Blood Gas Analyzer

User's Manual

Table of Contents

1. Security Guide....4

1.1 Safety Operation Guide....4

1.2 Safety Instructions for Use....4

1.3 Electromagnetic Compatibility....8

2. Product Overview....9

2.1 Intended Use....9

2.2 Introduction....9

2.3 Appearance....10

2.4 Composition....10

2.4.1 Display....10

2.4.2 Thermal printer....10

2.4.3 Power port....11

2.4.4 Network port....11

2.4.5 Scanner module....11

2.4.6 ON/OFF button....11

2.4.7 Cartridge slot....11

2.4.8 Speaker....12

2.4.9 Battery....12

2.4.10 Indicator light....12

2.5 Configuration....13

2.5.1 Product kit....13

2.5.2 Matching products....13

3. Installation....14

3.1 Open-box Inspection....14

3.2 Installation Requirements....14

3.2.1 Environmental requirements....14

3.2.2 Power requirements....15

3.3 Installation Procedure.....15
3.3.1 Connecting to an AC power.....15
3.3.2 Install/replace the thermal paper.....16

4. Collecting Blood Samples.....17

4.1 Animal Status 17
4.2 Preparation of Sample Collection and Anticoagulants Selection.....17
4.2.1 Preparation of sample collection.....17
4.2.2 Anticoagulants selection.....17
4.3 Blood Sample Collection.....18
4.3.1 Blood sample types.....18
4.3.2 Notes for operation.....18

5. Operating Procedure.....19

5.1 Turn on/off the Analyzer.....19
5.2 Login/logout.....20
5.3 User Management.....21
5.4 Settings.....24
5.4.1 Enter the settings interface.....25
5.4.2 System setting.....25
5.4.3 Network.....27
5.4.4 Print settings.....29
5.4.5 Detection settings.....29
5.5 Sample Testing.....33
5.5.1 Access the sample testing interface.....33
5.5.2 Scan/enter animal's information.....34
5.5.3 Scanning/entering animal information.....35
5.5.4 Insert cartridge.....36
5.5.5 Test results.....39
5.6 Quality Control.....40
5.6.1 Quality control.....41
5.6.2 Quality control analysis (Blood Gas Control Solution).....41
5.6.3 Quality control analysis (Electrical Control Cartridge).....46

5.7 Data....49
5.7.1 Access the data center....49
5.7.2 Sample results....50
5.7.3 Quality control results....52
5.7.4 Operation logs....54
5.8 About....55
5.9 Help....56

6. Cleaning, Maintenance and destruction....57
6.1 Cleaning and Disinfection....57
6.2 Care and Maintenance....58
6.2.1 Battery capacity, charging, and replacement....58
6.2.2 Printer and printer paper....59
6.2.3 Maintenance....59
6.2.4 Quality control....60
6.3 Destruction....60

7. Repair and After-Sales Service....61
7.1 Repair....61
7.2 After-Sales Service....62

Appendix....63
Appendix 1. Specifications....63
Appendix 1.1 General....63
A1.2 Mechanics....63
A1.3 Performance....63
A1.4 Pinter....64
A1.5 Battery....64
A1.6 Safety certification....65
Appendix 2. Troubleshooting Guide....66
Appendix 3. Symbols....69

1. Security Guide

Thank you for choosing Blood Gas Analyzer. To use the analyzer safely and effectively and avoid possible injuries, please read the user's manual in detail before use to fully understand the correct operation methods and ensure proper use of the analyzer. Please keep this manual safely.

This product manual contains proprietary information protected by copyright law, including but not limited to technical secrets, patent information and other trade secrets. The user has a duty of confidentiality and shall not disclose any content of this manual to unrelated third parties.

⚠ Caution

• To ensure the normal operation of Blood Gas Analyzer and the safety of users, please read this chapter before use. Please contact the authorized installation engineer to install and connect your analyzer.

1.1 Safety Operation Guide

◆The analyzer can meet the technical specifications when operating at an ambient temperature between 18°C to 30°C. Ambient temperatures outside this range may affect the accuracy of the analyzer and cause damage to components and wiring. To ensure that the power cord and network cable are not crushed, please leave at least a distance of 5cm around the analyzer.

◆The analyzer must be serviced by an authorized and qualified engineer. Please contact authorized dealers for parts replacement.

1.2 Safety Instructions for Use

To avoid possible injuries, please follow the safety instructions for use when operating the analyzer.

⚠ Warnings

1.This analyzer cannot be used for treatment.

2.The results provided by this analyzer are for reference only and cannot be used as the sole basis for diagnosis.

3.The test strips are intended for veterinary use only, not for use on humans.

4.Users must use this analyzer in strict accordance with the methods. Otherwise, the protection of this analyzer may be damaged.

5.Use the analyzer only for the purpose described in the manual.
6.Users must strictly follow the instructions when collecting and preparing samples.
7.Make sure that the analyzer is used under the conditions specified in this manual, otherwise, the analyzer may not function properly, and the results may be unreliable. The analyzer's components may be damaged in case of inadequate use and cause physical harm.
8.Do not place this analyzer in a location where it is difficult to disconnect.
9.Never use this analyzer in an environment where flammable gases are present.
10.This analyzer is not waterproof. Do not use this analyzer in a place where water or mist may enter the analyzer.
11.Do not let any liquid enter any openings of the analyzer as there may be a risk of electric shock.
12.Do not allow any debris to enter the sockets of the analyzer.
13.Users must ensure that the analyzer and power cord are not damaged before use. It is recommended to do an inspection once a week. Do not use the analyzer if it is damaged or not working properly.
14.Keep this analyzer dry and avoid moving it quickly from lower to higher temperatures, otherwise, condensation or water droplets may form and cause a short circuit.
15.Do not place containers with liquids on top of the analyzer.
16.The analyzer is a precision instrument. Please note the following requirements:
Transportation and storage conditions:
◆Ambient temperature: -20 °C to 55 °C
◆Relative humidity: 10 % to 93 % (no condensation)
◆Atmospheric pressure intensity: 68 kPa to 106.6 kPa
◆Avoid direct light exposure.
Operating conditions:
◆Ambient temperature: 18 °C to 31 °C
◆Relative humidity: 10 % to 85 % (no condensation)
◆Atmospheric pressure intensity: 68 kPa to 106.6 kPa
◆Avoid using it in places with strong electromagnetic interference.
17.Electric shock hazard - Make sure the power outlet is well-grounded. It is prohibited to use outlets without protective grounding. Make sure the ground wire is connected. Do not connect the three-wire cable of this instrument to a two-prong outlet.
18.Electric shock hazard - Never plug or unplug the power cord with wet hands. Make sure the hands are clean and dry when touching the power cord.
19.Before cleaning the analyzer, please turn it off and unplug the power cord to avoid electric shock.
20.Do not disassemble the analyzer outer case to avoid electric shock and potential damage to the analyzer.

21.Electromagnetic interference - Ensure that there are no strong electromagnetic sources (large CT scanners, NMR spectrometers, wireless transmitters, etc.) in the environment where the analyzer is used.

22.Electromagnetic interference - Do not use electromagnetic devices such as cell phones near this analyzer.

23.Operators should comply with the safety regulations and take safety precautions (e.g., wear protective clothes and gloves) when using the analyzer for sample and quality control tests.

24.Please do not use the electrical control cartridge in an environment with electromagnetic interference. Do not touch the electrical control cartridge with your hands during the quality control tests to avoid electric shock.

25.Do not use accessories that are not provided or authorized by manufacture, otherwise, it may cause damage and affect the performance and safety of the analyzer.

26.Please do not switch between power sources during the tests. The power adapters cannot be plugged or unplugged during tests, even when a battery is installed.

27.Battery use: Improper handling may cause the battery to heat up, catch fire, explode, be destroyed, or lose capacity. This analyzer uses rechargeable lithium-ion batteries (hereinafter referred to as "batteries"). Please read this manual carefully before use.

28.Batteries should be charged, used, and stored in a place away from static electricity.

29.The analyzer is used to test K^+, Na^+, Cl^-, iCa^{2+}, pH, pCO_2, pO_2, Glu, Lac, Hct, Hct parameters only. Test samples are potentially infectious, so please take precautions when using the analyzer. Test samples are kept in the cartridges after use. Please dispose of them as biohazard waste or according to the local regulations.

30.The cartridges are single-use only and cannot be reused.

31.The cartridges must be used before the expiration date specified by the manufacturer. Please follow the instructions provided by the manufacturer when using or storing the cartridges.

32.The disposal of used cartridges and expired control solutions should be handled in accordance with the relevant medical waste regulations.

33.Avoid abrupt operations during use, such as inserting and removing cartridges with force.

34.Do not use bent, twisted or deformed cartridges.

35.Please use water or 75% medical alcohol to clean the analyzer. Do not use other cleaning agents.

36.Residual chemical reagents must be removed after disinfection.

37.Please do not sterilize the analyzer and its accessories with autoclaves or gas.

38.Improper repair may cause damage to the analyzer. Operators must follow the instructions in this manual.

39.The analyzer should be subjected to periodic quality control tests to ensure that it is in proper working condition.

40.When using this analyzer, make sure the system date and time are updated, otherwise, it may cause misdiagnosis.

41.The analyzer should not be used beyond its service life, otherwise, the results may be inaccurate. When the service life is reached, the analyzer and its recyclable parts should be returned to the manufacturer for recycling or disposed of in accordance with the local regulations.

42.The transportation, storage, and usage of the analyzer, cartridges, and control solutions should be handled strictly according to the instructions in this manual.

43.The analyzer should be used in a location with a wired network or Wi-Fi so that it can perform data communication promptly when needed.

44.The network device used by the analyzer must have security certification.

45.Contraindication: none.

1.3 Electromagnetic Compatibility

⚠ Warnings

• It is prohibited to use this equipment next to strong radiation sources (e.g., non-shielded RF sources), as this may interfere with the normal operation of the equipment.

⚠ Caution

• It is recommended to evaluate the electromagnetic environment prior to use. This analyzer should not be used in proximity or stacked with other equipment. If it must be used in proximity or stacked with other instruments, it should be monitored to verify if it can operate properly in this configuration.

• It is the manufacturer's responsibility to provide customers or users with the EMC information of the analyzer.

• It is the user's responsibility to ensure the proper EMC environment is maintained.

2. Product Overview

⚠ Caution

• The pictures and interfaces in this manual are for reference only. Please refer to the final product purchased.

2.1 Intended Use

The Blood Gas Analyzer is intended to be used with the Blood Gas Test Cartridges produced by manufacture, for in vitro quantitative measurement of various analytes in fresh whole blood. The meter is intended for veterinary use only, not for use on humans.

2.2 Introduction

The measured parameters help veterinarians to give rapid and accurate diagnosis information to the users. After short training, veterinarians can use this analyzer to analyze blood samples.

This analyzer is suitable for use in professional veterinary settings where the physiological and pathological indicators of animal blood samples need to be analyzed quickly and accurately.

Cartridge details:

Measured parameters: K^+, Na^+, Cl^-, iCa^{2+}, pH, pCO_2, pO_2, Glu, Lac, Hct.

Calculated parameters: cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/-FiO_2, cH^+, iCa^{2+}(7.4), HCO_3-act, HCO_3-std, BE(ecf), BE(B), BB(B), AG, sO_2(est), tHb(est), TCO_2, pO_2(A-a), pO_2(a/A), RI, mOsm, pO_2/FiO_2.

⚠ Caution

• This analyzer must be used by a trained and qualified veterinary professional or used under their direct supervision.

• This analyzer is used for screening only. When making clinical judgments for animals on the basis of the analysis results, veterinarians are also required to consider the results of clinical examinations or other tests.

2.3 Appearance

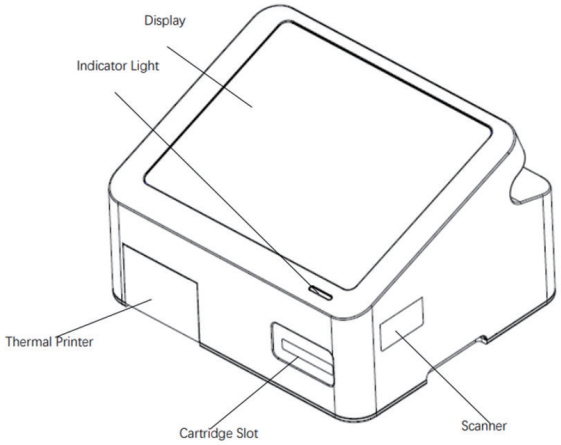


Figure 2-1 Appearance of the analyzer (1)

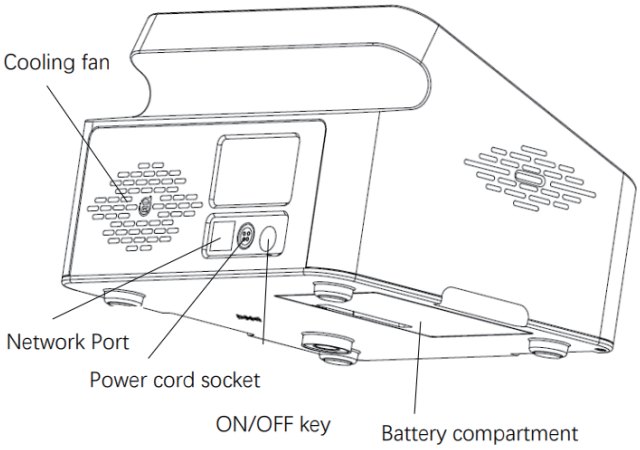


Figure 2-2 Appearance of the analyzer (2)

2.4 Composition

The product is made up of a data output module, a result printing module, a signal acquisition module, a cartridge insertion module, and a circuit control module, which together realize the intended functions of this product.

To help users understand and use the analyzer correctly, the introductions of its compartments, including display, thermal printer, power port, network port, scanner, ON/OFF button, cartridge slot, speaker, and battery are listed below.

2.4.1 Display

The analyzer communicates information to the operator via an LCD screen, which displays the interface, measurement results, database, system information, and prompt indications that help users complete the tests correctly.

The display is a capacitive touch screen. Users use the touch screen to perform operations, such as testing, entering information, and viewing results.

2.4.2 Thermal printer

The thermal printer is located at the front of the analyzer, and uses thermal paper to print out sample results, quality control results, animal information, etc.

2.4.3 Power port

The power port is located at the back of the analyzer and only allows the connection of power adapters provided by manufacture. The user must connect the appropriate power connector according to the labeled information on the power adapter.

2.4.4 Network port

The network port is intended for connecting to the wired network.

2.4.5 Scanner module

The scanner is built into the analyzer and is used to scan barcode or QR code information, including operator's ID, animal's ID, cartridge information, control solution information, etc.

The steps for scanning QR codes are as follows:

1) Follow the prompts, click the scan icon, and the scanner will emit a light beam.

2) Align the QR code with the scanner light. The distance between the QR code and the scanner should be about 5-15 cm.

3) If the scan is successful, you will hear a beep, and the scanner will turn off immediately. If the picked-up information meets the system requirements, the system will move to the next step, otherwise, a prompt box will appear.

⚠ Caution

• Do not look directly at the light beam emitted by the scanner to avoid eye injuries.

• Do not scratch the protective glass of the scanner with hard objects. Scratches may affect the scanning ability.

• Do not hit the protective glass of the scanner to avoid shattering, which may cause injuries.

• When the protective glass of the scanner is dirty, use a lint-free wipe to wipe it. Dirt on the scanner glass may affect the scanning.

2.4.6 ON/OFF button

The ON/OFF button is located at the back of the analyzer. It is used to turn the analyzer on or off.

2.4.7 Cartridge slot

The cartridge slot is located at the front of the analyzer, closest to the operator. It is used to insert cartridges for the corresponding tests or QC operations.

⚠ Caution

• Cartridges must be inserted in place. You will feel distinct haptic feedback when the cartridge is inserted in place. Then the test will start automatically.

• Do not insert other foreign objects into the cartridge slot to avoid damaging the analyzer.

• After the test is completed, please pull out the cartridge promptly. Do not leave used cartridges in the cartridge slot.

2.4.8 Speaker

The speaker is located at the bottom of the analyzer. It is used to send various alerts.

