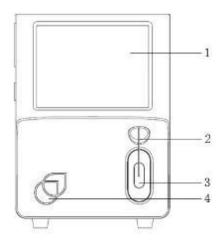


Figure 2-1 Front of the analyzer

1 ---- Display scree

2 ---- Sample probe

3 ---- [Aspiration] Key

4 ---- Power/status indicator

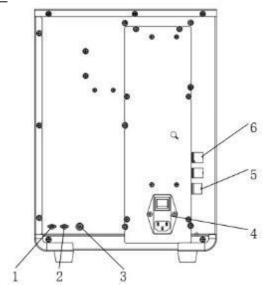


Figure 2-2 Back of the analyzer

1 --- Diluent inlet 2 --- Waste outlet

3 --- Waste sensor connector 4 --- Power input socket

5 --- Network interface 6 --- USB interface

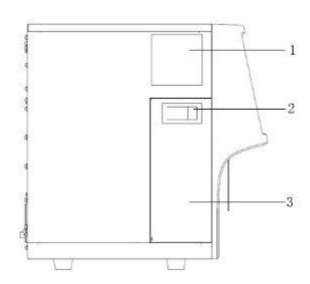


Figure 2-3 Left side of the analyzer

1 --- Built-in recorder 2 --- Locker

3 --- Side door

#### 2.9.1 Main unit

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

## 2.9.2 Power/status indicator

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

#### 2.9.3 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.

# **A**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.

## 2.9.4 [Aspiration] Key

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

#### 2.9.5 USB ports

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

# 2.10 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.

## 2.11 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 any sign of leakage or moisture is found, do not use the reagent.

#### **Notes**

- 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.

## 2.11.1 Reagents

#### Diluent

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

#### Lyse

Lyse breaks down the red cells and achieve WBC 3-part differential and the measurement of HGB.

**Probe Cleanser** 

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

#### 2.11.2 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 Z3 by ZYBIO.

# 2.12 Information Storage Capacity

Table 2-12 Data storage requirements

Data storage	Z3: 40,000 samples
capacity	
Information	The information stored should at least include the following: result information, histograms, patient information, flags as well as any special information of the analyzer.

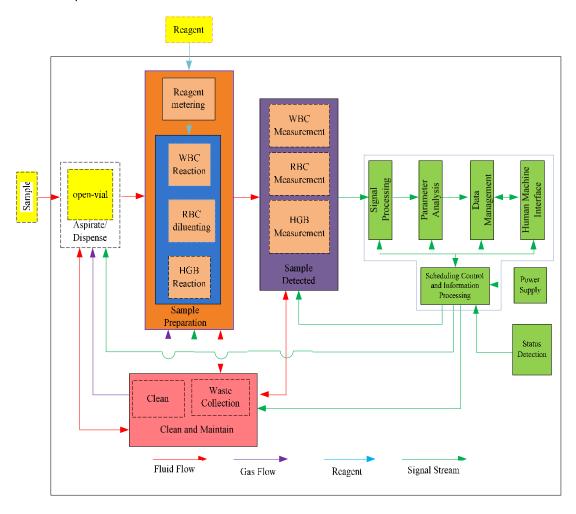
# **3 System Principles**

#### 3.1 Introduction

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

## 3.2 Analyzer Workflow

We have defined the whole operation workflow of the analyzer by its major functions: reagent system, sample loading and distribution, sample preparation, sample measurement, signal processing, parameter analysis, status monitoring, scheduling control and information processing, man-machine interface, power 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  $10\mu$ L 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 ( $20\mu L$  capillary sample needs to be diluted by 0.58 mL of diluent to form a 1:30 dilution), and then present the pre-diluted sample to the analyzer, which will aspirate 183uL of the sample.

#### 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

#### 3.5.1 Measurement Principle:

#### WBC measurement principle

The WBCs are counted by the impedance method. The analyzer aspirates certain volume of sample, dilutes it with certain volume of conductive solution, and delivers the dilution to the metering unit. The metering unit has a little opening which is called "aperture". A pair of electrodes is positioned on both sides of the aperture, 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 ranges of different channels, and the number of the pluses in the WBC channel indicates the number of the WBC particles. The cell size distribution width is represented by the number of particles falling in each channel.

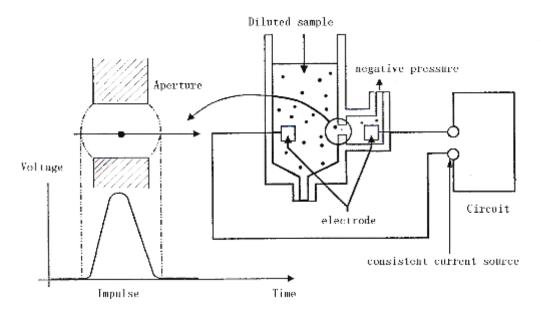


Figure 3-1 Metering diagram

#### 3.5.2 WBC-Related Parameters

#### White Blood Cell count

WBC (10<sup>9</sup>/L) is the number of leukocytes measured directly by counting the leukocytes passing through the aperture.

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

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

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

#### • 3-DIFF of WBC

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

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

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

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

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

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

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

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

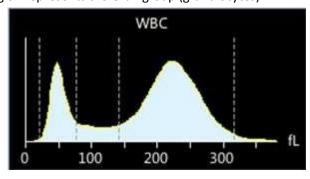
$$Mid\# = \frac{Mid\% \times WBC}{100}$$

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

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

#### White blood cell histogram

Besides the count results, the analyzer also provides a WBC histogram which shows the WBC size distribution, with the x-axis representing the cell size (in fL) and the Y-axis representing relative cell number (in 10<sup>9</sup>/L) (as shown below). The WBC histogram of a normal blood sample (lysed and processed) should show display 3 clear parts: the small cell (about 20~70fl) region represents the LYM group (lymphocytes); the mid-sized cell (about 70~150fl) region represents the Mid group (including monocytes, eosinophils and basophiles); and the large cell (over 150fl) region represents the Gran group (granulocytes).



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

#### 3.5.3 HGB Measurement

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

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

## 3.6 RBC/PLT Measurement

#### 3.6.1 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.

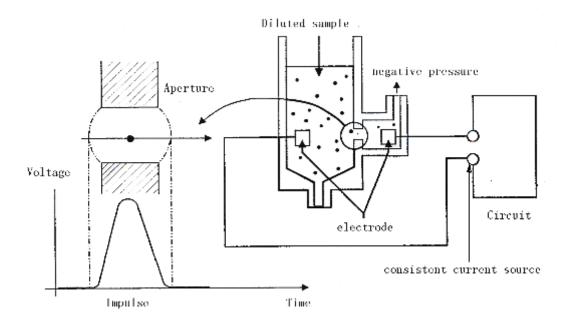


Figure 3-2 Metering diagram

#### 3.6.2 RBC-Related Parameters

#### Red Blood Cell count

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

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

Mean Corpuscular Volume

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

HCT, MCH and MCHC

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

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

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

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

Where RBC is expressed in 10<sup>12</sup>/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.

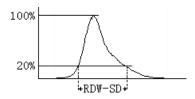
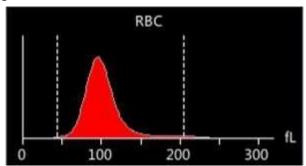


Figure 3-3

#### 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  $70^{\sim}120$ fl.



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.

#### 3.6.3 PLT-Related Parameters

#### Platelet count

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

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

#### Mean Platelet Volume

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

#### PDW

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

#### PCT

he analyzer calculates the PCT ( % ) as follows: where the PLT is expressed in  $10^9$  /L and the MPV in  $\mbox{fl}$ 

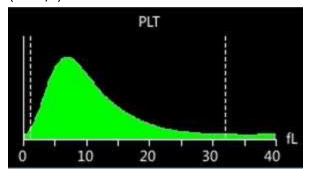
$$PCT = \frac{PLT \times MPV}{10000}$$

#### Platelet-Large Cell Ratio

The analyzer calculates the number of platelets larger than 12fl in size based on the platelet histogram 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  $0^2$ 0fl region, with the x-axis representing the cell size (in fL) and the Y-axis representing relative cell number (in  $10^9$ /L).



