

LiNEAR

RHEA

Automatic Immunoassay System User Manual



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CE
REV. B

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1. Summary

RHEA Analyzer 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.

1.1 Principle

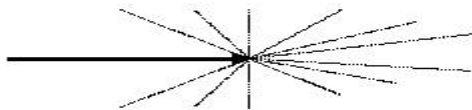
1.1.1 Nephelometric test principle

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 phenomena:

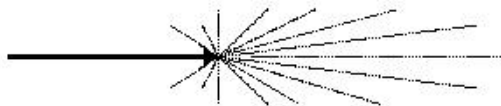
Rayleigh theory of Scattering

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 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	Linear range	100~4000 NTU Linear correlation coefficient ≥ 0.99
	RSD	RSD $\leq 8\%$
	Stability	The turbidity variation $\leq 10\%$
	Accuracy	Relative deviation $\leq 10\%$
Fluorescence	Linear range	100~1600AU, Linear correlation coefficient $r\geq 0.99$
	RSD	RSD $\leq 8\%$
	Stability	Fluorescence variation $\leq 15\%$
	Accuracy	Relative deviation $\leq 10\%$
	Sensitivity	Detection limit is not more than 2.5 $\mu\text{mol/L}$
Absorbency	Linear range	See attached table 1
	RSD	RSD $\leq 1\%$
	Stability	The absorbency deviation is not more than 0.005 at 340nm position within 20min
	Inter-channel RSD	RSD $\leq 5\%$
	Test temp. accuracy	37°C $\pm 0.5^\circ\text{C}$
	Wavelength accuracy	The wavelength deviation of 340nm、550nm、650nm is $\pm 3\text{nm}$,and half width is no more than 12nm
	Supply voltage	100V-240V,50/60HZ,100VA
	Input AC power	<100VA
	Size	410mm \times 280mm \times 355mm
	Weight	5kg
	Security classification	Class I for no application part

Attached table 1

Linear range of absorbency

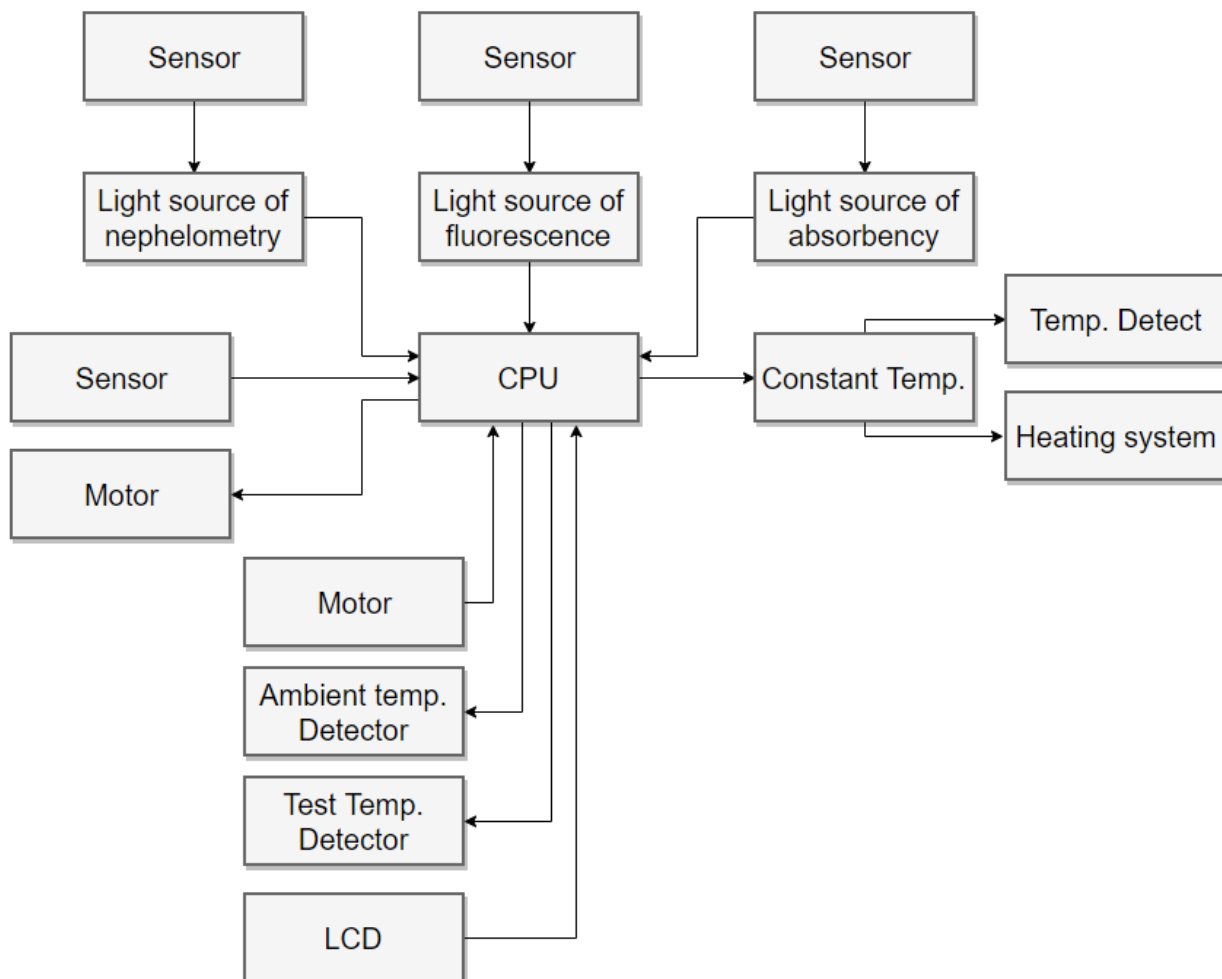
Linear range (A)	Deviation (%)
0.2~ ≤ 0.5	± 5
$> 0.5 \sim \leq 1.0$	± 4
$> 1.0 \sim \leq 1.8$	± 2

