Fluorescence Immunoassay Device

BR-FIA-2000

User Manual

Contents

Chapter 1 Introduction

1.1 Intended Use

The Fluorescence Immunoassay Device is an analyzer that is based on the detection of fluorescence emitted in a lateral flow immunoassay with antigen-antibody interaction. The analyzer is designed to provide quantitative or qualitative test results by the examination of human samples with specific *in vitro* diagnostic test units including Inflammation Markers, Tumor Markers, Nephrology, Diabetes, Cardiac Markers, Coagulation, Endocrinology, Autoimmunity, and Infectious Diseases etc. The Fluorescence Immunoassay Device offers the advantages of high accuracy, strong stability and fast results in a portable device. The Fluorescence Immunoassay Device should only be used with *in vitro* diagnostic tests manufactured by Biopanda Reagents Ltd as per the package insert provided with the specific test kits.

For professional *in vitro* diagnostic and point of care use.

Please read this User Manual carefully in full before operation.

1.2 Scope of Application

The Fluorescence Immunoassay Device works with certain fluorescent reagents. It is intended for professional *in vitro* diagnostic and Point of Care Use. It may be used in central laboratories of medical institutions, outpatient or emergency departments, clinical departments or medical services (such as community health centers), or medical centers, etc. It can also be used in research laboratories.

1.3 Product Name

Name: Fluorescence Immunoassay Device

Model: BR-FIA-2000

1.4 Principle

This analyzer uses a UV LED light source to excite europium microsphere labeled particles, then collects and analyzes the signal that is re-emitted to provide a test result.

Chapter 2 Analyzer Components and Parameters

2.1 Standard Equipment List

No.	Description	Model	Quantity
1	Analyzer	BR-FIA-2000	1
2	Charger	/	1
3	QC Test Cassette	/	2
4	User Manual	/	1
5	Printer Paper Roll	57*20 mm	1
6	Stylus	/	1
7	Scanner	/	Optional

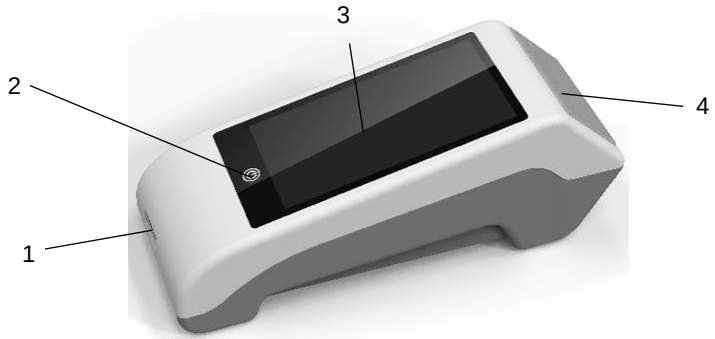
Upon receiving the analyzer, please check the accessory list and ensure there is nothing missing or damaged. The scanner is an optional accessory, which is available for specific requirements.

Please keep the original box that the analyzer and accessories were packaged in for future shipping/reference purposes.

Biopanda Reagents Ltd strives to provide the correct type of power cord suitable for each country. However, this may not always be possible. In such cases, please use an appropriate plug adapter to charge the analyzer.

Attention: If any accessories are missing or arrive damaged, please contact the manufacturer or your local distributor.

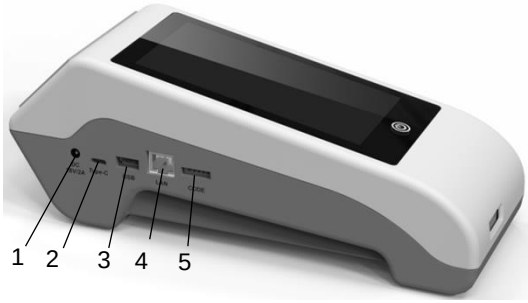
1) Analyzer View



1- Test cassette slot; 2- Power button; 3- Touch screen; 4- Built-in thermal printer

Fig 2.1 (Front view)

1. Test cassette slot: Insert the test cassette.
2. Power button: To turn the analyzer on and off.
   Note: The power button also indicates if the analyzer is on/off, and/or charging. See ***Chapter 4.1*** for detailed information.
3. Touch screen: Displays analyzer software interface.
4. Built-in thermal printer: Prints test results.



1- Power port; 2- USB Type-C port; 3- USB Type A port; 4- LAN port; 5- ID card slot.

Fig 2.2 (Left view)

1. Power port: Connect to the charger (Fig 2.3) to charge the device.
2. USB Type-C port: Used to transmit data.
3. USB Type-A port: For upgrading and exporting data, or for connecting a scanner.
4. LAN port: For connecting a network cable.
5. ID card slot: Insert the ID card here to import test information.

Note: The analyzer is tested for immunity to electrostatic discharge and complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6. However, when using the analyzer in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.), it may cause damaging static discharges that may cause erroneous results. Do not use the analyzer in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the analyzer.

2) Charger

Fig 2.3

3) QC test cassette

Fig 2.4

The QC test cassette is used to verify the analyzer is operating up to standard.

NOTE: The above pictures are for reference only, the actual product may differ slightly in appearance.

