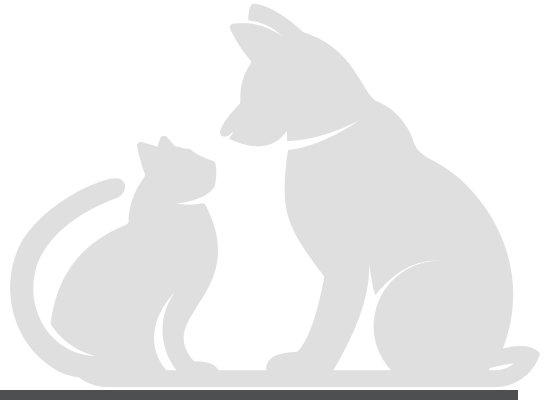
User Manual

Product Name: Vet Immunofluorescence Quantitative Analyzer
Model No: iRapid-1
Size: 213mm*243mm*195mm （W*D*H）



Jack up the packing box. The environment temperature is -10℃ to 40℃. Relative humidity should less than 93%. Harmful gas, flammable and explosive substances and corrosive gases are prohibited. If storage time exceeds 6 months, inform the professionals to maintain the Analyzer before use it.

VIII.2 Transportation

1. The Analyzer with package is suitable for highway, railway, aviation and waterway transportation.
2. Avoid severe vibration and shock during loading and transportation.
3. Keep away from damp.
4. Mix-package and mix-transportation with flammable and corrosive substances are prohibited.
5. More specific requirements can be according to the order contract.

IX Product Shelf life

1. Production date can be seen in the nameplate of Analyzer.
2. For Analyzer: the service life is 4 years except for man-made damage.
3. For accessories of Analyzer: the service life can be seen in warranty card. Note: except for man-made damage.
4. Obsolete Analyzer and accessories exceed the service life should be dealt with in accordance with the relevant provisions of local laws and regulations.

Notices: if continue to use the Analyzer which exceeds the service life, it should be tested and approved by the biomedical engineer in the hospital, and conduct performance detection periodically by the hospital engineer in the subsequent use of Analyzer.

VI Definitions

Symbols		Definitions	
IVD		Medical device for in vitro diagnostic	
	Biological Hazards. Please don't direct contact.		Attention, please refer to attached document.
		DC 12V	Direct current input of 12V
LIS	Serial interface 1	COM	Serial interface 2
LAN	Network interface	USB	USB interface
OFF/ON	Power switch	TF CARD	TF card

VIII Storage and Transportation Conditions

VIII.1 Storage

The device should be stored in original packing box in a well-ventilated and clean room.

Content

I Product Introduction

I.1 Composition and Structure

Vet Immunofluorescence Quantitative Analyzer (hereinafter referred to as “Analyzer”) mainly consists of optical unit, mechanical unit, control unit and output unit/display unit, the structure shown in Figure 1.

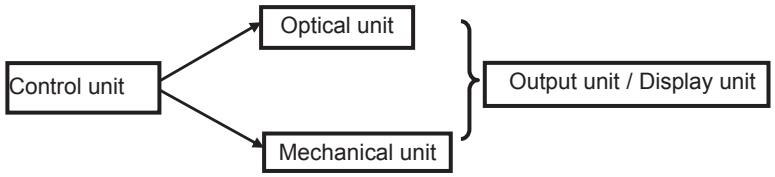


Figure 1

I.2 Range of Application

Suitable for matching specific test reagents based on fluorescence immunoassay method. It’s used for fluorescence immunoassay testing of animal specimen.
For *in vitro* diagnostic use only.
For professional use only.
Suitable for vet hospitals and clinics, central lab, outpatient room, emergency room, clinical department and other medical service points, medical centers and etc. It’s also suitable for research labs.

I.3 Technical Characteristics

I.3.1 Main parameters

Software version: Version 1
Operation system: Android
Exciting light: LED or Diode laser
Instrument connector: 1. USB interface*4
2. Ethernet interface*1
3. Serial port
3.1 Serial port 1: Automatic LIS uploading
3.2 Serial port 2: PC adjustment
Monitor: 24-bit true color LCD screen
Specimen type: Whole blood, serum, plasma and urine.
Power supply: Host input DC 12V 5A;
Adaptor input: 100-240VAC; 50/60Hz.
Standard curve
Storage method: ID card with 4K memory, 10 standard curves at maximum
Fitting ways: Four Standard ways including linear fitting, piecewise polynomial fitting, MMF four parameter growth model fitting, SPLINE cubic spline fitting)