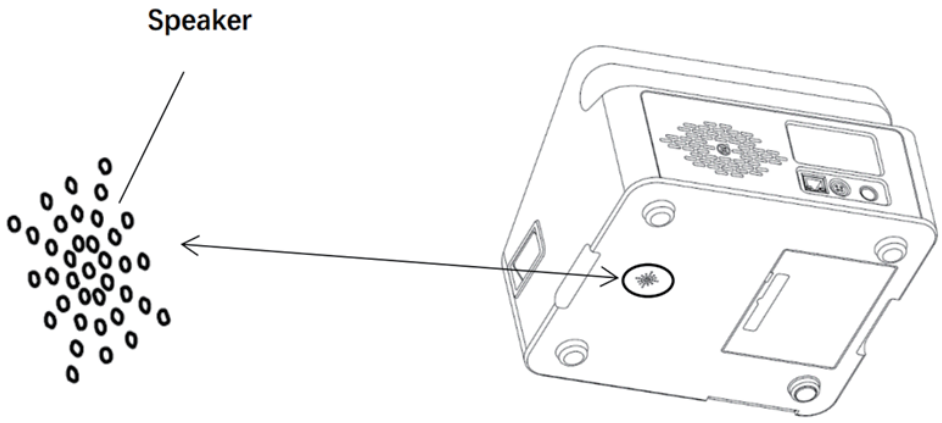


Figure 2-3 The speaker

2.4.9 Battery

The analyzer is equipped with a rechargeable battery. It is located at the bottom of the analyzer and is covered by the battery cover.

2.4.10 Indicator light

The indicator shows the current operating status of the analyzer:

◆ Green light: normal power-on state

◆ Yellow light: testing

◆ Red light: a malfunction occurred (e.g., self-test failed, malfunction in the detection process)

2.5 Configuration

2.5.1 Product kit

- ◆ Blood Gas Analyzer
- ◆ Power Cord
- ◆ Power Adapter
- ◆ Electrical Control Cartridge
- ◆ User's Manual
- ◆ Certificate of Conformity
- ◆ User Acceptance Form
- ◆ Packing List
- ◆ Thermal Printing Paper
- ◆ Quick Start Guide

2.5.2 Matching products

2.5.2.1 Cartridges

Use matching blood gas cartridges.

2.5.2.2 Quality control

Use the quality control products that are intended to be used with this product.

3. Installation

3.1 Open-box Inspection

Please check the outer package before unpacking. If it looks abnormal or damaged, please contact the logistics company immediately for a claim. After unpacking, please check the contents carefully according to the packing list and confirm that no damage was caused during transportation. Install the analyzer according to the instructions. If the package or the content is incomplete, damaged, or the wrong products are sent, please contact the authorized agents.

⚠ Warnings

- Do not use the product if it is damaged after unpacking.
- Avoid collisions and drops.

⚠ Caution

- Save the packaging material for future transportation or storage use.

3.2 Installation Requirements

3.2.1 Environmental requirements

The environment in which the analyzer is used is critical to its performance. Please select a location that meets the following environmental conditions:

- If an AC power is used as the power supply, the location of use should allow an easy access to connect the power cord to a power outlet with ground protection.
- Avoid direct exposure to bright light.
- Ambient temperature: 18°C to 30°C
- Relative humidity: 10 % to 85% (no condensation)
- Atmospheric pressure intensity: 68 kPa to106.6 kPa
- The analyzer should be placed on a flat surface with plenty of space around it. The working surface should be able to carry more than 5kg of weight.
- Avoid using it in places with strong electromagnetic field interference.
- Avoid the interference of dust and volatile gas.
- Ensure that the analyzer is kept away from explosive gases, vapors, and corrosive substances.

⚠ Caution

• The above requirements also apply to battery-powered analyzers.

• The results may not be reliable if the room temperature is outside the normal operating temperature range.

3.2.2 Power requirements

The power supply connected to the analyzer shall meet the following requirements:

Voltage	Allowable Range	Frequency
100V-240V	±10%	50Hz/60Hz

⚠ Warnings

• Make sure the analyzer is used under good grounding conditions.

• Make sure the input voltage meets the requirements of the analyzer.

3.3 Installation Procedure

⚠ Warnings

• The installation of this analyzer must be performed by authorized after-sales service personnel. Installation procedures performed by personnel not authorized or trained by manufacture may cause damage to the analyzer.

Place the analyzer on a platform that meets the installation requirements described in 3.2.1 before proceeding with the next steps.

3.3.1 Connecting to an AC power

Plug one end of the power adapter into the analyzer's power port and connect the other end to the power cord. Connect the power cord to a grounded outlet.

⚠ Caution

• Use power cords and outlets that have protective grounding wires.

• The power adapter must not be unplugged during a test.

3.3.2 Install/replace the thermal paper

The printer paper used by the analyzer is 57mm x 30mm thermal paper. When the analyzer performs printing operations, and no paper is installed, or the paper has run out, the display will show "Printer out of paper." and prompt the user to install or replace the paper.

◆ Install thermal paper:

1) Open the printer cover.

2) Place the new paper in the paper slot with the outer surface of the paper facing upwards towards the thermal print head. (Figure 3-1)

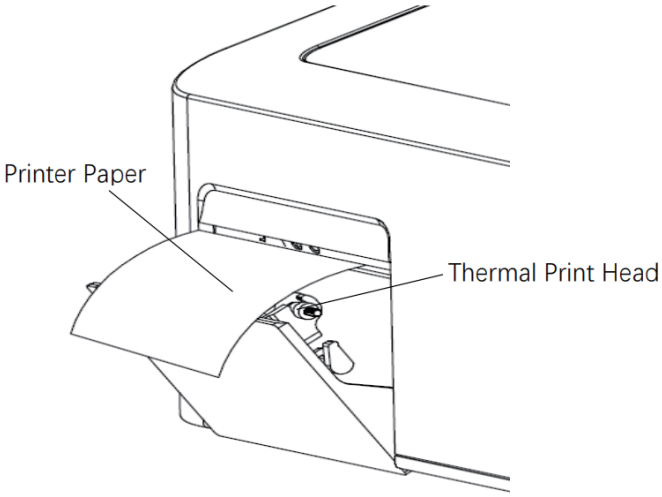


Figure 3-1 Installing printer paper

3) Pull out the paper by approximately 20mm. Be careful not to shift the paper when pulling out.

4) Close the printer cover.

◆ Replace the thermal paper:

After opening the printer cover, remove the old paper from the slot. The rest of the steps are the same as those for installing the paper.

⚠ Caution

• The printer cover must be closed unless the paper is being installed, replaced, or troubleshooting is being performed.

• Be sure to use printer paper provided by manufacture or the authorized dealers, otherwise, the built-in thermal printer may be damaged. Such damage shall not be covered by the warranty.

• Do not touch the print head or paper detector directly with your hands to avoid damage caused by static electricity, etc.

4. Collecting Blood Samples

⚠ Caution

• Please read this section carefully for the recommendations and rules for blood sample collection to avoid obtaining inaccurate or incorrect test results.

• It is recommended to use fresh, airtight, heparin-anticoagulated whole blood samples freshly collected.

• The sampling device may carry blood residues that are potentially biohazardous. Please avoid direct contact with the sampling device.

• When using this analyzer for measurement, the operator should comply with the safety operation regulations and wear the necessary personal protection (protective clothing, gloves, etc.).

4.1 Animal Status

The animal respiratory status should be stable prior to the blood sample collection.

The animals should be kept on stable ventilation before and during the blood sample collection. If the animal is hyperventilating due to anxiety, it may affect the blood gas measurement results.

If the condition permits, stop taking oxygen ventilation 30 minutes before blood collection, otherwise, the oxygen concentration and flow rate administered should be reported.

If the animal feels dizzy or experiences vertigo during needle insertion or blood collection, the needle should be removed immediately, and the animal should lie down for a moment to recover.

4.2 Preparation of Sample Collection and Anticoagulants Selection

4.2.1 Preparation of sample collection

Arterial blood gas needle/micro arterial blood gas collector/syringe, alcohol swabs, cotton swabs, etc. should be available before the start of the sample collection.

4.2.2 Anticoagulants selection

It is recommended to use a professional arterial blood gas needle or micro arterial blood gas collector with Ca2+-balanced heparin. If a blood gas needle is unavailable and a syringe is used to collect the blood sample, Ca2+-balanced heparin or lithium heparin is recommended as anticoagulant.

⚠ Caution

• Anticoagulants such as heparin benzohydroxymonium, EDTA, citrate, and fluoride can significantly affect the measurement result of pH and electrolytes in the blood.

4.3 Blood Sample Collection

This Blood Gas Analyzer uses whole blood to carry out tests. The minimum sample volume required is 150μL, and the amount of blood collected should meet the test requirements.

4.3.1 Blood sample types

• Arterial whole blood is recommended as blood sample for blood gas analysis. The blood collection operation should be performed by a veterinarian or a trained assistant and should be performed using the closed blood collection method.

• Venous whole blood is affected by the state of peripheral circulation and cellular metabolic demands. Generally, it should not be used to assess blood oxygen status and is not recommended for blood gas analysis. Venous whole blood may be used for electrolyte or other biochemical analysis.

4.3.2 Notes for operation

• The analyzer is a POCT device that uses a small sample volume. Users should avoid taking too many samples at once.

• When using syringes to collect blood samples, please evacuate the air in the syringe after sample collection. Rub the syringe back and forth several times with your palms and gently turn it upside down several times to adequately mix the sample and anticoagulant and prevent clot formation in the blood.

• To avoid blood being contaminated by the room air, recap immediately after blood collection.

• Clinical blood samples should be tested as soon as possible after collection. If the sample is used to measure blood gas or calcium ions, it should be left for no more than 10 minutes at room temperature. Otherwise, the sample should be left for no more than 30 minutes at room temperature.

• Used blood collection devices should be recycled as biohazard waste or disposed of in accordance with the local regulations.

5. Operating Procedure

5.1 Turn on/off the Analyzer

⚠ Caution

• Before turning on the device, make sure the power cord is connected.

◆ Turn on the analyzer:

Press the ON/OFF button at the back of the analyzer to turn it on. (Figure 5-1)

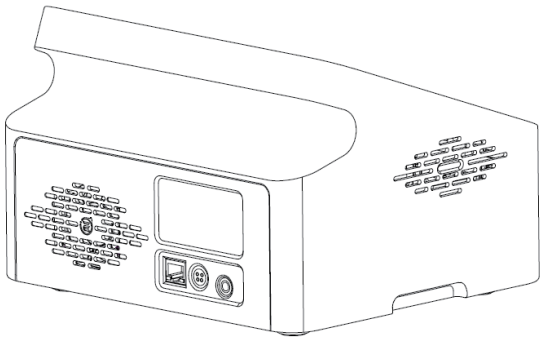


Figure 5-1 Turn on the analyzer

◆ Turn off the analyzer:

Method 1: Press and hold the ON/OFF button at the back of the analyzer for about 3 seconds. Release the button when the status indicator flashes. The analyzer will then turn off.

Method 2: Click on the icon at the upper left corner of the login screen to reboot or power off.

⚠ Caution

• When the analyzer is battery-powered, it will enter power-saving mode if no operation is performed within 60 minutes (tap the screen to return to normal). It will turn off automatically if no operation is performed within 4 hours.

5.2 Login/logout

◆ Login

1) Click the power-on button and the system will automatically perform a self-test. It will enter the login screen after the self-test is completed. (Figure 5-2)

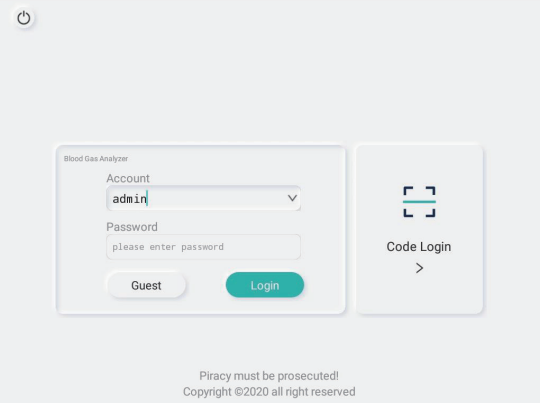


Figure 5-2 Login

2) Enter your account and password and click Login.

• When using the analyzer for the first time, please log in with the preset administrator account (account: admin, password: 123456). To add a new user or change the password, please refer to 5.3 User management.

• You can also click the scan button to open the scanner and log in with the QR code. (Note: To use the scanning function, you need to associate the corresponding QR codes when adding new users).

• If you have enabled guest login (please refer to 5.3 user management for how to enable guest login), you can click on Guest to log in directly without entering the password.

• If you forget your password, please contact the administrator to log into the administrator account and reset your password.

3) The system will prompt an error message if the account or password entered is wrong. After successfully logging in, you will enter the homepage (Figure 5-3).

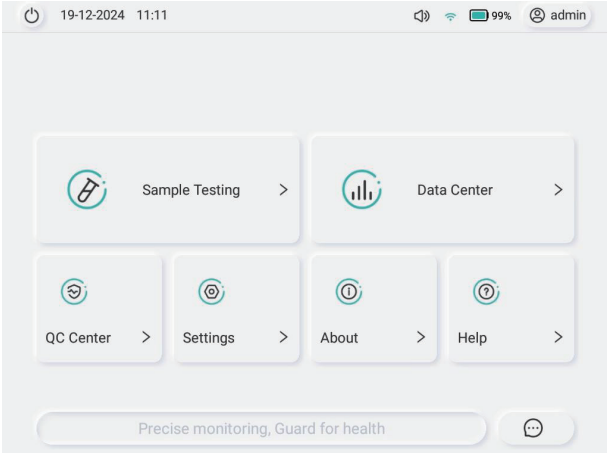


Figure 5-3 Homepage

• The current date and time will be displayed at the top of the interface. If the date and time are wrong, please click Settings and then click System Settings to modify.

• The interface shows the Sample Testing, QC, Data, Settings, About, and Help buttons, which can be clicked on to perform related operations.

• The right side of the display shows the current ambient temperature, humidity, air pressure, and printer or network error messages.

◆ Logout

1) Click the icon in the upper right corner of the login screen to log out of the current account.

⚠ Caution

• Please perform QC tests using the electrical control cartridge once a day after start-up to ensure there are no abnormalities before performing relevant tests.

• Please check the alerts after login and handle them in time.

• Please do not turn off the analyzer during sample testing or printing.

5.3 User Management

Only the administrator can access the user management interface. In there, you can view/modify user information, enable guest login, add/delete new users, and search for users.

Log into the administrator account. On the main screen, click admin, then click User Manage to enter the user management interface, which shows data for all users by default. (Figure 5-4)

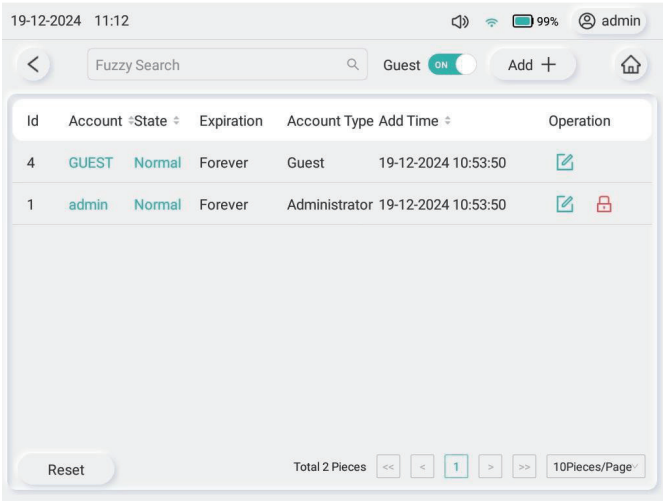


Figure 5-4 User management

◆ Enable guest users

In the user management screen, click Guest ON to enable/disable guest login. After it is enabled, the Guest icon will appear on the login screen. Click on this icon to log in without entering a password.

◆ Add users

1) Click Add + to add a user. (Figure 5-5)

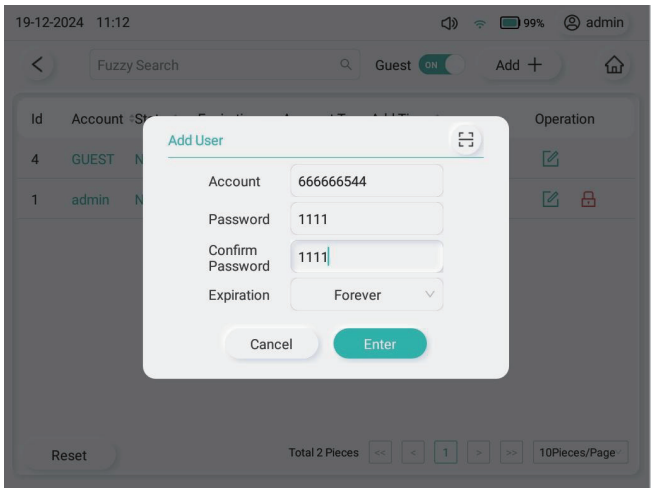


Figure 5-5 Add a user

2) Enter the account name and password as required and confirm the password. Set the validity period. It defaults to permanent, and you can change it to one month, one quarter, or one year as needed. You can also add a user by clicking on to scan and associate a QR code.

