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IVD

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Statement

The current version number of this manual is A/4, released on 2021-06. This manual may be modified as needed without prior notice.

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

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

Warranty Service

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

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

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

Customer Service Department

Manufacturer:	Genrui Biotech Inc.
Address:	4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China
Website URL:	www.genrui-bio.com
E-mail Address:	service@genrui-bio.com
Tel:	+86 755 26835560
Fax:	+86 755 26678789

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd
2595AA, The Hague, Netherlands
Email :peter@lotusnl.com

⚠WARNING

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

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

NOTE

1. This operation manual is written for the following laboratory professionals:

1) Daily system operators

2) Personnel for system maintenance and troubleshooting

3) Learners for system operation

2. When the instrument reaches the retirement period, it is recommended to stop using it or conduct a comprehensive inspection and maintenance before re-using it again.

Introduction

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

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

Prodcut Name: Auto Hematology Analyzer

Model: KT-6600/KT-6610

Product Composition: This product primarily comprises the host, accessories and software. The host includes a display screen, sampling assembly, fluidic system, optical 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 anticoagulated venous whole blood or capillary blood, as well as WBC 5-part differential analysis and WBC counting

Manufacturer: Genrui Biotech Inc.

Registered Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

Date of Manufacture: See the nameplate of the instrument

Instrument Service Life: 5 years

Manual Preparation Date: March 27, 2017

Manual Revision Date: June 30, 2021

Item No.: P01.91.300306-04

REF 21000012 (KT-6600) / 21000013 (KT-6610)

FCC ID: 2AZC7KT0301

Manual Overview

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

The text and figures in this manual take the KT-6610 as an example.

Who Should Read This Manual

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

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

How to Find Information

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

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

If you want to…	Please refer to…
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.
WARNING	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may cause personal injury.
CAUTION	Alerts the operator to follow the statement below the symbol while in operation, otherwise it may lead to analyzer damage or unreliable analysis results.
NOTE	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
IVD	For in vitro diagnostic use
SN	Product serial number
MC	Metrology certification mark
	Date of manufacture
	Manufacturer
CE	CE marking. The device is fully in conformance with the Directive 98/79/EC on in vitro diagnostic medical devices
EC REP	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
LOT	Batch code
	Expiry date
	Temperature limitation
	Consult the operation manual
20	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.
REF	Catalogue number

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.

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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 and fan 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 Genrui or its local distributors immediately. 3) Keep away from the inside of computer and printer in case of high voltage.

	Biohazard 1) All test samples, calibrators, controls, etc., should be considered contagious and protective gloves should be worn when coming into contact with these objects. 2) All waste liquid should be considered contagious and protective gloves should be worn when coming into contact with it. 3) Parts that have contacts with samples, such as sample probe, waste liquid tubing and waste container should be regarded as contagious and protective gloves should be worn when coming into contact with these objects. 4) When the instrument reaches its service life, it should be disposed according to the requirements of the local environmental protection department, cannot be disposed and discarded as common wastes.
	Corrosion 1) Some reagents are corrosive. Keep your hands and clothes away from them. Once contacted, wash with plenty of water and soap until they are clean. 2) If the reagents get in eyes, wash with plenty of water and consult an ophthalmologist.
	Combustion Do not use flammable dangerous goods, such as alcohol, ether, etc. near the analyzer.

1.2. Precautions

	Intended Use 1) The analyzer is designed for detecting the parameters of WBC, RBC, PLT, HGB, etc. (see Section 3.2. Parameters for details) in anticoagulated venous whole blood or capillary blood, as well as WBC 5-part differential analysis and WBC counting. Please consult Genrui 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 Genrui 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 Genrui 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 Genrui or the authorized Genrui 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 Genrui 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 Genrui may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of Genrui-authorized personnel.
- The installation, authorization, upgrade and modification of the analyzer software must be performed by Genrui-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 Genrui customer sercive department or your local distributor immediately.

2.2. Installer

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

2.3. Checking before Installation

Inspection for Damage

All the analyzers have been inspected strictly by Genrui 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 Genrui or Genrui-authorized local distributor.

If the outer packaging is intact, unpack it in the presence of Genrui 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 Genrui or Genrui-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 Genrui or its authorized local distributor.

NOTE

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

2.4. Installation Requirements

2.4.1. Space Requirements

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

1) proper height to place the analyzer;

2) at least 100cm between the left and right side door of the analyzer and the walls, which is the preferred access to perform service procedures;

3) at least 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 40kg of weight.

2.4.2. Power Requirements

Table 2-1 Power specification

	Voltage	Input power	Frequency
Analyzer	100-240V～	200VA	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: 10℃-30℃
2) Relative humidity: ≤ 85%
3) Atmospheric pressure: 70.0kPa-106.0kPa

NOTE

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

2.4.4. Moving and Installation Method

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

⚠WARNING

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

NOTE

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

2.5. Precautions for Use

- The analyzer performance may be declined if it has been placed in environment of high dustiness.
- The surface of the analyzer shall be cleaned and sterilized regularly with alcohol (75%).
- The aspirate key of the analyzer (see Figure 3-1 Front view of the analyzer) shall be wiped with alcohol (75%) regularly.
- If dangerous substances leak on the outside surface of the instrument or enter the inside of the instrument, wipe it with alcohol (75%).
- Do not use cleaning agents or disinfectants that chemically react with instrument parts or materials contained in the instrument and cause danger.
- If there is any doubt about the compatibility of the disinfectant or cleaning agent with the equipment parts or the materials contained in the equipment, you should consult the company's customer service or authorized agents.
- Sample collection and preparation must be done following standard procedures.
- If any of the pipes or fluidic components is worn out, stop using the analyzer and contact Genrui customer service department immediately for inspection or replacement.
- Check and make sure the pipes of reagents, including diluent, lyse and waste, are not pressed or bent.
- You must only use the Genrui-specified reagents, otherwise the analyzer may be damaged or provide unreliable results.
- 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 the KT-6610 Auto Hematology Analyzer.

3.2. Parameters

The parameters under CBC and CBC+DIFF mode are listed as follows:

Table 3-1 Parameters

Parameter Group	Name	Abbreviation	CBC	CBC+DIFF
WBC group (19), including8 RUO parameters	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#	/	√

Parameter Group	Name	Abbreviation	CBC	CBC+DIFF
	Large Immature Cells percentage	*LIC%	/	√
	Nucleated Red Blood Cells percentage	*NRBC%	/	√
	Nucleated Red Blood Cells number	*NRBC#	/	√
	Platelet Clumps percentage	*PLT Clumps%	/	√
	Platelet Clumps count	*PLT Clumps#	/	√
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-Standard Deviation	PDW-SD	√	√
	Platelet Distribution Width-Coefficient of Variation	PDW-CV	√	√
	Plateletcrit	PCT	√	√
	Platelet larger cell count	P-LCC	√	√
	Platelet larger cell ratio	P-LCR	√	√

NOTE

Parameters marked with * are for research use only. KT-6600 does not have this research parameter.

- **Histograms**

Table 3-2 Histograms

Name	Abbreviation	CBC	CBC+DIFF
Red Blood Cell Histogram	RBC Histogram	√	√
Platelet Histogram	PLT Histogram	√	√

- **Scattergrams**

Table 3-3 Scattergrams

Abbreviation	CBC	CBC+DIFF
Diff Scattergrams	/	√
WBC Scattergram	√	√

NOTE

"√" means "available under the mode", "/" means "not available under the mode".

3.3. Product Structure and Components

The analyzer mainly consists of a host and accessories. The host comprises the analysis module, information management module and result output module.

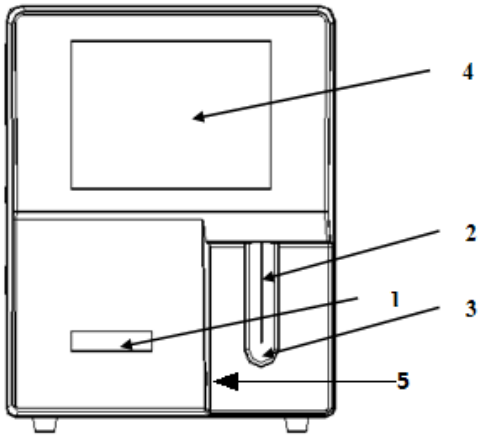


Figure 3-1 Front view of the analyzer

1--Status indicator 2--Sample probe

3--Aspirate key 4--Touch screen

5--Built-in barcode scanner(optional)

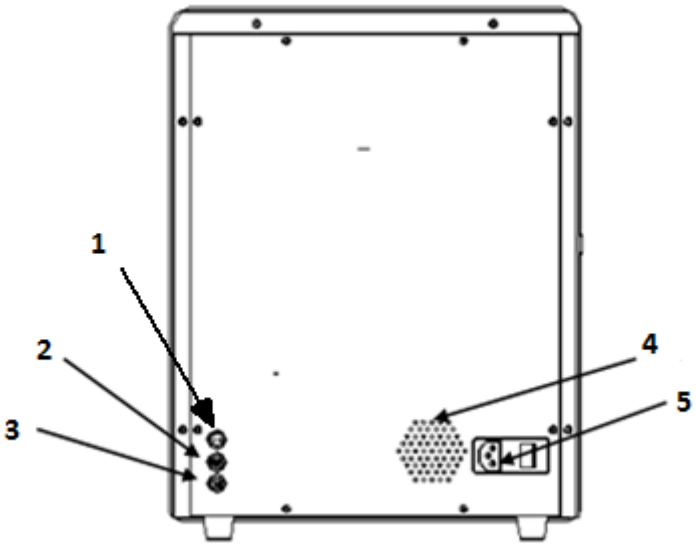


Figure 3-2 Back view of the analyzer

1--Waste sensor 2--Diluent inlet

3--Waste outlet 4--Fan channel

5--Power input socket

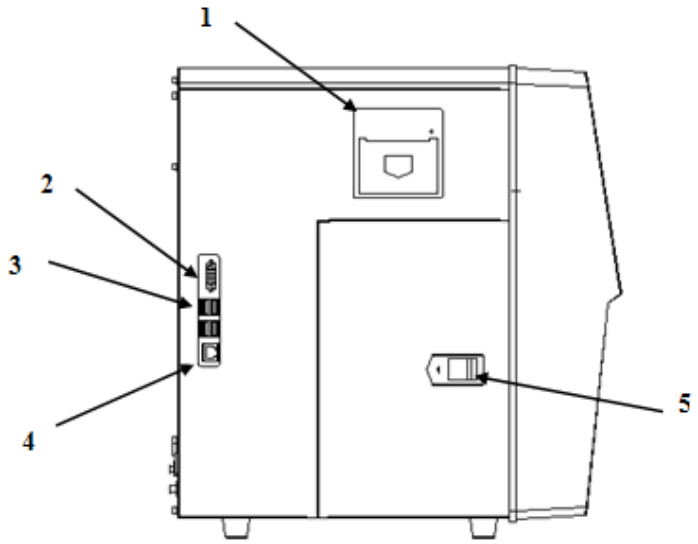


Figure 3-3 Left view of the analyzer

1--Recorder 2--Serial port

3--USB port 4--Network port

5--Latch

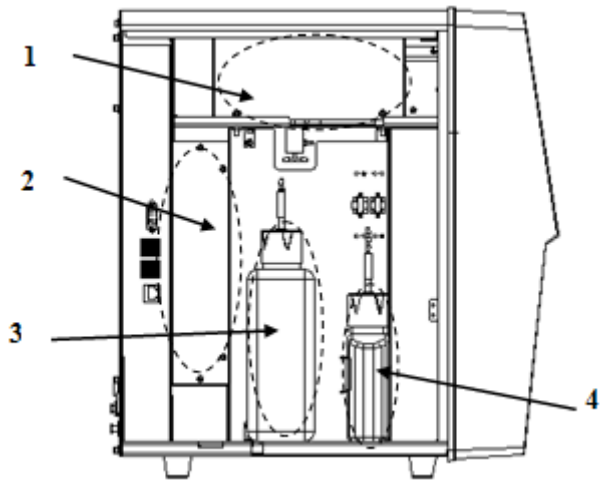


Figure 3-4 Left view of the analyzer (left door open)

1--Optical system 2--Power supply

3--DIFF lyse 4--LH lyse

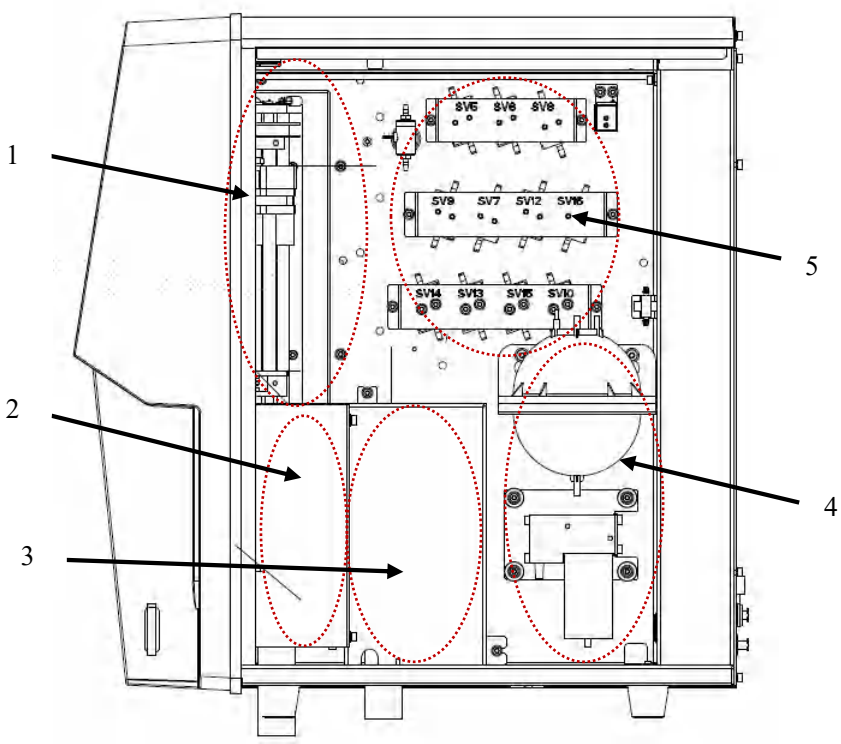


Figure 3-5 Right view of the analyzer (right door open)

1--Sampling assembly 2--RBC bath 3--WBC bath

4-- Waste assembly 5-- Liquid valve

3.3.1. Status Indicator

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

The indicator illuminates in 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.

When…	How…	Remark
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 side 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.

3.3.9. External Devices

- External Printer (optional)

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

The supported external printer models are: HP Color LaserJet Pro M252n, HP LaserJet Pro P1108, HP LaserJet Pro P1102, HP LaserJet 1020 plus and PCL6 protocol printer.

- Mouse (standard)

The mouse is connected to the analyzer via the USB port on the left side of the analyzer. It is used to operate the analyzer.

3.4. Reagents, Controls and Calibrators

As the analyzer, reagents (diluent, lyse and probe cleanser), controls, and calibrators are components of a system. Performance of the system depends on the combined integrity of all components. Only Genrui-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

- Diluent

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

- DIFF lyse

It is used to lyse red blood cells and differentiate WBCs.

- LH lyse

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

- Probe cleanser

It is used to clean the analyzer regularly.

3.4.2. Controls and Calibrators

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

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

4. Working Principles

4.1. Introduction

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

4.2. Aspiration

If you are to analyze a whole blood sample in the open vial sampling mode, the analyzer will aspirate 20μL (CBC+DIFF mode) or 12μL (CBC mode) of the sample.

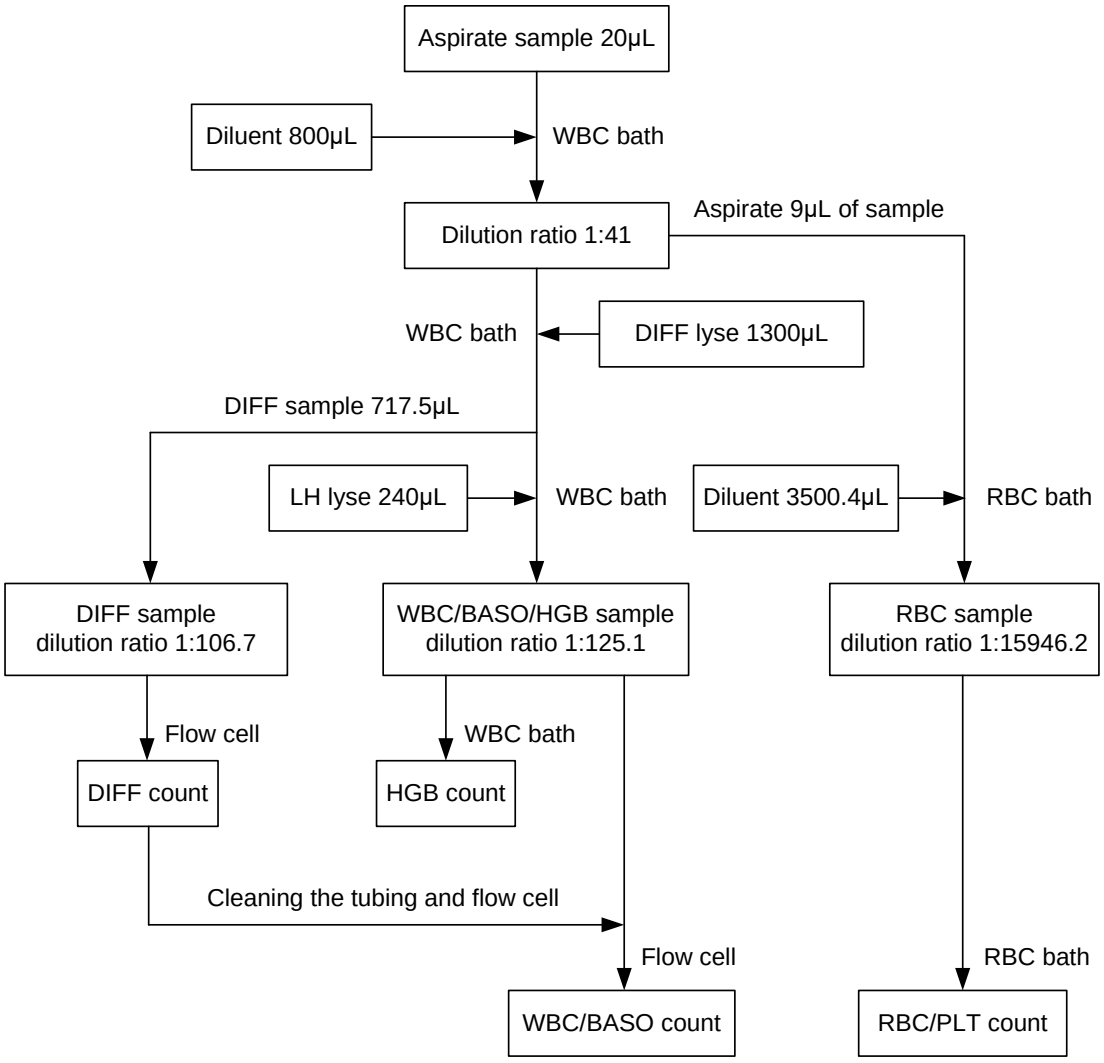
If you are to analyze a capillary blood sample in the open vial sampling mode, you should first manually dilute the sample (20μL of capillary sample needs to be diluted by 480μL of diluent, dilution ratio: 1:25) and then present the pre-diluted sample to the analyzer, which will aspirate 224μL of the sample.

4.3. Dilution

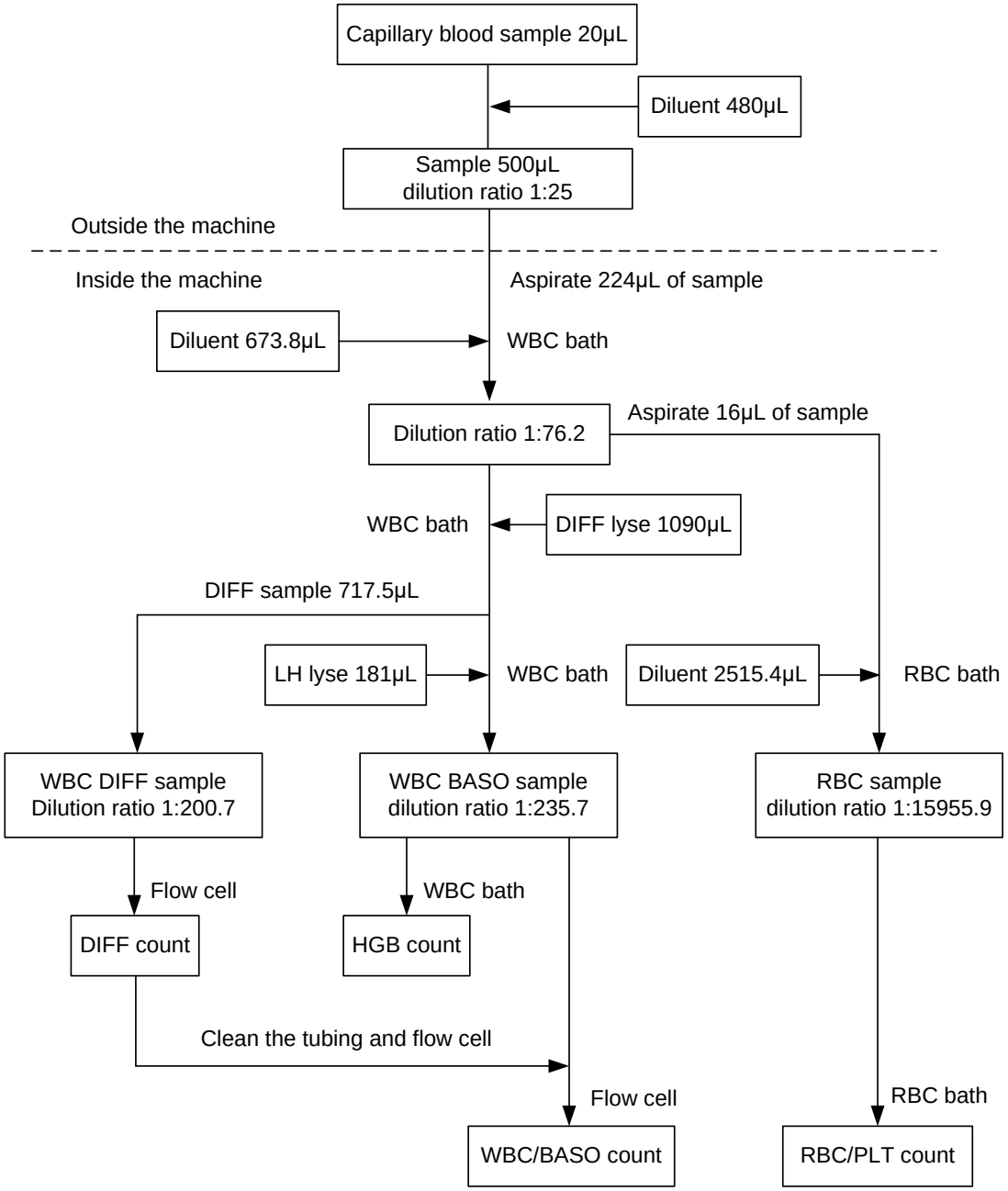
The aspirated sample will quickly and precisely be diluted in RBC bath and then segmented into two portions. One of these two portions will then be diluted again and processed by different reagents. After this, they are ready for analysis.

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

Whole Blood Mode



Prediluted Mode



4.4. WBC Measurement

Flow Cytometry by Laser

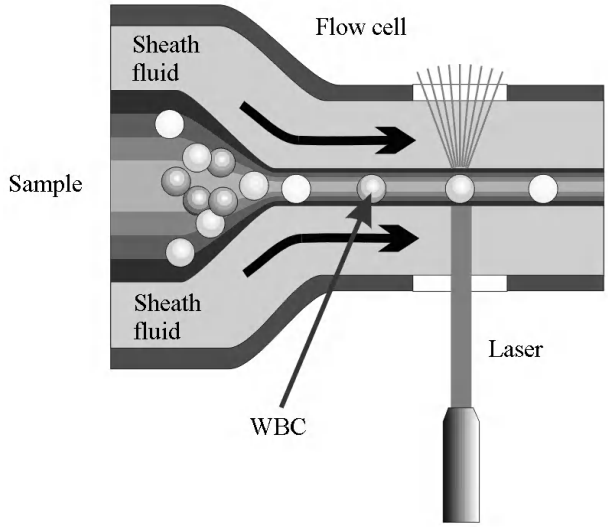


Figure 4-1 WBC Measurement

After a predetermined volume of blood is aspirated and diluted by a certain amount of reagent, it is injected into the flow cell. Surrounded with sheath fluid (diluent), the blood cells pass through the center of the flow cell in a single column at a faster speed. When the blood cells suspended in the diluent pass through the flow cell, they are exposed to a laser beam. The intensity of scatter light reflects the blood cell size and intracellular density. The low-angle scattered light reflects cell size, and the high-angle scattered light reflects intracellular density (nucleus size and density). The optical detector receives this scatter light and converts it into electrical pulses. Pulse data collected can be used to draw a 3-dimensional distribution (scattergram).

4.5. HGB Measurement

Colorimetric Method

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

HGB

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

HGB (g/L) = Constant x Log10 (Blank Photocurrent/Sample Photocurrent)

4.6. RBC/PLT Measurement

Electrical Impedance Method

RBCs/PLTs are counted and sized by the electrical impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. A pair of electrodes is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated represents the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

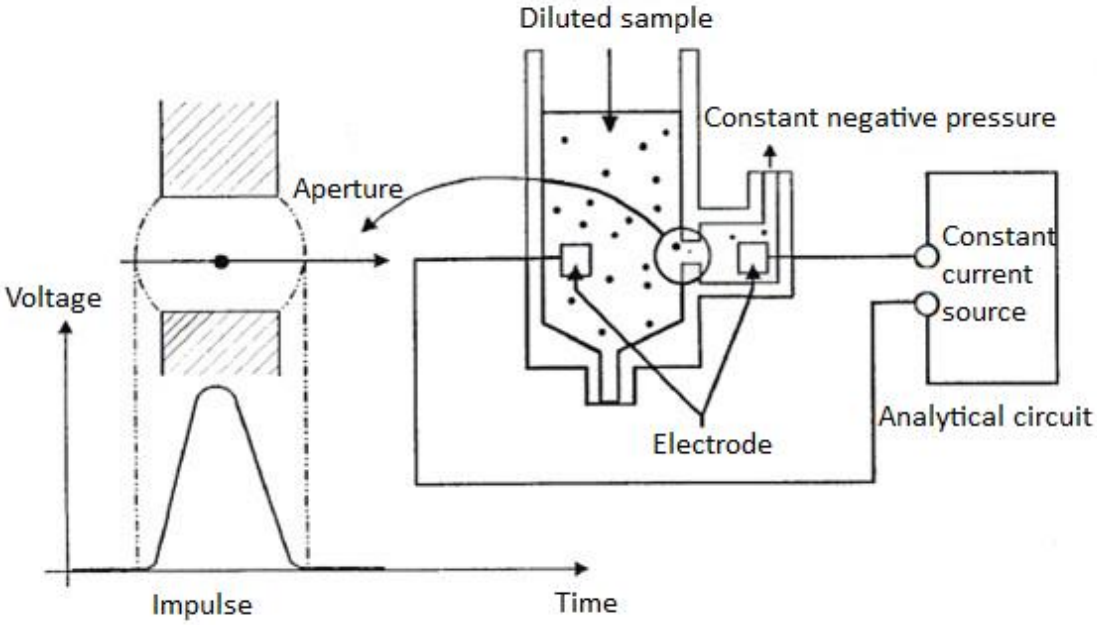


Figure 4-2 Electrical Impedance Method

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

Derivation of RBC-Related Parameters

- RBC

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

- MCV

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

- HCT, MCH, and MCHC

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

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

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

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

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

- RDW-CV

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

- RDW-SD

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

Derivation of PLT-Related Parameters

- PLT

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

- MPV

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

- PDW-CV

Platelet distribution width-Coefficient of Variation (PDW-CV) result is derived from the platelet histogram data and unit is %.