VI.2 Troubleshooting

Problem	Reason analysis	Solution	Remark
The Analyzer cannot start up	Power switch is not turned on	Turn on the switch	
	The power adapter is not connected	Reconnect the power adapter	
The screen cannot start	Screen breakdown	Please contact the after-sales service department.	
	Problem with operating system	Please contact the after-sales service department.	
Software system failure	Running fault of operating system	Please contact the after-sales service department.	
	Test analysis software cannot start	Please contact the after-sales service department.	
	Other tips appear during software running	Please record the complete error code and message and then contact the maintenance department	
Abnormal sound during the testing	The cartridge holder may be stuck	Turn off the Analyzer and turn it on again. Let it reset itself and start working again	
	Mechanical motion failure	Please contact the maintenance department.	
Suddenly stop during testing	Power interruption	Restart the Analyzer and retest.	
	Communication failure	Restart the Analyzer and retest.	
	Poblem still exists	Please contact the after-sales service department.	
Abnormal test result	Abnormal test result	Please contact the after-sales service department.	
	Pollution problem	Reduce pollution.	
Other fault	When occurs other fault	Please contact the after-sales service department.	

V QC

Quality control can be proceed by testing the control material of matching test cartridge when in first use and every starting up. Conduct quality control in the same way as testing a normal specimen, use Vet Immunofluorescence Quantitative Analyzer to determine the concentration of test cartridge with control material directly.

Continue to use the Analyzer if the quality control result meets the requirements of target value range of control material. If not, prohibit using the Analyzer! And timely contact with the after-sales service engineers to return calibration or maintain.

VI Maintenance and Care

VI.1 Daily Maintenance and Care

VI.1.1 Maintenance

The administrative staff must check the Analyzer and accessories regularly.
Confirm whether the power outlet relates to the ground. If not, please replace the power outlet.
To check whether the power cord is deformed or broken by visual inspection. If something wrong with power cord, please replace a new one immediately, in case of fire due to electric leakage.

VI.1.2 Protection

Before cleaning the Analyzer, turn off the power switch and disconnect the power cord.
When cleaning Analyzer host, wipe the dirt with a soft wet cloth and wipe the dust with a soft dry cloth.

⚠ **Notices:**

Please do not use gasoline, diluent or other organic solvents to wipe the Analyzer fuselage, otherwise it will cause the paint shell peeling, damage or deformation.

VI.1.3 Calibration

After 1 year of normal use, it's required to calibrate the Analyzer with standard substance. Calibrate in the same way as testing a normal specimen, use Vet Immunofluorescence Quantitative Analyzer to determine the concentration of test cartridge with standard substance directly. Continue to use the Analyzer if the calibration result meets the requirements of target value range of standard substance.

If calibration result occurs deviation, prohibit using the Analyzer! And timely contact with the after-sales service engineers to deal with.

Operation: One step operation. The cartridge holder will protrude automatically after switched on. After insert the cartridge into the holder, the Analyzer will recognize the cartridge's type and finish test without any other operation. At the same time, test results would be transferred to LIS system, then print out, and the cartridge will be discarded from the Analyzer.

I.3.2 Main performace

Repeatability: CV≤10%
Stability: σ≤±8%
Linearity correlation: r≥0.97
Accuracy: Δn≤±15%

I.4 Security Classification of Medical Electrical Equipment

Type of protection against electric shock is Class I.
Pollution grade is Class 2.
Facility category (overvoltage category) is Class II.

I.5 Contraindications

No.

I.6 Warning, Precautions and Limitations

⚠ **Notices:** for professional use only.

I.6.1 Precautions in operation place

⚠ **Warnings:**

Please try not to use parallel socket so as to avoid overload and cause fire.
It must use 12V/5A power adapter and an effectively grounded outlet.
Damaged or non-original or modified power cord has a risk of causing fire and electric shock. Do not over-bend or rolling the power cord so as to avoid a fire or electric shock.
When the Analyzer is loose or the parts are dropped out and damaged, please contact the manufacturer in time.
Do not use this Analyzer in unstable environment such as tilt, vibration, impact, etc.
Do not place the device in a location where it is difficult to disconnect the device
No water or debris should get into Analyzer. If yes, please contact the manufacturer.

