Operation Manual

Auto Hematology Analyzer

About this Manual

Release Date: March 2015

Item No.: P01.91.300254-00

Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which the manufacturer cannot be held liable.

The manufacturer reserves the right to modify and update this manual without prior notice.

The manufacturer reserves the final explanation right to this manual.

Warning

This system can only be operated by test professionals, doctors, lab workers or personnel for system maintenance and troubleshooting, who have been trained by the manufacturer.

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

Make sure to use the instrument under the provisions of this *Operation Manual.* Otherwise, the instrument may not work normally, the test result is unreliable and it may damage the instrument parts and endanger people's safety.

How to use the manual

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

The data in this manual has been calibrated and is efficient. If the instrument is used in special purpose, or the operational procedures/methods exceed the regulation of this manual, please contact with the manufacturer to inquire its validity and applicability. Otherwise the manufacturer 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 hazard or making the instrument damaged, resulting in incorrect measuring results.

Notice: To emphasize important information. All personnel that may operate, maintain, remove, service the instrument should read this manual carefully.

Safety notice

To operate the instrument safely and effectively, be sure to read the following notices first. Operating the instrument, without following the appointed methods of 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 power is on, the unauthorized maintenance personnel should not open the instrument.

2) If liquid enters into the instrument or the instrument has leakage, please shutoff the power immediately, and contact the Customer Service Department of the manufacturer or your local distributor in due course. Improper use of the liquid may cause electric shock and result in damaging the instrument.

• Defense for biohazard and chemical hazards

Improper use of the sample may result in being infected.

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

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

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

Reagents, quality control serum, some materials in the sample are controlled by Pollution Regulations and Standard for Discharge of

Pollutants. Please abide by the local discharge regulation and inquire related reagent manufacturer.

• Prevention of fire and explosion

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. 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 the Customer Service Department of the manufacturer or your local distributor if you need to change the state of the instrument.

• Limit of operator

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

• Maintenance and service

Be sure to service and maintain the instrument according to this manual strictly.

Table of Contents

Chapter 1 Instrument Introduction

1.1 Composition

This Auto Hematology Analyzer consists of two parts: the host and the accessories.

1.1.1 Host

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

1) Power supply unit

2) Central control circuit unit

3) Dilute unit

4) Display unit

5) Thermal recorder

1.1.2 Accessory

Including the following accessories:

1) Mouse

2) Keyboard

3) Printer (Optional)

4) Touch pen

5) Power cable

6) Ground cable

7) Serial port cable

1.2 Purpose

This analyzer is used for detecting the parameters of RBC, WBC, HGB and differential counting. The following 20 parameters and 3 histograms of blood can be obtained from the analysis.

Item	Abbreviation	Unit
White blood cell or leukocyte	WBC	10^3/μL
Lymphocyte	LYM#	10^3/μL
Mid-sized cell	MID#	10^3/μL
Neutrophil	NEUT#	10^3/μL
Lymphocyte percentage	LYM%	%
Mid-sized cell percentage	MID%	%
Neutrophil percentage	NEUT%	%
Red blood cell or erythrocyte	RBC	10^6/μL
Hemoglobin concentration	HGB	g/dL
Hematocrit	HCT	%
Mean Corpuscular (erythrocyte) 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 (erythrocyte) Distribution Width-Coefficient of Variation	RDW-CV	%
Platelet	PLT	10^3/μL
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

1.3 Specifications

• Standard Classification of the Instrument

According to anti-electrical shock hazard: Grade II, Pollution 2

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

According to the recommended disinfection/sterilization method of the

manufactory: 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 flammable anesthetic gas and air or gas mixture of oxygen and nitrous oxide.

According to the working status: Continuous running equipment

• Principles of Measurement

Blood cells are counted and sized by Electrical Impedance Method. Hemoglobin is determined by Colorimetric Method.

• Parameters of Measurement

Basic Parameters:

Item	Abbreviation	Unit
White Blood Cell	WBC	10^3/μL
Red Blood Cell	RBC	10^6/μL
Hemoglobin concentration	HGB	g/dL
Platelet	PLT	10^3/μL

Table 1-2

Derived from Histograms:

Item	Abbreviation	Unit
Lymphocyte percentage	LYM%	%
Mid-sized cell percentage	MID%	%

Neutrophil percentage	NEUT%	%
Mean Corpuscular (erythrocyte) Volume	MCV	fL
Red Blood Cell Distribution Width-Standard Deviation	RDW-SD	fL
Red Blood Cell (erythrocyte) Distribution Width-Coefficient of Variation	RDW-CV	%
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	%
Plateletcrit-Large Cell Ratio	P-LCR	%

Table 1-3

Calculated Parameters:

Item	**Abbreviation**	**Unit**
Lymphocyte	LYM#	10^3/μL
Mid-sized cell	MID#	10^3/μL
Neutrophil	NEUT#	10^3/μL
Hematocrit	HCT	%
Mean Cell Hemoglobin	MCH	pg

Mean Cell Hemoglobin Concentration	MCHC	g/dL
Plateletcrit	PCT	%

Table 1-4

Sampling Features:

Sample Volume:

Venous Blood Mode: 10μL Venous Blood

Capillary Blood Mode: 10μL Capillary Blood

Prediluted Mode: 20μL Capillary Blood

Reagent Volumes Required for Single Sample:

Diluent: 26mL

Lyse: 0.35mL

Venous and Capillary Blood Mode:

WBC/HGB 1:285

RBC/PLT 1:21667

WBC/HGB 1:500

RBC/PLT 1:43333

Cell Counting Aperture Size:

WBC: 100μm

RBC/PLT: 70μm

Throughput: Up to 35 samples per hour (KT-6200)

Up to 60 samples per hour (KT-6300)

Working mode:

Double counting pathway + independent HGB detection system

Display:

Liquid Crystal Display (LCD), touch screen resolution: 800*600

Language: English, Chinese, Spanish, etc. (Customizable)

Indicator: Power indicator light

Interface:

One power input socket

One printer port

One RS232/C serial port

One VGA interface

Four USB interfaces

Recorder:

Rapid Thermal Recorder: Recording width: 35mm, Paper width: 80mm

Precision Specifications of the Instrument

Repeatability:

Parameter	Repeatability
WBC	≤ 2.0%
RBC	≤ 1.5%
HGB	≤ 1.5%
MCV	≤ 0.4%
PLT	≤ 4.0%

Table 1-5

Linear Range:

Parameter	Measuring range	Measurement of the linear tolerance
WBC	0~5.9×10^9/L 6.0~99.9×10^9/L	(±0.3×10^9)/L ±5%
RBC	0~0.99×10^{12}/L 1.0~9.99×10^{12}/L	(±0.05×10^{12})/L ±5%
HGB	0~99g/L 100~300g/L	±2.0g/L ±2%
PLT	0~99×10^9/L 100~999×10^9/L	(±8.0×10^9)/L ±10%

Table 1-6

Screen display and the parameter ranges for report output

Parameter	Parameter Range	Parameter	Parameter Range
WBC	0.0-99.9x10^3/μL	NEUT#	0-99.9x10^3/μL
RBC	0.0-9.99x10^6/μL	HCT	0.0-100%
HGB	0.0-30g/dL	MCH	0.0-999.9pg
PLT	0-3000x10^3/μL	MCHC	0.0-99.9g/dL

MCV	0-250fL	RDW-SD	0.0-99.9fL
LYM%	0-100%	RDW-CV	0.0-99.9%
MID%	0-100%	PDW	0.0-30.0%
NEUT%	0-100%	MPV	0.0-30.0fL
LYM#	0-99.9x10^3/μL	PCT	0.0-9.99%
MID#	0-99.9x10^3/μL	P-LCR	0.0-99.9%

Table 1-7

Operation Condition

Temperature: 18℃-35℃

Humidity: 10%RH~90%RH

Atmospheric Pressure: 86.0kPa~106.0kPa

Storage Condition

Temperature: -10℃-40℃

Humidity: 10%RH~90%RH

Atmospheric Pressure: 50.0kPa~106.0kPa

This instrument should be placed at a good ventilation area.

Electric Specifications

Power Supply:

AC 100~240V, 50/60Hz, auto adapt according to the input voltage

Fuse: F3AL250V

Dimension and Weight

Dimension: 410mm×435mm×472mm (L×W×H)

