# Full-Auto Hematology Analyzer

**User Manual** 

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## **Statement**

#### **Statement**

- <Full-auto hematology analyzer user manual> involves the agreement for right and obligation coming into being and termination in product quality warranty and service between seller and user.
- User must read this manual carefully and strictly operate the instrument according to this manual. The obligation of seller does not include any malfunction or error resulting from improper operating the instrument.
- Upon request, seller may provide, with compensation, necessary circuit diagrams and other information to help qualified technician to maintain and repair some parts, which seller may define as user serviceable.

#### **Quality Warranty:**

Seller guarantees new equipment other than accessories to be free from defects in workmanship and material for a period of one year from date of shipment under normal use and service.

The obligation of seller under this warranty is only cost free maintenance, namely including the man-hour and material charge, but not the losses and additional charge resulting from stopping using the instrument. Illustrate as follows:

- Freight charges (include customs charge and insurance).
- Related losses caused by the instrument cannot be used normally

The obligation of seller does not include the following situations caused by direct, indirect or consequential damages and delay:

- Improper use.
- Maintain the instrument out of accordance with maintenance regulation.
- Use the reagent or accessories not provided or authorized by seller
- Replace accessories unauthorized by seller or personnel repairs or modifies the instrument unauthorized by seller.

#### **After Service**

We have competent and experienced customer service department. If you have any problem or advice, please contact us.

#### How to Use the Manual

You are welcome to read this manual. This manual includes the in-depth information about installation, daily operation, calibration, controlling and maintenance. To achieve the optimal performance, be sure to operate and maintain the instrument according to this manual. If you has chosen the optional accessories such as external printer, read the manuals of those.

The data in this manual has been calibrated and is efficient. If the instrument is used for a special purpose, or the operational procedures/methods exceed the regulation of this manual, please contact with seller to inquire its validity and applicability. Otherwise seller will not be able to ensure the accuracy and validity of the measuring results, and will not perform any obligation for the direct or indirect results resulting from this action.

#### **Avoidance from Potential Hazard:**

User should read the "Safety Notice" and "Operation Notice" carefully.

There are several safety warning signs in this manual to help operators avoid hurting themselves or making the instrument damaged, resulting in incorrect measuring results.



## ⚠ Warning:

The instrument must be operated as the operating procedures, or else, there will be great hazards to both operator and environment.

# ⚠ Caution:

Emphasize the operating methods that must be obeyed. Avoid potential hazards or making the instrument damaged, resulting in incorrect measuring results.

#### Notice: Some important information.

Be sure all the personnel operate, maintain, remove, service the instrument as instructed in the product manuals.

## **Safety Guide**

To operate the instrument safely and effectively, be sure to read the following notices first.

Operating the instrument, without following the appointed methods by the manufacturer, may break down the defensive function of the system, and cause bodily injury or damage the instrument.

#### ■ Avoid electric shock

- (1) When the instrument power-on, the unauthorized maintenance personnel should not open the instrument.
- (2) If liquid enter into the instrument or the instrument leakage, please shut off the power immediately, and contact with manufacturer Customer Service Department or local distributor in the course. Improper use of the liquid may cause electric shock and result in damaging the instrument.

#### ■ Defence for biohazard and chemical hazards

Improper use of the sample may result in being infected.

Avoid touching sample, reagent and waste with hands directly. When operate the instrument, be sure to wear gloves to avoid being infected.

If skin contacts the sample, manage it according to operator working standard or inquiring a doctor to take remedial immediately.

Use the reagent carefully to avoid hand and clothes touch directly.

Once hand or clothes touch, flush the touched area with soap and plenty of water immediately.

If the reagent enters into the eyes incautiously, flush with plenty of water at once, and inquire a doctor for further treatment.

#### ■ Waste disposal

Reagent, quality control and some materials in the sample are controlled by pollution regulations and standard for charge of pollutants. Please abide by the local discharge regulation and inquire related reagent manufacturer.

#### ■ Prevention of fire and explosion

Be sure not to use flammable dangerous materials around the instrument.

## **Operation Notice**

To operate the instrument safely and reliably, be sure to obey the following notices.

#### ■ Purpose

Pay attention to the application range of the instrument statement. Make sure your use does not exceed the application range.

#### ■ Limitation of Operating environment

The instrument should be installed according to the required installation environment of the manual. Installation and use out of the appointed range may cause unreliable results, and make the instrument damaged.

Contact with Manufacturer Customer Service Department or local distributor if you need to change the state of the instrument.

#### ■ Limit of Operator

Only trained and authorized personnel by manufacturer can operate the instrument.

#### ■ Maintenance and Service

Be sure to maintain and service instrument according to this manua

## **Chapter 1** Instrument Introduction

#### **1.1 Name**

The full name of the instrument is full-auto hematology analyzer, two models for single channel or double channel.

#### 1.2 Structure

Host and accessory

#### 1.2.1 Host

Control the process of sample collection, dilution and analysis, include following units:

- 1. Power Supply unit.
- 2. Central control circuit unit.
- 3. Dilute unit
- 4. Display unit.
- 5. Thermal recorder.

#### 1.2.2 Accessories

Including the following accessories:

- 1. USB mouse.
- 2. USB keyboard.
- 3. External printer (Optional)
- 4. Power line cable
- 6. Ground line cable

#### 1.3 Purpose

It is used for detecting the parameters of RBC, WBC, HGB and differential count.

The analyzer is used for determination of the following 20 parameters and 3 histogram blood specimens in Table 1-1:

Items	Abbreviation	Units
White blood cell or leukocyte	WBC	10³/uL
Lymphocyte	LYM#	10 <sup>3</sup> /uL
Mid-sized cell	MID#	10 <sup>3</sup> /uL
Granulocyte	GRAN#	10 <sup>3</sup> /uL
Lymphocyte percentage	LYM%	%
Mid-sized cell percentage	MID%	%
Granulocyte percentage	GRAN%	%
Red blood cell or crythrocyte	RBC	10 <sup>6</sup> /uL
Hemoglobin concentration	HGB	g/dL
Hematocrit	HCT	%
Mean corpuscular(erythrocyte)cell volume	MCV	fL
Mean cell hemoglobin	MCH	pg
Mean cell hemoglobin concentration	MCHC	g/dL
Red blood cell distribution width- standard deviation	RDW-SD	fL
Red blood cell distribution width- coefficient of variation	RDW-CV	%
Platelet	PLT	10³/uL
Mean platelet volume	MPV	fL

Platelet distribution width	PDW	%
Plateletcrit	PCT	%
Plateletcrit-large cell ratio	P-LCR	%
White blood cell histogram	WBC Histogram	
Red blood cell histogram	RBC Histogram	
Platelet histogram	PLT Histogram	

Table 1-1

#### 1.4 Specifications

#### ■ Standard Classification of the instrument

According to the defence for deleterious liquid: General Device (Closing device of non-defensive liquid)

Disinfectant device recommended by manufactory

According to safety degree in condition that using gas mixture of flammable anesthetic gas and air or gas mixture of oxygen and nitrous oxide: Do not use the equipment in condition that using gas mixture of oxygen and nitrous oxide

According to working status, continuous running equipment.

#### Principles of Measurement :

Blood cells are counted and sized by electrical impedance method. Hemoglobin is determined by colorimetry method.

#### ■ Parameters of measurement

Basic parameters:

Items	Abbreviation	Unit
White blood cell	WBC	10 <sup>3</sup> /uL
Red blood cell	RBC	10 <sup>6</sup> /uL
Hemoglobin	HGB	g/L
Platelet	PLT	10 <sup>3</sup> /uL

#### Derived from histograms:

Items	Abbreviation	Unit
Lymphocyte percentage	LYM%	%
Mid-sized cell percentage	MID%	%
Granulocyte percentage	GRAN%	%
Mean corpuscular(erythrocyte)cell	MCV	fL
volume		
Red blood cell distribution width-	RDW-SD	fL
standard deviation		
Red blood cell distribution width-	RDW-CV	%
coefficient of variation		
Mean platelet volume	MPV	fL
Platelet distribution width	PDW	%
Plateletcrit-large cell ratio	P-LCR	%

#### Calculated Parameters:

Items	Abbreviation	Units
Lymphocyte	LYM#	10³/uL
Mid-sized cell	MID#	10³/uL

Granulocyte	GRAN#	10³/uL
Hematocrit	HCT	%
Mean cell hemoglobin	MCH	pg
Mean cell hemoglobin concentration	MCHC	g/L
Plateletcrit	PCT	%

## ■ Sampling features:

## Sample Volume:

Venous blood mode: 9.8µL Venous Blood Prediluted mode: 20µL Capillary Blood

#### Reagent Volume required for Single Sample test:

 Diluent:
 20 mL

 Rinse:
 4 mL

 Lyse:
 0.5 mL

**Diluent Ratio:** 

Venus and Capillary mode: WBC/HGB 1:300

RBC/PLT 1:44600

Prediluted Mode: WBC/HGB 1:355

RBC/PLT 1:44500

#### Cell counting aperture size:

WBC gem aperture 100μm RBC gem aperture 70μm

#### ■ Display

LCD 800×600 dot with color display.

## ■ Language

English

#### ■ Indicator

20 parameters and 3 histograms

Alarm indication

Working status (Including Power) Indicator light

Alarm

#### ■ Interface

Power input socket: 1
Print port: 1
VGA display port: 1
RS-232 serial ports: 2
USB interface: 2

#### ■ Recorder

Rapid thermal recorder
Paper width: 57.5mm

#### **■** Linearity Range

Parameters	Linearity
WBC	0.0-99.9x10 <sup>9</sup> /L
RBC	0.00-9.99x10 <sup>12</sup> /L
HGB	0-300g/L
MCV	40 - 150fL

PLT 0-999x10 <sup>9</sup> /L
------------------------------

## ■ Screen display and the range for report output parameters

Parameters	range	Parameters	range
WBC	0.0 - 99.9x10 <sup>9</sup> /L	GRAN#	0 - 99.9x10 <sup>9</sup> /L
RBC	0.00 - 9.99x10 <sup>12</sup> /L	HCT	0.0 - 100.0%
HGB	00.0 - 300g/L	MCH	0.0 - 999.9pg
PLT	0 - 3000x10 <sup>9</sup> /L	MCHC	0.0 - 999.9g/L
MCV	0 - 250fL	RDW-SD	0.0 - 99.9 fL
LYM%	0 - 100%	RDW-CV	0.0 - 99.9%
MID%	0 - 100%	PDW	0.0 - 30.0%
GRAN%	0 - 100%	MPV	0.0 - 30.0fL
LYM#	0 - 99.9x10 <sup>9</sup> /L	PCT	0.0 - 9.99%
MID#	0 - 99.9x10 <sup>9</sup> /L	P-LCR	0.0-99.9%

## ■ Operating Ambient

Temperature:  $15^{\circ}\text{C} \sim 35^{\circ}\text{C}$ Humidity: 10-90%

Atmospheric pressure: 86.0kPa ~106.0kPa

## ■ Ambient Storage

Temperature: -10 °C ~40 °C

Humidity: ≤80%

Atmospheric pressure: 50.0kPa ~106.0kPa

## **■** Electric Specifications

Power supply: 220(1±10% )V AC; 50±1Hz, 150VA

Fuse: F3.15AL250V

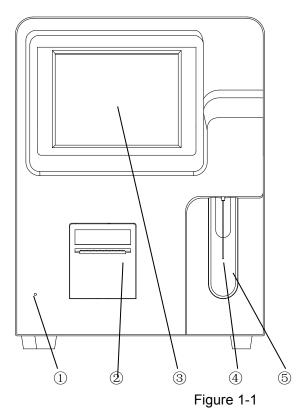
#### ■ Dimension/Weight

Dimension: 330mm×380mm×430mm

N.W.: 20Kg G.W.: 24.5Kg

# 1.5 Structure

## 1.5.1 Front Panel



①: Power light ②: Thermal recorder ③: Display ④: Sample needle ⑤: (START)key

# 1.5.2 Rear panel

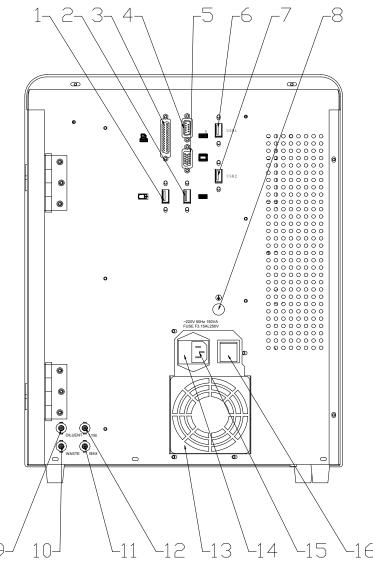


Figure 1-2

- ①: mouse socket
- 4: RS-232 socket 1
- ⑦: USB2
- 10: Waste connector
- (13): Air filter
- (16): Power switch

- ②: keyboard socket
- ⑤: VGA socket
- 8: Ground terminal
- (11): Rinse connector
- (14): Fuse holder
- ③: Printer socket
- ⑥:USB1
- 9: Diluent connector
- (12): Lyse connector
- (15): Power source socket

## 1.5.3 Right Door

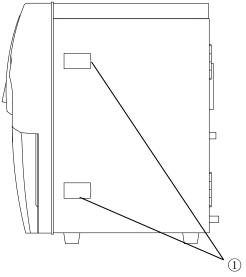


Figure 1-3

①: Side door fastener.