⚠ **Notices:**

Turn off the power and unplug the power plug before moving the Analyzer.
When moving the Analyzer, try to avoid vibration.
Place the Analyzer on the desktop that can load-bearing more than 2.5kg.
The Analyzer should be placed steadily. At least 5cm space should be saved to

ensure air circulation, good for heat dissipation.
Do not place objects on the Analyzer. This may block the vent and damage the Analyzer.
Place the Analyzer in the following conditions:
Dry, clean, flat, stable, horizontal surface;
Away from direct sunlight;
Away from high humidity area;
Away from strong magnetic field;
Away from electromagnetic waves and surge voltage;
Away from Storage site of chemicals;
Away from Corrosive gas places.
The Analyzer shall not be near radio, television, printer, fax machines and other sources of interference.
It cannot be used with other instruments such as microwave and other high-frequency equipment, in order to avoid electromagnetic interference that causing misoperation.

I.6.2 Precautions when in using

⚠ Warnings:

Read the instruction carefully before using the Analyzer. The operator must receive professional training, and be familiar with the instruction and operation method. The Analyzer must be operated by dedicated person.
Set the test parameters under the guidance of the professionals.
Gloves, goggles or other protective measures should be used when handling potential infectious materials.

⚠ Notices:

Make sure the Analyzer is in normal running status before use.
Make sure that all wires are properly connected and secure.
When using with other instruments together, be sure to read and clarify the operation precautions, otherwise there may be danger, please be careful.
Proper use of the Analyzer by professional operators, non-professional operators other than the staff shall not use the Analyzer.
After the test, make sure the cartridge is removed, cartridge holder reset, and then turn off the power.

I.6.3 Precautions for faults, storage and inspection

⚠ Warnings

When abnormal condition occurs, stop the Analyzer immediately. If there is smoke or scorched flavor, use the Analyzer continuously would cause fire. Operator should turn off the power immediately, unplug the power plug and contact the manufacturer or distributor.

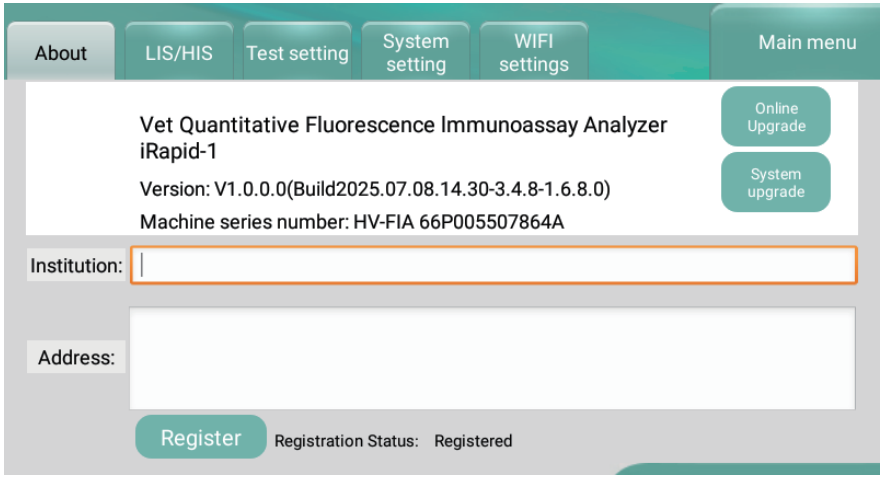


Figure 4.6.5

1. In the [Setting], you can check the organization information, test setting, LIS setting, system setting and operation viewing.
2. In [About Organization] of Figure 4.6.1, the user can check the organization name, organization address, report declaration and re-registration authority name.
3. In Figure 4.6.2, the initial value of specimen code, length and alignment can be set in [Test Setting].
4. If set the instant printing results, test report will be automatically printed after each test.
5. To set the number of days to keep the records, when the number is exceeded, it will be automatically deleted.
6. Set whether to automatically test. If selected, the system will automatically test once system detects any test cartridge inserted.
7. In Figure 4.6.3, to set the LIS uploading parameters, it needs firstly select the uploading way and then set the corresponding parameters.
8. To set the system time in Figure 4.6.4, it will go into effect after saving.
9. To calibrate the screen, after clicking the confirmation button, click the arrows that appeared and then restart to make the calibration go into effect.
10. The user can save the upgrade software package into the U disk, and then insert the USB port of the Analyzer, the system will update after detecting upgrading program. can detect the upgrade after the software upgrade.

