

# **OPERATION MANUAL FOR**



# **Microplate Reader**



# M.R.C LTD.

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#### How to use this manual

#### It's greatly appreciated you become the user of Microplate Reader.

Be sure to read this manual carefully before operating the instrument.

In order to obtain the best result, it is important for you to get familiar with our instruments

and their functions before performing clinical diagnostic tests.

This User's Manual is the operation instructions for Microplate, which including the contents of instrument installation, daily use, and maintenance etc.

Please reserve all the packing materials for the use of deposit, transportation and maintenance in the future.

As to the instruments of different version or configuration, their functions are slightly different.

**Notes:** Tips, advices and suggestions will be presented in italics for distinction.

Warning: The warning shall be strictly abided by in order to ensure that the instrument may works normally and the test results may be correct and authentic. Black letters are adopted for distinction.

# Symbols on the instrument



This symbol means that the labeled item is hot while the instrument is in use. Don't touch the labeled item as you could be burnt. The symbol is labeled on the lamp support of optic system.

The symbol is labeled on the lamp support of



This means that the labeled item could lead to personal injury and/or damage to the analyzer.

The symbol is labeled beside the power outlet and some external interface.



The symbols for "SERIAL NUMBER", The serial number shall be after or below the symbol, adjacent to it.



The symbol means the product is in vitro diagnostic medical device.



The symbol indicates the manufacturer and its address, after which are shown its name and address.



The symbol indicates the date of manufacture, after which are shown its manufacture date.



The symbol indicates EU representatives of the manufacturer and their addresses, after which are shown their names and addresses.



The symbol indicates biological pollution, marked in the part where the instrument contacts the clinical reagent. The symbol appears in black side and yellow background.



The symbol means that the environment of instruments must be dampproof in the course of transport, and instrument must be kept in a dry environment.



This means that instrument should handle with care in the course of transportation, so as not to damage it.



The symbol means the instrument packaged should not be upended at any time



The symbol means that the level piled up can't exceed 8 layers, as not to damage instrument.

The symbol indicates temperature range of the analyzers during storage and transportation.

# Warning and Safety Indication

This instrument is only used for in vitro diagnosis, please carefully read the following warnings before the usage, and strictly obeys them.

- The articles and materials used in some test items have biological dangers. While operating the instrument, protective suits and glasses must be put on, and the protective casing must be put down (enzyme label cover).
- Please don't discard the used medical materials as you pleases, it should be dealed with according to the medical wastes.
- Pharmaceutical affairs law and regulation: It is forbidden to refit the medical instruments.
- This instrument connects the earth by the groundwire of power line, and the groundline must be connected to the earth to avoid electrical shock.
- Power supply must be stable. It is prohibited to use power source with high-power equipments together.
- In the area with unstable voltage, please use UPS power supply to ensure the normal work of the instrument.
- When power line is pulled out, you must hold plug itself, not the power line.
- Turn off the power supply immediately and contact the seller if the instrument gives out smog, peculiar smell or strange sound.
- After finishing test work, analyzer must be turned off according to the standard procedures, in order to avoid data loss.
- Power supply must be cut off and the mainframe must be turned off while maintaining or disassembling the external shells due to other reasons.
- When the instrument is turned on and off, the switch key must be ensured to immediately block to the very position, so as to prevent system damages.
- Please put on rubber gloves while maintaining and protecting, please wash hands after the work of each time to avoid virus infections.
- Don't let your hands or other parts of your body contact with the reagent or patient samples. If the wounded parts touch the patient samples uncarefully, please wash and accept doctor checkups in time.
- When the enzyme plate is used to incubation, water under the plate must be cleaned. Otherwise, the internal wares of the instrument may be eroded, resulting in the inaccuracy of test results.
- The product is a bench-type testing device, without issues on taboo.

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# **1. Brief introduction of instrument**

#### 1.1. Brief introduction of product

1.1.1. Product name Microplate Reader

#### 1.1.2. Model of the product

#### 1.1.3. Product property

- 1. Open for reagent, and there is no specific restriction.
- 2. It's automatic measurement mode, except the automatic sample application and washing plate, it can automatically measure, calculate and display the results, so as to make it convenient for users to operate.
- 3. It can perform quantitative or qualitative tests, many kinds of calculation methods:
  - Absorbance mode
  - Cut-Off Qualitative Calculation
  - Single point calibration
  - Curve regression
  - Multiple points percentage
  - Linear regression
  - Index regression
  - Logarithmic regression
  - Power regression
  - Percentage logarithmic regression
  - Four-parameter regression
- 4. Visual distribution for microplate with 96 holes, blank position, control position, sample position and standard preparation position can be set up, the test of maximum 12 items can be performed at the same time on the same plate.
- 5. 8-channel test is rapid and accurate.
- 6. History data saving with large capacity.
- 7. Synthetic English report output with various styles.
- 8. Assistant administration function: internal department database, doctor database, system log, reagent administration and work statistics, etc.

