



DNM-9606 MICROPLATE READER

USER'S MANUAL

(Please read the instructions before using the product)

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Catalog

Biohazard and safety alert	4
Chapter One Introduction to Instruments	6
1 Overview	6
1.1 Intended use	6
1.2 Composition of the structure.....	7
1.3 working principle.....	7
1.4 The basic parameters of the instrument	7
1.5 normal working conditions and storage conditions	8
1.6 appearance	9
1.7 Wavelength accuracy	9
1.8 Absorbance accuracy	9
1.9 Linearity error.....	10
1.10 absorbance repeatability	10
1.11 absorbance stability.....	10
1.12 Sensitivity	10
1.13 Differences between channels.....	10
1.14 main function.....	10
1.15 safety requirements	12
1.16 Environmental Test Requirements	12
1.17 Electromagnetic compatibility requirements	12
1.18 Production Date	13
1.19 useful life	13
1.20 product contraindications.....	14
Chapter II Instrument Installation.....	14
2.1 Instrument unpacking	14
2.2 environmental requirements	14
2.3 to start the installation.....	15
Chapter III input operation	17
3.1 input operation.....	17
Chapter IV Boot.....	19
4.1 boot process	19
4.2 main menu	20
Chapter V Project Settings.....	22
5.1 Setting instructions	22
5.2 Setup Procedure	22
Chapter VI test operation.....	31
6.1 Precautions.....	31
6.2 detection.....	31
Chapter VII comprehensive report	37
7.1 Report form.....	37
7.2 by patient report.....	37
7.3 report by project.....	40

Chapter VIII Quality Control Management.....	41
8.1 Basic Operation	41
8.2 Quality control status.....	43
8.3 Quality Control Chart.....	44
Chapter IX System Management.....	45
9.1 basic functions	45
9.2 Hospital Information.....	46
9.3 General Settings.....	47
Chapter tenth instrument maintenance	50
10.1 Overview	50
10.2 Cleaning the instrument.....	50
10.3 Instrument Parts Replacement	51
10.4 Simple troubleshooting	52
Chapter XI Transportation and Storage	53
11.1 Transportation	53
11.2 Storage	53





Biohazard and safety alert

DNM-9606 microplate reader is an in vitro diagnostic medical device. Please read the following warning carefully before use and must be strictly observed.

1. Some substances may be biohazardous, so take precautionary measures before using this equipment: Wear protective clothing and gloves.
2. Do not touch the following when operating the instrument: patient samples, controls, standards, waste liquids, as they are considered contaminants and may be infectious.
3. Be extremely cautious when handling patient samples and may be at risk of being infected with the virus, be sure to wear rubber gloves. If samples spill and contaminate the equipment, wipe it with a germicide immediately, then rinse with water.
4. If contaminated with blood or waste fluid (especially if contact with eyes or wounds), wash immediately with plenty of water and follow the directions of your doctor.
5. Always wear rubber gloves when disposing of waste liquids or disinfecting equipment. Do not discard used test substances, discarded liquids must be decontaminated as required. After treatment with disinfectant to clean, then soap clean.
6. When disposing of waste liquid or end of life of the instrument, it shall comply with relevant national and local laws and regulations on waste disposal.
7. To avoid electrical shock, the instrument should be grounded through the ground wire, which should be well connected to the ground.

8. There is a more stable AC grid. It is forbidden to share the power with the electrical equipment with frequent power on and off to avoid large electromagnetic interference.
9. Only professionally trained healthcare personnel should operate this equipment and operate in strict accordance with the instructions provided.
10. To unplug the power cord, unplug the plug, do not pull the power cord.
11. If the device has smog, special smell and strange sound, please cut off the power and contact the dealer immediately.
12. After completing the work, disconnect the power switch, unplug the device power cord, cover the instrument dust cover.
13. Wear rubber gloves when servicing the equipment; if equipment needs to be removed, shut off the equipment and switch off the power.
14. After the fuse is blown, please replace the fuse of the same specification (fuse specifications see the instrument maintenance).
15. Don't disassemble the instrument by yourself unless it is repaired by the manufacturer and the authorized unit. Do not modify the instrument yourself.
16. This device is no contraindication, does not produce toxic and harmful gases.
17. The user is obliged to fulfill local or national regulations on waste disposal.
18. This instrument uses the following symbols and symbols:

sign	meaning
○	Alternating current shut down (electrical source cut)

I	Alternating current turn on (electrical source turn on)
	Warning: Waste liquid have potential bio-infective hazard.
	Protective ground
	In vitro diagnostic medical devices
	Warning! Note: please read carefully

Chapter One Introduction to Instruments

1 Overview

The instrument for in vitro diagnosis (IVD) medical equipment. Management Classification is Category II; Clinical Laboratory Equipment 6840-03 Immunoassay System.

The instrument uses large-screen full-character display, continuous operation, especially for domestic users. The reagents used in this instrument must be purchased by the user through the enzyme-free reagents that have been registered with the State Drug Administration.

1.1 Intended use

The product and enzyme-free reagents supporting the use of samples for clinical laboratory test absorbance, enzyme-linked immunosorbent assay

1.2 Composition of the structure

The instrument from the light source system by the instrument, the injection unit, the detection unit, control unit, operating software and display unit and print unit

1.3 working principle

The instrument is the use of enzyme-linked immunosorbent assay (ELISA) and Lambert-Beer's principle of work, the clinical immunology test equipment.

The instrument first detects the absorbance of the sample fluid to be tested and the standard solution / reference solution, and then analyzes and calculates the content of the analyte in the sample solution. The instrument and registered enzyme-linked immunosorbent supporting the use of the clinical use of photoelectric colorimetry on human samples for enzyme immunoassay and quantitative determination.

1.4 The basic parameters of the instrument

- 1) Operating wavelength range: 400-800 nm; half width of wavelength: 7 ± 2 (nm);
- 2) the detection range of the instrument: 0.000-4.000A;
- 3) light source lamp: 12V / 20W quartz halogen lamp
- 4) Resolution: 0.001;
- 5) Detection channel: eight;
- 6) Applicable plate type: 96-well plate (or 48-well plate);
- 7) reading speed: single wavelength, 5s; dual wavelength: 10s;
- 8) Filter standard configuration: 405,450,492,630. Up to 10 filters in the (400-800) nm

range;

9) Dimensions: 420 mm × 350 mm × 170 mm;

10) Quality: 10.5Kg;

11) Preheat the boot for 30 minutes.

1.5 normal working conditions and storage conditions

1.5.1 Normal working conditions

1) Ambient temperature: 10 °C ~ 30 °C;

2) Relative humidity: 30% ~ 80%;

3) Atmospheric pressure: 86kPa-106kPa;

4) away from strong electromagnetic interference sources, to avoid direct glare;

5) The workplace dust, vibration; the air may not contain acid, salt and other corrosive gases;

6) Power supply voltage range: 220 ~

7) Power frequency: 50Hz ± 1Hz;

8) Input power: 110VA;

9) has a good grounding environment.

1.5.2 Storage conditions

Packaged products should be stored at a temperature of -20 °C ~ 55 °C, the relative humidity of not more than 93%, non-corrosive gases and well-ventilated room.

1.6 appearance

- a) The text and logo should be clear and the labels should be firmly attached and should not be loosened or curled;
- b) The surface should be smooth, smooth, uniform color, no bumps, scratches and uneven bump defects;
- c) The fastener connection should be firm and reliable, without looseness;
- d) moving parts should be smooth, should not be stuck, sudden jump and significant empty back, the key group should be flexible bounce.

1.7 Wavelength accuracy

The center wavelength of the filter configured by the analyzer should not exceed ± 2 nm.

1.8 Absorbance accuracy

The accuracy of the absorbance detected by the analyzer should be in accordance with the following table:

Analyzer detection accuracy requirements

range of absorbency	Accuracy Error
0.000 \sim \leq 0.500	\pm 0.005
$>$ 0.500 \sim \leq 1.000	\pm 0.01
$>$ 1.000 \sim \leq 2.000	\pm 0.02
$>$ 2.000 \sim \leq 3.000	\pm 0.03

1.9 Linearity error

In the absorbance value of 0 ~ 3.000A range, the analyzer detection linear correlation coefficient (r) of not less than 0.995.

1.10 absorbance repeatability

The coefficient of variation (CV) for the analyzer's repeatability measurements should not exceed $\leq 0.5\%$.

1.11 absorbance stability

Series analyzer absorbance stability of no more than ± 0.005 ;

1.12 Sensitivity

With 450nm working wavelength detection of chromium 5mg / L potassium dichromate standard material (liquid volume 350ul / hole), the instrument measured absorbance value should be not less than 0.01.

1.13 Differences between channels

Taking air as reference, the difference of absorbance between two channels of the instrument requires no more than 0.02.