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

#### 3.7 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. Login

#### **User ID and Password for Service Level Access**

User ID: Service
Password: Service123

## 4.2 Review

## 4.2.1 Trend Graph

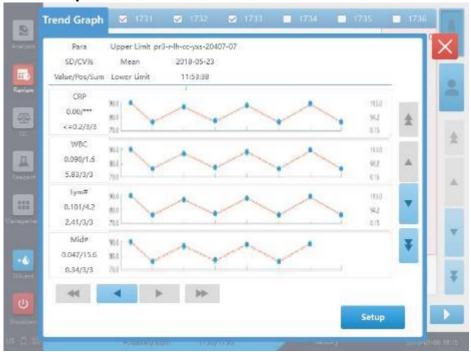


Figure 4-1 Trend graph screen

When the mean value of the selected parameter results are calculated, then the ordinates corresponding to the mean value point, the upper limit point and the lower limit point are Mean, Mean + Mean \* 10%, and Mean – Mean \* 10%.

Calculate the upper or lower limit of certain parameter result by "Mean + Deviation". If a result does not confirms to the acceptable data format, round it up to get the corresponding ordinates.

Tap the "Setup" button on the trend graph screen to enter the parameter limit setup screen (as shown below):



Figure 4-2

#### 4.3 Calibration

#### 4.3.1 Calibration Factors

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 factor is derived by below formula:

Calibration Factor = 
$$\frac{\text{Target}}{\text{Analysis Result}}$$

Calibration with fresh blood includes two modes of "WB" and "PD", which use different fluidic sequences. Perform calibration for each of the two modes separately.

Besides the calibration factor of the manufacturer, the factor of the users is also used to calculate the results. For example, under the CBC+DIFF mode, the final analysis results output by the analyzer are calculated as follow:

Analysis result = Measured value × Factory Calibration Factor × User Calibration Factor

Only the 5 traceable parameters are used in the calibration including: WBC, RBC, HGB, MCV and PLT.

# **A**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%.

#### 4.3.2 Calibration with Calibrator

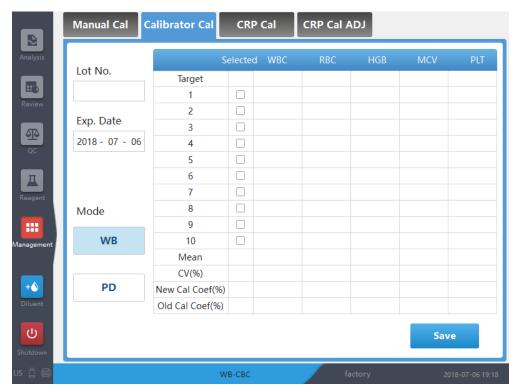


Figure 4-3 Calibration at Service Access Level

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 when exiting 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%].

# **A**CAUTION

• Never use expired calibrators.

# NOTE

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

# 4.4 Gain Setup

You can set up the gain for HGB on the "Gain Setup" screen. Gains for other parameters are obtained by gain calibration and cannot be edited.

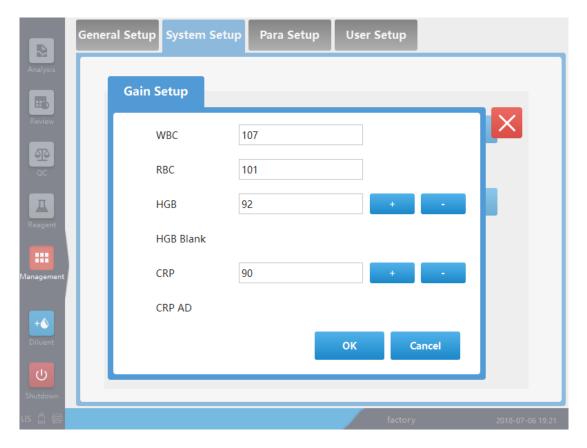


Figure 4-4 Gain Setup

Adjust the HGB gain by clicking + or - button to change HGB gain value to get HGB blank value around 4.5 $\pm$ 0.1V, then save HGB gain.

# NOTE

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

## 4.5 Performance

## 4.5.1 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.

#### 4.5.2 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 reproducibility requirements.

# NOTE

• End users usually use normal controls to calculate the reproducibility.

#### 4.5.3 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:

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

#### 4.6 Advanced Toolbox

#### **4.6.1** 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.

# 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.

# 4.7 Software Update

Prepare the USB for update

Unzip the file named "update.tar.gz", and then copy the "update" directory in the unzipped file to the 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.

# **A**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.

## 4.8 Status Indicator

## 4.9 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

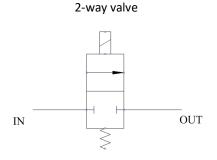
When The buzzer sounds Remarks					
Startup process completed	a short beep	Startup process is completed when the analyzer is started and ready for analysis			
Sample presentation/aspiration under open-vial mode is completed	2 short beeps				
On the analysis related screens (e.g.	A long beep	When there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

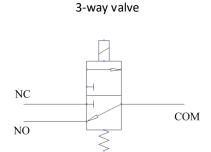
## 5 Fluidics

## 5.1 Introduction to Fluidic Parts

#### **5.1.1** Valves

#### Symbol:





#### Appearance:





#### • Function:

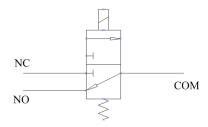
2-way valve: to build up or cut off a passage. When power off, the passage from the inlet of the valve to outlet is cut off; when power on, the passage is built up.

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



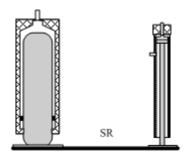
#### • Function:

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 is about 0.03. The SV02 in the fluidic charts is LVM fluidic valve.

## 5.1.3 Linkage Syringe Device

Symbol: SR



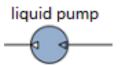
• Function: the linkage syringe device, driven by a motor and a unit of driving assembly, consists of two syringes: one with a high dispensing volume, the other with a low dispensing volume.

Table 5-1 Syringe specifications and functions

Name	Specification	Function		
Low volume syringe	250	Aspirate and dispense blood sample of precise volume, an 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.		

## 5.1.4 Vacuum pump

Symbol:



• Appearance:



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

## **5.1.5** Air pump

Symbol:





Appearance:



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

## 5.1.6 Sample probe

• Symbol:



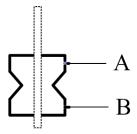
• Appearance:



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

## **5.1.7** 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.

#### 5.1.8 Baths

- WBC bath: consists of front bath, back bath and an aperture. It is where the WBC sample is mixed for analysis; supports the measurement of HGB and WBC.
- 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 WBC and RBC count (impedance method); and the front and back baths as well as the sample probe wipe are cleaned.
- WBC isolation chamber: provides an air space to isolate exterior interference.
- RBC isolation chamber: provides an air space to isolate exterior interference.

## 5.2 Sample Dilution Flow Chart

### 5.2.1 Whole Blood Mode

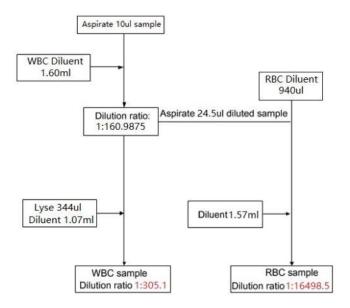


Figure 5- 1 Dilution under whole blood mode

#### **5.2.2** Pre-dilute Mode

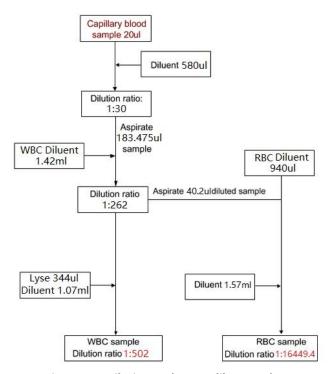


Figure 5- 2 Dilution under pre-dilute mode

#### 5.3 Introduction to Fluidic Channels

### 5.3.1 WBC/HGB channel

- Reagent used: 1) cyanide-free lyse (break out RBCs and PLTs and 3-differentiate WBCs based on cell size); 2) diluent (used for cleaning, and providing appropriate environment for reaction and measurement)
- **Measurement principle:** impedance method (for WBC count); colorimetric method (for HGB measurement)
- Measurement parameters: WBC and HGB
- Output graph: WBC histogram
- Dilution ratio: 1: 305.1 (whole blood mode); 1: 502 (pre-dilute mode)
- Aperture diameter: 100um
- Sample volume needed: 402.8µl; analysis time: 10s
- Function description: blood sample and diluent are mixed in the WBC bath to get diluted sample; then mixed 0.344ul of lyse. The sample solution after full reaction is then sucked into the back bath by vacuum pressure in the vacuum chamber. The cells are counted when they pass the aperture. Sample volume is calculated based on analysis time.

