

Laboratory Equipment Manufacturer www.mrclab.com CE - Ket -

Operation Manual for





PLEASE READ THIS MANUAL CAREFULLY BEFORE OPERATION

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MRC.VER.01-7.11

How to use UT-6500 user's manual

Thank you very much for becoming the user of UT-6500 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 the instrument and its performance before clinic application.

The user's manual is the operation instruction of MRC's UT-6500 Microplate Reader. which will show you the instrument specification, instrument installation, daily use, maintenance and other aspects.

If you have any questions, please contact with the distributor.

Please keep all the packing materials for future storage, transport and return to factory for repairing.

The instruments of different versions or configurations are featured with a little different function.

Attention: Notes, tips, advices and recommendations are shown in italics to clear differences.

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.

Statement

MRC has the final interpretation of this instruction.

The iconographs provided in this instruction only act as examples, may not be entirely consistent with the the actual show of the product, take the actual product as the priority, and should not be used for other purposes. Without the written consent of MRC, any individual or organization must not copy, modify or translate the contents of this manual.

Only meet all the following requirements, may MRC be considered to be responsible for the product safety, reliability and performance, namely:

 The installation, re-commissioning, expansion, improvement, and maintenance are all conducted by the personnel approved by MRC company;

- The product operation is carried out in accordance with this manual;
- The related electrical equipments are in line with national standards.

Note:

• The analyzer should only be operated by the professionals of medical inspection, or the trained doctors, nurses or laboratory assistants.

Warning

- If the end user can not establish a satisfactory maintenance/repair program, it may result in some abnormal analyzer failure, and may endanger human health.
- It should be guranteed that the analyzer must be operated under the conditions laid down in the manual, if it is operated beyond these conditions, it may result in that the analyzer can not operate normally, or the measurement results will be unreliable, and may even damage the analyzer components as well as damage to personal security.

The main icons used in this instrument



Temperature limitation

It shows that the transport packages shall be kept at the temperature limit.

Fragile, handle with care The breakables are loaded in the transport packages, so place them carefully and gently when carrying them.

Upward

To show that the correct position of the transport package should be vertical upward.



Rain vulnerable The package is rain vulnerable.



Stacking layer limit The maximum stacking layers of the same packing, 8 means the layer limit.



Biological contamination.



Note: Refer to the accompanying documents.

In Vitro Dignostic

Warnings and safety tips

Only in vitro diagnostic use, carefully read the following warnings before use, and must be strictly adhered to them.

- Some articles and materials used by certain test items have biological risk. When operating the instrument, must wear protective clothing and glasses, and must lay down the protective cover. (ELISA Cover Board).
- Do not discard the used medical consumables discretionarily, it is should be handled as the medical waste.
- Pharmaceutical Affairs Law: it is prohibited to modify medical devices.
- The instrument power cable ground wire should be earthed, in order to avoid electric shock, the ground wire must be connected to ground.
- The AC power must be stable, and it is prohibited to share power supply with the appliances of high power. The instrument should be placed at the position easy to disconnect the power.
- In the area of unstable voltage, please use the UPS power to ensure the normal work of the instrument.
- When unplugging the power cable, please seize the plug itself, rather than the power cable.
- If the instrument is found to have smoke, smell or abnormal sounds, immediately turn off the power, and contact the maintenance service center immediately.
- After completing the test, must turn off the analyzer in accordance with the standard program to prevent data loss.
- When repairing or demolition of housing for other reasons, must cut off the power and shutdown the mainframe.
- When turning off the instrument, must ensure the switching key to be connected in place rapidly to avoid damaging the system.
- Must wear rubber gloves when conducting maintenance, and clean your hands after

each operation to avoid infection.

- Do not allow hands or other parts of the body contact with reagents or patient samples, if some wound parts contact with the patient sample accidentally, please promptly clean and receive doctor examination.
- After completing the microplate incubation, must clean out the moisture in the plate bottom, otherwise, the inside parts may be corrode resulting in inaccurate test results.
- This product is a desktop test instrument, there is no contraindication problem.

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Chapter I Instrument Introduction

1.1. Product introduction

1.1.1. Product name

Microplate Reader

1.1.2. Product model

UT-6500

- 1.1.3 Classification
- According to the medical device management classification method, it is classified as the immunity analysis system of the clinical examination and analysis equipment (6840), and its management grade is Class II.
- Classifying by the electrical safety, the pollution grade of the analyzer is 2, facility category (over voltage category): Class II.
- 1.1.4 Product Performance
- 1. Reagent is open, no specific restrictions.
- 2. Automatic measurement mode, except for the automatic sampling and plate-washing function, the measurement, calculation, and results display can all be carried out automaticlly, so it is very convenient for the user.
- 3. Three methods of measurements: end-point method, two-point method, kinetics method.
- 4. Quantitative or qualitative detection, with a lot of calculation methods:
- Absorbance mode
- Cut-Off qualitative calculation
- Single standard
- Curve
- %ABS
- Linear regression
- Exponent regression
- Logarithmic regression
- Power regression
- Percentage logarithmic regression
- Four-parameter regression

5. 96-wells visualization layout, blank position, control position, sample position, and standard

position can be set discretionarily.

- 6. 8 channels detection can ensure that the detection is quick and accurate.
- 7. Large-capacity historical data storage.
- 8. Various outputs of comprehensive report.
- 9. Auxiliary management functions: built-in department database, doctor database, system

log, reagent management, as well as workload statistics and other functions.

1.2. Product performance structure and composition

It is mainly composed of the optical, mechanical, electronic and software components.

1.3. Product applicability

Adopt the principle of the optical colorimetry for the enzyme-linked immunosorbent assay (ELISA).