1.3 Accessories list

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

1.4 Instrument diagram

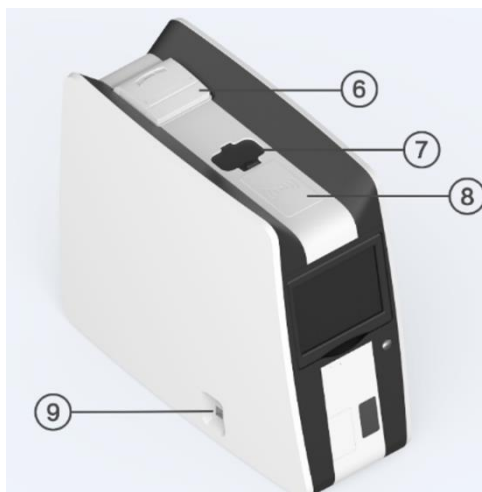
1.4.1 Instrument diagram



1.4.2 Instrument port



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



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



- 10, Battery 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

As RHEA analyzer 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°C (startup) 0-50°C (shutdown)
Humidity:	maximum 70%
Atmosphere pressure:	700hPa~1060hPa

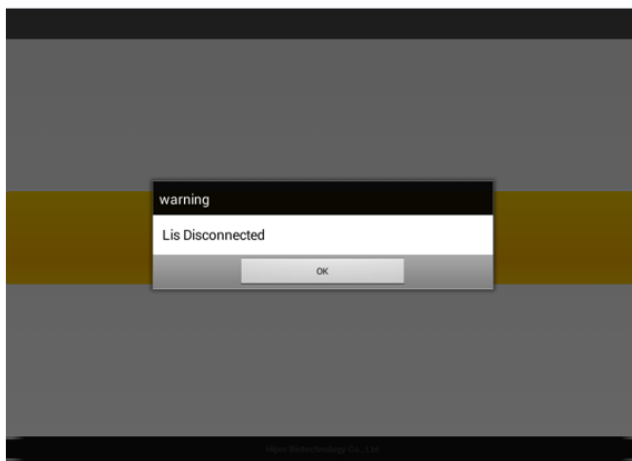
3. Operation

3.1 Startup

- Plug the 24V power supply into the power connector
- Press the "Power switch" for 1 second to startup.
- Software running then shelf test starts.



- Self-test 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 succeeds, 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.

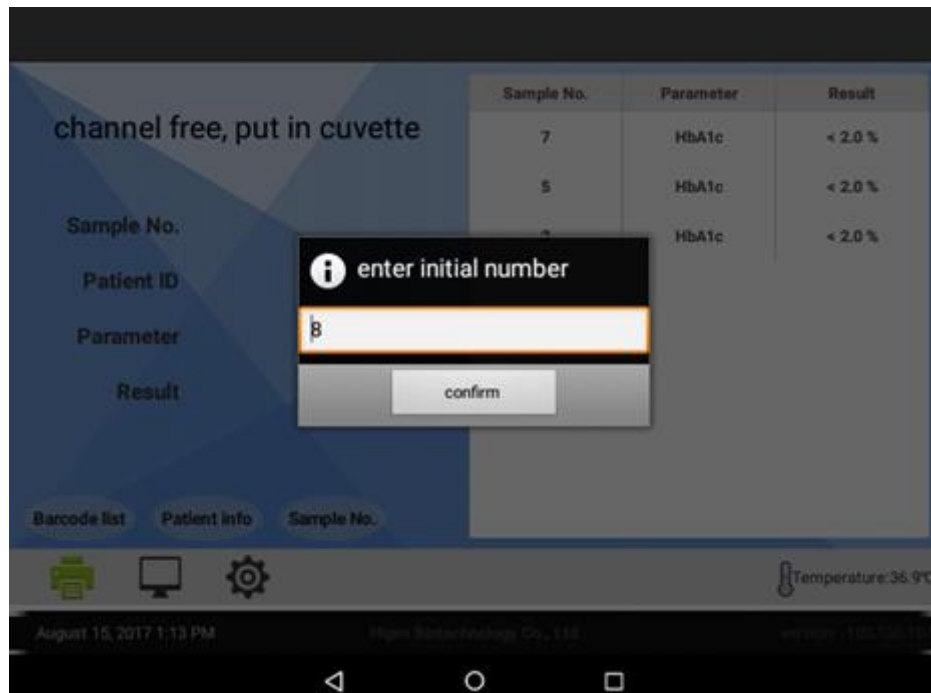
Menu: the connecting status of LIS and printer; setup the upload and print automatically; menu to switch the operation interface and power off; the device temperature.

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:

- Press the "sampler No"
- Enter the initial number, then press OK to finish.

3.2.1.3 Input the patient information

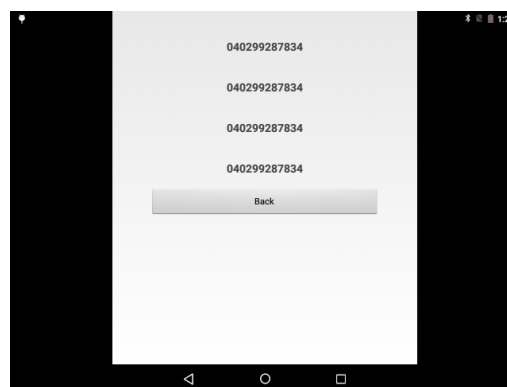


a) Press the "Patient Info"

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 shut down the device.


3.2.2 Result query

date: 7/10/2017 ~ 7/10/2017
name: project: result count : 3

sample No.	patient ID	project	result	reference range
2	2	hs-CRP	4.0 mg/L	0.0 ~ 10.0 mg/L
3	3	hs-CRP	4.0 mg/L	0.0 ~ 10.0 mg/L
8	8	hs-CRP	3.0 mg/L	0.0 ~ 10.0 mg/L

July 10, 2017 10:53 AM Hipo Biotechnology Co., Ltd. version: 1.0

To check the test results as following steps:

- Select the query type by press the “test results” or “Control results”
- Input the query condition as date, name and project, then press “” to search, the search results will be showing below.
- Touch & hold to print, upload, edit or delete.

