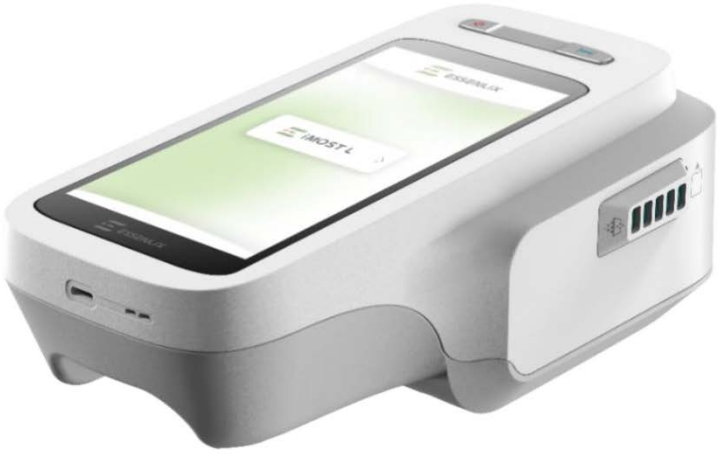
# iMOST-L Hematology Analyzer System

# User Manual



**Essenlix Corporation**

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# Statement

Users must strictly adhere to all operational guidelines and safety instructions provided in this User Manual. Failure to comply may result in improper use of the product and may void the warranty.

**Manufacturer Information**

Essenlix Biotechnology Co., Ltd.

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Production address: Room 101, Building 2, No. 60, Zhonghui Road, Minhang District, Shanghai, China

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**Essenlix Corporation**

Essenlix Corporation, 1 Deerpark Dr Suite R, Monmouth Junction, NJ 08852

**Terminology** For the purposes of this document, the iMOST-L hematology analyzer will be referred to as the hematology analyzer or the analyzer. The iMOST-L hematology Q-Card will be referred to as the hemoglobin/white blood cell test card or the test card.

# Chapter 1 Safety Instructions

## 1.1 Definition of Symbols

The following symbols will appear in the User Manual:

 **WARNING:** This symbol indicates that failure to follow the prescribed procedures or instructions may result in personal injury or damage to the analyzer.

The following symbols are displayed on the analyzer:

 **Read the accompanying documents carefully:** marked on the nameplate of the analyzer.

**In vitro diagnostic medical devices:** marked on the nameplate of the analyzer.

 **For other information, see the instruction manual:** marked on the nameplate of the analyzer.

 **Double insulation:** marked on the nameplate of the analyzer.

## 1.2 Electrical Safety

 **DANGER:** Improper use of the analyzer may result in electric shock, burns, fire, and other hazards.

- Do not open the analyzer casing at any time.
- Do not touch the power switch with wet hands.
- Do not clean the analyzer when it is powered on.
- Please turn off the power when the analyzer is not in use.

## 1.3 Electromagnetic Compatibility

- The manufacturer is responsible for providing customers or users with information regarding the Electromagnetic Compatibility (EMC) of the analyzer.
- The user is responsible for ensuring that the analyzer is operated within an appropriate electromagnetic environment to maintain proper functionality.
- The analyzer complies with the emission and immunity requirements specified in GB/T 18268. It is designed and tested in accordance with Class B instruments under GB 4824 standards.
- It is recommended that the electromagnetic environment be assessed before operating the analyzer.
- Operating the analyzer in a dry environment—particularly where synthetic materials such as artificial fabrics or carpets are present—may result in damaging Electrostatic Discharge (ESD), which could lead to inaccurate test results.
- The analyzer must not be used near strong sources of electromagnetic radiation, as such interference may disrupt normal operation.

## 1.4 Precautions for Use

- Basic safety precautions should always be observed, including those listed below and in Section 4.2.1.
- During testing, the analyzer may come into contact with blood. When used in clinical or medical settings, healthcare personnel must follow institutional infection control protocols, such as wearing gloves or appropriate personal protective equipment (PPE).
- Children or individuals requiring supervision must use the analyzer only under the direct supervision of a responsible adult. The analyzer should always be kept out of reach of children.
- Ensure that the supply voltage matches the rated input voltage of the analyzer during charging.
- Always unplug the power cord immediately after use.

- Never leave the analyzer unattended while it is connected to a power source.
- Operate the analyzer strictly in accordance with the instructions provided in this manual.
- Do not use any accessories or components not supplied or recommended by Essenlix.
- Do not use the analyzer if it is not functioning properly or has been damaged—for example, if the power cord or plug is damaged, the analyzer has been dropped, exposed to water, or submerged.
- The analyzer is not intended for diagnostic purposes.
- The analyzer is for in vitro use only.
- The built-in lithium battery (model: U-Link) is not user-replaceable. Battery replacement must be performed by Essenlix.
- Only test cards (iMOST-L Q-Cards) manufactured by Essenlix are compatible with the analyzer. Use of other test cards is not supported and may compromise performance.

# Chapter 2 Overview

The iMOST-L Hematology Analysis System is a lightweight, compact, and mobile automated quantitative analyzer that leverages innovative micro-nanotechnology combined with biochemistry and computer vision for blood analysis combined with iMOST-L Q-Card.

## Intended Use

iMOST-L is intended for use in community clinics, hospital emergency departments, inpatient wards, health centers, testing centers, point-of-care settings, and similar settings.

It is used for in vitro quantitative detection of hemoglobin concentration, total white blood cell count, white blood cell differential including neutrophil percentage, lymphocyte percentage, monocyte percentage, eosinophil percentage, basophil percentage, neutrophil count, lymphocyte count, monocyte count, eosinophil count and basophil count in human capillary whole blood or venous whole blood.

The iMOST-L system consists of a hematology analyzer, a hemoglobin/leukocyte test card (referred to as a test card or Q-card), and related accessories.

## Key Features

1) Large Data Storage – Stores up to 5,000 test records.
2) Rapid and Instant Testing – Results available within 4 minutes.
3) Minimal Sample Volume – Requires only 10 μL of blood.
4) Built-in Lithium Battery – Operates independently for up to 4 hours; the power adapter is used solely for charging.
5) Advanced Connectivity – Supports Bluetooth and Wi-Fi, enabling quick printing and cloud-based report uploads.

## Chapter 3 Technical Features

### 3.1 Name and Model

Product name: iMOST-L Hematology Analyzer

Model: LA001

### 3.2 Scope of Application

The iMOST-L Hematology Analyzer System is designed for in vitro quantitative detection of hemoglobin concentration, total white blood cell count, and white blood cell differential, including neutrophil percentage and count, lymphocyte percentage and count, monocyte percentage and count, eosinophil percentage and count, and basophil percentage and count.

The analyzer measures hemoglobin concentration within a range of 50 – 200 g/L and total white blood cell count within a range of 1 – 30 × $10^9$ /L. It is suitable for analyzing human capillary whole blood and venous whole blood samples.

This analyzer is applicable to a broad range of individuals, including children aged two years and above, adolescents, and adults. It is intended for use in medical and healthcare environments such as community clinics, hospital emergency departments, inpatient wards, health centers, testing centers, point-of-care settings, and similar institutions where rapid and reliable blood analysis is required.

The iMOST-L analyzer must be operated exclusively by professionally trained personnel from the aforementioned institutions. Operators must possess the appropriate qualifications and fundamental competencies in the use of medical diagnostic devices to ensure accurate, consistent, and reliable test results.

### 3.3 Performances

3.3.1 Limit of Blank

Meet the requirements of Table 1.

Table 1: Limit of Blank requirements

| Parameter | LOB |
|---|---|
| HGB | ≤ 2 g/L |
| WBC | ≤ 0.5 × $10^9$ /L |

3.3.2 Linearity

Meet the requirements of Table 2.

