

LiNEAR

STEL⁵

Automatic Hematology Analyzer

Service Manual



Linear Chemicals S.L.U.

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CE

REV. A



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⚠WARNING

- ♦ This analyzer can only be operated by test professionals, doctors or laboratory technicians who have been trained by LiNEAR or its distributors.
 - ♦ 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.
-
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NOTE

- ♦ This equipment must be operated by skilled/trained professional maintenance personnel.
 - ♦ Be sure to operate and service the analyzer strictly as instructed in this manual and the operation manual.
-

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2. Product Overview

2.1. Product Name

- Name: Auto Hematology Analyzer
- Model: STEL⁵
- Appearance:



1.1.1. Physical Specifications

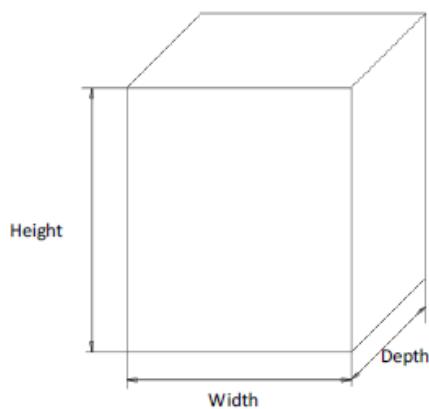


Table 1-1 Dimensions and weight

| Whole device | |
|--------------|--|
| Dimensions | Width ≤ 350mm Height ≤ 450mm (with foot) Depth ≤ 430mm |
| Weight | 28Kg |

1.1.2.Electrical Specifications

Table 1-2 Main unit power supply

| Parameter | Value |
|-------------|-----------|
| Voltage | 100-240V~ |
| Input power | 200VA |
| Frequency | 50/60Hz |

Fuse specification: 021806.3MXP, 6.3A250V, Φ5*20

WARNING

- Only fuses of the specified specification shall be used.
-

1.1.3.Environment Requirements

Table 1-3 Overall environment requirements

| | Operating environment requirements | Storage environment requirements | Running environment requirements |
|----------------------|------------------------------------|----------------------------------|----------------------------------|
| Ambient temperature | 10°C～30°C | -10°C～40°C | 10°C～40°C |
| Relative humidity | ≤ 85% | 10%～90% | 10%～90% |
| Atmospheric pressure | 70kPa～106kPa | 50kPa～106kPa | 70kPa～106kPa |

1.1.4.Product Specifications

- Measurement mode**

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

- Sample mode**

Three sample modes are provided: Whole Blood, Prediluted and Capillary Whole Blood.

Each of the three sample modes can be used in both CBC and CBC+DIFF mode.

- ♦ **Throughput**

The testing speed of STEL⁵ for Whole Blood/Capillary WB/Prediluted blood modes in open vial sampling mode is not lower than 60 samples per hour.

2.2. Testing Parameters

The parameters under CBC and CBC+DIFF mode are listed as follows:

Table 1-4 Parameters

| Parameter Group | Name | Abbreviation | CBC | CBC+DIFF |
|--|---------------------------------|--------------|-----|----------|
| WBC group (15), including 4 RUO parameters | White Blood Cell count | WBC | ✓ | ✓ |
| | Basophils number | Bas# | / | ✓ |
| | Basophils percentage | Bas% | / | ✓ |
| | Neutrophils number | Neu# | / | ✓ |
| | Neutrophils percentage | Neu% | / | ✓ |
| | Eosinophils number | Eos# | / | ✓ |
| | Eosinophils percentage | Eos% | / | ✓ |
| | Lymphocytes number | Lym# | / | ✓ |
| | Lymphocytes percentage | Lym% | / | ✓ |
| | Monocytes number | Mon# | / | ✓ |
| | Monocytes percentage | Mon% | / | ✓ |
| | Abnormal Lymphocytes number | *ALY# | / | ✓ |
| | Abnormal Lymphocytes percentage | *ALY% | / | ✓ |
| | Large Immature Cells number | *LIC# | / | ✓ |
| | Large Immature Cells percentage | *LIC% | / | ✓ |
| RBC group (8) | Red Blood Cell count | RBC | ✓ | ✓ |
| | Hemoglobin Concentration | HGB | ✓ | ✓ |
| | Mean Corpuscular Volume | MCV | ✓ | ✓ |
| | Mean Corpuscular Hemoglobin | MCH | ✓ | ✓ |

| Parameter Group | Name | Abbreviation | CBC | CBC+DIFF |
|-----------------|--|--------------|-----|----------|
| PLT group (6) | Mean Corpuscular Hemoglobin Concentration | MCHC | ✓ | ✓ |
| | Red Blood Cell Distribution Width - Coefficient of Variation | RDW-CV | ✓ | ✓ |
| | Red Blood Cell Distribution Width - Standard Deviation | RDW-SD | ✓ | ✓ |
| | Hematocrit | HCT | ✓ | ✓ |
| | Platelet count | PLT | ✓ | ✓ |
| | Mean Platelet Volume | MPV | ✓ | ✓ |

Table 1-5 Histograms

| Name | Abbreviation | CBC | CBC+DIFF |
|--------------------------|---------------|-----|----------|
| Red Blood Cell Histogram | RBC Histogram | ✓ | ✓ |
| Platelet Histogram | PLT Histogram | ✓ | ✓ |

Table 1-6 Scattergrams

| Abbreviation | CBC | CBC+DIFF |
|-------------------|-----|----------|
| Diff Scattergrams | / | ✓ |
| WBC Scattergram | ✓ | ✓ |

NOTE

- ♦ ALY#, ALY%, LIC# and LIC% are research parameters which are only intended for research purpose and cannot serve as basis for clinical diagnosis.
- ♦ “✓” means “available under the mode”, “/” means “not available under the mode”.

2.3. Product Description

- STEL⁵ Auto Hematology Analyzer primarily comprises the host, accessories and software. The host includes a display screen, sampling assembly, fluidic system, optical system, power interface, reagent interface and signal interface. Model differences are as follows:

| | STEL ⁵ |
|--------------------------------|----------------------------|
| Throughput | 60 samples/hour |
| Barcode scanning module | Standard |
| Memory | 50000 |
| RUO parameter | *ALY#, *ALY%, *LIC#, *LYC% |
| Other parameter | P-LCC, P-LCR |

WARNING

- This analyzer is heavy and may cause personal injury if handled by only one person. It requires at least two people to transport the analyzer. It is important to follow appropriate safety rules and use appropriate tools while handling.
-

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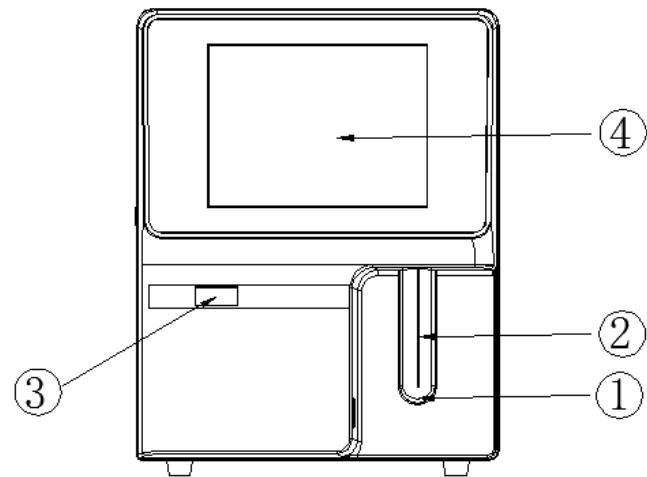


Figure 1-1 Front view of the main unit

- | | |
|---------------------|-------------------|
| 1--- [Aspirate] key | 2--- Sample probe |
| 3--- Indicator | 4--- Touch screen |

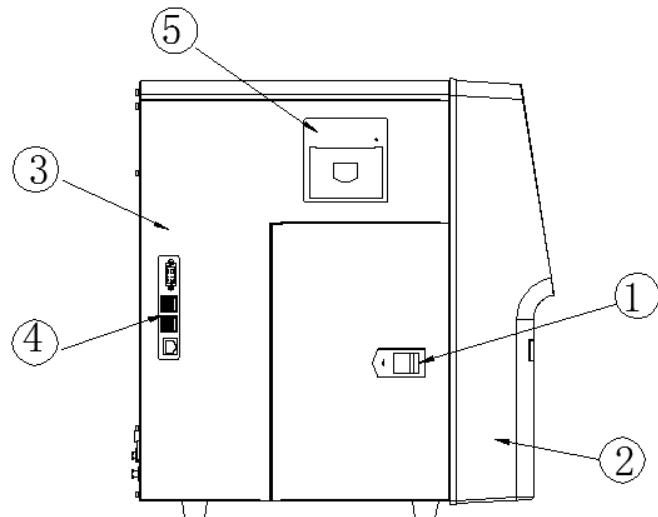


Figure 1-2 Left view of the main unit

- | | |
|-------------------------|-----------------------|
| 1--- Access door | 2--- Panel module |
| 3--- Left door assembly | 4--- Network/USB port |
| 5--- Recorder | |

2.3.1. Main unit

The machine for analysis and data processing, it is the main part of the product.

2.3.2. Indicator

The indicator is located in the lower left side of the analyzer (front side). It indicates the status of the analyzer including ready, running, error, standby and on/off, etc.

2.3.3. Power switch

The power switch is located on the rear side of the analyzer. It is used to turn on/off the analyzer.

CAUTION

- ♦ Do not turn on/off the switch repeatedly in a short time to avoid damaging the analyzer.
-

2.3.4. [Aspirate] key

The [Aspirate] key is located in the middle of the right front side. Press the key to start the selected analysis, dispense diluent or exit from standby mode.

2.3.5. Network/USB port

There are 4 USB ports, 1 network port, 1 9-PIN serial port on the left side of the main unit for peripheral connection or data transmission.

2.4. Product Configuration

The system configuration is composed mainly of the main analyzer unit, accompanying accessories and reagent system. The user can choose an optional external scanner.

The USB port can be used to connect the following printer models: HP Color LaserJet Pro M252n, HP LaserJet Pro P1108 and HP LaserJet Pro P1102.

2.5. 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. You should only use the specified reagents 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. Otherwise, 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 there is evidence of leakage or improper handling, do not use the reagent.

NOTE

- ♦ Store and use the reagents as instructed by instructions for use of the reagents.
 - ♦ 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.
-

2.5.1. Reagents

1. *Diluent*

It is used to dilute the blood samples to achieve functions such as blood cell counting, volume measurement and hemoglobin measurement.

2. *DIFF lyse*

It is used to lyse red blood cells and differentiate WBCs.

3. *LH lyse*

It is used to lyse red blood cells, count and differentiate WBCs, and determine the HGB.

4. *Probe cleanser*

It is used to clean the analyzer regularly.

2.5.2. Controls and Calibrators

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

The controls are industrial whole blood products, used for monitoring and evaluating the accuracy of the hematology analyzer. They are available in low, normal, and high levels. The calibrators are also commercially prepared whole blood products, used for calibration of the analyzer to establish metrological traceability for measurement results. Store and use the controls and calibrators as instructed by their instructions for use.



2.6. Information Storage Capacity

Table 1-7 Data storage requirements

| | |
|------------------|---|
| Storage capacity | STEL ⁵ storage capacity of sample data is not less than 50000 |
| Storage contents | The storage contents shall include at least the following information: counting results and diagrams (including histograms and scattergrams), sample information, patient information, alarm information, special information of the instrument |



3. Installation

3.1. Checking before Installation

All the analyzers have been inspected strictly before packing and shipping. When you received your analyzer, before opening the packaging, perform a thorough inspection and note whether there is any of the following damage:

1. Up-side-down or distortion of the packaging.
2. Obvious water marks on the packaging.
3. Obvious signs of being struck on the packaging.
4. Packaging shows signs of having been opened previously.

If you notice any of the above instances of damage, please immediately notify your local distributor.

If the outer packaging is intact, unpack it in the presence of your local distributor and conduct the following inspection:

1. Verify if all the components are equipped according to the packing list.
2. Carefully check the appearance of all the components to verify whether there is breakage, crash or deformity.

If you notice any shipping damage or missing part, please immediately notify your local distributor.

3.2. Installation Requirements

3.2.1. Space Requirements

Check the site for proper space allocation. In addition to the space required for the analyzer itself, arrange for:

1. proper height to place the analyzer;
 2. at least 100cm between the left and right-side door of the analyzer and the walls, which is the preferred access to perform service procedures;
 3. at least 50cm behind the analyzer for cabling and ventilation.
-

WARNING

- ♦ There should be enough room on and below the countertop to accommodate the reagents and waste containers.
 - ♦ The diluent container shall be put within 1.0m under the analyzer, lyse containers are placed inside the analyzer.
 - ♦ The countertop (or the floor) where the analyzer is placed shall be able to withstand at least 40kg of weight.
-

3.2.2. Power Requirements

Table 2-1 Power specification

| | Voltage | Input power | Frequency |
|----------|----------------|--------------------|------------------|
| Analyzer | 100-240V~ | 200VA | 50/60Hz |

WARNING

- ♦ Make sure the analyzer is properly grounded.
 - ♦ Before turning on the analyzer, make sure the input voltage meets the requirements.
-
-

CAUTION

- ♦ Using pinboard may bring the electrical interference and the analysis results may be unreliable. Please place the analyzer near the electrical outlet to avoid using the pinboard.
 - ♦ Please use the original power cable shipped with the analyzer. Using other power cable may damage the analyzer or cause unreliable analysis results.
-

3.2.3. Environmental Requirements

1. Operating temperature range: 10°C-30°C
 2. Relative humidity: ≤ 85%
 3. Atmospheric pressure: 70.0kPa-106.0kPa
-

NOTE

- ♦ The environment shall be as free as possible from dust, mechanical vibrations, loud noises, and electrical interference.
 - ♦ It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
 - ♦ Keep the analyzer away from strong sources of electromagnetic interference, as these may interfere with the proper operation.
 - ♦ Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close.
 - ♦ Do not place the analyzer in direct sunlight or in front of a source of heat or wind.
 - ♦ The environment shall be ventilated.
 - ♦ Place the analyzer on a horizontal flat surface.
 - ♦ Connect only to a properly earth grounded outlet.
 - ♦ Only use this analyzer indoors.
-

3.2.4. Moving and Installation Method

Moving and installation of the analyzer shall be conducted by authorized personnel. Do not move or install your analyzer without the presence of authorized personnel or your local distributor.

WARNING

- ♦ Installation by personnel not authorized or trained by LiNEAR may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of LiNEAR-authorized personnel or local distributor.
-
-

NOTE

- ♦ Before the analyzer is shipped out, the sample probe is fixed by a plastic cable tie to avoid damaging the sample probe during transportation. Remove the cable tie before using the analyzer.
-

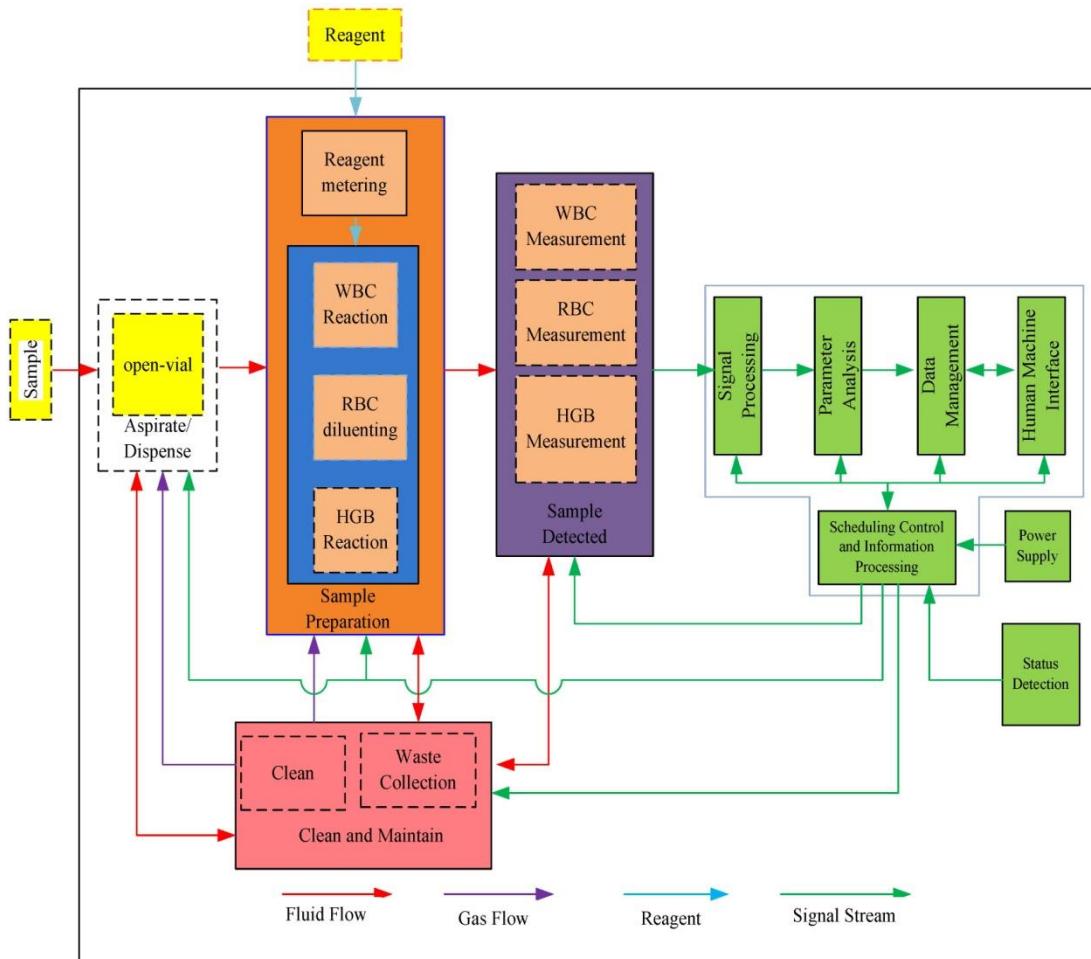
4. Working Principles

4.1. Overview

This analyzer uses Coulter principle to test the number of RBC and PLT; colorimetric method to determine HGB concentration; and semiconductor laser flow cytometry to obtain differential statistics of WBC. The analyzer will calculate the other parameters based on these results.

4.2. Workflow

The whole system contains the following main functions: reagent system, sample allocation, sample preparation, sample testing, signal processing, parameter analysis, data management, status monitoring, scheduling control and information processing, human machine interface, power supply, cleaning and maintenance. The relationship between these functions is as shown in the chart below.



The scheduling control and information processing function block controls other function blocks, which collaborate in accordance with the designed processes and requirements to complete the core task of the whole system, i.e. sample measurement and analysis.

4.3. Sample Aspiration

If you are to analyze a whole blood sample in the open vial sampling mode, the analyzer will aspirate 20 μ L (CBC+DIFF mode) or 12 μ L (CBC mode) of the sample.

In the open vial prediluted mode, the operator shall mix 20 μ L of capillary blood sample and 480 μ L of diluent outside the analyzer to obtain a diluted sample with the dilution ratio of 1:25, and send this diluted sample to the analyzer, which will aspirate 224 μ L of diluted sample.

4.4. WBC Measurement

4.4.1. Laser Flow Cytometry

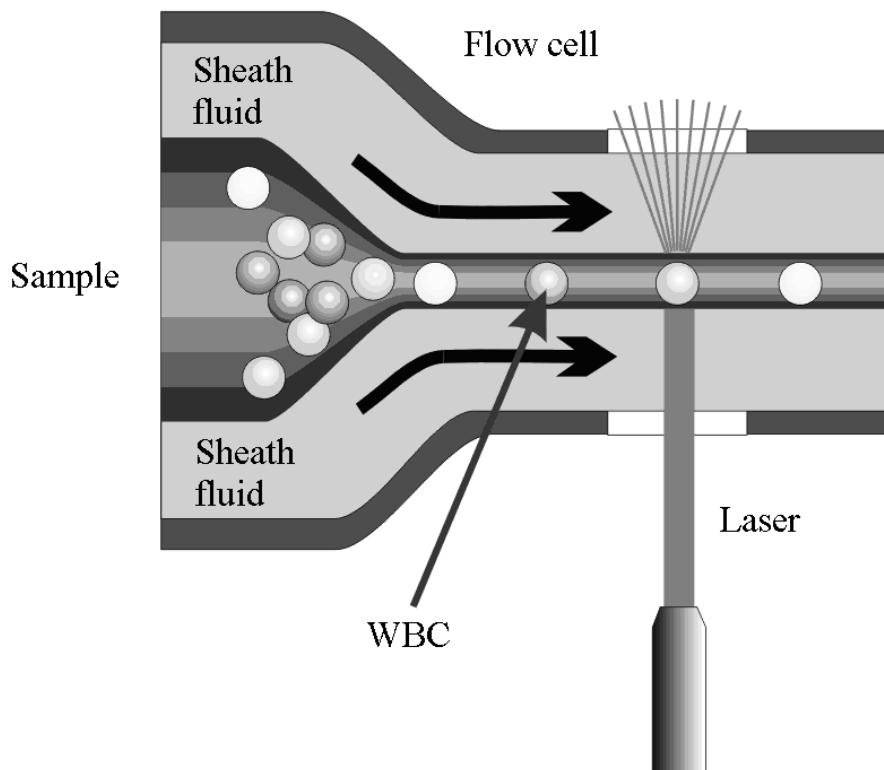


Figure 3-1 WBC Measurement

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

4.5. HGB Measurement

4.5.1. Colorimetric Method

After lyse is added into the diluted sample, the red blood cells will be lysed and release hemoglobin, which combines with lyse to form hemoglobin complexes. According to the Lambert-Beer's law, with the radiation of LED monochromatic light with a central wavelength of 530nm, it is possible to measure the transmitted light density of the hemoglobin complexes in the solution and background, by which the hemoglobin concentration can be calculated.

4.5.2. HGB Concentration Parameters

HGB concentration in g/L can be calculated from the following equation.

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

4.6. RBC/PLT Measurement

4.6.1. Electrical Impedance Method

This analyzer employs the impedance method to count the RBC/PLT. There is a small opening in the RBC bath, which is called inspection aperture. A pair of positive and negative electrodes on both sides of the aperture is connected to a constant current power supply. Since the cells are poor conductor of electricity, when the cells in the diluted sample pass through the aperture under a constant negative pressure, the resistance between the electrodes changes to generate a pulse signal across the electrodes, which is proportional to the cell size. The number of the pulses is equal to the number of cells that pass the aperture, and the amplitude of the pulses is proportional to the cell size.

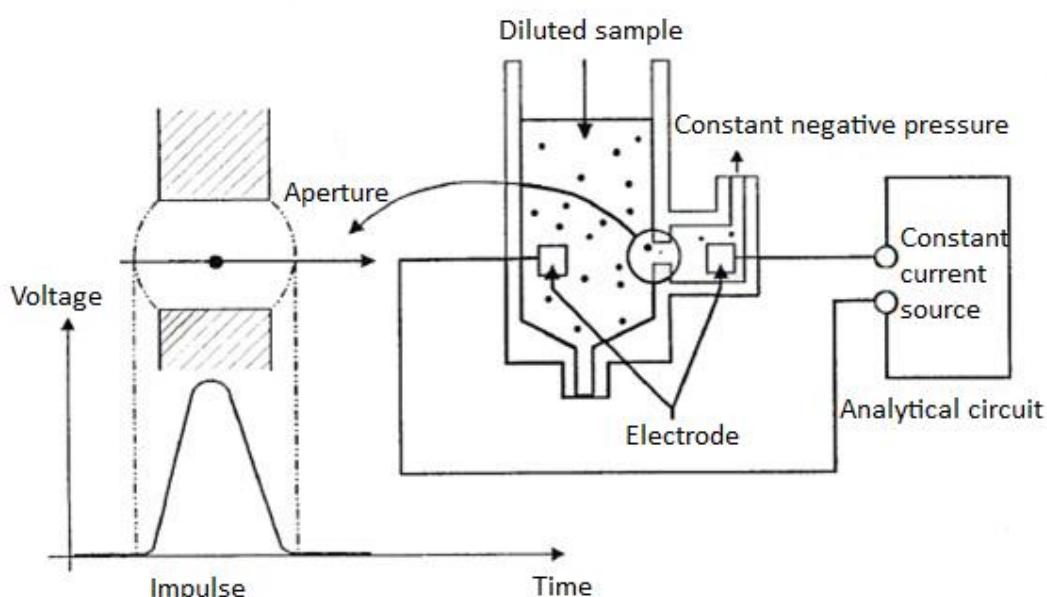


Figure 3-2 Counting principle

The collected electrical pulses are amplified and then compared with the channel voltage threshold corresponding to the size range of normal red blood cells/platelets, in order to calculate the number of the pulses of which the amplitudes are within the red blood cell/platelet channel. Therefore, the collected electrical pulses are classified according to the channel voltage threshold. The numbers of the electrical pulses within the red blood cell/platelet channel are the numbers of the red blood cells/platelets. The size distribution of the cells is determined by the numbers of the cells in each channel, which are classified according to the pulse voltage amplitude. The two-dimensional diagram, in which the horizontal axis represents the cell size and the vertical axis represents the relative number of the cells, are the histogram that reflects the distribution of the cell groups.

4.6.2. Derivation of RBC-Related Parameters

1. RBC

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

2. MCV

Based on the RBC histogram, this analyzer calculates the mean cell volume (MCV) and expresses the result in fL.

3. HCT, MCH and MCHC

This analyzer calculates the HCT (%), MCH (pg) and MCHC (g/L) as follows, where the RBC is expressed in $10^{12}/L$, MCV in fL and HGB in g/L.

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

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

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

4. RDW-CV

Based on the RBC histogram, this analyzer calculates the CV (Coefficient of Variation) of the erythrocyte distribution width, which is expressed in %.

5. RDW-SD

RDW-SD (RBC Distribution Width – Standard Deviation, fL) is obtained by calculating the standard deviation of erythrocyte size distribution.

4.6.3. Derivation of PLT-Related Parameters

1. PLT

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

2. MPV

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

3. PDW

Platelet distribution width (PDW) is the geometric standard deviation (GSD) of the platelet size distribution. Each PDW result is derived from the platelet histogram data and is reported as $10^{(GSD)}$.

4. PCT

This analyzer calculates the PCT as follows and expresses it in %, where the PLT is expressed in $10^9/L$ and the MPV in fL.

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

5. Software and Interface

5.1. Login

Log in using the service level username and password:

Username: Service

Password: GRKT03

NOTE

- The login password is case sensitive.
-

5.2. Calibration

5.2.1. Calibration Factor and Transfer Factor

The purpose of calibration is to obtain accurate blood analysis results.

The calibration method is multiplying the result by the calibration factor, so that the final analysis result is close to the target value. The calculation equation of the calibration factor is:

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

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

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

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

There are two calibration factors: factory calibration factor and user calibration factor.

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

$$\text{Analysis result} = \text{Measurement value} \times \text{Factory calibration factor} \times \text{User calibration factor}$$

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

$$\text{Analysis result} = \text{Measurement value} \times \text{Factory calibration factor} \times \text{Transfer factor} \times \text{User calibration factor}$$

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

CAUTION

- If login with service level password, the calibration will modify the factory calibration factor and transfer factor, also will modify the user calibration factor to 100.00%.

5.2.2. Calibration

| | | Sample Analysis | Review | QC | Reagent Setup | Diluent | Print | |
|---------------|------------|--------------------|--------|---------|---------------|---------|-------|---------------------|
| Lot No. | 66677787 | Target | Select | WBC | RBC | HGB | MCV | PLT |
| Exp.Date | 06-02-2017 | 1 | ✓ | 4.58 | 2.87 | 72 | 93.0 | 152 |
| | | 2 | ✓ | 4.38 | 2.88 | 72 | 93.2 | 169 |
| | | 3 | ✓ | 4.58 | 2.99 | 74 | 92.7 | 197 |
| | | 4 | ✓ | 4.48 | 3.03 | 73 | 92.7 | 226 |
| | | 5 | ✓ | 4.63 | 2.98 | 73 | 93.0 | 236 |
| | | 6 | ✓ | 4.56 | 2.94 | 73 | 92.6 | 245 |
| | | 7 | ✓ | 4.60 | 2.89 | 76 | 93.1 | 204 |
| | | 8 | ✓ | 4.09 | 2.93 | 71 | 93.2 | 196 |
| | | 9 | ✓ | 4.22 | 2.92 | 72 | 93.0 | 195 |
| | | 10 | ✓ | 4.11 | 2.91 | 71 | 92.9 | 185 |
| | | 11 | ✓ | 4.13 | 2.96 | 72 | 93.1 | 202 |
| | | 12 | | | | | | |
| | | DIFF-Mean | | 4.54 | 2.95 | 73 | 92.9 | 204 |
| | | DIFF-CV(%) | | 1.9 | 2.1 | 1.0 | 0.2 | 18.5 |
| | | CBC-Mean | | 4.23 | 2.92 | 72 | 93.1 | 196 |
| | | CBC-CV(%) | | 5.0 | 0.8 | 2.8 | 0.1 | 3.7 |
| | | New Cal. Factor(%) | | 176.41? | 135.67? | 164.76? | 96.91 | 97.96 |
| | | Transfer Factor(%) | | 107.33 | 101.03 | 100.59 | 99.80 | 103.96 |
| Export | | Mode: WB-CBC | | | | Service | | 16:41 06-02-2017 |

Figure 4-1 Service level calibration screen

The service level calibration with calibrators will generate the factory calibration factor and transfer factor at a time. The first 6 counts are performed in CBC+DIFF mode, and the last 6 counts are performed in CBC mode. After all the 12 counts are completed, the new calibration factor and transfer



factor will be automatically calculated. The operator will be prompted to save the calibration factor when exiting this screen.

Before calibration, be sure to set up the calibrator Lot No., the calibrator Exp. Date, analysis mode and calibration targets.

The range of calibration factor is [0.75, 1.25].

▲CAUTION

- ♦ Please use specified calibrators for calibration before their expiration date.
-
-

NOTE

- ♦ If the calibration factor and CV are beyond the above range, they will be displayed in red, and the current result will not be saved.
-

5.3. Sample Probe Debugging

The purpose of sample probe debugging is to check if the probe can move to each working position properly.

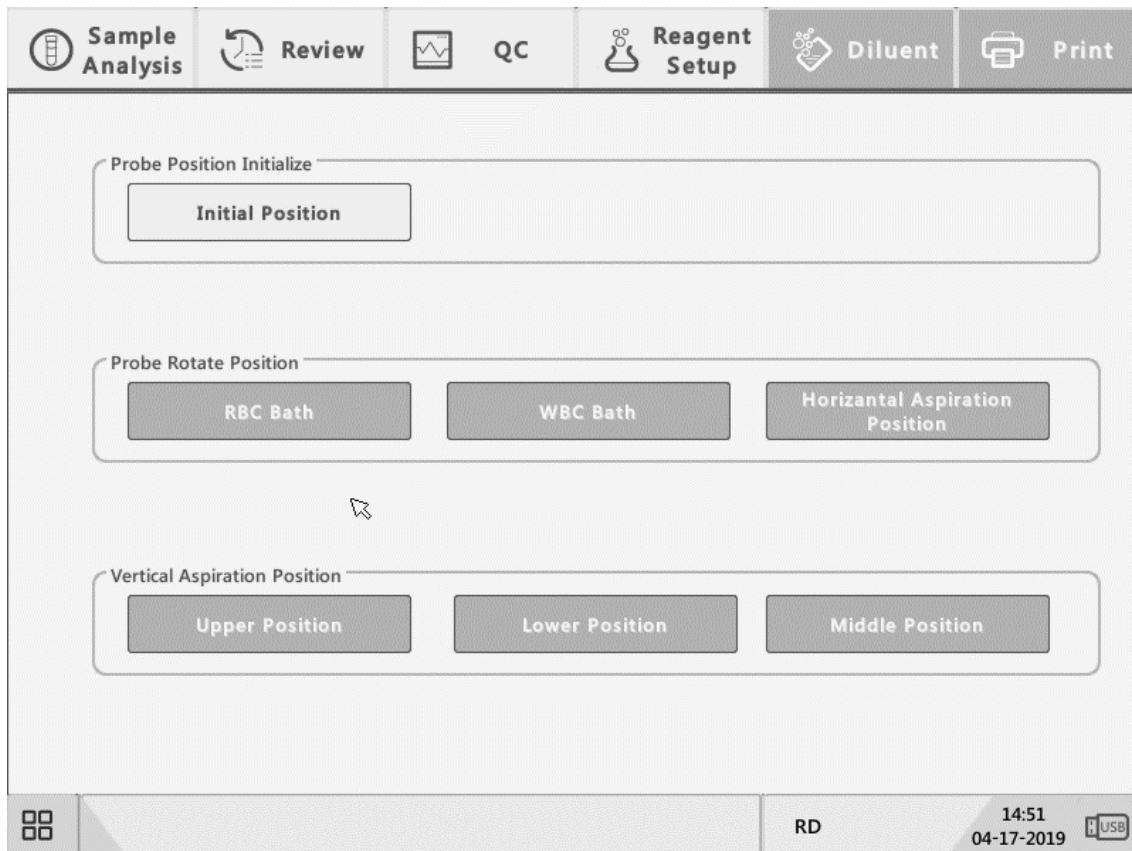


Figure 4-2 Sample probe debugging screen

Enter the sample probe debugging screen and click the “Initial Position” button. Wait until the initialization is completed before starting the sample probe debugging. For detailed information, please refer to Section 12.1 “Sample Probe Position Adjustment” in Chapter 12.

5.4. Temperature Calibration

The purpose of temperature calibration is to minimize the difference between the measured and the actual temperature in order to ensure the accuracy of sample analysis.

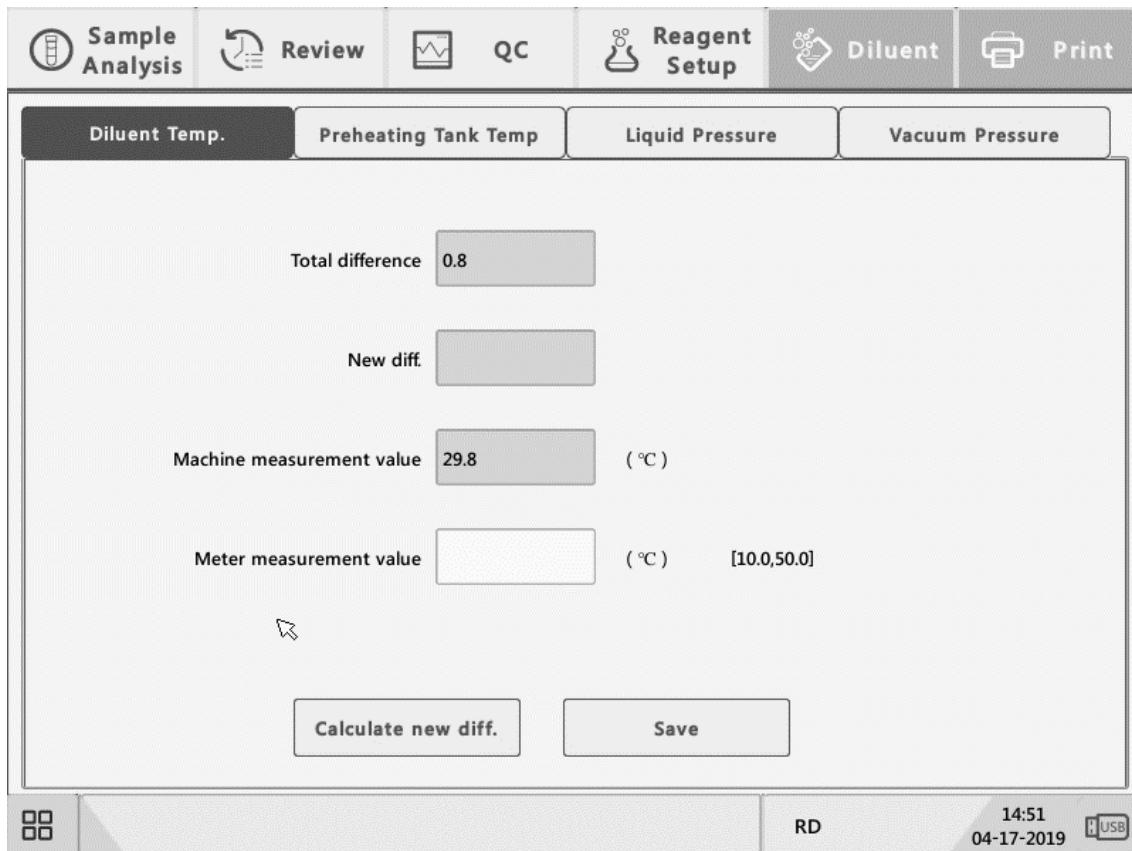


Figure 4-3 Temperature calibration screen

There are four quantities in this screen: total difference, new difference, machine measurement value and meter measurement value. This screen does not include one quantity: the actual measurement value, which is the actual temperature measured by the temperature sensor. These quantities satisfy the following equation:

$$\text{New difference} = \text{Meter measurement value} - \text{Actual measurement value}$$

After clicking "Save", the new difference is assigned to the total difference, i.e.:

$$\text{Total difference} = \text{New difference}$$

$$\text{Machine measurement value} = \text{Actual measurement value} + \text{Total difference}$$

5.5. Gain Setting

The optical gain, RBC gain and HGB gain can be set up in the Gain Setting screen.

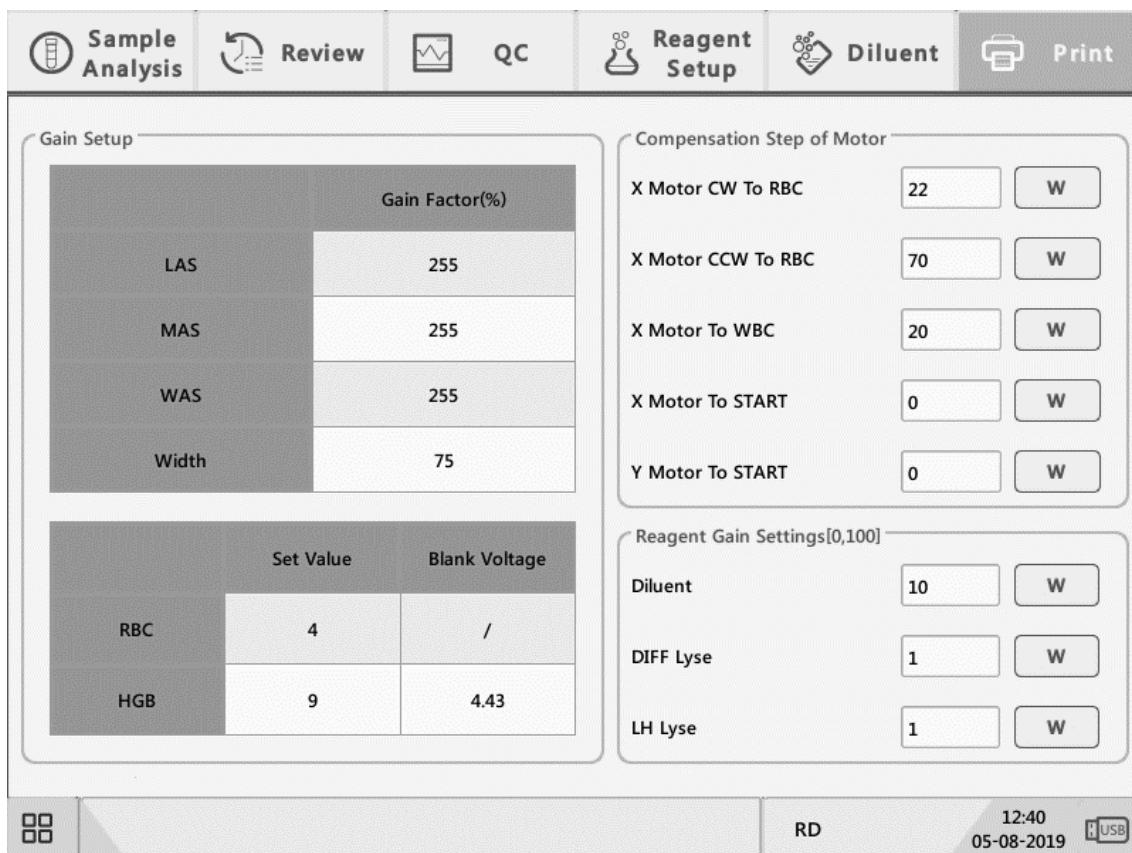


Figure 4-4 Gain setting screen

The optical gain is a software gain and shall be filled with the gain factor, which can be calculated by the following equation:

$$\text{Gain factor} = \frac{\text{CG target value}}{\text{Current count CG value} \times \text{Old gain factor}}$$

The gain factor is a percentage value. The Gain Setting screen allows the gain factor to be set as accurate to two decimal places.

The RBC gain and HGB gain are hardware gains, which require the digital potentiometer to be set. The range of gain setting is [0, 255].

The RBC gain setting can be calculated by the following equation:

$$\frac{\text{New MCV}}{\text{Old MCV}} = \frac{\text{New gain value} + 28.16}{\text{Old gain value} + 28.16}$$

The HGB gain setting does not need to be calculated by an equation, just modify the setting until the background voltage is equal to 4.5±0.1V.

NOTE

- ♦ The gain settings will have effect on the affectivity of the measurement. Please be careful with the setting.
- ♦ While the analyzer is in standby, the HGB voltage will not reflect the background voltage. In this event, the operator must exit the standby mode before adjusting the HGB gain.

5.6. Performance

5.6.1. Background test

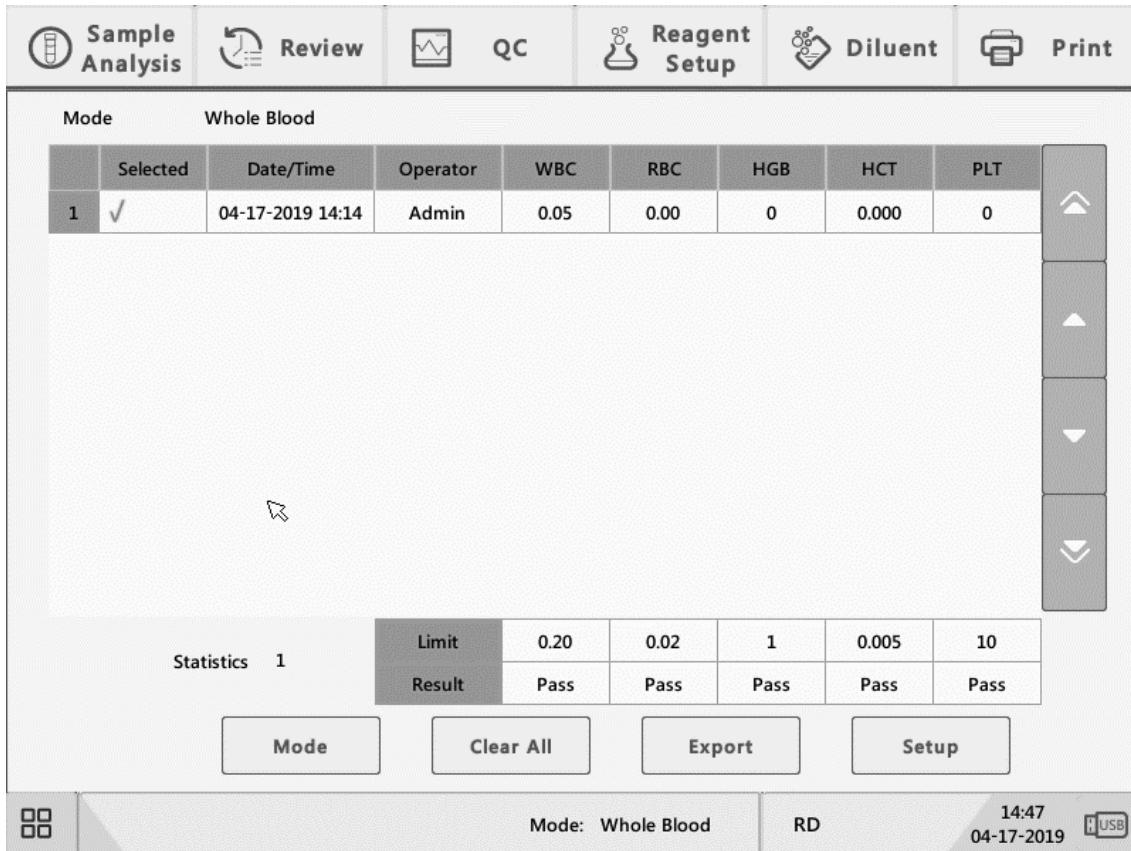


Figure 4-5 Background count screen

In the Background Count screen, pressing the aspirate key without using any sample will start the background count. In the Background Count screen, if “pass” is displayed in the Result column, then the background test is passed.

5.6.2. Carryover

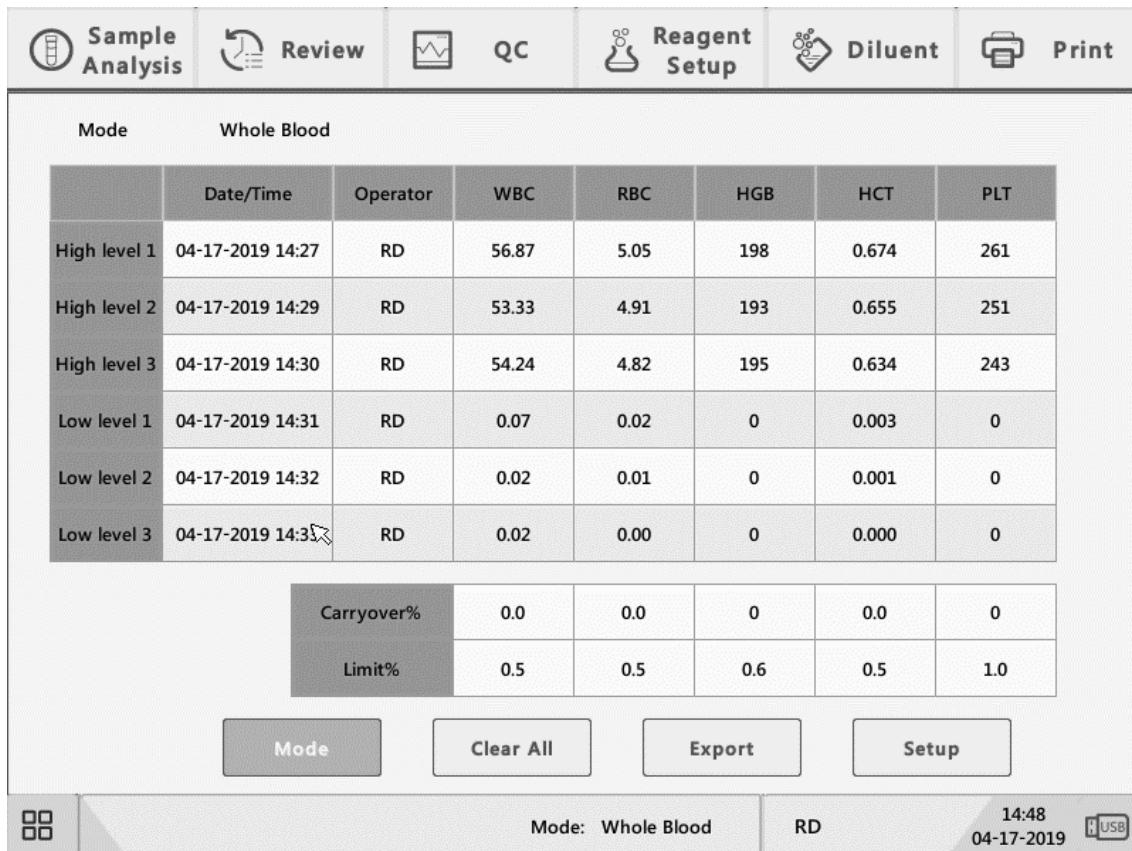


Figure 4-7 Carryover test screen

Test method: Under the stable condition of the analyzer, perform three consecutive measurements on the high-level sample immediately followed by three consecutive measurements on the low- level sample. The carryover can be calculated from the following equation:

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

5.7. Advanced Toolbox

5.7.1. System Configuration

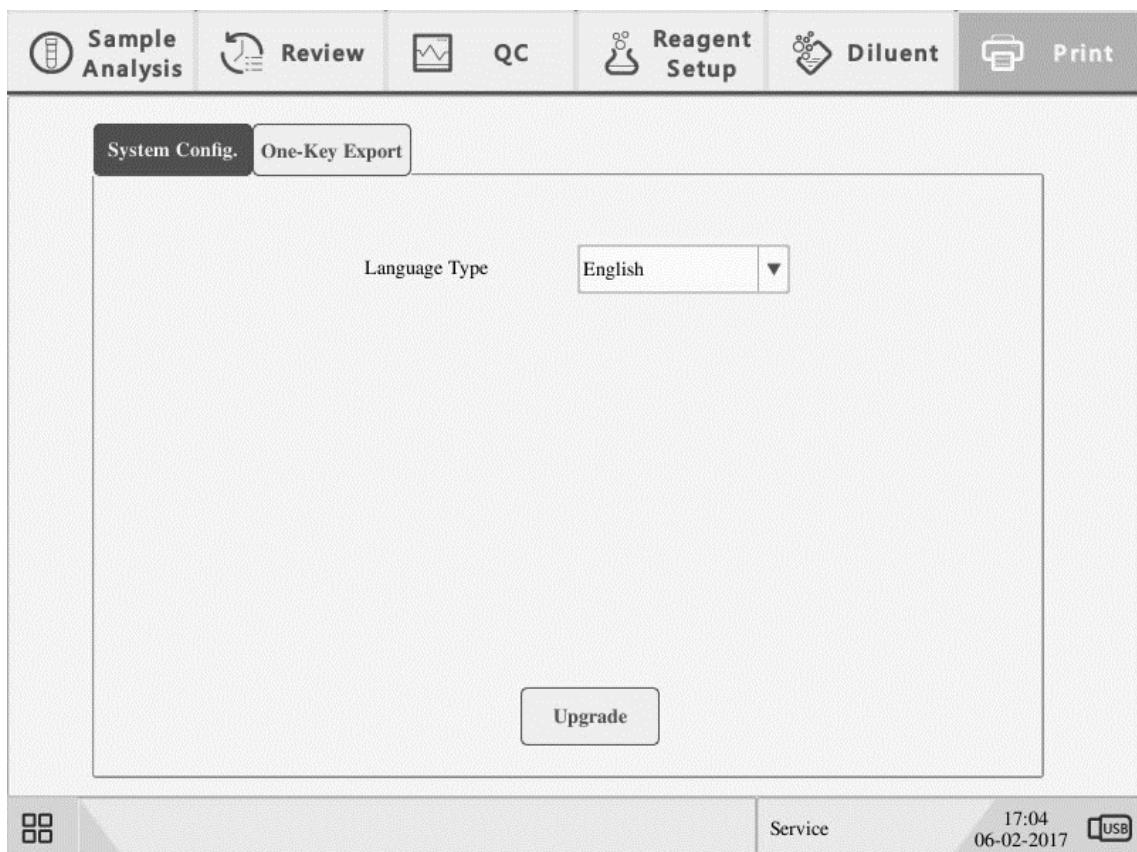


Figure 4-8 System configuration screen

On the System Configuration tab of the Advanced Toolbox, you can modify the language type and make software upgrades.

NOTE

- ♦ The modification to language type will not take effect until after the analyzer is restarted.
 - ♦ At most 500 inf. files can be saved. After 500 files are saved, the new files will overwrite the old files. (Automatic setting)
-

5.7.2. One-key Export

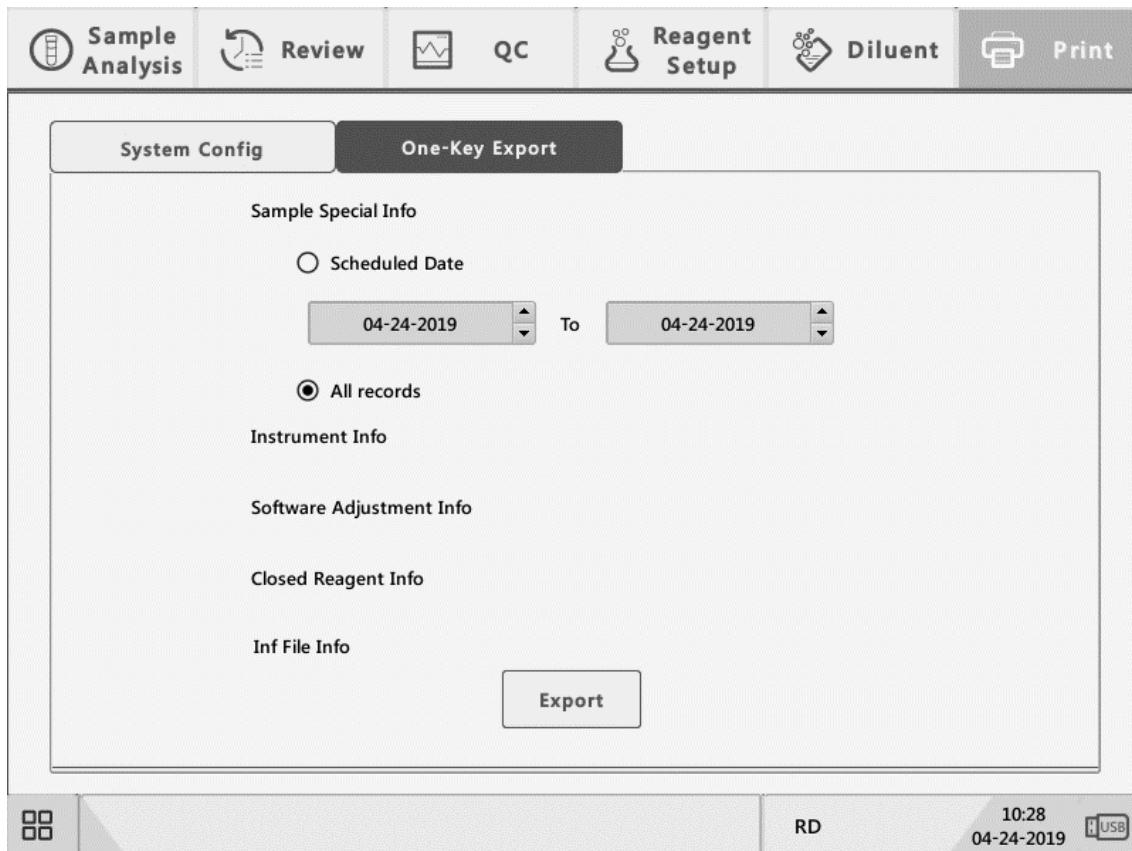


Figure 4-9 One-key export screen

The contents that can be exported by One-Key operation include:

- Inf. files
- Special information files
- Instrument information: includes version information, configuration parameter (gain and calibration), algorithm parameters, instrument status, software language and instrument name
- Software debug information includes parameter setting, error log, upgrade log and system log
- Closed reagent information includes closed reagent information and counter information

NOTE

- ♦ The USB flash drive has been preformatted as FAT32.
- ♦ There is enough free space in the USB flash drive. It is recommended to reserve 4G space.

