Automatic Immunoassay System

Operation Manual



Model: HP-AFS/1

Hipro Biotechnology Co., Ltd

(Please read this manual carefully before operating the product)

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1 Summary

Automatic Immunoassay System is made up of light absorption test module, scattered light test module, fluorescence test module, press components, data transmission interface and printer. And the absorption test module is made up of absorption light path unit, and light-absorption sensor part. The scattered light test module is made up of scattered light path unit and scattered light sensor part. It can utilize nephelometry, fluorescence and absorbency methodologies to test the protein quantitatively in the samples. The model of the instrument (HP-AFS/1) is defined by the number of the test channel.

1.1 Principle

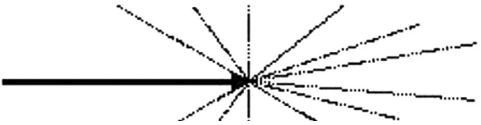
1.1. 1 Nephelometric test principle

The incident light with a certain wavelength illuminates the solution along the horizontal axis, the sample in the solution makes the incident light deflect and cause the light to be scattered. The angle of the scattered light is relevant to the wavelength of the incident light and the particle size of the sample. The intensity of scattered light is proportional to the content of the sample. The scattered light is collected by the sensor through the light path, and the sensor transfers the light signal into electric signal which can be turned into the corresponding concentration value of the sample through the calibration information.

Here are several scattering phenomenon:

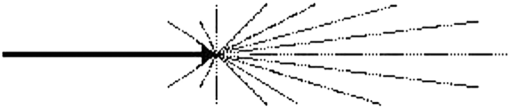
—Rayleigh theory of Scattering

When the particle diameter is less than the wavelength of the incident light, the light scatters in all directions evenly



—Rayleigh-Debye/Mie theory of Scattering

When the particle diameter is more than the wavelength of the incident light, the light basically scatters forward.



The product utilizes laser of 670 nm wavelength, less than the average diameter of antigen and antibody complex, so it can get the forward scattering of Rayleigh-Debye/Mie theory.

1.1.2 Fluorescence test principle

Fluorescence is a luminescence phenomenon. When the fluorescent substance is illuminated by the an incident light with certain wavelength, it absorbs the luminous energy and enters into a excited state, then it emits light whose wavelength is longer than the incident light. This emitting light is called fluorescence. The incident light is filtered by optical filter, and then the emitting light is collected by the sensor through the light path. The sensor transfers the fluorescence signal into electric signal which can be turned into the corresponding concentration value of the sample through the calibration information.

1.1.3 Absorbency test principle

The ratio of the intensity of transmission light and incident

light is transmissivity. The common logarithm of the transmissivity reciprocal is called absorbency. When the light with certain wavelength passes through the reaction solution, part of the light is absorbed by the substance in the solution. The absorbency is proportional to the concentration of the sample in the solution. The transmission light is collected by the sensor through the light path, and the sensor transfers the light signal into electric signal which can be turned into the corresponding concentration value of the sample through the calibration information.

1.2 Technical parameters

Nephelometry	Linearrange	100 ～ 4000 NTU Linear correlation coefficient ⩾ 0.99
	RSD	RSD ⩽ 8%
	Stability	The turbidity variation ⩽ 10%
	Accuracy	Relative deviation ⩽ 10%
Fluorescence	Linear range	100 ～ 1600AU, Linear correlation coefficient r ⩾ 0.99
	RSD	RSD ⩽ 8%
	Stability	Fluorescence variation ⩽ 15%
	Accuracy	Relative deviation ⩽ 10%
	Sensitivity	Detection limit is not more than 2.5μmol/L
Absorbency	Linear range	See attached table 1
	RSD	RSD ⩽ 1%
	Stability	The absorbency deviation is not more than 0.005 at 340nm position within 20 min

	Inter - channel RSD	RSD ≤ 5%
	Test Temperature accuracy	37℃ ±0.5℃
	Wavelength accuracy	The wavelength deviation of 340nm、550nm、650nm is ±3 nm, and half width is no more than 12nm
	Supply voltage	100V-240V, 50/60HZ, 100VA
	Input AC power	< 100VA
	Size	410mm×280mm×355 mm
	Weight	5kg
	Security classification	Class I for no application part

