SINNOWA

User's Manual

ER Series Microplate Reader
(ER-500,ER-502,ER-504)

Sinnowa Medical Science & Technology Co. ， Ltd

Table of Contents

1 Introduction

1.1 Main Features

The features of the filters are shown in table 1:

Table 1

Feature	Technical Parameter
Wavelength Accuracy（nm）	±2.0
Half-Width（nm）	≤10
Transmission Peak Ratio（%）	≥35

－O.D. Accuracy:≤ ±0.01A or ±1% .

－Linearity: r≥0.999 .

－O.D. Reproducibility:≤0.5% .

－O.D. Stability:Drift Error≤0.005A in 10mins；Drift Error≤0.005A when the supply voltage swings ±10% .

1.2 Specifications

－Graphical operating interface, menu designed for convenient use.

－500 programmable analysis items.

－ Four measure method ： Single wavelength/Dual wavelength/Fixed time/Kinetics.

－Eleven analysis means：

ABS / Cut-Off / Single point regression / Multipoint regression / Linear regression / ABS%/Exponential Regresssion / Logarithm Regression / Dual Logarithm Regression / Logit Regression / Polynomial Regression.

－Performing 12 different tests just in one plate. Flexible Plate Position with Blanks,Reference,Standards,Samples and QC in one screen.

－Proven optical system with 8 channels optical fiber scanning, auto plate centering system positions the center of the cell accurately.Get reading result in just 10 seconds.

－Printing patient reports with the thermal printer.

－Easy connect to PC,comprehensive functions with PC software.

1.3 External Features

Top View as figure 1:

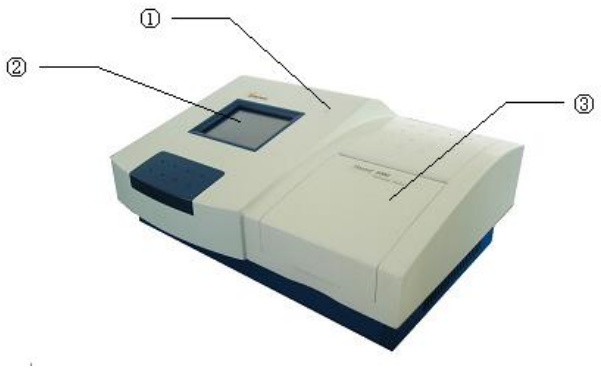

Figure 1

① Power indicator light

② LCD and Touch screen

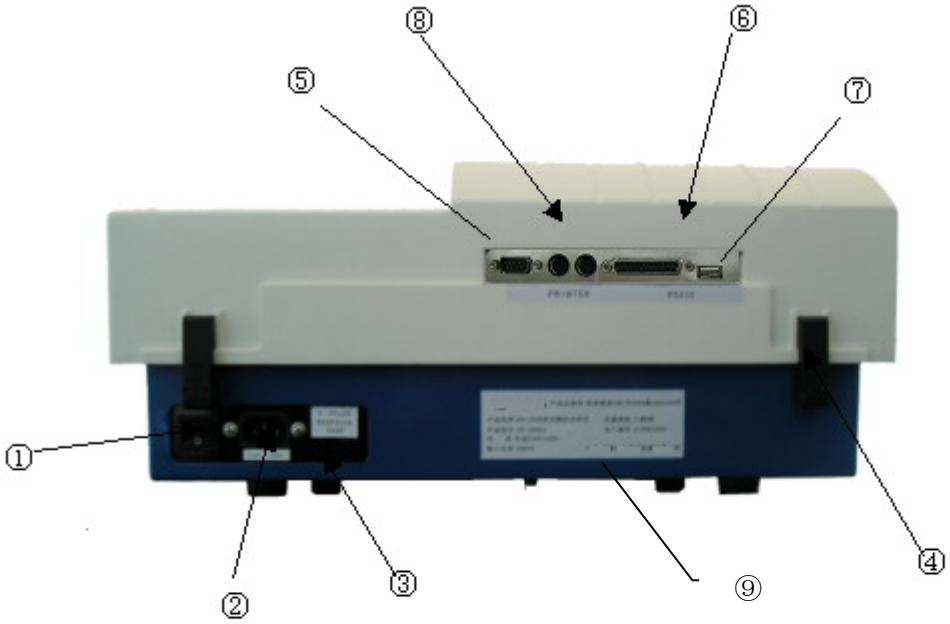

Figure 2

① Power ON/OFF switch

② Power cord receptacle

③ Fuses

④ Gemel

⑤ RS-232 serial interface

⑥ Parallel printer interface

⑦ USB interface

⑧ PS/2 mouse and keyboard interface

⑨ Serial Number Label

1.4 Specifications

Table 2

Weight：	10Kg
Outline Dimension：	460mm（L）×360mm（W）×210mm（H）
Supply Power：	AC(220±22)V，(50±1)Hz
Fuses：	F2AL250V 2-φ5×20 mm
Work environment：	Temperature：+5~+40℃；Relative humidity：20%~80%；Atmospheric pressure：860~1060hPa
Storage temperature：	-10℃~50℃
Light Source：	Tungsten Halogen Lamp, OSRAM64607，8V/50W
Wavelength：	405nm，450nm，492nm，630nm
Indication range：	0.000~4.000A
Reading speed：	Continuous mode≤10s，Stepping mode≤20s
Warm-up time：	10min
CPU：	ARM core series
Programmable Items：	500
Interface：	RS-232 serial、Parallel printer、USB、Mouse and keyboard interface
Display：	320×240 LCD
Input Mode：	Touch Screen ,Touch pen
Memory Capability：	2000 Plates（96 holes）test data

2 Instrument Set-up

2.1 Initial Start-up

- Place the instrument on a clean, sturdy table or bench.It is important to keep the instrument in a clean, relatively dust free environment to ensure maximum performance.

- Connect the power cord to the back of the instrument.Before connecting the instrument to the main electrical supply, check that the AC voltage is appropriate for the instrument.

3 Input operation

3.1 Touch Screen and pen

In the Microplate Reader，the pen is used to click on the area of the visual screen. The valid method of input operation is the single click, which means to touch the screen by the pen or the finger and then to remove immediately.

3.2 Digit soft keyboard

It is used to input the integer (like the time,date)and the decimal fraction(like the concentration) as Figure 3.

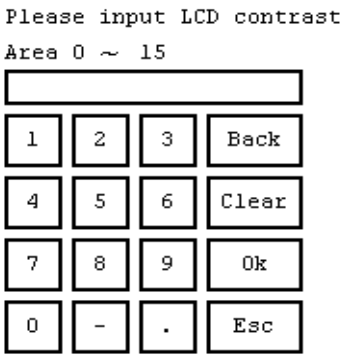

Figure 3

3.3 Character soft keyboard

Keybord is shown as Figure 4. It is used to input the character string. The "←" key is used to delete the character, and the "CAP" key is used to shift the uppercase and the lowercase of the character.

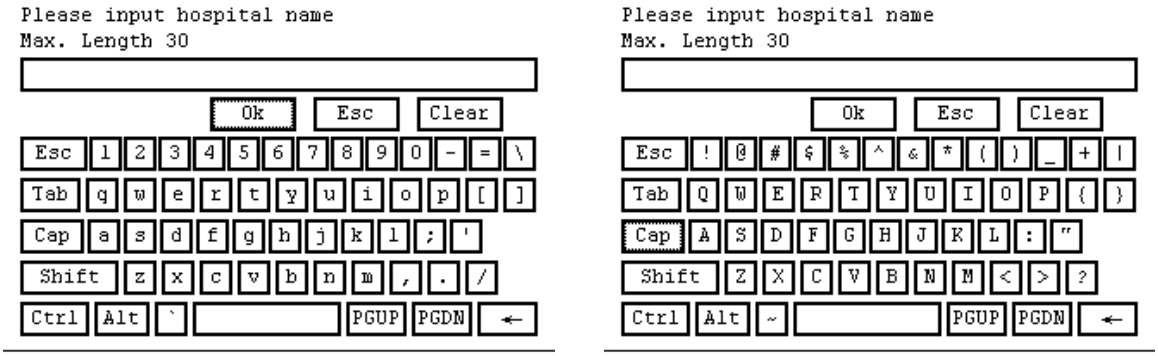

Figure 4

3.4 Date/time soft keyboard

It is used to input the date and the time as Figure 5. The format is Year-Month-Day and the “Today” is used to input the date of today quickly.