3.2.3 System setting

operator
check/edit operator

language
language switch

Lis
Lis auto upload ☐

print
result auto print ☐

Date & time

report form setup
set number of report to be printed

data backup
back data

data recover
recover data from backup

delete data
clear all data

error log
check error

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3.2.3.1 Operator

- a) Press "Operator".

administrator

operator name add operator

ID	name	status
1	Linear	0

Back

- b) Input the operator name then press "Add operator" to add more operator.
- c) Touch & hold to delete operator.

3.2.3.3 Printer and LIS system setting

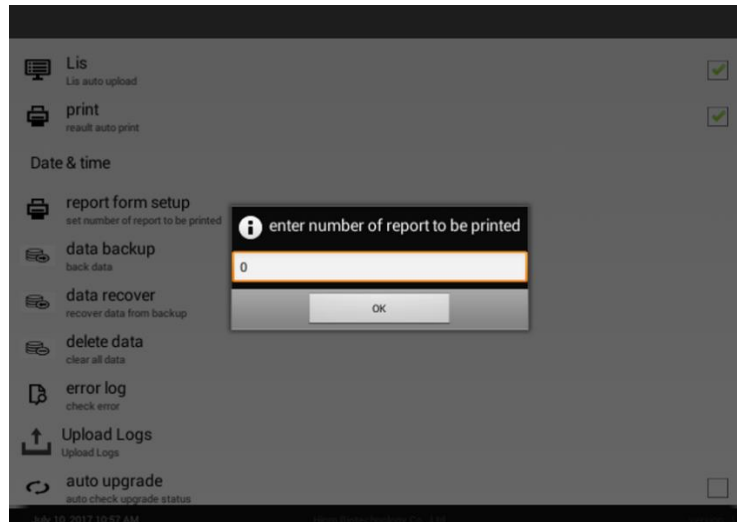
If LIS and print are ticked, the test results will print and upload automatically, if not, the results only print and upload by manual.

Lis
Lis auto upload ☒

print
result auto print ☒

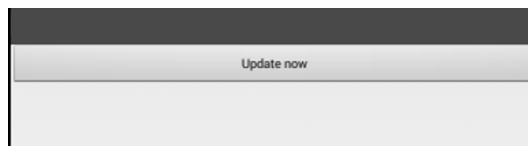
3.2.3.4 Report form setup

- Press "Report form setup"
- Enter number of reports to be reported, press "OK" to finish."



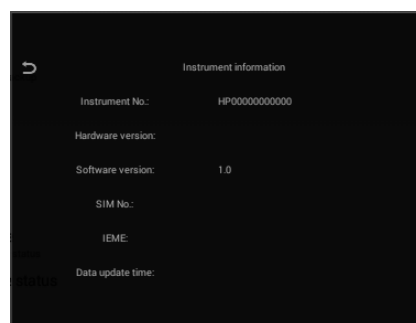
3.2.3.5 Auto Update

- Press "Auto update"
- Press "update now" to update the software.



3.2.3.6 Check the device detail

Press "About" to check the instrument information



3.2.4 Page switching

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

3.2.5 Calibration

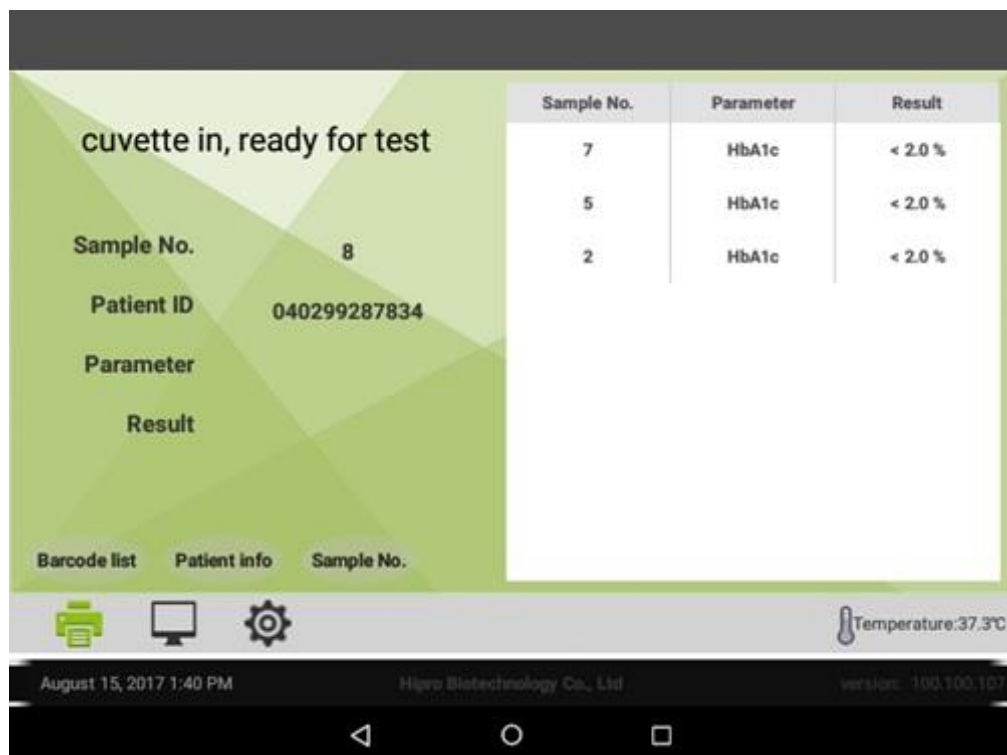
- Press "Control test" in "System Setting" interface.
- Input and take out the Cup A, Cup B and Cup C as the instruction. To cancel the calibration by press "Cancel" during the operation.
- The calibration completed when showing "Calibration done"

3.3 Sample test

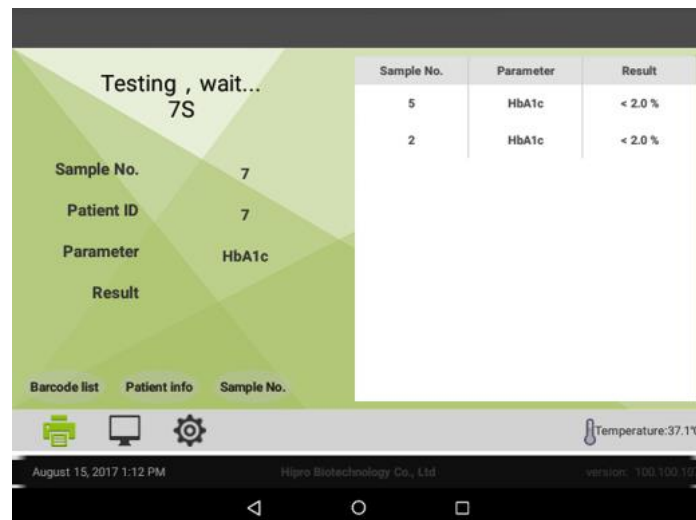
- Check the waste container. Place the waste container beside the discharge port, the cuvette will be discharge automatically. If there are not any cover in 10cm from the Discharge port, the cuvette should be discharged by manual.
- If needed input the patient information first, please input.
- If needed scan the barcode or ID card first, please scan.
- Insert the cuvette to start the test.