Attached table 1 Linear range of absorbency

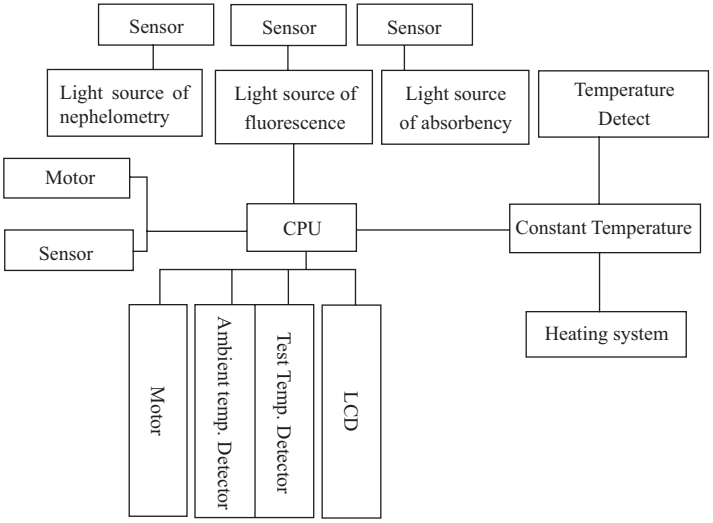
Linear range (A)	Deviation(%)
0.2 ~ <0.5	±5
>0.5 ~ ≤ 1.0	±4
>1.0~ ≤ 1.8	±2

1.3 Accessories list

Items	Quantity
Triphase power line	1
Certificate of quality	1
Warranty card	1
Operation manual	1
Instrument list	1

1.4 Instrument diagram

1.4.1 Instrument diagram



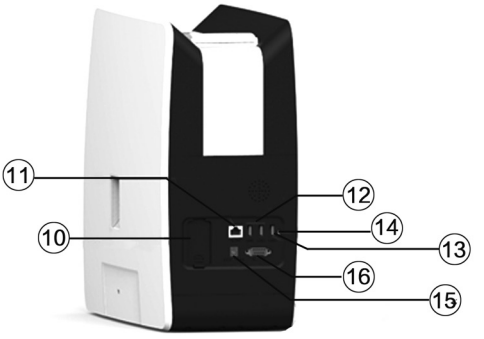
1.4.2 Instrument Port



1, LCD Screen
2, Power Switch
3, Barcode Scanner
4, Discharge port
5, Waste liquor sensor



6, Printer
7, Test channel
8, ID card scanner
9, USB port



10, Battery charge port
11, Internet access
12, USB port
13, Program writing port
14, Program writing switch
15, Power supply
16, RS232 Port

1.5 Scope of application

The instrument is applied to quantitative test of protein in human fluid sample. It can assist the doctors to make diagnosis for specific disease and to take corresponding measures of prevention, medical care, or treatment.

1.6 Prevention and precautions

Clinical samples handling is categorized as biological test, which should be paid enough attention. When dealing with various sample tube and reagent bottle, gloves should be worn. In case of the liquid leak, equipment surface and internal should be cleared

with dilute sodium hypochlorite solution.

> **Warning**
>
> **Automatic Immunoassay System does not control any user–defined reagent or sample, we do not provide any guarantee for reagent performance, system maintenance and any safety effect caused by the user–defined reagent or sample. The customer is responsible for the reagent selection, test method selection, test result, and relative error.**

1.7 Waste disposal

Waste disposal should be carried out according to the rules concerning chemical waste and contagious waste in WS/T249-2005 “Clinical Lab Waste Disposal instructions” or refer to the local laws and regulations..

1.8 Contraindication

N/A

2 Preparation and installation

2.1 Transport, storage and unpack

Transport, store and unpack the instrument with correct methods and avoid harsh environment.

- Transport

The instrument should be handled with care. The package should always be carried according to the upright sign.

- Storage

The instrument should remain in its package, and be placed according to the sign of the upward.

When the instrument is stored in the warehouse, be sure to leave enough space for move and inspection.

If the outside package has been damaged during transport and storage, the instrument must be rechecked. In case of abnormal performance or obvious damage, contact the manufacturer for repair or replacement.

Complete package can reduce risk of damage and ensure good performance. Store the instrument in a dry and dust-proof place.

- Unpack

Open the cases and take out the instrument carefully

2.2 Preparation

Be sure to leave some spare room when installing the instrument. Especially in the back of the instrument should be set aside 10 cm space for connection and heat dissipation. Place a waste container under the discharge port on the right of instrument.

2.3 Installation

2.3.1 Power connection

AC power supply (220V, 50Hz) is required in the lab with ground wire.

Installation warning: If emergency occurs, pull out the plug immediately.

2.3.2 Environmental Requirements

Working environment:	Indoor
Temperature:	10 – 30℃ (startup) 0 – 50℃ (shutdown)

Humidity:	Maximum 70%
Atmosphere pressure:	700hPa ~ 1060hPa

3 Operation

3.1 Startup

a) Plug the 24V power supply into the power connector.

b) Press the “Power switch” for 1 second to startup.

c) Software running then selftest starts.



d) Selftest finished, if did not connect to LIS system, the system showing as the following figure, press OK to enter the main interface. If the self checking succeed, the animation of “please put in the sampler” will be displayed.