### 5.3.2 RBC/PLT channel

- Reagent used: diluent (dilution, cleaning, providing conductive environment and processing cell sizes)
- Measurement principle: impedance method
- Measurement parameters: RBC and PLT
- Graphics: RBC histogram; PLThistogram
- Dilution ratio: 1: 16498.5 (whole blood mode); 1: 16449.4 (pre-dilute mode)
- Aperture diameter: 70um
- Sample volume needed: about 197.37µl; analysis time: 10s
- Function description: sample probe aspirates diluted sample from the WBC bath, and dispenses the sample as well as additional diluent to the RBC bath, where the sample and the diluent are further mixed with existing initial volume of diluent. After full mixing and reaction, the sample solution is then sucked into the back bath by vacuum pressure in the vacuum chamber. The cells are counted when they pass the aperture. Sample volume is calculated based on analysis time.

## **5.4** Sample Volume

**Table 5-2 Sample Volume** 

Whole Blood Mode	Pre-dilute mode	
10ul	Manual dilution: 20ul blood sample and 580ul diluent;	
	aspirate 183ul	

## 5.5 Introduction to Sequences

## 5.5.1 Fluidic diagram

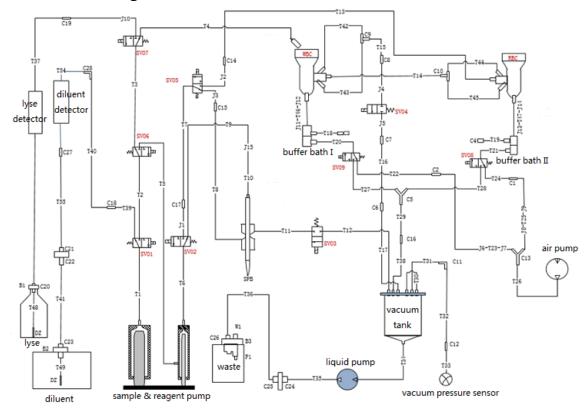


Fig. 5-3 Fluidic diagram

### 5.5.2 Sample Aspiration

Sample and reagent syringe aspirates sample into instrument cooperating with SV2.

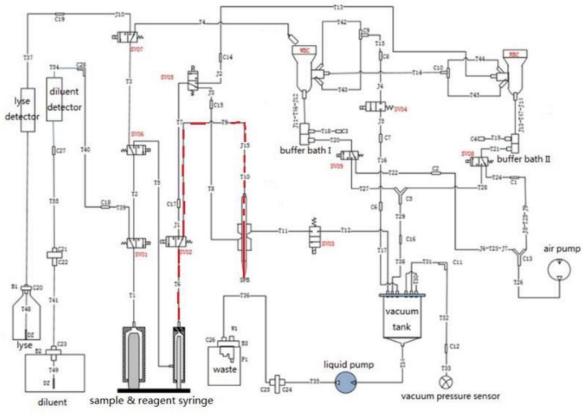


Fig. 5-4 Sample Aspiration

### 5.5.3 WBC Chamber Drain

Liquid goes through SV9 to vacuum tank.

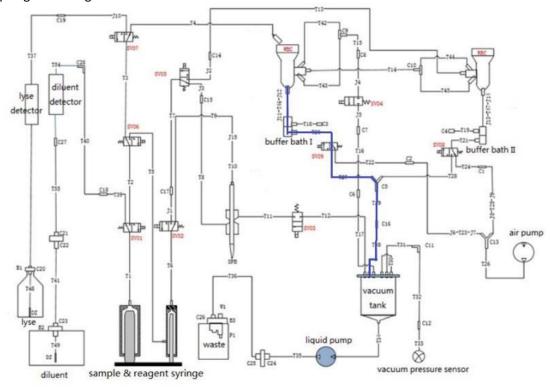


Fig. 5-5 WBC Chamber Drain

## **5.5.4** Sample Probe Outside Wash

Sample and reagent syringe push diluent goes through SV1-SV6-SV2-SV5 to probe wipes. Waste goes through SV3 to vacuum tank.

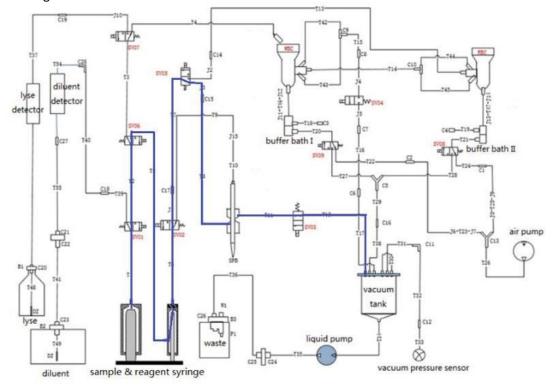


Fig. 5-6 Sample Probe Outside Wash

## 5.5.5 WBC Diluent Adding

Sample and reagent syringe push diluent goes through SV1-SV6-SV7 to WBC chamber.

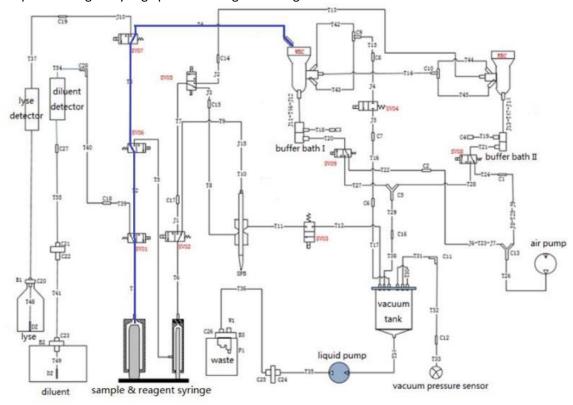


Fig. 5-7 WBC Diluent Adding

## 5.5.6 Add Sample with Diluent

Sample and reagent syringe push sample with diluent goes through SV1-SV6-SV2 to WBC or RBC chamber.

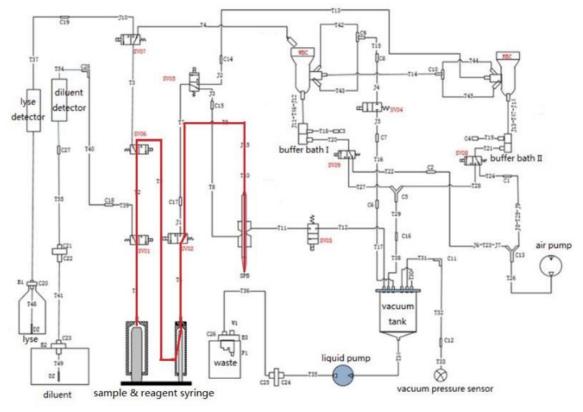


Fig. 5-8 Add Sample with Diluent

#### 5.5.7 Mix WBC and RBC Chamber

Air pump push bubble to WBC and RBC chamber by going through SV9 and SV8.