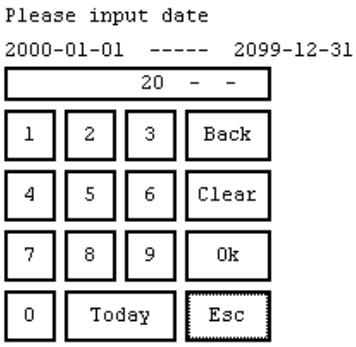

Figure 5

3.5 Formula soft keyboard

It is used to input the formula as figure 6. There are four N(Negative)、four P(Positive)、eight D(Standard)、MIN(get the minimum value)、MAX(get the maximum value) and the common operators.

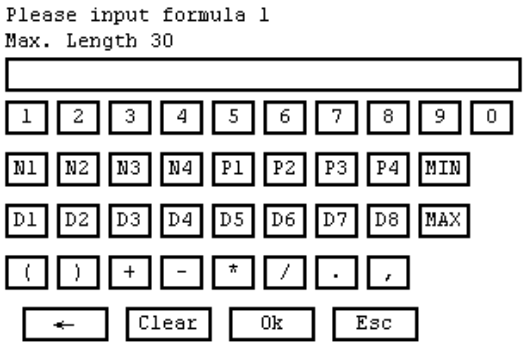

Figure 6

4 Start-up

4.1 Procedure of start-up

Turn on the power switch on the rear panel. After about three seconds, the instrument will perform an initial self diagnosis that requires about one minute. Please wait ten minutes for the instrument to warm up(reach thermal equilibrium)before reading plates.

The procedure of start-up includes：

1) Load the program;

2) Access the user data;
3) Wait for the stable light of the lamp. It is necessary to wait about five minutes for the stabilization of the lamp before the first reading.（The result of O.D. may be not accurate if the lamp is not stable.）
4) Self diagnosis of the optical and the mechanical system .The filter wheel will turn around and the plate will reciprocate once.

4.2 Main Menu

The screen displays the main menu after the procedure of start-up. The main menu has six different modes: Patient Information, Test, Report, System, Item Setup and Search as Figure 7.

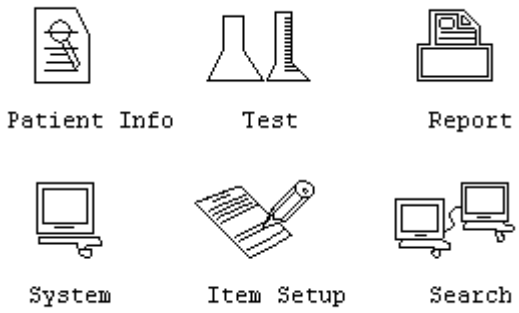

Figure 7

5 Item Setup

Choose the Item setting icon in the main menu and go into the item list window as Figure 8:

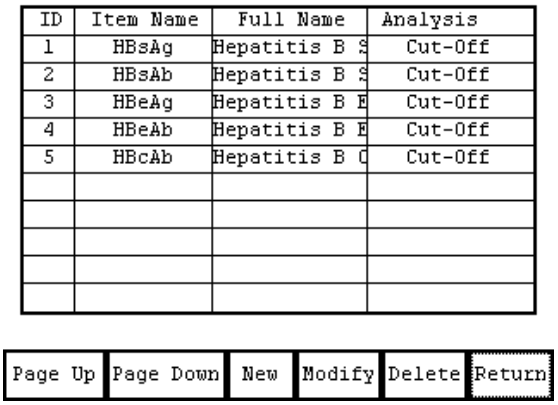

Figure 8

The user could set 500 different items at most.

5.1 Measure method

The reader has four measure methods.

5.1.1 Single wavelength

The method uses one wavelength to measure the OD.

5.1.2 Dual wavelength

The method uses two wavelengths to measure the OD. The result of OD is the difference of the main wavelength and the reference wavelength.

5.1.3 Fixed time

A first absorbance measurement is made for each sample after a programmed incubation period, and a second measurement is performed after a defined interval. The fixed time method should use the single regression analysis method.

5.1.4 Kinetics

A first measurement of absorbance is made against the BLANK after a programmed incubation period. Next, new measurements are made at defined intervals of time. The absorbance is calculated as the mean of the increase (or decrease) in absorbance per minute. The kinetics method should use only one wavelength.

5.2 Analysis method

There are eleven analysis methods, including the comprehensive qualitative and quantitative data-evaluation functions with cut-offs, curve-fits and transformation formulas.

5.2.1 O.D. mode

Measure the O.D. of the plate cell directly.

5.2.2 Qualitative(Cut-Off) mode

Cut-Off limit formula：$Cov = X \times NC + Y \times PC + Fac$

NC is the O.D. of the negative reference material，PC is the O.D. of the positive reference material，X，Y，Fac is the coefficient，which is set in the reagent instruction.All the other kind of qualitative formula can convert into this formula format.For example：if Sample OD/Negative Ref.OD≥2.1 is the Positive,then X=2.1，Y=0， Fac=0。

The ratio of the sample O.D. and the Cov is often used to define the qualitative result,and the unit is s/co.The normal s/co threshold is 1.

5.2.3 Quantitative mode

1) Single point regression mode：one standard needed，use the origin and the

standard O.D. to fit the curve as Figure 9.（X:concentrate，Y:O.D.）

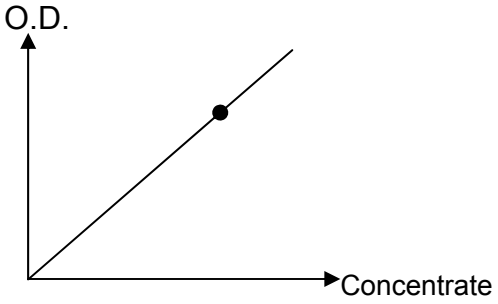

Figure9

2) Multi point regression：Two to eight standards needed，use all the standards O.D. to fit the curve as Figure 10:

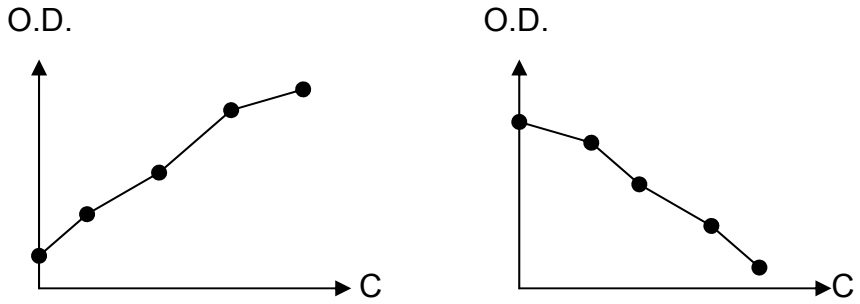

Figure 10

If the curve is not monotony(increase or decrease),the result is error as Figure 11:

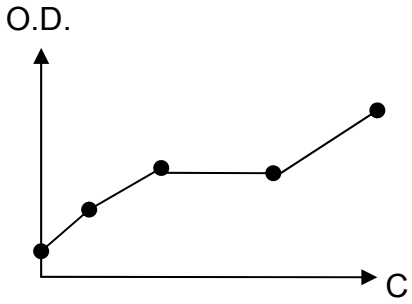

Figure 11

3) Linear regression：Two to eight standards needed，use these standards to fit the regression curve as $Y = kX + b$ in Figure 12:

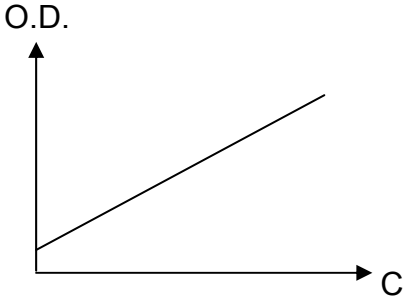

Figure 12

4) Exponential Regression： Two to eight standards needed， use these standards to fit the regression curve as $Y = ke^{bX}$,all the standard O.D. must be positive number.
5) Logarithm Regression：Two to eight standards needed，use these standards to fit the regression curve as $Y = kLnX + b$,all the standard O.D. must be positive number.
6) Dual Logarithm Regression：Two to eight standards needed，use these standards to fit the regression curve as $Y = 10^{(kLnX+b)}$,all the standard O.D. must be positive number. If setting the concentration as $X' = LnX$, $Y' = LnY$,then the regression formula turns to $Y' = k'X' + b'$.
7) log-logit Regression：Two to eight standards needed，use these standards to fit the regression curve as Log-Logit method. The abscissa of Log-logit curve is Concentrate，the ordinate is $\ln\frac{p}{1-p}$ ， $p = \frac{OD_{SAM}}{OD_{S0}}$ ，all the O.D. and the concentrate of the standard must be positive number. S0 is the standard 0.
8) Polynomial Regression：Two to eight standards needed，use these standards to fit the regression curve as $Y = kX^{b}$, all the standard O.D. must be positive number.