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

- 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.



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



- e) 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.

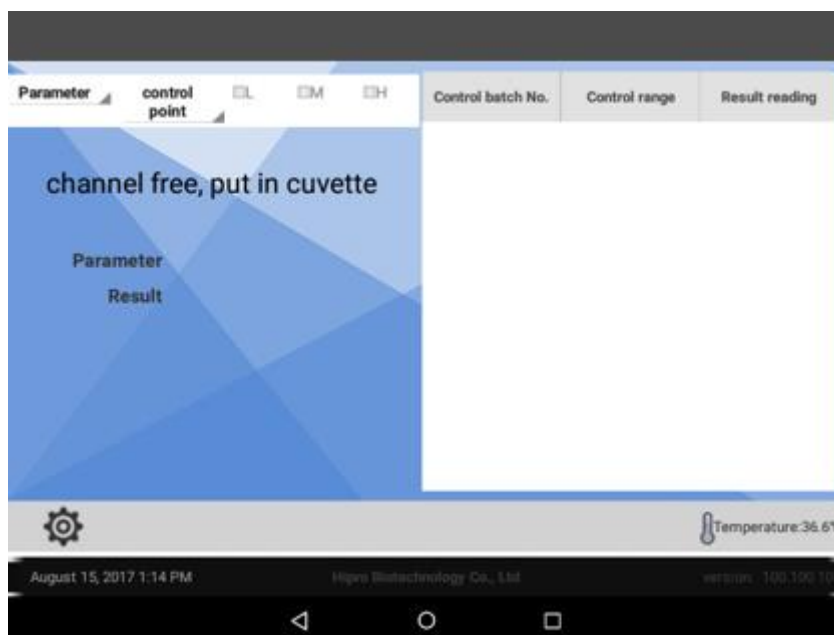


3.4 Calibration

3.4.1 Control test

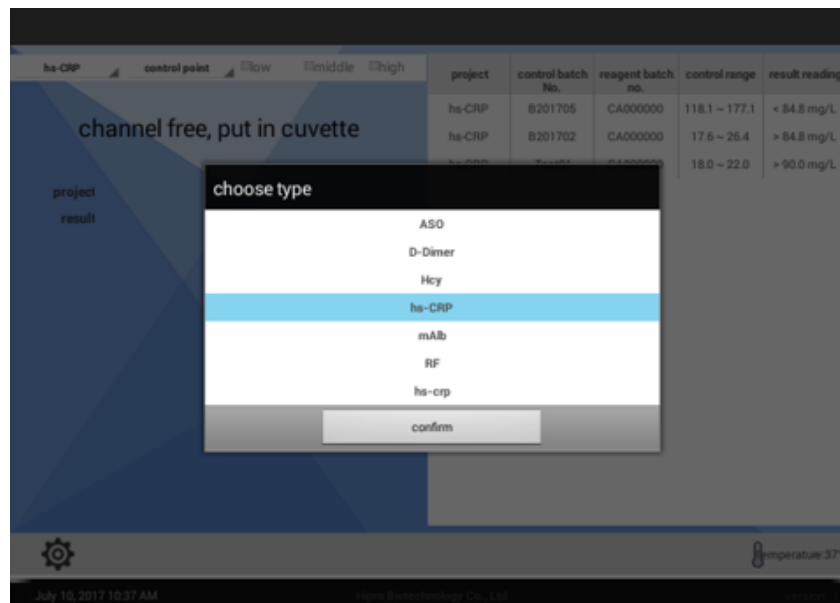
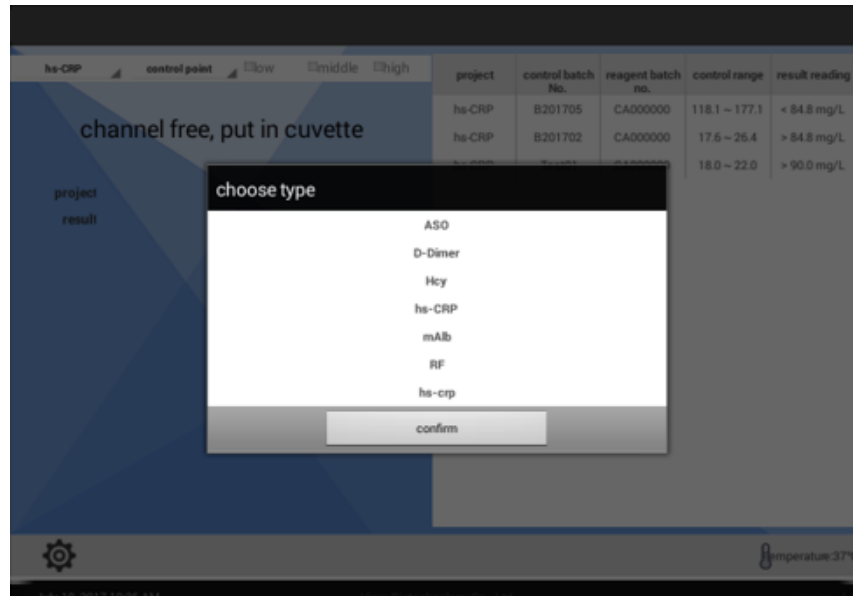
- Press “” to enter the system setting, then press “Control test”
- Scan the barcode of the calibration card to enter the “control test” directly.