#### 1.2. Technique parameter

Resolution:	0.001Abs (Display) ,0.0001 Abs (Internal calculation)				
Light source:	Halogen tungsten lamp				
Test channel:	8 test channel to test simultaneously				
Plate type:	Microplate or strip with 96 hole or other types				
Movelenge:	4 internal filters: 405, 450, 492, 630nm: in addition, 4				
wavelengn.	wavelengths can be added as optional;(400—700nm)				
Shaking plate:	Yes				
Interface:	RS-232C bidirectional communication				
Display:	External displayer				
Print:	External printer				
Working environment:	0°C∼40°C; relative humidity≤85%				
Fuse:	T3.15AL 250V, Φ5×20				
Overall dimensions:	454mm (L) x295mm (W) x146mm (H)				
Weight:	6.2kg				
Power supply:	a.c.110-220V, 50/60Hz				
Power input:	120VA				

# 1.3. Instrument components

#### 1.3.1. Front view figure



Fig. 1-1 Front view of instrument

① Microplate cover: It can prevent dusts from entering the Microplate and the interior of instrument, Microplate, the moving work platform and rails are under it.

2 Power supply indicator light: After the instrument is on, this indicating lamp is lightened.

③ Running indicator light: When the instrument is running, this indicating lamp is lightened.

④ Warning indicator light: When the instrument warns, this indicating lamp is lightened.

(5) Indicator light of light path power supply: When halogen lamp is on, this indicating lamp is lightened.

#### 1.3.2. Back view figure



Fig. 1-2 Back view of the instrument

- ① Power switch: Turn on or turn off the instrument.
- 2 Electrical outlet: It is used to connect with power supply.
- ③ Fuse: If there is still no power supply after turn on power switch, check the fuse of instrument.
- ④ RS-232: Serial communication interface is used to communicate with PC machine.
- (5) Label: It can label the type and specification of instrument, etc.
- 6 Hinge: It is used to connect the bottom shell of instrument and the upper cover.

#### **1.3.3.** Principle structure figure (Only for reference)



Fig. 1-3 Principle structure figure

- Optic and colorimetric system
- Signal amplification
- A/D transform
- Computer
- Printer
- Display

#### 1.4. How to use

First, use a RS-232 cable to connect the instrument and computer, then turn on the instrument and perform the procedures in the computer.

# 2. Instrument installation

#### 2.1. Instrument unpacking

Unsealing the instrument's package, and remove the materials in transportation. Preserve the packing box and materials well. It's convenient for you to repack the instrument someday in the future.

Take the instrument out of the box.

Take off the packing materials, and take the instrument out of the plastic package. Check the articles inside the package box, and confirm the following should be included:

- Microplate Reader
- User's Manual
- Packing list
- QC list
- Accessories

# Note: Please contact with your distributor if any component is damaged, or not in accordance with the packing list.

#### 2.2. Environment requirement

Find a place without direct sunshine in your working place. The surface of the selected working table should be flat, and there is enough space to place Microplate Reader and PC computer. The anterior edge of instrument should be near to the edge of working table. Avoid comparatively large shake of working table (For example, put hydroextractor on the working table).

# Note: The working environment of instrument is that temperature is between 0 $\mathcal{C}$ -40 $\mathcal{C}$ and relative humidity is below 85%.

In order to guarantee the normal working of instrument, the following places are forbidden to place the instrument:

- Places with extreme changes of temperature.
- Particularly hot or cold places.
- Places full of dust.
- Places nearer to the electromagnetic devices which produces magnetic field.

#### 2.3. Power source requirement

- a.c. 110-220V
- 50/60Hz
- 120VA

#### 2.4. Begin installation

#### 2.4.1. Connect instrument to power supply

- 1) Insert one end of the power line into the outlet of instrument.
- 2) Insert the other end of the power line into the outlet of power supply.

#### Warning:

- Power supply must be well earthed. (grounding voltage<5V).
- Power supply must be stable. It is prohibited to use power supply with high-power equipments together.
- When power line is pulled out, you must hold plug itself, not the power line.
- Turn off the power supply immediately and contact the seller if the instrument gives out smog, peculiar smell or strange sound.

#### 2.4.2. Connect external printer

This system is compatible with most types of USB Interfaces and parallel Interface printers. Please connect printer to the computer connected with this instrument according to the printer user's manual, and install.

#### 2.4.3. Connect instrument to computer

- 1) Cut off the power supply of instrument and computer.
- 2) Connect the two ends of RS-232 cable to the instrument and RS-232 serial port of computer respectively.