Table 2: Linearity requirements

| Parameter | Linear range | Linear correlation coefficient r |
|---|---|---|
| HGB | 50 g/L ~ 200 g/L | ≥0.990 |
| WBC | 1.0×$10^9$ /L ~ 30.0×$10^9$ /L | ≥0.990 |

3.3.3 Accuracy

Meet the requirements of Table 3.

Table 3: Accuracy requirements

| Parameter | Relative deviation range/% | In Detection range |
|---|---|---|
| HGB | ≤ 7.0 % or 7 g/L | 115 g/L - 175 g/L |
| WBC | ≤ 15.0 % or 0.5 × $10^9$ /L | 3.5 × $10^9$ /L - 9.5 × $10^9$ /L |

3.3.4 Precision

Meet the requirements of Table 4.

Table 4: Precision requirements

| Parameter | CV/% or SD | In Detection range |
|---|---|---|
| HGB | ≤ 3.0 % or 3 g/L | 115 g/L - 175 g/L |
| WBC | ≤ 6.0 % or 0.3 × $10^9$ /L | 3.5 × $10^9$ /L - 9.5 × $10^9$ /L |

3.3.5 Five-Part WBC Differential Test

The reference method for comparison can be either a five-part white blood cell (WBC) differential blood smear microscopy or a fully automated hematology analyzer that has been traceably

calibrated. These methods ensure accuracy and reliability in validating the test results obtained from the analyzer.

The analyzer's measurement results for neutrophils, lymphocytes, monocytes, eosinophils, and basophils are within the allowable range (99% confidence interval). When the reference method measurement result is 0, and the analyzer test result is ≤ 1.0 %, the test conclusion is qualified.

In our internal product release and quality control procedures for HGB, a stricter in-house acceptance range is applied: coefficient of variation (CV) ±2.5% for precision and ±6.0% for accuracy (relative deviation). This ensures higher product consistency and quality.

### 3.3.6 Analyzer Specifications

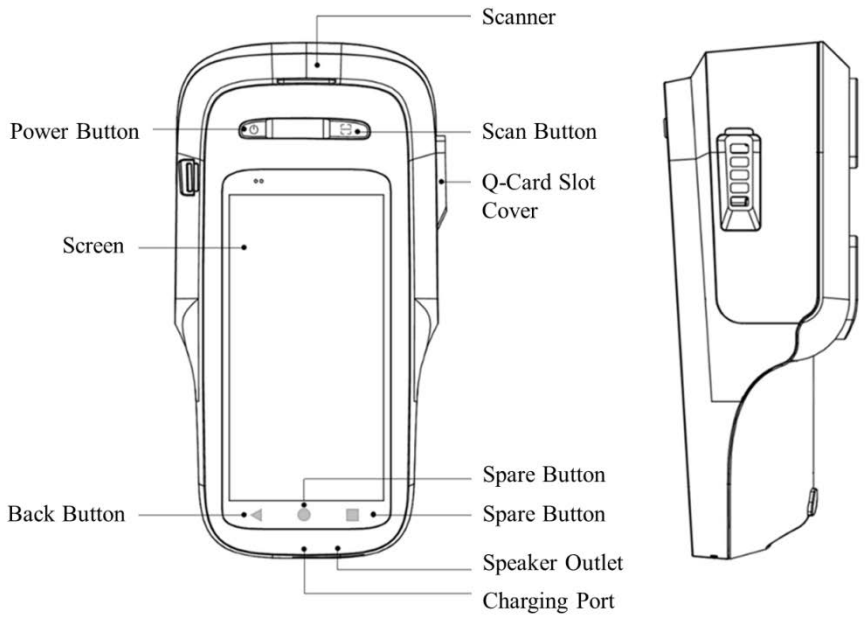
Size: 230 mm × 120 mm × 86 mm

Weight: ~1 kg

## 3.4 Product Composition

The analyzer consists of several key modules, each playing a crucial role in its operation. It is primarily composed of a control module, display module, optical module, camera module, mechanical module, power module, and software for control and data processing.

Below is the schematic diagram illustrating the structure of the analyzer:




Each button and module are as follows:

| Main Functional Modules | Module Description |
|---|---|
| Power button | Responsible for turning the analyzer on and off, long press to turn it on or off. |
| Scan key | Responsible for turning on the scanning function. According to the prompts on the screen, lightly press the scan button, the scanning head will turn on and light up red. At this time, you can scan QR codes and barcodes as needed. |
| Display | The touch display module can perform touch operations according to the instructions displayed on the screen. |
| Test card access cover | Open or close the cover to put in or take out the test card when the test starts or ends, according to the screen display. Keep the cover closed when not testing. |
| Charging port | The external power adapter provides 9V/3A DC power to charge the lithium battery. Please use the power adapter that comes with the analyzer. |
| Speaker outlet | Sound export |
| Back button ◄ | Return to previous page |

## 3.5 Software

(1) Name: iMOST-L hematology analyzer software.

(2) Specification model: LA001.

(3) Release version: V1

(4) Version naming convention: XYZB (all are integers); X represents a major enhancement software update, such as adding multiple modules, changing the overall architecture, or upgrading the functions; Y represents a minor enhancement software update, such as changing some functions; Z represents a corrective update; and B represents a software build.

(5) Software quality requirements

Performance efficiency: page loading and switching time < 2 seconds.

Information security tip: When non-system users log in, a message "Login failed" will be displayed.

Reliability: If the software cannot be used normally due to system freezing, you can restart the device and the system will automatically start the software service for normal use.

Compatibility: The software is compatible with the ARM architecture Android (version number: 13.0) platform.

Portability: The software is proprietary and may not be installed on other devices.

User interface: menus, windows, function keys.

User interface type: program interface, graphical interface.

Usage Restrictions: The product may only be used by authorized users.

System fault-tolerant feedback method: If a user misoperates the system, a prompt message will be displayed.

Software version and change notification: The system displays the software version number information on the information interface in the settings. If the software is updated, the version number will change synchronously.

Possible defects: Data loss may occur when the system hardware is damaged; system file anomalies may cause the storage area to be full, which may make the system unusable. When the operating system is overloaded or the memory is insufficient, normal services cannot be provided temporarily, which may cause system errors or data loss. Users should submit the test results to be saved to the medical information system of the medical institution for archiving, or print the test results for filing, and delete expired test results regularly.

The system provides LOG logs, including login logs, to record system operation status.

### 3.6 Classification

| Requirements | Class |
|---|---|
| European Council Regulation (EU)2017/746 | Class A |

### 3.7 Contraindications

None.

### 3.8 Term of Use

Service life: 5 years (under normal use and maintenance).

Production date: See the analyzer nameplate.

Analyzers and accessories that have exceeded their service life should be disposed of in accordance with local laws and regulations.

### 3.9 Accessories List

See the analyzer packing list for details.

# Chapter 4 Analyzer Testing and Storage Conditions

## 4.1 Transportation and storage

(1) Transport conditions for analyzers:

The iMOST-L analyzer is a precision and fragile device and must be handled with care. When moving the analyzer indoors over short distances, packaging is not required. However, for longer transport, it must be placed in its original packaging, and users are advised to properly store the packaging materials for future use. During transportation, the analyzer should be kept moisture-proof and shock-proof, placed horizontally, and handled with care. Inversion is strictly prohibited.

To prevent damage, the analyzer must be protected from severe impacts, rain, and direct sunlight exposure. It should be transported in an environment with a temperature range of -10°C to 40°C and a relative humidity not exceeding 90%. The analyzer should be transported under atmospheric pressure conditions between 75 kPa and 106 kPa.