1.14 main function

The main function of the instrument is shown in the following table.

Main function table

	Features	Main function
1	Operation method	touch screen
2	Filter selection	Manual
3	Vibration plate function	no
4	Input method	Chinese, English, Numbers
5	Program storage	200 project procedures and calibration parameters;
6	Test result storage	105 board test results
7	Detection function	With absorbance detection, qualitative detection and quantitative detection Visual layout function; veneer 12 test items function
8	Qualitative detection	Single threshold, S / CO
9	Quantitative calculation method	Straight-line method, point-to-point method, linear regression method, semi-logarithmic regression method, exponential regression method, full logarithmic regression method, ratio regression method, ratio semi-logarithmic regression method, quadratic curve, Logit-Log curve
10	Single / double hole selection	Single hole detection
	Single / dual wavelength selection	You can choose single wavelength detection or dual wavelength detection
11	Detect the output	Qualitative: sample absorbance, S / CO value, the critical value and the results of negative determination; Quantitative: sample absorbance, sample concentration, the normal reference value and test results. Can print the entire board test results, and print the Chinese comprehensive test report by the patient
12	Quality control function	With quality control function, output QC data and L-J QC chart and Westgrad multi-rule decision
13	Communication Interface	RS-232
14	printer	External printer or built-in micro-play
15	POST function	yes
16	Light source signal monitoring	Yes
17	Light source sleep	Yes

1.15 safety requirements

Equipment rated pollution level: 2; transient overvoltage category: II category.

Shall comply with GB 4793.1-2007 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements", GB 4793.9-2013 "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 9: Laboratory Special Requirements for Automatic and Semi-Automatic Equipment for Analysis and Other Purposes ", YY 0648-2008" Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Specific Requirements for Medical Equipment for In Vitro Diagnostics (IVD) " Terms of the requirements.

1.16 Environmental Test Requirements

Should be consistent with GB / T14710-2009 "Medical Appliances Environmental Requirements and Test Methods" Climate Group I , Mechanical Environment Group II requirements.

1.17 Electromagnetic compatibility requirements

Group classification Belongs to: 1 group A class. Should be consistent with GB / T 18268.1-2010 "Measurement, Control and Laboratory Electromagnetic Compatibility Requirements for Electrical Equipment Part 1: General Requirements" and GB / T 18268.26-2010 "Measurement, Control and Laboratory Electromagnetic Compatibility Sexuality requirements - Part 26: Requirements for the applicable clauses in IVD

medical devices with special requirements.



Warning

It is the user's responsibility to ensure that the equipment is compatible with the environment and that the equipment is working properly.

It is recommended to evaluate the electromagnetic environment before using the equipment.



Warning

Do not use this equipment near strong radiation sources (such as unshielded RF sources) as this may interfere with the normal operation of the equipment.



Warning

This equipment according to GB 4824 Class A equipment design and testing. In a home environment, this device may cause radio interference and require protective measures.

1.18 Production Date

The specific date of product production, see product labels

1.19 useful life

- a) The expected life of the product is 6 years.
- b) After the expiration of the validity period, the instrument can be disposed of according to local environmental protection regulations and medical device treatment regulations stipulated by relevant national laws or contact with our company for

recycling. Otherwise, the environment may be polluted.

1.20 product contraindications

No contraindications found for this product.

Chapter II Instrument Installation

2.1 Instrument unpacking

- 1) Unpack the instrument. Save the box and packaging materials, in the future you need to repack the instrument;
- 2) Check the contents of the package and confirm that it matches the packing list.

Note: If you find any missing or missing parts, contact your dealer.

2.2 environmental requirements

There is no direct sunlight, the choice of the work surface to be flat, and there is enough space to host microplate reader, to facilitate the operator to disconnect the power supply to avoid the workbench have a greater vibration (such as a centrifuge placed on the stage) . If you need to recommend users to filter power supply.

To ensure the normal operation of the instrument, it is forbidden to place it in the following places:

- Where the temperature changes very much
- In a particularly hot or especially cold place

- Where there is a lot of dust
- Close to electromagnetic devices that generate strong magnetic fields

2.3 to start the installation

2.3.1 Connect the instrument to the power supply

- 1) Plug the power cord assembly's connector into the instrument's appliance inlet.
- 2) Plug the power cord assembly into the AC outlet.

2.3.2 Connecting an external printer (if the user selected an external printer)

- 1) Make sure both the printer and the instrument are off.
- 2) Insert the square end of the USB interface's print cable into the USB port on the back of the printer.
- 3) Insert the flat end of the print cable into the printer's print port.
- 4) Connect the printer to the AC power supply with the power cord assembly supplied with the printer.

5) First open the enzyme host, then turn on the external printer to ensure the normal operation of the printer; when pulling or plugging the cable, it is best to turn off the power of the host and the printer, otherwise it may damage the printer interface to cause printing unusual. When a printing error occurs, be sure to unplug the printer, and then reconnect the power, the printer restarts.

If the user selects the built-in printer, check if the paper is loaded.

2.3.3 Connect Serial Line (If Using Workstation Software)

- 1) Determine the instrument, the PC is turned off.

2) The attached 9-pin serial port male to male PC1 COM1, the other end of the serial cable 232-communication interface.

Rear panel layout

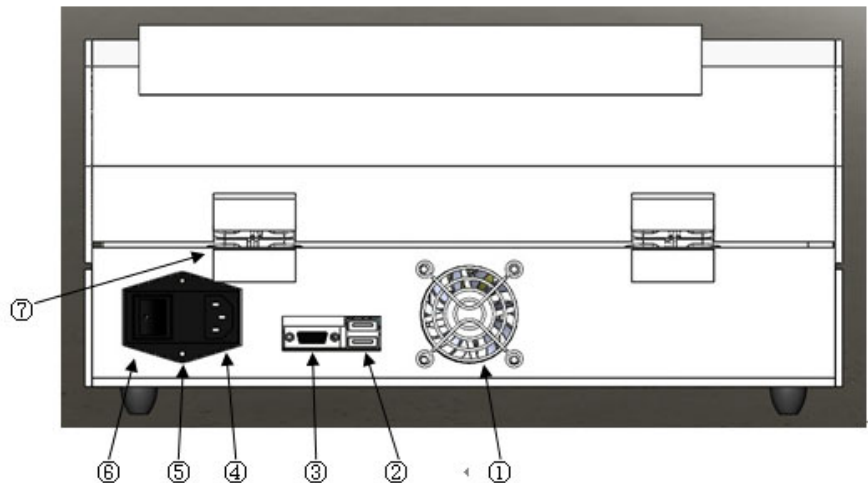


Figure 1 behind the layout of the instrument

① - cooling fan; ② - USB interface; ③ - 232 - communication interface; ④-appliance input socket; ⑤-fuse;
⑥ - power switch; ⑦ - chassis hinge;

2.3.4 plate method of placing the correct

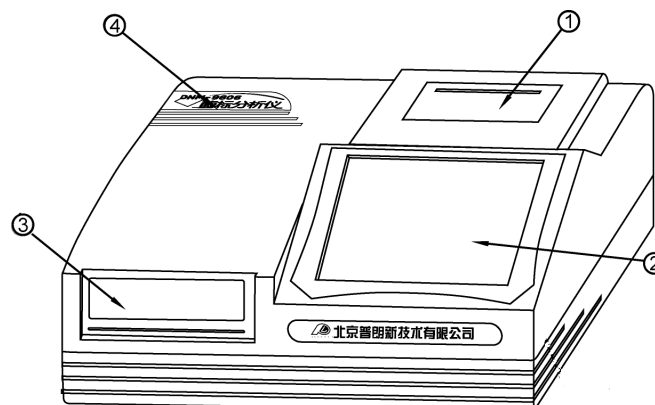


Figure 2 Front view of the instrument

- ① - micro-printer ② - LCD and touch screen ③ - import and export of ELISA plate
④ - Product Model

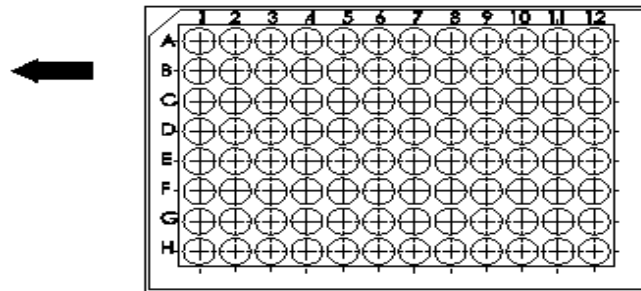


Figure 3 ELISA plate loading direction diagram:

Inspection in the layout of the front panel in the sequence number ④ plate ELISA plate loading and unloading, and marked by the plate marked the direction of the correct orientation. Placed ELISA plate, must not be too much force, and pay attention to flat.

