HB-7021
Automated Hematology Analyzer
Operation Manual
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How to use this manual

This manual contains general information on the use of equipment; this is information guidance to the new user to use instruments. Many users read brochures all over before their first use. You will learn about the characteristics of the instruments and methods of operation after you read the manual. You can use the directory to quickly find the necessary information in the course of day-to-day use.

The brochures include equipment operation, maintenance instructions and attention to issues, in order to maintain the performance of this equipment must be in accordance with the specification of the equipment to operate, maintain.

Practice in this manual:

[Warning] information that you should be aware of how to avoid the operator or others suffered injuries

[Cautions] information that you should be aware of how to avoid equipment damage and lead to unreliable results of the analysis
Appendix 1: Symbol note

 Equipotential

 Caution, Refer to random document

 Beware of electric shock

 Refer to manual

 In vitro diagnostic equipment
Chapter 1 Instrument Introduction

1.1 Function Introduction

The full name of the instrument is HB-7021 automated hematology analyzer (hereinafter referred to as equipment) is an automated hematology analyzer mainly used for clinical testing and analyzing multi-parameter of the tiny particles. Equipment will put blood sample, dilution, and the measurement, display screen and Recorder together.

Take the use of high-resolution display screen, 19 measured parameters and 3 histograms can be shown at the same time, and can be connected to the network, in order to achieve the real-time transmission of data. The use of advanced front-end data acquisition system can provide accurate and stable test data for Human peripheral blood and blood samples, to provide the necessary clinical diagnosis of reference.

1.2 Measurement Parameters

The instrument can make high-volume continuous measurement on human peripheral blood and blood samples, and shows 19 parameters of measurement data in Table 1-1. Machines can make analysis automatically of tested sample data. The histogram of WBC, RBC and platelet are given:

<table>
<thead>
<tr>
<th>English abbreviation</th>
<th>Chinese name</th>
<th>unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>total number of WBC</td>
<td>$10^9$ cells/L</td>
</tr>
<tr>
<td>LY#</td>
<td>Lymphocyte</td>
<td>$10^9$ cells/L</td>
</tr>
<tr>
<td>MO#</td>
<td>median cells</td>
<td>$10^9$ cells/L</td>
</tr>
<tr>
<td>GR#</td>
<td>Neutrophil</td>
<td>$10^9$ cells/L</td>
</tr>
<tr>
<td>LY%</td>
<td>Lymphocyte ratio</td>
<td>%</td>
</tr>
<tr>
<td>MO%</td>
<td>median cells ratio</td>
<td>%</td>
</tr>
<tr>
<td>GR%</td>
<td>Neutrophil ratio</td>
<td>%</td>
</tr>
<tr>
<td>RBC</td>
<td>total number of red blood cells</td>
<td>$10^{12}$ cells/L</td>
</tr>
<tr>
<td>HGB</td>
<td>Hemoglobin</td>
<td>g/L</td>
</tr>
<tr>
<td>HCT</td>
<td>Hematocrit</td>
<td>%</td>
</tr>
<tr>
<td>MCV</td>
<td>MCV</td>
<td>fL</td>
</tr>
<tr>
<td>MCH</td>
<td>The average haemoglobin content</td>
<td>pg</td>
</tr>
<tr>
<td>MCHC</td>
<td>The average concentration of hemoglobin</td>
<td>g/L</td>
</tr>
<tr>
<td>RDW-CV</td>
<td>the coefficient of variation of RBC distribution width</td>
<td>%</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------------------------------------------</td>
<td>----</td>
</tr>
<tr>
<td>RDW-SD</td>
<td>standard deviation of RBC distribution width</td>
<td>fl</td>
</tr>
<tr>
<td>PLT</td>
<td>total number of platelets</td>
<td>$10^9$cells/L</td>
</tr>
<tr>
<td>MPV</td>
<td>The average size of platelet</td>
<td>fL</td>
</tr>
<tr>
<td>PDW</td>
<td>Platelet distribution width</td>
<td>fL</td>
</tr>
<tr>
<td>PCT</td>
<td>Platelet pressure plot</td>
<td>%</td>
</tr>
</tbody>
</table>

### 1.3 Instrument Front Panel

Structure of instrument front panel is as shown in Figure 1-1.

1. Work status indicators show that the power and state of the instrument: indicator light is on after the power equipment: Green: Equipment in a wait state, can count analysis. Orange: Equipment in the state of Analysis, then the user should wait for

2. Sampling needle collect measuring samples

3. RUN counting analysis starting button, press in analysis of blood cell and quality control operation window can do count and analysis, click in other window is invalid.

4. Printers print test results through the built-in thermal grapher recording meter

5. Keyboard

A total of 25 on the keyboard keys, its function is as follows:

0~9 the number keys: A digital input operation on instrument .KEY: can enter the decimal point when you input data

排堵： Enforcement 排堵 procedures
Printer: start recording Built-in devices to print the test results
Menu button: function menu button, menu function calls or out of the current selection and returned to the main window of the blood cells.
Dilution key: liquor drainage key, discharge dilute solution from the sample needle, mainly for the pre-diluted of the peripheral blood;
Delete key: delete the number and text messages
Cleaning key: the implementation of cleaning procedures
Enter key: Enter key, to confirm the content of choice
ESC: In any interface, you can click here to exit the current menu
Mode keys: working methods conversion keys, the whole blood and pre-dilution mode conversion
↑ ↓ ← → key: direction Key, you can move your cursor; select the menu or project you need.
7. Display screen
5.5-inch LCD screen for liquid crystal display screen is divided into four regions, as shown in Figure 1-2:
Figure 1-2

The district of the working status: show the "Please wait count" when counting, counting completed, show the counting time of WBC, RBC; when equipment failure, show fault alarm.

System time zone: showed that the current system date and time.

Current code area: showed that the ID number of the current testing results.

Results: show that the current test results, also give three histograms.

Model: shows that the current test mode.

Repeat: the implementation of retry, ID is not changed.

1.4 The Instrument Rear Panel

The instrument rear panel is as shown in Figure 1-3.

a. COM

Communications port to connect an external standard RS-232 network, connect external printers, and connect an external keyboard.

b. mains jack for connecting external power.

Power switch for turning on or off the power of equipment.
c. SENSOR waste water sensor interface to connect waste water sensors.
d. equipotential ground terminals, used to connect the grounding of the hospital and the system.

1.5 Equipment Components

Instrument includes host, stylus printer (optional) and reagents three major components.

1.5.1 Host

Completion of the blood sample collection and the whole process of analysis, automatically displays test results after counting on the LCD screen. Host mainly includes the following components:

1.5.1.1 A / D and the Central Board

Central board is the control center of equipment, it controls the following parts:
The switch of liquid solenoid valve, the suction and perfusion of reagent, and the discharging of the waste.
The operation force pump and vacuum air pump provide the motion for suction and perfusion.
The control of the stepper motor is for inhalation and dilution of samples and adding reagents;
Control A /D transform of WBC, RBC/PLT, HGB, to provide front-end service for data processing; detect all of the actions of the photoelectric switch.

1.5.1.2 WBC Measurement Unit

WBC survey unit is composed of hard wares such as the signal collection plate, electroplate, mipor sensors, and liquid road.
Signal collection plate --- to provide a constant source for electrodes, will provide the collected pulse signal with amplification and processing to CPU Central Processing Unit.
Electrode --- WBC has two electrodes: one is internal, the other is external, the internal one is fixed in the internal of WBC probe, the external is fixed in the external, when the inner and outer electrodes immersed in the miscible liquid which is composed by diluents, constant flow source on electrode to form galvanic circle through Millipore sensors.
Millipore sensor --- WBC's Millipore sensors fixed in the front of the probe, its Millipore diameter is of 100 microns. To take a sample survey, the particle samples pass trough from the porous.
Road --- Use the negative pressure as the driving force, inhale the diluted liquid, fluid, washing liquor and test samples from their own containers to measuring pipe, and then discharge the measured waste liquid. In front of the WBC ;liquid road fixed the
hemolytic agent adding and blending part, through control of the stepper motor control board, join the appropriate amount of hemolytic agent in the WBC samples Cup, and then mix air by the compressed gas produced by the force pump.

1.5.1.3 RBC/PLT Measurement Unit

RBC / PLT survey unit is composed of hardwares such as the signal collection plate, electroplate micropor sensors, and liquid road:
Signal collection plate --- to provide a constant source for electrodes, will provide the collected pulse signal with amplification and processing to CPU Central Processing Unit.
Electrode --- RBC/PLT has two electrodes: one is internal, the other is external, the internal one is fixed in the internal of RBC/PLT probe, the external is fixed in the external, when the inner and outer electrodes immersed in the miscible liquid which is composed by diluents, constant flow source on electrode to form galvanic circle through Millipore sensors.
Millipore sensor --- RBC/PLT's Millipore sensors fixed in the front of the probe, its Millipore diameter is of 100 microns. To take a sample survey, the particle samples pass trough from the porous.
Road --- Use the negative pressure as the driving force; inhale the diluted liquid, fluid, washing liquor and test samples from their own containers to measuring pipe, and then discharge the measured waste liquid.

1.5.1.4 Tubing

Tubing is composed of solenoid pilot actuated valve, breaking valves, force pumps, vacuum pumps, and plastic piping: solenoid pilot actuated valve: the one with feeler microscope two-way or tee joint T to control the circulate of the liquid road.
Breaking valves --- control the flow of road by breaking the plastic tube; vacuum pump - inhale dilute solution in the fluid reservoir;
Liquor drainage pump ---- inhale the waste liquid by counting into waste liquor pail.
Force pump --- to provide positive pressure impetus for reverse washing and hemolytic blending.
Plastic tube - carrier of reagents, and the flow of waste water;
Vacuum chamber --- cause subpressure, and as a temporary waste water containers after sample test complete.

1.5.1.5 Display

HB-7021 adopts the display of 5.5-inch LCD liquid crystal display, can show 19 parameters and three histograms. Details, see § 1.3 "instrument front panel."

1.5.2 Reagents
In order to maintain the good performance of equipment, SINNOWA configuration on a special reagent for HB-7021. These reagents are took delivery inspection based on product standards and tested all the pre-qualified, the nominal metrics are obtained under the conditions that in the use of the reagents for HB-7021. Non-SINNOWA's reagent will affect the performance of equipment, lead a serious measurement error, and could lead to accidents. All reagents must be kept at room temperature in order to maintain the ideal chemical properties, in the preservation process should avoid the cold, overheating and direct sunlight, when the temperature is below 0 ℃, the reagent will be frozen, the chemical properties, electrical conductivity of reagents will be changed. In the process of the use, in order to minimize the evaporation of reagents, reduce pollution outside to the reagent, the reagent containers should be covered, the pipeline is put into reagents through the cover of container. However, the mass of reagents with the time passing will change, all reagents should be used in period of validity. when the reagent is replaced, can not pour unspent reagents into the new reagent barrels (bottles), prevent the new reagent from contamination.

1.5.2.1 Diluent

Dilute solution is a steady dilution of isotonic. To meet the test requirements as follows:

a) dilute WBC, RBC, PLT, HGB;
b) maintain cell shape in the process of measuring;
c) the provision of appropriate background values;
d) cleaning WBC, RBC sensor porous and fluid direction.