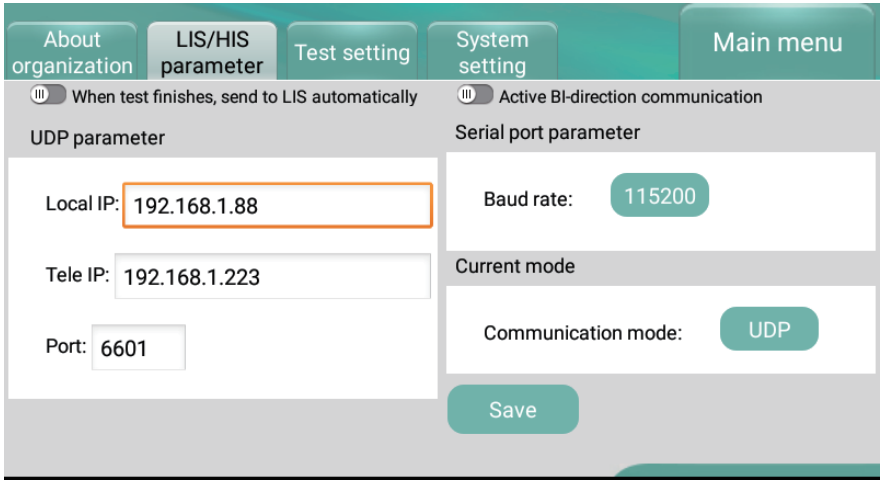


Figure 4.6.3

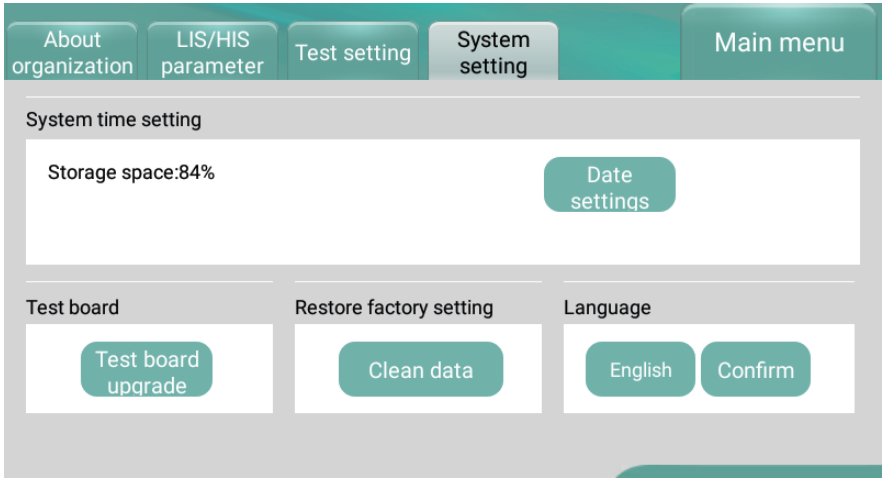


Figure 4.6.4

Except the maintenance personnel from manufacturer and the ones authorized by manufacturer, others are not allowed to remove, modify or repair the Analyzer. Any violation will lead to failure of normal warranty and maintenance. As the manufacturer, we will not bear any responsibility for possible personal injury and fire risk of electric shock caused by violation.

⚠ **Notices:**

The Analyzer and parts need to be checked regularly. Please notify the manufacturer for repair or replacement if it is damaged, cracks and other abnormal conditions.
Use a clean soft cloth and non-corrosive cleanser to clean the Analyzer surface to prevent scratching the shell and faceplate of the Analyzer.

I.6.4 Precautions for Electromagnetic Compatibility

⚠ **Warnings:**

The Analyzer is designed and tested according to the Class A equipment standard of GB 4824. If used in home environment, it may cause radio interference and require taking protective measures.
Do not use this equipment near strong radiation sources such as unshielded RF sources. Otherwise it may interfere with proper operation of the Analyzer.

⚠ **Notices:**

The user should ensure that the Analyzer is in an electromagnetic compatibility environment so that it can work properly.
It is recommended to evaluate the electromagnetic environment before using the Analyzer.
This Analyzer complies with the noise immunity and emission requirements which specified in the part of GB/T 18268.26. Details are shown in the following table.

Table 1:

Electromagnetic Immunity			
Immunity test item	**Basic standard**	**Test value**	**Compliance criteria**
Electro-Static discharge (ESD)	GB/T 17626.2	Contact discharge：±2kV, ±4kV Air discharge：±2kV, ±4kV, ±8kV	B
Radiofrequency electromagnetic field	GB/T 17626.3	3V/m, 80MHz~2.0GHz, 80%AM	A
Pulse group	GB/T 17626.4	Power cable: ±1kV(5/50ns,5kHz)	B

Surge	GB/T 17626.5	Cable to ground: ±2kV Cable to cable: ±1kV	B
Radiofrequency conduction	GB/T 17626.6	Power cable: 3V/m, 150kHz~80MHz, 80%AM	A
Power frequency magnetic field	GB/T 17626.8	3A/m，50/60Hz	A
Voltage sag, interrupt	GB/T 17626.11	1 cycle 0%； 5 cycle 40%； 25 cycle 70%； 250 cycle 5%	B C C C
Performance judgment: A. Normal performance within the standard limiting value. B. Function or performance is temporarily reduced or lost but can be self-recovered. C. Function or performance is temporarily reduced or lost, but requires operator intervention or system reset.			

