Operation Manual

HMT-70P

Auto Hematology Analyzer

Manufacturer

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Authorized Representative

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NOTE

1) Carefully read this manual before first operating the analyzer.
2) Inspect the electrical requirements of the analyzer before power on, and properly connect the grounding wire.
3) Turn off the power to the analyzer and disconnect the power cord if the analyzer is idle for a long time.
4) Do not run the analyzer if it's in an abnormal or damaged condition.
5) There is potential biohazard of the reagents and samples; operator should follow proper biosafety practices. Dispose of waste reagent and sample in accordance with local, national regulations.

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Copyright and Declaration

Declaration:

All contents in this manual were strictly compiled according to related laws and regulations in local, as well as the specific condition of HMT-70P Automated Hematology Analyzer, covering all the updated information before printing. Avecon Healthcare Pvt. Ltd. is fully responsible for the revision and explanation of the manual, and reserves 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 strictly in operation. In no event should Avecon Healthcare Pvt. Ltd. be responsible for failures, errors and other liabilities resulting from user's noncompliance with the procedures and precautions outlined here in.

Limited Responsibility for Quality Warranty:

The manual for HMT-70P Automated Hematology Analyzer, defines the rights and obligations between the manufacturer and the customers about the responsibility for quality warranty and after-sales service, also the related agreements on commencement and termination.

Avecon warrants the HMT-70P sold by the Avecon 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 instrument service life is 10 years.

Avecon assumes no liability in the following situations even during the period warranty:

1) Failure due to abuse the instrument or neglect the maintenance.
2) Use reagents and accessories other than manufactured or recommended by Avecon.
3) Failure due to the operation which is not under the instructions described in the manual.
4) Replace accessories which are not specified by Avecon. Maintain or repair the analyzer by a service agent who is not approved or authorized by Avecon.
5) Components have been dismounted, stretched or readjusted.

CAUTION:

THE ANALYZER IS FOR PROFESSIONAL AND PRESCRIPTION USE ONLY.

Technical service and troubleshooting are provided by the Service Department of Avecon. Professional technician and sale representative will be sent to offer you timely service when necessary.

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 manual uses the following warning conventions:

WARNING: Denotes a hazard which, if not avoided, could result in moderate to serious injury.

CAUTION: Denotes potential hazards that could result in a minor injury, also used for conditions or activities which could interfere with proper function of the analyzer.

NOTE: Denotes special operator/service information or standard practices.

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

Declaration

- HMT-70P complies with the emission and immunity requirements of IEC 61326-1 and IEC 61326-2-6.
- This instrument is designed and tested according to Class B equipment in IEC/EN 55011.
- Please make electromagnetic environmental assessment before using it.
- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

NOTE

- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
- It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

Chapter 1 System Description

1.1 Overview

The HMT-70P is a multi-parameter, automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories, to analyze the human blood cells, which provide the necessary reference to clinical diagnosis.

1.1.1 Function

The HMT-70P uses Coulter electrical impedance and colorimetry methods to test the parameters of WBC, RBC, PLT and HGB, does three differentials of WBC and provides the histogram information.

1.1.2 Intended Use

The HMT-70P is appropriate to the qualitative and quantitative analysis of the visible components in human beings blood.

1.1.3 Front Panel

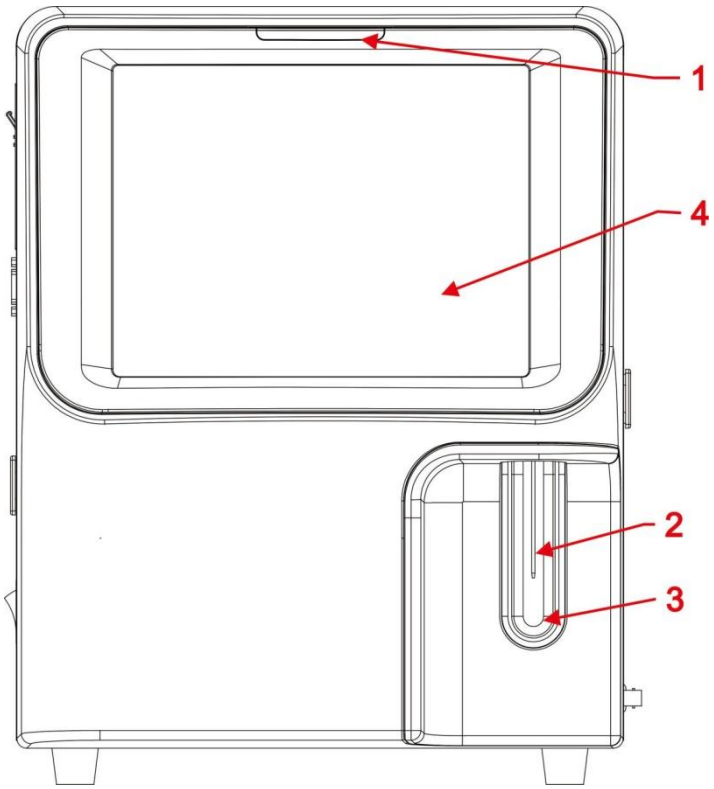

Figure1-1

1. Status Indicators

Run Indicator: Indicator light turns orange, denotes that the analyzer is running a sample or Performing related operations.

Standby Indicator: Indicator light turns green,denotes that the analyzer is ready to run a sample.

Alarm Indicator: Indicator light turns red, denotes that the analyzer has a fault condition.

2. Aspiration Probe

Aspirate samples.

3. RUN Key

Press the RUN key to startup the aspiration probe and then analyze specimen only when the screens of main menu and Quality Control are displayed. At other screens, the RUN key is invalid.

4. Touch Screen

10.4-inch color LCD. The screen is divided into 7 areas as showing in Figure 1-2：

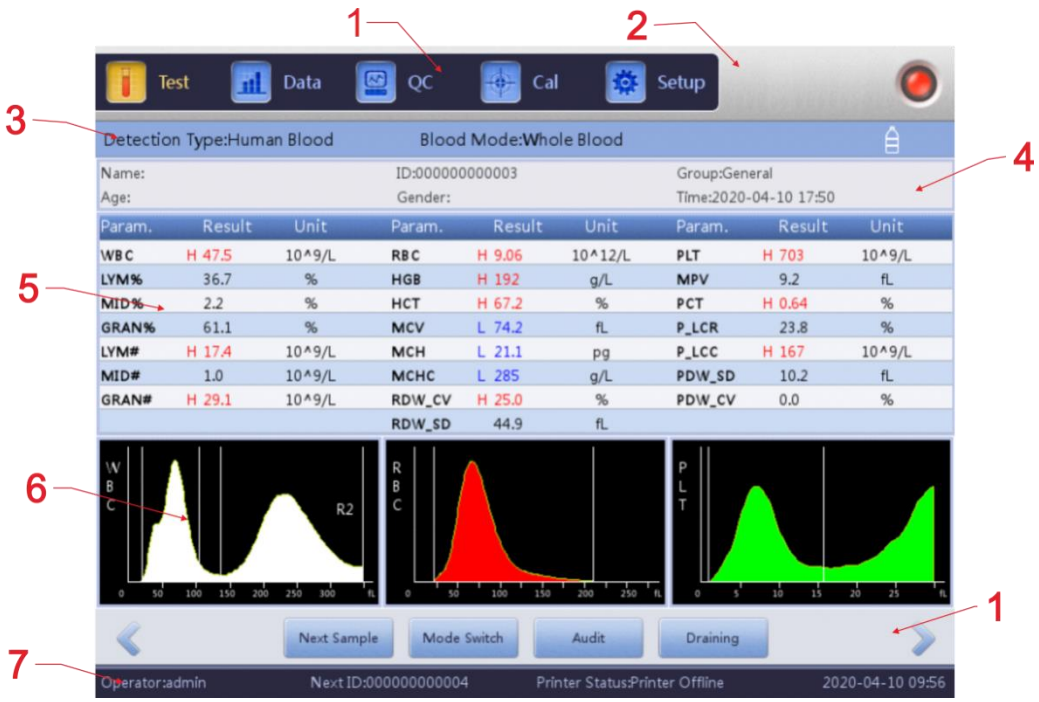

Figure 1-2

（1）Function Buttons Area

Display function buttons. There are three sets of function buttons.

The first set. See Figure 1-3:

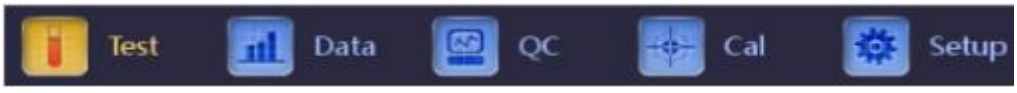

Figure 1-3

Test: Display the main interface.

Data: Enter data storage interface, and query sample results:

QC：Enter the QC interface to run quality control operation.

Cal：Enter the calibration interface to run calibration operation.

Setup：Enter the setup interface to set system parameters.

The second set. See Figure 1-4:

Figure 1-1

Next sample:new sample SN and edit it

Mode switch: switch the test mode to whole blood mode or diluent mode.

Audit: audit the sample

Draining：drain diluent from sample probe for diluent mode mainly.

The third set. See Figure 1-5:

Click or to enter the third set menu. See Figure 1-5:

Figure 1-5

Pre-record: to see the last record

Next record: to see the next record. If the current record is the last one, it shows gray.

Audit : audit the sample

Edit Result: modify sample results

Print: print the sample results

Transmit: transmit sample data

（2）Fault Prompt Area

Prompt the fault system information.

（3）Analysis Mode of Blood Sample Area

Select and indicate the system running state: whole blood sampling mode , diluent or peripheral blood mode.

（4）Patients' Information Area

Display the information of patient' sample.

（5）Parameter Information Display Area

Display each parameter results.

（6）Graphic Display Area

Display the histogram of WBC, RBC and PLT.

（7）Status Area

Display the current time, date, operator, next serial number and printer status.

1.1.4 Side Panel

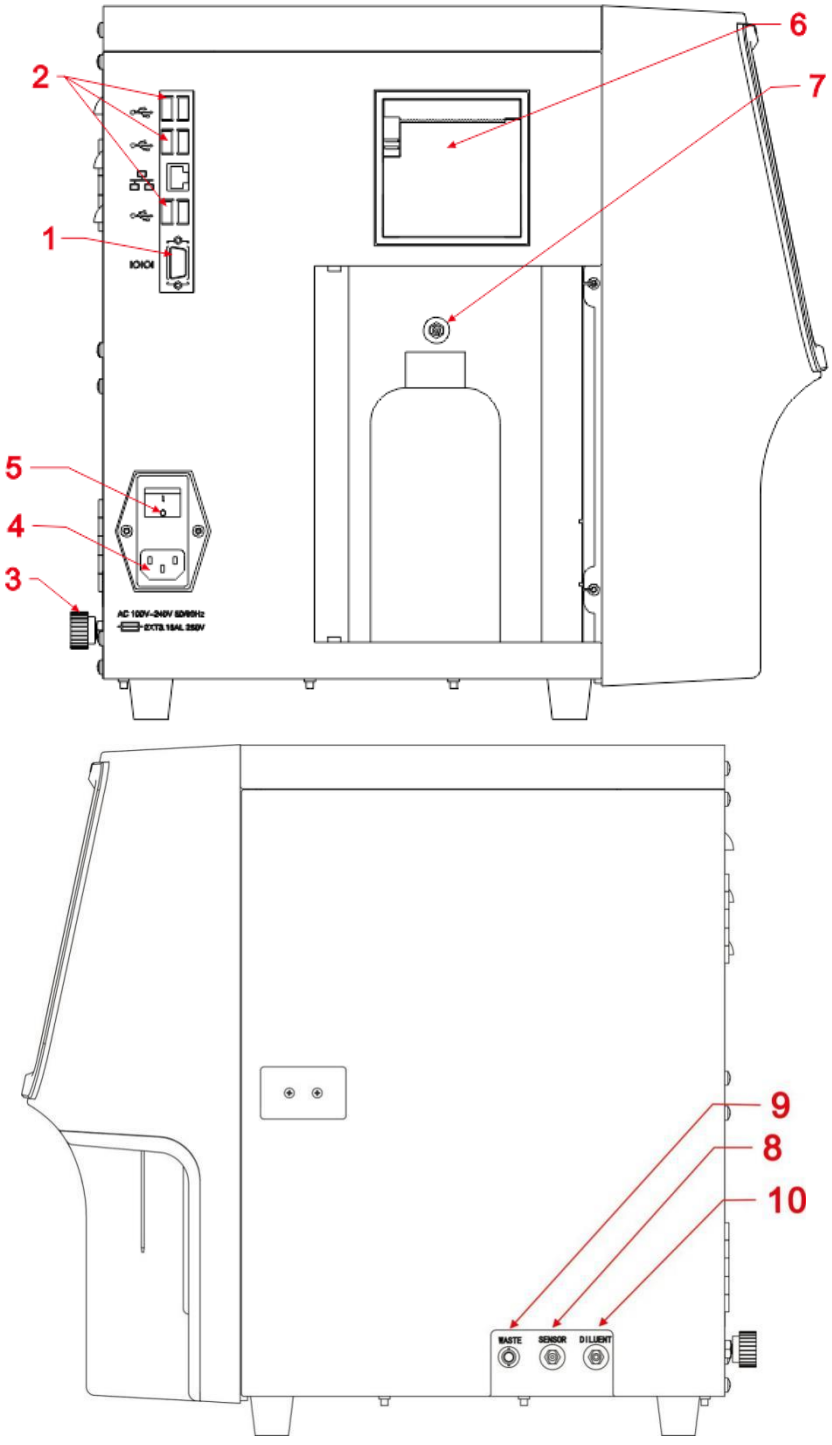

Figure 1-7

1. COM

Connect to the standard RS-232 network.

2. USB Port

Connect to USB equipment.

3. Grounding Terminal

It's used to ground the analyzer.

4. Power Receptacle

Connect to the main power cord to the analyzer.

5. Power Switch

Turn the power supply on or off.

6. Recorder

Print the test result.

7. LYSE

Lyse port connects to the lyse inlet tube.

8. SENSOR

Connect to the waste sensor.

9. WASTE

Waste port connects to the waste outlet tube.

10. DILUENT

Diluent port connects to the diluent inlet tube.

1.2 Parameters

The analyzer automatically analyses the sample data and displays the histogram of WBC (3 part differential count) , RBC and PCT.

Table 1-1

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（or g/dL）
HCT	Hematocrit (relative volume of erythrocytes)	%
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular Hemoglobin	pg
MCHC	Mean Corpuscular	g/L（or g/dL）

	Hemoglobin Concentration	
RDW_CV	Red Blood Cell Distribution Width repeat precision	%
RDW_SD	Red Blood Cell Distribution Width STDEV	fL
PLT	Platelet Count	10^9cells/L
MPV	Mean Platelet Volume	fL
PDW_CV	Platelet Distribution Width repeat precision	%
PDW_SD	Platelet Distribution Width STDEV	fL
PCT	Plateletcrit	%
P_LCR	Large Platelet Ratio	%
P_LCC	Large Platelet	10^9cells/L

1.3 Structure

The analyzer consists of flow system, electrical system, display etc.

1.3.1 Flow System

The flow system is composed of solenoid valves, vacuum pump, plastic tube.
Solenoid Valve---These contact two-way or three-way solenoid valves control the flow of reagent.
Vacuum Pump---Pump the waste generated in the processing out to the analyzer, and produce negative pressure.
Plastic Tube---Reagent and waste flow in the plastic tube.
Vacuum Chamber---Generate negative pressure and play the role of temporary waste reservoir. It can also generate positive pressure when flushing.

1.3.2 Electrical System

1.3.2.1 A/D and Central Control Board

The central control board is the control center of analyzer. It controls the following parts.

- All the valves open and close, reagent aspiration, rinse and waste discharge.
- Run force pump and vacuum pump to offer power to mix reagent,
- Eliminate clogs, aspirate and discharge reagents.

- Control step motors to aspirate sample and reagent.
- Control the A/D conversion of WBC, RBC/PLT and HGB; provide previous service for the computer's data processing.
- Check all the optical and electrical switch movements.

1.3.2.2 WBC/RBC/PLT Metering Assembly

WBC Metering Assembly is composed of signal collection board, electrodes, micro-aperture sensor and flow system.

- Signals Collection Board --- It provides electrodes constant current, amplifies and deals with the collected pulse signal for mainboard.
- Electrode --- There are two electrodes in sample cup, one inner electrode located in front chamber, and one outer electrode located in back chamber. Both electrodes are submerged in the conductive liquid, creating an electrical pathway through the micro-aperture.
- Micro-aperture Sensor --- Micro-aperture sensor is mounted on the front of the sample cup. The diameter of WBC and RBC/PLT metering assembly is 100μm and 68μm respectively.
- Flow System --- The flow system uses negative pressure to aspirate diluent and sample from each container into metering tube, and discharge waste at the end of the processing. There is a lyse adding and mixing unit in front of the sample cup. The control board controls the step motor. When testing the WBC, the lyse will be added into the sample cup, and then the vacuum pump will generate compressed gas to mix the samples.

1.3.3 Display

HMT-70P uses a 10.4-inch color LCD which displays 21 parameters (with 3 histograms).

1.4 Accessories

The accessories of the analyzer include power cord, grounding cord, printer (optional) etc., and printer should be supplied or authorized by Avecon.

1.5 Sample Volume

Whole Blood Mode:	Whole Blood (Venous Blood)	8.5 μl
Pre-diluent Peripheral Blood Mode:	Peripheral Blood	20 μl

1.6 Reagents Volume for Single Sample

Diluent: 25mL

Lyse: 0.4mL

NOTE: Reagent consumption is various according to the software version.

1.7 Test Speed

HMT-70P is able to process 70 samples per hour.

1.8 Storage

HMT-70P contains a memorizer which can store more than 1,000,000 samples data.

1.9 Background

WBC≤0.2×10^9/L；RBC≤0.02×10^{12}/L；HGB≤1g/L；PLT≤10×10^9/L.

1.10 Carryover

WBC≤0.5%；RBC≤0.5%；HGB≤0.6%；PLT≤1.0%.

1.11 Accuracy

The accuracy of analyzer should be complied with Table 1-2.

Table 1-2

Parameter	Acceptable Limits（%）	Accuracy Range
WBC	≤±8.0%	3.5×109/L～9.5×109/L
RBC	≤±4.0%	3.8×1012/L～5.8×1012/L
HGB	≤±4.0%	115g/L～175g/L
MCV	≤±3.0%	80fL～100fL
HCT	≤±5.0%	35%～50%
PLT	≤±10.0%	125×109/L～350×109/L

1.12 Precision

The precision of analyzer should be complied with Table 1-3.

Table 1-3

Parameter	Acceptable Limits（CV/%）	Precision Range
WBC	≤3.5%	3.5×10^9/L～6.9×10^9/L

	≤2.0%	7.0×10^9 /L～15.0×10^9 /L
RBC	≤1.5%	3.00×10^{12}/L ~6.00×10^{12}/L
HGB	≤1.5%	100 g/L ~180g/L
HCT	≤2.0%	35%~50%
MCV	≤1.0%	76fL ~110fL
PLT	≤5.0%	100×10^9 /L～149×10^9 /L
	≤4.0%	150×10^9 /L～500×10^9 /L

1.13 Linearity

The linearity of analyzer should be conformed to Table 1-4.

Table 1-4

Parameter	Linearity Range	Acceptable Limits
WBC	0×10^9/L~10.0×10^9/L	≤±0.3×10^9/L
	10.1×10^9/L ~99.9×10^9/L	≤±5%
RBC	0×10^{12}/L ~1.00×10^{12}/L	≤±0.05×10^{12}/ L
	1.01×10^{12}/L ~9.99×10^{12}/L	≤±5%
HGB	0 g/L ~70 g/L	≤±2g/L
	71 g/L ~300 g/L	≤±2%
PLT	0×10^9/L ~100×10^9/L	≤±10×10^9/L
	101×10^9/L ~999×10^9/L	≤±10%
HCT	0%～67%	±4%(HCT) or ±6%

1.14 Transport and Storage Specifications

a) Temperature: -10℃~55℃
b) Relative Humidity: 10%～93%
c) Barometric: 50kPa~106kPa

1.15 Environnement Requirement

a) Temperature: 10℃~35℃
b) Relative Humidity: 20%～85%
c) Barometric: 60kPa~106kPa

1.16 Electrical Requirement

Power Supply: AC 100V～240V
Frequency: 50/60Hz
Power: 130VA-180VA

Fuse: 250V/3.15A

1.17 Reagent

The reagent is formulated specifically for the HMT-70P flow systems in order to provide optimal system performance. Use of reagents other than those specified in this manual is not recommended as analyzer performance can be affected. Each HMT-70P is checked at the factory using the specified reagents and all performance claims were generated using these reagents. Thus non-Avecon reagents will lead to defects in the performance of the analyzer and serious mistakes, even accidents.

Reagents must be stored at room temperature to ensure optimal performance. All reagents should be protected from direct sunlight, extreme heat, and freezing during storage. Temperatures below 0℃ may cause reagent layering that changes the tonicity and conductivity of the reagents.

The reagent inlet tubes have a cap attached that minimizes evaporation and contamination during use. However, reagent quality may deteriorate with time. Therefore, use all reagents within the dating period.

1.17.1 Diluent

Diluent is a kind of reliable isotonic diluent to meet the requirements as follows:
a) Dilute WBC, RBC, PLT, HGB.
b) Keep the shape of cells during test process.
c) Offer appropriate background value.
d) Clean WBC and RBC micro-aperture and tubes.

1.17.2 Lyse

Lyse is a new reagent without NaN_3 complex and cyanide.It meets the requirements as follows:

a) Dissolve RBC instantly with minimum ground substance complex.
b) Transform the membrane of the WBC to diffuse the cytoplasm, and then WBC shrinks making membrane-bound nucleus. As a result, WBC is present in granular shape.
c) Transform the hemoglobin to the hemo-compound which is suitable for the measurement in the condition of 540nm wavelength.
d) Avoid scyanide’s serious pollution to the human body and the environment.