(2) Storage conditions of analyzer:

When packaged, the iMOST-L analyzer should be stored in a well-ventilated environment with a temperature range of -10°C to 40°C and a relative humidity not exceeding 90%. The storage area must maintain an atmospheric pressure between 75 kPa and 106 kPa and should be free from corrosive gases or substances to prevent damage to the analyzer.

## 4.2 Usage and Environmental Requirements

### 4.2.1 Usage requirements

The analyzer should not be used outdoors and must be placed on a level and stable surface. It must never be immersed in liquid or positioned in a location where it could fall into liquid. If the analyzer becomes wet, it should be unplugged immediately before handling.

To prevent damage and ensure proper ventilation, do not expose the analyzer to hot surfaces or place it in confined, poorly ventilated areas. The side card inlet and outlet serve as the machine's air inlets, while the bottom functions as the air outlet. These vents must not be blocked, and the analyzer should

not be placed on soft surfaces that could obstruct airflow. Ensure that the vents are kept away from soft cloth, hair, and dust particles.

Nothing should be placed on top of the analyzer. Unless specifically instructed in the user manual, do not drop or insert any objects into the device’s openings or joints. The analyzer must not be used in environments where aerosolized droplets are present or where oxygen is being administered. For optimal performance, the analyzer should be placed in a low-humidity, dust-free environment, away from water sources, heat sources, corrosive gases, and strong magnetic fields. Adequate ventilation must be maintained at all times to prevent overheating and ensure stable operation.

When in use, ensure adequate spacing around the analyzer:

At least 20 cm of space on the side for the test card inlet and outlet

At least 30 cm of space on the side for the power port

At least 30 cm of space above the analyzer

The analyzer should not be placed in a confined space that makes it difficult to operate or disconnect the power supply. This ensures ease of use and accessibility for plugging in and disconnecting the analyzer adapter.

The test card inlet and outlet slots and air outlet slots on the side of the analyzer are equipped with dustproof nets. Regular cleaning is required, and users should consult the Essenlix Customer Service Center for maintenance recommendations.

Excessively high ambient temperatures or direct exposure to strong light sources can negatively impact the analyzer's detection performance or cause malfunctions. To ensure accurate image detection, the analyzer must not be used in direct sunlight or under intense lighting conditions. The device should always be operated within the recommended environmental conditions.

 **When the analyzer is running, it must be placed horizontally on a stable surface. Do not move the analyzer during testing, as any movement may affect the accuracy and reliability of the results.**

4.2.2 Intended use environment

Adapter: Input: 100-240 VAC, 50/60 Hz, 0.9 A; Output: 5.0-20.0 V DC, 1.65-3.0 A

Lithium battery: Output: 3.85-3.95V DC, 1.0A,3.87W

Ambient temperature: 15℃～30℃. Relative humidity: ≤ 80% (no condensation)

Indoor use, altitude not exceeding 2000 m

Overvoltage category: Class II; Pollution level: Level 2

Keep away from mechanical vibration and shock

No strong electromagnetic field interference, no strong light direct exposure

### 4.3 Unboxing

After unpacking the analyzer, please ensure that the packaging is intact and verify that all accessories are included. This step is essential for confirming the analyzer's transportation safety and facilitating any after-sales support if needed.

Please refer to the packing list below to check the included items:

| Name | Specifications | Quantity |
|---|---|---|
| Tool box | Box | 1 |
| Analyzer | LA001 | 1 |
| Power adapter | UES3 3 LCP U -SP C | 1 |
| Power cord | TYPE C | 1 |
| Card Presser | QP001 | 1 |
| Instruction manual, quick operation guide, Certificate of conformity, warranty card | Set | 1 |

 **If the product is obviously damaged during transportation, please do not use it and contact the seller immediately!**

### 4.4 Analyzer Installation

Operators must read the entire instruction manual thoroughly before using this product for the first time.

Please follow the steps below for proper setup and initial power-on:

1) **Positioning the Analyzer** After removing the analyzer from its packaging, place it in a suitable location as specified in Section 4.2.1: Site of Use.
2) **Power Connection** Use the original power cord provided with the analyzer to connect to the power adapter, then plug the adapter into a standard AC power outlet.
3) **Initial Charging** Upon first receipt, the analyzer should be fully charged before its initial use to ensure optimal performance.

4) **Powering On the Analyzer** Press and hold the power switch for 2 seconds, then release. The analyzer will power on, the system software will initiate, and the display screen will illuminate.
5) **Shutting Down the Analyzer** To turn off the analyzer, press and hold the power switch for 3 seconds, then release. Follow the on-screen prompts to confirm shutdown. Once the analyzer has completely shut down, unplug the power cord from the power source.

### 4.5 Printer Connection (if necessary)

The printer is not included in the accessories of this product. If the user needs, the analyzer can be connected to a recommended model printer or an equivalent printer to print the test results. The connection of the printer requires:

1) Connect the printer power cord to the printer's power socket.

2) Turn on the printer and set it to be discoverable by Bluetooth devices.

3) Turn on the analyzer, enable the Bluetooth/WIFI function of the device, select the corresponding printer on the Bluetooth/WIFI interface, and select Connect

4) Try to print a test page. If the printed content is correct and clear, the printer is connected.

5) The recommended printer model is the thermal receipt printer GP-C200I; for more models, please consult Essenlix Customer Service Center.

 **If a printer other than the type specified by our company is connected to the analyzer, it may not produce correct printing results.**

### 4.6 Network Security

(1) Network security type

From a network security perspective, the analyzer control software is designed solely for operating the device and collecting raw test data; it does not include any patient management functionalities. Nevertheless, since the test data may contain patient-identifiable information, it is considered "health data" under medical device data protection regulations. Therefore, appropriate data protection measures must

be implemented to ensure patient confidentiality and compliance with applicable privacy laws and regulations. This includes secure data handling, restricted access by authorized personnel, and integration into a protected information system in accordance with institutional cybersecurity protocols.

(2) Operating environment

Software environment: Embedded software components based on Android ver 13.0.

Hardware environment: Based on Qualcomm 6490 chipset, memory no less than 12 GB, storage no less than 256 GB.

Network environment: You can upload the test results by connecting to LIS via Wi-Fi/5G, and output the test results to the printer via Wi-Fi or Bluetooth.

(3) Data interface

a) Wi-Fi: The application layer protocol is HL 7 FHIR R4 based on HTTPS, which is used to upload results to LIS in one direction; the application layer protocol is IPP protocol, which is used to connect to Wi - Fi printers to print test results and quality control test results.

b) Bluetooth: The application layer protocol is the ESC/POS protocol, which is used to connect to a Bluetooth printer to print test results and quality control test results.

(4) User access control

Use username and password to control access permissions.

 **Notice:**

The iMOST-L analyzer is a precision instrument that requires proper care and maintenance to ensure optimal performance. The hardware must be kept dust-proof and moisture-proof and should be maintained strictly according to the guidelines provided in the instruction manual.

For software maintenance, any necessary updates, including function upgrades, will be communicated by the manufacturer. In such cases, users will be informed of the process to return the analyzer to the factory for upgrades.

 **Notice:**

To prevent unexpected analyzer operation caused by external malware or network attacks, users must follow strict security measures. The analyzer should not be connected to unknown Wi-Fi networks or paired with unfamiliar Bluetooth devices. Additionally, users must avoid using unknown USB flash drives or plugging unauthorized devices into the analyzer's power port. Adhering to these precautions ensures the security and integrity of the iMOST-L analyzer, maintaining its reliable performance.

### 4.7 Connecting to LIS

The analyzer can be connected to the LIS system via Wi-Fi or 5G, and the test results of the analyzer can be uploaded to the LIS system. For details, please contact Essenlix Customer Service Center.