Table 2：

Electromagnetic Emission		
Emission test		**Compliance**
GB 4824	RF Emission	Group One
GB 4824	RF Emission	Class A
GB 17625.1	Harmonic Emission	N/A
GB 17625.2	Voltage fluctuation / flashing emission	N/A

I.6.5 Limitation requirements for toxic and hazardous substances

This Analyzer meets the limitation requirements of toxic and hazardous substances in SJ/T11363-2006 Regulation.

Table 3 Classification of electronic information products

Classification	Definition
EIP-A	homogeneous materials constitute electronic information products
EIP-B	Metal coating of all parts of electronic information products
EIP-C	Small parts or materials in electronic information products

IV.6 Settings

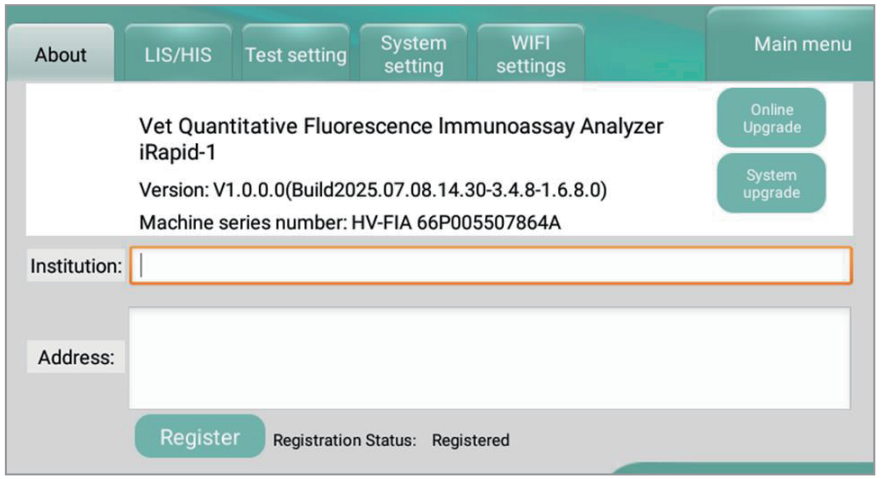


Figure 4.6.1

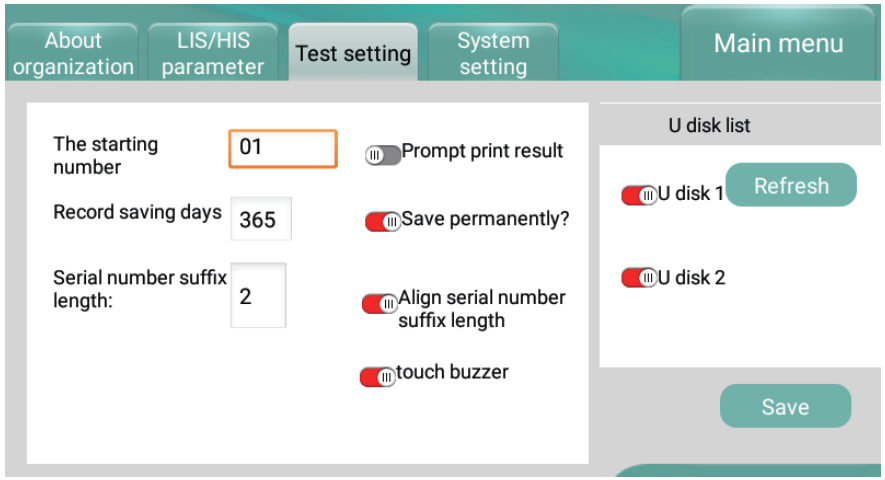


Figure 4.6.2

click [OK].

4. Click [Search] in Figure 4.4.1 to select the items to be viewed, and click [OK] to search the corresponding project records.
5. Click [Upload] in Figure 4.4.1 to upload the selected records or all records.
6. Click [Print] in Figure 4.4.1 to print the selected records or all resords.
7. Click [Export] in Figure 4.4.1 to export the selected records or all records.
8. Click [Advanced] in Figure 4.4.1 and select a single history to view the details.
9. Click [Classification Statistics] in Figure 4.4.2. After selecting the date range you need, click [OK] to view the statistics results.

