YHLO

VISION ESR Analyzer

Operation Manual

Released Software V1

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Customer service department

Manufacturer:	SHENZHEN YHLO BIOTECH CO., LTD.
Address:	Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, 518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Website:	www.szyhlo.com
E-mail Address:	service@szyhlo.com
Tel:	+86-755-26473359
Fax:	+86-755-26473319

EC –Representative

EC-Representative:	**Well Kang Limited**
Address:	The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland
Website:	www.CE-marking.eu
E-mail Address:	AuthRep@CE-marking.eu
Tel.:	+353(1)4433560
Fax:	+353(1)6864856

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c) the product is used in accordance with the instructions for use.

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Note

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Table of Contents

1. Introduction

1.1 Field of Application

VISION Pro (hereinafter referred to as the instrument) is a clinical diagnostic instrument for determining the sedimentation value of blood sample.

Used together with disposable EDTA tubes, the sample positions are 8, 16 and 32. During the test, the sample tube rack will be rotated 180° through a motor. After rotation the samples in the tube are fully mixed and placed vertically in a static way. Then the infrared emitter and receiver can scan the samples along the tubes. In this way, the blood cell sedimentation value can be collected and a dynamic sedimentation curve will be generated by the instrument software. And thus users can print the test results.

The instrument is operated in closed environment so that the operator is protected from the potential infection risk from the clinical samples. In the running process, the instrument is automatically performed.

1.2 Instrument Structure

The instrument consist of instrument shell, power supply, base, sample tube rack mounted on the supporter, mixing device and blood cell scanning device.

The instrument shell consists of two compartments: the upper shell, two side shell , the front shell, the back shell and the lower shell. The upper shell, the back shell and two side shell can be removed from the instrument so that it provides an easy access to maintenance.

The instrument is controlled by internal software which can save up to 5,000 test results. The software can control the instrument to perform the test. The power supply switch is located in the back of the instrument.

1.3 Operation Accessories

The accessories are included in the package list, please see the attachment for details and confirm. If any of the mentioned parts is lost or damaged, please contact YHLO technicians or local distributors.

1.4 Technical Data

Display	7 inch LCD touch Screen
Power Indicator	LED, Green
Operating system	Linux
Running Indicator	LED, Yellow
Fault Indicator	LED, Red
Test Speed	20 min/cycle
Model types	8 sample positions (VISION Pro-A) 16 sample positions (VISION Pro-B) 32 sample positions (VISION Pro-C)
Test Tube requirement	Any EDTA tube with a diameter of 12 / 13mm
Sample Volume	1.5ml~3.5ml
Scanning Device	Infrared emitting and receiving Device
Scanning Precision	0.25mm
Environment	See "*1.5 Installation Requirement*"
Printer	Internal thermal printer
Sample identification	Internal barcode scaner
Power Supply	100～240V, 50/60Hz
Input Power Supply	220VA
Fuse	250V 3A
Dimension	352mm X 365mm X325mm
Weight	11.5Kg/12Kg/12.5Kg

Table 1-1 Technical Data

1.5 Installation Requirement

Temperature Range	18℃~30℃
Moisture	40%RH~80%RH
Atmospheric Pressure	75.0kPa~106.0 k Pa
Power Supply	100-240V~, 50/60Hz
Miscellaneous	The instrument should be mounted in a well-ventilated room and connected with a three-wire power cord of good grounding performance. Avoid strong magnetic disturbance, keep away from explosion gas, dust, direct light and water immersion.

Table 1-2 Installation Requirements

2. Safety Instruction

2.1 Operator

The instrument is exclusively used for clinical diagnostics.

The operator is only limited to the YHLO engineers and personnel trained by the dealers.

2.2 Tube Requirement

Any EDTA plastic or glass tubes within a diameter of 12 to 13mm are applicable.

The scanner can scan the sample through the trademark and barcode labels attached to the tube. During scanning, please refer to the *Appendix II* and *III* to ensure test accuracy.

2.3 Sample

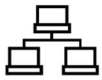
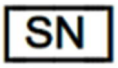
The sample is venous blood, and blood collection must avoid to produce bubbles.

The sample is anticoagulant whole blood, in which the ESR is affected by hematocrit (HCT), including the high cholesterol, hemolysis, and blood coagulation clot, etc. When the HCT increases, the ESR will not accelerate even though the erythrocyte accumulation increases. But when the HCT declines, the ESR will accelerate even though the erythrocyte accumulation is normal. Therefore, when the HCT is less than 35%, the ESR shall be calibrated according to its HCT.

Although the test is performed under closed environment, samples must be processed in accordance with Good Laboratory Practice (wear glove and uniform) because samples may contain hazardous materials that are detrimental to human health and environment. Disposable EDTA tubes should be handled as potentially infectious.

2.4 Symbol

You may find the following symbols on the analyzer.

Symbols	Meaning
	Attention! This symbol identifies a safety note. Ensure you understand the function before you operate.
	WARNING. Biological hazard.
	WARNING. Laser beam
	WARNING. Be careful with hand.
	Ethernet port
	USB port
SD	SD card slot
	Ordering code
	Serial number
	Consult instructions for use
	This symbol indicates that the system should be disposed of properly, in accordance with local, state, or federal laws. This symbol also indicates separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive
	Manufacturer information

2.5 Instrument Identification

Information listed on Identification Plate:

- Name of Instrument
- Model
- In vitro Diagnostics Instrument Marking
- Electrical Requirements and Maximum power consumption
- Serial Number
- Date of Manufacturing
- CE mark
- Registration Number
- Name of Manufacturer
- Address of Manufacturer

2.6 Emergency Power Switch

In case of emergency, cut off the electrical supply to the instrument by turning off the power switch located at the back of the instrument, or unplug the power outlet (The instrument should be placed in which the power switch is easy to access).

3. Instrument Installation

3.1 Preparation

3.1.1 Installation Personnel

The installation personnel are only limited to YHLO engineer or personnel authorized by customer service supplier.

3.1.2 Delivery, Storage and Unpacking

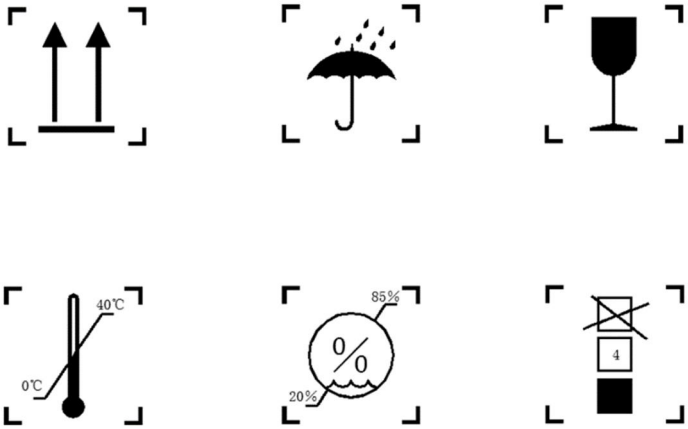


Fig. 3-1 Package Indicator

Please following the below requirements during delivery and storage.

- Do not store the instrument in humid environment. Keep away from direct sunlight and heating devices such as the heater.
- During delivery, the temperature should be kept between 0℃ to 40℃. Storage: 0～40℃，20～85%RH. Away from erosive gas and keep the storage space well ventilated.
- Do not leave the package in rainy or moisture condition.
- Away from magnetic disturbance or audio devices such as the speaker.
- Place the instrument on stable surface.
- Fall from high place or external physical collision may cause damage or malfunction of the instrument.

Please follow the below steps during unpacking:

- The package material is hard board. Please check the package before unpacking.

- Check the instrument and components in accordance with the packing list when unpacking.
- Softly place the instrument on the workbench.
- Check the serial number on the instrument nameplate, conformity certificate and the delivery list for consistency.
- Scrutinize the instrument to check if there are loose, bend or cracked components.
- After unpacking, please do not discard the package so that the instrument can be packed in case of storage, delivery or transfer when not used for a long time.

3.2 Installation

- Unpack the package and take out the instrument.
- Place the instrument in which there is an easy access to ground power outlet, and ensure that the distance between the instrument and the power outlet is greater than 30cm.
- Make sure there are enough room to open the upper lid.
- The workbench should not be less than 500mm (L) x 400mm (W) x 600mm (D) for instrument.
- The workbench should bear a weight not less than 40KG.
- The maximum inclined angle for the workbench should not exceed 0.3°.
- Connect the power cord to the instrument power interface.
- The instrument should be placed where there is an easy access to the power switch. In case of emergency, the user can shut down the instrument by switching it off or unplugging the power cord.
- Keep room well ventilated for cooling.
- Keep enough space in front of the instrument for easy operation.
- Place the instrument in a stable way to avoid impact or collision.
- Do not remove the instrument randomly.

4. Software Operation Instruction

4.1 System Start

Connect the power cord. Turn on the power switch on its back. The Login interface of the instrument displays.