## 1.6 Operation menu

Designed according to human engineering and transferring information to users by software windows and mouse, both are convenient for your operating.

## 1.6.1 Display Screen

The display screen is classified five sections:

INFORMATION SECTION	SHORTCUT KEY SECTION
IDOWS DISPLAY SECTION	
DOWS DIST LAT SECTION	
AUXILIARY OPERATING SECT	TION
	IDOWS DISPLAY SECTION

Figure 1-4

## ■ System Time Section

Display the system current date and time.

#### ■ Information Section

Display prompt information of the system.

## ■ Shortcut Key section

Display the function interfaces of the system.

#### ■ Windows Display Section

Display various results.

#### ■ Auxiliary Operating Section

Display the information of user.

#### 1.6.2 Menu

You can operate the Instrument by menu. Press right key of the mouse, directing to the function menu of the current window. Move the mouse to the required menu bar, and then press the left key of the mouse, the required function will be selected. Pressing the left key out of the menu area, the operation will be cancelled.

The common function are showed at the top right corner of the screen as shortcut key, Move the mouse to the function you wanted.

The menu functions are as follows:

Sample Mode: Choose the sample modes among venous, capillary, pre-diluted mode.

**Diluent:** Inject the diluent through the sample needle. This menu uses only in Pre-diluted

mode.

**Info:** Enter the information window of the next sample, input and modify the information. **Histogram:** Enter the histogram adjustment window of current sample. You can manually adjust

the histograms of the current sample.

**Print:** Output the data of the current sample to the appointed device.

Function: enter the function menu.

**Mute:** Stop the alert.

**Help:** Access the system help window

**About:** Display information of the instrument such as software and copyright etc.

Shutdown: Start the shutdown program to clean the measurement units automatically. Shut off

the power supply after the screen displays "Turn off the power now".

Review: Enter the review window. You can review, search or modify the measurement data

of the former sample.

**Calibration:** Enter the calibration window to calibrate the instrument.

Quality Control: Enter the quality control window to carry out quality control operation.

**Service:** Enter the setting menu. **Service:** Enter the service menu.

**Manual Calibration:** Enter the manual calibration window to calibrate the instrument manually. **Auto Calibration:** Enter the auto calibration window to calibrate the instrument automatically.

**QC Edit:** Enter the QC edit window, edit the QC parameters.

QC Run: Enter the QC run window to carry out the QC run.

**QC Graphs:** Enter the QC graph window to browse the selected QC graph. **QC Table:** Enter the QC table window to browse the selected QC tables.

**Time:** Enter time setting window to set the time of instrument.

**Printout:** Enter the printout window to set the functions such as printer or report.

**Config**: Enter the config window to set the functions such as print, sleep, clean and display

etc.

**Limits:** Enter the limits window to modify the limits.

**Department:** Enter the department window to set the department and abbreviation.

**Operator:** Enter the operator window to set the operators such as name, input, department

and states.

**Flush:** Get rid of the aperture clog.

**Enhanced Flush:** get rid of the hard aperture clog.

**Cleaning:** Run the normal cleaning program to clean the measurement unit.

**Enhanced Cleaning:** Clean the measurement units with cleaner.

**Drain Chambers:** Empty the liquid of the counter pool.

**Park:** Run the park program to clean and empty the tubing.

Prime diluent: Inject the diluent into appointed tubing.Prime lyse: Inject the lyse into appointed tubing.Prime cleaner: Inject the rinse into appointed tubing.

**Maintenance:** Run the maintenance program to maintain the instrument.

**Mechanic:** Enter the mechanic window to verify the functions of the instrument. **Special:** Enter the special window to maintain the instrument, just used by engineer.

#### 1.7 Detection Principle

#### 1.7.1 Detection principles of WBC, RBC, PLT

The count principle of the instrument is based on the measurement of changes in electrical resistance produced by a particle passing through an aperture sensor.

- a) The sample blood is diluted in a conductive liquid. As blood cells are non-conductive, the diluent is a good conductor. There are big differences between them.
- b) When the diluent passes through the aperture sensor, electrodes are submerged in the liquid on each side of the aperture to create continuous current.
- c) When cells pass through the aperture, the resistance between the electrode increases as the cell volume increasing, as shown in figure 1-5. According to the Ohm formulary: U=RI (U =Voltage I =Current R =Resistance), If I is a constant, U increase as the cell volume increasing.
- d) Passing through the magnification circuit, the voltage signal will be magnified and the noise will be filtered, then you will gain the analytical results, as shown in figure 1-5.
- e) One count bath and the detection circuit count the WBC, another count bath and the detection circuit count the RBC and PLT. The microprocessor of the instrument calculates and analyzes the cell(WBC,RBC and PLT), then gives out the histograms.
- f) PLT count adopts advanced liquid, electronics and software system. It settles the repetitive count of the cells on the side of aperture count area.

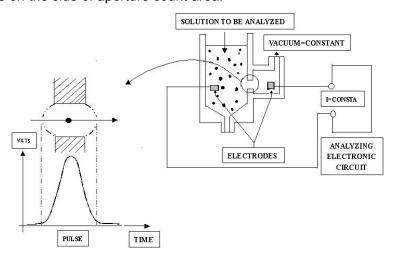


Figure 1-5

#### 1.7.2 Principle of HGB Measurement

Adding lyse into the blood, the red blood cells will rapidly be broken down and release hemoglobin. Hemoglobin and lyse form a new mixture, which can absorb the wavelength of 540 nm. Measure the absorbance between the pure diluent and the sample, the concentration of the sample hemoglobin is calculated.

#### 1.7.3 Volume Distribution of Blood Cells

When different types of cells pass through the aperture sensor, there will be different electrical pulse height. Because of the evident difference of the cells sizes, the instrument is able to differentiate the white blood cell, red blood cell and platelet by its pre-set program.

The volume distributions are as follows: (WBC, RBC, PLT etc.)

WBC	120—1000	fL
RBC	82—98	fL
PLT	2—35	fL

The leucocytes disposed by lyse can be divided into three types, according to their volumes: lymphocyte(LYM) Mid-sized cell (MID), granulocyte (GRAN).

LYM	35—90	
MID	90—160	fL
GRAN	160—450	fL

#### 1.7.4 Results and Calculation of Parameter Measurement

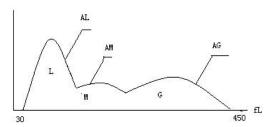
The parameters of sample blood test can be described in 3 ways:

- a) Measured directly, such as WBC, RBC, PLT, HGB.
- a) Derived from histograms, such as LYM%,MID%,GRAN%,MCV,RDW-SD,RDW-CV, MPV, PDW, P-LCR.
- b) Calculated, such as LYM#, MID#, GRAN#, HCT, MCH, MCHC, PCT.

The derivation formularies as follows:

- MCV derives from histograms and the instrument collecting and classifying the erythrocytes according to its volume. It is determined by measuring the average volume of individual erythrocytes, the unit is fl.
- RDW represents the volume distribution of the erythrocyte populations, derived from the RBC histogram. It can be expressed by the coefficient variation of erythrocyte volume as RDW-CV, and the units is %. It can also be expressed in standard deviation of the erythrocyte volume as RDW-SD, the units is fL.
- MPV is the average volume of individual platelets, derived from the PLT histogram. It represents the mean volume of the PLT population and can be expressed in fL
- PDW derived from the PLT histogram, It represents the geometry standard deviation(10 GSD) of the volume of the PLT populations.
- P-LCR derives from the PLT histogram, It represents the ratio of the bigger PLT and unit is %.
- HCT(%)= RBC x MCV/10
- MCH(pg)= 10 x HGB/RBC
- MCHC(g/L)= 100 x HGB/HCT
- PCT(%)= PLT x MPV/10
- LYM% = 100 x AL /(AL+AM+AG)
- MID% = 100 x AM /(AL+AM+AG)
- GRAN% =  $100 \times AG/(AL+AM+AG)$
- LYM# = LYM% x WBC/100

- MID# = MID% x WBC/100
- GRAN# = GRAN% x WBC/100



AL: Number of cells in LYM area;

AM: Number of cells between lymphocyte and granulocyte area;

AG: Number of cell in GRAN area;

## **Chapter 2 Installation**

#### 2.1 **Pack**

If packing damage is discovered after receiving the instrument, or the instrument is badly damaged, contact with the freight agent immediately to file a claim according to the damaged level. At the same time contact with your supplier to make sure the packing is complete. Then unpacking and installing the instrument as the following steps.

#### 2.2 Unpacking

Take out the instrument and accessories from the packing case carefully. Preserve the packing material for future transportation or storage.

- a) Check the accessories compared to the packing list.
- b) Check whether there are mechanical damages on the instrument and accessories.
- c) When moving the instrument, face to the front shell and hold up the bottom of the instrument with hands and carry it carefully.

If there is any problem, please recovery the packing and contact with your supplier immediately.

#### 2.3 **Installation Requirement**

#### 2.3.1 Installation Environment

The instrument should be placed on a clean steady room platform. Avoid direct sunlight and dust. Keep room temperature at 18~35℃, humidity no high than 70%, atmospheric pressure at 86.0~106.0Kpa.



#### Caution:

The instrument should avoid direct sunlight.



## 🗥 Caution:

The working environment of the instrument should avoid powerful equipment such as Centrifuge, CT, MRI,X-ray machine etc.



## 🗥 Caution:

Do not use equipment that may create strong radiation field such as mobile phone and cordless telephone. Strong radiation field will disturb some functions of the instrument.

#### 2.3.2 Space Requirement

At least 20cm on each side is the preferred access to ensure airiness.

#### Notice:

Reagents must be placed at the same working height as the instrument.

#### 2.3.3 Power Requirement

The power requirement as follows:

- 220(1±10%)V
- 50 Hz AC
- 150VA



# 🗥 Warning:

The instrument requires a single well-grounded power socket. Its grounding voltage is no more than 0.5V.



# 🗥 Warning:

A grounded outlet is required to connect with the grounding pole on the rear panel. Be sure to guarantee the reliability of the power grounding at working site.



## Caution:

Fluctuating electric will badly decrease the performance and reliability of the instrument. Proper action such as the installation of UPS (not provided by manufacturer) should be taken before use.

#### 2.4 Reagent Connections

There are three tube connectors in the back panel with color of red, green, blue on the rear panel of the instrument.