1.5.2.2 Lyse

Lyse solution is a new type of reagent without double nitrogen and cyanide. To meet the test requirements as follows:

a) quickly dissolve red blood cells, produce the matrix composites at least;
b) change the WBC epicyte, cytoplasm spread slowly, shrink the epicyte around the nucleus, WBC was granular.
c) Transformation of hemoglobin to form hemoglobin complex, suitable for testing under the optical wavelength of 540 nm;
d) non-cyanide, to avoid humans and the environment serious pollution

1.5.2.3 Detergent

Cleaning fluid contain active prolease conglomerate by albumen in pipeline, mainly used for WBC, RBC probe measuring cup and testing loop cleaning.
1.5.2.4 Probe Detergent

Probe cleaning fluid containing efficient oxides for cleaning equipment probe, mainly used for solution of WBC, RBC probe intractable plugging holes.

1.6 Sample Dosages

<table>
<thead>
<tr>
<th>Mode</th>
<th>Fluid Type</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>whole blood mode</td>
<td>whole blood (venous) blood</td>
<td>18ul</td>
</tr>
<tr>
<td>prediluted mode</td>
<td>distal blood</td>
<td>20ul</td>
</tr>
</tbody>
</table>

1.7 One-sample Reagent Dosage

<table>
<thead>
<tr>
<th>Component</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent</td>
<td>30ml</td>
</tr>
<tr>
<td>Washing liquid</td>
<td></td>
</tr>
<tr>
<td>Hemolytic solution</td>
<td>0.7ml</td>
</tr>
</tbody>
</table>

With different versions of the machines the amount of reagents will be changed.

1.8 Test Speed

The testing speed of this instrument is to about 60 / h.

1.9 Memory Capacity

Instrument equips with internal memory, can store not less than 200,000 samples test results.

1.10 Measurement Repeatability Error

Measurement repeatability error should be consistent with the requirements of Table 1-2.

<table>
<thead>
<tr>
<th>Measurement Project</th>
<th>Measuring repeatability error (CV/%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>≤2.0%</td>
</tr>
<tr>
<td>RBC</td>
<td>≤1.5%</td>
</tr>
<tr>
<td>HGB</td>
<td>≤1.5%</td>
</tr>
<tr>
<td>MCV</td>
<td>≤0.5%</td>
</tr>
<tr>
<td>PLT</td>
<td>≤5.0%</td>
</tr>
</tbody>
</table>

1.11 Accuracy

Measurements of WBC, RBC, PLT and HGB should be in the range of whole blood control standard value. The range of error should be consistent with the requirements of Table 1-3.

<table>
<thead>
<tr>
<th>Measurement Project</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td></td>
</tr>
<tr>
<td>RBC</td>
<td></td>
</tr>
<tr>
<td>HGB</td>
<td></td>
</tr>
<tr>
<td>MCV</td>
<td></td>
</tr>
<tr>
<td>PLT</td>
<td></td>
</tr>
<tr>
<td>Measurement Project</td>
<td>Measurement accuracy tolerances</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>WBC</td>
<td>≤±4%</td>
</tr>
<tr>
<td>RBC</td>
<td>≤±3%</td>
</tr>
<tr>
<td>HGB</td>
<td>≤±3%</td>
</tr>
<tr>
<td>MCV</td>
<td>≤±3%</td>
</tr>
<tr>
<td>PLT</td>
<td>≤±8%</td>
</tr>
</tbody>
</table>

1.12 Linear Range of Measurement

Linear measurement of equipment should meet the provisions of Table 1-4.

Table 1-4 linear range of test results requested

<table>
<thead>
<tr>
<th>Measurement Project</th>
<th>measuring range</th>
<th>Linear allow measurement error</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>0×10⁹/L ~ 6.0×10⁹/L</td>
<td>±0.3×10⁹/L</td>
</tr>
<tr>
<td></td>
<td>6.0×10⁹/L ~ 99.9×10⁹/L</td>
<td>±5%</td>
</tr>
<tr>
<td>RBC</td>
<td>0×10¹²/L ~ 0.99×10¹²/L</td>
<td>±0.05×10¹²/L</td>
</tr>
<tr>
<td></td>
<td>1.0×10¹² ~ 9.99×10¹²/L</td>
<td>±5%</td>
</tr>
<tr>
<td>HGB</td>
<td>0 g/L ~ 99 g/L</td>
<td>±2 g/L</td>
</tr>
<tr>
<td></td>
<td>100 g/L ~ 300 g/L</td>
<td>±2%</td>
</tr>
<tr>
<td>PLT</td>
<td>0×10⁹/L ~ 99×10⁹/L</td>
<td>±10×10⁹/L</td>
</tr>
<tr>
<td></td>
<td>100×10⁹/L ~ 999×10⁹/L</td>
<td>±10%</td>
</tr>
</tbody>
</table>

1.13 Storage and Transport Environment

a) the ambient temperature: -10 °C ~ 40 °C;
b) relative humidity: ≤ 80% RH;
c) atmospheric pressure: 80 kPa ~ 106kPa.

1.14 Using Environment

a) the ambient temperature: 18 °C ~ 35 °C;
b) relative humidity: ≤ 80% RH;
c) atmospheric pressure: 80 kPa ~ 106kPa.
1.15 Duration of Service

Instrument duration of service is five years, no more than eight years.

Chapter 2 Instruments Measuring Principle

This chapter introduces the measuring principle of HB-7021 automated hematology analyzer system. Equipment measures the amount and volume of blood cells by PLT-I, and hemoglobin content by flow method. Give the explanation of measuring parameters and method.

2.1 Measuring Principle

Measuring of instruments includes the amount of blood cells, the volume measurement and HGB measurement.

2.1.1 PLT-I Amount and Size of Blood Cell Measurement

Instruments used the classic method to measure cells and count. As shown in Figure 2-1, in the conductive liquid (mainly is dilute solution), provide constant current source to the electrode so that the circuit can form a steady impedance loop. When the cells through the porous, conductive fluid is replaced by cells, the circuit resistance changes, cause electrical pulse, when the cells of different size through the porous, their Vpp of electrical pulse are different, so that we can confirm the number and the volume of porous cells through the amount and Vpp of electrical pulse.
As the number of pulses is corresponding with the cells which pass through the porous, amplitude of pulse has the same size with the cells through the porous, instrument measures each of the cells, and make size classification in accordance with the size of them, equipment classify RBC, WBC and platelet in accordance with the software pre-classification procedure, usually classified according to the specific size of the following:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>35-450</td>
<td>fL</td>
</tr>
<tr>
<td>RBC</td>
<td>30-100</td>
<td>fL</td>
</tr>
<tr>
<td>PLT</td>
<td>2-30</td>
<td>fL</td>
</tr>
</tbody>
</table>

The WBC which is dealt with hemolytic agent can be divided into lymphocytes (LY), MO, neutrophilic granulocyte (GR) in accordance with its size, its interval of volume:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LY</td>
<td>35-98</td>
<td>fL</td>
</tr>
<tr>
<td>MO</td>
<td>98-135</td>
<td>fL</td>
</tr>
<tr>
<td>GR</td>
<td>135-450</td>
<td>fL</td>
</tr>
</tbody>
</table>

2.1.2 Flow Colorimetry Measurement HGB

When added to blood samples of hemolysis, hemolytic agents can quickly destroy the red blood cell membrane and combined with the hemoglobin as a complex which has an absorption characteristic of a wavelength of 540 nm, through the compare between the absorbance of dilution and the samples, the concentration of sample hemoglobin can be calculated.
2.2 Approach of Equipment Parameters Measuring

Parameters from blood sample test are composed of three forms: one is the direct parameters from the equipment measurement, such as the WBC, RBC, PLT, HGB, MCV; another is the parameters according to the histogram, such as LY%, MO%, GR%, HCT, RDW-CV, RDW-SD, MPV, PDW; the third is parameters derived from certain formula, such as LY #, MO #, GR #, MCH, MCHC, PCT.

Formula derivation is as follows:

\[ \text{HCT} \text{ (\%)} = \frac{\text{RBC} \times \text{MCV}}{10} \]

\[ \text{MCH} \text{ (pg)} = 10 \times \frac{\text{HGB}}{\text{RBC}} \]

\[ \text{MCHC} \text{ (g/L)} = 100 \times \frac{\text{HGB}}{\text{HCT}} \]

\[ \text{PCT} \text{ (\%)} = \frac{\text{PLT} \times \text{MPV}}{10} \]

\[ \text{LY} \text{ (\%)} = 100 \times \frac{\text{AL}}{\text{AL} + \text{AM} + \text{AG}} \]

\[ \text{MO} \text{ (\%)} = 100 \times \frac{\text{AM}}{\text{AL} + \text{AM} + \text{AG}} \]

\[ \text{GR} \text{ (\%)} = 100 \times \frac{\text{AG}}{\text{AL} + \text{AM} + \text{AG}} \]

Column diagram of WBC is as figure 2-2:

![Column diagram of WBC][1]

AL: cells quantity within the lymphatic region;
AM: cells quantity within the monocytes cells region between lymphocyte cells and granulocyte;
AG: cells quantity within the granulocyte region.

Calculation formula for absolute value of Lymphocyte LY #, monocyte MO #, granulocyte GR # as follows:
Lymphocyte (10^9/L) \( \text{LY#} = \text{LY\%} \times \text{WBC/100} \)

Monocyte (10^9/L) \( \text{MO#} = \text{MO\%} \times \text{WBC/100} \)

Granulocyte (10^9/L) \( \text{GR#} = \text{GR\%} \times \text{WBC/100} \)

RBC distribution width of the coefficient of variation (RDW-CV) is derived from red blood cells histogram, it said the volume of red blood cell volume distribution coefficient of variation, and the unit is %.

RBC distribution width of standard deviation (RDW-SD) is derived from red blood cells histogram, it said red blood cell changes in the size of standard deviation, and the unit is fL.

Platelet distribution width (PDW) is derived from the platelet histogram, it said the volume distribution of platelet groups.

### Chapter 3 Installation and Sample Analysis

To ensure that the performance equipment, achieved satisfactory clinical results, HB-7021 automated hematology analyzer must be installed and debugged by the engineers sent or authorized by SINNOWA for the first time, the equipment used mobile or off-site must in according with the installation process for installation and use.

CAUTION: Any unauthorized or without professional training of personnel for equipment installation may lead damage to equipment, such damage is not in the scope of the free warranty by SINNOWA. Personnel without SINNOWA authorize shall not install, off-site use this equipment.

#### 3.1 Check Box

a) Carefully takes the instrument and enclosure out from packing chest,  
b) Check the annex according with the packing list inventory  
c) check into whether there is an incoming-stream or water logging.  
d) check whether there were any mechanical defects.  
e) Check all the exposed wires, the inserted parts and annexes. If you have any questions please immediately contact the company customer service agent or the Department.

#### 3.2 Installation Requirements

Please refer to Chapter 10 of the brochure “precaution, restrict and harm” 10.2.

⚠️ WARNING: This equipment can not be used in the family.
WARNING: This equipment is not treatment equipment.