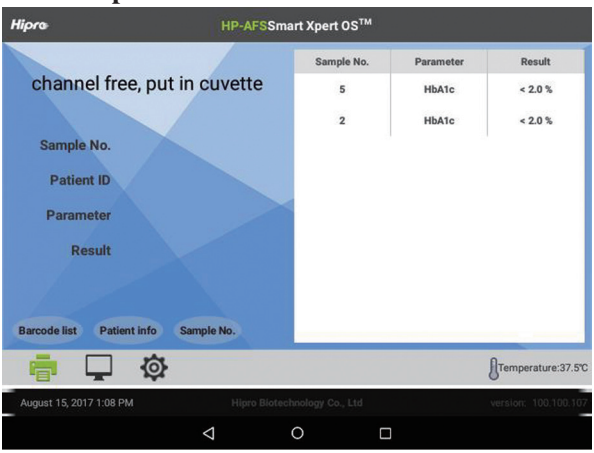


3.2 Software

The software consists of sample test, control test, result

query, system setting.

3.2.1 Sample test



 Printer  LIS Connecting  System menu

3.2.1.1 Sample test interface

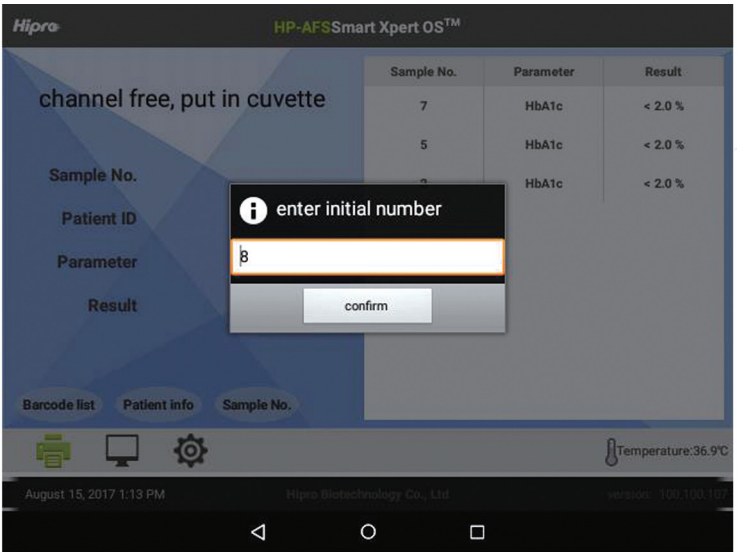
The interface divided into 3 parts: Test status, Test results and Menu.

Test status: the device status, the testing sample No., patient ID, testing item, test result, setup the sample No. and the patient information, view the barcode list.

Test results: showing the test results of that day.

Menu: the connecting status of LIS and printer; setup the upload and print automatically; menu to switch the operation interface and power off; the device temperature.

3.2.1.2 Setup the number of original sample

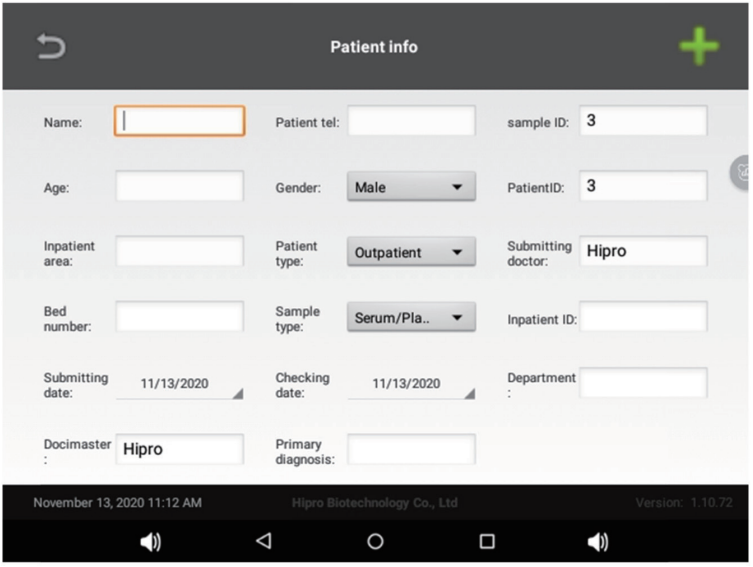


The number of samples will start from No.1 everyday by default, it will plus 1 after finished 1 test. Setup the number as below:

a) Press the “Sample No”

b) Enter the initial number, then press OK to finish.

