H 360

Haematology analyser



USER MANUAL

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Preface

The H360 User Manual is published by Erba Lachema. Neither the whole nor any part of the information contained herein may be adapted or reproduced in any material for, except with the prior written consent of Erba Lachema.
All information, of a technical nature, and particulars of the H360 Analyser and its use are given by Erba Lachema in good faith, but may contain errors. This manual is intended only to assist the user in the use of the H360 Analyser and therefore Erba Lachema shall not be liable for any loss or damage whatever arising from the use or any information or particulars in, or any errors, or omission in this manual.
Users must respect the precautions and notes intended to protect them against injuries and/or instrument damage.
Misuse of the instrument and none respect of the prescribed use and the instrument maintenance procedures will void the warranty and may result in injuries.

Declaration

This user manual may be modified without notice.
Erba Lachema reserves the right of final interpretation of this user manual.
The pictures in this user manual are for reference only. If there is inconsistency between the pictures and the actual product, the actual product shall prevail. Do not use the pictures for other than intended use.
Erba Lachema shall be responsible for the safety, security, and performance of the product only when all of the following conditions are met:

- The assembly, re-commissioning, extension, modification, and repair of the product are performed by the authorized personnel of Erba Lachema.
- The product is operated based on this user manual.
- The electrical appliances in the relevant working room comply with applicable national and local requirements.

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1 Manual Overview

1.1 Introduction

This chapter explains how to use this operator's manual of H360 Haematology Analyser, which is shipped with the H360 Haematology Analyser and contains reference information about the analyser and procedures for operating, troubleshooting and maintaining the analyser.
Read this manual carefully before operating the analyser and operate your analyser in strict accordance with this manual.

1.2 Who Should Read This Manual

This manual contains information written for clinical laboratory professionals to:
- Learn about the hardware and software of the analyser.
- Customize system settings.
- Perform daily operations.
- Perform system maintenance and troubleshooting.

1.3 How to Find Information

This operator's manual comprises 16 chapters. Find the information you need by referring to the Table 1-1.

Table 1-1 Description of chapters

See...	You can find...
1 Manual Overview	Instructions for using the H360 Haematology Analyser.
2 Installation	Installation requirements for the H360 Haematology Analyser.
3 System Overview	Applications, measurable parameters, instrument configuration, software interface and software operations of the H360 Haematology Analyser.
4 Working Principle	Measuring principle and procedures of the H360 Haematology Analyser.
5 Setup	Settings of the system parameters such as the software date format and parameter units.
6 Daily Operations	Daily operations such as sample collection and preparation, the analysis procedures, start-up and shutdown of the instrument.
7 Sample Analysis	Sample analysis procedure and handling of the analysis results.
8 Result Review	Review of the analysis results.
9 Quality Control	Basic requirements for quality control and the quality control methods provided by the H360 Haematology Analyser.
10 Calibration	Basic requirements for calibration and the calibration methods provided by the H360 Haematology Analyser.

11 Reagent Management	Settings and management of the reagents for the H360 Haematology Analyser.
12 Service	Methods for maintaining and testing the H360 Haematology Analyser.
13 Troubleshooting	Troubleshooting methods for the H360 Haematology Analyser.
14 Traceability and Reference Methods	Traceability and reference methods of hematology calibrator and controls.
15 Specifications	Specification indicators of the H360 Haematology Analyser.
16 Terms and Abbreviations	Terms and abbreviations for the H360 Haematology Analyser.
17 Packing List	Packing list for the H360 Haematology Analyser.

1.4 Conventions Used in This Manual

The texts with special meaning in the manual are highlighted by different fonts and formats.

Table 1-2 Meanings of format use in user manual

Format	Definition
[XX]	All uppercase characters enclosed in [ ] indicate the name of a key on the analyser or the (external) keyboard, such as [ENTER].
XX	Bold characters indicate text displayed on the screen, such as **Report**.
XX	*XX* indicates variables and the specific content depends on the actual situation.
XX	Bold and italic characters Indicate chapter titles, such as ***1.1 Introduction***.

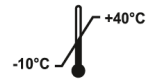
1.5 Symbol Conventions

When you see ...	Then...
	BIOLOGICAL RISK Follow the instruction below the symbol to avoid potential biocontamination.
	WARNING Follow the instruction below the symbol to avoid personnel injury.
	CAUTION Follow the instruction below the symbol to avoid analyser damage and failure, or unreliable analysis results.
NOTE	Follow the instruction below the symbol. The symbol highlights the important information in operating procedures that calls for special attention.
	Puncture Warning: The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.

The analyser or the outer packaging may have the following labels or symbols.

NOTE	If the labels are damaged or missing, please contact Erba Lachema or Erba Lachema's agents for replacement. All illustrations in this manual are provided as references only. They may not necessarily reflect actual analyser configuration or display.

When you see ...	Then...
	Caution
	Biological Risk
	Exercise caution to prevent puncture
	Instruction for Moving
	Network interface
	Protective grounding
	Alternating current (AC)
	For *in vitro* diagnosis only
	Lot No.
	Expiry date
	Serial No.
	European CE declaration of conformity
	Date of manufacture
	Manufacturer

When you see ...	Then...
	Storage temperature
	Humidity level for storage
	Atmospheric pressure level for storage
	See Instruction for Use
	Keep away from Sunlight
	Keep dry
	No rolling
	No Stacking
	Let this side face upward
	Fragile, handle with care
	Recyclable materials
	The symbol on the product indicates that this product may not be treated as a household waste. Instead it shall be handled to the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. Please contact your local city office or your distributor of this product. Pursuant to the EU directive 2002/96/EC for medical devices sold from that time by Erba Lachema the corresponding costs are divided up as described below: 1. The concerned device delivery to Erba Lachema will be paid by the Customer 2. Device dismantling sorting of parts and elimination of wastes will be supported by Erba Lachema according to the existing local regulation 3. In case of a sale to a third-party the first Customer shall inform Erba

When you see ...	Then...
	Lachema of the name and address of the new owner to guarantee the device traceability and to allow it's further elimination, and shall inform of the new owner that he will pay for the delivery of the device to Erba Lachema for its elimination 4. Otherwise the first Customer will pay all of the costs and all penalties that the legal authorities should impose on the manufacturer for default of the device elimination traceability as requested by the regulation – For medical devices sold before that time, except in particular cases, the elimination of the device will be supported by the Customer. Upon request Erba Lachema could provide this elimination. Contact us for quotation – For medical devices sold and used in other countries, the Customer should contact the Erba Lachema Representative to be informed of his responsibilities

1.6 Safety Information



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.
If leak happens to the analyser, the leak liquid is potentially biohazardous.



WARNING
Please check the firmness of all the door/ covers/panels before running the analyser to prevent unexpected opening or loosening when the analyser 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 Erba Lachema or Erba Lachema-authorized agents upon the identification of any damaged part.
Be careful when opening/closing and removing/installing the doors, covers and panels of the analyser.
Dispose the analyser according to government regulations.



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

2 Installation

2.1 Introduction



WARNING
Installation by personnel not authorized or trained by Erba Lachema may cause personal injury or damage to the analyser. Do not install the analyser without the presence of Erba Lachema-authorized personnel.

Your analyser has passed strict tests before it is shipped from the factory. Internationally-recognized symbols and instructions show the carrier how to properly handle this electronic instrument in transportation. When you receive your analyser, carefully inspect the packaging. If you see any sign of mishandling or damage, contact Erba Lachema customer service department or your local agent immediately.

2.2 Installation Personnel

The analyser should only be installed by Erba Lachema or its authorized agents. You need to provide the appropriate environment and space. When the analyser needs to be relocated, please contact Erba Lachema or your local agents.
When you receive the analyser, please notify Erba Lachema or your local agent immediately.

2.3 Installation Requirements



WARNING
Connect only to a properly grounded outlet.
Before turning on the analyser, make sure the input voltage meets the requirements.



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

Installation requirements for the analyser are in Table 2-1.

Table 2-1 Installation requirements

Installation Environment	Requirements
Site	• Level ground and stable workbench with load capacity ≥50kg. • Free of dust, mechanical vibration, heat and wind sources, contamination, heavy-noise source or electrical interference. • Avoid direct sunlight and keep good ventilation. • It's recommended to evaluate the electromagnetic environment of the laboratory before operating the analyser. • Keep the analyser away from sources of strong electromagnetic interference, otherwise, its proper functioning may be affected.
Space (In addition to the space required for the analyser itself, set aside:)	• At least 50 cm from each side, which is the preferred access to perform service procedures. • At least 20 cm from the back for cabling and ventilation. • Enough room on and below the countertop to accommodate for the diluent and waste containers. • Place the analyser near the electrical outlet and avoid being blocked by any objects, so that you can disconnect the power plug easily as required.
Temperature	15°C~30°C
Relative humidity	20%~85%
Operating atmospheric pressure	70kPa~106kPa
Ventilation	Keep air exchange to ensure good air circulation. The wind should not blow directly at the analyser.
Power Requirements	AC100V~240V, Input Power ≤200VA, 50/60HZ.
Electromagnetic Wave	Keep the analyser away from electric-brush motors, flashing fluorescent and electric-contact equipment which is switched on/off frequently.
Waste Disposal	Dispose of the waste as per the requirements of the local environment protection authorities.

2.4 Damage Inspection

Before packing and shipping, Erba Lachema has applied rigid inspection on all the analysers. Upon receiving the analyser, please check carefully before unpacking to see if there are any of the following damages.

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

Once you find the above damages, please notify your local agent immediately.

If the packaging is intact, please open the packaging in the presence of personnel from Erba Lachema or its agents and apply the following inspections:

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

2.5 Unpacking

Please unpack the analyser by taking the following steps:
Open the outer packing box; take out the accessory pack; take out the analyser together with the protective and cushioning materials.
Remove the foam and the protective PE bag.
Open the right door (open the linear-shaped cam lock on the right door with a slotted screwdriver).
Remove the binder clips, which are used for fixating two conveyor belts.

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

Remove the binder clips, which are used for fixating sampling assembly.

NOTE To avoid damage during the transportation, the sampling assembly of the analyser is fixated with clamps. Do remove the clamps before using the analyser.

2.6 Connecting the Analyser System

2.6.1 Electrical Connections

Please refer to Figure 2-1 for the electrical connections of the analyser.



Figure 2-1 Connecting the electrical devices

2.6.2 Reagent Connections

WARNING

Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.

If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.

CAUTION

Please make sure the length of the diluent pipe and the waste pipe should be no longer than 1 500mm; the length of the lyse pipe and the cleanser pipe should be no longer than 850mm.

Tighten the panel connector of the fluidic line so that the overall fluidic line is closed to prevent leakage and seepage caused by siphonage, etc.

Refer to Figure 2-2 for the connection of the reagents placed outside the analyser.

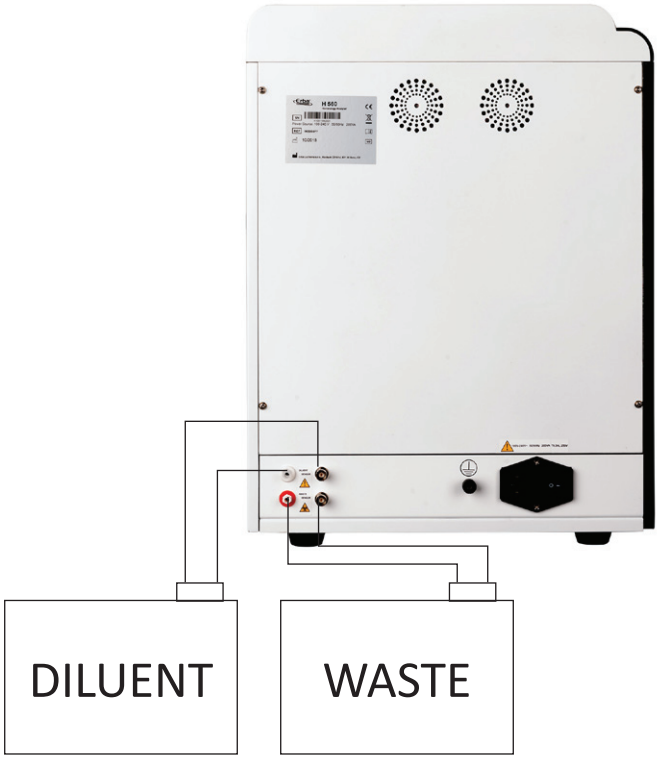


Figure 2-2 Connecting reagents placed outside the analyser

Refer to Figure 2-3 for the connection of the reagent placed inside the analyser.



Figure 2-3 Connecting reagents placed inside the analyser (left door opened)

2.6.3 Installing the Diluent Float Sensor and Replacing the Reagents

Please install the diluent float sensor and replace the diluent as per the approaches stated in this section.

2.6.3.1 Installing the Diluent Float Sensor

Install the diluent float sensor according to the following steps.

- Press down and remove the round cardboard with dotted cutting line on the top side of the diluent box so as to reveal a round hole.
- Pull out the cover of the container so that the cardboard around the round hole can seize the neck under the vial cap to prevent invagination.
- Turn and open the cap (keep the cap) and prevent any foreign objects from getting into the container.
- Install the diluent float sensor assembly in the accessory pack as shown in Figure 2-4. The float sensor shall be kept as vertical as possible during installation and the self-contained cap of the sensor shall be tightened.

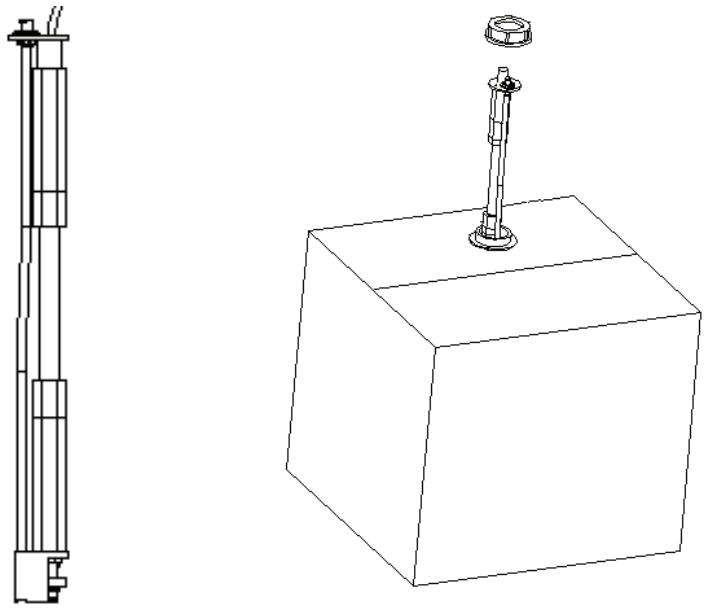


Figure 2-4 Installing the Diluent Float Sensor

2.6.3.2 Replacing Reagents

Steps for the replacing the diluent are the same as that for installing the sensor. Please keep the empty diluent container and the cap for future use.

2.6.4 Installing the Waste Float Sensor

NOTE The float sensors used in the analyser are only applicable to Erba Lachema-supplied waste containers or the containers with the same specification and model (such as the vacant diluent container).

- Take a proper waste container (it can be a vacant diluent container, the opening of which is required to be pulled out of the hole of the box to expose the opening) and open the vial cap.
- Install the waste float sensor assembly in the accessory pack as shown in Figure 2-5. The float sensor shall be kept as vertical as possible during installation and the self-contained cap of the sensor shall be tightened at the same time to prevent the spilling of the waste.

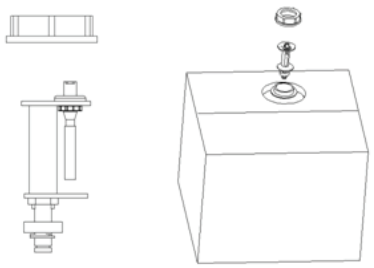


Figure 2-5 Installing the Waste Float Sensor

The waste container can be replaced according to the steps mentioned above. The replaced waste shall be properly disposed to avoid contamination.



WARNING
Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

2.6.5 Connecting the LIS

If the analyser needs to be connected to laboratory information system (hereinafter referred to as LIS), you can complete the connection by following the steps in this section.

2.6.5.1 Installing LIS Workstation

- Install LIS workstation and set instrument type and model.
- Enter LIS workstation network setup interface after installation and set monitoring IP address and port number.

NOTE Please contact the Erba Lachema customer engineer to get Description of LIS Communication Protocol for Haematology Analysers to complete the support of the LIS workstation to the LIS communication protocol.

2.6.5.2 Host Communication Settings

- Use a network cable to connect the analyser to LIS local area network.
- Please log on the H360 Haematology Analyser software as the administrator; if the analyser is turned on, skip this step.

For detailed, see **6.3 Start-up**.
The whole process lasts for 4 to 12 minutes. Please be patient.

- In the **Setup** interface, click **Host Communication** in the **Communication** selection to access the Laboratory Information System (LIS) communication setting interface. See *6.3 Start-up.*
- Set the IP address and other network information of the analyser according to the actual situation.

If the network is accessed through a router on the site, please select **Obtain an IP address automatically** and **Obtain DNS server address automatically**.
If the network is accessed through a network switch, or the analyser is directly connected to the LIS on the site, please select **Use the following address**, so as to manually set the IP address and subnet mask of the analyser. The IP addresses of the analyser and LIS must be in the same network segment. Furthermore, their subnet masks shall be the same, while other parameters can maintain null.

For detailed parameter descriptions, see **5.6.1 Host Network Settings**.

- Click **OK** to save the settings and close the dialog box.

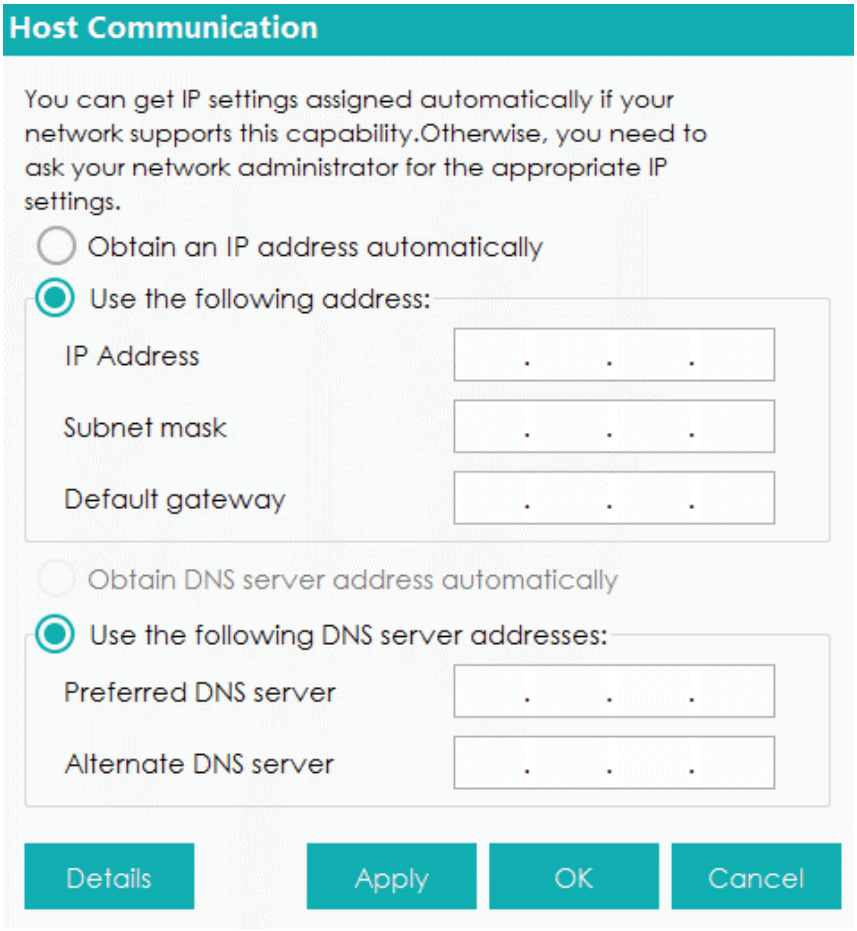


Figure 2-6 Host Communication Settings

2.6.5.3 Connecting Analyser with LIS

- Please log on the H360 Haematology Analyser software as the administrator; if the analyser is turned on, skip this step.

For detailed, see *6.3 Start-up*.

The whole process lasts for 4 to 12 minutes. Please be patient.

- In the **Setup** interface, click **LIS Communication** in the **Communication** selection to access the Laboratory Information System (LIS) communication setting interface. See Figure 2-7.
- Input the IP address and port of LIS workstation in **Network Settings** area.

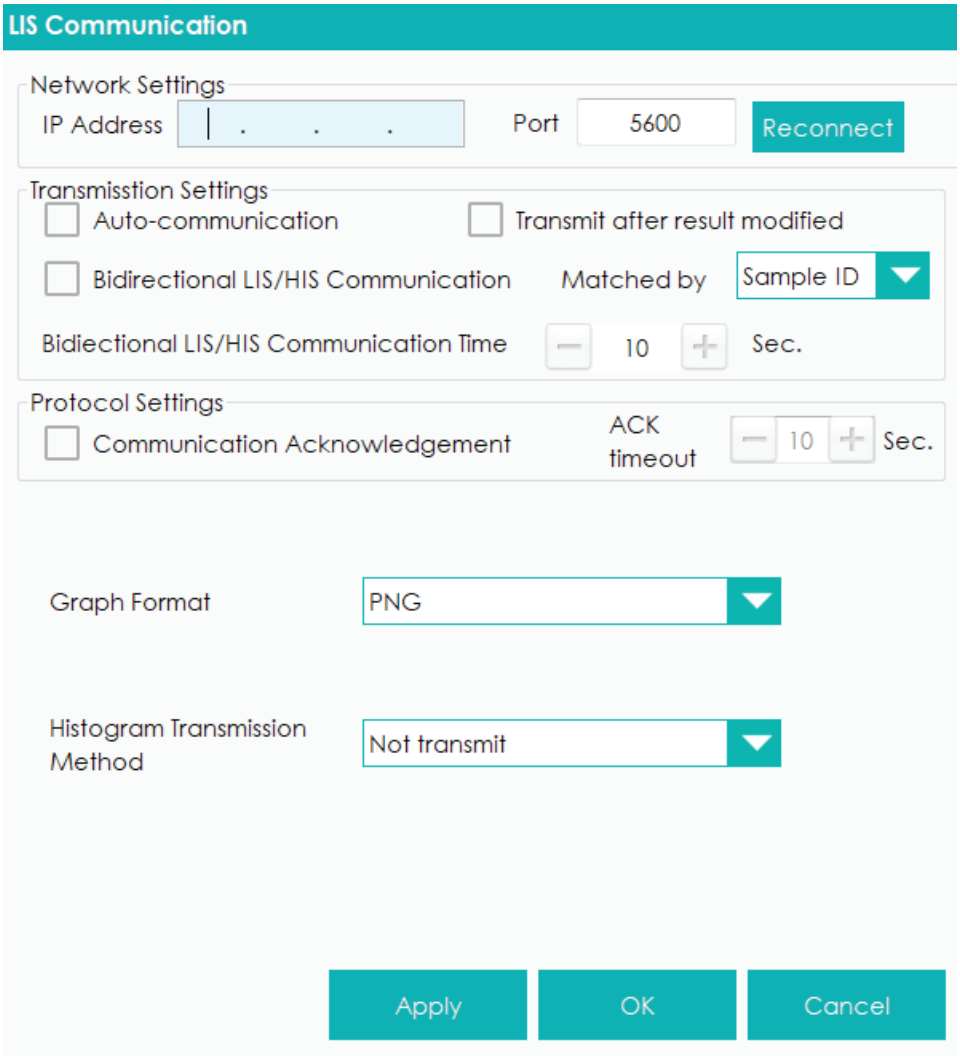


Figure 2-7 LIS Communication Settings

Find the IP address and port of LIS in the network setup interface in the LIS workstation; if IP address can't be found, try the method below:

- Enter the operating system of LIS workstation.
- Press combination key [Windows+R] to open the **Run** window.
- Input **cmd**, and then click **OK**.
- Input the **ipconfig** command into the cmd.exe window popped out.

The interface shows similar content as follows:

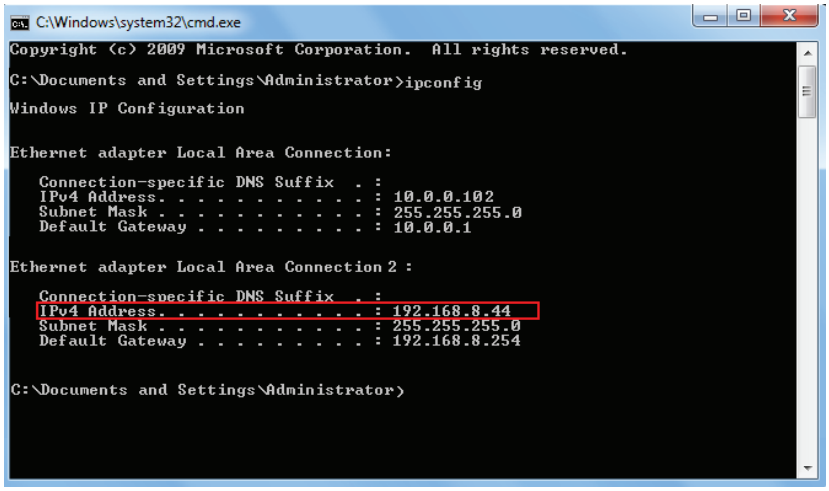


Figure 2-8 IPv4 address

The IPv4 address in the red box is the IP address of LIS workstation

- Click OK to save the settings.
- Check if the connection is successful.

The LIS icon in the upper right side on the analyser screen turns from white 

to green 

, which indicates H360 Haematology Analyser software is connected to LIS successfully.
If the icon stays grey, the connection fails. Please check if the IP address and port of LIS is correct and reconnect as the steps above; if the problem still exists, please contact the hospital network administrator or Erba Lachema customer service engineer to handle it.

2.6.6 Connecting the Printer Box (Optional)

If the analyser needs to be connected with the printer box, you can follow steps in this section to complete the connection.

2.6.6.1 Connecting the Analyser with the Printer Box

- Connect the analyser with the printer box physically.
- Access the software setting interface of the printer box, and set the IP address, port number, etc. of the printer box.

NOTE Please contact the Erba Lachema customer engineer to get ***Printer Box Operation*** Guide to complete the connection between the printer box and the analyser.

2.6.6.2 Setting Host Communication

You can skip this step if the analyser is connected with the printer box through a router on the site. If the analyser is connected with the printer box directly through a network cable, to make sure the successful connection, the administrator should set the IP address and other relative information on the **Host Communication** screen by following steps below.

1. Access **Setup > Communicate** interface, and click **Host Communication**. See Figure 2-9.

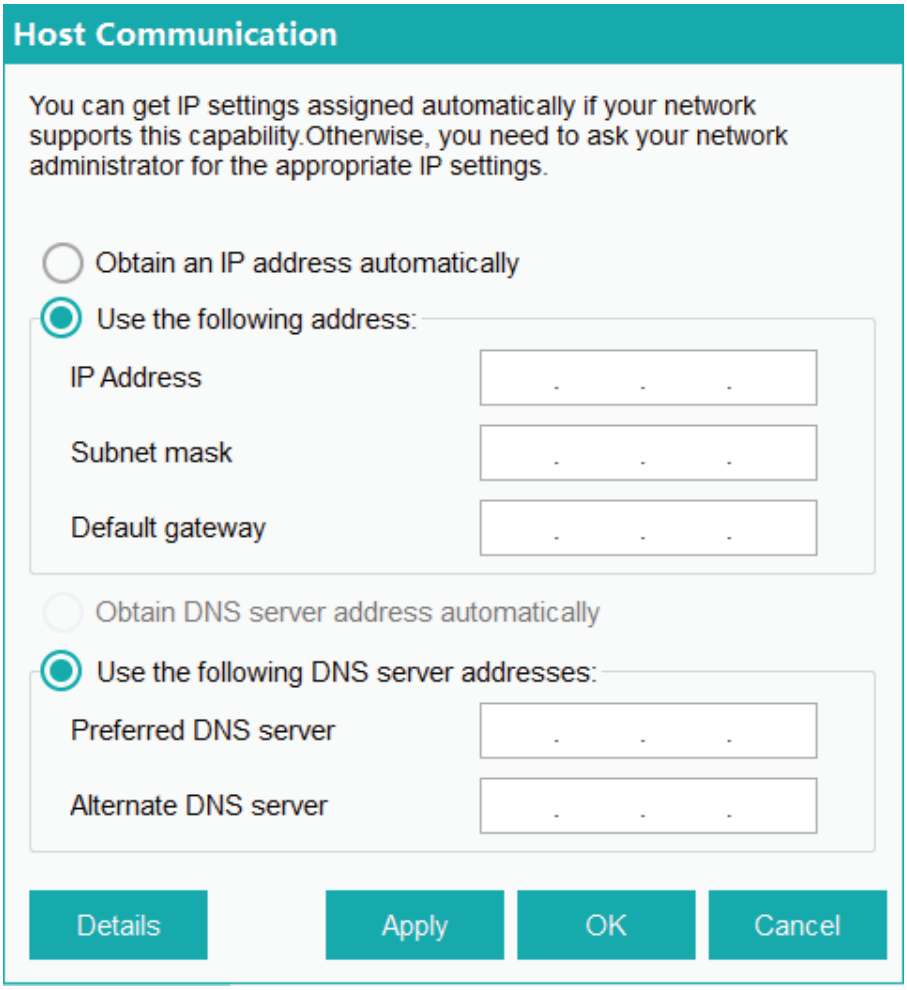


Figure 2-9 Host Communication

2. Click **Use the following address**, and set the IP address and subnet mask.
   The IP address of the analyser and the printer box must be in the same network segment, and their subnet masks should be the same. Other parameters can be left blank.
3. Click **Apply**
4. Click **OK** to save the setting and close the interface.

2.6.6.3 Printer Box Settings

1. Click **Setup > Print Settings > Printer Box Settings**. See Figure 2-10.

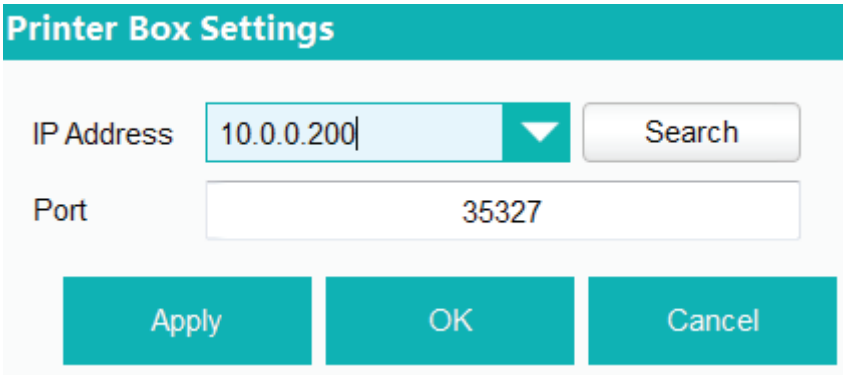


Figure 2-10 Printer Box Settings

2. Enter the IP address and port number of the printer box.

NOTE You need to enter the same IP address and port number set on the software of the printer box.

3. Click Apply.
4. Click **OK**.
5. Verify if the connection succeeds.

If the printer icon on the top right corner of the interface is changing from to , then the connection succeeds. If not, the connection fails. Please check if IP address and port number are correct, and try to reconnect again as described in this section; if it still fails, please contact Erba Lachema customer engineer.

6. Click **Setup > Print Settings > Printer driver**, click the dropdown list and select Printer Box. See Figure 2-11.

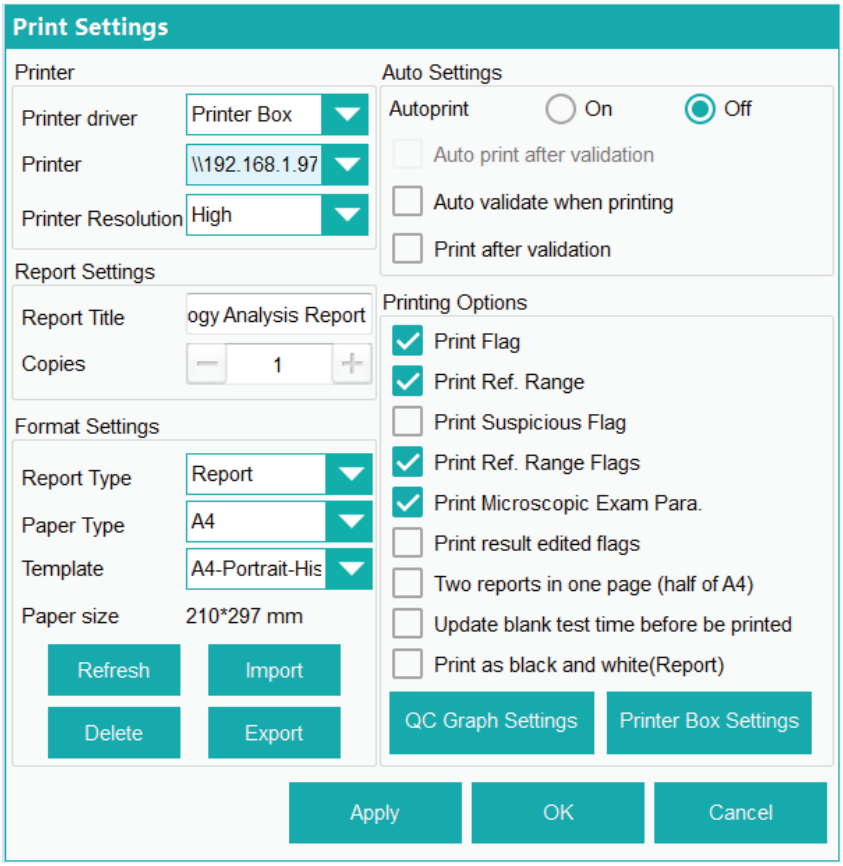


Figure 2-11 Print settings

7. The drop-down list of **Printer** shows all printers that match with the current printer box. You can select one of them as the default printer.

NOTE Known virtual printers are automatically blocked. If you select a virtual printer to print, you should restart the printer box.

8. Then you can perform the printing operation.

3 System Overview

3.1 Introduction

Auto Hematology Analyzer is a quantitative, automated haematology analyser and 3-part differential used in clinical laboratories offering automatic start-up, shut-down and sample analysis. This section describes in details the intended use, measurement parameters, structure, user interface and compatible reagents of the analyser.

3.2 Intended Use

The H360 is a fully automated 3-part differential hematology analyser for the *in vitro* diagnostic quantitative determination of cell counts in human blood. It is designed to report on the hematological status of patient samples, supporting the monitoring and diagnosis of pathological conditions. The H360 should be used by trained professionals in the hematology laboratory and only with Erba Mannheim reagents.

NOTE The analyser is intended for screening in the clinical examination. When making clinical judgment based on the analysis results, the doctors should also take into consideration the clinical examination results or other test results.

3.3 Measurement Parameters

As shown below, the analyser provides quantitative analysis results for 22 haematology parameters and three histograms.

Table 3-1 Parameters

Type	Parameter Name	Abbreviation
WBC (7 items)	White Blood Cell count	WBC
	Percentage of Granulocytes	Gran%
	Percentage of Lymphocytes	Lym%
	Percentage of Mid-sized Cells	Mid%
	Number of Granulocytes	Gran#
	Number of Lymphocytes	Lym#
	Number of Mid-sized Cells	Mid#

Type	Parameter Name	Abbreviation
RBC (8 items)	Red Blood Cell count	RBC
	Haemoglobin Concentration	HGB
	Mean Corpuscular Volume	MCV
	Mean Corpuscular Haemoglobin	MCH
	Mean Corpuscular Haemoglobin Concentration	MCHC
	Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV
	Red Blood Cell Distribution Width - Standard Deviation	RDW-SD
	Haematocrit	HCT
PLT (7 items)	Platelet count	PLT
	Mean Platelet Volume	MPV
	Platelet Distribution Width - Coefficient of Variation	PDW-CV
	Platelet Distribution Width - Standard Deviation	PDW-SD
	Plateletcrit	PCT
	Platelet-large cell ratio	P-LCR
	Platelet-large cell count	P-LCC
Histogram (3 items)	White Blood Cell Histogram	WBC Histogram
	Red Blood Cell Histogram	RBC Histogram
	Platelet Histogram	PLT Histogram

3.4 Structure of the Analyser



WARNING
Please check the firmness of all the doors, covers and boards before running the analyser. The analyser is heavy, so moving by one person alone may cause injury. It is advisable for two people to move it together when the transportation is necessary, and make sure you follow the instructions and use the proper tools.
Connect only to a properly grounded outlet.
To avoid electrical shocks, disconnect the power supply before opening the cover.
To prevent fire, use the fuses with specified model number and working current.



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

3.4.1 Main unit

The H360 Haematology Analyser consists of the main unit (analyser) and accessories. The main unit is the main part for analysis and data processing.

- Front of the analyser



Figure 3-1 Front of the analyser

1. *Aspirate key*
2. *Sample probe*
3. *Power/Status indicator*
4. *Touch screen*

- Back of the analyser

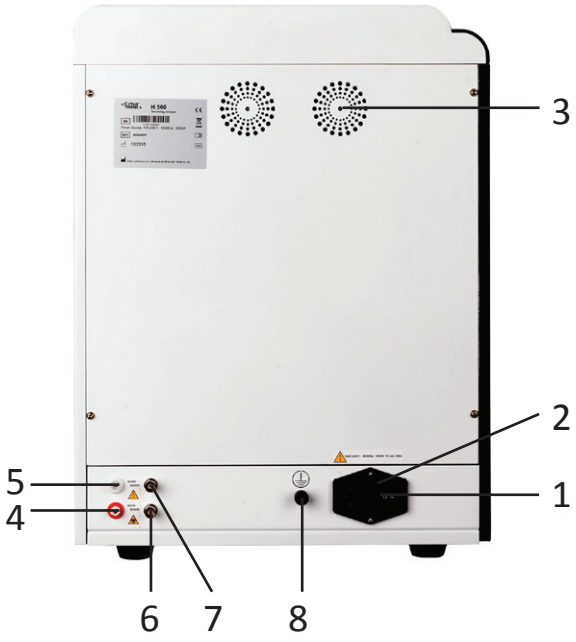


Figure 3-2 Back of the analyser

1. Power *switch*
2. *AC input*
3. *Cooling fan*
4. *Waste outlet*
5. *Diluent inlet*
6. *Waste level detection connector*
7. *Diluent presence detection connector*
8. *Ground* studs

- Side view of the analyser

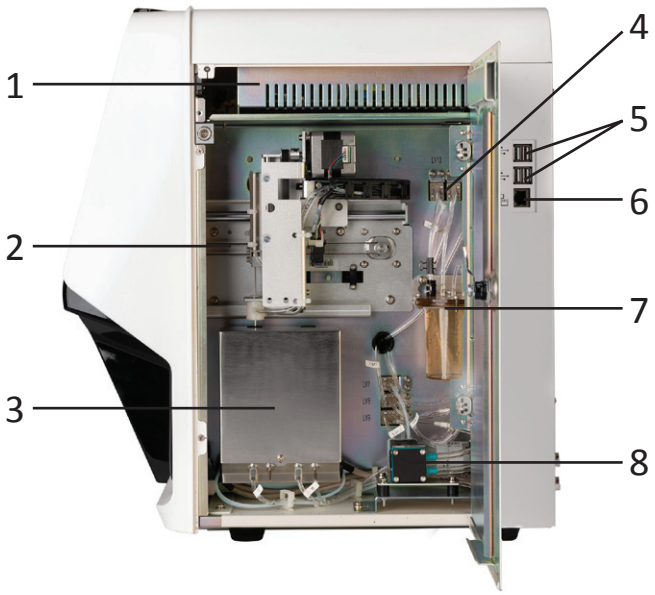


Figure 3-3 Right side of the analyser

1. *Power Supply*
2. *Sampling assembly*
3. *Count bath assembly*
4. *Valve assembly*
5. *USB interface*
6. *Network interface*
7. *Pressure chamber*
8. *Pump*

3.4.2 Touch screen

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

3.4.3 Aspirate key

The aspirate key is located in the middle of the front side (behind the sample probe) to start the sample analysis, to add diluent, or to cancel sleep.

3.4.4 Power/Status indicator

The status indicator is located in the middle section of the right part of the analyser (front side). It shows the status of the analyser including ready, running, error, sleep and on/off, etc.
The indicators change with the status of the main unit. Details are shown in Table 3-2.

Table 3-2 Main Unit Status Indicators

Instrument Status	Indicator Status	Remarks
Shutdown	Off	The main unit has been shut down.
Stopped running with error conditions	Red light on	Stopped running with the occurrence of errors
Running with error conditions	Red light flickering	Running with the occurrence of errors
Time sequence deactivated	Yellow light on	Initialization or sleep status irrelevant to running
Running	Green light flickering	Execution of the sequence actions is in process.
Ready	Green light on	Execution of the sequence actions is allowed.

NOTE While the analyser is running, if the indicator turns dim or off, please contact Erba Lachema or Erba Lachema's agent for maintenance.

3.4.5 Power switch

⚠ CAUTION
To avoid damage, do not power on/off the analyser repetitively within a short time.

A power switch is located in the bottom back of the analyser. It turns on or shuts down the analyser.

3.4.6 USB interface

The USB interface is located on the right side of the main unit. There are 4 interfaces in total for external equipment (printer, barcode scanner, mouse or keyboard, and so on) connection or data transmission.

3.4.7 Network interface

The network interface is located on the right side of the main unit. There is 1 network interface in total for connecting with the Ethernet.

3.4.8 External Equipment (Optional)

The analyser can be connected with the following external equipment:

- **Keyboard**
  The keyboard is connected with the USB interface on the right side of the analyser for controlling the analyser.