1.17.3 Probe Detergent

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

1.17.4 Note of Reagent Use

1) Using supporting reagents

Appropriate reagent is necessary for normal operation, daily maintenance and accurate results. The reagent used must match with analyzer model. The reasons are as follows:

a) Impedance method is to get the data according to cell pulse size and setting threshold value.
b) Cell pulse size is related to type, concentration and adding amount of lyse as well as hemolysis time.
c) Cell pulse size is related to osmotic pressure of diluents, ion strength and conductivity.
d) Cell pulse size is related to valve voltage, mesh current and pulse gain.

2) Please operate under professional ‘s instruction.
3) Avoid contacting with skin and eyes. If does, rinse with water and seek medical advice immediately.
4) Avoid inhaling reagent gas.

1.17.5 Reagent Storage

1) Please store in a cool place.
2) Seal the cap of the container to avoid evaporation and contamination.
3) Avoid freeze.
4) Reagent should be use within 60 days after open, if not, dispose as waste.
5) Please refer to package or label for model, batch number and date of manufacture.

Chapter 2 Principles of Operation

The principles of operation of HMT-70P automated hematology analyzer will be discussed in this chapter. The two independent measurement methods used in the analyzer are:

1) The electrical impedance method for determining the quantity and volume of blood cell.
2) The colorimetric method for determining the content of hemoglobin.

2.1 Test Principles

The test is split into blood cell counting, volume measurement and HGB measurement.

2.1.1 Electrical Impedance Principle for blood cells amount and volume metering

The analyzer uses the traditional electrical impedance for the blood cells testing and counting. As shown in Figure 2-1, electric liquid (mainly diluent) provides constant current source for electrode to help the circuit form a stable impedance loop. When cells pass through the aperture, the electric liquid is substituted by cells, and the resistance of loop changes to produce electrical pulses. As different volumes of cells passing through the aperture, different electrical pulses amplitude is generated. The number and size of cells are determined according to the number and amplitude of electrical pulses.

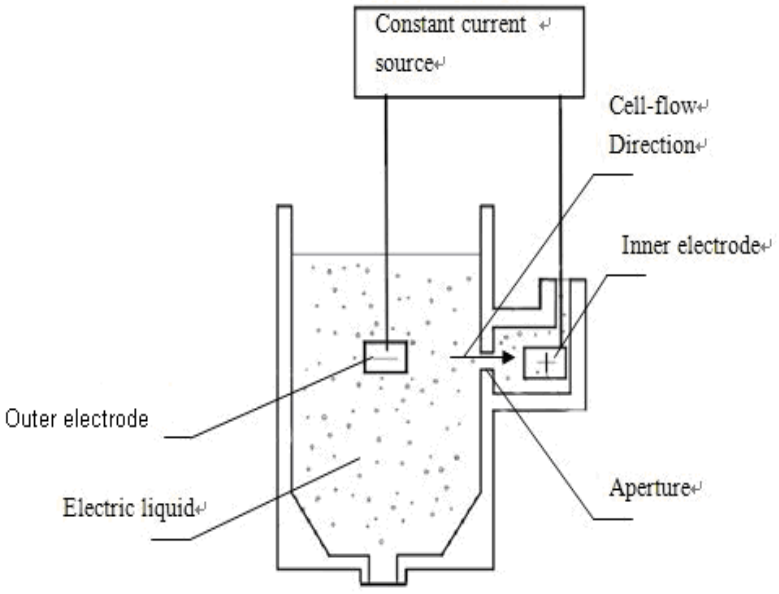

Figure 2-1

The number of pulses corresponds to the number of cells pass through the pores, the pulse amplitude corresponds to the volume of the cells, so the analyzer can count and classify the cells according to size of the cells. The analyzer automatically divides the cells into RBC, WBC, PLT and other groups in accordance with pre-set volume classification procedure.

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

According to the volume, WBCs handled by lyse can be subdivided into three categories: Lymphocyte (LYM), Monocyte (MID) and Granulocyte (GRAN).

LYM	35—98	fL
MID	99—135	fL
GRAN	136—350	fL

2.1.2 Colorimetry Principle for HGB Metering

Add lyse into the diluted sample, and then RBC will dissolve and release hemoglobin. Then the hemoglobin combines with lyse to form cyan hemoglobin. Measure the transmission light intensity of this compound in sample cup through the monochromatic light of 540nm wavelength and then compare it with the result in blank state to get the hemoglobin concentration (blank state refers to the state that only has diluent in sample cup).

2.2 Reagents Function

In HMT-70P, counting system has a high sensitivity of the cell volume. Cells which are suspended in conducting liquid should avoid physical condense and adhesion. Control the osmotic pressure of conducting liquid (mainly diluent) and keep the structure of cells so as to minimize the volume change. Lyse can dissolve the RBC membrane fleetly and keep the structure of WBC so that the instrument can count and classify cells.

2.3 Calculation of Parameters

All parameters of blood sample are expressed in three ways:

1) parameters generated by analyzer directly: WBC，RBC，PLT，HGB ，MCV
2) parameters generated by histograms: LYM%，MID%，GRAN%，HCT，RDW_CV，RDW_SD，MPV，PDW_CV，PDW_SD，P_LCR，P_LCC
3) parameters derived from certain formulas: LYM#，MID#，GRAN#，MCH，MCHC，PCT

The formulas are as follows:

- HCT（%）= RBC×MCV/10
- MCH（pg）= HGB/RBC
- MCHC（g/L）= 100×HGB/HCT
- PCT（%）=PLT×MPV/10000
- LYM（%）= 100×AL /（AL+AM+AG）
- MID （%）= 100×AM /（AL+AM+AG）
- GRAN（%）= 100×AG/（AL+AM+AG）

WBC histogram is as Figure 2-2.

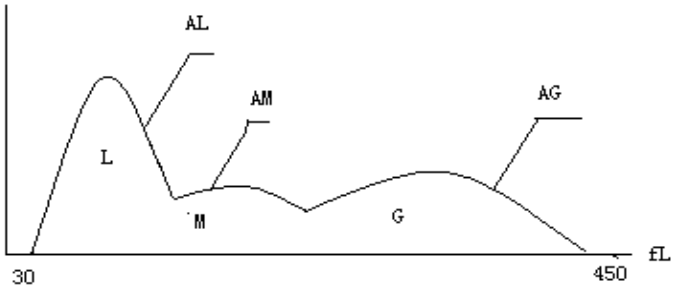

Figure 2-2

AL：quantity of cells in area of LYM

AM： quantity of cells in area of MID

AG：quantity of cells in area of GRAN

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

- Lymphocyte（10^9L） LYM# = LYM%×WBC/100
- Monocyte（10^9L） MID# = MID%× WBC/100
- Granulocyte（10^9L） GRAN# = GRAN%×WBC /100
- RBC Distribution Width Variable Coeffient（RDW_CV）is derived from RBC histogram, shows the volume distribution variable coefficient of RBC, with the unit of %.
- RBC Distribution Width Standard Difference (RDW_SD) is derived from RBC histogram， shows the volume distribution standard difference of RBC, with the unit of fL.
- PLT Distribution Width Variable Coeffient（PDW_CV）is derived from PLT histogram, shows the volume distribution variable coefficient of PLY, with the unit of %.
- PLT Distribution Width Standard Difference (PDW_SD) is derived from PLT histogram，shows the volume distribution standard difference of PLT, with the unit of fL.
- Mean Platelet Volume (MPV) is derived from PLT distribution histogram, its unit is fL.

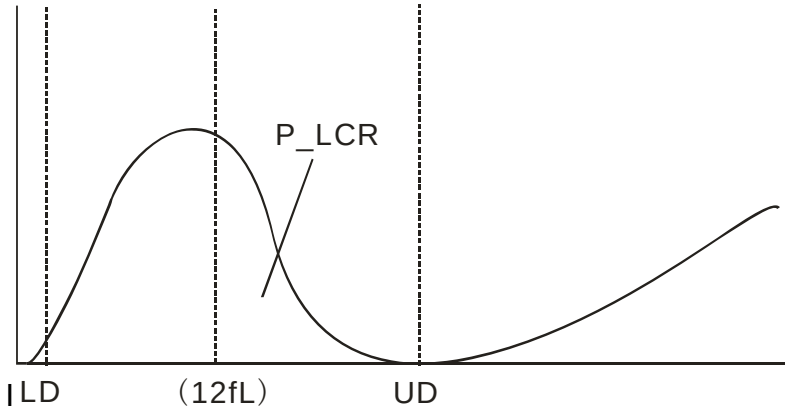

Figure 2-3 PLT Histogram

- P_LCR indicates the ratio of large platelet (≥12 fL). It is derived from PLT histogram. See Figure 2-3. LD,UD is the differentiating line of 2~6 fL and 12~30 fL. These two lines are decided by analyzer automatically. P_LCR is the ratio of particles between 12 fL line and UD to particles between LD and UD.
- P_LCC:Large platelet，it is the particles≥12 fL.

Chapter 3 Installation and Specimen Analysis

Initial installation of analyzer must be performed by a Avecon authorized engineer or representative to ensure that all system components are functioning correct 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 by Avecon could result in damage to the analyzer which is exclusive of the warranty. Never attempt to install and operate the analyzer without a Avecon 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 Avecon Customer Support Center if any problem occurs.

3.2 Installation Requirements

Please refer to section 11.2 of chapter 11.
WARNING: Not for home use.
WARNING: Not for therapy.

CAUTION: Away from direct sunlight.
CAUTION: Avoid temperature extreme.
CAUTION: Away from centrifuge, X-ray equipment, display or copier.
CAUTION: No cell phone, wireless phone and equipments with strong radiation 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. See Table 3-1 for details.

Table 3-1

Optimal Voltage	Voltage Range	Frequency
AC220V	AC（100—240）V	50/60Hz

WARNING: A grounded power outlet is required to connect directly with the grounding terminal on the rear panel. Be sure to guarantee the security of the work site.

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 Avecon) 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 Avecon) should be taken before operation.

3.4 Tubing Installation

There are four tube-connectors on the right panel: LYSE, DILUENT and WASTE, each of which is wrapped with a cap to avoid contamination by the Avecon before shipment. Uncover and set the caps aside carefully for further use on initial installation.

3.4.1 LYSE Tubing Installation

Remove the lyse tube with red faucet from accessory kit and attach it to LYSE connector on the right panel. Place the other end into the lyse container. Twist the cap until secure. Place the container on the same level as the analyzer.

3.4.2 DILUENT Tubing Installation

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

3.4.3 WASTE Tubing Installation

Remove the waste tube with black faucet from accessory kit and attach it to WASTE connector on the right 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.

CAUTION: Keep the tube in loose condition after installation, no distortion 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 Avecon Customer Support Centre for replacement.
WARNNING: The waste must be handled with biochemical or chemical methods before disposal, or it will cause contamination to the environment. Users have obligation to follow the local and national environmental regulations.

3.5 Printer Installation (optional)

Take out the printer from the shipping carton. Inspect the printer carefully according to its manual and Section 3.1 and perform the following procedures:

a) Find a suitable location adjacent to the analyzer. Location of at least 30cm away from analyzer on its right side is recommended.
b) Assemble the printer as directed in the printer manual.
c) The printer cable connects the printer and the USB or the socket labeled with printer logo on the rear panel of analyzer.
d) Be sure that the printer power switch is OFF; plug one end of power cord to power socket.
e) Install printing paper as directed in the manual.

3.6 Keyboard and Mouse Installation

Take out keyboard, and mouse from the shipping carton, and insert the plugs of keyboard and mouse into the USB port on the rear panel.

It is recommended to place the keyboard beneath the display. You can place anywhere convenient also.

3.7 Power Connection

Make sure the power switch is OFF (O) and the grounding terminal on the left panel is well grounded firstly, then connect the analyzer to the main power with the power cable.

3.8 Startup

Turn on the power switch on the left panel. The indicator is orange, and the analyzer program starts and enters self-checking interface. When the analyzer self-checks, it fills with diluent and lyse, and clean the fluid system.

Login interface pops up after initializing. See Figure 3-1.

Figure 3-1

Click input field, and the virtual keyboard appears. See figure 3-2.

Figure 3-1

Inputting user name and password, the analyzer enters test interface. See figure 3-3.

Figure 3-3

3.9 Background Test

Background test should be performed after startup and before blood sample test, operate as follows:

a) Put the clean empty tube under the aspiration probe. At main menu screen, click “Drain” to dispense the diluent into the tube.

b) At main menu screen, click “Info”, and then modify ID to 0, click “OK” back to save it.

Remark: 0 is the specialized ID number for background test. In blood sample test, the ID number cannot be 0.

c) Put the tube containing diluent beneath aspiration probe which should touch the bottom of tube.

d) Press RUN key on the front panel, move away the tube after the beep sounds. Then the analyzer starts to count and measure automatically.

e) The counting time of RBC, WBC will be displayed at the lower right corner of screen during counting. The analyzer will alarm and display the error at top left corner if the counting time is too long or too short.

Refer to Chapter 10 for problem correction.

f) The acceptable range of background is listed in Table 3-2.

Table 3-2

Parameter	Acceptable Range
WBC	≤0.2x10^9/L
RBC	≤0.02x10^{12}/L
HGB	≤1g/L
PLT	≤10x10^9/L

If the background result is out of acceptable range, repeat the above procedures until reach the acceptable results.

NOTE: ID number of background test is set to be 0 by the software to make the result not memorized in the analyzer.
NOTE: The ID number of 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

Avecon calibrates the analyzer in factory before shipment. On the initial installation, if the background results 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 Collection of Blood Sample

CAUTION: Consider all clinical specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear lab coats, gloves and safety glasses and follow required laboratorial or clinical procedures when handling these materials.
NOTE: Blood collection and disposal should be performed according to the local and national environmental regulations or laboratory's requirements.
NOTE: Be sure the blood collection clean and contamination-free. All specimens must be properly collected in tubes containing the EDTA

(EDTA-K2·2H2O) anticoagulant used by the laboratory.

NOTE: Do not shake the sample tube violently.

NOTE: Venous blood can only be stored for 4 hours at room temperature. Avecon recommends the blood sample be kept at temperature between 2-8℃ for longer storage

3.12.1 Whole Blood Collection

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

3.12.2 Perpheral Blood Collection (Pre-diluent)

Capillary blood is usually collected from fingertip. The volume of sample tube is set to be 20ul. Peripheral blood

CAUTION: Never over-press the finger avoiding collecting tissue liquid into sample tube, tissue liquid will cause error in results.

3.13 Mode Switch

Click “Mode Switch” in the main interface, and choose the mode you need in the dialog box. See figure 3-4.

Figure 3-4

Select the mode and click “OK”, then the blood test mode changes.

3.14 Sample Counting and Analysis

Sample counting and analysis is processed as following procedures.

3.14.1 Information Input

In the blood cell analyse interface, user click “Next sample” to input detailed sample information before sample analysis or after sample analysis. See figure 3-5.

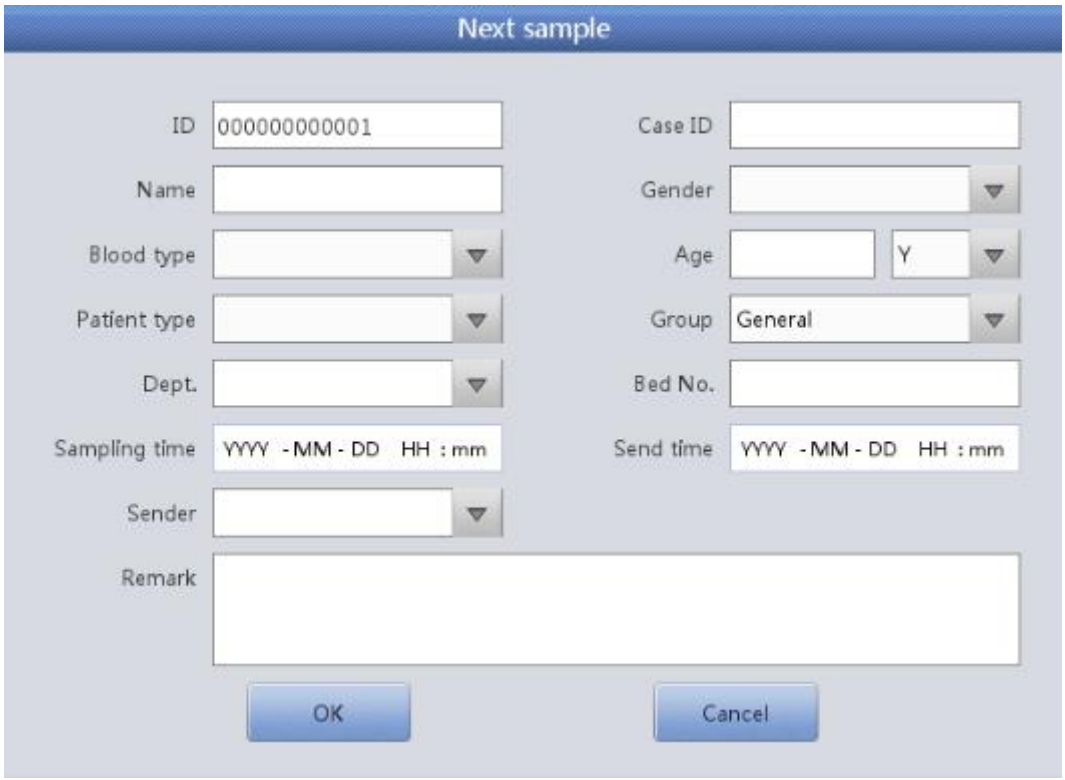

Figure 3-5

The system comes with Chinese phonetic alphabets input method and English input method, clicking on the corresponding input box shall pop up the virtual keyboard. If necessary, the user can connect to external PS2 or USB interface keyboard to help enter the information.

Name: Input alphanumeric characters.

Gender: Select male or female. If not selected, default as blank**.**

Age: Input Year, Month and Day.

Blood Type: Select A, B, O, AB, A Rh+, A Rh-, B Rh+, B Rh-, AB Rh+, AB Rh-. O Rh+, O Rh-. If not selected, default as blank.

Group: divided into male, female, Children, infants, newborns, general, custom1, custom2 and custom3.

System automatically selects corresponding group as age and gender are input. The reference values are listed as Table 3-3.

Table 3-3

Reference value	Age	Sex
General	No input	Blank, M, F
General	≥16-year	Blank
Man	≥16-year	M
Woman	≥16-year	F
Child	≥1-year and <16-year	Blank, M, F
Infant	≥1-month and < 1 year	Blank, M, F
Neonate	<1-month	Blank, M, F

ID: only numbers can be input here. If there's no SN input, the analyzer automatically plus 1 on the basis of last SN and take it as the new SN.

Case ID: Input patient's medical No.

Bed No.: Input bed No. of patient.

Dept.: Input department name or code of operator.

Sender: Input sender's name or code.

Patient type: Select the patient type, which outpatient, hospital, physical examination or emergency can be selected.

Sampling time: Input the blood sample collection time

Send time: time of sending sample to the department

NOTE: The ID number is set to 0 only under background test. The blood sample ID CAN NOT be 0.

3.14.2 Counting and Analysis

Counting and analysis should be performed within 3~4 minutes after blood collection.

■Pre-diluent peripheral blood mode:

a) Present the empty sample tube under the aspiration probe. At main menu screen, click "Drain"; the diluent will be dispensed into the tube.
b) Remove the tube, add 20ul of the blood sample to the tube, and gently shake the tube to make them well mixed.
c) Present the well-mixed sample under the aspiration probe; make sure the probe touches the tube bottom slightly.

d) Press RUN key on the front panel and remove the sample after hearing beep sound.
e) 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 beneath the probe, make sure the probe touches tube bottom slightly.
b) Press RUN key and remove the sample after hearing beep sound.
c) The results will be available after the analysis is performed.

■ Anti coagulated Peripheral Blood Mode

a) Gently shake the tube to well mix the blood sample, then present the sample tube beneath the probe, make sure the probe touches tube bottom slightly.
b) Press RUN key and remove the sample after hearing beep sound.
c) The results will be available after the analysis is performed.

The test results and histograms of WBC, RBC and PLT will be displayed at main menu screen after counting and analysis (see Figure 3-1).
If Auto Rec or Auto Print is ON (set in “system setting” interface), the test results will be printed out automatically.
If problems like clogs or bubbles occur during the counting and analysis procedures, the analyzer will alarm and give indication at the top left corner of the screen. The test results are invalid. Refer to Chapter 10 for solution.

3.14.3 Special Function

There are two kinds of alarms: parameter alarm and histogram alarm.

3.14.3.1 Parameter Alarm

1. ”H” or “L” present on the right side of the parameter means the result is out of the range of reference value.
2. “***” means the result is invalid or out of display range.

3.14.3.2 Histogram Alarm

If the WBC Histogram is abnormal, R1, R2, R3, R4, RM will be displayed on the right side of the histogram.
R1 indicates there is abnormality in the left side of LY wave peak, which

probably caused by incomplete hemolysis of RBC, platelet clump, giant platelet, plasmodium, nucleated RBC, abnormal lymphocyte, proteinic and fat granule, or electrical noise.

R2 indicates there is abnormality in the area between LY wave peak and MO wave, which probably caused by pathologic lymphocyte, plasmocyte, atypia lymphocyte, an increase in original cell or eosinophil, basophilia, .

R3 indicates there is abnormality in the area between MO wave and GR wave peak, which probably caused by immature granulocyte, abnormal cell subpopulation, eosinophilia.

R4 indicates there is abnormality in the right side of GR wave peak, which probably caused by an absolute increase in granulocyte.

RM indicates there are two or more preceding alarms.

When the histogram of PLT has abnormalities, PM alarm will be shown in the right side.

PM indicates there is ill-defined boundary between PLT and RBC, which probably caused by the present of giant platelet, platelet clump, small RBC, cell debris or fibrin.

3.15 Result Analysis

HMT-70P provides plenty and convenient result analysis functions.