3.4.2 Testing procedure




- a) Select the control value (If entered by scanning the barcode of calibration card, skip this step)

First choose type



Second select the control value, then press “confirm”


select control point			
Test01	serumplasma	middle	20
B201705	serumplasma	high	147.6
B201705	serumplasma	low	22
B201702	serumplasma	high	147.6
B201702	serumplasma	low	22
confirm			

Please ensure the “low, middle, high” are ticked as 

- b) Insert the cuvette filled with calibrator into the device. The barcode should face the printer.
- c) The calibration results showing the right side when tests finished.

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.Maintaince

4.1. Internet Real-time calibration

The internet real-time calibration means the calibration curve can be download in real-time via internet connection.

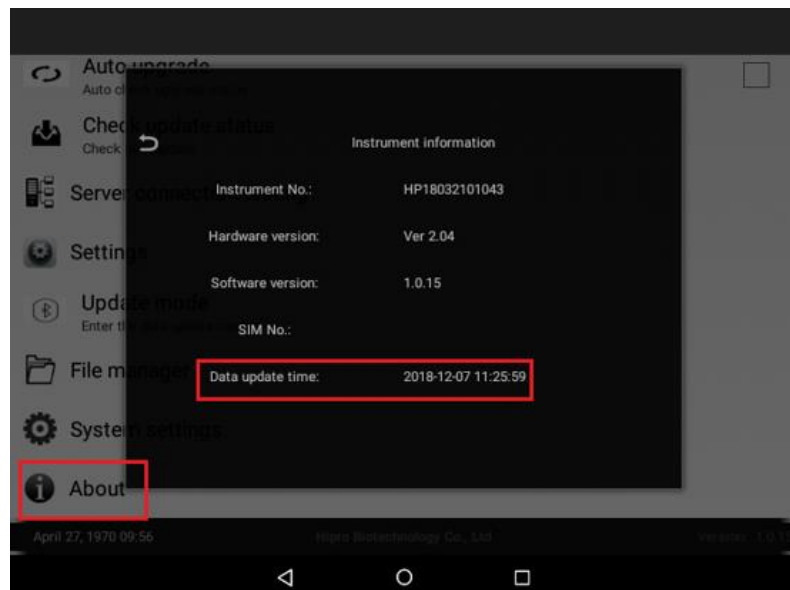
Each time when A1 start up, A1 will check the latest calibration curves when each start-up and download the latest calibration curves automatically.

Suggestions: Ensure A1 connect to the internet once a month.

4.2 Update step

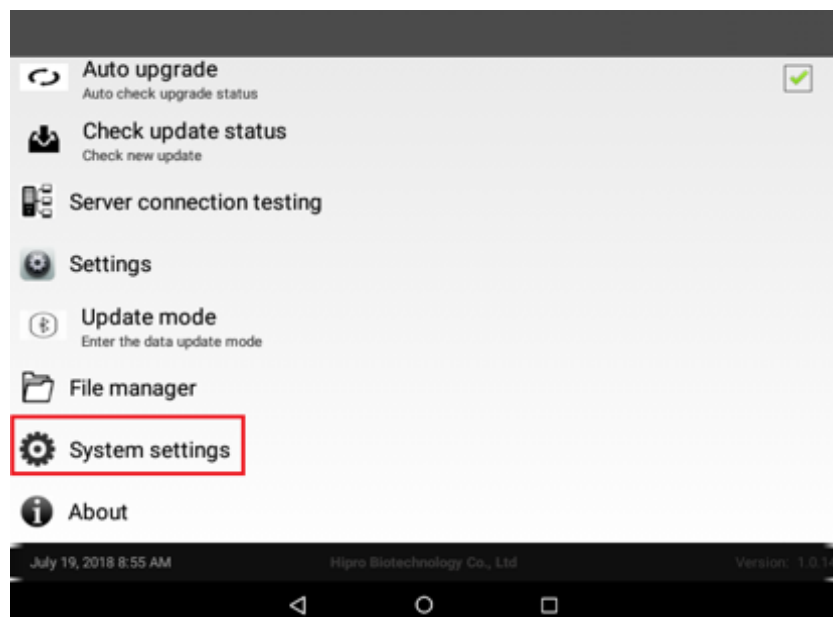
4.2.1 Check the latest update time.