3) Click "Confirm" to complete.

⚠ Caution

- Accounts may contain letters, numbers, or underscores up to 20 characters (case-sensitive).
- Minimum password length: 6 characters.

◆ Modify another user's information

1) Click on at the end of a user's row to modify the user's information. (Figure 5-6)

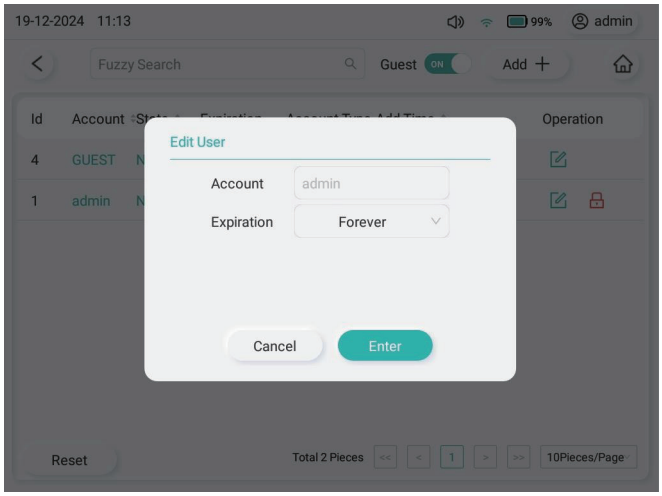


Figure 5-6 Modify another user's information

2) Enter the validity period and scan the associated QR code as required.

3) Click "Confirm" to complete the modification.

◆ Change another user's password

1) Click on icon at the end of a user's row to change the password. (Figure 5-7)

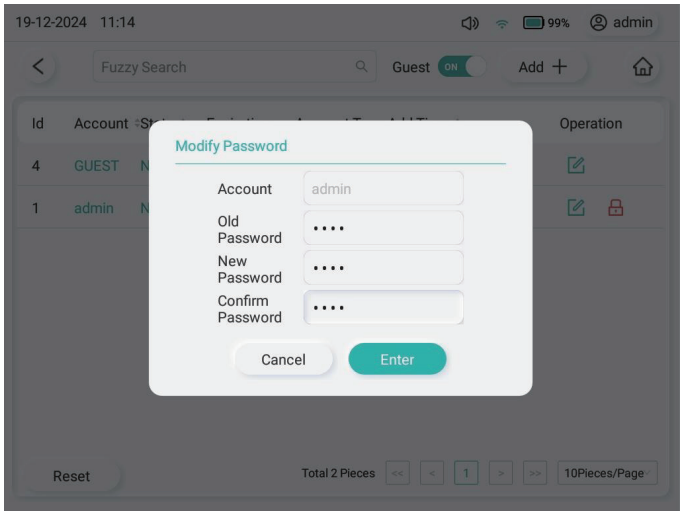


Figure 5-7 Modify another user's password

2) Enter the new password as required and then re-enter to confirm.

3) Click "Confirm" to complete the password change.

◆ Delete users

Click on at the end of a user's row to delete the user.

◆ Search for another user's information

1) Click on Fuzzy Search and then the input box will appear. (Figure 5-8)

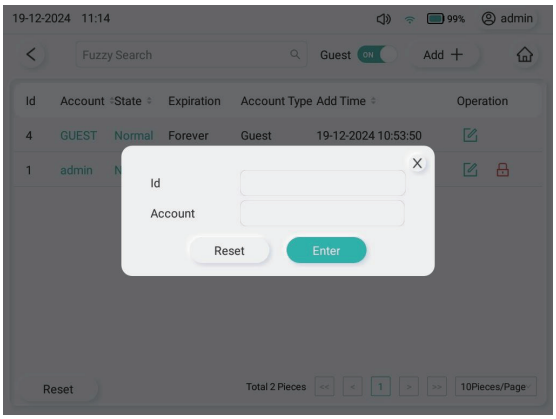


Figure 5-8 Search for another user's information

2) Enter the account information you are searching for.

3) Click "Confirm", and the results will be displayed.

4) Clicking "Reset" will clear the entered information.

5.4 Settings

The analyzer can perform under various settings to meet different clinical needs. The following settings can be modified as needed:

- System Setting
- Detection Settings

⚠ Caution

- To ensure the security of the analyzer, only the administrator can change the settings. Users cannot change the settings of the analyzer.
- The system will memorize the changed settings even if you turn off the analyzer.
- User settings are described in the user management section.

5.4.1 Enter the settings interface

Log in with your administrator account and click 

to enter the settings menu, or you can click  to return to the homepage first and then click 

(Figure 5-9)

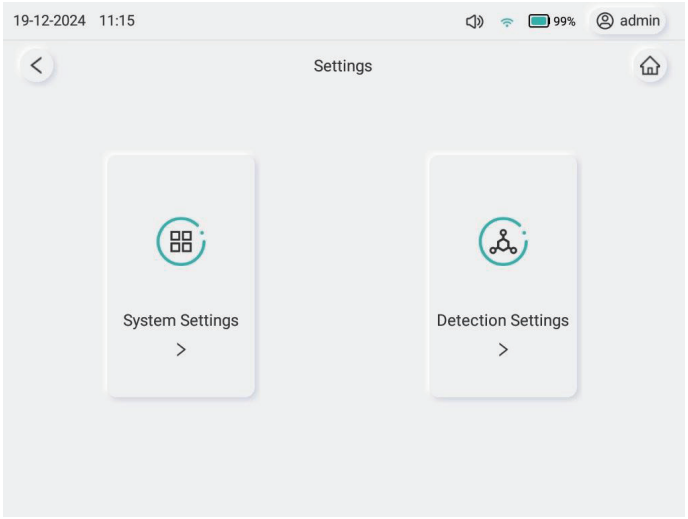


Figure 5-9 Settings interface

5.4.2 System setting

5.4.2.1 Volume setting

Volume Setting is used to set whether the Beep Sound of the analyzer is enabled or disabled, and to control the volume. The setup steps are as follows:

1) Click 

to see the Volume setting interface. This is shown in the following figure:

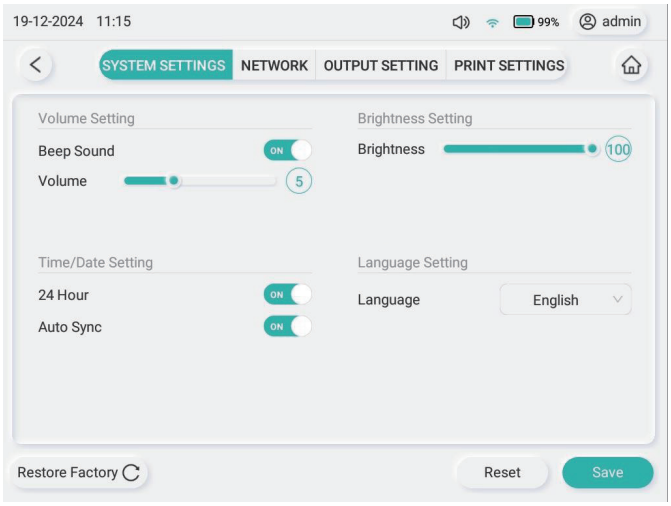


Figure 5-10 Volume setting

2) In the Volume setting interface, you can：

• Turn on or off the Beep Sound.

• When the Beep Sound is turned on, press and hold the volume slider and slide it left and right to adjust the volume.

3）Click Save to complete the setup. Click the "Reset" button to return to the last set parameters.

⚠ Caution

• Restoring the factory settings will clear the user information, all test records and restore the initial state of the analyzer. Please operate with caution.

5.4.2.2 Brightness adjustment

Brightness adjustment is used to set the brightness of the analyzer screen. The setup steps are as follows:

1) Click System Settings > ,as shown in Figure 5-10, the Brightness setting interface.

2) In the Brightness setting interface, you can：

• Press and hold the brightness slider and slide left and right to adjust the brightness.

• Click Save to complete the setup. Click the "Reset" button to return to the last set parameters.

⚠ Caution

• Restoring the factory settings will clear the user information, all test records and restore the initial state of the analyzer. Please operate with caution.

5.4.2.3 Time/ Date setting

Time/Date Setting is used to set whether the analyzer time enables a 24-hour system, whether automatic synchronization is enabled or no, and set date and time. The setup steps are as follows:

1）Click System Settings > to see the Time/Date setting interface. This is shown in Figure 5-10.

2）In the Time/Date setting interface, you can

• Use the 24-hour clock.

• Automatically synchronize network time or manually set system time.

• Click Save to complete the setup. Click the "Reset" button to return to the last set parameters.

⚠ Caution

• Restoring the factory settings will clear the user information, all test records and restore the initial state of the analyzer. Please operate with caution.

5.4.2.4 Language setting

Language Setting is used to set the language of the analyzer. The setup steps are as follows:

3) Click System Settings > to see the Language Setting interface. This is shown in Figure 5-10.

4) In the Language settings interface, you can:

• Select the language in the drop-down box for Language.

⚠ Caution

• Restoring the factory settings will clear the user information, all test records and restore the initial state of the analyzer. Please operate with caution.

5.4.3 Network

Network settings are used to set how the analyzer is connected to the network. Currently, both wired network and Wi-Fi are supported. The setup steps are as follows:

1) Click NETWORK to enter the Network setting interface, and click Local IP to enter the IP setting interface as follows:

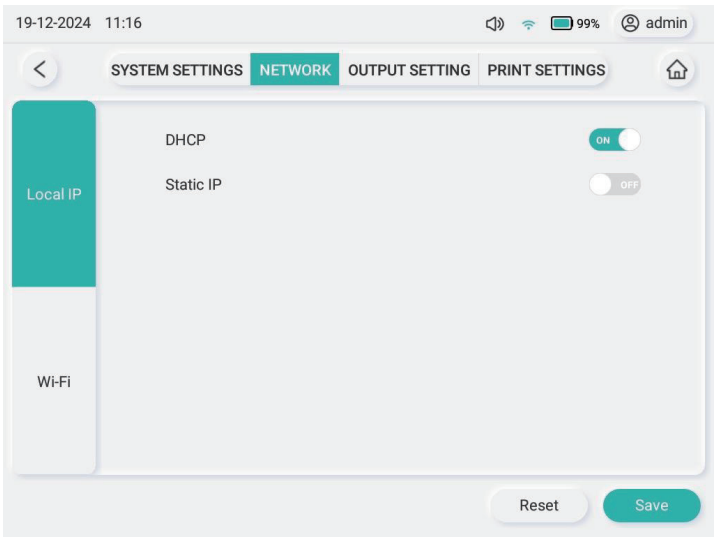


Figure 5-11 Network settings

2) In the network settings interface, you can modify:

◆Wired network settings: Select how to obtain IP addresses: Obtain IP addresses automatically (DHCP) or use static IP addresses. The default setting is to obtain an IP address automatically. When you choose to use a static IP address, you need to enter the IP address, subnet mask, and default gateway.

⚠ Caution

• When setting the IP address, it should be noted that the set IP address must be in the same network segment as the IP address of the POCT management system or LIS/HIS (server).

• Multiple analyzers connected to the same POCT management system or LIS/HIS (server) must have different IP addresses.

• The analyzer can transfer data to the POCT management system or LIS/HIS (server) only if both the POCT management system or LIS/HIS (server) and the analyzer are successfully linked.

◆ Wi-Fi Settings: Tap Wi-Fi to turn on Wi-Fi. The system will display the name of the searched network and whether it has a password identification and signal strength. Click the network you want to connect to, and a prompt box will pop up (as shown in the following figure). Enter the correct Wi-Fi password and click Connect . After the connection is successful, the Wi-Fi icon will be displayed in the status bar at the top of the interface.

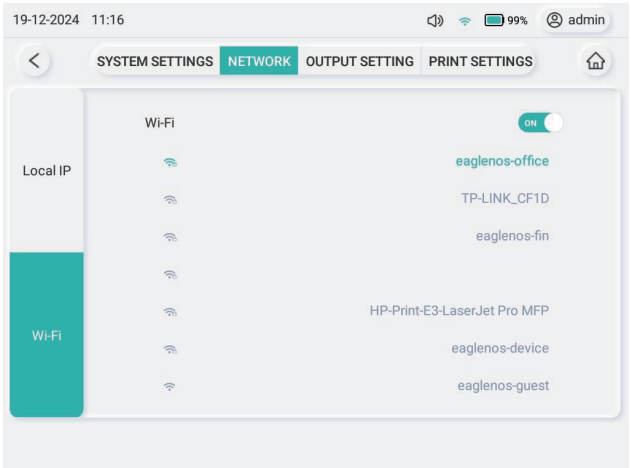


Figure 5-12 Wi-Fi password input box

⚠ Caution

• Make sure that the selected network is on the same network segment as the network used by the POCT management system or LIS/HIS (server).

3) Click "Save" to complete the settings. Click the "Reset" button to return to the original setting interface parameters.

5.4.4 Print settings

Print settings is used to set whether to automatically print test results (or quality control results) and the number of copies after a test. The setup steps are as follows:

1) Click to enter the Print settings interface, as shown in the following figure:

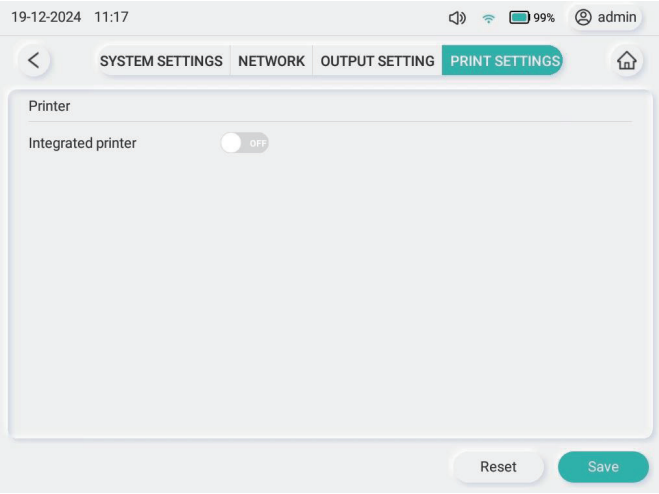


Figure 5-13 Print settings

2) In the Print settings interface, you can:

• Select the thermal printer's ON/OFF key to turn on automatic printing.

• Modify the number of automatic prints.

⚠ Caution

• The number of copies printed here is only valid when automatic printing is used.

3) Click "Save" to complete the setting; click the "Reset" button to return to the previous setting parameters.

5.4.5 Detection settings

You can view and set patient information for the analyzer, view reference ranges and unit settings. The reference range can be printed in the patient report, and the system will prompt ↑ or ↓ when the measurement results are outside the reference range. The setup steps are as follows:

1) Click , and then click PATIENT INFO to enter the Patient Information setting interface, which is the interface by default. This is shown in the figure below:

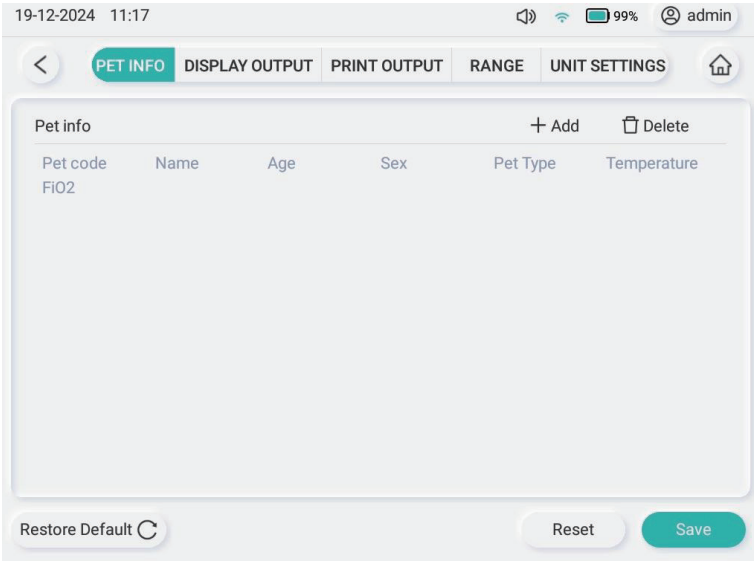


Figure 5-14 Patient information

2) Click DISPLAY OUTPUT to enter the Display Output interface. You can freely select or cancel the listed items for modification. If a parameter is cancelled, it will not be tested. Please select at least one parameter. After modification, if you click "Save", the settings will be completed. If you click "Reset", it will return to the unmodified state.

