WOODLEY
EQUIPMENT COMPANY LTD.

InSight V-IA® PLUS

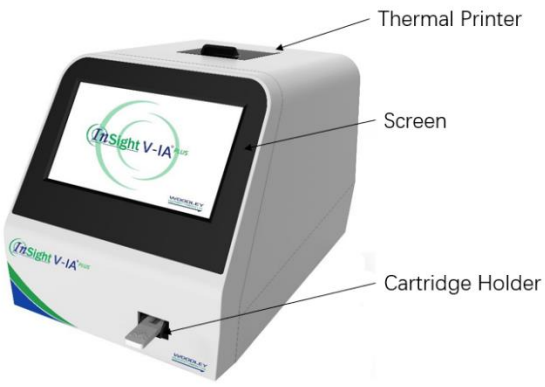
Veterinary Immunoassay Analyser

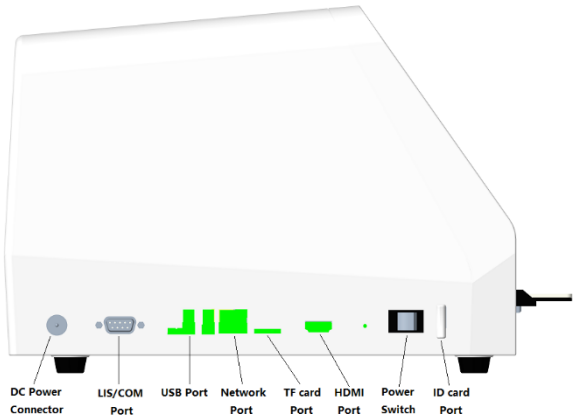
User Manual

Contents

I Product Introduction

I.1 Analyser Structure





I.2 Intended Use

InSight V-IA Plus Veterinary Immunoassay Analyser uses immunofluorescence technology to provide accurate, quantitative laboratory results.
For *in vitro* diagnostic use only.
For veterinary use only.
InSight V-IA Plus Veterinary Immunoassay Analyser is suitable for use in veterinary laboratories.

I.3 Technical Specifications

I.3.1 Main parameters

- Software Version: Version 1
- LED or Diode laser
- Outputs: 1. USB interface (2)
  2. Ethernet interface (1)
  3. Serial port: Automatic LIS uploading & PC adjustment
- Display: 24-bit true colour LCD screen
- Sample Type: Whole blood, serum and plasma
- Power Supply: Host Input DC: 12V 5A
  Adaptor Input: 100-240VAC; 50/60Hz
- Standard curve
  Storage Method: ID card with 4K memory
- Dimensions: 213 (W) x 243 (D) x 195 (H) mm
- Weight: 4kg
- Operating Temperature: 10-30°C
- Relative Humidity: ≤70%

I.3.2 Performance Specifications

- Repeatability: CV≤10%
- Stability: σ≤±8%
- Linear Correlation: r≥0.97
- Accuracy: Δn≤±15%

I.4 Analyser System

- Hardware Core: ARM Cortex™
- Software: Android 5.1
- Memory: 8G
- Data Capacity: 10,000 sets of patient and quality control data

I.5 Analyser Test Information

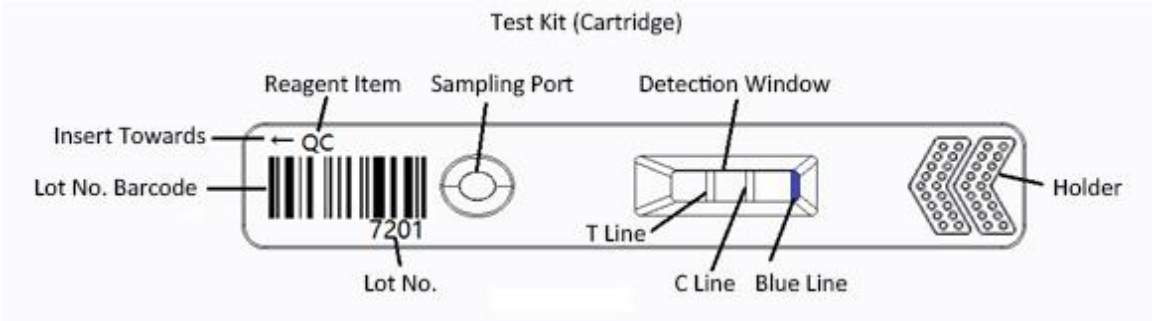
1.5.1 Cartridges

Only use genuine InSight V-IA cartridges provided by Woodley Equipment Company.

◆There is a barcode on the cartridge. It shows the Lot Number of the cartridge. InSight V-IA Plus will read the barcode to recognise which items and which Lot is being tested.

◆The Lot Number and the name will show on the information of the barcode.
Lot Number Name Rule:
Long Lot Number: H0ABYYMMXX
Short Lot Number: ABXX

Code	Meaning	Sample: H053210113	Sample Meaning
H0	Fluorescent products	H0	Fluorescent products
AB	Test name	32	T4
YYMM	Manufacture date	2101	Produce in January，2021
XX	Lot	13	Number of Lot
ABXX	Barcode No.	3213	Short Lot number



- The arrow indicates the direction the cartridge is inserted into the analyser.
- The sampling port is where the sample is added. Please follow the instructions provided with the test.

◆ The detection window is the area the analyser will read the fluorescent signal.

◆ C Line:

This cannot be seen by the user. It is a fluorescent control line which the analyser will use to check the result of the cartridge.

◆ T Line:

This cannot be seen by the user. It is a fluorescent test line. The analyser will read the fluorescent signal and ID chip information to give the result.

◆ Blue Line:

This can be seen at the end of the detection window. When the sample has been added to the cartridge correctly, the blue line will disappear after the sample has flowed over the detection window. If the blue line is still visible after the incubation time, the analyser will show ‘Test invalid’ after the test has been completed.

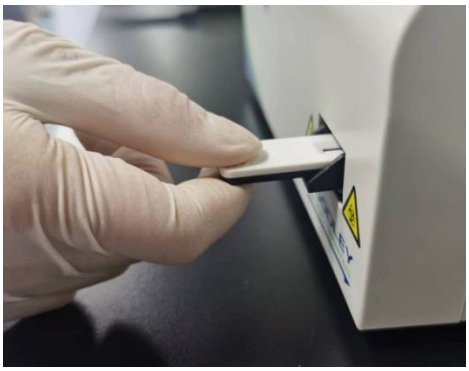
Caution: If the blue line is still obviously visible after analysis, please check if the test has been completed correctly.

After adding the sample correctly, the blue line should disappear.

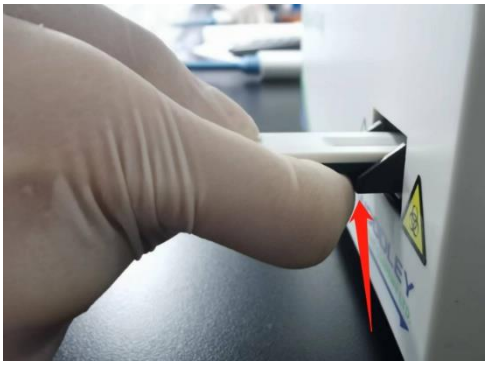
A new test kit or incorrect sample volume.

◆ Insert the Test Kit:

Notice: Please insert the test kit to the end of cartridge holder.



Correct



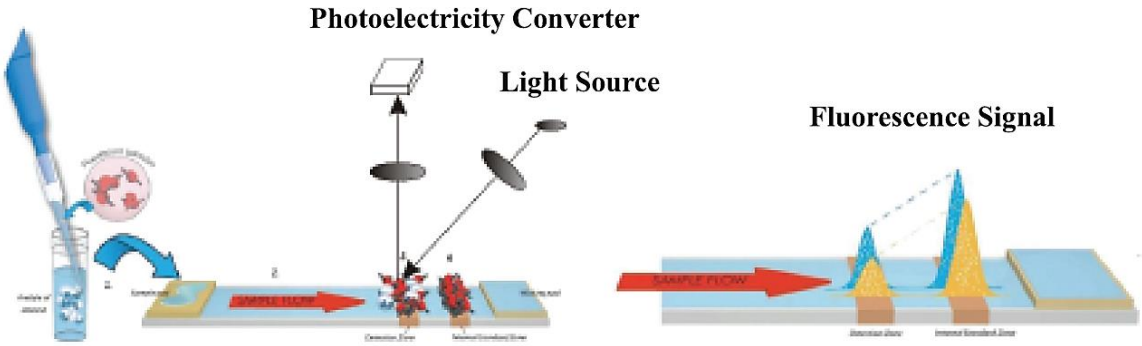
Incorrect, the finger is obstructing the cartridge holder

1.5.2 ID chip

All the parameters and information of the cartridge is saved in the ID chip. Each Lot Number of tests has a unique ID chip.
You can read the ID chip information on the Item page.

1.5.3 Test principle

1. Sample is added to cartridge and migrates to the fluorescent antibody that is labelled on the cartridge.
2. Laser light source excites fluorescence.
3. The emitted light is collected and converted into electrical signals.
4. The concentration is calculated from the signal and ID chip parameter.



II Contents

No.	Accessories	Quantity	Remark
1	Power Adaptor	1	Included
2	Instructions for Use	1	Included
3	Ethernet Cable	1	Included

III Installation

III.1 Installation

III.1.1 Unpacking and checking

1. Gently remove the analyser and accessories from the packaging box. Save the packaging materials for future transport or storage of the analyser. Check the accessories against the packing list.
2. Check the analyser and accessories to see if they are in good condition.

⚠ **Notice:** If there are any problems, please contact Woodley Equipment Company.

III.1.2 Analyser placement

1) The analyser should be placed in a clean and ventilated room with temperature between 10°C ~ 30°C, relative humidity of less than 70%, away from direct sunlight.
2) Make sure the vents are not obstructed and that there is at least 5cm of clearance around the analyser.
3) Connect the power adapter to the power interface of the analyser and turn on the power.
4) Do not place any items on top of the analyser.

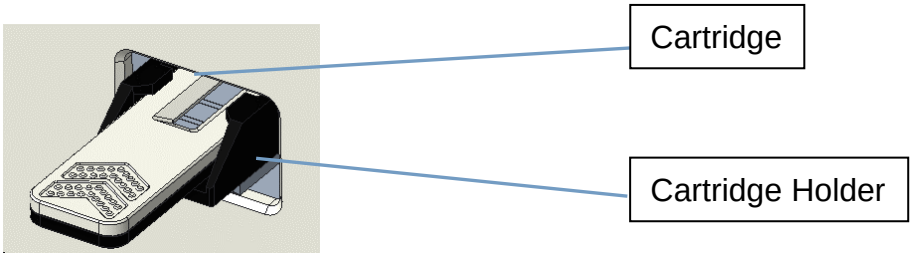
III.2 Instructions

Please note that the operating temperature of test reagents is based on each test kit's instructions. Perform tests in strict accordance with the cartridge operating instructions provided in each test kit.

III.3 Operation Procedures

III.3.1 Preparation

1) When switched on, the analyser will run a self-test and the cartridge holder retracts as shown below.



2) The software will start automatically and display the main home screen.
3) For the use and storage of reagents, please refer to the cartridge operating instructions.
4) Insert ID code chip for the test to be analysed. Select "Read ID Card".
5) Enter patient details in the 'detail' section.

6) Select standard test or instant test (refer to Section IV.2).
7) Place the test cartridge with sample (follow cartridge operating instructions) into the cartridge holder and run prepared test.

Notice:

- Do not touch the cartridge holder when it's moving.
- Do not interfere with the software during testing.

III.3.2 After analysis

1) The test cartridge will be released from the analyser once the test is complete.
2) The cartridge holder will reset.
3) Used test cartridges and pipette tips should be disposed as medical waste in accordance with local regulations.

III.4 Warnings

The sign denotes notifications and errors.

IV Software Introduction

IV.1 Main Interface

Figure 4.1

As shown in Figure 4.1, there is a home [Menu] key at the bottom of all screens. Click the [Menu] key and the screen in Figure 4.1 will display. From left to right, the screen will display [Test], [Batch Test], [History], [Item], [QC] and [Settings]. Select an icon to enter into the corresponding screen.

