URIT-3000

Automated Hematology Analyzer

Operation Manual

Guilin Botest Medical Electronic Co., Ltd.

Catalogue

Copyright and Declaration

Congratulations on becoming an esteemed customer of BME, and welcome to use URIT-3000 automated hematology analyzer, which will bring you brand-new experience and convenience.

The BME are fully responsible for the revision and explanation of the manual, and keeps the right to renovate the relevant contents without separate notification. Some of the demonstration pictures are for reference and subject to real object if any differences.

All instructions must be followed. In no event should BME be responsible for failures, errors and other liabilities resulting from customer's noncompliance with the procedures and precautions outlined herein.

Limited Responsibility for Quality Warranty:
The manual for URIT-3000 automated hematology analyzer defines the rights and obligations between the BME and the customers about the responsibility for quality warranty and after-sale service, also the related agreements on commencement and termination.

BME warrants the URIT-3000 sold by the BME and its authorized agents to be free from defects in workmanship and materials during normal use by the original purchaser. This warranty shall continue for a period of one year since the date of installation. The BME's liability shall be limited solely to the repairing, not including the economic losses or any additional expenses due to analyzer suspension, for instance:

- **Freight (including custom duty).**
- **Economic losses and time costs due to suspension.**
- **Accommodation and travel expenses.**
- **Losses brought by inconvenience.**
- **Other costs.**

The warranty does not cover damages or mal-function which:

- **Caused by abnormal use; without maintenance or already broken.**
- **Usage or replacements of reagents or accessories not provided or authorized by BME.**
- **Are caused by customer or third party abuse, misuse, negligence or by failure to comply with any requirement or instruction contained in the**

applicable URIT-3000 Operation manual.

- **Result from maintenance, repair or modification performed without authorization of BME.**
- **Result from disassembly, stretch, or debugging.**

The failure to implement a series of maintenance plan in each hospital or organization will lead to malfunctions to the analyzer.

Circuit diagrams could be provided for payment if any request, along with the calibration methods or other information, assisting qualified technicians in repairing the parts authorized by BME.

NOTE

No acquiescent warranty will cover the marketability and applicability for special purpose.

Do contact BME Customer Support Center through service hot-line for technical supports and solutions if any difficulty.

If any defects occur, be prepared to furnish details concerning the defects and keep BME authorized agents and BME Customer Support Center informed.

If a problem arises that cannot be resolved via online guidance, BME's engineers or field service representatives offer support.

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Guidance

General information for the operation of the analyzer is contained in this manual, which covers the best guidance for a new operator to master the characteristics of the analyzer and operation methods, as well as for daily inquiry. Do peruse before first operation.
This instruction includes instrument operation, maintenance and notice, to keep instrument function, do comply with instruction to operate and maintain it.
This instruction uses the following conventions:
WARNING: Might cause injury
CAUTION: Might cause damage to the analyzer or misleading result
NOTE: Important information.

Do read through this document before operation, maintenance, displacement to the analyzer.

Guilin Botest Medical Electronic Co., Ltd is abbreviated as Botest Company (or BME)
There are some words that appear in the instrument, we make an abbreviated word table for you.

Full Name	Abbreviation
Function	Func
Parameter	Param
Cauterize	Caut
Recorder	Rec
Calibration	Cal
Expiration	Exp.
Previous Page	Pgpre
Deviation Amplitude	Dev
Information	Info
Histogram	Histo
Transfer	Trans
Service	Serv
Delete	Del
Next Page	Pgnex
Default	Def

Chapter 1 System Description

This manual of Automated Hematology Analyzer covers the information for operation, maintenance and notes. Do comply with the instructions outlined in this document to attain the optimum status.

1.1 Overview

The instrument is multi-parameter hematology analyzer designed for in-vitro clinical use and particulate analysis, which assembles sample aspiration sector, dilution sector, measurement sector, display and recorder. The analyzer is equipped with big screen of high definition, which can at the same time display 19 parameters and 3 histograms. Connection to the network is also applied to transmit the data simultaneously. Adopting advanced data collection system, the analyzer can provide accurate, reliable test-data on capillary and venous blood for the reference of clinical diagnosis.

1.2 Measurement Parameters

The analyzer can conduct continuous measurements on pre-diluent and whole blood specimen in batch, forwarding the measurement data in 19 parameters (Listed in Table 1-1), and the data could be analyzed, arranged automatically, forming histograms on WBC of 3 categories, RBC and platelet.

Table1-1 Test Parameters

Abbreviation	Full Name	Unit
WBC	White Blood Cell Count	10^9cells/L
LYM%	Lymphocyte Percent	%
MID%	Monocyte Percent	%
GRAN%	Granulocyte Percent	%
LYM#	Lymphocyte Count	10^9cells/L
MID#	Monocyte Count	10^9cells/L
GRAN#	Granulocyte Count	10^9cells/L
RBC	Red Blood Cell Count	10^{12}cells/L
HGB	Hemoglobin Concentration	g/L
HCT	Hematocrit (relative volume of erythrocytes)	%
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular Hemoglobin	pg
MCHC	Mean Corpuscular Hemoglobin Concentration	g/L
RDW-CV	Red Blood Cell Distribution Width repeat precision	%
RDW-SD	Red Blood Cell Distribution Width STDEV	%

PLT	**Platelet Count**	**10^9cells/L**
MPV	**Mean Platelet Volume**	**fL**
PDW	**Platelet Distribution Width**	**fL**
PCT	**Plateletcrit**	**%**

1.3 Front Panel

Front panel structure list in Figure 1-1

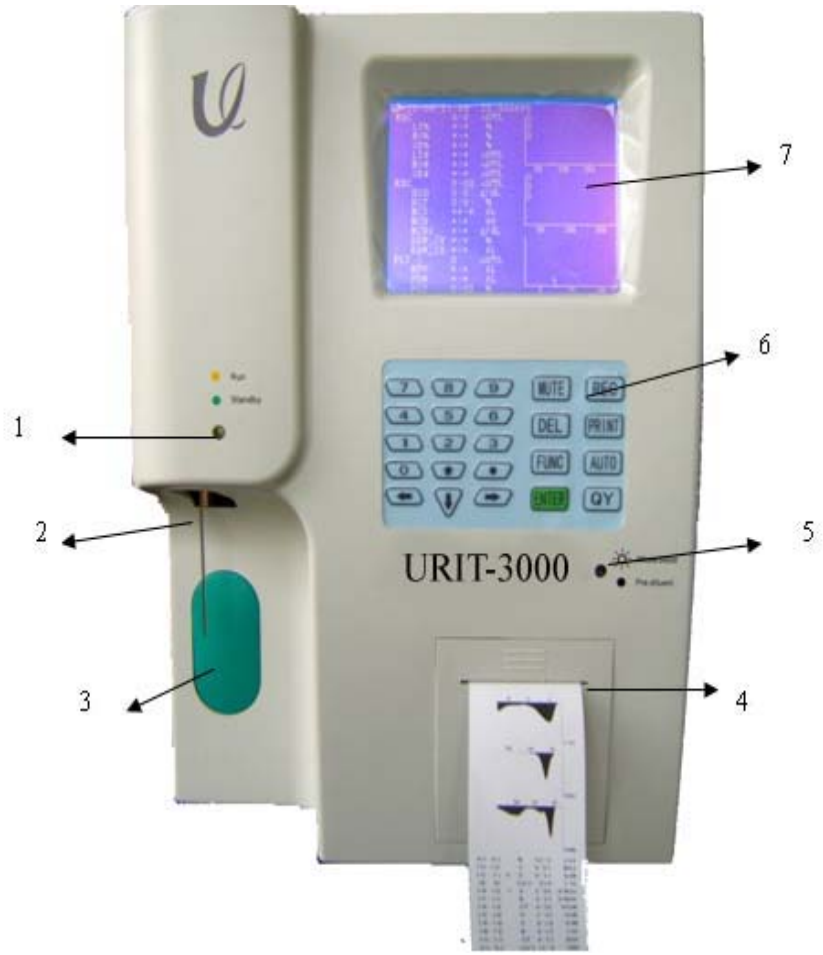


Figure 1-1

1. Work status indicate light:

Indicates the power and work status

The indicator is lighted after power on.

Green: Standby status for counting analysis.

Orange: Analysis status, please wait

2. Sample probe: Sample collection

3. RUN Button

Counting-analysis startup is only available in blood-cell analysis and quality control window.

4. Recorder

Print test result by inner heat-sense recorder

5. Work-mode indicate light
On is whole blood mode, off is pre-diluent mode.
6. Keyboard
Total 23 keystroke, its function as below:
0~ 9 numbers: Input number;
. : Input radix point while input data;
MUTE: Stops the alarm
REC: Startup inner printer, print test result.
FUNC: Function menu, menu function transfers or exit current choice, back to blood cell analyze window.
AUTO: Drain liquid from sample probe, mainly used in pre-diluent of capillary.
Del: Delete input number, character.
PRINT: Startup outer printer, print test result.
ENTER: Confirm the chosen content.
QY: Work-mode switch between whole blood and pre-diluent.
↑ ↓ ← → : Direction key can move cursor to choose needed menu or item.
7 Display
5.5 Inches LCD display divided into 4 sections as figure1-2:

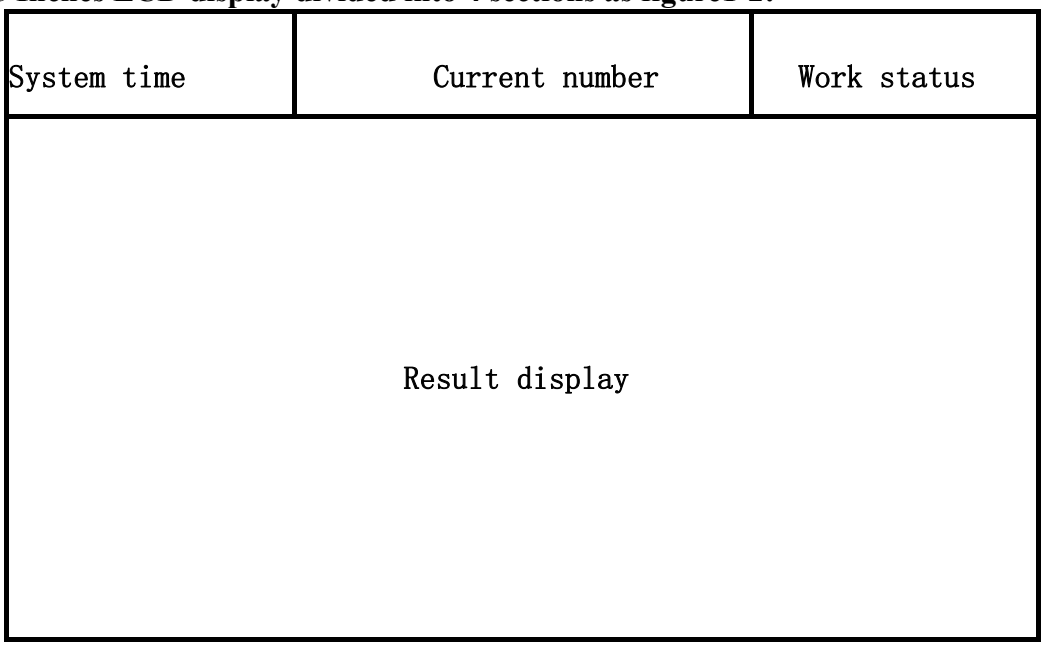


Figure 1-2

Work status section:
When counting, display" Counting, please wait"
After counting, display "Cleaning, please wait"
Instrument appears trouble, display trouble alarm.
System time section
Displays present date and time
Current number section
Display ID number of current test result.
Result display section

Displays current specimen test result and list three histograms.

1.4 Rear Panel

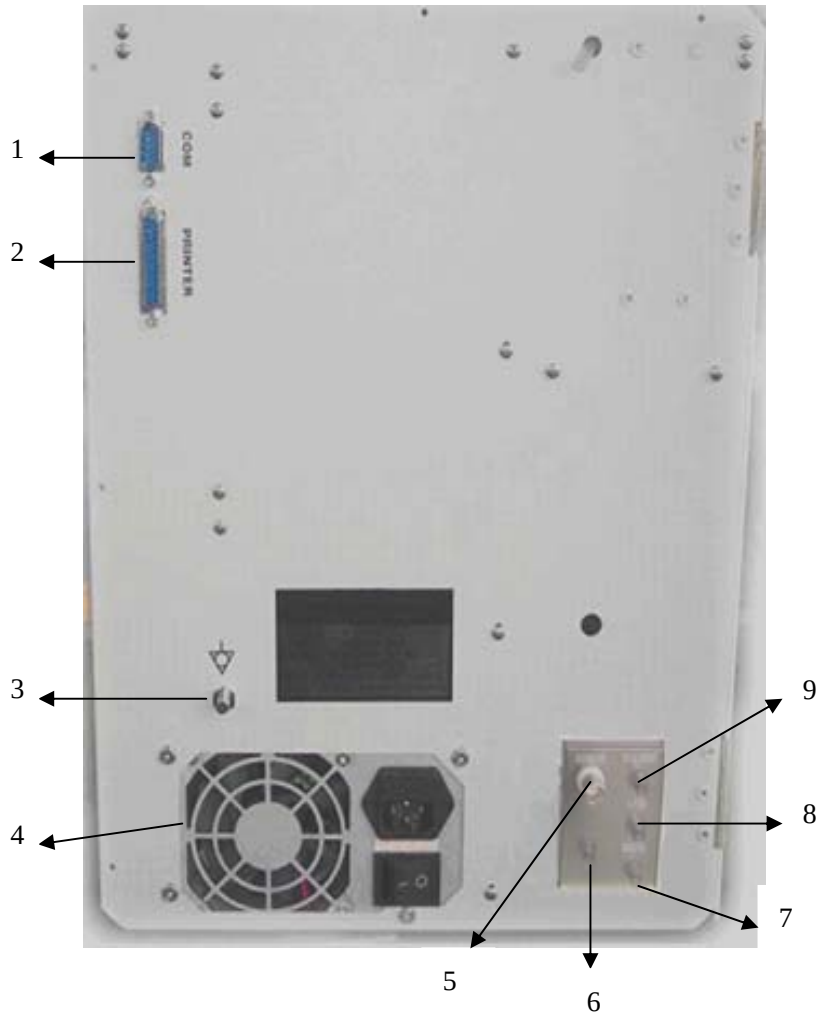


Figure 1-3

1. COM

Communication port connected to outer standard RS-232 network

2. PRINTER

Printer interface connected to outer printer

3. Equipotential grounding terminal

Grounding system used in connecting instrument to hospital

4. Power Supply

Power supply

5. SENSOR

Waste sensor interface connected to waste sensor

6. DETERGENT

Detergent faucet connected to detergent tube.