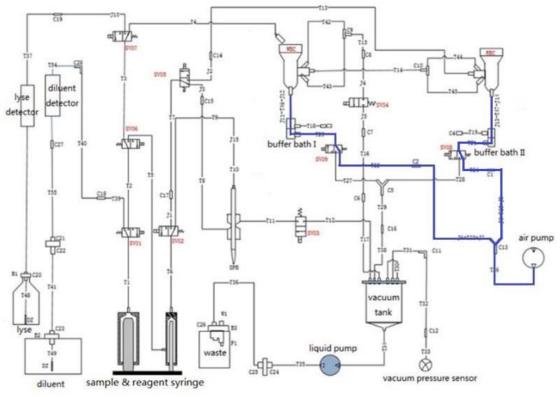


Fig. 5-9 Mix WBC and RBC Chamber

### 5.5.8 Aspirate Lyse

Sample and reagent syringe aspirate lyse by going through SV1-SV6-SV7.

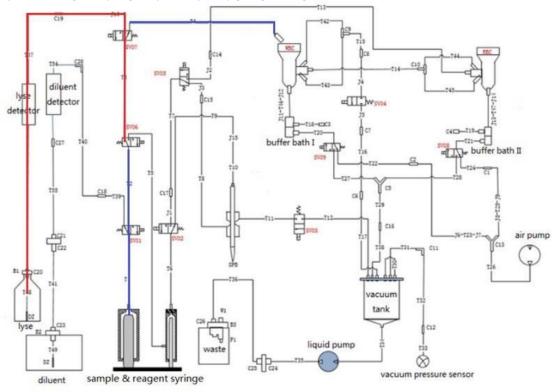


Fig. 5-10 Aspirate Lyse

## 5.5.9 WBC Chamber Add Lyse with Diluent

Sample and reagent syringe push lyse by going through SV1-SV6-SV7 to WBC chamber.

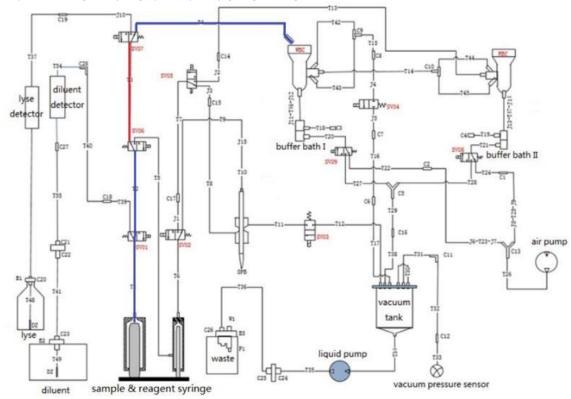


Fig. 5-11 WBC Chamber Add Lyse with Diluent

## 5.5.10 Counting Blood Cell

Vacuum tank aspirate sample by going through chamber's aperture and SV4.

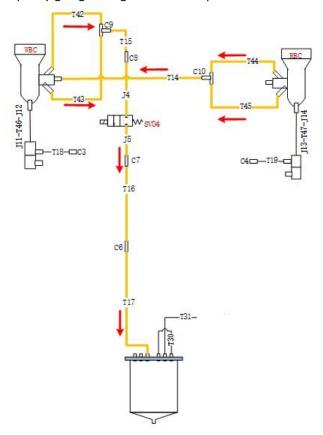


Fig. 5-12 Counting Blood Cell

## 5.5.11 Probe Cleanser Maintenance (Shutdown Sequence)

The probe cleanser maintenance during the shutdown process involves the following parts: the front and back baths of WBC and RBC baths, back bath tubing, sample probe as well as sampling tubing. The analyzer will perform "enhanced" probe cleanser maintenance after 1000 analyses. Compared with normal probe cleanser maintenance, the enhanced process uses a longer probe cleanser soak time (1 minute longer than normal maintenance).

Tap "Fluidic" on the "Maintenance" screen, the analyzer will perform enhanced probe cleanser maintenance.

### 5.5.12 Cleaning Procedure during Startup

The fluidic actions during the startup consist of the following parts:

- Initialization of fluidic components: initialize the aspiration module and syringe module, build and release vacuum.
- Overall cleaning: clean all the tubes, parts and components of the analyzer. Remove bubbles in the diluent preheating bath. No lyse is consumed.
- Background check: under whole blood mode.

If the background does not pass, the analyzer will perform the overall cleaning procedure one more time, and then check the background again.

When the analyzer starts after abnormal shutdown, it will perform the overall cleaning procedure twice.

## 5.5.13 **Standby**

The analyzer enters "Standby" mode when there is no action perform for 30~60 minutes (configurable, 30 minutes by default). When the analyzer is standby, you can still perform operations not involving fluidic actions.

- Exit standby status1: standby for less than 1 hour.
   Clean the exterior wall of sample probe and WBC bath, re-build isolation bubbles. The process does not consume lyse.
- Exit standby status2: standby for more than 1 hours.
   Equivalent of overall cleaning; all the tubing, parts and components will be cleaned, remove bubbles in the diluent preheating bath, remove the crystallization and bubbles at the diluent inlet.

## 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 Hardware System Function Block Diagram

The function block diagram of the hardware system is shown as below.

The hardware system consists of 5 major modules: system power, data flow channel, main control system, drive parts and peripheral interfaces.

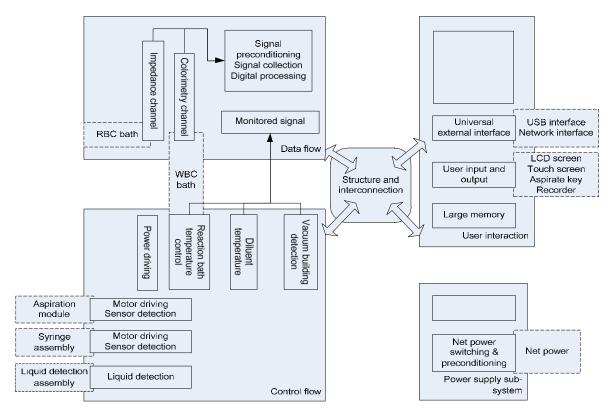


Figure 6-1 Function Block Diagram of the Hardware System

The functions of each module are shown below:

- System power: provide power of required specifications to all boards, parts and devices.
- Data flow channel: detect, condition, amplify, collect and pre-process signals.
- Main control system: collect and process data, display results and store sample information. Besides, main control system acts as the control and management center which controls and responds to all other components and devices.
- Drives/detectors: control valves, pumps and motors; monitor the photocouplers and other important parameters; collect information during analysis and send out flags.
- Peripheral interfaces: include interfaces to display/touch screen, USB ports (connecting to

printer, keyboard, and barcode scanner) and Ethernet interface. Besides, peripheral interfaces also include those to the working status indicator and the [Aspirate] key.

### 6.2 Electrical Connection Diagram

The electrical connection of the analyzer is shown as below:

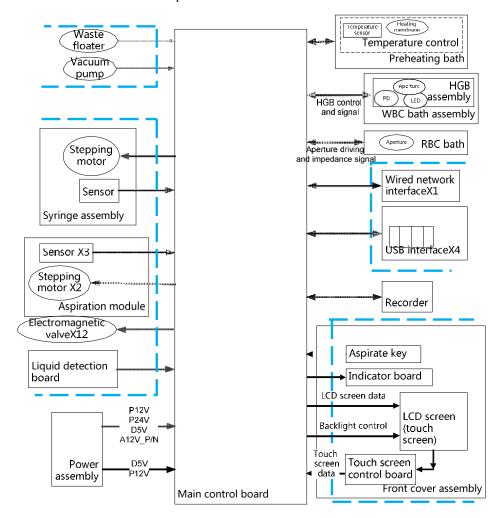


Figure 6-2 Electrical Connection

## 6.3 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 6-3 demonstrates the troubleshooting procedure for power supply errors. Figure 6-4 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.

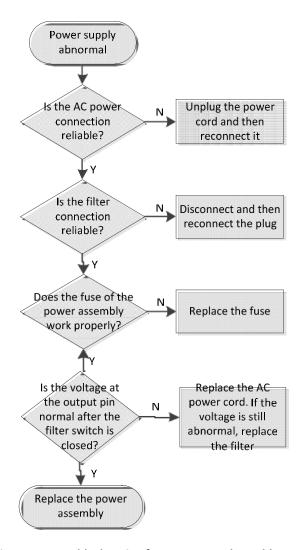


Figure 6-3 Troubleshooting for power supply problem



Figure 6-4 Power Filter

Figure 6-5 shows the troubleshooting flowchart for power-on protection.

