

Auto Chemistry Analyzer User's Manual

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1. Auto Chemistry Analyzer Help

1.1 Terminology

TERMINOLOGY

AD Value

The photo electric current generated from the light reaching the tester shall go through fixed resistance and be converted into photovoltaic (analogue signal). This voltage will be converted into corresponding value related to the selected AD digits through AD conversion. This value is known as AD value.

Dark Current

Dark current is the value of current output shown in AD value when the light source is not turned on (or light is not available). Dark current is similar to the circuit background and shall be offset in the calculation of absorbency.

Cuvette Blank

Cuvette blank is the value of absorbency when the cuvette is blank. Since the value of absorbency is relative, it can be set as a base to set the absorbency of cuvette blank to zero. Other absorbency shall be calculated by reducing the absorbency when the cuvette is blank.

Measurement Spot

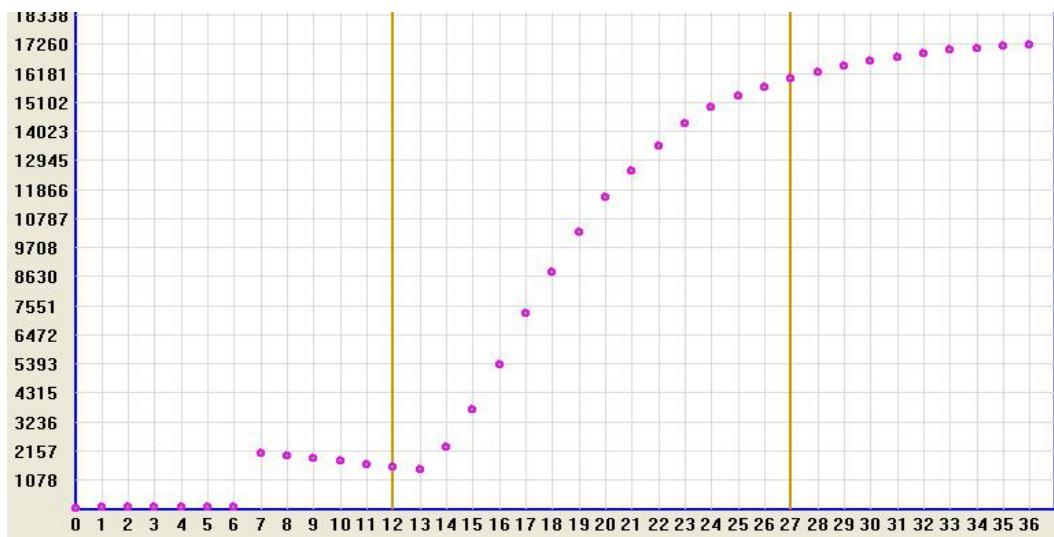
Measurement Spot is the specific moment for the photoelectric comparison. It is shown in values to indicate the strict and fixed time relationship of the measurements spots. There are 41 measurement spots for each reaction. At rapid mode, the time interval between two neighboring spots is 16 seconds. At regular mode, the time interval between two neighboring spots is 24 seconds.

Absorbency

Absorbency is the common logarithm transmission intensity divided by incident intensity. The incident intensity is the AD value of cuvette blank and the displayed absorbency is the calculated absorbency $\times 10^4$.

Reaction Curve

A series of dots formed by using measurement spots as the horizontal coordinates and absorbency as the vertical coordinates. A typical reaction curve is shown below:



1.2 Basic Operating Workflow

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "Item Parameters" in the pull-down menu to show the interface.
3. Click "Create" button, and enter the assay parameters according to the meaning and reagent specifications.
4. Click "Save" button.

Revise Assay Parameter

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "Item Parameters" in the pull-down menu to show the interface.
3. Click "Revise" button, and revise the assay parameters according to the meaning and reagent specifications.
4. Click "Save" button.

Delete Item

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "Item Parameters" in the pull-down menu to show the interface.
3. Select the item to delete and click "Delete" button to enter the interface.
4. Click "Yes" button.

Create Controller

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "QC Setup" in the pull-down menu to show the interface.
3. Click "Create" button, and enter the contents according to the meaning of the parameters, including name of controller, target value of the items, accumulation and control rules.
4. Click "Save" button.

Revise Controller

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "QC Setup" in the pull-down menu to show the interface.
3. Select controller to revise, click "Revise" button, and revise the contents according to the meaning of the parameters,

including name of controller, target value of the items, accumulation and control rules.

4. Click "Save" button.

Delete Controller

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "QC Setup" in the pull-down menu to show the interface.
3. Select the controller to delete and click "Delete" button to enter the interface.
4. Click "Yes" button.

Create Calibrator

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "Calibration Setup" in the pull-down menu to show the interface.
3. Click "Create" button, and enter the contents according to the meaning of the parameters, including name of calibrator, standard value of the items and position on calibration disc.
4. Click "Save" button.

Revise Calibrator

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "Calibration Setup" in the pull-down menu to show the interface.
3. Click the calibrator to be revised, click "Revise" button, and revise the contents according to the meaning of the parameters, including name of calibrator, standard value of the items and position on calibration disc.
4. Click "Save" button.

Delete Calibrator

1. Click hotkey "Show Menu" on the home page to show main menu.
2. Click "Assay Setup" on the main menu and select "Calibration Setup" in the pull-down menu to show the interface.
3. Select the controller to delete and click "Delete" button to enter the interface.
4. Click "Yes" button.

Set Reagent Position

1. Click hotkey "Reagent Disc"
2. Switch bookmark to the reagent disc needed.
3. Select the name of the reagent to set position. For dual reagent, select R1 and R2.
4. Double click an empty position to set the reagent to this position.

Change Reagent Position

1. Click hotkey "Reagent Disc"
2. Switch bookmark to the reagent disc needed.
3. Click on the reagent disc a reagent to change its position.
4. Double click an empty position to move the reagent to this position.

Delete Reagent Position

1. Click hotkey "Reagent Disc"

2. Switch bookmark to the reagent disc needed.
3. Click on the reagent disc a reagent to delete the reagent.
4. Click "Delete Position Taken" button.
5. Click "Yes" button.

1.3 Basic Assay Flow

1.3.1 Reagent Blank Assay Flow

1. Check the position of the reagent and make sure all the covers are removed.
2. Click hotkey "Start" on the home page and enter criteria on the pop-up interface.
3. Select Reagent disc No. (1-5) for the assay.
4. Click "Reagent Blank" column, select the reagent to be tested. (Click once to select and again to cancel.)
5. Place 5ml water at Position 10 of the sample stand. Click "OK" button.

1.3.2 QC Assay Flow

1. Click hotkey "Assay Application" or "Quick Application" on the upper left hand of the home page.
2. Check QC application box on the left, select a controller, sample disc No. (1-4), sample position (1-9). Select an item or portfolio. (Click once to select and again to cancel.) Click "Apply" button.
3. Repeat the above operations until all the QC applications are completed. Return to the homepage.
4. Click sample disc, click QC assay of sample disc on the new interface. Check the applied items for each controller to make sure there is no mistake.
5. Place the controllers at the applied positions on the controller disc.

1.4 Operating Flow for New Items

- 1 Create the parameters for the item.
- 2 Set reagent position for the item.
- 3 Create the calibrator for the item, or create density of the item on the existing calibrator.
- 4 Create controller for the item, or create target value and standard deviation of the item on the existing calibrator.
- 5 Perform calibration application for the item.
- 6 Start calibration assay.
- 7 After calibration assay, start QC application and QC assay.
- 8 After QC assay, regular sample assay can be started.

1.5 Daily Operating Flow

1. Check if there is enough printing paper. If not, add printing paper.
2. Check if the power is correct and if the wiring is reliable.
3. Check if the connection cables between printer, computer and analyzer are well connected
4. Check if there is water. Add water if there is not enough.
5. Empty the bucket and check if the waste discharge is smooth.
6. Check sample probe and mixer, with absorbent cotton dipped 75% alcohol to clean the dirt.
10. Take out reagent disc from fridge and put it into reagent storehouse, then open reagent bottle and then covered with lid storage reagent.

Power On

Turn on power in the following order:

1. Switch on power on the right side of the analyzer (so that the indication light will go on).
2. Switch on monitor power.
3. Switch on computer power.
4. Switch on printer power.

Procedures

Click hotkey on the homepage and log in. The following procedures shall be carried out:

1. All the moving parts shall reset.
2. Turn on temperature control and heat the reaction disc.

Preparation for Assay

1. Place the reagents at the preset positions. If reagent is not sufficient, add at once.
2. Place the calibrators at the preset positions on the sample disc.
3. Place the controllers at the applied positions on the controller disc.
4. Place the samples at the applied positions on the sample disc.

Start Assay

1. Click hotkey "Start".
2. Select the assay type.
3. Enter the sample scope to start the assay.
4. Click "Yes" button.

Result Confirmation

1. Confirmation
 - a) Click hotkey "Show Menu" on the homepage to show main menu.
 - b) Click "Statistic/Search" on the main menu and select "Calibration Setup" in the pull-down menu to show the interface.
 - c) Enter starting and ending dates, select the items, and click "Search" button to show the calibration record meeting the criteria.
 - d) Select a calibration record and click "Details" button at the lower part on the right to view the detailed information of the record.

2. QC Status Confirmation

- a) Click hotkey "View Result" on the homepage.
- b) Select a controller at the lower part on the left to view all the applied items. Select a complete item and click hotkey "Reaction Curve" at the bottom to view the reaction curve and reaction data.

3. Regular Result Confirmation

- a) Click hotkey "View Result" on the homepage.
- b) Select a controller at the lower part on the left to view all the applied items. Select a complete item and click hotkey "Reaction Curve" at the bottom to view the reaction curve and reaction data.
- c) To enter the patient information for a sample, select the number of the sample and enter the patient information directly on the upper part of the interface. Click "Save" button on the right.
- d) If an item needs to be tested again, check the "Test Again" box on the right of the result column. (Click once to select and click again to cancel.) Click the "Start Selected Retest" button.

Shutdown

Click hotkey "Exit" on the homepage. It will take about one minute to shut down the analyzer.

1. All the moving parts shall reset.
2. Exit operation system.

Power Off

Turn off power in the following order:

1. Turn off analyzing unit power.
2. Turn off computer power.
3. Turn off monitor power.
4. Turn off printer power.

Inspection after Shut-off

1. Remove the sample, calibrator and controller from the sample disc.
2. Replace the cover of the reagent bottle.
3. Clean the bench.
4. Wipe off the dirt and water from sample probe and mixer.
5. Check if there is air bubble or leakage on syringe.
6. Check sample bubble and leakage at syringe.

1.6 Operation Interfaces

1.6.1 Regular Setting












Regular Setting

Hospital Info Setting

Hospital info setting includes basic information of the hospital, department and doctor described below:

■ Hospital Info

AUTO CHEMISTRY ANALYZER

 Status
  Samp. Req.
  Run
  Stop
  Results
  Reagent
  Calibrat.
  Q.C
  Setting
  Mainten.
  Help

Hospital Info User Manage. Test Setup Print Setup

Hospital Info Department Info Physician Info

Hospital Name:
 Code:
 Director:
 Tele:
 Web Site:
 Addr:
 Remark:

1) Implication of Parameters

Parameter	Implication	Operation
Hospital	Name of the hospital	Enter in the field directly
Head of the Hospital	Head of the hospital	Enter in the field directly
Tel	Telephone No. of the hospital	Enter in the field directly
url	Hospital url	Enter in the field directly
Number of Staff	Number of staff in the hospital	Enter in the field directly
Number of Departments	Number of departments in the hospital	Enter in the field directly
Remarks	Additional information	Enter in the field directly

2) Sequence of Operation

Revise Hospital Info

- 1 Click "Revise" button;
- 2 Enter the required info in the fields for the parameters;

3

Click “Save” to keep the change or "Cancel" if you do not want to save it.

■ Department Info

The screenshot shows the 'AUTO CHEMISTRY ANALYZER' software interface. At the top, there is a toolbar with icons for Status, Samp. Req., Run, Stop, Results, Reagent, Calibrat., Q. C., Setting, Mainten., and Help. Below the toolbar are four buttons: Hospital Info, User Manage., Test Setup, and Print Setup. The 'Hospital Info' button is selected, and within it, the 'Department Info' tab is active. The 'Department Info Editor' section contains fields for No., Name, Director, and Tele., along with a Remark text area. Below this is the 'Department Detail' section, which is a table with columns: No, Department, Director, Tele, and Remark. The table is currently empty. At the bottom of the interface are five buttons: New, Modify, Delete, Cancel, and Save.

1) Implication of Parameters

Parameter	Implication	Operation
No.	No. of the department	Enter in the field directly
Department	Name of the department	Enter in the field directly
Head of Department	Head of the department	Enter in the field directly
Number of Staff	Number of staff in the department	Enter in the field directly
Tel	Telephone No. of the department	Enter in the field directly
Remarks	Additional information	Enter in the field directly

2) Sequence of Operation

Create Department Info

- 1 Click “Create” button;
- 2 Enter the required info in the fields for the parameters;

- Click “Save” button.

Revise Department Info

- Select the department in the list;
- Click “Revise” button;
- Enter the required info in the fields for the parameters;
- Click “Save” to keep the change or "Cancel" if you do not want to save it.

Delete Department Info

- Select the department in the list;
- Click “Delete” button;
- To delete the department, Click “Yes”; otherwise, click "No".

■ Doctor Info

[illegible]

- ### 1) Implication of Parameters

Parameter	Implication	Operation
Select Department	Select the department	Select from pull-down menu
No.	No. of the doctor	Enter in the field directly
Name	Name of the doctor	Enter in the field directly
Title	Title of the doctor	Enter in the field directly
Tel	Telephone No. of the doctor	Enter in the field directly
e-mail	e-mail of the doctor	Enter in the field directly
Add	Add of the doctor	Enter in the field directly
Remarks	Additional information	Enter in the field directly

2) Sequence of Operation

Create Doctor Info

- 1 Select department from the pull-down menu
- 2 Click “Create” button;
- 3 Enter the required info in the fields for the parameters;
- 4 Click “Save” button.