Chapter III input operation

3.1 input operation

There are several main operation keyboards in the operating system of this instrument.

Now, we introduce their operation methods respectively.

3.1.1 Numeric keypad

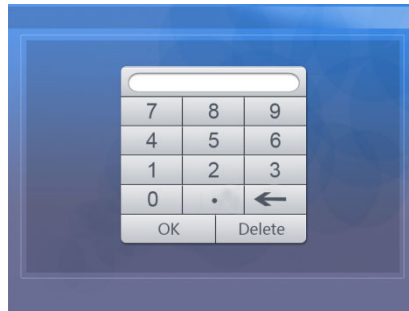


Figure 4 numeric keypad

The input window can be used to enter integers, decimals (such as standard concentration values). The input consists of 0-9 and the decimal point. Input is complete press "confirm" button. Press "Cancel" button to abandon the input, return directly. During input, press the "←" button to clear the entered characters. The other input interface "←, OK, Cancel" button has the same function here.

3.1.2 character input keyboard

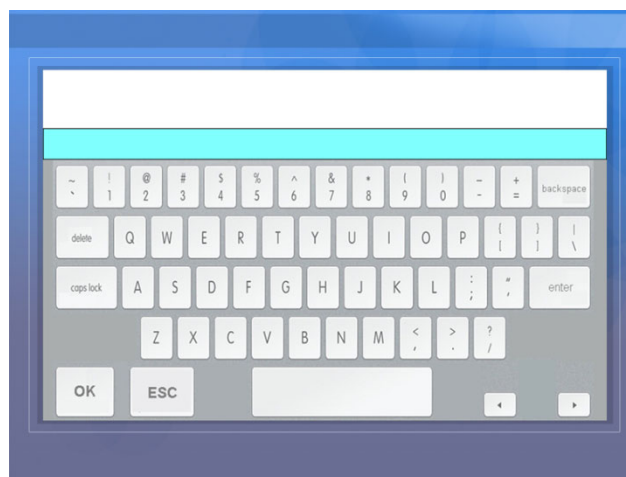


Figure 5 character input keyboard

Character input keyboard used to enter letters and Chinese characters. Used to set the name of the test items, hospital information and patient information. A series of 0-9

and A-Z characters are arranged in the form of a similar PC keyboard. The "caps lock" button is used to support case switching. The top text box shows the characters and Chinese characters that have been entered. If you want to enter the Chinese characters are not displayed in the text box on the right, then press the lower right corner ">" or "<" to display paging, and then select the corresponding Chinese characters. If you only enter English or characters, click "enter" to finish inputting and click "ok" to return to the original interface.

Chapter IV Boot

4.1 boot process

Turn on the power switch, this time the instrument automatically enters the POST process and gives a prompt on the screen:

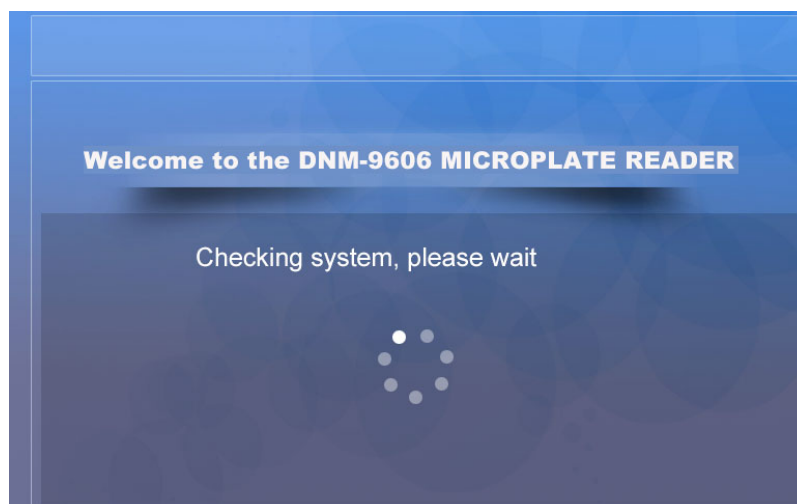


Figure 6 POST

DNM-9606 microplate self-test process to complete the following tasks:

- a) tray, filter disc action
- b) According to the order of the wavelength values set by the system, the working status of each wavelength value is detected in turn, and if a certain wavelength fails, a prompt is given.
- c) Detection of the entire light path, prompt failure promptly.

Self-test process, if there is an error occurs, the system will be prompted. Users can refer to the manual "Maintenance" chapter "common troubleshooting" to check. If you can not solve, please contact the seller.

After initialization, the instrument automatically displays the main menu, at this time, the user can operate the instrument as needed (programming or testing, etc.).

Note: After the instrument is powered on, it should be preheated for 30 minutes, then start to confirm the detection function for clinical examination.

4.2 main menu

After the boot process, enter the main menu window. The main menu is DNM-9606-type microplate reader entrance of all user functions, the user clicks the icon in the window, you can carry out the required specific functions.



Figure 7 main menu

Icon and the corresponding function as follows:

"Test" icon: select the test items have been entered for clinical testing. Requires at least the completion of a project to set up the test (the instrument has been stored in the trial program).

"Project Settings" icon: write, modify, delete the specific project parameters required for clinical testing;

"System Management" icon: Set the instrument used detection wavelength, system time, vibration board time, protocol and other parameters as well as the hospital name and doctor's name and other information.

Quality Control Icon: Displays, prints control data and quality control charts, manages multiple quality control items.

Comprehensive Report Icon: Displays and prints all the test results of a patient.

"Save and Exit" icon: Save the parameters used by the system (Note: Before each shutdown, you must click the "Save and Exit" icon, otherwise the detection data will be lost).

The lower right corner of the main menu shows the current system time, updated every

minute.

Chapter V Project Settings

5.1 Setting instructions

The instrument before use, should first be based on the actual needs of users to set up, in order to facilitate future work, the program number sequence should be based on the following principles:

- a) The most commonly used test items, in the front row;
- b) Combinations (eg hepatitis B two and a half) are grouped together.

5.2 Setup Procedure

5.2.1 Project Management

In the main menu, click "Project Settings", the following interface is displayed (the list of the set items is displayed in the interface):

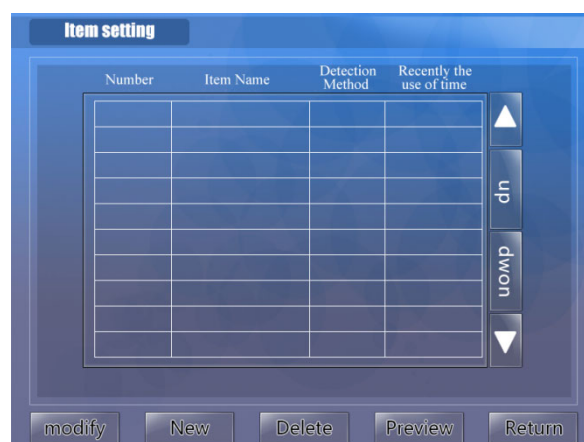


Figure 8 Project Settings

In this interface, the user can create a new test items, you can also create test items have been edited, deleted. Up to 200 items can be set. Specific button functions are as follows:

"Change": to modify the project has been established.

"New": create a new testing project. The program number is automatically assigned by the system.

"Delete": delete a test project has been established.

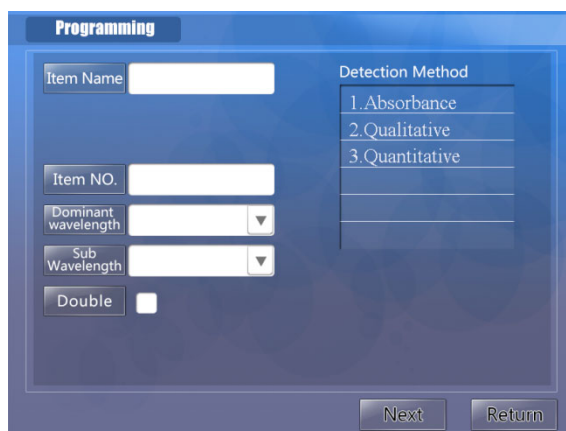
"Preview": For calibrated quantitative test items, you can view the calibration curve and calibration parameters.

"Back": return to the main menu.

Note: Each screen can display up to 18 test items, you can click on the right side of the screen "on the page", "page down" screen by screen display.

5.2.2 New Project

Project name and number: Click "New" button to enter the following menu:



The screenshot shows a software interface titled "Programming". It contains several input fields and a list:

- Item Name**: A text input field.
- Item NO.**: A text input field.
- Dominant wavelength**: A dropdown menu.
- Sub Wavelength**: A dropdown menu.
- Double**: A checkbox.
- Detection Method**: A list with three options: 1. Absorbance, 2. Qualitative, 3. Quantitative.
- Next** and **Return**: Two buttons at the bottom right.

