SMT-60

Automatic Hematology Analyzer

User Manual

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Seamaty Diagnostic Co., Ltd

Table of Contents

Introduction

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

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

Prodcut Name: Automatic Hematology Analyzer

Model: SMT-60

Product Composition: This product primarily comprises the host, accessories and software. The host includes a display screen, sampling assembly, fluidic system, , power interface, reagent interface and signal interface

Scope of Product Application: This product is applicable for detecting the parameters of WBC, RBC, PLT, HGB, etc. (see Section 3.2. Parameters for details) in whole blood and Capillary WB, as well as WBC 5-part differential analysis and WBC counting

Intended use: It is used to quantitatively detect the the number of blood cells in human blood samples in vitro

Date of Manufacture: See the nameplate of the instrument

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Manual Overviewa

This chapter explains how to use this operation manual, which is shipped with your auto hematology analyzer and contains reference information about the analyzer and procedures for operating,troubleshooting and maintaining the analyzer.Read this manual carefully before operating your analyzer and operate your analyzer strictly as instructed in this manual. The text and figures in this manual take the SMT-60 as an example.

Who Should Read This Manua

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

- Learn about hardware and software of the analyzer.
- Set system parameters.
- Perform daily operations.
- Perform system maintenance and troubleshooting.

How to Find Information

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

If you want to …	**Please refer to …**
learn about safety and precautions of the analyzer	Chapter 1 Safety and Precautions
learn about installation requirements of the analyzer	Chapter 2 Installation
learn about the intended use, parameters, structure, reagents, etc. of the analyzer	Chapter 3 System Description
learn about how the analyzer works	Chapter 4 Working Principles
learn about the process of sample collection and analysis, and how to use the analyzer to perform your daily operating tasks	Chapter 5 Basic Operations
review sample results	Chapter 6 Reviewing Results
learn about the basic requirements of quality control and how to use the quality control programs provided by the analyzer	Chapter 7 Quality Control
learn about the basic requirements of calibration and how to calibrate the analyzer	Chapter 8 Calibration
learn about how to set/adjust system settings	Chapter 9 Settings
learn about how to maintain/service the analyzer	Chapter 10 Service
learn about how to solve the problems of the analyzer	Chapter 11 Troubleshooting
learn about the technical specifications of the analyzer	Appendix A. Specifications

learn about the hazardous substances that may contain in the analyzer parts	Appendix B. Hazardous Substances

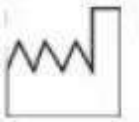
Symbols

You will find the following symbols in this manual:

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

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

Symbols	Meaning
	Consult accompanying documents.
	Biohazard (The background color of this symbol is yellow, the symbol itself and the outline is black.)
	High-voltage warning
	Laser beam warning

Symbols	Meaning
	Protective earthing
	Functional earthing
	Alternating current
	For in vitro diagnostic use
	Product serial number
	Metrology certification mark
	Date of manufacture
	Manufacturer
	CE marking. The device is fully in conformance with the Directive 98/79/EC on in vitro diagnostic medical devices
	Authorized representative in the European Community
	The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.

Symbols	Meaning
	Batch code
	Expiry date
	Temperature limitation
	Consult the operation manual
	This electronic product contains some poisonous and harmful substances. The environmental protection use period is 20 years, after this period, it should be put into the recycling system.

Conventions

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

1.Safety and Precautions

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

1.1. Safety

	**High Temperature** （1） Before replacing the lamp, turn off the power switch and wait at least 30 minutes until the lamp has cooled down. （2） Contact with the print head or metal objects around the print head may cause burns.
	**Bodily Injury** （1） Keep away from the sharp parts of the analyzer,such as sample probe tip, in case of body injury. （2） Do not touch the moving parts,such as sample probe when the analyzer is running.
	**Glare** Do not look directly into any beams to prevent possible damage to your eyes.
	**Electric Shock** （1） Front,side and back covers mustn't be opened when the power is on, except by authorized service personnel. （2） Do not splash liquid on the analyzer's countertop.In case liquid gets into the analyzer, turn of the power and contact Producer or its local distributors immediately. （3） Keep away from the inside of computer and printer in case of high voltage.

1.2. Precautions

	**Intended Use** （1） The analyzer is designed for detecting the parameters of WBC, RBC,HGB, etc.(see Section 3.2. Parameters for details) in whole blood and Capillary WB, as well as WBC 5-part differential analysis and WBC counting.Please consult Producer first if you want to use the system for other purposes. （2） To draw a clinical conclusion,please also refer to the patient's clinical symptoms and other test results.
	**Operator** The analyzer can only be operated by personnel who have trained and authorized by Producer or its local distributors.
	**Actions taken in case of failure** If the instrument has dangerous failure,such as fire,odor,smoke,etc.,anyone can directly disconnect the power of the instrument or the main power and contact Producer immediately.
	**Operating Environment** （1） Please install and operate the analyzer in an environment specified by this manual.Installing and operating the analyzer in other environment may lead to unreliable results and even analyzer damage. （2） If the operating environment of the analyzer needs to be modified, please contact Producer or the authorized Producer distributor for you region.
	**Electromagnetic Interference** （1） The analyzer is susceptible to electromagnetic interference during operation which may affect test results and lead to operational errors. Please do not use devices that emit electromagnetic radiation, such as electric drills, mobile phones or interphones while the analyzer is running （2） The analyzer will emit electromagnetic radiation during operation. Do not install or use electromagnetically-sensitive devices near the analyzer.

	**Improper Grounding** （1） The power supply must be properly grounded, or there is a risk of electric shock. （2） Ground impedance must be less than 0.1Ω. Poor grounding can cause instability in test results and electrical leakage from the enclosure, producing an electric shock hazard.
	**Liquid Leakage** （1） Check the pipe joints for possible leakage before conducting tests. Liquid leakage can cause inaccurate aspiration and discharge volume. （2） Do not place reagents and samples on the analyzer bench to avoid liquid spillage or leakage.
	**Probe Obstruction** Carefully check reagents and samples and make sure they do not contain insoluble floating substance such as cellulose and protein fibrin in case the probes may be blocked.
	**Water Quality** Water quality should meet Class 2 national standards for laboratory water, otherwise damage to valve and pump as well as difficulty in cleaning can be resulted.
	**Device Connection** （1） For a device not permanently connected, please do not place it at a location that is hard to disconnect. （2） For all the external switches or breakers and external over-current protection device, it is recommended to place them near the analyzer. （3） Devices connected with the network port of the analyzer should conform to the requirements of National Standards GB4793 of China as well as IEC60950.
	**Analysis Parameters** Perform calibration for different batches of reagents. Incorrect analysis parameters can lead to wrong test results. Please consult Producer or your reagent supplier for more information.

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

2.Installation

2.1.Introduction

⚠WARNING

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

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

2.2. Installer

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

2.3. Checking before Installation

Inspection for Damage

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

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

（2） Obvious water marks on the packaging.

（3） Obvious signs of being striked on the packaging.

（4） Packaging shows signs of having been opened previously.

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

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

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

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

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

Packing List

Check all the parts according to the packing list contained inside the packaging. If you notice any missing part, please immediately notify Producer or its authorized local distributor.

2.4.Installation Requirements

2.4.1.Space Requirements

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

- proper height to place the analyzer;
- at least 100cm between the left and right side door of the analyzer and the walls, which is the preferred access to perform service procedures;
- at least 50cm behind the analyzer for cabling and ventilation.

⚠WARNING

- There should be enough room on and below the countertop to accommodate the reagents and waste containers.
- The diluent container shall be put within 1.0m under the analyzer, lyse containers are placed inside the analyzer.
- The countertop (or the floor) where the analyzer is placed shall be able to withstand at least 60kg of weight.

2.4.2.Power Requirements

Table 2-1 Power specification

	Voltage	Input power	Frequency
Analyzer	100-240V~	250VA	50/60Hz

⚠WARNING

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

⚠CAUTION

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

2.4.3.Environmental Requirements

1) Operating temperature range: 18℃-35℃
2) Relative humidity: ≤ 70%
3) Atmospheric pressure: 70.0kPa-106.0kPa

NOTE

- The environment shall be as free as possible from dust, mechanical vibrations, loud noises, and electrical interference.
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.

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

2.4.4.Moving and Installation Method

Producer-authorized 0f,the presenceMoving and installation of the analyzer shall be conducted by personnel.Do not move or install your analyzer without Producer-authorized personnel or local distributor.

⚠WARNING

Installation by personnel not authorized or trained by Producer may cause personal injury or damage your analyzer.Do not install your analyzer without the presence of Producer-authorized personnel or local distributor.

NOTE

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

2.5. Precautions for Use

1. The analyzer performance may be declined if it has been placed in environment of high dustiness.

2. The surface of the analyzer shall be cleaned and sterilized regularly with alcohol (75%).

3. The aspirate key of the analyzer (see Figure 3-1 Front view of the analyzer) shall be wiped with alcohol (75%) regularly.

4. Sample collection and preparation must be done following standard procedures.

5. If any of the pipes or fluid ic components is worn out, stop using the analyzer and contact Producer customer service department immediately for inspection or replacement.

6. Check and make sure the pipes of reagents, including diluent, lyse and waste, are not pressed or bent.

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

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

3.System Description

3.1. Introduction

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

3.2. Parameters

In CBC+DIFF , the corresponding parameters are detailed in the following table:

Table 3-1 Parameters

Parameter Group	Name	Abbreviation	CBC+ DIFF
WBC group (15)	White Blood Cell count	WBC	√
	Basophils number	Bas#	√
	Basophils percentage	Bas%	√
	Neutrophils number	Neu#	√
	Neutrophils percentage	Neu%	√
	Eosinophils number	Eos#	√
	Eosinophils percentage	Eos%	√
	Lymphocytes number	Lym#	√
	Lymphocytes percentage	Lym%	√
	Monocytes number	Mon#	√
	Monocytes percentage	Mon%	√
	Abnormal Lymphocytes number	*ALY#	√
	Abnormal Lymphocytes percentage	*ALY%	√
	Large Immature Cells number	*LIC#	√
	Large Immature Cells percentage	*LIC%	√

Parameter Group	Name	Abbreviation	CBC+ DIFF
RBC group (8)	Red Blood Cell count	RBC	√
	Hemoglobin Concentration	HGB	√
	Mean Corpuscular Volume	MCV	√
	Mean Corpuscular Hemoglobin	MCH	√
	Mean Corpuscular Hemoglobin Concentration	MCHC	√
	Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV	√
	Red Blood Cell Distribution Width - Standard Deviation	RDW-SD	√
	Hematocrit	HCT	√
PLT group (6)	Platelet count	PLT	√
	Mean Platelet Volume	MPV	√
	Platelet Distribution Width	PDW	√
	Plateletcrit	PCT	√
	Platelet larger cell count	P-LCC	√
	Platelet larger cell ratio	P-LCR	√

- **Histograms**

Table 3-2 Histograms

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

- **Scattergram**

Scattergram

Name	Abbreviation
DIFF Scattergram	Diff Scattergram
White Blood Cell Scattergram	WBC Scattergram

3.3.Product Structure and Composition

This series of fully automatic five class blood cell analyzers mainly consists of a sampling needle, sampling components, automatic sampling rack components, optical components, flow chamber, counting cell, sample pump, negative pressure pump, main control board, and drive board.

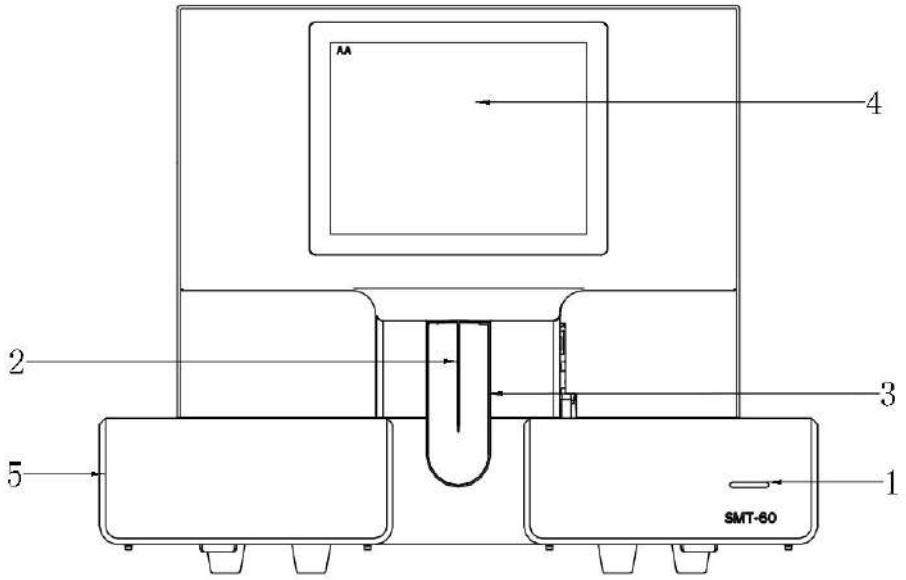


Figure 3-1 Front view of analyzer

1. Status indicator light 2, sampling needle
3. Sample suction button 4, display screen 5, automatic sample rack component

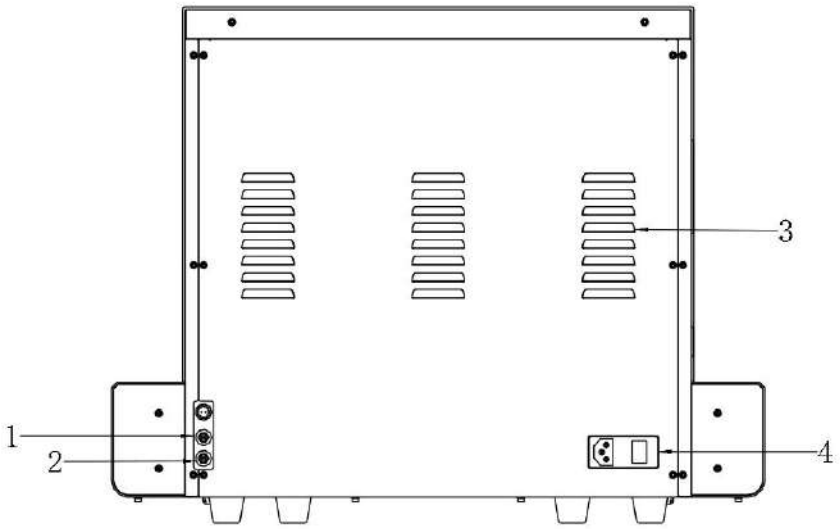


Figure 3-2 Back view of analyzer

1. Dilution interface 2, waste liquid interface
3. Fan channel 4, power switch interface

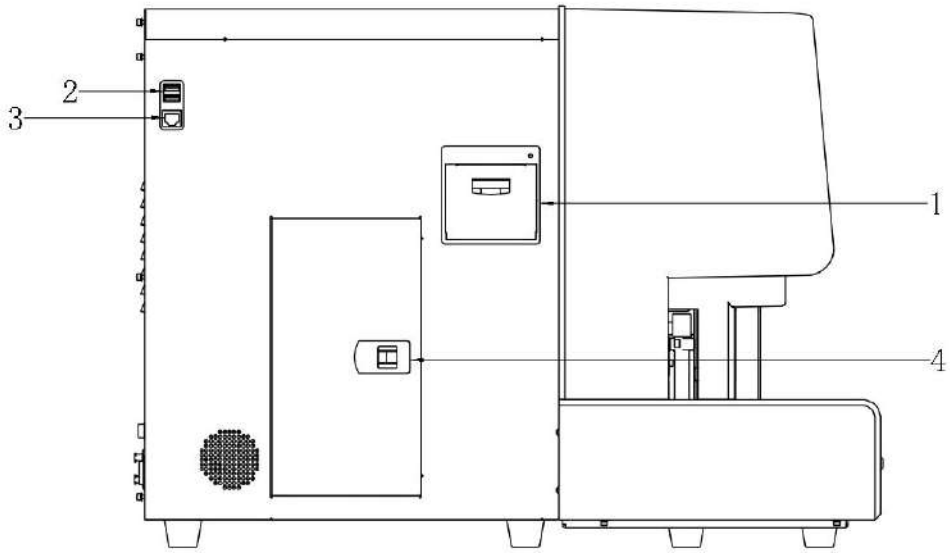


Figure 3-3 Left side view of the analyzer

1. Recorder 2, USB interface

3. Network port 4, door buckle

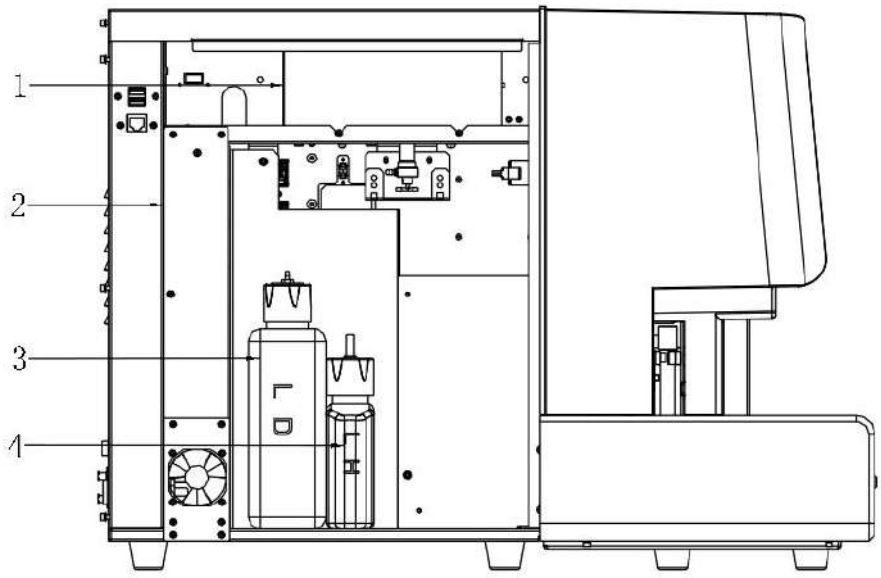


Figure 3-4: Left side of the analyzer (with the side door open)

1. Optical System 2, Power Supply

3. DIFF hemolytic agent 4, LH hemolytic agent

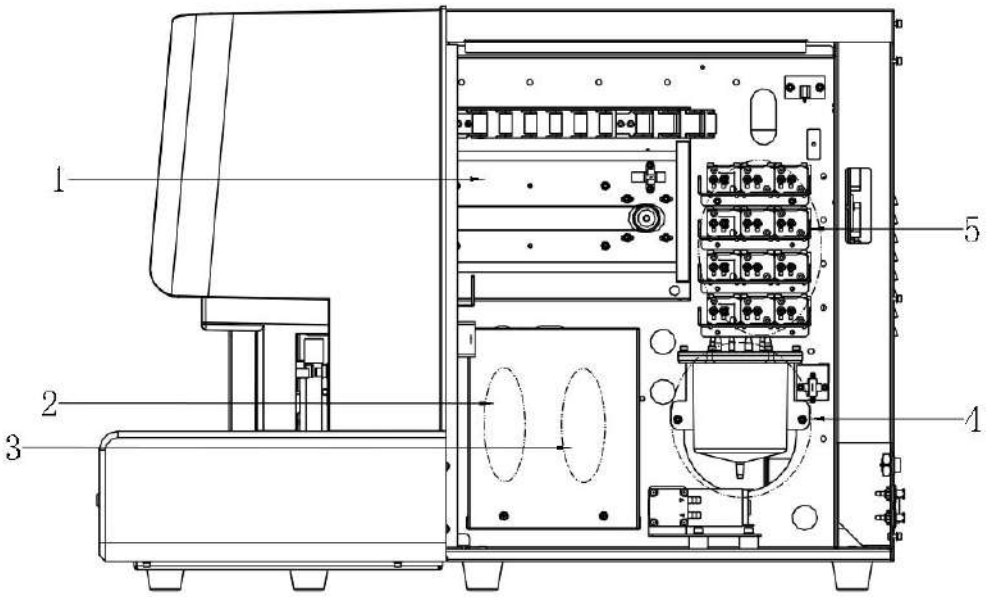


Figure 3-5 Right side of analyzer (side door open)

1. Sampling component 2, RBC detection cell 3, WBC detection cell

4. Waste liquid component 5, liquid valv

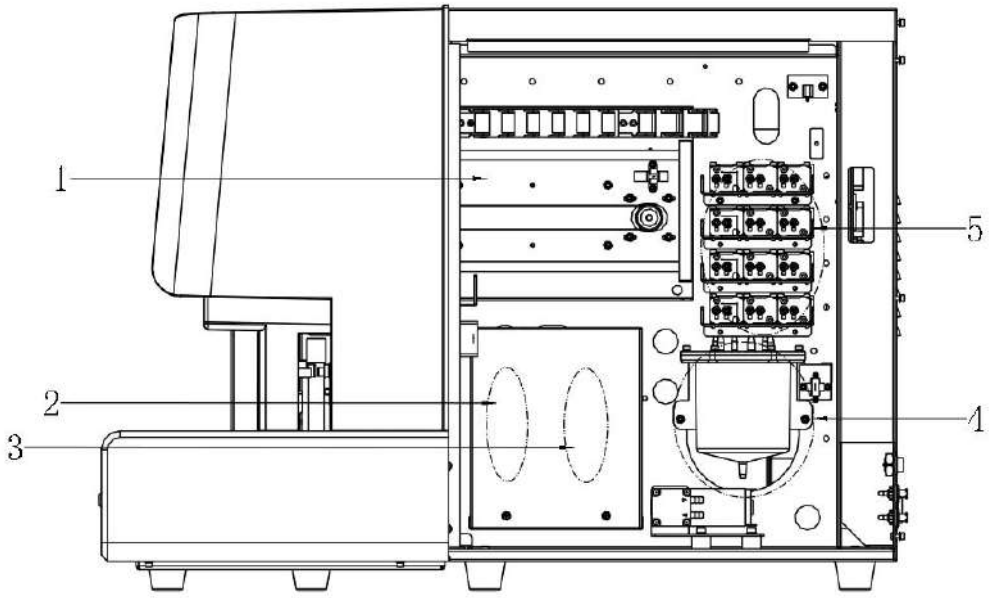


Figure 3-5 Right view of the analyzer (removing the right side sheet metal)

1.Sampling assembly 2.RBC Measurement component

3.WBC Measurement component 4.Pump 5.Liquid valve

3.3.1.Status Indicator

The status indicator is collected in the aspirate key,located at the front and bottom right of the main unit.It indicates the ready, running,error and standby status of the analyzer.

The indicator illuminates in 3 colors to indicate the current status of the analyzer.Its flickering interval is 3 seconds. See the following table:

Table 3-4 Indicator and analyzer status

Indicator	Analyzer status	Remark
Solid green	Ready	Ready to sequence actions
Flickering green	Running	Sequence actions in progress
Solid red	Error	An error has occurred, and the analyzer is not running
Flickering red	Running with error	The analyzer is running with error
Solid yellow	No error, but fluidic actions are not allowed	Initializing (not involving sequence actions) in startup process, standby status
Flickering yellow	Entering/exiting standby status	Entering/exiting standby status

3.3.2.Buzzer

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

Table 3-5 Buzzer and analyzer status

When…	How…	Remark
The startup process completes	1 short beep	The startup process completes and the analyzer ready to run analysis.
Open vial sample aspiration finishes	2 short beeps	/
Press the aspirate key at the analysis screens (including sample analysis, QC, calibration, reproducibility, carryover, background, aging, optical gain calibration screens) when analysis cannot be started.	1 long beep	When dialog box message is given, the buzzer may not beep.
Error	Long beeps at intervals	Tap the touch screen to turn off the buzzer.
The analyzer enters ready status	1 short beep	The analyzer enters ready status from other status.
When the analyzer screen turns black and the message "Please power off the analyzer" appears	Turn off the buzzer	If error occurs during the shutdown process, please turn off the buzzer when the screen turns black.

3.3.3.Power Switch

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

⚠CAUTION

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

3.3.4.Sample Probe

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

3.3.5.Aspirate Key

The aspirate key is located behind the sample probe. Press it to start analysis, dispense diluent or exit from standby mode.

3.3.6.Touch Screen

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

3.3.7.Analyzer Interfaces

- Power interface

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

- Reagent/Waste outlet

Used to connect with reagents or waste container via the reagent cap assembly.

- USB/Network port

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

3.3.8.Recorder

The recorder is located on the left side of the analyzer for printing reports and other information displayed on the screen.

3.4.Reagents, Controls and Calibrators

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

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

NOTE

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

3.4.1.Reagents

- SMT-5D

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

- SMT-5L-HV LH Lyse

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

- SMT-5L-D

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

- SMT-5C

It is used to clean the analyzer regularly.

3.4.2.Controls and Calibrators

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

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

4 .Working principle

4.1.overview

The measurement methods used in this analyzer are: the Electrical Impedance method for determining the WBC, RBC and PLT data; the colorimetric method for determining the HGB; flow cytometry by laser for determining the WBC 5-part differentiation.Other parameter results are obtained via calculation.

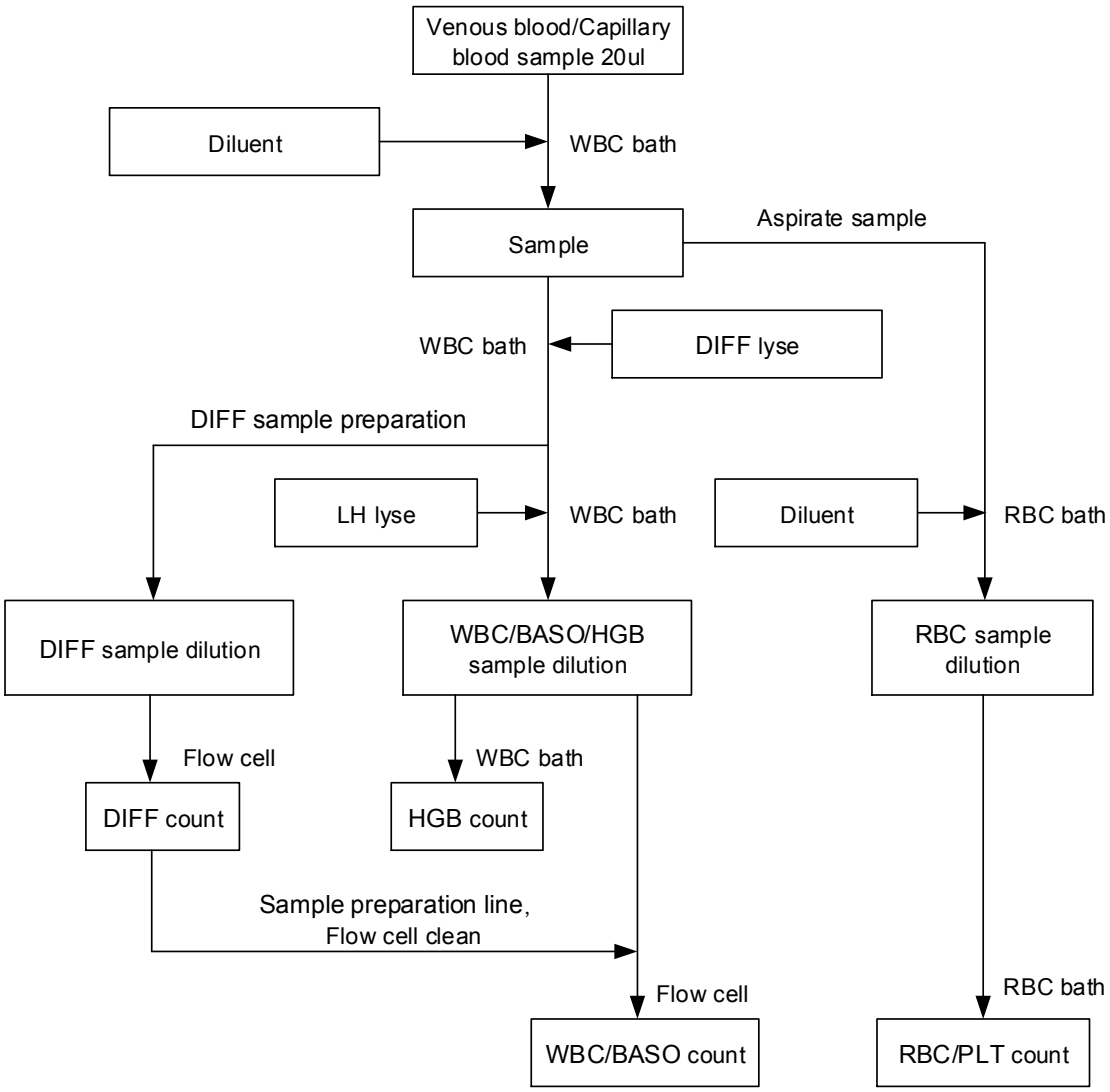
4.2.Extract samples

In the open injection whole blood working mode, the analyzer will draw 20 μ L (CBC+DIFF mode) of whole blood sample.
In the pre dilution mode of open injection, the operator should first mix 20 μ L of peripheral blood sample and 180 μ L of diluent outside the machine to form a diluted sample with a dilution ratio of 1:10, and then send this diluted sample to the analyzer for sampling. At this point, the analyzer will inhale 100 μ L of diluted sample.