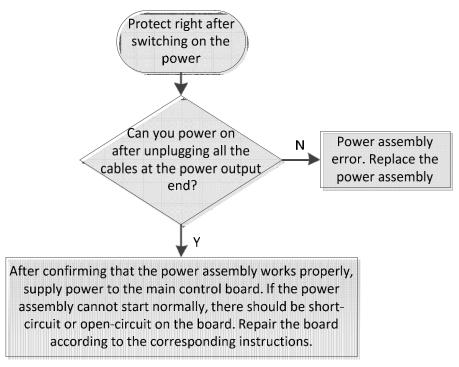


Figure 6-5 Troubleshooting for power-on protection problem

#### 6.4 Main Control Board

#### 6.4.1 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.

#### 6.4.2 Components

The structure of the main control board is illustrated in figure 8-6. 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

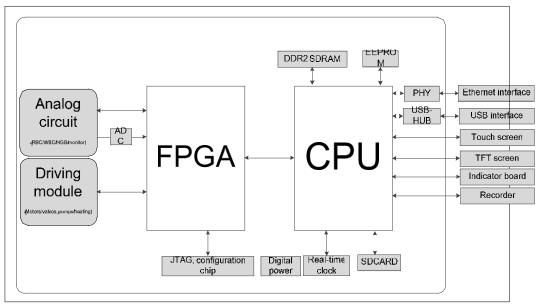


Figure 6-6 Main control board structure

#### 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.

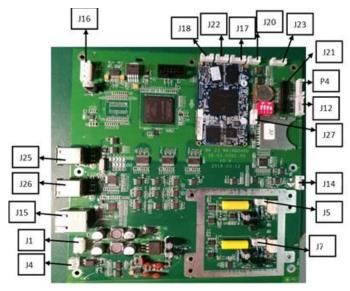


Figure 6-7Sockets on the main control board

#### **Definition of sockets**

The main control board has 18 sockets. See Table 6-1 for the socket functions; see Figure 6-4 for their positions.

Table 6-1 Socket functions on the main control board

Sockets	Function	PIN function description	Description
J16	Socket to digital	PIN1: 12V	/
	circuit	PIN2: GND	
		PIN3: 5V	
		PIN4: GND	
J1	Socket to analog	PIN1: -12V	/
	circuit	PIN2: AGND	
		PIN3:+12V	
J4	Socket topower	PIN1: DC110V	/
	circuit	PIN2: DC-GND	
J25,J26	USB ports	/	/
J15	Network port	/	/
J18	Communication	PIN4:RX	
	port with driver	PIN3:TX	
	board	PIN2:GND	
J22			Reserved
J17			Reserved
J20			Debug port for R&D
			only
J23	Printer port	PIN1: 5V	
		PIN2: GND	
		PIN3: TX	
		PIN4: RX	

		PIN5: GND	
P4	LCD backlight	/	/
	port		
J21	LCD data cable	/	/
	port		
J12	Touch screen	/	/
	port		
J14	HGB signal cable	PIN1: LED power+	/
	port	PIN2: LED power-	
		PIN3,4: AGND	
		PIN5: HGB signal input	
J5	RBC signal cable	PIN1,3: AGND	/
	port	PIN2: RBC signal input	
J7	WBC signal cable	PIN1,3: AGND	/
	port	PIN2: WBC signal input	
J27	CPU upgrading	/	/
	port		

## 6.4.3 Debugging and Troubleshooting

All the configurable parameters on the main board can be adjusted to command. Adjust the parameters on the software screens.

LED indicator functions

The functions of the LED indicators on the main control board are defined in Table 6-2:

Table 6-2 Functions of LED indicators on the main control board

Indicators	Functions	Possible causes when the LED does not light
LED3	3.3V power indicator	FPGA defective, main control board short- circuited
LED4	5V power indicator	Power board defective, DC circuit cable defective, main control board short-circuited
LED1	12V power indicator	Power board defective, DC circuit cable defective, main control board defective
LED2	-12V power indicator	Power board defective, DC circuit cable defective, main control board defective

#### **Test points**

The functions of the test points on the main control board are listed in Table 6-3.

If power defective are suspected, first pull out all other cables other than power cables to rule out the possibility of any short-circuited peripheral.

Table 6-3 Functions of test points on the main control board

1	TP10	12V power input test voltage is not 12V: main board is defective or power
		point supply is defective
2	TP7	5V power input testvoltage is not 5V: main board is defective or power
		point supply is defective
3	TP23	Digital earth /
4	TP18	3.3V power input test voltage is not 3.3V: main board is defective point
5	TP19	2.5V power input test voltage is not 2.5V: main board is defective point
6	TP20	1.8V power input test voltage is not 1.8V: main board is defective point
7	TP21	1.2V voltage test voltage is not 1.2V: main board is defective point
8	TP22	0.9V voltage test voltage is not 0.9V: main board is defective point
9	TP16	+12V voltage test voltage is not 12V: main board is defective or power point supply is defective
10	TP15	-12V voltage test voltage is not -12V: main board is defective or power point supply is defective
11	TP24	Analog +5 V voltage voltage is not 5V: main board is defective test point
12	TP14	Analog -5V voltage voltage is not -5V: main board is defective test point
13	TP11	57V voltage test point voltage is not 57V: main board is defective;

#### 6.4.4 Troubleshooting for Main Control Board

Table 6-4 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 similar problem. 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 J1~J16 on the board are normal (measure the voltages with a multimeter).
- Check whether the indicators on the main control board work properly against Table 6-2.

When you have confirmed all the cables are properly connected, all the input power and indicators work normally, follow the instruction in Table 6-4 for troubleshooting.

Table 6-4 Troubleshooting for main control board

No.	Error Troubleshooting for main control board Solution			
NO.	Error	Troubleshooting	Solution	
1	LCD	1. Check whether the cable connecting the main	Unplug and reconnect	
	screen	control board and the backlight socket, and the cable	the cable connecting	
	becomes	connecting the main control board and the LCD	the main control	
	black.	screen are properly connected. Unplug and then	board and the	
		reconnect such cables. Power on the analyzer again	backlight and the cable	
		and see whether the error is removed. If not, proceed	connecting the main	
		to next step.	control board and the	
			LCD screen.	
		2. Replace the cable connecting the main control	Replace the cable	
		board and the backlight and the cable connecting the	connecting the main	
		main control board and the LCD screen. If the error	control board and the	
		still exists, proceed to next step.	backlight and the	
			cable connecting the	
			main control board	
			and the LCD screen.	
		3. Use a multimeter to measure the voltage between	Replace the main	
		PIN1 and PIN5 of P4, when the result is not within the	control board	
		range of 10.5~13.5V, then the power supply to		
		backlight is with error. If can't solve problem, proceed		
		to next step.		
		4. Use a multimeter to measure the voltage between		
		PIN3 and PIN5 of P4, when the result is not within the		
		range of 4~5V, then there is backlight brightness		
		control error. If can't solve problem, proceed to next		
		step.		
		6. 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	Control board and the backlight and the cable	
		,		

		is removed. If not, proceed to next step.	connecting the main
		·	control board and the
			LCD screen.
			LCD screen.
		2. Replace the cable connecting the main control	Replace the cable
		board and the backlight and the cable connecting the	connecting the main
		main control board and the LCD screen. If the error	control board and the
		still exists, proceed to next step.	backlight and the
			cable connecting the
			main control board
			and the LCD screen.
		2 Danies the main control board if the group is	Double of the marin
		3. Replace the main control board. If the error is	Replace the main
		removed, then the problem is caused by main control	control board.
		board. If not, proceed to next step.	
		4. Replace the LCD screen (screen assembly). If the	Replace the screen
		error is removed, then the problem was caused by LCD assembly failure.	assembly
		,	
3	LCD displays	1. Reconnect the cable connecting the main control	Reconnect the cable
	strange patterns	board and the LCD screen. Power on the analyzer	connecting the main
		again and see whether the error is removed. If not,	control board and the
		proceed to next step.	LCD screen.
		2. Replace the cable connecting the main control	Replace the cable
		_	
		board and the LCD screen. If the error still exists,	connecting the main
		proceed to next step.	control board and the
			LCD screen.
		3. Replace the main control board. If the error	Replace the main control
		remains, proceed to next step.	board
		4. Replace the LCD screen (screen assembly). If the	Replace the screen
		error is removed, then the problem was caused by LCD assembly failure.	assembly
		· · · · · · · · · · · · · · · · · · ·	
4	Bad network	1. Check whether the IP of the PC falls in the same	Set the IP of the PC to
	connection	network segment of the main control board IP	192.168.0.1.
		(192.168.0.X). When it is not, reset the IP of the PC to	
		192.168.0.1, and see whether the network	
		The second of the second of the second	