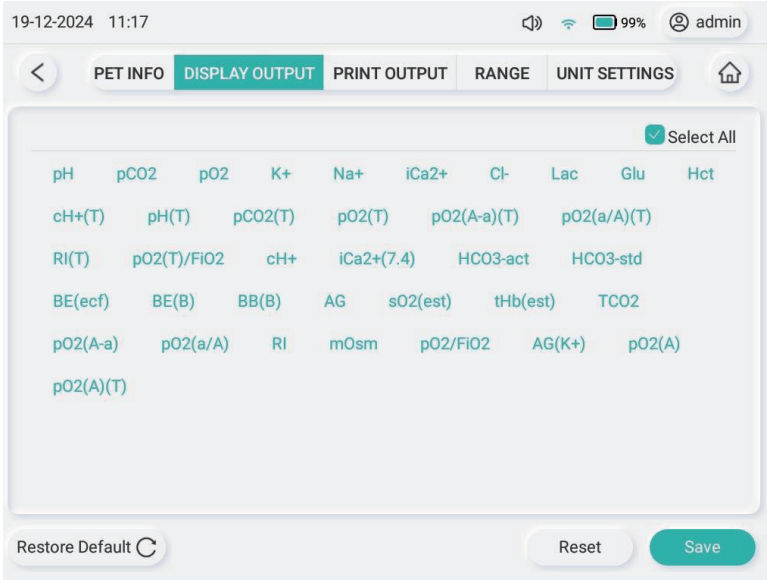


Figure 5-15 Display output

3) Click PRINT OUTPUT to enter the Display Output interface. You can freely select or cancel the listed items for modification. If a parameter is cancelled, the reference range of that parameter will not be printed when the thermal printer prints. After modification, if you click "Save", the settings will be completed. If you click "Reset", it will return to the unmodified state.

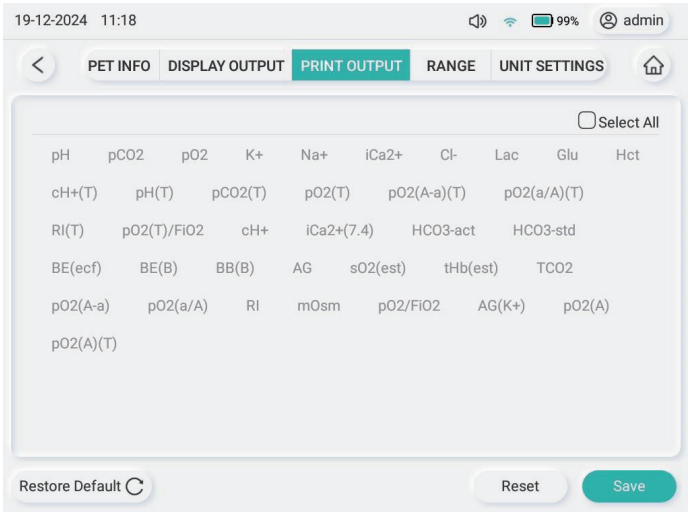


Figure 5-16 Print output

4) Click RANGE to enter the reference range interface. You can:

• Click Arterial Blood (the same applies to venous blood) to enter the interface for viewing arterial blood reference range. This is shown in the following figure:

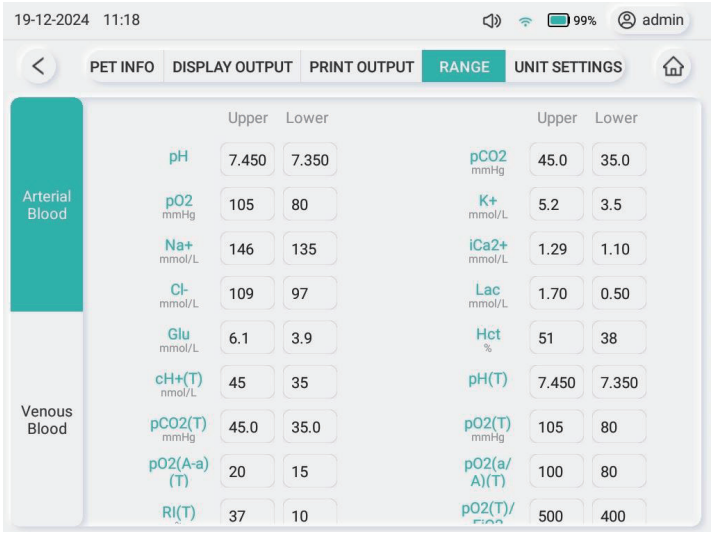


Figure 5-17 Reference range display

⚠ Caution

• The reference range is automatically linked to the selected blood sample, which is selected by the user at the time of the measurement.

5) Click RANGE to enter the reference range interface. You can:

• Click Venous Blood (similar procedure as for arterial blood) to enter the interface for viewing venous blood reference range. This is shown in the following figure:

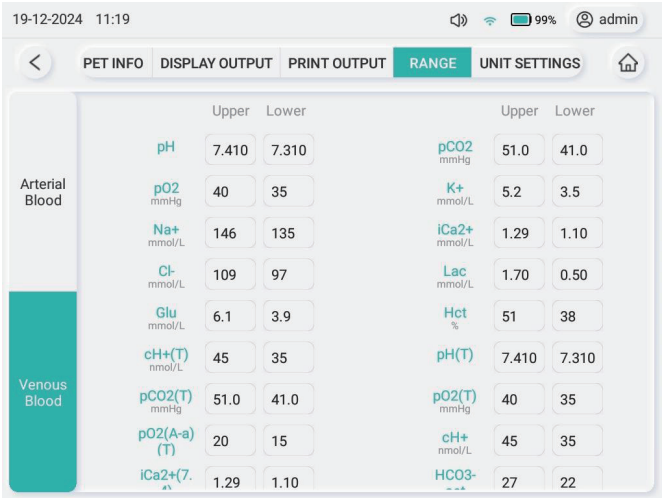


Figure 5-18 Reference range display

⚠ Caution

• The reference range is automatically linked to the selected blood sample, which is selected by the user at the time of the measurement.

6) Click UNIT SETTINGS to enter the Unit Settings interface. You can:

• Enter the Unit Settings interface. This is shown in the following figure:

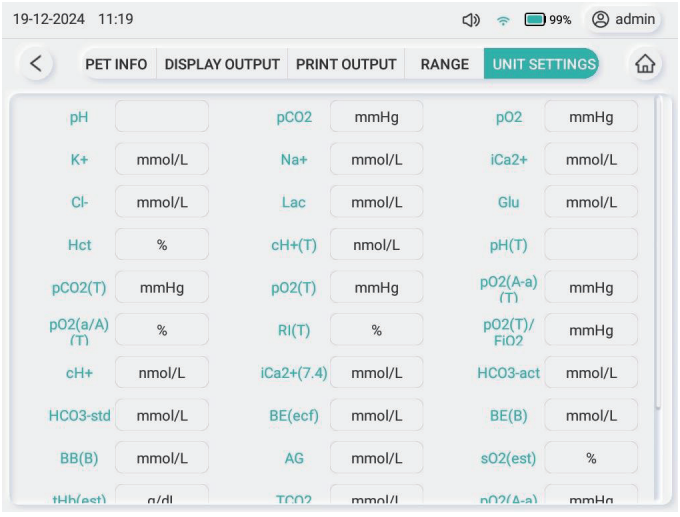


Figure 5-19 Unit settings display

⚠ Caution

• You can swipe up or down to see the units display for all indicators.

5.5 Sample Testing

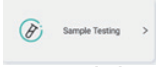
The analyzer provides easy and rapid analysis of K^+, Na^+, Cl^- , iCa^{2+}, pH, pCO_2, pO_2, Hct, Glu, Lac in whole blood samples. When performing the test, the analyzer should be placed on a vibration-free, horizontal surface. Please leave an appropriate amount of space for operation. Place it in a position where the switch can be disconnected easily at any time. Prior to the test, you should collect blood samples as described in section 4. Sample Collection.

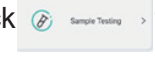
- Rub the syringe with your palms and gently flip it several times to mix the sample thoroughly.
- Place the cartridge flat on the table. Insert the syringe into the cartridge inlet and add the blood sample until it cannot be added (the cartridge limits the sample volume).

⚠ Caution

- Please follow the safety practices and wear personal protection (e.g., protective clothing, gloves) when working with potentially biohazardous samples.
- Samples should be analyzed as soon as possible after collection. If the sample is used to measure blood gases and calcium ions, test the sample within 10 minutes. If the sample is used to measure the levels of other analytes, complete the measurement within 30 minutes.
- Samples should be mixed well before analysis to avoid inaccurate measurements.
- Make sure that the sample is free of air bubbles and clots, otherwise the sample should be re-collected for testing.
- If a syringe is used, the first 2 drops of blood should be discarded. The needle should then be removed from the syringe and discarded. Insert the syringe into the cartridge inlet to add the sample. The minimum sample volume is 150 μL. Snap the sealing cap to seal the inlet.
- Please perform QC using the electrical control cartridge (5.6.3 Quality control analysis-electrical control cartridge) after the daily start-up to ensure there are no abnormalities before performing relevant tests.

5.5.1 Access the sample testing interface

After successful login, click 

to enter the sample testing interface. You can also click  to return to the home page and then click 

to enter the sample testing interface. This is shown in the following figure:

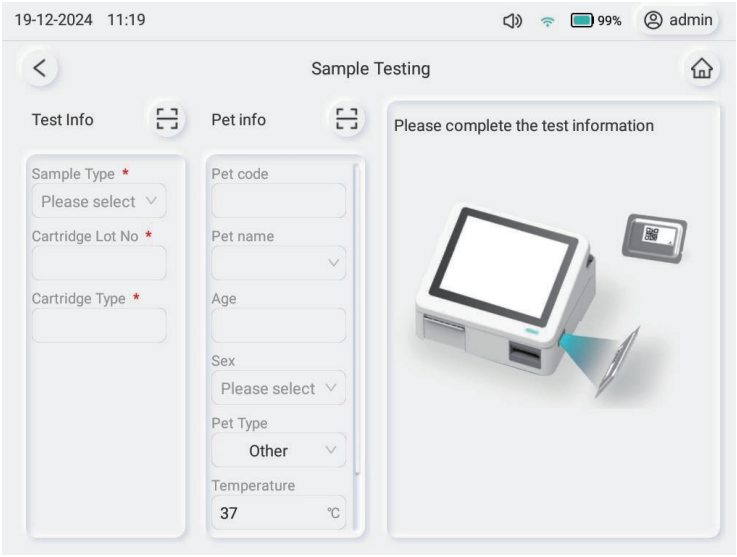


Figure 5-20 Sample detection main interface

⚠ Caution

• To leave the test interface and do other operations, click on to return to the homepage.

• If the cartridge slot is occupied, the system will prompt: "The cartridge slot is occupied". Please remove the cartridge.

• If the ambient temperature, humidity, or air pressure exceeds the normal working conditions, the system will prompt "abnormal environment (temperature/humidity/air pressure)".

5.5.2 Scan/enter animal's information

After entering the sample testing interface, select the Sample type (arterial/venous blood), and click on the Scan Code icon, as shown in the following figure:

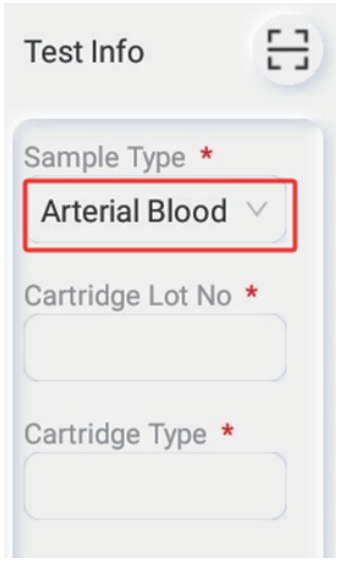


Figure 5-21 Scan cartridge

The steps for entering the cartridge's information are as follows: Click and scan the QR code on the new cartridge pouch with the scanner located on the right side of the analyzer. If the barcode is scanned successfully, the scanned cartridge's information will be displayed on the screen, and the analyzer will go back to the Sample Detection main interface.

⚠ Caution

- If no scanning is performed, the system will turn the scanner off after a period of time. To turn the scanner on again, press .
- For easy recognition, please slowly adjust the position and angle of the QR code during the scanning process.
- If the wrong QR code is scanned, the system will prompt "Invalid QR Code".

Note: The QR code of the lot of cartridges is located on the outer package of cartridges, which contains the valid date and CODE equation information of cartridges. The analyzer must read this information in advance, before each test, to ensure the use of cartridges within the validity period and the accuracy of measurement.

5.5.3 Scanning/entering animal information

After entering the Sample Testing interface, you can enter the patient information. This is shown in the following figure:

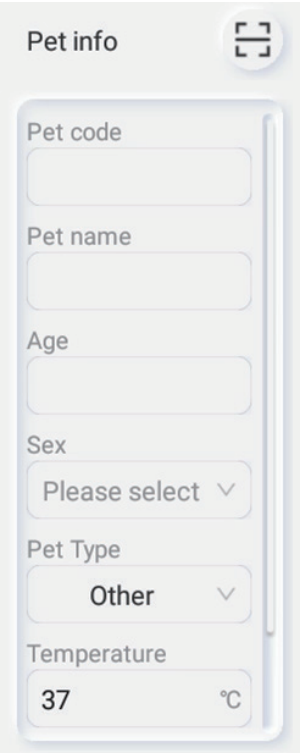


Figure 5-22 Scanning/entering patient information

Except for the temperature, which needs to be entered manually, there are two ways to enter other information.

Method 1: Manually input patient number, name, age, sex and FiO2.

Method 2: Click to turn on the scanner and place the patient's QR code or wristband barcode about 5 cm away from the scanning window on the right side of the analyzer for scanning. If the scan is successful, the patient information will be displayed on the screen.

Method 3: Do not input the patient's information first, directly insert the cartridge for detection, and click on the side of patient's information to edit and modify relevant information concerning the patient during the detection.

⚠ Note:

- If no scanning is performed, the system will turn the scanner off after a period of time. To turn the scanner on again, press .
- For easy recognition, please slowly adjust the position and angle of the QR code during the scanning process.
- If the wrong QR code is scanned, the system will prompt "Invalid QR Code".
- It is recommended that users use Method 3 to edit and modify patient information.

5.5.4 Insert cartridge

1) After seeing the interface of cartridge insertion, please confirm whether the lot number of the cartridge is correct or not. If you find that the lot number of the cartridge is wrong after verification, you need to click to rescan the correct QR code of the cartridge.

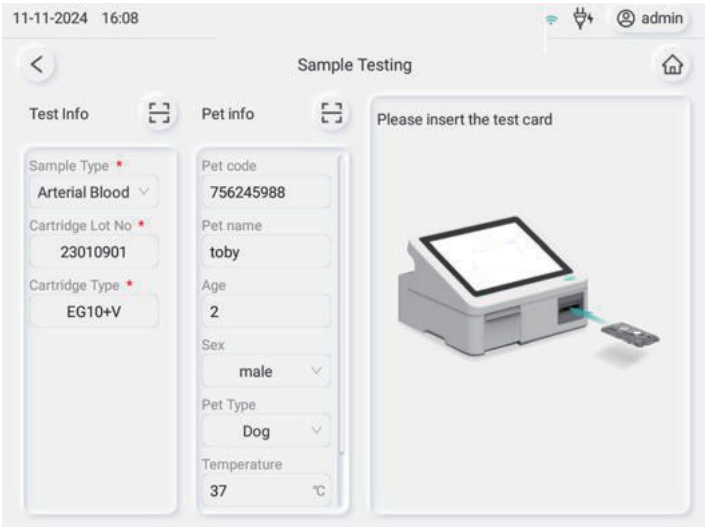


Figure 5-23 Inserting a cartridge

2) After confirmation, open the packaging bag and take out the cartridge. Place the cartridge flat on the table, add the sample, snap the sample seal cap on the cartridge to seal, insert the cartridge into the cartridge slot of the analyzer, and gently push it in to ensure that the cartridge is in place. If the inserted cartridge meets the system requirements, and the cartridge is inserted in the correct place, there will be obvious hand-feeling feedback. Meanwhile, the analyzer will send out the prompt of "start detection" to execute the testing action.