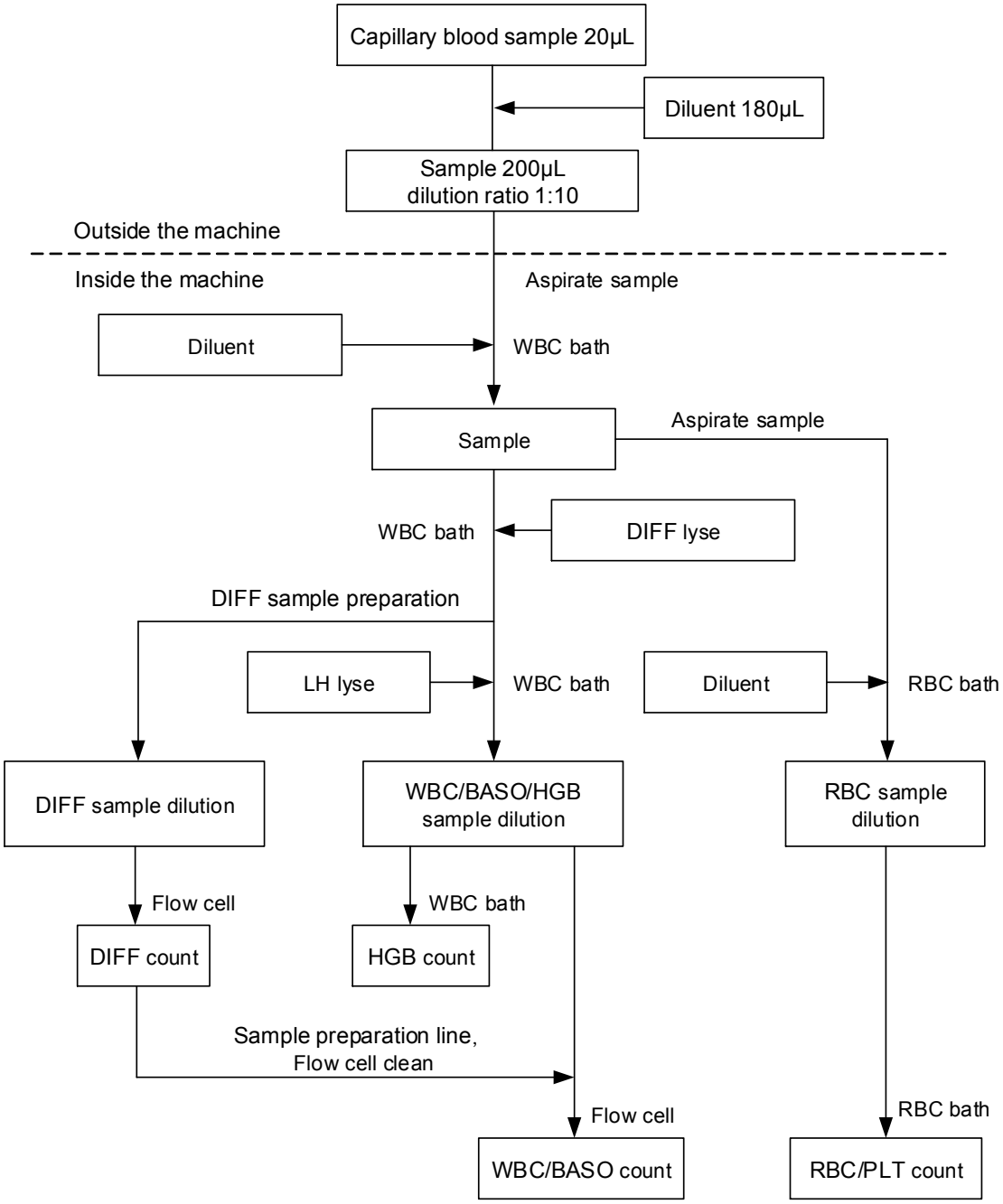
4.3.Dilute the sample

After being drawn into the host, the test sample is divided into two parts and subjected to different reagent reactions in a parallel dilution process to form detection samples for red blood cell/platelet measurement, white blood cell count/hemoglobin measurement,and white blood cell classification measurement.
According to different needs, the analyzer provides two working modes - whole blood working mode and pre dilution working mode.

Whole Blood Mode



Prediluted Mode



4.4.White blood cell measurement

- **Laser flow cytometry technology**

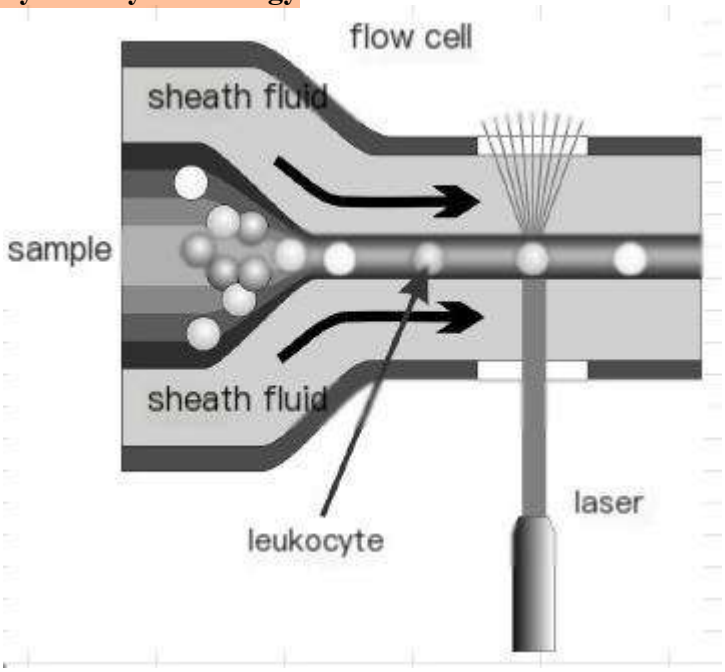


Figure 4-1 White blood cell measurement

After mixing hemolytic agents with blood samples, red blood cells are dissolved and white blood cells are stained.Stained white blood cells and red blood cell fragments are injected into a flow chamber filled with diluent through a sample needle.Under the sheath formed by the diluent, the cells are arranged in rows through the laser detection area after secondary acceleration.The scattered light generated by the irradiation of laser beams on cells is related to the size of the cells, the refractive index of the cell membrane, and the internal structure of the cells.Photodiodes receive these scattered light signals and convert them into electrical pulses.Based on the collected electrical pulse data, a three-dimensional distribution map of blood cell size and internal information can be obtained, called a scatter plot.The results of white blood cell five classification and counting can be obtained through DIFF scatter plot and WBC scatter plot.

4.5.Hemoglobin concentration measurement

Colorimetric Method

After adding hemolytic agent to the diluted sample, red blood cells dissolve and release hemoglobin, which combines with the hemolytic agent to form hemoglobin complexes. According to Lambert Beer's law, under the irradiation of monochromatic LED light with a center wavelength of 530nm, the transmitted light intensity of hemoglobin complex solution and background conditions can be measured, and the hemoglobin concentration can be obtained by calculation.

- **HGB**

The hemoglobin concentration (HGB) is calculated using the following formula, with units of g/L.

HGB = Constant × Ln(Reference Light Intensity / Sample Light Intensity)

4.6.Red blood cell/platelet measurement

Principle of Impedance Method

This analyzer utilizes the impedance method principle to achieve red blood cell/platelet counting. The RBC counting cell has a small opening called the detection orifice. There are a pair of positive and negative electrodes on both sides of the small hole, which are connected to a constant current power supply. Due to the fact that cells are poor conductors of electricity, when the cells in the diluted sample pass through the detection hole under constant negative pressure, the resistance between the electrodes changes, forming a pulse signal proportional to the volume of the cells at both ends of the electrode.The number of pulses is equivalent to the number of cells passing through the small hole, and the amplitude of the pulses is proportional to the volume of the cells.

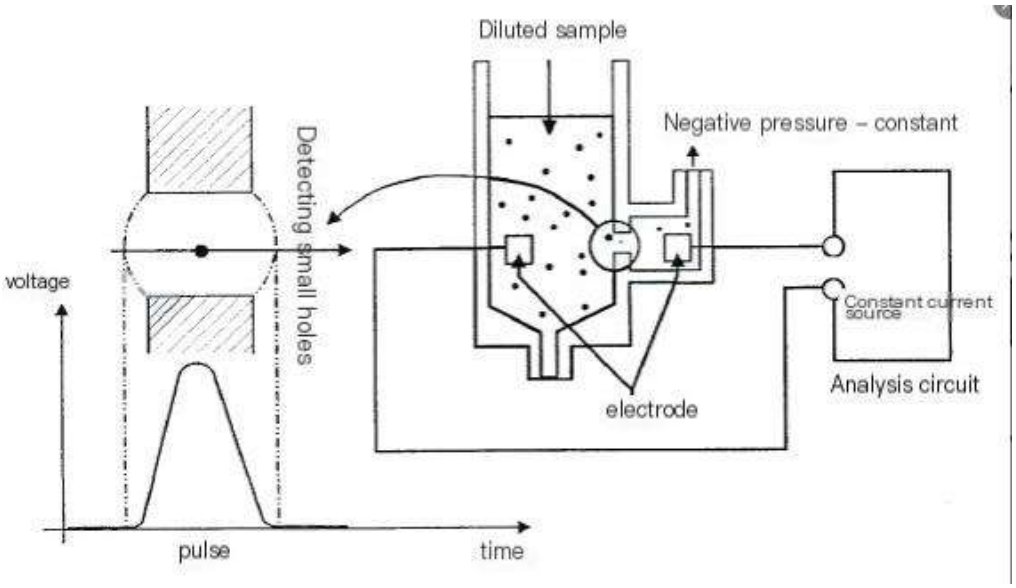


Figure 4-2 Counting Principle Diagram

Amplify the collected electrical pulses and compare them with the channel voltage threshold corresponding to the normal red blood cell/platelet volume range to calculate the number of electrical pulses with amplitudes falling within the red blood cell/platelet channel. Therefore, all collected electrical pulses are classified according to different channel voltage thresholds, and the number of electrical pulses falling in the red blood cell/platelet channel is the number of red blood cells/platelets. The number of cells within each channel range determined by the amplitude of the pulse voltage determines the volume distribution of the cells. A two-dimensional graph with the horizontal axis representing cell volume and the vertical axis representing the relative number of cells is a histogram that reflects the distribution of cell populations.

● **RBC Parameters**

RBC

The analyzer obtains the number of red blood cells (RBC) in 1012/L by directly measuring the number of electrical pulses corresponding to red blood cells.

MCV

Calculate the mean corpuscular volume (MCV) in fL based on the histogram of red blood cell distribution.

HCT、MCH、MCHC

Calculate the hematocrit (HCT) in% using the following formula; Mean corpuscular hemoglobin content (MCH), in pg; Mean corpuscular hemoglobin concentration (MCHC), in g/L.

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

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

$$MCHC = \frac{HGB}{RBC} \times 100$$

Among them, RBC unit is 1012/L, MCV unit is fL, and HGB unit is g/L.

RDW-CV

The coefficient of variation of red blood cell distribution width (RDW-CV) is obtained from the histogram of red blood cell distribution, measured in%.

RDW-SD

The standard deviation of red blood cell distribution width (RDW-SD) is obtained by calculating the standard deviation of red blood cell volume distribution, measured in fL.

● **PLT Parameters**

PLT

The analyzer obtains the platelet count (PLT) in units of 109/L by directly measuring the number of electrical pulses corresponding to platelets.

MPV

Calculate the mean platelet volume (MPV) in fL based on the platelet distribution histogram.

PDW

The platelet distribution width (PDW) is obtained from the platelet distribution histogram and is the geometric standard deviation (10GSD) of platelet volume distribution.

PCT

The analyzer calculates platelet hematocrit (PCT) in% using the following formula.

$$PCT = \frac{PLT \times MPV}{10000}$$

Among them, PLT unit is 109/L, and MPV unit is fL.

5.Basic Operations

5.1.Introduction

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

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

- Do not contact the patients' sample blood directly.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If reagents accidentally spill on your skin or into your eyes, rinse the area with plenty of clean water and seek medical attention immediately.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

⚠CAUTION

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

NOTE

- Use the reagents specified by the Producer only. Store and use the reagents as instructed by instructions for use of the reagents.
- Check if the reagent tubes are properly connected before using the analyzer.
- Be sure to use clean $EDTAK_2$ or $EDTAK_3$ anticoagulant collection tubes, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Be sure to use the evacuated collection tubes recommended in Appendix A.
- Be sure to use the Producer-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes etc.

5.2. Initial Checks

Perform the following checks before turning on the analyzer.

- **Checking the waste container**

Check and make sure the waste container is not full.

- **Checking reagents**

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

- **Checking tubing and power connections**

Check and make sure the reagents, waste and pneumatic unit tubes are properly connected and not bent.

Check and make sure the power cable of the analyzer is properly plugged into the power outlet.

- **Checking the printer (optional)**

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

5.3.Startup and Login

Start up the analyzer:

1. Change the power switch at the backside to ON position (“I”) will power on the instrument.
2. The indicator light turns on.
3. The analyzer will perform self-test, initialization and liquid path maintenance.

NOTE

- Time needed for initializing the fluidic system depends on how was the analyzer previously shut down.
- Background check is the measurement of particle and electric interference by the analyzer.
- If the results of the first background check do not meet the requirement, the analyzer will perform background check again.
- The sample ID of background check results is “background”.
- The error message “Background abnormal” will be given when the background results are out of range.

---

4. Enter the current user name and the password respectively into the “User Name” box and the “Password” box.

NOTE

- If the software cannot be started successfully after being launched for several times, contact Producer customer service department or the authorized distributors.
- After starting up the analyzer, check if the date/time is correct.
- The default user name for administrator is “Admin”, the password is 123456.
- The user name and password may be consisted of 1-12 letters, and the password cannot be null.

5. Click “Login” to enter the system.

NOTE

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

5.4.Daily Quality Control

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

5.5.Sample Collection and Handling

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

⚠WARNING

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

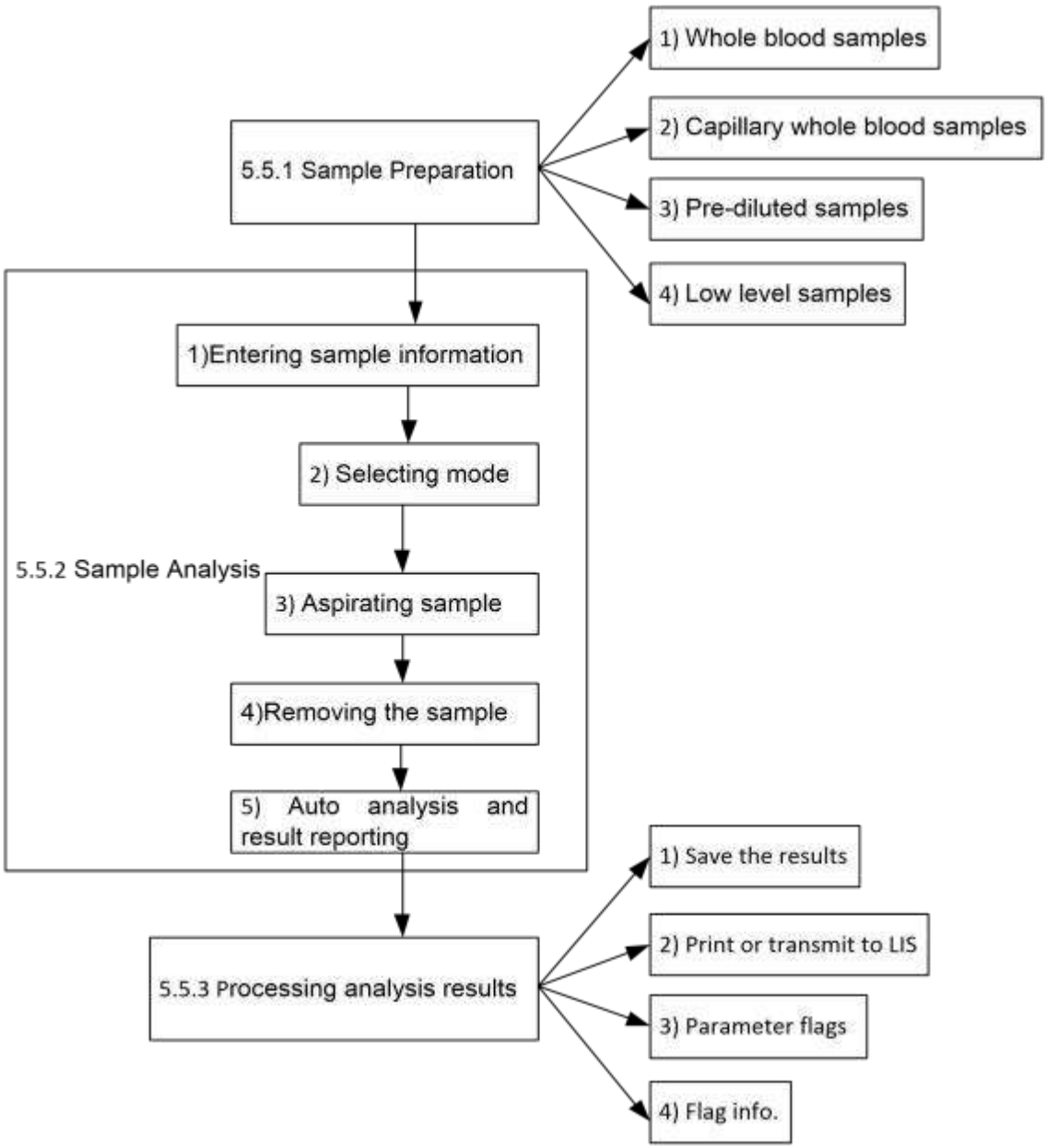
⚠CAUTION

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

NOTE

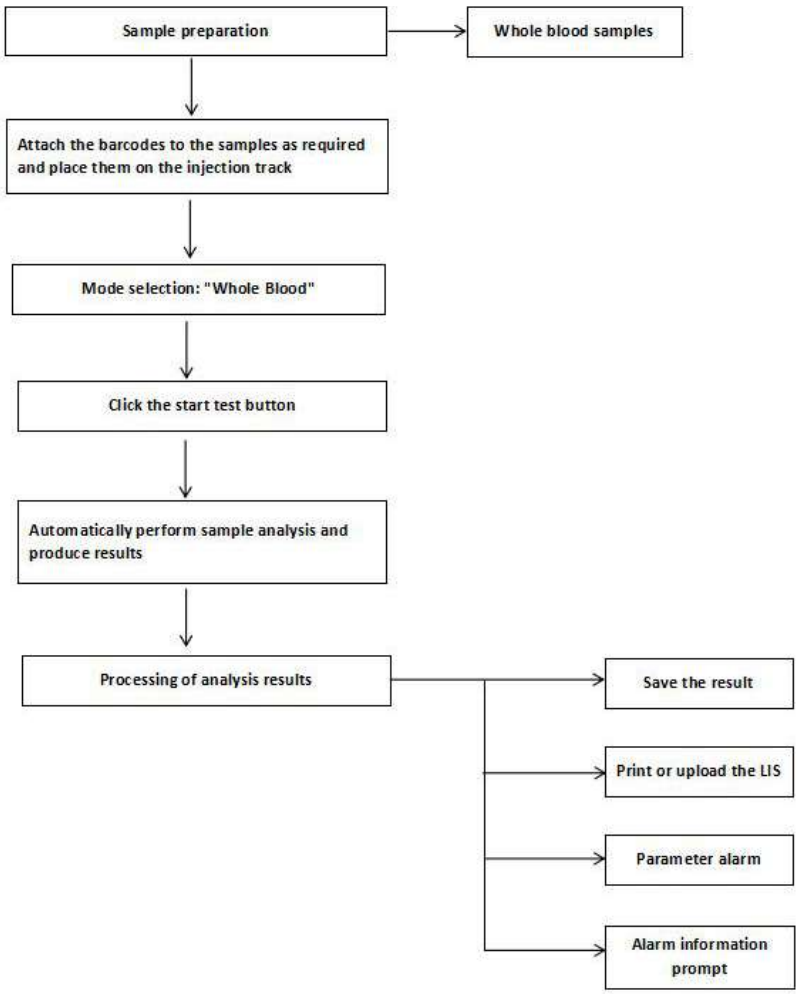
Make sure the probe tip does not contact the sample tube to avoid potential spillage.

Open measurement mode:



Auto measurement mode：

Before performing the automatic sample injection analysis, the user needs to prepare the standard test tube rack of Xilaiheng Medical Electronics Company and the test tubes of the specified specifications, and place them on the automatic sample injection track as required.



5.5.1. Sample Preparation

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

⚠CAUTION

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

---

1) Whole blood samples

1. Use clean $EDTAK_2$ or $EDTAK_3$ anticoagulant collection tubes to collect venous blood samples.

2. Mix the sample according to your laboratory's protocol.

⚠CAUTION

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

---

2) Capillary whole blood samples

Use tubes to collect capillary whole blood samples.

⚠CAUTION

Be sure to collect at least 120μL of capillary whole blood to ensure the accuracy of the results.

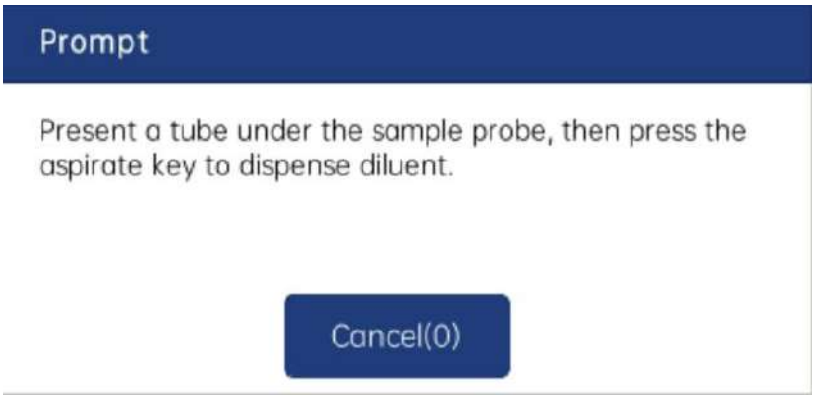
NOTE

Be sure to run the capillary whole blood samples within 3 minutes to 2 hours after being collected.

---

3) Pre-diluted samples

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



2. Present a clean tube to the sample probe, press the aspirate key to dispense diluents (180μL). The dispensing progress bar will be displayed on the screen.

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

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

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

NOTE

- You can also use pipette to aspirate 180μL of diluent.
- Be sure to keep dust from the prepared diluent.
- After mixing the capillary sample with the diluent, be sure to wait 3 minutes and then remix before running the sample.
- Be sure to run the pre-diluted samples within 30 minutes after the mixing.
- Be sure to mix any sample that has been prepared for a while before running it. Do not mix the samples with massive force using swirl mixer.

- Be sure to evaluate pre-diluted stability based on your laboratory's sample population and sample collection techniques or methods.

5.5.2. Sample Analysis

Click "Sample Analysis" to enter the sample analysis screen. Click "Mode" button to select "Whole Blood-CBC+DIFF", "Capillary WB-CBC+DIFF", "Predilute-CBC+DIFF" Mode.

1) Entering sample information

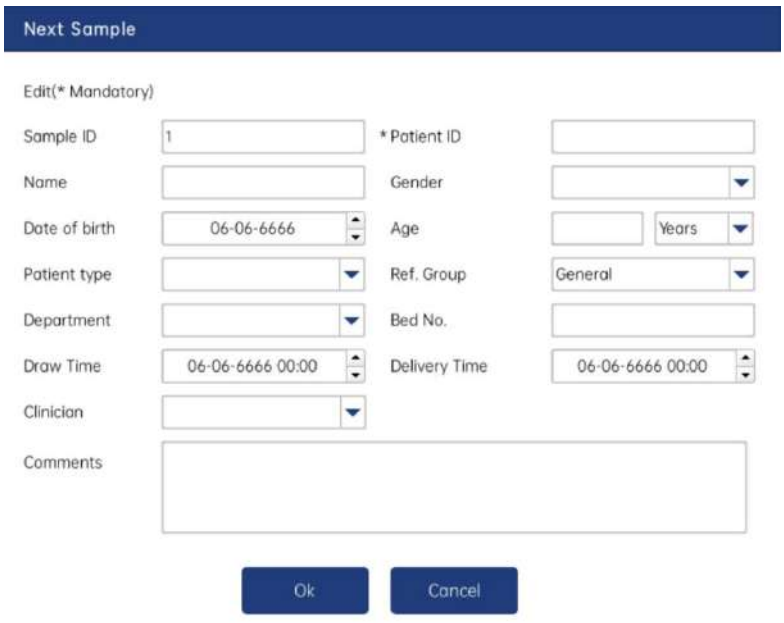
The analyzer provides two ways for you to enter sample information: entering sample ID only and entering all sample information.

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

- **Entering all information**

When the way to enter patient demographic information is set to "Enter all information", click "Next Sample" at the sample analysis screen, the following dialog box will display.

You may enter complete information of the next sample into the dialog box. The "Ref. group" will be selected by the system.



a) Entering the sample ID

Enter the sample ID in the “Sample ID” box.

b) Entering the medical record number

Enter the medical record number in the “Patient ID” box.

c) Entering the patient name

Enter the patient name into the “Name” box.

d) Selecting patient gender

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

e) Entering the date of birth

Enter the patient’s date of birth into the “Date of Birth” box. Its format must be the same with the system date format.

f) Entering the patient’s age

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

NOTE

- If the patient’s date of birth is entered, his/her age will be calculated automatically, and the age field will gray out and cannot be edited.
- If the entered date of birth is later than the current system, then it is considered invalid.

---

g) Entering the patient type

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

h) Entering the department name

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

i) Entering the bed number

Enter the number of the patient’s bed into the “Bed No.” box.

j) Entering the draw time

Enter the time when the sample is collected into the “Draw Time” box.

k) Entering the delivery time

Enter the delivery time of analysis into the “Delivery Time” box.

l) Entering the clinician

To enter the name of the person who sent the sample for analysis, enter the name into the “Clinician” box or select the desired name from the “Clinician” pull-down list (if there are previously saved names in the list). The saved contents will be added in the pull-down list automatically.

m） Entering comments

Enter comments in the “Comments” box.

n) OK

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

o) Cancel

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

- **Entering sample ID only**

When the way to enter patient demographic information is set to “Enter sample ID only”, click “Next Sample” at the sample analysis screen, the following dialog box will display.

Enter the sample ID in the “Sample ID” box. Click “OK” to save the ID and close the dialog box, the ID will be displayed on the screen as the next sample ID.

2）Selecting mode

Make sure the analyzer indicator is solid green. Select “Whole Blood”, “Capillary WB”, “Predilute” Mode. based on your needs on the mode selection screen. The selected mode will be displayed at the bottom of the screen.

3) Aspirating sample

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

4) Removing the sample

The sample probe will automatically aspirate sample. When you hear the beep sound, you may remove the sample.

5) Auto analysis and result reporting

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

NOTE

- During the analysis, if errors like clog occur, the analyzer will automatically display results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting for the way to remove errors.