Resolution:	0.0001Abs(displayed), 0.0001Abs(calculated)					
Light source:	Halogen tungstenlamp					
Measurement channel:	8 channels measurement conduct detection simultaneously					
Sample type:	96-wells or other types of plate or strip					
Wavelength range:	340nm ~ 900nm					
Plate shaking function:	Yes					
Temperature control	Feature Required, temperature control range: Ambient temperature +4C~50C					
Interface:	RS-232 bidirectional communication port					
Display :	External display					
Print:	External printer					
Working environment:	10 ~35 ; relative humidity≤85%					
Storage environment:	-10 ~40 ; relative humidity≤85%					
Fuse:	T3.15AL250V, Φ5 × 20					
Dimensions:	186mm(L)×440mm(W)×220mm(H)					
Weight:	9.0kg					
Power:	a.c.110V-220V; 50/60Hz					
Input power:	150VA					

1.4. Technical parameters

1.5. Instrument components

1.5.1 Front view

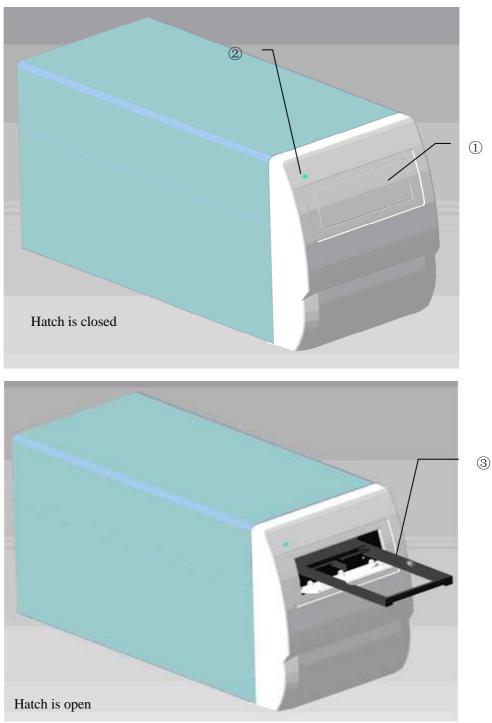


Figure 1-1 Front view

Hatch window: it can prevent dust and background miscellaneous light entering into the microplate or the instrument inside, when opening, the tray will be ejected, and then you may place in or take out the microplate (as shown in Figure 1-1).

- Power indicator: after starting up, the indicator is light.
- Tray: to carry microplate, with automatic clamping feature.
- 1.5.2 Back View

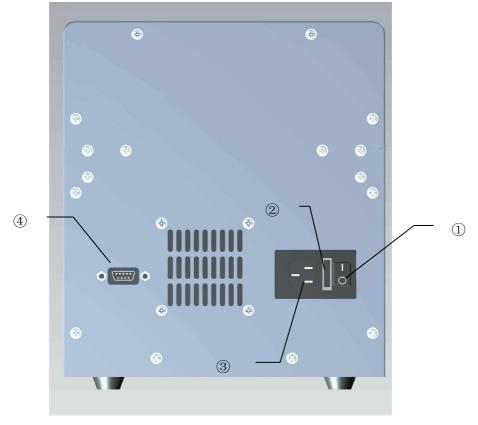


Figure 1-2 Back View

- 1 Power Switch: Open or close the power.
- ② Fuse: (located between the switch and the outlet, with a cover film for protection), after turning on the power switch, if there is no power, check the instrument fuse.
- ③ Power socket: to connect AC power cable.
- ④ RS-232: serial communication port for communication with the PC.
- 1.5.3 Principle structure diagram (only for reference)

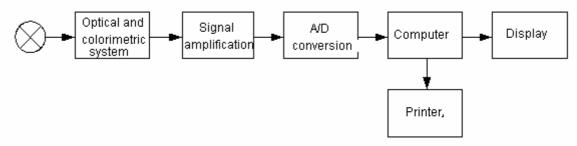


Figure 1-3 Principle structure diagram

1.6. Operation principle

Connect UT-6500 and computer with RS-232 cable firstly, switch on the instrument, and then

run software of UT-6500 in computer.

Chapter II Instrument Installation

2.1 Instrument unpacking

Unsealing the instrument's package and remove the materials for transport. Save the packing box and the packaging materials well, for your convenience in the future of re-packaging the instrument.

Take out the instrument from the box.

Take away the packaging materials, and take out the instrument from the plastic packaging bag.

Check the items in the box and confirm that the following items are within the box:

- UT-6500 Microplate Reader mainframe
- User's Manual
- Packing List
- Certification of inspection
- Accessory.

Note: If the items are inconsistent with the packing list or have any defects, please contact with the supplier.

2.2 Environmental Requirements

In your workplace, select a place without direct sunlight. The surface of the worktable should be flat, with enough space for placing UT-6500 Microplate Reader and PC computer. The front edge of the instrument should be close to the table edge. Keep the worktable free of big shock (if there is a centrifuge placed on the worktable).

Note: The instrument working environment temperature should be 10 -35 , and the relative humidity should be less than 85%. The instrument should be placed at the place with excellent ventilation.

In order to ensure the normal operation of the instrument, it is prohibited to place the instrument in the following places:

- A place with extreme temperature changes
- A place of particular heat or special cold
- A place of a large number of dusts
- A place close to the magnetic field of electromagnetic devices

2.3 Power Requirements

- a.c.110V-220V
- 50/60Hz
- 150VA

2.4 Start Installation

2.4.1 Connect the instrument to the power supply

- 1) Plug one end of the power cable into the power outlet of the instrument.
- 2) Plug the other end of the power cable into an AC power outlet.

Warning:

•The AC power supply must be well grounded (zero ground voltage <5V).