### Note: After connecting the instrument with computer by serial interface, turn on the power supply of instrument, and then perform the application procedures in the computer.

# 3. System log-in

#### 3.1. Serial number

When you are using the instrument for the first time or the serial number is empty, system asks the user to correctly input the serial number on the back of instrument. As shown in Figure 3-1.

Instrument serial ID	
Please input the Serial ID ba	ackside the instrument rightly!
Serial ID:	
	E
	<u> </u>

Figure 3-1 Machine serial number

If the user has already inputted the serial number, this dialogue box will not appear the next time.

Inputting serial numbers enable us providing maintenance service of instrument to users rapidly.

#### 3.2. User log-in

After you have inputted the serial number, the system appears user log-in window. As shown in Figure 3-2.

Name: Password:	administrator	
OK	Exit	

Figure 3-2 User log-in

Select user name in the list frame, input password in the password frame, and click "OK"

button. If the user name and password are correct, it will enter system self-checking, otherwise, the system will indicate the failure of user log-in. Click "exit" button to exit this system.

There are two kinds or authority of a user, administrator and common user.

#### 3.3. System self-checking

It will enter system self-checking after users correctly log-in, the system will automatically check whether the serial interface is available during the self-checking procedure. If it is not available, it indicates users whether it is correctly connected with instrument. If the serial interface is available, self-checking can be performed. Self-checking window is as shown in Figure 3-3.



Figure 3-3 System self-checking

After finishing self-checking, system enters the main menu.

#### 3.4. Log-in result

If system self-checking is succeeded, and it is logged in by administrator, then all the functions in the main menu are available. If it is common user log-in, parts of the menus are not available. If system self-checking is not successful, users only can operate "information management" and "check" menu. The menu is as shown in Figure 3-4.



Figure 3-4 Main menu

### 4. Information management

Including the patient's basic information input, the form information input, query, delete and add the functions of the items by the patients.

#### 4.1. Patient information

It includes the functions of basic information input of patient, menu information input, searching, deteling and adding the tests that patients have done. As shown in Figure 4-1.

Patient information					
Patient basic information	Sample NO	Patient name	Sex	Test date	
Sample NO Name	Þ				1
Sex Age					
Section Case history					
Department Bed NO					
Diagnose Remark					
Number of patient Blood type					
Identity Card					
Sheet information	<u> </u>				
Test doctor Send date 2006-12-21 -	Item name	Quantity	Quality	ABS	
Send doctor Test date 2006-12-21 -					
Auditing doctor					
Look					
Test date 2006-12-21 • to 2006-12-21 •					
Sample NO Name					
LOOK (L)	Item infoamation -				•
	<b>_</b>		•		
Add ( <u>A</u> )         Save ( <u>S</u> )         Delete ( <u>D</u> )         Exit ( <u>E</u> )	Add item $(\underline{T})$	Delete item( <u>l</u> )			

Figure 4-1 Patient information

#### 4.2. User management

It includes the functions of adding user, deleting user, revising password and changing authority. There are two kinds or authority of a user, administrator and common user. Only administrator has the authority of adding user, deleting user and revising authority. Common user only has the authority of changing password.

Adding user menu is as shown in Figure 4-2.

<u>s</u>	Name:
	Code name:
	Password:
	Affirm password:
	User purview: User

Figure 4-2 Adding user

#### 4.3. Basic settings

It includes five parts: hospital information, doctor information, department information, section information and diagnosis information. Doctor information is as shown in Figure 4-3.

Tes	Uuclui Send doc	tor Auditing doct	or ]			
П	Test doctor	Shortcut key			XXX	
Þ	XXX	2		Doctor Hame.		
Π	Administrator	1		Shortcut key:	2	
				Ac	Id (A)	Delete (D)
			-		(0)	E 1 (E)

Figure 4-3 Doctor information

Doctor information includes the laboratory doctor, the test-sending doctor and the checkup doctor.

#### 4.4. Department management

It includes work statistics and reagent information. Work statistics is mainly for the convenience of hospital to check the work of doctors in a certain period. Work statistics can search the plates, number of test items and patients that the doctor has done during a certain period.

The menu of work statistics is as shown in Figure 4-4.

Doctor name: Start date: End date:	X X X 2006-12-21 2006-12-21 Look (L) Preview (E) Exit (E)	•	The result of query The number of test plate The number of test items The number of test patien Item list of test	s Patients of test	
	Exit ( <u>E</u> )				

Figure 4-4 Word statistics

Reagent information includes the functions of reagent adding, deleting and revising, etc. As shown in Figure 4-5.