Revise Doctor Info

- 1 Select department from the pull-down menu
- 2 Select the doctor in the list;
- 3 Click “Revise” button;
- 4 Enter the required info in the fields for the parameters;
- 5 Click “Save” to keep the change or "Cancel" if you do not want to save it.

Delete Doctor Info

- 1 Select department from the pull-down menu
- 2 Select the doctor in the list;
- 3 Click “Delete” button;
- 4 To delete the doctor, Click “Yes”; otherwise, click "No".

User Access Control

User access control includes management and setting of user access described below:

■ User Management

AUTO CHEMISTRY ANALYZER

Status
 Samp. Req.
 Run
 Stop
 Results
 Reagent
 Calibrat.
 Q. C
 Setting
 Mainten.
 Help

Hospital Info
 User Manage.
 Test Setup
 Print Setup

Password Editor
 User Management
 Permission
 Workload statist

User Info Editor

User: Name:
 Password: Confirm Pswd:
 Working Tele: Mobile:
 Remark:

User Info

User	Name	Password	Department	Tele	Remark
AAA	AA	***		AA	

1) Implication of Parameters

Parameter	Implication	Operation
Username	Username to log in with	Enter in the field directly
Name	Name of the user	Enter in the field directly
Department	Department of the user	Enter in the field directly
Tel	Telephone No. of the user	Enter in the field directly
Access Code	Access Code to log in with	Enter in the field directly
Confirm Access Code	Confirm the access code to log in with	Enter in the field directly
Remarks	Additional information	Enter in the field directly

2) Sequence of Operation

Create User Info

- 1 Click "Create" button;
- 2 Enter the required info in the fields for the parameters;
- 3 Click "Save" button.

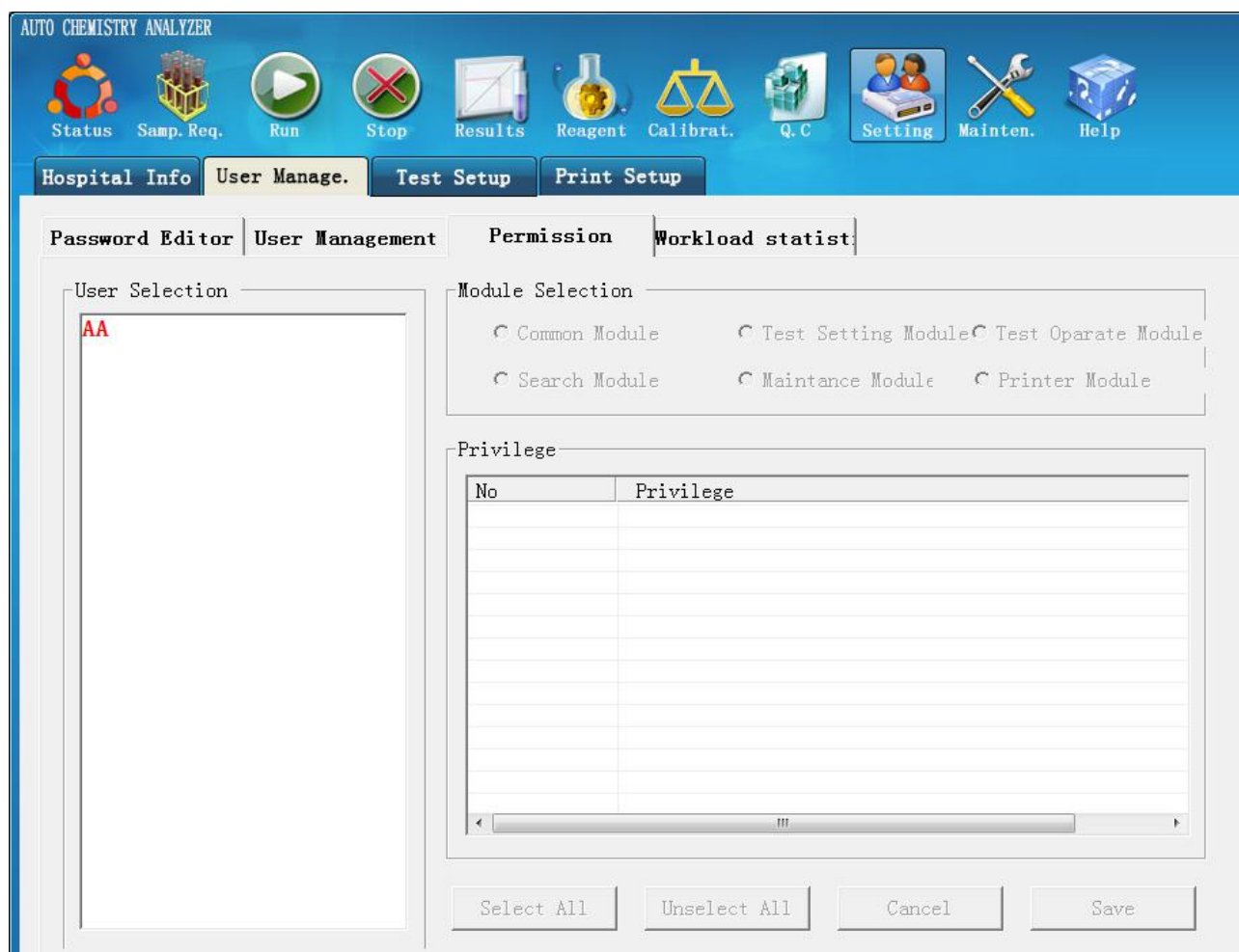
Revise User Info

- 1 Click ">> "or" <<" until the user to revise appears on the interface;
- 2 Click "Revise" button;
- 3 Enter the required info in the fields for the parameters;
- 4 Click "Save" to keep the change or "Cancel" if you do not want to save it.

Delete User Info

- 1 Click ">> "or" <<" until the user you want to delete appears on the interface;
- 2 Click "Delete" button;
- 3 To delete the doctor, Click "Yes"; otherwise, click "No."

■ User Access Control



1) Implication of Parameters

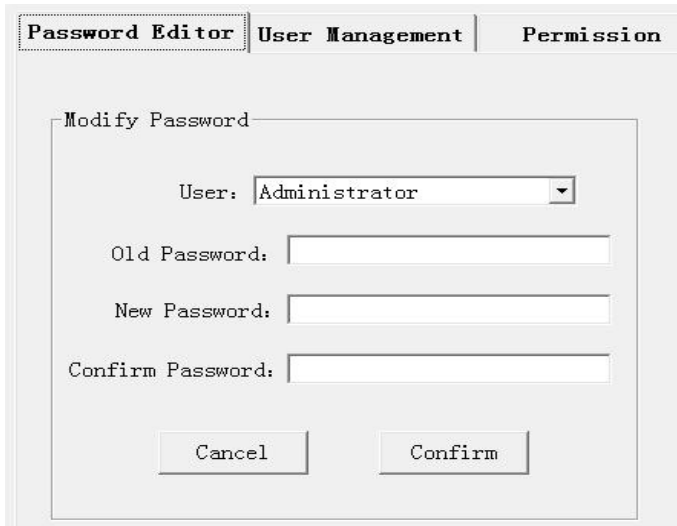
Parameter	Implication	Operation
User Name	User name to log in	Click ">> "or" <<" to display
Name	Name of the user	Click ">> "or" <<" to display

2) Sequence of Operation

User Access Control

- 1 Click ">>" or "<<" until the user to revise access for appears on the interface;
- 2 Set the rank at regular setup group;
- 3 Switch bookmark to other setup group to set the corresponding rank;
- 4 Click "Save" to keep the change or "Cancel" if you do not want to save it.

Change Access Code



1) Implication of Parameters

Parameter	Implication	Operation
User Name	User name to log in	Select a user name from the pull-down menu
Old Access Code	Access code to log in with	Enter in the field directly
New Access Code	Access code to change to	Enter in the field directly
Confirm Access Code	Confirm access code to change to	Enter in the field directly

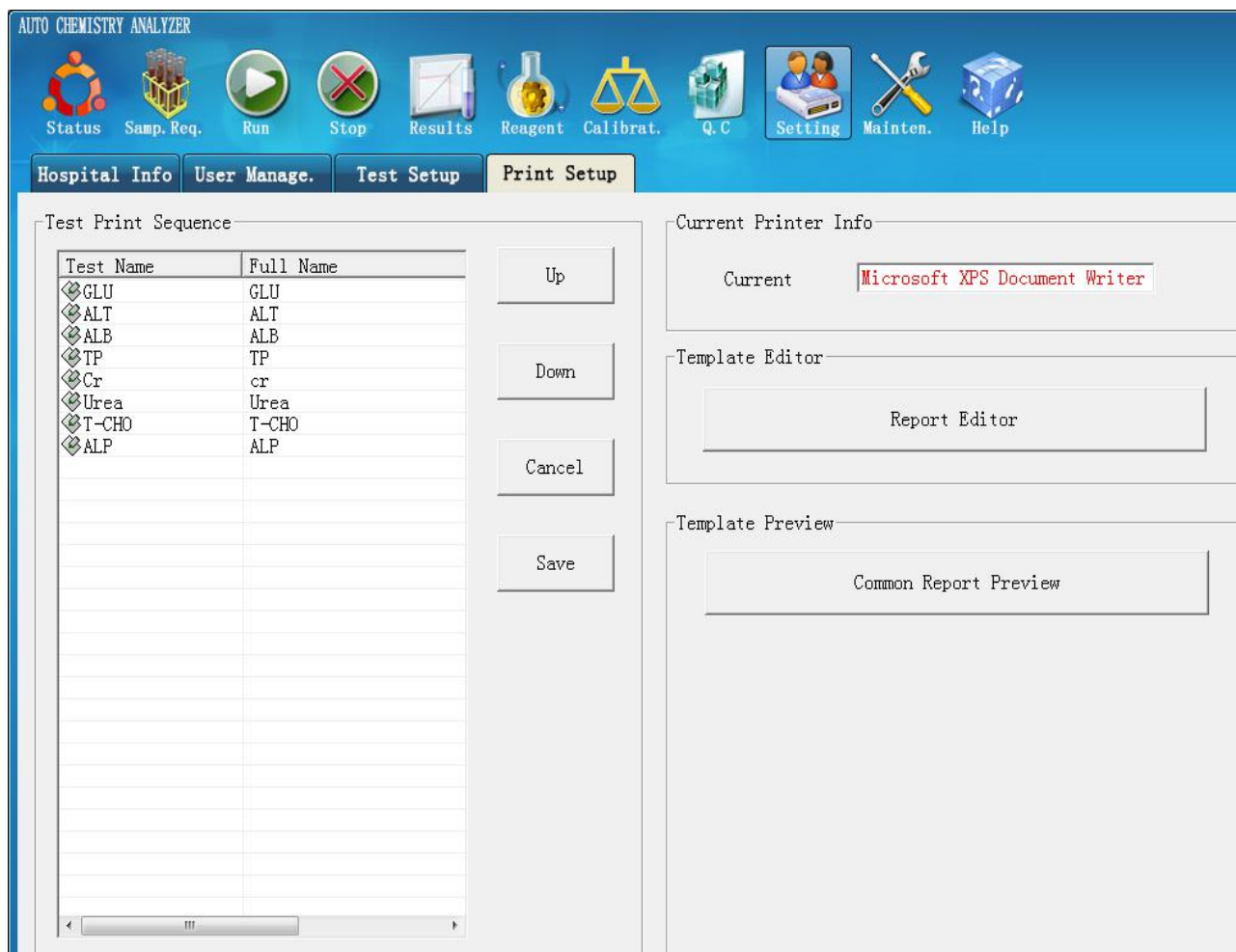
2) Sequence of Operation

Change Access Code

- 1 Select user name from the pull-down menu to change access code;
- 2 Enter the access code to log in with in the field;
- 3 Enter new access code in the field;
- 4 Enter new access code in the field to confirm new access code;
- 5 Click "Save" to keep the change or "Cancel" if you do not want to save it.

Print sequence of item

Item setting includes sequence of print calculate-items on report list.



(1) Sequence of basic operation

The sequence of print item will move forward.

- 1 To move the selected item.
- 2 Click "forward" button, the print projects sequence of a mobile in the future, continue to click on the "forward" until the project has set the print order.
- 3 Click button "OK" button to set up. Otherwise, click "Cancel" button.

The sequence of print item will move back.

- 1 To move the selected item.
- 2 Click button "move back" button, the print projects sequence of a mobile in the future, continue to click on the "move back" until the project has set the print order.
- 3 Click button "OK" button to set up. Otherwise, click "Cancel" button.

Unit of the Item

1) Implication of Parameters

Parameter	Implication	Operation
Unit	Name of the unit	Enter in the field directly
Remarks	Additional info	Enter in the field directly

2) Sequence of Operation

Create Unit for an Item

- 1 Click “Create” button;
- 2 Enter the corresponding info in the field;
- 3 Click “Save” button.

Revise Unit of the Item

- 1 Select the unit of the item to be revised in the list;
- 2 Click “Revise” button;
- 3 Enter the corresponding info in the field;
- 4 Click “Save” to keep the change or “Cancel” if you do not want to save it.

Delete a Unit

- 1 Select the unit of the item to be revised in the list;
- 2 Click “Delete” button;
- 3 To delete the unit of the item, Click “Yes”; otherwise, click “No.”

1.6.2 Assay Setting

Assay Setting

Item Parameters

AUTO CHEMISTRY ANALYZER

Status
 Samp. Req.
 Run
 Stop
 Results
 Reagent
 Calibrat.
 Q.C
 Setting
 Mainten.
 Help

Para. Setup Reagent Setup Calc. Test Profile

Test List

- GLU
- ALT
- ALB
- TP
- Cr
- Urea
- T-CHO
- ALP

Parameter

TestNo: Abbreviate: TestName:

Unit: ... N of Decimal: Method:

React. Slope: Wavelength. 1: Wavelength. 2:

Sample Vol.: (2--30) R1 Vol.: (150--300) R2 Vol.: (20--150)

Measuring Pt.: -- Samp. Blank: -- Reag. Blank OD: --

Ref. Range: -- ... Linear Rng: -- Prozone Chk. ☐ -- PC

Linearity%: Substrate Exhau.:

Calib.