#### 2.4.1 Lyse Connection

Take out the LYSE tube with red mark from the accessory kit. Connect tube to the connector with the red mark on the left side of the rear panel of the instrument.

Place the other end of the Lyse tubing into the Lyse container, and turn the container cover until secure.

#### 2.4.2 Diluent Connection

Take out the diluent tube with green mark from the accessory kit. Connect tube to the connector with the green mark on the left side of the rear panel of the instrument.

Place the other end of the diluent tubing into the diluent container, and turn the container cover until secure.

#### 2.4.3 Rinse Connection

Take out the rinse tube with blue mark from the accessory kit. Connect tube to the connector with the blue mark on the left side of the rear panel of the instrument.

Place the other end of the rinse tubing into the rinse container, and turn the container cover until secure.

#### 2.4.4 Waste Connection

Take out the waste tube with no mark from the accessory kit. Connect tube connector to the connector with no mark on the left side of the rear panel of the instrument.

Place the other end of the waste tubing into waste bottle.



## 🗥 Caution:

After completing all the tubing installation, keep the tubing natural state, without distortion, folding and twist.



## ⚠ Caution:

The reagent must be applied with the instrument. Otherwise it may easily cause inaccurate measurement results and incorrect classification of the blood cells, or make the tubing system badly damaged.



# ⚠ Caution:

Keep the reagent from direct sunlight.



#### Caution:

After replacing the reagent container, discard the rest of the reagent in the former container. Forbid putting the rest of the reagent into the replacing container. Avoid polluting the new replacing reagent.



## $^{ extcolored{L}}$ Caution

When replacing the reagent, avoid making the plastic tube (inserted into the reagent container) contact other things. Avoid polluting the new replacing reagent.



Avoid using frozen reagent.



Avoid using the reagent out of its expiration date.

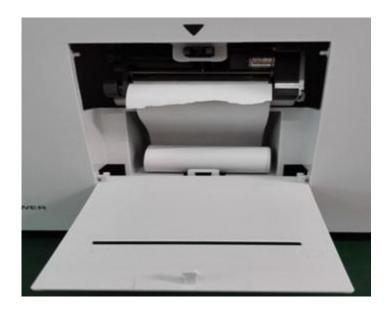


Handle and dispose of the waste according to acceptable laboratory, local state and national standards.

## 2.5 Record Paper Installation

- a) Tear down the gummed paper from the door of the recorder.
- b) Gently press the recorder door and open it.
- c) Insert the new paper into the paper entry, and make the printing side towards the thermal head.
- d) When the paper juts out from the other side, pull it out and keep it straight.
- e) Pull the paper out of the paper exit.

Shown as follows:



#### 2.6 Keyboard And Mouse Installation

Take out the keyboard, mouse from the packing case carefully.

Plug keyboard cable into the interface marked on the rear panel of the instrument.

Plug mouse cable into the interface marked on the rear panel of the instrument.

The keyboard and mouse can be placed where it is convenient for your operating, We suggest that the keyboard under the display screen of the instrument, the mouse at the right side of the keyboard.

## 2.7 External printer Installation (Optional)

Take out the external printer from the packing case carefully, Install the printer according to the printer manual.

#### Notice:

The printer cable can only be connected with the interface marked on the rear panel of the

instrument.

## 2.9 Power cable connection

Make sure the power switch is off (O) on the rear panel of the instrument. Insert one end of the power cable plug into the power cable interface on the instrument, the other end into the power socket. Connect the ground wire to the grounding port on the instrument.



Ensure the power is suitable for the instrument before connection.

## Chapter 3 Sample Analysis

#### 3.1 Preparation before startup

Every time before startup, the operator should do the following checks:

- a) Check whether the diluents and waste tubing are distortion, folding, twist, and whether the connection is secure.
- b) Check whether the power cable connection is secure.
- c) Check whether the accessory connection is secure.

#### 3.2 Startup

If external printer is equipped, turn on the printer power and ensure they are in ready status.

Press the power button on the rear panel of the instrument, then the power lamp on the front panel of the instrument lights on. The instrument automatically performs initialization program.

After complete initialization, the instrument will access self-test window. It tests the working conditions of each part and if there is enough diluent, cleaner and lyse. Simultaneously prime and clean the tubing.

After self-test, the instrument will access blood cell analyze window, as shown in figure 3-1 If the system detects malfunction, the failure information will be displayed on the information section.

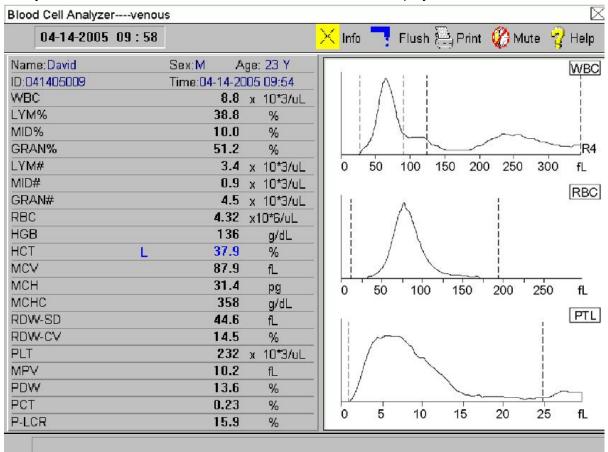


Figure 3-1

#### 3.3 Background Test

The background test is recommended after the instrument startup normally every time, the operator can also perform background test indeed. The operating procedures as follows:

a) In the blood cell analysis window, press "**Info**" button and pops up the information edit window. Then click the item textbox, change the ID No. as 999, then press "**OK**", return to blood cell

analysis window.

- b) In venous mode, press the "START" key below the sample needle directly for background count. In the pre-diluted mode, the sample needle aspirates some non-contaminated diluent from the sample cup for background count. The diluent pick-up method as follows( Analyzing the sample in pre-diluted mode, it is necessary to dilute sample with the diluent which is prior picked-up in this method):
  - 1) Press the right key of the mouse in the main operation area, pops up the menu. In menu operation area, select "Sample mode"; set the type as "Prediluted" as the sample mode;
  - 2) Press the right key of the mouse in the main operation area, pops up the menu. In menu operation area, select "Diluent";
  - 3) Place a clean empty sample cup or tube under the sample needle, press the "START" key to dispense the diluent into the sample cup or tube once. Press the "START" key once, the diluent is dispensed into the sample cup or tube once (The volume is enough for twice background test)
  - 4) Press "**Exit**" key, return to the main interface.
- c) The permissive range of the background test results are shown as table 3-1.

Parameters	Data	Unit
WBC	≤ 0.5	10 <sup>9</sup> /L
RBC	≤ 0.05	10 <sup>12</sup> /L
HGB	≤ 2	g/L
PLT	≤ 10	10 <sup>9</sup> /L

Table 3-1

If the value of the background test exceeds this permissive range, repeat the upper testing procedure until it can be accepted. If the test has been carried on above five times, the test result still cannot reach the standard required. Please refer to chapter 10 " troubleshooting" in this manual.

#### Notice:

Only five parameters WBC, RBC, HGB, HCT, PLT can be tested and displayed in the background test.

#### Notice:

The serial number 999 is a special number for the background test only

#### 3.4 Quality Control

It is necessary to perform quality control in installation for the first time or before sample analysis every day. Further information and procedures are given in Chapter 4 "Quality Control".

#### 3.5 Sample Collection

The sample can be collected either from capillary blood or from venous blood.



## ✓ Warning

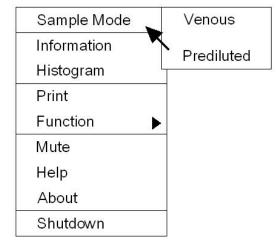
Avoid directly contacting with the blood sample, control and calibration in any case. Handle or dispose of these things according to acceptable laboratory or clinical standards.

#### 3.5.1 Venous Blood Collection

It is possible to collect venous blood by using negative pressure tube or in common collecting method. Add some anticoagulant in advance to the container for venous blood collection. EDTA.K2. 2H2O is commonly used as the anticoagulant, whose specified content is 1.5-2.2mg/ml blood.

#### 3.5.2 Prepare Samples in Pre-diluted Mode

In blood cell analyze window, select "Sample Mode/ Prediluted" in operation menu, then select "Diluent", when the "Diluent" pops up, place a clean sample cup obliquely under the probe. Press "START" key, the instrument starts to add diluent 2mL. When adding diluent, the indicator light glimmers quickly. Scrape the drops at the top of the sample needle into the sample cup when the indicator light glimmers slowly. Shown as follows:





Collect 20  $\mu$  L capillary sample in pipette. Wipe the blood attached on the outer layer of the pipette with clean tissues. Immediately mix up the sample in the diluents sample cup.

## ⚠Caution:

When adding the diluent, the sample cup must be placed obliquely under the sample needle, which allows the diluent to run down the cup wall without forming air bubbles.

#### Notice:

If there is a need to prepare samples in quantities in pre-diluted mode, user can use the "Diluent" function to continuously prepare the diluent.

#### 3.5.3 Sample Homogenization

The blood samples must be fully homogenized before use. The recommended method is: Shake up the tube up and down 3-5 minutes. Manufacturer's blood mixer is recommended to make the sample be fully homogenized and ensure the accuracy of measurement.

## ⚠ Caution:

If the sample has placed for a long time or mixed inadequately, it will easily cause measurement error and incorrect testing results.

#### **⚠**Caution:

Avoid shaking up the pipette violently.

## ⚠Caution:

The sample to be tested can only be stored at room temperature, and the test must be finished within

4 hours

#### 3.6 Sample Count and Analysis

After finishing sample collection, perform count and analysis procedure as follows.

#### 3.6.1 Input Sample Information

#### 3.6.1.1 Input Manual information

In blood cell analyze window, click "Info" button, pops up information edit window .Move the cursor to the required inputting item textbox. Input or select the data, and press "OK". The instrument will save the input information and returns to the blood cell analyzer window. Pressing "Cancel" key, the instrument cancels the information and returns to the blood cell analyzer window.

Name: Maximum 12 letters.

**Sex:** Select male or female, and the default is blank.

**Age:** Choose from year, month and day. Maximum 3 numbers while choosing year;maximum 2 numbers while choosing month and day.

**Blood:** Choose from A, B, O, AB, Rh+, Rh-. The default is blank.

Sample mode: The current sample mode.

Case Hist.: Maximum 12 letters.

Bed NO: Maximum 12 letters.

**ID:** The input range is: 00000000001 --9999999998. The instrument owns an intelligent number manager. The final number derives from the comprehensive information that the instrument adds the information of year, month and day in front of the input number according to the date. If user does not input the serial number, the instrument will accumulate the number from 000000001 everyday according to the measured date.

**Department:** Maximum 12 letters .You can also choose the recorded department information from the right optional textbox, or choose automatically by the instrument after inputting the code of the department in the left input textbox.

**Consigner:** Maximum 12 letters .You can also choose the recorded doctor information from the right optional textbox, or choose automatically by the instrument after inputting the code of the doctor in the left input textbox.

**Inspector:** Maximum 12 letters .You can also choose the recorded doctor information from the right optional textbox, or choose automatically by the instrument after inputting the code of the doctor in the left input textbox.

**Operator:** Maximum 12 letters .You can also choose the recorded doctor information from the right optional textbox, or choose automatically by the instrument after inputting the code of the doctor in the left input textbox.

**Limits:** Choose from general, man, woman, child, baby, define 1, define 2, define 3, automatically. While choosing "**Auto**", the instrument gives the reference value automatically as shown.

Reference value	Age	Sex
General	Not input	Blank ,Man, Woman
General	>13years old	Blank
Man	>13years old	Man
Woman	>13years old	woman
Child	>1month	Blank ,Man, Woman
	and<=13years	
Baby	<1month	Blank ,Man, Woman

Table 3-2

#### Notice:

The number 999999999 is the special number for background test. Please don't input this number in blood sample test.