 Reagent r	name:		
Manufact	urer:		
	Reagent r Manufactu	Reagent name:	Reagent name:

Figure 4-5 Reagent information

### 5. Test item programming

Click "Item Set" under "Item" in the main menu, or click "Item Set" on the toolbar, enter item settings menu. As shown in Figure 5-1.

104 101		
	New name         Initiality         Complete name         Unit           Test remited         End part         C diculation method         C an OF           Fast remited         End part         C diculation method         D out           Upper limit         0 000         L met limit         D out           CudOff Formula         1 000         New Not         E out           CudOff Formula         1 000         New Not         E out           CudOff Formula         1 000         X PC +         E out           CudOff Formula         1 000         X PC +         E out           CudOff Annual         1 000         X PC +         E out           CudOff Annual         1 000         X PC +         E out           CudOff Annual         1 000         X PC +         E out           CudOff Annual         1 000         X E out         E out           CudOff Annual         1 000         X E out         E out           CudOff Annual         1 000         X E out         E out           CudOff Annual         1 000         X E out         E out           CudOff Annual         P out         P out         E out	Coulds and in Annual Annu
	C relevation C method C metho	Valdy tomain lowy Likewy Families of the tee

Figure 5-1 Item settings

In this menu, items can be added, revised and deleted. The attribute of item mainly includes basic information of items, standard settings, quality control settings and the selection of effective formula.

100 items are permitted to be set at the most. The items set by users are displayed in the list on the left side of the window.

#### 5.1. Methodologies

There are three kinds of methodologies, endpoint, two points and Kinetics.

#### 5.2. Calculation methods

Microplate Reader supports many kinds of different calculation methods, and there are 3 types as following.

#### 5.2.1. Absorbance mode

Directly measure and output the sample's absorbance.

#### 5.2.2. Qualitative Calculation Cut-Off

Cut-Off threshold formula: Cov = X×NC+Y×PC+Z×CR+Fac

NC is the value of negative control absorbance, PC is the value of positive control absorbance, CR is the value of threshold serum absorbance. X, Y, Z and Fac are formula

coefficients, and they are inputted by users according to the reagent instructions. The qualitative formula of other forms can be changed to this pattern. For example: when sample OD/Negative control OD $\ge$ 2.1, it's positive, and X=2.1, Y=0, Z = 0, Fac=0.

Cut-Off calculation method can select single threshold or double thresholds.

The result of qualitative calculation is manifested as the retio of sample absorbance and Cut-Off threshold, and the unit is s/co.

#### 5.2.3. Quantitative Calculation

 Single point calibration: One standard needs to be set, take the line between the original point and standard point as calibration curve (X-axis is concentration, and Y-axis is absorbance, the same with the following). Single point calibration must set blank to adjust the zero point. As shown in Figure 5-2.



Figure 5-2 Single point calibration

2) Non-linear regression (point to point): 2-8 standard preparations are permitted to set, take the lines between all the standard points (it should be a monotonous ascending or descending polyline) as calibration curve, as shown in Figure 5-3.



Figure 5-3 Non-linear regression

If the absorbance of standard is not monotonously ascended or descended, the calibration results are wrong, as shown in Figure 5-4.



#### Figure 5-4 Wrong calibration results

- 3) Multiple-point percentage %ABS: 2-8 standard preparations are permitted to set, the biggest absorbance value is defined as 100% among the standard preparations, and the absorbances of other standards and samples to be test are manifested by the percentage to it. The calibration method is the same with that of non-linear regression.
- 4) Linear regression: 2-8 standards are permitted to set. Through these standard points, a straight line is regressed, Y = kX + b as the calibration curve, as shown in Figure 5-5.



Figure 5-5 Linear regression

5) Index regression: 2-8 standards are permitted to set. Through these standard points, an exponential curve is regressed,  $Y = ke^{bX}$  as the calibration curve. The absorbance values of all the standard preparations must be more than zero.

If get the logarithm (Y' = LnY) of absorbance value, index regression can be changed to the form of linear regression: Y' = k'X + b'

6) Logarithmic regression: 4-8 standards are permitted to set. Through these standard points, a logarithmic line is regressed, Y = kLnX + b as the calibration curve. The concentration values of all the standard preparations must be more than zero.

If get the logarithm of the concentration value (X' = LnX), logarithmic regression can

be changed to the form of linear regression: Y = kX' + b

- 7) Power regression: 2-8 standards are permitted to set. Through these standard points, a power curve is regressed,  $Y = kX^{b}$  as the calibration curve. The absorbance values and concentration values of all the standard preparations must be more than zero. If get the logarithm of concentration value and absorbance value (X' = LnX, Y' = LnY), power regression can be changed to the form of linear regression: Y' = k'X' + b'
- Percentage logarithmic regression
   Percentage logarithmic regression permits to set 4-8 standards, and the concentration of

each standard preparation must be more than 1.