7. WASTE

Faucet connected to waste tube.

8. LYSE
Lyse faucet connected to lytic reagent tube.
9. DILUENT
Diluent faucet connected to diluent tube.

1.5 Components

Host, pin printer and reagent.

1.5.1 Host

Performs collection and analysis of blood specimen, display test result automatically on LCD after counting, host mainly composed of below parts:

1.5.1.1 A/D and Central Control Board

Central control board is the control center of instrument, it controls below parts:

- **On-off of electromagnetism, aspiration and prime of reagent and waste drain.**
- **Running of rotate pump and vacuum pump, offer aspirate and drain power for tubing.**
- **Control step motor sample aspiration, diluent and reagent added.**
- **Control A/D switches of WBC, RBC/PLT, HGB, offer computer data-process front-port service; control running of all light and electricity switch.**

1.5.1.2 WBC Measurement Unit

WBC measurement unit mainly composed of collection board, electrode, micro-aperture sensor and tubing
a) Signal collection board---offer constant current power for electrode, offer collected plus signal via amplify, treatment to central control unit; it can transmit temperature variation signal sensed by temperature sensor to control board, give alarm when sample measured in unsuitable temperature.
b) Electrode---There two electrode of WBC: inner and outer, inner electrode installed inside WBC probe, outer outside WBC probe, when inner and outer electrode dip in mix liquid, constant current source on the electrode form electric loop through micro-aperture.
c) Micro-aperture sensor---WBC micro-aperture sensor installed in front of probe, diameter is about 100 micron. When doing sample measurement, sample granule through micro-aperture.
d) Tubing---Use negative pressure as power, inhale diluent, detergent, measure sample into measure tube from each container, then drain waste after

measurement. In WBC front part installed lytic reagent added, mix structure, through control-board controlled step motor add proper quantity lytic reagent in sample cup, then rotating pump produces compress gas to mix evenly.

1.5.1.3 RBC/PLT Measurement Unit

RBC/PLT measurement unit mainly composed of collection board, electrode, micro-aperture sensor and tubing
a) Signal collection board---offer constant current power for electrode, offer collected plus signal via amplify, treatment to central control unit.
b) Electrode---There two electrode of RBC/PLT: inner and outer, inner electrode installed inside WBC probe, outer outside RBC/PLT probe, when inner and outer electrode dip in mix electric liquid, constant current source on the electrode form electric loop through micro-aperture
c) Micro-aperture sensor---RBC/PLT micro-aperture sensor installed in front of probe, diameter is about 80 micron. When doing sample measurement, sample granule through micro-aperture.
d) Tubing---Use negative pressure as power, inhale diluent, detergent, measure sample into measure tube from each container, then drain waste after measurement. In WBC front part installed lytic reagent added, mix structure, through control-board controlled step motor add proper quantity lytic reagent in sample cup, then rotating pump produces compress gas to mix evenly.

1.5.1.4 Tubing

Tubing mainly composed of electromagnetism pump, solenoid valves, rotate pump, vacuum pump and plastic tube.
Electromagnetism pumps—touch two-position, three position electromagnetism pump control the tubing flow.
Solenoid valve---Control tubing flow by pressing plastic tube thoroughfare.
Vacuum pump---Inhale diluent into liquid-storage pot
Drain pump---Drain waste after counting
Plastic tube---Carrier of reagent and waste flow
Vacuum chamber---Produce negative pressure and waste temporally storage after sample test.

1.5.1.5 Display

Instrument adopts 5.5 Inches LCD. Can display 19 parameters and 3 histograms, details consult Chapter 1.3.

1.5.2 Reagent

To maintain the optimum status, a series of exclusive reagent was deployed for instrument by manufacture. The reagents are qualified for the tests on instrument and work well. All the measurement indexes are calibrated according to the tests of the exclusive reagents on instrument, thus non- manufacture reagents will lead to defects in the performance of the analyzer and serious mistakes, even accidents. The best chemical effect can be achieved only if the reagents are preserved under room temperature and away from temperature extreme or direct sunlight. Moreover, temperature below 0℃ will freeze up the reagents and induce changes in reagents' chemical character and conductivity. The containers should be airproof and the reagents should be transported through a tube across the cover of containers for the sake of minimizing the evaporation and outer pollution. However, the reagents must be fully utilized with the valid period since the quality of the reagents alters as the time goes by.

1.5.2.1 Diluent

Isotonic diluent is a kind of reliable isotonic diluent to meet the requirements as follows:

a) Dilutes WBC、RBC、PLT、HGB

b) Maintains the shape of the cell under measurement

c) Offers proper background value

d) Clean the aperture of WBC、RBC

1.5.2.2 Lytic reagent

Lytic reagent is a new type lytic reagent without NaN_3 complex and cyanide and meets the requirements as follows:

a) Dissolves RBC instantly with minimum complex.

b) Transforms the membrane of the WBC to diffuse the cytoplasm and granule the WBC through the membrane's shrinkage around the karyon

c) Transforms the hemoglobin to the hemo-compound suitable for the measurement in the condition of 540nm wavelength

d) Avoids cyanide's serious pollution to the body and the environment

1.5.2.3 Detergent

Detergent contains the active enzyme to clean the agglomerated protein in the WBC, RBC probes and measurement circuit.

1.5.2.4 Probe cleaner

Probe cleaner contains effective oxide to dredge the stubbornly-blocked apertures on the WBC, RBC probes

1.6 Sample Dosage

Whole blood mode: whole blood (venous blood) 18 uL
Pre-diluent mode: capillary blood 20 uL

1.7 Single Specimen Reagent Dosage

Diluent: 28mL;
Lytic reagent: 0.6mL;
Detergent: 12mL.
Reagent quantity will be different on various versions.

1.8 Test Speed

Test speed of this instrument is about 60/hour

1.9 Memory

The instrument equipped with inner memorizer, can store not less than 2,000 test result.

1.10 Measurement Repeatability

Measurement repeatability should accord with the requirement of table 1-2

Table 1-2 Measurement repeatability

Measurement item	Measurement repeatability (CV %)
WBC	≤2.0 %
RBC	≤1.5%
HGB	≤1.5%
MCV	≤0.5%
PLT	≤5.0%

1.11 Veracity

WBC, RBC, PLT and HGB measurement value should in the range of whole

blood control test standard value. Error range should accord with the requirement of table 1-3

Table 1-3 Veracity

Measurement item	Measurement veracity allowed
WBC	≤±4%
RBC	≤±3%
HGB	≤±3%
MCV	≤±3%
PLT	≤±8%

1.12 Storage, Using Environment

1.12.1 Power Supply

Voltage: 230 V
Frequency: (50±1) Hz
Consuming: Power ≤250VA

1.12.2 Storage and Transport Environment

Environment temperature: 18 ℃~**35** ℃
Comparative humidity: ≤80% RH
Barometric: 80kPa～106kPa

1.13 Print Paper

Recorder print paper specification: 57.5mm thermal print paper

Chapter 2 Principles of Operation

The measurement principles of URIT-3000 automated hematology analyzer are discussed in this chapter. The two independent measurement methods used in instrument are:
The impedance method for determining the quantity and volume of blood cell
The floating colorimetric for determining the content of hemoglobin
Then a detailed explanation of the theory used for parameter derivation is given.

2.1 Principles of Measurement

The measurement is mainly on the quantity, volume of blood cell and HGB.

2.1.1 Measurement on the quantity of blood cell

The measurement and counting of the cell is conducted with traditional resistance law. As Figure. 2-1 shows that, a circuit loop with steady resistance forms in the conductive liquid (mainly the diluent), which provides the electrode with permanent power supply. When cells push through the aperture, the change of the resistance generates electric impulse, the amplitude of which varies due to the variation of cells' volume. With the quantity and the amplitude of the electric pulse that across the aperture, the quantity and volume of the cells is available.

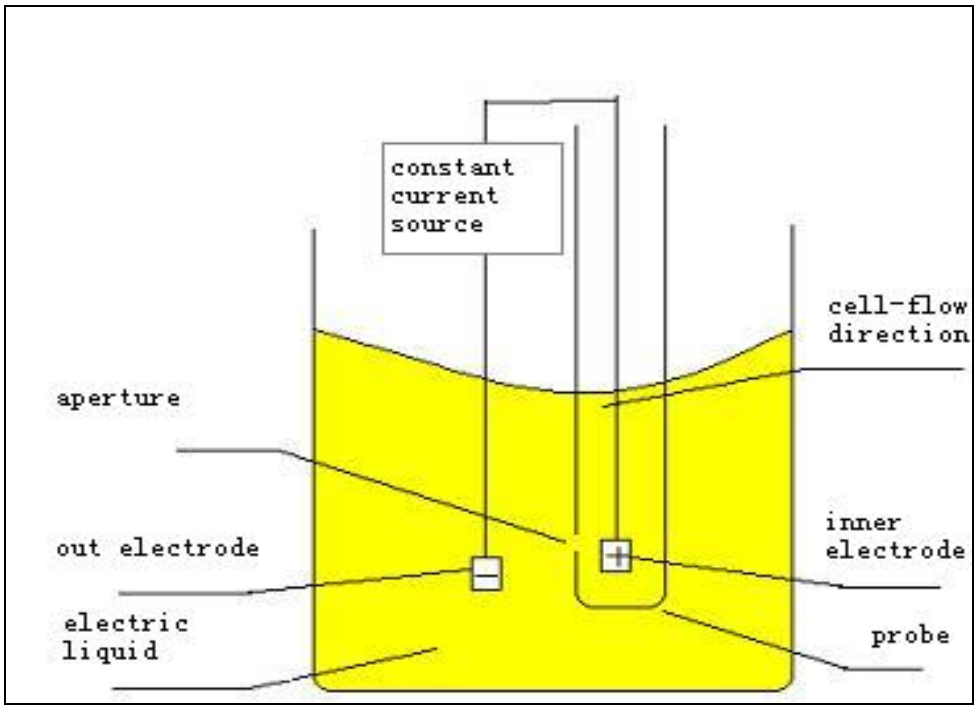


Figure 2-1

For the correspondence between the quantity of pulse and the cell across the aperture, also the amplitude of the pulse and the volume of the cell, the analyzer measure each cell and classify it according to its volume by a pre-set classification program. All the cells fall into categories (WBC, RBC, PLT etc.) as follows:

WBC	**35—450**	**fL**
RBC	**30—110**	**fL**
PLT	**2—30**	**fL**

According to the volume, leucocytes handled by lytic reagent can be subdivided into three Categories: Lymphocyte (LYM), Monocyte (MID) and Granulocyte (GRAN).

LYM	**35—98**	**fL**
MID	**99—135**	**fL**
GRAN	**136—450**	**fL**

2.1.2 Measurement of HGB

Lytic reagent added into the blood sample will crack the membrane of red blood cell promptly and transfer into a kind of compound which can absorb the wavelength of 540 nm. Through the comparison of the absorbance between the pure diluent and the sample, the concentration of sample hemoglobin is calculated.

2.2 Reagent's Functions

The counting system of instrument is highly sensitive to the volume of enumerated cell that suspends in conductive liquid, thus the physical coagulation and adhesion must be as few as possible. In order to maintain cells' organic structure and minimum the change of volume, the infiltrative pressure of conductive liquid (mainly diluent) must be controlled. Because lytic reagent can crack the membrane of red blood cell instantly and maintain the organic structure of leucocyte, the counting and classification can be conducted.

2.3 Methods for Parameter Measurement

The parameters of blood test are expressed in 3 ways:

a) Direct way, such as WBC, RBC, PLT, HGB, MCV;
b) Histogram, such as LYM %, MID %, GRAN %, HCT, RDW, MPV, PDW;
c) Derivation from certain formula, such as LYM #, MID #, GRAN #, MCH,

MCHC, PCT.

The derivation formulas are as follows:

- **HCT (%)= RBC x MCV/10**
- **MCH (pg)= 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 x AG/(AL+AM+AG)**

WBC histogram as Figure 2-2

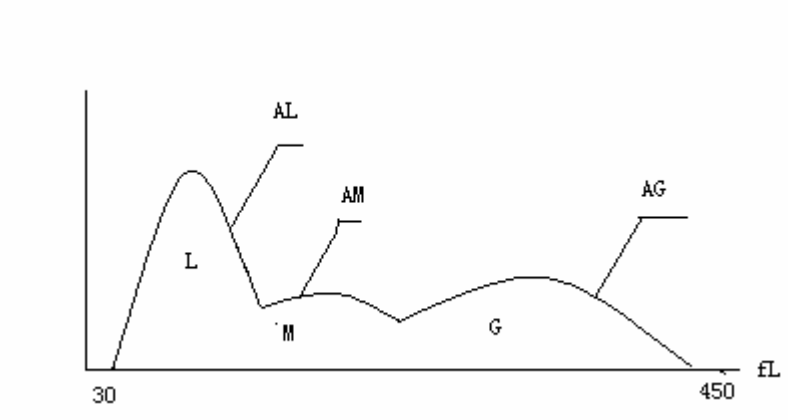


Figure2-2: WBC Histogram

AL: Numbers of cell in area of LYM;

AM: Numbers of cell between area of lymphocyte and area of granulocyte;

AG: Numbers of cell in area of GRAN;

The formulas for absolute value calculation on the number of lymphocyte (LYM#)、monocyte(MID#) and granulocyte(GRAN#) are as follows:

- **Lymphocyte（10^9L） LYM# = LYM% x WBC/100**
- **Monocyte（10^9L） MID# = MID% x WBC/100**
- **Granulocyte（10^9L） GRAN# = GRAN% x WBC /100**
- **RBC Distribution Width repeat precision（RDW－CV）is derived from RBC histogram，shows the volume distribution aberrance coefficient of RBC， with the unit of %.**
- **RBC Distribution Width standard difference（RDW－SD）is derived from RBC histogram，shows the RBC size aberrance coefficient of RBC，with the unit of fL.**
- **Platelet Distribution Width (PDW) is derived from PLT histogram，shows the volume distribution of PLT.**

Chapter 3 Installation and Specimen Analysis

Initial installation of instrument must be performed by a manufacture authorized engineer or representative to ensure that all system components are functioning correctly and to verify system performance. Installation procedures must be repeated if the analyzer is moved from the original installation site.

