

CliChem 240

Auto Chemistry Analyzer

User's Manual



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How to Use This Manual

Thank you very much for becoming a user of CliChem 240 Auto-Chemistry Analyzer!

In order to get the optimal effects, you must become familiar with our instrument and its performance before using it to perform clinically-diagnostic tests.

This User Manual discusses operating instructions of BGT BioGenTechnologies GmbH **CliChem 240 Auto-Chemistry Analyzer**. Its contents include instrument installation, routine operations, maintenance and service, and etc.

If you have any questions, please contact your distributor. Please keep all the packaging for storage, shipping and to send-back reparation in the future.

Instruments with different versions or configurations have slightly different functions.

Due to version upgrading, the manual contents may slightly change without notice.

Note

Hints, counsels and suggestions. Write in italics to show a distinction.

Warning Warnings must be strictly complied, so as to ensure the normal functioning of instrument as well as the validity and truth of the test results. Write in bold to show a distinction.

Statement

BGT BioGenTechnologies GmbH owns the final interpretation right of this manual.

The illustrations provided in this manual can only be used as examples, and they may be not fully accordant to the actual product. Therefore, please take the actual product as the standard. The illustrations should not be used for other purposes.

Without BGT BioGenTechnologies's written permission, any person or organization cannot reproduce, revise or translate the contents of this manual.

BGT BioGenTechnologies GmbH is responsible for product safety, reliability and performance if all the following requirements are met, i.e.:

- Assembly, re-debugging, expansion, modification and reparation should all be performed by personnel of BGT BioGenTechnologies's approval;
- Product operations are performed according to this manual;
- Relevant electric devices accord with national standards.

Note

- This instrument must be used by laboratory-medicine professionals, or trained doctors, nurses or laboratory technicians.

Warning

- If the user fails to perform the maintenance/service scheme satisfactorily, abnormal instrument failure may occur and it may endanger physical health.
- Please ensure that the analyzer is used under the conditions prescribed in the manual. If beyond the conditions, the analyzer may not function well; in that case, the test results are not reliable, and it is also possible to damage instrument components and cause physical injuries.

Warnings and Safety Hints

This instrument is only used for in vitro diagnosis. Please read the following warnings carefully before use. The warnings must be strictly complied.

Warning: Please carefully read the following precautions before using this instrument.

- If abnormal odor or smoke occurs, cut off the power supply immediately and pull the power plug out of the power socket. At this time, present an inspection application to your distributor or an agent of our company. If continuing to use the instrument at this time, fire, electric shock, or personnel injuries or death may occur.
- Liquid should not drip into the instrument; metal objects, such as staples and pins, should not fall into the instrument either. Otherwise, it is likely to cause short circuit, or fire and smoke.
- Operators shall not contact the electronic circuit within the instrument; in particular, contacting the circuit with wet hands has a higher risk of electric shock.
- Rubber gloves must be worn, and prescribed tools and components should be used when servicing and inspecting the instrument. After work, please wash your hands with disinfectant solution. Otherwise, the skin contacting the liquid may be burned or infected.
- When treating samples, please be very careful and wear rubber gloves; otherwise, it is possible to cause infections. If the sample enters the eyes or wounds, rinse well with clean water immediately and visit a doctor for examination.
- Used instrument consumables and other waste should be considered as medical waste or infectious waste, and should be properly disposed of according to the related national regulations.

Power voltage, connection and grounding

- Do not insert the power plug into a non-220V AC power socket. Otherwise, it is possible to cause fire or electric shock.
- When installing the instrument, the three-core power cable accompanying the instrument must be used and the grounding must be good. Otherwise, it is possible to cause fire or electric shock.
- Do not damage the isolation protection cover of power cables. Do not strongly draw the power cable or hang heavy objects on it. Otherwise, it is possible to cause short circuit or broken circuit, thereby inducing electric shock or fire.
- Before connecting peripheral devices, power supply must be first cut off. Otherwise, it is possible to cause electric shock or failure.

The Drug Administration Law prescribes that it is prohibited to modify medical instruments.

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Chapter 1 Instrument Introduction

1.1 Product Introduction

1.1.1 Product Name: Auto-Chemistry Analyzer

1.1.2 Model: CliChem 240

1.1.3 Product Principle

CliChem 240 is an analyzer for clinical biochemical tests, which is researched and developed by photoelectricity, automation and computer technologies. The analyzer tests samples by the transmission of specific-turbidity testing method, and calculates sample concentration according to the Lambert-Beer Law.

1.1.4 Product Application Scope

It is used for routine clinical biochemical assays and other absorbance determination.

1.2 Product Structure and Composition

It mainly includes an optical part, mechanical motion part and computer control part.

1.2.1 Structure Graph

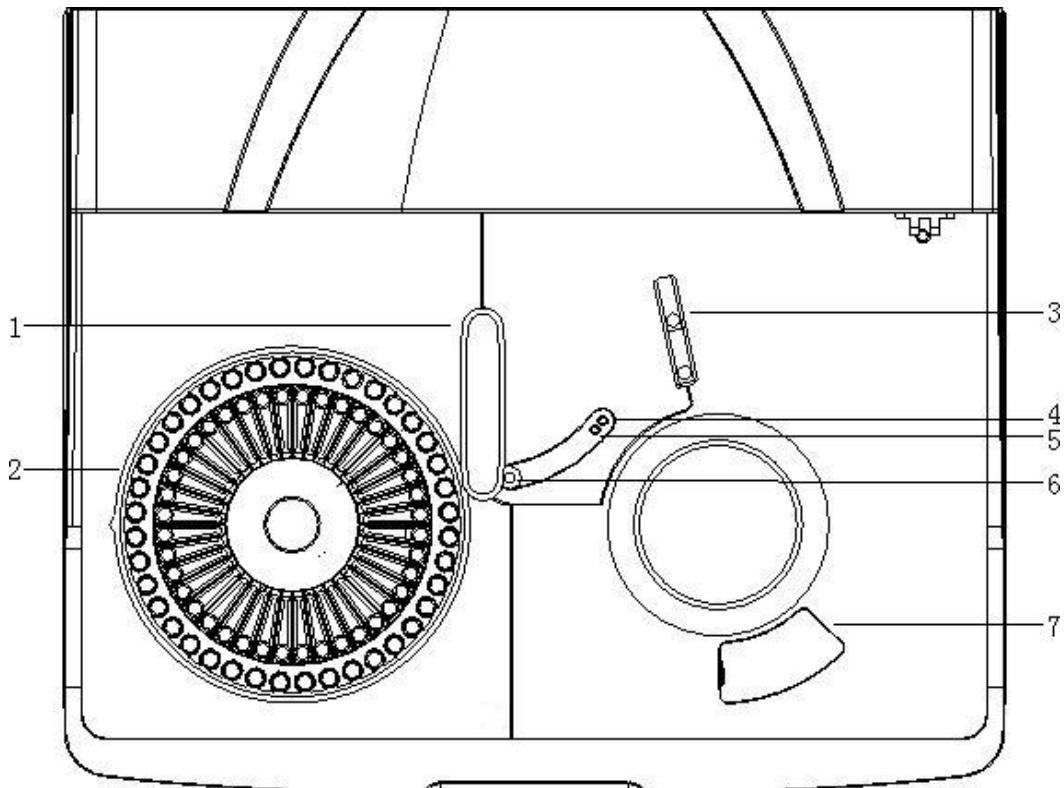


Figure 1-1 CliChem 240 vertical view

1 - Sampling needle

2 - Reagent/sample plate

3 - Mixing arm

4 - Pre-diluted sampling
position

5 - Sampling position

6 - Needle cleaning position

7 - Opening of reaction plate

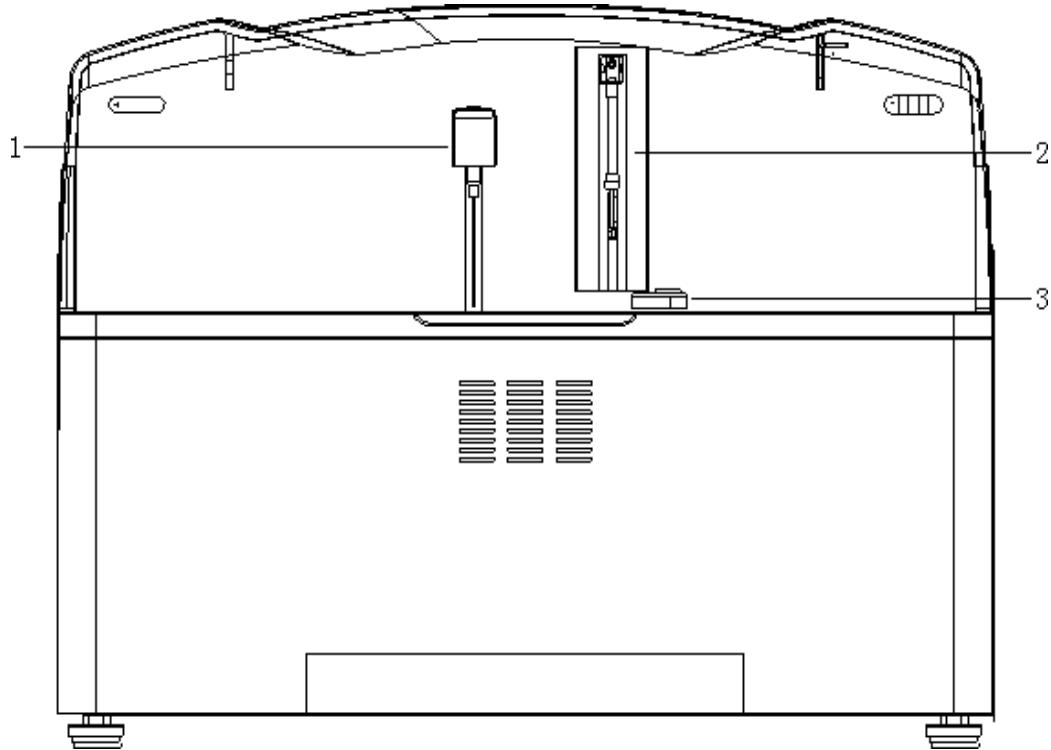


Figure 1-2 CliChem 240 front view

1 — Sampling needle 2 — Injector 3 — Mixing arm

1.2.2 Input and Output Interfaces on Analyzer Main-Part

1. RS-232: The series interface for analyzer main-part and computer communication;
2. AC INPUT;
3. Deionized water connection: Water inlet of the analysis part, the water supply tube entering the instrument from here;
4. Deionized water sensor: There is a liquid-level sensor in deionized water, leading out cables into the instrument;
5. Waste connection: Waster outlet, the waste tube leading out from here to the waste barrel;
6. Waste sensor: Waste liquid-level sensor leading out cables into the instrument;
7. Main-part reset button: Use for reset operations if the main-part abnormally goes down;
8. Grounding terminal: Protective grounding.

1.2.3 Computer interfaces

1. RS-232: The series interface for computer and analyzer main-part communications;
2. Network interface: The interface connecting inner and outer networks
3. Parallel interface: The interface connecting the computer and peripheral printer;
4. USB: The interface connecting computer and handheld bar-code scanner.

1.3 Instrumental Technical Parameters

Test method:	End-point method, Fixed-time method, Kinetic method.
Calculation method:	Factor, single-point standard, multiple-point standard, linear regression, non-linear regression etc.
Spectral mode:	8 pieces of optical filters (340, 405, 450, 510, 546, 578, 630, 670 nm)
Reagent position:	40 positions
Sample position:	40 positions
Light source:	12 V/20 W long-life halogen lamp
Stray light:	The absorbance should not be less than 4.0A.
Display:	LCD display
Printing:	Peripheral printer
Working conditions:	10°C~30 °C; relative humidity≤70%; without dew condensation; atmospheric pressure 86kPa~106kPa.
Storage conditions:	0°C~40 °C; relative humidity≤80%; stored in a well-ventilated room without corrosive gases.
Working power supply:	a.c.220V, 50Hz/60Hz
Power:	1500VA
Fuse:	T5.0AL250V, Φ5×20

Chapter 2 Installation and Calibration

2.1 Instrument Unsealing

Open the instrument packaging, remove shipping material and keep them appropriately stored, so as to repack the instrument in the future.

Take out the instrument from the box. Check if articles in the packing box correspond to those on the packing list.

Note: If any component is damaged or inconsistent with the packing list, please contact your distributor.

2.2 Instrument Installation

The CliChem 240 Auto-Chemistry Analyzer must be installed by specialized personnel. The instrument must be installed in a clean and dust-free room; oscillation, moisture, strong electromagnetic field and direct sunshine must be avoided. The requirements for the working environment are as follows:

temperature 10°C~30 °C, relative humidity≤70% (without dew condensation).

Its power supply must be a.c.220V, 50Hz/60Hz, and well-grounded. If the voltage variation > ±10%, it is recommended to install an external voltage stabilizer with the power of above 1500W. This analyzer is a precision instrument fully and automatically controlled by computer; therefore, an above-3000W UPS (uninterruptible power supply) must be configured.

Note:

- ***The AC power supply must be well-grounded (zero-ground voltage < 5V).***
 - ***The AC power supply must be stable. Do not share the power supply with high-powered electrical appliances.***
 - ***When pulling out the power cable, you must grab the plug itself, not the power cable.***
 - ***If there is smoke, peculiar smell or strange sound from the instrument, please turn off the power supply immediately and contact your distributor.***
-

Connecting control computer

- Connect mouse and keyboard to the corresponding interfaces at the back of the control computer.
- Insert one end of display cable into the signal interface of display, and the other end into the displaying interface at the back of control computer. Then, connect the display to AC power supply with power cable.
- Insert one end of print cable (parallel interface) into the signal interface of printer and lock up with wire thread; and then insert the other end of cable into the parallel printer port at the back of control computer. Then, connect the printer to AC power supply with the power cable accompanying with the printer.
- Connect the control computer to AC power supply with power cable.

Connecting instrument with control computer

Insert one end of series-interface cable into the series interface of instrument, and the other end into the series interface COM1 of control computer (or change the port setting to use the series interface COM2).

Connecting instrument to power supply

Connect the instrument to AC power supply with power cable.

2.3 Turning On/Off the Instrument

Turn on the Instrument

- Turn on the instrument power switch;
- Turn on the computer and start the instrument control software.

Turn off the Instrument

First, close the instrument control software; and then turn off the instrument power switch.

2.4 Instrument Calibration Requirements

Calibrators can be used for calibrating the instrument. It is not necessary to calibrate the instrument before each test; however, at least one calibration test should be performed for items needing to be calibrated. Changes of system environment may bring some influences on testing; therefore, it is recommended to perform a calibration test after each instrument start-up, so as to ensure the accuracy of test results.

Refer to “Chapter 6: Routine Testing” for calibration test methods.

Chapter 3 Login and Shutdown

3.1 Login

After start-up, run the CliChem 240 Software, and the system opens the user log-in interface (as illustrated in Figure 3-1):



Figure 3-1 Login

Select a user name and enter the password, and then press "OK" button to perform user login; otherwise, press "Cancel" to exit the software.

Note: The user name of system administrator is “Admin” and the initial password is “888888”. Users can freely change the password. Please remember once you have changed the password!

After login, the system automatically performs self-inspection and initialization. See the following figure:

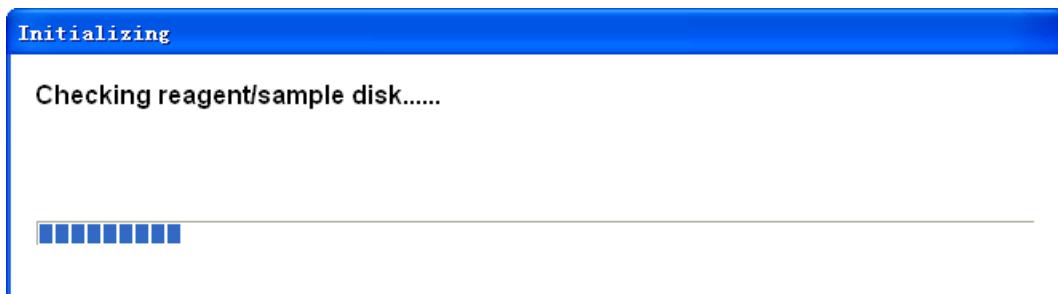


Figure 3-2 Initialization

Self-checking and initialization contains the following contents:

- Connecting the front end: Test if the communication of control software and intermediary-device software is normal.
- Module connection: Test if the statuses of all modules are normal.
- Parameter delivery: Read system parameters from the intermediary device.
- System resetting: Reset the whole system and perfuse the liquid line, so as to be ready for testing.

Note: If the system uses disposable cuvettes, please replace new cuvettes during each start-up.

After self-inspection and initialization, the system will wait for system light-source stabilization; at this time, the words "Lamp Stabilizing" will display on the left corner of the screen. After light-source stabilization, the word "Ready" will display on the left corner of the screen; only at this time can tests be performed. See the following figure:



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Figure 3-3 Main menu

Note: After each re-powering, it takes 30 minutes for light source to be stable. If tests are performed before light-source stabilization, the result accuracy will be affected.

3.2 Exit

Click “Exit” on the main menu to perform logout or exit operations. See Figure 3-4:

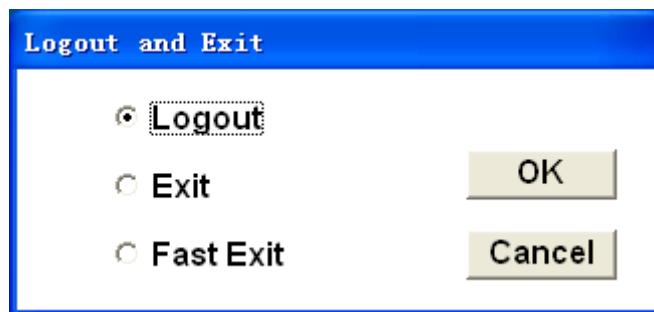


Figure 3-4 Logout and Exit

Select “Logout” to log out and log in again.

Select “Exit” to close the software system after system cleaning.

Select “Fast Exit” to directly close the software system without system cleaning.

Chapter 4 Parameter Setup

4.1 Test Parameter Setup

Function description: Setting test and control parameters of all test items.