NOTE: The equipment should avoid direct sunlight.

NOTE: Equipment working environment should avoid the cold and over-heated.

NOTE: Equipment working environment should avoid centrifuges, X-ray machines, monitors, copiers, and those instruments interfere with the test results of the equipment.

NOTE: Do not use mobile phones, cordless phones near the equipment, and so too have the radiation field equipment. A strong radiation field would interfere with the normal work of equipment.

### 3.3 Power Supply Inspection

Before installing equipment, have to check whether the power ground of the instruments is be up to the mustard, power specific requirements are as follows.

- **Voltage**: AC220 (1 ± 10%) V
- **Frequency**: (50 ± 1) Hz

Warning: The grounding-line after the instrument board must be grounded by connecting directly with the ground. The user places the obligation to ensure that to protect the reliability of power supply.

NOTE: inspection before equipment connected to power to ensure that all electrical equipment connected is plugs right and reliable.

NOTE: the regular fluctuations in voltage would result in equipment performance and reliability of the reduction, the user should resolve this issue before use the instruments, such as the installation of the exchange regulator (to be equipped with their own users).

NOTE: frequent disruptions will lead to electricity equipment performance and reliability of the serious decrease, or even damage to equipment, users should use instruments to resolve this issue before, such as the installation of an uninterruptible power supply (UPS) (to be equipped with their own users).

### 3.4 Reagents Tubing Connection

The latter Host panel equipped of four road interface. Equipment manufacturers in order to prevent pollution in the pipe line interface, installed the pipeline plug, it should be disconnected from the interface in the first installation and carefully conserved.

#### 3.4.1 LYSE Tubing Connection

Removed from the reagent box with red joints of hemolysis (LYSE) catheters,
connectors connect with the road connecting latter host board labeled LYSE, the other end of catheter insert into the hemolytic bottle, and screw the cap of hemolytic bottle. Hemolysis bottle must be placed in the same plane with equipment.

3.4.2 Diluents Tubing Connection

Remove the DILUENT tube with blue faucet from reagent kit and attach it to the connector marked “DILUENT” on the rear panel. Place the other end into the DILUENT container. Twist the cap until secure. Place the container on the same level as the analyzer.

3.4.3 WASTE Tubing Connection

Remove the WASTE tube with black faucet from reagent kit and attach it to the connector marked “WASTE” on the rear panel, connect BNC plug with the socket marked “SENSOR” on the rear panel. Twist the tube’s cap clockwise onto the waste container until secure. Place the container on the level at least 50cm lower than the analyzer.

3.4.4 DETERGENT Tubing Connection

Remove the DETERGENT tube with yellow faucet from reagent kit and attach it to the connector marked “DETERGENT” on the rear panel. Place the other end into the DETERGENT container. Twist the cap until secure. Place the detergent container on the same level as the analyzer.

CAUTION:
Keep all the tubes loose and relaxed after installation, no contortion or folding.

CAUTION:
All the tubes should be installed manually, no not utilize any tool.

CAUTION:
If any damage or leakage occurs in the reagent container, or the reagents have exceeded expiry date, it can not be used online, please contact SINNOWA agency or suppliers for replacement, or contact with SINNOWA Customer Service.

WARNING:
The waste must be handled with biochemical or chemical methods before outlet to the drainage, or it will cause contamination to the environment. Hospital and laboratory have obligation to follow the environmental regulation of municipal government.
3.5 Recorder Paper Installation

Please refer to Section 9.3.11 of Chapter 9 “Troubleshooting”.

3.6 Printer Installation (such as equipment)

Remove the printer from the shipping carton along with the manual, according to Section3.1 to inspect the printer carefully and perform the following procedures:

a) Find a suitable location adjacent to the analyzer, the recommended position is a distance of at least 30cm from right side of the analyzer.
b) Assemble the printer attachments as directed in the printer manual.
c) Attach cable plug to the side with “PRINTER” label on rear panel of the analyzer, the other end connect to the printer.
d) Be sure that the printer power switch is OFF, and plug one side of power cord into electric outlet.
e) Install printing ribbon, cable as directed in the manual.
f) Install printing paper as directed in the manual.
g) Turn the printer on and begin the printer’s self-test.

NOTE:
Do first turn on printer, and then turn on the instrument.

3.7 Power Cord Connection

Make sure the power switch on the backboard is off (O), and connect the analyzer with the power supply. The earth device on the rear panel should be well grounded.

NOTE:
The power cord should be connected to the special electric outlet.

3.8 Startup

Turn on the power switch on the rear panel, then the indicator light on the front panel will become orange, the analyzer start initialization, and automatically absorb diluent, lyse and detergent, then rinse the tubing. The **Blood Cell Analyze window** appears after initialization (See Figure 3-1). Under this window, next sample number could be altered. Detailed as follows:

a) At the window as figure 3-1, shift ↑↓ to select “Serial-number”, print ENTER, window shown as figure 3-2 appears:
b) Shift ← → to adjust the position of cursor, input the serial number, press ENTER, then edit the patient’s data. Press ENTER, the serial number is altered successfully, and this serial number is that of next sample; if not want to alter serial number, select ESC, return to the Blood Cell Analyze window, current serial number plus 1 automatically is that of sample.

3.9 Background Test

Background test should be performed after startup and before blood sample test, the procedures are as follows:

a) Present clean tube beneath the probe. At Blood Cell Analyze window, press DILUENT to dispense the diluent into the tube.

b) Press FUNC in instrument surface, shift ↑ ↓, select “Serial number” menu, press ENTER to modify the serial number to 0.

c) Put the tube beneath the probe; make sure the probe touch tube bottom lightly.

d) Press Run key on the front panel, the tube can be moved away only after hearing “Di”, instrument start to counting and measure automatically.

e) After counting, background test result display on screen, the acceptable range of the testing result for background test is listed in Table 3-1

f) Instrument will give trouble alarm and display on top right corner when the
sensor clog, please consult Chapter 9 «Troubleshooting».

Table 3-1 the acceptable range of

<table>
<thead>
<tr>
<th>parameter</th>
<th>background</th>
<th>u</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>≤ 1</td>
<td></td>
</tr>
<tr>
<td>RBC</td>
<td>≤ 1</td>
<td></td>
</tr>
<tr>
<td>PLT</td>
<td>≤ 1</td>
<td></td>
</tr>
<tr>
<td>UCB</td>
<td>≤ 2</td>
<td></td>
</tr>
<tr>
<td>HCT</td>
<td>≤ 3%</td>
<td></td>
</tr>
</tbody>
</table>

If the test results are out of this range, repeat the above a) ~d) step until the test results are within the expected range. Refer to Chapter 9 for “Troubleshooting” if the results still do not meet performance expectation after 5 times’ repetition.

NOTE:
Serial number for background test is set to be 0 by the software. After set to 0, test result will not be stored.

NOTE:
The serial number for blood sample test can NOT be set to 0.
3.10 Quality Control

Quality control should be performed before daily test or on the initial installation. Please refer to Chapter 5 “Quality control”.

3.11 Calibration

SINNOWA measure the analyzer severely at the factory before shipment. On the initial installation, if the test results of background and quality control are normal, recalibration is not necessary. If not and there are shifts or trends in some parameters, recalibrate the analyzer referring to Chapter 6 “Calibration”.

3.12 Blood Sample Collection
CAUTION:
Consider all the clinical specimens, controls and calibrators etc, that probably contain human blood or serum as being potentially infectious, wear standard laboratory clothing, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.

CAUTION:
Blood collection and disposal should be performed according to the municipal government or laboratory’s requirements.

NOTE:
Be sure the blood collection clean and contamination-free. Eligible gelation inhibitor is required.

NOTE:
Do not shake the sampler violently.

NOTE:
Venous blood can only be stored for 4 hours at room temperature. SINNOWA recommends the blood sample be kept at temperature between 2-8°C for longer storage, if the blood sample can not be disposed within short time.

3.12.1 Venous (whole) Blood Collection

Collect venous (whole) blood sample through vein-puncture and store in a clean sample tube with EDTA-K2· 2H2O, which can keep the configuration of WBC, RBC and control platelets aggregation, gently shake the tube 5~10 times to make it well mixed.

3.12.2 Peripheral (pre-diluted ) Collection

Generally, local puncture is employed for the collection of peripheral blood the typical method of which is fingertip puncture. The volume of blood collection tub is set to be 20ul.

CAUTION:
Precision and repeatability of instrument except for related with reagent and instrument quality also largely with operating and clinical doctor’s quality.

CAUTION:
Never over extrude the site of puncture when collect blood sample by fingertip puncture, to avoid
the tissue fluid from mixing with blood, thus causes error in results.

CAUTION:
Must insure blood collection is 20ul when collect blood sample by fingertip puncture, to avoid incorrect results due to blood volume insufficient.

3.13 Switch between Whole Blood and Pre-diluted Blood

Mode appears in the instrument screen is current operational mode.
In case current operational mode is “whole blood” mode, press mode key in the keyboard will pop up follow figure 3-2.

<table>
<thead>
<tr>
<th>Switch to pre-diluted mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>OK</td>
</tr>
<tr>
<td>ESC</td>
</tr>
</tbody>
</table>

Figure 3-2

Shift ← → to select “OK”, press ENTER, instrument returns to the Blood Cell Analyze window, current operational mode switches to “pre-diluent” mode.
Method of switching from “pre-diluent” to “whole blood” mode is the same as stated above.

3.14 Blood Sample Counting and Analysis

3.14.1 Counting and Analysis Process

Blood sample counting and analysis should be quickly done after collection, suggest within 3-5 minutes.

- Pre-diluted Mode

a) Present the empty clean tube beneath the probe. At Blood Cell Analyze window, presses DILUENT; the diluent will be dispensed into the tube. Remove the tube.
b) Add 20ul blood sample in the constant volume blood collection tube to the prepared tub filled with diluent quickly, and gently shake the tube to make them well mixed.
c) Present the tube filled with blood sample under the probe (keep probe touch the tube bottom lightly). Press Run key on the front panel and the working status indicator becomes orange. Only remove the tube after buzzer gives “Di”.
d) Instrument starts analyzing the sample automatically, please wait for the result.
### whole blood mode

a) Gently shake the tube to well mix the blood sample, then present the sample tube under the probe (keep the probe at the bottom of tube). Press **Run** key and the working status indicator in the front panel become orange. Only remove the tube after buzzer gives “Di”.

b) Instrument starts analyzing the sample automatically, please wait for the result.

The test results will be displayed behind relevant parameter at the **Blood Cell Analyze Window** after counting and analysis, and relative size histograms of WBC, RBC and PLT will be drawn. (As Figure 3-1 shown).

If problems like clogs or bubbles occur during the counting and analysis procedures, the analysis will be stopped automatically, the alarm rings and indication is given on the screen, the test results are invalid. Troubleshooting please refer to Chapter 9 “Troubleshooting” for solution.

If the test results for parameters exceed the expected limits, an “L” or “H” will appear in front of the parameter which appears in the screen and is printed out. “L” means test result is lower than the lower limit while “H” means test result is higher than upper limit.

If test result is ****, indicates that this data is invalid.