Figure 9 project name and number

In this interface, the user is required to specify the name of the test item, the

wavelength used for the test, the hole feature and the test method. Specific methods of operation are as follows:

- 1) "Project Name": Click the text box after "Project Name", and then pop-up the character input keyboard shown in 3.1.2, the user can input up to 18 characters (9 Chinese characters) as the project name;
- 2) "Project Number": automatically generated by the system;
- 3) "Wavelength": Refer to the detection wavelength used in the reagent manual and click "Main Wavelength" or "Sub Wavelength" to switch the wavelengths entered in the system settings.

When changing or adding system wavelengths, refer to the "System Management" chapter. If you do not use dual wavelength detection, you can keep the "secondary wavelength" to "no" can be;

- 4) "Two-hole": indicates that the current project requires that all samples and standards be double-checked and averaged.

Click "small hole" in front of the small box, when the "" means that this feature is selected, the instrument default single hole detection;

- 5) "test mode": List of the three detection methods, namely: absorbance test only absorbance test, without further processing; qualitative test method to test the absorbance, and then cut-off values were negative, positive determination; quantitative detection The method first tests the absorbance, and then calculates and analyzes the detected concentration result.

- 6) If you want to abandon the settings to return to the main menu, click the "Back"

button; need to continue to set Click the "Next" button. If you choose the absorbance detection method, you have completed the setup steps, the instrument shows the storage confirmation interface as shown below:

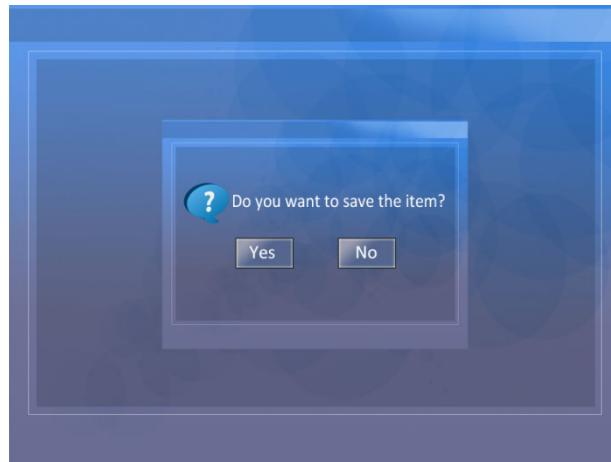


Figure 10 Confirm the save

Clicking the "Yes" button saves the current project information and returns to the main menu. Click the "No" button, do not save directly back to the main menu.

5.2.3 Qualitative detection method

In 5.2.2, if you select the "qualitative test" test mode, and click "Next" button, enter the setting interface of qualitative test, as shown below:

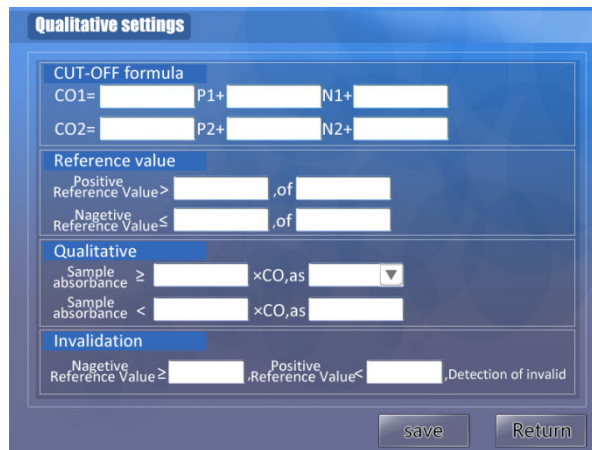


Figure 11 qualitative settings

In this interface, the user to enter the threshold formula, the range of control, qualitative determination and other parameters, the specific method of operation is as follows:

- 1) "CO" in the "Threshold Formula" screen indicates the abbreviation of Cot-Off. To meet the requirements of the qualitative control method and different reagents' critical value, $CO = A * P + B * N + F$ (fill in according to the instruction manual of the kit and do not fill in the data) Add value according to a single critical calculation.
- 2) "Control value": The range of the control value is selected according to the instruction manual of the kit, including "negative hole and positive hole". Two optional control holes are used to specify the range of absorbance value of the selected control hole at the time of the test. For example: Reagents instructions required, the negative control absorbance can not be less than 0.05, or 0.05 to calculate. Then you can set it like this: First, enter 0.05 in the first text box after the Negative Control value $\langle \rangle$, which satisfies the requirement.
- 3) "Qualitative Determination" column is used to set the test results of negative, positive conditions. Click to switch "positive" and "negative" directions. The two

judgment conditions respectively correspond to the negative judgment condition and the positive judgment condition, and the middle area of the two conditions is the "gray area". (The gray area is indicated by "?", And the user should double-check the sample again.)

4) "invalid judgment" according to the instructions of the kit selection, you can select the combination of invalid conditions. Do not enter any number that does not invalid judgment. When the test results meet the invalid conditions, will pop up a message.

5) Save the settings, click Save, discard the settings and click Back.

5.2.4 quantitative detection method

In 5.2.2, if you select the "Quantitative Detection" test mode, and click the "Next" button, enter the quantitative test method setting interface, as shown below:

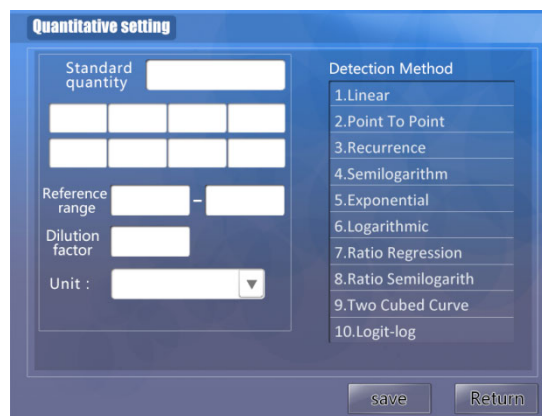


Figure 12 Quantitative Settings

This interface is used to complete the quantitative testing of the parameters used, the specific operation is as follows:

1) The number of "standard" behind the text box, according to the specific needs of the input 1-8 standard (only fill in the standard quantity, in the text box below to fill in the

specified number of standard concentrations). Select a good standard quantity, click the text box below, press the prompts to enter the corresponding standard concentration;

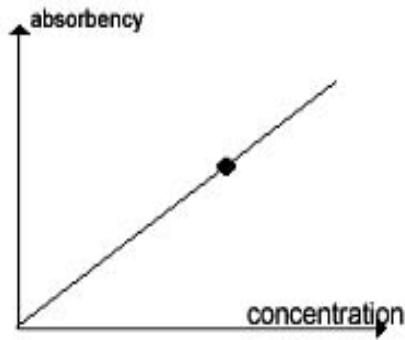
2) Two text boxes after the "Reference Range" to enter two values that determine the test result. Enter the lower limit of the reference range by clicking the first text box after the reference range, then click the second text box and enter the upper limit of the reference range. When the test result is lower than the value in the first text, it is identified by "L"; when the test result is higher than the value in the second text, it is identified by "H"

3) "Dilution Factor" Click on the textbox below to pop up the numeric keypad and input the dilution factor of the current item;

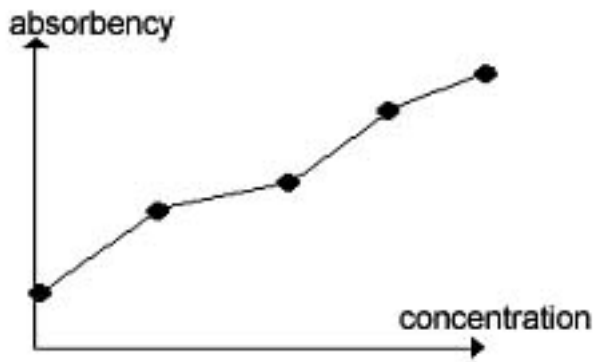
4) "Unit" Click the text box behind, select the unit of detection of the current project from the list of units switched;

5) "Calculation Formula" According to the requirements, click the calculation formula in the "Calculation Formula" list to indicate that it is currently selected for use. The specific formula is as follows:

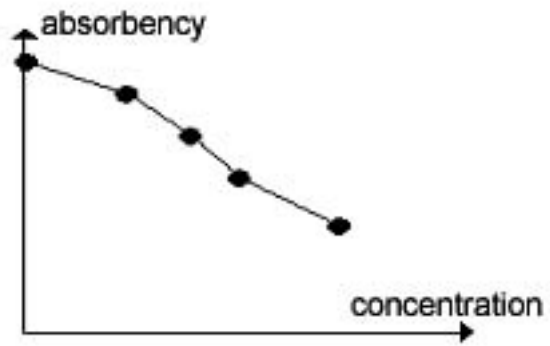
- "Straight line method": You need to set a standard. The calibration curve is the connection point between the origin and the standard point (abscissa is concentration, ordinate is absorbance). To calibrate a single point, you must set a blank hole to calibrate 0 point. As shown below:



- point-to-point method (broken line method). Allow to set 2-8 standard products, the standard point of connection for the calibration curve.