5.8. Software Upgrade

- Create an upgrade USB flash drive

Copy the file named "ktUpdate.dav" to a formatted USB flash drive.

NOTE

- ♦ The USB flash drive has been preformatted as FAT32.
 - ♦ "ktUpdate.dav" is stored directly under the root directory of the USB flash drive.
-

- Upgrade

Insert the USB flash drive into the USB port on the analyzer. Enter the Advanced Toolbox and launch Upgrade to upgrade the software according to the prompts. After the upgrade is complete, you will be prompted to shut down and restart the analyzer.

CAUTION

- ♦ Never disconnect the USB flash drive or the power supply during the upgrade process. Otherwise the analyzer may not be able to start.
-
-

NOTE

- ♦ The duration of the upgrade process varies with the upgrade contents. Typically, it will last for around 10 minutes.
-

- Troubleshooting

If the upgrade fails, try again.

5.9. Status Indicator

The system status is indicated by the three colors indicator on the panel door. All the flash cycles are 2 seconds. The indicator changes with the analyzer status as shown in the table below:

Table 4-1 Indication of the main unit status indicator

| Analyzer status | Indicator | Remark |
|---|--------------------------|--|
| Ready | Green light on | Sequence is allowed |
| Running | Green light flashing | Sequence is being performed |
| Running with error | Red light flashing | The analyzer is running with error |
| Stop with fault | Red light on | An error has occurred, and the analyzer is not running |
| No error, but fluidic actions are not allowed | Yellow light on | Initialization (not involving sequence actions) in startup process, standby status |
| Enter/Exit standby status | Yellow light flashing | Enter/Exit standby status |



5.10. Buzzer

When an error occurs, the buzzer will beep. The alarm will be automatically cleared by tapping the touchscreen or correcting the error. The buzzer alarm will stop when all the errors are cleared. It prompts to instruct the user with possible actions by the beep.

Table 4-2 Main unit buzzer prompts

| Process | Notification | Action |
|---|-------------------------|--|
| Startup completed | 1 short beep | Startup completed means the whole startup process has been completed and the analyzer is ready for operation |
| Open-vial aspiration completed | 2 short beeps | / |
| Press the aspirate key on the analysis screens (including sample analysis, QC, calibration, reproducibility, carryover, background, aging, optical gain calibration count, etc.) when analysis cannot be started. | 1 long beep | When dialog box message is given, the buzzer may not beep. |
| Error | Long intermittent beeps | Tap the touch screen to turn off the buzzer. |
| The analyzer enters ready status | 1 short beep | The analyzer enters ready status from other status. |
| When the analyzer screen turns black and the message "Please power off the analyzer" appears | Turn off the buzzer | If an error occurs during the shutdown process, turn off the buzzer when the screen turns black. |

6. Data Transmission

6.1. LIS Connection

- Communication setup (“Menu”>“Setup”>“System Setup”>“Communication Setup”)

The operator can perform the following setups in the “Communication Setup” screen.

- Protocol setup
- Transmission mode



Figure 5-1 Communication setup screen

- Protocol setup

IP address: IP address setting of the analyzer.

Subnet mask: The subnet mask of the analyzer, usually 255.255.255.0.

Default gateway: IP address of the gateway.

Mac address: Mac address of the analyzer, given by the factory, cannot be changed.

LIS IP address: IP address used in the PC where the LIS software is located.

LIS port: Port number occupied by the LIS software.

Comm. protocol: For selecting the protocol type. Click the pull-down list and select the appropriate communication protocol type from the options. Currently only HL7 protocol is supported.

ACK synchronous transmission: This function can be activated by selecting the “ACK Synchronous Transmission” checkbox. When this function is active, the ACK timeout is defaulted as “10” seconds.

NOTE

- ♦ The IP address of the analyzer is statically allocated. Before setup, please consult your network administrator to avoid IP conflict.
- ♦ For communication across subnets, the subnet mask and the gateway must be correct. Please consult your network administrator.

- ♦ Transmission mode

The operator can select required options by clicking the following checkboxes to activate corresponding communication setup as needed:

- Auto retransmit
 - Auto communication
 - Auto fetch info from LIS
 - Transmit as print bitmap data
-

NOTE

- ♦ “Auto retransmit” means that the communication can be resumed automatically after the network resumes. (To check the “Auto retransmit”, the “ACK Synchronous Transmission” must be checked first.)
 - ♦ “Auto communication” means that it is automatically uploaded to the LIS after the sample analysis is complete.
 - ♦ “Auto fetch info from LIS” is a two-way LIS function. If this option is selected, press the [Get LIS] button in the next sample information interface in the “Sample Analysis” interface, you can read the patient information from the LIS side.
 - ♦ “Transmit as print bitmap data” means that the transmission mode of graphics data is print bitmap data.
-

- ◆ Transmission method for histograms and scattergrams
 - ◆ Click the pull-down list and select the transmission method for histograms and scattergrams as required from the following options:
 - Not transmitted
 - Bitmap
 - Data
-

NOTE

- ◆ “Not transmitted” means that it will upload neither the picture nor the data to the LIS.
 - ◆ “Bitmap” means that it will upload histograms and scattergrams to LIS in BMP format.
 - ◆ “Data” means that the histograms and scattergrams will be converted into binary data by the system and uploaded to LIS in data format.
-

6.2. Communication Error Analysis

6.2.1. Physical Connection

Check if the network cable works properly and the physical network connections are correct.

1. Communication is completed. The analyzer communicates with the LIS normally.

The screenshot shows a software interface for a laboratory analyzer. At the top, there is a menu bar with icons for Sample Analysis, Review, QC, Reagent Setup, Diluent, and Print. Below the menu is a table with 15 rows of sample data. A modal dialog box is overlaid on the table, containing the text "Prompt" at the top, "Communication is completed." in the center, and an "OK" button with a checkmark icon at the bottom. The table columns are labeled: No., Sample ID, Status, WBC, Neu#, Lym#, Mon#, Eos#, Bas#, Neu%, and several empty columns for reagent setup and diluent. The bottom of the screen features navigation buttons (left, right, up, down arrows) and a footer with buttons for Graph Review, Edit Info, Search, Validate, Cancel Validate, Comm., and a date/time stamp (14:00 07-27-2017). There is also a USB port icon in the bottom right corner.

| No. | Sample ID | Status | WBC | Neu# | Lym# | Mon# | Eos# | Bas# | Neu% |
|-----|-----------|--------|-------|--------|--------|--------|--------|--------|-------|
| 21 | 22 | | L0.71 | L0.28 | L0.27 | L0.05 | L0.00 | H0.11 | L39.6 |
| 20 | 21 | | L0.82 | L0.32 | L0.33 | L0.04 | L0.00 | H0.13 | L39.2 |
| 19 | 20 | | | | | | | H0.15 | L34.3 |
| 18* | 19 | | | | | | | H0.16 | L46.8 |
| 17 | 18 | | | | | | | H2.18 | L46.3 |
| 16 | 17 | | | | | | | H7.23 | L6.7 |
| 15 | 16 | | | | | | | H3.22 | L36.1 |
| 14 | 15 | | | | | | | 0.05 | 53.6 |
| 13 | 14 | | | | | | | 0.09 | 55.0 |
| 12 | 13 | | L0.58 | L0.35 | L0.17 | L0.01 | L0.00 | 0.05 | 61.0 |
| 11 | 12 | | L0.03 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* |
| 10 | 11 | | L0.02 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* |

2. Please ensure that the network is connected. Cause of communication error: direct connection to the LIS terminal or connection to the LIS cable is not smooth.

| Sample Analysis | | Review | | QC | | Reagent Setup | | Diluent | | Print | |
|-----------------|-----------|--------------|-------|--------|--------|---------------|--------|---------------------|-------|-------|--|
| No. | Sample ID | Status | WBC | Neu# | Lym# | Mon# | Eos# | Bas# | Neu% | | |
| 21 | 22 | | L0.71 | L0.28 | L0.27 | L0.05 | L0.00 | H0.11 | L39.6 | | |
| 20 | 21 | | L0.82 | L0.32 | L0.33 | L0.04 | L0.00 | H0.13 | L39.2 | | |
| 19 | 20 | | | | | | | H0.15 | L34.3 | | |
| 18* | 19 | | | | | | | H0.16 | L46.8 | | |
| 17 | 18 | | | | | | | H2.18 | L46.3 | | |
| 16 | 17 | | | | | | | H7.23 | L6.7 | | |
| 15 | 16 | | | | | | | H3.22 | L36.1 | | |
| 14 | 15 | | | | | | | 0.05 | 53.6 | | |
| 13 | 14 | | | | | | | 0.09 | 55.0 | | |
| 12 | 13 | | L0.58 | L0.35 | L0.17 | L0.01 | L0.00 | 0.05 | 61.0 | | |
| 11 | 12 | | L0.03 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* | | |
| 10 | 11 | | L0.02 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* | | |
| | | | | | | | | | | | |
| | | Position/Sum | | 18/23 | | RD | | 13:59 07-27-2017 | | | |

6.2.2. Communication Setup

Check if the network setup is correct, including the communication setup of the analyzer and LIS.

- Usually LIS communication setting is not provided. It should be consistent with the IP address of the computer.
- The communication address of the analyzer and the LIS communication address must be on the same network segment. You need to set the IP address and port that are not occupied independently. The LIS IP address should be consistent with the IP address of the LIS.
- If the communication is not set correctly, the analyzer cannot communicate properly.

| No. | Sample ID | Status | WBC | Neu# | Lym# | Mon# | Eos# | Bas# | Neu% |
|-----|-----------|--------|-------|--------|--------|--------|--------|--------|-------|
| 21 | 22 | | L0.71 | L0.28 | L0.27 | L0.05 | L0.00 | H0.11 | L39.6 |
| 20 | 21 | | L0.82 | L0.32 | L0.33 | L0.04 | L0.00 | H0.13 | L39.2 |
| 19 | 20 | | | | | | | H0.15 | L34.3 |
| 18* | 19 | | | | | | | H0.16 | L46.8 |
| 17 | 18 | | | | | | | H2.18 | L46.3 |
| 16 | 17 | | | | | | | H7.23 | L6.7 |
| 15 | 16 | | | | | | | H3.22 | L36.1 |
| 14 | 15 | | | | | | | 0.05 | 53.6 |
| 13 | 14 | | | | | | | 0.09 | 55.0 |
| 12 | 13 | | L0.58 | L0.35 | L0.17 | L0.01 | L0.00 | 0.05 | 61.0 |
| 11 | 12 | | L0.03 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* |
| 10 | 11 | | L0.02 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* |

Prompt

Please ensure that the network is connected.

OK

<> <> >> >>

Graph Review Edit Info Search Validate Cancel Validate Comm. ->

Position/Sum 18/23 RD 13:59
07-27-2017 USB

4. Receiving response timed out. The analyzer turns on the ACK response mode and communicates with the LIS terminal. The analyzer can not receive the response signal from the LIS terminal.

| Sample Analysis | | Review | | QC | | Reagent Setup | | Diluent | | Print | |
|-----------------|-----------|-----------|-------|--------|--------|---------------|--------|---------------------|-------|-------|--|
| No. | Sample ID | Status | WBC | Neu# | Lym# | Mon# | Eos# | Bas# | Neu% | | |
| 21 | 22 | | L0.71 | L0.28 | L0.27 | L0.05 | L0.00 | H0.11 | L39.6 | | |
| 20 | 21 | | L0.82 | L0.32 | L0.33 | L0.04 | L0.00 | H0.13 | L39.2 | | |
| 19 | 20 | | | | | | | H0.15 | L34.3 | | |
| 18* | 19 | | | | | | | H0.16 | L46.8 | | |
| 17 | 18 | | | | | | | H2.18 | L46.3 | | |
| 16 | 17 | | | | | | | H7.23 | L6.7 | | |
| 15 | 16 | | | | | | | H3.22 | L36.1 | | |
| 14 | 15 | | | | | | | 0.05 | 53.6 | | |
| 13 | 14 | | | | | | | 0.09 | 55.0 | | |
| 12 | 13 | | L0.58 | L0.35 | L0.17 | L0.01 | L0.00 | 0.05 | 61.0 | | |
| 11 | 12 | | L0.03 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* | | |
| 10 | 11 | | L0.02 | ***.** | ***.** | ***.** | ***.** | ***.** | **.* | | |
| | | | | | | | | | | | |
| Graph Review | | Edit Info | | Search | | Validate | | Cancel Validate | | Comm. | |
| Position/Sum | | 18/23 | | | | RD | | 14:00 07-27-2017 | | | |

5. Receiving response error. The analyzer turns on the ACK response mode, communicates with the LIS terminal, the response data received by the analyzer does not conform to the protocol and does not contain MSA | AA |.
6. Sending data timed out. The analyzer communicates normally with the LIS terminal, sending data will be timed out when the network suddenly broken during the data transmission.

6.2.3. Network Firewall

Open the network connection license of LIS and data management software, and that of the analyzer's port to check for the firewall.

7. Optical System

7.1. Introduction to the Principles of Optical System

7.1.1. Operation Principles

The basic principle of optical system is the employment of flow cytometry-based laser scattering method. As shown in Figure 6-1, wrapped in the diluent sheath, the processed and diluted blood forms a sample stream carrying cells. This sample stream becomes very thin due to the focusing effect of the sheath, forcing the cells to flow one by one through the center of the chamber with a certain space between each other. Elongated elliptical Gaussian beam goes through the optical zone of the flow cell, irradiates individual cells to generate scattered light, which is received by the detector and transformed into photoelectric signals necessary for cell counting and categorizing.

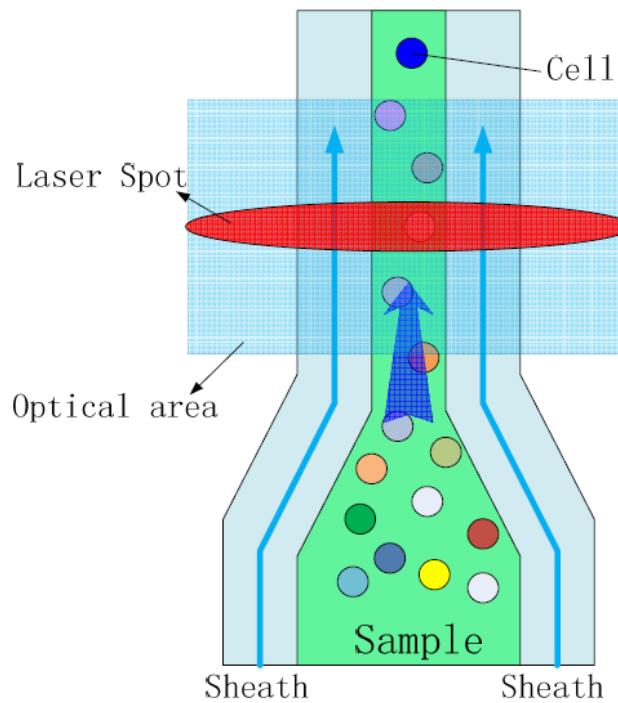


Figure 6-1 Laser scatter principle

Since the sample stream has a certain width, different cells will pass the beam zone at slightly different positions. In order to ensure the consistency of cell scatter signals, the Gaussian beam shall have a certain width in the direction perpendicular to the cell movement to minimize the density variation of the beam covering the sample stream, as shown in Figure 6-1. Meanwhile, in order to prevent the beam from radiating several cells at the same time, the beam shall be small enough in the direction of the cell movement, just being able to cover the entire cell. Therefore, the beam used for radiating the sample stream shall be an elongated elliptical beam.

7.1.2. Optical Path of the Optical system

As a component of the optical path, the optical zone of the flow cell is the zone that the laser spot passes. The optical path of the optical system is as shown in Figure 6-2. It is mainly composed of three parts as shown in the dashed box in the figure.

Light source assembly: Beam shaping function component, which shapes the divergent elliptical beam generated by the semiconductor laser to elongated beam and directs it into the flow cell.

Flow cell assembly: Both an optical component and a fluidic component. As the fluidic interface of the optical system, it provides stable sample streams. The optical performance of this component is also critical. Dirt, contamination or dust in the optical zone on the inside and outside surface of the flow cell may have great impact on the performance of the optical system.

Scattering detection assembly: consists of aperture and photoelectric sensor. Used for collecting the scattered light generated by the cells. There are three photoelectric sensors in the optical system for collecting scattered light of three angle ranges, including Low Angle Scattering (LAS), Medium Angle Scattering (MAS) and Wide Angle Scattering (WAS).

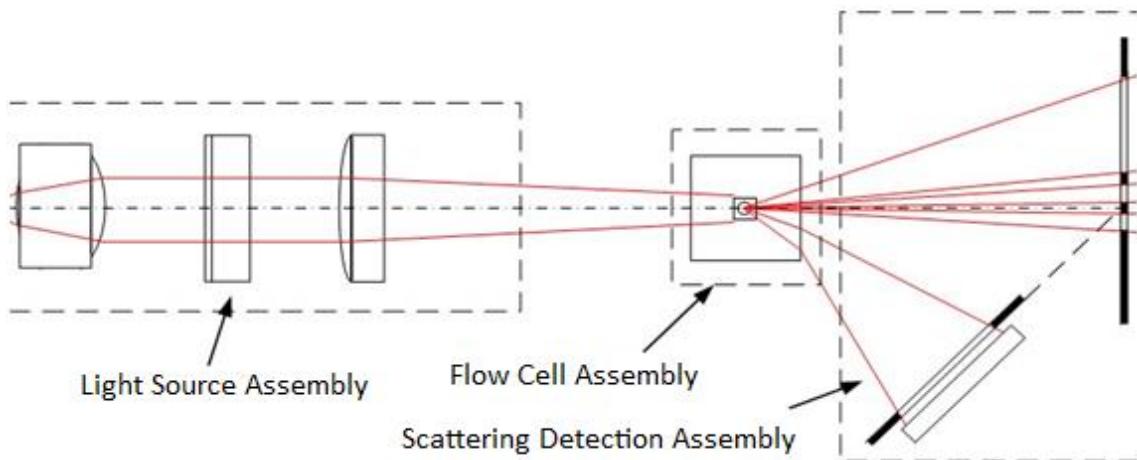


Figure 6-2 Optical path diagram of the optical system

The relative positional relationship between the three parts of the optical path is achieved by precise commissioning and fastening with special instruments, and therefore is not field serviceable.

7.2. Physical Structure

7.2.1. Overall Structure

The overall structure of the optical system is shown in Figure 6-3. According to different functions, the system can be divided into the following parts:

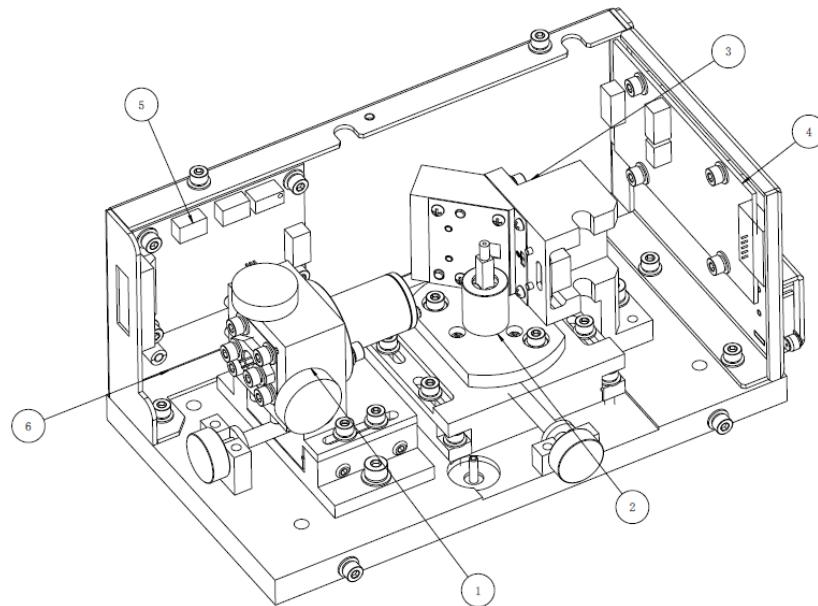


Figure 6-3 Overall structure model of the optical system

- | | |
|------------------------------------|---|
| 1---Light source assembly | 2---Flow cell assembly |
| 3---Rear optical assembly | 4--- Optical signal amplifying board assembly |
| 5--- Optical driver board assembly | 6--- Shield shell assembly |

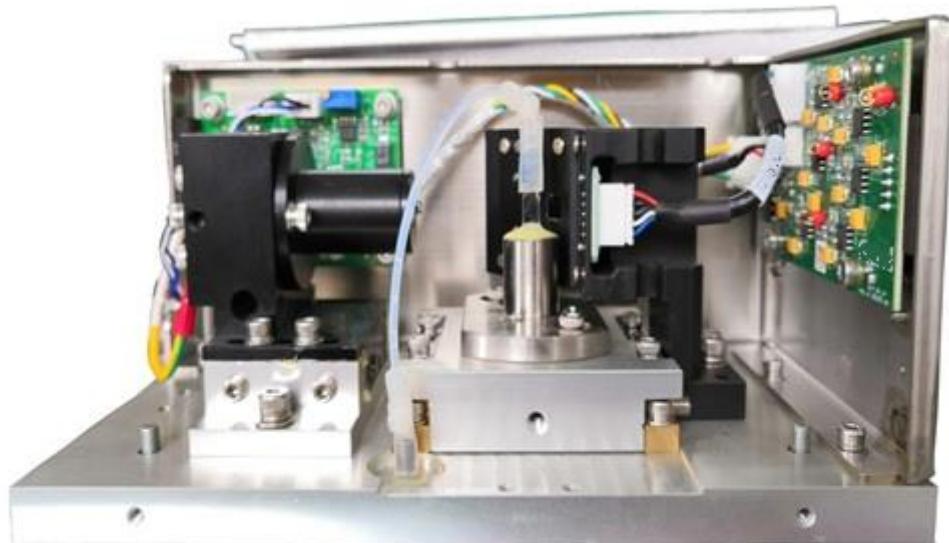


Figure 6-4 Physical structure of the optical system

7.2.2. Light Source Assembly

The light source assembly is used for providing light source output and beam shaping for the optical system, as shown in Figure 6-5. Both the removal of internal parts of the light source assembly and the removal of the assembly from the substrate are forbidden. Generally, if the light source assembly is determined to be faulty, the whole optical system shall be replaced.



Figure 6-5 Light source assembly

7.2.3. Flow Cell Assembly

The flow cell assembly is the fluidic interface of the optical system. The fluidics is turned into stable sheath stream under the pressure of the sheath fluid bath. After reaction, the cells are injected by the sample syringe into the flow cell assembly and are wrapped by the sheath. Then the cells go through the flow cell one by one for laser irradiation.



Figure 6-6 Physical view of the flow cell assembly

Both the removal of internal parts of the flow cell assembly and the removal of the assembly from the substrate are forbidden. Generally, if the flow cell assembly is determined to be faulty, the whole optical system shall be replaced.

7.2.4. Optical Substrate Assembly

The substrate assembly provides support, fixation and shock absorption for the optical system, as shown in Figure 6-7. The light source assembly and flow cell assembly mounted on the substrate assembly are not removable. If loose light source assembly and flow cell assembly result in abnormal condition of the optical system, the whole optical system shall be replaced.

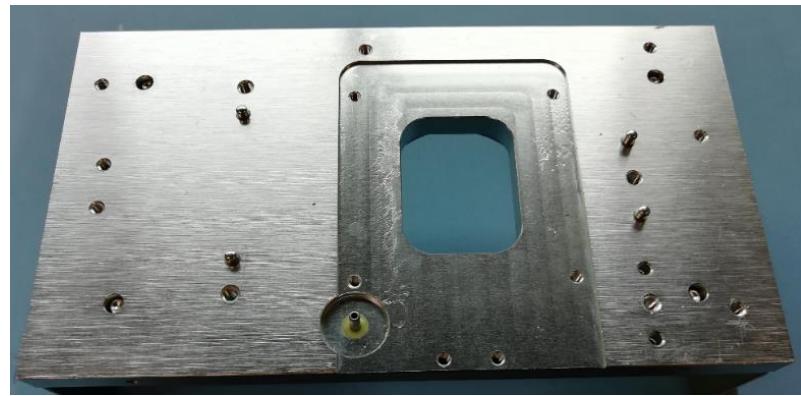


Figure 6-7 Optical substrate assembly

7.2.5. Optical Signal Amplifying Board Assembly

The optical signal amplifying board assembly is used for pre-amplifying the optical system signals, if it is determined to be faulty, it is possible to remove and replace it from the optical system, as shown in Figure 6-8.



Figure 6-8 Optical signal amplifying board assembly

7.2.6. Shield Shell Assembly

The shield shell is used for isolating the optical system from the outside to avoid interference of dust, stray light and electromagnetic noise, and for connecting the optical system to the analyzer, as shown in Figure 6-9.

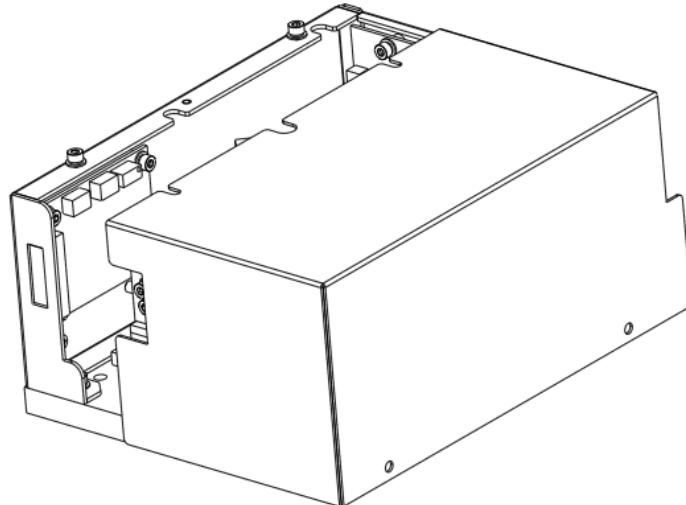


Figure 6-9 Shield Shell Assembly

7.2.7. Scattering Detection Assembly

As the detection unit of the optical system, the scattering detection assembly consists of medium/small angle PD and large angle PD and corresponding medium/small angle aperture and large angle aperture and support structure. The 3D model and physical view are shown in Figure 6-10. The scattering assembly is a whole unit and cannot be removed from the optical substrate, although the large angle PD assembly is removable. When the scattering detection assembly is determined to be faulty, it is necessary to replace the whole optical system.

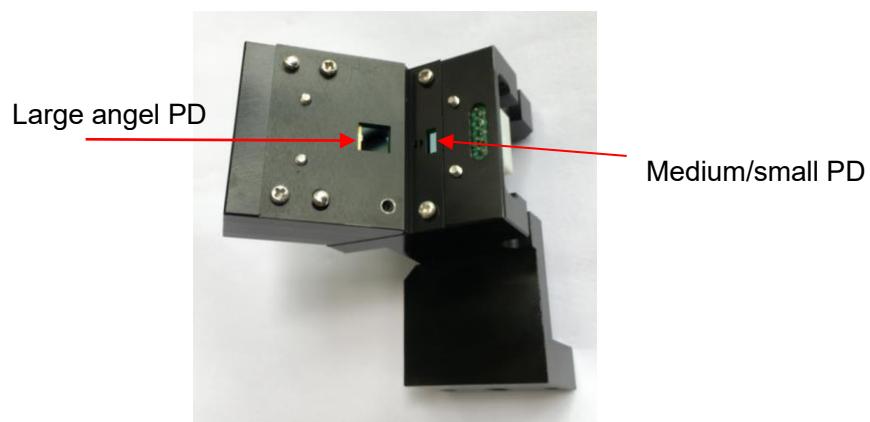


Figure 6-10 Scattering detection assembly

7.2.8. Optical Driver Board

The optical driver board is used for providing stable driving current for the laser to keep a full and stable laser output power, as shown in Figure 6-11. If the optical driver board is determined to be faulty, it is possible to remove and replace it from the optical system.

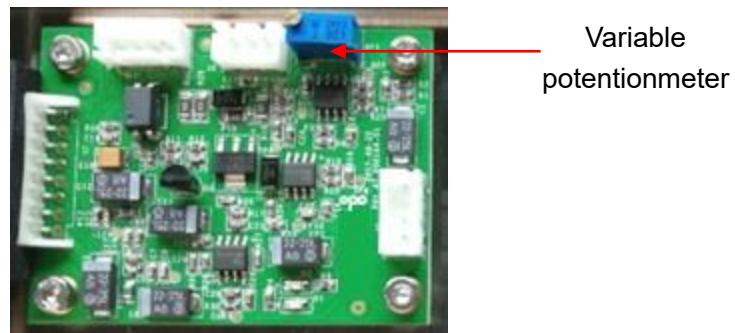


Figure 6-11 Optical driver board

7.3. Optical System Status Determination

When abnormal sample scattergram causes failed or incorrect categorization, and the reagent and fluidic connections are determined to be normal, it will be necessary to check the optical system status. In this section, the optical system status is tested with standard particles. Prior to the test, prepare the following items:

Consumables: 4k-07 standard particle ($7\mu\text{m}$) and 1.5mL centrifuge tube

The detailed procedure is as follows:

1. First, add about 1 mL of the diluent to a 1.5mL centrifuge tube (two dilutions can be added by instrument). Shake the $7\mu\text{m}$ standard particle bottle until the solution is well mixed, then add 3 drops of the solution into the 1.5mL centrifuge tube. Cap the tube and shake it until this solution becomes well mixed, as shown in Figure 6-12.



Figure 6-12 Preparation of the $7\mu\text{m}$ standard particle solution

2. Select the Service menu and enter the “Optical Debug” screen. Perform counting with the prepared standard particle solution. After the counting is completed, the result will be automatically displayed in the screen, as shown in Figure 6-13.
3. Determine the optical system status by the parameter Particle 1 according to the counting result. The optical system is OK if all the following requirements are met:

| Parameter | Total | CG Position | CV |
|-----------|-----------|-------------|--------|
| LAS | 1000-3000 | 30-35 | ≤ 6.50 |
| MAS | | 25-30 | ≤ 8.50 |
| WAS | | 80-150 | ≤ 5.00 |

4. Generally, if the parameters fail to meet the requirements, it may be caused by a dirty flow cell. The built-in maintenance program can be used to solve this problem. The method is as follows: click the “Service-->Maintenance” menu and select “Flow Cell Cleaning” in the “Cleaning” screen. The machine will automatically complete the cleaning operation (in about 1 minute).

After the maintenance, repeat step 2 and 3 to check if the result meets the requirements. If not, the manual maintenance is required, for details, please see the next section.

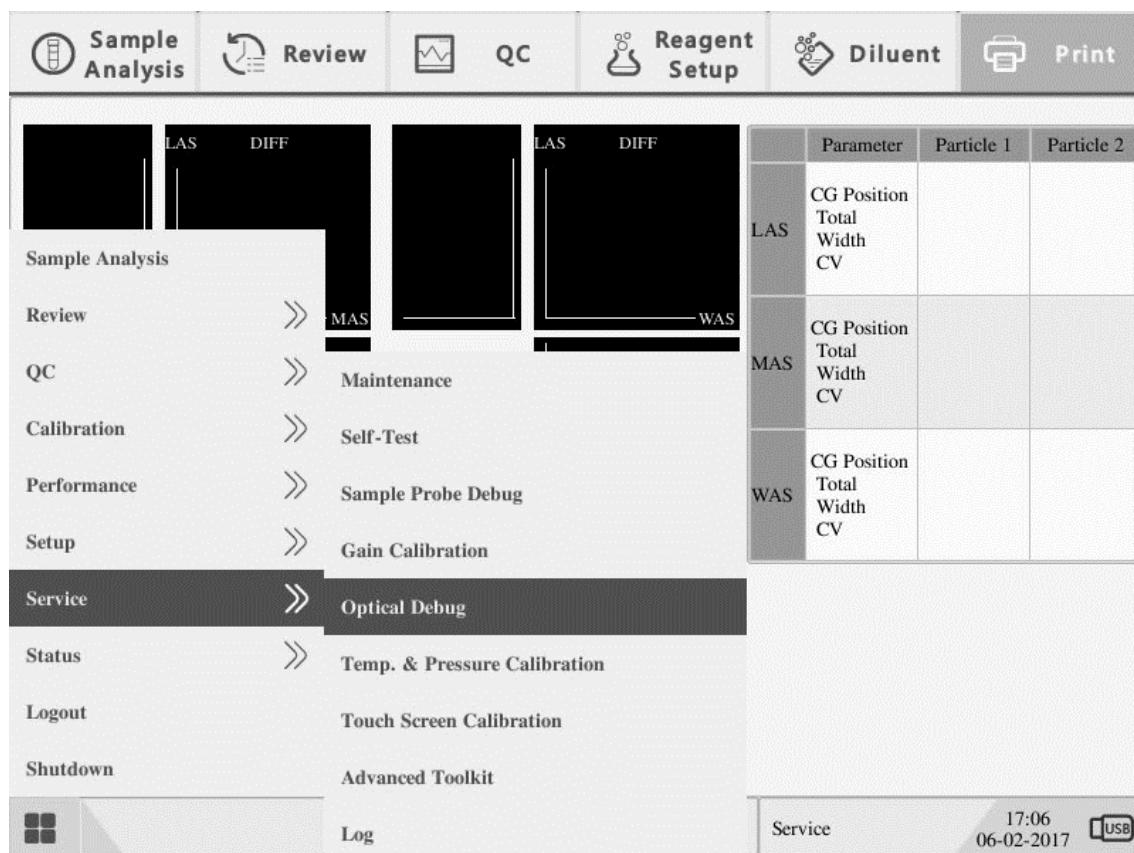


Figure 6-13 Optical debug screen of the standard particle

7.4. Optical System Maintenance and Replacement

When the optical system is determined as abnormal according to Section 6.3, and cannot be restored by automatic maintenance, then manual maintenance will be necessary. Furthermore, if the optical system is determined as normal according to Section 6.3, but the scattergram or categorization of the blood sample is abnormal, then other problems except the optical system shall be taken into account.

Before performing maintenance and replacement on the optical system, prepare the following items:

Tools: A crosshead screwdriver and a hex wrench set.

Consumables: 4k-07 standard particle ($7\mu\text{m}$), 1.5mL centrifuge tube, microfiber clean cloth, dehydrated alcohol and probe cleanser.

7.4.1. Maintenance of the Optical System

Before maintenance of the optical system, it is necessary to open the top cover of the optical system shield shell, as shown in Figure 6-14. Use a crosshead screwdriver to remove the locking screw and open the top cover carefully to reveal the internal structure of the optical system, as shown in Figure 6-14.

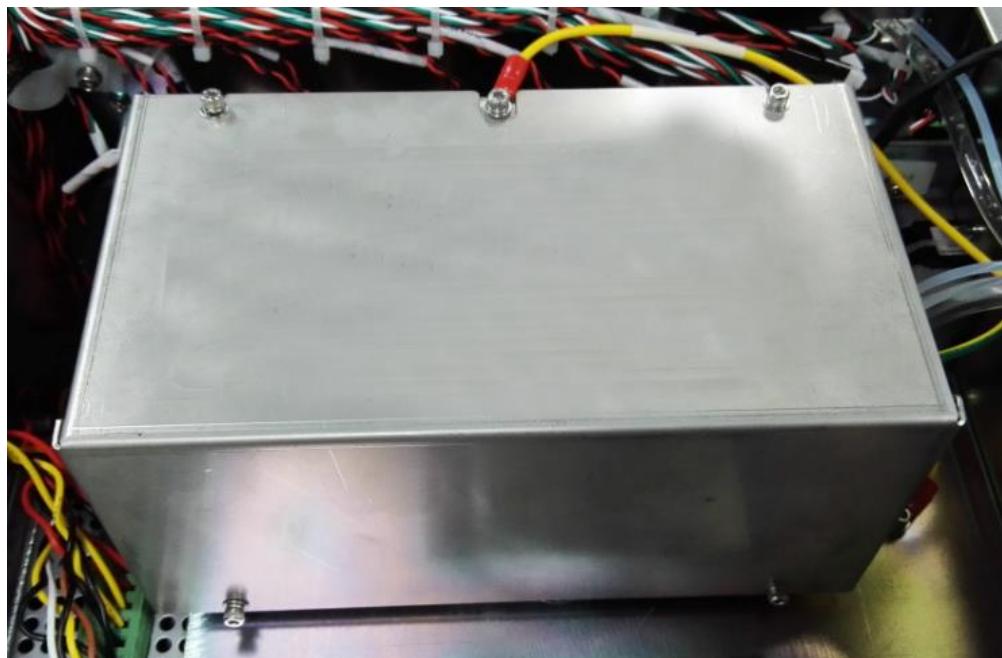


Figure 6-14 Location of the screws on the shield shell

Precautions before proceeding to the next step are as follows:

- ♦ Never look directly into the laser with eyes or through an optical instrument;
- ♦ During test of optical system with the top cover open, please shelter the optical system to prevent bright environmental light from irradiating the detector inside the optical system.

Generally, the following steps can be followed to determine which part needs to be maintained.

1. Check if the wires are firmly connected inside the optical system and if the optical path is blocked by wires.
2. Check if the output spot is normal. Place a small piece of white paper near the output exit and observe the light spot. The ideal spot shape is a vertical ellipse which is clipped at both top and bottom, as shown in the left in Figure 6-15. The actual spot is as shown in the right in Figure 6-15 with a faint halo around it.

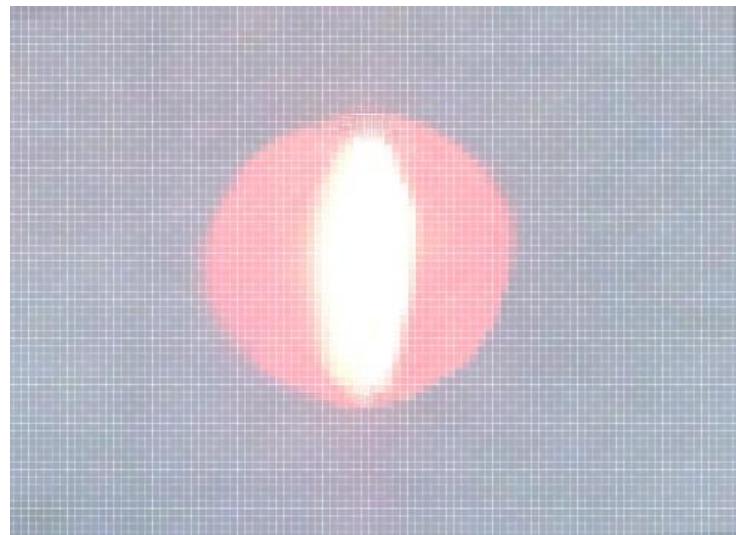


Figure 6-15 Light spot at the output exit

Abnormal spots can be different, including dark spot, spot clustered into a dot, spot with dark lines, spot with a scattered halo, seriously damaged spot, spot with multiple dark dots in the center, as shown in Figure 6-16.

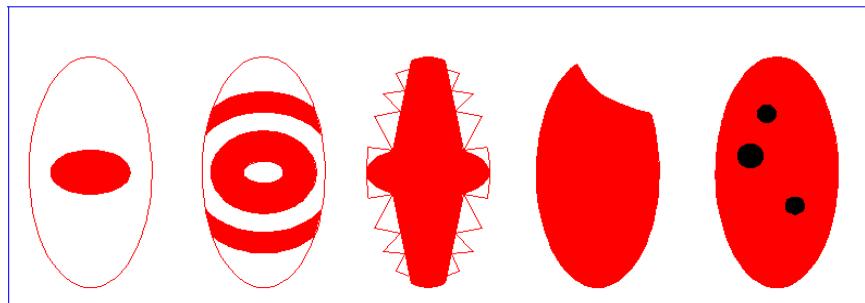


Figure 6-16 Example of abnormal output spots

Abnormal light spots are usually caused by damage or contamination of the optical driver board, the laser or the lens in the light source assembly.

Missing parts, dark lines or dark dots in the spot are usually caused by contaminated lens in the light source assembly. A clean cloth dampened with dehydrated alcohol may be used to wipe the lens gently, spiraling outward from the center. Be careful not to touch the interior of the lens barrel.

If the light spot disappears, darkens or diverges, then the optical driver board may be damaged. After the problem is determined, replace the optical driver board (be aware of static electricity) separately and adjust the variable resistor on the board. Perform a standard particle test in accordance with Section 6.3 to ensure the standard particle indicators to meet the requirements. After replacement, a gain calibration in accordance with Section 4.5 shall be performed on the optical system.

If the light spot disappears, converges, darkens or diverges, and the optical driver board is determined to be in good condition, then the laser could have been burned. Since the light source assembly cannot be replaced separately, it will be necessary to replace the optical system.

1. Observe the light spots on the surface and inside the flow cell from the following angles, as shown in Figure 6-17. If the exterior of the flow cell is very bright, then the exterior may be stained. Use a clean cloth dampened with dehydrated alcohol to wipe the exterior, until the bright part darkens or disappears, as shown in the right in Figure 6-17. If the interior of the flow cell is very bright and cannot be darkened by the built-in cleaning procedure, then it will be necessary to manually rinse the inside of the flow cell.
2. cell.

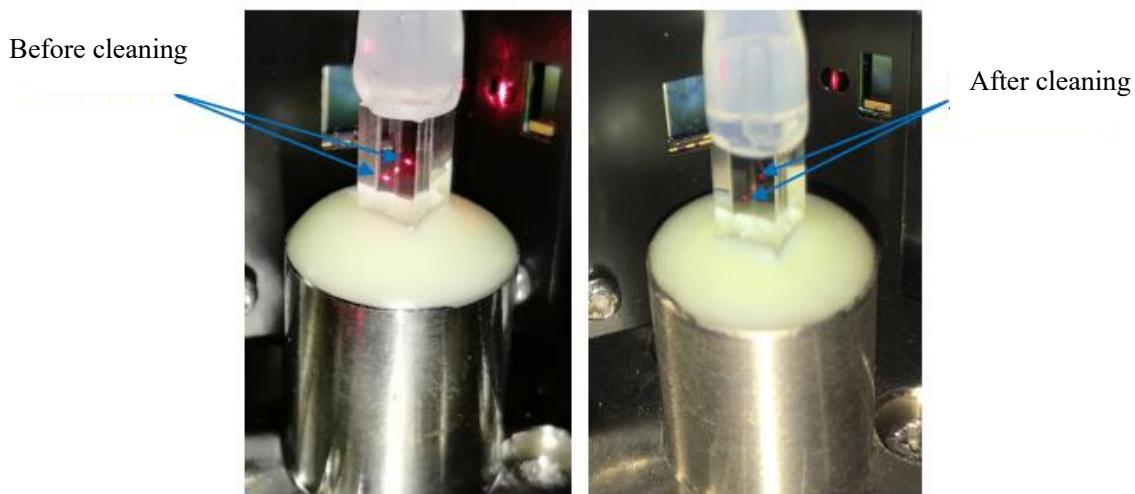


Figure 6-17 Flow cell before and after cleaning

The cleaning procedure is as follows: Prepare a syringe with a 100mm long Polyurethane tube, a 200mm long Polyurethane tube and probe cleanser, as shown in Figure 6-18. Shut down the analyzer and remove the tubes at the waste outlet and the sheath inlet of the flow cell. Connect the syringe to the waste outlet. Connect one end of the other Polyurethane tube to the sheath inlet, and put another end into the probe cleanser. Draw the probe cleanser with the syringe until the probe cleanser enters the syringe. At this time, the flow cell will be filled with the probe cleanser. After soaking for about 10 minutes, use clean water instead of the cleanser. Draw the syringe forcefully for 2 to 3 times, until the bright spots in the flow cell darken or disappear.

Connect the optical path and the tubes and verify the connection, and then turn on the analyzer power.



Figure 6-18 Preparation before cleaning the interior of the flow cell

3. Check if the output light is perpendicular to the flow cell. Place an inner hexagon spanner at the output exit. The output spot and the spot reflected by the flow cell shall appear simultaneously and strictly coincide with each other, as shown in Figure 6-19.

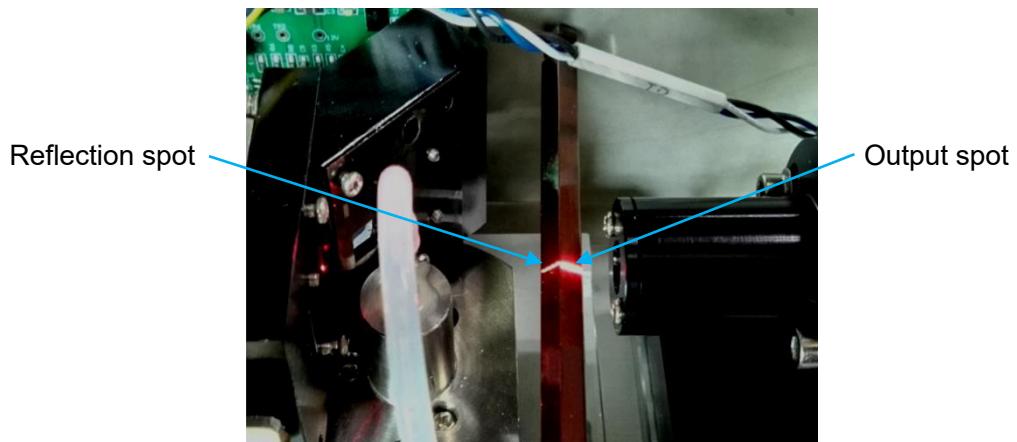


Figure 6-19 Output spot and reflection spot

After the maintenance is completed, verify if the optical system is working correctly in accordance with the steps in Section 6.3:

- ♦ If the standard particle CV meets the requirement, but the CG position is too low or too high, slightly adjust the variable resistor on the optical driver board as shown in Figure 6-11, until the CG position meets the requirement. After maintenance according to this procedure, a gain calibration in accordance with Section 4.5 shall be performed on the optical system.
- ♦ If the CG position meets the requirement but the CV doesn't, then the maintenance is not qualified. Perform another check and maintenance in accordance with this section.
- ♦ If the CG position and the CV cannot meet the requirements after the maintenance, then it will be necessary to replace the optical system.

7.4.2. Replacement of the Optical System

If the problem is not solved after maintenance, or if the problem is not serviceable, then it is necessary to replace the optical system with a new one. The replacement procedure is as follows:

1. Shut down the analyzer.
 2. Gently unplug the waste outlet tube of the optical system, connect the syringe, and then unplug the other tube. Remove the remaining liquid in the optical system with a syringe, unscrew the nut with a small wrench and unplug the signal line of the optical system, as shown in Figure 6-20.
-

NOTE

- ♦ Follow the steps to remove the optical system, preventing liquid from dripping into the rack to cause corrosion.
-

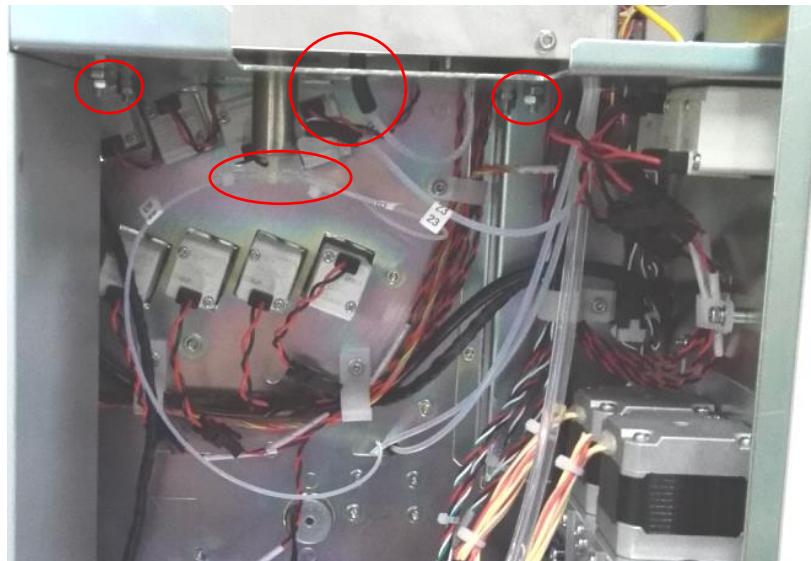


Figure 6-20 Remove the optical system

3. Remove the optical system carefully, lay it flat on the table, and then short the tubes of the optical system.

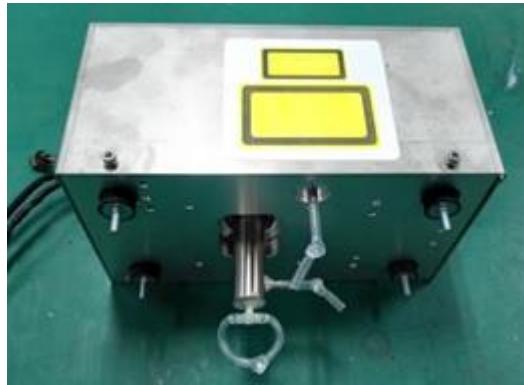


Figure 6-21 Short the tubes of the optical system

4. Install the new optical system into the analyzer. Connect the signal wires, fluidics and optical paths. Turn on the analyzer and verify the status of the new system in accordance with the steps in Section 6.3.
-

NOTE

- ♦ The fluidic interfaces of the optical system are very fragile. Be careful to avoid knocking them when connecting the tubes during installation.
-

5. Perform a gain calibration in accordance with Section 4.5 on the optical system.

8. Fluidic System

8.1. Measurement Flow

The fluidic system of the analyzer can be divided into two measurement channels:

- ◆ WBC&HGB channel
- ◆ RBC&PLT channel

The system flowchart of the WB-CBC+DIFF mode is shown below (DIFF lyse and DIFF sample configuration & measurement are not available in CBC mode):

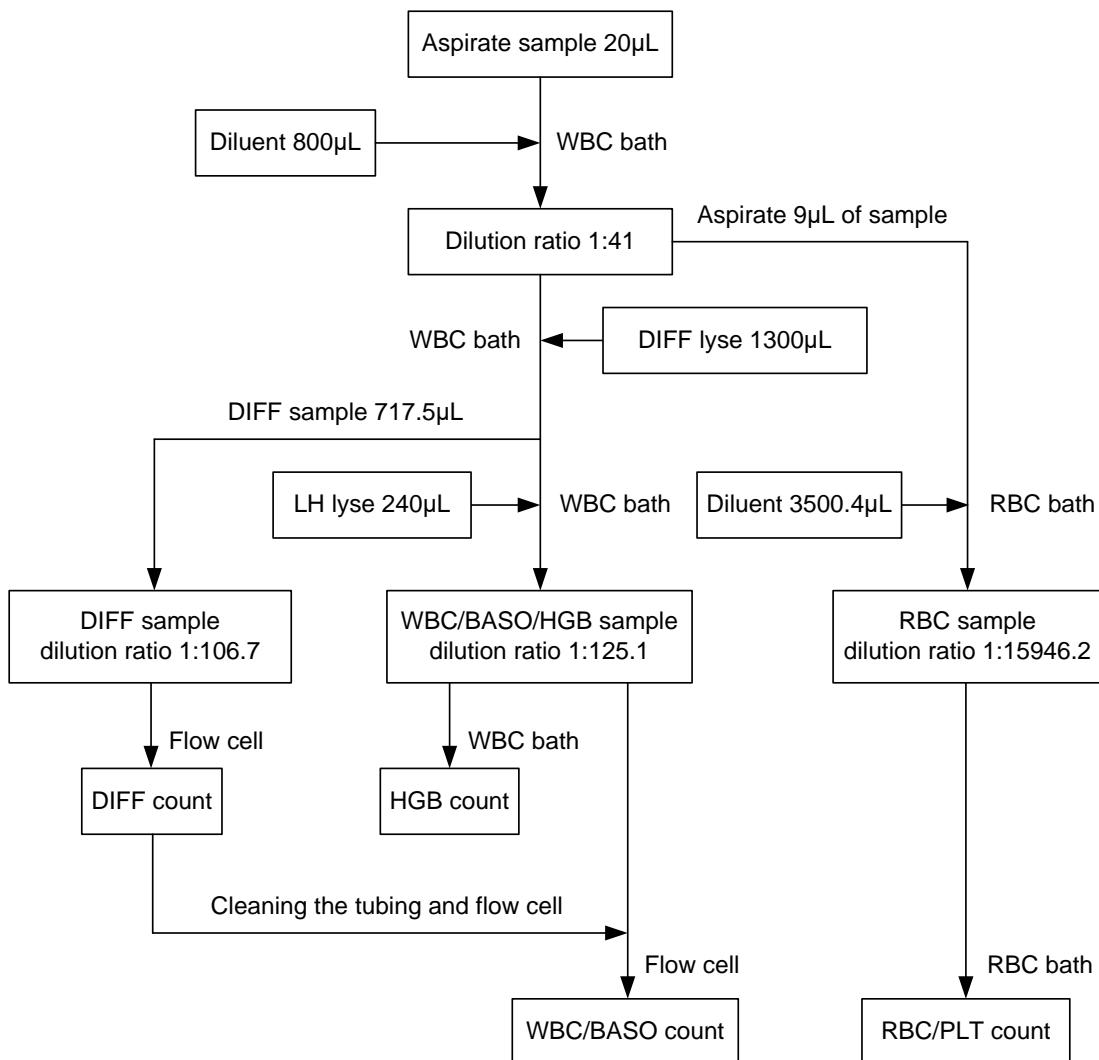


Figure 7-1 Fluidic system flowchart (WB-CD mode)

The system flowchart of the PD-CBC+DIFF mode is shown below (DIFF lysis and DIFF sample configuration & measurement are not available in CBC mode):

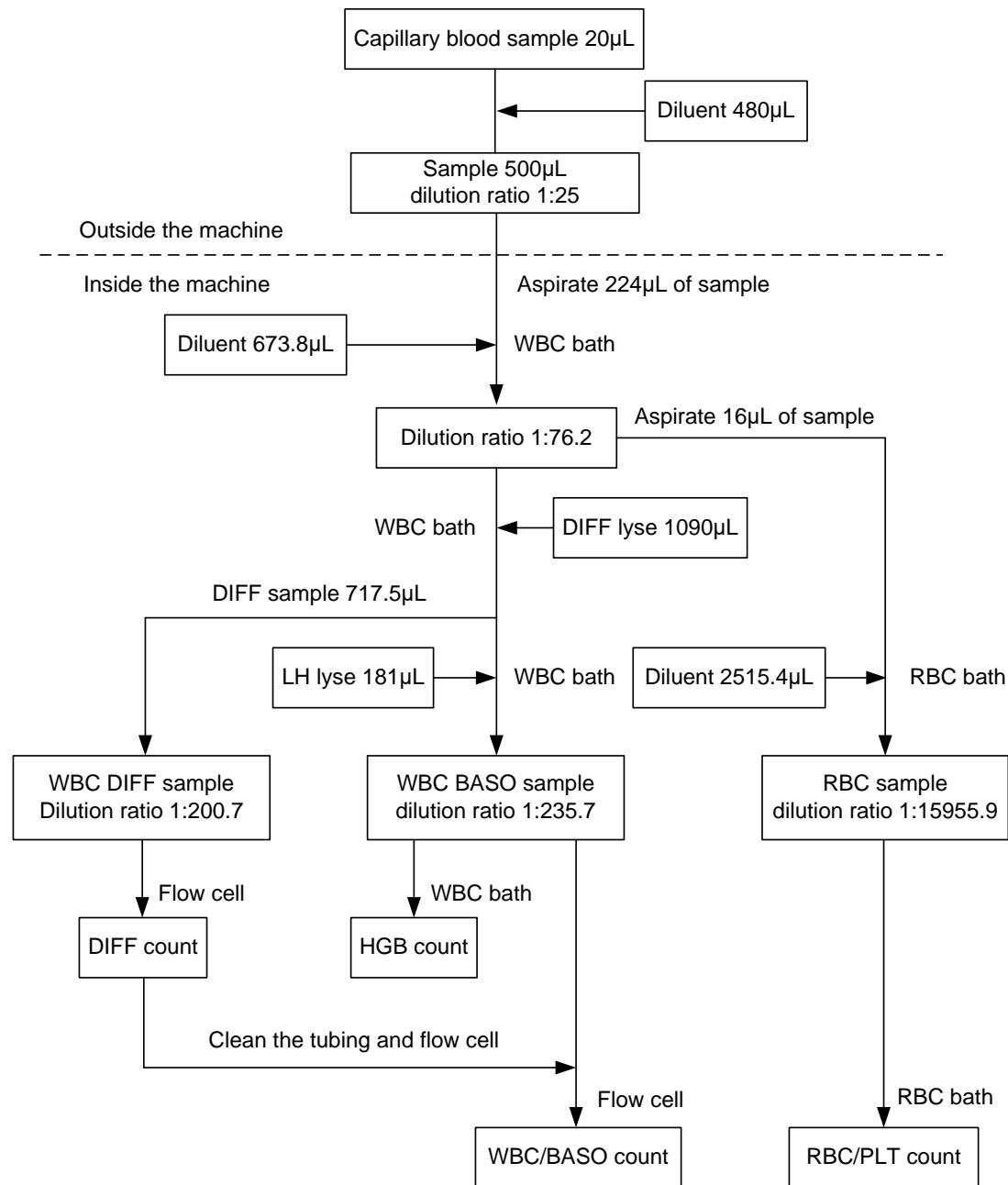


Figure 7-2 Fluidic system flowchart (PD-CD mode)

8.1.1. WBC&HGB Channel

▪ DIFF measurement

1. Reagents:

DIFF reagent: used for lysing of red blood cells and specialization of different white blood cells

Diluent: background solution, used for providing sheath fluid and cleaning

2. Measurement principle: flow cytometry and laser scatter

3. Measurement parameters: MONO#, MONO%, LYMPH#, LYMPH%, NEUT#, NEUT%, EOS#, EOS%

4. Graphics: 4 Differential scattergram

5. Dilution ratio: 1: 106.7

6. Counting duration: 9.1s

7. Counting flow: 0.008575417ml/s

8. Counting volume: the flow of the sample stream is constant, which can be converted to counting volume by controlling the counting duration

9. Function description: Mix 20 μ L of blood sample and 800 μ L of diluent in the WBC bath. After the secondary aspiration, add 1.3mL of DIFF lyse. After the reaction has been on for a certain time, place the prepared sample at the bottom end of the flow cell. The sample will be wrapped by a sheath stream generated by the large volume syringe of the syringe linkage and be pushed by the small volume syringe into the flow cell for the measurement.