The analyzer will be calibrated first, and after calibration is completed, it will automatically inject hydraulic samples for testing.

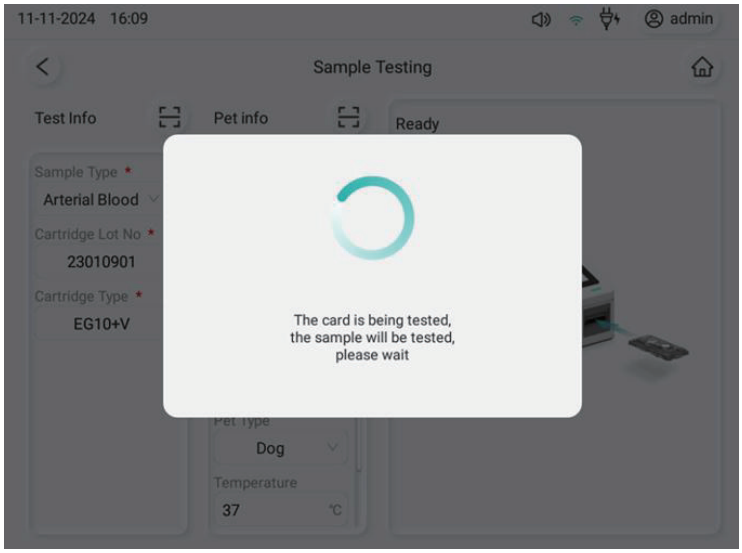


Figure 5-24 Testing start

If the system is performing the calibration test, the following screen will be displayed:

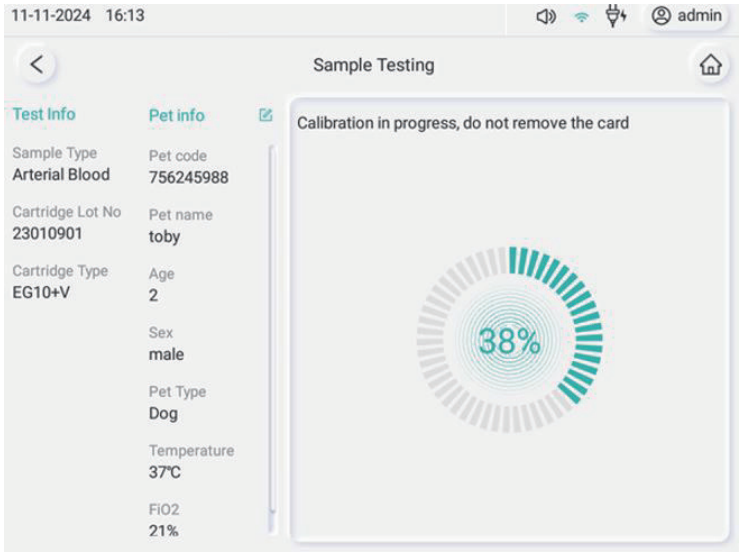


Figure 5-25 Calibration

If a sample test is in progress, the following screen will be displayed:

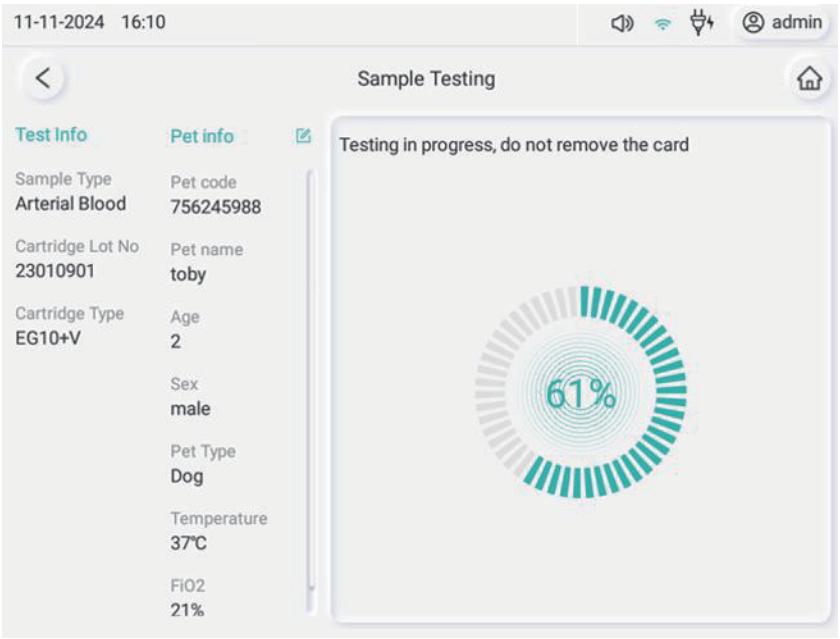


Figure 5-26 Testing

During the whole testing process, if it is found that the patient information needs to be modified or information needs to be added, click on the side of Patient Info to edit and modify, and the following interface will be displayed:

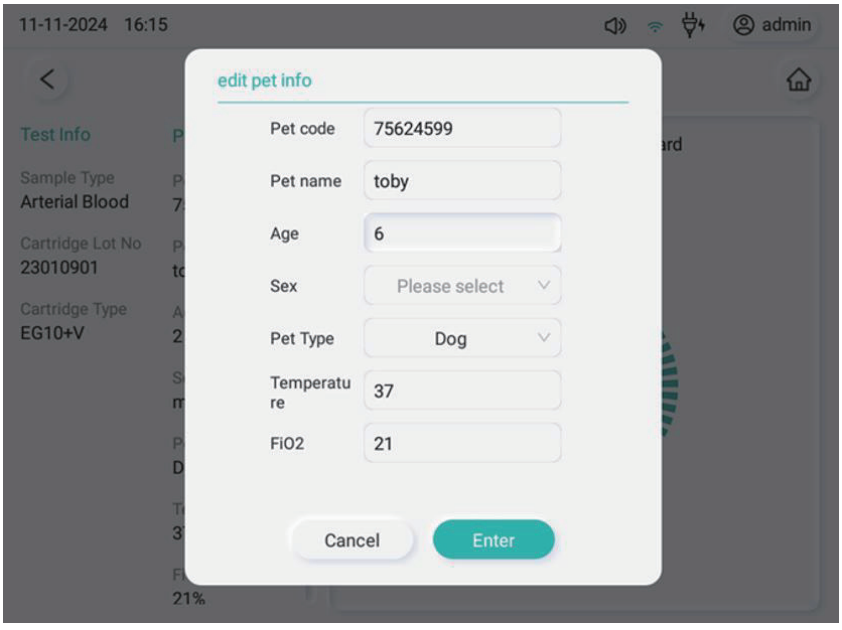


Figure 5-27 Editing patient information

⚠ Caution

• Before inserting the cartridge, if you want to abandon the test and do other operations, click on the interface to return to the main menu interface.

• Before inserting the cartridge, please confirm that the inserted cartridge is the cartridge that has been scanned.

• When inserting different types of cartridges, the analyzer will detect different test parameters.

• If the analyzer does not indicate that the cartridge cannot be removed, the cartridge can be removed at any time.

• If the ambient temperature, humidity, and air pressure exceed the normal working conditions, the system will prompt "abnormal environment (temperature/humidity/air pressure)" and the test will not be allowed or performed.

• Once the system reports an error, the cartridge will be invalid.

• Avoid tearing the QR code on the aluminum-plastic bag.

• To start the test, sample type, cartridge information, and cartridge type are required to be filled. However, the test can be completed without animal information.

• Once the system starts the test, no action can be undertaken until the test is complete.

5.5.5 Test results

After the sample test is completed, you will be taken to the results screen. If the test succeeds, you will see the patient's results. If the test fails, an abnormal message will be reported. If the test result is abnormal, you can see symbols at the end of each line indicating whether the value is high or low, out of linear range or reference range. ↑ or ↓ means the result is higher or lower than the reference range. × means the result is out of the linear range. - means the result is out of the measurement range.

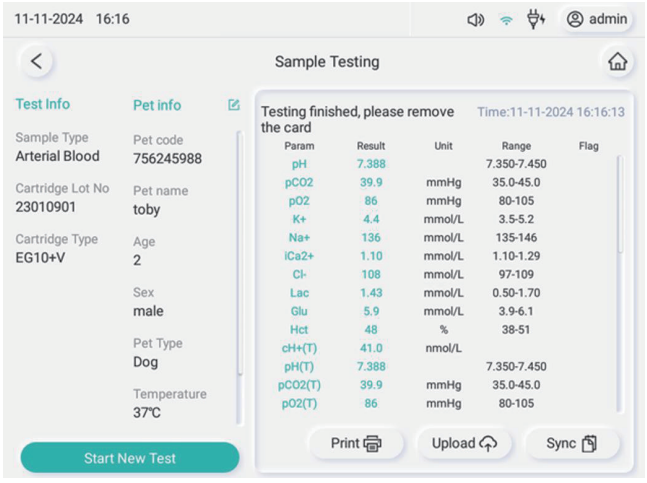


Figure 5-28 Sample test results

• After the sample test is completed, the analyzer screen will display the prompt "Please remove the cartridge", and the cartridge can be removed at this time.

• If a patient's body temperature is entered, the system will display the temperature-corrected blood gas analysis value.

• The sample results are automatically saved in the analyzer. They can be seen in the "Sample" section of the "Data Center" section.

• If auto-upload is turned on and the network connection is successful, the results will be automatically uploaded to the POCT management system or LIS/HIS (server) connected after each test. You can also upload results manually by pressing 

.

• If auto-print is turned on, the results will be printed automatically after each test. You can also click on 

to print results manually.

• If you want to continue testing other samples, click 

to re-enter the testing interface.

• To perform other operations, click on  to return to the homepage.

5.6 Quality Control

The analyzer ensures reliability and accuracy through the built-in self-test and quality control.

The self-test is used to confirm that the system is functioning properly. It is performed every time the system is turned on.

Quality control (hereinafter referred to as "QC") ensures that the analyzer and cartridges can work properly and get reliable test results. QC can be performed by 2 types of quality control products: electrical control cartridge and control solutions. The electrical control cartridge is used to test whether the analyzer can properly capture the signal to be tested on the cartridge. The control solutions use the same cartridges as sample testing. The only difference is that blood samples are used for sample testing, and QC solutions are used for QC.

Each user and the facility determine their own policy for QC testing. QC analysis is recommended in the following situations:

• Using the analyzer for the first time.

• To verify the storage conditions of the cartridges.

• Questioning the test results.

• To verify the performance of the analyzer and cartridges.

• A QC reminder has been set.

5.6.1 Quality control

After successfully logging in, click on 

to enter the QC interface. You can also click  to return to the homepage and then click on 

. This is shown in the following figure:

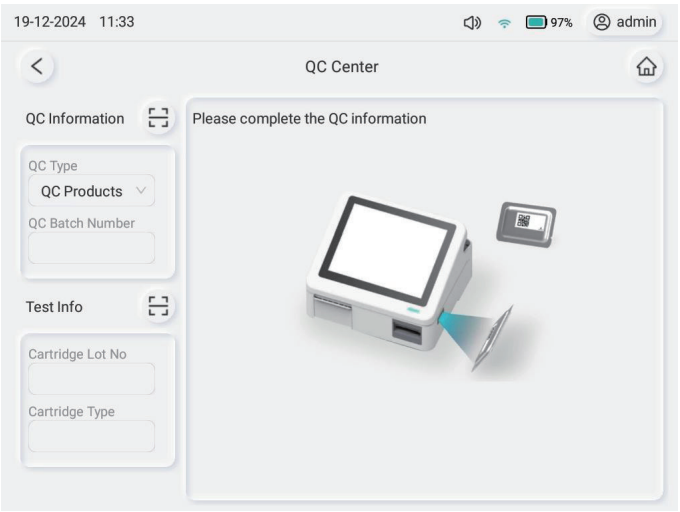


Figure 5-29 QC main interface

⚠ Caution

- If the cartridge slot is occupied, the system will prompt: "Cartridge slot is occupied". Please remove the cartridge.
- The default QC type is control solutions.
- To perform other operations, click on  to return to the homepage.

5.6.2 Quality control analysis (Blood Gas Control Solution)

QC analysis is performed to test whether the analyzer is working properly and performing as expected. The reference range is different for different control solutions. The corresponding reference range is indicated on the packaging of the control solutions. The results are abnormal if they are beyond the reference range.

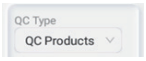
⚠ Caution

- Users must store and use control solutions in strict accordance with the instructions in the manual. Please only use the control solutions provided by manufacture or the authorized agents.
- The acceptable range for each parameter is given in the instruction manual of the control solutions provided by manufacture.

The QC steps are as follows:

1) Check the package to confirm that the control solutions are within the validity period. Select the control solutions according to your needs.

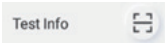
2) Remove the solution from the package and allow it to return to room temperature before use. Allow at least 4 hours for the ampoule to equilibrate to room temperature.

3) Select "QC Products" for the quality control type 

.

4) Click 

under the QC type. Scan the QR code of the control solution with the scanner on the right side of the analyzer. A prompt box will pop up if the code scanned does not meet the requirements. If the scan is successful, the contents of the QR code will be displayed on the screen.

5) Click 

under the cartridge type. Scan the QR code on the new cartridge package with the scanner. A prompt box will pop up if the code scanned does not meet the requirements. If the scan is successful, the contents of the QR code will be displayed on the screen and waiting for the cartridge to be inserted. This is shown in the following figure:

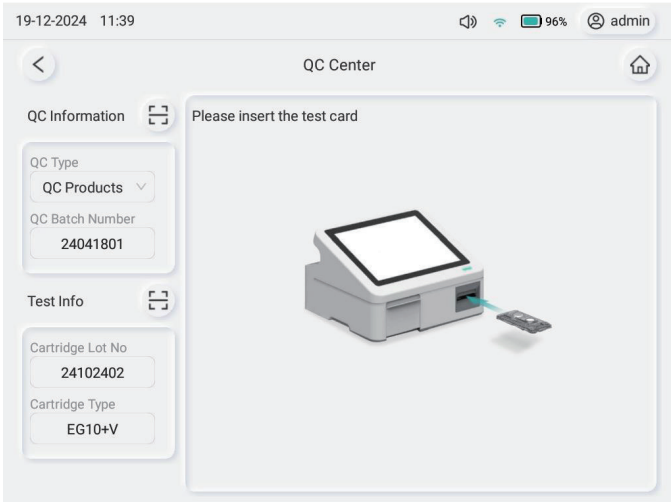


Figure 5-30 Inserting a cartridge

6) Open the package and take out the cartridge.

⚠ Caution

• Avoid tearing the QR code on the bag.

• If no scanning is performed, the system will turn the scanner off after a period of time. To turn it on again, press 
.

• If a wrong code is scanned, the system will display "Invalid QR code".

• If an expired cartridge or control solution is scanned, the system will display an expiration alert.

7) Before using the Blood Gas Control Solutions, hold the ampoule at the top and bottom (with index finger and thumb) and shake the solution 15-20 times to mix the solution. Tap the ampoule to allow the liquid to flow back down to the bottom. Open the ampoule by breaking the top where the scratch on the glass is located. Please use gauze, paper towels, gloves, or a suitable ampoule opener to avoid hurting your fingers. Immediately insert a syringe into the ampoule and slowly aspirate the solution. Remove the needle and discard the first 2-3 drops of solution. Insert the syringe into the sample inlet, inject the sample until full and snap the sealing cap immediately. For pH/blood gas testing, the QC should be performed within 1 minute of opening the ampoule. For electrolyte testing, the QC should be performed within 1 hour of opening.

⚠ Caution

• When opening the ampoule, make sure to take adequate safety measures to protect your fingers, such as using gloves and gauze as protection.

8) Insert the cartridge into the cartridge slot and gently push it inward to ensure it is inserted in the correct place.

• If the inserted cartridge meets the requirements, you will feel distinct haptic feedback when the cartridge is inserted in place. The test will then start automatically.