### 4.8 Upgrade Procedure

Customers cannot update the program by themselves and need to return the product to the factory for an upgrade. Please contact Essenlix Customer Service Center for details.

## Chapter 5 Analyzer Operation Settings

### 5.1 Check Before Starting

Before turning on the analyzer, please ensure the following:

- Verify that the **power supply meets the system requirements**.
- Confirm that the **power cord plug is correctly and securely inserted** into the power socket.
- Check that the **surrounding working environment** and **analyzer placement conditions** comply with the specified requirements.
- Ensure that the analyzer's **battery charge is above 30%** for optimal performance.

## 5.2 Boot Interface

### 5.2.1 Login interface

After the analyzer is turned on, it will automatically enter the software login interface. When logging in for the first time, create an administrator account. For other user creation, please refer to User Management in 5.3.5 Application Settings.

If you have already created an account, please refer to 5.4.1 below for the login interface.

On the login interface, enter the correct user password, click Login, and enter the main interface after passing the self-check. See (2) in 5.4.1 below.

On the main interface, click in the upper right corner to log out of the current user.

Click "..." in the login interface to display the setting interface. For setting methods, refer to 5.3.5 System Settings.

If the user password is correct, click "Change Password" on the login screen to display the following password change interface.
After entering the information, click "Confirm Change" to make the change effective.
Note that only administrators can set user permissions.

## 5.3 Software Main Interface Introduction

The main interface of the software consists of 4 main modules and a start button. The 4 modules are reporting module, tutorial module, quality control module, and setting module. Click "Start Test" to start the test process. See (2) in 5.4.1 below.

### 5.3.1 Test

On the main interface, click "Start Test". See 5.4 below for details.

### 5.3.2 Report

On the main interface, click "Report" to display the following list of historical test data arranged in chronological order. Click a record to enter the test result display interface. See 5.4.10.

### 5.3.3 Tutorial

On the main interface, click "Tutorial" to display the tutorial interface. You can scan the QR code or enter the link in the interface to watch the tutorial.

### 5.3.4 Quality Control

When logged in with an administrator account, on the main interface, click "Quality Control" to display the following quality control interface.

Click "QC Test" in the quality control interface, set the quality control parameters (quality control product type, quality control product batch, quality control product level), click "Next", scan or manually enter the batch number of the test card, and click "Next" to perform quality control testing. After the test is completed, you can click "View Report" to enter the quality control test result display interface.

Click "QC Report" in the QC interface to display the following chronologically arranged historical test data list. Click a record to enter the QC test result display interface. Click the button to output the results to the printer. 

### 5.3.5 Settings

On the main interface, click "Settings" to display the settings interface. The settings interface displays "App Settings" and "System Settings".

Click "App Settings" on the settings interface, and the display will be as follows:

User Management (Administrators only): Set up users and add/modify/delete administrator/operator accounts.

Log management (administrator only): Display login logs, which can show the time when users log in and out.

Data expiration (administrator only): Set the test result retention period, you can choose 3 months/6 months/12 months.

Device information: Displays the number of times the device has run tests and the software version.

FHIR Server (Administrators only): Set up a FHIR server, which can be configured with the URL, username, and password of the LIS server.

Test reference value (administrator only): Set the reference range

Auto-logout delay (administrator only): Set the auto-logout delay. You can choose 0 (off), 1 minute/2 minutes/3 minutes/5 minutes/10 minutes/15 minutes/20 minutes/30 minutes.

Settings interface Click "System Settings" to display the system settings interface.

Network connection: Set up Wi-Fi network, turn Wi-Fi on and off, scan and connect to networks, and add networks.

Bluetooth connection: Set up Bluetooth and pair with a Bluetooth printer.

Brightness setting: Set the screen brightness. You can click to adjust the brightness percentage.

Volume settings: Set the volume, and click to adjust the notification tone and vibration.

Language settings: To set the display language, click on the display language from the list.

Input method settings: Set the input method and select English or Chinese on-screen keyboard from the list.

Date and time: Set the date and time. You can automatically obtain or manually enter the time and time zone. You can choose whether to use a 24-hour format.

About Device: Displays the network information of the device.

### 5.4 Test Introduction and Operation Steps

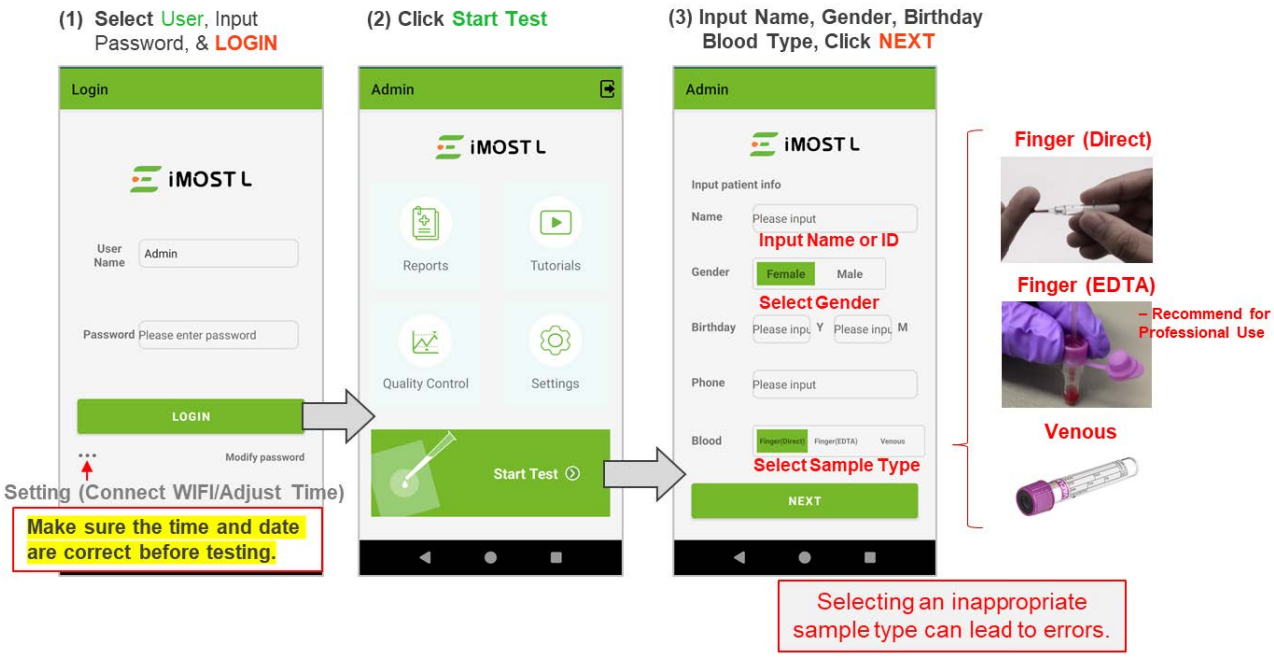
Before testing

- Ensure that both the analyzer and the test card are in a suitable operating environment. Testing must be performed within the specified temperature range of 15–30°C.
- Use only authorized iMOST-L test cards. Use of unauthorized or incompatible cards may result in damage to the analyzer or invalid test results.
- Store test cards in a cool, dry environment that complies with the specified storage conditions.
- Do not conduct measurements if there is condensation (e.g., visible water droplets) on the analyzer. Move both the analyzer and test cards to a dry, temperature-controlled area and allow surfaces to dry completely before use.

