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Operation Manual

HMT-60P

Auto Hematology Analyzer

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Preface

This manual introduces safety and the correct use of biochemical analyzer, read it carefully before use.

Store this operator’s manual properly for future reference.

Product Name: Auto Hematology Analyzer

Type/Model: HMT-60P

Serial No.: EC-20, EC-21, EC-28, EC-30, EC-31, EC-36, EC-38A, EC-38B, EC-38,EC-38 CRP

Product Components: mechanical system, flow path system, detecting system,control system and software system.

Scope of application: The detection items include maximum 21 parameters (WBC, Lym#, Mid#, Gran#, Lym%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, HGB, P-LCC(optional), P-LCR(optional)), white blood cell 3-part classification and 3 histograms(WBC histogram, RBChistogram, PLT histogram)

Declaration

This operator’s manual may be modified without notice.

The pictures in this operation manual are for reference only. If there is inconsistency between the pictures and the actual product, the actual product shallprevail. Do not use the pictures for other than intended use.

Avecon Healthcare Pvt. Ltd. shall be responsible for the safety, security, and performance of the productonly when all of the following conditions are met:

- The product is operated based on this operator's manual.
- The electrical appliances in the relevant working room comply with applicablenational and local requirements.

Note

- The system is to be operated only by clinical professionals, doctors or laboratoryexperimenters trained by our company or our authorized distributors.
- Ensures that the analyzer is used under the specified condition, if not, the analyzer may not operate normally, the test results will be unreliable, and theanalyzer components may be damaged.
- Keep the analyzer away from electric-brush motors, flashing fluorescent andelectric-contact equipment which is switched on/off frequently.

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1 Manual Overview

1.1 Introduction

This chapter explains how to use this operation manual of auto hematologyanalyzer, which is shipped with the auto hematology analyzer and containsreference information about the analyzer and procedures for operating,troubleshooting and maintaining the analyzer.

Read this manual carefully before operating the analyzer and operate your analyzerin strict accordance with this manual.

1.2 Scope of manual

This manual is written for clinical laboratory professionals, explain how to operatethe analyzer:

- Learn about the hardware and software of the analyzer
- System parameter setting
- Perform daily operations.
- Perform system maintenance and troubleshooting

1.3 Symbol

Safety symbol marks used in this manual

Ensure to understand well of below signs, it is important to you!

When you see...	Then…
Warning	This sign is warning you that a wrong operation will cause serious injury.
Caution	This sign is warning you that machine system was damaged or in an unreliable situation.
NOTE	This sign warning you some important information that requires yournote.
Biohazard	This sign warning you that will cause a potentially biohazardous condition.

The labels attached to the panels of the system use symbols to clarify the meaningof the text. The list below shows the symbols that are used on the analyzer.

Note

- If the labels are damaged or missing, please contact our customer service department or your local distributors.
- All illustrations in this manual are provided as references only. They maynot necessarily reflect actual analyzer configuration or display.

Symbol	Meaning
	Warning
	Biohazard
	Exercise caution to prevent puncture
S/N	Serial number
	Protective grounding
|	ON (main power)
○	OFF (main power)
ON	ON
OFF	OFF
~	Alternating current
IVD	In vitro diagnostic medical device
LOT	Lot No.
	Use by

CE	The device is in full compliance with the council directive concerning in vitro diagnostic medical devices IVDR 746.
	Date of manufacture
	Manufacturer

1.4 Safety

Biohazard

- All the samples, controls, calibrators, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.
- In case your skin contacts the sample, control or calibrator, follow standard laboratory safety procedure and consult a doctor.
- If leak happens to the analyzer, the leak liquid is potentially biohazardous.

Warning

- Please check the firmness of all the door/covers/panels before running the analyzer to prevent unexpected opening or loosening when the analyzer is working.
- Make sure all the safety measures are taken. Do not disable any safety device or sensor.
- Please respond to any alarm and error message immediately.
- Do not touch the moving parts
- Contact E-Lab or E-Lab authorized agents upon the identification of any damaged part.
- Be careful when opening/closing and removing/installing the doors, covers and panels of the analyzer.
- Dispose of the waste as per the requirements of the local environment protection authorities.

- The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.

Caution

- Please use the analyzer in strict accordance with this manual.
- Please take proper measures to prevent the reagents from being polluted.

2 System Description

2.1 Outline of function

Auto Hematology Analyzer is an in vitro diagnostic device used in clinical laboratories. It is intended for blood cell counting, 3-part classification of white blood cell and hemoglobin concentration measurement in clinical examinations.

2.2 Measurement principle

2.2.1 WBC,RBC,PLT measurement

The basic principle of analyzer detection is Electrical Impedance method. This method is based on the measurement of changes in electrical resistance produced bya particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode 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 thus generated is equal to the number of blood cell that passed through the aperture. The amplitude of each pulse is proportional to the volume of each blood cell. Different blood cells can be classified to counted according on the amplitude of pulse.

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. If the pulse generated is abovethe WBC/RBC/PLT lower threshold value, it is counted as a WBC/RBC/PLT. The cell volume distribution is determined by the cell count within each channel classified by the pulse amplitude.

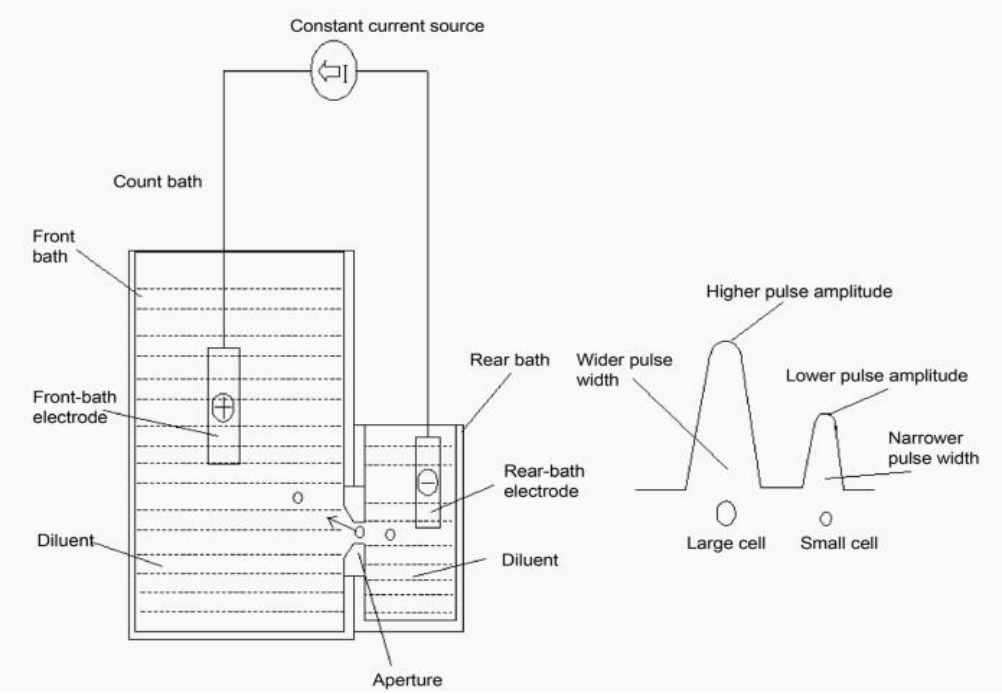


Figure2-1 Electrical Impedance method

2.2.2 Hemoglobin (HGB) measurement

HGB is determined by the colorimetric method. The WBC/HGB diluent is delivered to the HGB bath where it is mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 525nm.

An LED is mounted on one side of the bath and emits a beam of monochromatic light with a central wavelength of 525nm. The light passes through the sample andis then measured by an optical sensor mounted on the opposite side. The signal is then amplified and the voltage is measured and compared with the blank reference reading (readings taken when there is only diluent in the bath).

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

$$\text{HGB(g/L)}=\text{Constant}\times \text{Log}_{10}\left(\frac{\text{Blank Photocurrent}}{\text{Sample Photocurrent}}\right)$$

2.2.3 Result parameters

The parameters can be classified into three groups according to calculation method.

1. Parameters are obtained by measuring directly

   WBC, RBC, PLT, HGB, CRP(optional).

2. Parameters are obtained by the histogram

   LYM%, MID%, GRA%, MCV, RDW-SD, RDW-CV, MPV, PDW, P-LCR (optional),

   P-LCC(optional).

3. Parameters are obtained by calculating

LYM#, MID#, GRA#, HCT, MCH. MCHC, PCT.

The parameters are calculated as follows:

$LYM\% = 100 \times A_L / (A_L + A_M + A_G)$

$MID\% = 100 \times A_M / (A_L + A_M + A_G)$

$GRA\% = 100 \times A_G / (A_L + A_M + A_G)$

Among:

A_L= Cell count in the Lym zone

A_M = Cell count in the Mid zone

A_G = Cell count in the Gran zone

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

RDW-CV: Based on the RBC histogram, the analyzer calculates the CV (Coefficient of Variation, %) of the red blood cell distribution width.

RDW-SD: Based on the RBC histogram, the analyzer calculates the standard deviation of the red blood cell size distribution.

MPV: Based on the PLT histogram, this analyzer calculates the mean plateletvolume.

PDW: PDW is the geometric standard deviation of the platelet size distribution.Each PDW result is derived from the platelet histogram data.

P-LCR(optional): Based on the PLT histogram, the analyzer calculates the platelet-large cell ratio.

P-LCC(optional): P-LCC is platelet-large cell count, it is calculated based on the platelet-large cell ratio and platelet count.

LYM# = LYM%×WBC/100

MID# = MID%×WBC/100

GRA# = GRA%×WBC/100

HCT(%) = RBC×MCV/10

MCH (pg)= HGB/RBC×10

MCHC (g/L)= HGB/HCT×100

PCT (%)= PLT×MPV/10000

2.3 Structure of the analyzer

The auto hematology analyzer consists of mechanical system, flow path system,detecting system, control system and software system.

Take EC-38 for example, the structure of auto hematology analyzer is as follow:

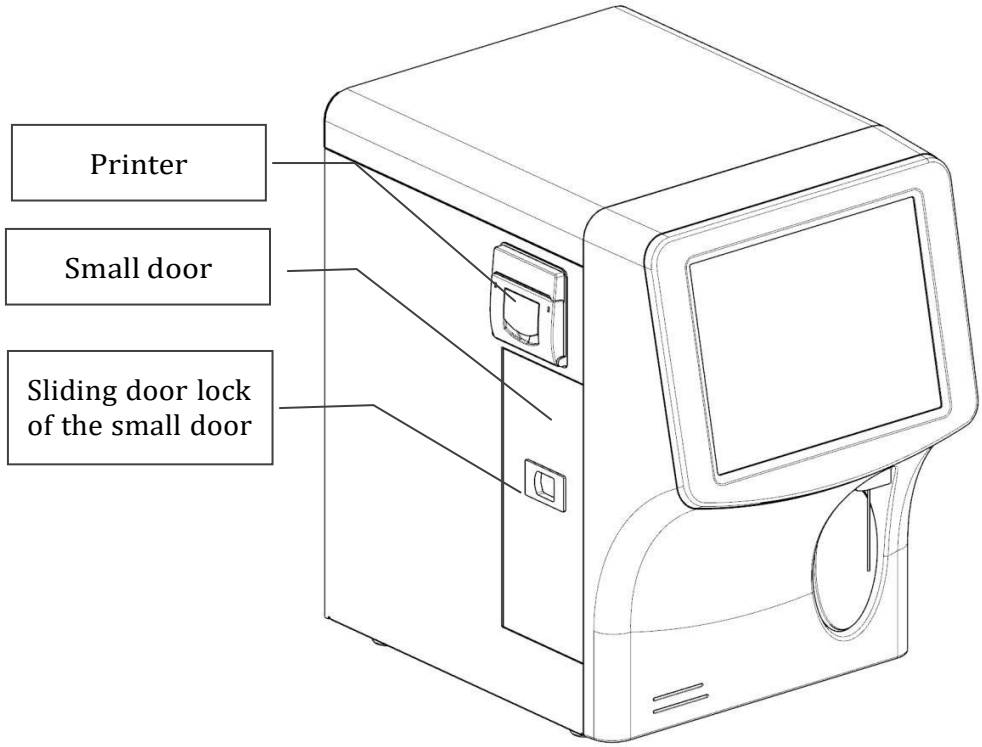


Figure 2-2Appearance of the analyzer

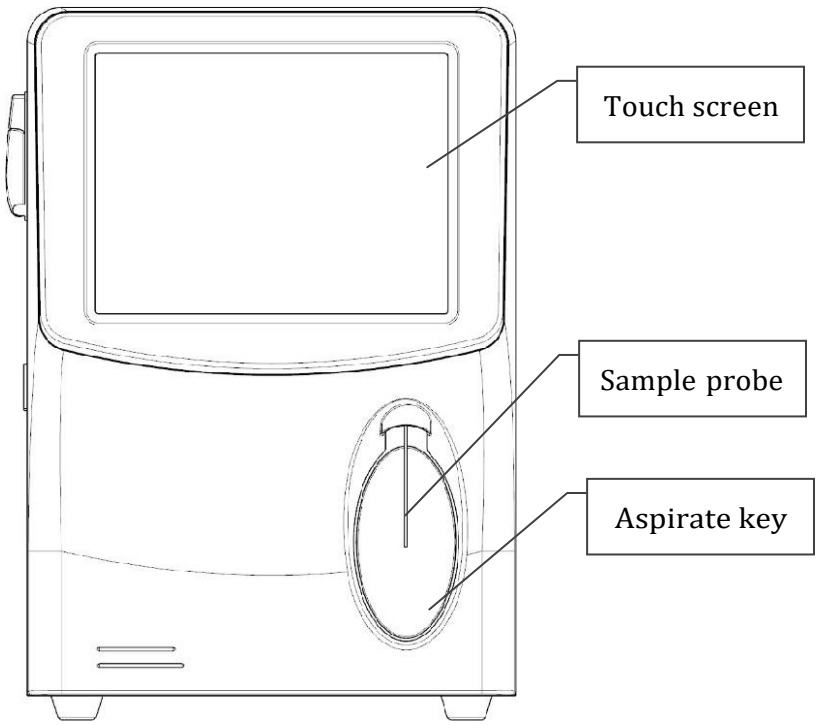


Figure 2-3 Front of the analyzer

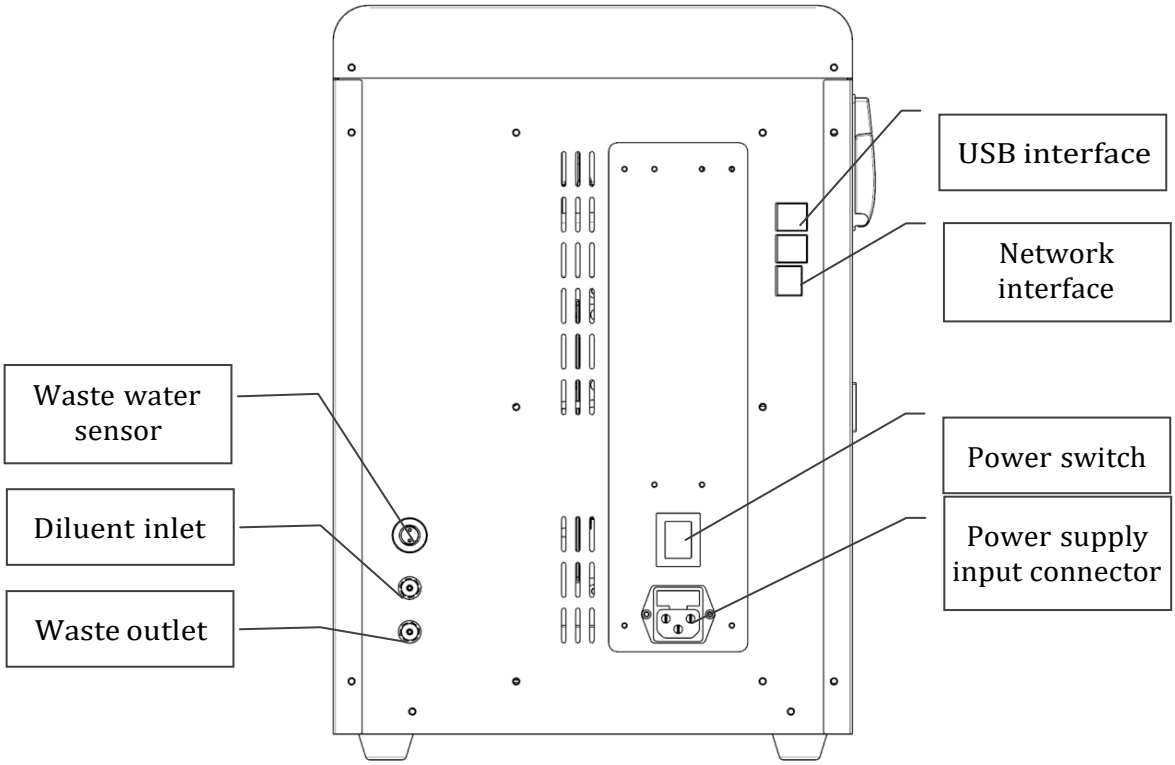


Figure 2-4 Back of the analyzer

2.3.1 Touch screen

The touch screen is located on the front side of the analyzer for performing interface operations and displaying the information.

2.3.2 Aspirate key

The aspirate key is located behind the sample probe to start the sample analysis, toadd diluent, or to cancel sleep.

2.3.3 USB interface

The USB interface is located on the back side of the analyzer. There are 4 USB interfaces in total for external equipment (printer, mouse or keyboard, and so on)connection or data import and export or software update.

2.3.4 Network interface

The network interface is located on the back side of the analyzer. There is 1 network interface in total for connecting with the external computer to realize the data transmission.

3 Installation

3.1 Overview

This chapter explains how to properly install the auto hematology analyzer.

The analyzer should only be installed by our engineer or our authorized personal.When the analyzer needs to be relocated, you should install the analyzer in accordance with this installation procedure or contact our customer service department.

Warning

- Installation by personnel not authorized or trained by our company maycause personal injury or damage to the analyzer. Do not install the analyzer without the presence of our authorized personnel.

The auto hematology analyzer has passed strict tests before it is shipped from the factory. The analyzer was carefully packed before transportation to avoid impact in transportation. When you receive the system, carefully inspect the package. If yousee any signs of mishandling or damage, contact our Customer Service Departmentor your local distributor immediately.

3.2 Unpacking

3.2.1 Inspection

When you receive the analyzer, please carefully before unpacking to see if there areany of the following damage:

1. The outer packaging is placed upside down or distorted.
2. The outer packaging shows obvious signs of having been exposed to humid conditions.
3. The outer packaging shows obvious signs of having been crashed.
4. The outer packaging shows signs of having been opened.

If you find anything missing or damaged, contact our Customer Service Departmentor your local distributor immediately.

After opening the package, please apply the following inspections:

1. Check if all the items listed in the packing list are in the packaging.
2. Carefully inspect the appearance of all the items to check if they are damaged or distorted.

3.2.2 Unpacking steps

Please unpack the analyzer by taking the following steps:

1. Select a level and stable workbench.
2. Open the outer packing box, take out the accessory pack, take out the analyzer together with the protective and cushioning materials, and put the analyzer on the level workbench.
3. Remove the foam and the protective PE bag.
4. Remove the right panel (Remove the screws on the back panel with a phillips screwdriver)
5. Remove the binder clips, which are used for fixating two conveyor belts.