- **Mouse**
  The mouse is connected with the USB interface on the right side of the analyser for operations on the analyser.
- **Printer**
  The printer is connected with the USB interface on the right side of the analyser for printing reports and other information displayed on the screen.
- **Barcode Scanner**
  The barcode scanner is connected with the USB interface on the right side of the analyser for entering barcode information in an easy and fast way.
- **USB flash disk**
  The USB flash disk is connected with the USB interface on the right side of the analyser for exporting sample data.

3.5 User Interface

After the start-up procedure, you will enter the user interface. See Figure 3-4.



Figure 3-4 Default screen

3.5.1 Sample analysis screen

The interface can be divided into several areas as follows according to their functions:

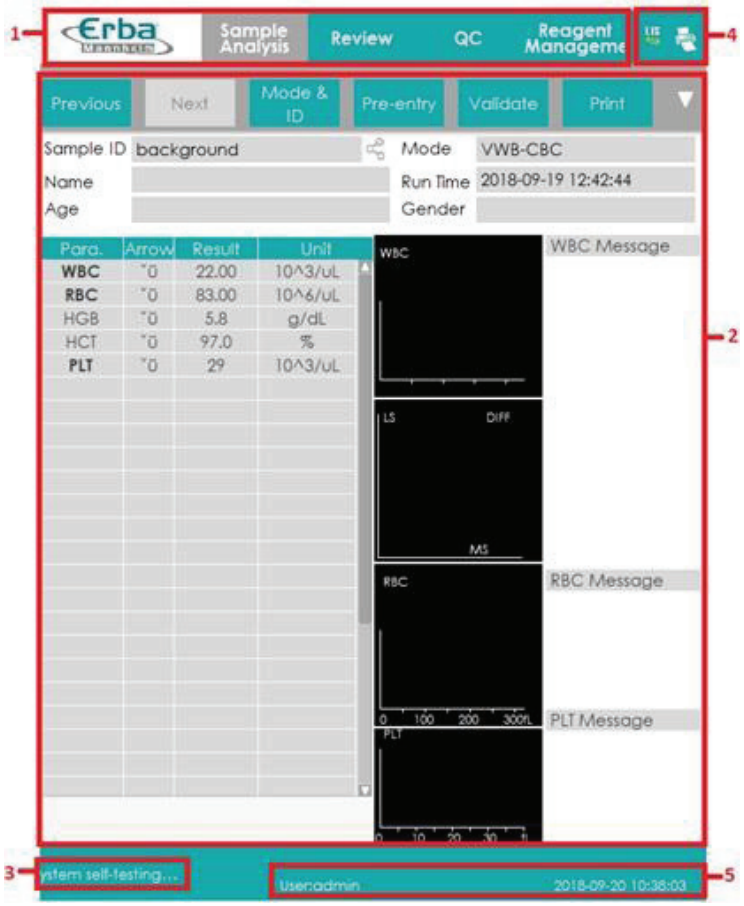


Figure 3-5 Sample analysis screen

1. Menu navigation area
   On the top of the screen is the menu navigation area. Once a menu button is pressed, the system goes immediately to the corresponding screen.
2. Menu content display area
   It displays the selected screen and the corresponding function buttons.
3. Error message area
   Upon the occurrence of a system failure, the corresponding error message will appear in this area. When there is more than one failure, the error message for the latest failure will appear in this area.
   Click in this area, you can deal with the failures in the popup dialog box of trouble-shooting help. For more information, see **13 Troubleshooting**.
4. Status display area
   On the top right of the screen is the status display area where the connection status between the analyser and the LIS system and printer status are displayed from left to right. The icons change with the status of the main unit, as shown in Table 3-3.

Table 3-3 Status Icon Description

Status	Icon	Remarks
LIS/HIS status	Grey icon	The computer is not connected to the LIS/HIS.
	Black icon	The computer is connected to the LIS/HIS.
Print status	Grey icon	The external printer is not connected to the analyser yet.
	Colour icon	The external printer is connected to the analyser.

5. Current user, date and time of the analyser.

3.6 Reagents

Because the analyser, reagents, controls, and calibrators are components of the system, system performance depends on the combined integrity of all the components. You should only use the Erba Lachema-specified reagents (see 15.2. **Reagents**), which are formulated specifically for the fluidic system of your analyser in order to achieve optimal system performance. Do not operate the analyser using reagents from multiple suppliers. Under such circumstances, the analyser may not achieve the performance specified in this manual and may generate unreliable results. All references to “reagents” in this manual refer to the reagents specifically formulated for this analyser. Each reagent package should be examined before use. Inspect the package for signs of leakage or moisture. If there is evidence of leakage or improper handling, do not use the reagent.

NOTE

After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
Store and use the reagents by following the instructions for use of the reagents.
When you have changed the diluents or lyses, run a background check 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.

3.6.1 Reagents

The following reagents are intended to be used with the analyser H360.

- **Erba H360 Dil**, cat. no. HEM00028
  Erba H360 Dil is an *in vitro* diagnostic reagent used for automated dilution of human blood for counting and sizing of blood cells on hematology analysers H360. It is designed to report on the hematological status of patient samples, supporting the monitoring and diagnosis of pathological conditions. The Erba H360 Dil should be used by trained professionals in the hematology laboratory and only with Erba Mannheim reagents.
- **Erba H360 Lyse**, cat.no. HEM00029
  Erba H360 Lyse is an *in vitro* diagnostic reagent used to lyse red blood cells for quantitative counting of white blood cells, 3-part differentiation of white blood cells and measuring of he-

moglobin in human blood on automated hematology analysers H360. It is designed to report on the hematological status of patient samples, supporting the monitoring and diagnosis of pathological conditions. The Erba H360 Lyse should be used by trained professionals in the hematology laboratory and only with Erba Mannheim reagents.

- **ELite H Clean**, cat.no. HEM00023
  ELite H Clean is an *in vitro* diagnostic solution used for cleaning, rinsing and washing of automated hematology analysers ELite 580, H560 and H360. The ELite H Clean should be used by trained professionals in the hematology laboratory and only with Erba Mannheim reagents.

3.6.2 Controls and Calibrator

The following controls and calibrator are used for quality control and calibration of H360.

- **Erba H3 CON L**, cat.no. HEM00033
- **Erba H3 CON N**, cat.no. HEM00034
- **Erba H3 CON H**, cat.no. HEM00035
  Erba H3 CON L/N/H is an *in vitro* diagnostic reagent used for control of the accuracy and precision of automated hematology analyser H360. Erba H3 CON L/N/H should be used by trained professionals in the hematology laboratory and only with Erba Mannheim reagents.
- **ELite H CAL**, cat.no. HEM00027
  ELite H CAL is an *in vitro* diagnostic reagent used for calibration of the parameters WBC, RBC, HGB, MCV and PLT on automated hematology analysers ELite 580, H560 and H360. Intended for screening, monitoring and diagnosis of risk various diseases according to the calibrated parameters. ELite H CAL should be used by trained professionals in the hematology laboratory and only with Erba Mannheim reagents.

4 Working Principle

4.1 Introduction

The measurement methods used in this analyser are: the electrical Impedance method for determining the RBC and PLT data; the colorimetric method for determining the HGB. During each analysis cycle, the sample is aspirated, diluted and mixed before the determination for each parameter is performed.

4.2 Aspiration

The analyser supports Whole Blood mode (including **Venous Whole Blood** and **Capillary Whole Blood**) and Predilute mode.
In Whole Blood mode, the analyser will aspirate 9µL of whole blood.
In Predilute mode, the analyser will aspirate the prediluted sample (with the dilution ratio of 1:10) which is a mixture of 20µL of whole blood/capillary blood sample and 180µL of diluent the diluted sample thus prepared is then delivered to the analyser for sampling and aspiration.

Probe cleaning – Auto probe wiper cleans the sample probe automatically after each sample aspiration externally and internally both.
Analyser performs duplicate counting for each WBC, RBC and PLT parameters to ensure precision without use of additional reagent.

4.3 Dilution

After being aspirated into the analyser, the sample is divided into two parts. After the reaction with reagents in parallel dilution procedures, each part forms the sample for red blood cell/platelet, white blood cell count/haemoglobin measurement.
To meet different needs, the analyser offers two working modes (Whole Blood and Predilute).

4.3.1 Dilution Procedure in Whole-blood Mode

Dilution Procedures in Whole-Blood Mode are shown in Figure 4-1.

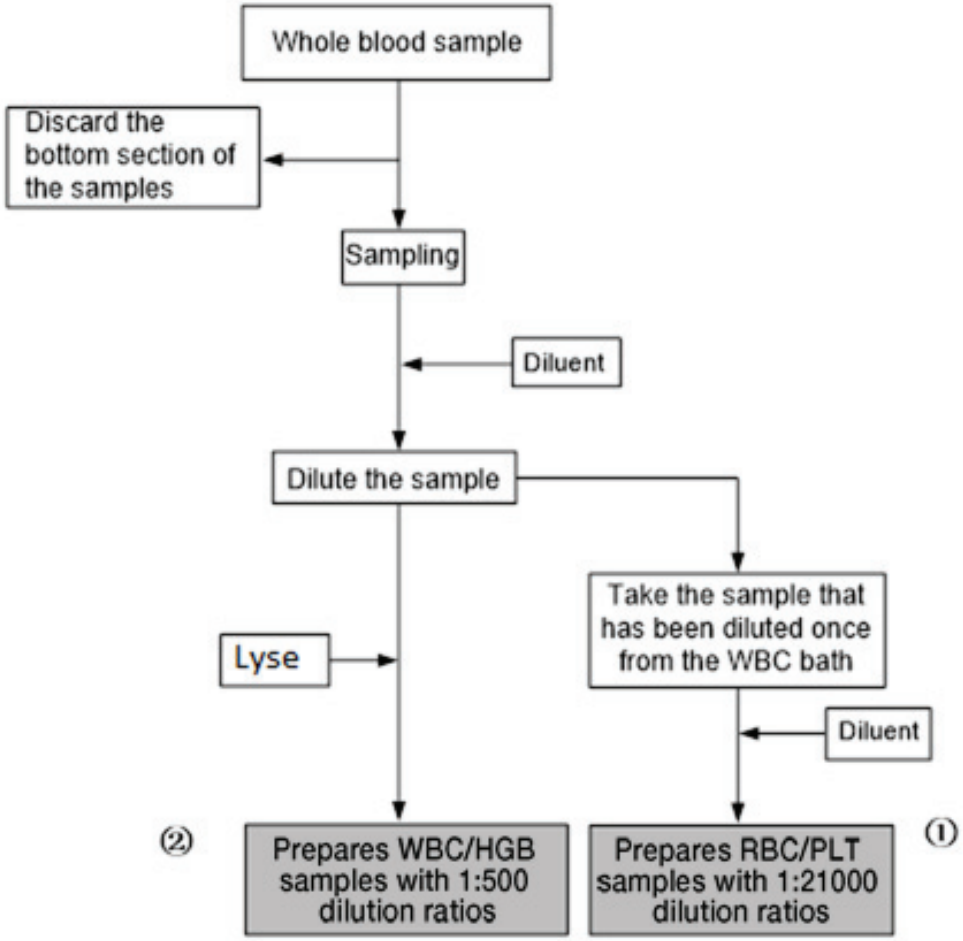


Figure 4-1 Dilution Procedure in Whole-blood CBC+DIFF Mode

Where,

1. is the dilution procedure for red blood cell and platelet
2. is the dilution procedure for white blood cell count/haemoglobin; namely CBC.

4.3.2 Dilution Procedure in Predilute Mode

The dilution procedure for the prediluted sample is shown in Figure 4-2.

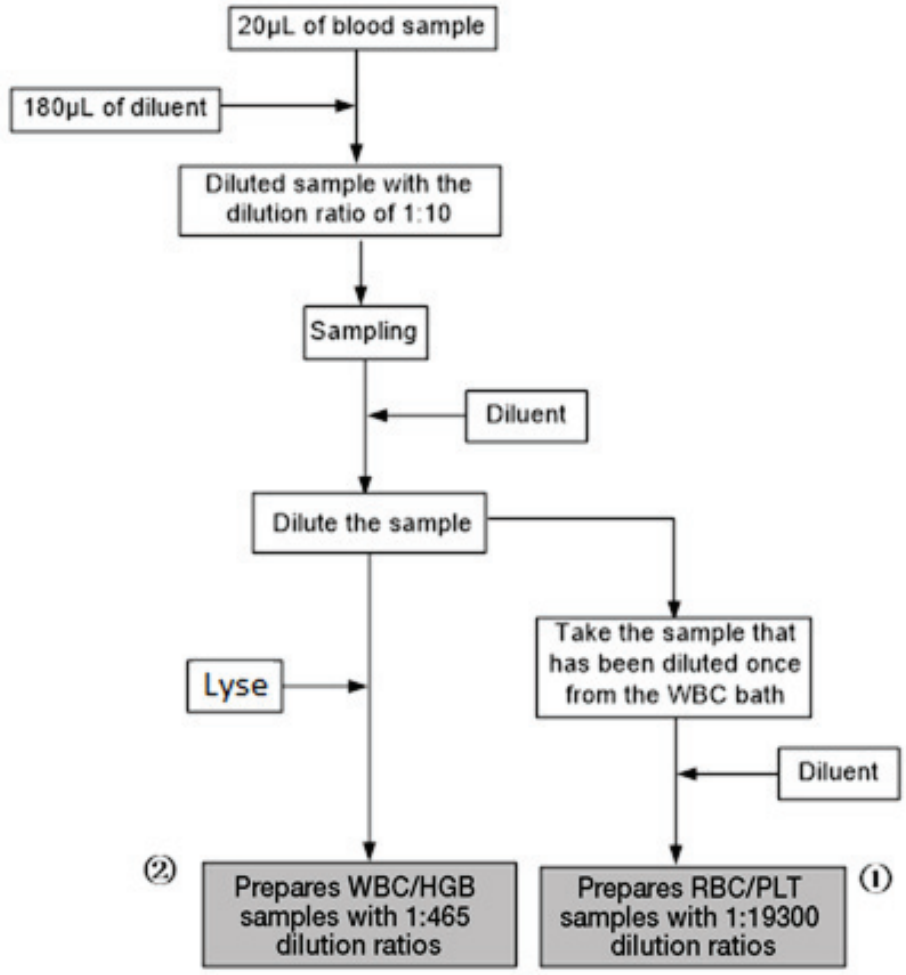


Figure 4-2 Dilution Procedure in Predilute CBC+DIFF Mode

Where,

1. is the dilution procedure for red blood cell and platelet;
2. is the dilution procedure for white blood cell count/haemoglobin; namely CBC.

4.4 WBC/RBC/PLT Measurement

The analyser detects the white blood cell count, red blood cell count and platelet count and their volume distribution by impedance method and eventually obtains the results of related parameters.

4.4.1 Electrical Impedance Method

WBCs/RBCs/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. 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 particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

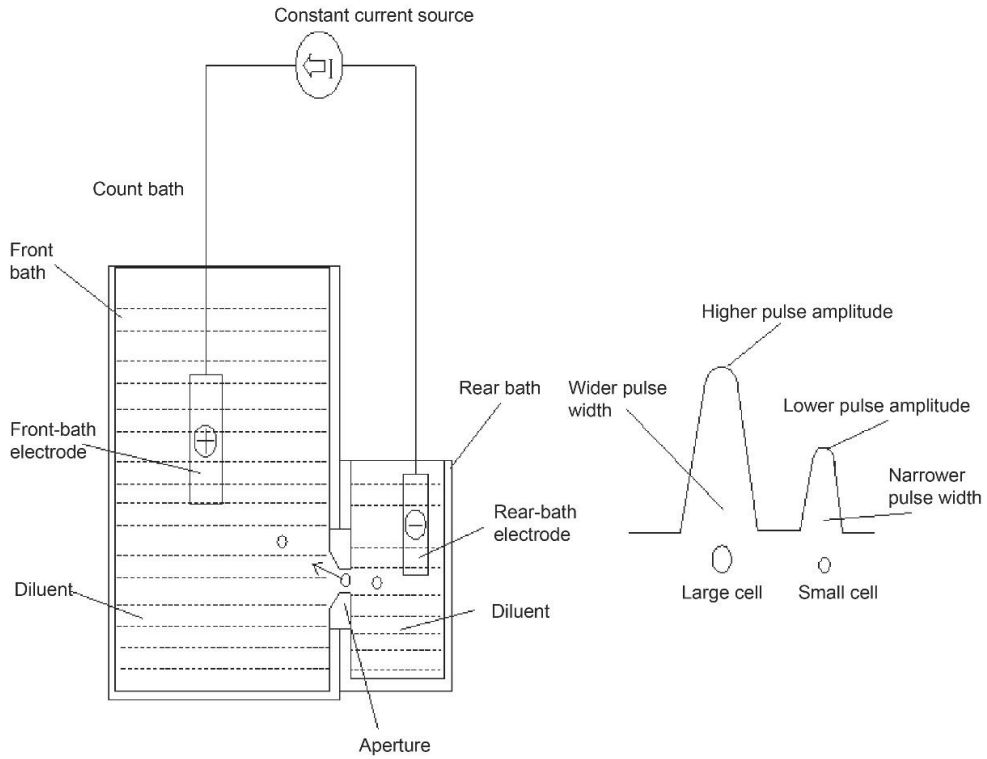


Figure 4-3 Electrical Impedance method

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 above the 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.
The analyser presents the WBC/RBC/PLT histogram, where the x-coordinate represents the cell volume (fL) and the y-coordinate represents the number of the cells.

4.4.2 Derivation of WBC-Related Parameters

White blood cells have a variety of types and can be categorized according to their volume. The volume of each type of cells varies with the added diluent, lyse and the lysing time. With the action of reagents, white blood cells can be classified into three groups, in the order from small volume to large volume: Lymphocytes, Mid-sized Cells (including Monocytes, Eosinophils and Basophils) and Granulocyte.Based on the white blood cell histogram and the analysis for the Lym zone, Mid zone and Gran zone, the analyser can get the percentage of lymphocytes (Lym%), the percentage of mid-sized cells (Mid%) and the percentage of granulocytes (Gran%), and then get the number of lymphocytes (Lym#), the number of mid-sized cells (Mid#) and the number of granulocytes (Gran#) based on the calculation with the white blood cell count obtained with the electrical impedance method. The unit of the number of cells is $10^3/\mu L$.

- White Blood Cell count
  WBC count is the number of leukocytes measured directly by counting the leukocytes passing through the aperture.
- Percentage of Lymphocytes (Lym%)
  $$\text{Lym\%} = \frac{\text{Particle count in the } \textit{Lym} \text{ zone}}{\text{Sum of particle count in the } \textit{Lym} \text{ zone, } \textit{Mid} \text{ zone and } \textit{Gran} \text{ zone}} \times 100\%$$
- Percentage of Mid-sized Cells
  $$\text{Mid\%} = \frac{\text{Particle count in the } \textit{Mid} \text{ zone}}{\text{Sum of particle count in the } \textit{Lym} \text{ zone, } \textit{Mid} \text{ zone and } \textit{Gran} \text{ zone}} \times 100\%$$
- Percentage of Granulocytes (Gran%)
  $$\text{Gran\%} = \frac{\text{Particle count in the } \textit{Gran} \text{ zone}}{\text{Sum of particle count in the } \textit{Lym} \text{ zone, } \textit{Mid} \text{ zone and } \textit{Gran} \text{ zone}} \times 100\%$$
- Number of lymphocytes (Lym#)
  $\text{Lym\#} = \text{WBC} \times \text{Lym\%}$
- Number of Mid-sized Cells
  $\text{Mid\#} = \text{WBC} \times \text{Mid\%}$
- Number of Granulocytes (Gran#)
  $\text{Gran\#} = \text{WBC} \times \text{Gran\%}$

4.4.3 RBC

- Red Blood Cell count
  RBC (10^6/µL) is the number of erythrocytes measured directly by counting the erythrocytes passing through the aperture.
- Mean Corpuscular Volume
  Based on the RBC histogram, this analyser calculates the mean corpuscular volume (MCV) and expresses the result in fL.
- Haematocrit (HCT), Mean Corpuscular Haemoglobin (MCH), Mean Corpuscular Haemoglobin Concentration (MCHC)
  This analyser calculates the HCT (%), MCH (pg) and MCHC (g/dL) as follows, where the RBC is expressed in 10^6/µL, MCV in fL and HGB in g/dL.
  $$\text{HCT} = \frac{\text{RBC} \times \text{MCV}}{10}$$
  $$\text{MCH} = \frac{\text{HGB}}{\text{RBC}}$$
  $$\text{MCHC} = \frac{\text{HGB}}{\text{HCT}} \times 100$$
- Red Blood Cell Distribution Width Coefficient of Variation (RDW-CV)
  Based on the RBC histogram, this analyser calculates the CV (Coefficient of Variation, %) of the erythrocyte distribution width.
- Red Blood Cell Distribution Width Standard Deviation (RDW-SD)
  RDW-SD (RBC Distribution Width – Standard Deviation, fL) is obtained by calculating the standard deviation of the red blood cell size distribution.

4.4.4 PLT

- Platelet count (PLT count, $10^3/\mu L$)
  PLT is measured directly by counting the platelets passing through the aperture.
- Mean Platelet Volume (MPV, fL)
  Based on the PLT histogram, this analyser calculates the MPV.
- Platelet Distribution Width Coefficient of Variation (PDW-CV)
  Based on the PLT histogram, this analyser calculates the CV (Coefficient of Variation, %) of the platelet distribution width.
- Platelet Distribution Width Standard Deviation (PDW-SD)
  PDW-SD is the geometric standard deviation (GSD) of the platelet size distribution. Each PDW-SD result is derived from the platelet histogram data and is reported as 10(GSD).
- Plateletcrit (PCT)
  This analyser calculates the PCT as follows and expresses it in %, where the PLT is expressed in $10^3/\mu L$ and the MPV in fL.

  $$PCT = \frac{PLT \times MPV}{10000}$$
- Platelet-Large Cell Count (P-LCC, $10^3/\mu L$)
  P-LCC is measured directly by counting the large platelets passing through the aperture.
- Platelet-Large Cell Ratio (P-LCR)

  $$P-LCR = \frac{P-LCC}{PLT} \times 100\%$$

4.4.5 Floating threshold

An automatic floating threshold for the correct separation of RBC's and PLT's during overlap in cases of Microcytic / large platelet.
The normal PLT goes at 2 to 30 fL, mainly at 2 to 15 fL and the floating threshold of large PLT is at 12 fL. PLT histogram has dividing line. If the size is more than 35 fL, then it will be considered as micro erythrocytes. Therefore, prevent recalculating the micro erythrocytes in PLT.

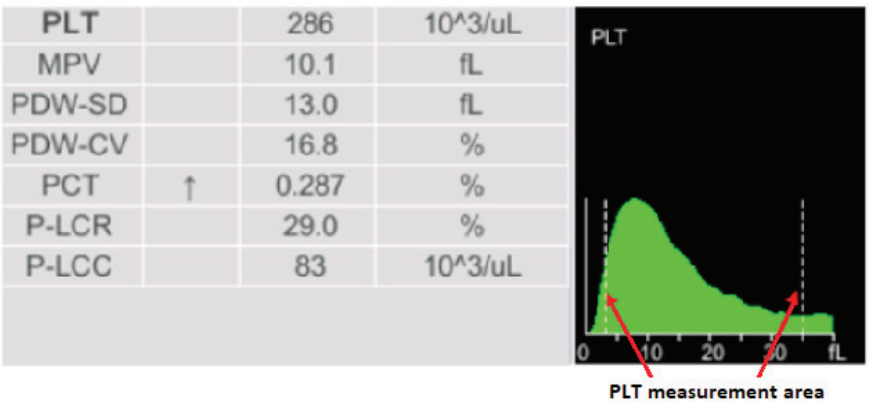


Figure 4-4 Tresholds for PLT

4.5 HGB Measurement

HGB is determined by the colorimetric method.

4.5.1 Colorimetric Method

The WBC/HGB diluent is delivered to the HGB bath where it is mixed with a certain amount of lyse, which converts haemoglobin to a haemoglobin complex that is measurable at 525 nm. 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 and is 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).

4.5.2 HGB

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

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

4.6 Flushing

After each analysis cycle, each component of the analyser is flushed.

5 Setup

5.1 Introduction

The analyser has been initialized before delivery. The interfaces upon the initial start-up of the analyser are system settings by default. Some parameters of the analyser can be reset to meet various demands in practical applications.
The analyser divides the operators into two access levels, common user and administrator. Note that an administrator can access all the functions accessible to a common user. This chapter introduces how to customize your analyser as an administrator.

5.2 Interface Introduction

After logging in the system (see **6.3 Start-up**), click **Setup** to access the **Setup** interface. See Figure 5-1.

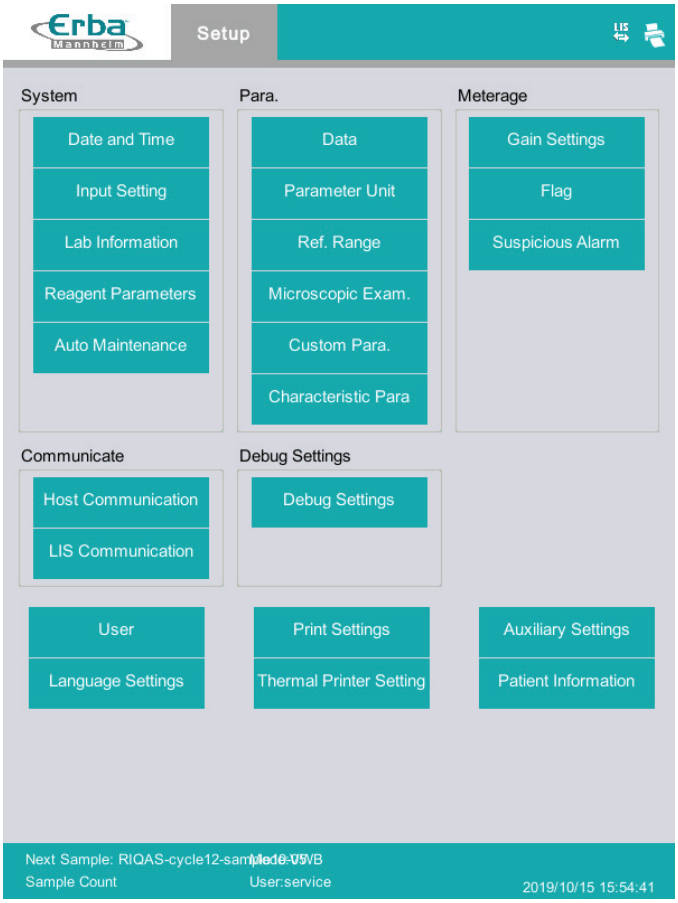


Figure 5-1 Setup

The administrator is allowed to set the following functions in the **Setup** interface:

- System settings
- Parameter settings
- Meterage settings
- LIS communication
- User management
- Print settings
- Auxiliary settings

5.3 System Settings

5.3.1 Date and Time

You can set the current date and time, as well as the date display format in the analyser system. Specific steps are shown below:

- Click **Date and Time** in the **System** area.

The date and time format setting interface pops up.

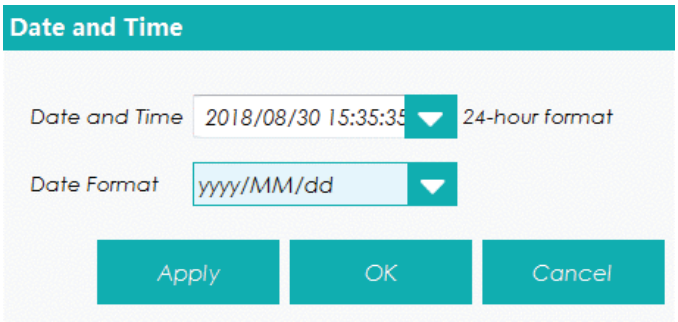


Figure 5-2 Setup of the date and time

- Click the Date and Time dropdown list and set the current date and time of the system in the popup dialog box.

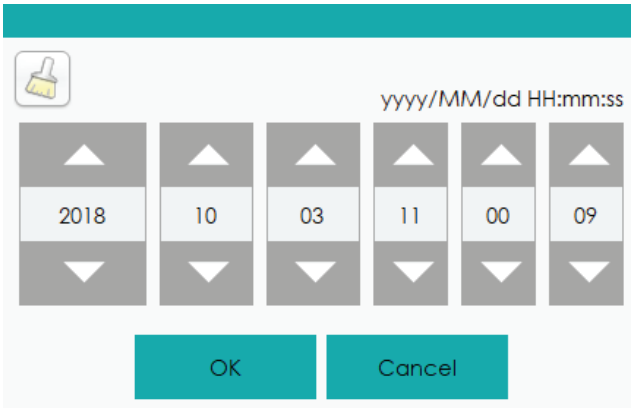


Figure 5-3 Setup of the date and time

Related descriptions:
The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm:ss**, you should input the data in the sequence of year, month, date, hour, minute, and second.
Click or to select a date and time or enter the information in the textbox directly.
Click to clear the current data and re-enter the information.

- Click **OK** to save and close the message box.
- Select the format setting from the dropdown list of the **Date Format**.

See Figure 5-4.

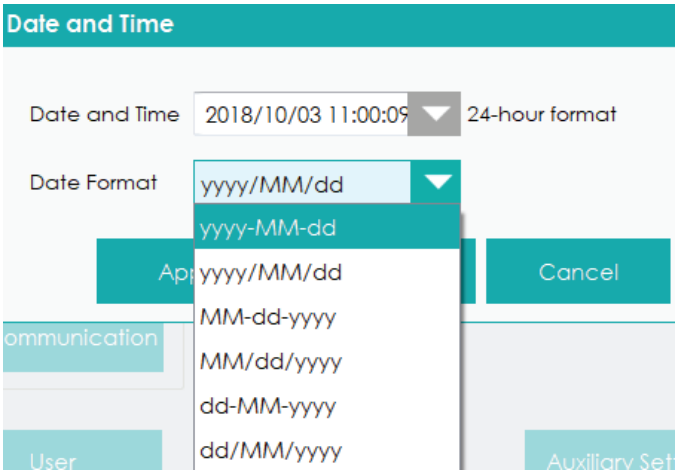


Figure 5-4 Setting the Date Format

- Click **Apply**.

The system message will pop up, indicating the successful setting. See Figure 5-5.

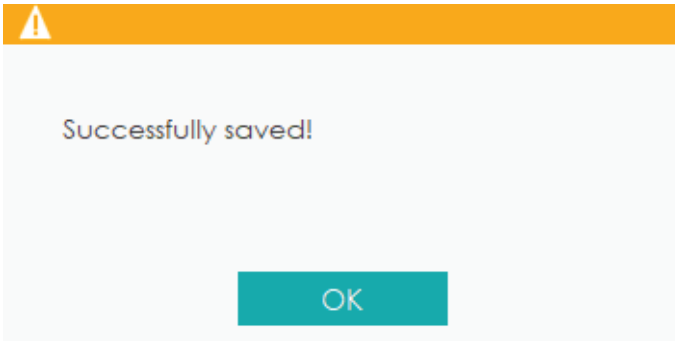


Figure 5-5 Successful Setting of the Date Format

The date and time at the bottom right corner will be displayed in the newly set format.

- Click **OK** to close the message box.
- Click **OK** to exit.

5.3.2 Input Settings

Click **Input Setting** in the **System** area, and then you can set the soft keyboard for screen input. As shown in Figure 5-6, you can set to turn the soft keyboard on or off.

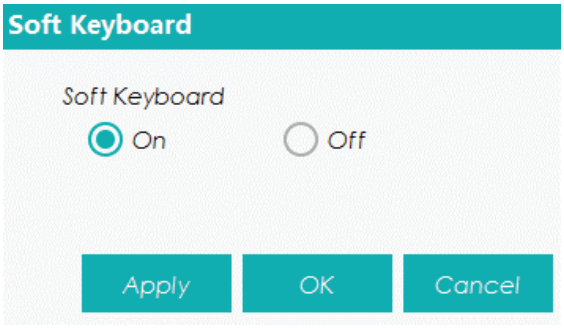


Figure 5-6 Input Settings

- Soft Keyboard

On (default)

You can enter content using the soft keyboard popped up on the screen. Functions and applications for the keys are shown in Figure 5-7.



Figure 5-7 Soft Keyboard

Off

You need to use an externally connected USB keyboard for entering content.

5.3.3 Lab Information

Click **Lab Information** in the **System** selection, then you can set the lab information. See Figure 5-8.

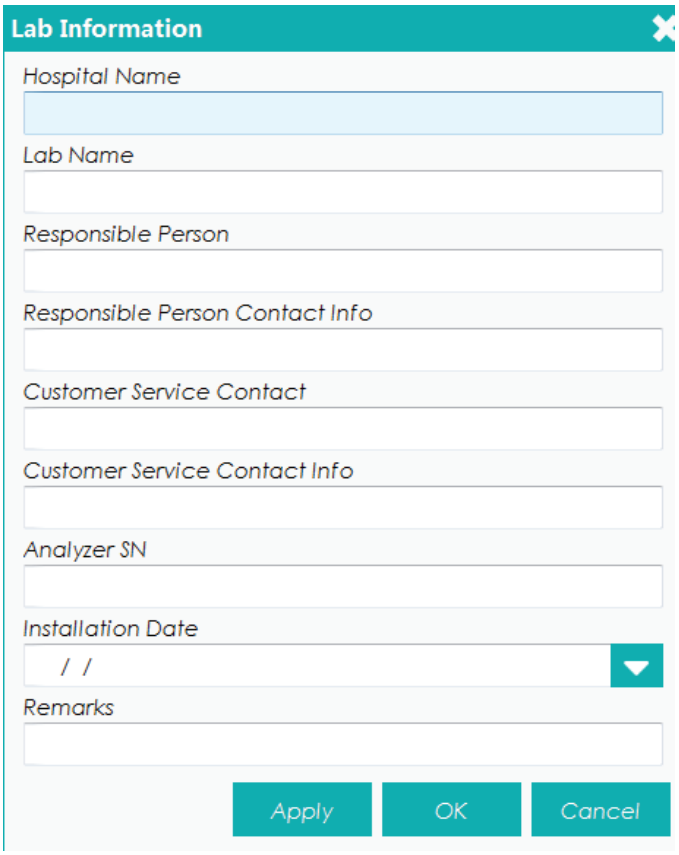


Figure 5-8 Setting Lab Information

NOTE Only the administrator has the access for setting the lab information. General users are only allowed to browse such information.

Refer to Table 5-1 for the detailed instructions of parameter setting.

Table 5-1 Setting Lab Information

Parameter	Setting Description
Hospital Name	Enter the name of the hospital where the lab is located.
Lab Name	Enter the lab name.
Responsible Person	Enter the responsible person of the lab.
Contact Information	Enter the contact information (telephone number or E-Mail) of the lab.
Contact in Service Department	Enter the name of the contact person in Service Department.
Contact Information of Service Department	Enter the contact information of the contact person in the Service Department.
Analyser SN	Display the serial number of the analyser. Read only.
Installation Date	Display the installation date of the analyser. Read only.
Remarks	Enter the remarks regarding the lab.

5.3.4 Auto Maintenance

Click **Auto Maintenance** in the **System** selection to access the **Auto Maintenance** setting interface. The system auto sleep waiting time and cleanser maintenance time can be set in the **Auto Maintenance** interface.

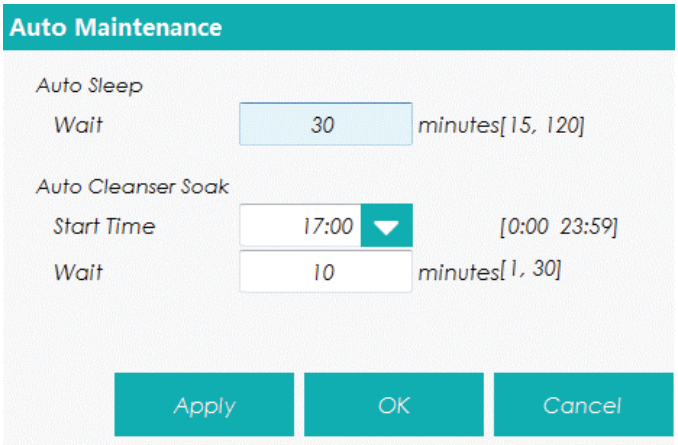


Figure 5-9 Auto Maintenance

Auto Sleep

In the **Wait** textbox, the administrators can set the waiting time for entering the sleep state after the main unit is halted. The range is between 15 and 120 minutes and the default value is 120 minutes.

Auto Cleanser Soak

The administrator is allowed to set the start time of the cleanser soak in the **Start Time** textbox. The acceptable value ranges from 0:00 to 23:59 and the default value is **17:00**.

In the **Wait** text box, the administrators can set the time interval to remind the user to perform the cleanser soak. When the system reminds the user to perform cleanser, if the user cancels the operation, the system will remind again after the set waiting time. The range is between 1 and 30 minutes and the default value is **10** minutes.

5.4 Parameter Settings

5.4.1 Data Dictionary

You can set shortcut codes for the relevant items of the patient information.

If a shortcut code is set, the shortcut code corresponding to the above mentioned item can be entered directly when the information is input or numbered, then the complete information can be displayed without entering (or selecting) complete information. It is a shortcut operation. Different items can share one shortcut code.

5.4.1.1 Accessing the interface

Click **Data** in the **Para**. selection to access the data dictionary setting interface. See Figure 5-10. You can set the shortcut code for the relevant items of the patient information in this interface.

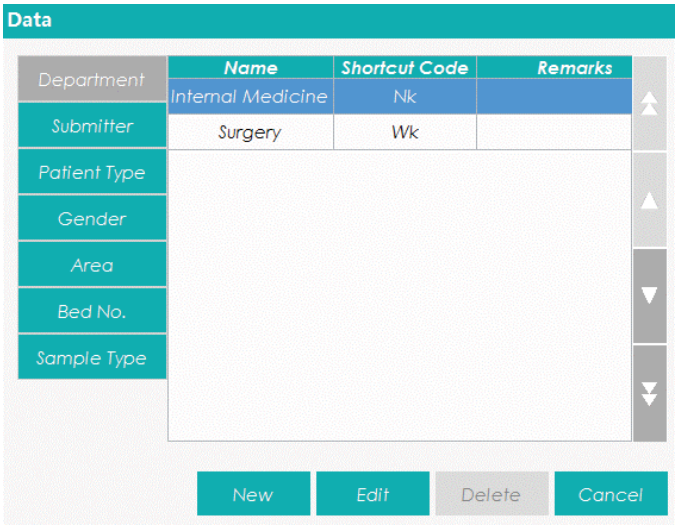


Figure 5-10 Shortcut Code

You can set the shortcut code for the following items: **Department**, **Submitter**, **Patient Type**, **Gender**, **Area**, **Bed No.** and **Sample Type**.

5.4.1.2 Adding a New Item

This section takes the adding of a new department as an example to introduce the method for adding a new item and its shortcut code. The method for adding other new items is similar and is not introduced in details herein.

Steps for adding a new department are shown as follows:

1. Click New in the Department interface.
   A dialog box will pop up as shown in Figure 5-11.

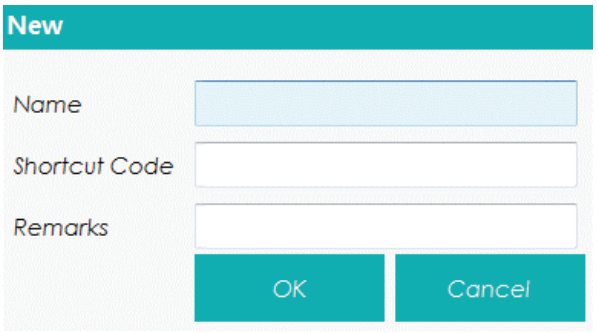


Figure 5-11 Adding a New Item

2. Enter a new department name, shortcut code and remarks.

NOTE

Newly added department name must be entered and it cannot be the same as existing ones.

The shortcut code is not necessary to be entered, but once set, every code must be unique.

3. Click **OK** to save the information about the new department.
   Information about the newly added department will be displayed in the department interface.

5.4.1.3 Editing Items/Shortcut Code

This section takes the editing of a department as an example to introduce the method for editing items and its shortcut code. The method for editing other new items is similar and is not introduced in details herein.

Steps for editing a department are shown as follows:

1. Select the department to be modified in the **Department** interface (for example the Internal Medicine), then click **Edit**.
2. Modify the **Name**, **Shortcut Code** and **Remarks** in each textbox according to the actual demand.

NOTE

Newly added department name must be entered and it cannot be the same as existing ones.

The shortcut code is not necessary to be entered, but once set, every code must be unique.

3. Click **OK** to save the information.
4.

5.4.1.4 Deleting a Shortcut Code

This section takes the deleting of a department as an example to introduce the method for deleting items and its shortcut code. The method for deleting other new items is similar and is not introduced in details herein.

Steps for deleting a department are shown as follows:

1. Select the department to be deleted in the **Department** interface, and then click **Delete**.
2. Click **Yes** to delete the department.

5.4.2 Parameter Unit

Some of the parameters of the analyser can use different units which can be chosen as per user demand.

5.4.2.1 Accessing the Interface

Click Parameter Unit in the Para. selection to access the Parameter Unit setting interface. See Figure 5-12.

