HT-300
Auto Hematology Analyzer
Operation Manual

IVD

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Statement

The current version number of this manual is A/2, released on 2018-05. This manual may be modified as needed without prior notice.

MR shall be liable for product safety, reliability and performance provided that the following requirements are met:

1) All installation operations, expansions, changes, modifications and repairs of this product are conducted by MR authorized personnel.
2) All replaceable parts involved in maintenance as well as the related accessories and consumables are original or approved by MR
3) Any associated electrical equipment complies with national standards and the requirements of this manual.
4) Use and operation of this product are performed in strict accordance with this manual.

Warranty Service

The entire machine is covered by a comprehensive warranty for a full year from the date of production. However, damage occurring under the following conditions shall not be covered by this warranty:

1) Man-made damage or damage caused by improper use.
2) Damage caused by mishandling during shipment.
3) Damage caused by uncontrollable natural factors such as earthquake, fire or war.
4) Environment in which the machine is used does not meet the requirements indicated in this manual.
5) Damage caused by use of an unspecified power supply or any other abnormality in the power supply.
6) Damage caused as a result of maintenance performed by personnel not authorized by MR
7) Malfunction of the instrument whose serial number is not legible enough.
8) Malfunction not caused by the instrument itself.

In the event you have any inquiries or questions while using the instrument, you can always contact MR

Customer Service Department

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Warning

- This analyzer can only be operated by test professionals, doctors or laboratory technicians who have been trained by MR or its distributors.
- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
- Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.

Note

- This operation manual is written for the following laboratory professionals:
  1) Daily system operators
  2) Personnel for system maintenance and troubleshooting
  3) Learners for system operation
- When the instrument reaches the retirement period, it is recommended to stop using it or conduct a comprehensive inspection and maintenance before re-using it again.

Introduction

We would like to sincerely thank you for choosing to purchase MR product.

Please read this manual carefully in order to ensure correct use of the product. After carefully reading this manual, please keep it safely stored so that you can refer to it when necessary.

Prodcut Name:	Auto Hematology Analyzer
Model:	HT-300
Product Composition:	This product primarily comprises the reagent and sample loading units and mixing systems, photoelectric colorimetric assembly, cleaning system, data acquisition unit, control unit and data processing system
Scope of Product Application:	This product is applicable for detecting the parameters of WBC, RBC, PLT, HGB, etc. in anti-coagulated venous whole blood or capillary blood, as well as WBC 3-part differential analysis and WBC counting
Date of Manufacture:	See the nameplate of the instrument
Manual Revision Date:	May 20, 2018
Item No.:	30170331001

Manual Overview

This chapter explains how to use this operation manual, which is shipped with your auto hematology analyzer and contains reference information about the analyzer and procedures for operating, troubleshooting and maintaining the analyzer. Read

this manual carefully before operating your analyzer and operate your analyzer strictly as instructed in this manual.

Who Should Read This Manual

This manual contains information written for clinical laboratory professionals or trained doctors, nurses or laboratory technicians to:

1) Learn about hardware and software of the analyzer.
2) Set system parameters.
3) Perform daily operations.
4) Perform system maintenance and troubleshooting.

How to Find Information

This manual contains 11 chapters and 2 appendices. Refer to the table below to find the information you need.

If you want to…	Please refer to…
Learn about safety and precautions of the analyzer	Chapter 1 Safety and Precautions
Learn about installation requirements of the analyzer	Chapter 2 Installation
Learn about the intended use, parameters, structure, reagents, etc. of the analyzer	Chapter 3 System Description
Learn about how the analyzer works	Chapter 4 Working Principles
Learn about the process of sample collection and analysis, and how to use the	Chapter 5 Basic Operations

If you want to...	Please refer to...
analyzer to perform your daily operating tasks	
Review sample results	Chapter 6 Reviewing Results
Learn about the basic requirements of quality control and how to use the quality control programs provided by the analyzer	Chapter 7 Quality Control
Learn about the basic requirements of calibration and how to calibrate the analyzer	Chapter 8 Calibration
Learn about how to set/adjust system settings	Chapter 9 Settings
Learn about how to maintain/service the analyzer	Chapter 10 Service
Learn about how to solve the problems of the analyzer	Chapter 11 Troubleshooting
Learn about the technical specifications of the analyzer	Appendix A. Specifications
Learn about the hazardous substances that may contain in the analyzer parts	Appendix B. Hazardous Substances
Learn about safety and precautions of the analyzer	Chapter 1 Safety and Precautions
Learn about installation requirements of the analyzer	Chapter 2 Installation

Symbols

You will find the following symbols in this manual:

Symbols	Meaning
	Alerts the operator to follow the statement below the symbol, otherwise it may take the risk of potential biohazard.
	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may cause personal injury.
	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may lead to analyzer damage or unreliable analysis results.
	Alerts the operator to follow the statement below the symbol, which emphasizes the important information or special attention to be paid while in operation.

You may find the following symbols on the analyzer, reagent, QC or calibrator:

Symbols	Meaning
	Consult accompanying documents.
	Biohazard (The background color of this symbol is yellow, the symbol itself and the outline is black.)
	Laser beam warning
	Equipotential symbol
	Protective earthing
	USB port

Symbols	Meaning
	Network port
	Alternating current
	Authorized representative in the European Community
	The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.
	For in vitro diagnostic use
	Batch code
	Expiry date
	Product serial number
	Date of manufacture
	Be careful of the sample probe tip

Symbols	Meaning
	Manufacturer
	Temperature limitation
	Consult the operation manual
	CE marking. The device is fully in conformance with the Directive 98/79/EC on in vitro diagnostic medical devices
	This electronic product contains some poisonous and harmful substances. The environmental protection use period is 20 years, after this period, it should be put into the recycling system.

Conventions

All illustrations provided in this manual are used for descriptive purposes or as examples only, not intended to be used for any other purposes. They may not necessarily reflect setup of the analyzer or data displayed.

Chapter 1Safety and Precautions

The following are warning symbols used for the analyzers. Ignoring these symbols may result in death or serious injury. The order in which the symbols are given is in no way indicative of importance and all symbols are of equal importance.

1.1 Safety

	**Bodily Injury** 1) Keep away from the sharp parts of the analyzer, such as sample probe tip, reagent probe tip and stirrer in case of body injury. 2) Do not touch the moving parts, such as sample probe, reagent probe, stirrer and fan when the analyzer is running.
	**Laser** Do not look directly into any beams to prevent possible damage to your eyes.
	**Electric Shock** 1) Front, side and back covers mustn’ t be opened when the power is on, except by authorized service personnel. 2) Do not splash liquid on the analyzer’ s countertop. In

	case liquid gets into the analyzer, turn of the power and contact Genrui or its local distributors immediately. 3) Keep away from the inside of computer and printer in case of high voltage.
	**Biohazard** 1) All test samples, calibrators, controls, etc., should be considered contagious and protective gloves should be worn when coming into contact with these objects. 2) All waste liquid should be considered contagious and protective gloves should be worn when coming into contact with it. 3) Parts that have contacts with samples, such as sample probe, reagent probe, stirrer, cuvette, waste liquid tubing and waste liquid container should be regarded as contagious and protective gloves should be worn when coming into contact with these objects. 4) When the instrument reaches its service life, it should be disposed according to the requirements of the local environmental protection department, cannot be disposed and discarded as common wastes.

1.2 Precautions

	**Intended Use** 1) The analyzer is designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine and cerebrospinal fluid (CSF) samples. Please consult MR first if you want to use the system for other purposes. 2) To draw a clinical conclusion, please also refer to the patient's clinical symptoms and other test results.
	**Operator** The analyzer can only be operated by personnel who have trained and authorized by MR or its local distributors.
	**Actions taken in case of failure** If the instrument has dangerous failure, such as fire, odor, smoke, etc., anyone can directly disconnect the power of the instrument or the main power and contact MR immediately.
	**Operating Environment** 1) Please install and operate the analyzer in an environment specified by this manual. Installing and operating the analyzer in other environment may lead to unreliable results and even analyzer damage. 2) If the operating environment of the analyzer needs to be

	modified, please contact MR or the authorized MR distributor for you region.
	**Electromagnetic Interference** 1) The analyzer is susceptible to electromagnetic interference during operation which may affect test results and lead to operational errors. Please do not use devices that emit electromagnetic radiation, such as electric drills, mobile phones or interphones while the analyzer is running 2) The analyzer will emit electromagnetic radiation during operation. Do not install or use electromagnetically-sensitive devices near the analyzer.
	**Improper Grounding** 1) The power supply must be properly grounded, or there is a risk of electric shock. 2) Ground impedance must be less than 0.1Ω. Poor grounding can cause instability in test results and electrical leakage from the enclosure, producing an electric shock hazard.
	**Liquid Leakage** 1) Check the pipe joints for possible leakage before conducting tests. Liquid leakage can cause inaccurate aspiration and discharge volume. 2) Do not place reagents and samples on the analyzer bench to

	avoid liquid spillage or leakage.
	**Probe Obstruction** Carefully check reagents and samples and make sure they do not contain insoluble floating substance such as cellulose and protein fibrin in case the probes may be blocked.
	**Water Quality** Water quality should meet Class 2 national standards for laboratory water, otherwise damage to valve and pump as well as difficulty in cleaning can be resulted.
	**Device Connection** 1) For a device not permanently connected, please do not place it at a location that is hard to disconnect. 2) For all the external switches or breakers and external over-current protection device, it is recommended to place them near the analyzer. 3) Devices connected with the network port of the analyzer should conform to the requirements of National Standards GB4793 of China as well as IEC60950.
	**Analysis Parameters** Perform calibration for different batches of reagents. Incorrect analysis parameters can lead to wrong test results. Please consult MR or your reagent supplier for more information.

	**Treating Waste Analyzer** Materials of the analyzer are subject to contamination regulations. Dispose of the waste analyzer in accordance with your local or national guidelines for waste disposal.

Chapter 2Installation

2.1 Introduction

The analyzer is tested and packed with care before it is shipped from the factory. Inspect the carton carefully when you receive your analyzer. If any sign of damage is found, contact MR customer sercive department or your local distributor immediately.

Warning

- Installation by personnel not authorized or trained by MR may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of MR-authorized personnel.
- The installation, authorization, upgrade and modification of the analyzer software must be performed by MR-authorized personnel.

2.2 Installer

The analyzer should only be installed by MR personnel or MR-authorized distributor. Users should provide appropriate environment and space for the installation. When the analyzer needs to be relocated, please contact MR or MR-authorized distributor. When you received your analyzer, please immediately notify MR or its authorized local distributor.

2.3 Checking before Installation

2.3.1 Inspection for Damage

All the analyzers have been inspected strictly by MR before packing and shipping. When you received your analyzer, before opening the packaging, perform a thorough inspection and note whether there is any of the following damage:

1) Up-side-down or distortion of the packaging.

2) Obvious water marks on the packaging.

3) Obvious signs of being striked on the packaging.

4) Packaging shows signs of having been opened previously.

If you notice any of the above instances of damage, please immediately notify MR or MR-authorized local distributor.

If the outer packaging is intact, unpack it in the presence of MR staff and/or authorized distributor personnel, and conduct the following inspection:

1) Check all the parts against the packing list contained inside the packaging.

2) Check the surface of all the parts for any crack, strike or distortion.

If you notice any shipment damage or missing part, please immediately notify MR or MR-authorized local distributor.

2.3.2 Packing List

Check all the parts according to the packing list contained inside the packaging. If

you notice any missing part, please immediately notify MR or its authorized local distributor.

Note

- Check the accessories in the supplied service pack, which is also included in the packing list.

2.4 Installation Requirements

2.4.1 Space Requirements

Check the site for proper space allocation. In addition to the space required for the analyzer itself, arrange for:

1) proper height to place the analyzer;
2) at least 50cm between the left and right side door of the analyzer and the walls, which is the preferred access to perform service procedures;
3) at least 20cm behind the analyzer for cabling and ventilation.

⚠Warning

- There should be enough room on and below the countertop to accommodate the reagents and waste containers.
- The diluent container shall be put within 1.0m under the analyzer, lyse containers are placed inside the analyzer.
- The countertop (or the floor) where the analyzer is placed shall be able to withstand at least 40kg of weight.

2.4.2 Power Requirements

Table 2-1 Power specification

	Voltage	Input power	Frequency
Analyzer	(100-240V～) ±10%	100-120VA	(50Hz/60Hz)±1Hz

Warning

- Make sure the analyzer is properly grounded.
- Before turning on the analyzer, make sure the input voltage meets the requirements.

Caution

- Using pinboard may bring the electrical interference and the analysis results may be unreliable. Please place the analyzer near the electrical outlet to avoid using the pinboard.
- Please use the original power cable shipped with the analyzer. Using other power cable may damage the analyzer or cause unreliable analysis results.

2.4.3 Environmental Requirements

1) Operating temperature range: 10℃~35℃
2) Relative humidity: 20%~85%
3) Atmospheric pressure: 70.0kPa~106.0kPa

Note

- The environment shall be as free as possible from dust, mechanical vibrations, loud noises, and electrical interference.
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
- Keep the analyzer away from strong sources of electromagnetic interference, as these may interfere with the proper operation.
- Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close.
- Do not place the analyzer in direct sunlight or in front of a source of heat or wind.
- The environment shall be ventilated.
- Place the analyzer on a horizontal flat surface.
- Connect only to a properly earth grounded outlet.
- Only use this analyzer indoors.s

2.4.4 Moving and Installation Method

Moving and installation of the analyzer shall be conducted by MR-authorized personnel. Do not move or install your analyzer without the presence of MR-authorized personnel or local distributor.

⚠Warning

- Installation by personnel not authorized or trained by MR may cause

personal injury or damage your analyzer. Do not install your analyzer without the presence of MR-authorized personnel or local distributor.

Note

- Before the analyzer is shipped out, the sample probe is fixed by a plastic cable tie to avoid damaging the sample probe during transportation. Remove the cable tie before using the analyzer.

2.5 Precautions for Use

1) The analyzer performance may be declined if it has been placed in environment of high dustiness.
2) The surface of the analyzer shall be cleaned and sterilized regularly with alcohol (75%).
3) The aspirate key of the analyzer (see Figure 2-1 Front view of the analyzer) shall be wiped with alcohol (75%) regularly.
4) Sample collection and preparation must be done following standard procedures.
5) If any of the pipes or fluidic components is worn out, stop using the analyzer and contact Genrui customer service department immediately for inspection or replacement.
6) Check and make sure the pipes of reagents, including diluent, lyse and waste, are not pressed or bent.

7) You must only use the MR-specified reagents, otherwise the analyzer may be damaged or provide unreliable results.

8) Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.

Chapter 3System Description

3.1 Introduction

This chapter introduces the parameters, major components, interfaces, buttons, menus, software help system, operation information and reagent system of the HA-300 Auto Hematology Analyzer.

3.2 Parameters

The analyzer determines 21 parameters and3 histograms of blood samples. The parameters are listed as follows:

Table 3-1 Parameters

Parameter Group	Name	Abbreviation
WBC group（7 items）	White Blood Cell count	WBC
	Lymphocytes number	LYM#
	Lymphocytes percentage	LYM%
	Middle cells number	MID#
	Middle cells percentage	MID%
	Granulocytes number	GRAN#
	Granulocytes percentage	GRAN%

Parameter Group	Name	Abbreviation
RBC group（8 items）	Red Blood Cell count	RBC
	Hemoglobin Concentration	HGB
	Hematocrit	HCT
	Mean Corpuscular Volume	MCV
	Mean Corpuscular Hemoglobin	MCH
	Mean Corpuscular Hemoglobin Concentration	MCHC
	Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV
	Red Blood Cell Distribution Width - Standard Deviation	RDW-SD
PLT group（6 items）	Platelet count	PLT
	Mean Platelet Volume	MPV
	Platelet Distribution Width	PDW
	Plateletcrit	PCT
	Platelet Large Cell Ratio	P_LCR
	Platelet Large Cell Count	P_LCC

Table 2-2 Histograms

Name	Abbreviation
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram
White Blood Cell Histogram	WBC Histogram

Note

- "√" means "available under the mode", "×" means "not available under the mode".

3.3 Product Structure and Components

The analyzer mainly consists of a host, accessories and client software. The host comprises a display screen, aspirate key, fluidic system, optical system, circuit board, power interface, reagent interface and signal interface.