NOTE:

Installation of the analyzer by an unauthorized or untrained person could result in damage to the analyzer which is exclusive of the warranty. Never attempt to install and operate the system without a manufacture authorized representative.

3.1 Unpacking and Inspection

Carefully remove the analyzer and accessories from shipping carton, keep the kit stored for further transport or storage. Check the following:

a) Quantity of accessories according to the packing list.
b) Leakage or soakage.
c) Mechanical damage.
d) Bare lead, inserts and accessories.

Do contact manufacture Customer Support Center if any problem occurs.

3.2 Installation Requirements

Please refer to Section 10.2 of Chapter 10.

WARNING:
Not for home use.
WARNING:
Not for therapy.
CAUTION:
Away from direct sunlight
CAUTION:
Avoid temperature extreme.
CAUTION:
Far from a centrifuges, X-ray equipment, display or copiers
CAUTION:
No cell phone, wireless phone and equipments with strong radiation around which will interfere with the normal operation of the analyzer.

3.3 Power Supply Inspection

Be sure that the system is located at the desired site before attempting any connections.
Voltage：230 V Frequency: (50±1) Hz
WARNING:
A grounded power outlet is required to connect directly with the grounding pole on the rear panel. Be sure to guarantee the security of the work site.
CAUTION:
Be sure that all the connections are correct and reliable before turning the analyzer on.
CAUTION:
A fluctuated voltage would impair performance and reliability of the analyzer. Proper action such as the installation of E.C manostat (not provided by manufacture) should be taken before operation.
CAUTION:
Frequent power failure will seriously decrease the performance and reliability of the analyzer. Proper action such as the installation of UPS (not provided by manufacture) should be taken before operation.

3.4 Tubing Installation

There are 4 tube-connectors on the rear panel: Waste, Lyse, Sensor and Diluent, each of which is wrapped with a cap to avoid contamination by the manufacturer before shipment. Uncover and set the caps aside carefully for further use on initial installation.

3.4.1 Lytic reagent Tubing Installation

Remove the LYTIC REAGENT tube with red faucet from reagent kit and attach it to the connector on the rear panel, place the other end into the LYTIC REAGENT container. Twist the cap until secure. Place the container on the same level as the analyzer.

3.4.2 Diluent Tubing Installation

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

3.4.3 Waste Tubing Installation

Remove the WASTE OUTLET tube with black faucet from reagent kit and attach it to the connector on the rear panel, connect BNC plug with the socket

marked "SENSOR" on the rear panel. Twist the tube's cap clockwise onto the waste container until secure. Place the container on the level at least 50cm lower than the analyzer.

3.4.4 Detergent Tubing Installation

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

CAUTION:

Loose the tube after installation, no contortion or folding.

CAUTION:

All the tubes should be installed manually. Do NOT utilize any tool.

CAUTION:

If any damage or leakage occurs in the reagent container, or the reagents have exceeded expiry date, contacts manufacture Customer Support Centre for replacement.

WARNING:

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

3.5 Recorder Paper Installation

Please refer to Section 9.3.10 of Chapter 9.

3.6 Printer Installation (if any)

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

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

NOTE:

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

3.7 Power Connection

Make sure the power switch is off (O), and connect the analyzer with the power supply. The earth device on the rear panel should be well grounded.
NOTE:
The power cord should be connected to the special socket for hospital's use.

3.8 Startup

Turn on the power switch on the rear panel, then the indicator on the front panel will become orange, the analyzer start initialization, and automatically absorb diluent and lytic reagent, then rinse the tubing. The Blood Cell Analyze window appears after initialization (See Figure 3-1).

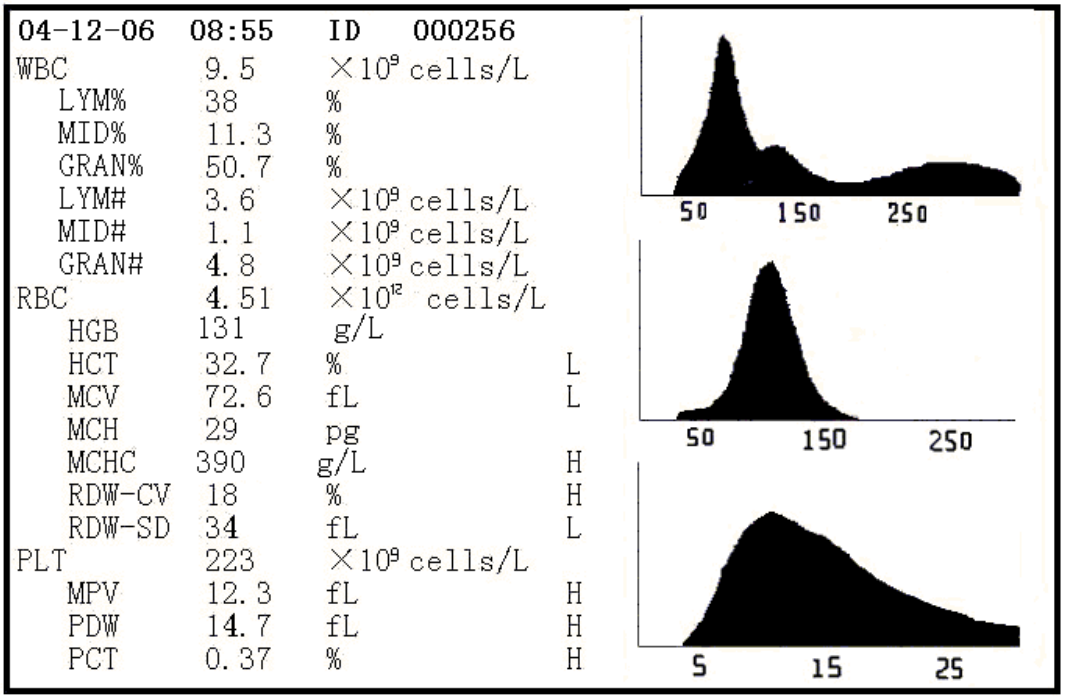


Figure 3-1

3.9 Background Test

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

a) Present clean tube beneath the probe. At Blood Cell Analyze window, press

AUTO to dispense the diluent into the tube.

b) **Press FUNC in instrument surface, shift ↑ ↓, choose "Serial number" menu, press ENTER modify the serial number to 0**
c) **Put the tube beneath probe, make sure probe touch tube bottom lightly.**
d) **Press Run key only can move away tube after hear "Di", instrument start to counting and measure.**
e) **After counting, display background test result on screen, the acceptable range of the testing result for background test is listed in Table 3-1**
f) **Instrument will give trouble alarm and display on top right corner when sensor clog, please consult Chapter 9 «Troubleshooting».**

Table 3-1 the range of the testing result

PARAMETER	BACKGROUND	UNIT
WBC	≤ 0.3	10^9/L
RBC	≤ 0.03	10^{12}/L
PLT	≤ 10	10^9/L
HGB	≤ 2	g/L
HCT	≤ 0.5	%

If the test results are out of this range, repeat the above a) ~d) step until the test results are within the expected range. Refer to Chapter 9 for problem correction if the results still do not meet performance expectation after 5 times' repetition.
NOTE:
Serial number for background test is set to be 0 by the software. After set to 0, test result will not stored.
NOTE:
The serial number for blood sample test can NOT be set to 0.

3.10 Quality Control

Quality control should be performed before daily test or on the initial installation. Refer to Chapter 5.

3.11 Calibration

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

3. 12 Blood Collection

CAUTION:
Consider all the clinical specimens, controls and calibrators etc, that contain human blood or serum as being potentially infectious, wear standard laboratory clothing, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.
CAUTION:
Blood collection and disposal should be performed according to the municipal government or laboratory's requirements.
CAUTION:
Be sure the blood collection clean and contamination-free.
CAUTION:
Do not shake the sampler violently.
NOTE:
Venous blood can only be stored for 4 hours at room temperature. Manufacture recommends the blood sample be kept at temperature between 2-8℃ for longer storage.

3. 12. 1 Whole Blood Collection

Collect whole blood sample through vein-puncture and store in a clean sample tube with EDTA-K2· $2H_2O$, which can keep the configuration of WBC, RBC and control platelets aggregation, gently shake the tube 5~10 times to make it well mixed.

3. 12. 2 Pre-diluent Blood Collection

Pre-diluent blood is usually collected via finger-stick method. The volume of sampler is set to be 20ul.
CAUTION:
Precision and repeatability of instrument except for related with reagent and instrument quality also largely with operating and clinical doctor's knowledge.。
CAUTION:
Never over press the finger to avoid the tissue liquid from mixing with capillary blood, thus causes error in results.
CAUTION:
Must insure blood collection is 20ul to avoid results incorrect due to blood insufficient.

3. 13 Pre-diluent Mode and Whole Blood Mode

Instrument is in whole blood mode when the indicator light on front panel is shine; dark is in pre-diluent mode.

In case current work mode is "whole blood" mode, press QY will pop up follow figure 3-2, shift ← → to select "OK", press ENTER, instrument back to the counting window, indicator light is in dark, current work mode switch to "pre-diluent" mode.

Method of switching from "pre-diluent" to "whole blood" mode is the same.

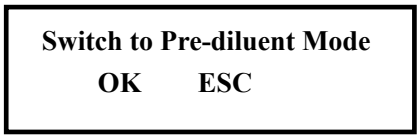


Figure 3-2

3.14 Counting and Analysis

3.14.1 Counting and Analysis Process

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

■ Pre-diluent Mode

a) Present the empty clean tube beneath the probe. At Blood Cell Analyze window, presses Auto; the diluent will be dispensed into the tube. Remove the tube.

b) Add 20ul of the blood sample to the diluent in the tube, and gently shake the tube to make them well mixed.

c) Present the tube with blood to the probe (keep probe touch the tube bottom lightly). Press Run key on the front panel and the indicator become orange. Only remove the tube after buzzer gives "Di".

d) The results will be available after the analysis is performed.

■ Whole Blood Mode

a) Gently shake the tube to well mix the blood sample, then present the sample tube to the probe (keep the probe at the bottom of tube). Press Run key and the indicator become orange. Only remove the tube after buzzer gives "Di".

b) The results will be available after the analysis is performed.

The test results and histograms of WBC, RBC and PLT will be displayed at Blood Cell Analyze after counting and analysis (See Figure 3-1).

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

If the test results for parameters exceed the expected limits, an "L" or "H" will appear in front of the parameter. "L" means test result is lower than the lower limit while "H" means test result is higher than upper limit.

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

CAUTION:

Insure correctly set work mode "whole blood" and "Pre-diluent" before counting,

specific consult chapter1, 1.1.1
CAUTION:
Perform blood analysis under "pre-diluent" mode, instrument can counting twice against drain once.
CAUTION:
Analyze in "Pre-diluent" mode, must use one-off tube and fix-capacity sample tube, repeat using will cause cross infection and lead to incorrect result.
CAUTION:
According to the requirement of clinical medicine, blood cell not distortion, work temperature for correct counting is 18 ℃~35℃. Customer should take proper measure keep this range to insure correct counting.

CAUTION:
To doubtful blood sample medically, should do artificial countercheck according to correlative stipulate.

3. 14. 2 Histogram Alarm

If some of the cells in the blood sample are immature, abnormal or untypical, the warning indication is given in the form of histogram. Warning information such as R1, R2, R3, R4, RM and PM will be displayed to the right of the histograms.

· R1: Indicates the left area of LYM is abnormal.
Probable cause: RBC not lysed thoroughly, platelets aggregated, huge platelets, plasmodiums, nucleolate RBC, abnormal lymphocytes, condensed globins and lipid particles, ect.
· R2: Indicates the area between LYM and MID is abnormal.
Probable cause: Anamorphic lymphocytes, abnormal lymphocytes, serum cells, acidophilic granulocyte, and increased basophilic granulocytes
· R3: Indicates the area between Mid and GRAN is abnormal.
Probable cause: Immature granulocytes, abnormal cells, acidophilic granulocytes
· R4: Indicates the right area of GRAN is abnormal.
Probable cause: Increased granulocytes
· RM: Indicates multiple areas within WBC other than the above-mentioned are abnormal.
Probable cause: Multiple causes as the above mentioned
· PM: Indicates the cross area between PLT and RBC is abnormal.
Probable cause: Platelets aggregated, huge platelets, little RBC, cell fragments and fibrins

3. 15 Report Output

There is an inner thermal recorder in instrument, and the outer printer is

optional according to customers' needs. The followings happen after blood sample analysis.
If Auto Print is on, recorder will print parameter test report in English.
If Auto Print is off, press REC, blood cell analyze report of current sample can print by inner recorder.
If Auto Print is off, press PRINT, blood cell analyze report of current sample can print by outer printer.
The modes of recorder, printer, network and test reports are set up at Settings. Refer to Chapter 4 for specific procedures.
CAUTION:
Do NOT pull the recorder paper violently when the recorder is running, or it may cause damage to the recorder.
CAUTION:
Never run the recorder without any recorder paper.

3.16 Shutdown

Shutdown procedure is performed after daily operation and before turning the analyzer off. Daily maintenance and tubing-rinse avoid protein aggregation during non-working and keep system clean.
Shutdown procedure is as follows:

a) Press FUNC, shift ↑ ↓, select "Shutdown" menu, press ENTER, screen pop-up "Shutdown "window, see Figure 3-3.

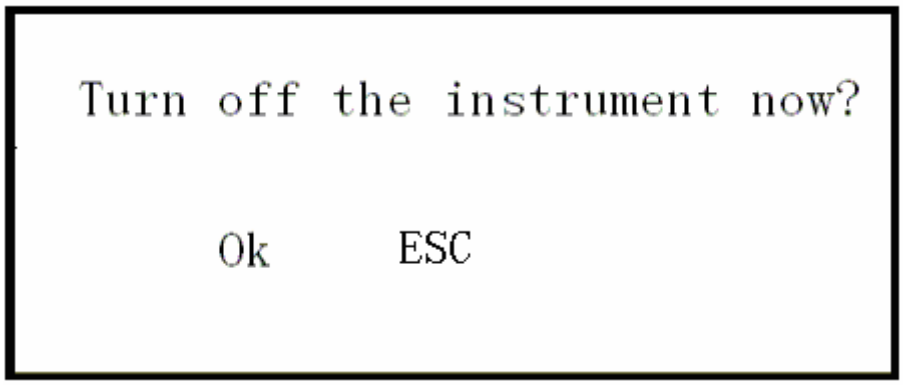


Figure 3-3

b) If turn off the instrument, click "OK".
c) Instrument begins cleaning and maintenance to tubing.
d) After turnoff procedures. "Thank you, now turn off power" will appear to instruct the operator to turn off the switch on the rear panel.
e) Tidy the work platform and dispose waste
f) Press Esc if the operator does not want to turnoff the analyzer, return to Blood Cell Analyze window.