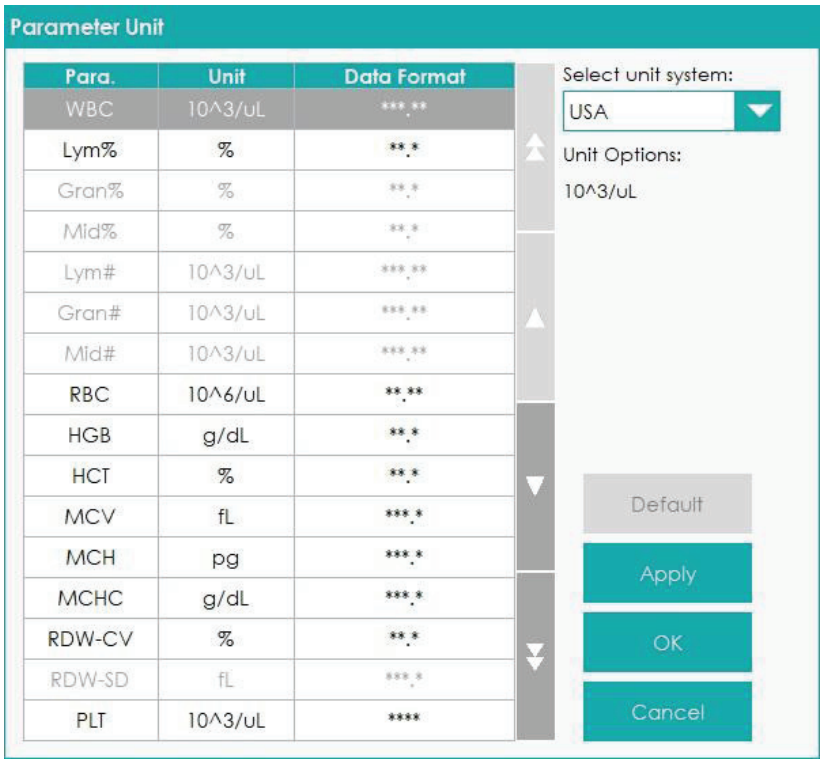


Figure 5-12 Setting Parameter Unit

5.4.2.2 Selecting Unit System

Click the **Select unit system** dropdown list and select a unit system for the parameters among the 6 unit systems (**Custom**, **International**, **Britain**, **Canada**, **USA** and **Netherlands**). The default unit system is **USA**.

NOTE

When selecting different unit standards, the corresponding unit list and unit option will be displayed differently.
If another option is selected except the Custom, then the unit of each parameter can only be browsed.

5.4.2.3 Customizing Parameter Unit

1. Select **Custom** from the dropdown list of **Select unit system**.
2. Click the parameter, of which the unit is to be set, from the parameter list (such as WBC).
3. Select a new parameter unit from the **Unit Options** list.
4. Click **Apply** or **OK** to save the configuration.

NOTE

For parameters in the same group, if the unit of any parameter changes, the units of the other parameters change accordingly. (In the list, parameters will be sorted by group; the first parameter will be displayed in black and the other parameters in the same group will be displayed in grey.)
If the parameters units change, the display format of the list data will change accordingly.

5.4.2.4 Retrieving Defaults

When setting the **Custom** unit system, if you click **Default**, the unit of the parameters can be restored to the initial default values.

5.4.3 Reference Range

It is recommended that each laboratory establish its own expected reference intervals based upon the laboratory's patient population. The CLSI document* C28-A2 contains guidelines for determining reference intervals and intervals for quantitative laboratory tests. If the analysis result of a sample is beyond the reference range, it will be regarded as clinically abnormal. The **Ref. Range** interface is where you view and set the high and low limits for your patients. The analyser flags any parameter value above ▲ or below ▼ these limits.
This analyser divides the patients into 5 demographic groups: General, Man, Woman, Child and Neonate. You can also customize other groups. The recommended limits are for reference only. To avoid misleading parameter flags, be sure to set the patient limits according to the characteristics of local population.

** How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline - Second Edition, CLSI document C28-A2, (ISBN P56238-269-I), CLSI (Clinical and Laboratory Standards Institute), 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 2000.*

Table 5-2 Preset reference intervals of General reference group

Parameter	Lower Limit	Upper Limit	Unit
WBC	3.50	9.50	10^9/L
Lym%	20.0	50.0	%
Gran%	50.0	70.0	%
Mid%	3.0	9.0	%
Lym#	1.10	3.20	10^9/L
Gran#	2.00	7.00	10^9/L
Mid#	0.10	0.90	10^9/L
RBC	3.80	5.80	10^{12}/L
HGB	115	175	g/L
HCT	35.0	50.0	%
MCV	82.0	100.0	fL
MCH	27.0	34.0	pg

Parameter	Lower Limit	Upper Limit	Unit
MCHC	316	354	g/L
RDW-CV	11.5	14.0	%
RDW-SD	35.0	56.0	fL
PLT	125	350	10^9/L
MPV	6.5	12.0	fL
PDW-CV	10.0	17.9	%
PDW-SD	9.0	17.0	fL
PCT	0.108	0.282	%
P-LCC	30	90	10^9/L
P-LCR	11.0	45.0	%

5.4.3.1 Accessing the Interface

Click **Ref. Group** in the **Para**. selection to access the reference group settings interface. See Figure 5-13.

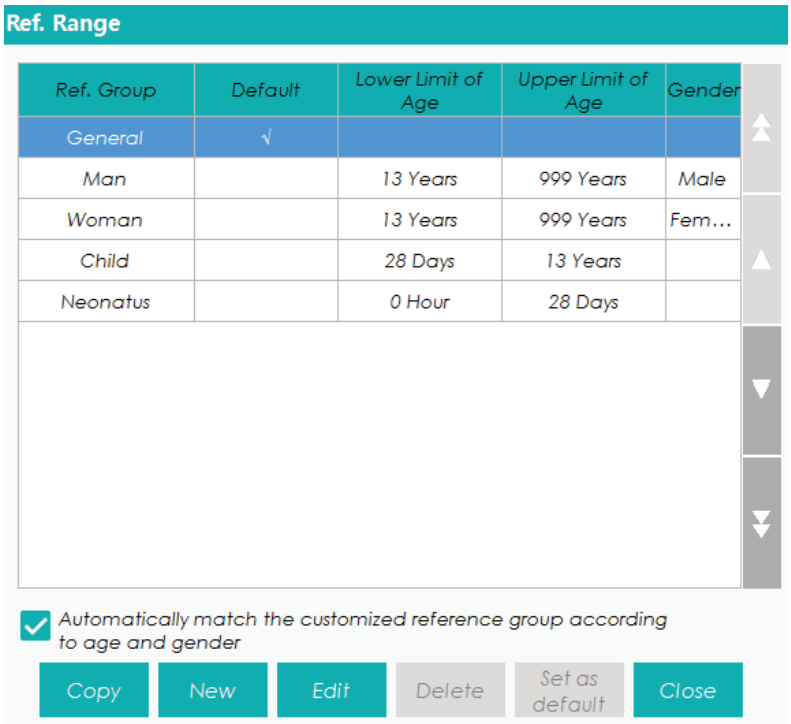


Figure 5-13 Ref. Range

5.4.3.2 Copying a Ref. Group

Select a reference group and click **Copy**, and a new reference group with everything the same except the name of the reference group will be added to the system and a screen as shown in Figure 5-14 will pop up.



Figure 5-14 Copying a Ref. Group

You can edit the new reference group. Save and close the screen, and then the copied reference group will be shown in the reference group list.

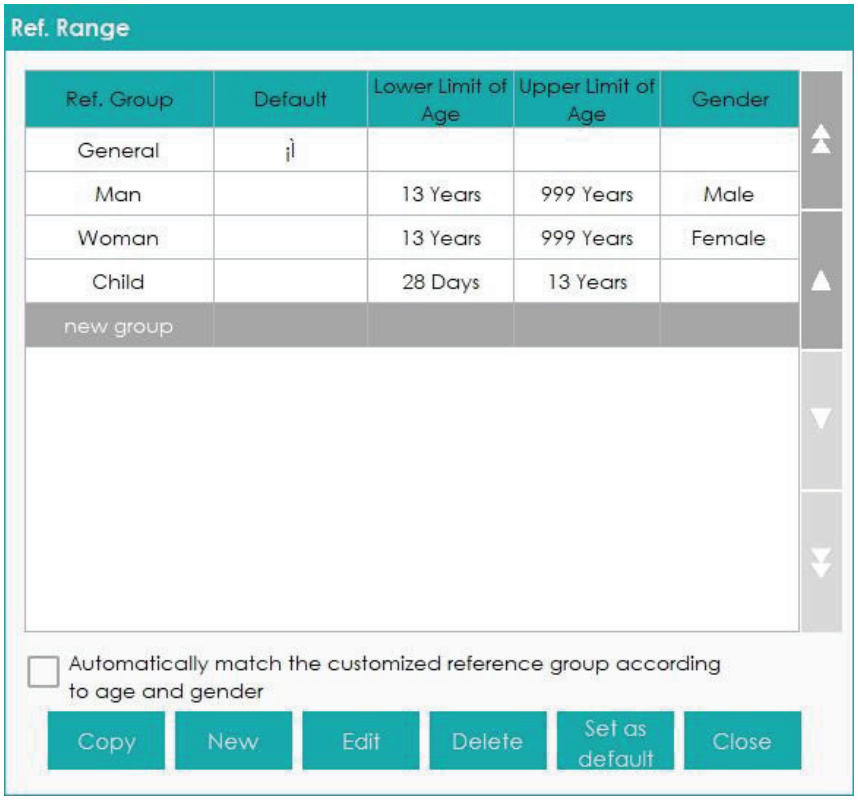


Figure 5-15 New reference group in the list

NOTE The reference group name entered is not allowed to be empty nor the same as the existing ones.

5.4.3.3 Adding a New Ref. Group

If the built-in reference groups cannot meet the actual demand, you can add new ones and manually enter the information such as reference ranges for each parameter, names and genders. The procedures are shown as below:

1. Click **New**, and a screen for adding a new reference group will pop up. See Figure 5-16.



Figure 5-16 Adding a New Ref. Group

2. Complete the entries for each parameter with reference to the parameter description in Table 5-3.

Table 5-3 Description of Ref. Group parameters

Parameter	Meanings	Operation
Ref. Group	Name of the new reference group.	Click the edit box and enter the information using the soft keyboard. English characters and numbers are allowed to be entered, while special characters are not. **NOTE** The reference group name entered is not allowed to be empty nor the same as the existing ones.
Lower Limit of Age	Lower limit of age of the reference group.	Enter an integer value in the textbox and select the age unit (**year**, **month**, **week**, **day**, or **hour**) from the drop list on the right. **NOTE** The **Lower Limit of Age** must be smaller than the **Upper Limit of Age**.
Upper Limit of Age	Upper limit of age of the reference group.	Enter an integer value in the textbox and select the age unit (**year**, **month**, **week**, **day**, or **hour**) from the drop list on the right. **NOTE** The **Upper Limit of Age** must be greater than the **Lower Limit of Age**.
Gender	Gender of the reference group.	Select **Man**, **Woman**, **Not defined** from the dropdown list. The default setting is empty.
Lower Limit (of parameter)	Lower limit of parameters of the reference group. If the test result is lower than this value, it would be regarded as clinically abnormal.	Click the **Lower Limit** cell which corresponds to the parameter and enter a new value. **NOTE** The **Lower Limit** must be smaller than the **Upper Limit**.
Upper Limit (of parameter)	Upper limit of parameters of the reference group. If the test result is higher than this value, it would be regarded as clinically abnormal.	Click the Lower Limit cell which corresponds to the parameter and enter a new value. **NOTE** The **Upper Limit** must be greater than the **Lower Limit**.

3. Click **Save** to save the settings.
4. Click **Close** to exit the interface.

5.4.3.4 Editing a Ref. Group

You can modify the reference range of the parameters according to actual needs and set suitable reference intervals (age range, gender, etc.).

The procedures are shown as below:

1. Select the reference group to be set, and click **Edit** to enter the interface as shown in Figure 5-17.



Para.	Lower Limit	Upper Limit	Unit	Para.	Lower Limit	Upper Limit	Unit
WBC	3.50	9.50	10^3/uL	**RBC**	3.80	5.80	10^6/uL
Lym%	20.0	50.0	%	HGB	11.5	17.5	g/dL
Gran%	50.0	70.0	%	HCT	35.0	50.0	%
Mid%	3.0	9.0	%	MCV	82.0	100.0	fL
Lym#	1.10	3.20	10^3/uL	MCH	27.0	34.0	pg
Gran#	2.00	7.00	10^3/uL	MCHC	31.6	35.4	g/dL
Mid#	0.10	0.90	10^3/uL	RDW-CV	11.5	14.5	%
				RDW-SD	35.0	56.0	fL
				PLT	125	350	10^3/uL
				MPV	7.0	11.0	fL
				PDW-SD	9.0	17.0	fL
				PDW-CV	10.0	17.9	%
				PCT	0.108	0.282	%
				P-LCR	11.0	45.0	%
				P-LCC	30	90	10^3/uL

Figure 5-17 Editing a Ref. Group

2. Refer to Table 5-3 for the description of the parameters to finish the editing.

NOTE

For the built-in reference group, you can modify the upper limit and lower limit of the parameters, but not its name, the upper limit and lower limit of age as well as gender.
Click Set as default to restore the setting of the selected reference group to the default value.
Non-built-in reference group (which is added by user) cannot restore defaults.

3. Click **Save** to save the modification.
4. Click **Close** to exit.

5.4.3.5 Deleting a Ref. Group

Click **Delete**, and select **Yes** in the pop-up dialog box to delete the selected customized reference group.

NOTE Built-in reference group cannot be deleted.

5.4.3.6 Setting Default Ref. Group

When you pre-enter patient information in the **Sample Analysis** interface, the **Ref. Group** displayed by default is the default reference group.

The default setting is **General**. You can change it as required. Select a reference group and click **Set as default** to set the selected reference group as the default reference group.

As shown in Figure 5-18, the reference group with a check mark in its **Default** column is a default reference group.

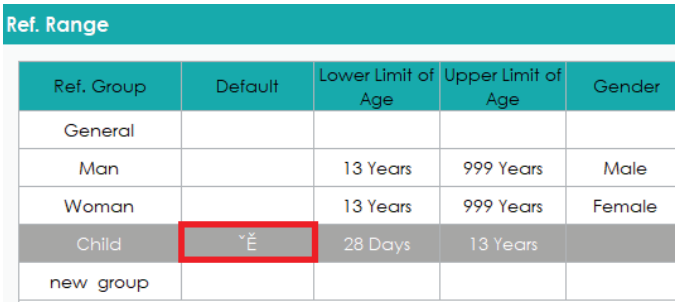


Figure 5-18 Setting Default Ref. Group

5.4.3.7 Automatically Match the Customized Reference Group According to Age and Gender

If **Automatically match the customized reference group according to age and gender** is checked, the customized reference group will be automatically assigned patients by the system according to their age and gender when the patient information is entered. If it fails to find a matching customized reference group for a patient, the patient will be assigned to the built-in reference group. When the system automatically matches the reference group according to age and gender, the rules listed in Table 5-4 shall be followed.

Table 5-4 Rules for Matching the Reference Group

Automatically match the customized reference group according to age and gender	Customized Ref. Group	Match the reference group
Unchecked	N/A	Built-in reference group
Checked	None	Built-in reference group
Checked	Created	Preferentially match the customized reference group

NOTE When the customized ref. groups are used to match the reference group, the matching will be performed from top down according to the customized ref. groups displayed in the screen.

5.4.4 Microscopic Exam. Settings

You can perform the microscopic exam. settings, including adding, editing, deleting and adjusting the list order as per the actual demand.

NOTE The operations of adding, editing, deleting and adjusting the list order do not affect the sample record in which the microscopic examination results have been entered and saved. Such operations are only valid for the record in which the microscopic examination results have not been saved, and the samples analysed after the setting operations.

5.4.4.1 Accessing the Interface

Click **Microscopic Exam.** in the **Para**. selection to access the microscopic examination setting interface. See Figure 5-19.

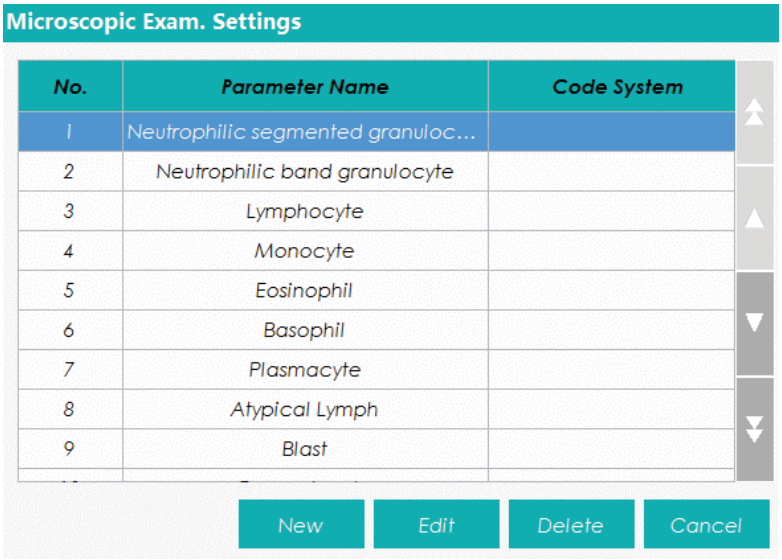


Figure 5-19 Microscopic Exam. Settings

5.4.4.2 Adding a New Microscopic Exam. Parameter

Do as follows to add a new microscopic examination parameter.

1. Click New in the Microscopic Exam. Settings interface.
   A dialog box will pop up as shown in Figure 5-20.

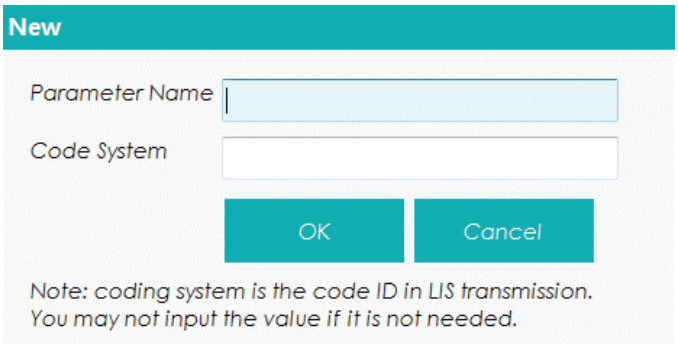


Figure 5-20 Adding a New Microscopic Exam. Parameter

2. Input the parameter name and its coding system in the corresponding textboxes.
   - The **Parameter Name** cannot be empty and up to 32 characters can be entered.
   - The **Code System** is the code ID of the parameter. It is used for LIS transmission only when the parameter is transmitted to the LIS. You may not input the value if it is not needed. Up to 20 characters can be entered.

3. Click **OK**.
   The name of the new parameter will be displayed in the microscopic exam. parameter list.

5.4.4.3 Editing a Microscopic Exam. Parameter

Select a parameter name from the list and click **Edit** to modify it. See Figure 5-21.

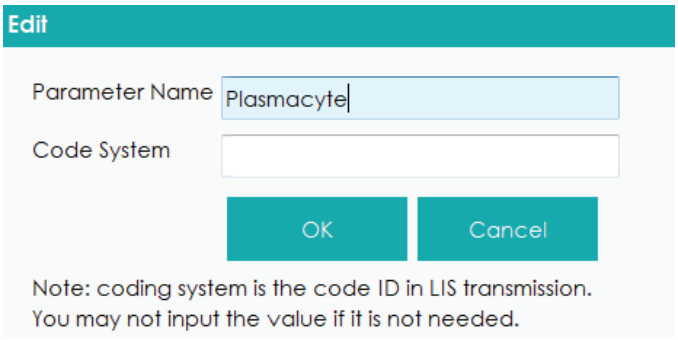


Figure 5-21 Editing a Microscopic Exam. Parameter

5.4.4.4 Deleting a Microscopic Exam. Parameter

Select a parameter name from the list, click the **Delete** button and then click **Yes** in the popup dialog box to delete this parameter.

5.4.4.5 Adjusting Parameter Order

Click **Adjust Order** to move the selected parameter to the top/bottom or move it upwards/downwards on the popup screen. Click **Restore Default**, and the parameter order will be restored to the default order. See Figure 5-22.

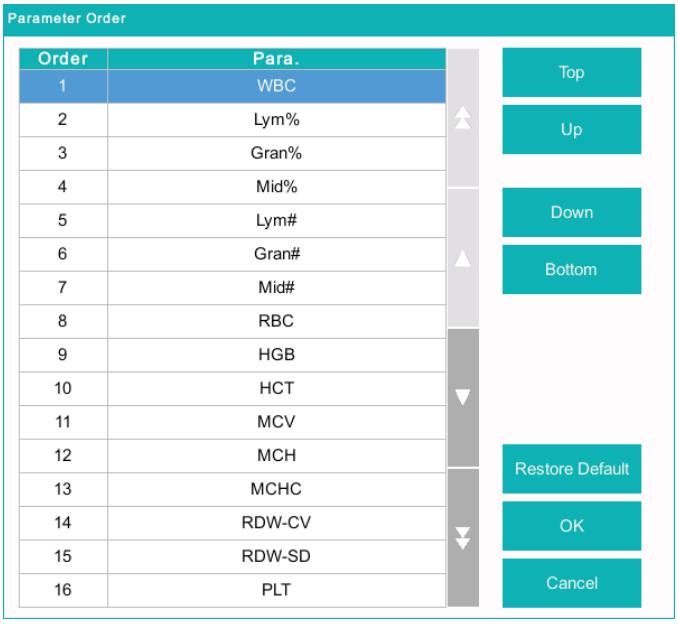


Figure 5-22 Parameter Order

5.4.5 Customized Parameters

Except for this analyser's analysis parameters, parameters collected from other testing instruments or via manual testing by the user are customized parameters. You can set customized parameters

so they can be printed together with this analyser's analysis parameter details on the Haematology Analysis Report.
This analyser's default customized parameters include: **Blood Type**, **RH Blood Group**, **ESR**, **C-reactive Protein** and **Reticulocyte**. You can set the unit and reference range of default customized parameters as well as add and set customized parameters.

5.4.5.1 Accessing the Interface

Click **Custom Para.** in the **Para.** selection.
The customized parameters setting interface as shown in Figure 5-23 will pop up on the screen.

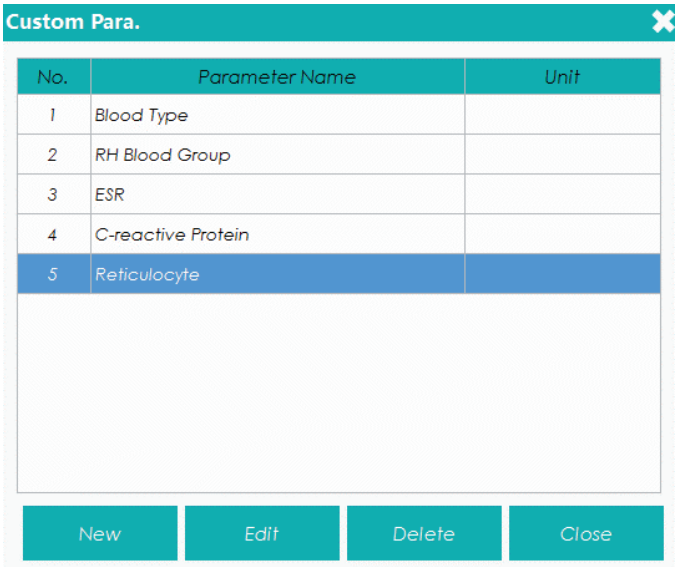


Figure 5-23 Customized Parameter Settings

5.4.5.2 Adding a Customized Parameter

1. Click New. The interface as shown in Figure 5-24 will pop up on the screen.

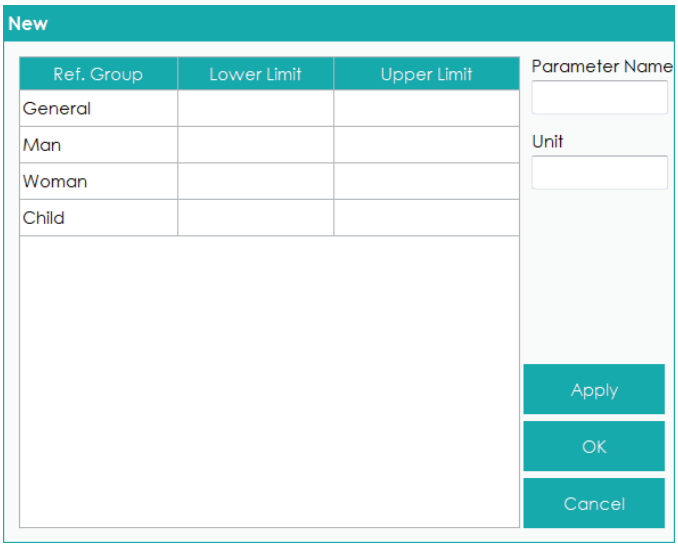


Figure 5-24 Adding a Customized Parameter

2. Click the textboxes of **Parameter Name** and **Unit** respectively, and enter the name and unit of the customized parameter.
3. Click corresponding cells of the **Upper Limit** and **Lower Limit** of the reference group, and input values.
4. Click **OK**.

The added parameter will be displayed in the customized parameter list.

5.4.5.3 Editing a Customized Parameter

You can set the unit and reference range of customized parameters. Detailed steps are shown below:

1. Select the customized parameter to be edited, and click **Edit**.
   The interface as shown in Figure 5-25 will pop up on the screen.

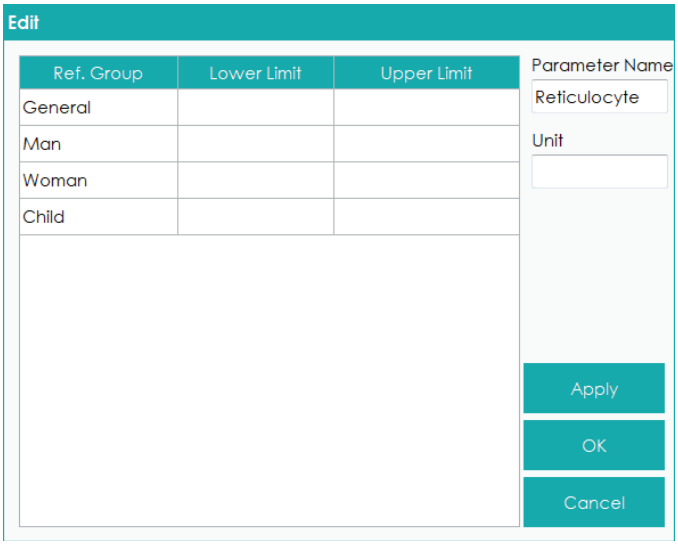


Figure 5-25 Editing a Customized Parameter

2. Click the textboxes of **Parameter Name** and **Unit** respectively, and modify the name and unit of the customized parameter.
3. Click corresponding cells of the **Upper Limit** and **Lower Limit** of the reference group, and modify the values.
4. You can also customize the reference group according to the actual situation. For details, see **5.4.3 Ref. Range**.
5. Click **Save**.

5.4.5.4 Deleting a Customized Parameter

Select a customized parameter, and click on **Delete**. Then, the parameter and its corresponding reference group will be deleted.

5.5. Meterage Settings

5.5.1 Gain Settings

You can adjust each digital pot at the **Gain Settings** interface. It is not recommended to adjust gains frequently.

Click **Gain Settings** in the **Meterage** selection to access the gain setting interface. Figure 5-26.

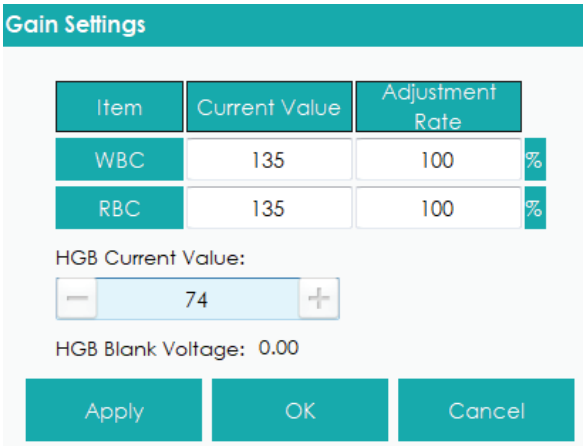


Figure 5-26 Gain Settings

NOTE New value of the gain adjustment = **Current Value** × **Adjustment Rate**.

- **Setting the WBC gain**
  The WBC gain here is in whole blood mode.
  Setting method I: click the **Current Value** of the WBC and enter the new value.
  Setting method II: click the **Adjustment Rate** cell of the WBC and enter the adjustment rate of the new value relative to the current value.
- **Setting the WBC gain**
  RBC channel gain.
  Setting method I: click the **Current Value** of the RBC and enter the new value.
  Setting method II: click the **Adjustment Rate** cell of the RBC and enter the adjustment rate of the new value relative to the current value.
- **Setting the HGB gain**
  Current digital circuit gain. The purpose for adjusting the HGB channel gain is to change the HGB background voltage.
  You can enter the value directly in the **HGB Current Value** textbox or click the adjusting button to adjust the HGB gain.
- **Setting the HGB Blank Voltage**
  The background voltage derived from HGB gain cannot be modified. HGB Background Voltage can be adjusted within the specified range (4.2~4.8V) by modifying **HGB Current Value**.

5.5.2 Flag

When the test result meets the requirement of the flag rules, the corresponding flag will be displayed on the screen. You can edit the flag rules as per the actual demand and relevant lab procedures.

5.5.2.1 Accessing the Interface

Click **Flag** in the **Meterage** selection to access the flag rules setting interface. See Figure 5-27.

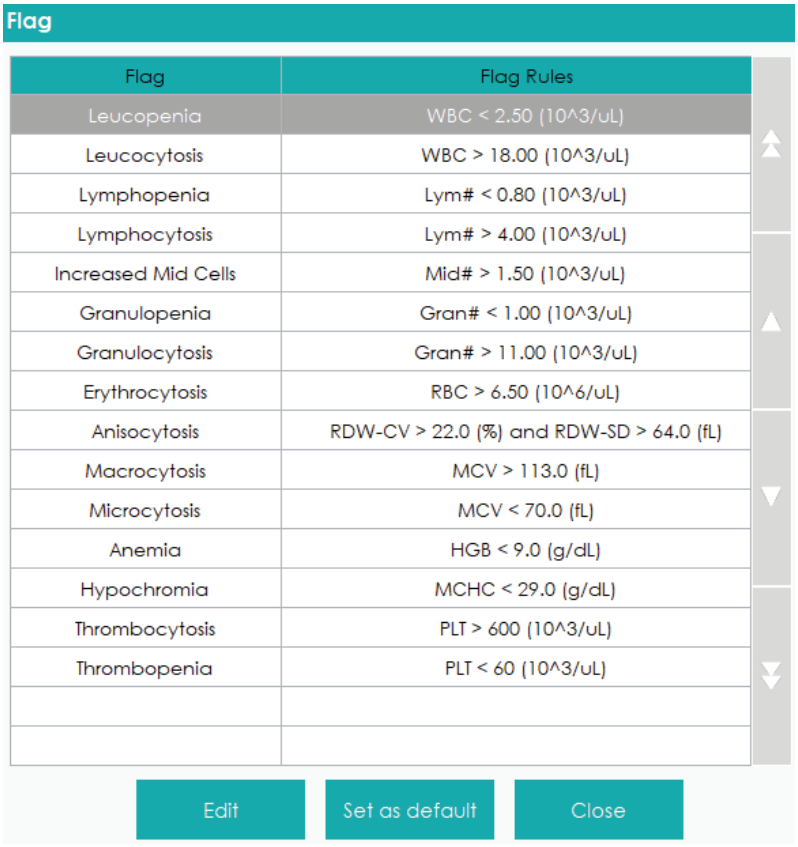


Figure 5-27 Flag

5.5.2.2 Setting Flag Rules

You can select the name of the **Flag** in the **Flag** interface, then click **Edit** to modify the rules in the popup dialog box. See Figure 5-28.

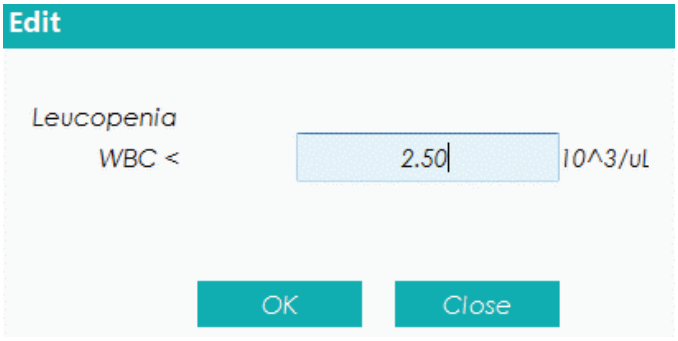


Figure 5-28 Setting Flag Rules

5.5.2.3 Restoring Defaults

Click **Set as default** to restore the parameter to the default value.

5.6 Communication Settings

5.6.1 Host Network Settings

On the host communication screen, you can set the network information of the analyser to enable its network connection.

Click **Host Communication** in the **Communicate** selection to access the host network setting interface. See Figure 5-29.

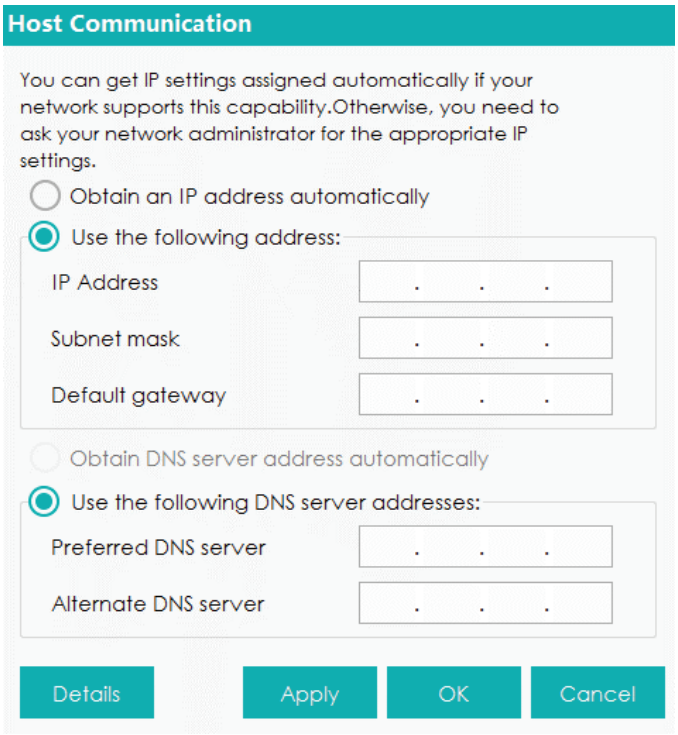


Figure 5-29 Host Network Settings

Refer to Table 5-5 for the description of relevant parameters.

Table 5-5 Description of Host Communication Setting Parameters

Parameter	It means	Operation
Obtain an IP address automatically	The host gets the IP address dynamically from a DHCP server or a PPP dial-up network access server. This option is not applicable for the dial-up connection of SLIP server.	Please choose according to the actual situation.

Parameter	It means	Operation
Use the following address:	Specify the host to use the manually set IP address. If this option is selected, you need to set: • IP address The IP address obtained from the network administrator or Internet service provider. • Subnet mask The subnet mask obtained from the network administrator or Internet service provider. • Default gateway The IP address of the default gateway; the router's IP address for connecting the independent IP network segment.	Obtain the IP address, subnet mask and default gateway of the host from the network administrator or Internet service provider.
Obtain DNS server address automatically	Automatically obtain the IP address of the Domain Name Server (DNS).	Please choose according to the actual situation.
Use the following DNS server addresses:	Specify the IP address of the DNS server of the host. • Preferred DNS server The IP address of preferred or primary DNS servers. • Alternate DNS server (Optional) The IP address of alternative or secondary DNS servers of the host. This server will be used if the specified IP address of the Preferred DNS server is not available or if the DNS name cannot be resolved as the IP address of the DNS server which the host has inquired.	Obtain the IP address of DNS server from the network administrator or Internet service provider.

NOTE You can click **Details** to check the network information of the analyser, including physical address, IP address, subnet mask, default gateway, DNS server, etc.

5.6.2 LIS Communication

In the LIS Communication interface, You can set the communication between the system and the LIS, including network settings, protocol settings and transmission mode.

Click **LIS Communication** in the **Communication** selection to access the Laboratory Information System (LIS) communication setting interface. See Figure 5-30.

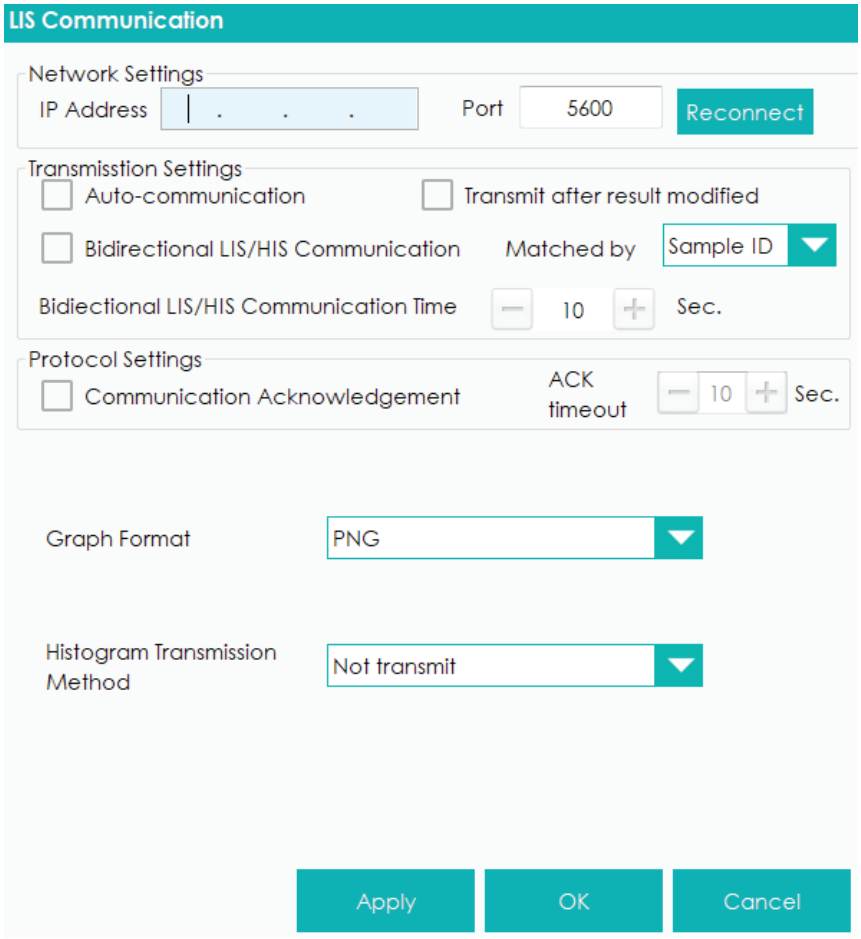


Figure 5-30 Setting LIS Communication

Refer to Table 5-6 for the description of relevant parameters.

Table 5-6 Description of LIS Communication Setting Parameters

Parameter		It means	Operation
Network Settings	IP address	The IP Address of the LIS.	Please set it according to the actual situation.

Parameter		It means	Operation
Network Settings	Port	The port of the LIS. The default value is 3600.	Please set it according to the actual situation. An integer between 1025 and 65535 can be entered. **NOTE** If the analyser is disconnected with the LIS, click the **Reconnect** button to connect the LIS again.
Transmission Mode	Auto-communication	Whether to upload the sample results automatically. • If checked, the system will automatically upload the result to the LIS upon the completion of the analysis. • If unchecked, the result of analysis will not be automatically uploaded. **NOTE** If the **Bidirectional LIS/HIS Communication** is checked, this parameter will be checked automatically.	Please choose according to the actual situation.
	Bidirectional LIS/HIS Communication	Whether to enable the bidirectional communication between the software and the LIS/HIS. • If checked, the system will automatically obtain the sample/patient information from LIS/HIS after the sample analysis is started or the patient information is edited, and automatically upload the result to the LIS upon the completion of the analysis. **NOTE** If the information is matched by sample ID, you only need to enter the sample ID; if the information is matched by Med Rec.No., you only need to enter the medical record number. • If unchecked, the software system will not obtain the sample/patient information, and decide whether to upload result based on the setting of the **Auto-communication** parameter.	Please choose according to the actual situation.

Parameter		It means	Operation
Transmission Mode	Matched by	The matching method of the analyser with the LIS/HIS sample information. • Sample ID The sample information of LIS/HIS is matched by the sample ID when running samples. • Med Rec. No. The sample information of LIS/HIS is matched by the Med Rec.No. when running samples. If the Med Rec.No. is empty, the sample information will not be matched. **NOTE** The parameter is only valid when the **Bidirectional LIS/HIS Communication** is checked.	Please choose according to the actual situation.
	Transmit after result modified	Whether to upload the sample results automatically after the sample results is edited. • If checked, the sample results will be uploaded automatically after the sample results is edited. • If unchecked, the system will no execute any operations.	Please choose according to the actual situation.
Protocol Settings	Communication Acknowledgement	If checked, the communication between the system and the LIS is successful when the ACK response from the LIS is received within the duration of **ACK timeout**; no response received indicates communication failure. If unchecked, the communication between the system and the LIS shall be considered successful no matter the ACK response from the LIS is received or not. **NOTE** The system will send the next message continuously no matter the communication is successful or not.	Please choose according to the actual situation.

Parameter		It means	Operation
Protocol Settings	ACK timeout	Timeout duration of the ACK response. The default value is 10 seconds, that is, the communication will be considered failed if the system receives no ACK response within 10 seconds.	Click ↑ or ↓ or directly enter in the textbox. An integer between 1 and 120 can be entered. Unit: Second (sec.) **NOTE** The parameter is valid only when the Communication Acknowledgement is checked.
Graph Format		Graph transmission format, including PNG and BMP.	Please choose according to the actual situation.
Histogram Transmission Method		The methods for transmitting the histogram to the LIS when the result is transmitted by the system, including: • Not tran smit Do not transmit the histogram to the LIS. • Bitmap Transmit the histogram to the LIS in the format of screen display. • Transmitting bitmap for printing The histogram is transmitted by the system to the LIS in the format of a printed report.	Please choose according to the actual situation.