IV.2 Testing Interface

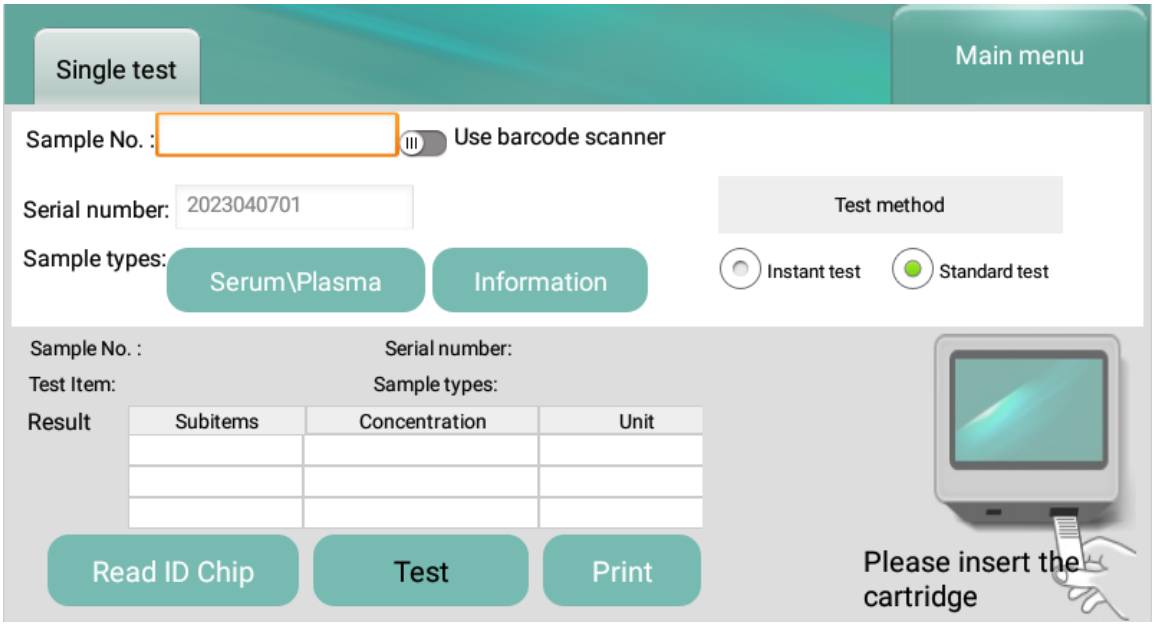


Figure 4.2.1

1. Click [Test] option on the main home screen and Figure 4.2.1 will display. (Test interface will be change in Bi-directional mode (see chart 6.2.5 below).
2. Insert ID chip in the ID Port on the side of the analyser and select “Read ID Card” before using a new lot of test cartridges.
3. After the ID chip is recognised, select sample type and manually input sample number if required.
4. Select [Detail] to input more detailed patient information (patient name, age etc).
5. Select [Standard Test] or [Instant Test] after inputting patient information. Standard Test means the analyser will countdown the reaction time, then analyse the cartridge and report results. This option is recommended for routine testing. Instant Test means the user needs to use a timer to countdown the reaction time before putting the cartridge in the analyser. Once the timer has completed, the user inserts the cartridge into the analyser to analyse the cartridge and report results. This option is recommended for multiple sample batch testing.
   Caution: Wrong test mode will cause incorrect test result.
6. Prepare sample according to each test kit insert. Then apply sample to the test cartridge. If Standard Test selected, insert the test cartridge into the cartridge port. If Instant Test selected, start the timer and leave the cartridge on the bench.
7. When patient information has been inputted, the user can select [Test] option to start the analysis.
8. After each test, the result will be displayed on the screen and will automatically print on the internal thermal printer.

IV.3 Batch Test

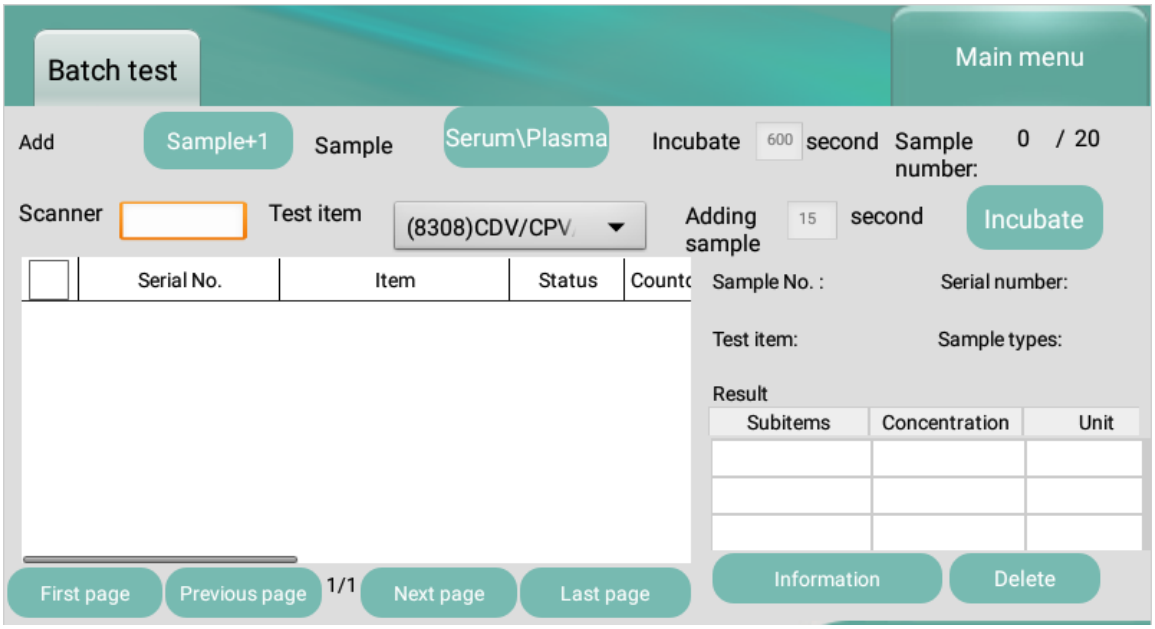


Figure 4.3.1

1. The screen for batch testing is shown in Figure 4.3.1. The user can select the sample type and test item and add or delete the item to be tested.
2. Select the test item to determine the time that is displayed in the interface [Time].
3. Select [Sample +1] to add another sample. Select the corresponding sample and select [Delete] to delete a sample. (Figure 4.3.2)

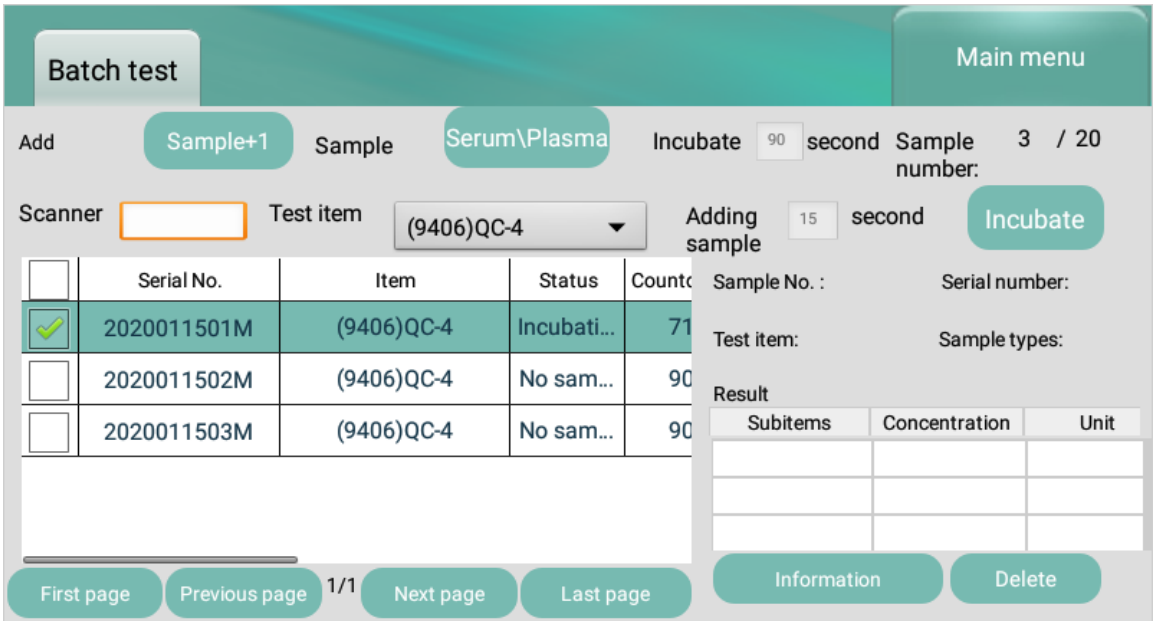


Figure 4.3.2

4. After the sample is added, a sample No. will be automatically assigned. The user has the option to customise the code, select the sample and select the [Sample Number] to edit the code.

5. Select [Start], the analyser will start to count down. Simultaneously, the next sample will count down. The analyser will prompt the user to insert the correct test kit when the countdown is complete.

IV.4 Results Records Interface

1. In the [History] screen, users can view previous test results.
2. After each test has completed, the system will automatically save the results to the analyser memory.
3. Adjust the dates to search for a sample. Select [OK].

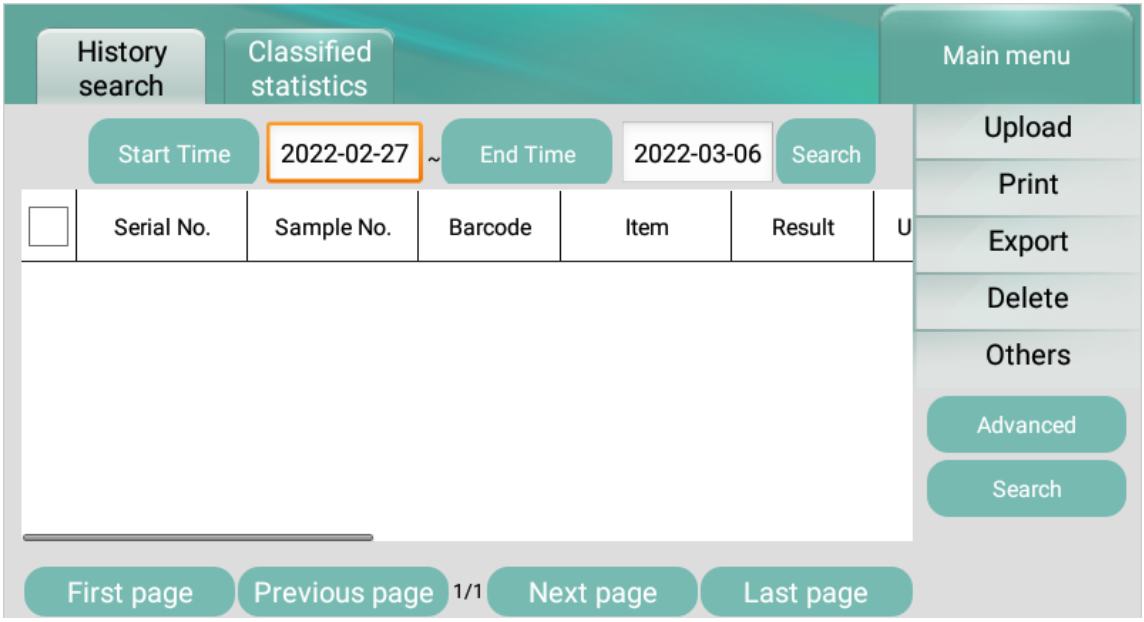


Figure 4.4.1

4. Select [Upload] in Figure 4.4.1 to upload the selected records or all records to the LIS/HIS.
5. Select [Print] in Figure 4.4.1 to print the selected records or all records on the internal printer.
6. Select [Export] in Figure 4.4.1 to export the selected records or all records to a USB.
7. Select [Delete] in Figure 4.4.1 to delete the selected records or all records.
8. Select [Advanced] in Figure 4.4.1 to check the advanced information. You can input or modify the patient information on the Advanced page as shown in Figure 4.4.2.
9. Select [History Search] in Figure 4.4.1, set the search date range and press confirm to search the results as shown in Figure 4.4.3
10. Select [Classified Statistics] in Figure 4.4.4. After selecting a date range, press confirm to view the statistics of how many tests have run within the selected time frame.