- Click histogram display area to modify the test results. Refer to Section 3.17 in this chapter for details.
- Click “Transmit” to transmit the data to network.
- Click “Print” to print data report of current blood sample by recorder or printer.
- Click “Mute” to mute or sound the alarm.
- Click “Help” to get necessary help.
- ”H” or “L” present on the right side of the parameter means the result is out of the range of reference value. “L” means result is lower than the lower limit while “H” means result is higher than upper limit.
- If counting time lower than system setting lower limit, the system will alarm “WBC bubble” or “RBC bubble”, at the same time display “B” before test result.
- If counting time higher than system setting time, the system will alarm “WBC clog” or “RBC clog”, at the same time display “C” before test result.

NOTE: The parameter value is *** means invalid data.
NOTE: If there is PLT Histogram Alarm, the PDW_SD probably is ***.
NOTE: WBC differentiation may be incorrect if WBC is lower than 0.5 $x10^9$ /L. Microscope examination is recommended.

3.16 Report Output

HMT-70P offers recorder and printer which are optional according to customer needs. After blood sample analysis completed, if Auto Print is ON, test report will be printed automatically by recorder or printer; if the Auto Trans is ON, test results will be transmitted to network automatically.

The recorder, printer, transmit and test reports are set up at Settings. Refer to Chapter 4 for details.
Click “Transmit” to transmit data of the current sample to network.
Click “Print” to print test report of current sample by recorder or printer.

3.17 Result Modification

If the auto-classification of floating limit for WBC, RBC and PLT do not reach clinical or laboratory requirements on special samples, manual classification is feasible.
CAUTION: Unnecessary or incorrect manual classification will cause unreliable test results. It is recommended to microscopic exam before manual classification.

The procedures are as follows:

a) In the main menu screen, click the graphics field with different pamameters, the cooresponding interface displays, see figure 3-6. the WBC histogram is selected.

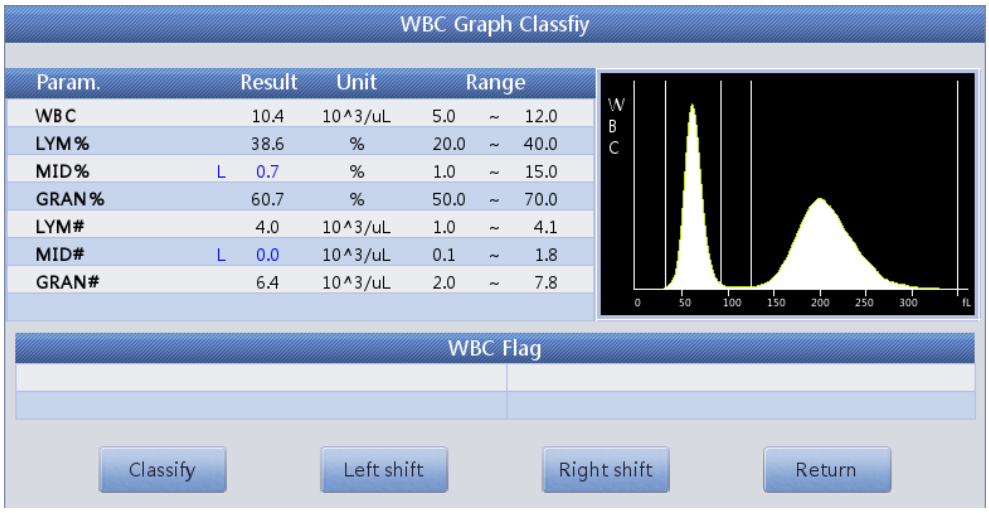

Figure 3-6

b) Once the diagram parameter needed to modify is selected, click “Class” to select the desired classification, then the classified line will change from white line to red line.

c) Click “Left Shift” or “Right Shift” to move the classified line, and the value of classified line will be indicated at the lower right of the screen.

d) Click “Return” after modification, the dialog box as shown in Figure 3-7 will display; click “Cancel” to cancel the modification, while click “OK” to save the modified results.

Figure 3-7

3.18 Shutoff

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

Shutoff procedure is as follows:

a) At main menu screen, click “Exit”, shutoff information will appear (see

Figure 3-8).

Figure 3-8

b) If turn off the instrument, click “OK”. After finishing the maintenance, cleaning and shutoff procedures, “Thank you, now turn off power” will appear to instruct the operator to turn off the power switch on the left panel.
c) Tidy the work platform and dispose waste.
d) Click “Cancel” if the operator does not want to shutoff the analyzer.

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

CAUTION: May lead to data loses if turn off the analyzer against procedures.

3.19 Data Query

After each counting, the results are automatically saved in a database that could store at least 100,000 results include 24 parameters (with 3 histograms).Operator could review all of the results and histograms that store in the database.

3.19.1 Data Query

Click “Data” to enter the query interface. See Figure 3-9.

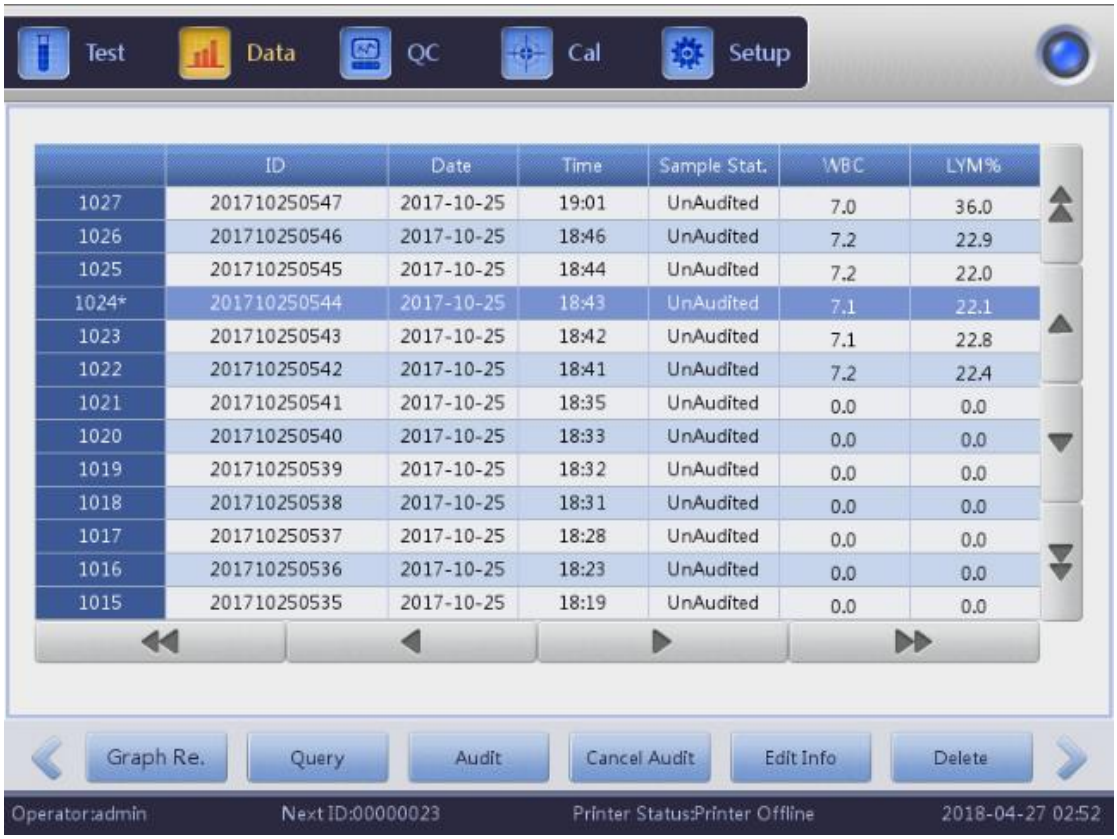

Figure 3-9

Click “Query” to pop up the following dialog box. See Figure3-10.

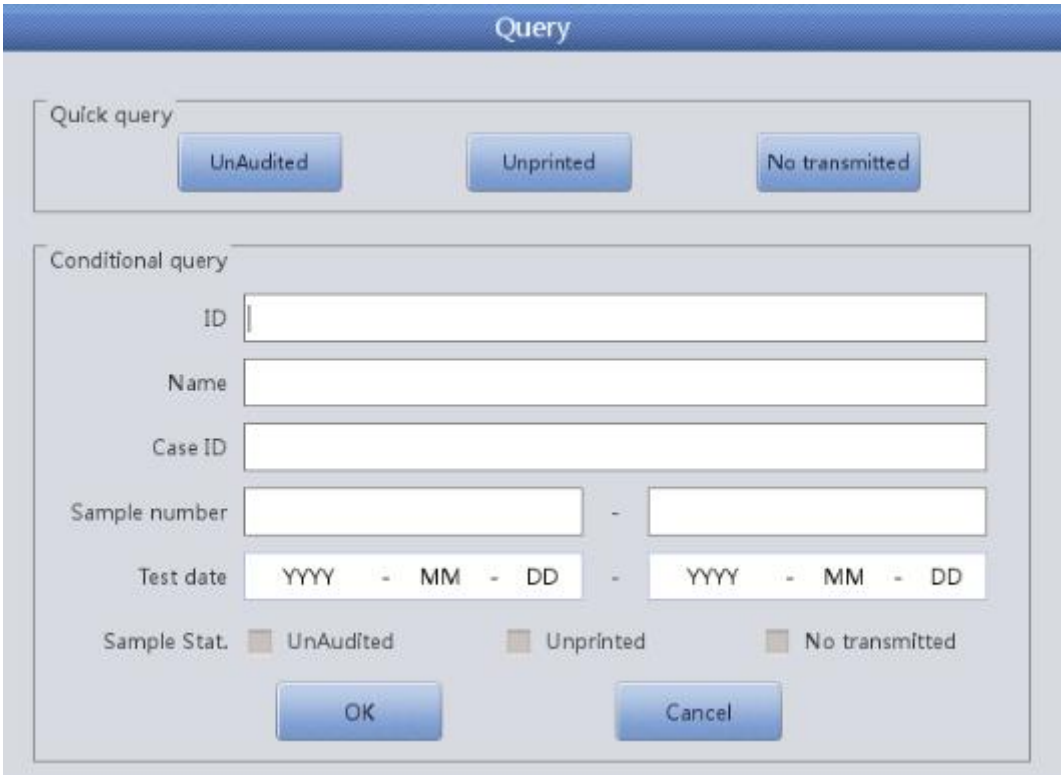

Figure 3-10

Data query: quick query, conditional query

- Quick query

Unchecked: display current unaudited sample
Unprinted: display current unprinted sample
No transmitted: display current not transmitted sample

- Conditional query

  Conditional query can achieved the function of exact search by input the specified “ID”, “Name” or “Case ID”. It also can query through the range of “Sample number”, or query through the range of “Test date”.

Conditional query can achieved the function of exact search by cooperate with “Sample State”.

3.19.2 Data Selection

There’s a “*” in front of selected sample ID. As shown in Figure 3-9, it shows records of sample 201710250544. Click “Graph Review” to see detailed data and graphs. See Figure 3-11.

Figure 3-11

3.19.3 Data Deletion

After processing plenty of samples, it is necessary to clean up or delete the

mass data stored in the analyzer according to the requirement of the operator. Both delete all and delete one are available. Click “Delete” to delete chosen data.

NOTE: Be aware that once the data are deleted, it can NOT be recovered. Please operate with caution.

3.19.4 Edit Information

Choose sample ID and click “Edit Info” to pop up dialog box, see Figure 3-12. Edit the information into the dialog box. Click “OK” to save edit, while click “Cancel” to give up saving.

The audited sample cannot be edited, if it need to be edited, please cancel the audit first. Please refer to Section 3.14.1 for information edit.

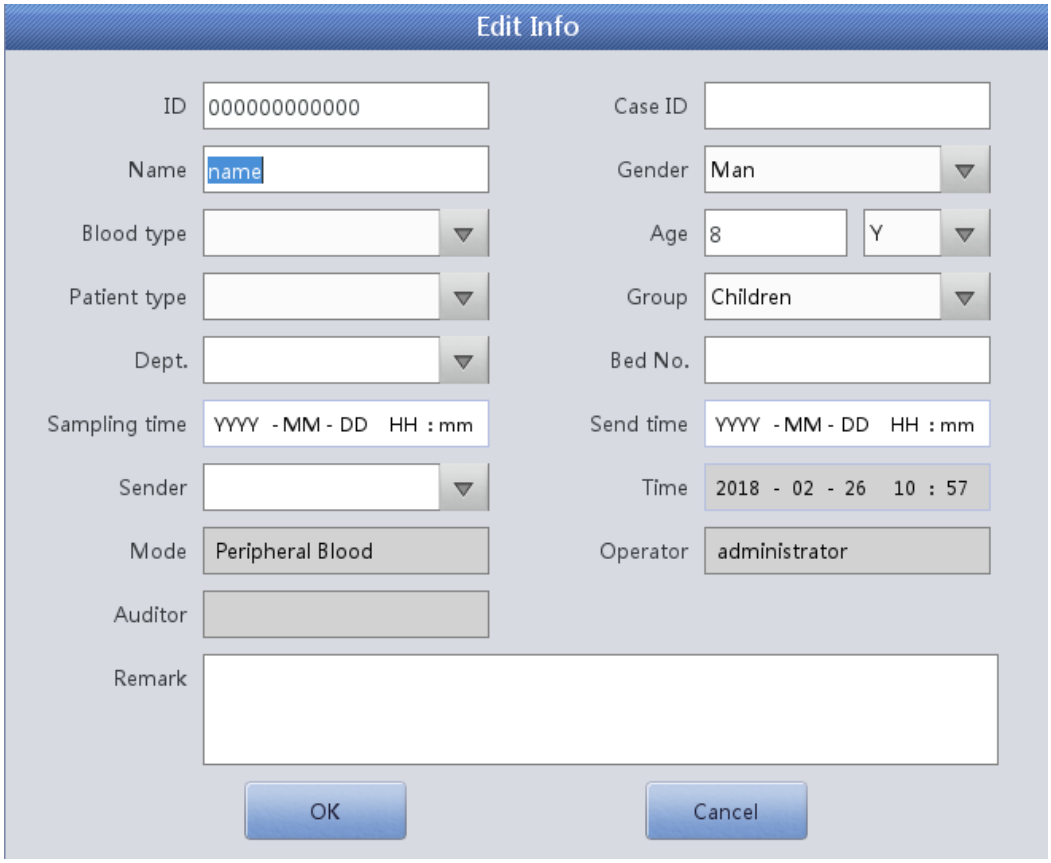

Figure 3-12

3.20 Special Function

3.20.1 Export

Click “Export” to pop up the following dialog box, see Figure 3-13:
Select “Chosen record” and “All records” in “Range”, and click relevant items in “Content”.
Please insert the U disk before exporting. Click “OK” to start export. The exported data is in Excel form. Click “Cancel” to cancel export.

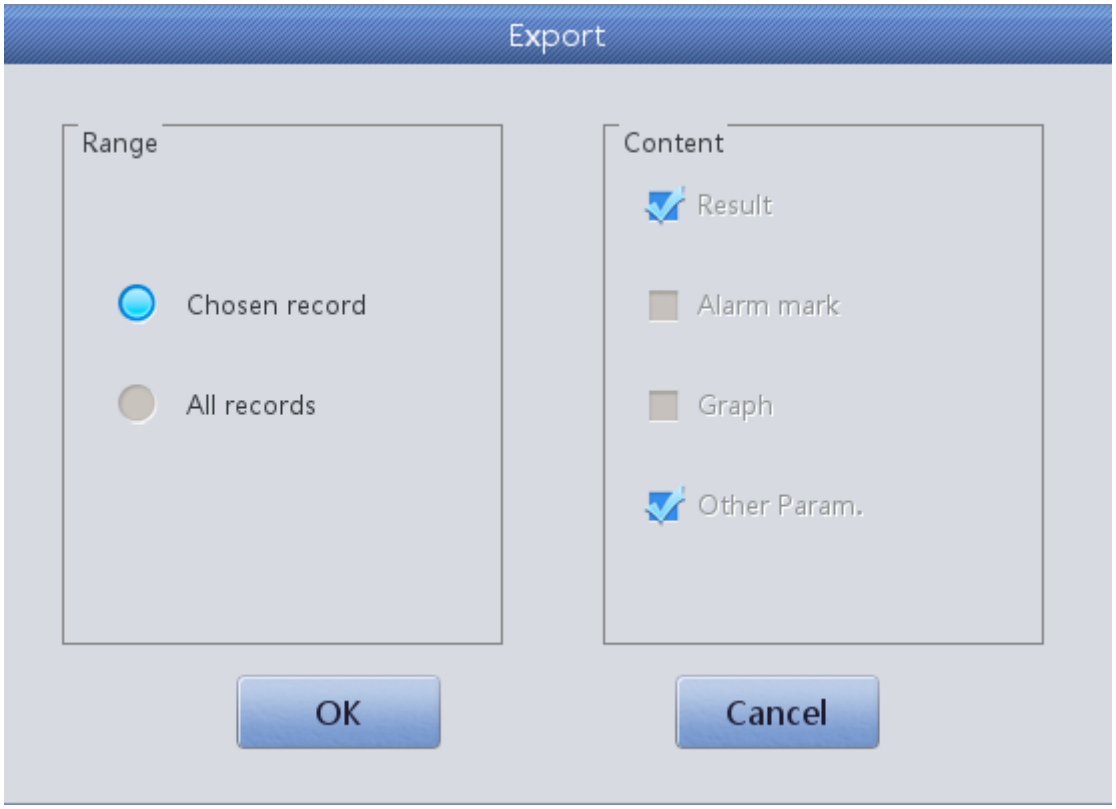

Figure 3-13

3.20.2 CV Value and Trend graph

To check the CV value, please do 11 times test of one same blood sample. Removed the first test result, choose the remaining results and click “CV” to see the CV value. See Figure 3-14.
Click “Trend graph” to see the trend graph of parameter. See Figure 3-15.

Figure 3-14

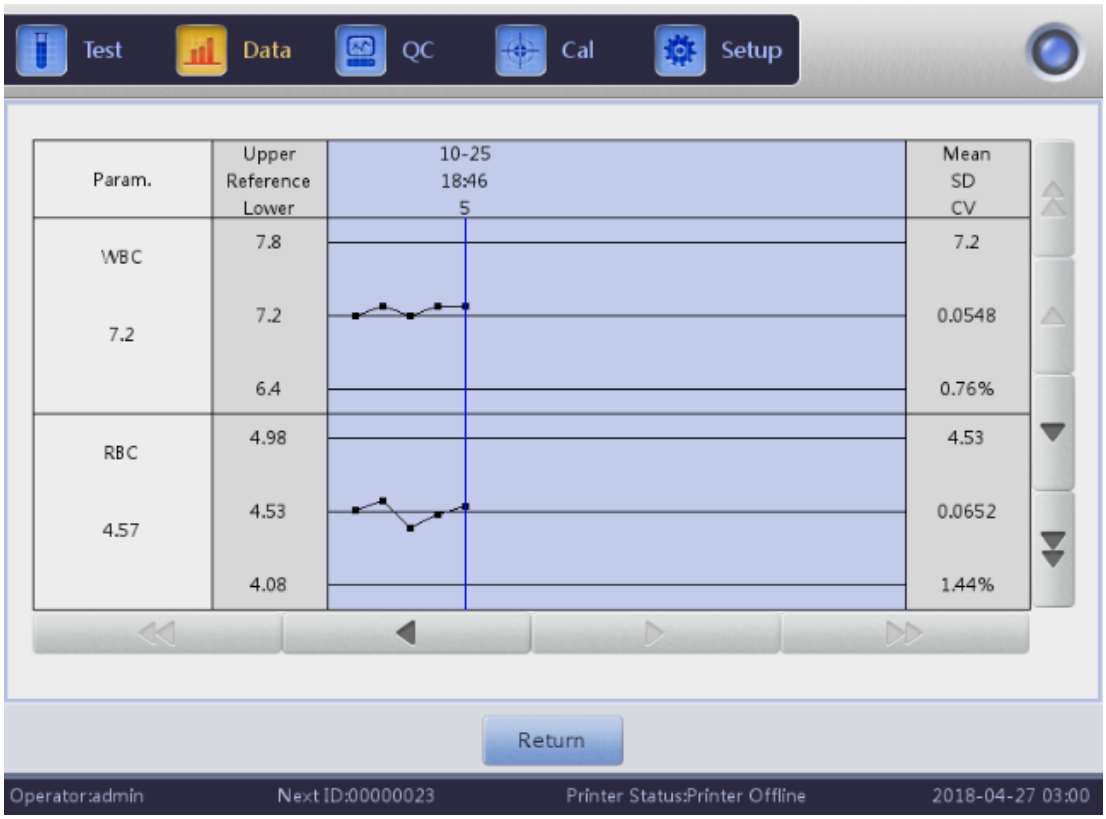

Figure 3-15

Chapter 4 System Setting

Initialization setting of HMT-70P has been done before delivery. Setting of the interface at the first boot is default. To meet the different needs, some parameters can be reset.

4.1 Setting

Click “Setup” to enter setting interface, see Figure 4-1.

Figure 4-1

4.2 System Maintenance

Click “Maintenance” to enter maintenance interface, see Figure 4-2.