Note

- To avoid the possible collision resulting from the slippage caused by shaking and slanting during transportation, the central position of thosetwo belts is fixated with binder clips before they are shipped from the factory. The binder clips must be removed during unpacking.

6. Cut off the cable tie and remove the foam, which are used for fixating sample assembly.

Note

- To avoid damaging the sampling assembly during the transportation, the sampling assembly of analyzer is fixated with cable tie and foam before leaving the factory. Do remove the cable tie and foam before using the analyzer

3.3 Installation requirement

Make sure that is installed in a place meeting the following requirement.

3.3.1 Environment condition

1. Temperature limitation: 15℃～30℃;

2. Relative humidity: 20%～85%;
3. Atmospheric limitation: 70kPa～106kPa;
4. Ventilation: Keep air exchange to ensure good air circulation. The wind shouldnot blow directly at the analyzer.

Warning

- Analyzers cannot be used in flammable and explosive environments.

Caution

- Operating the instrument in an environment other than the specifiedmay lead to unreliable test results.
- If the temperature or relative humidity does not meet the above-mentioned requirements, be sure to use air-conditioningequipment.

3.3.2 Power condition

1. Power supply: AC100V～240V, (50/60Hz)±1Hz; Input power: ≤150VA.
2. The distance between the power socket and the system should be less than 1 meters.

Warning

- To avoid the risk of electric shock, this equipment must only be connected supply mains with protective earth.
- Make sure that the input voltage meets the requirements of the analyzer before turning on the analyzer.

Caution

- Using a patch board may introduce electrical interference and generate incorrect analysis results. Please place the analyzer near the electrical outlet to avoid using the patch board.
- Please use the original electrical wires shipped with the analyzer. Using other electrical wires may damage the analyzer or generate incorrect analysis results.

3.3.3 Site condition

The analyzer installation shall meet the following conditions:

1. The instrument is for indoor use only,
2. Level ground and stable workbench with load capacity ≥50kg.
3. The bearing platform should be free of shaking.
4. Free of dust, mechanical vibration, heat and wind sources, contamination, heavy-noise source or electrical interference.
5. The installation site should not be in direct sun.
6. It's recommended to evaluate the electromagnetic environment of the laboratory before operating the analyzer.
7. Keep the analyzer away from sources of strong electromagnetic interference, otherwise, its proper functioning may be affected.

3.3.4 Space condition

1. At least 50cm from each side, which is the preferred access to perform service procedures.
2. At least 20cm from the back for cabling and ventilation.
3. Enough room on and below the countertop to accommodate for the diluent andwaste containers.
4. Place the analyzer near the electrical outlet and avoid being blocked by any objects, so that you can disconnect the power plug easily as required.
5. Do not place the device in a position, where is difficult to disconnect device.

3.4 Carry method

1. The analyzer has been used shall be carried after performing Pack-up operation.
2. Under short distance condition, the transportation tools such as carts can beused.
3. During the moving and transportation, the display screen and sample probe should be not subject to external force, no contact with other goods, and no damage.
4. The analyzer must be kept in the upright direction in transportation.
5. The analyzer should avoid shaking in transportation.

Warning

- The moving parts such as sample probe should be kept at a certain distance from the operator's clothing, hair, and hands, otherwise damagemay cause personal injury.

Warning

- Theanalyzer should be carried and installed by our engineer or our authorized personal. Do not carried the analyzer without the presence ofour authorized personnel.

3.5 Connecting the Analyzer System

3.5.1 Electrical connection

1. Take out the power cablefrom the instrument accessory bag;
2. Connect power cable from back side of the analyzer to power socket. Be sure to connect solidly.

3.5.2 Reagent connection

Warning

- Be sure to dispose of reagents, waste, samples, consumables, etc. According to local legislations and regulation.
- The reagents are irritating to eyes, skin and mucosa. Wear proper protective equipment(e.g. glove, lab uniforms, etc.) and follow laboratorysafety procedures when handling them in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see adoctor.

Note

- Please make sure the length of the diluent and the waste pipe should be no longer than 1500mm
- The top height of waste bucket and diluent bucket should be lower thanthe table placed by the instrument.
- After reagent is connected with the analyzer, tighten the reagent bottlecap to prevent the reagent from contamination.

1. Take out the diluent wipe and the waste pipefrom the instrument accessory bag.Plug one end of tube to their counterparts marked on the back side of the analyzer, put the other end of tube into the diluent bucket or waste bucket;
2. Open the small door on the left panel (open the sliding door lock on the small door with your hand), connect lyse tube to lyse bottle, put the lyse bottle into lyseslot.

4 Sample analysis

4.1 Preparing for analysis

4.1.1 Checking before turning on the analyzer

Biohazard

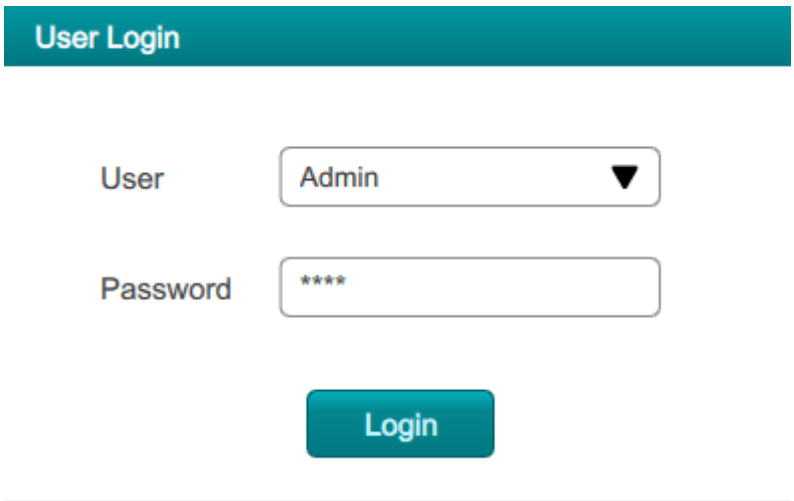
- All the samples, controls, calibrators, wastes are potentially bio hazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

You should do the following operations before turning on the analyzer.

1. Check the waste container. Make sure that the waste container is empty before starting the system daily.
2. Check the dilute and lyse is sufficient. Check the dilute tube and waste tube are connected properly and not bent.
3. Check the power cord of the analyzer is plugged safely into the power outlet.
4. Check the printer paper is enough and properly installed.

4.1.2 Startup

1. Place the power switch in the “I” position.
2. The ***Login*** dialog box of the operating software is displayed, as shown figure below.



3. Enter the correct user name and password in the ***Login*** message box.

4. The system will perform self-test and initialization in sequence, then do background test.

The system enters the ***sample analysis*** interface by default after the startupprocedure ends.

Note

- Running a test when the background is abnormal, you would obtain an unreliable testing result.
- If any error is detected during initialization (e.g. the background results is abnormal), the analyzer will activate the alarm. For details, see ***11 Troubleshooting.***
- The system will identify the user's authorization (administrator, engineer,user) according to the login user's name and password.
- To switch a user, click " " on the top left screen, reenter the user's nameand password, click "Login" button, then you can log in the software interface with another user identity.
- If you failed to start the analyzer continuously, please contact our customer service department or your local distributors.

For the background test, the system only displays the WBC, RBC, HGB, HCT, PLTand CRP(optional) values. The operator can do background test at any time. Take some dilute as the sample, put it into in the cleaning counting cup, and press the aspirate key to start background test.

If the background results exceed the Ref. Range, you should do background test repeatedly until the test results are normal. If the background results still are abnormal after five tests, please check the reagent and tube connection, and perform ***Clear Aperture, Overall Soak, Cleaning*** operation in service screen.

4.2 Preparing for sample

The analyzer measures two kinds of samples: whole blood samples (include capillary whole blood samples), prediluted samples.

Caution

- Prepare the samples as per the procedures recommended by the reagent manufacturer.
- To mix the sample thoroughly, all the samples need to be shaken as shown below.

- All the samples, controls, calibrators, wastes are potentially biohazardous.

Biohazard

Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

Warning

- Do not touch the patients' blood sample directly.

Caution

- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.

Note

- Be sure to use clean K_2EDTA vacutainer blood collection tubes with anticoagulant, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.

4.2.1 Whole blood samples (include capillary whole blood samples)

The procedure for preparing whole blood sample is as follows:

1. Use clean K_2EDTA vacutainer blood collection tubes with anticoagulant to collect venous blood samples.
2. Mix the venous blood with the anticoagulant well in the tube immediately.

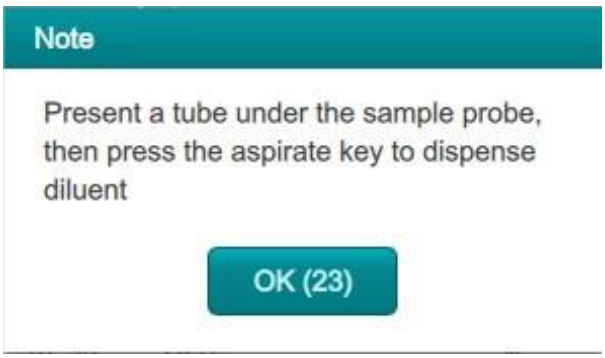
Note

- For the whole blood samples to be used for WBC classification or PLTcount, store them at room temperature and run them within 8 hoursafter collection.
- If you do not need the PLT, MCV and WBC differential results, you can store the samples in a refrigerator (2°C - 8°C) for 24 hours. You need to warm the keep samples at room temperature for at least 30 minutes before running them.
- Be sure to shake any sample that has been prepared for a while before running it.
- Run the whole blood sample within 5 minutes to 2 hours after its collection.

4.2.2 Prediluted samples

The procedure for preparing prediluted sample is as follows:

1. Click the "Dilute" button on the ***Sample analysis*** screen, a prompt box will popup on the screen as shown below:



2. Take a clean test tube, present it to the sample probe in a manner in which the probe tip is vertically in contact with the bottom of the tube so as to avoid bubbles, liquid attached to the inner wall or spatter.
3. Press the aspirate key and add the diluent (200μL).
4. If more portions of diluent are needed, repeat above steps.

5. Add 20μL of venous blood or capillary blood to the diluent, close the tube cap and shake the tube to mix the sample.
6. After the prediluted sample is prepared, click OK to exit dispensing the diluent.

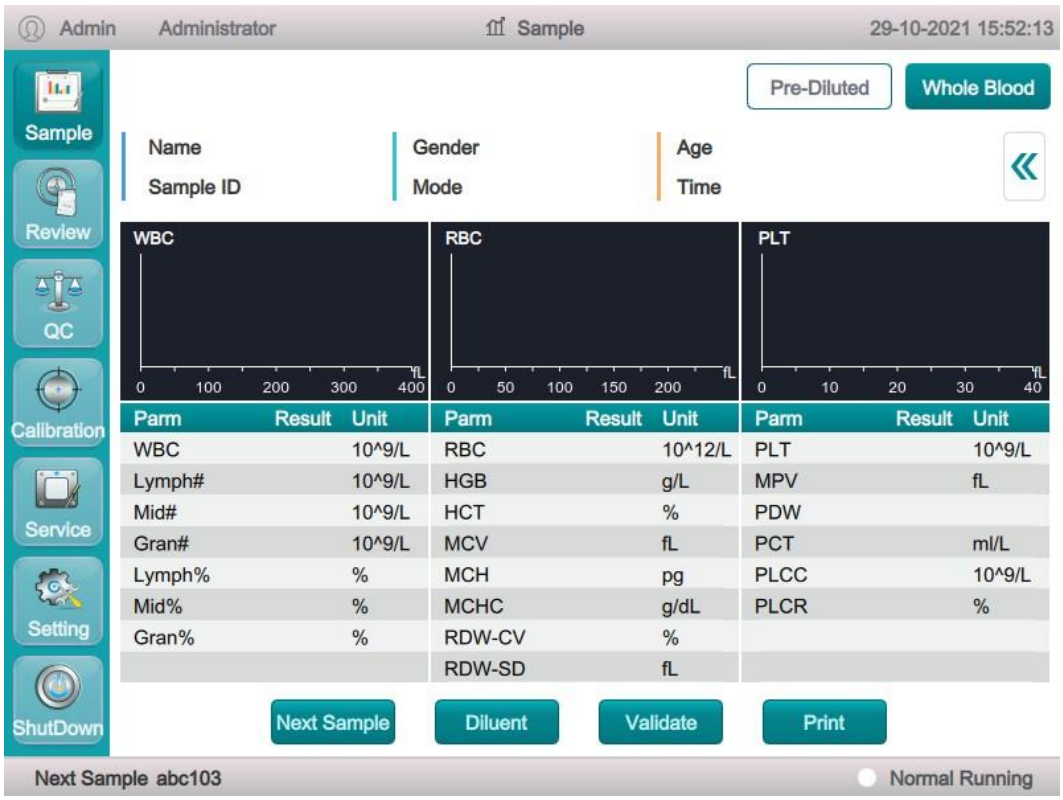
Note

- The operator can also dispense 200μL of diluent by pipette into the tube.
- Be sure to keep dust from the prepared diluent.
- Be sure to run the prediluted samples within 30 minutes after the mixing.
- Be sure to mix any sample that has been prepared for a while before running it.
- Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

4.3 Sample analysis

To ensure reliable analysis results, conduct daily QC analysis on the analyzer before running sample. Refer to **6 QC** for details.

Click ***Sample*** button to enter ***Sample analysis*** menu screen. In this screen, you can complete the operations such as inputting the sample information, performing sample analysis, reviewing/printing analysis results.

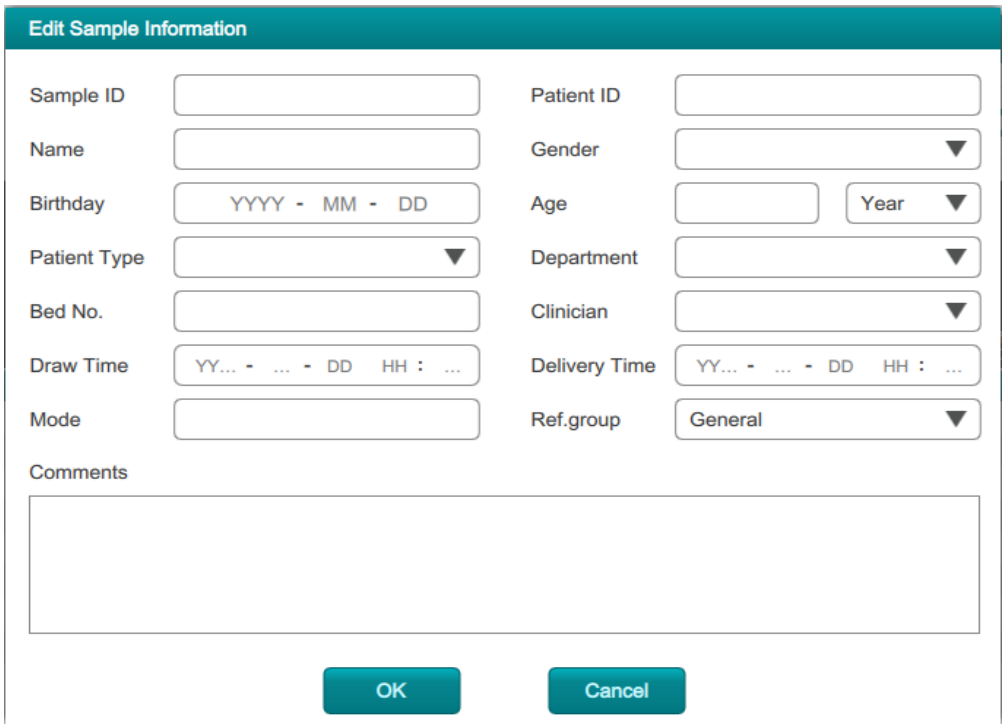


4.3.1 Entering sample information

There are two methods for inputting the sample information: Enter all informationand Entry sample ID.

Enter all information:

When the entry of next information is selected as ***Enter all information***, click ***Next Sample*** button in the ***Sample Analysis*** screen, the interface as shown in figure below will pop up on the screen. The operator can enter the full sample informationfor the next analysis sample in the dialog box. The Ref.group is automatically matched by the system without being manually by the user.



- **Sample ID:** Input the sample ID.
- **Patient ID:** Input the patient ID.
- **Name:** Input the name of patient.
- **Gender:** Select the gender of patient from the dropdown list.
- **Birthday:** Select the birthday of patient from the date control.
- **Age:** Select the unit of age from the dropdown list(Year, Month, Day or Hour) and enter the age of the patient in the textbox before the age unit.

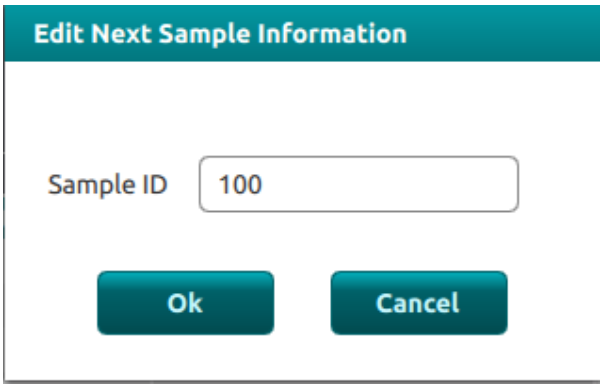
Note

- If the **Birthday** is set, the age will be displayed automatically.
- If the **Age** is changed, the birthday will be emptied.

- **Patient Type:** Select the type of patient from the dropdown list.
- **Department:** Select or input the department receiving the patient.
- **Bed No.:** Select or input the bed no. of inpatient.
- **Clinician:** Select or input a clinician.
- **Draw Time:** Select the date and time when the sample is collected.
- **Delivery Time:** Select the date and time when the sample is delivered.
- **Mode:** Display the test mode of sample.
- **Ref.group:** Select a reference group from the dropdown list. Reference group of the sample under analysis. The result is judged according to the reference rangeof the reference group and the result beyond the normal range will be flagged.
- **Comments:** Input the clarifications or notes.
- **Ok button:** Click this button to save the configuration, and return to the "Sample" screen.
- **Cancel button:** Click this button to cancel any configuration, and return to the "Sample" screen.

Entry sample ID:

When the entry of next information is selected as **"Entry sample ID"**, click "Next Sample" button in the Sample screen, the interface as shown in figure below will pop up on the screen, you can input the sample ID in this dialog box.



Edit the current sample information:

Click the patient information area in the Sample screen or Review screen, the "Edit Sample Information" dialog box will be popped up, it used to edit the information ofthe current sample. The background values and reviewed sample can not be edited.

4.3.2 Blood sample count

Biohazard

- All the samples, controls, calibrators, wastes are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling relevant items and areas in the laboratory.

- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

Take the following steps to perform sample analysis:

1. Prepare samples as instructed by ***4.2 Preparing for sample***.
2. After the sample is prepared, you can perform the operations for sample analysis:
   1) Select the blood sample mode: Whole Blood, Pre-diluted.
   2) Remove the tube cap carefully and place the sample under the probe so thatthe probe can aspirate the well-mixed sample.
   3) Press the aspirate key on the analyzer to start running the sample. The sample will be automatically aspirated by the sample probe, when the sampleprobe is lifted, remove the sample tube. The analyzer will automatically do thesample analysis.
   4) When the analysis is complete, the sample probe is reset and prepared for thenext sample analysis. The analysis result will be displayed on the analysis results area of the screen.
   5) If the automatic printing is set to ON, the analyzer will automatically printthe analysis report.
   6) Repeat steps above to run the remaining samples.