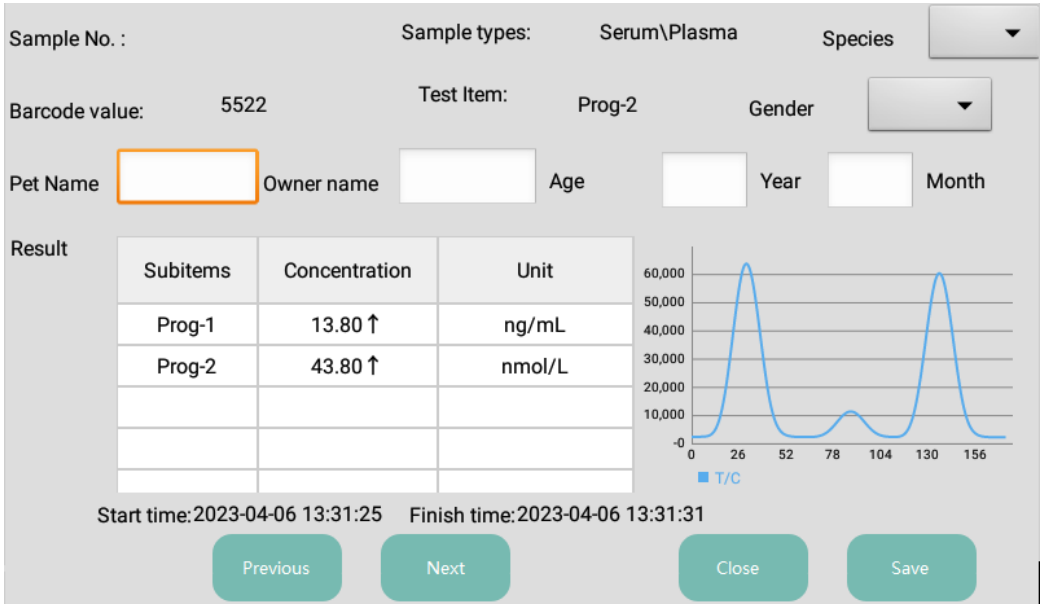


Figure 4.4.2.

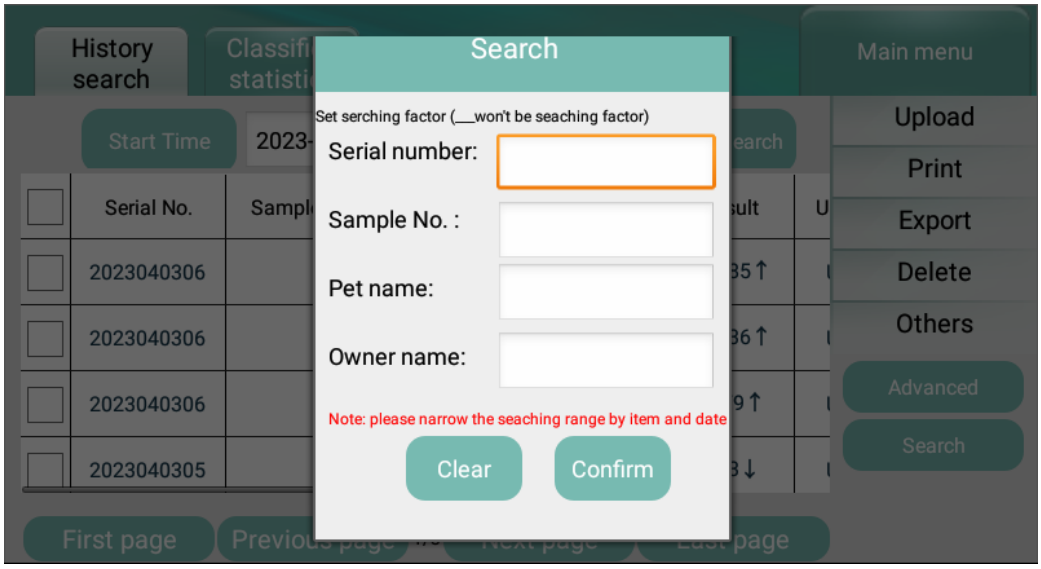


Figure 4.4.3

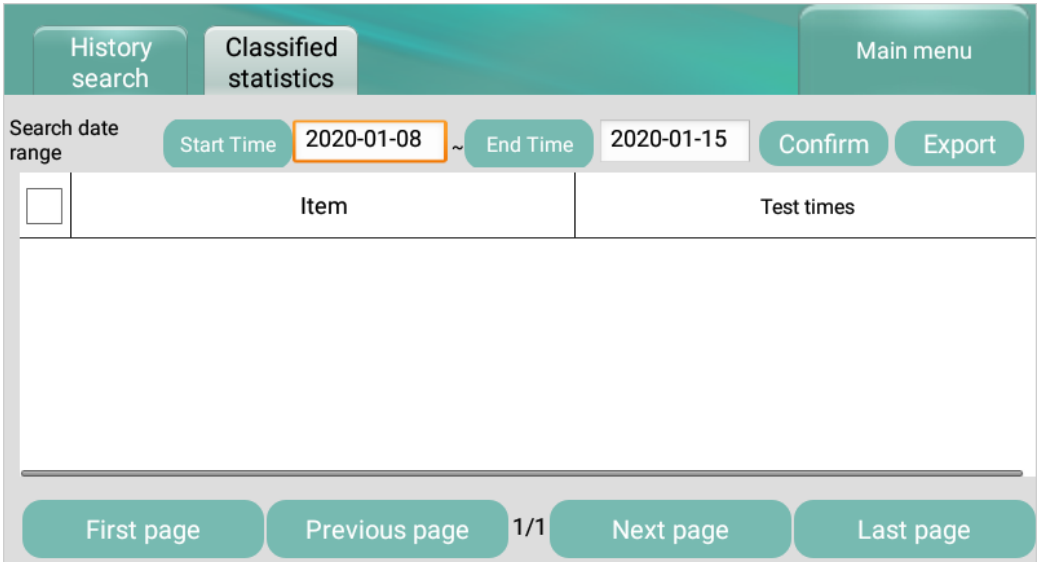


Figure 4.4.4

IV.5 Item Interface

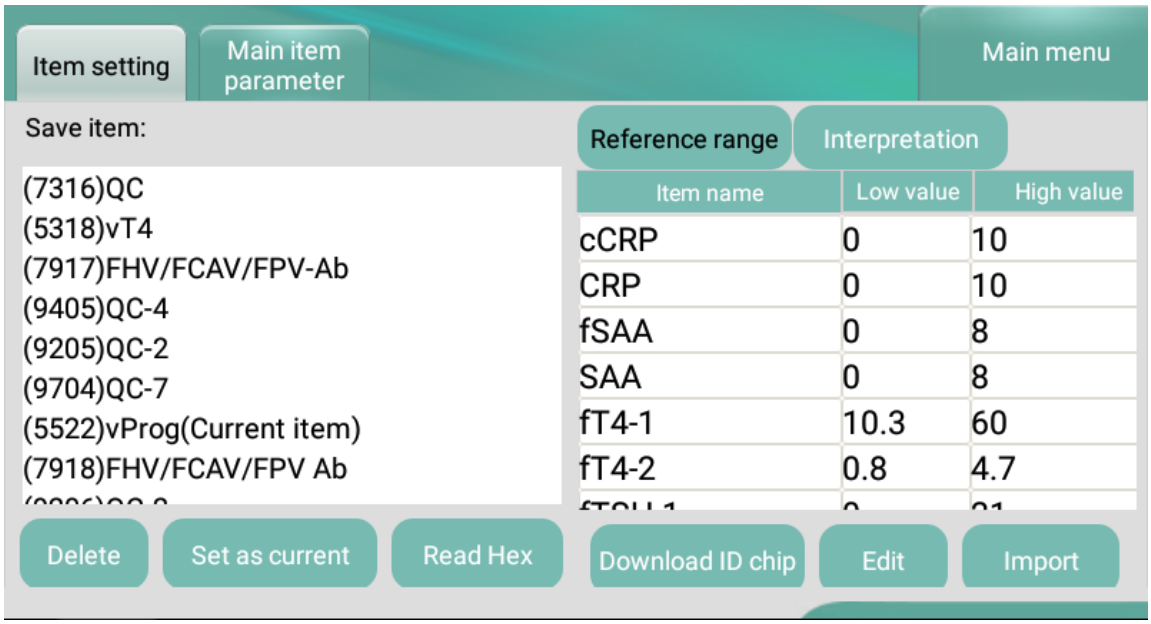


Figure 4.5.1

1. As shown in Figure 4.5.1, saved test lists can be viewed and reference ranges can be set in the [Item] screen.
2. The user can edit reference ranges as shown in Figure 4.5.2.

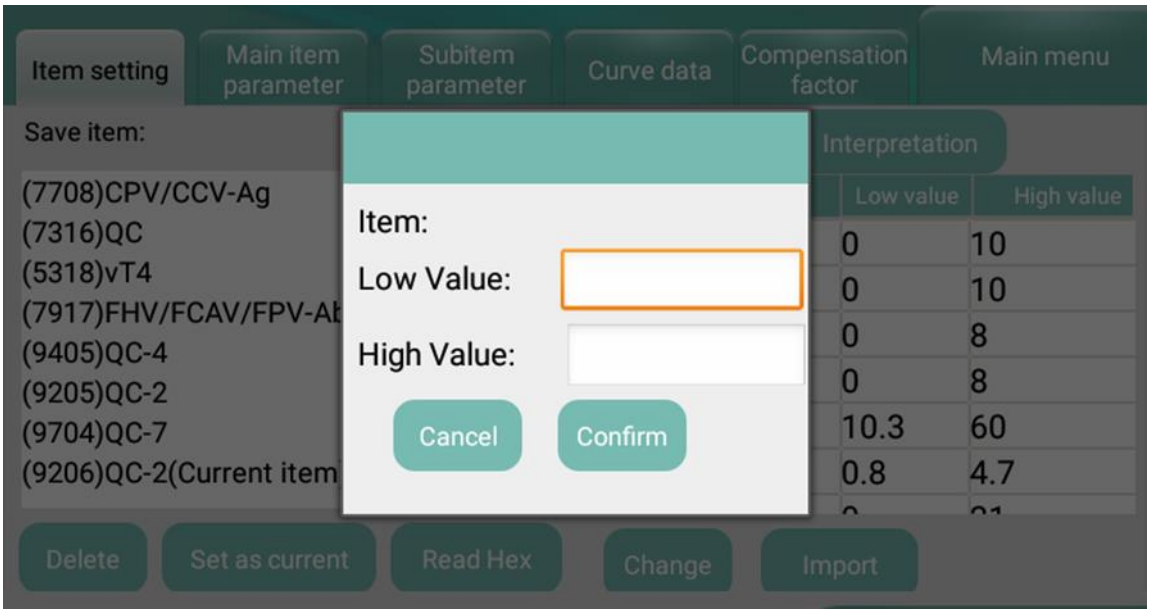


Figure 4.5.2

3. Import ID Chip Information:
   If the ID chip of the test item is lost, you can import the item information of the ID chip using the method below.
   ◆Read ID chip from USB device
   Provide the Lot No. of the test item and contact Woodley Equipment Company to get the ID chip Hex file.

Set a folder name of “Hex” in the USB device root directory. Transfer the Hex file, provided by Woodley Equipment Company, of the test item into the “Hex” folder as shown in Figure 4.5.3.

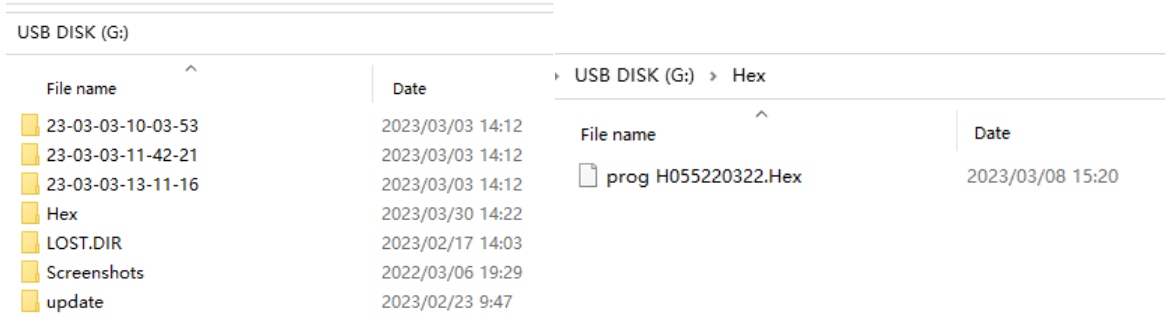


Figure 4.5.3

Press [Read Hex] in the Item setting page.
Select the Hex file and press confirm as shown in Figure 4.5.4.
Item information will be saved on the ‘Save item’ window.