5.5.3. Processing Analysis Results

1) Saving analysis results automatically

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

2) Printing and Transmission to LIS

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

3) Parameter flags

See the following section for details about parameter flags.

- If the parameter is followed by a "H" or "L", it means the analysis result has exceeded the upper or lower limit of the reference range (See section 9.2.3. Parameter Setup > Reference Range Setup).
- If the parameter is followed by an "R", it means the analysis result is questionable.
- If you see "*****", as opposed to the result, it means the result is invalid; if you see "+++++", as opposed to the result, it means the result is out of the display range (See Table 5-1 Display range for details).

Parameter	Display Range
WBC, Bas#, Neu#, Eos#, Mon#, Lym#, *ALY#, *LIC#	0.00 ~ 999.99× 10^9/L
Bas%, Neu%, Eos%, Mon%, Lym%, *ALY%, *LIC%	0.0 ~ 99.9%
RBC	0.00 ~ 18.00× 10^{12}/L
HGB	0 ~ 300g/L
HCT	0.0 ~ 80.0%
MCV	0.0 ~ 250.0fL
MCH	0.0 ~ 999.9pg
MCHC	0 ~ 9999g/L
RDW-SD	0.0 ~ 999.9fL
RDW-CV	0.0 ~ 99.9%
PLT	0 ~ 9999× 10^9/L
PDW	0.0 ~ 99.9
MPV	0.0 ~ 99.9fL
PCT	0.0 ~ 0.999%
P-LCC	0 ~ 9999× 10^9/L
P-LCR	0.0 ~ 99.9%

4) Flags of abnormal blood cell differential or morphology

The following table lists all flags and their indications.

Flag Type	Flag	Meaning	Judgment criterion
WBC Flag	WBC Abnormal	Abnormally low WBCs or incorrect classification	WBC<1×10^9/L and RBC>1×10^{12}/L and PLT>25×10^9/L and HGB>28g/L
	Aspiration or blank abn.	There may be a background abnormality or a sample abnormality	Under the condition of WBC<1×10^9/L or RBC<0.9×10^{12}/L or PLT<25×10^9/Lor HGB<28 g/L, three cases are removed: 1.Remove the normal sample situation: three parameters are greater than the corresponding value; 2.Removal of normal background: WBC<0.5×10^9/L,RBC<0.2×10^{12}/L, PLT<10×10^9/L and HGB<1g/L 3. Remove the normal condition of one channel of WBC and RBC: WBC>1×10^9/L and HGB>28 g/L, or RBC>0.9×10^9/L and PLT>25×10^9/L
	WBC histogram abnormal	There may be a classification abnormality	R1, R2, R3, R4 or RM alarm
	WBC decrease	WBC count is significantly lower	1×10^9/L≤WBC < 2.50×10^9/L
	WBC increase	WBC count is significantly higher	WBC > 18.00×10^9/L
	Neu decrease	Neutrophils are significantly lower	Neu# < 1.00×10^9/L

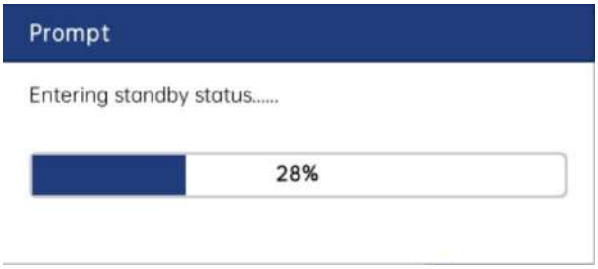
	Neu increase	neutrophils are significantly higher	Neu# > 11.00×10^9/L
	Lym decrease	Lymphocytes are significantly lower	Lym# < 0.80×10^9/L
	Lym increase	Lymphocytes are significantly higher	Lym# > 4.00×10^9/L
	Mon increase	Monocytes are significantly higher	Mon# > 1.5×10^9/L
	Eos increase	Eosinophils are significantly higher	Eos# > 0.70×10^9/L
	Bas increase	Basophils are significantly higher	Bas# > 0.20×10^9/L
	Pancytopenia	WBC, RBC and PLT decrease	At the same time meet: 1×10^9/L≤WBC < 4.0×10^9/L 0.9×10^{12}/L≤RBC < 3.5×10^{12}/L 25×10^9/L≤PLT < 100×10^9/L
RBC Flag	RBC Histogram Abn.	Possible presence of microcytes, macrocytes, anisocytosis, RBC agglutination	The distribution of RBC histogram is abnormal

		and dimorphic histogram	
	RBC agglutination?	RBC agglutination	Agglutination ratio of RBCs exceeds a certain range
	Bimodality	Multiple peaks appear in the RBC histogram	RBC histogram has two or more peaks
	HGB Abn./Interfere?	HGB abnormal or RBC agglutination, or interference may exist (e.g., WBC high)	MCHC> 380g/L or HGB interference calculation parameters are beyond a certain range
	Iron-deficiency?	Iron deficiency anemia	Comprehensive judgment of RDW-CV, MCV and MCHC
	Hypochromic	Hypochromic	MCHC<290 g/L
	Microcytosis	MCV low	MCV < 70fL
	Macrocytosis	MCV high	MCV > 110fL
	Anemia	Anemia	RBC>0.9×10^{12}/L 且HGB<90g/L
	Erythrocytosis	RBC high	RBC > 6.5×10^{12}/L

PLT Flag	PLT distribute abnormally	There may be abnormalities such as small RBCs, RBC debris, giant PLTs, and PLT aggregation.	PLT histogram PLT/RBC boundary is unclear to a certain extent
	PLT agglutination?	PLT agglutination	Comprehensive judgment of the degree of aggregation of RDW-CV, MCV and MCHC histograms
	PLT decrease	PLT low	$25\times10^9/L \leq PLT < 60\times10^9/L$
	PLT increase	PLT high	$PLT > 600\times10^9/L$

5.6.Standby

When the time for which the analyzer is free from fluidic operations reaches that you have set at the "Setup" screen of the analyzer (default setting is 10 minutes), a dialog box will pop up, prompting "Entering standby status…".



And the analyzer will prompt you to backup data.

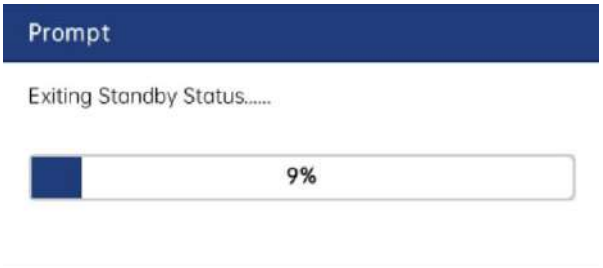
After entering standby status, the message "Standby. Press the aspirate key to exit." will be displayed at the bottom left of the screen.

NOTE

- The analyzer will not enter standby status from the Status screen.
- If it is time for auto-standby and the analyzer is reporting error, then the error must be resolved first.
- During this condition, you can still perform any other operations (e.g., printing and transmission) other than fluidic operations.
- Refer to Section 9.2.4 Maintenance Setup for how to edit waiting time before entering standby mode.
- Under standby mode, if there are unfinished printing or communication tasks, the analyzer will go on processing them.

Aspirate key

Press the aspirate key to exit the standby status.



After exiting the standby status, the dialog box above will close automatically.

NOTE

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

5.7.Shutdown

⚠CAUTION

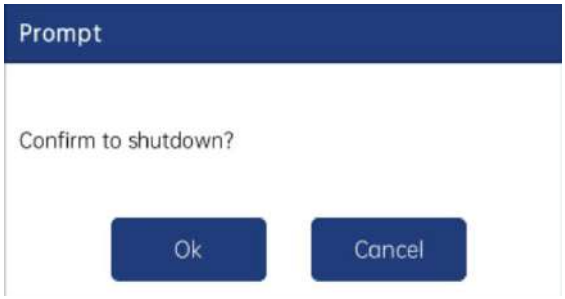
Do not start up the analyzer immediately after it is shut down. Wait for at least 10 seconds.

NOTE

To ensure stable analyzer performance and accurate analysis results, be sure to perform the shutdown procedure to shut down the analyzer after it has been running continuously for 24 hours.

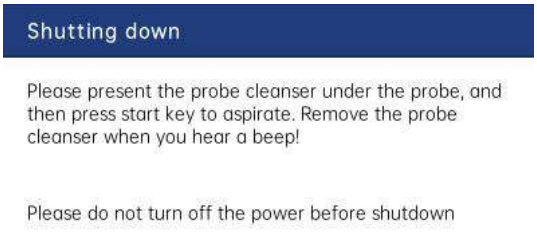
Perform the shutdown procedure to shut down the analyzer daily.

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



2.Click “OK”.

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



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

⚠WARNING

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

NOTE

- Do not disconnect power during the shutdown process.
- If error that will affect shutdown occurs during the showdown process, the analyzer will resume to its original status and report the error. See Chapter 11 Troubleshooting for solutions.

6.Reviewing Results

6.1.Introduction

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

6.2.Browsing in the “ Review” Mode

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

6.2.1.Table Area

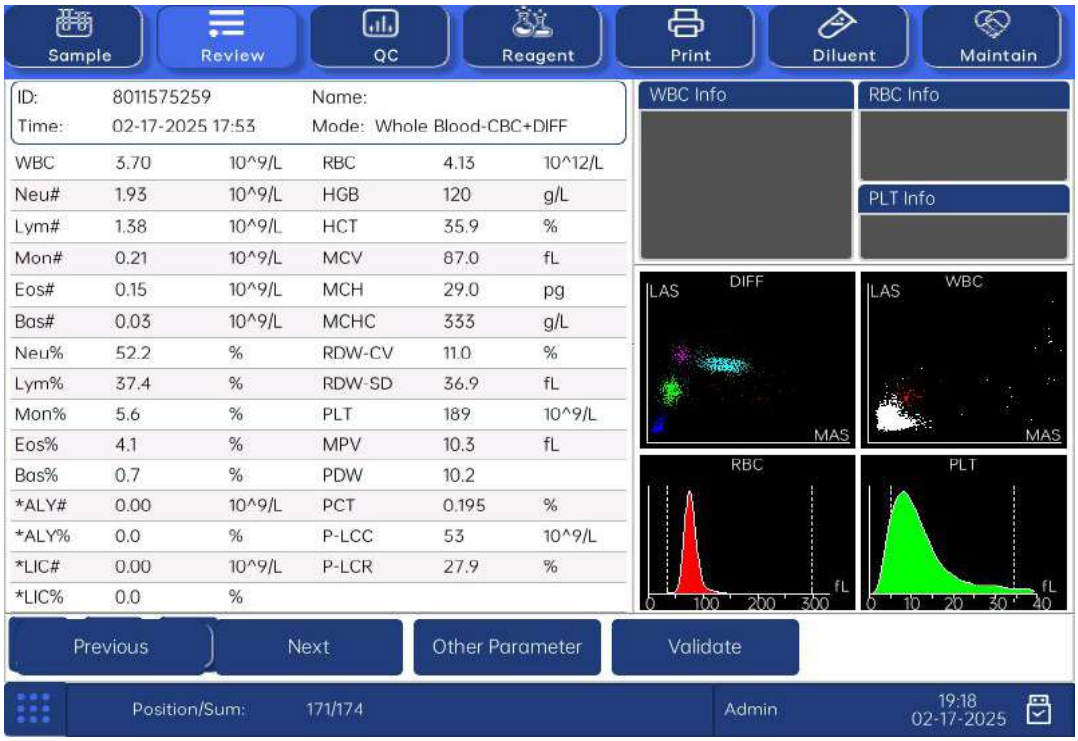
The table area lists all analyzed samples, including basic sample information like sample ID, sample status and so on.

NOTE

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

6.2.2.Graph Review

Click “Graph Review” button on the review menu to view the analysis results of samples.



6.2.3.Validate/Cancel Validation (for administrators only)

- Validate sample data

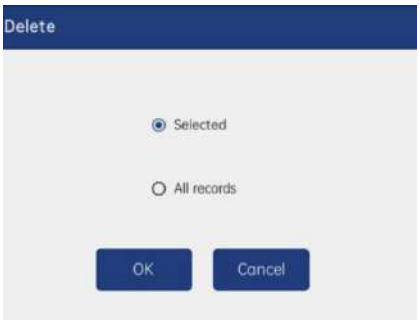
Select one or more sample records on the review menu, click “Validate”, the sample status of the record will be marked with “Validated”.

- Cancel Validation

Select one or more validated sample records at the review menu, click “Cancel Validation”, the “Validated” will disappear.

6.2.4.Delete (for administrators only)

1. Select the sample record to be deleted in the table area.
2. Click “Delete”, the following dialog box will display.

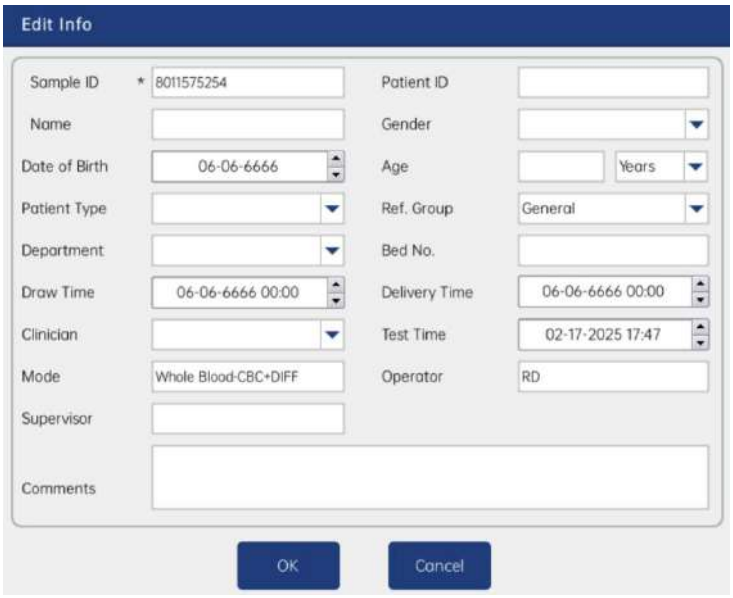


3. Click “Yes” to delete the record, and the dialog box will be closed.

6.2.5.Edit Information

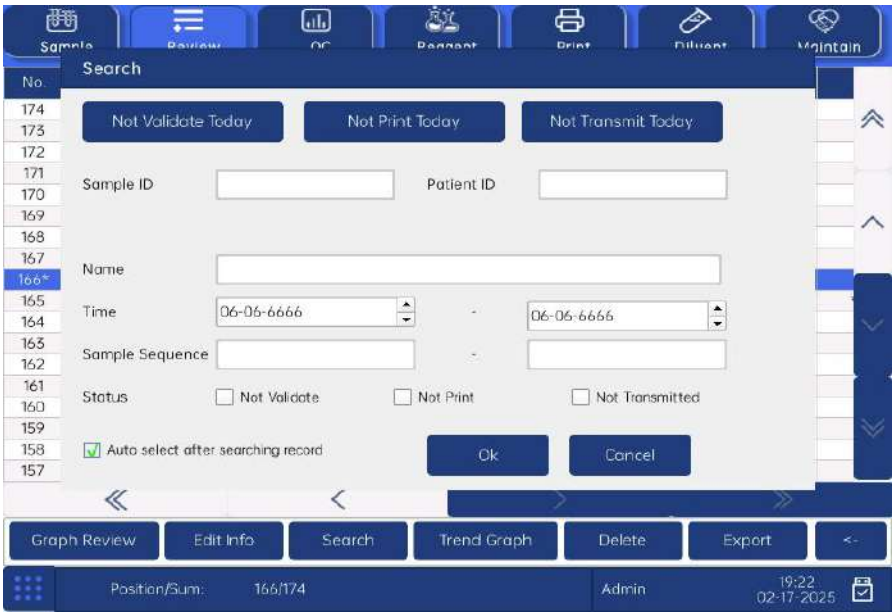
Click the desired sample result and it will be highlighted. Click the “Edit Info” button and the following dialog box will display.

You may edit the sample and patient information, and click “OK” to save the change. The information on the review menu will be refreshed.



6.2.6.Search

1. Click “Search”, the following dialog box will display.



2. Enter search conditions into the edit boxes or select them from the pull-down lists.
3. Click “OK” to start search, the results will be displayed in the table area.

6.2.7.Print

Print reports according to the default report template.

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

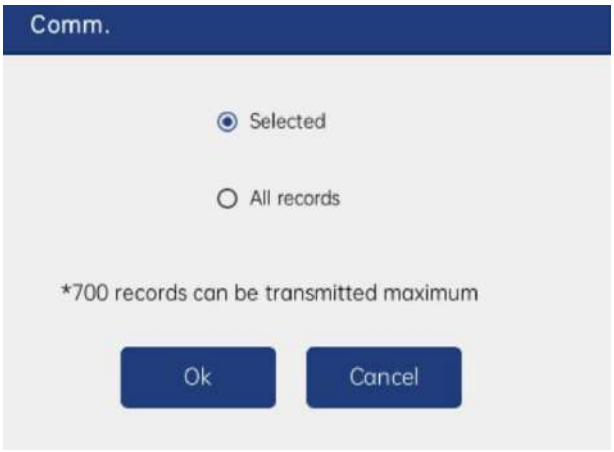
NOTE

In the sample status sector, “Validated” sign is prior to “Printed” sign.

6.2.8.Transmission

- Transmit selected data

1. Select samples to be transmitted at the review menu.
2. Click “Comm.”, the following dialog box will display.



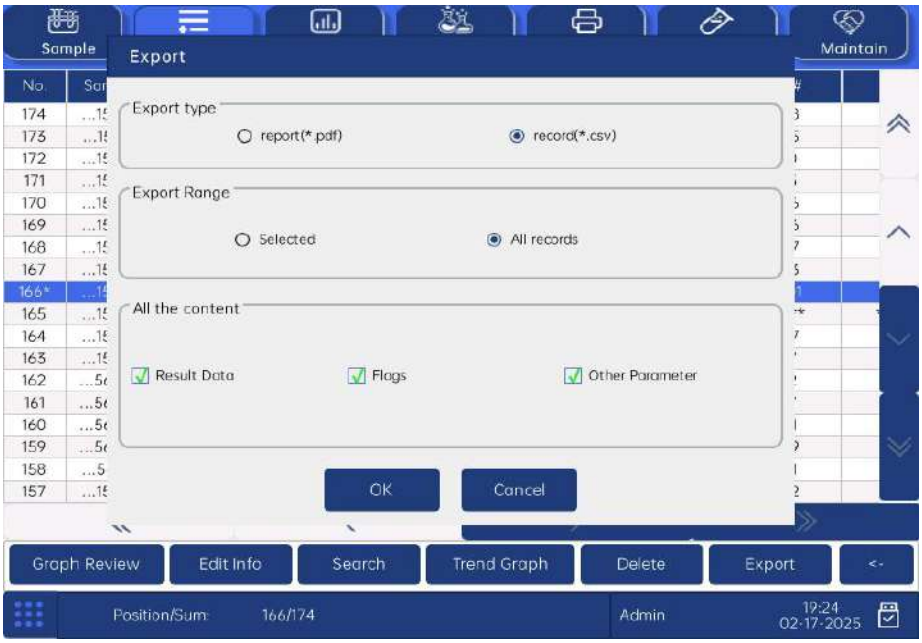
3. Click the “Selected” radio button.
4. Click “OK” to start transmitting specified results to the data management software.

- Transmit all data

1. Click the “All records” radio button in the above dialog box.
2. Click “OK” to start transmitting all results to the data management software.

6.2.9. Export

1. Click “Export”, the following dialog box will display.



2. Select “Selected” or “All records” in the “Export Range” area.

3. Check the type of information to be exported in the “All the content” area.

7.Quality Control

7.1. Introduction

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

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

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

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

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

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

⚠CAUTION

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

NOTE

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

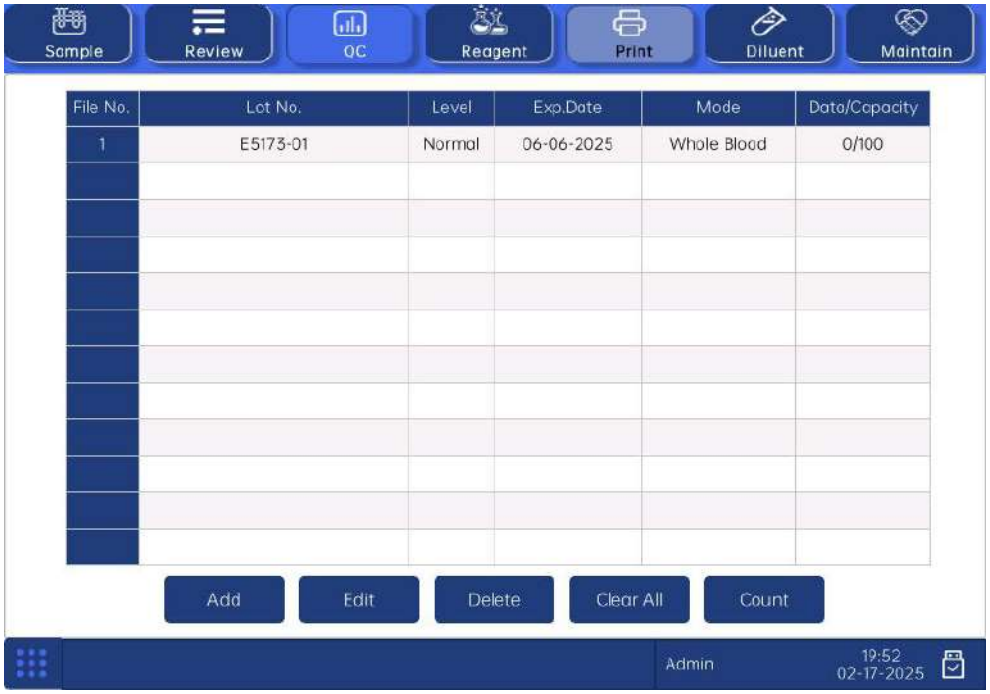
7.2.L-J QC

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

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

1. Click the menu option “QC” > “L-J QC” >

“Setup”. Enter the L-J QC setup screen.



Manual entry

You may set up the QC information by manual entry.

1) Enter the L-J QC setup screen.

2) Click “Add”, or select a QC file without QC results, and then click “Edit”.

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

NOTE

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

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4) Select the control level.

5) Enter the expiration date of the lot.

6) Select the QC mode.

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

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

Setting limits

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

1) Click “Set Limits”.

2) Click “By SD” to display the limits in the form of absolute value, or click “By CV” to display the limits in the form of percentage.

3) Click “OK” button to save the settings.

Import File

The user can complete the setting of the QC information through the file import in the QC file.

1) Download the QC target value file of the corresponding lot and level from the specified official website: LJSetup.csv, place the file in the root directory of the USB flash drive, and then insert the USB port on the instrument side;

2) Enter the L-J QC Setup interface.

3) Click the “Import File” button to open the import window, select the file and press the [OK] button. The Target, Limit, Level, Lot No, Exp.Date and other information in the quality control file will be imported into the current QC setup file.

NOTE

Keep consistent with the current language. For example, Chinese must import the QC file whose content is Chinese, and English must import the QC file whose content is English.

7.2.2.Running L-J QC

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

- Run controls under the “QC” screen.
- Put controls together with normal samples, and run the controls under the sample analysis screen.

Run controls under the “QC” screen

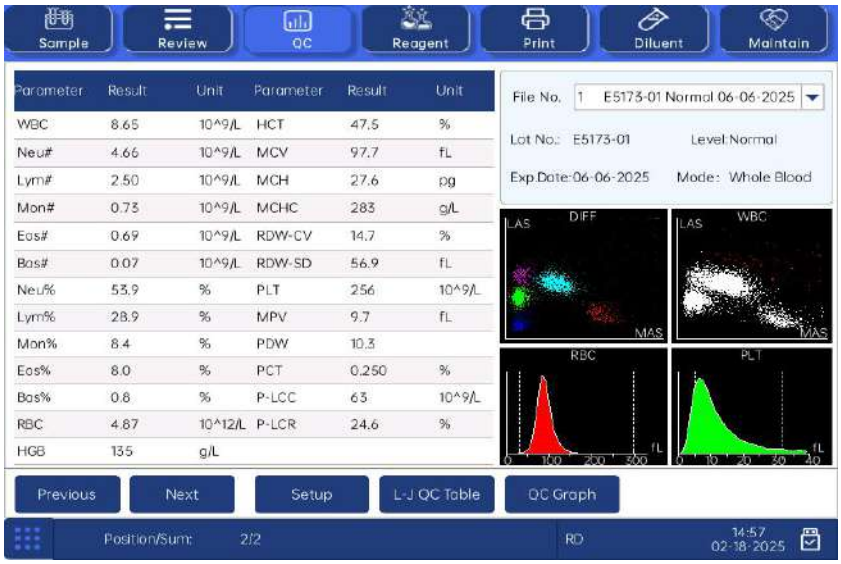
After editing the QC information, you can start QC analysis by one of the following ways according to the selected QC mode.

1) Whole Blood
2) Prediluted

NOTE

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

1、 Click the menu option “QC” > “L-J QC” > “Count” to enter the QC count screen.



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

NOTE

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

3、 Run QC analysis:

1) Make sure the analysis mode is “Whole Blood” or “Pre-diluted” and the indicator of the analyzer is green.

2) Shake the vial of sample as instructed by instructions for use of the control to mix the sample thoroughly.

3) Present the control sample to the sample probe. Press the aspirate key to start QC analysis.

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

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

NOTE

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

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

7.2.3.Reviewing L-J QC Results

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

1) QC Graph

2) QC Table

L-J QC graph review

1、 Click “QC Graph” button on the L-J QC screen to enter the L-J QC graph screen.

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

NOTE

If parameter targets/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters change accordingly, those changed data will be highlighted in yellow.

Print

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

NOTE

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

L-J QC table review

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

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

NOTE

If parameter targets/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters change accordingly, those changed data will be highlighted in yellow.

Print

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

Delete (for administrators only)

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

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

NOTE

The operation will be recorded in the system log.

Transmission

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

1) Click “Comm.”, the following dialog box will display.

2) Select to transmit “Selected” or “All” records.

3) Click “OK” to start transmitting specified results to the data management software.

NOTE

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

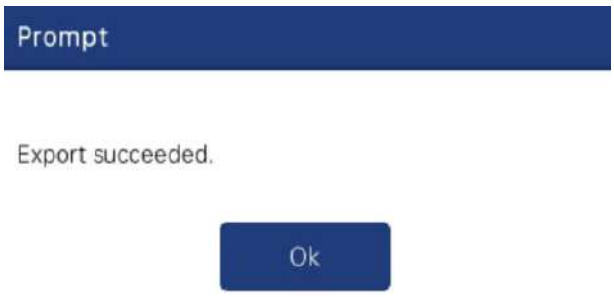
Export

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

1) Insert an USB and then click “Export”.

2) The system will detect the USB and export data automatically.

3) The prompt “Export succeeded.” will display.



7.3.X-B QC

7.3.1.Introduction

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

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

The analyzer implements X-B QC on the 3 parameters: MCV, MCH and MCHC, each group of samples for X-B analysis consists of 20-200 sample results obtained from normal analysis of both whole blood and pre-diluted modes. The analyzer can save up to 500 X-B QC results.

When the saved QC results have reached the maximum number, the newest result will overwrite the oldest.

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

1. Click the menu option “QC” > “X-B QC” > “Setup”.
2. Enter the X-B QC setup screen.

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

Editing X-B QC settings

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

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

Setting target/limits

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

NOTE

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

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

NOTE

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

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

Setting sample validity

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

a) Sample results exceeding the linearity range;

b) Background results;

c) Sample results not conforming to the "Sample Validity Setup";

d) QC data for QC mode other than X-B (e.g. L-J);

e) Calibration data;

f) Results generated while there are errors which could affect the accuracy of the results (e.g. insufficient aspiration volume or clogging).

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

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

Sample Validity Setup

Parameter	Lower	Upper
RBC	1.00	8.00
MCV	50.0	150.0
MCH	20.0	40.0
MCHC	240	440

2) Click "Yes" to save the setup.