Click “Parameter” on the main menu to open the Test Parameter Setup Page. See Figure 4-1:

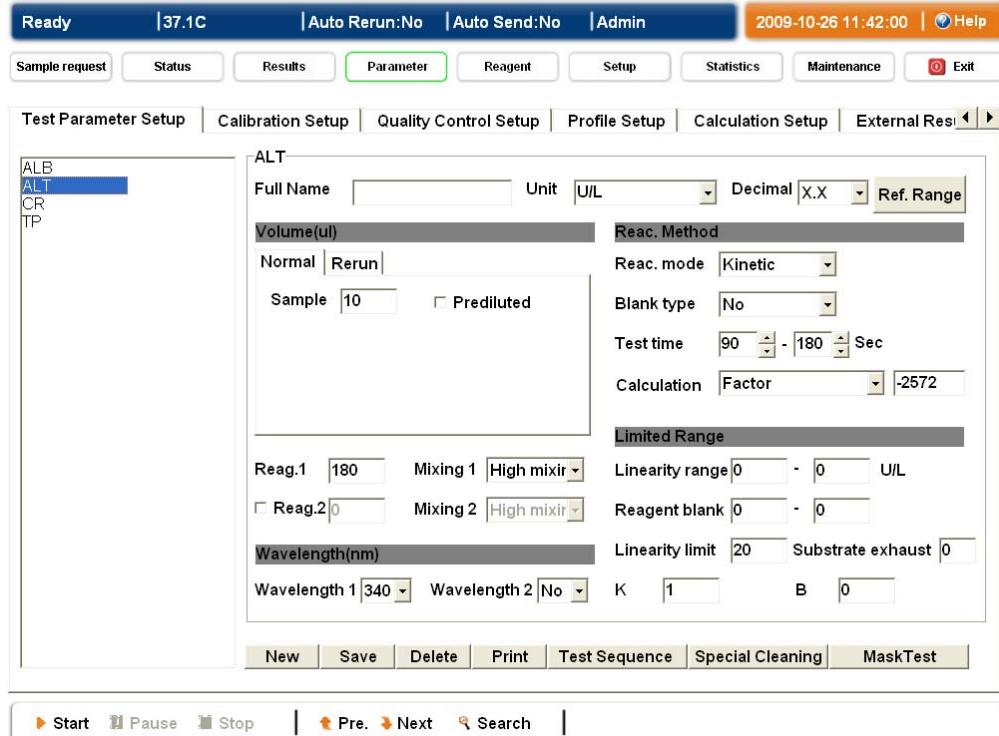


Figure 4-1 Test Parameter Setup

Add an item

Press “New” button and enter name of the new item; then enter all parameters of the new item one by one; after that, press “Save” button.

Modify an item

Select the item needed to modify from the list, and then its corresponding parameters will display on the right. Move the cursor to the parameters needed to modify one by one, and modify them; then press “Save” button.

Delete an item

Select the item needed to delete from the list, and then press “Delete” button.

Print item parameters

Select the item needed to print from the list; and then press “Print” button.

Item parameter description

- 1) **Full name:** Enter the full name or descriptive information of the item. It only appears in patient reports.
- 2) **Unit:** Enter or select the unit of item test result.
- 3) **Decimal:** Select the decimal point of item result for printing a summary report.
- 4) **Ref. range:** Designate the division standard of reference range and the corresponding values according to the reagent description. See Figure 4-2:

The screenshot shows a software interface titled 'Ref. Range' for the item 'ALB'. At the top, there are two checkboxes: 'By Age' (checked) and 'By Sex' (checked). Below these are three sections: 'Age' (with dropdown menus for < 3 Year, < 16 Year, < 35 Year, < 60 Year, and Above), 'Male' (with input fields for age ranges), and 'Female' (with input fields for age ranges). At the bottom right are 'Save' and 'Back' buttons.

Figure 4-2 Reference range

5) Volume

- Setting the sample volume for normal test: Enter sample volume; the applicable setup range is 3-45 µl and the precision is 0.1µl. If this item is needed to pre-dilute samples before test, check "Prediluted" option and enter the sample volume pre-diluted and diluent volume at one time in the box below the option. See the following figure:

The screenshot shows a software interface titled 'Volume(ul)'. It has tabs for 'Normal' (selected) and 'Rerun'. Under 'Normal', there is a 'Sample' field containing '10' and a 'Prediluted' checkbox which is unchecked.

Figure 4-3 Normal-test sample volume

- Setting the sample volume for rerun test: If the test result is beyond the linearity range, a rerun test can be performed. The designated sample volume should be re-pipetted according to higher or lower test results when rerunning test. Enter the sample volumes of higher retest and lower retest one by one. If it is necessary to pre-dilute sample before rerunning, check "Prediluted" option and enter the sample volume pre-diluted and diluent volume in the box below the option. See the following figure:

Volume(ul)

Normal	Rerun
Sample(Higher) <input type="text" value="3"/>	<input checked="" type="checkbox"/> Prediluted
Sample <input type="text" value="30"/>	Diluent <input type="text" value="270"/>
Sample(Lower) <input type="text" value="5"/>	

Figure 4-4 Second-test sample volume

- Reagent volume: The precision of reagent volume is 1 μ l. Enter the volume of Reagent 1 and select the mixing intensity after adding sample. For double-reagent testing, it is also to select “Reagent 2”, and then enter Reagent 2 and select the mixing intensity after adding sample.

Note: If the dilution ratio of patient sample is designated, all the tests of this patient sample should be pre-diluted according to the designated dilution ratio. Otherwise, tests should be performed according to the designated pre-dilution ratio in item setup parameters.

Note: Only the test result is beyond the instrumental linear range and performed an automatic or manual rerun, the test is performed according to the set “Rerun” volume. Otherwise, tests are performed according to the set “Normal” volume.

- 6) **Wavelength:** Set the wavelength required according to the reagent instructions. For single-wavelength tests, set only Wavelength 1 and select “None” for Wavelength 2. However, in order to eliminate external interference, it is recommended to use double-wavelength tests.
- 7) **Reac. mode:** Select “End Point”, “Fixed time” or “Kinetic”.
- 8) **Blank type:** Select “None”, “R.Blank”, “S.Blank”, “Pre-R.Blank” or “Pre-S.Blank”.
 - None: Meaning that it is not needed to subtract the blank value.
 - R.Blank: Meaning Reagent blank, the determination method is to test by converting the sample into distilled water according to the reagent and sample volumes during normal testing.
 - S.Blank: Meaning Sample blank, The determination method is to test by converting the reagent into distilled water or saline according to the reagent and sample volumes during normal testing.
 - Pre-R.Blank: Meaning that it is needed to subtract the absorbance of R1.
 - Pre-S.Blank: Meaning that it is needed to subtract the mixture's absorbance of R1 and sample .

Note:

- Using end-point method for reagent-blank test means subtract the absorbance of the reagent-blank test. Using fixed-time method and kinetic method for reagent-blank test means subtract the variation per minute of the reagent-blank test.
-

-
- **Only end-point method test can select “Pre-R.Blank”,and only end-point method for double-reagent test can select “Pre-S.Blank”.**
-

9) **Test time:** Set the measure beginning time and end time respectively. The measure time range for double-reagent items is 20-300 sec and that for single-reagent items is 20-600 sec.

Note: Generally, for tests using the end-point method, only one measure point is needed to designate; if multiple measure points are designated, the mean value of the multiple points is used as the calculation value. The measure time of fixed-time method cannot be less than 30 sec. In order to ensure the accuracy of test results obtained from speed method, it is recommended that the measure points should be less than six points, i.e., the measure time is longer than 90 sec. Moreover, for items using fixed-time method and kinetic method, set the measure time as long as possible.

- 10) **Calculation:** Select the corresponding calculation method according to actual requirements. If the "Factor" is selected, the factor values can be manually input.

Note: In speed method, the factor symbols of test items reflect the curve variation direction. For a downward reaction, the factor is a negative number; otherwise, it is a positive number.

- 11) **Linearity range:** It means the testable range of the instrument or reagents. If a test result is beyond the range, it is unreliable; in that case, a diluted retest or concentrated retest should be performed.
- 12) **Reagent blank:** It means the valid range of reagent blank. If the reagent blank is beyond this range, the system will treat the reagent as invalid. The unit is 1/10,000 absorbance.
- 13) **Linearity limit:** Only applicable to tests using speed method. The system automatically calculates the linearity during test period; if the linearity of reaction curve is beyond the set range, the result will be marked accordingly. The permissible setup range of linearity is 0-300 and the system default value is 20. The calculation formula of linearity limit is as follows:
- ◆ Test points > Nine points
Linearity = (Variation rate of the first six points - Variation rate of the last six points)/ Variation rate of all points
 - ◆ Four points ≤ Test points ≤ Eight points
Linearity = (Variation rate of the first three points - Variation rate of the last three points)/ Variation rate of all points
- 14) **Substrate exhaustion limit:** Only applicable to tests using two-point method and speed method. Some high-concentration (activity) samples exhaust the substrate, and the dynamic reaction cannot continuously proceed. In order to correctly reflect test results, it is needed to set the substrate exhaustion limit (at a specific absorbance). This absorbance limit should be just the critical point of median area and non-linear area (zero-grade dynamic method) in reaction curve, or the critical point of one-grade reaction area and multiple-grade reaction area (fixed-time method); it is the minimal (downwardness of reaction curve) or maximal (upwardness of reaction curve) absorbance value when the substrate is not exhausted during the reaction time period. The substrate exhaustion limit of an item closely correlates with the reagent kit used. The unit is 1/10,000 absorbance. The set value "0" means not judge.
- 15) **Corrective coefficient:** It is the linear corrective coefficient to system test results; result = measure value*K+B. Generally, it is not necessary to correct, and at this time, K=1, B=0. But for test items using factor method, this coefficient can be used to correct errors caused by the instrument.

Set test sequence

Press "Test Sequence" button to open a page, as illustrated in Figure 4-5:

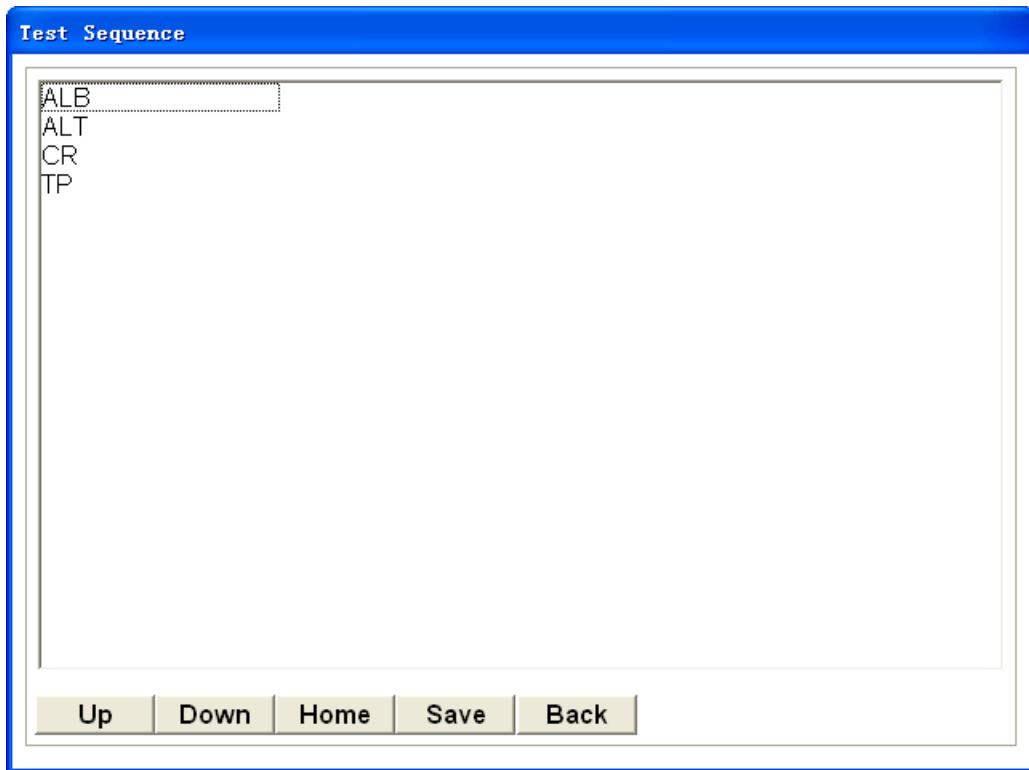


Figure 4-5 Test sequence setup

Select the item which test order is needed to adjust; and then press “Up” and “Down” buttons, or drag it with mouse to the proper position. After all items have been adjusted, press the “Save” button. In order to restore the default test order, press “Home” button and then press “Save” button.

Note: The default test order is according to the letter order of item names.

Set special cleaning

Press “Special Cleaning” button to open a page, as illustrated in Figure 4-6:

Contaminant test	Contaminated test	R1>R1	R1>R2	R2>R1	R2>R2
CR	*	RC	RC	40	40

Contaminant test: CR

Contaminated test: *

R1>R1: Routine cleaning Cleanser []

R1>R2: Routine cleaning Cleanser []

R2>R1: Routine cleaning Cleanser [40]

R2>R2: Routine cleaning Cleanser [40]

39:DILUENT 40:WATER

Save | Delete | Delete All | Back

Figure 4-6 Special cleaning setting

There is cross contamination in different reagents of some items, thereby affecting the test results. It is necessary to perform special cleaning to reduce or eliminate this effect. At this time, users can designate the system to perform a specific cleaning operation for the according case by the button “Special Cleaning”. For example, CR can contaminate other items; the sampling needle after sampling CR Reagent 2,

should be performed special cleaning with the liquid in Reagent Position 40 before sampling other reagents. At this time, set according to the figure above, and then press “Save” button.

To delete the set special cleaning item, select a set item from the list and press the “Delete” button. To delete all the set items, press “Delete All” button.

Note:

- “**” expresses all items.
 - If the special cleaning is not necessary between two reagents, select “Distilled water”; otherwise, select “Cleaning Solution”, and the position number of the special cleaning solution should be designated.
 - Performing special cleaning will consume the normal testing cycle and slow the instrumental testing speed. Therefore, please set special cleaning only if necessary!
-

Item mask setup

Press “Mask Test” button to open a page as illustrated in Figure 4-7:

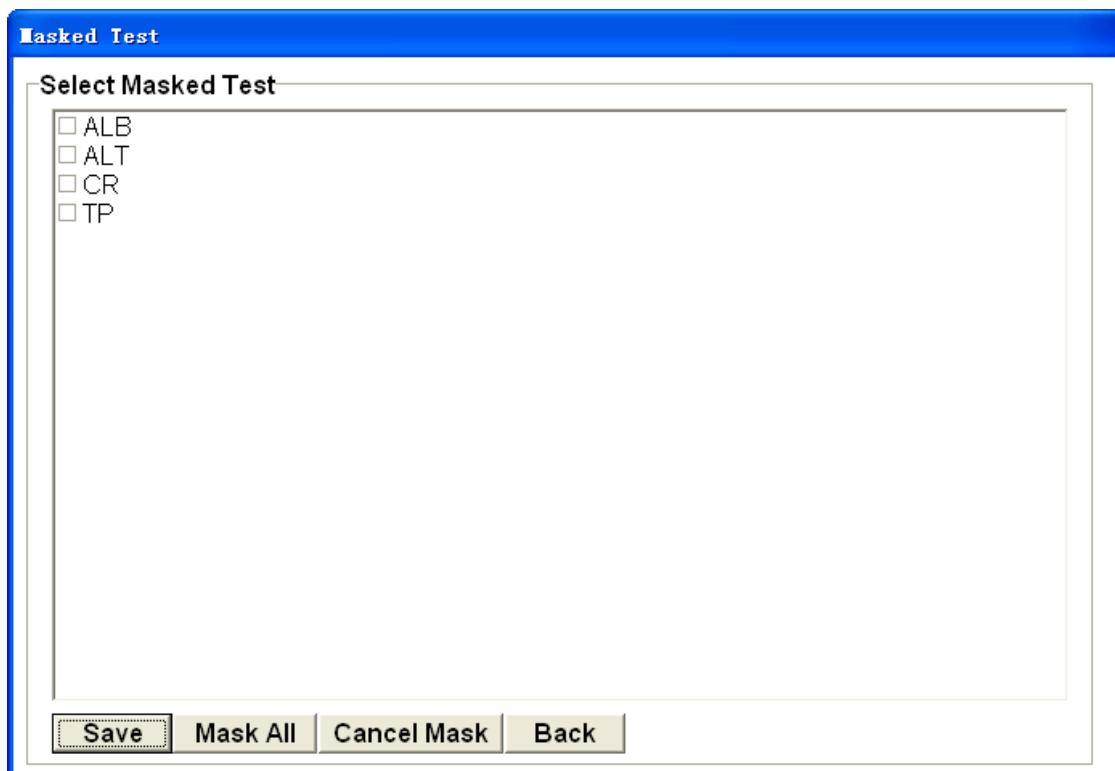


Figure 4-7 Item mask setup

Select the item needed to mask. And the system will automatically skip the item. Press the “Mask All” button to mask all items; press “Cancel Mask” button to cancel the item mask. Press “Save” button to save the modifications; otherwise, press the “Back” button not to save them.

4.2 Calibrator Setup

Function description: Set the parameters of calibrators used in the system.

Select “Calibration Setup” to open a page as illustrated in Figure 4-8:

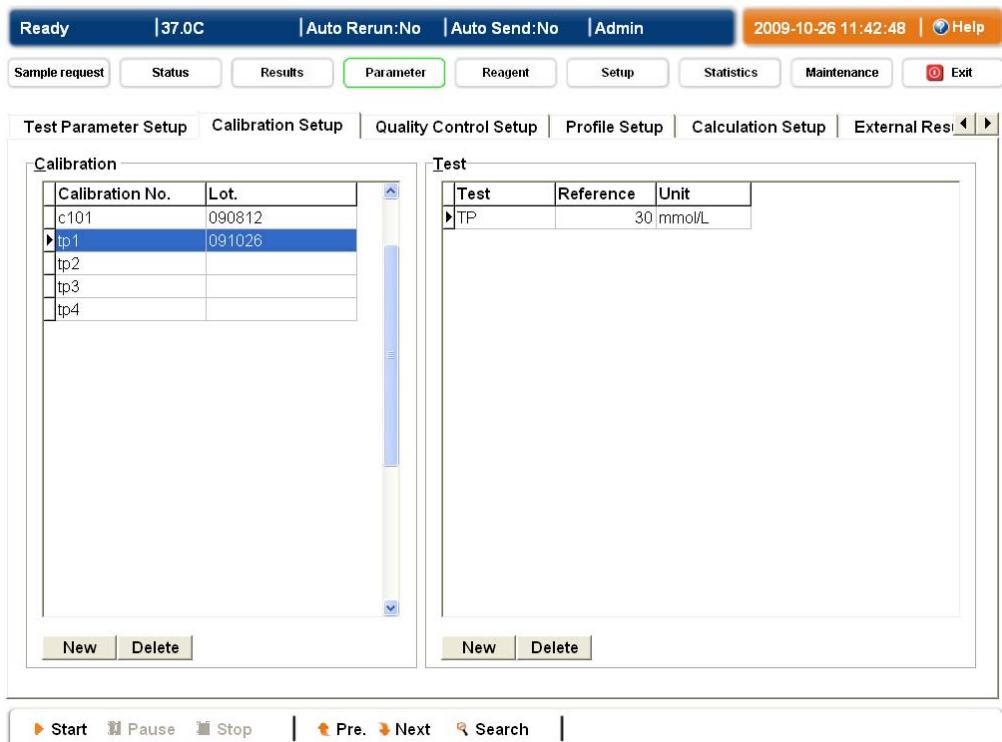


Figure 4-8 Calibration setup

Add a calibrator

Press “New” button under calibrator list, enter the calibration no. and lot. in the opened page, and click “OK” to save. Then, add all calibration items included in the calibrator one by one.