- PDW-SD

Platelet Distribution Width-Standard Deviation（PDW-SD）result is obtained by calculating the standard deviation of the platelet volume distribution and unit is fL.

- PCT

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

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

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

WARNING

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

⚠CAUTION

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

NOTE

- Use the reagents specified by the Genrui 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 Genrui-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 Genrui 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.

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

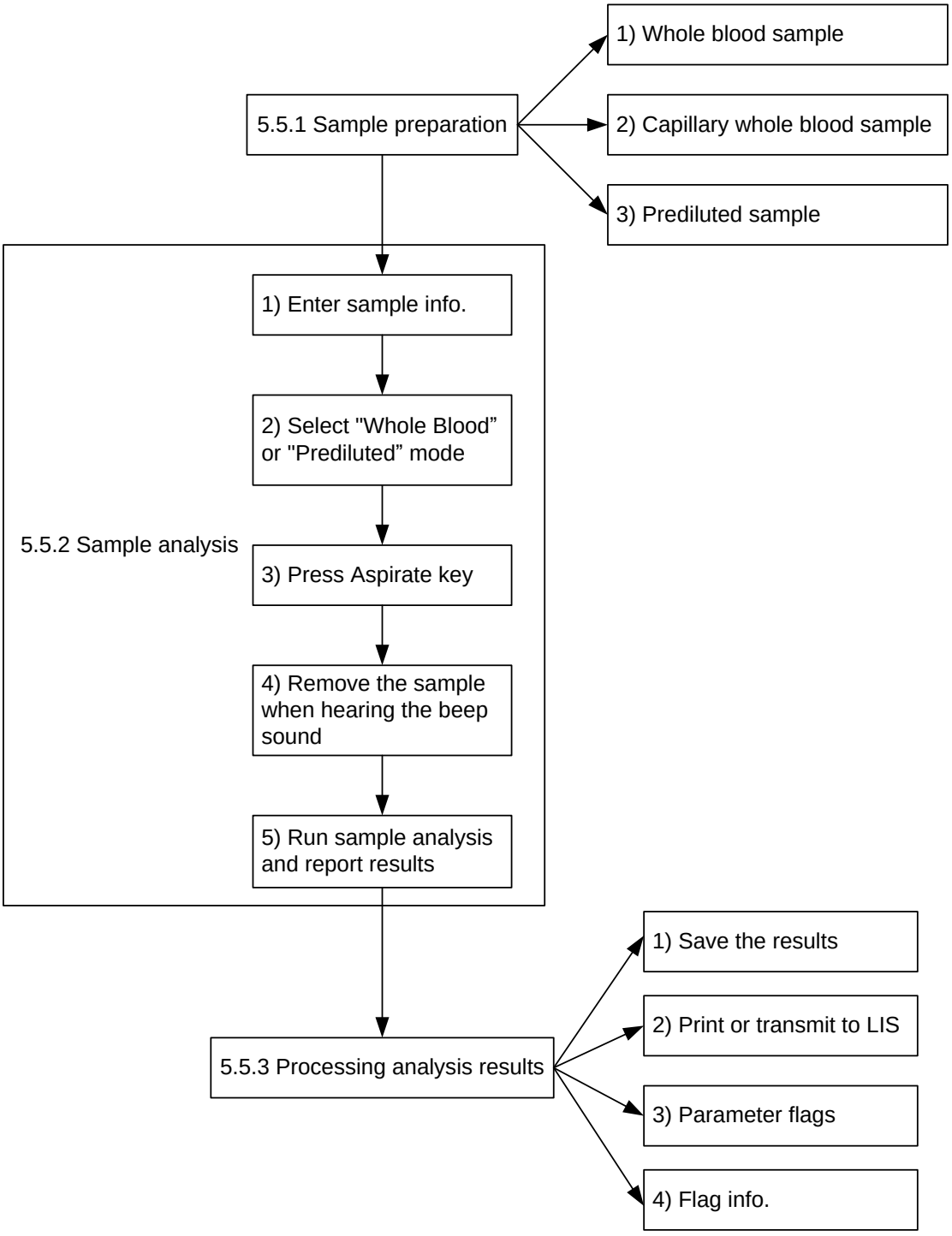
The sample probe is sharp and potentially biohazardous. Do not contact the sample probe during operations.

⚠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.

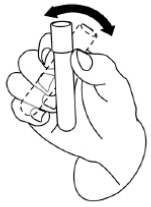


5.5.1. Sample Preparation

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

⚠CAUTION

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



1) Whole blood samples

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

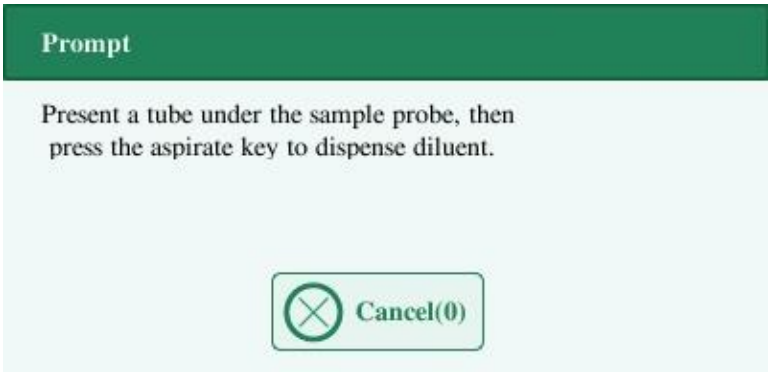
Be sure to collect at least 120μL of capillary whole blood to ensure the accuracy of the results.

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 (480μL). 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 480μL 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”, “Whole Blood-CBC”, “Capillary WB-CBC+DIFF”, “Capillary WB-CBC”, “Prediluted-CBC+DIFF” or “Prediluted-CBC” mode.

1) Entering sample information

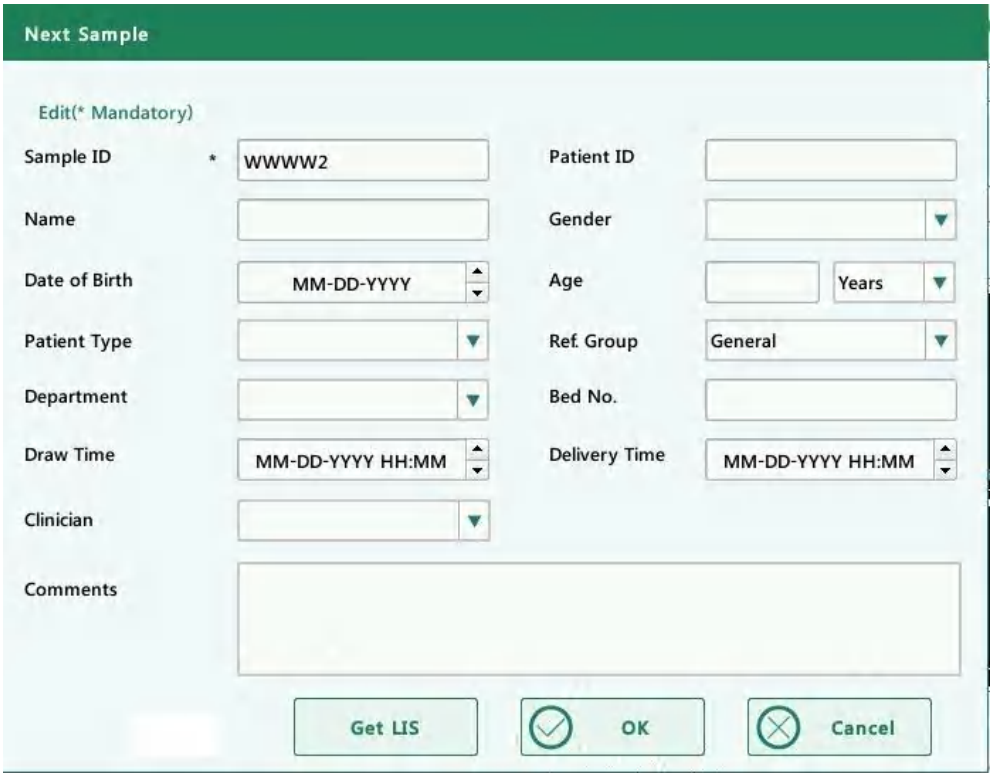
The analyzer provides two ways for you to enter sample information: entering sample ID only and entering all sample information.

If you want to enter sample information after analysis, you may skip this chapter, and enter sample information at the result review menu (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

Enter the type of patient in the "Patient Type" box, or 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) Get LIS

When the instrument is connected to the LIS, the "Get LIS" button is activated, and the operator can obtain the sample information in the LIS that is the same as the instrument sample number by clicking "Get LIS". (Note: When the communication protocol is selected as HL7 1.0, the LIS function is not obtained)

o) 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.

p) 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**

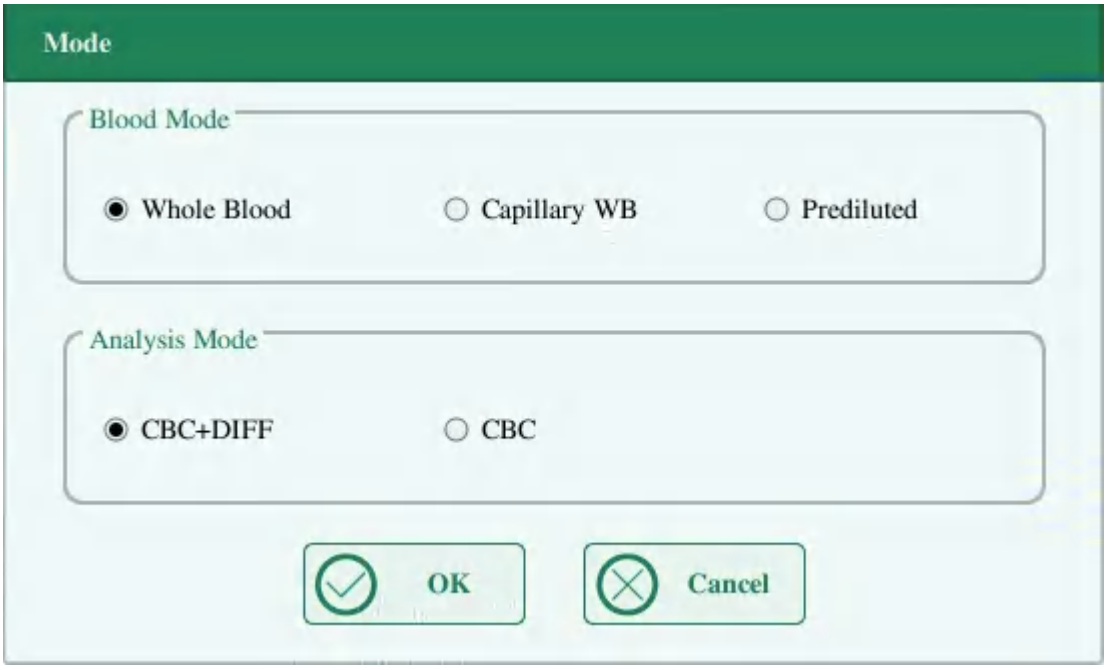
When the way to enter patient demographic information is set to “Enter sample ID only”, click “Next Sample” at the sample analysis screen, the following dialog box will display.

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 (CBC+DIFF or CBC), capillary whole blood (CBC+DIFF or CBC), or prediluted (CBC+DIFF or CBC) mode based on your needs on the mode selection screen. The selected mode will be displayed at the

bottom of the screen.



3) Aspirating sample

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

4) Removing the sample

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

5) Auto analysis and result reporting

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

NOTE

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

5.5.3. Processing Analysis Results

1) Saving analysis results automatically

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

2) Printing and Transmission to LIS

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

3) Parameter flags

See the following section for details about parameter flags.

- If the parameter is followed by a “H” or “L”, it means the analysis result has exceeded the upper or lower limit of the reference range (See section 9.2.3. 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).

Table 5-1 Display range

Parameter	Display Range
WBC, Bas#, Neu#, Eos#, Mon#, Lym#, *ALY#, *LIC#, *NRBC#, *PLT Clumps#	0.00～999.99×10^9/L
Bas%, Neu%, Eos%, Mon%, Lym%, *ALY%, *LIC%, *NRBC%, *PLT Clumps%	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-SD	0.0～99.9fL
PDW-CV	0.0~99.9%
MPV	0.0～99.9fL
PCT	0.0～0.999%

Parameter	Display Range
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.

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

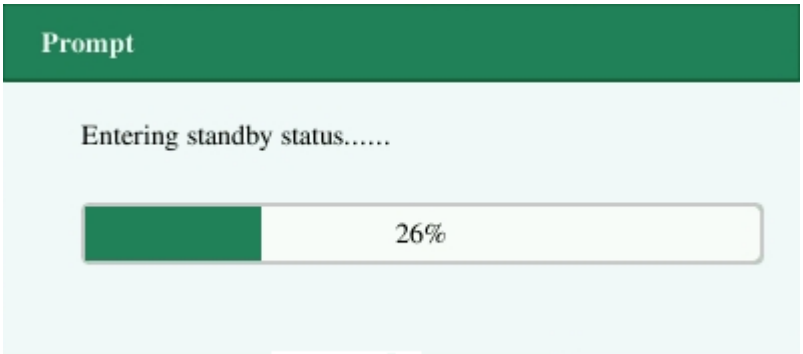
Flag Type	Flag	Meaning	Judgment criterion
WBC Flag	WBC Abnormal	Interference of PLT clump or NRBC to WBC count and differential may exist	The DIFF and BASO channels are unproportionate
	WBC scattergram abn.	Unclear boundary between particles of WBC scattergram	The number of particles at the boundary exceeds a certain range
	Immature Cell?	Immature cells or blasts may exist	Many scatter-points in the immature cell area of the scattergram
	Abn./Atypical Lympho?	Abnormal lymphocytes or atypical lymphocytes may exist	Many scatter-points in the abnormal/ atypical lymphocytes area of the scattergram
	WBC decrease	Low WBC analysis results	WBC < 2.50×10^9/L
	WBC increase	High WBC analysis results	WBC > 18.00×10^9/L
	Neu decrease	Low neutrophils analysis results	Neu# < 1.00×10^9/L
	Neu increase	High neutrophils analysis results	Neu# > 11.00×10^9/L
	Lym decrease	Low lymphocytes analysis results	Lym# < 0.80×10^9/L
	Lym increase	High lymphocytes analysis results	Lym# > 4.00×10^9/L
	Mon increase	High lymphocytes analysis results	MON# > 1.50×10^9/L

Flag Type	Flag	Meaning	Judgment criterion
	Eos increase	High eosinophils analysis results	EOS# > 0.70×10^9/L
	Bas increase	High basophils analysis results	BAS# > 0.20×10^9/L
	Pancytopenia	WBC, RBC and PLT low	WBC < 4.0×10^9/L RBC < 3.5×10^{12}/L PLT < 100×10^9/L
RBC Flag	RBC distribute abnormally	Possible presence of microcytes, macrocytes, anisocytosis, RBC agglutination and dimorphic histogram	The distribution of RBC histogram is abnormal
	RBC agglutination?	RBC agglutination	The ratio of agglutinated RBC 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
	Iron-deficiency?	Iron deficiency anemia	Comprehensive judgment of RDW-CV, MCV and MCHC
	Hypochromic	Hypochromic	MCHC<290
	Microcytosis	MCV low	MCV < 70fL
	Macrocytosis	MCV high	MCV > 110fL
	Anemia	Anemia	HGB < 90g/L
	RBC increase	RBC high	RBC > 6.5×10^{12}/L
PLT Flag	PLT distribute abnormally.	Possible presence of microcytes, red blood cell debris, giant PLT or PLT	The distribution of PLT scattergram is abnormal

Flag Type	Flag	Meaning	Judgment criterion
		clump	
	PLT agglutination?	PLT agglutination	Three indicators of PLT, MPV and PLT histograms comprehensively judge the degree of agglutination
	PLT decrease	PLT low	PLT < 60×10^9/L
	PLT increase	PLT high	PLT > 600×10^9/L

5.6. Standby

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



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

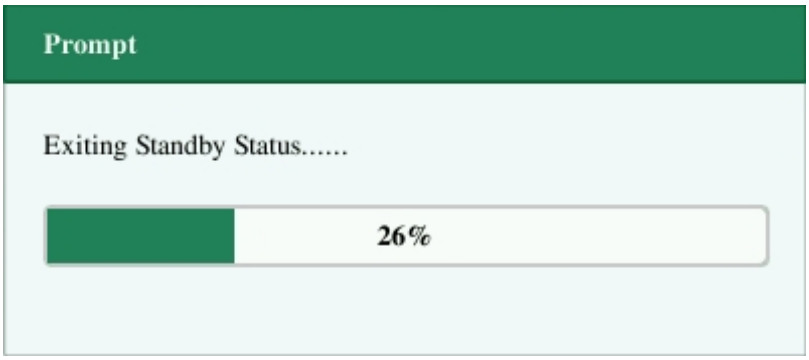
NOTE

- 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 green. And the analyzer indicator will also turn into solid green.

5.7. Shutdown

⚠CAUTION

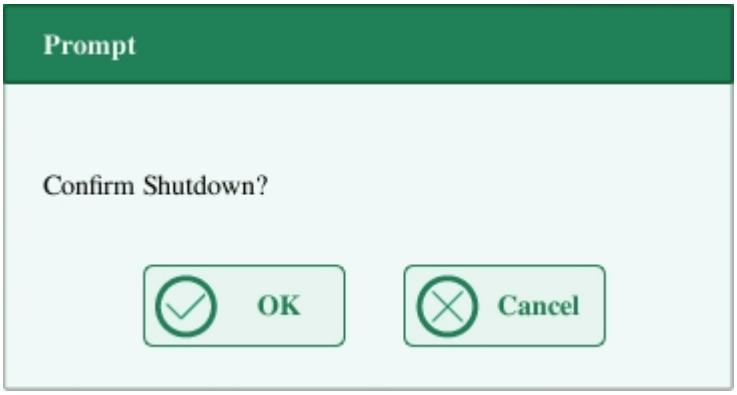
Do not start up the analyzer immediately after it is shut down. Wait for at least 10 seconds.

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, scattergrams 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.

No.	Sample ID	Status	WBC	Neu#	Lym#	Mon#	Eos#	Bas#
39	WWWW1		L 1.50	L 0.11	L 0.14	L 0.08	H 1.13	0.04
38	WWWW4	Printed	L 1.54	L 0.72	L 0.05	L 0.04	H 0.69	0.04
37	WWWW3	Printed	L 1.45	L 0.16	L 0.33	L 0.05	H 0.88	0.03
36	WWWW2		R7.87	R4.72	R1.57	R1.18	R0.24	R0.16
35	WWWW1	Printed	L 1.44	L 0.10	L 0.23	L 0.02	H 1.06	0.03
34	...WWWW4		R8.27	R4.96	R1.65	R1.24	R0.25	R0.17
33*	...WWWW3		R7.97	R4.78	R1.59	R1.20	R0.24	R0.16
32	...WWWW2		R7.75	R4.65	R1.55	R1.16	R0.23	R0.15
31	...WWWW1		R8.06	R4.84	R1.61	R1.21	R0.24	R0.16
30	...WWWW9		R8.65	R5.19	R1.73	R1.30	R0.26	R0.17
29	...WWWW8		R7.44	R4.46	R1.49	R1.12	R0.22	R0.15
28	...WWWW7		R8.55	R5.13	R1.71	R1.28	R0.26	R0.17

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”.

No.	Sample ID	Status	WBC	Neu#	Lym#	Mon#	Eos#	Bas#
39	WWWW1		L 1.50	L 0.11	L 0.14	L 0.08	H 1.13	0.04
38	WWWW4	Printed	L 1.54	L 0.72	L 0.05	L 0.04	H 0.69	0.04
37	WWWW3	Printed	L 1.45	L 0.16	L 0.33	L 0.05	H 0.88	0.03
36	WWWW2		R7.87	R4.72	R1.57	R1.18	R0.24	R0.16
35	WWWW1	Printed	L 1.44	L 0.10	L 0.23	L 0.02	H 1.06	0.03
34	...WWWW4	Validated	R8.27	R4.96	R1.65	R1.24	R0.25	R0.17
33*	...WWWW3	Validated	R7.97	R4.78	R1.59	R1.20	R0.24	R0.16
32	...WWWW2		R7.75	R4.65	R1.55	R1.16	R0.23	R0.15
31	...WWWW1		R8.06	R4.84	R1.61	R1.21	R0.24	R0.16
30	...WWWW9		R8.65	R5.19	R1.73	R1.30	R0.26	R0.17
29	...WWWW8		R7.44	R4.46	R1.49	R1.12	R0.22	R0.15
28	...WWWW7		R8.55	R5.13	R1.71	R1.28	R0.26	R0.17

- Cancel Validation

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

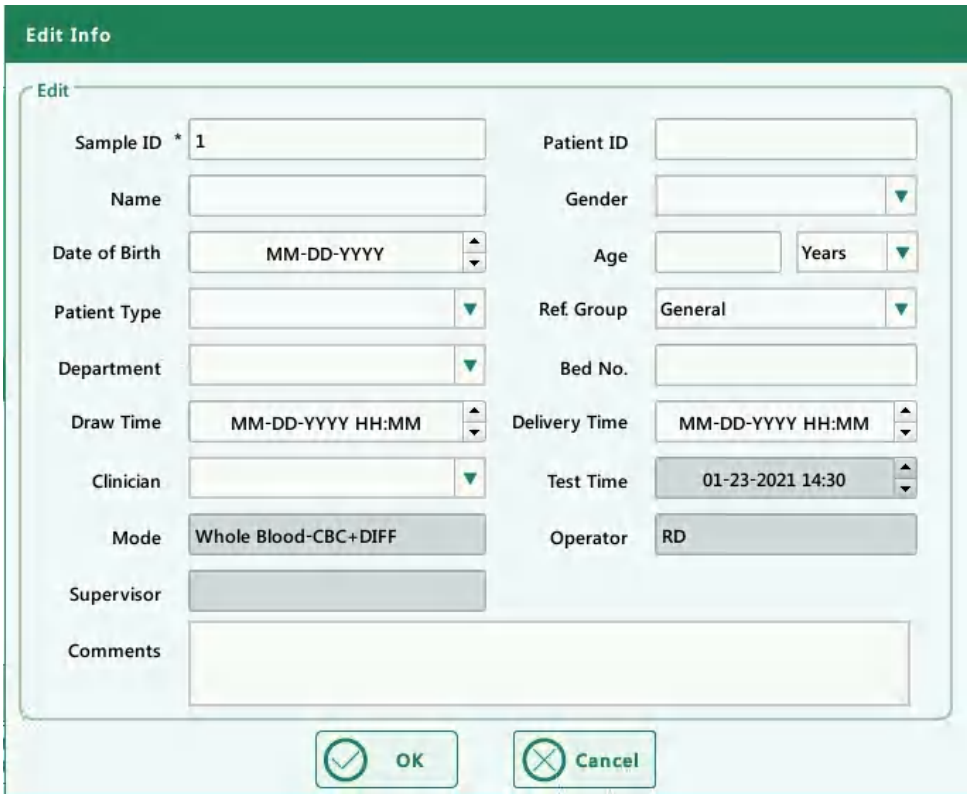
6.2.4. Delete (for administrators only)

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

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.

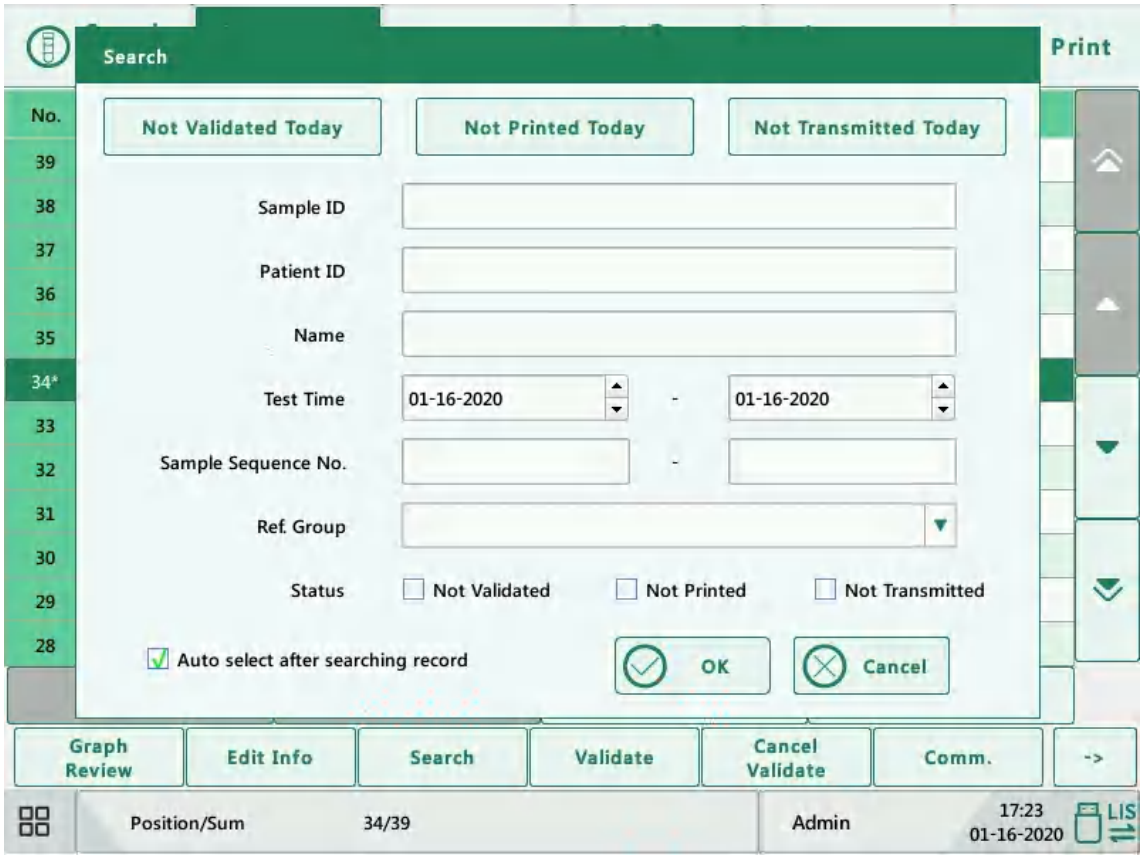
6.2.6. Edit Results

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

Modify the results and click “OK” to save the changes. The information on the graph review menu will be refreshed.

6.2.7. 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.

6.2.8. 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.

