Fluorescent Immunoassay Analyzer

User Manual

（LYOFIA® -I）

Hunan Kangxin Biotechnology Co., Ltd.

Revision history

Version	Revision date	Change Description
V1	2022-04-24	Initial release

Declaration

Thank you for choosing our Fluorescent Immunoassay Analyzer. Please carefully read the contents of this manual before use.

This analyzer has a data storage function inside, and the company is free of responsibility for user losses caused by analyzer damage or data loss, which was caused by user operations.

Please do not disassemble or repair the analyzer without authorization, otherwise the post-sales service provided to you will be automatically terminated. Please use the reagents provided by our company, otherwise our company is free of responsibility for the wrong test results. The company has the right to change product design and specifications without prior notice. A slight difference between the picture and the actual product may occur due to the printing process of this manual, please refer to the actual product.

You need to ensure that the accessories expansion, re-commissioning or maintenance of the analyzer are carried out by the personnel approved by the company; the relevant electrical equipment conforms to the local standards; the operation is strictly followed to instruction described in this manual. Otherwise, the company is not responsible for the safety, reliability and performance of the device.

This manual is formed in accordance to the requirements of EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements, EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)

- Part 1: Terms, definitions and general requirements, EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use, and point 20.1 of Annex I describe in Regulation EU 2017/746. This device meets the safety requirements specified in EN 61010-1:2010/A1:2019/AC:2019 Safety requirements for electrical equipment for detection, control, and laboratory use - Part 1: General requirements, and EN 61010-2-101:2017 Safety requirements for electrical equipment for detection, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment. This device also meets the electromagnetic compatibility requirements specified in EN 61326-1:2013 Electrical equipment for detection, control and laboratory use - EMC requirements - Part 1: General requirements and EN 61326-2-6:2013 Electrical equipment for detection, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment.

Content

Chapter I Warnings and Precautions

1. For *in vitro* diagnostic use only.

2. Before using, you should be acknowledged with relevant professional medical knowledge.

3. Please put the analyzer into use according to the intended use and operation method described in the manual, otherwise the protection that comes with the analyzer may be damaged, and any incorrect operation may lead to inaccurate test results.

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

5. Before starting the analyzer, make sure that the power supply is the working voltage that the analyzer conforms to. Please use the special power adapter provided with the analyzer. After starting, please do not leave the analyzer unattended.

6. This device is intended to be used by specially trained operators only, and it is recommended to follow the given procedures. The protection comes with the analyzer may be compromised if the operation is deviated from the methods specified in the manual.

7. Please wear protective gloves when operating the analyzer to avoid infection.

8. A well-ventilated room is required and the analyzer's surface should not be covered by any objects, including but not limited to large amounts of liquid or droplets. Do not place the analyzer in liquids or stuff other items into the test port.

9. Since the standard curve parameters vary among different batches of reagents, the batch number of reagent must be consistent with that of the standard curve during the assay.

10. All equipment maintenance must be operated by the technicians designated by our company. If parts need to be replaced during maintenance, new parts must be provided by our company.

11. If the analyzer is damaged during use or transportation, it cannot be turned on until repaired by the technicians designated by our company.

12. Disassembling the analyzer by yourself may cause leakage of harmful radiation and damage to the analyzer. For radiation warning prompts and symbols, please kindly see Chapter IX and X.

13. Cut the power off if the device is not used for a long time.

14. If the analyzer works abnormally, please refer to Section VIII, if the failures cannot be eliminated, please contact the supplier.

15. Electrostatic protection should be well performed in a dry environment or other places that may easily cause static electricity (such as artificial fabric carpets, etc.), otherwise it may cause destructive electrostatic discharge, resulting in wrong test results or damage to the analyzer.

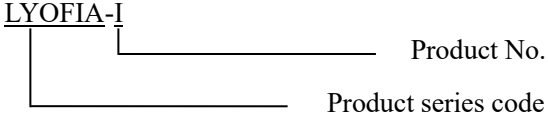
Chapter II Analyzer Summary

This device is a quantitative determination analyzer developed basing on modern optoelectronic technology and intended to be used in combination with fluorescent immunoassay strips to detect relevant parameters of human samples. The detection results could be used for clinical auxiliary diagnosis.

The analyzer applies a time-resolved method for detection. The principle is to use the characteristics of the long-lasting fluorescence of the lanthanide elements labeled in the test strip, that is, after removing the excitation light, the lanthanide elements can still maintain the continuous emission of the emitted light for a long time. However, other substances that can be excited to emit fluorescence cannot generate emission light in a very short time after the excitation light is removed. It is the application of the time-resolved method for detection that after turning off the excitation light for a certain period of time, and after other interfering substances cannot generate the emitted light, the light intensity is read. Through the optimized design of the optical path and the amplifier circuit, the weak fluorescence emission light signal can be detected, so as to achieve the purpose of reducing the background and interference.

Product name and model: Fluorescent Immunoassay Analyzer LYOFIA-I

Naming rules: Model description:



Software name: Fluorescent Immunoassay Analyzer Software System

Software release version: LYOFIA-I.V1

Chapter III Intended Use

This device is based on fluorescence immunoassay technology and intended to be used in combination with the detection kits manufactured by our company to quantitatively detect analytes in human serum, plasma or other body fluid samples in clinical practice.

And it is for professional use only, not for self-testing of untrained individuals, nor for near-patient testing.

Contraindications: None.