Type in the user name and password, click “Login” to enter the main interface

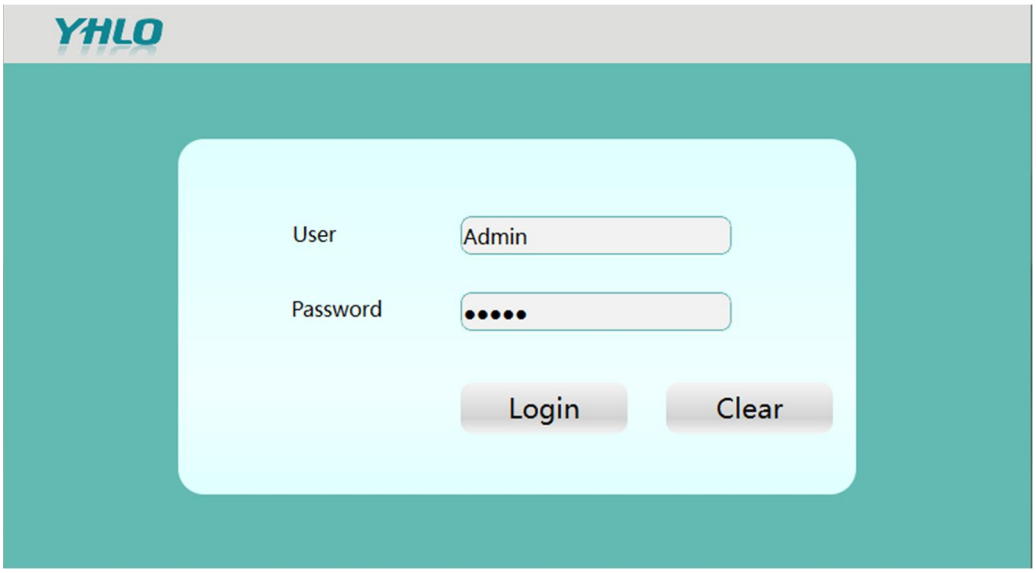


Fig. 4-1-1 Login Interface

➢ **Main interface:**

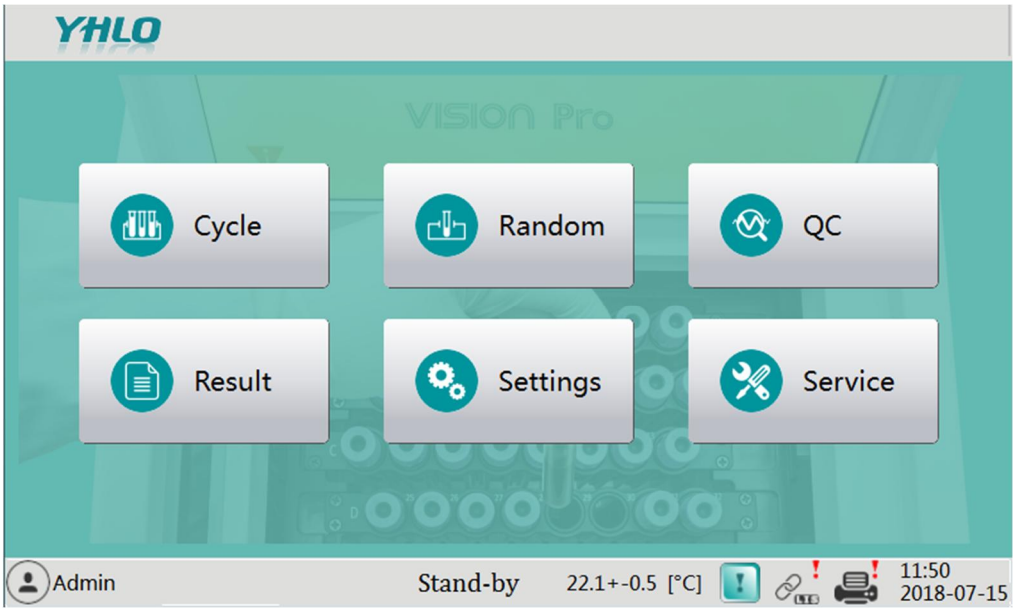
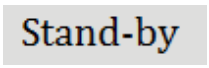
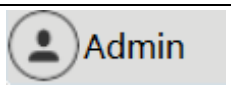
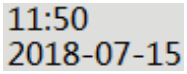


Fig. 4-1-2 Main Interface

Serial	Symbol icons	Meaning
1		It shows the LOGO of manufacturer.
2		It shows Instrument status.
3		It shows current instrument temperature, real-time display update.
4		It shows LIS connection status.
5		It shows printer connection status.
6		It shows the instrument state, and can be clicked into the failure detail list.
7		It shows the current user.
8		It shows the date of test.
9		It means batch mode with automatic detection.
10		It means STAT mode with plug and play.
11		It means quality control.
12		It means the result query.
13		It means parameter setting.
14		It means maintenance, only can be used by engineer account.

- **Operation performed by the user**

  The ESR Analyzer is an automatic instrument. The user only needs to scan sample barcode or type sample ID and insert the tubes.

4.2 Menu tree

The following is a listing of the VISION Pro menu tree.

4.2.1 Cycle Test Interface

Click “Cycle” and the instrument can perform a self check to make sure the instrument connection, lifting and mixing motors normal functions, home positions, infrared LED. If the above-mentioned functions are not normal or malfunctioned, the malfunction info will be displayed on the software screen.

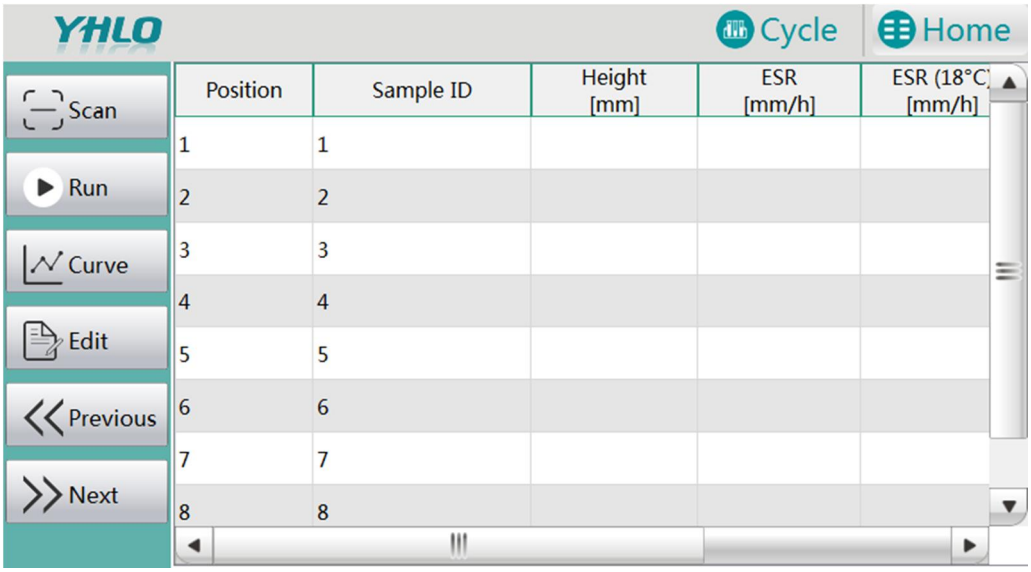


Fig. 4-2-1-1 Cycle Interface

- **Scan:** Click “Scan”, the instrument will proceed scanning and the “Height”, “ ESR”, "ESR(18℃), “Katz” column information are removed, “Sample ID” column information is retained. After scanning, The “Position” column with the color labeling indicates that there is a sample.
- **Run/Stop:** Click “Start”, the instrument start the tests. Click “Stop”, the instrument stops the tests.
- **Curve:** Click "Curve" to show the selected sedimentation curve.
- **Edit:** Click “Edit” to enter the interface shown in Fig. 4-2-1-2 and Fig. 4-2-1-3 below.
- **Previous:** Click "Previous" to go to the previous page.
- **Next:** Click "Next" to go to the next page.

Attention

The "Previous" and "Next" only display in the VISION Pro-B or VISION Pro-C.

- **Cycle:** Indicates the current function interface.
- **Home:** Click "Home" to back the main interface.

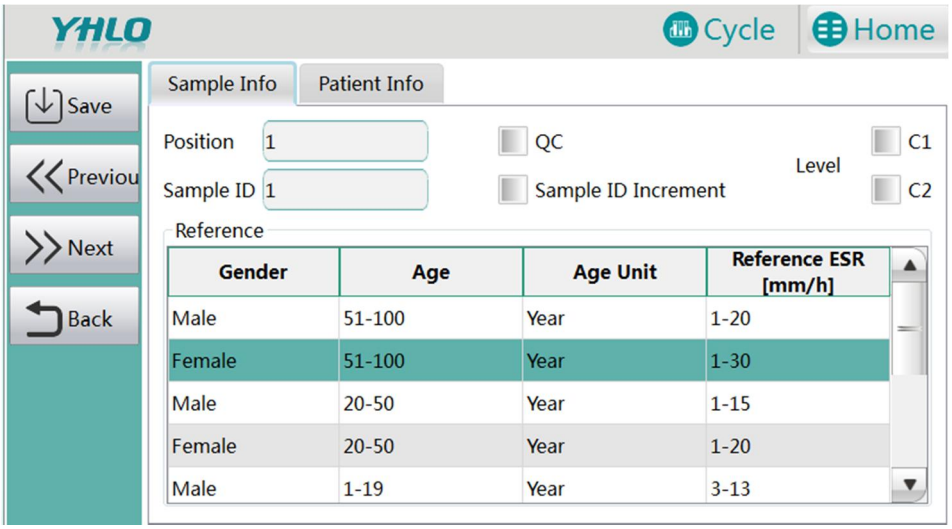


Fig. 4-2-1-2 Edit Sample Info Interface

- **Position:** The current sample position will be placed.
- **Sample ID:** Shows the current Sample ID.
- **Sample ID Increment:** When this option is enabled, the user may click “Save” and the interface will jump to the next position.
- **Reference:** Select reference range of the current sample.
- **QC:** When this option is enabled, the “Sample ID” will change into “QC Lot”, indicating that the tube in this position is a QC sample.
- **Save:** Saves the sample information.
- **Previous:** Goes to the previous position.
- **Next:** Goes to the next position.
- **Back**: Back to the Cycle interface.

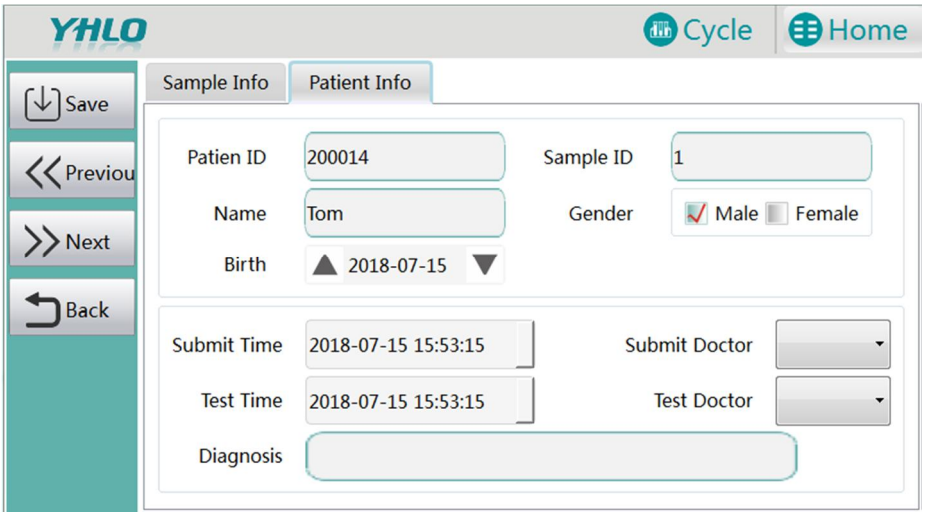


Fig. 4-2-1-4 Edit Sample Info Interface

- **Save:** Save the patient information.
- **Previous:** Goes to the previous position.
- **Next:** Goes to the next position.
- **Back**: Back to the Cycle interface.
- **Patient ID:** Enter the patient ID.
- **Sample ID:** Shows the current Sample ID.
- **Name:** Enter the name of patient.
- **Gender:** Select the gender of patient.
- **Birth:** Enter the birthday of patient.
- **Submit Time:** Select the delivering time of sample.
- **Submit Doctor:** Select the doctor who delivers the sample.
- **Test Time:** Select the test time of sample.
- **Test Doctor:** Select the doctor who tests the sample.
- **Diagnosis:** Enter the diagnosis of sample.

4.2.2 Random Interface

In the main menu, select the “Random” button to enter this screen. Click “Random” to start the random access of tubes to the analyzer. Prior to it, there will be a self-check procedure to run. The self check process is the same as the process described above.