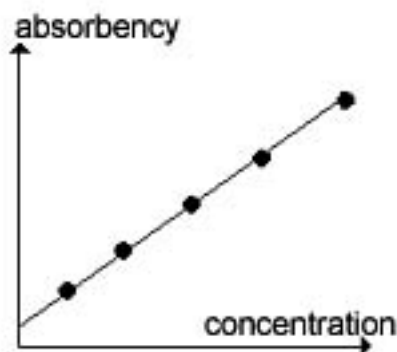


A-C is positive correlation



A-C is negative correlation

- Linear regression method. It is allowed to set 2-8 standards, through which a straight line $Y = kX + b$ ($A = kC + b$) is returned as a calibration curve.



Moreover:

- Exponential regression: A-C is exponentially related to $A = K10^{bC}$ and logarithmic

absorbance is converted to linear regression ($\lg A = \lg k + bC$) ;

- Logarithmic regression: A-C has a power function related $A = KC^b$, and logarithm of absorbance is converted into a linear regression form ($\lg A = \lg k + b \lg C$) ;

- semi-logarithmic regression: ($A = k \lg C + b$), direct regression processing;

- Ratio regression: ($A / A_0\% = kC + b$), directly for regression processing;

- Ratio semilogarithmic regression ($A / A_0\% = k \log C + b$); when placing standards, follow the precautions indicated above;

- Quadratic curve method ($A = aC^2 + bC + d$) .

Note: Ratio regression requires that the first standard be the one with the highest absorbance. For negative correlation regression, the first standard has the lowest concentration and the highest absorbance. For the positive correlation, the first standard has the highest concentration and the highest absorbance.

6) To return to the previous screen, click "Previous"; save the setting results, click "Save"; to abandon the settings, click "Back."

According to the above introduction, you can complete the setup of different detection methods.

Chapter VI test operation

6.1 Precautions

The instrument set up, you can conduct clinical tests. To ensure the accuracy of test results, please note the following:

- 1) Strictly follow the steps and requirements stipulated in the instruction manual of the kit;
- 2) When using the instrument for the first time or replacing the reagent of the new batch, the instrument must be rescaled; the reagent of different batches must not be mixed; the reagent within the valid period must be used; the parameter of the item stored in the instrument must be consistent with the parameter specified in the kit ;
- 3) It is suggested that the user establish the indoor quality control system, through the inspection of the quality control products, keep abreast of the quality status of on-site inspection;
- 4) remind the user not to touch the plate rack brackets;
- 5) Just boot can not be immediately tested, should be 30 minutes before the instrument warm-up, and then start the test.

6.2 detection

Click the "test" icon in the main menu to enter the detection function. The following figure shows the interface of the detection function.



Figure 13 Test interface

Into the detection interface, the interface is arranged above the sample plate can be used when the sample number, blank holes and standard hole and other hole types (followed by letters for the corresponding hole type abbreviation); which are arranged in accordance with the 96-well microplate corresponding button Array; the lower "Select Items" button is used to arrange a test item in the current board (up to 12 items can be arranged on each board); the "Clear All" button is used to clear all layout information of the current board.

The five buttons below the interface function as follows:

"Options" - can choose to add the items to be detected, the specific content to see the selection of a project 6.2.1.

Clear All - Clears the items that have been selected and the layout hole information that has been set.

"Report" - Before the test, you can use this key to go directly to the sample information input interface, which can process the information of the currently entered patient. Specific reference to the "comprehensive report" chapter content.

"OK" - to complete the hole setting, and put the plate under test to confirm that the function, the instrument began testing.

"Back" - stop detection, return to the main menu.

The first test of a project, you must set the calibration function hole, calibration. In the interface shown in Figure 16, after selecting the item, click the hole type above, then click the specific location button in the 96-hole layout. For example, to set two holes A1 and A2 as a negative hole, follow the steps below: Click the "Negative (N)" button. This button changes color to indicate that consecutive negative holes are to be set, and then click "A1, A2 "Button, said the two holes set negative hole. Positive holes, standard holes, blank holes, sample holes, etc. are operated according to this method. And then follow these kinds of operations one by one to set up other holes to complete the entire board layout can be.

"Sample No.": Click the "Sample" button to set the sample hole, click the hole position once as the starting point, click again as the end point, the hole which is not set between the two clicks is set as the sample hole, Sample number is automatically accumulated (sample number for each sample is unique, if different items use the same sample number is considered a sample of different items); sample number display text box is the value of the next sample number (Sample number from 000 to 999 total 1000). You can also set the sample's starting sample number.

"Current item": The selected item is displayed in the text box of the current item, which is also the item set by the current microtiter plate.

Specific operation process: Select the project → set the test information (hole layout) → OK.

6.2.1 Select the item

Select Project: Click "Project" in the following pop-up interface to select a project has been programmed (no option, can not be detected).

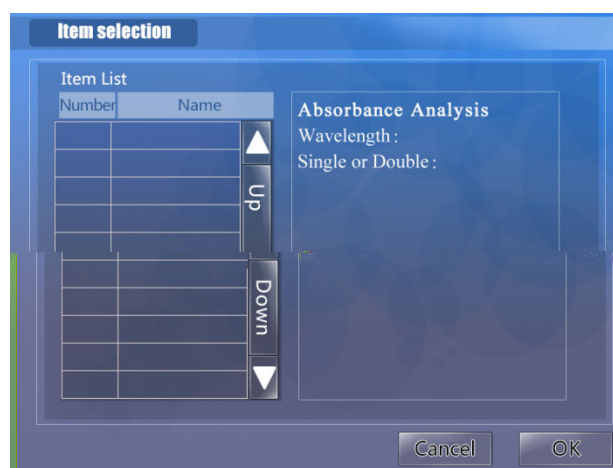


Figure 14 Select item

Click "item list" in an item, "👉" means that the item is selected, and the right side will display the specific content of the item, click the "cancel" button to abandon the selection item and return to the "testing" page; Click "OK" to select the specified item, then return to "Detect" page. Repeat item selection You can add one more item to a single sheet, allowing a maximum of 12 items to be continuously added.

6.2.2 test results

After the test is finished, the instrument will display the plate absorbance value of the

test as shown below:

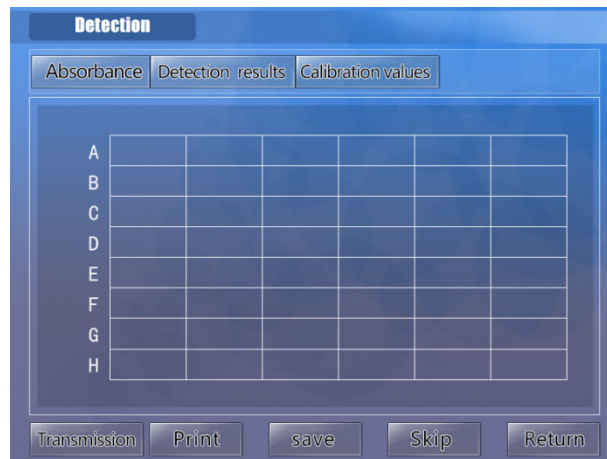


Figure 15 test results

This page shows the concentration of the corresponding wells in the format of a 96-well plate. You can view the entire content by clicking "Form Feed". Click on the bottom of the "print" button, you can print the entire plate results.

6.2.3 Printing

The Test Results page and the Absorbance page display exactly the same, except that the result of the determination is added after the calculated value for each well is displayed. For example: "-" and "+" in the qualitative test and "L" and "H" in the quantitative test (the qualitative test is the semi-quantitative S / CO; the quantitative test is the concentration). Click on the bottom of the "print" button, the entire board test results can be printed out. The following partial results print style

6.2.4 calibration value

After the test is finished, the "Calibration Value" page is displayed as follows, and the calibration can be reviewed.