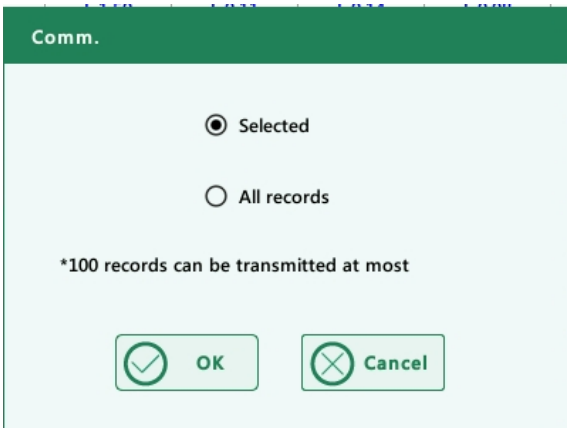
NOTE

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

6.2.9. Transmission

- Transmit selected data

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



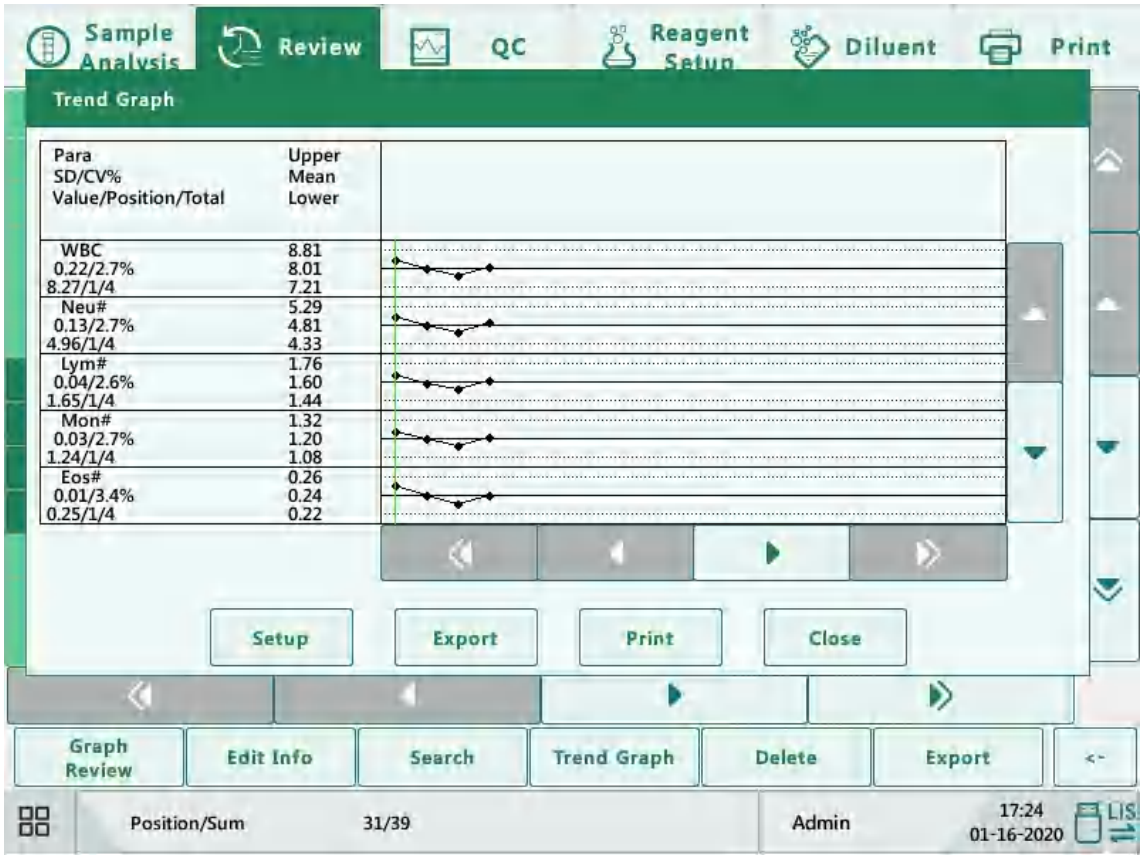
3. Click the “Selected” radio button.
4. Click “OK” to start transmitting specified results to the data management software.

- 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.

6.2.10. Trend Graph

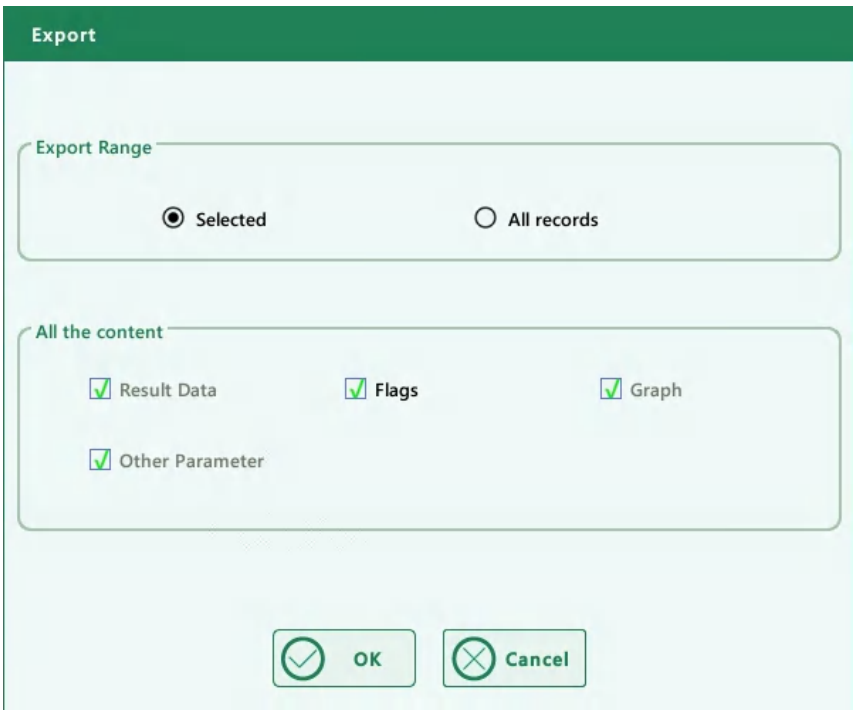
1. Click the "Trend Graph", the following dialog box will display.



2. Click the "Setup" button to set the deviation limit of each parameter;
3. Click the "Export" button to export the result data, alarm flags and trend graph data.
4. Click the "Print" button to print the trend graph, which is only supported by the printer and displayed in gray when connected to the recorder;
5. Click the "Close" button to close the trend graph dialog box and return to the list review interface.

6.2.11. 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. Genrui recommends you run the QC program daily with normal level controls.

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

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

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

⚠WARNING

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

⚠CAUTION

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

NOTE

- Use the controls and reagents specified by Genrui 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 Genrui-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”.
2. 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.

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

- 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

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

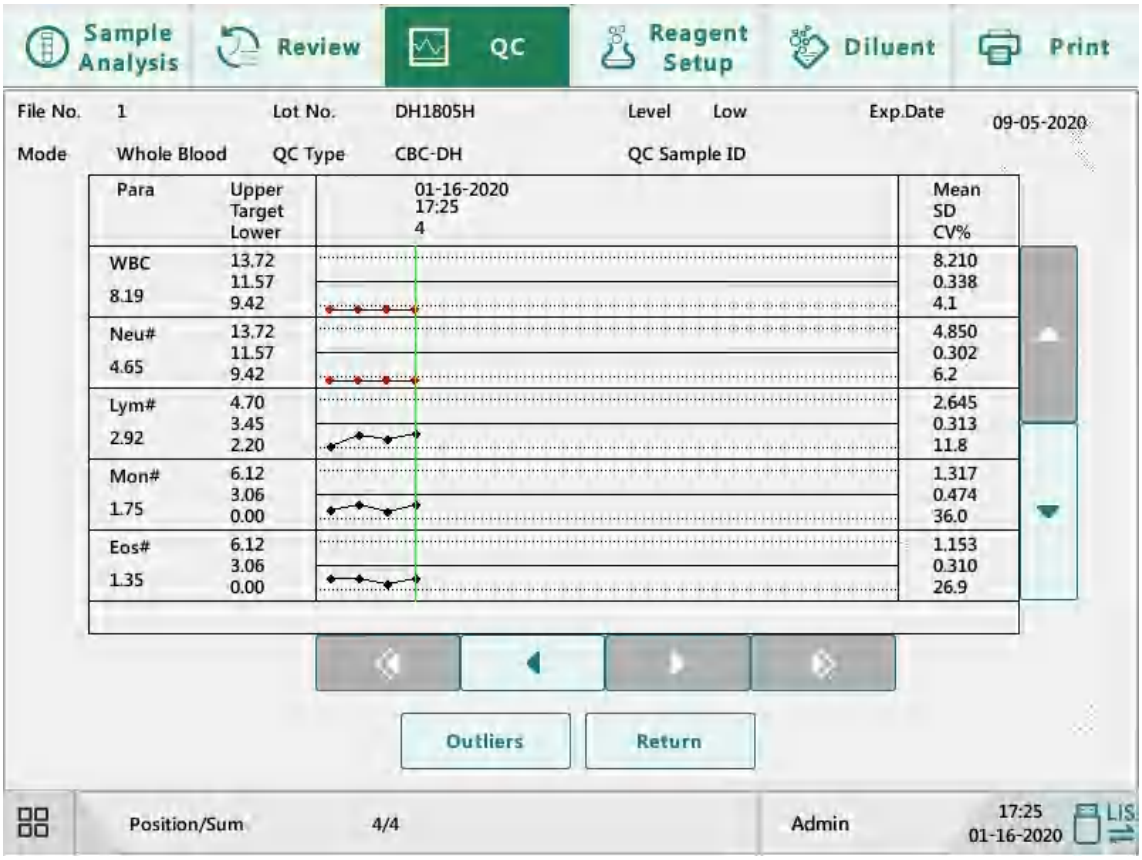
After QC analysis, you can review the QC results in the following ways:

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.



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

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.

	Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Bas#
Target	/	/	11.57	11.57	3.45	3.06	3.06	0.83
Limit(#)	/	/	2.15	2.15	1.25	3.06	3.06	0.83
4*	01-16-2020	17:25	L 8.19	L 4.65	2.92	1.75	1.35	0.36
3	01-16-2020	17:25	L 8.67	L 4.95	2.58	0.78	0.69	1.16
2	01-16-2020	17:25	L 8.12	L 4.57	2.85	1.68	1.27	0.92
1	01-16-2020	17:25	L 7.86	L 5.23	2.23	1.06	1.30	0.94

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

NOTE

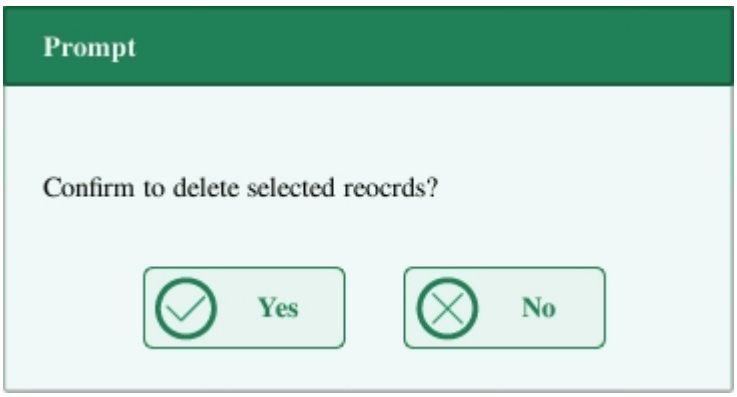
If parameter targets/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters change accordingly, those changed data will be highlighted in yellow.

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.

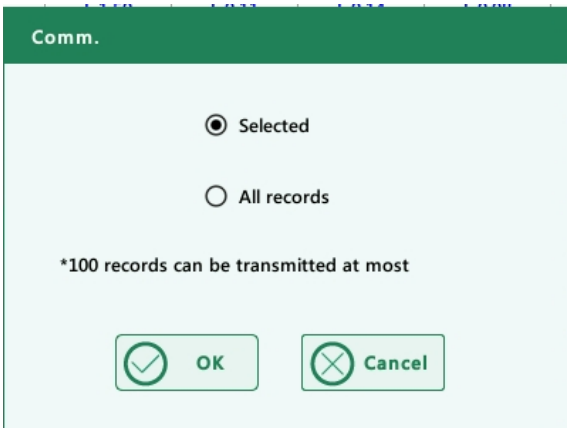
NOTE

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.

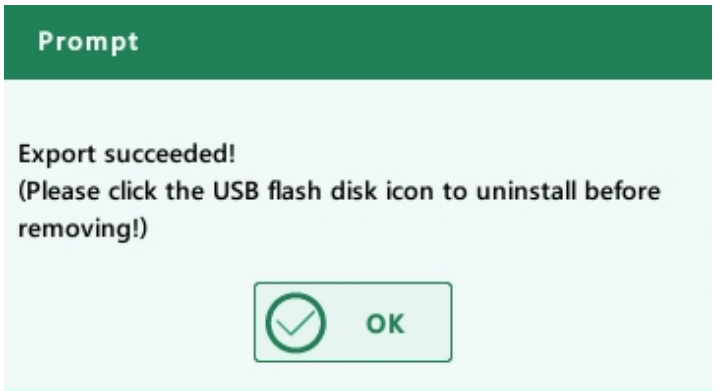
NOTE

- 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! (Please click the USB flash icon to uninstall before removing!)” 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.

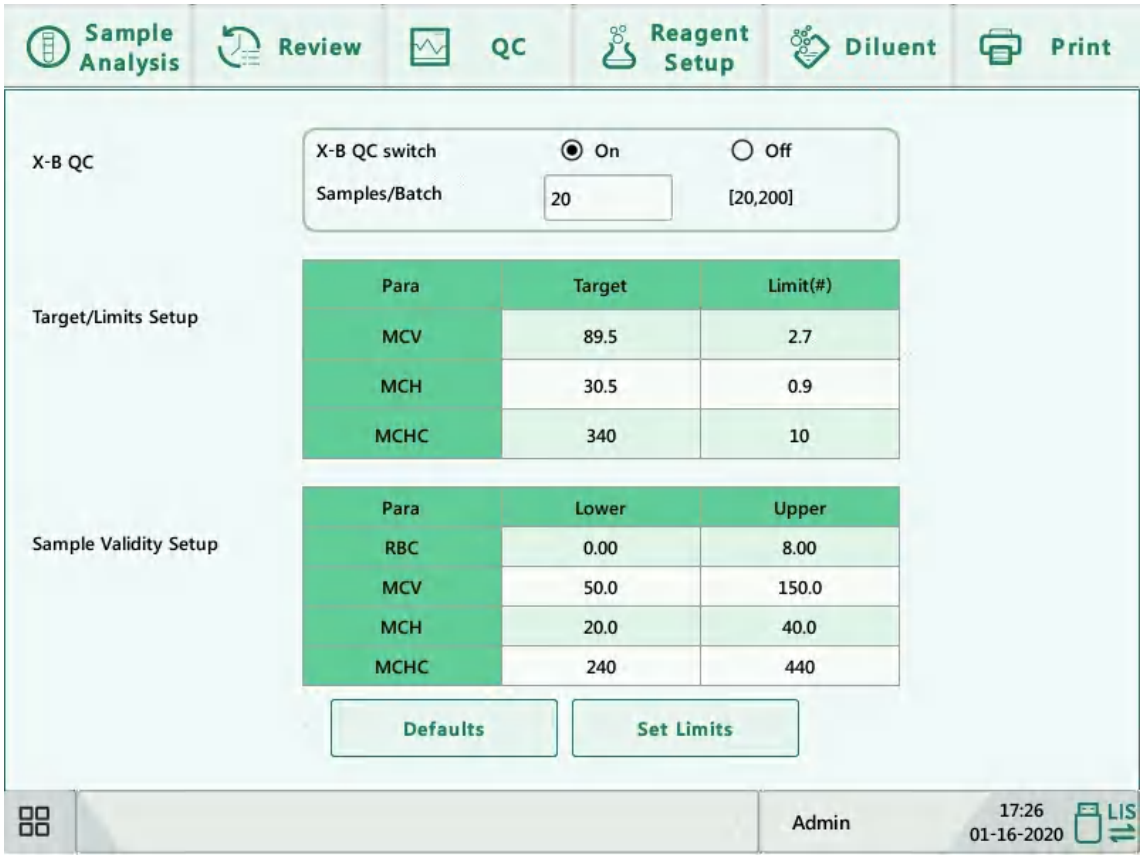
It is recommended the X-B analysis be activated when the sample volume of your laboratory is greater than 100 samples per day. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices. It observes the trend of QC results in the reference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

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

NOTE

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

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

Setting sample validity

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

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.

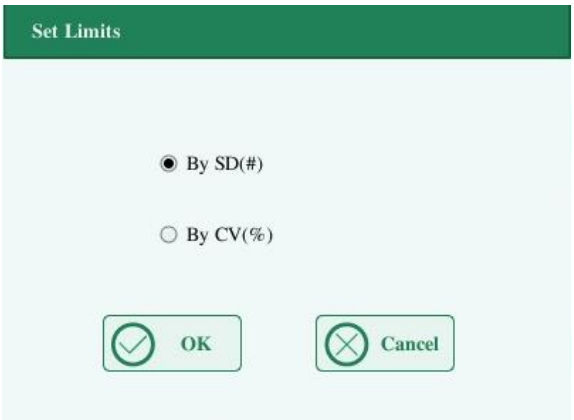
NOTE

- 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 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

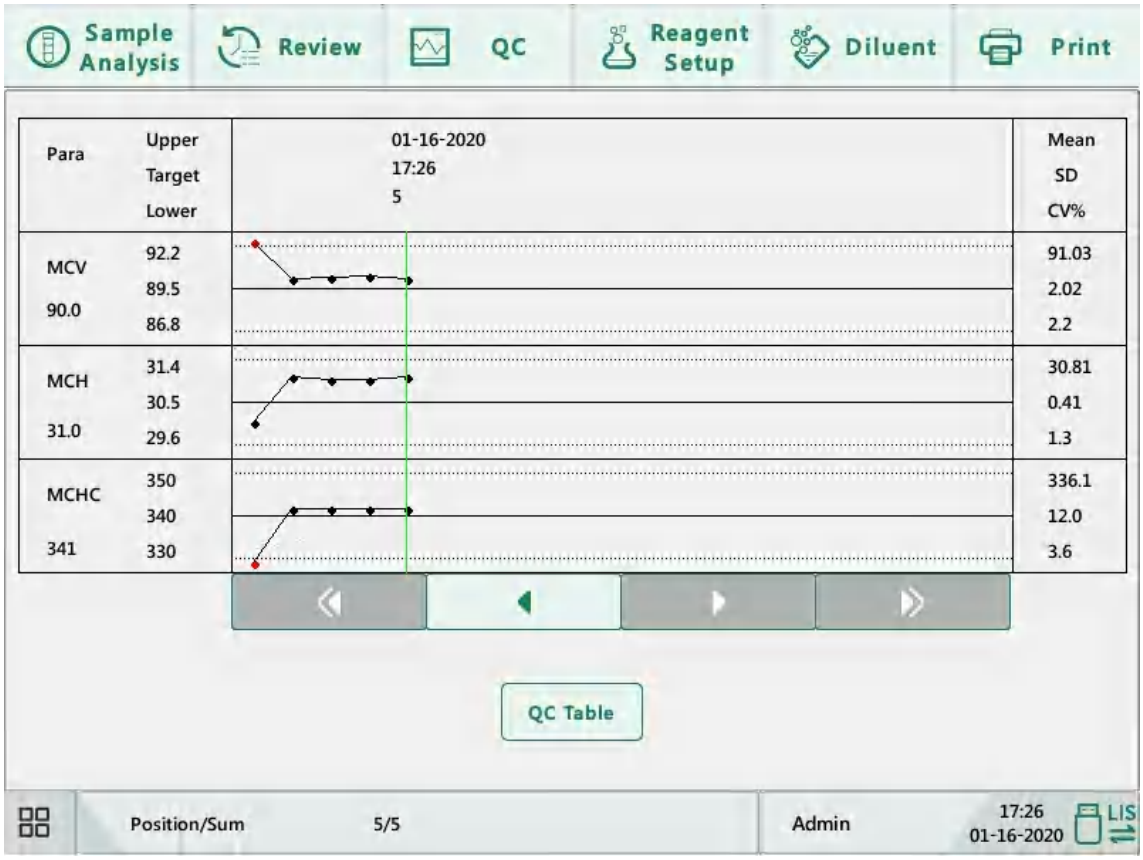
After QC analysis, you can review the QC results in the following ways:

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.

	Date	Time	MCV	MCH	MCHC
Target	/	/	89.5	30.5	340
Limit(#)	/	/	2.7	0.9	10
5*	01-16-2020	17:26	90.0	31.0	341
4	01-16-2020	17:26	90.2	31.0	341
3	01-16-2020	17:26	90.1	31.0	341
2	01-16-2020	17:26	90.1	31.0	342
1	01-16-2020	17:26	H 94.6	30.1	L 315

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

NOTE

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

8.3. How to Calibrate

8.3.1. 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 Genrui 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 -CBC+DIFF 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)
WBC	4.0×10^{9}/L～15.0×10^{9}/L	≤ 2.0%
RBC	3.50×10^{12}/L～6.00×10^{12}/L	≤ 2.0%
HGB	110g/L～180g/L	≤ 1.5%
MCV	70fL～120fL	≤ 1.0%
PLT	100×10^{9}/L～149×10^{9}/L	≤ 5.0%
	150×10^{9}/L～500×10^{9}/L	≤ 4.0%

Parameter	Range	Prediluted Reproducibility (CV)
WBC	4.0×10^{9}/L～10.0×10^{9}/L	≤ 4.0%
RBC	3.50×10^{12}/L～5.50×10^{12}/L	≤ 2.0%
HGB	110g/L～160g/L	≤ 2.0%
MCV	80fL～100fL	≤ 3.0%
PLT	100×10^{9}/L～300×10^{9}/L	≤ 8.0%

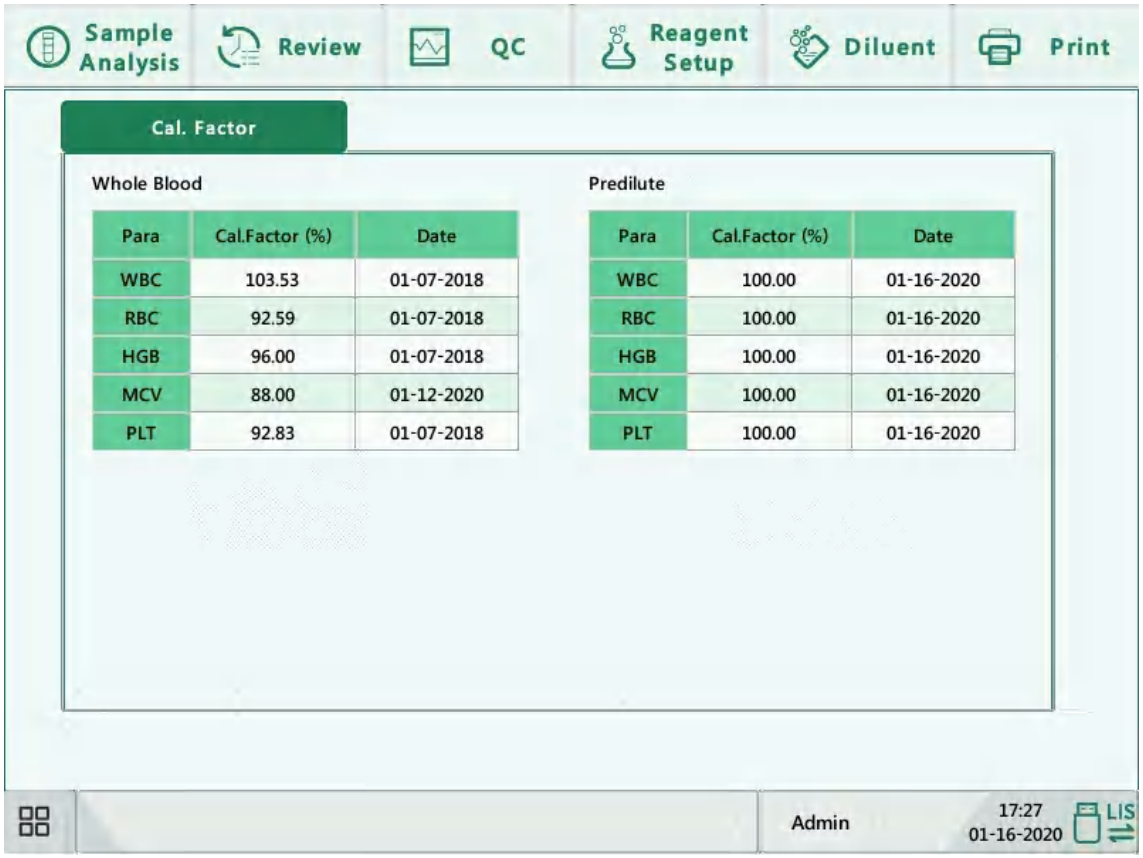
4. It is recommended that you create a log table for your analyzer. This log table should contain all necessary information that is pertinent to your analyzer. Suggested items that you may want to include in the log table are: calibration date, supplier of calibrator, lot number, expected results and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

NOTE

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

8.3.2. Manual Calibration

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



Whole Blood		
Para	Cal.Factor (%)	Date
WBC	103.53	01-07-2018
RBC	92.59	01-07-2018
HGB	96.00	01-07-2018
MCV	88.00	01-12-2020
PLT	92.83	01-07-2018

Predilute		
Para	Cal.Factor (%)	Date
WBC	100.00	01-16-2020
RBC	100.00	01-16-2020
HGB	100.00	01-16-2020
MCV	100.00	01-16-2020
PLT	100.00	01-16-2020

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.

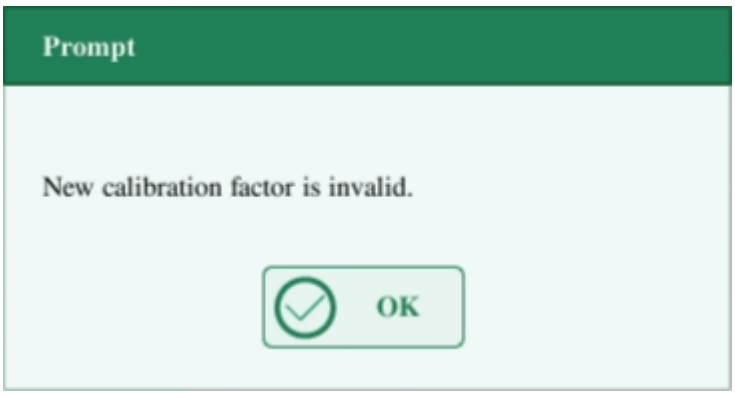
If the entered calibration factors are invalid, a dialog box will pop up prompting “Invalid entry” when you are switching to another screen. The new calibration factor will not be saved, and the calibration date will not be refreshed.

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.