Note

- If it occurs the clogging or bubble failure during the counting and analysis process, the alarm tips of block hole or bubble will be displayed on the information tips area.
- If the test result is exceeded the range of system output, the parameter results will display "*****" in this time, you should check the validity of sample.

4.3.3 Deal with the Analysis Result

The analysis results will be displayed on the screen after sample analysis, theanalysis automatically saves sample results.

- **Validate button:** Click this button to validate the sample analysis result.
- **Print button:** Click this button to print the analysis result of the current sample.

5 Review

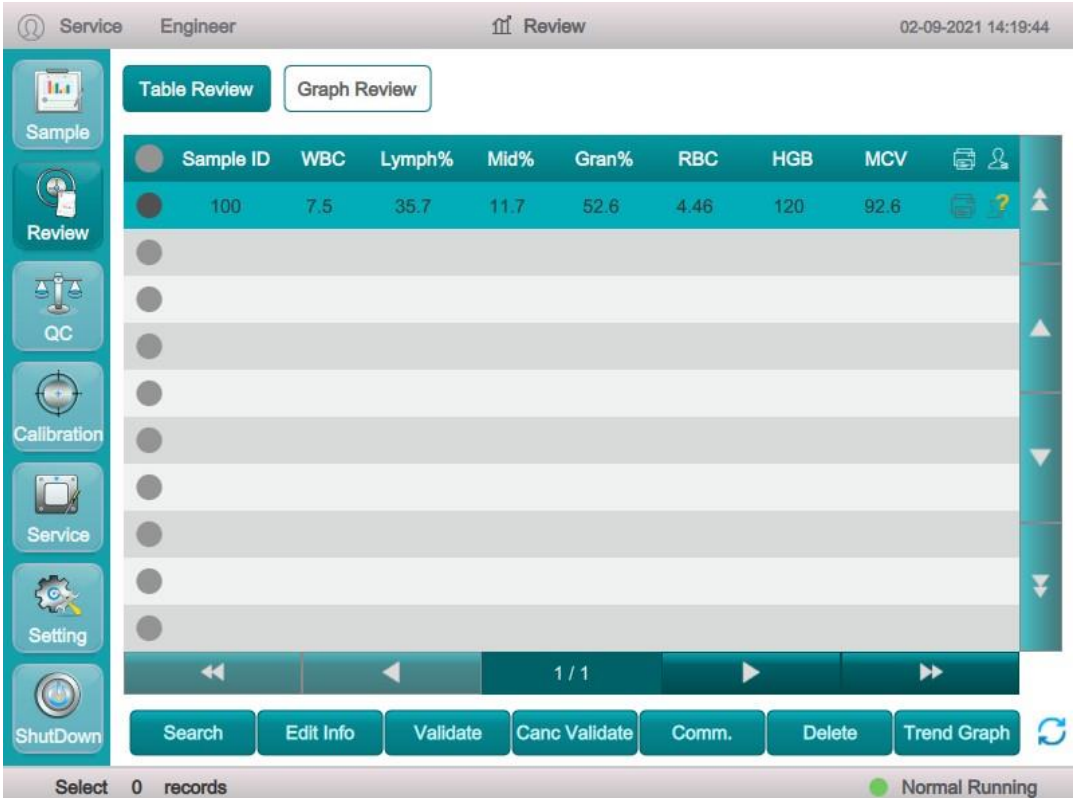
Upon the completion of each sample analysis, the analyzer will automatically save the test data. In the ***Review*** interface, you can review the parameter test data of allsample and histogram, and can print, modify or search the sample information forthe specified conditions.

Note

- A valid backup should be provided to prevent losing the data when hardware or software failure.

5.1 Table Review

Click "Review" button to enter the ***Table Review*** interface. You can browse, search,edit, validate, print the existing results and other operation in this interface.



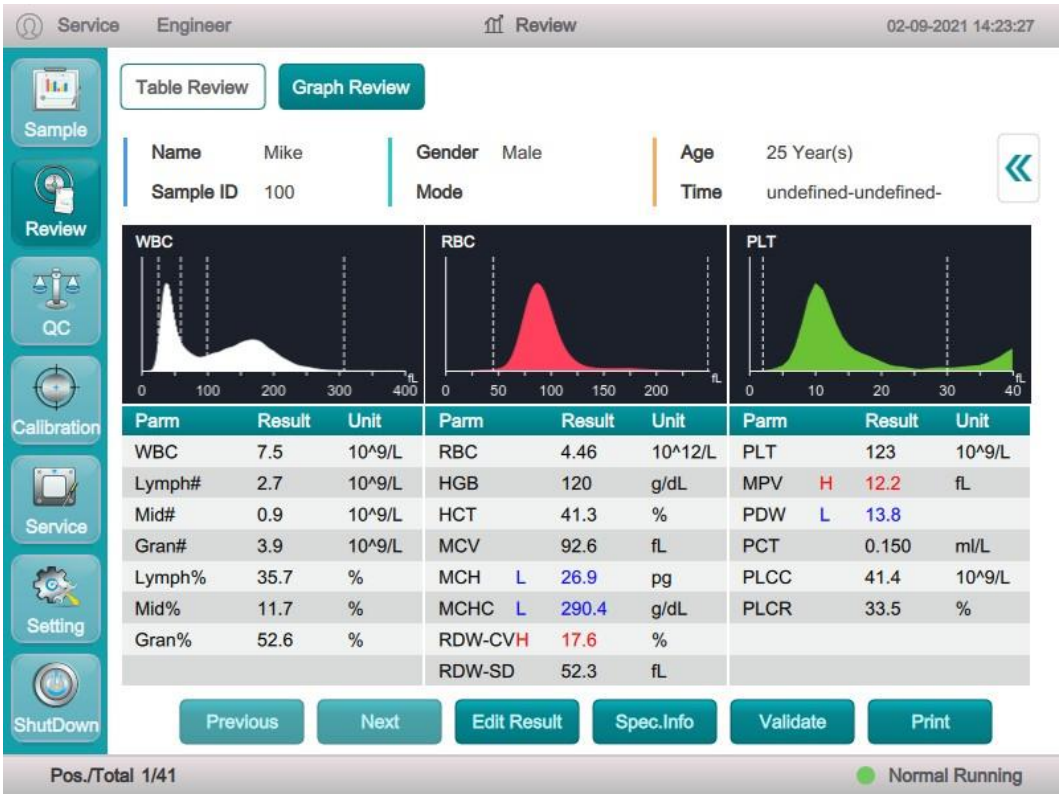
Click "", "", "", "" button to switch the display parameters.

Click "", "", "", "" button to display the test data of different sample ID.

- **Search button**: Click this button to open the Search Result dialog box. In this dialog box, you can input the query condition as needed, click **Ok** button to startsearching, the system will display all the search results which meet the condition.
- **Edit Info. button:**Select a row of record from the result list and click this button to open ***Edit Sample Information*** interface, you can edit the sample information in this interface.
- **Validate button:** Select the sample which needs to be validated from the result list, you can click this button to validate the sample. After validating, you can notedit the sample/patient information and result.
- **Canc Validate button:** Select the validated samples from the result list, you can click this button to cancel validate the sample. After canceling the validation, you can edit the sample/patient information and the result.
- **Comm. button:** Select one or several sample data to be communicated in the result list. Click this button transmit the selected sample data to the LIS system.
- **Delete button:** Select one or several sample data to be deleted in the result list,click this button to delete the sample.
- **Trend Graph button:** Select same sample results in the result list, click this button to view the trend graph of the sample.
- **Export button:** The operator can export the sample data to the USB flash disk for backup. Insert a USB flash disk in the USB interface on the analyzer, select records to be backed up, and click this button to export the sample records.
- **Print button:** Select one or several sample data to be printed in the results list,click this button to print the sample data.

5.2 Graph Review

Click “Graph Review” button to enter the ***Graph Review*** interface. You can browsethe sample graph results, parameter results.



- **Previous button:** Click this button, the screen will display the sample analysis results prior to the current one.
- **Next button:** Click this button, the screen will display the sample analysis results after the current one.
- **Edit Result button:** Click this button to open ***Edit Result*** dialog box, you can editthe sample result in this dialog box.
- **Spec.Info button:** Click this button to view the special information for analyzer diagnostic.
- **Validate/Cancel Validate button:** You can click Validate to validate the sample. After validating, the button will be replaced by **Cancel Validation**.

  If the current sample has been validated, the sample validation can be canceledby clicking **Cancel Validation**.
- **Print button:** Click this button to print the current sample result information.

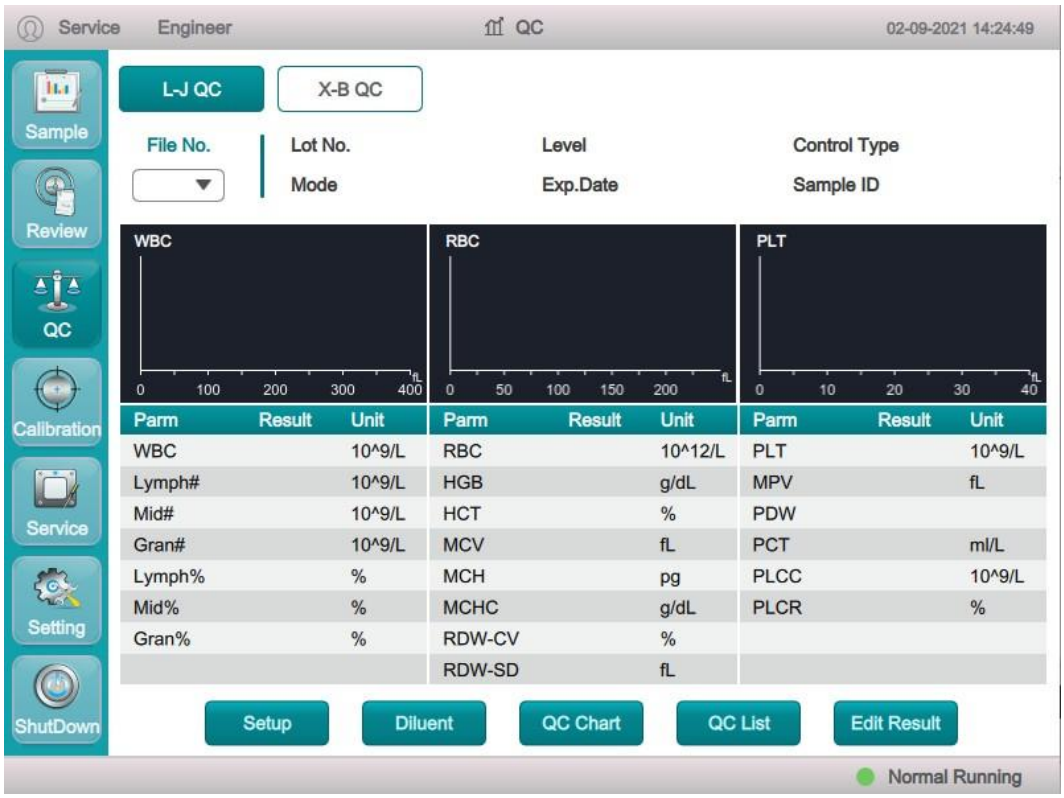
6 QC

The auto hematology analyzer may occur a certain degree of error during long-termuse. The error may cause inaccurate result tested by the analyzer. Quality Control (QC) is provided an effective way to detect possible errors. Only if the operator knows the QC theory and practical operation methods, the effect of the possible error on the test results may be eliminated.

To make sure the reliability of the sample results, it recommends running the QC program on a daily basis with low, normal and high level controls. A new lot ofcontrols should be analyzed in parallel with the current lot prior to their Exp.dates. This may be accomplished by running the new lot of controls twice a day forfive days using any empty QC file. The QC files calculate the mean, standard deviation and coefficient of variation for each selected parameter. The instrument-calculated results should be within the expected ranges published bythe manufacturer.

6.1 L-J QC

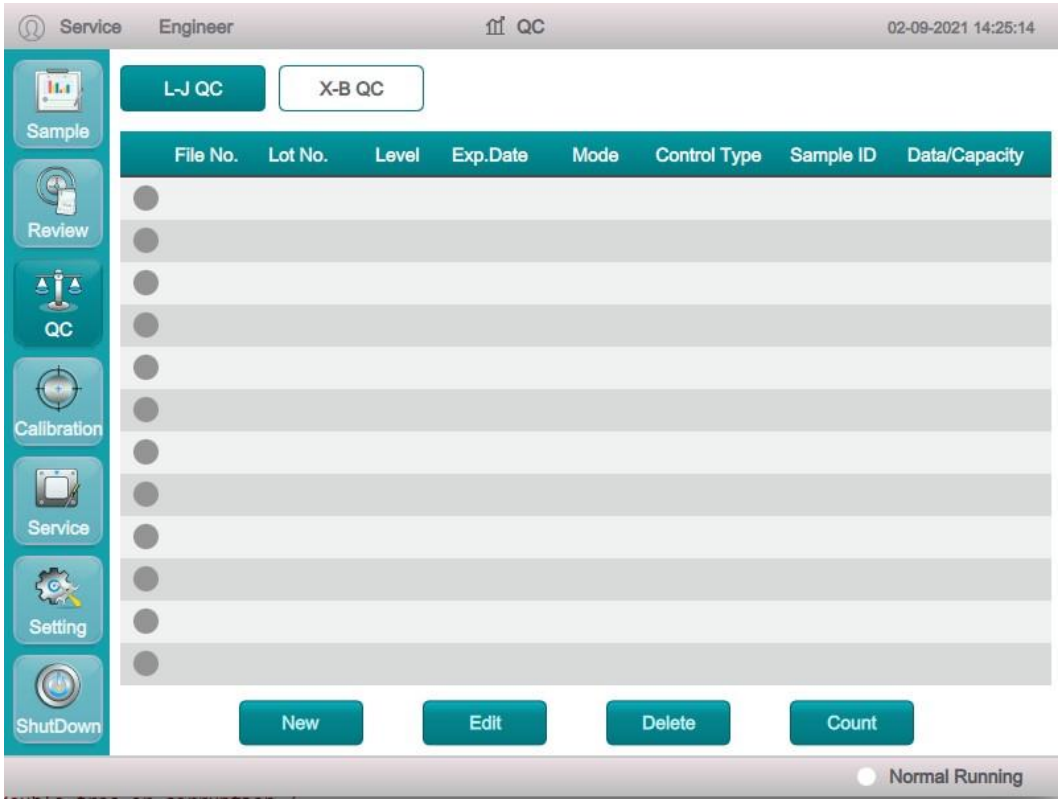
Click “OC” button to enter***L-J QC*** interface, as shown in the figure below:



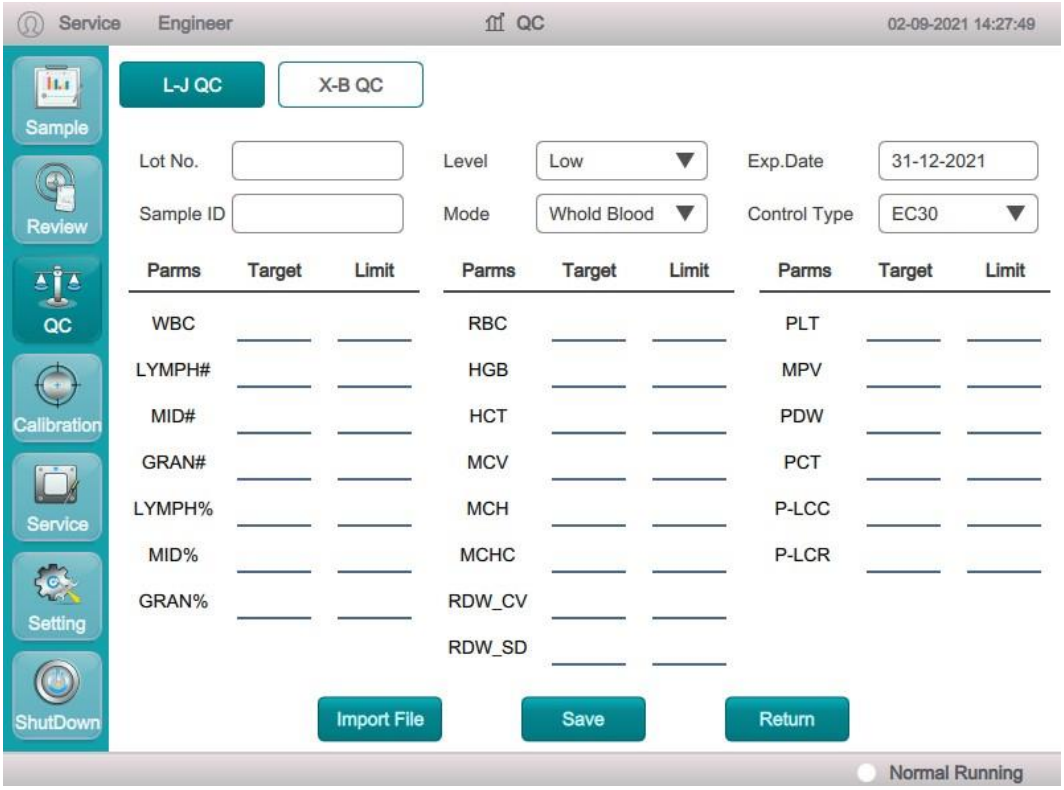
6.1.1 Setup

Before running a new batch of controls, you need to assign a QC file to each batch of controls.

Click “Setup” button to enter ***QC settings*** interface, as shown in figure below, youcan complete the QC settings by setting QC information in this interface.



- **New button:** Click this button to enter the new ***L-J QC*** interface, as shown in the figure below. The administrator can set the QC files by operations such as ImportFile, enter manual.



- **Lot No.:** Input the lot number of controls.
- **Level:** Select level of the controls from the dropdown list, including 3 level: High, Normal and Low.
- **Exp.Date:** Select the exp. date of the controls.
- **Sample ID:** Input the number of the QC sample.
- **Mode:** Select mode of the controls from the dropdown list, including Whole Blood and Pre-diluted.
- **Control Type:** Select the control type.
- **Parms, Target, Limit:** Input the targets and limits of the QC parameters.
- **Import File button:**Click this button, select the QC file which needs to be imported, click OK button, the QC information will be imported into the QC file.
- **Save button:** Click this button to save all the settings of the QC.
- **Return button:** Click this button, return to ***QC setting*** interface.

- **Edit button:** Select the QC file which needs to be edit, click this button to edit the selected QC information.
- **Delete button:** Select the QC file which needs to be deleted, click this button to delete the selected QC file.
- **Count button:** Click this button, return to L-J QC count interface.

Note

- Input the Lot No., Exp.Date, Target,Limit value of the controls accordingto the QC manual.
- The expired date entered by the operator shall be equal to the open-container date of control plus period after opening of control, or the expired date marked on the out packaging of the reagent. The validity date of the reagent can be no later than the validity indicated on the packaging and cannot be earlier than the current system date.

6.1.2 QC Count

Completing QC analysis in the L-J QC count interface.

1. Click QC button to access the L-J QC count interface;
2. Select the QC File No. to be run.
3. Click Setup button to complete the QC settings;
4. Prepare the controls according to the set control mode and control instructions.
5. Do QC analysis:
   1) Make sure the QC mode: Whole Blood or Pre-dilute.
   2) Shake the prepared control to mix it well according to control instructions.
   3) Place the controls under the sample probe where the probe can aspirate thewell mixed sample, press the aspiration key and start running the controls.
   4) Upon the completion of the aspiration, you can remove the controls.
6. When the running of QC analysis is complete, the QC results will be displayedin the current screen and saved in the QC file automatically.
7. Perform the above procedures to continue running the controls if necessary.