Net weight: 19kg

1.4 Structure

1.4.1 Front Panel

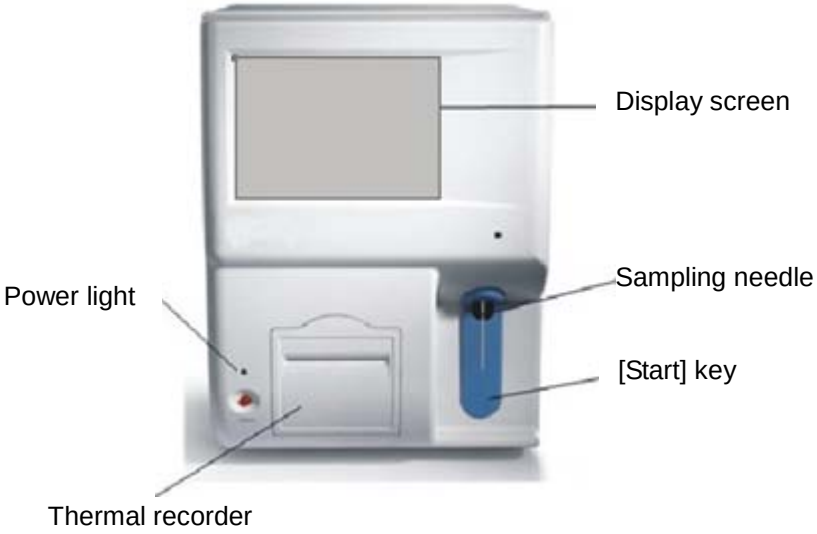


Figure 1-1

1.4.2 Rear Panel

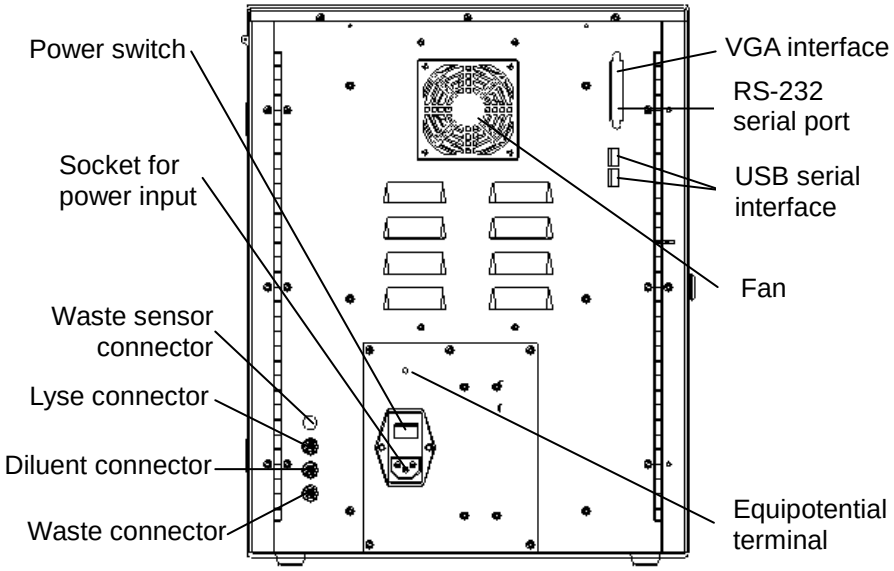


Figure 1-2

1.5 Operation

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

1.5.1 Display Screen

The display screen is classified into four sections:

SYSTEM LOGO SECTION	SHORTCUT KEY SECTION
AUXILIARY INFORMATION SECTION	
WINDOWS DISPLAY SECTION	

SYSTEM LOGO SECTION

Display the Logo of the system/system time.

SHORTCUT KEY SECTION

Display the function interfaces of the system.

WINDOWS DISPLAY SECTION

Display various results.

AUXILIARY INFORMATION SECTION

Fault information prompt area.

1.5.2 Menu

You can operate the instrument by button. In the hematology analyzer window, press “Menu” button, and the main menu window pops up, as shown in Figure 1-3.

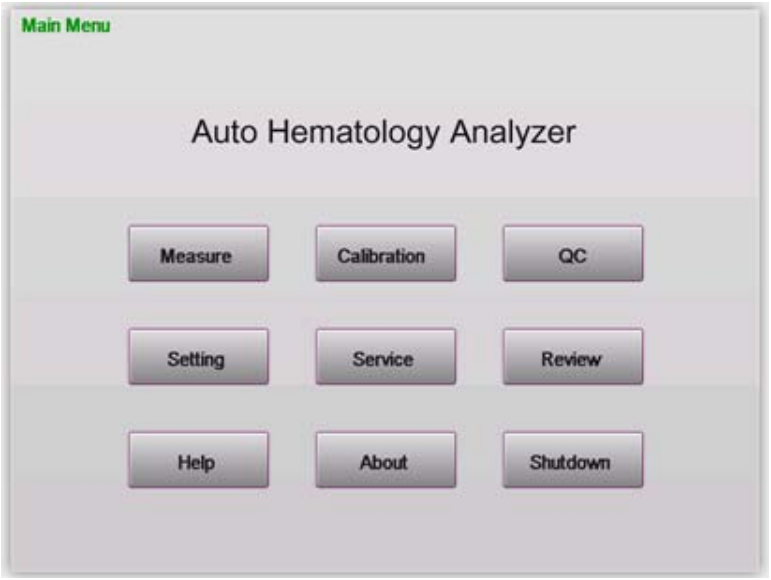


Figure 1-3

The button functions are as follows:

Measure: Used to test sample.

Calibration: Used to calibrate the instrument for correct test results.

1) Operator: Enter the operator calibration window to calibrate the instrument manually.

2) Auto: Enter the auto calibration window to calibrate the instrument automatically.

QC: Enter the quality control window to carry out quality control operation.

1) QCE: Enter the QC edit window to edit the QC parameters.

2) QCR: Enter the QC run window to carry out the selected QC files.

3) QCG: Enter the QC graphs window to browse the selected QC graphs.

4) QCL: Enter the QC table window to browse the selected QC tables.

Setting: Enter the setting menu.

1) Language: Enter the language setting window to set the language of the instrument.

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

3) Print: Enter the printout window to set the functions such as print or report.

4) Control: Enter the config window to set the functions such as print, sleep, clean, and display etc.

5) Limits: Enter the limits window to modify the limits.

6) Department Info: Enter the department window to set the department and abbreviation.

7) Doctor Info: Enter the operator window to set the department, abbreviation, department and operator.

8) Window Color: Select the background color.

9) Screen Calibration: Calibrate the screen.

Service: Enter the service menu.

1) Flush: To get rid of the aperture clog.

2) Enhanced Flush: To get rid of hard aperture clog.

3) Cleaning: Run the normal rinse process to rinse the measurement unit.

4) Prime Chamber Outside: Inject the solutions into the counter chambers.

5) Drain Chambers: Empty the liquid of the counter chambers.

6) Drain All: Run the Drain All program to rinse and empty the tubing.

7) Prime Diluent: Inject the diluent into the appointed tubing.

8) Prime Lyse: Inject lyse to the appointed tubing.

9) Prime: Inject the solutions.

10) Maintenance: Run the maintenance program to maintain the instrument.

11) Mechanic: Enter the Mechanic window to verify the functions of the instrument.

12) Special: Enter the Special window to maintain the instrument.

Review: Enter the review menu.

Help: Access the system help window.

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

Shutdown: Startup the shutdown program to rinse the measurement unit automatically.

1.6 Detection Principle

1.6.1 Detection Principles of WBC, RBC and 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.

1) 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.

2) When the diluent passes through the aperture sensor, electrodes are submerged in the liquid on each side of the aperture to create continuous current.

3) When cells pass through the aperture, the resistance between the electrodes increases as the cell volume increases, as shown in Figure 1-4. According to the Ohm's law: U=RI (U=Voltage, I=Current, R=Resistance). If I is a constant, U increases as the cell volume increases.

4) 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 1-4.

5) One counting chamber and the detection circuit count the WBC. Another counting chamber and the detection circuit count the RBC and PLT. The microprocessor of the instrument calculates and analyzes the cells (WBC, RBC, PLT), and then gives out the histograms.

6) PLT count adopts advanced liquid, electronics and software system. It settles the repetitive counting of the cells on the side of the aperture counting area.

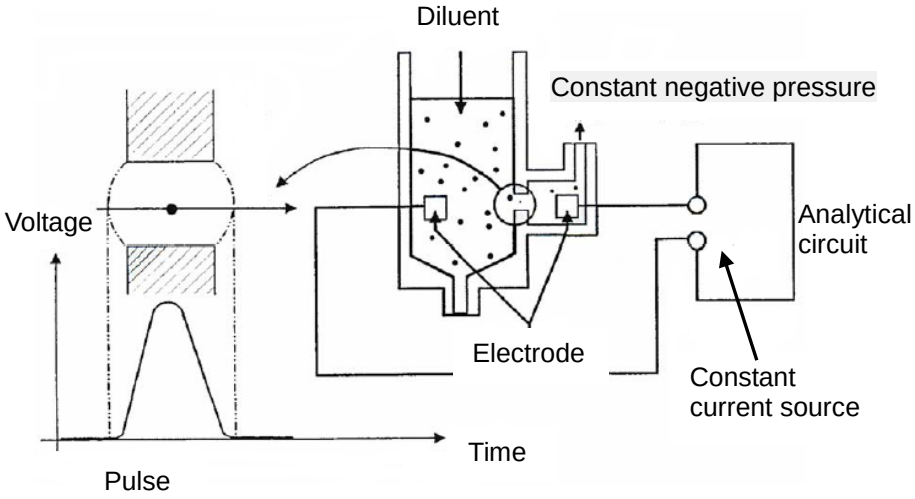


Figure 1-4

1.6.2 Detection Principle of HGB

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

1.6.3 Volume Distribution of Blood Cell

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 WBC, RBC and PLT by its pre-set program.

The volume distributions are as follows:

WBC: 20-1000fL

RBC: 82-98fL

PLT: 2-35fL

The leucocytes disposed by lyse can be divided into three types,

according to their volumes: lymphocyte (LYM), mid-sized cell (MID), Neutrophil (NEUT).

LYM: 35-90fL

MID: 90-160fL

NEUT: 160-450fL

1.6.4 Results and Calculation of Parameter Measurement

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

1) Measured directly, such as WBC, RBC, PLT, and HGB.

2) Derived from histograms, such as LYM%, MID%, NEUT%, MCV, RDW-SD, RDW-CV, MPV, PDW, P-LCR.

3) Calculated, such as LYM#, MID#, NEUT#, HCT, MCH, MCHC, PCT.

The derivation of the 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, and 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 the erythrocyte volume as RDW-CV, and the unit is %. It can also be expressed in standard deviation of the erythrocyte volume as RDW-SD, and the unit is fL.

MPV is the average volume of individual platelets, derived from the PLT histogram. It represents the mean volume of the PLT populations and can be expressed in fL.

PDW derives from the PLT histogram. It represents the geometry standard deviation (GSD) of the volume of the PLT populations.

P-LCR derives from the PLT histogram. It represents the ratio of the larger PLT, and the unit is %.

- HCT (%) = RBC × MCV/10
- MCH (pg) = 10 × HGB/RBC
- MCHC (g/L) = 100 × HGB/HCT
- PCT (%) = PLT × MPV/10
- LYM% = 100 × AL / (AL+AM+AG)
- MID% = 100 × AM / (AL+AM+AG)
- NEUT% = 100 × AG / (AL+AM+AG)
- LYM# = LYM% × WBC/100
- MID# = MID% × WBC/100
- NEUT# = NEUT% × WBC/100

AL: Number of cells in LYM area;

AM: Number of cells between lymphocyte and neutrophil area;

AG: Number of cells in NEUT area.

Chapter 2 Installation

2.1 Package

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 damage level. At the same time contact with your supplier to make sure the packing is complete. Then unpack and install the instrument according to the following steps.

