WOODLEY
EQUIPMENT COMPANY LTD.

InSight™ V-IA

Veterinary Immunoassay Analyser

User Manual

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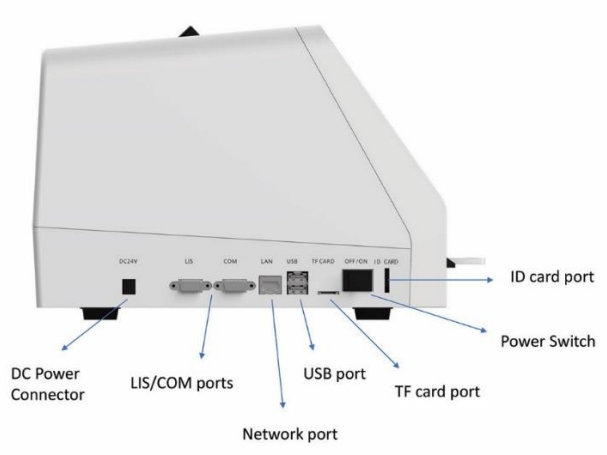
I Product Introduction

I.1 Analyser Structure



I.2 Intended Use

InSight V-IA 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 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 (4)
  2. Ethernet interface (1)
  3. Double serial port
     3.1 Serial Port 1: Automatic LIS uploading
     3.2 Serial Port 2: PC adjustment
- Display: 24-bit true colour LCD screen
- Specimen Type: Whole blood, serum and plasma
- Power Supply: Host Input DC: 24V 2.5A
  Adaptor Input: 100-240VAC; 50/60Hz
- Standard curve
  Storage Method: ID card with 4K memory
- Dimensions: 213 (W) x 303 (D) x 210 (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%

II Contents

No.	Accessories	Quantity	Remark
1	Power Adaptor	1	Included
2	Instruction 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.

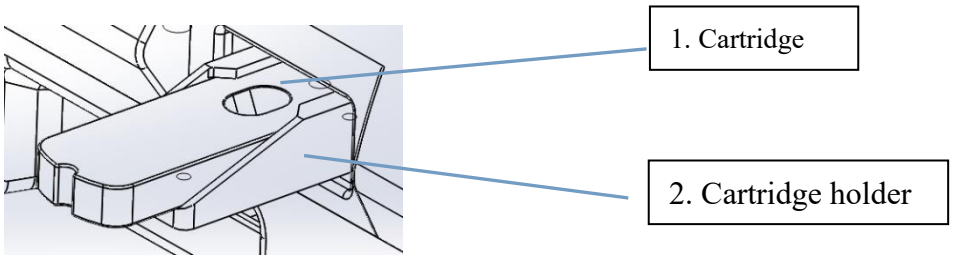
III.2 Instructions

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 specimen (follow cartridge operating instructions) onto 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