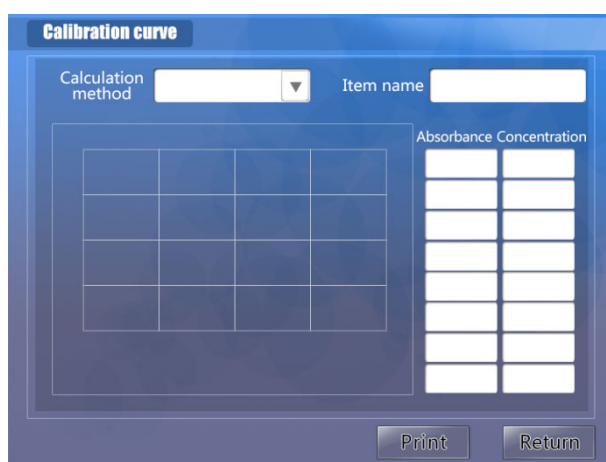


Figure 16 calibration value

The Scalings page shows the calibration parameters and calibration curve in the quantitative assay. The user selects an item as the currently displayed curve. The Current Calculation Method drop-down list shows the calculation formula used by the current project, allowing you to switch other calculation methods and recalculate the corresponding concentration and redraw the calibration curve. The image area on the left shows the calibration curve of the current project using the current calculation method. The eight text boxes below the "Absorbance" on the right correspond to the absorbance of the current project standard; the eight text boxes below the "Concentration" display the corresponding standard concentration values. This allows the user to modify the absorbance of the standard, then recalculate, plot.

The operator can select the one with the largest (r) based on the size and experience of the linear correlation coefficient (r), which should be greater than 0.975, and use the

calculated result as the final result of the sample to minimize the fitting error .

Chapter VII comprehensive report

7.1 Report form

Press the "Composite Report" icon in the main menu. Pop-up the following interface:

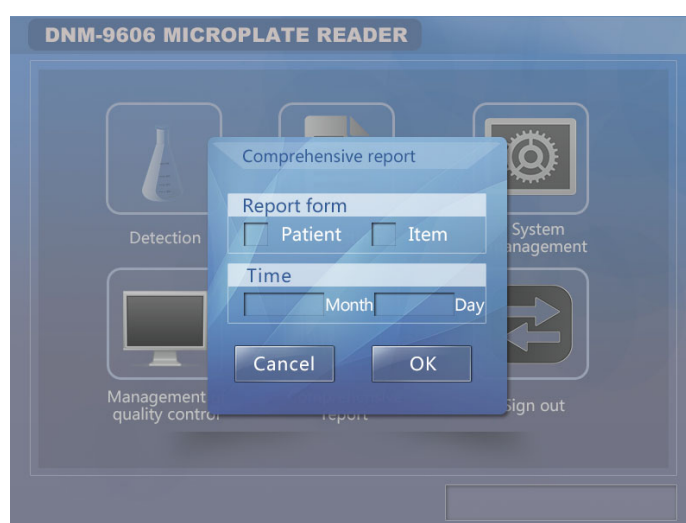


Figure 17 Synthesis Report

Select the required "report format": report by patient or by item. All sample numbers are indexed by patient's report; item numbers are indexed by project report. "Time" refers to the time corresponding to the operation query. Click "OK" to check the saving result of the entry time, click "Cancel" to return to the main menu.

7.2 by patient report

If you select "Patient" report form, the following screen will be displayed:

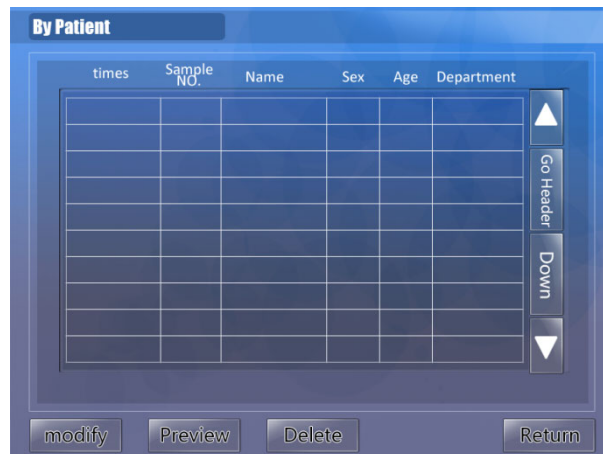


Figure 17 by patient search

7.2.1 Basic operation

Select a patient: click in the list, the selected patient appears "". Only one patient can be selected at the same time. Selected patients as the current patient, "preview", "change" operation is only for the current patient.

7.2.2 Modify patient information

Select a patient, press the "change" button to enter the patient information input window:

Figure 18 Patient Information

Which click on the "department" or "doctor", you can jump to the "hospital

information" interface, click the doctor and the department you want to select and then click back (default is the current first message). Click the text box after "Name", pop-up character input keyboard, enter the patient's name (support Chinese). Click on the "Age" text box, pop up the numeric keypad, enter the patient's age. Click in the "Inpatient / Outpatient" text box, pop-up character input keyboard, enter up to 10 characters. Click "bed number" pop-up numeric keypad, you can enter 0-65535 number. Enter the patient information is completed, click "OK" button to save the changes, click "Cancel" button to give up the changes. If you want to modify the next patient information in the current display, click the "Next" button.

7.2.3 delete test results

First mark the record you want to delete, and then click the "Delete" button, all the test results of the patient will be deleted.

7.2.4 Report Preview

After selecting a patient, click the "Preview" button to enter the preview interface as shown in the figure below. The test results of all the patients in the list are displayed in the list (maximum 10 test results per patient).

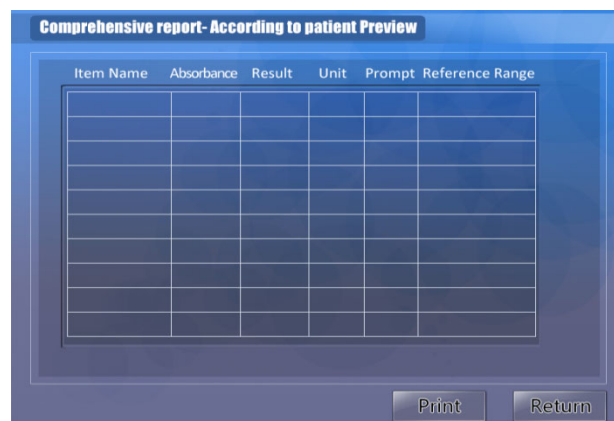


Figure 19 Preview Report

7.2.5 Print the report

Click the "Print" button, the patient detected the information will be printed out.

7.3 report by project

If you choose "By Project" report form, the following interface will be displayed:



Figure 20 reports by project

The basic operation of the item list screen (Check, Print, Preview, Delete) is the same as the Patient List screen. This is not repeated here.

7.3.1 Report Preview

After selecting an item, click the "Preview" button to enter the preview window. All the test results of the item are displayed in the list, as shown in the following figure:

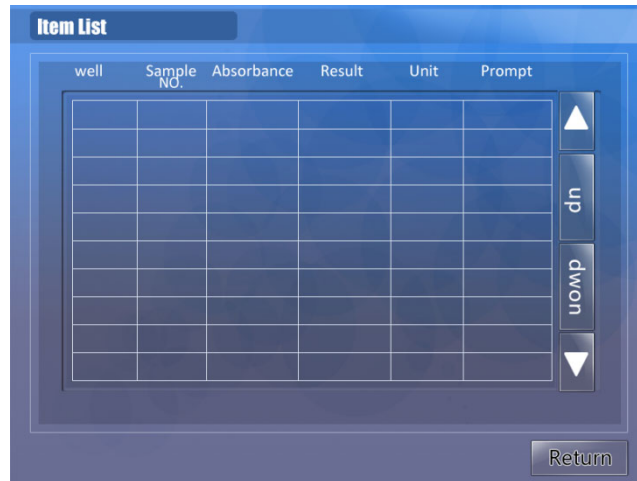


Figure 21 Project Information Preview

Chapter VIII Quality Control Management

8.1 Basic Operation

In the main menu, click the "Quality Control" icon, enter the quality control processing interface, as shown below:

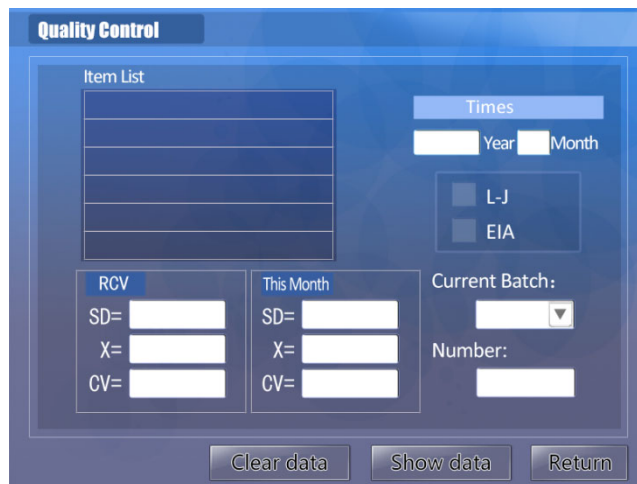


Figure 22 Quality Control

Listed in the Controlled Items List are items that require quality control during

inspection (specify a control hole for layout). The instrument supports a total of 6 groups of quality control items numbered from 1 to 6, and each quality control item can be controlled by three points (1 #, 2 #, 3 #). From the "Time" text box, 12 months quality control content. Note: Absorbance test items can not do quality control, quality control value is not allowed to 0. After selecting a QC item in the QC Item List, you can press the Clear QC Data button to clear the current QC data of the item or select Show QC Data to view the QC records of the current month. The "SD", "X" and "CV" contents in 'RCV' are the standard deviations and target values used for plotting LJ QC charts; the "SD", "X" and "CV" is calculated using quality control data this month, can only view. Without RCV: SD, X values, no QC chart can be formed. Once the user enters the RCV: SD, X value and the control hole is specified at the time of the test, the control automatically draws the control chart and performs a Westgard multi-rule runaway check and displays the relevant controls Information (QC information includes: Controlled, Alarms, Runaway Types <1-3s / 2-2s / 4-1s / R-4s / 10x>).