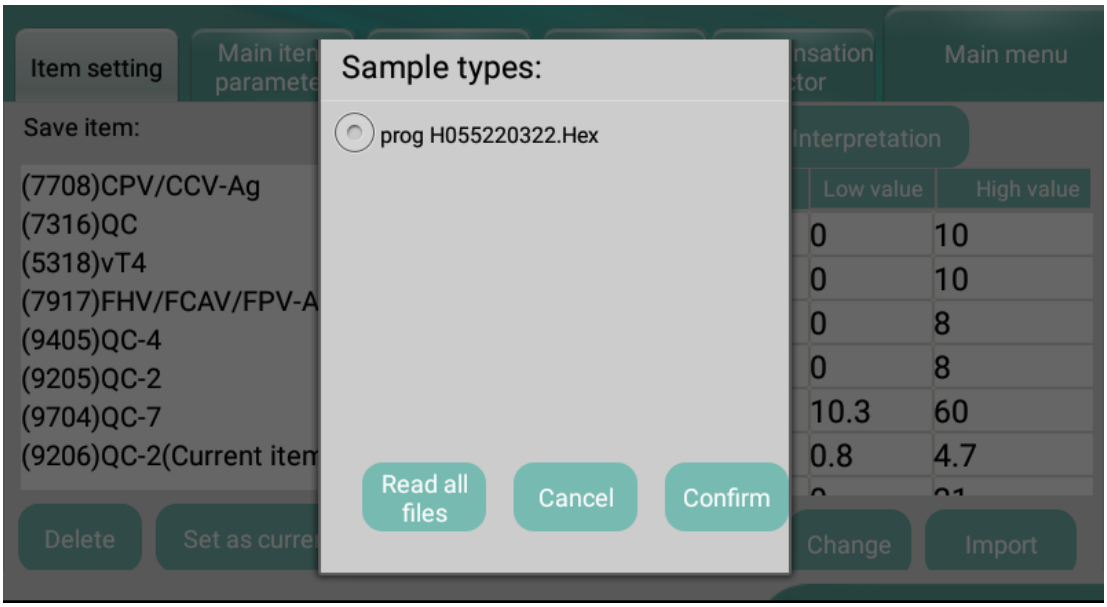


Figure 4.5.4

◆Download ID chip from Cloud

Note: The analyser must be connected to the Wi-Fi before downloading the ID chip. Please see Section IV Software Introduction for instructions on how to connect to the Internet.

◆Download ID chip before test

Click ‘Download ID chip’ on the Item setting page. Input the Lot No. of the test kit (4 digit number). Click confirm to download as shown in Figure 4.5.5.

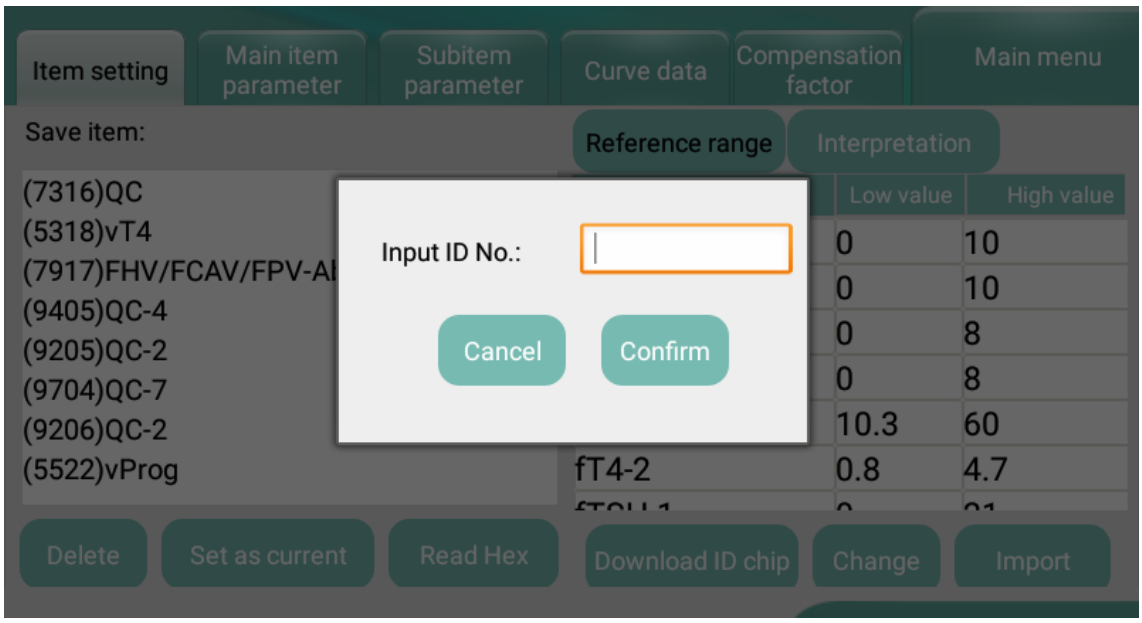


Figure 4.5.5

◆Download ID chip while testing (analyser must be connected to Wi-Fi)

If the ID chip has never been read before, when the test kit is inserted into the analyser to test, the analyser will show ‘Barcode doesn’t match any items in analyser’.

Press ‘Download ID chip’ and it will show the barcode number of the test kit.

Click confirm to download and new item information will save on the right window as shown in Figure 4.5.6.

Select the item and press ‘Set as current’ and test. Alternatively, press cancel and retest again. The new items that have just been downloaded will match the test kit.

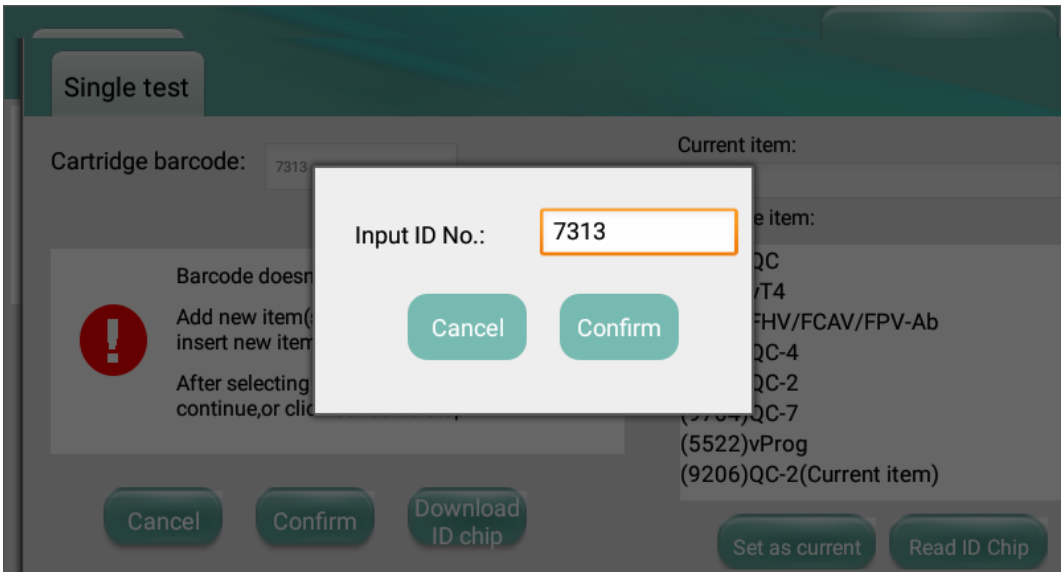


Figure 4.5.6

4. ID chip parameter

Click ‘Main item parameter’ to enter the ID chip parameter page. You can check detailed information about the current Lot of ID chip. See Figure 4.5.7.

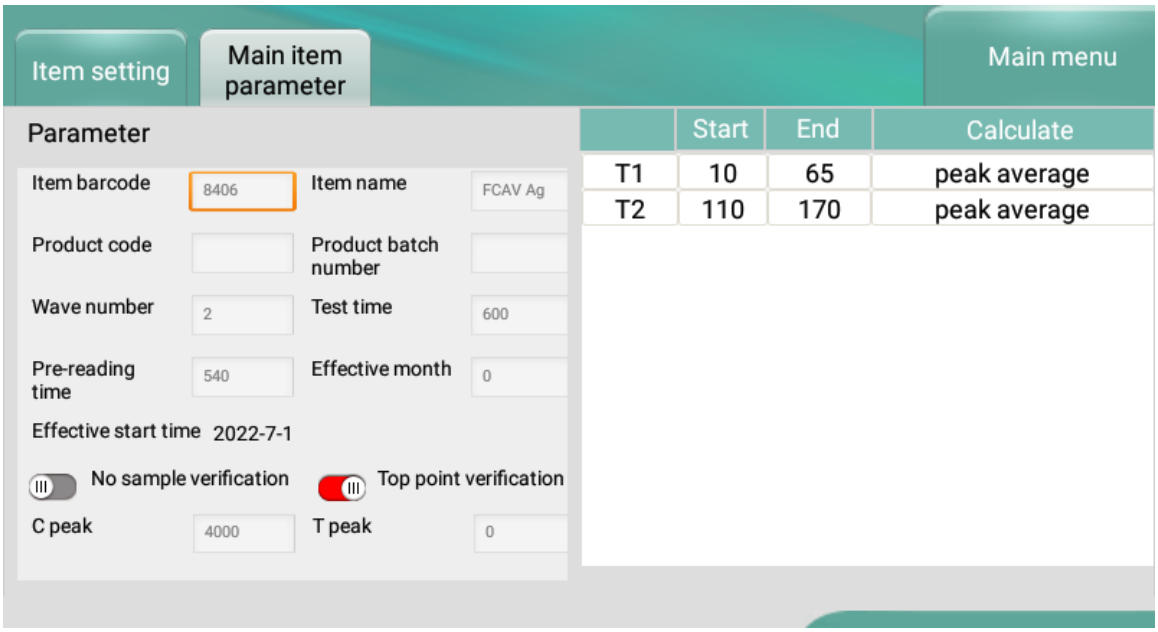


Figure 4.5.7

IV.6 Settings

In the [Setting] screen, Institution Information, Test Setting, LIS Setting, System Setting and Software Version can be viewed.

4.6.1 About and Institution
4.6.1.1 About Analyser
The analyser model and name will show on About page as shown in Figure 4.6.1.
The software version information is also shown on the About page. Users can upgrade the software online after connecting to the Wi-Fi. Users can also transfer software onto a USB device and then insert it into the USB port of the analyser. The software will automatically update after detecting the USB.

Version:
Version + Release Version Number + Version Build

Caution:

- Do not change the upgrade document name or change the file.
- Please ensure that the power is on during the upgrade before restart.
- The analyser supports FAT32 format USB device. It does not support NTFS format.
- Other settings like reference of reagent items will be reset to the original settings.
- Do not uninstall the software apk, the analyser will be reset by uninstalling the software.

4.6.1.2 Institution Information will be shown on the title of print paper.

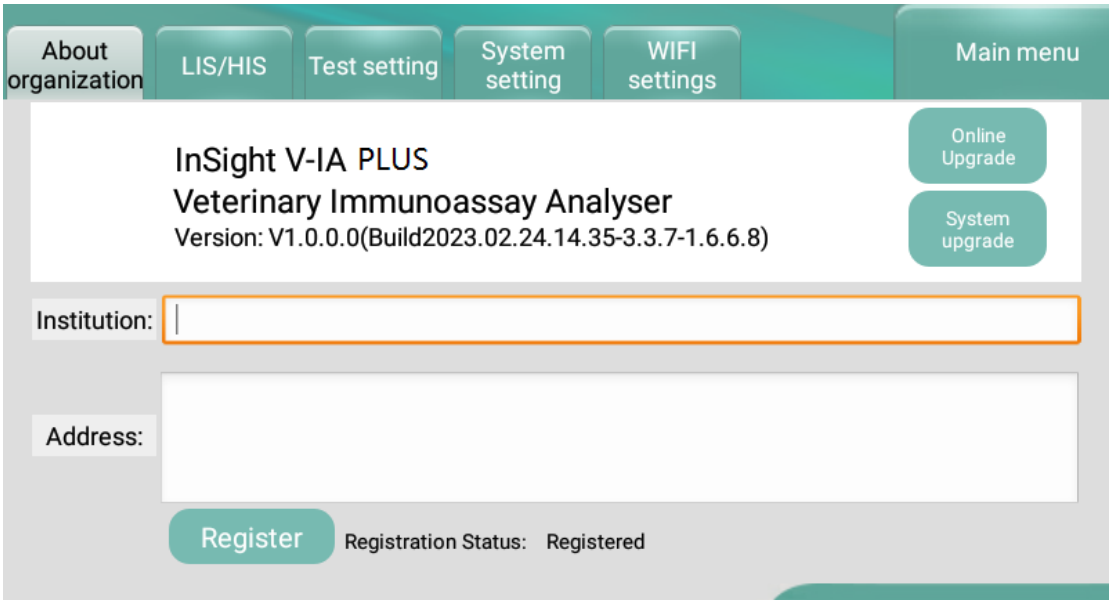


Figure 4.6.1

There are two methods of changing institution information:

◆ **Change the institution directly:**

1. Press the ‘Institution’ space.
2. Input the Institution name, press ‘Done’ and it will be saved automatically.

◆ **Change the institution by Register**

1. Press the [Register] button to enter the register page.

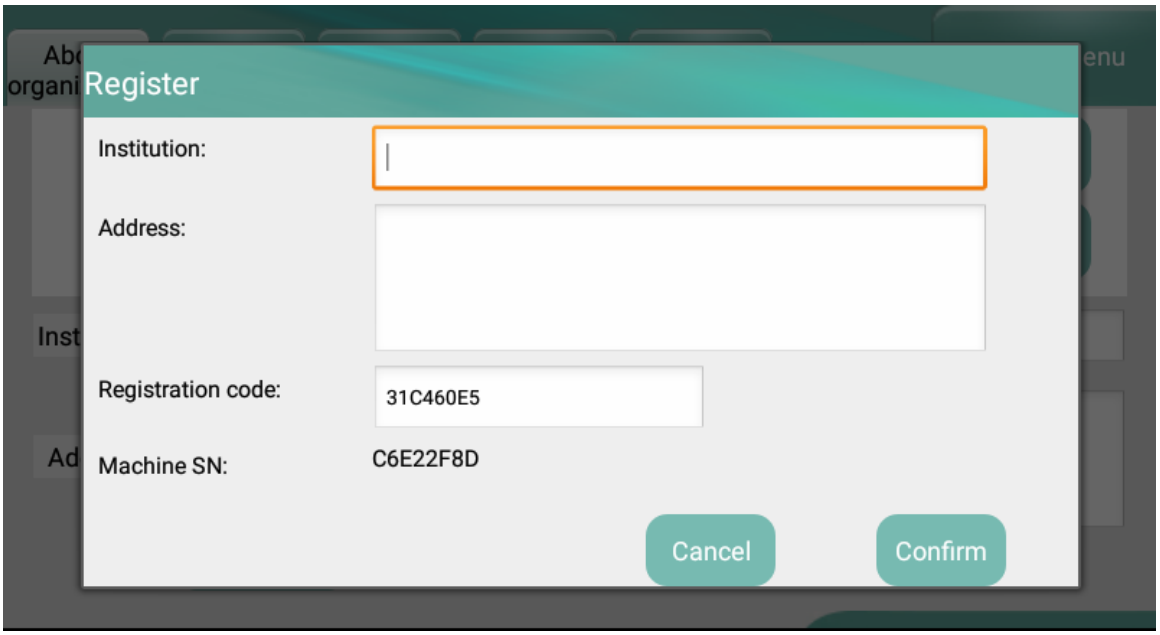


Figure 4.6.1.1

2. Input the institution. The following shows an example of registering the institution ‘Woodley Equipment Company Ltd’. The registration code will be created by the analyser and shown in the ‘Registration code’ space.

3. If analyser does not show the registration code, please contact Woodley Equipment Company. Provide the following information, [Serial number] and [Institution] on the register page (see the sample of Figure 4.6.1.3).
   Caution: Please provide the correct word, include uppercase and lowercase letters. The serial number on the register page consists of 8 characters. Do not use the SN (serial number) on the back label of analyser.
4. Key in the [registration code] from Woodley after providing the information of [Serial number] and [institution]. Please note the case of the letters (see Figure 4.6.1.4).
5. Restart the analyser to make the change.

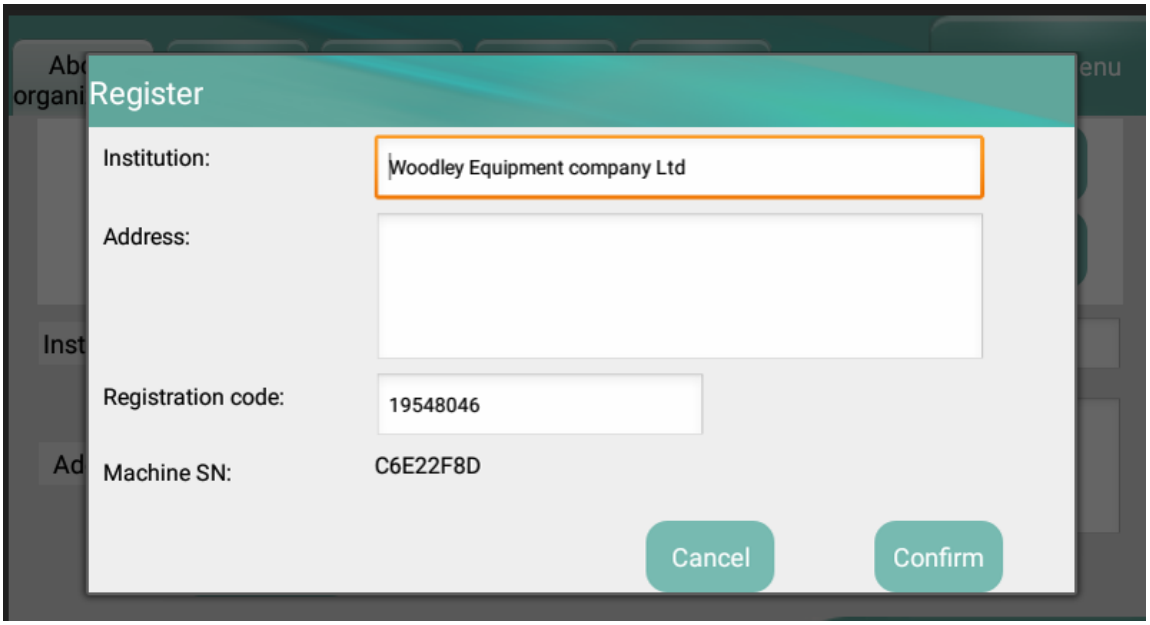


Figure 4.6.1.2

4.6.1.3 Software update

◆Upgrade the software by USB device

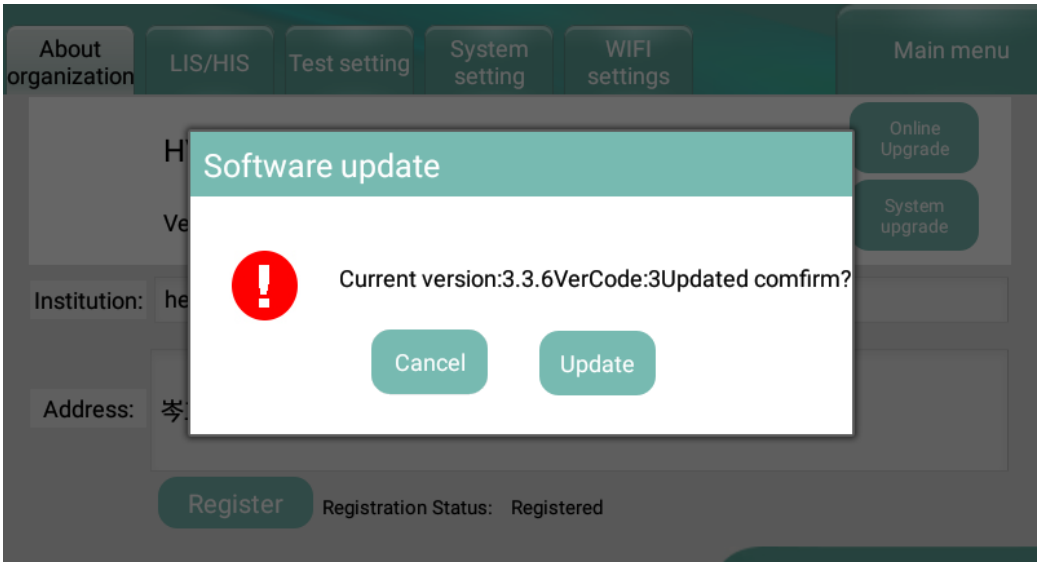


Figure 4.6.1.3

Transfer the upgrade software onto the root directory of the USB device. Insert the USB device into the USB port of the analyser.
Click ‘System upgrade’. If there is a new version on the USB device, the analyser will show a message asking you to confirm the software update. Press confirm and the analyser will install the software update. See Figure 4.6.1.3.

◆Upgrade the software by USB device on Android system
Insert the USB and the software will automatically update after detecting the USB device.
Click ⊗ button on the Menu page, exit the software to Android system. Click the button  on the left to enter the menu of the Android program. See Section IV.7 Android Setting.
Open XAPK Installer, select the new version of FCFluorescenceWoodley.apk.
The software will restart when it has finished installing. See Figure 4.6.1.4.

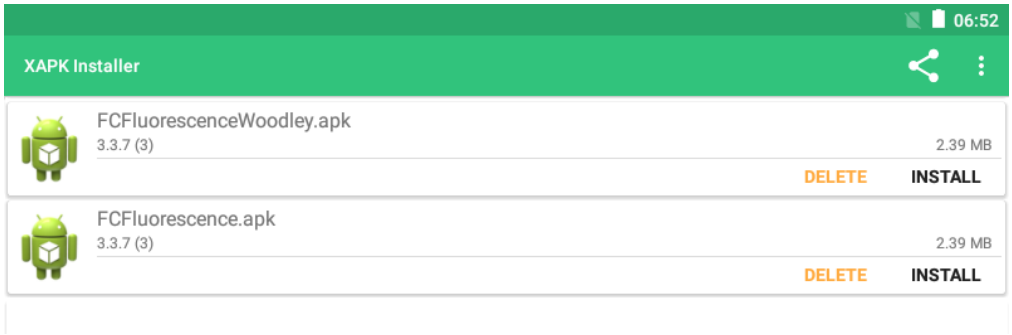


Figure 4.6.1.4

◆Upgrade the software online
The analyser will ask if you need to upgrade once it has connected to the network after being powered on. Click confirm to upgrade. See Figure 4.6.1.5.

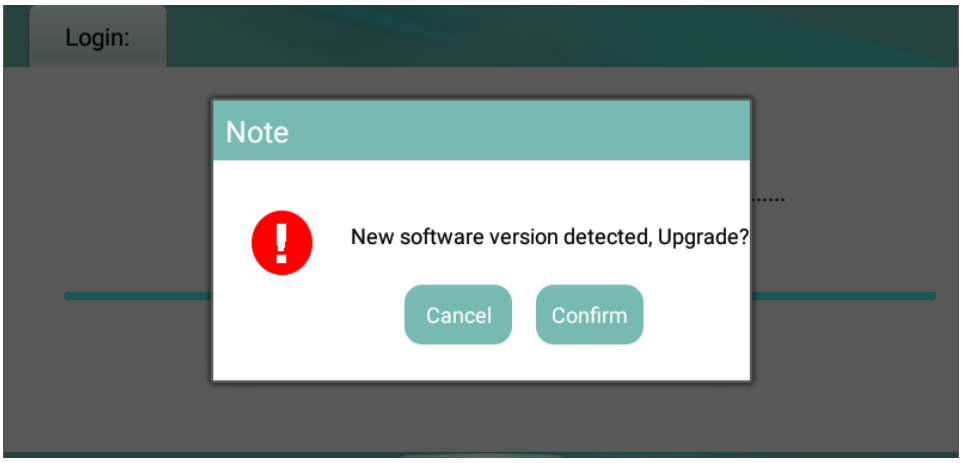


Figure 4.6.1.5

Click ‘Online Upgrade’ on the About page. The analyser will check if there is a new software version to upgrade. See Figure 4.6.1.6.

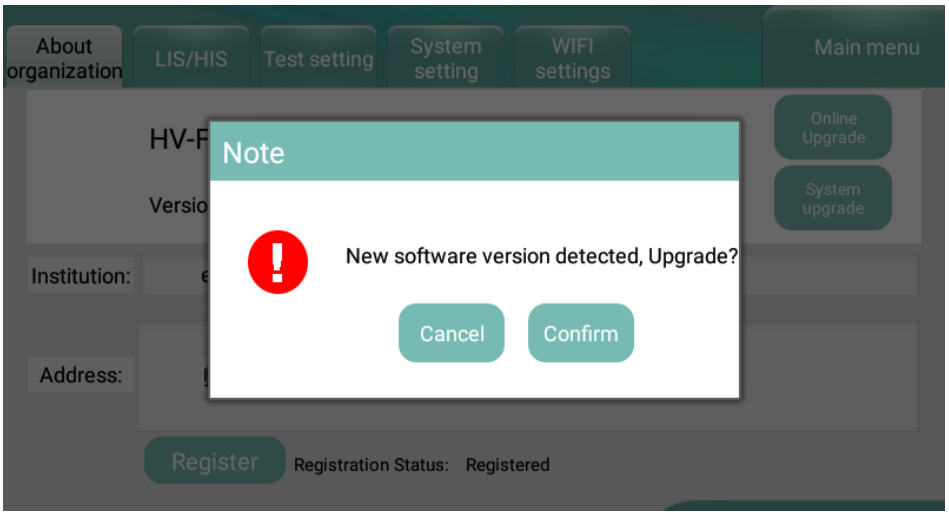


Figure 4.6.1.6

Caution:

- Do not change the upgrade document name or change the file. The name of the install program APK is FCFluorescenceWoodley.apk.
- Please ensure that the power is on during the upgrade before restart.
- The analyser supports FAT32 format USB device. It does not support NTFS format.
- Other settings like Reference of reagent items will be reset to their original settings.
- **Do not uninstall the software APK, the analyser will be reset by uninstalling the software.**

4.6.3 Test Setting

1. In Figure 4.6.3, the sample code, sample ID length and alignment can be set in [Test Setting] screen.
2. Switch on 'Auto print' to automatically print results after analysis.