- **WBC counting and BASO measurement**

1. **Reagents:**

LH lyse: used for lysing red blood cells and platelets, and separating the basophiles by volume from the other white blood cells

Diluent: used for providing sheath fluid and cleaning

2. **Measurement principle:** flow cytometry and laser scatter

3. **Measurement parameters:** WBC, BASO#, BASO%

4. **Graphics:** WBC histogram

5. **Dilution ratio:** 1:125.1

6. **Counting duration:** 11.5s

7. **Counting flow:** 0.008575417ml/s

8. **Counting volume:** the flow of the sample stream is constant, which can be converted to counting volume by controlling the counting duration

9. **Function description:** After DIFF reaction, add 240 μ L of LH reagent to the sample. After adequate reaction, place the prepared sample at the bottom end of the flow cell. The sample will be wrapped by a sheath stream generated by the large volume syringe of the syringe linkage and be pushed by the small volume syringe into the flow cell for the measurement.

- **HGB counting**

1. **Reagents:**

LH lyse: used for lysing red blood cells and combining hemoglobin

Diluent: used for diluting and cleaning

2. **Measurement principle:** colorimetric method

3. **Measurement parameters:** HGB

4. **Dilution ratio:** 1:125.1

5. **Function description:** The measurement principle of HGB channel is the colorimetric method, which obtains HGB concentration by comparing the transmitted light intensity between background and blood.

8.1.2. RBC/PLT Channel

1. Reagents:

Diluent: used for diluting, cleaning, providing conductive environment and equal volume processing of cells

2. **Measurement principle:** impedance method
 3. **Measurement parameters:** RBC, PLT
 4. **Graphics:** RBC histogram and PLT histogram
 5. **Dilution ratio:** 1:15946.2
 6. **Counting duration:** 9s
 7. **Counting pressure:** -30kPa
 8. **Measurement volume:** The measurement volume is controlled by controlling the vacuum and counting duration. Keep a stable vacuum to ensure a stable flow out of the aperture. The measurement volume can be calculated by controlling the counting duration
 9. **Function description:** Aspirate 9µL of sample (dilution ratio 1:41) with the sample probe from the WBC bath. Move the probe to the RBC bath and mix this sample with 3.5mL of diluent to prepare a sample with dilution ratio of 1:15946.2. After mixing, aspirate the sample with negative pressure in the vacuum chamber through the aperture into the secondary bath. The cells will be measured while passing through the aperture.
-

NOTE

- ♦ Dilution ratio refers to the dilution ratio in the whole blood mode.
-

8.2. Sample Volume

Table 7-1 Sample volume

| Item | Whole blood mode | Capillary blood mode | Prediluted mode |
|----------|------------------|----------------------|---|
| CBC+DIFF | 20µL | 20µL | Dilution outside the analyzer: 20µL of blood sample; 480µL of diluents, 224µL aspirated |
| CBC | 12µL | 12µL | Dilution outside the analyzer: 20µL of blood sample; 480µL of diluents, 224µL aspirated |

8.3. Temperature of Fluidics

Table 7-2 Temperature of fluidics

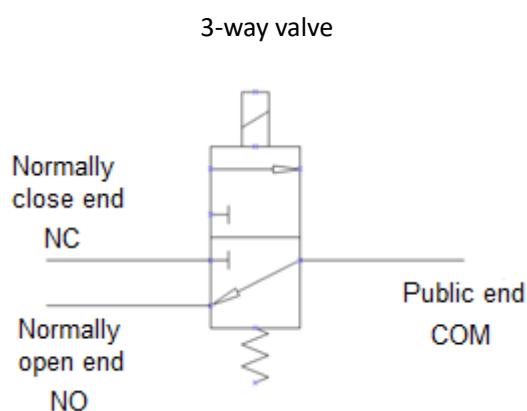
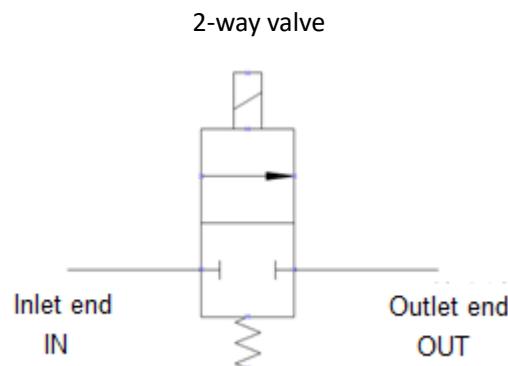
| Item | Preheat bath | Optical system | Diluent |
|-----------------------|-------------------------------------|----------------|---------------------|
| Target temperature/°C | Varies with the diluent temperature | / | Ambient temperature |
| Alarm temperature/°C | <32, >54 | / | <10, >40 |

8.4. Introduction to Fluidic Parts

A brief introduction to the fluidic parts and their respective functions is provided in this section. The symbols mentioned below refer to the symbols in the fluidics diagram.

8.4.1. LVMK Fluidic Valve

- Symbol



- Appearance

2-way valve



3-way valve



- 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 and the NO (normally open) end are connected; when power on, the public end and the NC (normally close) end are connected.

NOTE

- ♦ The operating voltage of LVMK fluidic valves is 12V, and maximal bearable pressure is 300kPa. 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.
-

8.4.2. LVM Fluidic Valve

- Symbol

Same as the LVMK fluidic valve.

- Appearance

3-way LVM fluidic valve



- Function

Same as the LVMK fluidic valve. Compared with LVMK fluidic valve, this valve provides smaller pump volume for more precise flow control.

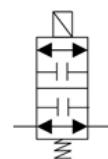
NOTE

- ♦ The maximal bearable pressure of the LVM fluidic valve is 200kPa, and the CV of the flow is about 0.03. SV11 in the fluidics diagram is a LVM fluidic valve.
-

8.4.3. Pinch Valve

- Symbol

PV17



- Appearance

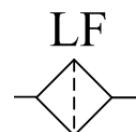


- Function

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

8.4.4. Liquid Filter

- Symbol



- Appearance

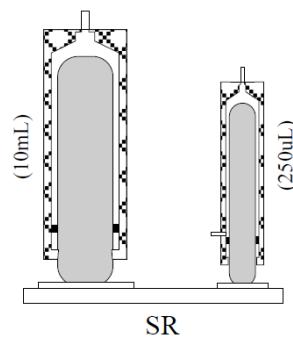


- Function

Used for filtering the impurities in the diluent.

8.4.5. Syringe Linkage

- Symbol



- Appearance



- Function

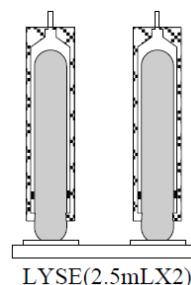
Composed of a large volume syringe and a small volume syringe, the syringe linkage is driven by a motor and a linkage. The parameter and the function of the syringe linkage are shown in the table below:

Table 7-4 Parameter and function list of the syringe linkage

| Name | Specification | Function |
|----------------------|------------------|--|
| Small volume syringe | Full scale 250ul | Used for quantitative aspiration, distribution and secondary aspiration of blood samples, and for injecting sample into the flow cell for measurement |
| Large volume syringe | Full scale 10ml | Used for quantitative addition of diluent to WBC and RBC bath, sample probe wash set fluid supply, cleaning of interior and exterior of sample probe and reaction bath, forcing the sheath into the flow cell, cleaning of the flow cell and sample preparation. |

8.4.6. Lyse Syringe

- Symbol



- Appearance



- Function

Composed of two syringes of the same volume, the syringe linkage is driven by a motor and a linkage. The parameter and the function of the syringe linkage are shown in the table below:

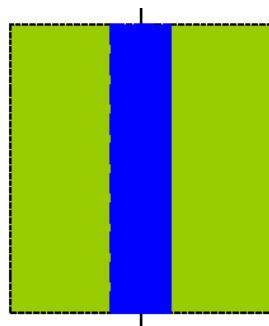
Table 7-5 Parameter and function list of the syringe linkage

| Name | Specification | Function |
|-------------------|------------------|--|
| DIFF lyse syringe | Full scale 2.5ml | Used for quantitative aspiration and distribution of DIFF lyse |
| LH lyse syringe | Full scale 2.5ml | Used for quantitative aspiration and distribution of LH lyse |

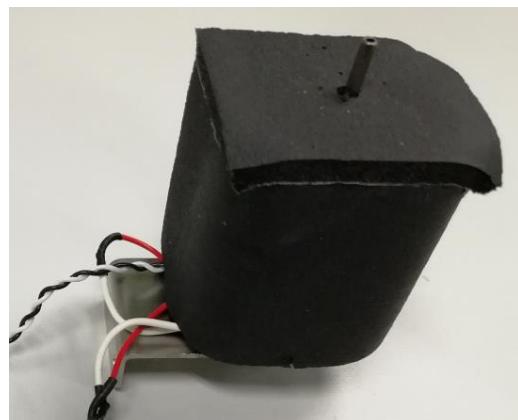
8.4.7. Preheat Bath

- Symbol

DH



- Appearance

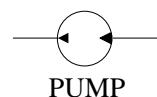


- Function

Used for heating DIFF reagent to ensure the temperature of DIFF reaction.

8.4.8. Vacuum Pump

- Symbol



- Appearance

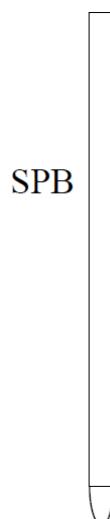


- Function

Used for draining the sample probe wash set, WBC bath, RBC bath and vacuum chamber, and for creating vacuum in the vacuum chamber.

8.4.9. Sample Probe

- Symbol



- Appearance

Open-vial sample probe



- Function

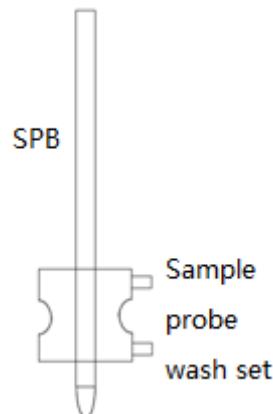
Used for providing a rigid cavity with resistance to blood sample corrosion, which can collect and dispense the blood as well as aspirate and dispense probe cleanser.

NOTE

- ♦ The sample probe is flat-tipped with a side opening to ensure normal aspiration in case that the tip touches the bottom of the sample tube.
-

8.4.10. Sample Probe Wash Set

- Symbol



- Appearance

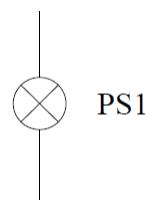


- Function

Provide a cavity for cleaning open-vial probe or piercing probe by liquid flow and collecting waste fluids on the interior or exterior.

8.4.11. Hydraulic pressure sensor

- Symbol



- Appearance

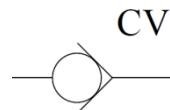


- Function

Used for monitoring the fluid pressure. When the pressure is obviously abnormal or beyond the setting range, the sensor will send an alarm signal.

8.4.12. Check Valve

- Symbol



- Appearance



- Function

Used for controlling the flow direction of the DIFF tube to prevent reverse aspiration.

8.4.13. Baths

- WBC bath

Used for providing a place for WBC sample reactions and supplying well reacted DIFF and BASO samples, and for HGB measurement.

- RBC bath

Composed of primary bath, secondary bath and aperture. Used for providing a place for RBC sample reactions and for RBC/PLT measurement.

- Vacuum chamber

Used for creating and keeping a stable negative pressure for RBC impedance count.

- WBC isolation chamber

Provide a gas chamber to block interference signals from outside.

- RBC isolation chamber

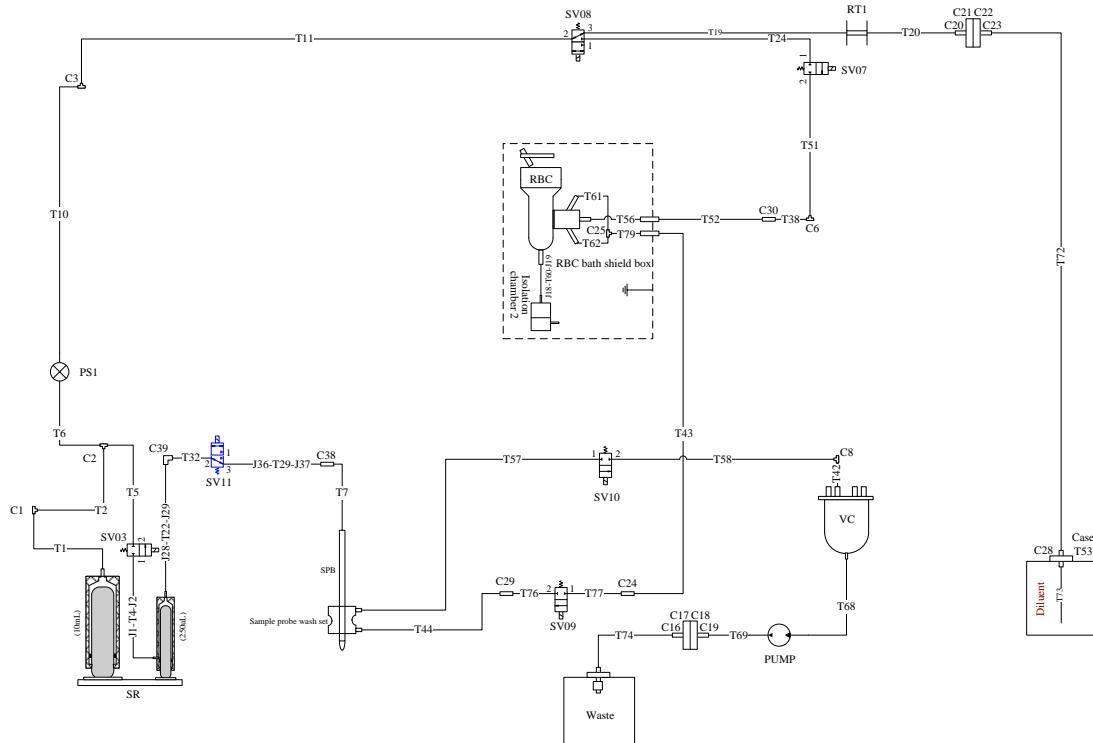
Provide a gas chamber to block interference signals from outside.

8.5. Detailed Introduction of Fluidic Structure

Please refer to Appendix A for the fluidic structure diagram

8.5.1. Sampling and dispensing channel

The structure of sampling and dispensing channel is shown below:



Main function:

1. Aspirate and dispense samples

Aspirate 20 μ L of blood sample by conjunctive use of small volume syringe of the syringe linkage (SR) and the sample probe (SPB) and dispense the blood sample.

2. Clean the interior and exterior of the sample probe

The interior is cleaned by the collaboration of the large volume syringe of the syringe linkage (SR) and SV03 and 11 valves. The exterior is cleaned by the diluent which is forced by the large volume syringe through SV08, SV07, secondary RBC bath and SV09 into the sample probe wash set, with waste fluid recovered by the sample probe wash set, SV10, vacuum chamber and waste pump.

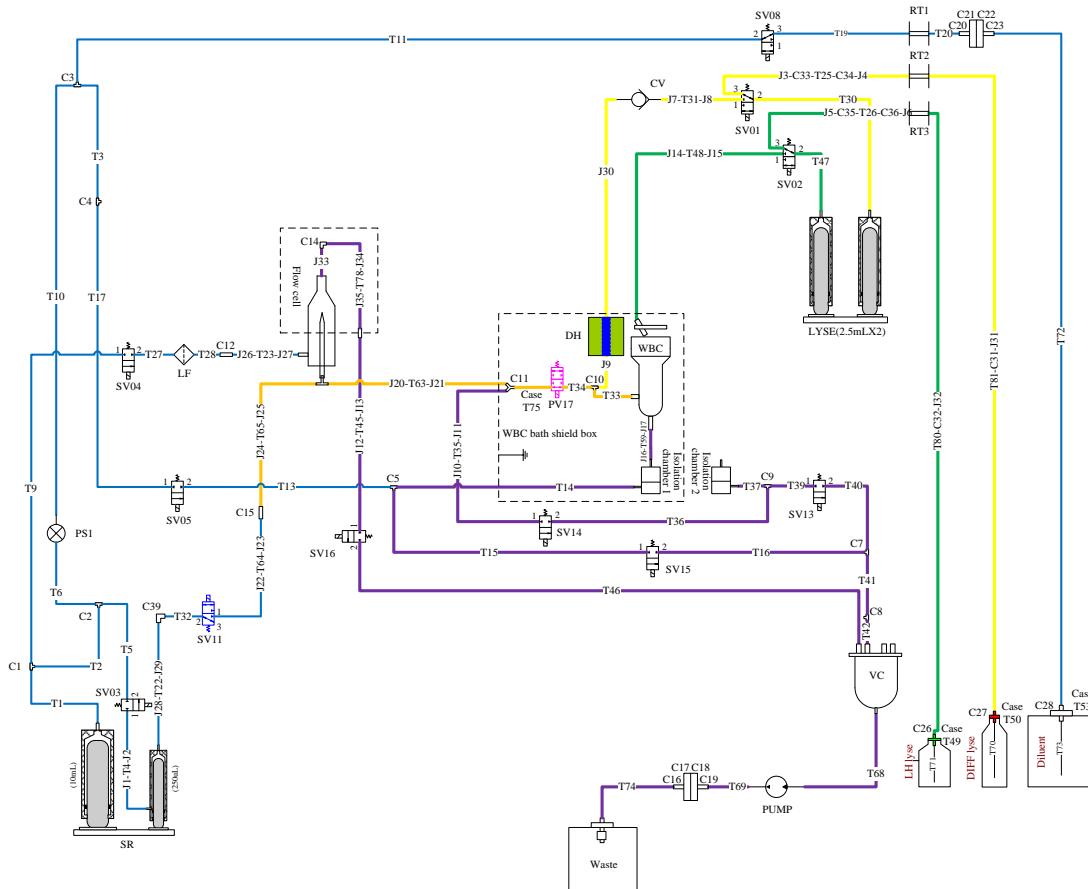
3. Aspirate and dispense probe cleanser

During the aspiration, the SV03 is energized. 2mL of probe cleanser will be aspirated by the SR from the SPB and stored mainly in the cleanser tanks (T7 and T29). During the dispensation, the SPB is transported by the sampling assembly to the RBC bath and WBC bath, and the SV03 is kept energized. A certain volume of probe cleanser in the SPB will be dispensed by the SR to the reaction baths.

8.5.2. WBC & HGB Channel

Part of the fluidic structure is shown as follows:

The blue lines are diluent flows; yellow lines are DIFF lyse flows; green lines are LH lyse flows; orange lines are sample flows; purple lines are waste fluid flows. Similarly, hereinafter.



DIFF measurement

- As the background solution, the diluent flows through the 10mL large volume syringe, SV03, SV11 and PV17 into the WBC bath.
- After the blood sample is dispensed by the sample probe to the WBC bath, the DIFF lyse is added by the DIFF lyse syringe through the SV01 and the preheat bath.
- The diluent is forced by the SR through SV05, T13 and T14 into the isolation chamber 1, generating bubbles which mix the sample fluid in the WBC bath.

4. The sample is then supplied along the illustrated orange lines to the bottom end of the flow cell.
5. A sheath flow is generated by the 10mL large volume syringe along the illustrated blue lines, and the sample is forced by the 250uL small volume syringe into the flow cell for measurement to obtain the differential results of the white blood cells.
6. After the measurement, use the sheath to clean the flow cell and the sample probe. Force the diluent through the SV03, SV11, C11, T35, SV14, T36 and T37 into the isolation chamber 2 to clean the sample supply tube.

BASO measurement & WBC counting

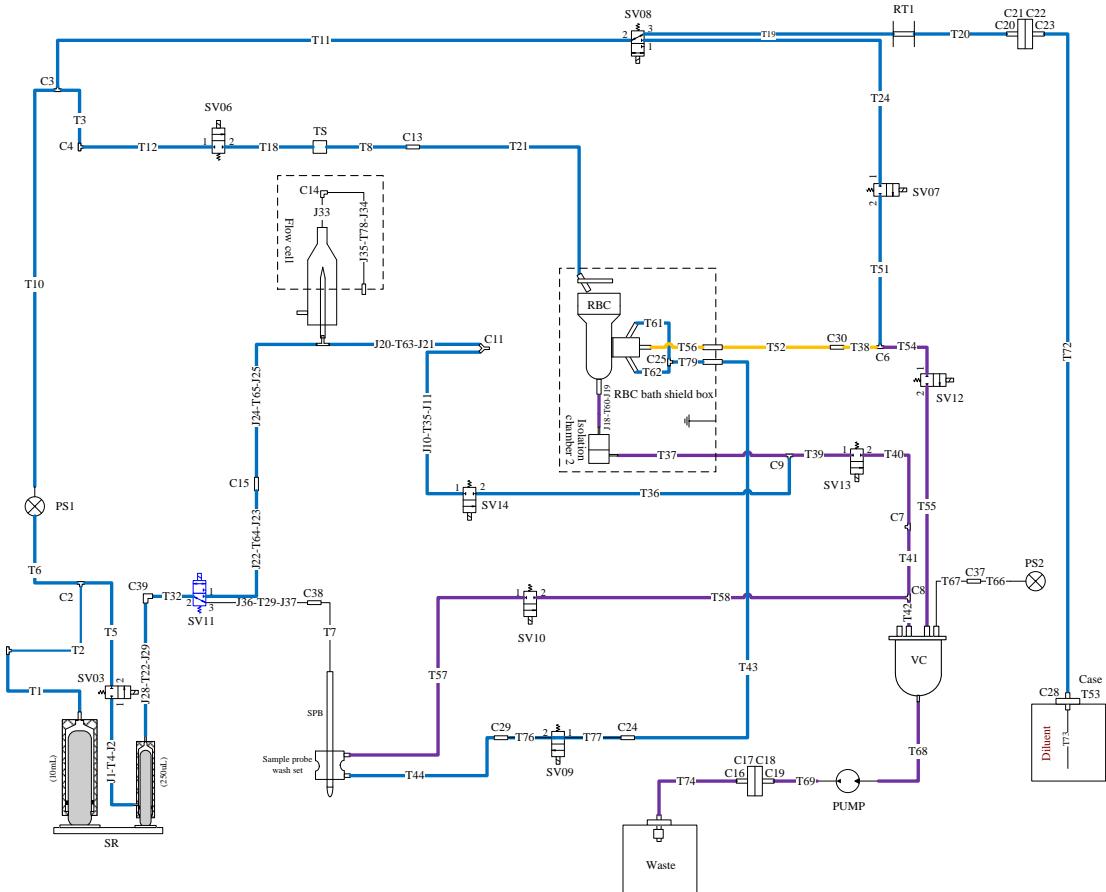
1. After DIFF sample enters the sample supply tube, the LH lyse is added by the LH lyse syringe through SV02 to the WBC bath.
2. The diluent is forced by the SR through SV05, T13 and T14 into the isolation chamber 1, generating bubbles which mix the sample fluid in the WBC bath.
3. After the DIFF sample measurement is completed and the sample supply tube is cleaned, the BASO sample is supplied along the illustrated orange lines to the bottom end of the flow cell.
4. A sheath flow is generated by the 10mL large volume syringe along the illustrated blue lines, and the sample is forced by the 250uL small volume syringe into the flow cell for measurement to obtain BASO differential result and WBC count.
5. After the measurement, use the sheath to clean the flow cell and the sample probe. Force the diluent through the SV03, SV11 and PV17 into the WBC bath to clean the sample supply tube and the WBC bath. During the cleaning process, part of the diluent flow away through C11, T35, SV14 and T36 to clean the 3-way connector C11.
6. Finally, the WBC bath is drained by SV15, vacuum chamber (VC) and waste pump.

HGB counting

The measurement principle of HGB channel is the colorimetric method, which obtains HGB concentration by comparing the transmitted light intensity between background and blood. The transmitted light intensity of the pure diluent in the WBC bath is measured at the beginning of the count. The transmitted light intensity of the diluent with blood is measured after the BASO reaction is completed (before preparation of the BASO sample). The HGB value can be calculated by comparing the above two values.

8.5.3. RBC/PLT Channel

Part of the fluidic structure is shown as follows:



1. The diluent is added by the SR along the blue line (T3, T12, SV06, T18, T8 and T21) to the RBC bath.
 2. The diluted blood sample is dispensed by the sample probe to the RBC bath, and then is mixed by the bubbles generated when waste cleaning fluid (for cleaning the DIFF sample fluid in the sample supply tube) enters the isolation chamber 2 through SV14, T36 and T37.
 3. The sample is aspirated by the negative pressure in the vacuum chamber into the secondary bath (orange lines in the illustration). The cells will be measured while passing through the aperture. The sample volume is calculated from the count duration.
 4. After the measurement, the RBC bath is drained by the waste pump, the vacuum chamber and the SV13. In order to clean the secondary bath, the diluent is forced by the syringe through SV07, T51, T38 and T52 into the secondary bath, then through T43 and SV09 into the sample probe wash set and drained by the waste pump.

8.5.4. Precautions for Assembly and Service

Precautions for installation of sampling assembly

| No. | Precautions |
|-----|--|
| 1 | Strap the tube above the sample probe at the positioning hole to prevent the tube connector from being stressed by the vertical motion of the sample probe. |
| 2 | Move the sampling assembly horizontally and vertically to ensure that the sample tube is unobstructed with no folding and interference with the preamplifier, fluidics separator, right door, motor, valves and tube straps. |
| 3 | Ensure that the sample tube is not squeezed or deformed at the tube straps. |
| 4 | Ensure that there is no folding or interference when the sample probe wash set fluid tube is moving horizontally or vertically in the sampling assembly. |

Precautions for installation of reaction bath assembly

| No. | Precautions |
|-----|---|
| 1 | Case T59 and T60 with flexible tubes. |
| 2 | The waste tube for the reaction bath needs to be wrapped in the vertical direction to a height above the liquid level with 3mL of liquid in the bath. |
| 3 | Install the aperture so that the surface with the tapered bore faces the primary bath. |

Precautions for servicing the whole fluidics

| No. | Precautions |
|-----|--|
| 1 | The tubes shall be unobstructed with no twisting, squeezing, creases and folds. |
| 2 | Never bend any of the tubes. Pay special attention to the Teflon tubes. If any Teflon tube is folded, be sure to replace it with a new tube. |
| 3 | The bending diameter of all the tubes should be greater than 30mm. |
| 4 | When cutting the tubes, the cutting face shall be perpendicular to the axis of the tube. |
| 5 | When connecting the transit tube with the Teflon tube, make sure the insertion depth is 10-13mm. Keep no clearance between the two connected rigid tubes as far as possible. Keep the end of the Teflon tubes smooth and unwrinkled. |
| 6 | Strap the connections between any 1.0 Teflon tubes and the transit tube. Strap at a position near the end of the Teflon tube, and leave 3-5mm of Teflon tube aside. |
| 7 | Thick Teflon tubes connect with thick 50 tubes, the insertion depth is at least 10mm. |
| 8 | If not specifically stated, when connecting hoses, transit tubes with connectors, valve ports or dosing tubes on the reaction bath, the end of the hose or transit tube shall be fully inserted. |

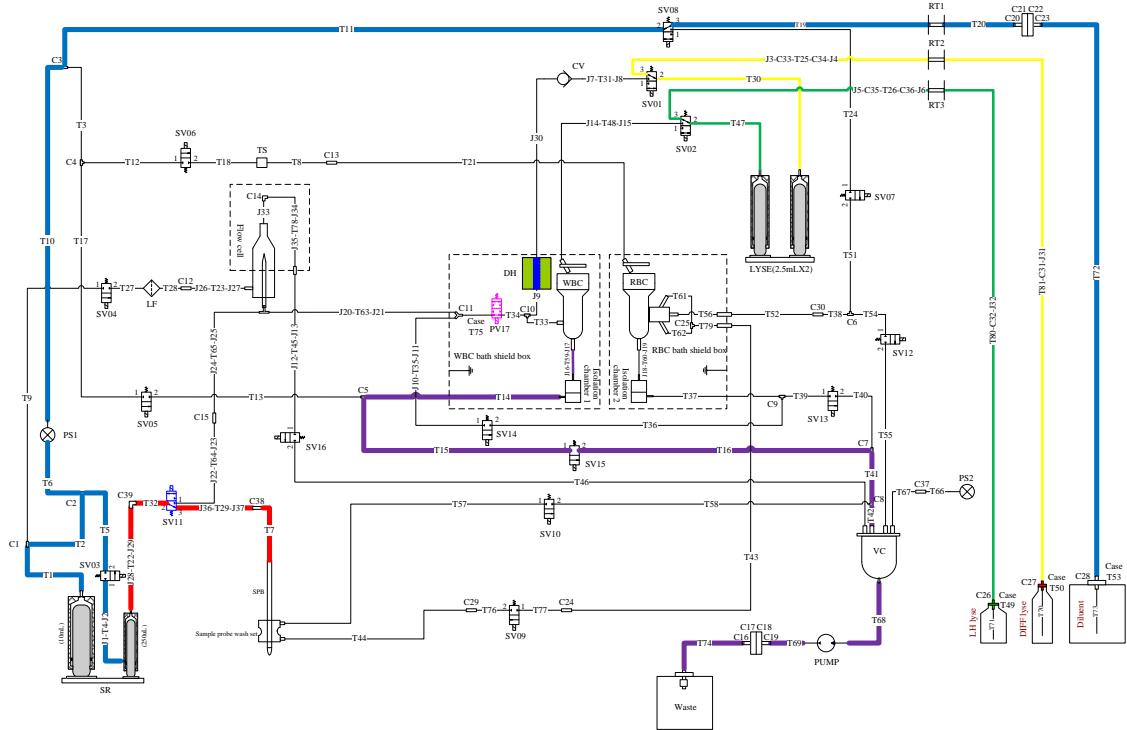
| No. | Precautions |
|-----|--|
| 9 | It is not necessary to over tighten the straps for fastening the tubes. |
| 10 | Strap all the tubes that need winding, ensuring that the tube is not deformed and folded. |
| 11 | For T-transit tubes and Y-transit tubes, the side ports and the middle port shall be treated differently. Please assemble them strictly in accordance with the requirements of the fluidic diagram, cannot be replaced. |
| 12 | There are strict tolerance requirements for lengths of the following tubes: T4 and T33: $\pm 1\text{mm}$, T63: $\pm 2\text{mm}$, T7 and T29: $\pm 3\text{mm}$. Tolerances for the other tubes: for length less than 50mm, the tolerance is $\pm 1\text{mm}$; for length between 50-400mm, the tolerance is $\pm 2\text{mm}$; for length more than 400mm, the tolerance is $\pm 5\text{mm}$. |
| 13 | When connecting or replacing tubes on the analyzer, never use any blades or other sharp tools. |
| 14 | If not specifically stated, never scald any hose with hot water. TPU tube can be scalded with hot water not higher than 80° before connection, without any fold deformation. Proceed to the next process after the tube is cooled. |
| 15 | Before or after assembly or maintenance, keep all the hoses, connectors or fluidic components intact and in good condition without any scratches, deformation or distortion. |
| 16 | Thick 50 tubes cannot be used again after disconnected from valve ports or connectors. |
| 17 | Cut T75 and case it between T34 and C11 |
| 18 | Assemble the check valves so that the bigger end is connected to the preheat bath |
| 19 | Assemble the filters in the right direction so that the assembly line is facing upwards |
| 20 | The valve ports shall be treated differently and assembled strictly in accordance with the requirements of the fluidic diagram. Each port of the valve is marked on the valve body. Three-way valve has three ports of 1, 2 and 3; two-way valve has two ports of 1 and 2. |

8.6. Introduction to Sequences

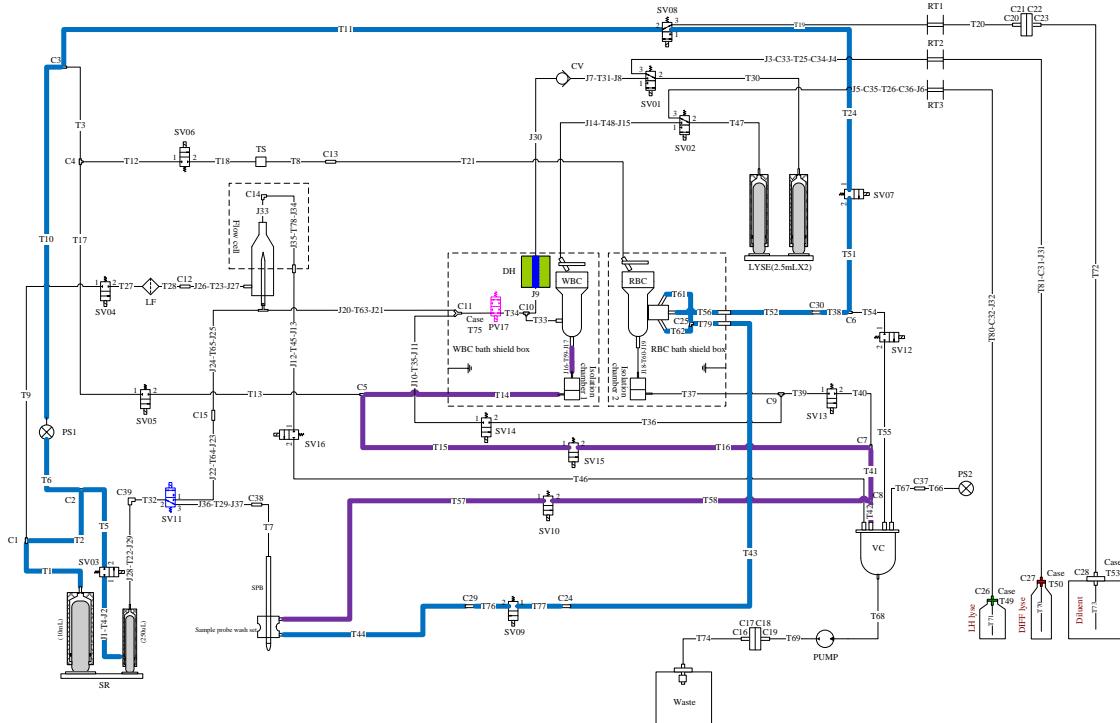
Taking the WB-CBC+DIFF mode of instrument with throughput of 60 samples per hour as an example:

8.6.1. Measurement Sequence in WB-CBC+DIFF Mode

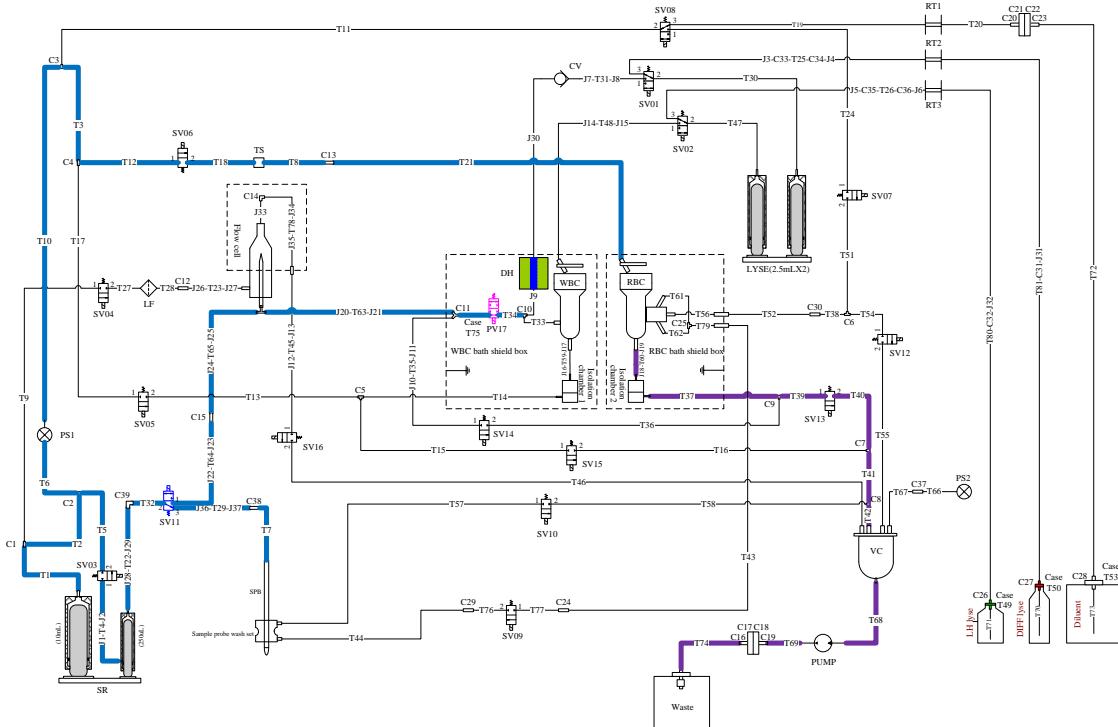
The sequence is described as follows:



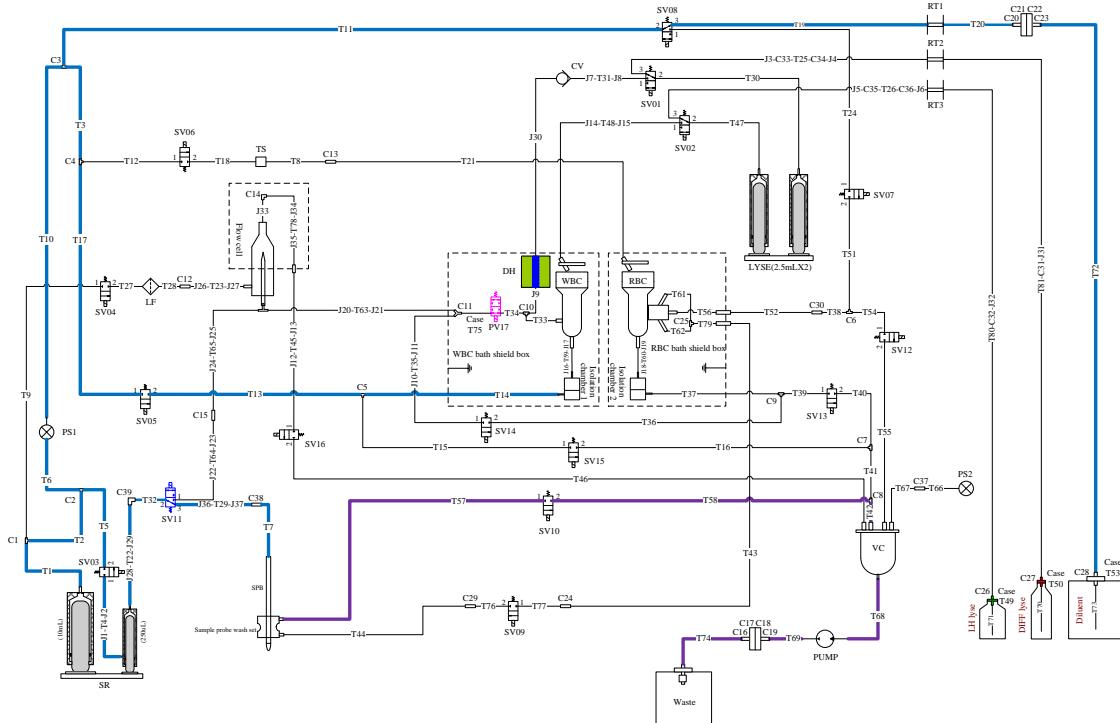
| No. | Time | Function |
|-----|----------|--|
| 1 | 0-0.9s | SR pump aspirates 20ul blood (sample probe-SV11-sample piston) and 800ul diluent (diluent-SV8-diluent piston). |
| 2 | 0.2s | Test the HGB blank voltage. |
| 3 | 0.6-2.9s | Open vacuum pump to drain WBC chamber (WBC buffer chamber-SV15-vacuum pump). |
| 4 | 1-2.7s | Diluent piston aspirates 5520ul diluent (diluent-SV8-diluent piston; SV3-SV11-PV17-WBC chamber). |
| 5 | 1.1-3.2s | Shock RBC aperture. |
| 6 | 0-3s | Lyse pump aspirates 2000ul DIFF lyse (DIFF lyse-SV1-DIFF lyse piston) and 2000ul LH lyse (LH lyse-SV2-LH lyse piston). |



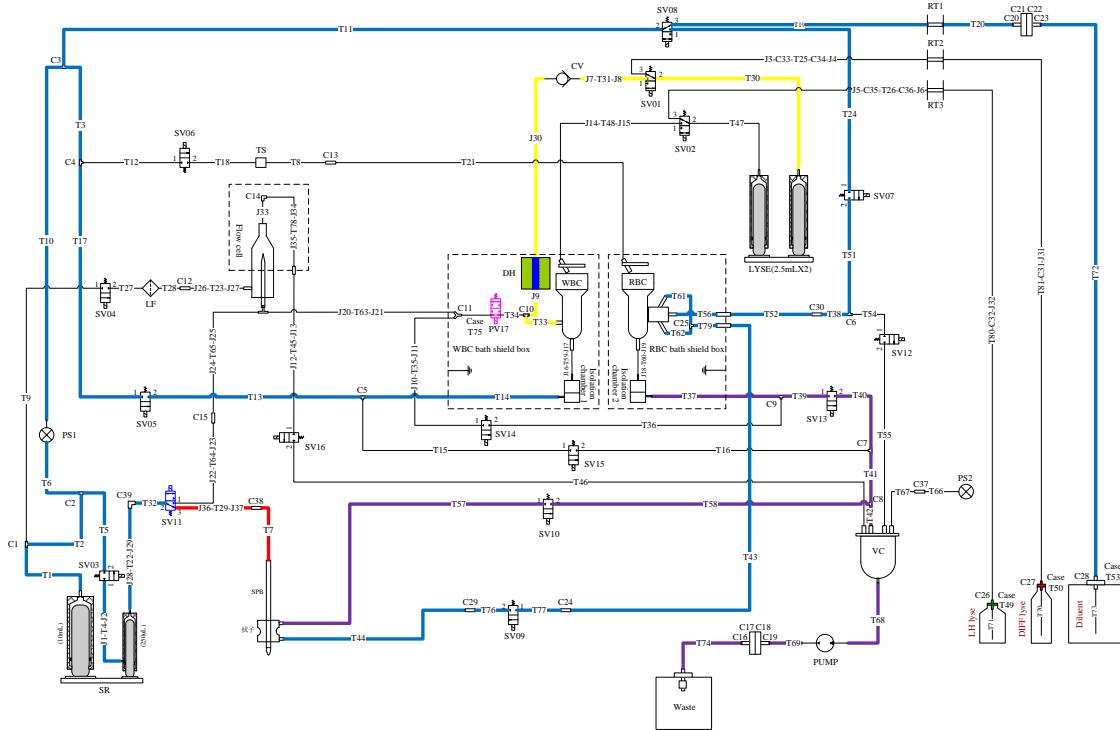
| No. | Time | Function |
|-----|-----------|---|
| 1 | 2.8-3.8s | Sample probe rises up. |
| 2 | 2.9-4.2s | Wash probe outside (SR pump-SV8-RBC chamber outside-SV9-sample probe wash set-SV10-vacuum tank), vacuum pump is always working for sample probe cleaning. |
| 3 | 4.25-5.2s | Sample probe rotates to WBC chamber position. |
| 4 | 4.2-5.2s | Drain WBC chamber again. |



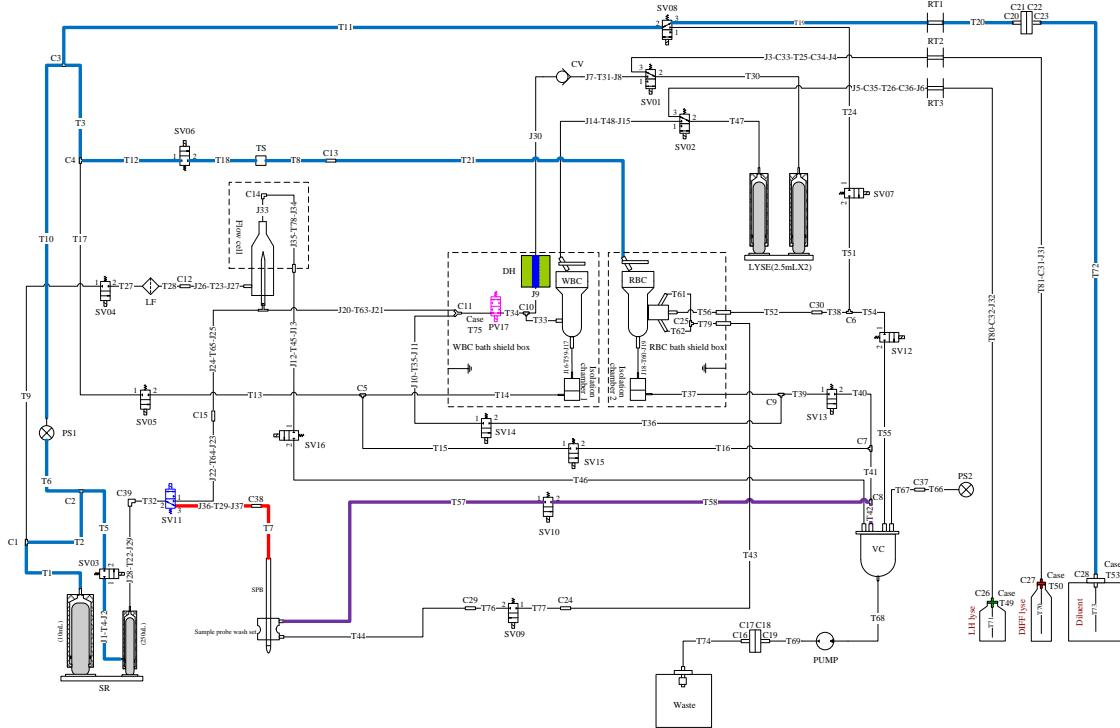
| No. | Time | Function |
|-----|-----------|--|
| 1 | 5.5s-6s | Diluent piston adds 364ul diluent to WBC chamber from bottom (diluent piston-SV3-sample piston-SV11-PV17-WBC chamber bottom). |
| 2 | 5.2-6s | Sample probe goes down into WBC chamber. |
| 3 | 6.1-6.5s | Add 23ul sample into WBC chamber (sample piston-SV11-sample probe inside-WBC chamber); Diluent piston adds 920ul diluent into RBC chamber to clean the tap above RBC chamber (diluent piston-SV6-the tap above RBC chamber). |
| 4 | 6.55-7.4s | SR pump adds 425ul diluent into WBC chamber from sample probe by high pressure to clean sample probe inside (diluent piston-SV3-sample piston-SV11-sample probe inside-WBC chamber). |
| 5 | 5.3-7.3s | Drain RBC chamber (RBC buffer chamber-SV13-vacuum tank). |



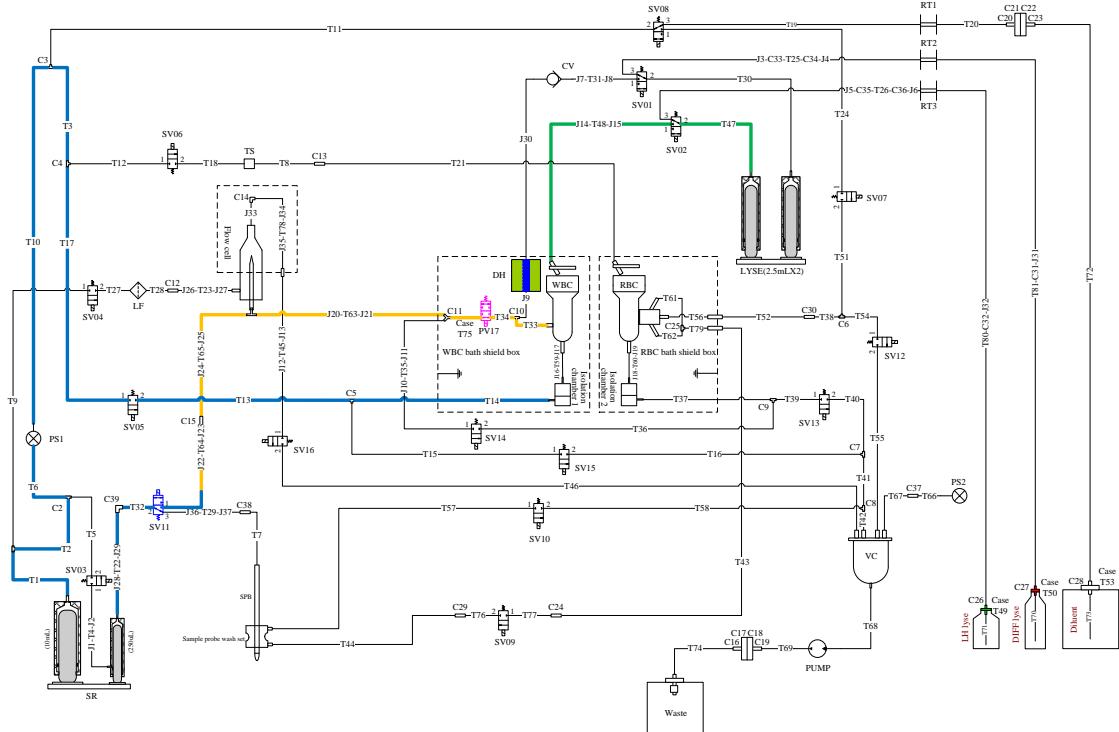
| No. | Time | Function |
|-----|------------|--|
| 1 | 7.37-8.15s | The sample probe rises to the sample probe wash set position and the liquid pump draws fluid from the sample probe wash set. |
| 2 | 7.55-8s | Mix solution inside WBC chamber (diluent piston-SV5-WBC buffer chamber-WBC chamber). |
| 3 | 8.1-8.4s | Wash sample probe inside (diluent piston-SV3-sample piston-SV11-sample probe inside), sample probe wash set drains waste till 9.2s (sample probe wash set-SV10-vacuum tank). |
| 4 | 8.5-9.3s | Diluent piston aspirates 2230ul diluent (diluent-SV8-diluent piston). |
| 5 | 9.35-10.3s | Mix solution inside WBC chamber again (diluent piston-SV5-WBC buffer chamber-WBC chamber). |
| 6 | 10.4-11.2s | Diluent piston aspirates 1840ul diluent (diluent-SV8-diluent piston). |