2.2 Unpack

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

1) Check the accessories according to the packing list.

2) Check whether there are mechanical damages on the instrument and accessories.

If there is any problem, please recover the package and contact with your supplier immediately.

2.3 Installation Requirements

Installation Environment

The instrument should be placed on a clean steady platform. Keep away from direct sunlight and dust.

Temperature: 18℃-35℃

Humidity: ≤70%

Atmospheric pressure: 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 machine, NMR equipment, 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.

Space Requirement

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

Notice:

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

Power Requirement

The power requirement is as follows:

• AC 100~240V, 50/60Hz

• The maximum power consumption is 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. Make sure of 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 (self-preparation) should be taken before use.

First Installation Notice

1) Open the right door, cut the ties binding to the sampling module and remove the ties.

2) Remove the protective film on the injection ports of the chambers.

3) Close the right door.

4) Remove this Notice.

5) Turn on the power.

2.4 Reagent Tubing Connection

There are three tube connectors with color of white, green and red on the rear panel of the instrument.

2.4.1 Lyse Connection

Take out the lyse tube with red connector from the accessory kit.

Connect the red lyse tubing connector with the tubing connector of the same color on the rear panel of the instrument.

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

2.4.2 Diluent Connection

Take out the diluent tube with green connector from the accessory kit.

Connect the green diluent tubing connector with the tubing connector of the same color on the rear panel of the instrument.

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

2.4.3 Waste Connection

Take out the waste tube with white connector from the accessory kit.

Connect the white waste tubing connector with the tubing connector of the same color.

Connect BNC plug with BNC socket marked “WASTE” on the rear panel of the instrument, turn the waste container cover clockwise until secure.

Caution:

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

Caution:

All the tubing connectors must be installed manually. Forbid using any tool.

Caution:

The reagent must be supplied with the instrument. Otherwise it may easily cause inaccurate measurement results and incorrect classification of the blood cell, 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.

Caution:

When replacing the reagent, avoid making the plastic tube inserted into the reagent container or contacted with other things. Avoid polluting the new replacing reagent.

Caution:

Avoid using frozen reagent.

Caution:

Avoid using the reagent out of its expiration date.

Warning:

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

2.5 Recorder Paper Installation

1) Tear down the gummed paper from the door of the recorder.

2) Gently press the door of the recorder to open it.

3) Insert the new paper into the paper entry and make the printing side towards the thermal head.

4) When the paper juts out from the other side, pull it out and keep it straight.

5) Pull the paper out of the paper exit.

2.6 Keyboard and Mouse Installation

Take out the keyboard, mouse cushion and mouse from the packing box carefully.

Plug keyboard cable into the interface marked with  . Plug mouse cable into the interface marked with  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 placed under the display screen of the instrument, the mouse cushion at the right side of the keyboard, and the mouse on the mouse cushion.

2.7 Printer Installation (Optional)

Take out the printer from the packing box carefully. Install the printer according to the printer manual.

Notice:

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

2.8 Power Cable Connection

Make sure the power switch on the rear panel of the instrument is off (O). Insert one end of the power cable into the power cable interface on the instrument, the other end into the power socket.

Connect the ground cable to the grounding port on the instrument.

Warning:

Ensure that 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:

1) Whether the diluent and waste tubing are distorted, folded or twisted, and whether the connection is secure.

2) Whether the power cable connection is secure.

3) 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 completing initialization, the instrument will enter into the self-test window. It tests the working conditions of each part and if there are enough diluent and lyse. Simultaneously prime and clean the tubing.

After self-test, the instrument will enter into the hematology analyzer window, as shown in Figure 3-1.

If the system detects malfunction, the failure information will be displayed on Information Section.

Figure 3-1

The button functions are as follows:

Info: Used to set patient information.

Print: Used to print report.

Flush: To get rid of the aperture clog.

Func: Used to change sample type, adjust classification line for current result and dispense diluents for prediluted test mode.

Menu: Used to get into the main menu.

3.2.1 Function

In the hematology analyzer window, press “Func” button to enter into the “Function” window, as shown in Figure 3-2.

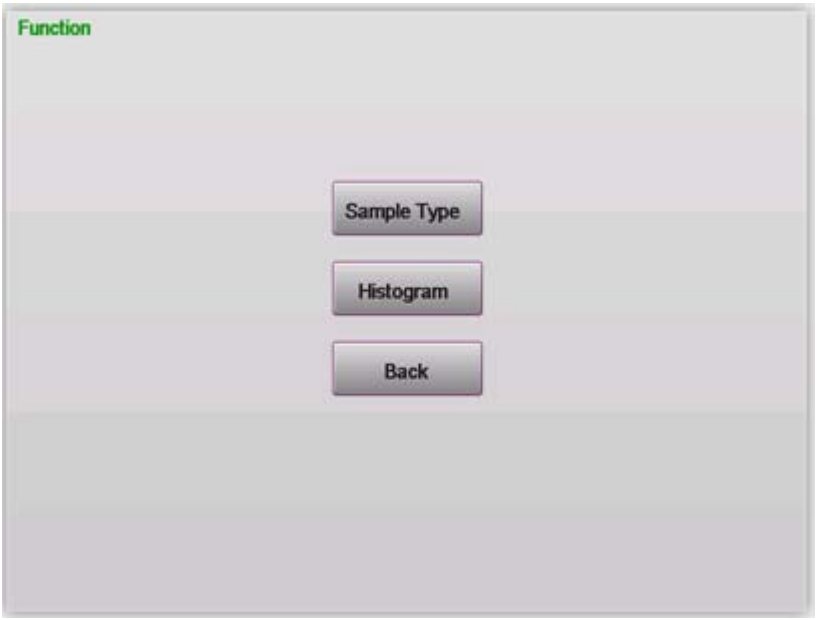


Figure 3-2

The button functions are as follows:

Sample Type: Select the sample type among Venous, Capillary and Prediluted, as shown in Figure 3-3.

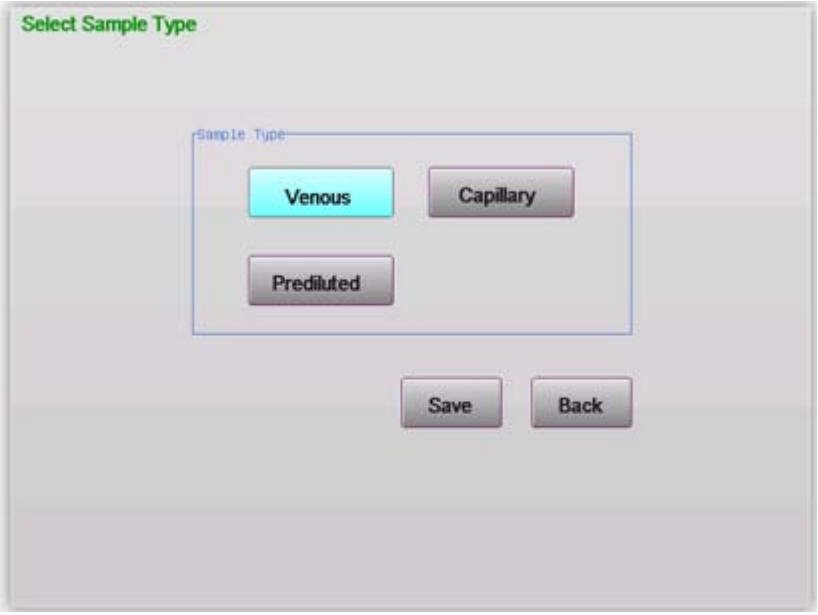


Figure 3-3

If select “Prediluted”, the “Function” window changes, as shown in Figure 3-4.

Figure 3-4

Diluent: Inject the diluent quantitatively by sample needle. This menu is used only in Prediluted mode, and “Diluent” button will not display in other modes.

Histogram: Enter the histogram adjustment window of the current sample. You can manually adjust the histograms of the current sample.

3.3 Background Test

Background test is recommended after the instrument starts up normally every time. The operator can also perform background test in need. The operating procedures are as follows:

1) In the hematology analyzer window, press “Info” button, the information editing window pops up. Click the item textbox to change the ID as 999, then press “Ok” to return to the hematology analyzer window.

2) In venous or capillary mode, press the “START” key below the sample needle directly for background count. In prediluted mode, the sample needle aspirates some non-contaminated diluent from the sample cup for background count. The diluent pick-up method is as follows. Analyzing sample in prediluted mode is also necessary to dilute sample with the diluent which is previously picked-up in this method:

(1) Press “Func” button to select “Sample Type”, set “Prediluted” as the sample mode.

(2) In menu operation area, select “Diluent”.

(3) Place a clean empty sample cup or tube under the sampling needle, press “START” key to dispense the diluent into the sample cup. Press the “START” key once, the diluent is dispensed into the sample cup or tube once. The quantity can be used for background count in the second prediluted mode. Press “Exit”, the instrument returns to the main operation area.

3) Permissive ranges of the background test results are shown in Table 3-1.

Parameter	Data
WBC	$\leq 0.2\times10^{9}$/L
RBC	$\leq 0.02\times10^{12}$/L
HGB	≤ 1g/L
HCT	≤ 0.5%
PLT	$\leq 5\times10^{9}$/L

Table 3-1

If the value of the background test exceeds the permissive range, repeat the above testing procedures until the testing result is acceptable. If the test has been carried on for more than five times, but the testing result still cannot reach the standard required, please refer to Chapter 10 “Troubleshooting” in this manual.

Notice:

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

Notice:

The serial number 999 is a special number for background test.

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 specified in Chapter 4 “Quality Control”.

3.5 Preparation for Sample Collection

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

3.5.1 Venous Blood Collection

It is possible to collect venous blood by using negative pressure tube or with common collecting method.

Add some anticoagulant in advance to the container for venous blood collection. EDTA-K_2·$2H_2O$ is commonly used as the anticoagulant, whose specified content is 1.5-2.2mg/mL blood.

3.5.2 Capillary Blood Collection

1) Gently massage the blood collection part to make it congest naturally, wipe the partial skin with tampon containing 75% alcohol, then air.