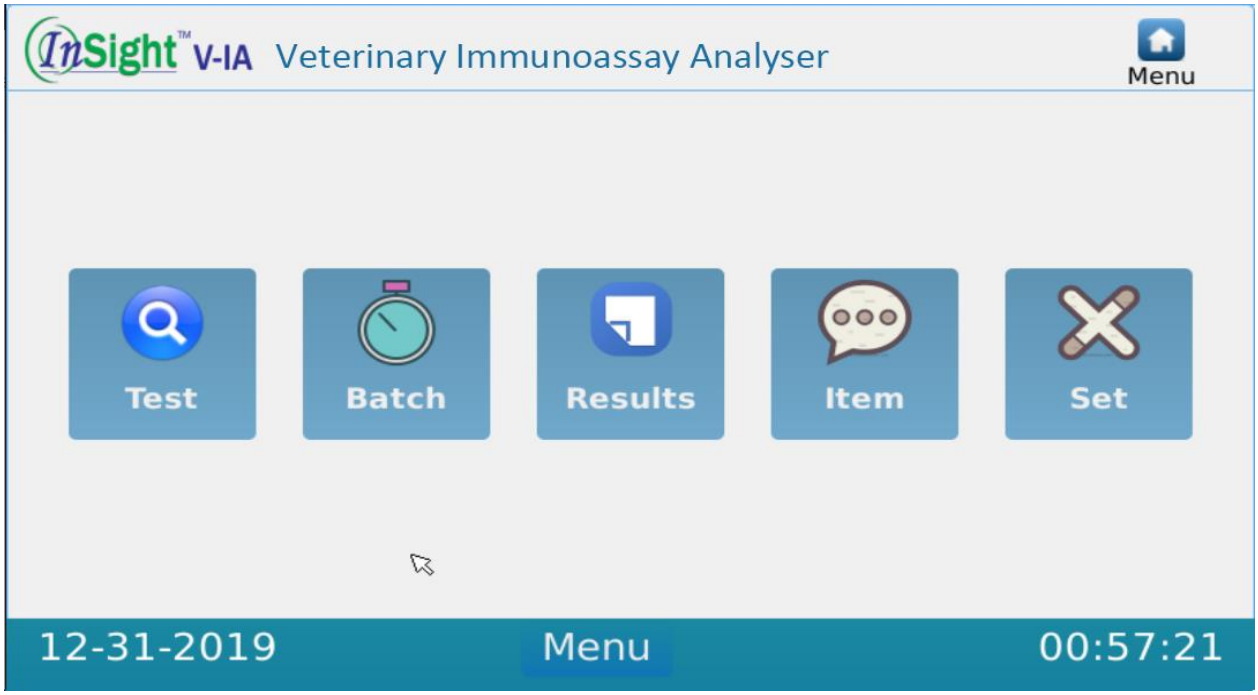


Figure 4.1

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 Testing], [History Record], [Parameter] and [Setting]. Select an icon to enter into the corresponding screen.

IV.2 Testing Interface

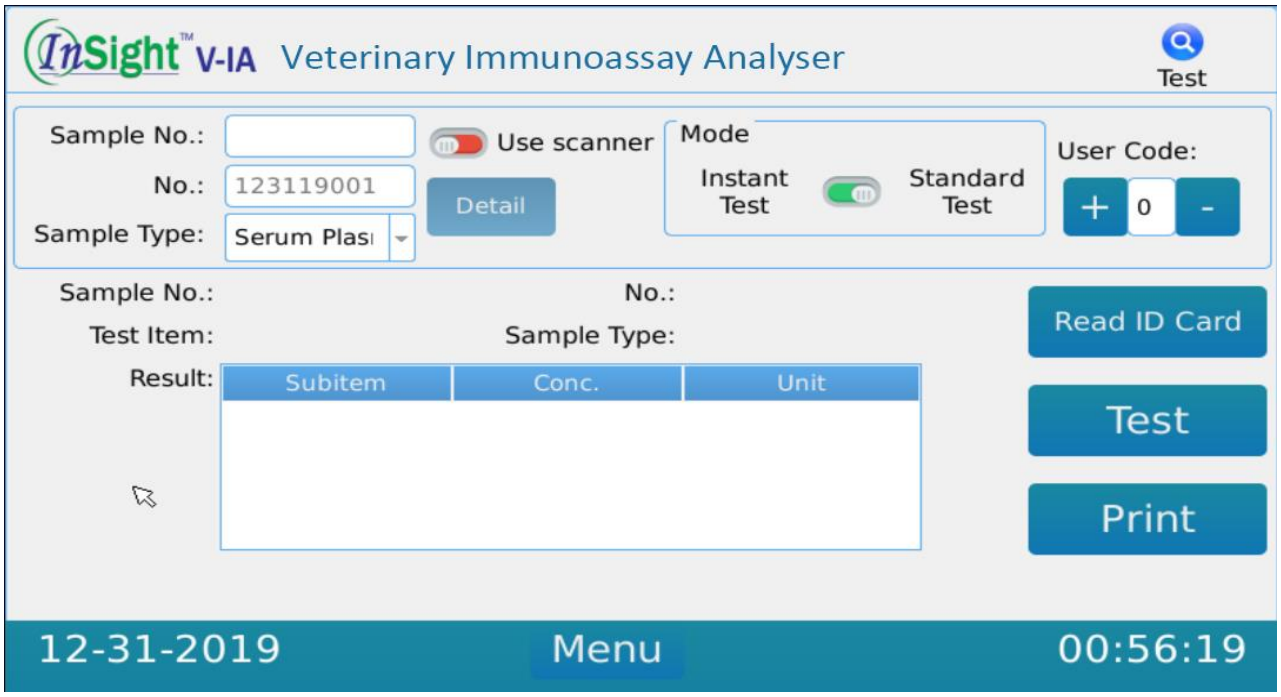


Figure 4.2.1

1. Click [Test] option on the main home screen and Figure 4.2.1 will display.
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).
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.
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 Testing