3.2.1.3 Input the patient information

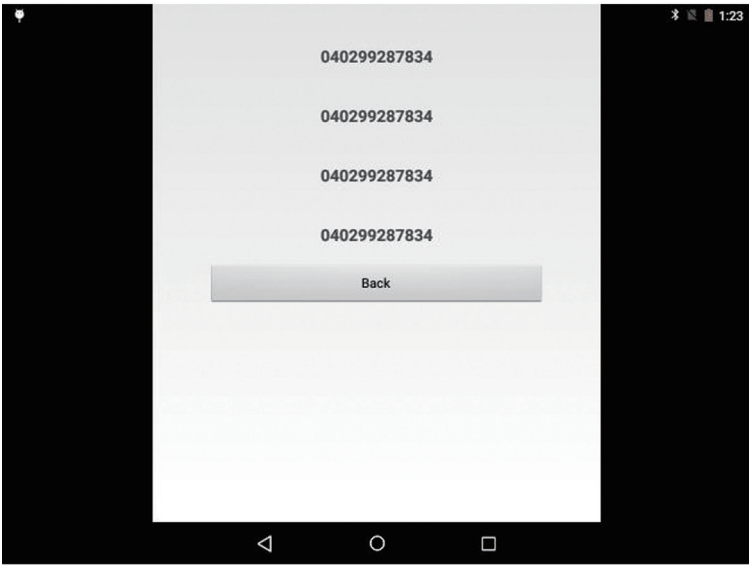


a) Press the “Patient info”

b) Input the patient information, press “ + ” to save, press “ ⮌ ” to return.

3.2.1.4 Scan barcode/ ID card

a) Press the “Barcode list”



b) Scan the barcode by Barcode Scanner, or the ID card scanned by the ID card scanner. Press “Return” to return the test interface; To delete the patient no by touch & hold then press “Delete”.

3.2.1.5 Printer, LIS system Setup

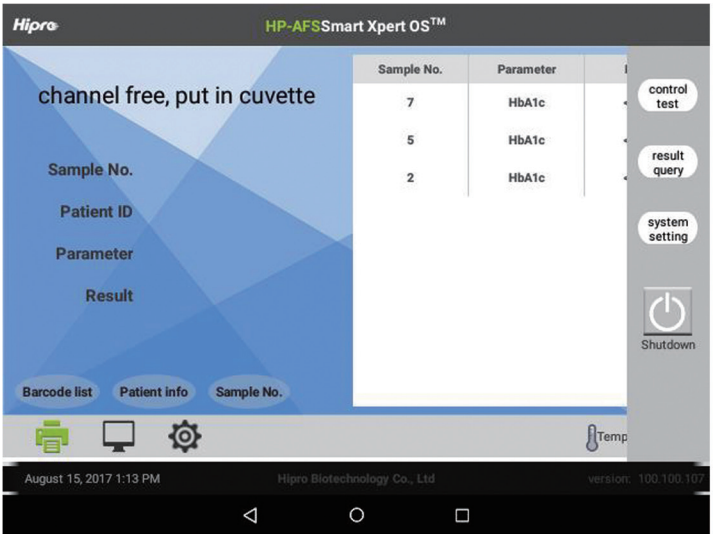
Printer and LIS system status: black indicates not available; white indicates print or upload the test results by manual; green indicates print or upload the test results automatically.

Press “ ” to switch LIS status.

Press “ ” to switch printer status.

3.2.1.6 Menu

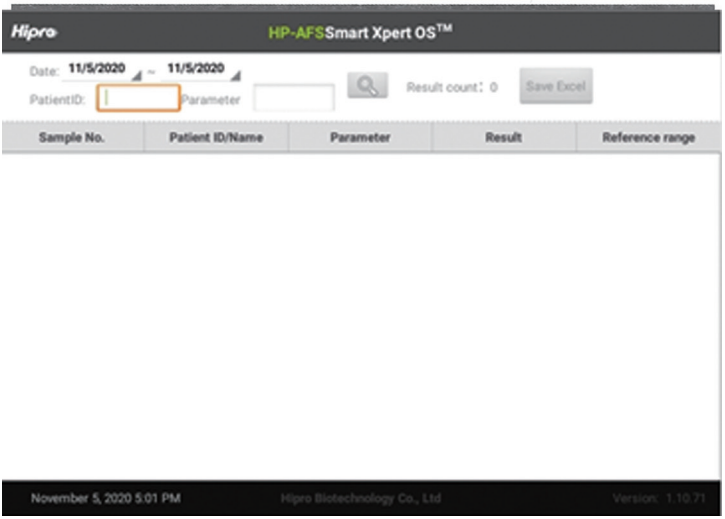
Press “ ” to enter the system setting interface.



Press “Control test”, “Result query” “System setting” to enter appropriate interface.

Press “Power off” to shutdown the device.