2) Pinch the puncturing part, and puncture it with aseptic sample needle quickly. The puncturing depth is about 2-3mm.

3) Wipe off the first drop of blood, and then start the collection.

4) Press the wound with tampon for a moment after finishing the collection.

Notice:

The capillary blood collection should follow the professional capillary blood collection standard. The general method is partial centesis. The typical collection is puncturing from the tip of the finger.

Caution:

If the blood flows not freely, press far away from the wound, not around the wound. Avoid making the histiocyte mixed into the blood, which may lead to incorrect analytical result.

3.5.3 Prepare Samples in Prediluted Mode

1) In the hematology analyzer window, press the “Func” button, select “Sample Type”, set “Prediluted” as the sample type, then press “Function” button. In menu operation area, select “Diluent”.

2) When the “Diluent” pops up, place a clean sample cup obliquely under the sampling needle. Press “START” key. The instrument starts to add diluent quantitatively. Scrape the drops at the top of the sample needle into the sample cup, collect 20μL 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 diluent 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 prediluted mode, users can use the “Diluent” function to continuously prepare the diluent.

3.5.4 Prepare Samples in Capillary Mode

Collect 40μL capillary sample in pipette. Immediately mix up the sample in anticoagulated warhead sample cup. You can also add the capillary blood to the anticoagulated warhead sample cup directly.

3.5.5 Sample Homogenization

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

Caution:

If the sample has been 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 Sample Information Input

3.6.1.1 Manual Input Information

In the hematology analyzer window, click “Info” button, the information editing window pops up. 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 hematology analyzer window. Press “Cancel” button, the instrument cancels the input information and returns to the hematology analyzer window.

Name: Maximum 19 characters.

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

Age: Choose from year, month and day. There are maximum 3 numbers while choosing year and day, maximum 2 numbers while choosing month.

Blood Type: Choose from A, B, O, AB, A RH+, B RH+, O RH+, AB RH+, A RH-, B RH-, O RH-, AB RH-, the default is blank.

Sample: The current sample mode.

Record No.: Maximum 15 characters.

Bed No.: Maximum 12 characters.

ID: The input range is: 001~998. 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 measured time. If user does not input the serial number, the instrument will accumulate the number from 001 everyday according to the measured time.

Department: 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.

Doctor: 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: 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.

Checker: 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, Newborn, Define 1, Define 2, and Define 3 automatically. Set the low and high limits of the corresponding parameters.

Notice:

The number 999 is a special number for background test. Please don't input this number in blood sample test.

Notice:

If there is a need to input the sample test information in quantities, users can concentrate on inputting the sample test information in the review window after the current sample test finished.

3.6.2 Procedures of Sample Count and Analysis

a) Place a sample cup under the sample needle, press “START” key, the instrument starts to aspirate the liquid.

b) The instrument starts to analyze the sample automatically. Please wait for the analytical result.

c) After the analysis finished, the result will be displayed behind the corresponding parameters on hematology analyzer window of the instrument, with histograms WBC, RBC, and PLT.

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

If there are clogs during the count and analysis process, the information section would display “Clog”.

3.6.3 Parameter Alarm

“C”: To indicate that clog appears in the test.

“↓”: To indicate that the data has exceeded the set lower alarm limit of the parameter.

“↑”: To indicate that the data has exceeded the set 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 0.5×10^9/L, the system will not perform 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 the lymphocyte and the mid-sized cell area. It may present atypical 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 neutrophil. It may present immature neutrophil, abnormal sub-population in the sample, or the increase of the number of the eosinophil.

"R4": To indicate the abnormality on the right of neutrophil area. It shows the increase of the number of the neutrophil.

"RM": To indicate that more than two areas occurs abnormality. The upper reasons exist simultaneously.

"PM": To indicate the abnormality and the blur demarcation between platelet and red blood cell area. Large platelet, platelet coagulation, small red blood cell, cell debris or fibrin may exit.

3.7 Analytical Results Modification

If users think that the results of WBC, RBC, and PLT differential cannot meet the needs of the classification of special samples in clinical or laboratory, they can manually adjust the histograms.

Operate as follows:

1) In the hematology analyzer window, select "Func", then press "Histogram", the instrument enters into the histogram adjustment window, as shown in Figure 3-5. Press "Para" button to adjust the

histogram.

Figure 3-5

2) After selecting the histogram, press “Line” button, and select the sorting line you want to adjust.

3) Press “Left” or “Right” button, you can move the sorting line to the left or right, the data of the line will be displayed at the top right corner of the screen.

4) Press “Back” button when the adjustment finished. If this operation did not change any data, the system would return to the hematology analyzer window 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 $0.5x10^9$/L, the system will not perform leukocyte differential automatically.

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 are as follows:

1) In the hematology analyzer window, press “Menu” button, then select "Shutdown" button, the shutdown window pops up.

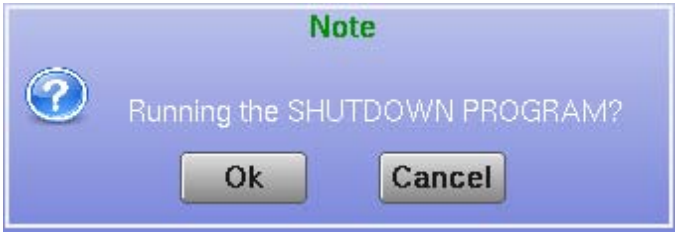


Figure 3-6

2) If you do not want to shutdown the instrument for the moment, click “Cancel” to return to the main menu window.

3) Press “Ok”, the instrument will perform daily maintenance and clean the measuring tubing. When the shutdown procedure finished, the screen displays “PLEASE TURN OFF THE POWER!”, turn off the power on the rear panel of the instrument.

Figure 3-7

4) Turn off the printer power (if equipped), clean the workbench and dispose the waste.

Notice:

Do not turn off the power of the instrument directly while performing the shutdown procedures.

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 users. It allows the operator to run quality control for the 12 parameters at the same time.

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

Caution:

Quality controls must be stored in appropriate conditions.

Caution:

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

Caution:

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

4.1 Edit Quality Control Files

The operating procedures are as follows:

1) In the main menu window, press “Quality Control” button, then select “QCE” in the menu. The instrument enters into the quality control edit window, as shown in Figure 4-1.

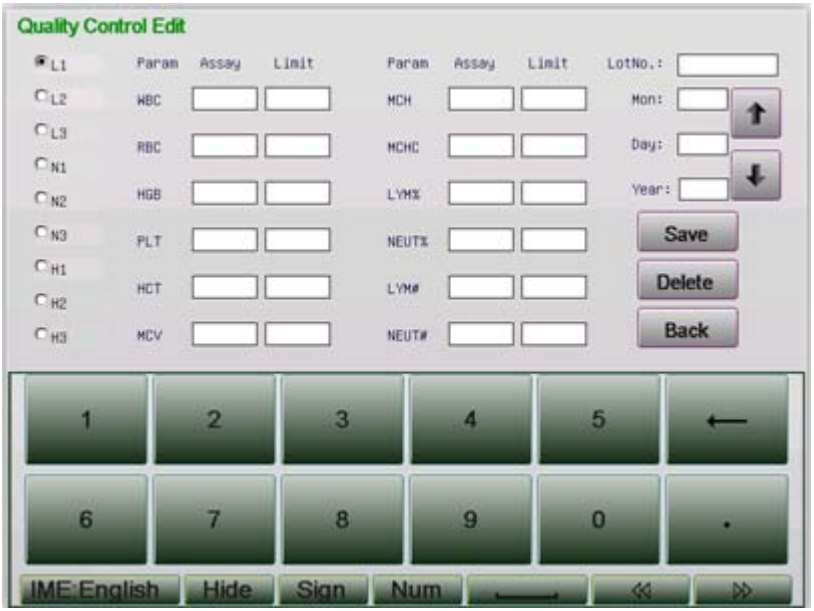


Figure 4-1

2) In quality control edit window, select the QC file you want.

3) Input lot number and expiration date of the control, the assay and limit of the quality control parameters.

4) Press “Save” button to save the data of the current QC file.

5) Press “Delete” button to delete the data of the current QC file.

6) Press “Back” button to save the data of the current QC file and return to the main menu 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 are as follows:

1) In the main menu window, press “Quality Control” button, then select “QCR” in the menu and select the QC file you want. The instrument enters into the quality control run window, as shown in Figure 4-2.

2) Prepare the controls and shake up the container until it well-mixed.

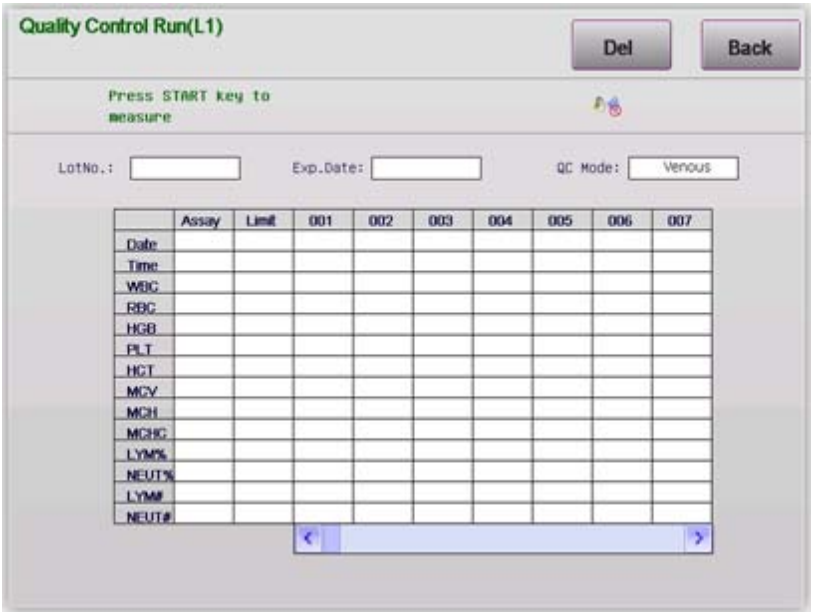


Figure 4-2

3) Place the controls under the sampling needle. Press “START” key, the indicator lamp starts to glitter, the instrument aspirates the controls,

move the controls away until the indicator lamp stops glittering.