Chapter IV Technical Characteristics

Detection principle	Fluorescence quantitative analysis
Storage	No less than 10,000 sample results
Speed	500 samples/hour
Interface	USB, RS232, LAN, power supply
Display	7" LCD
Button	Capacitive touch screen
Weight	1.8 Kg
Voltage	100-240V～ 50/60Hz
Size	275mm×230mm×100mm (Length × width × height)
Power	30VA
Repeatability	Coefficient of Variation (CV) ≤ 5%
Linearity	Linear correlation coefficient (r) ≥ 0.99
Stability	Relative deviation ≤±10%

Accuracy	Relative deviation ≤±10%

Chapter V Analyzer Structure

This device consists of mainframe, power adapter and software (software release version: LYOFIA-I.V1). The mainframe mainly includes Reaction module, Optical detection module (fluorescence), Data processing module, Motion control module, Display screen and Printer.

The analyzer appearance and components is described as the following picture:

1. LCD screen; 2. Thermal printer; 3. Reagent cassette interface.

4. Power interface; 5. USB interface 6. RS232 interface 7. Switch;
8. Network port; 9. Reagent information carrier interface.

Chapter VI Analyzer Installation

1. Analyzer standard configuration

1× Fluorescence immunoassay analyzer

1× Adapter

1× Manual

1× Quality control card

2. Analyzer installation

2.1 Before installation

Open the package according to the instructions of the packing box, check the accessories and documents provided with the analyzer against the packing list. After that, prepare for installation. If you have any questions, please contact our post-sales service department.

Notice:

The working environment of the analyzer:

Voltage: 100-240V～ 50/60Hz;

Ambient temperature: 10-30℃;

Relative humidity: ≤80%;

Keep away from strong electromagnetic interference sources;

Avoid direct exposure to strong light;

A good grounding environment;

Atmospheric pressure: 86 kPa～106 kPa.

2.2 Installation

Take the analyzer out of the carton. Check that the appearance of the analyzer is intact.

Take out the power adapter that comes with the mainframe and connect the AC power and the analyzer.

Before use, please follow the relevant chapters of the manual to check whether the analyzer is functioning properly.

Please place the analyzer on a sturdy flat surface and allow some space around the analyzer. Do not place it in a location where it is difficult to disconnect power.

3.Transportation and storage

The analyzer is packaged in a rigid carton outside and high-quality

pearl cotton foam inside, which is firm and shockproof. The packing box is equipped with simple anti-vibration facilities, which are suitable for air, railway, road and ship transportation, while rain splashing, snow splashing, inversion and collision should be kept away.

Stacked in multiple layers should be avoid, as well as placed close to the ground, walls and roofs.

Transportation conditions: packaged analyzer, temperature: -20℃ to +55℃; relative humidity ≤85%, keep away from rain and sunlight.

Storage conditions: packaged analyzer, temperature: -20℃ to +55℃; relative humidity ≤85%, do not close to the ground, walls and roof.

Chapter VII Analyzer Operation

1. Operation

Please following the three steps:

a) Scan the reagent information carrier, read and save the test item information;

b) Put the sample into the analyzer for detection;

c) Result view and query.

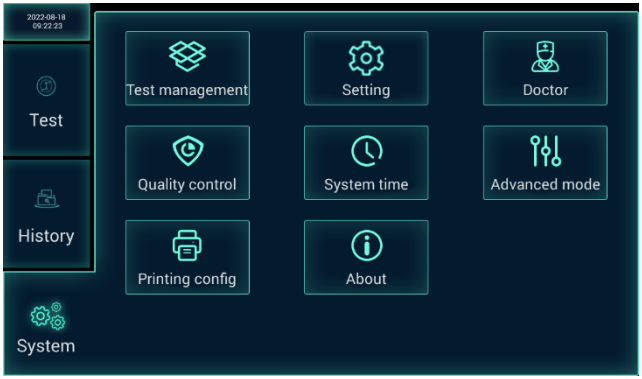
Step 1, Scan the reagent information carrier

If you need change the reagent batch or add new test items, you need to operate this step, otherwise you can skip this step, except for starting the analyzer.

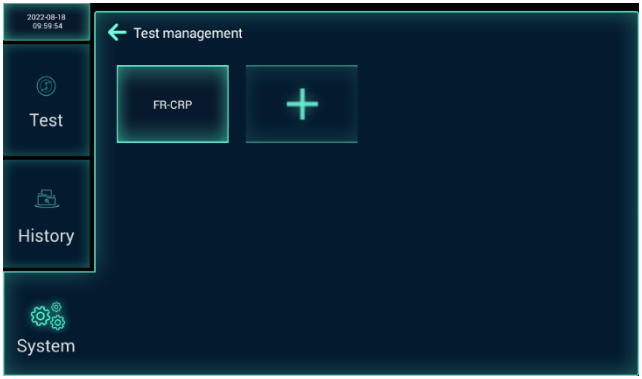
a) Start: Turn on the power switch, the analyzer will automatically run the self-test program. After that, a password input interface is displayed, please enter the power-on password "123456" to start the analyzer.

b) Calibration: Analyzer calibration requires reagent information carrier which is provided with test kits. The information recorded in the carrier mainly includes: kit name (if there is joint detection, replaced by joint detection classification), batch number, calibration curve, number of tests, serial number, item name (if there is joint detection, all test items will be displayed), detection range, reference interval, and unit.

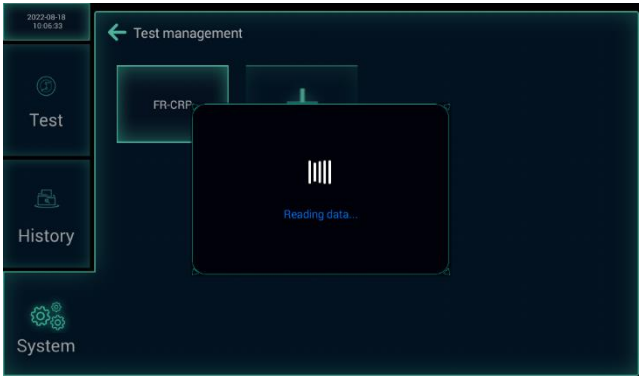
The method of importing the information is as follows: Click the "System" to enter the system interface.