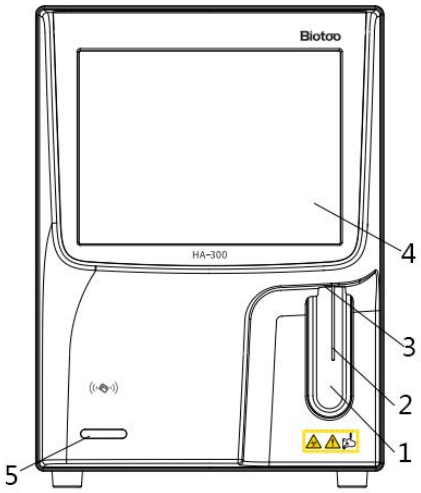


Figure 2-1 Front view of the analyzer

1-- Aspiratekey 2-- Sample probe 3-- Probe wipe block

4-- Touch screen 5-- Indicator

Figure 2-2 Back view of the analyzer

1--Waste outlet 2--Diluent inlet 3-- Waste detector

4--Power input socket 5-- Power switch

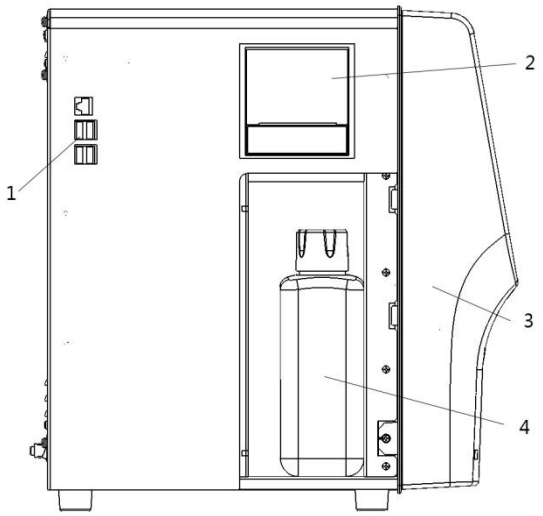


Figure 2-3 Left view of the analyzer (left door open)

1--Network/USB port　　2--Thermal printer

3--Panel module　　4--Lyse reagent position

3.3.1 Status Indicator

The status indicator is on the front of the analyzer. It indicates the ready, running, error and standby status of the analyzer.

The indicator illuminates in 4 colors to indicate the current status of the analyzer. See the following table:

Table 2-4 Indicator and analyzer status

Analyzer status	Indicator	Remark
Whole blood mode ready	Green light on	Sequence is allowed
Prediluent mode ready	Blue light on	Sequence is allowed
Running	Yellow light on	Sequence is being performed

Analyzer status	Indicator	Remark
Stop with fault	Red light on	An error has occurred and the analyzer is not running

3.3.2 Buzzer

The buzzer indicates errors of the analyzer. When you click the touch screen or the error is cleared, the alarming sound of the buzzer can be cleared.

3.3.3 Power Switch

The power switch is on the back of the analyzer. It is used to turn the analyzer on and off.

Caution

- Do not turn on/off the switch repeatedly in a short time to avoid damaging the analyzer.

3.3.4 Sample Probe

The sample probe is on the front of the analyzer. It is used to aspirate blood samples accurately and quantitatively.

3.3.5 Aspirate Key

The aspirate key is located behind the sample probe. Press it to start analysis,

dispense diluent or exit from standby mode.

3.3.6 Touch Screen

The touch screen is on the front of the analyzer. You can use it to perform interface operations and complete the display of information.

3.3.7.Analyzer Interfaces

1) Power interface

   Used to plug in the power cable connected to the network power supply.

2) Reagent/Waste outlet

   Used to connect with reagents and waste container via fluidic pipes.

3) USB/Network port

   The USB port and network port are on the left of the analyzer. They can be used to connect the keyboard, printer, etc., and to transmit data.

3.3.8.Thermal or External Printer (optional)

The thermal printer is on the left of the analyzer for printing reports and other on-screen displays. Theexternal printer is connected to the USB port on the left of the analyzer.

The supported external printer models are: EPSON LQ-590K, HP Laser Jet P1505N, HP Office Jet Pro K5300, HP LaserJet P1606DN.

3.3.9.External Devices

1) Keyboard (optional)

   The keyboard is connected to the analyzer via the interface on the back of the analyzer.

2) Mouse (optional)

   The mouse is connected to the analyzer via the interface on the back of the analyzer. It is used to operate the analyzer.

3.4 Reagents, Controls and Calibrators

As the analyzer, reagents (diluent, lyse and probe cleanser), controls, and calibrators are components of a system. Performance of the system depends on the combined integrity of all components. Only MR-specified reagents (see Appendix A Specifications), which are formulated specifically for the fluidic system of your analyzer in order to provide optimal system performance, could be used. Do not use the analyzer with reagents from multiple suppliers. Otherwise, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.

Each reagent package must be examined before use. Product integrity may be compromised in packages that have been damaged. Inspect the package for signs of leakage or moisture. If there is evidence of leakage or improper handling, do not

use the reagent.

Note

- Store and use the reagents as instructed by instructions for use of the reagents.
- When you have changed the diluent or lyse, implement a background test to see if the results meet the requirement.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.

3.4.1 Reagents

1) HA 3D 01Diluent

   It is used to dilute blood samples and provide a stable environment for counting and sizing blood cells.

2) HA 3L 02Lyse

   It is used to lyse red blood cells, count and differentiate WBCs, and determine the HGB.

3) Probe cleanser

   It is used to clean the analyzer regularly.

3.4.2 Controls and Calibrators

The controls and calibrators are used to verify accurate operation of and calibrate the analyzer.

The controls are commercially prepared whole-blood products used to verify that the analyzer is functioning properly. They are available in low, normal, and high levels. Daily use of all levels verifies the operation of the analyzer and ensures that reliable results are obtained. The calibrators are commercially prepared whole-blood products used to calibrate the analyzer. Store and use the controls and calibrators as instructed by their instructions for use.

All references related to controls and calibrators in this manual refer to the controls and calibrators specifically formulated for this analyzer by MR You must buy those controls and calibrators from MR or MR-authorized distributors.

Chapter 4Working Principles

4.1 Introduction

The measurement methods used in this analyzer are: the Electrical Impedance method for determining the RBC, WBC and PLT data; the colorimetric method for determining the HGB. Other parameter results are obtained via calculation.

4.2 Aspiration

If you are to analyze a whole blood sample in the open vial sampling mode, the analyzer will aspirate 10μL of the sample.

If you are to analyze a capillary blood sample in the open vial sampling mode, you should first manually dilute the sample (20μL of capillary sample needs to be diluted by 700μL of diluent, dilution ratio: 1:36) and then present the pre-diluted sample to the analyzer, which will aspirate 300μL of the sample.

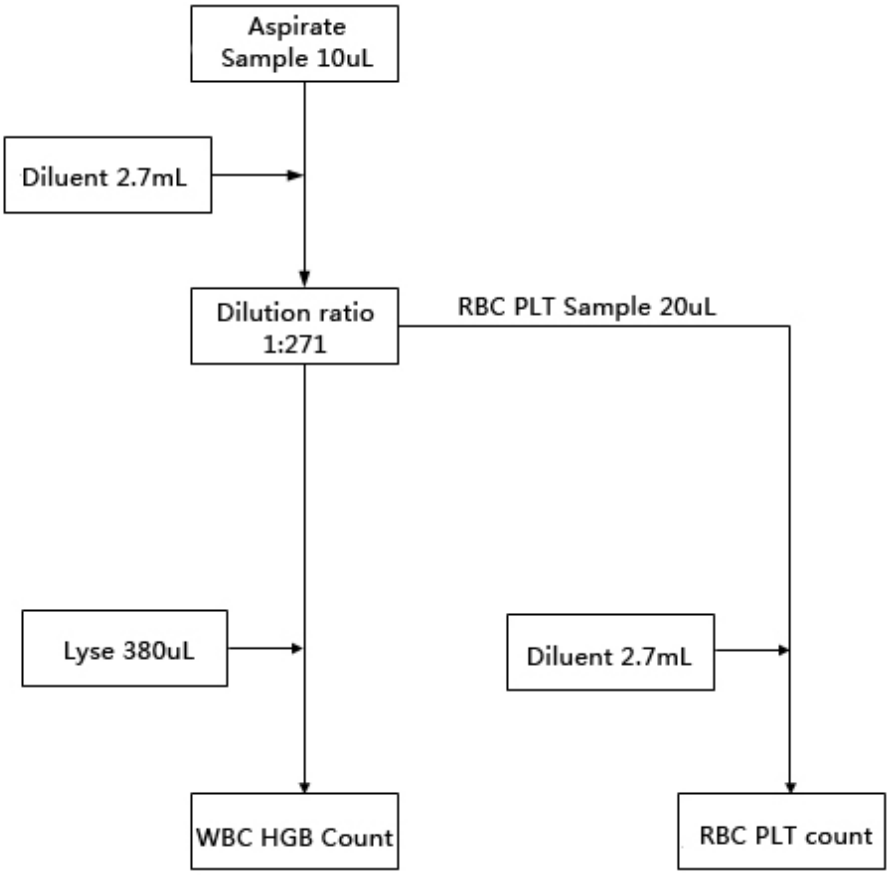
4.3 Dilution

The aspirated sample will quickly and precisely be diluted in RBC bath and then segmented into two portions. One of these two portions will then be diluted again and processed by different reagents. After this, they are ready for analysis.

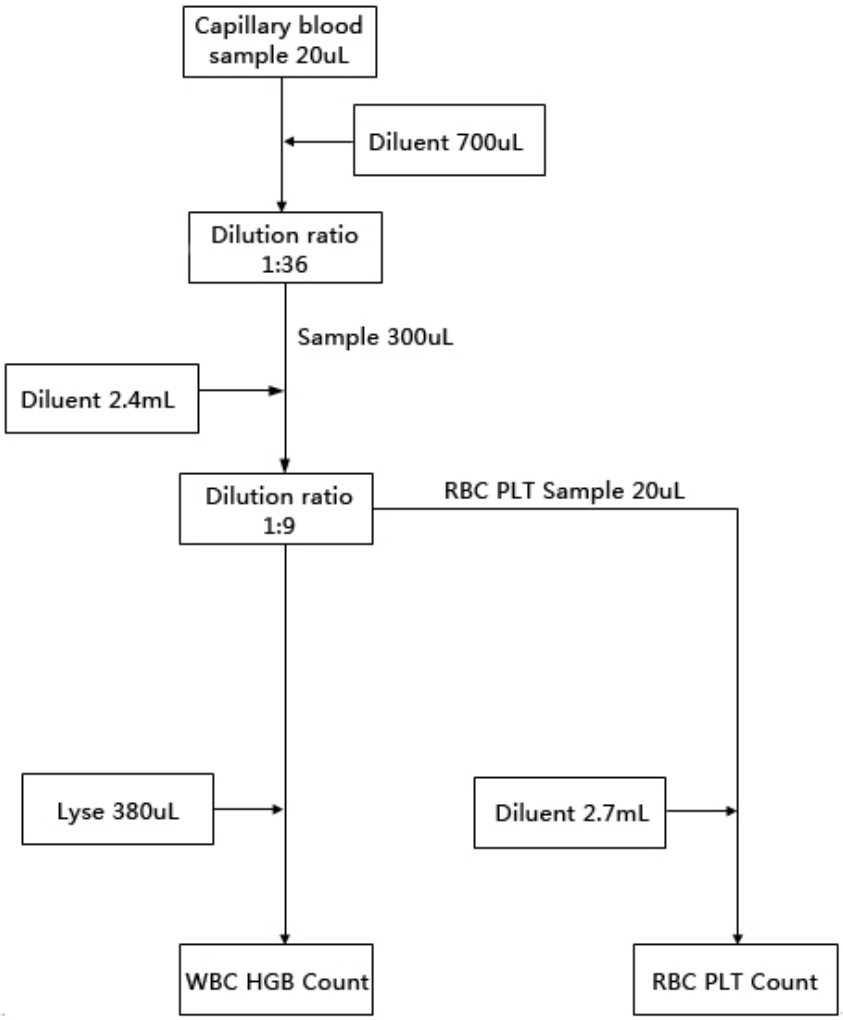
This analyzer can process two types of blood samples - whole blood samples and

prediluted samples.

4.3.1 Whole Blood Mode



4.3.2 Prediluted Mode



4.4 HGB Measurement

4.4.1 Colorimetric Method

The WBC/HGB dilution is delivered to the HGB bath where it is bubble mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 530nm. An LED is mounted on one side of the bath and emits a beam of monochromatic light, whose central wavelength is 530nm. The light passes through the sample and is then measured by an optical sensor that is mounted on the opposite side. The signal is then amplified and the voltage is measured and compared to the blank reference reading (readings taken when there is only diluent in the bath), and the HGB is measured and calculated in the analyzer automatically.

4.4.2 HGB

The HGB is calculated per the following equation and expressed in g/L.

$$\mathrm{HGB} = \mathrm{Constant} \times \mathrm{Ln}\left(\frac{\text{Blank Photocurrent}}{\text{Sample Photocurrent}}\right)$$

4.5 RBC/WBC/PLT Measurement

4.5.1 Electrical Impedance Method

RBCs/WBCs/PLTs are counted and sized by the electrical impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as

it passes through an aperture of known dimensions. A pair of electrodes is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated represents the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

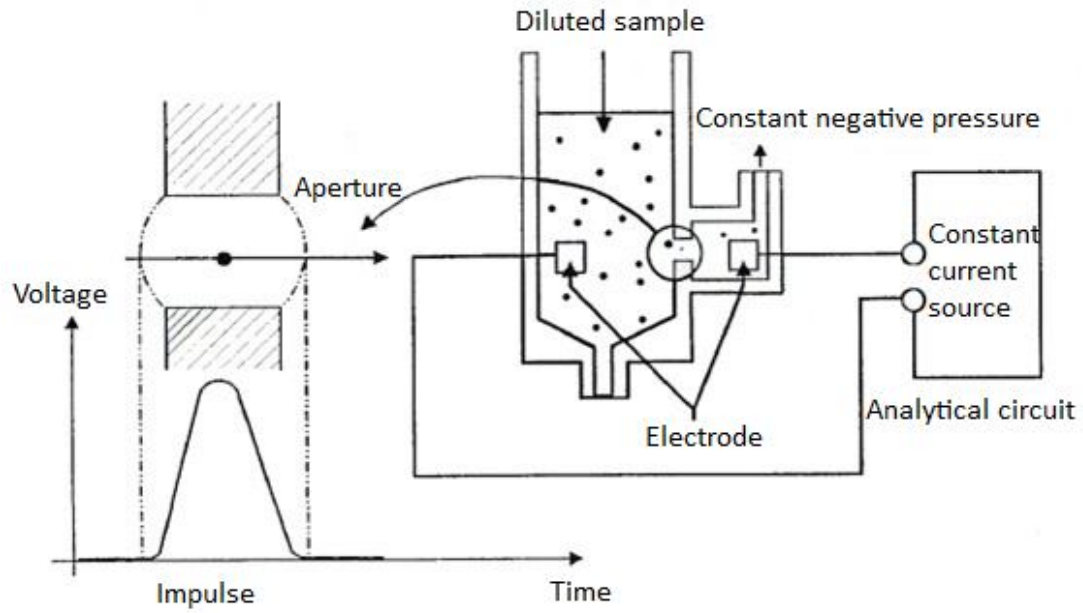


Figure 4-2 Electrical Impedance Method

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of certain amplitude. If the pulse generated is above the RBC/WBC/PLT lower threshold, it is counted as a RBC/WBC/PLT. The analyzer presents the RBC/WBC/PLT histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells.

4.5.2 Derivation of RBC-Related Parameters

1) RBC

RBC (10^{12}/L) is the number of erythrocytes measured directly by counting the erythrocytes passing through the aperture.

2) MCV

Based on the RBC histogram, this analyzer calculates the mean cell volume (MCV) and expresses the result in fL.

3) HCT, MCH, and MCHC

This analyzer calculates the HCT (%), MCH (pg) and MCHC (g/L) as follows:

$$\mathrm{HCT} = \frac{RBC \times MCV}{10}$$

$$\mathrm{MCH} = \frac{HGB}{RBC}$$

$$\mathrm{MCHC} = \frac{HGB}{HCT} \times 100$$

Where the RBC is expressed in 10^{12}/L, MCV in fL and HGB in g/L.

4) RDW-CV

Based on the RBC histogram, this analyzer calculates the CV (Coefficient of Variation) of the erythrocyte distribution width, which is expressed in %.

5) RDW-SD

Based on the standard deviation of erythrocyte size distribution, this analyzer calculates the RDW-SD, its unit is fL.

4.5.3 Derivation of WBC-Related Parameters

1) WBC

WBC (10^9/L) is the number of leucocytes measured directly by counting the leucocytes passing through the aperture.

2) MON, MID, GRAN

Based on the WBC histogram, this analyzer calculates the number(10^9/L) and percentage (%)of different kind of white blood cells.

4.5.4 Derivation of PLT-Related Parameters

1) PLT

PLT (10^9/L) is measured directly by counting the platelets passing through the aperture.

2) MPV

Based on the PLT histogram, this analyzer calculates the mean platelet volume (MPV, fL).

3) PDW

Platelet distribution width (PDW) is the geometric standard deviation (GSD) of the platelet size distribution. Each PDW result is derived from the platelet histogram data and is reported as 10(GSD).

4) PCT

This analyzer calculates the PCT as follows and expresses it in %.

$$\mathrm{PCT} = \frac{PLT \times MPV}{100000}$$

Where the PLT is expressed in 10^9/L and the MPV in fL.

Chapter 5Basic Operations

5.1 Introduction

This chapter provides step-by-step procedures for operating your analyzer on a daily basis. The operation process of sample analysis in different working modes is described in detail.

- All samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and contacted areas in laboratory.

Warning

- Do not contact the patients' sample blood directly.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If reagents accidentally spill on your skin or into your eyes, rinse the area with plenty of clean water and seek medical attention immediately.

- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

Caution

- Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.

Note

- Use the reagents specified by the MR only. Store and use the reagents as instructed by instructions for use of the reagents.
- Check if the reagent tubes are properly connected before using the analyzer.
- Be sure to use clean EDTAK2 or EDTAK3 anticoagulant collection tubes, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Be sure to use the evacuated collection tubes recommended in the Appendix.
- Be sure to use the MR-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes etc.

5.2 Initial Checks

Perform the following checks before turning on the analyzer:

1) Checking the waste container

   Check and make sure the waste container is not full.

2) Checking reagents

Check to see if the reagents are expired or frozen. Reagents must be equilibrated for 24 hours before use.

3) Checking tubing and power connections

Check and make sure the reagents, waste and pneumatic unit tubes are properly connected and not bent.Check and make sure the power cable of the analyzer is properly plugged into the power outlet.

4) Checking the thermal printer or external printer (optional)

Check and make sure enough printer paper is installed. Check and make sure the power cable of the printer is properly plugged into power outlet, and the printer is properly connected to the analyzer.

5.3 Startup and Login

1) Start up the analyzer:Change the power switch at the backside to ON position (“I”) will power on the instrument.

2) The indicator light turns on.

3) Background check, which is the measurement of particle and electric interference by the analyzer.

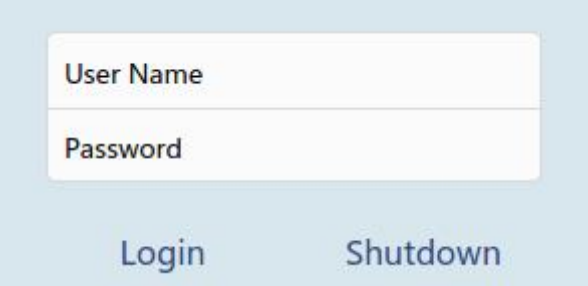
If the results of the first background check do not meet the requirement, the analyzer will perform background check again.

The sample ID of background check results is “background”.

The error message “Background abnormal” will be given when the

background results are out of range.

4) Enter the current user name and the password respectively into the "User Name" box and the "Password" box.



Note

- If the software cannot be started successfully after being launched for several times, contact MR customer service department or the authorized distributors.
- After starting up the analyzer, check if the date/time is correct.
- The default user name and password for administrator are both "Admin".
- The user name and password may be consisted of 1-12 letters, and the password cannot be null.

5) Click "Login" to enter the system.

Note

- If error occurs during the initialization process (e.g., background check fails), the analyzer will report the error. See Chapter 11 Troubleshooting for the solution.
- See Appendix A Specifications for the background range of each parameter.
- The system opens different function for the user according to the user level. The user level depends on the user name and the password when the user logs in.
- If user switching is necessary, click the "Logout" icon on the system menu. Enter the desired user name and the password into the pop-up dialog box and click the "OK" button to log in.

- Running sample with the background abnormal error present will lead to unreliable results.

5.4 Daily Quality Control

Perform daily quality control before running any samples. See Chapter 7 Quality Control for details.

5.5 Sample Collection and Handling

- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

Warning

- The sample probe is sharp and potentially biohazardous. Do not contact the sample probe during operations.

Caution

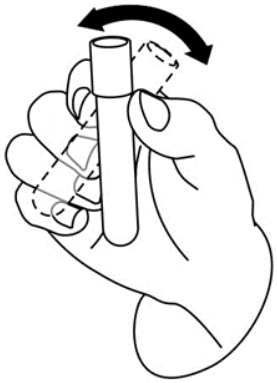
- Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.

Note

- Make sure the probe tip does not contact the sample tube to avoid potential spillage.

5.5.1 Sample Preparation

The analyzer can run 3 types of samples: whole blood samples, capillary whole blood samples and prediluted samples.



Caution

- Prepare samples following the recommend procedure of the manufacturer.
- All samples shall be mixed as shown in the following figure.

1) Whole blood samples

   a) Use clean EDTAK2 or EDTAK3 anticoagulant collection tubes to collect venous blood samples.

   b) Mix the sample according to your laboratory’ s protocol.

Caution

- Be sure to collect at least 0.5mL of blood to ensure the accuracy of the results.

2) Pre-diluted samples

a) Click the diluent dispensing icon, the following dialog box pops up.

b) Present a clean tube to the sample probe, press the aspirate key to dispense diluents (700μL). The dispensing progress bar will be displayed on the screen.

c) To continue with diluent dispensing, repeat the step 1-2.

d) Add 20μL of venous blood or capillary blood to the diluent, close the tube cap and mix it properly according to your laboratory' s protocol.

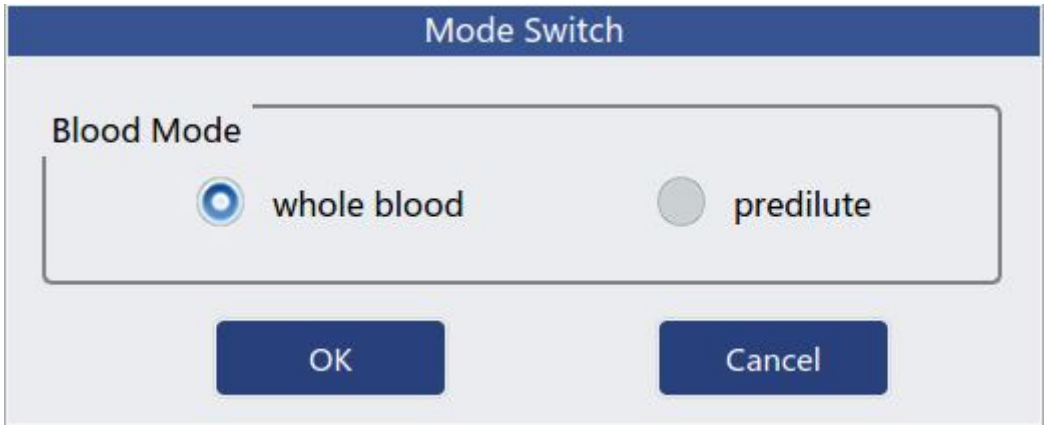
e) Click "Cancel" after preparing all the samples, the analyzer will clean the sample probe automatically.

Note

- You can also use pipette to aspirate 700μL of diluent.
- Be sure to keep dust from the prepared diluent.
- After mixing the capillary sample with the diluent, be sure to wait 3 minutes and then remix before running the sample.
- Be sure to run the pre-diluted samples within 30 minutes after the mixing.
- Be sure to mix any sample that has been prepared for a while before running it. Do not mix the samples with massive force using swirl mixer.
- Be sure to evaluate pre-diluted stability based on your laboratory' s sample population and sample collection techniques or methods.

5.5.2 Sample Analysis

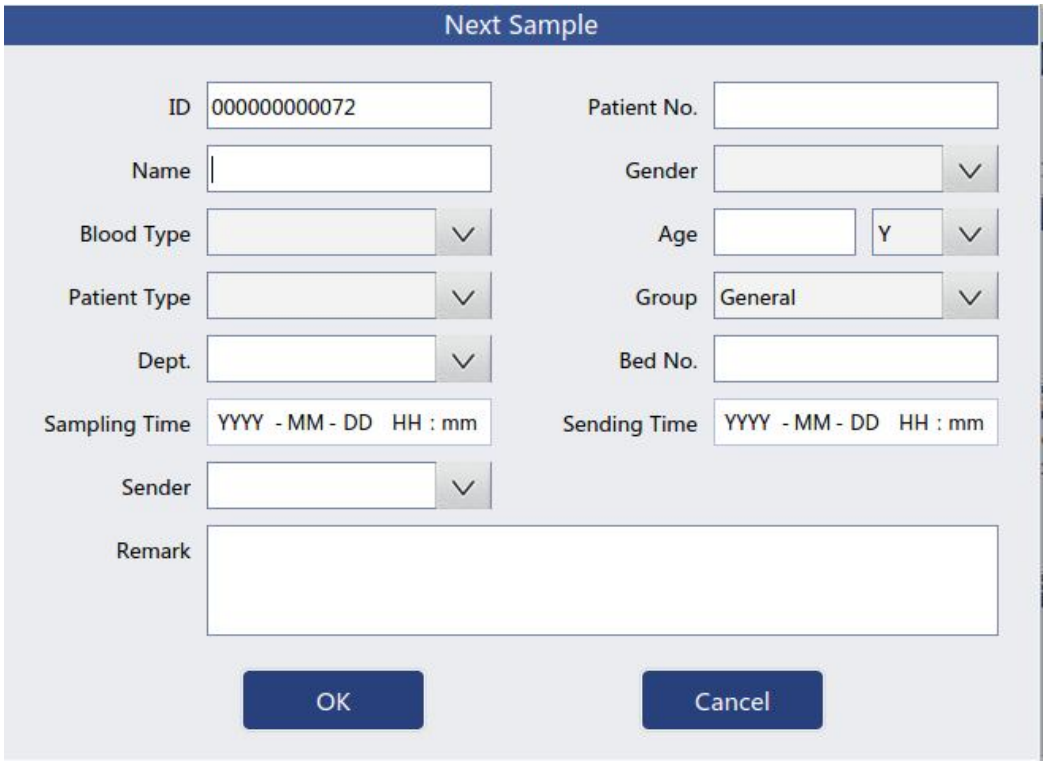
Click "Sample Analysis" to enter the sample analysis screen. Click "Sample Mode" button to select "Whole Blood", "Prediluted" mode.



1) Entering sample information

The analyzer provides two ways for you to enter sample information: entering sample ID only and entering all sample information.

If you want to enter sample information after analysis, you may skip this chapter, and enter sample information at the result review screen (see Chapter 6 Reviewing Results). You may first set up the way to enter sample information at the "Setup → System Setup → Auxiliary Setup" screen as instructed in Chapter 9 Settings, then you may enter sample information at the sample analysis screen.



a) Entering the ID

Enter the ID in the "ID" box.

b) Entering the medical record number

Enter the medical record number in the "Patient No." box.

c) Entering the patient name

Enter the patient name into the "Name" box.

d) Selecting patient gender

Select patient gender from the "Gender" pull-down list. There are two options: "Male" and "Female".

e) Selecting blood type

Select patient gender from the "Blood type" pull-down list.

f) Entering the patient's age

The analyzer provides four ways for you to enter the patient' s age - in years, in months, in days and in hours. The first way is designed for the adult or pediatric patients no younger than one year; the second for the infant patients one month to two years; the third for the neonatal no older than one month, and the fourth for the neonatal no older than 48 hours. You may choose one of the four ways to enter the patient age.

g) Entering the patient type

Select patient type from the "Patient Type" pull-down list.

h) Entering the department name

Enter the name of the department into the "Department" box or select it from the "Department" pull-down list (when there are previously saved records in the list). The saved contents will be added in the pull-down list automatically.

i) Entering the bed number

Enter the number of the patient' s bed into the "Bed No." box.

j) Entering the sampling time

Enter the time when the sample is collected into the "Sampling Time" box.

k) Entering the delivery time

Enter the delivery time of analysis into the "Send Time" box.

l) Entering the clinician

To enter the name of the person who sent the sample for analysis, enter

the name into the "Sender" box or select the desired name from the "Sender" pull-down list (if there are previously saved names in the list). The saved contents will be added in the pull-down list automatically.

m) Entering comments

Enter comments in the "Comments" box.

n) OK

When you have finished entering the work list information, click the "OK" button to save the changes and return to the sample analysis screen.

o) Cancel

If you do not want to save the entered work list information, click the "Cancel" button to return to the sample analysis screen without saving the changes.

2) Selecting mode

Make sure the analyzer indicator is solid green. Select whole blood, or prediluted mode based on your needs on the mode selection screen. The selected mode will be displayed at the bottom of the screen.

3) Aspirating sample

Present the sample to the sample probe. Press the aspirate key to start the analysis.

4) Removing the sample

The sample probe will automatically aspirate sample. When you hear the beep

sound, you may remove the sample.

5) Auto analysis and result reporting

The analyzer will automatically run the sample. When the analysis is finished, the results will be displayed on the screen.

Note

- During the analysis, if errors like clog or bubble occur, the analyzer will automatically display results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting for the way to remove errors.
- If the ambient temperature is out of the allowed range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal

ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting for solutions.

5.5.3 Processing Analysis Results

1) Saving analysis results automatically

The analyzer automatically saves sample results. When the maximum number of results that can be saved has been reached, the newest result will overwrite the oldest.

2) Printing and Transmission to LIS

If "Auto print after sample analysis" function is enabled, the analyzer will print reports automatically; and if "Auto communicate" function is enabled, the analysis results, sample and patient information will be transmitted to LIS automatically.

3) Parameter flags

See the following section for details about parameter flags.

If the parameter is followed by a "H" or "L", it means the analysis result has exceeded the upper or lower limit of the reference range (See section 9.2.4 Ref. range).

If the parameter is followed by an "R", it means the analysis result is questionable.

If you see "*****", as opposed to the result, it means the result is invalid; if

you see “+++++”, as opposed to the result, it means the result is out of the display range (See Table 5-1 Display range for details).

Table 5-1 Display range

Parameter	Display Range
WBC	0.0 ~ 999.9×10^9/L
GRAN#、MID#、LYM#	0.0 ~ 999.9×10^9/L
GRAN%、MID%、LYM%	0.0 ~ 99.9%
RBC	0.00 ~ 18.00 ×10^{12}/L
HGB	0 ~ 300 g/L
HCT	0.0 ~ 80.0 %
MCV	0.0 ~ 250.0 fL
MCH	0.0 ~ 999.9 pg
MCHC	0 ~ 9999 g/L
RDW-SD	0.0 ~ 999.9 fL
RDW-CV	0.0 ~ 99.9 %
PLT	0 ~ 9999 ×10^9/L
PDW	0.0 ~ 99.9
MPV	0.0 ~ 99.9 fL
PCT	0.0 ~ 0.9 %

Parameter	Display Range
P_LCR	0.0～ 99.9 %
P_LCC	0 ～ 9999 ×10^9/L

4) Flags of abnormal blood cell differential or morphology

The following table lists all flags and their indications.

Table 5-2 Flags of abnormal blood cell differential or morphology

Flag Type	Flag	Meaning	Judgment criterion
WBC Flag	WBC abnormity	Interference of PLT clump or NRBC to WBC count and differential may exist	The DIFF and BASO channels are unproportionate.
	WBC decrease	Low WBC analysis results	WBC < 2.5×10^9/L
	WBC increase	High WBC analysis results	WBC > 18.0×10^9/L
	GRAN decrease	Low Granulocytes analysis results	GRAN# < 1.0×10^9/L
	GRAN increase	High Granulocytes analysis results	GRAN# > 11.0×10^9/L
	LYM decrease	Low lymphocytes analysis results	LYM# < 0.8×10^9/L

Flag Type	Flag	Meaning	Judgment criterion
	LYM increase	High lymphocytes analysis results	LYM# > 4.0×10^9/L
	MID decrease	High Middle cells analysis results	MID# > 1.5×10^9/L
	All decrease	WBC, RBC and PLT low	WBC < 4.0×10^9/L RBC < 3.5×10^{12}/L PLT < 100×10^9/L
RBC Flag	RBC abnormity	Possible presence of microcytes, macrocytes, anisocytosis, RBC agglutination and dimorphic histogram	The distribution of RBC histogram is abnormal
	HGB abnormity	HGB abnormal or RBC agglutination, or interference may exist (e.g., WBC high)	MCHC > 380 g/L or HGB interference
	Microcytic RBC	MCV low	MCV < 70fL

Flag Type	Flag	Meaning	Judgment criterion
	Macrocytic RBC	MCV high	MCV > 110fL
	Anemia	Anemia	HGB < 90g/L
	RBC increase	RBC high	RBC > 6.5×10^{12}/L
PLT Flag	PLT abnormity	Possible presence of microcytes, red blood cell debris, giant PLT or PLT clump	The distribution of PLT histogram is abnormal
	PLT decrease	PLT low	PLT < 60×10^{9}/L
	PLT increase	PLT high	PLT > 600×10^{9}/L

5.6 Standby

When the time for which the analyzer is free from fluidic operations reaches that you have set at the "Setup" screen of the analyzer (default setting is 15 minutes), The analyzer will enter standy status, the screen will switch off automatically, and the probe will be drew back automatically.

Note

- The analyzer will not enter standby status from the Status screen.

- If it is time for auto-standby and the analyzer is reporting error, then the error must be resolved first.
- During this condition, you can still perform any other operations (e.g., printing and transmission) other than fluidic operations.
- Refer to Section 9.2.4 Maintenance Setup for how to edit waiting time before entering standby mode.
- Under standby mode, if there are unfinished printing or communication tasks, the analyzer will go on processing them.

1) Aspirate key

   Press the aspirate key to exit the standby status.

2) Touch screen

   Touch the screen to exit the stanby status.

Note

- When exiting from the standby status, the analyzer will perform different maintenance operations based on the time consumed entering standby status.
- If error occurs when the analyzer is exiting from the standby status, see Chapter 11 Troubleshooting for solutions.
- After exiting the standby status, the analyzer will resume its original status. The Analysis icon will turn into solid green. And the analyzer indicator will also turn into solid green.

5.7 Shutdown

Perform the shutdown procedure to shut down the analyzer daily.