- a) System setting
- b) About
- c) Data update time



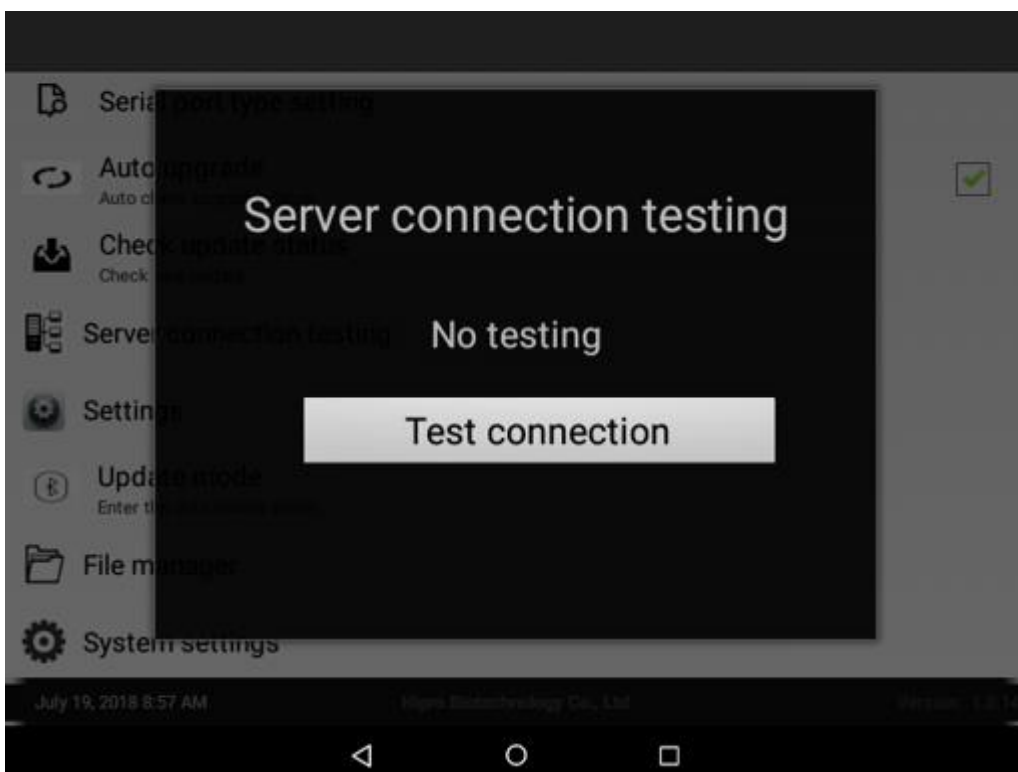
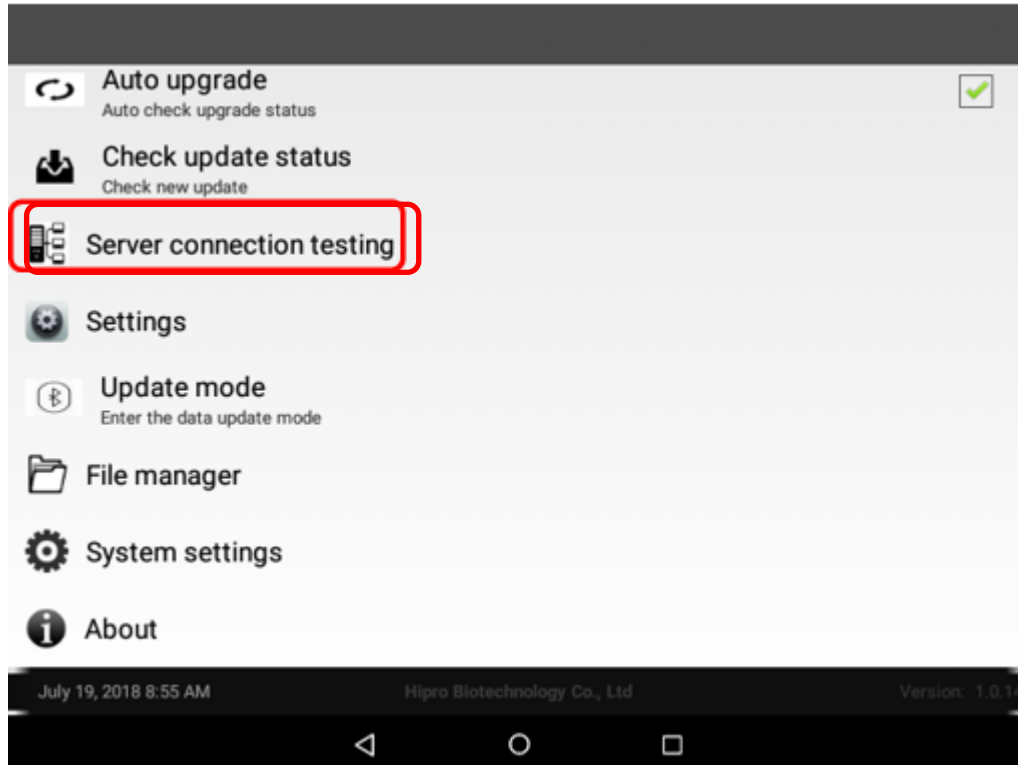
4.2.2 Connect to Internet via Wifi or Mobile's wifi

- a) System Setting
- b) Wi-Fi



4.2.3 Check Sever connection

- System setting
- Server connection testing
- test connection



4.2.4 Update Confirmation

- a) System setting
- b) About
- c) Data update time. The Data update time should same as the operation time.

5 Trouble shooting

5.1 Disturbance Display

5.1.1 QR CODE ERROR

A1 cannot read the QR code due to:

- A) The QR code face wrong Directions
- B) QR code is damaged or polluted by blood or samples
- C) The cuvette in lower position

Solution:

- A) Take out the cuvette, ensure the QR code face to the printer direction.
- B) The test scrapped
- C) Contact the engineer, remove the left shell, check the position of the cuvette, adjust the gear, make the cuvette seat in the right position.

5.1.2 MIX ERROR

Mix error means A1 cannot mix the reagents, it always happened with the abnormal noise. Need to remove the left shell for further check. This error caused by:

- A) The up-down gear in wrong position
- B) The hardware is stuck.

Solution:

Contact the engineer to

- A) Adjust the up-down gear via system setting, to make the cuvette seat in the right position.
- B) Dismantle the hardware, adjust their positions, Reassemble the machine.

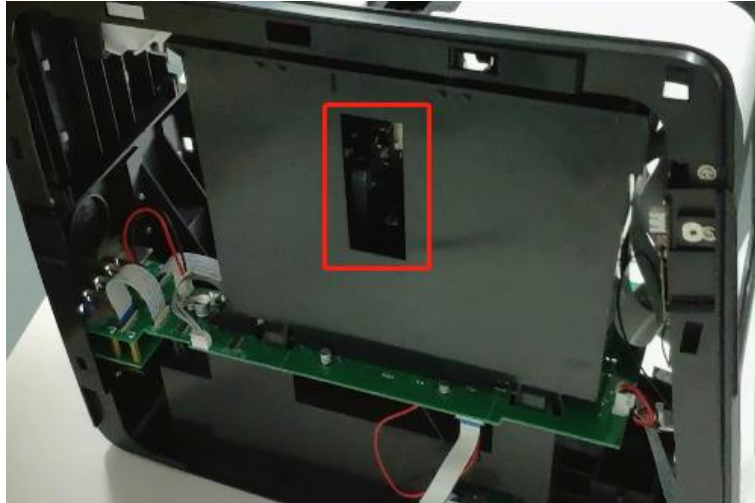
5.1.3 Press error

During the test, the R2 cannot press down to mix R1 and R2. It may be caused by:

- A. The hardware is stuck, cannot press.
- B. The moving holder is short of power to reach the right position, the press action lack of conditions to finish.

Solution:

- A. Remove the left and right shell, check if any other things inside, take out it from the window. If cannot, contact the engineer remove the inner shell, take out.



