

User Manual

Auto 3-Diff Hematology Analyzer TEK5000P

DRAWELL
A r t i s t o f S c i e n c e

Please read the manual before installation and operation.

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Declaration

DRAWELL has the final interpretation of this manual. In the case of satisfying all of the following requirements, DRAWELL will consider to deal with product safety, reliability and function:

- Assembling operation, expand, readjust, improvement and repair will be in progress by the professionals accepted by DRAWELL.
- All maintenance involving replacement of components and supporting the use of accessories, consumables are DRAWELL company Original or approved by DRAWELL.
- Related electrical equipment meets the national standards and the requirements of this manual.
- Product operation will follow this manual.

Guarantee period:

Products have no fixed use period, the product period is affected by using frequency, standardized operation and the impact of maintenance, consumables period follow its own period.

Warranty and maintenance services:

One year after the installation date, the main accessories warranty is also one year (except as otherwise provided). Consumables: refers to what is needed to be replaced after each use disposable consumable materials or periodic replacement of consumable materials, it has no warranty. If the guarantee period is different with above standard period or has other agreements in the contract between the dealer and you, please consult and confirm via calling DRAWELL service number 0791-88111613, without DRAWELL's confirmation, please contact and confirm with the dealer on time.

Product warranty period is from accompanying "equipment warranty card" "installation date" written on starting, "equipment warranty card" is the only proof computing warranty period. To protect your rights, please urge your staff send back the second page of "equipment warranty card" to DRAWELL within 30 days after install the machine. If you do not send it back on time, the warranty dates will be accounted after 45 days based on the dates of package box date.

During the warranty period, machines are free to accept after-sale service. But please pay attention, even during the warranty period, if the following situation occurs, DRAWELL will charge the maintenance and parts cost.

- The trouble caused by grid voltage exceeds a predetermined range of products
- The trouble caused by wild operation, using by mistake, operation by mistake.
- The trouble caused by removing, transporting, installation procedure and means which not permitted by our company.
- The trouble caused by man-made damage.
- The trouble caused by fire, earthquake, wind harm, flood, lightning strike, crime, terrorism, war and other irresistible natural disasters.

And other non-product itself caused the fault. After the warranty expires, DRAWELL company can continue to provide service in charge.

If you delay to pay for the maintenance charge, DRAWELL will suspend the service.

▲WARNING

- The system is limited to the company or through agents trained after DRAWELL's testing professionals, doctors or experimenters to operate.
- 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 person injury.
- 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.

▲CAUTION

- This equipment must be operated by skilled/trained clinical professionals.
 1. who operate the system daily
 2. who maintain and repair the system
 3. who learn to operate the system
-

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Charper1 Using This Manual

1. 1Introduction

This chapter explains how to use your TEK5000P operator's manual, which is shipped with your TEK5000P 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 TEK5000P analyzer and operate your TEK5000P analyzer strictly as instructed in this manual.

1.2 Who Should Read This Manual

This manual is intended to be read by clinical laboratory professionals. This equipment must only be operated by skilled/trained clinical professionals. This information contains information for clinical laboratory professionals to:

- Learn about the TEK5000P hardware and software.
- Customize system settings.
- Perform daily operating tasks.
- Perform system maintenance and troubleshooting.

1.3 How to Find Information

This operator's manual comprises 12 chapters and 4 appendices. Refer to the table below to find the information you need.

If you want to learn ...	you could see ...
application and measuring parameters of the analyzer	Chapter 3
the structure, interface and software	Chapter 3
test method and principals	Chapter 4
the requirements of installation	Chapter 2
how to set the date format, parameter units, etc.	Chapter 5
how to collect the sample and analysis the sample	Chapter 6
daily operates	Chapter 6
how to review the samples' result	Chapter 7
how to do quality control	Chapter 8
how to do calibration	Chapter 9
how to maintain and check the analyzer	Chapter 10
how to solve the problems	Chapter 11
how to edit the report printing format	Chapter 12
the specifications of analyzer	Appendix A
the toxic and hazardous substances and elements	Appendix B

1.4 Conventions used in this manual

This manual uses certain typographical conventions to clarify meaning in the text:

Format	Indication
[××]	All capital letters enclosed in[] indicate a key name on the analyzer or external keyboard, such as [ENTER]
“××”	Bold letters included in“”indicate text you may find on the screen of analyzer, such as “Clean”
× ×	bold letters indicate chapter titles, such as Chapter1 Using this manual

All illustrations in this manual are provided as examples only. They may not necessarily reflect setup of the TEK5000P or data displayed.

1.5 Safety Information

The following symbols are used to indicate danger and alert information in this manual.

when you see	meaning
	Read the statement below the symbols. The statement is alerting you to a potentially biohazardous condition.
 WARNING	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
 CAUTION	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
NOTE	Read the statement below the symbol. The statement is alerting you to information that requires your attention.



All the samples, control, 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.

If leak happens to the analyzer, the leak liquid is potentially biohazardous.

▲CAUTION

Please check the firmness of all the doors and covers before running the analyzer.
Make sure all the safety measurements are adopted. Disable any safety device or sensor is prohibited.

Please take action to any alarm and problem indication immediately.

Do not touch the moving parts.

Contact DRAWELL or DRAWELL-authorized distributors in time if any damaged part is found.

Be careful when opening /closing and removing/installing the doors, covers and boards of the analyzer.

Discard the analyzer according to government regulations.

▲WARNING

- Please use the equipment strictly according to the instructions in the user's manual.
 - Please do not install software without DRAWELL license on the instrument to prevent software virus and damage.
-

1.6 When you see ...

You will find the following symbols in this manual:

When you see	Meaning
	Read the statement below the symbols. The statement is alerting you to a potentially biohazardous condition.
 WARNING	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
 CAUTION	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
 NOTE	Read the statement below the symbol. The statement is alerting you to information that requires your attention.

You may find the following symbols of the analyzer system:

When you see	Meaning
	CAUTION, CONSULT ACCOMPANYING FILES
	BIOLOGICAL RISK
	EXERCISE CAUTION WHEN WORKING AROUND TO AVOID PRICKING

	PROTECTIVE EARTH(GROUND)
	ALTERNATING CURRENT
	FOR IN VITRO DIAGNOSTIC USE
	BATCH CODE
	EXPIRES TILL
	SERIAL NUMBER
	MEASUREMENT MARK
	MANUFACTURING DATE
	MANUFACTURER
	STORAGE TEMPERATURE
	CONSULT THE MANUAL
	CARRIAGE NOTICE
	NO RAINDROPS
	THIS SIDE UP

	FRAGILE
	NO SUN SHINE
	HIGH VOLTAGE
	WEEE COMPLAINT
	CE COMPLAINT
	RECYCLE IN 10 YEARS

Chapter 2 Installation

2.1 Introduction



➤ By DRAWELL company without being authorized or training of personnel out of the box or may cause personal injury or implement the installation process damage of the

~~host. Please do not present in DRAWELL company authorized personnel cases out of the the installation host.~~

The analyzer has been strictly inspected before launching. In order to avoid delivery hit, analyzer was carried out before shipping discreet packaging. When analyzer after the arrival of the goods, please carefully check the packaging of the analyzer, to see if there is physical injury, damage, if any, please immediately notify DRAWELL company's after-sales service agents or region.

2.2 Installation requirement

2.2.1 Space requirement

Ensure the needed space for repair and maintenance. Considering the normal flow of reagents without affection of instrument heat dissipation or squeezed liquid fluid conduit at the back of the host, the host installation must meet:

the reserved space between Host left and right side doors and the wall ≥ 100 cm

the reserved space between Host backboard and the wall ≥ 50 cm

Ensure there are enough space on the operating table and under the host, to place the sheath fluid stream, enzyme cleaning fluid and waste water containers.

2.2.2 Power supply

▲WARNING

- The host must be used under conditions of good grounding
 - Make sure the input voltage meet the instrument requirements, before turning on the host
-

▲CAUTION

- Using power strip may incur additional electrical interference and lead to erroneous results. Please place the host near electrical socket to avoid using power strip.
 - Please use the supplied power cord. Other power cords may damage the host or cause erroneous results.
-

	Voltage	Input Power	Fuse	NEWSUN (CR2032)	Frequency
Analyzer	100~240V	150VA	250VT2AL	3V	50Hz / 60Hz

2.2.3 Environment conditions

- Working temperature range: 10 C~35 C
- Working humidity range: not exceeding 90%
- Working atmospheric pressure: 70 kPa~106 kPa
- Environment should be without dust, mechanical vibration, pollution, big noise source and power disturbances.
- Assess the electromagnetic environment of the laboratory is recommended, before operating the equipment.
- Do not place the device near strong electromagnetic interference sources, to avoid affecting the normal operation of equipment.
- Do not be close to brush type motors, flicker fluorescent lights and frequent switched electrical contact device.
- Avoid direct sunlight and avoid placing it in front of heat source and air source.
- Select a well-ventilated place.
- Do not put the hosts on an incline.

2.2.4 Transporting and installing methods

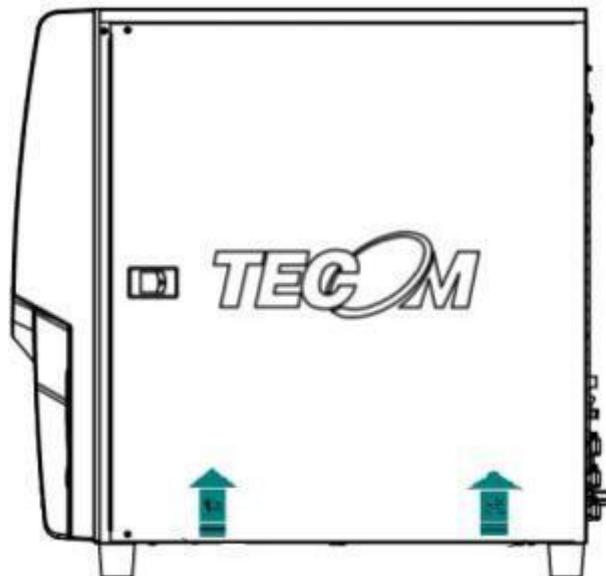
▲ CAUTION

- Transporting or installing the host by DRAWELL unauthorized personnel may cause personal injury or damage the host. Do not open the package or install the host, if DRAWELL authorized personnel are not present.
-

▲ WARNING

- In order to avoid damaging sampling component during the transport, we fasten them with a cable tie and clip when the instrument is shipped from our factory. Please remove cable ties and clips, before using the instrument.
-

The analyzer should be transported and installed by DRAWELL authorized & trained personnel. Do not transport or install the analyzer before contact DRAWELL service department or DRAWELL Agents.



2.3 System Connection

Before installation, please refer to the environmental instructions of the instrument to ensure that the instrument is used in a suitable environment.

The installation of the analyzer is carried out by our company or our distributor, or by trained technicians.

1. The installation of the analyzer shall be carried out by our company or our agent.

Unpack the instrument carefully and check the appearance. If there is any damage in handling, please declare it immediately. Check the instrument and check the packing list to ensure complete configuration. If you find that the configuration is incomplete, please inform DRAWELL company or your local distributor immediately.

If the user moves the equipment by himself, even if it is within the warranty period, it is not covered by the warranty. Please pay attention to this.

2. Ground wire

The power cord of the instrument adopts three pin plug. If there is a grounding jack on the power socket and the grounding Jack has been well connected with the protective ground wire, it can be directly inserted into the plug for use. If there is no grounding jack or the grounding Jack has been connected to the protective ground wire, the instrument shell must be grounded with an adapter.



Warning : caution, danger

- The instrument must be protected and grounded, otherwise it will cause electric shock hazard and instrument performance damage.

Power supply voltage stabilization

AC power supply of ~ 220 V and 50 Hz is required for the instrument, and the fluctuation is required to be within $\pm 10\%$.

Take out the power cord from the packing box, plug the power cord socket into the power input socket on the back of the instrument, and connect the power cord plug into the network power socket.

The instrument shall use special power supply and be used under the condition of stable voltage. Qualified users should be equipped with high-precision power supply.



Never plug the power plug into the power socket other than the specified power supply, otherwise, fire and electric shock will be caused.

When installing the instrument, the shell (case) or power supply must be grounded, otherwise the performance of the instrument will be unstable and the possibility of electric shock will be caused. Do not use the gas pipe as the grounding device.

Do not place heavy objects or pull hard on the power line, otherwise it will damage the power line, cause short circuit or disconnection, and cause fire or electric shock.

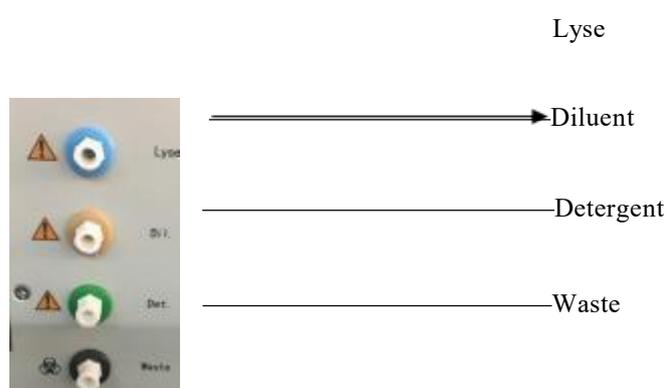
Pipeline connection

Take out diluent, hemolytic agent, cleaning solution and waste liquid pipe from accessory bag. One end is connected according to the pipeline interface mark at the back of the instrument, and the other end is connected with reagent (or waste liquid) tank. Please pay attention to the identification of each interface of the reagent pipeline, do not connect the wrong reagent, at the same time, protect the pipeline, do not let the pipeline fold.

NOTE

- Please make sure that the length of diluent and waste liquid pipes used is not more than 1500mm, and the lengths of all hemolytic and cleaning liquid pipes are not more than 850mm.

As shown in the figure below, connect the reagent pipeline.



5. Installation of consumables and options

1) Installation of printing paper

Thermal printer is used in the instrument, and the type and specification of printing paper are $57 \times 33\text{mm}$. According to the model of the selected thermal printer, the installation method of the built-in printing paper is also different. The user should refer to the corresponding operation method according to the printer model on the instrument.

Thermal printer printing paper installation method:



- 1、 **Open**Button 2、 **POWER**
- 3、 **STATUS** 4、 **FEED**

- ① Grasp the inverted slots on both sides of the upper cover plate and break them off
- ② Put the heat sensitive surface (smooth surface) downward, put the printing paper into the paper slot, expose a certain paper head, and then cover the upper cover plate; the thermal printing paper has both positive and negative sides, and only the front (smooth surface) can display the printing content

Introduction of indicator lights and keys

POWER (green/blue)	FEED (red)	Printer Status
OFF	OFF	Power- off
On	flashing	No paper
On	On	Available
With power on, press and hold the feed key		Feeding paper
Press and hold the feed key in the shutdown state, then turn on the power button at the same time, and then release the feed key after two seconds		Self- check

2) Installation of options

NOTE

Do not plug and unplug printers, bar code scanners, keyboards, mice and other devices in the boot state.

The specified external equipment must be used.

The equipment connected to the analyzer complies with CISPR 11 class I and class B standards.

The keyboard and mouse are directly connected to the keyboard / mouse interface of the analyzer; the printer is the specified model. Make sure that the instrument and printer are in the shutdown state, and then connect the interface of the specified printer to the printer parallel port or USB interface on the back of the instrument.

Chapter 3 Understanding your analyzer

3.1 Introduction

This chapter introduces test parameters, main parts, operation interface, operation software, report setup and supplementary reagent of TEK5000P auto hematology analyzer.