2.2 Technical Specification

No.	Parameter	Description
1	Principle	Fluorescence Immunoassay
2	Test formats	Cassette
3	Measurement	Quantitative, Qualitative
4	Read Time	< 20 seconds
5	Test Time	Variable depending on test
6	Specimen	Variable depending on test
7	Power Supply	DC 18 V 2 A
8	Charger Input	AC 100-240V 50/60 Hz
9	Dimension	275 mm*105 mm*100 mm (L*W*H)
10	Screen size	5 inches
11	Weight	1 kg

12	Spectrum	Mean excitation wavelength λ0=365nm Mean emission wavelength λ1=610nm
13	Memory	10,000 records
14	Printer	Built-in thermal printer
15	Ports	1×LAN, 1× USB Type-A1, 1×USB Type-C

2.3 Transportation and Storage Conditions

2.3.1 Packaging

Packing cases should be reinforced with shockproof liners and moisture-proof packing (plastic bags).

2.3.2 Transportation

- Temperature: -30~55°C;
- Relative humidity: ≤ 85%.

Note: No toxic gases, flammable, explosive substances and corrosive gases are allowed. Attention should be paid to avoid exposure to moisture, shock and severe vibration during transportation.

2.3.3 Storage

- Storage temperature: 5~45°C;
- Relative humidity: ≤ 85%;
- Atmospheric pressure: 86~106 kPa, no corrosive gas.

2.4 Operating Conditions

- Adapter input: 100-240 V AC, 50/60 Hz;
- Power: 36 VA;
- Environment temperature: 10~30°C;
- Relative humidity: ≤ 85%;
- Atmospheric pressure: 86 kPa~106 kPa.

Chapter 3 Analyzer Installation

3.1 Installation Requirements

The Fluorescence Immunoassay Device should be placed indoors on a flat work surface that meets the following requirements:

- The analyzer should be placed in an indoor environment free of dust, direct sunlight or corrosive gases. The countertop must be able to sustain a weight of 1.5 kg.
- No strong vibration source and strong electromagnetic fields around.
- The analyzer should be placed in a well-ventilated place. There should be at least 10 cm space around the analyzer to ensure the necessary space for operation and maintenance.
- The power supply of the analyzer varies between 100-240V/50/60 Hz AC depending on countries where the analyzer is used. The input voltage is 18 V DC. The power is 36 VA. Avoid short-circuit and electric shock during operation. The analyzer is grounded through the power adapter.

3.2 Loading Printer Paper

Install or replace the print paper roll in the order as shown below, the size of the paper roll is 57*20 mm.

Step 1: Pull out the buckle under the printer indicator (Fig 3.1), press the buckle slightly downward and pull out the printer cover (Fig 3.2).

Step 2: Take the printer paper roll along with the analyzer, remove the wrapping paper and insert the paper roll under the printer roll. Make sure the paper is placed flat against the printer roll in the directions shown in Fig 3.3.

Step 3: Close the printer cover and reset the buckle (Fig 3.4).

Fig 3.1

Fig 3.2

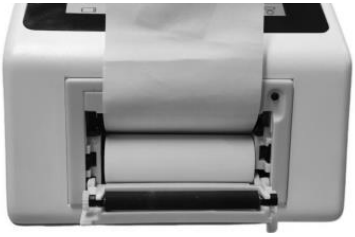


Fig 3.3

Fig 3.4

Note: Heat-sensitive paper must be placed flat in the center to prevent the paper from skewing or jamming. Pull out approximately 3-5cm of paper from the roll, then close the cover of the printer. The printer will only print on the outside surface of the roll. If placed incorrectly, the printer may not print.

Chapter 4 Instructions for Use

Please use the analyzer under the proper conditions listed in ***2.4 Operating Conditions***.

Prior to testing, read the user manual carefully and ensure sufficient understanding of the Fluorescence Immunoassay Device components.

4.1 Power on/off

- Charging:

  Connect the analyzer to a power socket with the charger provided with the analyzer for charging. The battery status is displayed at the top right corner of the screen.

  Note: Before turning the analyzer on, the analyzer should be fully charged (charging time should be 2-3 hours). Be careful not to overcharge or over-discharge, as this may damage the batteries and the analyzer.

- To turn the analyzer on:

  Press and hold the power button to turn the analyzer on and enter the initialization interface.

- To turn the analyzer off:

  Press and hold the power button to turn the analyzer off.

- Sleep mode:

  The default inactivity time before the analyzer enters sleep mode is 5 minutes. Please refer to ***4.5.2 Dormant Settings*** to change as per user preference.

Power Indicator Description

No.	Analyzer Status	Indicator Status
1	Power on	Green light. After entering the login interface, the green light will turn off indicating that battery power is sufficient for normal use.
		Red and green lights flicker alternately. The analyzer screen remains off indicating that battery power is very low. The analyzer needs to be charged sufficiently before use.
2	Power on and no operation within 5 minutes.	Green light is on, indicating the analyzer has entered sleep mode.

3	Power on and fully charged	No light.
4	Power off	Red light. The analyzer is turning off.
5	Power off and charging	The indicator flickers in the relevant colors depending on the battery power level (Green/Yellow/Red). Once fully charged, the indicator light will turn off.

Note: The indicator shows whether the analyzer has been turned on/off, it also indicates the battery status when charging. If the analyzer cannot be turned on and the indicator light does not light up, please try to charge the analyzer. If the problem persists, please contact the manufacturer or your local distributor.

4.2 Login

Press the power button to turn on the analyzer. The login interface will appear after analyzer initialization (Fig 4.1).