Then click the "Test management" to enter the Test management interface.



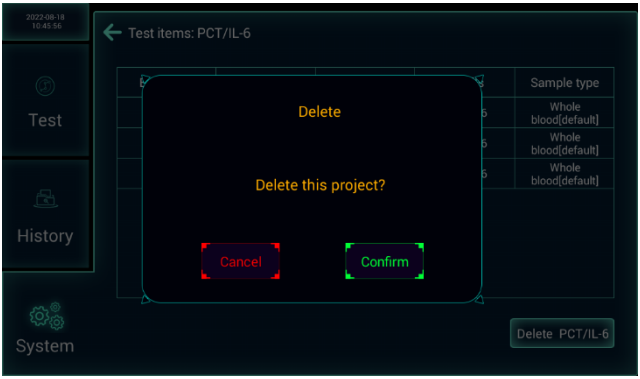
Insert the reagent information carrier that comes with provided kit, click the "+", the analyzer will read the information in the carrier which will be imported into the analyzer. The analyzer completes the calibration of the batch of kits according to the calibration curve by correlating the reagent information carrier with the corresponding batch of kits.



c) TEST item deletion: Select the test item which is expected to be deleted according to the actual need.

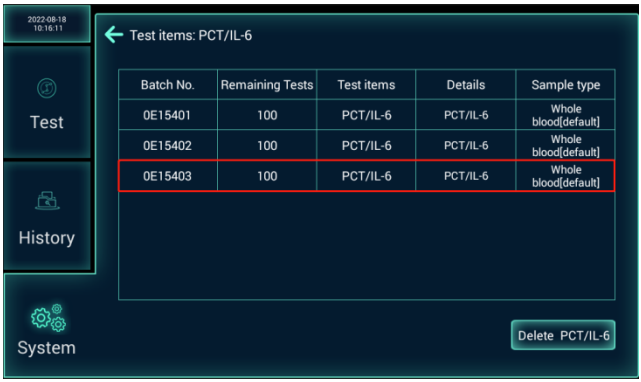
Click the "Delete" to delete the TEST.

Click "Delete" test item, a dialog box will pop up, click the "Confirm" to delete the test item.



TEST deletion

Click a data item in the test item, a dialog box will pop up, click the "Delete" to delete the reagent batch.

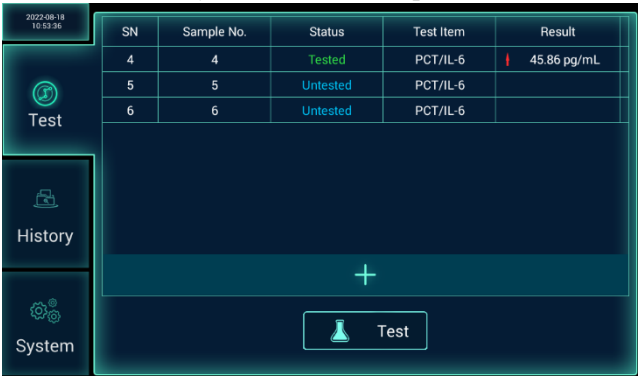


Delete this batch

If the reagent batch is changed or the test items are added, this step is required, otherwise this step can be skipped.

Step 2, Sample detection

a) Click “Test”, the analyzer enters the sample detection interface.



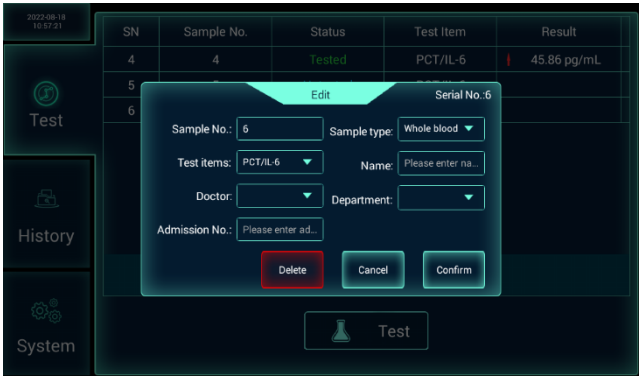
b) Click “+”, enter the information of the sample to be tested, the

information input is completed, and click the "Confirm", the sample is added successfully.

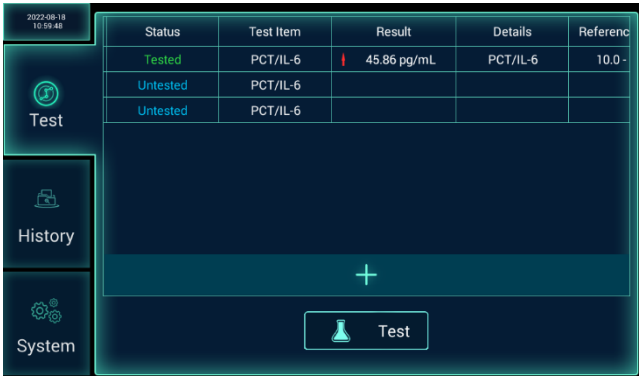
c) Continuous sample testing input: Click the "+", and a dialog box for inputting the sample information to be tested will pop up. If sample continues is required, select "Sample continues". To exit, click the "Cancel".

d) After editing the information of the sample to be tested, put the sample to be tested in the order of adding the sample information. If you want to delete the sample to be tested, click the sample data area to be deleted. After clicking, the following deletion prompt box will

pop up. If it is sure to delete the sample data, click the "Delete" in the prompt box.