Calib. Method:

Linearity: k: b: C = R/K

Correction Factor: Slope: Interception:

1) Implication of Parameters

Parameter	Implication	Operation
Item No.	Item No.	Generated by system and can't be changed
English Abbreviation	English abbreviation of the item	Enter in the field directly
Chinese Name	Chinese name of the item	Enter in the field directly
Decimal Places	Decimal places after round off	Select 0, 1, 2 or 3 from the drop-down list
Unit of Result	Unit of the result	Select from the drop-down list
Unit Setting	Set the unit of the item	Click to show the interface for unit of the item

	on-board	
Assay Type	Set the assay type of the item	Select Point End, Dichromatic and Kinetic from the drop-down list
Reaction Direction	Direction change of absorbence in the reaction	Select Up or Down from the drop-down list
Wavelengths	Main wavelength of the assay	Select from the drop-down list
Reference Wavelength	Sub-wavelength of the assay	Select among the remaining wavelengths from the drop-down list
Sample Volume	Sample volume for regular assay measured by μl	Enter in the field directly within the range of 2-30 and step by 0.1
More	Set sample volume for different types of condensation and dilution	Click to show the interface and enter in the field directly
1st Reagent	The first reagent for the assay measured by μl	Enter in the field directly within the range of 150-300 and step by 1
2nd Reagent	The second reagent for the assay measured by μl	Enter in the field directly within the range of 20-150 and step by 1
Reaction Time	Starting point for optical measurement	Enter in the fields directly, the first with L and the second with M, then the follow must be satisfied: (1)End point of single agent $1 \leq L < 6 \leq M \leq 41$ (2)End point of double agent $5 \leq L < 11 \leq M \leq 41$ (3)Bichromatic and Kinetic for single reagent $6 \leq L < M \leq 41$ (4)Bichromatic and Kinetic for dual reagent $11 \leq L < M \leq 41$
Help Info	Display the implication and time interval of the points	Click to display:
Calibration	Set the calibration type of the item	Select linear, Logit-4P, Logit-5P, Exponential-5P, Polynominal-5P, spline or factor from drop-down list. If a factor is selected, enter the actual value in the field.
Set parameters for calibration	If factor is not selected for the calibration type,	Click to show the interface: Enter the parameters in the fields.

curve	this button shall appear. After clicking it, the parameters can be entered.	
Slope a	Calibrate the result according to $y=ax+b$, in which x is the result of the assay, y is the result after calibration, a is the slope in the calibration formula and b is the intercept.	Enter the actual values in the fields. The default is 1.
Intercept b		Enter the actual values in the fields. The default is 0.
Linearity Limit of Reaction Curve	Make judgment on the linearity of the reaction curve	Enter integral values between 0-100
Substrate Exhaust Limit	The exhaust limit set for substrate obtained by absorbance multiplied by 10000.	Enter integral values between 0-40000
Prezone Inspection	Set whether the prezone inspection should be conducted, and set the starting point and limit of the prezone inspection. Prezone inspection is limited to End Point.	Check the box for prezone inspection; The three fields shall be enabled. The first field shows the starting time N, the second field shows the ending time P and the third field shows the limit PC. N&P must satisfy the following in relation to reaction time L&M: End point of single agent $1 \leq L < 6 \leq N < P < M \leq 41$ End point of double agent $6 \leq L < 11 \leq N < P < M \leq 41$ PC is an integral value between 0-100
Scope of Reference	Enter the default scope of reference	Enter the actual values in the two fields
Details	Click to enter scope of reference for sex, sample and age	Click to show the interface: Create Scope of Reference (1) Select sex and sample type from drop-down list (2) Click “Create” button to enter the range of age and scope of reference;

		(3) Click “Save” button. Revise Scope of Reference (1) Select the scope of reference to be revised from the list; (2) Click “Create” button to revise the range of age and scope of reference; (3) Click “Save” button. Delete Scope of Reference (1) Select the scope of reference to be deleted from the list; (2) Click “Delete” button; (3) Click “Yes” button.
Linearity range	Enter the linearity range of the item	Enter the actual values in the two fields
Reaction Range	Enter the reaction range	Enter the actual values in the two fields within the range of 0-40000
Absorbance Range of the 1st Reagent	Enter the absorbance range of the 1st reagent	Enter the actual values in the two fields within the range of 0-40000
Absorbance Range of Liquid	Enter the absorbance range of liquid	Enter the actual values in the two fields within the range of 0-40000

2) Sequence of Operation

Create Parameter

- 1 Click “Create” button;
- 2 Enter or select the corresponding item for the parameters;
- 3 Click “Save” to keep the change or “Cancel” if you do not want to save it.

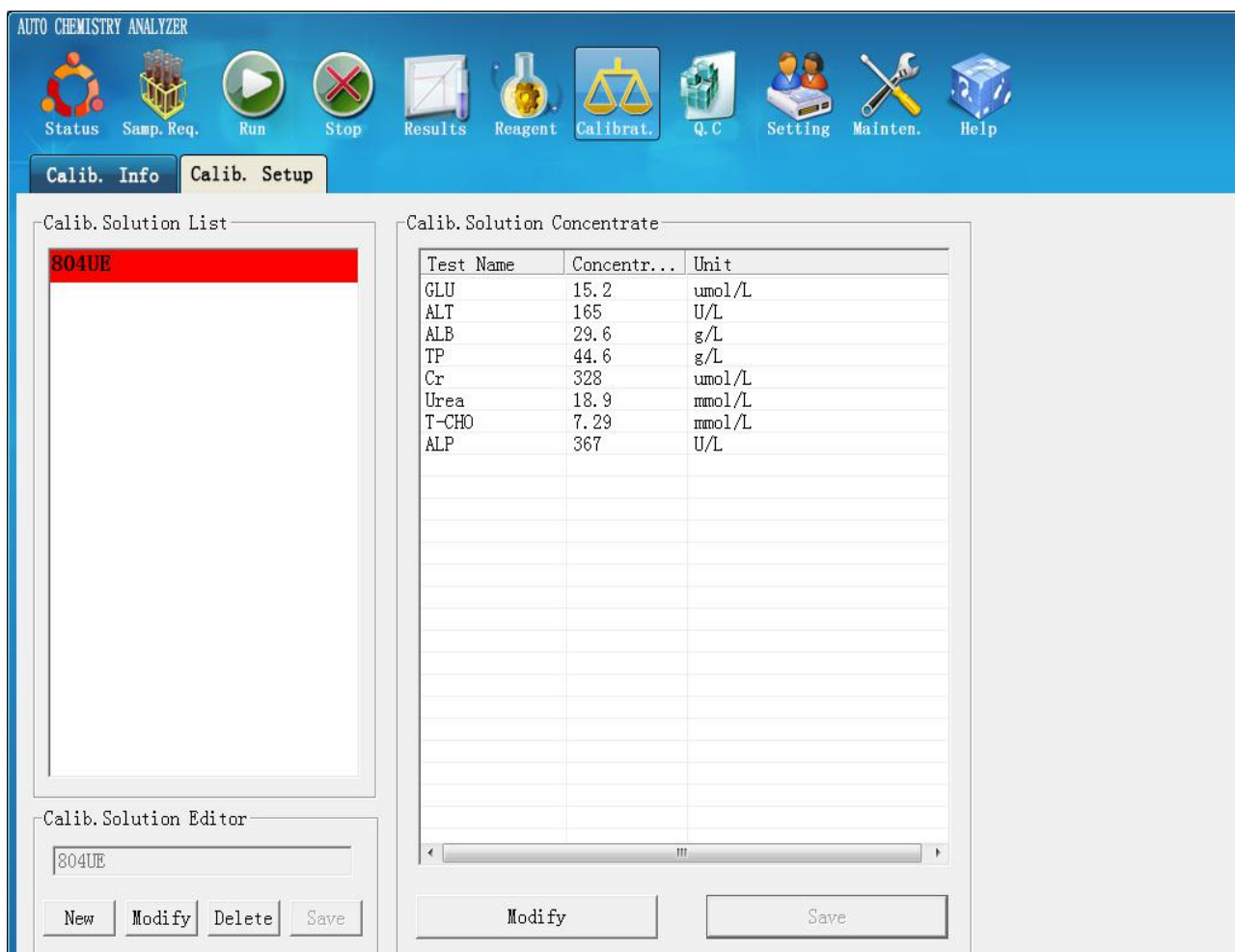
Revise Parameter

- 1 Click the item to be revised;
- 2 Click “Revise” button;
- 3 Enter or select the corresponding item for the parameters;
Click “Save” to keep the change or “Cancel” if you do not want to save it.

Delete Parameter

- 1 Click the item to be deleted;
- 2 Click “Delete” button;
- 3 To delete the doctor, Click “Yes”; otherwise, click “No.”

Calibration Setting



1) Implication of Parameters

Parameter	Implication	Operation
Calibrator	Enter the name of calibrator	Enter in the field directly
Position of Calibration Disc	Set the position of calibrator in the calibration disc	Click the relative position on the left calibration disc
Density	Set the density of the calibrator for the items	Enter in the field directly

2) Sequence of Operation

Create Calibrator

- 1 Click "Create" button;
- 2 Enter the corresponding items in the fields;
- 3 Click "Save" to keep the change or "Cancel" if you do not want to save it.

Revise Calibrator

- 1 Click the calibrator to be revised;

- ## Delete Calibrator

- ## QC Setting

1) Implication of Parameters

22

Standard Deviation	Set standard deviation of the controller	Enter in the field directly
Accumulation and Control Rules	Set the accumulation and control rules of the item	Select from the drop-down list

2) Sequence of Operation

Create Controller

- 1 Click “Create” button;
- 2 Enter the corresponding items in the fields;
- 3 Click “Save” to keep the change or “Cancel” if you do not want to save it.

Revise Controller

- 1 Click the controller to be revised;
- 2 Click “Revise” button;
- 3 Enter or select the corresponding items in the fields;
- 4 Click “Save” to keep the change or “Cancel” if you do not want to save it.

Delete Controller

- 1 Click the controller to be deleted;
- 2 Click “Delete” button;
- 3 To delete the controller, Click “Yes”; otherwise, click “No.”

Calculation

1) Implication of Parameters

Parameter	Implication	Operation
English Abbreviation	English abbreviation of the calculation item	Enter in the field directly
Chinese Name	Chinese name of the calculation item	Enter in the field directly
Unit of Result	Unit of the calculation result	Select from the drop-down list or leave it
Decimal Places	Decimal places for the calculation items	Select 0, 1, 2 or 3 from the drop-down list
Scope of Reference	Enter the default scope of reference	Enter the actual value in the two fields
Details	Click to enter scope of reference for sex, sample and age	Click to show the interface: Create scope of reference (1) Select sex and sample type from drop-down list (2) Click “Create” button to enter the range of age and scope of reference;

		<p>(3) Click “Save” button.</p> <p>Revise Scope of Reference</p> <p>(1) Select the scope of reference to be revised from the list;</p> <p>(2) Click “Create” button to revise the range of age and scope of reference;</p> <p>(3) Click “Save” button.</p> <p>Delete Scope of Reference</p> <p>(1) Select the scope of reference to be deleted from the list;</p> <p>(2) Click “Delete” button;</p> <p>To delete the scope of reference, Click “Yes”; otherwise, click “No.”</p>
--	--	--

2) Sequence of Operation

Create Calculation Item

- 1 Click “Create” button;
- 2 Enter or select the corresponding items in the fields;
- 3 Click item, value and symbol in the selection area to make an expression for the calculation item;
- 4 Click “Save” to keep the change or “Cancel” if you do not want to save it.

Revise Calculation Item

- 1 Select a calculation item to be revised in the display area for the calculation items;
- 2 Click “Revise” button;
- 3 Enter or select the corresponding items in the fields;
- 4 To change the expression, click “Reconstruct” button to re-enter the expression;
- 5 Click “Save” to keep the change or “Cancel” if you do not want to save it.

Delete Calculation Item

- 1 Select a calculation item to be deleted in the display area for the calculation items;
- 2 Click “Delete” button;
- 3 To delete the calculation item, Click “Yes”; otherwise, click “No.”

1.6.3 Statistics/Search

History Search

Search history assay result of normal sample

AUTO CHEMISTRY ANALYZER

Status
 Samp. Req.
 Run
 Stop
 Results
 Reagent
 Calibrat.
 Q.C
 Setting
 Mainten.
 Help

Results Now **History**

Sample Query **Test Query**

Condition
 Date: 2015/ 8/ 1 -- 2016/ 8/ 9
 Name: Sample No:
 Ward No: Barcode:
 Department: Physician:

Sample List

Date	Em...	Samp. No	Name	Sex	Age
<input type="checkbox"/> 2015-08-21 ...	0	1			0
<input checked="" type="checkbox"/> 2015-08-21 ...	0	2			0
<input type="checkbox"/> 2015-08-21 ...	0	3			0
<input type="checkbox"/> 2015-08-21 ...	0	4			0
<input type="checkbox"/> 2015-08-21 ...	0	5			0
<input type="checkbox"/> 2015-08-21 ...	0	6			0
<input type="checkbox"/> 2015-08-21 ...	0	1			0
<input type="checkbox"/> 2015-08-21 ...	0	2			0
<input type="checkbox"/> 2015-08-21 ...	0	3			0
<input type="checkbox"/> 2015-08-21 ...	0	4			0
<input type="checkbox"/> 2015-08-21 ...	0	5			0

Search Modify Preview Export LIS Data

Test List

Test Name	Samp. No	Result	Unit	Ref. Range
GLU	2	5.17	umol/L	3.89--6.11
ALT	2	116	U/L	5--40
ALB	2	28	g/L	35--55
TP	2	35	g/L	60--83
Cr	2	14	umol/L	66--99
Urea	2	4.8	mmol/L	1.7--8.3
T-CHO	2	3.4	mmol/L	2.3--5.7
ALP	2	217	U/L	0--0

(1)Basic explanation of parameter.