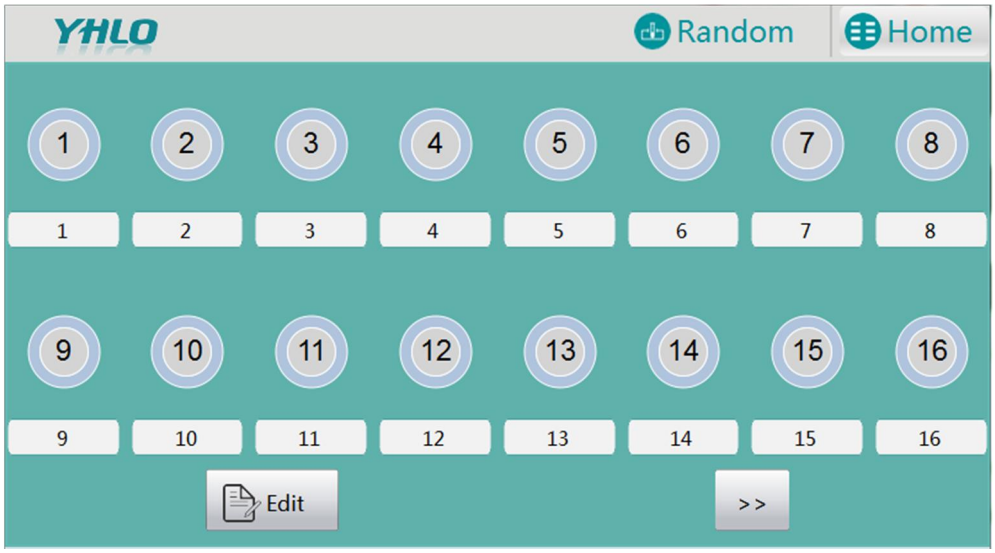


Fig. 4-2-2-1 Random Interface

- **Edit:** Click “Edit” to enter the interface shown in Fig. 4-2-2-2 and Fig. 4-2-1-3 below.
- **>>/<<:** Click ">>" to go to the previous page, click "<<" to go to the next page.

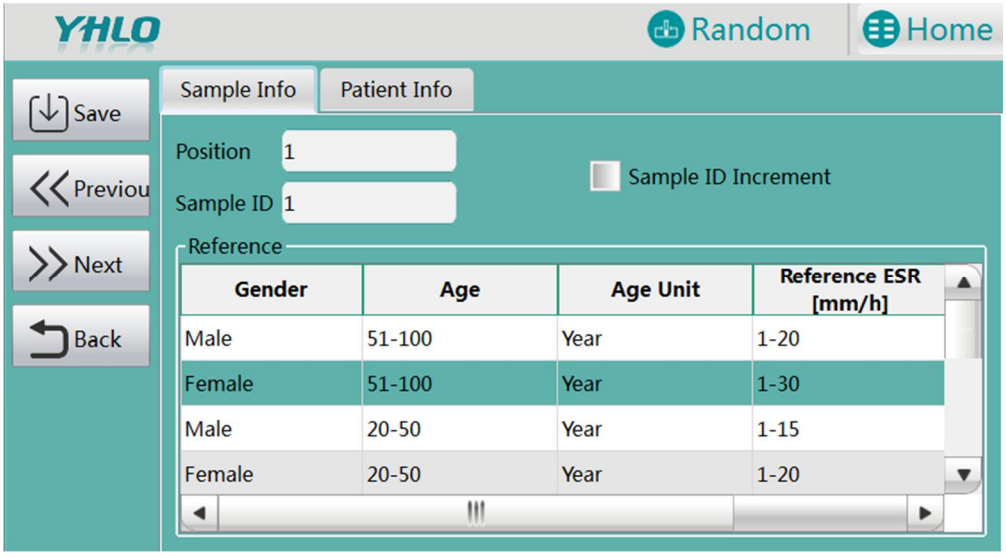


Fig. 4-2-2-2 Edit Sample Info Interface

- **Position:** The current sample position will be placed.
- **Sample ID:** Shows the current Sample ID.
- **Sample ID Increment:** When this option is enabled, the user may click “Save” and the interface will jump to the next position.
- **Reference:** Select reference range of the current sample.
- **Save:** Saves the sample information.
- **Previous:** Goes to the previous position.

- **Next:** Goes to the next position.
- **Back**: Back to the Cycle interface.

The description of patient information is the same as the "Cycle" (Fig. 4-2-1-3).

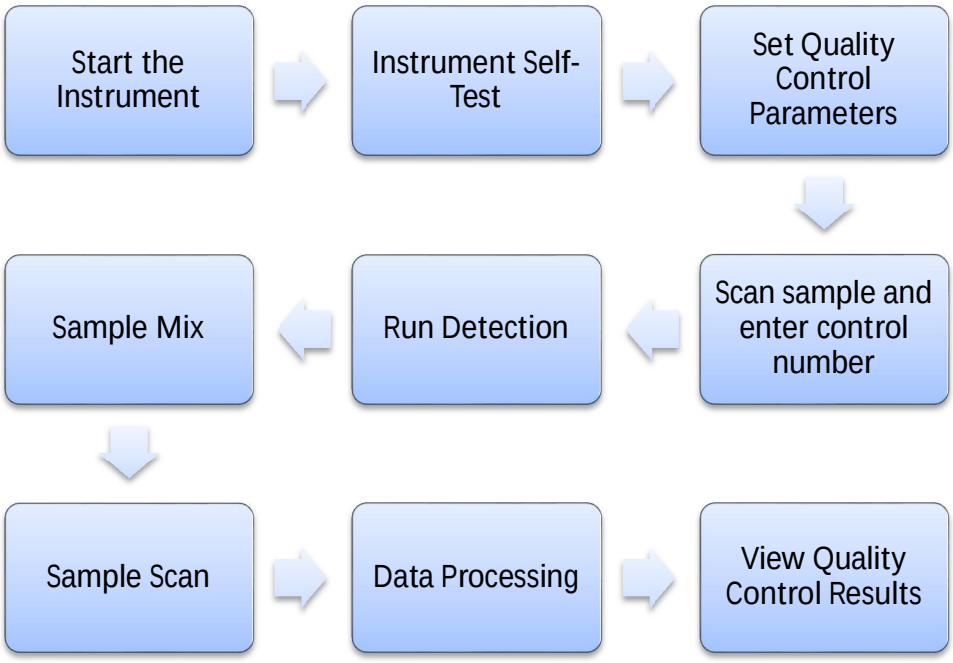
4.2.3 Quality Control

Quality control testing will use 2 levels of quality control, a high level and a low level.

Attention

Quality control can only be carried out in automatic detection mode! After each maintenance or fault handling operation, the quality control test is proposed to ensure the stability of the instrument performance.

4.2.3.1 Quality Control Test procedure



4.2.3.2 Quality Control parameter setting

Connect the instrument power cord. For the limited-activated instrument, turn on the power on the back of the instrument .After the boot interface is finished, input the user and password, click "Login". Then click "QC", login to the QC interface.

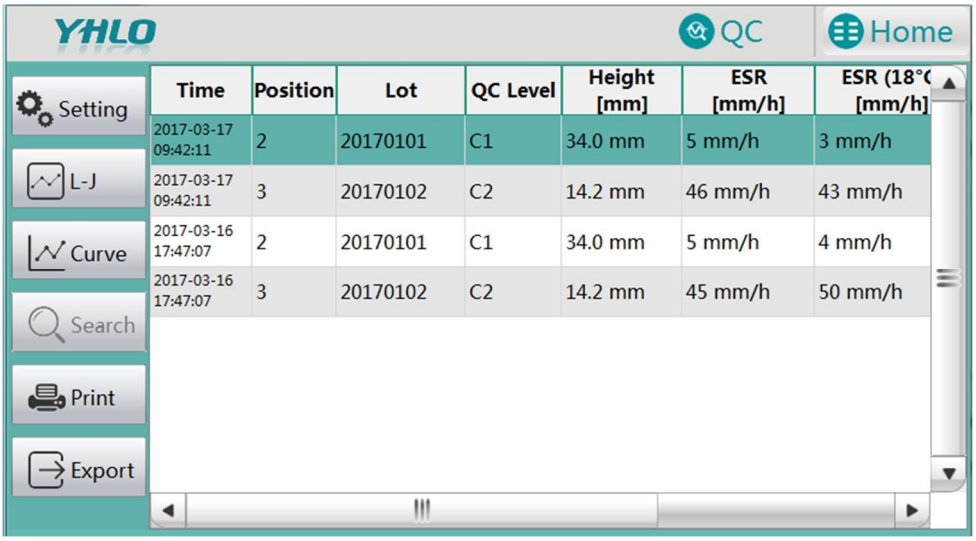


Fig. 4-2-3-1 QC Interface

- **Setting:** Click "Setting", the interface appears two levels of quality control products C1, C2, input the quality control number, reference mean, deviation range respectively and save. The interface will appear the quality control product information list that has been entered.

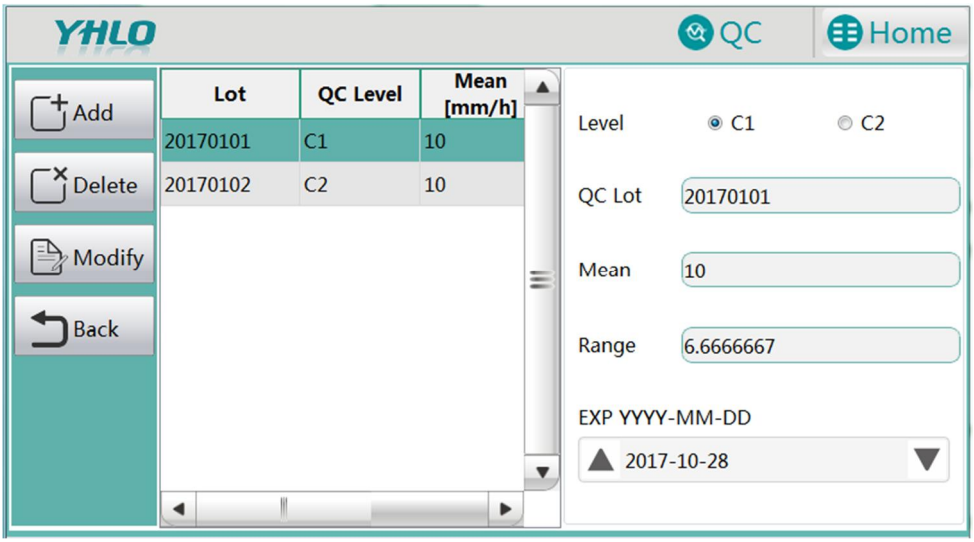


Fig. 4-2-3-2 QC Setting Interface

- **"Add":** Elect Level, input QC Lot, Mean, SD, elect the time, then click the "Add".
- **"Modify":** Elect the QC lever that you want to modify, you can modify the Lever, QC Lot, Mean, SD, Time. When you finished the modify, click the "Modify".
- **"Delete":** Elect the QC lever that you want to delete, click the "Delete".

Note

The same batch quality controller need to have only one control information.

- **L-J:** L-J chart takes the test time as the horizontal axis, the test result as the longitudinal shaft. It shows the controller result tendency in the specified time period. The value must be between the "Mean-3SD" and the "Mean+3SD".