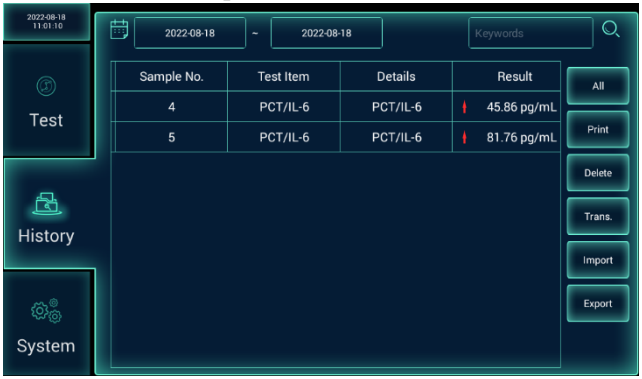


e) After editing the information of the sample to be tested, put the sample to be tested in the order of adding the sample information. The analyzer automatically scans the barcode to read the test parameter, and starts to detect. After the detection is completed, the result is displayed on the sample detection interface. Swipe left or right in the data area to view the complete information about the sample. If the QR code on the cassette fails to be scanned , you can remove and reinsert the test cassette. Please confirm whether the QR code is contaminated or the batch of reagents is not inputted.



Step 3, Result review and query.

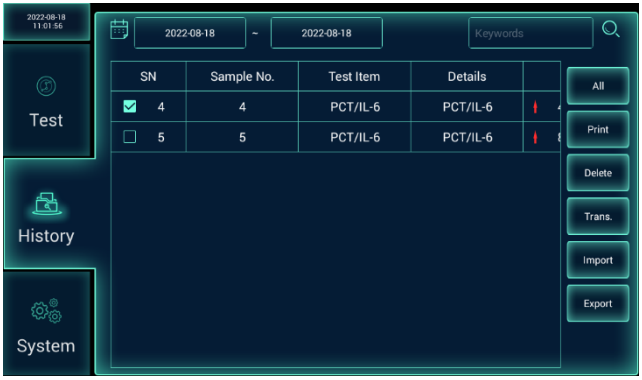
a) On the home interface, click the "History" to enter the history interface. This interface displays information about samples that have been tested. Swipe left or right in the data area to view complete information about the sample.



b) Enter the query conditions, and then click the “ ” to query the required detection data.

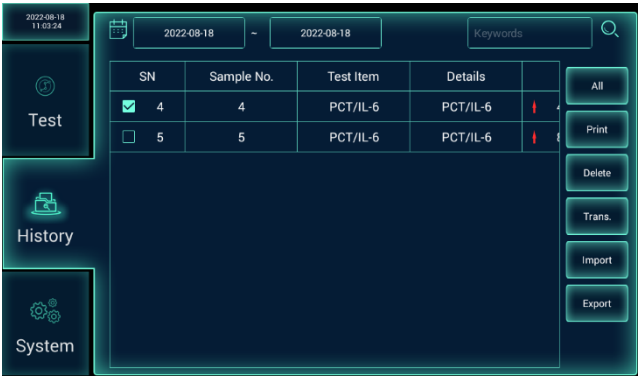
c) Select the detection results that need to be printed and transmitted, and click the "Print" or "Trans." to print or transmit the queried

results.

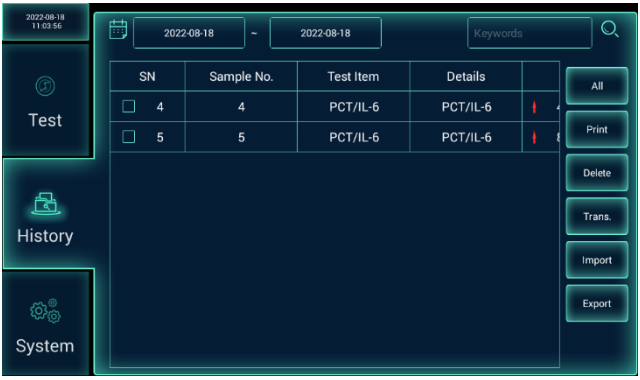


d) Click the sample information data area that needs to be modified, and then a prompt box for modifying information will pop up. The sample information can be modified as needed.

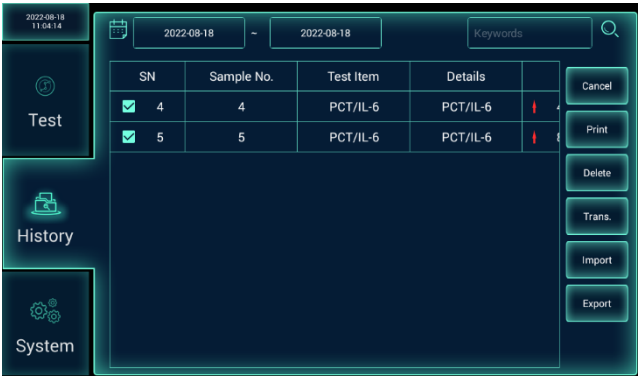
e) Deletion: Check the sample data to be deleted. Then click the "Delete" to delete the sample data.



f) Clear: Click the "All", and then click the "Delete" to clear all sample data.



"All" is not clicked



"All" is clicked

Note: Precautions during use

a) Users must wear disposable rubber gloves when operating the analyzer.