Parameter	signification	Operation
Date Determine	To search the starting date of sample	Input in the pane directly or choose down frame
Sample No.	To search the starting No. of sample	Input in the pane directly
Sample consistence	To search the thickness area of sample	Input in the pane directly
Patient name	To search the patient name of sample	Input in the pane directly
Patient sex	To search the patient sex of sample	Choose down frame
Patient age	To search the patient age of sample	Input in the pane directly
Unit age	To search the unit age of sample	Choose down frame
No.	To search the No. of sample	Input in the pane directly

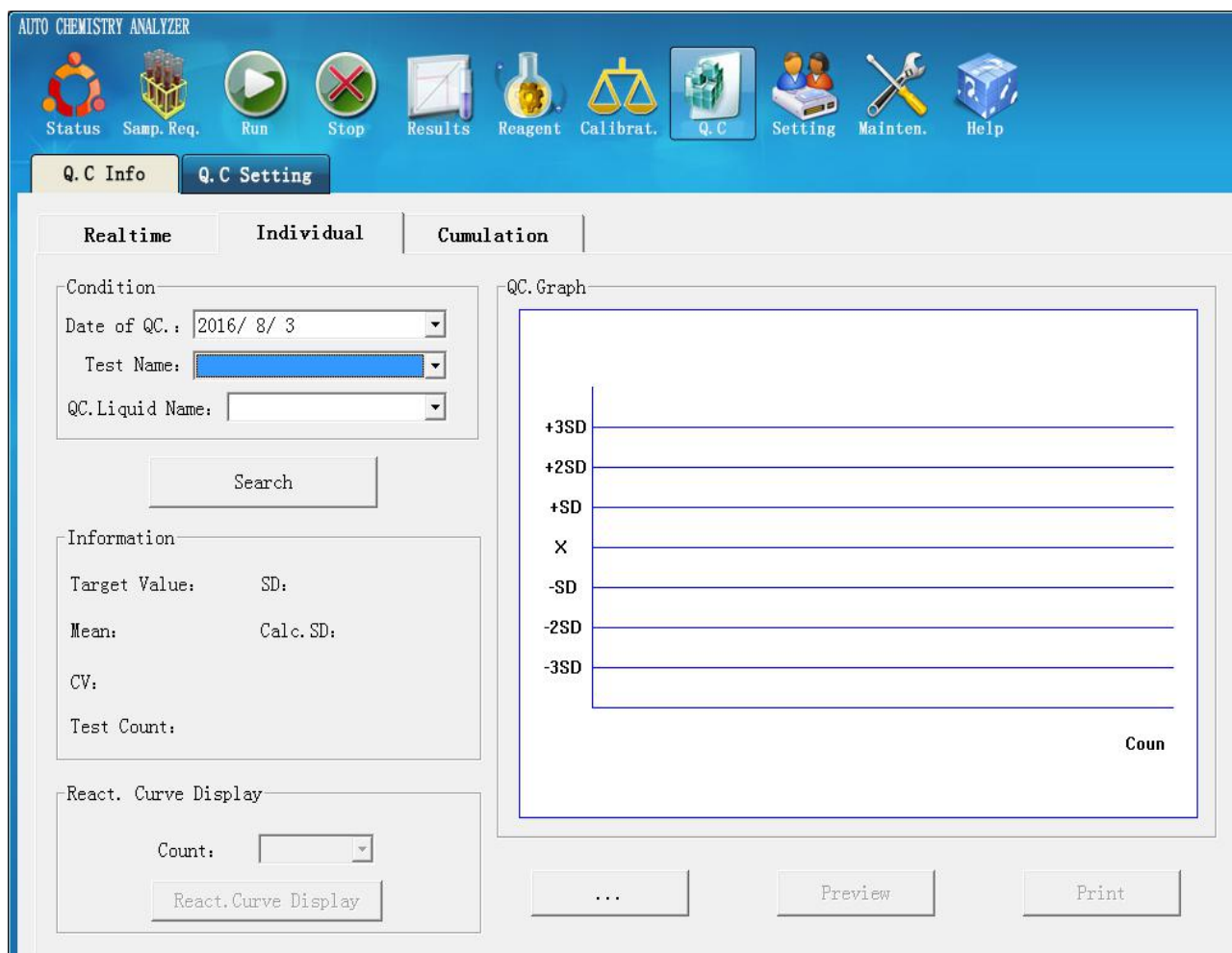
No. in Hospital	To search the No. in hospital of sample	Input in the pane directly
Sickbed No.	To search the sickbed No. of sample	Input in the pane directly
Check Doctor	To search the check doctor of sample	Input in the pane directly
Test Doctor	To search the test doctor of sample	Choose down frame
Sample ID	To search the mark No. of sample	Input in the pane directly

(2)Sequece of basic operation

- 1 Input and choose one or more search condition in the input area of query condition.
- 2 Choose one or more item in the choice area of query item.
- 3 Click "Search" button.
- 4 All the conditions of records will be showed on the areas with the inquiry.
- 5 Select a particular query record, click "reaction curve" button, can view the record of real-time reaction curve.
- 6 If only to search at the same time,the button "distribute map" to activate and can click to see all the records of the inquiries map at the same time.
- 7 Click "RETURN" button to return to main operation interface.

QC Search

Search QC status and QC map of each item,as follows:



Look over QC status:

- 1 Select type of QC search among real-time QC, QC for the Day and QC for Days in selection area;
- 2 Select the time period and item for the search;
- 3 Click "Search" to show all controllers in the controller display area and QC status in the status display area;
- 4 Click "Details" to show all the controller and all assay results in the selected period;
- 5 Click "Multi-rule QC Diagram", "Accumulation and QC Diagram" and "Twin Plot" to show the corresponding QC diagram during the time period;
- 6 Click "Print" button to print the corresponding QC diagram and data;
- 7 Click "Curve to Printer" button to print the corresponding QC diagram;
- 8 Click "RETURN" button to close QC status interface and return to main interface.

Calibration Search

AUTO CHEMISTRY ANALYZER

Status
 Samp. Req.
 Run
 Stop
 Results
 Reagent
 Calibrat.
 Q.C
 Setting
 Mainten.
 Help

Calib. Info Calib. Setup

Calibration Test List

GLU	ALT	ALB	TP	Cr	Urea
T-CHO	ALP				

Date

2016/ 8/ 9 - 2016/ 8/ 9 ☒ Ignore Time

Results

Date	Test Name	Full Name	Calib.Type	Factor	Active	Edited	Remark

Search Set Active Detail

1) Sequence of Operation

Search Calibration of Item

- 1 Select the starting date from date column;
- 2 Select an item to search. Click once to select and again to cancel;
- 3 Click "Search" to show all the matching records in the display area on the right;
- 4 Select a calibration record in the display area to view the details;
- 5 Click "Details" button to show the detailed information in the new interface;
- 6 To print a calibration record, select it and click "Print" button;
- 7 To set a calibration record as current record, select it and click "Set to Current" so that the later samples added to this item shall refer to this record for calculation of density;

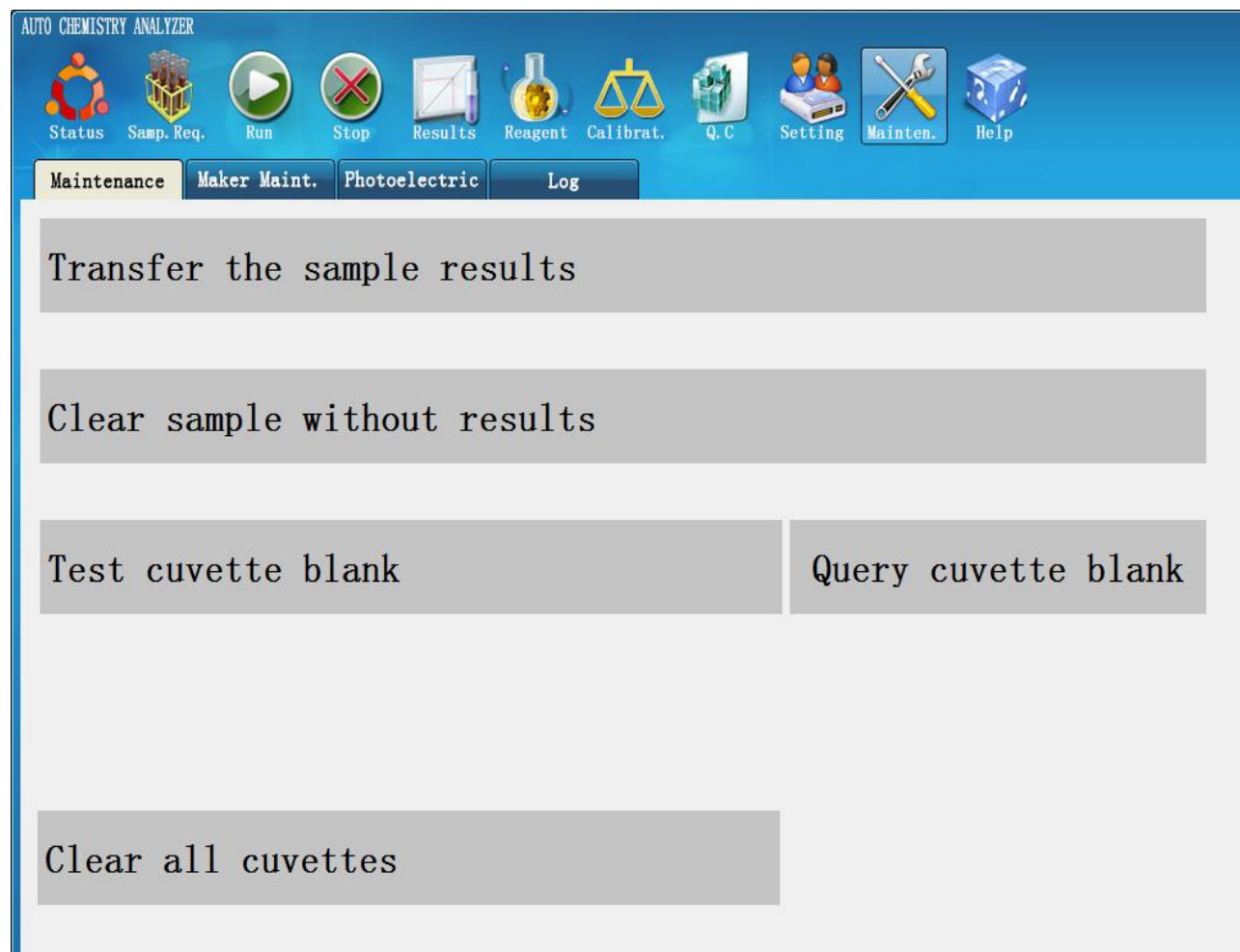
Workload

1.6.4 Maintenance

Maintenance

Maintenance is performed for main control unit, sample probe unit, mixer unit, reaction disc photoelectric unit and temperature control unit described as follows:

■ Main Control Unit

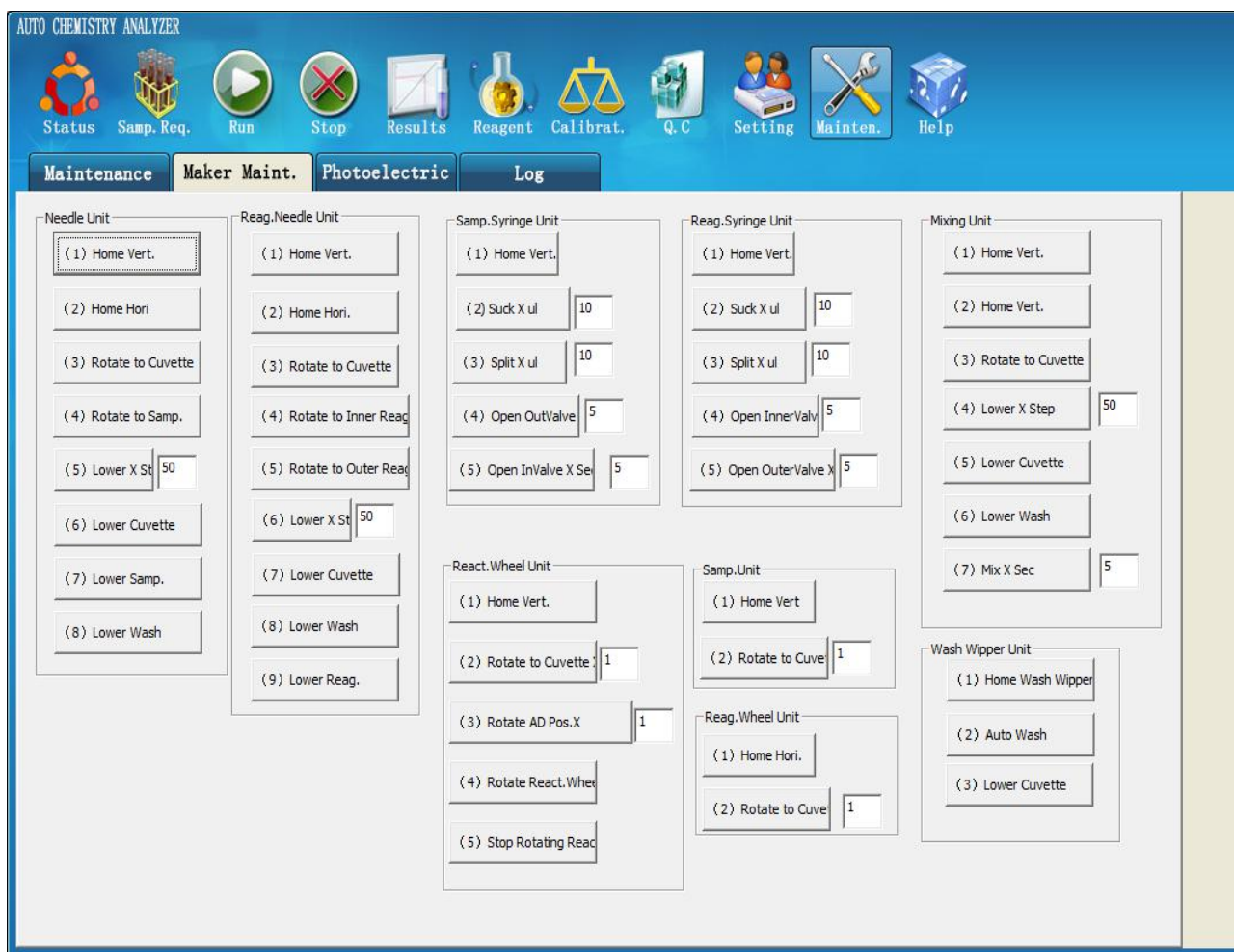


Description on Maintenance Action	
Handshaking	Handshaking between PC and chips of the units
Self Inspection for Auto Distribution	Reset of moving parts by steps
Cycle Assay Instruction	Give instruction for each assay