3.2.2 Result query

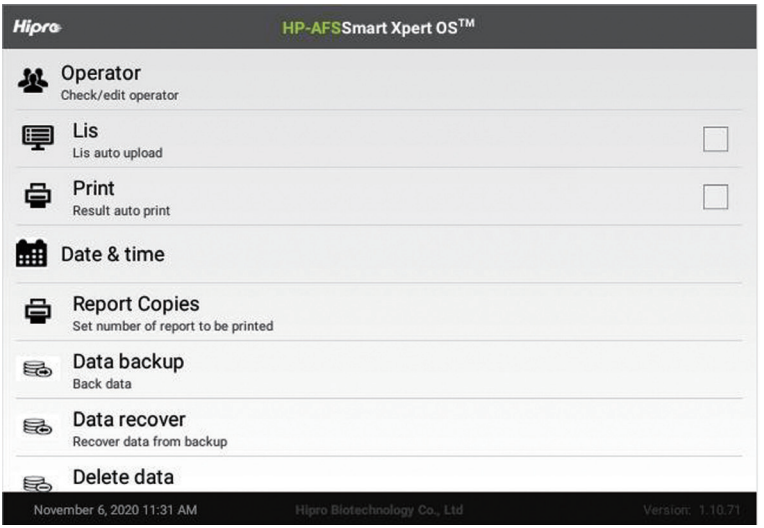


To check the test results as following steps:

a) Input the query condition as date, patient ID and project, then press “  ” to search, the search results will showing below.

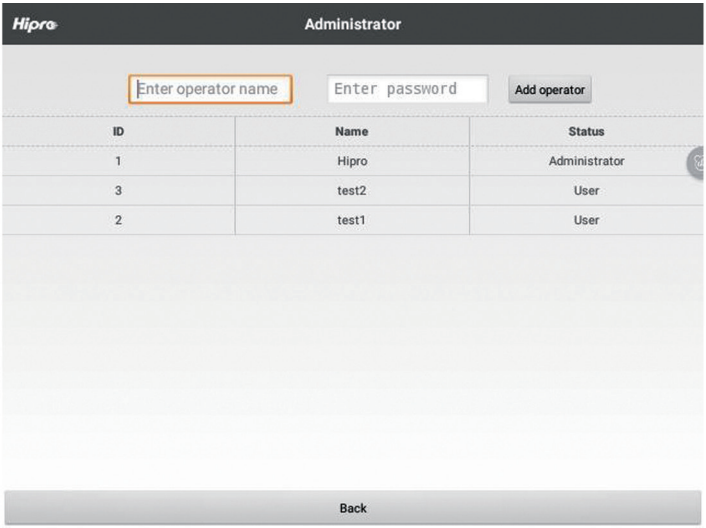
b) Touch & hold to print , upload , edit or delete.

3.2.3 System setting



3.2.3.1 Operator

a) Press “Operator”



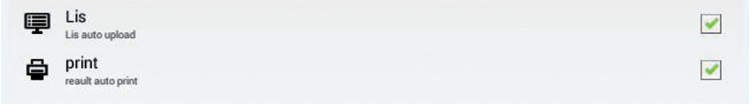
b) The administrator can enter the operator name and password then press “Add operator” to add more user.

c) The administrator can touch & hold the other users to delete.

d) Touch & hold the current user to modify the password.

3.2.3.2 Printer and LIS system setting

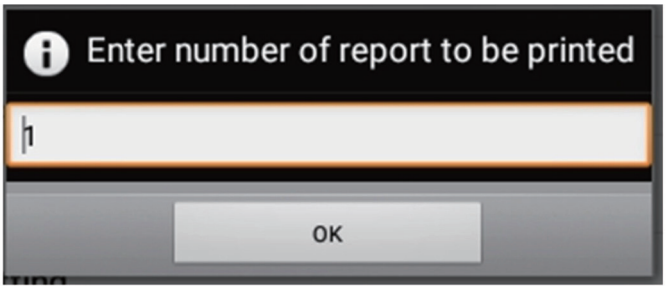
If LIS and print are ticked, the test results will print and upload automatically, if not, the results only print and upload by manual.



3.2.3.3 Report form setup

a) Press “Report Copies”.

b) Enter number of report to be reported, press “OK” to finish.



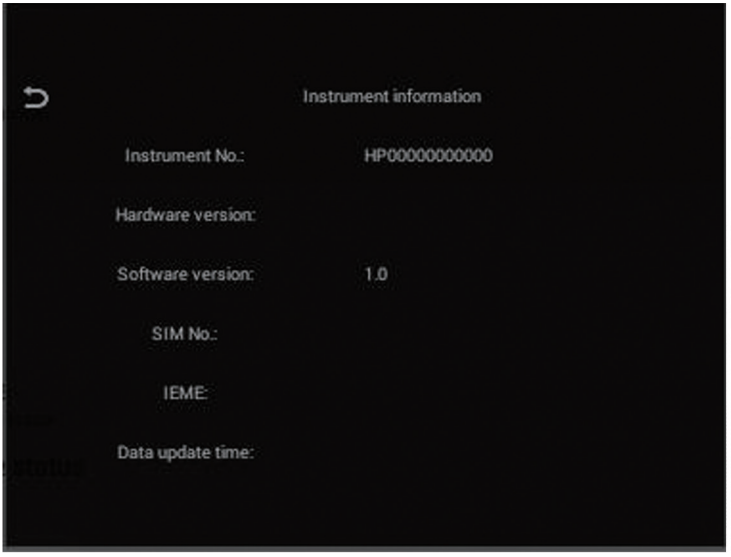
3.2.3.4 Software Upgrading

a) Press “Software Upgrading”.

b) Follow the prompt to upgrade software.