5.3 Add New Item

Choose the Item setup icon in the main menu and go into the item list window as Figure 13.

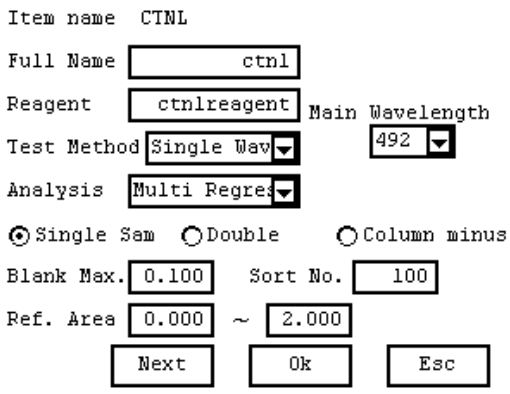

Figure 13

Select“New”key to add new item。

The parameter of the item setup：

- Item name: Item brief name, string including twenty characters at most，blank unallowed；

- Full name: Item full name, string including thirty characters at most, blank allowed.
- Reagent: Reagent name, string including twenty characters at most, blank allowed.
- Test Method: Select the test method from the four methods.
- Main/Second Wavelength: select from the wavelength list，and the second wavelength should be different with the main wavelength；
- Analysis: Analysis method, selected from the list of methods.
- Single Sam/Double Sam/Column minus: the type of the sample, the default setting is single sample, the double sample means double sample for each patient, the column minus method is a specific method, which uses the second column minus the first column as the sample value.
- Blank Max.：Define the max. value of the reagent blank.For example,the reagent needs the blank less than 0.05,then the upper blank must be 0.05.If the blank O.D. is larger than the upper blank, “Too large OD blank”will appear and the maximum blank is used as the blank automaticly.
- Sort No.: Define the sort of the item in the patient report. The small No. is in the front of the list. The default value is 100.
- Ref. Area: set the normal area of the item.The area is used in the report only.The area value don’t take part in the formula calculating. The default value of the area is 0.000 ～ 0.000, and the column will not print if the area is 0.000 ～ 0.000.
- Analysis Means：choose the analysis means from the list.According to the different means，the screen will appear different windows.
- Wait time：used in the Fixed time method and Kinetics method, the range of the value is 10 to 120；
- Test times：Used in the Kinetics method, the range of the value is 2 to 10.

If the analysis method is Cut-Off, click “Next” to view the menu as Figure 14:

- Negative/Positive Ref Area：The valid reference area of the Negative and Positive，the default value is 0.000～4.000；
- Negative/Positive 1～4：User can see the OD of the Negative/Positive after test, or set the OD directly without test.

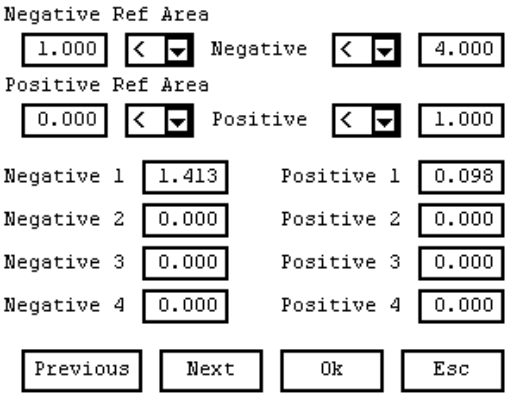

Figure 14

Click “Next”：

- Qualitative Group Name：User can define the name or signal of every group; Click the label “Group 1”～“Group 5” to set the predefined name，which will shift between the “Negative,Weak negative,Neutral,Weak positive,Positive”;
- Formula(Cut-Off value）：User can define the C.O. formula or value of every group, four formulas at most；

The relation of the Cut-Off value、OD value and qualitative is as Figure 15:

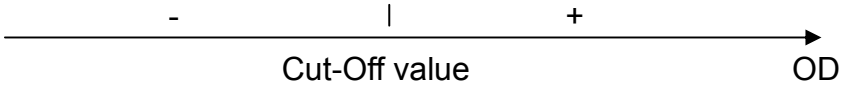

Figure 15

From the manual of the ELISA kit, the formula of the Cut Off is “Cut Off value=Negative × 2.1”， so the formula should be 2.1*NC1； If there are comments like“Minimum Negative OD = 0.05 ”，the meaning of the comments is to get the large value of the NC1 and 0.05，so the final C.O. formula is：

2.1*MAX(NC1,0.05)

This is the formula of the Group 1. There are four formulas at all. And the value of the formula must be “Formula 4 >Formula 3> Formula 2> Formula 1”. The five groups have four formulas.

If the item has more formulas, the CO value in S/CO could be selected from the four formulas. The default value is 1.

If the formula is longer than the viewing area, just click the formula before the group label to show the full formula in the last line as Figure 16.

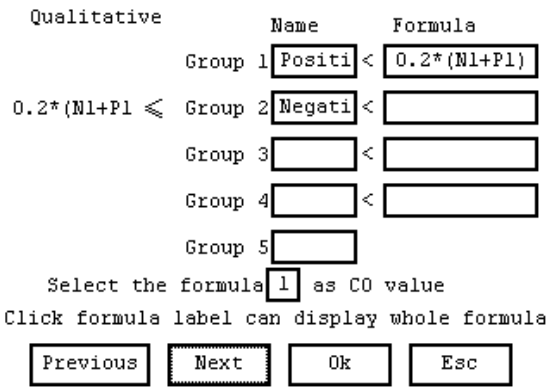

Figure 16

If the analysis method is quantitative method, click “Next” to view the menu:

- STD numbers: define the numbers of the STD.
- Dilute Multiple：define the dilute multiple of the sample, and the calculated value should multiply the dilute multiple.
- Unit: Choose unit from the 24 common units in the list.
- Dual STD: If check the dual STD,all the standards in the plate will be positioned double times.
- ABS percent: Check the box to use $\frac{D_i}{D_0}\times 100\%$ as the ordinate of the standard graph，the D0 is the reference standard of 100% O.D., and the D0 needs no concentrate. If the item selects the ABS percent, the first standard is D0 when position the plate. The dual logarithm regression cannot use the ABS percent because of the ordinate is in logarithm.
- STD concentrate table: Display and select the STD concentrate. Attention: All the STD concentrate should increase.
- Modify concentration: Modify the selected concentration as Figure 17.

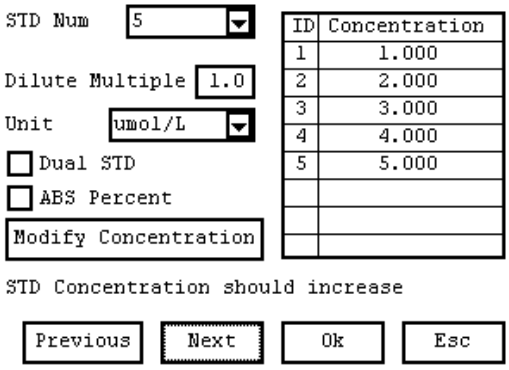

Figure 17

Click “Next” to set the qualitative group and formula as the Cut-Off item.

Click “Next” to set the Quality Control. The menu of QC is demonstrated in the

next section.

After setting all the parameters, click “OK” to save the item. Attention: The same name of the item is not allowed.

5.4 Quality Control Settting

The qualitative and quantitative items both could set two QC materials as Figure 18.