Parameter	Abbr.	Default Unit
White Blood Cells	WBC	$10^9 / L$
Lymphocytes	LYM#	$10^9 / L$
Mid-sized Cells	MID#	$10^9 / L$
Granulocytes	GR#	$10^9 / L$
Percentage of Lymphocytes	LY%	%
Percentage of Mid-sized cells	MID%	%
Percentage of Granulocytes	GR%	%
Red Blood Cells	RBC	$10^{12} / L$
Hemoglobin	HGB	g/L
Hematocrit	HCT	%
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L
Red Cell Distribution Width – Standard Deviation	RDW-SD	fL
Red Cell Distribution Width – Coefficient of Variation	RDW-CV	%
Platelets	PLT	$10^9 / L$
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	_____
Plateletcrit	PCT	%
Platelet Large Cell Ratio	P-LCR	%
Platelet Large Cell Count	P-LCC	$10^9 / L$
WBC Histogram	WBCHistogram	_____
RBC Histogram	RBCHistogram	_____
Platelet Histogram	PLTHistogram	_____

3.2 Parameters

NOTE

■ . . . This analyzer is using filtered clinical examination equipment. When make clinical judge according to analysis result, the doctor need consider clinical examination result or other test result in the meantime

The analyzer offers the below 21 parameters, 3 histograms

Parameters	Abbr.	Whole Blood Mode	Blood Mode	Prediluted Mode	CBC
White Blood Cells	WBC	*	*	*	*
Lymphocytes	LYM#	*	*	*	/
Mid-sized Cells	MID#	*	*	*	/
Granulocytes	GR#	*	*	*	/
Percentage of Lymphocytes	LY%	*	*	*	/
Percentage of Mid-sized cells	MID%	*	*	*	/
Percentage of Granulocytes	GR%	*	*	*	/
Red Blood Cells	RBC	*	*	*	*
Hemoglobin	HGB	*	*	*	*
Hematocrit	HCT	*	*	*	*
Mean Corpuscular Volume	MCV	*	*	*	*
Mean Corpuscular Hemoglobin	MCH	*	*	*	*
Mean Corpuscular Hemoglobin Concentration	MCHC	*	*	*	*
Red Cell Distribution Width – Standard Deviation	RDW-SD	*	*	*	*
Red Cell Distribution Width – Coefficient of Variation	RDW-CV	*	*	*	*
Platelets	PLT	*	*	*	*
Mean Platelet Volume	MPV	*	*	*	*
Platelet Distribution Width	PDW	*	*	*	*
Plateletcrit	PCT	*	*	*	*
Platelet Large Cell Ratio	P-LCR	*	*	*	*
Platelet Large Cell Count	P-LCC	*	*	*	*
WBC Histogram	WBCHistogram	*	*	*	*
RBC Histogram	RBC Histogram	*	*	*	*
Platelet Histogram	PLT Histogram	*	*	*	*

NOTE

➤ “*” means offering in this test mode , “/” means not offering in this test mode.

3.3 Product description

▲ CAUTION

- It may be making the analyzer infect virus, cause system damage or data error if you install other software in the attached equipment or use for other usage (such as playing games, go internet). So please be sure that the attached equipment only match up working for the analyzer.
-

3.3.1 Instrument

The instrument is using for analyzing and data processing.

Throughput: ≥ 60 samples/hour

3.3.2 Power/status light

Power/status light is located on the middle position of instrument's front left, it is using for indicating the instrument's status, such as ready, running, error, sleep, shutdown and so on.

3.3.3 Power switch

Power switch is located on the back side of the instrument, which is using for turning on or off the instrument.

NOTE

- Don't turn on and off the instrument repeatedly in a short time, which may damage the instrument.
-

3.3.4 [Start] Button

It is located in the front right position of the instrument, which is using for starting sample analysis, adding diluent, or awaking from the sleep mode.

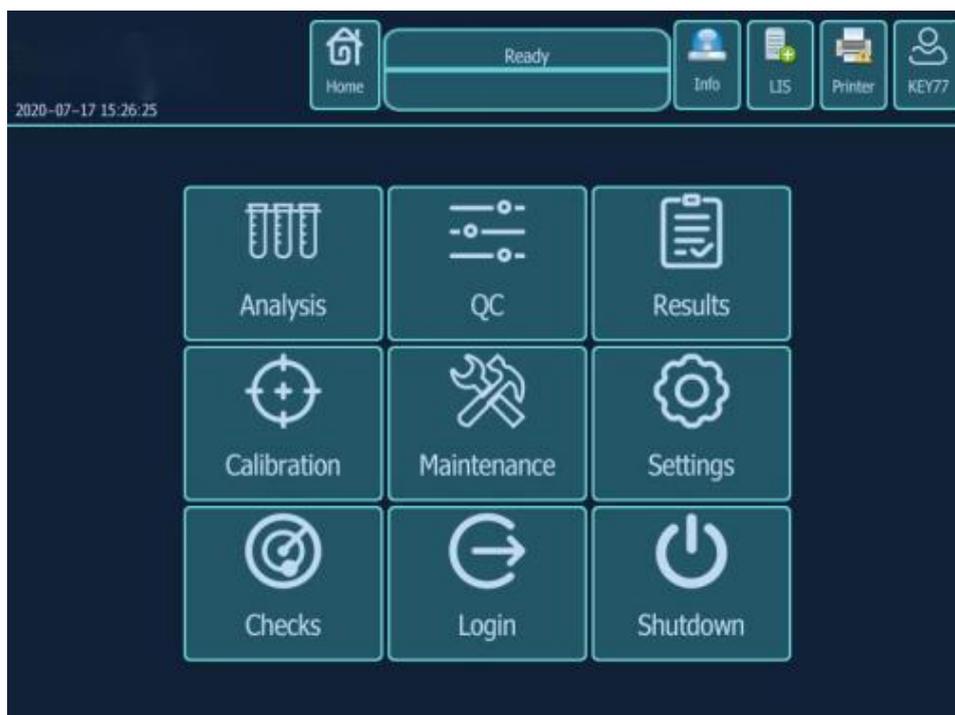
3.3.5 Network port

There is one network port on the back of the instrument, which is using for connecting with other equipment.

3.4 Operating System

3.4.1 Main menu

After finishing start, the user could login to the following menu.



The corresponding function menu buttons are shown in the following table:

Primary Menu	Sub Menu	Third Menu	Primary Menu	Sub Menu	Third Menu
Home			Maintenance	Reagent	Overall guidance
Status					Refill Diluent
Device					Refill Detergent
Printer					Refill Lyse
LIS				Daily	Aperture flush
Analysis	Whole Blood	Samples			Soaking wash
		Results	front back		

					flush
		Prompt			High pressure
		Patient			Search
		Audit			First
		Delete			Next
		Print			Previous
	Pre- diluted	Samples		Last	
		Results		Query	
		Prompt		First	
		Patient		Next	
		Audit		Previous	
		Add diluent		Last	
		Delete		Running Script	
		Print		restore data	
	QC	QC		Test	Data
Print			Import data		
Export			Upgrade update		
Value			Update Control board		
L-J			Update Counter board		
R			Assembly		
X			About		
Save			Settings	Parameters	Parameters
Cancel					Range
Delete					Units

	QC Set	Add		Sample	Boundary	
		Delete			Department	
		Cancel			Inspection	
		Save			Patient	
	XB	Data		Note		
		X-B Chart		Status		
	XB Set	Add		Diagnosis		
		Delete		Setting	System	
		Cancel			Comm	
	Save	Factory				
	Para	undo		Print		
		Save		RFid		
	Results	Results		Calculate	Account	Time
				Unaudit		Wifi
				Print		Up
				Send		Add
查询			Delete			
Search		Inquire	Cancel			
		Count	Save			
		Export	Down			
		First	LIS	Basic		
		Previous		Code		
		Next		Intruccion		
		Last		Pathological	add	

Calibration	Manual	Mode			delete	
		Save			cancel	
		Cancel			save	
	Automatic	Mode			Certification	
		Add diluent			Activated	
		Save	Checks			
		Delete	Login	Operator login		
	Add	Auditor login				
	Calibrator	Delete	Shutdown			
		Cancel				
		Save				
	History					

3.4.2 Information

After entering the test interface, you can see the public information on the interface. According to the function, the interface can be divided into the following areas, as shown in the following figure:



1 - sample information list area

When the mouse clicks the button in this area, the system will immediately enter the corresponding interface or pop-up dialog box.

2 - sample processing area

Located in the middle of the interface, from top to bottom are:

1) Result information selection

2) Sample information prompt (pathological indication of sample)

3) Sample information input selection

4) Sample review

5) Sample printing

6) Sample deletion

3 - click to return to the main interface

4. Display the current mode and sample test status

3.5 Software

Before using the software matching with the analyzer, please make sure that you are familiar with the following basic operations or the meaning of the interface display.

3.5.1 Reagent Prime

1. Check whether all pipelines are connected properly, including diluent, cleaning solution, hemolytic agent and waste liquid pipes.
2. Click "reagent guide" in "maintenance" of the main menu.
3. Choose "comprehensive guidance".
4. Click "execute reagent guidance" below.
5. Then the guided reagent operation can be carried out.

3.5.2 Blank test

1. Click "mode switch", select "blank mode", and click "OK".
2. Click the [sampling key] to test.
3. After the test is completed, check the results. If not, test several times more.

3.5.3 Sample test

1. Click "exit mode" in "sample test" in the menu bar.
2. Click "mode switch" in the menu bar again to select the required test mode, such as whole blood continuous test or pre dilution continuous test.
3. Click "OK" to enter the test interface.
4. Test samples directly.

3.5.4 Historical data query and statistics

1. Click "historical data" in "data query" in the menu bar to enter the historical data query interface.
2. Select the time period to query, for example:
3. Click "search" and the historical data will appear.
4. Select the required data in the historical data, and then click "Statistics", and the statistical results window will appear.

3.5.5 Calibration

1 . Manual Mode

- 1) Test the same sample continuously.
- 2) Statistics, calculate the mean and target deviation, and then manually calibrate according to the proportion.
- 3) Different samples were measured again, and the measured values were compared with the target values. If it's about the same, it's OK,

2 . Auto Mode

- 1) Select the calibration mode, whole blood continuous or pre dilution continuous.
- 2) Click "add" and enter the item of "calibrator setting".
- 3) Input the calibration target value into the test item corresponding to the reference value.
- 4) Click start.
- 5) Switch the test mode and start the test sample.

3.5.6 Quality Control

There are three quality control management procedures for quality control

1. The whole blood quality control is generally based on the commercial quality control material test results data and graphics quality control management procedures

- 1) By setting the required test items and quality control level of "quality control settings".
- 2) Click "QC receiving" to select test mode.
- 3) Sample test.

2. The floating mean value is generally monitored by the three indexes of MCV, MCH and MCHC

- 1) Quality control settings.
 - 2) After setting, click other places to save automatically.
 - 3) Set the number and type of sample groups, and click "Save Settings".
 - 4) Switch mode, test sample.
 - 5) Check the X-B quality control chart.
3. X-R quality control chart, i.e. mean range control chart

3.5.7 Maintenance

It mainly includes:

- 1) Reagent management, including reagent emergency, reagent guidance and reagent batch number management.
- 2) Daily maintenance, including gem hole washing, soaking cleaning, positive and back washing and high pressure burning.
- 3) Operation log query
- 4) Run log query
- 5) Data maintenance query
- 6) Component maintenance query
- 7) Version number query

3.5.8 Settings

It mainly includes parameter information, sample information, setting information, account management, LIS setting, pathology setting and authentication setting

- 1) Parameter information includes parameter management, reference value range, parameter unit, blank range and landmark setting
- 2) Sample information includes sample diagnosis, sending department, sending doctor and patient type
- 3) The setting information includes system settings, factory settings, print settings and RFID settings
- 4) Account management
- 5) LIS settings
- 6) Pathological setting
- 7) Authentication settings

3.6 Report format and printing

3.6.1 Report format

Open the main program and click "setting information" in "Settings". Enter the "print settings" window and select the type of report printing.

3.6.2 Printing

In the test interface, check the test results first, and then click Print. After the preview check is correct, you can print it.

3.7 Reagents, Controls and Calibrators

The Analyzer, Reagents, Controls and Calibrators constitute a system, must be used as a whole to be sure system's performance. Operator must use DRAWELL specified reagents (See appendix A specification). Or the analyzer may be damaged so that the performance may not reach like user manual describes. Unspecified reagent can not ensure the testing results. The reagents appointed in the user manual is the reagent which analyzer uses supplementary reagent.

Please check the package before using each kinds of reagents. It will effect the reagent quality if the package is damaged, package ensure no damp and leak. If there is damp and leak, don't use the reagent.

▲WARNING

- Please see the reagent's user manual about the reagent usage and storage.
 - Operator should do background detection after change Diluent, Lyse ,Detergent, ensure backgroundvalue is in normal, and get ready for sample analysis.
 - Ensure using the reagent in the reagent expiry date.
 - Reagents should stand for a period of time before use for its stability
-

3.7.1 Reagents

- Diluent
This product is a ph buffer action, appropriate ionic strength and conductivity of the electrolyte solution, used for blood sample dilution, forming a sheath flow, to analysis instrument for blood count, volume measurement and WBC count.
- Lyse

This product is used for blood analysis before the destruction of red blood cells, stripping hemoglobin, dyeing processing, to maintain the required analysis of cellular form, so as to facilitate cell count or the determination of hemoglobin.

■ Detergent

This product contains the surfactant and high levels of proteolytic enzyme solution, used for equipment cleaning and flushing of piping system, can effectively clear the residual blood component and other particles affect blood count.

■ Counting Chamber Cleaning

This product is a kind of maintenance with a cleaning fluid, used for counting chamber cleaning, need to avoid light and save in 2 °C to 8 °C.

3.7.2 Controls and Calibrators

Controls and Calibrators are using for analyzer's quality control and calibration. Controls are a kind of industrial production of whole blood products, using for checking the analyzer's counting function. Controls has low, middle, high levels. Every day run the three levels QC to check analyzer running condition. So that can ensure analysis result reliability. Calibrators are also a kind of industrial production of whole blood products, using calibrate the analyzer. Please see the Controls and Calibrators' user manuals to know the usage and storage conditions.

The mentioned 'Controls' and 'Calibrators' are DRAWELL specified ones in the user menu. User should buy them from DRAWELL specialized agent or DRAWELL Science Corporation.

Chapter 4 System principle

4.1 Introduction

The analyzer uses the electrical impedance method to determine the count and sizedistribution of RBC, WBC and PLT; and uses the colorimetric method to determine HGB. Based on the above data, the analyzer calculates other parameters.

WARNING

■ . . . During the test process, the instrument can not be used for functional operation, but can be consulted. In case of misoperation, a yellow font prompt will pop up at the bottom right of the main page; if other test interfaces are to be carried out, the "exit mode" should be selected first to carry out other operations.

4.2 Aspiration

The analyzer provides 7 analysis modes: Whole Blood, Pre-dilute, Blank, Whole Blood – CBC, Whole Blood – WBC, Whole Blood – RBC, and Whole Blood – HGB.

In the Blank Mode, you could press the [Start] button to test.

If you are to analyze a Whole Blood sample, present the sample to the analyzer directly, and the analyzer will aspirate 9 μL of the whole blood sample.