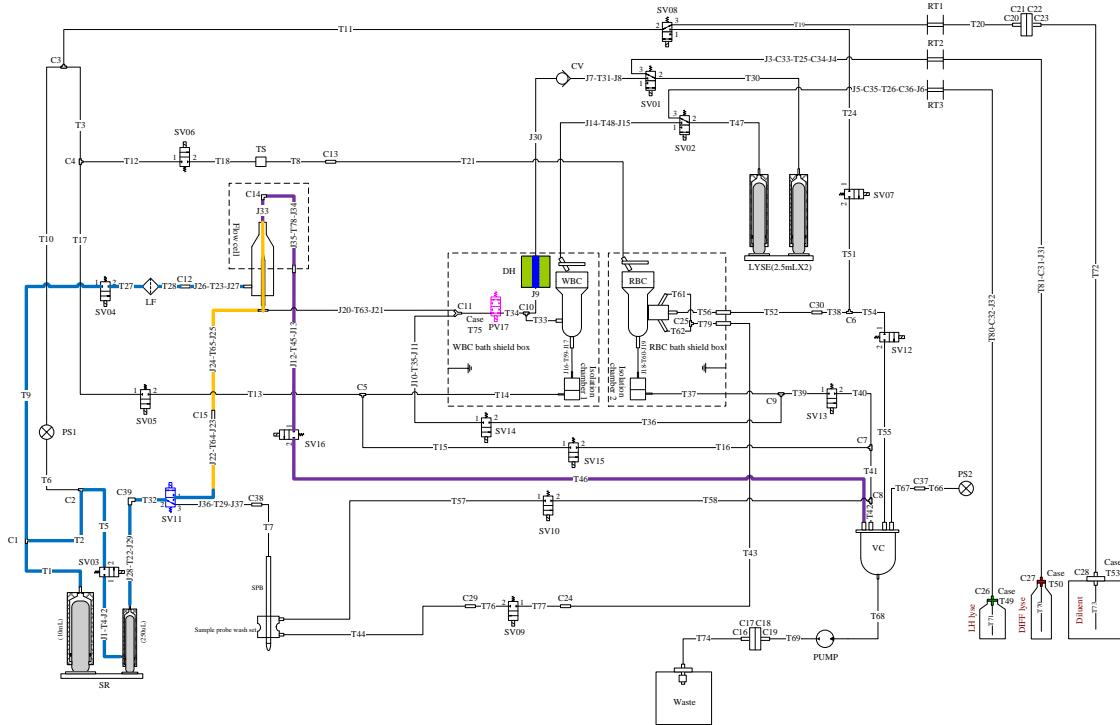
| No. | Time | Function |
|-----|--------------|---|
| 1 | 11.9-12.7s | Sample probe goes into WBC chamber. |
| 2 | 12.25-13.15s | Drain RBC chamber (RBC buffer chamber-SV13-vacuum tank). |
| 3 | 12.8-13.3s | Sample probe aspirates 9ul diluted sample (sample probe-SV11-sample piston), diluent piston aspirates 360ul diluent (diluent-SV8-diluent piston). |
| 4 | 13.3-14.45s | Sample probe rises up, wash sample probe outside (SR pump-SV8-RBC chamber outside-SV9-sample probe wash set-SV10-vacuum tank), vacuum pump is always working for sample probe cleaning. |
| 5 | 13.75-15.15s | Add 1300ul DIFF lyse into WBC chamber (DIFF lyse piston-SV1-WBC chamber). |
| 6 | 14.45-15.3s | Mix solution inside WBC chamber (diluent piston-SV5-WBC buffer chamber-WBC chamber). |
| 7 | 14.25-14.95s | Sample probe rotates to RBC chamber position. |
| 8 | 14.45-15.15s | Drain RBC chamber (RBC buffer chamber-SV13-vacuum tank). |



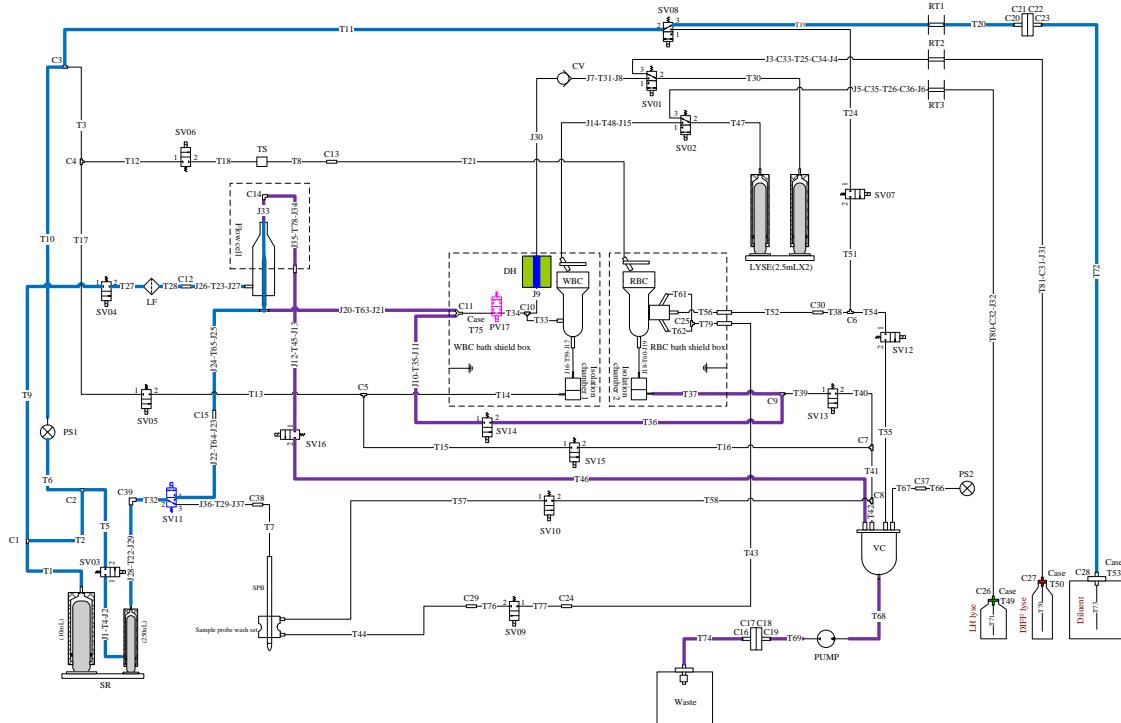
| No. | Time | Function |
|-----|--------------|--|
| 1 | 15.35-16.25s | Sample probe goes into RBC chamber. |
| 2 | 15.45-16.3s | SR pump adds 2454ul diluent into RBC chamber (SR pump-SV6-RBC chamber). |
| 3 | 16.4-17.9s | SR pump uses 952ul diluent to push 9ul sample (also clean sample probe inside) into RBC chamber (diluent piston-SV3-sample piston-SV11-sample probe inside-RBC chamber). |
| 4 | 17.95-22.05s | Sample probe rises up and sample probe wash set drains waste (sample probe wash set-SV10-vacuum tank). |
| 5 | 18-20.3s | SR pump aspirates 7310ul diluent (diluent-SV8-SR pump). |



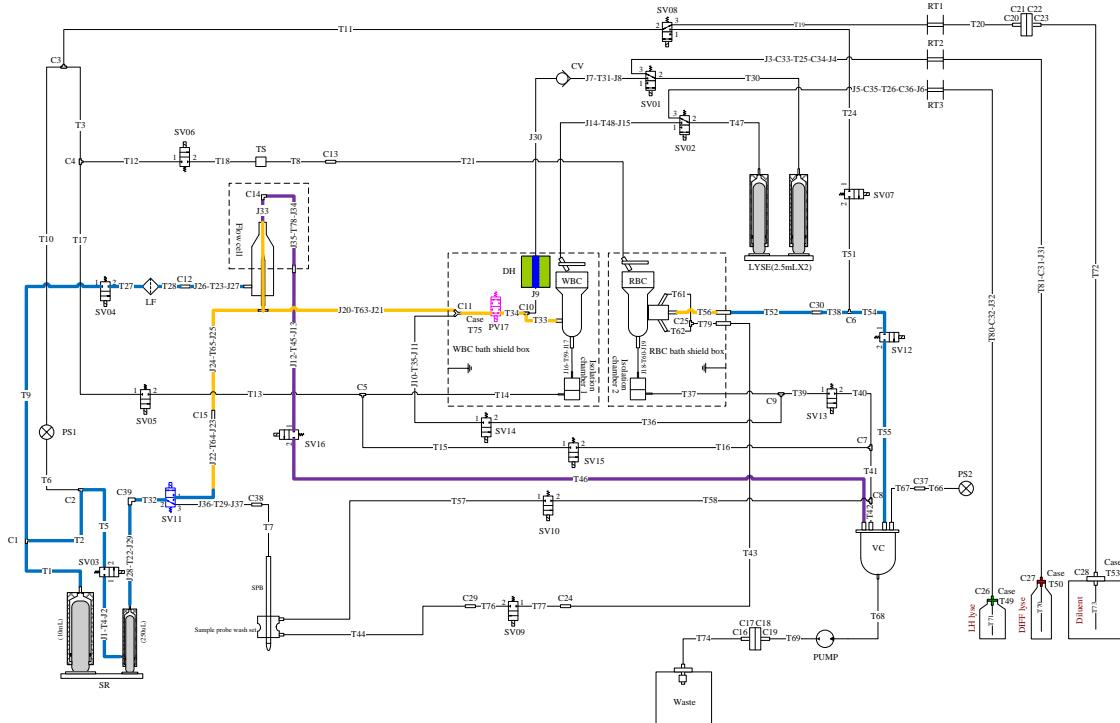
| No. | Time | Function |
|-----|--------------|---|
| 1 | 20.05-21.05s | Sample probe rotates to initial position. |
| 2 | 20.7-22.5s | SR pump aspirates 700ul DIFF sample to T63 and T65 (WBC chamber-PV17-T63, T65-SV11-SR pump), ready for DIFF counting. |
| 3 | 22.5-22.95s | Add 240ul LH lyse into WBC chamber (LH lyse piston-SV2-WBC chamber). |
| 4 | 22.9-23.5s | Mix solution inside WBC chamber (diluent piston-SV5-WBC buffer chamber-WBC chamber). |



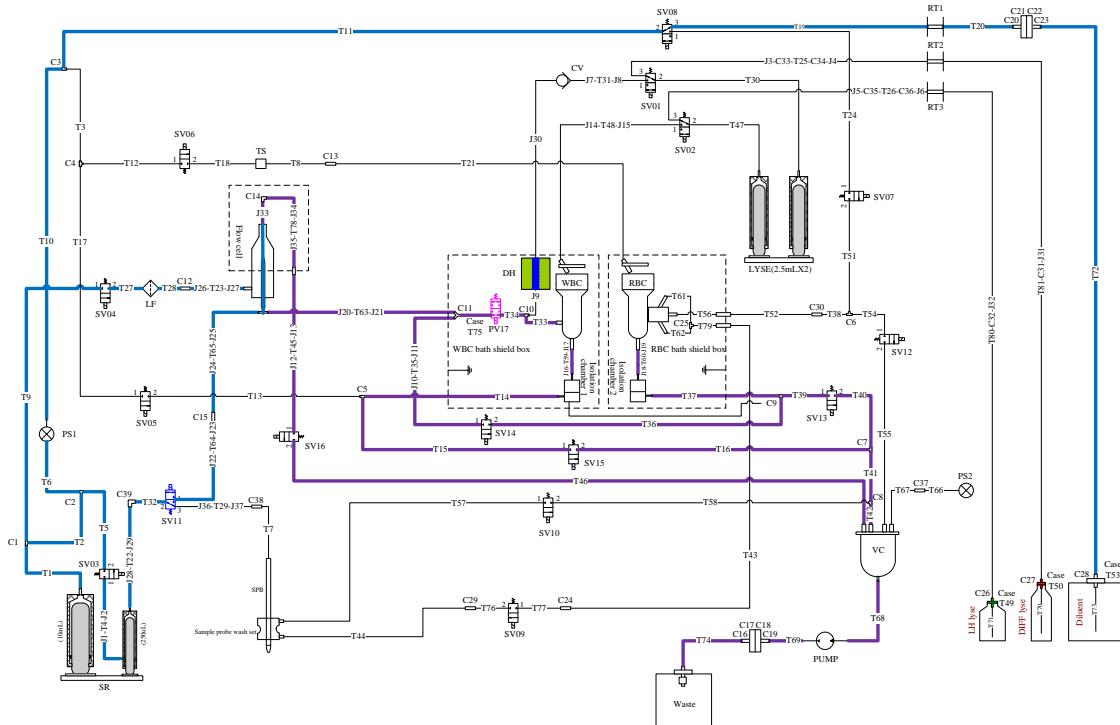
| No. | Time | Function |
|-----|--------------|---|
| 1 | 23.6-34.65s | Diluent piston pushes diluent into sheath flow module to form sheath flow (diluent piston-SV4-sheath flow module). |
| 2 | 23.6-23.73s | SV3 ON, the sample is pushed into sheath flow probe quickly by SR pump (diluent piston-SV3-sample piston-SV11-T64, T65-sheath flow probe). |
| 3 | 23.73-34.65s | SV3 OFF, sample piston pushes sample to go through flow cell constantly for differentiation, sample flow velocity is constant. (sample piston-SV11-T64, T65-flow cell). |
| 4 | 25.25-34.35s | DIFF counting. |
| 5 | 34.25s | HGB testing. |



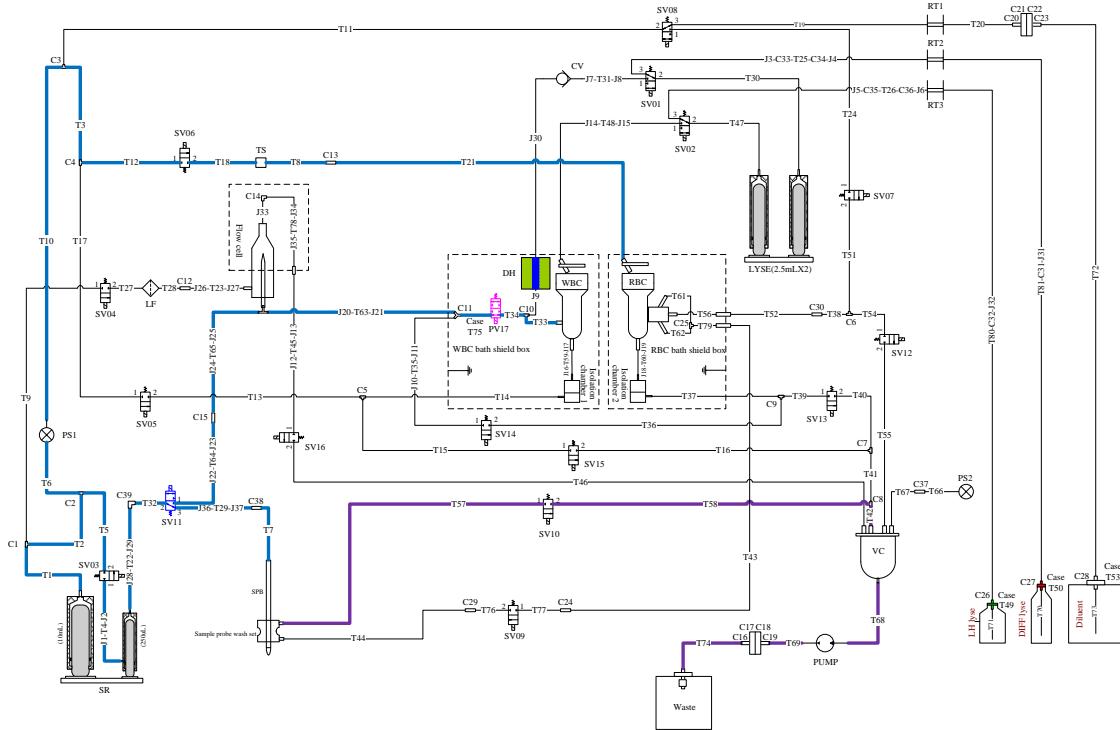
| No. | Time | Function |
|-----|--------------|---|
| 1 | 34.75-36.65s | Diluent piston aspirates 6250ul diluent (diluent-SV8-diluent piston). Sample piston aspirates 156.3ul sample from WBC chamber to wash the tubes between WBC chamber and Y-shaped connector C11 (WBC chamber-PV17-SV11-sample piston). |
| 2 | 37.05-38.55s | Wash sample preparation tubes (T64, T65, T63) and mix RBC chamber (SR pump-SV11-T64, T65, T63-SV14-RBC buffer chamber). Wash sheath flow module (diluent piston-SV4-sheath flow module-SV16-vacuum tank). |
| 3 | 34.55-42.15s | Form negative pressure in vacuum tank. |



| No. | Time | Function |
|-----|--------------|---|
| 1 | 38.85-40.1s | SR pump aspirates 780ul BASO sample to T63 and T65, ready for BASO counting (WBC chamber-PV17-T63, T65-SV11-SR pump). |
| 2 | 38.05s | Turn on constant current source inside RBC chamber. |
| 3 | 38.0-52.05s | Solution inside RBC chamber passes through aperture (RBC chamber-RBC chamber outside-SV12-vacuum tank). |
| 4 | 40.45-54.3s | Diluent piston pushes diluent into sheath flow module to form sheath flow (diluent piston-SV4-sheath flow module). |
| 5 | 40.45-40.58s | SV3 ON, the sample is pushed into sheath flow probe quickly by SR pump (diluent piston-SV3-sample piston-SV11-T64, T65-sheath flow probe). |
| 6 | 40.58-54.3s | SV3 OFF, sample piston pushes sample to go through flow cell constantly for differentiation, sample flow velocity is constant. (sample piston-SV11-T64, T65-flow cell). |
| 7 | 42.65-54.15s | BASO and WBC counting |
| 8 | 42.8-51.8s | RBC and PLT counting. |
| 9 | 53.05s | Turn off constant current source inside RBC chamber. |



| No. | Time | Function |
|-----|--------------|---|
| 1 | 54.15-56.65s | Drain RBC chamber (RBC buff chamber-SV13-vacuum tank). |
| 2 | 54.4-55.1s | Wash sample preparation tubes (T64, T65, T63), Y-shaped connector C11 (SR pump-SV11-T64, T65, T63-SV14-RBC buffer chamber). Wash sheath flow module (diluent piston-SV4-sheath flow module-SV16-vacuum tank). |
| 3 | 55.15-57.5s | SR pump aspirates 7800ul diluent. |
| 4 | 56.65-57.95s | Drain WBC chamber (WBC buffer chamber-SV15-vacuum tank). |
| 5 | 57.56-58.03s | Wash sample preparation tubes (T64, T65, T63), Y-shaped connector C11 (SR pump-SV11-T64, T65, T63-SV14-RBC buffer chamber). |
| 6 | 57.65-57.95s | Wash sheath flow module (diluent piston-SV4-sheath flow module-SV16-vacuum tank). |
| 7 | 57.83-59.5s | Wash the tubes between Y-shaped connector C11 and WBC chamber, wash WBC chamber (SR pump-SV11-PV17-WBC chamber). |
| 8 | 59.35-60.80s | Drain WBC chamber (WBC buffer chamber-SV15-vacuum tank). |



| No. | Time | Function |
|-----|-------------|---|
| 1 | 59.6-60.85s | Add 3800ul diluent into RBC chamber (diluent piston-SV6-RBC chamber). |
| 2 | 60.9-62.5s | Add 2460.5ul diluent into WBC chamber (SR pump-SV11-PV17-WBC chamber). |
| 3 | 62.1-63.5s | SV10 ON; the vacuum is released. |
| 4 | 62.6-63.5s | Sample probe goes down to sampling position. |
| 5 | 62.55-63.5s | Sample probe wash set drains waste (sample probe wash set-SV10-vacuum tank). |
| 6 | 63-63.4s | Sample piston aspirates 6ul air into sample probe inside to form isolation air column for next sample aspirate preparing (sample piston-SV11-sample probe). |

8.6.2. Measurement sequence in PD-CBC+DIFF mode

Measurement sequence in PD-CBC+DIFF mode is basically the same with the sequence in WB-CBC+DIFF mode, except for the sample volume. Because the blood sample has been prediluted outside the analyzer, 224 μ L of blood is aspirated in the PD mode.

8.6.3. Measurement sequence in CBC mode

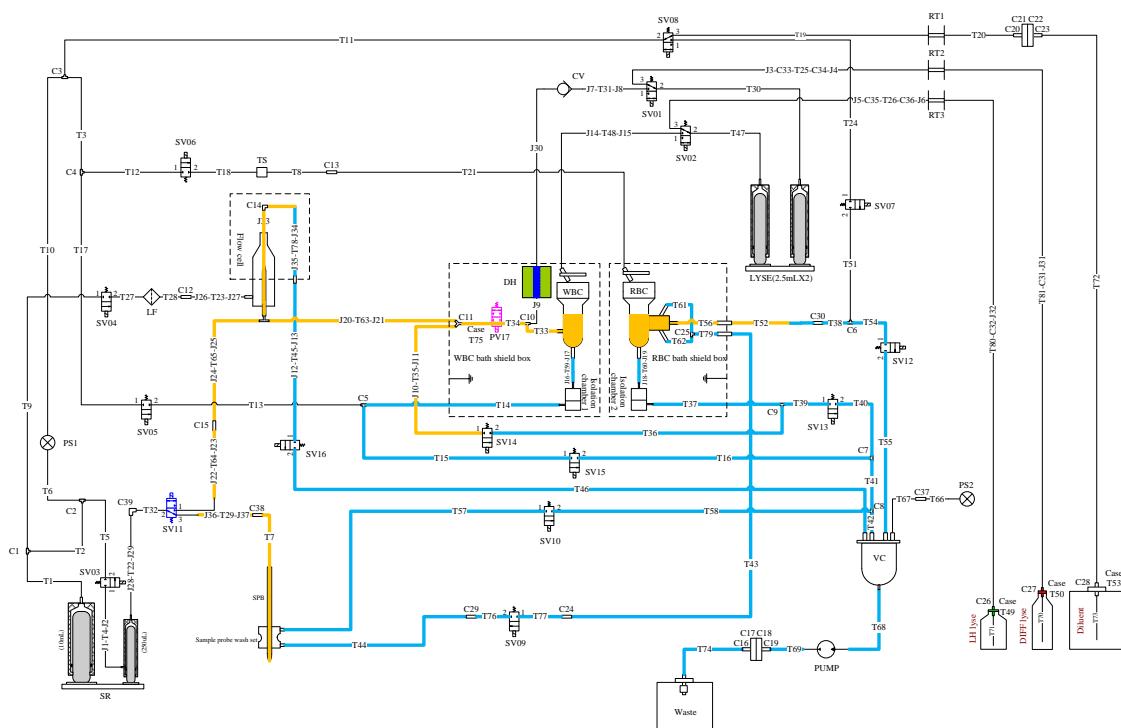
Compared with the sequence in CBC+DIFF mode, the measurement sequence in CBC mode is basically the same except that it does not include the actions of DIFF measurement. The main differences are as follows:

1. Sample volume. The sample volume is 20 μ L in the WB-CBC+DIFF mode, 12 μ L in the WB-CBC mode. The sample volume is the same between the PD-CBC+DIFF mode and PD-CBC mode.
2. There is no action related to DIFF measurement, including addition of DIFF reagent, preparation of DIFF samples, DIFF measurement, and cleaning process of the tubes and the flow cell after the DIFF measurement.

8.6.4. Introduction to the Maintenance Sequences

Probe cleanser maintenance (shutdown sequence)

The locations soaked by the probe cleanser are shown below. The orange lines are the locations soaked by the probe cleanser, and the blue lines are the locations passed by the probe cleanser.



An enhanced probe cleanser maintenance sequence will be called every 300 times of sample measurement (defaulted as 300,100-500 can be set). The main difference between the enhanced and the regular probe cleanser maintenance sequence is the soaking time.



The soaking time of enhanced maintenance is 3 minutes longer than regular maintenance.

In the Maintenance screen, the probe cleanser maintenance is defaulted as enhanced probe cleanser maintenance.

Startup

The fluidic actions on startup are shown in the following table:

| No. | Startup fluidic action | Description |
|-----|--------------------------------------|--|
| 1 | Initialization of fluidic components | Initialization of valves, pumps, sampling assembly and syringe assembly. |
| 2 | Vacuum self-test | Creating vacuum and detecting vacuum. |
| 3 | Reagent self-test | Checking if DIFF lyse, LH lyse and diluent is expired. |
| 4 | Startup maintenance | Including maintenance of all the tubes and fluidic components on the analyzer. |
| 5 | Background measurement | WB-CBC+DIFF measurement mode. |

Standby

The instrument will enter standby status after idling for 10 to 30 minutes (defaulted as 15 minutes). After entering standby status, operations without fluidic actions can be performed from the screen.

When exiting standby, depending on the standby time, the instrument performs a different exiting standby action, as shown in the following table.

| No. | Exit standby | Call condition | Description |
|-----|-----------------------|--|--|
| 1 | Exit standby status 1 | Standby time \leq 30 minutes | Clean the interior and exterior of the sample probe and the WBC bath and rebuild the isolation bubble without consumption of lyse. |
| 2 | Exit standby status 2 | 30 minutes < Standby time \leq 3 hours | Clean the interior and exterior of the sample probe, the WBC bath, the RBC bath, the sample supply tube and the flow cell, and rebuild the isolation bubble without consumption of lyse. |
| 3 | Exit standby status 3 | Standby time > 3 hours | The same as fluidic maintenance on startup, including maintenance of all the tubes and fluidic components on the analyzer; removing bubbles from the flow cell; discarding 2ml of DIFF reagent to eliminate the effects of bubbles in the preheat bath tube; discarding 0.15ml of LH reagent to eliminate the effects of crystal and bubbles at the inlet. |

9. Hardware System

9.1. Overview

The hardware system consists of not only main control board, signal board, driver board, indicator board, printer driver board and optical part, but also connecting wires between different boards and components.

9.1.1. Hardware Resources

| | |
|--------------------------|---|
| Display | 1. 10.4-inch color display \ LVDS interface \ resolution 800 × 600 \ appearance 236mm × 177mm |
| | 2. Resistive touch screen |
| Interface | 1. TCP/IP network port |
| | 2. 4 USB ports |
| | 3. Serial communication interface |
| Motor driver | 1. Capable of driving four-way two-phase stepper motor |
| | 2. 16W1-2 phase |
| | 3. Peak output current can reach 2.2A |
| Input and output sensor | 1. Can achieve the temperature collection requirements |
| | 2. Can achieve positive and negative pressure acquisition |
| | 3. Can read the photoelectric sensor signal correctly |
| | 4. Can read one-dimensional barcode correctly |
| Signal processing design | 1. Can read the converted optical WBC signal accurately |
| | 2. Can read the RBC/PLT signal accurately |
| | 3. Can read the HGB signal accurately |

9.1.2. System Troubleshooting

Common hardware system failures can be divided into board failures, wire failures and component failures. Generally, the troubleshooting procedures of these failures can be found in the board troubleshooting section below. However, when the system power supply cannot be guaranteed (such as failure to power up or immediate system self-protection after power-up), it will be necessary to start troubleshooting from the system level. The figure below shows the flowchart for power anomaly check.

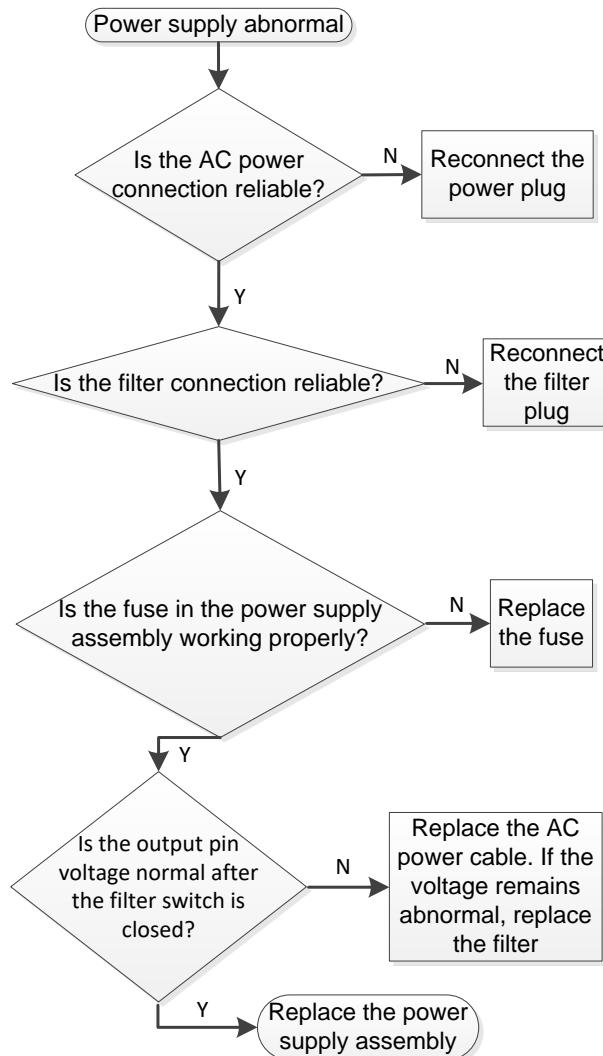


Figure 8-1 Power anomaly troubleshooting flowchart

9.2. Main Control Board Module

9.2.1. Main Input Signal

- 1) USB2.0, network port 100M (IEEE 802.3);
- 2) Signal board data input (TTL signal);
- 3) Barcode scanning signal input (serial signal);
- 4) Feedback signal (serial signal) of the driver board motion state;
- 5) SD card signal input (SD card 2.0);
- 6) Communicate with PC serial port (serial port);
- 7) Resistive touch screen signal input (analog signal).

9.2.2. Main Output Signal

- 1) Display data output (LVDS signal);
- 2) Issue a command to the driver board (serial signal);
- 3) Barcode scanning control signal (low level effective);
- 4) Printer data signal (serial signal);
- 5) Network port 100M (IEEE 802.3);
- 6) Communicate with PC serial port (serial port).

9.2.3. Function and Performance Realization

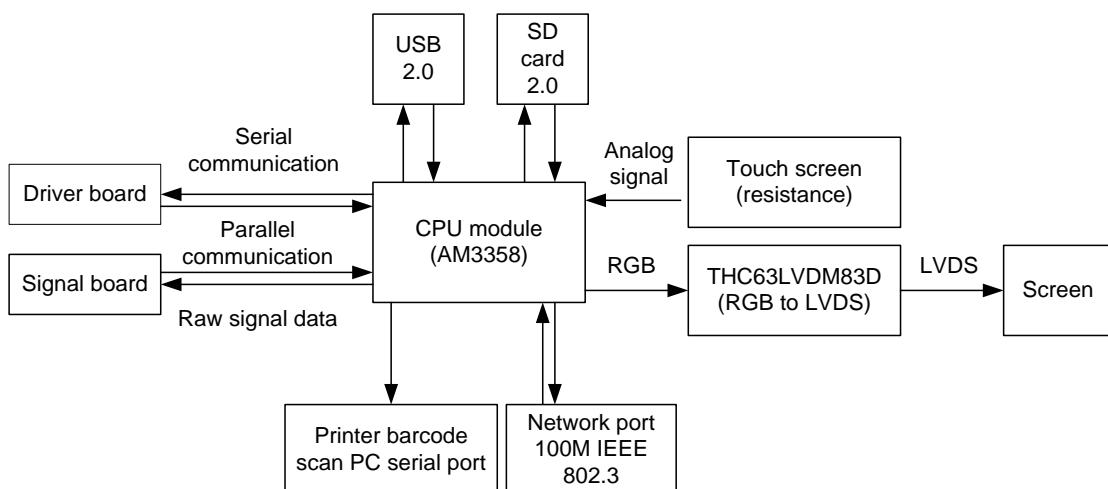


Figure 8-2 Main control board function module

9.2.4. Module Circuit Introduction

Screen display function and touch operation design

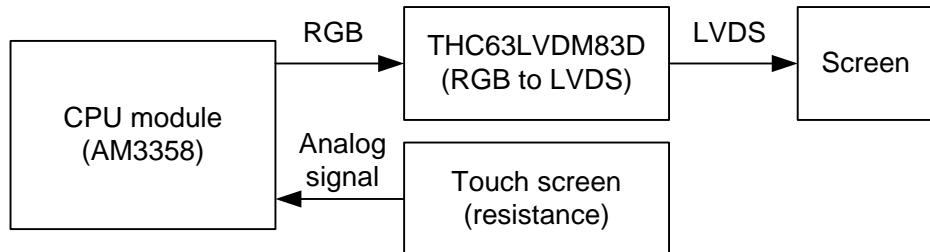


Figure 8-3 Display function module

As shown in the figure above, chip THC63LVDM83D is used to convert the RGB signals output from the CPU to the LVDS signal of the screen. The touch screen outputs analog signals in the X and Y directions, which are converted into digital signals by the internal AD of the CPU. The touch position is determined by the algorithm processing results, thereby realizing the touch function.

Network port communication design

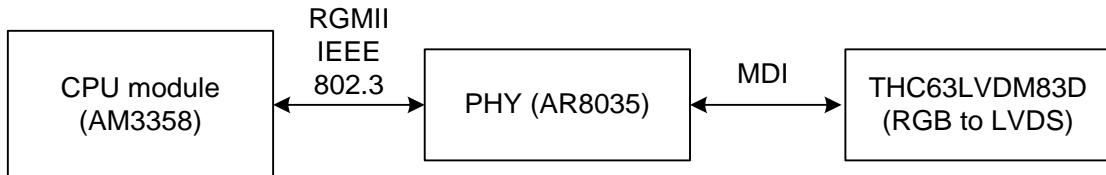


Figure 8-4 Network port function module

Use AR8035 to convert the RGMII signal to an MDI signal with a transmission data of 100M.

CPU and signal board communication design

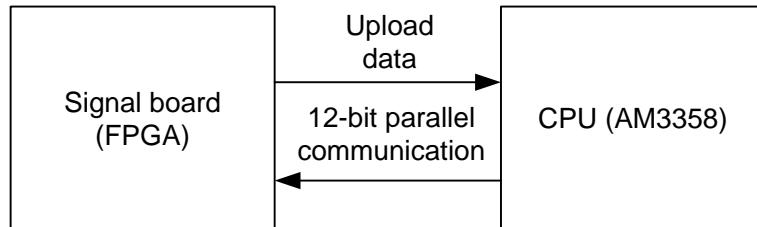


Figure 8-5 Interface function module

As shown in the figure above, the signal board FPGA will upload the signal data to the CPU and the CPU processes the signal data. The communication between them is 12-bit parallel communication and the transmission speed can reach up to 30M/S.

CPU and serial ports communication design

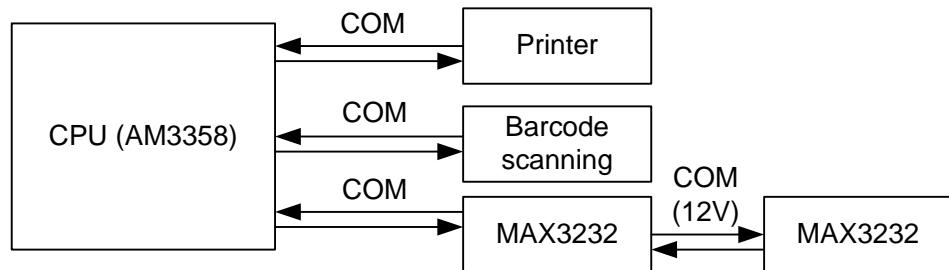
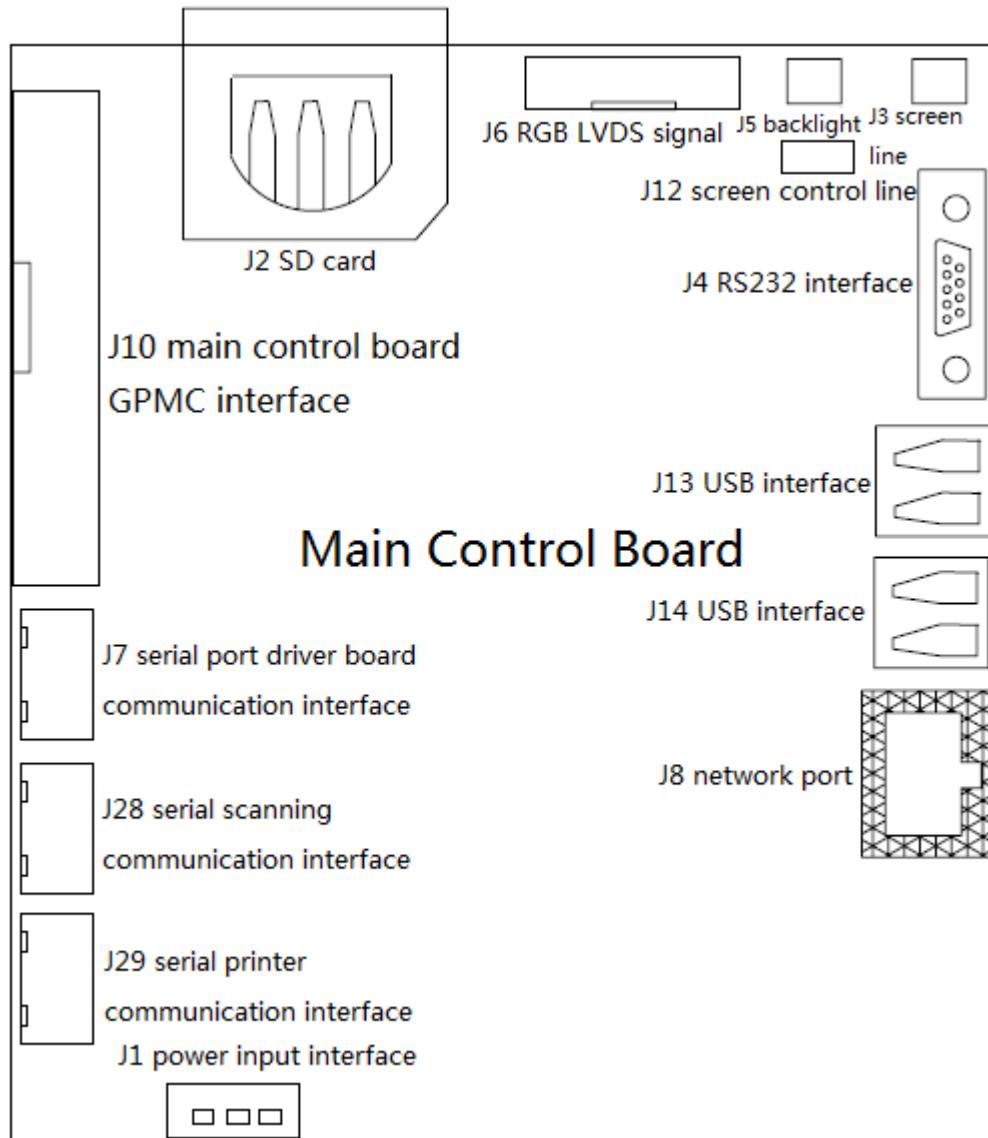


Figure 8-6 Interface function module

9.2.5. Troubleshooting





The table below lists common symptoms and relative corrections for the main control board only from the hardware side, not including symptoms caused by software. However, many problems will need to be tested by software.

Before troubleshooting problems related to the main control board, perform the following checks:

1. Whether there is any loose connecting wire or unreliable connection on the main control board;
2. Whether the bit numbers on the wires are matching the bit numbers on the main control board sockets; whether there is any broken or damaged wire;
3. Whether the input power of board socket J1 is working properly (measured with a multimeter, the voltage between the black and red lines is 5V).

After the wire connections, input power and indicators are verified to be normal, troubleshoot the problem in accordance with the following table.

| Symptom | Solution |
|--|---|
| 1. Cannot startup | <ol style="list-style-type: none">1. Check if the power supply is working properly. If so, proceed to the next step.2. Check if the voltage of 5V and 3.3V (marked on the board) on the voltage test point of the main control board is normal, if not check the board for a short circuit.3. Check if the backlight lights up, if not, whether the high-pressure bars are damaged.4. Check if the connection between the main control board and the backlight interface and LCD screen is reliable. If the fault disappears after re-plugging and re-attaching the power source, then the line connection is not reliable. Otherwise, proceed to the next step.6. Replace the LCD screen, if the fault disappears, it is the LCD screen component failure. |
| 2. Cannot load kernel at startup | <ol style="list-style-type: none">1. Check if the SD card is securely plugged in.2. Check if there is incomplete weld between the main control board and the core board connector, or the chip pin falls off with the pad. |
| 3. Cannot read the barcode information | <ol style="list-style-type: none">1. Check whether the barcode type is supported by the barcode scanner.2. Check the scanner cable for poor contact or breakage.3. Replace the scanner parts if the above faults have been excluded. |

| Symptom | Solution |
|---------------------------------|---|
| 4. Cannot print test results | 1. Check the printer cable for poor contact or breakage. 2. Replace the printer parts if the above faults have been excluded. |
| 5. Clock reset at every startup | Turn off the power and measure the voltage between the two ends of the battery clip with a multimeter with the battery in place. If the measured value is less than 2.8V, then the problem is caused by a low battery, replace the battery. |

9.3. Signal Board Module

9.3.1. Main Input Signal

The three input signals of high angle scatter (HS), medium angle scatter (MS) and low angle scatter (LS) are derived from the optical signal amplifying board. They are pulse signals, their cycles are the same and $T=2.5\mu s$, amplitude $V(HS)=1.2V$, $V(MS)=1V$, $V(LS)=0.8V$ (the above are approximate values).

The input signal of RBC is the pulse signal, derived from the RBC bath, the cycle $T=16\mu s$, the amplitude $V=1mV$ (it is an approximate value).

The input signal of HGB is derived from the HGB measuring cup, which is a DC signal with amplitude of about 1.5V.

9.3.2. Main Output Signal

Signal output of the signal board: FPGA uploads the collected data to CPU (main control board AM3358) after preliminary sorting. The communication mode between FPGA and CPU is data parallel communication protocol for 12-bit address lines.

9.3.3. Function and Performance Realization

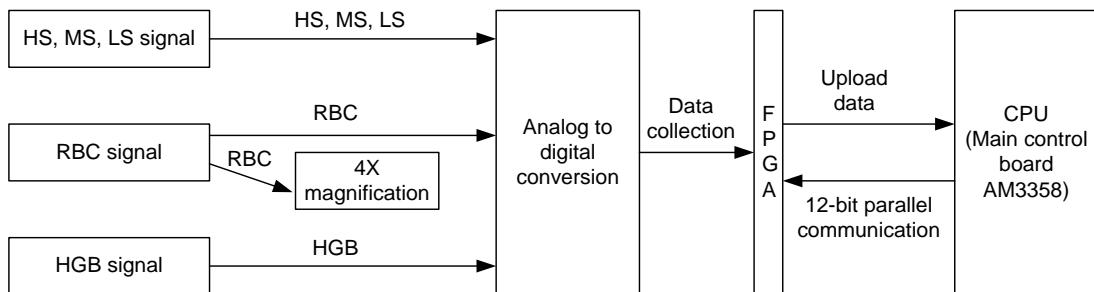


Figure 8-7 Signal function module

9.3.4. Module Circuit Introduction

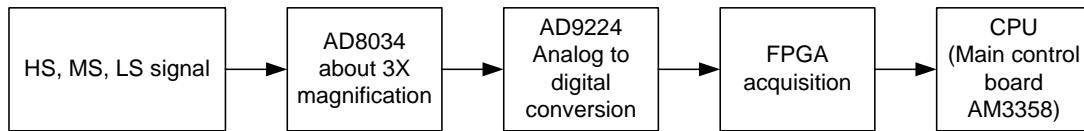


Figure 8-8 HS, MS, LS acquisition function module

HS, MS, LS is the pulse signal, the cycle is the same and $T=2.5\mu s$, the amplitude $V(HS)=1.2V$, $V(MS)=1V$, $V(LS)=0.8V$. The values change to $V(HS)=3.6V$, $V(MS)=3V$, $V(LS)=2.4V$ after amplified by AD8034 (the above specific magnification will vary depending on the target value, so the above are the approximate values). The AD9224 converts these analog signals into digital signals for FPGA acquisition and uploading them to the CPU.

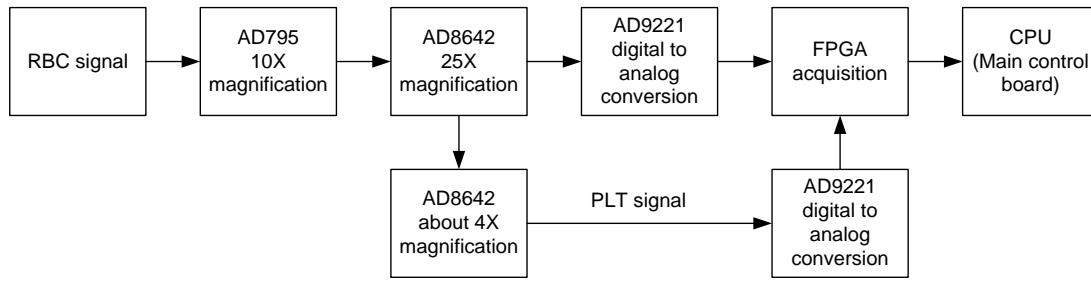


Figure 8-9 RBC acquisition function module

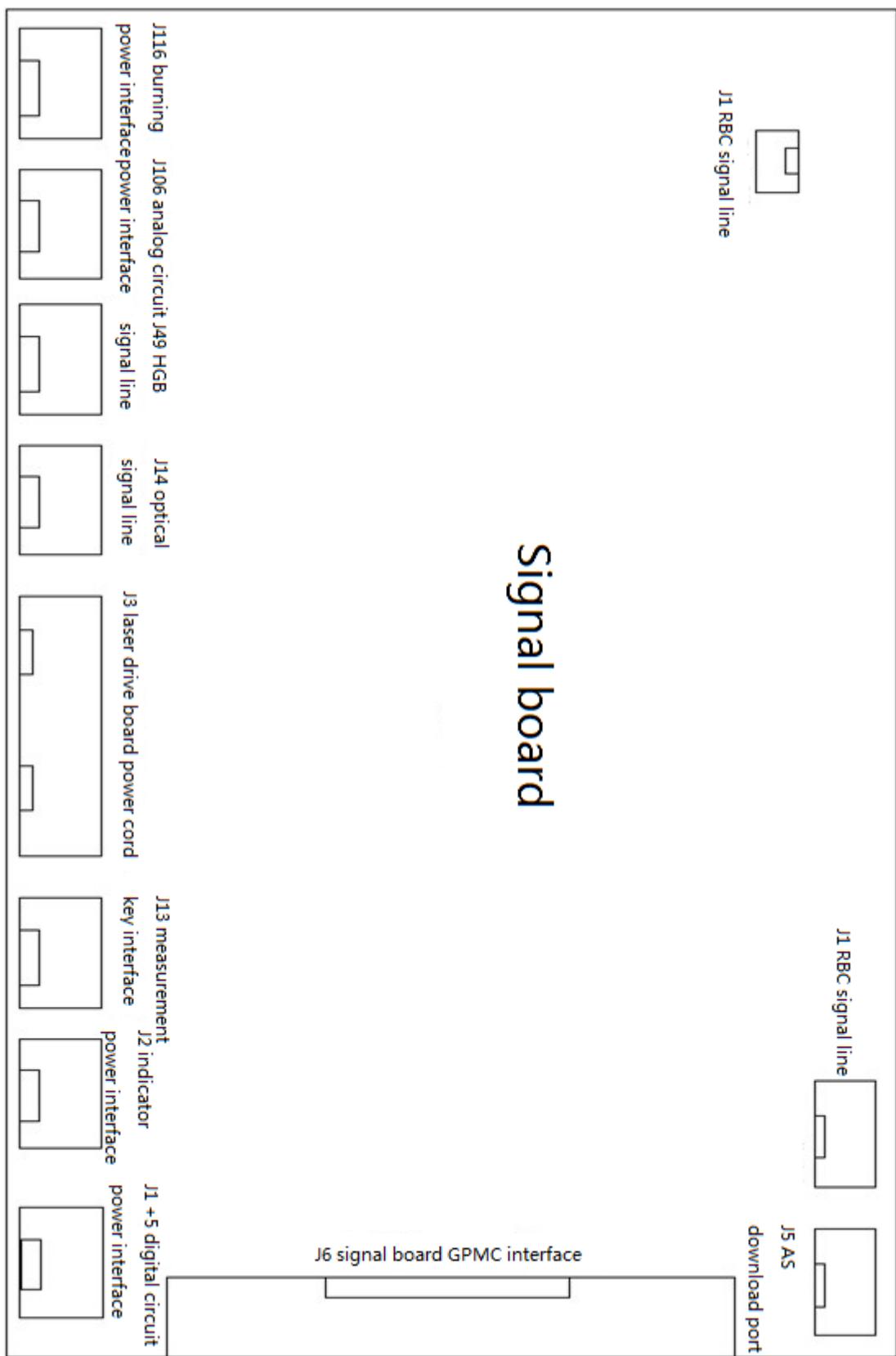
RBC signal is the pulse signal, the cycle $T=16\mu s$, the input amplitude $V=1mV$, which changes to about $0.9V$ after 250-500 times magnification, then AD9224 converts this signal into a digital signal for FPGA acquisition and uploading it to the CPU. After amplified 250-500 times, the RBC signal then amplified 4 times to get PLT signal, which is also the pulse signal, the cycle $T=16\mu s$, amplitude is about $3.6V$. It is then converted by AD9221 to digital signal for FPGA acquisition and uploading to the CPU.



Figure 8-10 HGB acquisition function module

HGB signal is a DC signal. The input amplitude is about $1.5mV$, which changes to about $1.5V$ after amplified by 1000 times. AD7265 then convert this signal into a digital signal for FPGA acquisition and uploading to the CPU.

9.3.5. Troubleshooting



Signal board circuit completes the adjustment and amplification of WBC, RBC/PLT and HGB signals, so that the signals are basically true and suitable for A/D conversion. A/D module is the interface of analog circuit and digital circuit, completing the sampling of the sensor signal and other monitoring signal, converts the analog signal to digital signal suitable for digital circuit processing.

| Symptom | Solution |
|---|--|
| 1. No response when pressing the aspirate key | 1. Check if the connecting wire of the aspirate key is loose or broken. If so, reconnect or replace the wire. 2. If step 1 does not solve the problem, remove the aspirate key switch plate to check if there is fluid inside. If so, clean the fluid and reinstall the switch plate. |
| 2. No WBC measurement value | Check if the optical signal line (J14) connection is reliable. If so, replace the main control board if there is still no value. |
| 3 No RBC measurement value | Check if the RBC signal line (J1) connection is reliable. If so, replace the main control board if there is still no value. |
| 4 No HGB measurement value | Check if the HGB signal line (J49) connection is reliable. If so, replace the main control board if there is still no value. |

9.4. Driver Board Module

9.4.1. Main Input Signal

- 1) The main control board issued instructions (serial signal)
- 2) Motor position signal feedback (photoelectric sensor signal)
- 3) Hydraulic pressure and negative pressure pump pressure signal feedback
- 4) Temperature sensor signal input

9.4.2. Main Output Signal

- 1) Feedback of the motion mechanism state to the main control board (serial signal)
- 2) Valve control signal
- 3) Stepper motor control signal
- 4) Pipeline liquid heating control signal

9.4.3. Function and Performance Realization

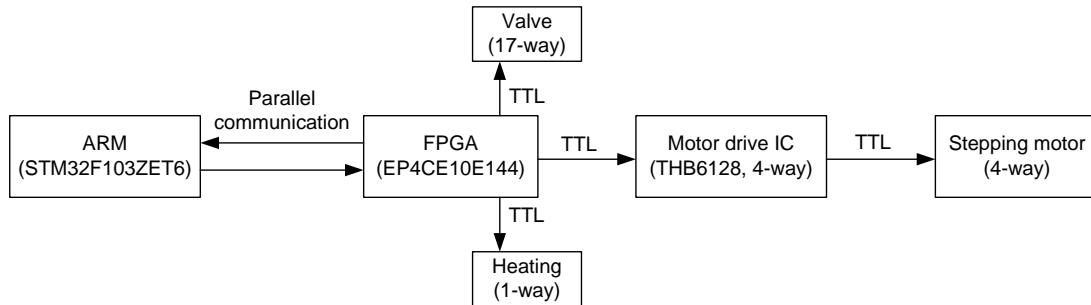


Figure 8-11 Driver board function module

9.4.4. Module Circuit Introduction

Stepper motor driving

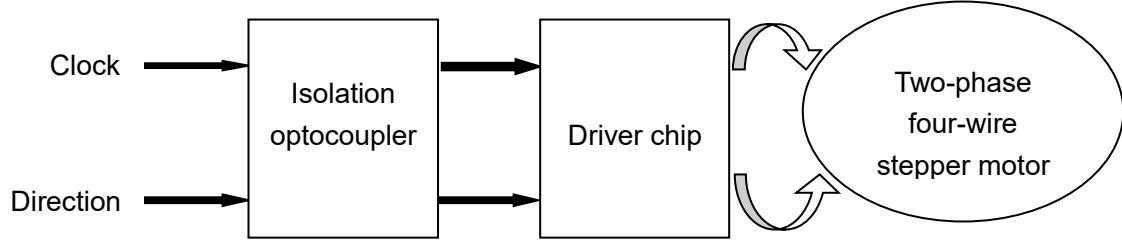


Figure 8-12 Stepper motor function module

Driving a stepper motor requires two circuits: 1. Driver chip; 2. Circuit that receives the optocoupler control signal and converts it to the rotation direction and the number of micro steps of the motor. FPGA outputs two signals: rotation direction: Direction; stepping pulse: Clock. The driving voltage of the stepper motor is 24V; the current is determined by VREF terminal voltage which sets the driver chip.