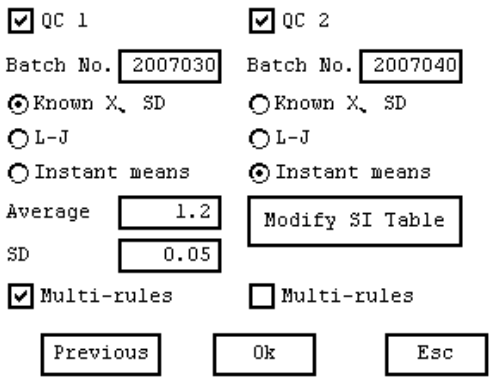

Figure 18

- Batch No.：The batch number of the QC materials，different batch QC materials should have different QC data；
- Average：The average value of the QC materials($\overline{X}$)；
- SD：The standard deviation of the QC materials (SD).

The routine quality control in room includes the routine conditions variance-knownvalues（RCVK） and routine conditions variance-unknown values （RCVU）.

For RCVK，select“Known $\overline{X}$ 、SD”，and input the $\overline{X}$ and SD in the manual of the QC materials.

For RCVU，select L-J or instant means. The Levey-Jennings rule uses the front 20 values to calculate $\overline{X}$ 、SD，and makes the QC graph from the 21st value. The instant means uses the SI table，calculates $\overline{X}$ 、SD and makes the QC graph from the 3rd value.

The limit of all these QC methods is $\overline{X} \pm 2S$. With the development of the computer，there are more and more efficient control methods. The instrument integrates a common multi-rules control method: Westgard Multi-rules. Here is the routine of Westgard Multi-rules as Figure 19:

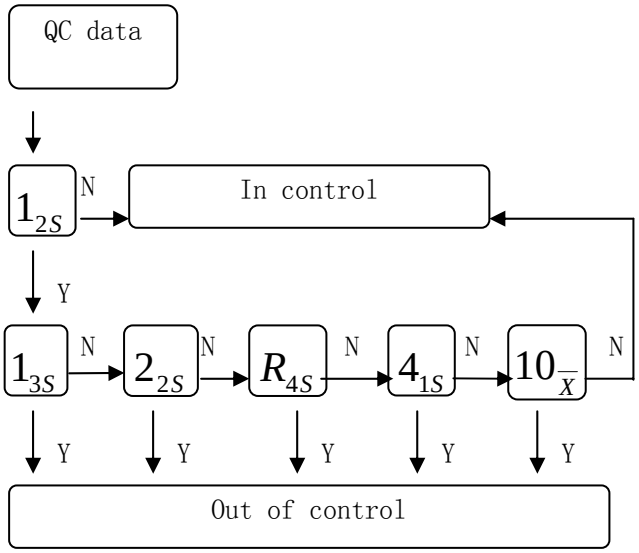

Figure 19

5.5 Modify the item

Select an item from the list and click the “Modify” key to modify the item setting.

The Cut-Off value will be cleared if the Cut-Off item is modified.

The quantitative curve and the STD concentrate will be cleared if the quantitative item is modified.

5.6 Delete the item

Select an item from the list and click the “Delete” key to delete the item. If the “ok” key in the confirm window is clicked,the item will be delete completely.If the “Cancel” key in the confirm window is clicked,the deleting will be cancelled.

6 Test

6.1 Test setting

Click the Test icon in the main menu and go into the plate reading mode.Select the parameter from the window to modify the setting as Figure 20.

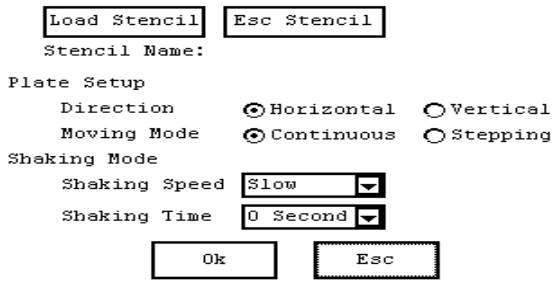

Figure20

- Load Stencil：load the preset stencil of position；
- Plate Direction：select Horizontal or Vertical position；
- Moving Mode：select the plate continuous moving or stepping moving；
- Shaking speed：select the slow、medium or fast shaking speed；
- Shaking time：select the time of shaking plate, user-defined area is from 10 to 180 second.

6.2 Plate Hole

Table 3

*	1	2	3	4	5	6	7	8	9	10	11	12
A	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	A12
B	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12
C	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12
D	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12
E	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12
F	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
G	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10	G11	G12
H	H1	H2	H3	H4	H5	H6	H7	H8	H9	H10	H11	H12

The direction of the plate's moving is ←——。

6.3 Stencil

Click the "Load Stencil" Button to go to the Plate Load Interface as Figure 21.

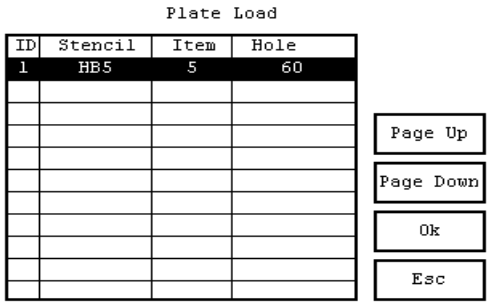

Figure 21

Select an available stencil in the list and click Ok to load the position of the stencil. All informations including the direction, moving mode, shaking speed, shaking time, the item and the type of each hole are stored in the stencil.

6.4 Hole Position

User can position the Sample(S), Blank(B), Reference (N,P), Standard(D),Quality Control(QC) in any hole of the standard 96 holes Plate as Figure 22.

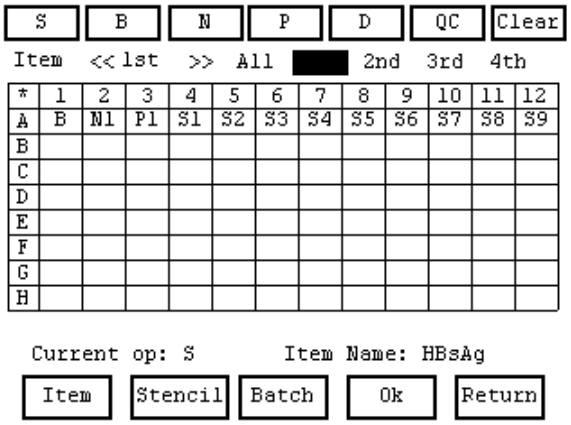

Figure 22

The procedure of the position:

a) Click “Item” to select the item;

b) Click “S,B,N,P,D,QC” to select the type of the sample;

c) Click the hole on the screen to position;

d) When multi-items position, after finishing the 1st item, click the “2nd,3rd,4th” to select the other item. Click the “>>”if position the 5th ~12th item. After changing the item, the positioned hole will be dark。

－Sample

User could click any hole to set the Sample.Click the hole again to modify the Sample No.The area of the Sample No. is from 1 to 999.

－Blank

The blank is used to do zero adjustment.It means that all the other hole’s OD should minus the Blank OD.If the Blank is not positioned, the default blank is zero.

Every item can position more than one blank holes.If there are several blank holes in the item, the result only displays a mean blank value.

－Negative Reference

The negative reference is valid only in the Cut-Off items.User can position the negative reference or positive reference according to the Cut-Off formula.Every item can position more references. If there are several Ref. holes in the item, the result only displays a mean Ref. value.

The values of the Ref are saved automaticly.If the next test of the item doesn’t position the reference, the program will use the saved reference value.

－Positive Reference

Positive Reference is set as same as Negative Reference。

－Standard

The Standard is valid only in the quantitative items.The user should position all the standards before reading the plate.If the item has the saved standards,it is not necessary to position the standards.

－Quality Control

Valid if the item has QC.

－Clear

User can click the hole to clear after select the “Clear” button. And only the hole of the current item can be cleared.

－Stencil

The Stencil button is used to save the positioned holes as a stencil. Click “Stencil” after finishing the position to go to the stencil operation interface. Input the name of the new stencil and click “Add” to save the stencil. Click “Modify” or “Delete” button to modify or delete the selected stencil. Load Stencil function is in the first interface of the test.

－Batch

Click “Batch” to enter the menu of batch position. Only the sample can be batch positioned. Select the Sample No., Start hole and the number of the sample to finish the batch position.