5.7 User management

After logging in the system, the administrator has the access to set the account information of general users and other administrators; common users can only browse the user list and change their own passwords.

5.7.1 Accessing the Interface

Click **User** in the **Setup** interface to access the user management interface as shown in Figure 5-31.

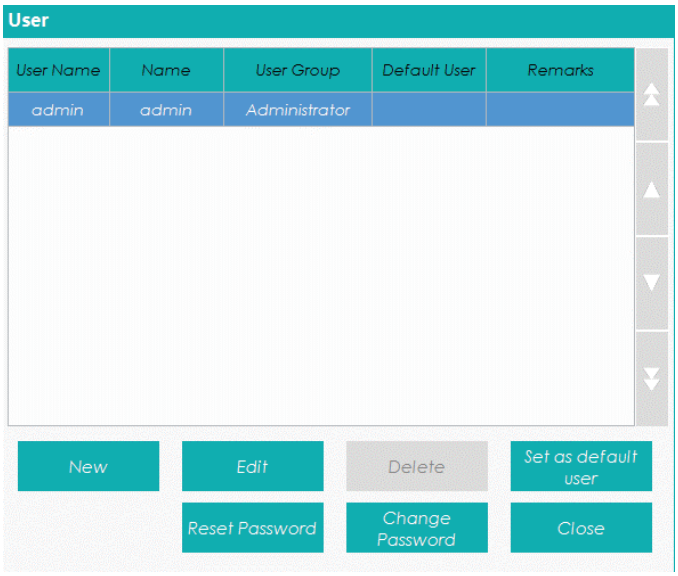


Figure 5-31 User management

5.7.2 Creating a User

Click **New** to set the account information of a new user in the popup interface, including username, first and last name, password, user group and remarks, etc. See Figure 5-32.

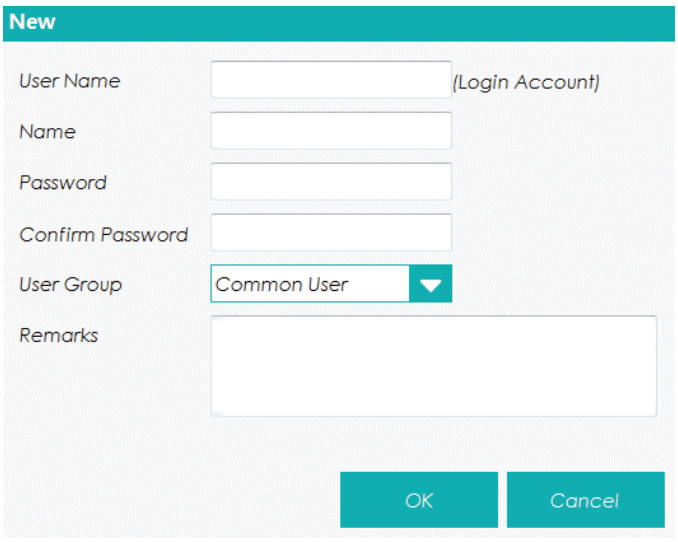


Figure 5-32 Creating a user

NOTE **User Group** includes **Common User** and **Administrator**. Users are assigned different access levels according to the user group they belong to.

Click **OK** after the setting is complete. The information of the new user will be shown in the user list.

5.7.3 Editing a User

Select the user to be edited and click **Edit** to modify the name and user group. See Figure 5-33.

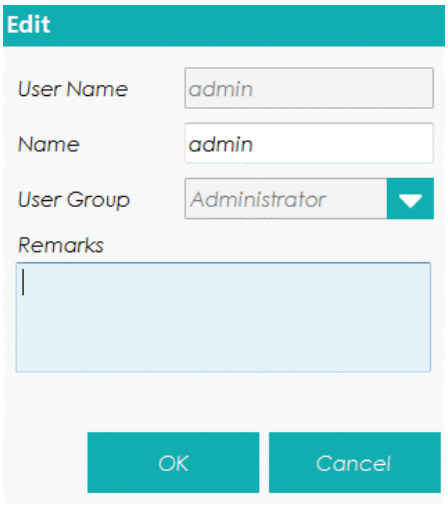


Figure 5-33 Editing a User

5.7.4 Deleting a User

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

NOTE The administrator cannot delete his/her own information.

5.7.5 Setting the Default User

Select a user and click **Set as default user** to set this user as the default user.
After it is set successfully, the default user name will be displayed in the login box next time and you only needs to enter the corresponding password. See Figure 5-34.

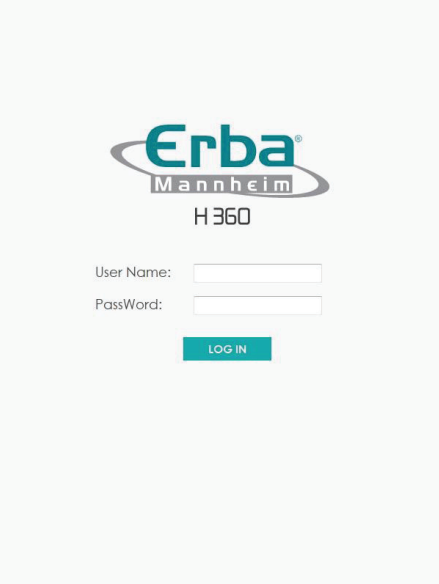


Figure 5-34 Login after Setting the Default User

5.7.6 Changing Password

Click **Change Password**, enter the old password and new password of the user and confirm the new password in the popup dialog box, then click **OK**.

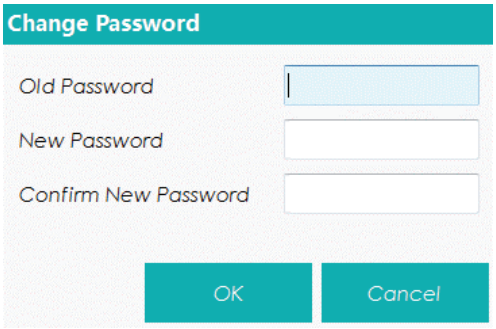


Figure 5-35 Changing Password

NOTE You can only change his/her own password and cannot change the password of other users.

5.7.7 Resetting Password

If the user forgets the password or the password is required to be reset due to other reasons, please click **Reset Password** to reset the password of the selected user to the initial password. The reset password is the same as the user name.

NOTE The administrator is allowed to reset the password of all administrators and general users; general users do not have the access to reset the password.

5.8 Print Settings

Click **Print Settings** in the **Setup** interface for relevant print settings, including the default printer, template, report, copies and margins, etc. See Figure 5-36.

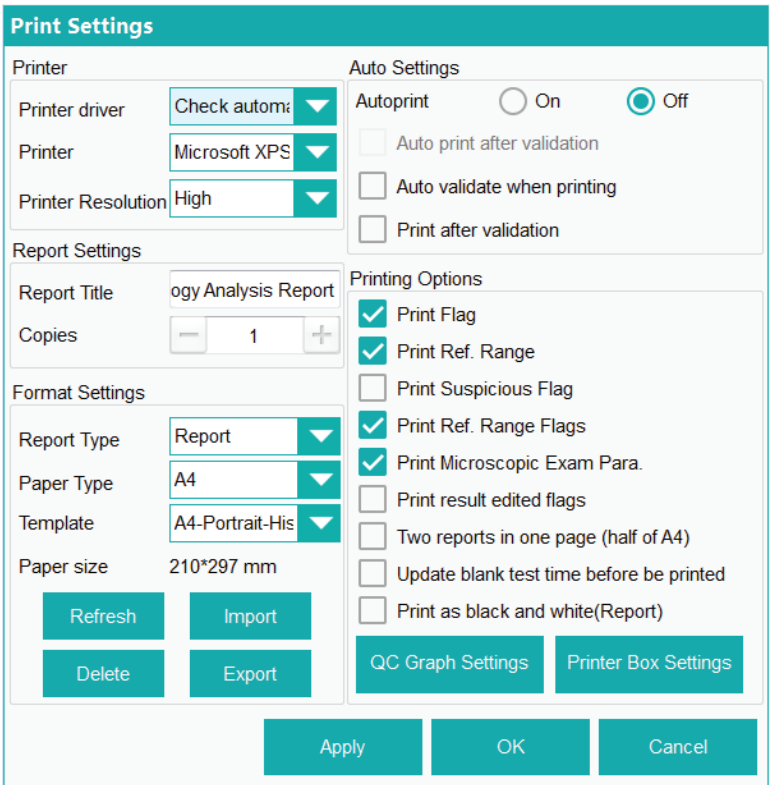


Figure 5-36 Print Settings

5.8.1 Printer Settings

You can set the printer and driver of the system in the Printer selection.

- **Printer Driver**
  The system automatically detects the printer driver by default.
- **Printer**
  Select a printer to be used from the dropdown list. If the dropdown list is blank, it indicates that no printer has been installed for the operating system. In this case, install a printer, and then perform the relevant settings and printing operations.
- **Printer Resolution**
  Select a proper resolution from the dropdown list. The higher the resolution of the printer, the better the print quality.

5.8.2 Report Settings

You can set relevant parameters of the report in the **Report Settings** combo box.

- **Report Title**
  Enter the title of the report in the **Report Title** textbox. The default setting is **Haematology Analysis Report**.

- **Copies**
  You can enter the number of copies to be printed for a report in the **Copies** textbox according to the actual demand. Click + to increase the number of copies and click − to decrease the number of copies or enter the number of copies in the edit box directly. Range of the copies is between 1 and 100 and the default value is 1.

5.8.3 Format Settings

Report type and template of prints can be set in the **Format Settings** combo box. See Figure 5-37.

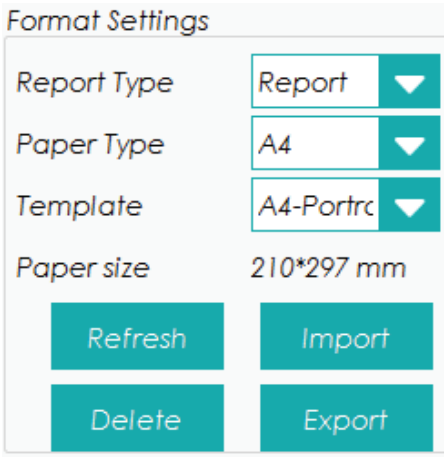


Figure 5-37 Format Settings

- **Selecting Report Type**
  Select the format type to be set from the dropdown list of the **Report Type**. The default setting is **Report**.
- **Selecting Paper Type**
  Select the paper type (size) from the dropdown list of the **Paper Type**, such as A4. After the selection is completed, the corresponding paper size will be shown at the bottom of the list, such as **210*148 mm**.
- **Selecting Template**
  Select the template to be set from the dropdown list of the **Template**.
- **Refresh**
  Click **Refresh** to refresh the format list after the customization by the administrator.
- **Importing/Exporting template**
  You can export the existing template to a USB flash disk, and edit the template. After editing, import the template to the system to complete the customization of the template.

NOTE Before importing/exporting template, insert a USB flash disk in the USB interface on the analyser.

- **Exporting template**
  Select the template to be exported from the dropdown list of **Template** and click **Export**. Select the export path in the popup dialog box, and click **Save**.
- **Importing template**
  Click **Import** and select the required template in the pop-up dialog box, then click **Open**.

- **Deleting template**
  Select the template to be deleted from the dropdown list of the **Template**.

NOTE Only customized templates can be deleted, the built-in templates cannot be deleted.

5.8.4 Auto Settings

- **Autoprint**
  The default setting is **Off**, which means the report should be printed manually after the results are obtained.
  If it is set to **On**, the system will automatically print the report of the sample as per the current report template once the counting results are obtained.

NOTE If Print after validation is checked, the autoprint function becomes invalid.
Auto print is not applicable for the background results.

- **Auto print after validation**
  It's unchecked by default, which means the system can print the report automatically without validation.
  If it's checked, the report will be printed automatically after it's been validated instead of being printed right after the results are obtained each time.

NOTE The parameter is valid only when the **Autoprint** is set to **On**.

- **Auto validate when printing**
  It's unchecked by default, which means the report will not be automatically validated by the system at the time of printing.
  If it's checked, the report will be automatically validated and printed by the system at the time of printing.
- **Print after validation**
  It's unchecked by default, which means the report can be printed without validation.
  If it's checked, the report can be printed only after validation and autoprint is inexecutable.

5.8.5 Printing Options

- **Print Flag**
  It's checked by default, which means the flag information will be printed in the report. If it's not checked, it will not be printed.
- **Print Ref. Range**
  It's checked by default, which means the reference range of the parameter will be shown in the printed report; If it's unchecked, the results alone, rather than reference range, will be shown in the printed report and the reference range will not.
- **Print Suspicious Flag**
  It's unchecked by default, which means the suspicious flag "?" will not be shown in the printed report; if it's checked, such flag can be shown.

- **Print Ref. Range Flags**
  It's checked by default, which means the printed report can show the ref. range flag (↑ or ↓); If it's unchecked, such a flag will not be shown.
- **Print Microscopic Exam. Para.**
  It's checked by default, which means the result of **Microscopic Exam. Parameters** will be printed in the report. If it's not checked, it will not be printed.
- **Print result edited flags**
  It's unchecked by default, which means the mark for the edited results will not be shown in the printed report.
  If checked, the mark (**M** or **m**) for the edited results will be shown in the printed report if the parameters have been modified.
- **Two reports in one page (half of A4)**
  It's unchecked by default. If this is checked, the default template size in Format Settings is half an A4 page (e.g., A4_Half-Portrait-Parameters), so two reports can be printed in one piece of A4 paper.

NOTE When **Autoprint** is **On**, a page remains to be printed with one report.

- **Update blank test time before be printed**
  It's unchecked by default, which means the blank test time will not be processed by the system. If it's checked, the **Delivery Time** will be automatically updated as the **Run Time** by the system at the time of printing.
- **Print as black and white (Report)**

NOTE The parameter is valid only when the **Report Type** is set to **Report**.

It's unchecked by default, which means the report will be printed according to the default settings of the printer.
If it's checked, the report will be printed as black and white.

5.8.6 Printer Box Settings

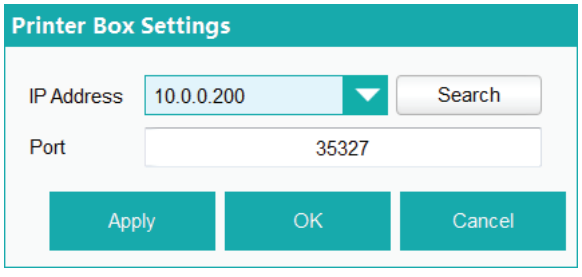


Figure 5-38 Printer Box Settings

- **IP Address**
  The default value is 10.0.0.200. You can input the address or select from the drop-down list. The IP address must be the same with the one on the software of the printer box.
- **Search**
  Search the IP address of the printer box in the current LAN. But you cannot search when the analyser is connected to the printer box with a network cable directly.

- **Port**
  The default port number is 35327. You can input if needed, and the input range is 1025-65535. The port number must be the same with the one on the software of the printer box.

5.9 Auxiliary Settings

Click **Auxiliary Settings** in the Setup interface to access the Auxiliary Settings interface. See Figure 5-39.

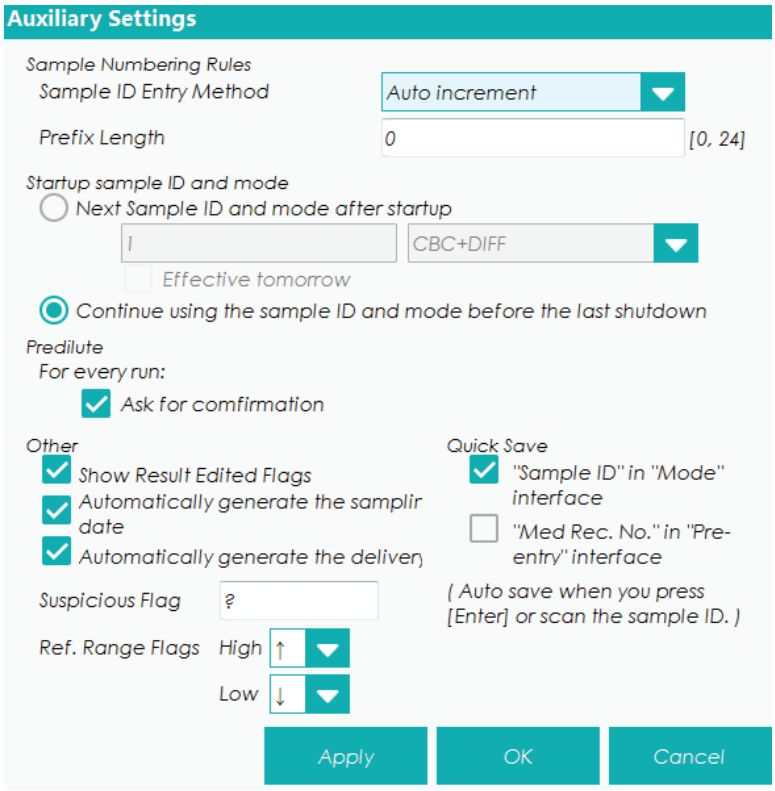


Figure 5-39 Auxiliary Settings

The administrator is allowed to set the following functions in the **Auxiliary Settings** interface:

- Sample Numbering Rules
- Start-up sample IP and mode
- Predilute
- Other

5.9.1 Sample Numbering Rules

Set the sample ID entry rules.

- **Sample ID Entry Method**
  Click the dropdown list of the **Sample ID Entry Method** and select the entry method of the sample ID from the following options.
  1. Auto increment (default setting)
  2. Manual entry

- **Prefix Length**
  When **Auto Increment** is selected as the Sample ID entry method, you can add a prefix to a certain batch of samples for identification.
  Enter the prefix length ranging from 0 to 24 (e.g. 2) of the sample ID in the **Prefix Length** textbox. The prefix length will applied to all sample IDs after the setting is saved.

5.9.2 Start-up sample IP and mode

Set the sample ID and measurement mode for the next sample after start-up.

- **Next Sample ID and mode after start-up**
  The sample ID and mode set by the user will be used by the system after the next start-up when the specified sample ID is entered into the textbox and the measurement mode (CBC or CBC+DIFF) is selected from the dropdown list.

NOTE If the **Effective tomorrow** is checked, the modification of the next sample ID and mode after start-up will become effective on the next day.

- **Continue using the sample ID and mode before the last shutdown**
  If checked, the system will by default add 1 to the last sample ID analysed before shutdown as the next sample ID after start-up.

5.9.3 Predilute

Set if you wish to see a popup dialog box when you perform the Predilute counting.

- Ask for confirmation (default setting): in the **Predilute** mode, when you press the aspirate key to start the analysis, a dialog box will pop up to remind you that the ongoing analysis is for **Predilute** counting.
- Do not ask for confirmation: the dialog box for confirming the Predilute counting will not pop up.

5.9.4 Quick Save

- **“Sample ID” in “Mode” interface**
  Set whether the Quick Save function is enabled for the **Mode** interface.
  If checked (default setting), when you enter the sample ID and press [Enter] (with the keyboard) or scan the sample ID (with barcode scanner) in the **Mode** interface, the sample information will be saved automatically.
  If unchecked, the sample information should be saved manually.
- **“Med Rec. No.” in “ Pre-entry” interface**
  Set whether the Quick Save function is enabled for the **Pre-entry** interface.
  If checked, when you enter the Med. Rec. No. in the **Pre-entry** interface and press [Enter] (with the keyboard), the sample information will be saved automatically.
  If unchecked (default setting), the sample information should be saved manually.

5.9.5 Other

- **Show Result Edited Flags**
  It’s unchecked by default, which means the edited results are marked with an **M** at the end, while the corresponding results with manual modifications are marked with an **m** at the end. M or m is displayed between the result data and the parameter unit by default.
  If unchecked, the edited result will not be marked with an **M** or **m**.

- **Automatically generate the delivery date**
  It is checked by default, which means you don't need to manually enter the **Delivery Time** when you modify patient information after running a sample. The operating date will be displayed in the date textbox.
  If unchecked, the **Delivery Time** shall be manually entered when patient information is modified in **Sample Analysis** interface.
- **Automatically generate the sampling date**
  It is checked by default, which means you don't need to manually enter the **Sampling Time** when you modify patient information after running a sample. The operating date will be displayed in the date textbox.
  If unchecked, the **Sampling Time** shall be manually entered when patient information is modified in **Sample Analysis** interface.
- **Suspicious Flag**
  A single character (an English letter only) can be re-entered in the textbox as a suspicious flag. The default value is **?**.
- **Ref. Range Flags**
  You can select the **Ref. Range Flags** from the dropdown list. The default high flag is ↑(or H) and the default low flag is ↓ (or L).

6 Daily Operations

6.1 Introduction

This chapter introduces the daily operations from the start-up to the shutdown of the analyser. A flow chart indicating the common daily operation process is presented below in Figure 6-1.

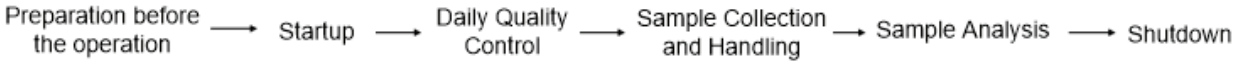


Figure 6-1 Daily Operations Procedure

6.2 Pre-operation Preparation

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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

WARNING

Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

Reagents can be irritating to the eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.

If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.

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.

NOTE

You should only use the Erba Lachema-specified reagents. Store and use the reagents as specified in instructions for use of the reagents.

Check if the reagents are connected correctly before using the analyser.

After long-distance transportation, the reagent must be allowed to settle for more than one day before use.

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.

Be sure to use the Erba Lachema-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.

Perform the following checks before turning on the analyser.

- Waste container

Check and make sure the waste container is empty.

- Fluidic tubing and power connections

Check and make sure the reagents and waste tubing are properly connected and not bent.
Check and make sure the power cord of the analyser is properly plugged into the power outlet.

- Printer (Optional)

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

- Network Cable (Optional)

Check and make sure the network cable is properly connected to the analyser.

6.3 Start-up

This section introduces the operations related to the start-up of the analyser.

NOTE If you failed to start the analyser continuously, please contact Erba Lachema customer service department or your local agent immediately.
After start-up, please make sure the data/time displayed on the screen is correct.

1. Place the power switch at the back of the analyser in the [I] position.
   The power indicator light will be on.
2. Check the indicator light on the analyser.
   If the indicator light is on, it indicates the analyser has been started up. The analyser will perform self-test and initialization in sequence. The whole process will last for 4 to 10 minutes. (Time needed for initializing the fluidic systems depends on how the analyser was previously shut down.)
3. Enter the correct user name and password in the Login message box. See Figure 6-2.

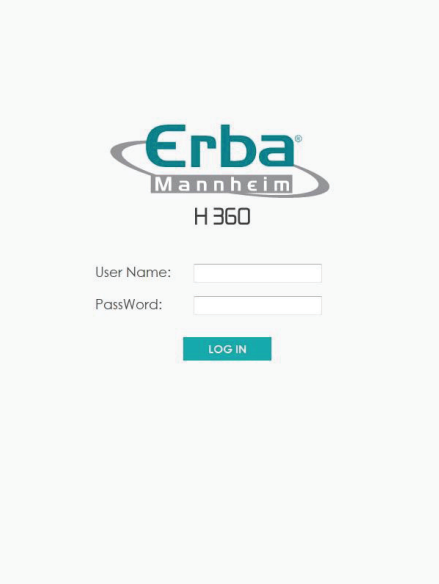


Figure 6-2 Login

The initial user name and password of administrator are **admin**, which was set by service engineer.

1 to 12 digits of numeric characters can be entered for the user name and the password. No Chinese character is allowed.

4. Click **Log in** to enter the user interface.
   The system will display the **Sample Analysis** screen by default and display the test result of the background when the analyser is started.

NOTE

The background test is designed for detecting particle interference and electrical interference.

For the background reference range of each parameter, please see **15.4.2 Normal Background**.

The sample ID for the background test is **background**.

If the background results exceed the Ref. Range for the first time during fluidics initialization, then the analyser will run the background test one more time.

Running a test when there is a Background abnormal, you would obtain an unreliable testing result.

If any error is detected during initialization (e.g. the background results exceed the Ref. Range), the analyser will activate the alarm. For details, see **13 Troubleshooting**.

6.4 Daily Quality Control

To ensure reliable analysis results, conduct daily QC analysis on the analyser before running samples. For details, see Quality ControlQuality Control.

6.5 Sample Collection and Handling



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 laboratory safety procedures when handling them and the relevant 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. Prepare the samples as per the procedures recommended by the reagent manufacturer.

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.
Be sure to use the Erba Lachema-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
For the cell blood count, store the whole blood at +15 to +25 °C and run them within 5 hours after collection.

6.5.1 Venous Whole Blood Samples

The procedure for preparing venous whole blood sample is as follows:
Use clean K_2EDTA (1.5 – 2.2mg/mL) vacutainer blood collection tubes with anticoagulant to collect venous blood samples.
Mix the venous blood with the anticoagulant well in the tube immediately.



CAUTION
For vacutainer blood collection tube (12 x 75 mm, cap excluded), please make sure the volume of the whole blood sample is not less than 0.5 mL.

6.5.2 Capillary Whole Blood Samples

Collect the capillary whole blood sample with a vacuum blood collection tube specified by the manufacturer.



CAUTION
To ensure the accuracy of the analysis, make sure the volume of the capillary whole blood sample is not less than 100 µL.

NOTE Run the capillary whole blood sample within 3 minutes to 2 hours after its collection.
The tube shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube may be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.

6.5.3 Prediluted Samples

⚠ Do not use anticoagulant during the prediluted sample analysis procedure; otherwise, the analysis result will be affected.

NOTE Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

The procedure for preparing prediluted sample is as follows:

1. Click the Erba Mannheim on the top left corner and enter the menu screen as shown in Figure 6-3.

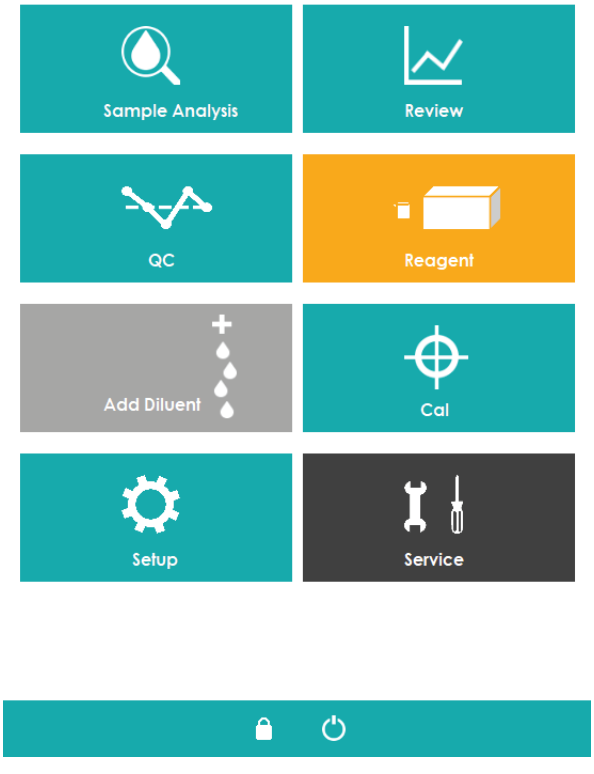


Figure 6-3 Menu Screen

2. Click the **Add Diluent** icon.
3. Take a clean centrifugal tube, uncap it and present it to the sample probe in a manner as shown in the following Figure 6 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.

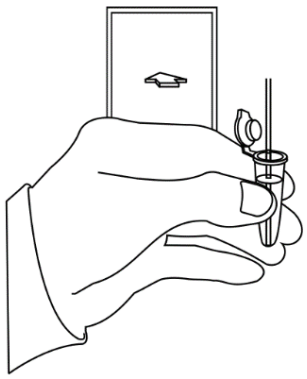


Figure 6-4 Sample under sample probe

4. Press the aspirate key and add the diluent (180 µL at a time). After the diluent is added and you hear a beep, you can remove the centrifugal tube.

NOTE You can also dispense 180µL of diluent by pipette into the tube.

5. If more portions of diluent are needed, repeat steps Take a clean centrifugal tube, uncap it and present it to the sample probe in a manner as shown in the following 4 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.~Press the aspirate key and add the diluent (480 µL at a time)..
6. Add 20 µL of blood to the diluent, close the tube cap and shake the tube to mix the sample.
7. After the prediluted sample is prepared, click **Cancel** to exit dispensing the diluent.

NOTE

The prediluted sample prepared after single blood collection can be counted twice.
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.
The centrifugal tube shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube would be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.

6.6 Sample Analysis

After the sample is prepared, you can perform the operations for sample analysis. For details, see **7 Sample Analysis**.

6.7 Shutdown



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.



The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.



CAUTION
Do not turn on the analyser immediately after its shutdown. Wait at least 10 seconds before power-on to avoid damage to the machine.

NOTE

To ensure stable analyser performance and accurate analysis results, be sure to perform the Shutdown procedure to shut down the analyser after it has been running continuously for 24 hours.
When the analyser is running or performing other fluidics sequence, do not force shutdown the analyser.
If any error is detected during shutdown procedure, the analyser will return to the status before the shutdown procedure is performed, and then activate the alarm. See **13 Troubleshooting**.
for details of removing the error.
Be sure to shut down the analyser in strict accordance with the instruction below.

Procedures for shutting down the analyser are as follows:

1. Click the button on the menu screen. The interface pops up a dialog box.
2. Click **Yes**.
   The system starts to execute the shutdown sequence and a message box pops up showing the procedures for cleanser maintenance.
3. Follow the instructions and set the cleanser under the sample probe, and press the aspirate key on the analyser or click **Aspirate** to run the cleanser aspiration.
   Place the [O/I] switch at the back of the main unit in the [O] position.
4. After shutdown, empty the waste in the waste container, and dispose of it.



WARNING
Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

7 Sample Analysis

7.1 Introduction

Sample analysis is the most important function of the H360 Haematology Analyser. You can get the blood cell count, HGB concentration and the 3-part classification counting results of the white blood cells by performing the sample analysis.
The summary of sample analysis procedures are as follows:

1. Entering the sample information.
2. Running the samples.
3. Processing the analysis results.

7.2 Interface Introduction

The **Sample Analysis** interface is the main interface of the analyser (Figure 7-1). You can complete the operations such as entering the sample information, performing sample analysis, reviewing/ printing analysis results in the **Sample Analysis** interface.



Figure 7-1 Sample analysis interface

Related descriptions:

- Function buttons
  You can perform operations such as setting the mode for the samples, pre-entering information, reviewing previous/next records and printing. Click and view all function buttons. See section **7.6 Functions of the Buttons**.
- **Patient information area**
  It displays the patient information corresponding to the current sample.
- **Analysis results area**
  It displays the analysis results of the sample, including the parameter results, Flags and histograms. They system displays the analysis results of the most recent run by default.

  Parameter Results
  - This list displays the analysis results of all the parameters of the samples.
    You can compare the values in the Result column with the corresponding Ref. Range. If the values are within the reference range, it means that they are normal. If not, it indicates that the sample may be abnormal and the corresponding symbols will be displayed in the Flag column.

  WBC Message
  - Displays the alert message regarding the WBC.

  RBC Message
  - Displays the alert message regarding the RBC.

  PLT Message
  - Displays the alert message regarding the platelet.

  RBC
  - RBC distribution histogram.

  PLT
  - Platelet distribution histogram.

  WBC
  - WBC distribution histogram

7.3 Entering Sample Information

You can enter the worklist information of the samples to be tested before the analysis.

NOTE

If the **Bidirectional LIS/HIS Communication** is checked and the sample information is Matched by Sample ID in the **Setup > Communicate > LIS Communication** interface, you don't need to pre-enter the sample information. The analyser automatically obtains the patient information from HIS/HIS by the sample ID entered in the **Mode** or **Worklist** interface. For details, see **5.6 Communication**.

If the **Bidirectional LIS/HIS Communication** is checked and the sample information is **Matched by** Med Rec.No. in the **Setup > Communicate > LIS Communication** interface, you only need to enter the **Med. Rec. No.**. The analyser obtains the other information of sample from LIS/HIS.

You can also enter sample/patient information after the sample analysis is completed. For details, please refer to Result **8 Result Review**.

Detailed steps are shown below:

1. Click the **Pre-entry** button in the function button area.

The interface as shown in Figure 7-2 will pop up on the screen.

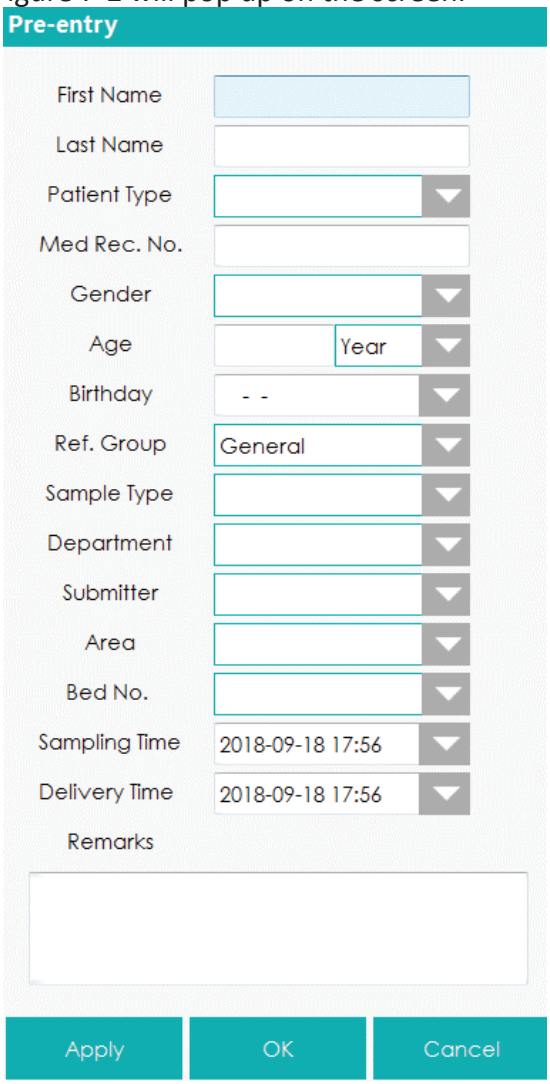


Figure 7-2 Pre-entering Patient Information

2. Enter patient information with reference to the parameter description in Table 7-1.

Table 7-1 Parameter Description

Parameter	It means	Operation
First Name	First name of patient.	Input in the textbox directly.
Last Name	Last name of patient.	Input in the textbox directly.
Patient Type	Type of patient. Values: • (Null) • Inpatient • Physical Examination • STAT • Outpatient	Select from the dropdown list.

Parameter	It means	Operation
Sample Type	Type of sample for microscopic examination. Values: • Venous blood • Capillary • Cord blood • Blood	Click the **Sample Type** dropdown list box and select the type of sample for microscopic examination.
Med Rec. No.	Medical record number of patient.	Input in the textbox directly.
Gender	Gender of patient. Values: • (Null) • Male • Female • Not defined	Select from the dropdown list.
Birthday	Birthday of a patient.	Select from the date control. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sequence of year, month, and date. • Click ▲ or ▼ to select the date or click the textbox to enter them directly. • Click 🧹 to clear the current data and re-enter the information.
Age	Age of a patient.	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.
Ref. Group	Reference group of the sample under analysis. The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.	Select from the dropdown list. **NOTE** If the **Automatically match the customized** reference group according to age and gender is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). Refer to 5**.4.3 Ref. Range** for the setting of the reference group and range.
Department	Department receiving the patient.	Select from the dropdown list.
Area	Ward area of patient.	Input in the textbox directly.

Parameter	It means	Operation
Bed No.	Bed No. of inpatient.	Select from the dropdown list or input directly. **NOTE** The bed No. is required to be filled only for inpatients.
Sampling Time	Date and time when the sample is collected.	Click the date control for the settings. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sequence of year, month, date, hour, and minute. • Click ▲ or ▼ to select the date or click the textbox to enter them directly. • Click  to clear the current data and re-enter the information. **NOTE** The system automatically displays the current time as sampling time. The sampling time can be no later than the current system time.
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.
Delivery Time	Date and time when the sample is delivered.	Click the date control for the settings. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sequence of year, month, date, hour, and minute. • Click ▲ or ▼ select the date or click the textbox to enter them directly. • Click  to clear the current data and re-enter the information. **NOTE** The system automatically displays the current time as sample delivery time. The delivery time can be no later than the current system time and cannot be earlier than the sampling time.
Remarks	Clarifications or notes.	Input in the textbox directly.

3. Click **Apply** or **OK** to save the configuration.

7.4 Running Samples

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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

WARNING
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 re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
Make sure that the entered sample ID and mode exactly match those of the samples to be run.

NOTE

The tube (or centrifugal tube) shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube may be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.
During aspiration, the tip of the probe should be kept at a certain distance from the bottom of the sample container, otherwise the accuracy of aspiration volume will be affected. Keep the tip of the probe from contacting with the wall of the test tube to avoid blood splashing.
Proper reference range shall be selected on the **Setup** interface before analysis. Otherwise, the results may be flagged erroneously.
The default system setting for counting mode is **Venous Whole Blood (VWB)**.
When the analyser is running the samples, you can switch to Review interface to perform operations including browsing and exporting, etc., and you can also switch to other interfaces. But all the functions related to the fluidics sequence are not available.

Take the following steps to perform sample analysis.

1. Prepare samples as instructed by **6.5 Sample Collection and Handling**.
   For details about the preparation of venous whole blood samples, see **6.5.1 Venous Whole Blood Samples**.
   For details about the preparation of capillary whole blood samples, see **6.5.2 Capillary Whole Blood Samples**.
   For details about the preparation of prediluted samples, see **6.5.3 Prediluted Samples**.
2. Shake the capped tube of sample for a homogeneous specimen.
3. When the green indicator light is steady-on, click **Mode & ID** in **Sample Analysis** interface.
   A dialog box will pop up as shown in Figure 7-3. The analyser supports six counting modes: venous whole blood (VWB), capillary whole blood (CWB), capillary whole blood (CWB)and Predilute (PD).

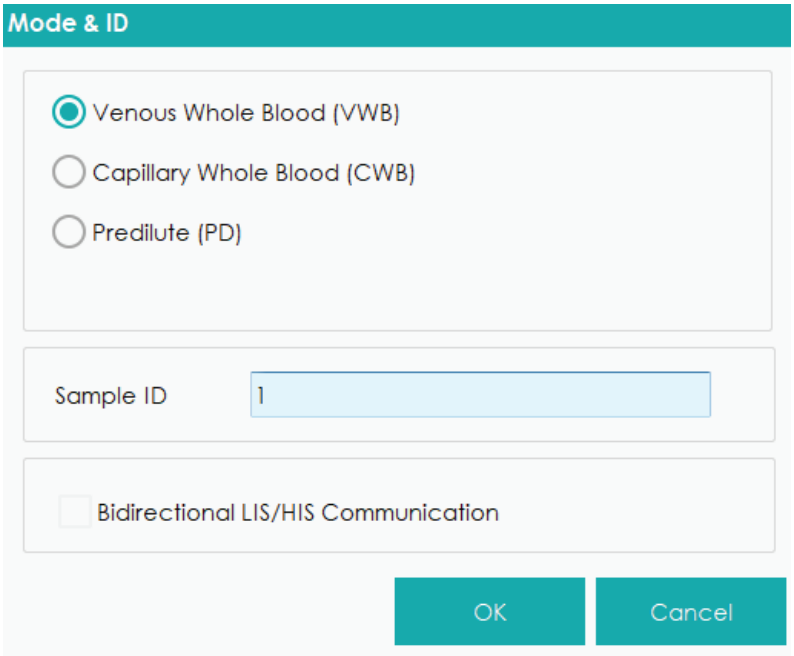


Figure 7-3 Mode & ID Settings

4. Select the blood sample mode Venous **Whole Blood (VWB)**, **Capillary Whole Blood (CWB)** or **Predilute (PD)** of the sample.
   - Letters, numbers and all characters that can be entered through the keyboard (including special characters) are allowed for the Sample ID. Chinese and other languages (such as Japanese, Korean, etc.) are not supported.
   - The length of the entries ranges from 1 to 25 and the entries shall not be empty.
   - The last character of a sample ID must be numeric, but a string of "0" only is not an acceptable sample ID.
5. Click **OK**.
6. Remove the tube cap carefully and place the sample under the probe so that the probe can aspirate the well-mixed sample.
7. Press the aspirate key on the analyser to start running the sample.
   The sample will be automatically aspirated by the sample probe.
8. When you hear a beep, remove the sample tube.
9. The analyser will automatically run the sample and the analysis status icon and analyser indicator is flickering in green. When the analysis is complete, the analyser indicator returns to constantly-on green.
10. Repeat steps a~h to run the remaining samples.

7.5 Dealing with the Analysis Results

7.5.1 Automatic saving of analysis results

This analyser automatically saves sample results. When the maximum number has been reached, the newest result will overwrite the oldest (already backed up).

7.5.2 Parameter Flags

- If parameter is followed by a "↑" or "↓", it means the analysis result has exceeded the upper or lower limit of the reference range but still within the display range.
- If the parameter is followed by a "?", it means the analysis result is suspicious.
- If you see "***" instead of a result, it means the result is either invalid or beyond the display range.

NOTE For the background test, the flags for parameters or abnormal blood cell differential and morphology are not available.