1) Click the shutdown button on the menu and the following shutdown dialog box will display.

2) Click "OK".

3) When dialog box prompting probe cleanser maintenance displays, place probe cleanser to the sample probe and press aspirate key. The probe will aspirate probe cleanser automatically.

4) After shutting down finishes, the message "Please turn off the power of the analyzer!" will be displayed. Press the Power switch on back of the instrument to power off.

Warning

- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.

Caution

- Do not start up the analyzer immediately after it is shut down. Wait for at least 10 seconds.

Note

- To ensure stable analyzer performance and accurate analysis results, be sure to perform the shutdown procedure to shut down the analyzer after it has been running continuously for 24 hours.
- Do not disconnect power during the shutdown process.
- If error that will affect shutdown occurs during the showdown process, the analyzer will resume to its original status and report the error. See Chapter 11 Troubleshooting for solutions.

Chapter 6Reviewing Results

6.1 Introduction

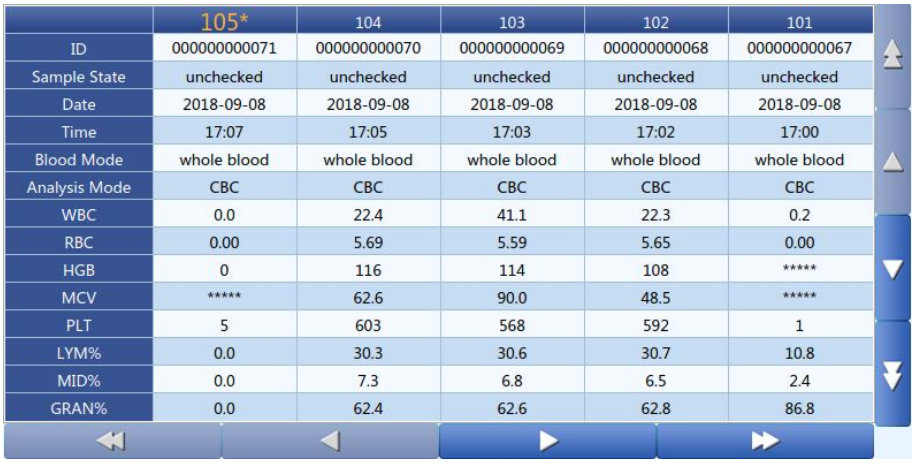
The analyzer automatically saves analysis results. You can review all the analysis results and histograms either in table or graph mode.

6.2 Browing in the “Review” Mode

Operators can review, validate, search, edit and export saved results on the “Review” screen. Click “Review” to enter the following screen.

6.2.1 Table Area

The table area lists all analyzed samples, including basic sample information like sample ID, sample status and so on.



	105*	104	103	102	101
ID	000000000071	000000000070	000000000069	000000000068	000000000067
Sample State	unchecked	unchecked	unchecked	unchecked	unchecked
Date	2018-09-08	2018-09-08	2018-09-08	2018-09-08	2018-09-08
Time	17:07	17:05	17:03	17:02	17:00
Blood Mode	whole blood	whole blood	whole blood	whole blood	whole blood
Analysis Mode	CBC	CBC	CBC	CBC	CBC
WBC	0.0	22.4	41.1	22.3	0.2
RBC	0.00	5.69	5.59	5.65	0.00
HGB	0	116	114	108	*****
MCV	*****	62.6	90.0	48.5	*****
PLT	5	603	568	592	1
LYM%	0.0	30.3	30.6	30.7	10.8
MID%	0.0	7.3	6.8	6.5	2.4
GRAN%	0.0	62.4	62.6	62.8	86.8

Note

- The table area displays the latest sample results at the top.

6.2.2 Graph Review

Enter “Test” to view the analysis results of samples.

6.2.3 Check/Cancle Check (for administrators only)

1) Check sample data

Select one or more sample records on the table data screen, click "Check", the sample status of the record will be marked with "Checked".

2) Cancel Check

Select one or more checked sample records at the table data screen, click "Cancel Check", the "Checked" will disappear.

6.2.4 Delete (for administrators only)

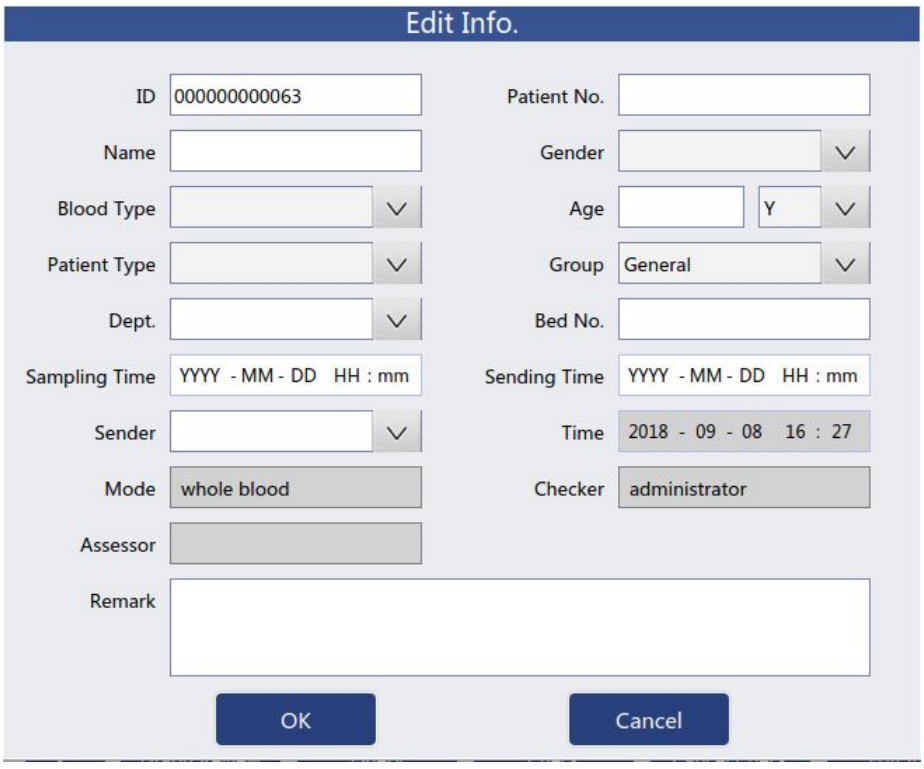
1) Select the sample record to be deleted in the table area.

2) Click "Delete", the following dialog box will display.

3) Click "Yes" to delete the record, and the dialog box will be closed.

6.2.5 Edit Information

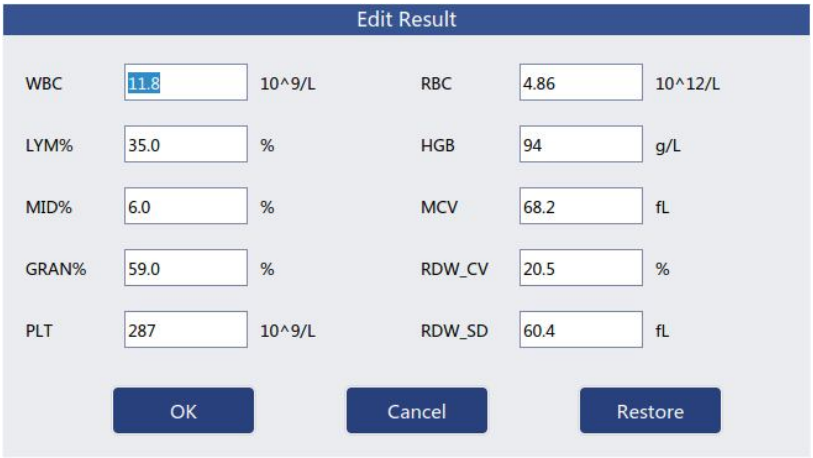
Click the desired sample result and it will be highlighted. Click the "Edit Info" button and the following dialog box will display.



You may edit the sample and patient information, and click "OK" to save the change. The information on the table review screen will be refreshed.

6.2.6 Edit Results

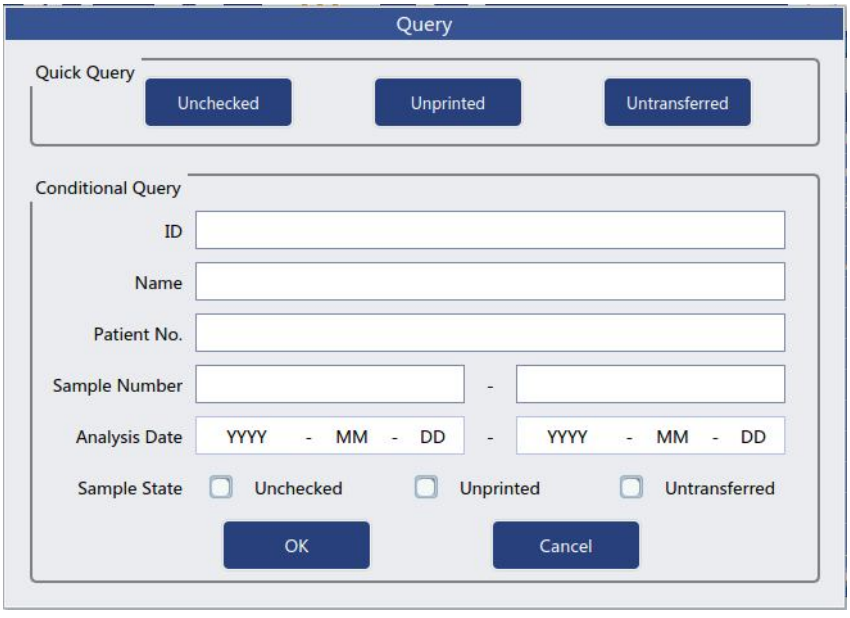
Click the desired sample result and it will be highlighted. Click the "Edit Result" button and the following dialog box will display.



Modify the results and click "OK" to save the changes. The information on the graph review screen will be refreshed.

6.2.7 Search

1) Click "Query", the following dialog box will display



2) Enter search conditions into the edit boxes or select them from the pull-down lists.

3) Click "OK" to start search, the results will be displayed in the table area.

6.2.8 Print

Select sample records to be printed, and then click "Print" to print them. In the table data interface, a "Printed" sign will be applied to each printed sample in the sample status sector.

Note

- In the sample status sector, "Checked" sign is prior to "Printed" sign.

6.2.9 Transmission

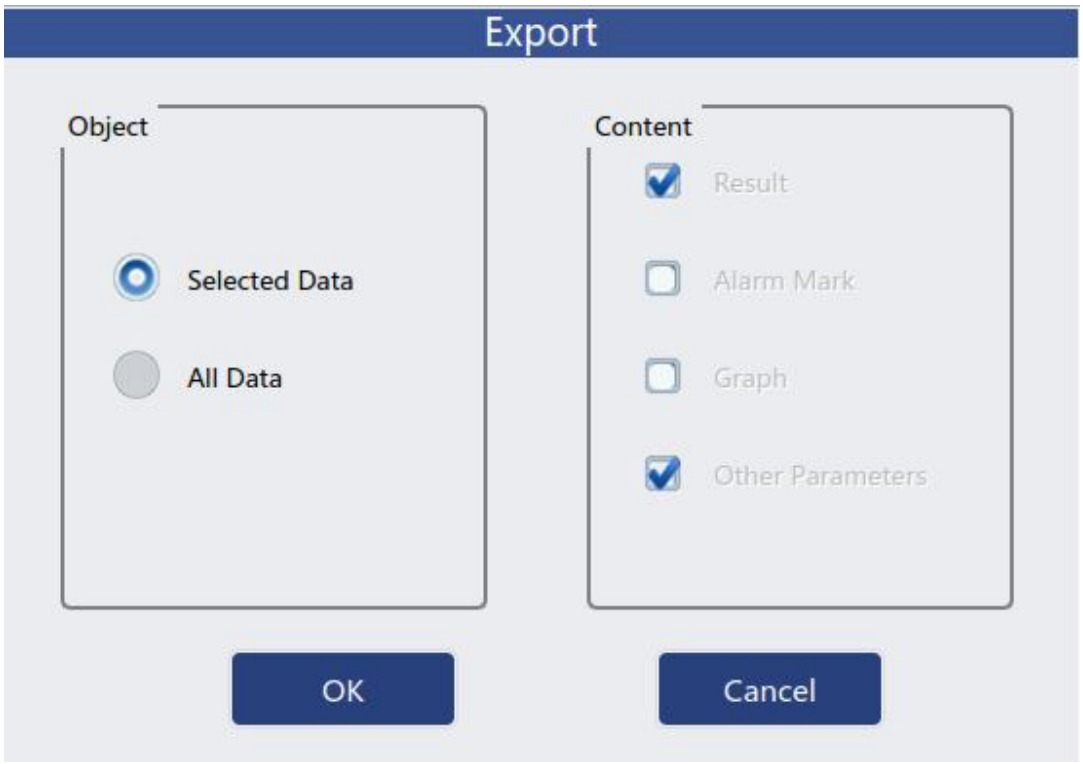
Transmit selected data

1) Select samples to be transmitted at the table data screen.

2) Click "Export", the following dialog box will display.

3) Select the "Chosen record" or "All records".

4) Click "OK" to start transmitting specified results to the data management software.


Export
Object
Selected Data
All Data
Content
Result
Alarm Mark
Graph
Other Parameters
OK
Cancel

Chapter 7Quality Control

7.1 Introduction

Quality Control (QC) consists of strategies and procedures that measure the precision and stability of the analyzer. The results imply the reliability of the sample results.

QC involves measuring materials with known, stable characteristics at frequent intervals. Analysis of the results with statistical methods allows the inference that sample results are reliable. MR recommends you run the QC program daily with normal level controls.

A new lot of controls should be analyzed in parallel with the current lot prior to their expiration dates. This may be accomplished by running the new lot of controls twice a day for five days using any empty QC files. The QC files calculate the mean, standard deviation and coefficient of variation for each selected parameter. The instrument-calculated means of these ten runs should be within the expected ranges published by the manufacturer.

This analyzer provides 2 QC programs: L-J QC and X-B QC.

- All the samples, controls, calibrators, reagents, wastes and areas contacted

them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

Warning

- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- The sample may spill from the uncapped collection tubes and cause biohazard. Exercise caution to the uncapped collection tubes.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If reagents accidentally spill on your skin or in your eyes, rinse the area with plenty of clean water and seek medical attention immediately.

Caution

- Running QC sample with error present will lead to unreliable results. If errors are reported during QC analysis, remove the errors first and then continue with the analysis.
- Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.
- Sample agglutination may result in inaccurate analysis results. Check the control samples to see if there is any agglutination, if yes, process the samples according to your laboratory’ s protocols.

Note

- Use the controls and reagents specified by MR only. Store and use the controls and reagents as instructed by their instructions for use.
- Refer to the instructions for use of the control for its use and storage.
- Be sure to mix any control sample that has been prepared for a while before running it.
- Be sure to use the MR-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes etc.

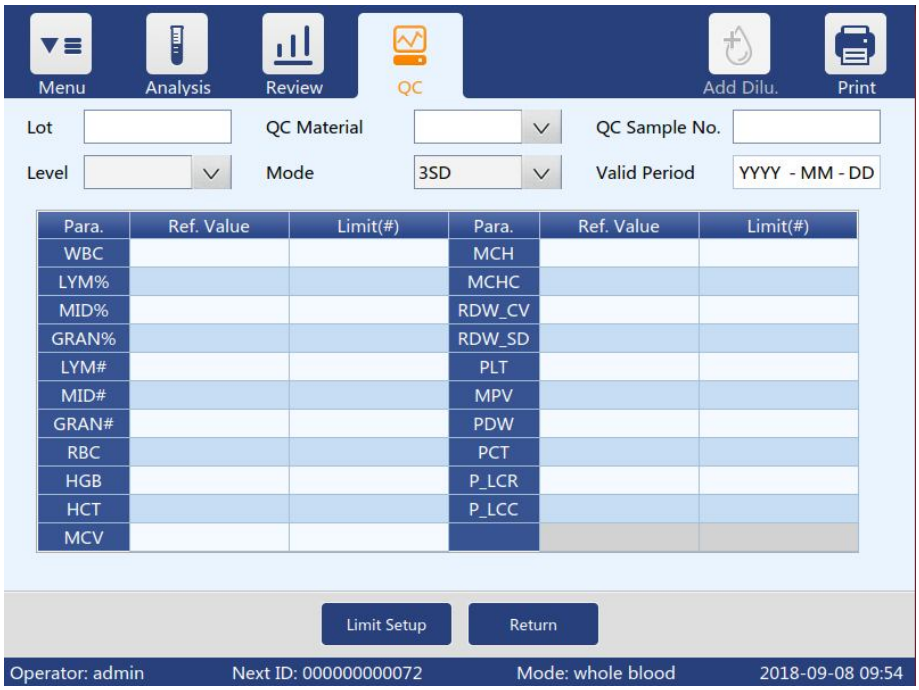
7.2L-J QC

7.2.1Editing L-J QC Settings (for administrators only)

Before running a new lot of controls, you must set up a QC file for each lot of controls.

1) Click the menu option "QC" > "L-J QC" > "Setup".Enter the L-J QC setup screen.Click "New", or select a QC file without QC results, and then click "Edit".