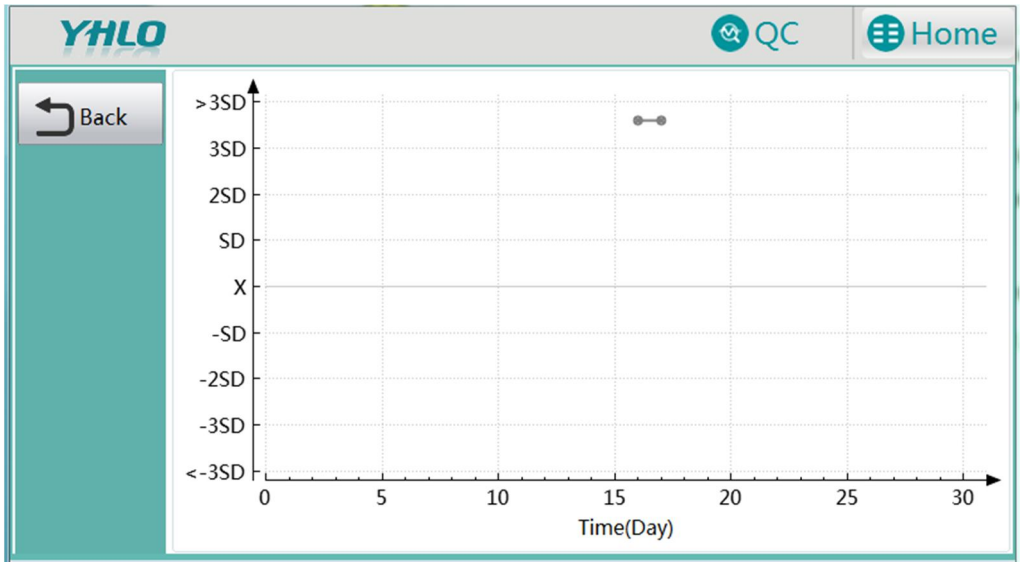


Fig. 4-2-3-3 L-J Interface

- Click L-J chart, the interface shows the using instrument code, controller level, controller batch number, control date and L-J chart, as shown in the following:
- Controller time is selected by month, so that L-J chart displays all the controller information in the selected month.
- Controller L- J chart shows all the test results for the controller in the same batch, and the average and standard deviation correspondingly.

- **"Curve":** Select a QC result and click “Curve” to view the ESR dynamic curve.
- **“Print”:** Select a result and click “Print” to print the result.
- **“Export”:** Select a result and click “Export” to export the result to a U disk.

4.2.3.4 Quality Control test application

- Connect the instrument power cord. For the limited-activated instrument.

Turn on the power on the back of the instrument .After the boot interface is finished, input the user and password, click "Login".

- Click "Cycle", then click "Scan ID" to begin the scan the self-check process will be run automatically. If the self-check goes through, the link will show green color. Otherwise it will show red color and prompt error messages.
- After completing the self-check, open the lid of instrument, click "Edit".
- Click the input box of "Sample ID", manually enter the Lot of QC Sample, and elect he Lever, insert the QC sample tube into the tube rack with corresponding position, and click "Save", then click "Run", the instrument starts mixing automatically.

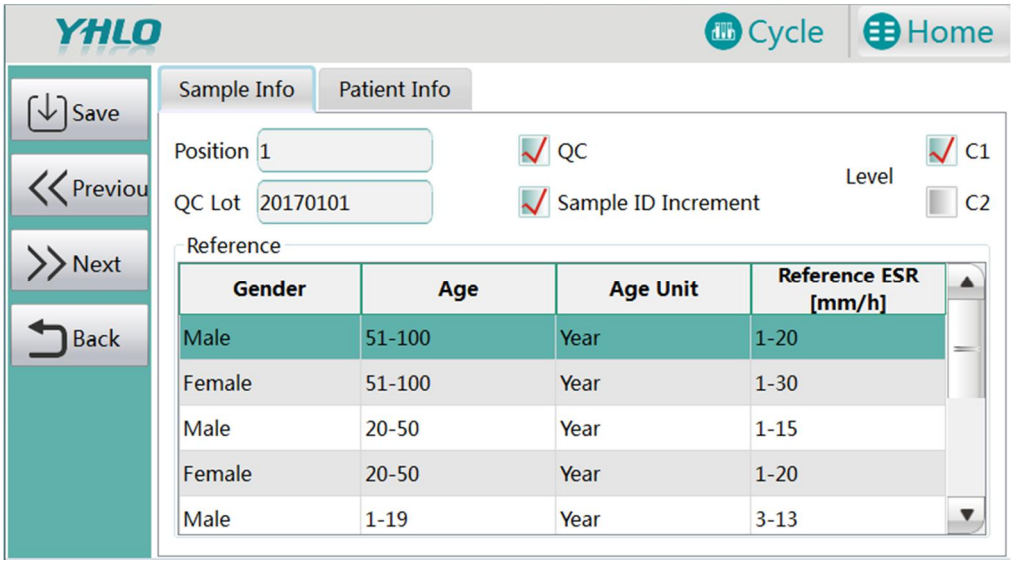


Fig. 4-2-3-4 QC Edit Interface

- Click "Next", do the same operation for the next samples.
- After putting lever 1 QC sample and lever 2 QC sample into the tube racks, click "Back" and close the lid of instrument. Click "Run" to start the test.
- The instrument begins collecting data after mixing 3 minutes.
- It takes 20 minutes to complete data collecting, select sample to view the ESR curve.

4.2.4 Result Interface

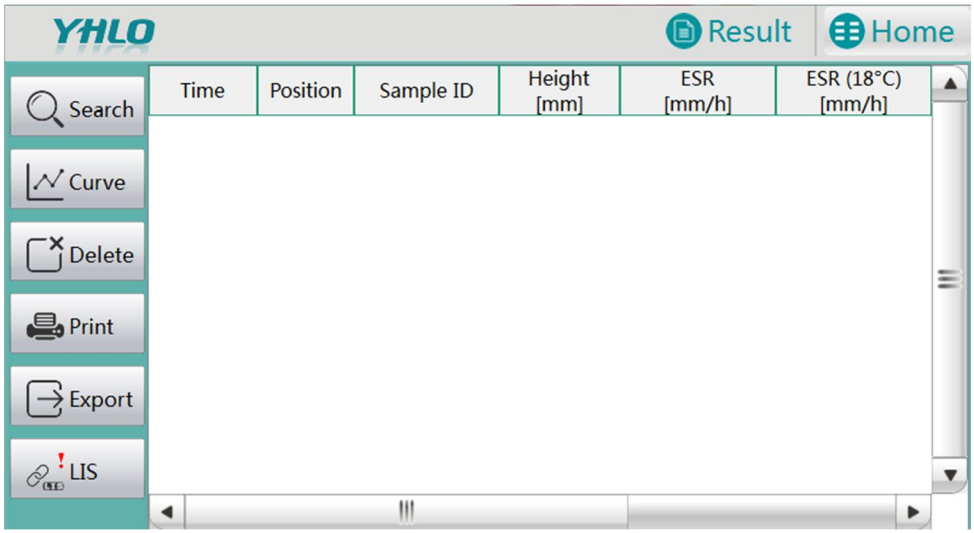


Fig. 4-2-4-1 Result Interface

Select “Result” in the main interface to view the test results. The “Position” column in black shows whether tests were performed in “Cycle” mode or “Random” mode. The “ESR” and “ESR (18°C)” columns both indicate results. The “ESR” column shows the observed results under the current environment. The “ESR (18°C)” column shows the corrected results according to the Manley temperature correction curve corresponding to 18°C.

- **Search:** Click “Search” to enter the search interface. You can search by Sample ID or by date as shown in the picture below (See Fig. 4-2-4-2).
- **Curve:** Select a result and click SED Curve to view the ESR dynamic curve (See Fig. 4-2-4-3).
- **Delete:** Select a result and click “Delete” to delete the result.
- **Print:** Select a result and click “Print” to print the result.
- **Export:** Select a result and click “Export” to export the result.
- **LIS:** Send the selected result to the LIS.

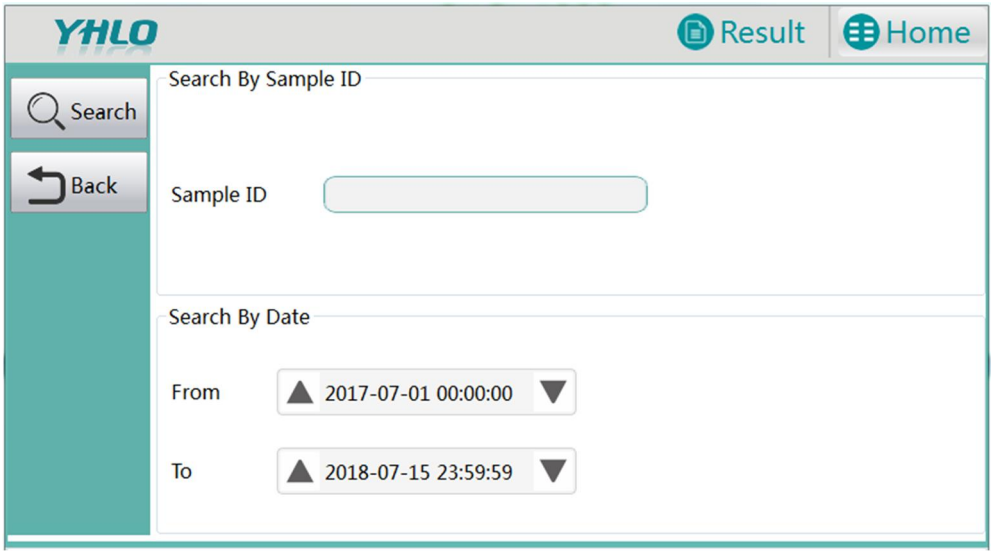


Fig. 4-2-4-2 Search Interface

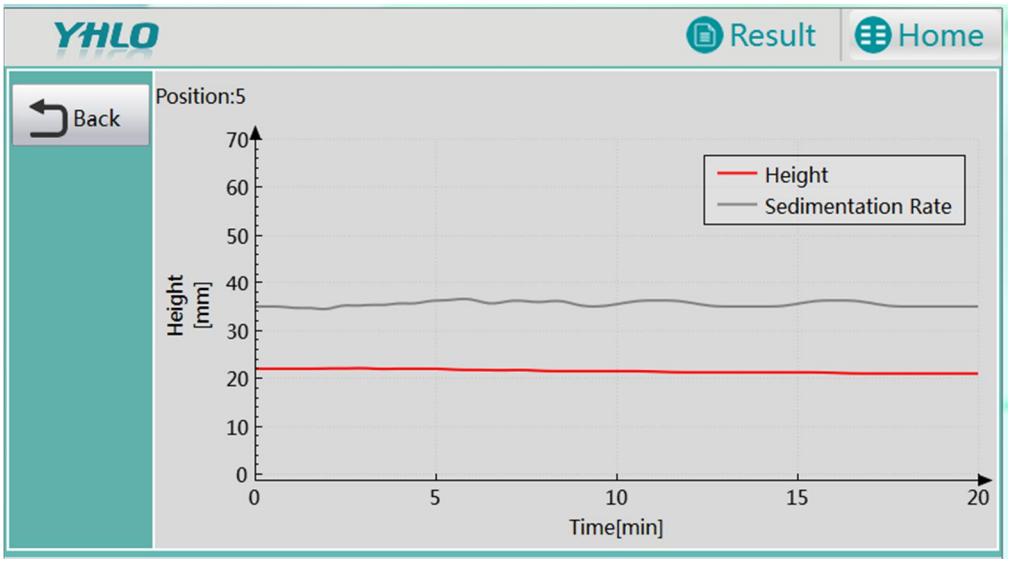


Fig. 4-2-4-3 Curve Interface

4.2.5 Settings Interface

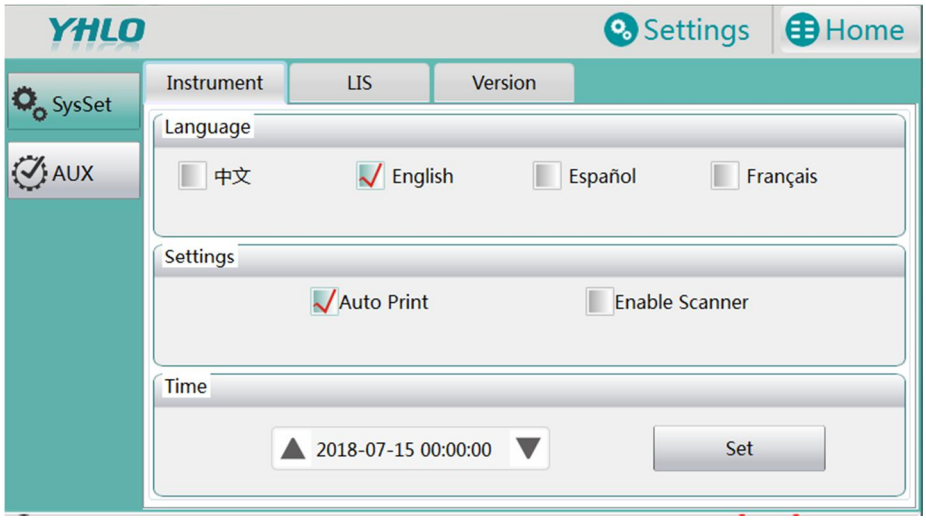


Fig. 4-2-5-1 Settings Interface

4.2.5.1 Sys Set Interface

Click “Settings” in the main menu to enter the display shown above (See Fig. 4-2-5-1 and Fig. 4-2-5-5) .