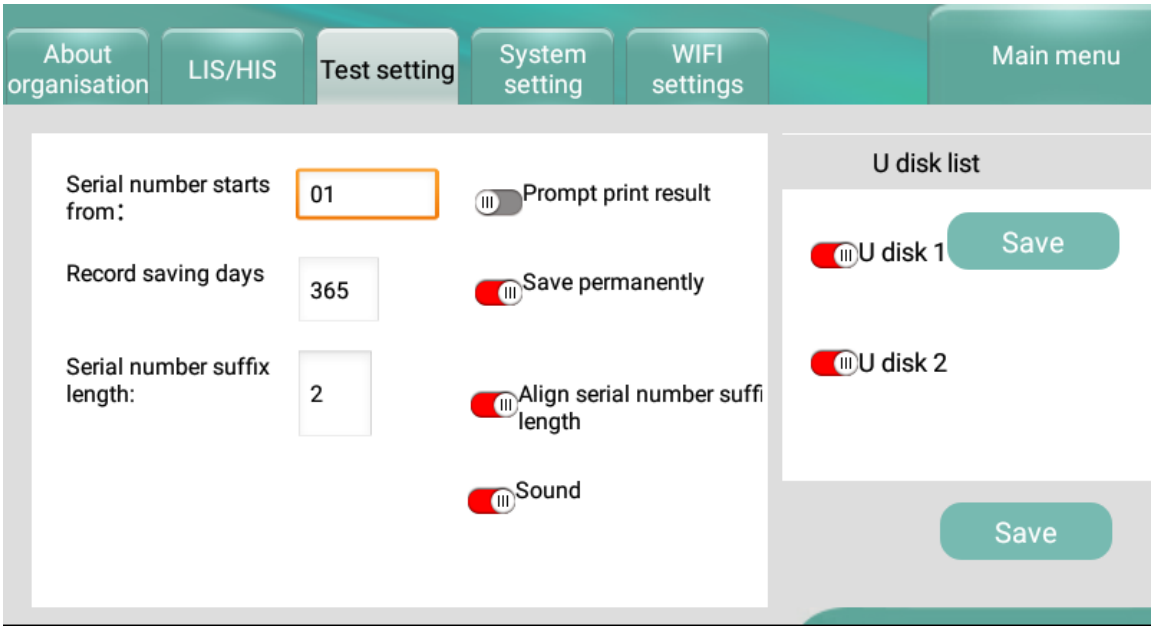
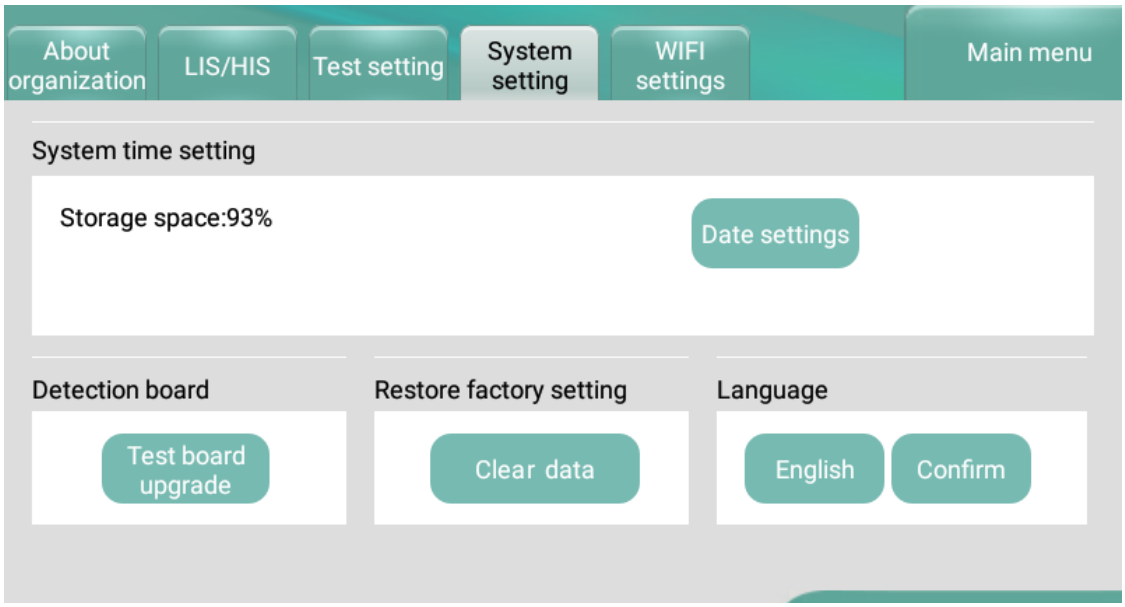


Figure 4.6.3

3. Switch on/off [Sound] to turn on/off the beep of the analyser.
4. User can switch on ‘Auto test’, the system will automatically start analysis once the system detects any test cartridge has been inserted.

4.6.4 System

1. To set the analyser time and date, click [Date Setting] in Android System. Restart the analyser save the change.
2. To reset the analyser, press [clear Data] button.
   Caution: All data will be deleted and the analyser will be reset.
3. Select the language and save to change the software language. Restart analyser to save the change.



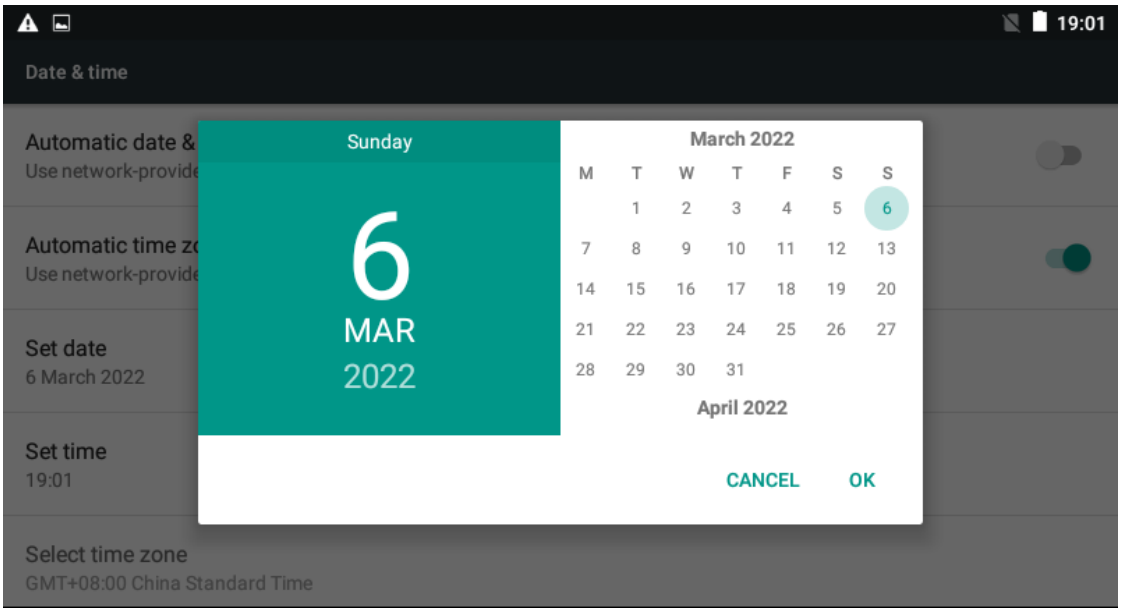


Figure 4.6.4

4.6.5 Wi-Fi Settings

Click the ‘Wi-Fi settings’ tab. Click ‘On’, select the SSID and input the password to connect to your chosen Wi-Fi network. See Figure 4.6.5.

Note: If you are connecting the analyser to Wi-Fi via a router, insert the ethernet cable into the analyser and it will automatically connect to the Wi-Fi.

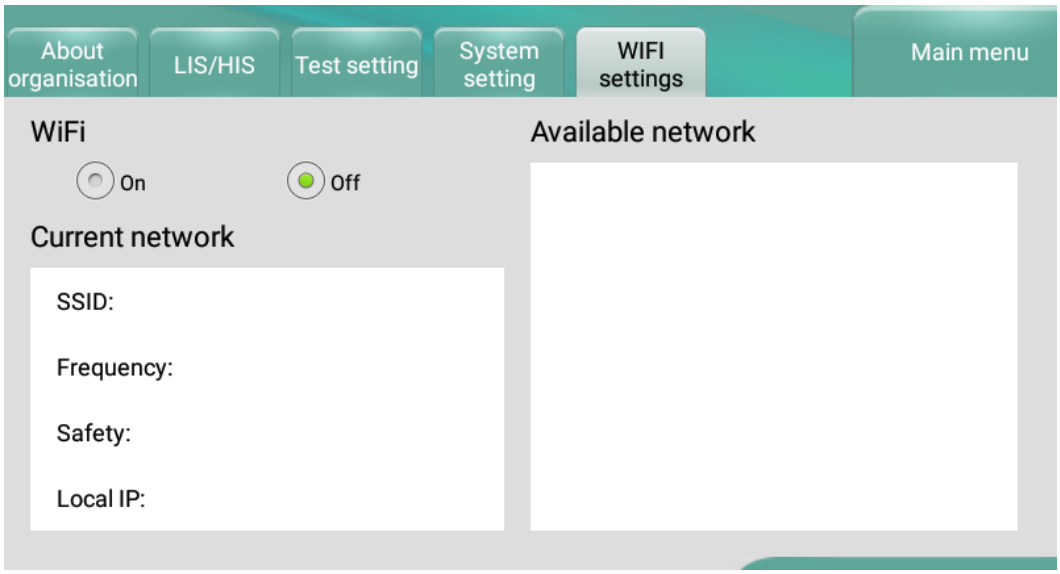


Figure 4.6.5

IV.7 Android Setting

Click the ⊗ button on the menu page and exit the software to Android system. See Figure 4.7.1.1.

Click the button on the left to enter the menu of the Android system. See Figure 4.7.1.2.

Click Settings to enter the settings page of the Android system.