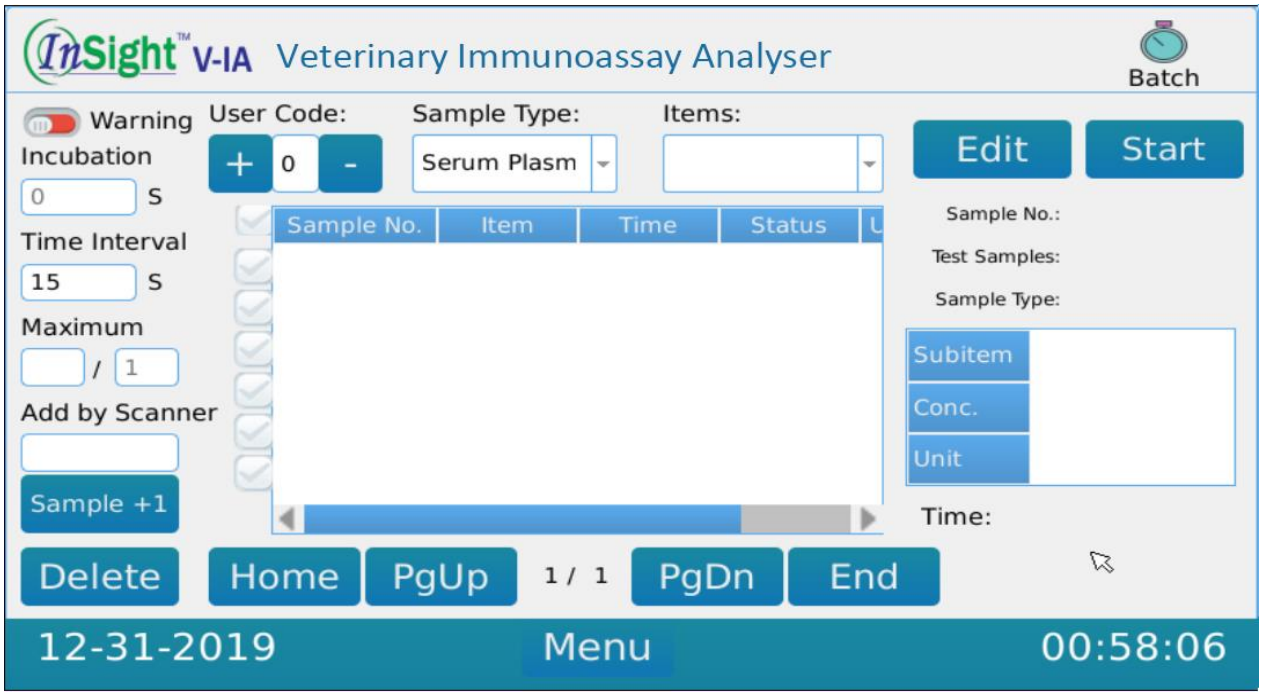


Figure 4.3.1

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.
4. After the specimen 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.