IV.5 Item Interface

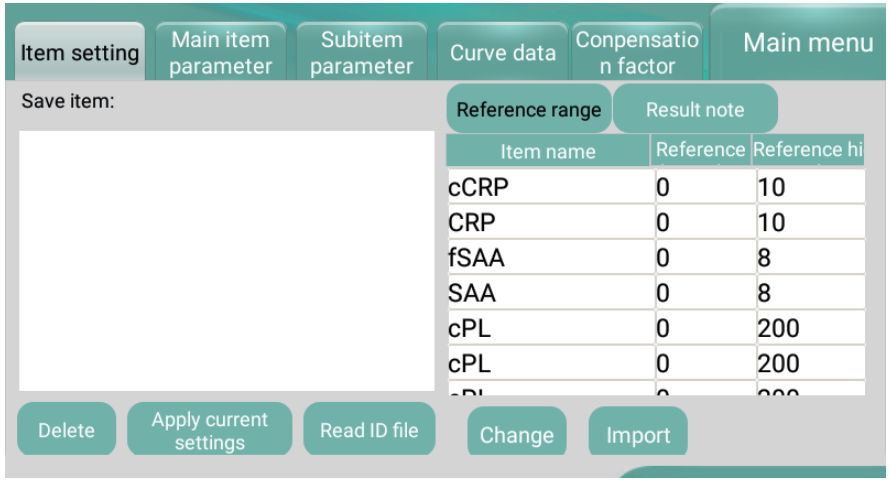


Figure 4.5.1

1. As shown in Figure 4.5.1, you can view the project list and set the item reference value in the [Item Setting].
2. It can check the item list stored in the system, and the items can be changed;
3. The user can modify and delete the item reference value, and the value can be used for printing test result to be reference for the patient.

	which cannot be further split in the existing conditions, generally refers to products with the specifications less than or equal to 4mm^3

Table 4 Limitation requirements for toxic and hazardous substances

(Unit: Mass fraction)

Classification	Limitation Requirements
EIP-A	In this type of unit, the content of lead, mercury, hexavalent chromium, polybrominated biphenyls, PBDE (except decabromodiphenyl ether) should not exceed 0.1%, cadmium content should not exceed 0.01%.
EIP-B	In this type of unit, lead, mercury, cadmium, hexavalent chromium and other harmful substances shall not be intentionally added.
EIP-C	In this type of unit, the content of lead, mercury, hexavalent chromium, polybrominated biphenyls, PBDE (except decabromodiphenyl ether) should not exceed 0.1%, cadmium content should not exceed 0.01%.

II Contents

No.	Accessories	Quantity	Remark
1	Power Adaptor	1	Standard equipped
2	Instruction for use	1	Standard equipped
3	RJ45 cable	1	Standard equipped

III Installation

III.1 Installation

Visually examine the package prior to unpacking. If there are any signs of mishandling or damage, contact the carrier to claim for damage.

III.1.1 Unpacking and checking

1. Gently remove the Analyzer and accessories from the package box. Save the packaging materials for future transport or preservation of the Analyzer. Sort the accessories by packing list.
2. Check the Analyzer and accessories to see if they are in good condition.
3. Connect the adapter and tester after check and confirmation.

⚠ **Notice:** If there are any problems, please contact the sales office or agent immediately.

III.1.2 Installation and debugging procedures

1) The Analyzer should be placed in a clean and ventilated room with temperature within 10 ℃ - 30 ℃, relative humidity of less than 70%, away from direct sunlight.
2) Make sure the vents are not blocked that there is at least 5cm of clearance around the Analyzer
3) Connect the power adapter to the power interface of the Analyzer and turn on the power.
4) The Analyzer has been debugged before shipping, and can be used directly
5) To ensure the Analyzer work properly, do not place any items on the Analyzer at all time.

III.2 Instruction for use

Please use this Analyzer in an environment where temperature is between 10°C to 30°C, and relative humidity is less than 70%. Please note that the operating temperature of test reagents is based on its instructions. Perform test in strict accordance with the operating instruction. If the Analyzer is not used in accordance with the written method, the protection provided by the Analyzer may be damaged.