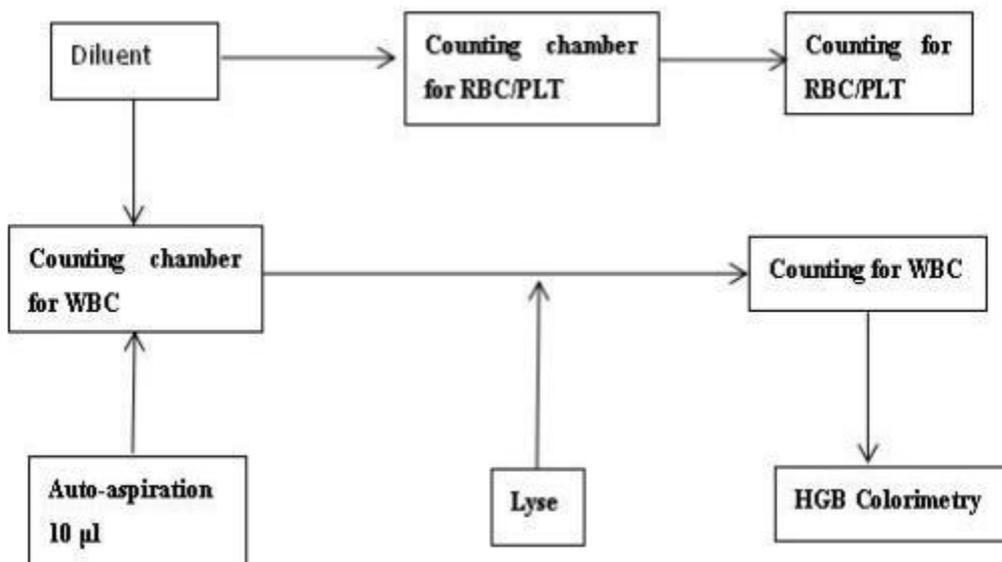
If you are to analyze a capillary blood sample under the pre-dilute mode, you should manually dilute the sample (40 μL capillary sample needs to be diluted by 1 mL of diluent to form a 1:25 dilution).

4.3 Dilution

This section takes CBC + diff mode as an example to introduce the dilution process of samples to be tested in whole blood and pre dilution mode respectively.

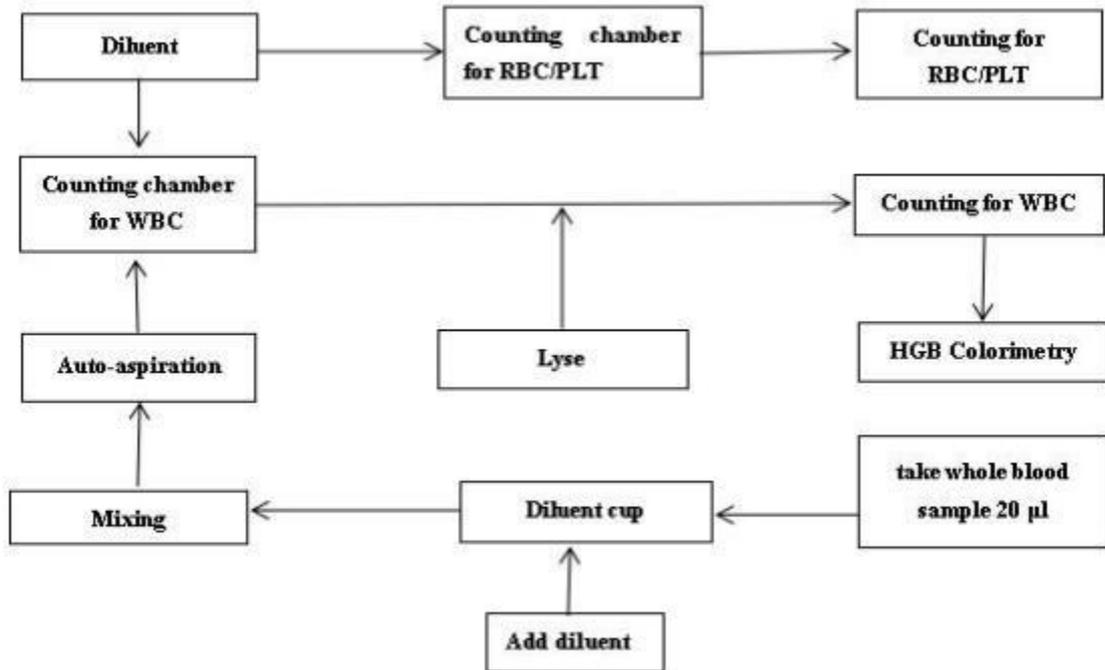
4.3.1 Whole blood ‘CBC+DIFF’ Mode

In CBC + diff mode, the sample to be tested is divided into two parts after being drawn to the host computer, and then the test samples for red blood cell / platelet measurement, white blood cell count / hemoglobin measurement / white blood cell classification measurement are formed after different reagents in the dilution process. As shown in the figure below:



4.3.2 Predilute mode

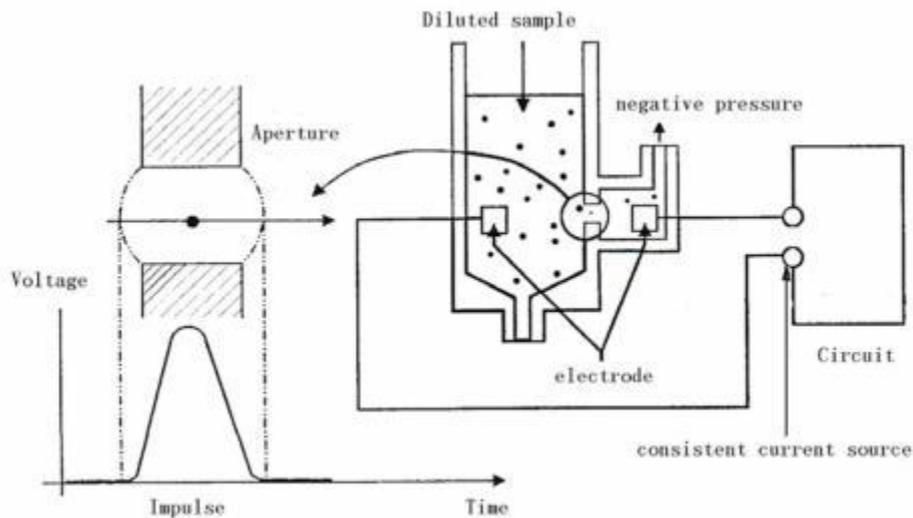
In the pre dilution CBC + diff mode, the sample to be tested is divided into two parts after being absorbed into the host machine, and then the test samples used for red blood cell / platelet measurement, white blood cell count / hemoglobin measurement / white blood cell classification measurement are formed respectively after being acted by different reagents in the dilution process. As shown in the figure below



4.4 WBC Measurement

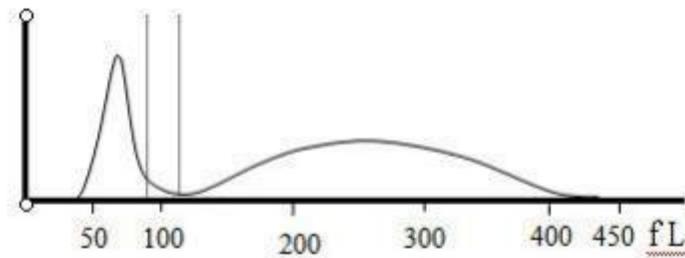
4.4.1 Impedance method

The WBCs are counted by the impedance method. The analyzer aspirates certain volume of sample, dilutes it with certain volume of conductive solution, and delivers the dilution to the metering unit. The metering unit has a little opening which is called "aperture". A pair of electrodes is positioned on both sides of the aperture to create a constant-current supply. As cells are poor conductors, when each particle in the diluted sample passes through the aperture under the constant negative pressure, a transitory change in the direct-current resistance between the electrodes is produced. The change in turn produces a measurable electrical pulse which is proportional to the particle size. And when the particles pass the aperture in succession, a series of pulses are produced between the electrodes. The number of pulses generated indicates the number of particles passed through the aperture; and the amplitude of each pulse is proportional to the volume of each particle.



Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. All the collected pulses are thus classified based on the reference voltage ranges of different channels, and the number of the pluses in the WBC channel indicates the number of the WBC particles. The cell size distribution width is represented by the number of particles falling in each channel

4.4.2 WBC-Related Parameters



Lyses and diluents change the sizes of each type of WBCs in various ways and at different time. The WBCs are thus separated into 3 parts (from the largest size to the smallest): lymphocytes, mid-sized cells (including monocytes, eosinophils, and basophils) and granulocytes.

The analyzer then calculates the lymphocyte percentage (Lymph%), mid-sized cell percentage (Mid%) and granulocyte percentage (Gran%) (all presented in %) based on the WBC histograms and in accordance with below formulae:

$$\text{LYM}\% = \frac{\text{PL}}{\text{PL} + \text{PM} + \text{PG}} \times 100\%$$

$$\text{MID\%} = \frac{\text{PM}}{\text{PL} + \text{PM} + \text{PG}} \times 100\%$$

$$\text{GRA\%} = \frac{\text{PG}}{\text{PL} + \text{PM} + \text{PG}} \times 100\%$$

In the formulae: PL indicates the number of cells falling in the lymphocyte region, PM the number of cells falling in the mid-sized cell region, and PG the number of cells falling in the granulocyte region. All three parameters are presented in $10^9 / \text{L}$.

When the three percentages are obtained, the analyzer automatically proceeds to calculate the lymphocyte number (Lym#), mid-sized cell number (Mid#) and granulocyte number (Gra#) with below formulae, all parameters expressed in $10^9 / \text{L}$.

$$\text{LYM\#} = \frac{\text{LYM\%} \times \text{WBC}}{100}$$

$$\text{MID\#} = \frac{\text{MID\%} \times \text{WBC}}{100}$$

$$\text{GRA\#} = \frac{\text{GRA\%} \times \text{WBC}}{100}$$

Lym%, Mid% and Gran% are expressed in %, while WBC is in $10^9 / \text{L}$.

4.5 HGB Measurement

4.5.1 Colorimetric Method

The HGB is determined by the colorimetric method. The diluted sample is delivered to the WBC count bath where it is bubble mixed with a certain amount of lyse, which breaks red blood cells, and converts hemoglobin to a hemoglobin complex. An LED is mounted on one side of the bath and emits a beam of monochromatic light with 540 nm central wavelength. The light is received by an optical sensor mounted on the opposite side, where the light signal is first converted to current signal and then to voltage signal. The voltage signal is then amplified and measured and compared to the blank reference reading (reading taken when there is only diluent in the bath), and the HGB (g/L) is measured and calculated automatically. The whole measurement and calculation process is completed automatically.

4.5.2 HGB Parameters

HGB is expressed in g/L.

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

4.6 RBC/PLT Measurement

4.6.1 Impedance Method

RBCs/PLTs are counted by the electrical impedance method. The analyzer aspirates certain volume of sample, dilutes it with certain volume of conductive solution, and delivers the dilution to the metering unit. The metering unit has a little opening which is called "aperture". A pair of electrodes is positioned on both sides of the aperture to create a constant-current supply. As cells are poor conductors, when each particle in the diluted sample passes through the aperture under the constant negative pressure, a transitory change in the direct-current resistance between the electrodes is produced. The change in turn produces a measurable electrical pulse which is proportional to the particle size. And when the particle passes the aperture in succession, a series of pulses are produced between the electrodes. The number of pulses generated indicates the number of particles passed through the aperture; and the amplitude of each pulse is proportional to the volume of each particle.

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. All the collected pulses are thus classified based on the reference voltage thresholds of different channels, and the number of the pulses in the RBC/PLT channel indicates the number of the RBC/PLT particles. The cell size distribution width is represented by the number of particles falling in each channel.

4.6.2 RBC-Related Parameters

■ . Red Blood Cell Count

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

■ . Mean Corpuscular Volume

The analyzer calculates the mean cell volume (MCV, in fL) based on the RBC histogram.

■ HCT, MCH and MCHC

The hematocrit (HCT, %), mean corpuscular hemoglobin (MCH, pg) and mean corpuscular hemoglobin concentration (MCHC, g/L) are calculated as follows:

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

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

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

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

■ . RDW-CV

Red Blood Cell Distribution Width - Coefficient of Variation (RDW-CV) is derived based on RBC histogram. It is expressed in %, and indicates the variation level of RBC sizedistribution.

■ . RDW-SD

Red Blood Cells Distribution Width - Standard Deviation (RDW-SD, in fL) measures the width of the 20% level (with the peak taken as 100%) on the RBC histogram.

4.6.3 PLT-Related Parameters

■ . Platelet count

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

■ . Mean Platelet Volume

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

■ PDW

Platelet distribution width (PDW) is derived from the platelet histogram, and is reported as 10geometric standard deviation (10 GSD).

■ . PCT

The analyzer calculates the PCT (%) as follows:

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

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

■ . Platelet-Large Cell Count

P-LCC($10^9 / L$) is measured directly by counting the large platelets passing through the aperture.

■ . Platelet-Large Cell Ratio

Based on the PLT histogram, this analyzer calculates the large platelet ratio (%).

4.7 Wash

After each analysis cycle, each element of the analyzer is washed:

The sample probe is washed internally and externally with diluent;

The baths are washed with diluent;

Other elements of the fluidic system are also washed diluent.

Chapter 5 Settings

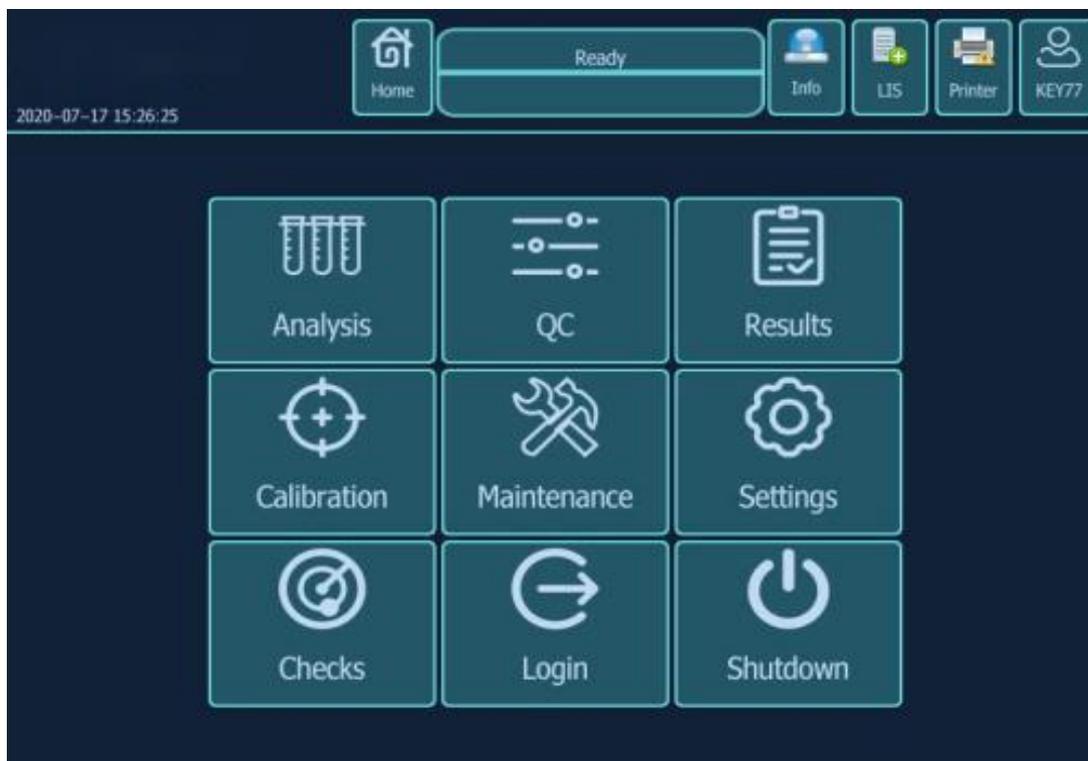
5.1 Introduction

The analyzer has been initialized at the factory, and the user interface after the initial boot is the default of the system. In order to meet the different needs of practical application, some parameters of the analyzer can be reset.