Pump/valve driving

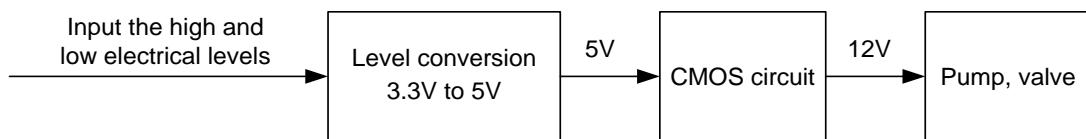


Figure 8-13 Pump, valve function module

FPGA outputs high and low electrical level to control the CMOS tube circuit switch to drive the pump and valve, each pump and valve corresponds to a CMOS tube circuit.

Groove sensor driving

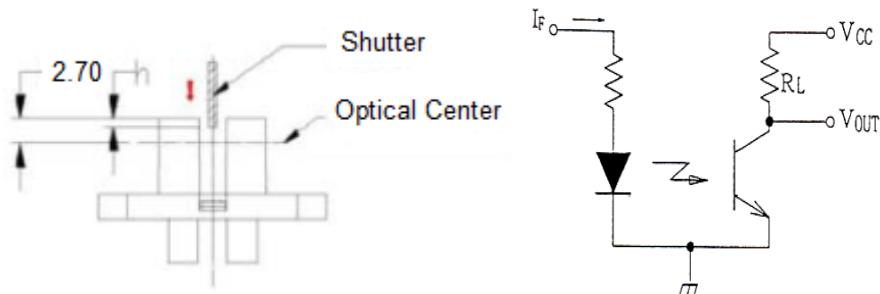


Figure 8-14 Groove sensor function module

The working principle of the groove sensor is to sense the stepping position of the motor through the groove gap of the code disc, and output high electrical level when the groove sensor is blocked, then pass the signal to FPGA through the logic circuit.

9.4.5. Troubleshooting

Before troubleshooting driver related problems, check whether there is any loose connecting wire or unreliable connection on the driver board, and whether the bit numbers on the wires are matching the bit numbers on the analog driver board sockets; whether there is any broken or damaged wire.

When analog driver board failure is suspected, verify whether the indicators on the driver board are normal.

After all the indicators are verified to be normal, verify the solenoid valves and moving parts through the “Self-test” function from the software interface and whether there is corresponding failure reported.

Troubleshoot the problem according to the type as shown in the table below.

| No. | Problem type | Description | Troubleshooting and solutions |
|-----|------------------------|---|--|
| 1 | Motor and photocoupler | a. The motor does not work b. The motor works, but motor failure or photocoupler failure is reported | 1. Check if the board power supply (24V, 12V, 5V, 3.3V, 2.5V, 1.2V, marked on the board) is working properly; 2. Check if the connection between the motor of the corresponding channel and the photocoupler is reliable, if the connectors on both ends are connected properly, if the marks on the photocoupler and motor connecting wires match their respective locations, and if there is any broken or damaged wire; 3. After verifying 1 and 2, try to correct the problem by performing maintenance operations from the software debugging screen to do single control on the corresponding failure; |



| No. | Problem type | Description | Troubleshooting and solutions |
|-----|--------------|-----------------------------------|--|
| | | | <p>4. Check if the photocoupler surface of the corresponding channel is contaminated by dust or fluids. If so, clean and reinstall the photocoupler. If the problem is not solved, replace this photocoupler;</p> <p>5. If the problem still exists after replacing the photocoupler, replace the driver board;</p> <p>6. If the problem persists, replace the corresponding channel motor;</p> <p>7. If the problem persists, then the problem may be caused by mechanical component failure (such as too much friction), please troubleshoot this problem as a mechanical problem.</p> |
| | | Abnormal motor noise | <p>1. Check if the corresponding channel motor connecting wire is loose, broken or damaged. If so, reconnect or replace the wire with the power off;</p> <p>2. Check if any fastening screw of the mechanical component is loose. If so, tighten this screw;</p> <p>3. If both 1 and 2 can be excluded, the problem may be caused by driver board failure. Replace the analog driver board;</p> <p>4. If the problem persists, it will be necessary to replace the motor assembly.</p> |
| 2 | Valves | The valve is not working properly | <p>1. Perform maintenance operations from the software debugging screen to check if the valve is opening and closing correctly (a clap will be heard on normal open/close of the valve). If so, then the problem is not in the valve drive, check the fault from the fluidics.</p> <p>2. If the valve is not opening and closing correctly, check if there is any loose or broken wire or unreliable connection. If so, reconnect or replace the connecting wire;</p> |



| No. | Problem type | Description | Troubleshooting and solutions |
|-----|---------------------|---|---|
| | | | 3. If the problem persists, use wires of other valves to connect this valve, and check if the problem is in the valve start circuit or in the valve itself from the Maintenance screen (for example, if valve 2 is suspected, use wires of valve 3 to connect valve 2; open and close valve from the Maintenance screen; if the valve is opening and closing correctly, then the analog driver board is damaged and needs to be replaced; if the valve is not opening and closing correctly, then the valve 2 is damaged and needs to be replaced). |
| 3 | Pumps | a. abnormal pressure b. the pump does not work | 1. Check if the vacuum pump is able to work properly from the Maintenance screen. If it is, check the fault from the gas circuit; 2. If the pump is not opening and closing correctly, please check if there is any loose or broken wire or unreliable connection. If so, reconnect or replace the connecting wire; 3. If the problem persists, replace the analog driver board; 4. If the problem persists, it will be necessary to replace the corresponding pump. |
| 4 | Communication | Communication failure reported | 1. Check if the main control board indicator and the driver board indicator are normal. If not, replace the corresponding board(s); 2 Check if the connecting wire between the main control board and the driver board is loose. If so, reconnect the wire; 3. If the problem persists, replace the connecting wire between the main control board and the driver board; 4. If the problem persists, replace the driver board and the main control board one after another. Most problems will be solved in this way. |
| 5 | Liquid level sensor | False alarm of level status | 1. Check if the connecting wire on the level sensor connector is loose, wet or broken. If so, disconnect and reconnect the connector, or reconnect the connector after cleaning the fluid, or replace the connecting wire. If not, measure the voltage of TC-1, TC-2 and TC-3, the voltage should be low (0-0.3V) if there is no liquid, should be high (4.9-5.0V) with liquid. 2. Otherwise, replace the liquid level sensor assembly. |

9.5. WBC Optical Signal Amplifying Board Module

9.5.1. Function and Performance Realization

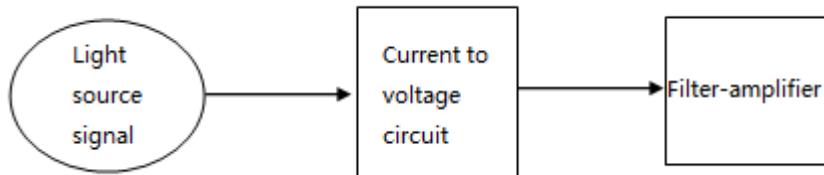


Figure 8-14 Optical signal function module

The light source signal in Figure 8-14 is from a semiconductor laser with a wavelength of 670nm. The laser irradiates the cells in the flow cell, which generate scattered light. This scattered light intensity is measured by photodiode (PD) from various angles. The measurement signal is then modulated, amplified, and transmitted to analog drive board for further processing. The scattered light measured by the photodiode can be divided into three angles: low angle scatter, medium angle scatter and high angle scatter. The type and size of the cell can then be determined by the distribution of scatter intensity on these angles.

9.5.2. Module Circuit Introduction

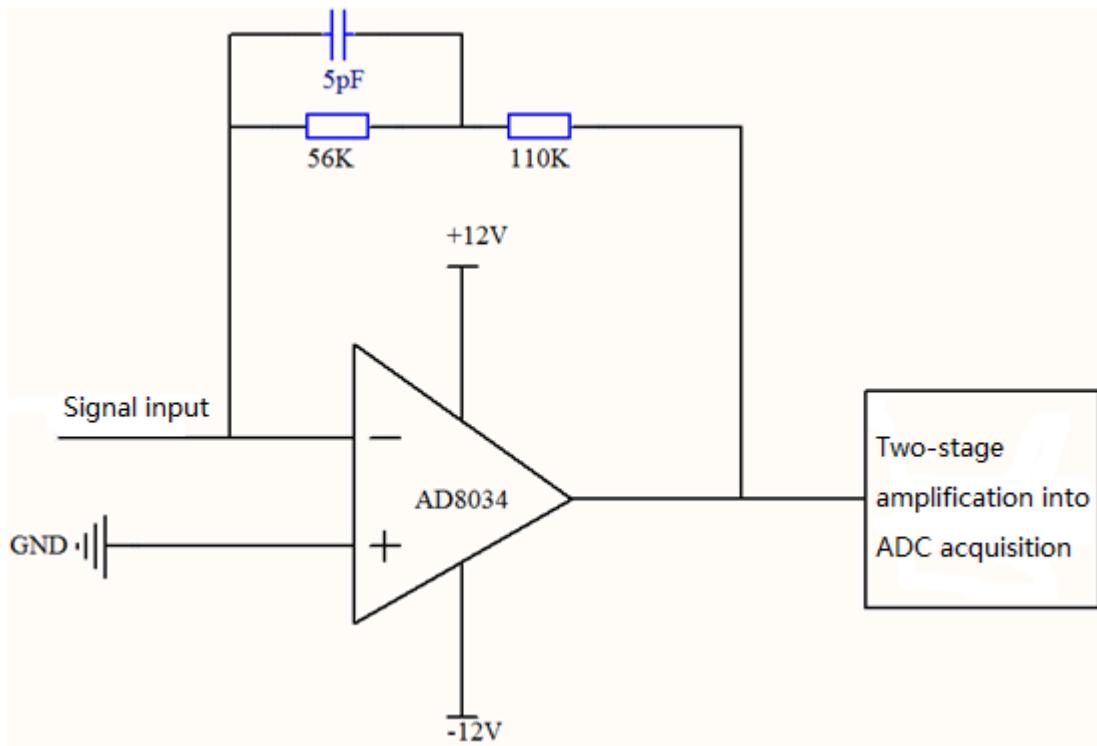
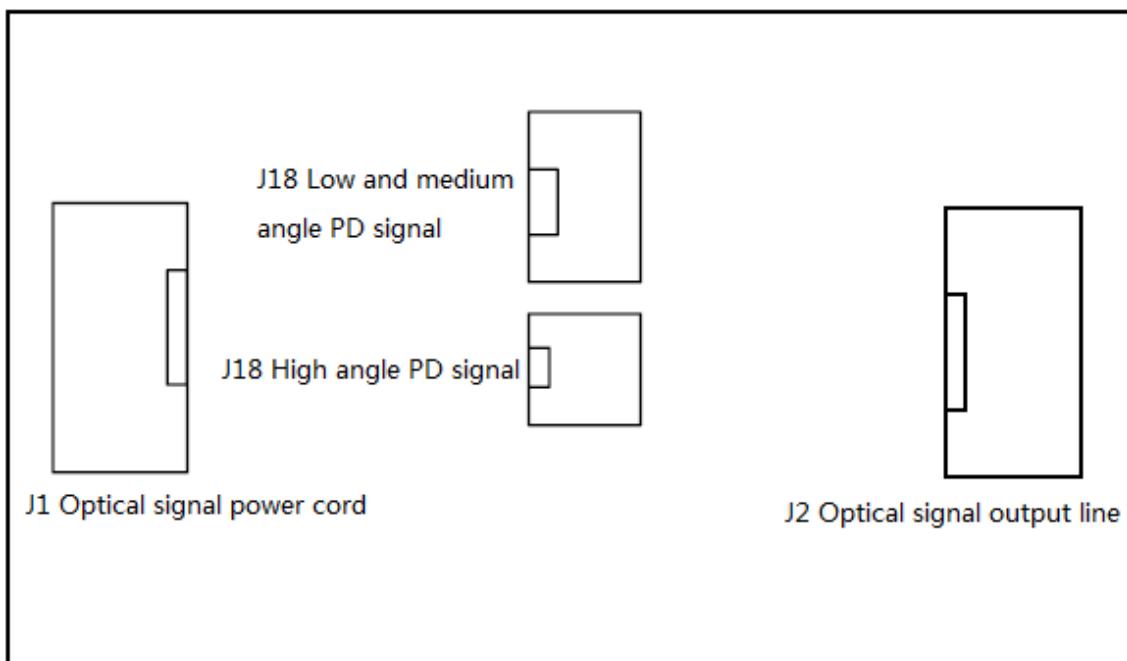


Figure 8-15 Current-to-voltage function module

Mainly to change the three-way photoelectric signal of WBC into a stable voltage signal.

9.5.3. Board Interface Introduction



9.5.4. Troubleshooting

Before troubleshooting photoelectric signal board related problems, check whether there is any loose connecting wire or unreliable connection on the photoelectric signal board, and whether the bit numbers on the wires are matching the bit numbers on the photoelectric signal board sockets; whether there is any broken or damaged wire.

When photoelectric signal board failure is suspected, verify whether the indicators on the board are normal.

| Symptom | Troubleshooting and solutions |
|--|--|
| No signal output from high, medium and low channel | <ol style="list-style-type: none"> 1. Check if the connecting wire between the photoelectric signal board and signal board is loose or broken. If loose, reconnect the wire. If broken, replace the wire. Otherwise, proceed to the next step. 2. Check the power supply of the optical system by observing LED1, LED2 to determine whether the voltage of +12V and -12V is normal. If not, check if there is problem in the power board. Otherwise, proceed to the next step. 3. If all the above faults are excluded, replace the optical signal board and check if the problem is solved. If the problem persists, replace the optical system. |

9.6. Laser Driver Board Module

9.6.1. Function and Performance Realization

A laser is generated when a current above the threshold flows through the laser diode. Temperature changes will affect the light output, in order to ensure that the output of the laser diode is not affected by temperature, constant current anti-design must be used.

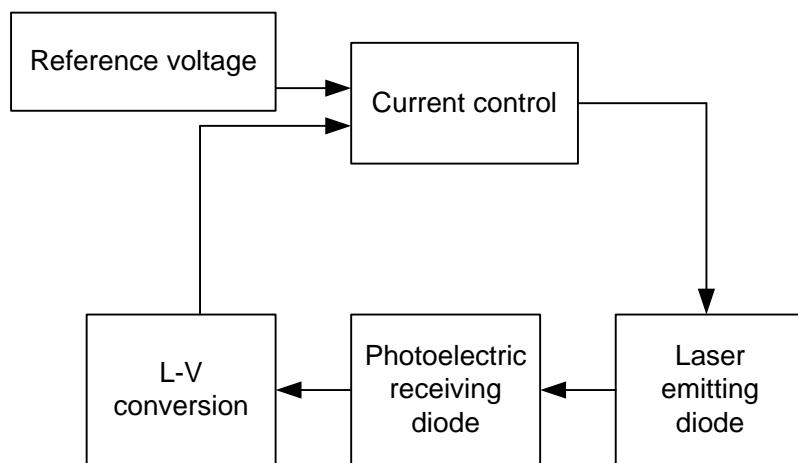
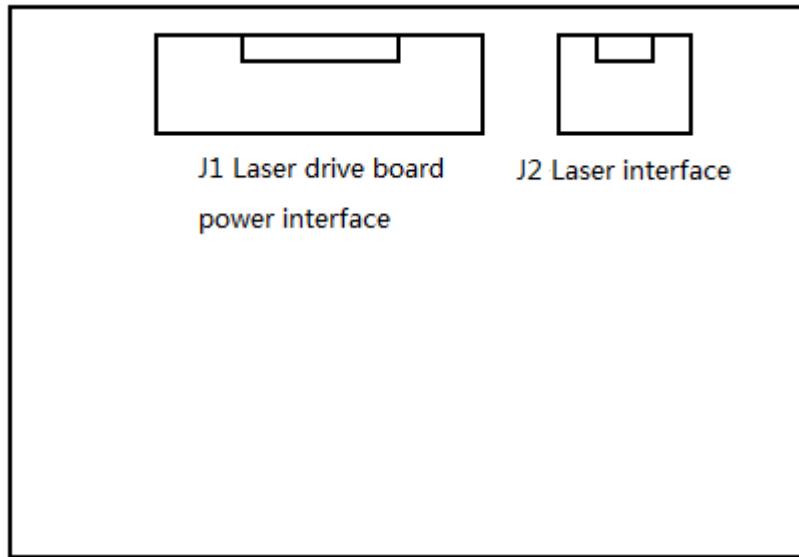


Figure 8-16 Laser drive function module

Since the current of PD is proportional to the amount of light output, so long as the current is constant, the light output is constant. When the laser enters the PD, the PD generates an output current. The current is converted to a feedback voltage by a resistor. This voltage is equal to the reference voltage, so it can control the forward current of the laser diode to obtain a stable light output.

9.6.2. Board Interface Introduction



| Symptom | Troubleshooting and solutions |
|---------------------|---|
| Laser does not work | <ol style="list-style-type: none"> 1. Check if the connecting wire between the optical system and signal board is loose or broken. If loose, reconnect the wire. If broken, replace the wire. Otherwise, proceed to the next step. 2. Check if the microswitch is working properly. Press the microswitch with power off, measure its continuity with a multimeter. If the measurement is normal, proceed to the next step. 3. Check the power supply of the optical system by measuring if the voltage of +12V and +5V is normal. If not, check if there is problem in the power board. Otherwise, proceed to the next step. 4. If all the above faults are excluded, then the problem is in the laser analog driver board or the laser. Replace the laser drive board. If the problem persists, replace the optical system. |

9.7. High Angle PD Board Module

9.7.1. Main Input Signal

Input signal of this board: Optical signal scattered from the flow cell at 45 degrees.

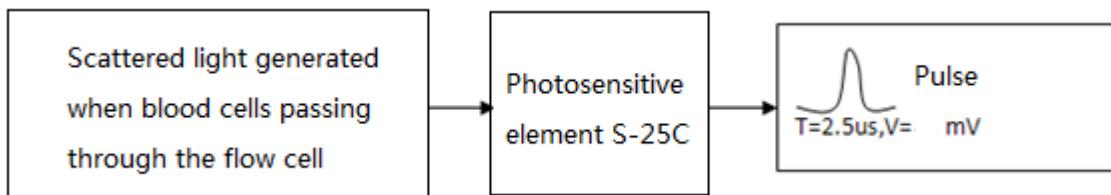
Characteristics of this optical signal: When blood cells passing through the flow cell, this light will be relatively strong, when the blood cells passed, this light is relatively weak.

9.7.2. Main Output Signal

Output signal of this board: Pulse signal

Characteristics of this pulse signal: The average cycle is 2.5us; amplitude is about a few mV.

9.7.3. Function and Performance Realization



After the laser passes through the flow cell, the scattered light at an angel of 45 degrees to the laser is irradiated onto the photosensitive element S-25C. When uniform diluent (ie, no blood cells) is flowing in the flow cell, the light on the S-25C is uniform and the S-25C outputs a few mV of DC. When the blood cells flow through the flow cell, the intensity of light on S-25C becomes stronger and S-25C outputs a few mV of forward pulse signal, the signal cycle is 25us, the amplitude is of several mV.

9.8. Board Removal and Installation

9.8.1. Removal

WARNING

- ♦ Please wear antistatic gloves when repairing and removing boards.
 - ♦ Please make sure power is off and the power cable is disconnected when mounting and removing boards.
 - ♦ Please make sure that the board and the surroundings have been cooled before the disassembly operation.
-

9.8.2. Installation

Install the boards as the disassembly procedure in reverse order.

Verification:

1. Check whether the board screws are fully installed.
 2. Connect the power cable, turn on the AC control switch, the machine enters the initialization state, various indicators on the board illuminate.
-

NOTE

- ♦ Ensure that the boards and the main unit enclosure are firmly connected with screws.
-

10. Heating System

10.1. Overview

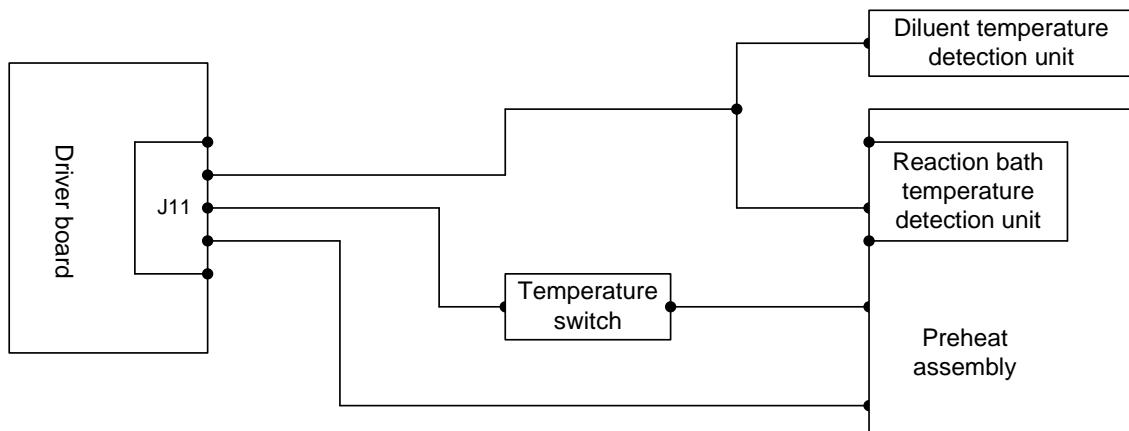
The heating system only has DIFF lyse heating system. The preheat bath heating system provides the best temperature range for the WBC bath.

The DIFF lyse heating system consists of diluent temperature detection assembly and preheat assembly. A diluent temperature sensor and a preheat sensor work together to detect and control the heating temperature of the preheat assembly.

The temperature ranges of each detection point are listed below:

| Name | Temperature Range |
|---|-------------------|
| Temperature of the diluent detection assembly | 10-40°C |
| Temperature of preheat assembly | 32-54°C |

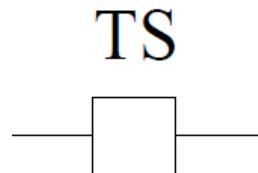
10.2. DIFF Lyse Heating System



Electrical structure diagram

10.2.1. Diluent Temperature Detection Assembly

- Symbol



- Appearance

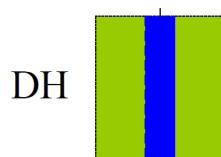


- Function

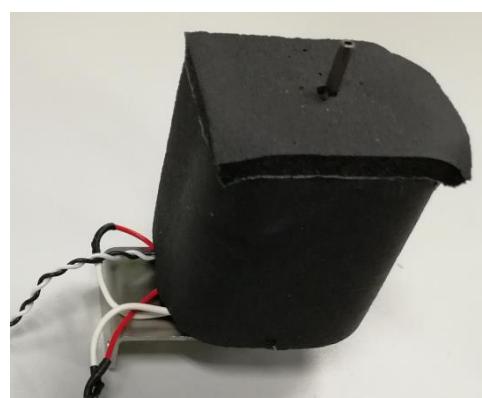
- Determine if the diluent temperature is within [10°C, 40°C]. If not, the analyzer will beep.
- Provides the diluent temperature to calculate the bath temperature.

10.2.2. Preheat Assembly

- Symbol



- Appearance



- Function

Heat the DIFF reagent to ensure the temperature of the DIFF reaction.

11. Troubleshooting

| Error | Trigger Mechanism | Related Factors | Potential Failure | Repair Guide | |
|----------------------------------|---|--|------------------------------|----------------------|--|
| | | | | Related screen | Troubleshooting Procedure |
| Driver board communication error | 1. Serial communication protocol error 2. No header, jumbo frames, insufficient frame length, checksum error, unrecognizable command | Driver board | Damaged communication module | / | 1. Check the connection between the main control board J7 and driver board J2 2. Replace the related boards. |
| | | Main control board | Damaged communication module | | |
| | | Connection between the main control board J7 and driver board J2 | Loose wire | | |
| System clock error | After startup, the instrument time is not in the range of 2000-1-1 ~ 2036-12-30 | Button battery | / | / | 1. Check if the button battery is installed on the digital board. 2. If the battery is installed, replace the battery and reset date and time in the Setup screen. Save and exit and reset the analyzer 3. If the problem persists, replace the main control board. |
| | | Main control board | / | | |
| No diluent | No reagent or abnormality lead to insufficient reagent addition | Diluent-related tubes | Bubbles in tubes | Reagent Setup screen | 1. Make sure that there is no error report on the reagent setup screen. 2. Make sure there is sufficient diluent in the container. 3. Check if there is no dead bend or leakage of the tubes outside the instrument. 4. Remove the cover of the analyzer, and check the diluent pathway (container cap assembly, valve, syringe, tube |
| | | | Leakage in tubes or valves | | |



| Error | Trigger Mechanism | Related Factors | Potential Failure | Repair Guide | |
|-------------------|---|--|---|---------------------------------|--|
| | | | | Related screen | Troubleshooting Procedure |
| No LH lyse | | | Bubbles in tubes | | connectors, etc.) |
| No DIFF lyse | No reagent or abnormality lead to insufficient reagent addition | 1. Lyse-related tubes 2. Anti-soluble samples | Leaking or folding of lyse related tubes and valves | Reagent Setup screen | <ol style="list-style-type: none"> 1. Make sure that there is no error report on the reagent setup screen. 2. Make sure there is sufficient lyse in the container. 3. Check if there is no dead bend or leakage of the tubes inside the instrument. 4. Remove the cover of the analyzer, and check the diluent pathway (container cap assembly, valve, electromagnetic metering pump, tube connectors, etc.) |
| Waste bucket full | Float status | Waste sensor assembly | <p>BNC connector of the waste sensor is not connected</p> <p>Unable to change the status correctly due to foreign matter on the float</p> | Sensor Status screen | <ol style="list-style-type: none"> 1. Check if the indicated information is as expected from the sensor status screen. 2. Check if the connecting wire of the waste sensor is correct. 3. Check if the float is able to change the status correctly. |
| Voltage abnormal | 56V voltage is not within [55, 65] V | Signal board | Board damaged | Voltage & Current Status screen | <ol style="list-style-type: none"> 1. Check if the Voltage & Current Status screen shows the expected information. 2. Check if the voltage at the test port of the signal board or driver board is as expected. 3. Check if the connection between the power board and the signal board or driver board is normal. 4. Replace the signal board or driver |
| | 12V voltage is not within [11, 14] V | Signal board / driver board | Board damaged | | |
| | -12V voltage is not within [-14, -11] V | Signal board | Board damaged | | |
| | 24V voltage is not within [20, 30] V | Driver board | Board damaged | | |

| Error | Trigger Mechanism | Related Factors | Potential Failure | Repair Guide | | |
|----------------------------|---|------------------------------------|--|---------------------------------|---|--|
| | | | | Related screen | Troubleshooting Procedure | |
| HGB blank voltage abnormal | HGB voltage is not within [3.8, 4.8] V | WBC bath | There is foreign matter in the bath | Voltage & Current Status screen | board. | |
| | | | The bath is not filled with diluent while measuring | | 1. Make sure there is no foreign matter in the WBC bath. 2. Make sure the bath is filled with reagent properly. 3. Verify the HGB blank voltage from the Voltage & Current Status screen. 4. Verify the HGB gain settings from the Gain Setup screen. 5. Check the HGB assembly. | |
| | | Analyzer setup | HGB gain setup incorrect | | | |
| | | HGB assembly | HGB assembly damaged | | | |
| Laser current abnormal | Laser current is not within [20, 60] mA | Optical system | Laser damaged | Voltage & Current Status screen | 1. Check if the laser current is abnormal from the Status screen. 2. Open the optical system shield box and turn the box switch on and off manually. If the laser is not illuminated, check in turn if the connections of the optical system, box switch and laser are reliable. If there is no connection problem, check if the laser driver board and analog driver board are working properly according to the hardware troubleshooting procedures. | |
| | | Laser driver board | Board damaged | | | |
| | | Optical system | Shield box switch damaged | | | |
| | | Optical system related connections | Loose wire | | | |
| | | | 3. If the laser illuminated properly, then check if the laser driver board is working properly according to the hardware troubleshooting procedures. | | | |

| Error | Trigger Mechanism | Related Factors | Potential Failure | Repair Guide | |
|---------------------------------------|---|---|---|----------------|---|
| | | | | Related screen | Troubleshooting Procedure |
| | | | | | Otherwise, replace the optical system. 4. If the laser is damaged, replace the optical system. |
| Preheat bath temperature out of range | Preheat bath temperature is out of range [32°C, 54°C] | Preheat bath assembly Assembly related connections | Heating rod damaged Temperature sensor damaged Temperature switch damaged Loose wire | Status screen | 1. Check if the temperature of the preheat bath and the diluent is as expected from the Status screen. Determine if the abnormal status is caused by too great temperature difference during the diluent replacement (recoverable, not a problem). 2. Check if the preheat bath is in an overtemperature status. 3. If the actual temperature of the preheat bath is not exceeded, component failures can be determined. 4. Replace the preheat assembly if reconnection does not work. |
| Diluent temperature out of range | Diluent temperature is out of range [10°C, 40°C] | Temperature sensor Temperature sensor connection | Temperature sensor damaged Loose wire | Status screen | 1. Check if the diluent temperature is as expected from the Status screen. 2. Check if the ambient temperature is within the specified operation temperature range of the product. 3. If the ambient temperature is not exceeded, component failures can be determined. 4. Replace the temperature sensor assembly if reconnection does |

| Error | Trigger Mechanism | Related Factors | Potential Failure | Repair Guide | |
|--------------------------|---|---------------------------------|---|-------------------------|---|
| | | | | Related screen | Troubleshooting Procedure |
| | | | | | not work. |
| Liquid pressure abnormal | Relative pressure of liquid exceeds 300kPa | Hydraulic sensor related tubes | Related tubes folded; Valve blockage or failure | Status screen | 1. Check if the liquid pressure is close to the current local atmospheric pressure from the Status screen. 2. Check if there is folding tube, blocked or broken valve in the analyzer tubes. 3. Check if there is obstruction in the sample probe or optical system. 4. Check if there is loose connection in hydraulic sensor and its connecting wire. |
| | | Optical system | Severely blocked | | |
| | | Hydraulic sensor and connection | Loose connection or sensor damaged | | |
| Vacuum pressure abnormal | Vacuum pressure is not within the range specified by the sequence | Waste pump | Dirt blockage or failure | Status screen | 1. Enter the Status screen. Check if the pressure building process is normal (e.g. if the waste pump is working properly). 2. Check if the pressure can be maintained from the Status screen. If not, check if there is leakage in related tubes or valves. 3. If pressure building fails, check if it is the waste pump failure or tube leakage. 4. If the waste pump is not working properly, check if the related connection is reliable and the driver board is working correctly. |
| | | Related solenoids | Dirt blockage or failure | | |
| | | Related tubes | Leakage | | |
| | | Driver board | Damaged board | | |
| Syringe assembly error | / | Photocoupler | Damaged photocoupler or dirty surface | System Self-test screen | 1. Enter the system self-test interface to confirm the problem. 2. Refer to the error code to check the wire, photocoupler, |
| | | Syringe motor | Damaged motor | | |



| Error | Trigger Mechanism | Related Factors | Potential Failure | Repair Guide | |
|---|-----------------------------------|---------------------------------|---|-------------------------|--|
| | | | | Related screen | Troubleshooting Procedure |
| Aspiration module lifting mechanism error | / | Related connections | Loose wire | System Self-test screen | motor, and motion interference. |
| | | Drive mechanism | Motion limited due to mechanical interference or other causes | | |
| Aspiration module rotary mechanism error | / | Vertical photocoupler | / | System Self-test screen | 1. Enter the system self-test interface to confirm the problem. 2. Refer to the error code to check the wire, photocoupler, motor, and motion interference. |
| | | Lifting motor | / | | |
| | | Mechanical stop | Motion interference | | |
| | | Related connections | Loose wire | | |
| Background abnormal | Background unqualified at startup | Deflection position optocoupler | / | System Self-test screen | 1. Enter the system self-test interface to confirm the problem. 2. Refer to the error code to check the wire, photocoupler, motor, and motion interference. |
| | | Deflecting motor | / | | |
| | | Mechanical stop | Motion interference | | |
| | | Related connections | Loose wire | | |
| Reagent abnormal | Analyzer tubes | Reagent contaminated or expired | Bad maintenance practice | / | 1. Verify the reagent quality. 2. If the background PLT is too high, verify the impedance channel shield (please refer to the treatment of impedance channel signal interference alarm). 3. Verify the cleanliness of the reaction bath and correct the maintenance practice. 4. Verify there is no leakage in tube connections and valves. |
| | | Abnormal shutdown | | | |
| | | Bad maintenance practice | | | |



| Error | Trigger Mechanism | Related Factors | Potential Failure | Repair Guide | |
|--------------|--|-------------------|---|----------------|--|
| | | | | Related screen | Troubleshooting Procedure |
| RBC clogging | Aperture voltage is too high or changes dramatically | RBC bath assembly | Aperture blockage or bad connection between primary bath and secondary bath | / | <ol style="list-style-type: none">1. Verify the tubes of the secondary bath are normal.2. Unclog aperture in Service - Maintenance - Maintenance interface.3. If the problem is not resolved, perform the overall soaking. |

12. Mechanical System

12.1. Overview

This section lists the locations of major analyzer components for the service personnel to remove and replace the components. The diagrams in this manual are based on STEL⁵.

12.1.1. Front View

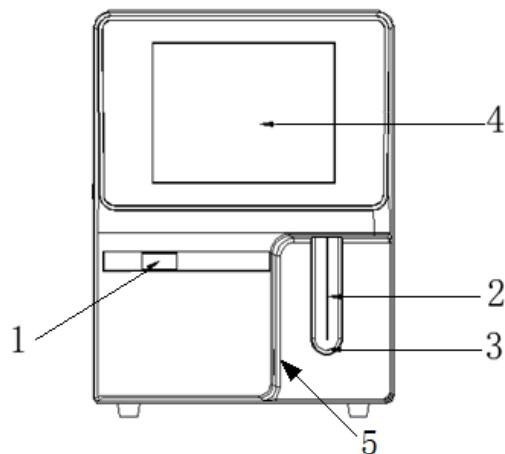


Figure 12-1 Front view of the main unit

- | | |
|----------------------|---------------------|
| 1---Status indicator | 2---Sample probe |
| 3---Aspirate key | 4---Touch screen |
| | 5---Barcode scanner |

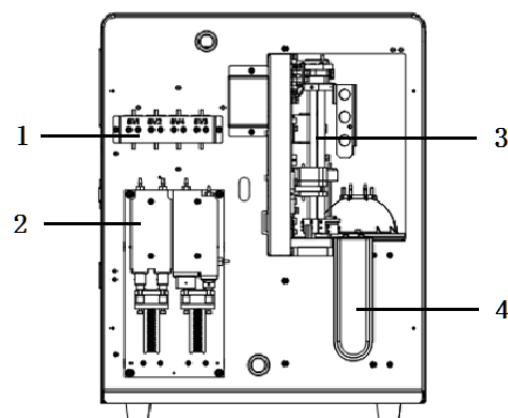


Figure 12-2 Front view of the main unit (cover open)

- | | |
|-----------------------|------------------|
| 1---Fluidic valve | 2---Syringe |
| 3---Sampling assembly | 4---Aspirate key |

12.1.2. Back View

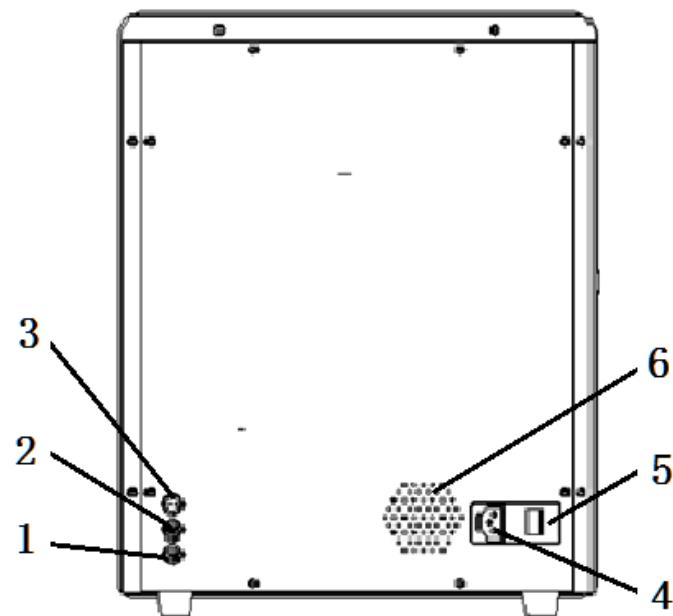


Figure 12-3 Back view of the main unit

- | | |
|------------------|------------------------|
| 1---Waste outlet | 2---Diluent inlet |
| 3---Waste sensor | 4---Power input socket |
| 5---Power switch | 6--- Fan channel |

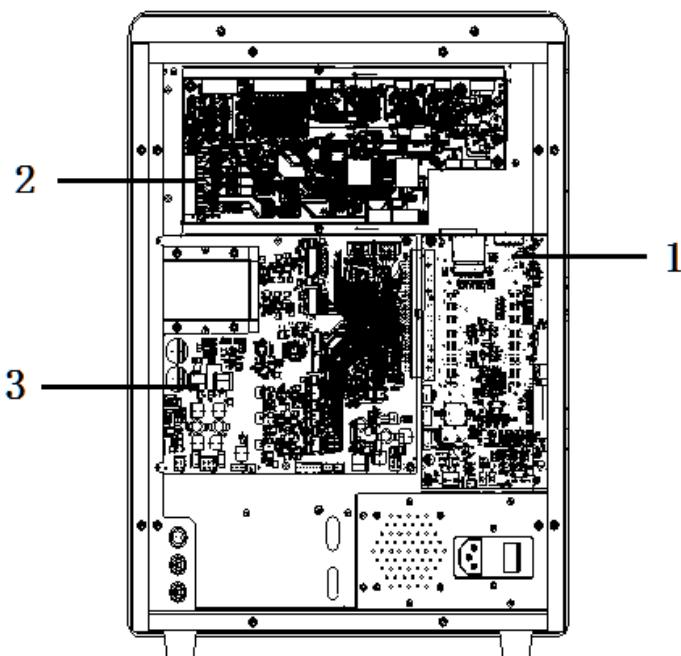


Figure 12-4 Back view of the main unit (internal structure)

- 1---Main control board 2---Driver board 3---Signal board

12.1.3. Left View

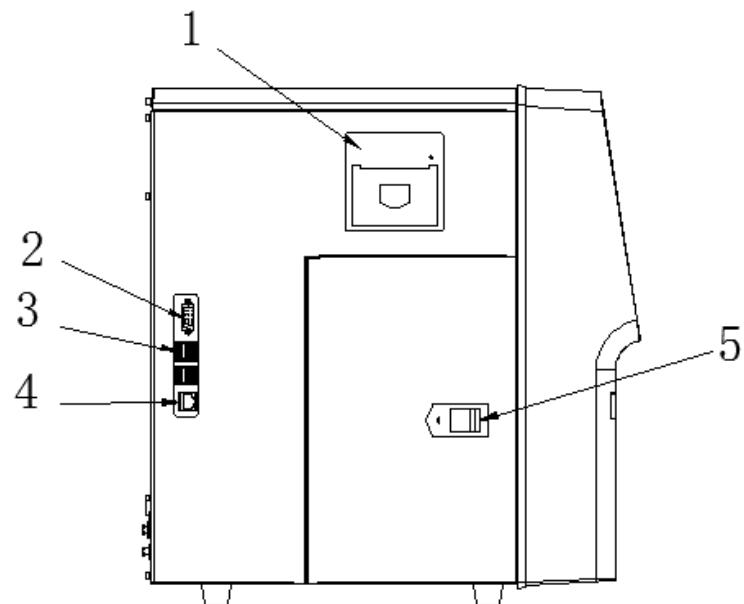


Figure 12-5 Left view of the main unit

1---Recorder

2---COM

3---USB port

4---Network port

5--- Door bolt

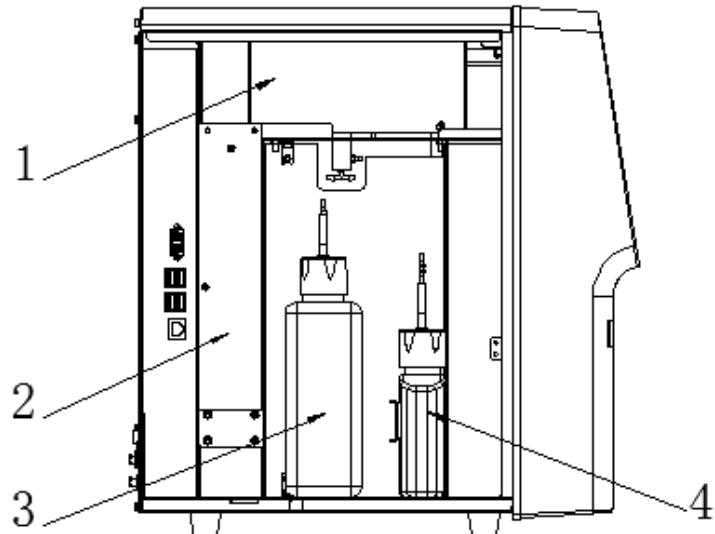


Figure 12-6 Left view of the main unit (left door open)

1---Optical system

2---Power supply

3---DIFF lyse

4---LH lyse

12.1.4. Right View

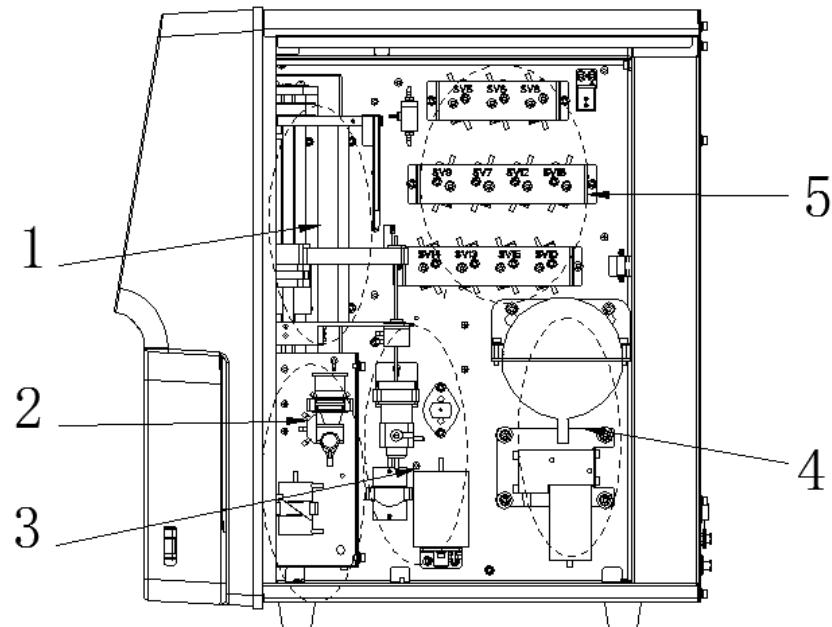


Figure 12-7 Right view of the main unit (right door open)

1---Sampling assembly 2---RBC counting pool
3---WBC counting pool 4---Waste tank assembly 5---Fluidic valve

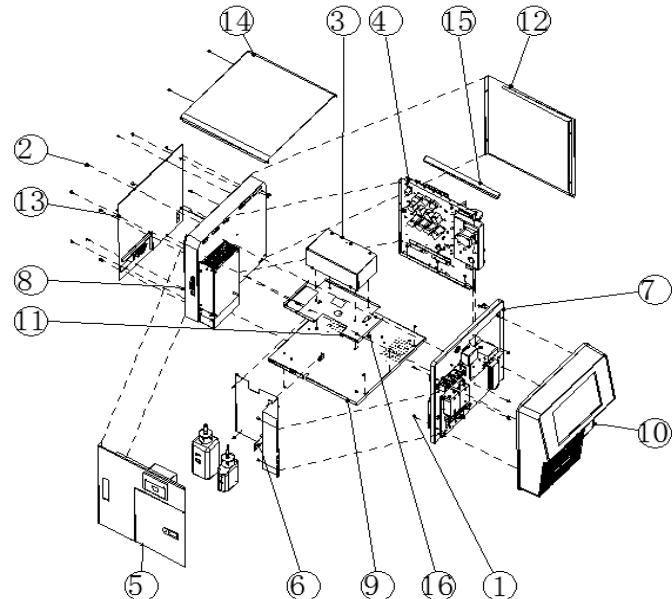
12.2. Components

12.2.1. Introduction

This section provides exploded view and parts list of the analyzer for the service personnel to understand the relationship between the components when removing and replacing the components.

12.2.2. Overall Unit

Exploded view

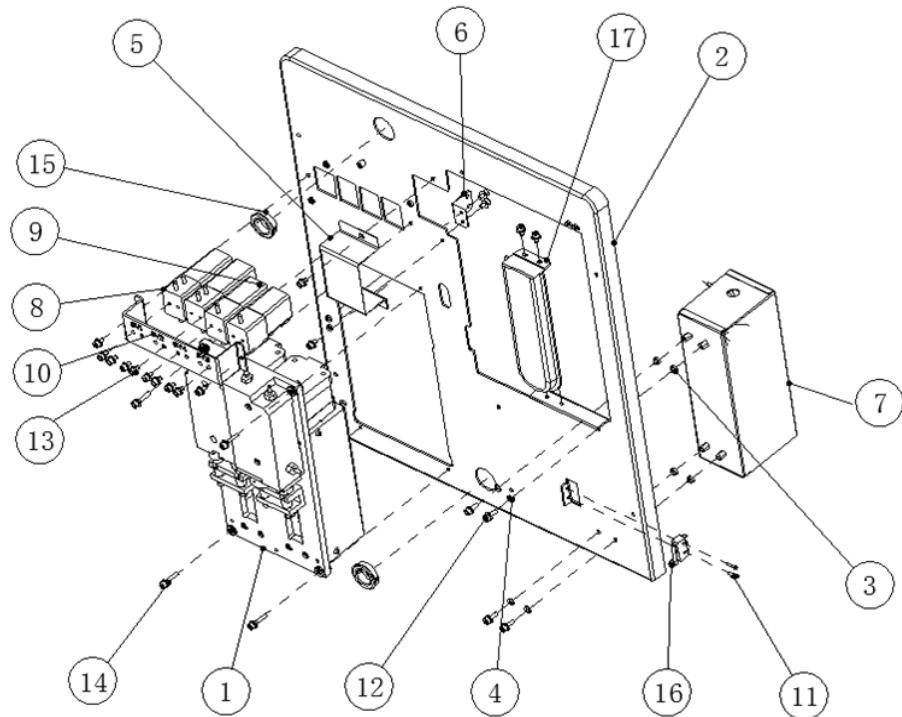


Parts list

| No. | Material description | Remarks |
|-----|----------------------------------|---------|
| 1 | Combination screw M3x10 | / |
| 2 | Combination screw M3x6 | / |
| 3 | Optical system assembly | / |
| 4 | Right baffle assembly | / |
| 5 | Left door assembly | / |
| 6 | Left baffle assembly | / |
| 7 | Main unit - Front panel assembly | / |
| 8 | Main unit - Rear baffle assembly | / |
| 9 | Main unit - Baseplate assembly | / |
| 10 | Shell assembly | / |
| 11 | Optical fixing plate | / |
| 12 | Right door | / |
| 13 | Main unit - Rear cover | / |
| 14 | Main unit - Top cover | / |
| 15 | Main unit - Crossbeam | / |
| 16 | Nut M4 | / |

12.2.3. Front Panel Assembly

Exploded view



Parts list

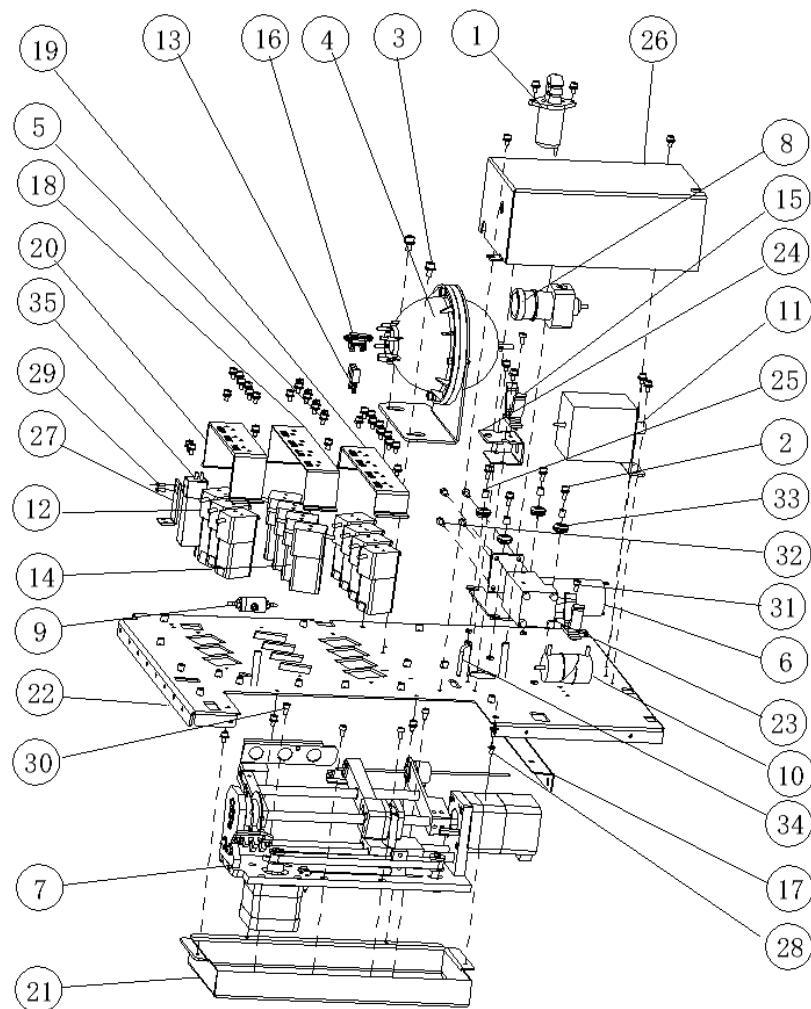
| No. | Material description | Remarks |
|-----|-------------------------------|---------|
| 1 | 2+2 syringe | / |
| 2 | Front panel | / |
| 3 | Insulated cap | / |
| 4 | Insulated flat pad | / |
| 5 | Sampling motor shield box | / |
| 6 | Baffle | / |
| 7 | RBC counting pool assembly | / |
| 8 | Three-way solenoid valve | / |
| 9 | Two-way solenoid valve | / |
| 10 | Solenoid valve holder 4 | / |
| 11 | Phillips pan head screw PM2×8 | / |
| 12 | Combination screw M3×10 | / |

LiNEAR

| | | |
|----|-------------------------|---|
| 13 | Combination screw M3x6 | / |
| 14 | Combination screw M3x16 | / |
| 15 | Protective ring | / |
| 16 | Microswitch | / |
| 17 | Aspirate key | / |

12.2.4. Right Baffle Assembly

Exploded view



Parts list

| No. | Material description | Remarks |
|-----|------------------------|---------|
| 1 | Pinch valve | / |
| 2 | Combination screw M3x8 | / |



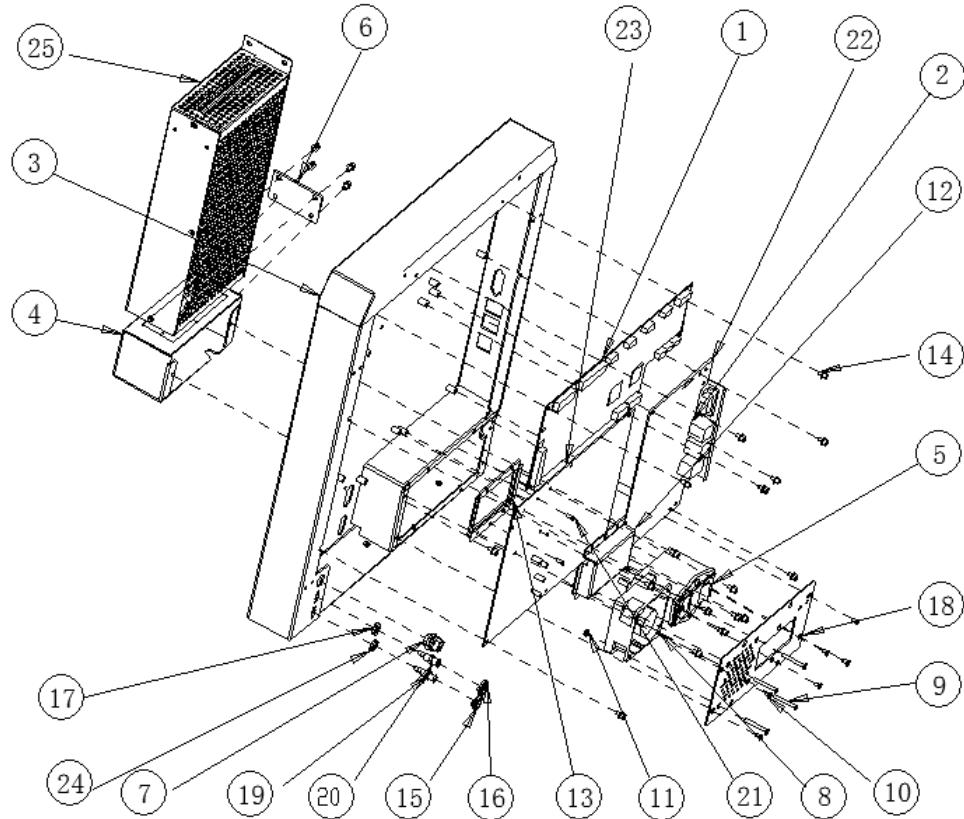
| | | |
|----|-----------------------------------|---|
| 3 | Combination screw M4x8 | / |
| 4 | Vacuum chamber assembly | / |
| 5 | Combination screw M3x6 | / |
| 6 | Pump KNF/NF30 KPDC12V | / |
| 7 | Sampling assembly | / |
| 8 | WBC counting pool assembly | / |
| 9 | Diluent temperature sensor module | / |
| 10 | Isolator (without filter) | / |
| 11 | Preheat components | / |
| 12 | 3-way solenoid valve | / |
| 13 | Photoelectric sensor | / |
| 14 | Two-way solenoid valve | / |
| 15 | Snap ring | / |
| 16 | Reagent detector | / |
| 17 | Bracket | / |
| 18 | Solenoid valve holder 1 | / |
| 19 | Solenoid valve holder 2 | / |
| 20 | Solenoid valve holder 3 | / |
| 21 | Sampling assembly fixing bracket | / |
| 22 | Right baffle | / |
| 23 | Pump fixing plate | / |
| 24 | Holder | / |
| 25 | Pipe sleeve | / |
| 26 | Shielding cover | / |
| 27 | Valve - bracket | / |
| 28 | Cross head screw KM3x4 | / |
| 29 | Cross head tapping screw M3x6 | / |



| | | |
|----|------------------------------------|---|
| 30 | Hexagon socket head cap screw M3×6 | / |
| 31 | Combination screw M3×6 | / |
| 32 | Hexagon socket head cap screw M3×8 | / |
| 33 | PU tube fixing sleeve | / |
| 34 | Lyse - elbow | / |
| 35 | 3-way solenoid valve LVM102R | / |