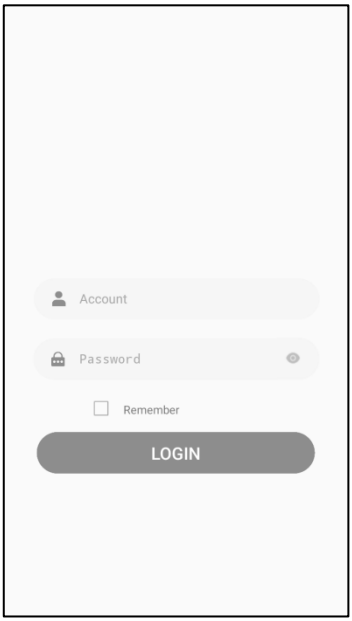


Fig 4.1

Enter the main account: **admin**; the default password is **123456.**

Tap “**LOGIN**” to enter the main interface, as shown in Fig. 4.2.

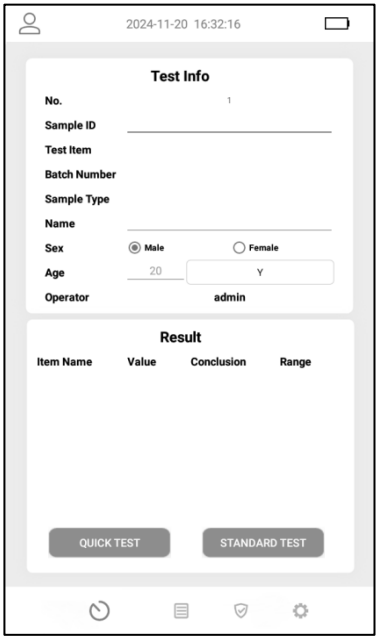


Fig 4.2

NOTE 1*: Admin** is the main account. To change the password, please refer to ***Section 4.5. User Settings.

NOTE 2*:** The **admin** account can create a sub-account, please refer to ***Section 4.4.

The sub-account will only have access to the **Test**, **History,** and **QC** functions, and cannot enter the **Settings** function. The admin account can view the historical data of all accounts.

***NOTE 3*:** User can tap the icon on the upper left of any interface to exit the current account and return to the login interface.

4.3 QC Test

Tap the icon on the main interface to enter the QC test interface, as shown in Fig 4.3.

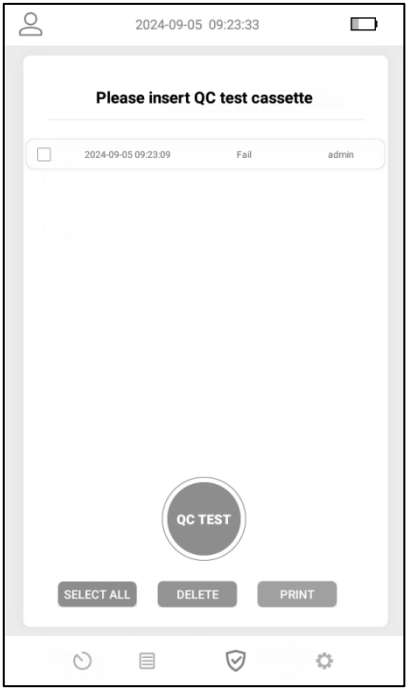


Fig 4.3

Insert the QC test cassette provided with the analyzer into the end of the test cassette slot as the arrow direction, with the sample well outward (Fig 4.4, Fig 4.5).

Fig 4.4

Fig 4.5

Tap “**QC TEST**” to start QC test. Once the QC test is complete, a pass or fail pop-up will be displayed on screen as seen in Fig 4.6 and Fig 4.7.

Fig 4.6

Fig 4.7

If the QC test fail message is displayed, please check whether the QC test cassette used is correct, restart the analyzer and test the QC cassette again.
If the QC test fail message continues to pop up, discontinue using the analyzer and contact the manufacturer or your local distributor.

Users are advised to perform the QC test in the following scenarios:
1) The analyzer is being used for the first time.
2) If the analyzer has not been used for an extended period
3) The analyzer has been transported from one place to another.
4) If the analyzer has been subject to any impact or shock e.g. dropped from a height.
NOTE: A QC test should be performed every 3 months under normal circumstances.

QC interface button definition:

Button	Operation
SELECT ALL	Select all QC records
DELETE	Delete the selected QC test record
PRINT	Print the selected QC record

4.4 History

Tap the button to enter the test result records interface.

1) Search test record

Enter the Name/Sample ID/Item/No. in the search bar and tap the icon to filter the target test result, as shown below in Fig 4.8.

Fig 4.8

2) View historical test details

- To view the details of a historical test record, the user can press and hold on the historical record to view the details page (Fig 4.9). On the details page, users can view Sample ID/Name/Sex/Age/Test Item/Sample Type/Operator /Test Time and test results.
- User can modify the Sample ID/Name/Sex/Age information on the test history details page. After modification, tap "**SAVE**" on the details page to save any changes.

- Tap “**PRINT**” to print the selected patient’s record if automatic printing is off.
- If the LIS system is connected, tap “**UPLOAD**” to transfer the history information to LIS. When upload successfully, “**Upload succeeded**” will be displayed on the analyzer screen. If the upload fails, “**Upload failed**” will pop up instead. If this error continues to appear, please contact the manufacturer or your local distributor.