•The AC power must be stable and it is prohibited to share power supply with the appliances of high power.

•When unplug the power cable, please seize the plug itself, rather than the power cable.

•If the instrument is found to have smoke, smell or abnormal sounds, immediately turn off the power, and contact the supplier.

2.4.2 External printer connection

This system supports most types of the USB interface printers and parallel interface printers. Please connect the printer to the PC host which is connected with the instrument referring to the user's manual of printer, and carry out the installation.

- 2.4.3 Connecting the instrument with the computer
- 1) Turn of the power of the instrument and computer.
- 2) Connect both ends of the serial cable to the RS232 serial ports of the instrument and the

computer host respectively.

Note: After connecting the instrument and computer through the serial cable, turn on the instrument power, and then run the program in computer.

Chapter III System Login

3.1 Instrument serial number

If it is the first time to use the instrument or the serial number is blank, the system will ask the

user to enter the serial number on the rear part of the instrument correctly.

As shown in Figure 3-1:

Instrument serial ID					
	Please input the Serial ID backside the instrument rightly!				
	Serial ID:				
	OK Exit				

Figure 3-1 Instrument serial number

If the user has entered the serial number, the dialog box will not pop up in the next use.

Entering the serial number makes us provide maintenance services for users more quickly and fast.

3.2 User Log

After the users enter the serial number, the system will pop up a user login window. As shown in Figure 3-2:

User log	Life and Analytical Sciences
Name: Password:	<u> </u>
Ok	Exit

Figure 3-2 User Logon

Select the user's name from the list box, enter the password in the password box, and then click "Enter" button, if the user's name and password are correct, the system will enter into self-checking state, otherwise the system will prompt the user that the login is failure. Click "ESC" button to exit the system.

User's authority includes two kinds: administrator and normal user.

3.3 System Self-check

If the logon is correct, the system will enter into self-checking state, during the self-checking period, the system will detect whether the serial port is available automatically, if not available, the system will prompt the user to check whether the connection with the instrument is correct, if available, the system will execute the self-checking operation. Self-checking window is shown as Figure 3-3

System check self	
	-

Figure 3-3 System Self-check

After completing the self-check, the system will enter the main menu interface.

3.4 Logon Result

If the self-check of the system is successful and the logon is conducted by an administrator, all the functions in the main menu are available, if the logon is conducted by a normal user, some of the menu can not be operated, if the self-check of the system is failure, the user only can operate "Information management" and "View" menu, its interface is shown as Figure

3-4:

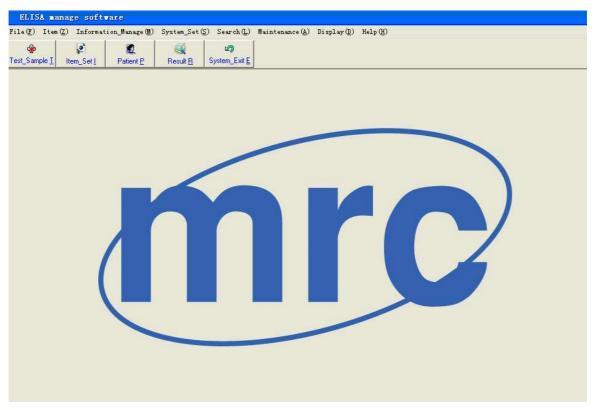


Figure 3-4 Main menu

Chapter IV Information Management

Information management includs four parts: patient information, user management, basic settings, and department management.

4.1 Patient Information

Including the patient's basic information input, form information input, inquiry, as well as deleting or adding the items conducted by the patient. As shown in Figure 4-1:

ELISA manage software - [Patient Information]						
File(F) Item(Z) Information_Manage(M) System_Set(S) Set	arch(L) Maintenance	(<u>A</u>) Display(<u>D</u>) He	Lp (H)			
Image: Section 1 Image: Section 2 Image: Section 2 <th 2<<="" image:="" section="" td=""><td>sit E</td><td></td><td></td><td></td><td></td></th>	<td>sit E</td> <td></td> <td></td> <td></td> <td></td>	sit E				
Patient basic information	Sample No.	Patient name	Sex	Test date		
Sample No. Name	5ample No.	Fatient hame	Jex	2010-4-28		
	002			2010-4-28		
	004			2010-4-28		
Diagnose Blood type						
Remark						
Identity card						
Sheet information	12				~	
Test doctor Send date 2010- 4-28 💌	1	-	3			
	Item name	Quantity	Quanlity	ABS		
Send doctor Test date 2010. 4-28 -	▶ 1 tp	0.0000 Error	Neg- Error	0.0000		
Auditing doctor	- · ·	End	Enor	1.0000		
Auditing doctor						
Search	p.				4	
Test date 2010- 4-28 💌 to 2010- 4-28 💌						
Sample No. Name						
Search (L)					~	
					>	
	Item information	1		-	-	
		1		l,		
Add (A) Save (S) Delete (D) Exit (E)	Add Item (T)	Delete Item (I)				

Figure 4-1 Patient Information

4.2 User management

Including adding users, deleting users, changing passwords and modifying the authority.

User authority is classfied as two kinds: administrator and normal user. Only the

administrator user has the authority to add users, delete users, and modify the authority.

Normal user only has the authority to change the password.

Adding the user interface is shown as Figure 4-2:

Add user		
Input user information		
	Name:	<u> </u>
	Code name:	
	Password:	
	Affirm passworc	
	User purview:	User
	OK (<u>O</u>)	Exit (E)

Figure 4-2 Adding user

4.3 Basic Settings

Include five parts: the hospital information, doctor information, division information, as well as ward information and diagnostic information.