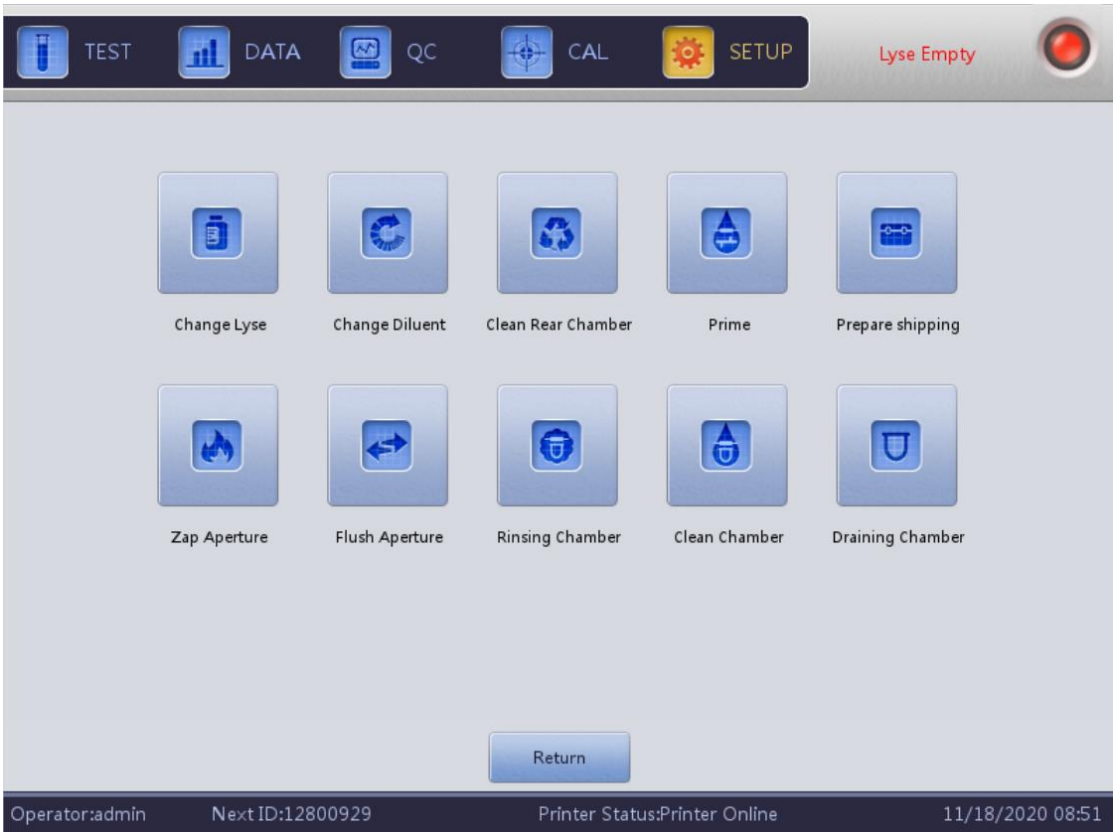

Figure 4-2

Change lyse: click “Change Lyse” to primes lyse automatically after replacement.

Change diluent: click “Change Diluent” to primes diluent automatically after replacement.

Clean Rear Chamber: click “Clean Rear Chamber” to primes diluent in the rear chamber automatically after replacement.

Cauterize aperture: click this button to eliminate clogging.

Flush aperture: click this button to eliminate clogging.

Rinsing cups： click this button as it plugging or getting high blank test result.

Prime: click this button to empty counting chamber.

Draining cups : click it to clean the impedance channels.

Prepare shipping: perform this function before shipping or unused for a long time to empty fluid in the tubing.

4.3 Limit

Click “Limit” to enter the interface. See chapter 5 for details..

4.4 Time

Click “Time” to set it.

There are three formats of date, which are YYYY-MM-DD, MM-DD-YYYY and DD-MM-YYYY. Y indicates Year, M indicates Month and D indicates Day. See Figure 4-3.

Date display format changes according to date format.

Click “OK” to save modified settings.

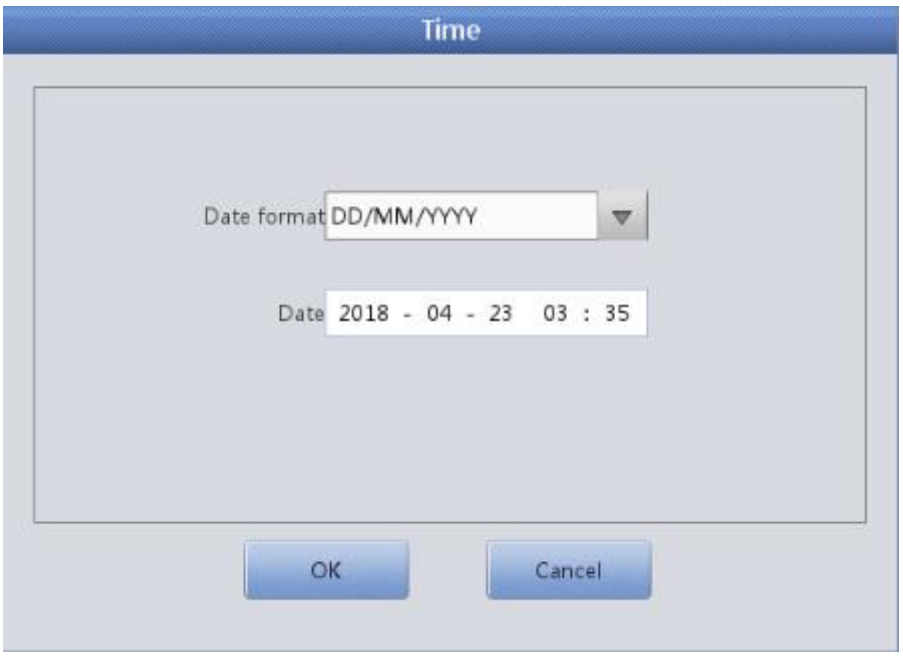

Figure 4-3

4.5 Parameter

Click “Parameter” to enter the interface. See Figure 4-4.

Choose unit of WBC, RBC, PLT and MCHC. Click “OK” to save modified settings.

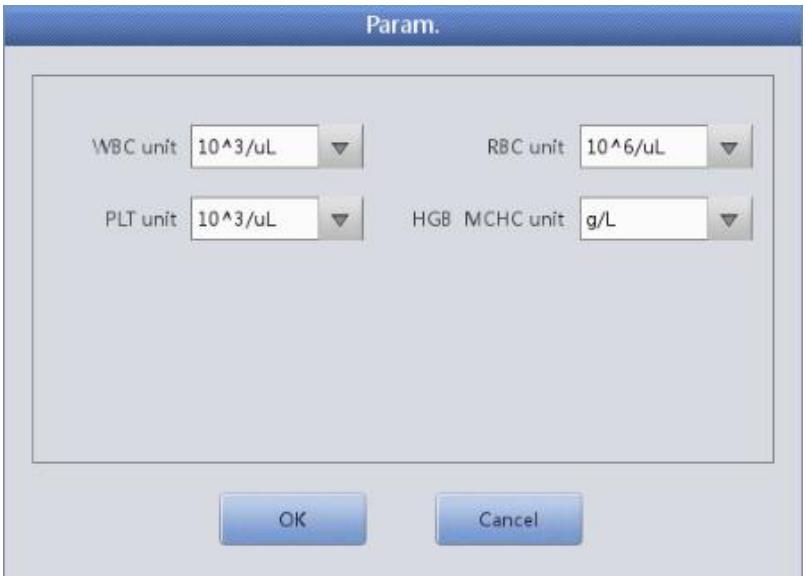

Figure 4-4

4.6 Print

Click “Print” to enter the interface. See Figure 4-5:
Printer type: USB port printer (A5), USB port printer (A4).
Print format: print with histogram, print without histogram.
Auto print: open/close auto print. If it’s open, test result is auto printed after counting. If it’s closed, it needs to manual print.
Printer title: input hospital name here, hospital name displays in printed report title. Click “OK” to save the modified settings.

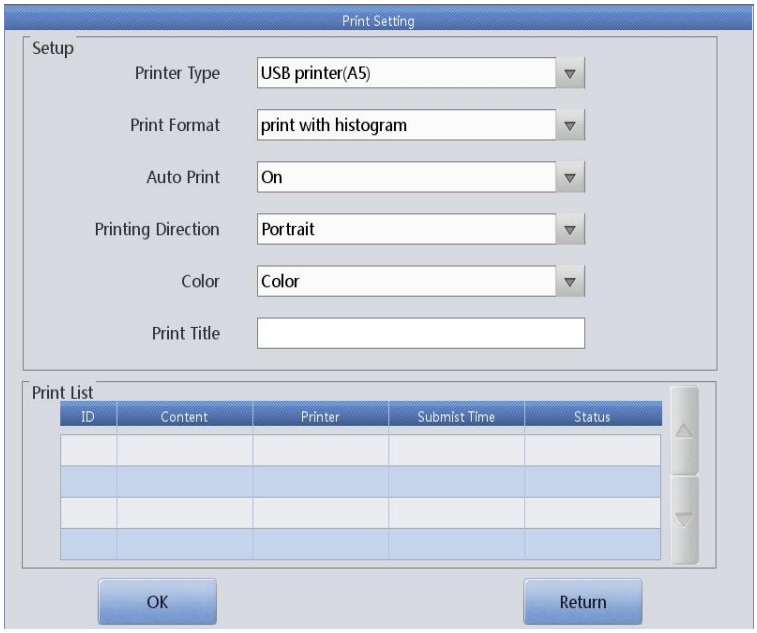

Figure 4-5

4.7 Transmit

Click “Transmitmit” to enter the interface as shown in Figure 4-6.
There are two transmission mode: internet transmission and serial transmission. User can make choice in transmission selection bar.

If choose internet transmission, please set the local IP, server IP, local mask, local gateway and port number as connecting with LIS system. The native mask and the local gateway can be selected by default, the others shall be reset. After finishing the setting ,click the button “save”, and then “unconnected”. If the button displays “connected”, it is connected successfully.
If choose serial transmission, please set Baud rat, stop bit, data bit, parity bit. The port number can be selected by default. Click “save” after setting.

Choose open/close auto transmit as connecting with LIS system.
Auto transmit: transmit the result through communication port after sample testing.

Figure 4-6

4.8 Maintenance

Click “Maintenance” to enter the interface. See Figure 4-7.

Figure 4-7

Auto blank: click  to select “On” or “Off” and then click “OK” to save settings as blank test is necessary in each boot. The analyzer does not perform it if it is “Off”.

Auto clean: the analyzer does not perform it if it is “Off”. Click  to select “Auto clean” and choose times (50 times, 75 times, 100 times, 125 times and 150 times) according to the need. Auto clean is performed after 50 sample testing, if 50 times is selected.

Diluent reminders: dialog box pops up in each counting if “On” is selected.

Auto sleep: the analyzer automatically enters the dormant state without any operation for an interval of time. Users can adjust dormancy length according to the necessary.

Soak and exit: prompts do not pop up if “Off” is selected. Soak is performed when shutting down, if “On” is selected. The analyzer prompts to put the detergent under the aspiration probe which absorbs it to soak sample cup. Shut down the analyzer after soaking.

Auto soak: click  to choose counting times. The analyzer reminds users of putting detergent under the sample probe and absorb it to soak sample cup, when counting times is over selected times.

4.9 Version

Click “Version” to pop up version dialog. See Figure 4-8.
The current version information displays here. Version upgrade can be achieved.
Click “Return” to return to setup interface.

Figure 4-8

4.10 User

Click “User” to enter the interface. See Figure 4-9

Figure 4-9

Click “Delete” to delete selected user.

Click “Add” to pop up “Add user” dialog to edit new user’s name, password and group. “Group” is divided into “Ordinary user” and “Administrator”, which are given different permissions. The administrator's permissions are higher than the Ordinary user’s. The administrator can operate all the functions, while the general user can not delete data, use the export function or calibrate the analyzer. See Figure 4-10.

Figure 4-10

4.11 Service

Click “Service” to pop up the following dialog. Only the Avecon service engineers can perform this function in maintenance. See figure 4-11.

Figure 4-11

4.12 Reagent

Click “Setup” as changing reagent. Click “Licence” to pop up below dialog.

Chapter 5 Quality Control

In order to maintain the analyzer precision and eliminate system errors, it's necessary to perform quality control. HMT-70P offers four quality control options: L-J QC, X-B QC, X-R QC and X QC. In following conditions, perform quality control using Avecon recommended control materials.

- After daily start-up procedures completed
- The reagent lot number changed
- After calibration
- After maintenance, or component replacement
- In accordance with the laboratory or clinical QC protocol
- In suspicion of parameter value

To ensure accuracy of the results, commercial controls must be handled as follows:

- Make sure the controls stored at low temperature and without leakage.
- Mix the controls according to the manufacturer's recommendations.
- Never use controls which are unsealed longer than the period recommended by the manufacturer.
- Never subject controls to extreme heat or vibration.
- Perform the high, normal and low controls of new lot, and compare the values with last lot to verify the difference.

CAUTION: Consider all clinical specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear lab coats, gloves and safety glasses and follow required laboratorial or clinical procedures when handling these materials.

5.1 Quality Control Options

(1) L-J QC

L-J QC (Levey-Jennings graph) is a simple and visual QC method with which operator can draw QC value directly on graph after get the Mean, SD and CV. Mean, SD and CV are derived from following formulas:

$$\overline{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{\sum (X_i - Mean)^2}{n-1}}$$

$$CV\% = \frac{SD}{Mean} \times 100$$

(2) X-R QC

In X-R QC method, X indicates mean value, R indicates range of value. X graph is mainly used to judge that if the mean value falls in required level. R graph is mainly used to judge that if the range of value falls in required level.

(3) X QC

X QC is the variation of X-R QC; they have the same basic principle. The difference is that the control dot in X graph indicates the mean value of two values other than one value. On this foundation, calculate the Mean, SD and CV.

(4) X-B QC

X-B QC is a moving average method which is first promoted in 1970s'. It's based on the principle that, RBC count is varied due to the concentration of dilution, human blood pathology and technical factor, but the hemoglobin content in specific unit is hardly interfered by those preceding factors. According to this characteristic, quality control the samples by surveying the value of MCV, MCH, and MCHC.

5.2 QC Mode Select

Click the button "QC" on the top of main interface, and select the QC mode. See figure 5-1. HMT-70P offers four quality control options: L-J QC, X-B QC, X-R QC and X QC. Select the mode in the drop-down box of QC mode, and the corresponding interface pops up.

Figure 5-1

5.3 L-J QC

Entering the QC interface, L-J mode is default.

5.3.1 L-J QC Setting

Click “setup” to enter setting interface, see figure 5-2.

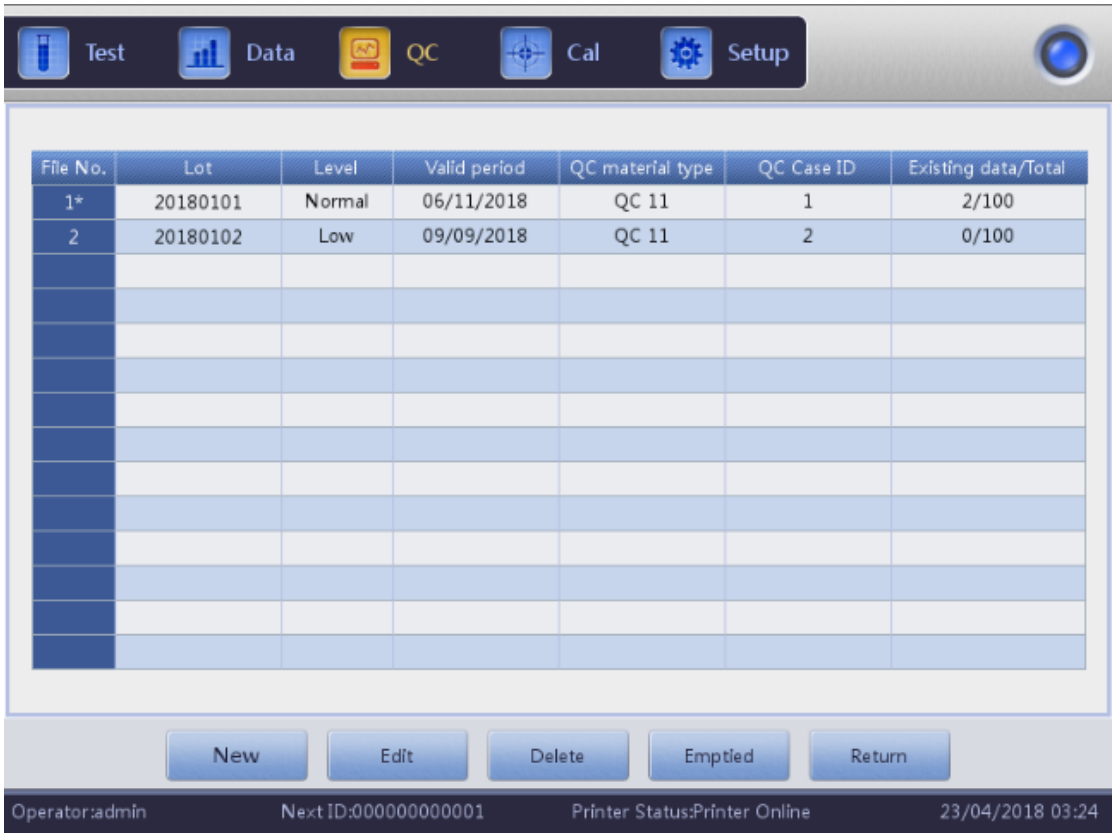

Figure 5-1

There are 14 different QC groups set. Users can set several groups if needed. Click “New” to setup one group of QC, and edit information.

A group of QC saves 100 test data at most.

Edit information: lot, QC material type, QC case ID., level, runaway mode, valid period, reference and limit.

Limit setup: calculated by absolute value and calculated as a percentage, click “Limit setup” to choose it.

Click “Return” after editing. Click “OK” in popup dialog box, and the setting is saved.

Choose one group and click “Test” to test in QC interface. Click “Edit” to edit selected group, click “Delete” to delete the selected group, click “Empty” to delete all groups.

Reference is the standard value of QC count. Limit gives the allowable deviation range. Please note that the limit cannot be greater than reference, otherwise, the new limit cannot be saved in database.

Format of valid period: year/month/day.

5.3.2 L-J QC Graph

Click “Test” after editing. Return to QC interface and start to QC count. Click “QC Graph” to check it. See Figure 5-3.

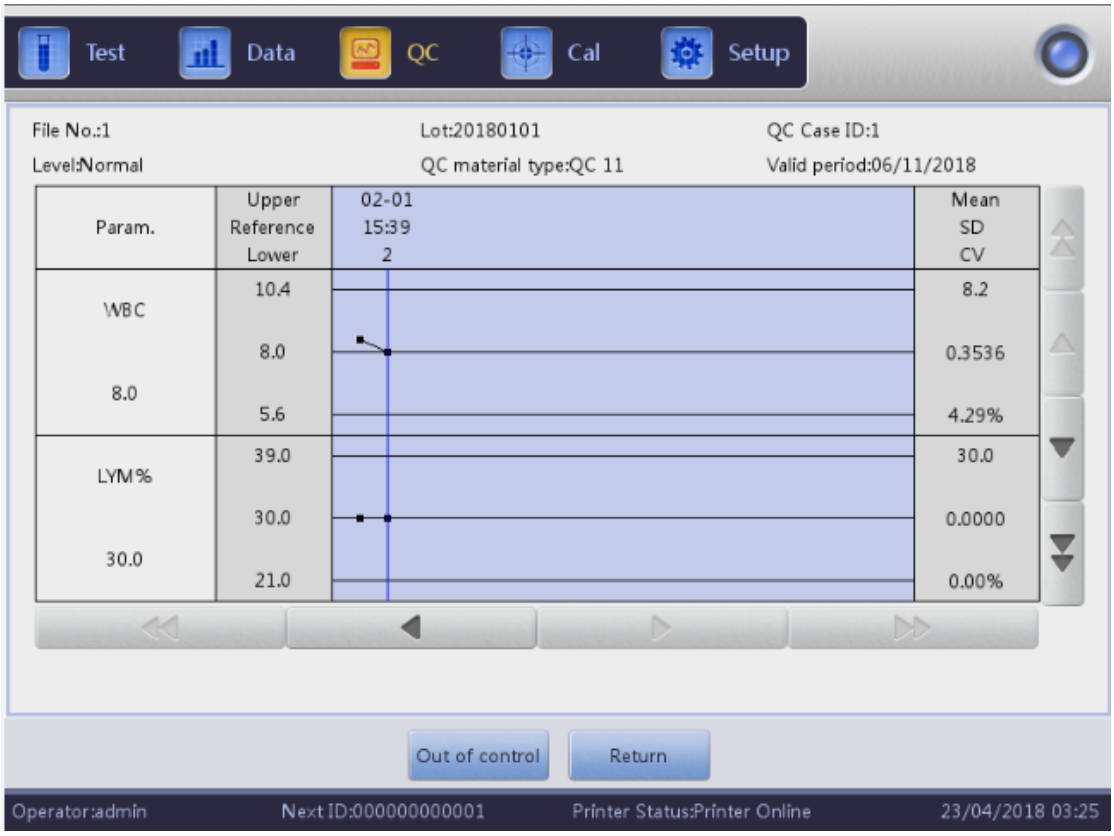

Figure 5-3

If the data is not in control area, choose this data dot and click “Out of control” to enter the interface. See Figure 5-4.

Choose the reasons of out of control or input other reasons manually. Click “OK” to save your settings.