- Before opening any packaging, verify that the test card, disposable capillary blood collection device, and disposable quantitative micropipette are within their validity period.
- Open the sealed pouch of the test card only when ready to perform a measurement. Use the test card immediately after removing it from the pouch.
- Test cards are single-use only. Do not reuse test cards that have been exposed to blood, control solution, or any contaminants.
- Disposable capillary blood collection devices and quantitative micropipettes are also for single use only.
- Do not touch the surface of the test card.
- Do not bend, cut, or modify the test card under any circumstances.
- If another person assists with sample collection or measurement, ensure they clean the analyzer thoroughly before use.

5.4.1 APP login and preparation (administrator or operator)

- Log in as an administrator or operator
- Click the "Start" button to start the test
- User information entry
- After clicking "Start", the user is prompted to enter basic information (name, gender, date of birth, mobile phone number) and blood type;
- **Blood type**:
  - **Fingerstick (direct): Directly** add fingertip blood to the test card using a disposable quantitative micropipette (10 μl, without anticoagulant); - this
  - **Fingertip (anticoagulant tube)**: **Recommended for professional use to ensure reliable and optimal performance.** Use the micro-collection tube (containing a specific concentration of $K_2$EDTA) recommended by Essenlix Company to collect samples (for more types of collection tubes, please consult Essenlix Customer Service Center). After mixing, use a disposable quantitative micro-pipette (10 microliters, without anticoagulant) or a pipette to add the capillary blood sample to the test card;
  - **Venous**: Add a venous blood ($K_2$EDTA) sample to the Test Card using a pipette or disposable quantitative micropipette (10 μl, without anticoagulant).




**Selecting the wrong blood type may lead to inaccurate measurement results!**

5.4.2 Test Card Preparation

Notice:

* It is recommended to use the test card immediately after opening. Do not use the test card if the packaging is damaged or the packaging bag has been opened for more than 2 hours. Otherwise, it may cause error information or inaccurate measurement results. If the packaging bag of the test card is found to be damaged, please contact Essenlix Customer Service Center immediately for consultation.

* **The entire process from blood collection, card making to card insertion and testing should be continuous. Do not pause or wait in the middle to avoid sample evaporation, blood cell coagulation or changes that may lead to errors or failures in test results.**

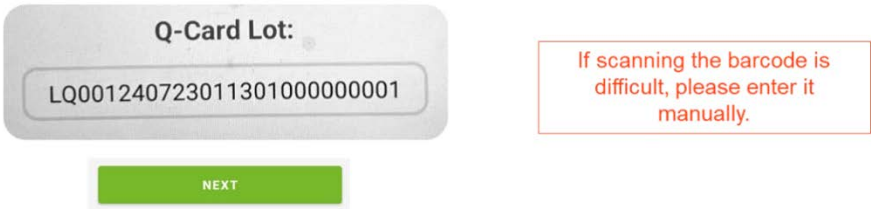
* The surface of the test card contains chemical reagents that may irritate the skin or eyes and cause harm if inhaled or swallowed.

1）Scan the QR code on Q-Card packaging and enter the test card information;

(1) Align the scanner at the front of the analyzer with the QR code on the Q-Card pouch

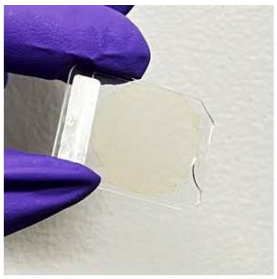

(2) Tap **the scan icon** on the screen or **the scan button** on the top right of the analyzer

(3) After the scan is complete, click "Next"

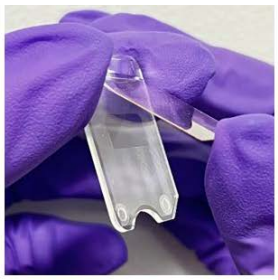



2）Hold sides of the test card or the silver strip with your fingers to take out the test card;

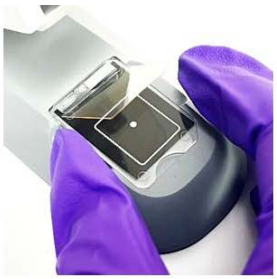
3) Lift the upper cover at the notch with your fingers, keeping the angle between 30° and 70°, place the thick lower plate underneath, and put it into the groove of the card press in the direction shown in the figure below.



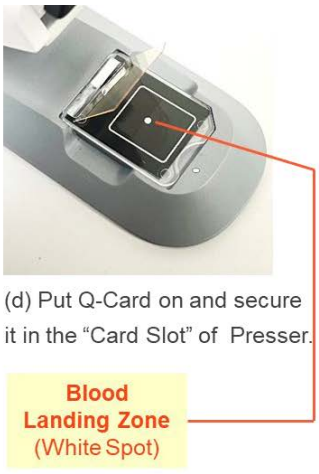
(a) Hold the Q-Card by its sides with two fingers.



(b) Open Q-Card by lifting the thin film of the top plate at the notch.



(c) Hold Q-Card by its sides.




(d) Put Q-Card on and secure it in the “Card Slot” of Presser.

**Notice:**

**Do not touch the inner surface of the test card. If there is direct skin contact, please rinse the contacted skin with clean water for about 5 minutes.**

**Please be sure to keep the surface of the test card clean and avoid contamination with oil, fingerprints, etc. A dirty surface of the test card may lead to erroneous test results.**

5.4.3 The user completes blood collection and sample addition according to the following instructions

Note: To reduce the chance of infection and ensure accurate results:

*This product has not been evaluated for other blood collection sites and can only be used with fingertip blood or venous whole blood.

* Before capillary blood collection, make sure your fingers are warm. You can use hot water or warm your hands to facilitate smooth flow of capillary blood.

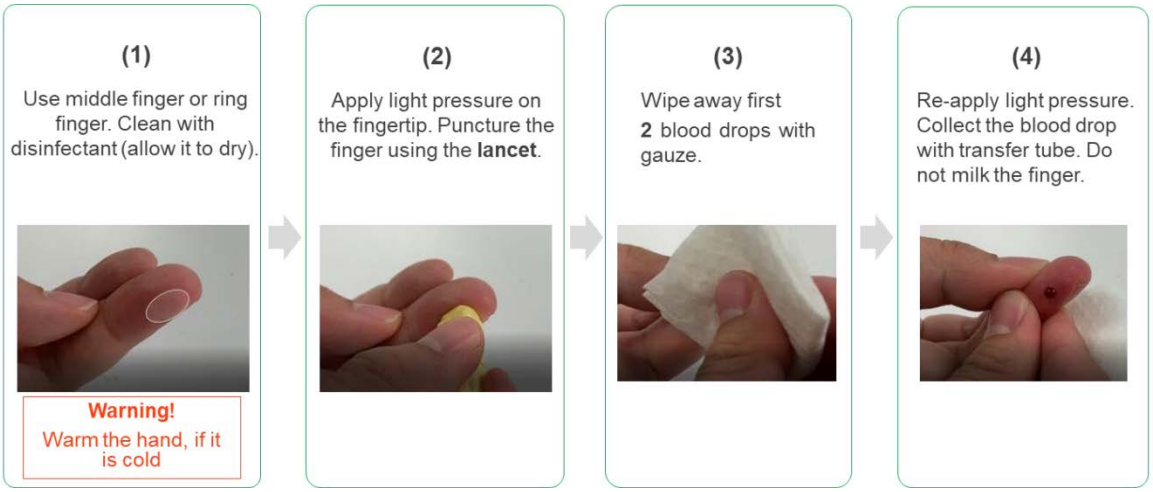
* Before blood collection, please wipe the blood collection site with alcohol cotton and wipe it dry after cleaning.

* The disposable blood collection device is for one person only. Do not reuse it or share it with anyone else.

* Always keep the analyzer and blood collection equipment clean.