Sequence of Operation	
1	Select an instruction on the left and click "Send";
2	To perform circulation delivery, select "Circulation Delivery", enter the time interval and number of

loop, then click "Send" button;

■ Mixer Unit

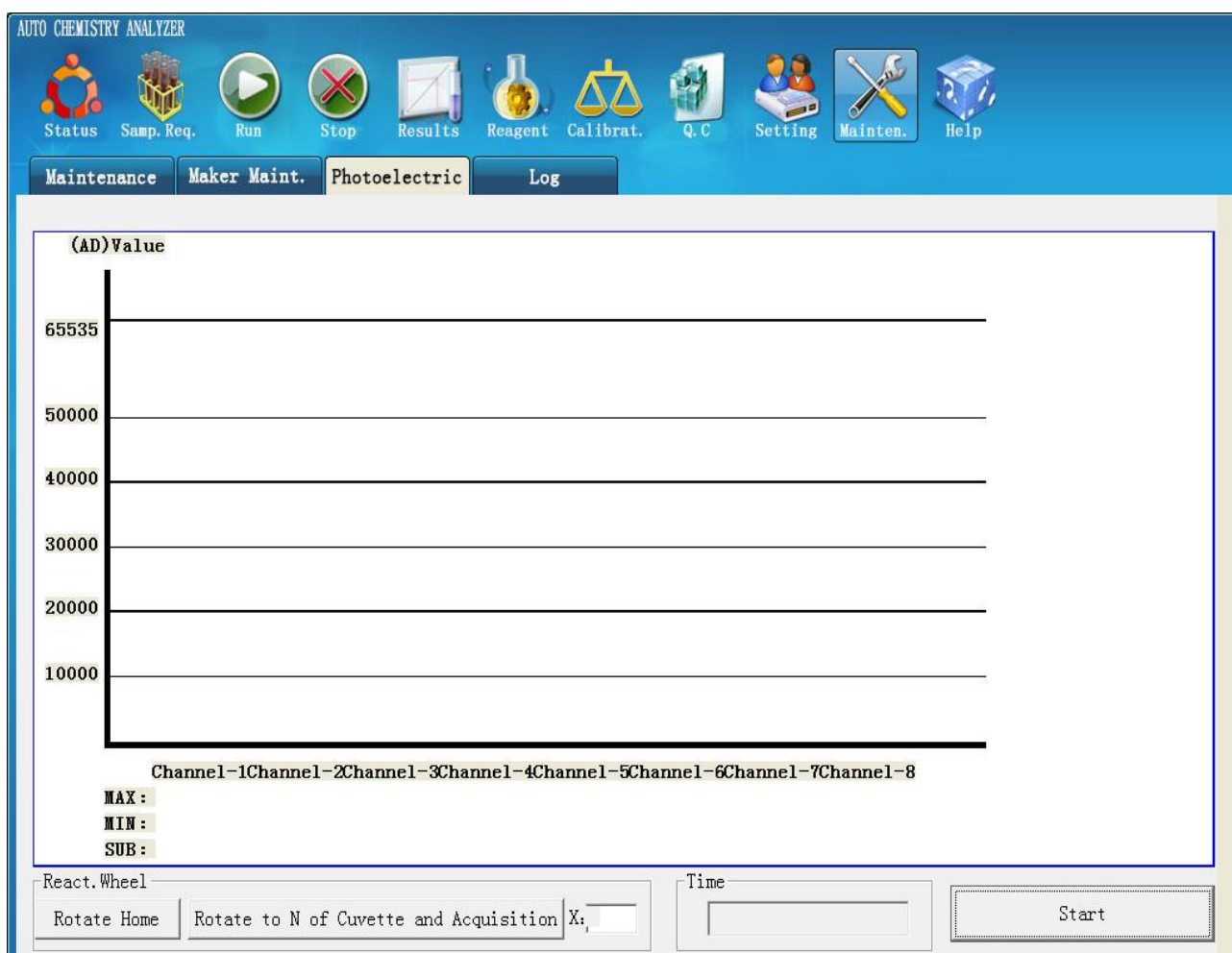


Description on Maintenance Action	
Handshaking	Handshaking between PC and main control unit, mixer chip
Vertical Resetting Instruction	Mixer returns to initial vertical position.
Rotate Resetting Instruction	Mixer stops at wash cup position after finds initial position of the rotate position.
Horizontal Return of Mixer	Mixer moves to initial position in horizontal position.
Horizontal Rotate of Mixer to Wash cup position	Mixer moves to washing position in horizontal position.
Horizontal Rotate of Mixer to Mixing Position at Reaction Disc	Mixer moves to mixing position in horizontal position.

Rotating of Mixer to Initial Position at Vertical Direction	Mixer rotates to initial position at vertical direction.
Moving of Mixer down to Wash cup position	Mixer lowers to wash cup position.
Lowering of Mixer down to Reaction Glass	Mixer lowers down to reaction glass.
Lowering of Mixer by Certain Steps	Mixer lowers by defined steps.
Lowering of Mixer to Reaction Glass (Return after Mixing)	Mixer lowers to reaction glass and returns to initial position in vertical direction after mixing.
Stir Permanently	Turn on mixing motor.
Stir for a Period	Run mixing motor till preset time.
Open Pump Permanently (Wash Outer Wall of Mixer)	Turn on pump.
Open Pump for a Period (Wash Outer Wall of Mixer)	Run pump till the defined time.

Sequence of Operation	
1	Select an instruction on the left and click "Send";
2	To perform circulation delivery, select "Circulation Delivery", enter the time interval and number of loop, then click "Send" button;

■ Reaction Disc Photoelectric Unit

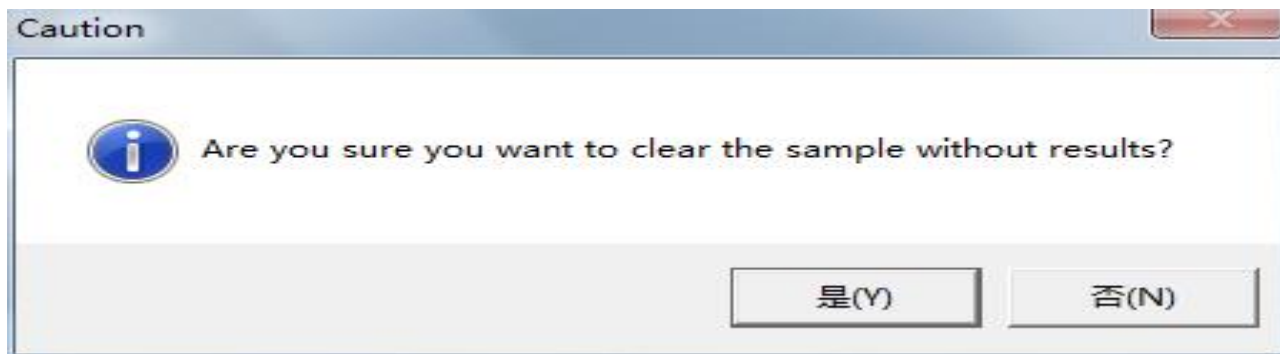


Description on Maintenance Action	
Handshaking	Handshaking between PC and main control unit, Reaction Disc Photoelectric Unit
Rotate Resetting	Reaction disc stops at No. 1 cuvette position through initial position.
Reaction Disc Rotates to Defined Cuvette Position through Initial Position	Reaction disc rotates to defined cuvette position through initial position.
Reaction Disc Rotates to Defined Cuvette Position Directly	Reaction disc rotates to defined cuvette position directly.
Reaction Disc Rotates by Defined Number of Cuvette Positions	Reaction disc rotates to defined number of cuvette positions from the present position.
Reaction Disc Rotates to Static Collection Cuvette Position	Reaction disc rotates to defined cuvette position for photoelectric collection.
Static Collection of AD Value	Static collection of AD value.
Rotate Reaction Disc Directly	Reaction disc rotate directly.
Stop Reaction Disc in Rotation	Reaction disc stops in rotation.

Sequence of Operation	
1	Select an instruction on the left and click "Send";
2	To perform circulation delivery, select "Circulation Delivery", enter the time interval and number of loop, then click "Send" button;

Clear Samples without Results

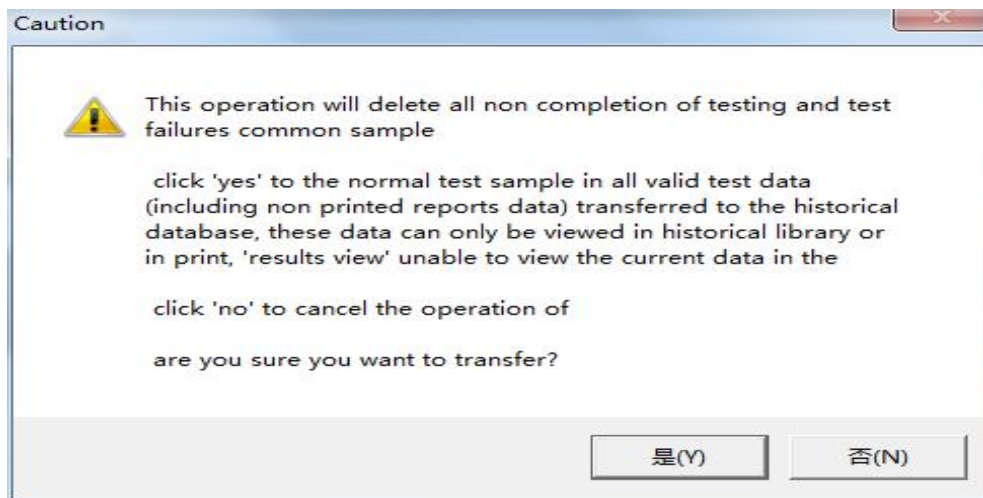
To clear the sample record applied but without result, click the menu to show the following interface:



Click "Yes (Y)" to clear corresponding records; or click "No (N)" to return to home page without clearing the records.

Transfer Assay Data to History

To transfer sample record to history, click to show the following box:



Click "Yes (Y)" to transfer the corresponding records; or click "No (N)" to return to home page without transferring the records.

1.6.5 Shortcut Button

Shortcut Button

Calibration Application

1) Sequence of Operation

Calibration Application	
1	Select an item in the selection area on the left. Click once to select and again to cancel.
2	Select one more calibrators from the calibration application on the left with reference to the calibrator type below.
3	For the calibration of more than one item, repeat Step 1 & Step 2 until all the items to be calibrated are selected.
4	Click "Apply" button.
5	Click "Calibration Application List" to view the details of the application list.
6	Click "Calibrator Setup" to set the calibrators.

Array Application


The application for the array of regular sample and QC sample is done in the following interface:

1) Implication of Parameters

Parameter	Implication	Operation
Sample No.	Sample No.	Enter in the field directly
Batch Entry	Batch entry of the same item	Enter the number of samples in the batch.
Sample No.	Select sample No. in the 4 discs	Select one from pull-down menu
Cuvette Position	Select one of the ten cuvette positions in a disc	Enter in the field directly, or click "View Remaining Positions" and select
View Remaining Positions	View the remaining positions on the current disc	Click to show interface. Select an empty position and click "OK" button
Sample Type	Select sample type	Select one from the drop-down list
STAT	Set the current sample as STAT	Check the box to set to STAT