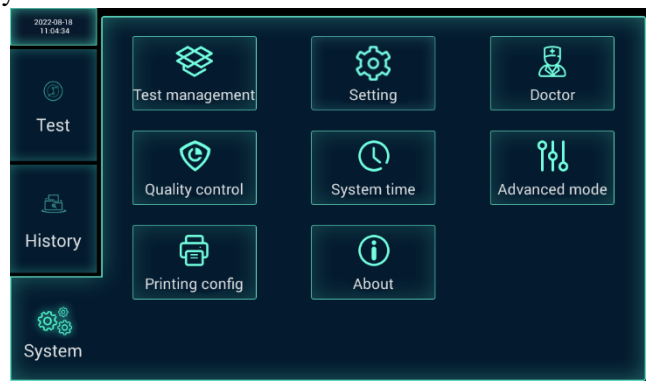
b) The setting function for engineering adjustment and testing can only be accessed by entering a password. It is only used by the manufacturer in the process of production and engineering adjustments/testing, and the professional maintenance personnel, while ordinary users are not allowed. The analyzer has been set before leaving the factory, and reset is not need by yourself.

If a mechanical failure is found during the use or the analyzer cannot be used, you should immediately stop using it and turn off the power, and then report to the supplier for repair.

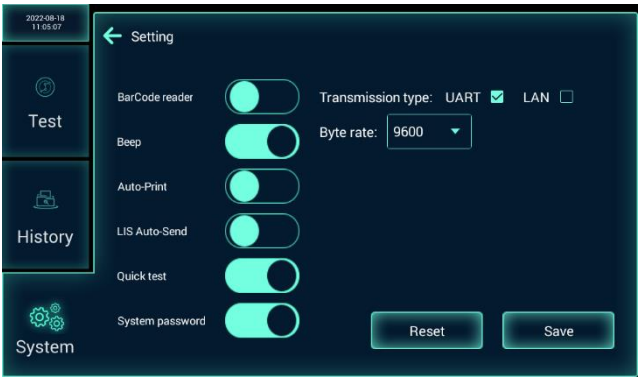
2. System setting

a) Turn on the power switch, the analyzer will automatically run the self-test program. After that, enter the power-on password (if

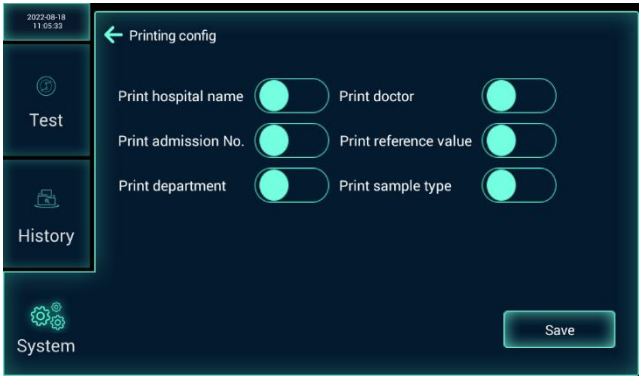
available), the analyzer automatically enters home interface. Click the "System" to enter the following system setting interface, where the system could be set.



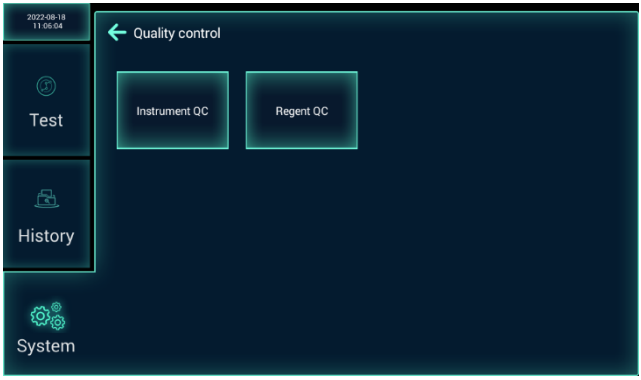
b) Test setting: Click “Setting” to enter test setting interface, which includes settings for “BarCode reader”, “Beep”, “Auto-Print”, “LIS Auto-Send”, “Transmission type” and etc.



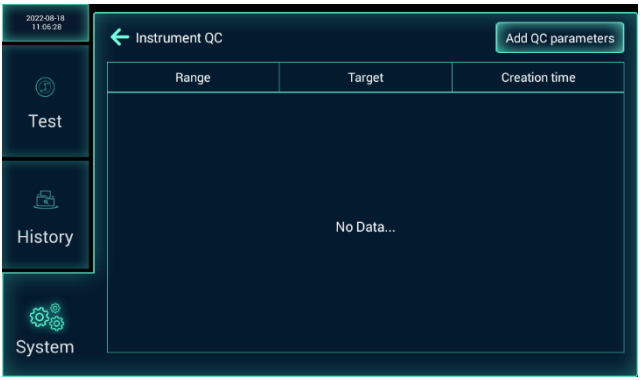
c) Printing setting: Click “Printing config” to enter printing setting interface, which includes settings for “Print hospital name”, “Print admission No.”, “Print department”, “Print doctor”, Print “reference value”, “Print sample type”, and etc.



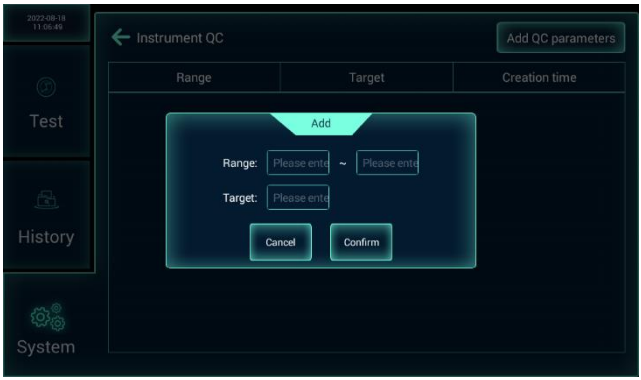
d) Control: Quality control (QC) include Instrument QC and Reagent QC. The Instrument QC requires the quality control card provided with the analyzer, and the Reagent QC requires the reagent and quality control provided with the supporting kits.



da) Click “Instrument QC” to enter the instrument quality control interface.