IV.4 Results Records Interface

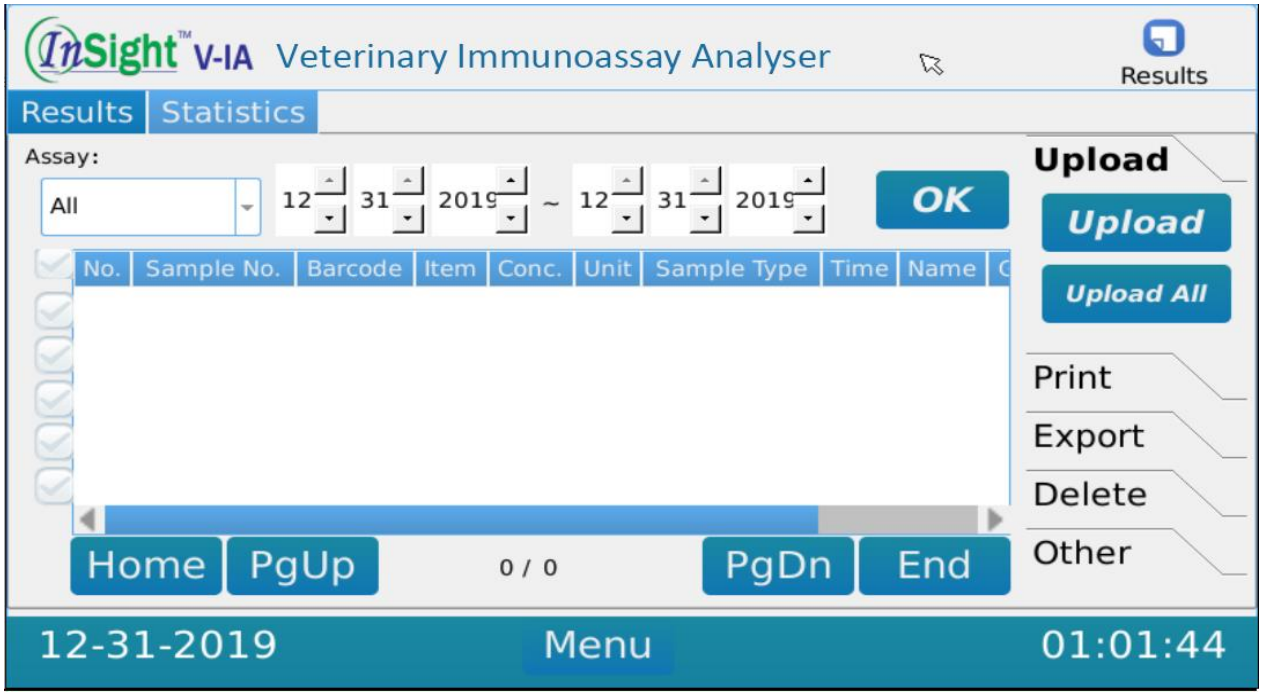


Figure 4.4.1

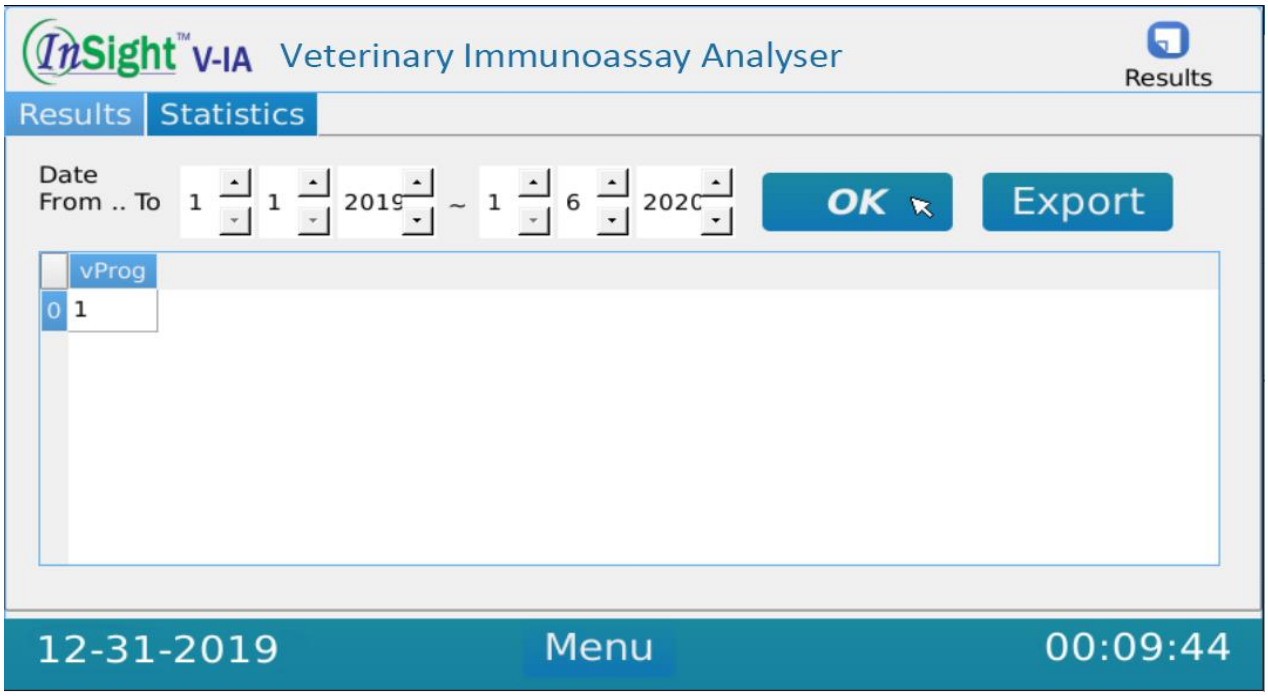


Figure 4.4.2

1. In the [Results] 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].
4. Select [Upload] in Figure 4.4.1 to upload the selected records or all records to the PNS.
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 [Statistics] in Figure 4.4.2. After selecting a date range, select [OK] to view the statistics of how many tests have run within the selected timeframe.