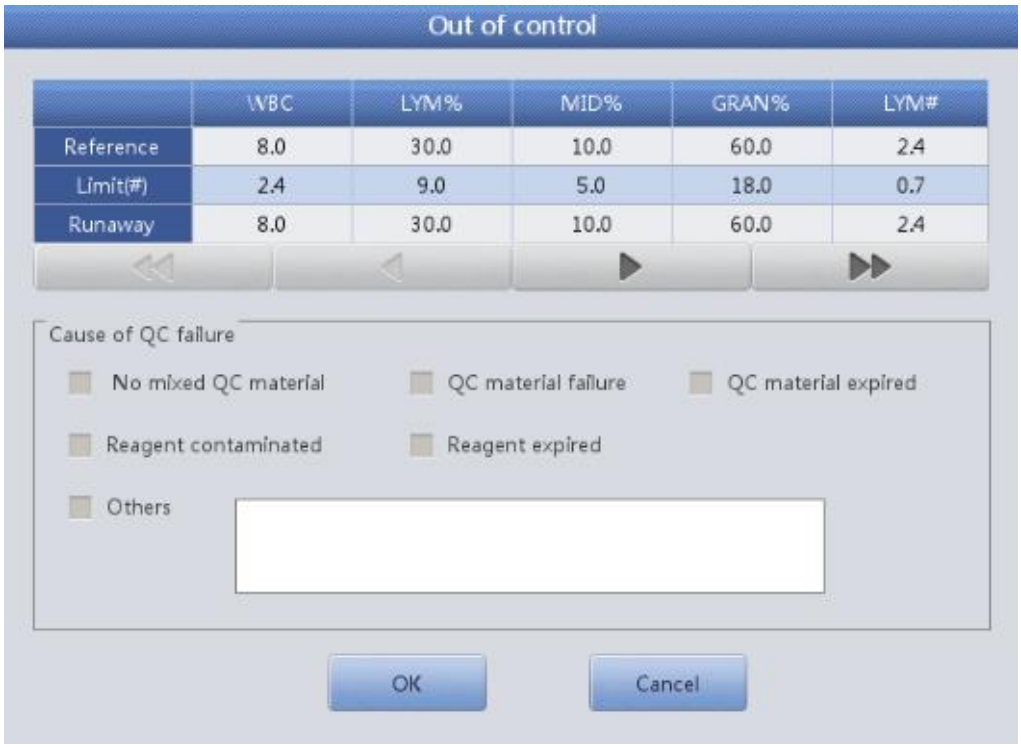

Figure 5-4

QC Graph Instruction

1. It's a graph with times of QC count on horizontal axis and results of QC count on vertical axis.
2. Every parameter graph displays 20 dots, page turning to see other dots.
3. The above line of every parameter graph means Reference plus limit.
4. The below line of every parameter graph means Reference value subtract limit.
5. The 3 values on the left side of parameter graph mean:
   - upper limit ——Reference + limit
   - middle line ——Reference
   - lower limit ——Reference –limit

Mean value=total value/sample number

If the control dot falls in the area between upper and lower limit of the corresponding graph, it means the dot is under control range, if not, the dot is not under control range. Each QC graph can only store up to 100 dots.

5.3.3 L-J QC List

Click "QC list" to see the test sample data. See Figure 5-5.

Figure 5-5

There are at most 100 pieces of data can be reviewed in QC list. Click  ,  ,  ,  ,  ,  , and  to review test results.

Click “Delete” to delete the selected test results.

The reference and limit shown in this interface are the value input in QC editing.

The reference and limit in QC list changes according to that in editing.

QC list save every QC test results.

5.4 X-B QC

X-B QC is a method without QC material.

5.4.1 X-B QC Edit

X-B QC is different to others. Only three parameters are edited, which are MCV, MCH and MCHC. Select X-B QC in the QC mode drop-down box, and enter X-B QC graph interface. See Figure 5-6.

Click “X-B setup” to enter edit interface. Click “Open” in XB setup, the number

between 20 to 200 is available in sample number. See Figure 5-7.

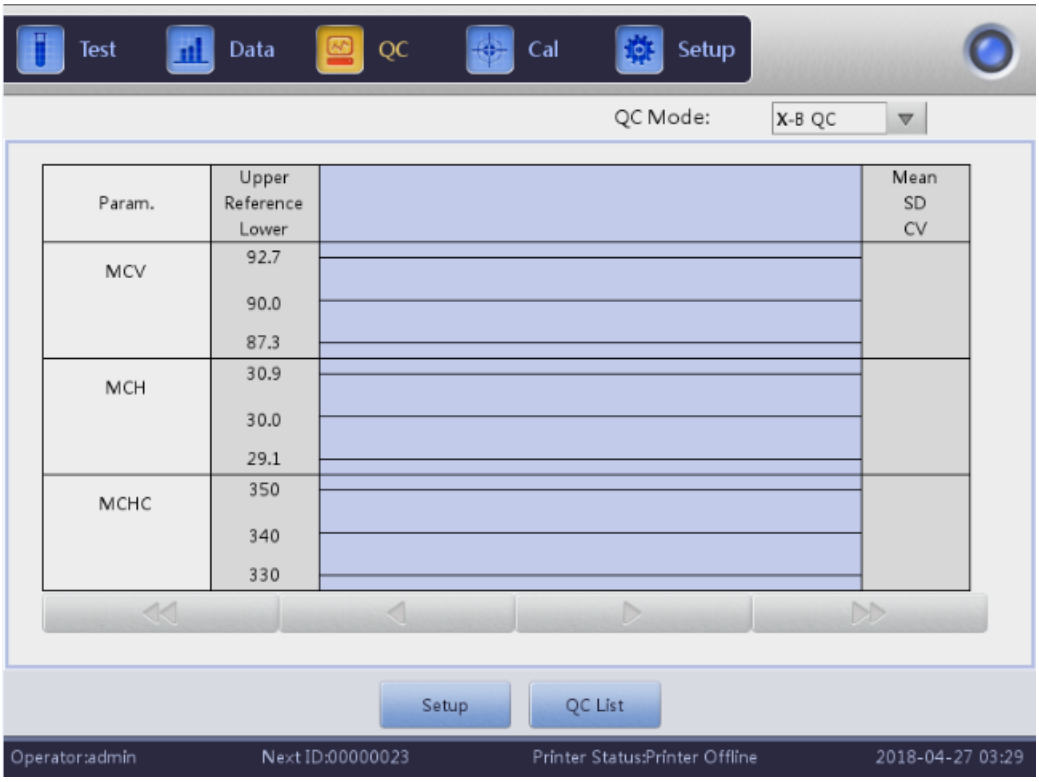

Figure 5-6

Figure 5-7

Click relevant text box to input reference and limit of MCV, MCH and MCHC. Sample validity setting is to set the valid range of RBC,MCV,MCH and MCHC. Only when the result all in the four valid range can the sample be counted by X-B QC.

"Absolute value" and "Percentage" can be selected in limit setup interface. See Figure 5-8.

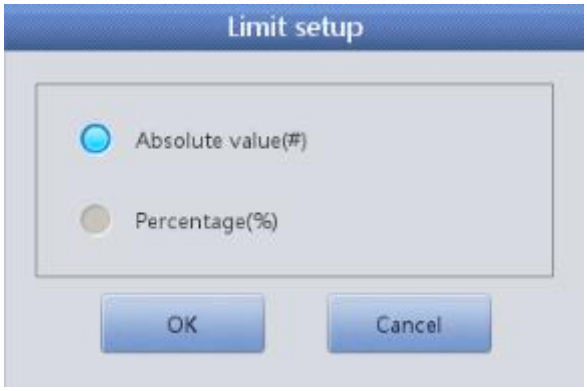

Figure 5-8

Reference is the standard value of QC count. Limit gives the allowable deviation range. Please note that the limit cannot be greater than reference, otherwise, the new limit cannot be saved in database. Click "Return" after setup. Click "OK" to save your settings in popup dialog and the setting is saved.

5.4.2 X-B QC Run

Returned to the main interface, test the sample in the test interface. The basic method of measuring X-B QC is the floating mean method.

In X-B QC setup interface, "On" and "Off" is to open and close X-B QC run. Select "On" to run the X-B QC. Sample number is to control sample amount of one group. For example, there are 20 samples in one group, the analyzer makes 20 times of X-B QC testing as choosing "On".

5.4.3 X-B QC Review

There are two ways of review, which are QC graph review and QC list review. The X-B graph is default after selecting the X-B QC mode.

QC graph review

Operator can review QC results of three parameters through graphs.

Dots of MCV, MCH and MCHC are drawn on the QC graph after a set of sample testing. For example, there are 20 samples in one group, the analyzer makes 20 times of X-B QC testing as choosing "On". One X-B QC result is automatically calculated and gets corresponding QC dot.

There are three graphs of MCV, MCH and MCHC. The graphs updates at once

after each set of QC counting.

Click  ,  ,  and  to review more test results. Each dot in graph has the corresponding date and time. The display date and time are subject to the final data's date and time within one group.

QC Graph Instruction

1. It's a graph with times of QC count on horizontal axis and results of QC count on vertical axis.
2. Every parameter graph displays 20 dots, page turning to see other dots.
3. The above line of every parameter graph means Reference plus limit.
4. The below line of every parameter graph means Reference value subtract limit.
5. The 3 values on the left side of parameter graph mean
   upper limit ——Reference + limit
   middle line ——Reference
   lower limit ——Reference –limit

If the control dot falls in the area between upper and lower limit of the corresponding graph, it means the dot is under control range, if not, the dot is not under control range.

QC list review

Operator can review QC results of three parameters through graphs. Click "QC list" in "X-B Graph" to enter the interface. See Figure 5-9.

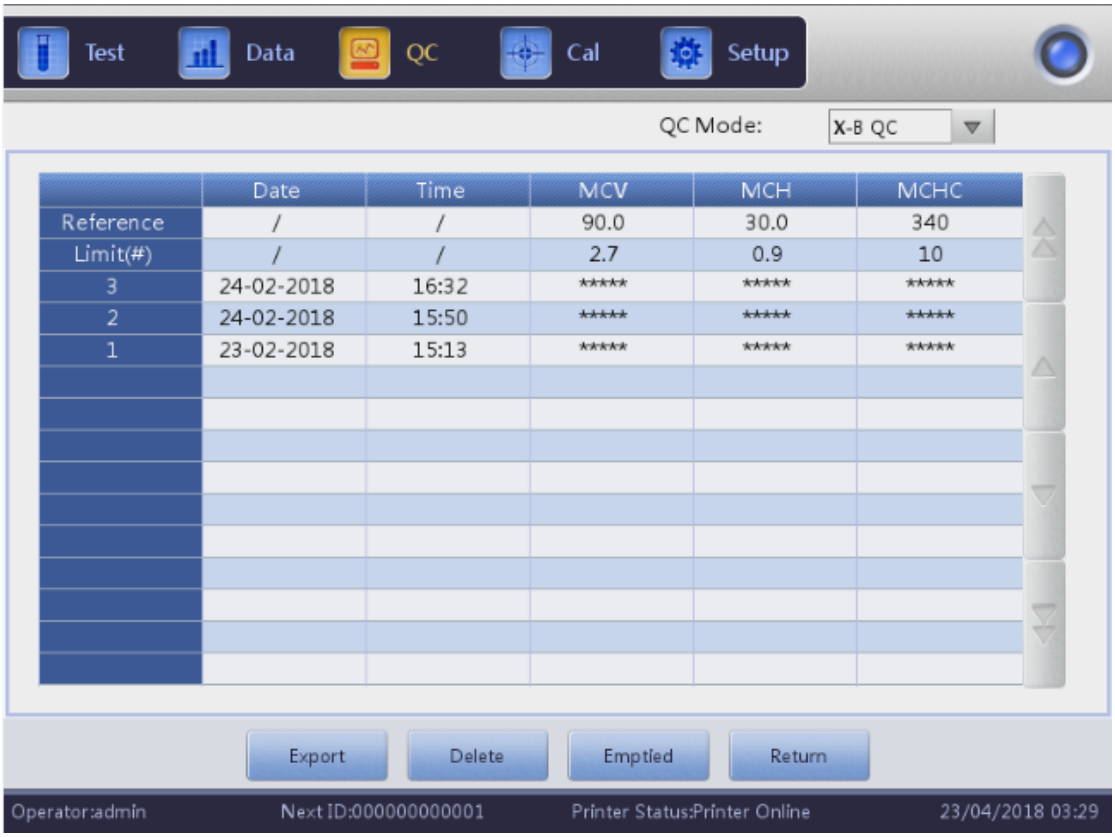

Figure 5-9

Click  ,  ,  and  to review test results. The average of a set of data is saved after testing. Click “Delete” to delete the selected test results. Click “Emptied” to delete all results. Click “Export” to export all data. Click “Return” to go back to X-B QC graph interface.

The reference and limit shown in this interface are the value input in editing. The reference and limit in QC list changes according to that in editing.

5.5 X-R QC

X-R QC which has the control material is one of the methods of QC. If running a blank count, the system alarms that QC count result is invalid.

Click “ QC” in main interface,and select the “X-R QC” in the drop-down box of QC mode. see Figure 5-10.

Figure 5-10

Setup: enter QC edit interface

QC Graph: check QC dots

QC List: check QC data

5.5.1 X-R QC Edit

Click “Setup” to edit it. See Figure 5-11.

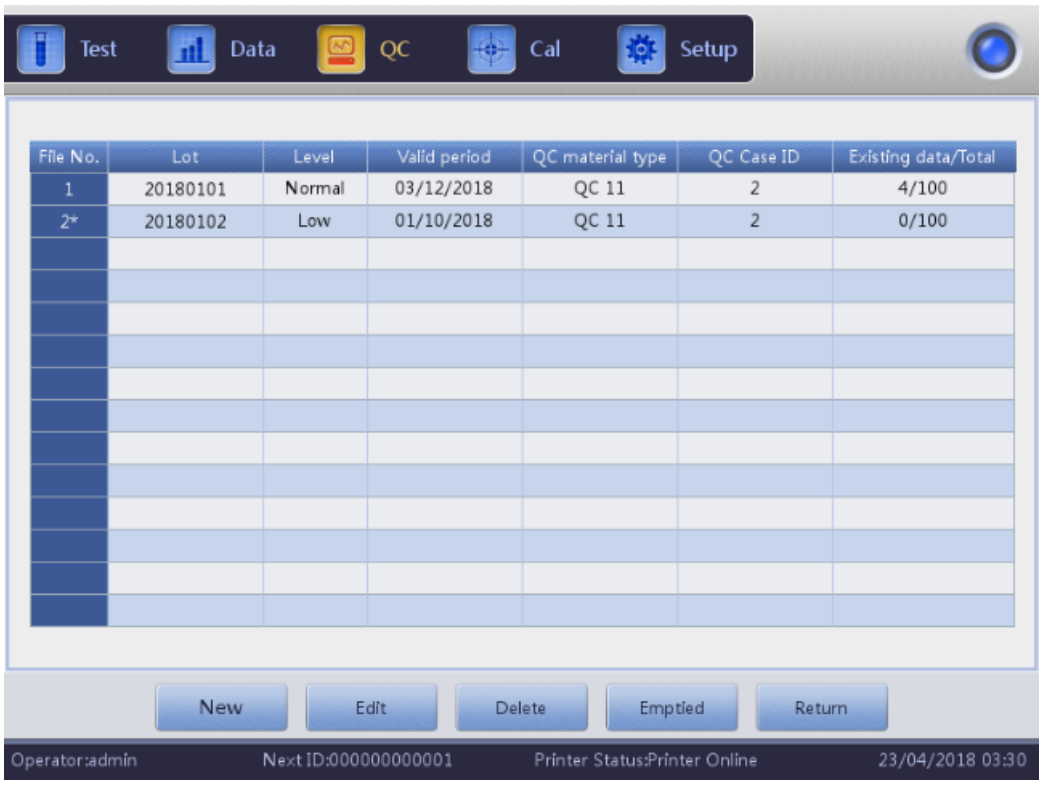

Figure 5-11

New: create a new set of QC

Edit: modify QC information which has already been edited

Delete: delete the selected QC

Emptied: delete all QC

Return: go back to X-R QC interface

Click “New” to pop up the dialog box as shown in Figure 5-12.

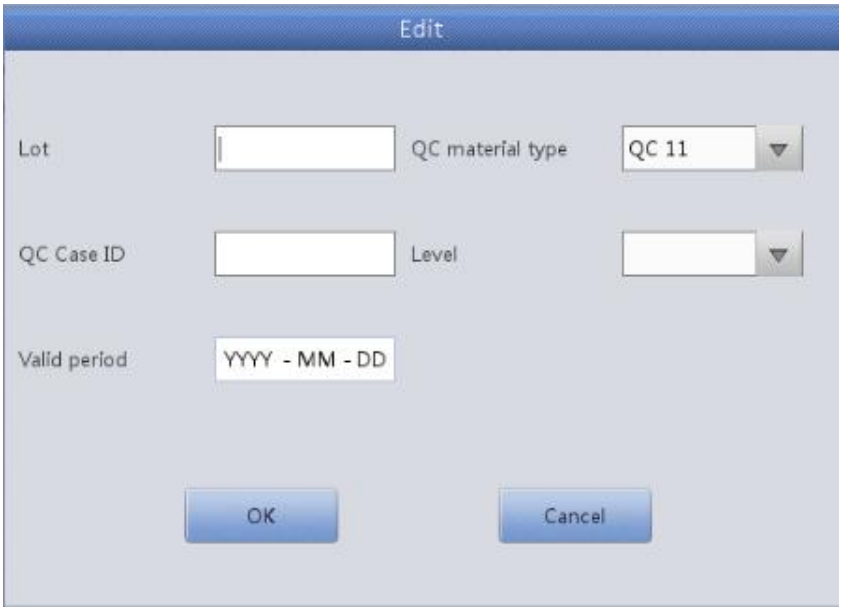

Figure 5-12

Edit information: lot, QC material type, QC case ID, level, valid period. Click " Cancel" to exit without saving. Click "OK" to save and return to edit interface. The edited QC information can be seen in edit interface. There are at most 100 sets of QC data tested

Click "Return" to go back to X-R QC interface to do QC test. The QC run interface displays two QC test results separately and automatically calculates twice mean and range after finishing the second QC count. The mean of two QC test data is one set of data.

5.5.2 X-R QC Graph

Click "QC graph" in X-R QC interface, see Figure 5-13.

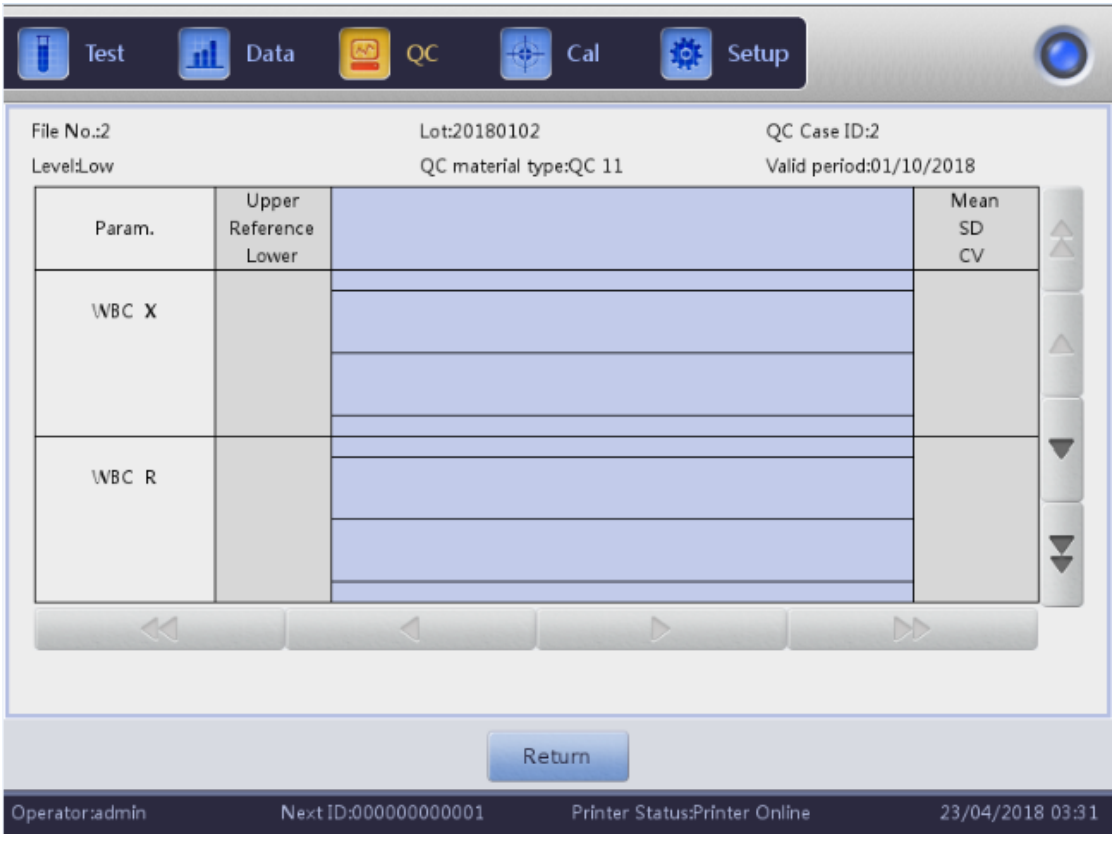

Figure 5-13

In X-R QC interface, there are X graph and R graph. X graph displays the mean value dot while the R graph displays the range dot.

If operator selects "Low" and do QC test twice, the dot is within X graph corresponding with low level. It also fits for the dots of other groups—the dot correspond with range are within corresponding R graph.

X-R Graph Instruction:

1. Graph abscissa indicates QC run times, ordinate indicates QC result.
2. Every parameter graph can display 100 dots.
3. Every parameter graph's center line indicates X (overall mean value of QC results).
4. Above line of every parameter graph means X upper limit＝X＋A×R.
5. Below line of every parameter graph means X lower limit＝X－A×R.
6. The 3 values on the left side of parameter graph mean
   upper limit —— X upper limit＝X＋A×R
   middle line —— X
   lower limit —— X lower limit＝X－A×R

R Graph Introduction:

1. It's a graph with QC times on horizontal axis and QC results on vertical axis.
2. Every parameter graph displays 100 dots.
3. Every parameter graph's center line indicates R (mean value of QC result range).
4. Above line of every parameter graph means R upper limit＝B×R.
5. Below line of every parameter graph means R lower limit＝C×R.
6. The 3 values on the left side of parameter graph mean
   upper limit —— R upper limit＝B×R
   middle line —— R
   lower limit —— R lower limit＝C×R

If the control dot falls in the area between above and below lines, it means the dot is under control range. If not, the dot is not under control range.

Click  ,  ,  and  to review test results. Click "Return" to go back to X-R interface.

5.5.3 X-R QC List

Select one set of QC in edit interface and click "QC list" in X-R QC interface. The displayed data is the selected QC data. See Figure 5-14.