- **Instrument- Language:** Select the corresponding language. After a restart, the language will be changed.
- **Instrument- Settings:** Select “Auto Print” to automatically print a result after testing is finished. Select “Enable Scanner” to switch on the barcode scanner. It will be turned off automatically during testing process and be turned on once testing is finished.
- **Instrument- LIS:** In the picture above, LIS connection information can be set. Input IP address and Port number of LIS, click “Connect” to connect.

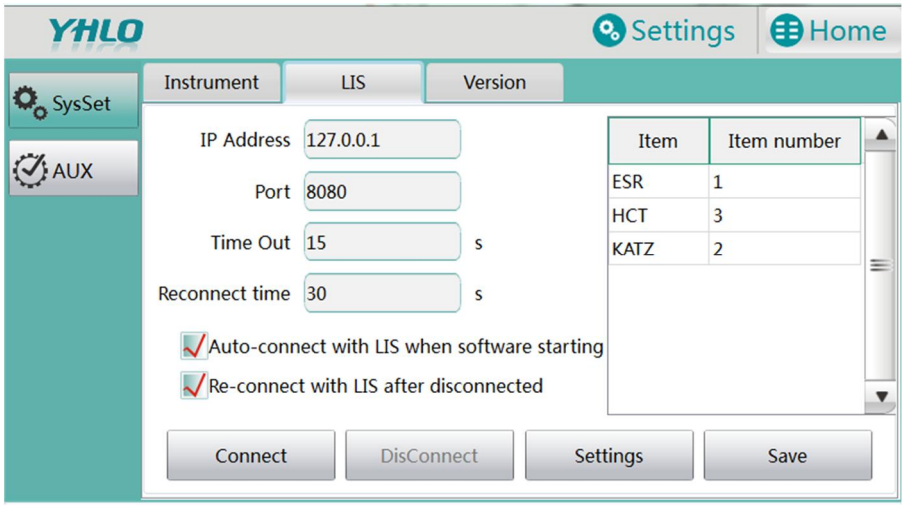


Fig. 4-2-5-2 Sys Set-LIS Interface

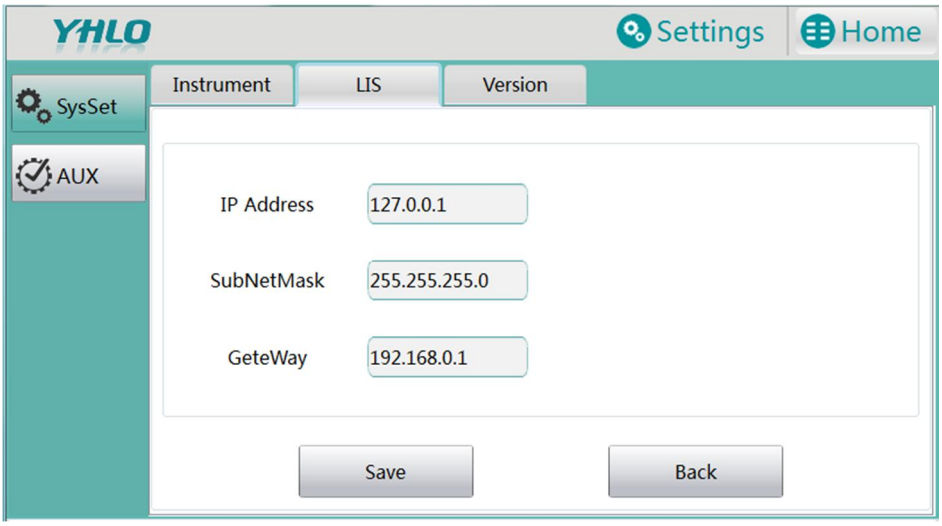


Fig. 4-2-5-3 LIS Settings Interface

- **Instrument-Version:** In the picture below(See Fig. 4-2-4-4), you can know the version of software.

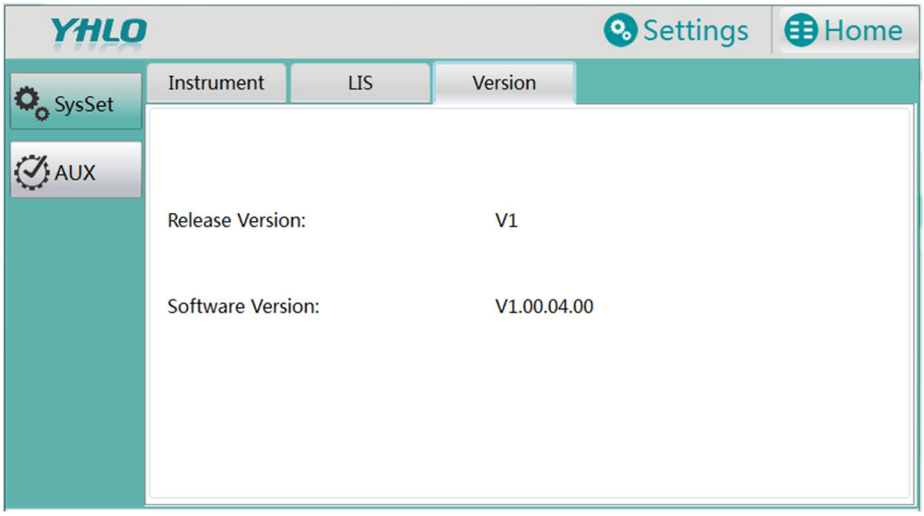


Fig. 4-2-5-4 Sys Set-Version Interface

4.2.5.2 Aux Interface

The interface is used to set the reference, user, log out and dictionary. (See Fig. 4-2-5-5).

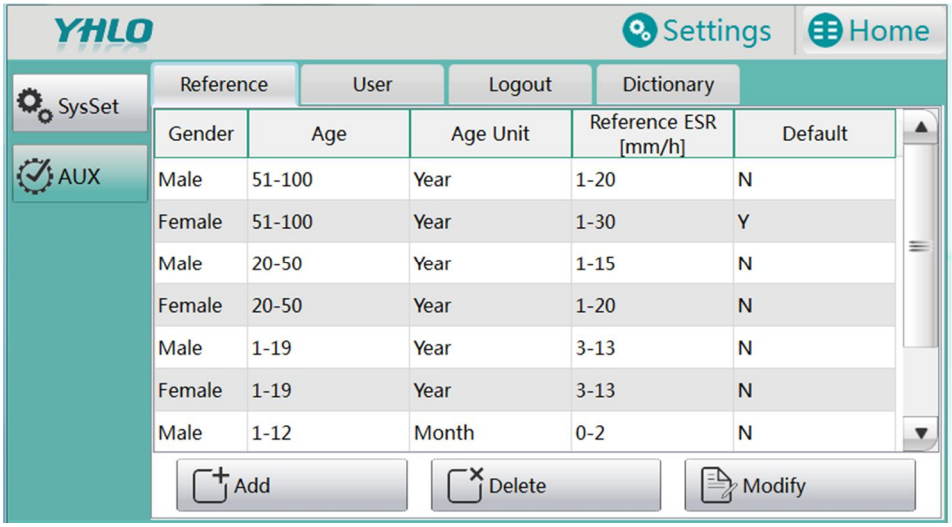


Fig. 4-2-5-5 Aux Interface

- **Aux-Reference:** This menu allows user to set the reference range of results.
  - **Add:** Click “Add” to add this reference range.
  - **Delete:** Select a reference range to be deleted on the left side, then click "Delete" to delete this reference range.
  - **Modify:** Select a reference range to be modified on the left side; after modifying the information on the right side, click "Modify" to modify this reference range.
- **Aux-User:** This menu allows user to set the permission of user accounts.

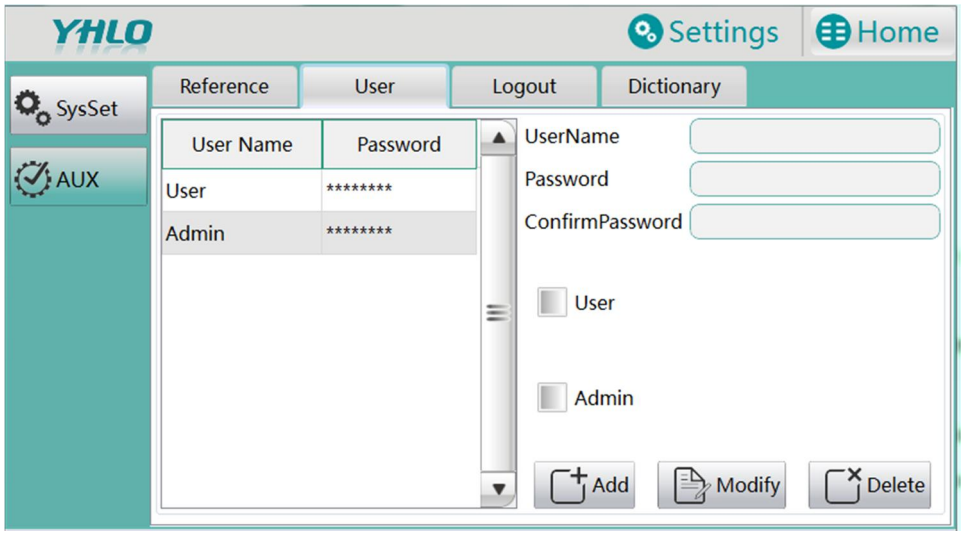


Fig. 4-2-5-6 Aux-User Interface

- **Add:** Input User Name, Password and Confirm Password, elect the user's permission, then click the "Add" .
- **Modify:** Elect the user that you want to modify, you can modify the

password or permission. When you finished the modification, click the "Modify".

- **Delete:** Elect the user that you want to delete, click the "Delete".

➢ **Aux-Log out:** This menu allows user to back to login interface.