IV.5 Item Interface

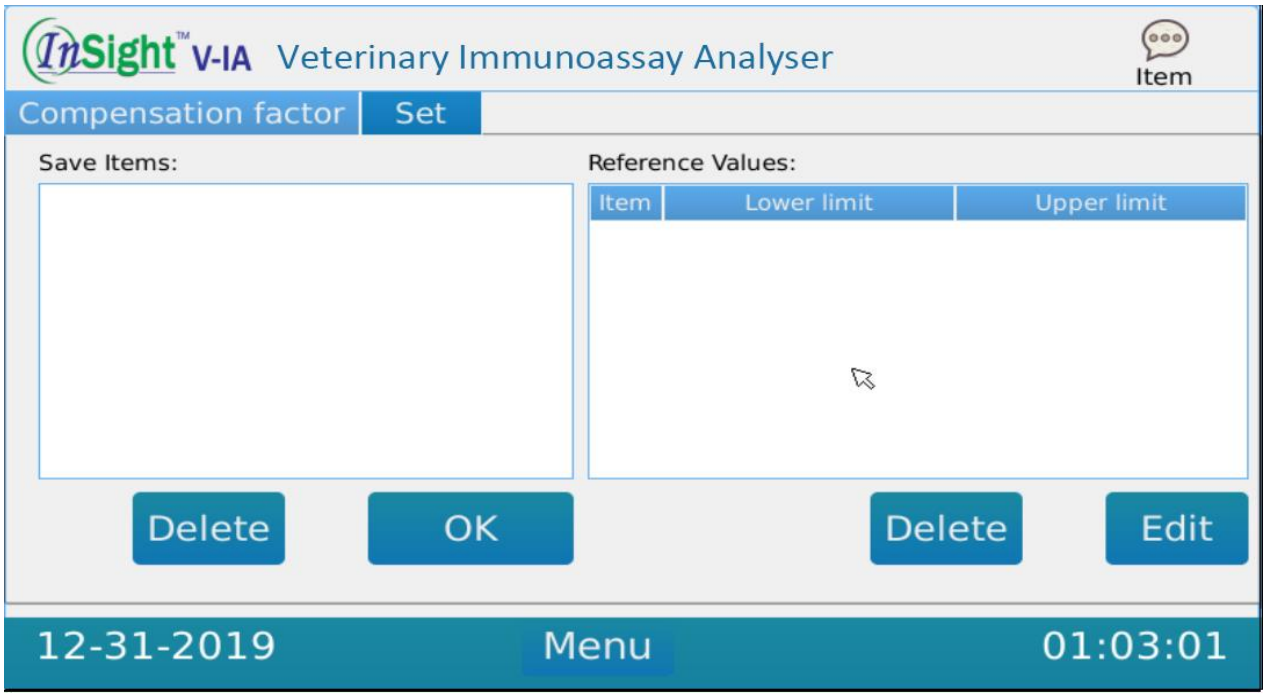


Figure 4.5.1

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

IV.6 Settings

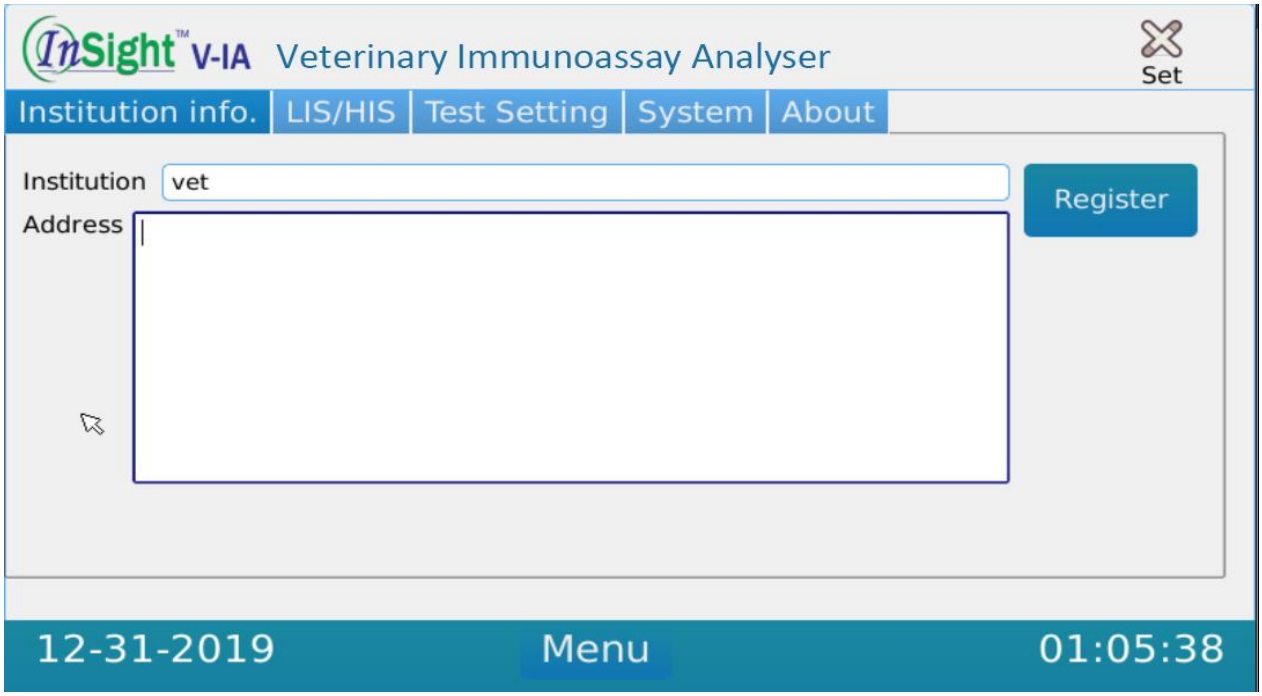


Figure 4.6.1

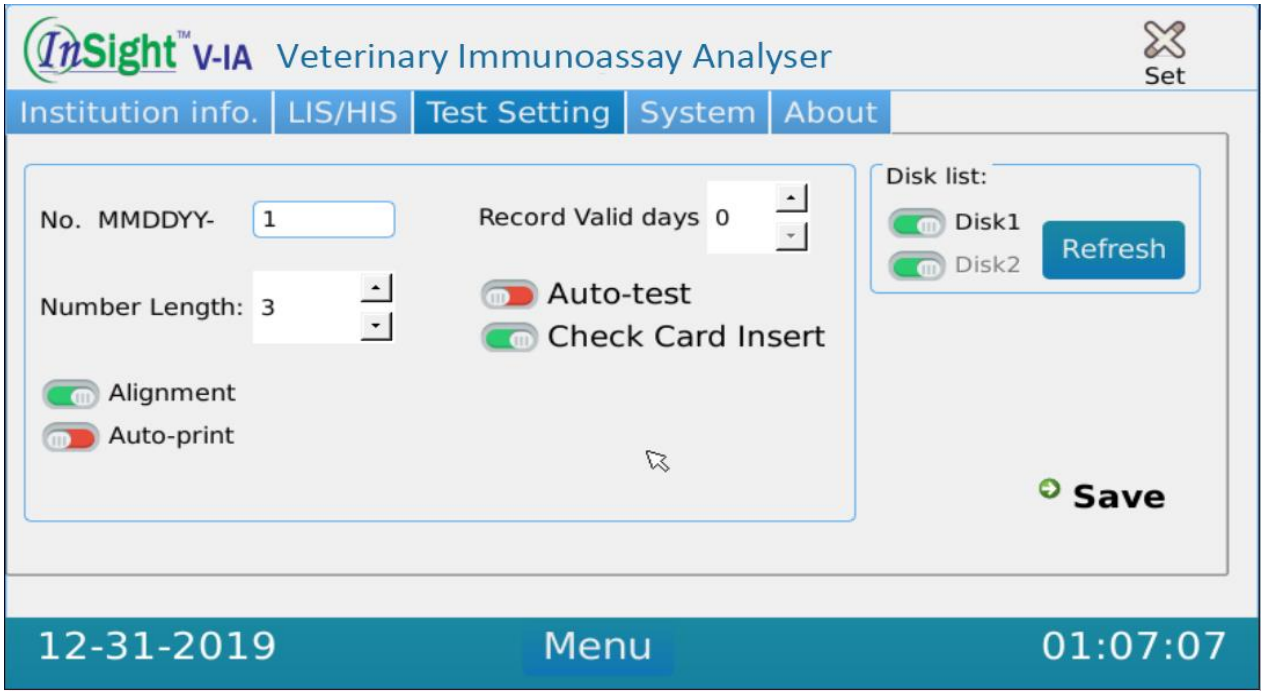


Figure 4.6.2

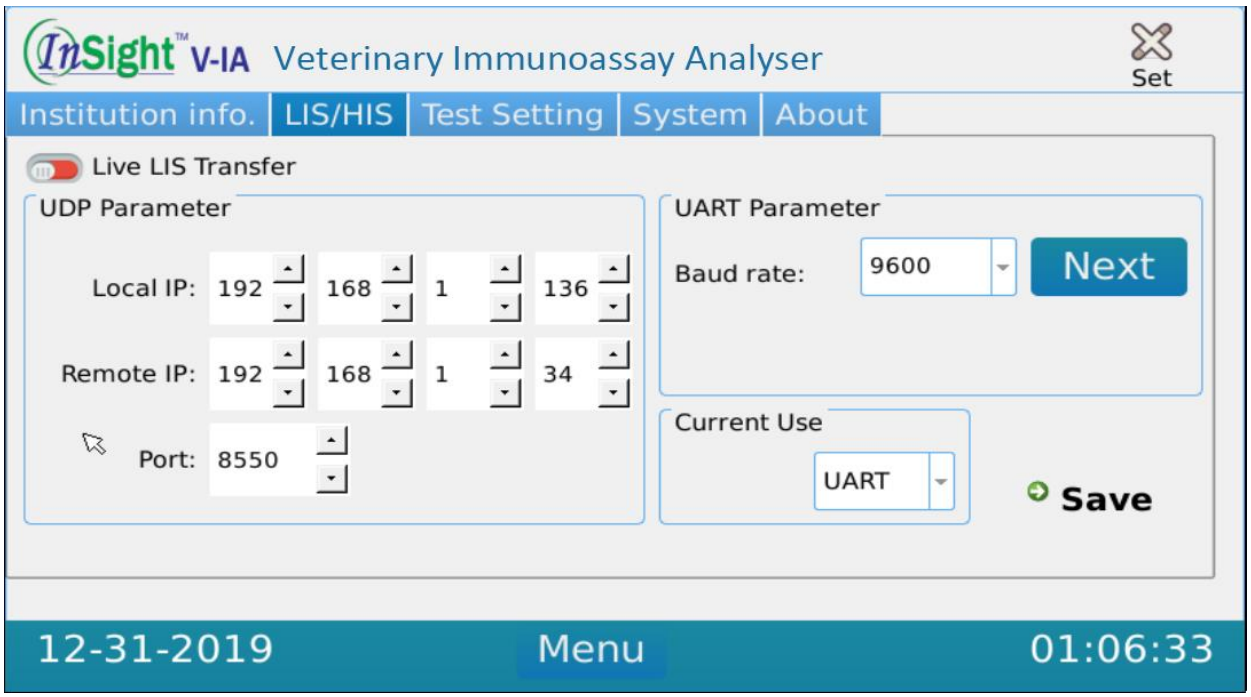


Figure 4.6.3

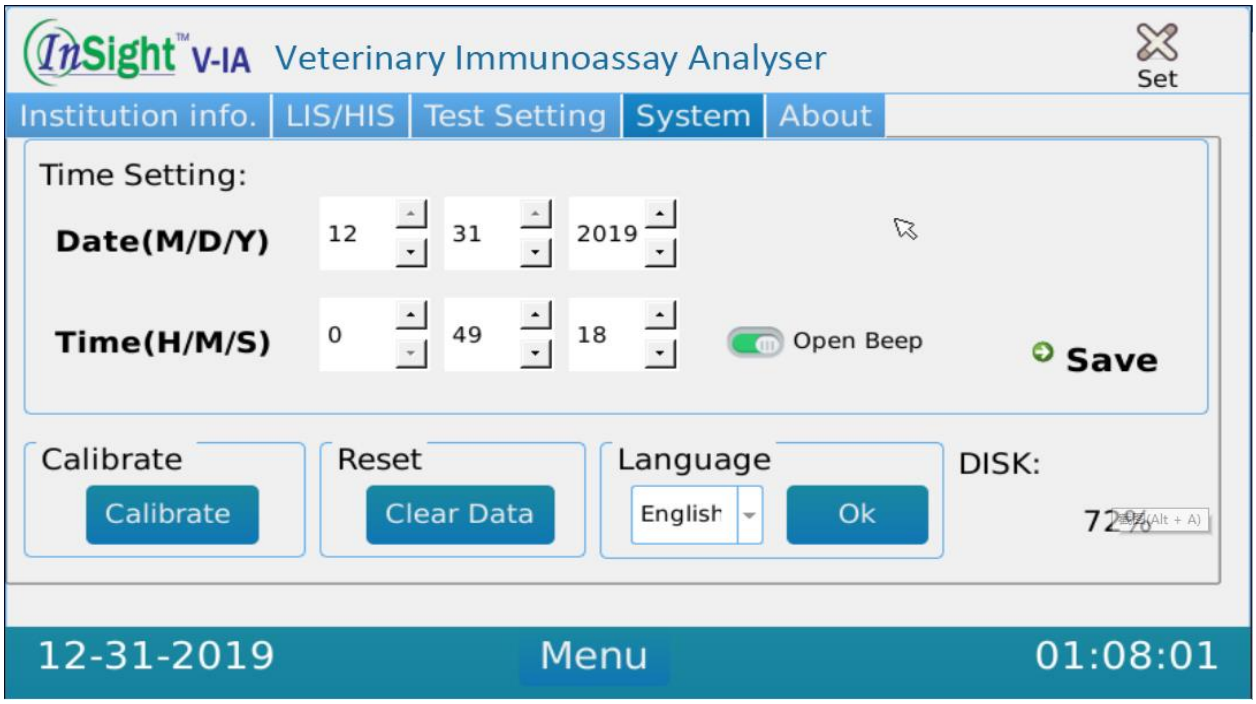


Figure 4.6.4

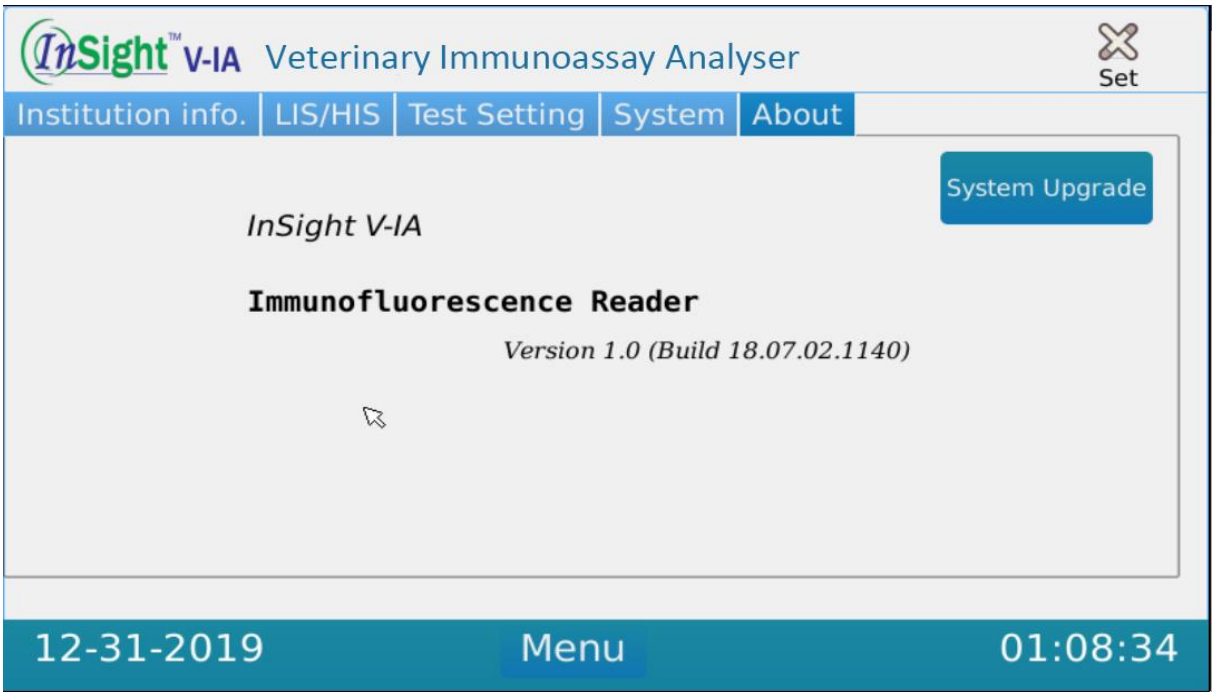


Figure 4.6.5

1. In the [Setting] screen, Institution Information, Test Setting, LIS Setting, System Setting and Software Version can be viewed.
2. In [Institution Information] of Figure 4.6.1, the user can add the clinic name and address.
3. In Figure 4.6.2, the sample code, sample ID length and alignment can be set in [Test Setting] screen.
4. Switch on ‘Auto print’ to automatically print results after analysis.
5. User can switch on ‘Auto test’, the system will automatically start analysis once the system detects any test cartridge has been inserted.