In which, the doctor information is shown as Figure 4-3:

De	Doctor information								
T	est doctor	Send doct	or Auditing doctor						
_									
	Test	doctor	Shortout key	^	Doct	or name	333		1
	2	22	WXL						
	• 3	33	333		Shor	tout key:	333		
						Add (4	<u>A)</u>	Delete (D)	
				~		Save (<u>'S)</u>	Exit (<u>E</u>)	
Ĺ									

Figure 4-3 Doctor Information

Doctor information includes doctor of examination, doctor of submission, and doctor of check.

4.4 Department management

Include workload statistics and reagent information. Workload statistics is used by hospital to verify the doctor's work at a certain stage. Through the workload statistics, the number of the plates, items and patients conduceted by a doctor in a certain period can be inquired. The function of the workload statistics is shown as Figure 4-4:

Vorkload stat	Ē				
			The result of query		
Doctor name:	MRC	•	The number of test plate	s	
Start date:	2010- 4-28	•	The number of test items		
End date:	2010- 4-28	•	The number of test patie	nts	
			Item list of test	Patient of test	
_	Search (<u>L)</u> Preview(<u>P)</u> Exit (<u>E</u>)				

Figure 4-4 Workload statistics

Reagent information includes adding reagent, delecting reagent, as well as modifying reagent and other functions.

Reagent information				
Reagent_ID Reagent_Name	Batch	Manufacturer	Production_Date	Edit_Date
Reagent ID:	Bear	gent name:		
	_			
Batch:		ufacturer:		
Production date 2010- 4-28	E dit a	date: 2010- 4-28	T	
Add (A)	Delete	(<u>D</u>) Sa	ave (S)	Exit (<u>E)</u>

Figure 4-5 Reagent information

Chapter V Item Settings

In the main menu, click on the "Item_Set" under the "Item" or directly click on the "Item_Set" on the toolbar, then you can enter the Item Settings dialog box. As shown in Figure 5-1.

ELISA manage softwa	re of
File(F) Item(Z) Information	on Manage (M) System_Set (S) Search (L) Maintenance (A) Display (D) Help (H)
Test_Sample I Item_Set [Image: Constraint product of the state product of the s
Item name list ep12 ods 1 1 tp sl tp_tem	Item name: p1 Complete name: p1 Unit: U/L Sterver: 00000 Test method: End point Calculation method: ABS Double sample: No Number of standard. First wavelength 450 Second wavelength: None Double cutoff: No Double standard. Image: Second wavelength: None Image: Second wavelength: Standard information Number of standard. Image: Second wavelength: Standard Concondition Stand
	Add (A) 🛃 Save (S) 📉 Delete (D) 🔄 🛃 Exit (E)

Figure 5-1 Item settings

In this interface, you can add, modify, or delete items. The item properties mainly include basic item information, standard settings, quality control settings, and the options of validity formulas.

100 items are permitted to be set at the most. The user pre-set items will be displayed at the left list of the window.

5.1 Measurement methods

Measurement methods include end-point method, two-point method and kinetics method

5.2 5.2 Calculation methods

UT-6500 Microplate Reader supports various of different calculation methods, which can be divided into the following three categories.

5.2.1 Absorbance Mode

Directly measure and output the sample absorbance.

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

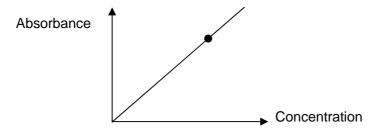
Where NC is the negative control absorbance value, PC is the positive control absorbance value, and CR is the threshold serum absorbance value. X, Y, Z, and Fac are the formula coefficients, which should be input by users according to the reagent instructions, at the same time all other forms of qualitative formulas can be transformed into this form. For example: when sample OD/negative control OD \geq 2.1, it is positive, then X = 2.1, Y=0, Z=0, Fac=0.

The calculation method of Cut-Off can choose single-threshold and double-threshold.

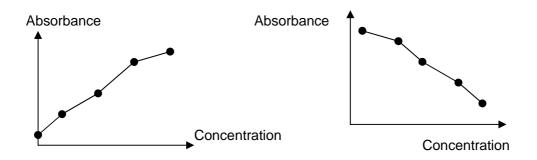
The results of qualitative calculation will be expressed by the ratio of the sample absorbance and the Cut-Off threshold, and the unit is s/co.

5.2.3 Quantitative Calculation

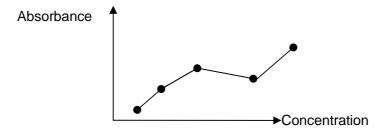
1). Single standard: It needs to set a standard, taking the connecting line between the origin point and the standard point as the calibration curve (The abscissa represents concentration, the ordinate represents the absorption, the same below), single-point calibration must set blank to calibrate 0 point.



2) Curve: Allow to set 2-8 standards, taking the connecting line between each standard point (It should be a non-linear of monotonic increase or decrease) as the calibration curve:

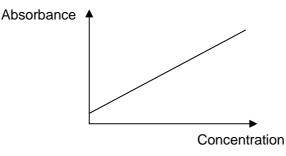


If the absorbance of the standard is not shown as monotonic increase or decrease, then the calibration result is wrong:



3) %ABS: Allow to set 2-8 standards, the maximum absorbance value of the standard is defined as 100%, the absorbances of other standards and the samples under test are all represents with the ratio percentage with it. The calibration method is the same with non-linear regression.

4) Linear regression: Allow to set 2-8 standards, through these standard points to regress out one line Y = kX + b, as the calibration curve:



5) Exponent regression: Allow to set 2-8 standards, through these standard points to regress out one exponential curve $Y = ke^{bX}$ as the regression calibration curve, and the absorbance value of each standard must be greater than 0.