		connection is OK. If the network connection still fails,	
		proceed to next step.	
		2. When the analyzer is powered on and connected	Reconnect or replace
		to PC, but network port LEDs do not light on, then the	the network cable.
		network connection is bad or the network cable is	
		damaged. If can't solve problem, proceed to next	
		step.	
		·	
		3. Network port LEDs do not light on, but network connection is OK.	Replace the main control board
5	USB ports fail	1. If D10 and D12 do not light on when the analyzer is	Replace the main
	to response.	powered on, then the USB HUB chip (U1) is with error.	control board
		If can't solve problem, proceed to next step	
		2. If D10 and D12 do light on when the analyzer is	Replace the devices
		powered on, replace the peripherals connected to the	connecting to the USB
		USB ports (mouse, keyboard or USB disk etc.). If the	ports.
		peripherals still cannot be used, proceed to next	
		step.	
		3. If the error still remains after all above steps,	Replace the main
		replace the main control board.	control board
6	Clock time	Power off the analyzer, and use a multimeter to	Replace the button
	resets every	measure the voltage between the two ends of the	cell.
	time after	button cell B1. When the measured voltage is <1.8V,	55
	startup	then the cell is with low power. If can't solve problem,	
	Startup	proceed to next step.	
			Bardana II
		2. Use a multimeter to measure the voltage between	Replace the main
		PIN1 and PIN4 of X2, crystal oscillator X2 is defective.	control board
7	Analyzer	1. Check whether the cable connecting to the	
	gives no	[Aspirate] key gets loose or broken. If yes, reconnect	
	respond	the cable or replace it.	
	when the	2. If the error remains after step 1, Disassemble the	
	[Aspirate]	connecting board to the [Aspirate] key switch, and	
		54	

key is	see whether there is liquid split on the switch. If yes,	
pressed	clean the liquid and re-install the board.	

### 6.5 Motor drive board

#### 6.5.1 Introduction

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

### **6.5.2** 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

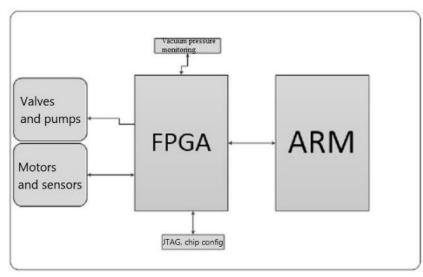


Figure 6-8 Motor drive board structure

#### 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

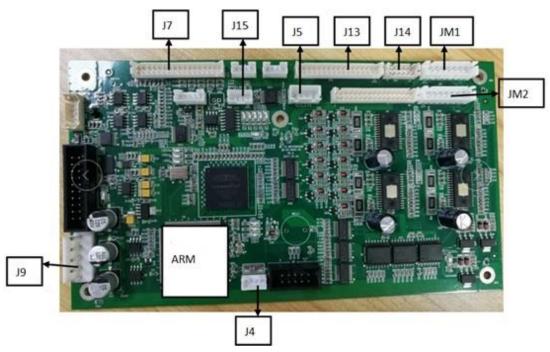


Figure 6-9 Sockets on the motor drive board

#### **Definition of sockets**

The motor drive board has 7 sockets. See Table 6-5 for the socket functions; see Figure 6-9 for their positions.

Sockets **Function PIN function description** Description J9 Socket to power **PIN1: 24V** / circuit PIN2: PGND PIN3: 12V PIN4: GND PIN5: VDD5V Photocoupler J7 Socket to and photocoupler reagent detect signals J13 Socket to valves J14 Socket to pumps JM1 Socket to motor Sample probe vertical motor Socket to motor JM2 Syringe motor J4 Socket to serial Communication port port with main control board

Table 6-5 Socket functions on the motor drive board

## 6.5.3 Debugging and Troubleshooting

All the configurable parameters on the main board can be adjusted to command. Adjust the parameters on the software screens.

#### LED indicator functions

The functions of the LED indicators on the main control board are defined in Table 6-6.

Table 6-6 Functions of LED indicators on the motor drive board

Indicators	Functions	Possible causes when the LED does not light
LED8	12V power indicator	Power supply defective, DC circuit
		cable defective, motor drive boardshort-
		circuited
LED9	24V power indicator	Power supply defective, DC circuit
		cable defective, motor drive boardshort-
		circuited
LED10	5V power indicator	Power supply defective, DC circuit
		cable defective, motor drive boardshort-
		circuited
LED1, LED11,	ARM working status indicator	Power supply defective, motor drive
LED12		board defective
LED2, LED13,	FPGA working status indicator	Power supply defective, motor drive
LED14		board defective
LED3-LED7	Motor running status	Power supply defective, motor cable
	indicator	or motor sensor defective, motor drive
		board defective

#### **Test points**

The functions of the test points on the main control board are listed in Table 6-7.

If power errors are suspected, first pull out all other cables other than power cables to rule out the possibility of any short-circuited peripheral.

Table 6-7 Functions of test points on the motor drive board

Test Points Introduction Troubleshooting			
Introduction	Troubleshooting		
24V voltage	Voltage is not 24V, motor drive board or power		
test point	supply is defective		
12V voltage	Voltage is not 12V, motor drive board or power		
test point	supply is defective		
5V voltage	Voltage is not 5V, motor drive board or power supply		
test point	is defective		
3.3V voltage	Voltage is not 3.3V, motor drive board or power		
test point	supply is defective		
2.5V voltage	Voltage is not 2.5V, motor drive board or power		
test point	supply is defective		
1.2V voltage	Voltage is not 1.2V, motor drive board or power		
test point	supply is defective		
	test point  12V voltage test point  5V voltage test point  3.3V voltage test point  2.5V voltage test point  1.2V voltage		

### 6.5.4 Troubleshooting for Motor drive Board

Table 6-8 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 similar

problem. 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 J9 on the board is normal (measure the voltages with a multimeter).
- Check whether the indicators on the motor drive board work properly against Table 6-6.

When you have confirmed all the cables are properly connected, all the input power and indicators work normally, follow the instruction in Table 6-8 for troubleshooting.

Table 6-8 Troubleshooting for motor drive board

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

#### 6.6 Power board

#### 6.6.1 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:

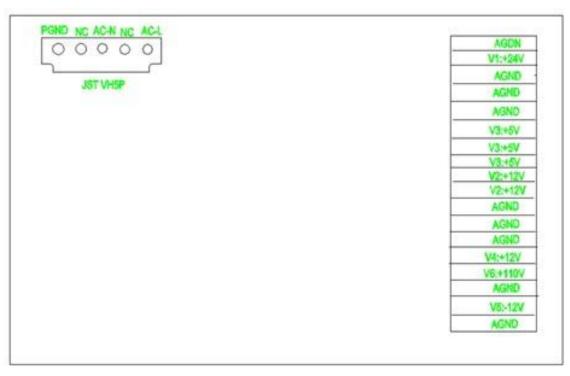


Figure 6-10 Interface connections on the power board

The functions of the interfaces are listed below:

Table 6-9 AC input connection cable

PIN	Definition	
AC-L	Live line terminal to AC	
AC-N	Zero line terminal to AC	

**Table 6-10 Outlet sockets** 

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

## 6.6.2 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:

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, and all the indicators on the board light on.