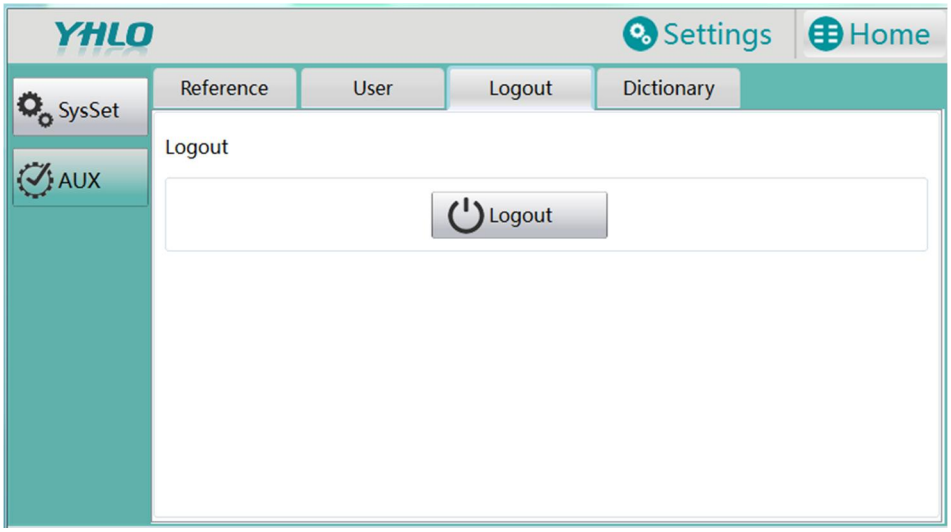


Fig. 4-2-5-7 Aux-Log out Interface

➢ **Aux-Dictionary:** This menu allows user to add or delete the classification.

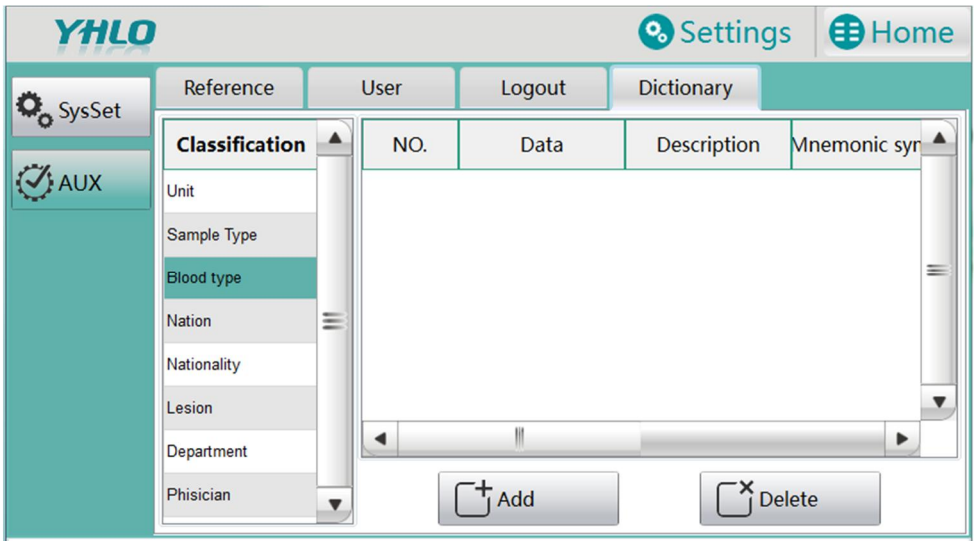


Fig. 4-2-5-8 Aux-Dictionary Interface

- **Add:** Click “Add” to add the classification.
- **Delete:** Select a classification to be deleted on the left side, then click "Delete" to delete this reference range.

5. Instrument Operation

The instrument is required to run a self-check before analysis.

There are two test modes for the instrument, “Cycle” and “Random”. Press “Cycle” to perform tests and the sample will be mixed automatically. Press “Random” to perform tests and the sample should be mixed by hand before test. During the test, new samples can be inserted into the instrument. Finished samples can be removed from the instrument for new samples to be tested.

Westergren’s method shall be used to perform the test as a reference for correction in the following conditions:

1） When the room temperature is not within the range of 18℃~25℃ (64℉~77℉), the system will correct the results automatically. Please refer to Appendix Ⅳ for the details.

2） When the test sample is a anemia sample (HCT＜35%). Please refer to Appendix Ⅴ for the details.

Attention

The power cord must be well connected before operation, sample volume must be more than 1.5ml otherwise the result will be invalid.

Attention

Two-layer barcode can be read through by instrument. Check and ensure the thickness of barcode layer does not exceed two layers before operation. The color of barcode background must not be black otherwise the result will be invalid.

5.1 Flow chart of Operation

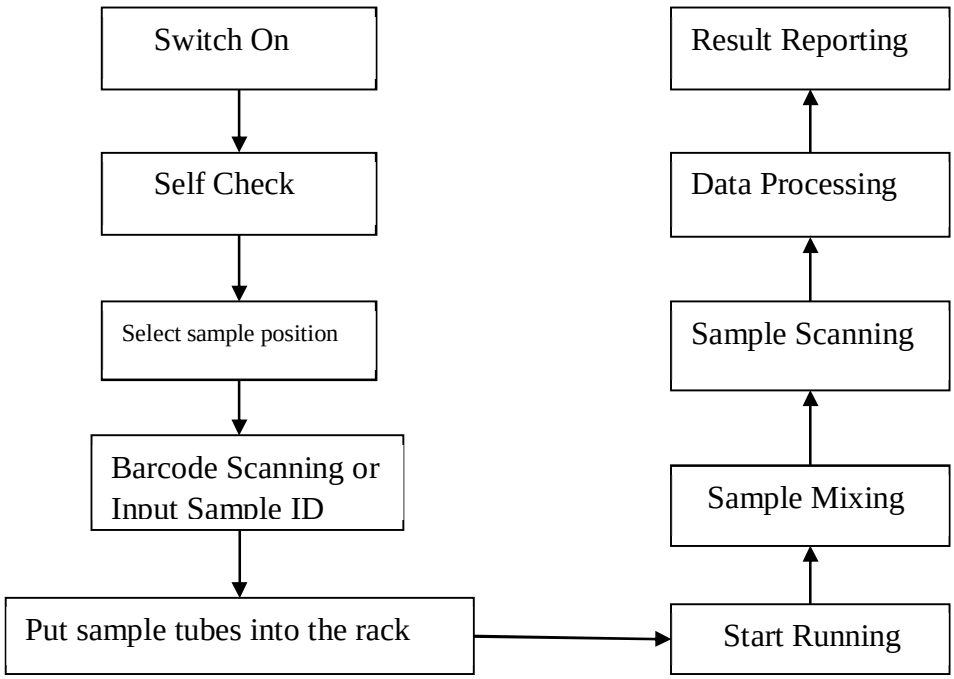


Fig. 5-1 Flow chart of operation (Cycle)

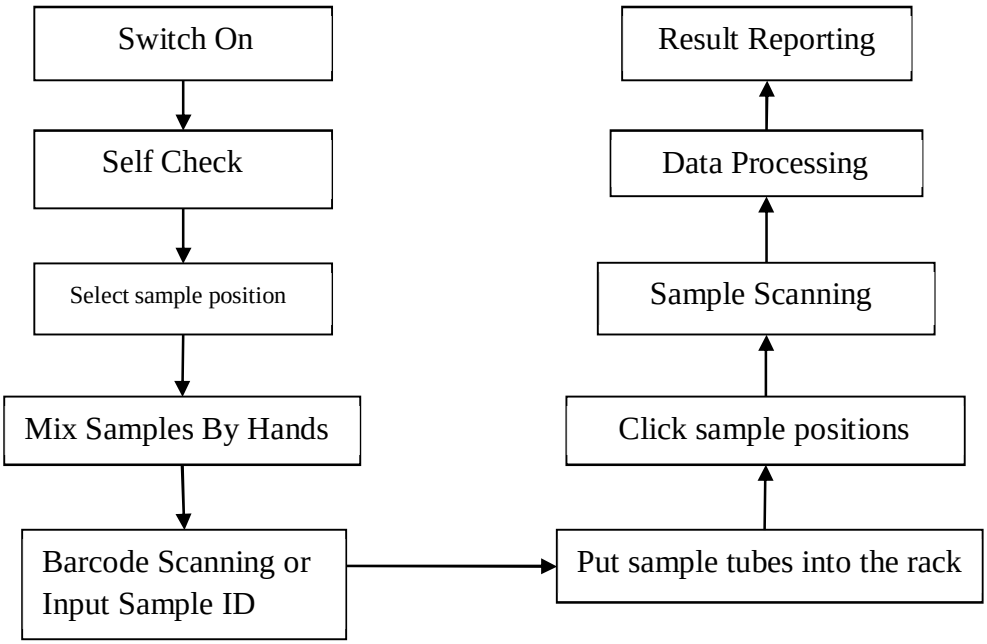


Fig. 5-2 Flow chart of operation (Random)

5.2 Test Procedures in “Cycle” Mode

Connect the power cord. If the instrument is a limited license, please insert a dongle. Turn on the power switch on its back.

1) After the boot interface is finished, input the user and password, click "Login".
2) Click "Cycle", then click "Scan ID" to begin the scan the self-check process will be run automatically. If the self-check goes through, the link will show green color. Otherwise it will show red color and prompt error messages.
3) After completing the self-check, open the lid of instrument, click "Edit".
4) Click the input box of "Sample ID", use the inner barcode reader to scan the sample barcode or manually enter the sample barcode, insert the sample tube into the tube rack with corresponding position, then select the "Reference", and click "Save", then click "Run", the instrument starts mixing automatically.
5) Click "Next", do the same operation for the next samples, based on the step 4).
6) After putting all the samples into the tube racks, click "Back" and close the lid of instrument. Click "Run" to start the test.

 **Note**

The sample tube should be put into the rack every time after inputting the barcode otherwise the sample barcode can’t match with corresponding tube.

 **Note**

The instrument won’t run unless there’s at least a sample in the rack.

7) The instrument begins collecting data after mixing 3 minutes.
8) It takes 20 minutes to complete data collecting, and each ESR result will be shown automatically in the report. Select sample to view the ESR curve.
9) Test results can be viewed in “Result” on the main menu.

5.3 Test Procedures in “Random” Mode

Connect the power cord. If instrument is a limited license, please insert a dongle card. Turn on the power switch on its back.

1) After the boot interface is finished, input the user and password, click "Login", then click "Random" to enter the interface.
2) Open the lid of the instrument, select the position, then click "Edit". Click the input box of "Sample ID", use the inner barcode reader to scan the sample barcode or manually enter the sample barcode, select the "Reference" and click "Save".

 **Note**

There should be minimum of eight complete inversions（180 ° X2） with the air bubble travelling from end to end of the tube. Mixing must not cause haemolysis. The sample tube should be put into the rack every time after inputting the barcode otherwise the sample barcode can’t match with corresponding tube.

3) Insert the sample tube into the tube rack with corresponding position.
4) Click "Back" and close the upper lid. Click the position number and the instrument will start test automatically.

 **Note**

The instrument won’t run unless there’s at least a sample in the rack.

5) During test, if there are other samples need to be tested, please repeat Step 2) and 4).
6) It takes 20 minutes to complete data collecting and the instrument will save results automatically. Take out finished samples and these samples can be tested again according to the previous steps.
7) Test results can be viewed in “Result” on the main menu.