- B. Remove the left and right shell, run the test again, checking the hardware movements to analysis the problem. Contact the Linear engineer for further supports.

5.2 Printer

The printer is not easily damaged parts, if cannot print the results, it may be caused by:

- A) The print paper is out.
- B) The auto-print is shut down
- C) The printer cable is damaged

Solutions:

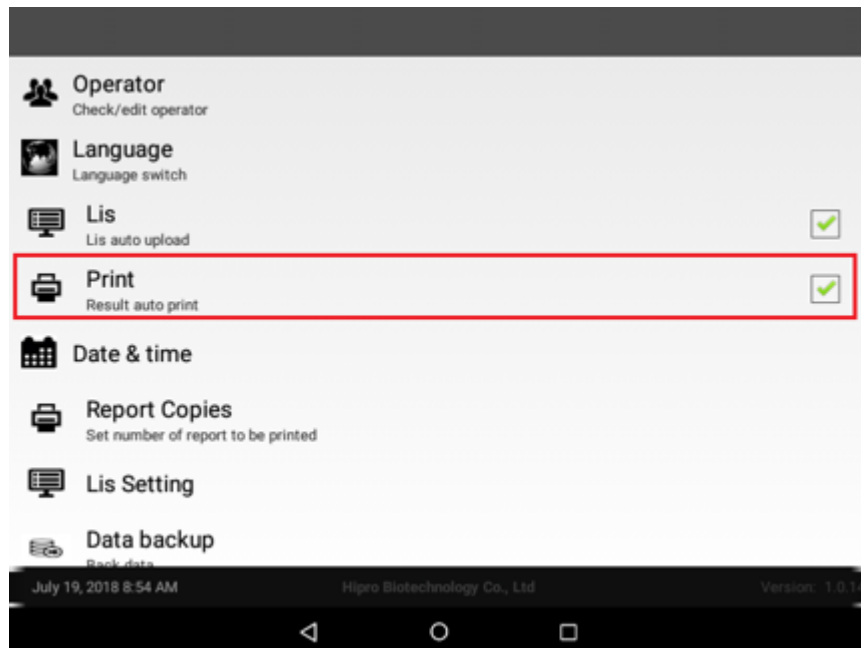
- A) Change the printer paper in the right way. The print paper size: Width 57 mm.



- B) Check the print setting in the Sample test interface, The button should be showing green to allow the auto-printing. If it is gray, turn on by click the Print button.

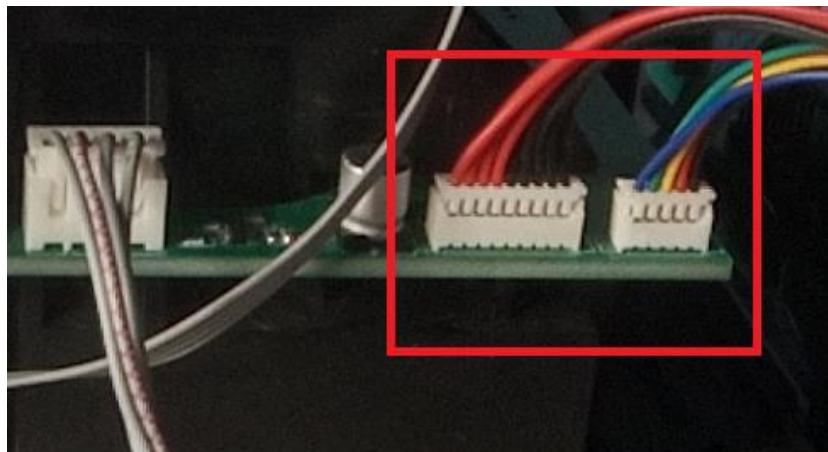


Or select the Print (Result auto print) in the System setting menu.



- C) First check the printer is working or not, select a historical result, long press to select “Print”, if not print out, checking printer connection.

Remove the right shell, check the printer cable connection as below:



5.3 Barcode Scanner

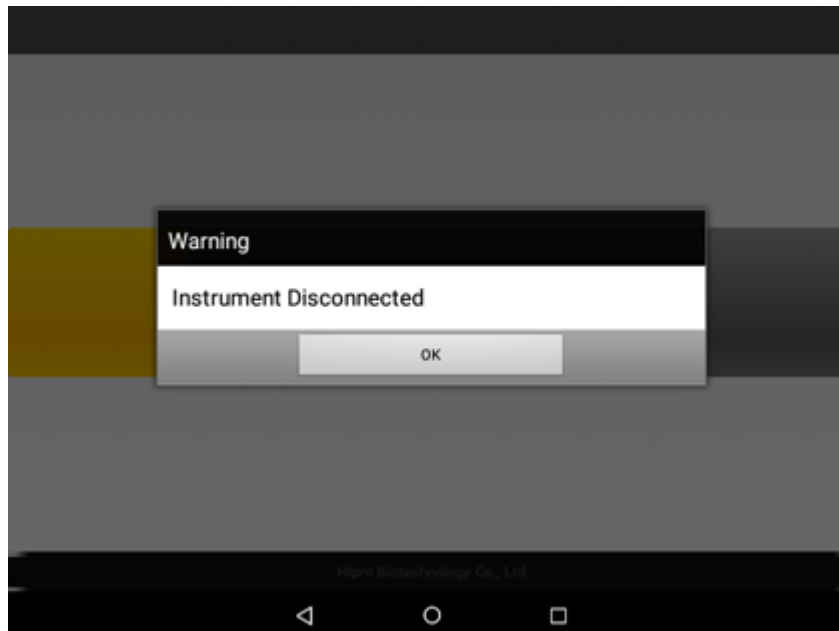
Barcode scanner not working during the test, it scans the barcode when the machine is free.

5.4 SIM card

A1 operation system is based on Android, if showing “no SIM card”, ignore the tip, click the blank area to skip the process.