NOTE: The admin account can view the test records of all accounts. Sub-accounts can only view their own test records.

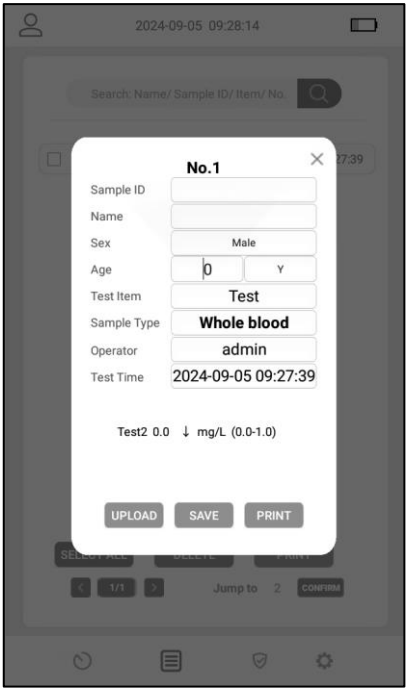


Fig 4.9

3) History interface button definition:

Button	Operation
SELECT ALL	Select all test records
DELETE	Delete the selected test record
PRINT	Print the currently selected test record

	Page back
	Page forward
	Input the page number and tap “**CONFIRM**” to show the test records on the target page.
	Search the test records

4.5 Settings

Tap the Settings  icon to access “**About**”, “**System**”, “**Time**”, “**User**”, and “**Debug**”, as shown in Fig 4.10.

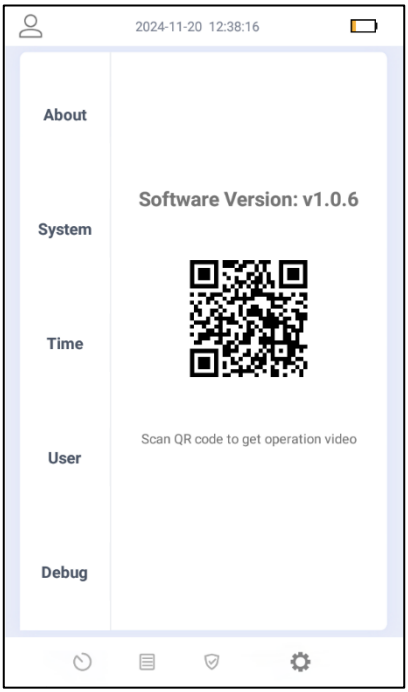


Fig 4.10

NOTE: Only the **admin** account has the access to the **Settings**.

4.5.1) About

Tap “**About**” to view the software version, as shown in Fig 4.10. The software version may be required for technical support. Scan the QR code on the interface to access the manufacturer website with operation video.

NOTE: The software version and QR code shown in Fig 4.10 are for reference only. Please refer to the software version and QR code displayed on the actual analyzer in use.

4.5.2) System

Tap “**System**” to enter the system interface, as shown in Fig 4.11.

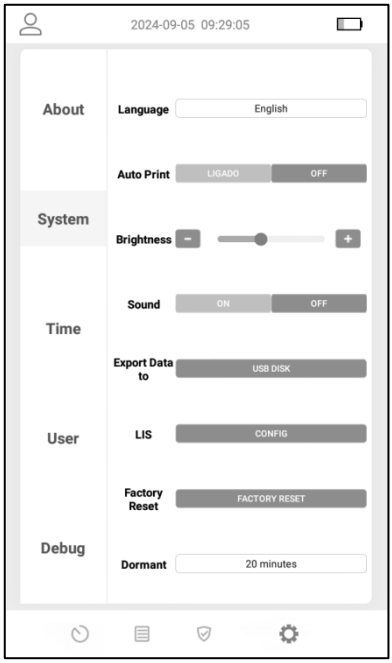


Fig 4.11

- **Language**

  Default language can be changed here.

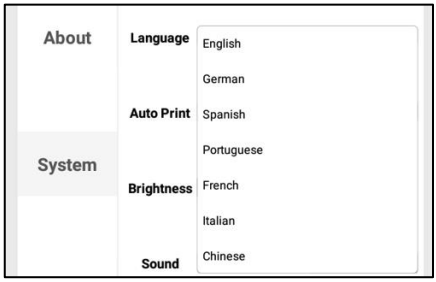


Fig 4.12

- **Auto Print**

Tap "**On**" or "**Off**" to turn automatic printing on/off. The selected option will turn blue to differentiate.

Fig 4.13

- **Brightness**

Tap "+" to increase screen brightness;

Tap "-" to reduce screen brightness.

NOTE: Users can change the screen brightness by dragging the slider on the progress bar left and right as an alternative method.

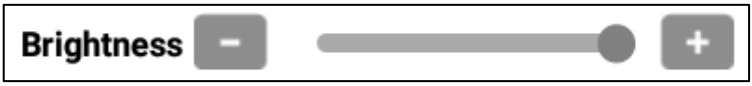


Fig 4.14

- **Sound**

Tap "**On**" or "**Off**" to turn the analyzer beeps on or off. When **"On"** is selected, the analyzer will emit a "**beep**" prompt tone at the end of each test.

Fig 4.15

- **Export Data to**

The function is used for exporting data. Data can be exported to a USB drive:

- Insert a USB drive into the USB Type-A port.
- Tap "**USB DISK**" button (Fig 4.16) and the historical test data will be

exported. If a USB is not inserted, the interface prompts a "**Please insert USB disk**" pop up, as shown in Fig 4.17.