Note

- Running quality controls in presence of errors may lead to incorrect analysis results. If you see the error alarms when running the quality controls, please stop and resume the analysis until the errors are removed.
- Sample clump may lead to incorrect analysis results. Check if clump exists before running the controls; if it does, handle it as per the related laboratory procedures.

Biohazard

- All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratorysafety procedures when handling relevant items and areas in the laboratory.
- The sample probe is sharp and potentially biohazardous. Exercise cautionto avoid contact with the probe when working around it.

Edit Result

Click **Edit Result** button in the L-J QC interface to edit the QC analysis result afterthe QC counting is performed, click **OK** button to save the edit results.

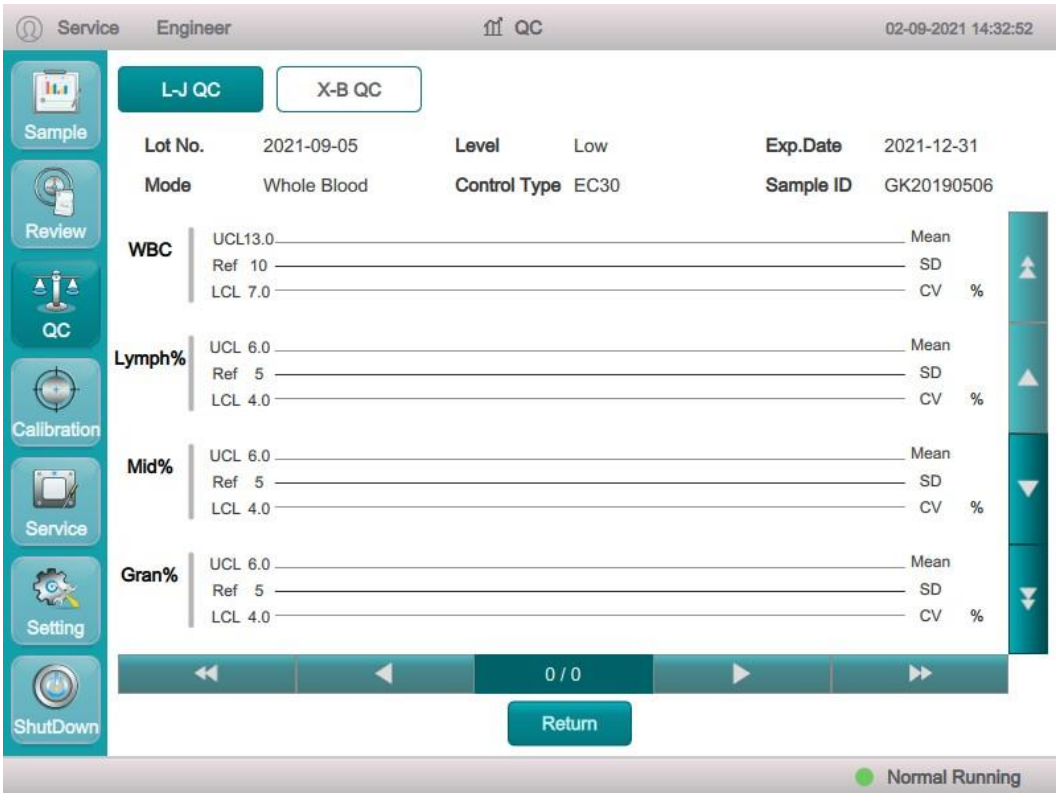
Click **Restore** button to restore to the original results.

6.1.3 QC Result Review

After running controls, you can review the QC results in the following two forms:QC Chart, QC List.

- **QC Chart**

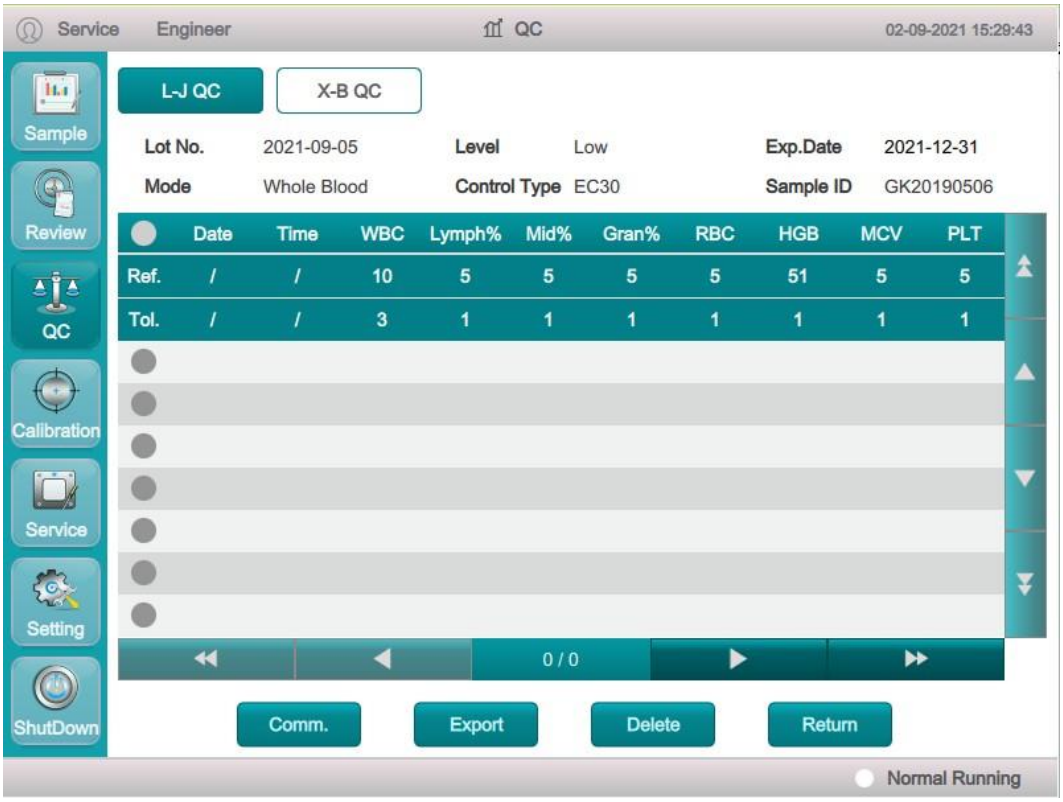
1. Click QC Chart button to enter the QC chart interface corresponding to the QC file, as shown in figure below:



2. Click the buttons at the right side of the QC graph, then you can browse QC chart of different parameters; click the buttons at the bottom of the QC graph,then you can browse all QC results.
3. Click Return button, return to ***L-J QC count*** interface.

- **QC List**

1. Click QC List button to enter the ***QC List*** interface corresponding to the QC file,as shown in figure below:



2. Click the buttons on the right of the table to browse the QC results. Click the buttons at the bottom of the table to browse the QC data of desired parameters.
   - **Comm. button:** Click this button to transmit the specified QC data to LIS server.
   - **Export button:** Insert a USB flash disk, click this button to export the information and the result of the current QC file.
   - **Delete button:** Click this button to delete the selected QC data.
   - **Return button:** Click Return button, return to L-J QC count interface.

6.2 X-B QC

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

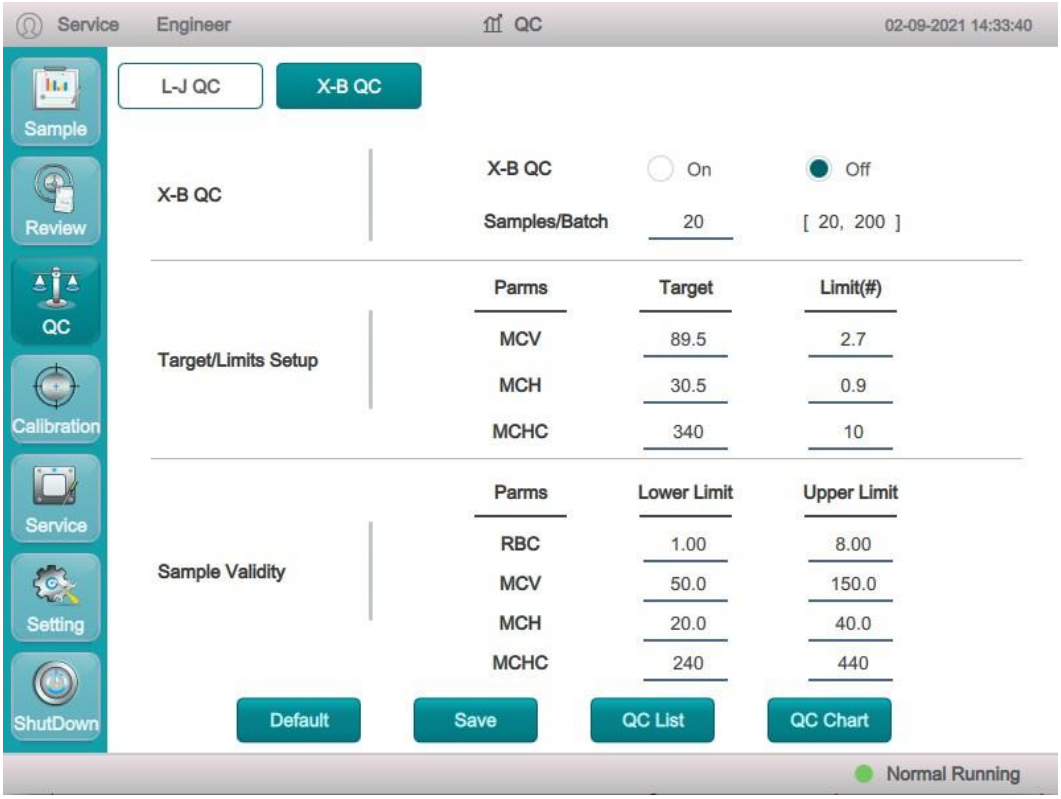
indicate the hematology instrument performance. This is QC with no controls, which is a method of performance control like QC with controls. Both methods reflect the analysis performance of the analyzer from different perspective. Thus,one method should not be replaced with the other.

It is recommended the X-B analysis be activated when the sample volume of your laboratory is greater then 100 samples per day. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewingof indices. A reference range is established by the given reference values as well as lower and upper limits for the purpose of observing the variation of QC results within the reference range.

The analyzer performs X-B QC for three parameters, MCV, MCH, and MCHC. Twenty to two hundred samples can be grouped together for X-B numerical analysis.The samples are derived from the results of normal analyzer counting, with no distinction of whole-blood or predilute mode.

6.2.1 QC Settings

Click “QC” button, click “X-B QC” button to enter ***X-B QC*** interface, as shown in figure below:



- **X-B QC:** Select the “On” or “Off” of X-B quality control. If you select the “On”, thesample results will be included to calculate the X-B.

  Input the amount of samples to be included in calculating for an X-B QC point,the range is between 20 and 200 and the recommended value is 20.

- **Target/Limits Setup:**Input the targets and limits of the QC parameters.

- **Sample Validity:** Setting sample validity is to set the valid range of four QC parameters, RBC, MCV, MCH and MCHC. To be incorporated into X-B QC calculation, the sample results should satisfy the validity ranges of all these four parameters.
- **Default button:** Click this button to restore the target/limits and sample validity to the default settings.
- **Save button:** Click this button to save all the setting of the QC.

6.2.2 QC Analysis

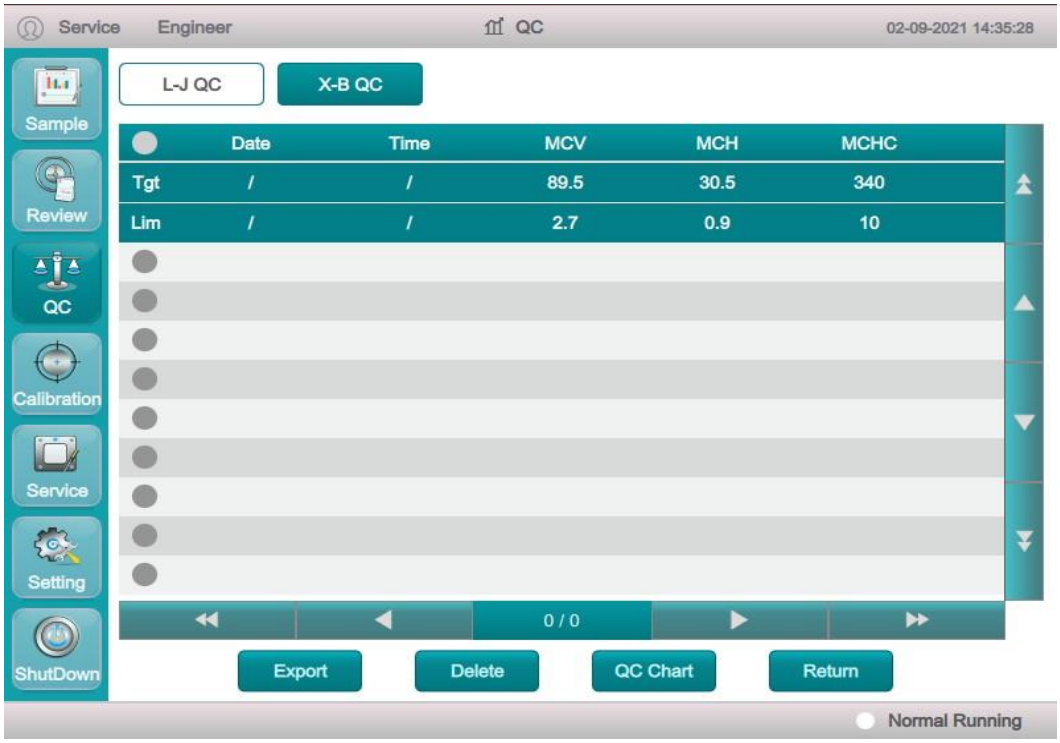
After the QC settings, the analyzer will automatically start the X-B QC analysis.

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

6.2.3 QC Result Review

You can review the QC results in the two forms: QC List, QC Chart.

- **QC List:** Click QC List button to enter X-B QC List interface, as shown in figure below.You can browse, export, delete the X-B QC results.



- **Export button:** Insert a USB flash disk, click this button to export the information and the result of the current QC file.
- **Delete button:** Click this button to delete the selected QC data.

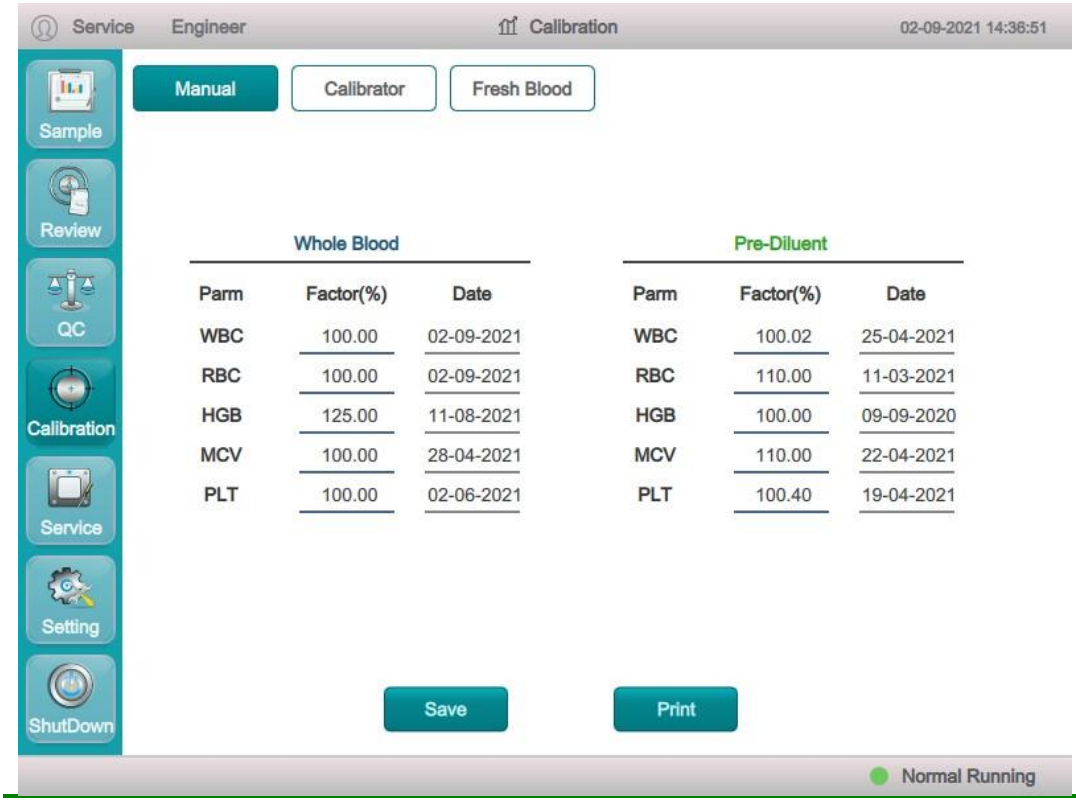
- **QC Chart button**: Click this button to view the chart of the selected control.
- **Return button:** Click Return button, return to X-B QC interface.

- **QC Chart:** Click QC Chart button to enter X-B QC Chart interface. You can view the QC chart information for the current control.

7 Calibration

7.1 Manual Calibration

Click “Calibration”→“Manual” button to access the ***Manual Calibration*** interface. See Figure below.



Note

- The login users with the access level of general users can not perform the calibration procedures but only browse the calibration coefficients on the current screen. To perform the calibration, please log out and then log inas users with administrator-level access.

Complete the manual calibration as per the following procedure:

1. Run the calibrator in the sample analysis interface for multiple consecutive times (at least 10 times)
2. Take and view the repeatability of WBC, RBC, HGB, MCV, PLT counting results in the Table Review interface and make sure they are within the range specified in **A.5.3 Precision indicators.**
3. Check the calibration coefficient in the Manual Calibration interface and calculate the new coefficient using the following equation.