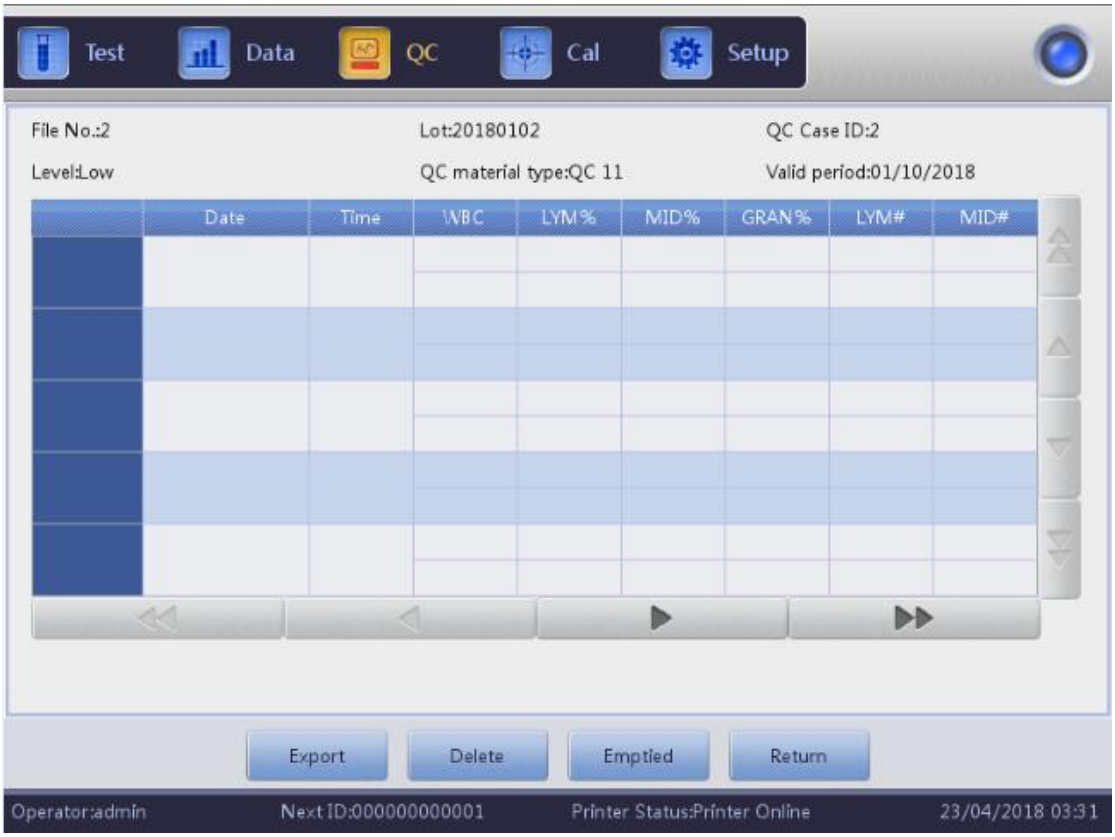

Figure 5-14

Export: export QC data

Delete: delete selected data

Emptied: delete all data

Return: go back to X-R interface

There are at most 100 pieces of data reviewed in QC list. Click  ,  ,  ,  ,  ,  ,  and  to review test results.

The X-R QC list review interface is different from X and L-J. X-R list interface only displays 5 pieces of result that includes mean value and range.

The QC data would update after running twice new controls. The data displayed in the QC list is the average of the twice QC count results.

5.6 X QC

X QC which has the control material is one of the methods of QC. The analyzer aspirates control material to operate QC. The operator could perform QC to 21 parameters. Considering the different needs, it is available to do the QC to some parameter. 3 QC documents of high, normal and low are provided for saving.

5.6.1 X QC

Click “ QC” in main interface, and select the “X QC” in the drop-down box of QC mode. see Figure 5-15.

Figure 5-15

Setup: enter QC edit
QC Graph: check QC dots
QC List: check QC data

5.6.2 X QC Edit

Click “Setup” to enter edit interface. See Figure 5-16.
New: create a new set of QC
Edit: modify QC information which has already been edited
Delete: delete the selected QC
Emptied: delete all QC
Return: go back to X QC interface

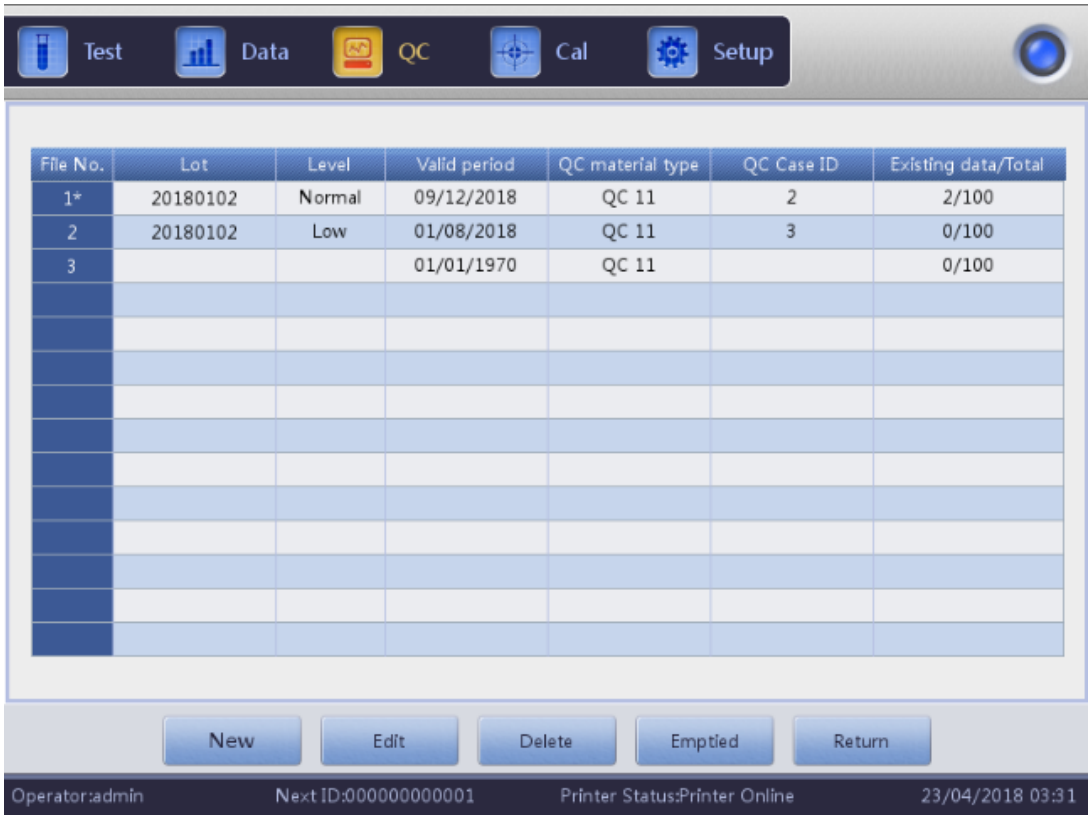

Figure 5-16

Click “New” to enter edit interface.

Lot, QC material type, QC sample NO., level, runaway mode, reference, limit and valid period can be edited. Click “Limit setup” to choose method. See Figure 5-17.

Figure 5-17

The QC run interface displays two QC test results separately and automatically calculates twice mean and range after finishing the second QC count. The mean of twice QC test data is one set of data.

5.6.3 X QC Graph

Click “QC Graph” in X QC interface, see Figure 5-18.

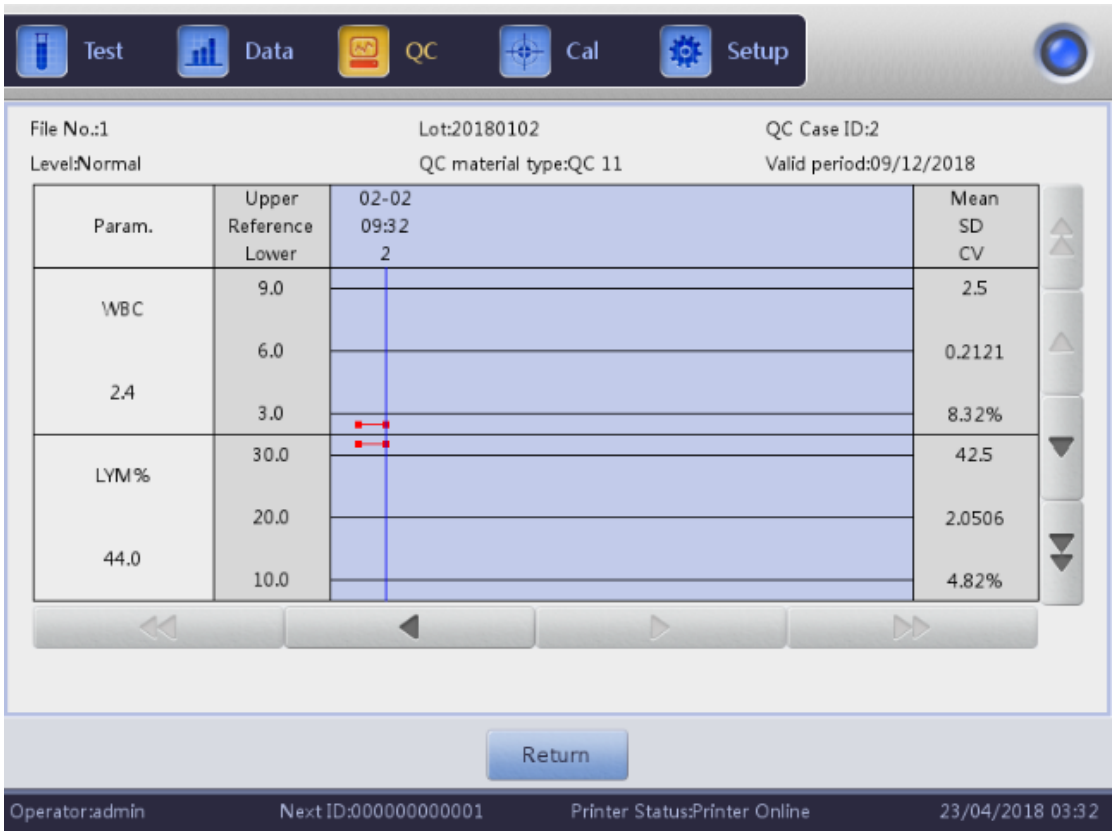

Figure 5-18

It’s almost the same as L-J QC that the operator could check 21 parameters’ result in QC graph.

Unlike L-J QC, the dot on the X QC Graph indicates the mean value of twice QC results. There are low, normal and high graphs. If select “Low” to run a control sample, the control dot presents in low graph. Other selections present in corresponding graph.

QC graph Instruction

1. It’s a graph with QC times on horizontal axis and QC results on vertical axis.
2. Every parameter graph displays 100 dots.
3. Above line of every parameter graph means Reference plus limit.
4. Below line of every parameter graph means Reference subtract limit.
5. The 3 values on the left side of parameter graph mean.
   upper limit ——Reference + limit
   middle line ——Reference

lower limit ——Reference - limit

If the control dot falls in the area between above and below lines, it means the dot is under control range. If not, the dot is not under control range.

5.6.4 X QC List

Select one set of QC in edit interface and click “QC list” in X QC interface. The displayed data is the selected QC data. See Figure 5-19.

Figure 5-19

Export: export QC data

Delete: delete selected data

Emptied: delete all data

Return: go back to X QC interface

There are at most 100 pieces of data reviewed in QC list. Click  ,  ,  ,  ,  ,  ,  and  to review test results.

Chapter 6 Calibration

Analyzer is detected and calibrated before delivery. For some reasons the result may be a little out of the range. Calibration is to insure the accuracy of results. Calibration is a process to standardize the analyzer by its deviation of value and parameter, calibration factor.

The analyzer provides three calibration modes, which are “Standard”, “Blood” and “Manual”.

COUTION: Only calibrators recommended by Avecon can be used to accomplish the calibration.
COUTION: Follow the use instruction to store and use calibrator.
COUTION: Check if the container is broken or cracked before using the calibrator.
COUTION: Make sure the calibrators are brought to room temperature and well mixed slowly before use.
COUTION: Make sure the calibrators are in the valid period.
COUTION: Make sure the analyzer without problem and precision meet the requirement before calibration.
COUTION: Never apply to the laboratory or clinic use unless all the parameters are accurately calibrated.

NOTE: Slowly remove a vial of blood calibrator from refrigerator, and warm it to room temperature by rubbing.
NOTE: Ensure the contents of a vial are well mixed by inverting the vial 30 times at least.

6.1 Calculation Frequency

To ensure precision and obtain reliable test results, the parameters (WBC, RBC, PLT, HGB and MCV) must be calibrated in the following situations.

1. Working environment changes greatly.
2. One or more parameters’ test results are moving.
3. Any major component that affects the measurement is replaced.
4. For long time no use.
5. Requirement of the laboratory or the clinic.

6. The reagent has been replaced.
7. The analyzer presents deviation when running quality control.

MCV and HCT are relative parameters to each other, thus one can be obtained from given value of the other. Only MCV can be calibrated by the analyzer. Usually the manufacturer gives the value for MCV and HCT at the same time.

WARNING: Considering all the clinic specimens, control materials and calibrators that contain human blood or serum as being potentially infectious, wear lab coats, gloves and safety glasses, and follow require laboratory or clinic procedures when handling these materials.

6.2 Preparation

Before calibration, inspect the analyzer as the following requirements.

1. Ensure the adequate reagents are in the shelf life and uncontaminated.
2. Run a blank test and make sure the results are accordance with Table 6-1.

Table 6-1

Parameter	Range
WBC	≤0.20×10^9/L
RBC	≤0.02×10^12/L
HGB	≤1g /L
PLT	≤10.0×10^9/L

3. Make sure there's no error.
4. Verify the accuracy of precision. Run continuous counting with mid-value control material or human blood for 11 times, take the results from the second to eleventh, and check CV in data interface. Make sure the CVs are accordance with Table 6-2.

Table 6-2

Parameter	Range	CV
WBC	≤3.5%	4.0×10^9/L ~ 15.0×10^9/L
RBC	≤1.5%	3.00×10^{12}/L ~6.00×10^{12}/L
HGB/	≤1.5%	100 g/L ~180g/L
HCT	≤2.0%	35%~50%
MCV	≤1.0%	76fL ~110fL
PLT	≤4.0%	100×10^9/L ~500×10^9/L

6.3 Calibration Modes

6.3.1 Manual Calibration

Click “Manual” in “Cal” interface. See Figure 6-1.

The principles of new calibration value

- Mean value=(value1+value2+value3+value4)/4
- New calibration value=(reference/mean value)×former calibration value
- If the new calibration value<70%, consider it equals to 70%, if the new calibration value>130%, consider it equals to 130%

For example, the reference value of PLT of the calibrator is 220, current calibration value is 103% and mean value is 230, thus the new calibration value is

New calibration value =103%×220/230=98.52%

Input calibration value after calculation and click “OK” to save it.

Figure 6-1

Click “Save” to save the new calibration value in database.

Click “Print” to print calibration value.

Click “Export” to export data sheet.

NOTE: The analyzer can calibrate a certain or all parameters of WBC，RBC，HGB，MCV，MPV, RDW_CV, RDW_SD, PLT，PDW_CV and PDW_SD.
NOTE: Do remember click “OK” to save calibration value before exiting Cal interface.

Validation of Calibration coefficient

After calibration, Avecon recommends to follow the steps to validate the calibration coefficients.

1. Test the calibrators three times at least, and check whether the results are within the allowed range.
2. Test level “High”, “Normal” and “Low”, and each one should be tested for three times at least. Check whether the results are within the allowed range.
3. Analyze three normal fresh blood samples, three times for each at least.

NOTE: The calibration coefficient is allowed in the range of 70%~130%, if the test values exceed the limit, the critical value in the limit range should be selected as the new coefficient for calibration. And in that case, operator should find out reasons and calibrate again.

6.3.2 Standard Calibration

Click “Standard” in “Cal” interface as Figure 6-2.

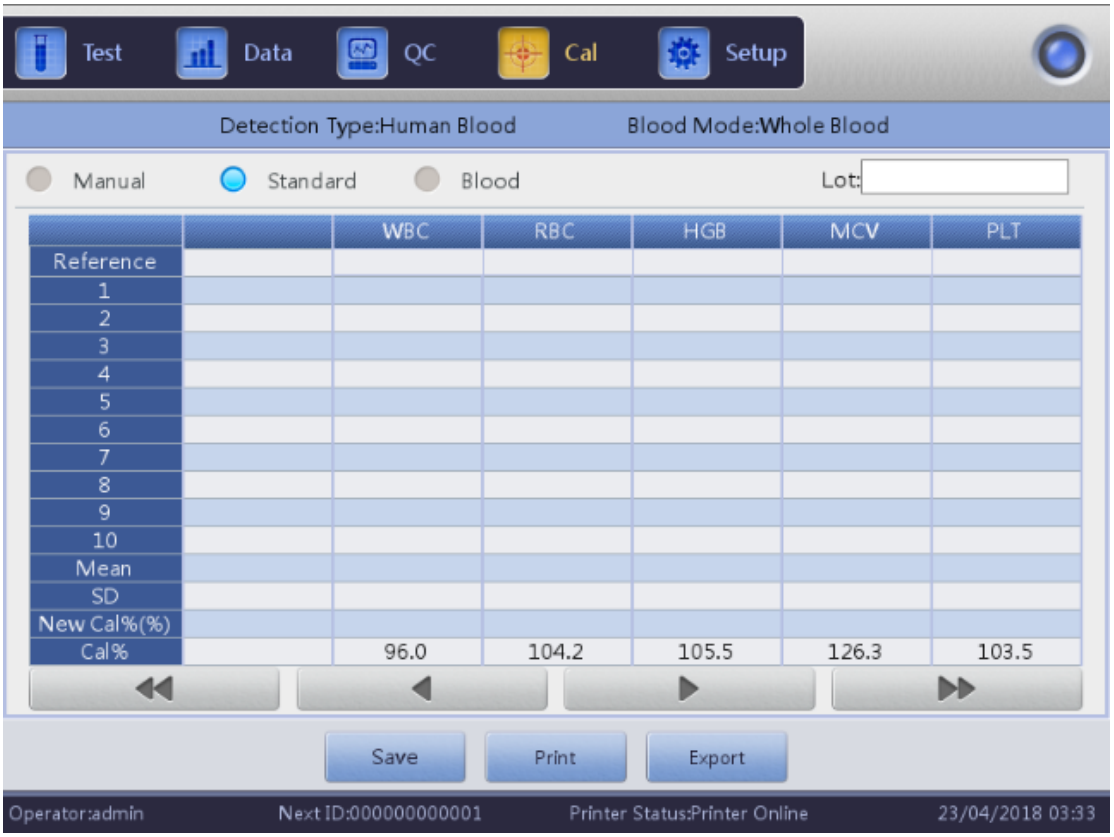

Figure 6-2

Please calibrate according to the following procedures

1. Input batch number according to Operation Manual.
2. Input reference according to Operation Manual, those reference values of parameters which do not need to be calibrated is blank.
3. Click “Test” to start calibration. The analyzer could automatically calculate the mean value of 10 tests at most. Avecon recommend testing 3 to 5 times at least.
4. The new calibration coefficient is automatically calculated according to the reference value of calibrators and mean.
5. Click “OK” to save new calibration coefficient, click “Print” to print the new calibration coefficient.
6. Click “Export” to export the backup calibration coefficient data.

Validation of Calibration coefficient

After calibration, Avecon recommends to follow the steps to validate the calibration coefficients.

1. Test the calibrators three times at least, and check whether the results are within the allowed range.
2. Test level “High”, “Normal” and “Low”, and each of it should be tested for three times at least. Check whether the results are within the allowed

range.

3. Analyze three normal fresh blood samples, three times for each at least. And check whether the results are within the allowed range.

Input reference in standard mode. Put the prepared calibrator under the aspiration probe and press button on the front housing. Counting starts and display test results in box. The first calibration test result display in value 1, and so on. The analyzer recalculates the new calibration value based on the reference and the measured mean after each counting.

The principles of new calibration value

$$\text{Mean}=\frac{\sum_{i=1}^{n} X_i}{n}$$

New calibration value=(reference/mean value)×former calibration value.

If the new calibration value<70%, consider it equals to 70%, if the new calibration value>130%, consider it equals to 130%.

6.3.3 Blood Calibration

Click “Blood” in “Cal” interface. See Figure 6-3.