III.3 Operation Procedures

III.3.1 Preparation

1) Make sure the Analyzer is placed in steady, non-direct sunlight and away from strong electromagnetic interference.
2) Connect the cable of power adapter. Insert one end of power adapter into the power socket of Analyzer. There is corresponding logo of power supply on the fuselage, details can refer to the description in Section VII of this operation manual. Insert the other end into standard grounded power outlet. If need to connect HIS/LIS, connect the network interface of the Analyzer and the RJ45 wall with RJ45 cable.
3) Switch on the Analyzer, it will run self-test, and the cartridge holder reset once as

IV.4 History Search

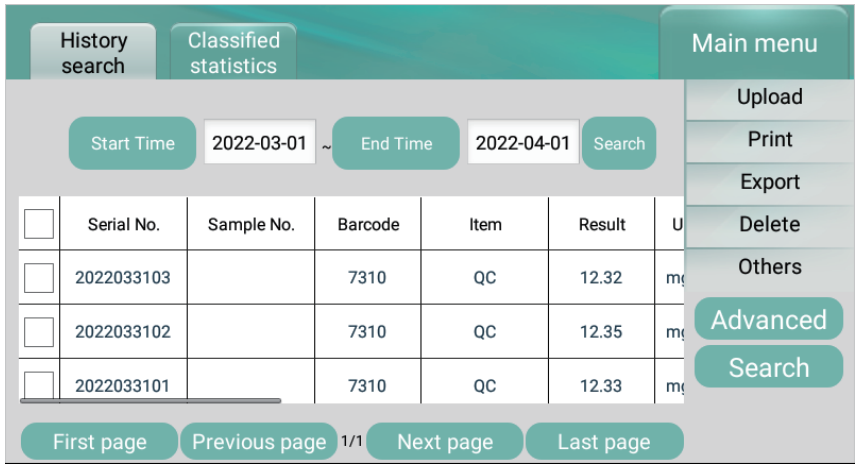


Figure 4.4.1

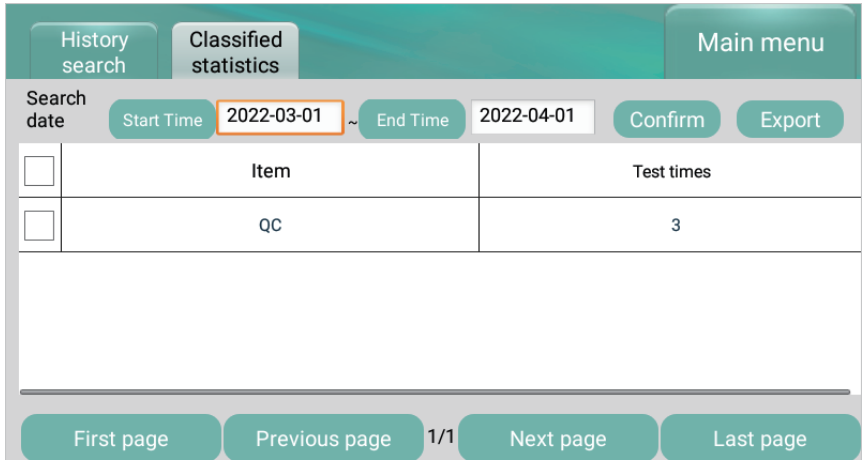


Figure 4.4.2

1. In the [History Search] interface, users can check historical tests and classified statistical operation.
2. After each test result, the system will automatically save the data to the local area, and the user can select the [History Search] to check it.
3. Click [Date] in Figure 4.4.1 to select the date range, you can view the record after

IV.3 Batch Test

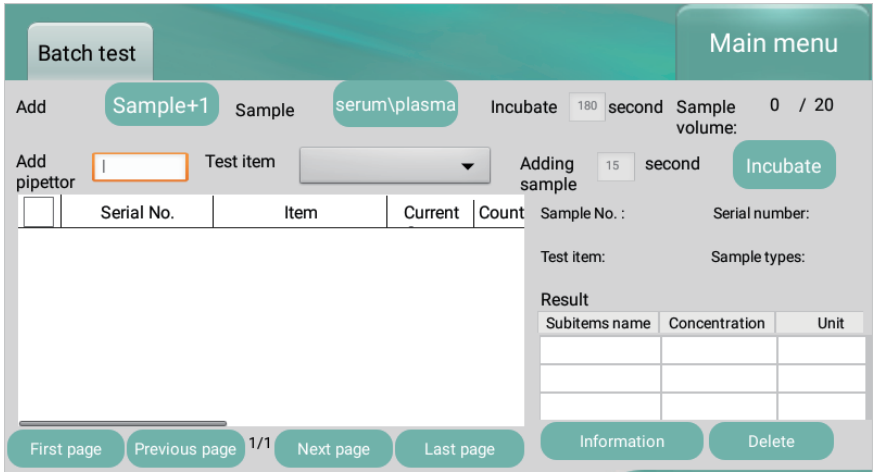
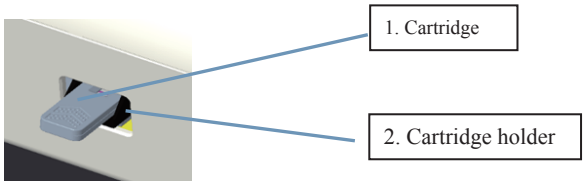