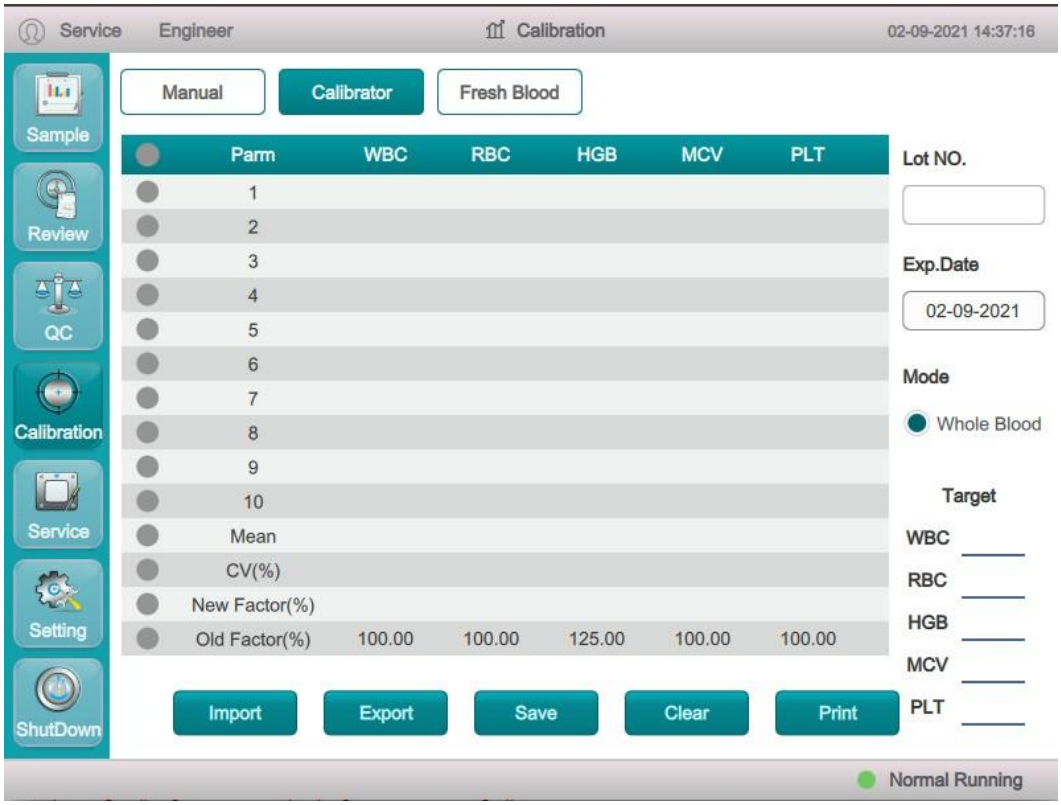
$$\text{New calibration factor} = \frac{\text{Current calibration factor} \times \text{Renference value}}{\text{Mean}}$$

The calculated calibration coefficients shall be between 75%~125%. In case of an invalid calibration coefficient, try to find out the reason (e.g. calibration materialnot thoroughly mixed, incorrect operation, etc.).Then recalibrate the analyzer and recalculate the calibration coefficients.

4. Enter the new calibration coefficients into the factor cell of the parameter that requires calibration, click “Save” button to save the new calibration coefficients.
5. Click “Print” button to print the current calibrationcoefficient.

7.2 Auto Calibration Using Calibrators

Click “Calibration”→ “Calibrator” button to access the ***Calibrator Calibration*** interface. See Figure below.



Complete the calibration with calibrators as per the following procedure:

1. Enter the lot No. of the calibrator into the **Lot No.** box.
2. Click the **Exp. Date** box, and then edit the Exp. Date.
3. Input the target values of the parameters in the corresponding cell.
4. Prepare the calibrators following their instructions for use and place the calibrators under the sampling probe.
5. Press the aspirate key to start the calibration counting.

6. After completing the each calibration count, the analyzer will process differently depending on the results:
   - The valid results within the linearity range will be displayed directly.
   - If the calibration counting data of any parameter in the current counting are out of the linearity range of the parameter, a message box will pop up on the screen prompting that the calibration data is invalid.

     Click OK to close the message box and delete the data from the table without saving.
   - If the calibration counting data of any parameter in the current counting areout of the display range of the parameter, a message box will pop up on the screen prompting that the calibration data is invalid.

     Click OK to close the message box and delete the data from the table withoutsaving.
   - If the new calibration coefficient has not been calculated, if the user switch the interface, a message box will pop up on the screen prompting that exiting willlose all calibration data and continue or not.

     Click OK to lose the existing calibration data and close the message box, the screen will switch to another interface without changing the original calibration coefficient.
7. Select at least 5 groups of data for the calculation of the calibration coefficients.The system will calculate the average of the calibration coefficients, namely, themean calibration coefficient (%), as the new calibration coefficient based on the five calibrators. you can also check at least five accurate calibration coefficients and the system will re-calculate the mean calibration coefficient (%)

The following describes the button function on this interface:

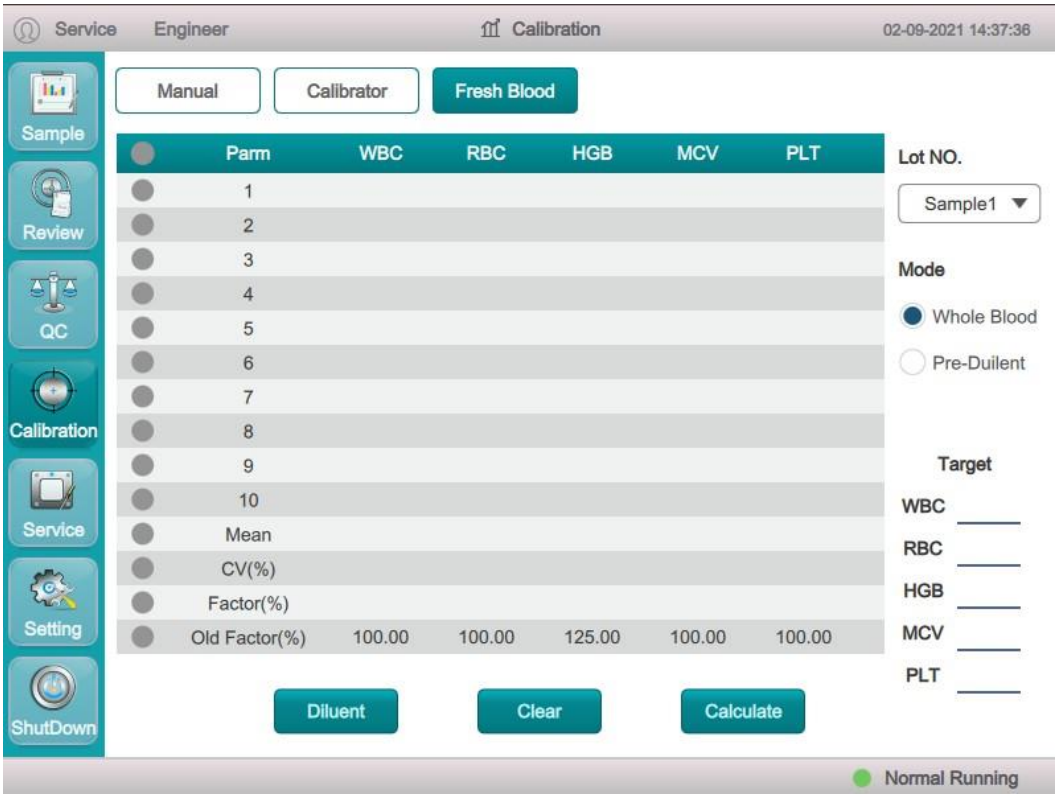
- **Import button:** Click this button, select the calibrator file which needs to be imported, click OK button, the calibrator information will be imported into the current calibration file.
- **Export button:** Click this button to export the selected calibration data of calibrators.
- **Save button:** Click this button to save the new calibration coefficient.
- **Clear button:** Click this button to delete the current data.
- **Print button:** Click this button to print the calibration results.

Note

- Calibrator calibration can only be performed in whole blood mode.
- See the instructions for use of the calibrators for the lot No., Exp. Date andthe target.

7.3 Auto Calibration Using Fresh Blood Samples

Click “Calibration”→ “Fresh Blood” button to access the ***Fresh Blood Calibration*** interface. See Figure below.



Complete the calibration using fresh blood samples as per the following procedure:

1. Prepare 3 to 5 normal fresh blood samples, run each of the prepared samples on the reference instrument five times at least. Average the results for your reference values. Or measure and calculate the results according to the referencemethod, the result data for your reference values.
2. Select the Lot No. of the current blood sample.
3. Select the analysis mode: Whole Blood, Pre-Duilent.
4. Input the reference values for the parameters to be calibrated in the corresponding Target textbox.
5. Prepare the whole blood or pre-diluted fresh blood samples.
6. Place the blood sample under the sampling probe, press the aspirate key on the analyzer to run the samples.
7. The system will calculate the values for WBC, RBC, HGB, MCV and PLT of the sample. After completing eachcalibration count, the analyzer will display the valid results.
8. Select at least 5 groups of data for the calculation of the calibration coefficients.

The system will calculate the average of the calibration coefficients, namely, themean calibration coefficient (%), as the new calibration coefficient based on the five calibrators. you can also check at least five accurate calibration coefficients and the system will re-calculate the mean calibration coefficient (%).

9. Select the other blood sample in the “Lot No.”, refer to above steps and performthe counting operations.
10. After obtaining at least three calibration coefficients of fresh blood samples, click “Calculate” button to open the calculation interface, the system will calculate the mean calibration coefficient (%).

8 Service

To ensure reliability, good performance and service life of the system, this chapter introduces how to regularly maintain, detect the analyzer status, and modify thesetting parameters of the analyzer if necessary.

This analyzer provides multiple maintenance functions for this purpose. This chapter introduces how to use the provided functions to maintain and troubleshootyour analyzer. Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition.

Caution

- Performing unauthorized maintenance procedures can damage your analyzer. Do not perform any maintenance procedures that are not described in this chapter.
- In case of problems not specified in this manual, contact our customer service department or your local agent for assistance.
- Disinfection operation may damage your analyzer. It is recommended to disinfect only if necessary in your hospital maintenance plan, and the equipment should be cleaned before disinfecting.

Biohazard

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

8.1 Regular maintenance

8.1.1 Check before analysis

External of analyzer: There are no dust and scratches on the outside of analyzer.The tube is connected well, the printer is not lack of paper, no leakage and no physical damage.

Safe: The power supply is connected well and grounded well.

Reagent: Use the specified reagent, diluent is sufficient, lyse is sufficient, and thewaste bucket is emptied.

Operation: The date and time are correct, and the key can work normally.

8.1.2 Startup and shutdown processes

The analyzer will detect the mechanical parts and background when starting on sothat the user can find problems early. The daily shutdown maintenance procedure is automatically run during the shutdown operation. After turning off the analyzer,you just need to clean the operation platform and clean the surface of the analyzer.

8.1.3 Cleaning the instrument surface

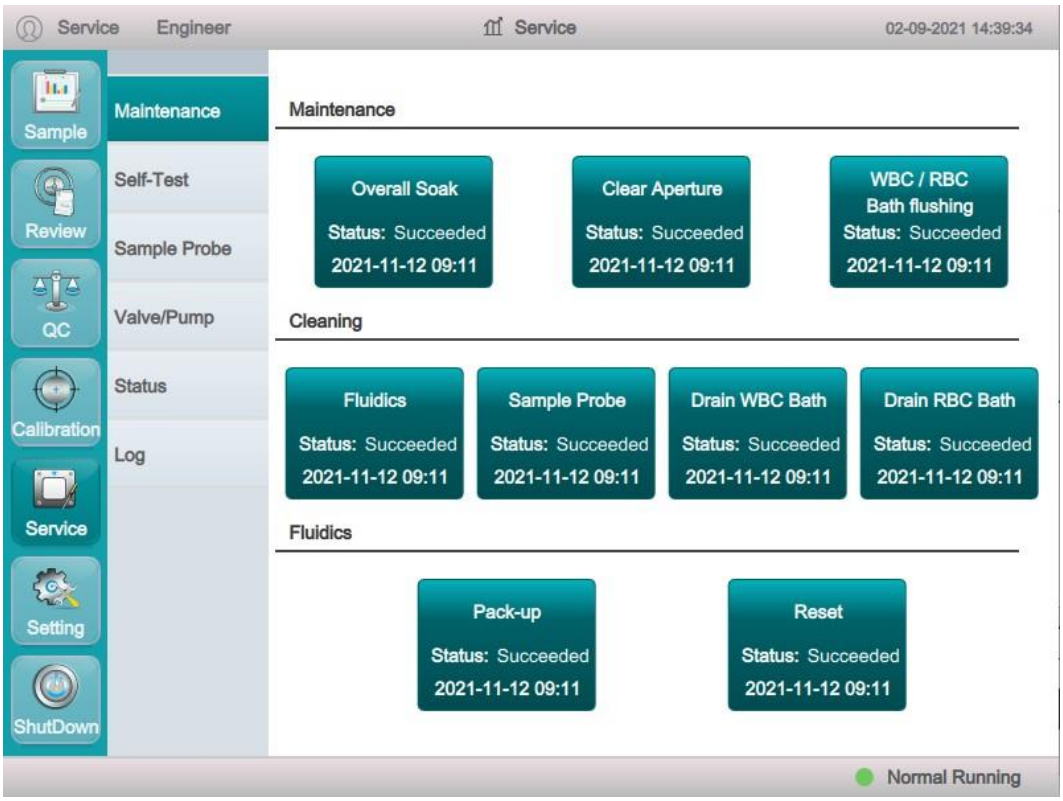
- Keep the work environment of the analyzer clean.
- You can wipe the surface of the analyzer with a neutral cleaner and a wet cloth.

8.2 Maintenance Procedure

8.2.1 Maintenance

Click "Service"→ "Maintenance" button to access to ***Maintenance*** interface.

Maintenance includes: maintenance, cleaning, and fluidics. See figure below.



- **Maintenance:**
  - **Overall Soak:** Click this button to perform cleanser overall soak.

    The overall soak should be performed under the following circumstances:

    1. When the problems including the background results exceed the Ref. Range

and clogging still exist after other maintenance procedures have been adopted.

2. The analyzer is turned off due to abnormal power off, then overall soak should be performed after turning on.

- **Clear Aperture:** Perform this operation to prevent and clear clogging failures.
- **WBC/RBC Bath flushing:** Perform this operation to prevent and clear clogging of WBC/RBC bath.

- **Cleaning:**
  - **Fluidics:** Perform this operation, the analyzer starts to perform the fluidics cleaning procedure.
  - **Sample Probe:** Perform this operation to clean sample probe. When the sample probe is dirty, you should clean the sample probe
  - **Drain WBC Bath:** Perform this operation to drain WBC bath.

    If the background results of WBC and(or) HGB are out of the backgroundrange, Drain WBC Bath should be performed.
  - **Drain RBC Bath:** Perform this operation to drain RBC bath.

    If the background results of RBC and(or) PLT are out of the background range, Drain WBC Bath should be performed.
- **Fludics:**
  - **Pack-up:** Perform this operation to pack up the machine.

    When the machine is not used for more than two weeks, perform this functionto empty the analyzer and clean it with distilled water (alcohol can not be used).
  - **Reset:** Click this button to perform reset operation.

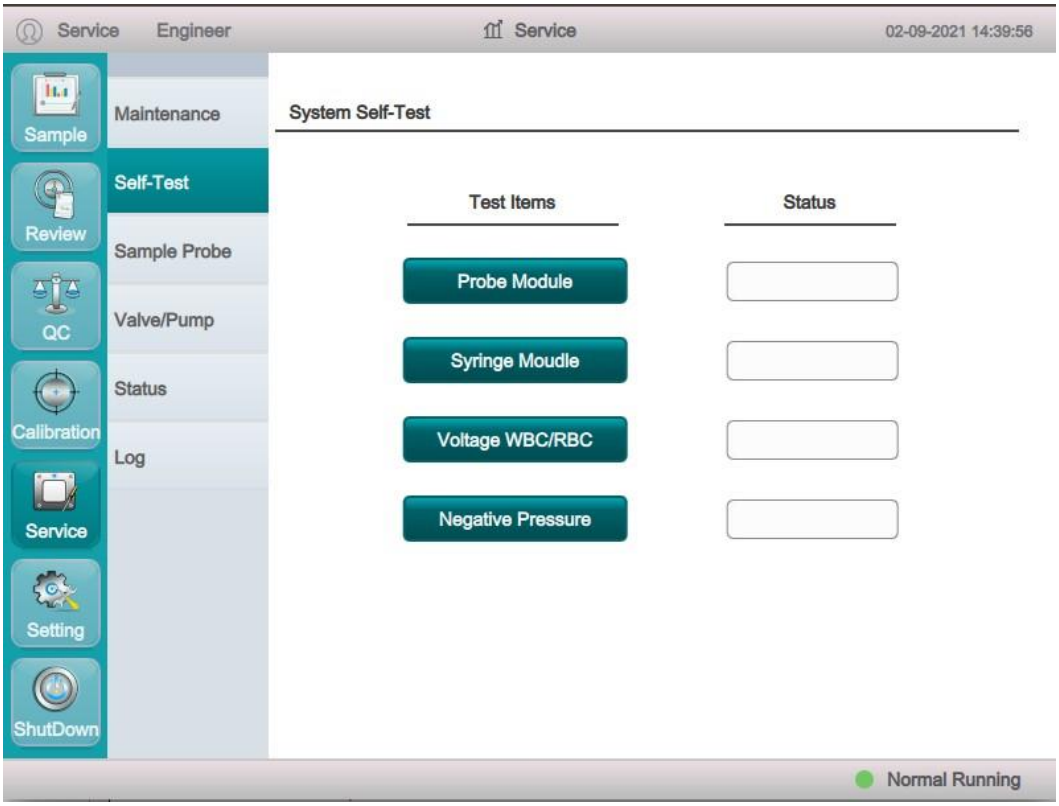
    If you replace the main components of analyzer or repair the flow path system,you should perform reset operation.

Biohazard

- All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratorysafety procedures when handling relevant items and areas in the laboratory.
- If the reagents accidentally spill on the skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into the eyes, wash them off with plenty of water and immediately go see adoctor.

8.2.2 System Self-Test

Click “Service”→ “Self-Test” button to access to ***System Self-Test*** interface.Seefigure below.

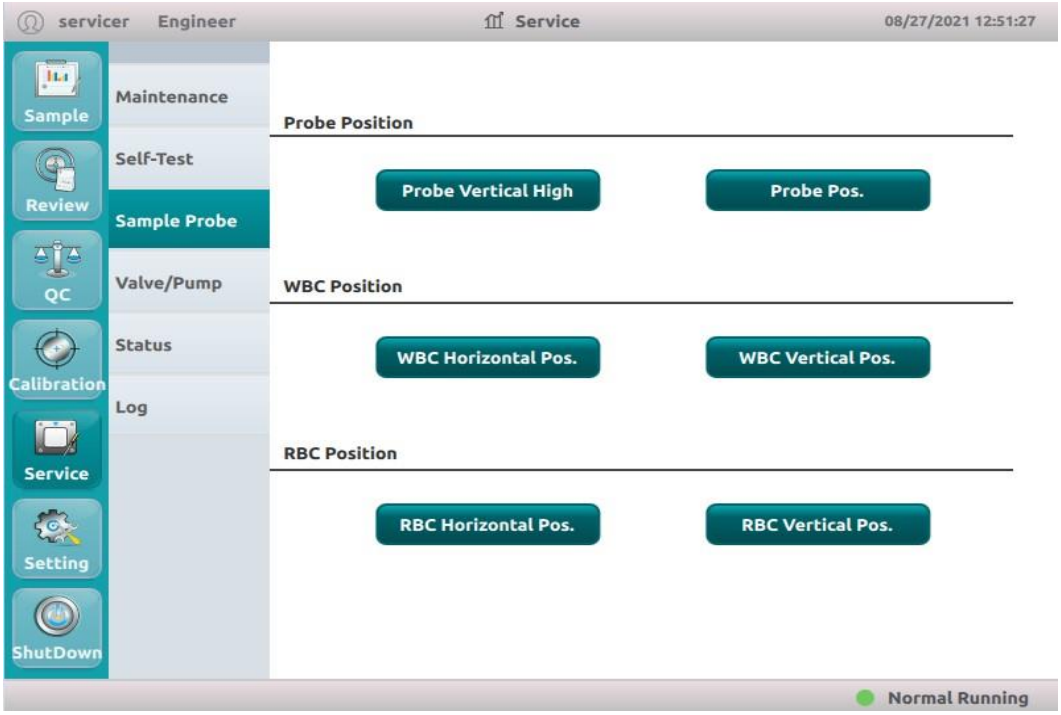


This feature is to test if some important components of the device can function properly or not, including probe module self-test, syringe moudle self-test, voltageWBC/RBC self-test, negative pressure self-test.