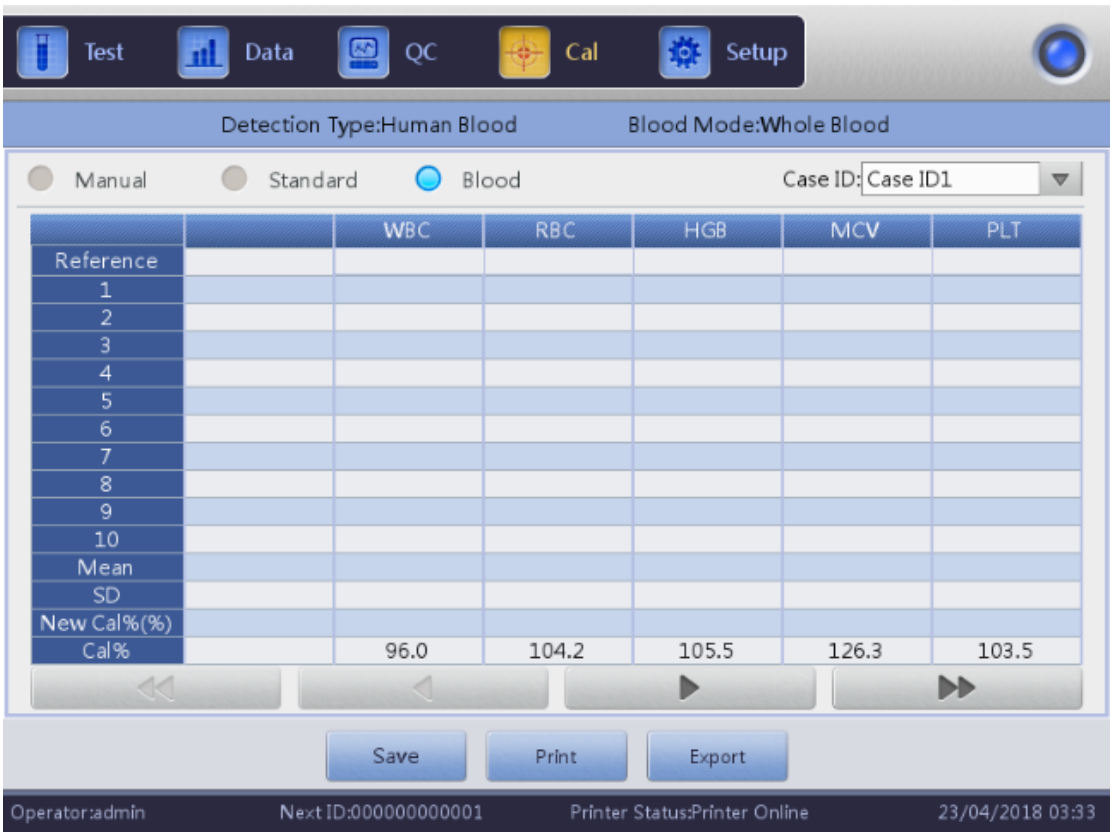

Figure 6-3

Calibrate the analyzer as follows.

1. Prepare 5 normal whole blood samples and test each of the prepared samples by other types of analyzer at least 5 times to get the mean and input the mean value into the reference value frame.
2. Select SN1 sample and press count button to make 5-10 times of counting and get mean value. Select SN 2 sample and make 5-10 times of counting and get mean value. And so on, for each of the five samples.
3. The system adds the measured values and calculates the average of parameters. System automatically calculates new calibration coefficient via reference, mean value and calibration coefficient.
4. Click “OK” to save new calibration coefficient, click “Print” to print it.
5. Click “Export” to export the backup calibration coefficient data.

New calibration value=(reference/mean value)×former calibration value

If the new calibration value<70%, consider it equals to 70%, if the new calibration value>130%, consider it equals to 130%

NOTE: Please remember click “OK” to save counting results before exit.

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 21 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.

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

7.1 Limit Review

At Limit Setting screen, operator may input proper parameter limits or use the default limits. Default limits are different depending on the patient group. Figure 7-1 depicts the Man group limits. Figure 7-2 depicts the User 1 group limits.

Figure 7-1

Figure 7-2

Click “group”, and select man, woman, Children, infants, newborns, general, custom1, custom2 and custom3. see Figure 7-3.

Figure 7-3

Click “Def.”, the system restore to factory setting. For example, click “Def” in the man group interface, the limit of man group restore to factory setting.

7.2 Limit Modification

Operate as following procedures to modify the parameter limit:

1. At main menu screen, click “Func”, then click “Limit” to enter limit setting screen.
2. Click “Group”, the screen displays the lower and upper limits of current group of parameters.
3. Click “Save” and the dialog below pops up. Clicking “Cancel” the interface goes back to parameter limit without modification. Click “OK” to save the modification.

Figure 7-4

7.3 Print

Click “Save” to save the edited group limit.
Click “Export” to output the current group limit.
Click “Print” to print the current group limit.
Click “Return” to return to setting interface.

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 Avecon Customer Support Centre.

Preventive maintenance should be performed daily, weekly and monthly. 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: Perform individual protection before instrument maintenance, such as wear glove, respirator, lab coat etc.

8.1 Daily Maintenance

HMT-70P is designed with daily auto-maintenance program. As in Figure 8-1, operator can select the auto-clean time to maintain the system. Please refer to Table 8-1 for time setting.

Table 8-1

Run time (hour)	Time for auto-clean (hour)
> 8	4
4< Run time<8	4
Run time< 4	2

Figure 8-1

8.2 Weekly Maintenance

8.2.1 Surface Maintenance

Clean the smudge on the surface of analyzer, especially the spilt blood on the aspiration probe and surrounding, to remove the protein buildup or debris and reduce the possibility of a blockage. Wipe the outside of the probe and surrounding 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 detergent.

8.2.2 Monthly Maintenance

Monthly maintenance mainly aims at mechanism maintenance, including lubricate motor axis of dilution unit, X, Y leaders of sampling organ etc.

NOTE: Ensure the power of host is off before monthly maintenance,

8.3 System Maintenance

Click “Setup” and then “maintenance” to enter maintenance interface. See Figure 8-2.

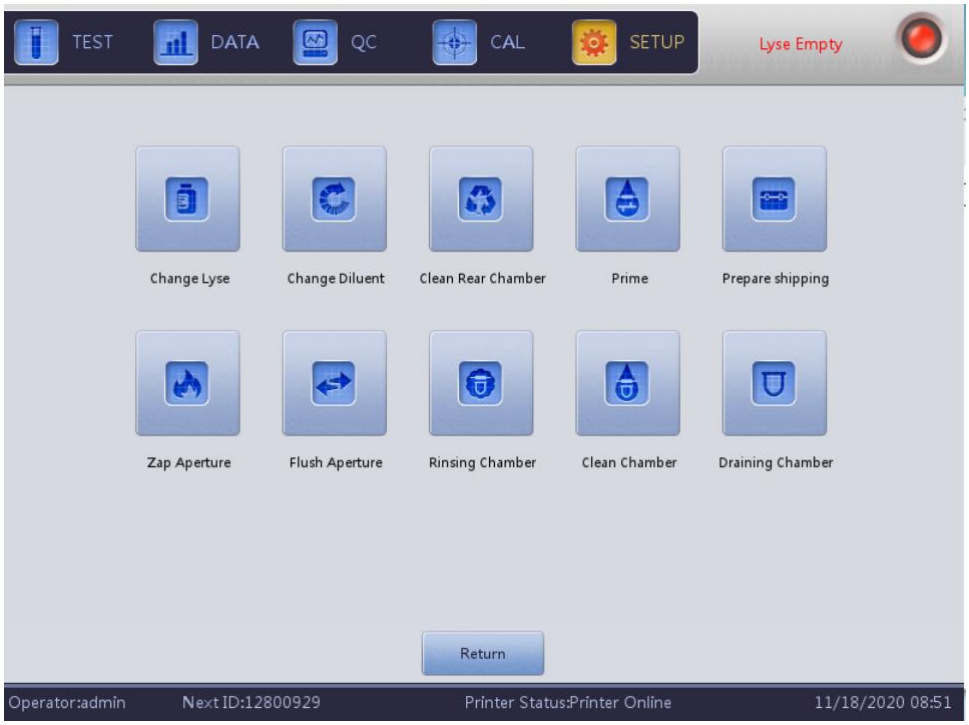

Figure 8-2

HMT-70P offers ten maintenance functions as follows:

- Cauterize Aperture
- Flush Aperture
- Clean cups
- Rinsing cups
- change lyse
- Change Diluent
- Clean Rear Chamber
- Prime
- Prepare Shipping

8.3.1 Cauterize Aperture

Cauterize Aperture may prevent and remove aperture clogs. Procedures as follows:

1. Select “Cauterize Aperture” at maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.
3. The operation is completed and back to the maintenance screen.

8.3.2 Flush Aperture

Flush Aperture may prevent and remove aperture clogs associating with Cauterize Aperture. The procedures as follows:

1. Select “Flush Aperture” in maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.
3. 3. The operation is completed and back to the maintenance screen.

8.3.3 Draining Cups

This operation will drain diluent out of WBC and RBC cups.

8.3.4 Clean Cups

This operation may rinse the aperture to prevent blockage if the counting time is too long. The procedures as follows:

1. Select “Rinse Cups” in maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.
3. The operation is completed and back to the maintenance screen.

8.3.5 Rinsing Cups

CAUTION: Consider the probe detergent is corrosive, operator should wear lab coats, gloves, and follow required laboratory or clinical procedures.

This operation may prevent blockage if the counting time is too long. Probe detergent is a kind of alkalescence detergent. Performance of Rinsing Cups is to rinse the WBC and RBC cups, and related tubing with probe detergent. If the analyzer is non-turnoff, perform Tubing Clean every three days. If the analyzer is turnoff the power daily, perform Rinsing Cups every week.

The procedures as follows:

1. Place the probe detergent under the aspiration probe, making the probe be able to aspirate the detergent. Select “Rinsing Cups” at Maintenance interface.
2. Click “Yes” in the promote dialog. Take the detergent away after the sample probe retracting back. About 10 seconds later, the probe return to initial position. When the analyzer promotes sucking up detergent again, place the probe detergent under the sample probe, and click “Yes”. Then progress bar displays. It takes about 6 minutes.
3. The operation is completed and back to the Maintenance interface.

8.3.5 Change Lyse

CAUTION: Consider all clinical specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear lab coats, gloves and safety glasses and follow required laboratorial or clinical procedures when handling these materials.

NOTE: Keep the lyse still for a certain time to ensure it stable.

NOTE: After replacement of diluent or lyse, perform background test to make sure the background values are in acceptable range.

In the following conditions, perform this operation:

- There are bubbles in lyse tubing.
- Replace a new lyse.

The procedure is as follows:

1. Select “Change Lyse” in maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.
3. The operation is completed and back to the maintenance screen.

8.3.6 Change Lyse

CAUTION: Consider all clinical specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear lab coats, gloves and safety glasses and follow required laboratorial or clinical procedures when handling these materials.

NOTE: Keep the diluent still for a certain time to ensure it stable.

NOTE: After replacement of diluent or lyse, perform background test to make sure the background values in acceptable range.

In the following conditions, perform this operation:

- There are bubbles in diluent tubing.
- Replace a new diluent.

The procedures as follows:

1. Select “Prime Diluent” in maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.
3. The operation is completed and back to the maintenance screen.

8.3.7 Change Diluent

CAUTION: Consider all specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear lab coats, gloves and

safety glasses and follow required laboratorial or clinical procedures when handling these materials.

NOTE: After replacement of diluent or lyse, perform background test to make sure the background values in acceptable range.

In the following conditions, perform this operation:

- There are bubbles in diluent tubing.

The procedures as follows:

1. Select “Change Diluent” in maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.
3. The operation is completed and back to the maintenance screen.

8.3.8 Clean Rear Chamber

CAUTION: Consider all clinical specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear lab coats, gloves and safety glasses and follow required laboratorial or clinical procedures when handling these materials.

NOTE: After replacement of diluent or lyse, perform background test to make sure the background values in acceptable range.

In the following conditions, perform this operation:

1. There are bubbles in diluent tubing.
2. Replace a new diluent.

This operation may rinse the associated fluidics. The procedures as follows:

1. Select “Clean Rear Chamber” in maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.
3. The operation is completed and back to the maintenance screen.

8.3.9 Prime

CAUTION: Consider all specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear lab coats, gloves and safety glasses and follow required laboratorial or clinical procedures when handling these materials.

The procedures as follows:

1. Select “Prime” in maintenance screen.
2. The analyzer starts to perform the function and all buttons turn to gray.

3. The operation is completed and back to the maintenance interface.

8.3.10 Prepare Shipping

Perform this function before shipping or leave unused for a long time. Refer to the 8.5 section for details. The procedures as follows:

1. Select “Prepare Shipping” in maintenance screen.
2. The analyzer starts to perform the function and all butons turn to gray
3. The operation is completed and back to the maintenance screen.

8.4 Components Replacement

Portunity and Required Tools for the analyzer components replacement

Name	Replacement Opportunity	Required Tools
Sample probe	1.Sample probe is bent or out of shape. 2.Sample probe is clogged, resulting in draining liquid and aspirating sample failure. 3.Surface is rusty.	Cross screwdriver, tweezers
Probe wiper	After 40000 sample tests.	Tweezers
Liquid filter	1.After 100000 sample tests. 2.Service for 5 years or more.	Tweezers
Air filter	Surface is rusty.	Tweezers
Diluter seal ring	After 40000 sample tests.	Cross screwdriver, tweezers
Clock battery	14 months or unexpected time loss.	Tweezers

8.5 Maintenance before Shipping

If the analyzer is leaved unused for three months or before shipping, maintain the analyzer as following:

a) Take out the diluent inlet tube connecting with diluent port on the right panel from container, discharge the diluent remained in tube.
b) Take out the lyse inlet tube connecting with lyse port on the right panel from container, discharge the lyse remained in tube.
c) Keep the remaining reagents in their containers and store them according to the instructions. Operator should establish and conform

to effective storage measures to prevent reagent from deteriorated, misusage or missdrinking.

d) Keep the diluent, lyse inlet tubes hang in the air.

e) At main menu screen, click “Prime” several times until the top right corner of the screen present No Diluent, No Lyse. Click “Prime” once again.

f) Insert diluent, lyse tubes into distilled water.

g) At main menu screen, click “Setup”, then click “Maint”, and then click “Prepare Shipping”. See Figure 8-3.

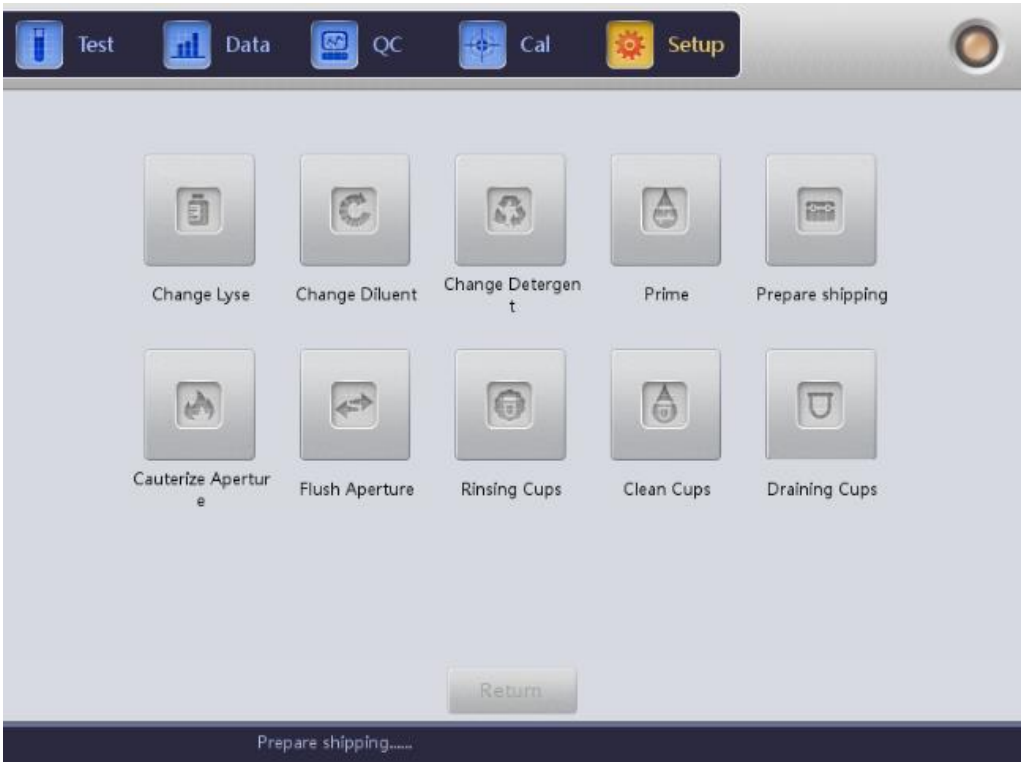

Figure 8-3

h) After completed, take out the diluent, lyse tubes from distilled water and click “Prepare Shipping” again to drain the reagent in tubes.

i) At main menu screen, click “Shutoff”, “Thank you, now turn off power” will appear to instruct the operator to turn off the power switch on the rear panel.

j) Pull out outlet tubes from the rear panel, clean it with distilled water and save it with plastic bag after dry by airing.

k) Cover the connectors of DILUENT, LYSE and WASTE on the rear panel with caps which taken out at initial installation

l) Disconnect the power cord of analyzer and save it in plastic bag.
Place the analyzer and components in plastic bags into the shipping carton.

Chapter 9 Service

This chapter introduces the Service function, with which operator may check the system status, valve and motor status, etc. More information is available at Avecon Customer Support Centre.

CAUTION: Incorrect maintenance may lead to analyzer function impaired. Please maintain the analyzer according to this manual.
NOTE: If there is any problems which cannot be find an answer in the manual, please contact the Avecon Customer Support Centre.

9.1 System Check

Click “Setup” at main menu screen, select “Service”, input “2006” in the pop-up dialog box to enter the System Check screen.

9.1.1 System Status Check

The System Status Check screen presents the current status information like temperature, vacuum etc.. See Figure 9-1.

Figure 9-1

NOTE: At System Status Check screen, operator may view the value of temperature, vacuum, etc. but cannot modify these values.
Click “Return” to return to the main menu screen.

9.1.2 Valve Check

At Valve Check screen (see Figure 9-2), the operator can check if the valves in normal condition.

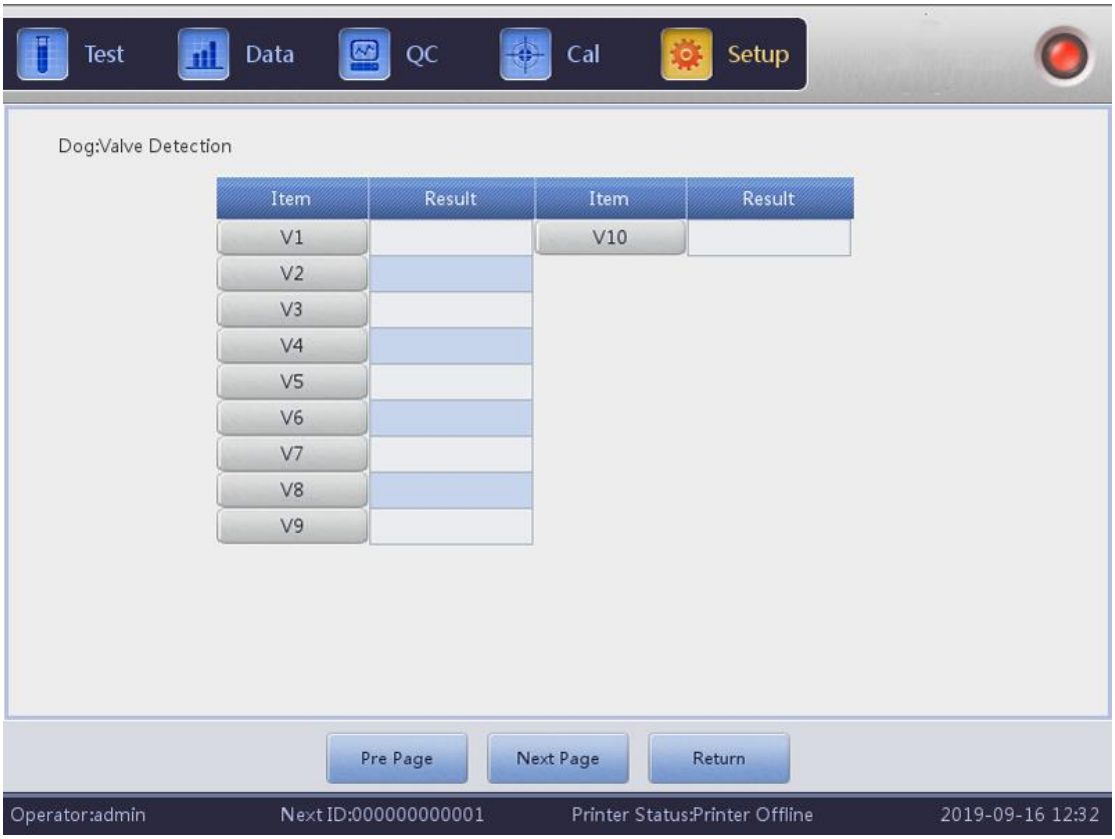

Figure 9-2

At Valve Check screen, click valve numbered, the corresponding results will be displayed.

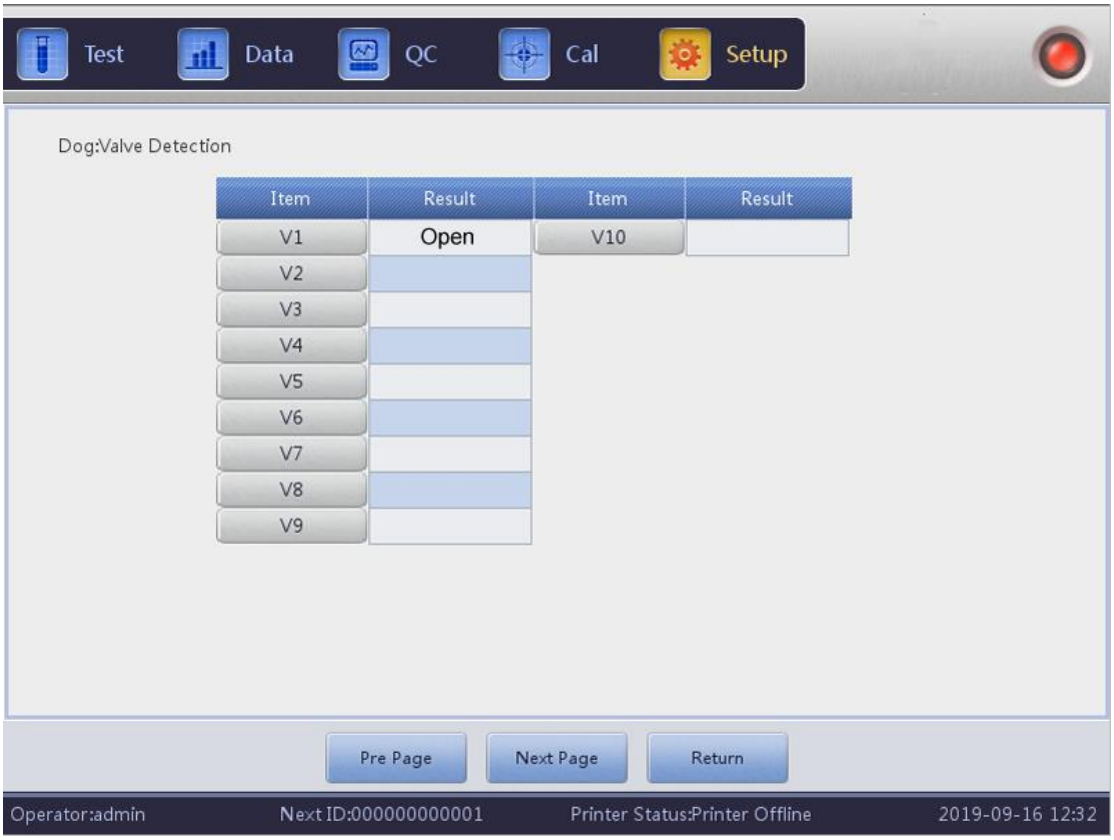

Figure 9-3

Click "Return" to return to the main interface of the system.