4) Enter the lot No. of the controls in the edit box manually.



Note

- The lot No. shall not be empty and up to 16 digits can be entered. You can enter characters, numbers, letters and special characters.

5) Select the control level.

6) Enter the expiration date of the lot.

7) Select the control type.

8) Select the QC mode.

9) Set QC sample ID: if you are used to analyze control together with blood samples, you can set a unique ID for the control. The analyzer will recognize the sample as control when it reads the unique ID. After the analysis completes, the results will be saved into the QC file of the QC sample ID.

10) Enter the target and limits in the edit boxes according to the package insert of the lot of controls.

11) Click other icons to switch screen and save the QC information.

■ **Setting limits**

You can adjust the format of limits according to the following procedure.

1) Click "Limit Setup".

2) Click "Absolute value" to display the limits in the form of absolute value, or click "Percentage" to display the limits in the form of percentage.

3) Click "OK" button to save the settings.

7.2.2Running L-J QC

You can select one of the two ways below to run controls:

1) Run controls under the "QC" screen.

2) Put controls together with normal samples, and run the controls under the sample analysis screen.

■ **From Way A**

After editing the QC information, you can start QC analysis by whole blood or prediluted according to the selected QC mode.

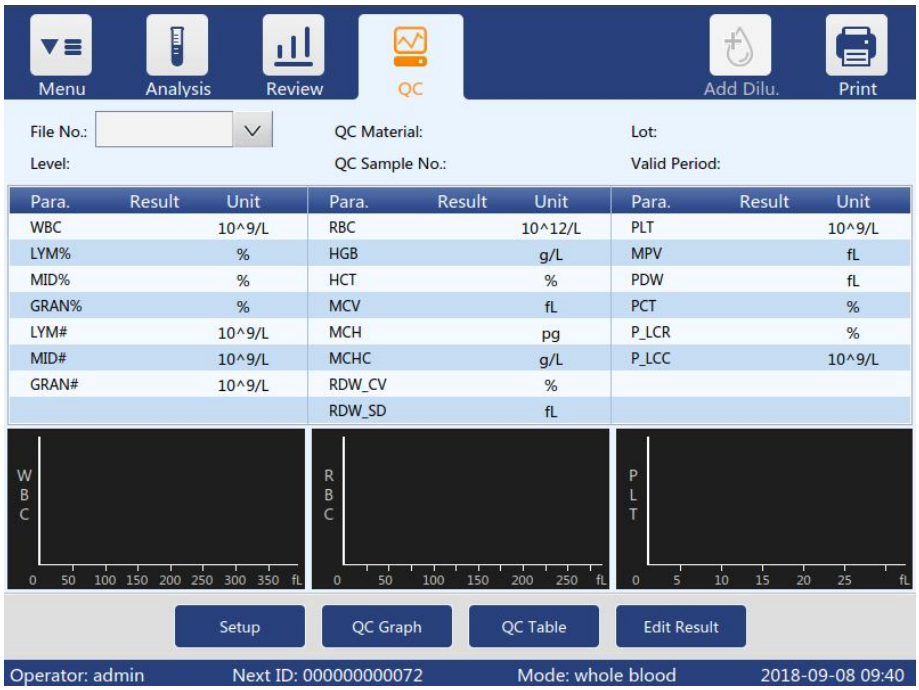
Note

- When switching mode from "Prediluted" to "Whole Blood", a progress bar will be displayed while the analyzer runs mode switching sequence.

1) Click the menu option "QC" > "L-J QC" > "Count" to enter the QC count screen.

Note

- Be sure that the level of the control to be run is the same with the current QC file, and the control is not expired.
- The expiration date of expired controls is displayed in red.



2) Prepare the control as instructed by the instructions for use of the controls.

3) Run QC analysis.

4) When analysis finishes, the QC results will be displayed in the current screen

and be saved in the QC file automatically.

5) Do the above procedures to continue running QC analysis if necessary.

Note

- Up to 100 QC results can be saved in each QC file.

■ **From Way B**

After setting special "QC Sample ID" for a control under the QC setup screen, you can put the control together with normal samples, and run it under the "Count" screen.

When editing worklist or entering next sample information in the "Next Sample" dialog box before daily analysis, enter the special "QC Sample ID" as "Sample ID".

Based on the QC mode selected, you can choose to run QC analysis from whole blood or prediluted.

Note

- When switching mode from "Prediluted" to "Whole Blood", a progress bar will be displayed while the analyzer runs mode switching sequence.

1) Prepare the control as instructed by the instructions for use of the controls.
2) Refer to section 5.5.1 Sample Preparation for sample preparation under whole blood and pre-diluted modes.
3) When it is ready to run a sample (i.e. the status icon and the analyzer indicator is green), present the sample to the sample probe, and then press the aspirate

key to start QC analysis.

4) When you hear the beep, remove the control.

5) When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

6) Do the above procedures to continue running QC analysis if necessary.

Note

- Up to 100 QC results can be saved in each QC file.

7.2.3Reviewing L-J QC Results

After QC analysis, you can review the QC results in the following ways.

1) QC Graph

2) QC Table

■ **L-J QC graph review**

1) Click "QC Graph" button on the" Count" screen to enter the L-J QC graph screen.

2) You can click the arrow buttons on the right of the graph to browse graphs of the parameters. You can click the arrow buttons under the graph to browse all the QC results.

3) Click the "Print" icon in the status bar to print information of the current QC file and the QC graph of all parameters.

Note

- The green vertical line and values of the corresponding QC points will not be printed.

■ **L-J QC table review**

1) Click "QC Table" button on the "Count" screen to enter the L-J QC table screen.

2) You can click the arrow buttons on the right of the table to browse all QC records. You can click the arrow buttons under the table to browse all the parameter results.

3) You can click the "Print" icon in the status bar to print the QC table.

■ **Delete (for administrators only)**

1) Click "Delete", the following dialog box will display.

2) Click "Yes" to delete the selected records.

Note

- The operation will be recorded in the system log.

■ Transmission

To transmit QC data to external data management software or HIS/LIS/HIS, do as follows.

1) Click "Comm.", the following dialog box will display.
2) Select to transmit "Selected" or "All" records.
3) Click "OK" to start transmitting specified results to the data management software.

Note

- If auto-communication is enabled and a sample is run during the transmission of the QC data, then only when the QC data transmission finished will the auto-communication of the sample result start.
- The QC data saved in the process of transmission will not be transmitted.

● Export

To export QC information and results of the current QC file, do as follows.

1) Insert an USB and then click "Export".
2) The system will detect the USB and export data automatically.
3) The prompt "Export succeeded." will display.

7.3X-B QC

7.3.1Introduction

The X-B analysis is a weighted moving average analysis that uses values obtained from patient samples. It uses the 3 red cell indices, MCV, MCH and MCHC to indicate the hematology instrument performance.

It is recommended the X-B analysis be activated when the sample volume of your laboratory is greater than 100 samples per day. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices. It observes the trend of QC results in the reference range formed by the specified target and limits.

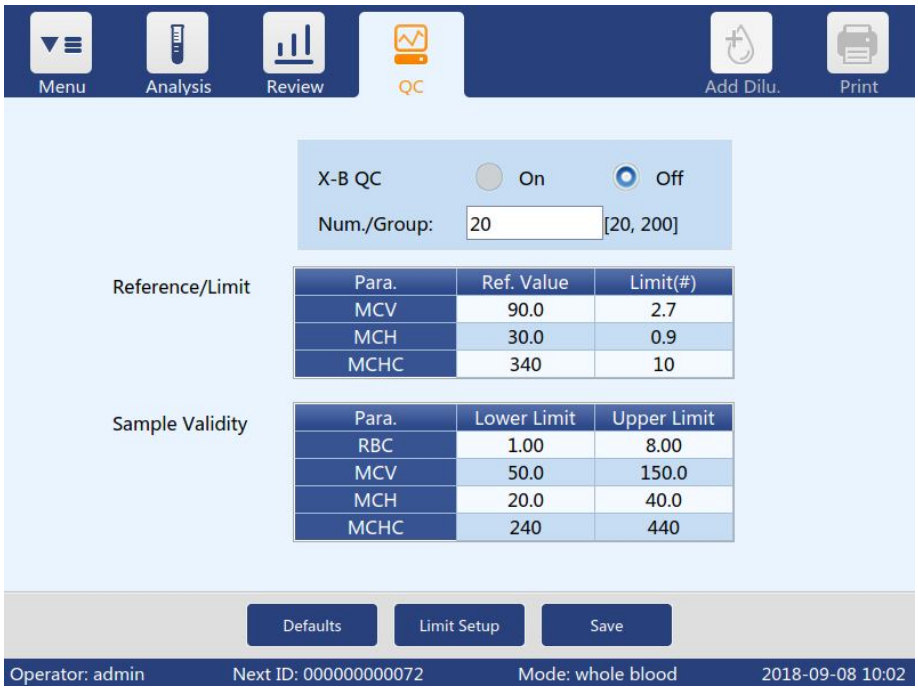
The analyzer implements X-B QC on the 3 parameters: MCV, MCH and MCHC, each group of samples for X-B analysis consists of 20-200 sample results obtained from normal analysis of both whole blood and pre-diluted modes. The analyzer can save up to 500 X-B QC results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest.

7.3.2Editing X-B QC Settings (for administrators only)

1) Click the menu option “QC” > “X-B QC” > “Setup”.

2) Enter the X-B QC setup screen.

3) At the X-B QC setting screen, you may activate/deactivate X-B QC, set target/limits, and configure the sample validity setup.



■ **Editing X-B QC settings**

1) In the "Samples/Batch" edit box, you may enter the amount of samples [within the range 20(default) to 200] to be included in calculating for an X-B QC point.

2) Activate/deactivate X-B QC. If X-B QC is activated, the samples meeting validity requirements will be included in X-B QC.

■ **Setting target/limits**

Before the X-B QC analysis, you shall set up the target and limit for each parameter on the X-B QC setup screen.

Note

- The units of target/limit of all parameters are the same as those in the parameter unit setup screen.

1) In the "Target/Limit" area of the X-B QC setup screen, specify the targets and limits in the "Target/Limit" table by entering manually.

Note

- Do not leave any of the targets and limits for the QC parameters blank.
- When used for the first time, the default setting will provide the initial values for the targets and limits of all QC parameters.

2) Click other icons to switch screen and save the settings.

■ **Setting sample validity**

In X-B QC, sample results conforming to any of the following conditions will be considered as invalid and cannot be used in the QC calculation.

1) Sample results exceeding the linearity range;
2) Background results;
3) Sample results not conforming to the "Sample Validity Setup";
4) QC data for QC mode other than X-B (e.g. L-J);
5) Calibration data;
6) Results generated while there are errors which could affect the accuracy of the results (e.g. insufficient aspiration volume or clogging).

"Sample Validity Setup" is to set up the ranges of valid RBC, MCV, MCH and MCHC results. Only when the results of all these four parameters are within the specified ranges, the sample results can be used for X-B QC calculation. Do as follows to set the sample validity.

1) Select "On" to activate X-B QC. On the "Sample Validity Setup" of the X-B QC setup screen, set the upper and lower limits of the 4 parameters in the sample validity setup area. The default validity range of each parameter is shown in the following figure.
2) Click "Yes" to save the setup.

Reference/Limit

Para.	Ref. Value	Limit(#)
MCV	90.0	2.7
MCH	30.0	0.9
MCHC	340	10

Sample Validity

Para.	Lower Limit	Upper Limit
RBC	1.00	8.00
MCV	50.0	150.0
MCH	20.0	40.0
MCHC	240	440

Note

- In the sample validity setup, the upper limit shall be no smaller than the lower limit. Otherwise, there will be prompted message asking you to revise.
- The valid ranges of the RBC parameters are their linearity ranges; the valid ranges of other parameters are their display ranges.

- All the entries shall be numbers with only one decimal point. The length of the number entered cannot be longer than the length of the text box.
- Once the validity range is changed, the previous results will not be used in the QC calculation as valid results. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the validity range after 10 groups of valid sample results have been acquired, these 10 groups of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.
- The units of lower and upper limits of all parameters are the same as those in the parameter unit setup screen. See section 9.2.4 Setup - Parameter Unit Setup.

■ **Setting limits**

You can adjust the format of limits according to the following procedure:

1) Click "Limit Setup".
2) Click "Absolute value" to display the limits in the form of absolute value, or click "Percentage" to display the limits in the form of percentage.
3) Click "OK" button to save the settings.

■ **Restore defaults**

If you want to restore the default targets and limits of the parameter, click "Defaults". The default values of the target and limits of each parameter are as follows:

Parameter	Target	Limits (#)
MCV	90	2.7
MCH	30	0.9
MCHC	340	10

7.3.3Running X-B QC

After editing X-B QC settings, the system will start X-B QC run automatically.

After every 20-200 results (determined by the setting) are obtained, the system will perform the X-B calculation once automatically. You can review the result in X-B QC graph or X-B QC table.

7.3.4 Reviewing X-B QC Results

After QC analysis, you can review the QC results in the following ways.

1) QC Graph

2) QC Table

■ **X-B QC graph review**

1) Click the menu option "QC" > "X-B QC" > "QC Graph", the following screen will display.

2) Select QC file No., the information of the file and the QC graph will be displayed on the screen.

3) You can click the arrow buttons under the graph to browse all the QC results.

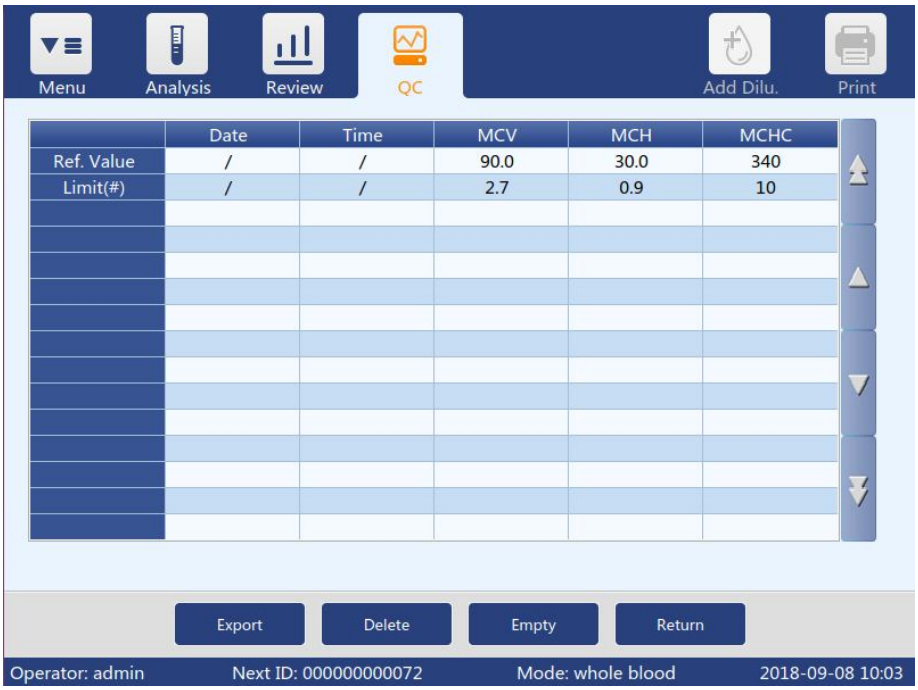
■ **X-B QC table review**

1) On the X-B QC graph screen, click "QC Table" button to enter the X-B QC table

screen.

2) You can click the arrow buttons on the right of the graph to browse all QC records.

3) The delete, print and export operations can all be performed same as stated in the L-J QC table review section.



Chapter 8Calibration

8.1Introdution

Calibration is a procedure to standardize the analyzer by determining its deviation under certain specified conditions. In order to get accurate sample analysis results, you should calibrate the analyzer according to the procedure below when necessary.

There are three calibration programs available on this analyzer: manual calibration, auto calibration using calibrators and auto calibration using fresh blood samples.

All the parameters or part of the parameters of WBC, RBC, HGB, MCV and PLT can be calibrated by the calibration programs.

- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory

procedures when handling them and the contacted areas in the laboratory.

- If reagents accidentally spill on your skin or in your eyes, rinse the area with plenty of clean water and seek medical attention immediately.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.

⚠Caution

- Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.

Note

- Be sure to use the MR-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes etc.
- Calibration procedures can only be performed by users of the administrator-level.
- Use the calibrators and reagents specified by MR only. Store and use the calibrators and reagents as instructed by their instructions for use.
- The analyzer identifies a sample as a calibration sample only if the analysis is started from the "Calibration" screen.
- Calculation of reproducibility is included in the calibration procedure.

8.2When to Calibrate

The analyzer is calibrated at the factory just before shipment. It is electronically stable and does not require frequent recalibration if you operate and maintain it as instructed by this manual. You only need to recalibrate this analyzer if.

1) you are going to use this analyzer for the first time (usually done by a Genrui-authorized representative when installing the analyzer).
2) an analytical component has been changed.
3) you are going to re-use the analyzer after a long-term storage.
4) the quality control results indicate there may be a problem.
5) use environment changes significantly.

Note

- All of the measured parameters must be calibrated before readings of the analyzer can be used as valid analysis results.