The ways to position the hole:

- Click the hole to set a hole;
- Click the number（1—12）to set a column of holes;
- Click the alphabet（A—H）to set a line of holes；
- Click the “*” to set all the holes.

All the ways is valid to Clear operation.

6.5 Plate test

After all the settings, click “Ok” to move the plate and read the absorbance automaticly. The first time of the test needs some minutes to stablizate the light source as Figure 23.

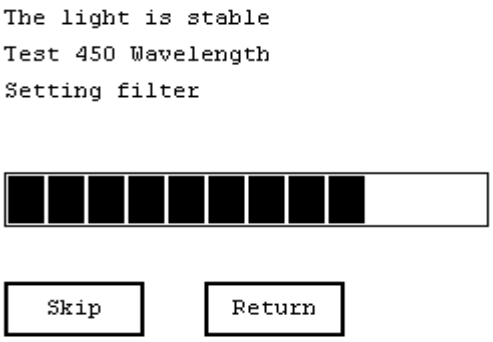

Figure 23

6.6 Result view and print

After the plate reading, click the “Position” to view the position of the plate. Click the “ABS” to view the value of absorbance. Click the sample hole to modify the value.Attention：If the value is larger than 4.000A,the value will display as 4.00*;If the value is less than 0.000A,the value will display as 0.00*.

Click “Qualitative” to view the qualitative of the result according to the setting of the item.

Click “Quantitative” to view the calculated value. In the Cut-Off item, the quantitative value is the value of S/CO. But in the quantitative item, the value is the calculated concentration.

Click “Standard” to view the standard curve.

The default setting is to show the result of all the items. If only one item is wanted, just click the Num or >> to shift the item。Click All to view all the items.

Click “Save” to save all the values of the plate. The memory of the instrument can save more than two thousand plates.

Click “Print” to print all the values by the position. The holes that not positioned will be neglected automaticly as Figure 24.

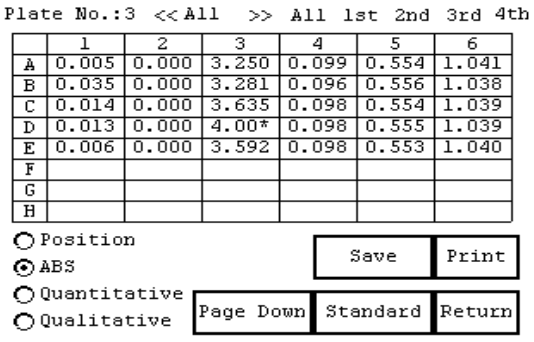

Figure 24

7 Patient Information

Click the “Patient Info” icon in the main menu to enter the setting of the patient information as Figure 25.

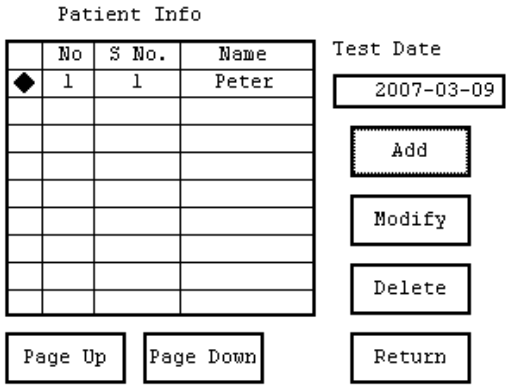

Figure 25

7.1 Summarization

Select the Test Date to view the list of the samples. The default sending date is the current date.

There are two modes of filling the information:

✧ First set the patient information:

Click the ‘Add’ key to set the patient information, and the first column flag ◆ show that the patient’s information is finished already.

✧ First test the sample:

After finishing the sample test, the first column flag ● show that the tested sample has no patient information. Select the ● row and click ‘Modify’ to input the patient information.

The meaning of the flag in the first column:

◆ Patient information existed, but no sample test result.

● Sample test result existed, but no patient information.

■ Both the patient information and the sample test result existed.

If the patient information and the sample test result both exist, click ‘Modify’ to modify the patient information.

If the added sample number already exists in the test result, the system will automaticly combine the two contents.

Click the Delete to delete the selected patient’s information and test results.

7.2 Information records

The patient information can be added or modified in the Patient info menu or

in the patient searching menu.

Sample NO.: Every patient has one and only sample number in one day. The sample number cannot be changed when modifying;

Name: 18 characters at most;

Sex: Select from Male, Female and unknown;

Age: the area of age is from 0 to 150;

Bed No.: 9 characters at most;

Record No.: the record number in hospital, 9 characters at most；

Sample：the type of sample, defined in the word book;

Department: the sending department, defined in the word book;

Sender：the sending doctor, defined in the word book;

Laboratory: the clinical laboratory, defined in the word book;

Analyzer: the analyzing doctor, defined in the word book;

Send date: the date sending the sample, defined in the word book;

Test date: the date testing the sample, defined in the word book.

Click OK to confirm the input, Esc to cancel the input as Figure 26.

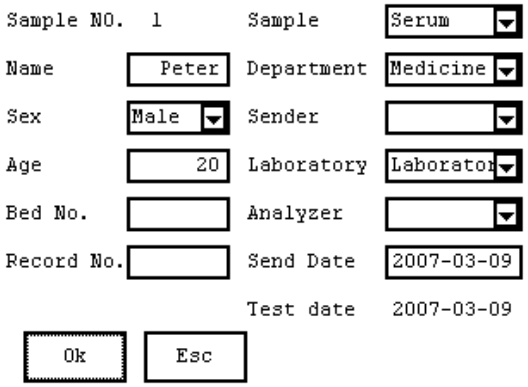

Figure 26

8 System Setting

Click ‘System’ icon in the main menu and go into the system setting menu. There are four functions: System set, System log, Data delete and Word Book as Figure 27.

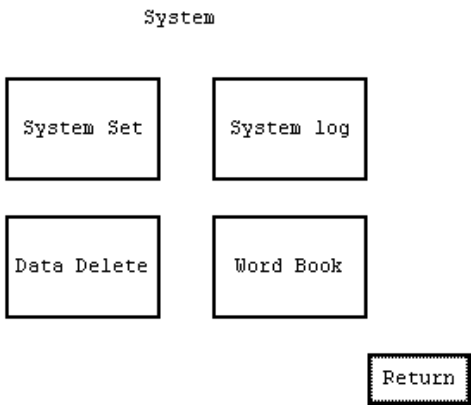

Figure 27

8.1 System setting

Select the ‘System set’ key and go into the system setting menu as Figure 28:

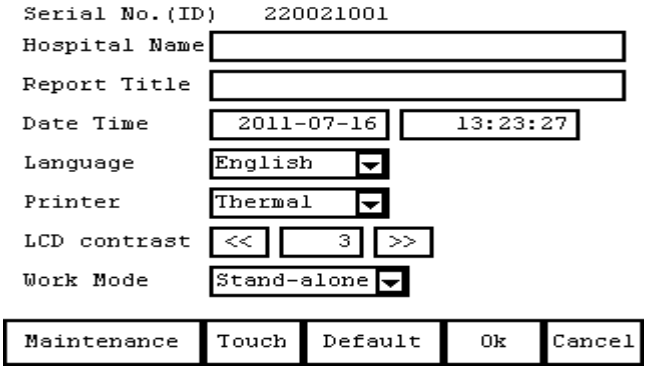

Figure 28

1）Serial No.（ID）: Show the identifier of the instrument, not allowed modified;

2）Hospital Name: The name will appear on top of the patient report;

3）Report Title: The name will appear following the Hospital Name;

4）Date: Set the date of the system;

5）Time: Set the time of the system;

6)Language:System supports Chinese and English;

Such as changing the language option, you need to press "OK" button to restart the instrument to take effect;

The Date and Time is used in the test and report, please adjust the date and the time before using the instrument.

7）Printer: Show the type of the printer, the default printer is the internal thermal printer. The internal thermal printer has three keys: OPEN key is pressed to open the door for adding the thermal paper (Attention: The outer side of the paper is the thermal layer. The thermal layer must touch the thermal head.); SEL key is red when online, LF key is green when the power is on. Press SEL to turn

off the red lamp and press LF to send the paper. Turn on the power while pressing the SEL, and then loose the key to do the self-test;

8）LCD contrast: Used to adjust the brightness of the LCD back light;

9）Work mode: Select the stand-alone mode or the PC control mode.