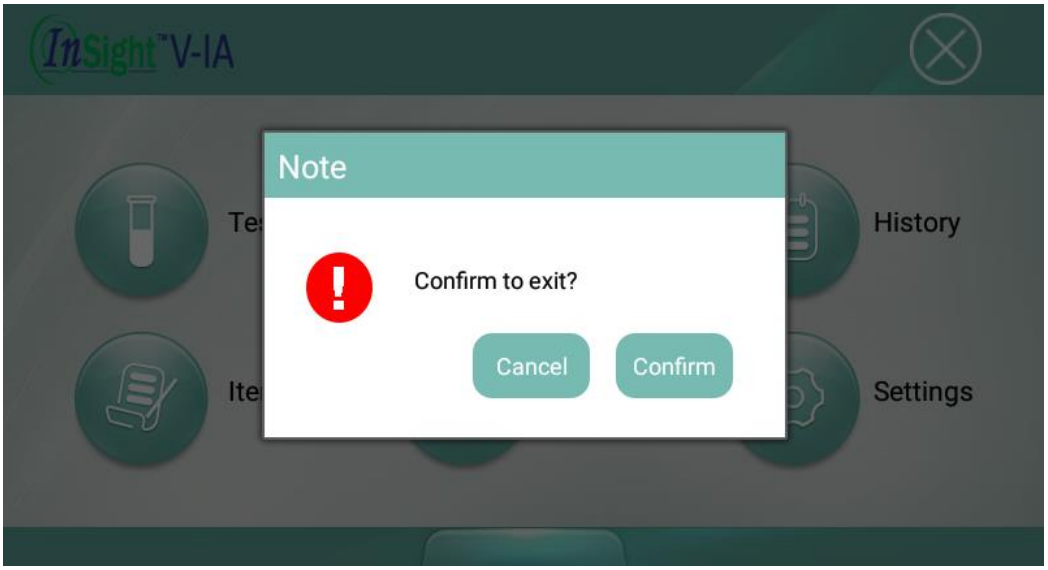


Figure 4.7.1.1

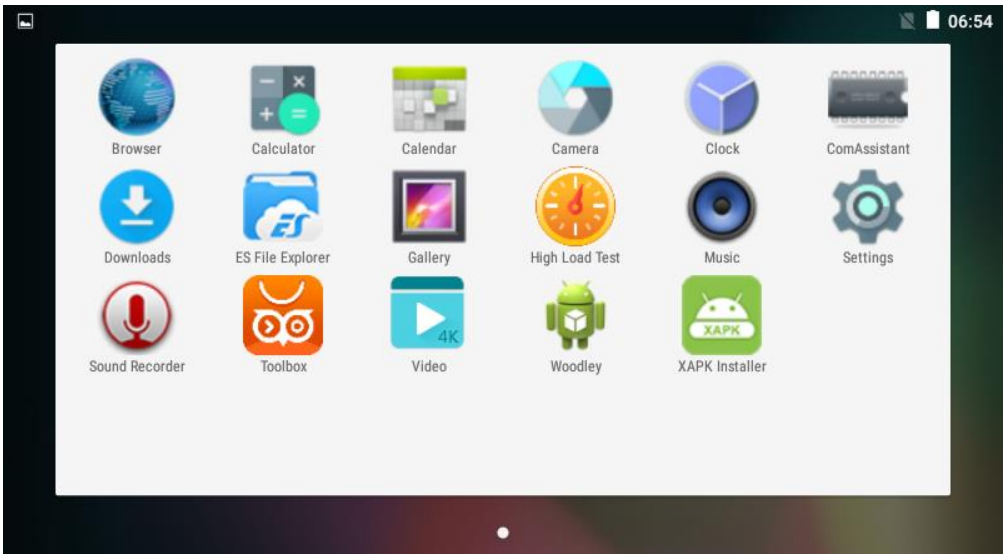
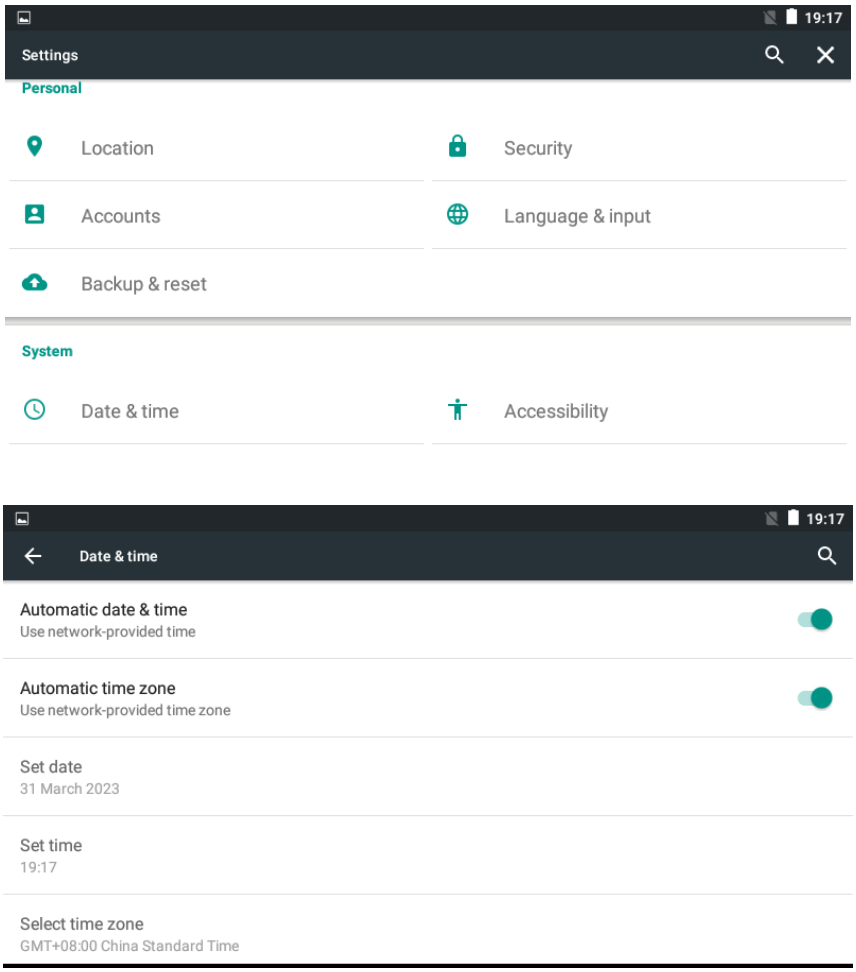


Figure 4.7.1.2

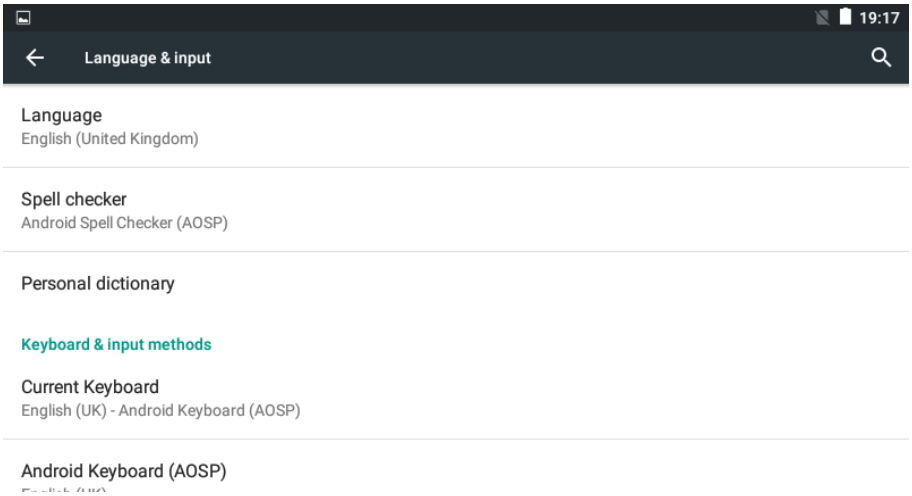
4.7.1 Android date setting

Click Date & Time to set the date and time. The date and time will automatically change when connected to the network.



4.7.2 Android languages and input setting

Only Android system languages can be set here. For software languages, please see Section IV.6 Point 4.6.4 System.



Caution: Please restart the analyser after changing the settings on the Android system to save the change.

V Quality Control

Quality control can be carried out by testing the InSight V-IA quality control cartridges. Use InSight V-IA Veterinary Immunoassay Analyser to determine the concentration of the test cartridges. There are 3 control level cartridges – low, mid and high.

Continue to use the analyser if the quality control result falls within the target value range provided. If results fall outside the target value, repeat the QC with a fresh QC cartridge and if results fall again outside the target value, stop using the analyser and contact Woodley Equipment Company.

5.1 QC test

1. ID chip information can be saved by pressing ‘Read ID card’. You can press ‘USB’ to upgrade the QC reference Range by USB that contains the newest upgrade progress.
2. Put the QC card in the cartridge holder and press ‘Test’. The analyser will give the QC result, check the value is within the set QC reference range (see Figure 5.1.1).
3. Print the QC test result.

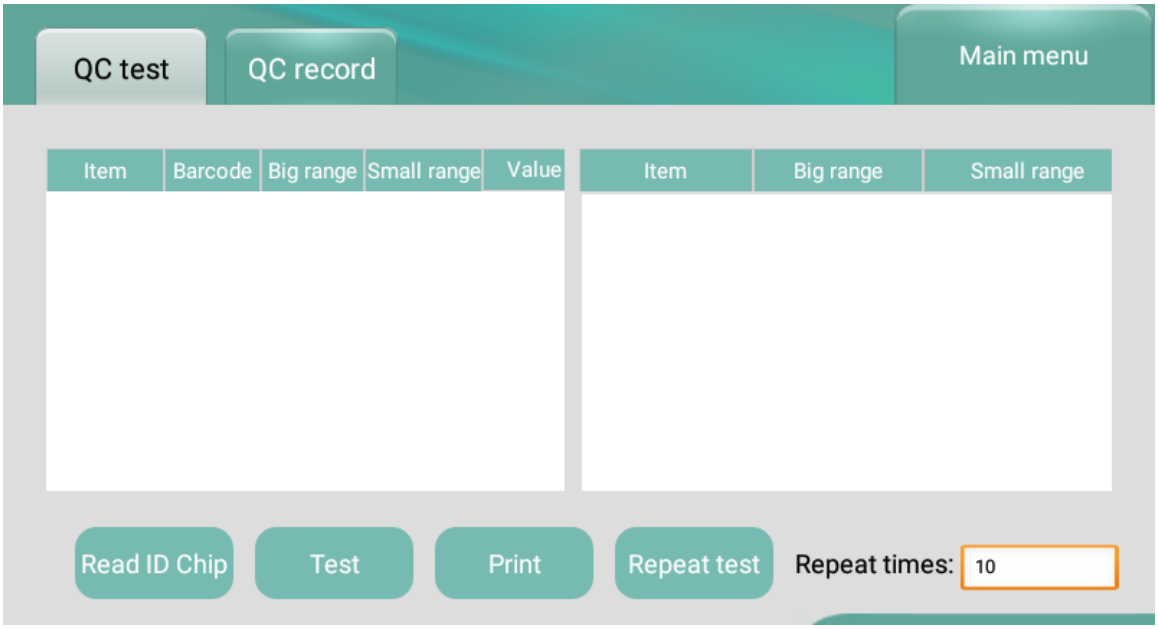


Figure 5.1.1

5.2 QC record

You can search, print, export or delete the test record on this page (see Figure 5.1.2).

1. Press search to find the record during the setting time.
2. Print the QC test record by pressing ‘Print’.
3. Export the QC test record to USB device by pressing ‘Export’.
4. Delete the QC test record by pressing ‘Delete’.

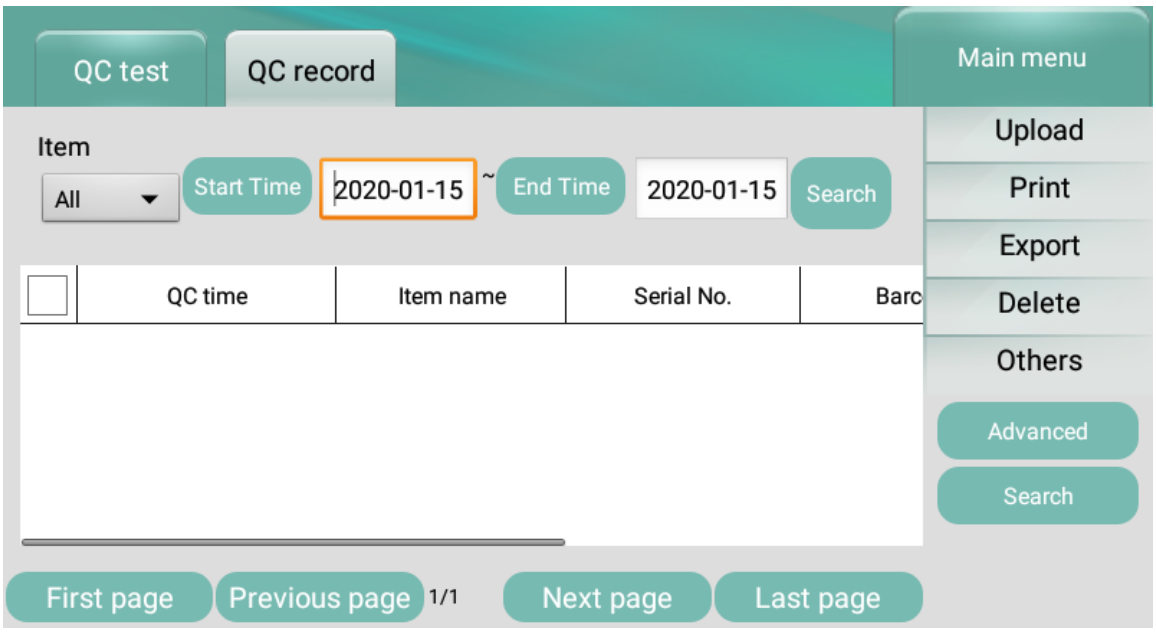

QC test
QC record
Main menu
Item
All
Start Time
2020-01-15
~
End Time
2020-01-15
Search
QC time
Item name
Serial No.
Barc
Upload
Print
Export
Delete
Others
Advanced
Search
First page
Previous page
1/1
Next page
Last page

Figure 5.1.2

VI Further Product Information

VI.1 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.

VI.2 Contraindications

No.

VI.3 Warnings, Precautions and Limitations

Notices: For veterinary use only.