If we take the logarithmic absorbance value (Y' = LnY), then the index regression can be transformed into one form of linear regression: Y' = k'X + b'

6) Ogarithmic regression: Allow to set 4-8 standards, through these standard points to regress out one logarithmic regression curve Y = kLnX + b as a calibration curve, the concentration value of the standard must be greater than 0.

If we take the logarithmic concentration value (X' = LnX), then the logarithmic regression can be transformed into one form of linear regression Y = kX' + b:

7) Power rgression: Allow to set 2-8 standards, through these standard points to regress out one power regression curve $Y = kX^{b}$ as the calibration curve, the absorbance values and the concentration values of all the standards must be greater than 0. If we take the logarithmic values of the concentrations and absorbances (X' = LnX, Y' = LnY), then the power regression can be transformed into one form of linear regression: Y' = k'X' + b'

8) Percentage logarithmic regression

Percentage logarithmic regression allows setting 4-8 standards, and the concentration of each standard must be greater than 1.

9) Four-parameter regression

Four-parameter regression allows to set 4-8 standards, you can input the corresponding concentration values according to the relavant reagent instructions, detect the absorbance value of the standard solution by instrument, and determine the regression curve with Gauss-Newton iteration method.

5.3 Basic item settings

As shown in Figure 5-1, the item settings include the following parameters: Item name: This part must not be empty, and pay attention to not repeat with the name already existed.

Manufacturer: you can choose from the list box according to the reagent used, can also be empty.

Wavelength: select from the list, notice that the dominant wavelength and the secondary wavelength can not be repeated.

- Measurement method: select from the list box.
- Calculation method: select from the list box.
- Double samples: If you choose double samples, when conducting plate layout, the adjacent wells will be automatically set as the repeated wells, and the system will take the average value of the absorbances of the two wells for calculating.
- Reference lower limit, upper limit: Mainly used as the reference range of the test results.
- Delay time, test time, and factor are mainly used for the Kinetics method settings.

Note: In accordance with the different types of calculation methods, the parameters of item settings may also be different.

1) The quantitative calculation - you must set the standard information for the item: Input according to reagent instruction:

• The number of the standards

Select 1-8 standards.

• Double standards

If you choose double-standards, when conducting plate layout, the adjacent well will be automatically set as the repeated well, and the system will take the average value of the absorbances of the two wells for calculating.

• Standard concentrations

Note that the order of the standard concentration must be monotone.

2) Qualitative calculation: Cut-Off formula settings window:

Input into the item settings dialog box according to the reagent instruction.

• Cut-Off formula factor

The qualitative formulas of various reagents may be expressed in different forms, such as S/N, (N-S)/N, etc., but they can be converted to the form of S/(X*N+Y*P+Z*C+Fac)totally. If you choose double-threshold, you can enter two Cut-Off formulas.

• Negative control, positive control, as well as the absorbance range of threshold serum

If the control absorbance exceeds the upper limit or the lower limit, the calculation should be conducted in line with the upper limit or lower limit respectively. For instance, there are some reagents require that if the negative control is less than 0.05, it should be calculated as 0.05, then the lower limit of the negative control should be set as 0.05.

• Control

It can be set discretionarily, but the control quantity of each test item can not exceed 12, and take the average value of all the control absorbances for calculating.

3) The positive and negative judgement settings

In this window, enter the critical values to determine negative and positive, under the absorbance mode, the critical value is the absorbance value; under the Cut-Off mode, the critical value is the ratio between the sample and the threshold; under the quantitative calculation mode, the critical value is the concentration value. The qualitative methods are divided into three categories:

• Positive threshold mode

Negative value < Negative critical value, Positive value≥Positive critical value, the area between the two parts is the gray area, the samples in this range is doubtful.

• Negative threshold mode

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

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

In quantitative mode, select "None"

4) Quality control settings

Quality control methods include ELISA (self value), ELISA (set value), and the immdiate method. ELISA method has four kinds of conditions to determine whether the quality control data is 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 the users to select from the formula library for each item.

Formula is the key point of the judgement of validity. The judgement of validity interface is shown as Figure 5-2.

Formula library					
Input formula of validity > = AND OR	NC1>0.005 NC1<0.08				
User can only put on hereinafter variable: NC1、NC2、NC3、NC4、NC5、NC6、NC7、NC8、NC9、NC10、NC11、NC12、NCv、NCx PC1、PC2、PC3、PC4、PC5、PC6、PC7、PC8、PC9、PC10、PC11、PC12、PCv、PCx CR1、CR2、CR3、CR4、CR5、CR6、CR7、CR8、CR9、CR10、CR11、CR12、CRv、CRx BK1、BK2、BK3、BK4、BK5、BK6、BK7、BK8、BK3、BK10、BK11、BK12、BKv、BKx Thereinto, NC express negtive control, PC express positive control, CR express CR, BK express blank;NCx express one negtive control at discretion,NCv express average of all negtive control,The other variables have same meaning.Can put on AND or OR,For example NC1>0.005ANDNC1<0.08 Add (A) Delete (D) Exit (E)					

Fugure 5-2 Formula library

Note: Users must enter a reasonable formula. Otherwise, the system will generate unnecessary warnings during the measurement process.

5.4 New item creation

Click the "Add" button to add new items. If the item quantity has already exceeded 100, it will not be able to create a new item, and the system will prompt "the item quantity is full". The operation of new item creation is the same with the steps to alter the old items, pay attention to that the name of the new items can not repeat the existing items. Otherwise, the system will warn "The item name is exist or some fields are invalid!".

Chapter VI Sample Test

Sample test interface is shown in Figure 6-1.