**CAUTION:**
Insure correctly set work mode “whole blood” and “Pre-diluent” before counting, specific consult 3.13.

**CAUTION:**
Analyze in “Pre-diluent” mode, count the remaining sample again when necessary.

**CAUTION:**
Analyze in “Pre-diluent” mode, must use one-off tube and fix-capacity sample tube, reusage will cause cross contamination and lead to incorrect result.

**CAUTION:**
According to the requirement of clinical medicine, blood cell does not distort, work temperature for correct counting is 18 °C~35°C. Customer should take proper measure to keep this range to insure correct counting.

**CAUTION:**
To doubtful blood sample medically, artificial countercheck should be done according to relevant regulation.

### 3.14.2 Histogram Alarm Message

If some of the cells in the blood sample are immature, abnormal or untypical, the warning indication is given in the form of histogram after blood sample test. According to different abnormal situations, warning information such as R1, R2, R3, R4, RM and PM will be displayed in the right of the histograms.
3.14.2.1 WBC Histogram Alarm

When WBC histogram appears unusual, R1, R2, R3, R4, RM means respectively as follows:

① R1  ：It indicates that the left area of lymphocyte is abnormal.

Probable cause：RBC 溶血不全、血小板凝结、巨大血小板、疟原虫、有核红细胞、异常淋巴细胞、冷凝球蛋白及脂类颗粒等。
RBC not lysed thoroughly, platelets aggregated, huge platelets, plasmodiums, nucleolate RBC, abnormal lymphocytes, condensed globins and lipid particles, etc.

② R2 ：It indicates that the area between lymphocyte and monocyte is abnormal.

Probable cause ：原幼细胞 等存在。
Allotypic lymphocytes, abnormal lymphocytes, plasma cells, eosinophilic granulocyte increased basophilic granulocytes, blasts and so on.

③ R3：It indicates the area between monocyte and granular cell is abnormal.

Probable cause ：Immature granulocytes, abnormal cells, eosinophilic granulocyte exist.

④ R4 ：It indicates that the right area of granular cell is abnormal.

Probable cause ：Increased granular cells

⑤ RM ：It indicates that in the sub area of WBC, many areas except for above areas are abnormal.

Probable cause ：Above causes co-exist.

3.14.2.2 PLT Histogram Alarm

When PLT histogram appears unusual, Pm alarm will appear in its right. Pm specific meaning is:
Pm : It indicates that the broader area between platelet and RBC is abnormal.

Probable cause : The clotting of platelets, large platelets, small RBC, cell debris and fibrin exist.

3.15 Report Output

Inner thermal recorder and the outer printer are optional according to customers’ needs. The followings happen after blood sample analysis.

① If Auto Print is on, parameter language is Chinese; Recorder will print parameter test report in Chinese.

② If Auto Print is off, press REC, blood cell analyze report of current sample can be printed by inner recorder.

③ If Auto Print is off, press PRINT, blood cell analyze report of current sample can be printed by outer printer.

The modes of recorder, printer, and test reports are set up at Settings. Refer to section 4.5 in Chapter 4 for specific procedures.

CAUTION:

Do NOT pull the recorder paper violently but push it at an even pace (匀速的送出) when the recorder is running, or it may cause damage to the recorder.

3.16 Shutdown

Shutdown procedure is performed after daily operation and before turning the analyzer off. Daily maintenance and tubing-rinse is needed to ensure no protein aggregation exist during non-working and keep sampling system clean. Specific shutdown steps as follow:

a) Add about 4ml detergent into tube.

b) Press FUNC, shift ↑↓, select “Shutdown ‘menu, press ENTER, “Shutdown “window pop-up in the screen, as Figure 3-3 shown.
c) Press **OK** to turn off the instrument, present sample tube with detergent to the probe (insure probe touch tube bottom lightly). Press **Enter** and the working status indicator in the front panel will become orange. Remove the tube until hear “Di”.

d) Instrument begins cleaning and maintaining the tubing.

e) After turning off the instrument, “**Thank you and now turn off power**” will appear to instruct the operator to turn off the switch on the rear panel.

f) Tidy the work platform and dispose waste liquor.

g) Press **Esc** if the operator does not want to turn off the analyzer, it will return to Blood Cell Analyze window.

**CAUTION:**
Wrong operations on turnoff procedure will decrease reliability and performance of the analyzer, any problems derived from that will **NOT** be guaranteed free by SINNOWA.

**CAUTION:**
Wrong turnoff leads to system data loss easily, and cause system operation failure.

**CAUTION:**
Wrong turnoff or not turnoff, instrument will not prime the tubing, it easily leads to albumen aggradations of blood sample in tubing and causes clog.

### 3.17 Test Result Inquiry

#### 3.17.1 Historical Data Choice, Review and Output

User can inquiry the parameter and histogram of tested blood sample, and can print out test data and histogram through outer printer. Details as follows:
a) At **Blood Cell Analyze window**, press FUNC, shift ↓ to select “Data Inquiry”, press ENTER, instrument enter into data inquiry window, as Figure 3-4 shown.

b) Press ↑ ↓ to review the data backwards or forwards. The data of 5 samples at most can be reviewed in one page in sequence of test time.

c) Press ← → on keyboard to select single sample, move cursor to the sample No. press ENTER into **Details Inquiry** window to browse specific historical sample data and print it out by recorder or printer.

d) Press FUNC, return to **Test Result Inquiry window**.

### 3.17.2 Historical Data Deletion

When the number of test samples reaches to certain quantity, data volume stored in instrument is too large; it will take a long time to review the data since there are so many pages. If necessary, all of the stored data can be deleted periodically by the customers. Deletion is divided into auto deletion and manual deletion.

<table>
<thead>
<tr>
<th>编号</th>
<th>000140</th>
<th>000139</th>
<th>000138</th>
<th>000137</th>
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<td>050403</td>
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</tr>
<tr>
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</tr>
<tr>
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<td>9.9</td>
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<td>91.7</td>
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</tr>
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</tr>
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</tr>
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<td>46.9</td>
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</tr>
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<td>298</td>
<td>302</td>
</tr>
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<td>MPV</td>
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<td>8.0</td>
<td>8.0</td>
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<td>PDW</td>
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<td>11.6</td>
<td>11.4</td>
<td>11.3</td>
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<td>0.25</td>
<td>0.33</td>
<td>0.32</td>
<td>0.33</td>
</tr>
</tbody>
</table>

**PAGE** 003/031
3.17.2.1 Auto Deletion

When storage test data nearly reach 2,000, instrument will indicate “memory full, please backup”, hereafter, user still can count for 50 times. After 50 times counting, instrument will delete all the data automatically, so should backup the stored test data after appear “memory full, please backup”.

3.17.2.2 Manual Deletion

Manual deletion is divided into single data deletion and all data deletion. Details as follows:

a) All data deletion

1) At blood cell analyze window, press FUNC, shift ↑↓, select “Data review”, press ENTER into Test Result Inquiry window, as Figure 3-4 shown:

b) Confirm that cursor is at the last sample ID of first page; Press DILUENT, then press DEL, OK, ESC and all deletion will appear at the lower left, as Figure 3-5 shown.

c) Shift ←→, select “OK,” all the stored historical data will be deleted, instrument will return to Blood Cell Analyze window, select “ESC” back to Test Result Inquiry window.
3) Single data deletion

a) At **blood cell analyze** window, press **FUNC, shift ↑↓, select “Data Inquiry”,**

press **ENTER** into **Test Result Inquiry** window, as figure 3-4 shown.

b) Press **DEL, OK** and **ESC** will appear in the screen.

c) Select **“OK”** to delete the last data; Select **“ESC”** to return to **Test Result Inquiry**

window.

NOTE:
After all data deletion, one historical data still displays at **Blood Cell Analyze**
Window, which can't be inquired at **Test Result Inquiry** window. This data will be

deleted automatically when a new data is stored.

NOTE:
Single data deletion, only can delete from the last one.

NOTE:
When “memory full, please backup” is indicated in the instrument, stored test data

should be backed up immediately.
Chapter 4 FUNC introduction

At Blood Cell Analyze window, press FUNC into function menu, as 4-1 shown.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Maintenance menu</td>
</tr>
<tr>
<td>2</td>
<td>Flush</td>
</tr>
<tr>
<td>3</td>
<td>Quality control</td>
</tr>
<tr>
<td>4</td>
<td>Query result</td>
</tr>
<tr>
<td>5</td>
<td>Normal range setting</td>
</tr>
<tr>
<td>6</td>
<td>Calibrations</td>
</tr>
<tr>
<td>7</td>
<td>System setting</td>
</tr>
<tr>
<td>8</td>
<td>Prime</td>
</tr>
<tr>
<td>9</td>
<td>External Keypad</td>
</tr>
<tr>
<td>10</td>
<td>Shutdown</td>
</tr>
</tbody>
</table>

Note: Operation introduced in this chapter will change some run actions of the instrument, please confirm the necessity of these changes.

4.1 Maintenance Menu

User can press “OK” to enter into this menu, so as to do "daily maintenance", "weekly maintenance", "yearly maintenance" for the instrument and pipe cleaning and emptying. As follow 4-2 shown:
4.2 Flush

User can kick back the jewel hole under this window, so as to discharge blockage. Attention: it is forbidden that changing the blood sample number into 0, because if the number is 0, the result will not be kept.

4.3 Quality Control

Specific method and step consult chapter 6 “Quality control”

4.4 Query Result

Users can inquiry the tested data, parameter and histogram of blood sample, and by the internally installed grapher recording meter or external connection printer, the data and parameter can be outputted. If necessary, users can delete selected test parameters or all test parameters. Specific operations consult 3.17 “Query Result Inquiry”

4.5 Normal Range Setting

The analytic system in the instrument gives 19 upper and lower limits of parameters. If the tested data range exceeds the setting value range, system will mark “H” or “L, H” besides the tested data, so as to indicate that it exceeds the upper limit of the parameters. If “L”, it means it exceeds the lower limit of that. Specific details consult chapter 7 “Parameter Boundary”. Users can set the normal ranges of people, children and animals. Attention: the software default it as “ordinary person”. If you want to choose other ranges, enter into it, and then ESC, it will be confirmed. As 4-3 shown:
4.6 Calibrations

Refer to the details followed.

4.7 System Setting

At window in Figure 4-1, select “System setting”, press ENTER, system setting window appears, see figure 7-1.
4.7.1 Printer Setting

Users can enter this menu to choose self-contained printer or off-line one, auto print. At system setting window as figure 7-1, shift ↑↓ to select Auto print, press ENTER, and shift ← →to select ON or OFF, press ENTER. Select ON, after counting, test report will be printed by recorder (printer) automatically.

Users can alter instruments time, specific methods as follows:
a) At system setting window as figure 7-1, shift ↑↓ to select “Time setting”.
b) Press ENTER, cursor will move to date automatically. You can choose date format as “YY-MM-DD”, “MM-DD-YY” and “DD-MM-YY”.
c) Press ← →to control the position of cursor. Input 0-9, you can alter Y, M, D and time.
d) After alteration, press ENTER, System setting window will come back.