Delete a calibrator

Select the calibrator needed to delete from the calibrator list, and press “Delete” button under calibrator list.

Add or modify calibration items

Select a calibrator and then press “New” button under test list. Select calibration item needed to modify in the opened page, enter reference values, and then press the “Save” button.

Delete calibration items

Select a calibrator from the calibrator list, and its contained calibration items will be displayed in the left list. Select the calibration item needed to delete, and then press “Delete” button.

Note: If an existent calibrator is deleted, the corresponding calibration results of this calibrator will also be deleted at the same time. If an existent calibration item is edited or deleted, the corresponding calibration results of this calibration item will also be deleted at the same time.

4.3 QC Setup

Function description: Set the parameters of quality controls used in the system.

Select “Quality Control Setup” page, as illustrated in Figure 4-9:

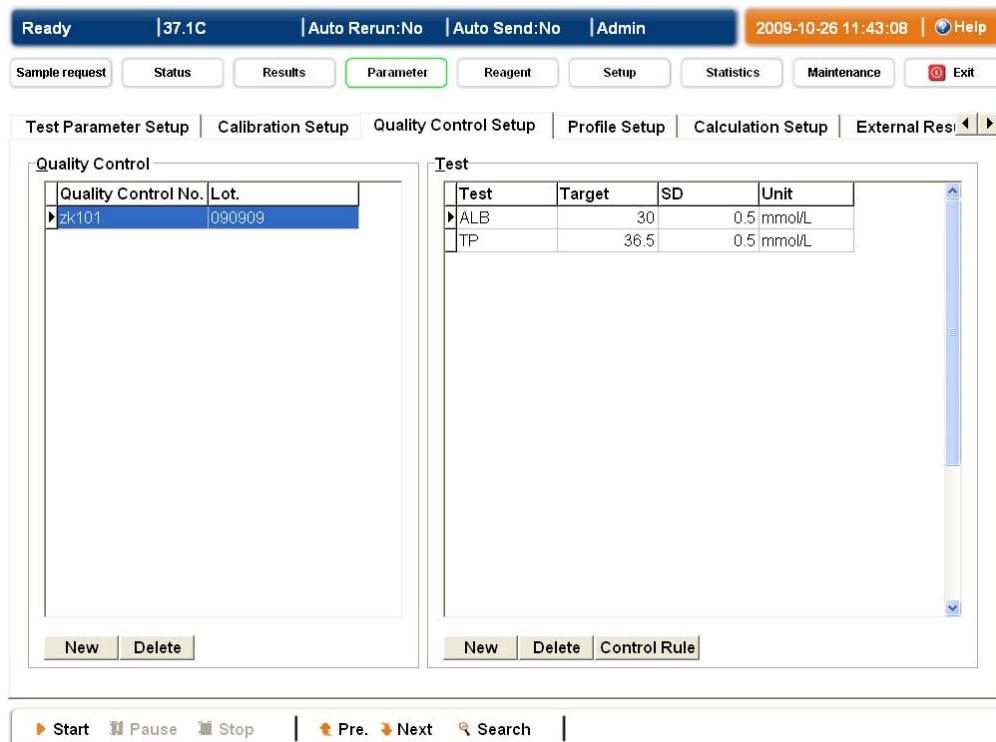


Figure 4-9 Quality control setup

Add a QC

Press “New” button, enter the control no. and lot. in the opened page, and click “OK” to save. Then, add the QC items contained in the quality control product one by one.

Delete a QC

Select the QC needed to delete from the QC list, and press “Delete” button.

Add or modify QC items

Select a QC and then press “New” button. Select the QC item needed to modify in the opened page, enter target value and SD, and then press the “Save” button.

Delete a QC item

Select a QC from the QC list and its contained QC items will be displayed on the left list. Select the QC item needed to delete, and then press “Delete Items” button.

Set QC rules

Select a QC from the QC list and its contained QC items will be displayed in the left list. Select the item needed to set QC rules, and then press “Control Rule” button to open a page as illustrated in the following figure:

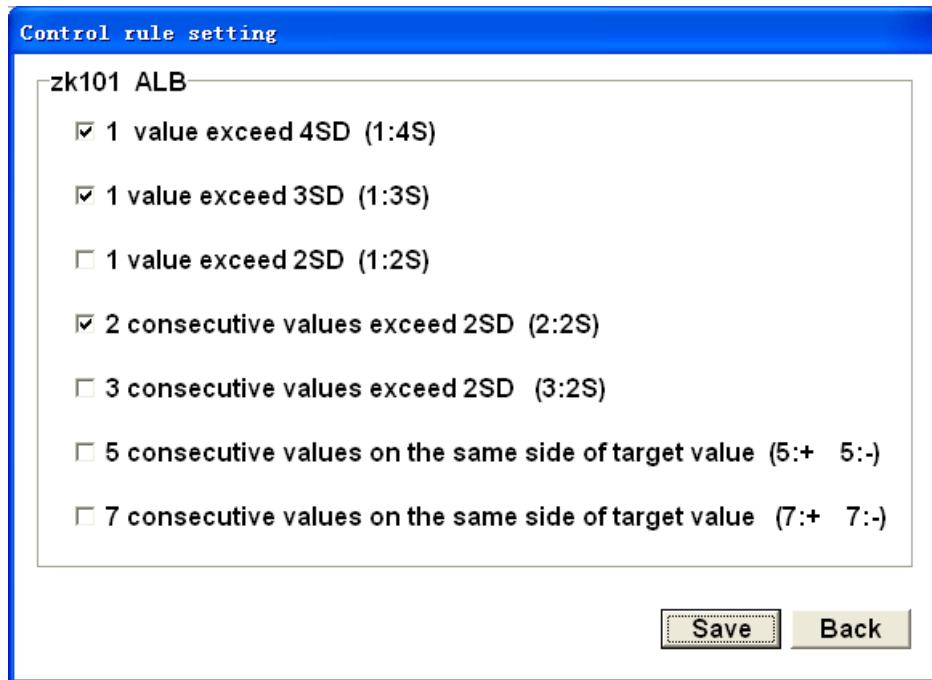


Figure 4-10 QC rule setup

Select a QC warning rule for this item from the seven rules, and then press “Save” button to save.

4.4 Profile Setup

Function description: Integrate multiple test items supporting a diagnosis into a set.

Select “Profile Setup” page, as illustrated in Figure 4-11:

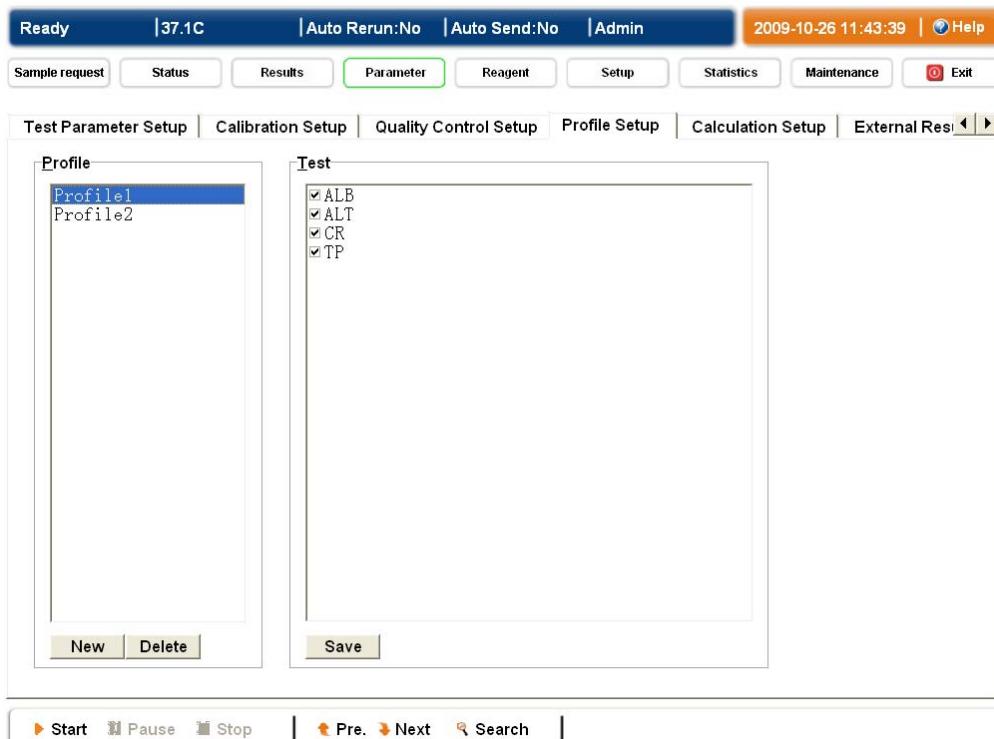


Figure 4-11 Integration setup

Add a profile

Press “New” button, enter the name of new profile, and then press “OK” button. Select the items contained in the profile, and then press “Save” button.

Modify a profile

Select the profile needed to modify from the profile list, modify the items contained in the profile, and then press “Save” button.

Delete a profile

Select the profile needed to delete from the profile list, and then press “Delete” button.

4.5 Calculation Setup

Function description: Set the items which results are obtained by calculating test items.

Select “Calculation Setup” page, as illustrated in Figure 4-12:

The screenshot shows the 'Calculation Setup' tab selected in a software interface. On the left, a table lists existing calculation items with columns for Test, Full Name, Unit, Decimal, and Formula. The first two rows show GLB and AST/ALT. A dropdown menu on the right lists additional items: ALB, ALT, AST, CR, and TP. At the bottom, there are fields for entering a new item's Test, Full Name, Unit, Decimal, and Formula, along with a note about input expression syntax. Navigation buttons like Start, Stop, and Search are at the bottom.

Test	Full Name	Unit	Decimal	Formula
GLB		mmol/L	x. xx	(TP) - {ALB}
AST/ALT			x. x	{AST} / {ALT}

Test: AST/ALT Full Name: Unit: Decimal: x.x
Formula: {AST}/{ALT}
Input expression including +, -, *, / and {Method}

Figure 4-12 Calculation setup

Add calculation items

Press “New” button; enter one by one the item name, full name, unit, decimal point and calculation formula of the new calculation item; and then press “Save” button. After that, enter the reference range of the new calculation item.

Modify calculation items

Select a calculation item from the list. Modify its full name, unit, decimal point and calculation formula. Then press “Save” button. Or modify the reference range of this item according to the “Reference Range”.

Delete calculation items

Select a calculation item from the list, and press “Delete” button.

Note: Calculation formulae can only be composed of +, -, *, /, (,), number and {item name}. Otherwise, the calculation formula is invalid.

4.6 External Result Setup

Function description: Before entering the external item results tested by other devices into this system, please first set external item parameters needed to enter.

Select “External Result Setup” page, as illustrated in Figure 4-13:

The screenshot shows a software interface for 'External Result Setup'. At the top, there's a menu bar with tabs: 'Ready' (highlighted), '37.1C', 'Auto Rerun:No', 'Auto Send:No', 'Admin', '2009-10-26 11:48:23', and 'Help'. Below the menu is a toolbar with buttons: 'Sample request', 'Status', 'Results', 'Parameter' (highlighted in green), 'Reagent', 'Setup', 'Statistics', 'Maintenance', and 'Exit'. A navigation bar at the top has tabs: 'Calibration Setup', 'Quality Control Setup', 'Profile Setup', 'Calculation Setup', and 'External Result Setup' (highlighted). The main area contains a table with columns: 'Test', 'Full Name', 'Quali./Quan.', 'Low', 'High', 'Unit', and 'Decimal'. The table lists items: WBC, RBC, PLT, and HbAsg. Below the table are input fields for 'Test' (text box), 'Full Name' (text box), 'Reference' (two text boxes separated by a dash), 'Unit' (dropdown), and 'Decimal' (dropdown). At the bottom are buttons: 'New', 'Save' (highlighted in blue), and 'Delete'. At the very bottom are control buttons: 'Start', 'Pause', 'Stop', 'Pre.', 'Next', 'Search', and a vertical scroll bar.

Figure 4-13 Setting non-biochemical items

Add external items

Press “New” button; enter one by one the item name, full name, qualitative or quantitative values, and reference values of the new non-biochemical item; and then press “Save” button.

Modify external items

Select the external item needed to modify from the list; edit its full name, qualitative or quantitative values, and reference values; and then press “Save” button.

Delete external items

Select the external item needed to delete from the list, and then press “Delete” button.

Chapter 5 System Setup

5.1 System Control Parameters

Function description: Including active sample disk, automatic rerun switch, automatic send switch, system temperature, and testing mode.

Click “Setup” in the main menu to open the system setup page, as illustrated in Figure 5-1:

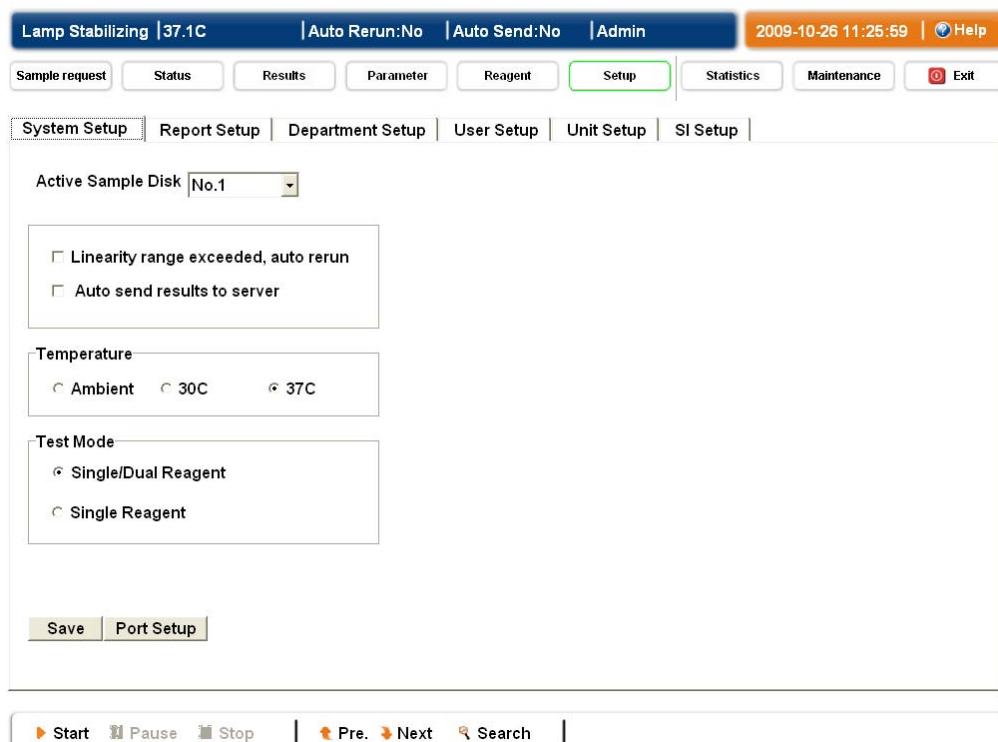


Figure 5-1 Setting system control parameters

Active sample disk

In total, the system has five worksheets and can be virtually divided into five sample disks. The system always tests “active disk”. Users can designate the disk needed to test by modifying active sample disk.

Setting control switch

- Selecting Option 1 means if the test result is beyond the linear range, the system will automatically retest the result after completing the normal-test.
- Selecting Option 2 means that the test result will send to the system-designated server in a real-time way. (The coordinated receiving software should be installed in the server.)

System temperature

Set the system target temperature.

Testing mode

- Single/Dual Reagent mode: Performing single-reagent and double-reagent constant-speed tests; single-reagent items and double-reagent items can be tested at the same time.
- Single Reagent mode: Only testing single-reagent items.

5.2 Print Setup

Function description: Set the title, annotations and print format of a summary report.

Select “Report Setup” tab to open a page as illustrated in Figure 5-2:

The screenshot shows a software interface for 'Lamp Stabilizing | 37.1C'. At the top, there are tabs for Sample request, Status, Results, Parameter, Reagent, **Setup** (highlighted in green), Statistics, Maintenance, and Exit. The date and time are shown as 2009-10-26 11:27:02. Below the tabs, a sub-menu has 'Report Setup' selected. The main area contains three input fields: 'Report format' set to 'A4-With Full Name', 'Report title' set to 'xx Hospital Report', and 'Report annotations' set to 'Note:xxxxxxxxxx'. At the bottom left are 'Save' and 'Print Sequence' buttons. At the bottom right are control buttons for Start, Pause, Stop, Pre., Next, and Search.

Figure 5-2 Print setup

Report format: Several report formats are available to select from.

Report title: Set the title of a patient's report, for example, Test Report of xxxxHospital.

Report annotations: Set the annotation information of a patient's report, for example, “Note: This test result is only responsible for this sample”.

Print sequence: Set the print order for items in a summary report.

5.3 Department Setup

Function description: Set the departments and doctors relevant to the patient information entry.

Select “Department Setup” tab to open a page as illustrated in Figure 5-3:

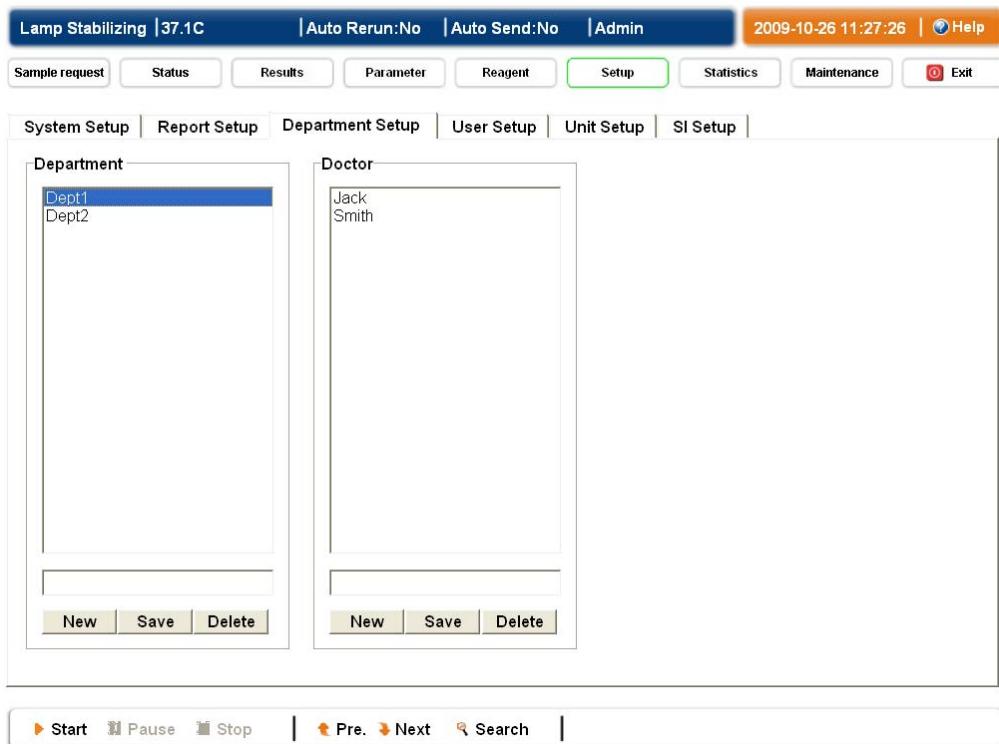


Figure 5-3 Department setup

Add a department

Press "New" button below the department list, enter the department name, and then press "Save" button.