When the parts of analyzer are moving, you should observe carefully whether theparts move gently and uniformly. If the testing result is abnormal, you should tryagain for several times; if the abnormalities persist, please contact our customerservice department or your local agent.

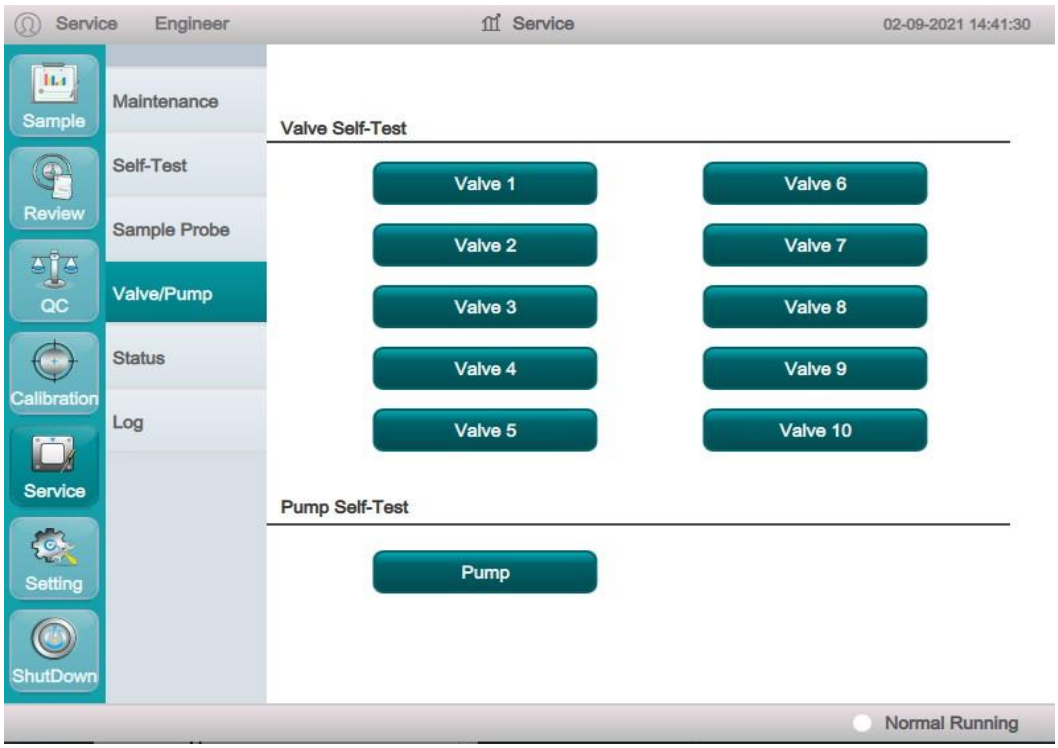
8.2.3 Sample Probe

Click “Service” → “Sample Probe” button to access to ***Sample Probe*** interface.Seefigure below.You can debug the initial position of the sample probe inthis interface.



8.2.4 Valve/Pump

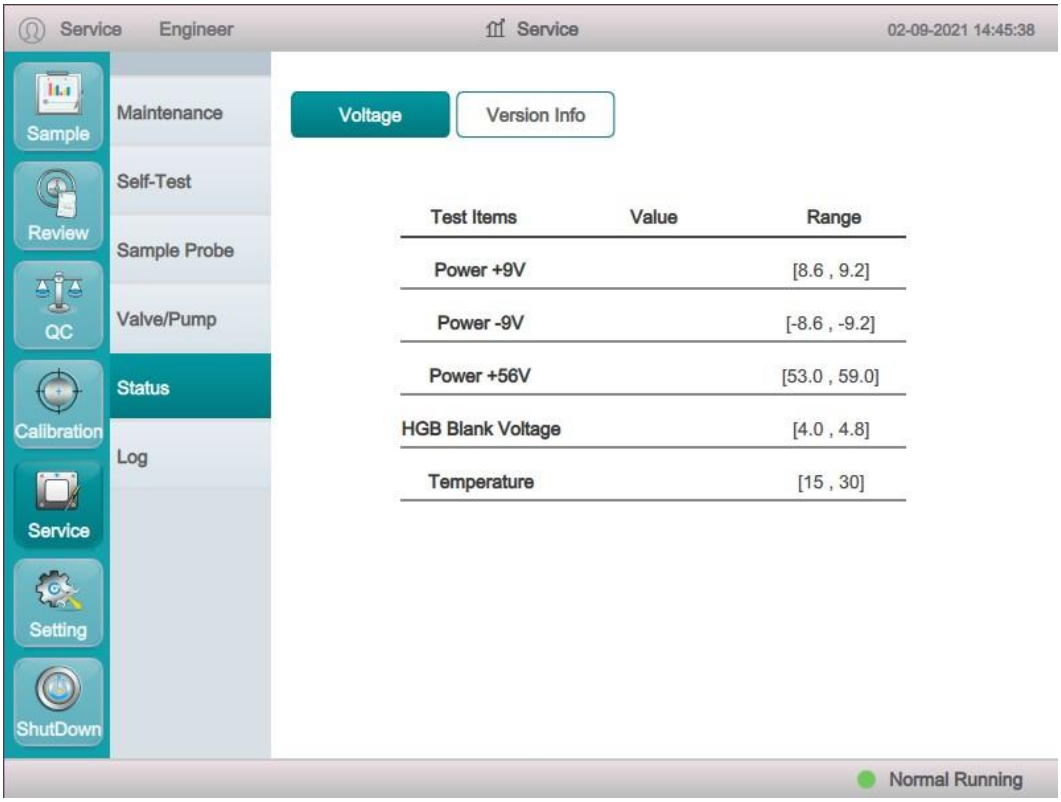
Click "Service" → "Valve/Pump" button to access to ***Valve Self-Test*** interface.Seefigure below. When controlling the switches of different valves (pumps),you can judge if the valves (pumps) are operating properly by the sound of opening, closing or manually touching the corresponding valves (pumps).



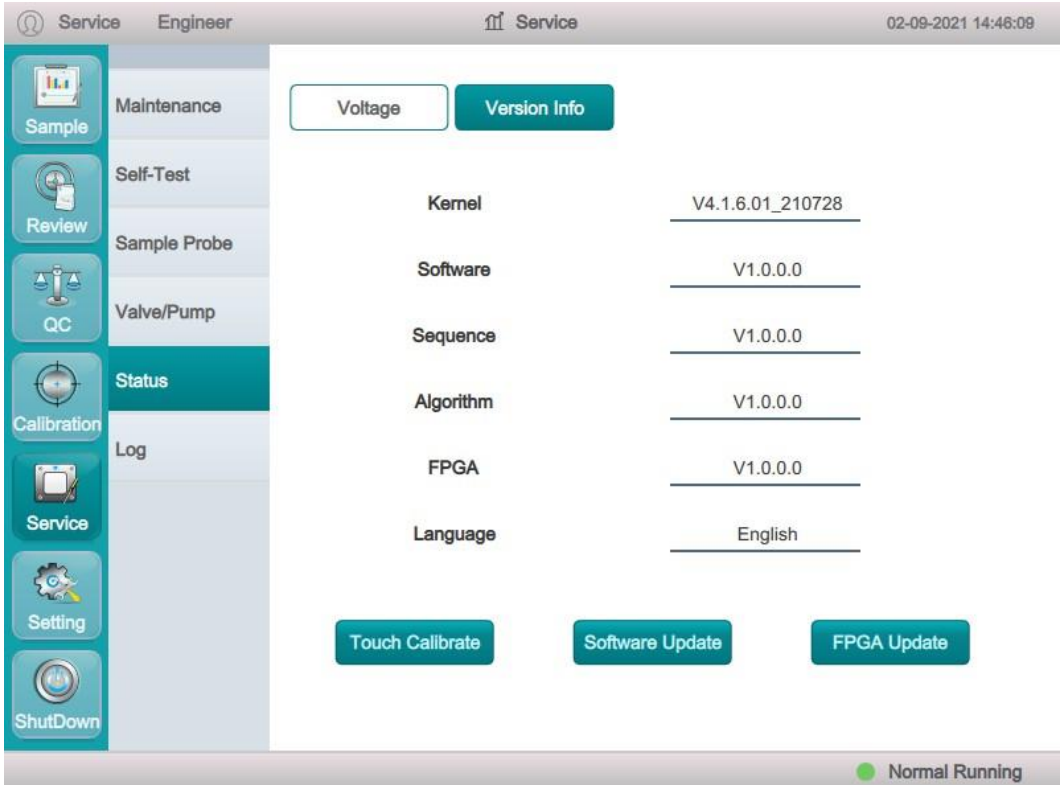
8.2.5 Status

Click “Service” → “Status” button to access to ***Status*** interface. You can view voltage status, version information, and do touch calibration, update software in this interface.

- **Voltage:**Click “Status”→“Voltage” button to access ***Voltage Status*** interface, see figure below. You can view the voltage and current information of the analyzer.



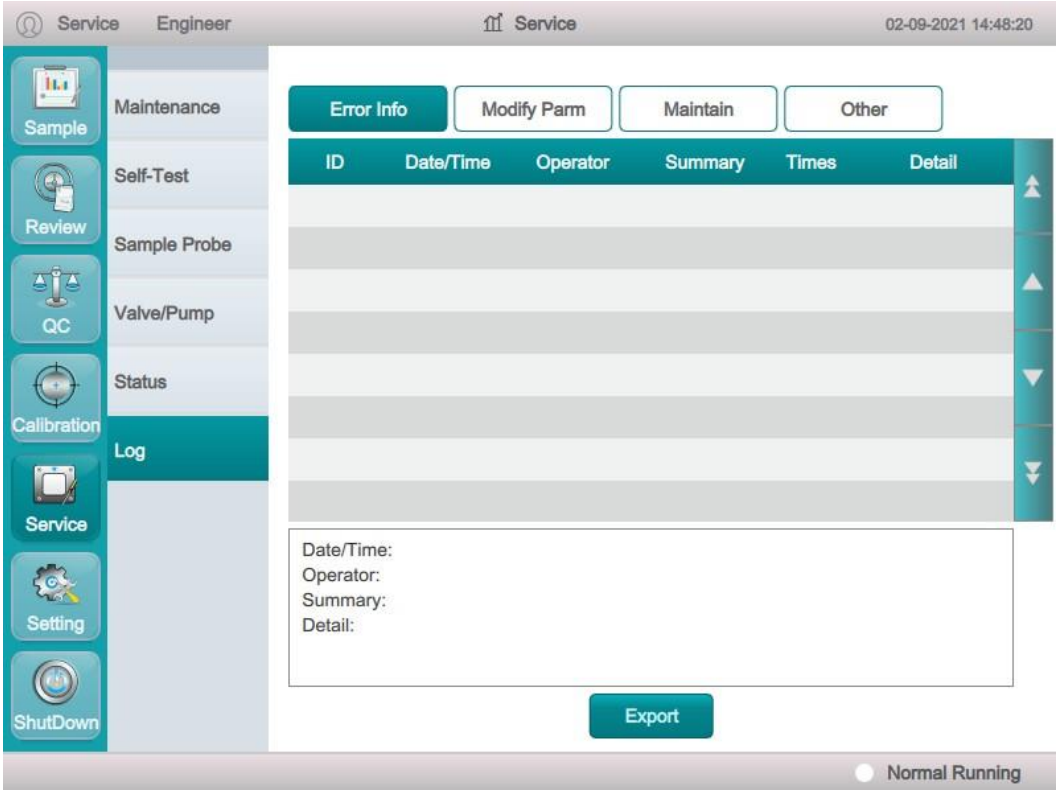
- **Version Info:** Click “Status”→ “Version Info” button to access ***Version Information*** interface, see figure below. You can view the current version information of all parts of the analyzer.



- **Touch Calibrate button:** Click this button, then click the calibration point "+" on the screen in order. When the calibration point disappears and the system return to the service screen, it indicates the completion of the calibration.
- **Software update button:** click this button to update the software.
- **FPGA Update button:** click this button to update FPGA.

8.2.6 Log

Click “Service”→ “Log” button to access to Log interface, see figure below. You can view error information, modify parameter, maintain information in this interface.



- **Export button:** Click this button to export the specified log information.

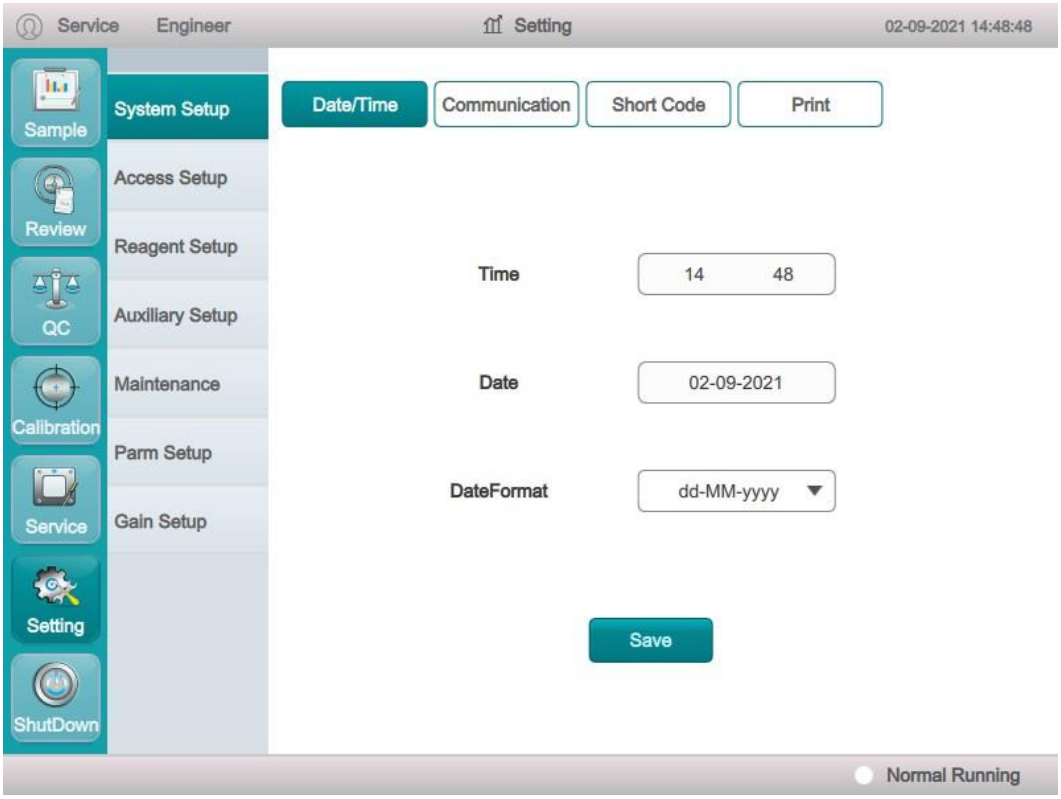
9 Setting

9.1 System Setup

Click “Setting” → “System Setup” button to access to ***System Setup*** interface. You can set the system parameters in this interface.

9.1.1 Date/Time Setting

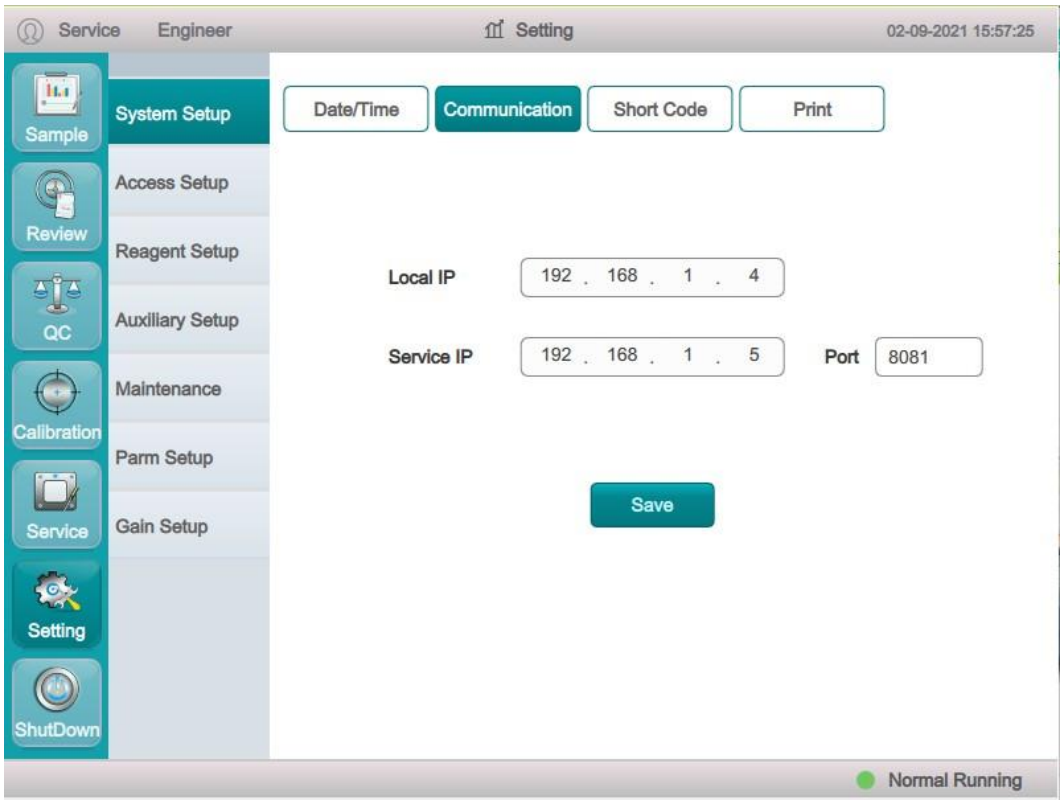
Click “Date Time”button to access to ***Date/Time Setting*** interface, See figure below.You can set the system time in this interface.



- **Time:** Input the system time.
- **Date:** Select the system date.
- **DateFormat:** Select the format setting from the dropdown list of the DateFormat.
- **Save button:** Click this button, the new date and time will be set.

9.1.2 Communication Setting

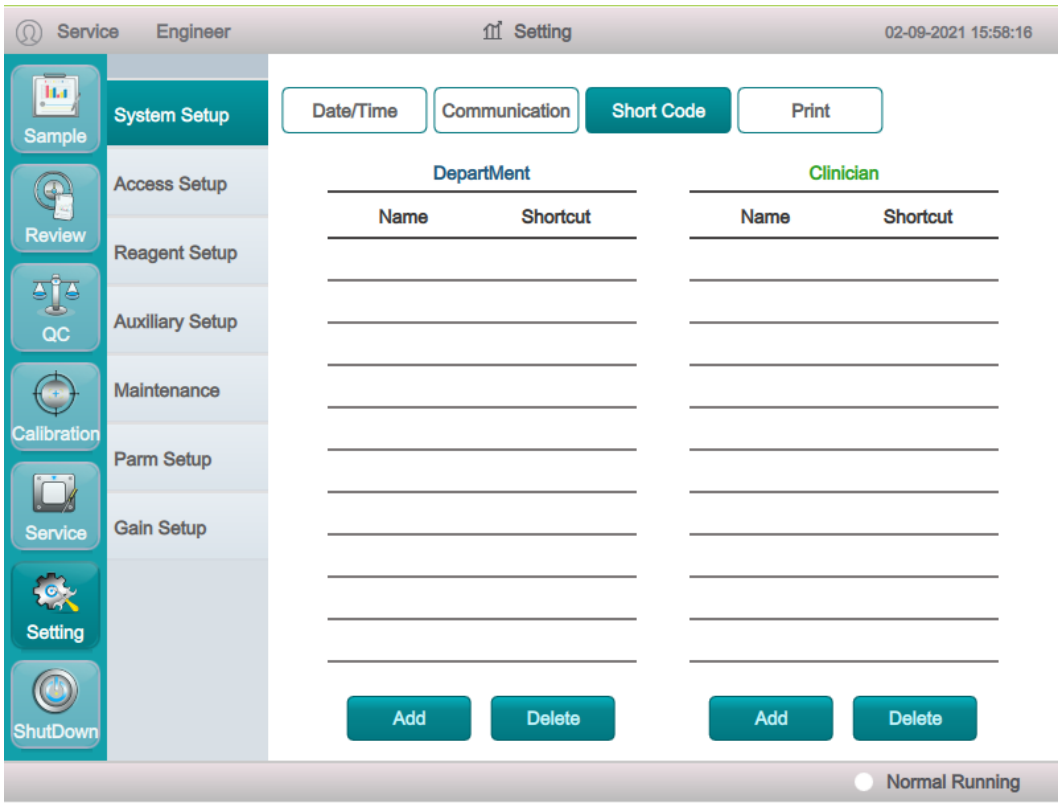
Click this button to access to communication interface, see figure below. You can setthe communication parameters of analyzer so that the analyzer can communicatewith LIS server.