7.5.3 Flags of Abnormal Blood Cell Differential or Morphology

The analyser will flag abnormal or suspicious WBC, RBC and PLT according to the scattergrams and histograms. The flag information is defined in the Table 7-2 below.

Table 7-2 Flags of abnormal blood cell differential or morphology

Flag Type		Flag information
WBC	Abnormal	Leucocytosis Leucopenia Granulocytosis Granulopenia Lymphocytosis Lymphopenia MID Increase
	Suspicious	Background/Aspiration Abn. WBC abnormal? Abnormal WBC histogram Abnormal WBC Channel
RBC/HGB	Abnormal	Erythrocytosis Anisocytosis Macrocytosis Microcytosis Anaemia Hypochromia
	Suspicious	Abnor. RBC Distr. Dimorphologic Iron Deficiency? HGB Abnor./Interfere? RBC Clump? Abnormal RBC Channel Abnormal HGB Channel
PLT	Abnormal	Thrombocytosis Thrombopenia
	Suspicious	Abnor. PLT Distr. PLT Clump?

7.6 Functions of the Buttons

7.6.1 Previous/Next

Click **Previous**, and the screen will display the sample analysis results prior to the current one.
Click **Next**, and the screen will display the sample analysis results after the current one.

7.6.2 Mode & ID

Click this button to set the sample mode and measurement mode during the sample analysis. See section **7.4 Running Samples**.

7.6.3 Pre-entry

Click this button, and you can pre-enter the information of the sample to be tested before performing the sample analysis. See section **7.3 Entering Sample Information**.

7.6.4 Validate/Cancel Validation

After running sample, you can click Validate to validate the sample. After validating, the button will replaced by **Cancel Validation**. After validating, you cannot edit the sample/patient information and the result.
If the current sample has been validated, the sample validation can be cancelled by clicking **Cancel Validation**. After cancelling the validation, you can edit the sample/patient information and the result.

7.6.5 Print

You can click **Print** to print the report of the sample result.

7.6.6 Patient Information

You can browse and edit the patient information of the selected sample in the **Sample Analysis** interface. The operation procedures are as shown below:

1. Click **Patient Info**. to enter the patient information setting interface as shown in Figure 7-4.

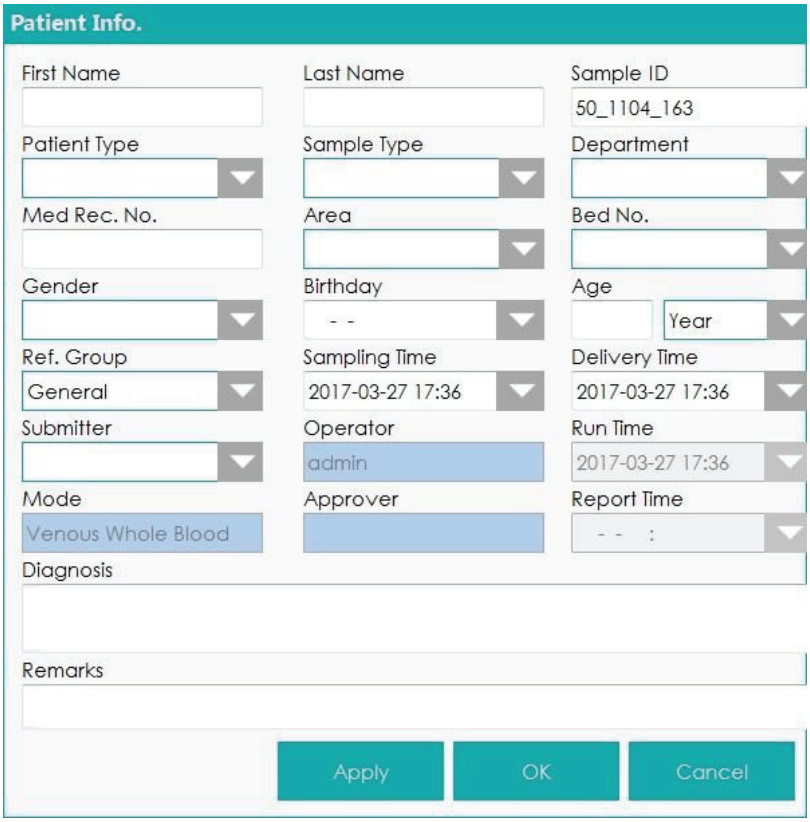


Figure 7-4 Patient Information

2. Enter patient information with reference to the parameter description in Table 7-3.

Table 7-3 Parameter Description of Patient Information

Parameter	Meaning	Operation
Sample ID	Number of the selected sample.	It will be displayed automatically, and you can modify it manually.
First Name	First name of patient.	Input in the textbox directly.
Last Name	Last name of patient.	Input in the textbox directly.
Patient Type	Type of patient. Values: • Inpatient • Physical Examination • STAT • Outpatient	Select from the dropdown list.
Sample Type	Type of selected sample. • Venous blood • Capillary • Cord blood • Blood	Select from the dropdown list.
Med Rec. No.	Med Rec. No. of patient.	Input in the textbox directly.
Gender	Gender of patient. Values: • (Null) • Male • Female • Not defined	Select from the dropdown list.

Parameter	Meaning	Operation
Birthday	Birthday of a patient.	Select from the date control. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sequence of year, month, and date. • Click ▲ or ▼ to select a date and time or enter the information in the textbox directly. • Click 🧹 to clear the current data and re-enter the information.
Age	Age of a patient.	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.
Ref. Group	Reference group of the sample under analysis. The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.	Select from the dropdown list. **NOTE** If the **Automatically match the customized reference group** according to age and gender is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). Refer to **5.4.3 Ref. Range** for the setting of the reference group and range.
Department	Department receiving the patient.	Select from the dropdown list.
Area	Ward area of patient.	Input in the textbox directly.
Bed No.	Bed No. of inpatient.	Select from the dropdown list or input directly. The bed No. is required to be filled only for inpatients.
Sampling Time	Date and time when the sample is collected.	Click the date control for the settings. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sequence of year, month, date, hour, and minute. Click ▲ or ▼ to select a date and time or enter the information in the textbox directly. • Click 🧹 to clear the current data and re-enter the information. **NOTE** The sampling time can be no later than the current system time.
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.

Parameter	Meaning	Operation
Mode & ID	Counting mode of the selected sample. The format is *blood sample mode-measurement mode*.	You do not need to enter it and it will be displayed automatically.
Delivery Time	Date and time when the sample is delivered.	Click the date control for the settings. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sequence of year, month, date, hour, and minute. • Click ▲ or ▼ to select a date and time or enter the information in the textbox directly. • Click 🧹 to clear the current data and re-enter the information. **NOTE** The delivery time can be no later than the current system time and cannot be earlier than the sampling time.
Operator	Personnel running the sample.	You do not need to enter it and it will be displayed automatically.
Run Time	Time when the sample is run.	You do not need to enter it and it will be displayed automatically.
Approver	Personnel validating the sample.	This parameter will be automatically displayed after the sample is validated.
Report Time	The date and time when the report is printed for the first time.	This parameter will be automatically displayed after the report is printed.
Diagnosis	Suspected diagnosis information.	Input in the textbox directly.
Remarks	Clarifications or notes.	Input in the textbox directly.

3. Click **Apply** or **OK** to save the settings.

7.6.7 Customized Parameters

You can browse and edit the customized parameters results of the selected sample in the **Sample Analysis** interface. The procedures are shown as below:

1. Click **Custom Para.** to enter the customized parameters setting interface as shown in Figure 7-5.

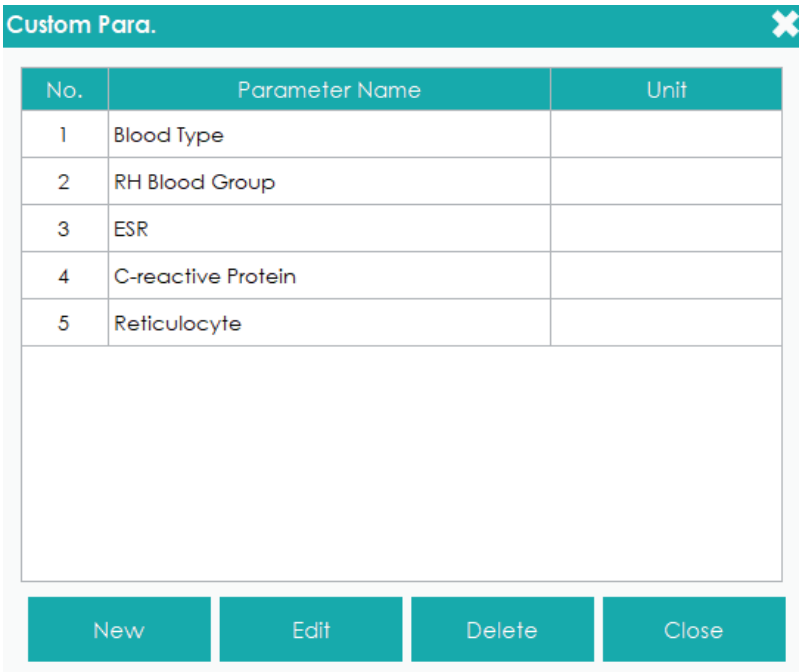


Figure 7-5 Customized Parameters

2. Click the cell corresponding to its **Value** column of the parameter, and enter the value. If the unit and reference range of parameters have been set in the **Setup > Parameter > Custom Para.** interface, the corresponding unit and range (lower limit~upper limit) will be displayed in this tab. When both the value and range of parameters are numbers, and the number is out of the reference range, the relevant mark ↑ or ↓ will be displayed in the **Flag** column. Please refer to **5.4.5 Customized Parameters** for customized parameters settings.

7.6.8 Microscopic Exam. Parameters

You can perform the microscopic exam. settings as per the following steps.

Click **Microscopic Exam. Para.**

The microscopic examination parameters interface as shown in Figure 7-6 will pop up on the screen.

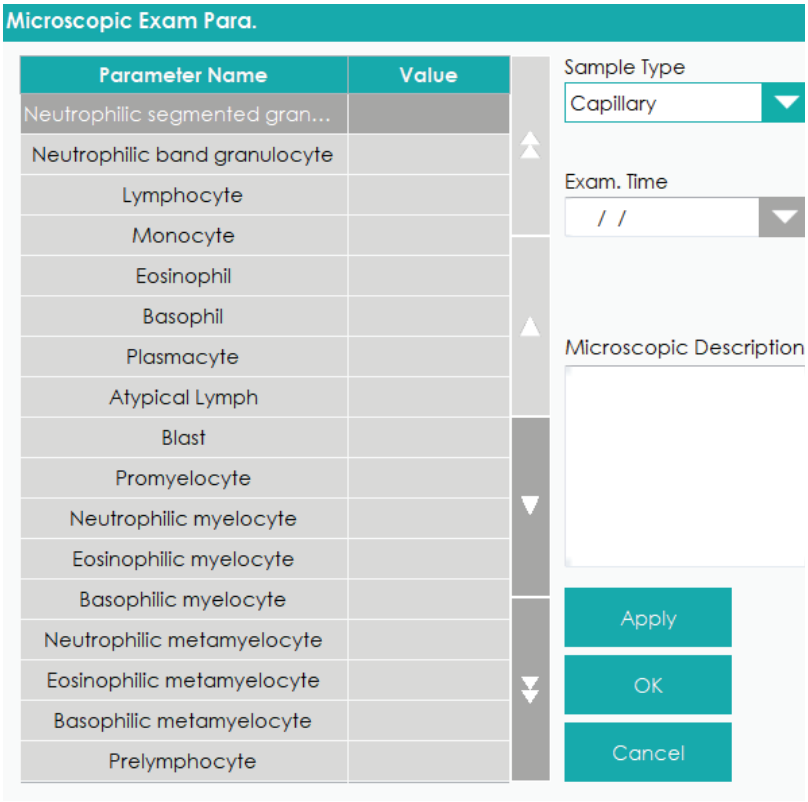


Figure 7-6 Adding a New Microscopic Exam. Parameter

Refer to Table 7-4 for parameter description and operation methods regarding the microscopic examination.

Table 7-4 Microscopic Exam. Parameters

Parameter	It means	Operation
Sample Type	Type of sample for microscopic examination. • Venous blood • Capillary • Cord blood • Blood	Click the Sample Type dropdown list box and select the type of sample for microscopic examination.
Exam. Time	Time of microscopic examination.	Click the Exam. Time combo box and select the time and date for the microscopic examination. **NOTE** The Microscopic exam. time can be no later than the current system time.
Microscopic Description	Description of cells morphology.	Enter the morphology information for WBC, RBC and PLT respectively into the multi-line textbox.

7.6.9 Communication

You can transmit the current sample data (except the background sample) to the LIS/HIS system in the **Sample Analysis** interface.

1. Click to unfold all function buttons.
2. Click **Comm.**.

7.6.10 Edit Result

NOTE You cannot edit the results of validated samples.
You cannot edit the results of the background.

You can edit the parameter result of the selected sample as per the following steps.

1. Click to unfold all function buttons.
2. Click **Edit Result**.

The **Edit Result** dialog box will pop up on the screen as shown in Figure 7-7.

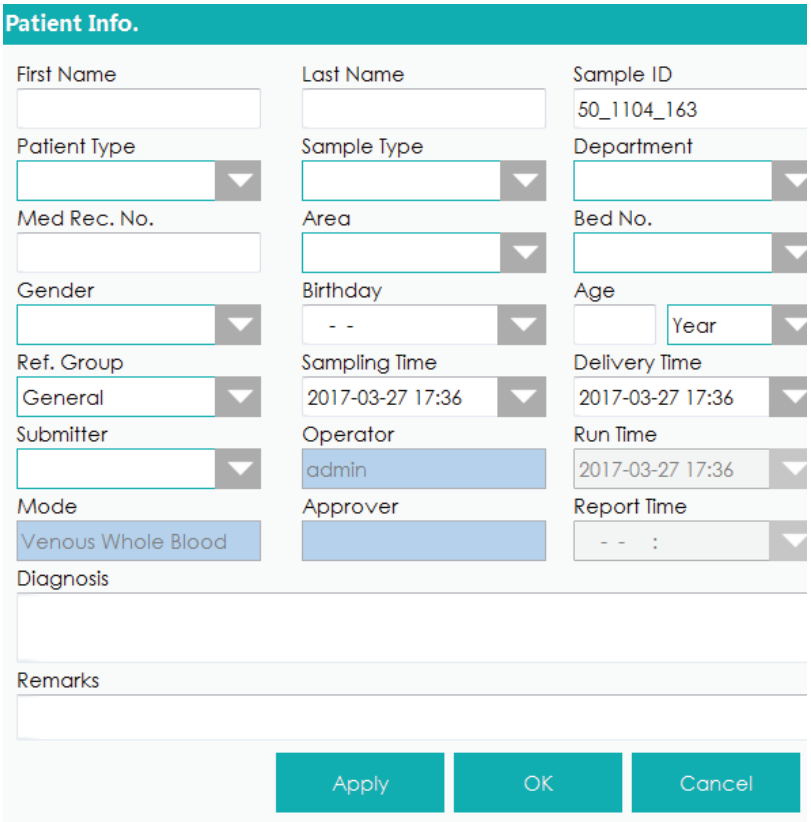


Figure 7-7 Editing Parameter Result

3. Modify the counting results of the corresponding sample parameters.
4. Click **Apply** or **OK** to save the changes.

If the sum of the percentage of the diff parameters is not equal to 100.00% or the WBC value is invalid after modification, the system will prompt in a message box that the entered value is invalid. Please re-enter after confirmation.

If the result of one parameter is modified, then the result of other related parameter(s) will be changed accordingly and the high or low/suspicious flags will also be updated.

NOTE The result of the parameter that you modified manually will be flagged with an **M**. If any parameter result is then changed due to the one that you modified manually, it will be flagged with an **m**.

7.6.11 Delete

Validated samples are not allowed to be deleted.
The common user has no access to delete the sample records.

1. Click to unfold all function buttons.
2. Click **Delete**, and then click **Yes** in the pop-up dialog box to delete the sample.

8 Result Review

8.1 Introduction

Upon the completion of each sample analysis, the analyser will automatically save the sample information, result data, flag messages, histograms and scattergrams to the Review Database. In the **Review** Interface, you can browse the saved sample information, result data, flag messages, histograms and scattergrams, and can search, compare or export the saved sample information.

8.2 Interface Introduction

You can browse, search, compare, print, and export the existing results in the **Review** interface. Click **Review** to enter the sample review interface. See Figure 8-1.

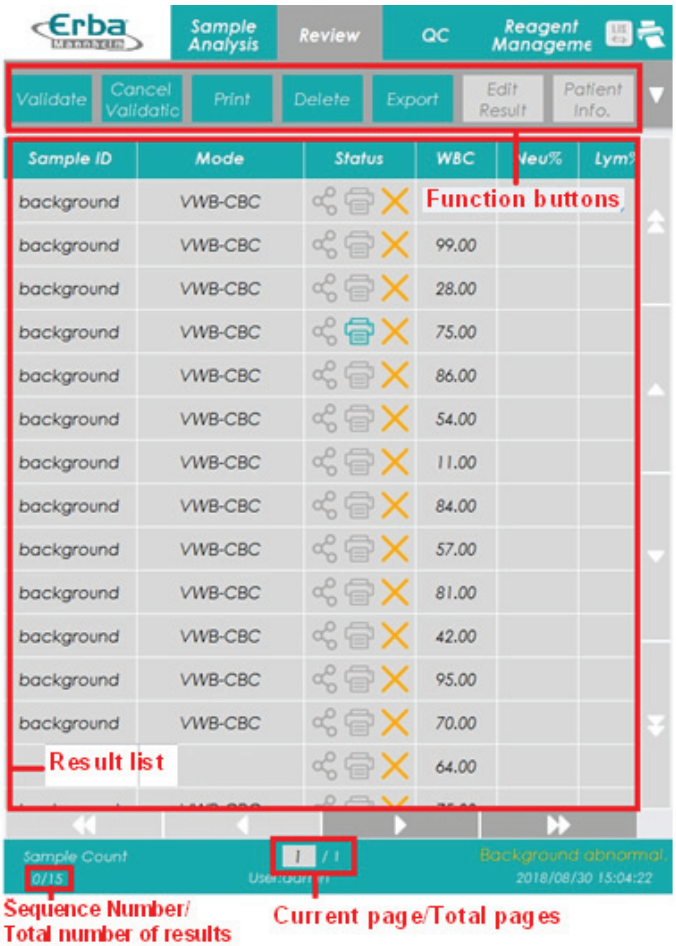


Figure 8-1 Review

Interface Description:

- Result list: you can browse detailed sample records.
- Function buttons: you can perform the operations such as comparing or searching the sample results, deleting and viewing the Run Charts, exporting and printing reports.

8.3 Sample List

The review interface shows a list of the analysed samples, which contains the sample number, status, mode and results of various parameters and other information.
Click a sample or multiple samples in the list area, then you perform operations such as exporting in batch for the selected samples. To cancel the selection, click the selected samples again.

8.4 Functions of the Buttons

8.4.1 Validate

NOTE After validating, you cannot edit the sample/patient information and the result.

After running samples, you can validate the samples as per the following steps.

1. Click **Validate**. A dialog box will pop up as shown in Figure 8-2.
2. Select the sample which needs to be validated.

Selected Records: The selected sample results with blue background.
Samples on current page: Results of all the samples shown on the current page.

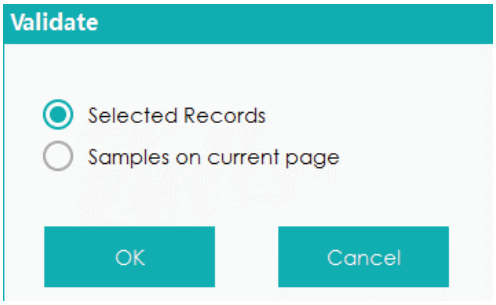


Figure 8-2 Options for validation of results

3. Click **OK**.
4. Click **OK** to close the message box.

8.4.2 Cancel Validation

NOTE After cancelling the validation, you can edit the sample/patient information and the result.

You can cancel the validation of validated samples. Detailed steps are shown below:

1. Click Cancel Validation.
2. Select the sample which needs to be validated.
   - Select **Selected Records**, and the system will cancel the validation for the selected sample results with blue background.
   - Select **Samples on current page**, and the system will cancel the validation for all the samples on the current page.
3. Click **OK**.
4. Click **OK** to close the message box.

8.4.3 Print

Click Print to **print** the result report of the selected sample.

8.4.5 Delete

NOTE Validated samples are not allowed to be deleted.
The common user has no access to delete the sample records.

1. Select one or several sample records to be deleted.
2. Click Delete.

A prompt box will pop up on the screen as shown in Figure 8-3.

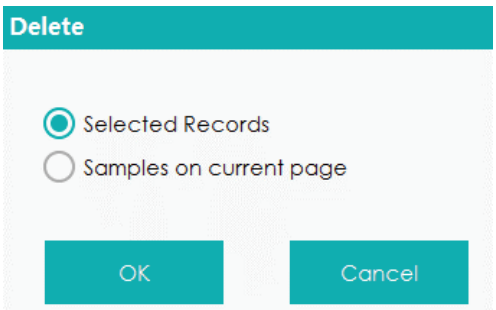


Figure 8-3 Delete Sample Records

3. Select one or several sample records to be deleted according to the actual situation.
   - Selected Records: The selected sample results with blue background.
   - Samples on current page: Results of all the samples shown on the current page.
4. Click OK to delete the selected record(s).

8.4.5 Export

The operator can export the sample data to the USB flash disk for backup. There are two ways of exporting the sample data: exporting selected records and exporting records of specified dates.

Export Selected Records

1. Insert a USB flash disk in the USB interface on the analyser.
2. Select records to be backed up, and click **Export**.

As shown in the Figure 8-4, the export range of the system is **Selected Records** by default.

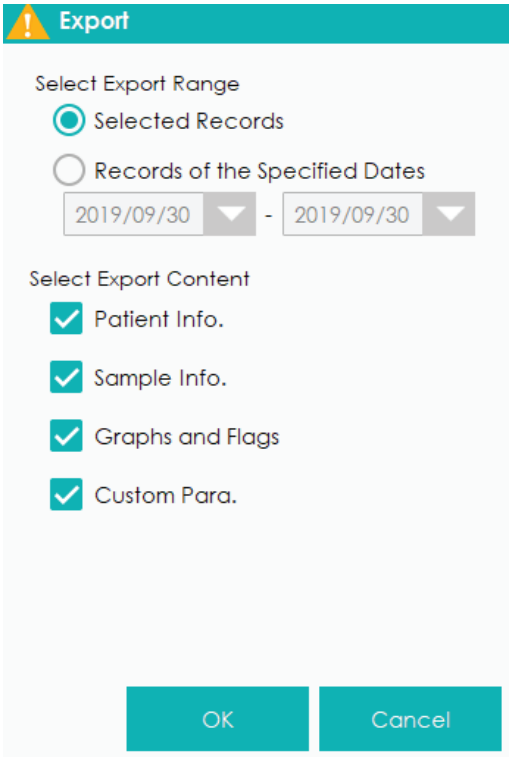


Figure 8-4 Export Selected Records

3. Select the content to be exported according to the actual demand.
   Content available for export includes: **Patient Info.**, **Sample Info.**, **Graphs and Flags**, **Custom Para.**
4. Click **OK**.
5. Select the data export path in the popup dialog box, enter the backup file name, and click **Save**.

The file will be exported to the root directory of the USB flash disk (/udisk/sda1) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.**csv**. Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.

6. Click **Save**.

The system pops up a dialog box to indicate that the data export is successful.

Export Records of the Specified Dates

1. Insert a USB flash disk in the USB interface on the analyser.
2. Click **Export**.
3. Select **Records of the Specified Dates** and set the run date range of sample in the two date textboxes. See Figure 8-5.

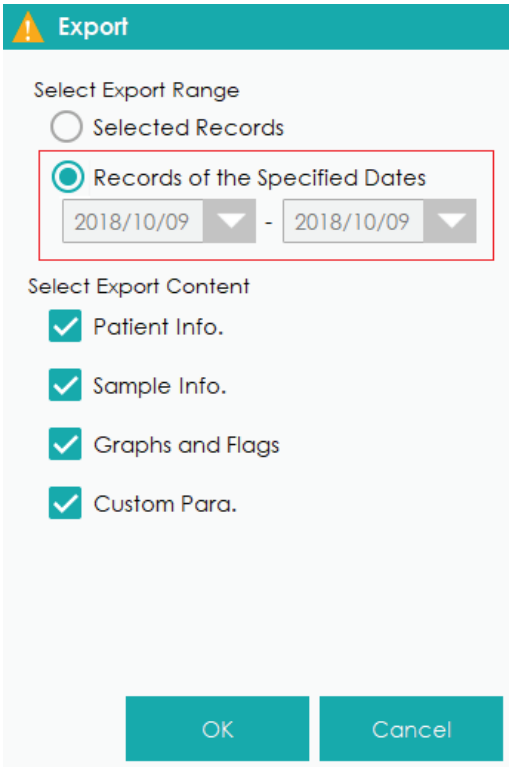


Figure 8-5 Export Records of the Specified Dates

4. Select the content to be exported according to the actual demand.
   Content available for export includes: **Patient Info.**, **Sample Info.**, **Graphs and Flags**, **Custom Para.**.
5. Click **OK**.
6. Select the data export path in the popup dialog box, enter the backup file name, and click Save.

The file will be exported to the root directory of the USB flash disk (/udisk/sda1) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.**csv**. Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.

7. Click **Export**.

The system pops up a dialog box to indicate that the data export is successful.

8.4.6 Edit Result

NOTE You cannot edit the results of validated samples.
Background result cannot be edited!

You can edit the parameter result of the selected sample as per the following steps:

1. Select a row of record from the result list and click the Edit Result button.

The Edit Result dialog box will pop up on the screen as shown in Figure 8-6.

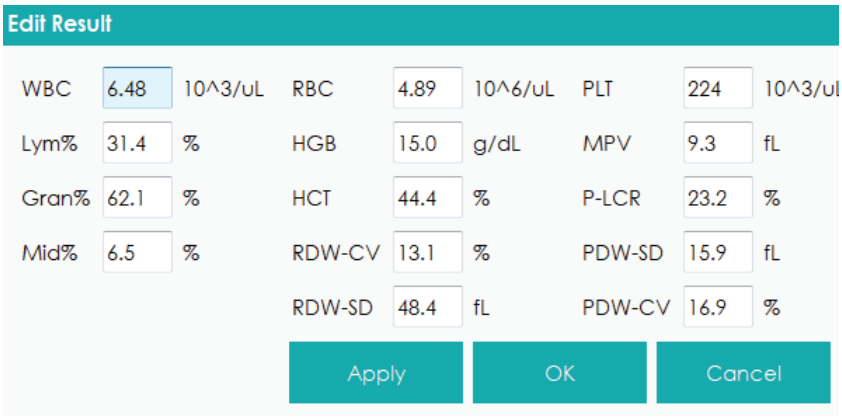


Figure 8-6 Editing Parameter Result

2. Modify the counting results of the corresponding sample parameters.
3. Click **Apply** or **OK** to save the changes.

If the sum of the percentage of the diff parameters is not equal to 100.00% or the WBC value is invalid after modification, the system will prompt in a message box that the entered value is invalid. Please re-enter after confirmation.

If the result of one parameter is modified, then the result of other related parameter(s) will be changed accordingly and the high or low/suspicious flags will also be updated.

8.4.7 Patient Info.

You can browse and edit sample/patient information after the sample analysis is completed. Detailed steps are shown below:

1. Click **Patient Info.**.

The interface as shown in Figure 8-7 will pop up on the screen.

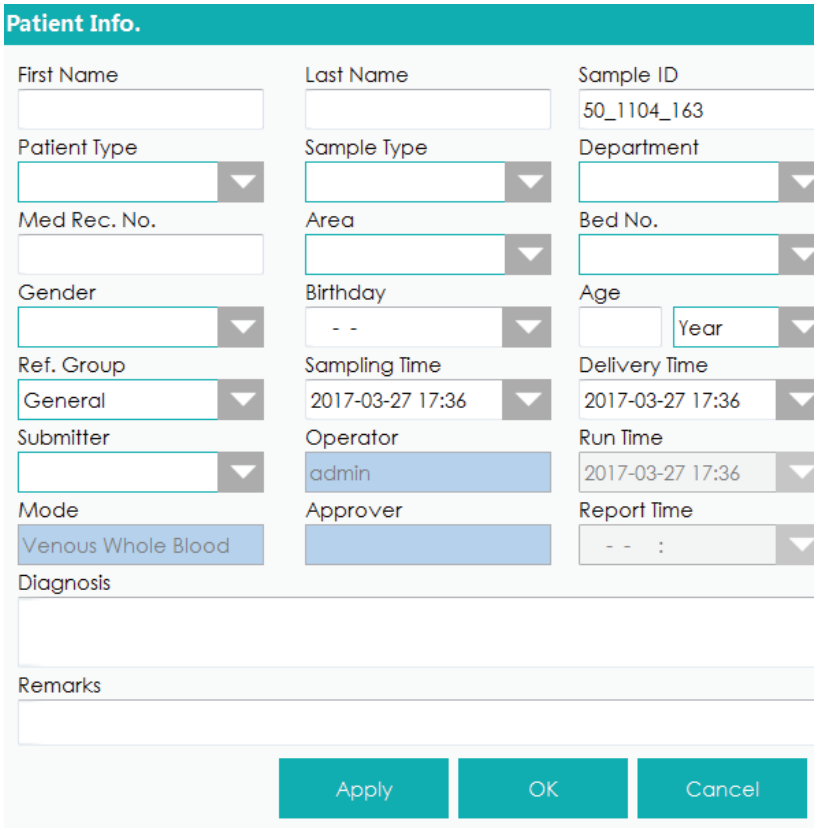


Figure 8-7 Patient Info

2. Enter patient information with reference to the parameter description in Table 8-1.

Table 8-1 Parameter Description

Parameter	It means	Operation
Sample ID	Number of the selected sample.	It will be displayed automatically, and you can modify it manually.
First Name	First name of patient.	Input in the textbox directly.
Last Name	Last name of patient.	Input in the textbox directly.
Patient Type	Type of patient. Values: • Inpatient • Physical Examination • STAT • Outpatient	Select from the dropdown list.
Sample Type	Type of selected sample. • Venous blood • Capillary • Cord blood • Blood	Select from the dropdown list.
Med Rec. No.	Med Rec. No. of patient.	Input in the textbox directly.

Parameter	It means	Operation
Gender	Gender of patient. Values: • (Null) • Male • Female • Not defined	Select from the dropdown list.
Birthday	Birthday of a patient.	Select from the date control. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sequence of year, month, and date. • Click or to select a date and time or enter the information in the textbox directly. • Click to clear the current data and re-enter the information.
Age	Age of a patient.	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.
Ref. Group	Reference group of the sample under analysis. The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.	Select from the dropdown list. **NOTE** If the Automatically match the customized reference group according to age and gender is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). Refer to Ref. RangeRef. Range for the setting of the reference group and range.
Department	Department receiving the patient.	Select from the dropdown list.
Area	Ward area of patient.	Input in the textbox directly.
Bed No.	Bed No. of inpatient.	Input in the textbox directly. **NOTE** The bed No. is required to be filled only for inpatients.

Parameter	It means	Operation
Sampling Time	Date and time when the sample is collected.	Click the date control for the settings. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sequence of year, month, date, hour, and minute. • Click ▲ or ▼ to select a date and time or enter the information in the textbox directly. • Click 🧹 to clear the current data and re-enter the information. **NOTE** The sampling time can be no later than the current system time.
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.
Mode	Counting mode of the selected sample.	You do not need to enter it and it will be displayed automatically.
Delivery Time	Date and time when the sample is delivered.	Click the date control for the settings. • The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd HH:mm**, you should input the data in the sequence of year, month, date, hour, and minute. • Click ▲ or ▼ to select a date and time or enter the information in the textbox directly. • Click 🧹 to clear the current data and re-enter the information. **NOTE** The delivery time can be no later than the current system time and cannot be earlier than the sampling time.
Operator	Personnel running the sample.	You do not need to enter it and it will be displayed automatically.
Run Time	Time when the sample is run.	You do not need to enter it and it will be displayed automatically.
Approver	Personnel validating the sample.	This parameter will be automatically displayed after the sample is validated.
Report Time	The date and time when the report is printed for the first time.	This parameter will be automatically displayed after the report is printed.
Diagnosis	Suspected diagnosis information.	Input in the textbox directly.
Remarks	Clarifications or notes.	Input in the textbox directly.

3. Click **Apply** or **OK** to save the configuration.

8.4.8 Query

You can view the test results of a patient within a certain test date range by entering the query conditions. The procedures are shown as below:

1. Click the **Query** button to enter the multi-conditional query dialog box as shown below.

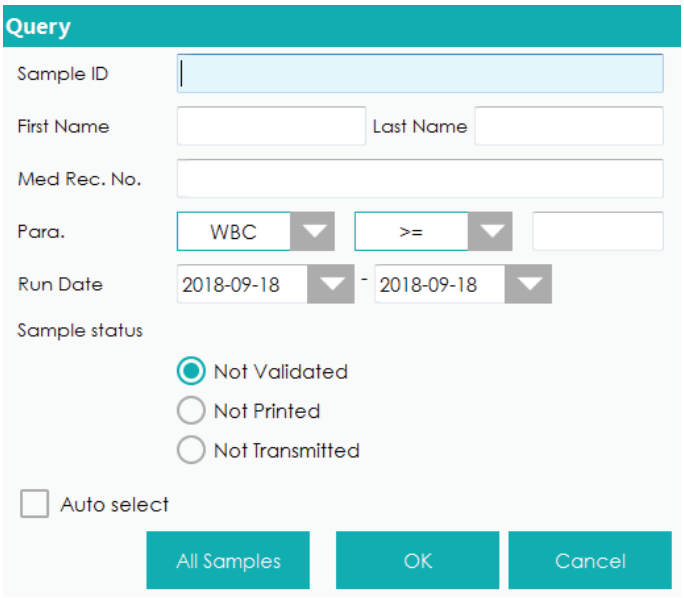


Figure 8-8 Query Conditions

2. Determine the query conditions as needed.

For the specific parameter description, see Table 8-2.

Table 8-2 Parameter Description of Query Conditions

Parameter	It means	Operation Description
Sample ID	Sample ID to be queried.	Input in the textbox directly.
Name	Name of patient.	Input in the textbox directly.
Med Rec. No.	Med Rec. No. of patient.	Input in the textbox directly.
Para.	Parameter and its range to be queried.	Select a parameter from the first dropdown list, and a comparison symbol (≥, >, ≤, <, =) from the second dropdown list, then input a value in the textbox. For example, if you select **WBC** and >, then input **3** in the textbox. The sample results which RBC value is greater than 3.0×10^6/μL will be queried and displayed.
Run Date	Test date range of sample.	Select the starting and ending dates of the sample test in the two data controls successively.
Sample status	Status of validation, printing or communication of the sample. • Not Validated • Not Printed • Not Transmitted	Please choose according to the actual situation. The default value is **Not Validated**.

NOTE

Auto select checked by default indicates that the query result is being selected (with a blue background colour). If it's unchecked, the query result will remain on a white background colour.

Click All Samples to close the current window, display all the samples again and re-store all the filter conditions to the default values.

3. Click Query.

The system will display all the query results which meet the conditions.

8.4.9 Graph

In the Review interface, you can click Graph to browse the selected sample graph results, parameter results and flag messages. The procedures are shown as below:

1. Select a result to review in graph interface.
2. Click to unfold all function buttons.
3. Click **Graph** to enter the graph interface of the selected sample.

In the Graph interface, you can view sample information such as parameter results, graph results and flag messages. In addition, you can also print the analysis report as. See Figure 8-9.

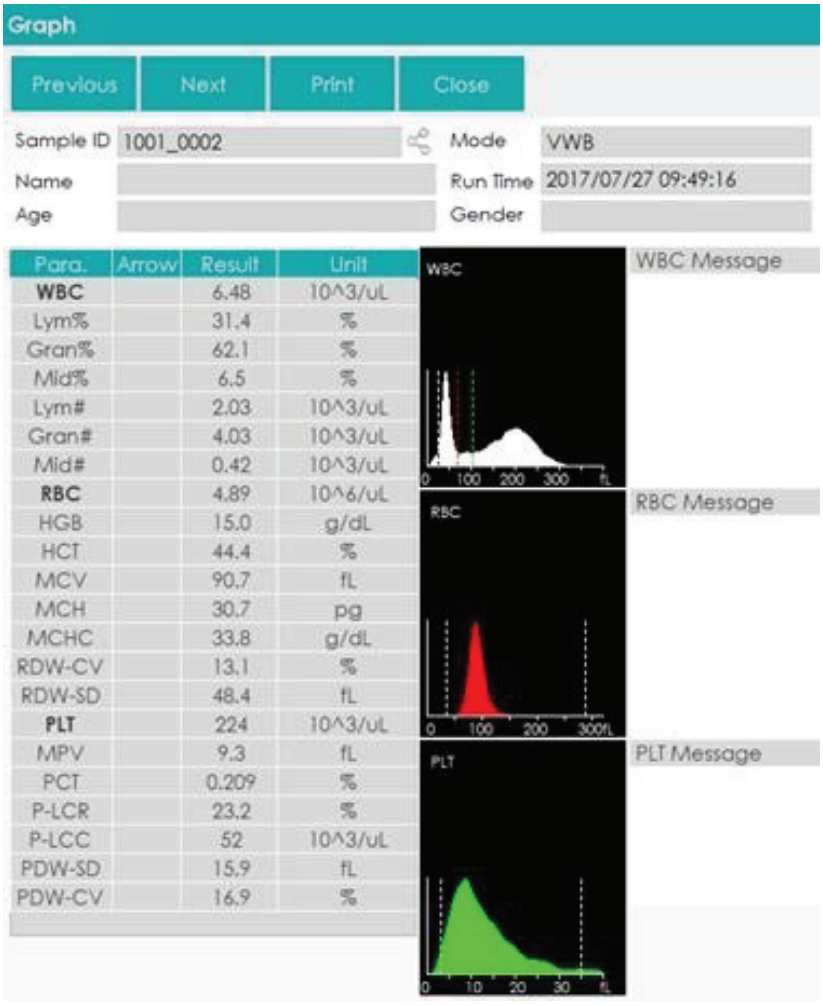


Figure 8-9 Graphs Review

8.4.10 Microscopic Exam. Parameters

You can perform the microscopic examination settings as per the following steps:

1. Click **Microscopic Exam. Para.**

The microscopic examination parameters interface as shown in Figure 8-10 will pop up on the screen.

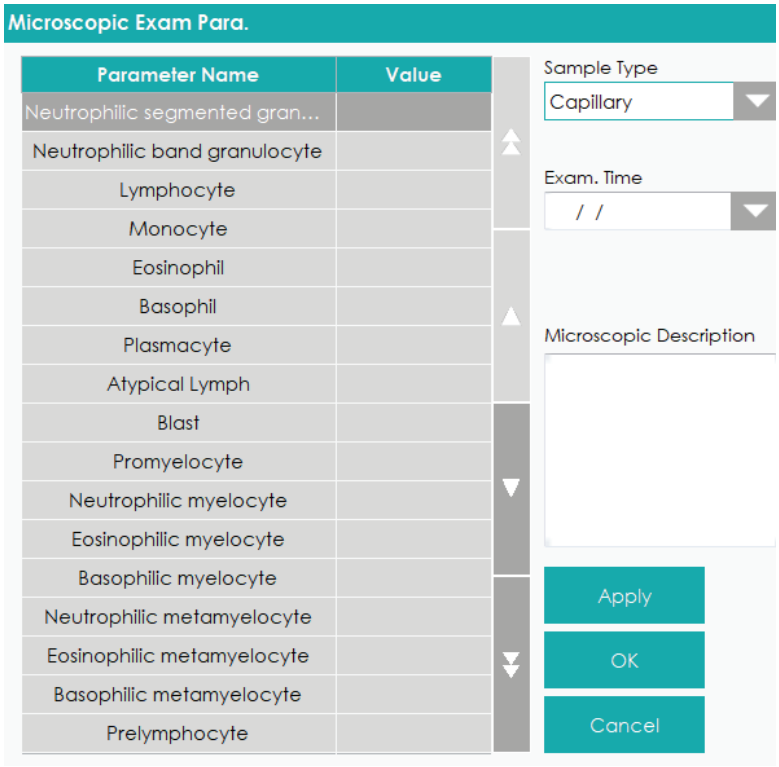


Figure 8-10 Adding a New Microscopic Exam. Parameter

2. Set the microscopic examination parameters by referring to Table 8-3.

Table 8-3 Microscopic Exam. Parameters

Parameter	It means	Operation
Sample Type	Type of sample for microscopic examination. • Venous blood • Capillary • Cord blood • Blood	Click the **Sample Type** dropdown list box and select the type of sample for microscopic examination.
Exam. Time	Time of microscopic examination.	• Click the date control for the settings. • The input sequence of the controls is year, month, date, hour, and minute. • Click ▲ or ▼ to select the date or click the textbox to enter them directly. • Click 🧹 to clear the current data and re-enter the information. **NOTE** The Microscopic exam. time can be no later than the current system time.
Microscopic Description	Description of cells morphology.	Enter the morphology information for cells into the multi-line textbox.

8.4.11 Customized Parameters

You can browse and edit the customized parameters results of the selected sample in the **Review** interface. The procedures are shown as below:

1. Select one sample.
2. Click to unfold all function buttons.
3. Click **Custom Para.** to enter the customized parameters setting interface as shown in Figure 8-11.