#### 3.6.2 Procedure of Sample Count and Analysis

- a) Place a sample cup under the sample needle, press "**START**" key, the indicator lamp on the front panel of the instrument begins to glimmer. The instrument starts to aspirate the liquid. Move the sample cup until the indicator lamp stops glimmering.
- b) The instrument starts to analyze sample automatically, please wait for the analysis result.
- c) After the analysis finished, the result will be displayed in the rear of the corresponding parameters on blood cell analyze window of the instrument, with histograms WBC, RBC, PLT .As shown in figure 3-1.

If "Auto" item is "ON", the recorder or printer will output the test results automatically.

If there are clogs or bubbles during the count and analysis process, the information section would display "Clog" or "Bubble".

#### 3.6.3 Parameter Alarm

- "B": To indicate that bubble appears in the test.
- "C": To indicate that clog appears in the test.
- "L": To indicate the data has exceeded the setup lower alarm limit of the parameter.
- "H": To indicate the data has exceeded the setup higher alarm limit of the parameter.
- "\*\*\*": To indicate that the data is invalid.

#### Notice:

When PM alarm occurs on PLT histogram, the result of parameter PDW is \*\*\*.

#### Notice:

If the result of WBC is less than  $0.5x10^9$ /L, the system will not perform the leukocyte differential. The display for all parameters related to leukocyte differential is \*\*\*.

#### 3.6.4 Histogram Alarm

- "R1": To indicate the abnormality of the lymphocyte hump on the left. It may present platelets coagulate, large platelet nucleated red cell, insolvable red cell, abnormal lymphocyte, protein etc.
- "R2": To indicate the abnormality between lymphocyte and the mid-sized cell area. It may present a typical lymphocyte, abnormal lymphocyte, plasma cell, original cell or the increase of the number of the eosinophil or basophil.
- "R3": To indicate the abnormality between the mid-sized cell and granulocyte, It may present immature granulocytes, abnormal sub-population in the sample, or the increase of the number of the eosinophil.
- "R4": To indicate the abnormality on the right of the granulocytes area. It shows the increase of the number of the granulocyte.
- "RM": To indicate that more than two areas occurs abnormality. The upper reasons exist simultaneously
- "PM": To indicate the abnormality the blur demarcation between platelet and red blood cell area. Large platelet, platelet coagulation, small red blood cell, cell debris or fibrin may exist.

#### 3.7 Result modification

If user thinks that the results of WBC, RBC, and PLT differential cannot meet the needs of the classification of special samples in clinical or laboratory, he can manually adjust the histogram. Operate as follows:

- a) In the blood cell analyze window empty area, press the right key of the mouse, pops up the menu, select "Histogram" in menu, the instrument accesses histogram adjust window, as shown in figure 3-2. Press "Para" button to adjust the histogram.
- b) After selecting the histogram, press "Line" button and select the sorting line you want to adjust.
- c) Press "Left "or "Right" button, remove the sorting line to the left or right, the data of the line will be displayed at the top right corner of the screen.
- d) Press "Exit" button when finished the adjustment. If this operation did not change any data, the system would return to the blood cell analyze windows directly. Or else pops up the "OK/Cancel" window, press "OK" to save the adjustment result, while select "Cancel" to cancel the adjustment result.



## ⚠ Caution:

Unnecessary and incorrect manual adjustment will cause unreliable analytical result. Make sure the necessity of the operation.

#### Notice:

If the result of WBC is less than 0.5 x10<sup>9</sup>/L, the system will not perform leukocyte differential automatically.

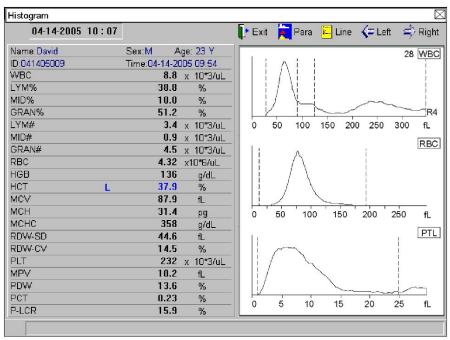


Figure 3-2

#### 3.8 Shutdown

Shutdown routine must be performed before turning off the power every day.

During shutdown procedure, the instrument will perform daily maintenance and clean the tubing automatically.

The procedures as follows:

- In the blood cell analyze window, press the right key of the mouse, pops up the menu. Select "Shutdown" in the menu, pops shutdown window, as shown in figure 3-3.
- If you do not want to shutdown the instrument for the moment, Click "Cancel" to return to the

blood cell analyze window.

- c) Press "**OK**", the instrument will perform daily maintenance and clean the measuring tubing. When the Shutdown procedure finished, the screen display as "**Turn off the power now**", turn off the power switch on the rear panel of the instrument.
- d) Turn off the external printer power, clean the workbench and dispose the waste.

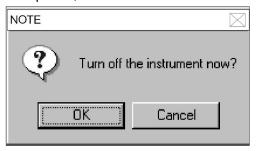


Figure 3-3

#### Note:

Do not turn off the power of instrument directly while performing the Shutdown procedure.

## **Chapter 4** Quality Control

Quality Control means the precision, accuracy and repeatability of the system. Quality control provides reliable and effective methods for the possible system errors in detection and prevention. The system errors may cause unreliable analytical result of the sample. To maintain the reliability of the analytical results, periodic quality control of the instrument is required.

The instrument provides 9 QC files for user. It allows the operator to run quality control to the 12 parameters at the same time.

At first select a QC file, enter the assay and limit of control data. The system allows the operator to run quality control with the 12 parameters or some of the 12 parameters simultaneously.



Manufacturer recommends controls specially designed for the use of full auto hematology analyzer. To unreliable results caused by using other controls, Manufacturer takes no responsibility.



Controls must be stored in appropriate conditions.



Do not use controls deteriorated or out of its expiration date.



Be sure to finish the quality control in a certain time every day.

## 4.1 Edit Quality Control Files

The operating procedures as follows:

a) In the blood cell analyze window, press the right key of the mouse, pops the menu, select "QC Edit" in the menu, the instrument enters Quality Control Edit window as figure 4-1:

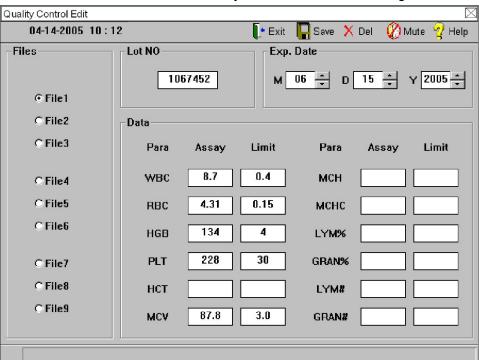


Figure 4-1

- b) In quality control edit window, select the QC file you want.
- c) Input the Lot NO. and Exp. Date of the control, the assay and limit of the quality control parameters

- d) Press "Save" button to save the data of the current QC file.
- e) Press "Del" button to delete the data of the current QC file.
- f) Press "Exit" button to save the data of the current QC file and return to the blood cell analyze window.

#### Notice:

If the parameter is an invalid data, the system will take the assay and limit as no assignment. It needs to re-input. Or else the quality control will only act on other parameters.

#### Notice:

If the lot number or expiration date is invalid, the system will take them as no assignment. It needs to re-input. Or else the QC file cannot run quality control program.

## 4.2 Quality Control Run

Input QC parameters and perform QC run of the specified file.

The operating procedures as follows:

- a) In the blood cell analyze windows, press right key of the mouse, pops up the menu. Select "QC Run" in the menu. The instrument enters quality control run window, as shown in figure 4-2.
- b) Prepare the controls and shake up the container until it well-mixed.

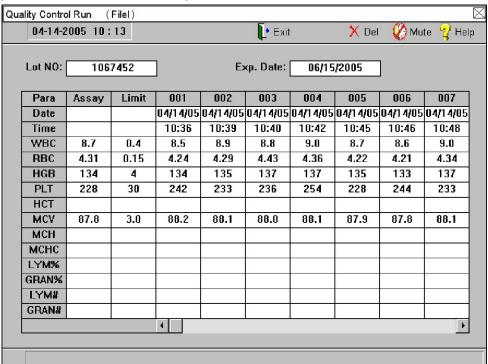


Figure 4-2

- c) Place the controls under the sample needle. Press "START" key, the indicator lamp start to glitter on the front panel of the instrument, the instrument imbibes the controls, move the controls away until the indicator lamp stop glittering.
- d) When the measurement finished, the result will displayed on the column of the current window. If alarm occurs in measurement, the current result may be incorrect, press "**Del**" button to delete the result and test again after the problem is solved.
- e) Press" Exit" button, the instrument will return to the blood cell analyze window.

#### Notice:

Each QC file can store up to 31 QC data.

#### 4.3 Quality Control Graph

The graph provides a visual observation of the control data, allowing the operator to observe the possible deviations, trends or shifts of the instrument performance.

In the blood cell analyze window, press the right key of the mouse, pops up the menu, Select "QC graph". The instrument enters quality control graph window, as shown in figure 4-3.

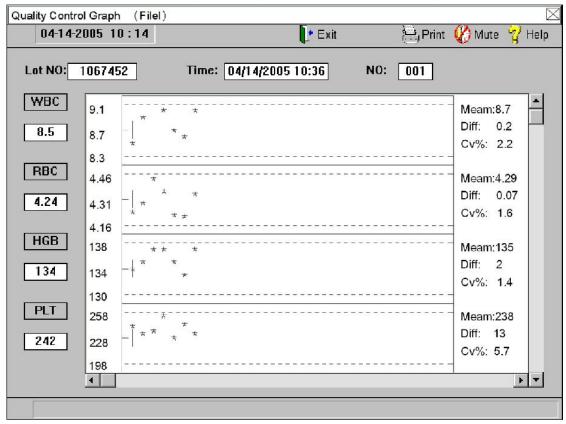


Figure 4-3

The screen can display 4 QC figures at the same time. The figure shows the lot number, time, serial number and distribution of the QC data. Click the scroll bar on the right of the screen, you can continuously select the QC graphs of different parameters.

The X-axis of the graph represents running times of quality control. The broken line above the QC graph: assay + limit. The broken line below the QC graph: assay-limit.

The three parameters at the left side of the QC graphs from top to bottom:

Assay + limit

Assay

Assay - limit

The three parameters at the right side of the QC graphs from top to bottom:

Mean: average value

Diff: standard deviation

CV: coefficient of deviation.

The vertical line in the middle of the QC graphs indicates the current chosen number. Click the scroll bar on the left of the screen. You can continuously select the different number.

The chosen number is displayed in the data box below the corresponding parameter. The test time for chosen number is displayed in the time box on the screen.

In the QC graphs window, the following marks represent:

- "\*": between the two broken line represents that the point is within the control range, otherwise, it is out of control range.
- ".": it means the parameter value is outside the operating range, or error has occurred during the

Blank: means there is no quality control on running.

Press "Print" button, it will print the data of the parameters on the screen.

Click "Exit" button to return to the blood cell analyze window.

#### 4.4 Quality control Table

The instrument supplies tabulated format for QC review. In the blood cell analyze windows, press the right key of the mouse, select "QC table". The instrument enters the quality control table window, as shown in figure 4-4.

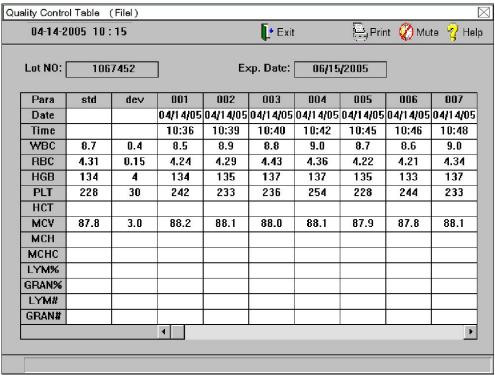


Figure 4-4

The screen can display the 12 QC parameters of 7 groups at the same time.