4.7.2 Measuring Unit

At system setting window as figure 4-7, shift ↑↓ to select “Alarm”, press ENTER, and shift ← →to select ON or OFF, press ENTER.

At system setting window as figure 4-3, shift ↑↓ to select “Key tone”, press ENTER, and shift ← →to select ON or OFF, press ENTER. Select ON, you will hear humming when press keyboard; select OFF, no humming.

4.7.3 Hospital Name

Users can enter this menu to amend or increase hospital names in the printed report. First, at system setting window as figure 4-1, shift ↑↓ to select “System setting”, press ENTER, enter figure 7-1, choose “hospital name” with the direction key, then press “OK”, see figure 7-2.
4.7.4 Liquid Level Sensor

用户在此菜单下可以选择缺稀释液，缺溶血素，缺清洗剂报警??

Users can choose alarm of lacking diluent, lyse and detergent.

At system setting window as figure 4-7, shift ↑↓ to select “Alarm”, press ENTER, and shift ← → to select ON or OFF, press ENTER.

Select “ON”, after counting, when reagent is not enough, there is letter twinkling hint on top right corner of screen, at the same time; buzzer gives “Di” for alarm. Select OFF, after counting, when reagent is not enough, there is no hint.

First, choose “Liquid level sensor” with the direction key, press “OK”, enter figure 7-3. You can choose all or certain ones. First, choose that with the direction key, then pitch on it with pressing “OK”

4.7.5 Display Language

Parameter language
At system setting window as figure 4-7, shift ↑↓ to select “Display language”, press
ENTER, shift ← → to choose “Chinese” or “English”, and press ENTER. Choose “Chinese”, parameter at the blood cell analyze window will display Chinese, as figure 4-5 shown. The printed report is Chinese format.

Choose “English”, parameter at the blood cell analyze window will display English, as figure 3-1 shown. The printed report is English format.

4.7.6 Measurement Gain

First, at system setting window as figure 4-1, shift ↑↓ to select “System setting”, enter figure 7-1, then select “Measurement gain”, enter figure 7-4. Users can magnify white cell or red cell one time or two times according to need.
4.7.7 Three-part Setting

Users can choose three–part setting or not.
First, at system setting window as shown in figure 4-1, shift ↑↓ to select “System setting”, enter figure 7-1, then select “Three-part setting”, press “OK”, enter this menu. If three–part setting is needed, select it. If not, do not select it.
If “Thanks for your support” appears in the screen, it indicates serial-number has passed confirmation of system, so you can go on using the instrument.
If “Password error” appears in the screen, it indicates serial-number is wrong. please try again..
Press MENU, the main display will come back.
NOTE:
1 The serial-number is on the barrelhead of the rubber drum which packs the diluents.
2 when input the serial-number:
a, press → on the keyboard, you can shift the position of cursor.
b, press the number key on the keyboard, you can input number.
c, “.” key on the keyboard is used for letters input: single - click to input A, double-click to input B, triple-click to input C , quadruple-click to input D, quintuple-click to input E, sextuple-click to input F.

4.7.8 Cleaning Time

Users can set instrument auto-cleaning. First, at system setting window as shown in figure 4-1, shift ↑↓ to select “System setting”, enter figure 7-1. On 7-1 interface, shift ↑↓ to select “cleaning time”, press ENTER to enter 7-8. According to need, users can clean instrument by pressing time or test times, and pressing both is ok.

<table>
<thead>
<tr>
<th>As per time cycle, every hour, clean one time</th>
</tr>
</thead>
<tbody>
<tr>
<td>As per test time, every time, clean one time</td>
</tr>
</tbody>
</table>

Figure 7-8

4.7.9 Report Format Setting

User can choose a prefer format to print the report. First, at the system setting window as figure 4-1 shown, shift ↑↓ to select “system setting”, enter into figure 7-1. In 7-1 interface, shift ↑↓ to select “report format setting”, press ENTER to figure 7-9, any format can be chosen.
4.7.10 Display Brightness

User can increase or reduce brightness here.
First, at the system setting window as figure 4-1 shown, shift ↑ ↓ to select “system setting”, enter into figure 7-1. In 7-1 interface, shift ↑ ↓ to select “display brightness”, press ENTER, and shift ← → to increase or reduce the display brightness.

4.7.11 Landmark Setting

Users can set minimal and maximal cells of WBC RBC PLT which participated in counting originally here.
First, at system setting window as figure 4-1 shown, shift ↑ ↓ to select “system setting”, press ENTER, enter into figure 7-1. In 7-1 interface, shift ↑ ↓ to select “landmark setting”, press ENTER to enter it, as figure7-11 shown. WBC_L: minimal WBC volume participated in counting; WBC_H: maximal WBC volume participated in counting; LY-MO : Delimitation landmark between lymphocyte and neutrophile cell; MO-GR: Delimitation landmark between neutrophile cell and granular cell; RBC_L: minimal RBC volume participated in counting; RBC_H : Maximal RBC volume participated in counting; PLT_L : minimal platelet volume participated in counting; PLT_H : Maximal platelet volume participated in counting;
4.7.12 Time Setting

Users can set or alter time and date or date format here. First, at system setting window as figure 4-1 shown, shift ↑ ↓ to select “system setting”, press ENTER, and enter into figure 7-1. In 7-1 interface, shift ↑ ↓ to select “time setting”, press ENTER to enter to select “time format ” or “time setting”, as figure 7-12 shown.

Time format is divided into three types: YMD, DMY and MDY.

![Figure 7-12](image)

NOTE:
After the instrument goes into auto dormancy, press any key on the keyboard to esc dormancy.

4.8 Prime

Prime and rinse the whole tubing to keep the whole tubing full of diluents. “Diluent prime”, “Lyse prime” and “Detergent prime” can be selected.

4.9 External Keypad

Users can select “External keyboard”, then press ENTER to change it into PS2.
4.10 Tubing Clean

Clean the obstinate stem in probe with the probe detergent. Specific as follow:

a) Put about 4 ml probe detergent to the clean test tube.
b) At the Blood Cell Analyze window, press FUNC into function menu window.
c) At function menu window, shift ↑ ↓ to select “Tubing clean”, press ENTER, “OK” and “ESC” will appear on the screen, as figure 4-6 shown.

d) Put the tube with probe detergent beneath sample probe, shift → to move cursor to “OK”, press ENTER, analyzer inhale probe detergent automatically into WBC and RBC probe cup separately, then soak for 6 minutes. Then progress bar will appear on the screen to show the progress, number on progress bar descending with course, as Figure 4-7 shown. Instrument will clean tubing automatically after 6 minutes, schedule bar disappear, back to Blood Cell Analyze window.

e) If users want to exit “Tubing clean” program in midway, Can press FUNC after the number on progress bar descending to 5, “OK” and “ESC” will appear. Select “OK”, number on progress bar turns to 1, instrument clean the tubing automatically,
after progress bar disappears, back to **Blood Cell Analyze** window; select “ESC”, instrument continues soaking the tube.

### 4.11 Shutdown

Shutdown procedure must be performed after daily operation and before turning the analyzer off. Instrument does daily maintenance and tubing-rinse to avoid protein aggregation in tubing during non-working and keep sampling system clean.

Specific step consults §3.16 《shutdown》

**NOTE:**
Wrong operation on turnoff procedure is prohibited, nor will it decrease reliability and performance of the analyzer. Any problems derived from that will NOT be guaranteed free by SINNOWA.

**NOTE:**
Wrong turnoff leads to system data loss easily and causes system operating failure.

**NOTE:**
Wrong turnoff will cause instrument does not Prime and clean the tubing, easily lead to albumen aggregations of blood sample in tubing, cause clog.

---

## Chapter 5 Quality Control

To ensure precision and accuracy of results produced by Sinnowa hematology analyzer, quality control (QC) measures are required. For quality control progress, it is strongly recommended to strictly follow the QC process and use Sinnowa recommended QC material.

QC measures should be performed:

a) After daily start-up, before beginning the analyses;

b) After reagent replacement;

c) After calibration;

d) After maintenance, repair or part replacement;

e) According to clinical laboratory QC regulation.

The instrument provides 12 parameters and 3 levels in a total of 9 groups of QC settings for users. During the QC program users can monitor 12 parameters at the same time or if required, an individual parameter also can be tested separately as well.

### 5.1 QC Material
Because of the QC material produced by different manufacturers, there should be variations for their mixture and treatment. To ensure the result accuracy, users should pay attention to the following matters when dealing with QC material:

a) Stored under the manufacturer's recommended storage conditions. It's better to place the QC material in the central part of the refrigerator. Do not leave it on refrigerator door or other places near the door, as these areas represent the extremes of temperature within the refrigerator.

b) Check the status of QC material and ensure there is no crack and breakage on it's container.

c) Be sure to follow the user's guide of QC material. Mix and warm it up slowly.

d) Check the expiry date of QC material. The use of any expired product is prohibited.

e) Any opened QC material over the manufacturer's recommended time is prohibited.

f) Intensive heat or vigorous shake of QC material is prohibited;

g) A new batch of high, medium and low levels of QC materials is used and each of them should be tested for three times. Compare the data obtained with the last batch and check variance of the test results.

CAUTION:
As all human derived products including clinical specimen, control and calibrator should be treated as a potential biohazard, all staff must wear appropriate personal protective equipment (eg, protective clothing, gloves, and goggles) and follow safe laboratory practices for dealing with biological materials.

5.2 Edit

The QC material manufacturers stated reference values and ranges should be previously input by user prior to running the quality control program. Any incomplete or illegal data input lead to unexpected consequences: the QC program will not run or only effective parameters can be monitored. The detailed operation process shows below:

a) From the blood cell analysis window, press the "menu" button and then "↑"/"↓" to access quality control item. Press "confirm" to execute to display the QC window as shown in fig.5-1
b) Select "QC Groups" and press "confirm" to access the submenu. Press "→" to select group 1, 2 or 3. After selection, press "confirm" to return to QC screen.
c) Move the cursor to "QC Levels" by pressing "↑"/"↓" and press "confirm" to access the submenu. Press "→" to select level high, normal or low. After selection, press "confirm" to return to QC screen.
d) Move the cursor to "QC Values Setup" by pressing "↑"/"↓" and press "confirm" to access the submenu (fig. 5-2) for QC parameters setup. Move the cursor to "Lot" item and input QC material batch number by pressing numerical key on the keyboard.
e) Press "→" to move the cursor to "QC material reference values". Input QC material reference values by pressing numerical key on the keyboard.
f) Press "→" to move the cursor to "QC material reference ranges". Input QC material reference ranges by pressing numerical key on the keyboard.
While edit is completed, press "menu" button and two icons of "confirm" and "cancel" appear at the bottom of the screen. Press "→" to select.

h) Return to QC screen for other QC operations.
NOTE:
If there is a illegal data input for one parameter, the reference value and range of which is a invalid data and will not be displayed. User should correct it. Otherwise, only effective parameters can be monitored.