NOTE:
Wrong operations on turnoff procedure will decrease reliability and performance of the analyzer, any problems derived from that will NOT be guaranteed free by manufacture.
NOTE:
Wrong turnoff lead to system data loss easily, cause system operation failure.
NOTE:
Wrong turnoff or not turnoff, instrument will not prime the tubing, easily lead to albumen aggradations of blood sample in tubing cause clog.

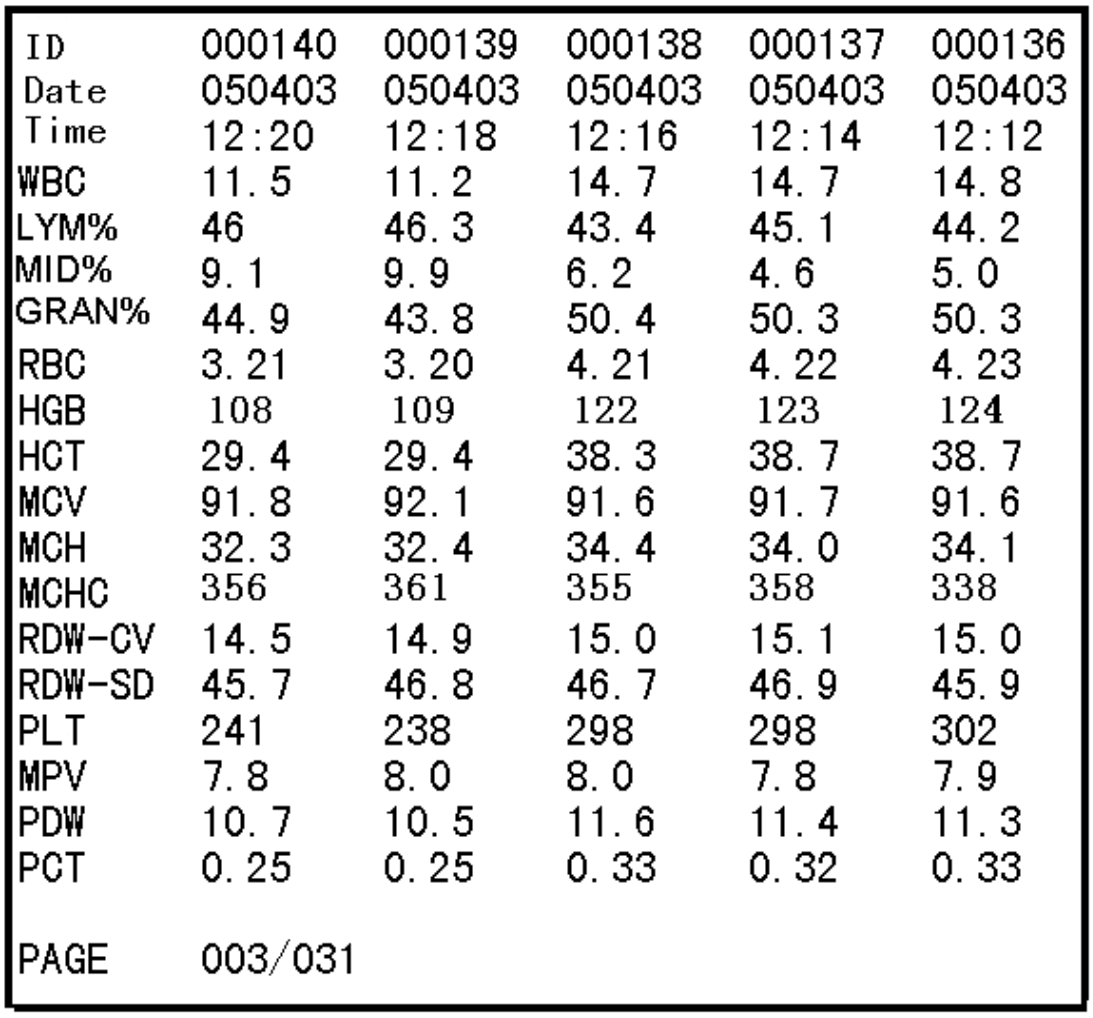
3.17 Test Result Review

3.17.1 Historical Data Review and Output

User can review the parameter and histogram of tested blood sample, and can print out test data and histogram through outer printer. Details as follows:
a) At Blood Cell Analyze window, press FUNC, shift ↓ to select "Data review", instrument enters into data review window, as Figure 3-4.
b) Press ↑ ↓ to review the data backwards or forwards. The data of 5 samples at most can be reviewed in one page in sequence of test time.
c) Press ← → on keyboard to select single sample, move cursor to the sample No you want to review, press ENTER into Details Review window to browse specific historical sample data and printed out by recorder or printer.
d) Press FUNC, return to Test Result Review window.

3.17.2 Historical Data Deletion

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



ID	000140	000139	000138	000137	000136
Date	050403	050403	050403	050403	050403
Time	12:20	12:18	12:16	12:14	12:12
WBC	11.5	11.2	14.7	14.7	14.8
LYM%	46	46.3	43.4	45.1	44.2
MID%	9.1	9.9	6.2	4.6	5.0
GRAN%	44.9	43.8	50.4	50.3	50.3
RBC	3.21	3.20	4.21	4.22	4.23
HGB	108	109	122	123	124
HCT	29.4	29.4	38.3	38.7	38.7
MCV	91.8	92.1	91.6	91.7	91.6
MCH	32.3	32.4	34.4	34.0	34.1
MCHC	356	361	355	358	338
RDW-CV	14.5	14.9	15.0	15.1	15.0
RDW-SD	45.7	46.8	46.7	46.9	45.9
PLT	241	238	298	298	302
MPV	7.8	8.0	8.0	7.8	7.9
PDW	10.7	10.5	11.6	11.4	11.3
PCT	0.25	0.25	0.33	0.32	0.33
PAGE	003/031				

Figure 3-4

3.17.2.1 Auto Deletion

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

3.17.2.2 Manual Deletion

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

All data deletion

a) At blood cell analyze window, press FUNC, shift ↑ ↓, select "Data review", press ENTER into Test Result Review window, see Figure 3-4

b) Affirm cursor at the last sample ID of first page; press AUTO, then press DEL, left downside will appear OK, ESC and all deletion, see Figure 3-5.

c) Shift ← →, select "OK" will all the stored historical data, back to blood cell analyze window, select "ESC" back to Test Result Review window.

ID	000140	000139	000138	000137	000136
Date	050403	050403	050403	050403	050403
Time	12:20	12:18	12:16	12:14	12:12
WBC	11.5	11.2	14.7	14.7	14.8
LYM%	46	46.3	43.4	45.1	44.2
MID%	9.1	9.9	6.2	4.6	5.0
GRAN%	44.9	43.8	50.4	50.3	50.3
RBC	3.21	3.20	4.21	4.22	4.23
HGB	108	109	122	123	124
HCT	29.4	29.4	38.3	38.7	38.7
MCV	91.8	92.1	91.6	91.7	91.6
MCH	32.3	32.4	34.4	34.0	34.1
MCHC	344	343	335	336	337
RDW-CV	14.5	14.9	15.0	15.1	15.0
RDW-SD	45.7	46.8	46.7	46.9	45.9
PLT	241	238	298	298	302
MPV	7.8	8.0	8.0	7.8	7.9
PDW	10.7	10.5	11.6	11.4	11.3
PCT	0.25	0.25	0.33	0.32	0.33
PAGE	003/031		OK ESC	DEL	ALL

Figure 3-5

Single data deletion

a) At blood cell analyze window, press FUNC, shift ↑ ↓, select "Data review", press ENTER into Test Result Review window, see figure 3-4

b) Press DEL, OK and ESC will appear.

c) Select "OK" to delete last data; select "ESC" to Test Result Review window.

NOTE:

Be aware that the data once they are deleted can NOT be recovered, please operate with caution.

NOTE:

After all data deletion, one historical data still display at Blood Cell Analyze window, this data can't review at Test Result Review window. When new data stored, this data deleted automatically.

NOTE:

Single data deletion, only can from last one.

Chapter 4 FUNC Introduction

At Blood Cell Analyze window, press FUNC into function menu, see Figure 4-1

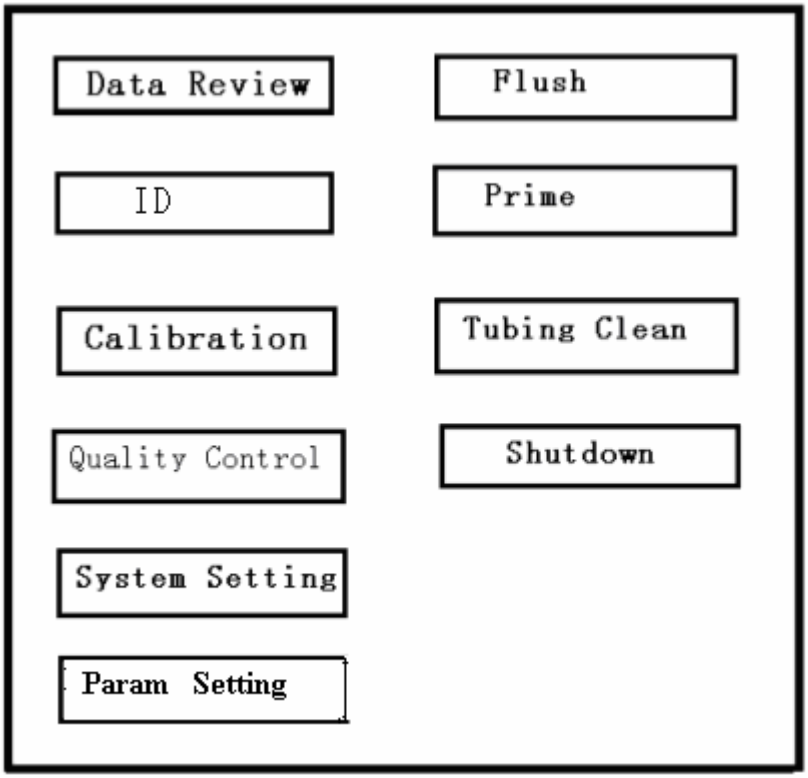


Figure 4-1

NOTE:
Operation introduced in this chapter will change some run action of the instrument, please confirm necessity of this change.

4.1 Data Review

User can review data, parameter and histogram of the tested blood sample; can get test data and histogram by inner recorder or outer printer. If necessary, user can delete selected test parameter or all the parameter, details consult 3.16<Test Result Review>

4.2 ID

User can change ID of next sample at this window, specific as follow:

a) At the window in Figure 4-1, shift ↑ ↓, select "ID", press ENTER, window in Figure 4-2 will appear.

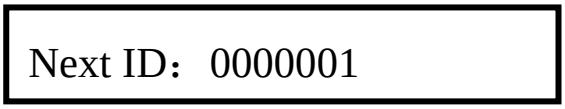


Figure 4-2

b) **Shift ← →， adjust position of cursor, input ID., press ENTER, OK and ESC appear. Select "Ok", ID modification successful, this ID become the ID of next sample; if don't want to change the ID , select ESC back to Blood Cell Analyze window, instrument adds 1 based on current ID as the ID of the next sample.**

NOTE:

Forbid changing blood sample ID into 0.

4.3 Calibration

Specific step consult chapter 6 "Calibration"

4.4 Quality Control

Specific step consult chapter 5 "Quality control"

4.5 System Setting

At window in Figure 4-1, select "System setting", press ENTER, System setting window appears, see Figure 4-3.

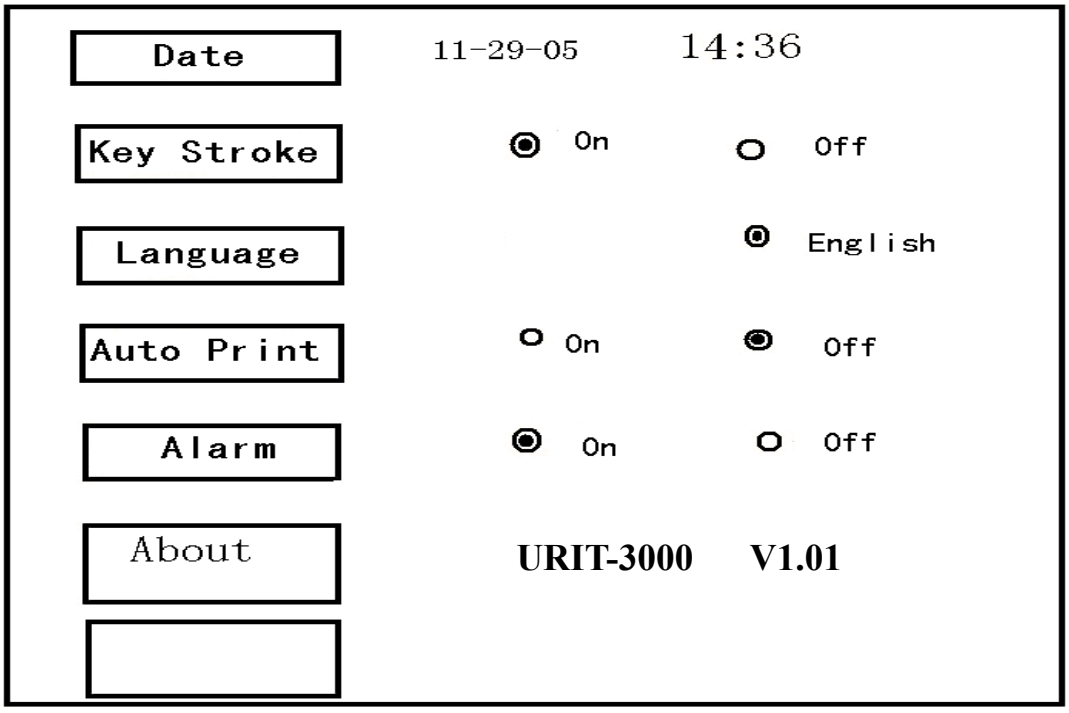


Figure 4-3

At the interface of Figure 4-3, press keyboard ↓, move the cursor to "About", continually press ↓, then it will show the interface of Figure 4-4.