## **A**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 have cooled off.

#### 6.6.3 Power Board Problem

Follow below procedure for power board troubleshooting.

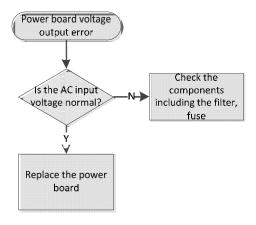


Figure 6-11 Troubleshooting for power board problem

### 6.7 Touch Screen Control Board

#### 6.7.1 Introduction

As the interface between the touch screen and the main control board, the touch screen control board transfers the touch actions from the users to recognizable signals by main control board. You may need to make some adjustment to the touch screen control board during use.

#### 6.7.2 Components

With the 4-wire touch screen controller chip TSC2007 as its core chip, the board communicates with the main control board about touch point positions through an I2C interface.

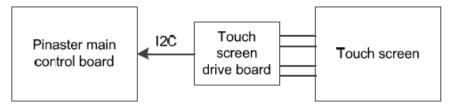


Figure 6-12 Connection of touch screen

#### 6.7.3 Touch Screen Control Board Problem

Table 6-11 Troubleshooting for touch screen problem

No.	Problem Description	Possible Cause	Solution
1	Touch screen does not response when being touched	Touch screen control board error/touch screen error/poor connection	1. Check whether the main control board works properly (e.g. check whether the display screen displays normally, and whether the analyzer can be operated with a mouse.). If there is any problem, start troubleshooting for the main control board first;  2. Check whether the connecting cable between the touch screen control board and the main control board get loose or broken. If yes, reconnect or replace the cable accordingly;
			<ul><li>3. If the error remains after step 1 and 2, replace the touch screen control board;</li><li>4. If the error still remains, replace the touch screen.</li></ul>

2	The cursor only moves in horizontal or vertical direction.	The cable connecting the touch screen control board and the touch screen gets broken	<ol> <li>Check whether is any crack on the touch screen. If yes, replace the touch screen.</li> <li>Reconnect the cable connecting the touch screen control board and the touch screen.</li> </ol>
3	The cursor cannot arrive at a certain position	Touch screen is not calibrated/touch screen gets cracked	1. Perform the touch screen calibration procedure to calibrate the touch screen again (if the cursor position deviates seriously from the intended touched position, so that you cannot even enter the touch screen calibration screen, use a USB mouse to operate and enter the calibration screen);  2. When the error still remains, check if there is any crack on the touch screen. If yes, replace the touch screen.
4	Buzzer	Buzzer won't sound when the analyzer rings alarms	<ol> <li>1. Check whether the main control board works properly (screen displays normally, and basic operations like sample analysis and information review can be run properly). If there is any problem, start troubleshooting for the main control board first;</li> <li>2. Check whether the cables connecting to the indicator board get loose or broken. If they get loose, reconnect the cables; if they get broken, replace it as well as the front panel signal cables;</li> <li>3. If cable errors can be excluded, replace the indicator board.</li> </ol>

## 6.8 Indicator Board

### 6.8.1 Introduction

The indicator board informs about the working status of the analyzer by sending out lights.

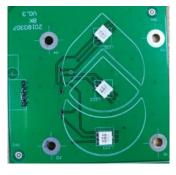


Figure 6-13 Indicator board

### 6.8.2 Components

The indicator board consists of a three color indicator (red, yellow and green) with its control circuit. You do not need to make adjustment to the indicator board during use.

### 6.8.3 Indicator Board problem

Table 6-12 Troubleshooting for indicator problem

Problem type	Problem description	Troubleshooting
Indicator	Indicator	1. Check whether the main control board works properly (screen
	won't light	displays normally, and basic operations like sample analysis and
	on	information review can be run properly). If there is any problem,
		start troubleshooting for the main control board first;
		2. Check whether the cables connecting to the indicator board get
		loose or broken. If they get loose, reconnect the cables; if they get
		broken, replace it as well as the front panel signal cables;
		3. If cable errors can be excluded, replace the indicator board.

## 6.9 Motors, Photocouplers and Micro-switches

#### 6.9.1 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.

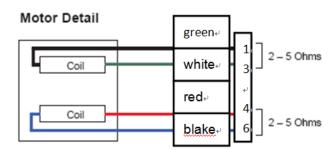


Figure 6-14 Motors illustrations

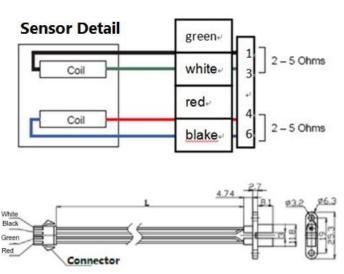


Figure 6-15 Photocouplers illustrations

## 6.9.2 Motor and Photocoupler problem

Table 6-13 Troubleshooting for motors, photocouplers and micro-switches

No.	Problem type	Problem description	Troubleshooting
1	Motors	The motor does not rotate.	<ol> <li>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;</li> <li>Check whether the cable connecting a motor and the main control board get loose or broken; reconnect and replace the cable if necessary;</li> <li>If cable errors can be excluded, replace the motor.</li> </ol>
		Motor won't stop at 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
2	Photocoupler	Motor rotates, but won't arrive at the designated position.	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.

## **6.10 Liquid Detection Board**

#### 6.10.1 Introduction

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



Figure 6-16 Liquid detection board

#### **6.10.2 Components**

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

### 6.10.3 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 an problem, check whether the test point are 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 Z3.

## 7.1.1 Front of the Analyzer

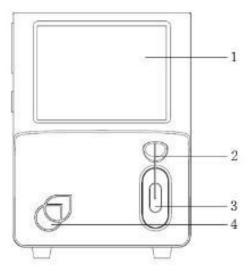


Figure 7-1 Front of the analyzer

1 ---- Display scree 2---- Sample probe

3 ---- [Aspiration] Key 4----Power/Status indicator

## 7.1.2 Front of the Analyzer (front cover open)

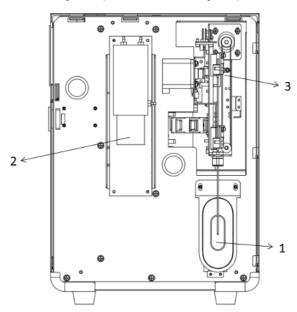


Figure 7-2 Front of the Analyzer (front cover open)

1 ---- [Aspiration] Key Module

2 ---- Syringe module

3 ---- Sampling Module

## 7.1.3 Back of the analyzer

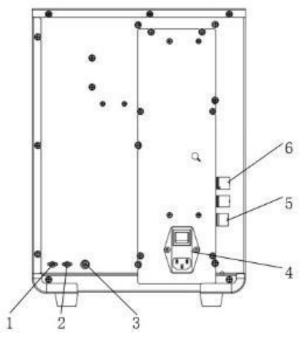


Figure 7-3 Back of the analyzer

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

## 7.1.4 Left Side of the Analyzer

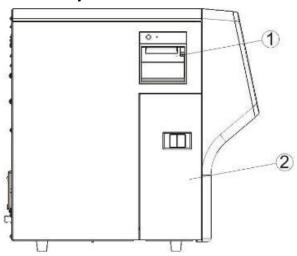


Figure 7-4 Left side of the analyzer

1 ---- Recorder 2 ---- Side door

## 7.1.5 Left side of the analyzer (left door open)

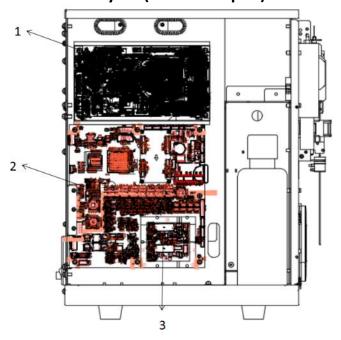


Figure 7-5 Left side of the analyzer (left door open)

1 ---- Motor Drive Board

2 ---- Main control board

3 ----Shielding Box

## 7.1.6 Right Side of the Analyzer (right door open)

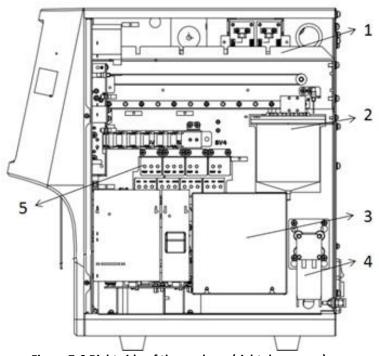


Figure 7-6 Right side of the analyzer (right door open)

1 --- Sampling track

2 --- Vacuum tank

3 --- Counting Chambers

4 --- Vacuum pump

5 --- Valve assembly

#### 7.2 Overview of Assemblies

#### 7.2.1 Introduction

This section displays the explosive views of various assemblies of the analyzer, so our service people may find the component quickly to remove or replace them.