9) Four-parameter regression

Four-parameter regression permits to set 4-8 standards. Input the concentration values according to the corresponding reagent instructoin manual, use instrument to test the

absorbance value of standard solutions, and get the regression curves by Gauss-Newton Iteration Method.

#### 5.3. Basic settings of item

As show in Figure 4-1 above, item settings include the following parameter settings:

- Item name: This item must be inputted and pay attention not to repeat the existed item names.
- Reagent manufacturer: Select from the list frame according to the used reagents, and it also can be blank.
- Wavelength: Select from the list, pay attention not to make first wavelength and second wavelength repeated.
- Test mode: Select from its list frame.
- Calculation method: Select from its list frame.
- Double samples: If double samples are selected, the adjacent holes of each sample hole are automatically set as the repeating holes while setting the plate. Take the mean value of both absorbances when they are calculated.
- Upper limit, Lower limit: They are mainly as the reference range of test results.
- Delayed Time, test time, and factors are used as the settings of Kinetics method.

# Note: The parameters of items to be set are various according to different types of calculation methods.

- 1) Quantitative Calculation Standard information of items must be set.
  - Input according to the reagent instructions.
- Standard number

Select 1-8 standards.

#### • Double standards

If double standards are selected, the adjacent holes of each sample hole are automatically set as the repeating holes while setting the plate. Take the mean value of both absorbances when they are calculated.

#### • Standard concentration

Pay attention to the order of standard concentrations, it must has the same monotonicity.

2) Qualitative Calculation - Cut-Off formula settings interface.

Input in this item settings dialogue frame according to the reagent instructions.

#### • Cut-Off formula coefficient

If the qualitative formula of all kinds of reagents has different forms, e.g. S/N and (N-S)/N, etc. All of them can be changed to S/(X\*N+Y\*P+Z\*C+Fac). If double thresholds are selected, two Cut-Off formulas can be inputted.

#### • Negative control, positive control and the absorbance range of threshold serum

When the control absorbance exceeds the upper limit and lower limit, it should be calculated as the upper limit and lower limit. For example, some reagents require the negative control less than 0.05 just calculate as 0.05, and the lower limit of negative control should be set as 0.05.

Control

Controls can be set discretionarily, but its number of each test item should not exceed 12, and take the mean value of all the control absorbances while calculating.

#### 3) Negative and positive judgement settings

Input the critical values to judge the negative and positive in this interface. Under absorbance mode, the critical value is the absorbance value. Under Cut-Off mode, the critical value is the ratio of sample to threshold value. Under quantitative calculation mode, the critical value is the concentration value. There are 3 kinds of qualitative methods.

#### • Positive threshold mode

Negative < Negative critical value, Positive ≥ Positive critical value, the area between these two is gray zone, and the samples in this zone is doubtful.

#### • Negative threshold mode

Negative >Negative critical value, Positive≤Positive critical value.

#### • Negative or positive don't need to be judged.

Select "no" in the qualitative mode.

#### 4) Quality control settings

Quality control method includes ELISA (self value), ELISA (setting value) and instant method. ELISA method has four conditions of judgement to decide whether the Quality Control Data are out of control. Either single item settings or group settings can be selected according to the condition.

#### 5) Judgement of validity

Judgement of validity requires user to select correctly for each item from formula base.

Formula is the key point of the judgement of validity. Menu of the judgement of validity is as show in Figure 5-6.

Formula library	
Input formula of validity	
User can only put on hereinafter variable: NC1、NC2、NC3、NC4、NC5、NC6、NC7、NC8、N PC1、PC2、PC3、PC4、PC5、PC6、PC7、PC8、PC CR1、CR2、CR3、CR4、CR5、CR6、CR7、CR8、C BK1、BK2、BK3、BK4、BK5、BK6、BK7、BK8、BK Thereinto, NC express negtive control, PC express positiv negtive control at discretion, NCv express average of all n AND or OR → For example NC1>0.005ANDNC1<0.08	IC9. NC10. NC11. NC12. NCv. NCx 3. PC10. PC11. PC12. PCv. PCx 7. PS. CR10. CR11. CR12. CRv. CRx 3. BK10. BK11. BK12. BKv. BKx re control, CR express CR, BK express blank:NCx express one egtive control, The other variables have same meaning.Can put on
Add (A)	Delete ( <u>D</u> )

Figure 5-6 Formula bases

# Note: User must input rational formula; otherwise unnecessary warning will be produced in the test.

#### 5.4. New item

Click "add" button to add new item. If the item number is more than 100, new item can not be established, system will indicates "the item number is full". The operation procedure of new item is same as that of changing old items. Please note that the name of new item cannot be the same as that of existed item, otherwise system will indicate that the item has been existed.