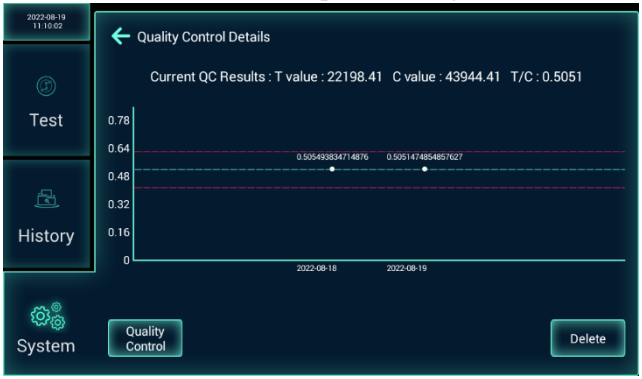
Click “Add QC parameters” to input the instrument quality control parameters



Enter the target value interval on the outer packaging label of the quality control card into the box shown in the figure above, and click the "Confirm" to complete the addition.

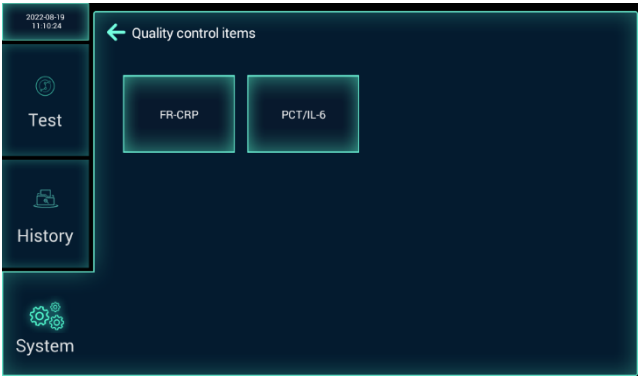
Click the quality control parameters added to enter the quality control details interface.

Insert quality control card into reagent cassette interface, click "Test" to start the instrument quality control, the control test results should fall within the specified target value interval.

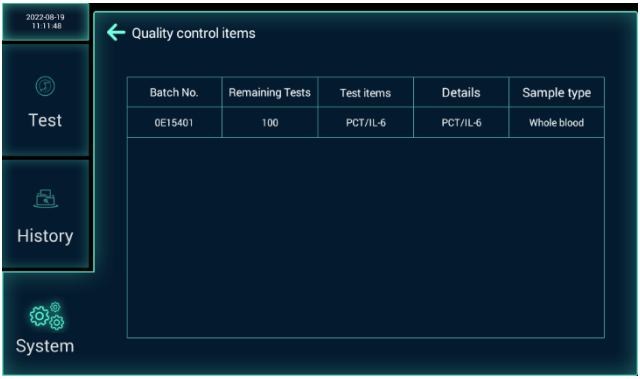


Quality control cycle: Perform instrument quality control at least once a month. If the quality control fails, please replace it with a new unopened quality control card and re-test or contact the manufacturer.

db) Click "Reagent QC" to enter the reagent quality control interface.

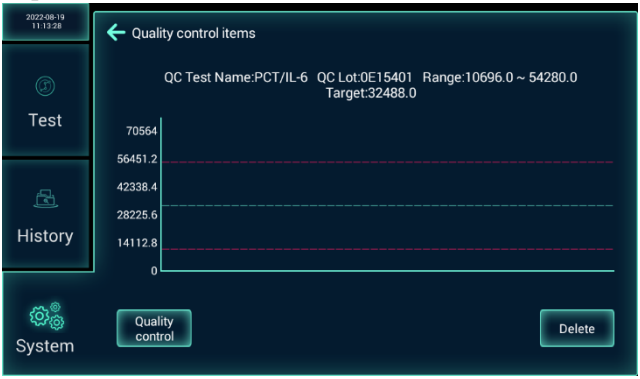


Select the quality control required test item to enter the batch selection interface.

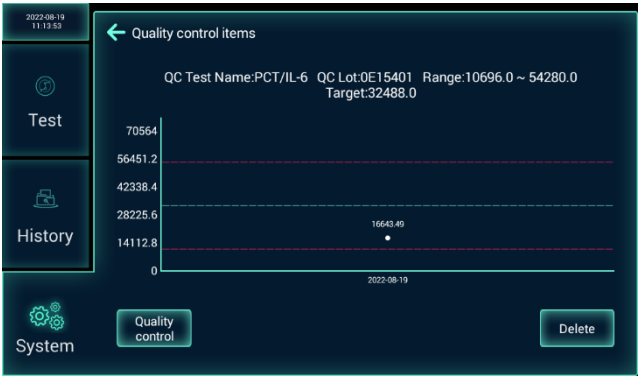


Select the quality control required project batch to enter the interface for the quality control parameters input. Click “Add QC parameters” and enter quality control parameters.

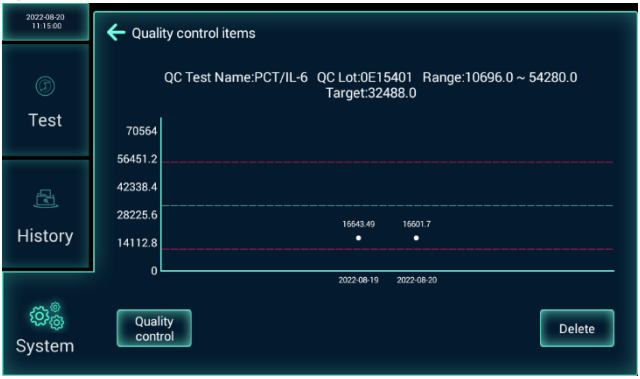
Enter the target value interval on the quality control bottle label or the target value list attached to the kit into the “Range” column shown in the figure above, and click the "Confirm" to complete the addition.