* Each time you measure, you should choose a different acupuncture point. Repeated acupuncture at the same site can cause soreness and produce nodules.

5.4.3.1 Capillary blood sampling




During the blood collection process, ensure that the blood flows out smoothly to avoid excessive squeezing of tissue fluid, which may lead to incorrect results.

Before taking blood, wipe off the first 2-3 drops of blood with gauze or cotton balls to avoid contamination by alcohol residue and residual substances on the finger surface.

5.4.3.2 Add blood sample to the test card

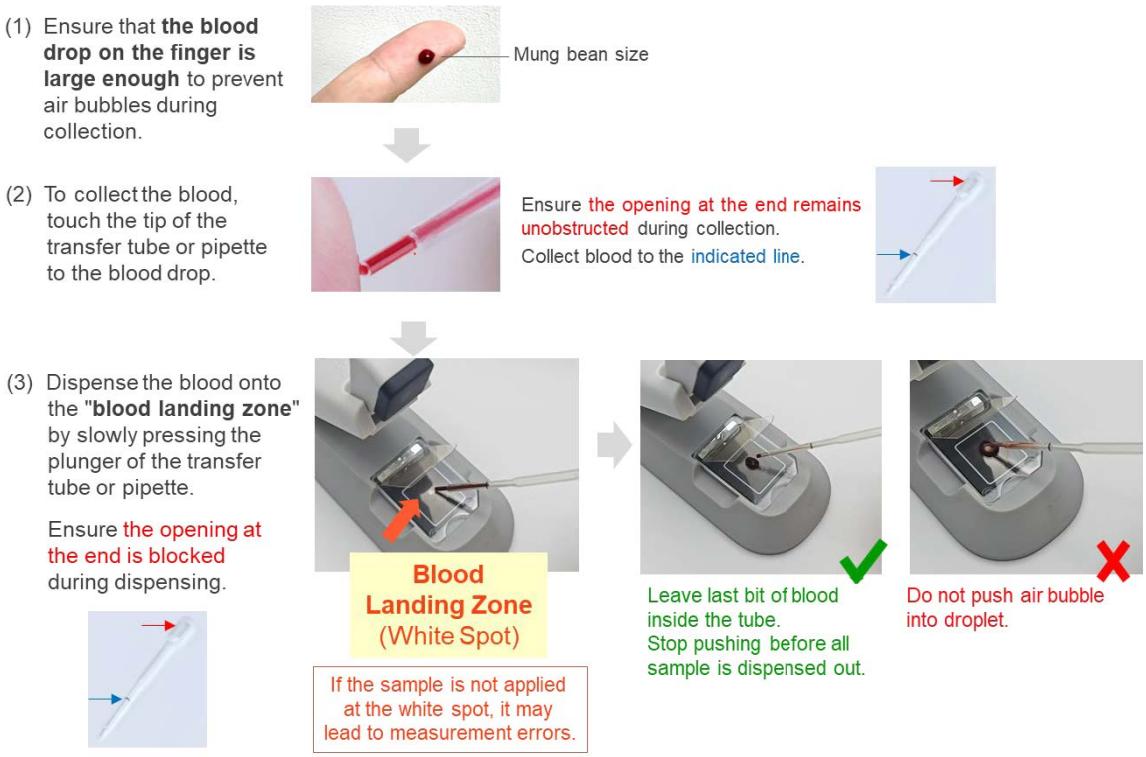
**1） Fingertip (direct) pipetting steps**

**Immediately** use a disposable quantitative micropipette to collect blood directly from the fingertip and apply the sample to the test card. This method is suitable when sample collection and application can be performed smoothly and without interruption, with steady blood flow from the fingertip and prompt transfer to the test card. Avoid delays, improper collection techniques, or situations where the blood clots too quickly, as these may lead to inaccurate or invalid test results.

 When sampling, make sure the blood drop is large enough, such as the size of a soybean, and draw out 10 microliters at ONE time.

 When adding sample to the test card, do not squeeze too much and push air bubbles into the blood drop.

 Add the sample to the designated white spot on the card presser. Otherwise, the result will be inaccurate.




## 2） Finger tip (anticoagulant tube) sampling steps

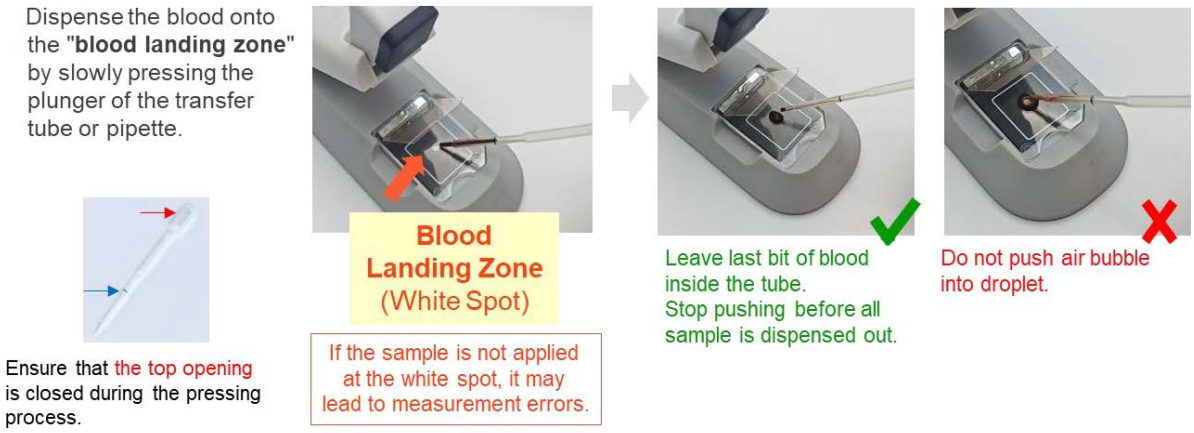
**<u>Recommended for professional use to ensure reliable and optimal performance.</u>**

Use capillaries (containing a specific concentration of **$K_2$ EDTA )** recommended by Essenlix Company to collect blood into blood collection tubes (this method can effectively avoid rapid blood coagulation leading to inappropriate test results):

**Notice:**

**Please mix the sample thoroughly before adding it to the blood test card: Please strictly follow the manufacturer's recommended method to operate and mix well. Insufficient shaking will lead to incorrect results.**


Use a disposable micropipette or pipette (10 μl) to draw blood from the capillary to the "indicator line", or use a pipette to take 10 μl of blood and add it to the test card.




### 3） Venous blood collection and sampling steps:

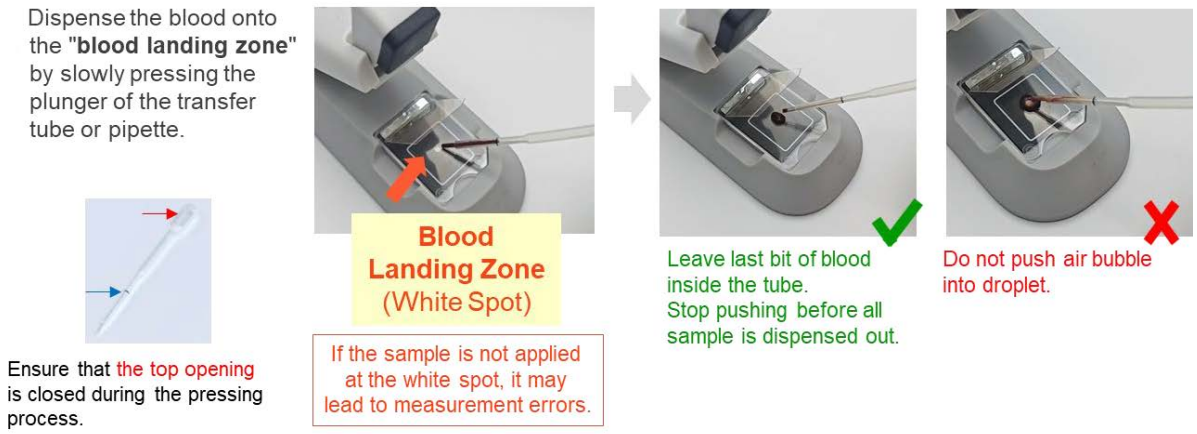
**Note: Venous blood sampling is only allowed by professional medical personnel.**

Using standard tubes containing $K_2$ EDTA.