## 6. Sample test

nplate types d types n Bats t calculation o	New Pate [End part	Ner C C C	angle typ Swipler NC PC CR		C QC C Standa C Black C Dear			flark tor (* Nore1 (* Nore1 (* Nore1 (* Nore1 (* Averag	darð. darð. rik gr. store blar	( 0 ( 0 ( 0	ve Slavik av blavik senspe kar b	iesk.	Save to	ngiate
Plate deecte	enerer ene F Rose C List	Г	1	2	1	4	5	5	2	4	3	10	11	12
Stat ND: Stat web	A 71 7	A	_	-		_	-					-	1	
End welk	H .12 .	< -	-	10.00		_	-			-	<u> </u>	10	-	
fove plate pa	A Continue C Stee	H	-	-			-	-			-	-	-	
Mis speed		¢					_					-	-	
His lines	5	0	-		10-1				-					
Delay times		£			b f				11					
Solici -		1		-							<u> </u>		1	
n	ate information		-	-	-		-	-		-	-	1	-	-
		12	-	-	-	_	-	-		-	<u> </u>	-		
		×	ļ,	-	10-10			1	16-10				1.0	
		_												

Sample test menu is shown as Figure 6-1.

Figure 6-1 Testing menu

Sample test menu mainly includes the select of template type, test mode, calculation method, settings of set plate parameter, plate moving parameter and the microwell settings on the Microplate. Microplate settings mainly include settings of sample type and the select of blank mode.

#### 6.1. Template type

Template type mainly includes two types, new template and existed template. If new template is secleted, the information on the Microplate is empty. The type of user selectsion sample is the same with that of sample, using mouse to click the microplate can perform plate arrangement. If the existed enzyme label plate is selected, click "Test" button to perform measurement.

#### 6.2. Test mode and Calculation method

Measurement include endpoint method, two points method and Kinetics method. After user selects the measurement mode, select calculation method from calculation method list frame, i. e. set sample information for this method on the Microplate.

#### 6.3. Set plate and plate moving settings

#### 6.3.1. Set plate parameter settings

Set plate parameter mainly includes settings as follows:

- Set plate direction: horizontal or vertical
- Original sample number.

#### • Original sample position.

Input original sample number (1-999) and original hole position (row number and column number), stop hole position (row number and column number), click "enter" button. All holes of the whole plate are set as samples according to current item. Sample number of original hole is inputted original sample number and sample number of stop hole is inputted stop sample number. Sample number of other hole positions increase successively according to set plate direction.

When "selecting all" function is used, all items and holes that have been set will be cleared. If want to set standard or control, please operate after selecting all.

#### 6.3.2. Plate moving parameter settings

Plate moving parameter mainly includes settings as follows:

- Plate moving mode: Continuous mode will increase testing velocity and step mode will improve the testing precision.
- Mixer parameter: There are 3 levels of mixer speed, high speed, medium speed and low speed, mixer time is 1-60 seconds. Not mixer can also be selected.
- Timing test: User set the preset time, test begins when it reaches the preset time.
- Delay test: Test is delayed until the time set by user.

#### 6.4. Select test item

Microplate Reader supports 12 different items test on the same plate, but for the test items with methodologies of two points and Kinetics, only one item can be set in the same plate.

#### 6.5. Set plate

Microplate Reader permits user to set the holes discretionarily in the range of 96 holes microplate. The switch of "select hole type" is above the window. User select the hole type to be set, then click on the hole position.

Hole position mark symbol: Sample: 1–999

Blank: BK1 – BK12 Negative control: NC1 – NC12 Positive control: PC1 – PC12 Threshold serum: CR1 – CR12 Standard: SD1–SD8 Quality control: QC

#### 6.5.1. Sample

User click the hole position to be set as sample discretionarily, the sample number increase from 1 automatically and is displayed at this hole position. If user wants to change sample number, double-click the hole position:

Input sample number again in the window that emerged. If the sample number inputed has been existed, system will display that "the sample number has been existed", the change is not valid. The range of sample number that is permitted for Microplate Reader is 1-999.

#### 6.5.2. Blank

Blank hole is adopted for zero settings of absorbance in item test, which means absorbance

of other holes should reduce the absorbance value of blank hole. According to the requirement of different item test, user may select whether set blank or not.

The patterns of blank include no blank; single point blank, multiple blank, single column blank, column average blank, single row blank, row average blank.

If users select single row blank or all rows blank, only need to click the row mark at the left of the microplate.

If users select single column blank or all columns blank, only need to click the column mark on the upper of microplate.

Saving and application of old blanks: The test results of blank holes will be automatically saved. If no blank is reset in the following tests of the same item, the system will automatically use the old blank to calculate.