In order to ensure the safety of product settings and data, the analyzer divides the operator into two levels: ordinary user and administrator (administrator has all permissions of ordinary user). The functions of each setting item are described in the following two permission levels

5.2 Ordinary Users

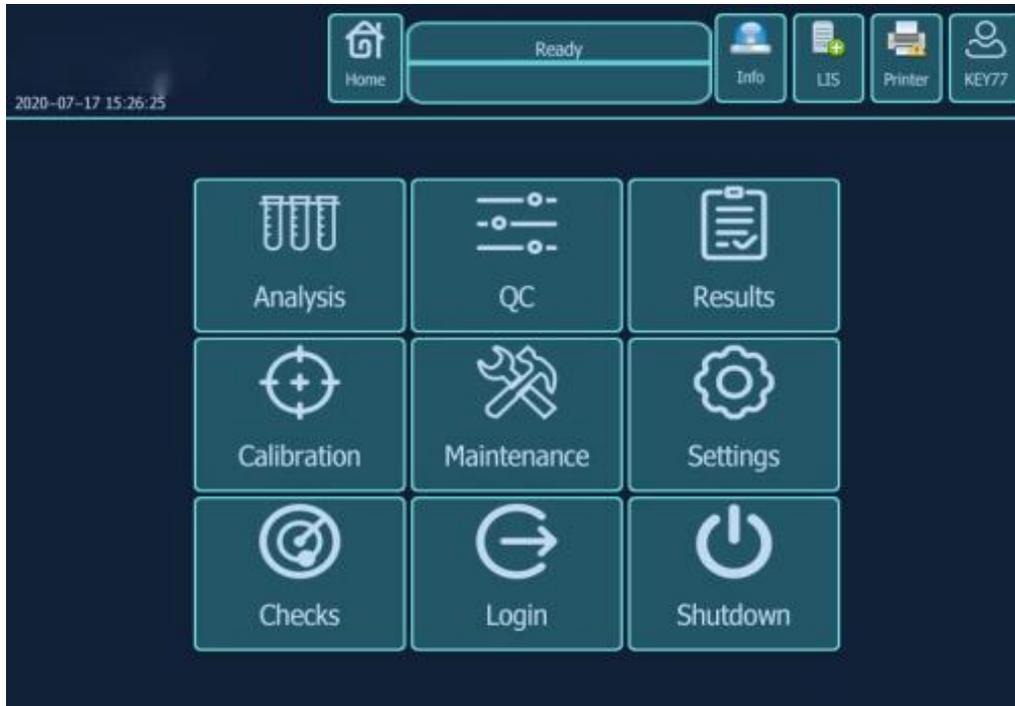
After the operator logs in at the ordinary user level, click "instrument settings" on the main menu to pop up the setting window. As shown in the figure below:



Ordinary users can not set the instrument, only operate and view the results.

5.3 Administration Users

If the operator logs in at the administrator level, the setting interface is as follows:



5.3. 1 Parameter Settings

Click the "Settings" button to enter the following setting interface.

The screenshot shows the 'Parameter Settings' interface. At the top, it has the same navigation bar as the dashboard but with the user profile 'admin'. Below the navigation bar is a table with columns: Parameter, Sample, Setting, Account, LIS, Pathological, Certification, and Activated. The main area is a table with columns: Items, Name, Default unit, and Decimal. The table lists various hematology parameters.

Parameter	Items	Name	Default unit	Decimal
	WBC	WBC	10 ⁹ /L	2
Units	Lym%	LYM%	%	1
	Mid%	MID%	%	1
Range	GR%	GR%	%	1
	Lym#	LYM#	10 ⁹ /L	2
Boundary	Mid#	MID#	10 ⁹ /L	2
	GR#	GR#	10 ⁹ /L	2
	RBC	RBC	10 ¹² /L	2
	HGB	HGB	g/L	0
	HCT	HCT	%	1
	MCV	MCV	fL	1
	MCH	MCH	pg	1
	MCHC	MCHC	g/L	0
	RDW_CV	RDW_CV	%	1
	RDW_SD	RDW_SD	fL	1
	PLT	PLT	10 ⁹ /L	0
	MPV	MPV	fL	1
	PCT	PCT	%	3
	PDW	PDW		1

- . In the Settings, you can add, modify, delete, save and cancel items, abbreviations, names, units, unit coefficients, decimal places, print or not, default reference value range and default pathological reference value.

- . In the reference value setting interface, you can set the reference value range of different categories.

The analyzer has seven reference ranges of general purpose, male, female, child, newborn, infant and quality control and three user-defined reference ranges. The default setting of the analyzer is "universal". Each laboratory should select the appropriate reference range according to the actual sample situation, and set the appropriate reference interval. The reference interval varies with race, gender, age and geographical location.

5.3.2 Sample Information Settings

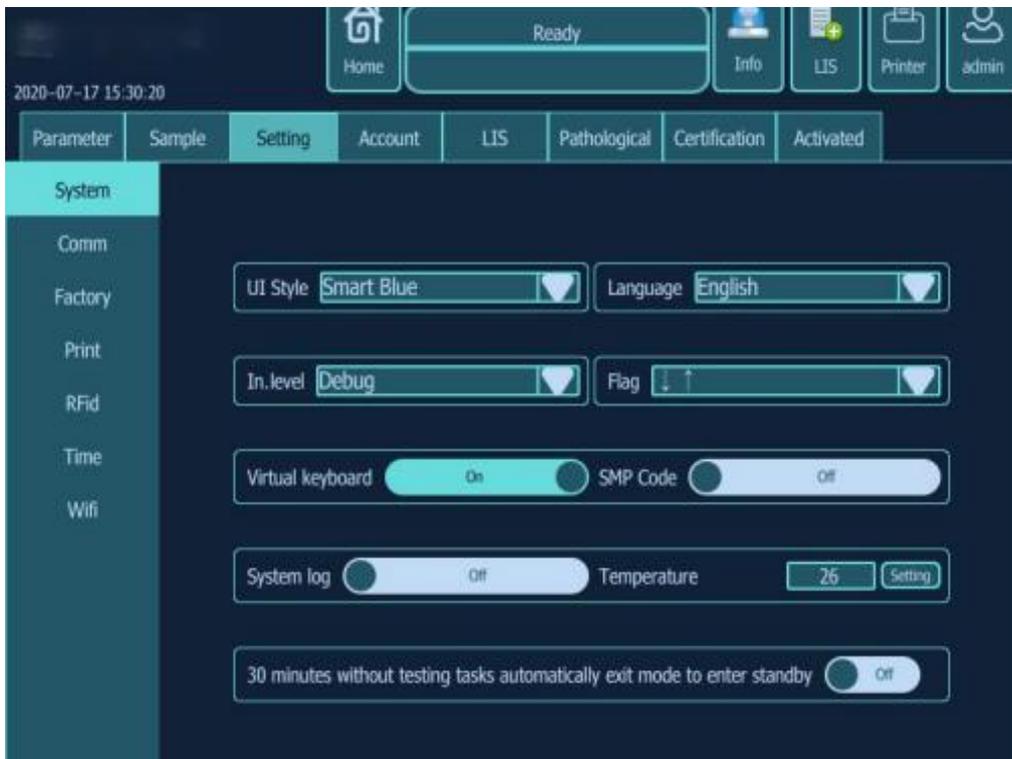
Click “ Sample” to enter the following interface :



- The term type of the sample can be added, and at the same time, multiple mnemonics can be added to the same term type, which is convenient to call in the test interface.

5.3.3 Settings

Click "System" to enter the following interface:



- . In the system settings, you can change the colors and the languages of the system.
- Click “Factory” to enter the following interface:



The instrument can be set up and HGB can be debugged

- Click “Pathological” to enter the following interface:



Pathological ID, activation, type, prompt information and judgment condition can be set.

5.3.4 Account Settings

Click the “Account” button to enter the interface as below:



User's access and passwords can be modified.

Chapter 6 Operating your analyzer

6.1 Introduction

This chapter introduces the whole daily operation process from the opening to closing of the analyzer, focusing on the detailed description of the sample analysis operation process in different working modes.

The daily operation process is as follows:

1. Preparation
 2. Power on
 3. Turn on the analyzer, start the software
 4. Daily quality control
 5. Prepare the sample
 6. Analysis the sample
 7. Power off
- Turn off the analyzer, close the software

6.2 Initial Checks

Before switching on the power supply of the analyzer, the operator must check the system according to the following requirements to ensure that the system is ready.



■ . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.), as well as the areas in contact with these substances, have potential biological infectious risks. When contacting relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc.).



- . . The operator is obliged to comply with the local and national regulations on the discharge and treatment of reagents, waste liquid, waste samples, consumables, etc.
 - . . The reagent can irritate the eyes, skin and mucous membranes. When contacting reagent related articles in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, mask, etc.).
 - . . Once the reagent comes into contact with the skin, wash it with plenty of water immediately. If necessary, ask a doctor for treatment. Once the reagent contacts the eyes, rinse it with plenty of water and receive medical treatment.
 - . Clothes, hair, hands, etc. must be kept at a certain distance from moving parts to prevent being pinched by moving parts.
 - . . The sampling needle is relatively sharp, and the blood sample, quality control material and calibrator that may be carried on the sampling needle have potential biological hazards, so avoid contact with the sampling needle.
-

NOTE

- . . The operator shall use the reagent specified by the company and store and use the reagent in strict accordance with the instructions.
 - . Before using the analyzer, check to make sure that the reagent is connected correctly.
 - . The reagent should be allowed to stand for a period of time before use.
 - . According to the user name and password, the system judges the operator's authority as administrator or ordinary user, and opens different functions in each interface according to the user's authority.
-

- . Check the waste bucket

The operator shall provide the waste liquid tank by himself and make sure that it has been emptied before starting the machine every day.

■ . . . Check liquid pipe and power supply

Check whether the pipeline of reagent and waste liquid is bent and whether the connection is reliable.

Check whether the power plug of the host is safely inserted into the power socket.

■ . . . Check the printer

Check whether the printer paper is sufficient and installed in place.

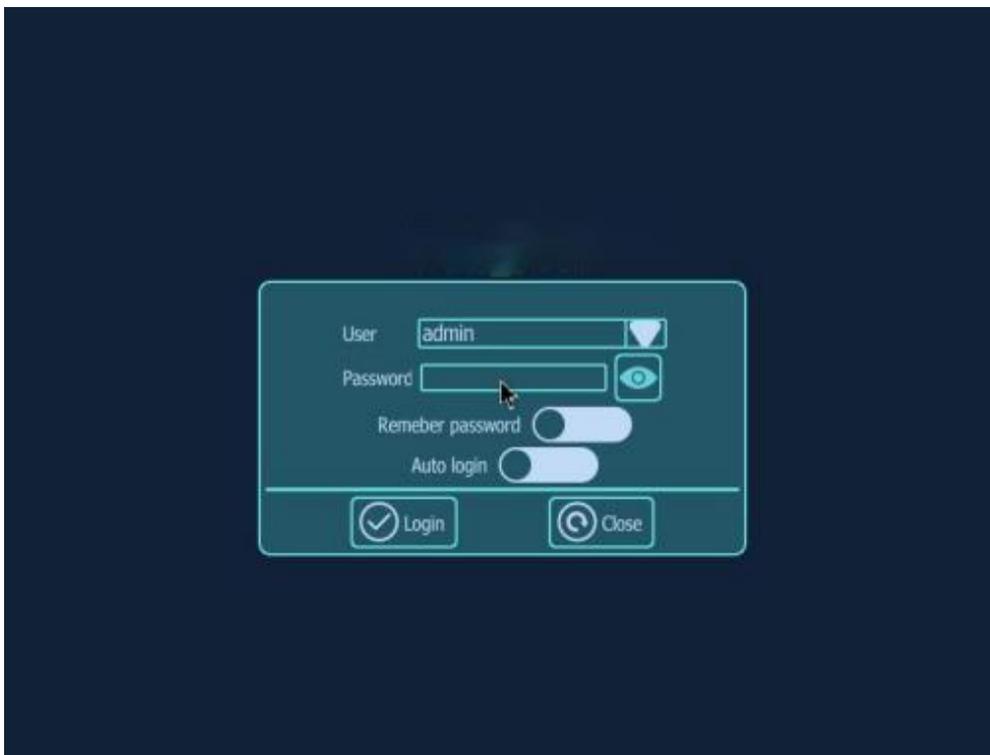
■ . . . Barcode scanner (optional), keyboard, mouse

Check whether the cables of barcode scanner, keyboard and mouse are connected with the analyzer.

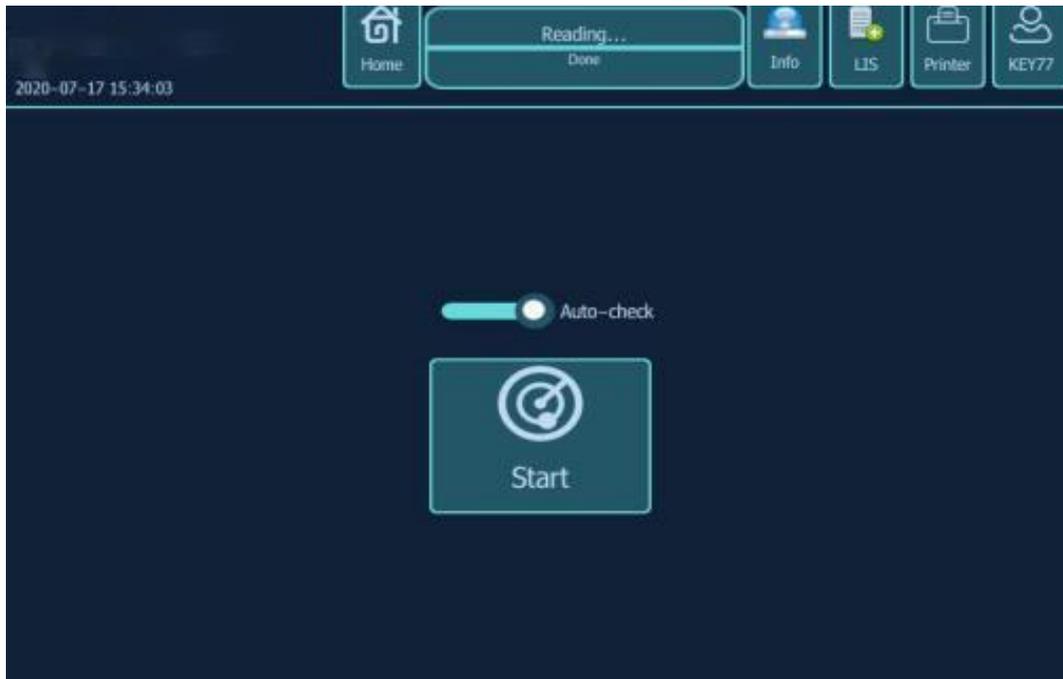
6.3 Startup and logon

6.3.1 Startup

1. Set the "O / I" power switch on the left side of the back of the analyzer to "I".
2. Confirm that the indicator light on the analyzer is on, indicating that the analyzer has been started.
3. After the software starts, the login dialog box as shown below will pop up.



4. Select the user name and password.
5. Click the "login" button to enter the following interface



6. After clicking start, the instrument will run the startup program, and the whole startup process lasts about 3-5 minutes.

7 After the initialization, it will automatically enter the work interface to view the detection results of the boot background.

8. After initialization, if the background is passed, the mode can be switched to test samples.

6.4 Daily Quality Control

Before sample analysis, it is necessary to carry out quality control analysis on the analyzer every day to ensure that the analyzer can get reliable analysis results. See Chapter 8 quality control for specific operation methods of quality control analysis.

6.5 Sample Preparation



■ . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.) and the areas in contact with these substances have potential biological infectious hazards. When contacting relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc.).



■ . Do not contact the patient's blood sample directly.