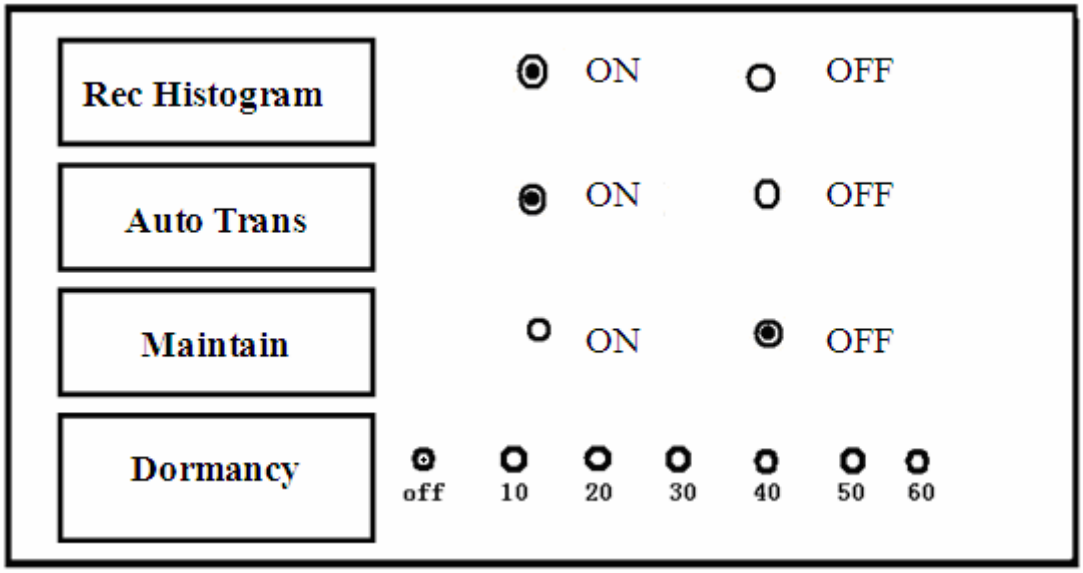


Figure 4-4

4.5.1 Date

User can change the time of instrument. Specific as follow:
a) At System setting window in Figure 4-3, shift ↑ ↓, select Date setting
b) Press ENTER, cursor move to date automatically, format is mm-dd- yy.
c) Press ← → to control position of cursor, by 0-9 input number to change date and time.
d) After changing, press ENTER back to System setting window.

4.5.2 Key Stroke

At System setting window, shift ↑ ↓, select System setting, press ENTER, shift ↑ ↓ to select keystroke, then shift ← → to select ON or OFF, press ENTER
Select ON, press keystroke gives buzz
Select OFF, press keystroke gives no buzz.

4.5.3 Language

The instrument is set in English, Chinese is unavailable.

4.5.4 Auto Print

At System setting window see Figure 4-3, shift ↑ ↓ to select Auto print, press ENTER, and shift ← →to select ON or OFF, press ENTER.
Select ON, after counting, test report will be printed by recorder (printer) automatically.

4.5.5 Alarm

At System setting window see Figure 4-3, shift ↑ ↓ to select Alarm, press ENTER, and shift ← →to select ON or OFF, press ENTER.
Select ON, after counting, when clog, there is letter twinkling hint on top right corner of screen, at the same time, buzzer gives "Di" for alarm.
Select OFF, after counting, when clog; there is only letter twinkling hint on top right corner of screen.

4.5.6 About

URIT-3000 in instrument model, V1.01 is current system version number. Version will change according to requirement.

4.5.7 Rec Histogram

In the interface of Figure 4-4 , shift ↑ ↓ to select Rec Histogram, press ENTER, shift ← → ,select ON or OFF , press ENTER.
Select OFF, recorder only prints out test result not histogram.

4.5.8 Auto Trans

In the interface of Figure 4-4 , shift ↑ ↓ to select Auto trans, press ENTER , shift ← →, select ON or OFF, press ENTER.
Select ON, instrument will transport test result to RS-232 port automatically after finished counting.

4.5.9 Maintain

In the interface of Figure 4-4, shift ↑ ↓ to select Maintain, press ENTER.
Select ON, instrument performs tubing-rinse one time every two hours automatically, "Maintain" will show on the screen, if counting over 25 times in two hours, instrument also performs self-tubing-rinse.

4.5.10 Dormancy

In the interface of Figure 4-4, shift ↑ ↓ to select Dormancy, press ENTER, shift ← →, select relevant time setting , press ENTER.
Instrument enter auto-dormancy status, press any keyboard can quit Dormancy.

4.6 Param setting

Software analyzes system gives 19parameter's upper and lower limit setting of sample test. When test value over this setting range, system will mark with "H" or "L" beside the test result, "H" indicates over parameter setting upper limit,

“L” indicates over parameter setting lower limit.
Details consult Chapter 7.

4.7 Flush

Through force pump, give force to micro-aperture of WBC and RBC probe, eliminate WBC or RBC micro-aperture clog.

4.8 Igloss

Adopt clog function to deal with obstinate clog, outer and inner electrode in measurement unit Produce electricity to eliminate obstinate clog.

4.9 Prime

Prime and rinse to the whole tubing to make the whole tubing full of diluent.

4.10 Tubing Clean

To clean obstinate stem in probe by using detergent, specific as follow:

a) Put probe detergent about 4ml into clean tube.
b) At Blood Cell Analyze window, press FUNC into function menu window.
c) At function menu window, shift ↑ ↓, select Tubing clean, press ENTER, “OK” and “ESC” will appear, see Figure 4-5.

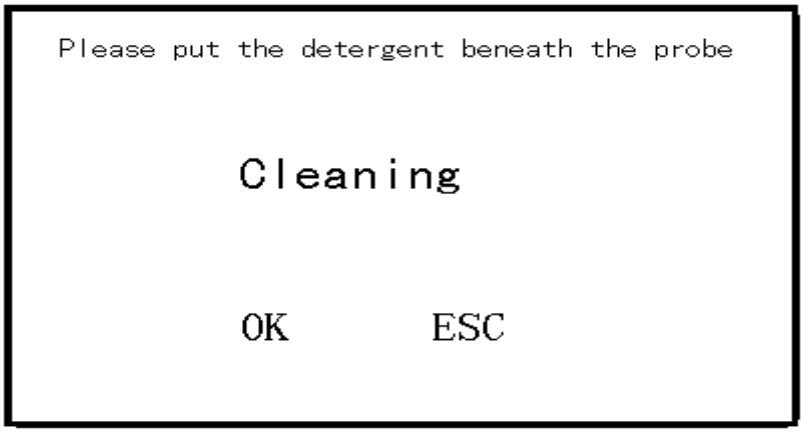


Figure 4-5

d) Put the tube with probe detergent beneath sample probe, shift →, move cursor to “OK”, press ENTER, analyzer inhale probe detergent into WBC and RBC cup separately, then soak for 6 minutes. Then appear schedule bar to show the schedule on screen, number on schedule bar descending with course, see

Figure 4-6. Instrument clean tubing automatically after 6 minutes, schedule bar disappear, back to Blood Cell Analyze window.

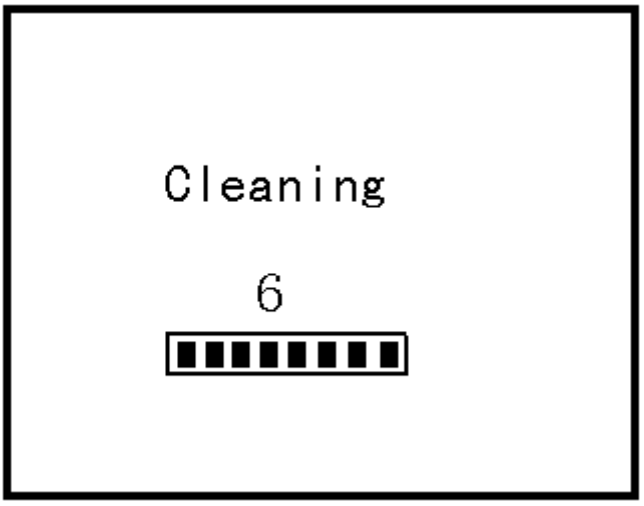


Figure 4-6

c) If want to exit "Tubing clean" program in midway, Can press FUNC when the number on schedule bar descending after 5, "OK" and "ESC" appear. Select "OK", number on schedule bar turn to 1, instrument clean the tubing automatically, after schedule bar disappeared, back to Blood Cell Analyze window; select "ESC", instrument continue soaking the tube.

4. 11 Shutdown

Shutdown procedure is performed after daily operation and before turning the analyzer off. Daily maintenance and tubing-rinse avoid protein aggregation during non-working and keep system clean.
Specific step consult 3.16.

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

NOTE:
Wrong turnoff lead to system data loss easily, cause system-operating failure.

NOTE:
Wrong turnoff or not turnoff, instrument will not Prime and clean to tubing, easily lead to albumen aggradations of blood sample in tubing, cause clog.

Chapter 5 Quality Control

Necessary quality control to the measurement system is required to insure the accuracy for counting and analyzing, as well as duly eliminating the system error. The quality control (QC) reagent produced by manufacture is recommended for quality control in these situations:

a) After daily start-up procedures are completed.
b) After replacing reagent..
c) After calibration.
d) After maintenance, or component replacement.
e) In accordance with the laboratory or clinical QC protocol.

5.1 Control

To ensure accuracy of the results, QC reagent must be handled as follows:
a) Verify the control reagent to make sure storage at low temperature and without leakage.
b) Always shake up the control reagent according to the manufacturer's recommendations.
c) Never use control reagent that is unsealed longer than the period recommended by the manufacturer.
d) Never subject control reagent to excessive heat or vibration.
e) Verify values for the new lot of control reagent by running each level (high, medium, and low) three times, comparing with the values for the last lot no.
WARNING:
Consider all the clinical specimens, controls and calibrators etc, that contain human blood or serum as being potentially infectious, wear standard laboratory clothing, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.

5.2 Edit

The instrument offers three QC levels including nine groups in all to monitor and validate analyzer performance.
The operator should firstly select a group, input reference data provided by the manufacturer and the control limits desired by the customer. 12 parameters can be controlled simultaneously, as well as separately. Quality control can not be run, or only be run for the valid reference parameters if the reference parameters and deviation input are not completed. Different manufacture has different method for mixing and handling. When using and storing quality

control reagent, pay attention to the following:

a) Store the control reagent at recommended temperature. Storage in the central location in the refrigerator, away from the influence of the door.

b) Carefully warm and resuspend the product according to the directions given in the package insert.

c) Check the expiry date and do not use reagent overdue.

Quality control edit procedure is as follows:

a) At Blood Cell Analyze window, press FUNC, shift ↑ ↓, select Quality control, press ENTER into QC window, and see Figure 5-1.

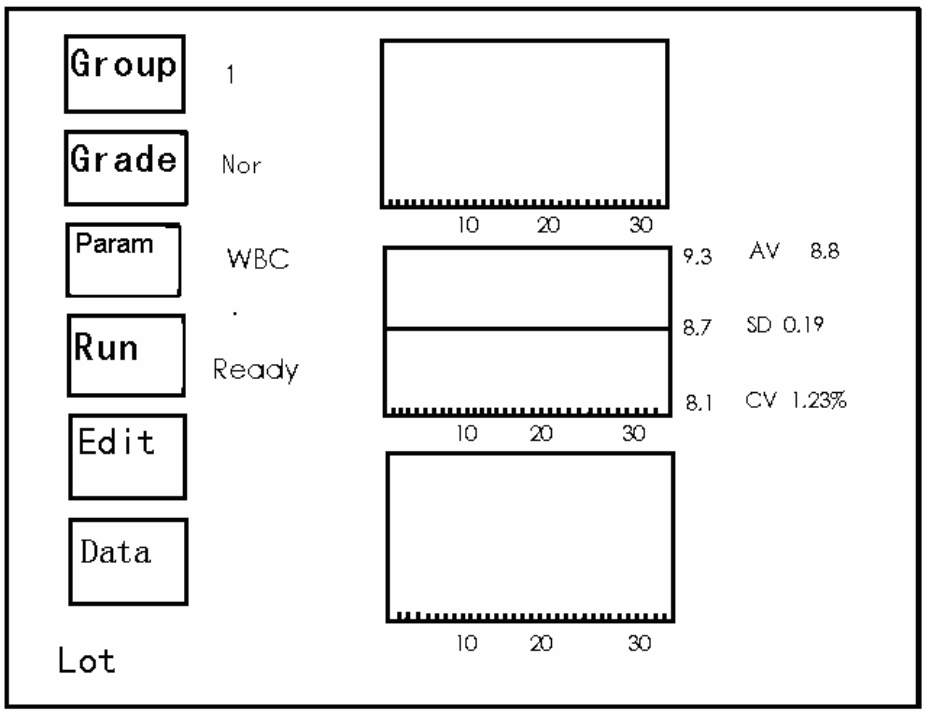


Figure 5-1

b) Select group icon, press ENTER, shift →can choose 1, 2, 3 different group, after confirm group, press ENTER back to Quality Control window.

c) Shift ↑ ↓, cursor move to Grade, press ENTER, press →to select. After selection, press ENTER back to Quality Control window. Each group has three grades: HIGH, NORMAL and LOW.

d) Shift ↑ ↓, cursor move to Edit, press ENTER into QC edit state, see Figure 5-2, cursor locates at lot No., input control lot No. by number key on keyboard.

e) Press→, input cursor will move to Control assay, input control assay by number key on keyboard.

f) Press→, input cursor will move to Limit, input control limit by number key on keyboard.