6. In Figure 4.6.3, to set the LIS settings, the user first needs to input the correct IP address. Please refer to document ‘LIS Protocol’ for detailed information.
7. To set the analyser time and date in Figure 4.6.4, select ‘save’.
8. To calibrate the screen, after clicking the calibrate button, touch the arrows that appear and follow the onscreen instructions. Restart the analyser for changes to be saved.
9. The user can save the upgrade software onto the USB disk and then insert into the USB port of the analyser. Switch on the analyser, the system will automatically update after detecting the USB.

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.

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 specimens 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 Precautions for Electromagnetic Compatibility

Warnings:

- The analyser is designed and tested according to the Class A equipment standard of GB 4824.
- Do not use this equipment near strong radiation sources such as unshielded RF sources. Otherwise, it may interfere with operation of the analyser.

Notices:

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

Table 1:

Electromagnetic Immunity			
Immunity test item	**Basic standard**	**Test value**	**Compliance criteria**
Electrostatic discharge (ESD)	GB/T 17626.2	Contact Discharge：±2kV, ±4kV Air Discharge：±2kV, ±4kV, ±8kV	B
Radiofrequency electromagnetic field	GB/T 17626.3	3V/m, 80MHz~2.0GHz, 80%AM	A
Pulse group	GB/T 17626.4	Power Cable: ±1kV(5/50ns,5kHz)	B
Surge	GB/T 17626.5	Cable to Ground: ±2kV Cable to Cable: ±1kV	B
Radiofrequency conduction	GB/T 17626.6	Power Cable: 3V/m, 150kHz~80MHz, 80%AM	A

Power frequency magnetic field	GB/T 17626.8	3A/m，50/60Hz	A
Voltage sag, interrupt	GB/T 17626.11	1 cycle 0%； 5 cycle 40%； 25 cycle 70%； 250 cycle 5%	B C C C
Performance judgement: A. Normal performance within the standard limiting value. B. Function or performance is temporarily reduced or lost but can be self-recovered. C. Function or performance is temporarily reduced or lost but requires operator intervention or system reset.			

Table 2：

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

VI.3.5 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.

	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	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 Customer Service.
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 Customer Service.
5	Abnormal communication	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 (24V/ 2.5a)
		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 (24V/ 2.5a)
		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		Product trademark of InSight V-IA	
	Biological Hazards. Avoid direct contact.		Attention, please refer to attached document.
		DC 12V	Direct current input of 12V
LIS	Serial interface 1	COM	Serial interface 2
LAN	Network interface	USB	USB interface
OFF/ON	Power switch	TF CARD	Micro SD card

VIX Transportation Conditions

VIX.1 Transportation

1. The InSight V-IA 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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