Click the quality control parameters added to enter the quality control details interface.



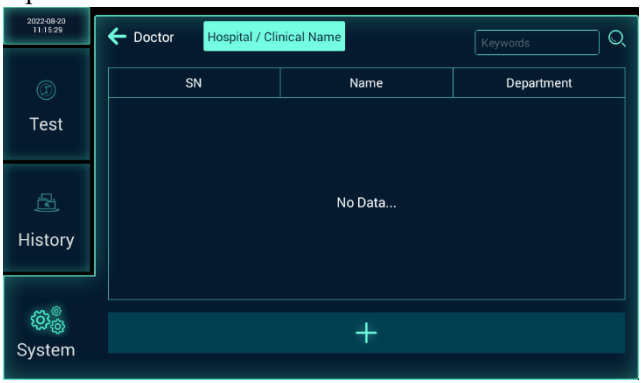
Take the quality control product as a sample, cooperate with the corresponding detection kit, and operate in strict accordance with the requirements of the kit instructions. After adding the sample, insert the test cassette into the reagent cassette interface, and then click " Quality control " to start the reagent quality control. the control test results should fall within the specified target value interval.



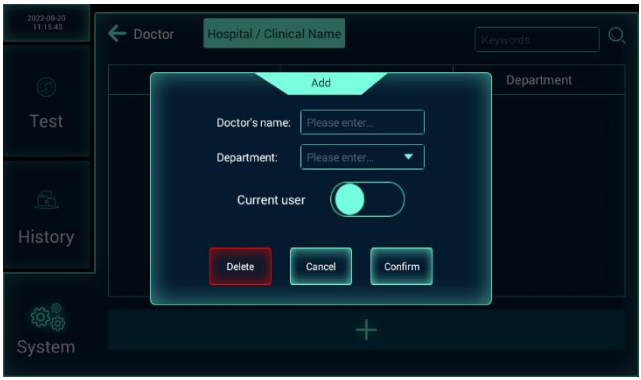
Quality control cycle: Perform reagent quality control at least once per batch. If the quality control fails, please replace it with a new unopened quality control product and re-test. If it still fails,

please perform the instrument quality control. If the instrument quality control fails, please contact the manufacturer.

e) Doctor management: Click the "Doctor" to enter the doctor management interface. This interface is for managing physician personal data. Click the "+", a dialog box for information input will pop up.

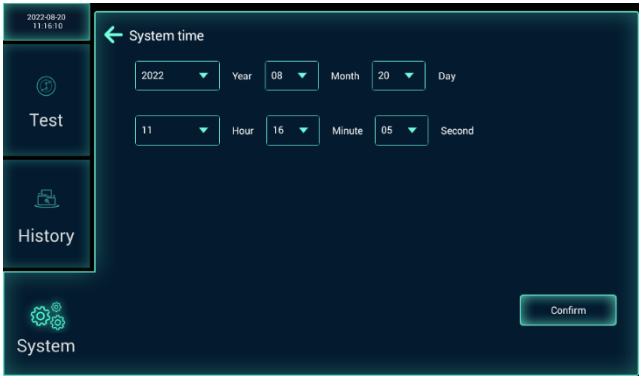


In the dialog box, enter the doctor's name, department and choose whether to set it as the current user.



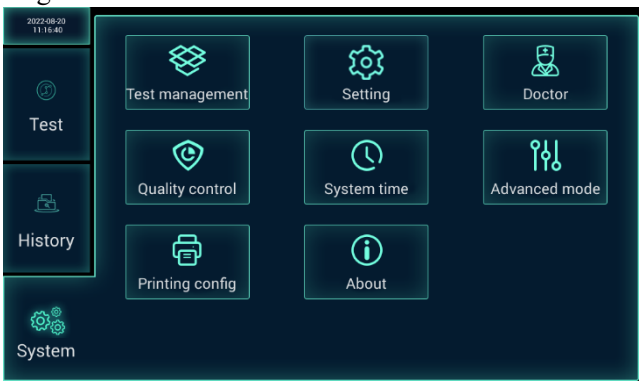
f) System time: Click "System time" to enter system time setting

interface. This analyzer supports manual time setting, click the "Confirm" to complete the setting.

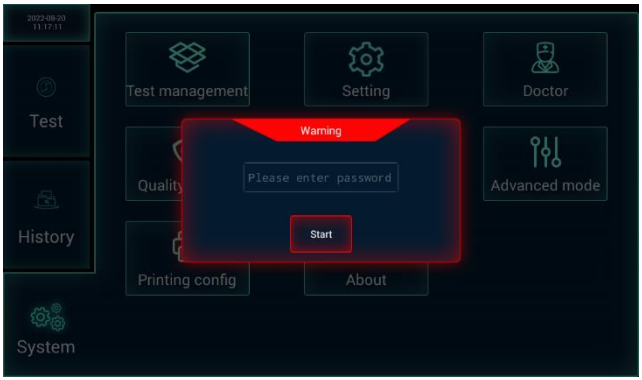


3. System maintenance

a) Turn on the power switch, the analyzer will automatically run the self-test program. After that, enter the power-on password (if available), the analyzer automatically enters home interface. Click the "System" to enter the following system setting interface, and click “Advanced mode” to enter the interface for engineering adjustments and testing.



Engineering adjustment and testing: The function can only be accessed by entering a password. It is only used by the manufacturer in the process of production and engineering adjustments/testing, and the professional maintenance personnel, while ordinary users are not allowed.