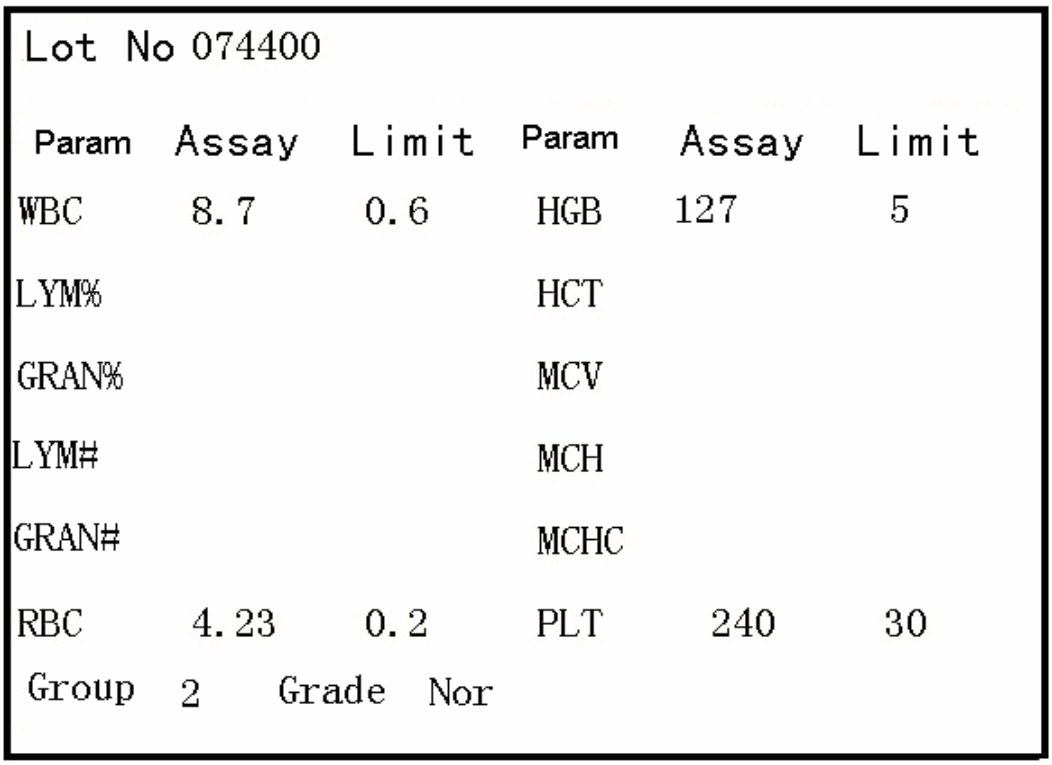


Figure 5-2

g) After edition, press FUNC, "OK" and "ESC" appear, see Figure 5-3, and shift →to select.

h) Back to Quality Control window can do other operation.

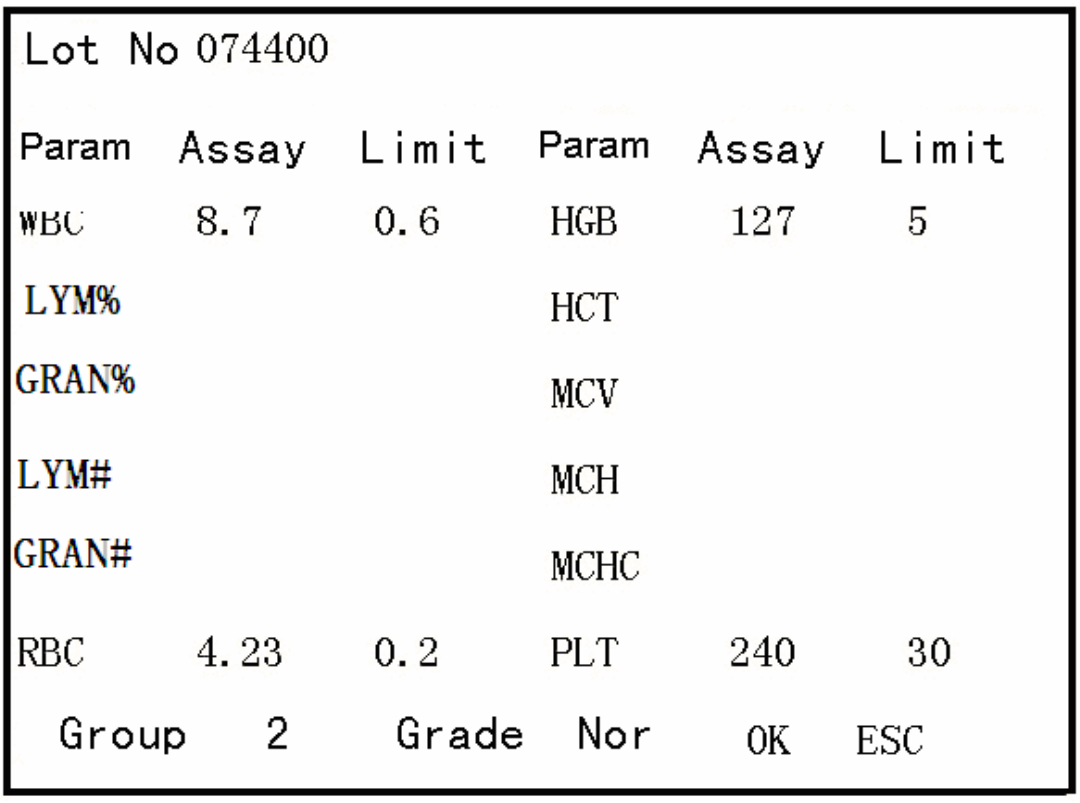


Figure5-3

NOTE:
If the data for one parameter is invalid, the reference value and deviation limits of this parameter will not be displayed after input is completed and need modification, or the quality control will be only applicable to the other valid parameters.

5. 3 Running Controls

The controls are applicable to certain parameter or all of 12 parameters according to actual need after selecting grades and inputting parameters.
It is recommended that the QC be run daily for three levels (High, Medium, and Low) or according to laboratory or clinical requirement.
QC procedure is as follows:
a) At Blood Cell Analyze window, press FUNC, shift ↑ ↓, select Quality Control into
Quality Control window, see Figure 5-1.
b) Shift ↑ ↓to select Group, press ENTER, shift →to confirm corresponding group, and press ENTER, Back to Quality Control window.
c) Shift ↑ ↓to select Grade, press ENTER, shift →to confirm corresponding grade, and press ENTER, Back to Quality Control window.
d) Shift ↑ ↓to select Run, press ENTER, Ready twinkling on screen, see Figure 5-4.

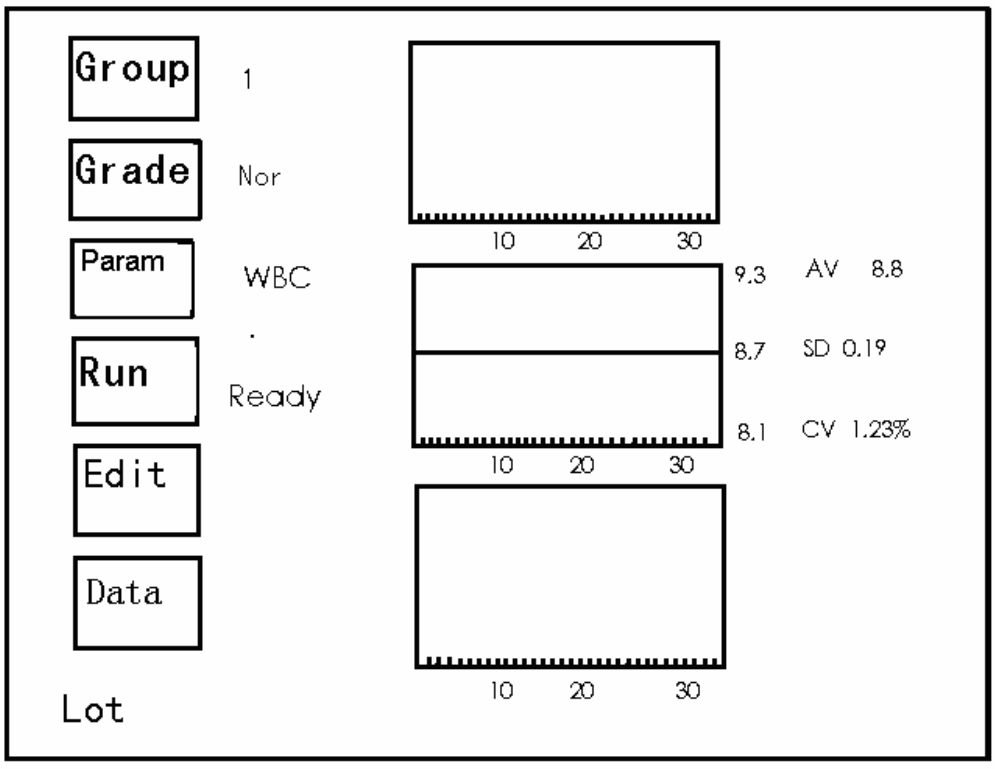


Figure 5-4

e) Put the ready control beneath probe, press RUN button on front panel(in

green color), instrument begin to analyze sample and Run display on screen, see Figure 5-5

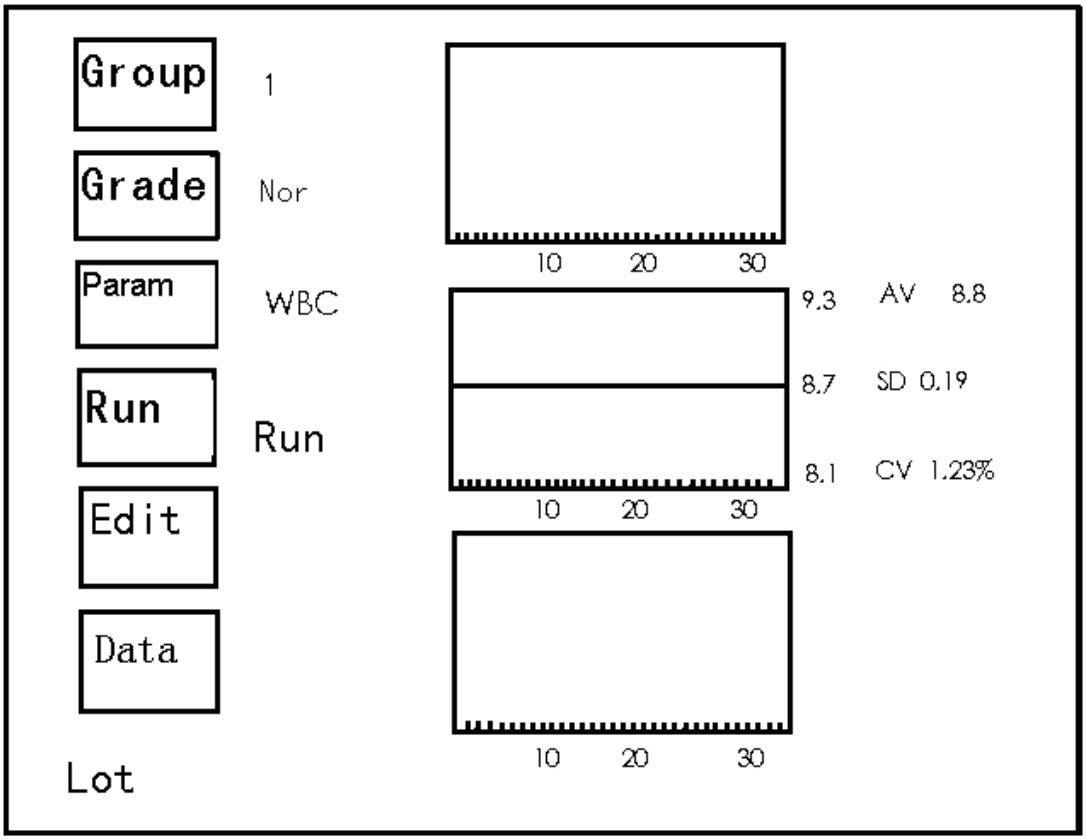


Figure 5-5

f) After analyzing, instrument back to the window in Figure 5-4, press FUNC to Quality Control window.

g) If don't want to counting, can under the condition of step d) (that is Figure 5-4), press FUNC, back to quality control window in Figure 5-1, user can do other operation.

NOTE:

If the number of recording results exceeds 31, hint will appear that the control cannot be continued. Enter into Quality Edit and press Del to delete all of the 31 results, and then QC can be run.

5.4 Quality Control Graphics

According to the QC Graph, the distribution, deviation and trend of the data can be estimated. A typical graph is LEVEY-JENNINGS, which is a unilateral Gauss normal school graph. Two dashed stand for minus and plus deviations respectively, while the midline stands for the average value. The right of the histogram stands for Mean, Diff and Cv, while the left stands for the upper, bottom value, and the median stands for average reference value of the standard deviations (See Figure 5-1). Up to 31 dots can be indicated on

LEVEY-JENNINGS graphics of high, normal and low levels.
Select Data icon can into QC Data window.
Select Edit icon can into QC Edit window.
Select Run icon can into QC Run window.
Press PRINT can print out LEVEY-JENNINGS graphics of current group by outer printer.

5.5 QC Data

5.5.1 QC Data Review

QC data for each measurement will be recorded and classified automatically by the analyzer thus can be reviewed. The accuracy and deviation of the test can be obtained through the comparison among reference value, deviation and QC results. The methods and procedures are as follows:
Press FUNC at Blood Cell Analyze window, shift ↑ ↓ to selects Quality Control into QC window, See Figure 5-1.
Shift ↑ ↓ to select Data, press ENTER, appear Quality Control Data window, see Figure 5-6

ID	000005	000004	000003	000002	000001
Date	050405	050404	050403	050402	050401
Time	08:10	08:10	08:10	08:10	08:10
WBC	8.9	8.8	8.9	8.7	8.7
LYM%	38.5	38.4	37.9	38.0	38.6
MID%	9.8	9.7	9.6	9.9	9.3
GRAN%	51.7	51.5	50.9	51.3	51.3
RBC	4.20	4.25	4.27	4.28	4.24
HGB	127	127	130	125	123
HCT	36.6	36.4	36.1	36.3	36.7
MCV	86.1	86.4	86.3	86.4	86.2
MCH	30.2	30.2	30.5	30.5	30.4
MCHC	351	355	354	358	354
RDW_CV	13.6	13.8	13.2	13.5	13.4
RDW_SD	46.7	46.8	46.4	46.3	46.2
PLT	227	218	230	234	226
MPV	7.9	7.8	8.0	8.1	7.8
PDW	10.7	11.0	10.4	10.9	11.3
PCT	0.32	0.34	0.35	0.32	0.34
PAGE	001/001				

Figure 5-6

Press Print to print Quality Control Data of current group by outer printer.

5.5.2 QC Data Deletion

When the number of QC data reaches to a large quantity, it will take a long time to review the data since there are so many pages. If necessary, all of the stored QC data can be deleted periodically by the customers.

5.5.2.1 Auto Deletion

Instrument will hint Memory full, please backup when data of QC Run reach 31. When next control running, all originally will be deleted automatically, at the same time take new control data as first ID

5.5.2.2 Manual Deletion

QC data deletion is done at QC data review window, divided into all deletion and single deletion, details consult section 3.16.2 Historical data deletion of Chapter 3 “ Installation and Specimen Analysis”.