5.3 Run QC

As the settings of QC groups, levels and relevant parameters are completed, QC program is able to run. According to the requirement of clinical laboratory, users can monitor one certain parameter or all 12 parameters for QC measurement. Users are advised to run QC program at high, medium and low levels everyday or follow the clinical laboratory regulation. The detailed operation process shows below:

a) From the blood cell analysis window, press the "menu" button and then "↑"/"↓" to access quality control item. Press "confirm" to execute to display the QC window as shown in fig.5-1.

b) Move the cursor to "QC Groups" by pressing "↑"/"↓" and press "confirm" to access the submenu. Press "→" to select corresponding group. After selection, press "confirm" to return to QC screen.

c) Move the cursor to "QC Levels" by pressing "↑"/"↓" and press "confirm" to access the submenu. Press "→" to select corresponding level. After selection, press "confirm" to return to QC screen.

d) Move the cursor to "RUN QC" by pressing "↑"/"↓" and press "confirm" to start QC program. The "Ready" sign is flashing on the screen.

e) Immerse the sampling probe into the well prepared sample. Press "RUN" and the instrument starts analysis. The "Run" sign is displayed on the screen as shown in fig 5-5.
f) While the counting process is completed, return to the window shown in fig 5-4. Press "Menu" button to return to the QC window.

g) If blood cell counting is not required, Press "Menu" button after the step d (see fig 5-4) and return to QC window for other operations (see fig 5-1).

NOTE:
If total number of QC data reaches 31, a tip of “Memory full, Please backup” appears in the window. User should enter the QC data window and backup stored QC data. After deleting all QC data, run the QC program again.

5.4 QC Chart

Assigned values (target value and accepted range) as well as averages, standard deviations (SD) and coefficients of variation (CV) are calculated based on the QC measurements and are displayed together with LEVEY-JENNINGS chart which is a Gaussian distribution. On the x-axis the number of the control run is plotted. A mark is made indicating how far off the actual result was from the mean. The central line represents the mean which is the expected value for the control. The dotted line on either side of the mean represents the +2 and –2 SD which is the reference range for the control. The high, medium and low levels of LEVEY-JENNINGS charts are displayed together. Each LEVEY-JENNINGS chart contains 31 QC data at most. Select "QC data" and access the QC data window. The current LEVEY-JENNINGS chart can be sent to an external printer by pressing "Print" button.

5.5 QC Data

5.5.1 QC Data Inquiry

QC input data and output results are auto-stored in the memory in chronological order and they can be retrieved at any time. Users can check the system precision and accuracy by comparing the actual QC results with the reference values and ranges. The detailed operation process shows below:

a) From the blood cell analysis window, press the "menu" button and then "↑"/"↓" to
access quality control item. Press "confirm" to execute to display the QC window as shown in fig.5-1.

b) Move the cursor to "QC Data" by pressing "↑"/"↓" and press "confirm" to access the QC Data Inquiry window (see fig 5-6).

<table>
<thead>
<tr>
<th>编号</th>
<th>000005</th>
<th>000004</th>
<th>000003</th>
<th>000002</th>
<th>000001</th>
</tr>
</thead>
<tbody>
<tr>
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<td>050405</td>
<td>050405</td>
<td>050405</td>
<td>050405</td>
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<td>08:10</td>
<td>08:10</td>
<td>08:10</td>
<td>08:10</td>
</tr>
<tr>
<td>WBC</td>
<td>8.9</td>
<td>8.8</td>
<td>8.9</td>
<td>8.7</td>
<td>8.7</td>
</tr>
<tr>
<td>LY%</td>
<td>38.5</td>
<td>38.4</td>
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<td>38.6</td>
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<tr>
<td>MO%</td>
<td>9.8</td>
<td>9.7</td>
<td>9.6</td>
<td>9.9</td>
<td>9.3</td>
</tr>
<tr>
<td>GR%</td>
<td>51.7</td>
<td>51.5</td>
<td>50.9</td>
<td>51.3</td>
<td>51.3</td>
</tr>
<tr>
<td>RBC</td>
<td>4.20</td>
<td>4.25</td>
<td>4.27</td>
<td>4.28</td>
<td>4.24</td>
</tr>
<tr>
<td>HGB</td>
<td>127</td>
<td>128</td>
<td>131</td>
<td>126</td>
<td>130</td>
</tr>
<tr>
<td>HCT</td>
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<td>36.4</td>
<td>36.1</td>
<td>36.3</td>
<td>36.7</td>
</tr>
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<td>86.1</td>
<td>86.4</td>
<td>86.3</td>
<td>86.4</td>
<td>86.2</td>
</tr>
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<td>MCH</td>
<td>30.2</td>
<td>30.2</td>
<td>30.5</td>
<td>30.5</td>
<td>30.4</td>
</tr>
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<td>352</td>
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<td>361</td>
<td>358</td>
<td>355</td>
</tr>
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<td>RDW_CV</td>
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<td>13.8</td>
<td>13.2</td>
<td>13.5</td>
<td>13.4</td>
</tr>
<tr>
<td>RDW_SD</td>
<td>46.7</td>
<td>46.8</td>
<td>46.4</td>
<td>46.3</td>
<td>46.2</td>
</tr>
<tr>
<td>PLT</td>
<td>227</td>
<td>218</td>
<td>230</td>
<td>234</td>
<td>226</td>
</tr>
<tr>
<td>MPV</td>
<td>7.9</td>
<td>7.8</td>
<td>8.0</td>
<td>8.1</td>
<td>7.8</td>
</tr>
<tr>
<td>PDW</td>
<td>10.7</td>
<td>11.0</td>
<td>10.4</td>
<td>10.9</td>
<td>11.3</td>
</tr>
<tr>
<td>PCT</td>
<td>0.32</td>
<td>0.34</td>
<td>0.35</td>
<td>0.32</td>
<td>0.34</td>
</tr>
<tr>
<td>PAGE</td>
<td>001/001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 5-6

The current items can be sent to an external printer by pressing "print" button.

5.5.2 QC Data Deletion

When the QC data reached a large amount, it is time-consuming work for user to search one certain result by browsing many pages. Therefore, if required, users are advised to delete useless data routinely.

5.5.2.1 Auto-Delete

If total number of QC data reaches 31, a tip of “Memory full, Please backup” appears in the window. while the next QC measurement is completed and regard as the first one, all previous QC data will be deleted automatically.
5.5.2.2 Manual-Delete

QC data deletion is conducted at QC inquiry window by a full delete or a single delete. For detailed process, please refer to 3.17.2 <History Data Deletion> in Chapter 3<Installation and Sample Analysis>

NOTE:
When all data are deleted, there is still a history data displayed in QC inquiry window. This data, however, can not be accessed and will be deleted automatically once new data are stored.

NOTE:
If deleting a single QC data, users only can start one by one from the last data.

NOTE:
If the warning “Memory full, Please backup” appears, user should backup stored QC data immediately.

Chapter 6 Calibration

During daily operation, excursion may occur gradually in results for many reasons, so it is necessary to recalibrate certain parameters. To ensure the analyzer’s precision and obtain reliable test results, the parameters (WBC, RBC, PLT, HGB, and MCV) should be calibrated in the following situations:

a) Working environment changes greatly.
b) One or multiple parameters’ test results are of excursion.
c) Any major component that could affect the measurement is replaced.
d) Requirement of the clinic or the laboratory.
e) The reagent has been replaced.

MCV, HCT parameters are relative, thus one can be obtained from given value of the other. Only MCV will be calibrated by the analyzer.

WARNING:
Before make all the parameters calibration accurate, the tested data should not be used in clinic or laboratory.

6.1 Pre-calibration

6.1.1 Calibrator

Only calibrators or control recommended by SINNOWA can be used to accomplish
the calibration.

**WARNING:**
Consider all the clinical specimens, controls and calibrators etc, that contain human blood or serum as being potentially infectious, wear standard laboratory clothing, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.

**CAUTION:**
Only calibrators recommended by SINNOWA can be used to

**CAUTION:**
Follow the recommendations provide by calibrator-maker to store the calibrators.

**CAUTION:**
Check if the container is broken or cracked before using the calibrator.

**CAUTION:**
Make sure the calibrators are brought to room temperature and well mixed slowly before use.

**CAUTION:**
Make sure the calibrators are within the expiry date.

### 6.1.2 Background Test

Background should be given before calibration to ensure no problem is indicated. Please consult section 3 of chapter 3 <Installation and sample analysis>.

### 6.1.3 Evaluation of Repetition Precision

To ensure accurate calibration, evaluate repetition precision firstly and perform calibration only when parameter’s repetition precision is within the limit range.

Methods for calibration are as follows:

a) Ensure the blood-collection method is that you need.

b) Use the calibrators or median controls to continuously measure 6 times, refer to Section 3.13 of Chapter 3 <Installation and sample analysis>.

c) Record the test data for WBC, RBC, HGB, MCV, and PLT. Divide the average value of the parameter by difference between the maximum value and minimum value. If the results are in the limits of Table 6-1, perform calibration.

d) If the test results is correspond with requests in Table 6-1, take mean of 6 data as measure mean, if the results don’t comply with the criteria, refer to Chapter 9<Troubleshooting>.

Table 6-1 Measure error requirement
<table>
<thead>
<tr>
<th>ITEM</th>
<th>ERROR ( % )</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>≤±4</td>
</tr>
<tr>
<td>RBC</td>
<td>≤±3</td>
</tr>
<tr>
<td>HGB</td>
<td>≤±3</td>
</tr>
<tr>
<td>MCV</td>
<td>≤±3</td>
</tr>
<tr>
<td>PLT</td>
<td>≤±8</td>
</tr>
</tbody>
</table>

**NOTE:**
When whole blood and capillary blood should be used, each of them should be calibrated; the calibration should not be performed until blood-collecting method is confirmed. Details consult item 1.13 of Chapter 1.

**CAUTION:**
Measurement should be performed under the same blood-collecting method when the method is confirmed.

**CAUTION:**
If any malfunction occurs during measurement, the test results are invalid. Repeat the measurement after troubleshooting.

**6.2 Calibration Coefficient Modification**

a) At Blood Cell Analyze window, press **FUNC**, shift ↑↓ to select **Calibration**; press **ENTER** into **Calibration** window, as shown in Figure 6-1. Choose “Auto calibration” or “Manual calibration”. If choose “Auto calibration”, target value should be firstly input, then test it for 4 times with the normal liquor, new factors will come out automatically.

![Figure 6-1](image)

If choose Manual calibration, operate as follow:

<table>
<thead>
<tr>
<th>WBC 100%</th>
<th>RBC 100%</th>
<th>HGB 100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCT 100%</td>
<td>MCV 100%</td>
<td>PLT 100%</td>
</tr>
</tbody>
</table>
b) Input cursor locates at the new reference value of WBC parameter; input the new reference values of WBC parameter by numeric keys on the keyboard.

c) Press OK, move input cursor to RBC reference value.

d) Refer to above method, input calibration reference value of other calibration parameters in turn.

e) Press OK after input, until cursor select ENTER, by now select ESC and OK. Select ESC to cancel current calibration result, select OK, instrument back to Blood Cell Analyze window after storing current calibration result.

NOTE: The calibration coefficient is allowed in the range of 70%~130%, if the test new calibration coefficient exceeds the limit, the maximum and minimum of coefficient range should be selected as new coefficient for calibration.