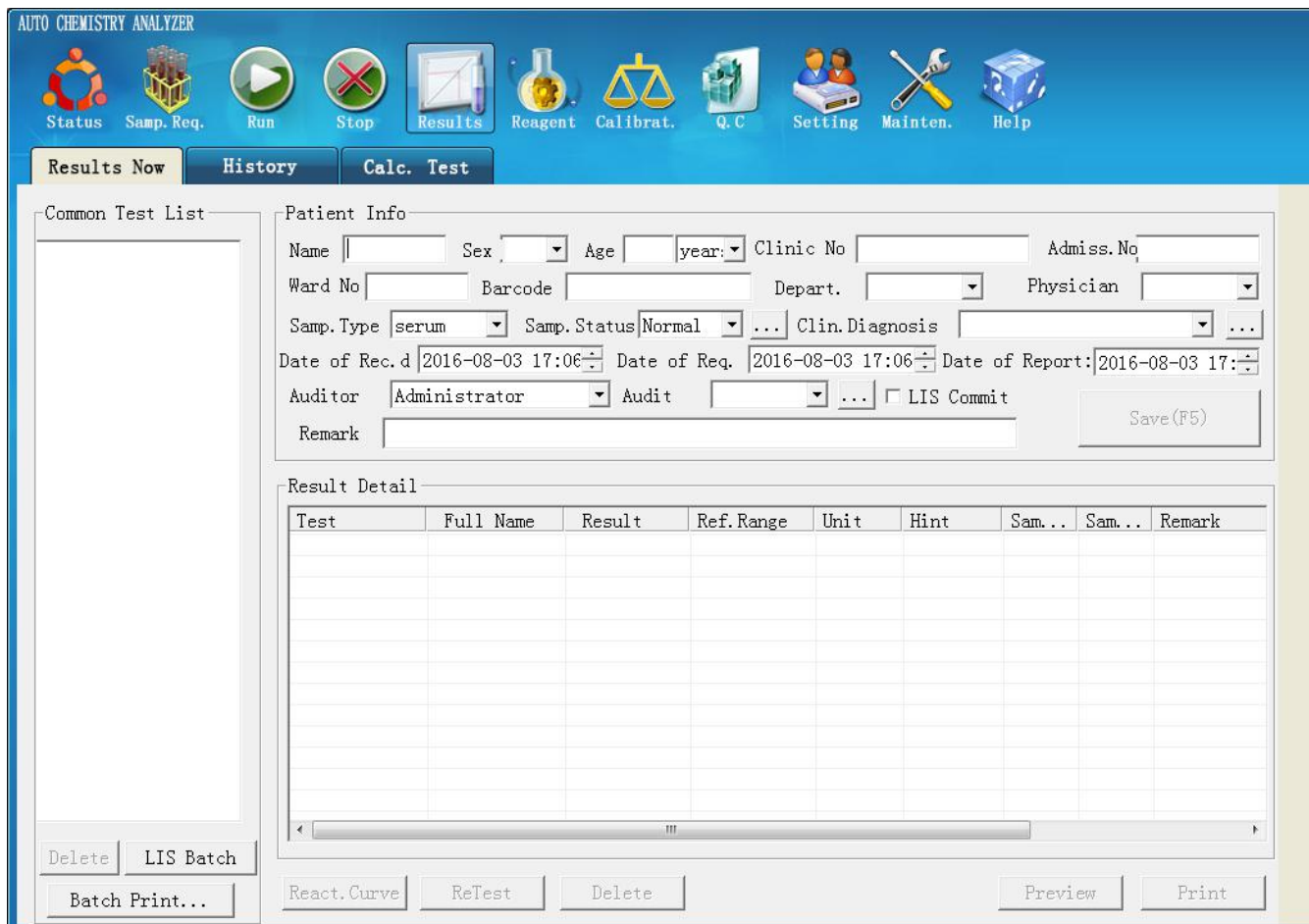
2) Sequence of Operation

Apply for Single Sample	
1	Enter Number of Sample
2	Select sample disc No., cuvette position and sample type.
3	In case of STAT array, check the box.
4	Select an item in the selection area on the left. Click once to select and again to cancel. Or select a portfolio in the portfolio area. Click once to select and again to cancel. To set a portfolio on-board, click "Set Portfolio" and work on the new interface.
5	Click "Apply" button.
Batch Application	
1	Enter the number of the sample to start and the number of samples in the batch.
2	Select sample disc No., cuvette position and sample type.

3	Select an item in the selection area on the left. Click once to select and again to cancel. Or select a portfolio in the portfolio area. Click once to select and again to cancel. To set a portfolio on-board, click "Set Portfolio" and work on the new interface.
4	Click "Apply" button.
	Note:
	<p>(1) For batch application, set the sample No. and the position on sample disc in the sequence of the starting sample No. and starting position.</p> <p>(2) Batch application and single application can be done at the same time.</p>

View Result

With this function, you can view the results of all the regular assays and QC assays, as shown below:



1) Implication of Parameters

Parameter	Implication	Operation
Name	Name of the patient	Enter in the field directly

Sex	Sex of the patient	Select one from pull-down menu
Age	Age of the patient	Enter in the first field and select from pull-down menu in the second field.
OPD Number	OPD Number of the patient	Enter in the field directly
Admission Number	Admission Number of the patient	Enter in the field directly
Department	Department of the patient	Enter the code or the department in the field directly
Bed Number	Select the bed number of the patient	Enter in the field directly
Clinical Diagnosis	Clinical diagnosis of the patient	Select one from pull-down menu, or Enter in the field directly
Doctor	Doctor who authorizes the assay for the patient	Enter the code or the name of the doctor in the field directly
Time	Time to deliver the sample	Click to select or enter directly
Sample Type	Sample type	Select one from pull-down menu
Sample Status	Sample status	Select one from pull-down menu
Approved by	Person who approves the assay	Select one from pull-down menu
Remarks	Special information of the sample	Enter in the field directly
Delete	Delete the information and related item of a regular sample that is not under test.	Click to show the interface and click "OK."
Delete All	Delete the information and related item of all regular samples that are not under test.	Click to show the interface and click "OK."

2) Sequence of Operation

View Current Result

- 1 Select a sample number in the display area on the left to view its result.
- 2 Results of all the selected samples can be displayed on the lower part on the right column. If an assay is not yet completed, the display area of the item shall be empty.
- 3 Click "Reaction Curve" for an item with result, the reaction curve and reaction data can be displayed.

Enter Patient Info

- 1 Select a sample number in the display area on the left to view the patient info.
- 2 Enter the related information on the upper part of the right column and click "Save" button.
- 3 To enter the information for the next patient, switch to another sample number and repeat Step 1 & Step 2.

Set Printing Template

- 1 Click "Printing Template" button to enter a new interface.
- 2 Select a template, or create a template and set as default.

Print Result

- 1 To print all the results, check "All Samples" and click "Print" button.
- 2 To print results for the selected samples, check "All Selected Samples" and click "Print" button.
- 3 To print results for a specified sample, check "Selected Sample", enter the number directly in the activated field and click "Print" button.

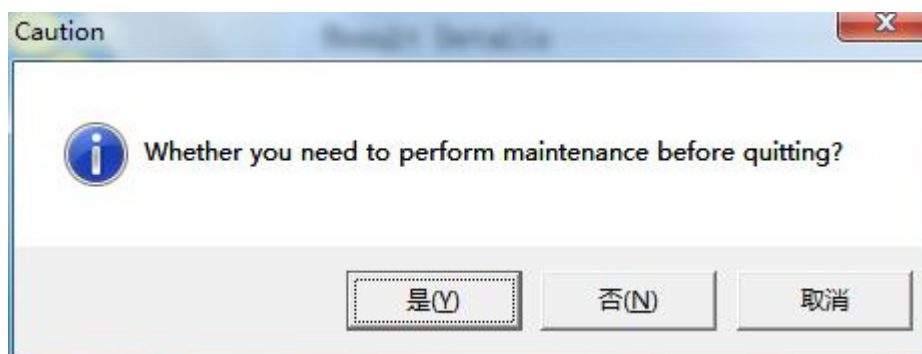
Stop

This function shall stop all the assays that are in process. It can be performed only when the user requests to do so.

Click "OK" to stop the analyzer at once. If you do not want to stop it, click "Return" button.

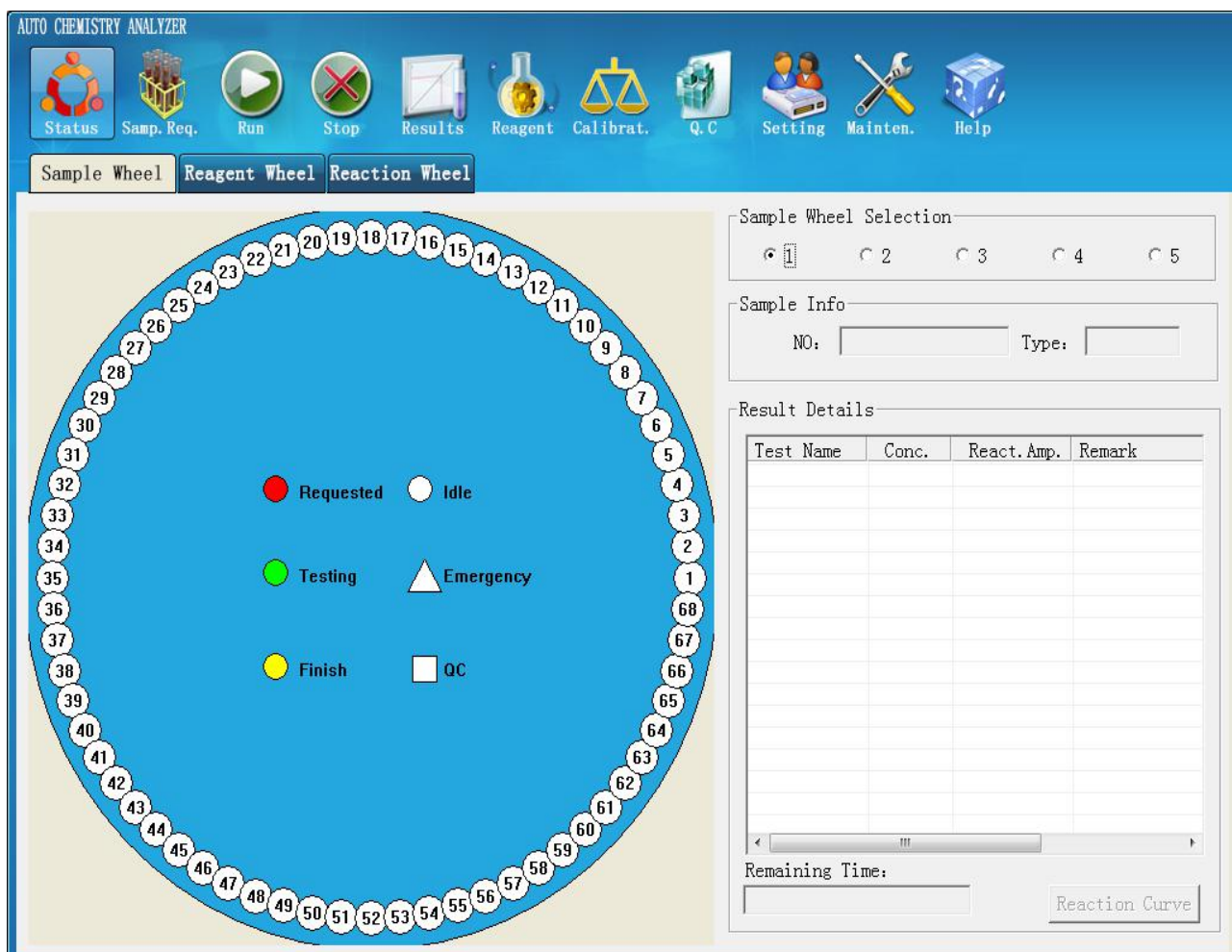
Exit

Exit from the system can only be performed when the analyzer is at standby mode.



Sample Disc

The application status of samples on the sample discs and calibration disc can be view as in the following diagram:

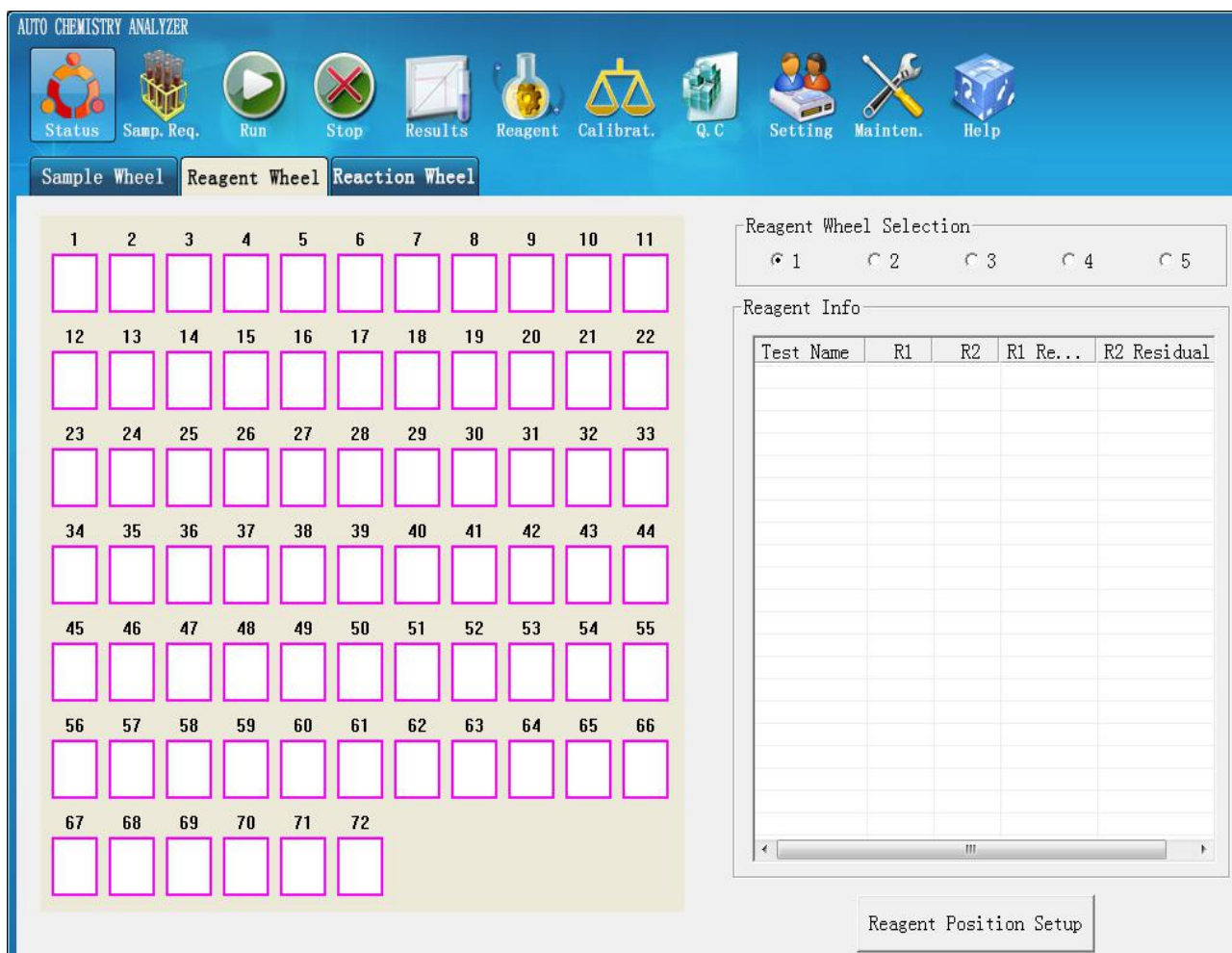


View Sample Disc Status

- 1 The status of the samples on the disc can be viewed by switching the bookmark
- 2 The different type and status can be shown by different shape and colors in the display area.
- 3 After selecting a sample on the disc, show the number and type of the sample in the display area on the right. Show all the applied items and the status of the sample on the display area. The time to take for the assay is displayed on the estimated time area.
- 4 Select a completed item in the display area, click "Reaction Curve of Complete Item" to view the reaction curve and reaction data.
- 5 Click "Return" to close the sample disc interface and go back to home page.