Chapter 6 Calibration

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

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

MCV, HCT parameters are relative, thus one can be obtained from given value of the other. The analyzer will calibrate only MCV. Usually the manufacturer will give the reference value for MCV, HCT at the same time.
WARING:
Consider all the clinical specimens, controls and calibrators etc, that contain human blood or serum as being potentially infectious, wear standard laboratory clothing, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials.

6.1 Pre-calibration

CAUTION:
Only calibrators recommended by manufacture can be used to accomplish the calibration.
CAUTION:
Follow the recommendations provided by manufacture to store the calibrators.
CAUTION:
Check if the container is broken or cracked before using the calibrator.
CAUTION:
Make sure the calibrators are brought to room temperature and well mixed slowly before use.
CAUTION:
Make sure the calibrators are within the expiry date.
CAUTION:
Make sure the analyzer has no problem before calibration.
CAUTION:
Never apply the test data to laboratory or clinic use unless all parameters are accurately calibrated.

Perform the calibration with recommended commercial calibrators or median controls. Background test must be performed before calibration to confirm that no problem occurs. Evaluate the system's repetition precision, prepare for calibrators, and then determine the calibration value.

6.1.1 Background Test

Consult Section 3.9 of Chapter 3, and ensure no problem is indicated.

6.1.2 Evaluation of Repetition Precision

o ensure accurate calibration, evaluate repetition precision firstly and perform calibration only when parameter's repetition precision is within the limit range.
Methods for calibration are as follows:

a) Select the blood-collection method.
b) Use the calibrators or median controls to continuously measure 6 times, refer to Section 3.13 of Chapter 3.
c) Record the test data for WBC, RBC, HGB, MCV, and PLT. Divide the average value of the parameter by difference between the maximum value and minimum value. If the results are in the limits of Table 6-1, perform calibration.
d) If the test results exceed error range in Table 6-1, take the mean of 6 data as measure mean, if the results still don't comply with the criteria, refer to Chapter 9.

Table 6-1 Measure error requirement

ITEM	ERROR（%）
WBC	≤±4
RBC	≤±3
HGB	≤±3
MCV	≤±3
PLT	≤±8

NOTE:
When whole blood and capillary blood should be used, each of them should be calibrated; the calibration should not be performed until blood-collecting method is selected. Details consult item 1.1.1 of Chapter 1.
CAUTION:
Measurement should be performed under the same blood-collecting method.
CAUTION:
If any malfunction occurs during measurement, the test results are invalid. Repeat the measurement after troubleshooting.

6.2 Calibration Coefficient Modification

a) At Blood Cell Analyze window, press FUNC, shift ↑ ↓ to select Calibration, press ENTER into Calibration window, and see Figure 6-1.

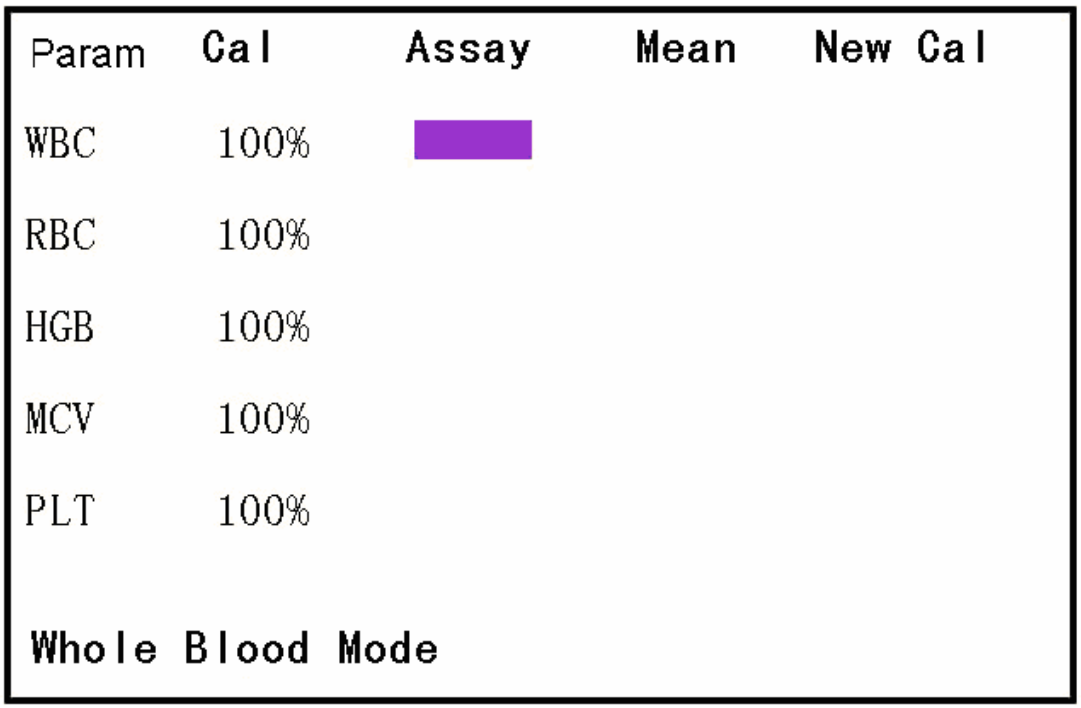


Figure 6-1

b) Input cursor locates at the reference value of WBC; input the reference values of WBC for calibration. Press→, move cursor to mean, input WBC measure mean.

d) Press→, move cursor to RBC reference value, at the same time, instrument work out new calibration coefficient automatically at WBC new calibration position.

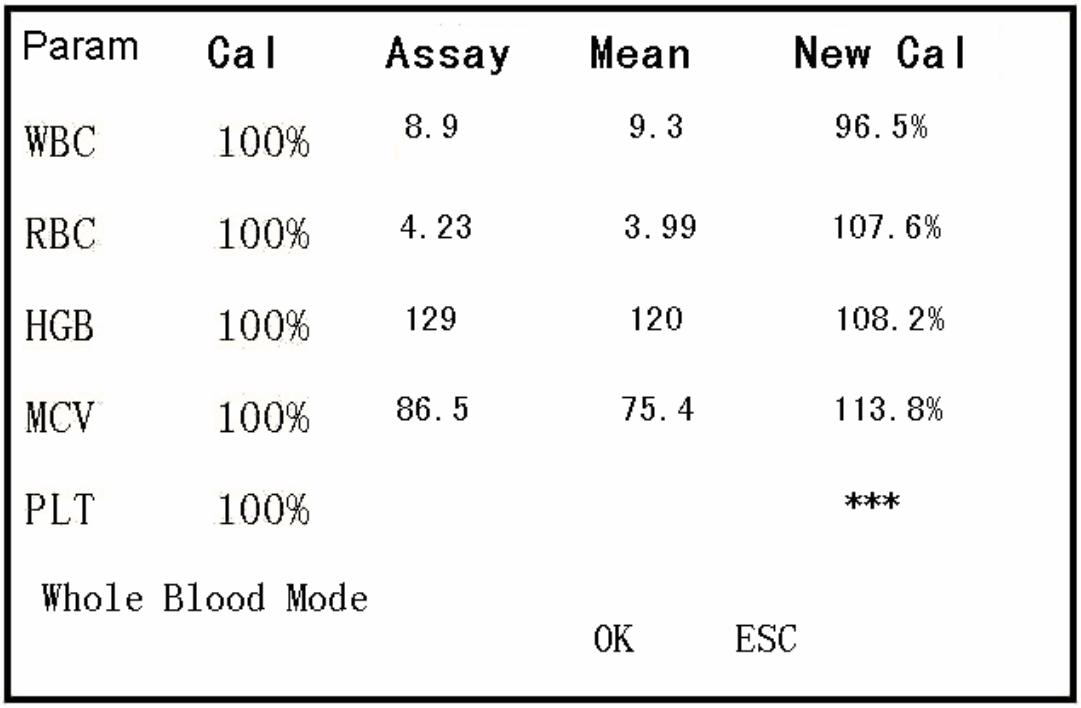


Figure 6-2

d) Consult above method, input calibration value reference value and measure mean of other calibration in turn.

e) Press FUNC after input, OK and ESC will appear, see Figure 6-2. Select ESC to ESC current calibration result, instrument back to Blood Cell Analyze window, select OK, instrument back to Blood Cell Analyze window after store current calibration result.

NOTE:
The calibration coefficient is allowed in the range of 70%~130%, if the test values exceed the limit; the maximum value in the limit range should be selected as new coefficient for calibration.
NOTE:
The analyzer calibrates not only single parameter (WBC, RBC, HGB, MCV and PLT), but also all the parameters.
NOTE:
Pre-calibration and calibration should be performed with the same blood-collecting method.
NOTE:
If any malfunction occurs during measurement, the test results are invalid. Repeat the measurement after troubleshooting.

6.3 Calibration Review

At Blood Cell Analyze window, press FUNC, shift ↑ ↓ to select calibration into Calibration window, press ENTER, see Figure 6-1. Instrument into Review state, can perform follow operation:
Press PRINT to print information under current blood-collect mode by outer printer.
Press FUNC, OK and ESC appear. Select ESC to ESC current calibration result, back to Counting window, select OK, back to Counting window after storing current result.

Chapter 7 Parameter Limit

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

NOTE:

Parameter limit is inner setting of instrument, is the important reference gist for clinic diagnosis.

The shift in parameter limit may cause changes in abnormal indication of hematology index. Please confirm the necessity for changing.

Detail step as follow:

a) **At Blood Cell Analyze window, press FUNC into FUNC menu window.**
b) **Shift ↑ ↓ to select Param setting , press ENTER into Param limit window, see figure 7-1**

Param	Up	Low	Param	Up	Low
WBC	10.0	4.0	MCH	32.0	26.0
LYM%	40.0	20.0	MCHC	360	320
MID%	15.0	1.0	RDW_CV	14.5	11.5
GRAN%	70.0	50.0	RDW_SD	46.0	39.0
LYM#	4.1	0.6	PLT	300	100
MID#	1.8	0.1	MPV	10.4	7.4
GRAN#	7.8	2.0	PDW	14.0	10.0
RBC	5.50	3.50	PCT	0.28	0.10
HGB	150	110	W_TIME	9.0	14.0
HCT	48.0	36.0	R_TIME	9.0	14.0
MCV	99.0	80.0			

Figure 7-1

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

d) Press FUNC to return after modification, OK and ESC appear (see Figure 7-2). Select OK, instrument save modified parameter limit and back to Blood Cell Analyze window; select ESC , instrument not save modified parameter limit and back to Blood Cell Analyze window

Param	Up	Low	Param	Up	Low
WBC	10.0	4.0	MCH	32.0	26.0
LYM%	40.0	20.0	MCHC	360	260
MID%	15.0	1.0	RDW_CV	14.5	11.5
GRAN%	70.0	50.0	RDW_SD	46.0	39.0
LYM#	4.1	0.6	PLT	300	100
MID#	1.8	0.1	MPV	10.4	7.4
GRAN#	7.8	2.0	PDW	14.0	10.0
RBC	5.50	3.50	PCT	0.28	0.10
HGB	150	110	W_TIME	9.0	14.0
HCT	48.0	36.0	R_TIME	9.0	14.0
MCV	99.0	80.0		OK	ESC

e) Press PRINT to print information under current blood-collect mode by outer printer.

Note: After modification, must shift → to store the data.

Chapter 8 Maintenance

Routine care and regular maintenance are essential to keep the best status and precision, to minimize system problems, as well as to prolong the life span. Procedures and instructions for preventive maintenance are discussed in this chapter. More information is available at manufacture Customer Support Centre.
Preventive maintenance should be performed daily, weekly, monthly and yearly. Pertinent maintenance is also included in this Chapter according to actual requirement.
WARNING: Analyzer failure will occur unless a normative maintenance criterion is performed strictly.
WARNING: Wear powder-free gloves when performing the maintenance procedures. If powder-free gloves are not available, rinse the gloves before performing the maintenance procedures. Powder from the gloves may cause analyzer problems.

8.1 Daily Maintenance

8.1.1 Rinse

Instrument will prime automatically to rinse on every startup, the whole process is about 2 minutes.
Instrument will prime automatically once for two hours during running to reduce clog rate, screen will display "Auto maintenance". Instrument also rinses automatically if counting over 25 times within 2 hours.
Also can perform artificial control prime during using the instrument, details as follow:

a) **Press FUNC into FUNC menu window, shift ↑ ↓, and select Prime at FUNC menu window, press ENTER, instrument will prime to rinse whole tubing system.**
b) **Can prime directly if perform eliminate tubing bubble, that is use diluent to rinse.**
c) **Can use probe detergent (main component is Javel water) to eliminate micro-aperture clog and prime, perform Tubing clean.**

NOTE: When system alarm Waste full, indicates waste is full in waste barrel, need to dispose in time.

8.1.2 Shutdown Prime

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

NOTE:
Wrong turnoff lead to system data loss easily, cause system operation failure.
NOTE:
Wrong turnoff or not turnoff, instrument will not prime the tubing, easily lead to albumen aggradations of blood sample in tubing that cause clog.

8.2 Weekly Maintenance

8.2.1 Instrument surface Maintenance

Clean the smudge on the surface, especially the spilt-blood on the sampler, to prevent the protein from deposition, molding or contaminating. Wipe the outside of the sampler with gauze soaked by litmusless detergent before cleaning other parts.
CAUTION:
Never use corrosive acids, alkali or volatile organic solvent (such as acetone, aether and chloroforms) to wipe the outside of the analyzer, but only litmusless cleaner.

8.2.2 Tubing Maintenance

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

a) Take out lytic reagent, diluent and detergent tube from mainframe.
b) At Blood Cell Analyze window, press FUNC into function menu window, shift ↑ ↓, select Prime, then press ENTER.
c) Repeat step b) until top full corner of screen alarm "DILUENT EMPTY", "LYSE EMPTY" and "DETERGENT EMPTY".
d) Take out diluent pipe from diluent barrel, put in detergent container. Connect yellow connector to mainframe. Repeat step b), until DILUENT EMPTY disappears.
e) 20 minutes later, take out the detergent pipe connector out of the mainframe repeat step b).
f) Connect lytic reagent, diluent and detergent tube corresponding position on mainframe, perform Prime three times till "DILUENT EMPTY", "LYSE EMPTY" and "DETERGENT EMPTY" disappears.

NOTE: When perform step f), should wash the tube end before putting into diluent barrel to prevent residue detergent pollute diluent.