12.2.5. Rear Baffle Assembly

Exploded view



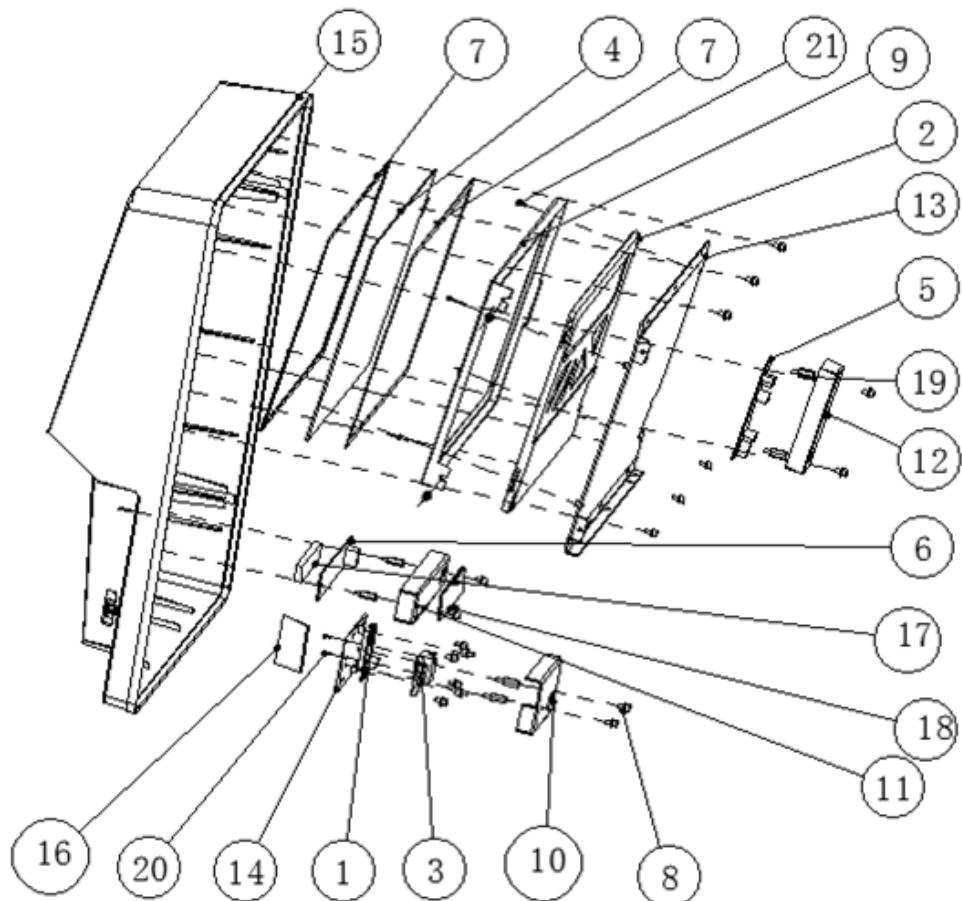
Parts list

| No. | Material description | Remarks |
|-----|------------------------|---------|
| 1 | Driver board assembly | / |
| 2 | Conductive post | / |
| 3 | Rear baffle | / |
| 4 | Power connector box | / |
| 5 | Power supply filter | / |
| 6 | Power connection board | / |
| 7 | Aviation plug | / |
| 8 | Fan 60*60 | / |
| 9 | Screw KM3×25 | / |
| 10 | Cross head screw KM3×4 | / |

| No. | Material description | Remarks |
|-----|--------------------------------------|---------|
| 11 | Nut M3 | / |
| 12 | Signal board shield box - top | / |
| 13 | Signal board shield box - bottom | / |
| 14 | Combination screw M3×6 | / |
| 15 | White thread connector fitting cover | / |
| 16 | Green thread connector fitting cover | / |
| 17 | Green thread connector nut | / |
| 18 | Power switch bracket | / |
| 19 | White thread connector | / |
| 20 | White thread connector | / |
| 21 | Cross head screw PM2×6 | / |
| 22 | Main control board | / |
| 23 | Signal board assembly | / |
| 24 | Threaded joint nuts | / |
| 25 | Switching power supply | / |

12.2.6. Panel Assembly

Exploded view



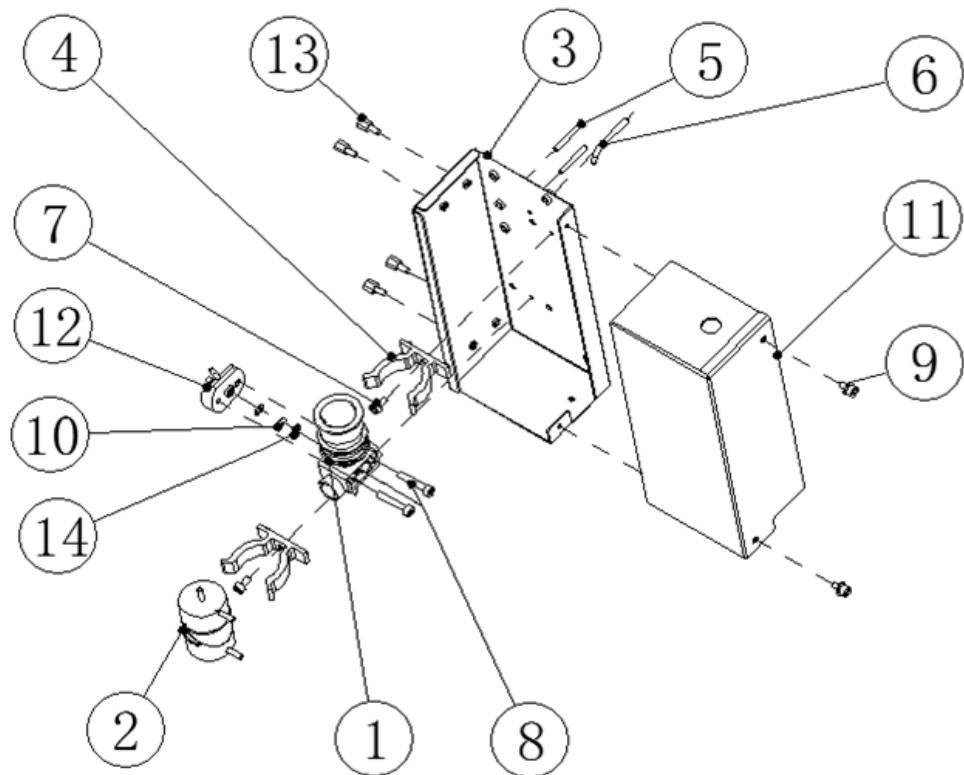


Parts list

| No. | Material description | Remarks |
|-----|--|---------|
| 1 | Barcode transfer board PCB | / |
| 2 | Display screen | / |
| 3 | Barcode scanning module | / |
| 4 | Touch screen | / |
| 5 | Inverter | / |
| 6 | Power indicator PCB | / |
| 7 | EVA cushion cotton single-sided adhesive 5×1 | / |
| 8 | Combination screw M3×6 | / |
| 9 | Screen insulation box | / |
| 10 | Shield cover | / |
| 11 | Indicator board shield box | / |
| 12 | Inverter shield | / |
| 13 | Screen fixing plate | / |
| 14 | Scanning module fixing plate | / |
| 15 | Cover | / |
| 16 | Scanning transparent plate | / |
| 17 | Indicator cushion | / |
| 18 | Lampshade | / |
| 19 | Copper stud M3×(6+12) | / |
| 20 | Cross head screw PM1.6×4 | / |
| 21 | Cross head screw PM2×6 | / |

12.2.7. RBC Counting Pool Assembly

Exploded view



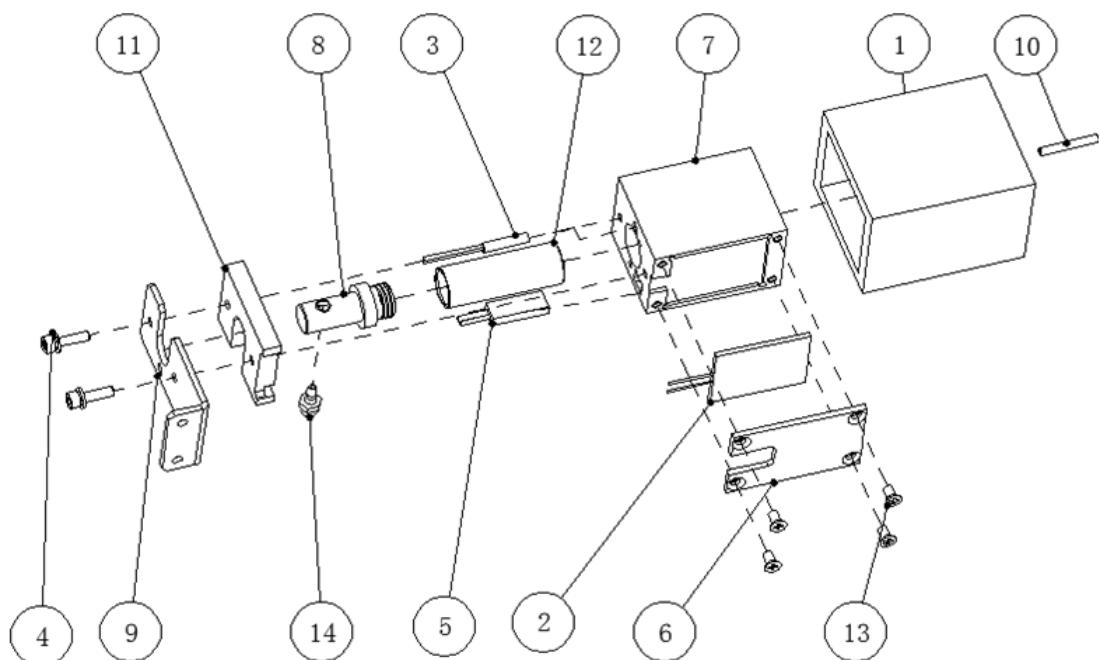
Parts list

| No. | Material description | Remarks |
|-----|---|---------|
| 1 | RBC counting pool assembly (without aperture) | / |
| 2 | Isolator (without filter) | / |
| 3 | RBC shielding box | / |
| 4 | Snap ring | / |
| 5 | Straight pipe | / |
| 6 | Diluent - elbow | / |
| 7 | Combination screw M3×6 | / |
| 8 | Socket head cap screw M3×18 | / |
| 9 | Combination screw M3×6 | / |
| 10 | Aperture (D0.07mm) | / |

| | | |
|----|----------------------------|---|
| 11 | RBC shield cover | / |
| 12 | Aperture compression cover | / |
| 13 | Copper stud M3×(6+6) | / |
| 14 | Washer | / |

12.2.8. Preheat Block Assembly

Exploded view



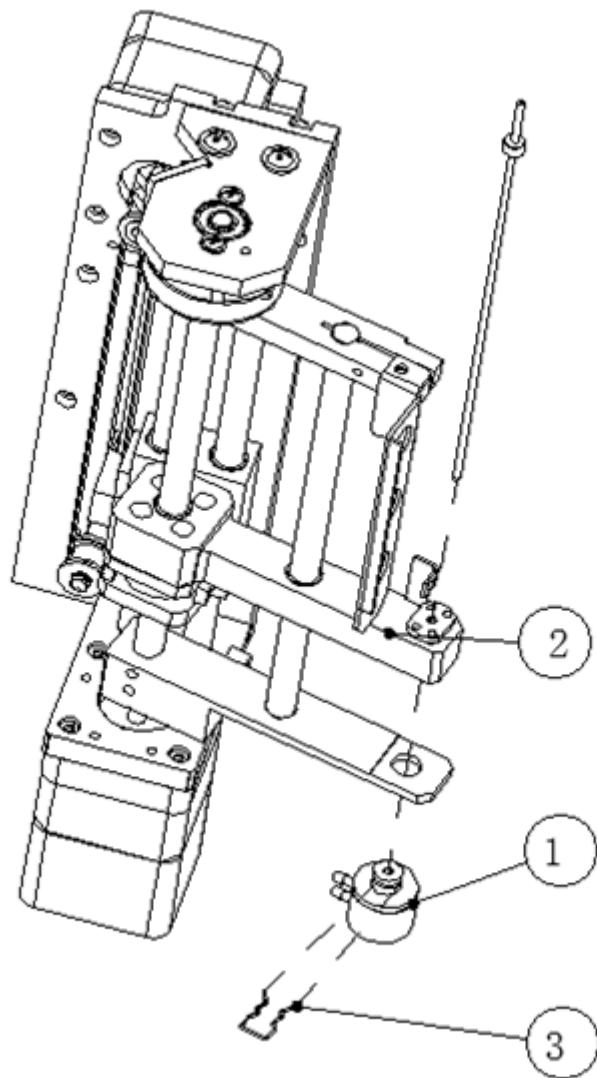
Parts list

| No. | Material description | Remarks |
|-----|--------------------------------|---------|
| 1 | Insulation cotton | / |
| 2 | Silicone film heater | / |
| 3 | Temperature control sensor | / |
| 4 | Combination screw M3×12 | / |
| 5 | Temperature control switch | / |
| 6 | Heated membrane pressure plate | / |
| 7 | Preheat block body | / |

| | | |
|----|-------------------------------|---|
| 8 | Preheat cylinder stopper | / |
| 9 | Preheat block holder | / |
| 10 | Straight pipe | / |
| 11 | Baseplate of preheat cylinder | / |
| 12 | Preheat cylinder | / |
| 13 | Cross head screw KM3x6 | / |
| 14 | Threaded pipe joint | / |

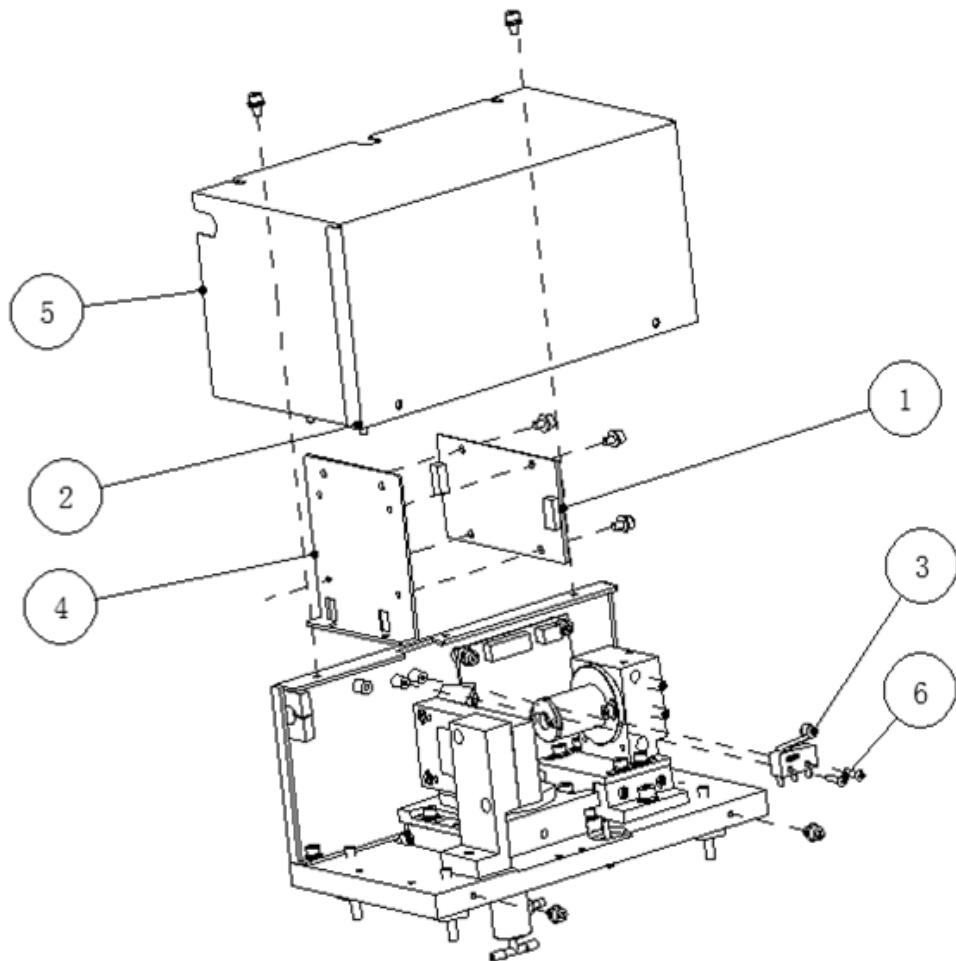
12.2.9. Sampling Assembly

Exploded view



Parts list

| No. | Material description | Remarks |
|-----|------------------------|---------|
| 1 | Cleaning assembly | / |
| 2 | Sampling body assembly | / |
| 3 | Clamp spring | / |

12.2.10.Optical Assembly**Exploded view****Parts list**

| No. | Material description | Remarks |
|-----|-------------------------------------|---------|
| 1 | Optical signal amplifying board PCB | / |



| | | |
|---|---------------------------------------|---|
| 2 | Combination screw M3×6 | / |
| 3 | Microswitch | / |
| 4 | Optical amplifying board bracket | / |
| 5 | Shield box | / |
| 6 | Cross recessed pan head screw PM2.5x8 | / |

12.3. Removal and Installation

12.3.1. Tools

The following tools may be needed during removal and replacement of components:

- Crosshead screwdriver (107)
- Flathead screwdriver
- Tweezers
- Pliers
- Cutting pliers
- Hex wrench set

12.3.2. Preparation for Disassembly

Before disassembling the analyzer, please make the following preparations:

- Stop the blood tests. Adjust the sample probe to the horizontal sampling position. Shut down the analyzer and disconnect all the connections with accessories and peripherals.
- Disconnect the external power supply.



- ♦ All the analyzer components and surfaces are potentially infectious. Take proper protective measures during operation and maintenance.
-

⚠WARNING

- ◆ The reagents are irritating to eyes, skin and mucosa. 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, seek medical advice; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go to see a doctor.
 - ◆ Please eliminate static electricity before disassembly. While removing the components with electrostatic sensitive mark, please wear protective equipment such as an antistatic wrist strap or antistatic gloves to avoid electro-static discharge damage to the components.
 - ◆ During reassembly, please connect the wires correctly and keep them in proper positions to avoid short circuit caused by damaged wires.
 - ◆ Use screws of suitable models during reinstallation. Using wrong screws may result in equipment damage. Furthermore, during usage after reinstallation, a wrong screw may become loose and fall off, resulting in unexpected product damage or personal injury.
 - ◆ Please disassemble the equipment in the correct order. Failure to do so may result in irreversible damage to the equipment.
 - ◆ Please make sure all connections have been disconnected before disassembling the components. Be careful not to break the wires or the connectors during disassembly.
 - ◆ Please store the removed screws and other parts in separate places for reinstallation purpose. Be careful not to drop, contaminate or lose these parts.
 - ◆ During disassembly, separate the materials by module to avoid misusing or missing materials during reassembly.
 - ◆ During reassembly, please assemble first the components then the main unit. Be careful with the wire connections. Place the wires in proper position.
-

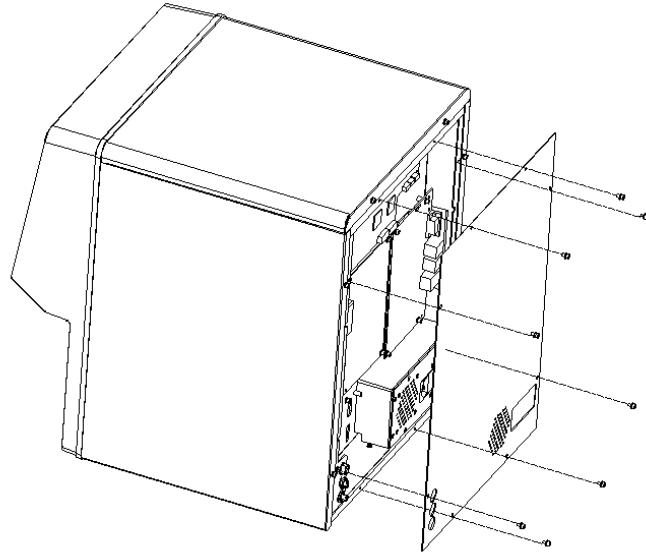
12.4. Disassembling the Main Unit

CAUTION

- ♦ During the disassembly, make sure the site is smooth without foreign materials to avoid screen scratches.
 - ♦ All operations must be done by professionals. Insulating gloves must be worn when servicing.
 - ♦ After assembly, check all the fluidic tubes. Folding is strictly prohibited.
-

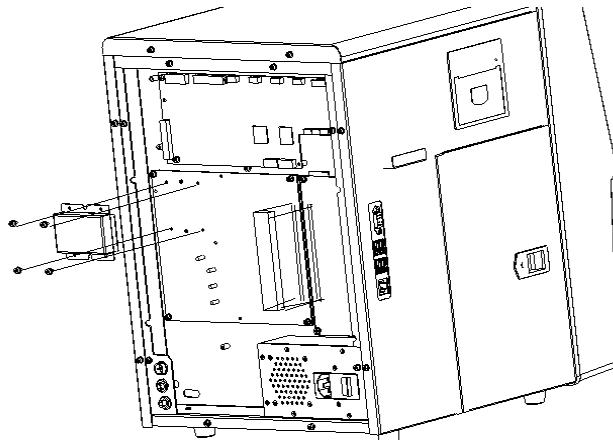
12.4.1. Removing the Back Plate

Place the analyzer flat on the table as shown below. Unscrew the 8 M3×8 combination screws and remove the back plate.

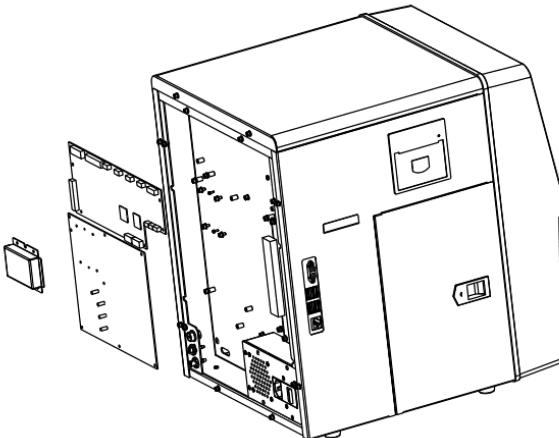


12.4.2. Removing the Signal Board/Driver Board

- 1) Remove the back plate in accordance with Section 11.4.1.
- 2) Remove the 4 M3x6 combination screws as shown below. Remove the top cover of the shield box and disconnect the RBC_PLT signal wire connector.



- 3) Remove all the cables from the signal board as shown below. Unscrew the 6 M3x6 combination screws and remove the signal board. Remove all the cables and pressure detection tube from the driver board, unscrew the 6 M3x6 combination screws and remove the driver board.



Installation:

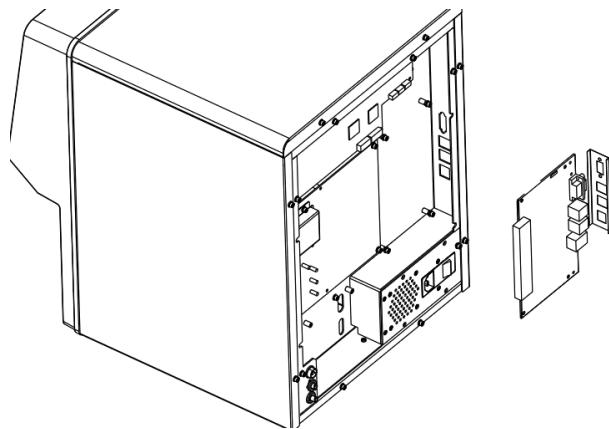
Install the boards as the removal procedure in reverse order.

Verification:

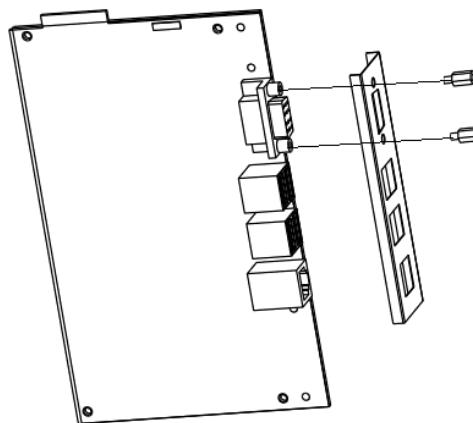
1. Check all the connections on the signal board and driver board and make sure there are no mistakes.
2. Start the analyzer and power on the driver board. Check if the board power and indicators are working properly.
3. Perform blank background count. If no alarm occurs, then the signal board is replaced successfully. Otherwise troubleshooting is needed.

12.4.3. Removing the Main Control Board or SD Card

- 1) Remove the back plate in accordance with Section 11.4.1.
- 2) Remove all the cables from the main control board as shown below. Unscrew the 4 M3x6 combination screws and remove the main control board.



- 3) As shown below, unscrew the 2 studs and remove the conductive patch.



- 4) Remove the SD card from the board.

Installation:

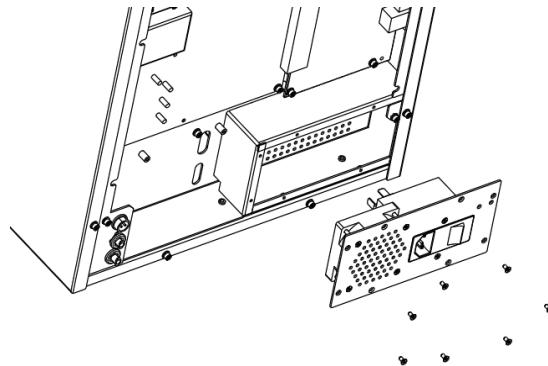
Install the board or SD card as the removal procedure in reverse order.

Verification:

1. Check all the connections on the main control board and make sure there are no mistakes.
2. Start the analyzer and power on the main control board. Check if the board power and indicators are working properly.
3. Perform blank background count. If no alarm occurs, then the main control board is replaced successfully. Otherwise troubleshooting is needed.

12.4.4. Removing the Power Back Plate Assembly

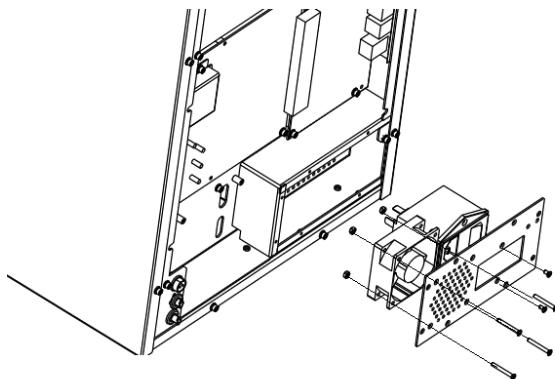
- 1) Remove the back plate in accordance with Section 11.4.1.
- 2) Place the analyzer flat on the table as shown below. Unscrew the 8 M3×6 crosshead screws. Remove the cables and ground wires connected with the power board.

**CAUTION**

- ♦ During installation, verify that the ground wire is connected to the correct ground pin properly.

12.4.5. Removing the Fan Assembly

- 1) Remove the power back plate assembly in accordance with Section 11.4.4.
- 2) Remove all the cables from the fan as shown below. Unscrew the 4 KM3×25 screws and remove the fan assembly.

**Installation:**

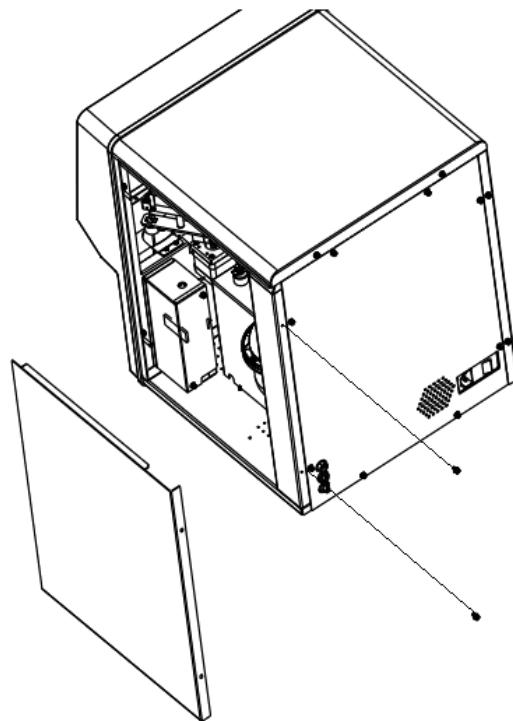
Install the fan assembly as the removal procedure in reverse order.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the electrical connections are correct.

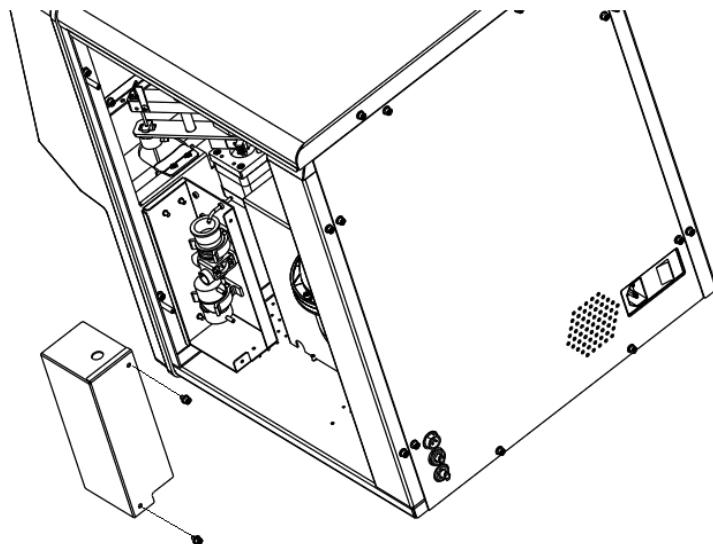
12.4.6. Removing the Right Door

Place the analyzer flat on the table as shown below. Unscrew the 2 M3×6 combination screws and remove the right door.

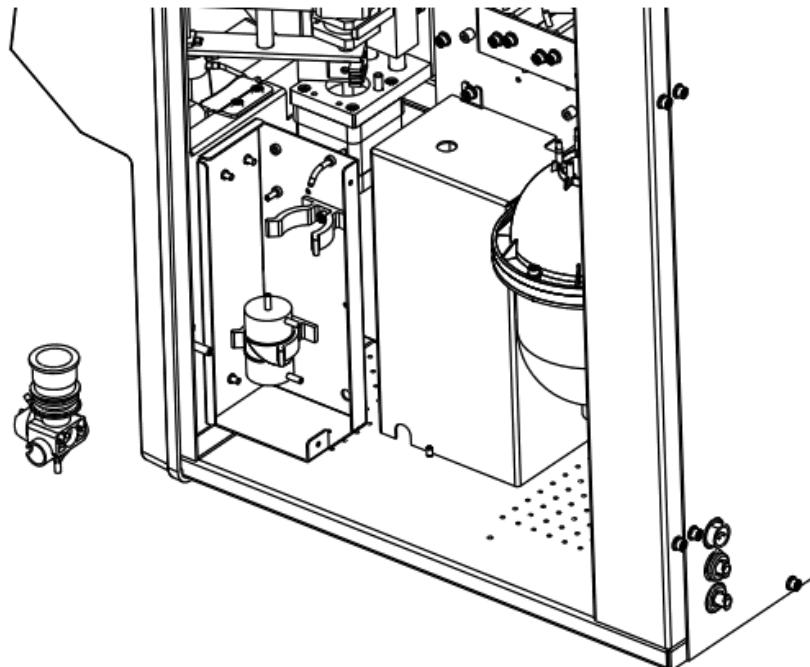


12.4.7. Removing the RBC Counting Pool Module

- 1) Follow step 1 and 2 in Section 11.4.2 to remove the top cover from the analog board shield box and disconnect the RBC_PLT signal wire connector.
- 2) Remove the right door in accordance with Section 11.4.6.
- 3) As shown below, unscrew the 2 M3×6 combination screws and remove the RBC shield box.



- 4) As shown below, unplug all the pipes below the counting pool and remove the grounded M3×6 combination screws to remove the counting pool assembly from the snap ring.

**Installation:**

Reverse the removal procedure.

Verification:

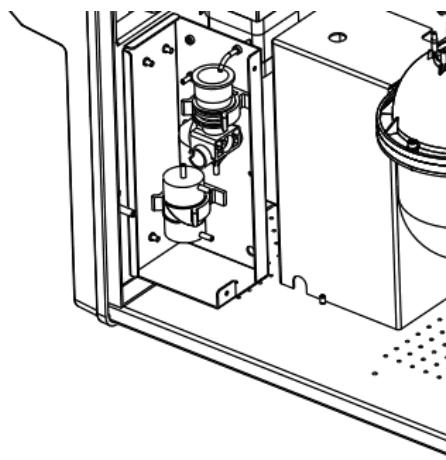
1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. Verify normal operations by starting the analyzer.

CAUTION

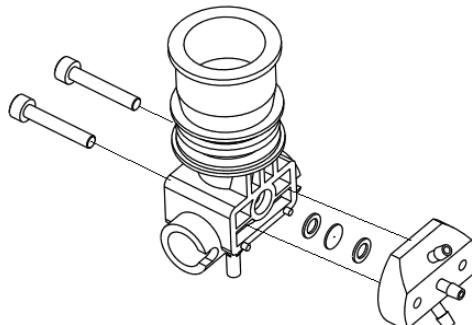
- ♦ Before removing the RBC counting pool shield box, please adjust the sample probe position, so that the sample probe leaves the shield box. Otherwise the sample probe may bend or hurt the operator.
-

12.4.8. Removing the Aperture

- 1) Follow step 2 and 3 in Section 11.4.7 to remove the RBC shield box.
- 2) As shown below, unplug all the pipes below the counting pool and remove the grounded M3×6 combination screws to remove the RBC counting pool assembly from the snap ring.



- 3) As shown below, remove the M3×18 screws to remove the compression cap, and use tweezers to remove the washer and aperture.



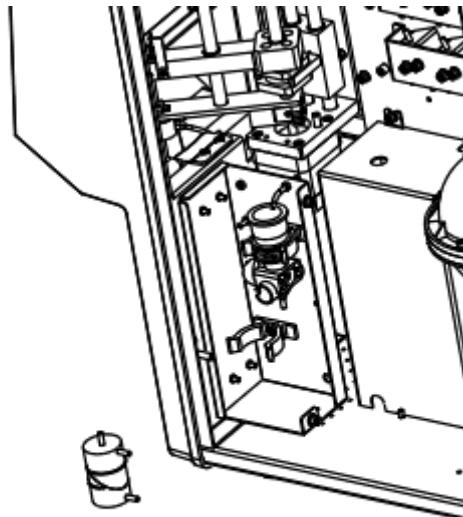
Note: Use angled tweezers to push the aperture out from the center of the RBC counting pool.

CAUTION

- ♦ Before removing the counting pool shield box, please adjust the sample probe position, so that the sample probe leaves the shield box. Otherwise the sample probe may bend or hurt the operator.
 - ♦ When installing the aperture, make sure that the concave of the sensor is facing the center of the RBC counting pool.
-

12.4.9. Replacing the RBC/WBC Isolator

- 1) Follow step 1-3 in Section 11.4.7 to remove the right door and the RBC shield box (or follow step 1-2 in Section 11.4.10 to remove the right door and the WBC shield box).
- 2) As shown below, remove the isolator from the snap ring.



Installation:

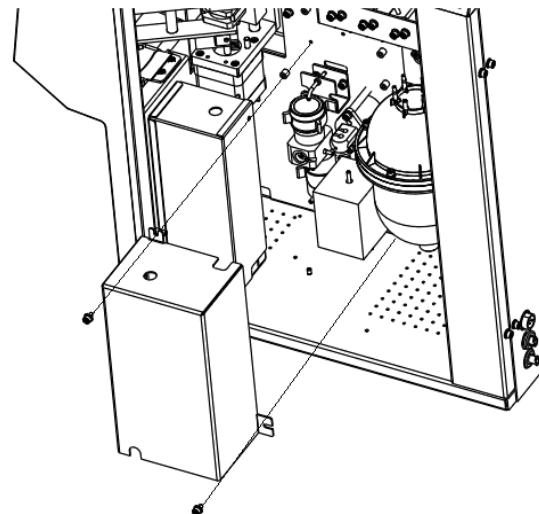
Reverse the removal procedure.

Verification:

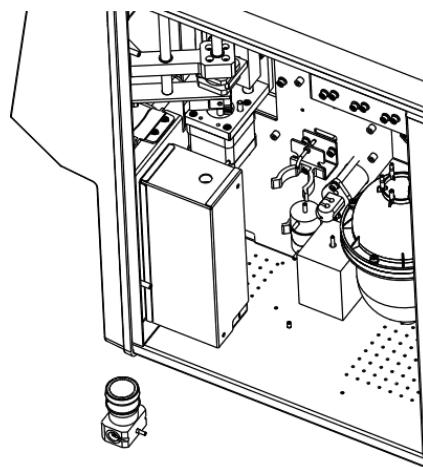
1. Check if all the components are installed and fastened in position.
2. Verify the tube connections are correct.
3. Verify normal operations by starting the analyzer.

12.4.10. Removing the WBC Counting Pool Module

- 1) Remove the right door in accordance with Section 11.4.6.
- 2) As shown below, unscrew the 2 M3x6 combination screws and remove the WBC counting pool shield box.



- 3) Follow the steps in Section 11.4.1 to remove the back plate and disconnect the HGB unit connector from the signal board.
- 4) As shown below, unplug all the pipes below the counting pool and remove the WBC counting pool assembly from the snap ring.



Installation:

Reverse the removal procedure.

Verification:

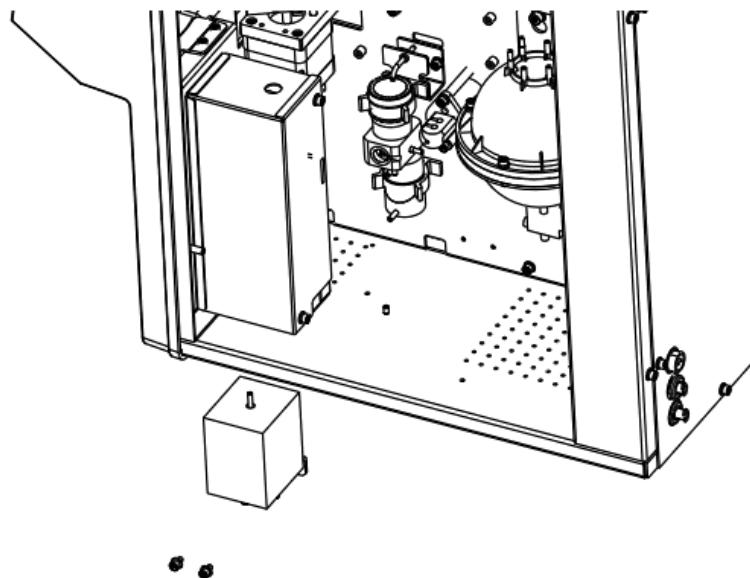
1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. Verify normal operations by starting the analyzer.

CAUTION

- Before removing the WBC counting pool shield box, please adjust the sample probe position, so that the sample probe leaves the shield box. Otherwise the sample probe may bend or hurt the operator.

12.4.11. Removing the Reagent Preheating Assembly

- Follow step 1 and 2 in Section 11.4.10 to remove the WBC counting pool shield box.
- As shown below, remove the tubes from the reagent preheating assembly. Unscrew the 2 M3x6 combination screws and remove the reagent preheating assembly. Pull the connector out from the hole. Disconnect the cable connector of the reagent preheating assembly (leave the connector at the left side for installation purpose).

**Installation:**

Reverse the removal procedure.

Verification:

- Check if all the components are installed and fastened in position.
- Verify the electrical connections are correct.
- After startup, press the “” button from the system menu, select “Status” → “Temp. & Pressure” and check if the “Reagent Preheat Temp.” column is displayed in red.

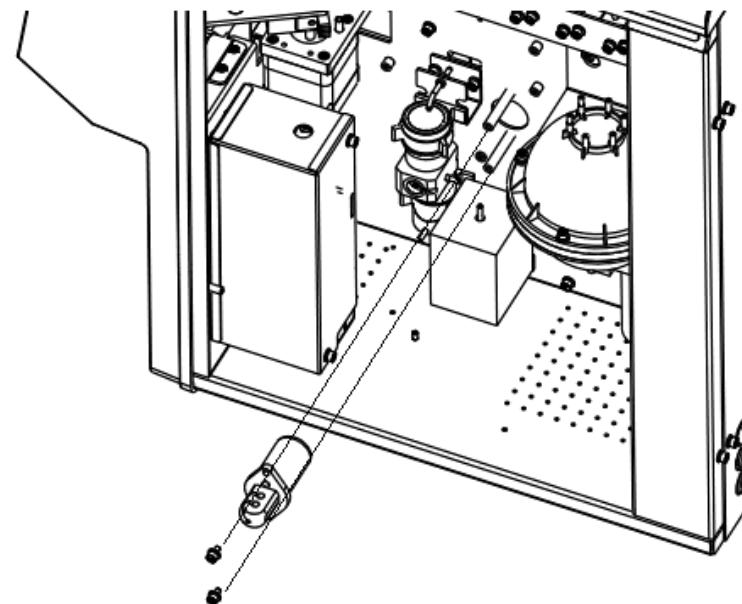
Note: If the wire head retracts back from the hole, please follow the steps in Section 11.4.22 to remove the left baffle.

CAUTION

- ♦ Before removing the WBC shield box, please adjust the sample probe position, so that the sample probe leaves the shield box. Otherwise the sample probe may bend or hurt the operator.

12.4.12. Removing the Electromagnet Pinch Valve Assembly

- 1) Follow step 1 and 2 in Section 11.4.10 to remove the WBC counting pool shield box.
- 2) As shown below, remove the tubes from the pinch valve. Unscrew the 2 M3×6 combination screws and remove the valve assembly. Pull the connector out from the hole. Disconnect the cable connector of the reagent preheating assembly (leave the connector at the left side for installation purpose).

**Installation:**

Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the electrical connections are correct.
3. After startup, press the “” button from the system menu, select “Service” → “Self-test” → “Valve Self-test” and click on valve 17 to see if it is working correctly.

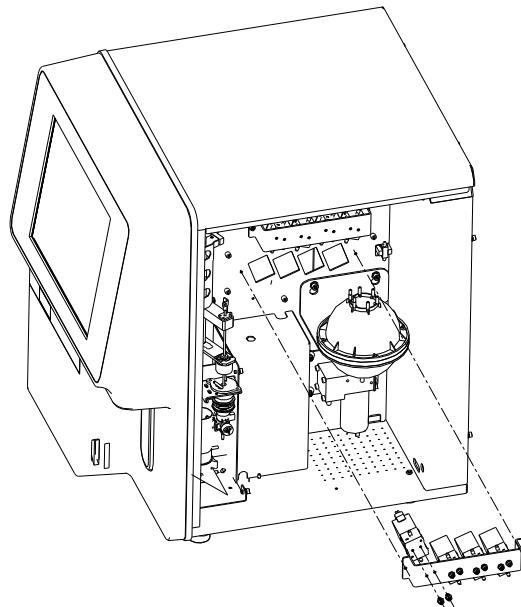
Note: If the wire head retracts back from the hole, please follow the steps in Section 11.4.22 to remove the left baffle.

CAUTION

- ♦ Before removing the WBC shield box, please adjust the sample probe position, so that the sample probe leaves the shield box. Otherwise the sample probe may bend or hurt the operator.

12.4.13. Removing the Right Valve Assembly

- 1) Remove the right door in accordance with Section 11.4.6.
- 2) As shown below, remove the tubes from the valve which needs service. Unscrew the 2 M3×6 combination screws from the mounting plate, remove the valve assembly and pull the connector out from the hole.

**Installation:**

Reverse the removal procedure.

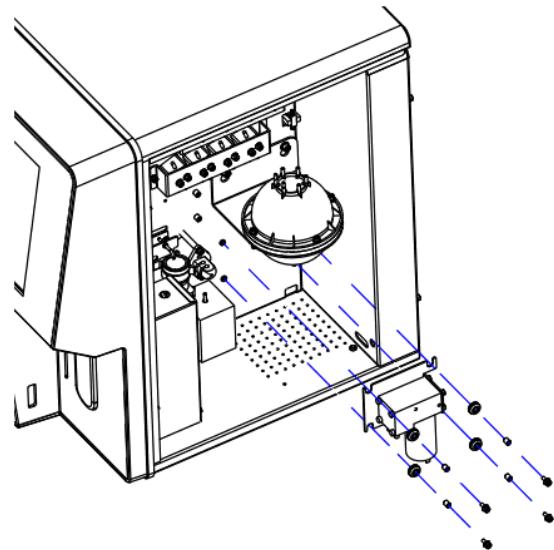
Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. After startup, press the “” button from the system menu, select “Service” → “Self-test” → “Valve Self-test” and click on the number (which is printed on the fluidics separator) to see if the corresponding valve is working correctly.

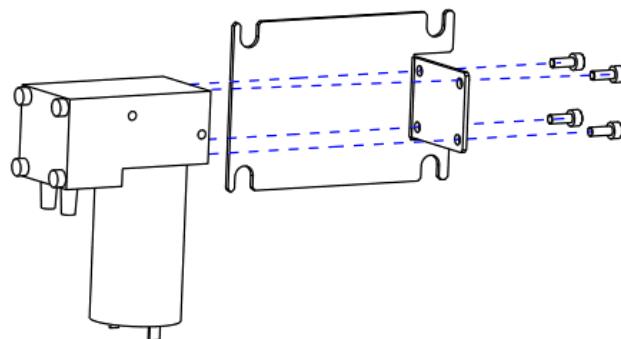
Note: If the wire head retracts back from the hole, please follow the steps in Section 11.4.22 to remove the left baffle.

12.4.14. Removing the Pump

- 1) Remove the right door in accordance with Section 11.4.6.
- 2) As shown below, remove the tubes from the pump. Unscrew the 4 M3×8 combination screws, remove the pump assembly and pull the connector out from the hole.



- 3) As shown below, unscrew the 4 M3×8 cross recessed tapping screws and remove the pump.

**Installation:**

Reverse the removal procedure.

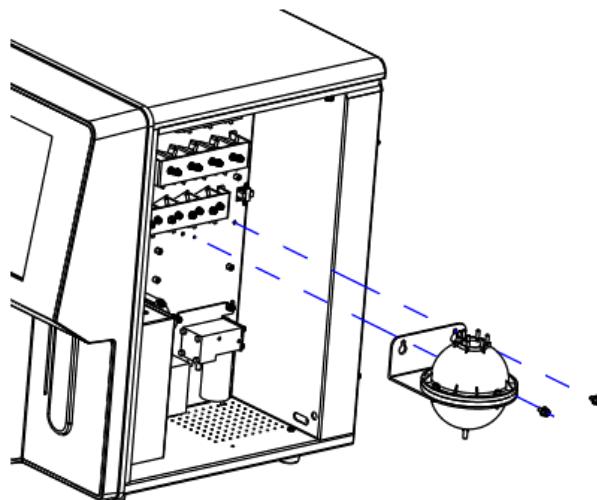
Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. Verify normal operations by starting the analyzer.

Note: If the wire head retracts back from the hole, please follow the steps in Section 11.4.22 to remove the left baffle.

12.4.15. Removing the Vacuum Chamber Assembly

- 1) Remove the right door in accordance with Section 11.4.6.
- 2) Remove the tubes from the vacuum chamber. Unscrew the 2 M4x8 screws and remove the vacuum chamber assembly.



Installation:

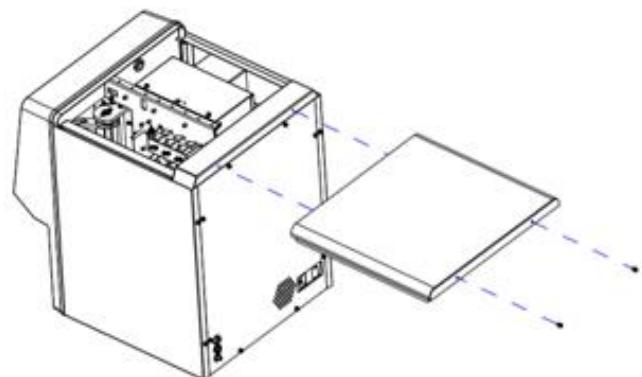
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. After startup, press the “” button from the system menu, select “Status” → “Temp. & Pressure” and check if the “Vacuum” column is displayed in red.
4. Verify normal operations by starting the analyzer.

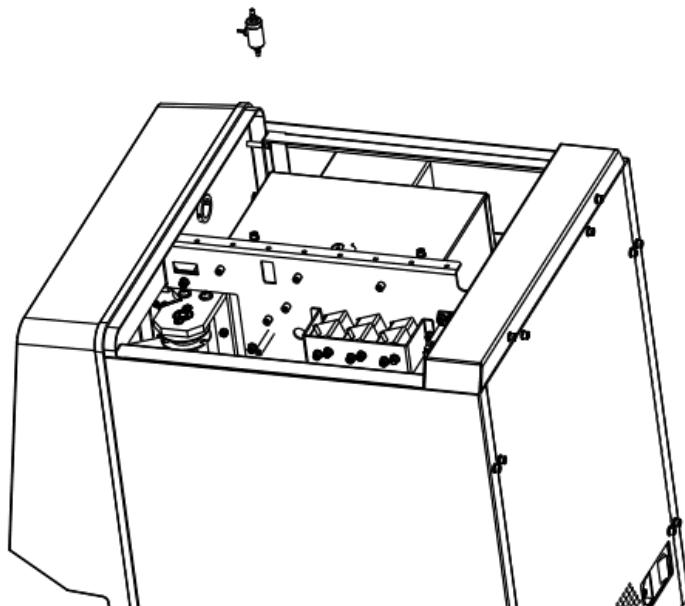
12.4.16. Removing the Top Cover

As shown below, unscrew the 2 M3x6 screws. Lift and remove the top cover from the rear edge.



12.4.17. Removing the Diluent Temperature Sensor

- 1) Remove the top cover in accordance with Section 11.4. 16.
- 2) Remove the cable connectors and tubes from the temperature sensor.

**Installation:**

Reverse the removal procedure.

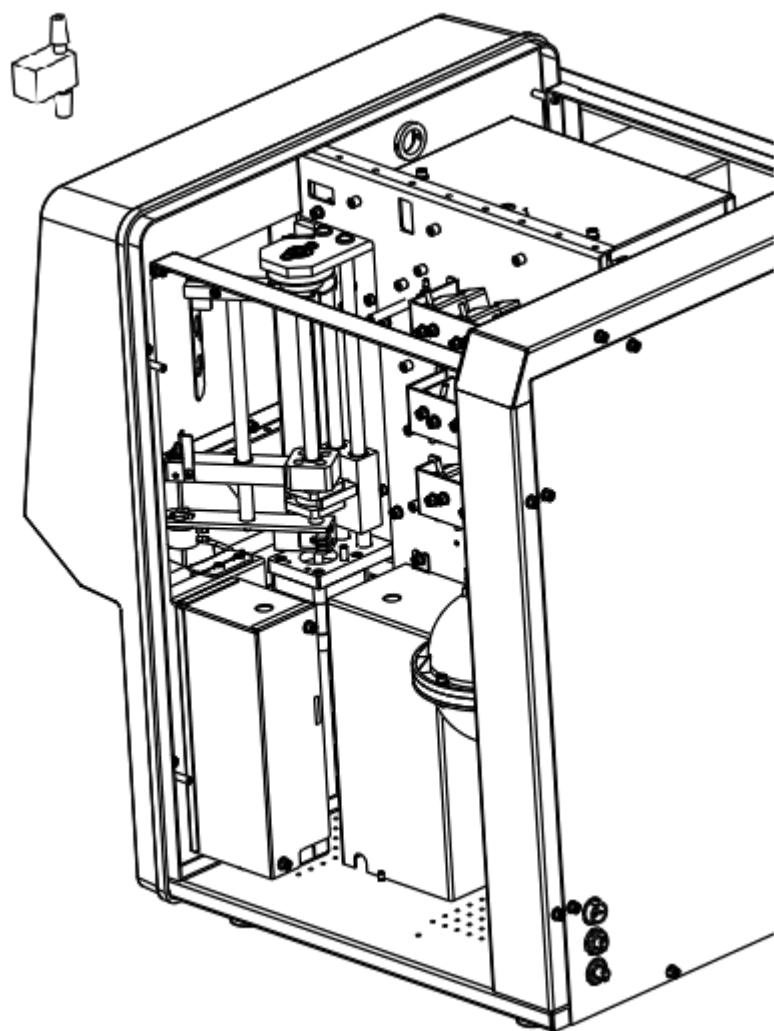
Verification:

1. Verify the tube connections and the electrical connections are correct.

2. After startup, press the  button from the system menu, select "Status" → "Temp. & Pressure" and check if the "Diluent Temp." column is displayed in red.

12.4.18. Removing the Hydraulic Detection Assembly

- 1) Remove the right door in accordance with Section 11.4.6.
- 2) Remove the top cover in accordance with Section 11.4.16. Remove the cable connectors and tubes from the hydraulic detection assembly sensor.