Fig 4.16

Fig 4.17

- During the data export process, the button "**Export Data to**" turns gray. Once exporting is complete, the button will turn from gray to blue and a message indicating that the data export is successful will display, as shown in Fig 4.18. If export fails, please contact the manufacturer and/or your local distributor.

Fig 4.18

➢ **LIS**

Before use, the user should contact a technician for requirements and enter the configuration information under the guidance of the technician. After configuring the LIS function, the test data can be uploaded to the LIS system.

Tap "**CONFIG**" (Fig 4.19) to enter the LIS configuration interface.

Fig 4.19

- **Factory Reset**

Tap "**Factory Reset**" to enter the restore factory settings interface, as shown in Fig 4.20.

Fig 4.20

In the pop-up interface, tap the "**Factory Reset**" option, tap "**Confirm**" to clear all data and restore the initial settings; tap "**Cancel**" to cancel the factory reset, see Fig 4.21.

Fig 4.21

- **Dormant**

Tap "**Dormant**" to set the automatic inactivity sleep timer. There are three options: 5 minutes, 15 minutes, and 20 minutes. (Fig 4.22)

Once the analyzer has entered sleep mode, the analyzer can be awakened by pressing the power button

If analyzer has been in sleep mode for 10 minutes, the analyzer will automatically turn off.

Fig 4.22

4.5.3) Time

Tap “**Time”** to change the date and time.

Set the year, month, day, hour and/or minute as appropriate. Tap “**Set**” to save any changes made. Tap “**Clear**” to remove all changes and restore to the previously set date and time (Fig 4.23).

4.5.4) User

Tap “**User**” to view all user accounts of the analyzer (Fig 4.24).

Admin can add, delete and change user account(s) in this interface.

Fig 4.23

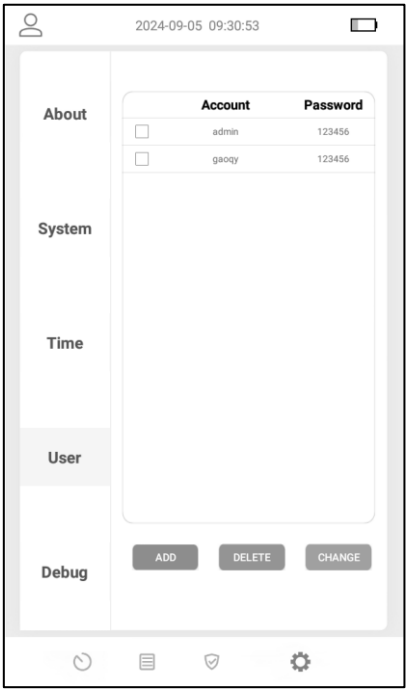


Fig 4.24

NOTE: The main account: **admin** cannot be deleted. After deleting a user account, all test records related to the account will be deleted. Please use this function with caution!

- **Add a User**

  Step 1: Tap “**ADD**” in Fig 4.24 to enter the **Add User** interface

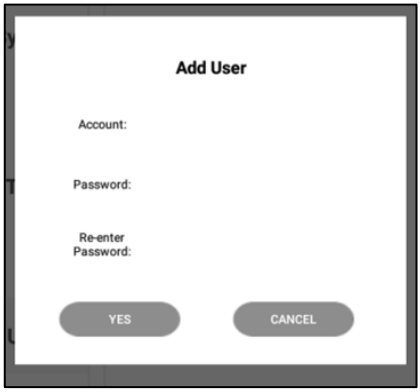


Fig 4.25

Step 2: Fill in the new user name in "**Account**", enter the password of the new user in "**Password**", and enter the password again in "**Re-enter Password**". Tap "**YES**" to complete the adding of a new user account. Tap "**CANCEL**" to clear the current content and return to the user interface. The user name and password can contain a maximum of 18 characters.

NOTE: When "The two passwords entered are not the same. Please re-enter the password." message is displayed, please check that the **Re-enter Password** input is the same as the **Password** input.

- **Delete a User**

  Tap "**DELETE**" (Fig 4.24) to delete the selected user account.

- **Change user account information**

  Step 1: Select the account that needs information updated in the **User** interface, and tap "**CHANGE**" to enter the **Change User** interface to change user account information (Fig 4.26).

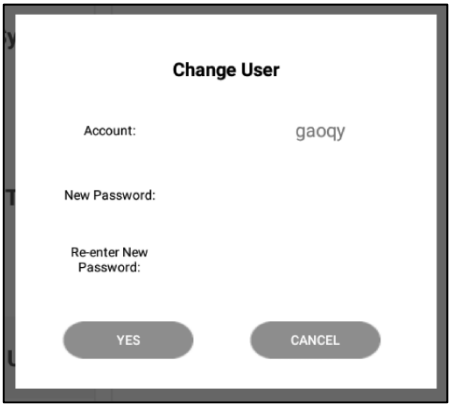


Fig 4.26

Step 2: Input a new password in "**New Password**" and "**Re-enter New Password**". Tap "**YES**" to save.

***NOTE*:** The username cannot be changed, only the password can be changed.

4.5.5) Debug

The debug function is used to handle after-sales problems under the guidance of an after-sales technician. This function does not affect the normal use of the analyzer.