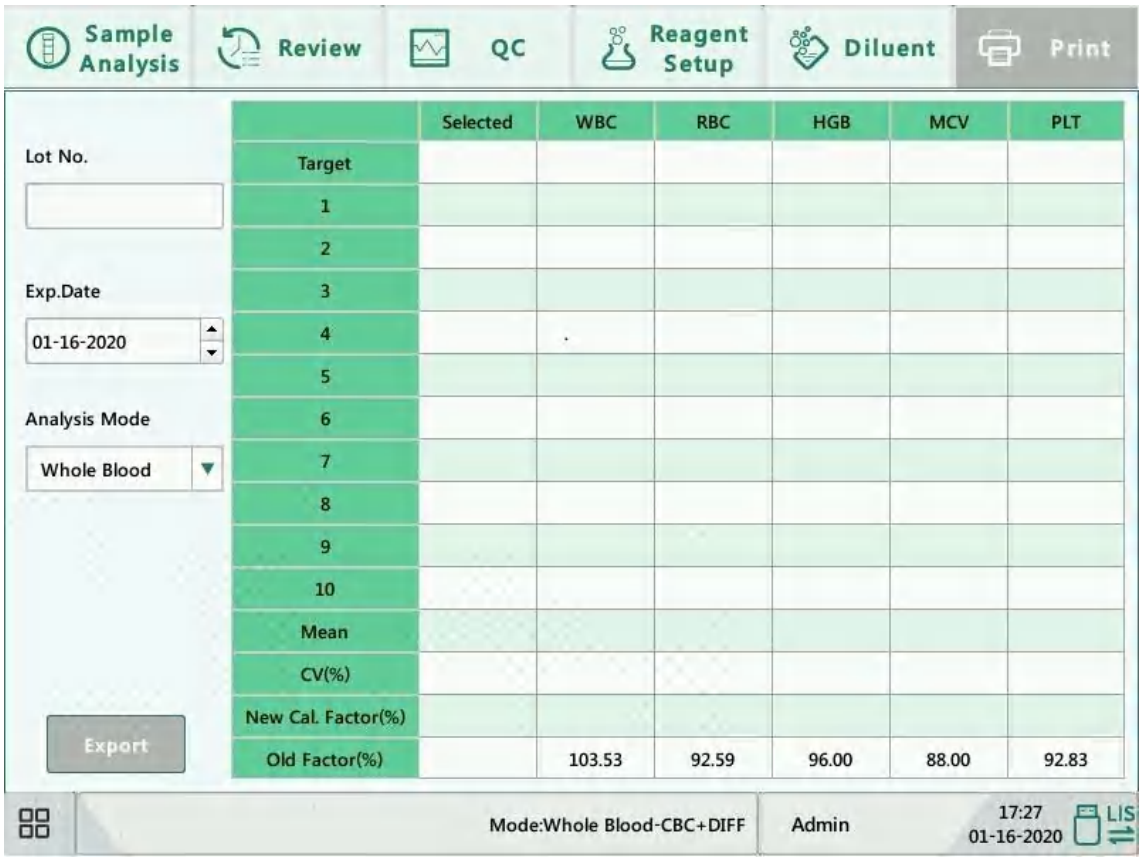


If the calibration factors are valid but not saved, a dialog box will display asking you to save

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 Genrui-specified calibrators shall be used. Genrui 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.

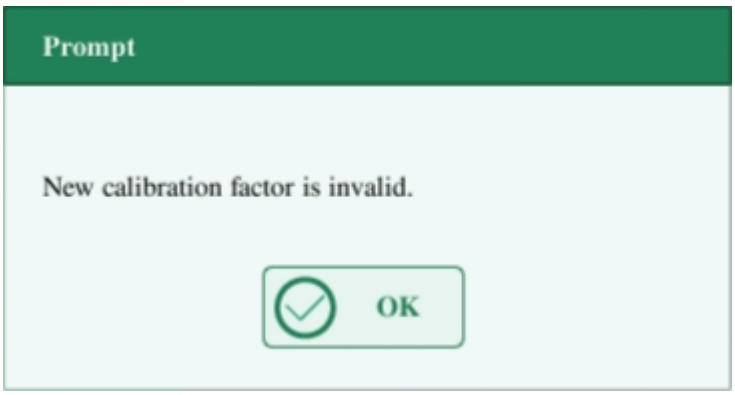
Do as follows to calibrate the analyzer with calibrators.

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.

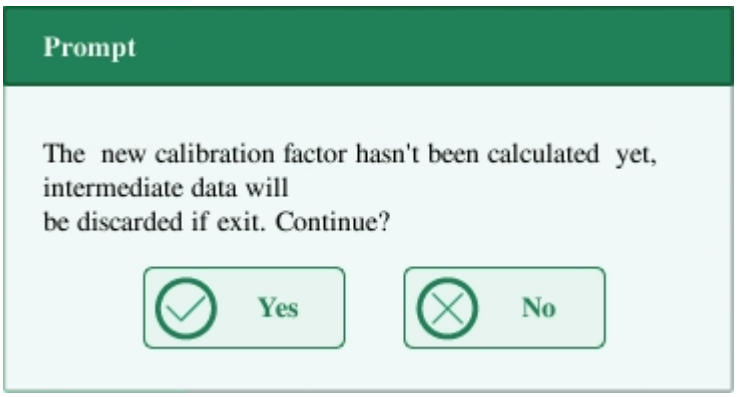
Click “OK” to close the message box, and the data will be deleted from the table without saving automatically.

- 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.

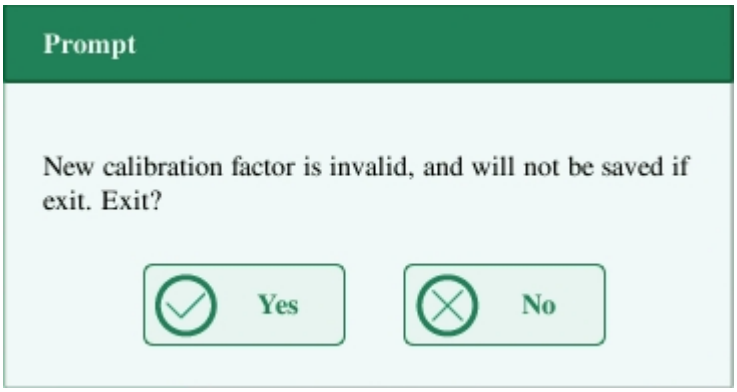
9. When calibration count has been performed to a sample for n times (n≥5), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with “√” (calibration data of the first run is not marked with “√”, so it is not included in the calculation).

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.

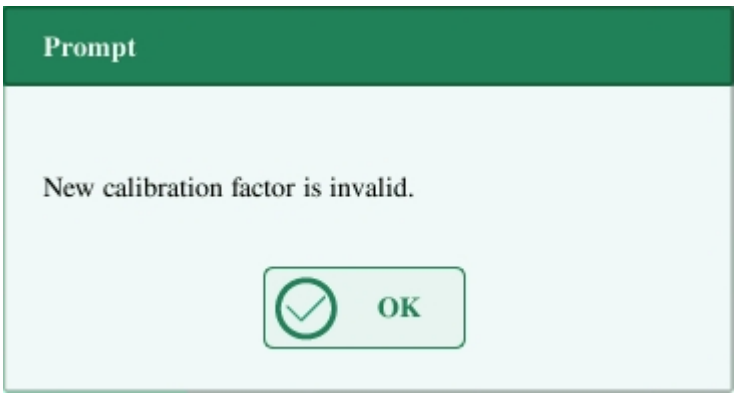
Do as follows to calibrate the analyzer with fresh blood.

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.

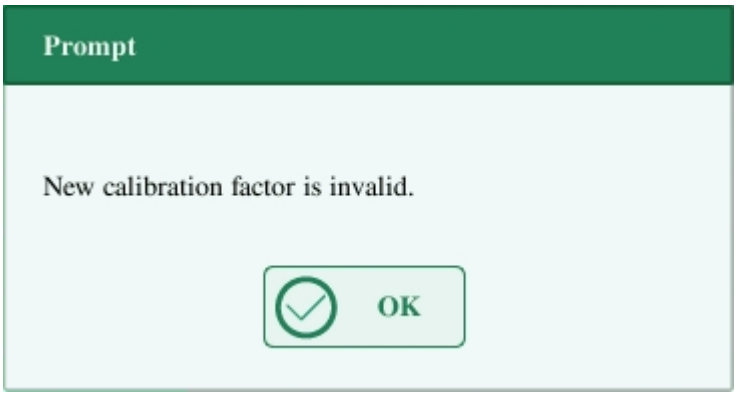
3. Select mode for fresh blood calibration, which can be Whole Blood or Prediluted.
4. Select the ID of current sample from the pull-down box “Current Sample ID”.
5. Enter the targets into the “Target” cells.
6. Prepare fresh blood sample.
7. Press the aspirate key to start calibration.
8. After the 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.

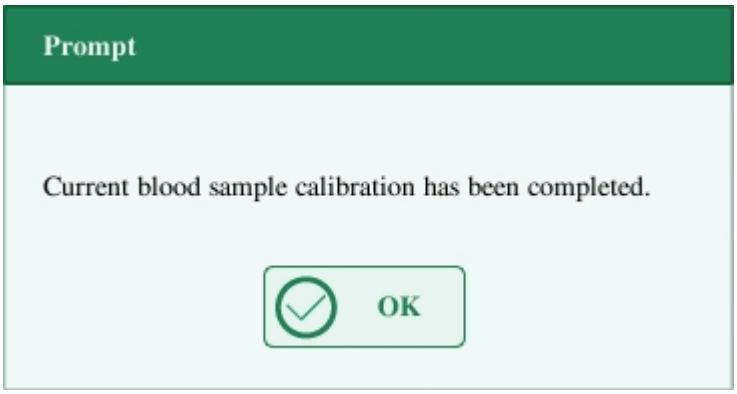
- The valid results within the linearity range will be displayed directly.

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

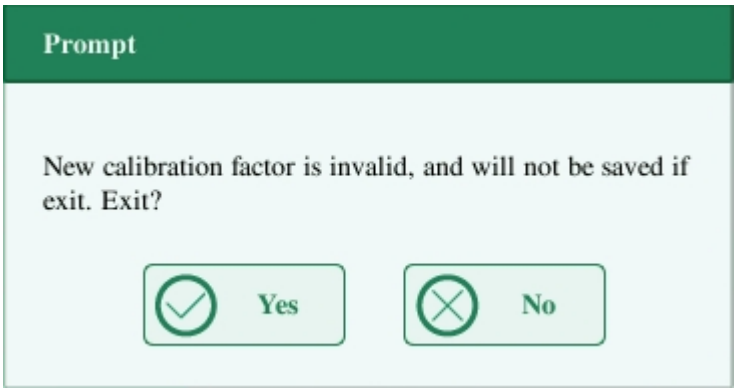
When the amount of valid calibration data in the list reaches 10, a message box will pop up when you start calibration again.



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.

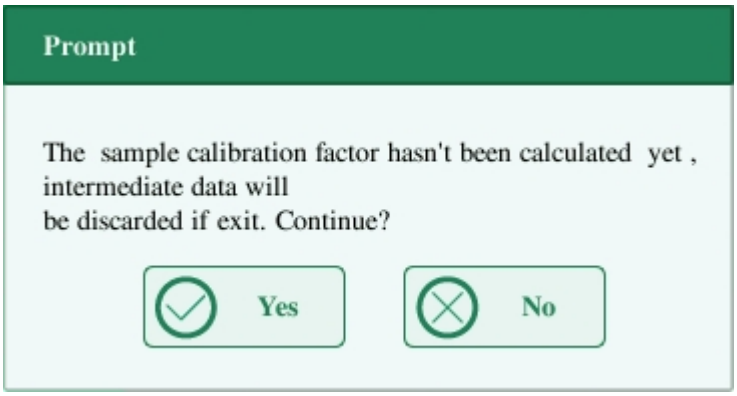
11. There may be several cases when switching to another blood sample:

- 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	WBC	RBC	HGB	MCV	PLT
New Factor(%)						
Cal. Factor 2(%)						
Cal. Factor 3(%)						
Cal. Factor 4(%)						
Cal. Factor 5(%)						
Mean Cal. Factor(%)						
Old Factor(%)		100.00	100.00	100.00	100.00	100.00

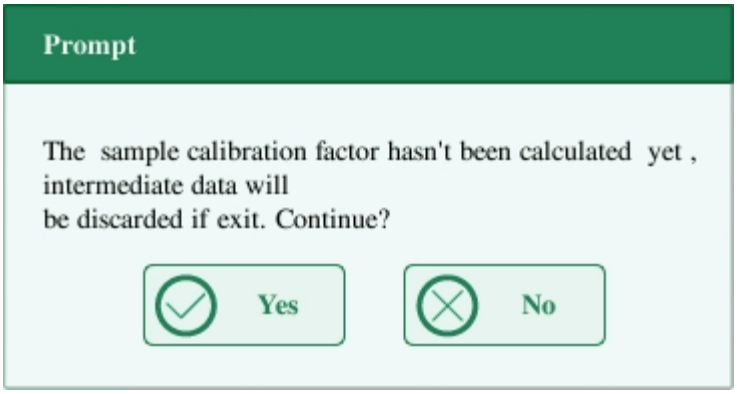
Select or deselect the calibration factors of a blood sample for the calculation of the mean calibration factors by clicking the check boxes before the calibration factors.

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

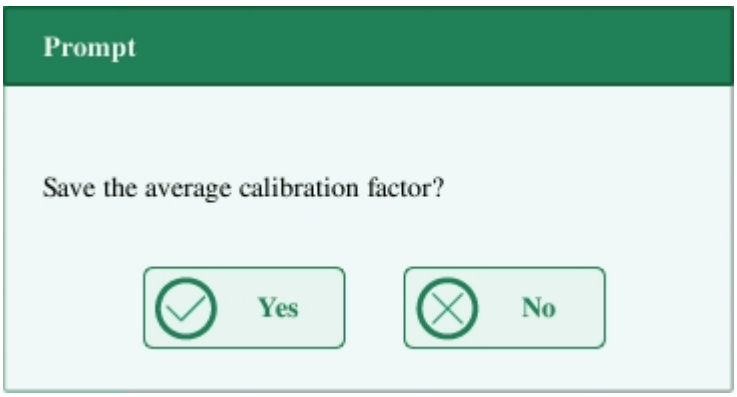
factors are regarded as invalid if the deviation of absolute value between the calibration factors included in calculating the mean and the original calibration factors reaches or exceeds 5%.

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.

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



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

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.

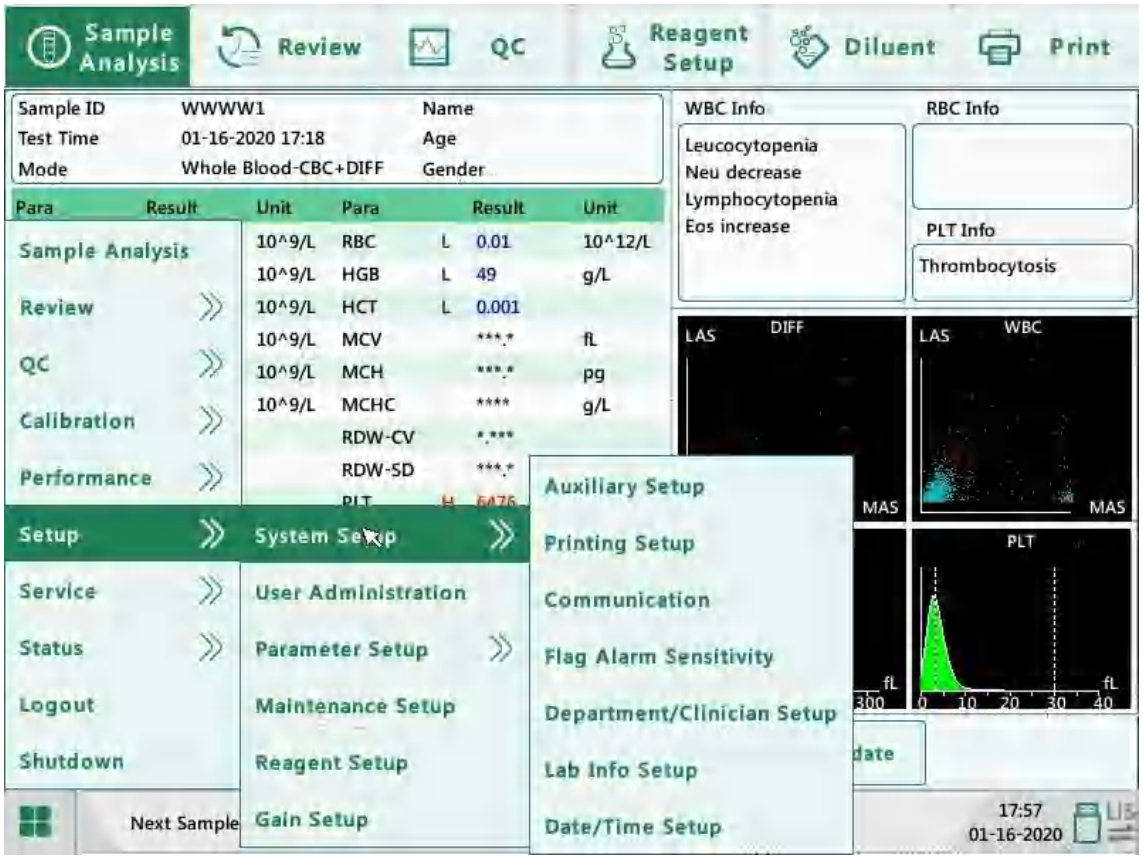
9. Settings

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.



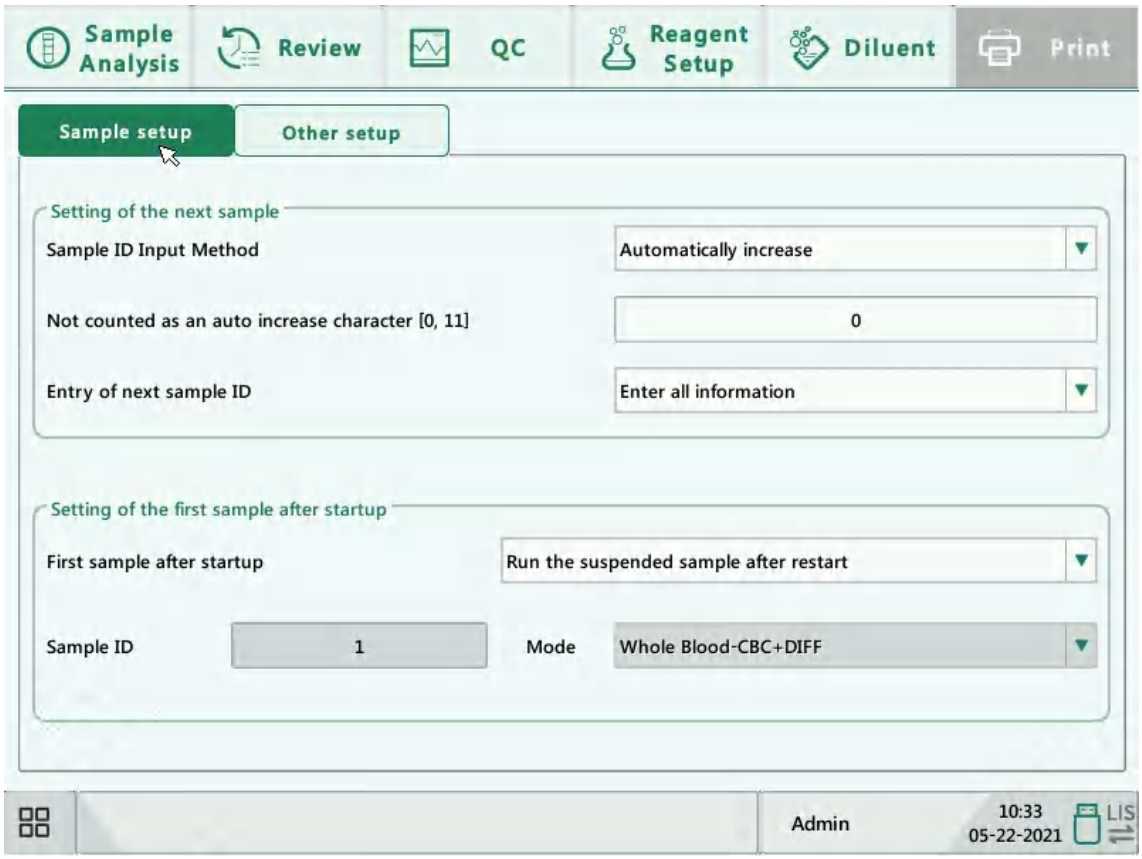
9.2. Setting Up the Analyzer

9.2.1. System Setup

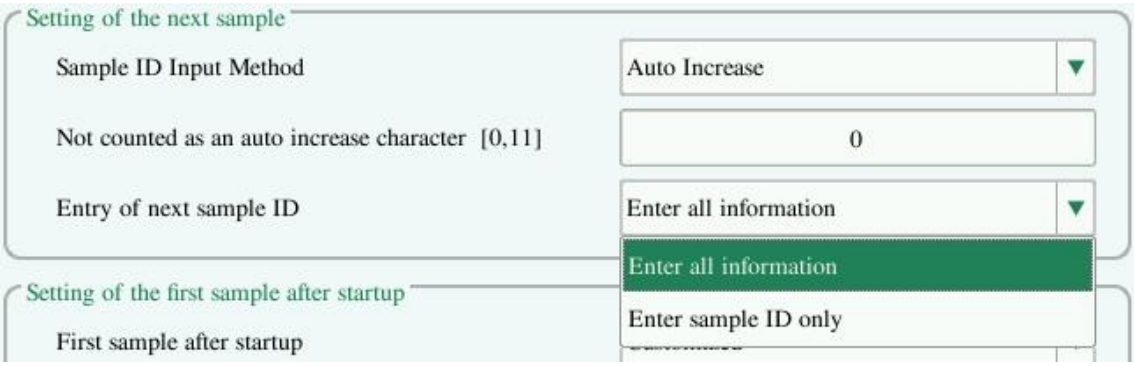
- **Auxiliary Setup**

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

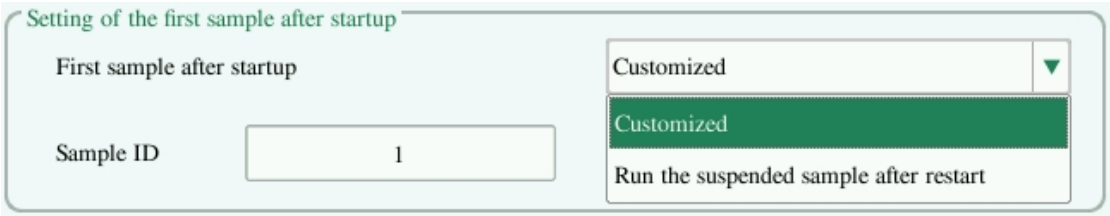
2) Not counted as an auto increase character

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.

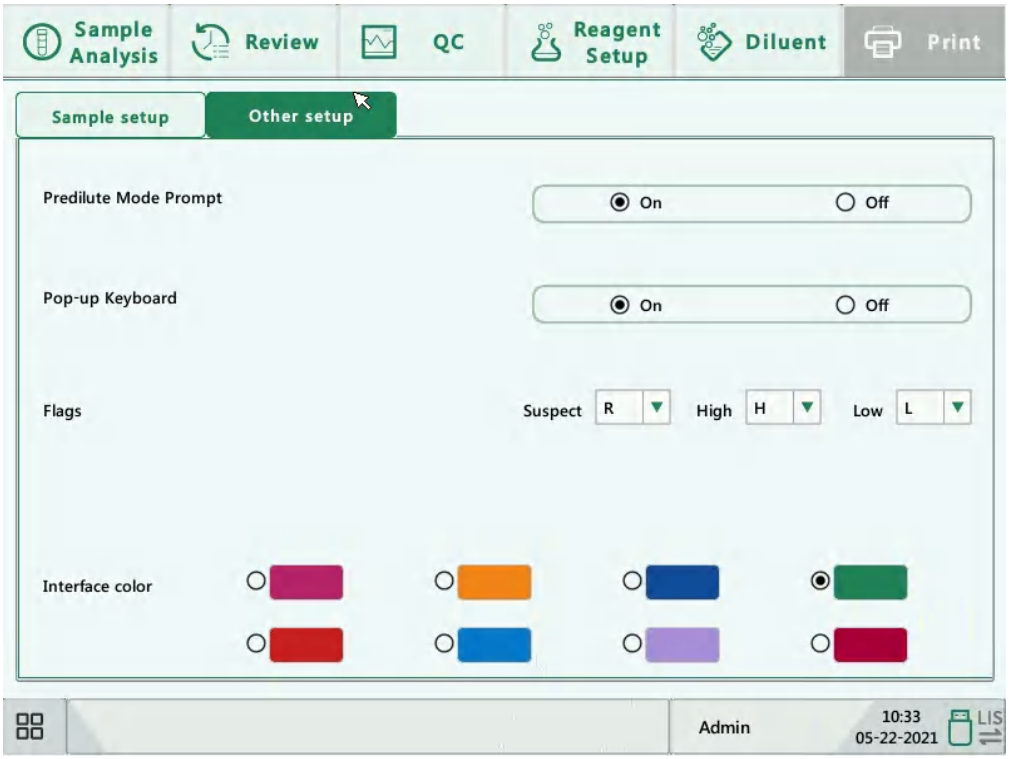
Enter a number n into the edit box. The first n characters in the sample ID will not be auto increased.

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”).

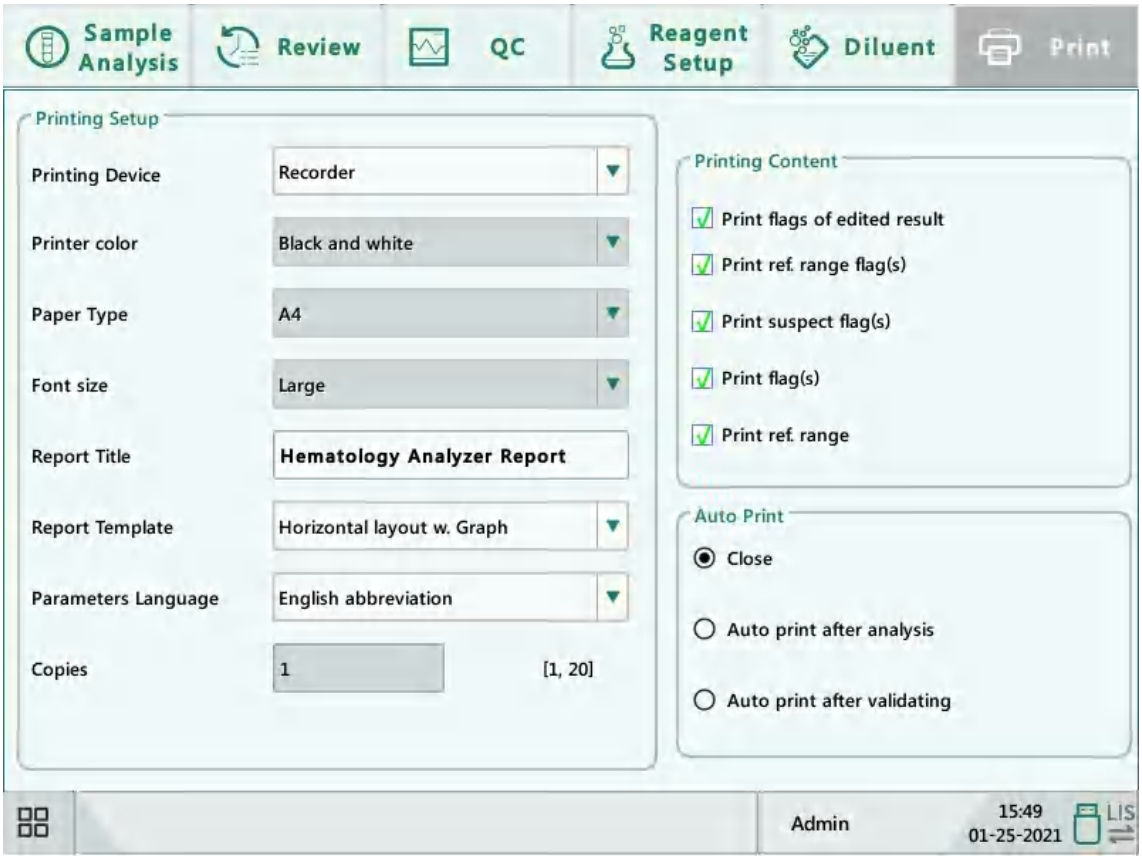
3) Interface color

Different interface colors can be selected and will take effect immediately after saving.

- **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

Print Device

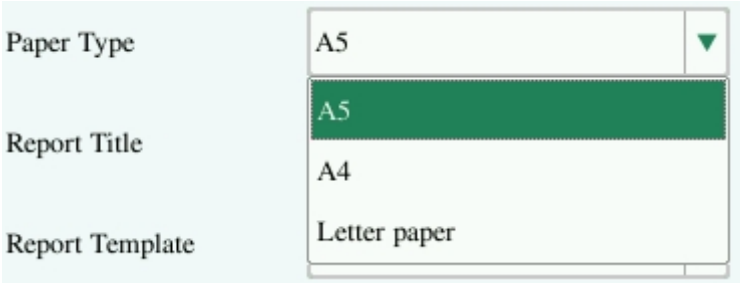
There are 2 types of printing device available: Printer and Recorder. You can select either of them from the pull-down list.