VI.3.1 Precautions

Warnings:

- To avoid electrical overload and potential fire risk, do not use a multi-socket adapter.
- Use a 12V/5A power adapter and an effectively grounded outlet.
- A damaged, non-original or modified power cord is a potential fire and electric shock risk. Do not bend or roll the power cord so as to avoid a fire or electric shock.
- If the analyser is damaged or has been dropped, please contact Woodley Equipment Company.
- Do not use this analyser in unstable environments such as on unlevel or vibrating surfaces etc.
- Do not place the analyser in a location where it is difficult to disconnect the device.
- Water or debris should not enter the analyser. If this occurs, please contact Woodley Equipment Company.

Notices:

- Turn off the power and unplug the analyser before moving it.
- When moving the analyser, try to avoid vibration.
- Desktops supporting the analyser should be able to hold at least 2.5kg.
- The analyser should be placed carefully, with at least 5cm space all around to ensure good air circulation.
- The analyser should not be covered to prevent the air vents from being blocked.
- Avoid using the analyser in the following conditions:
  Areas in direct sunlight
  Areas with high humidity
  Environments close to water

Areas with vibration and inclination
Areas with a strong magnetic field
Areas with electromagnetic waves and surge voltage
Storage sites of chemicals
Areas exposed to corrosive gas

- The analyser should not be near radios, televisions, printers, fax machines or any other sources of interference.
- The analyser cannot be used near instruments such as microwaves and any other high-frequency equipment in order to avoid electromagnetic interference that may cause errors in operation.

VI.3.2 Precautions When in Use

Warnings:

- Read the instructions carefully before starting the analyser.
- Set the test parameters under the guidance of trained personnel.
- When handling potentially hazardous substances such as animal samples or reagents, protective gloves or other protective measures are required.

Notices:

- Ensure the analyser is in normal running status before use.
- Ensure that all cables are properly connected and secure.
- Read the operation precautions before use.
- Only trained personnel should operate the analyser.
- After testing, confirm that the test cartridge has been removed.

VI.3.3 Precautions for Faults, Storage and Inspection

Warnings

- If abnormal conditions occur (for example, if there is smoke or a burning smell), stop using the analyser immediately. Turn off the power immediately, unplug the analyser and contact Woodley Equipment Company.
- Other than service personnel from Woodley Equipment Company and service personnel authorised by Woodley Equipment Company, other users are not permitted to remove, modify or repair the analyser. Any violation will invalidate the analyser warranty. Woodley Equipment Company will not bear any responsibility for possible personal injury, fire risk or electric shocks caused by violation of the warranty.

VI.3.4 Limitation Requirements for Toxic and Hazardous Substances

This analyser 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 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%.

VII Maintenance and Care

VII.1 Daily Maintenance and Care

VII.1.1 Maintenance

- The users must check the analyser and accessories regularly.
- Ensure the power outlet is connected correctly.
- Check if the power cord is damaged or broken by visual inspection. If the power cord is faulty, please replace.
- Before cleaning the analyser, turn off the power and disconnect the power cord.
- When cleaning the analyser, wipe using a damp, lint free cloth. The following solutions can be used for cleaning: alcohol or mild detergent.

⚠ **Notices:**

Please do not use gasoline, diluent or other organic solvents to clean the analyser.

VII.2 Troubleshooting – Common Faults and Solutions

Error	Reason	Solution
The analyser won't switch on	Power switch is not turned on	Turn on the switch.
	The power adapter is not connected	Reconnect the power adapter.
The screen doesn't display	Screen has broken	Please contact Woodley Equipment Company.
	Problem with operating system	Please contact Woodley Equipment Company.
Software system failure	Fault of operating system	Please contact Woodley Equipment Company.
	Please record the complete error code and message and then contact Woodley Equipment Company.	
Abnormal sound during testing	The cartridge holder may be stuck	Turn off the Analyser and turn it on again. Let it reset itself and repeat the test.
	Mechanical motion failure	Please contact Woodley Equipment Company.
Analyser stops during testing	Power interruption	Restart the analyser and retest.
	Communication failure	Restart the analyser and retest.
	Please contact Woodley Equipment Company.	

VII.3 Error Codes

A list of common faults is shown in the table below - if an issue not listed occurs, please contact Woodley Equipment Company.

12.3.1 Error Codes

Code	Error	Reason
1	Problem reading the barcode and ID Chip	The current test kit cannot find any ID chip information in the analyser. It could be misreading the ID chip or the analyser has read the test kit barcode incorrectly. Reinsert the ID chip.
2	Barcode not recognised	Cannot read the barcode of the test kit. Check barcode.
3	C line abnormal/test invalid	It means the test is invalid and that the control line on the test kit is invalid. There are a few reasons why the test may be invalid including reagent operation and analyser. Retest with new cartridge and contact Woodley Equipment Company.
4	The test results are not accurate	Check sample quality and procedure and repeat test. Contact Woodley Equipment Company.
5	Abnormal communication	It means there is error on the communication between hardware in the analyser. Restart the analyser.
6	Printer has no paper	There is no paper in printer or the printer cannot detect the paper. Check printer module and replace paper.
7	Please select data	No data has been selected before operation.
8	Time cannot be saved	The button cell battery of the mainboard in the analyser is no longer working. Contact Woodley Equipment Company.
9	Touch screen is unresponsive	If the touch point does not match the arrow pointer, please calibrate the screen on the settings page. If the touch screen is broken, please contact Woodley Equipment Company.
10	The screen does not switch on	Hardware broken or power supply problem. Contact Woodley Equipment Company.
11	Cartridge holder does not move	Hardware broken or power supply problem. Contact Woodley Equipment Company.
12	Analyser stopped during testing	Hardware broken or power supply problem. Contact Woodley Equipment Company.
13	QC out of range	Hardware broken or the analyser needs to be calibrated. Retest with a new QC and contact Woodley Equipment Company.

12.3.2 Error Codes Troubleshooting.
Here are the common ways to deal with the problem with common reasons. If the problem is not solved by following the instructions below, please contact Woodley Equipment Company.

	Error	Related Issue	Possible Cause	Troubleshooting
1	Problem reading the barcode and ID Chip	Operation	ID Chip does not match cartridge barcode	If corresponding ID Chip not used press cancel to abort this test. If "confirm" is pressed, the analyser will automatically select the first item of the left and right as the matching ID chip information by default. If the ID information does not match the reagent card, an incorrect test result will appear.
2	Barcode not recognised	Operation	Reagent cartridge in the wrong way, unable to read barcode	Insert the reagent cartridge in the correct direction, holding the non-slip position upward.
		Operation	The reagent cartridge is not inserted correctly	Ensure the reagent cartridge is inserted into the cartridge holder correctly.
		Reagent	Reagent cartridge barcode unclear / contaminated	Barcode contaminated or damaged. Repeat with new cartridge.
		Analyser	The analyser cannot read the barcode	Contact Woodley Equipment Technical Support.
		Operation	The reagent cartridge is not inserted to the bottom	Make sure the reagent cartridge is inserted into the innermost contact slot.
		Analyser	The analyser sensor could not detect the reagent cartridge	Contact Woodley Equipment Technical Support.
	C line abnormal / Test invalid	Operation	The reagent cartridge was placed in the analyser too long after the sample was added	Reagent cartridge inserted too long after the normal detection time, indicating abnormal c-line.
		Operation	The reaction time after adding the reagent cartridge was too short.	If the test is conducted in instant test mode, there is not enough time for the reaction after the reagent cartridge is added to the sample and the test result is invalid, showing abnormal c-line. Please ensure the correct test method is used.

3		Operation	The reagent cartridge is contaminated	Verify that the sample type is correct. If the reagent cartridge or sample is taken out of the refrigerator, please leave to warm to room temperature before testing.
		Operation	Wrong buffer tube is used	Confirm the buffer tube is from the correct kit. Check buffer volume is correct. Check correct sample volume used.
		Operation	Wrong blood tube type	Please refer to the instructions to use the correct anticoagulant tube. Different anticoagulants may affect the test.
		Sample	The sample well on the cartridge is red	Sample haemolysed, repeat with a fresh sample.
		Sample	The blood sample was contaminated	Ensure that blood samples are collected, transported and stored in accordance with the requirements. Check for sample interference.
		Reagent	Reagent cartridge failure	The reagent cartridge is damaged. Check temperature of reagents.
		Analyser	Analyser not detecting C-line	Use the QC standard cartridge to confirm the test value of the analyser. If it exceeds the standard cartridge detection range, please contact Woodley Equipment Company.
4	The test results are not accurate	Operation	The reagent cartridge was placed in the analyser too long after the sample was added	There was a delay inserting the test cartridge into the analyser.
		Operation	The reaction time after adding the reagent cartridge was too short	If tested in instant mode, the sample was not incubated for long enough and the test result is abnormal. Please repeat and follow the correct test method.
		Operation	The corresponding batch chip card was not read correctly	Please ensure correct ID chip is used.
		Operation	Incorrect buffer used	Please confirm the protocol for running a test in the reagent instructions. Check the buffer tube is from the correct kit. Buffer tubes of different tests should not be mixed. Is the buffer sample quantity correct? Is the buffer well mixed?
		Operation	Incorrect sample type selected	Please refer to the instructions to select the correct sample type for the test.

		Operation	Wrong blood tube type used	Please refer to the instructions to use the correct anticoagulant tube. Different anticoagulants may affect the test.
		Sample	The sample well on the cartridge is red	Sample haemolysed, repeat test with a fresh sample.
		Sample	The blood sample was contaminated	Ensure that blood samples are collected, transported and stored in accordance with the requirements. Check for sample interference.
		Reagent	Reagent cartridge failure	The reagent cartridge packaging is damaged. Check storage temperature of reagents.
		Analyser	Analyser not detecting reaction	Use the QC standard cartridge to confirm the test value of the instrument. If it exceeds the standard cartridge detection range, please contact Woodley Equipment Company.
5	Abnormal communicati on	Install	The power is not connected properly	Plug in the power and check the indicator light of the adapter.
		Install	Wrong adapter used	Replace with the original adapter (12V/5A).
		Hardware	The cable between two PCBA board	The cable is loose or has been damaged between detection board and system board.
		Hardware	Detection board damaged	Detection board damaged by wrong power adaptor.
		Software	Software failure	Update to the new version of the software with a USB flash drive.
6	Printer has no paper	Install	No printer paper	Replace thermal paper.
		Install	Incorrect printer paper used	Ensure thermal printer paper used and installed correctly.
		Analyser	Printer failure	Contact Woodley Equipment Technical Support.
7	Please select data	Operation	Data was not selected when printing	Click √ the square inside the box to the left of the historical data.
8	Time cannot be saved	Analyser	Circuit board failure	Contact Woodley Equipment Technical Support.
9	Touch screen is unresponsive	Analyser	Touch screen needs recalibrating	Operate the cursor through an external mouse via the USB interface, click on the main menu-Settings-System Settings-Screen Calibration.
		Analyser	Touch screen failure	Contact Woodley Equipment Technical Support
10	The screen does not switch on	Analyser	The power is not connected properly	Plug in the power and check the indicator light of the adapter.
		Analyser	The wrong adapter was used	Replace with the original adapter (12V/5A).
		Analyser	Screen failure	Contact Woodley Equipment Technical Support.

11	Cartridge holder does not move	Install	Cartridge holder needs resetting	Restart the analyser self-check reset, confirm whether the self-check is normal.
		Analyser	Cartridge stuck in holder	Contact Woodley Equipment Technical Support.
		Analyser	Motor failure	Contact Woodley Equipment Technical Support.
12	Analyser stopped during testing	Analyser	Power connection failure	Check power connection and restart analyser.
		Analyser	Analyser failure	Contact Woodley Equipment Technical Support.
13	QC out of range	Analyser	QC expired	Repeat with fresh QC.
		Analyser	QC stored incorrectly	Check QC storage conditions meet requirements. Repeat test with fresh QC.
		Analyser	Analyser issue	Stop using the analyser and contact Woodley Equipment Technical Support.

VIII Interpretation of Medical Device Label

InSight V-IA® PLUS		Product trademark of InSight V-IA Plus	
	Biological Hazards. Avoid direct contact.		Attention, please refer to attached document.
ID CARD	ID chip	DC 12V	Direct current input of 12V
LIS	Serial interface	COM	Serial interface
LAN	Network interface	USB	USB interface
OFF/ON	Power switch	TF CARD	Micro SD card

VIX Transportation Conditions

VIX.1 Transportation

1. The InSight V-IA Plus should be transported in the original packaging.
2. Avoid severe vibration during loading and transportation.
3. Keep away from damp.
4. Do not transport with flammable and corrosive substances.

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