- **Local IP:** Input the IP address of local host.
- **ServiceIP:** Input the IP address of the LIS service. Please set it according to the actual situation.
- **Port:** Input the port of the LIS. Please set it according to the actual situation.
- **Save button:** Click this button to save the communication setting.

9.1.3 Short Code

Click "Short Code" button to access to ***Short Code*** interface, see figure below. In this interface, you can set the Next Sample input way of Sample Analysis interface and short codes for the relevant items of the patient information.



- **Add Short code:**

1. Click "Add" button in the "Department" or "Clinician" list, open the ***Edit Shortcut Code*** interface.

2. Enter a new name, shortcut information.

3. Click "Save" button to save the information about the new shortcut code.

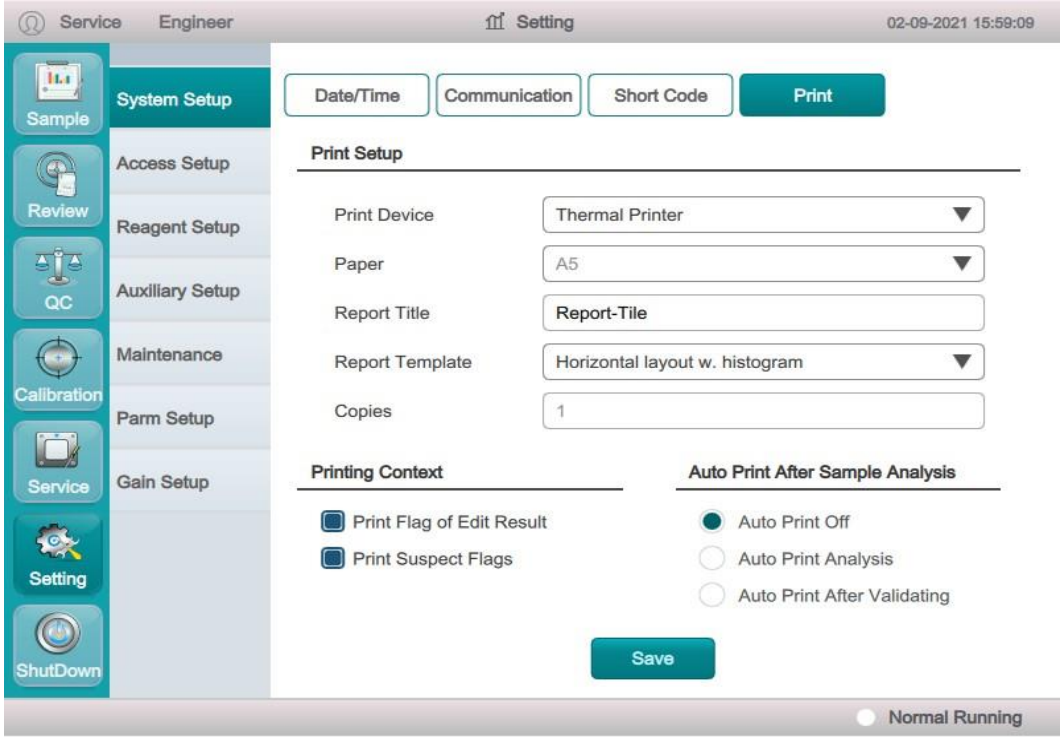
- **Delete Short code:**

1. Select the item in the short code list to be deleted;

2. Click "Delete" button to delete it.

9.1.4 Print

Click this button to access to Print Setting interface, see figure below. You can set relevant print in this interface, including the print setup, print context, auto print.



- **Print Setup:**
  - **Print Device:** Select the print device of the analyzer.
  - **Paper:** Select the paper type from the dropdown list of the ***Paper.***
  - **Report Title:** Input the title of report in the ***Report Title*** textbox.
  - **Report Template:** Select the template to be set from the dropdown list of the ***Template.***
  - **Copies:** You can enter the number of copies to be printed for a report in the Copies textbox according to the actual demand.
  - **Printing Context:** The operator can click the options to be printed in the checkbox, the relevant print setting will be activated.
  - **Auto Print After Sample Analysis:**

    Auto Print Off: It means the report should be printed manually after theresults are obtained.

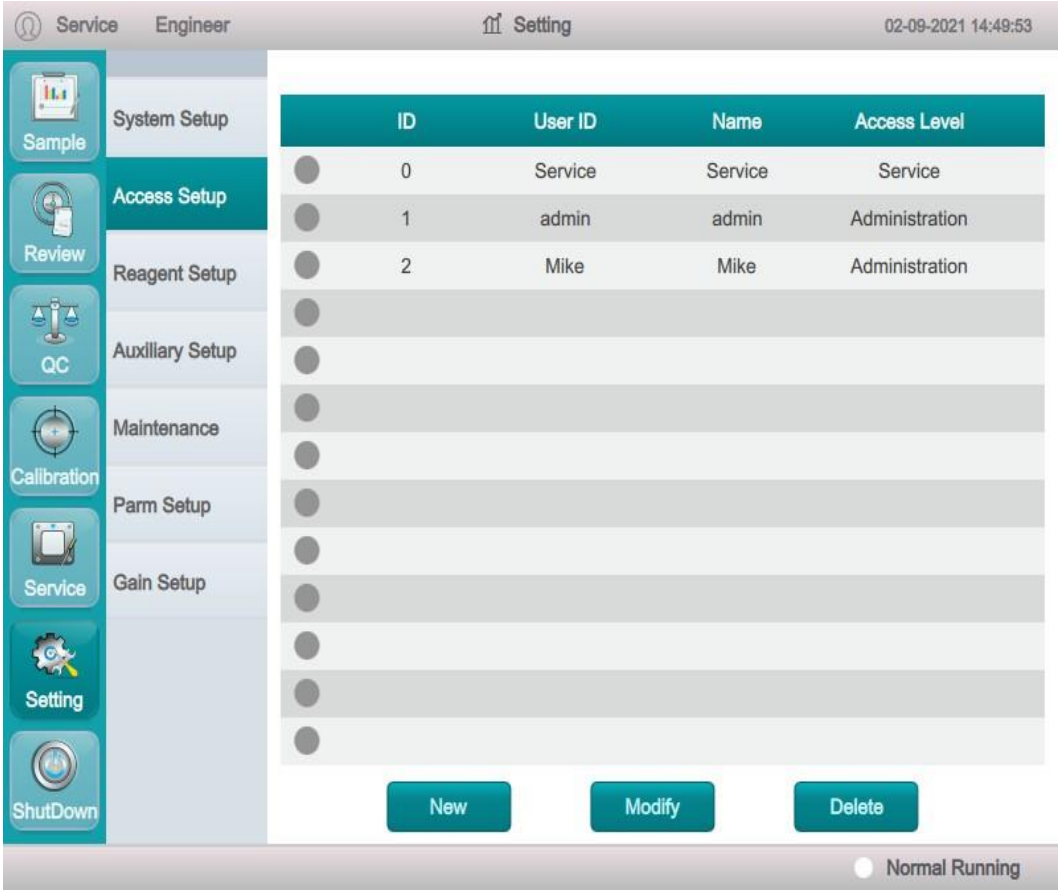
    Auto Print Analysis: If you select this option, the system will automaticallyprint the report of the sample as per the current report template once the counting results are obtained.

    Auto Print After Validating: If it's checked, the report will be printed automatically after it's been validated instead of being printed right after theresults are obtained each time.

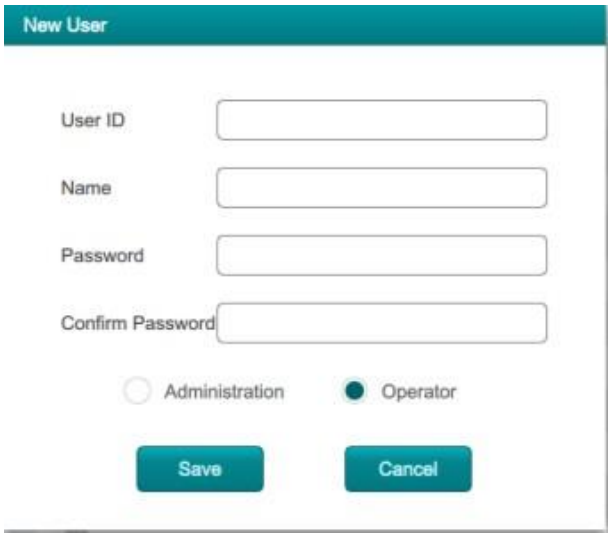
■ **Save button:** Click this button to save the print setting.

9.2 Access Setup

Click “Setting” → “Access Setup” button to access to ***Access Setup*** interface, see figure below. In this interface, the administrator has the access to set the accountinformation of general users and other administrators; common users can onlybrowse the user list and changetheir own passwords.

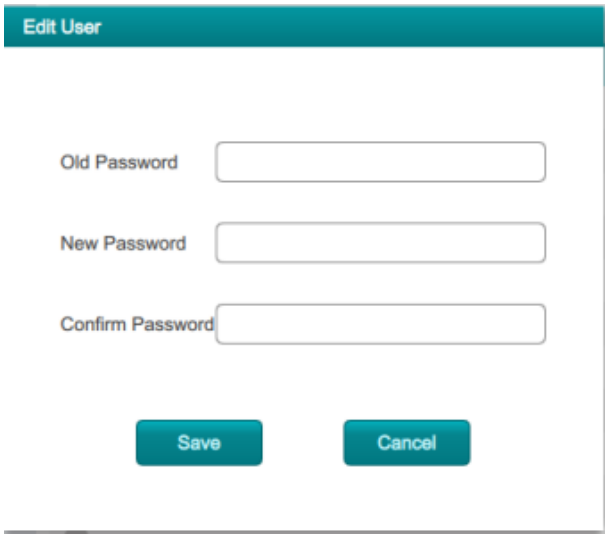


● **New button:** Click this button to open ***New User*** interface, you can set the account information of a new user in this interface.



- **User ID:** Input a user ID.
- **Name:** Input a user name.
- **Password:** Input a password.
- **Confirm Password:** Input a password again.
- **Administrator, Operator:** Users are assigned different access levels according to the user group they belong to.
- **Save button:** Click this button after the setting is complete. The information of the new user will be shown in the user list.
- **Cancel button:** Click this button to cancel creating a new user.

- **Modify button:** Select a user to be edited, and click this button to modify the user password.



- **Old Password:** Input the old password of the user.
- **New Password:** Input the new password of the user.
- **Confirm Password:** Input the new password of the user again.
- **Save button:** Click this button to modify the user password.
- **Cancel button:** Click this button to cancel any modification.

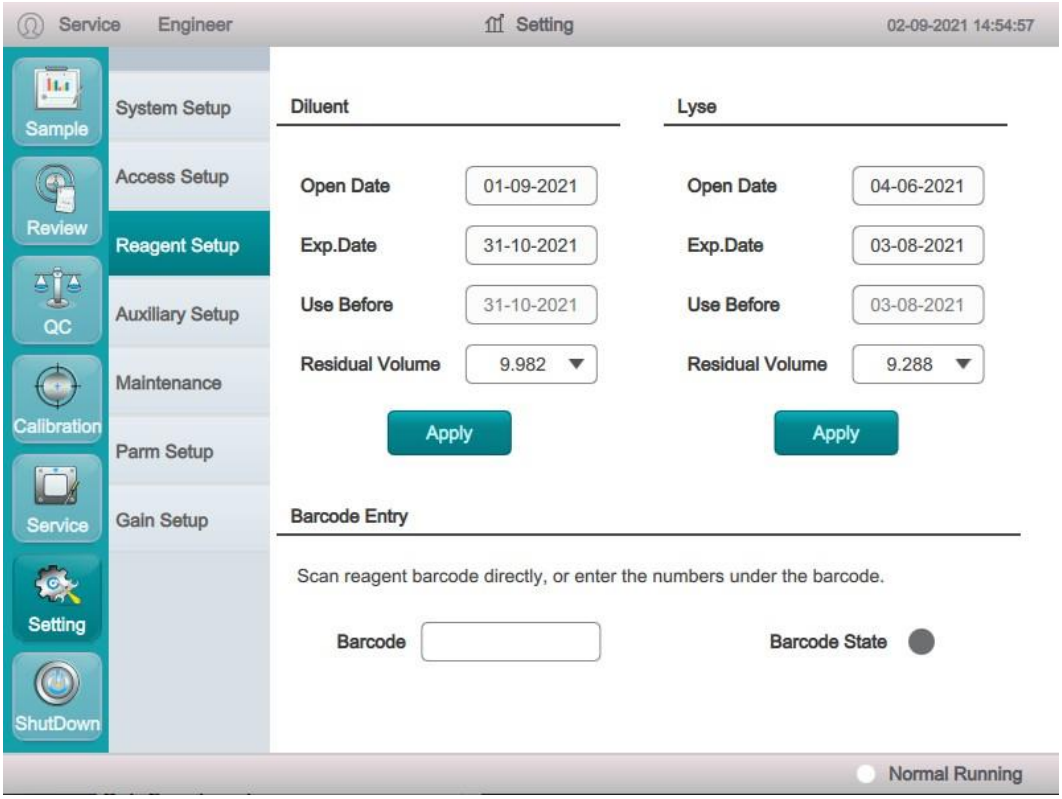
- **Delete button:** Select the user to be deleted and click this button, and then select OK in the pop-up dialog box to delete the user.

Note

- The administrator cannot delete his/her own information.

9.3 Reagent Setup

Click “Setting” → “Reagent Setup” button to access to ***Reagent Setup*** interface, see figure below. Once the new reagent is connected to the analyzer, you should performthis procedure for reagent replacement.



The user needs to replace the reagent in the following condition:

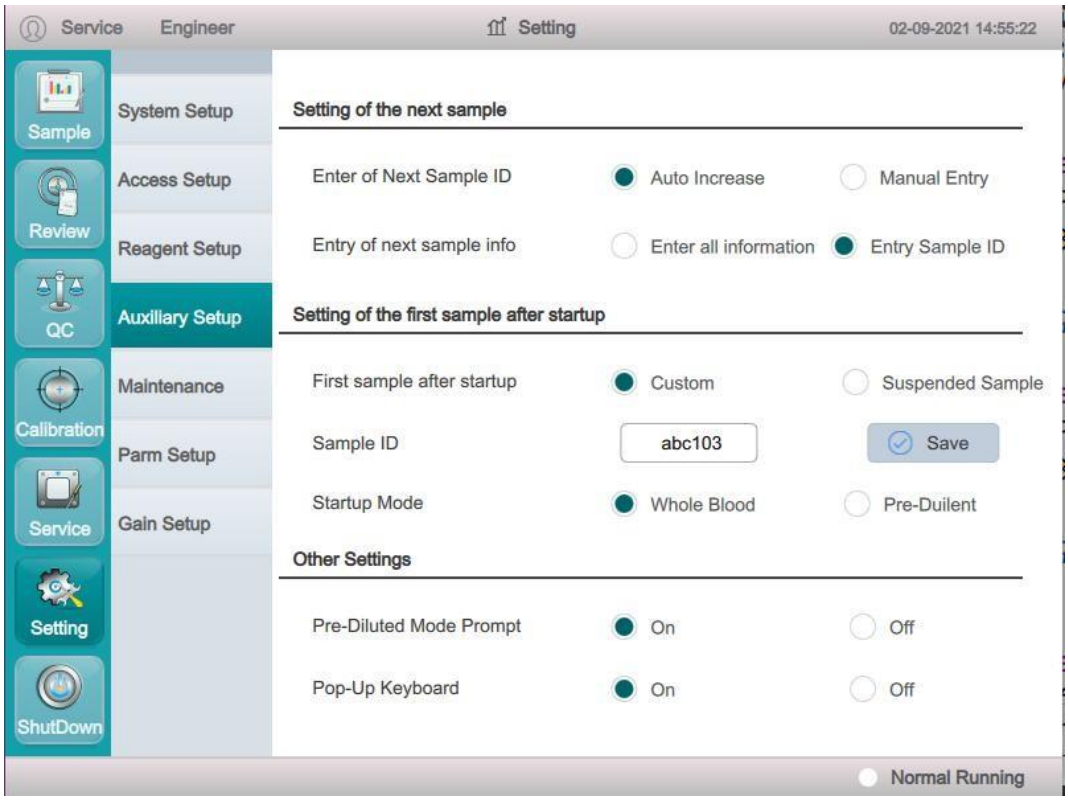
1. The full bucket/bottle of new reagent was replaced.
2. The reagent in the pipeline may be contaminated.
3. There are air bubbles in the pipeline.

- **Dilute replacement:** Select the open date, exp.date, use before date, residual volume of the diluent, click “Apply” button to save the input information and start replacing the diluent.
- **Lyse replacement:** Select the open date, exp.date, use before date, residual volume of the lyse, click “Apply” button to save the input information and start replacing the lyse.
- **Barcode Entry:** Input the barcode via a peripheral barcode scanner or manual input.

  If a peripheral barcode scanner is used, you can scan the replacing barcode scanner, the validity date and residue volume will be shown in the correspondingtextboxes.