Printer Color

Click the pull-down list to select printer color of the analyzer.

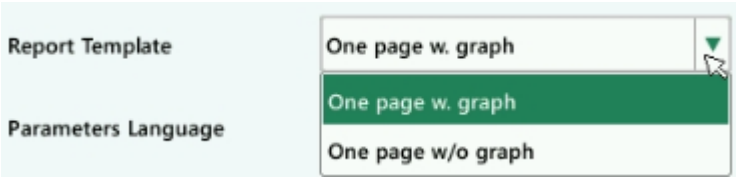
Paper Type

Click the pull-down list to select the paper type of the reports to be printed.



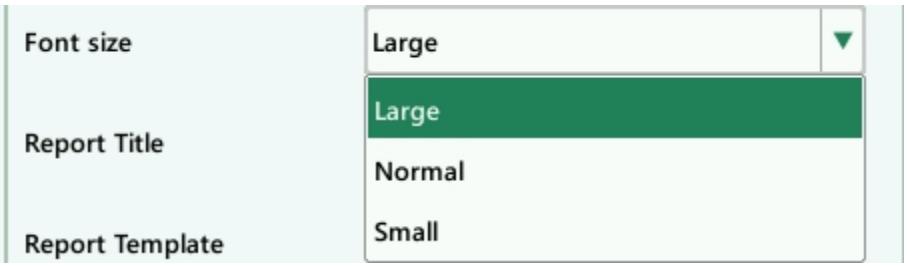
Report Title

Report Template



Font size

Set the font size for report printing.



Parameters Language

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

Copies

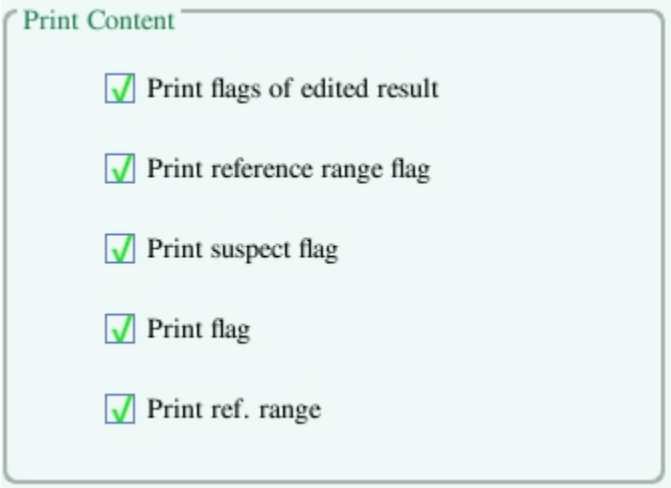
Enter the number of copies to be printed for each report into the edit box “Copies”.

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.

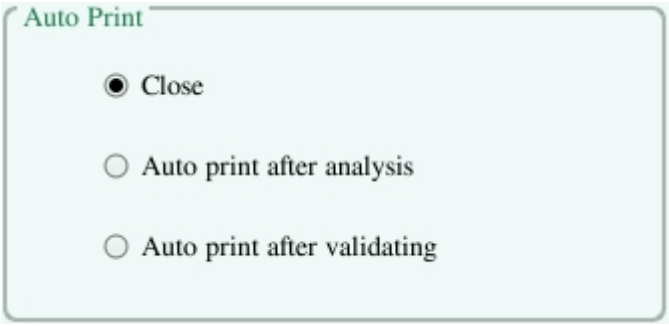
2. Print Content

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



3. Auto Print

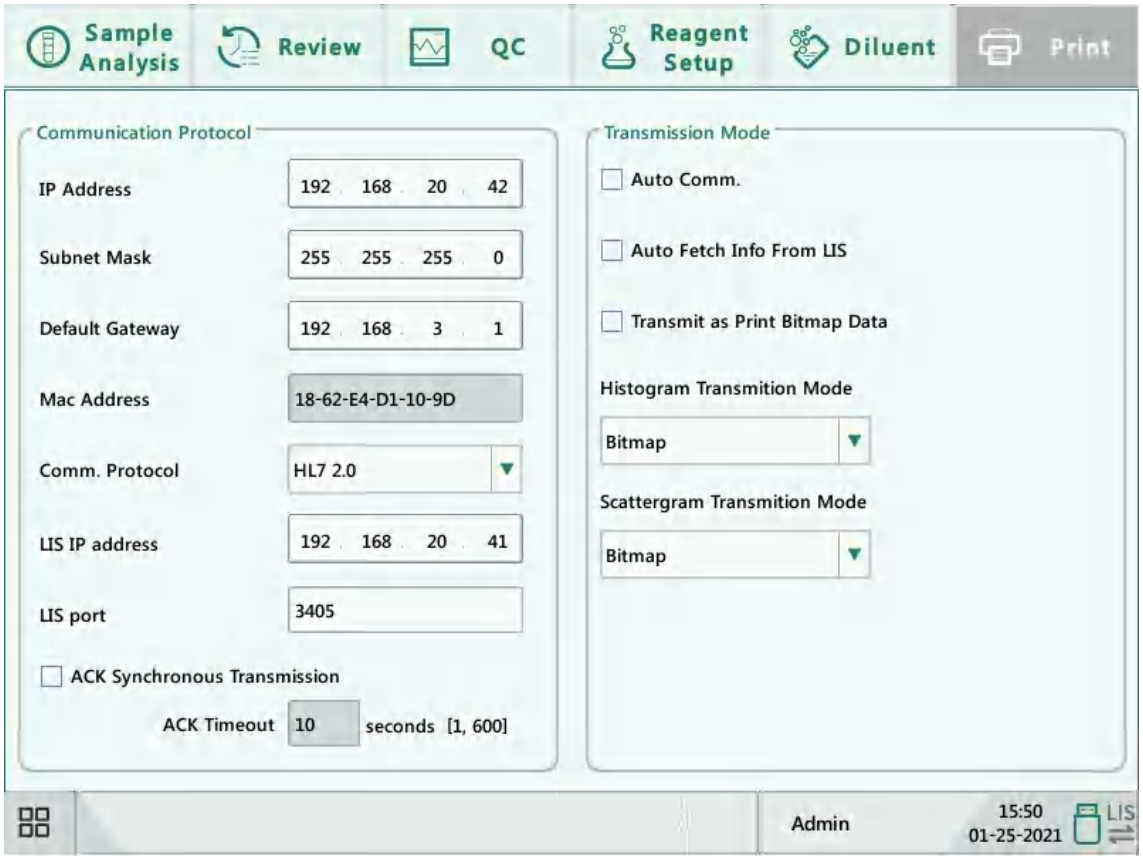
You can choose to disable auto print or set up printing conditions.



Communication

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

1. Communication Protocol
2. Transmission Mode



1. Communication Protocol

Click the “IP Address”, “Subnet Mask” , “Default Gateway” , LIS IP address and LIS port edit boxes to enter the contents.

Communication Protocol

Click the “Comm. Protocol” pull-down list to select the communication protocol.

ACK Synchronous Transmission

Click on the “ACK Synchronous Transmission” check box to activate the function.

When the function is activated, ACK timeout is 10 seconds by default. You can re-enter the ACK timeout in the edit box.

2. Transmission Mode

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

1) Auto Communicate
2) Auto Fetch Info from LIS
3) Transmit as Print Bitmap Data

Transmission mode of histogram and scattergram:

Click the pull-down lists to select the transmission modes of histogram and scattergram.

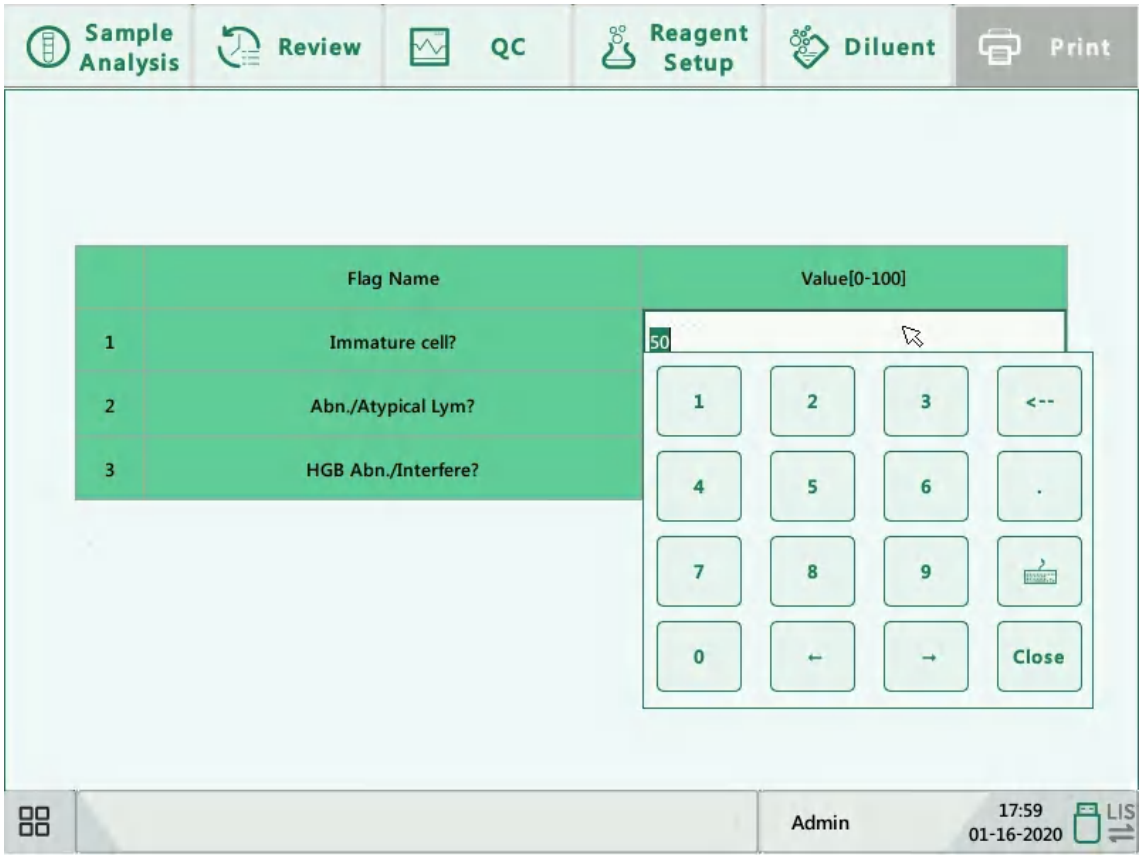
1) Not to be transmitted
2) Bitmap
3) Data

● Flag Alarm Sensitivity

Click “Setup” > “System Setup” > “Flag Alarm Sensitivity” in the menu to enter the following screen. This function allows you to set up flag alarm sensitivity based on your own needs.

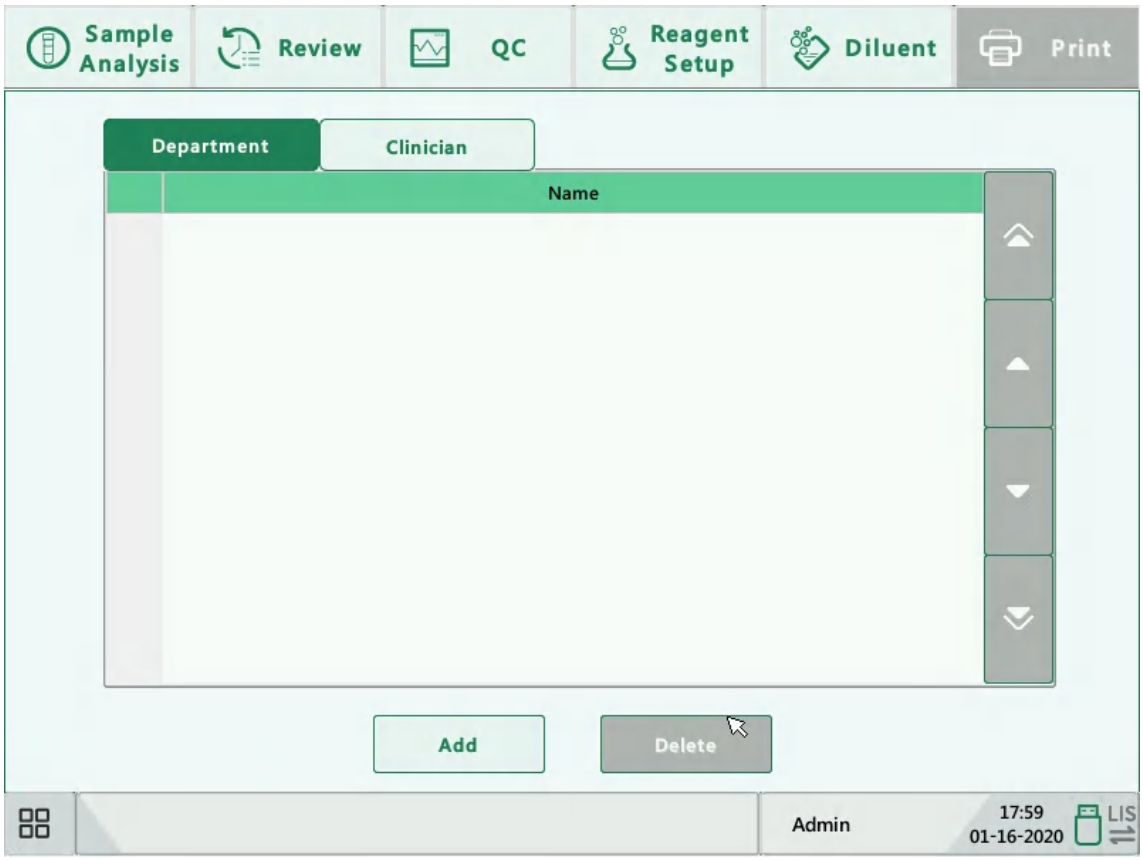
	Flag Name	Value[0-100]
1	Immature cell?	50
2	Abn./Atypical Lym?	50
3	HGB Abn./Interfere?	50

This screen shows the values that may trigger flag alarm. Operators of administrator access level can modify the reference values of the flags, which indicated the possibility of triggering flags. The higher the values are, the higher the possibility can be.



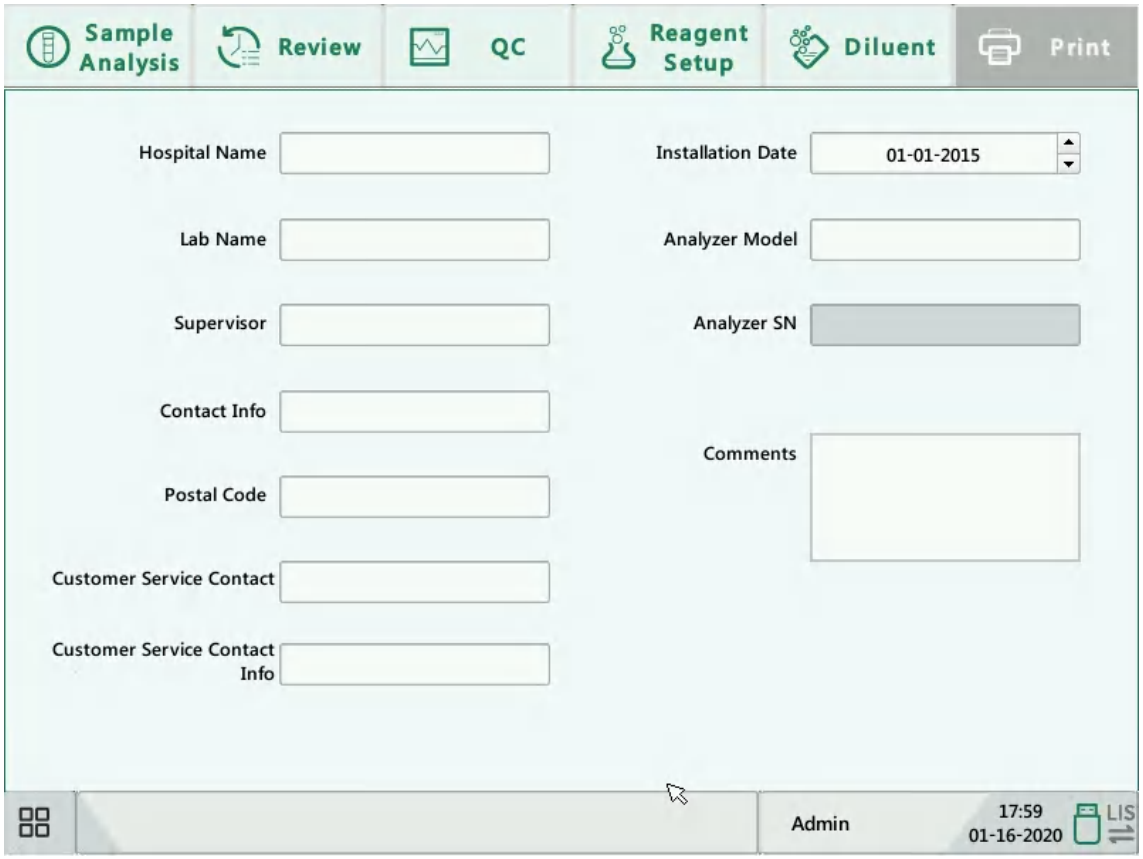
● Department/Clinician Setup

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.

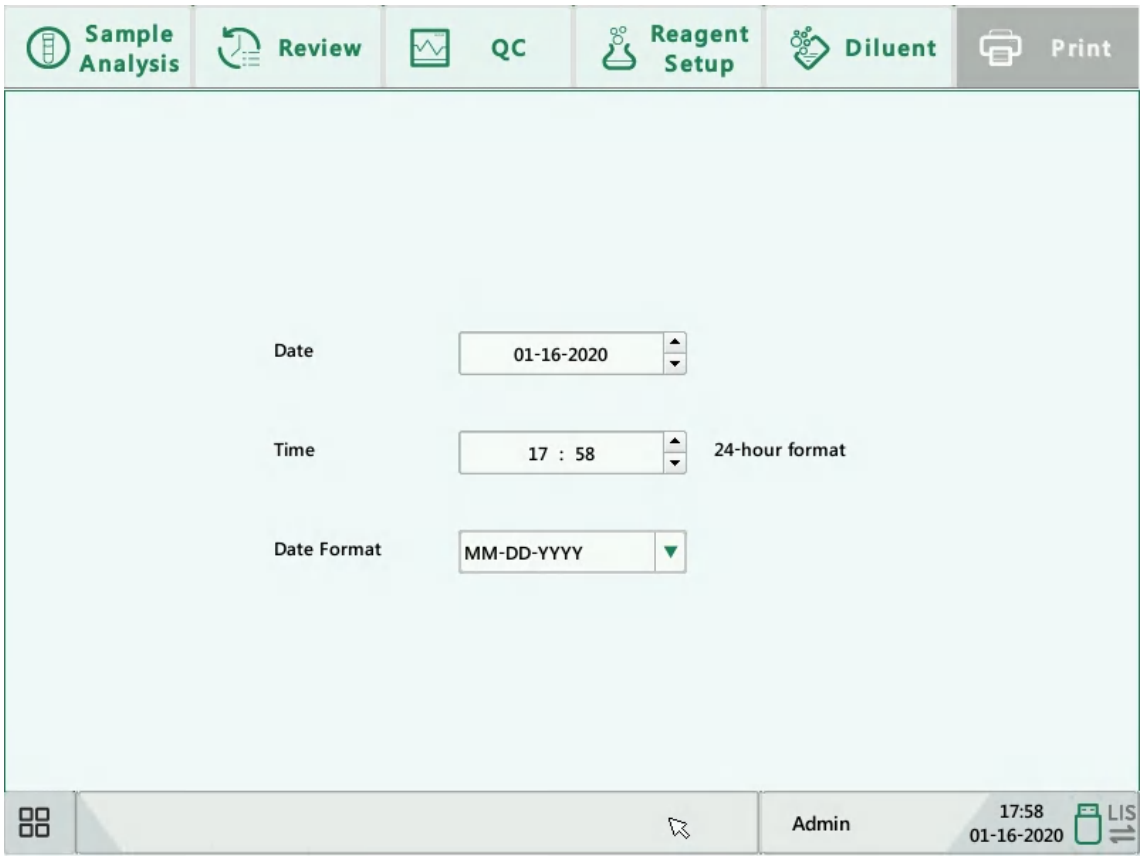


NOTE

- 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.

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.



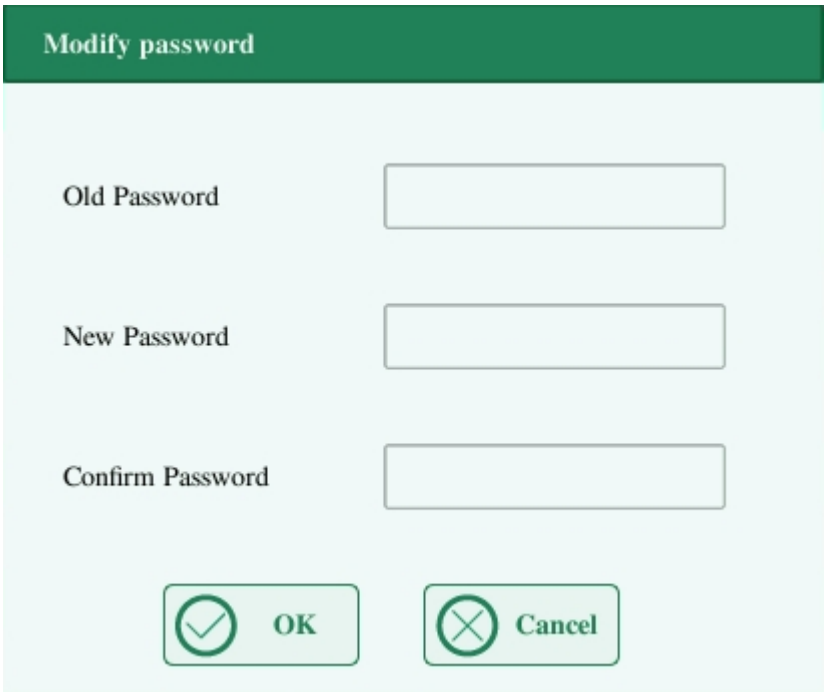
9.2.2. User Administration

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.

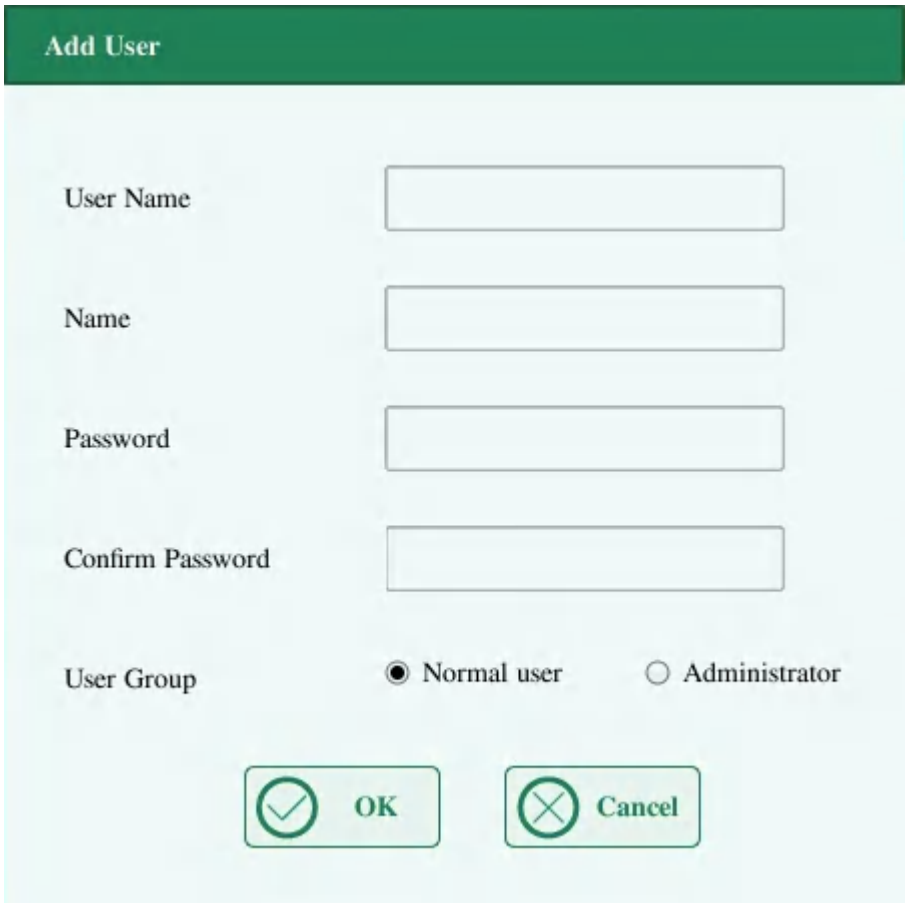
3) Click “OK” to save the change and close the dialog box.

NOTE

12 characters can be entered at most for the password.

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.
- 12 characters can be entered at most for the password.

3. Delete user

Select a user and then click “Delete” to delete it.

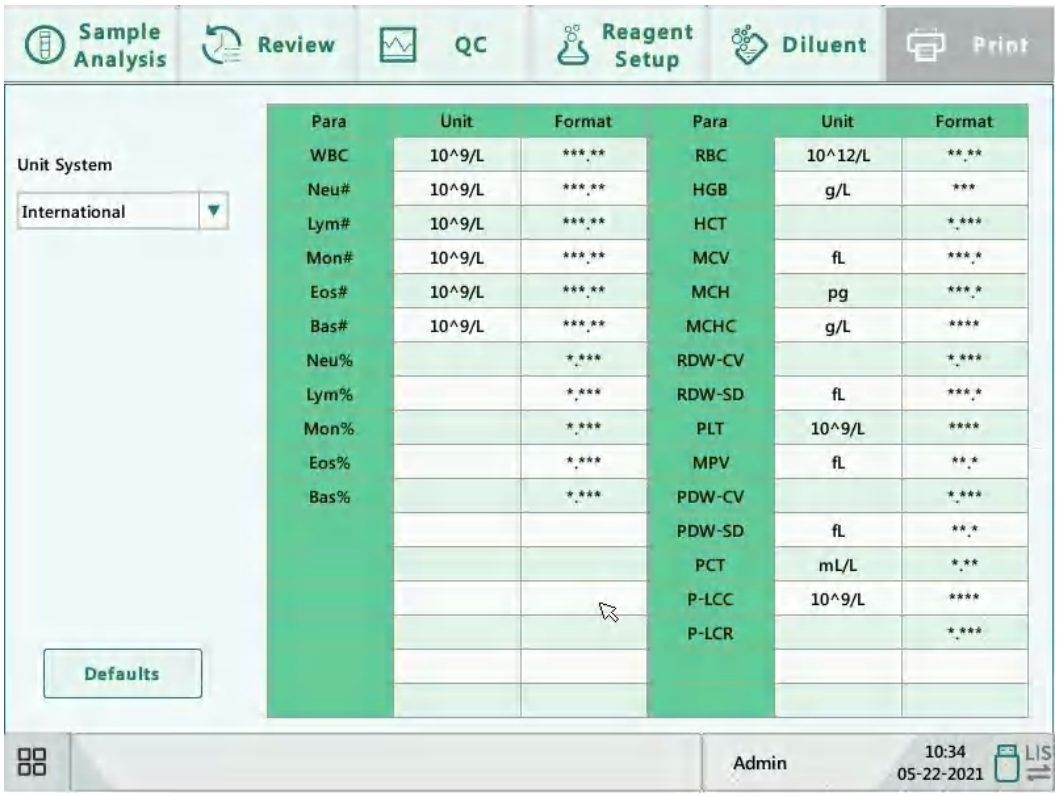
NOTE

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.