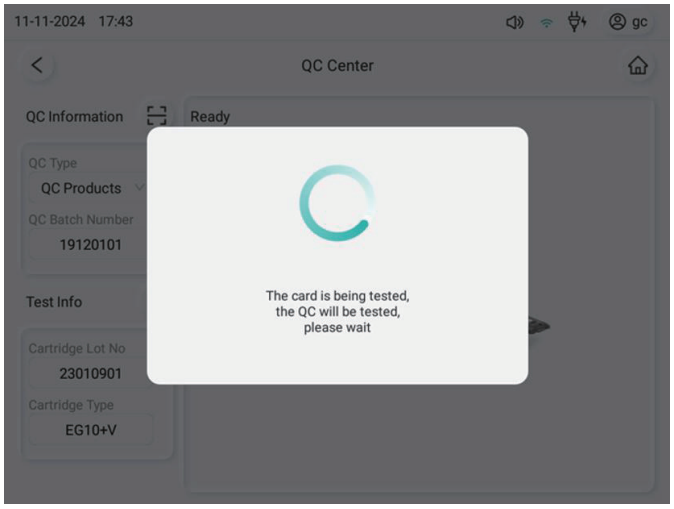


Figure 5-31 Testing starting

The following screen will be displayed during calibration:

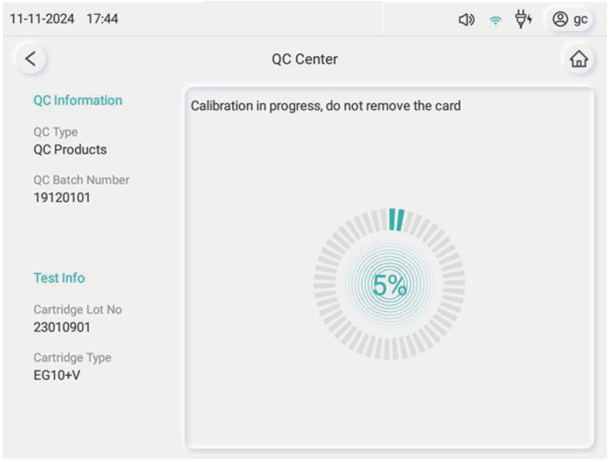


Figure 5-32 Calibration

The following screen will be displayed during the QC test:

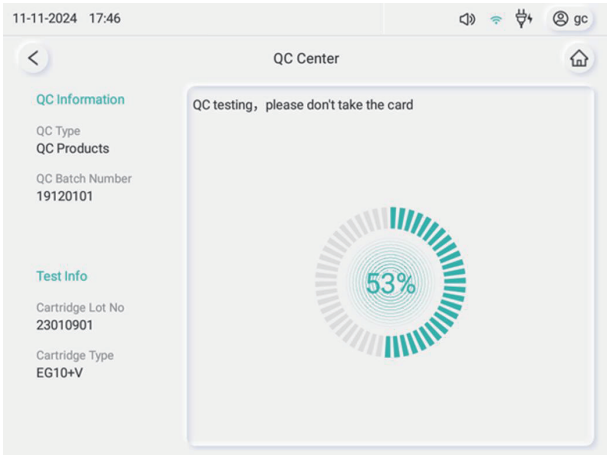


Figure 5-33 Quality control

⚠ Caution

• If you want to abandon the test to do other operations before the cartridge is inserted, click on to return to the homepage.

• Before inserting the cartridge, please make sure the cartridge you are about to insert is the cartridge you scanned.

• The cartridge can be removed at any time unless stated otherwise.

• Once the system reports an error, the cartridge will be invalidated.

• Avoid tearing the QR code on the cartridge package.

• Once the system has started the testing process, it will not be able to perform any other operations until the test is complete.

9) After the QC is completed, the system will automatically display the QC results. This is shown in the following figure:

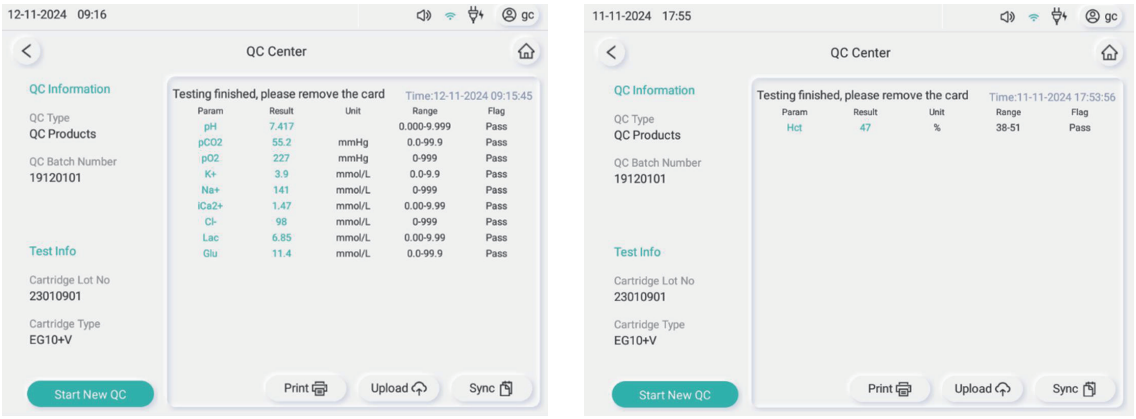


Figure 5-34 Quality control results of quality control samples

• After the QC is completed, the analyzer screen will display the prompt "Please remove the cartridge". The cartridge can be removed at this time.

• The QC results are automatically saved in the analyzer. They can be seen in the "QC Results" section of the "Data" section. (please refer to section 5.7.3)

• If auto-upload is turned on and the network connection is working, the results will be automatically uploaded to the POCT management system or LIS/HIS (server) connected after each test. You can also click on Upload to upload results manually.

• If auto-print is turned on, the results will be printed automatically after each test. You can also click on Print to print the results manually.

• To conduct a new QC, click Start New QC to enter the QC interface.

• To perform other operations, click on to return to the homepage.

⚠ Caution

• Control solutions can expire, so pay attention to the expiration date before use.

• If the QC result is abnormal, please check the following and then test again:

• Revisit the manual and confirm that the instructions were strictly followed.

• Make sure the cartridges and control solutions are stored properly and within their expiration date.

If all of the above are checked, but the results are still abnormal, please stop using the analyzer and contact your local authorized agent for assistance.

10) Please remove the cartridge from the analyzer.

5.6.3 Quality control analysis (Electrical Control Cartridge)

The electrical control cartridge is used to test whether the analyzer can properly capture the signal to be tested on the cartridge. The electrical QC results should be within the reference range of the arterial blood test values and are considered abnormal if outside that range.

⚠ Caution

• Electrical quality control can be performed at any time.

Here are the steps to perform an electrical quality control:

1) Select "Electronic QC" for the quality control type. As shown below:

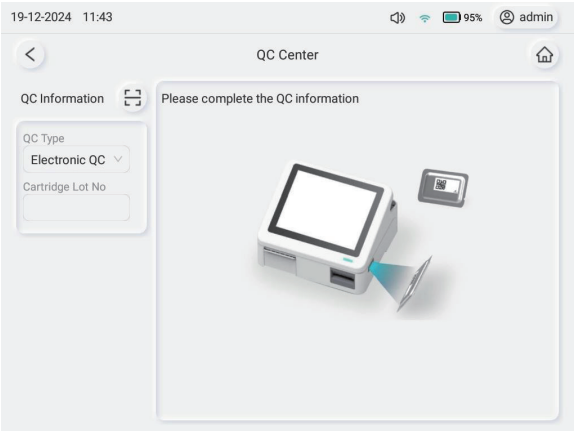


Figure 5-35 QC type selection

2) Click QC Information to scan the QR code on the cartridge package. A prompt box will pop up if the scanned code does not meet the requirements. If the scan is successful, the contents of the QR code will be displayed on the screen.

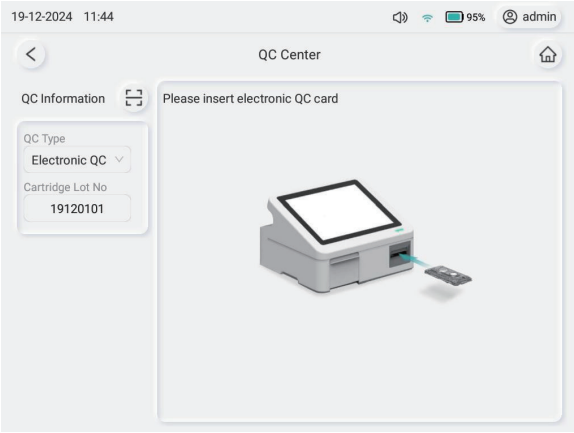


Figure 5-36 Waiting for electronic control card insertion

⚠ Caution

• If a wrong code is scanned, the system will display "Invalid QR code."

3) Insert the cartridge into the cartridge slot and gently push it inward to ensure it is inserted in the correct place.

• If the inserted cartridge meets the requirements, you will feel distinct haptic feedback when the cartridge is inserted in the correct place. The test will then start automatically.

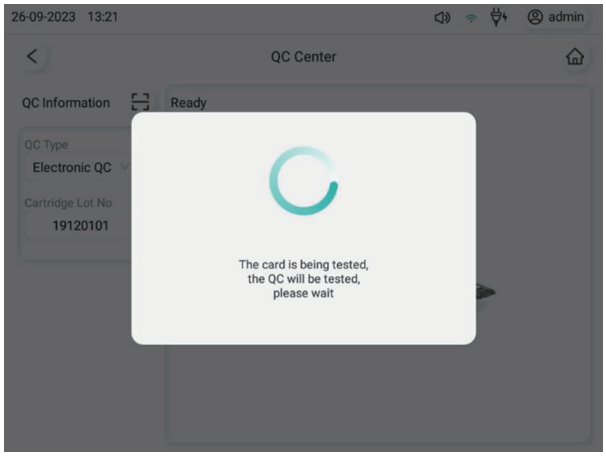


Figure 5-37 Testing start

If the system is performing a QC test, the following screen will be displayed:

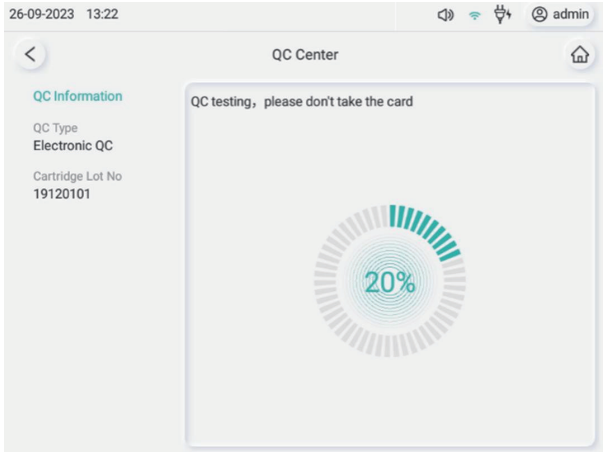


Figure 5-38 Quality control

⚠ Caution

• If you want to abandon the test to do other operations before the cartridge is inserted, click on  to return to the homepage.

• Before inserting the cartridge, please make sure the cartridge you are about to insert is the cartridge you scanned.

• The cartridge can be removed at any time unless otherwise stated.

• Once the system has started the testing process, it will not be able to perform any other operations until the test is complete.

4) After the QC is completed, the system will automatically display the electrical QC results. This is shown in the following figure:

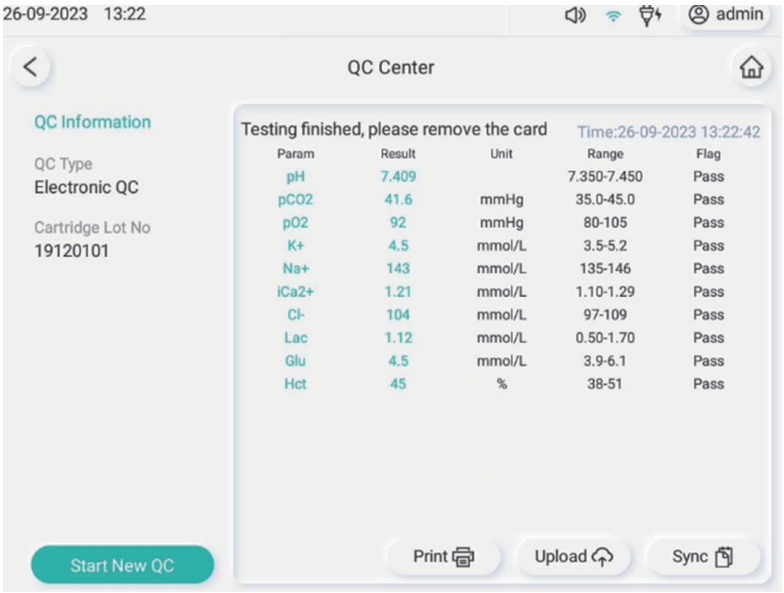
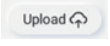


Figure 5-39 Quality control results of electronic quality control card

• After the QC is completed, the analyzer screen will display the prompt "Please remove the cartridge", and the cartridge can be removed at this time.

• The QC results are automatically saved in the analyzer. They can be seen in the "QC Results" section of the "Data" section. (please refer to section 5.7.3)

• If auto-upload is turned on and the network connection is working, the results will be automatically uploaded to the POCT management system or LIS/HIS (server) connected after each test. You can also click on  to upload results manually.

• If auto-print is turned on, the results will be printed automatically after each test. You can also click on  to print results manually.

• To conduct a new QC, click  to enter the QC interface.

• To perform other operations, click on  to return to the homepage.

⚠ Caution

• Please test again if the electrical QC results are abnormal.

• If all of the above are checked, but the results are still abnormal, please stop using the analyzer and contact your local authorized agent for assistance.

5) Please remove the electrical control cartridge from the analyzer.

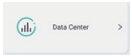
5.7 Data

The Blood Gas Analyzer has a powerful data management function, which stores sample results, quality control results, and operation logs. It can also upload the obtained data to the POCT management system or LIS/HIS (server).

Data transmission modes provided by the analyzer are:

• Data transfer to POCT management system or LIS/HIS (server) via network.

5.7.1 Access the data center

After logging in successfully, click on  to enter the data center interface. You can click on  to return to the homepage and then click on  . This is shown in the following figure:

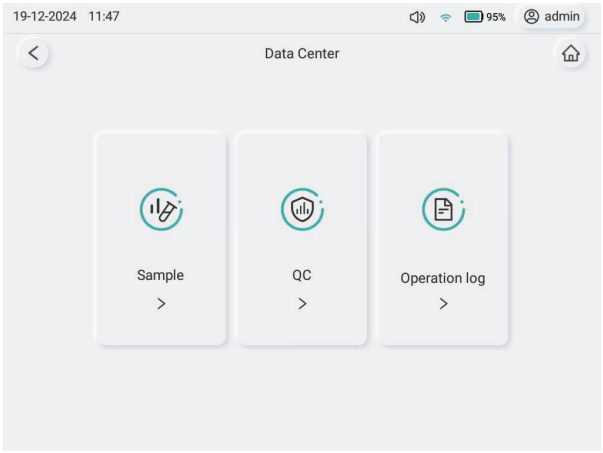


Figure 5-40 Data management main interface

⚠ Caution

• Operators can only see their own operation records. The administrator can see all records.

5.7.2 Sample results

Click on  to enter the sample results screen, as shown in the following figure:

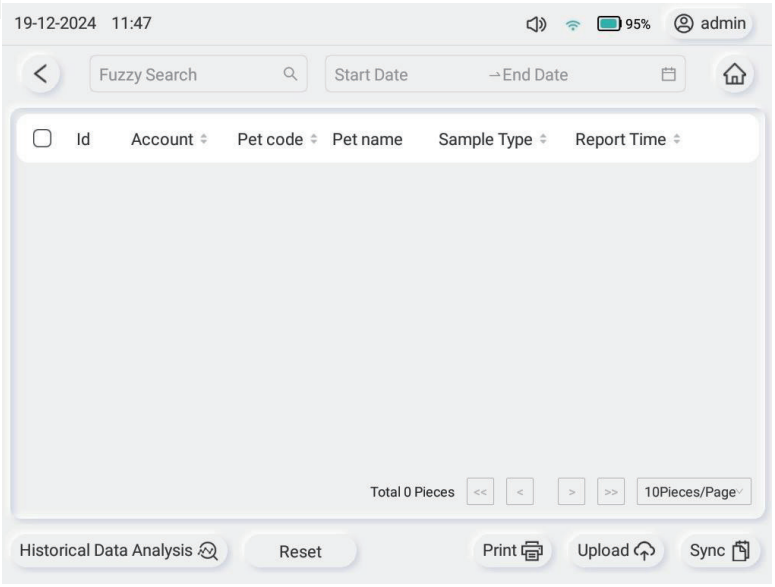
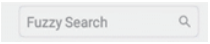


Figure 5-41 Sample test result database

◆ In the sample results screen, make selections by checking the checkbox at the front of the records. Click on  to upload manually, or click on  to print the results, or click on to analyze the selected results.