4) When the test finished, the result will be displayed on the column of the current window. If alarm occurs during the test, the current result may be incorrect.

5) Press “Del” button to delete the result and test again after the problem is solved.

6) Press “Back” button, the instrument will return to the hematology analyzer 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 operators to observe the possible deviations, trends or shifts of the instrument performance.

In the main menu window, press “QC” button, then select “QCG” in the menu and select the QC file you want. The instrument enters into the quality control graph window, as shown in Figure 4-3.

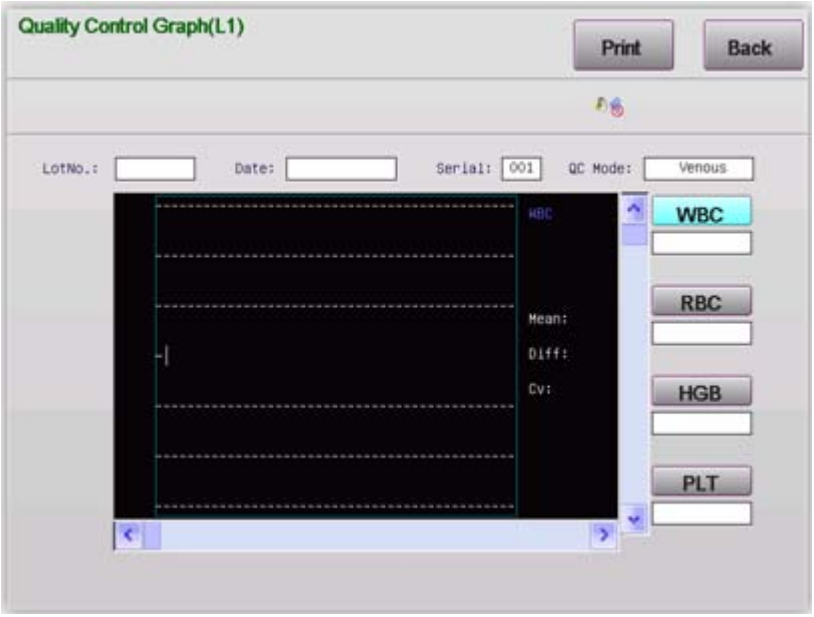


Figure 4-3

The screen can display QC graph of one parameter. The graph shows the lot number, date, serial number, QC mode and distribution of the QC data. Click the scroll bar on the right side of the screen, and continuously select the QC graph of different parameters.

The seven parameters at the left side of the QC graph from top to bottom:

Assay + 3limit

Assay + 2limit

Assay + limit

Assay

Assay - limit

Assay - 2limit

Assay - 3limit

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

Mean: average value

Diff: standard deviation

CV: coefficient of variation

The vertical line in the middle of the QC graph indicates the current chosen number. Click the scroll bar on the left side of the screen to continuously select the different number.

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

In the QC graph window, the following marks represent:

The mark “*” between the broken line represents that the point is within control range. Otherwise it is out of control range.

The mark “.” represents that the parameter value is outside the operating range, or error has occurred during the run. Blank represents that there is no quality control on running.

Press “Print” button, it will print the data of the parameters which you select.

Press “Back” button to return to the hematology analyzer window.

4.4 Quality Control List

The instrument supplies tabulated format for QC review. In the main menu window, press “Quality Control” button, then select “QCL” in the menu and select the QC file you want. The instrument enters into the quality control list window, as shown in Figure 4-4.

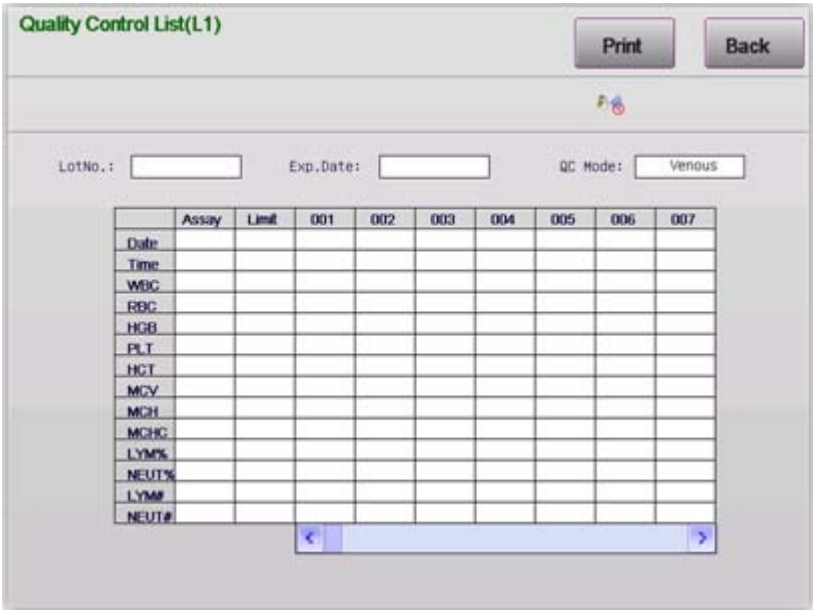


Figure 4-4

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

Click the scroll bar to select different serial number.

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

Press “Back” button to return to the main menu 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 to 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:

1) Installation for the first time or re-setup in a new place.

2) The instrument is maintained.

3) The result of quality control is abnormal.

4) Replace reagent.

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

Warning:

Calibrators should be stored and used properly according to the calibrator manual.

Warning:

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

Warning:

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

Check the instrument and reagents carefully before calibration. Make sure the instrument is in normal status, and the required sample mode of the measurement is selected.

5.1 Operator Calibration

5.1.1 Background Test

Refer to section 3.3 in Chapter 3 “Sample Analysis”, ensure that the background test meets the requirement and no malfunction occurs.

5.1.2 Assurance of Repeatability

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

The procedures are as follows:

1) In the hematology analyzer window, measure repeatedly with the calibration for no less than 3 times.

2) Record the data of WBC, RBC, HGB, MCV and PLT. Calculate the CV value according to the following formula. Only results in the limit of Table 5-1 can perform calibration.

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

$\overline{x}$ -- Average value of the test results

x_i -- Test result of the ith test

n – Test times of the sample

Parameters	CV (%)
WBC	≤ 2.0
RBC	≤ 1.5
HGB	≤ 1.5
MCV	≤ 0.4
PLT	≤ 4

Table 5-1

5.1.3 Calculate Calibration Factors

Calculate the new factors according to the following formula:

$$\text{New factor} = \frac{\text{Current factor} \times \text{Reference value}}{\text{Average value}}$$

5.1.4 Modify Calibration Factors

1) In the hematology analyzer window, press “Menu” button, select “Calibration” in the menu, then select “Operator” button to enter into the calibration window, as shown in Figure 5-1.

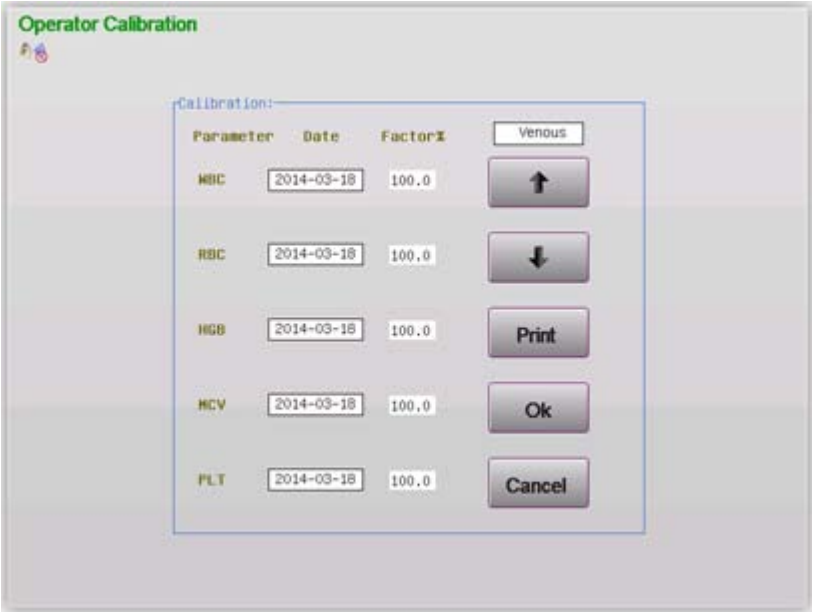


Figure 5-1

2) Select the needed calibration data from the calibration data menu box.

3) Press “Print” button. The instrument will print the current calibration result.

4) Press “Ok” button to save the current calibration result and return to the main menu window.

5) Press “Cancel” button. The instrument will cancel the current calibration result and return to hematology analyzer window.

5.2 Auto Calibration

The procedures are as follows:

1) In the hematology analyzer window, press “Menu” button, select “Calibration” in the menu, then select “Auto” button to enter into the calibration window, as shown in Figure 5-2.

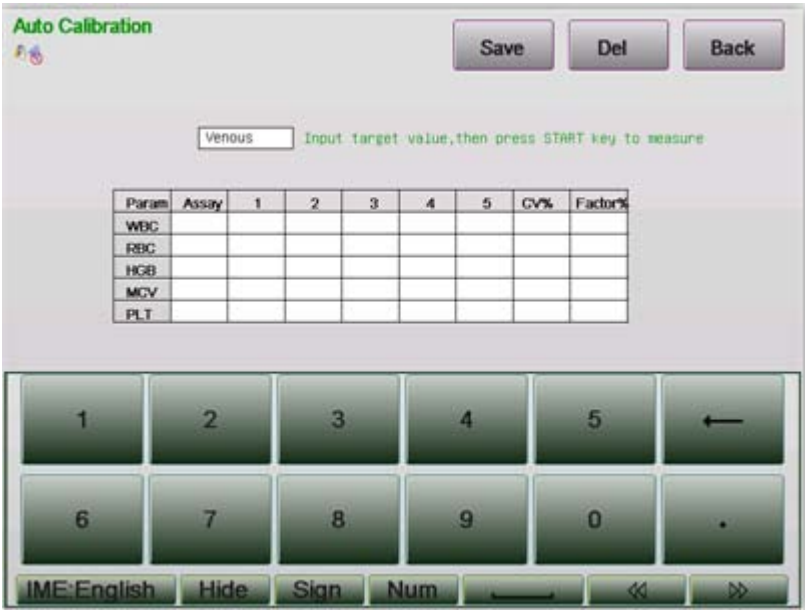


Figure 5-2

2) Input the reference value of each calibration parameter.