Para	Unit	Format	Para	Unit	Format
WBC	10^9/L	***.**	RBC	10^12/L	**.**
Neu#	10^9/L	***.**	HGB	g/L	***
Lym#	10^9/L	***.**	HCT		*.***
Mon#	10^9/L	***.**	MCV	fL	***.*
Eos#	10^9/L	***.**	MCH	pg	***.*
Bas#	10^9/L	***.**	MCHC	g/L	****
Neu%		*.***	RDW-CV		*.***
Lym%		*.***	RDW-SD	fL	***.*
Mon%		*.***	PLT	10^9/L	****
Eos%		*.***	MPV	fL	**.*
Bas%		*.***	PDW-CV		*.***
			PDW-SD	fL	**.*
			PCT	mL/L	*.**
			P-LCC	10^9/L	****
			P-LCR		*.***

Select unit system

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

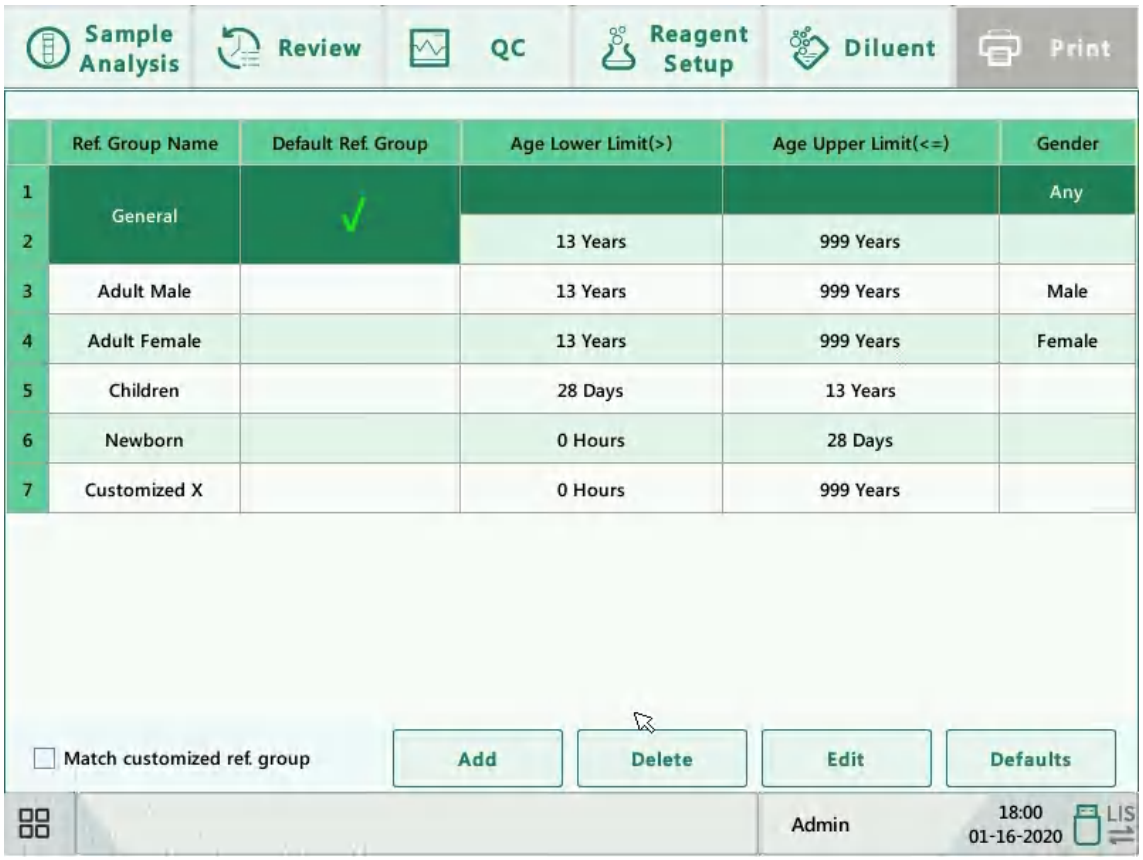
NOTE

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

Reference Range Setup

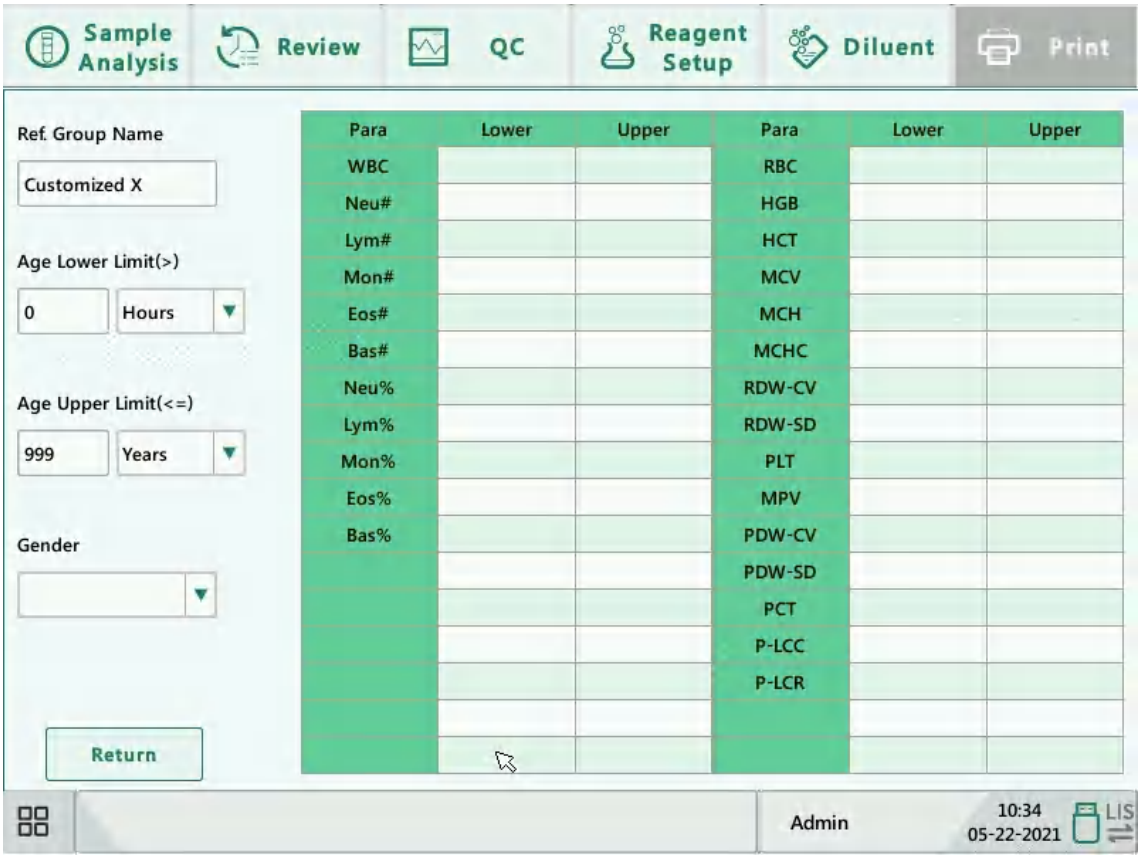
Click “Setup” > “Parameter Setup” > “Ref. Range Setup” in the menu to enter the following screen.

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

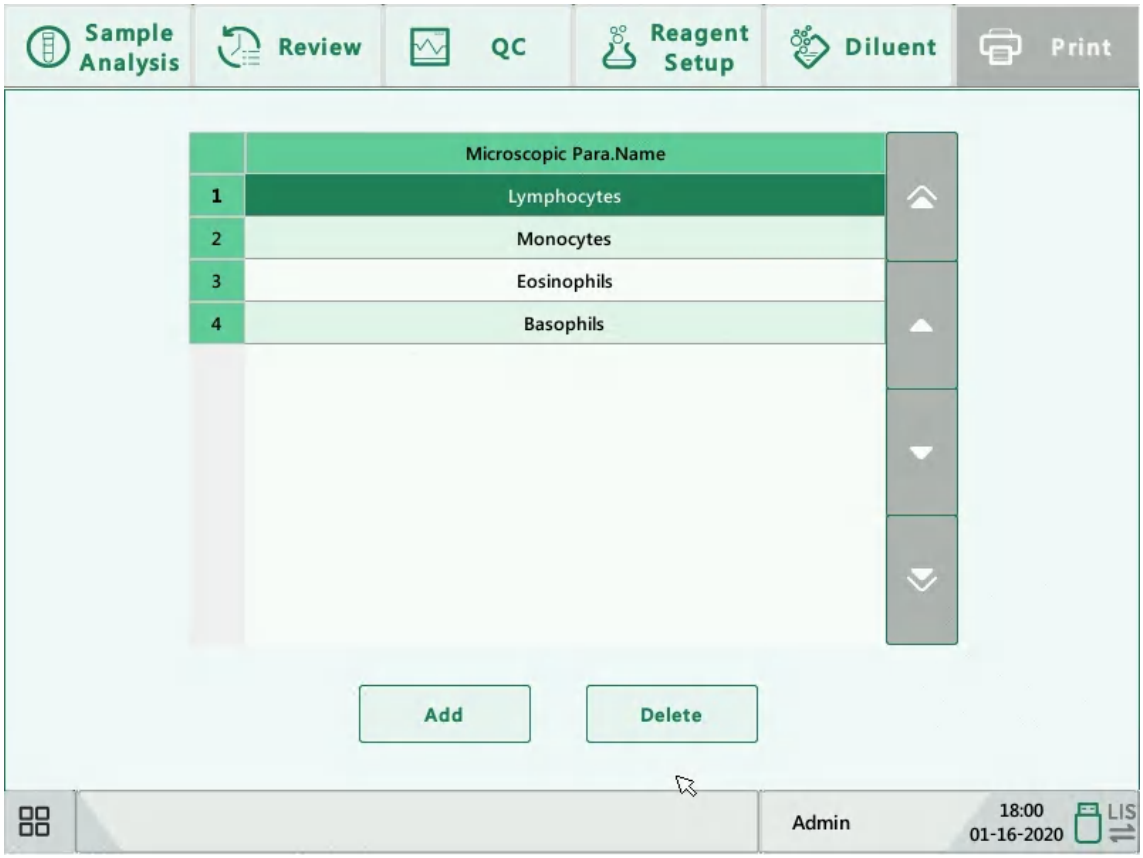
To modify the reference range of a reference group, select the group from the reference group list on the left, and then click the cells of upper and lower limits in the table and re-enter the values.

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

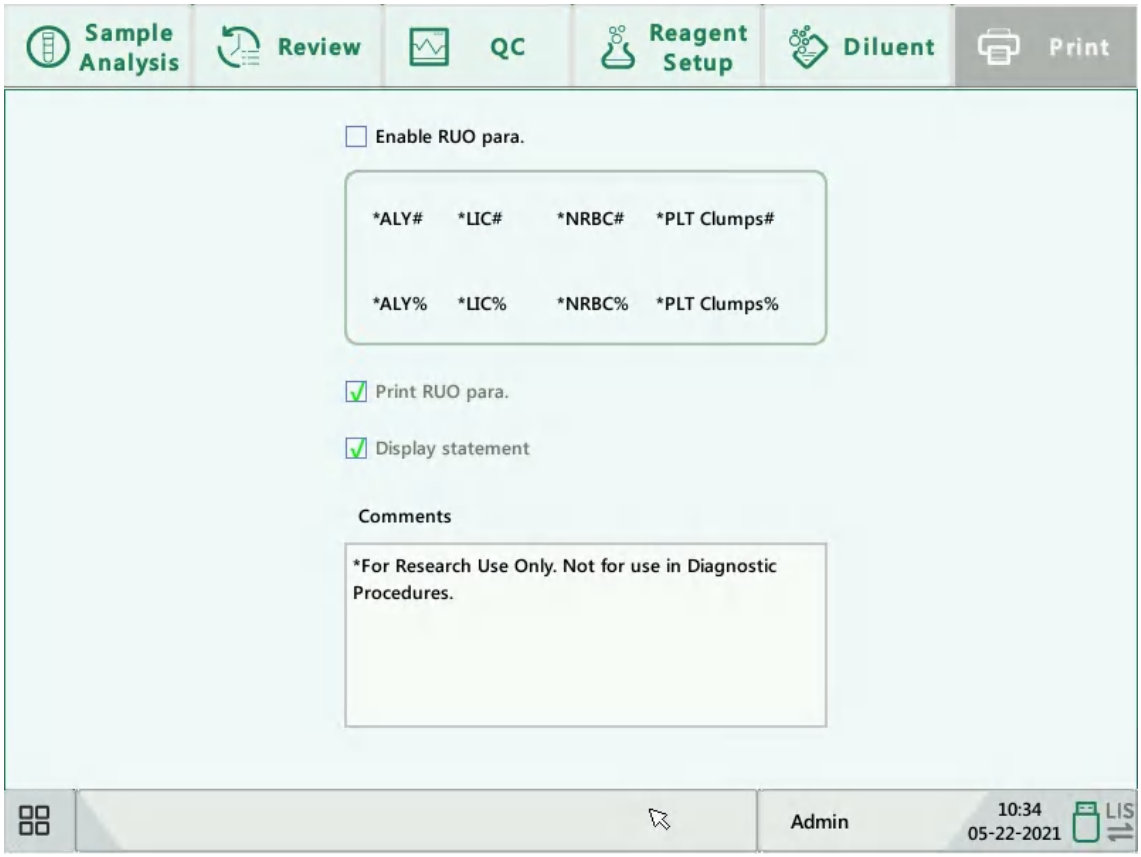
Click a parameter name in the table to edit the name.

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.

● RUO Parameter Setup

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



1. Eable RUO parameters

Select “Eable RUO para.”, the 4 RUO parameters will be displayed in the “Sample Analysis” and “Review” interface. Otherwise they will not be displayed.

2. Print RUO parameters

Select “Print RUO para.”, the 4 RUO parameter results will be printed out when printing graphical reports in the “Sample Analysis” and “Review” interface. Otherwise they will not be printed.

3. Display statement

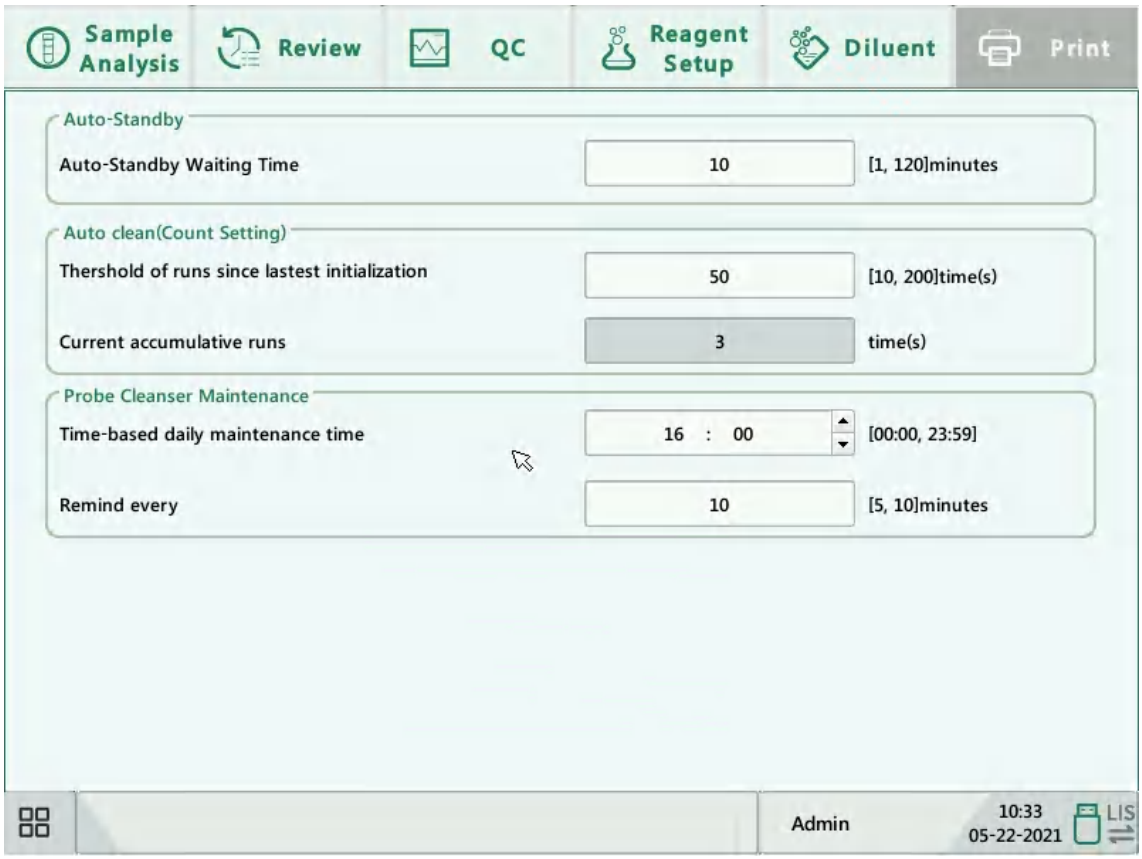
Select “Display statement”, the statement of RUO parameters will be displayed in the “Sample Analysis” interface. Otherwise it will not be displayed.

NOTE

The statement of RUO parameters is only displayed in 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 1-120 minutes, and the default setting is 10 minutes.

2. Auto clean

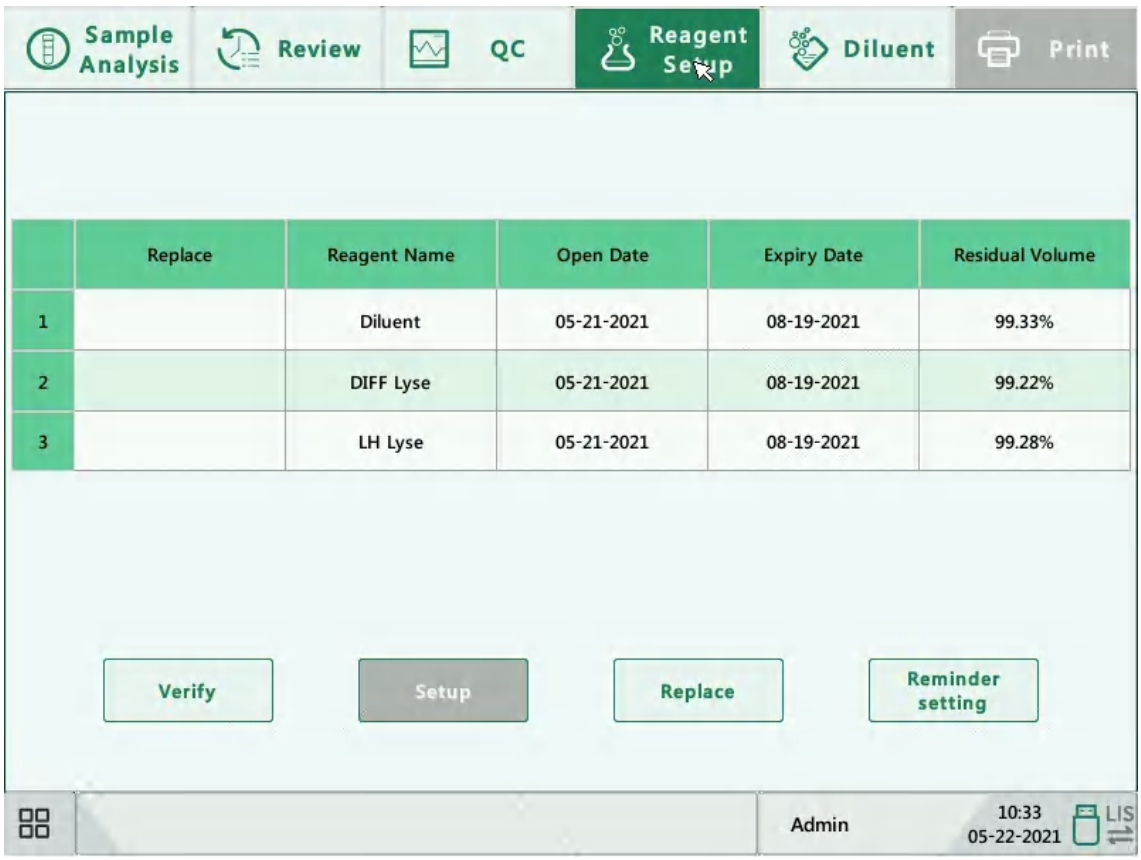
The operator can set a threshold for the cumulative number of runs. When the number of sample analyses reaches this threshold, it is automatically cleaned.

3. 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.



	Replace	Reagent Name	Open Date	Expiry Date	Residual Volume
1		Diluent	05-21-2021	08-19-2021	99.33%
2		DIFF Lyse	05-21-2021	08-19-2021	99.22%
3		LH Lyse	05-21-2021	08-19-2021	99.28%

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:

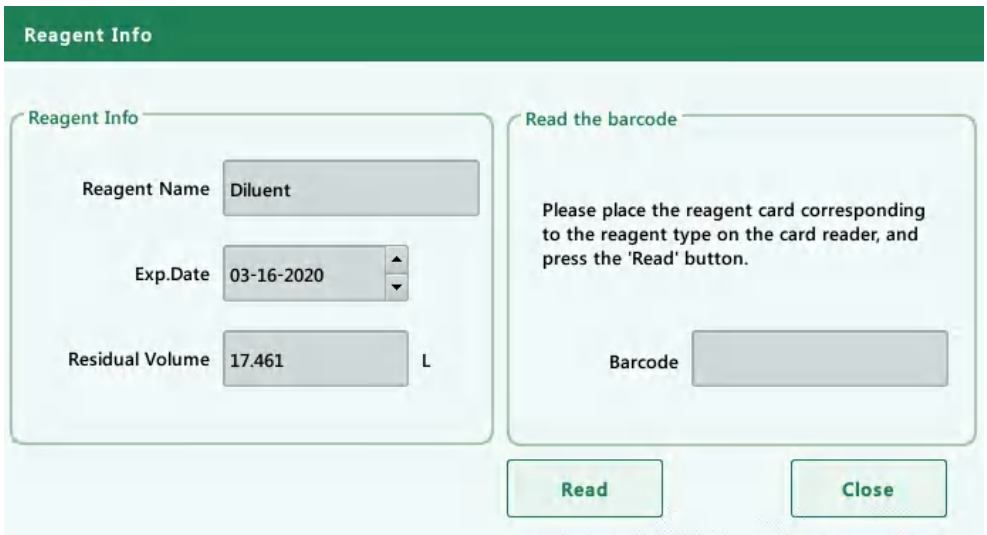
1) Diluent

2) DIFF lyse

3) LH lyse

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.

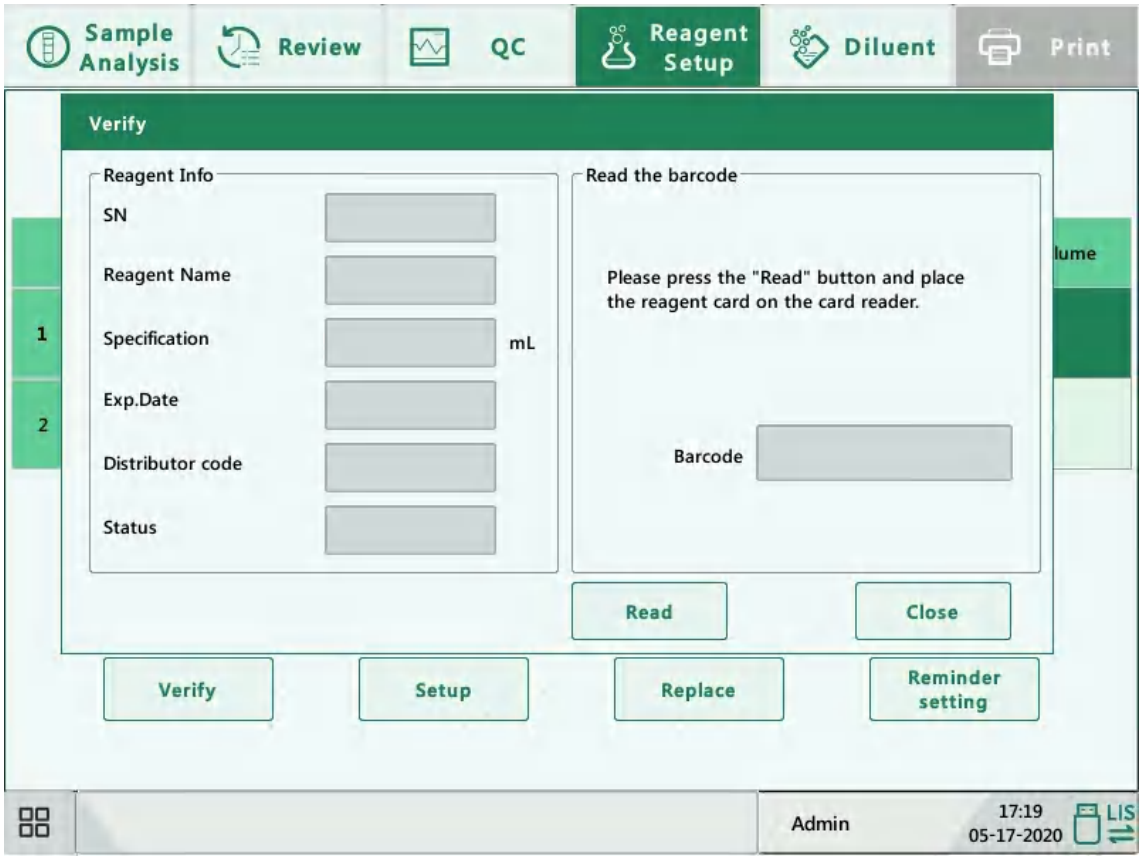
3. Press the [Replace] button on the reagent management screen to start the reagent change. The progress bar will be displayed in the window information area.

NOTE

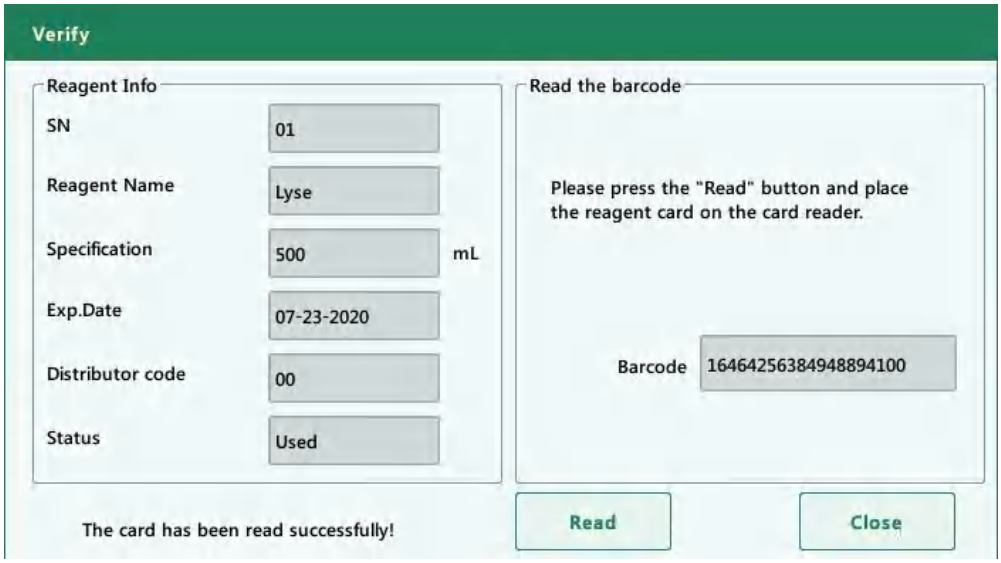
- Please keep the diluent container from severe shock or crashing against other object. Otherwise, the alarming would be unreliable.
- When replacing diluent container, insert the diluent cap assembly into the container and tighten the cap. Otherwise the alarming may be unreliable.