"Current batch": The batch number of this control, click the drop-down button to switch batches.

"Current lot number": Identifies the batch of quality control item, with 8 valid characters.

Click on the "L-J method" or "instant method" to switch the quality control method.

To view the QC data, QC status and QC chart for a given project, first select this project and then click the "Show QC Data" button to switch to the QC Data and QC Status screen.

8.2 Quality control status

The initial quality control of a project, more than 3 QC data and no more than 20 QC data, you can first use the instant method QC, more than 20 QC data can be used after the L-J quality control method

Judgment of instantaneous method: The SI upper limit value or SI lower limit value calculated by the control value of the control item has an alarm exceeding 2SD which is stipulated in the SI value table; 3SD which exceeds the SI value table is out of control; Control status.

Westgard Multi-Rule Decision: When controls are using the L-J method, multi-rule decisions are made based on entered or calculated "X" and "SD" values.

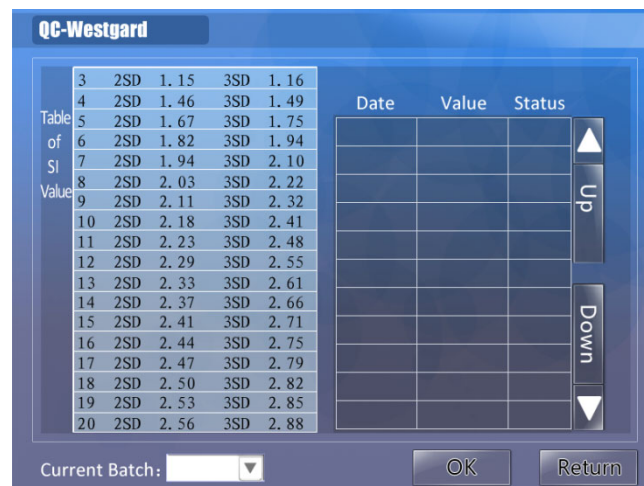


Figure 23 Quality Control Status

The left side is the SI value table, the right side will show the quality control data and determine the status, according to the requirements of the instant method of quality control, the corresponding data will be displayed (the instrument automatically calculates the SI upper limit and SI lower limit, and make determination). Below the "current batch" drop-down menu can be used to switch the current control of the

project's low, medium and high 3 groups of quality control records. Click "OK" to enter the L-J QC interface and display the QC chart.

8.3 Quality Control Chart

L-J quality control interface as shown below:

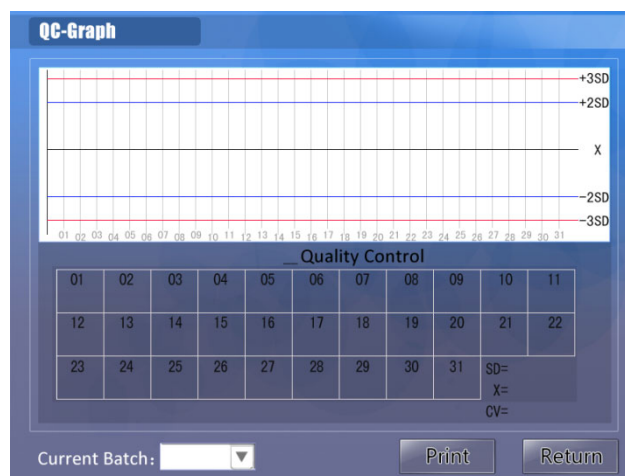


Figure 24 L-J QC Chart

When the test data exceeds two groups, a QC chart will be drawn. The RCV: SD and X values entered in the previous interface are used for drawing, and the SD and X values for the lower display are calculated values of the current QC data. Below the "current batch" drop-down menu can be used to switch the current control of the project's low, medium and high 3 groups of quality control records. Click Print to print control charts and quality control data. If the corresponding QC data is 0, it will be shown as invalid and will not be displayed.

Chapter IX System Management

9.1 basic functions

In the main menu, click the "System Management" icon to enter the system management function interface, as shown below:

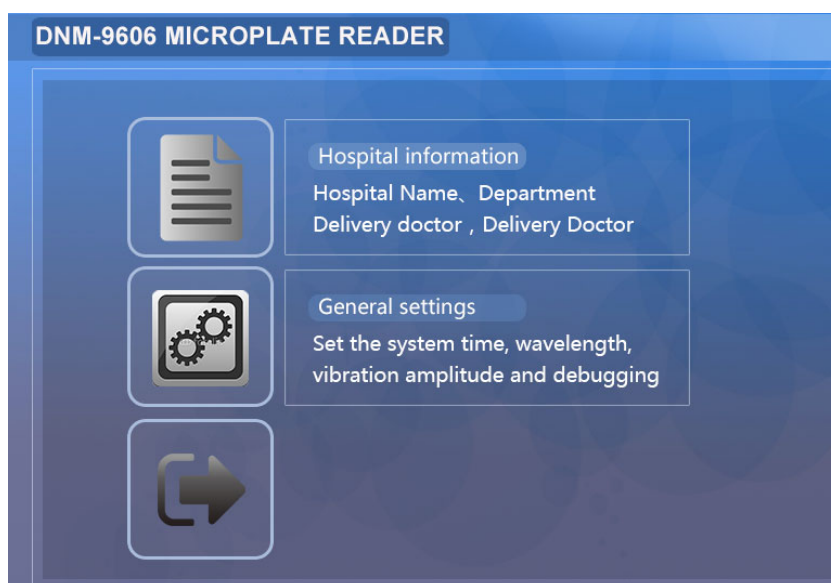


Figure 26 Hospital Information

After clicking the text box behind the "hospital name", a character input keyboard pops up where you can input the hospital name of 30 characters (15 characters). The name of the hospital is printed on the title bar when the patient's comprehensive report is printed. Click on the small box in front of the "submission doctor". When the background is blue, it indicates that the current doctor is performing the operation. Can click on the "Add" button to join a submission doctor (up to 20). When you want to delete a submission doctor, first select from the list, and then click the "delete" button. By the same token, when the small box in front of the "department" and "examiner" is selected, the corresponding adding and deleting functions can be

performed. When you click the "Clear All" button, the entire contents of the "Hospital Name", "Department", and "Submitting Doctor" entries will be cleared. Click the "Back" button to return to the "Main Menu" interface.

9.2 Hospital Information

System management interface, click the "hospital information" button, then enter the hospital information processing interface, as shown below:

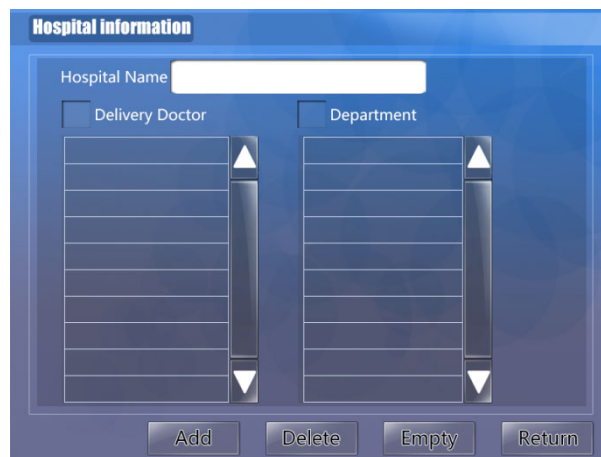


Figure 26 Hospital Information

After clicking the text box behind the "hospital name", a character input keyboard pops up where you can input the hospital name of 30 characters (15 characters). The name of the hospital is printed on the title bar when the patient's comprehensive report is printed. Click on the small box in front of the "submission doctor". When the background is blue, it indicates that the current doctor is performing the operation. Can click on the "Add" button to join a submission doctor (up to 20). When you want to delete a submission doctor, first select from the list, and then click the "delete" button. By the same token, when the small box in front of the "department" and

"examiner" is selected, the corresponding adding and deleting functions can be executed. When you click the "Clear All" button, the entire contents of the "Hospital Name", "Department", and "Doctor Examiner" entries will be cleared. Click the "Back" button to return to the "Main Menu" interface.