8.3 How to Calibrate

8.3.1Preparing Your Analyzer

Do the following pre-calibration procedures before calibration. If problems are detected during these checks, do not attempt to calibrate the analyzer. If necessary, contact MR customer service department or your local distributor for assistance.

1) Check and make sure enough reagents have been prepared for the calibration. You need to start over the calibration if the reagents run out during the process.
2) Check the background (for calibration right after startup) or blank count results. If the analyzer alarms for abnormal background results, see Chapter 11 Troubleshooting for solutions. (See Appendix B Specifications for the background range.)
3) Run a vial of normal control consecutively for 10 times under Whole Blood -CBC+DIFF mode. Enter the review screen to check the reproducibility of the results and make sure they meet the following requirements.

Param -eter	**Range**	**Whole Blood Precision (CV)**	**Prediluted Precision(CV)**
WBC	3.5×10^9/L ~ 15.0×10^9/L	≤ 2.0%	≤4.0%
RBC	3.00×10^{12}/L ~ 6.00×10^{12}/L	≤ 1.5%	≤3.0%
HGB	100 g/L ~ 180 g/L	≤ 1.5%	≤3.0%
MCV	70 fL ~ 120 fL	≤ 1.0%	≤2.0%
PLT	100×10^9/L ~ 149×10^9/L	≤ 6.0%	≤10.0%
	150×10^9/L ~ 500×10^9/L	≤4.0%	≤8.0%

4) It is recommended that you create a log table for your analyzer. This log table should contain all necessary information that is pertinent to your analyzer. Suggested items that you may want to include in the log table are: calibration date, supplier of calibrator, lot number, expected results and limits, and result of

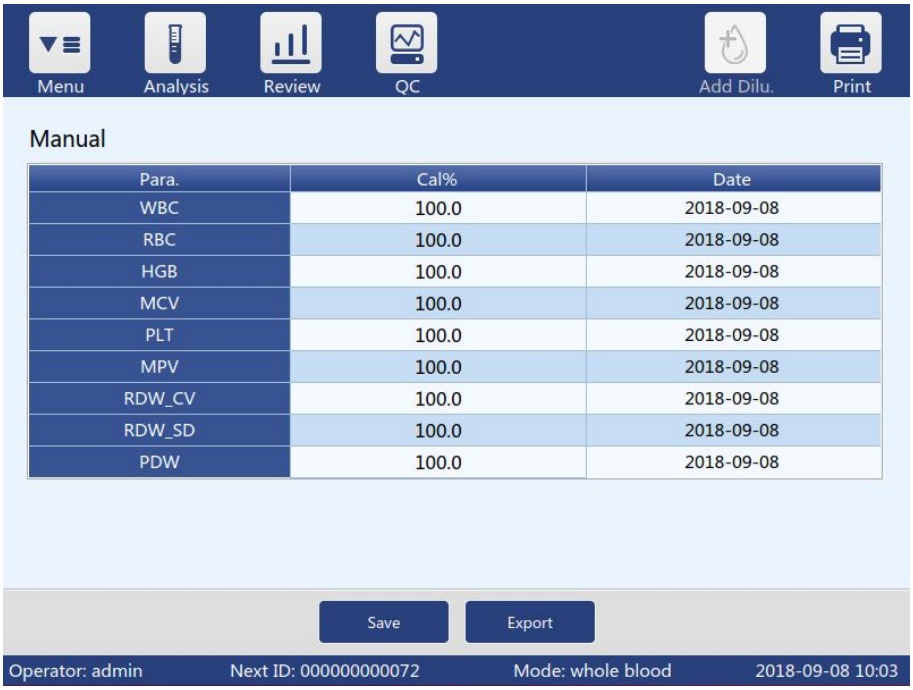
background check.

Note

- Be sure to use the evacuated collection tubes recommended in the Appendix.
- If fresh blood sample is used for reproducibility test, make sure the sample volume is enough to support the test.

8.3.2 Manual Calibration

Click the menu option "Calibration" > "Manual" to enter the following screen.



Note

- If you log in at the operator access level, you can only view the calibration factors. To perform calibration, please log out and then log in at the administrator access level.

Do as follows to calibrate the analyzer.

1) At the "Manual" calibration screen, check the calibration factors and calculate the new factors according to the following equation:

$$\text{New factor} = \frac{\text{Old factor} \times \text{Reference value}}{\text{caculated mean value}}$$

For example: Suppose the WBC reference value of a calibrator is 8.4, and the current calibration factor of the whole blood mode is 98.90%.

Run the calibrator under the whole blood mode for 11 consecutive times and take the WBC results of the 2nd to 11th runs to calculate: 8.1, 8.0, 8.1, 8.1, 8.3, 8.3, 8.2, 8.0, 8.1, 8.3. The obtained CV is 1.5% and the mean value is 8.16, which meet the requirements.

The new calibration factor is obtained.

$$\text{New factor} = \frac{98.90\% \times 8.4}{8.16} = 101.81\%$$

The calculated calibration factors shall be between 75.00% ~ 125.00%. In case of an invalid calibration factor, try to find out the reason (e.g. calibration material not thoroughly mixed, misoperation, etc.). Then recalibrate the analyzer and recalculate the calibration factors.

2) Enter the new calibration factors into the factor cell of the parameter that requires calibration.

3) When you switch screen after entering the new calibration factor, a prompt will display.

   a) If the entered calibration factors are valid, a dialog box will pop up asking you to save the new factor when you are exiting the screen. And the

calibration date of the corresponding parameter changes to the current system date.

b) If the entered calibration factors are invalid, a dialog box will pop up prompting "Invalid entry" when you are switching to another screen. The new calibration factor will not be saved, and the calibration date will not be refreshed.

4) Print

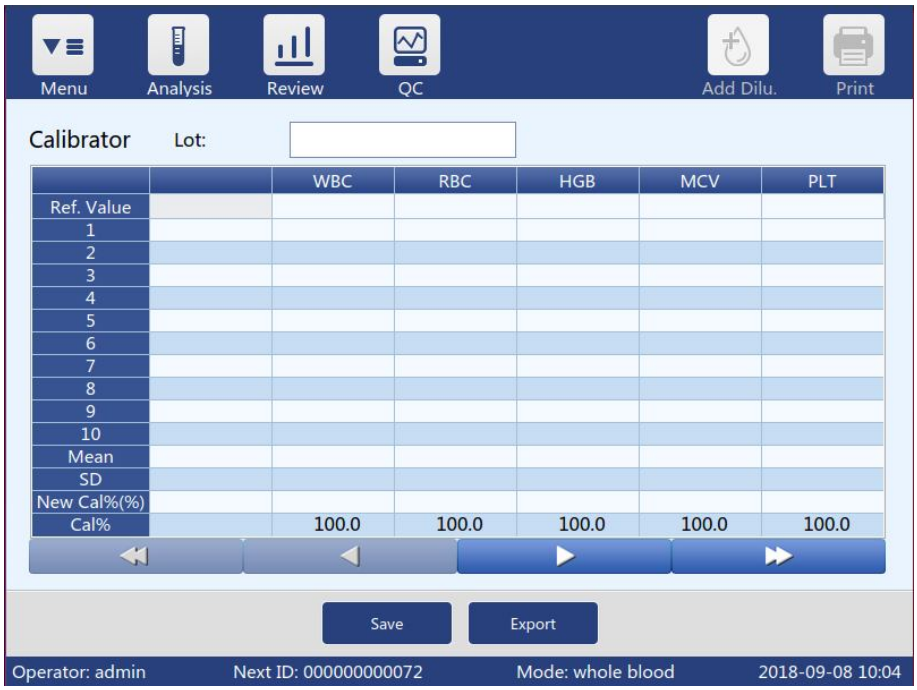
Click "Print" to print the current calibration factor.

If the calibration factors are invalid, you will not be able to print them and the dialog box "New calibration factor is invalid." will display.

If the calibration factors are valid but not saved, a dialog box will display asking you to save the factors. Click "Yes" to save and print the factors. Or click "No" to cancel the operation without saving or printing them.

8.3.3 Calibration with Calibrator

Click the menu option "Calibration" > "Calibrator" to enter the following screen.



Note

- The calibrator calibration can be performed under Whole Blood and Prediluted mode.
- Only MR-specified calibrators shall be used. MR will not be responsible for any erroneous result caused by using other calibrators.
- See the instruction for use of the calibrators for the lot No., expiration date and the target.
- The out-of-range CV% does not influence the display of calibration factors.

Do as follows to calibrate the analyzer with calibrators.

1) Check the mode on the analyzer screen.

2) Enter the lot No. of the calibrator into the "Lot No." box.

3) Enter the "Exp. Date". The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date,

whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.

4) Enter the targets into the "Target" cells.

5) Prepare the calibrator as instructed by instructions for use of the calibrators.

6) Press the aspirate key to start calibration.

7) After the analysis, the analyzer will have different responses to different analysis results.

When the current running is done, if there is a parameter whose calibration data is out of its linearity range but still within the display range, then the calibration data will be displayed in the list and a message box will also pop up. Click "OK" to close the message box, and the data will be deleted from the table without saving automatically.

When the running is done, if there is a parameter whose calibration data is out of the display range, then the non-numeric parameter values "***" will be displayed in the list and a message box will pop up.

Click "OK" to close the message box, and the data will be deleted from the table without saving automatically.

The valid results within the linearity range will be displayed directly.

Valid calibration results will be marked with "√" per the default setting, and will be taken to calculate calibration factors.

8) If the calibration factors have not been calculated but you switch to another screen, then a message box will pop up.

Click "Yes" to switch to another screen while discarding the calibration data and closing the message box. The original calibration factors remain.

9) When calibration count has been performed to a sample for n times (n≥5), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with "√" (calibration data of the first run is not marked with "√", so it is not included in the calculation).

You can select several data to calculate the calibration factors, but only after at least 5 groups of the data are marked with "√" can you get the calibration factors. The calibration factors will be refreshed whenever you select "√" or deselect "√".

When the amount of valid calibration data in the list reaches 10, a message box "Calibration is completed." will pop up. Then, if you press the aspirate key again, the analyzer will beep without starting analysis.

10) There may be two cases when you are switching to another screen:

If the calibration factors of any parameter is out of the range of 75%-125% or the CV% of any parameter exceeds the reproducibility range, then the calculated calibration factors of all parameters will not be saved and a message box will also pop up.

Click "Yes" to close the dialog box and switch to another screen. The calibration factors and dates of all parameters will not be changed.

If the calculated calibration factors of all parameter are within the range of 75%-125% and the CV% of all parameter are also within the reproducibility

range, then a message box "Save new calibration factor?" will pop up. Click "Yes" to save the new calibration factors while closing the message box and switching to another screen.

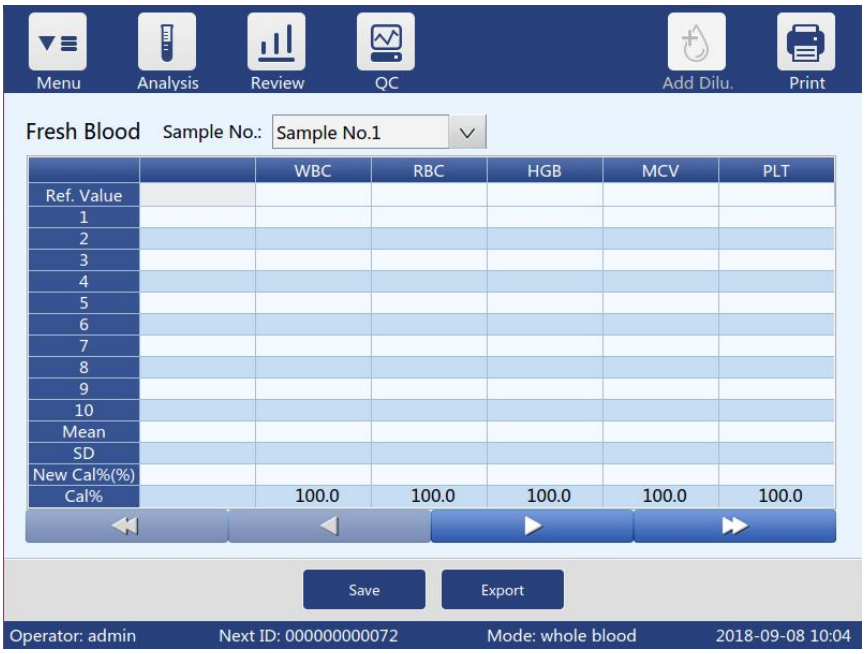
11) Print

If the calibration factors are invalid, click "Print", the dialog box "New calibration factor is invalid." will display.

If the calibration factors are valid but not saved, click "Print", a dialog box "Save new calibration factor?" will display asking you to save the factors. Click "Yes" to close the dialog box, save and print the calibration results. Or click "No" to cancel the operation without saving or printing them.

8.3.4 Calibration with Fresh Blood

Click the menu option "Calibration" > "Fresh Blood" to enter the following screen.



Do as follows to calibrate the analyzer with fresh blood.

1) Prepare 3 to 5 normal fresh blood samples as instructed by 5.5.1 Sample Preparation.
2) Run each of the prepared samples on the reference instrument (or by the reference method) five times at least. Calculate the mean values and use them as the targets. Or perform measurement and calculation according to the reference method and take the calculated data as the targets.
3) Select mode for fresh blood calibration, which can be Whole Blood or Prediluted.
4) Select the ID of current sample from the pull-down box "Current Sample ID".
5) Select the parameter needed to be calibrated in the first line of the check box.
6) Enter the targets into the "Target" cells.
7) Prepare fresh blood sample.
8) Press the aspirate key to start calibration.
9) After the analysis, the analyzer will have different responses to different analysis results.
10) When calibration count has been performed to a sample for n times (n≥5), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with "√" automatically.

    You can select several data to calculate the calibration factors, but only after at least 5 groups of the data are marked with "√" can you get the calibration factors. The calibration factors will be refreshed whenever you select "√" or

deselect "√".

When the amount of valid calibration data in the list reaches 10, a message box will pop up when you start calibration again.

11) Select other calibration sample ID from the "Current Sample ID" pull-down box and analyze other samples according to Step 8-9 above to obtain the calibration factors of all samples.

12) There may be several cases when switching to another blood sample:

13) After calibration factors of at least 3 fresh blood samples are obtained, click the "Calculate" button to enter the screen of calibration calculation.

Select or deselect the calibration factors of a blood sample for the calculation of the mean calibration factors by clicking the check boxes before the calibration factors.

When 3 or more groups of calibration factors are checked, CV% will be re-calculated automatically base on the checked calibration factors.

When 3 or more groups of calibration factors are checked, the mean calibration factor will be re-calculated automatically base on the checked calibration factors. The mean calibration factors are regarded as invalid if the deviation of absolute value between the calibration factors included in calculating the mean and the original calibration factors reaches or exceeds 5%.

14) If the mean calibration factors have not been calculated, when you exit the fresh blood screen or switch to another calibration mode, a dialog box will pop up.

Click "Yes" to discard the calibration data, close the dialog box, and switch to another screen or calibration mode. The original calibration factors and date remain the same.

15) If the calculated mean calibration factors are valid, when exiting the fresh blood calibration screen or switching to another calibration mode, a dialog box will pop up.

Click "Yes" to save the current mean calibration factors. Then, you can switch to another screen or calibration mode. Click "No" to close the dialog box and switch to another screen or calibration mode without saving the mean calibration factors and all the calibration data.

16) Print

If the mean calibration factors are invalid, click "Print", the dialog box "Calibration factor is invalid." will display.

If the mean calibration factors are valid, you can click "Print" to print the calibration factors of a group (or more) of blood samples in table form, no matter whether they are selected ("√") or not. The results obtained in the calibration process and the mean calibration factors can also be printed.

Chapter 9Settings

9.1Introduction

The analyzer is a flexible laboratory instrument that can be tailed to your working environment. You can use the “Setup” menu to customize the software options as introduced in this chapter.

For the security of the settings and data, two access levels are provided to the operator of the analyzer. The administrator access level provides the operator with access to more functions or settings, some of which can be configured to be accessible to operators.

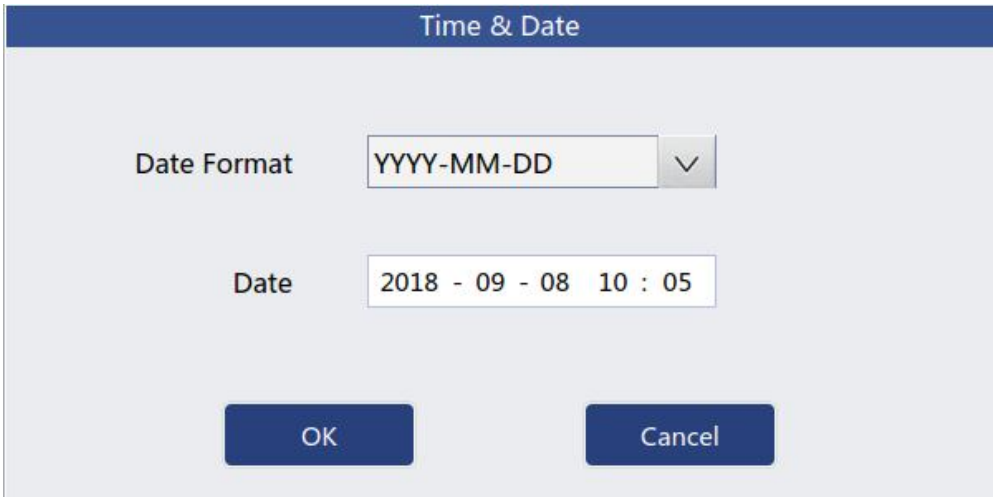
See the following figure for the setup menu.