Operate the scroll bar in to select different serial number.

Click "Print" button, it will print the data of the parameters on the screen.

Click "Exit" button to return to the blood cell analyzer window.

# **Chapter 5** Calibration

The instrument has been calibrated strictly at the factory. You may need to perform calibration procedures when you replace any component that involves the primary measurement characteristics, or when the shift occurs during controls. Calibration of the instrument is to provide the assurance that the instrument is providing results with accuracy as design.

The purpose of calibration is to ensure the accuracy of the measurement result meet the requirement of the design all the time.

To ensure the accuracy of the instrument and obtain reliable measurement results, it is necessary to calibrate the instrument in the following situations:

- a) Installation for the first time or re-setup in a new place.
- b) The instrument is maintained.
- c) The result of QC is abnormal.
- d) The reagent has been changed.

To ensure the instrument's precision and obtain reliable measured results, the instrument should be calibrated in these situations:



## 🗥 Warning:

Calibrators authorized by manufacturer recommended. Calibrators should be stored and used properly according to the calibrator manual.



Make sure the instrument is in a normal state before calibration.



Avoid using the result of the measurement on medical test or clinical before the calibration is finished accurately.

The commercial calibrator or neutral controls that manufacturer authorized is recommended. Check the instrument and reagents carefully before calibration. Make sure the instrument is in a normal status, and make sure the required sample mode of the measurement.

#### 5.1 **Manual Calibration**

#### 5.1.1 Background Test

Refer to chapter 3 "Sample Analysis/ section 3.3", Ensure that the background test meets the requirement and no malfunction occurs.

## 5.1.2 Assurance of Repeatability

To ensure the calibration accurate, it is necessary to evaluate the repeatability measurement of the instrument. Make sure the instrument is in normal status, then perform calibration program.

The procedures are as follows:

- a) In blood cell analyze window, measure repeatedly with calibrator (no less than 3 times)
- b) Record the data of WBC, RBC, HGB, MCV, PLT. Calculate the CV value according to the following formula. Only the result are in the limits of table 5-1 can perform calibration.

$$CV = \frac{\sqrt{\sum_{i=1}^{n} (X_{i} - \overline{X})^{2}}}{\frac{n-1}{\overline{X}}} \times 100\%$$

 $\overline{X}$  -- Average of test results

 $X_i$  -- Test result of the i times

n -- Test times

Parameters	CV(%)
WBC	≤4.0
RBC	≤2.0
HGB	≤2.0
MCV	≤3.0
PLT	≤8.0

#### 5.1.3 Calculate calibration factors

Calculate the new calibration factors according to the following formula:

New coefficient = 
$$\frac{\text{current coefficient} \times \text{reference of calibrator}}{AV}$$
 AV=average

## 5.1.4 Modify the calibration Coefficient

- a) In the blood cell analyze window, press the right key of the mouse, pops the menu, select "Manual Calibration" in the menu, enter the calibration windows, as shown in figure 5-1.
- b) Select the calibration data you need from the calibration data menu box.
- c) Click "Print" button, the instrument will print the current calibration result.
- d) Click "**OK**" button to save the current calibration result and return to the blood cell analyze window.
- e) Click "Cancel" button, cancel the current calibration result and return to the blood cell analyze window.

#### Notice:

The instrument allows the user to input the factors with the range between 70%~130%.

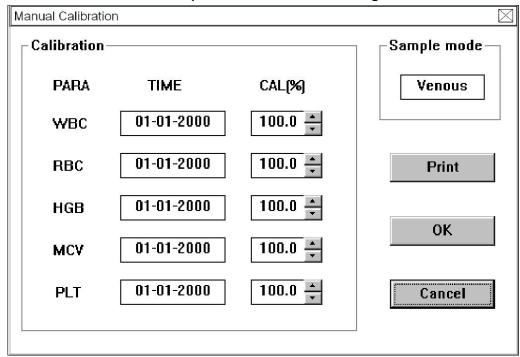


Figure 5-1

#### 5.2 Auto Calibration

The procedures are as follows:

a) In the blood cell analyze windows, press right key of the mouse, pops up the menu. Select "Auto

**calibration**" in the menu, the instrument enter into the auto calibration window, as shown in figure 5-2.

- b) Input the reference value of each calibration parameter.
- c) Prepare the calibrators and shake up the container until it well-mixed.
- d) Place the calibrators under the sample needle. Press "**START**" key, the indicator lamp start to glitter on the front panel of the instrument. The instrument imbibes the calibrators. Move the calibrators away until the indicator light stops glittering.
- e) When the measurement finished, the result will be displayed on the column of the current window. If alarm occurs in measurement, the current result may be incorrect.
- f) Click "Save" button, save the current calibration result.
- g) Click "Exit" button, back to the blood cell analyze windows.
- h) Press "Del" button to delete the result and test again after the problem is solved.

#### Notice:

Calibration can be performed 5 times at the most.

#### Notice:

The calibration result will be displayed after testing 3 times.

#### Notice:

If the parameter is an invalid data, the system will not perform calibration. It needs to re-input valid data.

#### Notice:

The permissive range of the factors is between 70% and 130%. If the result is exceeds the range, the system will not be able to save it, Find out the reason and perform calibration again.

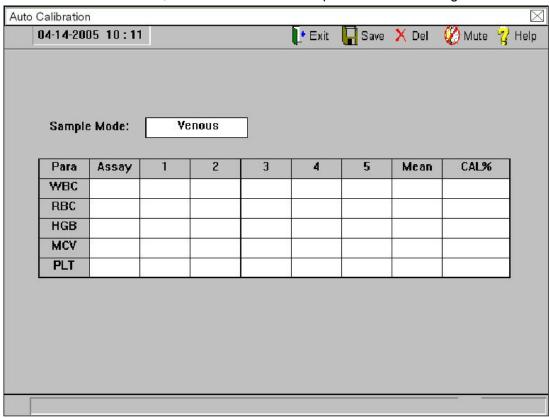


Figure 5-2

## Chapter 6 Setting

The instrument has accomplished all the settings at the factory. For customer's convenience, most of the system parameters can be setup by the operator so as to meet various requirements.

#### Notice:

The operation in this chapter will change the running state of the instrument. Please make sure the necessity of the changing before operating.

#### 6.1 Date & Time

In the blood cell analyzer window, press the right key of the mouse, pops up the menu. Select "Function/Setting/Date & Time". The instrument enters the time setting window. As shown in figure 6-1.

Click the menu bar to adjust setting item.

Click "OK", the instrument will save the current parameters and return to the blood cell analyze window.

Click "Cancel" button, the system will not save the current parameters and return to the blood cell analyze window.

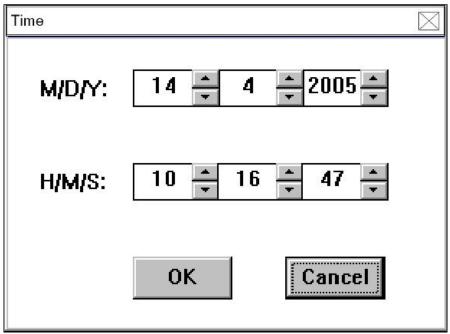


Figure 6-1

#### 6.2 Printout

In the blood cell analyzer window, press the right key of the mouse, pops up the menu. Select the "Function/Setting/ Printout", the instrument will enter the print window. As shown in figure 6-2.

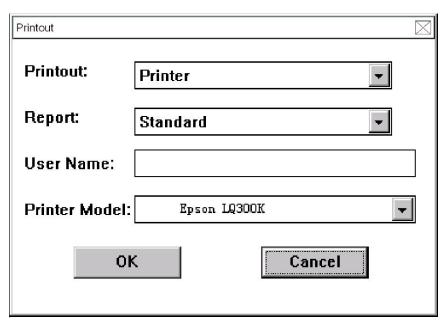


Figure 6-2

Click the menu box you want to adjust, pops up the optional window, Click the item you want to set.

Click "OK", save the current parameters and return to the blood cell analyzer window.

Click "Cancel" button, the system will not save the current parameters and back to the blood cell analyze window.

#### ■ Print select

Select recorder, the data will only be transported to the recorder.

Select printer, the data will only be transported to the printer.

Select net, the data will be transported to net.

Select recorder and net, the data will be transported to the recorder and net at the same time.

Select printer and net, the data will be transported to the printer and net at the same time.

#### Output formats of printer

There are different formats when selecting different settings, described as follows:

Printout set as "Recorder" or "Recorder, net":

Set the printing formats as default report format.

#### ■ Print headline

User can easily printout the headline on the report.

## ■ Print type

User can choose the type of the printer (Parallel lines). Epson: LQ-635K, LQ-630K

#### Notice:

The selected printer type must be Parallel lines, otherwise it will not be able to print normally.

## 6.3 Config

In the blood cell analyzer window, press the right key of the mouse, pops up the menu. Select "Function/Setting/Config", enter the print setting window. As shown in figure 6-2.

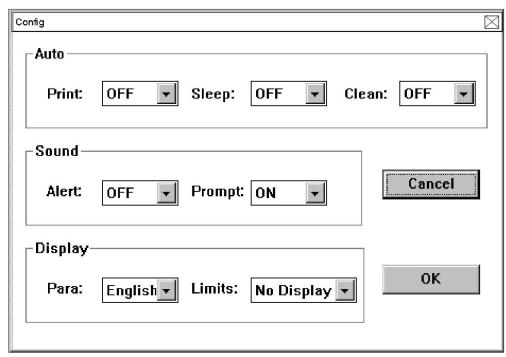


Figure 6-3

Click the menu box you want to adjust, pops up the optional window. Click the item you want to set. Click "**OK**", save the current parameters and return to the blood cell analyze window.

Click "Cancel" button, the system will not save the current parameters and return to the blood cell analyze window.

#### ■ Auto

Set "Print" as "ON", the system will print the test report automatically after sample test finished.

Set "Sleep" as "OFF", the instrument will keep working status all along. Set "Sleep" as data. When the time, which the user does not perform any operation, exceeds the setting time, the instrument will access sleep state. During sleep time, the instrument will turn off part of the circuit power, and take the sample needle back. Sleep function can greatly save electrical energy and extend the life of the instrument. Press the left key of the mouse or any key on the keyboard, sleep will be cancelled.

Set "Clean" as "OFF", the instrument will not perform auto-cleaning. Set "Clean" as data, When the running time of the instrument exceed the setting time, the instrument will perform "Clean" procedure once. It can ensure the measured tubing of the instrument clean and prevent the possible measurement malfunction and maintain the instrument.

#### ■ Sound

Set "Alert" as "OFF", when the instrument appears alarm, it will not make alarm sound, but display the alarm information in the information section.

Set "Alert" as "ON", when the instrument appears alarm, it will make alarm sound and display the alarm information in the information section.

Set "Prompt" as "OFF", when the sample measurement finished, the instrument make no sound.

Set "**Prompt**" as "**ON**", when the sample measurement finished, the instrument will make a prompt sound like "di".

## ■ Display

Set "Para" as "English", in parameter area of the blood analyze window, the parameters will be displayed in abbreviation.

Set "Limits" as "No display", in parameter area of the blood analyze window, the parameters will not display reference value of the current sample.

Set "Limits" as "Low to high", in parameter area of the blood analyze window, the reference value will be displayed from low to high.

Set "Limits" as "High to low", in parameter area of the blood analyze window, the reference value will be displayed from high to low.

#### 6.4 Limits

In the blood cell analyzer window, press the right key of the mouse, pops up the menu, Select" **Function/Setting/limits**", enter the limits setting window. As shown in figure 6-4.

The 8 group reference values are displayed at the left side of the screen. The dot in front of the reference value represents that this is the current selected reference group. The limits of the reference value are displayed on in the limits boxes on the screen.

Click the dot in front of the group to select the group required for setting.