3.2.3.5 Check the device detail

Press “ About” to check the instrument information.



3.2.4 Page switching

Slide your finger you can switch different page without repeated entry and exit menu repeatedly.

3.3 Sample test

a) Check the waste container. Place the waste container beside the discharge port, the cuvette will be discharge automatically. If there are not any cover in 10cm from the Discharge port, the cuvette should be discharged by manual.

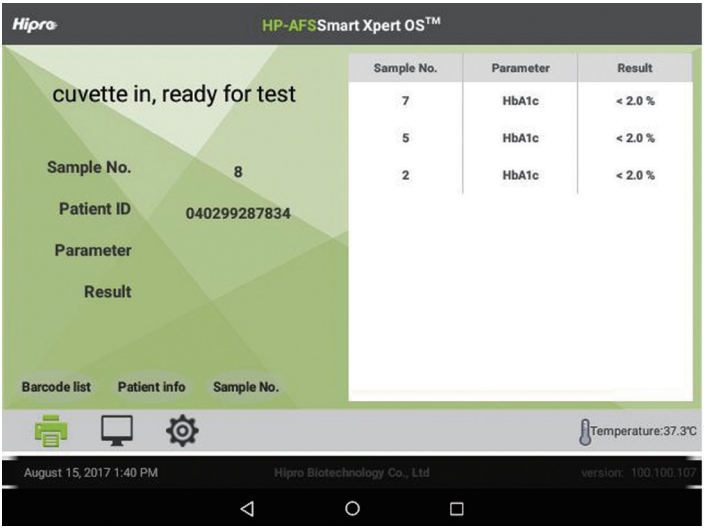
b) If needed input the patient information first, please input.

c) If needed scan the barcode or ID card first, please scan .

d) Insert the cuvette to start the test.

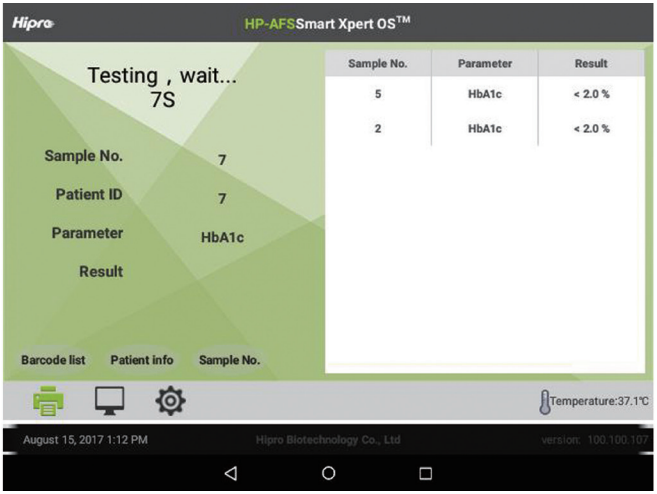
★ Attention: The barcode on the cuvette should face the printer.

e) Test preparation: The status is “cuvette in, ready for test”. The Sample No is the current sample No.; The patient ID showing the patient information if the barcode of ID card was scanned, if not, it is showing the sample No.

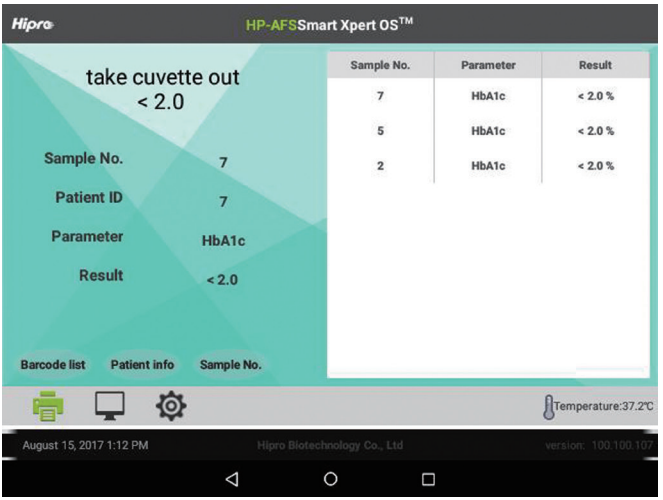


f) Testing: The status is “ Testing, wait”. If in the countdown, the waiting time is showing below. The project is showing the