8.2.3 Probe Maintenance

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

8.3 Yearly Maintenance

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

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

Prepare the analyzer for 3 months or longer inactivity or shipping as follows:

a) Remove the diluent tubing with a blue connector on the rear panel from the diluent container, and empty the liquid.

b) Remove the lytic reagent tubing with a red connector on the rear panel from the lytic reagent container, and empty the liquid.

c) Remove the detergent tubing with a yellow connector on the rear panel from the detergent container, and empty the liquid.

d) Cap the diluent, lytic reagent and detergent containers and keep them according to instruction. Efficient action should be taken to prevent the materials from deterioration, misapplication and misusing. Reagents should be free from temperature extremes.

e) Hang up the diluent, lytic reagent and detergent tubing.

f) Perform Prime several times until "Lyse empty" "Diluent empty" and "detergent empty" appears on top right corner.

g) Insert the diluent, lytic reagent and detergent tubing into the distilled water.

h) Perform Prime several times until "Lyse empty" "Diluent empty" and "detergent empty" disappears on top right corner.

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

j) Remove the diluent, lytic reagent and detergent tubing and rinse them with distilled water. Dry them in shady place, then pack them in plastic bags.

k) Perform Prime several times until "Lyse empty" "Diluent empty" and "detergent empty" appears on top right corner.

l) At Blood Cell Analyze, press Exit then "Turn off the analyzer now?" appears; press OK to turn off the power.

m) Remove waste tubing, and rinse it with distilled water, then dry it in shady place and pack it in plastic bag.

n) Seal the tubing faucet on the rear panel with the caps of different colors

which are removed in the initial installation.

o) Remove the power cord, and pack it in a plastic bag after cleaning.

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

Chapter 9 Troubleshooting

This Chapter gives instructions for identifying, troubleshooting, and correction of analyzer problems. If malfunction are not solved according to guidance or more information is needed, please contact manufacture Customer Support Centre.

9.1 Troubleshooting Guidance

The Troubleshooting Guidance is designed to assist the operator in identifying and resolving analyzer problems. Instructions are also given for obtaining technical assistance immediately from manufacture Customer Support Centre. The first step in the process is to understand normal analyzer operation and preventive maintenance. Good experience of the analyzer is essential for identifying and resolving operational problems. Logical troubleshooting may be divided into three steps:

1. Problem Identification

2. Problem Isolation

3. Corrective Action

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

Step 2: Problem Isolation means further classifying the problem. Analyzer problems are generally divided into three categories:

1. Hardware component related

2. Software computer programs related

3. Measurement related to sample analysis

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

Step 3: Corrective Action means taking appropriate action to correct the problem. If the operator can correct the problem, with or without technical assistance from manufacture, normal operation can quickly resume.

9.2 Obtaining Technical Assistance

Technical Assistance is obtained by calling the manufacture Customer Support Centre. When assistance is needed, please be prepared to provide the following information for Customer Support Specialists:

1. The analyzer model

2. Serial number and version number

3. Description of the problem and surroundings, including status and operation

4. The lot numbers of the reagents (lytic reagent, diluent and detergent)

5. Data and report of the problem

Familiar problems and disposals are given in this Chapter. The operator can identify the cause according to the warning information and operate according to Troubleshooting Guide.

9.3 Troubleshooting Disposal

Familiar problems and disposals are listed as follows. If the problems can not be corrected, or technical assistance is needed, please calls manufacture Customer Support Centre.

9.3.1 WBC Clog or RBC Clog

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

Correct the problem as follows:

a) Press MUTE to stop the alarm.

b) At Blood Cell Analyze window, press Flush 2 ~3 times.

c） In case above methods still can not settle ,please adapt Igloss solution.

d) If the above-mentioned are not applicable to serious clog, perform the next step.

e) Add approximately 4ml probe cleaner into clean tube.

f) At Blood Cell Analyze window, press FUNC into Function menu, shift ↑ ↓, select Tubing clean

g) Put the tube with probe detergent beneath sample probe (insure sample probe touch bottom lightly, press ENTER.

In case above method still cannot settle, can solve by adding probe detergent manually.

Figure 9-1

a) First perform Tubing clean with probe detergent.

b) As Figure 9-1 shows, open the left-side door.

b) Absorb probe detergent with syringe.

c) After sample adding organ stop running, as figure 9-2 shows, inject 1ml probe detergent into corresponding probe cup which appear clog, probe cup position as figure 9-2 shows.

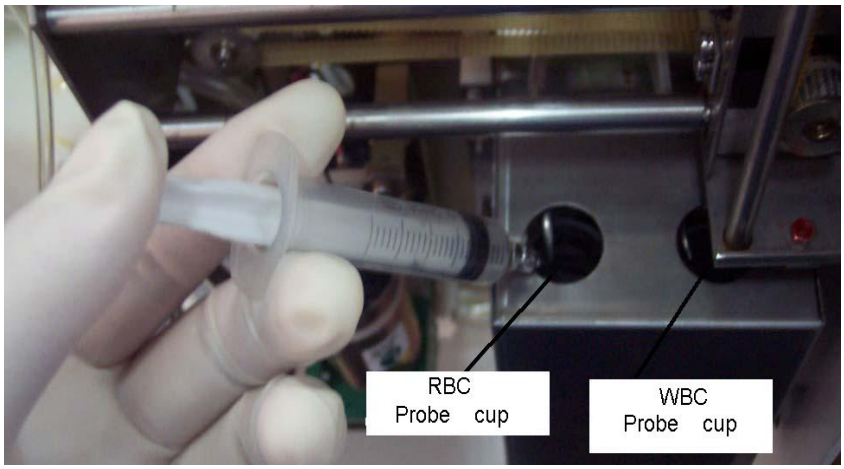


Figure 9-2

If above still cannot settle, please call manufacture Customer Support Center.

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

NOTE: When perform above operation, must do self-protection.

9. 3. 2 Abnormally High WBC

9. 3. 2. 1 Data Large

Probable causes:
· Abnormal sample
· Abnormal lytic reagent
Required action:
a) Replace blood sample (or using medium controls instead) and perform the measurement again.
b) If problem can not be corrected, remove the lye tubing with red connector on rear panel, empty the tubing and hang it up.
c) At Blood Cell Analyze window, press FUNC, shift ↑ ↓, select Prime several times until appear "Lyse empty".
d) Replace lytic reagent.
e) Perform step c) several times until Lyse empty disappear.
If above still cannot settle, please call manufacture Customer Support Center.

9. 3. 2. 2 Data Abnormally Change.

Probable causes:
Filter under probe cup jammed.
Required action:
a) As figure 9-1 shows, open the left-side door.
b) There are two filters under the probe cup at right down corner, as Figure 9-3 shows.

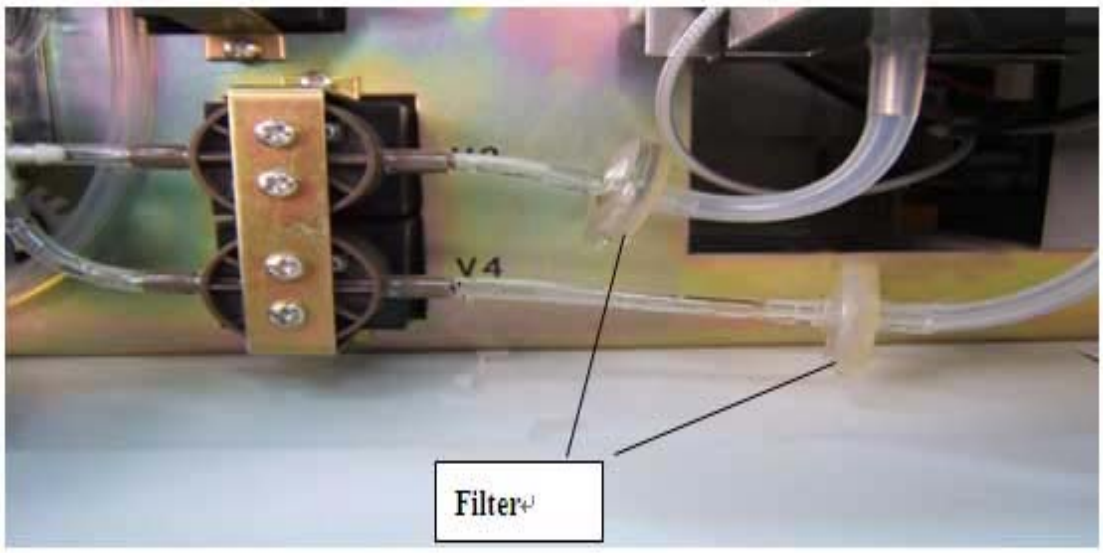


Figure 9-3

c) Sip up the liquid in correlative probe cup with syringe.
d) Open the connection pipeline on two ends of filter, take out filter, examine whether filter exist jam, replacing it in case exist.

If above still cannot settle, please call manufacture Customer Support Center.

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

NOTE: When perform above operation, must do self-protection.

9.3.3 WBC Bubbles or RBC Bubbles

The warning information appears with the air in WBC or RBC tubing.
Required action:
a) Press MUTE, stop the alarm.
b) At Blood Cell Analyze window, press FUNC, shift ↑ ↓ to select Prime, press ENTER
If above still cannot settle, please call manufacture Customer Support Center.

9.3.4 Vacuum Low

The warning information of low vacuum appears if the analyzer can't supply rating negative voltage within the set time.
Required action:
a) Press MUTE to stop the alarm.
b) At Blood Cell Analyze window, press FUNC, shift ↑ ↓ to select Prime, press ENTER
If cannot settle, call manufacture Customer Support Center.

9.3.5 Waste Full

Probable cause:
Waste is full.
Required action:
Empty the waste container.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.6 HGB Lamp Failure

Probable cause: Abnormal sample
Required action:
a) Press MUTE to stop the alarm.
b) Replace sample (or using medium controls instead), and perform the measurement again.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.7 Diluent Empty

Probable cause:
No diluent
Diluent draw-out pump cannot establish negative pressure.
Required action:
a) Replacing diluent
b) At Blood Cell Analyze window, shift ↑ ↓ to select Prime, press ENTER.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.8 Lyse Empty

Probable cause:
No lytic reagent
Lytic reagent sensor is dirty
Correlative pipeline is conglutination together due to long-playing extrusion.
Required action:
a) Press MUTE to stop the alarm.
b) Replacing the lytic reagent
c) At Blood Cell Analyze window, shift ↑ ↓ to select Prime, press ENTER.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.9 Detergent Empty

Probable cause: No detergent.
Required action:
a) Replace detergent
b) At Blood Cell Analyze window, shift ↑ ↓ to select Prime, and then ENTER.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.10 Time Error

Probable cause: Wrong setting of system setting
Required action:
a) Press MUTE to stop the alarm.
b) At Blood Cell Analyze window, shift ↑ ↓ to select System Setting, shift ↑ ↓ to select Date
c) Press ENTER, cursor moves to Date, format is mm-dd-yy.
d) Press → ←to control cursor; change into current time by input 0-9.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.11 Recorder NO Paper

Probable cause: No recorder paper left
Required action:

a) Gently press the recorder cover and open it.
b) Insert the paper into the feed-slot with printing-side against the thermal head.
c) Pull the paper in the other side of the printer, and make it straight.
d) Close the cover.
If above still cannot settle, please call manufacture Customer Support Center.
WARNING:
Unqualified recorder paper will lead to recorder failure, bad appearance or thermal head damage.
CAUTION:
Gently replace the paper to avoid impacting the thermal head.
CAUTION:
Don NOT open the recorder cover but for paper replacement or problem correction.

9.3.12 Recorder Temp Over

Probable cause: Thermal head is overheated.
Required action:
Intermit the recorder.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.13 Recorder Head Error

Probable cause: Thermal head out of place.
Required action:
Pull the switch on the left spindle downwards.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.14 Recorder Error

Probable cause: No recorder
Required action:
Please call manufacture Customer Support Center.

9.3.15 Printer Off-line

Probable cause: Connection cable between printer and host computer is loose or install printer without following the correct step.
Required action: Reinsert connection cable, following the correct installation step.
If above still cannot settle, please call manufacture Customer Support Center.

9.3.16 Printer Paper Out

Probable cause: Printer no paper or install printer without following the correct step.
Required action:
Install print paper following the method offer in instruction; consult Chapter 3.6 for correct printer installation step.
If above still cannot settle, please call manufacture Customer Support Center.

Chapter 10 Precautions, Limitations and Hazards

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

10.1 Limitations

a) The instrument is designed for in vitro diagnostic use.
b) Any operation, shipment, installation or maintenance to the analyzer must strictly follow the contents outlined in this manual, or if any problems derived from that, manufacture will not offer free warranty.
c) Manufacture has designed the instrument system components for optimal performance. Substitution for reagents, controls and calibrators and components recommended by other companies may adversely affect the performance of the analyzer or cause incidents, thus lose the free warranty.
d) Any repairing must be permitted and any accessory replacement must be specified by manufacture, if any problems derived from that, manufacture will not offer free warranty.
e) Follow the recommended maintenance schedules and procedures as outlined in Chapter 8. Any incompliance will shorten the life span and affect the test results, or cause incidents, thus lose the free warranty.

10.2 Location Limitations

a) Manufacture authorized Engineer must perform the initial installation.
b) Place the analyzer on a stable, level surface. Locate the system
· Away from direct sunlight,
· Away from path of a cooled or heated air outlet with temperature extremes
·Away from drying ovens, centrifuges, x-ray equipment, copiers or ultrasonic cleaner.
c) Place the reagent containers on the same level as the analyzer.
d) Adequate space should be provided around the analyzer. 40cm of space from the surrounding objects is needed for proper ventilation, and $2m^2$ space is needed for the analyzer and the reagent. Adequate space should be provided around the analyzer to perform necessary maintenance procedures.
e) Dust affects function and test result of instrument greatly, hospital should settle this problem before using.
f) Working voltage, temperature, humidity requirement consult section 1.12 《Storage and using environment》 of Chapter 1.12.

g) **Before operating the analyzer for the initial measurement, verify that each reagent tuning is connected to the appropriate inlet and reagent container. Make sure the outlet tubing is not twisted and the waste tubing is connected to the appropriate outlet and routed to a suitable waste container or drain.**
h) **Do not disconnect any electrical connection while the power is ON. Verify the analyzer is well connected with the ground to prevent electrical interfere and ensure the safety.**

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

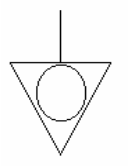
10.3 Safety Precautions and Infection Control

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

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

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

Appendix 1：Symbol note



Equipotential

Note: Consult documents along with instrument

Watch out electro-shock danger

Consult Operating Instructions

For In Vitro Diagnostic Instrument