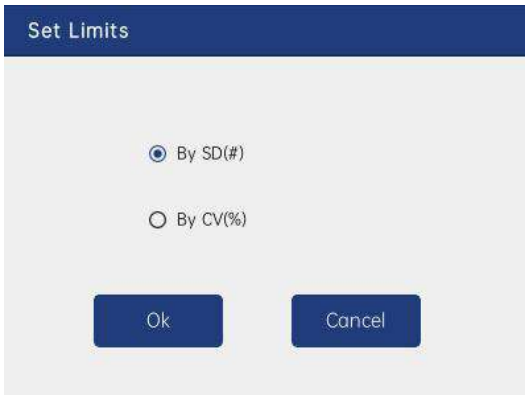
NOTE

- In the sample validity setup, the upper limit shall be no smaller than the lower limit. Otherwise, there will be prompted message asking you to revise.
- The valid ranges of the RBC parameters are their linearity ranges; the valid ranges of other parameters are their display ranges.
- All the entries shall be numbers with only one decimal point. The length of the number entered cannot be longer than the length of the text box.
- Once the validity range is changed, the previous results will not be used in the QC calculation as valid results. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the validity range after 10 groups of valid sample results have been acquired, these 10 groups of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.
- The units of lower and upper limits of all parameters are the same as those in the parameter unit setup screen. See section 9.2.3 Parameter Setup - Parameter Unit Setup.

Setting limits

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

1) Click “Set Limits”.



2) Click “By SD” to display the limits in the form of absolute value, or click “By CV” to display the limits in the form of percentage.

3) Click “OK” button to save the settings.

Restore defaults

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

Parameter	Target	Limits (#)
MCV	89.5	2.7
MCH	30.5	0.9
MCHC	340	10

7.3.3.Running X-B QC

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

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

7.3.4.Reviewing X-B QC Results

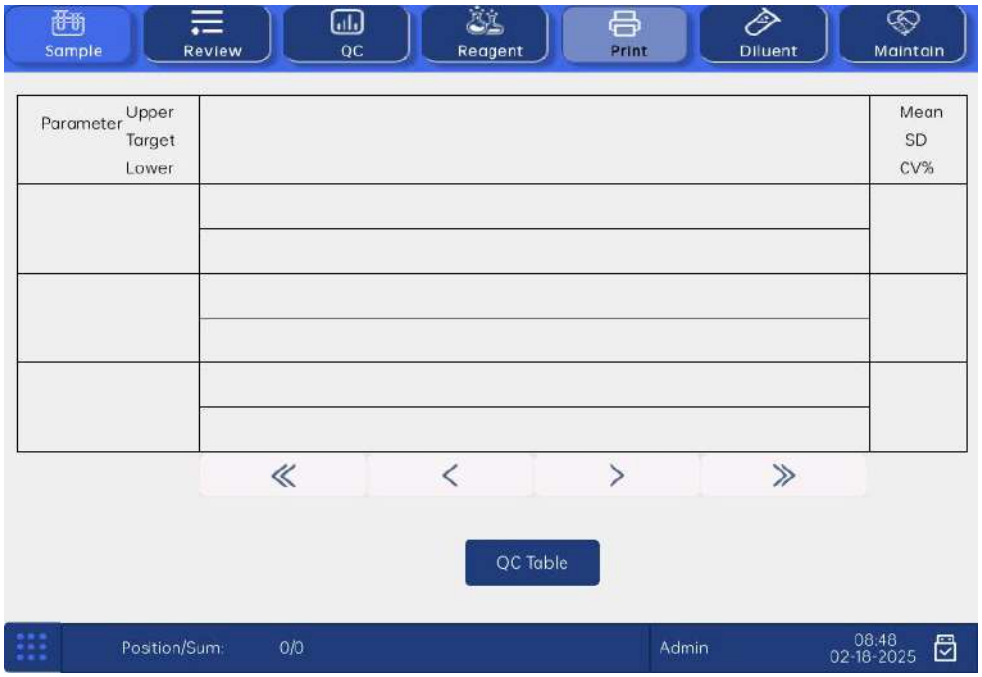
After QC analysis, you can review the QC results in the following ways:

1) QC Graph

2) QC Table

X-B QC graph review

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



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

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

X-B QC table review

1. On the X-B QC graph screen, click “QC Table” button to enter the X-B QC table screen.

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

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

8.Calibration

8.1.Introdution

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

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

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

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

⚠WARNING

- The reagents are irritating to eyes, skin and mucosa. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If reagents accidentally spill on your skin or in your eyes, rinse the area with plenty of clean water and seek medical attention immediately.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.

⚠CAUTION

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

NOTE

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

8.2.When to Calibrate

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

1） you are going to use this analyzer for the first time (usually done by a Producer -authorized representative when installing the analyzer).

2） an analytical component has been changed.

3） you are going to re-use the analyzer after a long-term storage.

4） the quality control results indicate there may be a problem.

5） use environment changes significantly.

NOTE

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

8.3.How to Calibrate

8.3.1.Preparing Your Analyzer

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

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

Parameter	Range	Whole Blood Reproducibility (CV/ absolute deviation d)	Prediluted Reproducibility (CV/ absolute deviation d)
WBC	3.50×10^9/L ~ 15.00×10^9/L	≤2.0%	≤4.0%
RBC	3.50×10^{12}/L ~ 6.00×10^{12}/L	≤1.5%	≤2.0%
HGB	110 g/L ~ 180 g/L	≤1.5%	≤2.0%
MCV	70 fL ~ 120 fL	≤1.0%	≤3.0%
PLT	100×10^9/L ~ 149×10^9/L	≤6.0%	≤8.0%
	150×10^9/L ~ 500×10^9/L	≤4.0%	≤8.0%

Note: Absolute deviation d = measurement value – measurement average

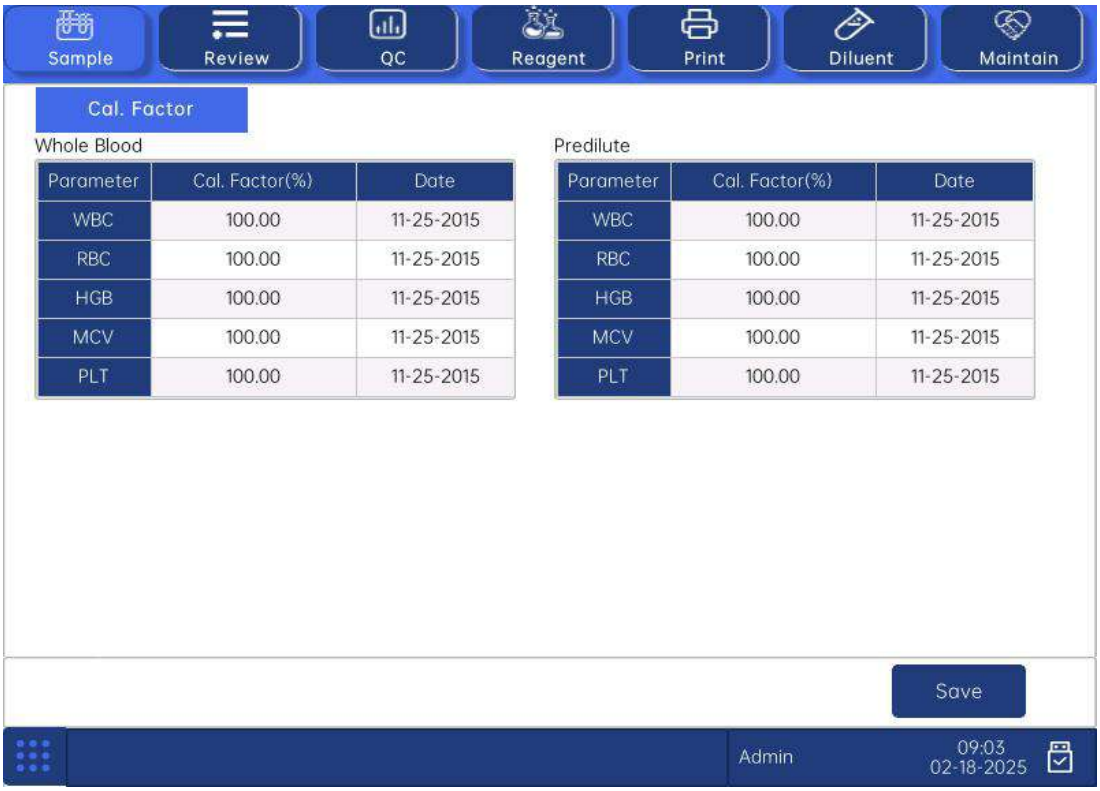
4. It is recommended that you create a log table for your analyzer. This log table should contain all necessary information that is pertinent to your analyzer. Suggested items that you may want to include in the log table are: calibration date, supplier of calibrator, lot number, expected results and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

NOTE

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

8.3.2.Manual Calibration

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



NOTE

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

Do as follows to calibrate the analyzer.

1. At the “Manual” calibration screen, check the calibration factors and calculate the new factors according to the following equation:

$$\text{New factor} = \frac{\text{old factor} \times \text{reference value}}{\text{calculated mean value}}$$

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

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

The new calibration factor is obtained:

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

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

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

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

If the entered calibration factors are valid, a dialog box will pop up asking you to save the new factor when you are exiting the screen. And the calibration date of the corresponding parameter changes to the current system date.

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

Other operations

Print

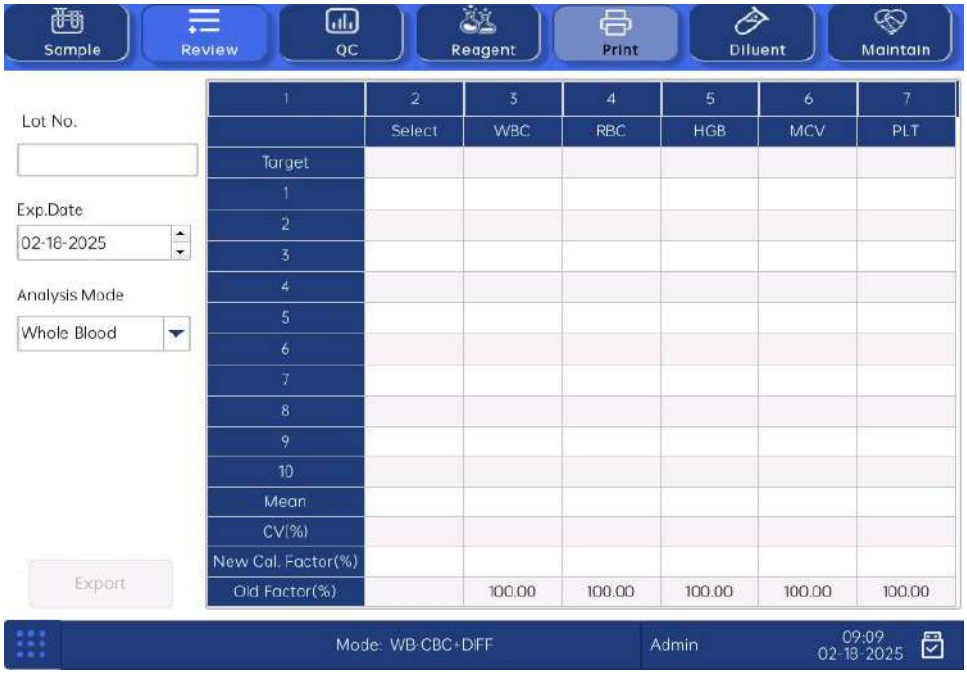
Click "Print" to print the current calibration factor.

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

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

8.3.3.Calibration with Calibrator

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



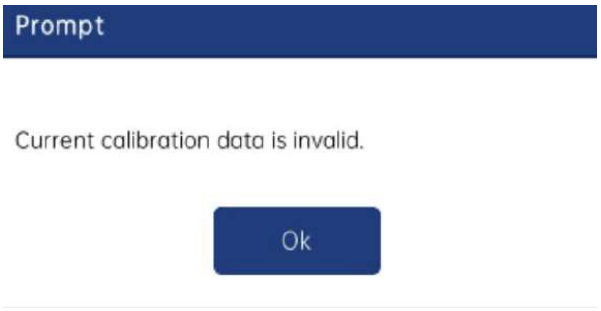
NOTE

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

Do as follows to calibrate the analyzer with calibrators.

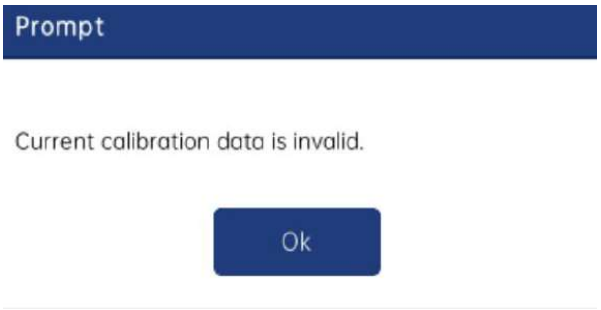
1. Check the mode on the analyzer screen.
2. Enter the lot No. of the calibrator into the “Lot No.” box.
3. Enter the “Exp. Date”. The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.
4. Enter the targets into the “Target” cells.
5. Prepare the calibrator as instructed by instructions for use of the calibrators.
6. Press the aspirate key to start calibration.
7. After the analysis, the analyzer will have different responses to different analysis results.

- When the current running is done, if there is a parameter whose calibration data is out of its linearity range but still within the display range, then the calibration data will be displayed in the list and a message box will also pop up.



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

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

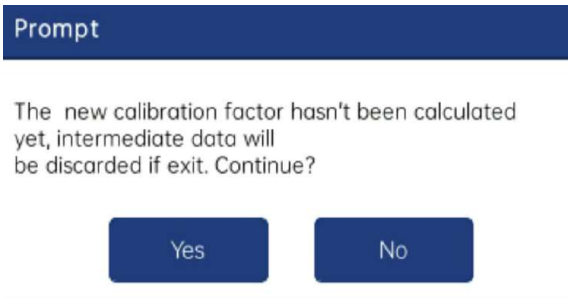


Click “OK” to close the message box, and the data will be deleted from the table without saving automatically.

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

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

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



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

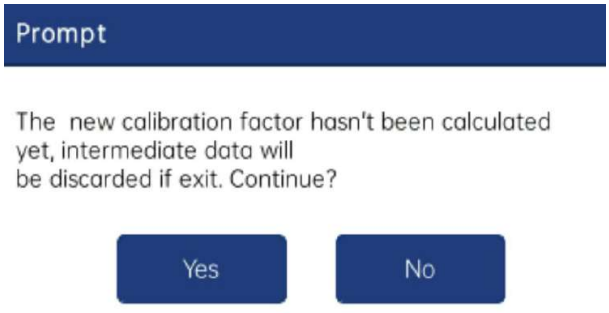
9. When calibration count has been performed to a sample for n times (n≥5), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with “√” (calibration data of the first run is not marked with “√”, so it is not included in the calculation).

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

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

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

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



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

If the calculated calibration factors of all parameter are within the range of 75%-125% and the CV% of all parameter are also within the reproducibility range, then a message box “Save new calibration factor?” will pop up. Click “Yes” to save the new calibration factors while closing the message box and switching to another screen.

Other operations

Print

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

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

8.3.4.Calibration with Fresh Blood

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

Do as follows to calibrate the analyzer with fresh blood.

1、 Prepare 3 to 5 normal fresh blood samples as instructed by 5.5.1 Sample Preparation.

2、 Run each of the prepared samples on the reference instrument (or by the reference method) five times at least. Calculate the mean values and use them as the targets. Or perform measurement and calculation according to the reference method and take the calculated data as the targets.

3、 Select mode for fresh blood calibration, which can be Whole Blood or Prediluted.

4、 Select the ID of current sample from the pull-down box “Current Sample ID” .

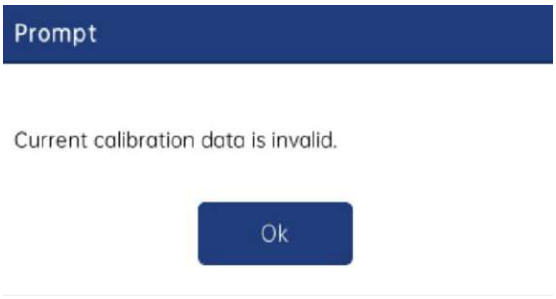
5、 Enter the targets into the “Target” cells.

6、 Prepare fresh blood sample.

7、 Press the aspirate key to start calibration.

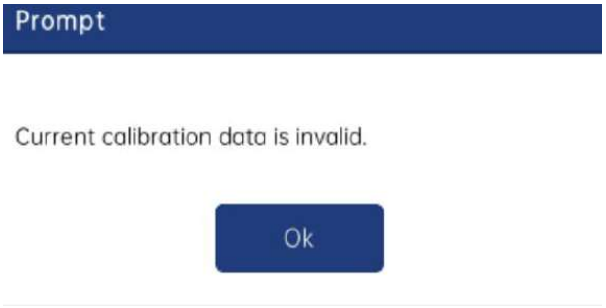
8、 After the analysis, the analyzer will have different responses to different analysis results.

- If the results are out of the linearity range but still within the display range, a dialog box will pop up when the results are displayed in the table.



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

- If the results are out of the display range, the non-numeric parameter values “***” are obtained and a dialog box will pop up.



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

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

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

9、 When calibration count has been performed to a sample for n times (n≥5), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with “√” automatically.

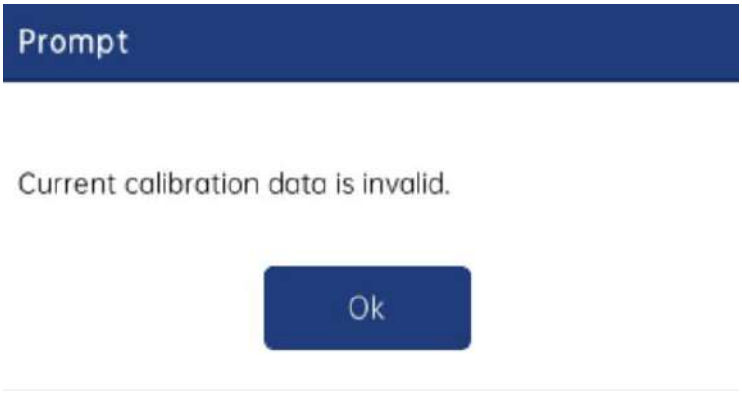
You can select several data to calculate the calibration factors, but only after at least 5 groups of the data are marked with “√” can you get the calibration factors. The calibration factors will be refreshed whenever you select “√” or deselect “√” .When the amount of valid

calibration data in the list reaches 10, a message box will popup when you start calibration again.

10、Select other calibration sample ID from the "Current Sample ID" pull-down box and analyze other samples according to Step 7-9 above to obtain the calibration factors of all samples.

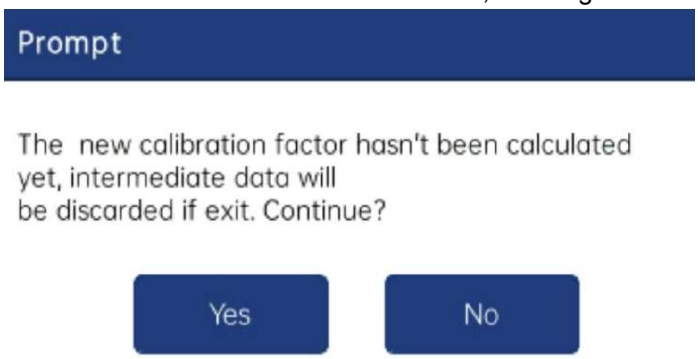
11、There may be several cases when switching to another blood sample:

- If the calibration factors of the blood sample are invalid or the CV% of any parameter exceeds the reproducibility range, a dialog box will pop up when switching to another blood sample.



Click "Yes" to empty the entered target of the current sample, all the calibration data obtained and each calculated value including calibration factors, then close the dialog box and switch to another blood sample.

- If the calibration factors have not been calculated, a dialog box will pop up.



Click "Yes" to empty the entered target of the current sample and all the calibration data obtained, then close the dialog box and switch to another blood sample.

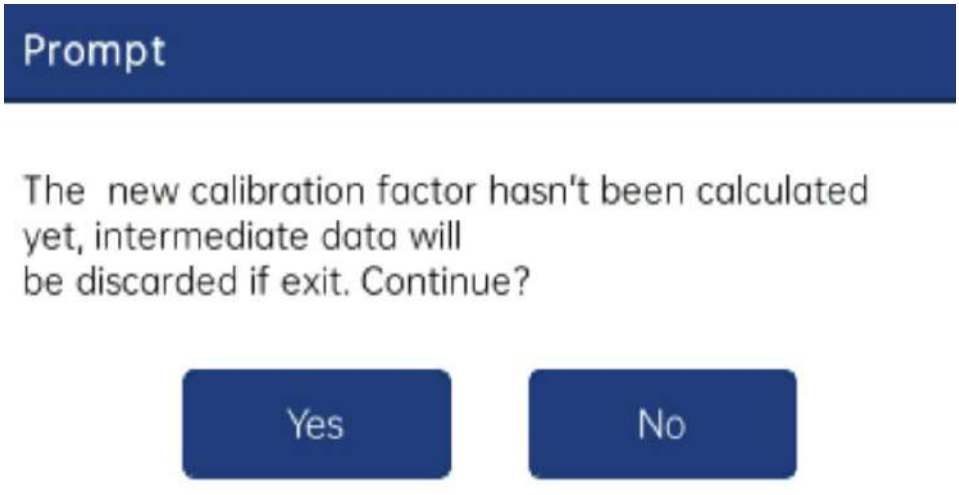
- If the calibration factors of the sample are valid and the CV% of all the parameters do not exceed the reproducibility range, you can switch to another blood sample directly.

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

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

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

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



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

Other operations

Print

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

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

9.Setup

9.1.Introduction

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

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

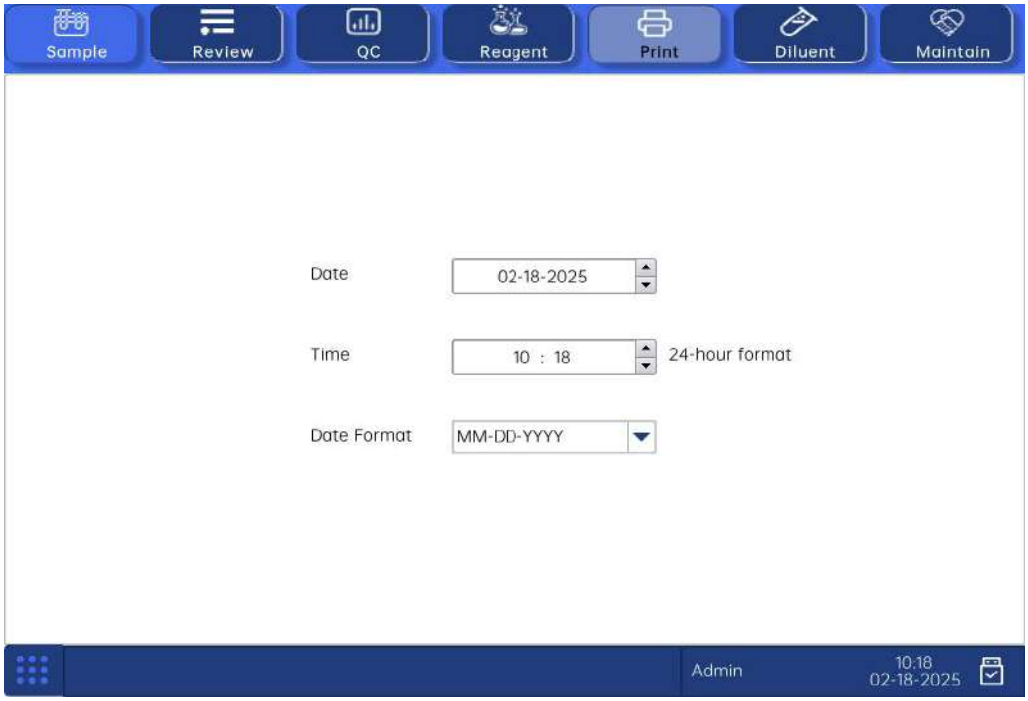
See the following figure for the setup menu.

9.2.Setting Up the Analyzer

9.2.1.System Setup

- **Date/Time Setup**

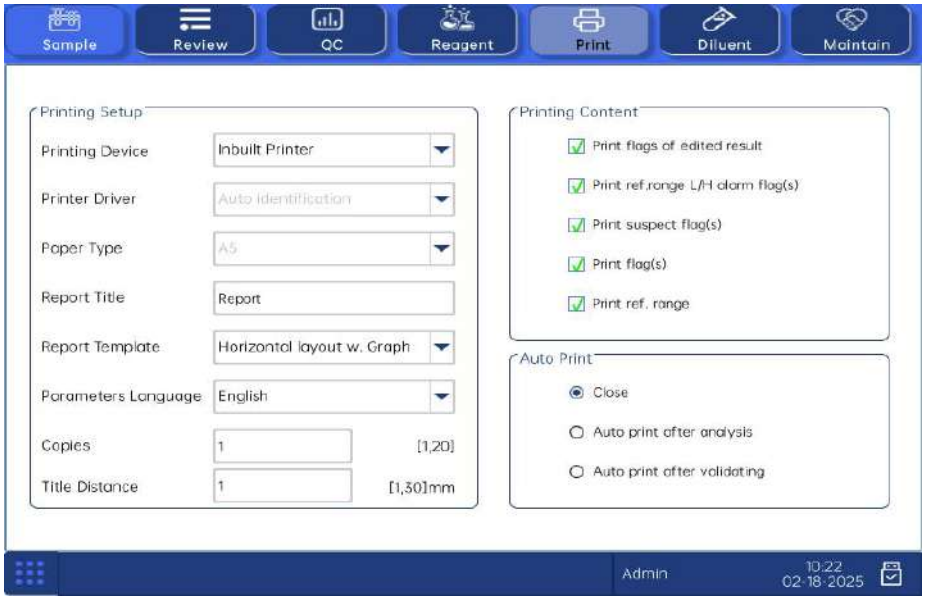
Click “Setup” > “System Setup” > “Date/Time Setup” in the menu to enter the following screen. You can set up the date, time and date format of the analyzer on the screen.



- **Print Setup**

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

1. Print Setup
2. Print Content
3. Auto Print



1. Print Setup

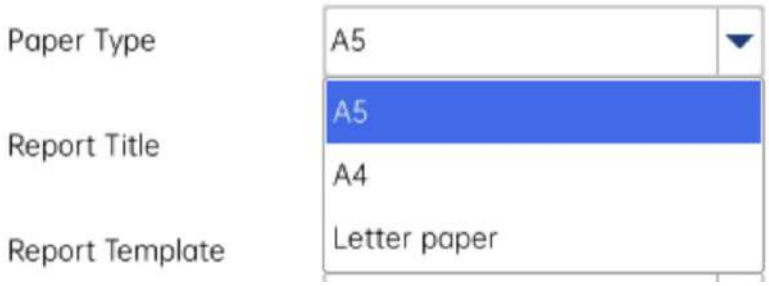
Printer Color

When the print device is selected as the printer, the print color is activated, and the printer color used by the instrument can be selected. The options are black and white and colours.

Special note: Only the printer selects color for the color printer, and the histogram can print the color, otherwise it is still black and white.

Paper Type

When the print device is a printer, the paper type is activated to set the paper type used for the report printing.



Parameters Language

Click the pull-down list to select the parameters language of the reports.

Copies

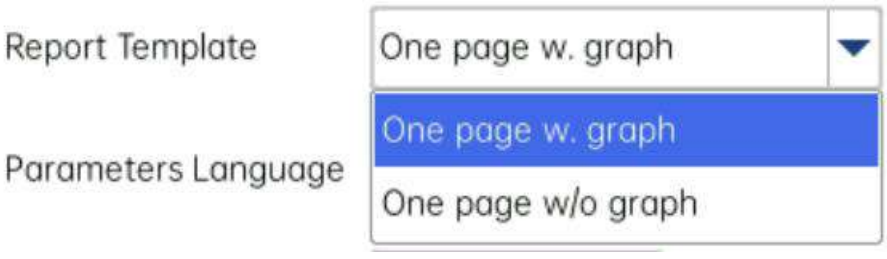
Enter the number of copies to be printed for each report into the edit box “Copies”.