Reagent Disc

This function allows you to view and set the position and volume of the reagent on the reagent discs and test the remaining volume at standby mode, as in the following diagram:



View Reagent Disc Status

Set Reagent Position

Change Reagent Position

Delete Reagent Position

- 2
- Click a reagent on the disc to delete position, and click "Delete Reagent Position" on the right to delete the reagent position.

Test Remaining Volume of Reagent

- 1
- Switch bookmark to the reagent disc needed.
- 2
- Click "Test Remaining Volume" button to show a new interface. Select the reagent to test remaining volume, and Click "OK" button.

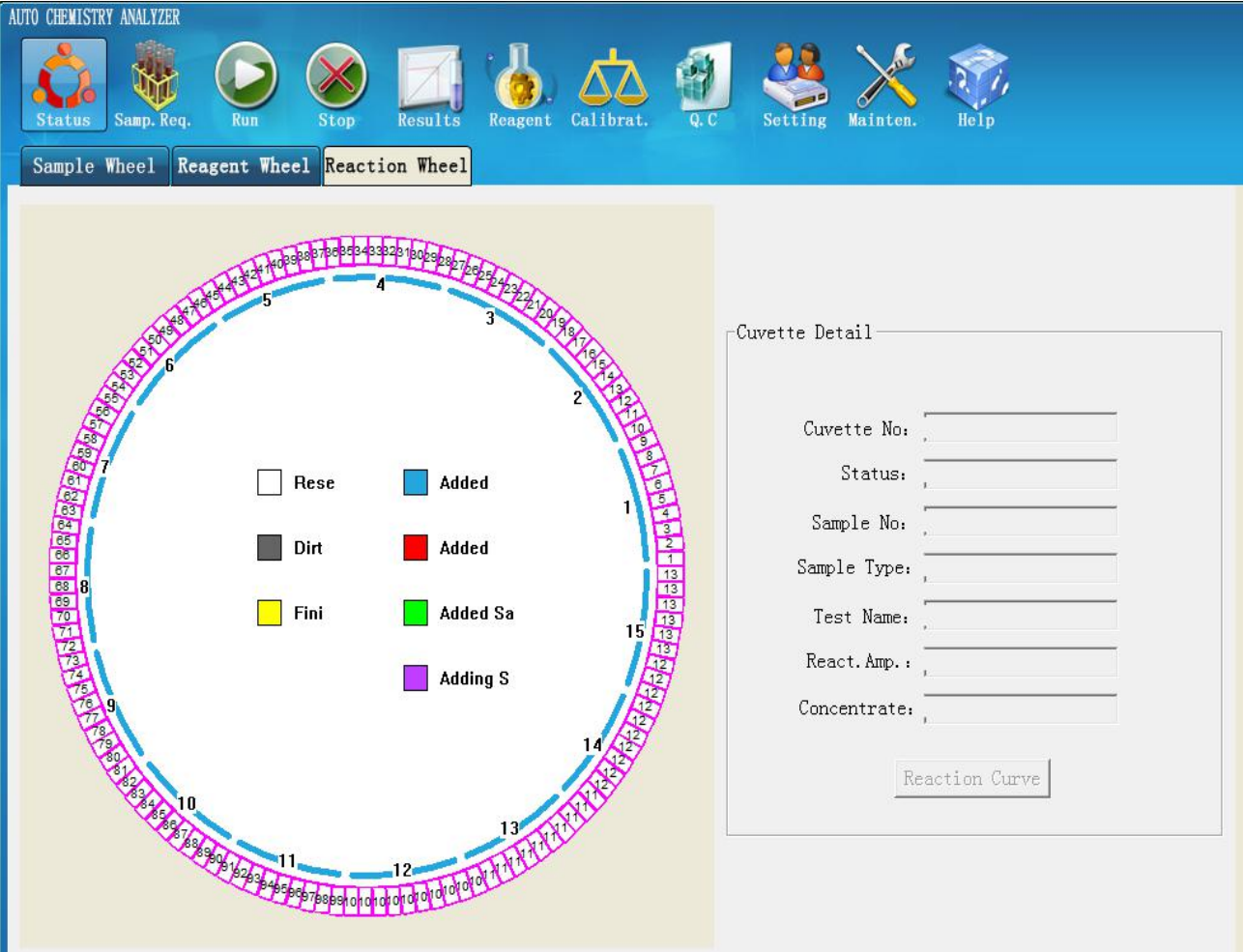


Note:

- (1)
- For dual reagent item, R1 and R2 must be placed on the same reagent disc.
- (2)
- Remaining volume can only be tested at standby mode.

Reaction Disc

The item and status of the items for the cuvette can be viewed as in the following diagram:



View Reaction Disc Status

- 1
- The status of the items for the cuvette is shown by different colors in the display area on the left.

1.7.3 Assay Type

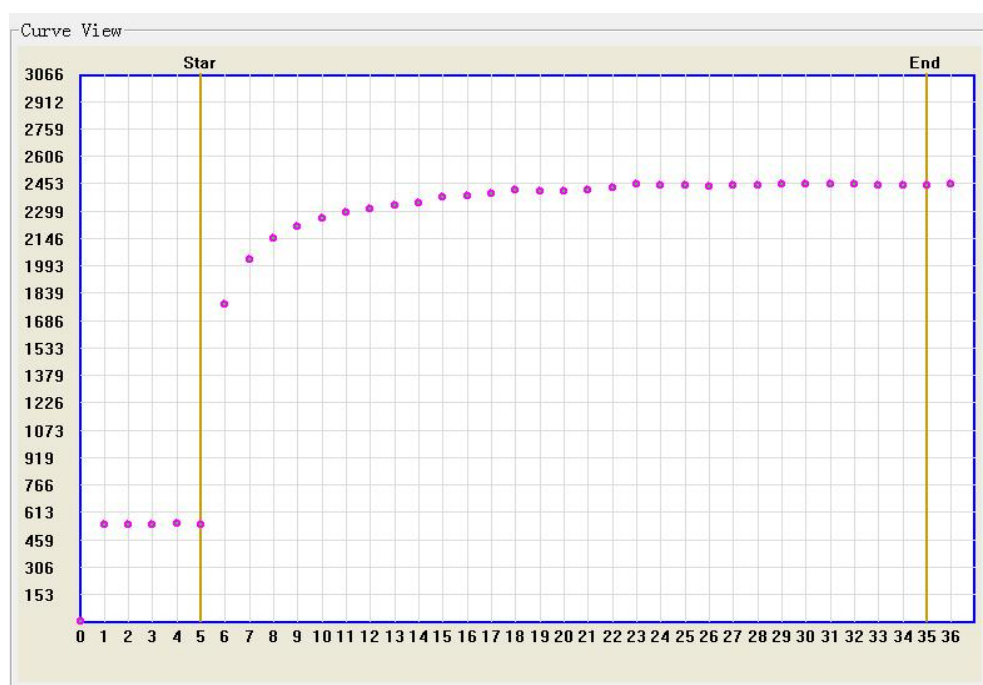
Assay Type

The reaction processes are categorized according to the characteristic of reaction speed. The three types are End-point, Dichromatic and Kinetic, as described below:

End-point

Reaction is carried out thoroughly and all the measured substances are monitored. The absorbance of the reaction liquid does not increase (or decrease). The increase (or decrease) of absorbance before and after the reaction is in direct proportion with the initial density of the measured substance.

Typical curve of an end-point reaction is shown in the following diagram:



Dichromatic

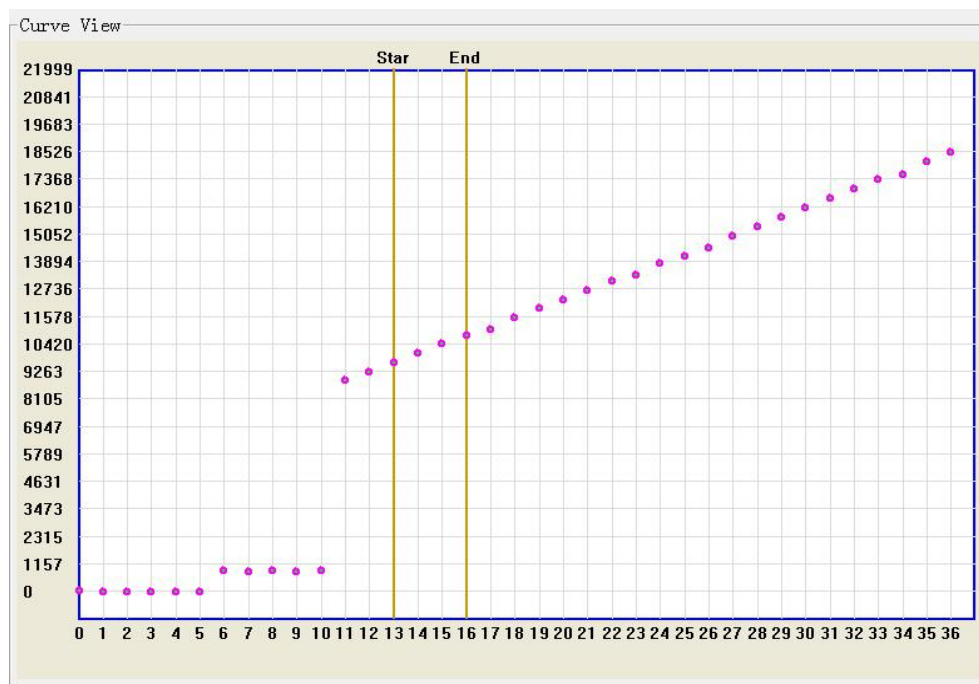
In the specific segment, reaction speed is in proportion to first power of the density of measured substance. In view of the continuous consumption of the measured substance, the reaction speed shall reduce and the speed for the increase (or decrease) of the absorbance ($\Delta A/t$) shall slow down. At this period of time, the increase (or decrease) of the absorbance shall be in proportion to the initial density of the measured substance.

Typical curve of a Dichromatic reaction is shown in the following diagram:

Kinetic

In the specific reaction period, when reaction speed is kept at the maximum (V_{max}), monitored substance is evenly generated at the top speed. This will be shown by the even decrease or increase of the absorbance ($\Delta A/t$), which is in proportion to activity or density of the measured substance for the measurement of enzyme activity.

Typical curve of a Kinetic reaction is shown in the following diagram:



1.7.4 Absorbance and Reaction Amplitude

Absorbance and Reaction Amplitude

Absorbance

Absorbance is calculated in the following formula:

$$\text{Solution Absorbance} = \text{Log} (\text{AD}_{\text{Empty}} - \text{AD}_{\text{Dark}}) / (\text{AD}_{\text{Solution}} - \text{AD}_{\text{Dark}})$$

In which,

- 1) "Log" is the common logarithm on the base number of 10.
- 2) "AD" is the value of the transmission density after photoelectric conversion and digital and analogue conversion.
- 3) AD Dark stands for AD value when light is off; AD Empty stands for AD value when the cuvette is empty; AD Solution stands for AD value when cuvette is full.

Reaction Amplitude

Reaction amplitude is defined as the change or rate of change of absorbance between the starting points of the reaction. Reaction amplitude is an intermediate data essential in the calculation process. For different assay type, the calculation is done in different ways, as described below:

- 1) End-point

$$\text{Reaction Amplitude} = \text{End-point Absorbance} - (\text{Starting-point Absorbance} * \text{Volume Correction Factor})$$

In which,

- End point and starting point are set by user at "Time Calculation" under "Item Parameters."
- For single wavelength, the absorbance is the absorbance of the main wavelength; for double wavelength, the absorbance of each point is the absorbance of the main wavelength minus the absorbance of the secondary wavelength.
- Volume Correction Factor = Start-point Volume / End-point Volume.

- 2) Dichromatic

$$\text{Reaction Amplitude} = \text{End-point Absorbance} - \text{Starting-point Absorbance}$$

In which,

- End point and starting point are set by user at "Time Calculation" under "Item Parameters."
- For single wavelength, the absorbance is the absorbance of the main wavelength; for double wavelength, the absorbance of each point is the absorbance of the main wavelength minus the absorbance of the secondary wavelength.

3) Kinetic

Reaction Amplitude=Absorbance Change between Starting-point and End-point

In which,

- End point and starting point are set by user at "Time Calculation" under "Item Parameters."
- For single wavelength, the absorbance is the absorbance of the main wavelength; for double wavelength, the absorbance of each point is the absorbance of the main wavelength minus the absorbance of the secondary wavelength.

1.7.5 Calibration

Calibration

Calibration Type

Calibration is divided into linear and non-linear calibration. Linear calibration, including single-point, two-point and multi-point calibration, is applicable to items with solution as reaction liquid. Non-linear calibration, including Logit-4P, Logit-5P and Spline, is applicable to items with suspension as reaction liquid, such as immune turbidimetric items.

Calibration Parameters

The number of parameters and calculation for different types of assays are different, as shown in the following.

1) Single Point Linear Calibration

$C=R/k$, with k as the only calibration parameter.

$$k= R_{Calibration}/C_{Calibration}$$

In which, C Calibration stands for the density of the standard and R Calibration stands for the reaction amplitude of the standard.

2) Double Point Linear Calibration

$C=(R-b)/k$, with k and b as the two calibration parameters.

$$k= (R_2-R_1)/(C_2-C_1)$$

$$b= R_1- C_1(C_2-C_1)/(R_2-R_1)$$

In which C_1 and C_2 stand for the density of Standard 1 & 2 and R_1 and R_2 stand for the reaction amplitude of Standard 1 & 2.