#### 6.5.3. Negative control

Be effective only in the item that calculation method is Cut-Off. According to the Cut-Off formula, user must set negative control except for the condition that negative control coefficient is 0. Each item is permited to set 12 negative controls at the most.

When item test is running, absorbance of control hole and the calculation results of corresponding Cut-Off value will be saved automatically. In the following test of the same item, if control is not set again, system will adopt the old Cut-Off value to calibrate.

#### 6.5.4. Positive control

It is similar to the settings of negative control.

#### 6.5.5. Threshold serum

It is similar to the settings of negative control.

#### 6.5.6. Standard

It become effective when Item settings need calibration with standard. If this item has tested old standard, user can select not to set standard (use old standard to calibrate) or to set all standards again. The condition that only a part of standards are set is forbidden. User click standard hole position successively, and system will successively mark them as SD1, SD2...

The settings of all standards are finished, if user click again, system will display" The number of standard is enough!". If user begin to test or add new item before the setup is finished, system will displays that "The item of () hasn't enough standard!"

#### 6.5.7. Quality control

There is no limit to the number of quality control.

#### 6.5.8. Clear

If user need to revise the hole position that has been set, after clicking clear switch, user can clear all set hole position of current item, and then setup again according to your requirement.

#### 6.6. Clear whole board

Clear all previously set item and hole position.

#### 6.7. Test

Click"measure"button, system displays the dialogue frame of being measuring. Clicking stop key button can cancel current test.

#### 6.8. Absorbance display

When the test is over, system will display absorbance automatically.

In some special situation, some users may need to revise the absorbance value of test sample or standard. They can double-click the whole position which needs to be revised.: Input absorbance value again in the displayed window. If there is some calibration error in the process of calibration, system may display "The calibration of the item is error!". The possible reasons include: absorbance is 0 or negative, linear regression error, standard absorbance-concentration curve is not monotonous etc.

#### 6.9. Quantitative result display

Click"quantitative result" can display the quantitative result.

#### 6.10. Qualitative result display

Click"qualitative result" can display the qualitative result, if the test item doesn't require qualitative result; only sample number will be displayed.

#### 6.11. Print

Click"print"button, the whole board results of current test (include hole position, test item, sample number, absorbance, quantitative result, qualitative result) can be printed according to the item and the form of microplate.

#### Note: Results should be saved before print.

#### 6.12. Save

Click"save", then the test result of this board can be saved in database for the later inquirement.

## 7. Result review

Result review includes test result, quality control information, calibration curve and system log.

#### 7.1. Test result

Test result is the primary information of this system, enquiry to the results of patients and printing of main reports are located in this window. Test result window is shown as Figure 7-1:

sin I hem_Set  Patient P	Rend B System	D LEVE					
y plate Report by item Report by a	satient   Blood workstation						
Colini In one week sice condition at time: 2006-12-27 d time: 2006-12-27 mple N0 me:	Sancie NO P	olert name See	Age	Bed NO	Sector	Tell doctor	Teil date
co lonat / Teo is sepance Thee is sepance * A4 pre * Dynamic pret her al	been NO	Guardity	Quality	A	Ø5		

Figure 7-1 Test result

This window includes three parts, "Report by plate", "Report by item "and" Report by patient". For each part, results can be inquired or printed according to the current day, in one week and user-defined time period.

### 7.2. Quality control information

Include the QC result enquiry of each item for a certain batch in certain time period. Quality control information includes maximum, minimum, average, variance and CV value of the quantitative and qualitative results in certain time period. The dialogue is showed as Figure 7-2:

Sangle ] San Sal   Pale	NE ROUTE Symmetres	
en nane Hitpia	OC method Amerge(CDs S00006 CHOO) Amerge(CDs CHOO) Amerge(CDs CHOO) Amerge(CD) Amerge(CD	ABI 07:04%
lach ID		24 1200
Nat See 2006-12.21	Aresign SD CV Maix Me	T4.1500

Figure 7-2 Quality control information

Select item in the Item name list frame, select batch number in the batch number list frame, and select the time period to be inquired. Click"search"button.

#### 7.3. Calibration curve

Calibration curve is mainly used to search calibration result of each item, its dialogue frame is showed as Figure 7-3:

Item name list IBsAg		
IBsAb	Standard curve	
iBeAb IBcAb		Standard ABS value     Standard curve
	0	ABS Concentration
	0	
em name:	Test mode: Calculatio	on method:
mplete name	Test unit: Preview	w ( <u>P</u> ) Exit ( <u>E</u> )

Figure 7-3 Calibration curve

### 7.4. System log

System log mainly records login user name, login time, logout time and reason etc, searchs the user login condition in a certain time period. Its dialogue frame is as Figure 7-4:

em log							
Start date	. 2006-12-21		nd time: 20	06-12-21		ook (L)	
			na ano. j	_	<u></u>		
Log_NO	User_Name	Log_Date	Log_Time	Exit_Date E	xit_Time E	xit_Result	
Þ							
I							
	Delete (D)		Preview	(P)		Evit (E)	
J			1 16 116 1				

Figure 7-4 System log

## 8. System settings

System settings includes system time, system self-checking, error warning.