3) Prepare the calibrators and shake up the container until it is well-mixed.

4) Place the calibrators under the sample needle. Press “START” key, the instrument aspirates the calibrators. Move the calibrators away until it stops.

5) 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.

6) Press “Del” button to delete the result and test again after the problem is solved.

7) Press “Back” button, the instrument will return to the hematology analyzer window.

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.

Chapter 6 Setting

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

Notice:

Operations in this chapter will change the running state of the instrument. Make sure of the necessity of changing before operating.

6.1 Date & Time

In the hematology analyzer window, press “Menu” button, select “Setting” in the menu, then select “Time”. The instrument enters into the time setting window, as shown in Figure 6-1. Click the menu bar to adjust the setting item. Press “Save” to save the current parameters and return to the setting window. Press “Back” to not save the current parameters and return to the setting window.

Figure 6-1

6.2 Printout

In the hematology analyzer window, press “Menu” button, select “Setting” in the menu, then select “Print". The instrument will enter into the print window, as shown in Figure 6-2.

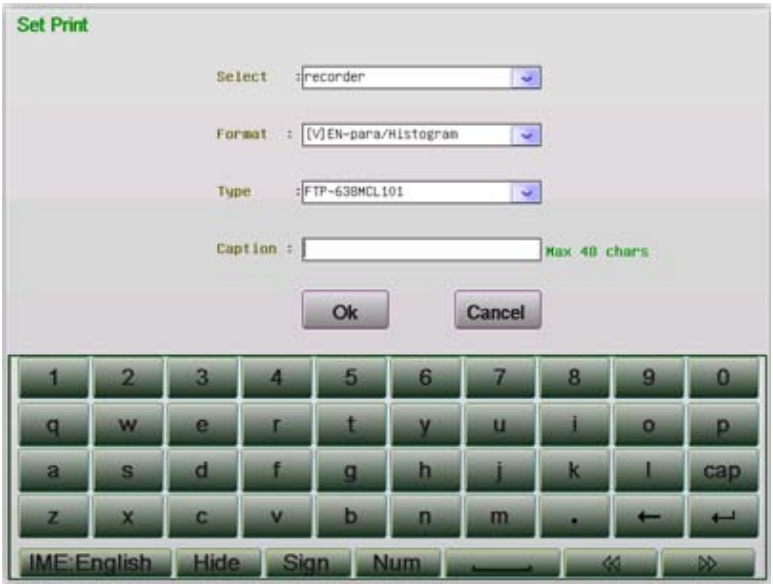


Figure 6-2

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

Press “Ok”, the system will save the current parameters and return to the setting window. Press “Cancel” button, the system will not save the current parameters and return to the main menu window.

Print select

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

Select serial port, the data will only be transported to the net.

Select recorder and serial port, the data will be transported to the

recorder and net at the same time.

Select Laser Jet, the data will be transported to the HP Laser Jet1018 printer or HP Laser Jet1008 printer.

Select Desk Jet, the data will be transported to the HP desk Jet1668 printer or HP Laser Jet 2668printer.

Select Network print, the data will be transported to the computer which connects with HP Laser Jet1008 printer.

Notice:

There are different formats when selecting different printer settings.

Print caption

Can easily printout the headline on the report.

Print type

User can choose the type of the printer.

Notice:

The selected printer type must be accord with the used one, otherwise it will not be able to print normally.

6.3 Control

In the hematology analyzer window, press “Menu” button, select “Setting” in the menu, then select “Control”, the instrument will enter into the control setting window, as shown in Figure 6-3.

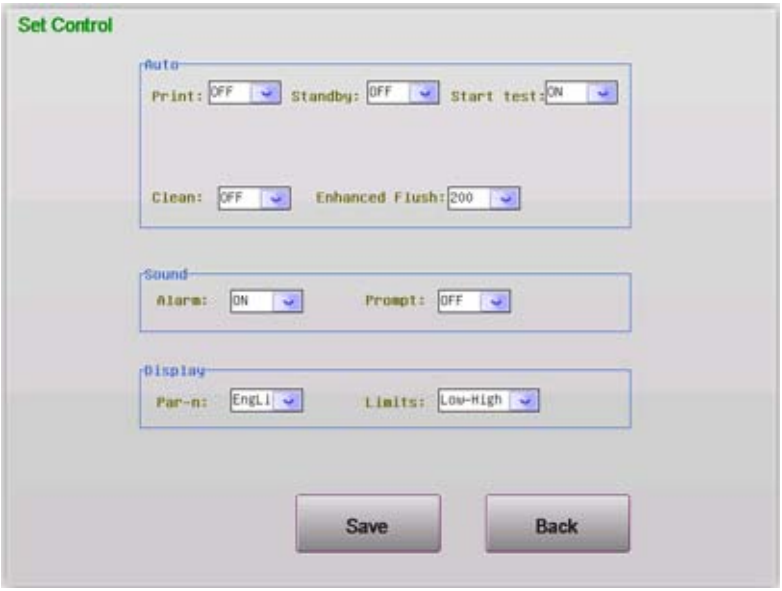


Figure 6-3

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

Press “Save”, the system will save the current parameters and return to the hematology window.

Press “Cancel” button, the system will not save the current parameters and return to the main menu window.

Auto

Set “Print” as “OFF”, the system will not print the test report automatically after the sample test finished.

Set “Standby” as “OFF”, the instrument will keep working status all along. Set “Standby” 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 canceled.

Set “Clean” as “OFF”, the instrument will not perform auto-cleaning. Set “Clean” as data. When the running time of the instrument exceeds 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 malfunctions and maintain the instrument.

Sound

Set “Alarm” as “OFF”. When the instrument appears alarm, it will not make alarm sound, but display the alarm information in the Information Section.

Set “Alarm” 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 test finished, the instrument makes no sound.

Set “Prompt” as “ON”. When the sample test finished, the instrument will make a prompt sound like “di”.

Display

Set “Para” as “English”. In parameter area of the hematology analyzer, the parameters will be displayed in abbreviations.

Set “Limits” as “No Display”. In parameter area of the hematology analyzer, the parameters will not display reference value of the current sample.

Set “Limits” as “Low-High”. In parameter area of the hematology analyzer, the reference values will be displayed from low to high.

Set “Limits” as “High-Low”. In parameter area of the hematology analyzer, the reference values will be displayed from high to low.

6.4 Limits

In the hematology analyzer window, press “Menu” button, select “Setting” in the menu, then select “Limits” to enter into 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 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 values 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 buttons:

Save: Save the reference values of the current group.

Print: Print the reference values of the current group.

Back: Exit from current window and return to main menu window.

Notice:

The default reference value may not suitable for the local conditions. Users 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 Information

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 hematology analyzer window, press “Menu” button, select “Setting” in the menu, then select “Department Info”, the instrument enters into the 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 “Back” button, the system exits from the current window and returns to the hematology analyzer window.

6.5.1 Add record information

Click “Add” button to enter into the record adding window, as shown in Figure 6-6.

Input the information of department and abbreviation.

Notice:

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

Click “Ok” button to save the current input information. The system returns to department setting window.

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

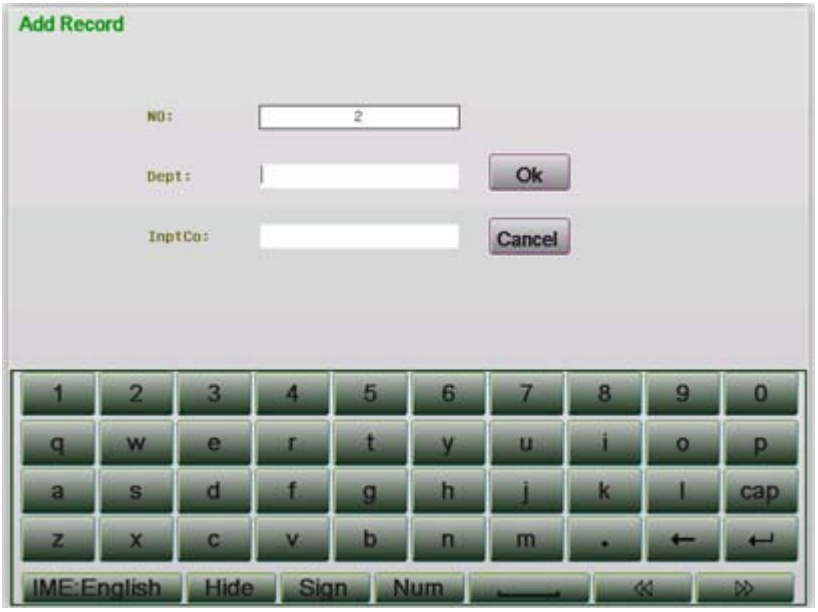


Figure 6-6

6.5.2 Print department information

Click “Print” button to print all the department information saved.

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 hematology analyzer window, press “Menu” button, select “Setting” in the menu, then select “Doctor Info”, the instrument

enters into the operator setting window, as shown in Figure 6-7.

Figure 6-7

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

Click “Back” button, the system will exit the current window and return to the main menu window.

6.6.1 Add operator information

Click “Add” button, the instrument enters into the record adding window, as shown in Figure 6-8.

Figure 6-8

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 input box of the department.

“Status” represents the status of the doctor, including: doctor, operator and checker. 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 remember. In most cases, abbreviation of the department name is recommended.

6.6.2 Print operator information

Click “Print” button, the instrument will print all the operators information saved.

Chapter 7 Review

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

7.1 Sample Review

In the hematology analyzer window, press “Menu” button, then select “Review” in the menu, as shown in Figure 7-1.