3) Multi-point Linear Calibration

$C=(R-b)/k$, with k and b as the two calibration parameters.

Calibration parameters are calculated according to multi-point linear regression.

4) Logit-4P

$R=R_0+K/[1+e^{(-a+b\ln C)}]$, with R_0 , K , a and b as the four calibration parameters. At least four standards are required, including the first one with density (activity) at zero, and corresponding R at R_0 . Other parameters are obtained through iteration procedure.

5) Logit-5P

$R=R_0+K/[1+e^{(-a+blnC+c*C)}]$, with R_0 , K , a , b and c as the five calibration parameters. At least five standards are required, including the first one with density (activity) at zero, and corresponding R at R_0 . Other parameters are obtained through iteration procedure.

6) Spline

$C-C_i=R_0i+a_i(C-C_i)+b_i(C-C_i)^2+c_i(C-C_i)^3-R$, with R_0i , a_i , b_i , and c_i as the $4i$ calibration parameters. At least two standards are required. Parameters at the segments are obtained through iteration procedure.

1.7.6 Density Calculation

When the assay type of all the items is Kinetic, calibration can be omitted. In this case, theoretic calculation factor F ,

- 1) whose density is reaction amplitude R multiplied by F , can be entered directly. For other types of assays, calibration must be done beforehand. The density can be calculated only after calibration parameters are obtained.
- 2) For linear calibration, Logit-4P or Polynomial-5P, density can be calculated with calibration parameters and reaction amplitude R .
- 3) For Logit-5P or Spline, density can be calculated with dichotomy to get positive real root according to reaction amplitude R and calibration parameters.

1.7.7 QC

QC

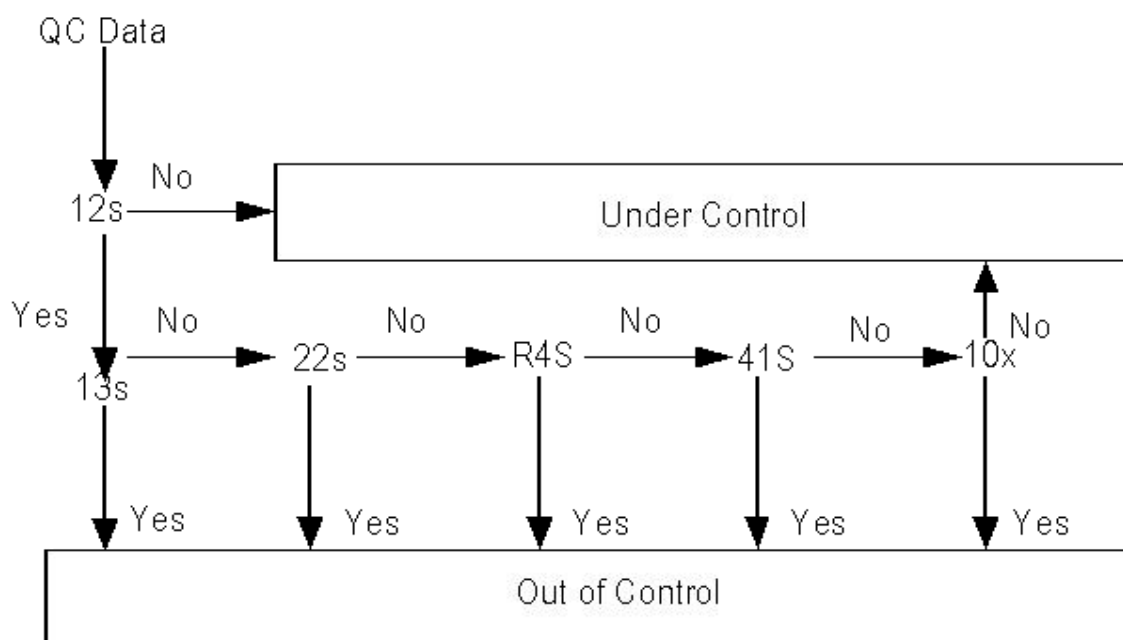
QC Rule

The default QC rule is West guard. Users can select one or more rules to determine the QC status for the different items according to the actual circumstance.

West guard multi-rule contains 10 sub-rules, which have the following meanings:

Symbol	Definition	QC Status
1_{2S}	A point falls beyond the average of +2SD or -2SD	Warning
1_{3S}	A point falls beyond the average of +3SD or -3SD	Out of control (random error and system error)
2_{2S}	Two points fall beyond the average of +2SD or -2SD.	Out of control (system error)
R_{4S}	The difference of two consecutive value is beyond 4SD.	Out of control (random error)
4_{1S}	Four consecutive points fall beyond the average of +1SD or -1SD.	Out of control (system error)
10_X	Ten consecutive points fall on the same side of the average value.	Out of control (system error)

The judgment on the sub-rules is shown in the following diagram:



QC Type

There are three types of QC, namely real-time QC, single-day QC and multi-day QC. The preset rules are used for the judgment of the status.

Real-time QC: Judgment made for 10 consecutive QC data within the day.

Single-day QC: Judgment made for all QC data within the day.

Multi-day QC: Judgment made for all QC data for several days.

QC Diagram

There are three types of QC diagrams, namely L-J, Accumulative and QC diagram, and Twin Plot.

1) L-J QC diagram

L-J QC diagram is done by using the actual QC data as the vertical coordinates, and drawing a horizontal line from QC target value. There are six lines, or +1SD (Standard difference, SD in short), +2SD, +3SD above -1SD, -2SD and -3SD, parallel with the average line. The value of the QC substance shall be marked on the diagram and connected with fine line.

2) Accumulative and QC Diagram

In this diagram, the accumulation of controller is calculated as the vertical coordinates, and the times of measurement is used as the horizontal coordinates. A horizontal line is drawn from zero to link to the control limit of accumulation h , which is calculated automatically according to the setup made by the user. Two lines parallel with the horizontal line are drawn and the accumulation each time is marked on the diagram and connected by the fine line. When a point is beyond the two horizontal lines, it is considered to be out of control.

1.7.8 Other Related Calculation

1) Calibration Sensitivity

Calibration sensitivity refers to the difference of reaction amplitude between calibrators with highest density and lowest density. If it is smaller than the preset value, it fails.

2) Blank Reaction Amplitude

Blank reaction amplitude refers to the reaction amplitude of calibrator with zero density. If it is smaller than the preset value, it fails.

3) Repeatability of Calibration

Repeatability of calibration refers to the difference between the maximum and minimum value in 3 measurements for the same controller. If it is bigger than the preset value, it fails.

4) SD of Calibration Curve

SD of calibration curve is only applicable to multi-point linear and non-linear calibration curve. It refers to the sum of squares of the difference between calibrator reaction amplitude (R) and reaction amplitude (R_i) according to the calculation of calibration curve.



Note:

Three measurements are taken for a calibrator. Cross out the one with the biggest deviation and work out the average of the other two. Therefore, n equals 2.

Exhaust of Substrate

Exhaust of Substrate is only applicable to Kinetic and Dichromatic. When some of the high-density (high-activity) sample is used up quickly, the reaction will no longer be the expected speed (Grade 0 or Grade 1. In order to show the result correctly, the exhaust of substrate should be determined in the following way:

1) Rising Reaction

When the amplitude of one or more points between starting and ending point is greater than the preset value, the substrate is exhausted.

2) Lowering Reaction

When the amplitude of one or more points between starting and ending point is smaller than the preset value, the substrate is exhausted.

Linearity Inspection

Linearity inspection is applicable to Kinetic. It is used to determine whether the linearity of the reaction curve satisfies the preset value between the starting and ending point according to the data from the measurement points. Specific calculation is as follows:

1) The number of measurement points between starting and ending point is more than 9.

Linearity = (Change of absorbance at the first 6 points - Change of absorbance at the last 6 points)/Change of absorbance at all points

2) The number of measurement points between starting and ending point is between 4 and 8.

Linearity = (Change of absorbance at the first 3 points - Change of absorbance at the last 3 points)/Change of absorbance at all points

3) Linearity is not calculated for the following situations.

- ◆ The number of measurement points is no more than 3.
- ◆ Change of absorbance is smaller than 0.006/m or the difference of absorbance change is smaller than 0.006/m.
- ◆ Reagent Blank Assay, Sample Blank Assay and Zero-density Calibrator Assay

Reaction Balance

Reaction balance is only applicable to End Point. It is used for determining if the balance of reaction is reached at the ending point according to the data at all the points. The specific calculation is as follows:

- 1) Calculate the difference between the ending points and three consecutive points following it.
- 2) If all the difference is smaller than 0.01, balance is reached. Otherwise, it is not reached.
- 3) If the ending point is greater than 38, reaction balance is not carried out.

1.8 Daily Maintenance

1.8.1 1 Tools

- 1) M3, M4 Hexagon Wrench
- 2) Stainless Steel Wire (Inner diameter at 0.3mm)
- 3) Plastic Syringe (Approx. 10ml, with no needle)
- 4) Clean Gauze
- 5) Clean Cotton Swab
- 6) Brush (for cleaning bucket)
- 7) Nonionic surfactant Detergent
- 8) 75% Alcohol
- 9) Disinfector
- 10) Surgical latex gloves

1.8.2 2 Daily Maintenance

2 Daily Maintenance

2.1 Clean Panel

Reagent, reaction liquid and serum dropped on the Panel should be cleaned in time. When turning off the analyzer, these steps should be followed:

- 1 Wipe the Panel with detergent placed on wet towel until all the stains are gone.
- 2 Wipe the Panel with disinfector placed on wet towel.
- 3 A quarter later, rinse wet towel and clean the Panel with it to remove the remaining disinfector on the Panel.



Warning: Corrosive

Disinfector is corrosive and should be handled with gloves on.



Warning: Biohazard

The Panel is treated as infectious and can only be touched when having gloves on.

2.2 Clean Sample Probe

The outer wall and tip of sample probe and the mixing part of the mixer can be attached with serum, reagent and water. Inspect carefully after shutting off the analyzer after use. In case of the above conditions, clean in the following way:

- 1 Move the sample probe to appropriate position.
- 2 Dip clean cotton swab in 75% alcohol and clean the tip gently until nothing is seen to attach to it.
- 3 Move the mixer to appropriate position.
- 4 Dip clean cotton swab in 75% alcohol and clean the flat part of the mixer gently until nothing is seen to attach to it.

2.3 Waste Bucket/Pipe Inspection

Waste pipe and its joint are at the left side of the analyzing unit. Check the waste pipe in the following order:

- 1 Check if there is any bending. If so, straighten it.
- 2 If waste bucket is used, check if there is any leakage or overflow. If there is leakage, replace the waste bucket. If there is overflow, empty the waste bucket. If waste is discharged directly into the sewage, check if there is any overflow. If so, clean out the sewage.



Warning: Biohazard

All the wastes are treated as infectious and can only be touched when having gloves on.

Waste discharge must be in conformity with the requirement of local environmental protection authorities.

1.8.3 3 Weekly Maintenance



Warning: Biohazard

All the stains are treated as infectious and can only be touched when having gloves on.

1.8.4 4 Monthly Maintenance

- 1 Turn off power of analyzing unit.
- 2 Move sample probe away from washing pool position.
- 3 Dip clean cotton swab in detergent and clean the outer and inner wall of the washing pool until no obvious stain is in sight. Then dry with gauze.
- 4 Move mixer away from washing pool position.
- 5 Dip clean cotton swab in detergent and clean the outer and inner wall of the washing pool until no obvious stain is in sight. Then dry with gauze.
- 6 Move sample probe and mixer back to the washing pool position.



Warning: Biohazard

All the stains are treated as infectious and can only be touched when having gloves on.

1.8.5 5 Irregular Maintenance

5 Irregular Maintenance

5.1 Replace Sample Probe

When the probe is blocked, broken or bent, it needs to be replaced.

- 1 Turn off power of analyzing unit.
- 2 Move the sample probe to an appropriate position. Open the cover of the swing arm ,pull out the pipe from the end of probe and unplug the cable for liquid level detector board.
- 3 Loose the thin slice to remove the sample probe.
- 4 Fixed the new probe on the swing arm,press the probe with thin slice, and connect with pipe,plug the cable to liquid level detector board and cover the swing arm.
- 5 Move the sample probe back to the washing Pool.



Warning: Biohazard

The sample probe is treated as infectious and can only be touched when having gloves on.

5.2 Replace Mixer

When the Mixer is broken, bent or constantly holds liquid, it needs to be replaced.

- 1 Turn off power of analyzing unit.
- 2 Move the mixer to appropriate position.
- 3 Loose the two screws on the turning shaft of the mixing motor, as shown below:
- 4 Remove the mixer, as shown below:
- 5 Fix the new mixer on the turning shaft of the mixing motor until it is stopped.
- 6 Fasten the mixer on the turning shaft of the mixing motor with two screws.
- 7 Move the mixer back above the wash cup.



Warning: Biohazard

The mixer is treated as infectious and can only be touched when having gloves on.

5.3 Replace Lamp

When lamp is used for over half a year, or when an alarm is give by the analyzer, the lamp needs to be replaced.

- 1 Turn off power of analyzing unit, lasting in half an hour.
- 2 After half an hour(so as the lamp is cooled down),remove the cover of reaction tray.
- 3 Loose the screws on the reaction tray and remove it to show the lamp as shown below:
- 4 Loose the screws on the lamp box as below:
- 5 Pull out the lamp from the box ,Unplug the power cable of the lamp, as shown below:
- 6 Remove the old lamp:
- 7 Fix the the new lamp, fasten screws and plug the cable .
- 8 Fix reaction disc and fasten the screws.
- 9 Cover the reaction tray.



Warning: Hot

Before changing light bulb, turn the power off and wait at least for 30 minutes until the bulb cools down.



Warning: Light Beam

Before changing light bulb, make sure the analyzing unit power is turned off. Otherwise the beam from the light may hurt your eyes.



Warning: Screw Falling

When loose and fasten the screw, make sure the screws do not fall off.