#### 8.1. System time

This function is mainly used to check and change the system time and date.

#### 8.2. System self-checking

System self-checking is as Figure 8-1. It is mainly used to inspect the instrument parameters, such as light intensity AD value of each wavelength of the instrument, ABS value and light intensity AD value of the selected wavelength.

ſ	1	1	
	Check self	Stop	
None	ABS value	Stop	
None	Optical AD value	Stop	

Figure 8-1 System self-checking

#### **Error warning**

Mainly record the warning condition of the instrument, as show in Figure 8-2.

or al	arm							
Γ	Start date:	2006-12-21	•	End date:	2006-12-21	•	Look (L)	
1								
	Log_NO	Alarm_Date	Alarm_R	esult				
ľ								
		Delete ( <u>D</u> )		Pre	view (P)		Exit ( <u>E</u> )	

Figure 8-2 Mistake warning

# 9. Data maintenance

#### 9.1. Database backup

Database backup is only a simple backup to the whole database; its dialogue frame is as show in Figure 9-1.

Destination path:	
Exit (E)	

Figure 9-1 Database backup

#### 9.2. Database recover

Database recover means recovering the database which has been backuped previously, as show in Figure 9-2.

Destination path:	
P	

Figure 9-2 Database recovers

## **10. Instrument maintenance**

Microplate Reader is a precise clinical analytic instrment. In order to keep the instrument in a good state, routine maintenance must be done. The maintenance of Microplate Reader is very simple, but it must be done carefully.

### Warning: Instrument repair must be operated by experts. When outer shell is dismantled becsuse of repair or other reasons, power must be cut off and the instrument must be turned off.

#### **10.1 Clean instrument**

- Keep the instrument working environment clean.
- Neutral cleaner and wet cloth can be used to clean the surface of instruments.
- Please use soft cloth to clean the LCD.

# Warning: Please don't let any solvent, lip and erosive material touch the instrument.

#### **10.2** Instrument components change

#### 10.2.1 Change fuse

- 1) Turn off the instrument.
- Fuse is installed in the fuse box at the behind of the instrument beside the power switch.
   Fuse standard: T3.15AL 250V, Φ5×20.
- 3) Close the cover of the fuse box, and restart the instrument.

#### Warning: Must use the fuse of the specifications above.

#### 10.2.2 Change halogen tungsten lamp

When Halogen tungsten lamp is damaged, change procedure is as follows:

- 1) Turn off the instrument, open the top cover of the instrument.
- 2) Loose the elastic pree slice of one of the lamps.
- 3) press the lamp lightly, then take out lamp and socket toghther, and pull the lamp out from the lamp socket.
- 4) Insert the new lamp into lamp socket correctly, reposit the new lamp.
- 5) Recover the elastic click slice of the lamp, tighten up the screw.
- 6) Close the cover, turn on the instrument again.

# 10.3 Trouble shooting

Trouble	Possible reason	Trouble shooting
Microplate Reader	Power supply is abnormal.	Check whether the instrument is switched on. Check whether the power plug is loose.
can not be started.	The interval time between power on and off is too short.	Check the fuse. Check the voltage. Restart the machine 30 seconds after power off.
Lamp is not lighted.	Power supply of the lamp is abnormal. Lamp is damaged.	Check power supply before changing lamps. Change lamps.
Light is too strong.	The filter is not correctly installed.	Check whether filter and the filter wheel are correctly installed.
Light is too weak.	Lamp is damaged.	Change lamps.
No reposition signal for the filter	The filter wheel is out of order.	Open the instrument cover, and check whether the position of transducer is accurate.
No reposition signal for the microplate	Location of the small can is too near to the right	Push the small car about 1 centimeter to the left.
Microplate doesn't move	Driving motor is out of order.	Open the machine cover, and check whether the driving motor is rotating.
Printer can not be started.	Power supply of printer is abnormal.	Check whether the power plug is loose. Check ON/OFF button.
Printer can not print.		Whether printer type is correctly set? Check whether print cable is correctly connected?
Printer manifests as color fading and the whole print quality descends.		Change ink box, and clean the printing head. (Refer to the printer user's manual for details)
Printer holds paper.		(Refer to the printer user's manual for details)
Other disorders of printer.		(Refer to the printer user's manual for details)