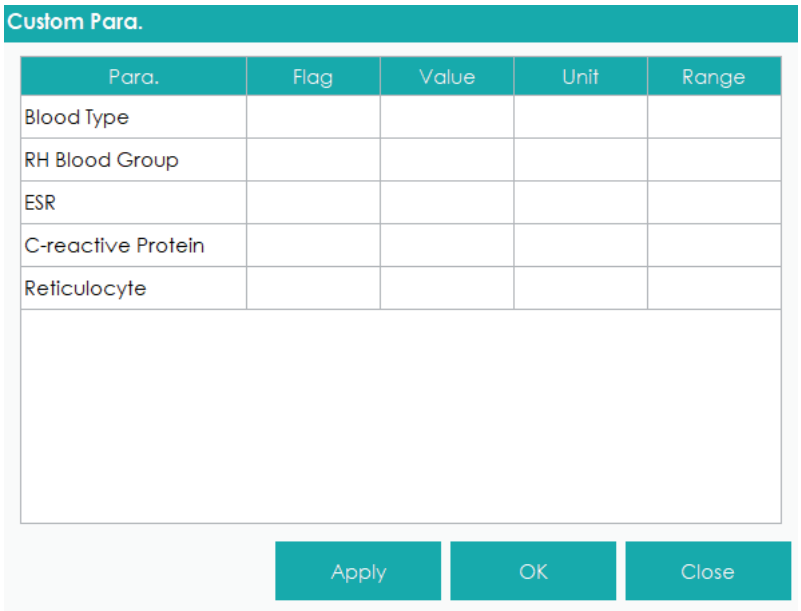


Figure 8-11 Customized Parameters

4. Click the cell corresponding to its **Value** column of the parameter, and enter the value.

If the unit and reference range of parameters have been set in the **Setup > Parameter > Custom Para.** interface, the corresponding unit and range (lower limit~upper limit) will be displayed in this tab. When both the value and range of parameters are numbers, and the number is out of the reference range, the relevant mark ↑ or ↓ will be displayed in the **Flag** column.

Please refer to **5.4.6 Customized Parameters** for customized parameters settings.

8.4.12 Communication

You can transmit the selected sample data, the data in the current page or the data within the specified date range to the LIS/HIS system in the **Review** interface.

- Selected Records
  1. Select one or several sample data to be communicated in the result list.
  2. Click to unfold all function buttons.
  3. Click **Comm.**.

A dialog box will pop up as shown in Figure 8-12. The default option is **Selected Records**.

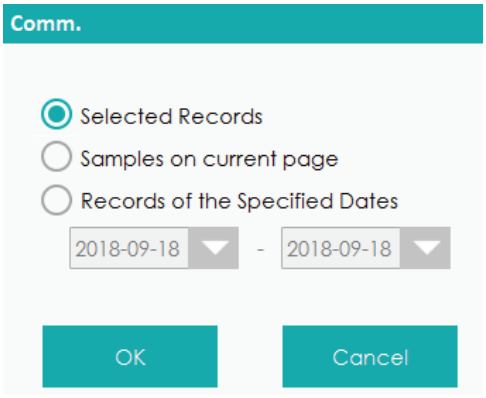


Figure 8-12 Communication for Selected Data

4. Click **OK**. After the data is transmitted to LIS/HIS, a message box will pop up.
5. Click **OK** to close the message box.

- Samples on current page
  1. Click to unfold all function buttons.
  2. Click **Comm.**
  3. Select **Samples on current** page. See Figure 8-13.

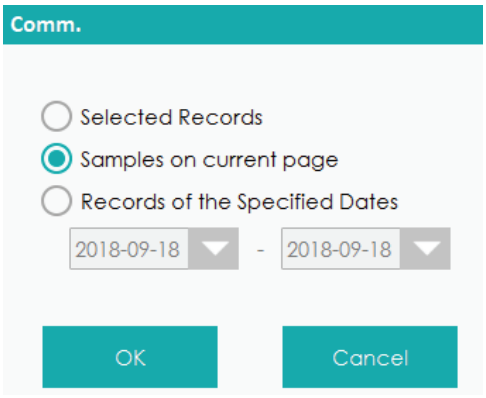


Figure 8-13 Communication for Data on Current Page

4. Click **OK**. After the data is transmitted to LIS/HIS, a message box will pop up.
5. Click **OK** to close the message box.

- Records of the Specified Dates
  1. Click to unfold all function buttons.
  2. Click **Comm.**
  3. Select **Specified Data**, and set the starting and ending dates of data to be communicated. See Figure 8-14.

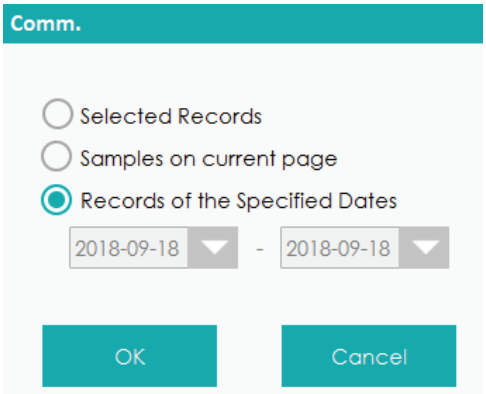


Figure 8-14 Communication for Data on Specified Dates

4. Click OK. After the data is transmitted to LIS/HIS, a message box will pop up.
5. Click OK to close the message box.

8.4.13 Run Chart

Operators can check and review run charts of sample parameter results in the database. There are three view modes: selected samples, samples on current page and samples on specified run dates.

- View the run chart of the selected sample (default)
  1. Check no fewer than three sample records.
  2. Click to unfold all function buttons.
  3. Click **Run Chart**. The system pops up a dialog box as in Figure 8-15.

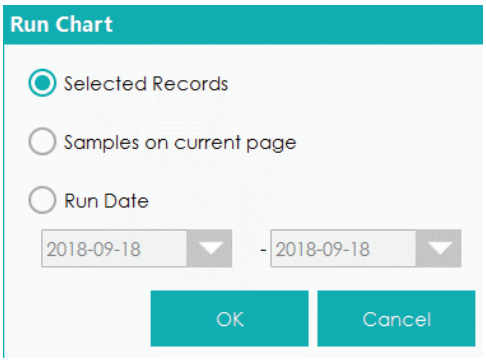


Figure 8-15 Viewing the Run Chart of the Selected Sample

4. Click **OK**.

The screen will show the parameter result run chart of the selected sample. Figure 8-16.

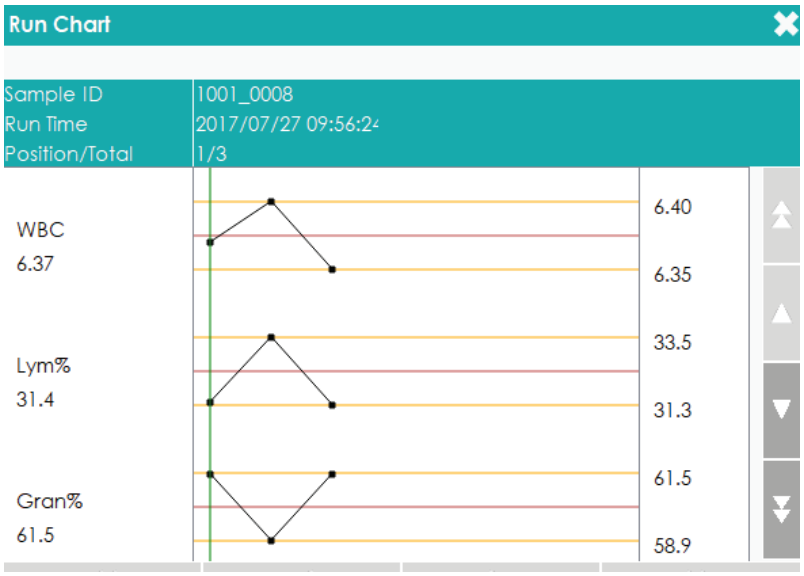


Figure 8-16 Run Chart

- View the run chart of samples on current page
  1. Click on the current page to unfold all function buttons.
  2. Click the **Run Chart** button and select Samples on current page in the pop-up dialog box. See Figure 8-17.

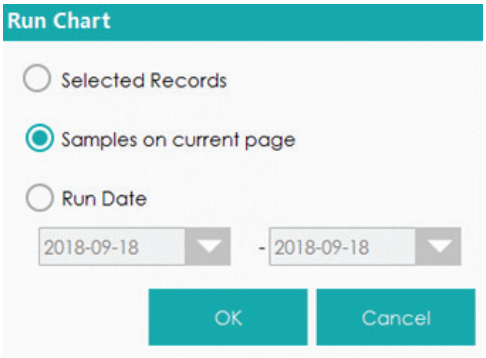


Figure 8-17 Viewing the Run Chart of Samples on the Current Page

  3. Click **OK**. The screen will show the parameter result run chart of the selected sample.

- View the run chart of samples on specified run dates
  1. Click to unfold all function buttons.
  2. Click the Run Chart button, and select Run Date in the pop-up dialog box. See Figure 8-18.

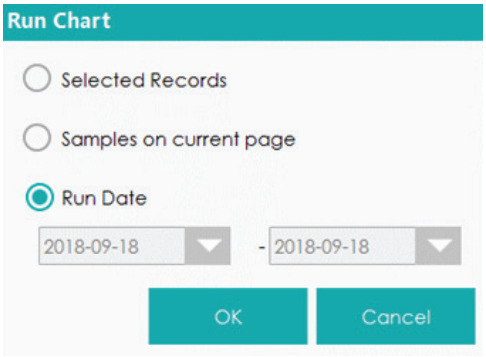


Figure 8-18 Viewing the Run Chart of Samples on Specified Run Dates

3. Click the date edit box, set a date range in the pop-up dialog box, then click **OK**.

The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sequence of year, month, and date.
Click or to select a date and time or enter the information in the textbox directly.
Click to clear the current data and re-enter the information.

4. Click **OK**. The screen will show the parameter result run chart of the selected sample.

9 Quality Control

9.1 Introduction

Quality Control (QC) consists of strategies and procedures that measure the precision and stability of the analyser. 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. Erba Lachema recommends running the QC program on a daily basis with low, normal and high level controls. A new lot of controls should be analysed 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 for five days using any empty QC file.

NOTE

You should only use the Erba Lachema-specified controls and reagents. Store and use the controls and reagents by following the instructions for use of the controls and reagents.
Controls beyond their Exp. date shall not be used. Controls (similar to standard blood samples) must be well mixed before use.
General users only have the access for browsing and executing the QC analysis other than editing.

9.2 L-J Quality Control

9.2.1 QC Principle

In the L-J quality control, quality control can be applied to 22 parameters. You can perform QC on relevant parameters according to the configured QC mode. After the QC settings, you can perform QC analysis on the corresponding parameters according to the set QC mode. Each QC file can be assigned 1 Lot number for high, normal and low level controls. Each QC file can store up to 500 QC results. When there are more than 500 QC results, the new QC results will overwrite the oldest results in sequence.

9.2.2 QC Settings



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

NOTE

Only users with administrator-level access can edit the L-J settings.
Before running a new batch of controls, you need to assign a QC file to each batch of controls. You can complete the QC settings by setting QC information in the QC files.

9.2.2.1 Entering QC Information

The administrator can set the QC files by operations such as Copy, New, and Edit. Detailed steps are shown below:

1. Click **QC** to access the **QC** interface.
2. Click **QC Settings** to enter the **QC Settings** interface. See Figure 9-1.

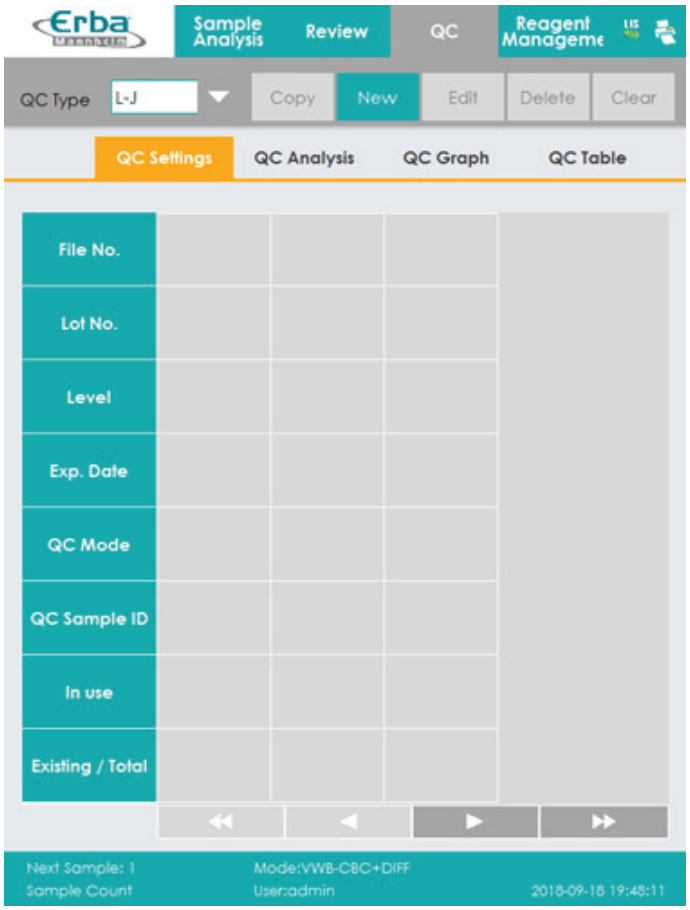


Figure 9-1 L-J Quality Control

3. Click the **New** button, or select a QC file (**Existing/Total** is **0/500**) without QC counting results and click the **Edit** button.

The interface as shown in Figure 9-2 will pop up on the screen.



Figure 9-2 Entering QC Information

You can also select the QC file of which data has been set and then click **Copy**, and edit the content based on the original data.

4. Set related information of the controls with reference to Table 9-1.

Table 9-1 QC File Information

Parameter	Parameter Description	Operation Description
File No.	QC file No.. The system provides 60 QC files in total for users to set the parameters.	Read only.
Lot No.	Lot number of controls.	Enter into the textbox directly. **NOTE** The lot No. cannot be empty and up to 16 digits can be entered. You can enter characters, numbers, letters and special characters, but no Chinese characters are allowed.
Level	Level of the controls, including 3 levels, i.e. High, Normal and Low.	Select from the dropdown list.
Exp. Date	Exp. date of the controls.	The default Exp. Date is the current system date and needs to be changed to the actual Exp. date of the controls.

Parameter	Parameter Description	Operation Description
QC Mode	QC mode of the controls, including **Whole Blood** and **Predilute**.	Select from the dropdown list.
QC Sample ID	Number of the QC sample • Users need to set the number of the controls here if he/she is used to performing the analysis with the controls placed among the daily samples. See section 9.2.3.2 **Completing QC Analysis in the Sample Analysis Interface**. • If the user performs the analysis in the **QC Analysis** interface, the ID cannot be entered.	Enter into the textbox directly. **NOTE** Letters, numbers and all characters that can be entered through the keyboard (including special characters) are allowed for the Sample ID. Chinese and other languages (such as Japanese, Korean, etc.) are not supported. The length of the entries ranges from 1 to 25 and the entries shall not be empty. The last character of a sample ID must be numeric, but a string of "0" only is not an acceptable sample ID.
Target	Target of the QC parameter.	Enter the targets in the cell corresponding to the expected QC parameter according to the control target list with the corresponding lot No. **NOTE** You can also click Get Preset Values button to read the saved preset target and limits (corresponding to the current level) into the current QC file. Please refer to 9.2.4.1 QC Graph for calculation and saving of the preset values.
Limits (#)	Limits (#) of the QC parameter.	Enter the limits in the cell corresponding to the expected QC parameter according to the control target list with the corresponding lot No. **NOTE** You can click Set Limits to set the display form of the limits or the calculation method of the limits among the pre-set values. By SD: the limits displays in form of absolute value. Click 2SD or 3SD to select either double or triple standard deviation to be the limits. By CV: the limits displays in form of percentage. Click 2CV or 3CV to select either double or triple coefficient of variation to be the limits.

Parameter	Parameter Description	Operation Description
In use	Set if you want to specify the QC sample ID in the selected file so that you can run the QC sample in the interface other than the QC interface. • If it's checked, you can run the sample with the corresponding sample ID in any interface and the system will run the QC analysis for this sample. • If it's not checked, you can only run the QC sample in the QC interface.	It's unchecked by default. Set the parameter according to the actual situation.
Existing/Total	The existing data and total QC results in the current QC file. Up to 500 QC results can be saved for each QC file.	Read only.

5. According to the target list of the corresponding lot No., enter the target and limits into the textboxes of the parameters to be included in the QC run.
6. Click the **Save** button to save all the settings of the QC.

9.2.2.2 Deleting QC Files

If you want to delete the QC files which will not be used any more, please take the following steps:

1. Click **QC** to access the **QC** interface.
2. Click **QC Settings** to enter the **QC Settings** interface.
3. Select the QC file to be deleted, and click **Delete**.
4. Click **Yes**.

All selected QC files together with their QC results will be completely deleted.

9.2.2.3 Clearing QC results

If you want to delete QC results of a specified file, please take the following steps:

1. Click **QC** to access the **QC** interface.
2. Click **QC** Settings to enter the **QC Settings** interface.
3. Select the QC file in which the QC results are expected to be cleared, and click **Clear**.
4. Click **Yes**.

QC results in the selected QC file will be deleted. See the Figure 9-3. The value in the **Existing/Total** line will be restored to the initial value.

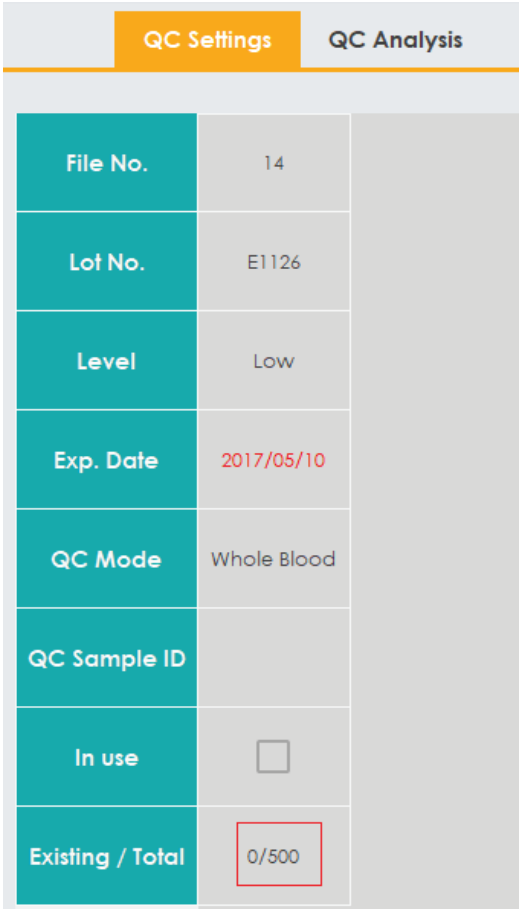


Figure 9-3 Clearing QC results

9.2.3 Quality Control Analysis

After completing the QC settings, you can choose one of the following two modes according to the selected QC mode to run the quality control samples.

- Completing QC analysis in the **QC Analysis** interface
- Completing QC analysis in the **Sample Analysis** interface

9.2.3.1 Completing QC Analysis in the QC Analysis Interface

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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

WARNING

The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.

The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.

Collection tubes broken may cause personal injury and/or biohazard. Be sure to



place the collection tubes in the right adapter before running, otherwise, the collection tubes may be broken and cause biohazard.
Keep your clothes, hairs and hands away from the moving parts to avoid injury.
Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.



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

NOTE

You should only use the Erba Lachema-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents. Using other controls may lead to incorrect QC results.
Before being used for analysis shake well the controls that have been settled for a while.
Be sure to use the Erba Lachema -specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.

After completing the QC settings, users can perform the QC analysis in the **QC Analysis** interface. Detailed steps are shown below:

1. Click **QC** to access the **QC** interface.
2. Click **QC Analysis** and enter the QC analysis interface as shown in Figure 9-4.

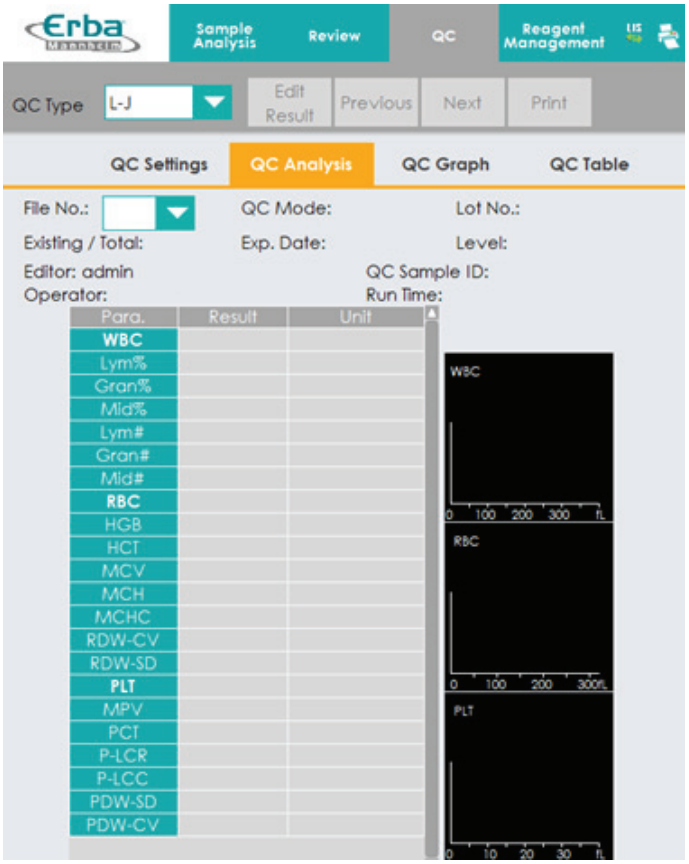


Figure 9-4 QC Analysis

3. Select the QC file No. to be run.
   The screen displays the corresponding file information, as shown in Figure 9-5

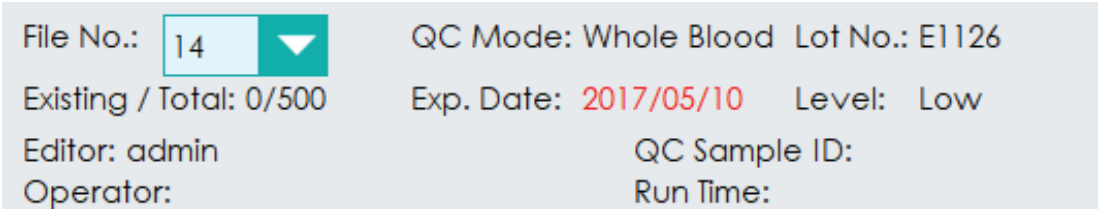


Figure 9-5 QC File Information

4. Be sure that the level of the control to be run is the same with the current QC file, and the control to be run is not expired.
5. Prepare the controls according to the set control mode and control instructions.
   Predilute the controls with reference to **6.5 Sample Collection and Handling** and get diluted QC samples if the QC mode is **Predilute**.

NOTE Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

6. Shake the prepared control as shown in Figure 9-6 to mix it well.

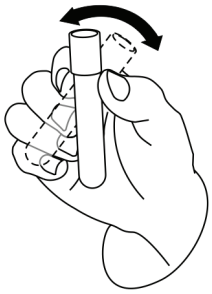


Figure 9-6 Mixing the Controls

7. In the ready for counting state (namely, the indicator light of the main unit is green), place the controls under the sample probe where the probe can aspirate the well-mixed controls.
8. Press the aspirate key and start running the controls.
9. Upon the completion of the aspiration, you'll hear a beep and you can remove the controls.
10. When the running of QC analysis is complete, the QC results will be displayed in the current screen (as shown in Figure 9-7) and saved in the QC file automatically.

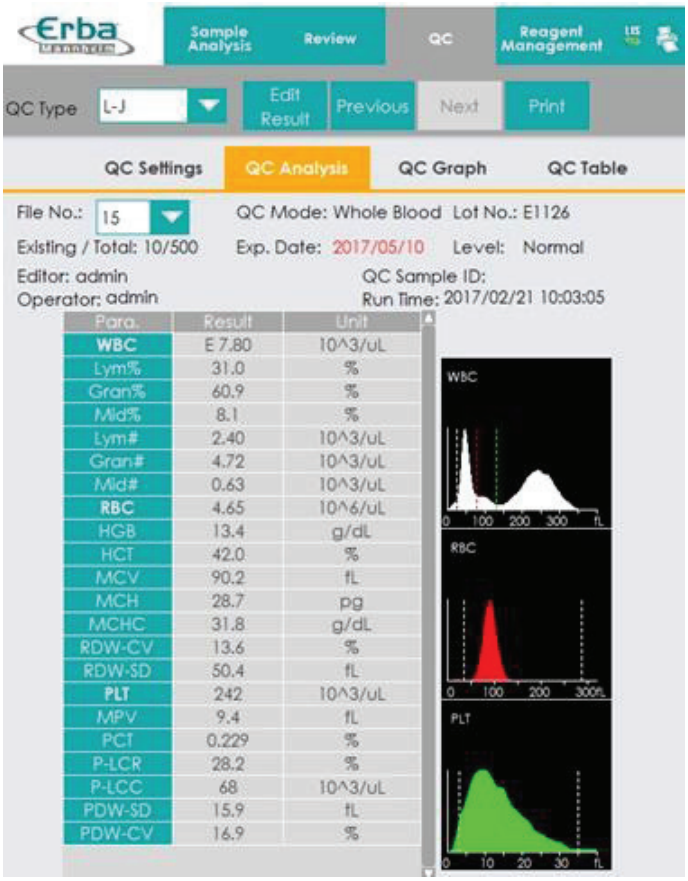


Figure 9-7 QC Analysis Results

11. Perform the above procedures to continue running the controls if necessary.

NOTE If the QC file is outdated, its valid period will be displayed in red.
"↑" or "↓" alarm symbol will be displayed next to the results with deviations exceeding the set limits.

9.2.3.2 Completing QC Analysis in the Sample Analysis Interface



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.



WARNING

The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.

The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.

Collection tubes broken may cause personal injury and/or biohazard. Be sure to place the collection tubes in the right adapter before running, otherwise, the collection tubes may be broken and cause biohazard.

Keep your clothes, hairs and hands away from the moving parts to avoid injury.

Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.

If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.



CAUTION

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.

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

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.

NOTE

You should only use the Erba Lachema-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents. Using other controls may lead to incorrect QC results.

Before being used for analysis shake well the controls that have been settled for a while.

Be sure to use the Erba Lachema -specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.

After completing the QC settings, you can place the controls among the daily samples and perform analysis together in the **Sample Analysis** interface. After the analysis is completed, the system will store the results to the QC file with the corresponding ID.

Specific steps for performing QC analysis in the Sample Analysis interface are as follows:

1. Prepare the controls according to the set control mode and control instructions. Predilute the controls with reference to **6.5 Sample Collection and Handling** and get diluted QC samples if the QC mode is **Predilute**.
2. Click **Mode & ID** in the Sample Analysis screen.

The interface pops up a dialog box as in Figure 9-8.

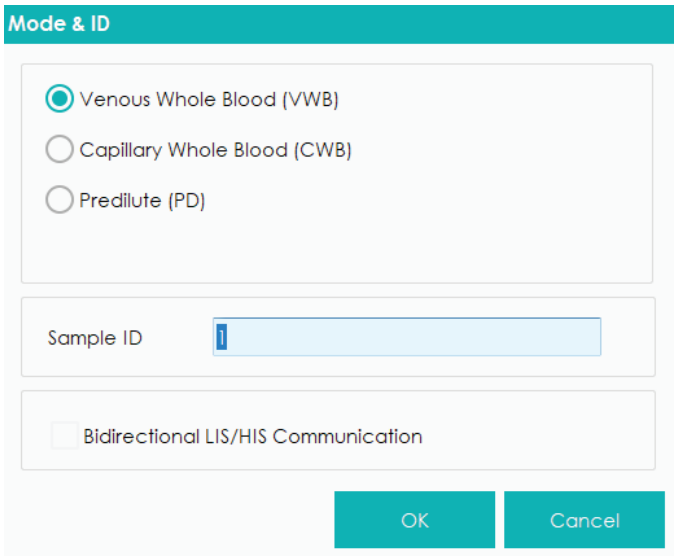


Figure 9-8 Set up mode and ID of the sample

3. Enter the set QC Sample ID in the **Sample ID** edit box (other options can be ignored).

Refer to **9.2.2.1 Entering QC** Information for the setting of the QC Sample ID.

4. Well mix the prepared controls.
5. In the ready for counting state (namely, the indicator light of the main unit is green), place the controls under the sample probe where the probe can aspirate the well-mixed controls.
6. Press the aspirate key and start running the controls.
7. Upon the completion of the aspiration, you'll hear a beep and you can remove the controls.

When the running of the controls is complete, the QC results will be saved in the QC file automatically.

8. Perform the above procedures to continue running the controls if necessary.

NOTE If the QC file is outdated, its valid period will be displayed in red.
"↑" or "↓" alarm symbol will be displayed next to the results with deviations exceeding the set limits.

9.2.3.3 Edit Result

Clicking **Edit** will allow you to edit the QC analysis result after the QC analysis is performed. See Figure 9-9.



Figure 9-9 Editing QC Results

The edited data will be marked with an **E** by the result.

Para.	Result	Unit
WBC	E 7.80	10^3/uL
Lym%	31.0	%

Figure 9-10 Editing QC Results

9.2.4 QC Result Review

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

- QC Graph
- QC Table

9.2.4.1 Graph

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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

You can review the result of L-J QC graph as per the following steps.

1. Click **QC** to access the QC interface.
2. Click **QC** Graph to enter the interface as shown in Figure 9-11.

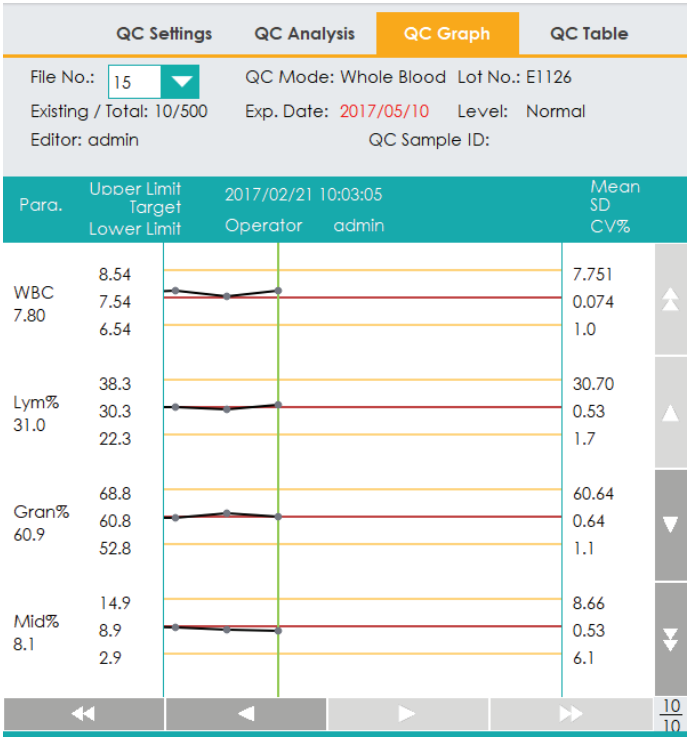


Figure 9-11 L-J QC Graph Interface

3. Select the QC **File No.** you want to review.

The screen will display the corresponding information and the graph.

4. Click the buttons at the right side of the QC graph, then you can browse QC graphs of different parameters; click the buttons at the bottom of the QC graph, then you can browse all QC results.

Introduction to the Graph Interface in Figure 9-12.



Figure 9-12 L-J QC Graph Interface

Interface Description:

1. The Mean, SD and CV% of all the QC results of each parameter in the current graph.
2. The saving date and time of the QC points located on the green line.

3. The operator who run the QC analysis and obtained the QC points located on the green line.
4. The QC results of the parameters that correspond to the QC points located on the green line.
5. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest. The QC points are connected by a line to illustrate the distribution trend.
6. The QC point corresponds to each QC result. Only the selected QC point displays its value under the parameter. The black QC point indicates the value is within the limit; the red QC point indicates the value is out of the limit.
7. When you clicking a QC point in the graph, the QC points of other parameters saved together with this one will be marked by a green line.
8. The relative position of the QC point located on the grey line and the total QC points saved currently.

NOTE The outliers are excluded from the calculation of Mean, SD and CV%.

Calculate Preset Values/Save Preset Values

If the QC file of the QC graph has 3 groups or more of valid data, the administrator can take the followings steps to calculate and save the preset values of the QC parameters.

NOTE If the valid data (without "*") in the QC file are less than 3 groups, the default value cannot be calculated.

1. Click **Cal Preset Values**.
   The screen will display two black lines for you to select the range for calculating the preset values.
2. Click and drag the two lines respectively to place them at the beginning and the ending of the range for calculating the preset values.
   The Mean, SD and CV% (on the right of the graph) will change into the new results obtained by calculating the selected range.
3. Click **Save Preset Values** to save the current Mean, SD and CV% as the preset values for the corresponding level (high/normal/low).
   Then, the two selecting lines will disappear and the Mean, SD and CV% will return to the calculated results of all QC results.

- **Delete**

The administrator can delete the QC results by the following steps:

- Delete a single QC result
  1. Move the green line to the desired QC result, and click **Delete**.
  2. Select **Current Data** in the pop-up dialog box.
  3. Click **OK**.
- Deleting all the QC results in the current QC file
  1. Click **Delete**.
  2. Select **All Data** in the pop-up dialog box.
  3. Click **OK**.
- Entering the Reasons for the **Outliers**
  Do as follows to enter the reasons for the outliers:

1. Move the green line to the desired QC point, and then click Outliers.

The pop-up window displays the QC results, reference values and deviation limits of all parameters corresponding to the green line as shown in Figure 9-13 .

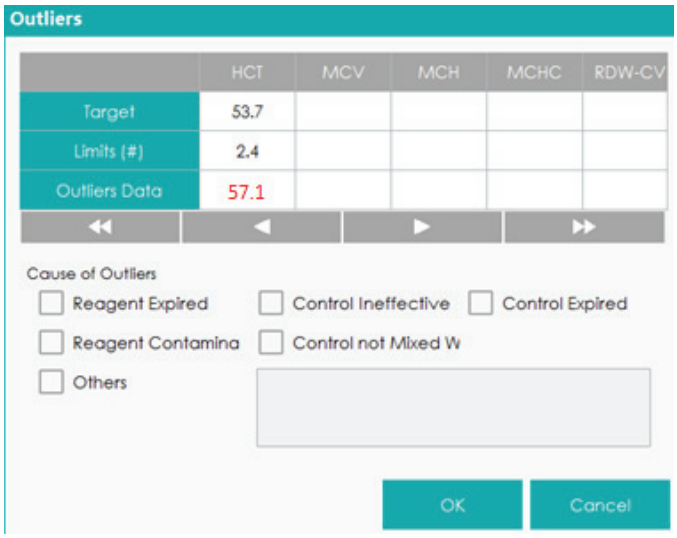


Figure 9-13 Enter Cause of Outliers

The QC results exceeding the limit will be displayed in red.

2. You can select the reason from the given ones or manually enter the reasons (up to 200 characters) into the textbox after selecting **Others**.
3. Click **OK** to save the reasons for the outliers and exit.

NOTE If you enter the reason for the group of QC points whose results are actually within the limits, then their corresponding QC data both in the QC Graph and QC Table will be displayed in red. And the data will return in black if you cancel the reason and then save the changes.

- **Print**

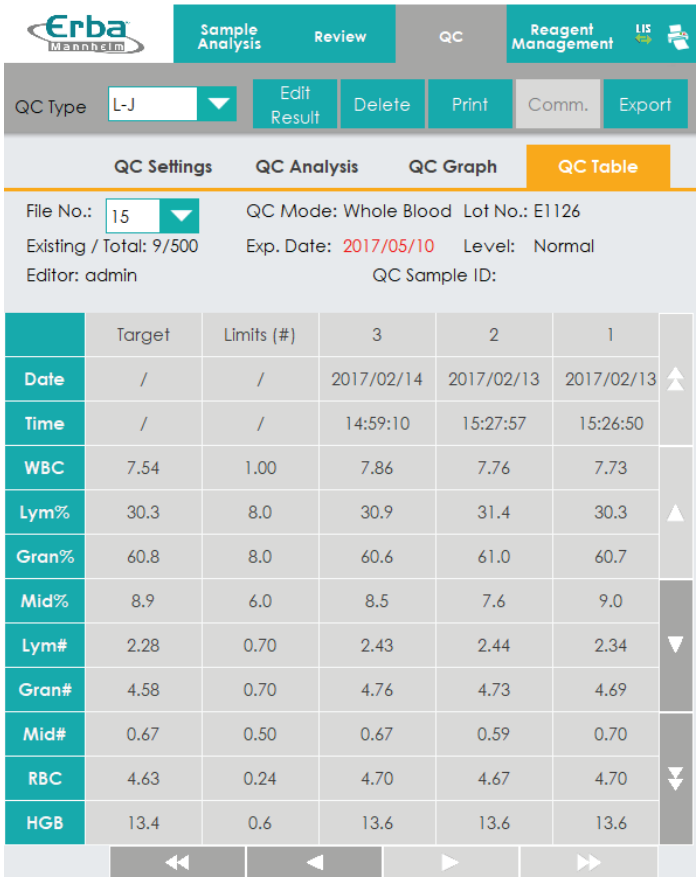
You can have the QC data of the current page or all QC data in the QC file printed by clicking the **Print** button.

NOTE The printed QC graph will not show any parameters which are not involved in the quality control.

9.2.4.2 Table

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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

1. Click QC to access the QC interface.
2. Click QC Table to access the interface as shown in Figure 9-14.



	Target	Limits (#)	3	2	1
Date	/	/	2017/02/14	2017/02/13	2017/02/13
Time	/	/	14:59:10	15:27:57	15:26:50
WBC	7.54	1.00	7.86	7.76	7.73
Lym%	30.3	8.0	30.9	31.4	30.3
Gran%	60.8	8.0	60.6	61.0	60.7
Mid%	8.9	6.0	8.5	7.6	9.0
Lym#	2.28	0.70	2.43	2.44	2.34
Gran#	4.58	0.70	4.76	4.73	4.69
Mid#	0.67	0.50	0.67	0.59	0.70
RBC	4.63	0.24	4.70	4.67	4.70
HGB	13.4	0.6	13.6	13.6	13.6

Figure 9-14 L-J QC Graph Interface

3. Select the QC **File No.** you want to review.

- **Editing**

Choose a row in the QC table and click **Edit**, then you can edit the selected QC data.
The edited data will be marked with an **E**.

- **Delete**

With the administrator-level access, users can delete the selected QC data, QC data on the current page and all QC data.

- Delete a selected QC result
  1. Click the column containing the desired QC result, and then click **Delete**.
  2. Select **Current Data** in the pop-up dialog box.
  3. Click **OK**.
- Delete QC data on the current page
  1. Click **Delete** on the page which contains the QC results expected to be deleted.
  2. Select **Current Page Data** in the pop-up dialog box.
  3. Click **OK**.
- Delete all QC results
  1. Click **Delete**.

2. Select **All Data** in the pop-up dialog box.
3. Click **OK**.
4. Click **Yes** to delete all the QC results in the current QC file.

- **Print**

You can print all the QC data or the data within the specified date range of the selected QC file. Detailed steps are shown below:

1. Select a QC File No. to be printed.
2. Click **Print**.
3. Select the QC data to be printed: all data or specified data.

   When **All Date** is selected, all the QC data of the table will be printed.

   When **Specified Data** is selected, and the date range is set in the date controls, the QC data within the specified date range will be printed.
4. Click **OK** to print the data.

- **Communication**

The current QC data, the data within the specified date range or all the QC data can be transmitted to LIS/HIS.

- Communication for current data
  1. Select a QC record to be transmitted, and click **Comm**.
  2. The default option is **Current Data**.
  3. Click **OK**.
  4. Click **OK** to close the message box.
- Communication for all data
  1. Click **Comm.**.
  2. Select **All Data**.
  3. Click **OK**.
  4. Click **OK** to close the message box.
- Transmitting the data within specified date range
  1. Click **Comm.**.
  2. Select **Records of the Specified Dates**, and set the starting and ending dates for the data to be communicated.
  3. Click **OK**.
  4. Click **OK** to close the message box.

- **Export**

If you wish to export the information and the result of the current QC file, do as follows:

1. Insert a USB flash disk in the USB interface on the analyser.
2. Click **Export**.
3. Select an export path for the data and enter the file name.

The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.**csv**. Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.

4. Click **Save**. When the export is finished, a message box will pop up.
5. Click **OK** to close the message box.

9.3 X-B Quality Control

9.3.1 QC Principle

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 haematology 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 analyser 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 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. 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 analyser 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 analyser counting, with no distinction of whole-blood or predilute mode. The analyser can save maximum 500 X-B QC results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest.

9.3.2 QC Settings



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

NOTE Only users with administrator-level access can edit the L-J settings.

Perform the QC Settings before running the controls. You can complete the QC settings by entering the QC information.

9.3.2.1 Entering QC Information

You can complete the X-B QC settings as per the following steps:

1. Click **QC** to access the **QC** interface.
2. Select **X-B** from the dropdown list of the **QC Type**.
3. Click **QC Settings**. You'll enter the **QC Settings** interface as shown in Figure 9-15.