ELISA na	nage softw	are														
File(F) Item((Z) Informati	on_Manage (M)	Syste	m_Set(<u>S</u>) Sear	ch (L)	laintenanc	e (<u>A</u>) D	isplay(D)	Help (H	Ø					
Test_Sample I	₽ Item_Set <u>I</u>	Ratient <u>P</u>	Res		System_											
Test type: Item list: Program: The calculation	End point		•		PC] с Q с S с В с С	andard ank			C Dr C Lis	one blar ne blank st blank	C	Many blan Row blank Average li:	(
					1	2	3	4	5	6	7	8	9	10	11	12
				A												
Set plate paran Plate direction		C List	1	В												
Start No.: Start well:	1 A •	1 🖵		С												
End well:	H 📕	12 🔽 🖸	к	D												
				E												
-	Plate Inoforma	tion		F												
				G												
				н												
The item of the	current well: method of the cu	irrent well:														
Move Out	Reset	Delete Plate	D	Test		ABS(<u>0)</u>	Quant	ly (E)	Quality ()	0 s	lave (<u>5</u>)	ToE	koel	Preview (<u>P</u>	Ex	it (E)

Figure 6-1 Sample test interface

Sample test menu mainly includes the selections 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 Measurement methods and calculation methods

Measurement methods include end-point method, two-point method, and kinetics method. After selecting the measurement method, the appropriate calculation method can be selected from the list box, and then sample information can be set for the Microplate.

6.3 The settings and selections of the testing process

The testing process includes three parts, that is, creating a new template, deleting a template, and an established template created by user. After choose "New" to add a new template of the testing process for the item settings, select the newly created template, if the item has the temperature settings, the incubating position of the instrument will start to heat, when the temperature reaches the requirement, the test will be executed, if there is no temperature settings, directly select the test button to start the test.

After creating a new template, the system will enter the testing process settings interface, as shown in Figure 6-2.

rogram selected	Program Incubate	Hour: 0 Delay time Hour: 0 Delay: Minute: 0 Delay:
	C Delay	Second: 0
	C Mix	Mix set Mix time
	⊂ Test	Mix speed:
		Test type Image: Continue Co
Add Delete Amend		te continue
Program name:		
	Save p	rogram Exit

Figure 6-2

Select the appropriate steps and execute the corresponding settings, clink on "Add" to add a step, and then the newly added steps and the implementation order will be displayed in the left view. If need to delete or modify some steps, select the specific test step and clink on

"Delete" and "Amend" to complete the operation. At last, enter the template name and clink on "Save program", now, the test step settings is completed.

6.4 Layout parameters settings

Layout parameters include the following settings:

- Layout direction: row or list.
- Start No.
- Start well and End well

Input start sample number (1-999) and start well position (row number and list number), end well position (row number and list number), click "OK" button. All wells of the whole plate are set as samples according to current item. Sample number of start well is inputted start sample number and sample number of end well is inputted end sample number. Sample number of other well positions increase successively according to set plate direction. When 'Delete Plate' function is used, all items and wells that have been set will be cleared. If want to set standard or control, please operate after deleting all.

6.5 Select test items

As for UT-6500 Microplate Reader, the same plate only can be set one test item.

6.6 Layout

UT-6500 Microplate Reader allows the user to set the well-position discretionarily within the plate of 96-well. At the top of the window is the "Set sample type" switch, the users need to select the well-type firstly, and then click on the well-pisition.

The mark symbol of the well-position:

- Sample: 1-999
- Blank: BK1 BK12
- Negative control: NC1 NC12
- Positive control: PC1 PC12
- Threshold serum: CR1 CR12
- Standard: SD1-SD8
- Quality Control: QC

6.6.1 Sample

When the user clicks on the well-position to be set as the sample, the sample number will

increase orderly from 1 and display at the well-position automatically. If you want to modify the sample number, just double-click the well-position:

Re-enter the sample number in the pop-up window, if the sample number already exists, the system will prompt that "The same No. is exist!", the modification is invalid. The allowable sample number for UT-6500 Microplate Reader is 1-999.

6.6.2 Blank

Blank well is used to conduct absorbance zero setting in the item test, that is, all the absorbances of other wells need to subtract the absorbance value of the blank well. According to the requirements of different test items, the user may choose whether to set a blank or not.

Blank methods include None blank, One blank, Many blank, List blank, Row blank ,Average list blank, and Average row blank. In which, If the user selects the "Row blank" or "Average row blank". just click the row mark at the left of the simulative microplate. If the user selects the "List blank" or "Average list blank", just click the list mark on the upper of the simulative microplate.

Saving and application of old blanks the test results of the blank well will be saved automatically, if you do not re-set the blank of the same item in the following test, the system will use the old blank to calculate automatically.

6.6.3 Negative control

Be effective only in the item that calculation method is Cut-Off. According to 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.

During the item-testing period, the absorbance of the control well and the corresponding calculation results of Cut-Off value will be saved automatically, as for the same item in the following test, if you do not reset the control, the system will use the old Cut-Off value to calibrate.

6.6.4 Positive control

It is similar with the negative control settings.

34

6.6.5 Threshold serum

It is similar with the negative control settings.

6.6.6 Standards

It will be valid when the item settings need to calibrate the standards. If the old standards for the item already exists, the user may choose not to set the standards (using the old standards for calibration), or reset all the standards, but it is not allowed to only set part of the standards. When the user clicks the standard wells in turn, the system will also mark it as SD1, SD2 ... in turn.

After completing the settings of the standards, if the user clicks again, the system will prompt "The number of standards is full". If the user begins to test or add a new item when the standard settings are not completed, the system will prompt "The number of standards is enough".

6.6.7 Quality Control

The number of quality control substance is not limited.

6.6.8 Clear

If you need to modify the pre-set well-position, press the clear switch, after clicking clear switch, user can clear all set well position of current item, and then re-set as required.