Attention: Before using the PC software, please choose the ‘PC control’ mode. The ‘Sample test’ key will disappear in the PC control mode, and the program should be in the main menu when using the PC software.

10）Maintenance: Some maintaining and calibrating functions;

11）Touch: Used to calibrate the touch screen. The touch screen is already calibrated before leaving factory, so do the calibration only when necessary.

The use of the calibration:

Firstly calibrate the abscissa K: Click the left part of the screen, the screen will display the real pixel point, then click the right part of the screen, there will be a pixel point also, if the horizon distance between the two points is longer than the two clicks, decrease the abscissa K, otherwise increase the abscissa K. Adjust the K until the distance is the same. Secondly calibrate the abscissa B: Click anywhere on the screen, if the displayed pixel point is not in the same position of the click, adjust abscissa B until the abscissa of the click is accurately. The calibration of the coordinate is the same as the abscissa. After finished the calibration, click OK to save and ESC to quit.

12）Default: Restore to the leaving factory state, and all the user’s input will be deleted. The initial setting includes 23 test items and some common words. But the setup in the System Config will be remained including the calibration of the touch screen and the setup of the filters.

Click OK to save the new setting, otherwise the new setting will disappear after shut down.

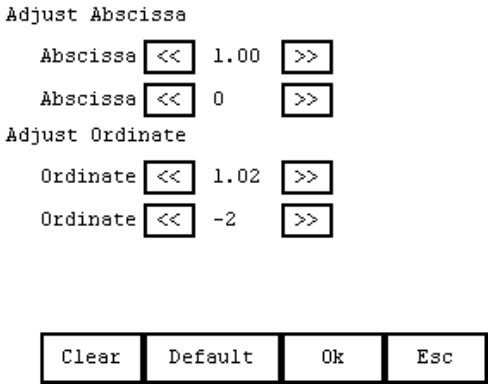

Figure 29

Click the ‘Maintenance’ key to go into the system maintenance menu as

Figure 29. The maintaining module consists of four functions: Add new filters, testing the new lamp, verify the repeatability and advanced function.

- Filters Setup: The start menu of the maintaining is used to add the filters. The filter wheel can install nine filters at most. When adding filters, firstly select the number of total filters, then fill in the wavelength of the filters in turn, at last press Calibrate Key to save the setting. Attention: If you want to add filters, please contact with the manufacturer or the distributor. Please don't dismantle the instrument and add uncertain filters.
- Testing the new lamp: Click the 'Lamp' key to go into the new lamp testing menu. Firstly select the one filter and click Start key, adjust the position of the lamp by hand, the value on the screen will change with the movement of the lamp. When the screen is full of data, click "Stop" to stop the test. Click "Page down" or "Page up" to view the next screen. Keep adjusting the lamp until the maximum value. The normal value of the baseline is more than 15000.
- Verify the repeatability: Click the 'Repeat' key to go into the repeatability test menu. Firstly select one filter, test times and row. The range of the test times is 5~8. Click "Start" key to test the certain row for 5 to 8 times. And the average value, repeatability and the CV will show when all the tests are finished.
- Advanced functions: Click the 'Advanced' key to go into the advanced functions as Figure 30. This module is only used by the serviceman.

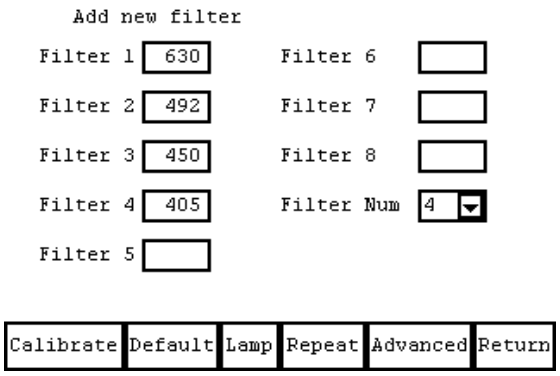

Figure 30

8.2 System Log

Note the important information of the system.

8.3 Date Delete

In the system menu as Figure 31, click the ‘Data Delete’ key to go into the menu of data deleting. It is suggested that the user delete the old data after half an year to keep the system faster.

There are five ways of deleting the patients:

- Delete the patients’ data three months ago.
- Delete the patients’ data one month ago.
- Delete all the patients’ data.
- And delete the QC data by item and date.
- Delete the Plate data by date and plate.

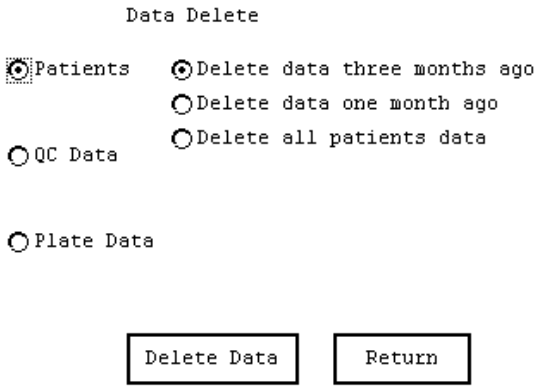

Figure 31

8.4 Word book

In the system menu as Figure 32, click the ‘Word book’ to go into the editing interface of the wordbook.

There are seven items in the workbook: Laboratory, Department, Analyzer, Sender , Sample, Diagnosis and Unit.

Firstly select the radio circle of the editing item, then edit;

Add: fill in the text box, and click the ‘Add’ key;

Modify: Select the item and fill in the textbox, then click the ‘Modify’ key;

Delete: Select the item and click the ‘Delete’ key.

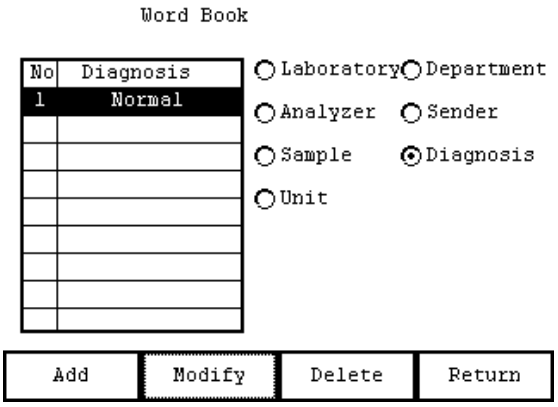

Figure 32

9 Search

Click the ‘Search’ icon in the main menu as Figure 33 to go into the menu of data searching. The Patient Data, Item Report, Plate, QC Report, Standard and Statistics can be selected from the column ‘Search Mode’. And more detail condition can be selected from the ‘Search Options’. After selecting the searching mode and option, just click ‘OK’ to begin searching.

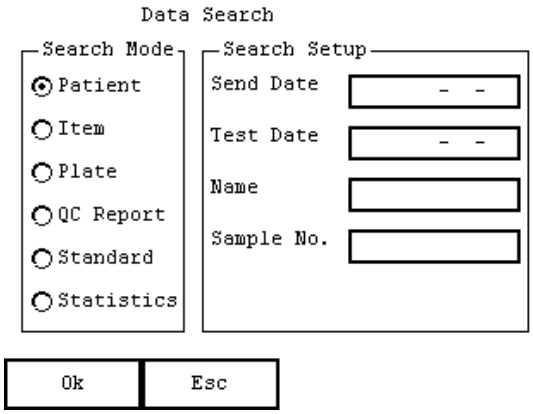

Figure 33

9.1 Patient data searching

Set the option of each searching and check the option box. If the option box is not checked, the searching condition is not valid.

If the patient information is not available, the sample data cannot be searched in the patient report.

It is suggested to set the content of each searching option before check the option box and to select the date before the name and sample number.

The table of the patient data searching result has five columns including the

sending date, sample number, name, sex and the total numbers.

Select the patient in the table. Click the ‘patient report’ key to see the patient reports. Click the ‘patient information’ key to see the information of the patient. Click the ‘Print’ key to print the patient’s report. The instrument supports the consecutive printing: there is a ‘P’ flag in front of the sending date after selecting the patient. Select all the reports you want to print and just click ‘Print’ key to print them.