9.4 Auxiliary Setup

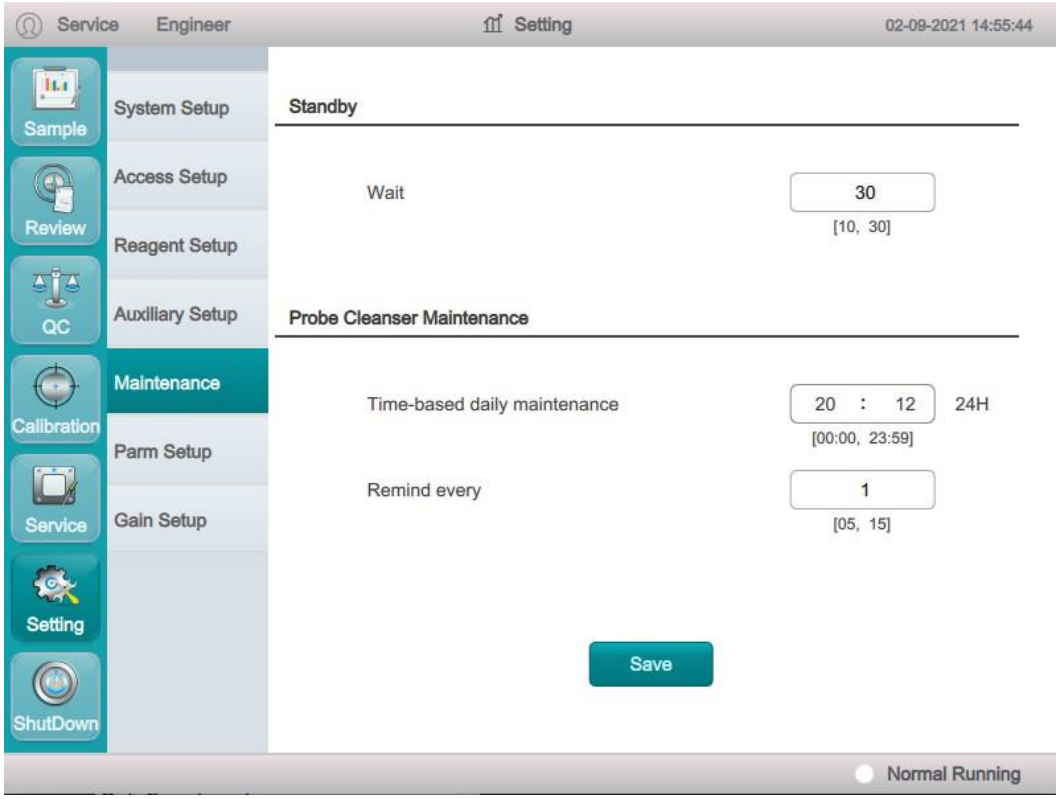
Click "Setting" → "Auxiliary Setup" button to access to ***Auxiliary Setup*** interface, see figure below. The operator is allowed to set the following functions in this interface: Setting of the next sample, Setting of the first sample after startup, Other Settings.



- **Setting of the next sample:**
  - **Enter of Next Sample ID:** Select the entry method of next sample ID: Auto Increase, Manual Entry.
  - **Entry of next sample info:** Select the entry method of next sample information: Enter all information, Entry sample ID.
- **Setting of the first sample after startup:**
  - **First sample after startup:** The user can select "Custom", the sample ID set by the user will be used after next startup when the specified sample ID is entered into the textbox. You can also select "Suspended Sample".
  - **Sample ID:** Input the first sample ID after startup.
  - **Startup Mode:** Select whole blood mode or Pre-Duilent mode.
- **Other Settings:** Select "On" radio box to activate to the corresponding function, select "Off" radio box to close the corresponding function.

9.5 Maintenance

Click "Setting" → "Maintenance" button to access to ***Maintenance*** interface, see figure below. The system standby time and probe cleanser maintenance time can beset in the Maintenance interface.

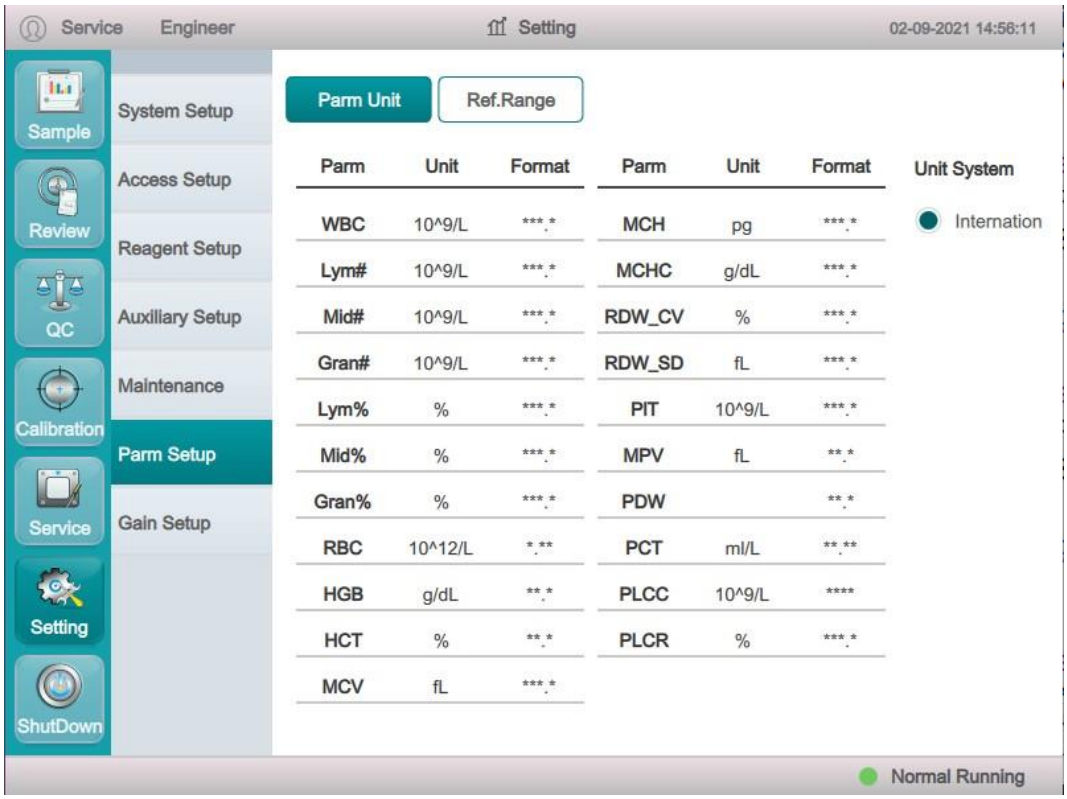


- **Standby:**
  - **Wait:** In this textbox, the administrator is allowed to set the waiting time for entering the sleep state after the main unit is halted.
- **Probe Cleanser Maintenance:**
  - **Time-based daily maintenance:** Input the start time of the probe cleanser**soak.**
  - **Remind every:** If you need to set the maintenance time of the probe cleanser soak, it can be entered in the Remind every textbox.

9.6 Parameter Setup

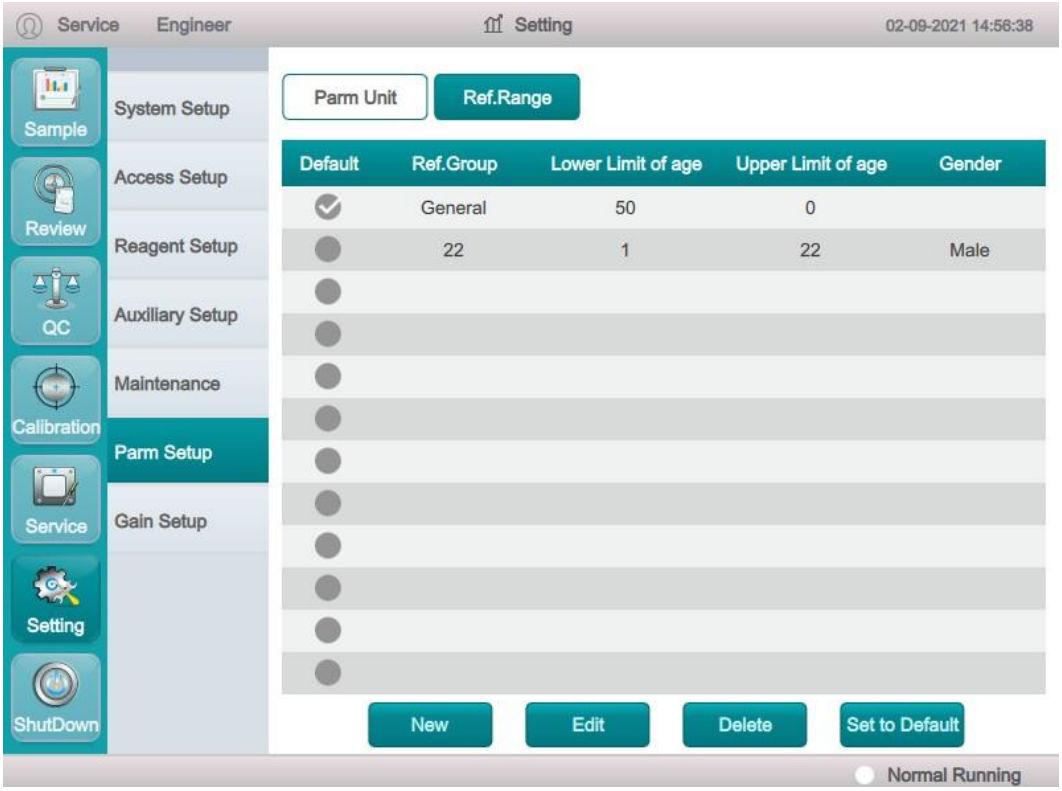
Click "Setting"→"Parm Setup" button to access to ***Parameter Setup*** interface, see figure below. You can set parameter unit and reference range in this interface.

- **Parameter Unit:**Click "Parm Unit" button to access to ***Parameter Unit*** interface, see figure below. In this interface, some of the parameters of the analyzer can usedifferent units which can be chosen as per user demand.



  - **Unit System:**Select a unit system for the parameters.

- **Ref. Range:** Click "Ref.Range" button to access to ***Reference Range*** interface, see figure below. The reference range based on various normal groups can be set forthe analyzer in the actual practice. If the analysis result of a sample is beyond the reference range, it will be regarded as clinically abnormal.

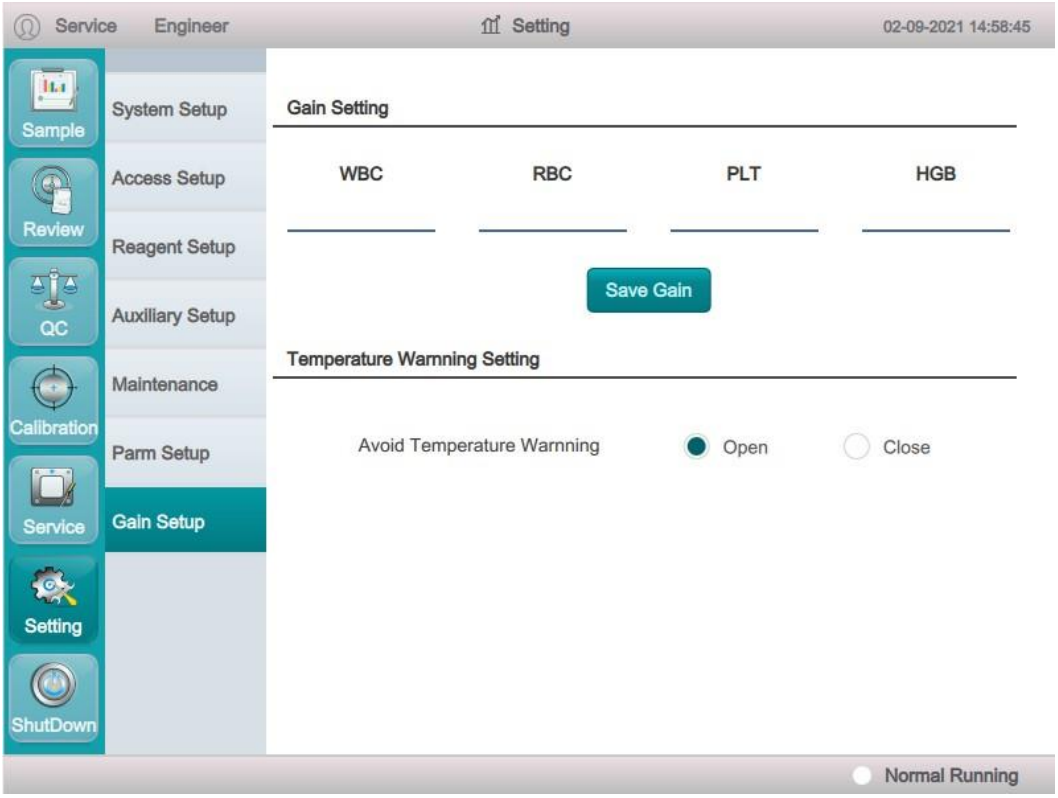


- **New button:** Click this button, a screen for adding a new reference group willpop up. In this interface, you can add a new reference group.
- **Edit button:** Select the Ref. group to be set, and click this button to access to ***Edit Ref. Group*** interface, you can modify the reference range of the parameters.
- **Delete button:** Select the reference group to be deleted, and click this buttonto delete the selected customized reference group.
- **Set to Default button:** Select a reference group and click this button to setthe selected reference group as the default reference group.

When you pre-enter patient information in the sample analysis interface, theRef. Group displayed by default is the default reference group.

9.7 Gain Setup (Engineer)

Click “Setting” → “Gain Setup” button to access to ***Gain Setup*** interface, see figure below. You can adjust the digital potentiometer, it is not recommended to adjust gains frequently.



- **Gain Setting:** Input the gain value in the corresponding parameter textbox, click “Save Gain” button to save the modification.
- **Temperature Warnning Setting:**If you select Close, system will prompt temperature alarm when the temperature of analyzer exceeds the normal working temperature.

  If you select Open, system will not alarm when the temperature of analyzerexceeds the normal working temperature.

10 Shut Down

You should perform procedure of shutting down before completing the daily work.During the shutdown, the analyzer will do daily cleanser maintenance.

Click the “Shutdown” button on the menu screen, the dialog box for ensuring will pop up, click OK button, the system starts to execute the shutdown sequence. Afterthe completion of the shutdown sequence, you can turn off the power supply of the analyzer.

Note

- Do not turn off the power directly without running the shutdown procedure.

11 Troubleshooting

11.1 Introduction

This chapter contains information that is helpful in locating and resolving problemsthat may occur during the operation of your analyzer.

Warning

- This chapter is not a complete service manual and is limited to problemsthat are readily diagnosed and/or corrected by the user of the analyzer.
- Most maintenance actions or procedures should be performed after turning off the power.

Biohazard

- All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous.
- Improper handling of samples, controls, calibrators, reagents, wastes may cause biohazardous. Do not touch it with your hands directly, wear proper personal protective equipment(e.g. gloves, lab uniform, etc.).

11.2 Dealing with Error Messages

In the use of the analyzer, when the system detects abnormalities, an error messagewill be displayed on the lower of the screen and the main unit will sound an alarm.

The popup dialog box displays the error description and its help information. The user can click the error message in the dialog box, and deal with the error messagesvia viewing its help information.

The following functions are provided in the dialog box:

- **Clear :** Click “Clear” button, normally, the system will automatically clear the errors and close the dialog box. For errors which cannot be cleared automatically,you can take appropriate actions by following the error help information.
- **Close:** Click “Close” button, close the dialog box.

Possible errors and the corresponding help information are shown in Table 11-1. Ifthe error does not be resolved, please contact our customer service department or your local distributor.

Table 11-1 Error Message Reference

Error description	Troubleshooting Information
Mainboard failure	1. Please power off the analyzer directly, and contact customer service department.
Diluent running out	1. Click “Clear” button, input the barcode for the new reagent to be replace in the pop-up reagent setup dialog box. 2. After installing a new container of diluent, click Apply button to start replacing reagent. 3. If the error still exists, contact our customer service department.
Lyse running out	1. Click “Clear” button, input the barcode for the new reagent to be replace in the pop-up reagent setup dialog box. 2. After installing a new container of lyse, click Apply button to start replacing reagent. 3. If the error still exists, contact our customer service department.
Insufficient lyse	1. Click “Clear” button, input the barcode for the new reagent to be replace in the pop-up reagent setup dialog box. 2. After installing a new container of lyse, click Apply button to start replacing reagent. 3. If the error still exists, contact our customer service department.
Diluent expired.	1. Click “Clear” button, input the barcode for the new reagent to be replace in the pop-up reagent setup dialog box. 2. After installing a new container of diluent, click Apply button to start replacing reagent. 3. If the error still exists, contact our customer service department.

Lyse expired	1. Click “Clear” button, input the barcode for the new reagent to be replace in the pop-up reagent setup dialog box. 2. After installing a new container of lyse, click Apply button to start replacing reagent. 3. If the error still exists, contact our customer service department.
Waste container is full	1. Empty the waste container or install a new waste container. 2. Click the “Clear” button to clear this error. 3. If the error still exists, contact our customer service department.
Abnormal power supply	1. Please power off the analyzer directly, and contact customer service department.
Syringe assembly failure	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Sampling assembly vertical motor failure	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Sampling assembly horizontal motor failure	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Abnormal background	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Abnormal HGB background voltage	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Abnormal negative pressure	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
WBC clogging	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.

RBC clogging	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Abnormal WBC aperture voltage.	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Abnormal RBC aperture voltage.	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.
Printer has no paper	1. Check sufficient printing paper is prepared for the printer. 2. If the error still exists, contact our customer service department.
Other error of printer	1. Check sufficient printing paper is prepared for the printer. 2. If the error still exists, contact our customer service department.
The communication connectionis disconnected	1. The communication connection is disconnected, please check the network connection. 2. Click the “Clear” button to clear this error. 3. Communicate it again, if the error still exists, contact our customer service department.
Communication failure	1. Click the “Clear” button to clear this error. 2. Communicate it again, if the error still exists, contact our customer service department.
Abnormal Temperature	1. Click the “Clear” button to clear this error. 2. If the error still exists, contact our customer service department.

11.3 Replace fuse

Analyzer Fuse Specification:

Follow the procedure given below to replace the fuse:

1. Remove the fusefrom the instrument accessory bag;
2. Turn off the power supply, and pull off the power plug;
3. Unplug the power cord from the host power outlet, and take out the fuse holder

from the power outlet;

4. The damaged fuse removed, and the new fuse into the fuse holder, and then plugthe fuse plug back into the power socket;
5. Connect the power plug.

Warning

- The operators use the same fuse, otherwise easy to cause the instrumentto be unable to work normally or damage the instrument.

12 Transportation and Storage

12.1 Transportation

Auto hematology analyzer in packaging, in order to the requirements of the contractof transport, the transport process must prevent subject to severe shock, rain and exposure. Auto hematology analyzer shall not be mixed with toxic, harmful and corrosive substances.

12.2 Storage

The storage conditions of auto hematology analyzer were: temperature limitation -40℃~ 50℃, humiditylimitation 10%~90%, atmospheric limitation 50kPa ~ 106kPa,no corrosive gas, good ventilation environment. Shall not be mixed with toxic, harmful and corrosive substances.

Appendix A Specifications

A.1Reagents

Reagent Type	Reagent Name
Dilute	Hematology Analyzer Diluent
Lyse	Hematology Analyzer Lyse
Probe rinse solution	Probe rinse solution

A.2Parameters

Parameter	Abbreviation	Unit
White Blood Cell	WBC	10^9/L
Lymphocytes	Lymph#	10^9/L
Mid-sized Cells	Mid#	10^9/L
Granulocytes	Gran#	10^9/L
Percentage of Lymphocytes	Lymph%	%
Percentage of Mid-sized Cells	Mid%	%
Percentage of Granulocytes	Gran%	%
Red Blood Cell	RBC	10^{12}/L
Hemoglobin	HGB	g/L
Hematocrit	HCT	%
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
Platelet	PLT	10^9/L
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	/

Plateletcrit	PCT	%
Platelet-large cell ratio (optional)	P-LCR	%
Platelet-large cell count(optional)	P-LCC	10^9/L
C reactive protein (optional)	CRP	mg/L
White Blood Cell Histogram	WBC Histogram	
Red Blood Cell Histogram	RBC Histogram	
Platelet Histogram	PLT Histogram	

A.3Input/Output device

1) Keyboard: USB2.0 interface (optional)
2) Mouse: USB2.0 interface (optional)
3) External barcode scanner (optional)
4) Printer (optional)