6.7 Clear the whole plate

Remove all the pre-set items and the wells.

6.8 Measurement

Click "Test" button, the system will pop-up a dialog box of Measurment.

Press stop button to cancel the current test. "Move Out" and "Reset" buttons can control the microplate moves out and reset respectively. During the testing period, the two buttons are unavailable.

6.9 Absorbance display

When completing the plate running test, the system will display the absorbance automatically. In some special case, users may need to modify the absorbance value of the sample or the standard measured by the experiment, and you can double-click the well-position to be modified:

Just re-enter the absorbance value into the pop-up window. During the calibration period, if the calibration has an error, the system may prompt "Item xxx calibration has an error." The possible reasons include: the absorbance is 0 or negative value, the linear regression has an error, as well as the absorbance-concentration curve of the standards is not monotonic, and so on.

6.10 Quantitative results display

Click on "Quantity" to display the values of the quantitative results.

6.11 Qualitative result display

Click on "Quality" to display the values of the qualitative results, if the test item does not need the qualitative results, it will only display the sample number.

6.12 Print

Click "Preview" button, all the plate results of the current test (including the well-position, test item, sample number, absorbance, quantitative results, and qualitative results) will be printed based on the layout format and the sub-items.

Note: Before printing the results, should save the results firstly.

6.13 Save

Click "Save" to save the test results of the present plate into the database for future observation.

Chapter VII Result View

Result View includes test results, quality control information, calibration curves and the system log.

7.1 Test results

Experiment results are the primary information of this system, while 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:

	Samp	ole ID	Name	Sex	Age	Bed No.	Section	Check doctor	Test date	Ú
🗂 Today) 00							Rayto	2010-4-28	
🔿 In one week	00							Rayto	2010-4-28	
Choice time Search (L)	00)4						Rayto	2010-4-28	
Choice condition										
Start time: 2010-04-28 💌										
End time: 2010-04-28 💌										
Sample No:										
Name										
Choice format										
💽 Two in sequence 🕥 A4 print										
		e		ult Quantity	Result Quality name	•	ABS			-
C Three in sequence C B5 print	i it	em name	nes							
C Three in sequence C B5 print		em name 1		0.0000	Neg	0	0.0000			
C Three in sequence C B5 print C Stylus printer C Dynamic print				0.0000 Error	Neg- Error					
C Three in sequence C B5 print Stylus printer C Dynamic print Report type		1					0.0000			
C Three in sequence C B5 print		1					0.0000			
C Three in sequence C B5 print Stylus printer C Dynamic print Report type		1					0.0000			
 C Three in sequence ○ B5 print Stylus printer ○ Dynamic print Report type Quality+quantity1 ○ Quantity Quality+quantity2 ○ Quality 1 		1					0.0000			
Three in sequence B5 print Stylus printer Dynamic print Peport type Quality+quantity1 Quantity		1					0.0000			
 C Three in sequence ○ B5 print Stylus printer ○ Dynamic print Report type Quality+quantity1 ○ Quantity Quality+quantity2 ○ Quality 1 		1					0.0000			
 C Three in sequence ○ B5 print Stylus printer ○ Dynamic print Report type Quality+quantity1 ○ Quantity Quality+quantity2 ○ Quality 1 		1					0.0000			
C Three in sequence C B5 print Stylus printer C Dynamic print Report type Quality+quantity1 C Quantity Quality+quantity2 C Quality 1 H-Quality+quantityC Quality 2		1					0.0000			
C Three in sequence C B5 print Stylus printer C Dynamic print Report type Quality+quantity1 C Quantity Quality+quantity2 C Quality 1 H-Quality+quantityC Quality 2		1					0.0000			

Figure 7-1 Test results

The window includes four parts, "Report by plate", "Report by item", "Report by patient" and "Report by collection". The frontal 3 parts of results can be inquired or printed based on the current day, within one week, or other optional time completely.

7.2 Quality control information

Include the results inquiry for a certain batch number of each item within a certain period. The quality control information includes the maximum, minimum, mean, SD and CV values of the quantitative and qualitative results within a certain period. The dialog box is shown as Figure 7-2:

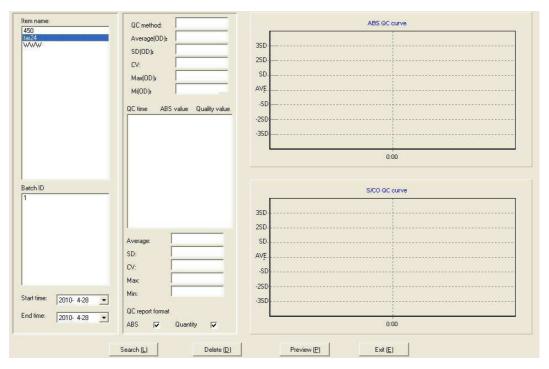


Figure 7-2 Quality control information

Select the item required in the Item Name list box, select the batch number in the Batch Number list box, and then select the desired inquiry time. Click "Search" button.

7.3 Calibration curve

The calibration curve is mainly used to check the calibration results of various items. The dialog box is shown as Figure 7-3:

ep1 ep12 cds fsa 1 if tp sl tp_tem	Standard curve
	0

Figure 7-3 Calibration curve

7.4 System Log

The system log mainly records the login user's name, login time, exit time and exit reason. Inquire the logon situation of the user within a certain period of time. The dialog box is shown as Figure 7-4:

ystem log				
Start date	2010- 4-28 💌	End date	2010- 4-28 💌	Search
	Delete (D)	Pre	view (<u>P)</u>	Exit (E)

Figure 7-4 System log

Chapter VIII System Settings

System settings include system time, system self-check, and error alarm.