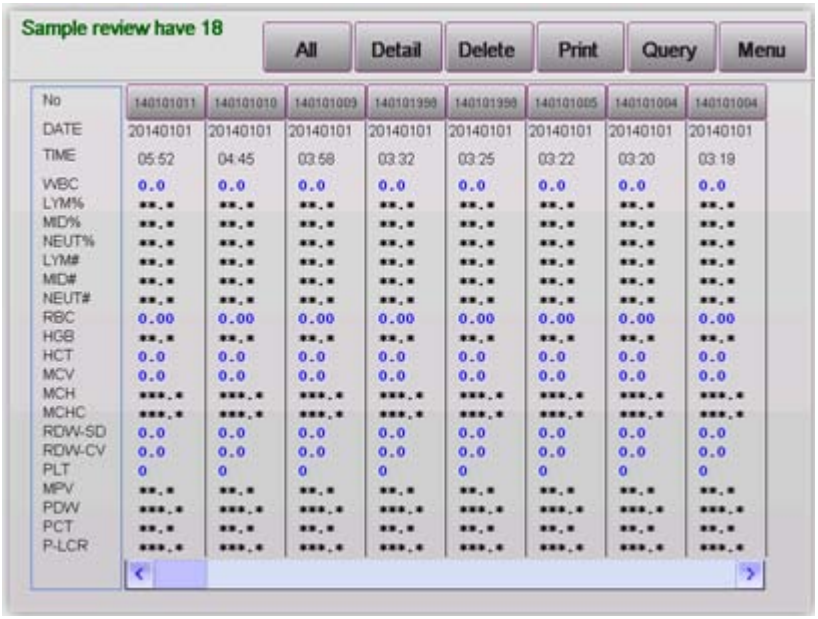


Figure 7-1

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 meanings of the characters are as follows:

"↑" is displayed following the parameter indicating that the results exceed the high limit of the system.

"↓" is displayed following the parameter indicating that the results exceed the low limit of the system.

"C" is displayed following the parameter indicating that clogs occur during the test.

Review the sample data

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

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

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

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

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

Delete the selected data

The procedures are as follows:

1) Click the sample ID, the corresponding sample result will be selected. Click again, the selection will be canceled.

2) Select "Delete" in the menu, a dialog box pops up, and choose to delete the data or not. Press "Ok" button, the data will be deleted. Press "Cancel" button, the operation will be cancelled.

Delete all data

The procedures are as follows:

1) Click "All" button, the data will be selected. Click again, the selection will be canceled.

2) Click “Delete” button, a dialog box pops up, and choose to delete the data or not. Press “Ok” button, the data will be deleted. Press “Cancel” button, the operation will be cancelled.

Print the current sample data in table

The procedures are as follows:

1) Click “All” button at the top of the screen, the data will be selected. Click again, the selection will be canceled.

2) Click “Print” button, the selected data would be printed in table.

Search sample data

Print the selected data as the following procedures:

1) Click “Query” in the menu, the search window pops up, as shown in Figure 7-2.

2) Click the button on the left of the item to be searched, input the keyword you want to search.

3) 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.

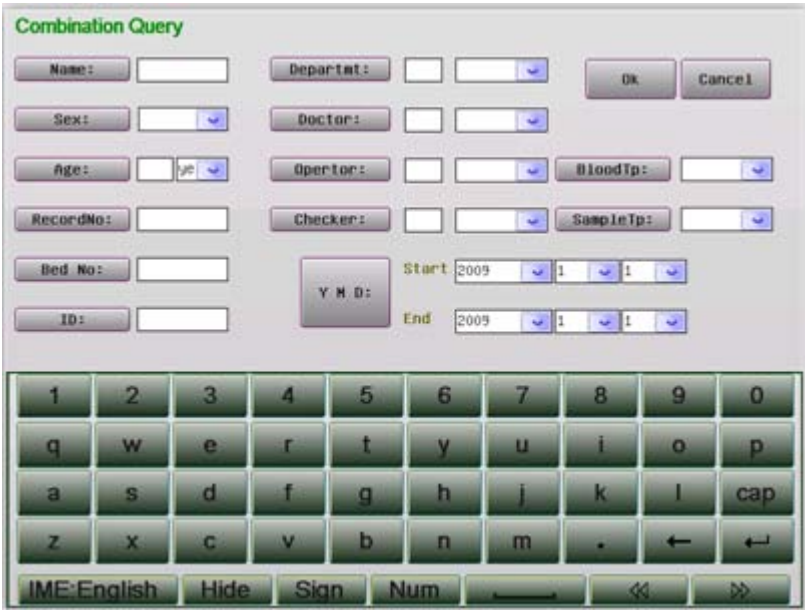


Figure 7-2

The functions of the menu buttons are as follows:

All: select or recover all the sample data.

Detail: Enter the detail review window.

Delete: Delete the selected data.

Print: Print the current data in table.

Query: Search the required sample data in any condition.

Menu: Exit from the current window.

7.2 Detail Review

In the detail review window, click “Detail” button. The instrument will enter into the detail review window, as shown in Figure 7-3. You can review, modify and print the sample data in graphs in this window.

Review

Click “Next” button to review the next data.

Click “Prev” button to review the previous data.

Modify Sample Information

Click “Info” button, “Information” window pops up. Refer to section 3.6.1 in Chapter 3 “Sample Analysis” for the operation of this window.

Modify Sample Data

Click “Histogram” button in the menu.

The operation procedures are as follows:

a) Click “Para” button to select WBC, RBC, and PLT in turn.

b) Click “Line” button to select the sorting lines in the histogram.

c) Click “Right” or “Left” button to move the line to the right or left.

Data calculated according to the new sorting line would be displayed in the data area at the left side of the screen.

d) Click “Back” button. If the sample data has been modified, a dialog box pops up. Users can select to save the modification result or not. Click “Ok” button to save the result. Click “Cancel” button not to save it and exit from the histogram modification status.

Figure 7-3

The functions of the menu buttons are as follows:

Histogram: Review the histograms.

Info: Input and modify the sample data.

Print: Print the current sample data.

Next: Review the next data.

Prev: Review the previous data.

Back: Exit from the current window and return to the main menu window.

Chapter 8 Service

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

In the hematology analyzer window, press “Menu” button, then select “Service” in the menu.

Figure 8-1

8.1 Flush

This function is used to solve general probe clogs. The instrument makes a fixed pressure and voltage act on the probe to get rid of clogs.

8.2 Enhanced Flush

This function is used to solve indolent probe clogs. Probe cleaner would be injected into WBC and RBC count chamber. Get rid of the

indolent probe clog by soaking it in the probe cleaner. Before performing the function, user should prepare the probe cleanser well.

8.3 Cleaning

This function is used to clean the sampling needle and tubes.

8.4 Prime Chamber Outside

This function is used for user to fill the chambers with diluents.

8.5 Drain Chambers

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

8.6 Drain All

The manufacturer suggests you not to use this function. If the instrument is not going to be used for 2 weeks or longer, use this function to clean and empty the instrument. Prepare distilled water before performing this function.

8.7 Prime Diluent

Prime diluent to the related tube.

8.8 Prime Lyse

Prime lyse to the related tube.

8.9 Prime

Prime diluents and lyse to the related tube.

8.10 Maintenance

Perform the weekly maintenance according to the prompt information on the screen. Prepare probe cleanser before maintenance.

8.11 Mechanic

Users can detect the valve, motor, circuit and interface in the “Mechanic” menu. It is helpful to the detection of malfunctions.

Figure 8-2

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 the motor has failure.

Recorder:

Click this button, the recorder will print a test paper.

Printer:

Click this button, the external print will print a test paper.

Back:

Return to the service menu and the instrument initializes automatically.

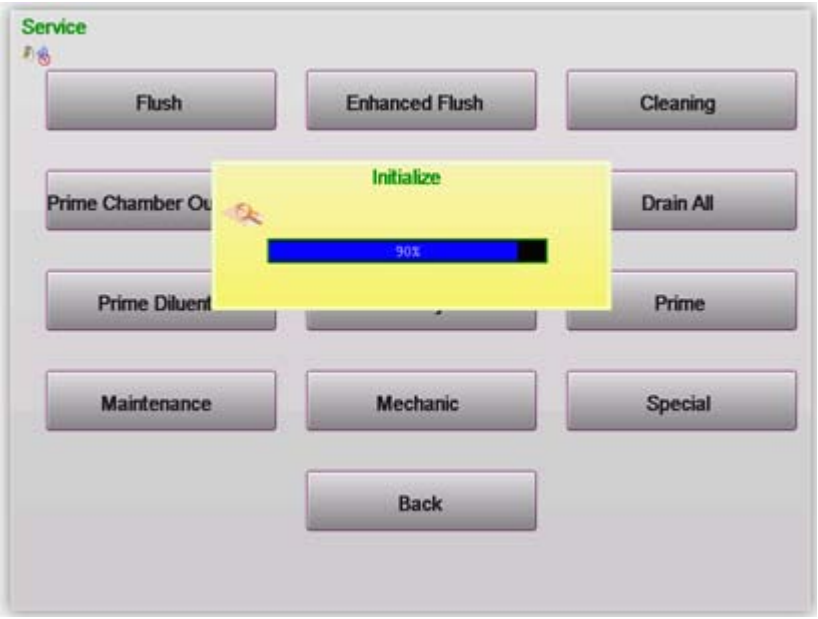


Figure 8-3

8.12 Special

The instrument enters special maintenance window. User can adjust the running control data. This function should be performed in guidance of the engineers authorized by the manufacturer.

Chapter 9 Maintenance

As a precise instrument, only careful daily service and periodic maintenance can the instrument has a good working status, and can we get the reliable measurement results and have few malfunctions.

This chapter introduces some preventive methods for service and maintenance.

If you want to know more related information, please contact the Customer Service Department of the manufacturer.

According to the requirements for maintenance of the instrument during the using procedures, the manufacturer divides the preventive service and maintenance into the following types: daily, weekly, monthly, yearly and maintenance according to the actual need.

Warning:

It is 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, alkali and volatile organic solvent, such as acetone, aether, chloroforms, to wipe the appearance of the instrument. Only neutral detergent can be used.

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 expediently.

Appointed specification of the fuse: F3AL250

Warning:

Only fuse with the appointed specification can be used.