9.1.3 Motor Check

At Motor Check interface, the operator can check if the motors in normal condition. At the screen, click motor icon, the corresponding result will be displayed. See Figure 9-4.

Figure 9-4

Click "Return" to return to the main interface of the system.

9.2 System Log

Click “Setup” at main menu screen, select “System log”, enter the System Log screen as Figure 9-5.

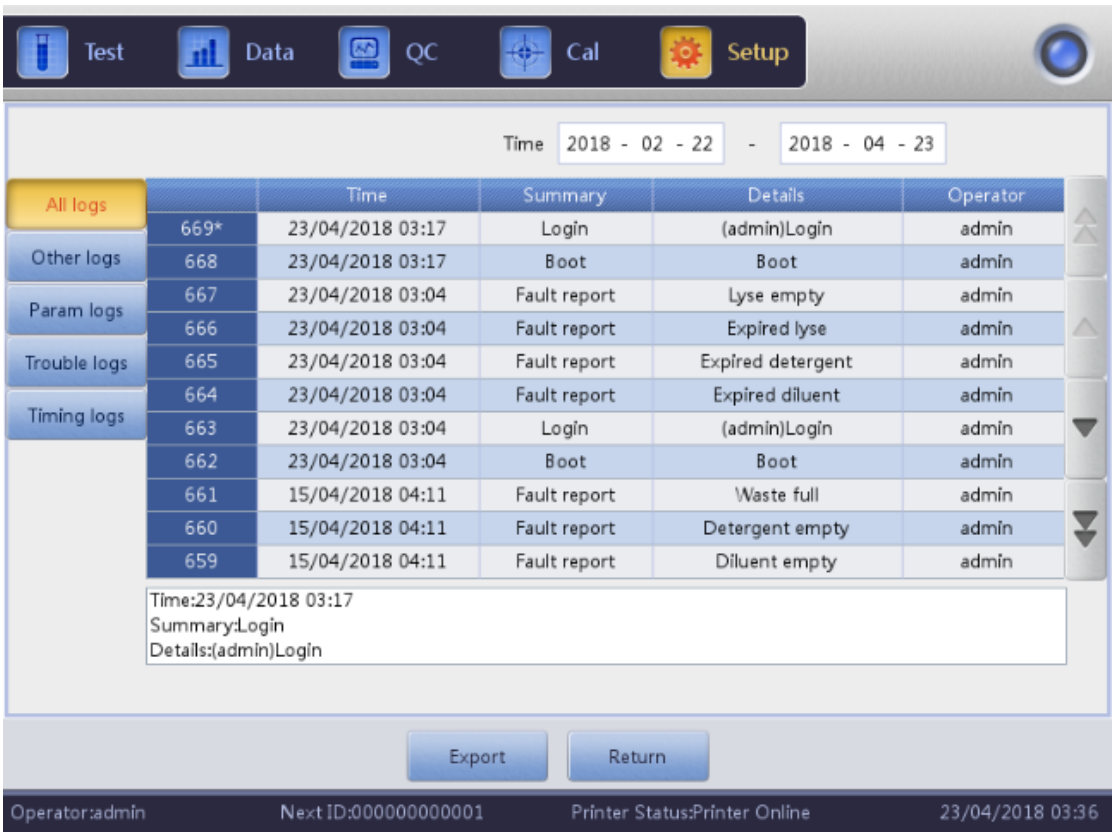

Figure 9-5

9.2.1 Date Query

In the system log query interface, select the begining and ending date and press Enter on the keyboard. Then the system log list displays. Besides, select the shortcut key on the left interface to make a shortcut query according to the log type. See Figure 9-5.

After the system log query, the analyzer can do the following operations:

1. Click “Export” to output the eligible system log. See Figure 9-6.
2. Click “Return” to exit the current interface.


Export
Time
2018 - 02 - 26
-
2018 - 04 - 27
All records
Chosen record
OK
Cancel

Figure 9-6

Chapter 10 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 Avecon Customer Support Centre.

10.1 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 Avecon 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 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 Avecon authorized engineer. The operator can correct sample measurement problems with assistance from Avecon 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.

10.2 Obtaining Technical Assistance

Technical Assistance is obtained by calling the Avecon 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)
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.

10.3 Troubleshooting

Familiar problems and corrective actions are listed as follows. If the problems can not be corrected, or technical assistance is needed, please contact with Avecon Customer Support Centre.

10.3.1 Faults Related to Reagents

Fault	Probable Cause	Corrective Action
Lyse Empty	1. Lyse is run out or lyse inlet tube is blocked. 2. Lyse inlet tube has bubbles.	1. Check that if the lyse is run out. 2. Perform Setup → Maintenance →Change Lyse. 3. If fault still occurs, please contact with Avecon.
Diluent Empty	1. Diluent is run out. 2. Diluent inlet tube has bubbles.	1. Check that if the diluent is run out. 2. Perform Setup →Maintenance →Change Diluent. 3. If fault still occurs, please contact with Avecon.

Waste Full	Waste container is full or waste sensor is in fault.	1. Check that if the waste is full. 2. Check that if the sensor is wet or short circuit. 3. If fault still occurs, please contact with Avecon.

10.3.2 Faults Related to Vacuum

Fault	Probable Cause	Corrective Action
Low Vacuum	The vacuum doesn't reach the standard value.	1. Click "Sevice", input password 2006 to enter System Check screen, ensure the vacuum items are in normal condition. 2. If fault still occurs, please contact with Avecon.

10.3.3 Faults Related to 5V Voltage

Fault	Probable Cause	Corrective Action
5V Voltage Problem	Power supply module abnormal.	1. Click "Sevice", input password 2006 to enter System Check screen, ensure the 5V Voltage in normal condition. 2. If fault still occurs, please contact with Avecon.

10.3.4 Faults Related to Test Value

Fault	Probable Cause	Corrective Action
High Background Value	Diluent is contaminated or overdue; diluents tube or cups contaminated.	1. Check that if the diluent is overdue or contaminated. 2. Enter maintenance screen and perform Prime. 3. If fault occurs, Perform Rinsing Cups at maintenance screen using probe detergent. Run a background test again to check if the fault disappeared. 4. If fault still occurs, please contact with Avecon.
HGB Inaccuracy	1. HGB background voltage hopping 2. Sample cup is dirty.	1. Click “Sevice”, input password 2006 to enter System Check screen, check the HGB_BACK and HGB_ZERO. 2. If the HGB_BACK and HGB_ZERO are out of range, contact with Avecon to modify the values. 3. Perform Prime and then run a background test to check if the HGB_BACK issatisfactory.
WBC Clog or RBC Clog	Ruby aperture clogged; WBC counting time incorrect; solenoid valve problem	1. Perform Cauterize Aperture or Flush Aperture in Maintenance, and then run a background test to check the counting time. 2. If fault occurs, perform Rinsing Cups in Maintenance. aspirate the probe detergent and rinse aperture. 3. If fault still occurs, please contact with Avecon.

10.3.5 Faults Related to Hardware

Fault	Probable Cause	Corrective Action
Motor sounds abnormally.	1. motor connecting wire loose 2. travel switch problem 3. motor problem 4. motor drive circuit problem	1. Click “Sevice”, input password 2006 to enter System Check screen, ensure the motor items are in normal condition. 2. If fault still occurs, please contact with Avecon.
Counting time is too long or no counting time.	1. Ruby aperture clogged. 2. Valve no movement.	1. If the fault occurs after eliminate the aperture clog, click “Sevice”, input password 2006 to enter System Check screen, ensure the Valves are in normal condition. 2. If fault still occurs, please contact with Avecon.

10.3.6 Faults Related to Temperature

Fault	Probable Cause	Corrective Action
Temperature abnormal	Temperature abnormal or temperature sensor problem.	1. Click “Sevice”, input password 2006 to enter System Check screen, check the temperature in System Status Check. 2. If the temperature is out the range of 15 ℃ -30 ℃ , please adjust the air conditioner to ensure the temperature is in the range. 3. If fault still occurs, please contact with Avecon.

Chapter 11 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.

11.1 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, Avecon will not offer free warranty.
c) Avecon 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 Avecon, if any problems derived from that, Avecon 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.

11.2 Location Limitations

a) A Avecon 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. Please do not placed the instrument in the location where difficult to operate the disconnect device. Adequate space should be provided around the analyzer to perform necessary maintenance procedures.

e) 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.
f) 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 Avecon should NOT remove the screws on the cover, or the customer must take all the responsibility.

11.3 Safety 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 clinical specimens, controls and calibrators etc. that contain human blood or serum as potentially infectious. Wear standard laboratory clothing, gloves and safety glasses and follow required laboratorial 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) 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 A: Instrument Specifications

Dimension and Weight

Dimension:
380mm(L)×305mm(W)×395mm(H)
Weight: 18Kg

Environmental Requirements

Temperature: 10℃~35℃
Relative Humidity: 20%～85%
Barometric: 60kPa~106kPa

Transport and Storage Specifications

Temperature: -10℃~55℃
Relative Humidity: 10%～93%
Barometric: 50kPa~106kPa

Power Specifications

Power Supply: AC 100V～240V
Frequency: 50/60Hz
Power: 130VA-180 VA
Fuse: 250V/3.15A

Appearance Specifications

Display: 10.4-inch LCD
Language: English/Simplified Chinese
Parameter: 21 parameters and 3 histograms
Indicator: Status Indicators/Work Mode Indicators
System Alert: Alert message/Alert beep
Ports: Power Receptacle
Printer Ports
RS-232 Port
USB Ports

Recorder Specifications

Recorder Width: 48mm
Paper width: 57.5mm
Paper Roll Diameter: 50mm
Print Speed: 12.5 mm/S

Sample Volume

Whole Blood Mode:	Whole Blood	8.5μL
Pre-diluent Peripheral Blood Mode:	Peripheral Blood	20μL
Anticoagulated Peripheral Blood Mode	Peripheral Blood	8.5μL

Reagent Volume for Single Sample

Diluent: 25mL

Lyse: 0.4mL

Background

WBC≤0.2×10^9/L；RBC≤0.02×10^{12}/L；HGB≤1g/L；PLT≤10×10^9/L

Carryover

WBC≤0.5%；RBC≤0.5%；HGB≤0.6%；PLT≤1.0%

Accuracy

Table A-1 Accuracy Specifications

Parameter	Acceptable Limits（%）	Accuracy Range
WBC	≤±8.0%	3.5×10^9/L～9.5×10^9/L
RBC	≤±4.0%	3.8×10^{12}/L～5.8×10^{12}/L
HGB	≤±4.0%	115g/L～175g/L
MCV	≤±3.0%	80fL～100fL
HCT	≤±5.0%	35%～50%
PLT	≤±10.0%	125×10^9/L～350×10^9/L

Precision

Table A-2 Precision Specifications

Parameter	Acceptable Limits（CV/%）	Precision Range
WBC	≤3.5%	3.5×10^9/L～6.9×10^9/L
	≤2.0%	7.0×10^9/L～15.0×10^9/L
RBC	≤1.5%	3.00×10^{12}/L ~6.00×10^{12}/L
HGB	≤1.5%	100 g/L ~180g/L
HCT	≤2.0%	35%~50%
MCV	≤1.0%	76fL ~110fL
PLT	≤5.0%	100×10^9/L～149×10^9/L
	≤4.0%	150×10^9/L～500×10^9/L

Linearity

Table A-3 Linearity Specifications

Parameter	Linearity Range	Acceptable Limits
WBC	0×10^9/L~10.0×10^9/L	≤±0.3×10^9/L
	10.1×10^9/L ~99.9×10^9/L	≤±5%

RBC	0×10^{12}/L ~1.00×10^{12}/L	≤±0.05×10^{12}/ L
	1.01×10^{12}/L ~9.99×10^{12}/L	≤±5%
HGB	0 g/L ~70 g/L	≤±2g/L
	71 g/L ~300 g/L	≤±2%
PLT	0×10^{9}/L ~100×10^{9}/L	≤±10×10^{9}/L
	101×10^{9}/L ~999×10^{9}/L	≤±10%
HCT	0%～67%	±4%(HCT) or ±6%

Appendix B: Instrument Icons and Symbols

Caution

Caution, risk of electric shock

Biohazard

Equipotentiality

Protective Grounding

Protect from heat and radioactive sources

Consult Instruction for Use

For In Vitro Diagnostic Use

Serial Number

Manufacturer

Metrology Certification

Appendix C: Communication

The system transfers sample data and analyzer information to outer computer through RS-232 COM. This operation can be done automatically after analysis or manually when the instrument is in idle mode. This appendix explains the settings of communication parameters and data communication formatter for easy operation.

Before communication, please ensure the analyzer has connected with outer computer through appropriate COM.

Communication can be done in hexadecimal format or ASCII format.

1 Hexadecimal Format Communication

1.1 Data Link MAC Sublayer Parameters Convention

Baud Rate: 115200
Parity Digit: None
Data Bit: 8 bits
Stop Bit: 1 bit

1.2 Data Link Layer Frame Format

1.2.1 Frame Format

STX	LENGTH	Message	ETX	LRC

1.2.2 Meaning of Each Field or Control Field

Name	Meaning	Value
STX	Start of Text	0x02
ETX	End of Text	0x03
Message	Sending Message	Determine by Message content.
LENGTH	Length (2 bytes)	Determine by Message length
LRC	Checksum	Determine by the content among STX and ETX, exclude STX.

1.2.3 Convention

Comply with Big-Enddian format, high byte is prior when transferring.

1.3 Message Field Structure

1.3.1 Message Structure

TYPE	DATA

Field Definition:

	Field	Length
1	TYPE	1
2	DATA	xx

TYPE Value:

Type	Value
TRANS_CONDITION	0x42

1.3.2 DATA Field Definition

DATA Type（1Byte）	DATA Content（depends on specific DATA type）

TYPE Value of DATA Field:

DATA Type	Value	Definition	Receive	Transmit
CON_TRANS	0x01	Request online status	Yes	
TRANS_CON	0x02	Transmit online status		Yes

DATA Field Content:

If TYPE value of DATA field is TRANS_CON and the opposite party can receive 0x01 message which sent by us, it means online is normal.

2 ASCII Format Communication

2.1 Message Transfer Format

Message transfer formats are <SB> ddddd <EB><CR>.

<SB> means the start of massage and its corresponding ASCII sign is <VT>, namely 0x0B;
<EB> means the end of message and its corresponding ASCII sigh is <FS>, namely 0x1C;
<CR> means the confirmation of termination and the field mark of different message, namely 0x0D;
ddddd is the actual transfer content. It includes several fields, each field will end with <CR>, namely 0x0D.

2.2 Massage Grammar

| Field mark
^ Component mark
& Child component mark
~ Repeat mark
\ Escape character

2.3 Data Type

CX	extended composite id which checks digit
CE	code element
CM	composite
CQ	composite quantity with units
DR	datetime range
DT	data
DLN	driver’s license number
EI	entity identifier
HD	hierarchic designator
FN	family name
FT	formatter text
IS	coded value for user-defined Tables
ID	coded values for HL7 Tables
JCC	job code
NM	numeric
PT	processing type
PL	person location
ST	string
SI	sequence ID
TS	time stamp
TQ	timing quantity

TX text data
XAD extended address
XCN extended composite ID number and name
XON extended composite name and ID number for organizations
XPN extended person name
XTN extended telecommunications number
VID version identifier

2.4 Message Type

The structure of message is as follows：

```
MSH                                  //Message Header
{
    [PID]                            //Patient Data
    {
        OBR                          // Medical Advice
        [OBX]                        //Inspection Result
    }
}
```

Definition of MSH (Message Header):

Number	Field	Type	Length	Remark
1	Field mark	ST	1	
2	Encoding chars	ST	4	
3	Sending Application	EI	180	
4	Sending Facility	EI	180	
5	Receiving Application	EI	180	
6	Receiving Facility	EI	180	
7	DateTime Message	TS	26	
8	Security	ST	40	
9	MessageType	CM	7	
10	Message Control ID	ST	20	
11	Processing ID	PT	3	
12	VersinID	VID	60	
13				Keep

14				Keep
15				Keep
16				Keep
17				Keep
18	Encoder	ST		Encoding (with UNICODE)

Example:
MSH|^~\&|CompanyName|InstrName|LIS|PC|20100930100436||ORU^R01|
CompanyName-BLD |P|2.3.1|||||UNICODE

Definition of PID(Patient Data) Field:

Number	Field	Type	Length	Remark
1	Set ID PID	SI	4	Confirm different fields, generally set 1
2	Patient ID	EI	20	
3	Patient Identifier List	CX	20	
4	Alternate Patient ID	CX	20	
5	PatientName	XPN	48	
6	Mother Maiden Name	XPN	48	Set null
7	Date/Time of Birth	TS	26	
8	Sex	IS	1	M or F
9	Patient Alias	XPN	48	Keep
10	Race	CE	80	Keep
11	Patient Address	XAD	106	Keep
12	County Code	IS	4	Keep
13	Phone Number	XTN	40	Keep
13	Phone Number Bus	XTN	40	Keep
14	Primary Language	CE	60	Keep
15	Marital Status	CE	80	Keep
16	Religion	CE	80	Keep
…	Basically, the Latter parts do not need to fill			

Example: PID|1|1010051|A1123145|15|Jame||19811011|M

OBR Field:

Number	Field	Type	Length	Remark
1	Set ID OBR	SI	4	Confirm different fields, generally set 1 or null
2	Placer Order Number	EI	22	
3	Assigned Patient Location	EI	22	
4	Universal Service ID	CE	200	
5	Priority	ID	2	Set null
6	Requested DateTime	TS	26	
7	ObservationDatetime	TS	26	
8	Observation DateTime end	TS	26	Set null
9	Collection Volume	CQ	20	Set null
10	Collector Identifier	XCN	60	Set null
11	SPE ActionCode	ID	1	Set null
12	Danger Code	CE	60	
13	Relevant Clinical Info	ST	300	Clinical information, diagnosis or remark etc.
14	SPE Received DateTime	TS	26	
15	SPE Source	CM	300	Blood, urine or others
16	Ordering Provider	XCN	120	
17	OrderCallback Phone Number	XTN	40	Set null
18	Placer Field1	ST	60	Inspection applicant
19	Placer Field2	ST	60	Set null
20	Filler Field1	ST	60	Set null
…	Do not need to fill basically			Set null

Example:

OBR|1|1010051|000001|CompanyName^InstrName||20101010093020|20101010093500|||||| Jaundice||BLD|Tom||011

OBX:

Number	Field	Type	Length	Remark
1	Set ID OBX	SI	4	Confirm different fields, generally use 1 or null
2	Value Type	ID	3	NM indicates number type, ST indicates value type
3	Observation Identifier	CE	590	Observation Identifier or item ID
4	Observation SubID	ST	20	
5	Observation value	ST	65535	Test result
6	Units	CE	90	
7	References Range	ST	90	
8	Abnormal Flags	ID	5	Value mark: L H N
9	Probability	ID	5	Set null
10	Nature of Abnormal Test	ID	2	Set null
11	Observe Status	ID	1	Observe results and take F as final result
12	Date Last Observe	TS	26	Set null
13	User Defined Access Checks	ST	20	Original result, such as absorbance
14	DateTime	TS	28	Use for biochemical result
15	Producer ID			
16	Responsible Observer			
17	Observation Method	CE	60	Use for biochemical analyzer

A complete ASCII data example:

<SB>

MSH|^~\&|[CompanyName]|[InstrName]|LIS|PC|[ResultTime]||ORU^R01|[InstrType]|P|2.3.1|||||UNICODE<CR>

PID|[PatType]|[PatID]|[PatBarCode]|[PatBedCode]|[PatName]|||[PatBirth]|[PatSex]<CR>

OBR|[SampleType]|[REQID]|[SampleID]|[CompanyName]^[InstrName]|||[SampleTime]|[StartTime]|||||||[Symptom]|||[SanpleType]|[SendDOCName]|||[SendDP]<CR>

OBX|[ResultType]|[ValueType]|[ItemID]|[ItemName]|[TestResult]|[Unit]|[ConsultValue]|[Flag]|||F||||[DocDP]|[DOCName]|<CR>

OBX|1|NM|[ItemID]^LeftLine||[TestResult]||||||F||||[DocDP]|[DOCName]|<CR>

OBX|1|NM|[ItemID]^RightLine||[TestResult]||||||F||||[DOCDP]|[DOCName]|<CR>

OBX|1|ED|[ItemID]|||[InstrID]^Histogram^32Byte^HEX^[TestResult]||||||F|||[DOCDP]|[DOCName]|<CR>

<EB>

<CR>

3 Communication Operations

If choose hexadecimal as transmission mode, the system will send data in hexadecimal format. Likewise, choose ASCII, the system will send data in ASCII format.

If automatic transmission is on, then after finish each analysis, the system will transmit data through COM automatically. If you do not need, please choose off in setting interface. Users can press “Transmit.” in main menu screen to transmit data.