Title Distance

The "Title Distance" option is visible when the paper type is selected as "A4" or "Letter".
You can set the distance between the report title and the top margin.

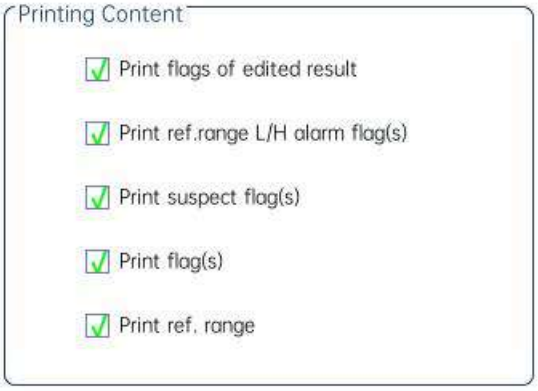
Report Title

Report Template



2. Print Content

You can choose to select the functions based on your needs by clicking on the check boxes.



3. Auto Print

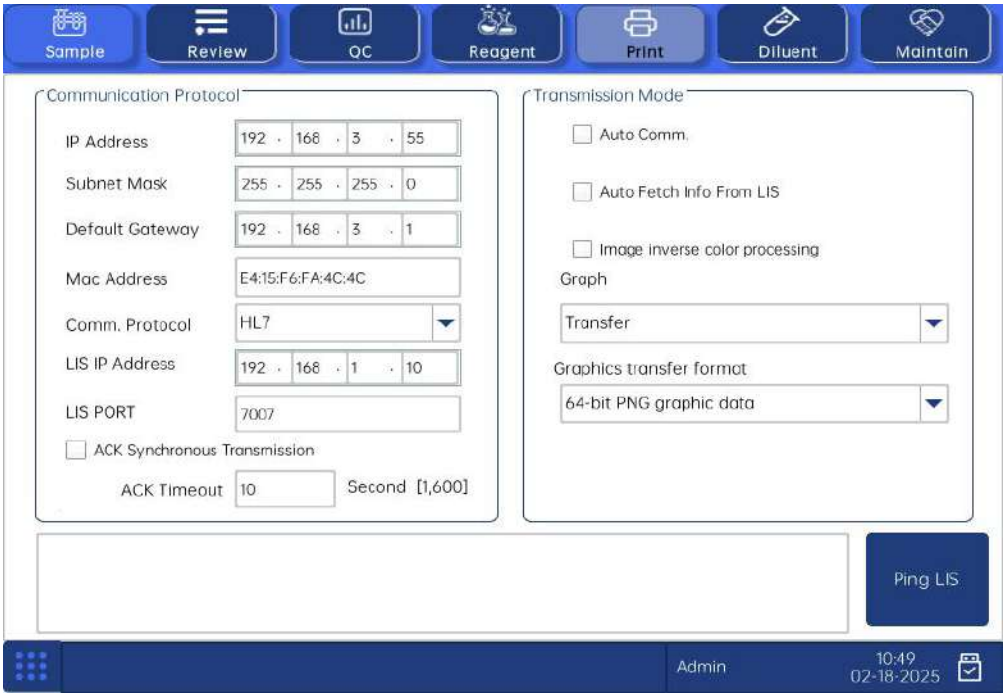
You can choose to disable auto print or set up printing conditions.

● Communication

Click “Setup” > “System Setup” > “Communication” in the menu to enter the following screen. You can set up the following contents:

1. Network Device
2. Communication Protocol
3. Transmission Mode

The "Title Distance" option is visible when the paper type is selected as "A4" or "Letter". You



■ **protocol settings**

Click on the "IP Address", "Subnet Mask", "Default Gateway", LIS IP Address, and LIS Port edit boxes, and enter the correct IP address, subnet mask, default gateway, LIS IP address, and LIS port.

communication protocol

Select the protocol type, click on the drop-down list, and choose the appropriate communication protocol type from the options.

ACK synchronous communication

Click and select the 'ACK Sync Communication' checkbox to activate this feature.

When this function is activated, the default timeout for ACK is "10" seconds, and the operator can re-enter it in the editing box.

■ **MODE**

The operator can activate the relevant communication settings by selecting the desired option from the following check boxes as needed:

- Automatic renewal
- automatic communication
- Automatically obtain sample information
- Transfer bitmap data for printing

Histogram and scatter plot transmission methods

Click on the dropdown list and select the desired histogram or scatter plot transmission method from the following options:

- No transmission
- Transfer in bitmap format
- Transmission in data format

● Flag alarm sensitivity

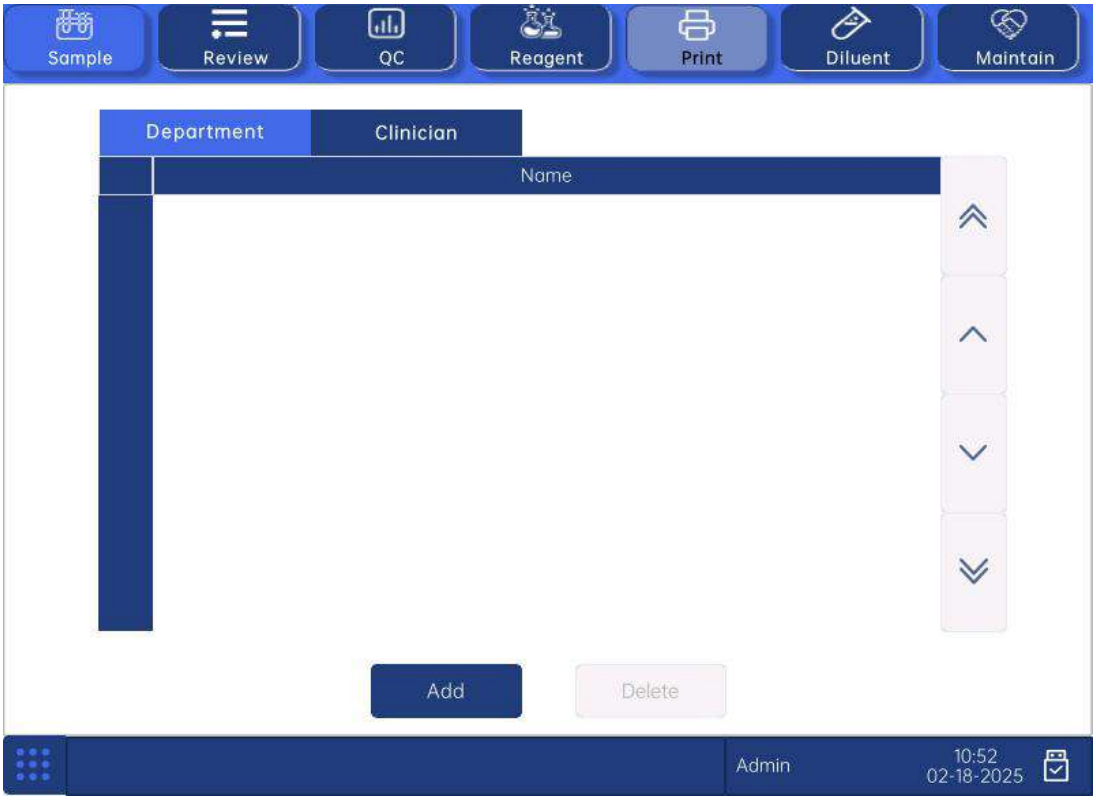
Select "Settings">"System Settings">"Flag Alarm Sensitivity" from the menu to enter the interface shown below. Flag alarm sensitivity provides sensitivity settings for corresponding alarms, which can be set according to actual needs.

	Flag Name	Value(0-100)
1	Immature Cell?	50
2	Abn./Atypical Lympho?	50
3	HGB Abn./Interfere?	50

er an alarm.The Flag page displays values that may trigger an alarm. Administrators can modify the reference value of Flag, and the reference value of Flag alarm displays the possibility of generating an alarm. The higher the value, the more likely it is to trigg

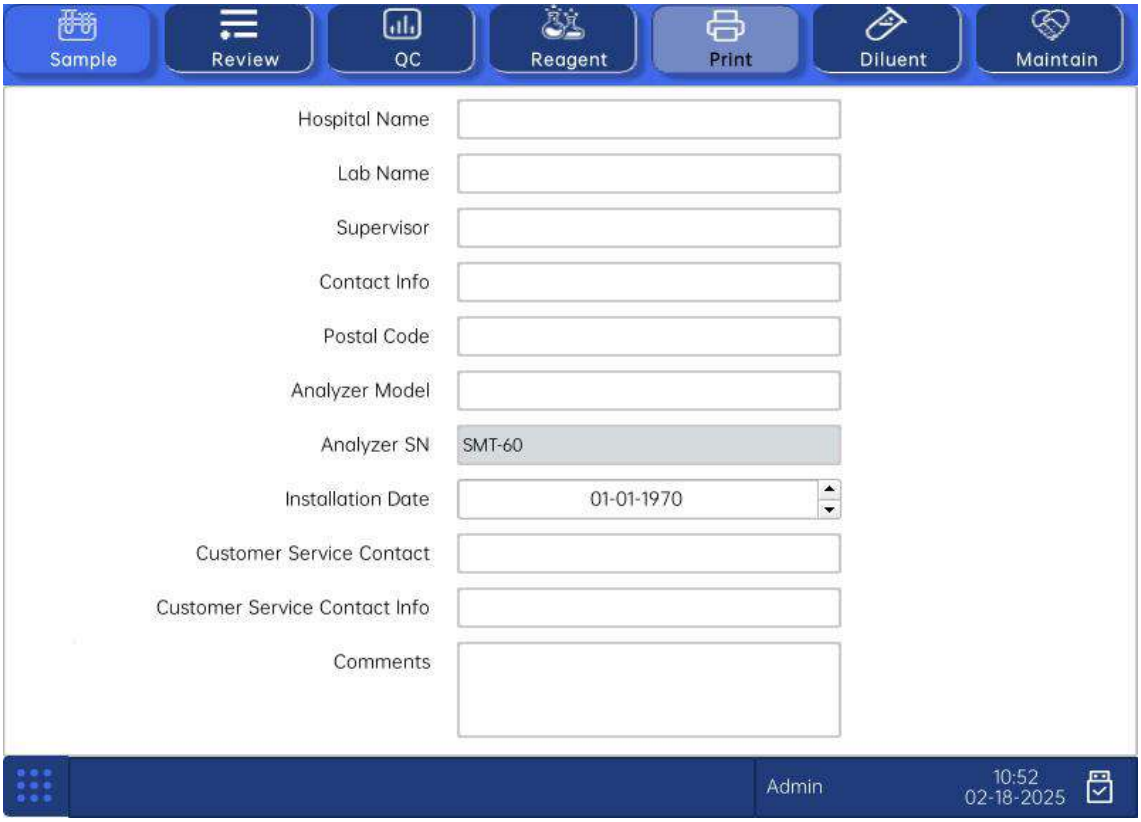
- **Department/Clinician Setup**

  Click “Setup” > “System Setup” > “ Department/Clinician Setup” in the menu to enter the following screen. This function allows you to set up department/clician information for the contents in sample information setup screens.



Lab Info Setup

Click “Setup” > “System Setup” > “Lab Info Setup” in the menu to enter the following screen. Opeators may enter, save and view lab information. Click on the edit boxes to enter the information as required.



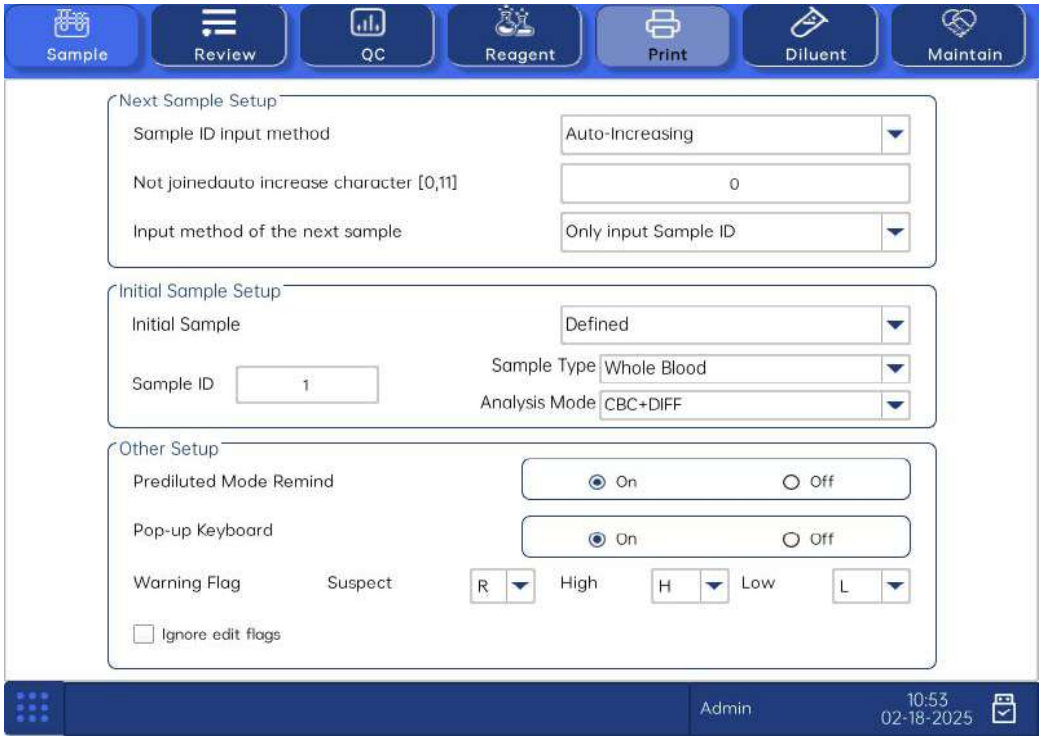
NOTE

- The analyzer SN cannot be edited.
- The installation date is the date the analyzer is installed by default. It can be edited, but cannot be later than the current system date.

Auxiliary Setup

Click “Setup” > “System Setup” > “Auxiliary Setup” in the menu to enter the following screen. You can set up the following contents:

1. Setting of the next sample
2. Setting of the first sample after startup
3. Other setup



1. Setting of the next sample

1) Select sample ID input method

Click the pull-down list to select the way to enter the next sample ID.

- Auto Increase
- Manual Entry

2) Not counted as an auto increase character

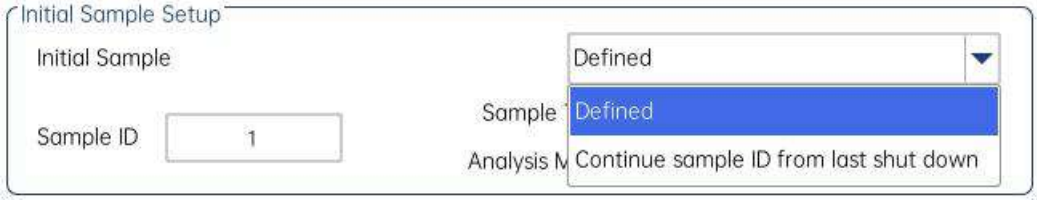
Operators can set up the number of characters in the sample ID that will not be auto increased.

When “Auto Increase” is selected as the way to enter the next sample ID, this edit box will be activated.

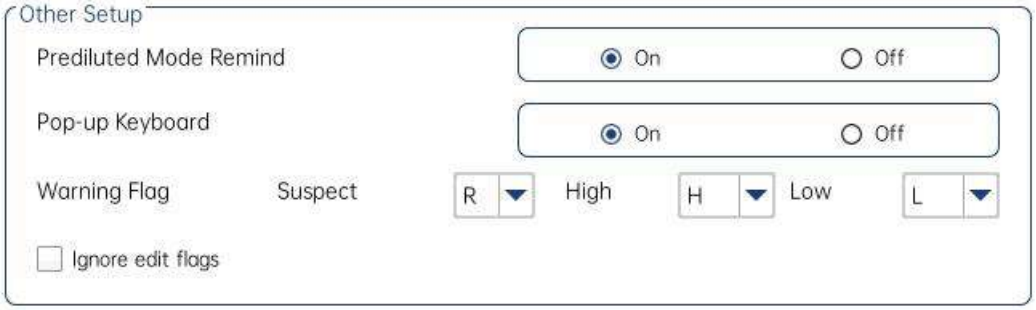
Enter a number ninto the edit box. The first n characters in the sample ID will not be auto increased.

2. Setting of the first sample after startup

Operators can customize the first sample ID after startup by entering it into the edit box. Or select to run the suspended sample after restart.



3. Other setup



1) Radio buttons

Select “On” or “Close” to activate or deactivate the functions.

2) Flags

Operators may set up the suspect flag by entering a character into the edit box, or selecting a letter from the pull-down list (the default character is “R”).

Operators may set up the high/low flag by entering two characters into the edit boxes, or selecting two letters from the pull-down lists (the default character of high flag is “H”, and that of low flag is “L”).

9.2.2.User Administration

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

1. Modify password

You can modify your own password.

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

2) Enter the required information in the edit boxes.

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

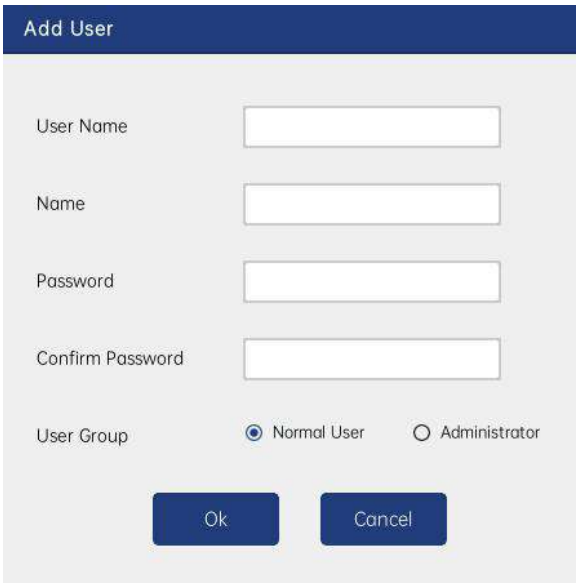
NOTE

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

---

2. Creat new user

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



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

3) Select user group of the user:

- Normal user
- Administrator

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

NOTE

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

---

3. Delete user

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

NOTE

The current login user cannot be deleted.

9.2.3.Parameter Setup

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

Parameter	Unit	Format
WBC	10^9/L	***.**
Neu#	10^9/L	***.**
Lym#	10^9/L	***.**
Mon#	10^9/L	***.**
Eos#	10^9/L	***.**
Bas#	10^9/L	***.**
Neu%	%	**.*
Lym%	%	**.*
Mon%	%	**.*
Eos%	%	**.*
Bas%	%	**.*
*ALY#	10^9/L	***.**
*ALY%	%	**.*
*LIC#	10^9/L	***.**
*LIC%	%	**.*

Parameter	Unit	Format
RBC	10^12/L	**.**
HGB	g/L	***
HCT	%	**.*
MCV	fL	***.*
MCH	pg	***.*
MCHC	g/L	****
RDW-CV	%	**.*
RDW-SD	fL	***.*
PLT	10^9/L	****
MPV	fL	**.*
PDW		**.*
PCT	%	*.***
P-LCC	10^9/L	****
P-LCR	%	**.*

Select unit system

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

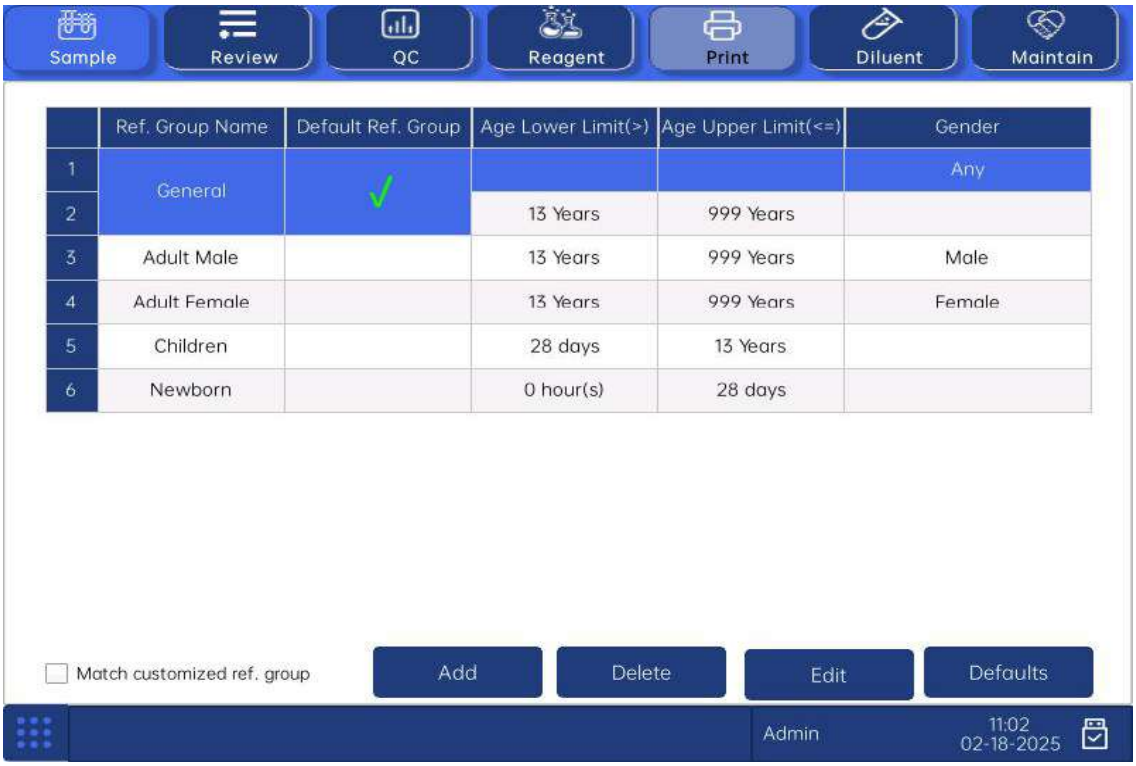
NOTE

The units displayed will be different when different unit system is selected.

- **Reference Range Setup**

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

5 factory reference groups and 5 customized reference groups are provided for your choice. Each laboratory shall select a proper reference range of its own based on its patient demographics. The reference range differs among races, genders, ages and geographic locations.



1. Customizing reference groups

Select a reference group and click “Add” or “Edit” to enter the reference group setup screen. You can set up the name, lower and upper limits of age and parameter range.

Click the “Defaults” button, the reference ranges of the selected factory reference group can be restored to the default settings.

NOTE

- The name of the reference group cannot be null.
- The names of the customized reference groups shall not repeat the names of the 5 default groups, and they shall not repeat each other either.

2. Setting as default reference group

Select a reference group and then click “Defaults” to set it as default reference group.

NOTE

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

3. Modify reference range

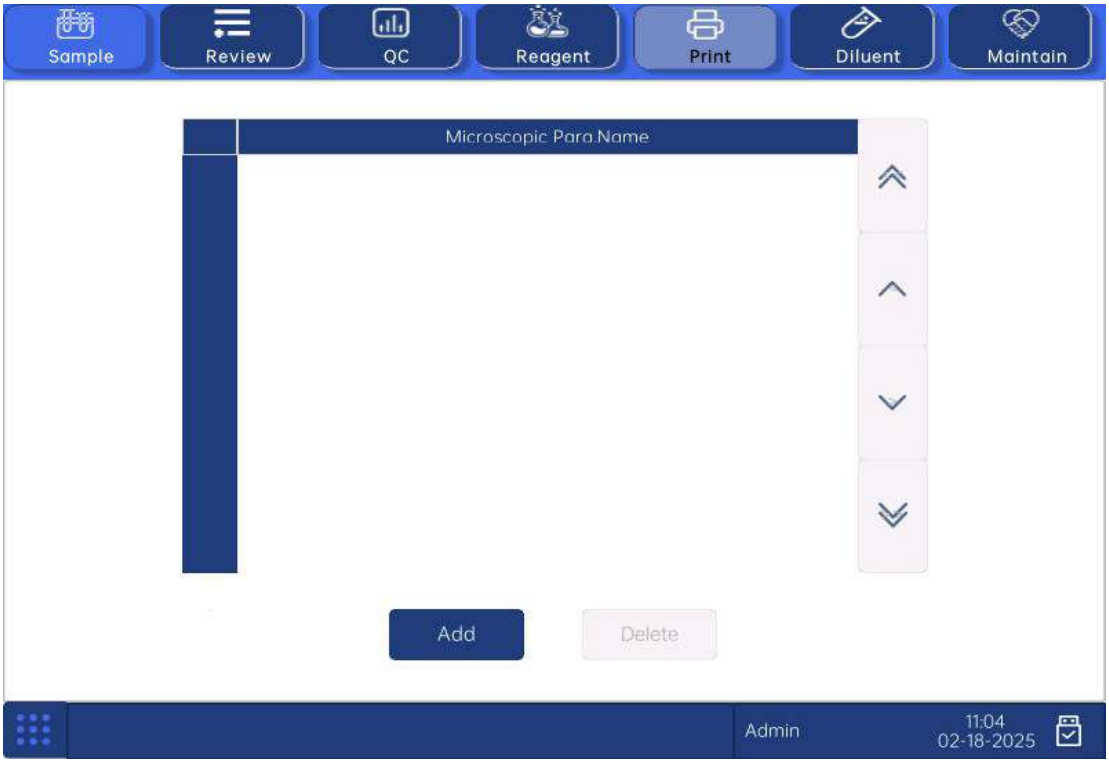
To modify the reference range of a reference group, select the group from the reference group list on the left, and then click the cells of upper and lower limits in the table and re-enter the values.

To restore the reference ranges to default, click the “Defaults” button on the bottom right of the screen.

Select “Match customized ref. group”, when the age ranges of the customized reference group and the default reference group contradicts with each other, the customized reference group will be matched first on the sample analysis and review menu.

● Microscopic Parameter Setup

Click “Setup” > “Parameter Setup” > “Microscopic Para. Setup” in the menu to enter the following screen. You may modify microscopic parameter related settings.



1. Add new parameter

Click the “Add” button to add a new row in the table, and then you can enter the name of the parameter in the row.

2. Delete

Select a row in the table, click the “Delete” button to delete the parameter.

3. Edit parameter name

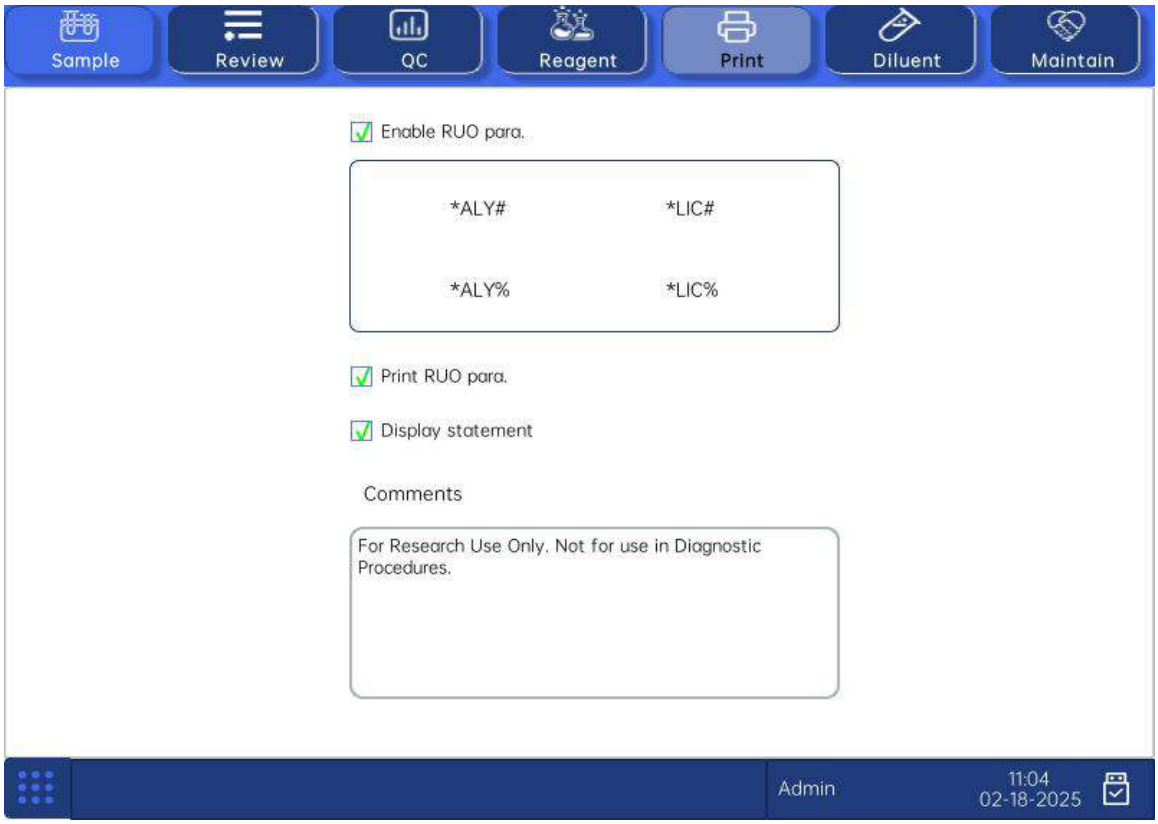
Click a parameter name in the table to edit the name.