Delete a department

Select the department needed to delete from the department list, and press "Delete" button.

Add a doctor

Select a department and all doctors in this department will be displayed in the doctor list. Below the doctor list, press "New" button, enter the doctor name, and press "Save" button.

Delete a doctor

Select a department and all doctors in this department will be displayed in the doctor list. Select the doctor needed to delete from the doctor list, and press the "Delete" button.

5.4 User Setup

Function description: Set a user's authority and password.

Select "User Setup" tab to open a page as illustrated in Figure 5-4:

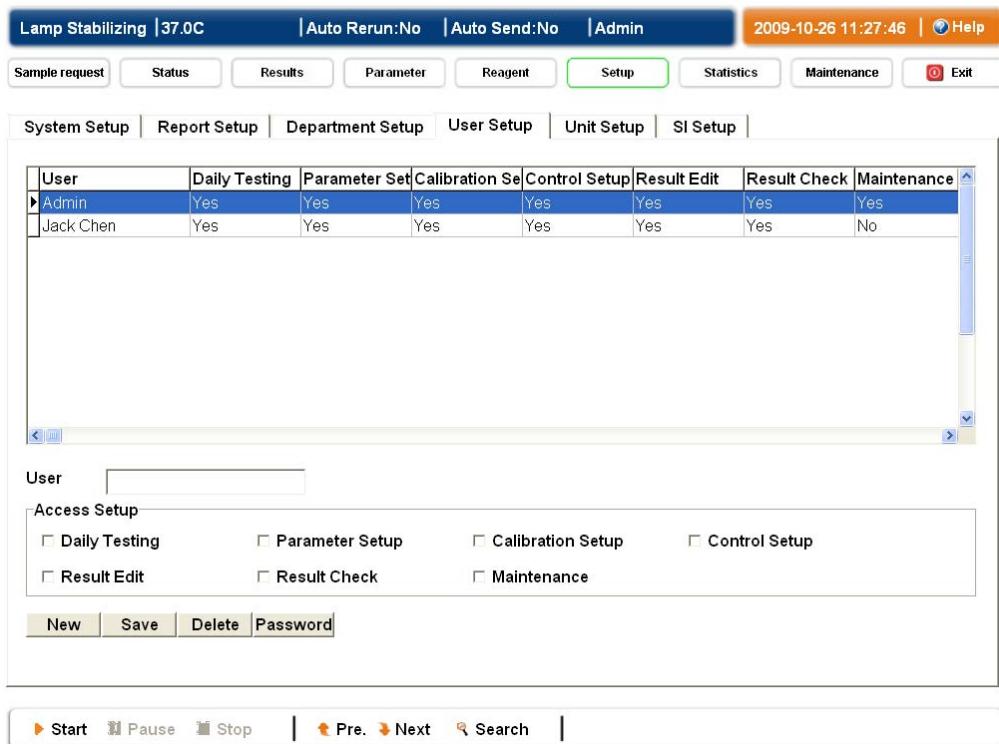


Figure 5-4 User setup

Add a user

Press “New” button and then enter the user name in the “User” entry box. Select to set the authority, and then press “Save” button.

Modify a user’s authority

Select a user from the list, select again the authority setup, and then press “Save” button.

Delete a user

Select a user from the list, and then press “Delete” button.

Note: Only the administrator (user name: “Admin”) can add and delete users, and modify a user’s authority.

Modify a password

Select a user from the list, and then press “Password” button to open a page as illustrated in Figure 5-6:

Revise password

User	Jack Chen
Password	*****
New Password	*****
Input Again	*****
<input type="button" value="Revise"/> <input type="button" value="Cancel"/>	

Figure 5-5 Password modification

Enter user password and new password; enter the new password again to confirm; and then press

“Revise” button.

5.5 Unit Setup

Function description: Set commonly-used units of the system, so as to select them from the list when setting item parameters.

Select “Unit Setup” tab to open a page as illustrated in the following figure:

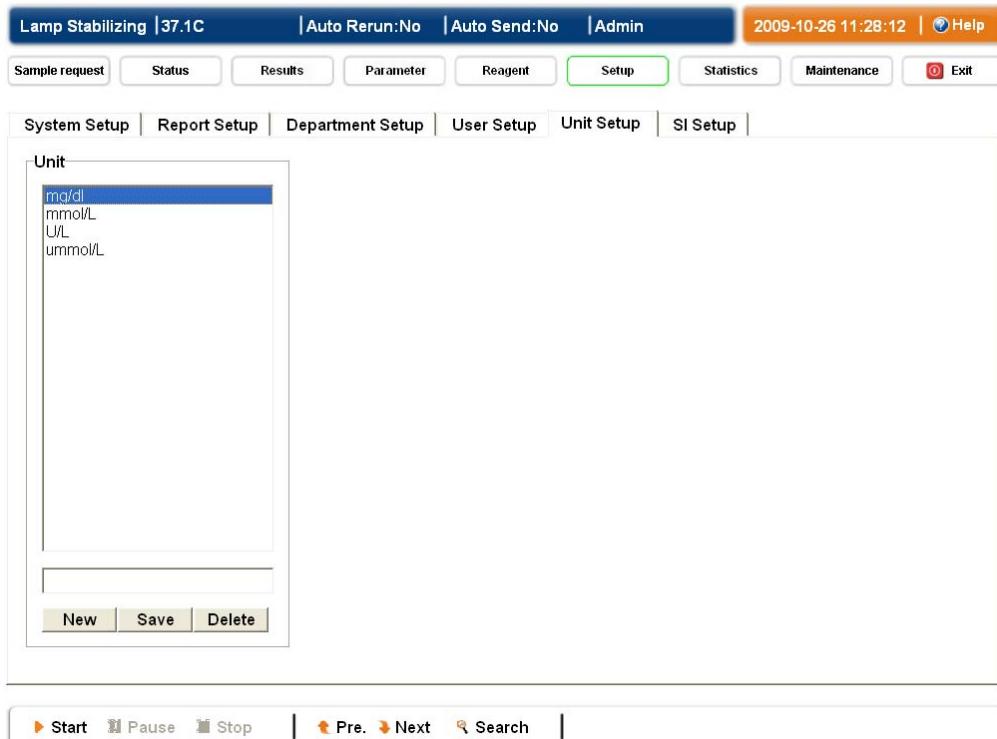


Figure 5-6 Unit setup

Unit list: Displaying all units defined by users;

Add a unit: Press “New” button, enter a unit in the entry box, and then press “Save” button;

Delete a unit: Select the unit needed to delete from the list, and press “Delete” button.

5.6 SI Setup

Function description: If testing turbidity, hemolysis or icterus of patients' samples, please first set the test and calculating parameters of sample information before test.

Select “SI Setup” tab to open a page as illustrated in Figure 5-2:

Figure 5-7 Setup of sample information testing

SI test parameters

When performing SI tests, dilute the sample according to the set dilution parameter, and then analyze the diluted sample to obtain the sample information. The test parameters include sample volume, reagent volume (diluent volume), and reagent position (diluent position).

Calculation parameters

The basic information of serum includes turbidity (L), hemolysis (H) and icterus (I). A, B, C, D, E and F are calculation parameters.

Markers

Set the correlation of information and markers in the report.

SI test switch

- Selecting “Turbidity Examination” means need to examine the turbidity of patients’ samples.
- Select “Hemolysis Examination” means need to examine the hemolysis of patients’ samples.
- Select “Icterus Examination” means need to examine the icterus of patients’ samples.

Note: If the system has selected any item of sample information examinations, the SI item tests will be automatically performed before testing the patient’s sample..

5.7 Reagent Setup

Function description: Designate reagent positions and other reagent information for test items.

Click “Reagent” in main menu to open the reagent setup page, as illustrated in Figure 5-8:

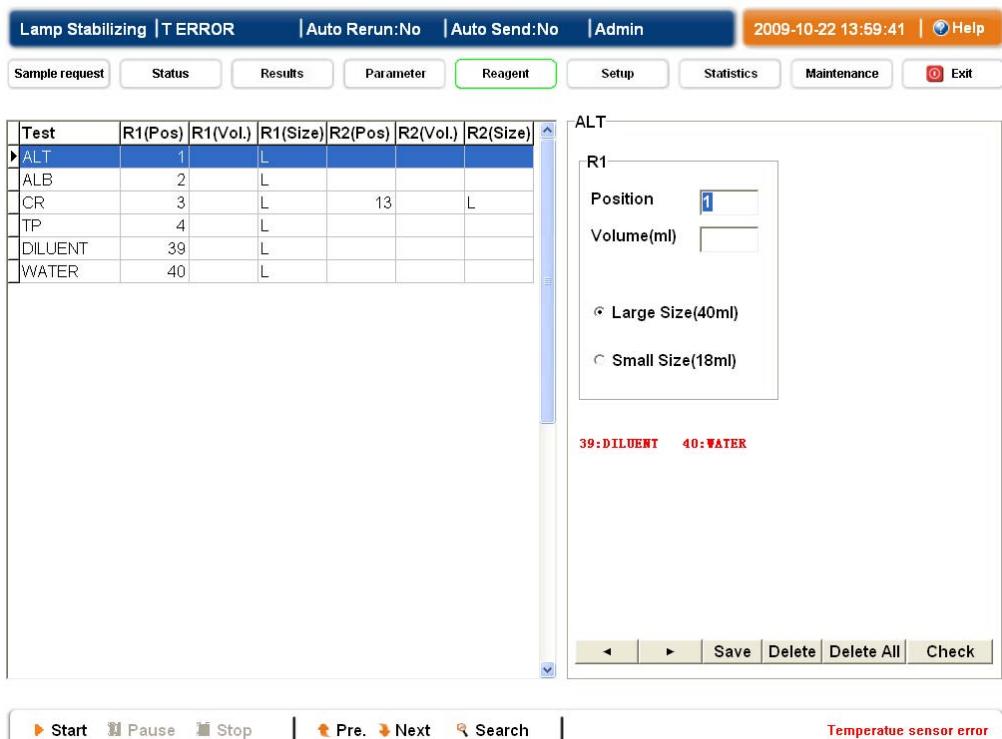


Figure 5-8 Reagent setup

Modify reagent information

Select an item; set the positions of Reagent 1 and Reagent 2, surplus (volume), and model of reagent bottle respectively; and then press “Save” button. (If the fixed bar-code scanning module is available, please set the corresponding reagent bar-code.)

Note: The Reagent Positions 39 and 40 are respectively used to place diluent and deionized water; other items cannot use them.

Delete reagent information

Select an item, and press “Delete” button to delete the reagent information of this item. Press “Delete All” button to delete the reagent information of all items.

Reagent checking

Press “Check” button, and the system begins to test the reagent surplus (volume) in the designated position.

Chapter 6 Routine Testing

6.1 Sample Request

Function description: Edit worksheets (sample disks) and set test items for samples.

Click “Sample request” in main menu to open the sample request page, as illustrated in Figure 6-1:

The screenshot shows the 'Sample request' interface. At the top, there's a header bar with 'Lamp Stabilizing | 37.0C', 'Auto Rerun:No', 'Auto Send:No', 'Admin', the date '2009-10-26 11:29:09', and a 'Help' button. Below the header are navigation tabs: 'Sample request' (highlighted in green), 'Status', 'Results', 'Parameter', 'Reagent', 'Setup', 'Statistics', 'Maintenance', and 'Exit'. A sub-header below the tabs says 'Sample Disk No.1 Active'. There are several input fields: 'Position' (set to 6), 'Repeat' (set to 1), 'Dilution ratio' (set to 'No'), and two radio buttons for 'Routine' or 'STAT'. A 'Patient Sample' section contains 'Sample No.' (0910261001) and 'Sample Type' (Serum). On the right, a 'Test' list includes ALB, ALT, CR, and TP, each with a checked checkbox. To the right of the test list are checkboxes for 'Profile1' and 'Profile2'. At the bottom, there are 'Batch Save' and 'Save' buttons, and a note: 'Input position, and press "Delete" (eg.1-5,8 * means all)'. Below this are control buttons: 'Start', 'Pause', 'Stop', 'Pre.', 'Next', 'Search', and a numeric input field containing '6'.

Figure 6-1 Sample request

6.1.1 Select a sample disk

The system provides five editable worksheets; in each worksheet, 40 test samples can be entered; in total, 200 test samples can be entered. Users can get five virtual sample disks from the five worksheets. The system only tests active sample disk; therefore, users can realize the test to designated disk by setting different disks as active sample disk. (Please refer to “Chapter 5: System Setup” for setting active sample disk.)

6.1.2 Sample Request

- **Edit single sample**

- Step 1: Designate “position”; (Input the sample position and press “Enter” button, then the stored information of the sample will be displayed.)
Step 2: Select repeat times and dilution ratio; (The default repeat times is “1” and dilution ratio is “None”.)
Step 3: Select sample type as “Routine” or “STAT”;

- Step 4: Input sample no. (Press “Edit” button to input the basic patient information of the entered sample);
- Step 5: Select test items and test profile;
- Step 6: Press “Save” button;
- Step 7: A sample request is completed.

- **Edit multiple sample in batch**

- Step 1: Select repeat times and dilution ratio; (The default repeat times is “1” and dilution ratio is “None”).
- Step 2: Input the initial sample no.;
- Step 3: Select test items and test profile;
- Step 4: Press “Batch Save” button to open a page as illustrated in Figure 6-2:



Figure 6-2 In-batch saving

- Step 5: Input the initial and end sample positions, and then press the “OK” button.
- Step 6: A batch sample request is completed.

Note: When using the “Batch Save”, the system will automatically generate sample no.; the generation rule is “date” + “sample disk number” + “sample position”, such as, 0906161001. After request, users can modify it manually. If small sample tubes are used, please select “Small Tube”.

6.1.3 Quality Control Request

Select “Quality Control Request” tab to open a page as illustrated in Figure 6-3:

Lamp Stabilizing |37.0C | Auto Rerun:No | Auto Send:No | Admin | 2009-10-26 11:29:41 | Help

Sample request Status Results Parameter Reagent Setup Statistics Maintenance Exit

Sample Disk No.1 Active

Sample Request Quality Control Request Calibration Request List Test

Position 5 Small Tube

Repeat 1

Quality Control

Control No. zk101

5 Delete Delete All Input position, and press "Delete" (eg.1-5,8 * means all)

Start Pause Stop | Pre. Next Search |

Figure 6-3 Quality control request

- Step 1: Designate “Position”.
- Step 2: Select repeat times.
- Step 3: Select control no. , and the QC items contained in the quality-control product will be displayed in the right list.
- Step 4: Select QC items from the list.
- Step 5: Press “Save” button.
- Step 6: A QC request is completed.

6.1.4 Calibration Request

Select “Calibration Request” tab to open a page as illustrated in Figure 6-4:

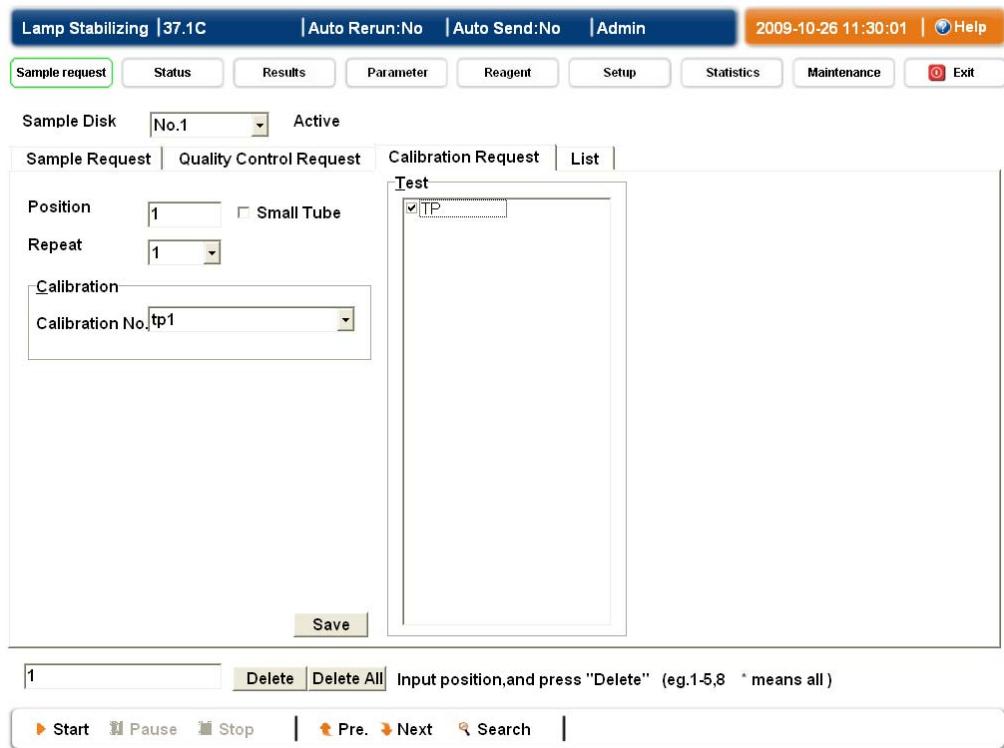


Figure 6-4 Calibration request

- Step 1: Designate “position”;
- Step 2: Select repeat times;
- Step 3: Select a calibration no. and the calibration items contained in the calibrator will be displayed in the right list;
- Step 4: Select calibration items from the list;
- Step 5: Press “Save” button;
- Step 6: A calibration request is completed.

List

Select “List” page, as illustrated in Figure 6-5:

The screenshot shows a software interface for 'Lamp Stabilizing | 137.0C'. The top menu bar includes 'Auto Rerun:No', 'Auto Send:No', 'Admin', '2009-10-26 11:30:21', and 'Help'. Below the menu is a toolbar with buttons for 'Sample request' (highlighted in green), 'Status', 'Results', 'Parameter', 'Reagent', 'Setup', 'Statistics', 'Maintenance', and 'Exit'. A dropdown menu 'Sample Disk' shows 'No.1 Active'. Below the toolbar is a navigation bar with tabs: 'Sample Request', 'Quality Control Request', 'Calibration Request', and 'List' (selected). A large table lists sample details:

Position	Small Tube	Sample No.	Test	Profile	Test Type	Repeat	Diluti
1	No	tp1	TP,		Cali.	1	No
2	No	tp2	TP,		Cali.	1	No
3	No	tp3	TP,		Cali.	1	No
4	No	tp4	TP,		Cali.	1	No
5	No	zk101	ALB,TP,		QC	1	No
6	No	0910261001	ALB,ALT,CR,TP,		Routine	1	No
7	No	0910261002	ALB,ALT,CR,TP,		Routine	1	No
8	No	0910261003	ALB,ALT,CR,TP,		Routine	1	No
9	No	0910261004	ALB,ALT,CR,TP,		Routine	1	No
10	No	0910261005	ALB,ALT,CR,TP,		Routine	1	No

At the bottom left is an input field with '1' and buttons for 'Delete' and 'Delete All'. To the right is a note: 'Input position, and press "Delete" (eg.1-5,8 * means all)'. Below the table are control buttons: 'Start', 'Pause', 'Stop', 'Pre.', 'Next', 'Search'.