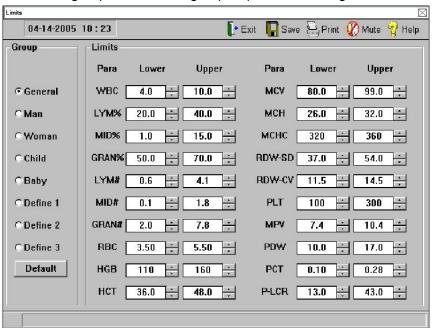


Figure 6-4

Click "default" button, the instrument will select the default reference value to replace the current reference values

Click the adjustable bar of the limits box to adjust the upper and lower limit of the reference value.

Function of menu and shortcut key:

**Save**: Save the reference value of the current group.

**Print:** Print the reference value of the current group.

Mute: To clear the sound of the occurred malfunction alarms.

Help: Enter into help window, you can obtain help on line.

**Exit**: Quit currently window, and return to blood cell analyzer window.

#### Notice:

The default reference value may not suitable for the local condition. User can modify it according to the local specific circumstances.

## **⚠**Caution:

The changing of the reference value will cause variation of abnormal prompt on hematology target. Please make sure the necessity of the variation.

### 6.5 Department

The department information can help user setup perfect sorting information in advance, and quicken the input speed and management of the sample information. Especially the abbreviation greatly improves the communication and standardization construction of laboratory digital information. In the blood cell analyzer window, press the right key of the mouse, pops up the menu, Select" **Function/Setting/ Department**, the instrument enters department setting window. As shown in figure 6-5.

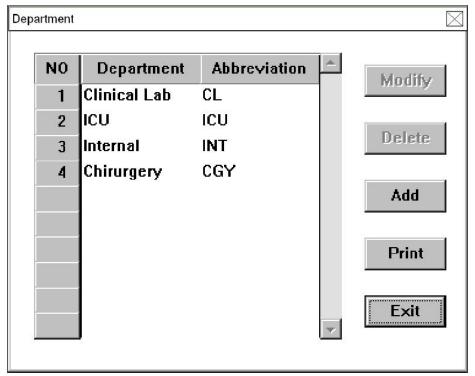


Figure 6-5

Click the scroll bar at the right side of the window, the instrument can record the serial number continuously.

Click "Exit" button, the system exit from the current window and return to blood cell analyze window.

## 6.5.1 Add Record Information

Click "Add" button, enters add window, as shown in figure 6-6.Input the information of department and abbreviation

Click "Cancel" button, the current input information will be cancelled, system returns to the department setting window.

Click "**OK**" button to save the current input information. The system returns to the department setting window.

#### Notice:

The coding method of the abbreviation should be easy to memory. In most circumstances, the abbreviation of the department name is recommended.

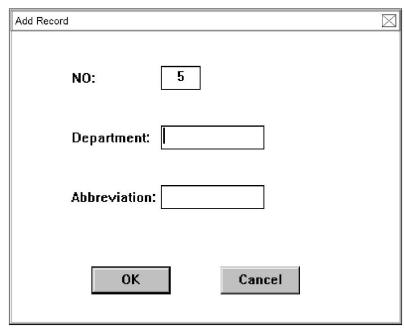


Figure 6-6

## 6.5.2 Modify Department Information

Click the serial number you want to modify, then click "**Modify**" button, the system enters to modify window, as shown in figure 6-7.

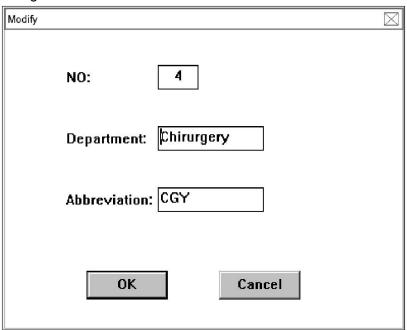


Figure 6-7

Modify the information you want to change.

Click "Cancel" button, the current input information will be canceled, system returns to the department setting window.

Click "OK" button to save the current input information, system returns to the department setting window.

## 6.5.3 Delete department information

Click the serial number you want to delete, then click "**Delete**" button, the selected department information will be deleted.

### 6.5.4 Print Department Information

Click "Print" button, print all the department information stored.

## 6.6 Operator Information

The operator information can help user setup perfect sorting information in advance, and quicken the input speed and management of the sample information. Especially the name greatly improves the communication and standardization construction of laboratory digital information.

In the blood cell analyzer window, press the right key of the mouse, pops up the menu. Select" **Function/Setting/ Operator**", the instrument enters the operator setting window. As shown in figure 6-8.

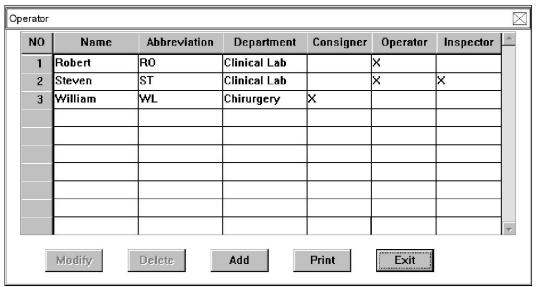


Figure 6-8

Click the scroll bar at the right side of the window to display continuously the records of different numbers.

Click "Exit" button, the system will exit the current window and return to blood cell analyzer window.

## 6.6.1 Add Operator Information

Click "Add" button, enters the adding record window, as shown in figure 6-9.

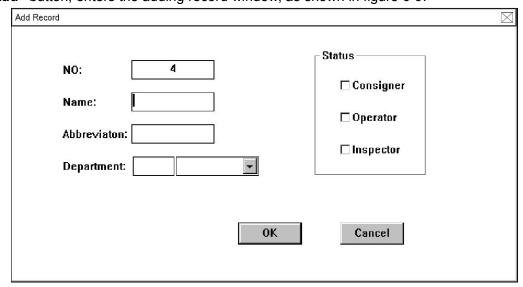


Figure 6-9

Input the information of name and abbreviation.

Input abbreviation information at the left input box of department, the system will select department automatically. You can also select the department directly from the right box of the department.

"Status" represents the status of the doctor, including: consigner, operator, inspector, click the box in the left directly, blank means no choice, black fork means selected. Selecting more than one item is allowed.

#### Notice:

The coding method of the abbreviation should be easy to memory. In most circumstances, the abbreviation of the department name is recommended.

### 6.6.2 Modify Operator Information

Click the serial number you want to change, then click "**Modify**" button, the system would enter to record modify window, as shown in figure 6-10.

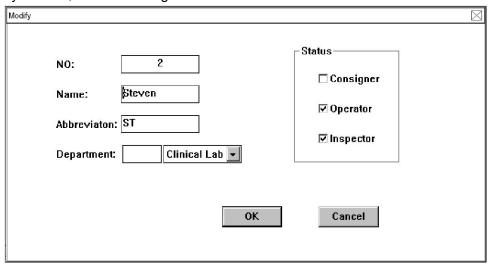


Figure 6-10

Modify the information of department and abbreviation as you want.

Click "Cancel" button, the current input information will be canceled, system returns to the department setting window.

Click "OK" button to save the current input information, and returns to the department setting window.

## 6.6.3 Delete Operator Information

Click the serial number you want to delete, then click "**Delete**" button, the selected department information will be deleted.

## 6.6.4 Print Operation Information

Click "Print" button, print all the operator information stored.

## Chapter 7 Review

The instrument can automatically store the result after each sample analysis. User can review, search, modify, print and delete the data.

## 7.1 Sample Review

In the blood cell analyze window, press the right key of the mouse, select the "Function/review" in the menu, as shown figure 7-1.

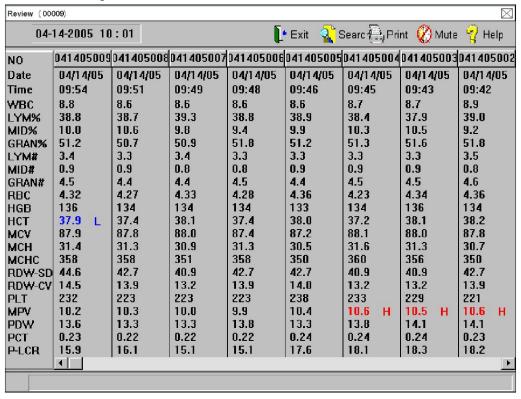


Figure 7-1

The data can be reviewed and printed in table.

8 sample parameters are displayed in each review screen in the order of time sequence.

The button of scroll bars at the bottom of the screen shows the current position.

The meaning of the characters as following:

- **T**: is displayed following the parameter indicating that the reagent temperature or environment temperature has exceeded the setup range.
- **H:** is displayed following the parameter indicating that the results exceeded the high limit of the system.
- **L:** is displayed following the parameter indicating that the results exceeded the low limit of the system.
- **C:** is displayed following the parameter indicating that clogs occur during the test.
- **B:** is displayed following the parameter indicating that bubbles occur during the test.

In this interface have functions such as review, search, print, etc.

Exit: Exit from the current window and return to blood cell analyze window

**Search:** Search the required sample data in any condition.

**Print:** Print the current data in table.

Mute: Get rid of the malfunction alarm.

**Help:** Enter into help window to obtain the help on line.

#### ■ Review the sample data

Click the left button of scroll bar at the bottom of the screen to review the next data.

Click the right button of scroll bar at the bottom of the screen to review the front data.

Click the left side of button at the bottom of the screen to review the front page of the data.

Click the right side of the button at the bottom of the screen to review the next page of the data.

Hold the button at the bottom of the screen, and draw the mouse to review the sample data quickly

#### Print the current sample data in table

The procedures as follows:

- a) Click the sample "**NO**" at the top of the screen, the data will be selected, click again, the selection will be cancelled
- b) Click "Print" shortcut key, the selected data would be printed in table.

#### ■ Search sample data

Print the selected data as follow steps:

- a) Click the right key of the mouse, pops up the menu, select "**Search**" in the menu, pops up the search window, as shown in figure 7-2.
- b) Click the box on the left of the item in need to search,"X" in the box means you have chosen the item, input the key word you want to search.
- c) Repeat the b) procedure until the current inputting item finished. Click "Cancel" button to cancel the searching. Click "OK" button, start to search the data. When the searching finished, the proper sample data will be displayed on the screen.

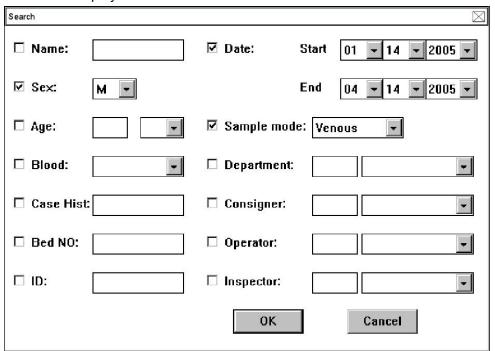


Figure 7-2

## 7.2 Detail operation in review interface

In the review interface window, press the right key of the mouse in the empty blank area, pops up the detail operation menu as follows:

Select All	
Detail	
Delete	
Print	
Mute	
Help	
Exit	

Select all: select or recover all the sample data.

**Detail:** turn into the detail review window.

**Delete:** Delete the selected data.

Print: Print the current data in table.Mute: Get rid of the malfunction alarm.

**Help:** Enter into help window to obtain the help on line.

**Exit:** Exit from the current window and return to blood cell analyzer window.

#### ■ Delete all data

The procedures as follows:

- a) Press the right key of the mouse, pops up the menu, then click "**Select All**" button, the data will be selected, Click again, the selection will be cancelled.
- b) Press the right key of the mouse, then clock "**Delete**" button, pops up a dialog box, let user choose to delete all the data or not. Select "**OK**", the data will be delete, select "**cancel**", the operation will be cancelled

### ■ Delete selected sample data

The procedures as follows:

- a) Click the sample "NO." at the top of the screen, the data will be selected, Click again, the selection will be cancelled.
- b) Press the right key of the mouse, pops up the menu, select "**Delete**" in the menu, pops up a dialog box, let user choose to delete the data or not, press "**OK**" button, the data will be deleted, press "**Cancel**" button, the operation will be cancelled.