9.2 Daily Maintenance

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

Running

The instrument has installed daily maintenance procedure. When in running, it can execute auto-cleaning procedure according to the quantity of the sample to keep the instrument in good working status. Set the auto-cleaning procedure according to section 6.3. The general setting principles are:

Working time > 8 hours, auto-cleaning time = 8 hours;

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

Working time < 4 hours, auto-cleaning time = 2 hours;

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:

Prepare the washing liquid for the probes well.

Hematology Analyzer Window → Main Menu → Service → Maintenance

Finish all the operations according to the prompts on the screen.

Turn off the power of the instrument.

Note: Hematology Analyzer is a kind of precise instrument, so it is recommended to do maintenance every 4 to 5 days. If you have a big amount of samples, you should increase the maintenance times appropriately.

9.4 Monthly Maintenance

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

Operate as follows:

1) Turn off the power of the instrument, and pull out the power cord.

Open the right side door and brush away the internal dust of the instrument gently.

Note: We must prevent the dust fall into the measuring cup to contaminate it and make an abnormal test result.

2) When the cleaning is done, do not use the instrument immediately. We should start the washing system to make sure the inner side of the pipeline is cleaned.

9.5 Yearly Maintenance

It's necessary to perform preventive maintenance once every year. Because of the high requirements for yearly maintenance, the maintenance should be performed by engineers authorized by the manufacturer. Please contact the Customer Service Department of the manufacturer before yearly maintenance.

9.6 Maintenance before Transport or for the Instrument that will not be used for a long time

If the instrument hasn't been used for more than two weeks or need to be packaged for transportation, do as the following steps:

1) The remaining reagents should be covered and tighten. Follow the instructions to do the reagents' storage and protection. The user should establish and maintain effective reagents-storage measures to prevent the reagents' deterioration, misuse and be eaten.

2) Attach the pipe plugs unplugged in the first installation to the line

interfaces on the rear panel of the instrument, according to the colors' one to one correspondence.

3) Separately clean the diluent catheters, the lyse catheters, waste catheters with distilled water, then dry them in a shade place and package them with plastic bags.

4) Clean the power cable with a clean cloth dampened with neutral detergents, place it in a shade place and put it in a plastic bag.

5) Put the instrument and plastic bags with components into the packaging box

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, the user should contact the Customer Service Department of the manufacturer.

10.1 Abnormal Startup

Methods and procedures:

1) Check if the power is on.

2) Check if the power socket is loose.

3) Check if the fuse is broken. If broken, replace it as section 9.1.2.

10.2 Waste Full

Methods and procedures:

Dispose of the waste in waste container.

10.3 Diluent Empty

Methods and procedures:

1) Replace diluent.

2) In the hematology analyzer window, select “Menu/Service/Prime Diluent”.

10.4 Lyse Empty

Methods and procedures:

1) Replace lyse.

2) In the hematology analyzer window, select “Menu/Service/Prime Lyse”.

10.5 WBC Clog or RBC Clog

If the count time exceeds high limit of the setting during measurement, there will be “Clog” alarm.

Methods and procedures:

1) In the hematology analyzer window, press “Flush” button.

2) If the upper method could not solve the problem, perform as the following procedures.

3) In the hematology analyzer window, select “Menu/Service/Enhanced Flush” and follow the screen prompt information to finish it.

10.6 HGB Error

Methods and procedures:

1) In the hematology analyzer windows, select “Menu/Service/Cleaning”.

2) If the upper method could not solve the problem, perform as the following procedures.

3) In the hematology analyzer window, select “Menu/Service/Enhanced Flush”.

10.7 HGB Bubbles

Methods and procedures:

1) In the hematology analyzer windows, select “Menu/Service/Cleaning”.

2) If the upper method could not solve the problem, perform as the following procedures.

3) In the hematology analyzer window, select “Menu/ Service/Enhanced Flush”.

10.8 Recorder out of Paper

Methods and procedures:

1) Gently press the recorder door to open it.

2) Insert the new paper into the paper entry, and make the printing side towards the thermal head.

3) When the paper juts out from the other side, pull it out and keep it straight.

4) Pull the paper out of the paper exit.

5) Close the door of the recorder.

10.9 Recorder too Hot

Possible reasons:

The thermal head of the recorder is too hot.

Methods and procedures:

Suspend using the recorder for 5 minutes.

10.10 The Result of Background Test too high

Methods and procedures:

1) In the hematology analyzer window, select “Menu/Service/Cleaning”.

2) If the above method could not solve the problem, repeat the procedure 3 times. If the problem still cannot be solved, perform as the following procedures.

3) In the hematology analyzer window, select “Menu/ Service/Enhanced Flush”.

4) If the above method could not solve the problem, repeat the procedure 3 times. If the problem still cannot be solved, perform the upper procedure after replacing all the reagents.

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 hematology analyzer window, select “Menu/Help”, the help window will pop up, as shown in Figure 11-1.

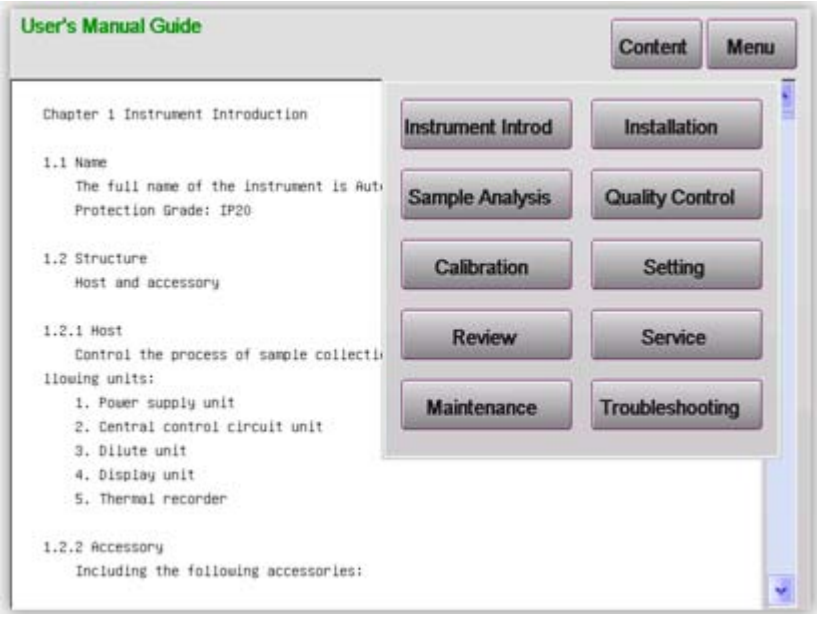
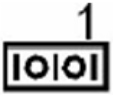
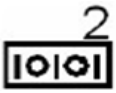


Figure 11-1

This window shows in chapter mode. User can search help information conveniently. Click the scroll bar up and down to read the previous or next information.

Appendix 1 Symbol

Symbol	Meaning	Symbol	Meaning
	COM 1 Interface		USB Interface
	COM 2 Interface		Equipotential Terminal
	Display Interface		Biohazard
	Keyboard Interface		High Temperature
	Mouse Interface		Caution

Appendix 2 Specification

A 2.1 Reagent

Diluent, lyse and probe cleanser

A 2.2 Parameter Information

Item	Unit
WBC	10^9/L
Neu#	10^9/L
Lym#	10^9/L
Mid#	10^9/L
Neu%	%
Lym%	%
Mid%	%
RBC	10^{12}/L
HGB	g/L
HCT	%
MCV	fL
MCH	pg

MCHC	g/L
RDW-SD	fL
RDW-CV	%
PLT	10^9/L
MPV	fL
PDW	None
PCT	%
p-LCR	%
RBC Histogram	None
PLT Histogram	None
WBC Histogram	None

2-1 Parameter Information

A 2.3 Sampling Characteristics

Test Mode	Sample Volume
Venous	10μL
Capillary	10μL
Prediluted	20μL

2-2 Sampling Characteristics

A 2.4 Performance Index

Item	Range
WBC	0~200.0×10^9/L
RBC	0~20.00×10^{12}/L
HGB	0~300g/L
PLT	0~2000×10^9/L
HCT	0%~80%

2-3 Performance Index

A 2.5 Background Range

Item	Range
WBC	≤ 0.2×10^9/L
RBC	≤ 0.02×10^{12}/L
HGB	≤ 1.0g/L
HCT	≤ 0.5%
PLT	≤ 5.0×10^9/L

2-4 Background Range

A 2.6 Linear Range

Item	Range	SD
WBC	0~5.9×10^9/L 6.0~99.9×10^9/L	(±0.3×10^9)/L ±5%
RBC	0~0.99×10^{12}/L 1.0~9.99×10^{12}/L	(±0.05×10^{12})/L ±5%
HGB	0~99g/L 100~300g/L	±2.0g/L ±2%
PLT	0~99×10^9/L 100~999×10^9/L	(±8.0×10^9)/L ±10%

2-5 Linear Range

A 2.7 Repeatability Index

Test the sample for 11 times, and use the results from the second to eleventh test to get repeatability statistics.

Item	CV	Range
WBC	≤2.0%	(4.0~15.0×10^9)/L
RBC	≤1.5%	(3.5~6.0×10^{12})/L
HGB	≤1.5%	(110.0~180.0)g/L
MCV	≤0.4%	(80.0~110.0)fL
PLT	≤4.0%	(100.0~500.0×10^9)/L
LYM%	≤8.0%	LYM%≥15.0%, WBC≥4.0×10^9/L
MID%	≤10.0%	MID%≥5.0%, WBC≥4.0×10^9/L
NEUT%	≤8.0%	NEUT%≥30.0%, WBC≥4.0×10^9/L

2-6 Repeatability Index

A 2.8 Pollution Rate

Item	Result
WBC	≤1%
RBC	≤1%
HGB	≤1%
PLT	≤1.5%

2-7 Pollution Rate

A 2.9 Input / Output

Touch Pen

Keyboard

Mouse

Printer (Optional)

R232 Port

VGA Port

Power Supply:

	Voltage	Frequency
Main Unit	100~240VAC	50/60Hz

Item No.: P01.91.300254-00