Figure 6-5 List

The list displays all the applied sample tests, QC tests and calibration tests of the worksheet. It can be used check and confirm applied test contents in the worksheet.

Note: After users complete the entire sample request, please select “List” to review and confirm, so as to avoid errors or omissions!

Delete samples

Select the sample from the list, or enter the sample position needed to delete in the entry box at the left bottom of the page (entry format: such as 1, 3, 5-8, 12), and then press “Delete” button. Press “Delete all” button to delete all samples in the worksheet.

6.2 Sample Testing

Function description: Start to perform the applied tests in the current worksheet.

Press “Start” button at the bottom of the screen, and then a pop-up box (as illustrated in Figure 6-6) appears:

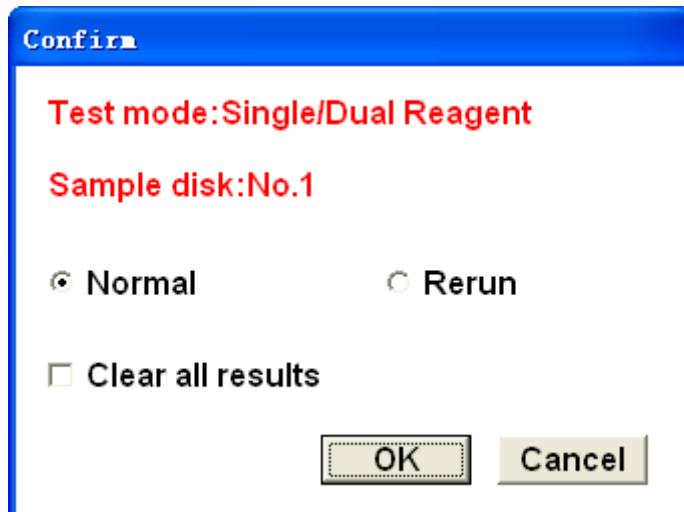


Figure 6-6 Worksheet confirmation

Test mode

It indicates the current selected test mode. Refer to the description in “5.1 System Control Parameters”.

Note: *The Single/Dual-Reagent mode can test both double-reagent items and single-reagent items; but the Single-Reagent mode can only test single-reagent items.*

Normal test

It indicates to perform the normal test to the uncompleted or retested tests in the current worksheet.

Rerun test

It indicates to perform a rerun test to the completed test with the result beyond the linearity range.

Clear all results

It means clear the results of completed tests in current worksheet, and restart all the tests.

Before confirming to start tests, please confirm the information above; if needing to modify, press “Cancel” button. Otherwise, press “OK” button and then the test sorting page appears, as illustrated in the following figure:

Test sorting (Normal)						
Position	Sample No.	Test	Repeat	Type	Status	Remark
1	c101	ALB	1	Cali.		
2	zk101	ALB	1	QC		
3	zk101	ALB	1	QC		
4	0909141001	ALB	1	Routine		
4	0909141001	ALT	1	Routine		
6	0909141002	CR	1	Routine		

Total:6

By Test | By Sample | OK | Cancel |

Figure 6-7 Test sorting

The system-default ordering method is the designated order according to “Test Sequence” (refer to “4.1 Test Parameter Setup”). If users need to readjust the order, press “By Test” button or “By Sample” button, or drag the tests in the list with mouse. After readjusting, press “OK” button to start tests; otherwise, press “Cancel” to abandon tests.

Note: The Column “Status” in the list indicates if a test is completed. If the test is completed, it displays “Completed”; otherwise, it displays none. The Column “Remark” indicates if the test is masked; if the test is masked, it displays “Masked”; otherwise, it displays none.

For the first test after startup or replacing cuvettes, the system will automatically test the cuvette blank before sampling. The possible test results are as follows:

Result 1: All cuvette blanks are valid and the system starts to test;

Result 2: Some cuvette blanks are invalid and the system reminds users to select if replacing the cuvettes. See the figure:

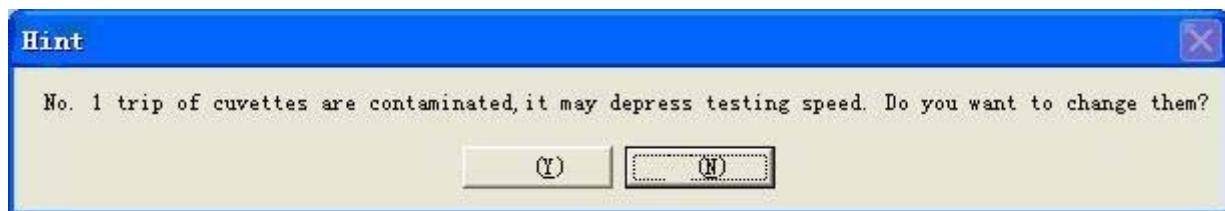


Figure 6-8 Reminding to replace cuvettes

Select “Yes” to cancel this test. After that, users can replace the cuvettes.

Select “No” to continue this test. And the system will automatically skip the cuvettes that cannot be used.

Result 3: If the cuvette blank energy is too low (all the cuvette blanks at 340 nm are lower than 30,000), the system will automatically display the following information:



Figure 6-9 Reminding of lower cuvette -blank energy

At this time, users should locate the trouble according to the reminder; for example, whether the gain setup is normal and clean cuvettes have been placed. If the trouble is caused by aging of light source, please contact product service personnel to replace the light source.

Note: If the system is equipped with the auto-cleaning module, cuvettes should be cleaned after startup and replacing cuvettes. Otherwise, the accuracy of test results will be affected. It takes about 20 minutes to clean all cuvettes.

6.3 Testing Status

Function description: View the test results and status of the current worksheet.

Click “Status” in main menu to open a page as illustrated in the following figure:

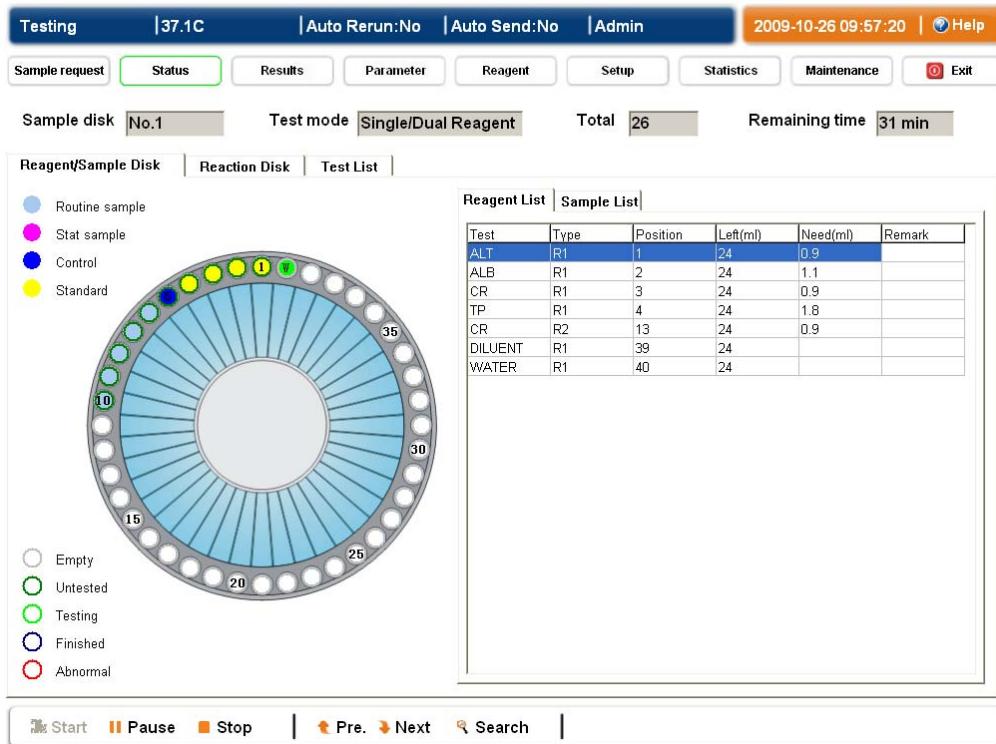


Figure 6-10 Testing status-reagent/sample disk

Sample Disk(Current worksheet)

It indicates the worksheet that the system is testing. The system has a total of five worksheets; but only the current worksheet can be tested. If needing to modify “active sample disk”, refer to “5.1 System Control Parameters”.

Total

Indicating the total test amount of “current worksheet”

Remaining time

Indicating the remainder time to finish the tests of “current worksheet”

Reagent/Sample Disk

- **View the testing status of designated sample:** Click “Sample List” page and select “Position” from the list, and all the corresponding tests will be displayed in the list. Select a test from the list, and press “Curve” button to view the corresponding reaction curve of the test, or press “Retest” for retesting request .
- **View reagent status:** Click “Reagent List” page and the reagent information designed in the worksheet will be displayed in list.

Reaction Disk

Click the “Reaction Disk” tab in the main menu to open a page as illustrated in the figure:

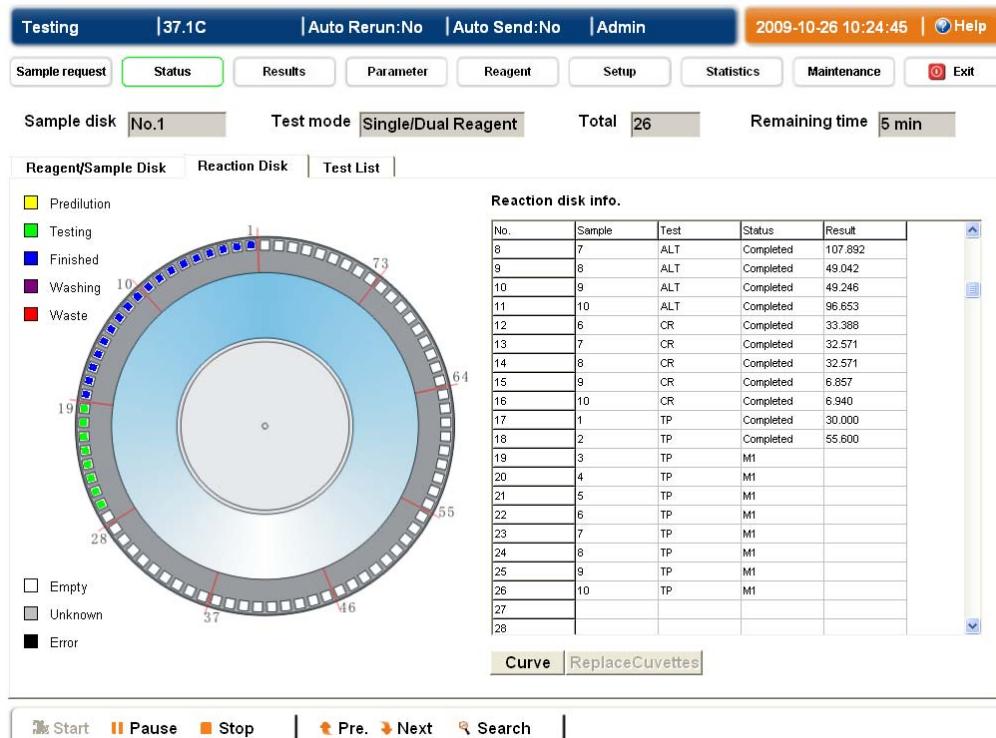


Figure 6-11 Testing status - Reaction disk

- **Replacing cuvettes:** All cuvettes can be replaced by pressing the “Replace cuvettes” button.
- **View reaction curve:** Select the reaction cuvette from the list or illustrations of reaction plate, and then press “Reaction curve” to view the reaction curve of this test. See the figure:

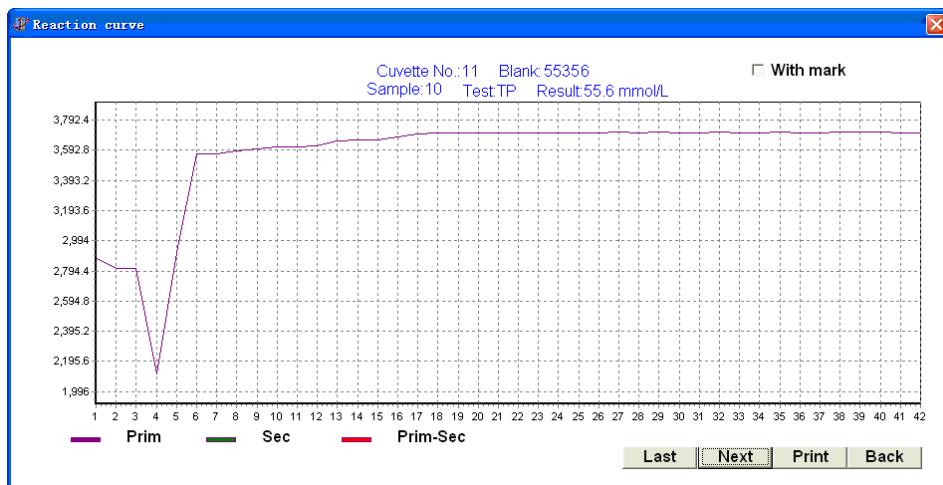


Figure 6-12 Reaction curve

Press “Last” and “Next” to view the reaction curves of reaction cuvettes at each position in order.
 Press “Print” button to print the reaction curve of the reaction cuvette at current position.
 Press “Back” button to exit the viewing of reaction curves.

Test list

View all tests, completed tests and uncompleted tests of the current worksheet respectively. See the figure:

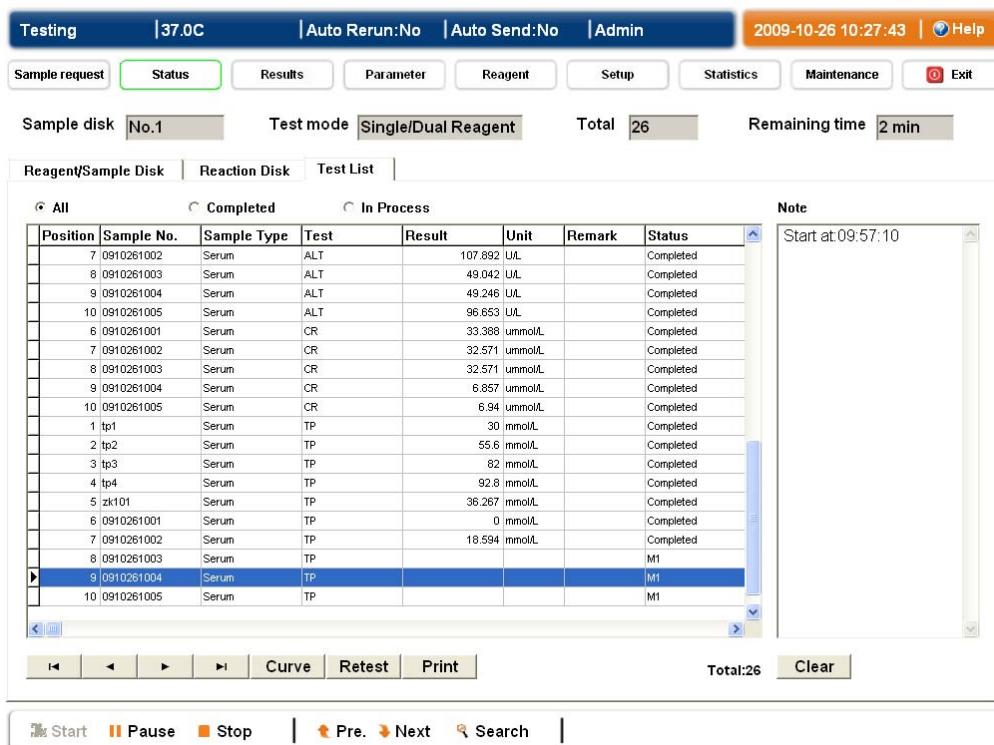


Figure 6-13 Test list

- Select records to be displayed:** Select “All”, “Completed” or “In process”, to display test records respectively according to different requirements.
- Display reaction curves:** Select a test from the list, and press “Reaction curve” button to view the corresponding reaction curve of the test.
- Retest:** Select the result needed to retest from the list, and then press “Retest” to mark the selected record as “Retest”. If the system is testing, the record will be automatically superadded and marked as a “Retest” test; otherwise, the system will automatically perform a retest to the test marked as “Retest”.

Reminder information

Displaying the reminder information during the process of worksheet testing, including beginning and end time of the test, information of deficient reagents/samples, and etc. Press “Clear” button to remove the information in the list.

Remarks

The symbols “A<” and “A>” express that test results are beyond linear range.
The symbol “**” expresses that the retest result is still beyond linear range.

Status

“PREP.” indicates that testing will begin soon;
“R1” indicates adding Reagent 1;
“S” indicates adding test samples;
“M1” indicates performing the first time of mixing;
“R2” indicates adding Reagent 2;
“M2” indicates performing the second time of mixing;
“Completed” indicates that the testing is completed.

Unit

“SE” indicates that the substrate is exhausted.
“OL” indicates that the result is beyond linear range.

Chapter 7 Result Search

7.1 Searching Patient Records

Function description: Search the patient records meeting designated conditions.
Users can edit and view the selected basic patient information and test results one by one.

Click the “Result” in the main menu to open the patient record page as illustrated in Figure 7-1:

The screenshot shows a software interface for a laboratory system. At the top, there is a header bar with the text "Lamp Stabilizing | T ERROR" and several status indicators: "Auto Rerun:No", "Auto Send:No", "Admin", "2009-10-22 14:07:54", and a "Help" button. Below the header is a navigation bar with buttons for "Sample request", "Status", "Results" (which is highlighted in green), "Parameter", "Reagent", "Setup", "Statistics", "Maintenance", and "Exit".

The main area contains a table titled "Patient" with columns: Sample No., Clinic No., Name, Sex, Age, Department, and Sent by. A row for sample "090909001" is selected, showing details: Clinic No. G123456, Name Jack, Sex Male, Age 24Y, Department ABCDefgh, and Sent by Leo Chen. To the right of this table is another table titled "Test" with columns: Test, Result, Unit, and Remark. This table lists several test results for the selected sample, including ALB, ALT, CR, TP, and GLB.

Below the tables are input fields for entering patient information: Sample No. (090909001), Clinic No. (G123456), Sex (Male), Department (ABCDefgh), Name (Jack), Age (24), and Sent by (Leo Chen). There are also buttons for "New", "Save", "Find", "Delete", "Print", "Send", "Calculate", "Check", and "Select All".

At the bottom of the interface are control buttons: "Start", "Pause", "Stop", "Pre.", "Next", "Search", and a message "Temperature sensor error".