9.2 Setting Up the Analyzer

9.2.1 System Setup

1) Date/Time Setup

Click "Setup" > "System Setup" > "Date/Time Setup" in the menu to enter the following screen. You can set up the date, time and date format of the analyzer on the screen.



2) Print Setup

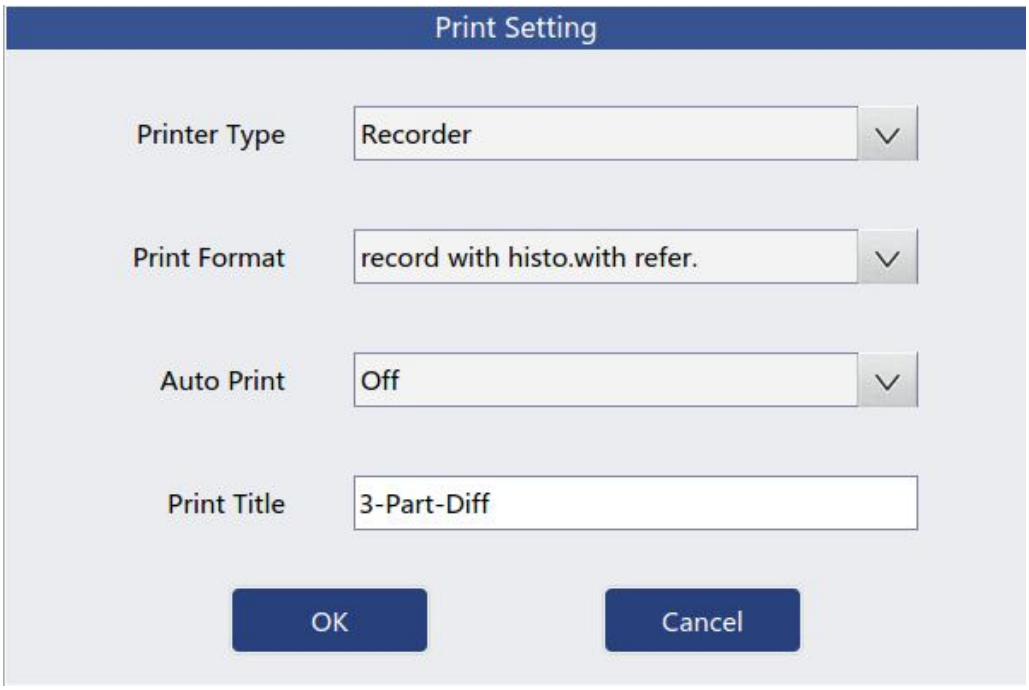
Click "Setup" > "System Setup" > "Print Setup" in the menu to enter the following screen. You can set up the following contents:

a) Print type

b) Print format

c) Auto print

d) Print title



3) Print type

There are 2 types of printing device available: Printer and Recorder. You can select either of them from the pull-down list.

4) Print format

You can select "Print with histogram" or "Print without histogram".

5) Auto print

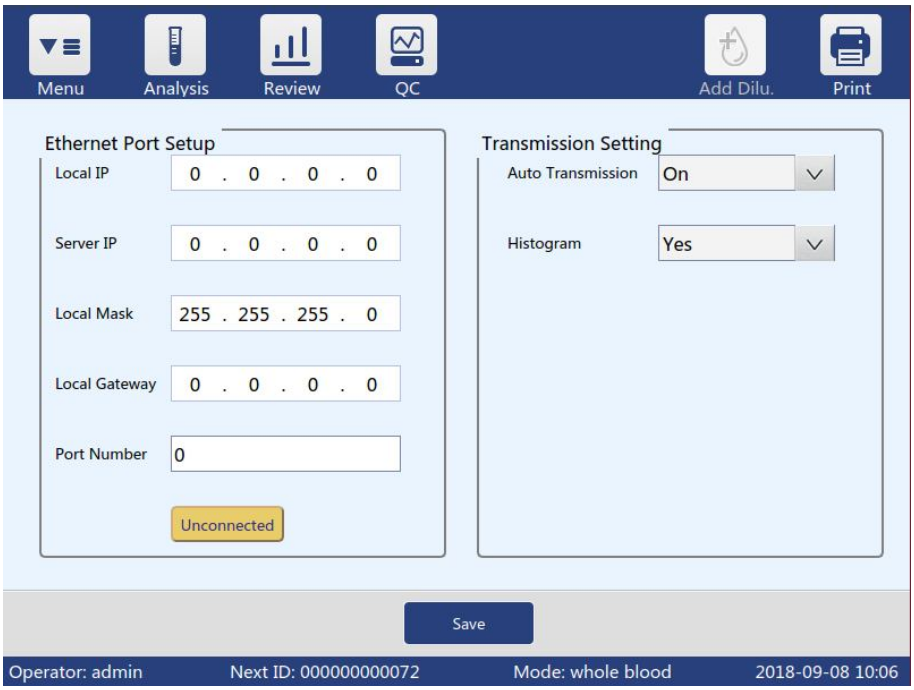
Select "On" or "Off".

6) Print title

Input the printing title.

7) Communication

Click "Setup" > "System Setup" > "Communication" in the menu to enter the following screen. You can set up the Communication port and Transmission setting.



8) Communication port setup

Click the "Local IP", "Server IP", "Local Mask" and "Local Gateway" edit boxes to enter the contents.

9) Transmission setting

Select the communication protocol type from the pull-down list.

10) Auto transmission

Click the pull-down list to select "On" or "Off".

11) Transmission mode of histogram

Click the pull-down list to select "Yes" or "No" to decide to transmis the histogram.

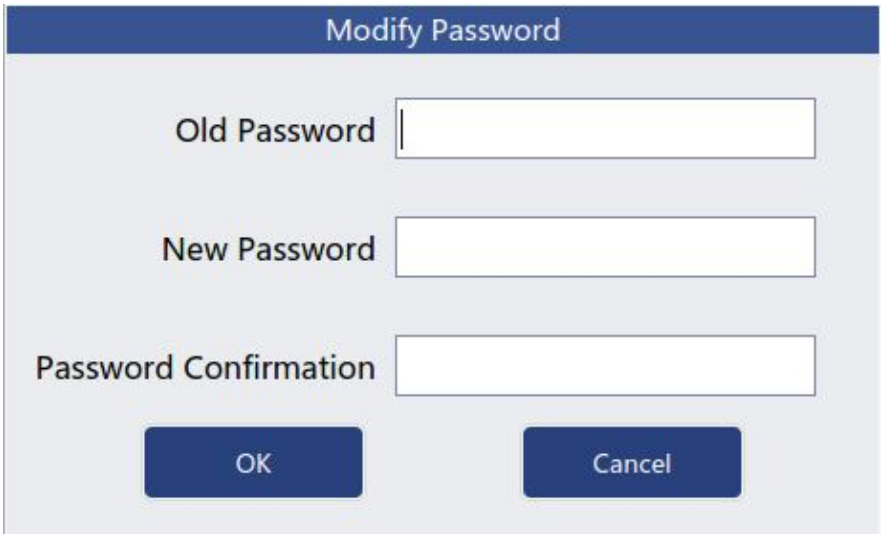
9.2.2User Administration

Click "Setup" > "User Administration" in the menu to enter the following screen.

1) Modify password

You can modify your own password.

a) Select the current user, and then click "Modify Password", the following dialog box will display.



b) Enter the required information in the edit boxes.

c) Click "OK" to save the change and close the dialog box.

Note

- The password cannot be null, and 12 characters can be entered at most.

2) Creat new user

a) Click "Add", the following dialog box will display.

b) Enter the "User Name", "Name" and "Password" information.

c) Select user group of the user.

d) Click "OK" to save the change and close the dialog box.

Note

- The user name cannot be null, and 12 characters can be entered at most.
- The name cannot be null, and 20 characters can be entered at most.
- The password cannot be null, and 12 characters can be entered at most.

3) Delete user

Select a user and then click "Delete" to delete it.

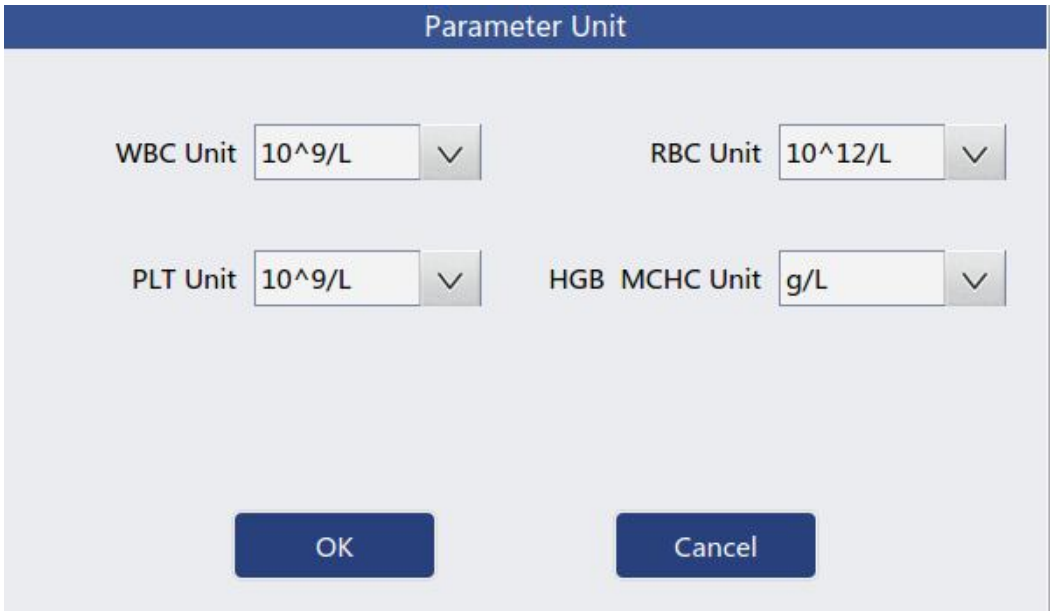
Note

- The current login user cannot be deleted.

9.2.3 Parameter Setup

1) Parameter Unit Setup

Click "Setup" > "Parameter Setup" > "Parameter Unit Setup" in the menu to enter the following screen. You can set up parameter unit on this screen.



2) Select unit system

Click the "Unit System" pull-down list to select the unit system.

3) Reference Range Setup

Click "Setup" > "Parameter Setup" > "Ref. Range Setup" in the menu to enter the following screen.

9 factory reference groups and 3 customized reference groups are provided for

your choice. Each laboratory shall select a proper reference range of its own based on its patient demographics. The reference range differs among races, genders, ages and geographic locations.

Para.	Lower Limit	Upper Limit	Para.	Lower Limit	Upper Limit
WBC	3.5	10.0	MCV	80.0	100.0
LYM%	20.0	40.0	MCH	26.0	34.0
MID%	1.0	15.0	MCHC	315	360
GRAN%	50.0	70.0	RDW_CV	11.0	16.0
LYM#	0.6	4.1	RDW_SD	35.0	56.0
MID#	0.1	1.8	PLT	100	350
GRAN#	2.0	7.8	MPV	6.5	12.0
RBC	3.50	6.00	PDW	9.0	17.0
HGB	110	175	PCT	0.10	0.28
HCT	35.0	54.0	P_LCR	11.0	45.0
			P_LCC	11	135

4) Customizing reference groups

In the Group setup screen, input the parameters directly to set up the name, lower and upper limits of age and parameter range.

5) Setting as default reference group

Click "Group" enter below screen, then select one of the reference group. Click "OK", the selected reference group can be restored to the default settings.

Note

- The name, lower and upper limits of age and gender of the factory reference groups cannot be modified.
- The input range of age is [0,999].

6) Modify reference range

To modify the reference range of a reference group, enter the cells of upper and lower limits in the table.To restore the reference ranges to default, you can click the "Default" button.

9.2.4Maintenance Setup (for administrators only)

Click "Setup" > "Maintenance Setup" in the menu to enter the following screen. You can set up the following content.

1) Auto Blank

Select "On" to save the setting if you need to do one time blank test at each time' s startup.

2) Auto Clean

There are 30times, 50times, 75times, 100times, 125times and 150times to be selected. If you select 50times, the machine will process auto clean when test number is up to 50 samples. If test samples have not been up to 50times, it will switch off, then recount after start up.

3) Diluent Reminder

If you need the reminder of counting function in prediluent mode, you can select "On". Then a pop-up dialog will appear every time to remind you if you want to count after setup.

4) Auto Sleep

If there is no operation during an interval time, the machine will go to sleep automatically. You can also setup the sleeping time according to your need.

Chapter 10Service

10.1 Introduction

Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition. This analyzer provides multiple maintenance functions for this purpose.

This chapter introduces how to use the provided functions to maintain and troubleshoot your analyzer.

- All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.

Warning

- The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If reagents accidentally spill on your skin or in your eyes, rinse the area with plenty of clean water and seek medical attention immediately.

Caution

- Improper maintenance may damage the analyzer. Operators must follow the

instruction of this manual to perform maintenance operations.

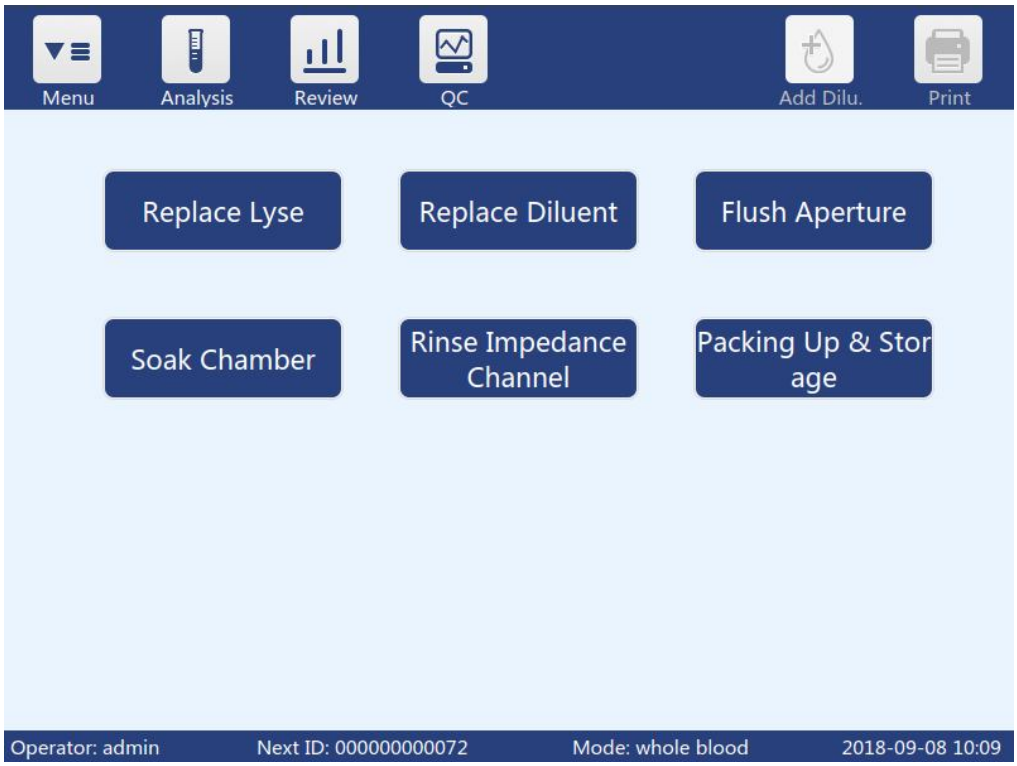
- For any questions, contact MR customer service department.
- Only MR-supplied parts can be used for maintenance. For any questions, contact MR customer service department.
- Avoid contact with the sharp sample probe when performing maintenance.

The following table lists the tools that may be used in maintenance.

No.	Tools
1	Cross-headed screwdriver
2	Slotted head screwdriver
3	Medical gloves
4	Alcohol

10.2 Maintaining Your Analyzer

Maintenance options of the analyzer includes: maintenance, cleaning and fluidics maintenance.



10.2.1Change Lyse, Change Diluent

Click the above button can do the replacement.

You can change Lyse under below condition:

1) There are bubbles in reagent tube.

2) Reagent was polluted.

3) Reagent was run off.

Changing reagents procedures are:

1) Click “ Change Lyse” / “Change Diluent.

2) When all buttons appear to grey, the process will go on.

3) The buttons will go normal once replacement is done.

10.2.2Flush aperture

Unclogging includes zapping and flushing the aperture. When clog error is reported, you should unclog the aperture.

The unclogging procedures are:

1) Click the "Flush aperture" button to start unclogging.
2) Do the above procedures to continue unclogging aperture if necessary. If the error persists, perform probe cleanser maintenance of the related channels.