5.5 Instrument Disconnected

Running the SmartXpert, when showing “instrument disconnected” means cannot connect to the hardware,



It may be caused by:

- A) Switched into debugging mode, the hardware and software cannot connect.
- B) Serial port type setting is wrong.
- C) The configuration files is deleted
- D) The mainboard is damaged

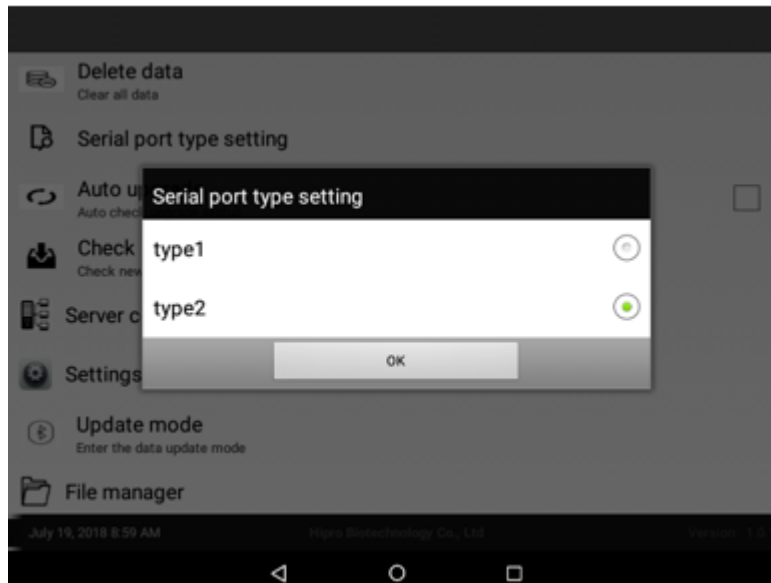
Solutions:

- A) Check the debug switch, turn on.

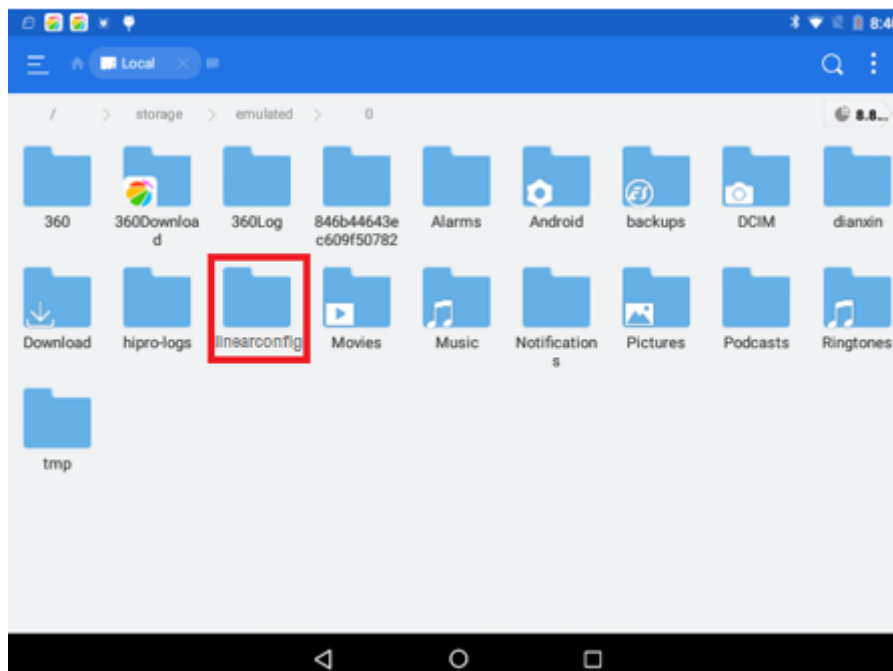


Try switch it when the A1 is power off.

- B) When showing “instrument disconnected”, click the blank area to skip into the App, click the “Serial port type setting” from the system setting, set the port type as type 2 or type 3, try different port connection. The changes will take effect when the A1 is restarted.



- C) Enter the “File manager” of Android system setting, locate the file “LinearConfig” to check the number of subfolders, if less than 3, the file is damaged. Please provide the Serial number of the damaged A1 to receive the right configuration files. Install the new configuration files, restart the A1.



- D) If the previous steps are all right, please contact Linear Engineer to check the mainboard problems.

5.6 No responding

The instrument no responding including there is no self-test when start, do not run the test when insert the cuvette.

It may be caused by switched into debugging mode.

Check the debug switch position, turn on.



5.7 The auto-discharge error

The finished cuvette cannot discharge automatically from the discharge port. It may be caused by:

- A) No waste box placed in the right of the instrument or placed in the wrong position.
- B) The waste box sensor is damaged.
- C) If the waste box is placed right, the cuvette cannot discharge

Solution:

- A) The waste box should place close to the sensor as below



The waste box should be not completely lucid. The distance between waste box and sensor should keep in 2mm, not too close to the sensor.

- B) Ensure the waste box placed in the right position, then remove the left and right shell, checking the discharge movement. If there is not any discharge movement means cannot detect the waste box, check the waste box sensor cable connection.
- C) If detecting the discharge movement, but the cuvette cannot release from the cuvette seat, means the cuvette seat is too tight, loose the cuvette seat by hand, or use the file to make the cuvette seat more smoothly.

5.8 Server connection error

If showing server connection error, it may be caused:

- A) The wifi connection is failed.
Try other wifi connection or mobile wifi.
- B) The server is on maintenance
Contact the Linear engineer to check the server status, try later.

5.9 Test results or clinical results problem

Contact the Linear engineer, provide the following conditions for further analysis

The A1 serial number, the reagent batch number, the sample type, the sample condition, operation procedure and the test results.

If comparison results, the comparison device method, linearity range, reference range, unit and the comparison result also needed.

6. Calibration

If the control test results not in the control target range, first analysis the error, eliminate the instrument, operation and environment factors, then calibrate:

6.1 Internet real-time calibration

Contact the Linear engineer to provide:

- a) Instrument serial number
- b) reagent batch number
- c) the control/comparison test results including 2 levels (high, low) results, repeat test each level twice.

Then follow the instructions of the engineer to update the calibration curve by connect to the wifi, checking the "Server connection testing".

6.2 System calibration

Enter the A1 calibration mode to finish the calibration

See 3.4 Calibration.

7 Contact

Linear Service Department

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