### NOTE

 The material IDs listed in the BOM shall only be used by service people to find the material numbers of maintenance spare parts. Provide the material ID when purchasing any maintenance spare part.

### 7.2.2 Whole Device Explosive view

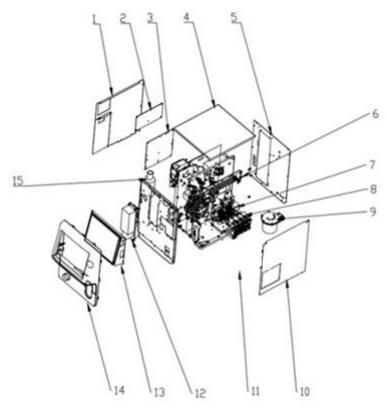


Figure 7-7 Whole Device Explosive view

1 Left side door	2 Motor drive board
------------------	---------------------

3 Main control board	4 Up board
5 Iviairi coriti or board	T Op board

5 --- Back board 6--- Sampling system

7 --- Cell counting assembly 8 --- Valve assembly

9 --- Vacuum tank assembly 10 --- Right side door

11 --- Reserved 12 --- Syringe assembly

13 --- LCD assembly 14 --- Front cover assembly

15 --- Lyse bottle

## 7.2.3 Sampling System

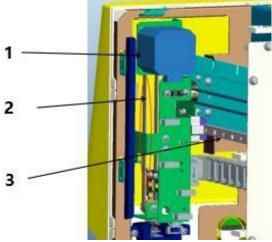


Figure 7-8 Sampling system

- 1 --- Sample system vertical motor
- 2 --- Vertical motor belt
- 3 --- Sampling system horizontal sliding rail

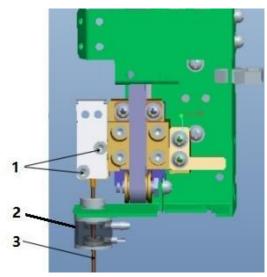
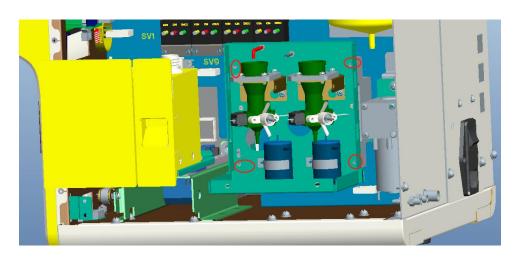


Figure 7-9 Sampling system

- 1 --- Sample system vertical motor3 --- Vertical motor belt
- 2 --- Wash wiper

## 7.2.4 Cell counting assembly



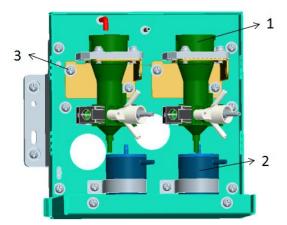


Figure 7-10 Cell counting assembly

1 --- RBC chamber

- 2 --- Isolation chamber
- 3 --- Screw for WBC chamber fixing

## 7.2.5 WBC chamber assembly

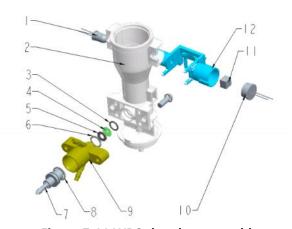


Figure 7-11 WBC chamber assembly

- 1 --- LED lamp 3 --- Aperture O ring
- 3 --- Aperture O ring5 --- Aperture washer
- 7 --- Back bath electrode
- 9 --- Back bath
- 11 --- Sensor fixer

- 2 --- Front bath
- 4 --- Aperture
- 6 --- Aperture O ring
- 8 --- O ring
- 10 --- Optical sensor
- 12 --- HGB bracket

## 7.2.6 Power supply assembly

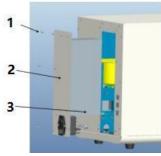




Figure 7-12 Power supply assembly

1 --- Fixing screws

- 2 --- Power supply fixing board
- 3 --- Power supply assembly

## 7.2.7 Vacuum tank assembly

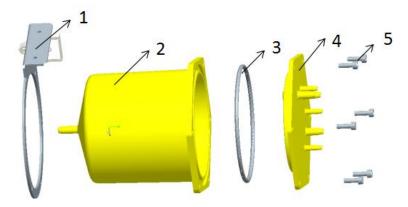


Figure 7-13 Vacuum tank assembly

- 1 --- Vacuum tank bracket
- 3 --- Vacuum tank O ring
- 5 --- Fixing screws

- 2 --- Vacuum tank body
- 4 --- Vacuum tank cover

## 7.2.8 Vacuum pump assembly

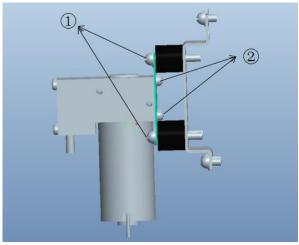


Figure 7-14 Vacuum pump assembly

1 --- Pump board fixing screws

2 --- Pump fixing screws

## **7.2.9** Air pump



Figure 7-15 Air pump

## 7.2.10 Valve assembly

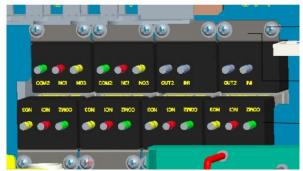


Figure 7-16 Valve assembly

## 7.2.11 Syringe assembly

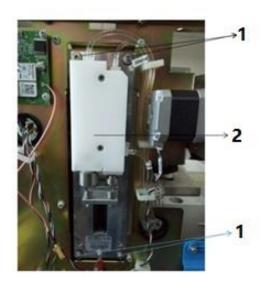
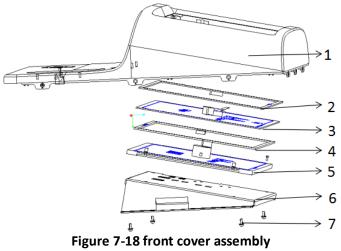


Figure 7-17 Syringe assembly

## 7.2.12 Front cover assembly



- 1 --- Front cover
- 3 --- Touch panel
- 5 --- LCD screen
- 7 --- Fixing screws

- 2 --- Touch panel rubber blanket
- 4 --- Screen EVA blanket
- 6 --- LCD bracket

# 8 Troubleshooting

Error	Code	Troubleshooting	Solution
Abnormal	0x01000001	Communication error.	Reconnect communication cable or
communication Voltage Abnormal	0x01000002	AD out of range [2.44-2.55]V	replace PCBA board.
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		Check reagent expire time, replace
Diluent Expired	0x01000107	System time is later than expire time	and prime diluent.
Lyse Expired	0x01000108	System time is later than expire time	Check reagent expire time, replace and prime Lyse.
Wastes Full	0x01000110	<ol> <li>Check once in startup, and the status is full;</li> <li>Check for 3 times when the analyzer is idled, and the results all show that the status is full.</li> </ol>	Check the floater, connecting cable.
Diluent Empty	0x01000114	The reagent detection reports no diluent	
Diluent Empty	0x01000115	The reagent detection reports no diluent	
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: $51.5V \sim 61.5V$	/
Voltage Abnormal	0x01000202	Digital board +12V out of range [11.0 , 13.0]V, +12V: $10.5V \sim 13.5V$	/
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%	/
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 control board or motor drive board.
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.