**Installation:**

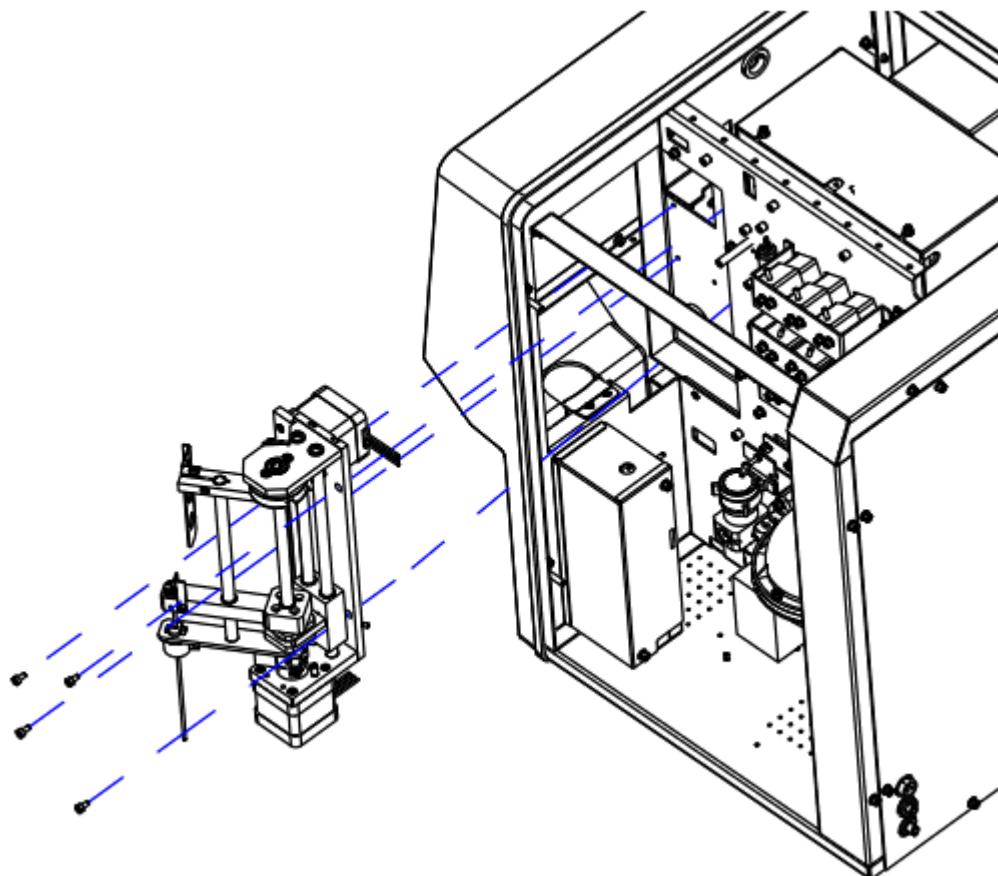
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. Verify normal operations by starting the analyzer.

12.4.19. Removing the Sampling Assembly

- 1) Remove the right door in accordance with Section 11.4.6.
- 2) Follow the steps in Section 11.4.16 to remove the top cover and disconnect the cable connectors of the motor and the upper/lower sensors from the sample probe assembly.
- 3) As shown below, remove the tubes from the sample probe. Unscrew the 4 M3×12 screws and flat washers and remove the sample probe assembly upwards.

**Installation:**

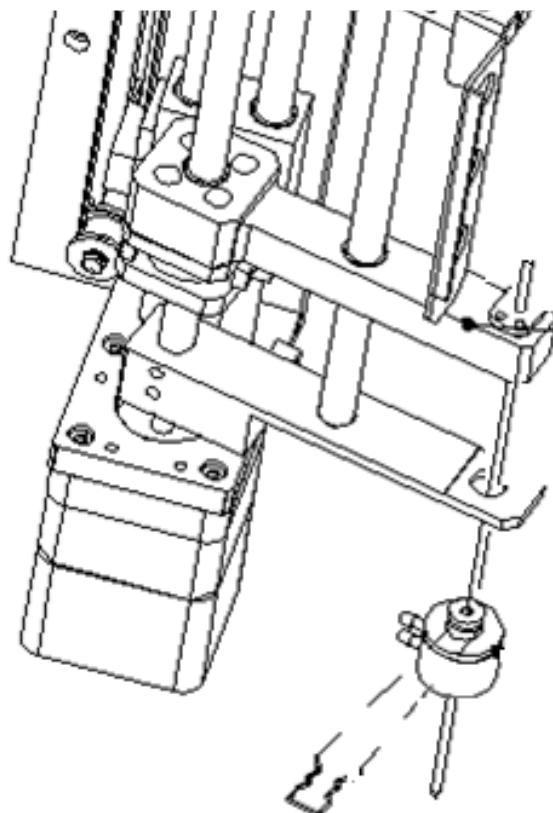
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. After startup, press the  button from the system menu, select “Service” → “Sample Probe Debug” to verify the three positions of the sample probe (“Initial Position”, “Upper Position”, “Middle Position” and “Lower Position” of “RBC Bath” and “WBC Bath”) and ensure the reliable operation of the sample probe.
4. Verify normal operations by starting the analyzer.

12.4.20. Removing the Sample Probe Wash Set

- 1) After startup, press the “” button from the system menu, select “Service” → “Sample Probe Debug”. Click on the “Initial Position”, the “RBC Bath”, and then click on the “Upper Position” to adjust the sample probe to above the RBC bath.
- 2) Follow step 1 and 2 in Section 11.4.7 to remove the right door and the RBC shield box.
- 3) As shown below, remove the clamp and the sample probe wash set. Disconnect the tube from the wash set.



Installation:

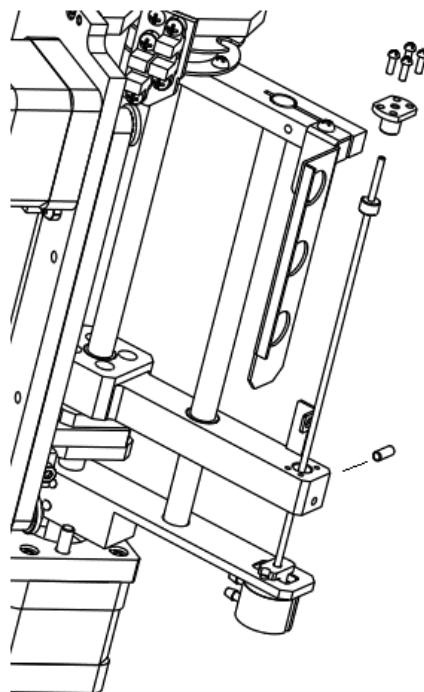
Reverse the removal procedure.

Verification:

1. Verify the tube connections are correct.
2. After startup, press the “” button from the system menu, select “Service” → “Sample Probe Debug” to verify the three positions of the sample probe (“Initial Position”, “Upper Position”, “Middle Position” and “Lower Position” of “RBC Bath” and “WBC Bath”) and ensure the reliable operation of the sample probe.
3. Start the analyzer and perform the sample probe cleaning sequence. Check if any fluid flows out from the bottom of the sample probe wash set.

12.4.21. Replacing the Sample Probe

- 1) After startup, press the “” button from the system menu, select “Service” → “Sample Probe Debug”. Click on the “Initial Position”, the “RBC Bath”, and then click on the “Upper Position” to adjust the sample probe to above the RBC bath.
- 2) Remove the sample probe wash set in accordance with Section 11.4.20.
- 3) As shown below, remove the tubes from the sample probe. Remove the 4 M2×8 screws and the T-type press plate and remove the sample probe.



Installation:

Reverse the removal procedure.

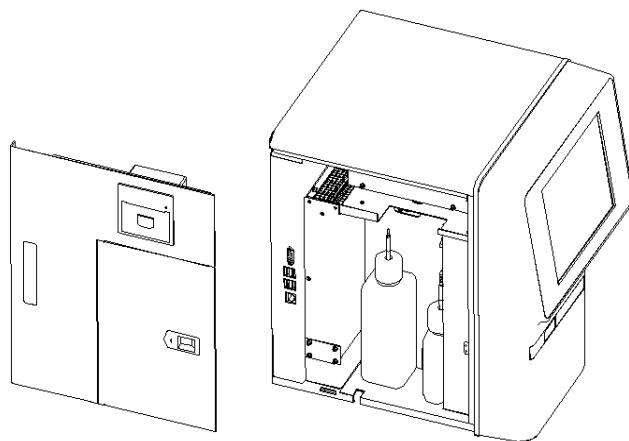
Verification:

1. Verify the tube connections are correct.

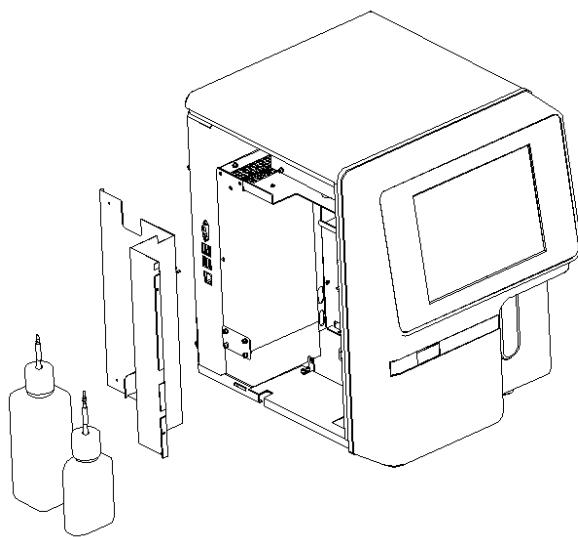
2. After startup, press the “” button from the system menu, select “Service” → “Sample Probe Debug” to verify the three positions of the sample probe (“Initial Position”, “Upper Position”, “Middle Position” and “Lower Position” of “RBC Bath” and “WBC Bath”) and ensure the reliable operation of the sample probe.

12.4.22. Removing the Left Baffle

- 1) Place the analyzer flat on the table as shown below, unscrew the 2 M3×6 combination screws on the left door, unplug all the cables on the printer and unscrew the grounded screws, and remove the left door.



- 2) As shown below, remove the tubes from the two reagent detectors, move the tubes towards the top end of the left baffle from the reagent bottle plate. Remove the reagent bottle (with the tubes) and put it away. Unscrew the 4 M3×6 combination screws and remove the left baffle.

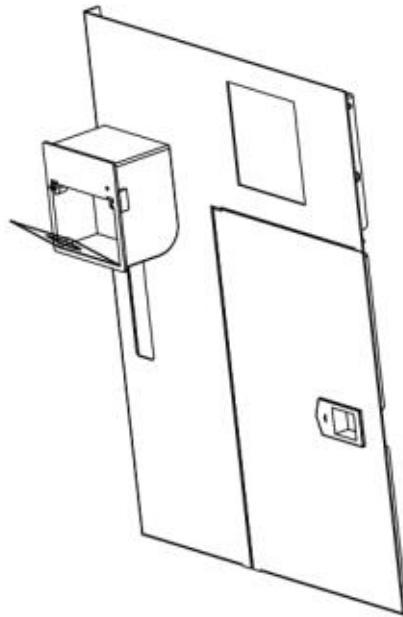


NOTE

- ♦ When installing the left door assembly, the hook beneath the left door should be hooked to the bottom plate to ensure that the left access door does not shake.
-

12.4.23. Replacing the Thermal Recorder

- 1) Follow step 1 in Section 11.4.22 to remove the left door.
- 2) Disconnect all the cable connectors on the recorder and unscrew the grounded M3 screws.
- 3) Open the recorder cover and unscrew the M2.5 screw until the recorder can be removed from the square hole on the left door.

**Installation:**

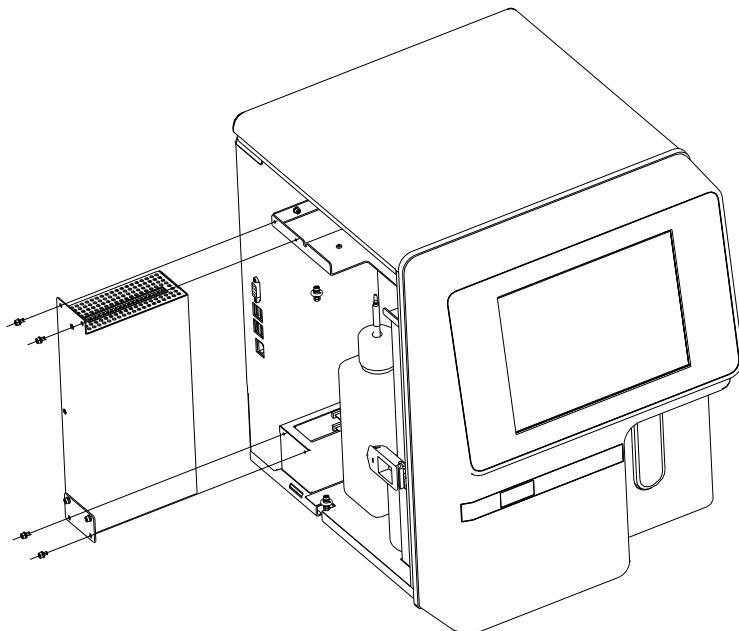
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Verify normal operations by starting the analyzer.

12.4.24. Replacing the Switching Power Supply

- 1) Follow step 1 in Section 11.4.22 to remove the left door.
- 2) Remove the top cover in accordance with Section 11.4.16.
- 3) Disconnect all the cable connectors above the power box and place the DIFF reagent bottle in a front position on the table.
- 4) As shown below, unscrew the 4 M3×6 combination screws. Remove the switching power supply and disconnect the connecting wires of the power socket from inside.



Installation:

Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Verify normal operations by starting the analyzer.

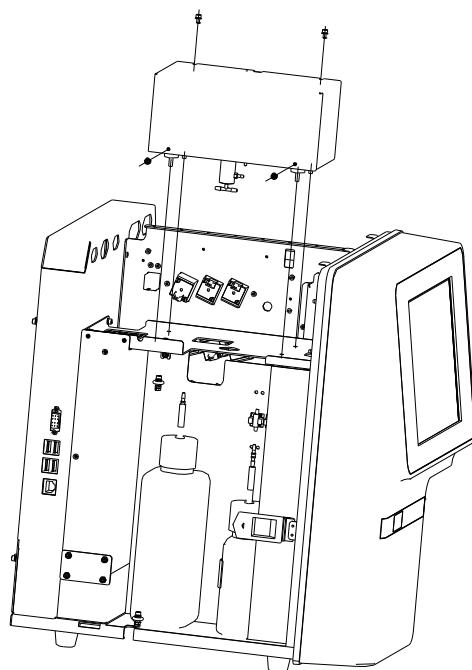
12.4.25. Removing the Optical System

Please refer to Section 6.4.2 Replacement of the Optical System.



12.4.26. Removing the Optical System Cover

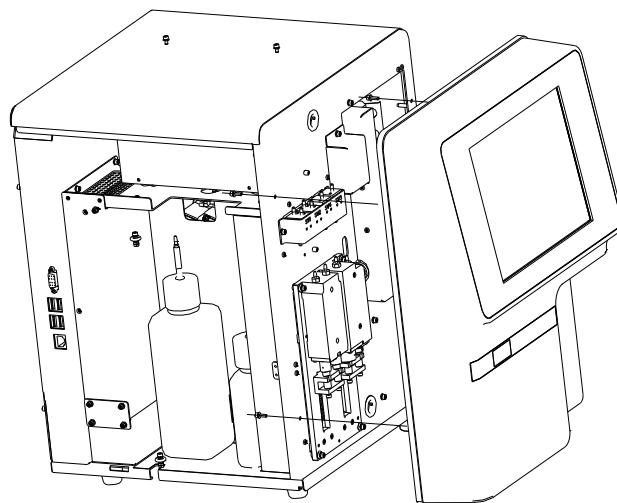
- 1) Remove the right door assembly in accordance with Section 11.4.6.
- 2) Remove the top cover in accordance with Section 11.4.16.
- 3) As shown below, unscrew the 4 screws and remove the optical system shield cover.



Please refer to Section 6.4.1 Maintenance of the Optical System.

12.4.27. Removing the Panel Assembly

- 1) Remove the right door in accordance with Section 11.4.6 and follow step 1 in Section 11.4.22 to remove the left door.
- 2) As shown below, unscrew the 4 M3×10 combination screws. Remove the panel assembly and place it flat on the table.

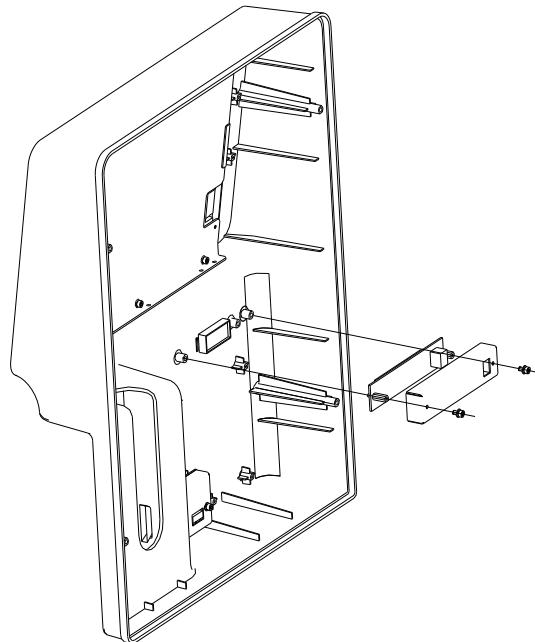


- 3) Follow the steps in Section 11.4.1 to remove the back plate and disconnect the cable connectors of the panel assembly from the main control board.
- 4) Follow the steps in Section 11.4.22 to remove the left baffle. Move the front panel signal wire from the back to the front and remove it.

Note: During installation, the excess part of the signal wire shall be completely inserted into the analyzer. Failure to do so will result in signal interference.

12.4.28. Removing the Indicator board PCBA

- 1) Follow step 1-3 in Section 11.4.27 to remove the front panel and put it on the table. Remove the cable connector from the indicator.
- 2) As shown below, unscrew the 2 M3×6 combination screws and 2 M3× (12+6) studs, remove the shield cover and indicator board PCBA.



Installation:

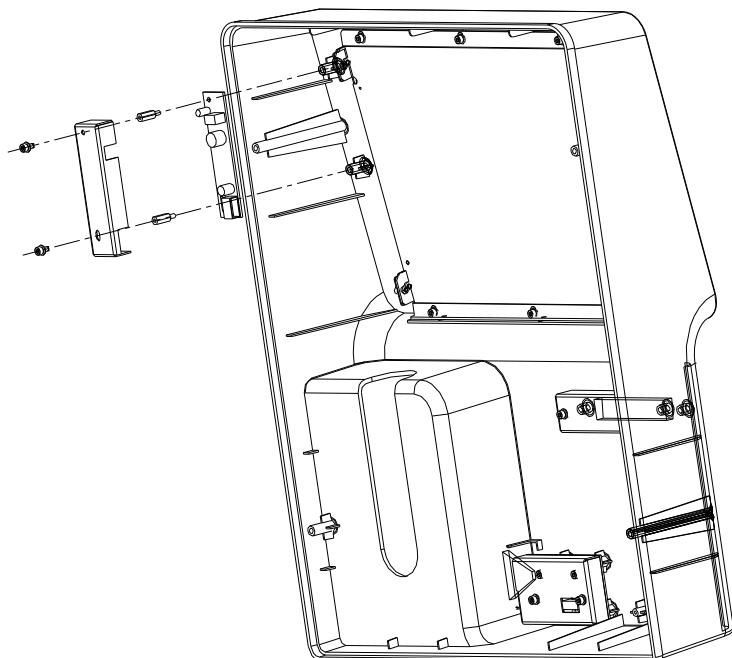
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Start the analyzer and verify the indicators can be illuminated.

12.4.29. Removing the Touch Screen Inverter

- 1) Follow step 1-3 in Section 11.4.27 to remove the front panel and put it on the table. Remove the cable connector from the inverter drive board.
- 2) As shown below, unscrew the 2 M3x6 combination screws and 2 M3x (12+6) studs, remove the shield cover and inverter.

**Installation:**

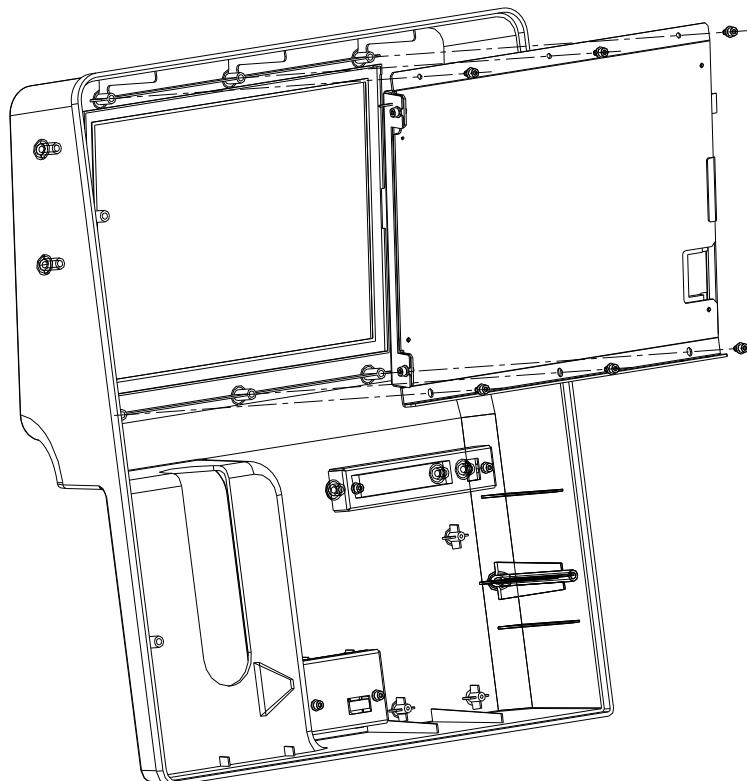
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Start the analyzer and verify normal operations of the touch screen.

12.4.30. Removing the LCD Module

- 1) Follow step 1-2 in Section 11.4.29 to remove the inverter shield box and disconnect the cables.
- 2) As shown below, unscrew the 6 M3x8 combination screws which fasten the LCD module, and the 2 screws which fasten the strap. Remove the LCD module and disconnect all the cables from the screen.

**Installation:**

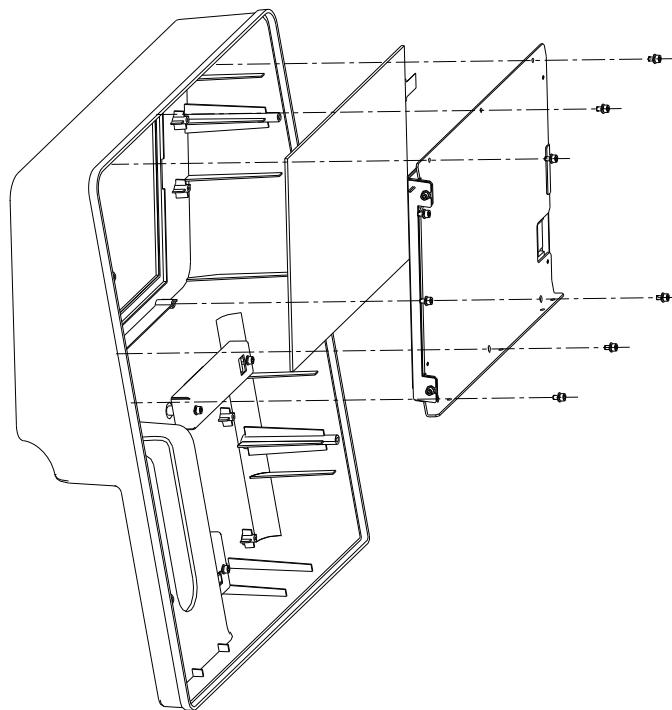
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Start the analyzer and verify that the screen is working correctly.

12.4.31. Removing the Touch Screen

- 1) Follow step 1-2 in Section 11.4.29 to remove the inverter shield box and disconnect the cable connector from the inverter drive board.
- 2) As shown below, unscrew the 6 M3x6 combination screws which fasten the LCD module, and remove the touch screen assembly (without disconnecting the cables).



- 3) Remove the touch screen from the front cover.

Installation:

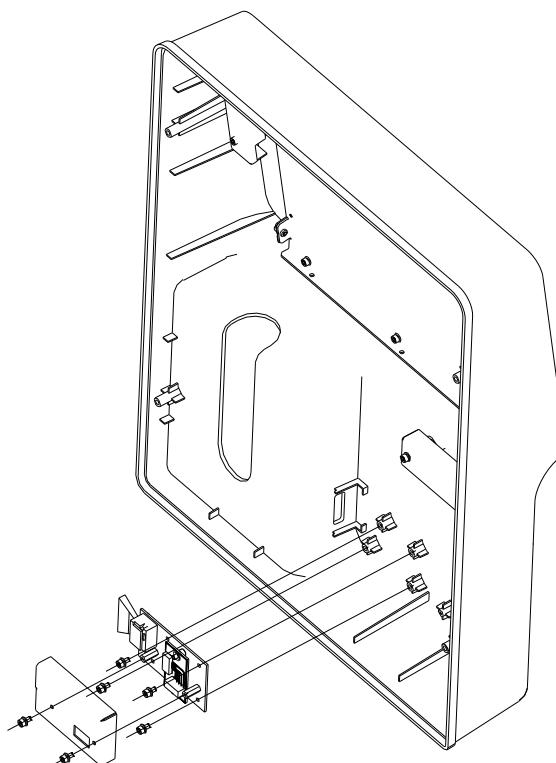
Reverse the removal procedure.

Verification:

1. Check if each connecting wire of the LCD module is locked.
2. Check if all the components are installed and fastened in position.
3. Calibrate the touch screen.
4. Start the analyzer and verify normal operations of the touch screen.

12.4.32. Removing the Scan Head Adapter Board

- 1) Follow step 1-3 in Section 11.4.27 to remove the front panel and put it on the table.
- 2) Unscrew the 2 M3x6 combination screws and 2 studs, remove the shield cover.
- 3) Unscrew the 2 M3x6 combination screws, remove the adapter board.

**Installation:**

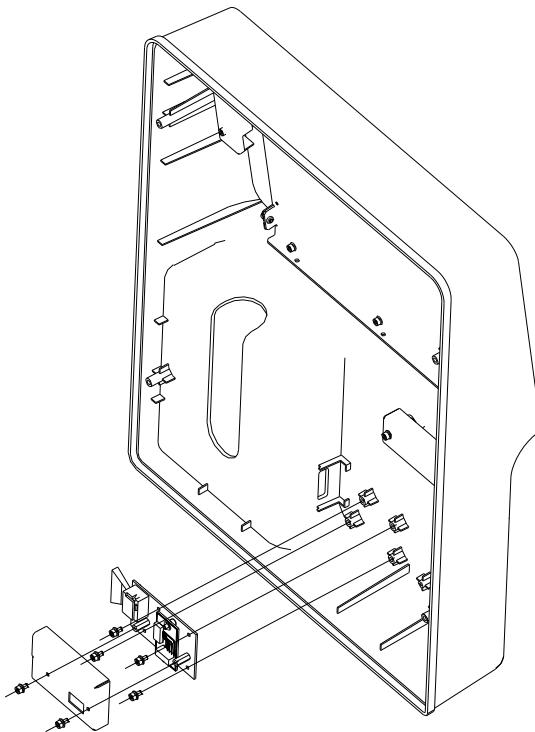
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Verify normal operations by starting the analyzer.
4. Open the barcode scanning interface to verify that it can scan correctly.

12.4.33. Removing the Scan Head

- 1) Follow step 1-3 in Section 11.4.27 to remove the front panel and put it on the table.
- 2) Unscrew the 2 M3x6 combination screws and 2 studs, remove the shield cover.
- 3) Unscrew the 4 M3x6 combination screws from the panel, remove the mounting plate.
- 4) Unscrew the 2 M1.6x3 screws from the mounting plate, remove the scan head.

**Installation:**

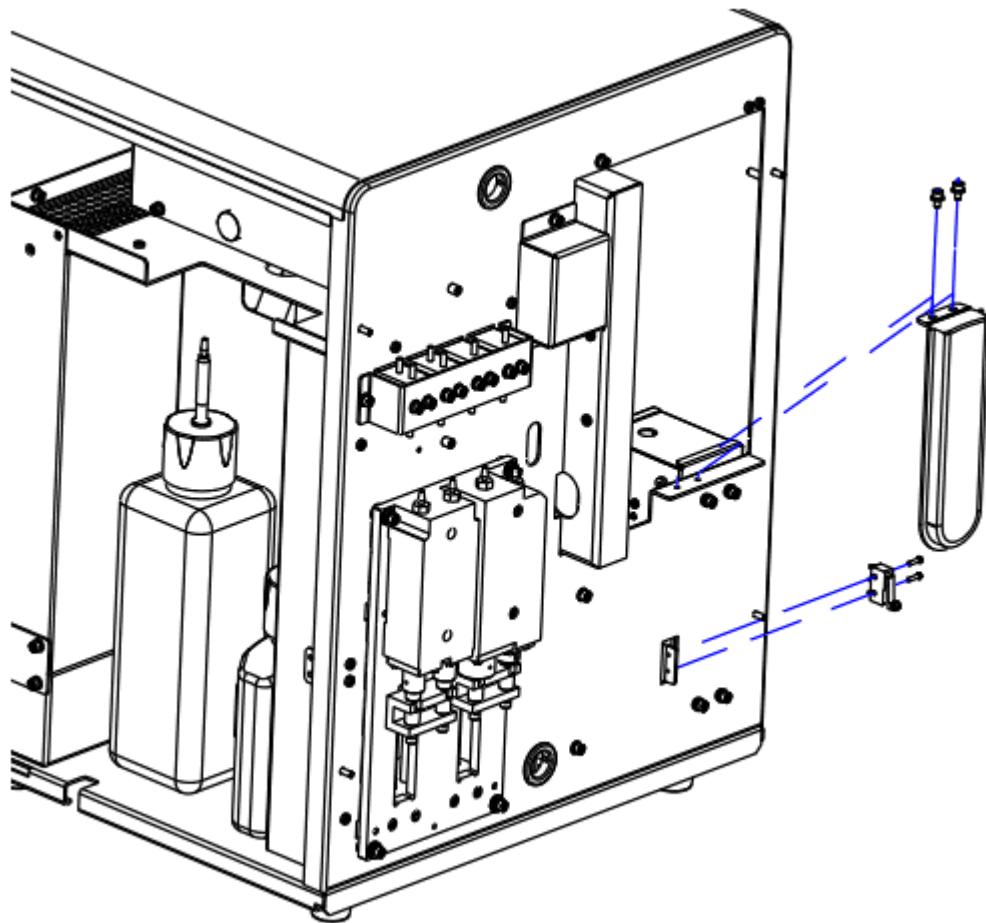
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Verify normal operations by starting the analyzer.
4. Open the barcode scanning interface to verify that it can scan correctly.

12.4.34. Removing the Microswitch Assembly

- 1) Follow step 1-3 in Section 11.4.27 to remove the front cover and put it on the table.
- 2) Remove the back plate in accordance with Section 11.4.1. Disconnect the connections from the microswitch.
- 3) As shown below, unscrew the 2 M3×6 combination screws and remove the sampling keystroke.
- 4) As shown below, unscrew the 2 M2×8 screws and remove the microswitch assembly from the small hole in the front panel.

**Installation:**

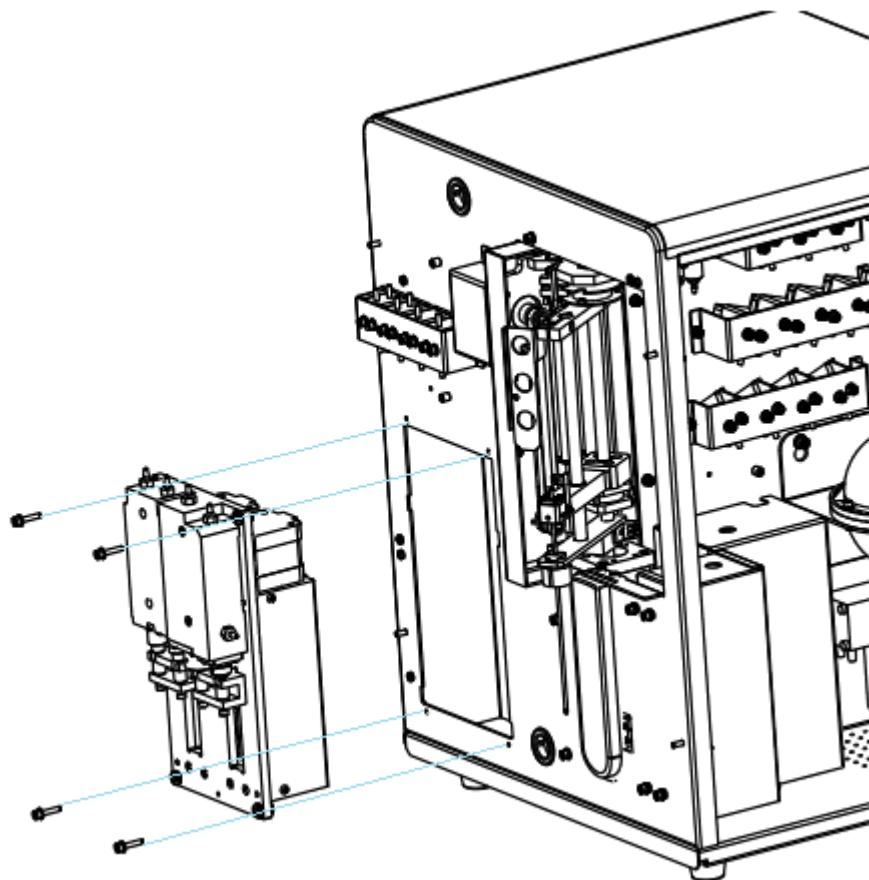
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. The Start key can be pressed down and released normally with an audible “click”.
4. Verify normal operations by starting the analyzer.

12.4.35. Removing the Syringe

- 1) Follow step 1-3 in Section 11.4.27 to remove the front cover and put it on the table.
- 2) Remove the tubes from the syringe assembly.
- 3) As shown below, unscrew the 4 M3x16 screws. Remove the syringe assembly and remove the cables from the syringe.

**Installation:**

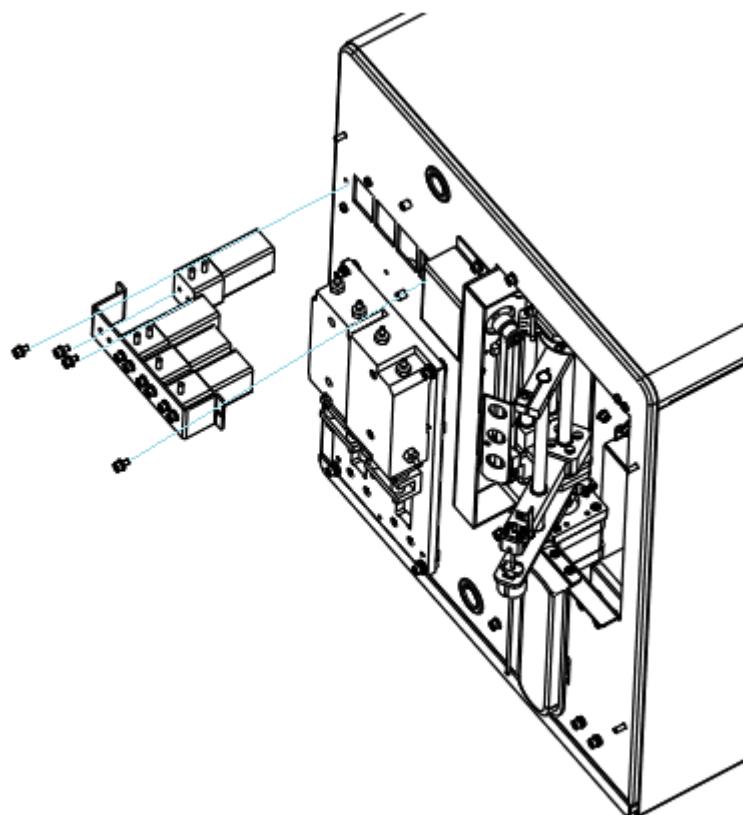
Reverse the removal procedure.

Verification:

1. Check if all the components are installed and fastened in position.
2. Verify the cable connections are correct.
3. Verify normal operations by starting the analyzer.

12.4.36. Removing the Electromagnetic Valve from Front Panel

- 1) Follow step 1-3 in Section 11.4.27 to remove the front panel and put it on the table.
- 2) As shown below, remove the tubes from the valve which needs service. Unscrew the 2 M3x6 combination screws, remove the electromagnetic valve and pull the connector out from the hole.

**Installation:**

Reverse the removal procedure.

Verification:

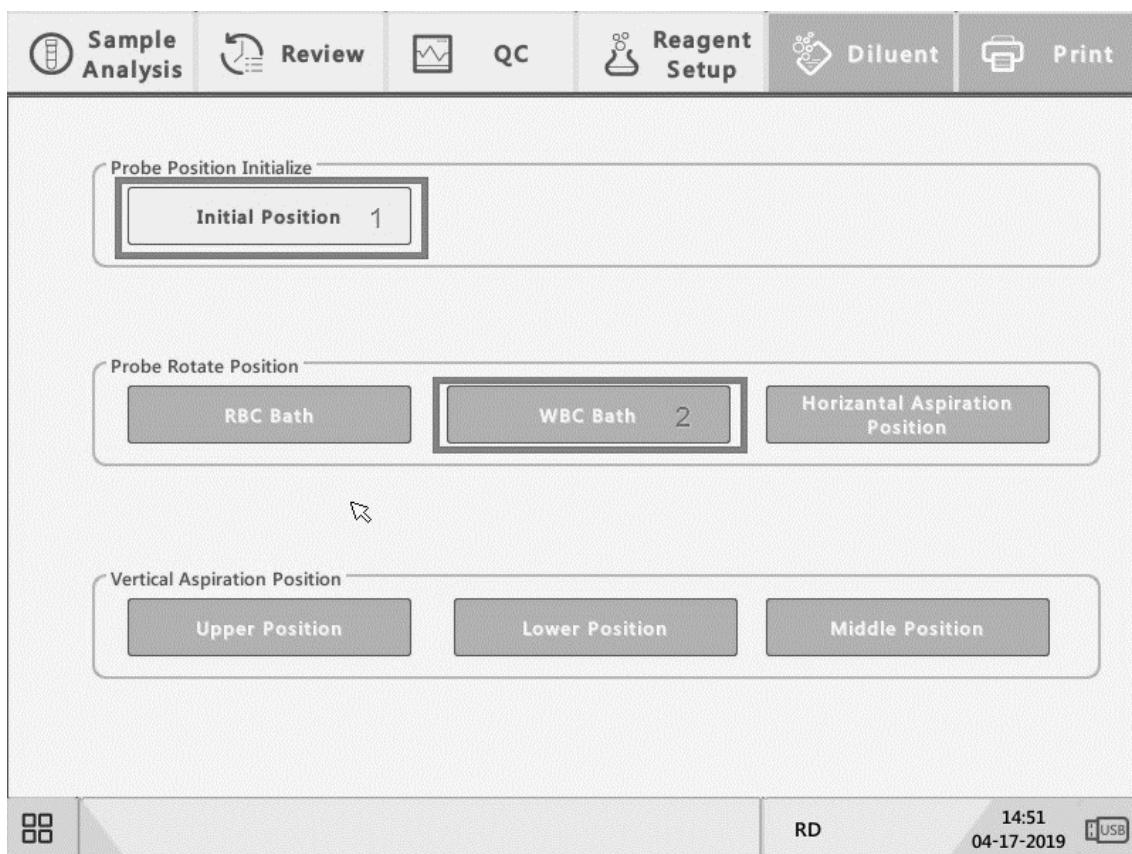
1. Check if all the components are installed and fastened in position.
2. Verify the tube connections and the electrical connections are correct.
3. Verify normal operations by starting the analyzer.

13. Debugging

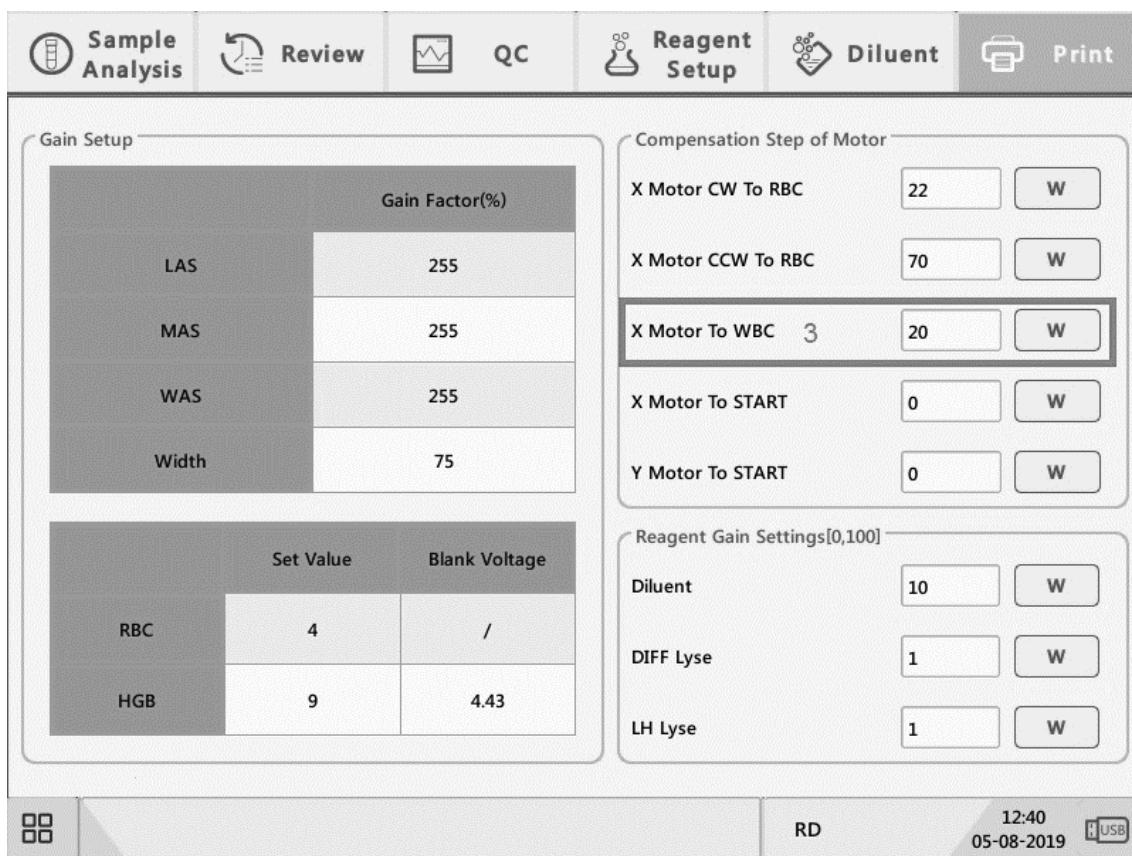
13.1. Sample Probe Position Adjustment

13.1.1. Sample Probe to the Center of the WBC Bath

- 1) Remove the WBC shield cover. Press the “” button, select “Service” → “Sample Probe Debug”, and then click “Initial Position”, the sample probe is reset. Click “WBC Bath”, check if the sample probe is located above the center of the WBC bath, otherwise press the “” button and select “Setup” → “Gain Setup”, set the compensation steps for X motor to WBC, and then click “W” beside it to save the value.



Sample probe to the WBC bath

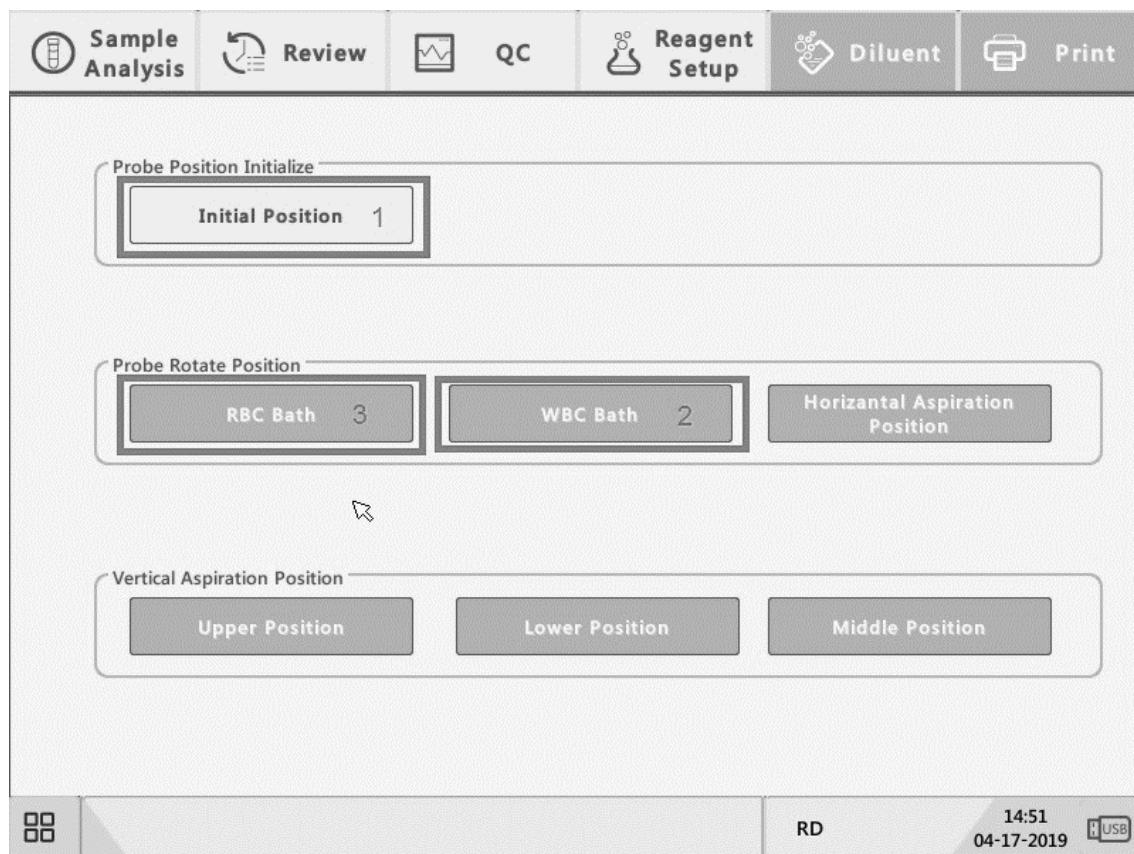


X motor to WBC compensation step setup

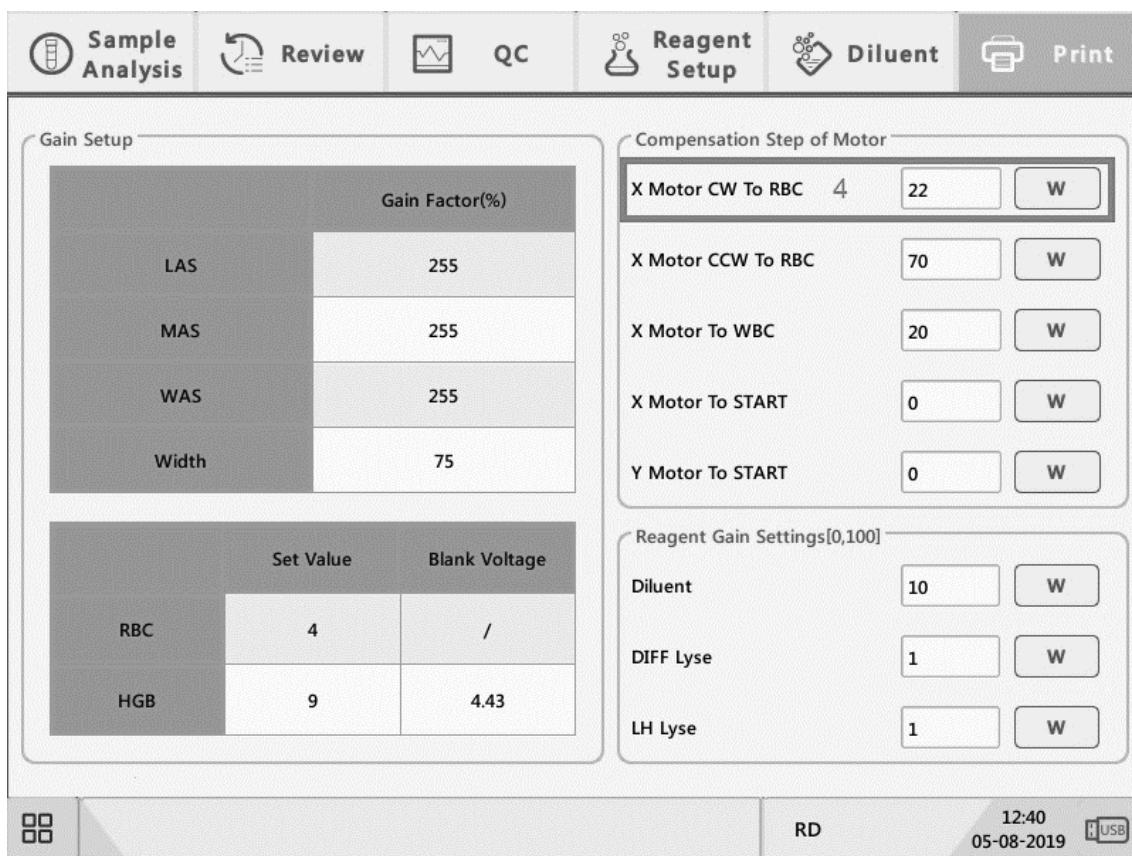
- 2) Enter the sample probe debugging interface again, click “Initial Position” → “WBC Bath” to check if the position is adjusted in place, or repeat the above operations until the probe tip is adjusted to the center of the WBC bath.
- 3) Install the WBC shield cover. Use the same method to see if the sample probe may contact the shield cover, otherwise re-adjust the sample probe position.

13.1.2. Sample Probe Clockwise to the Center of the RBC Bath

- 1) Remove the RBC shield cover. Press the “” button, select “Service” → “Sample Probe Debug”, and then click “Initial Position”, the sample probe is reset. Click “WBC Bath” → “RBC Bath”, check if the sample probe is located above the center of the RBC bath, otherwise press the “” button and select “Setup” → “Gain Setup”, set the compensation steps for “X Motor CW to RBC”, and then click “W” beside it to save the value.



Sample probe clockwise to the RBC bath

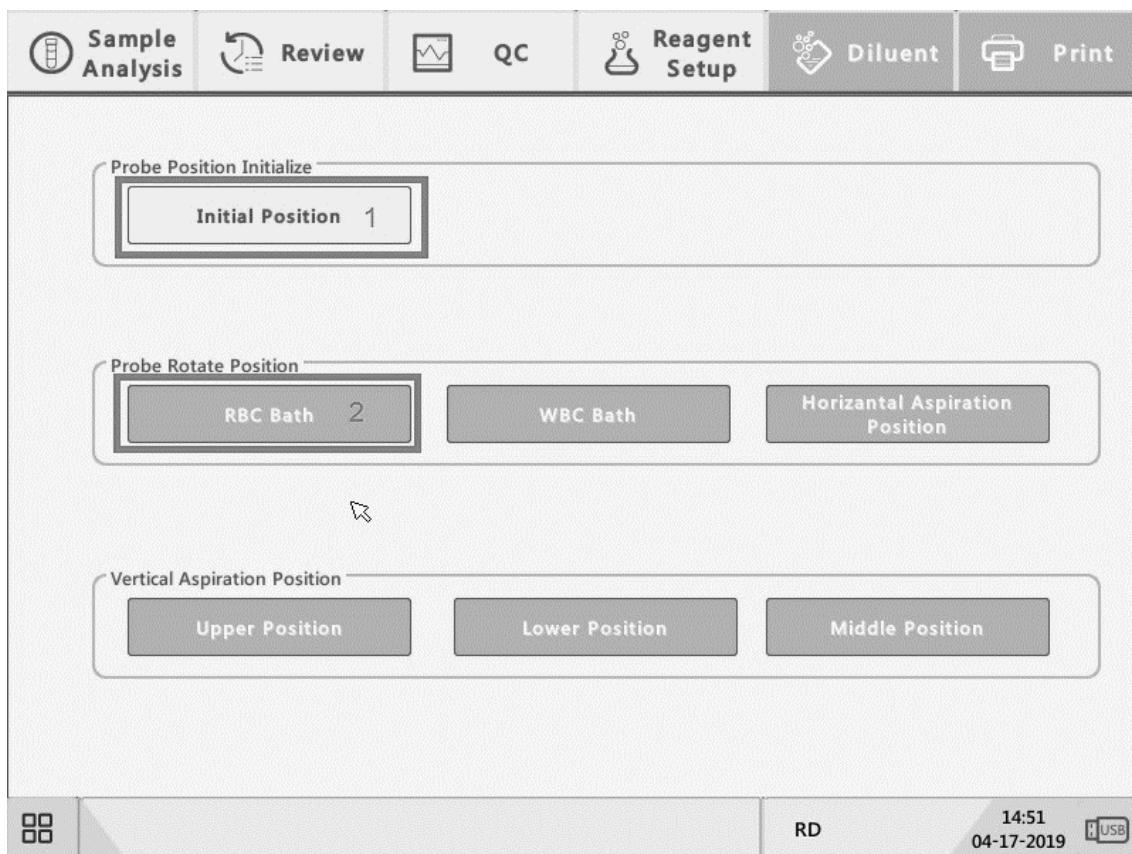


X motor clockwise to RBC compensation step setup

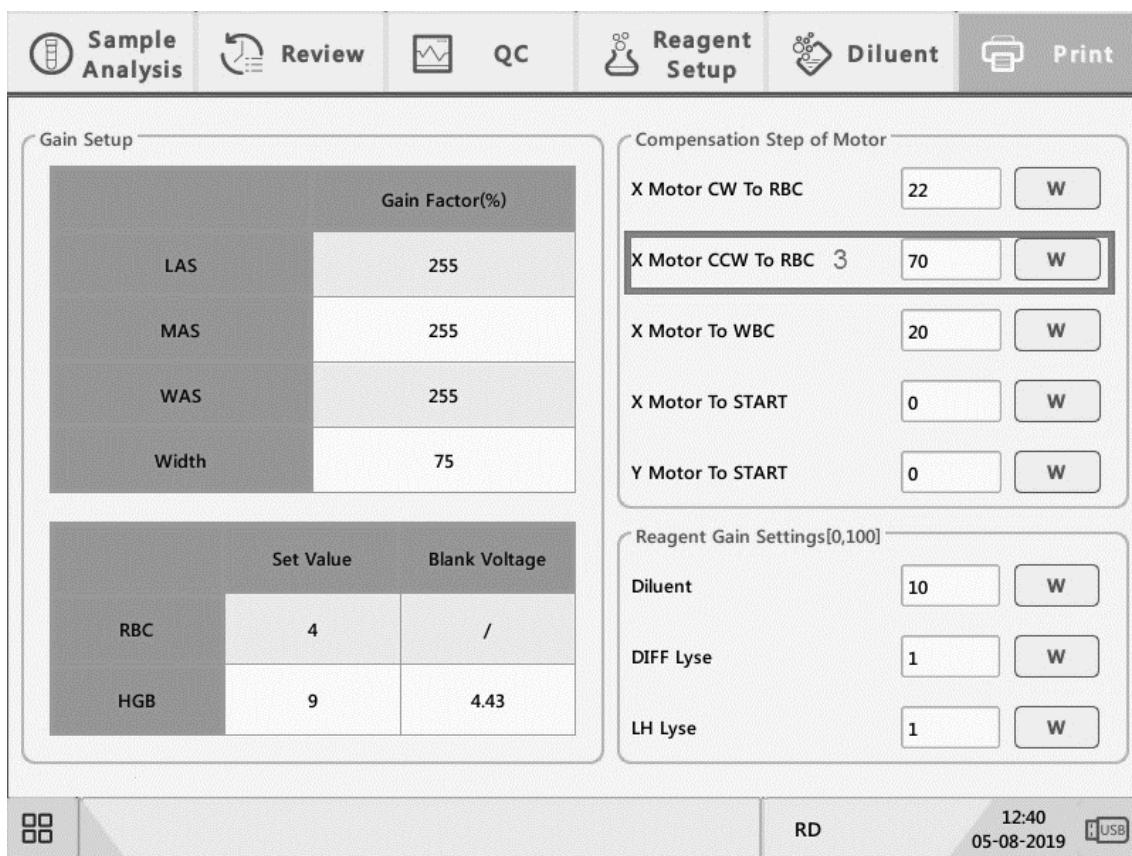
- 2) Enter the sample probe debugging interface again, click “Initial Position” → “WBC Bath” → “RBC Bath” to check if the position is adjusted in place, or repeat the above operations until the probe tip is adjusted to the center of the RBC bath.
- 3) Click “Lower Position” to check the distance between the sample probe and the elbow, the distance should not be too close.
- 4) Install the RBC shield cover. Use the same method to see if the sample probe may contact the shield cover, otherwise re-adjust the sample probe position.