6. Service and Maintenance

VISION Pro employs an enclosed design and will not produce waste liquid during test. The instrument will not come into contact with blood samples, and it does not contain other parts requiring routine maintenance. Only the following maintenance will be carried out when the device is used normally:

Remove dust on the surface of the device, including the light transmitting window of scanner.

Turn off the power switch when all tests on the current day are finished.

7. Troubleshooting

Any simple fault of the device can first be eliminated according to this manual. If the problem still exists, please contact the local after-sales service center, the local agent, or the manufacturer. This device with the Certificate of Conformity supplied is entitled to technical repair service; please keep the Certificate of Conformity properly.

7.1 Fault Content

When fault happens, the device status becomes “Fault”. Click the alarm status button  , software will show the fault content.

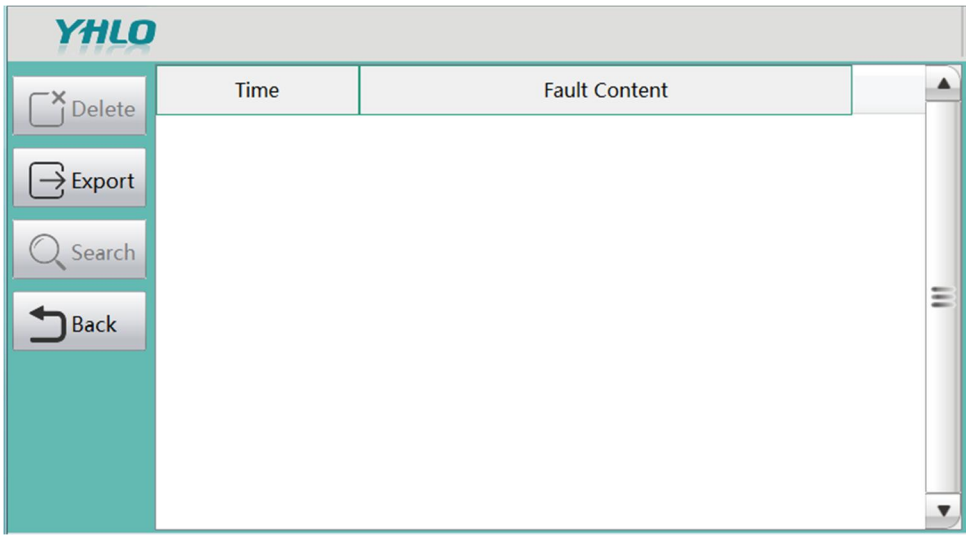


Fig. 7.1 Fault Content Interface

Fault Content	Meanings
Mixing motor home failed!	Error when the mixing motor returns to home position
Linear motor home failed!	Error when the linear motor returns to home position
Dark reading error : Channel	Dark light reading error of XX channel
Weak light reading error : Channel	Weak light reading error of XX channel
Strong light reading error : Channel	Strong light reading error of XX channel

Table 7-1 Meanings of Fault Content

7.2 Fault Causes and Handling

This part provides information of maintenance for users (e.g. Engineers),

- Mixing/ Linear motor home failed!: An error occurs when the mixing/linear motor returns to home position

  Fault cause:

  1) The motor is not properly fixed, or the synchronous belt is loosened;
  2) Wires of mixing motor and linear motor are reversely connected to the main board;
  3) Sensors of mixing motor and linear motor are reversely connected;
  4) Abnormality of voltage supply to the motor;
  5) 24V voltage input to the motor is normal, but the motor does not move; the motor malfunctions in most cases;
  6) The main board malfunctions.

  Solution:

  1) Mixing motor: Check whether the motor pulley is loosened; check the tightness of synchronous belt; the mixing motor has been properly installed if the test tube rack cannot swing freely in the horizontal direction;
  2) Linear motor: Check whether the pulley is loosened; check the tightness of synchronous belt; the linear motor has been properly installed if the infrared transmitting/receiving unit cannot be adjusted freely;
  3) Check whether the motor wires are connected to the main board reversely;
  4) Check whether the sensor wires of mixing motor and linear motor are

reversely connected;

5) Test whether the 24V supply voltage to the main board is normal; replace the abnormal power supply;
6) Replace the motor;
7) Replace the main board.

- Dark/weak/strong light reading error: Dark/weak/strong light reading error of channel

  Fault cause:

  1) In a strong-light environment (e.g. a balcony exposed to direct sunlight), dark light reading error can occur easily;
  2) The infrared transmitting tube is damaged or the emitted light intensity is reduced, or the reading of corresponding receiving chip is less than 3500 when weak/strong light is enabled, resulting in weak/strong light reading error; generally, the error is reported by a single channel;
  3) The infrared receiving chip malfunctions or the receiving performance is degraded, or the reading is less than 3500 when weak/strong light of corresponding transmitting tube is enabled, resulting in weak/strong light reading error; generally, the error is reported by a single channel;
  4) The transmitting and receiving board wires are connected in a misaligned way, or the wires are not properly inserted, or the wires broken/damaged result in abnormality in signal transmission and dark/weak/strong light reading error; generally the error is reported by multiple channels;
  5) The transmitting and receiving boards are installed in a misaligned way, resulting in the fact the transmitting tube is not aligned with the receiving chip;
  6) Power supply failure.

  Solution:

  1) Close the upper cover of the device, and transfer it to a weak-light environment;

2) Move the optical component to the home position; enable the Weak/Strong button of the error reporting channel in sequence. If the LED reading of the error reporting channel is less than 3500 and the optical reading of the right-side channel is also much lower than the normal value (weak light: around 1500; strong light: 4095), it will be considered that the LED light of the error reporting channel malfunctions and the transceiver board E should be replaced. If the error reporting channel is No. 8 channel and the reading of No. 8 channel is around 1500 when weak light of No. 7 channel is enabled, it will also be considered that the LED light of No. 8 channel malfunctions and the transceiver board E should be replaced.
3) Move the optical component to the home position; enable the Weak/Strong button of the left-side error reporting channel in sequence. The reading of the error reporting channel should be around 1500 when weak light is enabled and be 4095 when strong light is enabled; if the reading is too small, it will be considered that the receiving chip of the error reporting channel malfunctions and the transceiver board A should be replaced. If the error reporting channel is No. 1 channel and the reading of No. 2 channel is around 1500 when weak light of No. 1 channel is enabled, it will also be considered that the receiving chip of No. 1 channel malfunctions and the transceiver board A should be replaced.
4) Check whether the appearance of transceiver wires and the sockets are in good condition; check whether the wires are properly connected;
5) Check whether the transceiver boards are properly installed;
6) Test whether the 12V supply voltage to the main board is normal; replace the abnormal power supply.

Appendix Ⅰ Quick Guide

1 Switch On

1) Check and ensure the power cord well connected. Switch on the Instrument by means of the power switch on its back.
2) After self check, the software main menu will be displayed.

2 Preparation for Sample Analysis

1) The sample can be used for testing within 4 hours after sampling and should always be kept in the room temperature.
2) In “Random” mode, the sample must be mixed manually before test.

3 Operation and Analysis

A: Perform test in “Cycle” mode

1) Click "Cycle", the self-check process will be completed automatically.
2) Open the lid of instrument, Click "Scan" to begin the scan.
3) After finishing the scan, click "Edit".
4) Click the input box of "Sample ID", use the inner barcode reader to scan the sample barcode or manually enter the sample barcode, insert the sample tube into the tube rack with corresponding position, then select the "Reference", and click "Save".
5) Click "Next", do the same operation for the next samples, based on the step 4).
6) After putting all the samples into the tube racks, click "Back" and close the lid of instrument. Click "Run" to start the test.
7) It takes 20 minutes to complete all the tests. The results will be saved automatically.

B: Perform test in “Random” mode

1) Click "Random" to enter the interface.
2) Open the lid of instrument, select the position, then click "Edit";
3) Click the input box of "Sample ID", use the inner barcode reader to scan the sample barcode or manually enter the sample barcode, select the "Reference" and click "Save".
4) There should be minimum of sixteen times complete inversions (180 ° X2) with the air bubble travelling from end to end of the tube before inserting it into the tube rack. Mixing must not cause haemolysis.
5) Insert the sample tube into the tube rack with corresponding position.
6) Click "Back" and close the upper lid. Click the position number and the instrument will start test automatically.
7) If new sample tube is needed to be inserted into the instrument, open the upper lid and repeat Step 2) to 6).
8) It takes 20 minutes for each sample to complete the test. The results will be saved automatically.

4 Switch Off

After completing the test, turn off the power switch.

Notes:

1) There are two test modes for the VISION Pro, “Cycle” and “Random”. As to ensure the samples are well mixed, it is recommended to use the “Cycle” mode to perform the test.
2) After each sample ID is entered, the sample tube must be inserted into the corresponding tube rack before scanning the next one.
3) Gloves must be worn at all time during operation to avoid body injury and infection.
4) Place the instrument in an appropriate position to avoid direct sunlight and humid and dusty environment.
5) The samples may contain hazardous material, all the used samples should be handled according to the regulations on processing potentially biohazardous waste in the lab.

Please do not hesitate to contact us in case of any question.

Appendix Ⅱ Precautions for Operation

Operation Requirement:

1. Please run tests under 18°C ~30°C and keep the room temperature stable.
2. Do not run tests in vibrant or dusty environment.

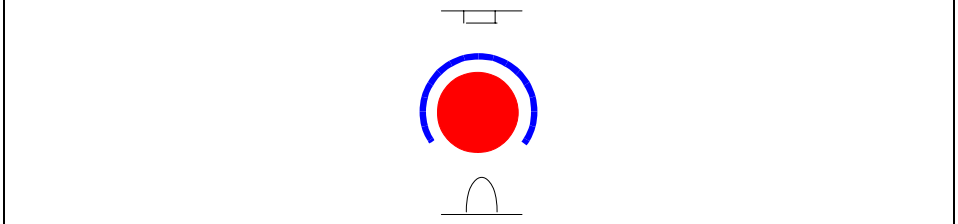
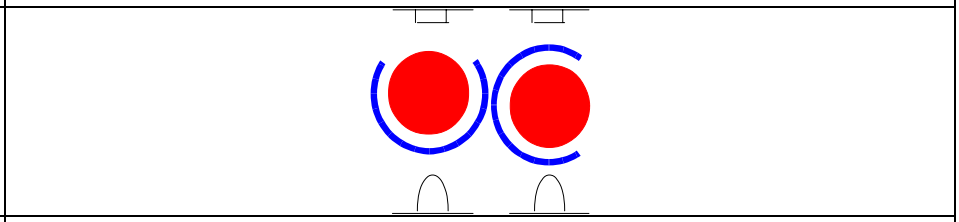
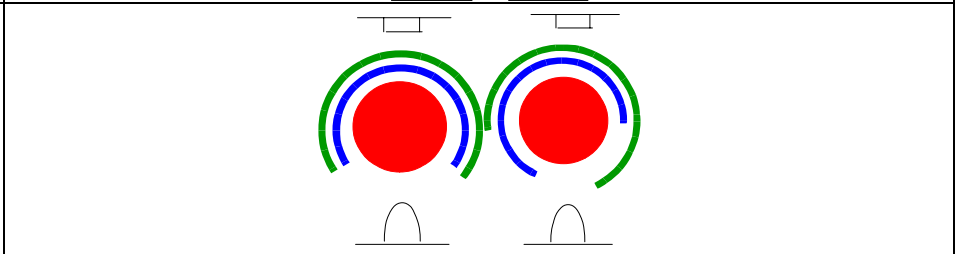
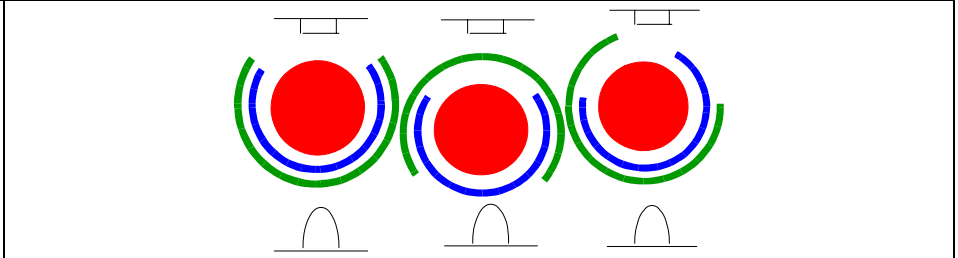
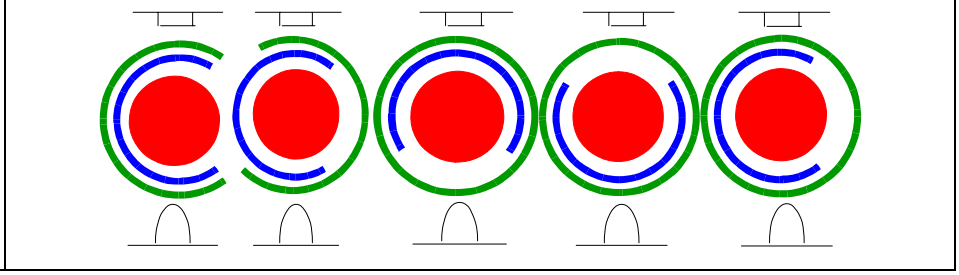
Sample Requirement:

1. Blood samples should be tested within 4 hours after collection.
2. The recommended sample volume is 2ml~2.5ml. At least 1.5ml of sample volume is required to run the test. The maximum sample volume is 3.5ml.
3. The tube cap must tightly seal the test tube to prevent samples from leaking during mixing process on VISION Pro.

Operation Requirement:

1. Please do not stick more than 2 labels on the test tube. If it is required to stick 2 labels, please overlap the second label on the first one. When inserting the tube into the VISION Pro, please place the unlabelled tube side facing to the LED light to prevent labels from interfering with scanning results.
2. When samples are tested in auto mixing mode, if red cells are in complete sediment before test, please mix the samples before inserting tubes (reverse the tube upside down for once). Otherwise, samples may fail to get result due to low level of red cells.
3. When samples are tested in random mode, There should be minimum of sixteen times complete inversions（180mpl） with the air bubble travelling from end to end of the tube before inserting it into the tube rack. Mixing must not cause haemolysis.
4. During test, it is not allowed to remove or take out samples or move the VISION Pro randomly. Otherwise, it may lead to result failure.

Appendix Ⅲ Sample Labeling

		LED	receiver	sample tube	tube label	barcode label
One layer label	Highly recommended					
	Acceptable					
Two layer labels	Highly recommended					
	Acceptable					
	NO					

Appendix Ⅳ Sedimentation Rate Correction for Variations in Room Temperature

It is noted that sedimentation rates vary with room temperature. In high temperature, low red blood clumping cause sedimentation at faster rate; in low temperature, intensive red blood clumping result in slower sedimentation rate. The sedimentation rate, therefore, shall be determined within the range of 18℃~25℃ (64℉~77℉). When room temperature is out of the range, the following correction nomogram (Figure A-1, Roger W. Manley. J.Clin.Path.1957, 10:354-356.) shall be used to correct the sedimentation rate as below:

Record the room temperature before, during and after the test and calculate the arithmetic mean value. Then apply the mean value and observed sedimentation rate into the nomogram and connect them into a straight line. Extend the straight line to the Correction Line. The intersection point is the corrected sedimentation rate. For example, if the mean value of the room temperature is 30℃ and the observed sedimentation rate is 30 mm/h, the corrected rate is 20 mm/h.

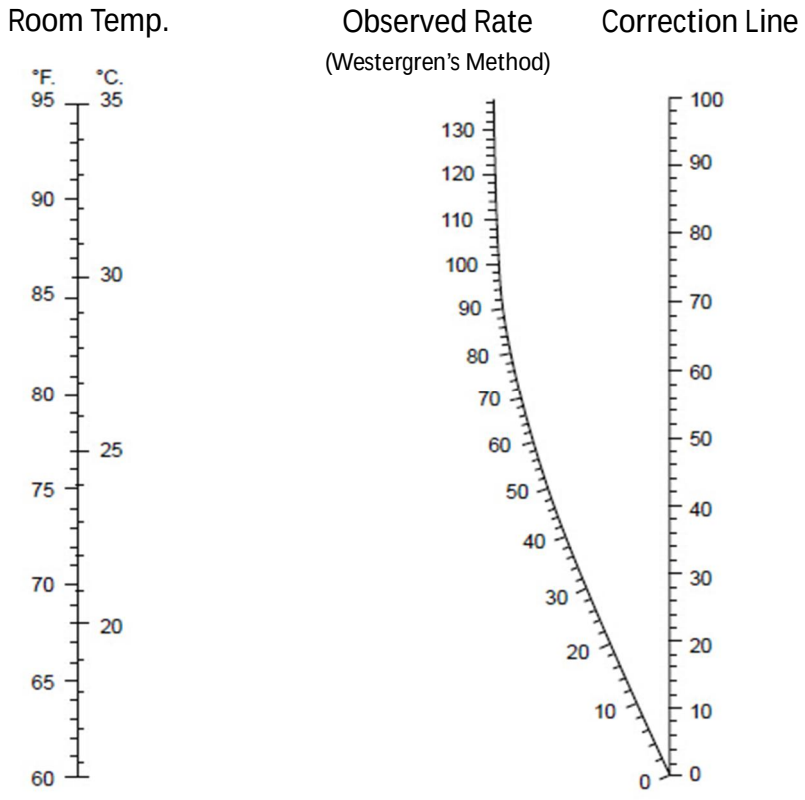


Fig.A-1 Sedimentation Rate Correction for Variations in Room Temperature (Westergren's Method)

Appendix Ⅴ Sedimentation Rate Correction for Anemia Sample

Anemia is a medical condition in which there are too few red cells in blood. Westergren's Method is the international standard method made by ICSH to perform ESR test. When Westergren's method is performed to test anemia samples, the test result is higher than the real sedimentation rate due to the reasons below:

The sedimentation curve is often divided into three components: (1) an initial slow phase or period of aggregation, during which rouleau formation takes place and the rate of fall gradually increases; (2) a period of constant and maximum rate of fall, represented by a straight line; (3) a period of packing, in which the rate becomes progressively slower as the cells pile up on the bottom of the tube.

Generally the sedimentation rate and the reverse resistance of plasma in lower tube position can keep a relative balance. However, if the red blood cell (HCT) and the erythrocyte reverse resistance declines, the sedimentation rate is accelerated accordingly. Therefore, the ESR curve shall be corrected when anemia samples are tested.

A research on the correction for the calculation of anemia sample sedimentation rate is done by Nelson K. Ordway and Richard B. Singer from Philadelphia University (Nelson K. Ordway, Richard B. Singer. The Journal of Laboratory and Clinical Medicine. 1948, 33:511-518.). In this research, a nomogram (Ordway-Singer nomogram) is plotted to correct the sedimentation rate done by Westergren's Method. Nelson and Richard validated their method by performing the tests as below：

(1) Determine the sedimentation rate of a patient with nutritional anemia before and after transfusion and then correct observed sedimentation rates using the foregoing nomogram. Compare the corrected rates.

(2) Determine the sedimentation rates of capillary and venous blood samples of a patient and then correct observed sedimentation rates using the foregoing nomogram. Compare the corrected rates.

The precision of this technique is illustrated by the examples given in Test (1) and Test (2). Test (1) illustrates the effect of a variation in packed cell volume on the observed sedimentation rate, while the corrected rate remains practically unchanged. In Test (2), it also remains unchanged for the correspondence of the corrected rates for venous and capillary blood in the same patient.

This method has proved its practicability in seven years of use in the Hospital of the University of Pennsylvania.

To correct the sedimentation rate of anemia samples with Ordway-Singer nomogram (See Fig. A-2), apply the observed sedimentation rate and HCT value into the nomogram in Fig. A-2 and then connect them into a straight line. The intersection of the straight line and the correction line is the corrected sedimentation rate. For example, if the HCT value is 26% and the observed ESR is 78 mm/h, the corrected sedimentation rate is 23 mm/h; if the HCT is 38% and the observed sedimentation rate is 70 mm/h, the corrected rate is 48 mm/h.

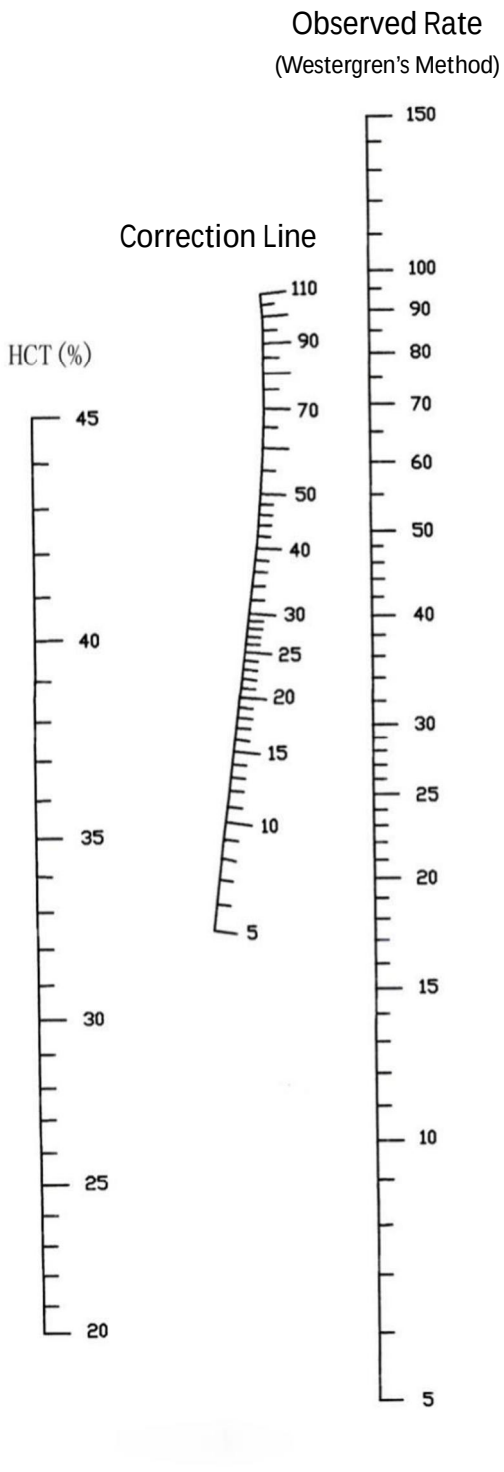


Fig.A-2 Ordway-Singer Nomogram Sedimentation Rate Correction for Anemia Sample (Westergren's Method）