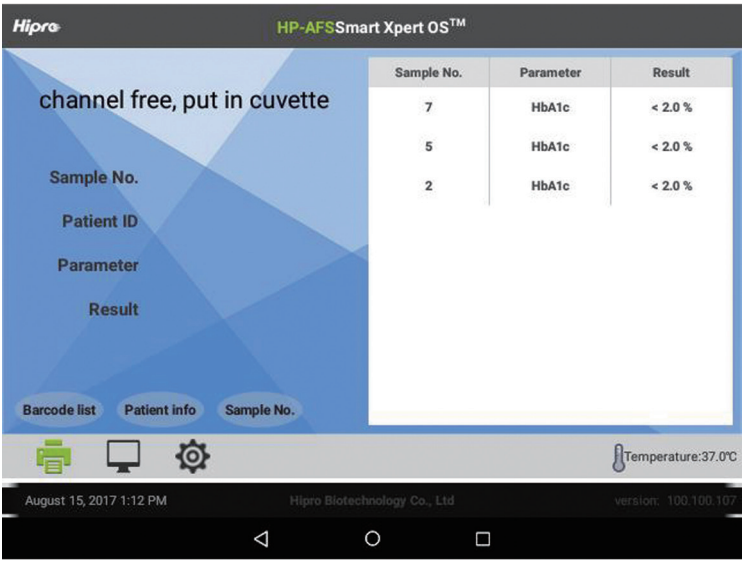
corresponding test project.



g) Test completed: If did not placed any waste container, the device will remind you take out the cuvette and the test result. If did, the interface will be only showing the test result. The test results are showing on the "Test results" field.



h) Waiting for next test after the cuvette take out by manual or discharged automatically.

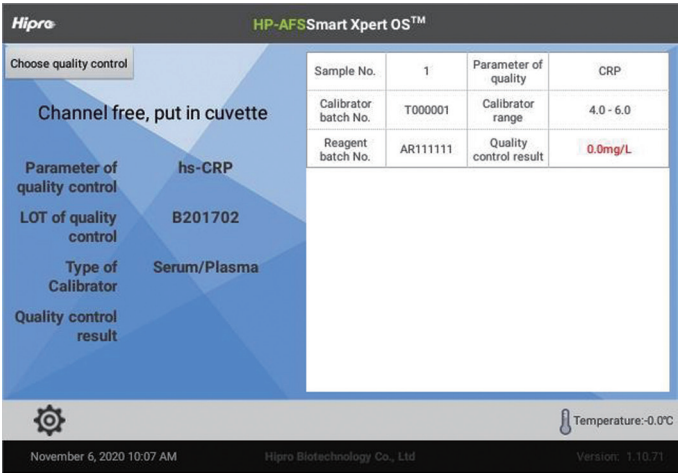


3.4 Calibration

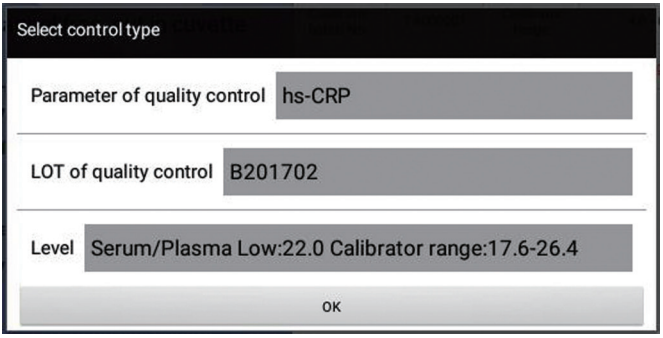
3.4.1 Control test

Press "⚙" to enter the system setting, then press "Control test"

3.4.2 Testing procedure



a) Select the quality control, click the quality control item, quality control batch, and quality control point in turn, and click OK after the selection is completed. After the selection is completed, the page displays the selected quality control points.

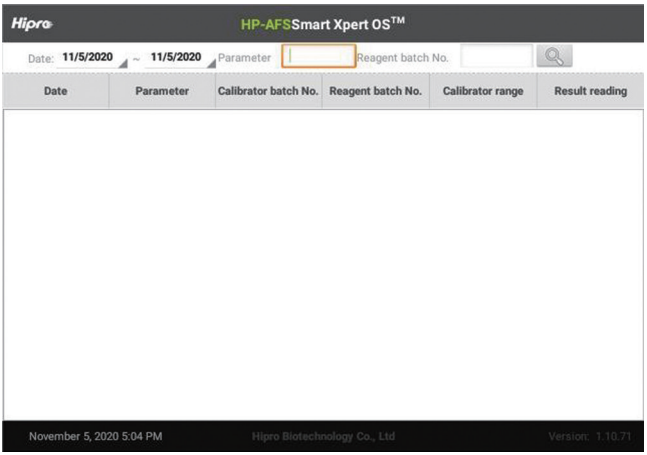


b) Put the test with selected control into the instrument for testing, and pay attention to the barcode facing the printing

direction when placing the test cup.

c) After the control test is completed, the result of this control test will be displayed on the right.