Figure 7-1 Patient record

Search patient records

Press “Find” button to open a page as illustrated in Figure 7-2:

Find Patient

Sample No.	<input type="text"/>
Clinic No.	<input type="text"/>
Name	<input type="text"/>
Sex	<input type="text"/>
Age	<input type="text"/> Year <input type="button" value="▼"/>
Department	<input type="text"/>
Send by	<input type="text"/>
Tested by	<input type="text"/>
Checked by	<input type="text"/>
<input checked="" type="checkbox"/> Date From <input type="text" value="2009-10-22"/> <input type="button" value="▼"/>	
To	<input type="text" value="2009-10-22"/> <input type="button" value="▼"/>
<input type="button" value="OK"/> <input type="button" value="Back"/>	

Figure 7-2 Searching conditions of patient records

Enter the searching conditions and then press “OK” button. The list will display all the patient records meeting the conditions.

Edit patient information

Select a patient from the list and the corresponding basic information will be displayed beneath the list. Edit it as required, and then press “Save” button.

Edit patient test results

Click a patient record and the corresponding test results of the patient will be displayed in the right list. Users can add, modify or delete the test results.

Add patient records

Press “New” button and then directly enter a patient’s basic information beneath the list. After that, press “Save” button.

Note:

- ***The retested, manually-added or manually-modified test results are marked with the symbol “*”.***
- ***The symbols “↑” and “↓” respectively express that the result is too high and too low.***
- ***The new-added patient sample no. cannot be as same as the existing ones; otherwise, the system will update the existing patient information.***

Delete patient records

Select the records needed to delete from the patient record list, or press “Select All”; and then press “Delete” button. The system will delete the designated patient records and all the corresponding test records.

Check patient results

Select the patient records from the patient record list, or press “Select All”; and then press “Check” button. The checked by doctor of the selected patients will be automatically updated as current operator.

Indirect calculation

Select the patient record needed to perform indirect calculation from the patient record list, or press “Select all”; and then press “Calculate” button. The system will automatically calculate the calculation item results of the selected patients according to the system setup parameters.

Send patient test results

Select the patient record needed to deliver from the patient record list, or press “Select all”; and then press “Send” button. The system will send test results of the selected patient to the designated receiving software.

Print patient report

Select the patient records needed to print a report from the patient record list, or press “Select all”; and then press “Print” button. The system will automatically print the patient report.

7.2 Searching Test Records

Function description: Search the test records meeting designated conditions.

Select the “Test” page, as illustrated in Figure 7-3:

Figure 7-3 Test records

Search test records

Press “Find” button to open a page as illustrated in Figure 7-4:

Figure 7-4 Searching conditions of test records

Enter the searching conditions and then press “OK” button. The list will display all the test records meeting the conditions.

Note: The retested, manually-added or manually-modified test results will be marked with the symbol “*” behind them.

Delete test records

Select the records needed to delete from the test record list, or press “Select All”; and then press “Delete” button.

Print test records

Select the record needed to print from the test record list, or press “Select All”; and then press “Print” button.

View reaction curve

Click the test records needed to review and press “Reaction curve” button. The system will display the reaction curve of the test, as illustrated in Figure 7-5:

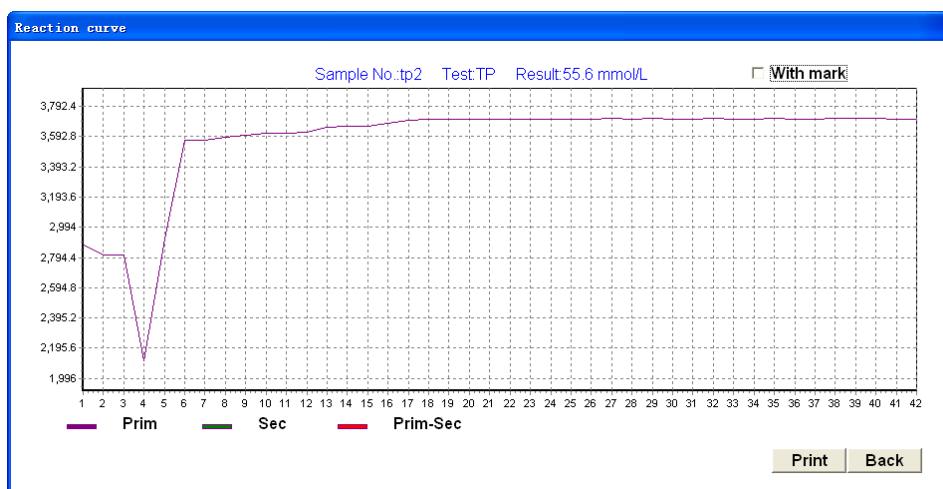


Figure 7-5 Reaction curve

Press “Print” button to print the curve.

7.3 Calibration Search

Function description: Search the calibration results of designated items.

Select “Calibration” page, as illustrated in Figure 7-6:

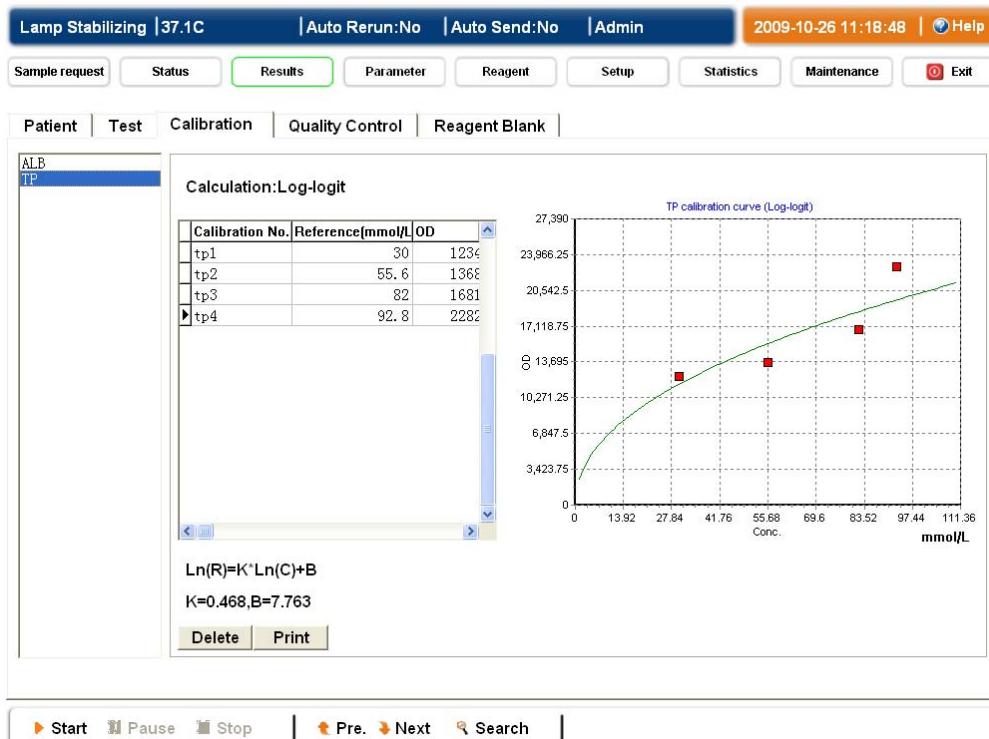


Figure 7-6 Standard Search

Delete calibration results

Select the calibration results needed to delete from the calibration data list, and press “Delete” button.

Print calibration results

Select the item needed to print its calibration results from the left list, and press “Print” button.

7.4 QC Search

Function description: Search the test results of designated QC item within the designated time period.

Select “Quality Control” page, as illustrated in Figure 7-7:

The screenshot shows a software interface for quality control search. At the top, there's a menu bar with tabs for 'Lamp Stabilizing | 37.1C', 'Auto Rerun:No', 'Auto Send:No', 'Admin', '2009-10-26 11:19:21', and 'Help'. Below the menu is a toolbar with buttons for 'Sample request', 'Status', 'Results' (which is highlighted in green), 'Parameter', 'Reagent', 'Setup', 'Statistics', 'Maintenance', and 'Exit'. The main area has several tabs: 'Patient', 'Test', 'Calibration', 'Quality Control' (which is selected and highlighted in blue), and 'Reagent Blank'. On the left, a table lists 'Quality Control No.' and 'Test' for two entries: zk101 (ALB) and zk101 (TP). On the right, a large grid displays 'Date' and a list of test results for each entry. The results grid shows dates from October 5 to October 26, 2009, with values ranging from 35.53 to 37.10 mmol/L. At the bottom of the grid are buttons for 'Graph', 'Delete', and 'Print', and a checked 'Select All' checkbox. Below the grid is a footer with buttons for 'Start', 'Pause', 'Stop', 'Pre.', 'Next', 'Search', and navigation arrows.

Figure 7-7 QC search

View QC data

Select the QC item needed to view from the left list and designate the searching date range. Then, all the test results meeting the conditions will be displayed in the right data list.

View QC graph

Select the data points needed to draw from the data list, and then press “QC Graph” to display the QC graph:

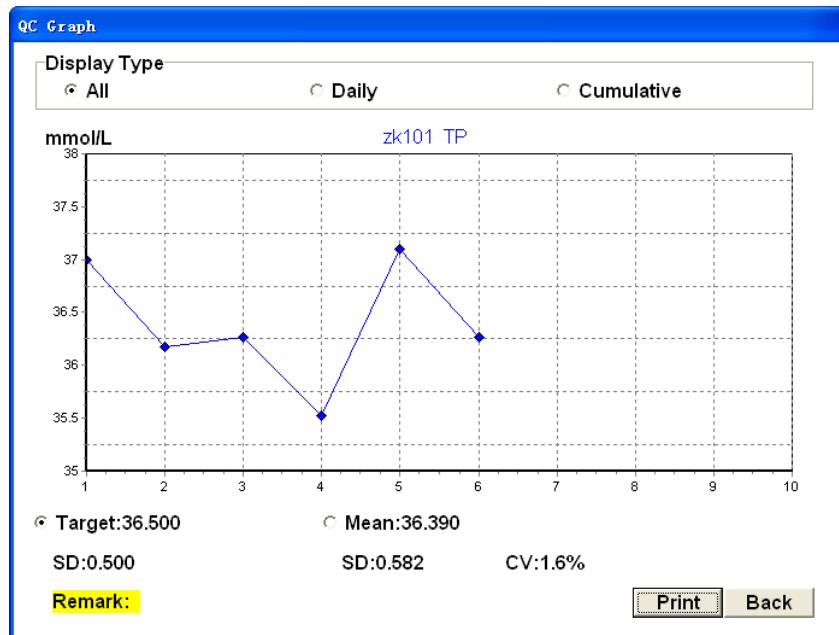


Figure 7-8 QC graph

This page displays the target value and SD value of the QC item, as well as the statistical results of the selected data: mean value, SD and CV. The system can automatically convert the QC graph according to the user-designed drawing mode. Press “Print” button to print a QC graph as illustrated in the figure.

- **Real-time QC graph:** All data are drawn, and each QC data corresponds to a different abscissa of the graph.
- **Daily QC graph:** Average the data obtained in the same day. Only the corresponding points of daily mean values are drawn and the daily mean values correspond to different abscissa.
- **Accumulation graph:** All data are drawn and the data obtained in the same day correspond to the same abscissa.

Delete QC data

Select the QC data needed to delete from the QC data list, and press “Delete” button.

Print QC data

Select the QC data needed to print from the QC data list, and press “Print” button.

7.5 Searching Reagent Blank

Function description: Search the reagent-blank history records of designated items.

Select the “Search Reagent Blank” page, as illustrated in Figure 7-9:

The screenshot shows a laboratory management software interface. At the top, there is a menu bar with tabs: Sample request, Status, Results (highlighted in green), Parameter, Reagent, Setup, Statistics, Maintenance, and Exit. To the right of the menu is the date and time: 2009-10-26 11:20:18, and a Help button. Below the menu is a navigation bar with tabs: Patient, Test, Calibration, Quality Control, and Reagent Blank (highlighted in blue). On the left, a search bar contains the text "ALB". To the right of the search bar is a table titled "Reagent Blank" with columns: Date, Reagent Blank, and Remark. The table lists several entries with dates ranging from 2009-10-12 to 2009-10-26, and remarks indicating some values are outside the normal range ("OR"). At the bottom of the table are buttons for Delete, Delete All, and Print. Below the table is a control panel with buttons for Start, Pause, Stop, Pre., Next, and Search.

Date	Reagent Blank	Remark
2009-10-12 10:00:00	8015	OR
2009-10-12 10:00:00	8015	OR
2009-10-13 10:12:00	8065	OR
2009-10-14 11:00:00	8034	OR
2009-10-20 10:00:00	8051	OR
2009-10-25 10:00:00	8023	OR
2009-10-26 10:00:00	1235	OR

Figure 7-9 Reagent-blank searching

The left list displays all items tested reagent blank. Click the item needed to search and the right list will display the history reagent-blank record of the item.

Press “Delete” button to delete the selected reagent-blank record in the list.

Press “Delete all” button to delete all reagent-blank records in the list.

Press “Print” button to print all reagent-blank records in the list.

Note: The blank results beyond reagent-blank range will be marked with “OR”.

Chapter 8 Statistics

8.1 Worksheet Statistics

Click “Statistics” in the main menu to open the worksheet statistics page as illustrated in Figure 8-1:

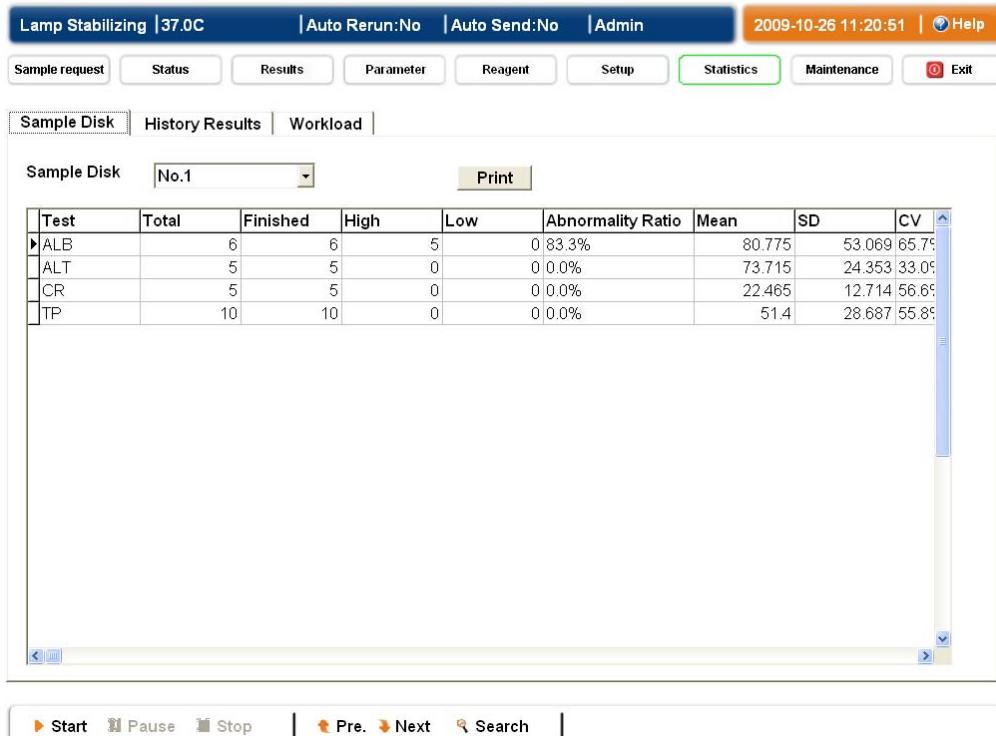


Figure 8-1 Worksheet statistics

Select the worksheet needed statistics from the pull-down list, and the statistical results of the worksheet will be displayed beneath the list. The statistical results include total amount, completed amount, higher amount, lower amount and abnormality rate.

8.2 Statistics of History Results

Select “History Results” page, as illustrated in Figure 8-2:

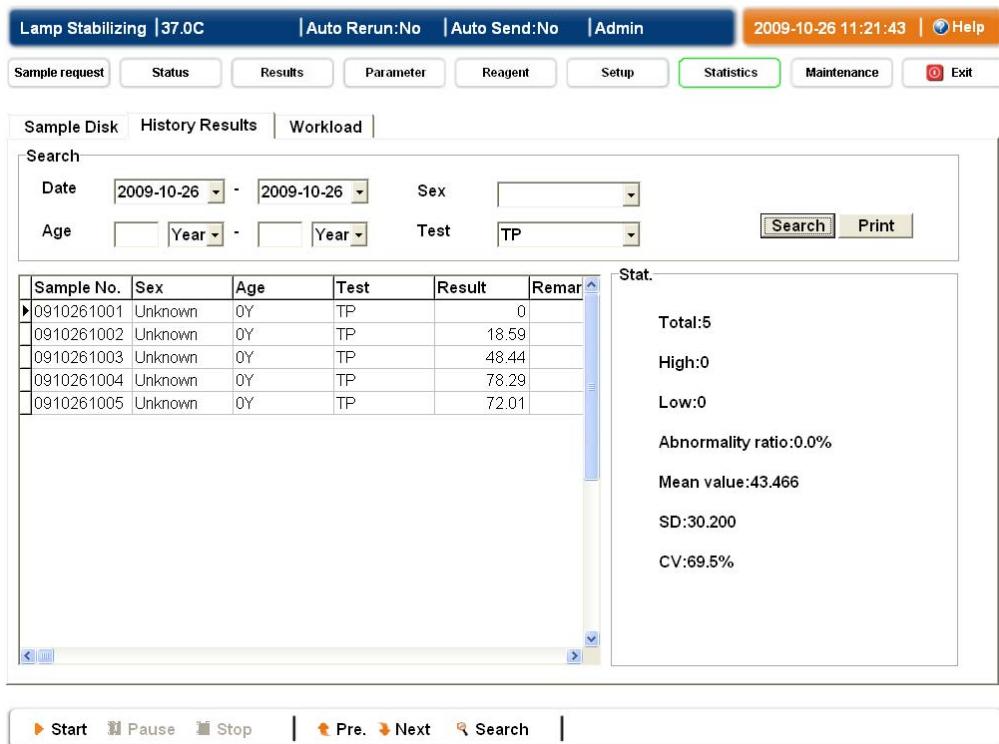


Figure 8-2 Statistics of History Results

Designate searching conditions (date, sex, age and Test) as required, and then press “Statistics” button. The system will display the test records meeting the conditions in the list, and perform the result statistics automatically.

The statistics include total amount, higher amount, lower amount, abnormality rate, mean value, SD and CV.