The sample with no patient information can not be searched in the patient searching.

9.2 Item searching

The function of the module is to search for the records of the same item by the date as Figure 34.

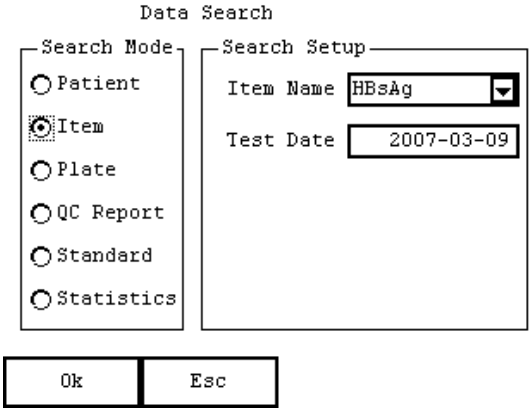

Figure 34

The item searching result show the patient’s name, sample number, result value and the qualitative of the specific item and date as Figure 35.

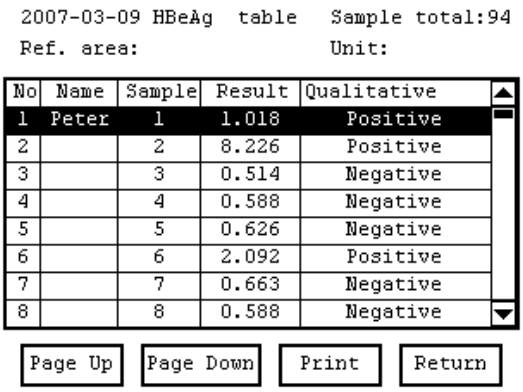

Figure 35

9.3 Plate Searching

Select Plate mode and set the date and the plate number to search the plate

as Figure 36.

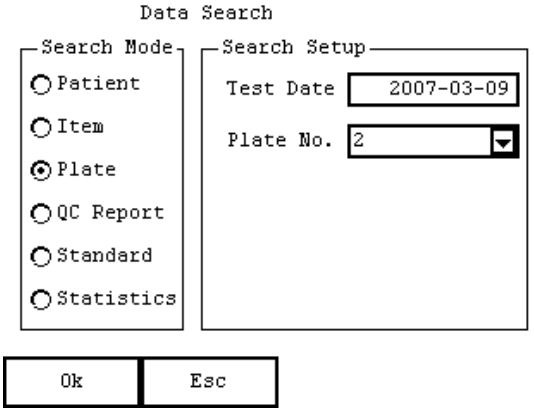

Figure 36

9.4 QC Searching

Select QC report mode and set the item name, month and the number to search the QC data as Figure 37.

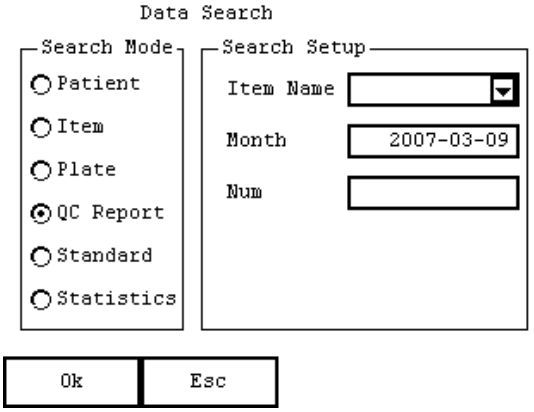

Figure 37

The searching result show the QC data、X、SD and CV value。The 2nd QC has a prefix of *.

Click “QC graph”to view the graph of QC as Figure 38.

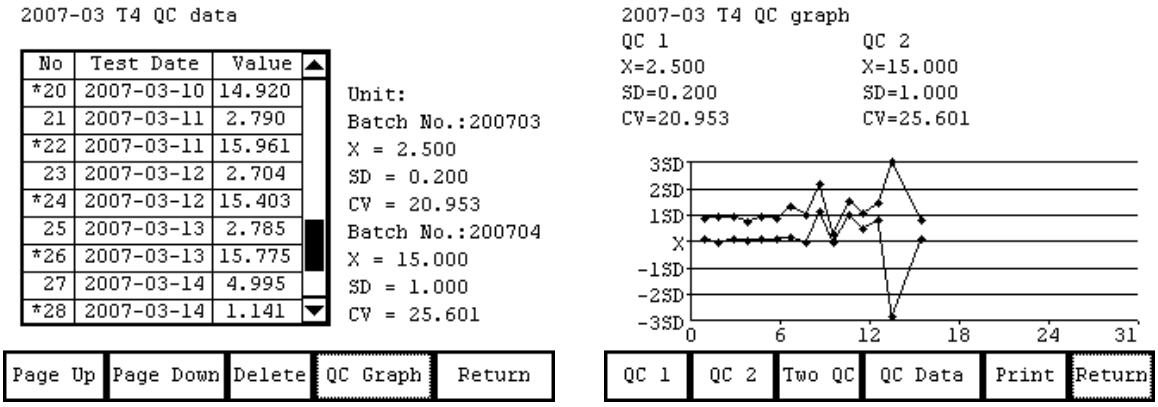

Figure 38

9.5 Standard Searching

Select Standard mode and set the item name to search the standard data as Figure 39.

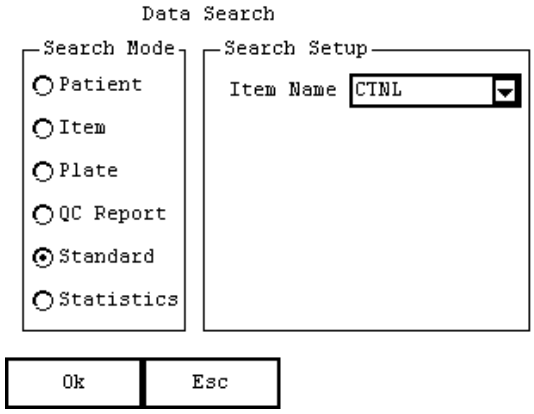

Figure 39

TheCut-Off item shows the absorbance of the reference and the formula.

The quantitative item shows the table of the concentration and absorbance of the standards, and the graph of the standards as Figure 40.

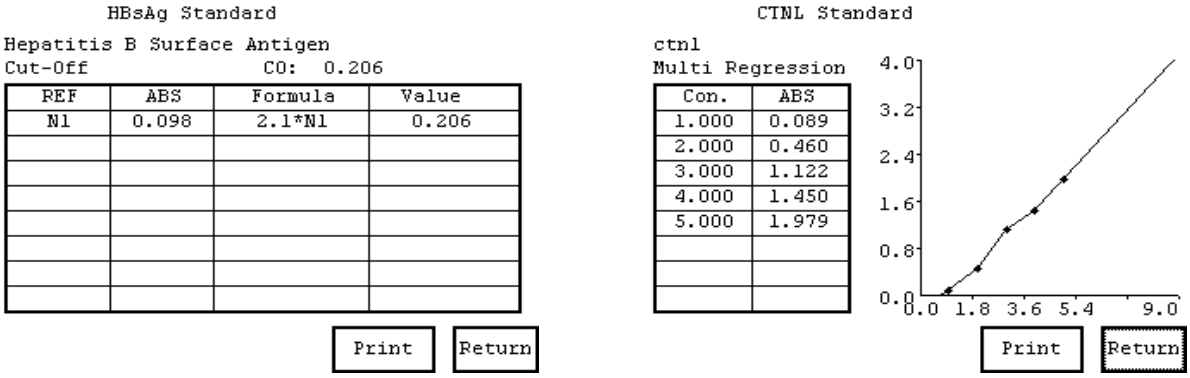

Figure 40

9.6 Statistics

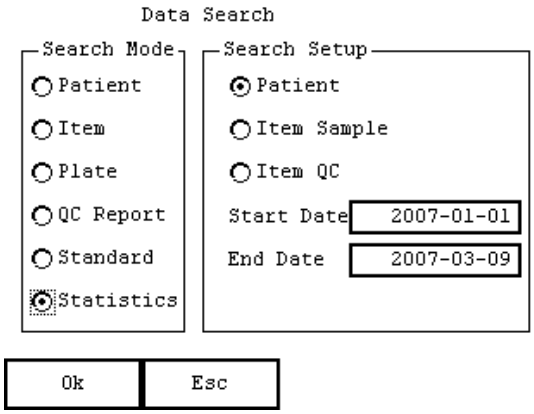

Figure 41

The Statistics Function is used in the statistics of the patients, samples and QC data in the customizing time as Figure 41 &42.