4.6 Test

1) Item information Import

Step 1: Take out the ID card (Fig 4.27) provided with test kit from the specific test, and insert the ID card into the ID Card Slot, as shown in Fig.4.28.

Fig 4.27

Fig 4.28

Step 2: The ID card information import interface will display on the screen, as shown in Fig 4.29. Tap "**OK**".

Fig 4.29

***NOTE*:** The pop-up window should display the project name and Curve Code, indicating that the ID card information has been successfully imported.

Step 3: Remove the ID card after the information is imported successfully.

***NOTE 1*:** ID card information for one lot of test should only be imported once. If a **Factory Reset** was performed, the user needs to import the ID card information again.

***NOTE 2*:** If a message indicating that the ID card information has failed to import, reinsert the ID card and try again.

If the import continues to fail, stop using the analyzer and contact the manufacturer or your local distributor.

2) Testing Procedures

There are two modes for testing: **Quick Test** and **Standard Test**.

Quick Test Mode: Incubation of the test cassette is carried out outside the analyzer. It is the responsibility of the user to insert the test cassette for reading after the correct amount of time has elapsed.

Standard Test Mode: Incubation of the test cassette is carried out inside the analyzer, and the cassette is automatically read at the prescribed reading time.

Mode 1: Quick Test Mode

Step 1: Fill in the sample and patient information

Tap the icon, and fill in the details as shown in Fig 4.30.

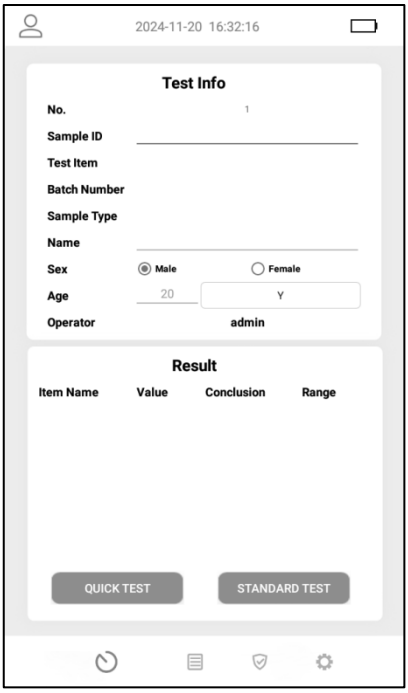


Fig 4.30

***NOTE 1*: ‘**No.’ is automatically advanced for each test and cannot be modified or customized. After a factory reset has been carried out, the numbering will restart at 1.

***NOTE 2*:** The age options are Y, M and D; where Y indicates the year, M indicates the month, and D indicates the day.

Step 2: Add the sample to the sample well, and insert the test cassette into the analyzer after incubation.

Add the sample and/or buffer to the test cassette as per the instructions for use for the test, and place the test cassette on a clean and flat surface by the side of the analyzer for incubating. The incubation time is mentioned in the package insert.

After incubation, insert the test cassette into the end of the test cassette slot **with the sample well facing outward**, as shown in Fig 4.4, Fig 4.5.

***NOTE*:** Do not use excessive force when inserting the test cassette, otherwise the analyzer alarm may be triggered during the test. When the analyzer alarm is triggered, take out the test cassette and restart the analyzer. If the alarm continues to sound after restarting the analyzer, please contact the manufacturer and/or your local distributor. This also applies for the Standard Test mode.

Step 3: Tap "**QUICK TEST**". The analyzer will read the QR code information on the test cassette and the Test Type, Batch number and Sample Type will display on the interface. At the same time, the analyzer will read the test cassette. After reading, the analyzer will display the test result on the interface (Fig 4.31). The test cassette will automatically be ejected.

NOTE: If the test item supports more than one sample type, a window will pop up to confirm the sample type used. The user can select the sample type accordingly (Fig 4.32) and then tap "**YES**". This also applies for the Standard Test mode.

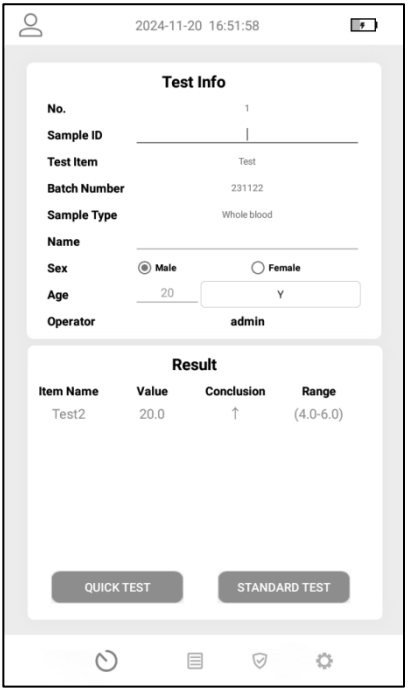


Fig 4.31

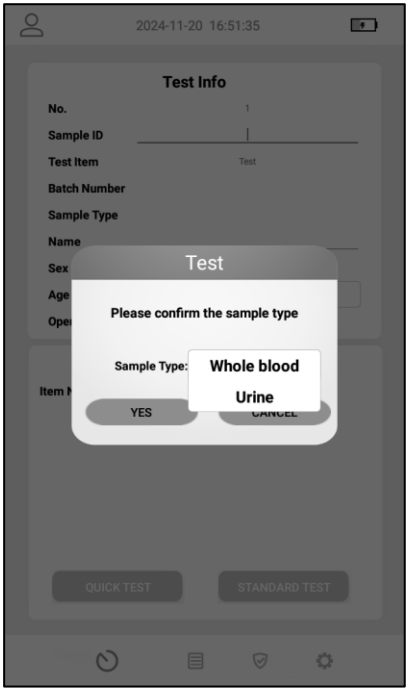


Fig 4.32

Mode 2: Standard Test Mode

Step 1: Fill in the sample and patient information

Tap the button and fill in the information as shown in Fig 4.30.