#### ■ Detail review

In the detail review window, select "**Detail**" by menu or shortcut key. The instrument will access the detail review window, as shown figure 7-3.

This window can be review, modify, and print the sample data in graphs

#### 1 Review

Click "Next" button to review the next data.

Click "Previews" key to review the previous data.

#### 2 Modify Sample information

Click "Info" shortcut key, pops up "Information" window. The operation of this window refers to Chapter 3 "Sample analysis/ section 3.6.1".

#### **3** Modify Sample Data

Click the right key of the mouse, pops up the menu. Select "Histogram" in the menu.

The operation procedure as follows:

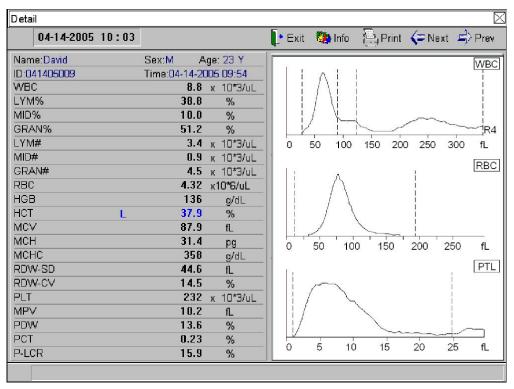


Figure 7-3

- a) Click "Para" shortcut key, you can select WBC, RBC, PLT in turn.
- b) Click "Line" shortcut key, you can select the class line in the histogram.
- c) Click "Right" or "Left" shortcut key, you can move the sorting line in the histogram to right or left. The data calculated according to the new sorting line would be displayed in the data area at the left side of the screen.
- d) Click "Exit" shortcut key, If user has modified the sample data, pops up a dialog box, user can select save the modification result or not. Click "OK" button, the result will be saved, Click "Cancel", the result would not be saved and the system exit from histogram modification status.

The function of the menu and shortcut key as follows:

**Previous**: review the previous data.

**Next**: review the next data.

**Information**: Input and modify the sample data.

**Print**: Print the current sample data. **Mute**: Get rid of the malfunction alarm.

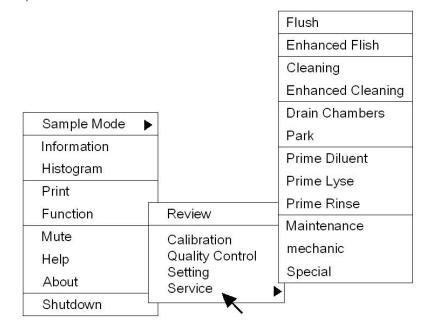
**Help:** Enter into window to obtain the help on line.

**Exi**t: Exit the current window and return to blood cell analyze window.

## **Chapter 8** Service

This chapter gives the description of various service functions provided by the instrument. These functions will bring convenient and pleasure.

In the blood cell analyzer window, press the right key of the mouse, pops the menu, Select" **Function/Service**", the menu shown as follows:



#### 8.1 Flush

This function is used for solving the general probe clogs.

The instrument makes a fixed pressure and voltage act on the probe to get rid of the clogs.

#### 8.2 Enhanced Flush

This function is used to solving indolent probe clogs.

Concentrated cleaner would be injected into WBC and RBC count pool, Get rid of the indolent probe clog by soaking it in the strong cleaner. Before performing the function, user should prepare the strong cleaner well.

### 8.3 Cleaning

This function is used for routine cleaning of the probe, sample needle, measuring tube.

#### 8.4 Enhanced cleaning

This function is used for the enhanced cleaning of the probe, sample needle, measurement tubing.

#### 8.5 Drain Chambers

This function is used for user to observe the count pool. The instrument will empty the liquid in the count pool.

### 8.6 Park

If the instrument is not going to be used in 2 week or longer, use this function to clean and empty the instrument. It is convenient for user to store the instrument. Prepare distilled water before performing the function.

#### 8.7 Prime Diluent

Filling full of the relative tube

## 8.8 Prime Lyse

Filling full of the relative tube

#### 8.9 Prime cleaner

Filling full of the relative tube

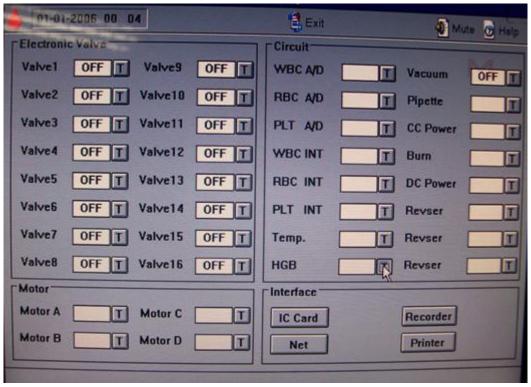
#### 8.10 Maintenance

User can finish the weekly maintenance according to the prompt information on the screen. Prepare cleaner and strong cleaner before performing the function.

#### 8.11 Mechanic

The password is 6000(for double channel model) or 6800(for single channel model), then enter into the mechanic interfaces.

Enter mechanic window. User can complete the detection of the valve, motor, circuit and interface. It is helpful to the insurance of the malfunction. Shown as follows:



#### Valve:

"ON" represents the valve is on.

"OFF" represents the valve is off.

### Motor:

"OK" represents that the motor is in normal status.

"FAIL" represents that the motor is failure.

#### Circuit:

"OK" represents the circuit is in normal status.

"FAIL" represents the circuit is failure.

'OFF' represents no negative pressure.

"ON" represents there is negative pressure.

"LOW" represents the temperature is lower than 15℃.

Function of menu and shortcut keys:

**Mute**: Close the alarm sound.

Help: turn into help windows, obtain the help on line.

**Exit**: Exit from the currently window, return to blood cell analyze window.

## 8.12 Special

Enter into special maintenance interface, user can adjust the running control data.

## **Chapter 9 Maintenance**

As other precision instrument, only careful daily service and periodic maintenance can keep the hematology analyzer in a good working status, and can get the reliable measurement results and have few malfunctions. This chapter introduces some preventive methods for service and maintenance.

According to the requirements for maintenance of the instrument during the using procedures, we divide the preventive service and maintenance into the following types: daily, weekly, monthly and yearly. Please perform them as actual need.

## ⚠Warning:

It is very important for the hospital or organization that employs this instrument to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown.

### 9.1 Routine Maintenance

## 9.1.1 Clean the Appearance

Wipe the appearance of the instrument with neutral detergent or distilled water.

## **⚠**Caution:

Avoid using corrosive acids and alkali, volatile organic solvent such as: acetone, aether chloroforms to wipe the appearance of instrument. Only neutral detergent can be used.

## **A**Caution

Avoid wiping the inner of the instrument.

## 9.1.2 Replace Fuse

The fuse is installed in the fuse-box on the side of power switch, open the box to replace the fuse. Fuse specification appointed: F3.15AL250V, shown as following:



## 🗥 Warning:

Only use the appointed fuse.

## 9.2 Daily Maintenance

It can be divided into two types: run and shutdown.

#### ■ Run

The instrument has installed daily maintenance procedure. On running, it can execute auto cleaning procedure according to the quantity of the sample to keep the instrument in a good working status. Set up the auto cleaning procedure according to the section 6.3. The general setting principles are: Working time > 8 hours, auto-clean time=8 hours;

4 hours<Working time<8 hours, auto-clean time=4 hours;

Working time< 4 hours, auto-clean time=2 hour;

The auto-cleaning time will decrease 1 hour year by year.

#### ■ Shutdown

When the instrument is shutdown, it will run daily shutdown auto cleaning procedure, you only need to clean the workbench and wipe the appearance of instrument when power-off.

## 9.3 Weekly Maintenance

This instrument has installed weekly maintenance procedure. Act as follows:

- a) Prepare concentrated cleaner and strong cleaner.
- b) In the main operation window, press the right key of the mouse, pops the menu, in the menu area, select "Function/Service/maintenance", Operate as screen shows.
- c) Turn off the power supply.
- d) Wipe the appearance of instrument as section 9.1.1.

## 9.4 Monthly Maintenance

It is necessary to clean the dust of the instrument monthly.

Operate as follows:

- a) Turn off the power supply, pull out the power line.
- b) Hold up the air filter cover with screwdriver.
- c) Take off the cover and the net, clean them with neuter detergent with brush and put them in the shade. Airing naturally. Brush away the dust clinging on the air filter grid at the rear panel of instrument.
- d) Put the air filter grid on the air filter net carefully.

## **Notice**

Only can use the neutral detergent cleaning the air filter. Avoid airing it with heat.

## 9.5 Yearly Maintenance

It's necessary to perform preventive maintenance once every year. Because of the highly-requirements for yearly maintenance, the maintenance should be performed by the authorized engineer. Please contact with customer service department of seller before yearly maintenance.

## 9.6 Maintenance before transport or not using for a long time

If the instrument is not going to be used in 2 week or longer, or need to pack and transport, performing the following procedures:

- a) In the main operation window, press the right key of the mouse, select the "Function/Service/park".
- b) Operate as screen shows.
- c) Rotate the bottle covers of rest reagents and store them as reagent operation introduction. User should perform efficient action to prevent the material from deteriorating, and misusing.
- d) Plug the stopples which were pulled out at first installation into the corresponding tube connector.
- e) Pull out diluent connection tube, cleaner connection tube, lyse connection tube and waste connection tube and clean them with distilled water. Dry them in shady place, then pack with plastic bag.
- f) Pull out the power wire, packing it in plastics after cleaning with neuter detergent.
- g) Put the instrument and parts packed in plastic into the packaging cases.

## **Chapter 10** Troubleshooting

This chapter contains information that is helpful in identifying and resolving instrument problems that may occur in the operation of the analyzer. If the problems cannot be corrected with the aid of this chapter, then should contact the Customer Service Department of seller.

## 10.1 Abnormal startup

Methods and procedures

- a) Check the power on or not.
- b) Check the power socket is loose or not.
- c) Check the fuse is broken or not. If the fuse is broken, replace it as section 9.1.2.

#### 10.2 Waste Full

Methods and procedures:

Dispose of the waste in the waste container.

## 10.3 Diluent empty

Methods and procedures:

- a) Replace diluent.
- b) In the blood cell analyzer window, press the right key of the mouse, pops up the menu, select "Function/Service/Prime diluent" in the menu.

## 10.4 Lyse empty

Methods and procedures:

- a) Replace lyse bottle.
- b) In the blood cell analyzer window, press the right key of the mouse, pops up the menu, select "Function/Service/Prime lyse".

## 10.5 Cleaner empty

Methods and procedures:

- a) Replace Cleaner (Rinse)
- b) In the blood cell analyzer window, press the right key of the mouse, pops the menu, select" **Function/Service/Prime cleaner**".

## 10.6 WBC Clog or RBC Clog

If the count time exceeds high limit of the setting during measurement, the "Clog" alarm will occurs. Such as "WBC CLOG" or "RBC CLOG".

Methods and procedures:

- a) In the blood cell analyze window, press "Flush" shortcut key.
- b) If the upper method could not resolve the problem, perform as the following procedures.
- c) In the blood cell analyze window, press right key of the mouse, pops up the menu, select" Function/ Service/ Enhanced cleaning" in the menu. Follow the screen prompt information to finish it.
- d) If any other methods cannot resolve this problem, please consider to break up the test chamber as components, clean the aperture sensor carefully, re-assemble it again. Then run the "Function/ Service/ Enhance cleaning" and "Function/ Service/ prime diluent", after that, run background test again. The test chamber graph as following:

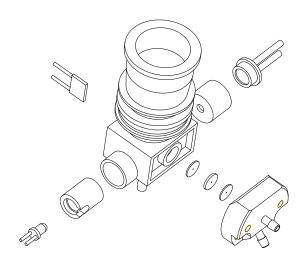


Figure 10-1

## 10.7 WBC Bubbles or RBC Bubbles

If the count time exceeds lower limit of the setting during measurement, there will be "Bubble" alarm occurs, such as "WBC BUBBLES", "RBC BUBBLES"

Methods and procedures:

In the blood cell analyze window, press the right key of the mouse, pops up the menu ,select" **Function/ Service/Enhanced Flush**" in the menu. Follow the screen prompt information to finish it.