3.4.3 Quality control result query



a) Swipe left from the quality control test page to enter the quality control result query.

b) Enter the search condition, you can search by date, test item, reagent lot number; after entering the conditions, click the “  ” button, and the result will be displayed in the result display area below.

3.5 Power off

a) Switch to “Sample test” interface.

b) Press “  ” to enter the system setting.

c) Press “ 

”

d) Touch & hold the “Power switch” 1 second to shutoff.

4 Maintenance and troubleshooting

4.1 Warranty

This product (including the instrument and components) has a warranty period of 12 months from the date of purchase. The warranty does not cover the following cases, in which the customer should pay the required maintenance costs.

A Instrument damage caused by incorrect operation.

B Instrument damage caused by dismantles by anyone other than Hipro.

C Instrument damage caused by improper storage or maintenance, such as high temperature, high humidity, corrosion etc.

After-sales service

A, After equipment acceptance, Hipro engineer will offer regular maintenance.

B, Maintenance request under warranty will be answered within 24 hours. If the instrument cannot operate normally due to non-human factors, all maintenance costs will be covered by Hipro. In case the instrument needs to be shipped back to the manufacturer's plant, Hipro will also cover the transportation costs.

C, Maintenance service beyond the warranty period, we give a reply within 24 hours after receipt of the notice of the Buyer, responsible for device debugging or replacement of damaged parts. For the service costs beyond the warranty period will be signed by another agreement.

D, Hirpo provides life-long maintenance to instrument.

4.2 Planned maintenance

A, Change the waste container after 30 tests.

B, Instrument cleaning: Shut off the instrument before cleaning. Soak a soft cloth with diluted soapy water and wring it dry. Then wipe the instrument housing. At last wipe it again with a dry cloth.

C, Always check the cable connection; abnormal case should be handled in time

D, If the instrument is not in use for a long time; cover it with the dust cover to prevent dust or foreign objects into the test channel. Conduct a self-checking every 15 days during this period to ensure that the system is in good working condition.

E Light source: service life:5000 hours

4.3 Trouble shooting

When the instrument is started up, it will go through a self-checking program. If any abnormal condition is detected, an error message will be displayed. And the system will stop running.

The possible errors are listed below:

ERR 2412	Check if the sampler gets stuck, and restart the instrument. If the problem cannot be solved, contact technical support.
ERR 8200	Check if the two dimension code is destroyed or in opposite direction. If the problem cannot be solved, contact technical support.

ERR 1 800	Check if the sampler gets stuck, and restart the instrument. If the problem cannot be solved, contact technical support.
ERR 2000	The assay cup not in the right position, take out the assay cup and re-insert. If the problem cannot be solved, contact technical support.
Power supply error	Check the power port and the power switch. If the problem cannot be solved, contact technical support. Do not change the adaptor by yourself.

5 Explanation of symbols

IVD In vitro diagnostic device

Warning: Refer to the instruction for use

Biohazard: Pay attention to protection and treatment

Date that the device is manufacturedSN

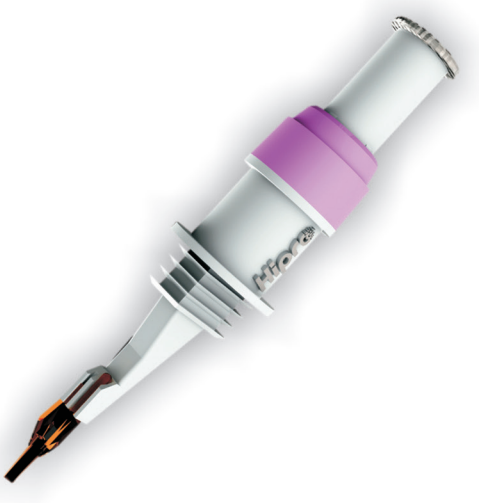
SN Serial No. of the device

Name and Address of the manufacturer

EC REP Name and Address of the European Representative



Waste disposal: dispose the waste properly



Manufacturer & European Agent

Manufacturer: Shijiazhuang Hipro Biotechnology Co., Ltd

Address of Manufacturer：No.3 Building, Block C, Fangyi Science. Park,

No. 313 Zhujiangdadao Road, Hi-tech Zone, Shijiazhuang, 050000, Hebei ,China.

Tel: 86-311-83855889

Fax: 86-311-83859087

After-sales service: Shijiazhuang Hipro Biotechnology Co., Ltd

Date of manufacture: refer to the label

European agent：Lotus Global Co., Ltd

European agent address：15 Alexandra Road, London, NW8 0DP, UK