Venous blood is stored at room temperature, and it is recommended to complete the test within 8 hours.

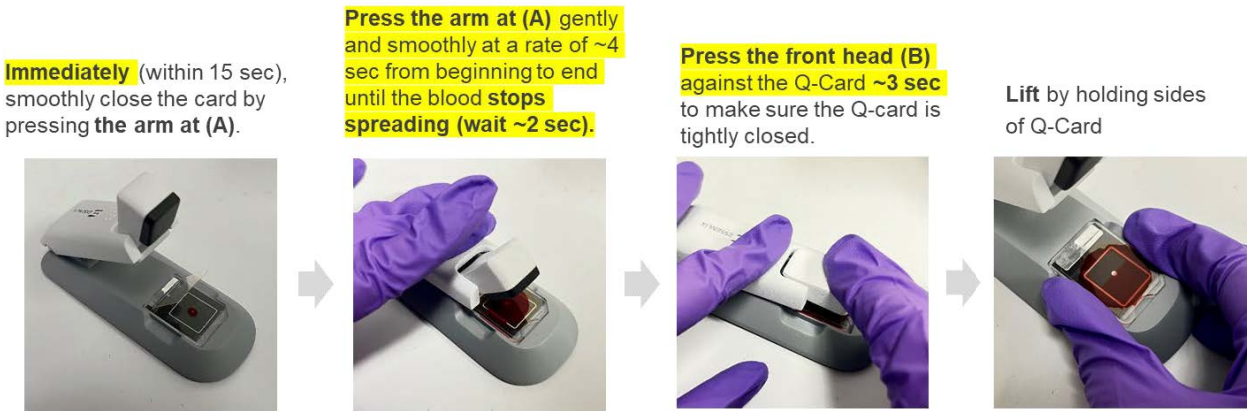
Mix the sample thoroughly before adding to the blood test card: gently invert the tube 10-15 times by hand or use an intravenous tube mixer for two minutes.

Use a disposable quantitative micropipette to draw blood from the anticoagulant tube to the "indicator line" (about 10 μL), or use a pipette to draw 10 μL of blood and add it to the test card:




3.4 The user **immediately** completes the card making with the card presser as following. The whole process should be continuous and not stopped midway.

⚠ Add the sample to the white spot on the card presser. Otherwise, the result will be inaccurate.


3.5 Check the sample in the test card

(1) The blood must cover the white reference square,
otherwise discard the Q-Card and make a new one.

(2) No large visible air bubble or dust,
otherwise discard the Q-Card and make a new one.

**Notice:**

**If the above adverse conditions occur during the card pressing process, please discard the test card and make a new one.**

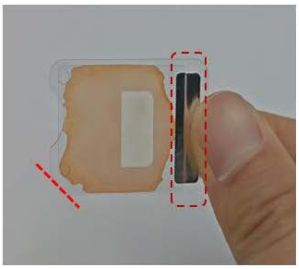
**Do not reopen the test card before testing. If you accidentally open the test card, discard the test card and make a new one. Test cards that do not meet the card making requirements will cause incorrect test results.**

5.4.6 Insert the test card **immediately** into the card reader socket of the analyzer

After the card is made, the user needs to **immediately** insert the prepared test card into the designated position and close the card slot cover.

Hold the card on silver strip, with the **front side** facing you

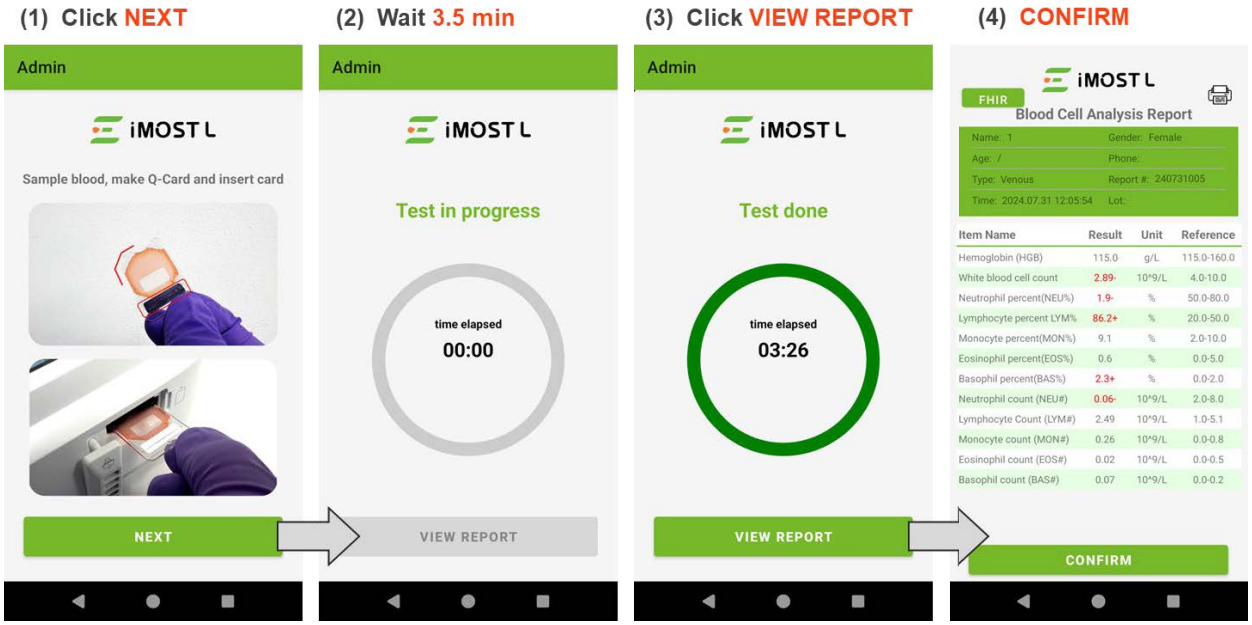
**Immediately**, gently insert the Q-Card into the analyzer until **a physical stop is reached**.




**Note: If blood overflows from the edge of the test card, please do not insert it into the card reader slot of the analyzer! Please prepare a qualified test card for testing again!**

5.4.7 **Testing**

Click "Next" on the analyzer interface, the test will start, the interface will prompt the test process, and the required time will be prompted; please wait patiently. Please refer to the manual of the hematology analyzer for more detailed operation steps.




**Notice:**

**During the test, keep the work surface stable and do not tilt or move the instrument until the test is completed.**

**If the battery level is less than 15% when the test starts, charge the battery to at least 30% before testing again.**

After the test is completed, the analyzer directly gives the test results. After the user confirms the operation, the next test can be carried out. The results can be printed or uploaded to the relevant medical data management system via FHIR (if the medical institution requires it).

Go back to the main interface and click the test report button to see the user's test report.

In the result display interface,

Click "FHIR" to upload the test results to the LIS system.

Click the  button to choose to output the test results to a Wi-Fi printer or a Bluetooth printer .

5.4.8 Interpretation of test results

If the sample measurement value is within the reference range of the iMOST-L hemoglobin/leukocyte test card, the specific test result value (g/L, /L and %) will be given.