NOTE: The analyzer calibrates not only single parameter (WBC, RBC, HGB, MCV, HCT and PLT), but also all the parameters.

NOTE: Pre-calibration and calibration should be performed with the same blood-collecting method.

NOTE: If any malfunction hint occurs during measurement, the test results are invalid. Repeat the measurement after troubleshooting.

6.3 Calibration Review

At Blood Cell Analyze window, press FUNC, shift ↑ ↓ to select calibration into calibration window, as figure 6-2 shown. Instrument goes into Review state.

Chapter 7 Parameter limit

To monitor abnormal blood sample measurement, it is essential for the operator to setup normal ranges of the parameter according to laboratory or clinical requirement.
Information or indication is given if the test values exceed the range. The limits of 19 parameters are given in this instrument. Any results exceeding the range will be marked “H” or “L” besides the test results. “H” means the results are higher than the upper limits, while “L” means the results are lower than the lower limits.

NOTE:
Parameter limit is inner setting of instrument, is the important reference gist for clinic diagnosis.
The shift in parameter limit may cause changes in abnormal indication of hematology index. Please confirm the necessity for changing.
Detail step as follow:
a) At Blood Cell Analyze window, press **FUNC** into **FUNC** menu window.

b) Shift ↑↓ to select **Para setting;** press **ENTER** into **Para limit** window, as shown in figure 7-1.
c) Choose your needed ranges, press “OK” to enter, as shown in figure 7-2.

<table>
<thead>
<tr>
<th>参数</th>
<th>上限值</th>
<th>下限值</th>
<th>参数</th>
<th>上限值</th>
<th>下限值</th>
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<tbody>
<tr>
<td>WBC</td>
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<td>4.0</td>
<td>MCH</td>
<td>32.0</td>
<td>26.0</td>
</tr>
<tr>
<td>LY%</td>
<td>40.0</td>
<td>20.0</td>
<td>MCHC</td>
<td>360</td>
<td>260</td>
</tr>
<tr>
<td>MO%</td>
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<td>1.0</td>
<td>RDW_CV</td>
<td>14.5</td>
<td>11.5</td>
</tr>
<tr>
<td>GR%</td>
<td>70.0</td>
<td>50.0</td>
<td>RDW_SD</td>
<td>46.0</td>
<td>39.0</td>
</tr>
<tr>
<td>LY#</td>
<td>4.1</td>
<td>0.6</td>
<td>PLT</td>
<td>300</td>
<td>100</td>
</tr>
<tr>
<td>MO#</td>
<td>1.8</td>
<td>0.1</td>
<td>MPV</td>
<td>10.4</td>
<td>7.4</td>
</tr>
<tr>
<td>GR#</td>
<td>7.8</td>
<td>2.0</td>
<td>PDW</td>
<td>14.0</td>
<td>10.0</td>
</tr>
<tr>
<td>RBC</td>
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<td>3.50</td>
<td>PCT</td>
<td>0.28</td>
<td>0.10</td>
</tr>
<tr>
<td>HGB</td>
<td>150</td>
<td>110</td>
<td>W_TIME</td>
<td>14.0</td>
<td>9.0</td>
</tr>
<tr>
<td>HCT</td>
<td>48.0</td>
<td>36.0</td>
<td>R_TIME</td>
<td>17.0</td>
<td>23.0</td>
</tr>
<tr>
<td>MCV</td>
<td>99.0</td>
<td>80.0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 7-2

d) Shift ← → to select the parameter that need to set, press 0~9 to input its upper and lower limit value.

e)Press → after modification, then press FUNC, “OK” and “ESC” appear at the bottom of your screen, as shown in figure 7-3. Select OK, instrument save modified parameter limit and back to Blood Cell Analyze window; select ESC, the modified parameter limit are not save in the instrument, return to Blood Cell Analyze window.
Chapter 8 Maintenance

Routine care and regular maintenance are essential to keep the best status and reach the designed precision, to minimize system problems, as well as to prolong the life span. Procedures and instructions for preventive maintenance are discussed in this chapter. More information is available at SINNOWA Customer Support Centre. Preventive maintenance should be performed daily, weekly, monthly and yearly, according to maintenance requests in use process. Pertinent maintenance is also included according to actual requirement.

WARNING:
Analyzer failure will occur unless a normative maintenance criterion is performed strictly in all hospitals or institutions which use the instrument. The operator must wear powder-free gloves when performing the maintenance procedures. If powder-free gloves are not available, rinse the gloves before

<table>
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<tr>
<td>MCV</td>
<td>99.0</td>
<td>80.0</td>
<td>确认 取消</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 7-3

f) Press PRINT to print information under current blood-collect mode by outer printer.
performing the maintenance procedures. Powder from the gloves may cause analyzer problems.

8.1 Daily Maintenance

8.1.1 Rinse

Instrument will prime automatically to rinse on every startup, the whole process is about 2 minutes. In order to reduce the percentage of plugged hole, automatic prime is performed when the instrument in running. Automatic rinse can be performed every two hours according to the user’s need; “automatic maintenance” will appear in the screen. The instrument will rinse automatically if the count exceeds 25 times within two hours. Also can perform artificial control prime during using the instrument, details as follow:

Press FUNC into FUNC menu window, shift ↑↓, and select Prime at FUNC menu window, press ENTER, instrument will prime to rinse whole tubing system. Prime directly if eliminate tubing bubble, that is using diluents to rinse.

8.1.2 Shutdown Prime

Must perform this procedure before turn off the instrument, specific method for making probe cup full refer to section 3.16 of Chapter 3.

NOTE:
Wrong turnoff or not turnoff, instrument will not prime the tubing, easily lead to albumen aggregations of blood sample in tubing that cause clog.

8.2 Weekly Maintenance

8.2.1 Instrument Surface Maintenance

Clean the smudge on the surface, especially the spilt-blood on the sampler, to prevent the protein from deposition, molding or contaminating. Wipe the outside of the sampler with gauze soaked by neutral detergent before cleaning other parts.

CAUTION:
Never use corrosive acids, alkali or volatile organic solvent (such as acetone, aether and chloroforms) to wipe the outside of the analyzer, but only neutral cleaner.
8.2.2 Tubing Maintenance

Do use detergent to rinse measure tubing once a week to ensure there is no albumen aggradation in tubing. Details as follow:

a) Take out blue connecter of diluent pipe from mainframe.
b) At Blood Cell Analyze window, press FUNC into function menu window, shift ↑ ↓, select Prime, then press ENTER.
c) Repeat step b) until top full corner of screen alarm DILUENT EMPTY.
d) Take out diluent pipe from diluent barrel, repeat step b), until DILUENT EMPTY disappears.
e) 20 minutes later, repeat step a)-c).
f) Connect blue connecter of diluent pipe to corresponding position on mainframe, the other end still in diluent barrel, perform Prime three times

CAUTION:

As executing step (f), users should wash the pipe with distilled water before inserting the pipe into the diluent bucket, invoiding the contamination of diluent by the residual detergent.

8.2.3 Probe Maintenance

Rinse WBC and RBC probe once every week at least, details consult section 4.9 Tubing Clean of Chapter 4

8.3 Yearly Maintenance

Good yearly maintenance will keep the analyzer in best status and prolong the lifespan. Because of the strict requirements, the maintenance should be performed by the engineer authorized by SINNOWA. Please contact customer service office of SINNOWA before the yearly maintenance.

8.4 Maintenance for a Prolonged Period of Non-use or for Shipping

Inactivity or shipping for three months because of various causes, please do as follows:

a) Remove the diluent tubing with a blue connector on the rear panel from the diluent container, and empty the liquid downward.
b) Remove the hemolytic agent tubing with a red connector on the rear panel from the diluent container, and empty the liquid downward.
c) Cap the diluent and hemolytic agent containers and keep them according to instruction. Efficient action should be taken to prevent the materials from deterioration, misapplication and misusing. Reagents should be free from temperature extremes.

d) Hang in the air the diluent and hemolytic agent tubing.

e) Perform Prime for several times until “No Diluent”, “No Hemolytic agent” and “No washing liquid” appears on top right corner.

f) Insert the diluent and hemolytic agent tubing into the distilled water.

g) Perform Prime for several times until “No Diluent”, “No Hemolytic agent” and “No washing liquid” disappears on top right corner.

h) Press RUN on the front panel at Blood Cell Analyze, press RUN again after measurement.

i) Remove the diluent and lyse tubing and rinse them with distilled water. Dry them in shady place, then pack them in plastic bags.

j) Perform Prime for several times until “No Diluent”, “No Hemolytic agent” and “No washing liquid” appears on top right corner.

k) At Blood Cell Analyze, press Shutdown then “thanks for your using, please turn off the power” appears, then turn off the power switch on the rear panel.

l) Pluck the waste tubing, and rinse it with distilled water, then dry it in shady place and pack it in plastic bag.

m) Install the caps which are removed in the initial installation into the tubing faucet

管路接口 on the rear panel.

n) Pluck the power cord, and pack it in a plastic bag after cleaning.

o) Pack the analyzer and parts in plastic bag and put them into the carton.

Chapter 9 Troubleshooting

This chapter describes the method for instrument troubleshooting. If the failure cannot be eliminated in accordance to this chapter or more technical files are required, please contact SINNOWA custom service division.

9.1 Troubleshooting Guidance
The troubleshooting guide is designed for supporting users to find and clear faults during the operation of the instrument, as well as providing the information for users about how to receive the timely technical support and help from SINNOWA Customer Service.

Excellent problem cleaning and eliminating skills root from deep understanding about the instrument and experience accumulated day by day. In order to find and eliminate problems accurately and quickly, users should read this manual and know instrument normal operation and contingency maintenance. Generally, Logical troubleshooting may be divided into three steps:

1. Problem Identification
2. Problem classification
3. Trouble clearing

**Step 1: Problem Identification** means not only identifying what is wrong but also what is right. The investigation should identify the problem area and eliminate areas that are right. Once this done, the trouble shooting process moves quickly to next step.

**Step 2: Problem classification** Analyzer problems are generally divided into three categories:
1. Hardware component related
2. Software computer programs related
3. Measurement related to sample analysis

Hardware and software problems can only be corrected by a SINNOWA authorized engineer. The operator can correct sample measurement problems with assistance from SINNOWA engineers.

**Step 3: Trouble clearing** Maintenance engineers can take appropriate action to correct the problem. If the operator can correct the problem, with or without technical assistance from SINNOWA, waste time will be decreased sharply.

### 9.2 Seeking for Technical Assistance

If assistance from SINNOWA is needed when the instrument goes wrong, please calling the SINNOWA Customer Service or contact with the agency. The phone and fax number is shown in preface. Detailed and clear problem description and related data must be provided when seeking for technical assistance. Details as follow:

a) The analyzer model
b) Serial number and version number
c) Detailed and clear description of problem phenomenon and operation surroundings. (As what is done with what window and status)
d) The lot numbers of the reagents (lyse, diluent and detergent)
e) Related data and report.

Familiar problems list and disposals are given in this Chapter. The operator can identify the cause according to the warning information and operate according to the troubleshooting provided in the list.
9.3 Troubleshooting Disposal

Familiar problems and disposals are listed as follows. If the problems can not be corrected, or technical assistance is needed, please call SINNOWA Customer Service.