10.2.3 Pack up

If the analyzer is not to be used for over 2 weeks or before shipment, you should perform this procedure.

Do as follows to pack up:

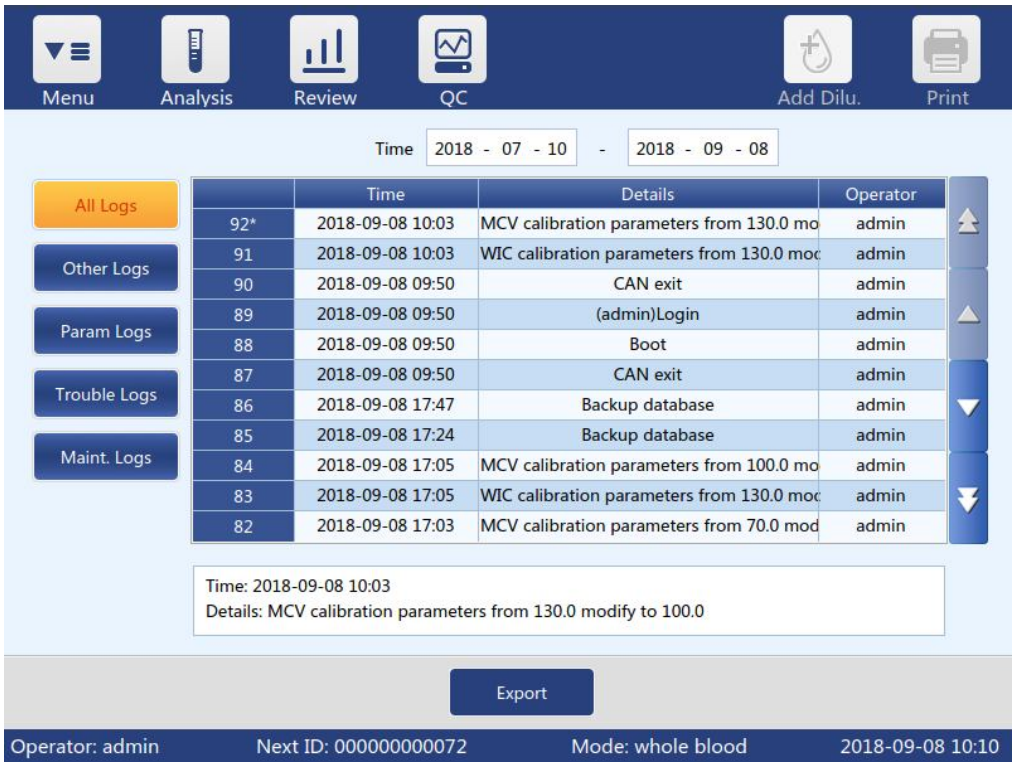
1) Take out all the tube connectors from the machine back side.
2) Seperately store the reagent tubes and the remained reagents well, keep them away from dust.
3) Click "Prepare shipping", click "Yes" to perform the pack up procedure after the dialog pop up.
4) The machine start packing up.
5) Return to the Maintenance screen after pack up.

Note

- This software can still be used after the pack up.

10.3Viewing Logs

Click “Maintenance” > “Log” in the menu to enter the following screen.



You may view the error information, parameter modification information and records of daily operation in the log.

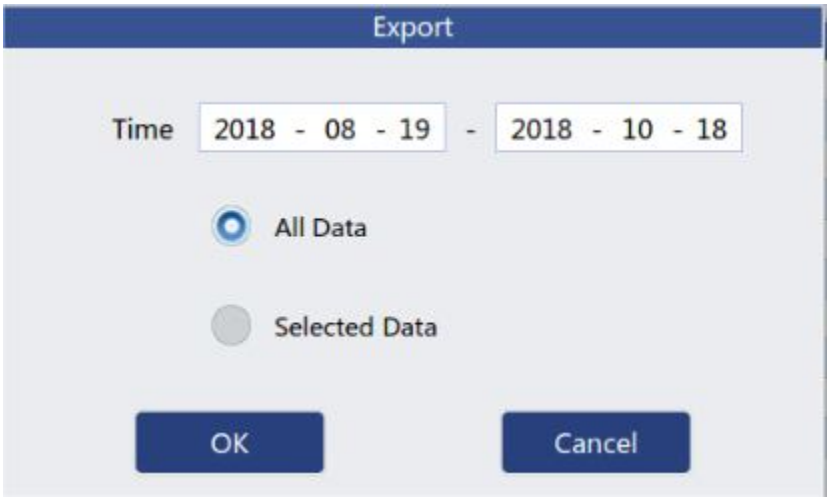
The “Log” screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

Note

- The oldest record will be overwritten automatically when number of log records reaches the utmost.
- Records of two years can be stored at most.

■ **Exporting logs**

1) Click "Export", the following dialog box will display.



2) Select the range of the logs that you want to export.

3) Click "OK" to close the dialog box and export the logs.

10.4 Version Info.

Click "Setup" > "System Setup" > "Version" in the menu to enter the following screen.

You may view the current version information of the analyzer.


Version
Software
V1.00.180904
Library Version
V1.00.180904
FPGA Version
V1.00.180904
MCU Version
V1.00.180904
Print
Return

Chapter 11Troubleshooting

11.1 Introduction

This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analyzer.

Note

- This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer.

11.2 Error Information and Handling

During the operation, if error(s) is detected, the analyzer will beep and display the corresponding error message in the error information area at the bottom right of the screen. Meanwhile, the indicator will turn red.

The following figure is the error information dialog box.

The name and troubleshooting method of the errors are displayed. Names of the errors are displayed by the order of their occurrence.

You may click to select the error, and view its troubleshooting information in the error help box. The troubleshooting information of the first error is displayed by default. Please follow the error help to resolve the error by sequence.

The following functions are provided:

1) Remove error

Click the "Remove Error" button to clear all the errors that can be removed automatically. For the errors that cannot be removed automatically, follow the troubleshooting method to solve them.

2) Close the error information dialog box

Click "Close" to close the dialog box, but the errors will still be displayed in the error information area on the screen. Click the error information area again, the dialog box will be displayed.

The possible error(s) and the corresponding troubleshooting information are listed below.

Error Name	Possible Causes	Actions
Diluent ran out	Diluent ran out	● Check whether there is diluent in the diluent container. ● If there is no diluent, replace with a new bucket of diluent. Click

Error Name	Possible Causes	Actions
		"Maint." > "Change Diluent" to clear the error automatically. ● If the error still exists after replacing the diluent, contact our customer service department.
Lyse ran out	Lyse ran out / lyse tube was clogged	● Check whether there is lyse in the reagent container. ● If there is no lyse, replace with a new bucket of lyse. Click "Maint." > "Change Lyse" to clear the error automatically. ● If the error still exists after replacing the lyse, contact our customer service department.
Waste container full	Waste container full /waste sensor is broken	● Check the waste container Is full or not. ● Check the sensor connector is short circuit or not. ● If the error still exists, contact our

Error Name	Possible Causes	Actions
		customer service department.
Blank test failed	Reagent or reagent tube were polluted or out of valid date etc	● Check whether the reagent was polluted or out of valid date. ● Click "Maint." > "Rinse impedance channel" to clean the tube ● If the error still exists, click " Soak impedance transducer", then do blank test again to confirm the error is clear or not. ● If the error still exists after replacing the cleanser, contact our customer service department.
HGB result inaccurate	HGB blank voltage abnormal	● Check "HGB blank voltage result" in " System status detection " screen. ● If "HGB blank voltage" is beyond the reference range, contact our customer service department, readjust " HGB background

Error Name	Possible Causes	Actions
		voltage" under our instruction.
WBC clogging or RBC clogging	Aperture clogging or WBC counting time wrongly setup or valves default	● Click "Maint." > "Flush Aperture", then do a blank test counting to check the counting time. ● If the erros still exists, click "Maint." > "Soak impedance transducer" to aspirate the probe cleanser to soak the aperture. ● If the error still exists, contact our customer service department.
Startup no response	● Power cable is disconnected with the power outlet ● Power fuse was maybe burned out	● Check the power cable is well connected or not. ● Check the power fuse is burned or not. ● If the error still exists, please switch off , then contact our customer service department.
Motor abnormal	● Poor connection of motor signal	Switch off the power, then contact our customer service department.

Error Name	Possible Causes	Actions
sound	cable ● Trip optocoupler fault ● Motor failure ● Motor drive circuit failure	
Printer no response	● Cable ● Printer failure	● Check the printer power cable and connection cable, if it still cannot be printed, re-plug the connection cable and restart the machine and printer. ● If the error still exists, connect the printer to a normal PC to check if it can work or not. ● If the error still exists, contact our customer service department.

If there is any other error(s), the processing method should be based on the software prompt.

Appendix ASpecifications

A.1 Classification

According to the 98/79/EC, the analyzer belongs to in vitro diagnostic medical device. It was classified into Others device, not in annex II and not for self-testing, not for performance evaluation.

A.2 Reagents

Diluent	HA 3D 01
Lyse	HA 3L 02
Probe cleanser	D 01

A.3 Applicable Tubes

The following tubes can be used:

1) Φ12~15×75mm evacuated collection tube (without cap) for whole blood mode.
2) Φ11×40mm (1.5ml centrifugal tube) and 0.5ml centrifugal tube for predilute and capillary whole blood mode.

A.4 Parameters

Parameter Name	Abbreviation	Default Unit
White Blood Cell count	WBC	10^9 / L
Granulocytes number	GRAN#	10^9 /L
Granulocytes percentage	GRAN%	%
Lymphocytes number	LYM#	10^9 /L
Lymphocytes percentage	LYM%	%
Middle cells number	MID#	10^9 /L
Middle cells percentage	MID%	%
Red Blood Cell count	RBC	10^{12}/ L
Hemoglobin Concentration	HGB	g/L
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L
Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV	%
Red Blood Cell Distribution Width - Standard Deviation	RDW-SD	fL
Hematocrit	HCT	%
Platelet count	PLT	10^9 / L

Parameter Name	Abbreviation	Default Unit
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	None
Plateletcrit	PCT	%
Platelet larger cell ratio	P_LCC	10^9 / L
Platelet larger cell count	P_LCC	%
Red Blood Cell Histogram	RBC Histogram	None
Platelet Histogram	PLT Histogram	None
White Blood Cell Histogram	WBC Histogram	None

A.5 Sampling Features

A.5.1 Sample Volumes Required for Each Analysis

Refers to all terms present in the calibration curve expression with the exception of concentration and reactivity.

Whole blood and capillary whole blood mode	≤10μL
Prediluted mode	≤20μL

A.5.2 Throughput

60 samples/hour

A.6Performance Indicators

A.6.1Display Range

Parameter	Display Range
WBC	0.0×10^9/L ~ 999.9×10^9/L
RBC	0.00×10^{12}/L ~ 18.00×10^{12}/L
HGB	0 g/L ~ 300g/L
PLT	0×10^9/L ~ 9999×10^9/L
HCT	0%~80%

A.6.2 Background/Blank Count

Parameter	Background/Blank Count Requirements
WBC	≤ 0.2×10^9 / L
RBC	≤ 0.02×10^{12}/ L
HGB	≤1g/L
PLT	≤ 10×10^9 / L

A.6.3 Linearity Range

Parameter	Linearity Range	Deviation Range (Whole Blood)	Linearly Dependent Coefficientr
WBC	0.0×10^9/L ~ 10.0×10^9/L	≤±0.3×10^9/L	≥0.990
	10.1×10^9/L ~ 100.0×10^9/L	≤±5%	
RBC	0.10×10^{12}/L ~ 1.00×10^{12}/L	≤±0.05×10^{12}/L	≥0.990
	1.01×10^{12}/L ~ 8.00×10^{12}/L	≤±5%	
HGB	0 g/L ~ 70g/L	≤±2g/L	≥0.990
	71 g/L ~ 250 g/L	≤±2%	
PLT	0×10^9/L ~ 100×10^9/L	≤±10×10^9/L	≥0.990
	101×10^9/L ~ 1000×10^9/L	≤±8%	

A.6.4Accuracy

Parameter	Detection Range	Relative deviation/%
WBC	3.5×10^9 /L ~ 9.5×10^9 /L	≤±5.0
RBC	3.8×10^{12} /L ~ 5.8×10^{12} /L	≤±2.0
HGB	115 g/L ~ 175 g/L	≤±2.0
PLT	125×10^9 /L ~ 350×10^9 /L	≤±8.0

HCT	35%～50%	≤±3.0
MCV	82 fL～100 fL	≤±3.0

A.6.5Precision

Parameter	**Detection Range**	**Whole Blood Precision (CV/absolute deviation d)**
WBC	3.5×10^9/L～15.0×10^9 / L	≤2.0%
RBC	3.00×10^{12} / L ~ 6.00×10^{12} / L	≤1.5%
HGB	100 g/L ~ 180 g/L	≤1.5%
PLT	100×10^9 / L ~ 149×10^9 / L	≤6.0%
	150×10^9 / L ~ 500×10^9 / L	≤4.0%
HCT	35%～50%	≤2.0%
MCV	70 fL～120 fL	≤1.0%

A.6.6 Carryover

Parameter	**Deviation Requirements**
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
PLT	≤1.0%

A.7 Input/Output Device

Warning

- Be sure to use the specified devices only.

Note

- If the analyzer is to be connected with LIS, the PC must be configured with dual network cards.

A.7.1 External Computer (Optional)

Recommended PC configurations: CPU Intel® 1.6GHz and above

RAM: 1G or above

Hard disk: 160GB or above

Recommended resolution of the display: 1280*1024 (standard), 1680*1050 (wide screen) Operating system: Microsoft Windows 7 or above, with DVD-ROM.

A.7.2. Keyboard (Optional)

101-Key alpha-numeric keyboard

A.7.3. Mouse (Optional)

A.7.4. External Barcode Scanner (Optional)

A.7.5. Printer (Optional)

A.8 Interfaces

4 USB ports and one network port.

A.9 Power Supply

	Voltage	Input power	Frequency
Analyzer	(100-240V～) ±10%	100-120VA	(50Hz/60Hz)±1Hz

A.10Fuse

Warning

- Be sure to use the specified fuse only.

Fuse specification: 250VT3.15AH

A.11EMC Description

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

This equipment complies with the emission and immunity requirements of the EN 61326-1:2013 and EN 61326-2-6:2013.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

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.

A.12 Sound Pressure

Maximal sound:65 dBA

Note

- Be sure to use and store the analyzer in the specified environment.

A.13 Operating Environment

Optimal operating temperature: 10℃ ~ 35℃

Optimal operating humidity: 20% ~ 85%

Atmospheric pressure: 70kPa ~ 106kPa

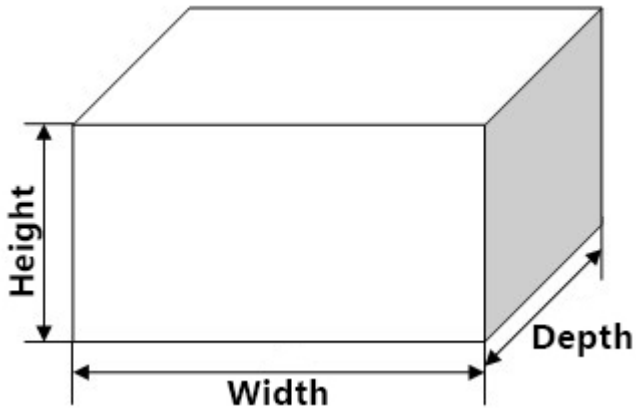
A.14Storage Environment

Ambient temperature: -20℃ ~ 40℃

Relative humidity: 10% ~ 90%

Atmospheric pressure: 50kPa ~ 106kPa

A.15Dimensions and Weight



Dimensions	Width(mm) ≤ 285 Height (mm) ≤ 375 (without foot) Height (mm) ≤ 390 (with foot) Depth (mm) ≤ 390
Weight	≤ 18Kg (Net weight)

A.16Safety Classification

Overvoltage category: II

Pollution degree: 2

Means of protection: Class I

Appendix BHazardous Substances

Parts name		Hazardous substances					
		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Host	shell	○	○	○	○	○	○
	PCBA	×(1)	○	○	○	○	○
	sheet metal parts	○	○	○	○	○	○
	machining part	○	○	○	○	○	○
	plastic pieces	○	○	○	○	○	○
	metal pieces	○	○	○	○	○	○
	connection cable	○	○	○	○	○	○
	fluid path components	○	○	○	○	○	○
Accessories	Labels	○	○	○	○	○	○
	Closure assembly	○	○	○	○	○	○
	Maintenance tools	○	○	○	○	○	○
	Probe wipe block	○	○	○	○	○	○
Package	Packaging materials	○	○	○	○	○	○

○: means the content of the hazardous substance in all homogeneous materials of the part is in the limited requirement according to the standard of SJ/T 11363-2006.

×: means the content of the hazardous substance in at least one of the homogeneous materials of the part is beyond the limited requirement according to the standard of SJ/T 11363-2006.

1）some parts of the circuit board used lead solder during processing.

Notice: the product marked with "×" is because there has no other technologies or parts to be replaced at present stage, under normal use conditions, leak and mutation will not occur in 5 years, and it will not cause environment pollution or harm to people and property.

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