NOTE

- You can add up to 40 microscopic parameters.
- The reconfigured setup will not be applied to sample records which already have microscopic results saved, but only applied to sample records with unsaved microscopic results and records attained after the new setup is applied.

- Research parameter settings

Select "Settings">"Parameter Settings">"Research Parameter Settings" from the drop-down menu to enter the interface shown below. The operator can set the parameters related to microscopic examination.



- Enable research parameters

After selecting the checkbox before 'Enable study parameters', the study parameters will be visible in the sample analysis and review interface, otherwise they will not be displayed.

- Printing research parameters

After selecting the checkbox before 'Print research parameters', print the graphical report form for sample analysis and review, and print the results of the research parameters at the same time. Otherwise, do not print.

- Display Declaration

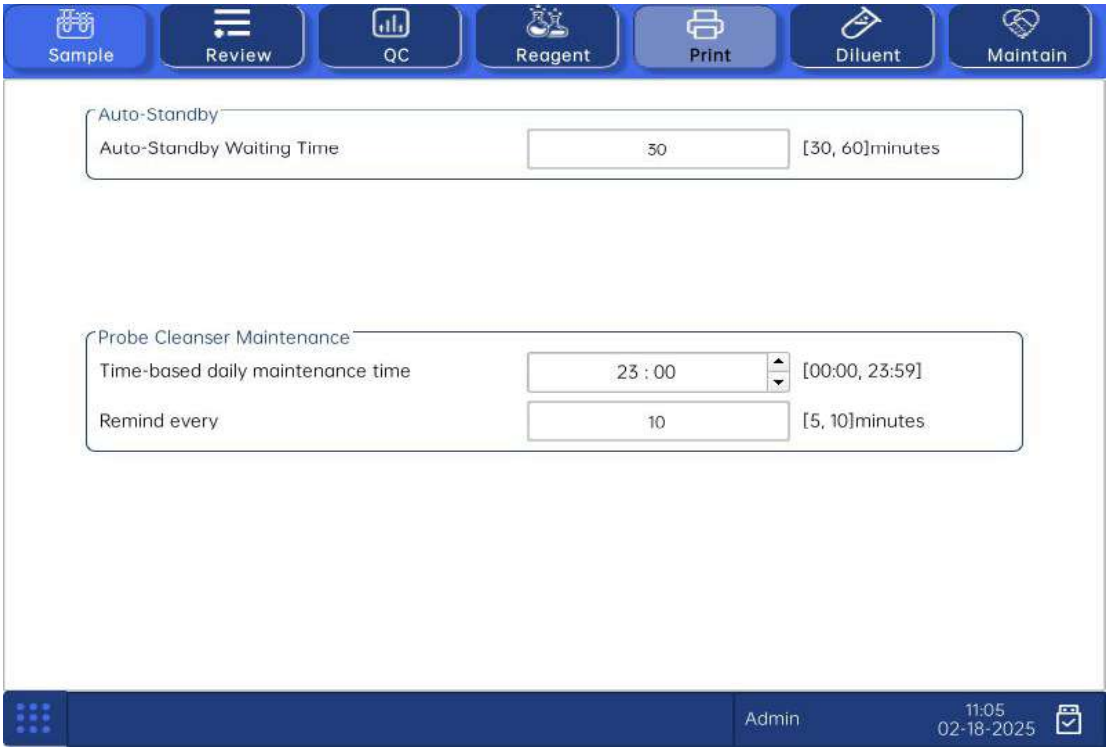
After selecting the checkbox before 'Display Declaration', the declaration of research parameters will be visible in the sample analysis interface, otherwise it will not be displayed.

NOTE

- The research parameter declaration is only displayed on the sample analysis interface.

9.2.4.Maintenance Setup (for administrators only)

Click “Setup” > “Maintenance Setup” in the menu to enter the following screen. You can set up the following contents:



1. Auto-Standby

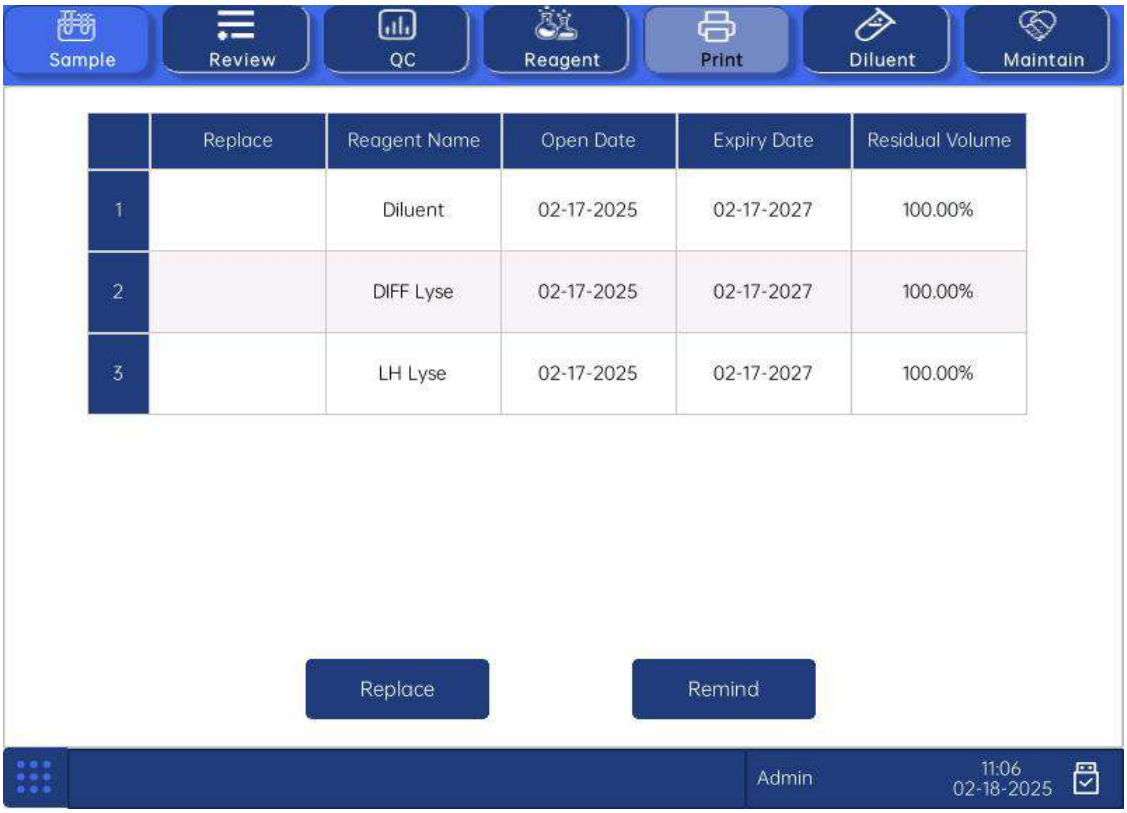
Click the text box "Auto-Standby Waiting Time" and enter the waiting time before entering the auto-standby status. The range allowed is 10-30 minutes, and the default setting is 10 minutes.

2. Probe Cleanser Maintenance

Click the first text box in the "Probe Cleanser Maintenance" area to enter the time to start time-based probe cleanser maintenance. Click the second text box to enter a time in the text box. Then when the operator cancels the time-based maintenance, a reminder dialog box will pop up after the defined minutes.

9.2.5.Reagent Setup

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



This function may also be used to refill reagent inside the fluidic system when a new container of reagent is loaded.

NOTE

- The reagents must be kept still for at least a day after long-term transportation.
- When you have changed the diluent or lyse, run a background test to see if the results meet the requirement.

You should replace reagents when:

1) the reagent ran out and a new container of reagent is installed.

2) the reagent in the tubing is contaminated.

3) there are bubbles in the tubing.

You can replace the following reagents in the fluidics:

1) Diluent

2) lyse

3) the reagent ran out and a new container of reagent is installed. Do as follows to replace the reagents.

1. Click the reagent you want to replace, and then click “Setup”.

2. In the setup interface, press the [Read] button and place the reagent card on the read card area. If the reagent card is read successfully, it will prompt “XXX Setup succeeded!”, and the prompt box “Replacing is required after loading, please verify the connnected reagent and click [OK] to start." for requesting reagent perfusion will pop up. Press [OK] to perform the replacement.

3. Press the [Replace] button on the reagent management screen to start the reagent change. The progress bar will be displayed in the window information area.

NOTE

- Please keep the diluent container from severe shock or crashing against other object. Otherwise, the alarming would be unreliable.
- When replacing diluent container, insert the diluent cap assembly into the container and tighten the cap. Otherwise the alarming may be unreliable.

9.2.6.Gain Setup

Click “Setup” > “Gain Setup” in the menu to enter the following screen. Gain setup function allows you to adjust the digital potentiometers. The operation shall not be performed frequently.

1. RBC gain

Click the RBC “Set Value” cell, and enter the new value of RBC gain.

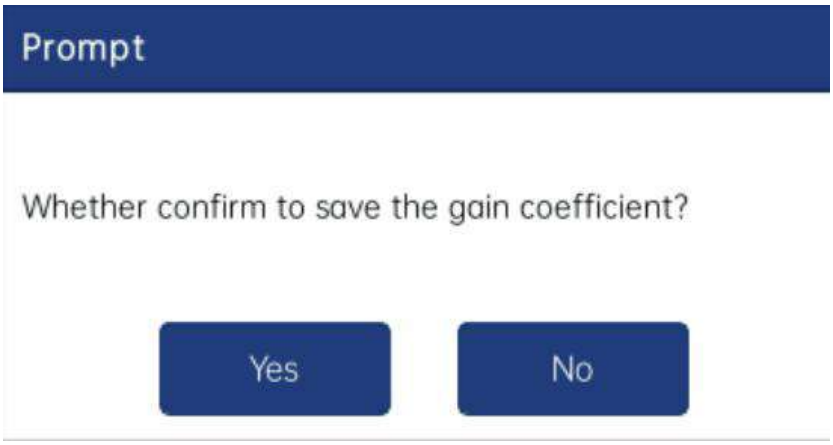
2. HGB gain

The purpose of adjusting HGB gain is to change HGB background voltage.

Click the HGB “Set Value” cell, and enter the new value of HGB gain.

9.3.Saving the Settings

To save the modified settings, you may switch to another screen, the following dialog box will display.



Click “Yes” to save the settings and switch to the corresponding screen. Click “No” to switch to the corresponding screen without saving the setti

10.Service

10.1.Introduction

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

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

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

⚠WARNING

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

⚠CAUTION

- Improper maintenance may damage the analyzer. Operators must follow the instruction of this manual to perform maintenance operations.
- For any questions, contact Producer customer service department.
- Only Producer-supplied parts can be used for maintenance. For any questions, contact Producer customer service department.
- Avoid contact with the sharp sample probe when performing maintenance.

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

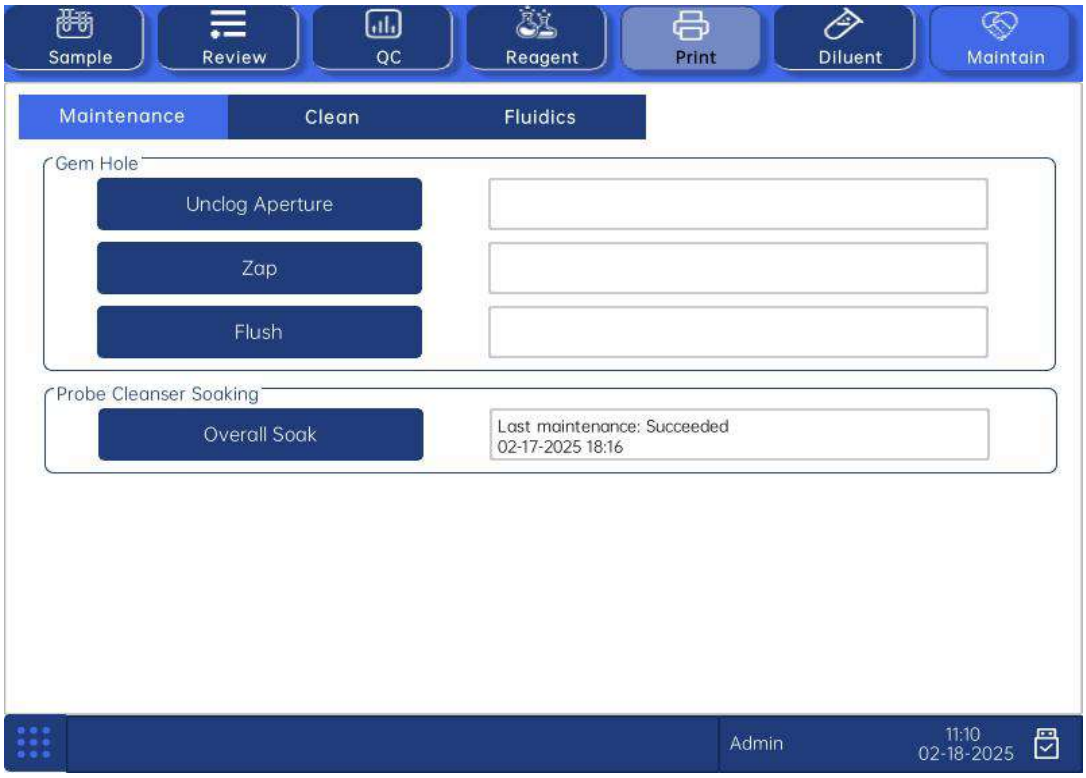
No.	Tools
1	Cross-headed screwdriver
2	Slotted head screwdriver
3	Medical gloves
4	Alcohol

10.2.Maintaining Your Analyzer

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

10.2.1.Maintenance

Click “Service” > “Maintenance”, and select the “Maintenance” tab to enter the following screen.



1. Unclog aperture

Unclogging includes zapping, flushing and cleaning of WBC bath and RBC bath. When clog error is reported, you should unclog the aperture.

The unclogging procedures are:

1、 Click the "Unclog aperture" button to start unclogging.

2、 When the progress ends, a message will display indicating "Maintaining finished!".

3、 Do the above procedures to continue unclogging aperture if necessary. If the error persists, perform probe cleanser maintenance of the related channels.

■ Probe cleanser maintenance

You should perform the probe cleanser soaking procedure when:

■ background results are out of range, QC results abnormal or when other maintenance operations fail to solve the clog error.

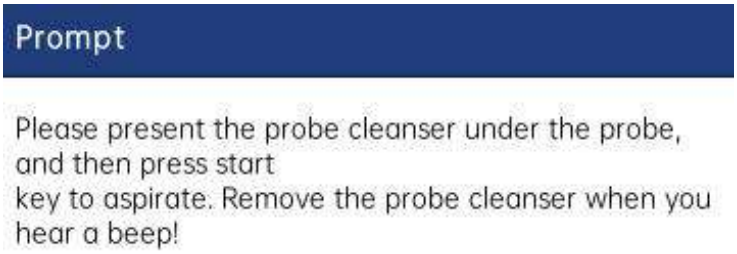
■ the analyzer shuts down due to abnormal power break-off, probe cleanser maintenance must be performed after it is started up again.

The probe cleanser maintenance procedures are:

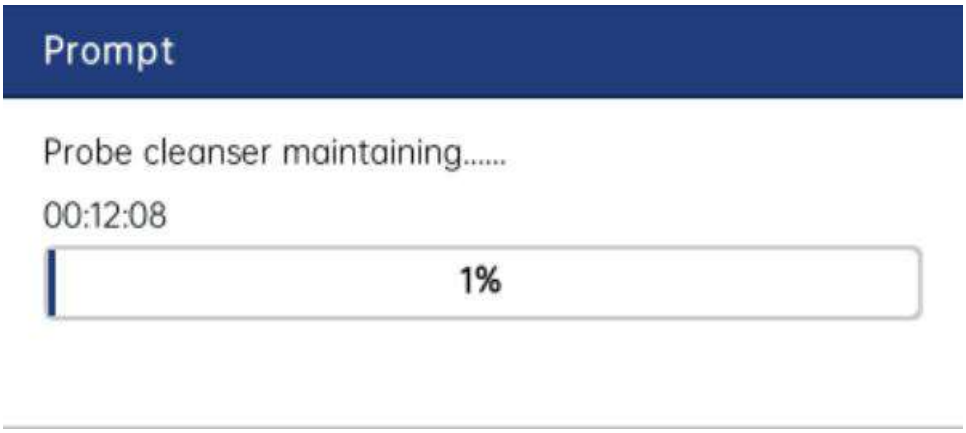
1) Click "Overall Soak" button, the following dialog box will display.

2) Click "Yes", the analyzer starts to prepare for the maintenance.

3) When the preparation is done, the following dialog box will display.



4) After aspirating probe cleanser, the analyzer performs probe cleanser soaking automatically, and a progress bar will display indicating the progress.



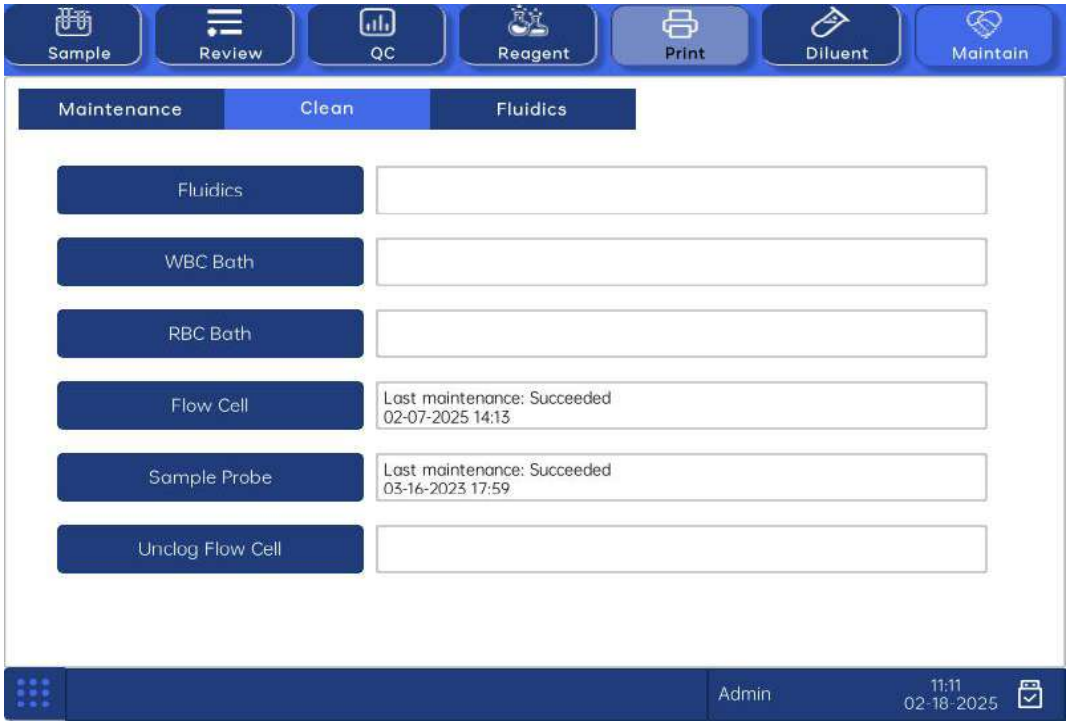
5) When the progress ends, the following dialog box will display, click “OK” to close the dialog box.

10.2.2.Cleaning

You should clean the following components when:

- WBC and (or) HGB background results exceed their limits, perform WBC bath cleaning. If WBC bath cleaning does not solve the problem, perform WBC probe cleanser maintenance.
- RBC and (or) PLT background results exceed their limits, perform RBC bath cleaning. If WBC bath cleaning does not solve the problem, perform RBC probe cleanser maintenance.
- sample probe gets dirty, perform sample probe cleaning.

Click “Service” > “ Maintenance”, and select the “Clean” tab to enter the following screen.



You may perform cleaning operation to the following components:

- Fluidics
- Flow cell
- Sample probe
- Unclog flow cell
- WBC bath
- RBC bath

The cleaning procedures are:

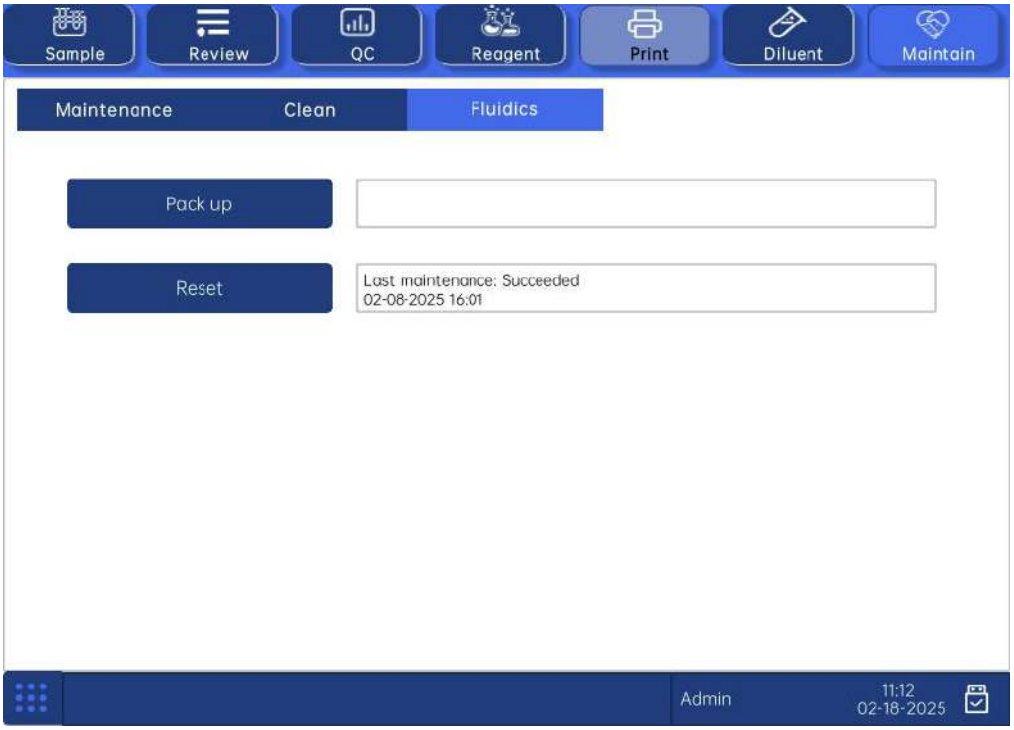
1、 Click the button of the component you want to clean. The message “Cleaning in process. Please wait…” will display.

2、 When the progress ends, a message will display indicating “Cleaning finished!”.

3、 Clean other components according to the above procedures if needed.

10.2.3.Servicing the Fluidics

Click “Service” > “Maintenance”, and select the “Fluidics” tab to enter the following screen.



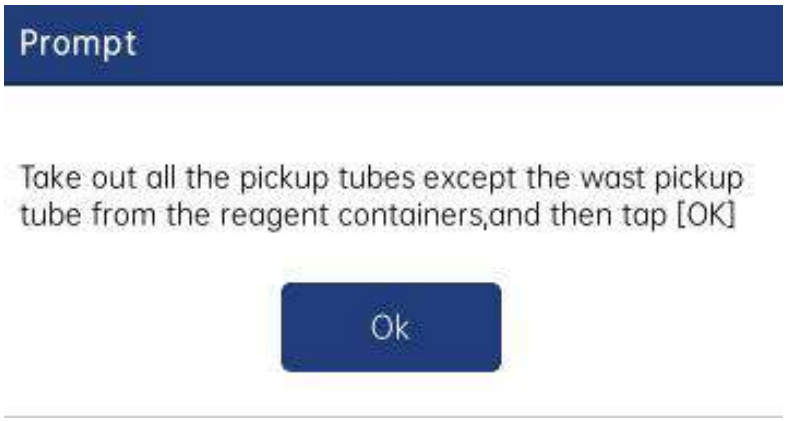
1. Pack up

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

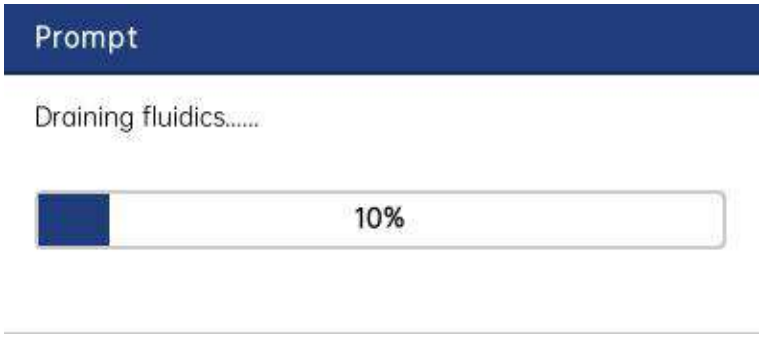
Do as follows to pack up:

1) Click “Pack up”, the dialog box “Start pack-up?” will pop up.

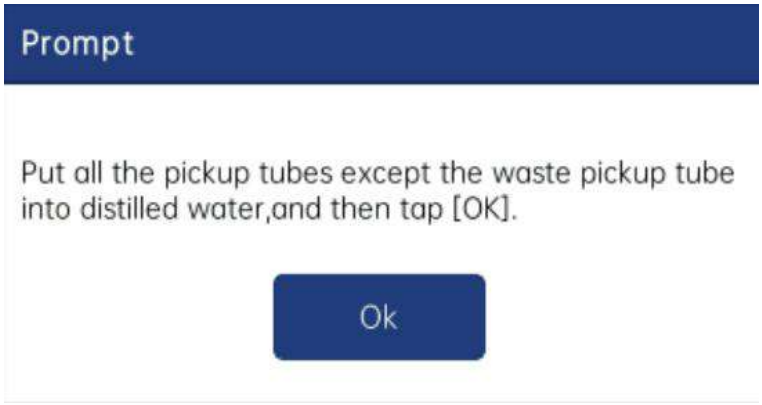
2) Click “Yes” to perform the pack up procedure. The following dialog box will be displayed.



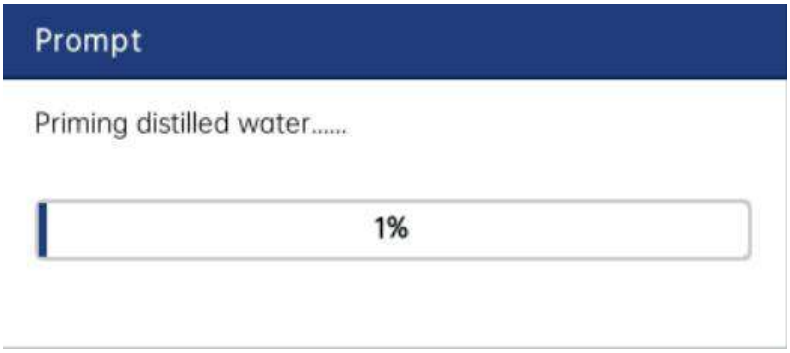
3) Take out the tubes as instructed and then click “OK” to drain the fluidics.