CAUTION

- . . Do not reuse disposable items.
-

NOTE

- . . The operator should use clean k2edta anticoagulant vacuum blood collection vessel, silica glass / plastic test tube, centrifugal tube and borosilicate glass capillary tube.
 - . . Please use a vacuum blood collection vessel with the size recommended in the appendix.
-

6.5.1 Whole Blood Samples

The whole blood sample preparation steps are as follows:

1. Venous blood samples were collected with k2edta (1.5 ~ 2.2mg/ml blood) anticoagulant vacuum tube.
 2. Quickly mix the venous blood in the tube with anticoagulant.
-

NOTE

- . . In the open injection mode and automatic injection mode, ensure that the whole blood sample volume is not less than 3.0 ml.
-

CAUTION

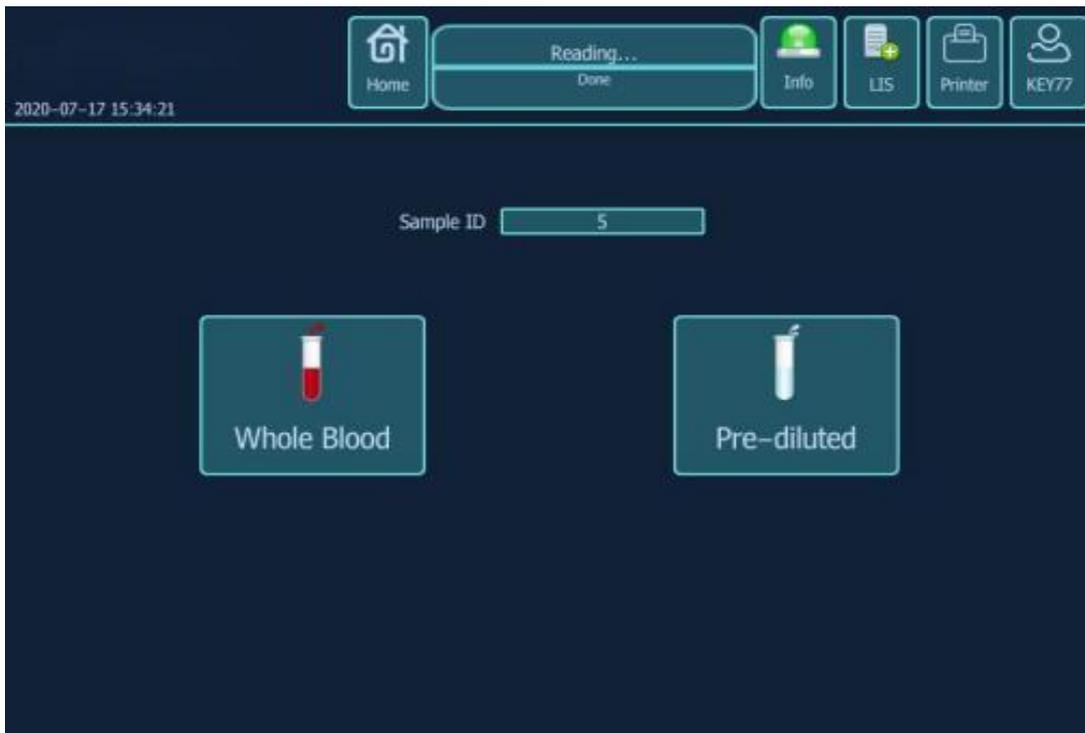
- . . Samples requiring leukocyte classification or platelet count should be kept at room temperature and analyzed within 8 hours of collection.
 - . . If the results of PLT, MCV or leukocyte classification are not needed, they can be stored in refrigerator at 2 °C ~ 8 °C for 24 hours. Refrigerated samples should be kept at room temperature for at least 30 minutes before analysis.
 - . . Samples placed for a period of time should be re mixed before analysis.
-

6.5.2 Pre-diluted Samples

NOTE

- . . For the preparation of pre diluted samples, 1.5ml centrifuge tube should be selected.
-

1. Click the "analysis" button in the main interface, and the following dialog box will pop up ; select "pre-diluted".



2. Take a clean centrifuge tube and place it under the sample aspirating needle obliquely. (about 240 μ l at a time).
3. Click "distribute diluent" in the upper right corner of the host screen, and the instrument will automatically enter the diluent distribution. (about 500 μ l at a time).

NOTE

- Since the instrument needs to inhale a section of air to isolate the diluted blood sample under the pre dilution mode, the amount of pre diluted sample can only be prepared once at a time to prevent the test result from being unstable.
- . . . When adding diluent, the centrifuge tube must lean against the wall of the sample aspirating needle to prevent bubbles or splashing.

4. The peripheral blood of 20 μ l was collected and quickly injected into the centrifuge tube containing diluent. After the cover was covered, the mixture was well mixed.
5. After the diluent is added, press the [START] button on the analyzer to suck the diluted blood sample for testing.
6. To prepare multiple diluents, repeat steps 2-4.

NOTE

- . . . The operator can also use the pipette to suck about 500 μ l diluent.
- . . . The prepared diluent should not be mixed with dust, otherwise it will cause analysis error.
- . . . After the peripheral blood reacts fully with the diluent, it needs to be placed for 3 minutes, and then it can be analyzed after re mixing.
- . . . Make sure that the sample is analyzed within 30 minutes after dilution, otherwise the

analytical results obtained are unreliable.

- . . . Samples placed for a period of time should be re mixed before analysis.
 - . . . Each laboratory should evaluate the stability of sample analysis results in pre dilution mode according to the sample size, sample collection method and technical level.
-

6.6 Sample Analysis Procedures



■ . . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.) and the areas in contact with these substances have potential biological infectious hazards. When contacting relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc.).



■ . . . The sampling needle is sharp, and the blood samples, quality control materials and calibrators that may be carried on the sampling needle have potential biological infectivity, so avoid contact with the sampling needle.



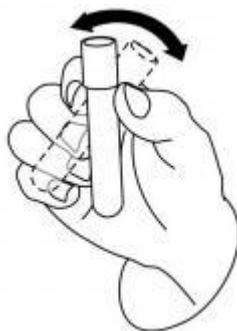
- Do not reuse disposable items.
 - Repeated puncture of the vacuum blood collection vessel will damage the rubber cap, and the fragments may lead to inaccurate analysis results. It is suggested that the number of puncture should not exceed three.
 - Confirm that the input sample number and mode are completely corresponding to the sample to be analyzed.
-



- . . . Do not open the front housing after starting the count.
 - . . . During the sampling process, the sampling needle should keep a certain distance from the bottom of the container, otherwise the accuracy of the inhaled liquid volume will be affected.
 - . . . Before sample analysis, it is necessary to select the appropriate parameter reference value range in the "reference value" drop-down menu, otherwise the default reference range selected by the analyzer is "general", which may cause incorrect alarm prompt.
 - . . . If LIS / his is selected in the setting, after the sample number is scanned in with keyboard input or barcode scanner and saved, all relevant information is read from LIS / his system, and then counting is performed according to this information. After counting, the result data and graphic sample / patient information were uploaded to LIS / his immediately.
-

Whole Blood Mode

1. Select the "whole blood - continuous test" mode, select the reference range of the analysis sample in the reference value drop-down list, complete the input of other sample information, and click "save".
2. When the count is ready (i.e. the status icon and the indicator light of the instrument are yellow and long on), shake the whole blood sample as shown in the figure below to completely mix the sample.



3. Open the cover and insert the sample aspirating probe under the liquid level of the sample.
4. Press the [START] button to start the test.
5. After the analysis, the analyzer will display the analysis results in the analysis results area of the screen, and prepare for the next sample analysis.
6. Follow this procedure to analyze the remaining samples.

NOTE

- In the process of analysis, in case of plugging or bubbles, the analyzer will automatically set the relevant measurement parameters as invalid.
 - The analysis data of research parameters can be viewed by clicking the "instrument parameters" button.
 - After the analysis is started, the sample number will be automatically increased by 1 according to the setting.
-

Pre-diluted Mode

1. Prepare pr-diluted sample diluent.
2. Select "pre dilution" mode, complete the input of sample information, and click save.
3. Open the cover and insert the sample aspirating probe under the liquid level of the sample.
4. Press the [START] button to start the test.
5. After the analysis, the analyzer will display the analysis results in the analysis results area of the screen, and prepare for the next sample analysis.
6. The rest samples were analyzed according to this process.

NOTE

- . In the analysis process, the operator can browse, audit, edit sample information, print and other operations in the work order interface, or switch to other interfaces.
- . During the analysis process, it is not allowed to perform any other functions related to the time sequence of the liquid path.

6.7 Input worksheet data

In the open injection mode and automatic injection mode, the operator can input the work order information of the sample to be analyzed before sample analysis.

NOTE

- Abnormal shutdown will result in the loss of unsaved sample information in the work order.
- . If the operator wants to input complete work order information after analysis, please refer to Chapter 7 result review.

Click the "Analysis" menu, and then click the "worksheet" menu item to enter the following worksheet interface.



After the operator clicks "patient" and enters the basic sample information, click "save" button to add a new record at the top left of the work order list, and the blank

record will be displayed in the list. Each field in the information entry area displays the default value and starts.

- **Input sample ID**

Input the sample ID in the "sample ID" box and click "save".

NOTE

- The sample number allows you to enter letters, numbers, and all characters supported on the keyboard, including special characters.

- The length range of sample number allowed to be entered is [1, 20], which cannot be empty.

- The ending character of the sample number must be a number, but the sample number cannot be all digits "0".

- **Select modes**

In the "sample ID" drop-down list, the optional modes are: n includes "whole blood continuous", "CBC continuous", "HGB continuous", "WBC continuous", "RBC continuous"; P means "Pre-diluted", B means "Blank mode", and A means "automatic injection".

- **Select reference range**

Select the reference range for this sample in the reference value drop-down list. The analyzer will judge the counting result according to the reference range of the selected reference value and give an alarm for the result beyond the normal range. The setting of reference range is shown in the relevant Chapter 5.

NOTE

- . . If the operator inputs the patient's gender and age, the system will automatically match the reference value according to the corresponding relationship.

- . . If the matching reference value is inconsistent with the original reference value selected by the operator, the automatic matching reference value is adopted.

- . **Input Patient ID, Bed ID**

Enter the inpatient number of the patient in the inpatient number box. Enter the bed number of the patient in the bed number box.

- **Input Patient's Names**

Enter the patient's name in the name box.

- **Input Patient's Gender**

Type in the gender box or select the gender of the patient in the gender drop-down list.

- **Input Patient's age**

For patients of different ages, the analyzer provides four age input methods: input by "year", input by "month", input by "day" and input by "hour". It is suitable for: people over one year old,

people with full moon but less than one year old, people born more than one day but less than one month old and people born less than 24 hours. The operator can select the input mode of the patient's age according to the patient's age.

In the "age" drop-down list, select the input method of age as "year", "month", "day" or "hour", and enter the patient's age in the input box before the age unit.

NOTE

- After the date of birth is entered, the age field will be automatically calculated according to the difference between "current system date" and "date of birth", and the newly calculated age value and unit will be displayed in the age value edit box and the unit combination box. At this time, the age edit box is grayed out. After clearing "date of birth", the age edit box will be restarted.

- **Input Sample type**

Type in the specimen name box or select the patient type in the specimen Name drop-down list.

- **Sample Status**

Type in the specimen status box or select the patient specimen category from the specimen status drop-down list.

- **Input the Dept.**

Enter the name of the Department to perform the sample analysis in the sending Department box or in the sending Department drop-down list (when there are records in the drop-down list).

- **Input the Applicant Doctor's, Operating Doctor's, and Audit Doctor's names**

Enter the name of the applying doctor in the apply for doctor box or select the name of the applying doctor from the drop-down list (when there is a record in the drop-down list). Enter the name of the laboratory doctor in the laboratory doctor box or select the name of the laboratory doctor from the inspection doctor drop-down list (when there are records in the drop-down list). Enter the name of the audit doctor in the audit doctor box or select the name of the audit doctor from the audit doctor drop-down list (when there is a record in the drop-down list). ■

Input Diagnostic Result

Enter some suspected diagnostic information in the "diagnosis" box.

- **Input Remark Content**

Enter some information to be declared in the "remarks" box.

- **Input test tube rack number**

Enter the test tube rack in the test tube rack number box

- **Save**

After inputting the work order information, click the "save" button or press the shortcut

key [Alt + S] to save all the current information.

6.8 Analysis result processing

■ Save the analysis result

The analyzer can save the analysis results automatically. When the number of sample results reaches the upper limit of storage, the new sample analysis results will automatically cover the oldest and backup sample analysis results. The maximum storage limit of sample results is 40000.

■ Parameters Alarm

On the right side of the parameter results, the "+", or "t" and "↓" are displayed, which means that the analysis results obtained exceed the preset parameter reference value range, but are still in the display range.

The "?" displayed in the instrument parameters indicates that the analysis results obtained are suspicious.

The analysis result is displayed as "* *", indicating that the measurement result is invalid or beyond the display range.

NOTE

■ The analyzer will not give parameter alarm and classification or abnormal shape alarm for background detection results.

■ Classification or abnormal shape alarm

The analyzer will alarm WBC, RBC and PLT abnormally or suspiciously according to the scatter diagram and histogram. The definition of the prompt information is shown in the table below.

Type	status	Notice information	Judgment Condition
WBC	On	leucocytosis?	[WBC] < [NMIN]
WBC	On	Leukocytosis?	[WBC] > [NMAX]
WBC	On	The number of single cells increased?	[Mid%] > [NMAX]
WBC	On	Monocyte reduction?	[Mid%] < [NMIN]
WBC	On	The number of lymphocytes is reduced?	[Lym%] < [NMIN]
WBC	On	Increase in lymphocytes?	[Lym%] > [NMAX]
RBC	On	β-globin produce Aplastic anemia ?	(([RBC] > [NMAX]) AND ([MCV] < [NMIN]) AND ([MCHC] < [NMIN]))
RBC	On	erythremia ?	[RBC] > [NMAX]
RBC	On	aglobulia?	[RBC] < [NMIN]
RBC	On	macrocyte?	[MCV] > [NMAX]
RBC	On	microcyte ?	[MCV] < [NMIN]
RBC	On	Red blood cells vary in size?	[RDW_CV] > [NMAX]
RBC	On	Low pigment or anemia?	[HGB] < [NMIN]
RBC	On	Cold condensation?	(([RBC] < [NMIN]) AND ([MCHC] > [NMAX]*1.05))
OTH	On	Whole blood cell reduction?	(([WBC] < [NMIN]) AND ([RBC] < [NMIN]) AND ([PLT] < [NMIN]))

6.9 Power-off



■ . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.) and the areas in contact with these substances have potential biological infectious hazards. When contacting relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, mask, gloves, etc.).

▲WARNING

■ . . The sampling needle is sharp, and there may be potential biological infection hazards. Be careful not to contact the sampling probe when operating the host.

NOTE

■ . . In order to ensure the stability of the analyzer and the accuracy of the analysis results, please shut down the analyzer according to the requirements after 24 hours of continuous operation.

■ . The operator must follow the following steps to perform the normal shutdown procedure.

Shutdown includes two parts: shut down the host and exit the software. The following describes the operation steps of "exit the software system" and "shut down the host device".

■ . Exit the software

1. Click "Shutdown" in the main menu to automatically run the shutdown program.

■ . Power-off

1. The screen will turn off

2. Switch the power button on the back of analyzer.

6.10 Weekly maintenance

1. Check whether the power supply and ground wire meet the requirements.
2. The instrument shall be soaked and rinsed once or aperture washing.
3. External cleaning of instrument

Wipe the outside of the instrument with a clean wet cloth and soapy water or detergent (do not use chemical reagents or abrasives), wipe off the blood stains in time, and then clean them with water



Warning: caution, danger

- When cleaning, the power plug should be pulled out, and the power plug can be plugged in after the instrument is clean and not damp, so as to avoid electric shock.

6.11 Monthly maintenance

The system diagnosis program is set up in the instrument, and the system diagnosis is carried out once a month for each component of the system to ensure that all parts of the system can work normally.



 **Warning: caution, danger**

- Before opening the instrument for internal maintenance, the power supply must be cut off to prevent electric shock and failure.

 **Biological hazards**

- During operation, maintenance and inspection of instruments, rubber gloves must be worn and laboratory safety operation regulations must be observed.
- Do not touch these materials (samples, reagents, quality control materials, standard materials, waste liquid, etc.) when operating, decomposing, assembling relevant components or treating waste liquid, because they have potential biological infectivity risk. If the waste

liquid is accidentally stained, first clean it with disinfectant (such as 0.1% benzalkonium bromide or refer to hospital regulations), and then wash them thoroughly with soap.

6.12 Necessary maintenance

6. 12. 1. Necessary maintenance of aperture pipe

The system maintenance program includes three washing procedures: soaking washing, gem hole washing and gem hole burning. When the measuring value is not accurate and the repeatability is not good, the gem hole may be partially blocked or the test pipeline is not clean. The above three methods can be used to clean and maintain the gem hole and test pipeline according to the situation.

1) Aperture washing

When the aperture washing starts, the system repeatedly flushes the aperture with 5 ml concentrated cleaning solution. This procedure is specially used for serious plugging of aperture.

2) Soaking and flushing

In the process of soaking and flushing, the system used 38 ml detergent and 60 ml diluent repeatedly to soak and flush the counting cell and related pipelines for 4 minutes.

This program is used when the dirt in the counting cell and related pipelines is not easy to be eluted or there is a background.

3) frontward and backward flushing

When performing the frontward and backward flushing, the system flushes the aperture frontward and backward repeatedly. This program is specially used for serious plugging of aperture.

4) High pressure burning

When the aperture is burning, the system will automatically burn the aperture under high pressure. This program is specially used for serious plugging of gem hole.

6. 12.2. Necessary maintenance after reagent

replacement

After changing the reagent, do a reagent guide, which can prevent the inhalation of air during the determination, so as to ensure the accuracy of the test.

Chapter 7 Review of Results

7.1 Summary

After each sample analysis, the analyzer will automatically store the sample information, result data, flag prompt information, histogram and scatter plot in the historical database. The analyzer can store up to 100000 samples.

The operator can review the stored sample information, result data, flag prompt information, histogram and scatter diagram in the graphic review and list review interface.

7.2 Graphic Review

Click "result" in the main menu to enter the data query interface.

The screenshot shows a mobile application interface for viewing test results. At the top, there is a navigation bar with a 'Home' icon, a 'Reading...' status bar, and icons for 'Info', 'LIS', 'Printer', and 'KEY77'. Below this, the date '2020-07-17 15:37:30' is displayed. The main content area features a 'Results' tab and a 'Search' input field. A table displays the following data:

Time	Sample ID	Name	WBC	RBC	HGB	MCV	PLT	Lym#
2020-07-17 09:33:35	4		0.00	0.00	0	0	0	0
2020-07-17 09:21:23	3		6.72	4.04	119	87.0	316	1.41
2020-07-17 09:18:55	2		9.34	4.35	137	88.3	293	1.75
2020-07-17 08:51:21	1		0.00	0.00	0	0	0	0

Navigation controls on the left include 'Inquire', 'Count', 'Export', and 'First', 'Previous', 'Next', 'Last' buttons. A 'Print archive' button is located at the top right of the table area.

Click the time to query, as shown in the figure below

The screenshot shows the same application interface, but with a calendar overlay for July 2020. The date '2020-07-17' is selected. The main content area displays a detailed view of a sample with the following data:

Items	Results	Unit	Reference
WBC	0.00	10 ⁹ /L	0-0.2
RBC	0.00	10 ¹² /L	0-0.02
HGB	0	g/L	0-1
PLT	0	10 ⁹ /L	0-10

The interface also includes a 'Calculate' button, an 'Unaudit' button, and 'Print' and 'Send' buttons. A navigation bar at the bottom contains 'Info', 'LIS', 'Printer', and 'KEY77' icons.

Select the sample to be viewed and click "details" to query the sample graph.

7.2.1 Sample / patient information

The operator can browse the sample records one by one by using the work list column of the interface. Record sample / patient information can be viewed at the top of the interface. In the patient information, except the examiner and the auditor, the operator is allowed to edit directly. For the editing of relevant information, please refer to the relevant contents of "entering work order information" in Chapter 6 daily operation.

7.3 List review

Click "statistical query" of "results", as shown in the following figure:

The screenshot shows the 'Results' interface with a table of sample records and search filters. The table has columns for Time, Sample ID, Name, WBC, and RBC. The search filters include From, To, Per page, Sample ID, Patient ID, Name, and Department.

Time	Sample ID	Name	WBC	RBC
2020-07-17 09:33:35	4		0.00	0.00
2020-07-17 09:21:23	3		6.72	4.04
2020-07-17 09:18:55	2		9.34	4.35
2020-07-17 08:51:21	1		0.00	0.00

Select the date range, and then click "search", as shown in the figure below. Click any sample information to view the sample results and histogram in detail at the bottom of the page.

The screenshot shows the 'Results' interface with a table of sample records and search filters. The table has columns for Time, Sample ID, Name, WBC, RBC, HGB, MCV, PLT, and Lymf. The search filters include From, To, Per page, Sample ID, Patient ID, Name, and Department.

Time	Sample ID	Name	WBC	RBC	HGB	MCV	PLT	Lymf
2020-07-17 09:33:35	4		0.00	0.00	0	0	0	0
2020-07-17 09:21:23	3		6.72	4.04	139	87.0	316	1.41
2020-07-17 09:18:55	2		9.34	4.35	137	88.3	293	1.75
2020-07-17 08:51:21	1		0.00	0.00	0	0	0	0

7.4 Data export

In the "statistical query" interface, select the time period of the required data, click "search", and then select the data to be exported,

Click "export" (NTFS format if required)

The screenshot shows the TECOM software interface. At the top, there is a navigation bar with icons for Home, Pending, Info, LIS, Printer, and a user profile labeled KEY77. Below this is a search bar and a 'Search' button. The main area displays a table with columns: Time, Sample ID, Name, WBC, RBC, HGB, MCV, PLT, and Lym#. The table contains four rows of data. A red callout box labeled 'Tick Sample' points to the first row. On the left side of the table, there are buttons for 'Inquire', 'Count', 'Export', and navigation controls (First, Previous, Next, Last). A 'Print archive' button is located at the top right of the table area.

Time	Sample ID	Name	WBC	RBC	HGB	MCV	PLT	Lym#
2020-07-17 09:33:35	4		0.00	0.00	0	0	0	0
2020-07-17 09:21:23	3		6.72	4.04	119	87.0	316	1.41
2020-07-17 09:18:55	2		9.34	4.35	137	88.3	293	1.75
2020-07-17 08:51:21	1		0.00	0.00	0	0	0	0

(you can tick all or some samples to export directly)

7.5 Statistics

The operator can view the repeatability index values of the selected results, including mean, SD and CV%. The calculation formula is as follows:

$$\text{Mean} = \frac{\sum_{i=1}^n X_i}{n} \quad \text{SD} = \sqrt{\frac{\sum (X_i - \text{Mean})^2}{n-1}} \quad \text{CV}\% = \frac{\text{SD}}{\text{Mean}} \times 100$$

Where n is the number of selected samples and Xi is the i-th analysis result of the specified parameter.

Select the data to be counted and click statistics. According to the data to be selected, click OK to display the statistical results, as shown in the following figure:

	WBC	Lym#	Mid#	GR#	Lym%	Mid%	GR%	P_LCR	P_LCC
Statistic	4	4	4	4	4	4	4	4	4
Mean Value	4.01	0.79	0.28	2.94	9.90	3.47	36.63	13.30	40.50
SD	4.76	0.92	0.35	3.49	11.47	4.06	42.29	15.38	46.77
CV	118.50%	116.80%	123.21%	118.70%	115.83%	116.81%	115.47%	115.60%	115.47%
Range	9.34	1.75	0.72	6.87	20.90	7.70	73.60	27.50	81.00

	RBC	HGB	MCV	HCT	MCHC	RDW_CV	RDW_SD	MCH
Statistic	4	4	4	4	4	4	4	4
Mean Value	2.10	64.00	43.83	18.40	173.75	5.88	18.48	15.25
SD	2.43	74.27	50.61	21.29	200.78	6.79	21.48	17.63
CV	115.63%	116.04%	115.48%	115.69%	115.56%	115.52%	116.25%	115.59%
Range	4.35	137.00	88.30	38.40	357.00	12.00	40.00	31.50

	PLT	MPV	PCT	PDW
Statistic	4	4	4	4
Mean Value	152.25	5.28	0.16	7.15
SD	176.05	6.09	0.19	8.26
CV	115.63%	115.47%	115.59%	115.48%
Range	316.00	10.60	0.33	14.40

7.6 Log query

Click "operation log" in "maintenance", as shown in the following interface:

2020-05-22 16:00:17

Home Reading... Done Info LIS Printer KEY88

Reagent Daily Log **Running** Data Assembly About

2020-05-22 to 2020-05-22 Current 1 Page Each page 50 Items Total 14 Items Pages 1 Page

Code	Grade	Time	Status	Info
0000097	prompt	2020-05-22 15:56:05		Successful operation parameters configuration
0000007	prompt	2020-05-22 15:56:00		ttyS4Count plate serial ports open success
0000007	prompt	2020-05-22 15:56:00		ttyS0Control panel serial port open success
0000007	prompt	2020-05-22 15:55:59		ttyS4Count plate serial ports open success
0000007	prompt	2020-05-22 15:55:59		ttyS4Count plate serial ports open success
0000007	prompt	2020-05-22 15:55:45		ttyS4Count plate serial ports open success
0000007	prompt	2020-05-22 15:55:45		ttyS4Count plate serial ports open success

Navigation: First, Next, Previous, Last

Chapter 8 Quality Control

8.1 Summary

The automatic blood analyzer may produce a certain degree of error in the process of long-term use. The existence of errors may lead to incorrect or unreliable analysis results. The quality control procedure provides an effective method for the detection of possible errors. Only when the operator is familiar with the theory of quality control and master the actual operation method, can the influence of error on the analysis result be effectively eliminated.

In order to ensure the reliability of sample analysis results, it is suggested that the operator should use low, medium and high quality control materials to control the analyzer once a day. When it is necessary to use the new batch of quality control materials, the new batch of quality control materials and the existing quality control materials should be used in parallel for 5 days, run twice a day, and the results should be within the reference range specified in the use instructions of the quality control materials. When replacing instrument parts, it is recommended to do a quality control test. When replacing the random reagent, it is recommended to do a quality control test.

The analyzer provides two quality control methods: whole blood quality control and X-B floating average method quality control.

NOTE

The operator shall use the quality control materials and reagents designated by the company, and store and use the quality control materials and reagents in strict accordance with the instructions. The quality control material must be used before its expiration date, and the quality control material (similar to the standard blood sample) must be fully mixed before use.

8.2 Whole blood quality control

8.2.1 Quality Control Edit



■ . . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.) and the areas in contact with these substances have potential biological infectious hazards. When contacting relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, mask, gloves,

etc.).

NOTE

- . . . Only the administrator level users have the right to edit quality control.
- . . . For quality control files with quality control results, if the reference values or deviation limits of parameters are changed and saved, the changed data will be highlighted with yellow background color and recorded in the system log.

Before analyzing the new batch of quality control materials, it is necessary to set a quality control file for each batch number of quality control materials.

1. Click the "whole blood quality control" button in "quality control calibration", as shown in the following interface:



2. Click "quality control settings", as shown in the following interface:



3. Edit quality control documents

- . quality control batch number
 - . . enter the quality control batch number in the "quality control batch number" text box.
- . quality control level
 - . . select from the "quality control level" drop-down list according to the level of quality control material (high, medium and low).
- . manufacturer
 - . . enter the manufacturer of the quality control material in the "manufacturer" text box.
- . term of validity
 - . . select the validity period of the quality control material on the right side of the "validity period" text box.
- . test items (multiple test items can be set)
 - . select from the test item drop-down list.
- . target value, SD (standard deviation), deviation
 - . . enter the target value of the test item
- . save and delete
 - . . after the setting is completed, click "save"; if the setting is wrong, click "delete" to reset.

8.2.2 Quality Control Analysis

- . the operator can select the following two methods for quality control analysis according to the operation habits:
 1. Use the quality control material to complete the quality control analysis in the quality control counting interface;
 2. Place the quality control materials in the daily samples, and complete the quality control analysis in the sample counting interface.
- . after completing the quality control editing, return to the "L-J quality control chart" interface, and click "quality control receiving". According to the selected quality control mode, one of the following methods can be selected for quality control analysis:
 - Whole blood - continuous
 - pre dilution - continuous
 - automatic injection
- . quality control analysis (whole blood - continuous)



■ . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.) and the areas in contact with these substances have potential biological infectious hazards. When contacting with relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

▲ CAUTION

- . . The needle is sharp and may be contaminated with potentially biohazard substances. Be careful not to contact the sampling probe when operating the host.
- . It is possible that the sample may spill out from the uncovered collection vessel and cause biological contamination. Please be careful when handling the open blood collection vessel.
- . . When loading the blood collection vessel, make sure that the blood collection vessel is not inverted, otherwise it may cause rupture of the blood collection vessel and cause biological pollution.
- . . Before analysis, make sure that the blood collection vessel is in the correct adapter, otherwise it may cause rupture of the blood collection vessel and cause biological pollution.
- . . Rupture of the blood collection vessel may cause personal injury and / or biological contamination. Be careful not to damage the blood collection tube when loading or removing the blood collection vessel from the blood collection frame.
- . . Clothes, hair, hands, etc. must be kept at a certain distance from moving parts to prevent being pinched by moving parts.
- . . The reagent can irritate the eyes, skin and mucous membranes. When contacting reagent related articles in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).
- . . Once the reagent comes into contact with the skin, wash it with plenty of water immediately. If necessary, ask a doctor for treatment. Once the reagent contacts the eyes, rinse it with plenty of water and receive medical treatment.

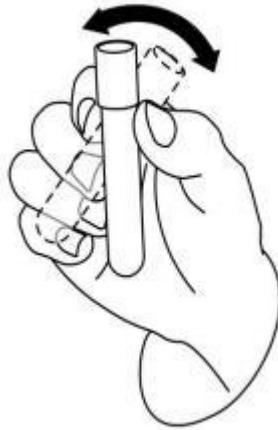
▲ WARNING

- . Do not reuse disposable items.
- . Sample aggregation may lead to inaccurate analysis results. Please check whether the quality control material agglomerates before the quality control analysis; if so, please handle according to the relevant operation requirements of the laboratory.

NOTE

- . The disposable products, such as vacuum blood collection tube, centrifugal tube and capillary tube, must be used.
- . If the test mode is switched from "pre dilution" to "whole blood", the analyzer will automatically execute the mode switching sequence and give a progress bar prompt on the interface.

-
1. Click "quality control result" to enter quality control interface.
 2. Select the batch number for quality control analysis.
 3. Confirm that the quality control material level to be analyzed is consistent with the current quality control document.
 4. Confirm that the quality control materials to be analyzed are not expired.
 5. Prepare the quality control materials according to the instructions.
 6. Quality control analysis :
 - 1) Click "quality control test", the counting status icon and host indicator light are yellow.
 - 2) Shake the quality control material as shown in the figure below to completely mix the sample.



3) Put the quality control material under the sample aspirating needle, and click the "sample aspiration" button to test the quality control material.

7. After the analysis, the obtained quality control results will be displayed in the current interface, as shown in the figure below, and automatically saved to the current quality control file.



NOTE

Each quality control file can store up to 300 quality control results.

8. If necessary, the quality control analysis can be continued according to the above steps.

quality control analysis (pre dilution - continuous)

The operation mode is the same as that of quality control analysis (whole blood - continuous).

8.2.3 Review of Quality Control Results

After completing the quality control analysis, users can review the quality control results in the following two ways:

(1) quality control chart

(2) quality control data

1. Review of quality control results



■ All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.), as well as the areas in contact with these substances, have potential biological infectious risks. When contacting with relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

① Click to enter L-J quality control interface.

② Select quality control batch number.

③ Select "L-J quality control chart" to see the trend of test value, as follows:



④ Click "quality control value" to see the specific measured value.

2. Delete

Under the authority of the administrator, the quality control results can be deleted according to the following steps.

① If you want to delete a single quality control result, click the column of the quality control result you want to delete ; if you want to delete all the data of the current quality control document, go to step 2 directly.

② Click the "delete" button to provide 4 options for deletion.

③ Click the data you want to delete.

④ Click the "OK" button to delete the selected data.

NOTE

■ . . . The deletion is recorded in the log.

3. Print

If you want to print the quality control list, you can follow the steps below:

① Click the "print" button to display the print preview interface;

② Print after checking.

8.3 Floating Average

X-B floating average method can monitor the performance of the analyzer by monitoring the stability of MCV, MCH, MCHC and other red blood cell parameters. It belongs to the quality control without quality control materials, and belongs to the performance monitoring means of the analyzer with the quality control material control, which can reflect the analytical performance of the analyzer from different aspects, and can not replace each other.

When the daily sample size of the analyzer is greater than 100, it is recommended to use X-B quality control. This quality control method requires the use of random samples, so it is not suitable for samples classified by disease type. It consists of a given reference value and upper and lower limits to form a reference range. Observe the change trend of quality control results in the reference range.

The analyzer carries out X-B quality control on three parameters of MCV, MCH and MCHC. The number of samples for X-B numerical analysis in each group can be set as 20-200. The samples

come from the normal count results of the analyzer, and the whole blood and pre dilution mode are not distinguished. The analyzer can store up to 500 X-B quality control results. When the stored quality control results exceed the maximum number, the new quality control results will cover the earliest results.

8.3.1 Quality Control Edit



■ All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.), as well as the areas in contact with these substances, have potential biological infectious risks. When contacting with relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

NOTE

- . Only the administrator level users have the right to edit quality control.
- . For quality control files with quality control results, if the reference values or deviation limits of parameters are changed and saved, the changed data will be highlighted with yellow background color and recorded in the system log.

Before analyzing the new batch of quality control materials, it is necessary to set a quality control file for each batch number of quality control materials. In the quality control file, the quality control information can be edited by any of the following methods.

1. Click "quality control" in the main menu.
2. Click "quality control settings".

Set from the quality control information provided by the quality control material manufacturer. The quality control setting interface is as follows:



3. In the test items (MCV, MCH, MCHC), set the target value, deviation, upper and lower limit of quality control materials. You can also add or delete other items.

4. Input the number of valid sample results selected for each X-B quality control point in the "sample number / group" edit box. The selection range is 20-200, and the recommended number is 20.

5. Click the "on" button, and then click "Save Settings".

8.3.2 Quality Control Analysis



■ . . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.) and the areas in contact with these substances have potential biological infectious hazards. When contacting with relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

After quality control setting, the system will automatically start to execute X-B quality control counting.

For every 20-200 valid sample results (determined according to the settings), the system will automatically perform an X-B quality control calculation, and the obtained quality control results can be reviewed in the X-B quality control chart.

The following sample results are not valid sample results of X-B quality control and will not be included in X-B quality control calculation.

- ① Samples whose results are beyond the linear range of the instrument
- ② Background sample of startup
- ③ Quality control data of other quality control modes (such as whole blood quality control) below X-B quality control
- ④ Calibration data
- ⑤ Test sample in case of instrument failure

8.3.3 Review of Quality Control Results

After the quality control analysis, users can review the quality control results through the quality control chart. As shown in the figure below:



Chapter 9 Calibration

9.1 Summary

Calibration is to obtain accurate measurement results and determine the deviation correction factor of blood sample analysis under specified conditions. In order to obtain accurate blood sample analysis results, the analyzer should be calibrated according to the procedures given in this chapter when necessary.

The analyzer provides two calibration methods: manual calibration and automatic calibration.

All or part of parameters in WBC, RBC, HGB, MCV and PLT can be calibrated.

The calculation of HCT, MCH and MCHC can refer to the calculation formula in Chapter 3.

NOTE

- . . . Only the operator with administrator authority can carry out calibration operation.

 - . . . The operator shall use the calibrators and reagents designated by the company, and store and use them in strict accordance with the instructions for the use of the calibrators and reagents.

 - . . . Only the calibrator count performed in the calibration interface is the calibration operation.

 - . . . The calculated repeatability should also be included in the calibration procedure.
-

9.2 Calibration Frequency

The analyzer has been calibrated before delivery. Because the performance of the analyzer is stable, it does not need to be calibrated frequently. In the following cases, the operator still needs to calibrate the analyzer:

Before the first use;

After replacing the main parts;

When the host is not used for a long time, it is restored to use;

Check the quality control data of the day every day to see if there is obvious deviation.

NOTE

- . The analyzer must be calibrated before the measured data can be used as valid data.
 - . For laboratories carrying out routine tests, calibration should be carried out at least once every six months.
-

9.3 Calibration Method

9.3.1 Prepare



■ . . . All materials (samples, quality control materials, calibrators, reagents, waste liquid, etc.), as well as the areas in contact with these substances, have potential biological infectious risks. When contacting with relevant articles and areas in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

▲WARNING

- . . . The sampling needle is sharp and may be stained with substances with potential biological pollution hazards. When operating the analyzer, be careful not to contact the sampling probe.
 - . . . The reagent can irritate the eyes, skin and mucous membranes. When contacting reagent related articles in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).
 - . . . Once the reagent comes into contact with the skin, wash it with plenty of water immediately. If necessary, ask a doctor for treatment. Once the reagent contacts the eyes, rinse it with plenty of water and receive medical treatment.
 - . . . Clothes, hair, hands, etc. must be kept at a certain distance from moving parts to prevent being pinched by moving parts.
 - . . . The operator is obliged to comply with the local and national regulations on the discharge and treatment of reagents, waste liquid, waste samples, consumables, etc.
-

NOTE

- . . . Do not reuse disposable items.
-

▲CAUTION

■ . . . The operator shall use the quality control materials and reagents designated by the company, and store and use the quality control materials and reagents in strict accordance with the instructions.

- . . The disposable products such as vacuum blood collection vessel, centrifugal tube, capillary tube, etc. must be used.
 - . . Please use a vacuum blood collection vessel with the size recommended in the appendix.
-

Before calibration, check according to the following steps to confirm that the background range, repeatability and carrying pollution rate of the analyzer are within the range specified in the manual. Otherwise, it is necessary to find out the cause and determine whether calibration is needed after the problem is solved. If unable to solve the problem, please contact Tekang after-sales service department.

1. Check the host and reagent to ensure that the amount of reagent is enough to complete the whole calibration process. If the reagent is used up in the calibration process, it needs to be calibrated again.
2. Carry out background detection. If there is "abnormal background" at the bottom of the screen, refer to Chapter 11 "troubleshooting" for handling to ensure that the background detection results meet the requirements (see Appendix A for background range).

Use median quality control material to count 11 times in the "whole blood continuous" mode, take the count results from the second to the eleventh time, and check the repeatability of the second to eleventh count results in the "list review" interface to confirm whether they meet the requirements.

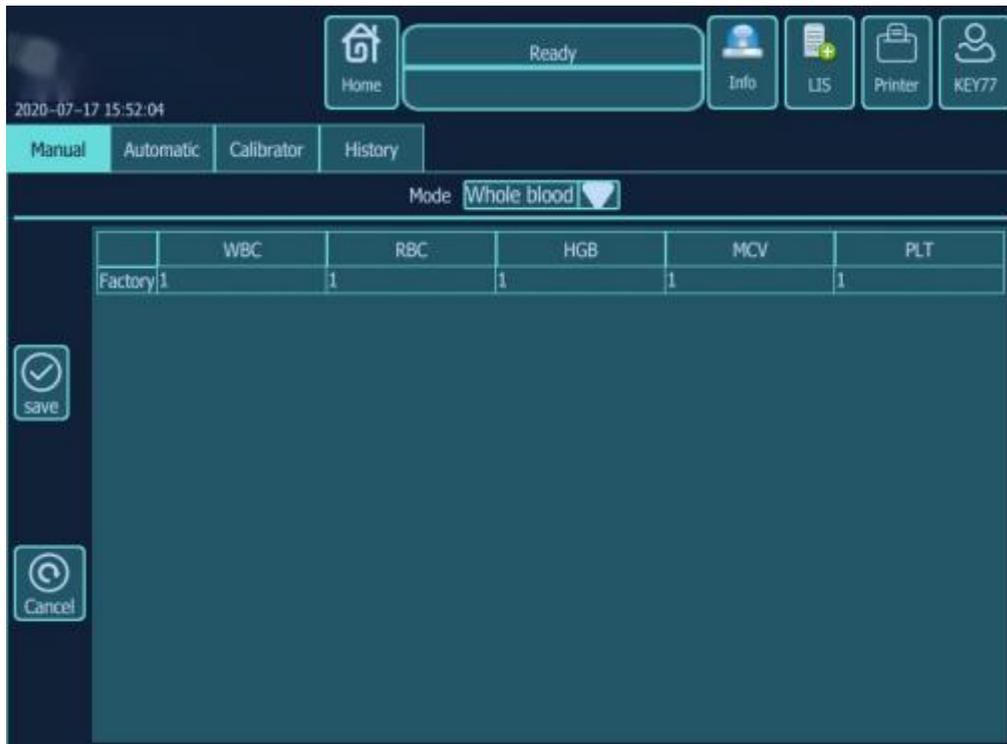
3. Count three times with high-value quality control material, and then count three times with matching diluent, and then calculate the carrying pollution rate according to the following formula to confirm whether it meets the requirements.

$$\text{Carrying pollution rate (\%)} = \frac{\text{First low value sample result} - \text{third low value sample result}}{\text{Third high value sample result} - \text{third low value sample result}} \times 100\%$$

9.3.2 Manual Calibration

Follow the steps below to complete the manual calibration.

1. The operator clicks "QC calibration" and selects "calibration" to enter the calibration coefficient interface. As shown in the figure below: the calibration coefficient interface displays the calibration of whole blood mode, pre dilution mode and automatic injector mode coefficient by default



NOTE

- . . The operator who logs in as an ordinary user can only view the calibration coefficient of the current interface, and cannot carry out calibration operation. If the analyzer needs to be calibrated, he should first log off the current user, and then log in as an administrator.

2. The operator enters the "calibration coefficient" interface to view the calibration coefficient, and uses the following formula to calculate the new calibration coefficient of each calibration parameter:
 New calibration coefficient= $\frac{\text{current calibration coefficient} \times \text{reference value}}{\text{Mean value of measurement}}$

For example, suppose the WBC reference value of a calibrator is 8.4, and the calibration coefficient of current whole blood mode is 0.989.

The WBC parameters of the calibrator were measured 11 times in the whole blood mode, and the results from the second to the eleventh (n = 10)) were taken. The results were 8.1, 8.0, 8.1, 8.1, 8.3, 8.3, 8.2, 8.0, 8.1, 8.3. The repeatability index CV = 1.5%, mean = 8.16. The average value of measurement is valid.

The new calibration coefficient was calculated

The new calibration coefficient = $0.989 \times 8.4 = 1.0181$

8.16

If the calculated calibration coefficient of a parameter exceeds the effective range (75.00% - 125.00%), the calibration coefficient is invalid. In this case, the operator should find out the cause (sample not fully mixed or wrong operation, etc.). The calibration coefficient was calculated.

NOTE

- . The input calibration coefficient should be in the range of 75.00% - 125.00%, and only two decimal places can be reserved

3. After obtaining the new calibration coefficient, input the new calibration coefficient in the calibration factor cell of the calibration parameter to be calibrated.

4. Click "save".

9.3.3 Auto calibration

1. Click "calibration coefficient" in "QC calibration" in the menu bar.

2. Click "auto calibration" again. Enter the following interface:



3. Click "add". Enter the information of the calibrator (name, batch number, expiration date, etc.). At the same time, input the reference value of each parameter.

4. Click "save".

5. Switch the test mode and start the test sample.

6. Repeat steps 4-5 to save 3-5 valid calibration count results.

7. After obtaining the new calibration coefficient within the calibration range, it is necessary to exit the calibration interface and verify the new calibration coefficient in the counting interface. (standard coefficient greater than or equal to 0.7, less than or equal to 1.3)

9.3.4 Calibration History

Click "calibration history" on the "calibration coefficient" interface to enter the "calibration history" interface. As shown in the figure below:

	Time	Operator	Mode	Method	WBC	RBC	HGB	MCV	PLT
1	2020-05-22 16:01	KEY88	Whole bl...	Manual	1.1	0.97	1	1	1
2	2020-05-22 16:01	KEY88	Whole bl...	Manual	1.1	1	1	1	1
3	2020-05-22 16:01	KEY88	Whole bl...	Manual	1	1	1	1	1

The operator can view the detailed calibration history data, including: date, operator, selection mode, calibration method, injection mode and calibration coefficient of each parameter.

Chapter 10 Services

10.1 Summary

In order to ensure the accurate and effective operation of the analyzer, the operator shall carry out routine maintenance for the analyzer according to the requirements of this chapter. The analyzer provides a number of maintenance functions to facilitate the operator to complete the maintenance work.

This chapter introduces the maintenance functions of the analyzer and some treatment measures in case of failure and alarm.



-
- . . . There are potential biological infectious substances on the surface of all components of the analyzer, and safety protection measures should be taken during operation and maintenance.
 - . . . During operation and maintenance, attention should be paid to sample aspirating needle and puncture needle to avoid contact with blood sample.
-

CAUTION

- . . . Improper maintenance may damage the analyzer. The operator must carry out maintenance according to the instruction manual.
 - . . . If there is no clear problem in the manual, please contact the after-sales service department of Tekang company, and the professional personnel designated by Tekang company will give maintenance suggestions.
 - . . . The analyzer must be maintained with parts provided by TECAN. If you have any questions, please contact Tekang after sales service department.
 - . . . During maintenance, avoid touching the sharp tip of sampling probe.
 - . . . Before cleaning, maintaining and moving the analyzer, the power supply of the analyzer should be turned off, otherwise the operator may get electric shock.
 - . . . The operator shall regularly clean the surface of the analyzer with clean water and cloth.
-

10.2 Maintenance

10.2.1 Reagent replacement

▲WARNING

- . . . The reagent can irritate the eyes, skin and mucous membranes. When contacting reagent related articles in the laboratory, the operator shall comply with the laboratory safety operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).
- . . . Once the reagent comes into contact with the skin, wash it with plenty of water immediately. If necessary, ask a doctor for treatment. Once the reagent contacts the eyes, rinse it with plenty of water and receive medical treatment.

▲CAUTION

- . . . The reagent should be allowed to stand for a period of time before use.
- . . . The operator should carry out background detection after changing diluent, cleaning solution or hemolytic agent to ensure that the background value is within the normal range, so as to prepare for sample analysis.

The operator needs to change the reagent under the following conditions:

- ① the whole barrel / bottle of new reagent was replaced.
- ② the reagent in the pipeline is suspected to be contaminated.
- ③ It is suspected that there is air bubble in the pipeline.
- ④ The reagent is contaminated or expired.

The operator must guide the reagent after replacing it. Click "reagent guide" in "maintenance" on the main menu. The following interface appears :



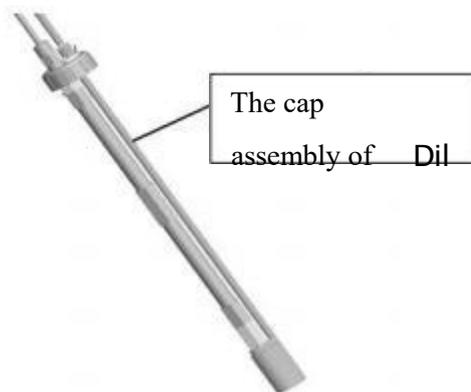
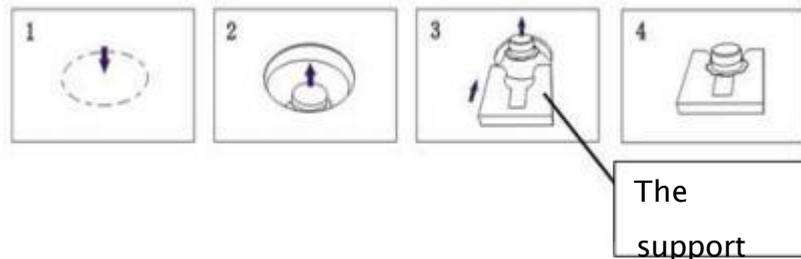
Select the replaced reagent and click "execute reagent guidance" to guide the reagent.

Users can change the following reagents:

- Diluent
 - Detergent
 - Lyse
-

NOTE

- . Do not make the diluent tank vibrate violently or collide with other objects, otherwise the alarm may be unreliable.
- When the reagent is almost consumed, the reagent soft barrel should be tilted and the liquid level alarm should be immersed in the liquid level, so as to reduce the residual amount of reagent and false alarm of reagent.
- . When replacing the diluent barrel, please follow the following steps: 1) use the diluent barrel support plate to block the bucket mouth, as shown in the figure below; 2) insert the diluent bottle cap assembly (as shown in the figure below) vertically into the diluent barrel, and screw the bottle cap tightly. Otherwise, the alarm may be unreliable.



10.2.2 Aperture Flush

The user needs to clean the counter under the following circumstances:

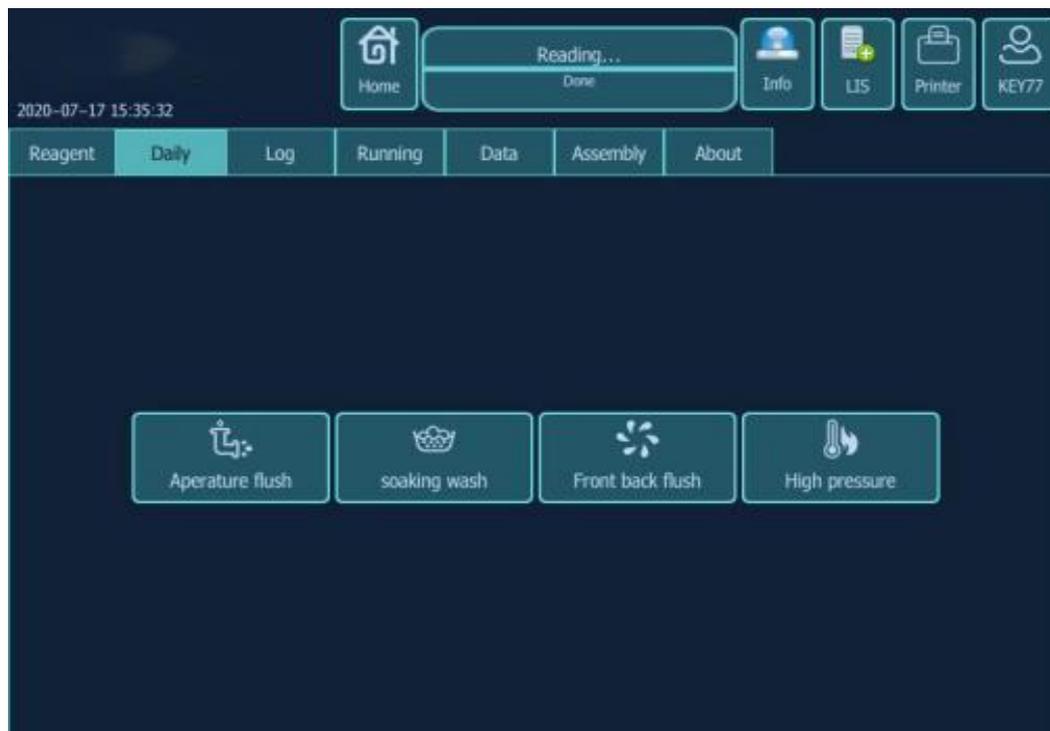
If the background results of WBC and / or HGB are beyond the background range;

If RBC and / or PLT results exceed the background range;

If the working load of the instrument is too high on that day;

If the analyzer is ready for calibration;

Click maintenance – Aperture Flush in "maintenance" of the main menu. Enter the following interface:



The instrument will automatically clean the following parts:

- WBC Cup
- RBC Cup
- Aspirating needle
- Aperture
- Associated pipings

The whole cleaning process takes about 10 minutes. The cleaning steps are as follows:

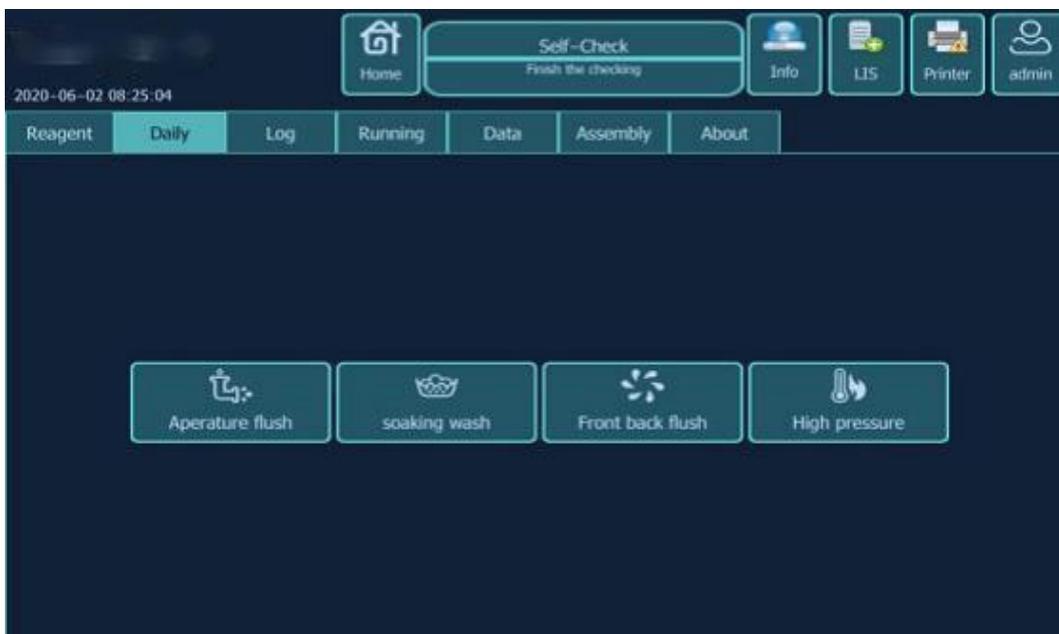
1. Click "perform maintenance".
2. Insert the sampling probe into the concentrated cleaning solution.
3. Click [sample aspiration].
4. The instrument is cleaned automatically.

NOTE

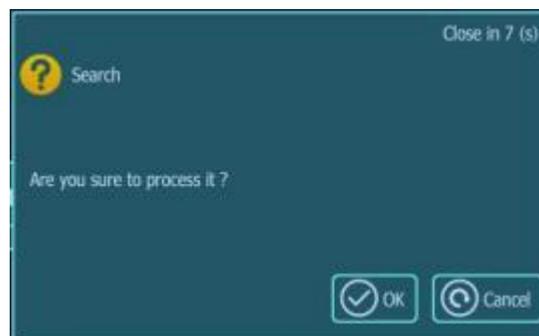
- . After using quality control blood test, the " Aperture Flush" procedure should be implemented.
 - . If the background is not good during the test, the " Aperture Flush" procedure should also be carried out.
-

10.2.3 Soaking Wash

If there is hole plugging fault and old samples are tested for many times, users can perform the operation of recoiling gem hole. On the main menu, click "soaking wash" in "maintenance". The window appears as follows:



1. Click "*" *" for maintenance, and the following window will appear



2. Click the "OK" button, the instrument will automatically enter the maintenance operation.

10.2.4 Component maintenance

Click "component maintenance" in "maintenance" on the main menu. The window appears as follows:



Chapter 1 1 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.
 - It is recommended to do a quality control after replacing a new spare parts or reagents.
-

11.2 Error Information and Handling

During the operation, if error(s) is/are detected, the analyzer will beep and display the corresponding error message in the error information area. Meanwhile, the indicator will turn red.

According to the severity of the errors, the colors of error messages are red, orange, blue.

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.

11.3 TroubleshootingReferences

Error name	Actions
Diluent ran out	<ol style="list-style-type: none"> 1. Firstly check if the diluent container is empty or not. If so, please replace a new one. 2. After replacing a new one, start to prime the diluent by following the instructions on Chapter 10.2. 1. 3. If the problem still persists after replacing the diluent, please contactour customer service department.
Detergent ran out	<ol style="list-style-type: none"> 1. Firstly check if the detergent container is empty or not. If so, please replace a new one. 2. After replacing a new one, start to prime the detergent by following the instructions on Chapter 10.2. 1. 3. If the problem still persists after replacing the detergent, please contactour customer service department.
Lyse ran out	<ol style="list-style-type: none"> 1. Firstly check if the lyse container is empty or not. If so, please replace a new one. 2. After replacing a new one, start to prime the lyse by following the instructions on Chapter 10.2. 1. 3. If the problem still persists after replacing the lyse, please contactour customer service department.
Waste container full	<ol style="list-style-type: none"> 1. Empty the waste container or use a new waste container. 2. If the problem still persists, contact our customer servicedepartment.
Ambient low temperature	Ensure that the ambient temperature is within [15,40] .
Lyse low temperature	Ensure that the lyse temperature is within [30,50]
Emergency stop	<ol style="list-style-type: none"> 1. Exit the software program, close the EXE file in the task manager, and then log in to the software again. 2. If the fault still exists, please contact our after-sales service department.
Failed to open communication port	Exit the program and log in again.
The instrument is not in idle state, please wait	Do not operate other instruments. Do not operate other instruments until the current test is completed.
No response from analyzer	<ol style="list-style-type: none"> 1. Check whether all parts of the analyzer are connected well. If not, connect the components that are not connected properly. 2. If the fault still exists, please contact our after-sales service department
Please exit test mode first	Exit the test mode first, and then perform other operations.

Chapter 12 Report

12.1 Introduction

The operator can use the built-in printer to print on the terminal software, or connect the external printer to print the report.

12.2 Choose the format

Click "Setting" in "Settings" of the main menu. Enter report settings. A window appears as follows:



1. Some basic settings of printing report can be set, such as: hospital name, printer selection, printing template, etc.
2. The order of printing sample items can be sorted.
3. Serial port setting of print settings.
4. Print template settings.

Appendix A Specifications

A. 1 Classification

According to the CE classification, the TEK5000P belongs to In vitro diagnostic medical devices other than those covered by Annex II and devices for performance evaluation.

A.2 Reagents

Type	Name
Diluent	Diluent
Lyse	Lyse
Detergent	Detergent

A.3 Sampling Features

A.3. 1 Sample Volumes Required for Each Analysis

Whole blood mode 10pl Predilute mode 20pl

A.3.2 Throughput

≥60 samples / hour

A.4 Dimensions and Weights

	Analyzer
Width (mm)	440 mm
Height (mm)	350 mm

Depth (mm)	440 mm
Weight (Kg)	17 kg

A.5 Applicable Tubes

12×75 (mm) 13×75 (mm)

A. 6 Performance Specifications

A.6.1 Display Ranges for Major Parameters

Parameter	Linear Range	Display Range
WBC (10 ⁹ /L)	0.00~100.00	0.00~999.99
RBC (10 ¹² /L)	0.00~10.00	0.00~99.99
HGB (g/L)	0~300	0~300
PLT (10 ⁹ /L)	0~1000	0~9999
MCV (fL)	30.0~250.0	0.0~250.0

A.6.2 Blank Count Parameter Specifications

Parameter	Requirement
WBC	$\leq 0.2 \times 10^9/L$
RBC	$\leq 0.02 \times 10^{12}/L$
HGB	$\leq 1g/L$
PLT	$\leq 10 \times 10^9/L$

A.6.3 Reproducibility

Parameter	Condition	CV%
WBC	$(4.0 \sim 10.0) \times 10^9/L$	$\leq 2.0\%$
RBC	$(3.50 \sim 5.50) \times 10^{12}/L$	$\leq 1.5\%$

HGB	(110~160)g/L	≤ 1 0%
MCV	(80~100)fL	≤ 0.5%
PLT	(100~300) ×10 ⁹ /L	≤4.0%

A.6.4 Carryover

Parameter	Carryover
WBC	≤ 1.5%
RBC	≤ 1.0%
HGB	≤ 1.0%
PLT	≤2.0%

A.7 Input/Output Devices

A.7.1 Touch Screen

A.7.2 Keyboard

A.7.3 Mouse

A.7.4 Barcode scanner (Optional)

A.7.5 Printer

A.8 Environment Requirments

AmbientConditions	Operating Environment	Storage Environment
Ambient Temperature	1 0 C~3 5 C	- 10C~5 5 C
Humidity Range	≤90%	≤95%
Atmospheric pressure range	70.0kPa~106.kPa	50.0kPa~106.0kPa

A.9 Power Supply

	Voltage	Input Power	Fuse	NEWSUN (CR2032) Button Cell Voltage	Frequency
Analyzer	100~240V	150 VA	250VT2AL	3V	50Hz / 60Hz

A. 10 Sound Pressure

Maximal sound pressure: 67.7 dB

A. 11 EMC Description

This equipment complies with the emission and immunity requirements of the EN61326- 1:2006 and EN 61326-2-6:2006.

This device complies with the Class A, CISPR 11. 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.

A. 12 Approximate Service Life

The designed service life of the product is 7 years, but it is also affected by the use environment, frequency of use, standard operation and maintenance. Any non-standard operation and lack of maintenance may reduce the service life of the product.

Note: The service life of regular replacement parts and consumables is also shown in the description of accessories and consumables.

Appendix B Toxic and Hazardous Substances and Elements Content Table

Part Name		Toxic and Hazardous Substances and Elements					
		Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr(VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Instrument	Shell	○	○	○	○	○	○
	PCBA	×(1)	○	○	○	○	○
	Stamping Parts	○	○	○	×(2)	○	○
	Machining Parts	○	○	○	○	○	○
	Plastic Parts	○	○	○	○	○	○
	Ceramic Parts	○	○	○	○	○	○
	Hardware	○	○	○	○	○	○
	Cables	○	○	○	○	○	○
	Water flow	○	○	○	○	○	○
Accessories	Label	○	○	○	○	○	○
	Cap	○	○	○	○	○	○
	Tools	○	○	○	○	○	○
	Swab	○	○	○	○	○	○
	Height setter	○	○	○	○	○	○
Package	Packing	○	○	○	○	○	○

i 1

○ : This toxic and hazardous substance or element if contained in any or all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-- -2006.
 × : This toxic and hazardous substance or element contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-- -2006.
 (1) Some parts on PCB contain Lead, and use lead solder during processing.
 (2) Use Hexavalent Chromium on coating during sheet working.

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