9.3 General Settings

9.3.1 General parameters

System management interface, click the "General Settings" button to enter the system parameter settings interface,

To modify the system time, you can directly click the text box corresponding time, and then pop up the numeric keypad, enter the correct time. The eight text boxes behind "Wavelength Value" indicate the filters installed on the current system. A value of 0 means no use. The vibration selection system supports "0 ~ 5" five vibration plate modes, which are used to detect pre-mixed samples and adjust the time 0 ~ 60s according to requirements. "Debug" function is mainly used for the production or maintenance test light path (users do not need to operate this). Click the "Protocol" text box to switch the two protocols, the user first select the communication protocol, and then press the "Send" button during the test, the instrument can detect the absorbance sent to the PC. For a detailed description of the communication protocol, refer to section 9.3.3. The "Delete All Test Results" button is used to clear all the stored test data (the data that the comprehensive report can check). The Back button returns to the Main Menu screen.

General settings interface:

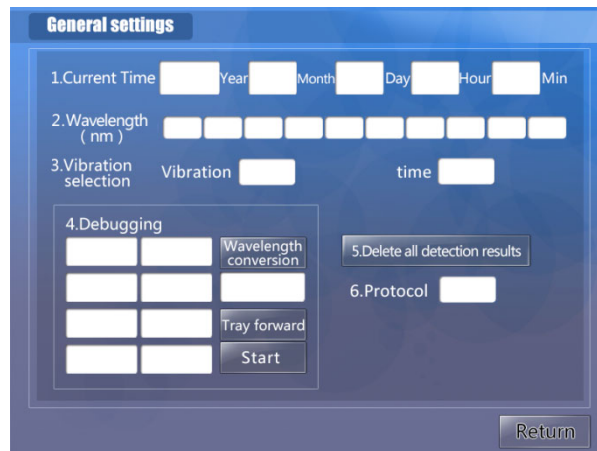


Figure 27 General Settings

9.3.2 Debugging

Click "Debug" to enter the AD data adjustment function, this function is the manufacturer's factory self-test debugging function.

9.3.1 Communication Protocol Description

The two communication protocols used by the instrument are: Communication Protocol 1 or Communication Protocol 2. Communication protocol 1 is the announced external software data interface protocol (normal protocol). Communication protocol 2 is developed by the company ELISA workstation software data interface protocol (encryption protocol).

1) The description of communication protocol 1 is as follows:

Serial communication: RS232C

Baud rate: 2400 bps

Data bits: 8 bits

Parity: None

Stop bit: 1 bit (the instrument works within the microcontroller: 8-bit UART mode 1)

2) Data format of protocol 1: Leader + 96 absorbance value. Each absorbance value consists of 3 bytes, the total number of bytes transferred: $1 + 96 \times 3 = 289$, hexadecimal representation.

3) The order of the holes in communication protocol 1: Leader + A1 hole + B1 hole + C1 hole + + G12 hole + H12 hole

4) Communication protocol 1 data representation:

'@' + [(Fractional part x 1000/128) of the + (fraction of absorbance + (fractional part x 1000/128) Remainder))]

For example, receive the following sequence of hexadecimal numbers:

40 03 02 42 00 00 73

Leader '@' A1 Hole absorbance B1 Hole absorbance $0 + (0x73 / 1000) = 0.115$

Integer part: 3

Fractional part 1: $(2 \times 128) = 256$

Fraction part 2: 0x42 (hexadecimal form) Decimal number 66

Absorbance was $(3 + (256 + 66) / 1000) = 3.322$

Chapter tenth instrument maintenance

10.1 Overview

The service life of the instrument is 6 years, the instrument has a self-test function, can automatically prompt abnormal failure.

The instrument in normal use, just the normal cleaning and maintenance can, but the following parts after a long time work, failure or failure may occur, please go to the designated repair point or ask the user for maintenance under the guidance of professionals. In order to keep the instrument in good condition, routine maintenance work must be done.

WARNING: INSTRUMENT MAINTENANCE REQUIRES PROFESSIONAL OPERATION AND SHOULD HAVE BEEN DISCONNECTED AND TURNED OFF BECAUSE OF REPLACEMENT OF HOUSING FOR REPAIR OR OTHERWISE.

10.2 Cleaning the instrument

- 1) Keep the instrument working environment clean.
- 2) The instrument surface cleaning, you can use a mild detergent and a damp cloth.
- 3) Please use a soft cloth to clean the LCD.
- 4) When the patient samples or reagents spilled on the instrument, disinfectant should be promptly disinfected and wiped clean.

Warning: Do not allow any solvent, grease, or corrosive materials to come into contact

with the instrument.

10.3 Instrument Parts Replacement

10.3.1 Replace the fuse

1) Turn off the power switch.

2) The fuse tube is installed in the fuse holder beside the power switch on the rear of the instrument, unscrew the fuse holder cross screw and replace the same type of fuse:
 $\varphi 5 \times 20$ F2AL250V

10.3.2 Replace the filter

After a period of use of the filter, its transmittance will decline. When descending to the instrument does not work, the instrument will automatically give a display to remind users to replace. Replacement method is as follows: Open the instrument cover, find the filter disc, check the failed filter, remove the old film has failed, put on the new film (diameter 12mm) can be.

10.3.3 Replacing the light source lamp

When the light source is damaged, the instrument will automatically give a display, then open the instrument cover, check to determine the bulb is damaged, unplug the lamp socket, gently remove the light bulb from the bottom up, replace the new with the same specifications Light (12V / 20W) can be. If you replace the new lamp, the instrument still indicates a fault, please notify the company professionals to go debug.

10.3.4 Battery

Battery does not need to be replaced, because the battery is rechargeable lithium

battery, the voltage is below 3V, the boot automatically recharge the instrument.

Battery model: SONYCR1220

10.4 Simple troubleshooting

phenomenon	Cause	Solution
Instrument can't be activated (LCD screen is not displayed)	Power is not normal	Check whether the power, the power plug is inserted, the fuse is blown, the power switch is normal.
Pallet movement is not normal	Stepper motor lead plug bad; timing belt loose; moving parts shift stuck, positioning optocoupler loose or damaged	Correction of transmission, please adjust the professionals. Re-check each connection, tighten the loose optocoupler.
Self-test is not normal	Optical system failure, filter aging; wavelength setting error	Check the light source is bright, reset the wavelength of the instrument system, replace the same specifications of the new filter.
The test result is incorrect	1.Light source signal is too low 2.2. Detection of signal instability; 3.3. Reagent failure; no re-calibration after changing reagent batch; 5. The sample is abnormal.	1Timely replacement of new light source or filter; 2. Exclude sources of interference; 3. Replacing reagents and rescaling 4. Repack the sample.
Printer light often flash	The printer receives the error and sends the data in error	Turn off the printer and wait for a while before changing the print control panel

Chapter XI Transportation and Storage

11.1 Transportation

The instrument is shipped in a well-packaged condition and the means of transport shipping the equipment should be clean, free of dirt and hazardous materials. In the transport process must be protected from severe impact, rain and exposure. If the station, dock and other transit, should be stacked in the warehouse, had to be stacked for a short time, it must be covered with rain, snow cloth, while the bottom to use wood and other pad.

11.2 Storage

The instrument should be placed in a cool dry, moisture-proof ventilation, can not be piled open, but can not be piled on the soil directly on the ground. Such as short-term piling up, should prevent rain and snow immersed.

11.2.1 Storage and transportation Environmental conditions

- a) Ambient temperature range: $-20\text{ }^{\circ}\text{C} \sim +55\text{ }^{\circ}\text{C}$;
- b) Relative humidity range: $\leq 93\%$;
- c) Non-corrosive gas, well-ventilated.

packing list

Names	Quantity
1) Host	1
2) Instruction manual	1
3) Product certification	1
4) Delivery acceptance list	2
5) User acceptance of a single program	1
6) Accessories	
a. wire assembly	1
b. Tubular fuse F2AL 250V	2
c. plastic hood	1
d. a number of printing paper (as required by the contract)	
7) Accessories (optional by the user)	
Printer	1

quality promise

1) If the user can not work normally due to quality problems within one year from the date of delivery, the manufacturer will repair or replace the product at no expense for the user under the conditions that the user complies with the provisions of this manual. For the violation of the provisions of this manual or user disassembly caused by the failure, damage to the instrument, you will be charged maintenance costs. A year later,

the company paid for the instrument's lifetime maintenance.

2) When the user has the ability to repair, the company can provide user-requested technical information necessary for maintenance.

3) The instrument's factory date, see the instrument label.