8.3 Workload Statistics

Select “Workload” page, as illustrated in Figure 8-3:

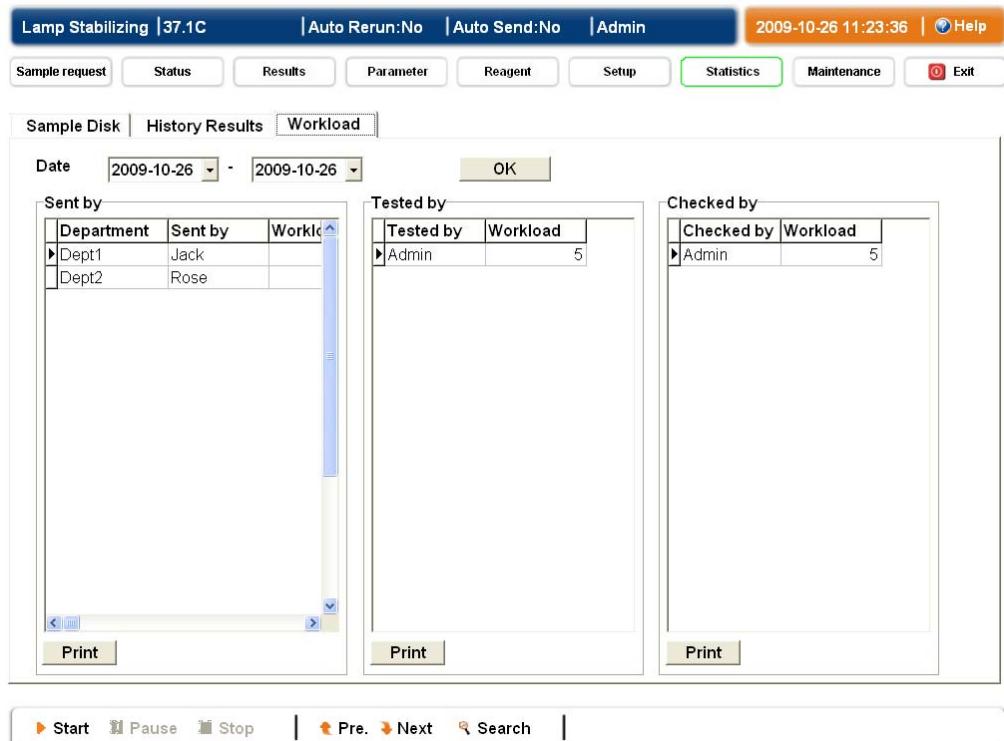


Figure 8-3 Workload statistics

Designate a time period, and then press “Statistics” button. The system will perform the workload statistics to all the sent by doctors, tested by doctors and checked by doctors within the time period.

Chapter 9 Service

In order to ensure that the instrument can function accurately and reliably, as well as to prolong the service life of parts and components, users need to perform proper routine maintenance according to the requirements. This chapter will introduce the instrumental routine maintenance, suggestions on locating troubles, calibration and replacement of commonly-used components, etc.

Note:

- ***There is potential biological contamination on the component surface of the instrument; therefore, proper safety protection measures should be taken during operation and reparation.***
 - ***Improper maintenance may damage the instrument. Operators must perform the maintenance according to the manual.***
 - ***If the troubles or problems in your instrument are not listed in this manual, please contact BGT BioGenTechnologies GmbH's Customer Service Department. The specialized personnel approved by BGT BioGenTechnologies GmbH will give you the maintenance suggestions.***
 - ***The parts and components provided by BGT BioGenTechnologies GmbH must be used when performing maintenance.***
 - ***If you have any questions, please contact BGT BioGenTechnologies GmbH's Customer Service Department.***
-

9.1 Maintenance Guide

9.1.1 Inspection before Analysis

1. The analyzer main-part has no obvious physical damages. There is no accumulated dust and liquid on the tabletop of the main-part worktable. The lines connect well. The connection of the instrument to computer, printer and etc is normal.
2. The power supply is well-connected and well-grounded.
3. The waste barrel is empty and the cleaning solution is enough.

9.1.2 Periodic Maintenance

1. Daily maintenance: Clean the dust on the worktable with a duster cloth that has soaked in neutral cleaning solution.
2. Weekly maintenance:
 - 1) Softly clean the sampling needle and mixing arm with a duster cloth dipped in alcohol.
 - 2) Make sure that the flow rate of cleaning water-flow in the two cleaning pools is normal.
3. Monthly maintenance:
 - 1) Cleaning the external cleaning-solution water-tank;
 - 2) Cleaning the water supply and drainage systems.
4. Non-periodic maintenance (as required):
 - 1) Check and replace the halogen lamp once per 1000 hours
 - 2) Check the injector piston once per 150 hours.
 - 3) Check and replace the diaphragm pump once per 1000 hours.
 - 4) Check and replace the mixing arm once a year.

Note: The replacement of diaphragm pump and mixing arm must be performed under the permission of BGT BioGenTechnologies GmbH's engineers.

9.2 Common Troubles and Measures

The software cannot function normally.

- Check if the analyzer main-part is turned on.
- Check if the control computer and analyzer are normally connected by the control series-interface cable.
- Check if the control computer uses the port designated by system software.

The cuvette blank is invalid.

- Check if replacing clean cuvettes;
- Check if the light-source energy is normal;
- Check if the cuvette-blank is invalid.
- Check if the corresponding gain coefficient of each wavelength is rational.

The sampling volume is inaccurate.

- Check if the sampling lines are well-sealed;
- Check if the liquid lines are well-perfused;
- Check if the corrective coefficient of liquid volume is normal;
- Check if the injector status is normal;
- Check if the deionized water is exhausted.

The sampling needle cannot accurately localize.

- Check if the sampling needle is vertically downward;
- Check if standard reagent bottles and sample tubes are used.

There is residual liquid on the surface of the sampling needle.

- Check if there is dirt on the outer wall of sampling needle;
- Check if the tube of sampling needle is worn;
- Check if the fountain height in the cleaning pool is proper when cleaning the sampling needle;
- Check if the sampling lines are well-sealed;
- Check if the liquid lines are well-perfused;
- Check if the deionized water is exhausted.

The mixing arm cannot accurately localize.

- Check if the sampling needle is vertically downward;
- Check if standard reagent bottles and sample tubes are used.

9.3 Maintenance

Click “Maintenance” in the main menu of software to open the maintenance page.

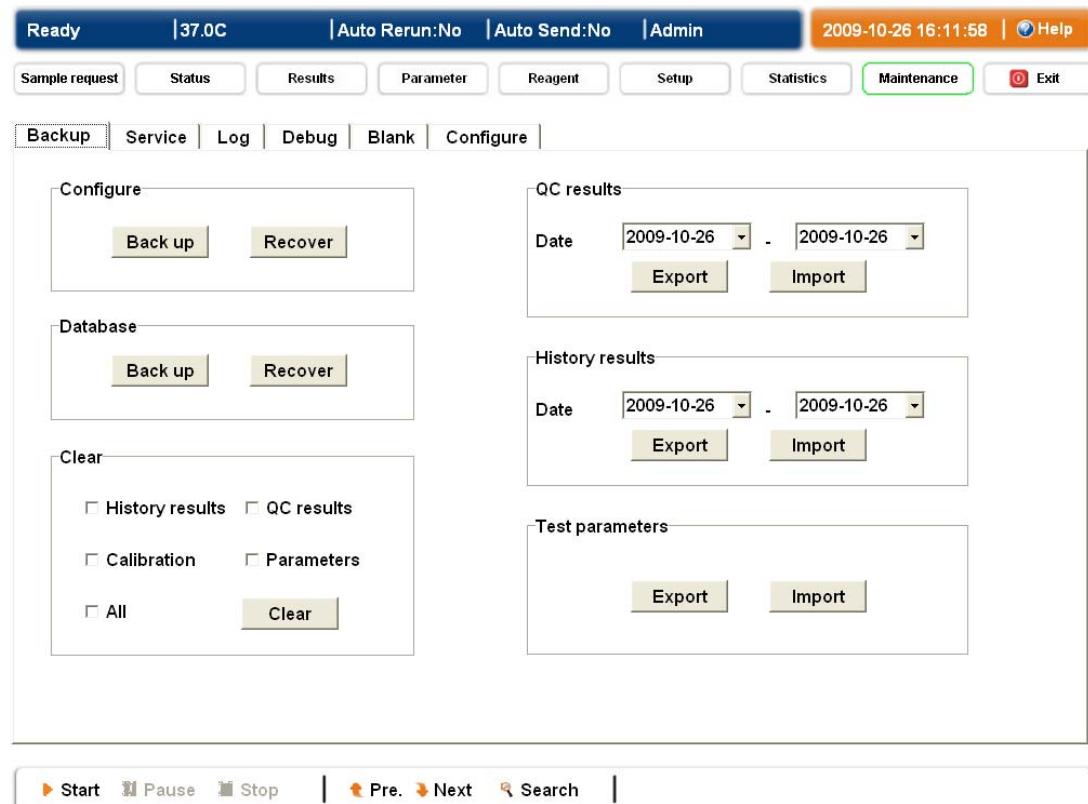


Figure 9-1 Maintenance-data maintenance

Backup and restoration of configuration parameters

Configuration parameters are the optimal corrective parameters that can adapt the hardware system and are obtained by debugging during the instrument production process. These parameters include localization parameter, motor control parameter, temperature corrective parameter, gain parameter, cuvette-blank threshold value and filter configuration parameter. The functions of each parameter are as follows:

- The localization parameter is used for correcting the mechanical localization parameter of the system; such as, the descending height of sampling needle, the positions of liquid pipetting and releasing, the position of photoelectric acquisition, etc.
- The motor control parameter is used for controlling the working mode of each motor.
- The temperature corrective parameter is used for correcting the temperature-control accuracy of the reaction plate and preheating.
- The gain parameter is used for controlling the corresponding signal gain coefficient of each wavelength.
- The cuvette-blank threshold value is used for setting the cuvette-blank warning limit. If a cuvette-blank is beyond the set range, the system considers it as invalidity and will not use this cuvette.
- The filter configuration parameter is used for recording the corresponding wavelength of each filter configured by the system.

Damages or loss of configuration parameters can cause abnormal functioning of the instrument. In order to prevent it, please back up the configuration parameters under normal status, so as to restore them to the backup status by using the "restoration" function if necessary.

Backup and restoration of database

The database is used for storing data documents on setting parameters and history test results. Please periodically back it up, so as to restore it to the backup status if the data are damaged or lost.

Data removal

It is used for removing the data with designated types in database. The data types can be selected according to the actual requirements; the removed data cannot be restored!

- History data: Meaning patients' test results and patients' basic information records.
- QC data: Meaning QC test results.
- Calibration data: Meaning calibration test results.
- Set parameters: Meaning the user-entered item setup parameter, calibrator setup parameter, QC setup parameter, integration setup parameter, calculation-item setup parameter, non-biochemical item setup parameter, reagent setup parameter, system setup parameter, worksheet setup and test data.
- Overall data: Including all the data above.

Export and import of QC results

Export all the QC test results within designated time period; and the exported data will be saved to the designated path. If required, the QC results within designated time period can be imported from the file.

Export and import of history data

Export the patient sample test results within designated time period; and the exported data will be saved to the designated path. If required, the patient sample test results within designated time period can be imported from the file.

Export and import of item setup parameters

Export the current item setup parameter of the system; and the exported data will be saved to the designated path. If required, the item setup parameters can be imported from the file.

Note: Only the administrator can perform the operations of configuration-parameter restoration, database restoration, QC data import, history data import, importing of item setup parameters and data removal!

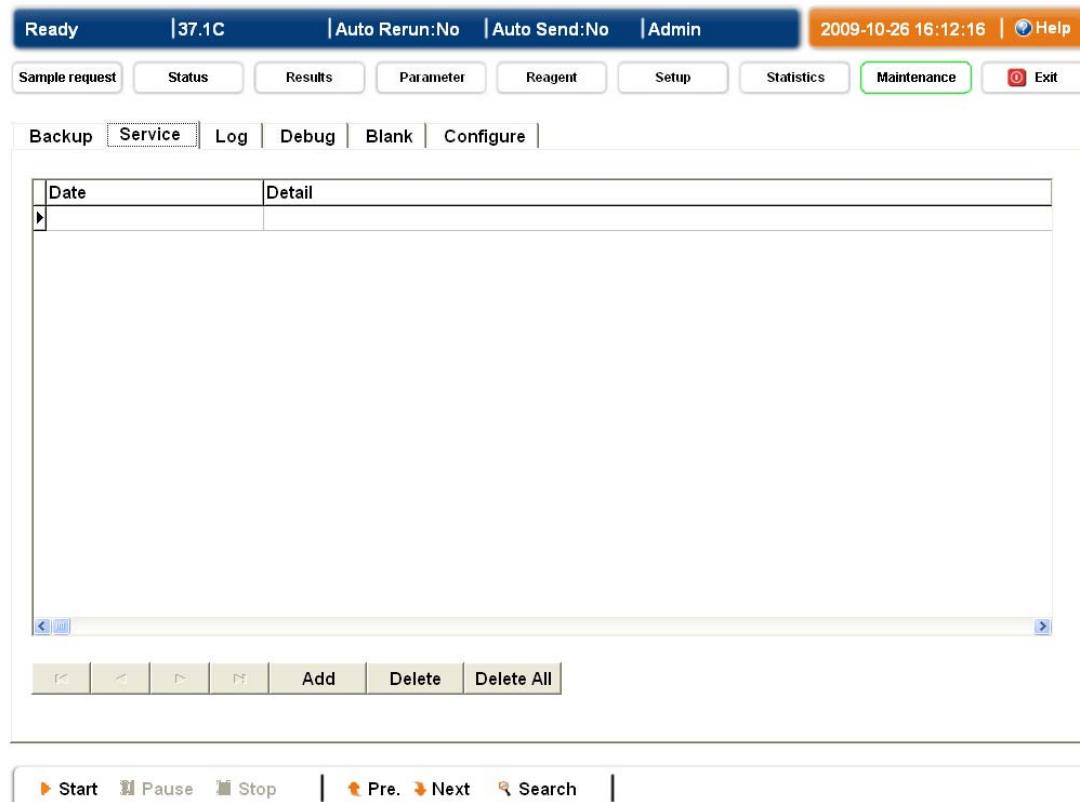


Figure 9-2 Maintenance-Service record

Add a service record

Press “Add” button; enter the service record needed to add in the opened new form; and then press “Save”.

Delete a service record

Select the record needed to delete from the list, and then press “Delete” button. If needing to delete all the service records, press directly “Delete all” button.

Note: Only the administrator can add and delete service records!

The screenshot shows a software interface for managing service records. At the top, there's a toolbar with buttons for Ready, Temperature (37.0C), Auto Rerun:No, Auto Send:No, Admin, Date (2009-10-26 16:12:27), Help, Sample request, Status, Results, Parameter, Reagent, Setup, Statistics, Maintenance (which is highlighted in green), and Exit. Below the toolbar is a menu bar with Backup, Service, Log (which is selected and highlighted in blue), Debug, Blank, and Configure. The main area contains a table titled "Log" with columns for Time, Event, and User/Code. The table lists numerous entries of "Logging in" events for the user "Admin" at various dates and times. At the bottom of the log table are navigation buttons (Back, Forward, Home, Clear Log) and a set of control buttons for Start, Pause, Stop, Pre., Next, and Search.

Time	Event	User/Code
2009-10-22 11:59:28	Logging in	Admin
2009-10-22 13:43:05	Logging in	Admin
2009-10-22 13:44:11	Logging in	Admin
2009-10-22 13:46:51	Logging in	Admin
2009-10-22 14:41:38	Logging in	Admin
2009-10-22 14:42:29	Logging in	Admin
2009-10-22 15:08:43	Logging in	Admin
2009-10-22 17:05:00	Logging in	Admin
2009-10-23 17:01:08	Logging in	Admin
2009-10-26 09:33:20	Logging in	Admin
2009-10-26 09:41:03	Logging in	Admin
2009-10-26 09:42:33	Logging in	Admin
2009-10-26 10:55:39	Logging in	Admin
2009-10-26 11:00:51	Logging in	Admin
2009-10-26 11:10:00	Logging in	Admin
2009-10-26 11:10:03	Logging in	Admin

Figure 9-3 Maintenance - Log

The list displays all the system log records. If needing to delete all log records, press “Clear Log” button.

Note: Only the administrator can remove logs!

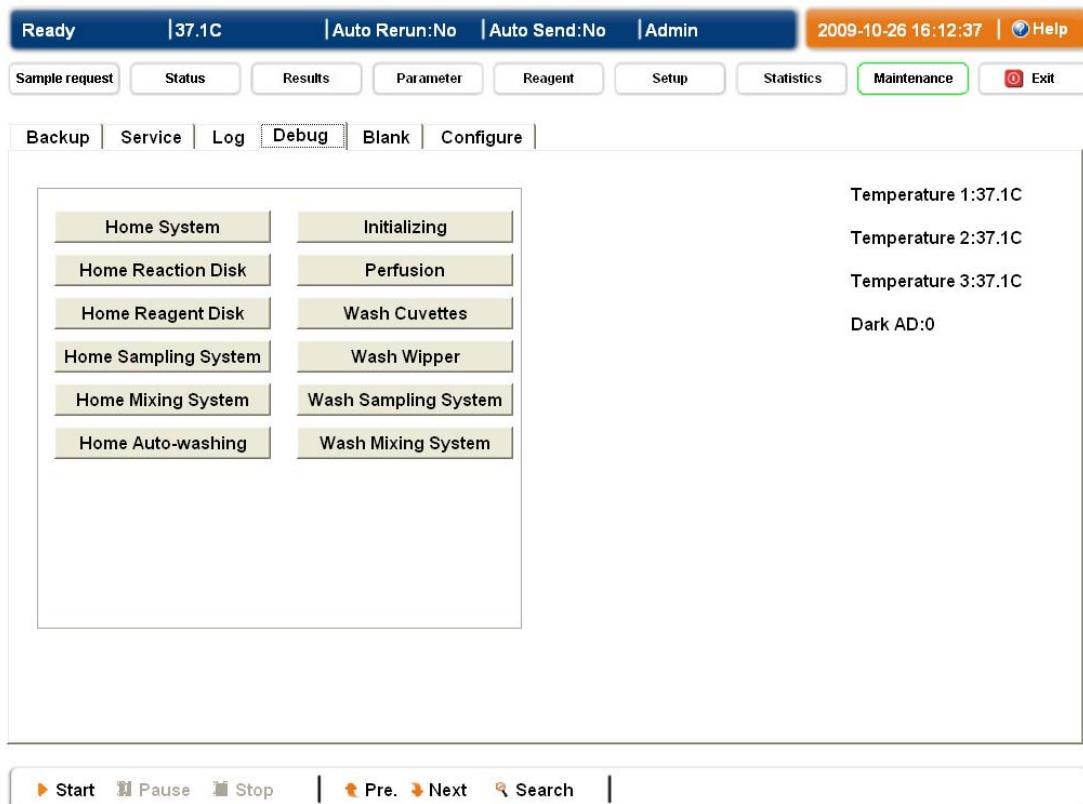


Figure 9-4 Maintenance - Debug

In "Status testing" page, the status testing of all components can be performed.