- The “Verify” function provides the operator with information about the reagent card, such as SN, Reagent Name, Specification, Exp.Date and Status of the reagent card.

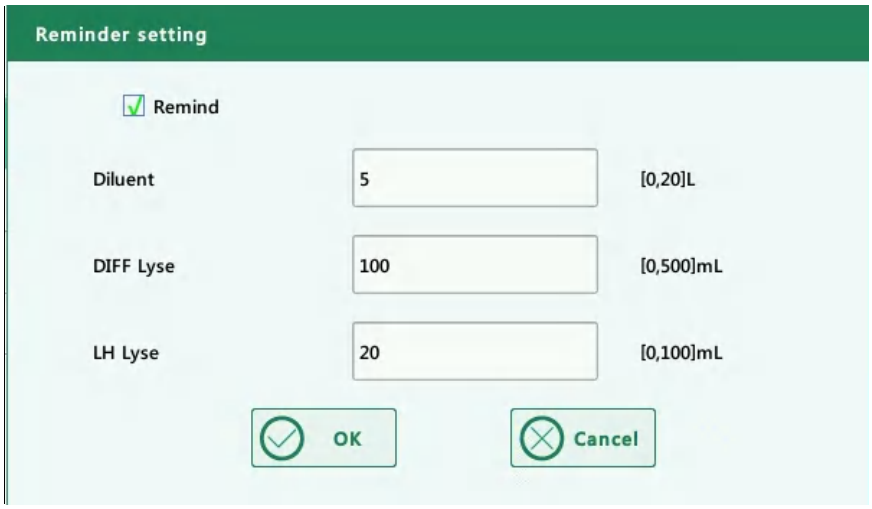
5. Click “Verify” and the interface will pop up as shown below：



6. Click “Read”, place the reagent card on the card reader, and read the reagent information.

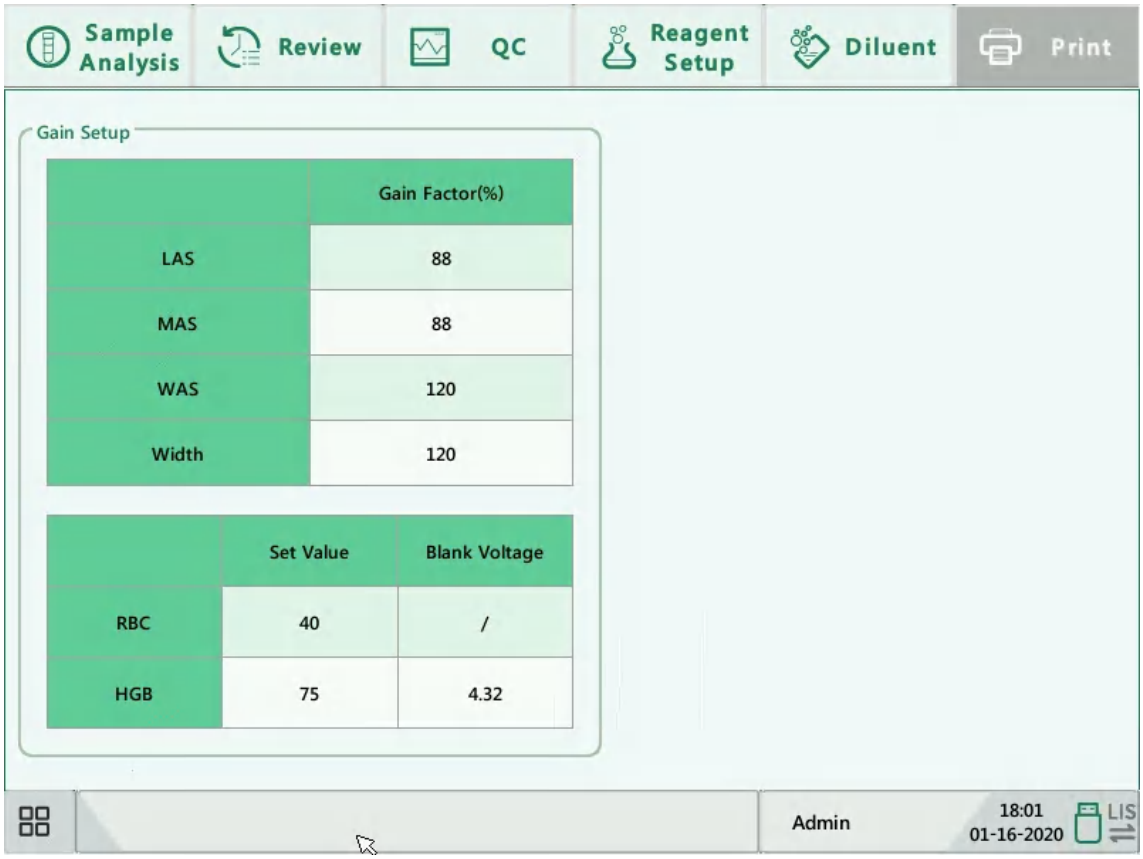


- The “Reminder setting” button can set the reminder value of the reagent remaining amount for the operator, but when the reagent remaining amount reaches the value set by the user, the user can be reminded to prepare the reagent in advance.



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.

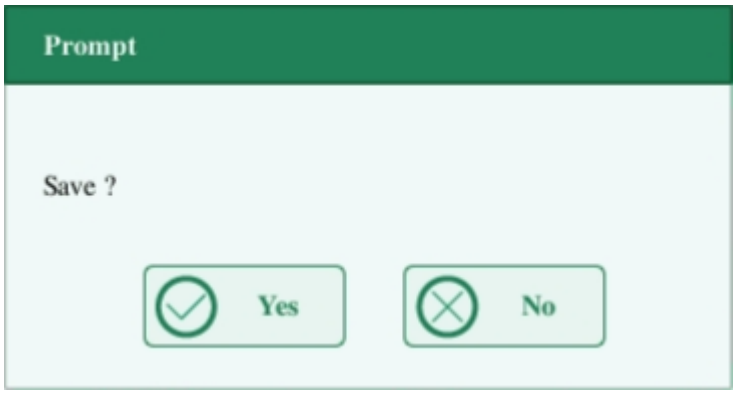
Click the HGB “Set Value” cell, and enter the new value of HGB gain.

NOTE

The gains of LAS, MAS, WAS and Width cannot be modified.

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 settings.

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 Genrui customer service department.
- Only Genrui-supplied parts can be used for maintenance. For any questions, contact Genrui 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.

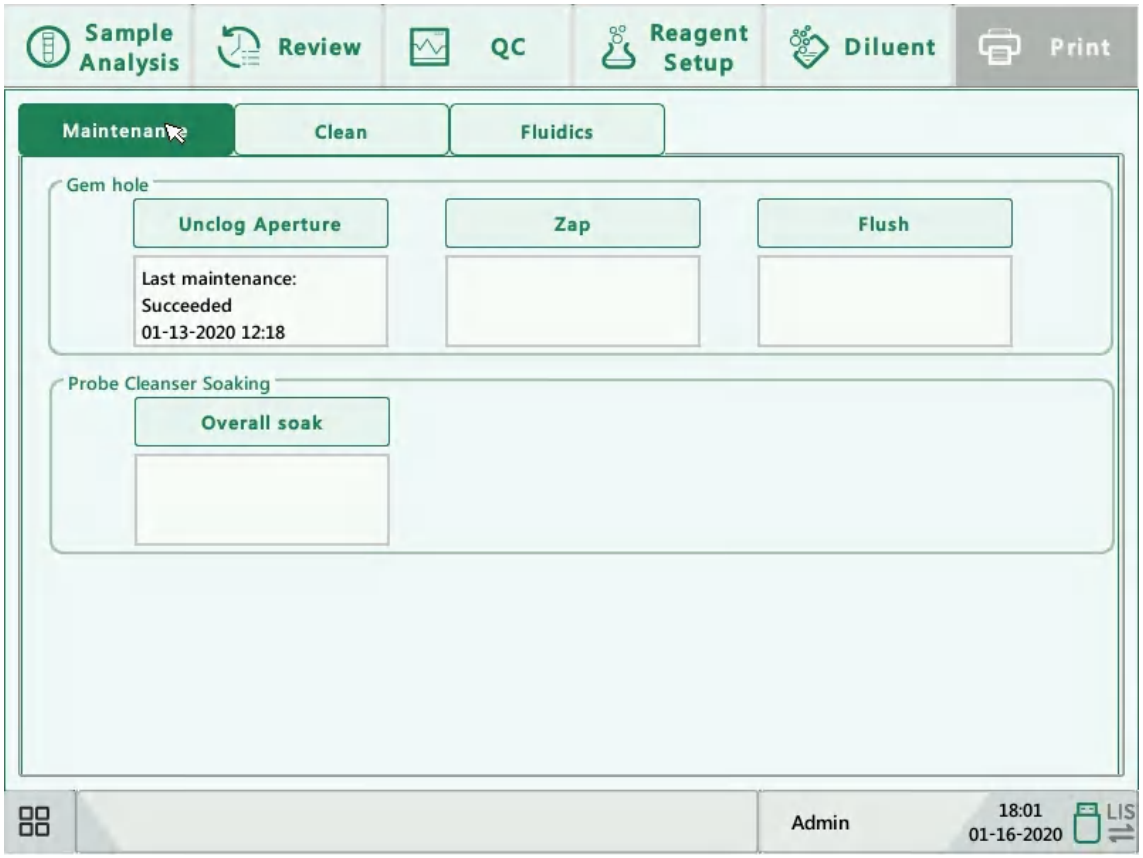
No.	Tools
1	Cross-headed screwdriver
2	Slotted head screwdriver
3	Medical gloves
4	Alcohol

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 and flushing the aperture. 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.

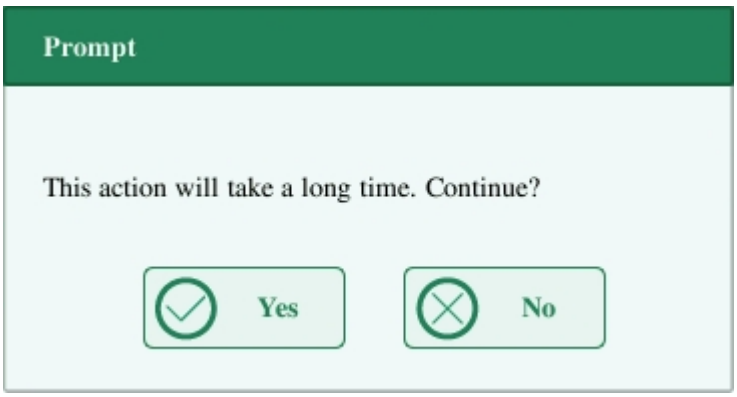
2. Probe cleanser maintenance

You should perform the probe cleanser soaking procedure when:

- background results are out of range, QC results abnormal or scattergram abnormal due to long term idleness of the analyzer, 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.

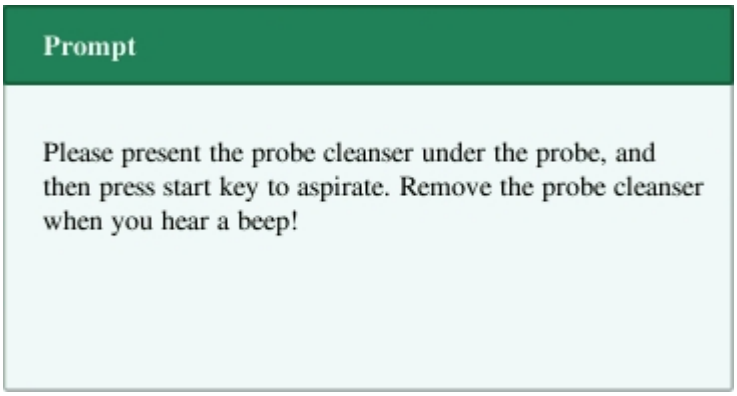
The probe cleanser maintenance procedures are:

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

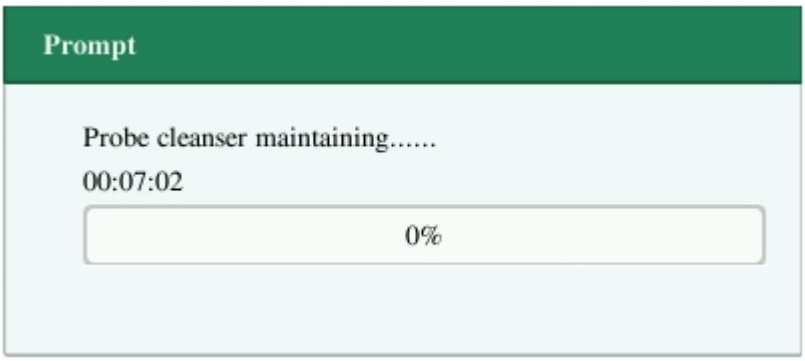


2) Click “Yes”, the analyzer starts to prepare for the maintenance.

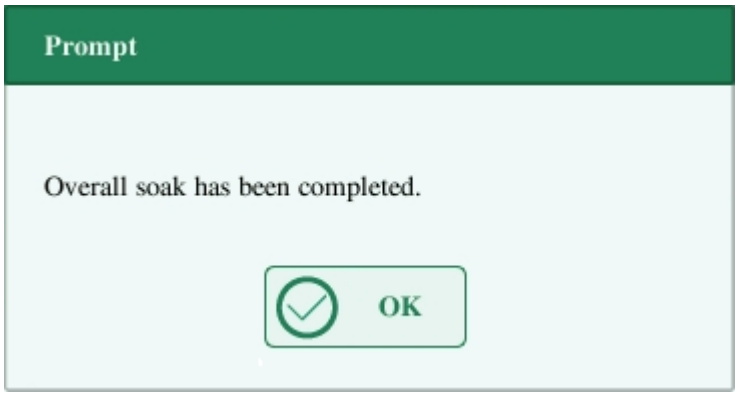
3) When the preparation is done, the following dialog box will display.



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.

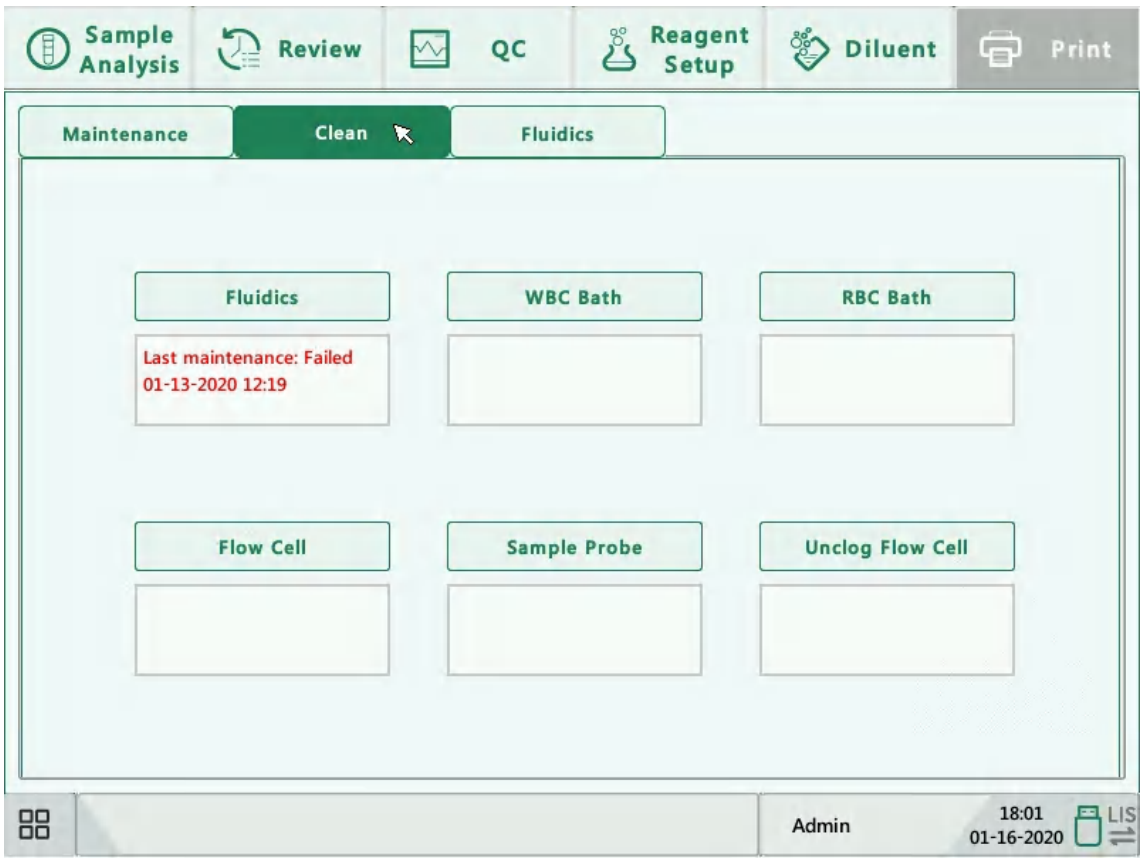


10.2.2. Cleaning

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 RBC bath cleaning does not solve the problem, perform RBC probe cleanser maintenance.
- there are too many particles in the scattergram of background results, perform WBC bath cleaning. If WBC bath cleaning does not solve the problem, perform WBC 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:

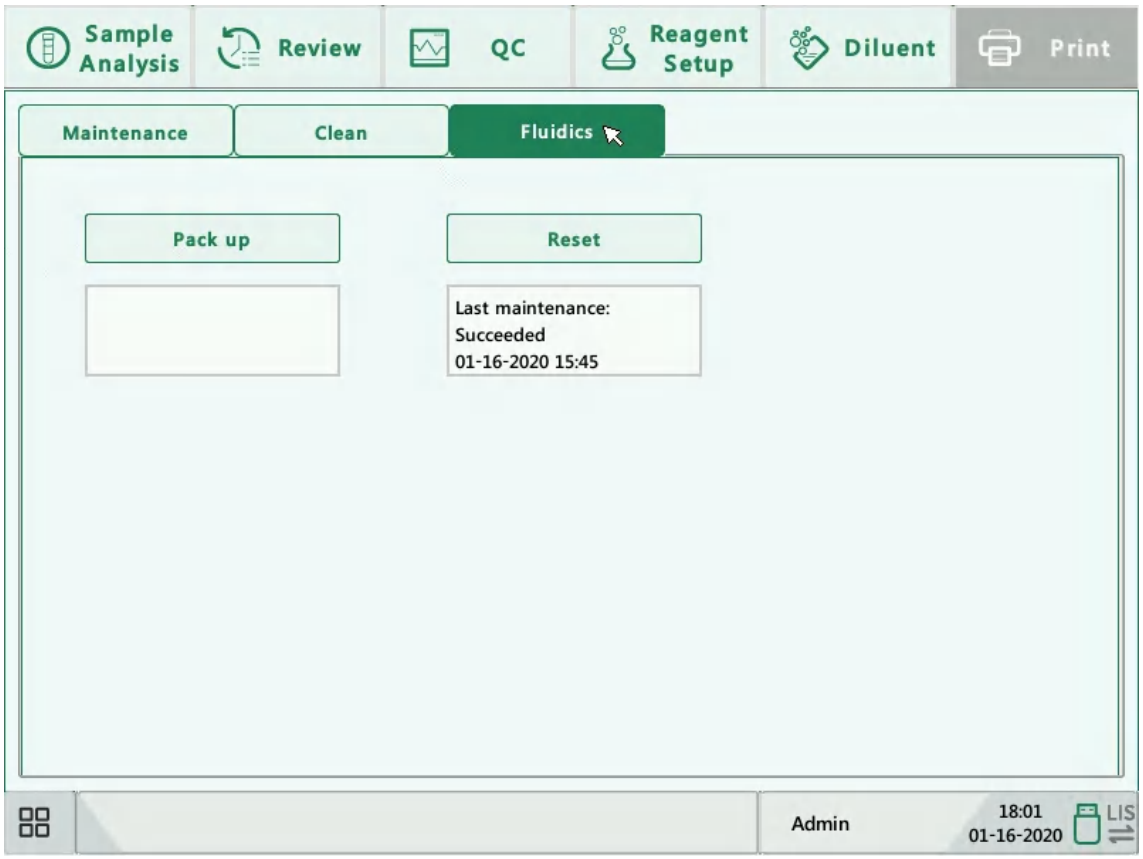
- Fluidics
- Flow cell
- Sample probe
- Unclog flow cell
- WBC bath
- RBC bath

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.



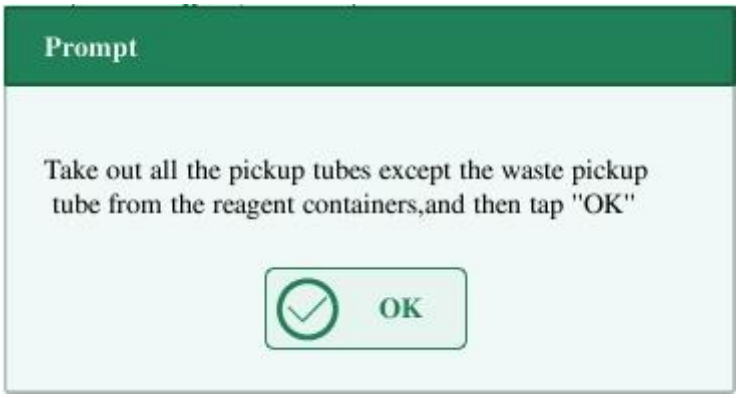
1. Pack up

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

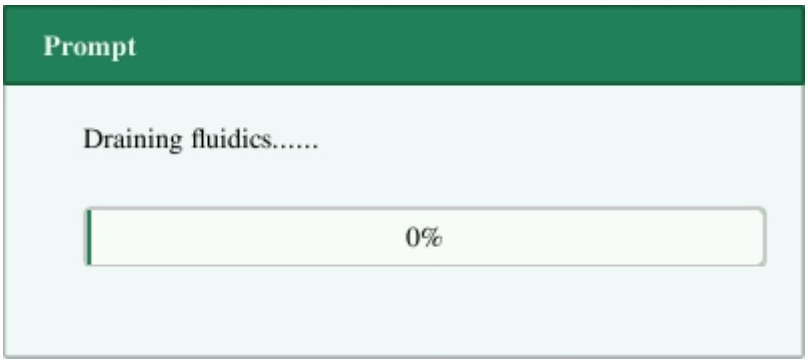
Do as follows to pack up:

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

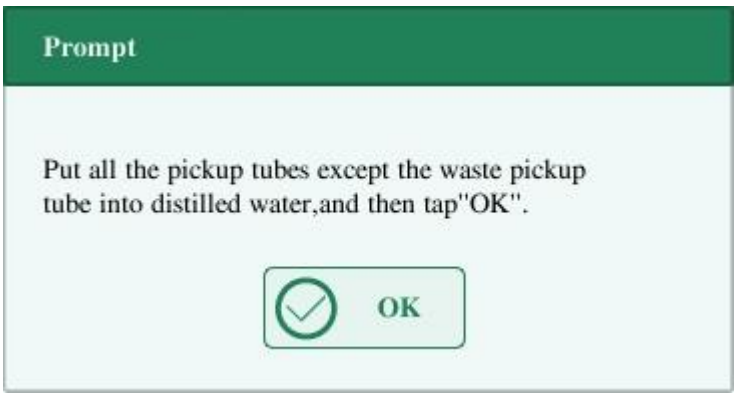
2) Click “Yes” to perform the pack up procedure. The following dialog box will be displayed.



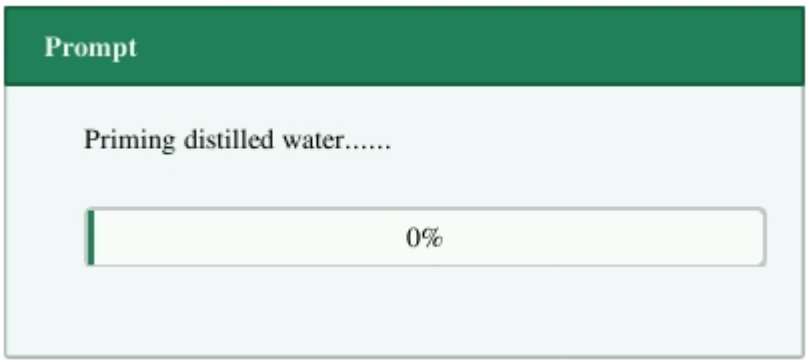
3) Take out the tubes as instructed and then click “OK” to drain the fluidics.



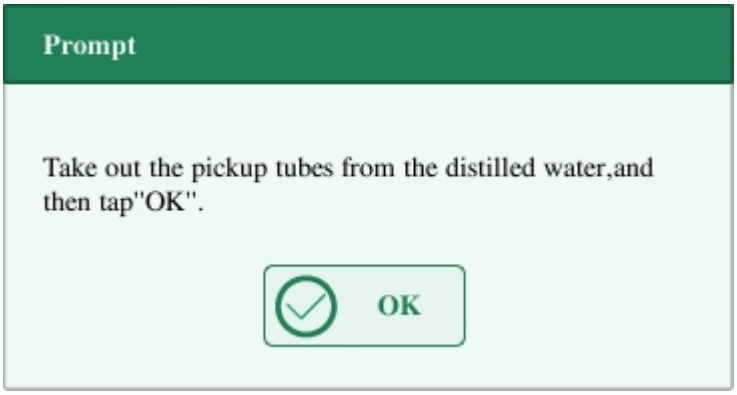
4) The following dialog box will be displayed after draining the fluidics.



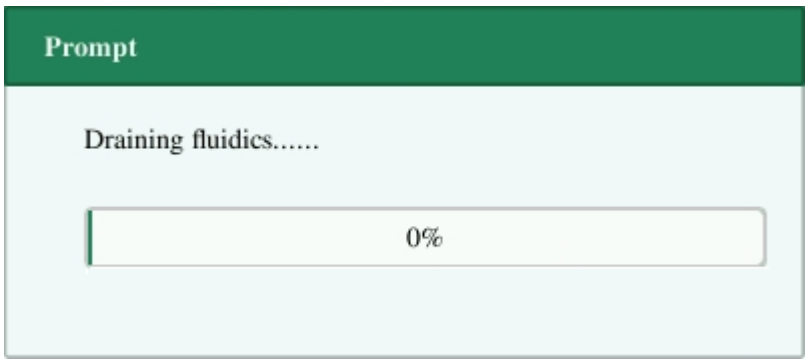
5) Put the tubes into distilled water as instructed, and click “OK” to start priming.



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.