Chapter VIII Maintenance

1. Analyzer cleaning

Please use a neutral cleaning solution and a damp cloth to wipe the surface of the analyzer and the touch screen.

2. Analyzer maintenance

a) Keep the working environment and the surface of the analyzer clean, prevent the touch screen from being bumped and malicious pressing.

b) Replace the printing paper: When the printing paper of the printer has a red edge, it means that the paper is almost used up, and it should be replaced as soon as possible. Open the printer cover to replace the printing paper.

c) Do not repair or disassemble the instrument by yourself. If there is a quality problem, or you need to replace the vulnerable parts and key parts, please call the customer service hotline for consultation, and any repairs can only be carried out by authorized service engineers.

d) When equipment is taken out of service due to repair or disposal, please clean, sanitize, and package well to minimize hazards.

3. Waste disposal

a) The disposal of used samples, test cassettes, and protective gloves should be handled in accordance with the relevant local standards for medical waste disposal.

b) The disposal of the analyzer should be handled in accordance with the relevant local standards for electronic waste disposal.

4. Common failures handling

Failures	**Reasons**	**Handling measures**
Black screen on boot	Power is not reliably connected	Verify that the power supply is properly connected and turn on the switch
	Electricity failure	Contact supplier
Test cassette detection error	The cassette is not inserted correctly	Check if it is inserted backwards or not in place, and re-insert the card.
	test item data is not input	Insert reagent information carrier and reading the information.
	The QR code on the cassette failed to be scanned	Check if the QR code is dirty, if it is dirty, please clean it. If the QR code is fuzzy, please replace it. If the failure occurs frequently,

Failures	Reasons	Handling measures
The printer does not respond or prompts lack	Lack of printing paper	Install new printing paper

Note: After the instrument has a failure that cannot be easily repaired, do not repair it by yourself, please immediately contact the post-sales department for repair.

5. Warranty Description

Within one year from the date of purchase, if the analyzer fails under normal use, our company will provide free maintenance. However, it does not include failures caused by improper use, self-disassembly or self-maintenance of the analyzer.

The warranty obligations are limited to situation where our company are responsible for repairing failures or replacing products.

6. Accessories, consumables, manufacture date, and service life

a) Accessories and consumables: none.

b) Manufacture date: labeled on the analyzer nameplate.

c) Service life: Valid for 5 years from the date of manufacture.

The service life of this product is determined according to the aging method. During the use process, maintenance and repair on the product should be performed according to the requirements of the product manual. Products that have been confirmed to maintain their basic safety and effectiveness after maintenance or repair can be used normally.

The validity period of the supplied quality control card is as follows:

- Unopened, the validity period is 1 year.
- After opening, store it in a dry and sealed environment, and keep it away from sunlight, the validity period is 1 month. Do not use it more than 2 times per day.
- After opening, store it in a dry and sealed environment, and keep it away from sunlight. Do not use it more than 100 times in total.

Chapter IX Electromagnetic Compatibility Instructions

a) Our company can provide the electromagnetic compatibility information of the analyzer according to your needs.

b) It is your responsibility to ensure the electromagnetic compatibility environment of the analyzer so that it can work normally.

c) This analyzer complies with the emission and immunity requirements specified in IEC 61326-1/ EN 61326-1.

d) This analyzer is designed and tested in accordance with CISPR 11 Class A equipment. This equipment may cause radio interference in a domestic environment, which requiring taking precautions.

e) It is recommended to evaluate the electromagnetic environment before use, and do not use this analyzer near strong radiation (such as unshielded radio frequency sources), otherwise the normal operation of the analyzer maybe be interfered with.

Chapter X Symbols and description

IVD : IN VITRO DIAGNOSTIC MEDICAL DEVICE	: KEEP DRY
: FRAGILE	: HUMILITY LIMIT
: UPWARD	: CAUTION
: TEMPERATURE LIMIT	: BIOHAZARD WARNING
: USB INTERFACE : REAGNTE INFORMATION CARRIER INTERFACE : DC POWER INTERFACE	: NETWORK INTERFACE RS232 : SERIAL RS232 INTERFACE

EC REP : AUTHORIZED REPRESENTATITVE IN THE EUROPEAN COMMUNITY	: DO NOT DISCARD IT CARELESSLY, HAND IT OVER TO APPROPRIATE FACILITIES
: DATE OF MANUFACTURE	: MANUFACTURER

Chapter XI Contact

Manufacturer name: Hunan Kangxin Biotechnology Co., Ltd.

Address: Room 301, 3rd Floor, Warehouse 5#, Block 6#, Xiangtan Comprehensive Free Trade Zone, 46#, Free Trade Road, Peace Street, Xiangtan Economic Development Zone, 411215, Xiangtan, PEOPLE'S REPUBLIC OF CHINA

Tel: +86 28 61800230

Website: www.vacurebiotech.com

E-mail: info@vacurebiotech.com

Post-sales service provider: Hunan Kangxin Biotechnology Co., Ltd. or its authorized agents.

Address: Room 301, 3rd Floor, Warehouse 5#, Block 6#, Xiangtan Comprehensive Free Trade Zone, 46#, Free Trade Road, Peace Street, Xiangtan Economic Development Zone, 411215, Xiangtan, PEOPLE'S REPUBLIC OF CHINA

Tel: +86 28 61800230

E-mail: info@vacurebiotech.com

Our authorized representative in the European Community / Union

CMC Medical Devices & Drugs S.L.

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Tel: +34 951 214054 Fax: +34 952 330100

E-mail: info@cmcmedicaldevices.com

CE

Chapter XII Vigilance

If any serious incident has occurred in relation to this product, please contact the manufacturer and report to the local competent authority.