#### 10.8 HGB error

Methods and procedures:

- a) In the blood cell analyze window, press the right key of the mouse, select "Function/ Service/cleaning", following the screen prompt information to finish it.
- b) If the upper method could not solve the problem, In the blood cell analyze window, press the right key of the mouse, pops the menu, select "Function/ Service/ Enhance cleaning" in the menu. Follow the screen prompt information to finish it.
- c) If the upper method could not solve the problem, can check the HGB Voltage is good or not, you can adjust it as following step:

Select "Function/ Service/ Mechanic", input password: 6000(for double channel model) or 6800(for single channel model), then enter into the mechanic interfaces, shown as follows:

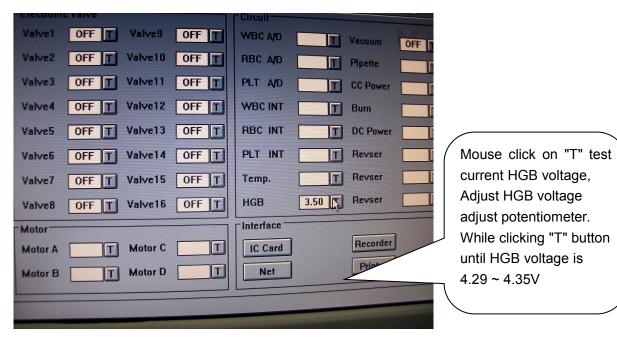


Figure 10-2

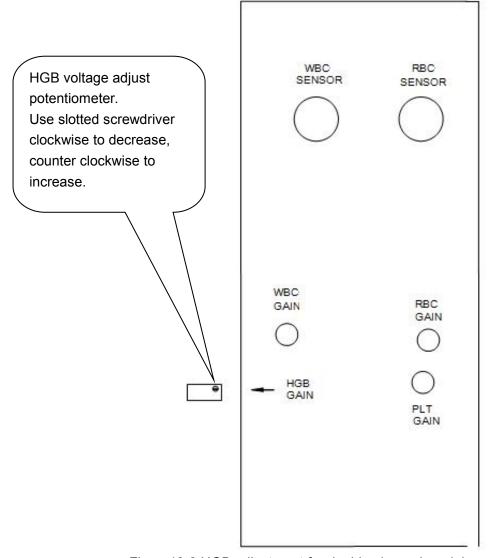


Figure 10-3 HGB adjustment for double channel model

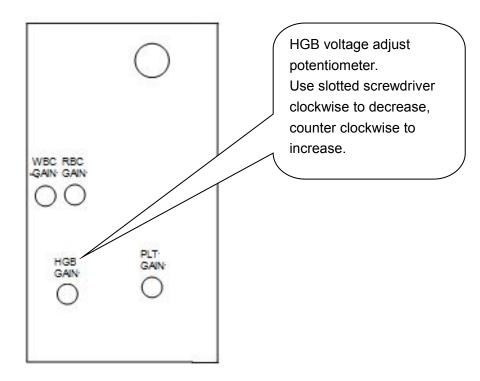


Figure 10-4 HGB adjustment for single channel model

#### 10.9 HGB Bubbles

Methods and procedures:

- a) In the blood cell analyze window, press the right key of the mouse, pops the menu, select "Function / Service/cleaning".
- b) If the upper method could not solve the problem, perform as the following procedures
- c) In the blood cell analyze window, press the right key of the mouse, pops the menu, select "Function/ Service/cleaning" in the menu. Follow the screen prompt information to finish it.

## 10.10 Recorder out of paper

Methods and procedures:

- a) Gently press the recorder door to open it.
- b) Insert the new paper into the paper entry, let the printing side towards the thermal head.
- c) When the paper just out from the other side, pull the paper out and keep it straight.
- d) Put the paper out of the recorder door.
- e) Close the door of the recorder.

## 10.11 Recorder too hot

The thermal head of the recorder is too hot.

Methods and procedures:

Suspend pause using the recorder for 5 minutes

## 10.12 The background test too high

Methods and procedures:

- a) In the blood cell analyze window, press the right key of the mouse, pops the menu, select "Function/ Service/cleaning".
- b) If the upper method could not solve the problem, repeat the procedure 3 times. If the problem still cannot be resolved, perform as he following procedures
- c) In the blood cell analyze window, press the right key of the mouse, pops the menu, select

"Function/ Service/ Enhance cleaning" in the menu. Follow the screen prompt information to finish it, then select "Function/ Service/ prime diluent"

- d) If the upper method could not solve the problem, repeat the procedure c) 3 times. If the problem still cannot be resolved, perform the upper procedures after replace all the reagents
- e) The dilutor of the instrument has too dirty, break up the dilutor as components, clean the diluent seal, piston and diluent room with alcohol carefully, assemble it again. Then run the "Function/ Service/ Enhance cleaning" and "Function/ Service/ prime diluent", after that, run background test again. If it cannot resolve the problem also, please change the seal. The dilutor graph as follows:

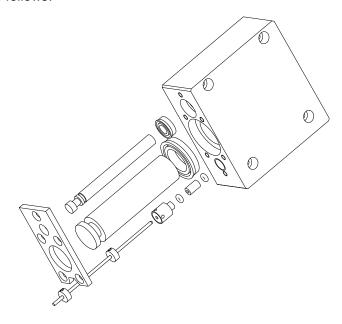


Figure 10-5

f) The sample needle clean room had more dirty, please break up the dilutor as components. Clean the oring seal and cleaning room with alcohol carefully.

The sample needle clean room as shown:

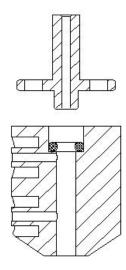


Figure 10-6

## 10.13 The result is not stable

a) The sample volume is not accurate, please break up the sample piston and o ring seals from the dilutor, change it o ring seals, re-assemble it again, shown as figure 10-5.

b) The vacuum pump had problem, please inject little water in the top of it, run the test procedure, there have some air bubbles get out of the top of the pump, the seals had been to break. Please break up the dilutor as components, change the seal and cleaning room with alcohol carefully. The pump graph as follows:

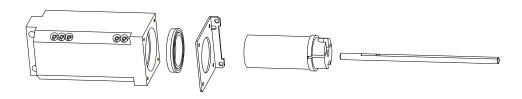


Figure 10-7

## 10.14 The liquid bath graph for the double channel model

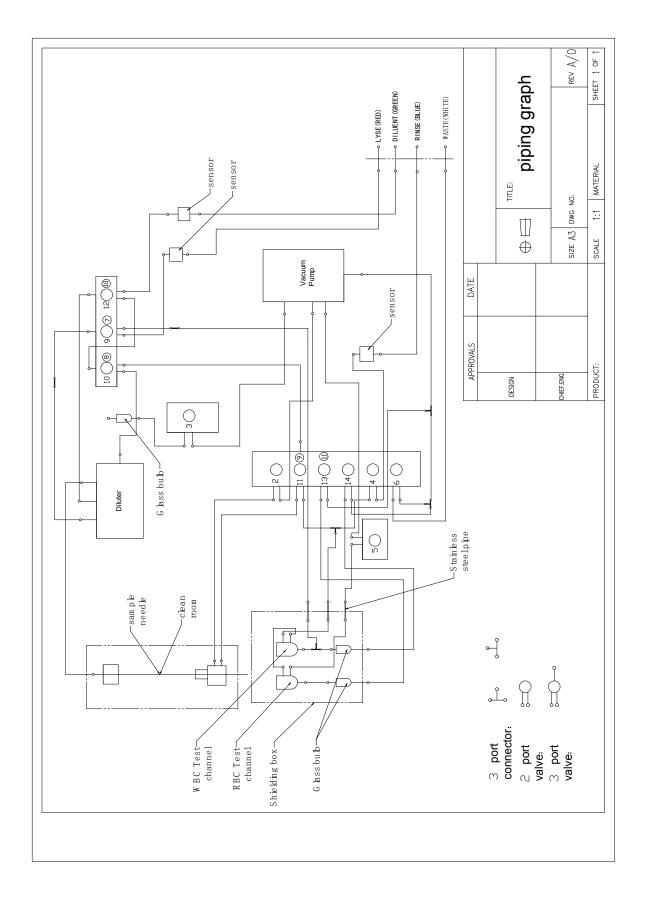


Figure 10-8

## 10.15 The liquid bath graph for the single channel model

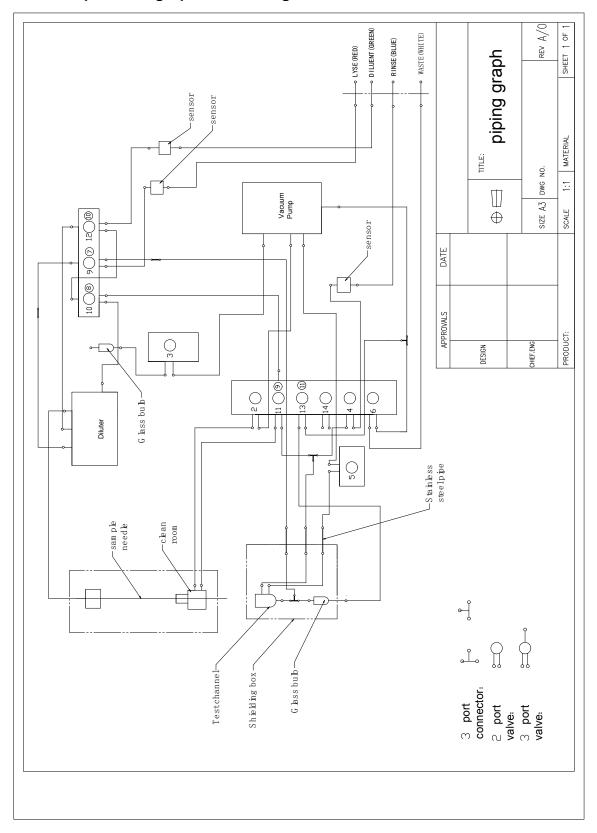
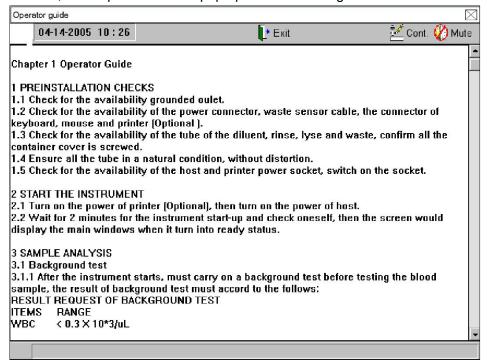


Figure 10-9

## **Chapter 11** Help

The instrument provides **on-line** help during operation. It is helpful for user to solve common problems and indicate the next operation.

Besides the instrument provides help for user to read and search the information in window. In the blood cell analyze window, press the right key of the mouse, pops up the menu. Select "Help" in the menu, the help windows will pop up. As shown in figure 11-1.



This window shows in chapter mode, user can search help information conveniently.

Click the scroll bar up and down, read the information front and back.

Function of the menu and shortcut keys.

Cont: Select the required contents Mute: Get rid of the alarm sound

Exit: Exit from the current window and return to blood analyze window

# Appendix 1: Symbol



Earth pin



Notice



Dangerous Voltage



COM 1 Socket



COM 2 Socket



Display Socket



Keyboard Socket



Mouse Socket



Printer Socket