13.1.3. Sample Probe Counterclockwise to the Center of the RBC Bath

- 1) Remove the RBC shield cover. Press the “” button, select “Service” → “Sample Probe Debug”, and then click “Initial Position”, the sample probe is reset. Click “RBC Bath”, check if the sample probe is located above the center of the RBC bath, otherwise press the “” button and select “Setup” → “Gain Setup”, set the compensation steps for “X Motor CCW to RBC”, and then click “W” beside it to save the value.



Sample probe counterclockwise to the RBC bath



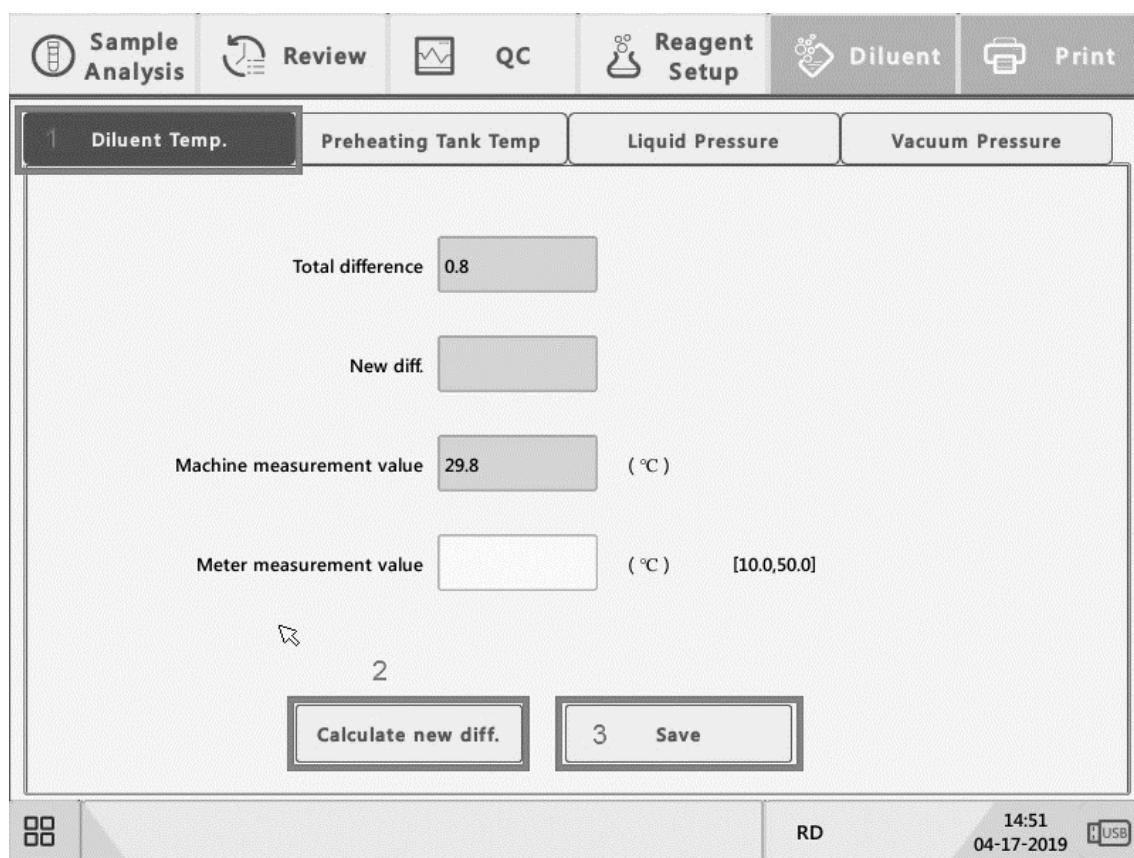
X motor counterclockwise to RBC compensation step setup

- 2) Enter the sample probe debugging interface again, click “Initial Position” → “RBC Bath” to check if the position is adjusted in place, or repeat the above operations until the probe tip is adjusted to the center of the RBC bath.

13.2. Temperature/Pressure Detection and Calibration

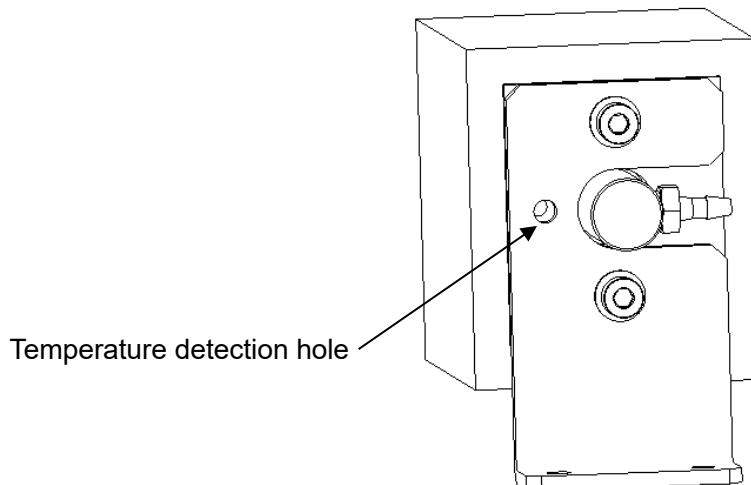
13.2.1. Diluent Temperature Calibration

- 1) Detect the ambient temperature with a thermometer and record the measured value after the temperature is stable.
- 2) Press the “” button, select “Service” → “Temp. & Pressure Calibration” → “Diluent Temp.”, input the thermometer reading value into the “Meter measurement value” box, and then click “Save”.



13.2.2. Preheat Bath Temperature Calibration

- 1) 5 minutes after starting the analyzer, place the thermometer probe into the bottom of the preheat bath temperature detection hole and record the measured value after the temperature is stable.



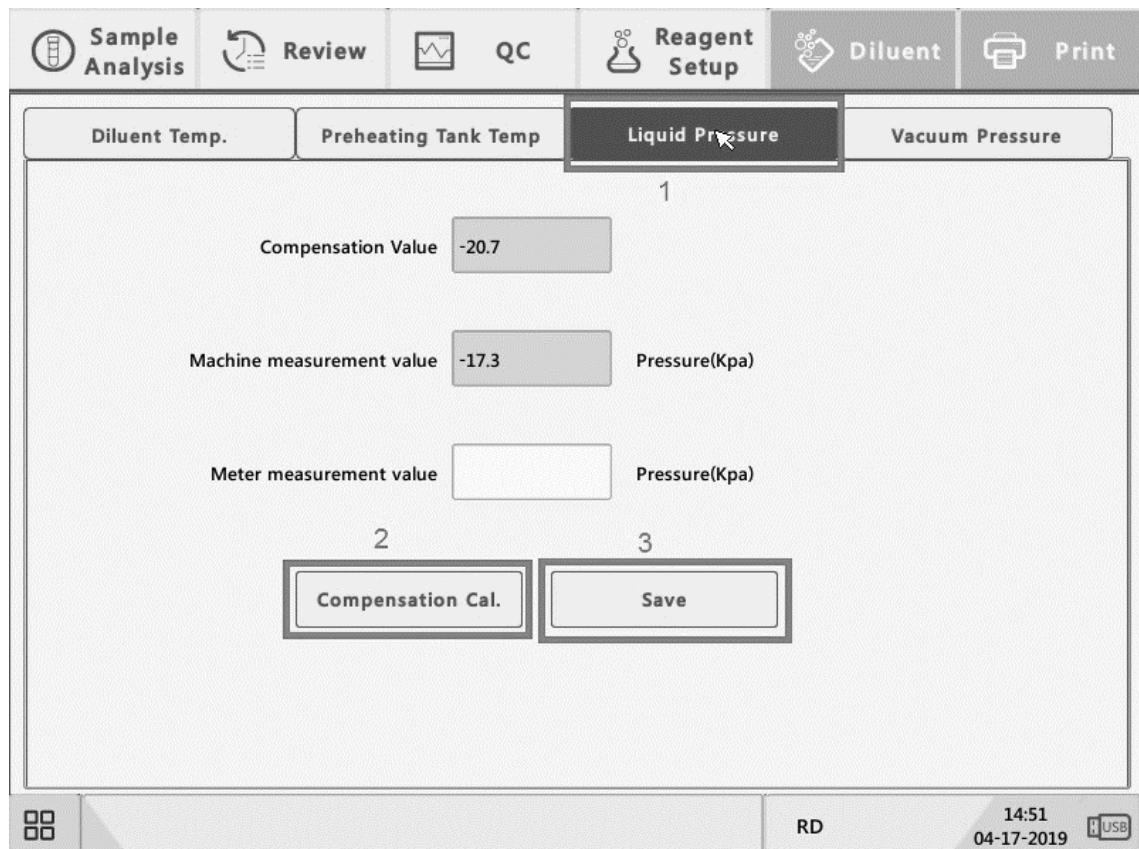
- 2) Click "Preheat Bath Temp.", input the reading value into the "Meter measurement value" box, and then click "Save".

The screenshot shows the software interface for calibration. At the top, there is a navigation bar with icons for Sample Analysis, Review, QC, Reagent Setup, Diluent, and Print. Below the navigation bar, there are four tabs: Diluent Temp., Preheating Tank Temp (which is highlighted with a mouse cursor), Liquid Pressure, and Vacuum Pressure. The main area contains several input fields and buttons:

- Diluent Temp.**: A dropdown menu showing the value "1".
- Total difference**: A text box containing "-5.2".
- New diff.**: An empty text box.
- Machine measurement value**: A text box containing "48.6" followed by "(°C)".
- Meter measurement value**: An empty text box followed by "(°C)" and a range "[10.0,55.0]".
- Buttons**: Two buttons at the bottom labeled "2" and "3". Button "2" contains the text "Calculate new diff." and button "3" contains the text "Save".
- Bottom status bar**: Shows icons for a square grid, RD, 14:51, 04-17-2019, and a USB port.

13.2.3. Liquid Pressure Calibration

Click “Liquid Pressure”, first input 0 into the “Meter measurement value” box to view the machine measurement value, and then input the opposite value of the machine measurement value into the “Meter measurement value” box to make the machine measurement value close to 0, and then click “Save”.



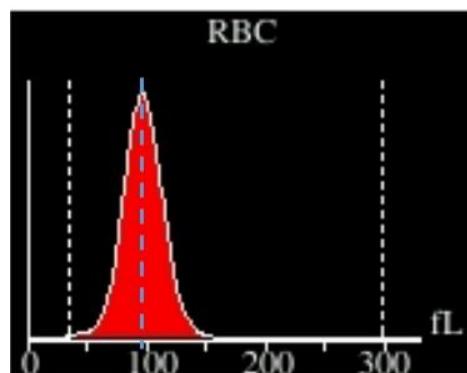
13.3. HGB Blank Voltage Setup

- 1) Before setting the HGB blank voltage, prime the liquid system Ensure that the fluid path and the WBC bath priming are normal.
- 2) Press the “” button and select “Setup” → “Gain Setup”, click the HGB “Set Value” box and input the value to adjust the blank voltage to be within $4.5 \pm 0.1V$.



13.4. RBC Gain Setup

- 1) Prepare a control with normal value. Keep it at room temperature for 15 minutes after taking out from the refrigerator, and then mix it well by back and forth rubbing the collection tube with both hands.
- 2) Present the control to the sample probe. Press the aspirate key to start analysis.
- 3) After the analysis, check the abscissa value corresponding to the crest of the RBC histogram with a ruler, which should be close to the target value of the control MCV.



- 4) In the gain setup interface, set the RBC gain value and run the QC analysis again. Repeat the above operations until the peak value is close to the target value of the control.

The screenshot shows the "Gain Setup" interface of the Linear software. The top navigation bar includes "Sample Analysis", "Review", "QC", "Reagent Setup", "Diluent", and "Print".

Gain Setup

| Gain Factor(%) | |
|----------------|-----|
| LAS | 255 |
| MAS | 255 |
| WAS | 255 |
| Width | 75 |

| RBC | Set Value | Blank Voltage |
|-----|-----------|---------------|
| RBC | 4 | / |
| HGB | 9 | 4.43 |

Compensation Step of Motor

| | | |
|--------------------|----|---|
| X Motor CW To RBC | 22 | W |
| X Motor CCW To RBC | 70 | W |
| X Motor To WBC | 20 | W |
| X Motor To START | 0 | W |
| Y Motor To START | 0 | W |

Reagent Gain Settings[0,100]

| | | |
|-----------|----|---|
| Diluent | 10 | W |
| DIFF Lyse | 1 | W |
| LH Lyse | 1 | W |

Bottom status bar: RD, 12:40, 05-08-2019, USB

13.5. WBC Gain Setup

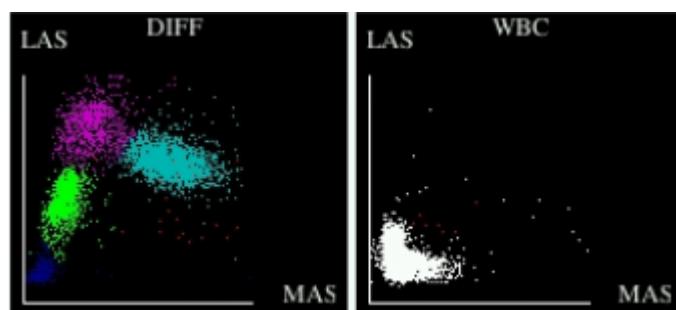
- 1) Select the sample according to the range of the table below. Test samples under the "Whole Blood-CBC+DIFF" mode.

| Paramter | Range |
|----------|--|
| WBC | $4.0 \times 10^9/L \sim 15.0 \times 10^9/L$ |
| Neu% | 50.0% ~ 70.0% |
| Lym% | 20.0% ~ 40.0% |
| Mon% | 5.0% ~ 10.0% |
| Eos% | 2.0% ~ 5.0% |
| Bas% | 0.5% ~ 1.5% |
| RBC | $3.50 \times 10^{12}/L \sim 6.00 \times 10^{12}/L$ |
| HGB | 110g/L ~ 180g/L |
| MCV | 70fL ~ 120fL |
| PLT | $150 \times 10^9/L \sim 500 \times 10^9/L$ |

- 2) After the test is completed, check the differential scattergram in the main interface. It is best that the graph occupies 3/4 of the entire range. If the graph is out of the boundary, decrease the corresponding gain factor, e.g. adjust the gain factor of LAS appropriately if beyond the LAS boundary. If the graph occupies less than 3/4 of the entire range, increase the gain factor. If the graph huddled and scattergram classification is not obvious, re-debug the optical system.



Optical gain setup



14. Commissioning and Verification after Servicing

| Part Name | Commissioning Requirements after replacement | Confirmation |
|--------------------------------------|---|--|
| Main control board assembly | Check the corresponding version information from the "Version Info." screen | Version information is correct |
| Core board | Check the corresponding version information from the "Version Info." screen | Kernel version information is correct |
| Signal board assembly | Check the corresponding version information from the "Version Info." screen | Software version information is correct |
| Driver board assembly | Check the corresponding version information from the "Version Info." screen | Software version information is correct |
| SD card application component (16GB) | 1. Backup the data before replacing the SD card (if possible). 2. Restore the configuration data. | Software version information is correct |
| 2+2 syringe linkage | Check the lyse syringe and diluent syringe in the System Self-test screen. | No failure |
| Sampling assembly | 1. Move the sampling assembly horizontally and vertically to ensure that the sampling line is unobstructed with no folding and interference with the preamplifier, fluidics separator. 2. Ensure that the sample tube is not squeezed or deformed at the line straps. 3. Ensure that there is no folding or interference when the sample probe wash set | 1. Sampling assembly self-test is fault free. 2. Reproducibility qualified. |
| Sample probe wash set | | |
| Sample probe | | |

| Part Name | Commissioning Requirements after replacement | Confirmation |
|-------------------------------|--|--|
| | <p>fluid line is moving horizontally or vertically in the sampling assembly.</p> <p>4. The orientation of the aspiration hole of the sample probe must be correct.</p> <p>5. Commissioning of the position between the sample probe and the WBC/RBC bath</p> <p>6. Recalibration</p> | |
| RBC counting pool module | <p>1. Commissioning of the position between the sample probe and the bath.</p> <p>2. The waste tube of the bath needs to be wrapped in the vertical direction and cannot be folded.</p> <p>3. Perform RBC gain calibration</p> <p>4 Recalibration</p> | Reproducibility qualified. |
| WBC counting pool module | <p>1. Commissioning of the position between the sample probe and the bath.</p> <p>2. The waste tube of the bath needs to be wrapped in the vertical direction and cannot be folded.</p> <p>3. Perform HGB gain calibration</p> | <p>1. Reproducibility qualified.</p> <p>2. HGB background voltage is 4.5V.</p> |
| Vacuum chamber assembly | Check the vacuum value in the "Temp. & Pressure" interface | Verify that the baths can be correctly drained and the vacuum is in the normal range |
| Liquid pump | | |
| 2-way solenoid valve assembly | Check valve 1-16 in turn in the "Valve self-test" interface | <p>1. Verify that the orientation of the inlet/outlet is correct.</p> <p>2. The hose shall be fully inserted.</p> <p>3. Thick 50 tuebs</p> |
| 3-way solenoid valve assembly | | |
| 3-way solenoid | | |

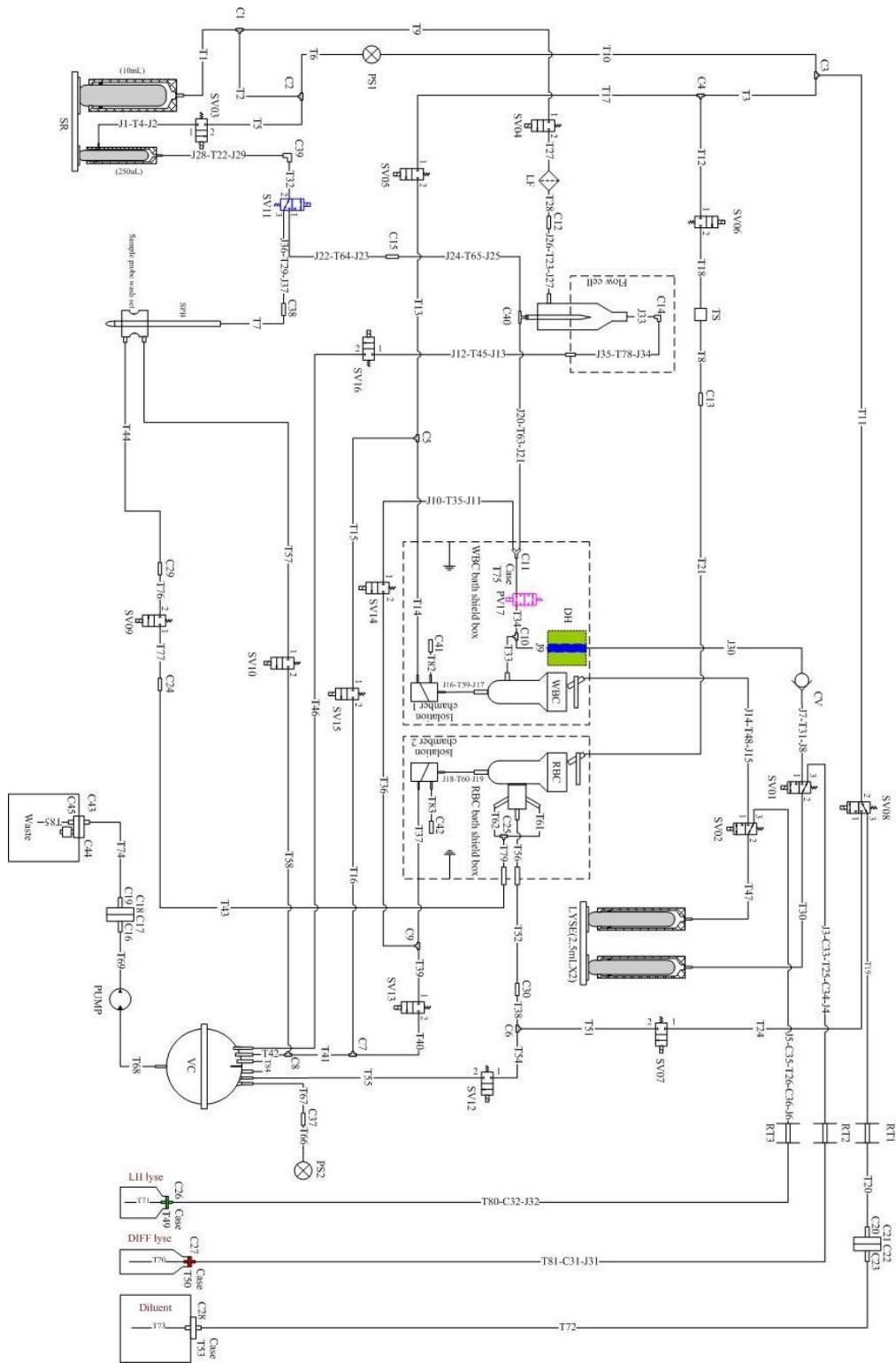
| Part Name | Commissioning Requirements after replacement | Confirmation |
|-------------------------------------|--|---|
| valve assembly (withstand voltage) | | cannot be used again after disconnected from valve ports or connectors. |
| TAKASAGO valve assembly | Check valve 17 in turn in the "Valve self-test" interface | 1. Verify that the pinch tube (T34) is properly positioned in the valve. 2. Cut T75 and put it on T34, between the pinch valve and the Y-type connector. |
| Touch screen | Perform touch screen calibration | Verify normal operations of the touch screen |
| Display screen | / | Can display properly |
| Inverter | | |
| Reagent preheating assembly | 1. The hose shall be fully inserted. The black silicone tube must be inserted into the bottom of the straight tube. 2. Use a thermometer to measure the component temperature in the "Temp. & Pressure Calibration" interface, and then perform temperature compensation. | Verify the temperatures are within the ranges from the "Status" interface |
| Diluent temperature sensor assembly | Use a thermometer to measure the ambient temperature in the "Temp. & Pressure Calibration" interface, and then perform temperature compensation. | Verify the temperatures are within the ranges from the "Status" interface |
| Button battery CR2032\3.0V\Φ20 | Set time and date in the "Date/Time Setup" interface. Save the settings and restart the analyzer. | After startup, the date remains the same |
| Fan NMB\60*60*25 | / | Verify if the fan rotates |



| Part Name | Commissioning Requirements after replacement | Confirmation |
|-------------------------------|---|---|
| Switching power supply | Check the power supply output voltage before the instrument is powered on | The voltage is normal |
| Power filter | / | Startup normally |
| Filter | / | Performance test passed |
| Optical system assembly | / | The standard particle test is qualified or the scattergram is normal. |
| Photoelectric sensor assembly | Check the sensor blocking status in the "Status - Sensor" interface. | Check if it is blocked according to the fluidic priming state. |
| Microswitch assembly | / | 1. The [Aspirate] key is working properly. 2. Optical system alarm. |
| Indicator board assembly | / | The indicator is displayed normally. |
| Analyzer tubes | / | See Section 7.5.4 Precautions for Assembly and Service in the service manual. |

15. Appendix

15.1. Appendix A Fluidic Diagram



15.2. Appendix B Connection and Tube

| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|-----------------------|-----------------------|--------------------------------|---------------------------------|
| 1 | Syringe | SR&LYSE(2.5mLx2) | 2+2 syringe linkage | E1&E2 |
| 2 | Flow cell | Flow cell assembly | Flow cell assembly | C2&C3 |
| 3 | WBC bath | WBC | WBC counting pool assembly | C5 |
| 4 | RBC bath | RBC | RBC counting pool assembly | C5 |
| 5 | Vacuum chamber | VC | Vacuum chamber assembly | E6 |
| 6 | Liquid pump | PUMP | Liquid pump assembly | E6 |
| 7 | Sample probe | SPB | Sample probe | E5 |
| 8 | Sample probe wash set | Sample probe wash set | Sample probe wash set assembly | E5 |
| 9 | Isolation chamber | Isolation chamber 1 | Isolator (without strainer) | C5 |
| 10 | Isolation chamber | Isolation chamber 2 | Isolator (without strainer) | C5 |
| 11 | Solenoid valve | SV01 | 3-way solenoid valve assembly | B5 |
| 12 | Solenoid valve | SV02 | 3-way solenoid valve assembly | B5 |
| 13 | Solenoid valve | SV03 | 2-way solenoid valve assembly | E2 |
| 14 | Solenoid valve | SV04 | 2-way solenoid valve assembly | C2 |
| 15 | Solenoid valve | SV05 | 2-way solenoid valve assembly | D2 |
| 16 | Solenoid valve | SV06 | 2-way solenoid valve assembly | B2 |
| 17 | Solenoid valve | SV07 | 2-way solenoid valve assembly | B6 |
| 18 | Solenoid valve | SV08 | 2-way solenoid valve assembly | A5 |
| 19 | Solenoid valve | SV09 | 2-way solenoid valve assembly | E4 |
| 20 | Solenoid valve | SV10 | 2-way solenoid valve assembly | D4 |
| 21 | Solenoid valve | SV11 | 3-way solenoid valve assembly | D2 |

| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|-----------------|---------------------|--|---------------------------------|
| 22 | Solenoid valve | SV12 | 2-way solenoid valve assembly | C7 |
| 23 | Solenoid valve | SV13 | 2-way solenoid valve assembly | D6 |
| 24 | Solenoid valve | SV14 | 2-way solenoid valve assembly | D4 |
| 25 | Solenoid valve | SV15 | 2-way solenoid valve assembly | D5 |
| 26 | Solenoid valve | SV16 | 2-way solenoid valve assembly | D3 |
| 27 | Pinch valve | PV17 | Pinch valve assembly | C4 |
| 28 | Pressure sensor | PS1 | Hydraulic pressure sensor | D1 |
| 29 | Pressure sensor | PS2 | Air pressure sensor | D7 |
| 30 | Preheat bath | DH | Reagent preheating assembly | B4 |
| 31 | Check valve | CV | Check valve | B5 |
| 32 | Sensor | TS | Diluent temperature sensor assembly | B3 |
| 33 | Filter | LF | Filter, AP19FV0012P1P\ϕ3.2-ϕ3.2\cpc | C2 |
| 34 | Reagent test | RT1 | Reagent detector | A7 |
| 35 | Reagent test | RT2 | Reagent detector | B7 |
| 36 | Reagent test | RT3 | Reagent detector | B7 |
| 49 | Tube | T1 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | E1 |
| 50 | Tube | T2 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | D1 |
| 51 | Tube | T3 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | C1 |
| 52 | Tube | T4 | Teflon tube, ⌀ 1.02× ⌀ 1.68, white | E1 |
| 53 | Tube | T5 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | D2 |
| 54 | Tube | T6 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | D1 |
| 55 | Tube | T7 | Tube, ID1.6XOD3.2, EVA, colorless and transparent | D2 |
| 56 | Tube | T8 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | B3 |
| 57 | Tube | T9 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | D1 |



| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|---|---------------------------------|
| 58 | Tube | T10 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | D1 |
| 59 | Tube | T11 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | D2 |
| 60 | Tube | T12 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | B2 |
| 61 | Tube | T13 | Polyurethane tube, ⌀ 2.4x ⌀ 4.0\ Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D3 |
| 62 | Tube | T14 | Polyurethane tube, ⌀ 2.4x ⌀ 4.0\ Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D4 |
| 63 | Tube | T15 | Polyurethane tube, ⌀ 2.4x ⌀ 4.0\ Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D4 |
| 64 | Tube | T16 | Polyurethane tube, ⌀ 2.4x ⌀ 4.0\ Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D5 |
| 65 | Tube | T17 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | A3 |
| 66 | Tube | T18 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | B2 |
| 67 | Tube | T19 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | A6 |
| 68 | Tube | T20 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | A7 |
| 69 | Tube | T21 | TPU tube, ID2.0XOD3.5, colorless and transparent | B4 |
| 70 | Tube | T22 | Tube, PTFE, 0.066"IDX0.098"OD | D2 |
| 71 | Tube | T23 | Tube, PTFE, 0.066"IDX0.098"OD | C2 |
| 72 | Tube | T24 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | B6 |
| 73 | Tube | T25 | Tube, EVA tube, ID1.6XOD3.2, colorless and transparent | A6 |
| 74 | Tube | T26 | Tube, EVA tube, ID1.6XOD3.2, colorless and transparent | B6 |
| 75 | Tube | T27 | Tube, 3.2TPU tube, ID1/8"XOD1/4", colorless and transparent | C2 |
| 76 | Tube | T28 | Tube, 3.2TPU tube, ID1/8"XOD1/4", colorless and transparent | C2 |
| 77 | Tube | T29 | Tube, PTFE, 0.066"IDX0.098"OD | D2 |
| 78 | Tube | T30 | Transit tube, 1/16"X3/16", F-5500-A, Fluran | B6 |
| 79 | Tube | T31 | Tube, PTFE, 0.066"IDX0.098"OD | A5 |



| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|--|---------------------------------|
| 80 | Tube | T32 | Tube, ID2.0XOD3.5, TPU, colorless and transparent | D2 |
| 81 | Tube | T33 | Small silicone tube, $\frac{3}{8}$ "x $\frac{1}{4}$ "\white | C4 |
| 82 | Tube | T34 | White pinch tube, silica gel\Pure-Fit SPT-6oL\1.6X3.2mm | C4 |
| 83 | Tube | T35 | Teflon tube, $\frac{1}{4}$ "x $\frac{1}{2}$ "\white | C4 |
| 84 | Tube | T36 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D5 |
| 85 | Tube | T37 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D5 |
| 86 | Tube | T38 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | C6 |
| 87 | Tube | T39 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D6 |
| 88 | Tube | T40 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D6 |
| 89 | Tube | T41 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D6 |
| 90 | Tube | T42 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D6 |
| 91 | Tube | T43 | Polyurethane tube, $\frac{1}{4}$ "x $\frac{7}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | E6 |
| 92 | Tube | T44 | Polyurethane tube, $\frac{1}{4}$ "x $\frac{7}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | E3 |
| 93 | Tube | T45 | Tube, PTFE, 0.066"IDX0.098"OD | C3 |
| 94 | Tube | T46 | Polyurethane tube, $\frac{3}{8}$ "x $\frac{5}{8}$ "\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D4 |
| 95 | Tube | T47 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | B6 |
| 96 | Tube | T48 | Tube, PTFE, 0.066"IDX0.098"OD | B5 |
| 97 | Tube | T49 | Hose, $\frac{1}{2}$ "x $\frac{1}{2}$ "\colorless and transparent\Saint-Gobain ACF02007 TYGON E-3603 ID1/8"\xOD1/4" | E7 |
| 98 | Tube | T50 | Hose, $\frac{1}{2}$ "x $\frac{1}{2}$ "\colorless and transparent\Saint-Gobain ACF02007 | E7 |



| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|--|---------------------------------|
| | | | TYGON E-3603 ID1/8"×OD1/4" | |
| 99 | Tube | T51 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 4.0\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | C6 |
| 100 | Tube | T52 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 3.2\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | C6 |
| 101 | Tube | T53 | Hose, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 3.2\colorless and transparent\ Saint-Gobain ACF02007 TYGON E-3603 ID1/8"×OD1/4" | E8 |
| 102 | Tube | T54 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 4.0\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | C6 |
| 103 | Tube | T55 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 4.0\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D6 |
| 104 | Tube | T56 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 3.2\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | C5 |
| 105 | Tube | T57 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 4.0\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D3 |
| 106 | Tube | T58 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 4.0\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D5 |
| 107 | Tube | T59 | Tube, PTFE, 0.066"IDX0.098"OD | C4 |
| 108 | Tube | T60 | Tube, PTFE, 0.066"IDX0.098"OD | C5 |
| 109 | Tube | T61 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 3.2\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | C5 |
| 110 | Tube | T62 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 3.2\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | C5 |
| 111 | Tube | T63 | Teflon tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD | C3 |
| 112 | Tube | T64 | Tube, PTFE, 0.066"IDX0.098"OD | D2 |
| 113 | Tube | T65 | Teflon tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD | C2 |
| 114 | Tube | T66 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 3.2\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | D7 |
| 115 | Tube | T67 | Polyurethane tube, $\frac{1}{8}$ " ID × $\frac{1}{4}$ " OD 3.2\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | D7 |
| 116 | Tube | T68 | 3.2TPU tube, ID1/8"XOD1/4", colorless and transparent | E6 |
| 117 | Tube | T69 | 3.2TPU tube, ID1/8"XOD1/4", colorless | E6 |

| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|---|---------------------------------|
| | | | and transparent | |
| 118 | Hard tube | T70 | PP tube, $\varnothing 3.2 \times \varnothing 5.2$ \colorless and transparent\hard tube | E7 |
| 119 | Hard tube | T71 | PP tube, $\varnothing 3.2 \times \varnothing 5.2$ \colorless and transparent\hard tube | E7 |
| 120 | Tube | T72 | 2.4TPU tube, ID3/32" XOD3/16", colorless and transparent | C8 |
| 121 | Hard tube | T73 | PP tube, $\varnothing 3.2 \times \varnothing 5.2$ \colorless and transparent\hard tube | E8 |
| 122 | Tube | T74 | 3.2TPU tube, ID1/8"XOD1/4", colorless and transparent | E5 |
| 123 | Tube | T75 | Hose, $\varnothing 3.2 \times \varnothing 6.4$ \colorless and transparent\Saint-Gobain ACF02007 TYGON E-3603 ID1/8"×OD1/4" | C4 |
| 124 | Tube | T76 | Polyurethane tube, $\varnothing 2.4 \times \varnothing 4.0$ \Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | E4 |
| 125 | Tube | T77 | Polyurethane tube, $\varnothing 2.4 \times \varnothing 4.0$ \Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | E4 |
| 126 | Tube | T78 | Teflon tube, $\varnothing 1.02 \times \varnothing 1.68$ \white | B3 |
| 127 | Tube | T79 | Polyurethane tube, $\varnothing 1.6 \times \varnothing 3.2$ \Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02002 | C5 |
| 128 | Tube | T80 | Tube, ID1.6XOD3.2, EVA, colorless and transparent | C7 |
| 129 | Tube | T81 | Tube, ID1.6XOD3.2, EVA, colorless and transparent | C7 |
| 130 | Tube | T82 | Polyurethane tube, $\varnothing 2.4 \times \varnothing 4.0$ \Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D4 |
| 131 | Tube | T83 | Polyurethane tube, $\varnothing 2.4 \times \varnothing 4.0$ \Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D5 |
| 132 | Tube | T84 | Polyurethane tube, $\varnothing 2.4 \times \varnothing 4.0$ \Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | D6 |
| 133 | Tube | T85 | Tube, 3.2TPU tube, ID1/8"XOD1/4", colorless and transparent | E5 |
| 166 | Transit tube | J1 | Silicone tube, ID0.8mm×OD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | E1 |
| 167 | Transit tube | J2 | Silicone tube, ID0.8mm×OD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | E1 |
| 168 | Transit tube | J3 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | A6 |

| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|--|---------------------------------|
| 169 | Transit tube | J4 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | A6 |
| 170 | Transit tube | J5 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | B6 |
| 171 | Transit tube | J6 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | B6 |
| 172 | Transit tube | J7 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | A5 |
| 173 | Transit tube | J8 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | A5 |
| 174 | Transit tube | J9 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | C4 |
| 175 | Transit tube | J10 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C4 |
| 176 | Transit tube | J11 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C4 |
| 177 | Transit tube | J12 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | C3 |
| 178 | Transit tube | J13 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | C3 |
| 179 | Transit tube | J14 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | B5 |
| 180 | Transit tube | J15 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | B5 |
| 181 | Transit tube | J16 | Polyurethane tube, ⌀ 2.4x ⌀ 4.0\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | C4 |
| 182 | Transit tube | J17 | Silicone tube, 1/16"X3/16", TYGON 3350 | C4 |
| 183 | Transit tube | J18 | Polyurethane tube, ⌀ 2.4x ⌀ 4.0\Pvc\colorless and transparent\ Saint-Gobain TYGON ND-100-65 ADF02004 | C5 |
| 184 | Transit tube | J19 | Silicone tube, 1/16"X3/16", TYGON 3350 | C5 |
| 185 | Transit tube | J20 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C3 |
| 186 | Transit tube | J21 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C3 |
| 187 | Transit tube | J22 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | D2 |
| 188 | Transit tube | J23 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | D2 |
| 189 | Transit tube | J24 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C2 |
| 190 | Transit tube | J25 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C2 |



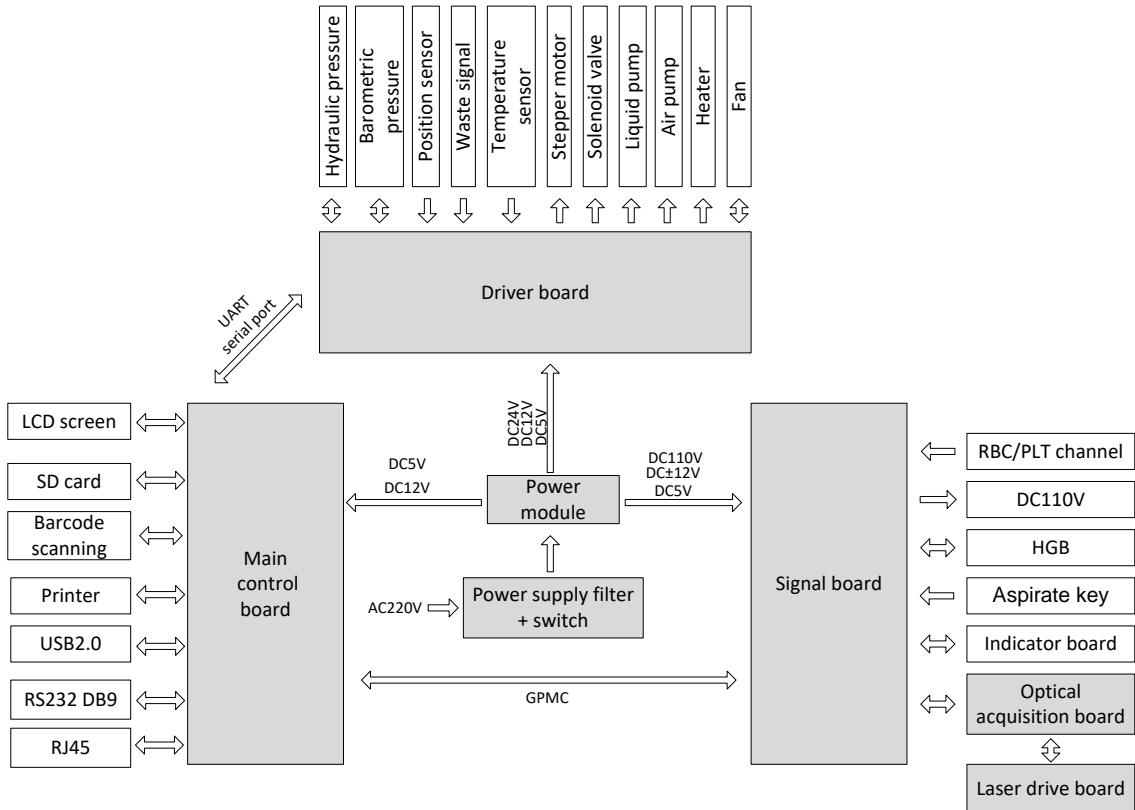
| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|---|---------------------------------|
| 191 | Transit tube | J26 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | C2 |
| 192 | Transit tube | J27 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | C2 |
| 193 | Transit tube | J28 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | E2 |
| 194 | Transit tube | J29 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | D2 |
| 195 | Transit tube | J30 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | B4 |
| 196 | Transit tube | J31 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | E7 |
| 197 | Transit tube | J32 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | E7 |
| 198 | Transit tube | J33 | Silicone tube, 1/16"X3/16", TYGON 3350 | B3 |
| 199 | Transit tube | J34 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C3 |
| 200 | Transit tube | J35 | Silicone tube, ID0.8mmxOD4mm\STHT-C-030-2\silica gel\white\Saint-Gobain | C3 |
| 201 | Transit tube | J36 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | D2 |
| 202 | Transit tube | J37 | Black transit tube, 1/16"X3/16", F-5500-A, Fluran | D2 |
| 209 | Connector | C1 | T-type tube connector, 3/32, nylon, white, T420-1 | D1 |
| 210 | Connector | C2 | T-type tube connector, 3/32, nylon, white, T420-1 | D1 |
| 211 | Connector | C3 | T-type tube connector, 3/32, nylon, white, T420-1 | C1 |
| 212 | Connector | C4 | T-type tube connector, 3/32, nylon, white, T420-1 | B1 |
| 213 | Connector | C5 | T-type tube connector, 3/32, nylon, white, T220-1 | C3 |
| 214 | Connector | C6 | T-type tube connector, 3/32, nylon, white, T220-1 | C6 |
| 215 | Connector | C7 | T-type tube connector, 3/32, nylon, white, T220-1 | D6 |
| 216 | Connector | C8 | T-type tube connector, 3/32, nylon, white, T220-1 | D6 |
| 217 | Connector | C9 | T-type tube connector, 3/32, nylon, white, T220-1 | D6 |
| 218 | Connector | C10 | T-type tube connector, 3/32, PVDF, colorless and transparent, T420-J1A | C4 |
| 219 | Connector | C11 | Y-type tube connector, 3/32, PVDF, | C4 |



| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|--|---------------------------------|
| | | | colorless and transparent, Y420-J1A | |
| 220 | Connector | C12 | Straight-through tube connector - large, medium, 1/8-3/32, nylon, white, N430-N420-1 | C2 |
| 221 | Connector | C13 | Straight-through tube connector, 3/32, nylon, white, N420-1 | C3 |
| 222 | Connector | C14 | L-type tube connector, 3/32, PVDF, colorless and transparent, L420-J1A | B3 |
| 223 | Connector | C15 | Straight-through tube connector, 3/32, PVDF, colorless and transparent, L420-J1A | D2 |
| 224 | Connector | C16 | Threaded tube connector, nylon\white\FTLLB230-1 | E6 |
| 225 | Connector | C17 | Threaded tube connector nut, 1/4-28UNF thread\nylon\white\LNS-1 | E6 |
| 226 | Connector | C18 | Threaded tube connector fixing cover, nylon\white\CCLR-1 | E6 |
| 227 | Connector | C19 | Threaded tube connector cap, nylon\white\MTLL230-1 | E6 |
| 228 | Connector | C20 | Threaded tube connector, nylon\white\FTLB220-1 | A7 |
| 229 | Connector | C21 | Threaded tube connector nut, 1/4-28UNF thread\nylon\green\LNS-4 | A7 |
| 230 | Connector | C22 | Threaded tube connector fixing cover, nylon\green\CCLR-4 | A7 |
| 231 | Connector | C23 | Threaded tube connector cap, 3/32\nylon\green\MTLL220-4 | A7 |
| 232 | Connector | C24 | Straight-through tube connector, 3/32, nylon, white, N420-1 | E4 |
| 233 | Connector | C25 | T-type tube connector, 3/32\nylon\white\T220-1 | C5 |
| 234 | Connector | C26 | Straight-through tube connector - large - small (AC-J1A), 1/8-1/16, PVDF, colorless and transparent | E7 |
| 235 | Connector | C27 | Straight-through tube connector - large - small (AC-J1A), 1/8-1/16, PVDF, colorless and transparent | E7 |
| 236 | Connector | C28 | Straight-through tube connector - large - medium (DC-1), 1/8-3/32, nylon, white | E8 |
| 237 | Connector | C29 | Straight-through tube connector, 3/32, nylon, white, N420-1 | E4 |
| 238 | Connector | C30 | Straight-through tube connector - medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | C6 |
| 239 | Connector | C31 | Straight-through tube connector - | C7 |

| No. | Material Type | Name in the Diagram | Name and Description | Position in the Fluidic Diagram |
|-----|---------------|---------------------|--|---------------------------------|
| | | | medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | |
| 240 | Connector | C32 | Straight-through tube connector - medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | C7 |
| 241 | Connector | C33 | Straight-through tube connector - medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | B6 |
| 242 | Connector | C34 | Straight-through tube connector - medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | B6 |
| 243 | Connector | C35 | Straight-through tube connector - medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | B6 |
| 244 | Connector | C36 | Straight-through tube connector - medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | B7 |
| 245 | Connector | C37 | Straight-through tube connector, 3/32, nylon, white, N420-1 | D7 |
| 246 | Connector | C38 | Straight-through tube connector - medium - small, 3/32-1/16, PVDF, colorless and transparent, N420-410-J1A | D2 |
| 247 | Connector | C39 | L-type tube connector, 3/32, PVDF, colorless and transparent, L420-J1A | D2 |
| 248 | Connector | C40 | 3-way connector, SL2.4\L: 18, ID: 1.5, OD1: 2.35, OD2: 3.0 | C3 |
| 249 | Connector | C41 | Tube connector, 2.4 plug, ID3/32, nylon, white, PIP220-1 | D4 |
| 250 | Connector | C42 | Tube connector, 2.4 plug, ID3/32, nylon, white, PIP220-1 | D5 |
| 251 | Connector | C43 | Connector, PMS230-6005 (Φ 3.2- Φ 3.2), transparent PP, for 1/4-28UNF thread | E5 |
| 252 | Connector | C44 | Threaded tube connector fixing cover, nylon\white\CLLR-1 | E5 |
| 253 | Connector | C45 | Threaded tube connector nut, 1/4-28UNF thread\nylon\white\LNS-1 | E5 |

15.3. Appendix C Hardware Block Diagram





15.4. Appendix D Commissioning and Verification Form

| Product Model | | | Serial Number | | |
|---------------|--|---|--|--|--|
| No. | Inspection Item | Description | Requirement | Result | Conclusion |
| 1 | Electrical connection | Power cable connection | Refer to related graphic files in the appendix | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 2 | Indicator color | Color | Red indicates problems, green indicates OK | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 3 | Indicator sound | Sound | Alarms when problems exist | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 4 | Touchscreen | Touchscreen calibration | Touchscreen calibration completed | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 5 | Time and date | Enter time and date | The date and time are entered correctly | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 6 | Version | Version and configuration information | Is the latest version | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 7 | Syringe and sampling mechanism self-test | Syringe and sampling mechanism self-test | Normal operation | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 8 | Valves self-test | Valves | Normal operation | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 9 | Fan self-test | Fan | Normal operation | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 10 | Mechanical position adjustment | Adjustment of the relative position between the sample probe and the WBC bath | Refer to Mechanical position adjustment | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 11 | Mechanical position adjustment | Adjustment of the relative position between the sample probe and the RBC bath | Refer to Mechanical position adjustment | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |



| Product Model | | | Serial Number | | |
|---------------|------------------------------|--|---------------------------|--|--|
| No. | Inspection Item | Description | Requirement | Result | Conclusion |
| 12 | Pressure verification | Vacuum pressure | Pressure within the range | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 13 | Temperature calibration | Preheat bath temperature calibration | Machine measurement value | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 14 | Temperature calibration | Preheat bath temperature calibration | FRU value | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 15 | Temperature calibration | Preheat bath temperature calibration | Total difference | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 16 | Counting channel measurement | Bubbles in the sample tube or not | No bubbles | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 17 | Counting channel measurement | Fluid residue on the sample probe | No residue | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 18 | Counting channel measurement | The sample probe is below the liquid level and has no contact with the counting pool | Normal down position | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 19 | Counting channel measurement | Bubbles in the sample supple tube or not | No bubbles | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 20 | Counting channel measurement | Bubbles in the WBC bath or not | Bubbles in the WBC bath | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 21 | Counting channel measurement | Bubbles in the RBC bath or not | Bubbles in the RBC bath | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 22 | Counting channel measurement | Aperture voltage | [16, 21]V | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 23 | Counting channel measurement | Splash when WBC bubbling? Bubbles on filling tube? | No splash and no contact | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 24 | Counting channel measurement | Splash when RBC bubbling? Bubbles on filling tube? | No splash and no contact | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 25 | Counting channel measurement | WBC bath can be drained correctly or | Drained correctly | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |



| Product Model | | | Serial Number | | |
|---------------|---|--|--|--|--|
| No. | Inspection Item | Description | Requirement | Result | Conclusion |
| | | not | | | |
| 26 | Counting channel measurement | RBC bath can be drained correctly or not | Drained correctly | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 27 | Counting channel measurement | WBC bath wall | No residue | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 28 | Counting channel measurement | RBC bath wall | No residue | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 29 | Counting channel measurement | Counting pool shield box installation | Screws tightened | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 30 | Counting channel measurement | Sample probe movement | Sample probe moves with no interference | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 31 | Counting channel measurement | Sample probe tube | Sample probe tube does not interfere with other structures | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 32 | Maintenance | Perform maintenance and cleaning | Refer to the Operation Manual | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 33 | Counting pool voltage measurement and setup | RBC aperture voltage | [16, 21]V | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 34 | Analyzer status verification - count | RBC | $\leq 0.02 \times 10^{12}/L$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 35 | Analyzer status verification - count | HGB | $\leq 1g/L$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 36 | Analyzer status verification - count | HCT | $\leq 0.5\%$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 37 | Analyzer status verification - count | PLT | $\leq 10 \times 10^9/L$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 38 | Optical system | Connect the optical | Refer to the service | <input type="checkbox"/> OK | <input type="checkbox"/> PASS |



| Product Model | | | Serial Number | | |
|---------------|--|---|--------------------------------|-----------------------------|--|
| No. | Inspection Item | Description | Requirement | Result | Conclusion |
| | tube connection | tubes and prime fluids | instructions | <input type="checkbox"/> NG | <input type="checkbox"/> FAIL |
| 39 | Analyzer voltage | Constant current source voltage (directly measured) | [55.0, 65.0]V | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 40 | Analyzer voltage | LAS background voltage | [0, 1.5]V | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 41 | Background test | WBC | $\leq 0.2 \times 10^9 / L$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 42 | Background test | RBC | $\leq 0.02 \times 10^{12} / L$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 43 | Background test | HGB | $\leq 1 g/L$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 44 | Background test | HCT | $\leq 0.5\%$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 45 | Background test | PLT | $\leq 10 \times 10^9 / L$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 46 | Standard particle graphic parameter test | Total LAS | 1500~3000 | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 47 | Standard particle graphic parameter test | LAS CG | 38~42 | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 48 | Standard particle graphic parameter test | LAS CV | $\leq 6.50\%$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 49 | Standard particle graphic parameter test | Total MAS | 1500~3000 | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 50 | Standard particle graphic parameter test | MAS CG | 107~158 | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 51 | Standard particle graphic parameter test | MAS CV | $\leq 3.0\%$ | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 52 | Standard particle | Total WAS | 1500~3000 | | <input type="checkbox"/> PASS |



| Product Model | | | Serial Number | | |
|---------------|--|------------------|--------------------------|--|--|
| No. | Inspection Item | Description | Requirement | Result | Conclusion |
| | graphic parameter test | | | | <input type="checkbox"/> FAIL |
| 53 | Standard particle graphic parameter test | WAS CG | 135~220 | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 54 | Standard particle graphic parameter test | WAS CV | ≤8.0% | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 55 | Optical gain | LAS | N/A: Not applicable | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 56 | Optical gain | MAS | N/A: Not applicable | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 57 | Optical gain | WAS | N/A: Not applicable | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 58 | Optical gain | Width | N/A: Not applicable | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 59 | Impedance gain | RBC | N/A: Not applicable | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 60 | HGB gain | HGB | N/A: Not applicable | | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |
| 61 | Shutdown | Shutdown process | No fault or alarm occurs | <input type="checkbox"/> OK <input type="checkbox"/> NG | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL |