White Blood CellAnalyzer

For veterinary use only

Operating Manual

Jiangsu Accuracy Biotechnology Co., Ltd.

About this Manual

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Statement

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety. Keep this manual carefully after reading, so that it can be obtained conveniently when needed.

It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Jiangsu Accuracy Biotechnology Co., Ltd. (hereinafter called "**Accuracy**") cannot be held liable.
Accuracy holds the rights to modify, update, and ultimately explain this manual. Accuracy owns the copyrights of this manual. Without prior written consent of Accuracy, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact us.

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your measuring system.

Important Statement

Thank you for choosing Accuracy's WBC series white blood cell analyzer, which is used for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood. This analyzer can only be used in combination with reagents produced by Accuracy
The WBC analyzer is intended for in vitro diagnostic use only; it is indicated for use in clinical laboratories and for point-of-care settings.
The equipment is Class II equipment of protection against electric shock,

Class II of overload category, Class II of pollution degree.
Do not repair the device without authorization; otherwise the user will be entitled to terminate the service.
Use matched reagents supplied by Accuracy only to ensure the measurement accuracy.
All disposable products are not reusable.
Accuracy reserves the right to change the product design and specifications, subject to change without notice.

Accuracy is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Accuracy authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements;
- the equipment is used in accordance with the instructions for use.

All analyzer components are designed and manufactured with the highest security. Any other non-designated analyzer components used may reduce the security.

Conventions

WARNING: Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

CAUTION: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE: Provides application tips or other useful information to ensure that you get the most from your product.

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1 Product Information

1.1 Introduction

The white blood cell analyzer is a portable in vitro diagnostic device that is only to be used with Accuracy's reagents, intended for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood.

The design principle of the white blood cell analyzer includes injection, optics, detection and display. Injection pretreatment is the process to carry out hemolysis, dilution and dyeing of specimen. Inject specimen to test card: a single cell thickness is the thickness of the test card, which can evenly distribute the monolayer cells to the card plane. The optical principle is to irradiate cells by optical means and amplify the cells by magnifying optical imaging. The principle of detection is to detect the amplified cells and display the count. The specimen is pretreated with Accuracy's reagents and injected into the test card. The white blood cells were filled in the inner space of the test card along the inside of the test card, and the white blood cells were arranged in a single layer. The test card with the specimen is placed in the analyzer and irradiated by the light source in the optical system, and the direct and scattered light intensity generated is related to whether there is a cell. The place with weak light intensity indicates white blood cells existing. The sample was amplified using optical microscopy imaging. The two-dimensional distribution map of white blood cells is obtained by image light intensity measurement through the image sensor. The detection system collects microscopic images and analyzes them to obtain the results. The measurement results are displayed in analyzer screen.

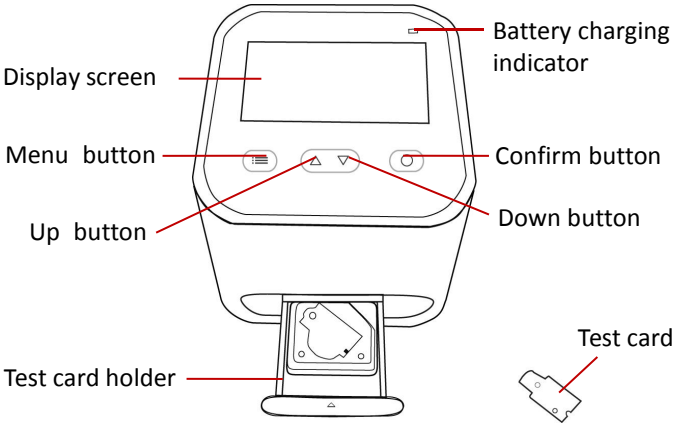
A blood sample of approximatedly 10μL is drawn into the cavity of test card. The test card is placed in the analyzer. The result is obtained within 3 minutes. The test card serving as the specimen carrier is disposable, and there is no flow path in the analyzer, so there is no carrying pollution. The analyzer is small in size, light in weight and easy to move, and is suitable for use outside the central laboratory, such as bedside diagnosis.

1.2 Contraindications

None

1.3 Components

1.3.1 Front View



Display screen:

- Show test results and function information.

Battery charging indicator:

- The indicator lights red during charging; the indicator lights green after charging completed.

Button **Up**:

- Turn page in measuring mode menu;
- View measurement results backwards in the history menu;
- Select the setting item in the setup menu.

Button **Down**:

- Turn page in measuring mode menu;
- View measurement results forward in the history menu;
- Select the setting item in the setup menu.

Button **Menu**:

- Switch menu (measurement mode, history, setup)

Button **Confirm**:

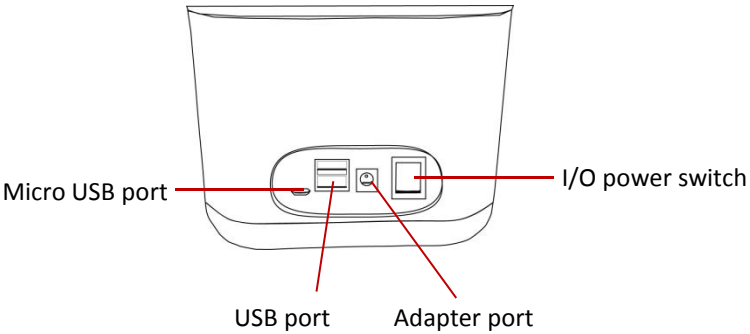
- Confirm options or settings;
- Press and hold this button for 3 seconds to start the quick test during measuring.

Test card holder:

- Place the test card into the holder.

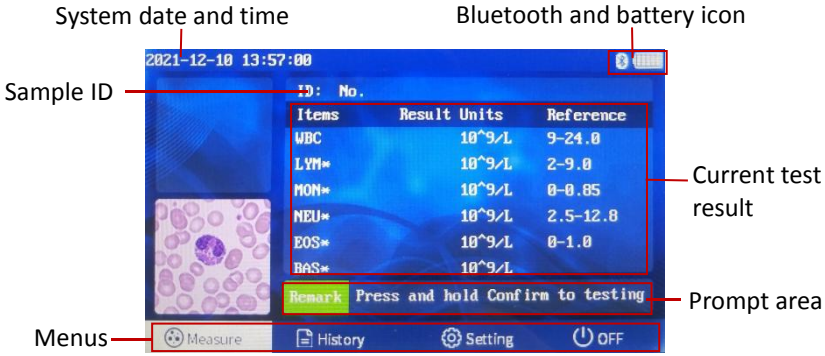
Note: Place the test card correctly according to the shape of the test card placing area.

1.3.2 Back View



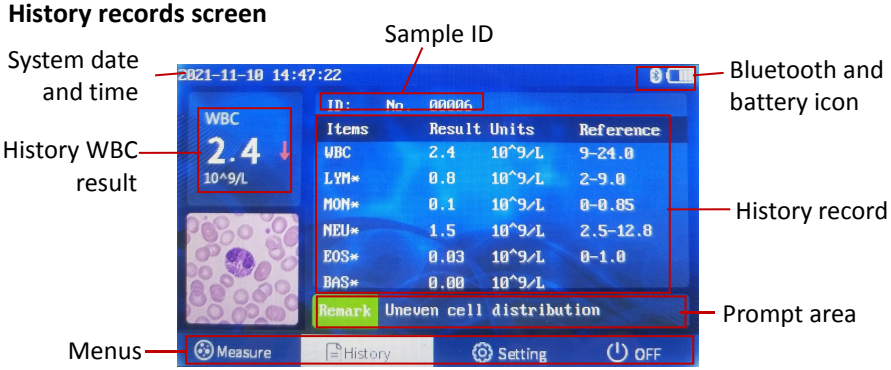
1.3.3 Display screen

Measure screen



Note: The result of test items with * are for reference only, and cannot be used as clinical basis.

History records screen



Settings screen

OFF screen

1.4 Safety Information

WARNING

- **Before using the analyzer, you need access to professional medical knowledge.**
- **Follow the instructions to use the equipment; any improper operation may lead to inaccurate measurements.**
- **Wear protective gloves to avoid bacterial infection during operation.**
- **Care must be taken when dealing with urine specimens or abandoned strips. Any incorrect sequence of operations is likely to lead to infection.**
- **It is very dangerous for user making self-judgment or self-treatment through the measurements. Please follow the doctor's advice. Self-judgment may make the disease worse.**
- **Use only the specific power adapter. Use other adapters may result in a fire or electric shock.**
- **Do not leave the equipment unattended when using AC power supply.**
- **When the equipment is used by children, disabilities or patients, or use the equipment near the above person, it is necessary to monitor the equipment closely.**
- **Do not drop anything or put it into test card holder of the analyzer, except for those items specified in this manual.**
- **Do not use the equipment in locations where aerosol droplets or oxygen controlled.**
- **Do not use the WBC analyzer outdoor.**

CAUTION

- **Unplug the power cord after charging the analyzer with adapter.**
- **Do not place the analyzer into the liquid, and do not put the analyzer in place where may fall into liquids.**

- **Do not place the analyzer in location that is easy to fall, falling and crashing may cause the malfunction of analyzer.**
- **To ensure user safety, use only parts and accessories specified by Accuracy or in this manual.**
- **Do not use the analyzer if it is not working properly or damaged.**
- **Do not place the analyzer or its data cable on the object surface with higher temperature.**
- **Do not place anything on the top of the analyzer.**

NOTE:
- **The pictures and interfaces in this manual are for reference only.**
- **This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact us.**

1.5 Symbol and Explanation

NOTE: Some symbols may not appear on your equipment.

Symbol	Explanation	Symbol	Explanation
IVD	In vitro diagnostic devices		Max. stack quantity
	Date of manufacture		Manufacturer
	Keep dry		Temperature limitation
	Pressure		Recycle
	Moisture		Biological risk
	Alternating current		Direct current
	Class II equipment	SN	Serial number
	Battery status indicator	P/N	Part number
	Fragile-handle with care		Caution
	ON (power supply)		Operation instructions

Symbol	Explanation	Symbol	Explanation
	OFF (power supply)		Date of manufacture
	This side up		USB interface
	Batch code		Do not reuse
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.		Refer to instruction manual/booklet

2 Installation

2.1 Getting Started

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier.

If the packing case is intact, open the packing case in a right way, take out the analyzer and its accessories from the packing case, and check according to the Packing List. Check all materials as per the packing list and check for any mechanical damage. If you have any questions, please contact us.

Fill in the service warranty card carefully, and return it to our company, so that we can track the quality of products and supply you our service timely.

NOTE:

- **Please save the packaging materials for future transport or storage use.**
- **Keep the packing material out of children's reach. Dispose of the packaging material, observing the applicable waste control regulations**
- **The system may be contaminated by microorganism during transport, storage and use. Verify the packaging, especially the packaging for the single use accessories, is intact. In case of any damage, contact the carrier or our company immediately.**
- **Disposal of this product and its accessories and packaging (plastic bags, foam and cartons, etc.) are subject to local laws and regulations.**

2.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in ***A.3 Environmental Specifications.***

Do not use the analyzer in places where are wet, containing corrosive gases, with strong dust, strong electromagnetic interference to ensure the normal use of it.

When the analyzer is moved from one place to another, condensation may occur because of temperature or humidity difference. In this case, never start the analyzer before the condensation disappears.

The analyzer should be placed on a clean, stable surface. D o not use the analyzer in direct sunlight or splashing places.

Do not place the device in a location where it is difficult to disconnect the power supply.

2.3 Connect the Power supply

The analyzer can be powered by AC adapter or built-in rechargeable Li-ion battery.

Adapter specifications:

Input: 100-240V ~ ±10%, 50/60±3Hz, 30VA;

Output: 5±0.3V ⎓, 2A

NOTE:

- **Use only the power adapter supplied or specified by Accuracy.**

2.4 Using Batteries

The analyzer can be powered by built-in rechargeable Li-ion battery. If the AC power supply is suddenly off, the analyzer can be powered by battery.

The battery will be charged when the analyzer is connected to AC power supply.

There is a battery charging indicator on the analyzer main unit. The indicator lights red during charging. And the indicator lights green when the battery is fully charged.

Battery icons' explanations are as follows:

-  Indicates that the battery is working properly.
-  Indicates that the battery capacity is low, charge it in time.
-  Indicates that the battery is charging.

NOTE:

- **Do not charge the battery separately with other charger.**
- **Charge the battery with power adapter supplied or specified by Accuracy.**
- **It is recommended that you charge the battery within 2 months to ensure proper use of the analyzer if long period no use of it.**
- **Ensure that the battery has enough capacity in measurement; lower capacity may lead to inaccurate results.**

3 Operation

The analyzer is calibrated at the factory and the user does not need to calibrate. If necessary, it must be calibrated by a designated qualified person of Accuracy. The analyzer is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Any operations of the analyzer by unauthorized or untrained person are prohibited.

NOTE: Please strictly follow the operation described in user manual to operate the analyzer. If not, the analyzer may be damaged, unable to operate or get inaccurate measurements.

3.1 Power ON/OFF

Power on

1. Before you start to make measurements, check the analyzer for any mechanical damage and make sure that accessories are properly connected.
2. Plug the power cord into the AC power source. If you run the analyzer on battery power, ensure that the battery is sufficiently charged.
3. Turn the I/O power switch on the back of the analyzer to position "**I**", the analyzer screen lights up, the startup screen is displayed, and the self-test is performed. The self-test result can be viewed in the setup screen. The self-test code "**00**" indicates that the analyzer is normal, and other codes indicate that the analyzer is abnormal.
4. The analyzer displays the **Measure** screen after finishing the self-test.

WARNING

- **Do not use the analyzer if it is mechanically damaged or appears abnormal. Contact our company or our service personnel.**
- **The analyzer will not turn on when battery is low if battery power used only.**
- **The power-on state is to prompt the alarm by displaying the different codes: self-test code "00" means normal, other codes represent abnormalities.**

Power Off

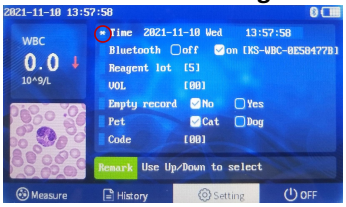
1. Make sure there is no test card in the analyzer before turning off the analyzer.
2. Use button **Menu** to switch to the **OFF** screen as shown below.

3. Press and hold button **Confirm** 3 seconds, the screen prompts that it is shutting down.
4. Turn the power switch on the back of the analyzer to "**O**"and the analyzer turns off.

3.2 Analyzer Settings

3.2.1 Set time

1. Press **Menu** button to switch to the **Settings** screen as shown below.



2. Press **Confirm** button to enter the time setting, * becomes >. The year digit will be flashing as shown in below figure.

3. Press button **Up** or **Down** to adjust value, then press **Confirm** button to confirm the setting, the next digit is flashing.
4. Adjust the values of year, month, day, hour, week, hour, minute, and second in turn. Press **Confirm** button to confirm the setting each time, and finally press **Confirm** button to save all settings. The symbol > before time changes to *.

3.2.2 Turn on or off the Bluetooth

1. In **Setting** screen, press button **Up** or **Down** to move cursor to select "**Bluetooth**", * is displayed before Bluetooth.

2. Press **Confirm** button to enter the setting, * becomes >.

3. Press button **Up** or **Down** to select off or on. Off means turning off Bluetooth connection; on means turning on Bluetooth connection.
4. Press **Confirm** button to save setting, the symbol > before Bluetooth changes to *.

3.2.3 Set reagent lot

1. In **Setting** screen, press button **Up** or **Down** to move cursor to select "**Reagent lot**", * is displayed before it.

2. Press **Confirm** button to enter the setting, ***** becomes **>**.

3. Press button **Up** or **Down** to adjust the lot number.
4. Press **Confirm** button to save setting, the symbol **>** changes to *****.

3.2.4 Set volume

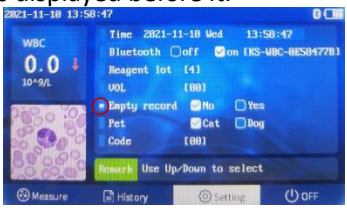
1. In **Setting** screen, press button **Up** or **Down** to move cursor to select "**VOL**", ***** is displayed before it.

2. Press **Confirm** button to enter the setting, ***** becomes **>**.

3. Press button **Up** or **Down** to adjust the volume number.
4. Press **Confirm** button to save setting, the symbol **>** changes to *****.

3.2.5 Empty record

1. In **Setting** screen, press button **Up** or **Down** to move cursor to select "**Empty record**", ***** is displayed before it.



2. Press **Confirm** button to enter the setting, ***** becomes **>**.

3. Press button **Up** or **Down** to select "**No**" or "**Yes**". "**No**" means to cancel the clear record operation. "**Yes**" means to clear all data stored in analyzer.
4. Press **Confirm** button to save setting, the symbol **>** changes to *****.

3.2.6 Set pet

1. In **Setting** screen, press button **Up** or **Down** to move cursor to select "**Pet**", ***** is displayed before it.

2. Press **Confirm** button to enter the setting, ***** becomes **>**.

3. Press button **Up** or **Down** to select "**Cat**" or "**Dog**".
4. Press **Confirm** button to save setting, the symbol **>** changes to *****.

3.2.7 View self-test code

In **Setting** screen, you can view the self-test code.

This code is start-up self-test code, if the code is not "**00**", please check if the analyzer has obvious damage or abnormality. If there is no code, please turn the analyzer off and reboot it after 10 minutes. View the self-test code again, if the code is not "**00**", indicates that the analyzer may be malfunctioning, please contact the after-sales service personnel.

3.3 Testing

Required equipment and reagents

- WBC analyzer
- WBC control solutions and test card
- Micropipettor
- Sterile lancet (collecting capillary specimen)

- Pipette or other transfer devices (collecting venous specimen)

Note: The sterile lancet is the general-purpose device with registered certificate. Micropipettors and pipettes or other transfer devices are common equipment commonly used in laboratories. All of the above are purchased by the user.

Operating restrictions

1. **Measurement must be carried out within 1 minute when the test card filled with specimen.**
2. **Do not repeat the measurement of the used test card.**
3. **Studies have shown that patients' blood specimen containing > 2% of nucleated red blood cells (NRBC) may incorrectly increase white blood cell count.**

Reference Range

Cat: 9-24.0×10^9/L
Dog: 6-17.0×10^9/L
It is recommended that each laboratory establish its own reference range based on the cats and dogs population being tested.

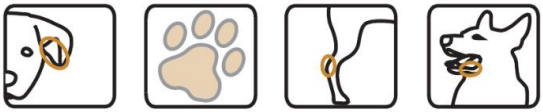
Test procedure:

1. Turn the **I/O power switch** on the back of the analyzer to position "**I**", the analyzer screen lights up.
2. The analyzer displays the **Measure** screen after finishing the self-test.
3. Press **Menu** button to switch the screen to **Setting**.
4. In **Setting** screen, set the Pet to **Cat** or **Dog** according the sample type.
5. Press **Menu** button to switch the screen to **Measure**. And pull out the test card holder.
6. See section ***3.3.1 Capillary Blood Specimen Testing*** for capillary blood specimen testing details.
7. See section ***3.3.2 Venous Blood Specimen Testing*** for venous blood specimen testing details.
8. Complete the testing and pull out the test card holder, and then remove and dispose the test card according to local regulations.

3.3.1 Capillary Blood Specimen Testing

Collecting capillary blood samples at the following recommended sites:

- The ear – (cats and dogs)
- Paw – (cats and dogs)
- Leg callus (dogs)
- Inner lip (dogs)



Sometimes it can be difficult to get a blood sample. Here are some recommendations how to improve the procedure:

- Warming the puncture site by means of a warm cloth;
- Gently rubbing of the puncture site;
- Puncturing twice very nearby to form one blood drop out of the punctures.

1. Clean the puncture site (shave first if there is too much fur) with disinfectant and allow drying completely or wiping off with a dry lint-free wipe.
2. Puncture the puncture site using the lancet.
3. When the blood drop is large enough, collect 10µL specimen with micropipettor and add the specimen into container with staining solutions. Use the pipette tip to stir and mix the blood and solution, and simultaneously suck and drain the mixture for at least 10 times to mix the samples thoroughly.

4. Add 10µL of the mixed solution by a micropipettor to the test card specimen tank, and the mixture will evenly spread the inner cavity of the test card. When sucking the mixture, be careful to suck from the bottom to avoid inhaling air bubbles generated by the mixing operation in the upper layer.
5. Place the test card in the test card holder and gently push the test card holder back into the analyzer to start the testing. Or press and hold

Confirm button 3 seconds to start quick test.

6. After the time countdown is finished, the analyzer will beep to indicate that the test is complete, and the result is displayed on the screen.
7. Pull out the test card holder, remove and dispose the test card according to local regulations.

NOTE:

- **Icon "⧗" is displayed during testing, do not move the analyzer or perform other operations.**
- **The test card is disposal accessory, do not reuse.**
- **The test card should be started test immediately after filling with specimen. Prolonged exposure to air can affect measurement results.**
- **The test card should be completely filled in one continuous process, do not refill.**
- **Always handle blood specimens with care, as they might be infectious. Consult local environmental authorities for proper disposal.**

3.3.2 Venous Blood Specimen Testing

1. If the venous blood specimen has been stored in a refrigerator, it will be viscous and the blood should be allowed to warm up to room temperature 15-35°C (59-95°F) before mixing. Using a mechanical stirrer to stir the sample at least 1-2 minutes or using hand to upside down 10-20 times of the sample tube to make the venous blood samples was thoroughly mixed.

2. Draw 10μL specimen with micropipettor and add the specimen into container with staining solutions. Use the pipette tip to stir and mix the blood and solution, and simultaneously suck and drain the mixture for at least 10 times to enhance the mixing effect.

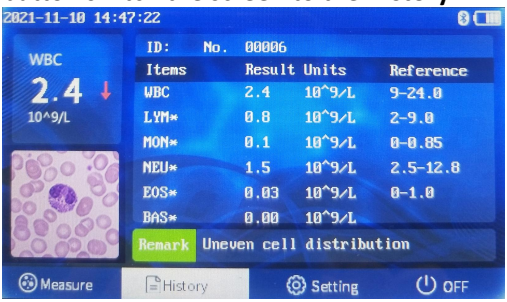
3. Add 10μL of the mixed solution by a micropipettor to the test card specimen tank, and the mixture will evenly spread the inner cavity of

the test card. When sucking the mixture, be careful to suck from the bottom to avoid inhaling air bubbles generated by the mixing operation in the upper layer.

4. Place the test card in the test card holder and gently push the test card holder back into the analyzer to start the testing. Or press and hold the **Confirm** button 3 seconds to start quick test.
5. After the time countdown is finished, the analyzer will beep to indicate that the test is complete, and the result is displayed on the screen.
6. Pull out the test card holder, remove and dispose the test card according to local regulations.

3.4 Review history record

1. Press **Menu** button switch the screen to the **History**.



2. Press button **Up** or **Down** to view the history records one by one.

3.5 Upload measurements

The analyzer can upload the measurements to the desired device. The upload function needs software supporting; please contact our service personnel for details.

Three methods can be used to upload the measurements:

- Upload measurements to PC via USB data cable(Optional).
- Upload measurements to PC or intelligent terminals via Bluetooth (Optional).

4 Care and Cleaning

Use only the substances approved by us and methods listed in this chapter to clean your equipment. Warranty does not cover damage caused by unapproved substances or methods.

4.1 Cleaning the analyzer

1. Clean the display screen and shell using a soft, clean cloth dampened with 75% alcohol.
2. Wipe off all alcohol residues with a dry cloth after cleaning if necessary.
3. Dry the analyzer in a ventilated, cool place.

To avoid damage to the analyzer, follow these rules:

- Do not immerse the analyzer into liquid.
- Do not pour liquid onto the analyzer or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish)

4.2 Cleaning the test card holder

1. Turn the analyzer off, and pull out the test card holder.
2. Wipe the holder with a soft cotton swab dampened with 75% alcohol.
3. After cleaning, push the test card holder into the analyzer.

NOTE:

- **Keep the working environment and the analyzer surface clean and do not damage the screen.**
- **The gasoline, benzene organic solvent cleaning are forbidden to use, these tests will make the analyzer deformation or paint removed and affect the performance or appearance.**
- **Clean the test card holder after using everyday.**
- **Do not contaminate or damage the color block when cleaning the card holder.**
- **Any service of this analyzer can only be performed by an authorized service engineer. Do not maintain and disassembly the analyzer. If any quality problems occur, please call our customer service.**
- **The test card holder must be kept clean to avoid affecting the accuracy of the test results.**

4.3 Daily maintenance

After each use the analyzer should be cleaned according to the instructions described in section ***4.1 Cleaning the analyzer*** and ***4.2 Cleaning the test card holder***. And then turn the analyzer off after cleaning.

The analyzer performs self-test when turning on each time. Check the self-test code, "**00**" indicates that the analyzer is normal, others code indicate that the analyzer has obvious damage or abnormality. If there is no code, please turn the analyzer off and reboot it after 10 minutes. View the self-test code again. If "**00**" displayed, it indicates that the analyzer is normal. If other codes displayed, please turn the analyzer off and then contact Accuracy's service personnel.

CAUTION:

- **The analyzer should be routinely maintained according to the method describe in this manual, otherwise the service life will be shortened and the test results will be inaccurate.**

4.4 Disposal of waste

Discard used specimens, strips and protective gloves in accordance with local regulations on disposal of bio-hazard waste.

The analyzer should be disposed in accordance with local standards for the disposal of electronic waste when after the expiry of the analyzer's life.

4.5 Analyzer Maintaining

When the analyzer is not used for a long time, please clean it according tosection ***4.1 Cleaning the analyzer*** and ***4.2 Cleaning the test card holder***. After cleaning, use the stored box and packaging materials to pack the analyzer. Store and transport the product after packaging according to ***A.3 Environmental Specifications***.

CAUTION:

- **The analyzer should be routinely maintained according to the method describe in this manual, otherwise the service life will be shortened and the test results will be inaccurate.**
- **When storing and transporting, the analyzer must be in off state, otherwise the analyzer may be damaged.**

5 Warranty and Service

5.1 Service

The analyzer has a warranty period of 12 months from the date of arrival. The service or repair will be charged according to regulations when the system is out of the warranty period. Any changes or modifications to this analyzer not expressly approved by manufacturer may void your authority to operate this analyzer.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. All faulty components can free repair or replace during the warranty period.

To protect your rights, please keep the evidence, such as invoices, receipts and so on well and fill in the warranty card and post it to the manufacturers. The manufacturer will repair or replace the analyzer for free during its warranty period and any damage caused by non-human factors.

5.2 Contact information

If any questions in equipment operation, please contact the manufacturer or local agency.

Customer Service Department

Jiangsu Accuracy Biotechnology Co., Ltd.

Address: NO.8, Shengchang West Road, Danyang Development Zone, Jiangsu Province, 212300, P.R.China

Tel: 0086 25 83681231-606

E-mail: sales@accuracy-js.top

Website: https://www.accuracybio-js.com

6 Accessories and spare parts

NOTE:

- **Use only the data cable, power supply cable and adapter supplied or specified by Accuracy.**
- **Disposable accessories should not be resterilized and reused.**

The following accessories and spare parts are available:

Accessory name/Model	Remarks
Power adapter	Standard configuration
USB to DC power supply cord	Standard configuration
USB data cable	Optional

7 Troubleshooting

Some common troubles will occur during the operation of analyzer. Follow the below description to solve the troubles.

Symptoms	Potential Causes	Solution
The analyzer cannot turn on.	Battery capacity is low and no AC power is connected.	Plug in the adapter and check if the power indicator is red. If it does not turn on, or it still does not start after turning on the power, please contact our service personnel.
After loading the test piece, nudge the test piece bracket bracket without responding.	Test card holder is damaged.	Replace the new test card holder.
	The test card holder is blocked by foreign matter.	Remove the foreign matter from the test card holder, restart the analyzer, and contact our service personnel if the trouble still exits.
	Analyzer is damaged.	Replace a new analyzer
	Battery capacity is low and no AC power is connected.	Connect to the AC power supply to charge battery and make a new measurement.
	Test card expired	Replace a new test card within the validity period.
Self-test code displays during turning on the analyzer.	There is hardware problem.	Please check the analyzer for obvious damage or abnormality. If there is no code, please turn the analyzer off and reboot it after 10 minutes. View the self-test code again. If "**00**" displayed, it indicates that the analyzer is normal. If other codes displayed, please turn the analyzer off and then contact Accuracy's service personnel.

The self-test code and the corresponding fault list are as follows:

Self-test code	**Fault**
00	Normal, no fault
01	Camera failure
02	Real-time clock failure
04	Battery failure
10	Voice failure
20	Printing failure
40	LED failure

8 Electromagnetic Compatibility

1. The equipment complies with the electromagnetic compatibility requirements specified in IEC 61326-1-2012 and IEC 61326-2-6:2012.
2. The following requirements should be strictly observed during operation. Otherwise, it may cause electromagnetic interference to other equipment or reduce the electromagnetic interference resistance of the analyzer, or even lose the basic performance.
3. It is recommended to evaluate the electromagnetic environment before using the equipment. Do not use the equipment near strong radiation sources. Doing so may affect the equipment's normal operation.
4. It may cause damaging electrostatic discharge, and resulting in inaccurate test results when using the equipment in a dry environment, especially in a dry environment with artificial materials (such as artificial fabrics, carpets, etc.).
5. The equipment is designed and tested according to Class A equipment of CISPR 11. The equipment may cause radio interference, protective measures are required when using in home.
6. The Oxygen Concentrator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is unavoidable, the device should be observed to verify normal operation.
7. Portable and mobile RF communications equipment may affect the description of medical electrical equipment: Portable and mobile RF communications equipment may affect the normal operation of the equipment, and portable and mobile RF communications equipment should be guaranteed to meet certain spatial distances, See the requirements in Table 4 for specific requirements.

Table 1

Guidance and manufacturer's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment—guidance**
Conducted emissions CISPR 11	Group 1, Class A	The analyzer uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Radiated emissions CISPR 11	Group 1, Class A	The monitor is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61326	Not applied	
Voltage fluctuations Flicker emissions IEC 61326	Not applied	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 61326 Test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±4 kV contact ±8 kV air	±4 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst Immunity Test (EFT) IEC 61000-4-4	±1 kV for power supply lines	±1 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV for line to line	±1 kV for line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0%U_T,for1cycle(inU_t,100%dip) 40%U_T,for5cycle(inU_t,60%dip) 70%U_T,for25cycle(inU_t,30%dip) 5%U_T,for5s(inU_t, 95%dip)	<0%U_T, for 1 cycle <40%U_T, for 5 cycle <70%U_T, for 25 cycle <5% U_T, for 5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the measuring system requires continued operation during power mains interruptions, it is recommended that the measuring system be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	If a work abnormality occurs, it is necessary to keep the device away from the power frequency magnetic field or install a magnetic shield at the site. The power frequency magnetic field in the intended installation site should be measured to meet the requirements below the compliance level.

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 61326 Test level**	**Compliance level**	**Electromagnetic environment**
Conducted RF IEC61000-4-6	3V (effective value) 150 kHz-80 MHz	3 V (effective value)	Portable and mobile RF communications equipment should be used no closer to any part of the oxygen concentrator including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC61000-4-3	3 V/m 80 MHz-2.0 GHz	3 V/m	Recommended Separation Distances $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz～800 MHz $d=2.3\sqrt{P}$ 800 MHz～2.0 GHz Where: P—is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a]a should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity

			of equipment marked with the following symbol: 

Note 1: From 80 MHz to 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the measuring system is used exceeds the applicable RF compliance level above, the measuring system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the oxygen concentrator.
[b]Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the monitor			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Outputpower of transmitter in Watt (W)	Separation distance according to frequency of transmitter(m)		
	150 KHz - 80 MHz $d=1.2\sqrt{P}$	80 MHz - 800 MHz $d=1.2\sqrt{P}$	800 MHz - 2.0 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: From 80 MHz to 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

A Product Specifications

A.1 Analyzer type

Electric shock protection	Class II equipment and internal powered equipment
Degree of protection against liquid	IPX0
Work mode	Continuous
Product life	5 years

A.2 Physical Specifications

Model	Configuration	Dimensions	Weight
WBC-2	Main unit+USB	138 X 140 X 116mm	about 750g
WBC-5	Main unit+USB+Indicator		

A.3 Environmental Specifications

Operating environment	Temperature: 15°C-35°C; Relative humidity: ≤80%RH
Operating atmospheric pressure	70kPa-110kPa
Storage and transportation environment	Temperature: -20°C-60°C; Relative humidity: ≤80%RH
Barometric pressure	50kPa-110kPa

A.4 Technical Specifications

Principles of Measurement	Photometric detection method
Measurement range	(0.3-50.0)×10^9/L, the maximum value is 50.0×10^9/L
Measuring Mode	Normal mode and Quick test mode
Blank Counting	WBC < 0.3×10^9/L
linearity	WBC linearity range and error should meet the following requirements: 0.3×10^9/L-4.0×10^9/L, linearity error should not more than ±0.3×10^9/L。 4.0×10^9/L-30.0×10^9/L, linearity error should not more than ±5%

Specimen Type	Capillary or venous whole blood
Specimen size	10μL
Test time	≤3min
Repeatability	When WBC is in range of 4.0×10^9/L-10.0×10^9/L, precision≤6.0%
Data Storage	30000 results can be stored
Test velocity	In normal mode: finish one test within 3 minutes In quick mode: finish one test within 30 seconds
Interfaces	USB interface
Data transmission	USB
Display screen	4.3 inch TFT
Power supply (Adapter)	Input: 100-240V ~ ±10%, 50/60±3Hz, 30VA; Output: 5±0.3V ⎓, 2A
Released version of software	1.0
Software Environment	Linux system

B Symbols and Abbreviation

B.1 Units

Abbreviation	Full name
µl (µL)	microliter
A	ampere
°C	centigrade
V	volt
W	watt
mm	millimeter
kPa	kilopascal
h	hour
Hz	hertz
L	liter

B.2 Symbols

Symbol	Explanation
—	negative
%	percent
/	per; divide; or
-	to
+	positive
≤	less than or equal to
≥	greater than or equal to
©	copyright

B.3 Terms

Abbreviation	Full name
AC	Alternating current
CV	Coefficient of Variation
DC	Direct current
TEMP	Temperature
USB	Universal serial bus
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
WBC	White blood cell

Jiangsu Accuracy Biotechnology Co., Ltd.
Address: NO.8, Shengchang West Road, Danyang Development Zone, Jiangsu Province, 212300, P.R.China
Tel: 0086 25 83681231-606
E-mail: sales@accuracy-js.top
Website: https://www.accuracybio-js.com