8.1 System time

The system time is mainly used to view or modify the system time and date.

8.2 System self-check

As shown in Figure 8-1. The system self-check is mainly used to test the instrument parameters, such as the light intensity AD value of various wavelengths of the instrument, the ABS value and light intensity AD value of the selected wavelength.

System check self				
		Check self	Stop	
	None	ABS value	Stop	
	None	Optical AD value	Stop	
	Incubation com	ponent select: 🔽	Save	
<pre></pre>				
	Preview (<u>E</u>)	Exit (<u>E)</u>		

Figure 8-1 System self-check

8.3 Error alarm

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

ror alarm							
Start date:	2010- 4-28	• I	End date	2010- 4-28	×	Search	
Î I							
	Delete (D)		Previ	ew (P)		Exit (<u>E</u>)	
_							

Figure 8-2 Error Alarm

Chapter IX Data Management

9.1 Database Backup

Database backup is a simple backup of the entire database, the dialog box is shown as Figure 9-1.

Save as	
Destroyee and	
Destination path:	
Save (S)	Exit (E)

Figure 9-1 Database backup

9.2 Database recovery

Database recovery refers to recovering the previous backup database.

As shown in Figure 9-2.

Database resume			
Destination path:			
OK (<u>C</u>	<u></u>	Exit (<u>E</u>)	

Figure 9-2 Database Recovery

Chapter Instrument Maintenance

UT-6500 Microplate Reader is a sophisticated clinical analyzer, so in order to maintaining the instrument in a good condition, you must do the routine maintenance work well. The maintenance of UT-6500 Microplate Reader is very simple, but it must be conducted carefully.

Warning: The instrument maintenance must be executed by the professionals, when repairing or demolition of housing for other reasons must cut off the power and shutdown the mainframe.

10.1 Cleaning the instrument

- Keep the instrument working environment clean.
- Neutral detergent and wet cloth can be used to clean the surface of instruments.
- LCD display must be cleaned with a soft cloth.

Warning: Do not allow any solvents, fats and oils, or corrosive substances contact with the instrument.

10.2 Instrument part replacement

10.2.1 Fuse replacement

1) Turn off the power switch.

2) The fuse is installed in the fuse box which is located at the rear of the instrument and close to the power switch. Open the box cover, and then replace the fuse with the same specification.

Fuse specification: T3.15AL 250V.

3) Close the fuse cover, restart the machine.

Warning: Must use the fuse with above specification.

10.2.2 The replacement of the halogen tungsten lamp.

When the halogen tungstenlamp is damaged, execute the following steps to replace it:

- 1) Turn off the power switch, open the right lower cover of the instrument.
- 2) Gently press and open a flexible clasp when the lamp is not hot.
- 3) Remove the lamp from the holder, unplug the blub wire.
- 4) Connect the new bulb with the blub wire, and then put the new bulb into the holder.
- 5) Clamp the bulb with the elastic clasp.
- 6) Close the cover, restart the machine.

Phenomena	Reasons	Solutions
Microplate Reader	The power is not	Check power on or not
can not start up	normal	Check whether the power plug is loose
		Check the fuse
		Check the voltage
	The on-off interval	Shutdown for more than 30 seconds, and
	is too short	then restart
Bulb does not light	The bulb power is	Check the power before replacing the bulb
	not normal	
	The bulb is	Replace the bulb
	damaged	
The light is too	The filter is not	Check whether the filter and filter wheel is
strong	installed correctly	installed correctly
The light is too	The bulb is	
weak	damaged	Replace the bulb
weak	uamageu	
Filter wheel has no	The filter wheel has	Open the cover, and check whether the
reposition signal	a failure	positon of the sensor is correct
. op oom on orginal		
Microplate can not	Driving motor has a	Open the cover, and check whether the
move	failure	driving motor rotates.
Printer can not start	_	Check whether the power plug connection is
up	The printer power is	loose
	not normal	Check the ON/OFF button

10.3 Simple Troubleshooting

Printer can not print	Check whether the type of the printer is set correctly Check whether the printer cable is properly connected
Color fading, the overall printing quality declines	Replace the ink cartridge, clean the print head (see the printer user's manual)
Printer is jammed by paper	(See the printer user's manual)
Other printer faults	(See the printer user's manual)

Note:

1. If there is an error that you can't solve or an error recurred, please contact with the supplier.

2. As for the different version of the instrument, its configuration may be changed slightly, these changes are made under the premise of not affecting the performance and use of the instrument, please feel free to use it.

3. In order to keep the security of the user's data, we shield the remote service function of the instrument and take this function as optional.

4. If the accessory needs to be replaced, please contact with the manufacturer or provided by the agent.

Appendix: The names and the contents of the

toxic and hazardous substances or



elements in the product

1. The names and the contents of the toxic and hazardous substances or elements

	The toxic and hazardous substances or elements					
Part Name	Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Built-in circuit board	×	0	0	0	0	0
Shell	×	0	0	0	0	0
Display	×	0	0	0	0	0
Opto-electro nic components	×	0	0	0	0	0
Internal e-wire	0	0	0	0	0	0
Accessories	×	0	0	0	0	0

o: indicates that the contents of the toxic and harmful substances in all the homogeneous materials of the component are below the limited content prescribed by SJ/T11363-2006 standard.

x: indicates that the contents of the toxic and harmful substances in at least one of the homogeneous materials of the component exceed the limited content prescribed by SJ/T11363-2006 standard.

2. Label Description

Environmental protection service life label.



Label meanings: This electronic information product contains certain toxic and hazardous substances, and the environmental protection service life is 20 years, during the environmental protection service life, please feel free to use it, however, if beyond the environmental protection service life, please put it to the recycling system.