9.3.1 WBC clog or RBC clog

If the counting time exceeds upper limit during measurement, the alarm rings and warning information is given: “WBC CLOG” or “RBC CLOG”.

Disposal ways and steps:

a) Press any key in the front panel to stop the alarm.
b) At Blood Cell Analyze window, select “Maintenance”, then select “Daily Maintenance”, then makes the probe in the bottle which is filled with concentrate abluent, press “OK”.
c) If the above-mentioned are not applicable to serious clog, perform as follow step.
d) Add approximately 4ml probe cleaner into clean tube.
e) At Blood Cell Analyze window, press FUNC into Function menu, shift ↑↓, select “Daily Maintenance”.
f) Put the tube with probe detergent beneath sample probe (insure sample probe touch bottom lightly), press ENTER. In case above method still can not settle, solve it by adding probe detergent manually.
g) Perform “Tubing clean” with probe detergent.

Figure 9-1

b) As Figure 9-1 shows, open the left-side door.
c) After sample adding organ stop running, suck the probe detergent with the injector,
as figure 9-2 shows, inject 3ml probe detergent into corresponding probe cup which appear clog, probe cup position as figure 9-2 shows.

Figure 9-2

If above still cannot settle, please call SINNOWA Customer Service or contact with the agency.

NOTE:
Personnel unauthorized or untrained by SINNOWA can not perform above operation, any error and instrument malfunction caused by incorrect operation, SINNOWA Company will not take on any responsibility.

NOTE:
Please do self-protection when perform above operation.

9.3.2 WBC Data Change Abnormally

9.3.2.1 Data becomes Large

Probable causes :

Abnormal sample ;

abnormal lyse ;

Lyse can not be added

in ;

a) Replace blood sample (or using medium controls instead) and perform the measurement again.
b) If problem can not be corrected, remove the lye tubing with red connector on rear panel from the lyse, empty the tubing and hang it up.
c) At Blood Cell Analyze window, press FUNC, shift ↑↓, select Prime several times until appear “No Lyse” in the screen right corner.
d) Replace lyse.
e) Perform step c) several times until No Lyse disappear.
f) As for disposing the failure of lyse addition, please refer to 9.3.8 problem disposal methods.

9.3.2.2 Data abnormally change

Probable causes: Filter under the probe cup is jammed.

Disposal methods:
a) As figure 9-1 shows, open the left-side door.
b) There are two filters under the probe cup at right down corner, as Figure 9-3 shows.

c) Sip up the liquid in WBC probe cup with syringe.

d) Open the connection pipeline on two ends of filter under the WBC probe cup, take out filter, examine whether there is jam in filter, and replace it if there is. If above still cannot be settled, please call SINNOWA Customer Service or contact with the agency.

NOTE:
Personnel unauthorized or untrained by SINNOWA can not perform above operation, any error and instrument malfunction caused by incorrect operation, SINNOWA Company will not take on any responsibility.

NOTE:
Please do self-protection when perform above operation.

9.3.3 WBC BUBBLES or RBC BUBBLES

The warning information appears when the air enters WBC or RBC tubing.

Required actions:
a) Press MUTE in the front panel to stop the alarm.
b) At Blood Cell Analyze window, press FUNC, shift ↑↓to select Prime, press ENTER.
9.3.4 VACUUM is Low

The warning information of low vacuum appears if the analyzer can’t supply rating negative voltage within the set time.
Required actions:
a) Press MUTE in the front panel to stop the alarm.
b) At Blood Cell Analyze window, press FUNC, shift ↑↓to select Prime, press ENTER.
If above still cannot be settled, please call SINNOWA Customer Service or contact with the agency.

9.3.5 WASTE is full

Probable cause: Waste is full.
Required action: Empty the waste container.

9.3.6 HGB Problem

Probable cause: After liquid is blended, bubble is left in the sample.
Required action:
a) Press MUTE in the front panel to stop the alarm.
b) After perform “Prime”, perform the measurement again.

9.3.7 DILUENT Empty

Probable cause: No diluent or diluent prime pump can not establish negative pressure
Required action:
a) Replacing diluent
b) At Blood Cell Analyze window, press FUNC, shift ↑↓to select Prime, press ENTER.
If above still cannot be settled, please call SINNOWA Customer Service or contact with the agency.

9.3.8 LYSE Empty

Probable cause:
No lyse
Lyse sensor is dirty
Correlative pipeline is conglutination together due to long-playing extrusion.
Required actions:
a) Press MUTE in the front panel to stop the alarm.
b) Replace the lyse
c) At **Blood Cell Analyze** window, press **FUNC**, shift ↑↓to select **Prime**, press **ENTER**.
   
a) As figure 9-1 shows, open the left-side door.

b) Find solenoid valve V14 behind the vacuum chamber as Figure 9-6 shows.

If above method can not solve, maybe Correlative pipeline is conglutinated together, please settle it according to follow step.

![Figure 9-6](image)

If there are lyse in pipeline, instrument still alarm, it indicates sensor is dirty; you should get rid of dust inside and outside of the sensor.

d) If lyse can not be added in, maybe pipeline is conglutinated together, you can take out pipeline in solenoid valves which near valve board, disjoin the conglutination together part, change another position, then repress the pipeline into the solenoid valve.

If above still cannot settle, please call SINNOWA Customer Service.

**NOTE:**

Personnel unauthorized or untrained by SINNOWA can not perform above operation, any error and instrument malfunction caused by incorrect operation, SINNOWA Company will not take on any responsibility.

**NOTE:**

Please do self-protection when perform above operation.

**9.3.9 Detergent Empty**

**Probable causes**： No detergent.

**Required action**:

a) Replace detergent.
b) At blood cell analyze window, press FUNC, shift ↑↓ to select Prime, press ENTER.

9.3.10 Time Error

Probable cause: Wrong setting of system setting

Required action:

a) Press MUTE in the front panel to stop the alarm.

b) At Blood Cell Analyze window, shift ↑↓ to select System Setting, shift ↑↓ to select Date Setting

c) Press ENTER, the cursor moves to Date automatically, date format is MM-DD-YY.

d) Press → ← to control cursor; change time into current time by input 0-9.

If above still cannot settle, please call SINNOWA Customer Service.

9.3.11 No Paper in Recorder

Probable cause: No recorder paper left

Required action:

a) Gently press the recorder cover and open it.

b) Insert the new papers into the feed-slot with z printing-side against the thermal head.

c) Pull the paper in the other side of the printer, and make it straight.

d) 将纸从记录仪门的出纸口送出。Make the print paper pass through the recorder.

e) Close the cover.

WARNING:
Qualified recorder paper is required; otherwise unqualified recorder paper will lead to recorder failure, inferior record quality or thermal head damage.

CAUTION:
Gently replace the paper to avoid impacting the thermal head.

CAUTION:
Do no open the recorder cover but for paper replacement or problem correction.

9.3.12 Recorder Temp is high
Probable cause: Thermal head is overheated.

Required action: Intermit the recorder.

9.3.13 Recorder Head Error

Probable cause: Thermal head of the recorder is out of place.

Required action: Pull the switch on the left spindle downwards.

9.3.14 Recorder Error

Probable cause: No recorder is installed.

Required action:
Please call SINNOWA Customer Service or contact with the agency.

9.3.15 Recorder off-line

Probable cause: Connection cable between printer and host computer is loose or install printer without following the correct step.

Required action: Reinsert connection cable, correct installation step consult §3.6.

9.3.16 Printer Paper Out

Probable cause: No paper in printer or install printer without following the correct step.

Required action: Install print paper following the method offer in instruction; correct printer installation step consult §3.6.

Chapter 10 Precautions, Limitations and Hazards

Improper operation will never attain optimal performance; even cause damage to the
operator or others. So to avoid the damage and get a successful measurement, a criterion should be designed to perfect the service conditions.

10.1 Using Limitations

a) HB-7021 is designed only for reference analysis of vitro diagnostic.
b) Any operation, shipment, installation or maintenance to the analyzer must strictly follow the contents outlined in this manual, or if any problems derived from that, SINNOWA will not offer free warranty.
c) Reagent, controls and calibrators recommended by SINNOWA had been detected strictly by SINNOWA and the instrument will receive good measurement analysis results. If the materials are not recommended by SINNOWA, it may affect the performance of the analyzer or cause incidents, and then you will lose the free warranty.
d) Any repairing must be permitted and any component replacement must be specified by SINNOWA, if any problems derived from that, SINNOWA will not offer free warranty.
e) Follow the recommended maintenance schedules and procedures as outlined in Chapter 8. Any incompliance will shorten the life span and affect the test results, or cause incidents, thus lose the free warranty.

10.2 Installation Limitations

a) SINNOWA authorized Engineer must perform the initial installation.
b) Place the analyzer on a stable, level surface. Locate the system
   Away from direct sunlight,
   Away from path of a cooled or heated air outlet with temperature extremes
   Away from drying ovens, centrifuges, x-ray equipment, copiers or ultrasonic cleaner.
c) Place the reagent containers on the same level as the analyzer.
d) In order to keep fine ventilation, adequate space should be provided around the analyzer. At least 40cm of space from the surrounding objects is needed for proper ventilation, and about 2m² space is needed for the analyzer and the reagent. Adequate space should be provided around the analyzer to perform necessary maintenance procedures.
e) Dust affects function and test result of instrument greatly; hospitals should settle this problem before using.
f) Working voltage, temperature, humidity requirement consult §1.13, §1.14, §3.3.
g) Before operating the analyzer for the initial measurement, verify that each reagent tuning is connected to the appropriate inlet and reagent container. Make sure the outlet
tubing is not twisted and the waste tubing is connected to the appropriate outlet and routed to a suitable waste container or drain.

h) Do not disconnect any electrical connection while the power is ON. Verify the analyzer is well connected with the ground to prevent electrical interfere and ensure the safety.

**CAUTION:**
Anyone without authorization of SINNOWA should **NOT** remove the screws on the cover, or the customer must take all the responsibility.

## 10.3 Personal Protective and Infection Control

a) Follow required laboratory or clinical procedures during daily operation or maintenance. Wear gloves and safety glasses to avoid direct contact to the samples.
b) Consider all the clinical specimens, controls and calibrators etc, that contain human blood or serum as being potentially infectious, wear standard laboratory clothing, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials. Do not smoke, eat or drink at working area. Do not suck or blow the tubing.
c) Consider the blood samples and waste have potential source of biological and chemical hazard, the operator should handle with extreme care during the disposal process and follow criterion of the local government when cleaning, handling, discharging.
d) Cannot put reagent which isn’t use up into new reagent container to prevent new reagent pollution.
e) Follow the manual to store reagent, calibrators and controls. The customer have obligation to take actions and management to prevent the reagent, calibrators and controls from deterioration, misapplication or eating by mistake. The reagent should be away from temperature extremes.

**CAUTION:**
Reagent will freeze when it is below 0°C, for which the reagent can not be used.

**CAUTION:**
Keep the reagents away from direct sunlight to avoid evaporation and contamination. Seal the cap of the container. Minimize the diameter of the hole to avoid evaporation and contamination.