Step 2: Add the sample and/or buffer to the sample well as per the instructions for use for that test, then immediately insert the test cassette into the test cassette slot **with the sample well facing outward**, as shown in Fig 4.4 and Fig 4.5.

Step 3: Select "**STANDARD TEST**" and the analyzer will begin the incubation timer. The analyzer will read the QR code information on the test cassette and the Test Item, Batch number and Sample Type information will show on the interface (Fig 4.33).

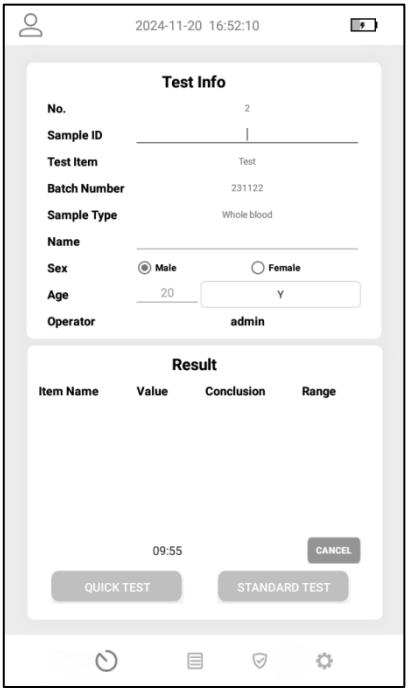


Fig 4.33

Step 4: After the incubation countdown, the analyzer will read the test cassette and display the test result (Fig 4.31). The test cassette will automatically eject itself from the analyzer.

***NOTE*:** If the user wants to stop the standard test, tap the "**CANCEL**" button shown in Fig 4.33. The analyzer will stop the test and eject the test cassette.

***NOTE*:** If "**Auto Print**" is on, the analyzer will automatically print the results after testing is complete. If "**Auto Print**" is off, manually tap "**PRINT**" to print the test results (refer to Fig 4.8).

Chapter 5 Maintenance and Cleaning

5.1 Attention

1) Ensure that the power socket is reliably grounded. If not, replace the power socket.
2) Visually check whether the charger is damaged or broken. Damaged or broken chargers may cause fires due to electric leakage. Contact technical support immediately to replace the charger.

5.2 Analyzer Maintenance and Cleaning

1) The analyzer only needs external cleaning and dust removal, no special maintenance items.
2) Before cleaning the analyzer, turn the analyzer off and ensure that the power cord plug is disconnected to prevent short circuits and electric shocks. Do not clean and disinfect the analyzer while it is charging
3) When cleaning the analyzer, use a wet cloth and 70% ethanol to clean the outer surface of the analyzer. Do not use strong bleach (≥0.5% solution) as oxidants and solvents may damage the analyzer casing and touch screen. Be careful not to clean any internal parts or internal surfaces.
4) Check the printer daily to ensure there is sufficient paper to prevent unnecessary delays when carrying out tests.
5) If the customer wishes to follow instructions other than those in this manual to clean the analyzer, please consult the technical service personnel first.
6) If the analyzer is not used for a long time, it must be thoroughly disinfected and stored in the original packaging in accordance with the storage conditions set out in ***2.3.3 Storage***.

Chapter 6 Safety and Precautions

1) For professional use only.

   ***NOTE*:** Persons other than those specified above should not operate the analyzer. Biopanda Reagents Ltd will not be responsible for any malfunctions of the analyzer in these cases.
2) Use test kits manufactured by Biopanda Reagents Ltd and supplied by authorized distributors of Biopanda Reagents Ltd only. The customer should prepare for the analyzer installation according to the instructions.
3) Analyzer installation, maintenance and cleaning, after-sales service, and repairing work should only be carried out by professionals.
4) Improper operation of the analyzer under abnormal electrical conditions will cause damage to the analyzer. Do not interfere with the normal movement of the analyzer.
5) If there is liquid inside the analyzer, turn off the analyzer immediately and cut off the power. Seek a professional technician for assistance.
6) Operations specified in the User Manual to be performed by technical service personnel must be performed by authorized technical engineers.
7) Materials from human or animal sources, as well as tissue or in vitro cultures, must be handled in accordance with the principle of potential risk of infection. Always wear appropriate protective equipment such as approved disposable gloves, waterproof laboratory coats, and safety goggles when handling biohazardous materials. Dispose of biohazardous materials according to equipment biohazard procedure.
8) The following items must be treated as potential biohazards: all in vitro diagnostic devices, pretreatment equipment, samples, serum-based calibration reagents, QC products, and waste materials.
9) Waste disposal must comply with local laws and regulations.
10) Always wear approved protective equipment when operating or maintaining the analyzer. Protective equipment must include, but is not limited to, approved protective gloves, waterproof lab coat, protective masks, and safety glasses.
11) If biohazardous material spills onto the analyzer, it should be cleaned immediately, washed with residual material and disinfected with disinfectant.