◆ Click on  , and a search box will be displayed, as shown in the following figure:

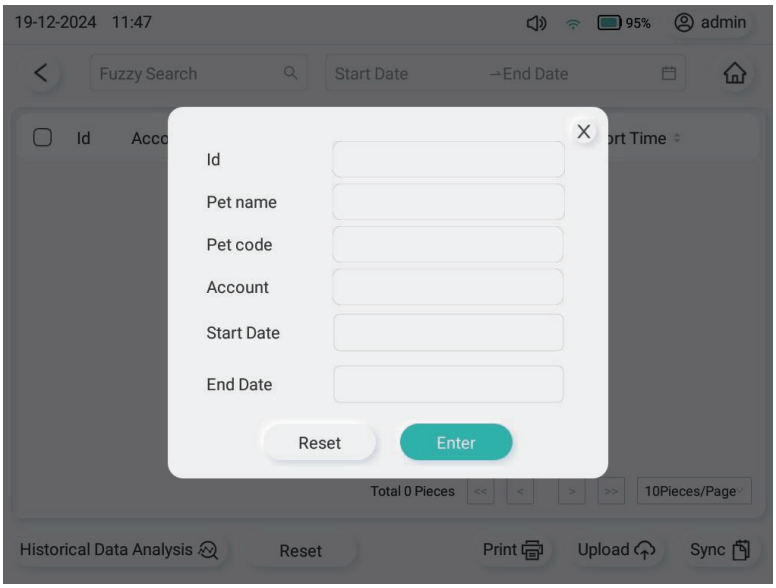


Figure 5-42 Enter the search criteria

Click on ✕ to close the search box. Click Reset to clear the entered information, allowing for re-entry. After entering the criteria, click on Enter, and the results will be listed as shown below:

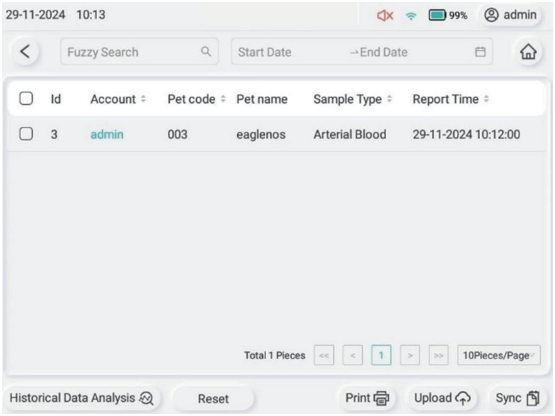


Figure 5-43 Search results

◆ In the sample results screen, click on 3 admin 756245988 eaglenos Arterial Blood 26-09-2023 10:13:42 to view a specific result. The result will be displayed as follow:

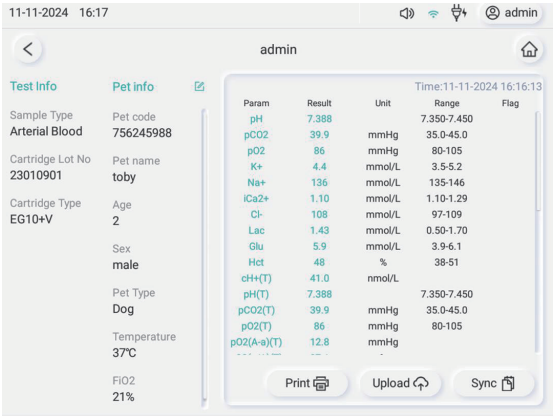


Figure 5-44 Test results in detail

- Click on Upload to upload the current patient's sample result.
- Click on Print to print the current patient's sample result.
- Click on < to return to the sample results screen.
- Click on ⌂ to return to the homepage.

◆ In the sample results screen, click on ⇕ next to the time, and the results will be sorted by time in ascending/descending order.

◆ In the sample results screen, click on < to return to the data management screen.

◆ In the sample results screen, click on ⌂ to return to the homepage.

5.7.3 Quality control results

Click on  to enter the QC results screen, as shown in the figure below:

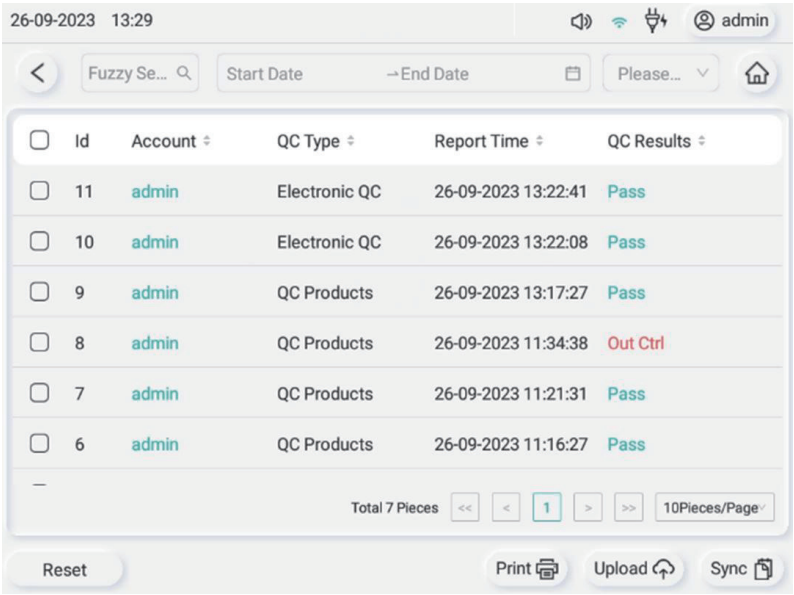


Figure 5-45 QC results database

◆ In the QC results screen, make selections by checking the checkbox at the front of the records. Click then on  to upload manually or click on  to print the results.

◆ Click on , and a search box will be displayed. (Figure 5-46)

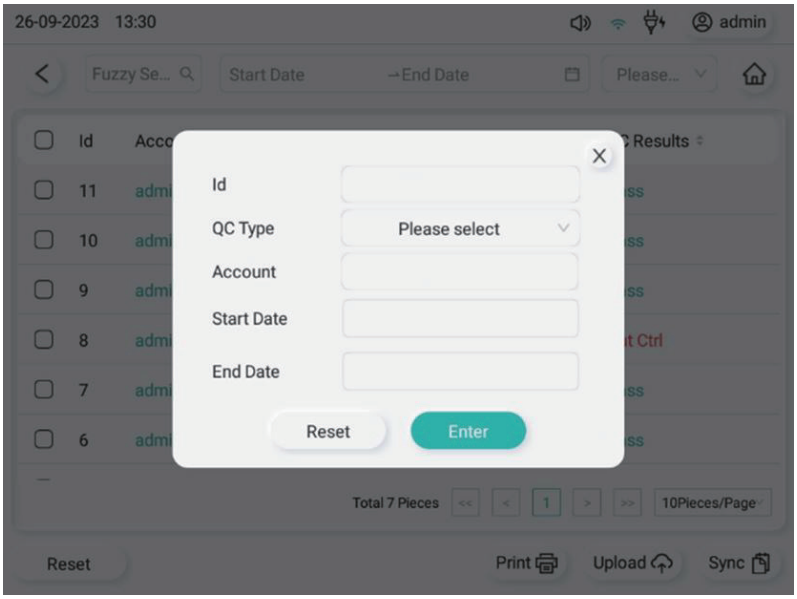


Figure 5-46 Enter the search criteria.

Click on close the search box. Click on Reset to clear the entered information, allowing for re-entry. After entering the criteria, click on Enter, and the results matching the criteria will be listed as shown below:

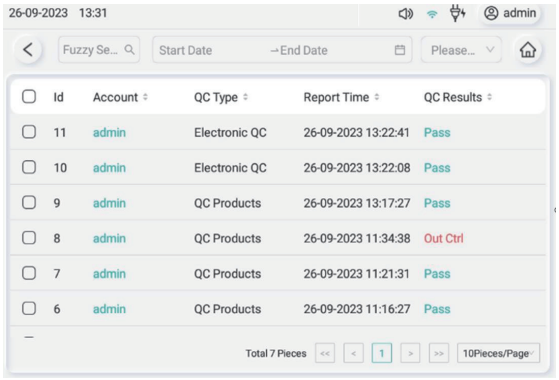


Figure 5-47 Quality control results found after a search

◆ In the QC results screen, click on 11 admin Electronic QC 26-09-2023 13:22:41 Pass to view a specific result. The results will be displayed as follows:

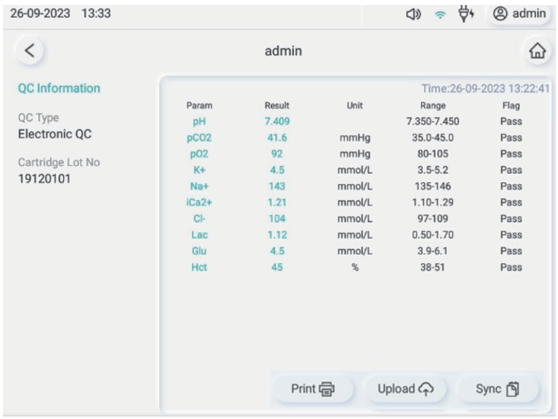


Figure 5-48 QC results in detail

- Click on Upload to upload the current QC result.
- Click on Print to print the current QC result.
- Click on < to return to the QC results screen.
- Click on ⌂ to return to the homepage.

◆ In the QC results screen, click on ⇕ next to the time, and the results will be sorted by time in ascending/descending order.

◆ In the QC results screen, click on < to return to the data management screen.

◆ In the QC results screen, click on ⌂ to return to the homepage.

5.7.4 Operation logs

Click on  to enter the operation logs. (Figure 5-49)

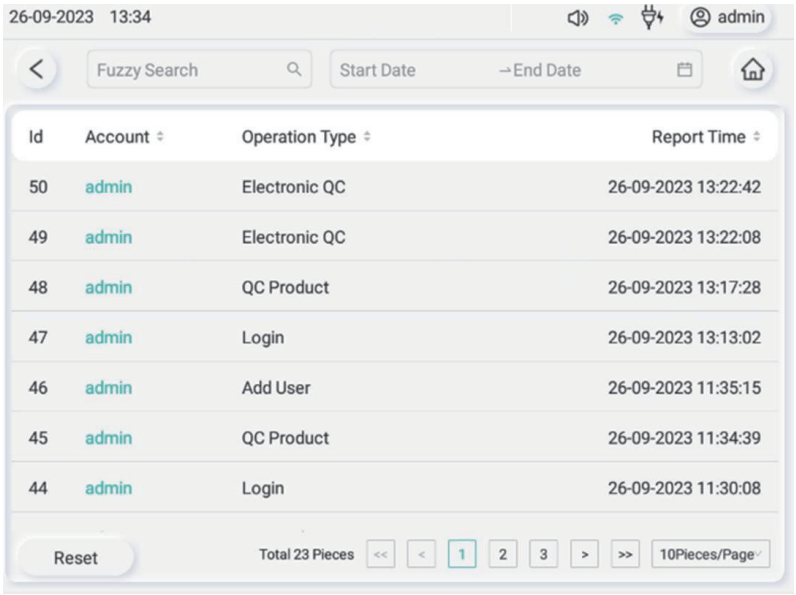


Figure 5-49 Operation logs

◆ Click on and a search box will be displayed. (Figure 5-50)

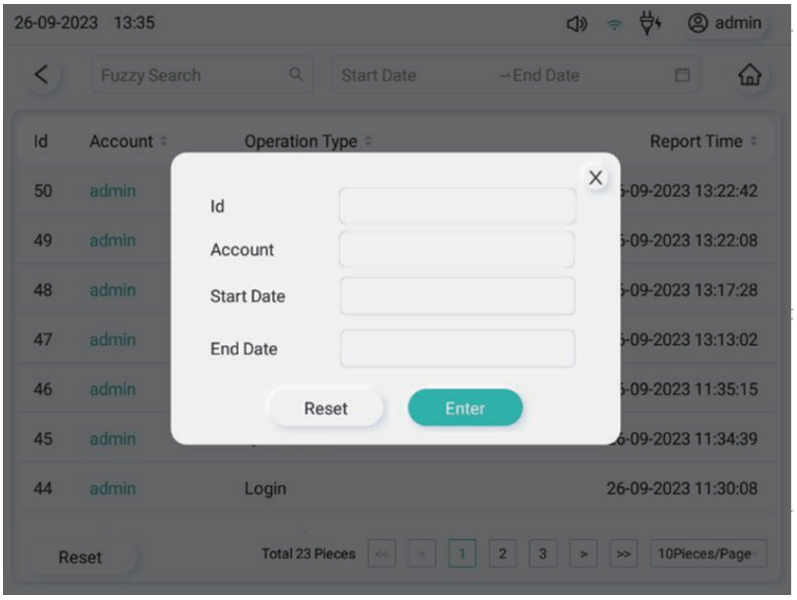


Figure 5-50 Enter the search criteria

Click on to close the search box. Click on Reset to clear the entered information, allowing for re-entry. After entering the criteria, click on Enter, and the matching results will be listed as below:

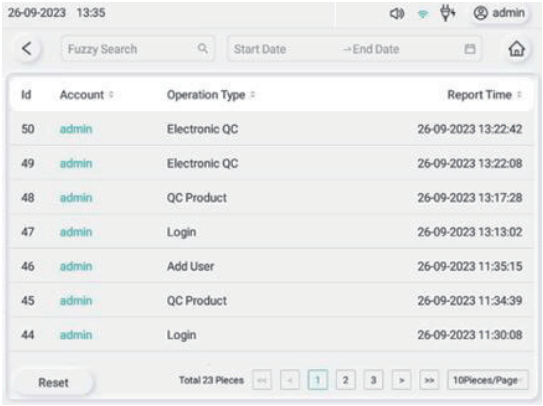


Figure 5-51 Operation log search results

• Click on to return to the operation log screen.
• Click on to return to the homepage.

◆ In the operation log screen, click on next to the time, and the results will be sorted by time in ascending/descending order.
◆ In the operation log screen, click on to return to the data management screen.
◆ In the operation log screen, click on to return to the homepage.

5.8 About

The "About" section contains basic information about the analyzer, the system info, and the storage state. You can also check the software version and update it when needed.

Click on to enter the About screen:

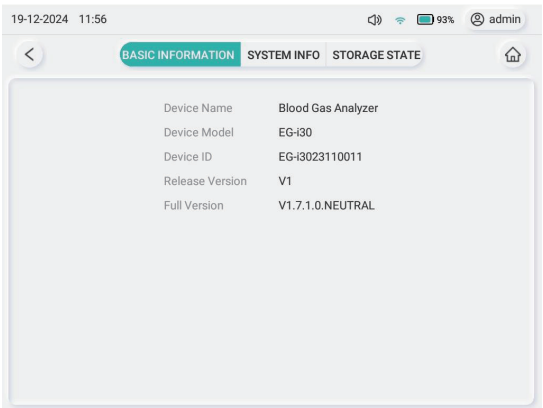


Figure 5-52 About

◆ Click on BASIC INFORMATION to view the device name, ID, and software version.

◆ Click on SYSTEM INFO to see the current battery level, ambient temperature, humidity, and air pressure.

◆ Click on STORAGE STATE to see the number of test results, QC results, users, and operation logs stored on the analyzer.

◆ Click on < or ⌂ to return to the homepage.

5.9 Help

In the Help section, there are guidance videos for sample testing, QC testing, data management, and system settings. These videos will guide you in using the analyzer.