Figure 4.3.1

1. The interface for batch test is shown in Figure 4.3.1, and the user can select the specimen type, test item, and add or delete the test item;
2. First select the test item to determine the time, that is displayed in the interface [Time];
3. Select [Sample +1] to perform a new test. If want to delete the certain test result, check the corresponding test and click the [Delete] button.
4. After the specimen is added automatically with assigned specimen code. If want to customize the information， select the test and click on the [Information] to modify the code.
5. Click [Incubate], the Analyzer starts to count down, simultaneously the next specimen will be counted down the time interval, respectively.

shown below.



4) The software will enter the main interface automatically;
5) To use and store the reagents, please refer to reagent's instruction;
6) Steadily place the test cartridge with specimen to the cartridge holder, and following the software's guidance to run the test.
7) Choose proper parameter settings according to specific test item. The operator should be trained and guided by professional technicians.

III.3.2 Start test

Control the Analyzer through software and run the test.

⚠ **Notice:**

Stay away from cartridge holder when it's moving .
Do not interfere with software during testing.

III.3.3 Finish test

1) The test cartridge should be take out from the Analyzer after test.
2) Cartidge holder will reset.
3) Switch off the Analyzer and end the test.
4) The waste coming from the use of the Analyzer shall be handled by the professionals in accordance with the Regulations of the State Council on the Administration of Medical Waste and other relevant provisions.

⚠ **Warnings:**

By checking the above steps, if any signs proving there is instrumental function damage or error reminder, please stop testing immediately and contact the manufacturer for after sale service.

III.4 Warning signs

The sign of ⚠ means notifications and warnings.

IV Software Introduction

IV.1 Main Interface

Figure 4.1

As shown in Figure 4.1, there is a home key at the bottom of all interfaces. Click the home key, interface as Figure 4.1 will show. From left to right, user will find [Test], [Batch test], [History], [Item], [QC] and [Setting]. Click the key to enter into corresponding operation interface.

IV.2 Test Interface

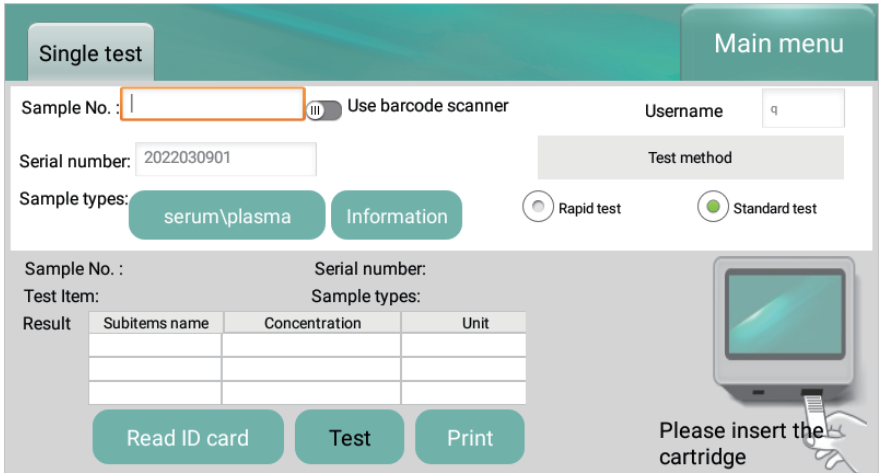


Figure 4.2.1

1. Click [Test] key on main interface and Figure 4.2.1 will show.
2. Insert ID chip to read the information about the corresponding parameter before every new lot of test cartridges.
3. After the ID chip is recognized, choose specimen type and manually input specimen number if needed.
4. Click [Information] to input more detailed information of patient.
5. Choose [Standard Test] or [Rapid Test] after inputting information. Standard Test means the Analyzer counts down according to reaction time of certain parameter and then scan the test cartridge and give results. Rapid Test means the Analyzer scans the test cartridge immediately and gives results.
6. The user code is used to calculate the total amount of tests performed and test parameters details.
7. When finishing information input, user could click [Test] key to run a test. Result will be shown in corresponding value box in Figure 4.2.1
8. After each test, user could click [Print] to print the result.