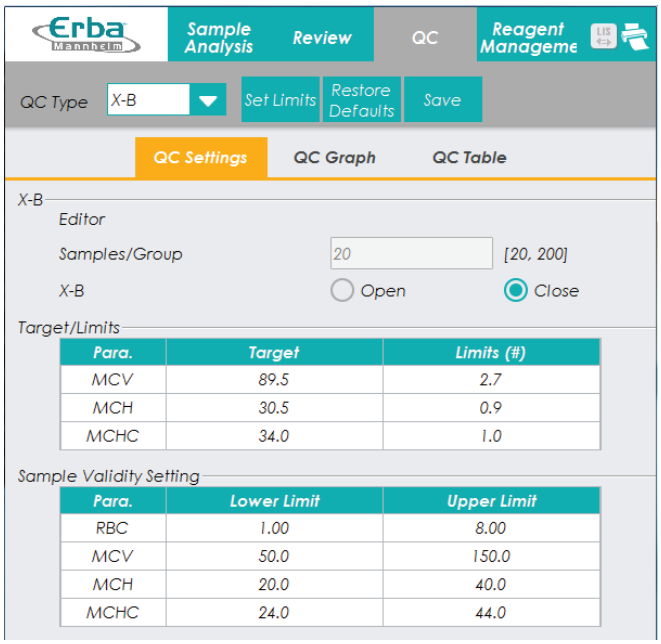


Figure 9-15 X-B QC Settings

4. In the **Samples/Group** edit box, enter 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.

NOTE

Once the **Samples/Group** is changed, the number of valid sample results will be re-calculated. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the value of **Samples/Group** after 10 group of valid sample results have been acquired, these 10 group of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.

5. Click the **Open** button of **X-B** to open the X-B quality control. The samples results will be included to calculate the X-B.
6. Enter the targets and limits for the QC parameters.

NOTE

All the targets and limits for the QC parameters must be entered.
When first use, the default setting will provide the Initial values for the targets and limits of the three QC parameters.
If the QC data have existed in the QC file, you are not allowed to edit the target and limits.

You can set the display form of the limits or the calculation method of the limits among the preset values. See section **9.3.2.2 Setting Limits**.

7. Set the valid upper and lower limits for the QC parameter in **Sample Validity Setting** field. 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.
8. Click the **Save** button to save all the settings of the QC.
   If the entered value exceeds the acceptable range or the upper limit is lower than the lower limit, a reminder message will pop up and you will be prompted to re-enter the correct data and save the entry again.

9.3.2.2 Setting Limits

You can take the following steps to adjust the display format of the limits and the calculation method of the pre-set limits.

1. Click **Set Limits**. The interface pops up a dialog box as in Figure 9-16 .

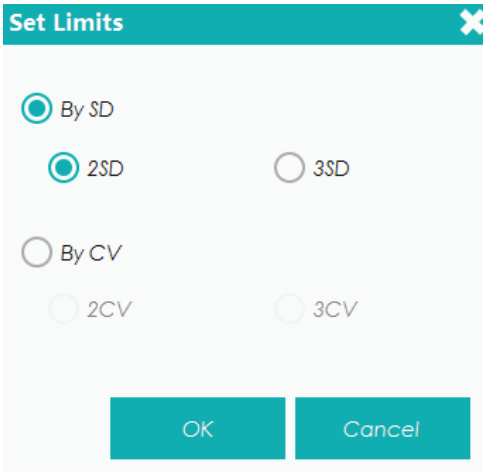


Figure 9-16 Set limits for X-B QC

2. Select **By SD** or **By CV** according to the actual needs.
   - If **By SD** is selected, the limits will be displayed in form of absolute value.
     Click **2SD** or **3SD** to select either double or triple standard deviation to be the limits.
   - If **By CV** is selected, the limits will be displayed in form of percentage.
     Click **2CV** or **3CV** to select either double or triple coefficient of variation to be the limits.
3. Click **OK** to save all the settings for the limits.

9.3.2.3 Restoring Defaults

In QC setting, click **Restores Defaults** button to restore the parameter reference values, limits and sample validity to the default settings.

NOTE If the QC data have existed in the QC file, you are not allowed to restore the parameters. Clicking Restores Defaults can only store the default settings of Target, Limits and Sample Validity Setting, while Samples/Group, X-B QC switch and limit settings cannot be restored.

9.3.3 Quality Control Analysis

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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

After the QC settings, the analyser will automatically start the X-B QC analysis.
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 graph or X-B table.

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.
Sample results exceeding the linearity range

- Background results
- Sample results not conforming to the **Sample Validity Setting**
- QC data for other QC programs (such as L-J QC)
- Calibration data
- Results generated while there are errors which could affect the accuracy of the results (insufficient aspiration volume or clogging for example).

9.3.4 QC Result Review

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

- QC Graph
- QC Table

9.3.4.1 QC Graph



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

Access the X-B QC Graph interface by taking the following steps:

1. Click **QC** to access the **QC** interface.
2. Select **X-B** from the dropdown list of the **QC Type**.
3. Click **Graph**.

The X-B QC Graph interface will be displayed. See Figure 9-17.

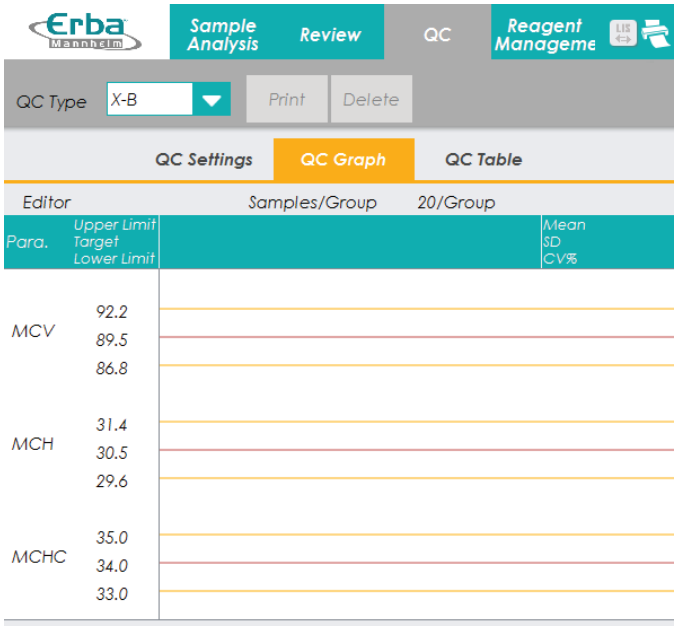


Figure 9-17 QC Graph

4. You can also drag the scroll bar down to the graph horizontally to browse all the QC results. Introduction to the Graph Interface in Figure 9-18.

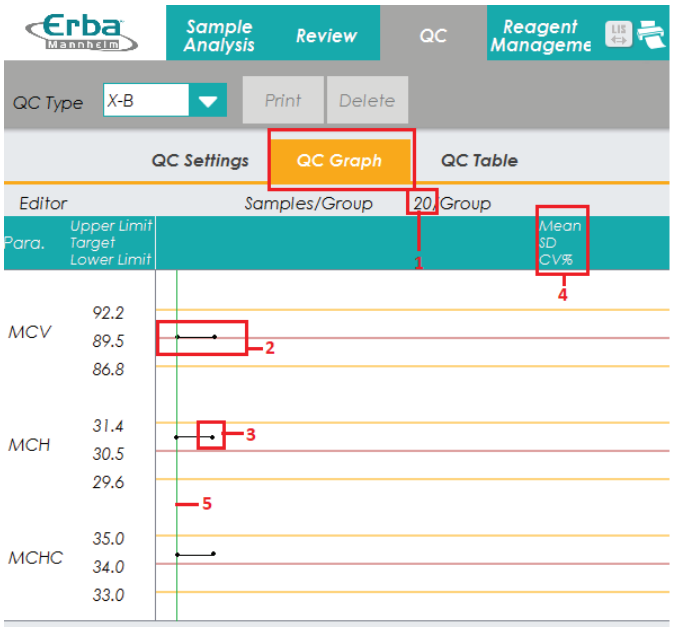


Figure 9-18 X-B QC Graph

1. The amount of samples included in calculating for each QC point.
2. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest. The QC points are connected by a line to illustrate the distribution trend.
3. The QC point corresponds to each QC result. Only the selected QC point displays its value under the parameter. The black QC point indicates the value is within the limit; the red QC point indicates the value is out of the limit.
4. The Mean, SD and CV% of all the QC results of each parameter in the current graph.
5. When you clicking a QC point in the graph, the QC points of other parameters saved together with this one will be marked by a green line.

- **Delete**

The administrator can delete the QC results by the following steps:

1. Delete a single QC result
2. Move the green line to the desired QC result, and click **Delete**.
3. Select **Current Data** in the pop-up dialog box.
4. Click **OK**.

- Deleting all the QC results in the current QC file
  1. Click **Delete**
  2. Select **All Data** in the pop-up dialog box
  3. Click **OK**.
- **Print**

Click the **Print** button to print the QC graph.

9.3.4.2 Table

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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

Access the X-B QC Graph interface by taking the following steps:

1. Click **QC** to access the **QC** interface.
2. Select **X-B** from the dropdown list of the **QC Type**.
3. Click **QC Table**.

The X-B QC table interface will be displayed. See Figure 9-19.

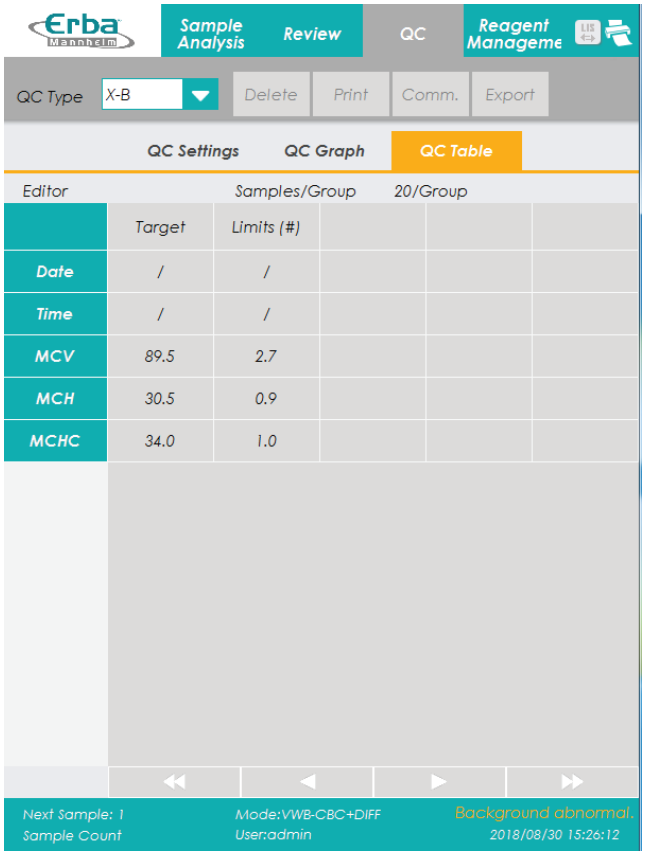


Figure 9-19 QC Table

- **Delete**

With the administrator-level access, users can delete the selected QC data, QC data on the current page and all QC data.

- Delete a selected QC result
  1. Click the column containing the desired QC result, and then click **Delete**.
  2. Select Current Data in the pop-up dialog box.
  3. Click **OK**.
- Delete QC data on the current page
  1. Click **Delete** on the page which contains the QC results expected to be deleted.
  2. Select **Current Page Data** in the pop-up dialog box.
  3. Click **OK**.

- Delete all QC results
  1. Click **Delete**.
  2. Select **All Data** in the pop-up dialog box.
  3. Click **OK**.
  4. Click **Yes** to delete all the QC results in the current QC file.
- **Print**

You can print all the QC data or the data within the specified date range of the selected QC file. Detailed steps are shown below:

1. Select a QC file No. to be printed.
2. Click **Print**.
3. Select the QC data to be printed: all data or specified data.
   - When **All Date** is selected, all the QC data of the table will be printed.
   - When **Specified Data** is selected, and the date range is set in the date controls, the QC data within the specified date range will be printed.
4. Click **OK** to print the data.

- **Communication**

The current QC data, the data within the specified date range or all the QC data can be transmitted to LIS/HIS.

- Communication for current data
  1. Select a QC record to be transmitted, and click **Comm.**
  2. The default option is **Current Data**.
  3. Click **OK**.
  4. Click **OK** to close the message box.
- Communication for all data
  1. Click **Comm.**
  2. Select **All Data**.
  3. Click **OK**. After the data is transmitted to LIS/HIS, a message box will pop up.
  4. Click **OK** to close the message box.
- Transmitting the data within specified date range
  1. Click **Comm.**
  2. Select **Records of the Specified Dates**, and set the starting and ending dates for the data to be communicated.
  3. Click **OK**. After the data is transmitted to LIS/HIS, a message box will pop up.
  4. Click **OK** to close the message box.
- **Export**

If you wish to export the information and the result of the current QC file, do as follows:

1. Insert a USB flash disk in the USB interface on the analyser.
2. Click **Export**.
3. Select an export path for the data and enter the file name.

   The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo**_*yyyyMMdd_hhmmss*.**csv**. Among which, *yyyyMMdd_hhmmss* means data export year, month, date, hour, minute, and second.
4. Click **Save**. When the export is finished, a message box will pop up.
5. Click **OK** to close the message box.

10 Calibration

10.1 Introduction

Calibration is a procedure to standardize the analyser by determining its deviation, if any, from calibration references and to apply any necessary correction factors. To get accurate blood analysis results, perform calibration of the analyser following the procedures given in this chapter when it's needed.

NOTE

Calibration procedures can only be performed by users with the administrator-level access. The login users with the access level of general users cannot perform the calibration procedures but only browse the calibration coefficients.
You should only use the Erba Lachema-specified calibrators and reagents. Store and use the calibrator and reagents following the instructions for use of the calibrations and reagents.
The analyser identifies a sample as a calibration sample only if the analysis is started from the Cal interface.
The calculation of repeatability is included in the calibration procedure.

10.2 When to Calibrate

This analyser 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 need to recalibrate this analyser if:
It is the first time this analyser has been used (usually done by an Erba Lachema-authorized representative when installing the analyser).
An analytical component has been changed.
The quality control results indicate that there may be a problem.
The operating environment (such as the temperature) has changed significantly.

NOTE

All of the measured parameters must be calibrated before readings of this analyser can be used as valid analysis results.
For laboratories conducting routine tests, the calibration should be applied at least once every six months.

10.3 How to Calibrate

There are three calibration programs available on this analyser: manual calibration, auto calibration using calibrators and auto calibration using fresh blood samples.
All or part of the parameters of WBC, RBC, HGB, MCV and PLT can be calibrated by the calibration procedure.

10.3.1 Preparation



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.



WARNING
The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.
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 local legislations and regulations.



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

NOTE

You should only use the Erba Lachema-specified controls and reagents. Store and use the controls and reagents by following the instructions for use of the controls and reagents.
Be sure to use the Erba Lachema -specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.

Carry out the calibration only when the background range, repeatability and carryover are within the specified limits given in the manual, otherwise, the problems must be identified and solved before you determine if calibration is needed. If you cannot solve the problems, please contact Erba Lachema Service Department.

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. Do the background check.
   If the analyser alarms are activated for abnormal background results, see **13 Troubleshooting** for solutions.(Refer to **15.4.2. Normal Background** for background range.)
3. Do the repeatability test.
   Run the median controls in whole blood-CBC+DIFF mode consecutively for 11 times.
   Take and view repeatability of the counting results from the 2nd run through the 11th run in the **Review** interface and make sure they are within the range specified in **15.4.4 Repeatability**.
4. Do the carryover test.
   Run the corresponding diluent for 3 times immediately after running the high-level controls for 3 times. Calculate the carryover by the following formulas:

$$\text{Carryover (\%)} = \frac{\text{First low-value sample result} - \text{Third low-level sample result}}{\text{Third high-value sample result} - \text{Third low-level sample result}} \times 100\%$$

   The calculated carryovers shall meet the requirements in **15.4.5 Carryover**.
5. It is recommended that you create a log table for your analyser. The 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.

10.3.2 Manual Calibration

Complete the manual calibration as per the following procedure:

1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Manual** to access the manual calibration interface. See Figure 10-1. The calibration coefficients of whole blood mode and predilute mode are displayed on the Manual interface.

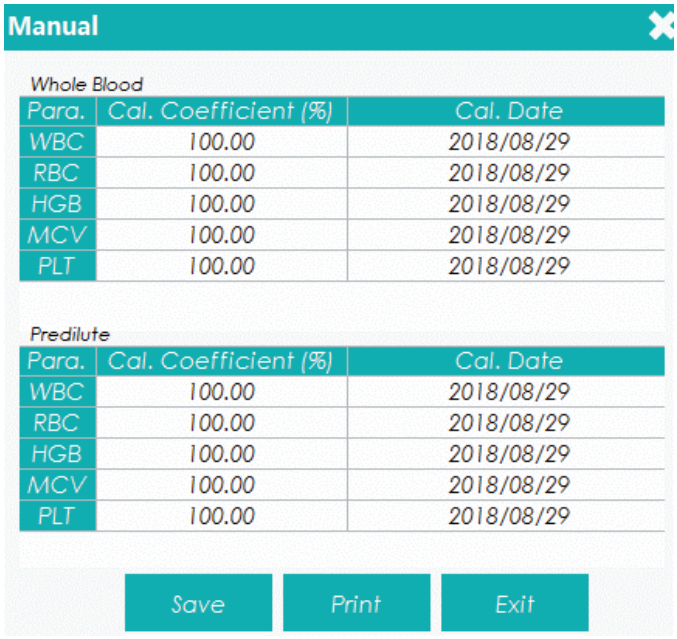


Figure 10-1 Manual Calibration

3. Check the calibration coefficient and calculate the new coefficient using the following equation.

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

For example, the WBC reference value of a calibrator is 8.3, and the current calibration coefficient of the whole blood mode is 99.00%.

Run the calibrator in whole blood mode for 11 consecutive times and calculate the WBC results of the 2nd to 11th runs (n=10):The obtained CV is 1.1% and the Mean is 8.22, which meet the requirements.

The new calibration coeftficient is obtained:

$$\text{New calibration factor} = \frac{99.00\% \times 8.3}{8.22} = 99.96\%$$

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 material not thoroughly mixed, incorrect operation, etc.).Then recalibrate the analyser and recalculate the calibration coefficients.

4. Enter the new calibration coefficients into the factor cell of the parameter that requires calibration.

NOTE The entered calibration coefficients shall be between 75.0%~125.0% (calculation results rounded to two decimal places).

5. Click **Save**.

On the screen, the calibration coefficient is refreshed to be the new one and the calibration date is refreshed to be the current system date.

- If the new calibration coefficients are invalid, the message box will pop up. Click **OK** to close the message box and enter a valid factor.

6. (Optional) Click **Print** to print the current calibration coefficient.
7. Click **Exit** to close the Manual interface.

10.3.3 Auto Calibration Using Calibrators



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

NOTE Only Erba Lachema-specified calibrators shall be used. Erba Lachema will not be responsible for any erroneous result caused by using other calibrators.
See the instructions for use of the calibrators for the lot No., Exp. Date and the target.

Complete the calibration with calibrators as per the following procedure:

1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Calibrator**. The **Calibrator** interface pops up as shown in Figure 10-2.

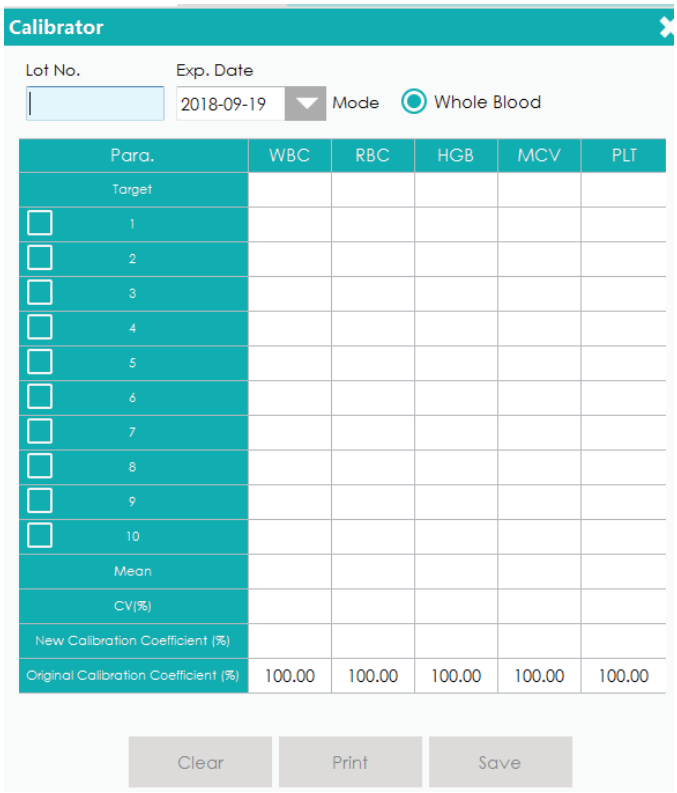


Figure 10-2 Auto Calibration Using Calibrators

3. Enter the lot No. of the calibrator into the **Lot No.** box.
4. Click the **Exp. Date** box, and then edit the **Exp. Date**.

NOTE

The **Exp. Date** can be no earlier than the current system date.
The entered **Exp. Date** should be either the **Exp. Date** printed on the labelling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date on which the container is opened + the open-container stability days.

5. Input the target values of the parameters in the corresponding cell of the Target.
6. Prepare the calibrators following their instructions for use and place the calibrators under the sampling probe.
7. Press the aspirate key to start the calibration counting.
   After every calibration run, the progress bar will close automatically and the analyser will have different responses according to different analysis 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 display range or linearity range of the parameter, a message box will pop up on the screen prompting that the calibration data is invalid.
8. Click **OK** to close the message box and delete the data from the table without saving.
   If any of the parameter's value in the calibration counting differs from the Target value by more than 50%, the system will prompt you with a message box asking if the calibration counting results should be kept. To keep the results, click **Yes**; to remove the results, click **No**.

NOTE After the valid calibration result is obtained, the parameters with corresponding checkboxes ticked off will be involved in the calculation of the calibration coefficients by default.
If you switch to other interfaces before the new calibration coefficients are obtained, the system will discard the current calibration data and keep the original calibration coefficients.

9. To get 10 valid counting results, repeat steps Prepare the calibrators following their instructions for use and place the calibrators under the sampling probe.~Press the aspirate key to start the calibration counting. ten times.
   The analyser will, by default, calculate the Mean, CV% and the new calibration coefficients based on all the ticked-off calibration data according to the formulae.
10. Select at least 5 groups of data for the calculation of the calibration coefficients.
    When the amount of the valid calibration data in the list reaches 10, a message box of **Calibrator calibration done!** will pop up. Click **OK** to close the message box.
    If the calibration coefficients are invalid, click **Yes** to close the dialog box. Then click **Clear** to delete the current data and redo the calibration.

NOTE The out-of-range CV% does not influence the display of the calibration coefficients.

11. Click **Save**.
    If the calculated calibration coefficients of all parameter are within the range of 75%~125% and the CV% of all parameter are also within the repeatability, then a dialog box prompting the successful calibration setting will pop up. Click **OK** to close the message box.
    If the obtained calibration coefficient of any parameter is not within the range of 75%~125% or the CV% of any calibrated parameter does not meet the repeatability, the calibration coefficient will not be saved and a dialog box indicating invalid new calibration coefficient will pop up. Click **Yes** to close the dialog box and repeat the calibration operations.
12. (Optional) Click **Print** to print the calibration results.

10.3.4 Auto Calibration Using Fresh Blood Samples



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 laboratory safety procedures when handling them and the relevant areas in the laboratory.

Complete the calibration using fresh blood samples as per the following procedure:
1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Fresh Blood**. The fresh blood sample calibration interface pop up, as shown in Figure 10-3.

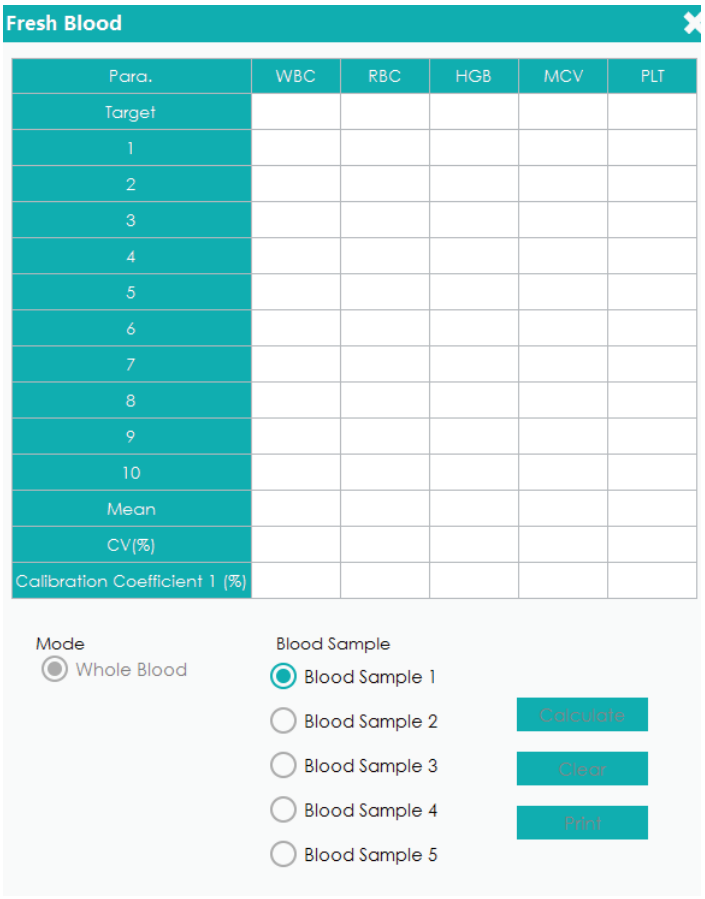


Figure 10-3 Auto Calibration Using Fresh Blood Samples

3. Prepare 3 to 5 normal fresh blood samples as instructed by **6.5 Sample Collection and Handling**.
4. Run each of the prepared samples on the reference instrument three times at least. Average the results for your reference values.

NOTE The reference instrument must be a properly running standard analyser so as to ensure the accuracy of the reference values.

5. Enter the reference values for the parameters to be calibrated in the corresponding **Target** textbox.
6. Place the blood sample under the sampling probe, press the aspirate key on the analyser to run the samples.
7. The system will calculate the values for WBC, RBC, HGB, MCV and PLT of the sample.
8. Repeat step Place the blood sample under the sampling probe, press the aspirate key on the analyser to run the samples for 10 times and calculate the counting results for sample No. 1 in the 10 runs.

   The system will calculate the Mean, CV and Calibration coefficient for each parameter of the sample. If the obtained calibration coefficient for any sample is not within the valid range or CV% or any calibrated parameters does not meet the repeatability, a dialog box indicating invalid new calibration coefficient will pop up. Click **Clear** to delete the calibration data of the sample. Redo the calibration or redo the calibration with another sample meeting all criteria.

9. Refer to steps f. and g. and perform the counting operations for the remaining four blood samples. The system will calculate the Mean, CV and Calibration Coefficient for each parameter of the remaining 4 blood samples.
10. Click **Calculate**.
    The system will calculate the average of the calibration coefficients, namely, the mean calibration coefficient (%), as the new calibration coefficient based on the five blood samples.
    You can also check at least three accurate calibration coefficients and the system will re-calculate the mean calibration coefficient (%).

NOTE The mean calibration coefficient is invalid if its absolute value of deviation from the original calibration coefficient is greater than or equal to 5%.

11. Click **Save**.
    If the mean calibration coefficient is within the valid range (the absolute value of deviation from the original calibration coefficient is less than 5%), you'll be prompted that the mean calibration coefficient is saved successfully.
    If the mean calibration coefficient is not within the valid range (the absolute value of deviation from the original calibration coefficient is greater than or equal to 5%), you'll be prompted that the mean calibration coefficient is invalid.

NOTE CV% out of standard will not affect the display of calibration coefficient.

12. (Optional) Click **Print** to print the calibration results.

10.4 Verifying Calibration Coefficients

It is recommended that you take the following steps to verify the calibration coefficients:

1. Run the calibrator at least three times and check whether the means of the obtained results are within the expected ranges.
2. Run the low-, normal- and high-level controls each for three times at least, and check whether the means of the obtained results are within the expected ranges.
3. Run at least three fresh blood samples with known reference values, each for six times at least, and check whether the means of the obtained results are within the expected ranges.

10.5 Calibration History

Click **Cal > History** to enter the calibration history screen. You can view the calibration history list and the detailed calibration data.

- **Calibration History List**
  The list shows the latest 100 calibration history records, including the following items:
  Date: The operating system date when the calibration coefficient is saved.
  Cal. Operator: The one who performs the calibration operations, such as the Admin.
  Calibration Method: Including **Manual**, **Calibrator** and **Fresh Blood**.
  Calibration Mode: The mode adopted for the calibration, including **Whole Blood** and **Predilute**.

Description: Supplementary description of the calibration information about the corresponding entries.

- **Detailed Calibration Data**
  Select any row of record in the Calibration History List to view the detailed calibration data of that record.
  If the calibration method of the selected record is Fresh Blood, you can click **Details**... next to each intermediate calibration record and view the detailed calibration data of each intermediate calibration record.
- **Print**
  You can click the **Print** button to print the calibration record.

11 Reagent Management

Once the new reagent is connected to the analyser, you can set the reagent configurations, including validity period, residue volume and reagent barcode on the Reagent Management interface. Upon the completion of reagent configuration, you can perform the procedures for reagent replacement.

WARNING
Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.

NOTE
After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
When you have changed the diluents, cleansers or lyses, run a background check to see if the results meet the requirement.

11.1 Accessing the Interface

Click **Reagent Management** in the menu navigation area, to access the reagent management setting interface. See Figure 11-1.



Figure 11-1 Reagent Management

Refer to Table 11-1 for related parameter descriptions.

Table 11-1 Parameter Description for Reagent Management

Parameter	NOTE
Reagent Name	Name of the reagent.
Exp. Date	Exp. Date of the unopened reagent will be shown upon the completion of the reagent settings. Any reagent, regardless of its container being opened or not, should not be used beyond this date.
Open-container Date	The date on which the reagent container is opened. The default open-container date is the date on which the reagent settings are completed.
Period after opening (PAO)	The validity period (days) after the reagent container is opened. It will be shown upon the completion of the reagent settings.
Open-container Exp. Date	Expiration date of the opened reagent, and it will be shown upon the completion of the reagent settings.
Residue Volume	The current residue volume of the reagent, and it will be shown in ml upon the completion of the reagent settings. The unit is ml.

11.2 Setting Reagent Information

Once the new reagent is connected to the analyser, you should set the reagent configurations, including validity period, residue volume and reagent barcode on the **Reagent Management** interface. Upon the completion of reagent configuration, you can perform the procedures for reagent replacement.

Taking **Insufficient Erba H360 Lyse** as an example, this section introduces the setting procedures for the closed reagent:

1. When the **Insufficient Erba H360 Lyse** is prompted on the lower right of the screen, double click the message.
2. Select the error name in the popup dialog box, and click **Remove Error**. A dialog box pops up.
3. Attach the RF card attached to the reagent packing on the RF card reader in front part of the analyzer and keep it for 3-4 seconds.
4. The beeping of the card reader and a pop-up dialog box indicate the successful reagent settings.
5. Click **OK**.

The RF card is intended for single use only.
If the verification fails, try to attach the card by front side back on the RF reader.
If the verification fails again, please follow the system prompts and use a valid RF card for re-reading.

NOTE Once the reagent settings are successfully completed, the system prompt at the lower right corner of the screen will show that the reagent has not been replaced. To remove this error, click the error message and then click **Remove Error** in the pop-up dialog box. The analyser will complete the replacement of the reagent and remove the error.

11.3 Replacing Reagents

After completing the reagent settings, you should perform the reagent replacement operations. You can select to replace one type of reagent at a time or all reagents. The method is applied as follows:

1. Select a type of reagent to be replaced, and click **Replace**; or click **Replace All** to replace all the reagents.
2. After the replacement is completed, a message box will pop up on the screen. Click **OK** to close the message box.

NOTE When you have changed the reagents, run a background check to see if the results meet the requirement.

12 Service

12.1 Introduction

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



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



CAUTION
Performing unauthorized maintenance procedures can damage your analyser. Do not perform any maintenance procedures that are not described in this chapter.
In case of problems not specified in this manual, contact Erba Lachema customer service department or your local agent for assistance.
Only Erba Lachema -supplied parts can be used for maintenance. For any question, contact Erba Lachema customer service department or your local agent.
Exercise caution to avoid contact with the sharp sample probe when performing maintenance.

12.2 Maintenance

The analyser provides multiple service functions helping users to perform daily maintenance.

12.2.1 Reagent Replacement



WARNING
Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.

NOTE

After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
When you have changed the diluents, cleansers or lyses, run a background check to see if the results meet the requirement.

You should replace the reagents when:

- The system indicates that the reagent is used up
- The suspicious flag indicates that the reagent in the pipeline is contaminated
- The reagent is contaminated or expired
- WBC or RBC bubbles are identified.

You can replace any of the following reagents:

- Erba H360 Dil
- Erba H360 Lyse

Do as follows to replace the reagents:

1. Refer to Figure 2-2 in **2.6.1 Electrical Connections** for reagent connections.
2. Click the **Service** icon in the menu page to access the Service interface as shown in Figure 12-1.

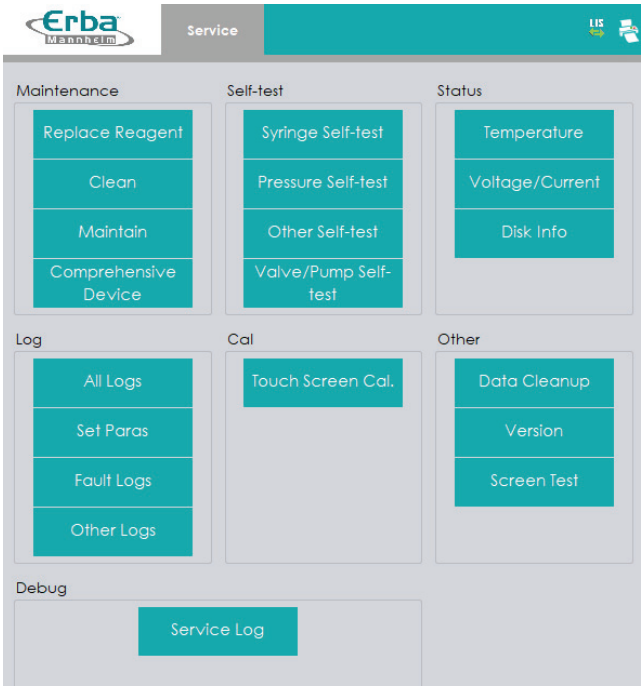


Figure 12-1 Service

3. Click **Replace Reagent** in the Maintenance selection. The interface as shown in Figure 12-2 will pop up on the screen.



Figure 12-2 Reagent Replacement

4. Click the name of the reagent that needs to be replaced, such as **Replace All Reagents**.
5. Click **OK** to close the message box.
6. Perform the above procedures to replace other reagents if necessary.

12.2.2 Cleaning

Clean corresponding parts according to the actual situation:

- Cleaning of WBC bath:
  - When the background of WBC- and/or HGB-specific parameters exceeds the reference range
- Cleaning of RBC bath:
  - When the background of RBC- and (or) PLT-specific parameters exceeds the reference range
- Cleaning of sample probe
  - When the sample probe is dirty

The cleaning procedures are as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Clean** in the **Maintenance** selection, an interface as shown in Figure 12-3 will pop up on the screen.

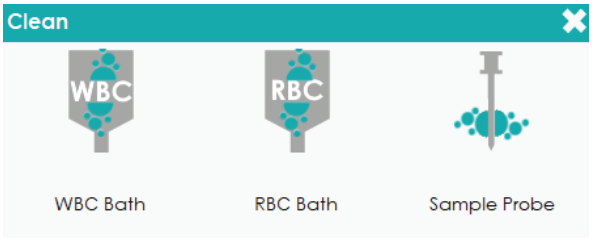


Figure 12-3 Cleaning

3. Click the icon of the part that needs to be cleaned, such as **Clean Sample Probe**.
4. When the system cleaning is complete, the message box will pop up to show that the cleaning is done.
5. Click **OK** to close the message box.
6. Perform the above procedures to clean other components if necessary.

12.3.3 Maintenance

Maintenance of the analyser includes unclog and cleanser soak.

12.2.3.1 Unclogging

If clogging is found, or it is suspected that the counting results are not accurate due to aperture clogging, you can perform the unclogging operations. The unclogging procedures are shown as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Maintain** in the **Maintenance** selection. The interface as shown in Figure 12-4 will pop up on the screen.

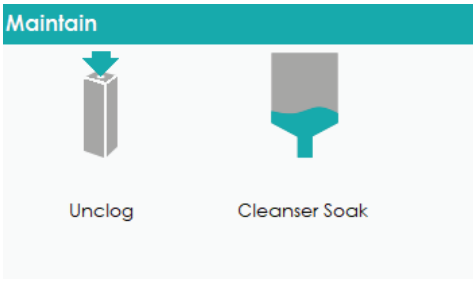


Figure 12-4 Maintenance

3. Click the **Unclog** icon.
4. Click **OK** to close the message box.
5. Perform the above procedures to continue unclogging if necessary.

12.2.3.2 Cleanser Soak

The cleanser soak should be performed under the following circumstances:

- When the problems including the background results exceed the Ref. Range and clogging still exist after other maintenance procedures have been adopted.
- Analyser has been running for more than 24 hours.

The cleanser soak procedures are shown as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Maintain** in the **Maintenance** selection.
3. Click the icon of **Cleanser Soak**.
4. Click **Yes**.
5. Present the cleanser to the sample probe as per the prompt, and press the aspirate key or click the **Aspirate** button.
6. After one minute of soaking, you can stop it manually. Click the **Stop soaking** button, or wait for 19 minutes until the automatic soaking is completed. After the soaking is completed, a prompt **Cleanser Maintenance done!** appears.
7. Click **Close**.
8. Perform the above procedures to perform the cleanser soak again if necessary.

12.2.4 Comprehensive Device Maintenance

The comprehensive device maintenance feature includes fluidics initialization, comprehensive device cleaning, emptying fluidics and preparing to ship.

12.2.4.1 Fluidics Initialization

After maintaining the fluidic system or replacing a main part of the analyser, you should perform this procedure to initialize the fluidic system. Do as follows to perform the fluidics initialization:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection. The interface as shown in Figure 12-5 will pop up on the screen

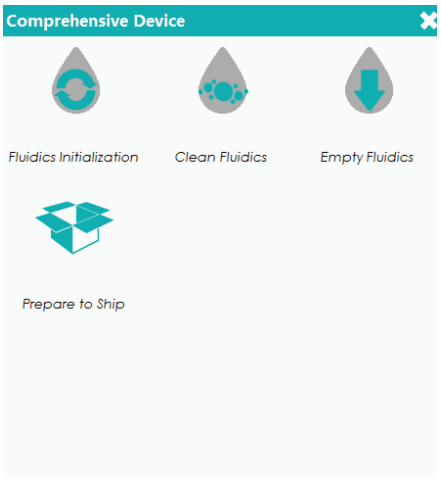


Figure 12-5 Comprehensive Device Maintenance

3. Click the icon of **Fluidics Initialization**.
4. The analyser starts to perform the fluidics initialization procedure. After the initialization is complete, a message box will pop up. Click **OK**.

12.2.4.2 Clean Fluidics

If the background results of parameters are out of the background range, the comprehensive device cleaning should be cleansed. Procedures for comprehensive device cleaning are shown as below:

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.
3. The analyser starts to perform the fluidics cleaning procedure. After the cleaning is completed, the message box will pop up. Click **OK**.

12.2.4.3 Empty Fluidics

This function enables the device to empty fluidics to prevent crystallization and maintain device performance when the device has not been used for more than one week. Procedures for emptying fluidics are shown as below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.
3. Click the icon of **Empty Fluidics**.

4. Click **Yes**.
5. Remove all reagent pickup tube assemblies according to the prompt, and then click OK to start emptying the fluidic system. After the emptying is complete, a message box will pop up:

   Empty Fluidics done. Please power off the analyzer!

6. Place the [O/I] switch at the left side of the main unit in the [O] position.
7. After shutdown, empty the waste in the waste container, and dispose of it.



Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

12.2.4.4 Prepare to Ship

If the analyser is not to be used for over two weeks or needs be transported over a long distance (transporting time>2h), you should perform this procedure:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.
3. Click the icon of **Prepare to Ship**.
4. Click **Yes**.
5. Remove all reagent pickup tube assemblies according to the prompt, and then click **OK** to start emptying the fluidic system.
6. Place all reagent pickup tube assemblies into the distilled water, and then click **OK** to start priming.
7. Take out the diluent and lyse pipes from the distilled water as per the prompt, then click **OK**.
8. Place the [O/I] switch at the left side of the main unit in the [O] position.
9. After shutdown, empty the waste in the waste container, and dispose of it.



Be sure to dispose of reagents, waste, samples, consumables, etc. according to local legislations and regulations.

NOTE

Be sure to use distilled water in order to ensure the normal use of the device in the future. In addition, the beaker holding the distilled water needs to be cleaned thoroughly.

The diluent pipe and lyse pipes should be stored separately in two beakers.

12.2.5 Auto Clean

There will be a certain amount of contamination accumulated after running a certain amount of samples without shutting down the analyser. When the sample count amounts to over 100, the analyser will perform the cleaning procedure automatically once, and a prompt will be displayed on the screen.

In addition, the analyser will perform the auto clean procedures if there has been no fluidics sequential operation for more than one hour.

NOTE Once the auto clean is performed or the analyser is shut down, the statistical data of auto clean will be cleared automatically.