Click on Help to enter the help screen. (Figure 5-53)

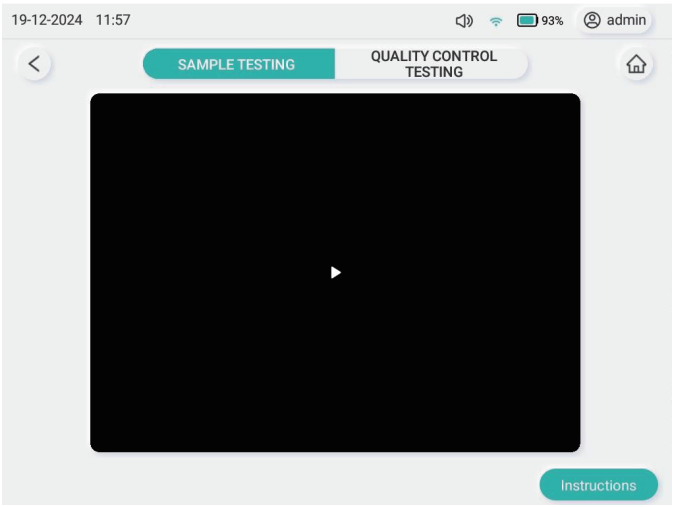


Figure 5-53 Help

◆ Click on SAMPLE TESTING to view the video on how to perform sample testing.

◆ Click on QUALITY CONTROL TESTING to view the video on how to perform a QC test with control solutions or an electrical control cartridge.

◆ Click on < to learn how to view the data.

◆ Click on ⌂ to learn how to change the settings.

◆ Click on < or ⌂ to return to the homepage.

6. Cleaning, Maintenance and destruction

Routine cleaning, repairs, and maintenance of the analyzer are required to ensure that it remains in optimal working condition.

6.1 Cleaning and Disinfection

The analyzer requires cleaning and disinfection to remove dust and stains from the surface. The frequency of cleaning and disinfection can be determined by your facility.

When cleaning and disinfecting the analyzer, the operators should comply with the safety regulations and take safety measures (such as wearing protective clothing and gloves).

⚠ Caution

• Users should strictly follow the instructions in this manual for cleaning and disinfection operations.

Steps to clean and disinfect the outer surface of the analyzer:

1) Power off the analyzer. (refer to section 5.1)

2) Unplug the power cord and power adapter from the analyzer.

3) If the analyzer is connected to other devices, unplug the connection cables.

4) Wipe the exterior of the analyzer with a damp cloth.

5) After the outer surface of the analyzer has fully dried, gently wipe the outer surface with a lint-free wipe and disinfectant.

6) Dispose of the lint-free wipe in a biohazard waste bag.

7) After the outer surface of the analyzer has fully dried, plug in the connection cable, power adapter, and power cord again.

⚠ Caution

• Disinfect the outer surface only after it is fully dry.

• The lint-free wipe used for cleaning should be damp but not dripping.

Cleaning agent: water or 75% medical alcohol

6.2 Care and Maintenance

6.2.1 Battery capacity, charging, and replacement

⚠ Warnings

• Improper handling may cause the battery to heat up, catch fire, explode, self-destroy, or lose capacity. Before using the battery, please read this manual and the precautions carefully.

⚠ Caution

• When the analyzer is powered solely by the power adapter, the adapter icon will be displayed in the status bar at the top of the screen.

• When the analyzer is powered solely by the battery, the battery icon will be displayed in the status bar with the current battery level at the top of the screen.

• When both the adapter and the battery are used and the battery is charging, only the battery icon is displayed in the status bar (the battery icon changes dynamically).

• When both the adapter and the battery are used and the battery is not charging, the corresponding icon is displayed in the status bar.

◆ Battery charging

The analyzer has a rechargeable lithium battery with a charging control circuit. When using the battery for the first time, the power is usually insufficient due to the loss during storage and transportation. You may need to charge the battery before use.

Please connect to AC power to charge the battery.

⚠ Caution

• If the battery has not been used for a long time (more than two months), the user should charge the battery before use.

◆ Battery replacement

When the battery reaches the end of its service life, or if you find the battery leaks or has a bad odor, please contact the authorized agents to replace the battery.

⚠ Warnings

• Please use the same rechargeable lithium battery model as the one provided by manufacture or the authorized agents.

• The positive and negative terminals of the battery cannot be reversed, otherwise it may cause an explosion.

• To prevent the battery from becoming unusable due to over-discharge, please charge the battery at least once every 6 months if the battery is not used frequently.

• Old batteries should be returned to manufacture for disposal or disposed of in accordance with the local regulations.

6.2.2 Printer and printer paper

⚠ Caution

• Please be sure to use the thermal paper provided by manufacture, otherwise the built-in thermal printer may be damaged. Such damage is not covered by the warranty.

Please follow the requirements below when storing printer paper:

• Printer paper should be stored in a dry, cool place, away from heat, humidity, and sunlight.

• Avoid prolonged placement under fluorescent lights.

• Printer paper should not be stored in an environment with polychlorinated ethylene plastic, which may cause discoloration of the paper.

6.2.3 Maintenance

⚠ Caution

The analyzer should be subjected to periodic safety tests (once every 6 months as recommended), including:

1) Inspection of the mainframe and accessories for mechanical and functional damage.

2) Check if the safety signs are damaged.

3) Verify the functionality of the analyzer according to the instructions.

The tests should be performed by trained and qualified personnel, and the results should be recorded. The analyzer must be repaired if any problems are discovered during the above tests.

Analyzers:

1) Please keep the analyzers away from high temperature, sunlight, moisture, or dust. Do not crush the analyzer. Avoid violent vibrations when moving.

2) Do not allow any liquid to enter the analyzer, which may affect its performance and safety.

3) Please contact our maintenance department to test the performance of the analyzer periodically.

Please replace the accessories according to the actual usage.

See label for the production date. The service life is 5 years.

6.2.4 Quality control

The analyzer should be subjected to periodic accuracy confirmation (at least once every 3 months or every 2000 tests, whichever comes first). Please refer to section 5.6 Quality Control for the QC method and result interpretation. The analyzer's detection accuracy cannot be guaranteed without performing QC.

6.3 Destruction

Cartridges are potentially biohazardous after use and should be disposed of in accordance with biohazard waste recycling or local administrative regulations.

7. Repair and After-Sales Service

7.1 Repair

The warranty for this analyzer covers all equipment failures caused by the material or production process. All damaged parts can be repaired or replaced for free within the warranty period. Please check the warranty card for details.

◆ Manufacturing process and materials

Manufacture guarantees that the production process and the materials that were used meet the requirements. If the analyzer fails under normal use and repair, please send a failure report within the warranty period from the date of shipment, and manufacture will repair or replace the hardware for you.

◆ Software

If the software installed in the manufacture hardware products fails, please send a failure report within the warranty period from the date of shipment, and manufacture will fix or update the software for you.

Note: Manufacture's obligations under this warranty do not include shipping and other charges.

No part in this product can be repaired by the user. Repair and maintenance can only be performed by manufacture approved engineers and technicians.

Manufacture is not responsible for direct/indirect/final damage or delay caused by:

- Human damage
- Unforseen natural disasters
- Components that are disassembled, stretched, or commissioned
- Replacement or usage of parts not approved by manufacture or having the analyzer repaired or modified by non-authorized personnel
- Damage caused by abnormal use beyond the conditions specified in this manual
- Replacement or removal of the original lot number label or factory mark
- Failures not caused by the product itself

7.2 After-Sales Service

When the analyzer fails, please try the corresponding solutions mentioned in Appendix 2, troubleshooting guide. If the analyzer cannot be restored to normal, please turn off the power, and stop using the analyzer. Pull out the cartridge if there is one and clean the analyzer if necessary. Store it appropriately, and then contact authorized technical support to arrange a repair. Do not use the analyzer in question.

The analyzer is a high-precision analytical instrument and must not be disassembled without authorization. The maintenance and software upgrade must be carried out by the authorized agents.

Manufacture can continue to provide repair services after the warranty period is exceeded.

Appendix

Appendix 1. Specifications

Analyzers	Operating conditions	Temperature: 18°C to 30°C
		Relative humidity: 10% to 85% (no condensation)
		Atmospheric pressure intensity: 68 kPa to 106.6 kPa
	Transportation and storage conditions	Temperature: -20°C to 55°C
		Relative humidity: 10% to 93% (no condensation)
		Atmospheric pressure intensity: 68 kPa to 106.6 kPa

A1.2 Mechanics

Dimensions	235mm×210mm×160mm (±10mm)
Weight	3.0±0.5 kg (with battery)
Display	Touch screen
Power supply	Lithium battery (16.8V) or 19VDC (AC input: ~100V - 240V, 50/60Hz, input power: 90VA)
Network	Ethernet, Wi-Fi
Scanner	Built-in
Printers	Built-in
Data storage	≥100000 sample test results;≥10000 quality control results

A1.3 Performance

Parameters	Accuracy	Limit of detection	Linear			Intra-batch precision
			Interval	Deviation	Correlation coefficient r	
K^+	The results were within ±0.3mmol/L.	≤2.0 mmol/L	2.0-9.0 mmol/L	The results were within ±0.3mmol/L.	≥0.995	CV≤1.5%
Na^+	The results were within ±4mmol/L.	≤100 mmol/L	100-180 mmol/L	The results were within ±4mmol/L.		CV≤1.5%
Cl^-	The results were within ±5.0%.	≤65 mmol/L	65-140 mmol/L	The results were within ±5.0%.		CV≤1.5%
iCa^{2+}	For test results ≥1.00 mmol/L, the results were within ±5.0%. For test results <1.00 mmol/L, the results were within ±0.05 mmol/L.	≤0.25 mmol/L	0.25-2.50 mmol/L	For test results ≥1.00 mmol/L, the results were within ±5.0%. For test results <1.00 mmol/L, the results were within ±0.05 mmol/L.		CV≤1.5%

Blood Gas Analyzer User's Manual

pH	The results were within ±0.04.	≤6.500	6.500-8.000	The results were within ±0.04.		SD≤0.02
pCO_2	For test results ≥ 62.0 mmHg, the results were within ±8.0%. For test results <62.0 mmHg, the results were within ±5.0 mmHg.	≤10.0 mmHg	10.0-150.0 mmHg	For test results≥ 62.0 mmHg, the results were within ±8.0%. For test results <62.0 mmHg, the results were within ±5.0 mmHg.		≥62.0 mmHg, CV ≤4.0% <62.0 mmHg, SD ≤2.5 mmHg
pO_2	For test results ≥100mmHg, the results were within ±15.0%. For test results <100mmHg, the results were within ±15 mmHg.	≤10 mmHg	10-700 mmHg	For test results ≥100mmHg, the results were within ±15.0%. For test results <100mmHg, the results were within ±15 mmHg.		CV≤5.0%
Glu	For test results≥4.0 mmol/L, the results were within ±10.0%. For test results <4.0 mmol/L the results were within ±0.4 mmol/L.	≤1.1 mmol/L	1.1-38.0 mmol/L	For test results ≥4.0 mmol/L, the results were within ±10.0%. For test results <4.0 mmol/L, the results were within ±0.4 mmol/L.	≥0.995	≥4.0 mmol/L, CV 5.0%. <4.0 mmol/L, SD≤0.2 mmol/L
Lac	For test results ≥ 5.00 mmol/L, the results were within ±12.0%. For test results <5.00 mmol/L, the results were within ±0.6 mmol/L.	≤ 0.50 mmol/L	0.50-20.00 mmol/L	For test results≥ 5.00 mmol/L, the results were within ±12.0%. For test results <5.00 mmol/L, the results were within ±0.6 mmol/L.		≥5.00 mmol/L, CV ≤6.0% <5.00 mmol/L, SD≤0.3 mmol/L
Hct	The results were within 10.8%PCV	≤10% PCV	10%-70% PCV	The results were within 10.8% PCV		≥50% PCV, CV ≤3% <50% PCV, SD ≤ 1.5% PCV

A1.4 Pinter

Printer	Built-in thermal printer with thermal paper
Print width	57mm

A1.5 Battery

Type	Rechargeable lithium battery
Duration	Continuous times ≥ 60 times
Charging time	Less than 6 hours
Limited charging voltage	≤ 16.8 V
Charging method	Constant Current/Constant Voltage
Charging current (standard)	1A
Maximum continuous discharge current	1340 mAh
Cycle life	≥ 300 times
Rated energy	< 98 Wh

A1.6 Safety certification

Safety standards and requirements	IEC 61010-1–Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements IEC 61010-2-101–Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61326-2-6 –Electrical equipment for measurement, control, and laboratory use. EMC requirements - Part 2-6. Particular requirements. In vitro diagnostic (IVD) medical equipment IEC 61326-1–Electrical equipment for measurement, control, and laboratory use - EMC requirements - Part 1: General requirements
Safety temperature	This analyzer cannot be operated in an environment where the temperature is higher than 30°C
Safe humidity range	When the temperature rises to 30°C, the maximum relative humidity is 85%. When the temperature rises to 55°C, the relative humidity drops to 60%.
Pollution level	2
Degree of liquid ingress prevention	Ordinary equipment, cannot prevent liquid ingress
Safety level in the presence of combustible gases	Not suitable for use in environments with combustible gases
Anti-electric shock class	Class I instrument

Appendix 2. Troubleshooting Guide

This chapter describes conditions that can cause erroneous patient test results. Users can refer to the solutions provided below when the problems occur.

Error number	Questions	Solutions
E01	Abnormal ambient temperature; Abnormal ambient humidity; Abnormal ambient pressure	• Confirm that the ambient temperature around the analyzer is within the range of 10 °C to 31 °C, the relative humidity is within the range of 10% to 85% (without condensation), and the atmospheric pressure is within the range of 68 kPa to 106.6 kPa. • If the problem persists, please contact technical support.
E02	Invalid QR Code	• Select a cartridge or quality control product that matches selected the cartridge type. • If the problem persists, please contact the authorized dealer.
E03	Data storage failure	• Reboot or power off the device. • Contact the authorized administrator to check the storage status. • If the problem persists, please contact the authorized dealer.
E04	Cartridge expired	• Test with an unexpired cartridge. • If the problem persists, please contact the authorized dealer.
E05	Data upload failure	• Contact the authorized administrator to check the network configuration • Re-upload • If the problem persists, please contact the authorized dealer.
E06	Cartridge slot is occupied	• Check if the cartridge slot is occupied • If the problem persists, please contact the authorized dealer.
E07	Printer failure	• Check the printer status according to the alert • If the problem persists, please contact the authorized dealer.
E08	Control solutions expired	• Retest with an unexpired control solution • If the problem persists, please contact the authorized dealer.
E09	Communication abnormalities	• If the problem persists, please contact the authorized dealer.
E10	Wrong cartridge type	• Reinsert a cartridge that meets the requirements. • If the problem persists, please contact the authorized dealer.

Error number	Questions	Solutions
E11	Code scanning exception	• Scan the code again • Restart after powering off the device (not reboot) • If the problem persists, please contact the authorized dealer.
E12	Low power, please charge in time	• Insert the power adapter for charging
E13	Standard abnormal, please take out the card	• Reinsert a cartridge that meets the requirements. • Restart after powering off the device (not reboot) • If the problem persists, please contact the authorized dealer.
E14	Sample abnormal, please take out the card	• If the sample size is insufficient or there are bubbles or loose covers in the sample, reinsert a cartridge that meets the requirements. • Restart after powering off the device (not reboot) • If the problem persists, please contact the authorized dealer.
E15	Self check failed, please contact the administrator	• Restart after powering off the device (not reboot) • If the problem persists, please contact the authorized dealer.

Fault issues

Questions	Solutions
Long press the power on button but the analyzer cannot be turned on	• Press and hold the button again to confirm if it can be turned on. • If the problem persists, please contact the authorized dealer.
Touch screen failure	• Unplug the power cord and turn it back on • If the problem persists, please contact the authorized dealer.
Click on a button, and the corresponding interface or event is not triggered	• Unplug the power and plug it back on • If the problem persists, please contact the authorized dealer.
The scanner is unavailable or non-functional	• Restart after powering off the device (not reboot). • If the problem persists, please contact the authorized dealer.
Unable to take out the cartridge	• Restart after powering off the device (not reboot). • If the problem persists, please contact the authorized dealer.
Printer jam	• Rearrange the printer paper • If the problem persists, please contact the authorized dealer.
The analyzer cannot be charged	• Restart after powering off the device (not reboot). • If the problem persists, please contact the authorized dealer.
Multiple tests with abnormal data	• Restart after powering off the device (not reboot). • If the problem persists, please contact the authorized dealer.
Strange sounds occur or the screen flashes during testing	• Restart after powering off the device (not reboot). • If the problem persists, please contact the authorized dealer.

Appendix 3. Symbols

The following graphics, symbols, and abbreviations may appear on product packaging, labels, displays, and instructions. Their meanings are explained in the following table:

	Consult instructions for use
	Lot number
	Caution
	Biohazards
	Serial number
	Date of manufacture
	Expiry date
	Fragile, Handle with care
	This way up
	Keep dry