If the measured value is higher or lower than the upper or lower limit of the reference interval, the test result value given will be displayed in red, and there will be a "+" or "-" indicator after the specific test result data.

The reference interval can be revised based on the characteristics of the local population and validated clinical data in Admin account.

If the measured value is higher or lower than the upper or lower limit of the detection range, the specific test result data will be followed by a “ >” or “<” indication.

The test results are for reference only. If the measurement results are outside the range recommended by your treating physician, it is recommended to consult a physician.

The interpretation of test results needs to be combined with the patient's medical history, clinical symptoms and other diagnostic methods.

When performing routine blood tests, if the test is not used in the intended use environment given by the manufacturer, or if inappropriate auxiliary materials are used, erroneous test values may result.

## Chapter 6 Common Problems and Solutions

During the use of the analyzer, certain issues may arise. Understanding these potential problems and addressing them promptly is essential to maintaining the safety and effectiveness of the device. Proper troubleshooting ensures accurate performance and minimizes disruptions in testing. Users should familiarize themselves with common failures, follow the recommended solutions, and seek technical support when necessary.

| Warning/Symbol | Possible Cause | Action |
|---|---|---|
| Warning: Q-Card not detected or incorrect Q-Card used. | No Q-Card inserted, incorrect Q-Card inserted, or Q-Card inserted incorrectly. | Please verify that you are using the correct Q-Card and retest. |
| Warning: Q-Card is not fully inserted. | The Q-Card is not fully inserted into the slot. | Please remove and reinsert the Q-Card until it reaches the physical stop position. |
| Warning: Insufficient blood sample. | Insufficient blood sample in the Q-Card. | Please refer to the user guide and ensure that the Q-Card contains enough blood. |
| N/A in certain parameter in “Results” | Certain parameters are rejected due to improper samples, incorrect Q-Cards, or defects on the card. | Use a new Q-Card, repeat the measurement |
| N/A in certain parameter in “Results” again | This sample’s parameter is improper to be tested in iMOST system. | This sample’s parameter is improper to be tested in iMOST system. |
| Abnormal noise from inside the device | Foreign matter is present inside the device. | Please turn off the power and unplug the device. Check the Q-Card compartment and heat dissipation holes, then remove any foreign matter. |
| Hardware Error | Hardware Error. | Please retest or use a new Q-Card. If the same error persists, contact customer support. |
| Warning: Over Temperature Protection | The internal temperature of the iMOST system exceeds acceptable levels. | Please check the surrounding environment, as well as whether the Q-Card cover and the vent at the bottom of the instrument are blocked. |
| Long test duration warning | The duration of a single test is longer than usual. | Please retest or use a new Q-Card. If the same error persists, contact customer support. |

In the event of unknown faults or errors, users should carefully document the issue in as much detail as possible. A clear and precise record of the fault phenomenon will assist technicians in diagnosing the problem and identifying potential solutions. Providing comprehensive information enables a more

efficient troubleshooting process, allowing technicians to analyze the issue accurately and offer appropriate recommendations for resolution.

 **If the analyzer encounters a failure and the displayed error is not listed in the troubleshooting table, immediately stop operation and contact the Essenlix Customer Service Center for assistance. Do not attempt to continue using the analyzer until further guidance is provided to prevent potential damage or inaccurate test results.**

# Chapter 7 Care and Maintenance of the Analyzer

## 7.1 Analyzer Cleaning

### 7.1.1 Analyzer surface cleaning

The surface of the analyzer should be cleaned regularly using a soft cloth slightly moistened with clean water. After cleaning, the surface must be thoroughly dried with a dry, lint-free cloth. If disinfection is required, a standard medical-grade surface disinfectant may be used. After disinfection, the surface should be wiped again with a soft cloth dampened with clean water to remove any chemical residue, and then completely dried with a clean, dry cloth. Proper cleaning and disinfection help maintain the analyzer's performance and extend the lifespan of the device.

### 7.1.2 Cooling vent cleaning

The heat dissipation hole (cooling vent) is located at the bottom of the analyzer. If the vent becomes blocked by dust or other impurities, it may affect the analyzer's performance and compromise test accuracy. To maintain proper ventilation and ensure optimal device operation, it is recommended to clean the heat dissipation hole every three months. A gentle cleaning method, such as using an air blower or balloon to remove dust and debris, is advised to avoid causing damage to internal components.

 **Before cleaning the analyzer, turn off the power and unplug the power cord.**

 **If a cleaning method other than the one recommended by the manufacturer is to be used, please consult the Essenlix Customer Service Center in advance to ensure safety and avoid potential damage to the analyzer.**

 **If water or other liquids accidentally enter the inlet and outlet covers of the test card and the bottom air outlet during cleaning, please contact Essenlix Customer Service Center immediately.**

### 7.2 Analyzer Protection

- Only use the original power supply provided with the analyzer. Even if another adapter has similar output voltage and power, using a non-certified power adapter may result in device damage or serious personal injury due to electrical mismatch.
- Use only the power cord supplied by the original manufacturer.
- Discontinue use immediately if the power cord appears kinked, frayed, or damaged.
- Avoid strong mechanical shocks to the analyzer, such as drops or impacts.
- Do not expose the analyzer to any liquids other than the sample intended for testing.
- After transportation or storage, allow the analyzer to acclimate to room temperature before use to avoid condensation damage.
- Do not place the analyzer in direct sunlight or near heat sources.
- Do not place the analyzer in or near wet environments, such as sinks or washbasins.
- Do not insert anything into the USB port other than a compatible USB cable.
- After completing a test, do not shut down the analyzer immediately. Keep the analyzer in standby mode for at least 5 minutes to allow the internal cooling fan to operate and reduce internal temperature.

 **There are no user-serviceable parts inside the analyzer. Disassembly of the analyzer without authorization is prohibited.**

 **If the battery is replaced with an incorrect type, there is a risk of explosion or fire.**

### 7.3 Disposal of Used Test Cards and Equipment

7.3.1 Disposal of Test Cards

Universal precautions must always be observed when handling blood or blood-derived materials. This includes the use of appropriate personal protective equipment (PPE). After use, test cards should be disposed of in sealed biohazard containers specifically designated for potentially infectious medical waste.

All medical waste disposal procedures must comply with applicable local, regional, and institutional regulations to ensure both personnel safety and environmental protection.

### 7.3.2 Disposal of the Analyzer

When the analyzer is no longer in use, please contact the Essenlix Customer Service Center for proper disposal instructions regarding the analyzer and its associated components. If returning the analyzer to Essenlix, follow the official return guidelines, and ensure the device has been thoroughly disinfected prior to shipment.

For local disposal, the analyzer must be properly disinfected before disposal. The entire disposal process must comply with all relevant local environmental, health, and safety regulations. This includes following appropriate procedures for disposing of electronic equipment and power supplies in accordance with regional guidelines.

## Chapter 8 Quality Control

The analyzer is factory-calibrated and does not require additional calibration prior to use. The iMOST-L system conducts an automatic self-test with each measurement. If the self-test fails, an error message will be displayed, and the system will stop the measurement process.

To maintain optimal detection accuracy, users should adhere to routine maintenance protocols and implement appropriate quality control (QC) procedures. Regular use of Liquid Quality Controls (LQC) is strongly recommended to assess the performance of both the analyzer and the reagents. LQC is a quality control material recommended by Essenlix, produced by an independent third-party manufacturer and approved by relevant regulatory authorities. All LQC materials must be stored and used in accordance with the manufacturer's instructions. Quality control testing should be performed using the same procedure as patient testing, to ensure consistency, accuracy, and reliability of the system's performance.

## Chapter 9 Service

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