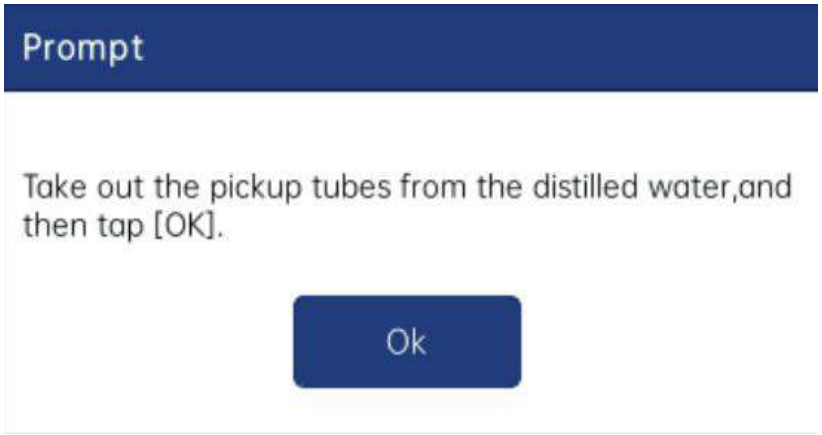
4) The following dialog box will be displayed after draining the fluidics.



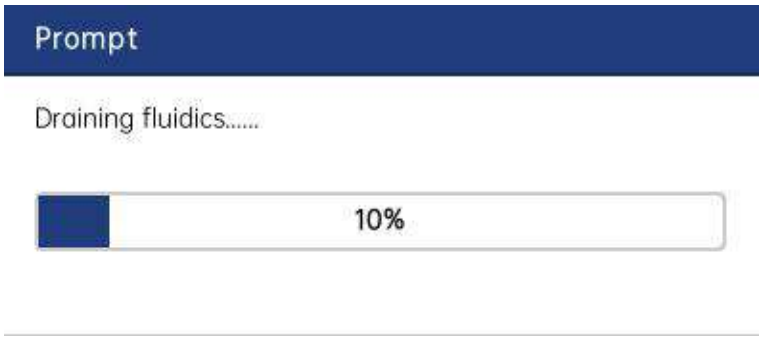
5) Put the tubes into distilled water as instructed, and click “OK” to start priming.



6) When the priming progress ends, the following dialog box will be displayed.



7） Take out the tubes as instructed and then click “OK” to drain the fluidics again.



8） When the pack-up is finished, shut down the analyzer as prompted.

NOTE

This software can still be used after the pack up.

---

2. Reset

When major components of the analyzer have been replaced, or the fluidic system has been serviced, you must reset the fluidics.

Do as instructed below:

1） Click “Reset”, a dialog box will pop up asking you to confirm the operation.

2） Click “OK” to start initialization, the message “Resetting fluidics. Please wait…” will be displayed.

3） When the progress ends, a dialog box will display indicating “Resetting fluidics finished!”.

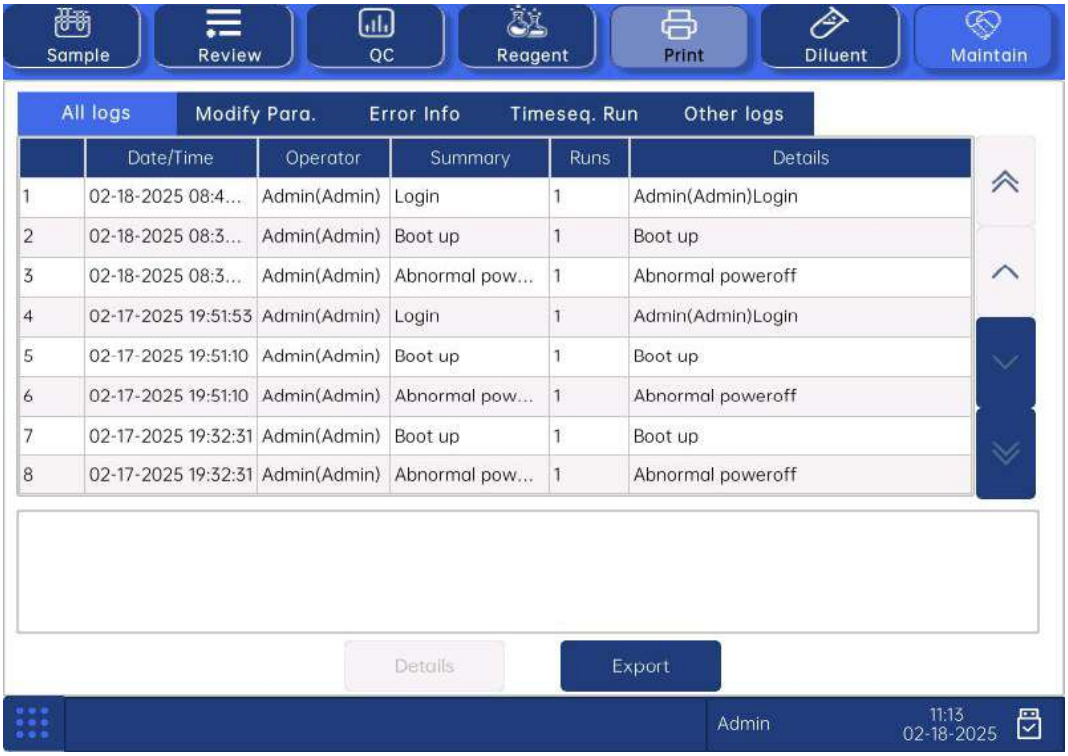
4） Do the above procedures to continue resetting fluidics if necessary.

10.3.Touch Screen Calibration

Click “Service” > “Touch Screen Calibration” in the menu to enter the following screen.

10.4.Viewing Logs

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



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

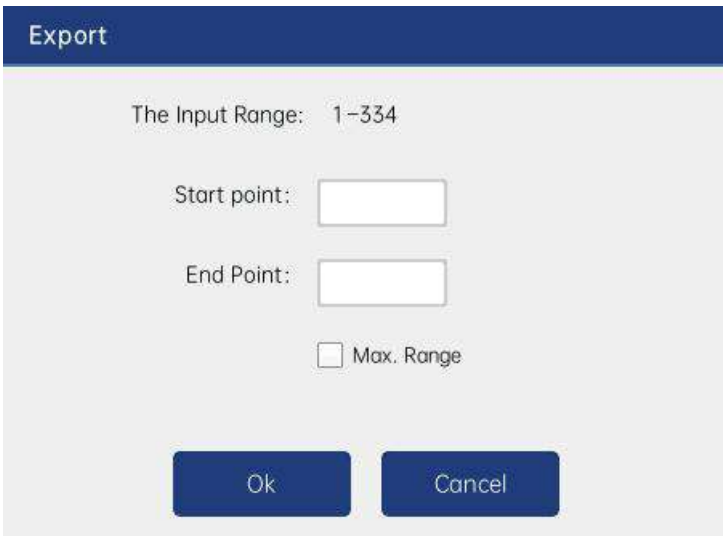
The "Log" screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

NOTE

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

Exporting logs

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



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

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

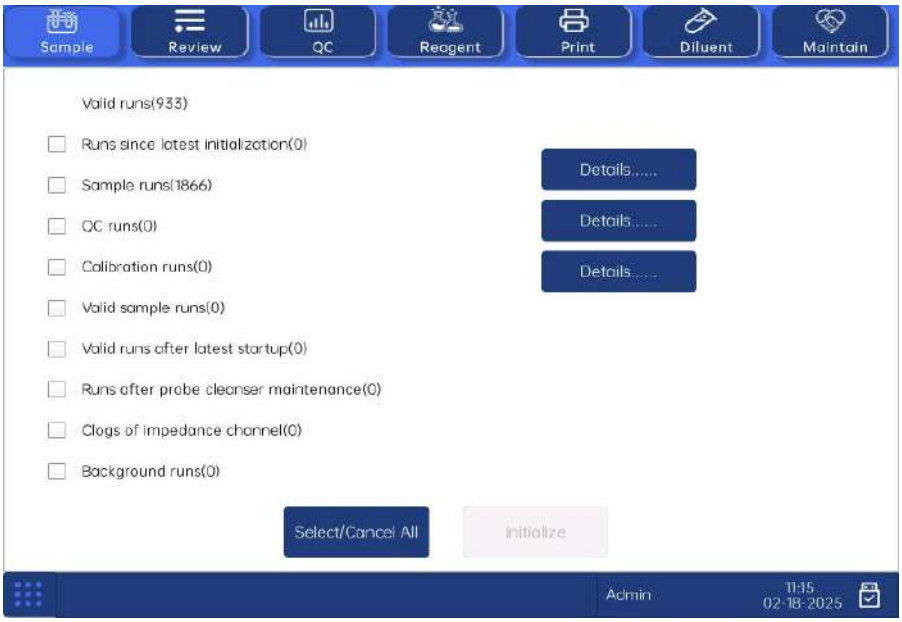
10.5.Checking the Analyzer Status

NOTE

If the status is outside normal range, it will be highlighted with red background.

10.5.1.Counter

The counter counts the running times of the analyzer and the occurrence times of some major parameters.



1. Viewing details

You may click the “Details……” buttons following “Sample runs”, “QC runs” or “Calibration runs” to view the related details.

2. Print

Click the “Print” icon to print all information on the screen.

10.5.2.temperature and pressure

Select "Status">"Temperature and Pressure" from the menu to enter the interface shown below.

Users can query the current temperature and pressure information on this interface, and export or print the information.

10.5.3.Voltage and Current

Select "Status">"Voltage and Current" from the drop-down menu to enter the interface shown below. Users can query the current voltage and current information on this interface.

10.5.4.Version information

Select "Status">"Version Information" from the menu to enter the interface shown below. Users can query the current version information of the instrument on this interface.

10.6.Instructions for Eliminating or Reducing Disuse

Provide the responsible person with instructions to eliminate or reduce disuse and risks involved in transportation or disposal. The instructions should contain the requirements to minimize the biohazard:

1) Blood samples, reagents or other liquids are deemed to be infectious. If a small amount of liquids spattered onto the instrument surface, use a cotton ball dipped with “75% alcohol” to wipe it away, otherwise, contact with the surface may lead to infection and other biohazard; if a large amount of liquids splashed and penetrated into the instrument, stop using it and pull out the plug, then contact Producer or your local distributor.

2) For any carry, transfer, presentation, lending, maintenance, etc., thoroughly disinfect the instrument surface to minimize the biohazard. Once the instrument gets any collision or falls off, no matter if there’s any obvious surface or internal damage, stop using it immediately and contact Producer or your local distributor.

3) If the instrument breaks down after the warranty period, ask Producer service engineer, hospital equipment department engineer or other authorized maintenance engineer to repair it. Otherwise it may lead to risks such as electric shock. It is suggested to get in contact with Producer before the maintenance.

4) It is recommended to stop using the instrument when it reaches the retirement period, or continue the use based on an overall inspection and maintenance of Producer.

5) Only personnel trained and authorized by Producer or its distributors can use this instrument, otherwise it may damage the protection provided by the instrument or greatly affect the test results.

11.Troubleshooting

11.1. Introduction

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

NOTE

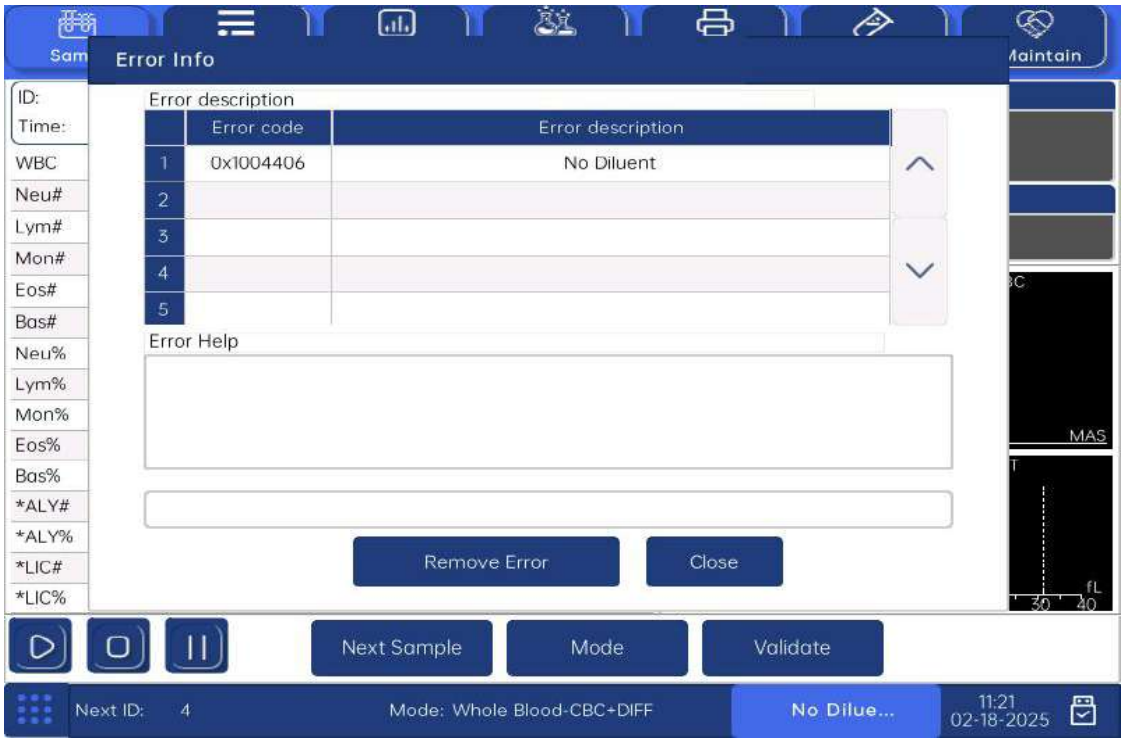
This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer.

11.2.Error Information and Handling

During the operation, if error(s) is detected, the analyzer will beep and display the corresponding error message in the error information area at the bottom right of the screen. Meanwhile, the indicator will turn red. According to the severity of the errors, the colors of error messages are red, orange, blue and green.

- Red: fatal error. When this kind of error occurs, the analyzer will stop running immediately, and any further operation is prohibited.
- Orange: error that stops operation. When this kind of error occurs, the analyzer will stop running immediately.
- Blue: error that restricts certain operations. When this kind of error occurs, the analyzer can still continue with the current operation, but any other operations related to the error will be restricted.
- Green: Prompt level. When this kind of error occurs, the analyzer can still continue with the current operation, and any other operations will not be restricted.

The following figure is the error information dialog box.



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

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

The following functions are provided:

1. Remove error

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

2. Close the error information dialog box

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

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

Error Name	**Actions**
Driver board communication error	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Clock error	1. Set the time in the "Date/Time Setup" interface.

Error Name	Actions
	2. If the error still exists, contact our customer service department.
No diluent	1. Replace the diluent. 2. Click "Remove Error", and enter the new barcode of the diluent into the reagent setup dialog box. 3. If the error still exists after replacing the diluent, contact our customer service department.
No lyse	1. Replace the lyse. 2. Click "Remove Error", and enter the new barcode of the lyse into the reagent setup dialog box. 3. If the error still exists after replacing the lyse, contact our customer service department.
Diluent is insufficient	1. Replace the diluent. 2. Click "Remove Error", and enter the new barcode of the diluent into the reagent setup dialog box. 3. If the error still exists after replacing the diluent, contact our customer service department.
Lyse is insufficient	1. Replace the lyse. 2. Click "Remove Error", and enter the new barcode of the lyse into the reagent setup dialog box. 3. If the error still exists after replacing the lyse, contact our customer service department.
Diluent expired	1. Replace diluent within the validity period. 2. Click "Remove Error", and enter the new barcode of the diluent into the reagent setup dialog box. 3. If the error still exists after replacing the diluent, contact our customer service department.
Lyse expired	1. Replace lyse within the validity period. 2. Click "Remove Error", and enter the new barcode of the lyse into the reagent setup dialog box. 3. If the error still exists after replacing the lyse, contact our customer service department.
Waste full	1. Empty the waste container or use a new waste container. 2. Click "Remove Error" to see if the error can be removed. 3. If the error still exists, contact our customer service department.

Error Name	Actions
Syringe module error	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Sample probe horizontal motor action error	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Sample probe vertical motor action error	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Instrument startup unfinished	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Background abnormal	1. It is recommended to carry out the background test several times and then carry out the sample test after the background test passed. 2. If the background test is still not passed, it is recommended to perform the probe cleanser maintenance before test again. 3. If the error still exists, contact our customer service department.
Exiting standby mode failed	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
HGB blank voltage abnormal	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
WBC clogging	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.
RBC clogging	1. Click "Remove Error" to see if the error can be removed. 2. If the error still exists, contact our customer service department.

Appendix A. Specifications

A.1. Classification

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

A.2. Reagents

Diluent	SMT-5D Diluent
Lyse	SMT-5L-D DIFF Lyse
	SMT-5L-H LH Lyse
/	Probe cleanser

A.3. Applicable Tubes

Before performing the automatic sample analysis, users need to prepare the standard test tube rack of Xilaiheng Medical Electronics Company and the test tubes of the specified specifications, and make the test tube barcodes as required. When placing the test tubes, place them vertically in the test tube slot of the test tube rack and gently press them to the bottom to facilitate the scanning of the barcode by the scanner.

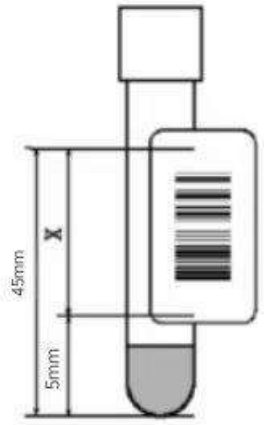
NOTE

Sample tubes (whole blood) of the following sizes can be supported: φ13x75mm

When removing the tube, gently lift it up.

Bar code tag

To read the barcode correctly, the label must be pasted correctly. The operator must stick the barcode within the range of area X as shown in the following figure.



Barcode pasting range

NOTE

Blood, scrapings, or powder on gloves, etc. can interfere with the correct reading of the barcode. Operators need to ensure that there is no blood, scratchings, or powder on gloves on the barcode labels to ensure the barcode reading rate.

A.4. Parameters

Parameter Group	Name	Abbreviation	Default Unit
WBC group (15)	White Blood Cell count	WBC	10^9/L
	Neutrophils percentage	Neu%	%
	Lymphocytes percentage	Lym%	%
	Monocytes percentage	Mon%	%
	Eosinophils percentage	Eos%	%
	Basophils percentage	Bas%	%
	Neutrophils count	Neu#	10^9/L
	Lymphocytes count	Lym#	10^9/L
	Monocytes count	Mon#	10^9/L
	Eosinophils count	Eos#	10^9/L
	Basophils count	Bas#	10^9/L

Paramet Group	Name	Abbreviation	Defaut Unit
	Abnormal Lymphocytes number	*ALY#	10^9/L
	Abnormal Lymphocytes percentage	*ALY%	%
	Large Immature Cells number	*LIC#	10^9/L
	Large Immature Cells percentage	*LIC%	%
RBC group (8)	Red Blood Cell count	RBC	10^{12}/L
	Hemoglobin Concentration	HGB	g/L
	Mean Corpuscular Volume	MCV	fL
	Mean Corpuscular Hemoglobin	MCH	pg
	Mean Corpuscular Hemoglobin Concentration	MCHC	g/L
	Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV	%
	Red Blood Cell Distribution Width - Standard Deviation	RDW-SD	fL
	Hematocrit	HCT	%
PLT group (6)	Platelet count	PLT	10^9/L
	Mean Platelet Volume	MPV	fL
	Platelet Distribution Width	PDW	None
	Plateletcrit	PCT	%
	Platelet larger cell count	P-LCR	%
	Platelet larger cell ratio	P-LCC	10^9/L

Parameter Group	Name	Abbreviation	Default Unit
Histogram	Red Blood Cell Histogram	RBCHistogram	/
	Platelet Histogram	PLT Histogram	/
Scattergram	Diff Scattergram	Diff Scattergram	
	White Blood Cell Scattergram	WBC Scattergram	

A.5. Model Differences

Model	SMT-60
Throughput	⩾60 samples/hour
Screen size	10.4 inch
Memory	100000
Appearance	The front shell color is white

A.6. Performance Indicators

A.6.1. Display Range

Parameter	Display Range
WBC	0.00×10^9/L ~ 999.99×10^9/L
RBC	0.00×10^{12}/L ~ 18.00×10^{12}/L
HGB	0g/L ~ 300g/L
PLT	0×10^9/L ~ 9999×10^9/L
HCT	0% ~ 80%

A.6.2. Background/Blank Count

Parameter	Background/Blank Count Requirements
WBC	≤0.20×10^9/L
RBC	≤0.02×10^{12}/L
HGB	≤1g/L
PLT	≤10×10^9/L
HCT	≤0.5%

A.6.3.Linearity Range

Parameter	Linearity Range	Deviation Range (Whole Blood)
WBC	0.00×10^9/L ~ 10.00×10^9/L	≤±0.30×10^9/L
	10.01×10^9/L ~ 100.00×10^9/L	≤±5%
RBC	0.00×10^{12}/L ~ 1.00×10^{12}/L	≤±0.05×10^{12}/L
	1.01×10^{12}/L ~ 8.00×10^{12}/L	≤±5%
HGB	0g/L ~ 70g/L	≤±2g/L
	71g/L ~ 250g/L	≤±2%
PLT	0 ×10^9/L ~ 100×10^9/L	≤±10×10^9/L
	101×10^9/L ~ 1000×10^9/L	≤±8%

A.6.4 .Accuracy

Parameter	Range	Deviation Range
WBC	3.5 ×10^9/L ~ 9.5 ×10^9/L	≤ ± 10%
RBC	3.80 ×10^{12}/L ~ 5.80 ×10^{12}/L	≤ ± 5%
HGB	115 g/L ~ 175g/L	≤ ± 5%
PLT	125 ×10^9/L ~ 350 ×10^9/L	≤ ± 12%
HCT/MCV	35% ~ 50% （HCT） or 82fL ~ 100fL （MCV）	Not exceeding ± 9.0% （HCT） or ±7.0 （MCV）

A.6.5. Carryover

Parameter	Carryover
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
HCT	≤0.5%
PLT	≤1.0%

A.6.6. Reproducibility

Whole blood sample reproducibility requirements:

Parameter	Detection Range	Whole Blood Reproducibility (CV/absolute deviation d)
WBC	3.50×10^9/L ~ 15.00×10^9/L	≤2.0%
RBC	3.50×10^{12}/L ~ 6.00×10^{12}/L	≤1.5%
HGB	110g/L ~ 180g/L	≤1.5%
MCV	70fL ~ 120fL	≤1.0%
PLT	100×10^9/L ~ 149×10^9/L	≤6.0%
	150×10^9/L ~ 500×10^9/L	≤4.0%

Prediluted sample reproducibility requirements:

Parameter	Detection Range	Prediluted Sample Reproducibility (CV/absolute deviation d)
WBC	3.50×10^9/L ~ 15.00×10^9/L	≤4.0%
Neu%	50.0% ~ 70.0%	±8.0(d)
Lym%	20.0% ~ 40.0%	±6.0(d)
Mon%	5.0% ~ 10.0%	±4.0(d)
Eos%	2.0% ~ 5.0%	±2.5(d)
Bas%	0.5% ~ 1.5%	±1.2(d)
RBC	3.50×10^{12}/L ~ 6.00×10^{12}/L	≤2.0%
HGB	110g/L ~ 180g/L	≤2.0%
MCV	70fL ~ 120fL	≤3.0%
PLT	100×10^9/L ~ 149×10^9/L	≤8.0%
	150×10^9/L ~ 500×10^9/L	≤8.0%

A.7. Input/Output Device

WARNING

Be sure to use the specified devices only.

NOTE

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

A.7.1. External Computer (Optional)

Recommended PC configurations: CPU Intel® 1.6GHz and above

RAM: 1G or above

Hard disk: 160GB or above

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

A.7.2. Mouse (Standard)

A.7.3. External Barcode Scanner (Optional)

A.7.4. Printer (Optional)

A.7.5 Interfaces

2 USB ports

1 network port, compatible with TCP / IP protocol

A.8. Fuse

Fuse specifications: F6.3A L250V

⚠WARNING

Be sure to use the specified fuse only.

A.9. EMC Description

- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.
- This equipment complies with the emission and immunity requirements of the EN 61326-1:2013 and EN 61326-2-6:2013.
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

NOTE

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

A.10. Sound Pressure

Maximal sound: 65 dBA

NOTE

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

A.11. Operating Environment

- Optimal operating temperature: 18℃~35℃
- Optimal operating humidity: ≤70%
- Atmospheric pressure: 70kPa～106kPa

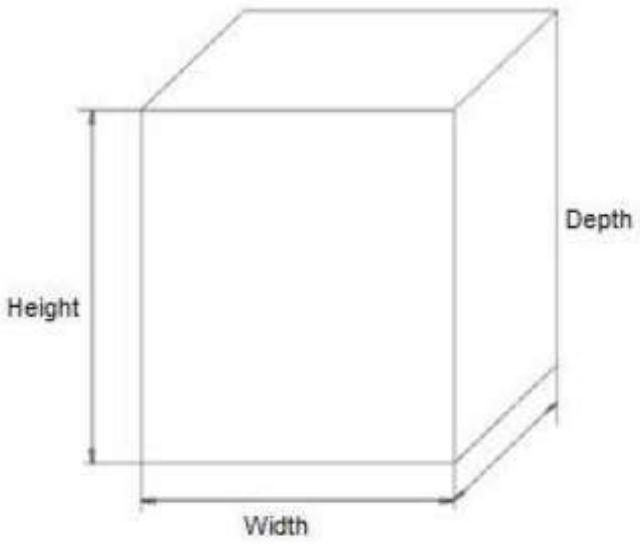
A.12. Storage and Transportation Environment

- Ambient temperature: -10℃~55℃
- Relative humidity: -10%～90%
- Atmospheric pressure: 50kPa～106kPa

A.13. Running Environment

- Ambient temperature: 10℃~40℃
- Relative humidity: 10%～90%
- Atmospheric pressure: 70kPa～106kPa

A.14. Dimensions and Weight



Dimensions	Width(mm)≤592mm Height (mm)≤468mm （with foot） Depth (mm)≤645 mm
Weight	≤48Kg

A.15. Safety Classification

Overvoltage category: II

Pollution degree: 2

A.16. Training

To ensure that users can properly use the analyzer and that the device will perform optimally, Producer will send an internal dedicated service engineer or a Producer designated distributor to the user to assist with the training.

A.17. Contraindications

Non

Appendix B. Hazardous Substances

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

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

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

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

Contact Information

Product information

Seamaty Diagnostic Co., Ltd.

11th Floor,Building H,And,6th Floor Building B,SZZT Industrial Park,TongGuan Road, Yutang Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster, Germany

After-sales service:

After-sales service provider: Seamaty Diagnostic Co., Ltd.

After-sales service address: 11th Floor,Building H,And,6th Floor Building B,SZZT Industrial Park,TongGuan Road, Yutang Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China

After-sales service telephone: 0755-28235680

E-mail: allen.xiao@seamaty.com

Date of preparation: December 1, 2024

Version：A0

斯马特诊断技术(深圳)有限公司
Seamaty Diagnostic Co., Ltd.
11the Floor of Building H, SZZT Industrial Park, TongGuan Road, Tianliao Community, Yutang Street,
Guangming District, Shenzhen 518107, P.R.CHINA
Website:www.seamaty.com; Email: info@seamaty.com
Tel: +86-028-60230308; Fax: +86-028-60230307

Declaration on Hemoglobin (HGB) Sensitivity and Linearity Performance

To whom it may concern,

We, Seamaty Diagnostic Co., Ltd., hereby declare that the SMT-60 automated 5-DIFF hematology analyzer demonstrates reliable hemoglobin (HGB) measurement performance in terms of sensitivity and linearity, based on the Instructions for Use (IFU) and internal validation data.