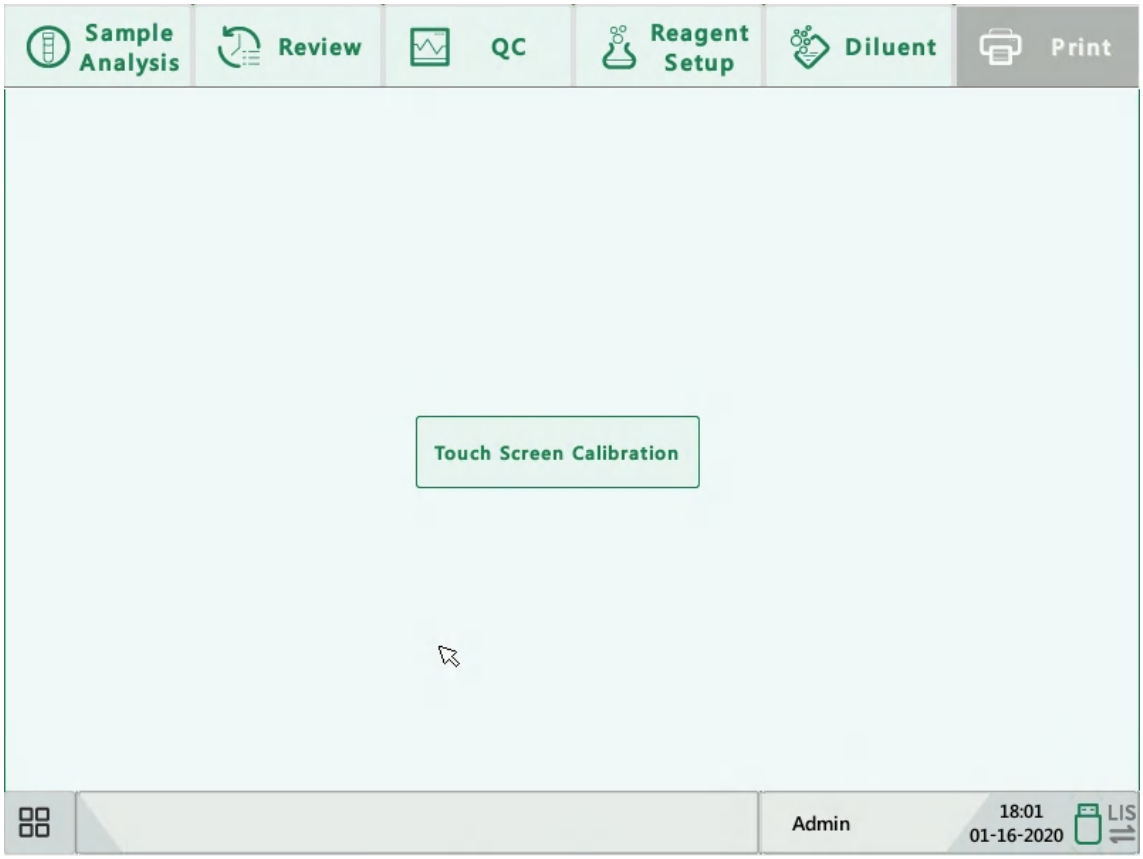
2) Click “OK” to start initialization, the message “Resetting fluidics. Please wait...” will be displayed.

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



10.4. Viewing Logs

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

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

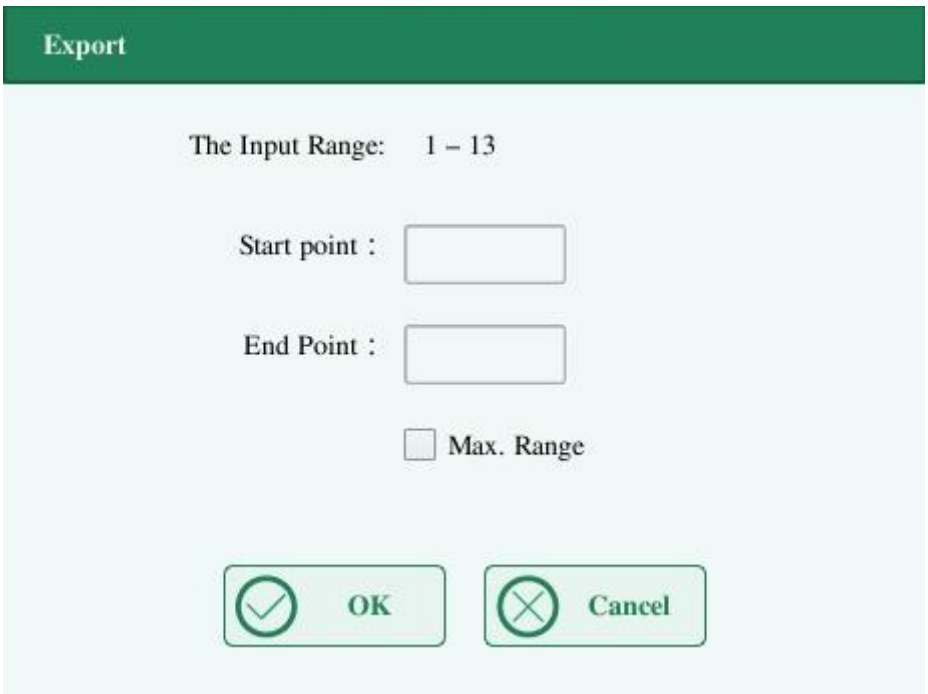
The “Log” screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

NOTE

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

Exporting logs

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



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

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

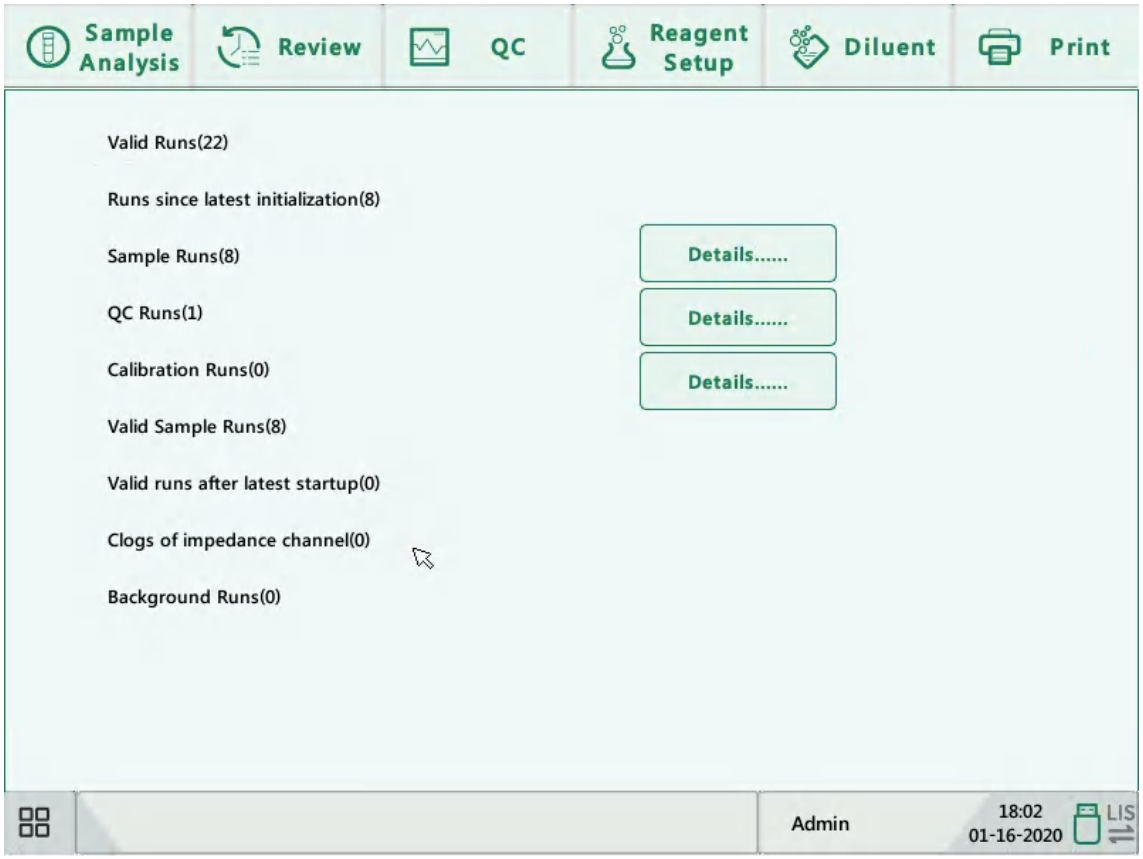
10.5. Checking the Analyzer Status

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.

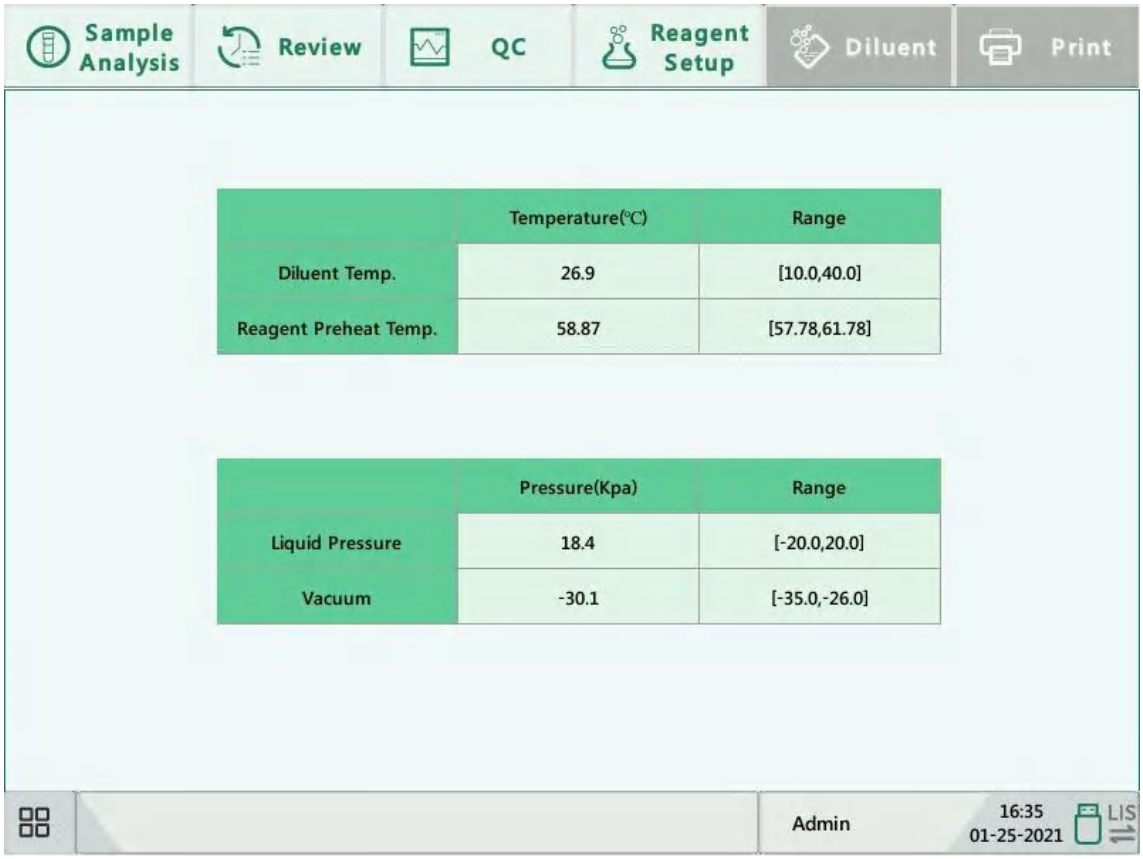
2. Print

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

10.5.2. Temp. & Pressure

Click “Status” > “Temp. & Pressure” in the menu to enter the following screen.

You may check, export or print the temperature and pressure values of different components of the analyzer.



	Temperature(℃)	Range
Diluent Temp.	26.9	[10.0,40.0]
Reagent Preheat Temp.	58.87	[57.78,61.78]

	Pressure(Kpa)	Range
Liquid Pressure	18.4	[-20.0,20.0]
Vacuum	-30.1	[-35.0,-26.0]

10.5.3. Voltage and Current

Click “Status” > “Voltage & Current” in the menu to enter the following screen.

You may check the voltage and current values of different components of the analyzer.

	Voltage (V)	Range
Power (+12V)	11.70	[11.00,14.00]
Power (+24V)	23.82	[20.00,30.00]
Digital	59.60	[55.00,65.00]
Analog Voltage (+12V)	12.06	[11.00,14.00]
Analog Voltage (-12V)	-12.18	[-14.00,-11.00]
HGB Blank Voltage	4.32	[3.80,4.80]
LAS Blank Voltage	/	[0.02,1.00]

	Current	Range
Laser Diode Current	29.48	[20.00,60.00]

10.5.4. Sensor

Click “Status” > “Sensor” in the menu to enter the following screen.

You may check the sensor status of the analyzer.

Appliance Part		Status
Float Sensor	Waste	Not Full
Syringe Photocoupler	Diluent Syringe	Uncovered
	Lyse Syringe	Cover
Sample Components Photocoupler	Vertical Photocoupler	Uncovered
	Inside Photocoupler	Uncovered
	Outside Photocoupler	Cover
Others	Laser Cell	Off
	Aspirate Key	On

10.5.5. Version Info.

Click “Status” > “Version Info.” in the menu to enter the following screen.

You may view the current version information of the analyzer.

Software Version	Guidance Software	V1.1.002
	Kernel	V1.02.008
	System Software	V01.11.726
	Printer Driver	V1.1.002
	Printing Template	V1.1.002
	Time Sequence	V01.07.353
	Language	V1.1.002
	Algorithm	V1.6.026
	Main Board Driver	V1.0.17
Hardware Version	Signal Board FPGA	V01.03.41
	Driver Board FPGA	V01.03.00.008
	Driver Board MCU	V01.07.00.052
Installed Version	Disk	V01.11

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 Genrui 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 Genrui or your local distributor.
3) If the instrument breaks down after the warranty period, ask Genrui 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 Genrui 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 Genrui.
5) Only personnel trained and authorized by Genrui 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

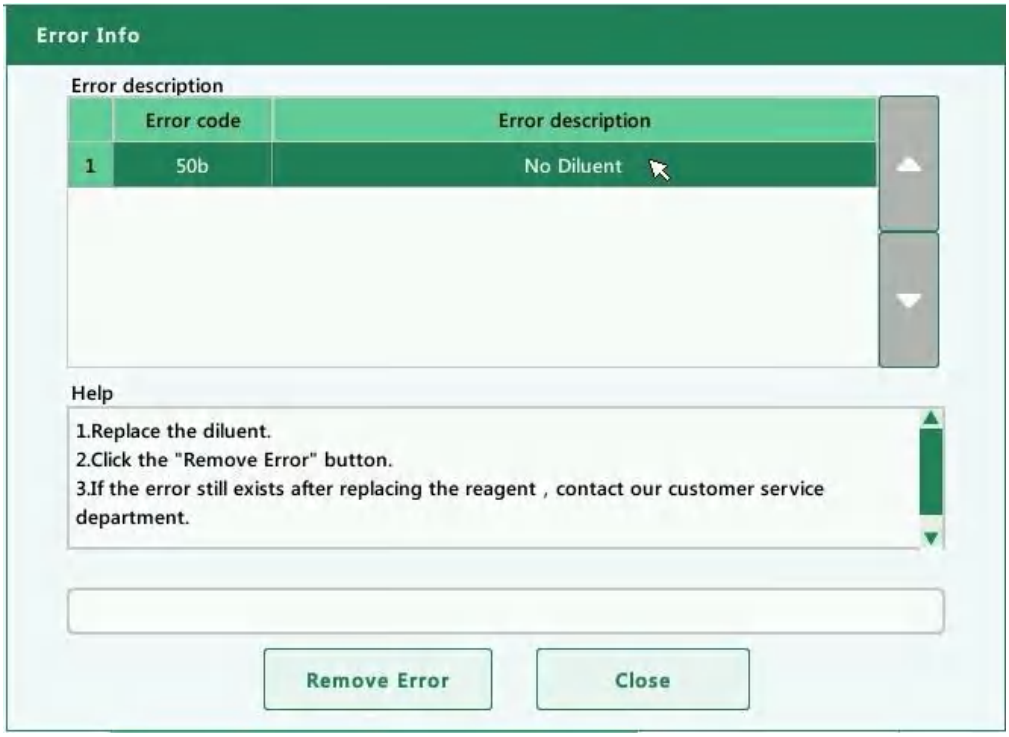
This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer.

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. 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 LH lyse	3. Replace the LH lyse. 4. Click “Remove Error”, and enter the new barcode of the LH lyse into the reagent setup dialog box. 5. If the error still exists after replacing the LH lyse, contact our customer service department.
No DIFF lyse	4) Replace the DIFF lyse. 5) Click “Remove Error”, and enter the new barcode of the DIFF lyse into the reagent setup dialog box. 6) If the error still exists after replacing the DIFF 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.
LH lyse is insufficient	1. Replace the LH lyse. 2. Click “Remove Error”, and enter the new barcode of the LH lyse into the reagent setup dialog box. 3. If the error still exists after replacing the LH lyse, contact our customer service department.
DIFF lyse is insufficient	1. Replace the DIFF lyse. 2. Click “Remove Error”, and enter the new barcode of the DIFF lyse into the reagent setup dialog box. 3. If the error still exists after replacing the DIFF lyse, contact

Error Name	Actions
	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.
LH lyse expired	1. Replace LH lyse within the validity period. 2. Click “Remove Error”, and enter the new barcode of the LH lyse into the reagent setup dialog box. 3. If the error still exists after replacing the diluent, contact our customer service department.
DIFF lyse expired	1. Replace DIFF lyse within the validity period. 2. Click “Remove Error”, and enter the new barcode of the DIFF lyse into the reagent setup dialog box. 3. If the error still exists after replacing the diluent, 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.
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.
Aspiration 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.
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

Error Name	Actions
	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.
Vacuum pressure abnormal	1. Click “Remove Error” to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Liquid pressure abnormal	1. Click “Remove Error” to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Preheating tank temperature is out of range	1. Click “Remove Error” to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Diluent temperature is out of range	1. Diluent temperature shall be within [10℃, 40℃]. 2. Click “Remove Error” to see if the error can be removed.
Clogging	1. Click “Remove Error” to see if the error can be removed. 2. If the error still exists, contact our customer service department.
Signal board FPGA communication abnormal	1. Click “Remove Error” to see if the error can be removed. 2. If the error still exists, contact our customer service department.

In the event that the errors cannot be removed after performing the required actions, or faults not present in the above list or caused by user operation errors occurred, please contact Genrui customer service department.

12. Transportation and Storage

12.1. Transportation Requirements

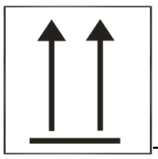
The analyzer must be transported in its intact packaging according to the order contract and protected against severe shocks, vibration, rain, snow and sunlight.

12.2. Storage Conditions

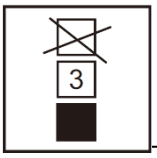
The packaged analyzer should be stored at -10□～55□ and in a well ventilated environment with relative humidity less than 93% and without corrosive gases.

12.3. Product's Outer Packaging Illustration

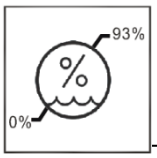
——"Fragile": Carefully carry and place.


——"Up": Upward to place and transport the product.

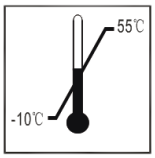
——"Rain Proof": Protect the package from the rain.



——"Layer limit": Maximum pile up layers of the same package.



——"Humidity Limit": Humidity limit for transportation and storage environment.



——"Temperature Limit": Temperature limit for transportation and storage environment.

Note: The illustrations are for reference only, subject to pictures on the outer package.

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	Diluent
Lyse	DIFF lyse
	LH lyse
/	Probe cleanser

A.3. Applicable Tubes

The following tubes can be used:

1) Φ12~15×75mm evacuated collection tube (without cap) for whole blood mode.
2) Φ11×40mm (1.5ml centrifugal tube) and 0.5ml centrifugal tube for predilute and capillary whole blood mode.
3) Φ10.7×42mm small closed anticoagulated tube (without cap), 0.5ml, can be used with cap opened, for capillary whole blood mode.

A.4. Parameters

Parameter Name	**Abbreviation**	**Default Unit**
White Blood Cell count	WBC	10^9/L
Basophils number	Bas#	10^9/L
Basophils percentage	Bas%	%
Neutrophils number	Neu#	10^9/L
Neutrophils percentage	Neu%	%
Eosinophils number	Eos#	10^9/L
Eosinophils percentage	Eos%	%

Parameter Name	Abbreviation	Default Unit
Lymphocytes number	Lym#	10^9/L
Lymphocytes percentage	Lym%	%
Monocytes number	Mon#	10^9/L
Monocytes percentage	Mon%	%
Abnormal Lymphocytes number	ALY#	10^9/L
Abnormal Lymphocytes percentage	ALY%	%
Large Immature , Cells number	LIC#	10^9/L
Large Immature Cells percentage	LIC%	%
Nucleated Red Blood Cells percentage	*NRBC%	10^9/L
Nucleated Red Blood Cells number	*NRBC#	%
Platelet Clumps percentage	*PLT Clumps%	10^9/L
Platelet Clumps count	*PLT Clumps#	%
Red Blood Cell count	RBC	10^{12}/L
Hemoglobin Concentration	HGB	g/L
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L
Red Blood Cell Distribution Width - Coefficient of Variation	RDW-CV	%
Red Blood Cell Distribution Width - Standard Deviation	RDW-SD	fL
Hematocrit	HCT	%
Platelet count	PLT	10^9/L
Mean Platelet Volume	MPV	fL
Platelet Distribution Width- Standard Deviation	PDW-SD	fL
Platelet Distribution Width- Coefficient of Variation	PDW-CV	%
Plateletcrit	PCT	%

Parameter Name	Abbreviation	Default Unit
Platelet larger cell ratio	P-LCR	%
Platelet larger cell count	P-LCC	10^9/L
Red Blood Cell Histogram	RBC Histogram	None
Platelet Histogram	PLT Histogram	None
Differential Scattergram	Diff Scattergram	None

A.5. Sample Volumes Required for Each Analysis

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

Whole blood and capillary whole blood mode	≤20μL under CBC+DIFF mode ≤12μL under CBC mode
Prediluted mode	≤20μL under both CBC and CBC+DIFF modes

A.6. Model Differences

Model	KT-6600	KT-6610
Throughput	40 samples/hour	60 samples/hour
Barcode scanning module	None	Optional
Memory	40000	60000
RUO parameter	None	*ALY#, *ALY%, *LIC#, *LIC%,*NRBC%,*NRBC#,*PLT Clumps%,*PLT Clumps#
Other parameter	24 parameters	24 parameters+ P-LCC, P-LCR

A.7. Performance Indicators

A.7.1. 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.7.2. 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.7.3. Linearity Range

Whole blood mode linearity requirements:

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～100×10^{9}/L	≤ ±5%
	100.01×10^{9}/L～500×10^{9}/L	≤ ±10%
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

Parameter	Linearity Range	Deviation Range (Whole Blood)
	101×10^9/L～1000×10^9/L	≤ ±8%
	1001×10^9/L～5000×10^9/L	≤ ±12%

Prediluted mode linearity requirements:

Parameter	Linearity Range	Deviation Range (Prediluted)
WBC	0.00×10^9/L～10.00×10^9/L	≤ $\pm0.5\times10^9$/L
	10.01×10^9/L～100×10^9/L	≤ ±5%
	100.01×10^9/L～500×10^9/L	≤ ±10%
RBC	0.30×10^{12}/L～1.00×10^{12}/L	≤ $\pm0.05\times10^{12}$/L
	1.01×10^{12}/L～8.00×10^{12}/L	≤ ±5%
HGB	0g/L～70g/L	≤ ±2g/L
	71g/L～250g/L	≤ ±3%
PLT	0×10^9/L～100×10^9/L	≤ $\pm10\times10^9$/L
	101×10^9/L～1000×10^9/L	≤ ±10%
	1001×10^9/L～5000×10^9/L	≤ ±12%

A.7.4 Accuracy

Parameter	Range	Deviation Requirement
WBC	3.5×10^9/L～9.5×10^9 / L	≤±10%
RBC	3.8×10^{12}/L ~ 5.8×10^{12}/L	≤±6%
HGB	115g/L ~ 175g/L	≤±6%
MCV	82fL～100fL（MCV）or 35% ~ 50%（HCT）	≤±7%
PLT	125 $\times10^9$/L ~350×10^9/L	≤±15%

A.7.5. Carryover

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

A.7.6. Reproducibility

Whole blood sample reproducibility requirements:

Parameter	Detection Range	Whole Blood Reproducibility (CV/absolute deviation d)
WBC	4.0×10^9/L～15.0×10^9/L	≤ 2.0%
Neu%	50.0%～70.0%	≤ ±4.0(d)
Lym%	20.0%～40.0%	≤ ±3.0(d)
Mon%	5.0%～10.0%	≤ ±2.0(d)
Eos%	2.0%～5.0%	≤ ±1.5(d)
Bas%	0.5%～1.5%	≤ ±0.8(d)
RBC	3.50×10^{12}/L～6.00×10^{12}/L	≤ 2.0%
HGB	110g/L～180g/L	≤ 1.5%
MCV	70fL～120fL	≤ 1.0%
PLT	100×10^9/L～149×10^9/L	≤ 5.0%
	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	4.0×10^9/L～10.0×10^9/L	≤ 4.0%
Neu%	50.0%～70.0%	±8.0(d)
Lym%	20.0%～40.0%	±6.0(d)

Parameter	Detection Range	Prediluted Sample Reproducibility (CV/absolute deviation 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～5.50×10^{12}/L	≤ 2.0%
HGB	110g/L～160g/L	≤ 2.0%
MCV	80fL～100fL	≤ 3.0%
PLT	100×10^{9}/L～300×10^{9}/L	≤ 8.0%

A.8. 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.8.1. 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.8.2. Mouse (Standard)

A.8.3. External Barcode Scanner (Optional)

A.8.4. Printer (Optional)

A.8.5 Interfaces

4 USB ports

1 network port, compatible with TCP / IP protocol

1 DB9 serial port

A.9. Fuse

⚠WARNING

Be sure to use the specified fuse only.

Fuse specification: 021806.3MXP, 6.3A250V, Φ5*20

A.10. Over-temperature Protection Device

Analyzer over-temperature protection device specification: 90℃±5℃, 4A/DC12V

Inspection instructions: The inspection cycle of the over-temperature protection device is 36 months. If the machine has been used for this cycle, please contact the company's after-sales service department for regular inspection of the over-temperature protection device.

A.11. 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.12. Sound Pressure

Maximal sound: 65 dBA

NOTE

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

A.13. Operating Environment

- Optimal operating temperature: 10□～30□
- Optimal operating humidity: ≤85%
- Atmospheric pressure: 70kPa～106kPa

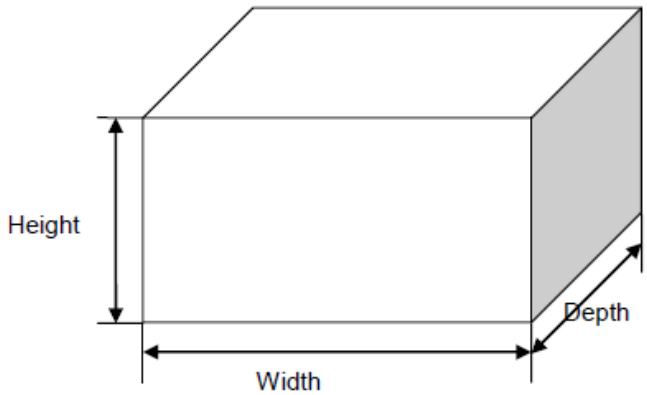
A.14. Storage and Transportation Environment

- Ambient temperature: -10□～55□
- Relative humidity: ≤93%
- Atmospheric pressure: 50kPa～106kPa

A.15. Running Environment

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

A.16. Dimensions and Weight



Dimensions	Width(mm) ≤ 350 Height (mm) ≤ 430 (without foot) Height (mm) ≤ 450 (with foot) Depth (mm) ≤ 430
Weight	28Kg

A.17. Safety Classification

Overvoltage category: II

Pollution degree: 2

Means of protection: Class I

A.18. Software Version

A.19. Training

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

A.20. Contraindications

None

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.