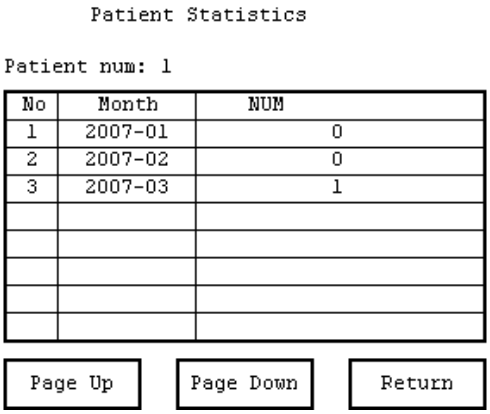

Figure 42

10 Report

In the main menu as Figure 43, click the 'Report' key to go into the patient report menu. The patient report is a shortcut of the latest patient searching. The result of searching by the patient in the latest sending date is as same as the patient report list.

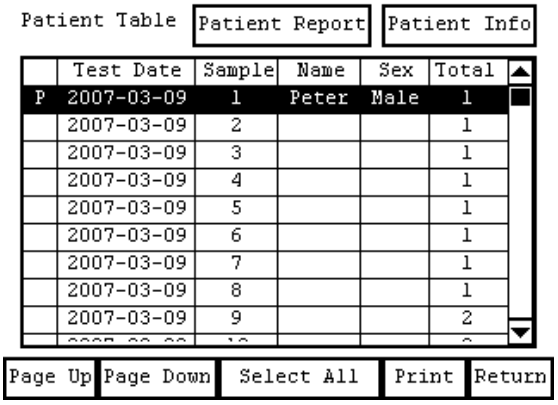

Figure 43

The module is used to search and print the latest patient report quickly. The patient table is in the latest sending day. If there is no patient in the day, the result may be in the old days.

Select the printing line, and the first column of the line will appear a "P" which means the line will be printed. Multilines can be selected to print. And click "Select All" to select all the lines in the table. If there are more than one P before the line, the patient report will be printed out continuously. The P will disappear after report was printed.

Click the "Patient Report" or "Patient Info" key to view the report or the information of the selected patient as Figure44.

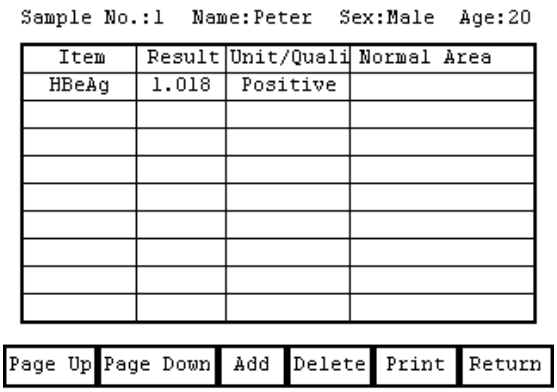

Figure 44

11 Shut Down

When finished using the instrument, shut down the power directly. All the saved data is stored in the Flash memory and reliable for long time.

12 PC mode

12.1 Software Installation

The instrument can be controlled by a PC through the serial port, using the PCsoftware interface, more powerful, easy to connect hospital management system,if using this method, the instrument must be set as follows: (software, see the software online help)

- Click "System "
- Select the "PC Mode"
- Click "OK"

Note: To install the software, please contact the dealer or manufacturer. Set to"PC Control", the main interface on the "sample test" button will disappear.

12.2 Software Operation

Operating system：Windows XP

Hardware environment： Pentium III350 above, memory 128M, 500M or more free hard disk capacity, resolution 800 * 600 and above

Communication: Serial Communication

Communication Interface: RS232 serial port

Communication baud rate :19200

12.3 Software serial communication protocol and code

1) Frame format

Table 4

Frame head	Sequence	length	PDU type	Data	Check
A5H	1 byte	2 bytes	2 bytes	N bytes	1 byte

Frame head：Because synHeader is A5H, therefore may not appear the same byte as A5H in the other fields in a frame, in order to avoid the frame analysis grammatical ambiguity; if in other fields appears A5H, then in after that fills again an A5H byte. Receiver when analysis，meets single A5H byte to think it is the synHeader，meets two consecutive A5H byte to think it is other data byte，this time should neglect an A5H byte.

Sequence：Back end may wilfully fill in; front end must fill in the same sequence number in the response frame.

Length：The length is the total length of PDU type field and data field, not including the synHeader, sequence and checkCode

PDU： See Part 2

Data：See Part 2

Check：Single-byte XOR checksum algorithm, computation scope: sequence number, length, PDU type, and data.

2）PDU type and data

0x0001	reset
0x0002	Read the front version
0x0003	front version
0x0010	command completes and no data is returned
0x0011	Command to complete, but an error occurred
0x0101	shake; Vibration ELISA Plate
0x0102	switch the light filter
0x0103	read the air's AD value
0x0104	AD value
0x0105	ELISA test board
0x0106	ABS Value
0x0107	AD value of the last test
0x0108	AD value
0x0109	lamp switch（0 Open，1 Close）
0x010A	read lamp's state
0x010B	lamp's state
0x010C	read machine's ID
0x010D	machine's ID

3）Send commands and responses

Table 5

Type	Command function	Receive /Send	Data	Expected response	Timeout	Other explanations
0x0001	reset	Send	none	0x0010	5 seconds	After power on,use this command to judge whether the correction of coefficient is correct
0x0002	Read the front version	Send	none	0x0003	1 seconds	
0x0003	front version	Receive	4 bytes	none	none	
0x0010	command completes and no data is returned	receive	none	none	none	
0x0011	Command to complete, but an error occurred	receive	two bytes	none	none	
0x0101	Vibration ELISA plate	Send	two bytes first byte is speed Second byte is times	0x0010	Vibration time +3 seconds	Vibration Speed : 1. slowly 2. middle 3. fast Vibration time: 1-60 seconds
0x0102	switch the light filter	Send	one byte: filter number(0-7)	0x0010	3 seconds	installs seven light filters, the user can increase two
0x0103	read the air's AD value	Send	none	0x0104	1 second	
0x0104	the air's AD value	Receive	16 bytes of AD value	none	none	8 row 16 AD value of the air
0x0105	ELISA test board	Send	One byte test mode (0:	0x0106	Continuous: 10	

			continuous; 1: Step)		seconds Step: 30 seconds	
0x0106	Absorbance test Value	Receive	192 bytes, 96 holes of the 16 absorbance value	none	1 seconds	192 bytes of data, all values have expanded 1,000 times 10005 absorbance said too much 10,006 that is too small absorbance
0x0107	AD value of the last test	Send	none	0x0108	1 seconds	Executive Directive to be tested
0x0108	AD value	Receive	208 bytes, 96 holes of the 16 AD value +8 rows the 16 air AD	none	1 seconds	
0x0109	lamp switch	send	0 means open, 1 means closed	0x0010	1 second	
0x010A	read lamp's state	send	none	0x010B	1 second	
0x010B	lamp's state	receive	one byte: lamp's state two bytes: switch lamp time	none	none	
0x010C	read machine's ID	send	none	0x010D	1 second	
0x010D	machine's ID	receive	nine bytes: machine's ID	none	none	

4）Error number

0x1101 self-test error

0x1102 Order overtime

0x1103 Illegal orders

0x1104 Illegal orders investigation

0x1201 Invalid filter

0x1202 Invalid Vibration ELISA plate time

0x1203 Invalid Vibration ELISA plate speed

0x1204 Invalid Vibration ELISA plate mode

0x1205 No reduction filter signal

0x1206 ELISA plate without reset signal

0x1207 ELISA plate fixed or positioning signal slot Optocoupler

0x1208 AD not OK signal

0x1209 Invalid voltages

0x120F Light source is too strong

0x1210 Light source is too weak

5）Serial communication parameters

Baudrate: 19200

Parity: 'N'

Databits:8

Stopsbits:1

ISO9001＆ISO13485 Certified

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