According to IFU (Page 122, Section A.6.3 – Linearity Range), the analyzer shows the following performance characteristics:

1. Low Concentration Range:
- Linearity Range: 0 g/L – 70 g/L
- Deviation (Whole Blood): ≤ ±2 g/L

This confirms that within the low hemoglobin concentration range, the analyzer maintains excellent linearity with minimal deviation. In combination with a background hemoglobin level of ≤ 1 g/L, the system demonstrates the capability to detect and accurately measure very low hemoglobin concentrations, supporting a sensitivity of approximately 1 g/L.

2. High Concentration Range:
- Linearity Range: 71 g/L – 250 g/L
- Deviation (Whole Blood): ≤ ±2%

This ensures accurate, stable, and consistent performance across the normal clinical measurement range.

Conclusion: Based on the above, the SMT-60 analyzer provides a low background signal (≤ 1 g/L) and reliable linear response in the low concentration range (0–70 g/L), forming a complete and consistent performance basis to support a hemoglobin measurement sensitivity of approximately 1 g/L.

This declaration is issued for tender and documentation purposes.

Seamaty Diagnostic Co., Ltd.
斯马特诊断技术(深圳)有限公司
Seamaty Diagnostic Co., Ltd.
Date: 2026-03-19

结业证书

CERTIFICATE

We, Seamaty Diagnostic Co., Ltd.

Addressing at Floor 11, Building H, Zhengtong Electronics Industrial Park, No. 3 Yutang Community, Yutang Street, Guangming District, Shenzhen City, China do hereby acknowledge to

POHILCO IRINA

From **Sanmedico SRL** has attended training of H**ematology Product Line (SMT-30/ SMT-50/SMT-60)** on 2nd March 2026

The certificate is valid until 01.03.2027

seamaty
斯马特

Seamaty Diagnostic Co.. Ltd. 02.03.2026

数网信认证

质量管理体系认证证书

注册号：87623Q0262R0M

兹证明

成都斯马特科技股份有限公司

统一社会信用代码：91510100052533028R

注册地址：成都高新区合作路 333 号 1 栋 1 层 1 号、2 栋 1 层 1 号

经营地址：成都高新区合作路 333 号 1 栋 1 层 1 号 306-316、2 栋 1 层 1 号四楼南区

审核地址：成都高新区合作路 333 号 1 栋 1 层 1 号 306-316、2 栋 1 层 1 号四楼南区

质量管理体系符合

GB/T19001-2016/ISO9001:2015

通过认证范围：

许可范围内的用于体外诊断的生化分析设备及免疫分析设备的研发、生产及销售

初次颁证日期：2023 年 11 月 08 日

有效期至：2026 年 11 月 07 日

本次颁证日期：2024 年 10 月 15 日

总经理：

日期：2024 年 10 月 15 日

1. 本证书有效性查询可扫描二维码
2. 同时可登陆 www.swxrz.com 查询
3. 也可登陆国家认证认可监督管理委员会官方网站 www.cnca.gov.cn 查询
4. 获证组织必须定时接受监督审核并经审核合格此证书方继续有效

公众号　　证书查询

数网信认证服务（北京）有限公司

认证机构地址：北京市朝阳区广渠路 36 号院 5 号楼 13 层 1327　电话：010-59775801　邮编：100020

Data Network Information Authentication

QUALITY MANAGEMENT SYSTEM CERTIFICATION

CERTIFICATION

Registration Number:87623Q0262R0M

This is to certify that

Chengdu Seamaty Technology Co.,Ltd

Unified Social Credit Code:91510100052533028R

Registered address: No.1 Floor 1 Building1,No.1 Floor 1 Building2,No.333 Hezuo Road, Hi-Tech Zone of Chengdu, Sichuan 611731, P.R. China

Address: Room 306-316 of No.1 Floor 1 Building1 and Floor 4 South Part of No.1 Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone 611731 Chengdu, Sichuan Province, P.R.China

Audit address: Room 306-316 of No.1 Floor 1 Building1 and Floor 4 South Part of No.1 Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone 611731 Chengdu, Sichuan Province, P.R.China

Quality management system in Accordance with

GB/T19001-2016/ISO9001:2015

Scope of certification

Research and development, production and sales of biochemical analysis equipment and immunoanalysis equipment for in vitro diagnosis within the scope of license

Date of initial certification:November 08th,2023

Expiry Date : November 07th,2026

Date of this certification:October 15th,2024

General manager: 申爱萍

Date:October 15th,2024

1.The validity of this certificate can be inquired by scanning QR code

2.Or inquiry by visiting www.swxrz.com

3.You can also visit the official website of National certification and Accreditation Administration: www.cnca.gov.cn to query.

4.Certified organization shall customize and pass surveillance audit to make this certificate continue to be valid.

official account　　Certificate query

Data network information Authentication service (Beijing) Co., Ltd

Address of certification authority:Room 1327, Floor 13, Building 5, Yard 36, Guangqu Road, Chaoyang District, Beijing

Telephone:010-67723875　　Postcode:100020

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 107895 0001 Rev. 02

Holder of Certificate: **Chengdu Seamaty Technology Co., Ltd.**
Room 306-316 of No.1 Floor 1 Building1
and Floor 4 South Part of No.1
Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone
611731 Chengdu, Sichuan, Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of biochemical analysis instrument , immunoassay instrument and blood gas electrolyte analyzer instrument for in vitro diagnosis**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 107895 0001 Rev. 02

Report No.: SH23171901

Valid from: 2024-04-26
Valid until: 2027-04-25

Date, 2024-03-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 107895 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Chengdu Seamaty Technology Co., Ltd.
Room 306-316 of No.1 Floor 1 Building1, and Floor 4 South Part of No.1 , Floor 1 Building 2, No.333 Hezuo Road, Hi-Tech Zone, 611731 Chengdu, Sichuan, Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

seamaty

SMT-60

5-Part Hematology Analyzer

Basic Parameters

Test Speed	60T/H
Principle Technology	Triangular laser scattering and sheath flow for leukocytes, impedance for erythrocytes and platelets, and cyanide-free for hemoglobin
Channels	2 Channels
Gemstone Hole Aperture	RBC/PLT Gemstone Hole Diameter: 70um
Graph	2 scattergrams, 2 histograms
HGB lamp Wavelength	LED lamp wavelength 530nm
Sample Volume	Whole Blood Mode: 20μl, Pre-Dilution Mode: 20μl
Measurement Items	37 test items: WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#,Mon#, Neu#, EOS#, BaS#, RBC, HGB,HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC, LIC%, LIC#, ALY%.ALY#,NLR,PLR,PDW-CV,PDW-SD,NRBC#,NRBC%,PLT-C#, PLT-C%

Hardware

Calibration	Manual, automatic and fresh blood calibration
Counting Mode	Whole blood, capillary whole blood, pre-diluted
Printing	Automatic/manual printing
LiS System	LIS support

Reagents

Diluent: 20L
L-H Lyse: 100ml
Diff Lyse: 500ml

Chengdu Seamaty Technology Co., Ltd

CE ISO ISO13485

Other

Working Temperature	10-30℃
Power Supply	100~240 AC, 50/60Hz, 200VA
Relative Humidity	≤85%
Atmospheric Pressure	70.0kPa-106.0kPa

Specifications

Inputs	10.4 inch touch screen, keyboard and mouse
Output	Built-in printer, support external printer
Printing Paper	57x35mm
Communication	2 USB ports, 1 LAN port
Memory	50,000 results
Clogging Clearance	High Voltage Burning, High-pressure Rinsing
Full auto-sampling mode	Auto-loader of 50 samples (5 *10 samples/rack)
Auto Rotary Sweep	Automatic rotary scanning of ID barcode
Automatic Sample Shaking	Sample tube fixation automatic shaking
Sample Tube Puncture	Supports cap-pierce function
STAT function	Yes
Dimensions	641 x592 x465mm
Net Weight	35KG

Performance

Item	CV
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
PLT	≤1.0%

Precision

Item	Background
WBC	≤ $0.2x10^9$/L
RBC	≤ $0.02x10^{12}$/L
HGB	≤1g/L
HCT	≤ 0.5%
PLT	≤ $10x10^9$/L

Background

Item	Whole blood sample CV (CV/absolute deviation d)	Pre-diluted sample CV (CV/absolute deviation d)	Measurement range
WBC	≤2.0%	≤4.0%	(4.00~15.00)*10^9/L
RBC	≤1.5%	≤2.0%	(3.50~6.00)*10^{12}/L
HGB	≤1.5%	≤2.0%	(110~180)g/L
PLT	≤4.0%	≤8.0%	(150~500)*10^9/L

Accuracy

Item	Linearity range	Deviation from linearity (whole blood mode)
WBC	(0.00~300.00)*10^9/L	±5%
RBC	(0.00~8.00)*10^{12}/L	±5%
HGB	(0~250)g/L	±2%
PLT	(0~1000)*10^9/L	±8%

Linearity

www.seamaty.com

A0-SMT60-20250108-EN

seamaty

Chengdu Seamaty Technology Co., Ltd.

Address: No. 111, Longyun 1st Road, Eastern New Area, Chengdu 641419 P.R.C.

Tel: +86-028-60230308

Fax: +86-028-60230307

Email: info@seamaty.com

seamaty

Declaration of Conformity

IVD

File No:SMTSZ-DOC-25060301 Version：A0

Manufacturer: Seamaty Diagnostic Co., Ltd. SRN:CN-MF-000033945

Address:11th Floor,Building H,And,6th Floor Building B,SZZT Industrial Park,TongGuan Road, Yutang Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China

We, the manufacturer, here with declare that the products:

Product Name: Automatic Hematology Analyzer Model: SMT-50/60 GMDN:35476

Basic-UDI-DI: 6975347780066FA

Intended Use: This product is applicable for detecting the parameters of WBC, RBC, PLT, HGB, etc. in anti-coagulated venous whole blood or capillary blood, as well as WBC 5-part differential analysis and WBC counting.

Applied Standards:

EN61010-1: 2010+A:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

EN 61010-2-101:2018 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61326-1: 2020 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

EN 61326-2-6: 2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

EN ISO 13485: 2016 Medical devices — Quality management systems — Requirements for regulatory purposes

EN 13612: 2016 Performance evaluation of in ivtro diagnostic medical devices

EN ISO14971: 2019 Medical devices —Application of risk management to medical devices

EN ISO 15223-1:2021/Amd 1:2025 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

EN ISO 18113-01: 2013 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in virto diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU(IVDR),which apply to it.

Conformity assessment procedure: Annex II and Annex III.

It bears the mark CE

European Authorized Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Münster, Germany

SRN of the Authorized Representative:DE-AR-000000002

Every article we sell is covered by a technical file. Technical files are provided to the European Authorized representative and kept up to date by us.
This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
We manufacturer is exclusively responsible for the declaration of conformity.
The declaration is valid for 3 years

Tao Liu

Shenzhen 2025.06.03	Management representative
Place , date	*Legally binding signature, Function*

EC Declaration of Conformity

We, Manufacturer Name: Seamaty Diagnostic Co., Ltd. SRN code: CN-MF-000033945
Address:11th Floor,Building H,And,6th Floor Building B,SZZT Industrial Park,TongGuan Road, Yutang Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China
As the Manufacturer of
Product Name: Cleaner Model: SMT-5C Specification: 50ml/200 ml
Basic-UDI-DI: 697534778SMT5CWS GMDN: 58236
Intend Use: It can be used to clean and wash the liquid system of corresponding analyzer.

Applied Standards:
EN 13612: 2016 Performance evaluation of in vitro diagnostic medical devices
EN ISO 13485: 2016 Medical Devices – Quality Managements Systems – Requirements for Regulatory Purposes
EN ISO 18113-1: 2013 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) –Part 1: Terms, definitions and general requirements
EN ISO 18113-2: 2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2021/Amd 1:2025 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO 14971: 2019 Medical devices -Application of risk management to medical devices
ISO 23640: 2015 In vitro diagnostic medical devices-Evaluation of stability of in vitro diagnostic reagents

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU(IVDR),which apply to it.
Classification: Classification A according to Annex VIII of the Regulation (EU) 2017/746 according to rule 5.
Conformity assessment procedure: Annex II& Annex III from Regulation 2017/746
It bears the mark CE

European Authorized Representative: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Münster, Germany SRN: DE-AR-000000002
Every article we sell is covered by a technical file. Technical files are provided to the European Authorized representative and kept up to date by us.
This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
We manufacturer is exclusively responsible for the declaration of conformity.
The declaration is valid for 3 years.

Tao Liu

Shenzhen 2025.03.19 Management representative

Place , date *Legally binding signature, Function*

EC Declaration of Conformity

File No:SMT-3D-250302 Version：A0

We, Manufacturer Name: Seamaty Diagnostic Co., Ltd. SRN code: CN-MF-000033945

Address:11th Floor,Building H,And,6th Floor Building B,SZZT Industrial Park,TongGuan Road, Yutang Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China

As the Manufacturer of

Product Name	GMDN	Basic-UDI-DI	Model	Specification
Diluent	58237	697534778SMT3DWN	SMT-3D	5L、10L、20L
		697534778SMT5DWU	SMT-5D	5L、10L、20L

Intended Use: It is used for blood cell analysis, sample dilution and cell suspension preparation before analysis. The reagent is intended for human sample testing

Applied Standards:

EN 13612: 2016 Performance evaluation of in vitro diagnostic medical devices

EN ISO 13485: 2016 Medical Devices – Quality Managements Systems – Requirements for Regulatory Purposes

EN ISO 18113-1: 2013 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) –Part 1: Terms, definitions and general requirements

EN ISO 18113-2: 2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic instruments for professional use

EN ISO 15223-1:2021/Amd 1:2025 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

EN ISO 14971: 2019 Medical devices -Application of risk management to medical devices

ISO 23640: 2015 In vitro diagnostic medical devices-Evaluation of stability of in vitro diagnostic reagents

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU(IVDR),which apply to it.

Classification: Classification A according to Annex VIII of the Regulation (EU) 2017/746 according to rule 5.

Conformity assessment procedure: Annex II& Annex III from Regulation 2017/746

It bears the mark CE

European Authorized Representative: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Münster, Germany SRN Code: DE-AR-000000002

Every article we sell is covered by a technical file. Technical files are provided to the European Authorized representative and kept up to date by us.
This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
We manufacturer is exclusively responsible for the declaration of conformity.
The declaration is valid for 3 years.

Tao Liu

Shenzhen 2025.03.19 Management representative

Place, date *Legally binding signature, Function*

EC Declaration of Conformity

We, Manufacturer Name: Seamaty Diagnostic Co., Ltd. SRN code: CN-MF-000033945
Address:11th Floor,Building H,And,6th Floor Building B,SZZT Industrial Park,TongGuan Road, Yutang Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China
As the Manufacturer of

Product Name	GMDN	Basic-UDI-DI	Model	Specification
Lyse	61165	697534778SMT3LX6	SMT-3L	1L、500mL、250mL、200mL、100mL、50mL
		697534778SMT5LD36	SMT-5L-D	1L、500mL、250mL、200mL、100mL、50mL
		697534778SMT5LH3E	SMT-5L-H	1L、500mL、250mL、200mL、100mL、50mL

Intended Use: It is used to dissolve red blood cells and release hemoglobin before analysis, so as to count white blood cells and determine hemoglobin concentration. The reagent is intended for human sample testing

Applied Standards:
EN 13612: 2016 Performance evaluation of in vitro diagnostic medical devices
EN ISO 13485: 2016 Medical Devices – Quality Managements Systems – Requirements for Regulatory Purposes
EN ISO 18113-1: 2013 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) –Part 1: Terms, definitions and general requirements
EN ISO 18113-2: 2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2021/Amd 1:2025 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO 14971: 2019 Medical devices -Application of risk management to medical devices
ISO 23640: 2015 In vitro diagnostic medical devices-Evaluation of stability of in vitro diagnostic reagents

We declare on our own responsibility that the above-mentioned product meets all the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU(IVDR),which apply to it.
Classification: Classification A according to Annex VIII of the Regulation (EU) 2017/746 according to rule 5.
Conformity assessment procedure: Annex II& Annex III from Regulation 2017/746

It bears the mark

CE

European Authorized Representative: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Münster, Germany
SRN: DE-AR-000000002

This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
Every article we sell is covered by a technical file. Technical files are provided to the European Authorized representative and kept up to date by us.
We manufacturer is exclusively responsible for the declaration of conformity.
The declaration is valid for 3 years.

Tao Liu

Shenzhen 2025.03.19 Management representative

Place , date *Legally binding signature, Function*

Cleaner User Manual

【Product Name】

Cleaner

【Model】

SMT-5C

【Specification】

50mL/200mL

【Intended Use】

It can be used to clean and wash the liquid system of corresponding analyzer.

【Components】

Sodium hypochlorite, Antiseptic, Surfactant, Protease.

【Storage Conditions & Period of Validity】

1.Unopened reagent, stored in dry place at 2℃～30℃, avoiding direct sunshine. The validity period is 12 months.

2. The validity of the product is 60 days after opening when it is used at the temperature of 15℃～30℃.

【Attention】

1.This product is not edible. Once eaten, it must be treated immediately.

2.Avoid skin contact. Once contacted, rinse with plenty of water immediately.

3. Avoid eye contact. Once contacted, rinse with plenty of water and consult a doctor immediately.

4. This product should not be used after the expiration date.

5. Wastes, surplus products and contaminated packaging should be treated in accordance with local regulations.

6. Please note that the reagent should be matched with the analyzer. Do not mix or combine with other reagents not produced by our company. Otherwise, it will cause measurement error.

【Label】

IVD	In vitro diagnostic medical devices		Expiration date
	Date of production		Manufacturer
		LOT	Lot number
	Consult instructions for use		Temperature limitation
EU REP	EC Authorised representative	CE	Conformity to specified European directives
	Importer		

Seamaty Diagnostic Co., Ltd
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EU REP
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

【Issued date and Version】

Issued date: March 19th, 2025

Version: A0

Diluent User Manual

【Product Name】

Diluent

【Model】

SMT-3D/5D

【Specification】

5L、10L、20L

【Intended Use】

It is used for blood cell analysis , sample dilution and cell suspension preparation before analysis.

The reagent is intended for human sample testing

【Method of Use】

1. Open the external packaging material, connect pipeline of analyzer with mouth of soft bag or mouth of reagent bottle in the carton.

2. When using the product, please refer to instructions for the related instrument.

NOTE: The product is for professional use only.

【Principle】

It is used for blood cell analysis , sample dilution and cell suspension preparation before analysis.

【Components】

Nacl, Cell stabilizer, buffer, preservative and Distilled water

【Storage Conditions & Period of Validity】

1. Unopened reagent, stored in dry place at 2℃～35℃, avoiding direct sunshine. The validity period is 18 months.

2. The validity of the product is 60 days after opening when it is used at the temperature of 15℃～30℃.

【Application Instrument】

SMT Series Automatic Hematology Analyzer manufactured by Seamaty Diagnostic Co., Ltd.

【Sample Requirements】

1. Samples must contain EDTA-2K anticoagulant. Blood coagulation, hemolysis or severe lipid samples cannot be tested.

2. If the samples can not be tested in time after collection, they should be stored at 2℃～8℃.

【Reference Intervals】

Please refer to the manual of corresponding analyzer.

【Performance】

1. pH value is 6.90±0.30 at 25℃±1℃

2. Conductivity is 18.90±0.50mS/cm at 25℃±1℃.

3. Osmotic concentration is 315±10 mOsm/kg.

4. Blank counting: WBC ≤ 0.2×10^9/L, RBC ≤ 0.02×10^{12}/L, HGB ≤ 1g/L, PLT≤ 10×10^9/L.

5. Accuracy: WBC does not exceed ±7.5%, RBC does not exceed ±3.0%, HGB does not exceed ±3.5%, PLT does not exceed ±12.5%,HCT does not exceed ±3.0%.

6. Lot difference：ΔpH ≤ 0.40, ΔConductivity ≤ 1.0mS/cm, ΔOsmotic concentration ≤ 20mOsm/kg.

【Attention】

1.This product is not edible. Once eaten, users must be treated immediately.

2.Avoid skin contact. Once contacted, rinse with plenty of water immediately.

3.Avoid eye contact. Once contacted, rinse with plenty of water and consult a doctor immediately.

4.This product should not be used after the expiration date. Wastes, surplus products and contaminated packaging should be treated in accordance with local regulations.

5.If the reagent is frozen, it should be reversed and mixed after thawing and restoring to room temperature, then it could be used when the of blank counting meet the performance.

【Label】

IVD	In vitro diagnostic medical devices		Expiration date
	Date of production		Manufacturer
	Do not reuse	LOT	Lot number
	Consult instructions for use		Temperature limitation
EU REP	EC Authorised representative	CE	Conformity to specified European directives
	Importer		

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【Issued date and version】

Issued date: March 19th，2025 Version:A0

Lyse User Manual

【Product Name】

Lyse

【Model】

SMT-3L/ 5L-D/5L-H

【Specification】

50ml、100mL、 200ml、250ml 、500mL、1L

【Intended Use】

It is used to dissolve red blood cells and release hemoglobin before analysis, so as to count white blood cells and determine hemoglobin concentration.

The reagent is intended for human sample testing

【Method of Use】

1. Open the external packaging material, connect pipeline of analyzer with mouth of soft bag or mouth of reagent bottle in the carton.

2. When using the product, please refer to instructions for the related instrument.

NOTE: The product is for professional use only.

【Principle】

The reagent is used to dissolve red blood cells and release hemoglobin.

【Components】

Surfactant, cell stabilizer, buffer and Distilled water

【Storage Conditions & Period of Validity】

1. Unopened reagent, stored in dry place at 2℃～35℃, avoiding direct sunshine. The validity period is 18 months.

2. The validity of the product is 60 days after opening when it is used at the temperature of 15℃～30℃.

【Application Product】

SMT Series Automatic Hematology Analyzer manufactured by Seamaty Diagnostic Co., Ltd.

【Sample Requirements】

1. Samples must contain EDTA-2K anticoagulant. Blood coagulation, hemolysis or severe lipid samples cannot be tested.

2. If the samples can not be tested in time after collection, they should be stored at 2℃～8℃.

【Performance】

1. pH value is 7.40±0.50 at 25℃±1℃.

2. Absorptive peak wavelength(λmax) is 540±10nm.

3. 3. Blank counting: WBC ≤ 0.3×109/L, HGB ≤ 2g/L.

4. Accuracy: WBC does not exceed ±7.5%, HGB does not exceed ±3.5%.

5. Lot difference： ΔpH ≤ 1.0; Δλmax ≤ 10nm.

【Attention】

1. This product is not edible. Once eaten, users must be treated immediately.

2. Avoid skin contact. Once contacted, rinse with plenty of water immediately.

3. Avoid eye contact. Once contacted, rinse with plenty of water and consult a doctor immediately.

4. This product should not be used after the expiration date.

5. Wastes, surplus products and contaminated packaging should be treated in accordance with local regulations.

6. If the reagent is frozen, it should be reversed and mixed after thawing and restoring to room temperature, then it could be used when the of blank counting meet the performance.

【Label】

In vitro diagnostic medical devices

Expiration date

Date of production

Manufacturer

Do not reuse

Lot number

Consult instructions for use

Temperature limitation

EC Authorised representative

Denotes conformity to specified European directives

Importer

Seamaty Diagnostic Co., Ltd

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【Issued date and version】

Issued date: March 19th，2025

Version:A0

Instructions for Hematology Control

Product Name

Hematology Control

Model

DM-SD

Packaging

3mL × n

(n indicates 1, 2 or 3)

Intended Use

Hematology Control is used in the Quality control of parameters including WBC, RBC, HGB, MCV and PLT for blood cell analyzers manufactured by Shenzhen Dymind Biotechnology Co., Ltd, to monitor and evaluate test results.

Principle

Hematology Control contains a variety of small particles, which have the properties similar to the leukocytes, erythrocytes and platelets in human blood. These particles can accurately simulate human blood and calibrate the analyzer.

The Control also contains reagents for preservation and preservation, which stabilizes the cell particles and stably stores the Control for more than a few months.

Composition

Hematology Control is an in vitro diagnostic reagent composed of animal-derived simulated leukocytes, animal-derived erythrocytes, simulated platelets, depositary agent and preservatives.

NOTE:

- The Control is traceable to the internationally agreed reference method.
- The reference values may vary from batch to batch, see the the reference table of Controls for the corresponding batch.

Storage and Stability

The product can be stably stored for 60 days at 2°C~8°C. Opened tubes are stable for 7 days, provided they are handled properly.

Date of manufacture and expiration : see product label.

NOTE: Protect tubes from severe vibration and freezing.

Applicable Instruments

The product is applicable to the following hematology analyzers produced by Dymind: DH51, DH53, DH56, D1-CRP, D3-CRP, D5-CRP, DH51CRP, DH53CRP, DH56CRP, UN73, UN71, UN76, DF50, DF51, DF52, DF53, DF55, DF56, DH71, DH73, DH76, D2-CRP, D6-CRP, D7-CRP, DH71-CRP, DH73-CRP, DH76-CRP, DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP, HS-5, HS-7, HS-5CRP.

Test Method

1. Remove the Control from the refrigerator and allow to warm at room temperature (15°C~30°C) for 15 minutes.
2. Mix the Control manually. (Do not mix on a mechanical mixer.
   a. Hold the tube horizontally between the palms of the hands. Roll the tube back and forth for 20~30 seconds; occasionally invert the tube. Mix thoroughly, but do not shake.
   b. Repeat step a until the red cells are completely suspended.

      NOTE: Tubes stored for a long time may require extra mixing.
   c. Gently invert the tube 8~10 times immediately before sampling.
3. Refer to the hematology analyzer operator's manual for calibration procedure.
4. Compare the mean value for each parameter to the assigned value.

   ¬ If the difference is within the Acceptable Deviation, calibration is not required. The test ends.

   ¬ If the difference is not within the Acceptable Deviation, calibration may be needed. Perform the calibration and then continue to the next step.
5. Verify calibration results.

   Reanalyze the Control 5 times in the main interface of the instrument. Mean values should be within the Acceptable Range.
6. After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight. Return the tube to the refrigerator.

Interpretation of Test Results

The Control provides targets for the applicable models.

The targets are determined on a well-maintained, properly calibrated instrument using the original reagents. To ensure product performance, use the original reagents and operate and maintain according to the manufacturer's instructions.

Performance Specifications

The calibration within-bottle homogeneity should meet the requirements of the following table.

Parameter	WBC	RBC	HGB	HCT	MCV	PLT
CV/%	≤2.0	≤1.5	≤1.5	≤2.0	≤1.0	≤4.0

The calibration between-bottle homogeneity should meet the requirements of the following table.

Parameter	WBC	RBC	HGB	HCT	MCV	PLT
CV/%	≤2.5	≤1.0	≤1.0	≤1.0	≤1.0	≤4.0

Test the Control, the deviation of assignment accuracy should meet the requirements of the following table.

Parameter	WBC	RBC	HGB	MCV	PLT
Acceptable Deviation Range	±5.0%	±2.0%	±2.0%	±2.0%	±9.0%

Precautions

1) Controls must be used by qualified personnel or trained clinical staff.
2) Before use, verify that the lot number on the tube matches the lot number on the table of assay values.
3) Before use, mix the Control according the instructions. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.
4) Use product before the expiration date.
5) Do not use deteriorated product. Darkly colored supernatant may be indicative of product deterioration; however, moderately colored supernatant is normal and should not be confused with product deterioration.
6) The product is used only for in vitro diagnosis. Do not inhale. If reagent is spilled onto a human body part such as skin or eye, the affected body part must be flushed with fresh water. If ingested by mistake, the victim must be sent to a hospital immediately for therapy.
7) POTENTIAL BIOHAZARDOUS MATERIAL. The product contains human-sources and/or potentially infectious components. Each human donor/unit used in the preparation of this product has been tested by licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the equivalent biosafety procedures.
8) Dispose of waste carefully according to government regulations.

Interpretation of symbols

 Temperature limit

 Date of manufacture

 For in vitro diagnosis only

 Validity

 Lot No.

 Biological risks

 Consult Operation Manual

Contact Information

Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd.

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CE