12.2.6 Auto Prompt for Cleanser Soak

If the analyser has been running for more than 24 hours but hasn't performed cleanser maintenance when the auto maintenance time is reached, the system will prompt to perform cleanser soak immediately, so as to prevent the accumulation of contamination.

- Click **Yes**, then you can perform the cleanser maintenance as per the prompt and the description in **12.2.3.2 Cleanser Soak**.
- Click **No**, the cleanser maintenance will be cancelled temporarily. You will be reminded after set waiting time and you can cancel 3 times at most. When the system reminds the forth time, you must perform the maintenance, otherwise the normal operation of the analyzer may be affected.

NOTE

At the **Self-test** or **Status** interface, the analyser does not ask for confirmation to perform the cleanser soak.

If the analyser is running or has problems when the conditions of auto prompt for cleanser soak is satisfied, the analyser will prompt again after the current operation is completed or the problems are resolved.

After cleanser soak is completed, the accumulative count values will be cleared automatically.

Cleanser soak is an important step in comprehensive device maintenance. It is recommended not to stop soaking halfway.

12.2.7 Auto Sleep

When the fluidics system stops working for a specified waiting time for auto sleeping (30 minutes by default), the analyser will enter the sleeping status automatically. You can change the waiting time for auto sleeping as needed.

When the analyser is in the sleep mode, a prompt will be displayed on the screen. Touch the screen or press the aspirate key on the analyser to wake it up.

NOTE

If it is the time to auto sleep but the analyser is error status, then only after the error is removed will auto sleep start accordingly.

Different maintenances will be performed by the analyser automatically when exiting the sleep mode, and the exiting time depends on how long the analyser was in the sleep mode.

If errors occur when you are trying to cancel the auto sleep of the analyser, please refer to **13 Troubleshooting** for solving the problems.

12.3 Self-test

This feature is to test if some important components of the device can function properly or not, including syringe and sampling assembly self-test, pressure and vacuum self-test, valve self-test and other self-test.

NOTE If the testing result is abnormal, you should try again for several times; if the abnormalities persist, please contact Erba Lachema customer service department or your local agent.

12.3.1 Syringe and Sampling Mechanism

You can test the performance of all syringes and sampling mechanisms. The self-inspection procedures are shown as below:

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Syringe Self-test** in the **Self-test** selection. The interface as shown in Figure 12-6 will pop up on the screen.

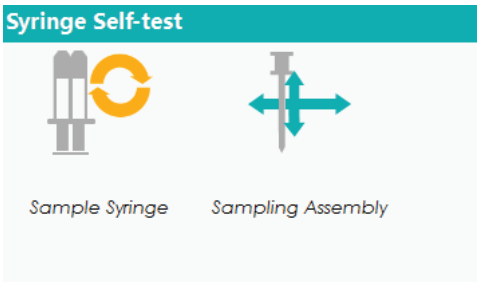


Figure 12-6 Syringe

3. Click the part that needs to be tested, e.g. **Sample Syringe**, and wait for the self-inspection results.
4. Click **OK** to close the message box.

12.3.2 Pressure and Vacuum

This feature is to test the pressure and vacuum inside the device.

Procedures for pressure (or vacuum) self-inspection are shown as below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Pressure Self-test** in the **Self-test** selection. The interface as shown in Figure 12-7 will pop up on the screen.

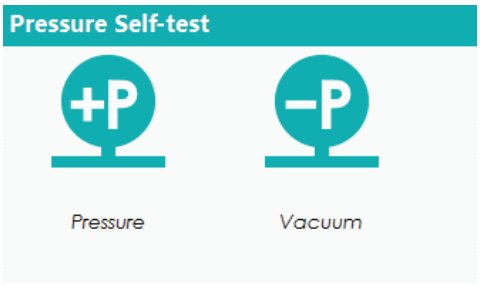


Figure 12-7 Pressure and Vacuum Self-inspection

3. Click **Pressure** (or **Vacuum**). The system will perform the corresponding self-test operations. After the self-test is completed, a dialog box will pop up to show the self-test results.
4. Click **OK** to close the message box.

NOTE LIQUID PUMP is used for generating PRESSURE / VACUUM.

12.3.3 Valve & Pump

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). The procedures for valve self-inspection are shown as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Valve/Pump Self-test** in the **Self-test** selection. The interface as shown in Figure 12-8 will pop up on the screen.

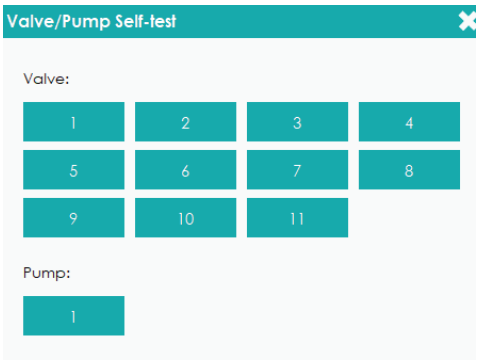


Figure 12-8 Valve Self-test

3. Click the desired valve number (e.g. **1**), then confirm whether it works properly by the sound of its opening and closing.

12.3.4 Others

You can perform the self-test for WBC and RBC aperture voltage.

Take the self-test for RBC aperture voltage as an example, its operation steps are as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Other Self-test** in the **Self-test** selection.
   The interface as shown in Figure 12-9 will pop up on the screen.

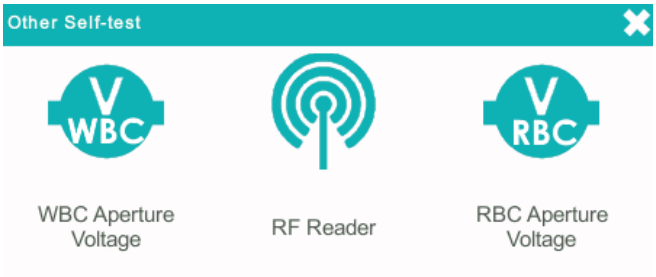


Figure 12-9 Other Self-test

3. Click **RBC Aperture Voltage** to start self-test.
   The system will perform the corresponding self-test operations. After the self-inspection is completed, a dialog box will pop up to show the self-inspection results.

12.4 System Status

You can view the current status information of the analyser in the **Status** selection, including temperature, voltage and current, and version information.

12.4.1 Temperature

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Temperature** in the **Status** selection. The interface as shown in Figure 12-10 will pop up on the screen.

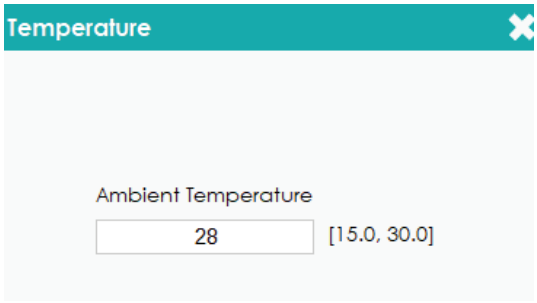


Figure 12-10 View Temperature Status

User can view the current ambient temperature of the analyser. If the results of the temperature testing exceed the normal range, they will be highlighted by the orange background.

12.4.2 Voltage and Current

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Voltage/Current** in the Status selection. The interface as shown in Figure 12-11 will pop up on the screen.

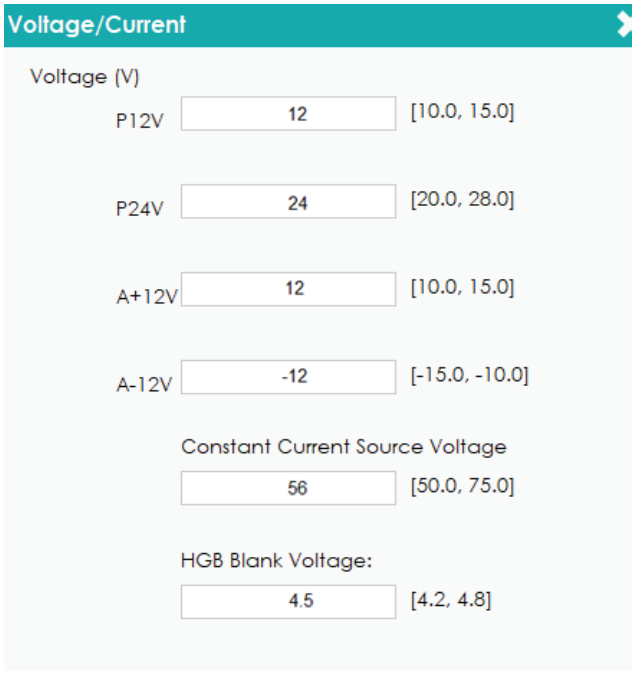


Figure 12-11 Voltage and Current

You can view the voltage and current information of the analyser. The voltage or current value that exceeds the normal range will be displayed in an orange background.

12.4.3 Disk Information

You can view the disk information of the analyser, including disk name, capacity and used space. Specific steps are shown below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Disk Info** in the **Status** selection. The disk information interface displays. See Figure 12-12.

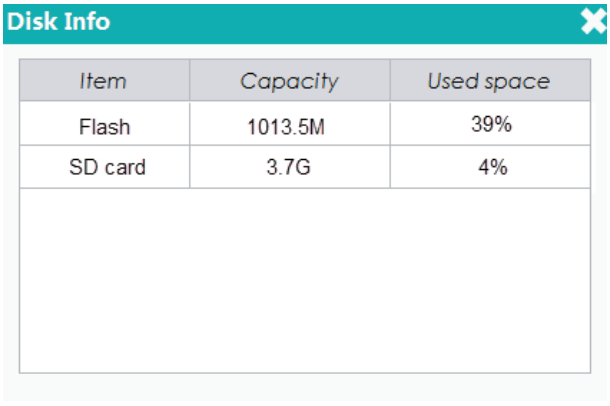


Figure 12-12 Disk Information

12.5 Log

In the Log interface, you can view the records of **Set Paras**, **Other Logs**, **Fault Logs** and **All Logs**.

NOTE

If a new record is added when the log is full, the newest record will overwrite the oldest one automatically.

The administrator can view both his/her own operation logs and the general users' operation logs, while the general users can only review their own operation logs.

The log can keep records of up to 5 years.

12.5.1 All Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Log > All Logs** to access the **All Logs** interface. You can view all logs and reagent logs (available to the user of the current access level). See Figure 12-13. All logs interface is displayed by default, and you can click the drop-down list to select reagents logs.

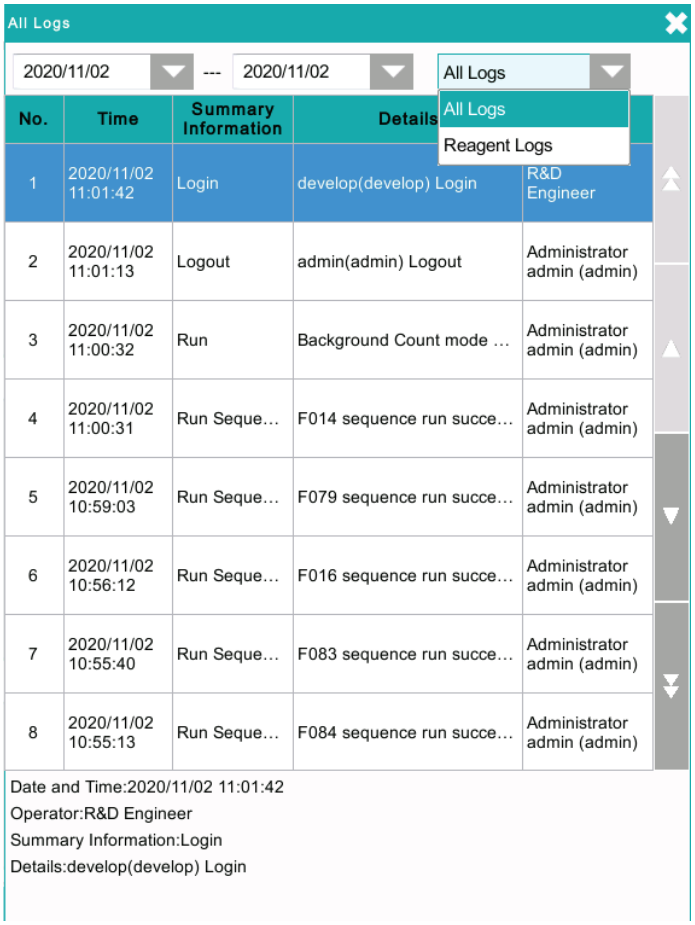


Figure 12-13 All Logs

All Logs

Select the dates in the two date textboxes, and then you can view all logs within the date range, which includes operation date and time, operation details and the operator.

Reagent Logs

Click the drop-down list of **All Logs**, and select **Reagent Logs**.

Select the dates in the two date textboxes, and then you can view all logs within the date range, which includes operation date and time, operation details, the operator and reagent expiration date.

12.5.2 Parameter Revision Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Set Paras** in the **Log** selection. You can view the parameter revision logs as in Figure 12-14 (which can be viewed by the user with the current level of access) within a specified date range.



Figure 12-14 Parameter Revision Logs

3. Select the dates in the two date textboxes, and then you can view the parameter revision logs within the date range, including the revision date and time, revision summary and the operator.

12.5.3 Fault Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Fault Logs** in the **Log** selection. You can view all logs as in Figure 12-15 (visible to the users of the current access level).



Figure 12-15 Fault Logs

3. Select the dates in the two date textboxes, and then you can view the fault logs within the date range, including date and time when the faults occur, fault description and the operator.

12.5.4 Other Logs

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Other Logs** in the **Log** selection. You can view other logs besides parameter revision logs and fault logs as in Figure 12-16.

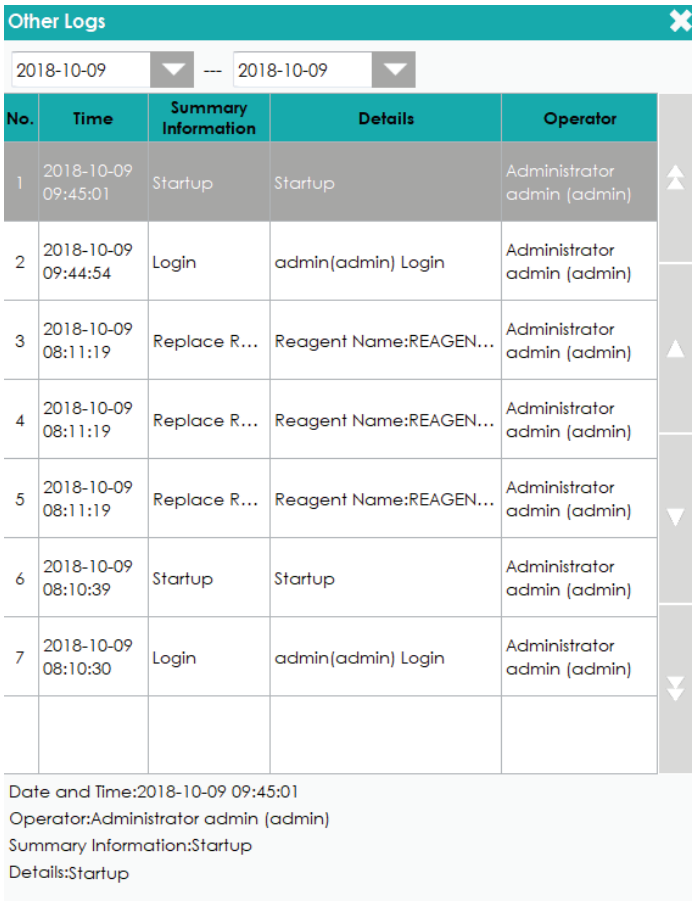


Figure 12-16 Other Logs

3. Select the dates in the two date textboxes to view the logs within the date range, including operation date and time, operation records and the operator.

12.6 Data Clean-up

You can clean up the data stored in the analyser. Specific steps are shown below.

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Data Clean-up** in the **Other** selection. The data clean-up interface displays. See Figure 12-17.

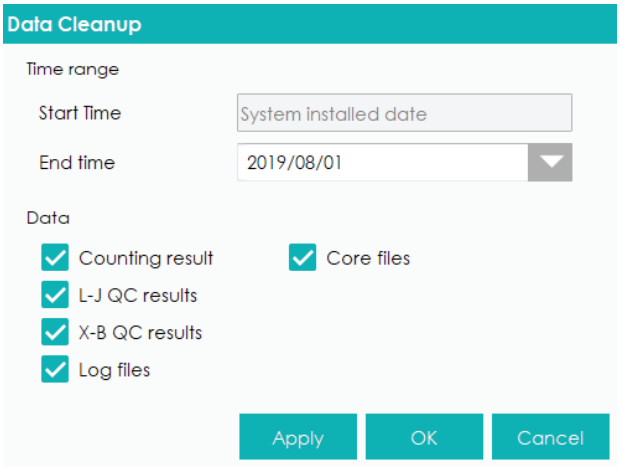


Figure 12-17 Data Clean-up

3. Click the **End time** combo box, set the date range of the data to be cleaned up in the popup dialog box.
   - The input sequence of the controls is the same with the date format on the top right corner of the dialog box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sequence of year, month, and date.
   - Click or to select a date and time or enter the information in the textbox directly.
   - Click to clear the data and input again.

For example, If the **End time** is set to **2016/03/31**, the data generated from system installation date to 31 March 2016 will be cleared.

4. Click **OK** to save the settings and close the dialog box.
5. Select the data to be cleaned up.
   - You can clean up the following data:
   - Counting results
   - L-J QC results
   - X-B QC results
   - Log files
6. Click **Apply** or **OK**.

12.7 Version Information

You can view the current version information of all parts of the analyser, and export the version information to a USB flash disk. Detailed steps are shown below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Version Info.** in the **Other** selection. Version information interface will pop up on the screen. See Figure 12-18.

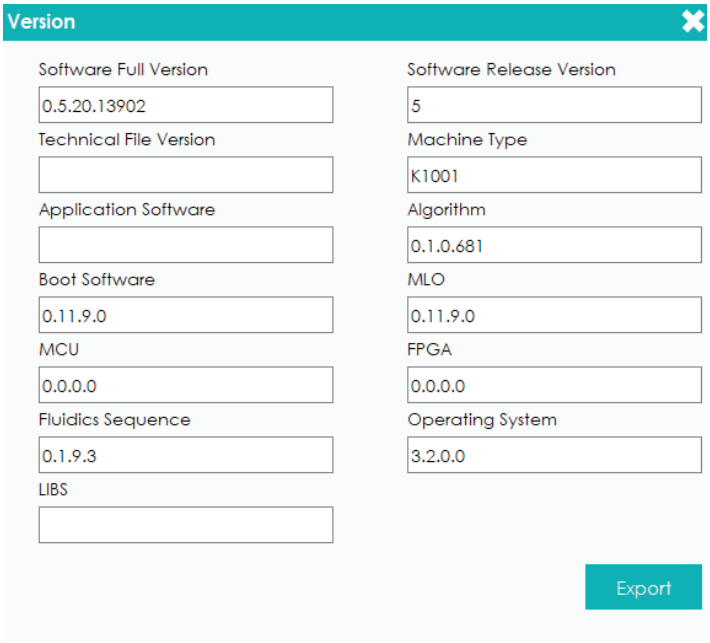


Figure 12-18 Version Information

3. Insert a USB flash disk in the USB interface on the analyser.
4. Click **Export**, and select the export path in the dialog box, and then enter the file name.

The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) by default as shown below.

5. Click **Save** to start exporting.
6. Click **OK** to exit.

12.8 Touch Screen Calibration

When the touch screen has offset, it needs to be recalibrated. Detailed steps are shown below:

1. Click the Service icon in the menu page to access the Service interface.
2. Click Touch Screen Cal. in the Cal selection.
3. 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.

12.9 Downloading Service Logs

In the use of the analyser, when errors occur and cannot be removed, it’s recommended that you export the service logs file to a USB flash disk and send the file to Erba Lachema customer service engineer. Specific steps are shown below.

1. Insert a USB flash disk into the USB interface on the analyser.
2. Click the **Service** icon in the menu page to access the **Service** interface.
3. Click **Service Log** in the **Debug** selection. Select the data range of the logs to be exported in the pop-up dialog box. See Figure 12-19.

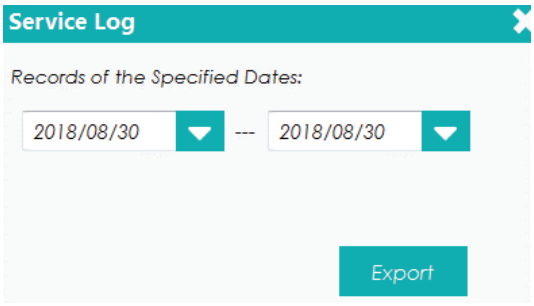


Figure 12-19 Downloading Service Logs

4. Click **Export**.
5. The **host_download.tar** file is exported to the root directory of the USB flash disk.
6. Send the **host_download.tar** file to our customer service engineer.

13 Troubleshooting

13.1 Introduction

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

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 analyser. If the recommended solution fails to solve the problem, contact Erba Lachema customer service department or your local agent.

13.2 Dealing with Error Messages

In the use of the analyser, when the software detects abnormalities, an error message will be displayed on the lower right of the screen as shown in Figure 13-1 and the main unit will sound an alarm.



Figure 13-1 Error Messages

You can refer to the following steps to deal with the error messages.

1. Click the error message area.

As shown in Figure 13-2, the popup dialog box displays the error description and its help information. The error descriptions are displayed in the order of error occurrence.

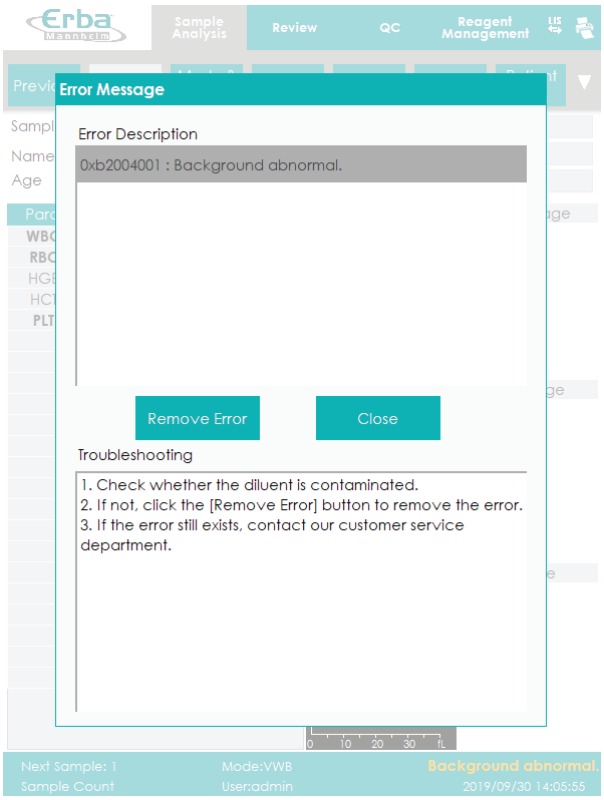


Figure 13-2 Error Message Dialog Box

2. Touch the screen to disable the beep.
3. Click **Remove Error**.

Normally, the system will automatically remove the errors. For errors which cannot be removed automatically, you can take appropriate actions by following the error help information or Error **13.3 Message Reference**.

13.3 Error Message Reference

Possible errors and the corresponding help information are shown in Table 13-1.

Table 13-1 Error Message Reference

Problem Name	Troubleshooting Information
Abnormal -12V power.	1. Please power off the analyser directly and restart later. 2. If the error still exists, contact our customer service department.
Abnormal voltage of constant-current voltage abnormal.	1. Please power off the analyser directly and restart later. 2. If the error still exists, contact our customer service department.
Startup failure.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Startup initialization is not executed.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.

Problem Name	Troubleshooting Information
Right side door is open.	1. Close the right side door. 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
Abnormal +12V power.	1. Please power off the analyser directly and restart later. 2. If the error still exists, contact our customer service department.
Erba H360 Dil expired.	1. Check if the Erba H360 Dil diluent expires. If so, replace it with a new container of Erba H360 Dil. 2. Click the **Remove Error** button, the **Reagent Management** screen will be displayed. 3. Set the reagent information by referring to **11 Reagent Management**. 4. If the error still exists, contact our customer service department.
Erba H360 Lyse expired.	1. Check if the Erba H360 Lyse expires. If so, replace it with a new container of Erba H360 Lyse. 2. Click the **Remove Error** button, the **Reagent Management** screen will be displayed. 3. Set the reagent information by referring to **11 Reagent Management**. 4. If the error still exists, contact our customer service department.
Abnormal HGB background voltage	1. Adjust the HGB background voltage within the specified range (4.2V~4.8V), preferably 4.5V. Refer to **5.5.1 Gain Settings**. 2. If the error still exists, contact our customer service department.
Abnormal RBC aperture voltage.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal WBC aperture voltage	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
RBC clogging	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, see **12.2.3.2 Cleanser Soak** to dip the RBC bath in the cleanser. 3. If the error still exists, contact our customer service department.
WBC clogging.	1. Click the **Remove Error** button to remove this error. 2. If the error is reported frequently, see **12.2.3.2 Cleanser Soak** to dip the RBC bath in the cleanser. 3. If the error still exists, contact our customer service department.
Abnormal background	1. Check whether the diluent is contaminated. 2. If not, click the **Remove Error** button to remove the error. 3. If the error still exists, contact our customer service department.
Failed to read sample syringe parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to configure sample syringe parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.

Problem Name	Troubleshooting Information
Sample syringe timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Sample syringe is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Command parameter error of the sampling assembly.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Sampling assembly timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Sampling assembly is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor instruction parameter error.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read vertical motor parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read the remaining steps of vertical motor.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read ambient temperature.	1. Make sure the temperature sensor is correctly installed. 2. Click the **Remove Error** button to remove the error. 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 **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
Failed to read horizontal motor parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to configure Horizontal motor parameter.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Horizontal motor timeout	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal horizontal-motor photocoupler.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Horizontal motor is busy.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.

Problem Name	Troubleshooting Information
Erba H360 Dil running out.	1. Check whether the Erba H360 Dil container is empty. If so, install a new container of Erba H360 Dil. 2. Click the **Remove Error** button to remove this error. 3. If the error still exists, contact our customer service department.
Erba H360 Lyse running out or air bubbles in inlet tubing.	1. Check whether the Erba H360 Lyse is running out or there are air bubbles in the inlet tubing of Erba H360 Lyse. If it is running out, install a new container of Erba H360 Lyse; If there is still plenty of Erba H360 Lyse or there are bubbles, perform step 2. 2. Click the **Remove Error** button to remove the error. 3. If the error still exists, contact our customer service department.
Erba H360 Dil not replaced.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Erba H360 Lyse not replaced.	1. Click the **Remove Error** button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal 12V driving power supply.	1. Please power off the analyser directly and restart later. 2. If the error still exists, contact our customer service department.
Abnormal 24V driving power supply.	1. Please power off the analyser directly and restart later. 2. If the error still exists, contact our customer service department.
Insufficient Erba H360 Lyse.	1. Check whether the Erba H360 Lyse container is empty. If so, perform step 2; or if there is still plenty of Erba H360 Lyse, contact our customer service department. 2. Install a new container of Erba H360 Lyse. 3. Click the Remove Error button, the **Reagent Management** screen will be displayed. 4. Set the reagent information by referring to **11 Reagent Management**. 5. If the error still exists, contact our customer service department.
Insufficient Erba H360 Dil.	1. Check whether the Erba H360 Dil container is empty. If so, perform step 2; or if there is still plenty of Erba H360 Dil, contact our customer service department. 2. Install a new container of Erba H360 Dil. 3. Click the Remove Error button, the **Reagent Management** screen will be displayed. 4. Set the reagent information by referring to **11 Reagent Management**. 5. If the error still exists, contact our customer service department.

The printer box is not connected.	1. The printer box is not turned on. 2. The connecting line of the printer box is abnormal. 3. The IP or port number of the printer box is misconfigured. 4. There exists an error in the printer box, try to restart the printer box. 5. Click **Remove Error** to automatically remove the error. 6. If the error still exists, please contact our company's customer service department.
Printing Error	1. The printer connected to the printer box is out of paper or has other errors. 2. The printer box is not connected to the designated printer. 3. If the above errors are excluded, try to restart the printer box. 4. Click **Remove Error** to automatically remove the error. 5. If the error still exists, please contact our company's customer service department.

14 Traceability and Reference Methods

14.1 Traceability

The assigned values of *in vitro* diagnostic medical calibrator ELite H CAL are traceable to internationally recognised reference methods for WBC, RBC, HGB, HCT and PLT, according to the recommendations of International Council for Standardization in Haematology (ICSH) and Clinical and Laboratory Standards Institute (CLSI).
The chain of traceability is based on ISO 17511 [1] (5.4 section) and is shown in Figure 14-1.

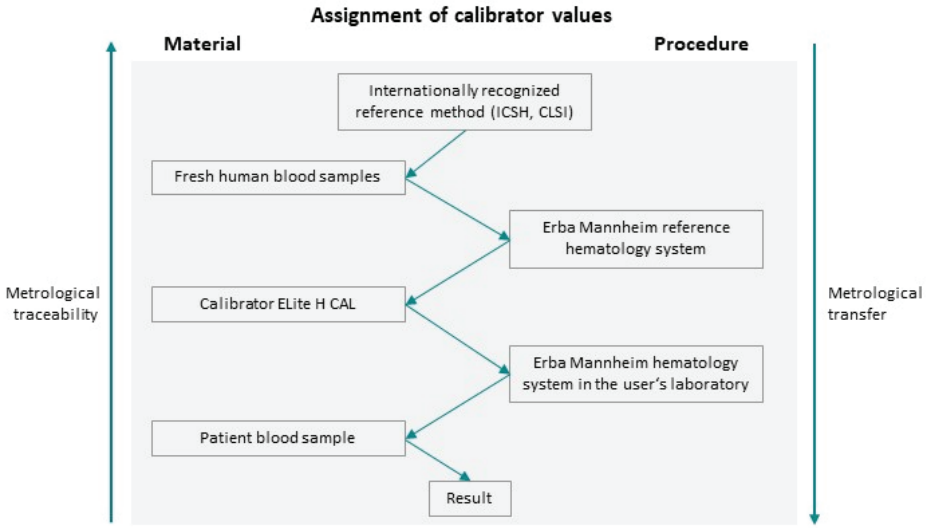


Figure 14-1 Value traceability chain of hematology analyser

14.2 Reference Methods

The hematology reference analyzers are regularly calibrated with fresh human blood samples directly against the reference methods recommended by ICSH and CLSI.

WBC: A 1:500 dilution is prepared using a 100 mL Class A volumetric flask filled with isotonic diluent. 1.2 mL of diluent is removed. Sample is added to the flask using a 200 µL calibrated positive displacement pipette, followed by 1.0 mL lysing agent. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

RBC: A 1:50,000 dilution is prepared using a 1000 mL Class A volumetric flask filled with isotonic diluent. Sample is added to the flask using a 20 µL T.C. micropipet. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

HGB: A 1:251 dilution is prepared using a 50 mL Class A volumetric flask filled with the CLSI recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method [2]. Sample is added to the flask using a 200 µL calibrated positive displacement pipette. The sample is filtered with a 0.2 µm filter immediately before reading. Readings are made at 540 nm in a colorimeter/ spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations [2].

HCT: Plain glass microhematocrit tubes (not coated with anticoagulant) are filled with sample, sealed with sealing putty and centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H07-A3 document [3]. After centrifugation, the length of the whole column including the plasma, and the length of the red blood cell column, are viewed and measured using a microscope with graduated stage and an ocular micrometer. The hematocrit (packed cell volume) is calculated as the ratio of the two measurements. No correction is made for trapped plasma.

MCV: On some instruments MCV is the calibrated parameter instead of the HCT. The MCV is calculated from the HCT and RBC using the formula: MCV = HCT × 10/RBC

PLT: A 1:126 dilution is prepared using a 50 mL Class A volumetric flask filled with filtered 1% ammonium oxalate. Sample is added to the flask using a 400 µL calibrated positive displacement pipette. The dilution is plated onto a clean, dry Neubauer ruled phase type hemocytometer. The hemocytometer is left for 10 minutes in a humidified chamber. Using phase contrast optics, the platelets in the entire central square millimeter on both sides of the hemocytometer are counted. The two counts are averaged and multiplied by 1260 (dilution factor 126 × volume factor 10 = 1260).

1. ISO 17511:2003 *In vitro* diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials.
2. Clinical Laboratory Standards Institute. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood: Approved Standard-Third Edition. CLSI document H15-A3.
3. Clinical Laboratory Standards Institute. Procedure for Determining Packed Cell Volume by the Microhematocrit Method: Approved Standard-Third Edition. CLSI document H07-A3.

15 Specifications

15.1 Classification

According to the CE classification, the H360 Haematology Analyser belongs to *in vitro* diagnostic medical devices, rather than those covered by Annex II and devices for performance evaluation.

15.2 Reagents, controls and calibrator

Consumables	Type Name	Catalog number
Diluent	Erba H360 Dil	HEM00028
Lyse	Erba H360 Lyse	HEM00029
Medical cleanser	ELite H Clean	HEM00023
Low control	Erba H3 CON L	HEM00033
Normal control	Erba H3 CON N	HEM00034
High control	Erba H3 CON H	HEM00035
Calibrator	ELite H CAL	HEM00027

15.3 Parameters

Parameter	Abbreviation	Default Unit
White Blood Cell count	WBC	10^3/µL
Number of Granulocytes	Gran#	10^3/µL
Number of Lymphocytes	Lym#	10^3/µL
Number of Mid-sized Cells	Mid#	10^3/µL
Percentage of Granulocytes	Gran%	%
Percentage of Lymphocytes	Lym%	%
Percentage of Mid-sized Cells	Mid%	%
Red Blood Cell count	RBC	10^6/µL
Haemoglobin Concentration	HGB	g/dL
Haematocrit	HCT	%
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Haemoglobin	MCH	pg

Parameter	Abbreviation	Default Unit
Mean Corpuscular Haemoglobin Concentration	MCHC	g/dL
Red Blood Cell Distribution Width Standard Deviation	RDW-SD	fL
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV	%
Platelet count	PLT	10^3/μL
Mean Platelet Volume	MPV	fL
Platelet Distribution Width Standard Deviation	PDW	fL
Platelet Distribution Width Coefficient of Variation	PDW	%
Plateletcrit	PCT	%
Platelet-large cell ratio	P-LCR	%
Platelet-large cell count	P-LCC	10^3/μL
Red Blood Cell Histogram	RBC Histogram	N/A
Platelet Histogram	PLT Histogram	N/A
White Blood Cell Histogram	WBC Histogram	N/A

15.4 Performance Specifications

15.4.1 Display Range

Parameter	Linearity Range	Display Range
WBC	0~300×10^3/μL	0~999×10^3/μL
RBC	0.00~8.50×10^6/μL	0~18.00×10^6/μL
HGB	0~25 g/dL	0~30 g/dL
PLT	0~3000×10^3/μL	0~5000×10^3/μL
HCT	0~67%	0%~80%

15.4.2 Normal Background

Parameter	Normal Background
WBC	≤0.2×10^3/μL
RBC	≤0.02×10^6/μL
HGB	≤0.1 g/dL
PLT	≤10×10^3/μL
HCT	≤0.5%

15.4.3 Linearity Range

Parameter	Linearity range	Deviation range (Whole blood mode)
WBC	(0.00~100.00)×10³/μL	±0.30×10³/μL or ±5%
	(100.01~300.00)× 10³/μL	±10%
RBC	(0.00~8.50)× 10⁶/μL	±0.05×10⁶/μL or ±5%
HGB	(0~25) g/dL	±0.2g/dL or ±2%
PLT	(0~1000)× 10³/μL (RBC≤7.0)	±10×10³/μL or ±8%
	1001~3000×10³/μL (RBC≤7.0)	±12%
HCT	0~67%	±2% (HCT value) or ±3% (deviation percent)

15.4.4 Repeatability

These repeatability requirements apply only to the situation in which a qualified sample has been run for 11 times and the results of the 2nd to 11th runs are used to calculate the repeatabilities.

Parameter	Condition	Whole Blood Repeatability (CV%/absolute deviation d*)
WBC	(7.0~15.0)×10^3/μL	≤2.0%
	(4.0~6.9)×10^3/μL	≤3.5%
RBC	(3.5~6.5)×10⁶/μL	≤1.5%
HGB	(10~18)g/dL	≤1.5%
MCV	(70~110)fL	≤0.5%
PLT	(150~500)×10³/μL	≤4.0%

*: Absolute deviation d = analysis result – average of analysis results

15.4.5 Carryover

Parameter	Carryover
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.5%
PLT	≤1.0%
HCT	≤0.5%

15.5 Sample Interference

If there is sample interference, the analysis results of the sample may be affected. See the table below.

Table 15-1 Possible sample interference

Parameter	Analysis Results	Interference Source
WBC	Low WBC count	Leukoagglutination
	High WBC count	• Possible Platelet agglutination • Cool insoluble protein • Cryoglobulins • Fibrin • Excessive numbers of giant platelets (platelets>1000×10³/μL) • Nucleated red blood cells
RBC	Low RBC count	• Agglutinated RBCs (Cold agglutinins) • Microcythemia • Schistocytes
	High RBC count	• Leukocytosis (>100×10³/μL) • Excessive numbers of giant platelets (platelets>1000×10³/μL)
HGB	High HGB count	• Leukocytosis (>100×10³/μL) • Chylaemia • Jaundice • Paraprotein
HCT	Low HCT value	• Agglutinated RBCs (Cold agglutinins) • Microcytes • Schistocytes
	High HCT value	• Leukocytosis (>100×10³/μL) • Severe diabetes • Uraemia • Spherocytes
PLT	Low PLT count	• Possible Platelet agglutination • pseudo thrombocytopenia • Giant platelets
	High PLT count	• Microcytes • Schistocytes • WBC fragments • Cool insoluble protein • Cryoglobulins

15.6 Input/output Device



WARNING
Accessory equipment connected to the analogue and digital interfaces must comply with the relevant Safety and EMC standards (e.g., IEC 60950 Safety of Information Technology Equipment Standard and CISPR 22 EMC of Information Technology Equipment Standard (CLASS B)).Anyone who connects additional equipment to the signal input or output ports and configures an IVD system is responsible for ensuring that the system works properly and complies with the safety and EMC requirements. If you have any problem, consult the technical services department of your local agent.
Be sure to use specified fuse only.

Analyser
- Touch screen: 10.4 inches embedded touch screen with a resolution of 800×600
- One LAN interface
- 4 USB interfaces

Power
- Voltage: A.C 100V~240V
- Input power: ≤200VA
- Frequency: 50/60 Hz

Fuse: T6.3AL 250V
Keyboard (Optional, USB)
Mouse (Optional, USB)
External barcode scanner, 2D Barcode scanner (optional, USB)
External printer (optional, USB)
USB flash disk (optional, USB)
Recorder
- Built-in thermal recorder.
- The type of thermal printer is SP-PMD8C. The length is 80mm, the width is 80mm, the depth is 53mm and the roll diameter is 50mm.

Throughput
- 60 tests per hour

Memory capacity
- 50,000 with histograms

Aperture diameter
- WBC: 100 µm
- RBC: 70 µm

Operating System
- LINUX operating system

Electric system
- H360 has integrated micro-processing technology

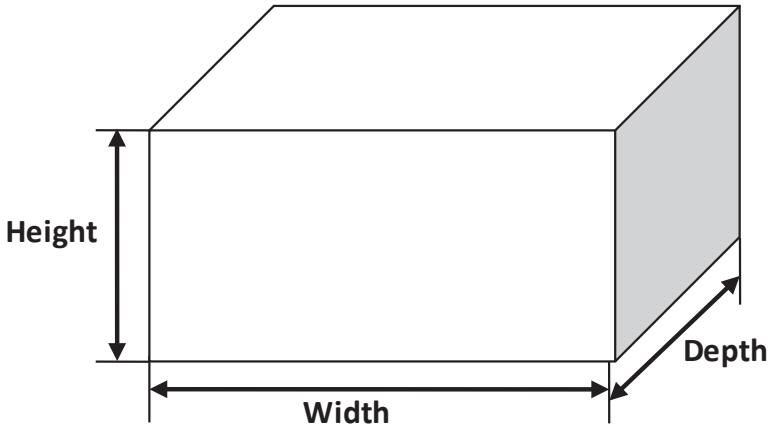
Noise level
- 80 dB

15.7 Environment Conditions

NOTE Be sure to use and store the analyser in the specified environment. A temperature sensor in H360 detects the ambient temperature.

Environment Conditions	Operating Environment	Storage Environment	Running Environment
Ambient temperature	15°C~30°C	-10°C~40°C	5°C~40°C
Relative humidity	20%~85%	10%~90%	10%~90%
Atmospheric pressure	70kPa~106kPa	50kPa~106kPa	70kPa~106kPa

15.8 Dimensions and Weight



Analyser	Dimensions and Weight
Width (mm)	364
Height (mm)	477
Depth (mm)	417
Weight (kg)	25

15.9 Expected Service Life

8 years.

15.10 Contraindications

None

16 Terms and Abbreviations

CWB Capillary Whole Blood
PD Predilute
VWB Venous Whole Blood

17 Packing List

No.	Parameter	Quantity	Unit
1	H360 Haematology Analyser	1	PCS
2	Power Cable	1	PCS
3	Grounding Cable	1	PCS
4	Operator’s Manual	1	PCS
5	Quick Operation Guide Card	1	PCS
6	Diluent Adapter Tube	1	PCS
7	Waste Float Adapter Tube	1	PCS
8	Warranty Card	1	PCS
9	Waste container	1	PCS
10	H360 Haematology Analyser Inspection Record	1	PCS
11	Packing list	1	PCS
12	Barcode scanner	1	PCS
13	Reagent Operation Guide	1	PCS

18 Contact

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