12) If any biohazard comes into contact with skin, wash immediately and disinfect with disinfectant in accordance with laboratory practice, and consult a doctor.
13) Fire regulations in the medical field must be strictly observed and enforced. Fire extinguishers for both electrical and non-electrical fires must be provided.
14) For electrical fires, use only specific extinguishers. Water or other liquid extinguishers can cause serious injury. To minimize the risk of electric shocks, the power supply should be cut off before extinguishing the fire.
15) Keep flammable materials away from the analyzer when using alcohol for repair or maintenance. When using ethanol on or around the analyzer, do not exceed 20 mL at a time. Isopropyl alcohol and ethanol (70%) are flammable substances and present combustion, explosion, and burn hazards.
16) When using the analyzer, the electrical equipment associated with the analyzer should comply with local standards.
17) Biopanda Reagents Ltd. will not be held responsible for the safety, reliability and performance of the products in the following cases:
    - The analyzer is disassembled for repair without the authorization or guidance of Biopanda Reagents Ltd.;
    - The analyzer is not used correctly in accordance with this manual.
18) Any serious incident that has occurred in relation to the analyzer shall be reported to the manufacturer and the competent authority.

Chapter 7 Troubleshooting, Service and Disposal

This chapter lists the possible faults that may occur during the use of the analyzer and the solutions to these faults. When the user comes across a fault, the user can troubleshoot the fault according to the instructions in this chapter by referring to the type of fault. If a fault occurs that is not covered in this chapter, please contact the manufacturer or your local distributor.

7.1 Common Faults and Troubleshooting

Fault code	Fault phenomenon	Possible cause	Solutions
ERR 3	Command is Error	Test invalid	Replace the test cassette. If the problem persists, contact the manufacturer or local distributor.
		Analyzer detects component failure	Restart the analyzer. If the problem persists, contact the manufacturer or local distributor.
ERR 6	Motor is not Initialized	Mechanical motion failure	Restart the analyzer. If the problem persists, contact the manufacturer or local distributor.
ERR 7	Motor exceeds the software limitation	Config error	Contact the manufacturer or local distributor.
ERR 8	Motor meets the Limit Sensor	Mechanical movement failure or operation error	Restart the analyzer. If the problem persists, contact the manufacturer or local distributor.
ERR 11	Motor is out-of-step	Other fault	Contact the manufacturer or local distributor.
ERR 12	Motor driver is error		Contact the manufacturer or local distributor.
ERR 27	The original sensor is not found		Contact the manufacturer or local distributor.

7.2 Service and Disposal

The internal structure of the analyzer, including the circuit board, optical detection module, touch screen, printer, camera and other important parts, can only be replaced and checked by Biopanda Reagents Ltd; no third party is allowed.

If the product runs abnormally due to a fault and user cannot solve the problem, please contact the manufacturer or your local distributor who will provide remote technical support to help troubleshoot.

If, for any reason, the user needs to destroy the product, it is recommended that the user does so in accordance with the Regulations for Class B electronic Analyzers.

During use, the user should maintain and repair the analyzer in accordance with the requirements of the analyzer user manual.

The analyzer that is confirmed to maintain the essential safety and effectiveness after maintaining and repair can be used normally. Biopanda Reagents Ltd declares that the above service guarantee can only be obtained under the condition of complete compliance with the instructions in this manual. Otherwise, Biopanda Reagents Ltd will not take any responsibility.

This product is required to comply with the European Unions' Waste Electrical & Electronic Equipment (WEEE) Directive. If you wish to discard electrical and electronic equipment (EEE), please discard according to your local regulations.

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Appendix

A. Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within one year of purchase.
For your records, write the purchase date of your starter kit here:

_____

Note: This warranty applies only to the analyzer in the original purchase. It does not apply to the other materials included with the analyzer.
Biopanda Reagents Ltd warrants to the original purchaser that this analyzer will be free from defects in materials and workmanship for a period of one year (12 months). The one-year period starts from the latter date: date of original purchase or installation (except as noted below). During the stated one-year period, **Biopanda Reagents Ltd** shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. **Biopanda Reagents Ltd** shall not be responsible for shipping charges incurred in the repair of such an analyzer.
This Warranty is subject to the following exceptions and limitations:
This warranty is limited to the repair or replacement of the analyzer due to defects in parts or workmanship. Parts required which were not defective can be replaced at an additional cost. **Biopanda Reagents Ltd** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the analyzer in accordance with the operations manual, or maintenance by anyone other than **Biopanda Reagents Ltd.**
Furthermore, **Biopanda Reagents Ltd** assumes no liability from malfunction or damage to analyzers caused by the use of products other than products manufactured by **Biopanda Reagents Ltd. Biopanda Reagents Ltd** reserves the right to make changes in the design of this analyzer without obligation to incorporate such changes into previously manufactured analyzers.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by **Biopanda Reagents Ltd**.

Limitations of Liability

In no event shall **Biopanda Reagents Ltd** be liable for indirect, special, or consequential damages, even if **Biopanda Reagents Ltd** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.

B. Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within one year of purchase.

Purchaser	
Model	
Serial Number	
Date of Purchase	
Address	
Telephone Number	
E-Mail Address	