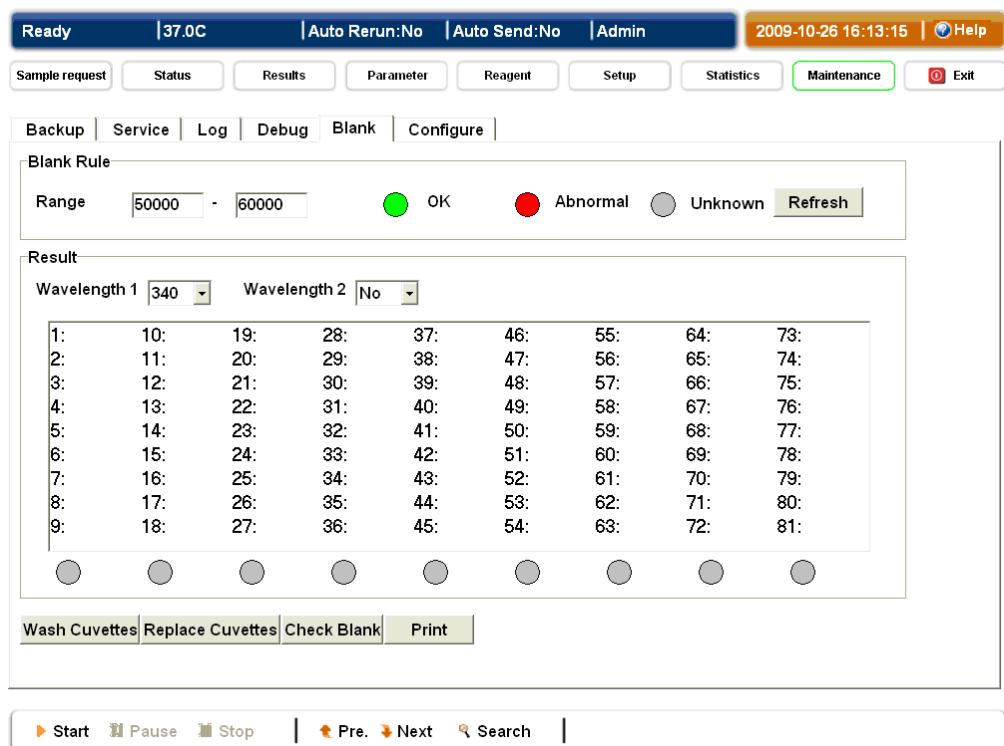


Figure 9-5 Maintenance - Cuvette blank

Wash cuvettes(Option function, standard instrument does have this function)

Press “Wash cuvettes” and then the system begins to clean the 81 cuvettes in the reaction plate one by one; users can press “Stop” button to stop cleaning at any time during the cleaning process. (Applicable to the system equipped with auto-cleaning modules.)

Replace cuvettes

Press “Replace cuvettes” and then the system turns the nine-set cuvettes to the manual replacing window one by one, and remind users to replace. Press “stop” button to stop replacing the rest cuvettes.

Test cuvette-blank

Press “Check Blank” button and then the system begins to automatically test the cuvette-blank of the 81 cuvettes at each wavelength; after completion, the system will automatically display the corresponding cuvette-blank value of designated wavelength.

Blank screening

Set the screening range of the corresponding cuvette-blank of designated wavelength, and then press “Refresh” button. The system will automatically judge the validity of each set of cuvette blank according to the set range, and mark with colors.

Print

Press “Print” button, and the system will automatically print the cuvette-blank value displayed in the list.

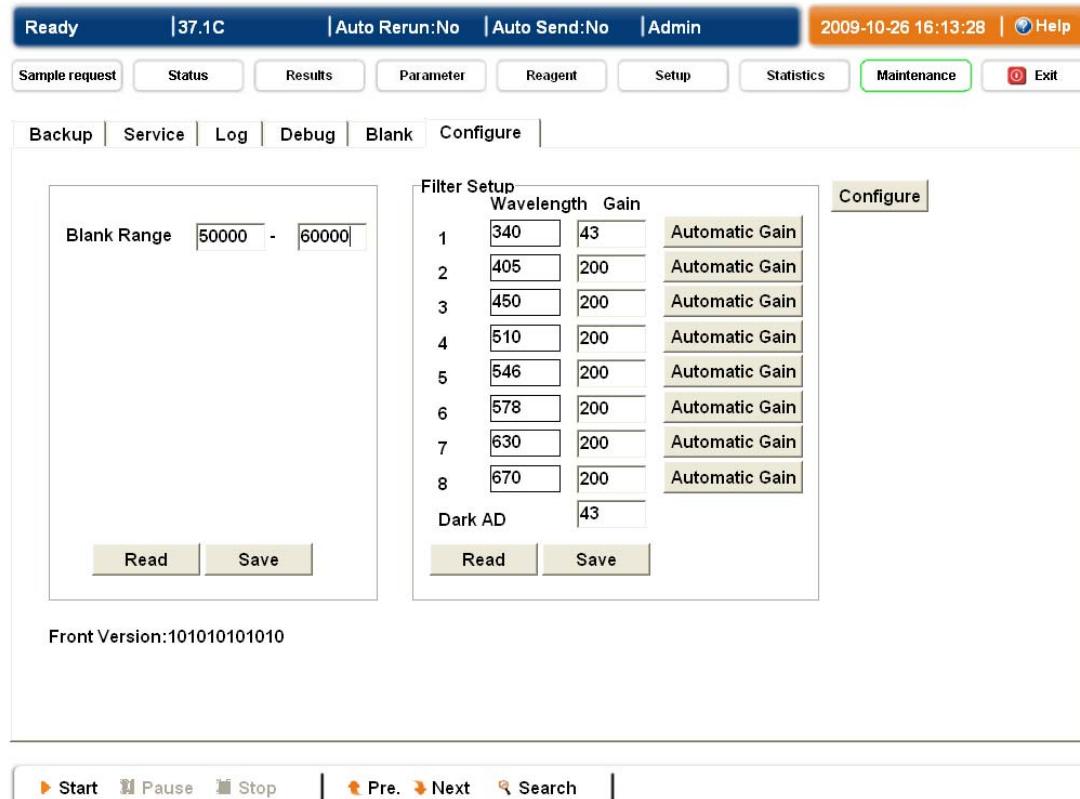


Figure 9-6 Maintenance - Configuration

Limit parameters

Blank range is the standard for judging if the reaction cuvette can be used. If the blank of the reaction cuvette is within the range, it is judged as valid; otherwise, it is judged as invalid. The system will automatically skip the invalid reaction cuvettes. Press “Read parameters” button to obtain the current blank limit parameters of the system. Enter the blank range, and then press “Update Parameters” button to save.

Note: The blank range must be obtained by actual testing. If the range is not rationally set, the system cannot test normally! When replacing different batches of reaction cuvettes, please open “Blank” page first and view the cuvette-blank range of this batch; then, set a proper limit parameter according to the test results of all wavelengths.

Filter parameter

“Wavelength” displays the corresponding wavelengths of the eight filters configured by the system one by one. The Column “Gain” displays in turn the corresponding gain coefficients of the eight wavelengths. If needing to adjust the gain coefficient corresponding to a certain wavelength, users can directly modify it by hand; or press “Automatically Configure Gain” to automatically obtain a proper gain coefficient, and then press “Update Parameters” to save the obtained parameter. (If the cuvette-blank energy of a certain wavelength is too low, increase the corresponding gain coefficient; conversely, decrease the gain coefficient.)

Note: Common users shall not modify the parameters in “Configuration” page; otherwise, the accuracy of system testing may be affected!

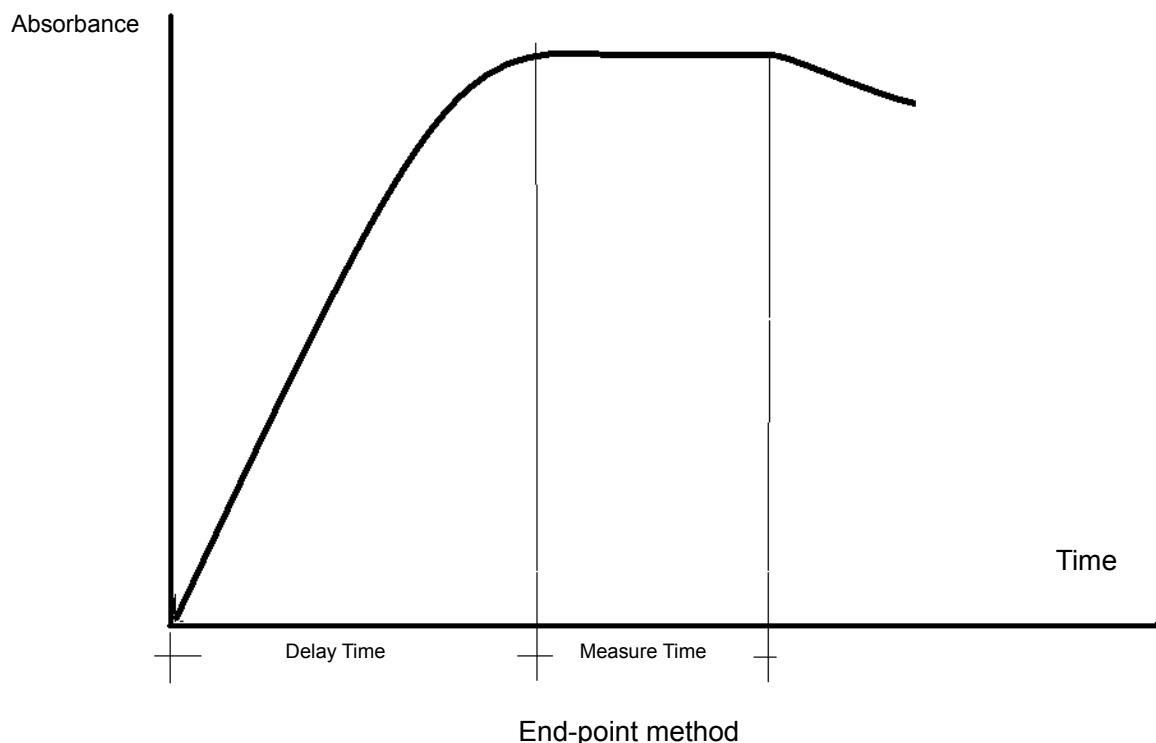
Chapter 10 Using Precautions

No.	Precautions	Cause
1	The instrument must be kept far away from all oscillation sources and electromagnetic interference, so as not to affect the signal acquisition.	Avoid affecting signal acquisition
2	Please check water supply and drainage tubes before use. Do not bend and fold them.	Avoid affecting sample adding and avoid causing liquid to spill
3	Do not let any object enter the working area when the instrument is functioning, so as to avoid collision.	Avoid collision
4	Please do not replace cleaning solution and distilled water during the testing process; otherwise, the liquid seal cannot form in the liquid lines, thereby affecting the injector sampling.	Avoid affecting sample adding
5	If the system always reminds of invalid blank, please confirm if the cuvettes are contaminated or worn, if the gain coefficient is proper, and if the light source is aging.	Affect the test accuracy
6	Please do not start testing before the light source and temperature are stable.	Affect the test accuracy
7	The opening of reaction plate must be always closed during the testing process.	Affect the test accuracy
8	The cuvettes must be placed at a proper location and cannot be shaken.	Affect the test accuracy
9		

Appendix A: Calculation Methods

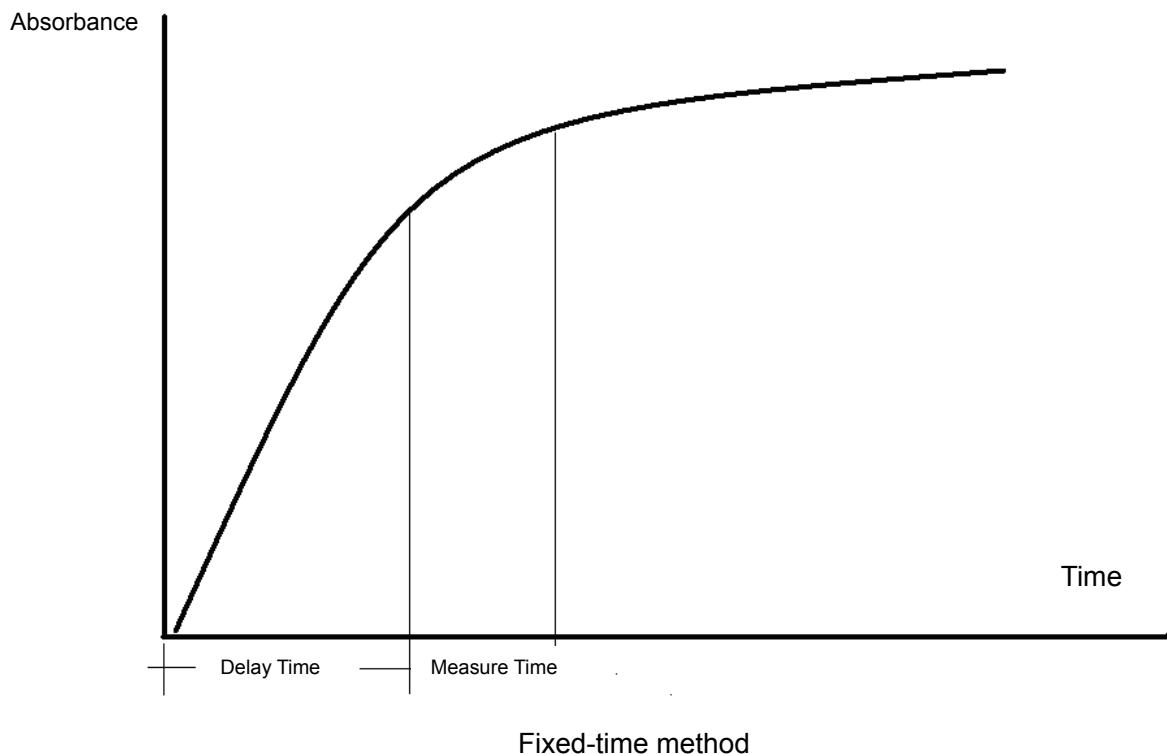
A.1 End-Point Method

After a period of time, the test material is fully converted into product during the reaction course. At this time, the absorbance of the reaction solution does not increase (or decrease) any more, i.e., reaching the reaction end-point. Calculate the concentration of test material according to the absorbance value at the reaction end-point. This method is named as end-point method.



A.2 Fixed-Time Method

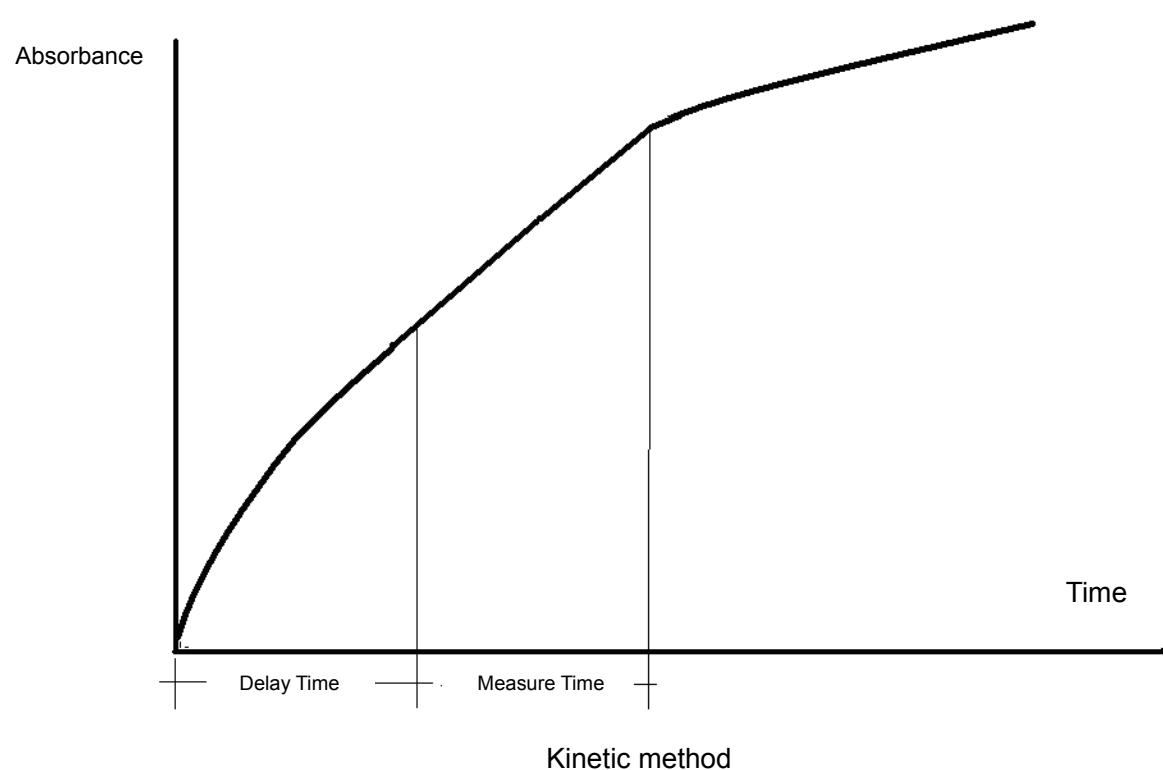
The fixed-time method means that within a certain reaction time, reaction speed is directly proportional to reactant concentration. The reactant continues to consume, therefore, the overall reaction speed continues to be reduced; i.e., the speed of absorbance increase (or decrease) continues to lower. The measure must be performed within a specific time period; and within the time period, the absorbance increase (or decrease) is directly proportional to the concentration of test material.



A.3 Kinetic Method

It means that reaction speed is directly proportional to the zero power of test-material concentration, i.e., irrelevant to the concentration of test material. Therefore, during the entire reaction course, the reactant can generate a certain product uniformly; this causes the absorbance of test solution at a certain wavelength to decrease or increase uniformly, the decrease or increase speed ($\Delta A/\text{min}$) is directly proportional to the activity or concentration of test material. Speed method, i.e. generally called dynamic method, is also named as continuous monitoring method; it is mainly used for the determination of enzyme activity.

In fact, the substrate concentration is impossible to be large enough; therefore, during the reaction course, when the substrate is consumed to a certain degree, the reaction speed is not directly proportional to enzyme activity. So, the speed method is applicable to a specific time period.



Appendix B Name and Content of Toxic and Harmful Substances or Elements in Product

1. Name and content of toxic and harmful substances or elements

Component name	Toxic and harmful substances or elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr(VI))	Polybrominated Biphenyl (PBB)	Polybrominated Diphenyl Ether (PBDE)
Internal circuit board	×	○	○	○	○	○
Housing	×	○	○	○	○	○
Display screen	×	○	○	○	○	○
Photoelectric components	×	○	○	○	○	○
Internal electronic wires	○	○	○	○	○	○
Attachments	×	○	○	○	○	○

○ : Expressing that the contents of the toxic and harmful substance in all uniform materials of this component are lower than the limit content prescribed in the Standard SJ/T11363-2006.
 ×: Expressing that the content of the toxic and harmful substance at least in a uniform material of this component exceeds the limit content prescribed in the Standard SJ/T11363-2006.

2. Marker description

Environmental-Protection Service-Life Marker



Marker meaning: This electronic-information product contains some toxic and harmful substances. Its environmental-protection service life is 20 years. Within the environmental-protection service life, users can use it securely; beyond the environmental-protection service life, it should enter the recycling system.